# Medtronic HVAD PAL™ System

## Clinician Manual

Medtronic

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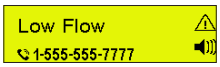
# Quick Reference Guide for Alarms

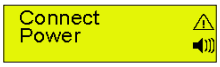
| Alarm Type: Critical | | | |
|---|---|---|---|
| **Alarm Signal** | **Controller Message** | **What it means** | **What action to take** |
| **Flashing RED back light**<br>  <br>**Flashing alert symbol**<br>**Loud audio signal and vibration**<br>**Unable to mute alarm** | **[Change Controller]**<br>  | • Controller failure.<br>• Controller component failed.<br>• Pump failure.<br>• Pump unable to start in five (5) attempts. | • Change the controller immediately.<br>• Contact Medtronic Clinical Support. |
| | **[Connect Pump Cable]**<br>  | • Pump cable (driveline) disconnection.<br>• Driveline fracture.<br>• Connector is malfunctioning or broken.<br>• Pump electrical failure. | • Connect the pump driveline to the controller.<br>• If the alarm persists:<br>– Change the controller.<br>– Contact Medtronic Clinical Support. |
| | **[Plug In Power Cord]**<br>  | • Disconnecting external battery without a power cord connected could risk pump stop.<br>• The Internal battery has limited time remaining, is unreliable, disconnected or has failed AND<br>• The external battery has less than fifteen (15) minutes runtime remaining or is unreliable. | • Connect the AC or DC power adapter to the controller.<br>• DO NOT disconnect the external battery before connecting the AC or DC power adapter.<br>• If the alarm persists:<br>– Change the controller.<br>– Contact Medtronic Clinical Support. |
| | **[Connect Power]**<br>  | • The internal battery has limited time remaining or is unreliable. | • Change the external battery or connect the AC or DC power adapter.<br>• If the alarm persists:<br>– Change the controller.<br>– Contact Medtronic Clinical Support. |

# Quick Reference Guide for Alarms (continued)

| Alarm Type: Non-critical | | | |
|---|---|---|---|
| **Alarm Signal** | **Controller Message** | **What it means** | **What action to take** |
| **Solid YELLOW back light**<br>  <br>**Flashing alert symbol**<br>**Periodic beep with escalating volume and vibration**<br>**Able to mute alarm** | **[Plug In Power Cord]**<br>  | • Disconnecting external battery without a power cord connected could risk pump stop.<br>• The internal battery has limited time remaining, is unreliable, disconnected or has failed AND<br>• The external battery has less than thirty (30) minutes runtime remaining or is unreliable. | • Connect the AC or DC power adapter to the controller.<br>• DO NOT disconnect the external battery before connecting the AC or DC power adapter.<br>• Confirm that the AC or DC power adapter is powering the controller.<br>Mute option: Two five (5)-minute mutes, then cannot be muted |
| | **[Keep Power Connected]**<br>  | • Disconnecting external power could risk pump stop.<br>• The internal battery has limited time remaining, is unreliable, or has failed. | • DO NOT disconnect the external power.<br>• If the external battery needs to be changed, connect the AC or DC power adapter before disconnecting the external battery to prevent the pump from stopping.<br>• If the alarm persists for one (1) hour:<br>– Contact Medtronic Clinical Support.<br>– The internal battery may need to be changed.<br>Mute option: Five (5) minutes |
| | **[Electrical]**<br>  | • A fault in the normal operation of the pump-to-controller electrical connection. The fault could be in the pump motor, driveline and connector, or within the controller.<br>• Pump is running on a single motor stator and consuming slightly more power. | • DO NOT change the controller.<br>• Check the controller driveline, pump driveline and connections for visible damage.<br>• Contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Technical]**<br>  | • Controller component or power source malfunction. | • View the Alarm Log screen for any additional alarms.<br>• Contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |

| Alarm Type: Non-critical | | | |
|---|---|---|---|
| **Alarm Signal** | **Controller Message** | **What it means** | **What action to take** |
| **Solid YELLOW back light**<br>  <br>**Flashing alert symbol**<br>**Periodic beep with escalating volume and vibration**<br>**Able to mute alarm** | **[High Power]**<br>  | • The pump power exceeds the alarm threshold setting. | • Confirm the correct settings for the [High Power] alarm, the pump speed, and Hematocrit.<br>• Assess the power signal on the Trends screen for any increasing trend or fluctuations.<br>• Assess the patient for potential causes:<br>• Perform lab tests (INR, etc.).<br>• Check patient for clinical signs of hemolysis.<br>• Consider echocardiography.<br>• If no potential patient cause can be identified, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Low Flow]**<br>  | • The flow is less than the alarm threshold setting. | • Confirm the correct settings for the [Low Flow] alarm limit and Hematocrit.<br>• Assess the flow signal on the Trends screen for any decreasing trend or fluctuations.<br>• Assess the patient for potential causes:<br>• Check blood pressure and volume status (confirm MAP <85 mmHg).<br>• Consider echocardiography.<br>• Consider inotropic drugs if right ventricle function is poor.<br>• If no potential patient cause can be identified, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |

# Quick Reference Guide for Alarms (continued)

| Alarm Type: Non-critical | | | |
|---|---|---|---|
| **Alarm Signal** | **Controller Message** | **What it means** | **What action to take** |
| **Solid YELLOW back light**<br>  <br>**Flashing alert symbol**<br>**Periodic beep with escalating volume and vibration**<br>**Able to mute alarm** | **[Suction]**<br>  | • The suction algorithm has identified a ventricular suction condition. | • Assess the patient for potential causes:<br>• Check blood pressure and volume status.<br>• Consider echocardiography.<br>• Evaluate the flow trends.<br>• Consider decreasing the pump speed if a clinical cause cannot be identified or corrected.<br>• Consider volume loading if indicated and there is good right ventricle function.<br>• Consider inotropic drugs if right ventricle function is poor.<br>• If no potential patient cause can be identified, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Connect Power]**<br>  | • No external power source is connected (for at least twenty (20) seconds). | • Connect the AC or DC power adapter or change the external battery.<br>Mute option: Two 5-minute mutes, then cannot be muted |
| | **[Temperature]**<br>  | • The controller internal battery is too hot or too cold.<br>• The controller's temperature is out of recommended range. | • Move the controller to a room temperature environment and wait for the controller to return to normal temperature.<br>• If the alarm persists for one (1) hour, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Change Battery]**<br>  | • The external battery has fifteen (15) minutes or less time remaining.<br>• There could be a potential problem with the external battery's power output, the connection or its ability to charge. | • Change the external battery OR<br>• Connect the AC or DC power adapter to the controller.<br>Mute option: Fifteen (15) minutes |
| | **[Connect Cap or Battery]**<br>  | • A PAL Cap or external battery is not connected to the controller, while the AC or DC power adapter is connected. | • Attach the PAL Cap or an external battery to the controller to protect it from dust, dirt, fluids, or electrical interference.<br>Mute option: Fifteen (15) minutes |

**For additional information on monitor alarm display, see Section 6.1.**

# 1.0 Introduction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**Foreword**

The HeartWare™ HVAD™ System is indicated for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. Clinical users include physicians, registered nurses, perfusionists and biomedical engineers. The implant of the device must be performed by a qualified cardiac surgeon trained by Medtronic-authorized personnel. Clinical users of the HVAD System should attend Medtronic training, should have a working knowledge of the principles of ventricular assist devices (VADs), and should be aware of the physical and psychological needs of patients undergoing VAD therapy. Patients and caregivers should complete a user training program and demonstrate their ability to use the system prior to hospital discharge. Frequency and duration of clinical user and patient/caregiver training should be determined per hospital protocol.

Clinicians should read the entire Instructions for Use before using the system. This manual may serve as a reference for detailed information including specific information on device function, system setup, implant and maintenance. This manual is not intended to replace comprehensive educational programs or to supersede acquired knowledge or proper medical judgment.

**Figure 1: HeartWare HVAD System**

# 1.0 Introduction

**In this manual, there will be the following symbols:**

| | | |
|---|---|---|
| Indicates there is more information available in the manual and the location in the manual. | Identifies information as a Warning.<br>A Warning is a statement about the possibility of injury, death or other serious adverse reaction associated with the use or misuse of the device. | Identifies information as a Caution.<br>A Caution is a statement or instruction designed to prevent device misuse, malfunction or damage. |

**WARNING!** The Instructions for Use (IFU) manual is intended to be used by physicians, nurses, and other clinical professionals. Setup and operation of this device should only be undertaken by personnel who have completed a HVAD System product training program. A thorough understanding of technical principles, clinical applications and risks associated with the HVAD System is required before using this product. Failure to understand these principles, applications and risks may result in improper operation of the system and potential harm to the patient or to the user.

**WARNING! Carefully read this entire manual prior to implanting or operating the device.** Improper operation of the system and potential harm to the patient and to the user could result.

## 1.1 Introduction

The HVAD System is designed to assist a weakened, poorly functioning left ventricle. The HVAD System utilizes a centrifugal blood pump, the HeartWare HVAD Pump (the "pump"), which is implanted in the pericardial space with a cannulation that goes from the left ventricular apex to the ascending aorta, for left ventricular support. The inflow conduit, which is partially sintered, is integrated with the pump. A 10 mm gel impregnated outflow graft with a strain relief is attached to the pump. A percutaneous driveline connects the pump to an external controller (PAL™ Controller). The controller, powered by an external battery or by electricity from a wall or car outlet, regulates the pump function and monitors the system. This controller also features hardware for Bluetooth® wireless technology, but wireless capability is not currently supported. The monitor is used to display system performance and to change controller operating parameters. A battery charger is also included.

All components of the HVAD System are designed to be used only in conjunction with each other. They are neither compatible nor intended to be used with other manufacturers' devices.

## 1.2 Indications for Use

The HVAD System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

## 1.3 Contraindications

The HVAD System is contraindicated in patients who cannot tolerate anticoagulation therapy.

**CAUTION:** Safety and effectiveness in persons less than 18 years of age and in persons with a BSA of less than 1.5 $m^2$ have not been established.

**CAUTION:** The HVAD System has had limited use in patients with artificial mitral or aortic valves and therefore the risks are currently unknown. Caution should be used in selecting patients with artificial mitral or aortic valves for HVAD System therapy.

## 1.4 Warnings

### WARNINGS

1. **WARNING!** Serious and life-threatening adverse events, including stroke, have been associated with use of this device. The risk of death as a result of stroke has been observed in randomized clinical trials to be higher with the HVAD than with alternative treatment options. The HVAD has been associated with a rate of stroke of 22% at one year and 29.7% at two years. A blood pressure management protocol may reduce the overall incidence of stroke to 16.9% at one year and may reduce the incidence of disabling strokes at one year from 8.1% to 6.5%. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation. Refer to clinical study results for the stroke data in Section D. Safety and Effectiveness Results of Appendix F, (US Clinical Study: Destination Therapy). Data has shown that appropriate patient management can mitigate the risk of stroke. The following patient management guidelines should be adopted:
   - Monitor and treat mean arterial pressure. Maintain MAP less than 85 mmHg, as tolerated.
   - Set speed on the HVAD Pump to maintain adequate pump flow index; which generally will not need to exceed 2.6 L/min/$m^2$.
   - Maintain anticoagulation within the recommended INR range of 2.0-3.0.
   - The daily aspirin doses should be:
     - more than 81 mg should be given daily.
     - in general, 81 mg alone is not recommended unless testing for aspirin resistance is performed.
     - in absence of platelet function testing, consider combination therapy, such as: ASA 81 mg plus Aggrenox® (ASA plus extended –release dipyridamole) or ASA 81 mg plus Plavix 75 mg.
2. **WARNING!** The Instructions for Use (IFU) manual is intended to be used by physicians, nurses, and other clinical professionals. Setup and operation of this device should only be undertaken by personnel who have completed a HVAD System product training program. A thorough understanding of technical principles, clinical applications and risks associated with the HVAD System is required before using this product. Failure to understand these principles, applications and risks may result in improper operation of the system and potential harm to the patient or to the user.
3. **WARNING! Carefully read this entire manual prior to implanting or operating the device.** Improper operation of the system and potential harm to the patient and to the user could result.
4. **WARNING!** DO NOT use the HVAD System in pregnant women. Any woman receiving a HVAD System who is of childbearing age and sexually active should use a reliable method of birth control. Use of anticoagulants during pregnancy has been associated with birth defects and bleeding.

## 1.4 Warnings (continued)

### WARNINGS

5. **WARNING!** ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.
6. **WARNING!** ALWAYS connect an AC adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC adapter) provides power for an unlimited period of time.
7. **WARNING!** DO NOT use any components other than those supplied by Medtronic with the HVAD System, as this may affect system operation.
8. **WARNING!** DO NOT allow patients to take baths or swim, as this may damage the HVAD System components and/or result in infection of the driveline exit site.
9. **WARNING!** DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact Medtronic.
10. **WARNING!** DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.
11. **WARNING!** DO NOT allow water or other fluids to enter the controller, power cords, external batteries, battery charger or connectors, as this may damage the HVAD System components. If equipment is damaged, contact Medtronic.
12. **WARNING!** DO NOT allow hearing impaired patients to shower unless their caregiver is close by to hear alarms.
13. **WARNING!** DO NOT allow patients to shower until they have received permission from their clinician to do so. Inappropriate shower technique could lead to patient harm or controller damage. Patients who shower must use the HeartWare Shower Bag.
14. **WARNING!** DO NOT use damaged equipment as it could lead to patient harm. Damaged equipment should be reported to Medtronic.
15. **WARNING!** DO NOT attempt to repair,service, or modify any component of the HVAD System as this may damage the component. If the equipment malfunctions, contact Medtronic.
16. **WARNING!** DO NOT operate the PAL Controller in temperatures below -5°C (+23°F) or above +40°C (+104°F) or the controller may fail.
17. **WARNING!** ALWAYS ensure that the PAL Controller is in Implant state during the implant procedure. Connecting the driveline in the Ready state will automatically start the pump.
18. **WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller IMMEDIATELY to restart the pump.
19. **WARNING!** ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.
20. **WARNING!** ALWAYS keep the backup controller and spare external batteries close to the patient in a dry environment where the temperature is between -5°C and +40°C (+23°F to +104°F).
21. **WARNING!** NEVER disconnect the pump driveline from the controller when loading equipment into the PAL Sport Pack as this will lead to a pump stop and potential harm. Bag loading does not require driveline disconnection.
22. **WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

## WARNINGS

23. **WARNING!** IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.
24. **WARNING!** ALWAYS switch to the backup controller if there is a [Change Controller] alarm since the pump may not be running.
25. **WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Muting a non-critical alarm does not resolve the alarm condition and may lead to sub-optimal therapy.
26. **WARNING!** The HVAD Pump may cause interference with AICDs. If electromagnetic interference occurs, it may lead to inappropriate shocks, arrhythmia and possibly death. The occurrence of electromagnetic interference with AICD sensing may require adjustment of lead sensitivity, proximal placement of new leads or replacement of an existing sensing lead.
27. **WARNING!** DO NOT use if package is damaged or opened. Sterile components are intended for single use only. DO NOT re-sterilize or re-use as this will increase the risk of infection.
28. **WARNING!** ALWAYS check for a click when connecting the driveline to the controller or to the driveline extension cable. Failure to ensure a secure connection may lead to a pump stop.
29. **WARNING!** NEVER turn on the HVAD Pump in air as this may damage the pump. DO NOT use a HVAD Pump that was turned on without total submersion in fluid during the Pre-Implant Wet Test and prior to implantation: the HVAD Pump must be completely submerged in fluid before being turned on.
30. **WARNING!** DO NOT implant gel impregnated vascular prostheses in patients who exhibit sensitivity to polyester or materials of bovine origin, as this may lead to severe reactions.
31. **WARNING!** The manufacturing process for gelatin sealed vascular grafts uses the cross-linking agent formaldehyde to achieve the graft performance. All gelatin sealed grafts are thoroughly rinsed with reverse osmosis water to reduce residual formaldehyde, however residual amounts may be present in the finished graft. Formaldehyde is also found at low levels naturally in the body, some of which is derived from food. Formaldehyde is known to be mutagenic and carcinogenic. The risks of these potential harms from the product have not been established clinically.
32. **WARNING!** DO NOT allow the Gelweave prostheses non-sterile foil pouch or outer tray to be introduced to the sterile field as this may contaminate the sterile field. Only the innermost tray is sterile.
33. **WARNING!** DO NOT preclot the outflow graft. Preclotting may disrupt the gel matrix, resulting in bleeding. Gelweave prostheses are sealed grafts and must not be preclotted.
34. **WARNING!** DO NOT implant the Gelweave prostheses more than one month after removal from the foil pouch. This may disrupt the gel matrix, resulting in bleeding.
35. **WARNING!** DO NOT allow anyone but a surgeon, physician's assistant or surgical assistant trained in the procedure to attach the outflow graft to the pump, as a loose graft connection may lead to bleeding and/or an air embolus.
36. **WARNING!** ALWAYS position the clamp screw so that it is located on the inner side of the outflow conduit to avoid tissue irritation or damage.
37. **WARNING!** DO NOT over-loosen the sewing ring's screw or it may fall off the sewing ring and be lost in the sterile field.

## 1.4 Warnings (continued)

### WARNINGS

38. **WARNING!** DO NOT cut the outflow graft too short or too long, as it may kink. Prior to chest closure, ensure that the graft is not kinked or compressed. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.
39. **WARNING!** DO NOT immerse the Gelweave grafts in saline solution for longer than five minutes. Longer periods of soaking in saline solution may disrupt the gel matrix, resulting in bleeding.
40. **WARNING!** ALWAYS position the driveline exit site so that the tunneler does not contact any vital organs or structures.
41. **WARNING!** ALWAYS remove all air from the HVAD Pump and its conduits to reduce risk of air embolism.
42. **WARNING!** DO NOT de-air the HVAD Pump when there is inadequate blood volume in the pump or leaks in the inflow or outflow connections, as air may enter the pump and outflow graft resulting in a delay in de-airing and possible air embolism.
43. **WARNING!** DO NOT place the percutaneous driveline into the sterile field during HVAD Pump explant as it may lead to contamination. The percutaneous driveline is not sterile.
44. **WARNING!** Patients should AVOID areas with high magnetic forces, such as theft detection devices or airport security systems, as this may affect the HVAD System operation.
45. **WARNING!** DO NOT let the patient have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD Pump. Doing so could cause harm to the patient or could cause the pump to stop.
46. **WARNING!** The PAL Controller internal battery should only be changed by trained personnel. Patients and caregivers should not attempt to change the controller internal battery.
47. **WARNING!** Patient should AVOID therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm. Therapeutic levels of ultrasound energy may also affect HVAD System operation.
48. **WARNING!** The HVAD System components should not be used adjacent to or stacked with equipment other than equipment specified in the IFU. If adjacent to or stacked use is necessary, the HVAD System and other equipment should be monitored regularly to verify normal operation.
49. **WARNING!** Patients should AVOID devices and conditions that may induce strong static electricity discharges (e.g., close vicinity to CRT television or CRT computer monitor screens) as static electricity discharges can damage the electrical parts of the system and cause the pump to perform improperly or stop.
50. **WARNING!** Patients should ALWAYS have a backup controller with fully-charged internal battery and fully-charged external batteries with them and readily available in case of primary controller malfunction. Whenever possible, a caregiver should be nearby when changing a power source or controller in case unusual alarms occur. They should be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.
51. **WARNING!** DO NOT drop the controller or other equipment. Dropping the controller may cause sudden stoppage of the pump. Dropped equipment should be reported to Medtronic.

## 1.4 Warnings (continued)

### WARNINGS

52. **WARNING!** DO NOT disconnect the driveline from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller IMMEDIATELY to restart the pump.
53. **WARNING!** NEVER clean the battery charger when it is connected to an electrical outlet, as this may lead to an electrical shock.
54. **WARNING!** NEVER clean the monitor when powered on, as this may lead to an electrical shock. DO NOT use alcohol or detergent on the monitor display. Gently wipe the display with a soft, lint-free cloth.
55. **WARNING!** Use of accessories and cables other than those specified or provided by Medtronic for use with the HVAD System could result in increased electromagnetic emissions or decreased electromagnetic immunity of the HVAD System and result in improper operation.

## 1.5 Precautions

### PRECAUTIONS

1. **CAUTION:** Safety and effectiveness in persons less than 18 years of age and in persons with a BSA of less than 1.5 $m^2$ have not been established.
2. **CAUTION:** The HVAD System has had limited use in patients with artificial mitral or aortic valves and therefore the risks are currently unknown. Caution should be used in selecting patients with artificial mitral or aortic valves for HVAD System therapy.
3. **CAUTION:** DO NOT reuse or share PAL Controllers on multiple patients to avoid risks associated with an inadvertent mismatch of controller pump speed settings.
4. **CAUTION:** ALWAYS keep the primary controller that is connected to a pump in a carrying case except when changing external batteries. Failure to keep equipment in a carrying case may lead to damage of the controller and external peripherals.
5. **CAUTION:** DO NOT pull, kink, or twist the driveline, as these actions may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare Shower Bag.
6. **CAUTION:** DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or controller display of less than -2.0 L/min, or greater than +10.0 L/min may indicate: incorrect hematocrit entry or an occlusion, and/or thrombus or other materials (e.g., tissue fragments) in the device. Inaccurate assessment of HVAD Pump flow may lead to less than optimal treatment.
7. **CAUTION:** DO NOT enable the [Suction] alarm while the patient is in a suction condition. To optimize operation of the suction detection the patient should be hemodynamically stable prior to enabling the [Suction] alarm.
8. **CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HVAD System may not function as intended.
9. **CAUTION:** Patient should AVOID changing power sources in or near water (e.g., shower, rain, ocean, etc.), as this may damage the controller. If equipment is damaged, contact Medtronic.

## 1.5 Precautions (continued)

### PRECAUTIONS

10. **CAUTION:** ALWAYS have an external battery or cap connected to the battery connector even while using an AC or DC adapter with the controller. An uncovered battery connector can lead to electrostatic discharge (ESD) events.
11. **CAUTION:** DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
12. **CAUTION:** ALWAYS recharge fully depleted external batteries within 24 hours to avoid permanent battery damage.
13. **CAUTION:** ALWAYS verify that the battery symbol is present on the PAL Controller screen to confirm that the external battery is properly locked on to the controller in order to maintain optimal therapy.
14. **CAUTION:** DO NOT attempt to charge the controller using the USB data port. The USB data port should be used only for data transfer and will not provide power to the controller.
15. **CAUTION:** ONLY use the PAL Controller or PAL Battery Charger to charge PAL Batteries. Other battery chargers will not charge the external batteries and may lead to battery damage.
16. **CAUTION:** Patient should AVOID placing the controller in the following conditions to prevent harm from excessive heat:
    - Between the legs when sleeping or sitting.
    - Under the body while sleeping or sitting.
    - Under covers in a warm room.
    - In a heated room (e.g., sauna, steam room, hot yoga class, etc.).
    - Under a thick or thermal (hypothermia) blanket.
    - Under a heat lamp.
    - In direct sunlight.
17. **CAUTION:** Use caution when moving equipment around in a carrying case to avoid tugging on the driveline exit site.
18. **CAUTION:** ALWAYS place the driveline connector inside the HeartWare Shower Bag when showering. Exposing the driveline connector to water may lead to electrical faults, unrepairable damage to the equipment, and disruption to therapy.
19. **CAUTION:** DO NOT allow patients to touch the monitor screen, as this may lead to the entering of unintended parameters into the system.
20. **CAUTION:** Entering an incorrect hematocrit value will lead to flow estimation errors. Flow estimation should not be the sole assessment parameter relative to the clinical efficacy of the HVAD System.
21. **CAUTION:** DO NOT use Medtronic equipment in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. (**Note:** Flammable anesthetics are typically ether based).
22. **CAUTION:** ALWAYS program the backup controller identically to the primary controller to avoid a change in therapy when backup equipment is used.
23. **CAUTION:** ALWAYS keep external power connected to the controller while in Implant state in order to prevent accidental shutdown.
24. **CAUTION:** DO NOT exert excessive tension or force on the Gelweave prostheses as this will damage the polyester fibers and the gelatin impregnation, which may result in bleeding.

## PRECAUTIONS

25. **CAUTION:** ALWAYS ensure the inflow cannula position is pointed toward the mitral valve and parallel to the interventricular septum to optimize HVAD Pump operation.
26. **CAUTION:** ALWAYS position the sewing ring to permit access to its screw after cannulation.
27. **CAUTION:** ALWAYS use round body taper point needles when implanting Gelweave prostheses to minimize fiber damage. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.
28. **CAUTION:** The driveline connector is made of nickel-coated brass which may cause a rash in patients with a nickel allergy.
29. **CAUTION:** ALWAYS be aware of the position of the driveline to avoid damage by surgical instruments and needles during HVAD Pump implantation and/or re-operation.
30. **CAUTION:** DO NOT grasp or pull the driveline as this may damage the driveline. To remove the driveline cap from the driveline, unscrew the outer sleeve, then pull back on the grooved area of the connector.
31. **CAUTION:** ALWAYS use the smallest possible needle for de-airing; 19-gauge is normally sufficient. Hypodermic needles have a cutting point which may result in blood leakage and may require repair by suturing.
32. **CAUTION:** DO NOT rely on HVAD Pump flow estimation during the de-airing procedure. Flow estimation may not be accurate.
33. **CAUTION:** Recommended HVAD Pump speeds are between 2400 RPM and 3200 RPM. HVAD Pump speeds outside this range may result in less than optimal HVAD Pump operation. Speeds below 2400 RPM or above 3200 RPM should be used with caution.
34. **CAUTION:** ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Driveline damage may affect the HVAD System performance.
35. **CAUTION:** DO NOT expose the pump driveline to direct or indirect sunlight. ALWAYS keep the driveline completely covered when in the sun. Instruct patients not to use tanning lights or black lights. The light from these sources contains ultraviolet radiation which may damage the outer sheath of the driveline.
36. **CAUTION:** DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine (betadine), or polymyxin-neomycin-bacitracin ointment on the exit site. These ointments can injure the tissue next to the driveline.
37. **CAUTION:** Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta, use clinical judgment. If chest compressions have been administered, confirm function and positioning of the pump.
38. **CAUTION:** DO NOT apply high power electrical treatment (e.g., deep tissue heating which can be used for treatment of arthritis and/or some injuries) directly to the patient, as this may affect HVAD System operation.
39. **CAUTION:** Patient should AVOID therapeutic ionizing radiation since it may damage the device. This damage may not be immediately detectable.
40. **CAUTION:** Follow ESD prevention practice when replacing the internal battery:
    - Perform the battery replacement in an ESD-safe area whenever possible.
    - Discharge ESD by touching a metal object in the room other than the controller.
    - Avoid making contact with the internal battery connector and the controller battery compartment connector.

## 1.5 Precautions (continued)

### PRECAUTIONS

41. **CAUTION:** Internal battery replacement should be performed on a secure surface such as a table to avoid damage to components. If the internal battery is dropped during the procedure, discard the battery and retrieve a new kit. Dispose of the dropped battery according to federal, regional, and local regulations.
42. **CAUTION:** DO NOT use any component from the original back cover when replacing an internal battery. Use of these components may lead to interruption of normal system operating conditions and possible patient harm.
43. **CAUTION:** DO NOT disassemble, heat above the manufacturer's maximum temperature limit, or incinerate the internal battery. Doing so could present a risk of fire or chemical burn if mistreated. Only replace the battery with a battery that has the manufacturer's name or end product manufacturer's name and part number on it. Use of another battery may present a risk of fire or explosion.
44. **CAUTION:** DO NOT disassemble or reconstruct the battery pack. The battery pack has safety functions and a protection circuit to avoid danger. If those have serious damage, the pack may generate heat, smoke, rupture, or burn.
45. **CAUTION:** DO NOT short-circuit the battery pack by connecting the positive (+) and negative (-) terminals with metals (such as wire) or carry or store the battery pack with metal objects (such as wire, necklace, or hairpins). The large current flow may lead to heat generation, smoking, rupture, or burning.
46. **CAUTION:** DO NOT incinerate or heat the battery pack. This may lead to melting of the insulator, damage of the gas release vent or safety function, or ignition of electrolyte resulting in heat generation, smoking, rupture, or burning.
47. **CAUTION:** DO NOT reverse-charge or reverse-connect the battery pack. The battery pack has polarity and doing so may lead to heat generation, smoking, rupture, or burning. If the battery pack is not connected with the charger or equipment smoothly, do not force them to connect, but do check the polarity of the battery pack. If the battery pack is connected to the opposite polarity of the charger, it will be reverse-charge and an abnormal chemical reaction will occur.
48. **CAUTION:** DO NOT reconnect power to the controller after completing the palliative shutdown sequence while the driveline is still connected. This will restart the pump.
49. **CAUTION:** DO NOT expose external batteries to temperatures outside the storage and operational ranges to avoid shorter battery runtime.
    Battery operating and storage temperatures:
    a. Operating: discharge (normal use with the HVAD System): -5°C to +40°C (+23°F to +104°F). Operation at temperatures below 0°C (+32°F) will temporarily reduce battery capacity but the battery will operate.
    b. Storage: -20°C to +45°C (-4°F to +113°F). Long-term storage outside of this range may permanently reduce the battery capacity. The best condition for storage is at room temperature.
50. **CAUTION:** ALWAYS keep HVAD System components away from children and pets. Children and pets may cause damage to components or be harmed by damaged batteries or components. If damage to equipment results, contact Medtronic.
51. **CAUTION:** DO NOT disassemble, crush, or puncture an external battery to avoid personal injury and battery damage.

## PRECAUTIONS

52. **CAUTION:** DO NOT use damaged external batteries as it may lead to interrupting VAD therapy. Dispose of external batteries according to federal, regional, and local regulations.
53. **CAUTION:** DO NOT short circuit the external contacts on an external battery as this may result in battery damage.
54. **CAUTION:** DO NOT touch the fluid if a battery pack is leaking fluid. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least fifteen (15) minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention. Dispose of external batteries according to federal, regional, and local regulations.
55. **CAUTION:** DO NOT expose external batteries to excessive shock or vibration as this may affect battery operation.
56. **CAUTION:** DO NOT dispose of batteries in fire or water. Dispose of batteries according to federal, regional, and local regulations.
57. **CAUTION:** DO NOT place external batteries in water or liquid as this may damage them.
58. **CAUTION:** DO NOT use a machine for drying the carrying cases as it may accelerate the end of useful service. The carrying case should only be air dried.
59. **CAUTION:** The safety and effectiveness of the Lavare™ Cycle has not been evaluated in a prospective clinical study.

## 1.6 Potential Complications

Implantation of a HVAD Pump is an invasive procedure requiring general anesthesia and entry into the thoracic cavity. These surgical procedures are associated with numerous risks. Risks associated with the implant procedure and use of the device may include, but are not limited to, the following:

- Arterial Non-central nervous system (Non-CNS)
  - Air Embolism
  - Thromboembolism
- Bleeding
  - Bleeding, perioperative or late gastro-intestinal (GI) bleeding or arteriovenous malformations (AVM)
- Burn
- Cardiac Arrhythmias
- Death
- Device Malfunction
  - Device Thrombus
  - Electrostatic discharge (ESD) damage to device
- Hemolysis
- Hepatic Dysfunction
- Hypertension
- Major Infection
  - Driveline Infection
  - Internal Pump Component, Inflow or Outflow tract Infection
  - Local Infection
  - Sepsis
- Myocardial Infarction
- Neurological Dysfunction
  - Stroke
    - Ischemic Cerebral Accident (ICVA)
    - Hemorrhagic Cerebral Accident (HCVA)
    - Transient Ischemic Attack (TIA)
- Pericardial Effusion or Tamponade
- Pneumothorax
- Psychiatric Episodes
  - Suicide
- Renal Dysfunction
- Respiratory Dysfunction
- Right Ventricular Failure
- Venous Thromboembolism
- Wound Dehiscence
- Other
  - Aortic Insufficiency
  - Cardiopulmonary Arrest
  - Multi-organ failure
  - Platelet Dysfunction
  - Pleural Effusion
  - Organ damage during driveline tunneling
  - Pain
  - Syncope
  - Tissue Erosion and other tissue damage
  - Worsening Heart Failure

## 1.7 Data Security

Medtronic has designed safeguards to protect patient information and device data.

Maintaining physical security of the controller is the primary mitigation for unauthorized data access and tampering. Users should inspect the housing of the primary and backup controllers for evidence of tampering before use. A disturbance to the screws or stickers is an indicator that unauthorized changes may have been made to the device, and therefore the device should not be used. Users should maintain physical control of primary and backup controllers to reduce opportunities for tampering and ensure data security. In the event of a suspected data security breach, contact Medtronic.

Users should only allow access to the controller USB port to trusted HeartWare Monitors. The controller responds only to authorized commands set by the clinician or Medtronic. This controller also features hardware for Bluetooth® wireless technology, but wireless capability is not currently supported.

**Note:** System settings cannot be changed via Bluetooth®.

# 2.0 HeartWare HVAD System Overview


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2.6 Carrying Cases and HeartWare Shower Bag ..... 21


**System Component Overview**

See **Section Appendix A: System Components** for a complete list of system components.

The primary components of the HeartWare HVAD System (excluding the Monitor) are intended for single patient use.

**STERILE: All Medtronic implantable components, surgical tools and accessories used at implant are provided sterile.**

## 2.1 HeartWare HVAD Pump and Surgical Tools

The HeartWare HVAD System consists of a blood pump with an integrated, partially sintered inflow cannula, a 10 mm diameter gel impregnated polyester outflow graft, and a percutaneous driveline. A strain relief is used on the outflow graft to prevent kinking and secures the outflow graft to the pump. The driveline cable is wrapped with woven polyester fabric to encourage tissue in-growth at the skin exit site. The small, durable pump has a displaced volume of 50 cc and weighs 160 grams. The HeartWare HVAD Pump has a single moving part, an impeller, which spins blood to generate up to 10.0 L/min of flow.

An integrated inflow cannula is inserted into the left ventricle and the outflow graft connects the HeartWare HVAD Pump to the aorta. A sewing ring attaches to the myocardium. The device size and short inflow cannula allow for pericardial placement, which eliminates the need for abdominal surgery and device pockets (**Figure 2**).

**Figure 2: HeartWare HVAD Pump and Left Ventricular (LV) Cannulation**

**For more information about the HeartWare HVAD Pump, see Section 3.0.**

## 2.1 HeartWare HVAD Pump and Surgical Tools (continued)

### Surgical Tools and Accessories are Provided Sterile for Surgical Implantation.

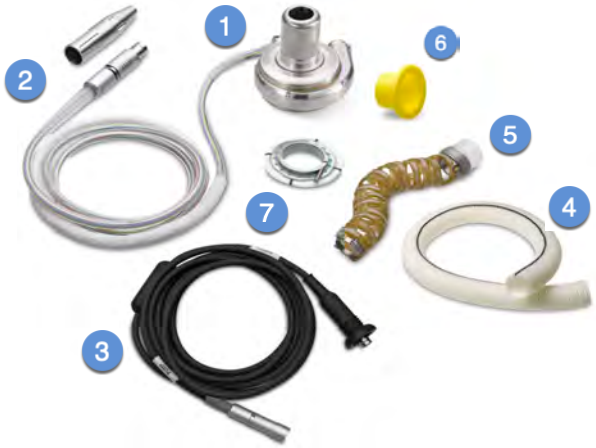
**Figure 3: Surgical Tools**

1. **Tunneler**
2. **Apical coring tool**
3. **Sewing ring wrench**
4. **Strain relief wrench**

All tools and accessories used during implantation are for single-use only.


**Figure 4: Components used at Implant**

1. **HeartWare HVAD Pump and driveline**
2. **Driveline cap**
3. **Driveline extension cable**
4. **Outflow graft**
5. **Strain relief**
6. **Inflow cap**
7. **Sewing ring**




**For additional information on implantation, see Section 7.0.**

## 2.2 HeartWare Monitor

The monitor (**Figure 5**) is a touchscreen tablet that uses proprietary software to display system performance and to permit adjustment of selected controller parameters. When connected to a controller, the monitor receives continuous data from the controller and displays real-time and historical pump information. The monitor also displays alarm conditions and can provide notification of available controller software updates.

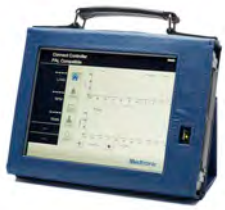


**Figure 5: HeartWare Monitor**

**For additional information about the HeartWare Monitor, see Section 6.0.**

## 2.3 PAL Controller

The controller (**Figure 6**) is a microprocessor unit that controls and manages the HeartWare HVAD System operation. It sends power and operating signals to the pump and collects information from the pump providing audible, visual, and vibratory alerts, system status condition, and instructions to the patient.

**Figure 6: PAL Controller**

**CAUTION:** DO NOT reuse or share PAL Controllers on multiple patients to avoid risks associated with an inadvertent mismatch of controller pump speed settings.

**For additional information about the controller, see Section 4.1.**

## 2.4 Controller External Power Sources

There are four external power sources for the controller. The controller requires at a minimum one external power source with a running internal battery for safe operation: either one Single Battery, one Dual Battery, an AC adapter or a DC adapter (**Figure 7**). While active, patients will typically use a Single or Dual Battery. While relaxing or sleeping, patients should use power from an electrical outlet (AC adapter) because it provides power for an unlimited period of time. Patients may also use an AC adapter or DC adapter to charge external batteries through the controller.

**Power Sources**

1. Single Battery
2. Dual Battery
3. AC Adapter
4. DC Adapter


**Figure 7: Controller Power Sources**

## 2.4 Controller External Power Sources (continued)

The controller has four power configurations to operate under normal use conditions (**Table 1**).

**Table 1: Power Configurations**

| Configuration | Image |
|---|---|
| **1.** Controller with External Battery (Single) |  |
| **2.** Controller with External Battery (Dual) |  |
| **3.** Controller with Power Cord and Cap |  |
| **4.** Controller with Power Cord and External Battery (Single) |  |

**WARNING!** ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.

**WARNING!** ALWAYS connect an AC adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC adapter) provides power for an unlimited period of time.

**For additional information on using the External Batteries, see Section 4.3.5.**

**For additional information on using the AC or DC Adapter, see Section 4.3.4.**

## 2.5 Battery Charger

The battery charger (**Figure 8**) is used to simultaneously recharge up to four batteries. It can take up to six (6) hours to fully charge a depleted battery. Each external battery slides into a bay and is connected to the battery charger. It is safe to leave the batteries in the charger.

**Figure 8: Battery Charger**

**For additional information on using the Battery Charger, see Section 4.4.**

## 2.6 Carrying Cases and HeartWare Shower Bag

The PAL Sport Pack and PAL Accessories Bag are used to safely secure, store and carry the primary and backup equipment. They can be used in or out of the hospital. The Sport Pack is intended to carry a controller that is connected to the pump. The Accessories Bag is intended to carry backup equipment. To ensure safe and appropriate use of the Sport Pack, all patients and caregivers should be trained on pack operation prior to use.

A HeartWare Shower Bag is available for use in conjunction with the HeartWare HVAD System. To ensure safe and appropriate use of the HeartWare Shower Bag, all patients and caregivers should be trained on HeartWare Shower Bag operation prior to use.

**Figure 9: PAL Sport Pack**

**Figure 10: PAL Accessories Bag**

**Figure 11: HeartWare Shower Bag**

**For additional information on configuring and wearing the Carrying Cases and Shower Bag, see Section 4.6.**

## 2.6 Carrying Cases and HeartWare Shower Bag (continued)

**WARNING!** DO NOT use any components other than those supplied by Medtronic with the HVAD System, as this may affect system operation.

**WARNING!** DO NOT allow patients to take baths or swim, as this may damage the HVAD System components and/or result in infection of the driveline exit site.

**WARNING!** DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact Medtronic.

**WARNING!** DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.

**WARNING!** DO NOT allow water or other fluids to enter the controller, power cords, external batteries, battery charger or connectors, as this may damage the HVAD System components. If equipment is damaged, contact Medtronic.

**WARNING!** DO NOT allow hearing impaired patients to shower unless their caregiver is close by to hear alarms.

**WARNING!** DO NOT allow patients to shower until they have received permission from their clinician to do so. Inappropriate shower technique could lead to patient harm or controller damage. Patients who shower must use the HeartWare Shower Bag.

**WARNING!** DO NOT use damaged equipment as it could lead to patient harm. Damaged equipment should be reported to Medtronic.

**WARNING!** DO NOT attempt to repair, service, or modify any component of the HVAD System as this may damage the component. If the equipment malfunctions, contact Medtronic.

**CAUTION:** ALWAYS keep the primary controller that is connected to a pump in a carrying case except when changing external batteries. Failure to keep equipment in a carrying case may lead to damage of the controller and external peripherals.

**CAUTION:** DO NOT pull, kink, or twist the driveline, as these actions may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare Shower Bag.

# 3.0 HeartWare HVAD System Pump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## 3.1 Principles of Operation

### Background

The HeartWare HVAD Pump is a continuous flow pump. It contains a rotating impeller that adds energy to the blood by converting the rotational kinetic energy into mechanical energy (**Figure 12**). The impeller blades push the fluid through the pump using hydrodynamic and centrifugal forces. The net effect is to build up the fluid pressure, sometimes referred to as pump head (i.e., related to the differential pressure across the device) or just head, such that the fluid is moved from the inlet to the outlet of the pump. Pump head is the difference between the afterload and the preload. The energy to rotate the impeller is provided through electromagnetic coupling between permanent magnets (rotor magnet) attached or enclosed within the impeller and the motor stators. The motor stators consist of coils of wire that are sequentially charged by electrical current, turning the coils into electromagnets. These electromagnets have the effect of spinning the rotor magnets around an axis of rotation. The HVAD Pump is efficient at pumping adequate blood against moderate amounts of resistance.

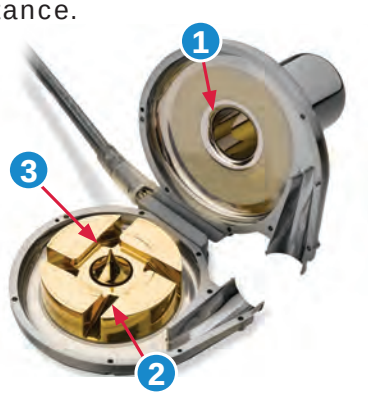


**Figure 12: Open view of the HVAD Pump**

1. Inflow Cannula
2. Impeller
3. Center Post

### Device Tracking and Reporting Requirements

The HeartWare HVAD Pump is considered a life-sustaining medical device and must be tracked per US Food and Drug Administration (FDA) and other foreign regulatory agency regulations. Compliance is mandatory. Accordingly, all device tracking paperwork must be completed and promptly returned to Medtronic. In addition, any device malfunctions must be reported to Medtronic by the implanting center.

## 3.1 Principles of Operation (continued)

**Blood Flow Characteristics**

The amount of flow a rotary pump can generate is dependent upon the diameter of the impeller, the geometry of the impeller blades, the housing design, the motor capacity, the rotational speed, and the pressure differential that exists across the pump. This design allows for in-vitro pump characterization for a specific pump and is the basis for blood flow estimation.

The HVAD System estimates blood flow rate using HVAD Pump characteristics (electrical current, impeller speed) and blood viscosity. Viscosity is calculated from the patient's hematocrit. To obtain the most accurate estimate of blood flow, the patient's hematocrit must be entered into the HeartWare Monitor. Flow estimation should be used as a trending tool only, as it cannot adapt to changing fluid conditions.

**For additional information on flow estimation, see Section 3.2.1.**

The flow rate generated by the HVAD Pump is determined by the rotational speed of the impeller and by the pressure differential across the pump. The pressure that the HVAD Pump must work against is similar to the mean arterial pressure. If the pump speed (RPM) is set too low, then the device may not generate enough forward pressure. This can lead to retrograde flow (flow from the aorta back through the device and into the left ventricle). The maximum rotational speed is determined by how much flow is available from the right heart. If the speed is set too high and the pump attempts to pump more blood than is available, ventricular suction may occur.

The controller's motor speed range is between 1800 and 4000 RPM. The appropriate speed should be determined based on the patient condition.

**Note:** Recommended HVAD Pump speeds are between 2400 RPM and 3200 RPM. HVAD Pump speeds outside this range may result in less than optimal HVAD Pump operation.

## 3.2 Physiologic Control Algorithms

The HVAD Pump control algorithms provide clinicians information about device performance and HVAD Pump blood flow estimation.

### 3.2.1 Flow Estimation

Estimated HVAD Pump blood flow is calculated using pump power, speed parameters, and hematocrit, which is based on a blood sample from the patient. The default hematocrit setting is 30%, but for accurate flow estimation, the patient's hematocrit should be entered into the monitor. Adjustments to the hematocrit setting on the monitor should be made for hematocrit changes of ± 5% or greater.

**Note:** Update the hematocrit settings on the monitor whenever the hematocrit changes by plus or minus 5% or more.

The valid range of estimated blood flow is -2.0 to 10.0 L/min. **Table 2** shows monitor and controller display messages and what they mean.

**Table 2: Monitor and Controller Display Messages**

| Monitor and Controller Display | Estimated Flow Range |
|---|---|
| "--" | Invalid, not available |
| "< -2.0 L/min" | less than -2.0 L/min |
| "-2.0 L/min" up to "10.0 L/min" | -2.0 to 10.0 L/min |
| "> 10.0 L/min" | greater than 10.0 L/min |

### 3.2.1 Flow Estimation (continued)

The error of the estimated flow is either ±1.0 L/min or 20%, whichever is greater. Flow estimation accuracy can be maintained only if accurate hematocrit values are entered.

Out of range values on the low side (less than -2.0 L/min), are invalid in terms of estimated flow but could indicate an incorrect hematocrit value used in the flow estimation or an occlusion of the inflow or outflow conduits. Out of range values on the high side (greater than 10.0 L/min), may occur due to thrombus or other materials (e.g. tissue fragments) in the device, due to an incorrect hematocrit value used in the flow estimation or during an electrical fault.

**Note:** Flow estimation should only be used as a trending tool. Actual flow may differ from displayed value due to variability of patient's hematocrit.

**CAUTION:** DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or controller display of less than -2.0 L/min, or greater than +10.0 L/min may indicate: incorrect hematocrit entry or an occlusion, and/or thrombus or other materials (e.g., tissue fragments) in the device. Inaccurate assessment of HVAD Pump flow may lead to less than optimal treatment.

### 3.2.2 [Suction] Alarm

A suction condition may occur due to ventricular collapse or inflow occlusion. Ventricular collapse occurs when a continuous flow pump attempts to pump more blood from the left ventricle than is available, resulting in considerable reduction in ventricular volume. Left ventricular collapse can be the result of clinical events affecting left ventricular preload, including hypovolemia (bleeding), right heart failure, arrhythmia or pulmonary embolus. An inflow occlusion occurs when the inflow cannula is obstructed, causing a suction condition. Temporary inflow obstruction can occur as a result of surgical positioning, patient position or during straining (e.g., during Valsalva maneuver).

The [Suction] alarm functions by monitoring the estimated flow and searches for a sudden decrease in flow rate. A flow baseline is established by continuously tracking the minimum flow values. The alarm is triggered when flow is 40% below the estimated flow baseline. An indication of suction is obtained when the minimum flow falls below this trigger level. The alarm will be triggered if this condition is maintained for ten (10) seconds.

The flow value that triggers the [Suction] alarm is also used as a threshold to clear the alarm. The alarm clears if the flow is maintained above the alarm limit for longer than twenty (20) seconds. The estimated flow baseline is continuously compared to this limit. The [Suction] alarm will be cleared if the flow baseline is maintained above the trigger level for twenty (20) seconds (**Figure 13**). This is an indication that the suction condition has cleared.

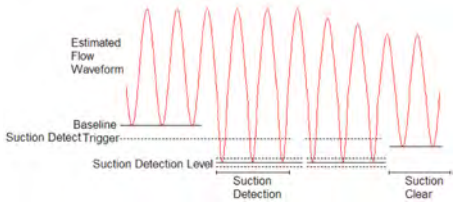


**Figure 13: [Suction] alarm Detection Level**

The [Suction] alarm can only be enabled from the System Screen of the monitor. Therefore, only the clinician has access to control the state of this alarm. The default setting for [Suction] alarm is "Off". In this setting, there will be no alarm during a ventricular suction condition. An "Sx Off" message will be displayed on the lower left corner of the monitor screen beneath the "Lavare" setting display. When [Suction] alarm is enabled (via the "Alarm" button), the "Sx On" message will be displayed on the lower left corner of the monitor screen beneath the "Lavare" state display.

# 3.2 Physiologic Control Algorithms (continued)

## 3.2.2 [Suction] alarm (continued)

**For additional information on the monitor, see Section 6.0.**

**Note:** The [Suction] alarm may be enabled once the patient's intravascular volume and pump flow have been stabilized.

If a [Suction] alarm is triggered, the clinician should evaluate whether the alarm was triggered by a transient, reversible condition which corrects itself, or whether the alarm is more serious and requires intervention. Transient alarms often occur at certain times during the day and/or under particular circumstances such as bending over or lying on one side. They usually resolve quickly without problems. If the [Suction] alarm is persistent and there are clinical symptoms of decreased blood flow, such as dizziness or hypotension, or if a [Low Flow] alarm is active, then the patient should be evaluated. This can be accomplished by checking the pump flow waveform on the monitor for evidence of suction, or if necessary, by visualizing the left ventricle with echocardiography. The clinician should attempt to identify and treat the underlying cause of the suction event. If the cause for the suction event cannot be determined, or if the cause is refractory to treatment, then the clinician should manually adjust the speed to resolve the suction condition.

**CAUTION:** DO NOT enable the [Suction] alarm while the patient is in a suction condition. To optimize operation of the suction detection the patient should be hemodynamically stable prior to enabling the [Suction] alarm.

**The ventricular suction detection function will temporarily deactivate if:**

- The estimated flow value becomes invalid. Once the flow estimation is within valid range, the ventricular suction detection will resume.
- The baseline flow value is less than 1.8 L/min: the algorithm loses sensitivity if the baseline and, therefore, the suction detection level gets too low. Once the baseline value is above 1.8 L/min, then the ventricular suction detection will resume.
- The clinician changes the hematocrit input: the algorithm recognizes that a change in the fluid viscosity will cause a change in the estimated flow. The ventricular suction detection algorithm reactivates once a new baseline is established.
- Lavare Cycle is active: the Lavare Cycle has a direct impact on the [Suction] alarm tracking parameters, so the algorithm is temporarily disabled. The ventricular suction detection algorithm re-activates with the previous baseline once the Lavare Cycle is completed.
- The clinician changes the speed input: ventricular suction detection algorithm is paused until there is a new baseline. The algorithm recognizes that a change in speed will result in a rapid change in flow and disables the alarm until the speed stabilizes and a new baseline is established.

## 3.2.3 Power Tracking

Power Tracking is an algorithm which drives the [High Power] alarm in place of the [High Power] alarm limit. The algorithm functions by comparing the current operating power to the historical baseline.

The Power Tracking algorithm establishes a historical baseline using a slow-moving average of pump power. The slow-moving average is continuously compared to a faster-moving average representative of the current operating power. If a significant upward deviation in pump power is detected (using a combination of power differential and time), the controller will trigger a [High Power] alarm. The detected increase in Power consumption could occur due to clinical conditions such as thrombus.

### 3.2.3 Power Tracking (continued)

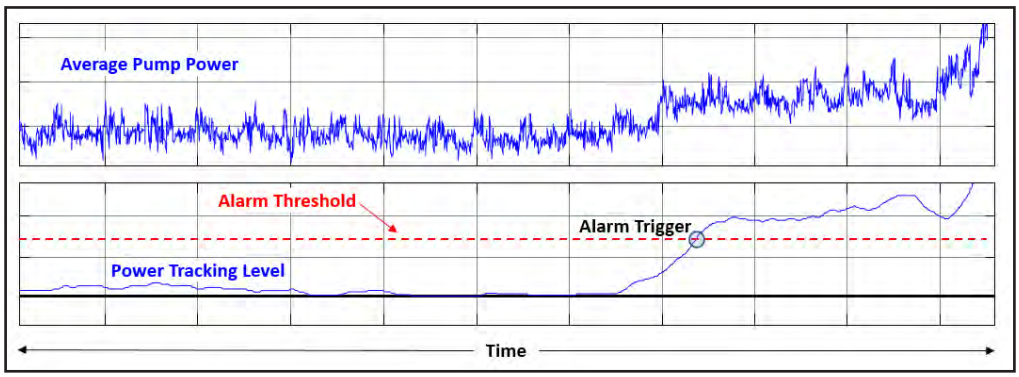


**Figure 14: Power Tracking Level Related to Alarm Threshold**

By default, the Power Tracking algorithm is OFF, and the [High Power] alarm is driven by the [High Power] alarm limit. Power Tracking can be enabled within the Alarm Settings tab on the monitor (Section 6.4.2). If Power Tracking is enabled, the [High Power] alarm limit cannot be set manually (High Power Alarm Limit button is disabled and displays "Auto"), as the algorithm will determine high power conditions.

**Turning the Algorithm "On":**

It is recommended the Power Tracking algorithm only be enabled when the patient is hemodynamically stable during recovery, prior to hospital discharge.

**Note**: Ensure that the backup controller is also be programmed to match the primary controller when enabling Power Tracking.

**When the Alarm Triggers:**

If a [High Power] alarm is triggered, the clinician should evaluate whether the alarm was triggered by a transient, reversible condition which corrects itself, or whether the alarm is more serious and requires intervention. The clinician should attempt to identify and treat the underlying cause of the event following medical protocol.

Once the root cause of the [High Power] alarm is resolved and the patient is hemodynamically stable, the Power Tracking algorithm may then be re-enabled and reset using the "Reset" button prior to hospital discharge.

**Power Tracking Reset**

When the Power Tracking algorithm is enabled, a "Reset" button will appear in the Alarm Settings tab. The function of the "Reset" button is to reestablish the baseline power level for the algorithm in cases where clinical factors cause the power tracking level to change. One example of when the "Reset" button might be used is after the treatment of a suspected pump thrombosis.

**In addition to pressing the "Reset" button on the monitor, the following actions will cause the Power Tracking algorithm to reset automatically and begin capturing a new baseline power:**

- The clinician changes the set speed of the pump
- The controller is powered off (e.g., following a controller exchange)
- Following an [Electrical] or certain [Technical] alarms

**Note**: If any of the above reset conditions are met, the algorithm will re-enter the 24-hour "learning" period to establish the power baseline. During this 24-hour period, Power Tracking can still trigger a [High Power] alarm using known operating limits of HVAD operation. Once enough data is collected and the baseline Is established, the "learning" period is over and the algorithm functions by comparing the current operating power to the historical baseline.

# 3.2 Physiologic Control Algorithms (continued)

## 3.2.4 Lavare Cycle

The Lavare Cycle is a speed modulation algorithm designed to reduce areas of potential blood stasis within the left ventricle. As depicted in **Figure 15**, the Lavare Cycle decreases the pump speed by 200 RPM below the set speed for two (2) seconds then increases the pump speed to 200 RPM above the set speed for one (1) second followed by the return to the original set speed for sixty (60) seconds. Once activated the Lavare Cycle continues until deactivated.

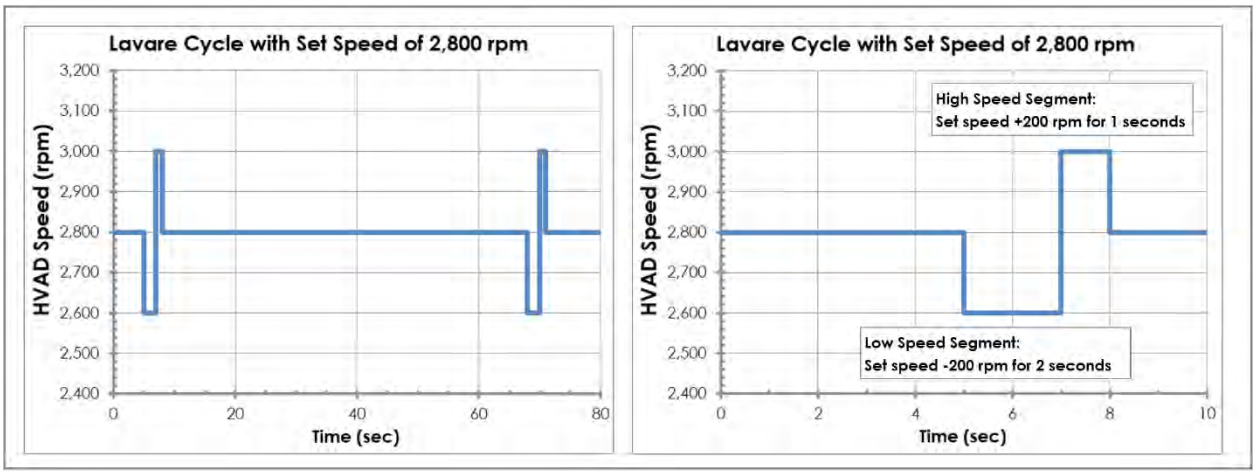


**Figure 15: Lavare Cycle Example: full cycle (left); speed modulation (right)**

Lavare Cycle is limited by pump speed range of 1800 – 4000 RPM during the low and high speed portions of the cycles. Accounting for the ±200 RPM change with respect to the set speed during the Lavare Cycle, set speeds below 2000 or above 3800 will not allow for the full ±200 RPM change. For example, if the set speed is 1900 RPM, the Lavare Cycle will operate between 1800 RPM and 2100 RPM, instead of 1700 RPM and 2100 RPM.

The Lavare Cycle has two settings, OFF and ON, which can be set by the clinician via the HeartWare Monitor. It is recommended that the Lavare Cycle be initiated once the patient is hemodynamically stable and it is confirmed that the patient can tolerate the two (2) seconds of reduced support.

**If the patient is hemodynamically stable, the following conditions might occur:**

- HVAD Pump flow is maintained within the targeted range for the patient.
- The patient's intravascular volume is stable requiring no serial blood product transfusions (no active bleeding).
- Inotropic, vasoactive and anti-arrhythmic drugs are at constant dosages or being decreased.

It is recommended that the Lavare Cycle be deactivated if the use of the Lavare Cycle has a detrimental effect on the patient such as increased suction events or [Low Flow] alarms.

**Note:** If thrombus is suspected within the device, the Lavare Cycle should be set to "Off" until the thrombus is resolved.

# 4.0 System Peripherals and Accessories


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## 4.1 PAL Controller

### 4.1.1 Controller Overview

The PAL Controller (**Figure 16**) is a wearable, water-resistant, ergonomically designed microprocessor-based device, which is worn by the patient and monitors and controls the HeartWare HVAD System operation. The controller attaches to the pump driveline cable. It provides power, transmits operating settings, and collects pump performance information from it. The controller monitors the pump status and issues alerts to the patient using vibratory, visual, and audible alarms. The controller transmits alarm and pump operating information to the monitor. Pump status, battery capacity and time remaining, alarm conditions and troubleshooting tips are displayed on the controller screen. The controller utilizes power from an external power source: an external battery, electrical outlet (with AC adapter) or car outlet (with DC adapter). An internal, replaceable, rechargeable lithium ion battery in the controller is used to power the controller and pump when changing external power sources.

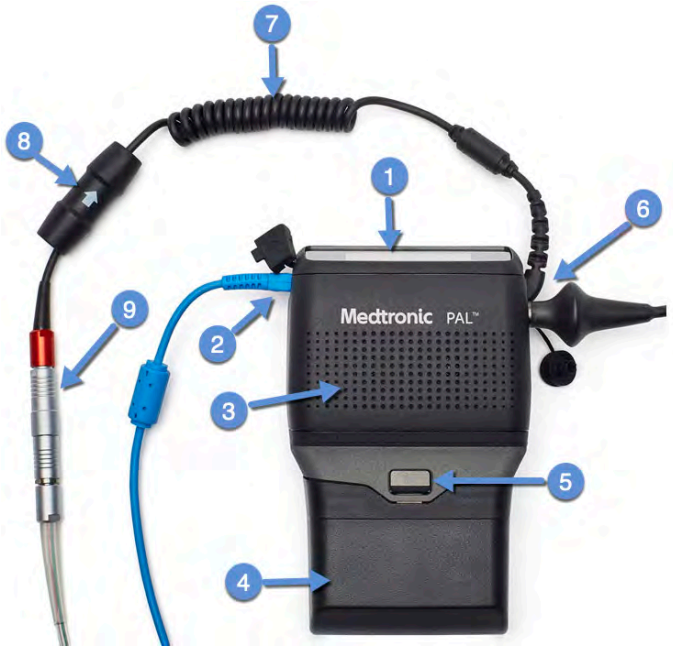



**Figure 16: Parts of the PAL Controller**

1. **Touchscreen display**
2. **Data port**
3. **Speakers**
4. **Single Battery**
5. **"Battery release" button**
6. **Power connector port**
7. **Coiled Cable**
8. **Driveline cover**
9. **Coiled Cable connector**

# 4.1 PAL Controller (continued)

## 4.1.1 Controller Overview (continued)

**WARNING!** DO NOT operate the PAL Controller in temperatures below -5°C (+23°F) or above +40°C (+104°F) or the controller may fail.

# 4.2 Controller Screens

## 4.2.1 Screen Overview

The controller display incorporates visual indicators and changes colors to report the status of the system and alert the user when an alarm condition exists. Pressing navigation buttons on the touchscreen display allows the user to view several screens that report different information related to system operation.

**Figure 17: Controller touchscreen display**


**Figure 18: Example of navigation button (heart symbol) and display of controller system information**

The background color of the screen indicates the overall status of the system (**Table 3**).

**Table 3: Background Screen Colors**

| Background Color | Example of Screen |
|---|---|
| **BLUE Background**<br>When the Home screen has a solid blue backlight, the system is running normally. |  <br>**BLUE** (Normal) |
| **YELLOW Background**<br>When the Home screen has a solid yellow backlight, a non-critical alarm is active. |  <br>**YELLOW** (Non- critical alarm) |
| **RED Background**<br>A flashing red backlight indicates an active critical alarm that must be addressed immediately. |  <br>**RED** (Critical alarm) |

# 4.2 Controller Screens (continued)

## 4.2.1 Screen Overview (continued)

**Note:** The background color will turn off after sixty (60) seconds of inactivity unless there is an active unmuted alarm. Touching the screen anywhere will reactivate the background color.

**WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

**WARNING!** IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.

**Table 4: Guide to Controller Symbols**

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| ♥ | Displays on the Home screen when the controller is running a pump, called the Running state. Press the heart ♥ symbol to view the VAD Status screen. | ℹ | Press the information ℹ symbol to view the Controller Information screens. When there is important information related to the internal or external battery replacement, a flashing ℹ symbol will display on the Home screen, in place of the symbol for the controller state. Press the flashing ℹ symbol to display the pertinent information. |
| ⚙ | Displays on the Home screen when the system is in Ready state. Press the Ready state ⚙ symbol to view the VAD Status screen. | ♥⚙ | Displays on the Home screen when the system is in Implant state. Press the Implant state ♥⚙ symbol to view the VAD Status screen. |
| ▭ | Displays to indicate the external or internal battery's charge. | ▭⚡ | Displays while the external or internal battery is charging. When the lightning bolt disappears, the battery is fully charged. |
| 01 h 02 m ▭ | Displays the runtime remaining (hours and minutes) of the external battery. | ▭ | Displays when the external or internal battery no longer has a charge and is not charging. |
| ⊘▭ | Displays when the external or internal battery is not connected or is not found. | 🔌 | Displays when the controller is powered by an AC or DC adapter. |
| 🔊 | Displays when one or more alarms is sounding. Pressing anywhere on the screen will temporarily mute a non-critical alarm. | 🔇X | Displays when the alarm is muted. |

# 4.2 Controller Screens (continued)

## 4.2.1 Screen Overview (continued)

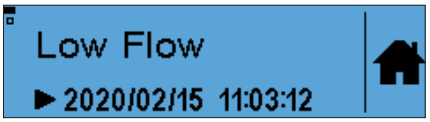
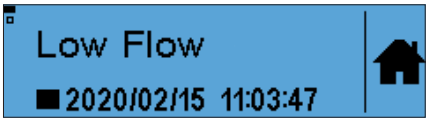
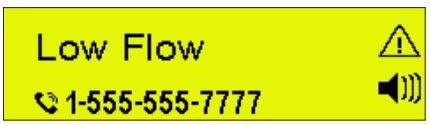
**Table 4: Guide to Controller Symbols (continued)**

| Symbol | Description | Symbol | Description |
|---|---|---|---|
|  | Press the alarm bell symbol to view the active and resolved alarms in the Alarm History. |  | A down arrow symbol flashes on the left side of the controller screen to indicate that there are multiple active non-critical alarms currently active. Press the screen to mute the audible tone, then press again to cycle through the alarms. The highest priority alarm will display first. Press until all alarm messages have been viewed. |
|  | The hourglass symbol displays while the controller is shutting down. |  | Indicates the patient should call clinician at the telephone number displayed. |
|  | Up to 10 small boxes display on the left side of the screen and indicate that there are multiple alarm messages to view. Press the center of the screen to cycle through the messages. Note that the highlighted rectangular box represents the message currently being displayed. |  | Displays when one or more alarms are active.<br><br>Active alarms must be investigated and resolved as soon as possible. |
|  | Displays on the Alarm History screen next to the date and time that an alarm began. |  | Displays on the Alarm History screen next to the date and time an alarm was resolved. |
|  | Displays on Controller Information screens indicating that the system feature is OFF. |  | Displays on Controller Information screens indicating that the system feature is ON. |
|  | Press the home symbol to return to the Home screen.<br><br>**Note:** The controller automatically returns to the Home screen after sixty (60) seconds if there is no active alarm. | | |

# 4.2 Controller Screens (continued)

## 4.2.1 Screen Overview (continued)

**Table 5: Screen Definitions**

| Screen Definition | Example of Screen |
|---|---|
| **Home screen** – Shows the system state and the status of the connected power sources. |  Figure 19: Home screen |
| **VAD Status screen** – Shows the pump flow in liters per minute (L/min), current pump speed in RPM, and pump operating power in Watts. |  Figure 20: VAD Status screen |
| **System screen** – Allows access to the Controller Information screens, the Alarm History screens, and the Home screen. |  Figure 21: System screen |
| **Controller Information screens** – Shows the status of connected batteries, programmed controller settings, and pump performance information. |  Figure 22: Example of a Controller Information screen |
| **Alarm History screen** – Shows past onset (unresolved) and past (resolved) alarms. Each alarm page includes the alarm message, and time stamp related to onset and resolution status. **Figure 25** shows an active alarm screen. |  Figure 23: Alarm onset screen<br>  Figure 24: Alarm resolved screen<br>  Figure 25: Alarm History - active |
| **Alarm Notification screen** – When the alarm condition is activated, the controller Home screen is replaced by an Alarm Notification screen. |  Figure 26: Alarm Notification screen |

**Note**: Pressing the home symbol will display the Home screen.

# 4.2 Controller Screens (continued)

## 4.2.2 Operating States

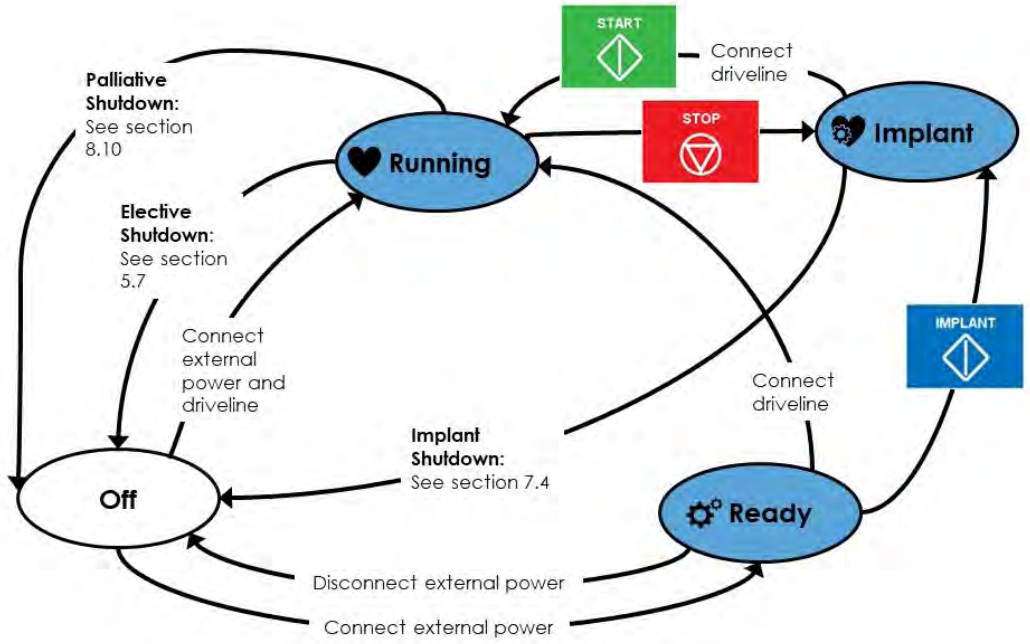
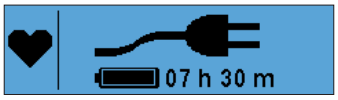



**Figure 27: Diagram of all Operating States**

The controller has the following operating states:

**Table 6: Operating State Definitions**

| Home Screen | What it represents: | What it means: |
|---|---|---|
| | **Off state** | The controller is off and will not power the pump when connected. |
|  | **Ready state** | The controller is on but not connected to a pump. The pump will immediately start when the driveline is connected. |
|  | **Implant state** | This state is only achievable via the monitor. The controller is on; automatic pump start is disabled allowing the pump to be connected without running; speed is set to the minimum 1800 RPM. |
|  | **Running state** | The controller is on and powering a pump. |

**WARNING!** ALWAYS ensure that the PAL Controller is in Implant state during the implant procedure. Connecting the driveline in the Ready state will automatically start the pump.

**Note:** The use of the monitor is required for transitioning in and out of the Implant state.

### 4.2.3 Screen Navigation

Refer to **Figure 28** for an overview of the screen navigation for the PAL controller.

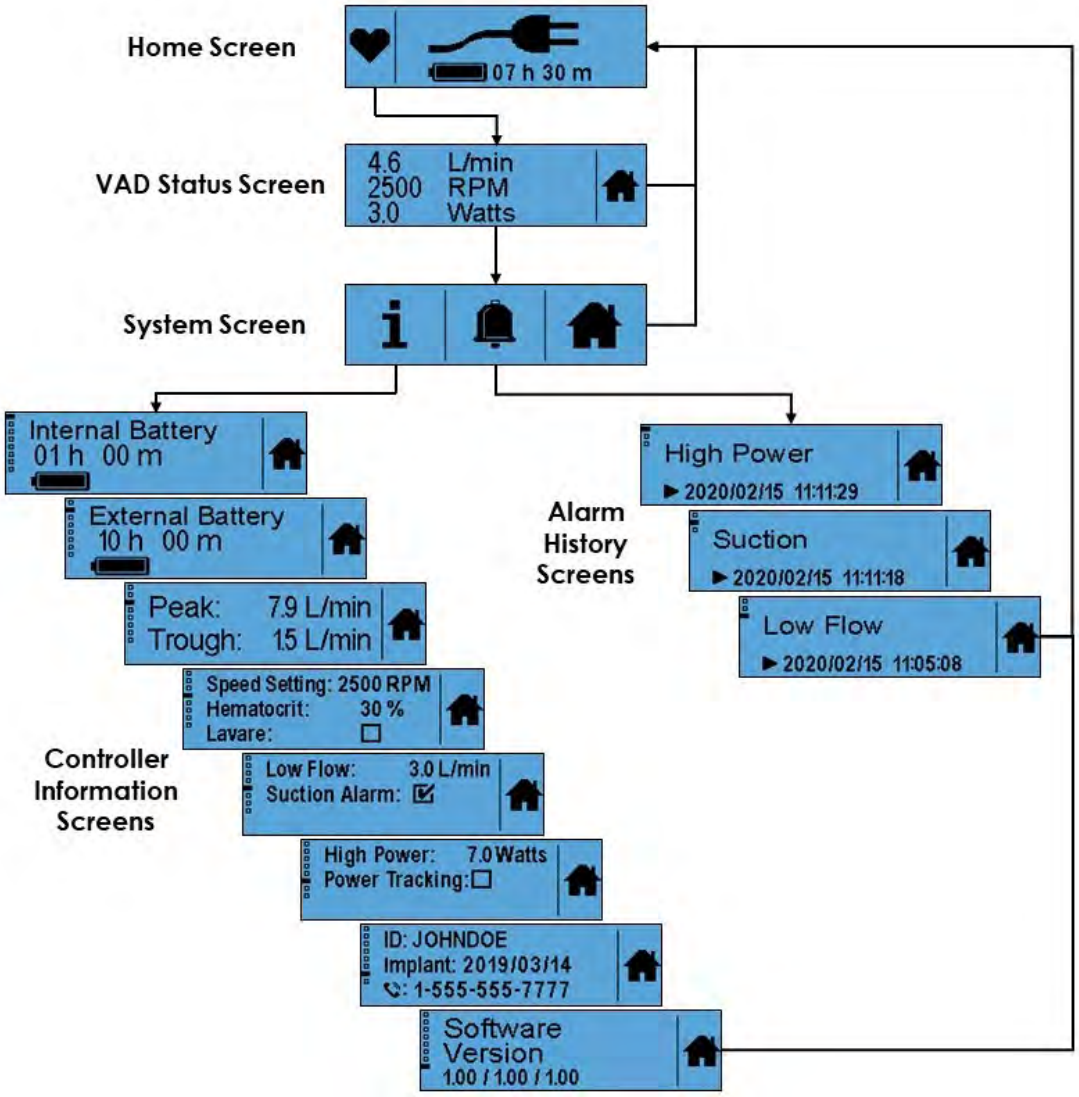



**Figure 28: Controller Screen Navigation**

- The controller will return to the Home screen automatically after sixty (60) seconds of inactivity.
- Press the home symbol to manually return to the Home screen.
- To cycle through the Controller Information screens or the Alarm History screens, press the center of the current screen.

# 4.2 Controller Screens (continued)

## 4.2.4 Screen Definitions

The Home screen displays the pump and the power source status, including battery runtime remaining, battery connection status, charge level, charging status, and power adapter connection status. When the Home screen is **BLUE**, the system is running normally.

**Note**: The estimate of time remaining for an external battery may adjust for a few seconds after a power source change.

**WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

**WARNING!** IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.

**Table 7: Home Screen Variations**

| Home Screen | Meaning of Symbols on Screen |
|---|---|
|  Figure 29: Ready state<br>  Figure 30: Implant state<br>  Figure 31: Pump running | • ⚙ - Ready state - The controller is on but not connected to a pump.<br>• ♥⚙ - Implant state - The controller is on; automatic pump start is disabled.<br>• ♥ - Running state - Pump is running.<br>• 🔌 - AC or DC adapter power is connected.<br>• 🔋 - Connected external battery level of charge.<br>• **08 h 30 m** - Time remaining until the external battery is depleted. |
|  Figure 32: Pump running; adapter only | • ♥ - The pump is running.<br>• 🔌 - AC or DC adapter power is connected. |
|  Figure 33: Connected and charging | • ♥ - The pump is running.<br>• 🔌 - AC or DC adapter power is connected.<br>• 🔋 - Connected external battery level of charge.<br>• ⚡ - Indicates battery is charging.<br>• **07 h 00 m** - Time remaining until the external battery is depleted. |
|  Figure 34: Pump running; external battery only | • ♥ - The pump is running.<br>• **09 h 00 m** - Time remaining until the external battery is depleted.<br>• 🔋 - Connected external battery level of charge. |

### 4.2.4 Screen Definitions (continued)

| Home Screen | Meaning of Symbols on Screen |
|---|---|
|  Figure 35: Important information | • When the operating state symbol changes to a flashing ℹ symbol, it indicates that there is important information related to internal or external battery replacement. |
|  Figure 36: Pump running; no external power connected | • ♥-Pump is running.<br>• No external power connected, or the external battery is fully depleted.<br>• This screen displays for a twenty (20)-second period after all external power is removed. If power is not connected within twenty (20) seconds, the non-critical [Connect Power] alarm activates. The non-critical alarm will escalate to a critical alarm after thirty (30) minutes or if the internal battery has fifteen (15) minutes or less time remaining. |
|  Figure 37: Non-critical alarm is occurring | • Example of a non-critical alarm occurring.<br>• Non-critical alarms display on the screen with a yellow background.<br>• For information about specific alarms, see **Section 5.0**. |

Pressing the state symbol on the Home screen will display the VAD Status screen. After sixty (60) seconds of inactivity, the Home screen will appear.

#### Controller Information Screens

The Home screen, VAD Status screen, and Controller Information screens may all be used to view pump and controller information when a monitor is not available.

**Table 8: Accessing the Controller Information Screens**

| Example of Screen | Description |
|---|---|
|  | • Home screen is the default viewing screen.<br>• Access the VAD Status screen by pressing the Controller state symbol ♥ or ♥ or ⚙. |
|  | • Access the System screen from the VAD Status screen by pressing the left side of the screen. |
|  | • Access the Controller Information screens from the System screen by pressing the information ℹ symbol. |


**Figure 38: Press the center of the screen**

To navigate through the screens, press the center of the current screen (as shown in **Figure 38**).

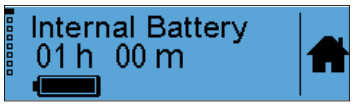
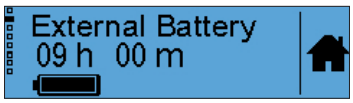
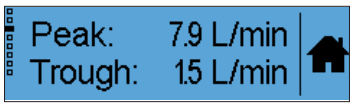
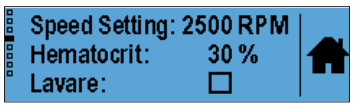
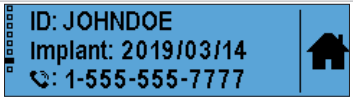
# 4.2 Controller Screens (continued)

## 4.2.4 Screen Definitions (continued)

The small boxes along the left side of the controller screen indicate that there are more information screens available for viewing. After the last information screen, navigation will return to the first information screen. The controller will return to the Home screen automatically after sixty (60) seconds of inactivity. Press the home symbol to immediately return to the Home screen.

The Controller Information screens include pump and controller information, some of which is programmed from the monitor (**Table 9**).

**Table 9: Controller Information Screens**

| Example of Screen | Description |
|---|---|
|  | • Internal battery connection status<br>• Charge level<br>• Runtime remaining<br>• Charge status |
|  | • External battery status<br>• Charge level<br>• Runtime remaining<br>• Charge status |
|  | • Pump peak flow<br>• Pump trough flow |
|  | • Pump speed setting<br>• Hematocrit setting<br>• Lavare setting |
|  | • [Low Flow] alarm setting<br>• [Suction] alarm setting |
|  | • [High Power] alarm setting<br>• Power Tracking setting |
|  | • Patient Identification Number<br>• Implant date (YYYY/MM/DD)<br>• Clinician phone number |
|  | • Software version |

## 4.2.4 Screen Definitions (continued)

### Controller Alarm History Screens

The controller Alarm History screens show the status of the ten (10) most recently occurring alarms. Both critical and non-critical alarms are recorded in the Alarm History, excluding the [Change Battery] alarm, the [Connect Power] alarm, and the [Connect Cap or Battery] alarm.

**Table 10: Accessing the Alarm History Screens**

| Screen Navigation Steps | Description |
|---|---|
|  | • The Home screen is the default viewing screen.<br>• Press the controller state symbol ♥ or 💔 or ⚙ to access the VAD Status screen. |
|  | • Press the left side of the VAD Status screen to access the System screen. |
|  | • Press the bell 🔔 symbol to access the Alarm History screens. |

To navigate through the screens, press the center of the current screen (as shown in **Figure 39**).

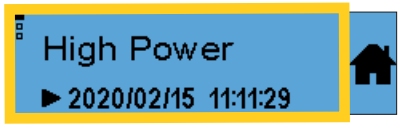
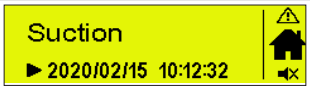
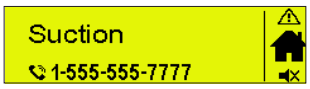
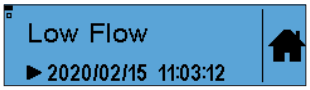
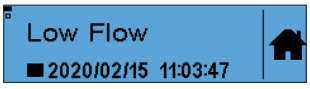



**Figure 39: Example of an Alarm History screen**

After the last Alarm History screen, navigation will return to the first Alarm History screen. The controller will return to the Home screen automatically after sixty (60) seconds of inactivity. To exit the Alarm History screen manually, press the home 🏠 symbol.

**Table 11: Examples of Alarm History screens (Active and Resolved)**

| Type of Alarm | Alarm History Screen Display |
|---|---|
| **Active** |  <br>**Figure 40: [Suction] alarm (onset)**<br>  <br>**Figure 41: Active [Suction] alarm** |
| **Resolved** |  <br>**Figure 42: [Low Flow] alarm (onset)**<br>  <br>**Figure 43: [Low Flow] alarm (resolved)** |

# 4.2 Controller Screens (continued)

## 4.2.4 Screen Definitions (continued)

### Controller Alarm History Screens (continued)

Active alarms will display first, in order of priority. The small boxes along the left side indicate the number of alarms available for viewing. The black (filled) box shows the position of the currently displayed alarm in the Alarm History. Both active and resolved alarms display two lines which can include the alarm name, time, and instruction. Alarms that are still active display the alarm name followed by a triangle (onset) ▶ symbol and the time of the alarm onset. This alternates with the clinician phone number. A flashing alarm ⚠ symbol indicates that the alarm condition has not yet been resolved. Alarms that have been resolved display the alarm name followed by a triangle (onset) ▶ symbol and the time of onset, which alternates with a square (resolved) ■ symbol and the time of resolution.

# 4.3 Controller Connections

## 4.3.1 Connections Overview

There are four connection ports on the controller:

1. Data Cable Connection (**pg. 41**)
   - Connects to the data cable from the monitor
   - Covered with a dust cover


2. Driveline Connection (**pg. 42**)
   - Connects to the pump driveline cable
   - Must always be connected to the pump for continuous pump operation
   - Must always be covered by the driveline cover


3. Power Cord Connection (**pg. 44**)
   - Connects to the AC or DC power adapter
   - Covered with a dust cover


4. External Battery Connection (**pg. 47**)
   - Connects to the Single or Dual Battery
   - Covered with a PAL Cap

## 4.3.1 Connections Overview (continued)

**CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HVAD System may not function as intended.

**CAUTION:** Patient should AVOID changing power sources in or near water (e.g., shower, rain, ocean, etc.), as this may damage the controller. If equipment is damaged, contact Medtronic.

## 4.3.2 HeartWare Monitor Connection

Before connecting the PAL Data Cable to the controller, make sure that an external battery or AC or DC adapter is attached. Refer to **Section 6.0** for how to use the monitor application.

| | |
|---|---|
| **1.** Connect the USB Type A connector of the data cable to the monitor. |  **Figure 44: Connect USB** |
| **2.** Lift the data cable dust cover. |  **Figure 45: Lift the dust cover** |
| **3.** Align the USB Type B connector and controller so that the alignment indicators are facing upward and gently push the data cable into the controller port. DO NOT twist the connector but allow it to naturally slide into the port. |  **Figure 46: Slide the USB cable in** |

**Note:** When correctly connected, controller information will display at the bottom of the monitor screen.

# 4.3 Controller Connections (continued)

## 4.3.3 Driveline (Pump Cable) Connection

### Connecting the Driveline:

| | |
|---|---|
| **1.** Align the red line on the controller Coiled Cable connector with the alignment marker on the pump driveline connector. |  **Figure 47: Align the red line with the red dot/black line** |
| **2.** Push the pump driveline connector straight into the port until there is a click.<br>**Note:** To ensure proper connection, verify that the pump is running. There will be a heart ♥ symbol displayed on the controller or on the monitor. If the controller was in the Implant state, the "Start" button will be enabled on the monitor after pump connection. |  **Figure 48: Push the driveline connector into the port** |
| **3.** Slide the driveline cover over the connectors until the cover is securely in place. |  **Figure 49: Slide the cover over connectors** |

**WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller IMMEDIATELY to restart the pump.

**CAUTION:** DO NOT pull, kink, or twist the driveline, as these actions may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare Shower Bag.

# 4.3 Controller Connections (continued)

## 4.3.3 Driveline (Pump Cable) Connection (continued)

### Disconnecting the Driveline from the controller:

| | |
|---|---|
| **1.** Slide the driveline cover towards the controller to reveal the whole silver connector. |  **Figure 50: Slide the driveline cover** |
| **2.** Grasp the pump driveline cable below the connector with one hand, avoiding the grooved area, as shown in **Figure 51**. |  **Figure 51: Grasp the pump driveline cable** |
| **3.** With the index finger and thumb of the same hand, pinch the grooved area of the pump driveline connector (**Figure 52**). |  **Figure 52: Pinch the grooved area of the pump driveline connector** |
| **4.** With the other hand, pinch the grooved area of the controller Coiled Cable connector (**Figure 53**). |  **Figure 53: Pinch the grooved area of the controller Coiled Cable connector** |
| **5.** Release the locking mechanism by pulling the controller driveline connector away from the pump Coiled Cable connector (**Figure 54**).<br><br>**Note:** Only pull on the grooved area of the connectors. If any other area of the driveline or connector is pulled back, the driveline will not release from the controller. |  **Figure 54: Release the locking mechanism** |

# 4.3 Controller Connections (continued)

## 4.3.4 AC or DC Adapter Connection

### AC or DC Adapter Overview

The AC Adapter **(Figure 55)** connects to the controller and a receptacle for connection of an AC Power Cord. Prior to connection to the controller, verify proper connection of the Power Cord to the AC Adapter Brick **(Figure 56)** and to the electrical outlet. If adapter connector is not properly connected, perform the following steps:

1. Make sure the AC adapter and the AC power cord are not connected to the controller or to an electrical outlet.
2. Insert the AC Power Cord into the power adapter receptacle on the adapter brick.
3. Ensure that the AC power cord is secure in the power adapter receptacle.

When connected to an electrical outlet, a blue indicator light on the adapter will indicate proper connection. Ensure that the power indicator on the AC or DC Adapter brick turns blue before plugging the adapter into the controller. Since the AC Adapter does not contain a power switch, the AC power cord acts as the disconnection device from mains power. Position the AC adapter so the AC power cord can be easily disconnected from the electrical outlet or AC adapter if needed.

**Figure 55: AC Adapter with AC Power Cord**

**Figure 56: AC Power Cord connection to AC Adapter Brick**

**Figure 57: DC adapter**

The DC Adapter (**Figure 57**) can be plugged into the power port located in most vehicles. When the DC Adapter is properly connected to power, a blue indicator light will display on the adapter.

**Note:** The DC Adapter is for use in vehicles only and may not fit in some vehicles. The vehicle must have at least a 10-amp DC adapter fuse.

**WARNING!** ALWAYS connect an AC Adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC Adapter) provides power for an unlimited period of time.

## 4.3.4 AC or DC Adapter Connection (continued)

### Connecting an AC or DC Adapter:

| | |
|---|---|
| **1.** Lift the power cord dust cover. |  **Figure 58: Lift the dust cover** |
| **2.** To connect an AC Adapter or DC Adapter, grasp the power cable near its connector. |  **Figure 59: Grasp the cable near its connector** |
| **3.** Align the solid yellow line on the cable connector with the solid yellow line on the controller power connector port (**Figure 60**). |  **Figure 60: Align the cable connector with the controller power connector port** |
| **4.** Gently push the cable into the controller power connector port. DO NOT twist the connector but allow it to naturally slide into the power connector port. |  **Figure 61: Allow the cable to slide into the controller power connector port** |

# 4.3 Controller Connections (continued)

## Connecting an AC or DC Adapter: (continued)

**Note**: When correctly connected, the controller will vibrate, and the screen will display a power cord symbol.


**Figure 62: Controller screen**

**WARNING!** ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.

**CAUTION**: ALWAYS have an external battery or cap connected to the battery connector even while using an AC or DC adapter with the controller. An uncovered battery connector can lead to electrostatic discharge (ESD) events.

**CAUTION**: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

## Disconnecting an AC or DC Adapter:

| | |
|---|---|
| **1.** Grasp the power cord and pull it straight out from the controller. |  **Figure 63: Pull the power cord out** |
| **2.** Cover the power cord port with the power cord dust cover. |  **Figure 64: Cover the port with dust cover** |

# 4.3 Controller Connections (continued)

## 4.3.5 External Battery and PAL Cap Connection

### External Batteries Overview

External Batteries are available in two sizes: Single and Dual. The Single and Dual Batteries contain lithium ion cells to power the HVAD Pump for approximately six (6) hours and thirteen (13) hours, respectively. When connected to the controller, the battery will communicate battery capacity and other parameters to the controller. The capacity (hours of support) of each battery is based on:

- Controller and HVAD Pump operating power consumption
- Number of battery charge and discharge cycles
- Battery temperature

**Note**: The amount of battery time may increase or decrease significantly depending on pump operating conditions.

For best runtime, fully-charged external batteries should be connected to the controller. There are two steps to know if the external battery is fully charged and ready for use:

1. Press the "Battery Capacity" button on the battery (**Figure 65**).

**Figure 65: "Battery Capacity" button**

2. The battery capacity indicator will light up showing how much power is in the external battery. See **Table 12**.

**Table 12: Battery Capacity Display**

| Battery Capacity | Battery Capacity Indicator |
|---|---|
| Full | 4 GREEN lights |
| High | 3 GREEN lights |
| Medium | 2 GREEN lights |
| Low | 1 GREEN light |

**Note**: If no light displays at all, the battery is fully depleted. Connect the battery to a charger.

**CAUTION**: ALWAYS recharge fully depleted external batteries within 24 hours to avoid permanent battery damage.

# 4.3 Controller Connections (continued)

## 4.3.5 External Battery and PAL Cap (continued)

**WARNING!** ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.

The controller will provide three (3) indications to prompt the user to change an external battery.

1. The display background color will be yellow (**Figure 66**).
2. The display will show a non-critical [Change Battery] alarm (**Figure 66**).
3. The controller will vibrate and emit a sound indicating a non-critical alarm (**Figure 66**).


**Figure 66: Non-critical alarm [Change Battery]**

The message is resolved when a charged external battery is connected to the controller.

**Note:** If a depleted external battery is not exchanged and the internal battery is used for thirty (30) minutes, a critical alarm will sound, the display background color will flash RED and the message on the controller display will read [Connect Power] (**Figure 67**). During this condition, a charged battery or adapter (AC or DC) should be attached immediately to the power port.


**Figure 67: Critical alarm [Connect Power]**

**WARNING!** ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

## 4.3.5 External Battery and PAL Cap (continued)

### Connections to the External Battery and the PAL Cap

The same mechanism is used to connect and disconnect the Single Battery, Dual Battery, and PAL Cap.

### Connecting an External Battery

1. Insert the tabs of the fully-charged battery into the openings on the battery connector and pivot the battery to snap it into the controller.


**Figure 68: Insert tabs of the battery on the battery connector**

**Note:** DO NOT force the connection between the battery and the controller. Allow it to naturally lock into place. A successful connection will result in a vibration.

2. Look at the screen of the controller display. The hours and minutes of the battery capacity's time remaining will be displayed using the following conventions:


**Figure 69: Estimation of remaining time for battery capacity**

**Table 13: Estimated Time Remaining Reporting Increments**

| Estimated Time Remaining | Estimated Time Remaining Reporting Increments |
|---|---|
| >=6 hours | 30 minutes |
| >=3.5 to 6 hours | 15 minutes |
| >=1.5 to 3.5 hours | 5 minutes |
| <1.5 hours | 1 minute |

# 4.3 Controller Connections (continued)

## 4.3.5 External Battery and PAL Cap (continued)

**CAUTION**: ALWAYS verify that the battery symbol is present on the PAL Controller screen to confirm that the external battery is properly locked on to the controller in order to maintain optimal therapy.

### Disconnecting an External Battery

1. Make sure there is a fully-charged external battery available to replace the used or depleted battery.

**Note:** Change the external battery in a dry, clean and dust-free location.

2. While holding the battery (so it does not drop), press the "Battery Release" button.


**Figure 70: Press the "Battery Release" button**

3. Pivot the battery away from the battery latch to detach the battery tabs.


**Figure 71: Detach the battery tabs**

**Note:** If an external power source is not connected within twenty (20) seconds, the [Connect Power] message will be displayed on the controller display and a non-critical alarm will sound. The alarm will automatically clear when another power source is connected to the controller.

**WARNING!** ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

**WARNING!** ALWAYS keep the backup controller and spare external batteries close to the patient in a dry environment where the temperature is between -5°C and +40°C (+23°F to +104°F).

## 4.3.5 External Battery and PAL Cap (continued)

### Charging External Batteries through the Controller

**An external battery can be charged either by the primary or backup controller in temperatures between +10˚C (+50˚F) to +30˚C (+86˚F)**. It can take up to six (6) hours to fully charge a depleted battery.

| | |
|---|---|
| **1.** Make sure the external battery is properly connected to the controller. |  **Figure 72: Battery connected** |
| **2.** To connect an AC adapter or DC adapter, grasp the power cable near its connector. |  **Figure 73: Grasp power cable** |
| **3.** Align the solid yellow line on the cable connector with the solid yellow line on the controller. |  **Figure 74: Align the yellow lines** |
| **4.** Gently push the cable into the controller. DO NOT twist the connector but allow it to naturally slide into the port. |  **Figure 75: Push cable into controller** |

**Note:** When correctly connected, there will be a vibration and the controller screen will display a power cord symbol.


**CAUTION**: DO NOT attempt to charge the controller using the USB data port. The USB data port should be used only for data transfer and will not provide power to the controller.

# 4.4 Battery Charger

## Charging the External Batteries

External batteries can be charged when inserted into the Battery Charger.

**1.** Connect the AC power cord to the back of the battery charger.

**Figure 76: Connect the AC power cord**

**2.** Plug the other end of the cable into an electrical outlet.

**Note**: Since the Battery Charger does not contain a power switch, the AC power cord acts as the disconnection device from mains power. Position the Battery Charger so the AC power cord can be easily disconnected from the electrical outlet or Battery Charger if needed.

**Figure 77: Plug cable into outlet**

**3.** Once the battery charger is connected to power, the blue power light, located on the front center of the charger, will turn on.

**Figure 78: Blue power light turns on**

**4.** Place the battery into the charging bay, matching the curvature of the battery case to the curvature in the bay until it is seated in place. When it is properly seated, the battery charging status light will illuminate.

**Figure 79: Place battery into charging bay**

**5.** Repeat step 4 for all batteries. The battery charger can hold up to four (4) batteries at one time.

**Figure 80: Holds up to 4 batteries**

## 4.4 Battery Charger (continued)

### Status of External Batteries and Battery Charger

Each charging bay has an indicator light to show the battery charging status. A solid green light means the battery is fully charged. It can take up to six (6) hours to fully charge a depleted battery. It is safe to leave the fully-charged batteries in the battery charger.

**Figure 81: Green battery status indicator lights**

**Table 14: Battery Status Light**

| Battery Status Light | What it Means |
|---|---|
| **Off** | Battery not charging |
| **Solid Green** | Battery fully charged |
| **Flashing Green** | Battery charging |
| **Solid Red** | Battery fault or incorrect placement<br><br>Try removing and reconnecting the external battery. If the fault persists, replace the battery. |
| **Flashing Red** | Temporary battery fault (temperature) or a communication error |

The Battery Charger also has an indicator light to show the status of the charger.

**Figure 82: Battery Charger blue status Indicator Light**

**Table 15: Battery Charger Status Light**

| Charger Status Light | What it Means |
|---|---|
| **Off** | Charger off |
| **Solid Blue** | Charger operating normally |
| **Solid Red** | Charger fault<br>Try disconnecting and reconnecting the battery charger power. If the fault persists, replace the battery charger. |

## 4.4 Battery Charger (continued)

### Status of External Batteries and Battery Charger (continued)

**WARNING!** DO NOT use damaged equipment as it could lead to patient harm. Damaged equipment should be reported to Medtronic.

**CAUTION:** ONLY use the PAL Controller or PAL Battery Charger to charge PAL Batteries. Other battery chargers will not charge the external batteries and may lead to battery damage.

## 4.5 Internal Battery

The controller's internal battery contains lithium ion cells that power the controller for at least thirty (30) minutes with a new internal battery when fully charged. Over time, the internal battery may provide shorter periods of backup power.

### Intended Use

The controller internal battery is intended to provide power while changing from one external power source to another (external batteries, AC adapter, or DC adapter). The internal battery in the controller is a backup power source and should never be used as the only source of power for the controller for extended periods of time. The internal battery is designed to provide safe and continuous pump operation during the exchange of external power sources.

**WARNING!** ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.

**WARNING!** The PAL Controller internal battery should only be changed by trained personnel. Patients and caregivers should not attempt to change the controller internal battery.

**Note**: After twelve (12) months of use, the internal battery should be replaced within the next six (6) months.

**For additional information on Internal Battery Replacement, see Section 8.9.**

When no external power sources are active, the controller internal battery will automatically begin to provide power to the pump. Whenever the pump is running on the internal battery alone, the [Connect Power] message will appear on the controller display.

- If external power is not connected within twenty (20) seconds, the message will escalate to a non-critical alarm with vibration and sound. This alarm may be muted by pressing on the center of the controller screen. After ten (10) minutes (e.g., two 5-minute mutes), the alarm cannot be muted.

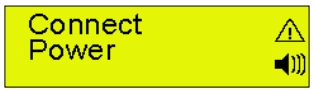



**Figure 83: Non-critical [Connect Power] alarm**

- If external power is not connected within thirty (30) minutes of running on the controller internal battery, or when the internal battery has only fifteen (15) minutes of power remaining, a critical [Connect Power] alarm will sound.


**Figure 84: Critical [Connect Power] alarm**

The [Connect Power] alarm will clear as soon as an external power source (charged external battery, AC adapter, or DC adapter) is connected.

## 4.5 Internal Battery (continued)

### Charging the Internal Battery

The controller internal battery is recharged whenever there is an external power source attached to the controller. The amount of time the internal battery has remaining is displayed in the Controller Information screens. When external power is connected to a controller with an internal battery low on charge, the [Keep Power Connected] alarm will continue until the internal battery is sufficiently charged.


**Figure 85: [Keep Power Connected] alarm**

**Note**: A new controller may have a [Keep Power Connected] alarm to indicate the internal battery needs to be charged. This may take up to 2.5 hours.

**CAUTION**: Patient should AVOID placing the controller in the following conditions to prevent harm from excessive heat:

- Between the legs when sleeping or sitting.
- Under the body while sleeping or sitting.
- Under covers in a warm room.
- In a heated room (e.g., sauna, steam room, hot yoga class, etc.).
- Under a thick or thermal (hypothermia) blanket.
- Under a heat lamp.
- In direct sunlight.

## 4.6 Carrying Cases and HeartWare Shower Bag

### 4.6.1 Overview

The PAL Sport Pack, PAL Accessories Bag, and the HeartWare Shower Bag are used to safely secure, store and carry the controller and external batteries. They can be used during normal daily activities.

The HeartWare Shower Bag is available for use in conjunction with the HVAD System. To ensure safe and appropriate use of the HeartWare Shower Bag, all patients and caregivers should be trained on the HeartWare Shower Bag operation prior to use.

**Figure 86: PAL Sport Pack**

**Figure 87: PAL Accessories Bag**

**Figure 88: HeartWare Shower Bag**

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.2 Sport Pack

**WARNING!** NEVER disconnect the pump driveline from the controller when loading equipment into the PAL Sport Pack as this will lead to a pump stop and potential harm. Bag loading does not require driveline disconnection.

**Figure 89: Parts of the PAL Sport Pack**


**Figure 90: PAL Sport Pack**

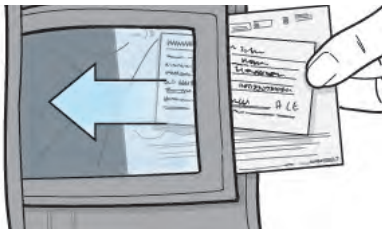
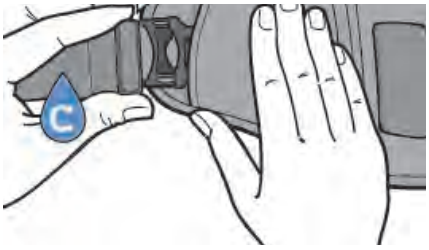
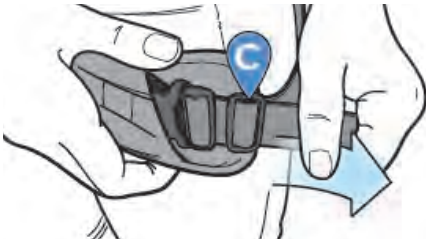

**Figure 91: PAL Sport Pack straps & belts**

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.2 Sport Pack (continued)

### Wearing the Sport Pack waist configuration

***(Refer to the Sport Pack illustrations in Figure 91)***

| | |
|---|---|
| **1.** Place the Emergency Responder Guide and Patient ID Card into the back pocket of the pack. |  |
| **2.** Connect one waist belt buckle (**C**) to the pack buckle and wrap the strap around the waist. Make sure that the zipper opening of the pack is facing up. |   |
| **3.** Connect the remaining waist belt buckle (**C**) to the pack buckle. |   |
| **4.** Adjust the length of the elastic strap to create a supportive and comfortable fit. |   |
| **5.** Slide the loops along the strap to secure any unused extra length. |   |

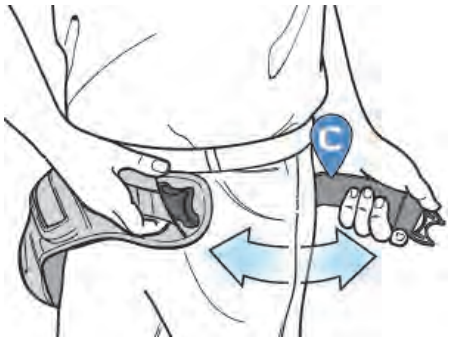
**Note:** The Sport Pack waist configuration can be worn either in front, on the side, or at the back of the body.

**CAUTION:** Use caution when moving equipment around in a carrying case to avoid tugging on the driveline exit site.

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

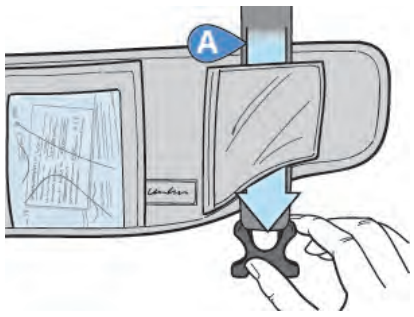
## 4.6.2 Sport Pack (continued)

### Removing the Sport Pack waist configuration

| | |
|---|---|
| **1.** Disconnect the waist belt buckle from the pack buckle. |  |
| **2.** Remove the pack. |  |

### Wearing the Sport Pack shoulder configuration

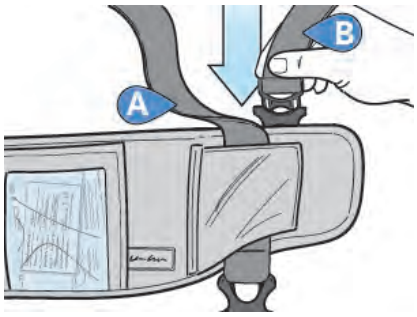
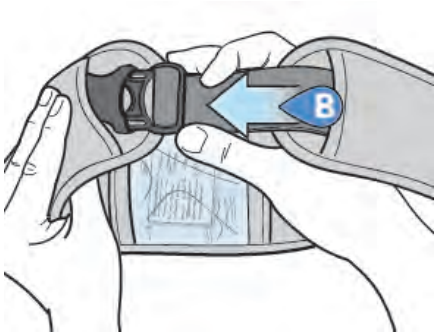
***The following buckle connection steps should be modified, depending on which shoulder is to be used. The following instructions are compatible with left shoulder configuration.***

| | |
|---|---|
| **1.** Place the Emergency Responder Guide and Patient ID Card into the back pocket of the pack. |  |
| **2.** With the pack face down, slide the shoulder belt (**A**) through the shoulder belt loop on the side on which the bottom of the controller will be located. |  |

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.2 Sport Pack (continued)

### Wearing the Sport Pack shoulder configuration (continued)

| | |
|---|---|
| **3.** Connect one shoulder strap (**B**) buckle to the shoulder strap sliding buckle that is on the same side as the shoulder belt. |  |
| **4.** Connect the other shoulder strap (**B**) buckle to the waist belt buckle on the opposite side of the pack. |  |
| **5.** Place the shoulder strap (**B**) over the shoulder and adjust the length using the adjustable slides. |  |
| **6.** Adjust the position of the shoulder padding for a supportive and comfortable fit. |  |

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.2 Sport Pack (continued)

### Wearing the Sport Pack shoulder configuration (continued)

| | |
|---|---|
| **7.** Connect the shoulder belt (**A**) buckles to the PAL Sport Pack and adjust the length. |  |
| **8.** Slide the loops along the strap to secure any unused extra length of shoulder belt. |  |

**Note:** The Sport Pack shoulder configuration can be worn either in front, on the side, or at the back of the body.

**CAUTION:** Use caution when moving equipment around in a carrying case to avoid tugging on the driveline exit site.

### Removing the Sport Pack shoulder configuration

| | |
|---|---|
| **1.** Disconnect the shoulder belt buckles. |  |

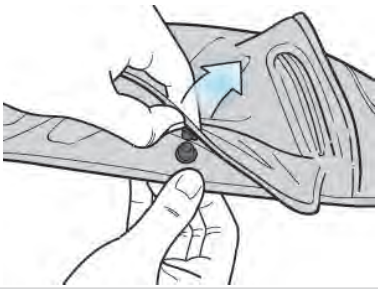
# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.2 Sport Pack (continued)

### Removing the Sport Pack shoulder configuration (continued)

| | |
|---|---|
| **2.** Remove the Sport Pack off the shoulder. |  |

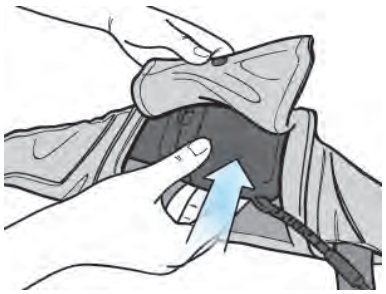
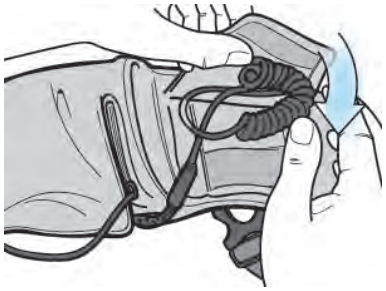
### Loading the Sport Pack

| | |
|---|---|
| **1.** Place the Emergency Responder Guide and Patient ID Card into the back pocket of the pack. |  |
| **2.** Unbutton the top snap and the Velcro® of the pouch flap. |  |
| **3.** Grasp the middle of the zipper bar and pull it away from the snap button to open the pouch.<br>**Note:** Individual zippers may need minor adjustments. |  |

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.2 Sport Pack (continued)

### Loading the Sport Pack (continued)

| | |
|---|---|
| **4.** Place the controller in the pack pouch.<br>**Note:** The speakers on the controller must face away from the patient's body. However, the controller can face left or right to allow for easier screen visibility. |  |
| **5.** Grasp the middle of the zipper bar and pull it towards the snap button until the zipper is completely secure. |  |
| **6.** Button the top snap and secure the Velcro® of the pouch flap. Be careful not to damage the driveline. |  |
| **7.** Open the preferred driveline pocket (left or right side) and position the extra driveline (either as a loop or carefully folded, depending on the length of driveline) in the appropriate area. Secure the flap over the driveline by pressing on the Velcro® portion. |  |
| **8.** **Optional**: A mobile phone may be placed in the phone pocket. |  |

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.2 Sport Pack (continued)

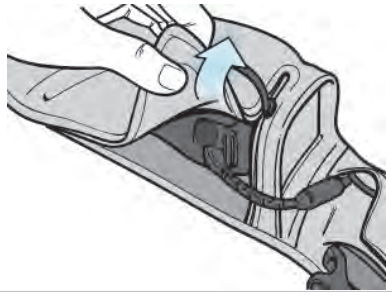
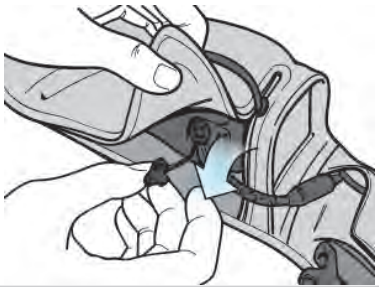
### Loading the Sport Pack (continued)

**WARNING!** NEVER disconnect the pump driveline from the controller when loading equipment into the PAL Sport Pack as this will lead to a pump stop and potential harm. Bag loading does not require driveline disconnection.

**Note:** The AC adapter should only be connected to the controller while loaded in the bag if the power cord connection is facing upwards or through one of the side viewing windows in the PAL Cap only configuration.

### Connecting the Controller in the Sport Pack to an AC or DC Adapter

**If the power cord connection is facing upward:**

| | |
|---|---|
| **1.** Detach the Velcro® corner of the pouch flap nearest to the power cord connection.<br>**2.** Slightly unzip the flap nearest to the power cord connection until the dust cover can be seen. |  |
| **3.** Remove the dust cover from the port. |  |
| **4.** Attach the adapter to the controller. |  |

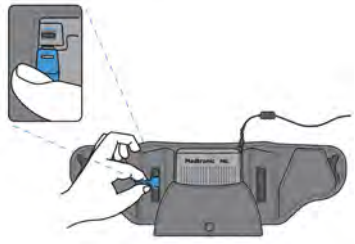
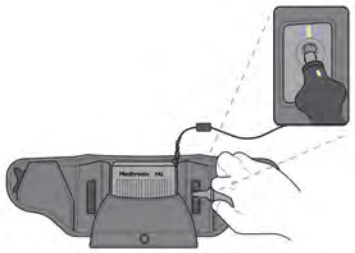
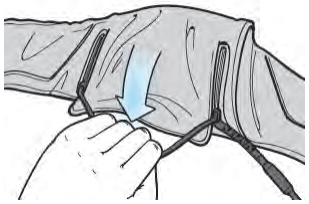
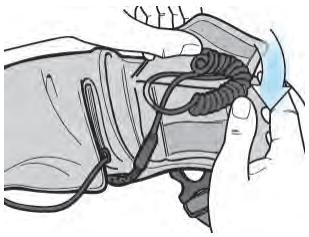
**If the power cord and data cable need to be connected at the same time:**

| | |
|---|---|
| **1.** Place the controller connected to the PAL Cap in the Sports Pack with the screen facing the pouch opening. Ensure the adapter port dust cover and the data port cover are removed.<br>**Note**: The speakers on the controller must face away from the patient's body. |  |

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

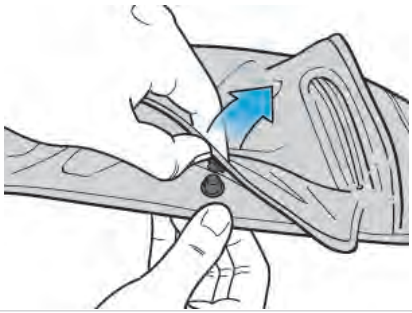
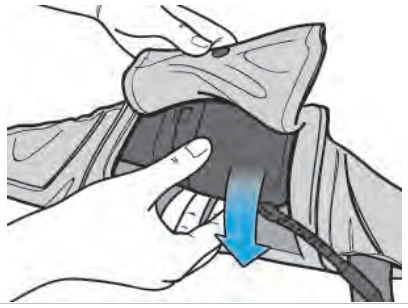
## 4.6.2 Sport Pack (continued)

### Connecting the Controller in the Sport Pack to an AC or DC Adapter (continued)

| | |
|---|---|
| **2.** Attach the data cable to the controller through the side window on the bag pouch. |  |
| **3.** Attach the adapter to the controller through the other side window on the bag pouch. |  |
| **4.** Grasp the middle of the zipper bar and pull it towards the snap button until the zipper is completely secure. |  |
| **5.** Button the top snap and secure the Velcro® of the pouch flap. Be careful not to damage the driveline. |  |
| **6.** Open the preferred driveline pocket (left or right side) and position the extra driveline (either as a loop or carefully folded, depending on the length of driveline) in the appropriate area. Secure the flap over the driveline by pressing on the Velcro® portion. |  |

## 4.6.2 Sport Pack (continued)

### Unloading the Sport Pack

| | |
|---|---|
| **1.** Unbutton the snap and detach the Velcro® of the pouch flap. |  |
| **2.** Grasp the middle of the zipper bar and pull it away from the snap button to open the pouch. |  |
| **3.** Remove the controller from the pack. |  |

## 4.6.3 Accessories Bag

Patients should place the following equipment in the Accessories Bag so that it is readily available at all times:

- 1 Backup Controller with attached Cap
- 2 Single or Dual Batteries
- 1 AC or DC Adapter
- 1 Patient ID Card
- 1 Emergency Responder Guide

**Figure 92: Accessories Bag**

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.3 Accessories Bag (continued)

### Loading the Accessories Bag

1. Unzip the Accessories Bag.
2. Place the Emergency Responder Guide and Patient ID Card into the internal pocket of the Accessories Bag.
3. Place the backup equipment in the compartments as shown in the picture (**Figure 93**).

   Backup equipment includes:

   - 1 Backup Controller
   - 1 AC Adapter or DC Adapter
   - 2 Batteries
4. Use the zipper to close the Accessories Bag.


**Figure 93: Compartments of PAL Accessories Bag**

**Note:** Do not place objects on top of the Accessories Bag.

### Unloading the Accessories Bag

1. Unzip the Accessories Bag.
2. Remove the contents from the bag.

## 4.6.4 HeartWare Shower Bag

The cover of the HeartWare Shower Bag has a zipper closure that allows the driveline to exit the bag without being damaged by the zipper. An adjustable shoulder strap is used to wear the bag while showering.

### Recommendations for Showering:

- Keep the driveline exit site covered and as dry as possible while showering.
- Try not to pull or move the driveline. Pulling or moving the driveline could injure an already healed exit site. DO NOT kink or bend the driveline.
- Be careful not to catch the driveline in the zipper when closing the HeartWare Shower Bag.
- Prior to showering, make sure the external battery is completely charged.
- If the patient is hearing impaired, make certain someone is always close by to hear alarms. If any alarm sounds during showering, the shower should be turned off and the alarm condition immediately addressed.
- The shower floor should be made of a non-slip surface or have a textured rubber mat.
- The shower stall should have a handrail and a shower chair.

## 4.6.4 HeartWare Shower Bag (continued)

### Getting Ready to Shower

**1.** Unzip and inspect the HeartWare Shower Bag for rips or tears. Make sure the inside of the bag is dry.

- If the bag has any rips, tears or is wet, do not use the bag and do not proceed to shower.
- Contact your clinician to get a replacement HeartWare Shower Bag, if needed.

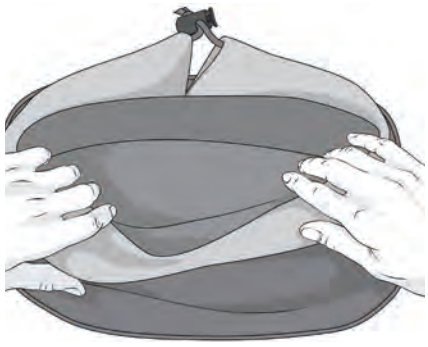


**Figure 94: Unzip and inspect**

**2.** Place the controller attached to an external battery inside the inner pouch of the HeartWare Shower Bag. Always tuck the driveline connector inside the HeartWare Shower Bag.

- The controller should be facing upward so the display is seen easily if an alarm occurs.
- The controller can be in or out of the Sport Pack.

**3.** Pull the drawstring to close the inner pouch of the HeartWare Shower Bag.

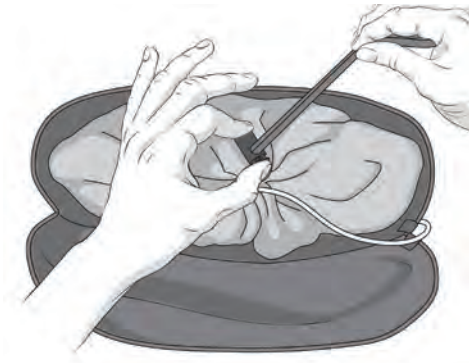


**Figure 95: Pull the drawstring**

**4.** With the HeartWare Shower Bag opening away from the patient, position the driveline toward the farthest right corner of the zipper.

- This part of the zipper is covered to prevent the driveline from being damaged when zipping the bag.

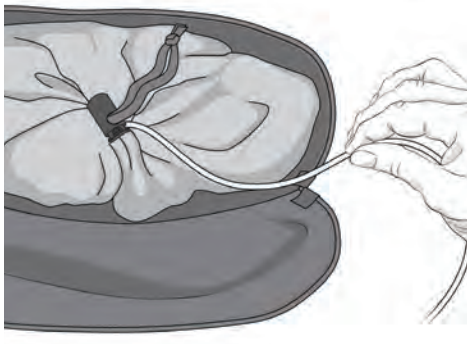


**Figure 96: Position the driveline toward the farthest right corner of the zipper**

# 4.6 Carrying Cases and HeartWare Shower Bag (continued)

## 4.6.4 HeartWare Shower Bag (continued)

### Getting Ready to Shower (continued)

**5.** Use the zipper to close the HeartWare Shower Bag and fold the top flap down over the zipper.

- Avoid catching the driveline in the zipper; this could damage it.

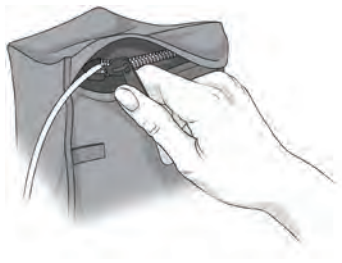


**Figure 97: Zip to close bag**

**6.** Guide the portion of the driveline that exits the bag between the two Velcro® strips on the side of the bag.

**Figure 98: Guide the driveline between the Velcro® strips**

**7.** Firmly fasten the two Velcro® strips around the driveline.

- The driveline will form a "U" shape as it exits the bag. This helps prevent water draining from the driveline into the bag.

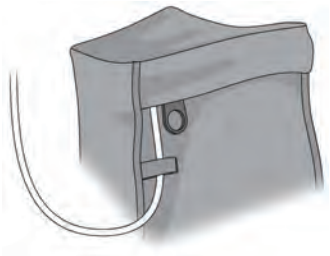


**Figure 99: Fasten Velcro® strips around the driveline**

**8.** Place the HeartWare Shower Bag strap over the head and across the shoulder so it is hanging at the patient's side.

- Adjust the strap so the bag does not pull on the driveline while showering.
- There should be some slack in the driveline so that the flap is completely folded over the zipper.

**Figure 100: Bag should be hanging at patient's side**

**CAUTION:** ALWAYS place the driveline connector inside the HeartWare Shower Bag when showering. Exposing the driveline connector to water may lead to electrical faults, unrepairable damage to the equipment, and disruption to therapy.

## 4.6.4 HeartWare Shower Bag (continued)

### After Showering

1. Set the HeartWare Shower Bag on a flat, stable surface and dry the bag, the controller, and the battery, using a clean towel.
2. Transfer the controller and external battery to the carrying case.
3. Change the exit site dressing using the normal procedure. If the area around the exit site is wet, dry it off with a sterile gauze bandage before applying the new dressing.
4. Allow the HeartWare Shower Bag to air dry before using it again. Make sure the HeartWare Shower Bag is dry before the next use.

**WARNING!** DO NOT allow patients to take baths or swim, as this may damage the HVAD System components and/or result in infection of the driveline exit site.

**WARNING!** DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact Medtronic.

**WARNING!** DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.

**WARNING!** DO NOT allow water or other fluids to enter the controller, power cords, external batteries, battery charger or connectors, as this may damage the HVAD System components. If equipment is damaged, contact Medtronic.

**WARNING!** DO NOT allow hearing impaired patients to shower unless their caregiver is close by to hear alarms.

**WARNING!** DO NOT allow patients to shower until they have received permission from their clinician to do so. Inappropriate shower technique could lead to patient harm or controller damage. Patients who shower must use the HeartWare Shower Bag.

**CAUTION:** DO NOT pull, kink, or twist the driveline, as these actions may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare Shower Bag.

## Notes

# 5.0 Alarms and Emergencies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## 5.1 Alarm Overview

The Controller's alarms utilize visual, auditory and vibratory feedback to alert clinicians and patients about system conditions that require attention or action to be taken. All controller alarms are logged and maintained within the controller unless cleared through a command from the monitor. The alarm log persists in the event of purposeful and accidental shutdown. The time of controller deactivation is not logged. When the alarm log reaches capacity, the oldest events are overwritten.

**WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

**WARNING!** IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.

**A quick reference guide for alarms is located in the front of this IFU. See "Quick Reference Guide for Alarms".**

Alarm conditions are classified as critical (red) and non-critical (yellow).

Each of these alarms has a (1) visual display (2) vibration (3) sound, (4) message. See **Table 16**.

## 5.1 Alarm Overview (continued)

**Table 16: Alarm Conditions: Critical and Non-critical**

| | Critical | Non-critical |
|---|---|---|
| **Controller Display** | Flashing Red back light with message and symbols. | Yellow back light with message and symbols. |
| **Controller Vibration** | Controller vibrates and displays the alarm message. | Controller vibrates and displays the alarm message. |
| **Controller Audio** | Loud periodic beep. | Periodic beep that becomes louder after five (5) minutes. |
| **Controller Muting** | Cannot be muted by pressing screen. | May be muted for five (5) minutes or for fifteen (15) minutes depending on the alarm type, by pressing the screen. |
| **Controller Message** |  Critical Alarm displays action to be performed. |  Non-critical alarm displays phone number to be called. |

**Note:** For critical alarms, the controller screen will only display the action required for resolution.

**Note:** If no clinician's phone number is programmed in, the non-critical alarm screen will instead display "Call Clinician".

## 5.2 Critical Alarms

A critical alarm condition is the highest priority and loudest alarm; the controller vibrates, the screen flashes **RED**, the display message indicates immediate action needs to be taken, and the loudest audible alarm is sounded. Critical alarms cannot be muted, and the alarm condition must be resolved as soon as possible. Critical alarms sound when the pump has stopped, the controller has failed, or when the system is in danger of stopping due to limited power.

After the condition is resolved, the audible alarm stops, the alarm message clears from the controller display, returning it to the default Home screen, and the alarm condition is logged in the Alarm History screen. See **Table 17** for critical alarm messages and their possible meaning(s).

## 5.2 Critical Alarms (continued)

**Table 17: Critical Alarms**

| Alarm Signal | Controller Message | What it means | What action to take |
|---|---|---|---|
| Flashing RED back light<br>  <br>Flashing alert symbol<br>Loud audio signal and vibration<br>Unable to mute alarm | [Change Controller]<br>  | • Controller failure.<br>• Controller component failed.<br>• Pump failure.<br>• Pump unable to start in 5 attempts. | • Change the controller immediately.<br>• Contact Medtronic Clinical Support. |
| | [Connect Pump Cable]<br>  | • Driveline disconnection.<br>• Driveline fracture.<br>• Connector is malfunctioning or broken.<br>• Pump electrical failure. | • Connect the pump driveline to the controller.<br>• If the alarm persists:<br>– Change the controller.<br>– Contact Medtronic Clinical Support. |
| | [Plug In Power Cord]<br>  | • Disconnecting external battery without a power cord connected could risk pump stop .<br>• The Internal battery has limited time remaining, is unreliable, disconnected or has failed AND<br>• The external battery has less than fifteen (15) minutes runtime remaining or Is unreliable. | • Connect the AC or DC power adapter to the controller.<br>• DO NOT disconnect the external battery before connecting the AC or DC power adapter.<br>• If the alarm persists:<br>– Change the controller.<br>– Contact Medtronic Clinical Support. |
| | [Connect Power]<br>  | • The internal battery has limited time remaining or is unreliable. | • Change the external battery or connect the AC or DC power adapter.<br>• If the alarm persists:<br>– Change the controller.<br>– Contact Medtronic Clinical Support. |

For instructions on how to change the controller, see Section 5.6.

**WARNING!** IMMEDIATELY switch to the backup controller if there is a [Change Controller] alarm since the pump may not be running.

## 5.2 Critical Alarms (continued)

### The Following are Critical Alarms

**[Change Controller]:** Indicates a potential controller failure and that the controller should be exchanged for a new controller. The HVAD Pump may not be running.

**[Connect Pump Cable]:** The driveline is disconnected and should be reconnected immediately to restart the pump.

**[Plug In Power Cord]:** This alarm indicates an AC or DC adapter must be connected immediately. The critical [Plug In Power Cord] alarm is displayed when the internal battery is not reliable due to low capacity, temperature, a failure, or disconnection. This alarm only occurs when a power cord is not connected and is followed by a non-critical [Keep Power Connected] alarm, and the external battery has less than fifteen (15) minutes remaining, or it is not reliable due to temperature or a failure.

**[Connect Power]:** Displayed when the internal battery is used for power and is nearly depleted or is not reliable due to temperature or a failure. The message indicates to connect a power source (external battery, AC adapter, or DC adapter) to the controller.

The critical alarm will clear as soon as an external power source is connected. When external power is restored, the controller internal battery will immediately begin to charge.

If the alarm persists after power has been restored, replace the controller.

## 5.3 Non-critical Alarms

When an alarm occurs that is not immediately critical to pump function, it is considered a non-critical alarm.

Non-critical alarms display on the controller screen with a **YELLOW** background, and the controller vibrates for ten (10) seconds prior to the first audible alarm. Pressing the touchscreen will prevent or mute audio alarms for a brief period or until an additional alarm occurs.

A non-critical alarm may resolve on its own without intervention, but patients are given an instruction on the screen, which may be to call their clinician.

When an alarm condition is resolved, it no longer displays on the controller screen but is stored in Alarm History. Up to ten (10) alarms, starting with the highest priority active alarms followed by the most recent resolved alarms, are stored in Alarm History at any given time. Alarms typical to normal use, such as [Connect Power], [Change Battery], and [Connect Cap or Battery] are not stored in Alarm History.

The controller screen instructs the patient to complete an action and/or to call a clinician for instructions. The phone number displayed is programmed by the clinician using the monitor. **Table 18** describes non-critical alarms and their meaning.

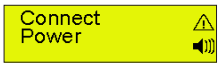
## 5.3 Non-critical Alarms (continued)

**Table 18: Non-critical Alarms**

| Alarm Signal | Controller Message | What it means | What action to take |
|---|---|---|---|
| **Solid YELLOW back light**<br>  <br>**Flashing alert symbol**<br>**Periodic beep with escalating volume and vibration**<br>**Able to mute alarm** | **[Plug In Power Cord]**<br>  | • Disconnecting external battery without a power cord connected could risk pump stop.<br>• The internal battery has limited time remaining, is unreliable, disconnected or has failed AND<br>• The external battery has less than thirty (30) minutes runtime remaining or Is unreliable. | • Connect the AC or DC power adapter to the controller.<br>• DO NOT disconnect the external battery before connecting the AC or DC power adapter.<br>• Confirm that the AC or DC power adapter is powering the controller.<br>Mute option: Two five (5)-minute mutes, then cannot be muted. |
| | **[Keep Power Connected]**<br>  | • Disconnecting external power could risk pump stop.<br>• The internal battery has limited time remaining, is unreliable, or has failed. | • DO NOT disconnect the external power.<br>• If the external battery needs to be changed, connect the AC or DC power adapter before disconnecting the external battery to prevent the pump from stopping.<br>• If the alarm persists for one (1) hour:<br>– Contact Medtronic Clinical Support.<br>– The internal battery may need to be changed.<br>Mute option: Five (5) minutes |
| | **[Electrical]**<br>  | • A fault in the normal operation of the pump-to-controller electrical connection. The fault could be in the pump motor, driveline and connector, or within the controller.<br>• Pump is running on a single motor stator and consuming slightly more power. | • DO NOT change the controller.<br>• Check the controller driveline, pump driveline and connections for visible damage.<br>• Contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Technical]**<br>  | • Controller component or power source malfunction. | • View the Alarm Log screen for any additional alarms.<br>• Contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |

| Alarm Signal | Controller Message | What it means | What action to take |
|---|---|---|---|
| **Solid YELLOW back light**<br>  <br>**Flashing alert symbol**<br>**Periodic beep with escalating volume and vibration**<br>**Able to mute alarm** | **[High Power]**<br>  | • The pump power exceeds the alarm threshold setting. | • Confirm the correct settings for the [High Power] alarm, the pump speed, and Hematocrit.<br>• Assess the power signal on the Trends screen for any increasing trend or fluctuations.<br>• Assess the patient for potential causes:<br>• Perform lab tests (INR, etc.)<br>• Check patient for clinical signs of hemolysis.<br>• Consider echocardiography.<br>• If no potential patient cause can be identified, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Low Flow]**<br>  | • The flow is less than the alarm threshold setting. | • Confirm the correct settings for the [Low Flow] alarm limit and Hematocrit.<br>• Assess the flow signal on the Trends screen for any decreasing trend or fluctuations.<br>• Assess the patient for potential causes:<br>• Check blood pressure and volume status (confirm MAP <85 mmHg).<br>• Consider echocardiography.<br>• Consider inotropic drugs if right ventricle function is poor.<br>• If no potential patient cause can be identified, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |

## 5.3 Non-critical Alarms (continued)

| Alarm Signal | Controller Message | What it means | What action to take |
|---|---|---|---|
| **olid YELLOW back light**<br>  <br>**Flashing alert symbol**<br>**Periodic beep with escalating volume and vibration**<br>**Able to mute alarm** | **[Suction]**<br>  | • The suction algorithm has identified a ventricular suction condition. | • Assess the patient for potential causes:<br>• Check blood pressure and volume status.<br>• Consider echocardiography.<br>• Evaluate the flow trends.<br>• Consider decreasing the pump speed if a clinical cause cannot be identified or corrected.<br>• Consider volume loading if indicated and there is good right ventricle function.<br>• Consider inotropic drugs if right ventricle function is poor.<br>• If no potential patient cause can be identified, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Connect Power]**<br>  | • No external power source is connected (for at least twenty (20) seconds). | • Connect the AC or DC power adapter or change the external battery.<br>Mute option: Two five (5)-minute mutes, then cannot be muted |
| | **[Temperature]**<br>  | • The controller internal battery is too hot or too cold.<br>• The controller's temperature is out of recommended range. | • Move the controller to a room temperature environment and wait for the controller to return to normal temperature.<br>• If the alarm persists for one (1) hour, contact Medtronic Clinical Support.<br>Mute option: Fifteen (15) minutes |
| | **[Change Battery]**<br>  | • The external battery has fifteen (15) minutes or less time remaining.<br>• There could be a potential problem with the external battery's power output, the connection or its ability to charge. | •Change the external battery OR<br>•Connect the AC or DC power adapter to the controller<br>Mute option: Fifteen (15) minutes |
| | **[Connect Cap or Battery]**<br>  | • A PAL Cap or external battery is not connected to the controller, while the AC or DC power adapter is connected. | • Attach the PAL Cap or an external battery to the controller to protect it from dust, dirt, fluids, or electrical interference.<br>Mute option: Fifteen (15) minutes |

**For additional information on monitor alarm display, see Section 6.1.**

### The Following are Non-critical Alarms:

**[Plug In Power Cord]:** The non-critical [Plug In Power Cord] alarm is displayed when the internal battery is not reliable due to low capacity, temperature, a failure, or disconnection and an external battery, with less than thirty (30) minutes remaining or that is unreliable, is powering the system. This alarm only occurs when a power cord is not connected and is followed by a non-critical [Keep Power Connected] alarm. This alarm indicates an AC or DC adapter must be connected immediately. If an adapter is not connected within fifteen (15) minutes, this alarm escalates to the critical version of the same alarm.

**[Keep Power Connected]:** The internal battery is not reliable due to low capacity, temperature, a failure, or it is not connected.
Make sure that an external power source is attached at all times. If the external battery needs to be exchanged for a fully-charged battery, be sure to connect an AC or DC adapter before disconnecting the external battery to prevent the pump from stopping.
The alarm may automatically clear over time if the cause of the alarm was internal battery temperature or low battery capacity. The screen directs the patient to call the clinician and provides a phone number. The internal battery may need to be replaced at a clinic if the alarm is due to a more permanent failure.

**Note:** Make sure that an external power source is attached at all times. If the external battery needs to be exchanged for a fully-charged battery, be sure to connect an adapter before disconnecting the external battery to prevent the pump from stopping.

**[Technical]:** A controller malfunction may have occurred, but the controller is still functioning and running the pump. Ask the patient about:

- the frequency and duration of the alarm
- other active alarms
- changes in pump flow, speed, or power
- clinical symptoms including dizziness, shortness of breath, angina and/or palpitations
- power sources connections.

Based on the patient's responses, the following course of action should be taken:

| Alarm Profile | Actions |
|---|---|
| If the [Technical] alarm only occurs while one of the AC or DC adapters is connected. | Instruct the patient to use external batteries or alternate power adapters and order a replacement power adapter. |
| If a single [Technical] alarm occurred that self-resolved and was not associated with a change in pump or clinical parameters. | • Instruct the patient to report any additional alarms when they occur.<br>• Download the controller log files at the patient's next clinic visit and send them to Medtronic for analysis. |
| If a [Technical] alarm:<br>• occurred and resolved multiple times over a 24-hour period<br>• occurred in combination with other alarms but has not affected pump flow, power or speed and there are no concurrent clinical symptoms. | • Instruct the patient to return to the implanting center at their earliest convenience (not urgently) so the controller log files may be downloaded and sent to Medtronic for analysis.<br>• The decision to change the controller may be made based on clinical assessment of patient conditions. |

## 5.3 Non-critical Alarms (continued)

| Alarm Profile | Actions |
|---|---|
| If a [Technical] alarm:<br>• occurs frequently (more than once per hour)<br>• occurred and has not yet been resolved<br>• occurred in combination with other alarms and it is associated with a change in pump flow, speed or power or any adverse clinical symptom, such as lightheadedness or shortness of breath. | • Instruct the patient to change the controller.<br>• Instruct the patient to return to the implanting center within an appropriate time frame (12 - 16 hours).<br>• Download the log files from both the original controller and current controller and send them to Medtronic for analysis. |

**Note:** The audio and vibratory portion of this alarm can be permanently disabled via the monitor.

**For additional information on the Alarm Settings tab, see Section 6.4.2.**

**[Electrical]:** A fault in the normal operation of the pump-to-controller electrical connection triggers this alarm. The fault could be in the HVAD Pump motor, driveline, or within the controller. When this alarm condition occurs, the HVAD Pump runs on a single motor stator and consumes slightly more power. DO NOT change controllers during an active [Electrical] alarm.

Download controller log files and send to Medtronic for review.

**Note:** The audio and vibration portion of this alarm can be permanently disabled via the monitor.

**[Suction]:** The ventricular suction detection alarm is triggered if a ventricular suction condition has been identified. This may self-clear if the suction is temporary.

**For additional information about the suction alarm, see Section 3.2.2.**

**[Low Flow]:** The [Low Flow] alarm is triggered if average flow drops below the [Low Flow] alarm threshold. This may self-clear if the reduction in flow is temporary.

**[High Power]:** This alarm warns of a [High Power] condition. The alarm is triggered when the Watts level exceeds the [High Power] alarm threshold. The [High Power] alarm watt value will change to "Auto" when the power tracking algorithm is turned on. If the power tracking algorithm is enabled, this alarm may indicate a sudden increase in power compared to a long-term trend for the patient. This may occur due to thrombus or other materials (e.g. tissue fragments) in the device.

**For additional information on the Alarm Settings tab, see section Section 6.4.2.**

**For additional information on the Power Tracking algorithm, see Section 3.2.3.**

**[Connect Power]:** The [Connect Power] alarm occurs when no external power sources are powering the controller for at least twenty (20) seconds. At that time, the controller switches to its internal battery. Onset of the alarm has a twenty (20) second delay to allow the patient to change power sources without disruption. This alarm can be muted for ten (10) minutes with two 5-minute mutes. After that, the alarm sounds continuously until external power is restored. The patient should always connect an external power source when this alarm occurs.

If external power is not connected after thirty (30) minutes of running on the controller internal battery, or if the internal battery has fifteen (15) minutes or less of power remaining, a critical [Connect Power] alarm will sound. The [Connect Power] alarm will clear as soon as an external power source (external battery, AC adapter, or DC adapter) is connected.

## 5.3 Non-critical Alarms (continued)

**[Temperature]:** This alarm displays if the controller gets too warm or cold. In the event of a [Temperature] alarm, the patient should assess the environment the controller is in, such as outside on an extremely hot or cold day, or if the controller was placed under a thick or thermal blanket or heavy coat. Instruct the patient to return controller to normal operating temperature range. If the controller feels warm to touch, go to a cool location, air conditioned if possible, and allow the controller to cool down. Ensure that an external battery or power cord is attached to the controller since the internal battery may not charge in these conditions.

**Note:**

- Multiple conditions may impact the temperature of the controller, such as power consumption and prolonged exposure to extreme ambient temperatures.
- If the controller is in a hot environment, the surface of the controller may be hot to touch, and the patient should avoid extended skin contact.
- If the controller temperature continues to progress toward extreme hot or cold temperatures, the [Keep Power Connected] alarm will occur.

**[Change Battery]:** The external battery has fifteen (15) minutes remaining before it is depleted. When the [Change Battery] alarm begins, the patient may mute the alarm for fifteen (15) minutes by touching the screen. If the external battery is not changed or an adapter is not connected, the controller will switch to the internal battery and a [Connect Power] alarm will sound.

The patient should connect to an AC or DC power adapter or exchange the external battery with a fully-charged battery as soon as possible.

**[Connect Cap or Battery]:** A power cord is connected to the controller and the battery connector is open. Attach an external battery or PAL Cap on the controller battery connector. Onset of this alarm has a twenty (20) second delay to allow the patient to connect an external battery or cap without disruption from an alarm.

## 5.4 Multiple Alarms

It is possible to have simultaneous alarm conditions. For multiple alarms, the screen will display the color and sound of the most severe alarm. A down arrow ↓ symbol is displayed on the left side of the controller screen for multiple active non-critical alarms (**Figure 101**). Press the center of the screen to cycle through the non-critical alarms. They will display in order of importance.


**Figure 101: Controller displaying multiple alarms**

**Table 19: Multiple Alarms**

| Alarm Indicator and Alarm Sound for Multiple Alarms | | |
|---|---|---|
| **Multiple Alarm Condition** | **Controller Screen** | **Alarm Sound** |
| Multiple alarms with at least one (1) critical alarm | RED <flashing> | Loud, continuous, unable to mute |
| Multiple non-critical alarms | YELLOW | Increase in volume after five (5) minutes if alarm is NOT muted |

**WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

## 5.4 Multiple Alarms (continued)

**Note:** When an alarm of higher importance is resolved, the audible and vibratory signal pattern for any active alarms of lower priority will restart.

## 5.5 How to Mute Alarms

Critical alarms CANNOT be muted. However, non-critical alarms can be muted for five (5) or fifteen (15) minute intervals by pressing anywhere on the controller screen. The vibration precedes the audio of the alarm for a few seconds allowing the patient to mute the alarm before the audio begins. Muting an alarm pauses the audio and vibration.

The alarm will sound again if a new alarm condition occurs during the mute interval. The vibration will precede the audio of the alarm. The non-critical [Electrical] alarm and [Technical] alarm can be permanently muted by accessing the Alarm Settings in the monitor's System screen, by pressing the associated "Permanently Silence" button.

**For additional information on the Alarm Settings tab, see Section 6.4.2.**

**For additional information about the mute durations of non-critical alarms, see Table 18 in the Non-critical Alarms, Section 5.3.**

**WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Muting a non-critical alarm does not resolve the alarm condition and may lead to suboptimal therapy.

## 5.6 Changing the Controller

A backup controller and fully-charged external batteries must be available at all times for controller failures or malfunctions. The backup controller should be set with the same pump parameters and patient information as the primary controller.

**WARNING!** ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

**WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

**WARNING!** IMMEDIATELY replace a controller that has a blank display. This condition is predictive of a controller failure.

**CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HVAD System may not function as intended.

## 5.6 Changing the Controller (continued)

**Note:** Patients with a fused aortic valve, an aortic valve sewn shut due to aortic valve regurgitation, or patients with very poor ventricular function should be educated in the importance of having a backup controller readily available at all times including when changing power sources.

A controller failure or serious controller malfunction will generate a critical alarm and "Change Controller" will display on the screen.


When doing a controller exchange, the priority is to restart the pump quickly. It may be helpful to remember the following:

POWER... Connect a power source to the backup controller.

PUMP... Restart the pump by connecting the driveline to the new controller.

### Steps to Changing the Controller:

| | |
|---|---|
| **1.** Have patient sit or lie down and place the new (backup) controller within easy reach. |  **Figure 102: Patient should sit or lie down** |
| **2.** Remove the PAL Cap on the backup controller by pressing the battery release button on the controller. |  **Figure 103: Press button to remove the cap** |
| **3.** Insert the tabs of the charged battery into the opening on the battery connector. Pivot the battery to snap it into the backup controller. |  **Figure 104: Insert tabs** |
| **4.** Disconnect the driveline from the original controller and connect the driveline to the new controller. This will restart the pump.<br>**Note:** It is normal and expected that the original controller will have a new critical [Connect Pump Cable] alarm displayed if it did not already have a critical alarm.<br>*See next page for detailed steps on disconnecting driveline.* |  **Figure 105: Disconnect the driveline** |

## 5.6 Changing the Controller (continued)

### Disconnecting the Driveline from the Controller:

**1.** Slide the cover of the pump driveline towards the controller to reveal the whole silver connector.

**Figure 106: Slide the cover of the pump driveline**

**2.** Grasp the pump driveline cable below the connector with one hand, avoiding the grooved area, as shown in **Figure 107**.

**Figure 107: Grasp the pump driveline cable**

**3.** With the index finger and thumb of the same hand, pinch the grooved area of the pump driveline connector (**Figure 108**).

**Figure 108: Pinch the grooved area of the pump driveline connector**

**4.** With the other hand, pinch the grooved area of the controller driveline Coiled Cable connector (**Figure 109**).

**Figure 109: Pinch the grooved area of the controller Coiled Cable connector**

**5.** Release the locking mechanism by pulling the controller Coiled Cable connector away from the pump driveline connector (**Figure 110**).

**Note:** Only pull on the grooved area of the connectors. If any other area of the driveline or connector is pulled back, the driveline will not release from the controller.

**Figure 110: Release the locking mechanism**

### Connecting the Driveline from the Controller:

| | |
|---|---|
| **1.** Align the red line on the controller Coiled Cable connector with the alignment marker on the pump driveline connector (**Figure 111**). |  <br>**Figure 111: Align the red line with the red dot/black line** |
| **2.** Push the pump driveline connector straight into the port until there is a click.<br><br>**Note**: To ensure proper connection, verify that the pump is running. There will be a heart ♥ symbol displayed on the controller or on the monitor. the monitor will also show values for flow, power, and speed. |  <br>**Figure 112: Push the driveline connector into the port** |
| **3.** Slide the cover of the pump driveline over the connectors until the cover is securely in place. |  <br>**Figure 113: Slide the cover over connectors** |
| **4.** Use the Elective Shutdown procedures in **Section 5.7** to shut down the original controller. | |

**WARNING!** DO NOT attempt to repair, service, or modify any component of the HVAD System as this may damage the component. If the equipment malfunctions, contact Medtronic.

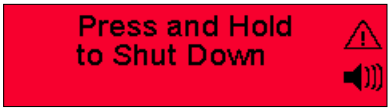
**CAUTION:** DO NOT pull, kink, or twist the driveline, as these actions may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare Shower Bag.

**For additional information on making good connections, see Section 4.3.**

**For additional information on alarms, see Section 5.0.**

## 5.7 Elective Shutdown

Perform an elective shutdown to turn the controller off using the following procedures.

| Follow these procedures: | Controller Screen | |
|---|---|---|
| | Elective Controller Shutdown | Emergency Controller Shutdown |
| **1.** Disconnect all external power sources from the controller. |  **Note**: A [Connect Power] message will appear, which will progress to an audible non-critical [Connect Power] alarm after twenty (20) seconds. |  |
| **2.** Disconnect the driveline. |  **Note**: A critical alarm will appear. |  |
| **3.** Wait ten (10) seconds for the Elective Shutdown screen to appear. |  |  |
| **4.** Press and hold the screen for five (5) seconds.<br>The bar at the bottom of the screen will shrink until it disappears. |  |  |
| **5.** An hourglass briefly displays while the controller shuts down. |  |  |

**Note:** If any of these steps are not executed, the controller will continue alarming until the process is complete. To exit the shutdown, reconnect the pump and/or the power.

# 6.0 Using the HeartWare Monitor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6.7 Powering Monitor Off ..... 120


## 6.1 General Overview

The HeartWare Monitor is designed to provide a user-friendly way to monitor and program the HeartWare HVAD System. The monitor has the following functions:

- It displays system information
- It monitors and reports system errors and alarm conditions
- It enables transfer of data from the controller
- It allows programming of the controller, including pump parameters.

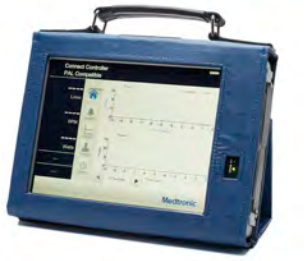


**Figure 114: HeartWare Monitor**

**Note:** ALWAYS fully charge the monitor's internal battery prior to patient use so that the monitor has redundant power sources in case of emergency.

**CAUTION:** DO NOT allow patients to touch the monitor screen, as this may lead to the entering of unintended parameters into the system.

The monitor (**Figure 114**) is designed to use AC adapter power from an electrical outlet. The monitor can also use its internal battery during patient transportation. Keep the monitor's battery charged by connecting the monitor AC adapter to an electrical outlet at all times — even while in storage. It takes approximately five (5) hours to charge a depleted battery. If the monitor is going to be stored for a long period, removing the battery and leaving the monitor unplugged is also an option.

**Note:** The monitor should always be connected to AC adapter power except during patient transport.

**Note:** The monitor should be stored in a secure location to minimize security threats.

## 6.1 General Overview (continued)

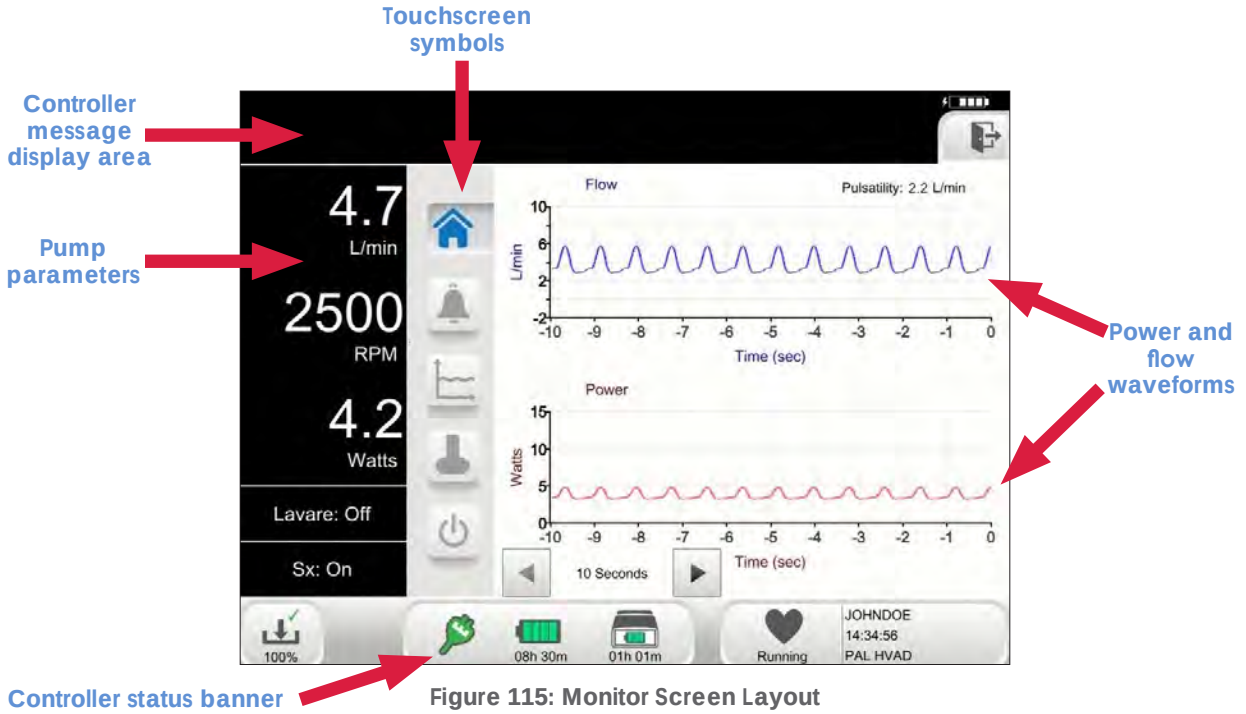


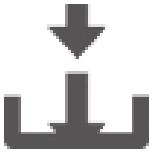

**Figure 115: Monitor Screen Layout**

There are five touchscreen symbols (**Figure 115**) on the monitor to access system information and to manage pump operation. The symbols are displayed on all screens in the application.

**Table 20: Guide to HeartWare Monitor Screen Symbols**

| Symbol | Description |
|---|---|
|  | Press the Home symbol to view the Home screen. Used for routine monitoring that displays real-time power and flow waveforms. |
|  | Press the Alarm Bell symbol to view alarm history, event history and controller information. Also provides actionable troubleshooting instructions during active alarms. |
|  | Press the Graph symbol to view historical trend waveforms. Offers multiple time interval displays (60 min, 4 hours, 24 hours, 3 days, 7 days, 14 days, 30 days). |
|  | Press the Pump symbol to change and review the pump settings. Requires an access code – 68773 (i.e., “NURSE” when using the keypad letters). |

**Table 20: Guide to HeartWare Monitor Screen Symbols (continued)**

| Symbol | Description |
|---|---|
|  | Press the Power symbol to turn monitor off. |
|  | Indicates that log files are downloading from the controller to the monitor. A green check mark indicates the download is complete and a red "**X**" indicates the download was interrupted. The percentage of download is displayed, and the arrows move downward to indicate that the download is in progress. |
|  | Displays controller adapter information.<br>• Green indicates the adapter is powering the controller.<br>• Light grey indicates no connection. |
|  | Displays controller external battery information.<br>• A green outline of the symbol indicates it is powering the system.<br>• The internal bars indicate the level of charge.<br>• Green bars indicate the system and battery are operating normally.<br>• Yellow or red internal bars indicate there is an alarm associated with the external battery power.<br>• Grey bars indicate the controller is disconnected.<br>• A charging ϟ symbol to the right indicates the external battery is charging. |
|  | Displays controller internal battery information.<br>• A green outline of the symbol indicates it is powering the system.<br>• Green internal bars indicate the level of charge.<br>• Yellow or red internal bars indicate there is an alarm associated with the internal battery power.<br>• Grey bars indicate the controller is disconnected.<br>• A charging ϟ symbol to the right indicates the internal battery is charging. |
|  | Displays when the connected controller is in the Ready state. |
|  | Displays when the connected controller is in the Implant state. |

## 6.1 General Overview (continued)

**Table 20: Guide to HeartWare Monitor Screen Symbols (continued)**

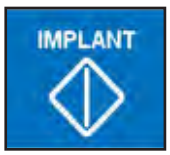
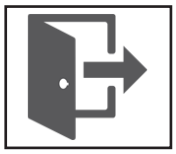
| Symbol | Description |
|---|---|
|  | Displays when the connected controller is in the Running state. |
|  | Displays flashing on top banner of monitor screen when the controller has new software available for upgrade. |
|  | Displays flashing on top banner of monitor screen when the controller has new language available for upgrade. |
|  | Displays flashing on top banner of monitor screen when the controller internal battery's power is critically low and needs to be charged. |
|  | Displays flashing on top banner of monitor screen when the controller internal battery needs to be replaced. |
|  | Press the "Set VAD" button to turn the pump on or off and to change the controller states.<br><br>For more information on "Set VAD" button pump and controller states, see **Table 22**, in **Section 6.4.2** |
|  | Pressing arrow buttons allows for adjustment of the display interval for the associated waveform |
|  | Displays on top banner of monitor screen to indicate there are more alarms that should be investigated. |

**Table 20: Guide to HeartWare Monitor Screen Symbols (continued)**

| Symbol | Description |
|---|---|
|  | Displays at the top of the monitor screen when logged in with clinical access. Press this symbol to log out of the clinical access on the monitor. |
|  | Displays on top banner of monitor screen to indicate an alarm is sounding. This symbol can be pressed to mute the active alarm(s) on the controller, if the active alarms are mutable. |
|  | Displays on top banner of monitor screen to indicate the active alarm(s) are muted. |

### Monitor Message Display

The monitor will display messages and a bell icon on the top banner when a critical (red text) or noncritical (yellow text) alarm is active on the connected controller.


**Figure 116: Monitor screen showing alarm message display**

## 6.1 General Overview (continued)

See below for the messages that display on the monitor for each controller alarm signal:

**Critical Alarms**

| Controller Alarm Signal | Monitor Message |
|---|---|
| **[Change Controller]** | "VAD Stopped" alternating with "Change Controller" |
| **[Connect Pump Cable]** | "VAD Stopped" alternating with "Connect Driveline" |
| **[Plug In Power Cord]** | "Critical Power" alternating with "Connect Adapter" |
| **[Connect Power]** | "Critical Power" alternating with "Connect Power" |

**Non-Critical Alarms**

| Controller Alarm Signal | Monitor Message |
|---|---|
| **[Plug In Power Cord]** | "Connect Adapter" alternating with "Call Clinician" |
| **[Keep Power Connected]** | "Keep External Power Connected" alternating with "Call Clinician" |
| **[Electrical]** | "Electrical" alternating with "Call Clinician" |
| **[Technical]** | "Technical" alternating with "Call Clinician" |
| **[High Power]** | "High Power" alternating with "Call Clinician" |
| **[Low Flow]** | "Low Flow" alternating with "Call Clinician" |
| **[Suction]** | "Suction" alternating with "Call Clinician" |
| **[Connect Power]** | "Internal Battery Only" alternating with "Connect Power" |
| **[Temperature]** | "Temperature" alternating with "Call Clinician" |
| **[Change Battery]** | "Low Battery" alternating with "Change Battery" |
| **[Connect Cap or Battery]** | "Connect Cap or Battery" |

**For additional information on monitor alarm troubleshooting, see Section 6.3.**

## 6.1 General Overview (continued)

The monitor may also display a status message on the top of the screen for specific situations. The following are potential status messages:

**Table 21: Status Message Display**

| Message | Potential Cause |
|---|---|
| **VAD Off** | Driveline connected to controller and HVAD Pump manually stopped (controller is in the Implant State). |
| **Log file storage is full** | Patient data cannot be stored due to reaching the maximum number of patients or lack of storage space. |
| **Connect Controller - PAL™ Compatible** | Instruction to connect a PAL compatible controller |


**Figure 117: Monitor screen showing status message display area**

## 6.2 Powering Monitor On

To turn the monitor ON, press and hold the power button on the top left side of the monitor until the application starts up. The System Select screen (**Figure 118**) is used to load the Monitor application for specific HVAD System controllers. The PAL application will automatically load from the System Select screen if a PAL Controller is connected. It can also manually be loaded by pressing on the PAL Controller image on the screen.

If the application for the other system controller is open, restart the monitor to launch the System Select screen.


**Figure 118: Controller Selection on Monitor**

**Note:** If using a different HVAD System controller, refer to the appropriate IFU for further monitor instructions.

# 6.3 Informational Screens

## Home Screen

The Home screen displays the clinical waveforms with real-time estimated flow (L/min), power (Watts). The waveform window can be changed by pressing the arrows next to the time interval. The waveforms display high resolution data, starting from the time that the controller was connected to the monitor. A pulsatility value is displayed to show the average peak to trough difference in flow.

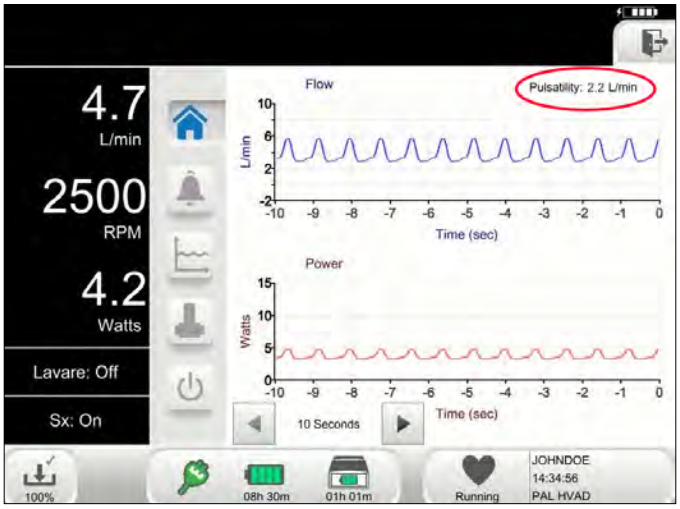



**Figure 119: Home screen with Pulsatility value**

**For additional information on flow waveforms and setting speed, see Section 8.1.1.**

## Alarm Screens

The Alarm screens display occurrences of current and past alarms, troubleshooting instructions, system events, and peripherals information.

The four (4) tabs are found at the top of the Alarm screens page. They are:

1. Alarm Log
2. Troubleshooting
3. Event Log
4. Information

A sample of each tab is shown in **Figure 120 (Alarm Log), Figure 121 (Troubleshooting), Figure 122 (Event Log), and Figure 123 (Information)**:

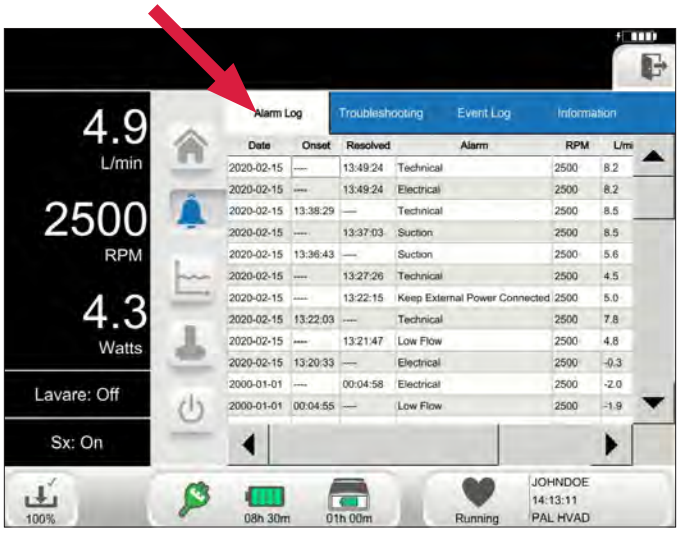



**Figure 120: Alarm Screen - Alarm Log tabT**

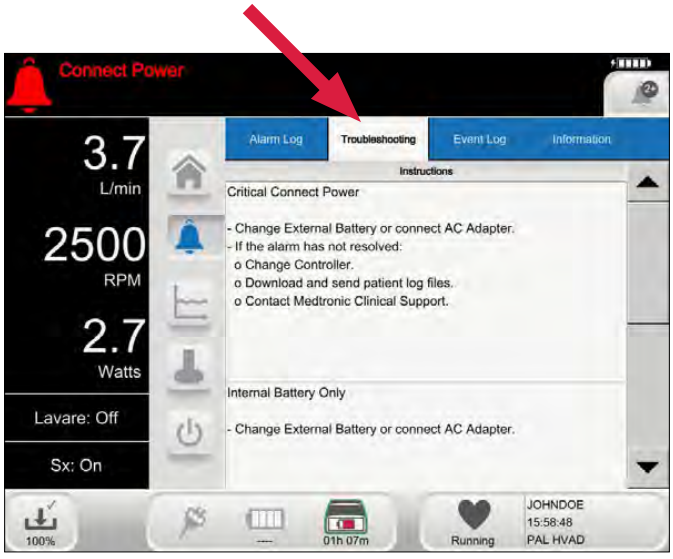



**Figure 121: Troubleshooting tab**

# 6.3 Informational Screens (continued)

## Alarm Screens (continued)

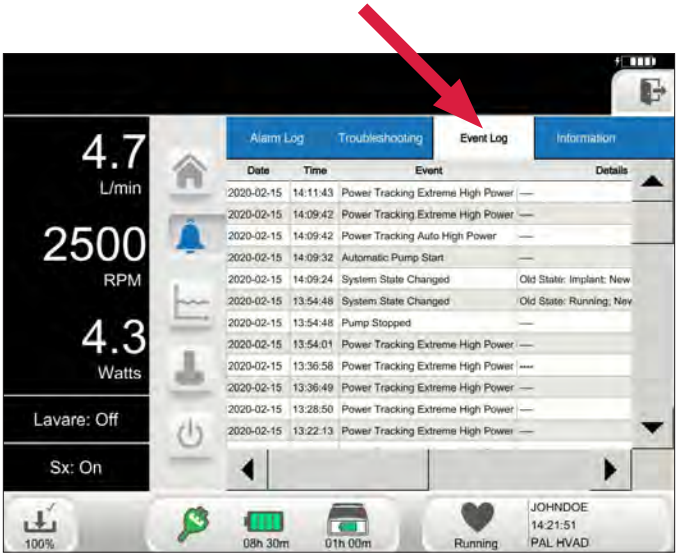



**Figure 122: Event Log tab**

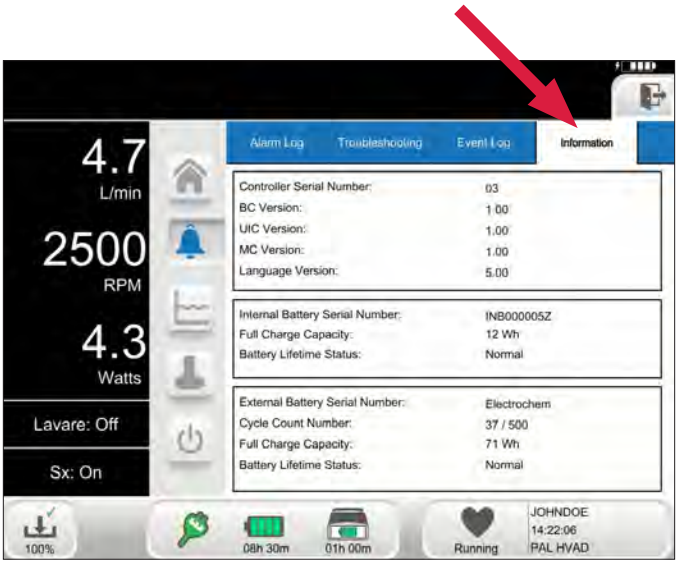



**Figure 123: Information tab**

**For additional information on alarms, see Section 5.0.**

## 6.3 Informational Screens (continued)

### Trend Screens

The Trend waveform screens display historical trend data captured every five (5) minutes for flow, speed, power, peak and trough. The waveform window can be changed by pressing the arrows next to the time interval. Trend data is uploaded from the controller to the monitor by connecting the monitor data cable to the controller.

The three (3) tabs are found at the top of the Trend screens page:

1. Flow/Speed
2. Flow/Power
3. Flow/Peak/Trough

A sample of each tab screen is shown below.

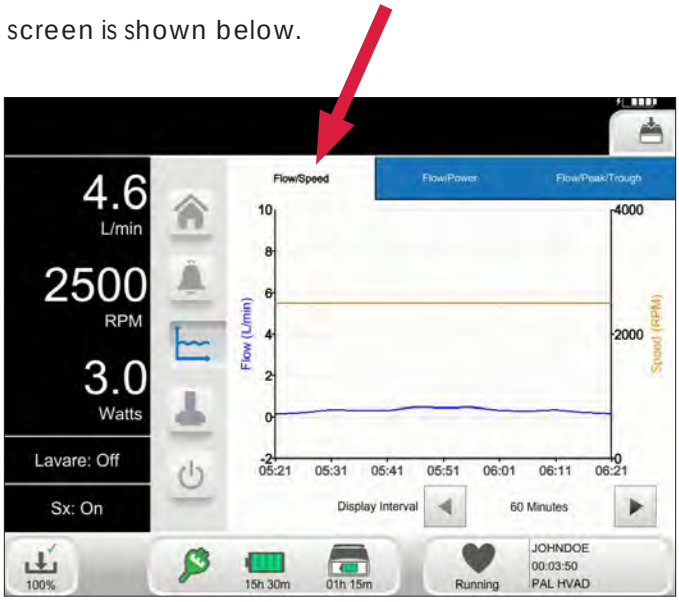



**Figure 124: Flow/Speed tab**

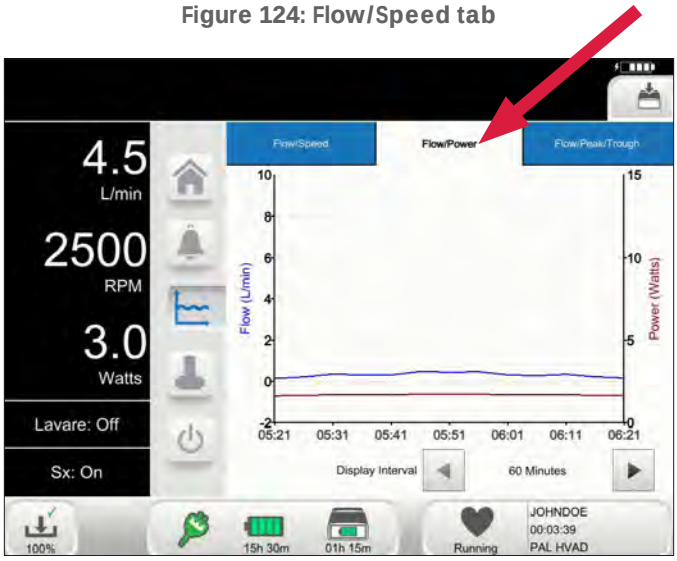



**Figure 125: Flow/Power tab**

## 6.3 Informational Screens (continued)

### Trend Screens (continued)

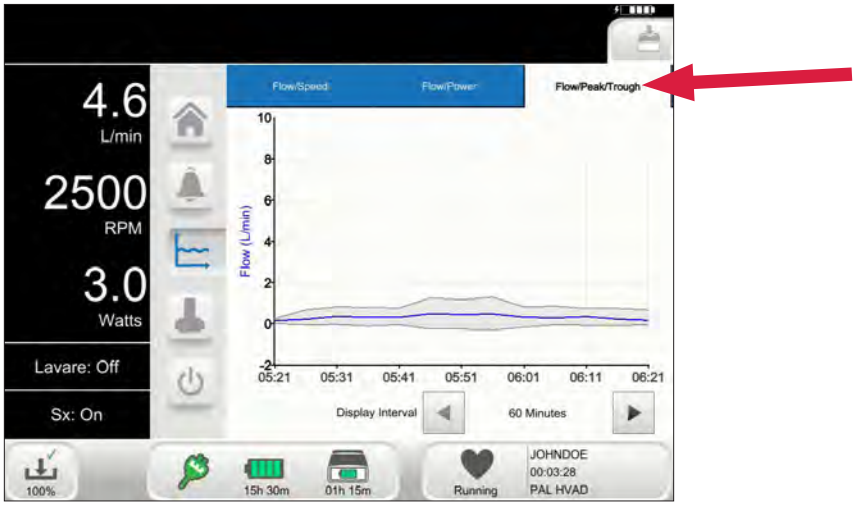



**Figure 126: Flow/Peak/Trough tab**

## 6.4 Programming the Monitor and Controller

### System Screens

The System screens are accessed by pressing the HVAD Pump symbol on the screen.


**Figure 127: System Screens - Speed Settings tab**

The System screens require a access code to prevent inadvertent access. The dialog box (**Figure 128**) is used to enter the numeric code. User access is timed out after eleven (11) minutes of non-use.

The access code is **68773**, (i.e., "**NURSE**" when using the keypad letters)


**Figure 128: Access code dialog box**

**Note**: If an incorrect access code is entered, press the "Clear" button and re-enter the code.

# 6.4 Programming the Monitor and Controller (continued)

## System Screens (continued)

Once in the system screens there are multiple pages, each identified by a tab. The main three (3) tabs are found at the top of the System screen page:

1. Speed Settings tab
2. Setup tab
3. Alarm Settings tab.

The controller is programmed using the monitor's System screens. An overview of the monitor's System screens, their sub-tabs, and the controller parameters that can be programmed are shown on **Table 22**. A sample of each tab screen is shown on the pages indicated in the table.

**Table 22: System Screens & Programming the Monitor and Controller**

| System Screen Tab | Sub-Tab | System Parameter | Page |
|---|---|---|---|
| **Speed Settings** | ***Flow*** | Pump speed | 103 |
| | ***Power*** | Set VAD (System State) | 104 |
| **Setup** | **Patient** | Patient ID | 105 |
| | | Implant Date | 106 |
| | | Hematocrit % | 106 |
| | | Clinician Contact (Phone Number) | 106 |
| | | Log Files | 117 |
| | **VAD** | VAD ID | 107 |
| | | [Suction] alarm setting | 108 |
| | | Lavare Cycle | 108 |
| | **Controller** | Controller Date | 109 |
| | | Controller Time | 109 |
| | | Controller Decimal Format | 110 |
| | | Controller Language | 110 |
| | **Monitor** | Monitor Date | 102 |
| | | Monitor Time | 102 |
| | | Monitor Decimal Format | 102 |
| | | Monitor Language | 102 |
| | | Touchscreen Calibration | 102 |
| **Alarm Setting** | ***N/A*** | [Low Flow] alarm limit | 111 |
| | | [High Power] alarm limit | 111 |
| | | Power Tracking | 112 |
| | | Silence [Technical] alarm (if active) | 112 |
| | | Silence [Electrical] alarm (if active) | 113 |

## 6.4.1 Programming the Monitor

### Setup Tab

When the Setup tab is pressed, four additional tabs are displayed and include:

1. Patient tab
2. VAD tab
3. Controller tab
4. Monitor tab

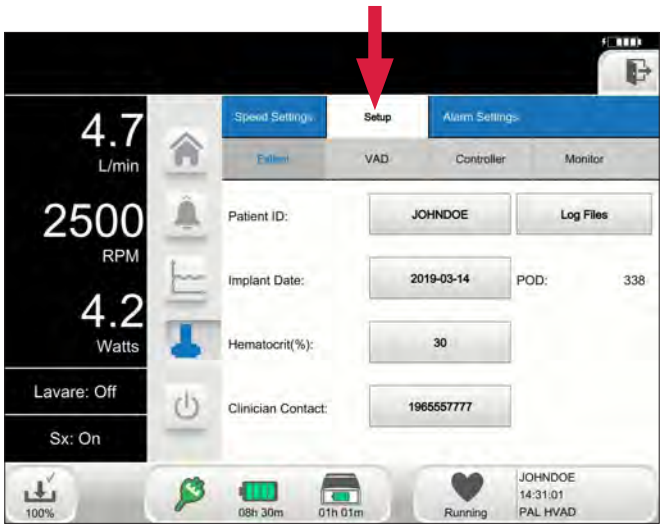



**Figure 129: Setup tab - Patient**

To begin setting up the monitor, click on the Monitor tab.

### Monitor Tab

The Monitor tab is used to program the monitor and to calibrate the monitor touchscreen.

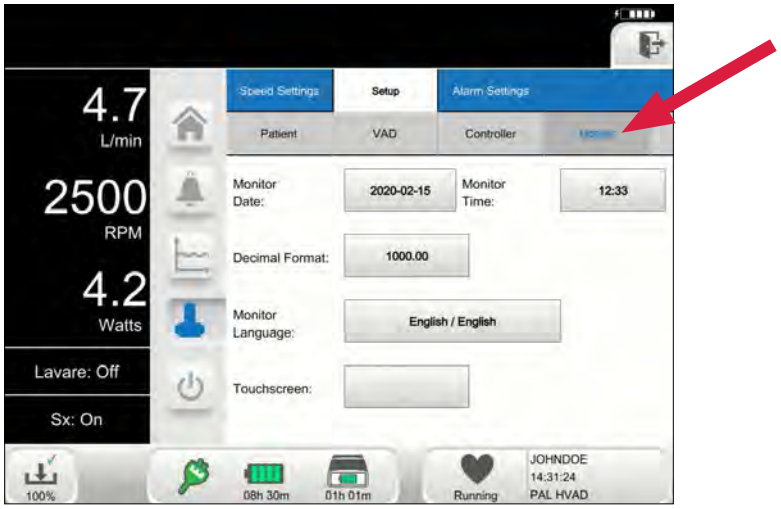



**Figure 130: Monitor tab**

# 6.4 Programming the Monitor and Controller (continued)

## 6.4.1 Programming the Monitor (continued)

### Monitor Tab (continued)

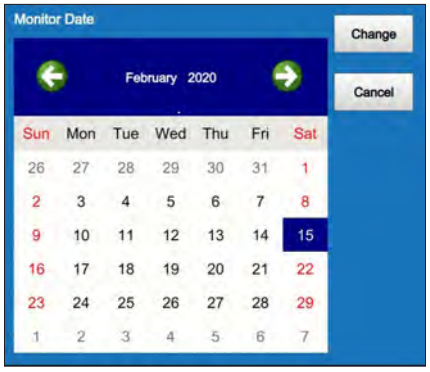



**Figure 131: Monitor Date dialog box**

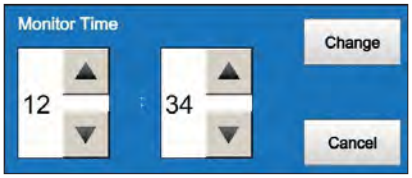



**Figure 132: Monitor Time dialog box**

- "**Monitor Date**"(**Figure 131**) and "**Monitor Time**"(**Figure 132**): These buttons set the date and time for the monitor.

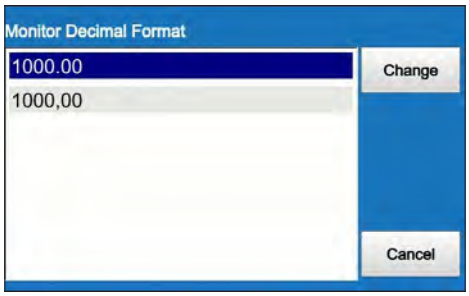



**Figure 133: Monitor Decimal Format dialog box**


**Figure 134: Monitor Language dialog box**

- **Decimal Format**"(**Figure 133**): Press this button to select the decimal format for the monitor screens.
- "**Monitor Language**"(**Figure 134**): Press this button to select the monitor language. The default is English.

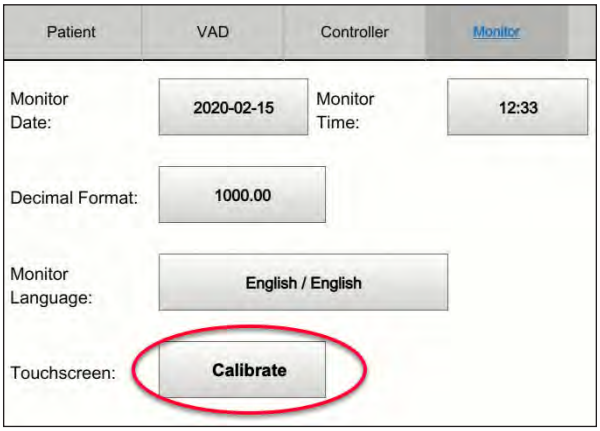



**Figure 135: Monitor tab, "Touchscreen" button**

- "**Touchscreen**" (**Figure 135**): Press the "**Calibrate**" button to initiate touchscreen calibration for the monitor. The monitor will only initiate the calibration sequence if a controller is NOT connected to the monitor.

## 6.4.2 Programming the Controller

### Speed Settings Tab

The Speed Settings tab displays waveforms with real-time estimated flow (L/min) or real-time power (Watts) and allows pump parameter modifications.


Figure 136: Speed Settings tab


Figure 137: Speed Settings dialog box

The preferred waveform is selected by pressing the Flow or Power tab (**Figure 138**).

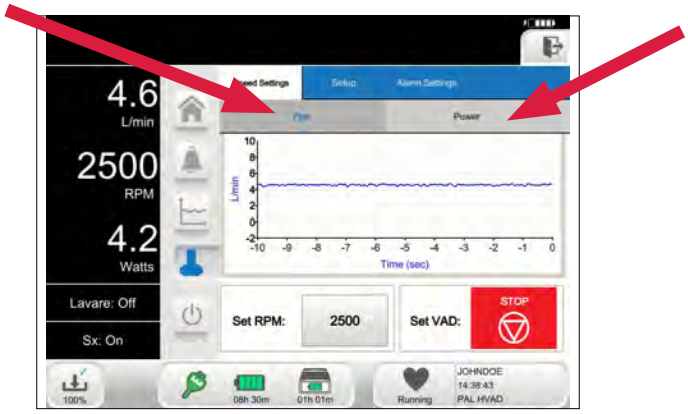



Figure 138: Speed Settings Flow and Power tabs

**Note:** Changing pump speed may cause the Flow waveform to momentarily display a 0 L/min flow reading until flow estimation is reset.

The Speed Settings tab is used to adjust RPM and to turn the pump on or off. Press the "Set RPM" button to adjust the pump speed (RPM) between 1800 RPM and 4000 RPM and press the "Set VAD" button to change pump and controller state. When the "Set RPM" button is pressed, a dialog box will display with an up arrow and a down arrow. Pressing the up or down arrow will change the pump speed in increments of 20 RPM. Confirm the speed adjustment by pressing the "Change" button. The "Set VAD" button is colored and labeled according to the state of the HVAD Pump and Controller.

**Note:** After perioperative period, recommended pump speed during patient support is 2400 RPM to 3200 RPM.

# 6.4 Programming the Monitor and Controller (continued)

## 6.4.2 Programming the Controller (continued)

### Speed Settings Tab (continued)

The "Set VAD" button is used to transition into and out of the Implant state. The button is colored and labeled based on the current state of the HVAD Pump and Controller. In the Implant state, automatic pump start is disabled. When the blue "Implant" button is pressed on the monitor, the speed is automatically reduced to 1800 RPM, as is required for the Pre-Implant Wet Test and for the initial start of the pump during implant. **Table 23** shows how the "Set VAD" button transitions the controller from one state to another.

**Table 23: "Set VAD" button, Pump Status and Controller States:**

| PUMP STATUS | CONTROLLER STATE CHANGE | | | |
|---|---|---|---|---|
| | CURRENT STATE | | MONITOR BUTTON | NEW STATE |
| **Not Connected** | **Ready**  | → |   | → **Implant**  |
| **Connected but not Running** | **Implant**  | → |   | → **Running**  |
| **Connected and Running** | **Running**  | → |   | → **Implant**  |

**WARNING!** ALWAYS ensure that the Controller is in Implant state during the implant procedure. Connecting the driveline in the Ready state will automatically start the pump..

**Note**: A dialog box will appear prompting the user to confirm each action.
**Note**: In order to go from Implant state back to Ready, the controller must be shut down and then powered back on.

**For additional information on operating states, see Table 6 in Section 4.2.2.**

### Setup Tab

When the Setup tab is pressed, four (4) sub-tabs are displayed and include:

1. Patient tab
2. VAD tab
3. Controller tab
4. Monitor tab

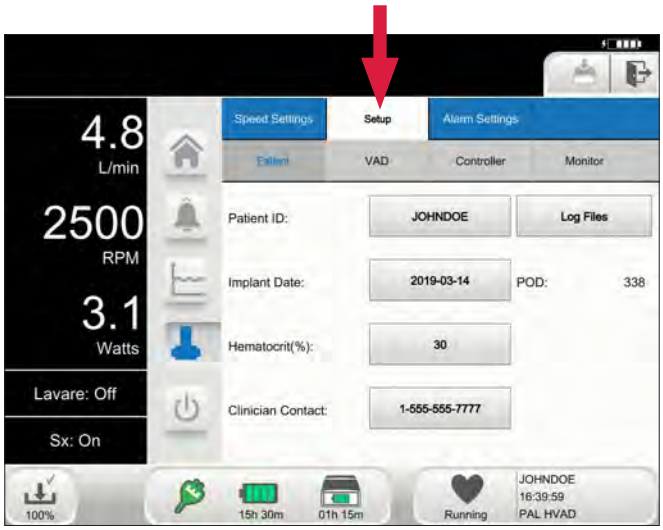



**Figure 139: Setup tab - Patient**

The function of Patient, VAD, and Controller sub-tabs are described below.

### Patient Tab

The Patient tab is used to enter Patient ID, Implant Date, Hematocrit, and Clinician Contact. It is also used to view the number of the post operation days (POD) for the patient, as well as downloading patient log files.

**For additional information on downloading patient log files, see Section 6.5.**

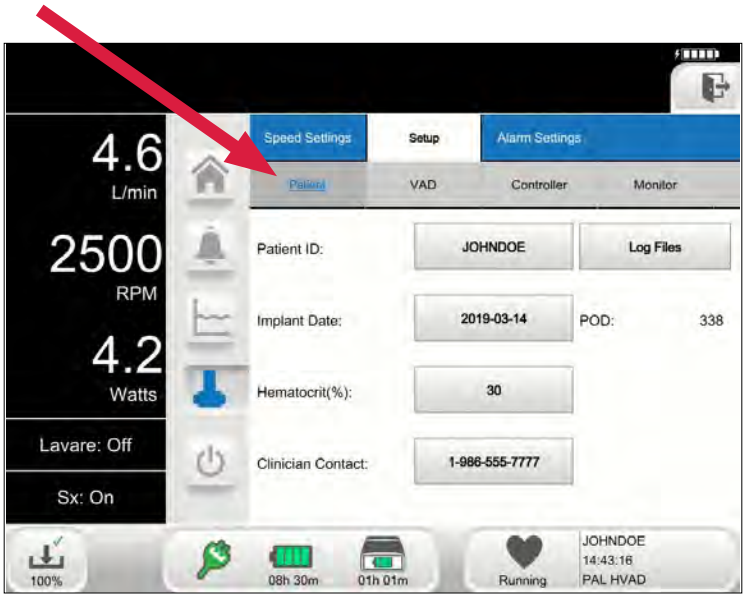



**Figure 140: Patient tab**

# 6.4 Programming the Monitor and Controller (continued)

## 6.4.2 Programming the Controller (continued)

### Patient Tab (continued)

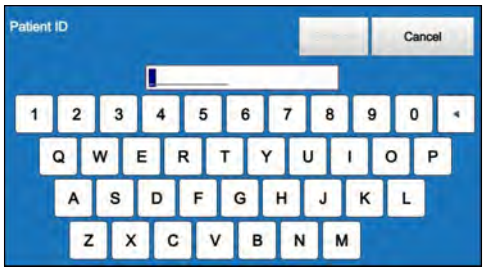



**Figure 141: Patient ID dialog box**

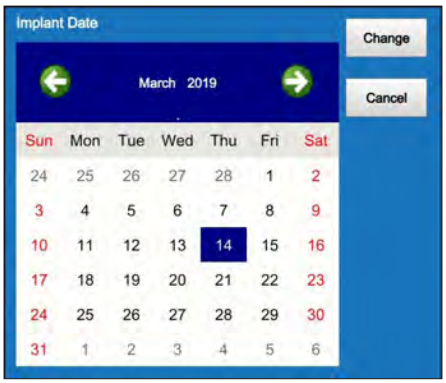



**Figure 142: Implant Date dialog box**

- **Patient ID** (**Figure 141**) - Press the "Patient ID" button to enter patient identification. The Patient ID is entered by using the keypad (**Figure 141**). The A to Z and 0 to 9 tabs allow entry of numbers or letters. Press the "Change" button to confirm the entry or press the "Cancel" button to cancel the entry.
- **Implant Date** (**Figure 142**) - Press the "Implant Date" button and enter the HVAD Pump implant date using the calendar. Press the "Change" button to confirm the entry or press the "Cancel" button to cancel the entry.

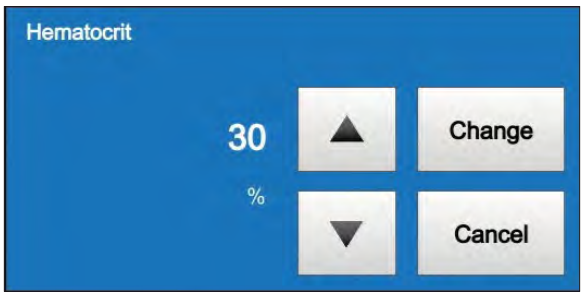



**Figure 143: "Hematocrit" dialog box**

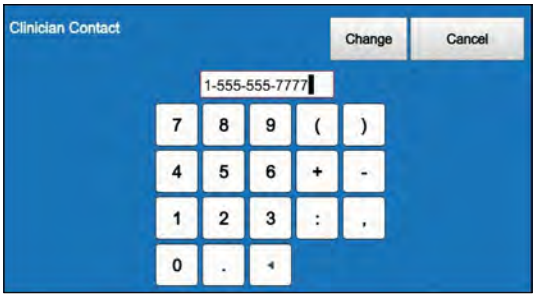



**Figure 144: Clinician Contact dialog box**

- **Hematocrit** (**Figure 143**)**-** Press the "Hematocrit" button to input the patient's hematocrit value based on a measurement obtained from a blood sample. The default hematocrit value is 30%. Press the "Change" button to confirm the entry or press the "Cancel" button to cancel the entry. Press the arrows to go higher or lower.
- **Clinician Contact** (**Figure 144**)- Press the "Clinician Contact" button to enter the clinician's contact information using the keypad. Press the "Change" button to confirm the entry or press the "Cancel" button to cancel the entry. The phone number entered will display on the controller screen during some non-critical alarms. It should be the phone number that the patient calls when they have an alarm. If a phone number is not set up, the controller will display "Call Clinician" when an alarm occurs.

**CAUTION**: Entering an incorrect hematocrit value will lead to flow estimation errors. Flow estimation should not be the sole assessment parameter relative to the clinical efficacy of the HVAD System.

## 6.4.2 Programming the Controller (continued)

### VAD Tab

The VAD tab (**Figure 145**) is used for the following three (3) functions:

1. To enter the HVAD Pump VAD ID,
2. To enable or disable the [Suction] alarm,
3. To enable or disable the Lavare Cycle.

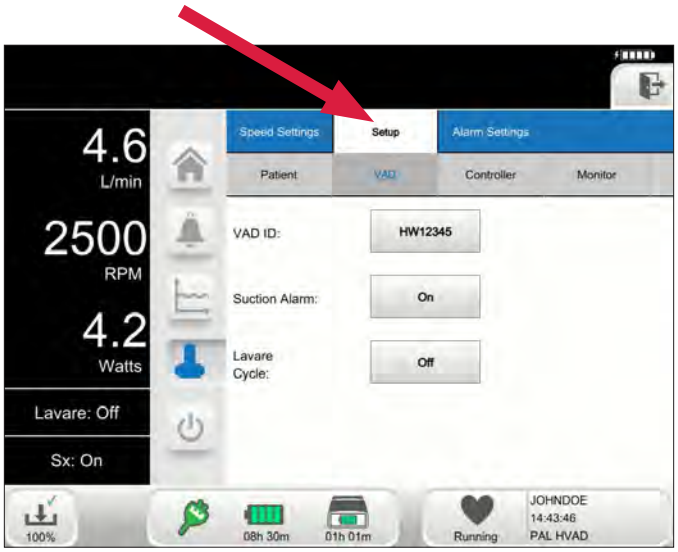



**Figure 145: VAD tab**

Press the "VAD ID" button to enter the HVAD Pump serial number from the Implant Kit package. (Refer to Step #7 in the Implant procedures, **Section 7.2**). After pressing the "VAD ID" button, a dialog box displays (**Figure 146**) and the serial number is entered by using the keypad to enter letters and numbers. The first two letters of the VAD ID are fixed with the letters "HW". After the information is entered, press the "Change" button. If an incorrect number is entered, press "Cancel" and start again.

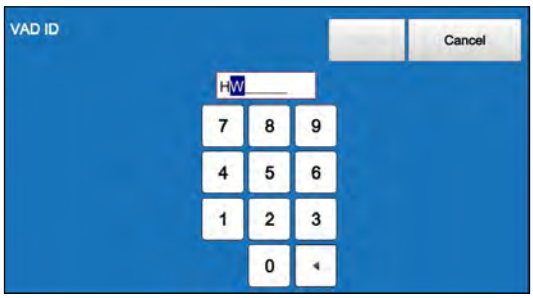



**Figure 146: VAD ID dialog box**

# 6.4 Programming the Monitor and Controller (continued)

## 6.4.2 Programming the Controller (continued)

### [Suction] Alarm

Press the "Suction Alarm" button to enable or disable the [Suction] alarm.

The Suction Alarm dialog box includes two (2) options for suction detection:

1. [Suction] alarm "Off". This is the default setting.
2. [Suction] alarm "On". An alarm will sound if a suction event is detected.

Press "Change" to save the selection. Press "Cancel" to prevent saving the change.

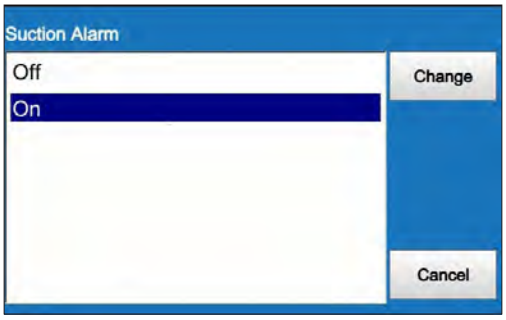



**Figure 147: Suction Alarm dialog box**

**For additional information on the suction alarm, see Section 3.2.2.**

### Lavare Cycle

Press the "Lavare Cycle" button to enable or disable Lavare. The Lavare Cycle dialog box includes two (2) options for Lavare:

1. Lavare Cycle "Off". This is the default setting.
2. Lavare Cycle "On". This enables the Lavare Cycle.

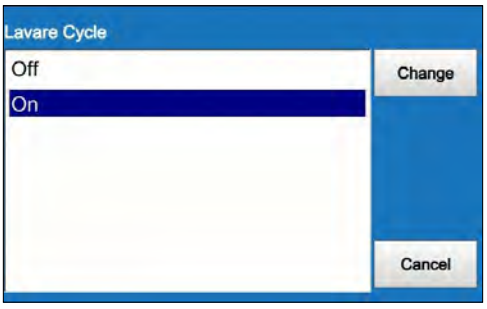



**Figure 148: Lavare Cycle dialog box**

**For additional information on the Lavare Cycle, see Section 3.2.4.**

## 6.4.2 Programming the Controller (continued)

### Controller Tab

The Controller tab (**Figure 149**) allows the user to enter the controller date, time, decimal format and controller language.


**Figure 149: Controller tab**

- Press the "Controller Date" button to enter the controller date.

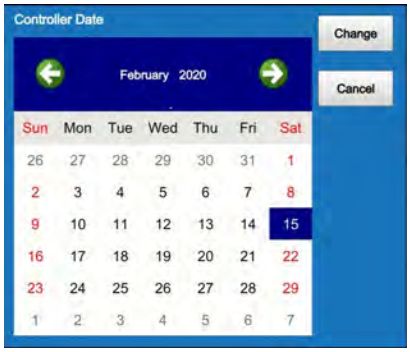



**Figure 150: Controller Date dialog box**

- Press the "Controller Time" buttons to enter the controller time.

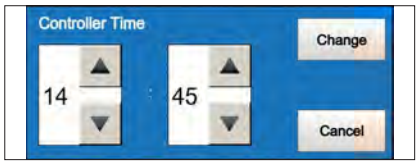



**Figure 151: Controller Time dialog box**

# 6.4 Programming the Monitor and Controller (continued)

## 6.4.2 Programming the Controller (continued)

### Controller Tab (continued)

- Press the "Decimal Format" button to select the decimal format setting to be used for the controller

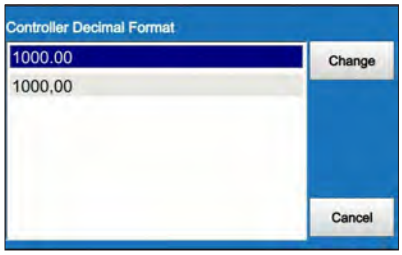



**Figure 152: Controller Decimal Format dialog box**

- Press the "Controller Language" button to select the language for the controller.


**Figure 153: Controller Language dialog box**

**Note**: The settings selected in Controller Date, Time, Language, and Decimal Format dialog boxes will revert to default values upon reconnection to monitor if VAD ID (on VAD tab) is not set.

### Alarm Settings Tab

The Alarm Settings tab (**Figure 154**) is used to set the [Low Flow] alarm threshold, Power Tracking, and [High Power] alarm threshold. Both flow and power are averaged values not instantaneous values. Selecting "Power Tracking" allows Power Tracking to be enabled or disabled.


**Figure 154: Alarm Settings tab**


Figure 155: Low Flow Alarm Limit dialog box


Figure 156: High Power Alarm Limit dialog box

**Table 24: [Low Flow] and [High Power] Thresholds**

| | Range | Increment | Default | Note |
|---|---|---|---|---|
| **[Low Flow]** | 1.0 – 10.0 L/min | 0.1 L/min | 1.0 L/min | • Should be set at 2.0 L/min below patient's average flow. Do not set the [Low Flow] alarm below 2.0 L/min |
| **[High Power]** | 1.0 – 25.0 Watts | 0.1 Watts | 8.0 Watts | • Should be set 2.0 Watts above the patient's average power |

If the flow drops below the [Low Flow] threshold (e.g. 1.0 L/min) or the power exceeds the [High Power] threshold (e.g. 8.0 Watts), an alarm is triggered. Clinicians should set the [Low Flow] and [High Power] alarm thresholds close to the patient's flow and power values, respectively.

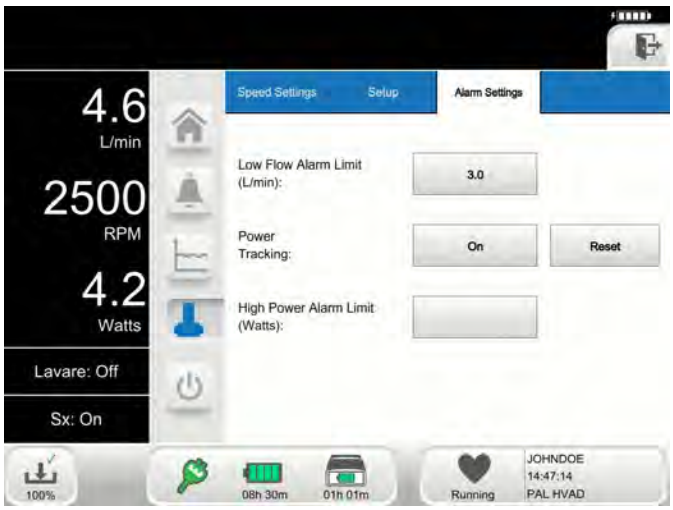



Figure 157: Alarm Limit with Power Tracking "On"

# 6.4 Programming the Monitor and Controller (continued)

## 6.4.2 Programming the Controller (continued)

### Power Tracking

Press the "Power Tracking" button to enable or disable pump power tracking.

The Power Tracking dialog box includes two (2) options for power tracking:

1. "Off" - This is the default setting.
2. "On" - When enabled, the option to set [High Power] alarm limit will be disabled. The Power Tracking algorithm will then drive the [High Power] alarm. The setting is shown as "Auto".

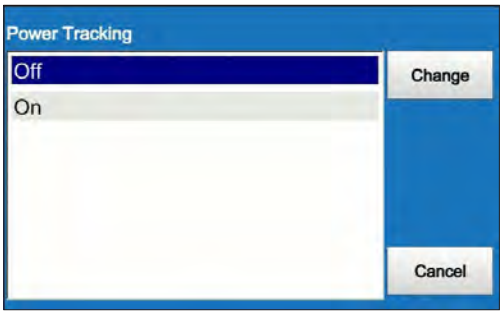



Figure 158: Power Tracking dialog box

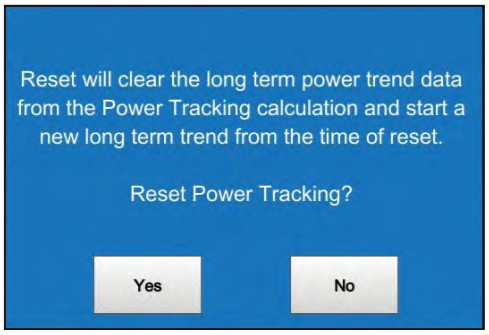



Figure 159: Power Tracking Reset dialog box

**Note:** The "Reset" button can be used to establish a new pump power baseline.

When certain alarm or fault conditions exist, the Alarm Settings tab may be used to access additional controls to mute the audio and vibration component of the alarm or fault for extended time periods. The "Silence Technical Alarm" button displays during a non-critical [Technical] alarm. The "Silence Technical Alarm" button can be pressed to permanently mute a [Technical] alarm. However, the controller and monitor will continue to display the [Technical] alarm until the condition is resolved.

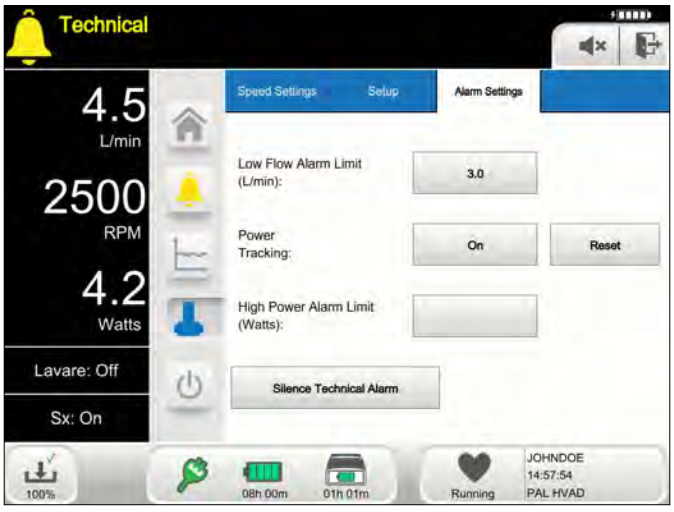



Figure 160: "Silence Technical Alarm" button

## 6.4.2 Programming the Controller (continued)

### Power Tracking (continued)


**Figure 161: Permanently Silence Technical Alarm dialog box**

Permanently muting the [Technical] audible and vibratory alarm is a two-step process.

1. On the monitor's Alarm Settings tab screen (**Figure 162**), press the "Silence Technical Alarm" button to bring up a dialog box.
2. On the dialog box (**Figure 163**), press the "Yes" button to mute current non-critical [Technical] alarm.

Subsequent [Technical] alarms will produce new audible alarms.

The "Silence Electrical Alarm" button displays during a non-critical [Electrical] alarm. The "Silence Electrical Alarm" button can be used to permanently mute an [Electrical] alarm. However, the controller and monitor will continue to display the [Electrical] alarm until the condition is resolved.

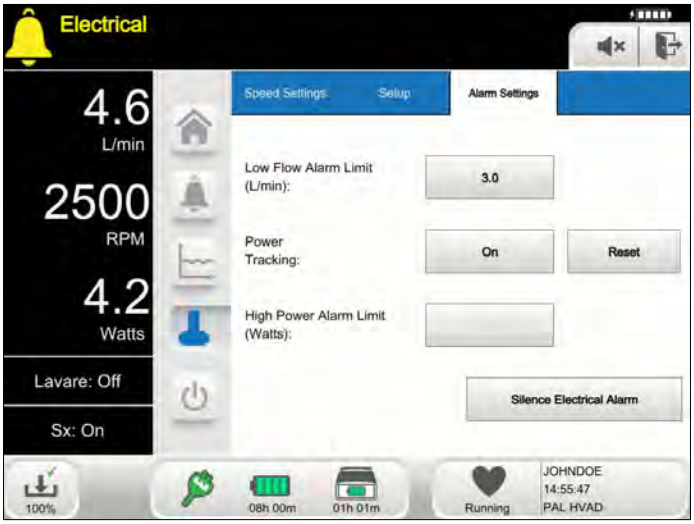



**Figure 162: "Silence Electrical Alarm" button**

# 6.4 Programming the Monitor and Controller (continued)

## 6.4.2 Programming the Controller (continued)

### Power Tracking (continued)


**Figure 163: Permanently Silence [Electrical] Alarm dialog box**

**For additional information on alarms, see Section 5.0.**

**WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Muting a non-critical alarm does not resolve the alarm condition and may lead to sub-optimal therapy.

The user should always log off the System screens after completing system adjustments. To log off, press the "Logout" button and confirm by pressing the "Yes" button to return to the Home screen. If the System screen is not used for eleven (11) minutes, the user is automatically logged out and needs to enter the access code to access these screens.

## 6.5 Downloading Controller Log Files

All logs are maintained in the controller in non-volatile flash memory. The "Log Files" button allows the clinician to obtain alarm and trend data from the controller and to transfer it from the patient's controller to a USB flash drive.

To download log files from the controller to the monitor:

1. Connect the blue data cable from the monitor to the data port on the controller (**Figure 164**). The monitor will begin to automatically download log files from the controller.

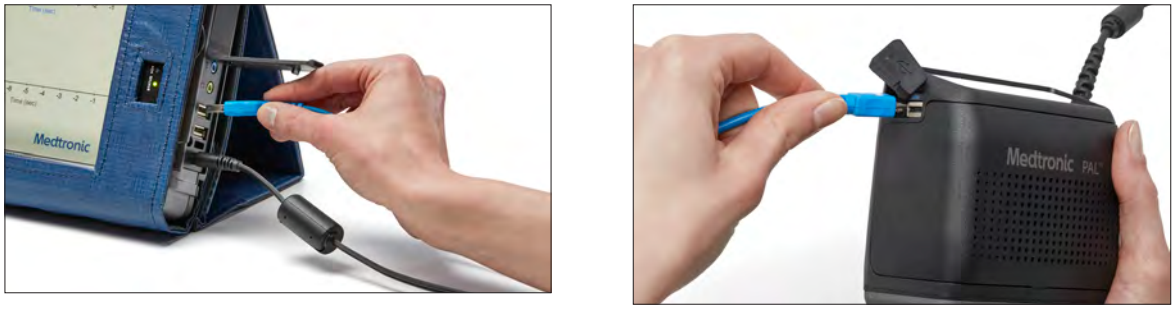



**Figure 164: Data cable from monitor to controller**

2. The download symbol in the lower left corner of the monitor screen will have a percent complete and an arrow moving downwards (**Figure 165**). This indicates the download is in progress. It may take up to five (5) minutes for the download to complete.

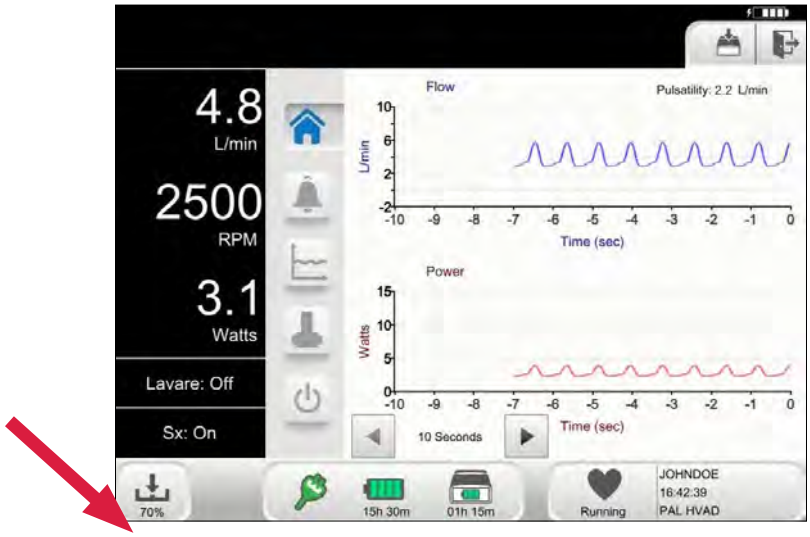



**Figure 165: Percent of download completion indicator (lower left corner)**

3. When the download symbol shows 100%, a green check mark, and the arrow is not moving (**Figure 166**), the data download is complete.

# 6.5 Downloading Controller Log Files (continued)

## To download log files from the controller to the monitor (continued)

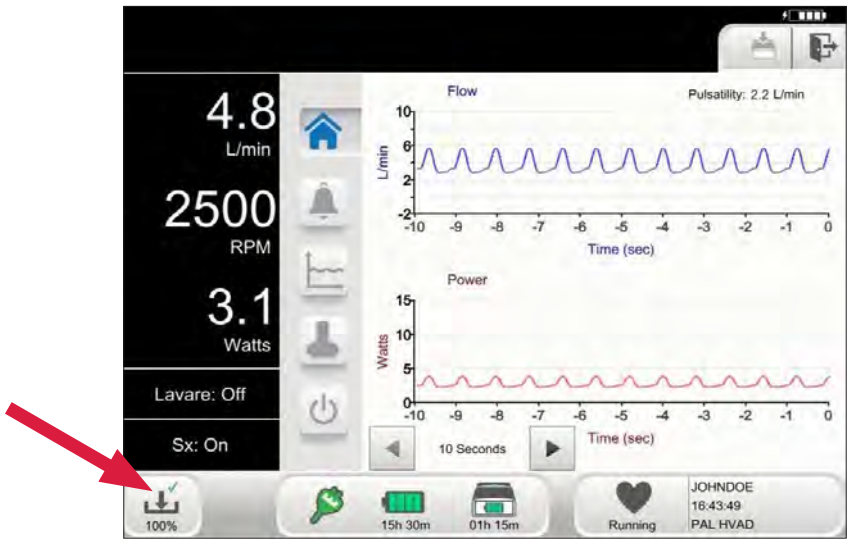



**Figure 166: Indication of download completion (e.g., 100% with green checkmark)**

**Note:** DO NOT disconnect the controller from the monitor when the download symbol is flashing, as data is being transferred. If the message "Log Transfer Not Complete" displays, re-connect the controller to the monitor to complete the data transfer.

**Note:** DO NOT connect two controllers to the monitor at the same time. A dialog box will indicate that two controllers are connected simultaneously and instruct to disconnect one of the controllers from the monitor.

## To download log files from the monitor to a USB Flash Drive:

**Figure 167** shows the monitor screen with the "Log Files" button displayed.

1. Disconnect the controller from the monitor.
2. Press the Setup tab, then press the Patient tab.

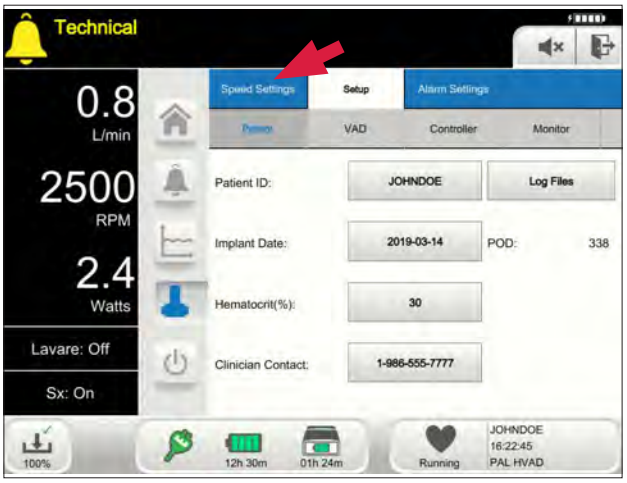



**Figure 167: Setup tab > Patient tab > "Log Files" button**

To download log files from the monitor to a USB Flash Drive:

3. Press the "Log Files" button.

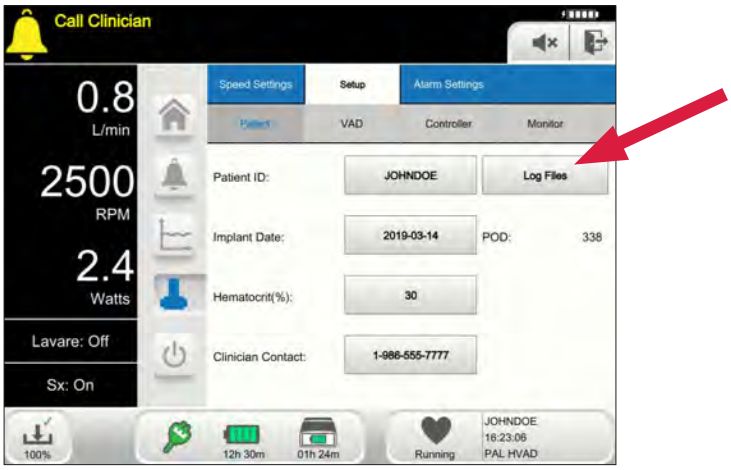



**Figure 168: "Log Files" button**

4. Insert the Medtronic-provided USB flash drive into the USB port of the monitor.


**Figure 169: USB flash drive in USB port**

5. Choose the patient's log file to download and follow the prompts to save the files.

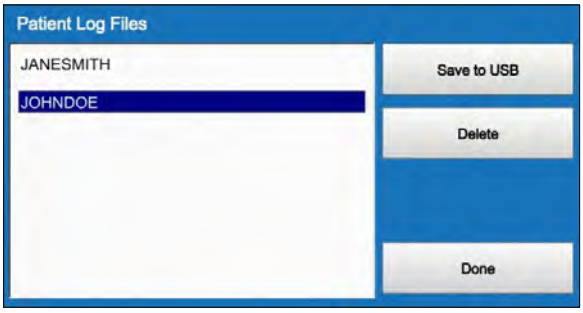



**Figure 170: Buttons to save or delete patient's log files**


**Figure 171: Prompts to save patient's log files**

**Note:** The "Delete" button is used to permanently delete from the monitor all log files associated with the selected Patient ID.

## 6.6 Upgrading Software and Language on the Controller

Software and language on the Controller may be upgraded using the HeartWare Monitor when new versions of the software are available. Some upgrades can be performed on a primary controller that is connected to and running a pump without interruption to therapy. When a new version of controller software or language is available for installation a notification and USB flash drive from Medtronic will be sent for the upgrade.

**Note:** If needed, a Medtronic representative will update the monitor software and confirm that the monitor is able to perform the controller software update.

The monitor will display a message that a software or language upgrade is available when a controller compatible with that update is connected. Controller software updates include software for the controller's BC (Board Controller), UIC (User Interface Controller), and/or MC (Motor Controller).

### To Identify if a Controller is Ready for a Software Upgrade:

1. Take the USB flash drive sent by Medtronic and connect it to the monitor.
2. Download the controller software upgrade files to the monitor following the directions on the screen.
3. After the download, disconnect the USB flash drive.

**Note:** Steps 1 – 3 only need to be performed once. The upgrade files will then be available on the monitor for all compatible controllers.

Upgrades should always be performed on the backup controller first, followed by the primary controller.

4. Connect both an external battery and AC adapter to the backup controller.
5. Connect the controller to the monitor using the data cable.
6. When a software upgrade compatible with the connected controller is available, there will be a flashing controller symbol in the top right corner of the screen next to the "Logout" button (**Figure 172**). To proceed with the controller update, press the flashing symbol and follow the instructions on the screen.

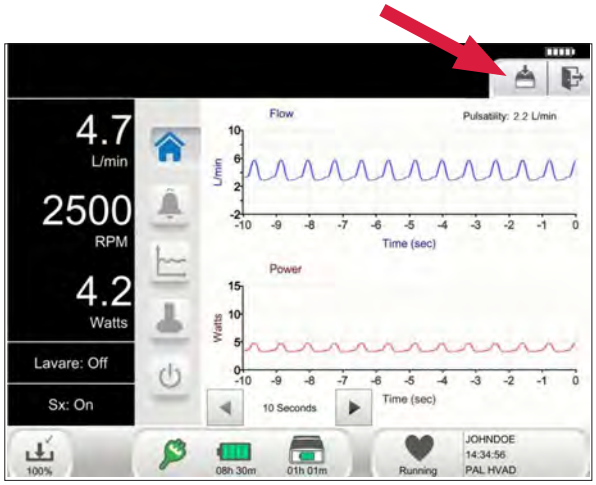



**Figure 172: Screen indicating the controller is ready for software upgrade**

7. A dialog box will display indicating Controller software upgrade files have been found. To continue, press the "Yes" button.

### To Identify if a Controller is Ready for a Software Upgrade (continued):

8. A pop-up screen will appear showing current and available software versions (**Figure 173**).
9. Press "Upgrade Controller" to begin.
10. Wait for the new software to transfer to the controller.
11. Press the "Update" button to complete the installation


**Figure 173: Software upgrade summary dialog box**

**Note**: During software upgrade, the controller screen and monitor communication may briefly reset during the process. This is normal.

**Note**: During the language upgrade, the controller will switch to the default language English. If the upgrade is interrupted, English will remain the controller language.

12. Disconnect the backup controller from the monitor and set aside.
13. Perform the same steps on the primary controller.

### To Upgrade the Primary Controller

To upgrade the primary controller, first follow the steps performed above to update the backup controller. Upgrades can be performed on a primary controller that is running a pump without interruption to therapy.

**Note:** For upgrades with new MC (Motor Control) software, there will be additional communication from Medtronic.

1. Have the patient sit or lie down.
2. Connect both an external battery and AC adapter to the primary controller.
3. Connect the controller to the monitor using the data cable.
4. When a software upgrade compatible with the connected controller is available, there will be a flashing controller symbol in the top right corner of the screen next to the "Logout" button.
5. To proceed with the controller update, press the flashing symbol and follow the instructions on the screen. A pop-up screen will appear showing current and available software versions.
6. Press "Upgrade Controller" to begin.
7. Wait for the new software to transfer to the controller.
8. Press Update to complete the installation.
9. Disconnect the primary controller from the monitor.

**Note**: The controller screen and monitor communication may briefly reset during the process. This is normal.
**Note**: For upgrades with new MC (Motor Control) software, there will be additional communication from Medtronic.

# 6.7 Powering Monitor Off

## Monitor Shutdown

The Monitor Off symbol is used to shut down the monitor program.

**Note:** The monitor should not be powered off using the button on the side of the monitor.

A confirmation dialog box displays after the Monitor Off symbol is pressed.

Press "Yes" to shut down the monitor.

OR

Press "No" to leave it powered on in the PAL application.


**Figure 174: Confirming Monitor Shutdown dialog box**

# 7.0 Surgical Implant and Explant of the HVAD Pump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## 7.1 Preparing for Implantation

**Equipment for Implant**

The following HeartWare HVAD System packages are required for use at implant:

- **HeartWare HVAD Pump Implant Kit**
- **HeartWare HVAD Pump Surgical Tools**
- **Outflow graft**
- **Driveline extension cable –** used only during the Pre-Implant Wet Test to keep the non-sterile controller isolated from the sterile field.
- **HeartWare Pump Implant Accessories** - used only if one of the accessory components in the Pump Implant Kit are damaged and need replacement (contents include: sewing ring, strain relief, driveline cap and inflow cap)

The following non-sterile system components are required for use at Implant:

- 1 HeartWare Monitor with Monitor AC Adapter
- 1 PAL Data Cables
- 2 PAL Controllers (referred to as primary and backup controllers) with PAL Cap
- 2 PAL AC Adapters with country-specific Power Cord
- 2 PAL Dual Batteries
- 2 PAL Single Batteries
- 1 PAL Battery Charger with country-specific Power Cord
- 1 PAL Sport Pack

Additional components that may be issued after implant include:

- 1 PAL DC Adapter
- 1 PAL Accessories Bag
- 1 HeartWare Shower Bag

**Note:** All the non-sterile components above are packaged individually.

**WARNING!** The HVAD Pump may cause interference with AICDs. If electromagnetic interference occurs, it may lead to inappropriate shocks, arrhythmia and possibly death. The occurrence of electromagnetic interference with AICD sensing may require adjustment of lead sensitivity, proximal placement of new leads or replacement of an existing sensing lead.

# 7.1 Preparing for Implantation (continued)

**Equipment for Implant** (continued)

**Figure 175: Components in the Pump Implant Kit Include:**

1. **HeartWare HVAD Pump**
2. **Driveline cap** - to protect the driveline connector when tunneling
3. **Strain relief** - to prevent outflow graft kinking
4. **Inflow cap** - to cover the pump inflow cannula after the Pre-Implant Wet Test and prior to implantation
5. **Sewing ring** - to secure the pump to the left ventricle

**Components packaged individually include:**

6. **Outflow graft** - a 10mm diameter gel impregnated graft with titanium ring
7. **Driveline Extension Cable** - used only during the Pre-Implant Wet Test to keep the non-sterile components isolated from the sterile field


**Figure 176: Components in the surgical tools include:**

1. **Tunneler and handle** – to tunnel the pump's percutaneous driveline through the skin to the exit site
2. **Apical coring tool** – to core the LV apex
3. **Sewing ring wrench** – to tighten the screw on the sewing ring
4. **Strain relief wrench** – to secure the strain relief and outflow graft to the HVAD Pump


All tools and accessories used during implantation are for single-use only.

**CAUTION:** DO NOT use Medtronic equipment in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. (**Note**: Flammable anesthetics are typically ether based).

## 7.1 Preparing for Implantation (continued)

**Primary and Backup Controllers**

1. Connect both the primary and backup controller to AC adapters to begin charging the internal battery. Full charge of the internal battery can take at least two and a half (2.5) hours and should be done prior to the pump implant procedure.
2. Verify availability of four (4) fully-charged external batteries. If batteries are not fully charged, start charging depleted batteries at least six (6) hours before the pump implant procedure.

**Battery Charger**

1. Connect the battery charger power cable to an electrical outlet. Verify the blue power light located on the front center of the charger is lit.
2. Verify availability of four (4) fully-charged external batteries. If batteries are not fully charged, start charging depleted batteries at least six (6) hours before the pump implant procedure.

**Monitor**

1. Connect the Monitor AC adapter, and data cable.
2. Power the monitor on.
3. Select the PAL Application on the System Select Screen

**For additional information about the monitor, see Section 6.0.**

## 7.2 Programming the Controllers for Implant

The following are the programmable parameters for the controller. The user should check "Programming the Backup Controller" and "Programming the Primary Controller" sections to set up the configurations for options 1-15 below:

1. Pump Speed
2. Patient ID
3. Implant Date
4. Hematocrit %
5. Clinician Contact (Phone Number)
6. VAD ID
7. [Suction] alarm
8. Lavare Cycle
9. Controller Date
10. Controller Time
11. Decimal Format
12. Controller Language
13. [Low Flow] Alarm Limit
14. [High Power] Alarm Limit
15. Power Tracking

**CAUTION:** ALWAYS program the backup controller identically to the primary controller to avoid a change in therapy when backup equipment is used.

## 7.2 Programming the Controllers for Implant (continued)

### Programming the Backup Controller

Follow the steps below to program the backup controller. This should be done before the primary controller. The backup controller should be used to conduct the Pre-Implant Wet Test.

1. Power up the backup controller using an external battery.
2. Connect the controller to the monitor with a data cable. Ensure that the PAL application has loaded if it had not been selected already, and that the application indicates a controller is connected.
3. Access the monitor System Screens by pressing the pump icon on the main screen, and entering the access code: 68773 (i.e., "NURSE" when using the keypad letters).
4. Press the Speed Settings tab if it is not already loaded. Change the set speed to 1800 RPM.
5. Press the Setup tab to display the Patient, VAD, Controller, and Monitor tabs.

**For more information on programming the controller, see Section 6.4.2.**

6. Press the Patient tab and enter the Patient ID, Implant Date, and Clinician Contact number.
7. Confirm that the default Hematocrit setting is at 30%.
8. Press the VAD tab and enter the pump serial number in VAD ID. Verify that the [Suction] alarm is "Off" and the Lavare Cycle is "Off".
9. Press the Controller tab and enter Controller Date, Time, Decimal Format, and Controller Language information.
10. Press the Alarm Settings tab. Confirm that the default settings are at 1.0 L/min for [Low Flow], 8.0 Watts for [High Power], and that Power Tracking is "Off".
11. After programming the backup controller, shutdown the controller by removing the external battery and data cable. Connect a PAL Cap to the controller to protect the connection from damage or debris.

### Programming the Primary Controller

Follow the steps below to program the primary controller. It is important to ensure power remains connected to the primary controller after it is set aside. This will allow for a manual pump start via the monitor when instructed by the surgeon. The primary controller should be used during the implant procedure.

1. Power up the primary controller by attaching a fully charged dual battery.
2. Connect the controller to the monitor with the data cable.
3. Place the controller into the Sport Pack battery first and seat the controller so that the data cable exits the pouch flap.
   a. The controller Coiled Cable should also exit out of top of the pack.
   b. Secure by closing the pouch.
4. Navigate to the Speed Settings screen on the monitor and press the blue "IMPLANT" button. This will put the controller into Implant state which automatically changes the set speed to 1800 RPM and disables the pump automatically starting upon driveline connection.
5. Press the Setup tab to display the: Patient, VAD, Controller, and Monitor tabs.

**For more information on programming the controller, see Section 6.4.2.**

6. Press the Patient tab and enter the Patient ID, Implant Date, and Clinician Contact number.

**Programming the Primary Controller (continued)**

7. Confirm that the default Hematocrit setting is at 30%.
8. Press the VAD tab and enter the pump serial number in VAD ID. Verify that the [Suction] alarm is "Off" and the Lavare Cycle is "Off".
9. Press the Controller tab and enter the Controller Date, Time, Decimal Format, and Controller Language information.
10. Confirm that the default settings are at 1.0 L/min for [Low Flow], 8.0 Watts for [High Power], and that Power Tracking is "Off."
11. Press the "Home" button to return to the Clinical screen.
12. Disconnect the monitor side of the data cable but leave the other end of the cable connected to the controller. The driveline pockets on the Sport Pack can be used to keep the data cable and controller Coiled Cable organized until connected.
13. Position the Sport Pack close to the OR table, so the data cable can be reconnected to the monitor and the driveline can be connected to the controller Coiled Cable after tunneling.

**WARNING!** ALWAYS ensure that the PAL Controller is in Implant state during the implant procedure. Connecting the driveline in the Ready state will automatically start the pump.

**CAUTION:** ALWAYS keep external power connected to the controller while in Implant state in order to prevent accidental shutdown.

**Note:** Any changes to the primary controller should also be made to the backup controller.

## 7.3 HeartWare HVAD Pump Pre-Implant Wet Test and Pump Assembly

1. Examine the pump implant kit package and other component packaging. They must be unopened and without any visible damage including abrasion, delamination or punctures.

**WARNING!** DO NOT use if package is damaged or opened. Sterile components are intended for single use only. DO NOT re-sterilize or re-use as this will increase the risk of infection.

2. Set up a sterile back table to prepare and test the pump.
3. Open the driveline extension cable first. Pass it onto the sterile field, wipe it off with a damp sponge and set on sterile back table. Dispose of sponge and change gloves.
4. Grasp the Tyvek® lid of the pump implant kit package at the point indicated and peel back, taking care not to contaminate the inner sterile tray.
5. Pass the pump tray and other components aseptically onto the sterile field. Examine all components, including the surgical tools, for damage, corrosion or any abnormalities that might affect the safety or functionality of the tools. If any abnormalities are noted, use the appropriate backup supplies.
6. Cover the pump with a sterile towel. With the driveline extended on the back table, remove the Tyvek® sleeve (peel off by hand) covering the polyester covered portion of the driveline (**Figure 177**). Wipe the driveline with a lap sponge moistened with antibiotic irrigation and discard the sponge.
7. On the sterile field, fill a basin with enough 5% dextrose solution to establish at least 4.0 inches (10.2 centimeters) of fluid above the pump inflow (**Figure 178**).
8. Attach the sterile driveline extension cable to the pump driveline connector.

**Figure 177: Tyvek® sleeve covering polyester on driveline**


4.0 in. (10.2 cm) above inflow

**Note:** Not drawn to scale.

**Figure 178: Submerged HVAD Pump**

**WARNING!** ALWAYS check for a click when connecting the driveline to the controller or to the driveline extension cable. Failure to ensure a secure connection may lead to a pump stop.

9. Clamp the sterile portion of the extension cable to the sterile field on the table to prevent cable movement.
10. Completely submerge the pump in the dextrose solution. Fill the pump with dextrose solution and gently rotate it in the dextrose solution to allow any trapped air to escape.
11. At least 4.0 inches (10.2 centimeters) of dextrose solution must be above the pump inflow and outflow conduits. Failure to have enough fluid above the inflow cannula may result in air ingestion, damage to the pump and [Low Flow] alarms.

12. When the pump is completely submerged in the sterile basin and is de-aired, point the inflow cannula towards the wall of the basin and position a hand above the pump outflow to prevent dextrose from squirting out of the basin.
13. The non-sterile assistant should connect the open portion of the driveline extension cable to the backup controller Coiled Cable. Push the driveline covers forward from both cable sides to cover the exposed metal connectors.
14. After verifying that the pump is submerged in the dextrose solution, remove the PAL Cap from the backup controller and connect an external battery. This will start the pump.

**WARNING!** NEVER turn on the HVAD Pump in air as this may damage the pump. DO NOT use a HVAD Pump that was turned on without total submersion in fluid during the Pre-Implant Wet Test and prior to implantation: the HVAD Pump must be completely submerged in fluid before being turned on.

15. Run the pump for thirty (30) to sixty (60) seconds. As part of the normal pump startup algorithm, the monitor and controller may momentarily display power values greater than 3.0 Watts before settling at a lower power. Allow for both power and speed to stabilize (this may take 5 - 10 seconds). If after the pump has started and both the power and speed have stabilized the power exceeds 3.0 Watts, DO NOT use the pump. Set it aside and repeat this test using the backup pump.
16. After the test is complete, perform a Palliative shutdown of the backup controller.

**For more information on programming the controller, see Section 8.10.**

17. Reconnect a PAL Cap to the controller to protect the connection from damage or debris.
18. Wearing clean dry gloves, disconnect the driveline extension cable from both the controller and the pump.
19. Connect the driveline cap to the pump driveline by pushing both connectors together until there is a "click" (**Figure 179**).
20. To protect the connector from exposure to fluids, cover the inflow cannula of the pump with the yellow inflow cap.

**Figure 179: Driveline cap connection**

## 7.3 HeartWare HVAD Pump Pre-Implant Wet Test and Pump Assembly (continued)

**Outflow Graft Attachment**

1. Examine the outflow graft package. It must be unopened and without visible damage.

**WARNING!** DO NOT implant gel impregnated vascular prostheses in patients who exhibit sensitivity to polyester or materials of bovine origin, as this may lead to severe reactions.

**WARNING!** The manufacturing process for gelatin sealed vascular grafts uses the cross-linking agent formaldehyde to achieve the graft performance. All gelatin sealed grafts are thoroughly rinsed with reverse osmosis water to reduce residual formaldehyde, however residual amounts may be present in the finished graft. Formaldehyde is also found at low levels naturally in the body, some of which is derived from food. Formaldehyde is known to be mutagenic and carcinogenic. The risks of these potential harms from the product have not been established clinically.

2. Open the package aseptically, taking care not to contaminate the sterile graft.

**WARNING!** DO NOT allow the Gelweave prostheses non-sterile foil pouch or outer tray to be introduced to the sterile field as this may contaminate the sterile field. Only the innermost tray is sterile.

**WARNING!** DO NOT preclot the outflow graft. Preclotting may disrupt the gel matrix, resulting in bleeding. Gelweave prostheses are sealed grafts and must not be preclotted.

**WARNING!** DO NOT implant the Gelweave prostheses more than one month after removal from the foil pouch. This may disrupt the gel matrix, resulting in bleeding.

3. Pass the outflow graft onto the sterile field.

**WARNING!** DO NOT allow anyone but a surgeon, physician's assistant or surgical assistant trained in the procedure to attach the outflow graft to the pump, as a loose graft connection may lead to bleeding and/or an air embolus.

4. Slide the strain relief over the outflow graft (**Figure 180**). Next, stretch the outflow graft over the HVAD Pump outflow conduit (**Figure 181**). Hemostats can be used to assist with the procedure. Verify that the outflow graft is not kinked or twisted. If necessary, reattach graft if kinking or twisting occurs.

**Figure 180: Strain relief over outflow graft**

**Figure 181: Stretch outflow graft over pump outflow conduit**

**Outflow Graft Attachment (continued)**

**CAUTION:** DO NOT exert excessive tension or force on the Gelweave prostheses as this will damage the polyester fibers and the gelatin impregnation, which may result in bleeding.

5. Loosen the graft clamp screw and place the graft clamp over the lip of the HVAD Pump outflow conduit. Verify that the clamp screw is on the outflow conduit and attached to the graft clamp. If the clamp screw is completely removed or if it falls out, be sure to re-insert it correctly as the clamp has threads on only one side.
6. Position the clamp screw so that it is located on the inner side of the outflow conduit (**Figure 182**). Tighten the clamp screw until resistance is met.
7. Gently pull on the outflow graft to verify secure placement of the graft clamp to the outflow conduit.

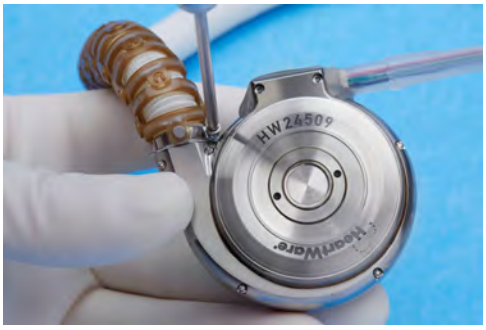


**Figure 182: Position the clamp screw to inner side of outflow conduit**

**WARNING!** ALWAYS position the clamp screw so that it is located on the inner side of the outflow conduit to avoid tissue irritation or damage.

8. Inspect the outflow graft and strain relief for any kinks or twisting. Reattach the outflow graft, if necessary. (**Figure 183**)
9. Clamp the outflow graft with a vascular clamp. Then wrap the HVAD Pump and outflow graft in a clean towel.

**Figure 183: HVAD Pump with strain relief and outflow graft attached**

## 7.4 Surgical Implant Procedure

**Note:** In order to optimize patient outcomes Medtronic suggests that the following techniques be considered at the time of the pump implant:

- **TEE**
  - Inspect LA and LV for thrombus – thoroughly remove any thrombus present.
  - Check for PFO – PFO should be surgically repaired prior to the pump implant.
- **Coring**
  - After coring, make sure margins of the core are clean and smooth.
  - Perform visual inspection of cored area and remove any loose tissue and/or clots.
- **De-Airing**
  - After placement of the pump in the LV, passively fill the LV and the pump.
  - Expose the apex of the heart and shake gently to remove any entrapped air in the heart or pump.
  - Clamp the distal outflow graft. After anastomosis of the outflow graft to the ascending aorta, complete the de-airing process using standard technique.
- **Pump Speed (RPM)**
  - Prior to starting the pump, the LV should be full. The pump must always start at 1800 RPM.
  - Speed should be increased by no more than 100 RPM at a time. Increase the pump speed slowly to avoid suction events. Suction events can lead to the ingestion of tissue or clot from inside the LV and may also lead to episodes of ectopy.

### Pump Implantation Preparation

1. After the primary incision is made, open the pericardium to expose and access the left ventricle (LV) apex.
2. When attaching the pump outflow graft, if a thoracotomy approach is used, it may be necessary to perform an additional small thoracic incision.
3. Consider a transesophageal echocardiography (TEE) prior to placing the patient on cardiopulmonary bypass to assess for a patent foramen ovale (PFO). If present, correct the defect prior to the pump implantation.
4. Consider flooding the field with $CO_2$ when appropriate to reduce residual intracardiac air during surgery.

### Left Ventricle (LV) Apex Cannulation

1. Expose the LV apex.
2. Select the insertion site for the pump inflow cannula. It should be anterior to the LV apex with the inflow cannula pointing to the mitral valve and parallel to the interventricular septum. Evaluate where the pump will sit when implanted. If it appears that it will directly contact adjacent rigid structures, such as the chest wall, consider placing the pump on the diaphragmatic surface, opening the left pleural space, or wrapping it in a sheet of PTFE.

**CAUTION:** ALWAYS ensure the inflow cannula position is pointed toward the mitral valve and parallel to the interventricular septum to optimize HVAD Pump operation.

**Left Ventricle (LV) Apex Cannulation (continued)**

3. Attach the sewing ring to the myocardium using 8-12 pledgeted, double-armed polypropylene sutures. Use felt strips or a felt ring for reinforcement if necessary.

**CAUTION:** ALWAYS position the sewing ring to permit access to its screw after cannulation.

4. Perform a full-thickness cruciate incision inside the sewing ring using an 11-blade scalpel.
5. Using the apical coring tool (**Figure 184**), create and remove the apical core. To use the apical coring tool:
   - Insert the thumb in the thumb ring and wrap the first two fingers around the handle. Push the ring forward with the thumb, extending the cutting head.
   - After the cutting head is completely extended, place the cutting head through the myocardium. Release tension.
   - Grasp the tool with one hand and use the other to rotate the cutting head as it retracts.
   - Cored tissue is captured within the cutting head.

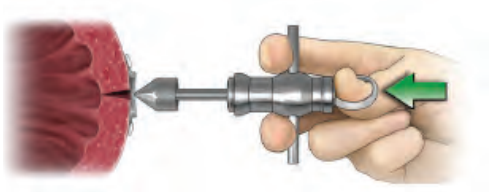

**Figure 184: Apical coring tool**

**Note**: The sewing ring is packaged at the optimal open diameter to allow for insertion of the inflow cannula. If adjustments are made, check to be sure the inflow cannula passes easily through the sewing ring. If it is too tight to pass cannula through sewing ring, loosen the screw on the sewing ring to prevent damaging of the O-ring during pump insertion.

6. Perform a visual inspection of the left ventricle and remove any thrombus or potential obstruction to the inflow cannula.
7. Remove the inflow cap from the pump inflow cannula and keep the pump outflow graft cross-clamped.
8. Insert the pump inflow cannula into the ventricle, keeping the cannula perpendicular to the sewing ring (**Figure 185** and **Figure 186**), so as not to damage the O-ring on the inflow cannula.
9. Ensure that the pump housing is aligned with the sewing ring housing.
10. Use the sewing ring wrench to tighten the sewing ring's screw around the pump inflow conduit (tighten the screw until an audible click is heard).

## 7.4 Surgical Implant Procedure (continued)

### Left Ventricle (LV) Apex Cannulation (continued)

**WARNING!** DO NOT over-loosen the sewing ring's screw or it may fall off the sewing ring and be lost in the sterile field.

**Pump Inserting into the left ventricle**

Figure 185: Sewing ring wrench

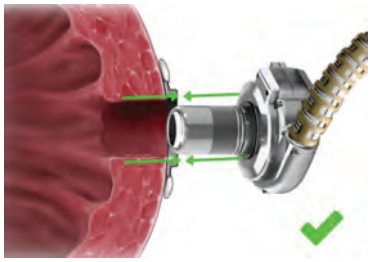

Figure 186: Correct

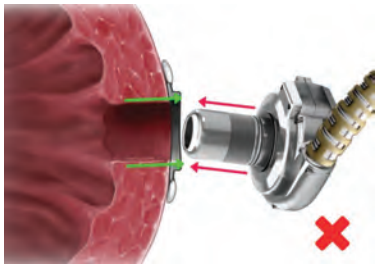

Figure 187: Incorrect

**11.** Verify that there is no blood or air leakage around the sewing ring. Add reinforced pledgeted sutures as needed. If bleeding or an air leak is observed:

1. Loosen the sewing ring screw,
2. remove the pump, and
3. inspect the O-ring on the inflow cannula.

Replace the pump if the O-ring is damaged.

**12.** Add reinforced pledgeted sutures as needed.

### Outflow Graft Anastomosis

1. Gently stretch the outflow graft, measure and cut to length. The outflow graft should lie without kinking or over-stretching.
2. Place a partial occlusion clamp on the portion of the ascending aorta where the outflow graft will be placed.
3. Make a longitudinal arteriotomy and sew the outflow graft to the aorta with 4-0 or 5-0 polypropylene (or similar material) sutures.
4. Remove the partial occlusion clamp from the aorta and ensure an intact anastomosis without bleeding, while keeping the pump outflow graft clamped.

**WARNING!** DO NOT cut the outflow graft too short or too long, as it may kink. Prior to chest closure, ensure that the graft is not kinked or compressed. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.

**WARNING!** DO NOT immerse the Gelweave grafts in saline solution for longer than five minutes. Longer periods of soaking in saline solution may disrupt the gel matrix, resulting in bleeding.

**CAUTION:** ALWAYS use round body taper point needles when implanting Gelweave prostheses to minimize fiber damage. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.

### Driveline Placement

1. Select the location where the driveline will exit the skin. Consider the position of major organs and structures when determining the path of the tunneler.
2. The tunneler is designed so that the handle can be attached and detached. To attach the handle to the tunneling rod, depress the locking pin, insert the tunneling rod into the handle until it bottoms out, release the locking pin and rotate the handle until the locking pin pops out.
3. Using the tunneler, tunnel the driveline lead to the point of exit.
4. Adjust distance of exit site from costal margin to fit body habitus and prevent rubbing against the costal margin.

**WARNING!** ALWAYS position the driveline exit site so that the tunneler does not contact any vital organs or structures.

**CAUTION:** The driveline connector is made of nickel-coated brass which may cause a rash in patients with a nickel allergy.

**CAUTION:** ALWAYS be aware of the position of the driveline to avoid damage by surgical instruments and needles during HVAD Pump implantation and/or re-operation.

5. Once the tunneling path has been made, screw the driveline cap onto the tip of the tunneler. Ensure that the two-piece driveline cap has not separated and remains tightly fastened.

## 7.4 Surgical Implant Procedure (continued)

### Driveline Placement (continued)

6. Pull the driveline through the tunneling path once it is secured to the tunneler.

**Note:** Failure to follow instructions on protecting the driveline connector or improper use of the driveline cap could result in contamination or damage to the connector and [Electrical] alarms could occur.

7. Disconnect the tunneling rod from the driveline cap. Do not remove the driveline cap until it is time to connect the driveline to the primary controller. Make sure to protect the driveline connector from contamination during this time.
8. Pass the driveline out of the sterile field to a non-sterile assistant wearing clean, dry gloves prior to removing the driveline cap. The assistant should perform all driveline connection steps.
9. To remove the driveline cap, unscrew the outer sleeve and pull back on the grooved area of the connector.
10. Verify that the connector is dry and clean before connecting to the primary controller. If the driveline connector contains any fluid, tissue or foreign material, thoroughly clean it with isopropyl alcohol and dry it with a clean cloth.
11. Attach the driveline to the primary controller and slide the driveline cover forward to cover the silver connectors.
12. Immobilize the driveline at the exit site with retaining sutures.

**CAUTION:** DO NOT grasp or pull the driveline as this may damage the driveline. To remove the driveline cap from the driveline, unscrew the outer sleeve, then pull back on the grooved area of the connector.

### De-airing Procedure

1. Start ventilation.
2. Be sure that all IV catheters and pressure monitoring lines are closed to the atmosphere to reduce the possibility of air entering the heart and the pump.
3. Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and the pump.
4. Place a sterile 19-gauge needle into the outflow graft between the pump and the outflow graft clamp.

**CAUTION:** ALWAYS use the smallest possible needle for de-airing; 19-gauge is normally sufficient. Hypodermic needles have a cutting point which may result in blood leakage and may require repair by suturing.

5. If the monitor has logged out, return to the Speed Settings tab by re-entering the access code. Start the pump using the green “START” button on the monitor. This will put the controller into the Running state from the Implant state. Pump speed will start at 1800 RPM.

**De-airing Procedure (continued)**

6. With the pump speed set at 1800 RPM, use TEE to assess air in the left ventricle and aorta.

**WARNING!** ALWAYS remove all air from the HVAD Pump and its conduits to reduce risk of air embolism.
**WARNING!** DO NOT de-air the HVAD Pump when there is inadequate blood volume in the pump or leaks in the inflow or outflow connections, as air may enter the pump and outflow graft resulting in a delay in de-airing and possible air embolism.

**CAUTION:** DO NOT rely on HVAD Pump flow estimation during the de-airing procedure. Flow estimation may not be accurate.

7. After all air is removed, remove the 19-gauge needle and over-sew the needle hole with pledgeted sutures.
8. Release the outflow graft cross clamp.
9. Gradually increase pump set speed to achieve the desired flow and wean from cardiopulmonary bypass as tolerated.

**Note:** Increase the pump speed in increments of 100 RPM with a twenty (20)-second interval between speed changes to gradually increase flow and to help prevent ventricular collapse.

10. Once the case is complete, ensure alarm limits, hematocrit and settings are accurately programmed on the primary controller.
11. To program the backup controller with the same settings, power up the backup controller by removing the PAL Cap and connecting an external battery.
12. Disconnect the data cable from the primary controller and reconnect it to the backup controller. Program all settings to match the primary controller.

**For more information on pump speed and other settings, see Section 8.1.1.**

13. After programming the backup controller, shutdown the controller by removing the external battery and data cable. Reconnect a PAL Cap to the controller to protect the connection from damage or debris.

## 7.5 HeartWare HVAD Pump Explant

**At Transplant**

1. Surgically expose the pump and sewing ring.
2. Place patient on cardiopulmonary bypass according to institutional guidelines.
3. Connect the controller to the monitor and load the Speed Settings tab. Press the red "STOP" button to turn off the pump.
4. Cross-clamp two (2) sections of the outflow graft.
5. Cut outflow graft between two (2) clamps.
6. Cut and remove the percutaneous driveline.
7. Remove the pump with the heart.

**Myocardial Recovery/ Pump Exchange**

1. Surgically expose the pump and sewing ring.
2. Place patient on cardiopulmonary bypass according to institutional guidelines.
3. Connect the controller to the monitor and turn off the pump.
4. Cross-clamp two (2) sections of the outflow graft.
5. Cut outflow graft between two (2) clamps.
6. Cut and remove the percutaneous driveline.

**WARNING!** DO NOT place the percutaneous driveline into the sterile field during HVAD Pump explant as it may lead to contamination. The percutaneous driveline is not sterile.

7. Excise the remaining outflow graft from the aorta and repair the arteriotomy site.
8. Use the sewing ring wrench to loosen the sewing ring screw.
9. Remove the pump.

**Note:** During the pump removal for recovery or exchange it may be difficult to withdraw the pump from the left ventricle due to tissue ingrowth on the sintered portion of the inflow cannula. It may be necessary to excise tissue adjacent to the sintering potentially resulting in bleeding and/or air emboli.

10. For the pump exchange, refer to "Left Ventricle (LV) Apex Cannulation" in Section 7.4, "Surgical Implant Procedure" (starting at step #6). For myocardial recovery, follow the steps below.
11. Repair the hole in the LV.
12. Close sternum and skin incision per routine.
13. Once the pump is explanted, rinse gently with sodium chloride (NaCl).
14. Place the pump in 5% Formaldehyde for at least two (2) days.
15. Allow the pump to thoroughly dry.
16. Follow the packaging instructions provided in the Explant Kit (provided by Medtronic) and return the HVAD Pump in the Explant Kit.

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# 8.0 Patient Management and Education


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## 8.1 Postoperative Management

After implantation, the patient is returned to the intensive care unit. Fluids are given to maintain pump flow index (pump flow ÷ Body Surface Area (BSA)) at greater than 2.0 L/min/m² with central venous pressure and left atrial pressure less than 20 mmHg. Some vasopressor and/or vasodilatory pharmacologic assistance can be used as required to adjust vasomotor tone. Patients may require inotropic assistance to improve right ventricular function.

**WARNING!** Serious and life-threatening adverse events, including stroke, have been associated with use of this device. The risk of death as a result of stroke has been observed in randomized clinical trials to be higher with the HVAD than with alternative treatment options. The HVAD has been associated with a rate of stroke of 22% at one year and 29.7% at two years. A blood pressure management protocol may reduce the overall incidence of stroke to 16.9% at one year and may reduce the incidence of disabling strokes at one year from 8.1% to 6.5%. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation. Refer to clinical study results for the stroke data in Section D. Safety and Effectiveness Results of Appendix F (US Clinical Study: Destination Therapy). Data has shown that appropriate patient management can mitigate the risk of stroke. The following patient management guidelines should be adopted:

- Monitor and treat mean arterial pressure. Maintain MAP less than 85 mmHg, as tolerated.
- Set speed on the HVAD Pump to maintain adequate pump flow index; which generally will not need to exceed 2.6 L/min/m².
- Maintain anticoagulation within the recommended INR range of 2.0-3.0.
- The daily aspirin doses should be:
  - more than 81 mg should be given daily.
  - in general, 81 mg alone is not recommended unless testing for aspirin resistance is performed.
  - in absence of platelet function testing, consider combination therapy, such as: ASA 81 mg plus Aggrenox® (ASA plus extended –release dipyridamole) or ASA 81 mg plus Plavix 75 mg.

# 8.1 Postoperative Management (continued)

## 8.1.1 Setting Speed with HeartWare HVAD Pump

The pump speed for each patient should be individualized based on body surface area and clinical condition.

Similar to other continuous flow VADs, setting speed appropriately is important to optimize outcomes. The 2013 ISHLT Guidelines (Feldman, et.al., 2013 ISHLT MCS Guidelines. The Journal of Heart and Lung Transplantation, Vol 32, No 2, February 2013) make the following recommendations when setting speed with a continuous flow device:

- Speed should be maintained at a minimum level to: attain satisfactory hemodynamics (MAP ≤ 80 mmHg, cardiac index > 2.2 L/min/m$^2$, end organ perfusion) and optimal decompression of the heart without leftward shift of the intraventricular septum or suction.
- Echocardiography can be helpful when setting speed. It can provide detailed information on right heart function, aortic and mitral valve function, septal positioning and inflow cannula positioning.

One of the operating goals for the HVAD Pump is to maintain device operation in the "Normal Pulsatility Region" to avoid retrograde flow and suction events. HVAD Pump flow pulsatility is the difference between the maximum (peak) and the minimum (trough) flows which are displayed in the flow waveform on the HeartWare Monitor. Pulsatility is reflected in a positive waveform (similar in form to an arterial line waveform) where the trough value represents the flow during left ventricular diastole and the peak value represents the flow during left ventricular systole (see **Figure 188**). Pulsatility is affected by a number of patient conditions including left ventricular contractility, right heart function and left ventricular afterload.

The flow waveform trough is the minimum value of the HVAD Pump flow waveform. The trough value should be > 2.0 L/min and there should be > 2.0 L/min of pulsatility. An example of a flow waveform with a trough of > 2.0 L/min and pulsatility of > 2.0 L/min is shown in **Figure 189**.

**Figure 188: HVAD Pump flow waveform**

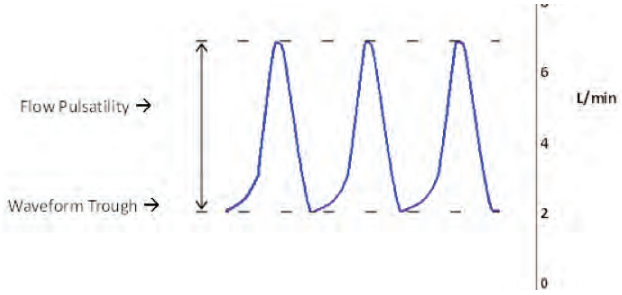



**Figure 189: HeartWare Monitor screen showing HVAD Pump flow waveform**


**CAUTION:** Recommended HVAD Pump speeds are between 2400 RPM and 3200 RPM. HVAD Pump speeds outside this range may result in less than optimal HVAD Pump operation. Speeds below 2400 RPM or above 3200 RPM should be used with caution.

### 8.1.1 Setting Speed with HeartWare HVAD Pump (continued)

Between implant and discharge, a patient's therapy and physiological conditions can change significantly. Prior to patient discharge, the HeartWare HVAD System speed, algorithms settings, and alarms limits should be reviewed and adjusted as appropriate. This pre-discharge HVAD settings adjustment, which should be performed with echocardiographic guidance, establishes a baseline that can be used for future comparison.

For both the primary and backup controllers:

- HVAD Pump speed should be set between 2400 RPM and 3200 RPM.
- Suction Detection, Lavare Cycle, and Power Tracking algorithms should be set as determined by the clinician.
- Set the [Low Flow] alarm limit 2.0 L/min below the patient's average flow. (Do not set the [Low Flow] alarm below 2.0 L/min.)
- If Power Tracking is off, set the [High Power] alarm limit 2.0 Watts above the patient's average power.

**Note:** The [Low Flow] and [High Power] alarm limits should be set as recommended unless specified differently by a clinician.

### 8.1.2 Blood Pressure Maintenance

Managing blood pressure post continuous flow VAD implant is described in the ISHLT Guidelines. Similar to the ISHLT Recommendations, monitoring of blood pressure following HVAD implant has shown to be very important to optimize patient results, in particular to minimize risk of stroke.

Since the HVAD Pump provides continuous flow resulting in narrow arterial systolic and diastolic pulse pressure, it is best to monitor the mean arterial pressure (MAP).

Blood pressure should be monitored during both the immediate post-operative period as well as for the duration of device support. To monitor blood pressure after the removal of the invasive arterial line utilize either an automated cuff or Doppler method.

Blood pressure management goals should be individualized to the patient conditions. The following are recommended blood pressure management practices:

- Prior to discharge, patients and/or caregivers should be trained to obtain blood pressure readings and record values.
- For patients with a palpable pulse, MAP targets should be ≤ 85 mmHg.
- For patients without a palpable pulse, a manual cuff and a Doppler device is the preferred method with a MAP target of ≤ 90 mmHg.
- Patients should be provided specific MAP targets for notification of their clinician for possible intervention as part of their discharge instructions.

# 8.1 Postoperative Management (continued)

## 8.1.3 Anticoagulation

Prior to HVAD Pump implantation, many patients with refractory heart failure have abnormal coagulation due to abnormal liver function and chronic use of anticoagulation. Prolonged INR can be associated with significant postoperative bleeding. The INR, PTT, and platelet count should be performed prior to HVAD Pump implantation. The return of each of these parameters to a normal range prior to HVAD Pump implantation is an important goal.

Anticoagulation should be individualized for each patient. In general, begin low-dose heparin at ten (10) units/kg/hr on postoperative day one to a target PTT of forty (40) to fifty (50) seconds. Prior to initiation of anticoagulation, chest tube drainage should be less than forty (40) ml/hr for approximately three hours; the HCT should be stable without the need for transfusion of blood products, and coagulation factors approaching normal. Gradually increase the heparin dosage to maintain the aPTT in a range of fifty (50) to sixty (60) seconds.

The recommended long-term oral anticoagulation regimen for the HVAD Pump is a combination of warfarin and aspirin. In general, aspirin should be started at a dose such as 325 mg/day within twenty-four (24) hours after implant if there are no postoperative bleeding complications. However, if ASA alone is the medication chosen for anti-platelet therapy, a check for ASA resistance with a reliable test (e.g., VerifyNow®) is recommended to establish the dose or to select an alternative medication. Multi-drug options include:

- ASA 81 mg plus Aggrenox® (ASA (25 mg) plus extended –release dipyridamole (200 mg))
- ASA 81 mg plus clopidogrel 75 mg daily

For patients who are aspirin sensitive or otherwise intolerant, clopidogrel at doses of 75-150 mg/day is a viable alternative. A clopidogrel loading dose of 300 mg followed by 75 mg/day is recommended to reduce the lag time in reaching full therapeutic benefit (typically a three (3) to four (4) day lag). Warfarin should be started within four (4) days post-op and titrated to maintain an INR of 2.0 to 3.0.

## 8.1.4 Right Heart Failure

Right heart failure is common in patients receiving LVADs. Right heart failure usually develops within the first 24 hours after LVAD implant. Warning signs include increasing right atrial pressure (RAP) with concurrent decreases in the pulmonary capillary wedge pressure (PCWP) and LVAD flow. Systemic hypotension, tachycardia and a decrease in urine output soon follow. Volume should be given to increase the RAP to 15-18 mmHg. This can be accomplished quickly and easily in the operating room while the patient is on cardiopulmonary bypass. Increasing the RAP to > 20 mmHg is usually ineffective. After optimizing intravascular volume, increasing inotropic drug support in conjunction with pulmonary vasodilators such as nitric oxide is usually effective. If volume and pharmacological therapy fail, a right ventricular assist device (RVAD) should be considered. Late right heart failure (weeks to months) post LVAD implant is unusual but would manifest itself with similar but less acute symptoms. The etiology of late right heart failure may be a progression of chronic heart disease such as coronary artery disease and/or right ventricular infarction. The cause of the right heart dysfunction should be identified and treated appropriately.

## 8.1.5 Arrhythmias

The HVAD Pump functions most effectively when adequate and stable amounts of preload are available. A stable supraventricular rhythm helps to optimize right heart performance and provide the HVAD Pump with preload. Many heart failure patients will have permanent pacemakers and internal defibrillators in place by the time a pump is implanted. These devices are often needed in the early postoperative period.

## 8.1 Postoperative Management (continued)

### 8.1.6 Infection Control Guidelines

For prevention of infection, remove unnecessary IV lines and replace old IV lines before HVAD Pump implantation. Administer antimicrobial prophylaxis based on the hospital's nosocomial and microbial sensitivity profile with sufficient coverage for staph aureus, staph epidermidis and enterococcus. Use pre-operative scrub with antiseptic the night before and again the morning of the operation. After HVAD Pump implantation, continue systemic antimicrobials prophylaxis for 48 to 72 hours. Remove mediastinal and pleural drains as soon as appropriate. Early extubation, removal of monitoring lines, and patient ambulation are encouraged. Rapid restoration of oral nutrition should be attempted using tube feeding if necessary. Turning the patient side to side can start once the patient is clinically stable. Physical therapy and active range of motion can begin on the first postoperative day. The patient can be moved to a chair and should use an exercise bicycle or treadmill as soon as possible. Nursing measures to decrease infection include frequent hand washing and strict aseptic technique during contact with invasive lines and during HVAD Pump dressing changes.

*Infection Control Guidelines and Driveline Care based on recommendations from "Multicenter Experience: Prevention and Management of Left Ventricular Assist Device Infections". Chinn et al. ASAIO Journal 2005; 51:461–470

## 8.2 Driveline Care

To minimize the risk of infection, driveline exit site dressings should routinely be changed. Routine driveline exit site care is the responsibility of the patient and the primary caregiver. For proper HVAD Pump driveline and exit site care, ensure the following:

1. Use good hand-washing technique before and after dressing changes.
2. Always use aseptic technique.
3. Change dressings per institutional protocol and guidelines.
4. Once the exit site dressing is removed, the driveline should be visually inspected for kinks, tears or other damage. If blood is seen within the lumen of the driveline, the implanting center should be notified immediately.

**CAUTION:** ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Driveline damage may affect the HVAD System performance.

**CAUTION:** DO NOT expose the pump driveline to direct or indirect sunlight. ALWAYS keep the driveline completely covered when in the sun. Instruct patients not to use tanning lights or black lights. The light from these sources contains ultraviolet radiation which may damage the outer sheath of the driveline.

5. In general, exit site care is performed every 24-48 hours using an antiseptic cleansing agent, such as a diluted chlorhexidine scrub solution. Following aseptic cleansing, dry the site to avoid tissue injury. Aseptic technique should be followed anytime the dressing is removed and the exit site is exposed, inspected, dressed or handled. When performing exit site care, be sure to wear a cap, mask and sterile gloves.

## 8.2 Driveline Care (continued)

**CAUTION:** DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine (betadine), or polymyxin-neomycin-bacitracin ointment on the exit site. These ointments can injure the tissue next to the driveline.

6. Immobilize the driveline with a dressing and stabilize it with a binder or device, such as a Foley anchor, Montgomery strap, or a custom-made percutaneous lead immobilization belt. Keep the extra external length of the driveline under a binder or clothing.
7. Complicated, non-routine driveline dressing changes that involve exit site infections may require assistance and/or supervision from a health care professional.
8. For wounds and/or incisions other than the driveline exit site that require dressing changes and/or other care, the ability of the patient and caregiver to provide that care will be evaluated by the implanting center. Treatment plans will be dependent upon this evaluation.

## 8.3 Physical Rehabilitation

Physical Rehabilitation begins as soon as the patient admitted to the intensive care unit is stable. Early extubation, removal of monitoring lines, and patient ambulation are encouraged. Turning the patient from side to side should start once the patient is clinically stable. Physical therapy and active range of motion may begin on the first postoperative day. The patient may be moved to a chair and should use a bed bike, exercise bicycle or treadmill as soon as possible.

Within a few days of VAD implant, the patient should be ambulating in the halls and performing mild exercise under the supervision of a physical therapist. The nursing, physical therapy, and occupational therapy staff will work together to prepare the patient for hospital discharge — whether to home or a rehabilitation facility. If discharged to home, at the clinician's discretion, the patient may attend a structured outpatient cardiac rehabilitation program.

## 8.4 Patient Education

Patient training is critical to ensure safe and successful outcomes. The patient must be able to demonstrate proficiency in operating the HVAD System and in responding to emergencies. In order to ensure their understanding and ability, patients should be trained using hands-on demonstrations. At the end of the training, the patient should be able to do the following:

- Identify the AC adapter and successfully connect it to the controller and an electrical outlet.
- Identify the battery connection on the controller and be able to successfully replace external batteries as indicated.
- Successfully recharge external batteries with the battery charger.
- Estimate time remaining for battery on the Home screen of the controller.
- Identify audible and text alarm messages on the controller.
- Understand the meaning of alarms and demonstrate appropriate responses to alarm conditions.
- Successfully switch from one controller to another controller.
- Properly use and manage the peripherals.
- Understand the importance of not pulling, twisting or kinking the driveline or power cables.

Patients should be educated in the importance of having a backup controller readily available at all times including when changing power sources. Clinicians should emphasize this education for patients who may be at risk of catastrophic cardiovascular collapse if a pump shutdown occurs. Patients at risk include those with a fused aortic valve, an aortic valve that has been sewn shut due to aortic valve regurgitation, or patients with very poor ventricular function.

## 8.4 Patient Education (continued)

Following hospital discharge, the patient's understanding of HVAD System operation and alarms should be re-evaluated during routine follow-up visits. This training should include reinforcement of the procedure for switching to a backup controller in the case of an emergency. Advise patients to consult their clinician before entering environments that could adversely affect the operation of the device.

**WARNING!** Patients should AVOID areas with high magnetic forces, such as theft detection devices or airport security systems, as this may affect the HVAD System operation.

## 8.5 Recommended Equipment for Use at Home

Patients with the HVAD System should have this equipment close to them and readily available at all times (when in the hospital, at home, or when traveling overnight).

- 2 PAL Controllers (1 active, 1 backup)
- 1 PAL Battery Charger
- 1 PAL Controller DC Adapter
- 2 PAL Controller AC Adapters
- 4 PAL Batteries (2 Single and 2 Dual)
- 2 PAL Caps
- 1 or more carrying cases (PAL Sport Pack)
- 1 HeartWare Shower Bag
- 1 PAL Accessories Bag
- 1 Patient Manual
- 2 Emergency Responder Guides
- 2 Patient ID Cards

**WARNING!** ALWAYS connect an AC adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC adapter) provides power for an unlimited period of time.

**Note:** The monitor is not recommended for use at home.

## 8.6 Recommended Equipment for Use Outside the Home

Whenever patients with the HVAD System leave their house on a short trip such as running errands, in addition to what they are currently using, they should bring the following equipment as backup:

- 1 Backup PAL Controller with PAL Cap
- 1 PAL Controller AC Adapter or DC Adapter
- 2 PAL Batteries
- 1 PAL Accessories Bag
- 1 Emergency Responder Guides
- 1 Patient ID Cards

## 8.7 Medical Emergencies

In the event of an emergency, such as a cardiac arrest, patients with the HVAD System may be defibrillated with either an internal or external defibrillator. The HVAD System can be left on; nothing needs to be turned off or disconnected. If chest compressions are performed, confirm function and positioning of HVAD Pump once the patient is stable.

**CAUTION:** Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta, use clinical judgment. If chest compressions have been administered, confirm function and positioning of the pump.

## 8.8 Patient Follow Up

### System Check List

To minimize risk of peripherals failure and interruption to therapy, complete a standard system status check of the primary and backup controllers, internal batteries, and external batteries. This should be done during scheduled patient visits at least every six (6) months. Check for and address the following maintenance activities:

- Software upgrade available for primary and backup controller.
- Language upgrade available for primary and backup controller.
- Internal batteries for primary and backup controller are fully charged.
- Internal battery needs replacement for primary and backup controller indicated on the monitor while the controller is connected.
- External battery needs replacement indicated by controller information screen or monitor while each external battery is connected to the controller.
- Visible damage of any peripherals, such as controller, external batteries, driveline, carry bag, etc.
- Inconsistent settings programmed for primary and backup controller.

### Managing the Backup Controller

The patient's backup controller should be powered on and its internal battery should be charged to full capacity at least once every six (6) months at a clinical follow up visit. The backup controller should also be connected to the monitor to check if the internal battery requires replacement, or if any software upgrades are available. All settings on the backup controller should be confirmed to be consistent with the primary controller.

**WARNING!** DO NOT let the patient have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD Pump. Doing so could cause harm to the patient or could cause the pump to stop.

**WARNING!** Patient should AVOID therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm. Therapeutic levels of ultrasound energy may also affect HVAD System operation.

**CAUTION:** DO NOT apply high power electrical treatment (e.g., deep tissue heating which can be used for treatment of arthritis and/or some injuries) directly to the patient, as this may affect HVAD System operation.

**CAUTION:** Patient should AVOID therapeutic ionizing radiation since it may damage the device. This damage may not be immediately detectable.

**CAUTION:** The primary controller and backup controller shall be programmed identically.

## 8.9 Internal Battery Replacement

The monitor and controller will provide notification when the internal battery needs to be replaced. Pressing the notification icon will load dialog boxes with instructions for performing the replacement. The following time frames indicate replacement:

- At twelve (12) months of use - Notification will display on monitor when the controller is connected.
- At sixteen (16) months of use - Notification symbol will display on the controller home screen and will be viewable on the Controller Information screen. The patient should communicate to their clinician that the notification occurred, and the internal battery should be replaced during the next visit.
- At eighteen (18) months of use - The internal battery is at its end of life. - Monitor and Controller notification will display.

After twelve (12) months of use, the internal battery should be replaced within the next six (6) months, using the PAL Internal Battery Replacement Kit.

Components of the kit include:

1. PAL Internal Battery (1)
2. Controller cover (1)
3. 2 mm blue hex wrench (1)
4. 1.5 mm white hex wrench (1)

**WARNING!** The PAL Controller internal battery should only be changed by trained personnel. Patients and caregivers should not attempt to change the controller internal battery.

**CAUTION:** Follow ESD prevention practice when replacing the internal battery:

- Perform the battery replacement in an ESD-safe area whenever possible.
- Discharge ESD by touching a metal object in the room other than the controller.
- Avoid making contact with the internal battery connector and the controller battery compartment connector.

**CAUTION:** Internal battery replacement should be performed on a secure surface such as a table to avoid damage to components. If the internal battery is dropped during the procedure, discard the battery and retrieve a new kit. Dispose of the dropped battery according to federal, regional, and local regulations.

**1a.** If the controller internal battery is within six (6) months from the end of life (EOL) and the controller is connected to the monitor, the internal battery replacement symbol will flash near the top right corner of the monitor display.


**Figure 190: Internal Battery replacement symbol flashing at top right of screen**

## 8.9 Internal Battery Replacement (continued)

**1b.** The Controller will notify the patient via the flashing information **i** symbol on the Home screen (**Figure 191**) when the battery is two (2) months from end of life (EOL). The Internal Battery Status Information screen will include the clinician's phone number when it is time to replace the internal battery.


Figure 191: Information screen


Figure 192: EOL Internal Battery Status screen

**2.** Locate an Internal Battery Replacement Kit from inventory and check that it is within the "Use By" date on the package label.


Figure 193: Use By date symbol

**3.** Connect both an adapter and a charged external battery to the controller.

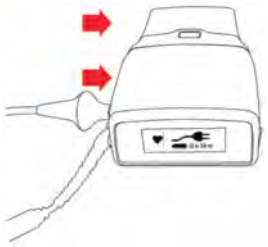


Figure 194: Connect adapter and battery

**4.** Locate the BLUE 2 mm hex wrench and WHITE 1.5 mm hex wrench enclosed in the Internal Battery Replacement Kit.

Figure 195: Blue and White hex wrenches

**5.** Have the patient sit or lie down.

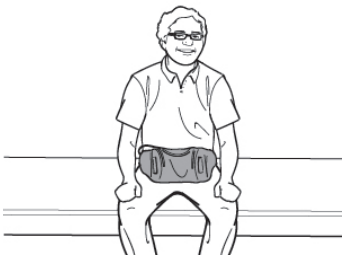


Figure 196: Sitting

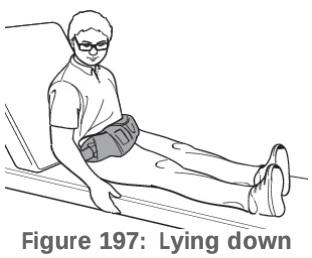
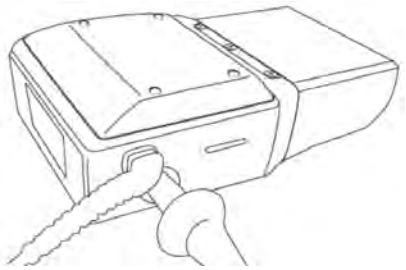
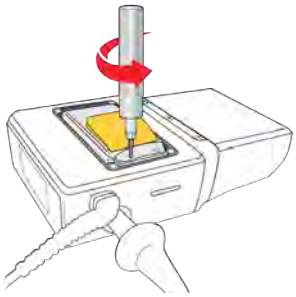
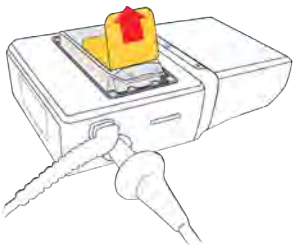
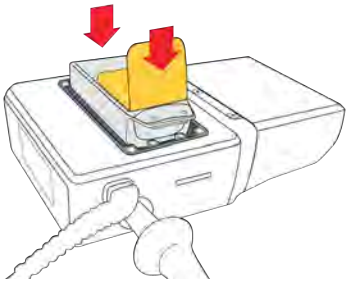


Figure 197: Lying down

| | |
|---|---|
| **6.** Place the controller on a table. |  <br>**Figure 198: Place controller on table** |
| **7.** Use the BLUE 2 mm hex wrench tool to loosen all four (4) screws, then open and discard the cover of the battery compartment. |  <br>**Figure 199: Loosen screws** |
| **8.** Use the WHITE 1.5 mm hex wrench to loosen the internal battery connector screws until they spin freely.<br>**Note:** Screws cannot fully be removed. |  <br>**Figure 200: Loosen internal battery screws** |
| **9.** Disconnect the internal battery by pulling the yellow tab away from the controller.<br>**Note:** A [Keep Power Connected] alarm will activate. |  <br>**Figure 201: Disconnect internal battery** |
| **10.** Connect the new internal battery by aligning the connector screws with screw holes. |  <br>**Figure 202: Connect new internal battery** |

## 8.9 Internal Battery Replacement (continued)

**11.** Use the WHITE 1.5 mm hex wrench to tighten the internal battery, alternating screws every three (3) turns, until the wrench clicks for each screw.

**Note**: The controller will vibrate while the internal battery is being tightened to confirm electrical connection. Continue to tighten the internal battery until the wrench clicks for each screw to confirm mechanical connection.

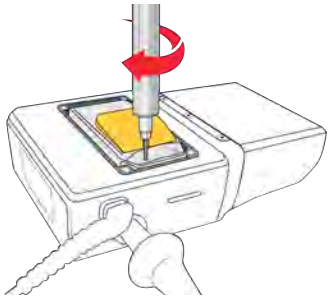


Figure 203: Tighten internal battery screws

**12.** Check the Controller Information screen or the monitor for the internal battery time remaining.

**Note:** As long as the time remaining doesn't show dashes (--), it is connected.

**Note**: The [Keep Power Connected] alarm will typically appear after successful connection of a new internal battery and will last around sixty (60) minutes until sufficiently charged.

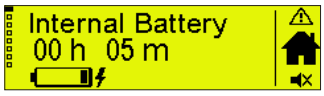



Figure 204: Controller Internal battery time remaining

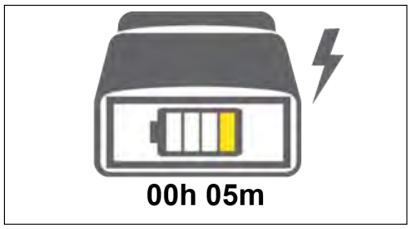



Figure 205: Monitor Internal battery time remaining

**13.** Take the replacement back cover and use the BLUE 2 mm hex wrench to tighten the back cover until the wrench clicks for each screw.

Figure 206: Tighten back cover

**14.** Check the Controller Information screen or the monitor for internal battery time remaining.

**Note:** As long as the time remaining doesn't show dashes (--), it is connected.

**Note**: The [Keep Power Connected] alarm will typically appear after successful connection of a new internal battery and will last around sixty (60) minutes until sufficiently charged.

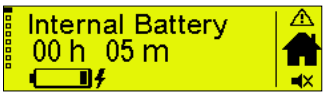



Figure 207: Controller internal battery time remaining


Figure 208: Monitor internal battery time remaining

**15.** If the [Keep Power Connected] alarm has not resolved after sixty (60) minutes, continue to keep the external battery and adapter attached while the internal battery charges.


Figure 209: [Keep Power Connected] alarm

**Note:** If alarm continues for more than ninety (90) minutes, call Medtronic personnel.

**CAUTION:** DO NOT use any component from the original back cover when replacing an internal battery. Use of these components may lead to interruption of normal system operating conditions and possible patient harm.

**CAUTION:** DO NOT disassemble, heat above the manufacturer's maximum temperature limit, or incinerate the internal battery. Doing so could present a risk of fire or chemical burn if mistreated. Only replace the battery with a battery that has the manufacturer's name or end product manufacturer's name and part number on it. Use of another battery may present a risk of fire or explosion.

**CAUTION:** DO NOT disassemble or reconstruct the battery pack. The battery pack has safety functions and a protection circuit to avoid danger. If those have serious damage, the pack may generate heat, smoke, rupture, or burn.

**CAUTION:** DO NOT short-circuit the battery pack by connecting the positive (+) and negative (-) terminals with metals (such as wire) or carry or store the battery pack with metal objects (such as wire, necklace, or hairpins). The large current flow may lead to heat generation, smoking, rupture, or burning.

**CAUTION:** DO NOT incinerate or heat the battery pack. This may lead to melting of the insulator, damage of the gas release vent or safety function, or ignition of electrolyte resulting in heat generation, smoking, rupture, or burning.

**CAUTION:** DO NOT reverse-charge or reverse-connect the battery pack. The battery pack has polarity and doing so may lead to heat generation, smoking, rupture, or burning. If the battery pack is not connected with the charger or equipment smoothly, do not force them to connect, but do check the polarity of the battery pack. If the battery pack is connected to the opposite polarity of the charger, it will be reverse-charge and an abnormal chemical reaction will occur.

## 8.10 Palliative Shutdown

Palliative Shutdown is a feature of the PAL Controller that allows palliative care professionals to power down the Controller and stop the HVAD Pump without activating alarms. To perform palliative shutdown, use the following procedure:

| When these screens display: | Follow these procedures: |
|---|---|
|  | **1.** Press the controller state symbol (e.g., ♥) to go to the VAD Status screen. |
|  | **2.** Press the center of the screen to go to the System screen. |
|  | **3.** Simultaneously press and hold the information ℹ and home symbols for five (5) seconds or until the code screen with **A B C D** appears. |
|  | **4.** Enter the code, **A C A D B**, to turn off the pump. |
|  | **5.** The screen will display [Remove Power]. |
|  | **6.** Remove all external power from the controller. An hourglass briefly displays while the controller shuts down. The controller will power off within three (3) seconds.<br>**Note:** It's not imperative that the driveline be disconnected immediately. however, it should be disconnected as soon as possible. |

**CAUTION:** DO NOT reconnect power to the controller after completing the palliative shutdown sequence while the driveline is still connected. This will restart the pump.

**Note:** If any of these steps are not executed within sixty (60) seconds, the controller will automatically return to the Home screen and regular system operation.

# 9.0 Care, Cleaning, and Maintenance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## 9.1 Electrostatic Discharge (ESD) Prevention

Electrostatic discharge (ESD) may interfere with HeartWare HVAD System electrical components, including the Controller, the Charger. the Batteries, the Internal Battery, the Controller AC/DC adapters, HeartWare Monitor, and the Monitor AC adapter. Dry environments and some materials, such as silk clothing and carpeting, can increase the likelihood of static electricity.

If the controller is affected by ESD, some examples of possible effects are:

1. Damage to components.
2. Unexpected behavior of components
3. Improper pump operation, or pump stop.

**WARNING!** Patients should AVOID devices and conditions that may induce strong static electricity discharges (e.g., close vicinity to CRT television or CRT computer monitor screens) as static electricity discharges can damage the electrical parts of the system and cause the pump to perform improperly or stop.

**WARNING!** Patients should ALWAYS have a backup controller with fully-charged internal battery and fully-charged external batteries with them and readily available in case of primary controller malfunction. Whenever possible, a caregiver should be nearby when changing a power source or controller in case unusual alarms occur. They should be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.

## 9.1 Electrostatic Discharge (ESD) (continued)

**To reduce the chance of electrostatic discharge (ESD) damage to the HeartWare HVAD System components instruct patients to:**

1. Make safe, secure connections when changing power sources, connecting data cables, or performing a controller exchange.
   - **Avoid Contacting Connectors** -- Do not touch the controller connector ports, or let foreign objects or materials come near a disconnected controller power port.
   - **Change Power Sources Quickly** -- Have new external battery within reach before disconnecting power source and when possible, have a caregiver nearby in case an alarm occurs.
   - **Do Not Expose Connectors** -- Only leave power source ports on controller open for the time it takes to change the power sources.
2. Avoid contacting connectors on the battery charger and controller.
   - Make sure the controller USB port cover is secured.
   - Make sure the power source port cover is secured whenever the power adapters are not connected.
3. Be careful near materials and electronic devices prone to static electricity, such as: carpeted floors, silk clothing, CRT TV screens, microwaves when in operation, and laptop or CRT computer screens.
   - Avoid changing power sources, performing a controller exchange, or making monitor data connections near the above materials and electronic devices.
   - Avoid vacuuming.
   - Avoid removing clothes from the dryer.
   - Use anti-static dryer sheets and fabric softener.
   - Recommend using a humidifier in the home.

For patients who may be at risk of catastrophic cardiovascular collapse associated with a pump shutdown (fused aortic valve, aortic valve sewn shut due to aortic valve regurgitation, or patients with very poor endogenous ventricular function) ESD education is extremely important. Controller exchanges should be performed in a controlled clinical setting whenever possible, using the ESD guidance above.

## 9.2 Peripheral Care and Maintenance

**CAUTION:** Patient should AVOID placing the controller in the following conditions to prevent harm from excessive heat:

- Between the legs when sleeping or sitting.
- Under the body while sleeping or sitting.
- Under covers in a warm room.
- In a heated room (e.g., sauna, steam room, hot yoga class, etc.).
- Under a thick or thermal (hypothermia) blanket.
- Under a heat lamp.
- In direct sunlight.

### 9.2.1 Controller Care

**Once a week:** Instruct the patient to inspect the controller power connections and battery contact for dirt. This inspection can be done while the patient is changing external batteries or when using the AC adapter. DO NOT disconnect the pump to examine the percutaneous lead or controller connection. This connector should be inspected only during a controller exchange. The patient should not attempt to clean the controller connectors but should be instructed to contact their clinician if they notice the connectors are dirty. Exterior surfaces of the controller should be cleaned using a clean cloth. A damp cloth may be used but a wet cloth should not be used.

**Periodically or as needed:**

Clean the exterior surface of the controller periodically to remove dirt and debris. Use a cotton cloth with a cleaning agent (see the list of recommended cleaning agents below for options) in a circular motion for a minimum of twenty (20) seconds.

**The *controller* may be cleaned with the following agents:**

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- Diluted bleach solution (8.25% bleach solution diluted 1:10 with water, or equivalent, resulting in a 0.825% sodium hypochlorite concentration)
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

**WARNING!** DO NOT drop the controller or other equipment. Dropping the controller may cause sudden stoppage of the pump. Dropped equipment should be reported to Medtronic.

**WARNING!** DO NOT disconnect the driveline from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller IMMEDIATELY to restart the pump.

### 9.2.2 External Batteries Care

1. To preserve battery life, batteries should be stored at room temperature.
2. Protect external batteries from extreme high and low temperatures. Avoid storage in direct sunlight.
3. Protect the battery connectors from moisture, dirt and metal at all times.
4. AVOID touching the inside of the connectors.
5. Do not drop the external batteries or let them hit hard objects.
6. Do not let external batteries get wet.
7. Do not force battery connection to the controller or battery charger.
8. External batteries should be stored in the battery charger or in the Accessories Bag. Store batteries fully charged.
9. Rotating use of external batteries will allow all batteries to age at a similar rate, so no battery has significantly fewer charge cycles than the others.

# 9.2 Peripheral Care and Maintenance (continued)

## 9.2.2 External Batteries Care (continued)

**CAUTION**: DO NOT expose external batteries to temperatures outside the storage and operational ranges to avoid shorter battery runtime.
**Battery operating and storage temperatures**:

**a.** Operating: discharge (normal use with the HVAD System): -5°C to +40°C (+23°F to +104°F). Operation at temperatures below 0°C (+32°F) will temporarily reduce battery capacity but the battery will operate.

**b.** Storage: -20°C to +45°C (-4°F to +113°F). Long-term storage outside of this range may permanently reduce the battery capacity. The best condition for storage is at room temperature.

**CAUTION:** ALWAYS keep HVAD System components away from children and pets. Children and pets may cause damage to components or be harmed by damaged components. If damage to equipment results, contact Medtronic.
**CAUTION:** DO NOT disassemble, crush, or puncture an external battery to avoid personal injury and battery damage.
**CAUTION**: DO NOT use damaged external batteries as it may lead to interrupting VAD therapy. Dispose of external batteries according to federal, regional, and local regulations.
**CAUTION**: DO NOT short circuit the external contacts on an external battery as this may result in battery damage.
**CAUTION**: DO NOT touch the fluid if a battery pack is leaking fluid. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least fifteen (15) minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention. Dispose of external batteries according to federal, regional, and local regulations.
**CAUTION**: DO NOT expose external batteries to excessive shock or vibration as this may affect battery operation.
**CAUTION**: DO NOT dispose of batteries in fire or water. Dispose of batteries according to federal, regional, and local regulations.
**CAUTION:** DO NOT place external batteries in water or liquid as this may damage them.

**Once a week:** Inspect external batteries and connectors for physical damage. DO NOT use batteries that appear damaged. Damaged batteries must be replaced.

**Periodically or as needed:**

- External batteries may be cleaned periodically to remove dirt and debris. Use a cotton cloth with a cleaning agent (see the list of recommended cleaning agents below for options) in a circular motion for a minimum of twenty (20) seconds.
- Remind patients to bring all external batteries to clinic visits.

**The *External Batteries* may be cleaned with the following agents:**

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- Diluted bleach solution (8.25% bleach solution diluted 1:10 with water, or equivalent, resulting in a 0.825% sodium hypochlorite concentration)
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

**Note**: The Batteries are expected to have a useful operating life of 500 charge and discharge cycles in which the external battery can reach at least 70% of full capacity; this should provide patient support for two years. Batteries that reach the end of their useful life should be replaced.

### 9.2.3 Battery Charger Care

**Once a week:**

- Inspect the battery charger for signs of physical damage, such as dents, chips, or cracks. DO NOT use the battery charger if it shows signs of damage. Contact Medtronic for a replacement battery charger.
- Inspect the power cord used to connect the battery charger to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. DO NOT use the cord if it shows signs of damage. Contact Medtronic for a replacement power cord.

**Periodically or as needed:** To clean the battery charger, remove the external batteries and unplug the battery charger from the electrical outlet. Clean the exterior surface of the battery charger periodically to remove dirt and debris. Use a cotton cloth with a cleaning agent (see the list of recommended cleaning agents below for options) in a circular motion for a minimum of twenty (20) seconds. AVOID placing the battery charger in water or liquid.

**Note:** Following cleaning it may be necessary to dry the battery charger. Use a dry cotton cloth on the exterior surfaces of the battery charger and ensure that the battery terminals in the bays of the battery charger are absent of visible fluid.

**WARNING!** NEVER clean the battery charger when it is connected to an electrical outlet, as this may lead to an electrical shock.

**The *Battery Charger* may be cleaned with the following agents:**

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- Diluted bleach solution (8.25% bleach solution diluted 1:10 with water, or equivalent, resulting in a 0.825% sodium hypochlorite concentration)
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

### 9.2.4 AC Adapter or DC Adapter Care

**Periodically or as needed:** The adapters may be cleaned periodically to remove dirt and debris. Use a cotton cloth with a cleaning agent (see the list of recommended cleaning agents below for options) in a circular motion for a minimum of twenty (20) seconds.

**The *controller AC and DC adapters* may be cleaned with the following agents:**

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- Diluted bleach solution (8.25% bleach solution diluted 1:10 with water, or equivalent, resulting in a 0.825% sodium hypochlorite concentration)
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

# 9.2 Peripheral Care and Maintenance (continued)

## 9.2.5 Carrying Cases Care

**Periodically or as needed:** The Sport Pack may be cleaned using a washing machine to remove dirt and debris, followed by air drying. Washing parameters include:

- Cold water
- Gentle laundry setting
- Mild detergent

**Note:** The Sport Pack should be washed separate from other items. Ensure all Velcro®, zippers, and buttons on the Sport Pack are fastened together prior to washing to maintain durability.

**Periodically or as needed:** The Accessories Bag may be spot cleaned with a damp rag or towel to remove dirt and debris.

**CAUTION:** DO NOT use a machine for drying the carrying cases as it may accelerate the end of useful service. The carrying case should only be air dried.

## 9.3 External Battery Replacement

When an external battery needs to be replaced due to end of life, the controller will notify the patient to call their clinician. The notification means the external battery should be replaced as soon as possible. The patient should communicate to their clinician that the notification occurred.

The Controller will notify the patient via the flashing information symbol on the Home screen (**Figure 210**). The External Battery Status information screen will include the clinician's phone number (**Figure 211**) when it is time to replace the external battery.


**Figure 210: EOL Home screen**


**Figure 211: EOL External Battery Status screen**

The external battery status can also be viewed on the monitor through the Information tab under the Alarm screen page (**Figure 212**). If the Battery Lifetime Status shows "End of Life", this means the battery needs to be replaced.

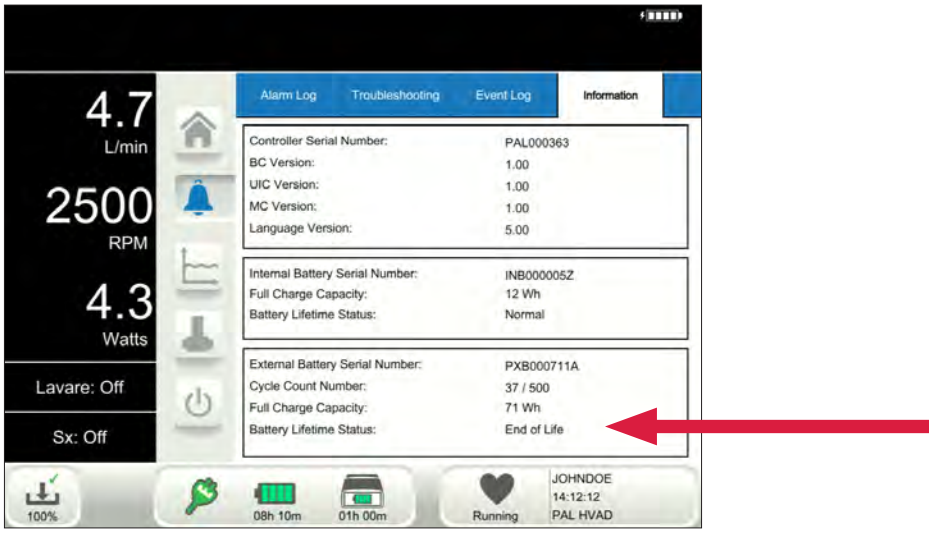


**Figure 212: Information Tab - "End of Life" indication in Battery Lifetime Status**

## 9.4 HeartWare Monitor Care

**Once a month:** If the monitor is not in use, check to be sure it is plugged into an AC outlet. This will keep the internal monitor battery charged. If the monitor battery fails to hold a charge, or lasts less than one hour, contact Medtronic. Also, check the monitor AC adapter and AC power cord for wear or damage and confirm they are working correctly. Turn off the monitor prior to cleaning. Clean the monitor screen with a cotton cloth using a cleaning agent (see the list of recommended cleaning agents below for options) in a circular motion for a minimum of twenty (20) seconds. A damp cloth may be used but a wet cloth should not. Use care to avoid scratching or damaging the screen.

**WARNING!** NEVER clean the monitor when powered on, as this may lead to an electrical shock. DO NOT use alcohol or detergent on the monitor display. Gently wipe the display with a soft, lint-free cloth.

**Periodically or as needed:**

**The *HeartWare Monitor* may be cleaned with:**

- Alcohol (Isopropyl 90% or Ethyl 70%).
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

**The *Monitor AC Adapter* may be cleaned with the following agents:**

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

**The *Data Cable* may be cleaned with the following agents:**

- Alcohol (Isopropyl 90% or Ethyl 70%),
- Hydrogen peroxide solution (1.4%),
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

# 10.0 Appendices


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# Appendix A: System Components & System Model Numbers

## A.1 System Components

| Implantables (Supplied Sterile - ETO) |
|---|
| • HeartWare HVAD Pump<br>• 10 mm gel impregnated polyester graft<br>• Sewing Ring<br>• Strain Relief |
| **Surgical Tools and Accessories (Supplied Sterile - ETO)** |
| • Tunneler Rod and Handle<br>• Sewing Ring Torque Wrench<br>• Coring Tool<br>• Driveline Extension Cable<br>• Driveline Cap<br>• Strain relief wrench<br>• Inflow Cap |
| **Externals (Supplied Non-Sterile)** |
| • PAL Controller (includes Controller AC Adapter/Power Cord*)<br>• PAL Controller DC Adapter<br>• PAL Sport Pack<br>• PAL Accessories Bag<br>• HeartWare Shower Bag<br>• HeartWare Monitor with Display Case (includes Monitor AC Adapter/Power Cord*, Data Cable*)<br>• PAL Battery Charger (includes Power Cord)<br>• PAL Batteries (Single and Dual)<br>• USB Flash Drive<br>• Explant Kit<br>• PAL Internal Battery Replacement Kit<br><br>*Also available as individual item |
| **Accompanying Documents** |
| • Instructions for Use<br>• Patient Manual<br>• Emergency Responder Guide<br>• Patient ID Card |

# Appendix A: System Components & System Model Numbers (continued)

## A.2 System Model Numbers

| Medtronic HVAD PAL System Component | Model # |
|---|---|
| HeartWare HVAD Pump Kit | 1103/ MCS1705PU |
| HeartWare HVAD Pump Surgical Tools | 1318/ MCS1718ST |
| HeartWare HVAD Pump Surgical Tools - Extended Length | 1328/ MCS1728ST |
| Outflow Graft | 1125/ MCS1725OG |
| Driveline Extension Cable | 100US |
| HeartWare HVAD Pump Implant Accessories Kit | 1153-/MCS1753AK |
| PAL Controller | MCS3101CO |
| PAL Single Battery | MCS3205SB |
| PAL Dual Battery | MCS3215DB |
| PAL AC Adapter | MCS3425AC |
| PAL DC Adapter | MCS3435DC |
| PAL Accessories Bag | MCS3335AB |
| PAL Sport Pack | MCS3315SP |
| PAL Battery Charger | MCS3255BC |
| PAL Cap | MCS3235CP |
| PAL Internal Battery Replacement Kit | MCS3225IB |
| PAL Data Cable | MCS1585DC |
| MCS Patient Power Cord | MCS2450PC |

# Appendix B: System Component Useful Life & Disposal

## B.1 Expected Useful Life

The expected amount of time the PAL components were designed and tested to function:

**Table 25: Expected Useful Life**

| PAL Component | Expected Useful Life | Shelf Life |
|---|---|---|
| HeartWare HVAD Pump | at least 2 years | 2 years |
| Surgical tools & accessories | N/A - single-use only | 2 years |
| Driveline Extension Cable | N/A - single-use only | 1 year |
| PAL Controller | at least 2 years | 2 years |

# Appendix B: System Component Useful Life & Disposal (continued)

| PAL Component | Expected Useful Life | Shelf Life |
|---|---|---|
| PAL Internal Battery | 1 year to elective replacement; 18 months to end of life (EOL) | 15 months |
| PAL External Batteries (Single and Dual) | at least 2 years or 500 charge and discharge cycles | 15 months |
| PAL Cap | at least 2 years | N/A |
| PAL Battery Charger | at least 2 years | 2 years |
| PAL Controller AC adapter or DC adapter | at least 2 years | 2 years |
| HeartWare Monitor | at least 2 years | N/A |
| HeartWare Monitor AC adapter | at least 2 years | 2 years |
| USB flash drive | at least 2 years | N/A |
| PAL Data cable | at least 2 years | N/A |
| Carrying Cases (PAL Sport Pack, PAL Accessories Bag, and HeartWare Shower Bag) | at least 1 year | N/A |

Equipment that reaches the end of life should be replaced.

## B.2 Product Disposal

Dispose of all expired or damaged equipment according to applicable local, regional, and federal laws and regulations. For additional product disposal support and information, contact Medtronic.

Disposal of Medtronic-supplied internal and external batteries require special consideration. Medtronic Li-ion battery cells DO NOT contain lead. Dispose of or recycle batteries promptly, in compliance with all applicable local, regional, and federal laws and regulations. Keep away from children. DO NOT disassemble a battery and DO NOT dispose of a battery in fire.

**Figure 213: Look for the Waste Li-ion battery symbol or the waste of electrical and electronic equipment (WEEE) symbol on the device label**

# Appendix C: Product Specifications

| Essential Performance | |
|---|---|
| • The HVAD Pump maintains flow. | |
| • Critical Alarms. | |
| **Pump** | |
| Mass (or weight) | 160 g |
| Volume | 50 cc |
| Materials | Titanium, Titanium Nitride, PEEK® and ceramic |
| Inflow Cannula Outer Diameter | 20.7 mm |
| **Outflow Graft** | |
| Length | 60 cm |
| Diameter (or size) | 10 mm |
| Materials | Gelatin sealed polyester and Titanium |
| **Strain Relief** | |
| Material | PEEK® and Titanium |
| Inner Diameter (tightened) | 10 mm |
| **Pump Driveline** | |
| Length | 119 cm |
| Diameter | 4.8 mm |
| Materials | ETFE (Ethylene tetrafluoroethylene) PTFE coated MP35N DFT wire in a silicone inner sleeve with a polyurethane outer sleeve along with a polyester sleeve |
| **Sewing Ring** | |
| Materials | Titanium, polyester |
| **Controller** | |
| Weight | 0.7 kg |
| Dimensions | 10.4 x 10.9 x 6 cm (not including connectors) |
| Display | Monochrome LCD with colored backlight |
| Messages | Status, 2 alarm priorities, information, instructions |
| Controls | Touchscreen |
| Audible Alarm Volume | Critical Alarms: 79-100 dBA SPL<br>Noncritical Alarms: 58-70 dBA SPL |
| **Internal Battery** | |
| Type | Li ion, rechargeable |
| Weight | 0.1 kg |
| Dimensions | 7.6 x 3.8 x 2.2 cm |
| Ratings | 7.2 Vdc, 15.1 Wh. |
| Charge Time | 90 min [**Note**: 90 min nominal; 2.5 hrs. max] |
| **External Battery** | |
| Type | Li ion, rechargeable |
| Weight | Single: 0.3 kg; Dual: 0.5 kg |
| Dimensions | Single: 9.6 x 7.6 x 4.8 cm; Dual: 9.6 x 12.0 x 4.8 cm |
| Indicators | Battery level LED |
| Ratings | Single: 14.4 Vdc, 46.1 Wh.; Dual: 14.4 Vdc, 92.2 Wh. |
| Recharge time | Single Battery or Dual Battery: up to 6 hours<br>(Charge times may increase at temperatures above +30°C) |

# Appendix C: Product Specifications (continued)

| Battery Charger | |
|---|---|
| Capacity | 4 batteries |
| Weight | 1.7 kg |
| Dimensions | 36.5 x 20.1 x 8.3 cm |
| Indicators | 1) Charger status LED<br>2) Four (4) battery status LEDs |
| Electrical Ratings | 100-240 VAC, 50-60 Hz, 160 VA input, 135 VA output |

| Controller AC Adapter | |
|---|---|
| Weight | 0.5 kg |
| Dimensions | 12.1 x 7.6 x 4.7 cm |
| Output cable length | 2.8 m |
| Input cable length | 2.5 m |
| Electrical Ratings | 100-240 VAC, 50-60 Hz, 140 VA input, 18 Vdc, 3.3A output |
| **Controller DC Adapter** | |
| Weight | 0.5 kg |
| Dimensions | 12.1 x 7.6 x 4.7 cm |
| Output cable length | 2.0 m |
| Input cable length | 1.0 m |
| Electrical Ratings | 12.0-15.6 V, 7 A input; 18 Vdc, 3.3 A output |
| **Controller Coiled Cable** | |
| Length (extended) | 71.1 cm |
| Length (non-extended) | 40.6 cm |
| Diameter | 3.5 to 4.0 mm |
| Materials | main cable jacket is TPU (thermoplastic polyurethane) |
| **USB Data Cable** | |
| Connector Type | Controller: USB micro-B<br>Monitor: USB Type A |
| Length | 2.8 m |
| **Monitor** | |
| Type | Tablet with touchscreen input |
| Weight | 3.0 kg |
| Dimensions | 28.5 x 21.0 x 4.1 cm (without case)<br>29.9 x 29.9 x 6.4 cm (with case) |
| Electrical Ratings | 19 V, 3.4 A maximum input |
| **Monitor AC Adapter** | |
| Weight | 0.7 kg |
| Dimensions | 16.6 x 9.6 x 5.6 cm |
| Electrical Ratings | 100-240 V, 50-60 Hz, 215 VA input; 19 V, 4.7 A output |

**Note:** All dimensions are given as length x width x height. PEEK is a registered trademark of Victrex plc.

# Appendix C: Product Specifications (continued)

### Software Parameters, Ranges & Factory Default Settings

| Parameter | Range | Resolution | Factory Default |
|---|---|---|---|
| Pump Speed | 1800 to 4000 RPM | 20 RPM | 2500 RPM |
| [Low Flow] alarm | 1.0 to 9.9 L/min | 0.1 L/min | 1.0 L/min |
| [High Power] alarm limit | 1.0 to 25.0 Watts | 0.1 Watts | 8.0 Watts |
| Power Tracking | Off, On | N/A | Off |
| [Suction] alarm | Off, On | N/A | Off |
| Hematocrit | 20-50% HCT | 1% | 30% |
| Data Logging | 5 minutes | 5 minutes | N/A |
| Lavare Cycle | Off, On | N/A | Off |

**Safety Standards:**

IEC 60601-1:2012 (Ed. 3.1)
IEC 60601-1/A2:1995
IEC 60601-1-11:2015
IEC 60601-1-8:2012
IEC 60601-1-6:2013 (IEC 62366)
IEC 62133:2012
IEC 60950-1:2001

EN 60601-1:2006/A1:2013
EN 60950-1:2006/A11:2009

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Ed. 3.1)

CAN/CSA C22.2 No. 601.1
CAN/CSA-C22.2 No. 60601-1:14 (Ed. 3.1)
CAN/CSA C22.2 No. 60950-1-07

UL 60601-1:2003
UL 60950-1:2007
UL 2054:2004
UL 1642:2012

UN/DOT Part III, subsection 38.3:2011

ISO 14708-5:2010

**EMC Standards:**

IEC 60601-1-2:2014
RTCA DO-160G
EN 50498:2010

ISO 7637-2:2011

ISO 16750-2:2012

**Bluetooth® Standards:**

EN 301489-17:2017

EN 300 328 v2.1.1

## IEC 60601-1 Classifications

**Type of protection against electric shock:**

Controller AC adapter – Class II

Controller DC adapter – Class II

Controller – Class II, Internally Powered

Applied Parts - HVAD Pump and driveline: Type CF Defibrillation-Proof

Battery charger – Class II

Monitor AC adapter – Class I
(Warning: To avoid the risk of electric shock, the Monitor AC Adapter must only be connected to a supply mains with protective earth).

Essential performance for the HVAD controller and pump, as defined by IEC 60601-1, is:

- at speeds between 1800 RPM and 4000 RPM under normal conditions, flow shall be maintained within +/-10% of original set flow rate without excursions longer than 15 sec.
- critical audible alarms operate as intended.
- The other devices in the HVAD system do not have essential performance, as defined by IEC 60601-1.

# Appendix C: Product Specifications (continued)

## IEC 60601-1 Classifications (continued)

**Degrees of protection against the ingress of foreign objects and fluid:**

IP20 (Controller alone)
IP54 (Controller connected to external battery or Cap)
IP65 (Driveline extension cable)
IP21 (Monitor)
IP22 (Controller AC & DC adapter)
IP54 (External battery)
IP22 (Monitor power adapter, data cable)
IP21 (Battery charger)

### Recommended environmental conditions

| Component | Temperature Range | Relative Humidity | Atmospheric Pressure |
|---|---|---|---|
| PAL Controller (including Internal Battery) | Full Operating: +10 to +30°C (+50 to +86°F)<br>*Extended Operating: -5 to +40°C (+23 to +104°F) | Operating: 15% to 95% | Operating: 700 to 1060 hPa |
| | Storage and Transport: -20 to +45°C (-4 to +113°F) | Storage and Transport: 10% to 95% | Storage and Transport: 500 to 1060 hPa |
| PAL Internal Battery Replacement Kit | Storage and Transport: -20 to +45°C (-4 to +113°F) | Storage and Transport: 10% to 93% | Storage and Transport: 500 to 1060 hPa |
| PAL Controller AC and DC Adapter | Operating: -5 to +40°C (+23 to +104°F) | Operating: 15% to 95% | Operating: 700 to 1060 hPa |
| | Storage and Transport: -40 to +70°C (-40 to +158°F) | Storage and Transport: 10% to 95% | Storage and Transport: 500 to 1060 hPa |
| PAL External Battery | Operating: -5 to +40°C (+23 to +104°F) | Operating: 15% to 95% | Operating: 700 to 1060 hPa |
| | Storage and Transport: -20 to +45°C (-4 to +113°F) | Storage and Transport: 10% to 95% | Storage and Transport: 500 to 1060 hPa |
| PAL Battery Charger | Operating: +5 to +40°C (+41 to +104°F) | Operating: 15% to 95% | Operating: 700 to 1060 hPa |
| | Storage and Transport: -40 to +70°C (-40 to +158°F) | Storage and Transport: 10% to 95% | Storage and Transport: 500 to 1060 hPa |
| HeartWare Monitor and Monitor AC Adapter | Operating: +10 to +40°C (+50 to +104°F) | Operating: 15% to 95% | Operating: 700 to 1060 hPa |
| | Storage and Transport: -40 to +70°C (-40 to +158°F) | Storage and Transport: 10% to 95% | Storage and Transport: 500 to 1060 hPa |

Do not store Medtronic equipment in an area exposed to ultraviolet light.
The box label details conditions for transport and storage.
The device label details the environmental condition limits under which the device should be operated.

*Full versus Extended Operating: Extended Operating does not support battery charging functionality and nominal battery runtime.

# Appendix C: Product Specifications (continued)

### Wireless/RF Specifications

**CAUTION:** Modifying the device without the approval of Medtronic can void your authority to operate the radio equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

RF/Wireless allocations and technical parameters may be different outside of the United States, possibly affecting the functioning of the device. Contact Medtronic if there are any concerns about using RF/wireless capabilities of this device when outside of the Unites States.

Use of this device near other emitters such as microwaves or WiFi routers (in-band) may result in reduced or degraded log-file transmission quality. Move the device away from the interference and re-attempt any action.

| Protocol | Bluetooth + Low Energy |
|---|---|
| Frequency of Operation | 2402 - 2480 MHz |
| Output power | -3.2 dBm measured + 1.5 dB uncertainty = -1.7 dBm 0.676 mW EIRP |
| Modulation | Gaussian Frequency Shift Keying |
| Channelization | Number of channels: 40<br>Channel spacing: ≤ 2 MHz |
| Maximum Range | 1 meter |
| Duty cycle | ≤ 100% |
| Duplex/Simplex | Semi-Duplex |
| RF Exposure (SAR) | N/A – Maximum RF Output < 20 mW |
| Applied EU standards | EMC EN 301 489-1, -17 |
| | RF EN 300 328 |
| | Safety IEC/EN 60601-1 |
| | RF Exposure EN 62311 |
| Antenna Information | Antenna Type: Monopole |
| | Manufacturer: Murata |
| | Model number: LBCA2HNZYZ |
| | Antenna Gain: -0.6 dBi |
| | Polarization: Linear |
| Model: MCS3101CO Major Market Certifications | FCC ID: LF5MCS3101CO |
| | IC ID: 3408D-MCS3101CO |

# Appendix D: Electromagnetic Compatibility (EMC) Guidance

**Electromagnetic Compatibility**

The HeartWare HVAD System needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile radio frequency (RF) communications equipment can affect the HeartWare HVAD System.

## Guidance - Electromagnetic Emissions

The HeartWare HVAD System is indicated for use in the electromagnetic environments specified below.

The user of the HVAD System should assure it is used in such an environment.

| Emissions | Compliance | Guidance |
|---|---|---|
| Radiated and Conducted RF Emissions<br><br>CISPR 11 | Group 1 Class B (all except Monitor)<br><br>Class A (Monitor) | The HVAD System (except the monitor) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.<br><br>The HVAD Monitor is suitable for use in non-domestic establishments and those directly connected to a dedicated supply system (e.g. hospitals and clinics). |
| Harmonic Current Emissions<br><br>IEC 61000-3-2 | Complies | |
| Voltage Changes, Voltage Fluctuations and Flicker<br><br>IEC 61000-3-3 | Complies | |
| Aircraft Radiated and Conducted Emissions<br><br>RTCA/DO-160G Section 21 | Category M | The HVAD System with battery pack and/or controller AC adapter is suitable for use on board aircraft. |
| Automotive Broadband and Narrowband Radiated Disturbances<br><br>EN 50498:2010 | Complies | The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles. |
| Automotive Conducted Transient Disturbances<br><br>EN 50498:2010 | Complies | The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles. |

# Appendix D: EMC Manual Requirements Guidance Document (continued)

### Guidance - Electromagnetic Immunity

The HVAD System is indicated for use in the electromagnetic environments specified below. The customer or the user of the HVAD System should assure it is used in such an environment.

**CAUTION:** If operation of the HVAD System is degraded, or if essential performance is not met due to suspected electromagnetic interference (EMI), move to a suitable environment.

| Immunity Test | Compliance Level | Guidance |
|---|---|---|
| Electrostatic Discharge<br><br>IEC 61000- 4-2 | ± 8 kV Contact<br><br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air | Refer to **Section 9.1** for guidance on minimizing the impact of ESD.<br><br>The HVAD System is suitable for use in all establishments. |
| Electrical Fast Transient / Burst<br><br>IEC 61000-4-4 | ± 2 kV on Power Supply Ports<br><br>± 1 kV on Signal Input/Output Ports | Mains power quality should be that of a typical hospital, clinic, or home environment. |
| Surge<br><br>IEC 61000-4-5 | ± 1 kV on Power Supply Ports (for the Controller AC adapter)<br>± 2 kV on Power Supply Ports (for the Monitor AC adapter) | Mains power quality should be that of a typical hospital, clinic, or home environment. |
| Voltage Dips<br><br>IEC 61000-4-11 | 0% $U_T$; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.<br><br>0% $U_T$; 1 cycle and 70% $U_T$; 25/30 cycles single phase: at 0°.<br><br>25/30 means 25 periods at 50Hz or 30 periods at 60Hz. | Mains power quality should be that of a typical hospital, clinic, or home environment.<br><br>The HVAD System will always have a battery backup power supply connected. |
| Voltage Interruptions<br><br>IEC 61000-4-11 | 0% $U_T$; 250/300 cycles<br><br>250/300 means 250 periods at 50Hz or 300 periods at 60Hz. | Mains power quality should be that of a typical hospital, clinic, or home environment.<br><br>The HVAD System will always have a battery backup power supply connected. |

**Note:** $U_T$ is the AC mains voltage prior to application of the test level.

| Immunity Test | Compliance Level | Guidance |
|---|---|---|
| Power Frequency Magnetic Fields<br><br>IEC 61000-4-8 | 30 A/m | The HVAD System is suitable for use in all establishments. |
| Conducted Disturbances Induced by RF Fields<br><br>IEC 61000-4-6 | 3 Vrms from 0.15 MHz to 80 MHz<br><br>6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz | The HVAD System (except the Monitor) is suitable for use in all establishments. |
| | 3 Vrms from 0.15 MHz to 80 MHz<br><br>6 Vrms in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz | The HVAD Monitor is suitable for use in professional healthcare facilities. |

# Appendix D: EMC Manual Requirements Guidance Document (continued)

## Guidance and Manufacturer's Declaration - Electromagnetic Immunity (continued)

<table>
<tr><th>Immunity Test</th><th>Compliance Level</th><th>Guidance</th></tr>
<tr><td rowspan="2">Radiated RF EM Fields<br><br>IEC 61000-4-3</td><td>10 V/m from 80 MHz to 2.7 GHz<br>80% AM at 1 kHz</td><td>The HVAD System (except the Monitor) is suitable for use in all establishments.</td></tr>
<tr><td>3 V/m from 80 MHz to 2.7 GHz<br>80% AM at 1 kHz</td><td>The HVAD Monitor is suitable for use in professional healthcare facilities</td></tr>
<tr><td>Proximity Fields from RF Wireless Communications Equipment<br><br>IEC 61000-4-3</td><td>Complies with 8.10 (Table 9) of IEC 60601-1-2:2014</td><td>The HVAD System is suitable for use in proximity to common RF wireless communications equipment.</td></tr>
<tr><td>Dipole Radiated RF Immunity<br><br>ISO 14117:2019</td><td>
<table>
<tr><th>Frequency (MHz)</th><th>Test Level (Wrms)</th><th>Separation Distance (cm)</th></tr>
<tr><td>450, 600</td><td>0.2</td><td>1.5</td></tr>
<tr><td>680</td><td>0.2</td><td>2.0</td></tr>
<tr><td>745</td><td>0.2</td><td>1.5</td></tr>
<tr><td>800, 825, 850</td><td>2</td><td>1.5</td></tr>
<tr><td>875, 900, 930</td><td>8</td><td>1.5</td></tr>
<tr><td>1610</td><td>2</td><td>1.5</td></tr>
<tr><td>1750</td><td>4</td><td>1.5</td></tr>
<tr><td>1850, 1910</td><td>2</td><td>1.5</td></tr>
<tr><td>2310, 2450, 2600</td><td>0.2</td><td>1.5</td></tr>
<tr><td>3000</td><td>2</td><td>1.5</td></tr>
</table>
</td><td>The HVAD System is suitable for use in proximity to common RF wireless communications equipment.</td></tr>
<tr><td>Aircraft Radiated and Conducted Immunity<br><br>RTCA/DO-160G Section 20</td><td>Category R</td><td>The HVAD System with battery pack and/or controller AC adapter is suitable for use on board aircraft.</td></tr>
<tr><td>Automotive Conducted Transient Immunity<br><br>ISO 7637-2:2011</td><td>Severity Level 4</td><td>The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles.</td></tr>
<tr><td>Automotive Electrical Loads<br><br>ISO 16750-2:2012</td><td>Sections 4.3, 4.4 (Severity Level 4), 4.5, 4.6, 4.7, 4.9, 4.10, 4.11, 4.12</td><td>The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles.</td></tr>
<tr><td colspan="3">Note: The replaceable cables are the Controller AC adapter input power cable(2.5m long), Monitor AC adapter input power cable (2.5m long), and USB data cable (2.8m long); the replacement accessories are the AC power adapters for the controller and monitor and the DC power adapter for the controller.</td></tr>
</table>

**WARNING!** The HVAD System components should not be used adjacent to or stacked with equipment other than equipment specified in the IFU. If adjacent to or stacked use is necessary, the HVAD System and other equipment should be monitored regularly to verify normal operation.

**WARNING!** Use of accessories and cables other than those specified or provided by Medtronic for use with the HVAD System could result in increased electromagnetic emissions or decreased electromagnetic immunity of the HVAD System and result in improper operation.

# Appendix E: Pivotal US Clinical Study: Bridge-to-Transplant

### Pivotal Clinical Study Design

This was a multi-center, prospective, contemporaneous control trial. The trial was non-randomized and open label. Enrollment in the study is complete, subjects have all reached the primary endpoint as described and specified in the protocol, but follow-up of subjects is ongoing.

Subjects were consented for participation and then assessed against the inclusion and exclusion criteria for participation in the study and implantation of the HVAD Pump. After the surgical recovery period, patients were allowed to leave the hospital if they met additional criteria for hospital discharge. Each patient was followed to 180 days, death, device explant for recovery, or cardiac transplantation, whichever occurred first.

Patient outcomes were compared to a contemporaneously treated cohort of patients as recorded in the Interagency Registry for Mechanical Assisted Circulatory Support (INTERMACS). All patients enrolled in the INTERMACS registry over the same enrollment period as the trial that met the control group inclusion and exclusion criteria comprised the control group.

## Study Objectives

### Primary Objective

The purpose of the HVAD System study was to evaluate the safety and effectiveness of the HeartWare HVAD System in patients listed for cardiac transplantation with refractory, advanced heart failure at risk of death. The primary endpoint is success at 180 days which was defined as alive on the originally implanted device or transplanted or explanted for recovery. If explanted for recovery patients must have survived 60 days post-explant to be considered successful.

Effectiveness was measured by the primary endpoint. The proportion of study patients alive, transplanted, or explanted for recovery at 180 days was compared to the same proportion obtained from the INTERMACS registry cohort and tested for non-inferiority.

### Secondary Objectives including Safety

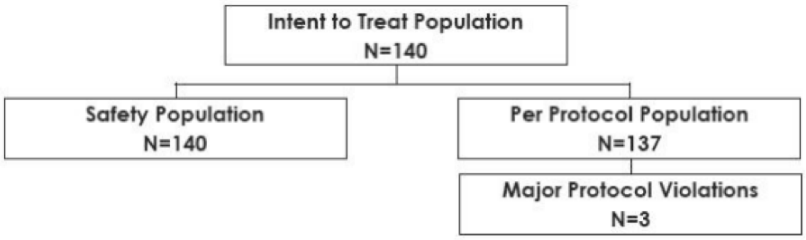
Secondary endpoints included: overall survival; incidence of all serious adverse events, including neurocognitive status and unanticipated adverse device effects; incidence of all device failures and device malfunctions; Quality of Life improvement, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) and European Quality of Life Assessment (EuroQol) EQ-5D; and functional status improvement, as measured by New York Heart Association (NYHA) classification and 6-minute walk.

Safety measures included the frequency and rates of adverse events, overall and for each specific event, which were collected throughout HVAD System support.

### Study Population Demographics and Baseline Parameters

There were three analysis populations defined for this trial. These are the intent-to-treat population, (ITT), the Safety population (SAF) and the Per Protocol population (PP).

**Figure 214: Study Population Demographics**



# Appendix E: Pivotal US Clinical Study: Bridge-to-Transplant (continued)

Subjects were predominately male (72.1%) and 53.3 ± 10.3 years of age. BSA and BMI were 2.1 ± 0.3 $m^2$ and 28.6 ± 6.1 $kg/m^2$ respectively. The principal etiology of heart failure was ischemic heart disease (41%) and the average LVEF was 17.8 ± 7.1 %. Pulmonary Capillary Wedge Pressure (PCWP) was elevated at 23 ± 9 mm Hg and pulmonary artery pressures were also high: (49 ± 15)/(25 ± 9) mmHg. The majority of patients were classified as NYHA IV (95%). Laboratory values at baseline were, in general, unremarkable except for an elevated BUN (26 ± 14 mg/dL) and a depressed hematocrit (34 ± 5.8 %).

Eighty percent of subjects in the HVAD System treatment group were on inotropic therapy at baseline. Some (23%) were on more than one inotrope. IABP therapy at baseline was reported for 25% of subjects and 85% presented with an AICD. Subjects received typical medications for congestive heart failure with diuretics (82%) most common.

### Comparison of Selected Baseline Characteristics between Treatment and Control Groups

The mean age of implant recipients in the HVAD System group was 53.3 (range 22-70) and for the control group, 52.2. Other parameters available to compare included gender, BSA, BUN, right atrial pressure and creatinine. In all cases, the values for both the HVAD treatment and control groups were not statistically significantly different (**Table 26**).

**Table 26: Select Baseline Characteristics for HVAD and INTERMACS Groups**

| Characteristics | HVAD System N=140 | INTERMACS N=499 | p-value |
|---|---|---|---|
| Age (years) | 53.3 ± 10.3 | 52.2 ± 12.2 | 0.19 |
| Female Gender, n (%) | 39 (28%) | 120 (24%) | 0.36 |
| BSA ($m^2$) | 2.06 ± 0.28 | 2.07 ± 0.30 | 0.59 |
| BUN (mg/deciliter) | 25.3 ± 13.5 | 28.9 ± 20.9 | 0.94 |
| Right atrial pressure (mmHg) | 10.8 ± 3.3 | 11.5 ± 5.0 | 0.53 |
| Serum creatinine (mg/dL) | 1.3 ± 0.4 | 1.4 ± 0.6 | 0.89 |

# Appendix E: Pivotal US Clinical Study: Bridge-to-Transplant (continued)

## Effectiveness Results

### Primary Endpoint

The analysis of the primary endpoint demonstrated HVAD non-inferiority to the control group (**Table 27**). The difference in success rates between the HVAD group and control groups was less than the 15% non-inferiority margin (p <0.0001). The 95% one-sided UCL on the difference in success rates was 4.5% for the Safety (SAF) population analysis and 0.9% for the Per Protocol (PP) population analysis. The pre-specified primary endpoint was achieved.

**Table 27: Success Rates and Inference on Non-Inferiority**

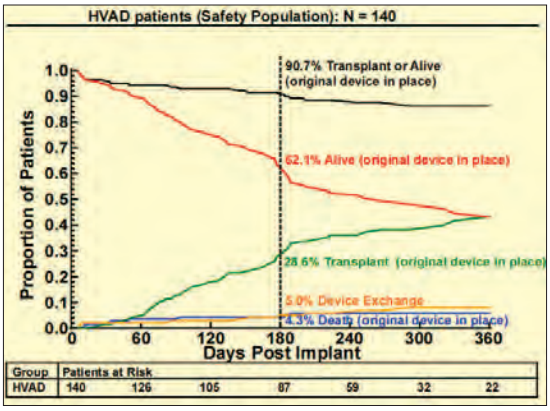
| | Implanted (N) | Successes N (%) | UCL (%) | p-value |
|---|---|---|---|---|
| Safety Cohort | | | | |
| HVAD™ | 140 | 127 (90.7) | 4.5 | <0.0001 |
| Controls | 497 | 448 (90.1) | | |
| Per Protocol Cohort | | | | |
| HVAD™ | 137 | 126 (92.0) | 0.9 | <0.0001 |
| Controls | 497 | 448 (90.1) | | |

P-value: From significance test of non-inferiority
UCL: 95% one-sided upper confidence limit on the difference in success rates
**Note**: The table accounts for 497 of the 499 INTERMACS patients; the remaining 2 patients, who withdrew consent before 180 days, have a missing success/failure outcome.

### Competing Outcomes

A competing risks analysis was performed (**Figure 215**), estimating the time-related probability of experiencing each of the component events. These data are calculated from all events occurring during the study duration, including deaths, transplants and exchanges occurring after 180 days but ending with last-patient, last-visit.

**Figure 215: Competing Risk Outcomes (HVAD Safety Population)**




### Deaths

There were eight subject deaths during the 180-day study period. Six deaths occurred in subjects with their originally implanted device and two deaths occurred after device exchange.

# Appendix E: Pivotal US Clinical Study: Bridge-to-Transplant (continued)

### Safety Results

This study was not randomized and used a contemporaneous control group for the sole purpose of comparing a pre-defined success outcome. The adverse events reported here are unique to the HVAD System and have no randomized comparator arm.

### Exposure

The total support (exposure) on the original HVAD System was 20,698 days or 56.7 patient-years. The mean duration on device for the 140 subjects was 147.8 days (standard deviation 52.8) with a median 180 (range 6 – 180 days). The mean duration on study was 222.5 days (standard deviation 119) with a median of 196 (range 11 – 588 days). Duration on study exceeds duration on device, because the follow-up post-transplant is included.

### Adverse Events

A total of 776 events (**Table 28**) were reported by investigators during the 180 day period on the original device. Of these 437 (437/776, 56.3%) were INTERMACS defined specific events, and 338/776 (43.6%) events were recorded under the INTERMACS category of "Other." One UADE was reported during the 180-day primary endpoint period.

**Table 28: Summary of All Investigator-Reported Adverse Events**

| Event | Total | % |
|---|---|---|
| INTERMACS defined Events | 437 | 56.3% |
| INTERMACS "Other" AE's | 338 | 43.6% |
| UADE | 1 | 0.1% |
| Total | 776 | 100% |

### INTERMACS Events

The INTERMACS defined adverse events for the 180-day primary endpoint on original device are summarized below and are separated into the perioperative (0-30 days) and post-perioperative (31-180 days) periods. Events meeting INTERMACS criteria are shown in **Table 29**. Bleeding, infections and arrhythmia were the most common. Most bleeding events qualified due to transfusions (see definition below). On the other hand, all reoperations due to bleeding were in the first 30-days post-op (23 vs. 0 events post-30 days).

# **Appendix E:** Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Table 29: INTERMACS Events by Type and Time of Onset (HVAD System N=140)**

| INTERMACS defined AEs | Day of Event Onset | | | |
|---|---|---|---|---|
| | 0-30 Days | | 31-180 Days | |
| | Events N | Subjects N (%) | Events N | Subjects N (%) |
| Bleeding | | | | |
| Re Op[1] | 23 | 20 (14.3) | 0 | 0 |
| Transfusion Criteria[2] >4 Units within 7 Days | 10 | 10 (7.1) | 0 | 0 |
| Any Units at > 7 Days | 31 | 25 (17.9) | 46 | 20 (14.3) |
| Infections | | | | |
| Local (Non-device) | 20 | 20 (14.3) | 17 | 17 (12.1) |
| Driveline Exit | 5 | 5 (3.6) | 14 | 11 (7.9) |
| Sepsis | 3 | 3 (2.1) | 8 | 7 (5.0) |
| Neurological Events | | | | |
| Ischemic CVA | 7 | 7 (5.0) | 3 | 3 (2.1) |
| Hemorrhagic CVA | 2 | 2 (1.4) | 2 | 2 (1.4) |
| TIA | 2 | 2 (1.4) | 5 | 4 (2.9) |
| Respiratory Dysfunction Arrhythmia | 26 | 22 (15.7) | 8 | 5 (3.6) |
| Ventricular | 15 | 14 (10.0) | 14 | 11 (7.9) |
| Supraventricular | 25 | 21 (15.0) | 7 | 6 (4.3) |
| Right Heart Failure | | | | |
| Inotropes | 17 | 17 (12.1) | 8 | 7 (5.0) |
| RVAD | 3 | 3 (2.1) | 1 | 1 (0.7) |
| Arterial Thromboembolism | 0 | 0 | 2 | 2 (1.4) |
| Venous Thromboembolism | 4 | 4( 2.9) | 3 | 3 (2.1) |
| Renal Dysfunction | 8 | 8 (5.7) | 6 | 5(3.6) |
| Psychiatric Event | 5 | 5 (3.6) | 4 | 4 (2.9) |
| Myocardial Infarction Event | 0 | 0 | 1 | 1 (0.7) |
| Hypertension | 1 | 1 (0.7) | 0 | 0 |
| Hepatic Dysfunction | 3 | 3 (2.1) | 1 | 1 (0.7) |
| Hemolysis Event[3] | 1 | 1 (0.7) | 1 | 1 (0.7) |

[1]4 procedures were not included: elective hysterectomy, elective repair of hemorrhoids, HVAD exchange and RVAD placement.
[2]Transfusion criteria include: ≥ 20cc/kg packed red blood cells (PRBC) within any 24 hour period during the first 7 day post-implant and any transfusion of packed red blood cells (PRBC) after 7 days following implant with the Investigator recording the number of units given.
[3]Two cases were excluded: 1 case hemolysis < 72 hours post-implant; 1 case hemolysis occurring in the presence of tPA/Integrillin for VAD thrombosis.

# **Appendix E:** Pivotal US Clinical Study: Bridge-to-Transplant (continued)

The majority of infections did not involve the driveline or cause sepsis. The local, non-device category encompasses a host of sites, including the urinary tract, lungs, sinuses, IV punctures, colon and skin. Infections involving the driveline exit site were more common after hospital discharge (> 30 days). Similarly, subjects were somewhat more likely to experience sepsis from 31-180 days (5.0% of subjects) than perioperatively (2.1%). Nearly a third (11/32) of the supraventricular arrhythmias were bouts of atrial fibrillation, requiring drug therapy. Nearly all the ventricular arrhythmias were ventricular tachycardia. AICD shocks were recorded in 24/29 episodes of ventricular arrhythmia and 2/29 received external cardioversion. Nearly all patients with a reported episode of ventricular tachycardia were subsequently placed on amiodarone.

Respiratory problems were more common in the perioperative period, declining from 26/34 events at 0-30 days to about one-third that number (8/34) from 31-180 days. Subjects were more likely to experience right heart failure events in the perioperative period (20/29). The most common treatment for right heart failure was the use of inotropic drugs and the pulmonary vascular dilator, nitric oxide (25/29). Three subjects required an RVAD and a fourth was exchanged for a pneumatic biVAD at 75 days post-implant. Ischemic strokes (ICVA) were more common overall (10/14 events) and occurred with greater frequency in the perioperative period (7/9 perioperative strokes). Four hemorrhagic strokes (HCVA) were recorded. Three of these resulted in deaths. TIAs were more common in the 31-180 day period (5/7 TIA events). While HCVAs were generally fatal (75%) they were most often associated with hypertension (MAP > 90 mm Hg). Three of the 4 HCVAs had a mean arterial pressure of ≥ 95 mm Hg at the time of the stroke and the one normotensive patient was septic and had an INR of 2.7 (high normal range).

Overall 70% of the patients who experienced ICVAs were transplanted or remained eligible. It is noteworthy that 6/10 ICVA events occurred within 48 hours of implant and may have been related to surgical procedural factors, such as ragged coring of the myocardium for inflow insertion or incomplete device de-airing. These issues were addressed by improvements to the coring tool and by site retraining. The overall stroke survival for the combined ICVAs and HCVAs on the original device was 77% (10/13 patients).

Venous thrombosis occurred in 5% of subjects. Most of these were cases of DVT in the lower extremities. In the arterial thromboembolism category, a case of VAD thrombosis was treated with tPA and resolved and in another case a clot was removed from the left main coronary artery following cardiac catheterization. A third case appeared to involve a shower of small emboli to the periphery.

No subject required permanent dialysis. Psychiatric events were recorded for nine subjects (6.4%). All recovered without sequelae. Two hemolysis events were detected by strict INTERMACS criteria in the absence of VAD thrombosis. These resolved spontaneously.

One subject experienced a myocardial infarction and one subject had a hypertensive event during the perioperative period. Hepatic dysfunction was noted in four subjects.

Adverse events were generally more common in the perioperative period.

# Appendix E: Pivotal US Clinical Study: Bridge-to-Transplant (continued)

### Serious Adverse Events

A total of 452 serious adverse events on the original device occurred in 118 (84.3%) subjects (**Table 30**). A total of 287 INTERMACS defined events met the definition of an SAE, and 164 INTERMACS "other" events met the definition of an SAE.

**Table 30: Summary of Serious Adverse Events (HVAD System N=140)**

| Serious Adverse Events (SAEs) | Number of SAEs | Subjects N (%) |
|---|---|---|
| Total Serious Adverse Events | 452 | 118 (84.3) |
| INTERMACS | 287 | 98 (70.0) |
| "Other" | 164 | 75 (53.6) |
| UADE | 1 | 1 (0.7) |

### Device Exchange

Device exchange occurred in 7 patients (7/140, 5.0%) in the SAF population during the period 180 days post-implant. Of these 7 exchanges, 3 were resultant from retained tissue being pulled into the pump from the ventricle in the very early post-operative period and were deemed to be procedure related, 2 were exchanged due to thrombus inside the pump, one was exchanged for a high power event of unknown cause and one due to latent right heart failure which caused the patient to require a biventricular support system.

### Device Malfunctions

A device malfunction is defined as a failure of one or more of the components of the HVAD System, which either directly causes or could potentially cause or induce a state of inadequate circulatory support (low cardiac output state) or death. There was information on 26 malfunctions from 20 subjects entered into the clinical database during the study period (**Table 31**).

**Table 31: Malfunctions by Suspected Component**

| HVAD System N=140 Device Component ID | Events N (%) |
|---|---|
| Pump | 7 (5.0) * |
| Controller | 7 (5.0) |
| Battery | 1 (0.7) |
| Battery Charger | 0 |
| Monitor | 0 |
| Driveline | 2 (1.4) |
| Controller AC Adapter | 6 (4.3) |
| Other Component | 3 (2.1) |

*Described in Pump Exchange section

# Appendix E: Pivotal US Clinical Study: Bridge-to-Transplant (continued)

## Quality of Life: Kccq And EuroQol

**Kansas City Cardiomyopathy Questionnaire (KCCQ):** At baseline, 128/140 (91.4%) patients were able to complete the KCCQ and at month 6 there were 88 patients available to complete the test (39 had received a transplant, six had died, seven had met an endpoint receiving a device exchange) (**Table 32**), Of the 88 patients available for assessment, 74 patients had data at month 6, Reasons for missing the month 6 data included: 9 of 14 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with mRS score of 2), 2 were too sick, 1 had no form available, 1 had been transplanted within the 14 day visit window, and 1 had refused. Seventy patients (70) had both baseline and month 6 data. These 70 patients who were on HVAD therapy continuously for 180 days had a 31 point improvement in KCCQ Overall Summary Score, over the 180 day period.

**Table 32: KCCQ - Overall Summary Score**

| KCCQ | Baseline | Month 6 | Change from Baseline |
|---|---|---|---|
| N | 128 | 74 | 70 |
| Mean (SD) | 34.9 (18.9) | 67.5 (20.4) | 30.9 (26.5) |
| Median | 31.5 | 71.4 | 34.5 |
| Min, Max | 0.0, 84.1 | 19.3, 100.0 | -49.4, 80.5 |
| 95% CI | 31.6, 38.2 | 62.8, 72.2 | 24.6, 37.3 |

**European Quality of Life (EuroQol):** At baseline, 130/140 (92.9%) of patients were able to complete the test, and at month 6 there were 88 patients available to complete the test, (39 had received a transplant, six had died, seven had met an endpoint receiving a device exchange) (**Table 33**). Of the 88 patients available 75 had data at month 6. Reasons for missing the month 6 data included: 9 of 13 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with mRS score of 2), 2 were too sick, 1 had been transplanted within the 14 day visit window, and 1 had refused. Seventy-two patients (72) had both baseline and month 6 data showing an improvement of 30 points over the 180 day period.

**Table 33: EuroQol (EQ-5D) - Summary of Quality of Life**

| EuroQol | Baseline | Month 6 | Change from Baseline |
|---|---|---|---|
| **Overall Summary Score** | | | |
| N | 130 | 75 | 72 |
| Mean (SD) | 39.7 (23.5) | 69.8 (19.8) | 29.5 (25.2) |
| Median | 40.0 | 75.0 | 30.0 |
| Min, Max | 0.0, 92.0 | 4.0, 100.0 | -36.0, 80.0 |
| 95% CI | 35.6, 43.7 | 65.2, 74.4 | 23.6, 35.4 |

## Functional Analyses: 6 Minute Walk

**6 Minute Walk:** Of the 132 patients assessed for the 6-minute walk test, the mean distance walked was 89.4 meters. Seventy-Five (75) of the 88 patients on pump at month 6 completed the test (**Table 34** and **Figure 216**). Reasons for missing the 6 minute walk test at month 6 included: 9 of 14 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with mRS score of 2), 2 were too sick, 1 had no form available, 1 had been transplanted within the 14 day visit window, and 1 had refused. These 75 patients showed a mean distance walked of 246 meters, a mean change of 150 meters from baseline.

# Appendix E: Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Table 34: Functional Status – 6 Minute Walk**

| 6 Minute Walk | Baseline | Month 6 | Change from Baseline |
|---|---|---|---|
| Distance Walked in Meters | | | |
| N | 132 | 75 | 74 |
| Mean (SD) | 89.4 (141.3) | 246.0 (203.9) | 150.1 (214.1) |
| Median | 0.0 | 274.0 | 108.3 |
| Min, Max | 0.0, 600.2 | 0.0, 991.8 | -273.1, 700.9 |
| 95% CI | 65.1, 113.7 | 199.1, 292.9 | 100.5, 199.8 |

**Figure 216: 6 Minute Walk Test**

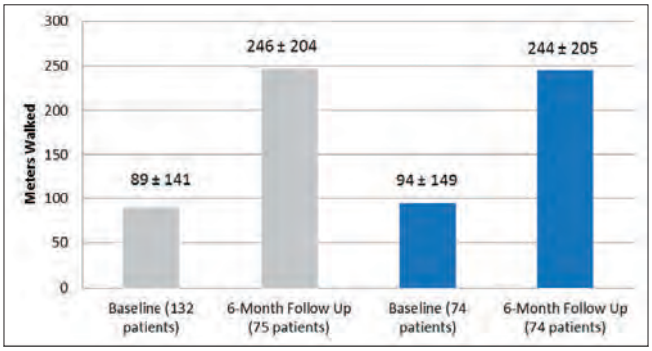



**Table 35** shows a breakdown of results of patients who walked at both baseline and at 6 months as well as those patients that did not walk at baseline but did walk at 6 months.

**Table 35: 6 Minute Walk – Breakdown of Patients Walking vs. Not Walking at Baseline**

| HVAD System Patients | Baseline (m) | Month 6 (m) |
|---|---|---|
| Patients walking at baseline and at 6 months | 260 ± 140 (n=25) | 338 ± 202 (n=25) |
| Patients NOT walking at baseline (for any reason) but walking at 6 months | N/A | 333 ± 125 (n=30) |

### Overall Conclusions from Clinical Data

The HVAD System bridge-to-transplant study (ADVANCE) was a multi-center, prospective, contemporaneous control trial. The purpose of this study was to evaluate the safety and effectiveness in patients listed for cardiac transplantation with refractory, advanced heart failure at risk of death. The primary endpoint was success at 180 days which is defined as alive on the originally implanted HVAD Pump or transplanted or explanted for recovery.

The analysis of the primary endpoint yielded non-inferiority of the HVAD System to the INTERMACS control. The 95% one-sided UCL on the difference in success rates was 4.5% for the Safety Group and 0.9% for the Per Protocol Group. Each of these limits was less than the 15% non-inferiority margin (p-value <0.0001).

- The pre-specified primary endpoint was achieved.
- Both quality of life and functional capacity showed improvements following implant of the HVAD Pump.
- The HVAD System has an adverse event profile that supports its safe use for bridge-to-transplant patients.

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant

## Summary of the Post-Approval Study Methods

**Study Objective**

The purpose of the HW-PAS-03 follow-up study was to continue the evaluation of the longer-term safety and effectiveness of the HeartWare Ventricular Assist System through 5 years in patients who were enrolled in the ADVANCE pivotal study presented above in Section 1.7.

**Study Design**

This was an observational, prospective study, conducted at multiple study sites with no new enrollment. As, no new patients were screened or implanted with the HeartWare VAS for this study; it is a continued follow-up study only. HW-PAS-03 included, patients who were enrolled from the ADVANCE Trial, and a continuation of that study, known as the continuous access protocol (CAP).

## Study Population and Data Source

**Patient population**

The original ADVANCE cohort implanted 140 bridge-to-transplant (BTT) patients, and the Continued Access from the ADVANCE trial (CAP) implanted 242 additional patients using the same inclusion criteria.

Patients who participated in the prior (BTT and CAP) were approached for participation in this continued follow-up PAS if eligible according to the HW-PAS-03 protocol version 3.0 04Sep2013.

BTT and CAP patients eligible for participation in HW-PAS-03 were:

- Patients who were alive at the start of enrollment for the PAS who either
  - were on continued HeartWare VAS support (original or exchange device), or
  - had been explanted for transplant or recovery and had not yet completed six months of follow-up.

At the time of enrollment, all surviving patients from the BTT cohort had been followed for at least 37.7 months, and all surviving patients from the CAP cohort had been followed for at least 4.4 months.

A total of 152 subjects (39.8% of the original combined BTT and CAP cohorts) survived to the Premarket approval of the HeartWare VAS, were still enrolled in the original BTT or CAP trials and were therefore eligible for enrollment into HW-PAS-03.

The PAS results below include three main cohorts:

- On Device: Patients in this cohort (N=84) were still on the HeartWare HVAS device upon enrollment into the HW-PAS-03 study.
- All Enrolled: This cohort includes all 101 patients who enrolled into the HW-PAS-03 study. It includes On Device patients (N=84), as well as Off Device patients.
- Off Device patients (N=17) were enrolled into HW-PAS-03 less than six months post-transplant or explant for recovery (no device in the body upon enrollment). These patients only participated in the study through completion of their 6 months' follow-up.

This PAS does not include 51 patients (33.6% of eligible subjects) from the total BTT+CAP population who were eligible but declined. See **Table 36** below for specific reasons.

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Table 36:Reason for Not Participating in HW-PAS-03**

| Reason | Total Number of Patients |
|---|---|
| Patients whose eligibility expired: they completed the required 6-month post-explant visit between approval and enrollment | 17 |
| Patient declined participation | 12 |
| Patient died between approval and enrollment | 8 |
| Site declined participation | 7 |
| Patient is lost to follow-up | 3 |
| Patient transferred to another non HW-PAS-03 site/moved to another city | 2 |
| Patient's condition did not allow enrollment per PI | 1 |
| Enrollment visit could not be performed within the enrollment period | 1 |
| Total | 51 |

**Key Study Endpoints**

Endpoints for this study were observational only. The endpoints assessed included:

- Overall survival on device
- Final patient status
- Re-hospitalizations
- INTERMACS® adverse events
- Quality of Life measures
- Functional Status

Safety measures included the frequency of adverse events, which were collected throughout HeartWare Ventricular Assist System support.

## Total number of Enrolled Study Sites and Subjects, Follow-up Rate

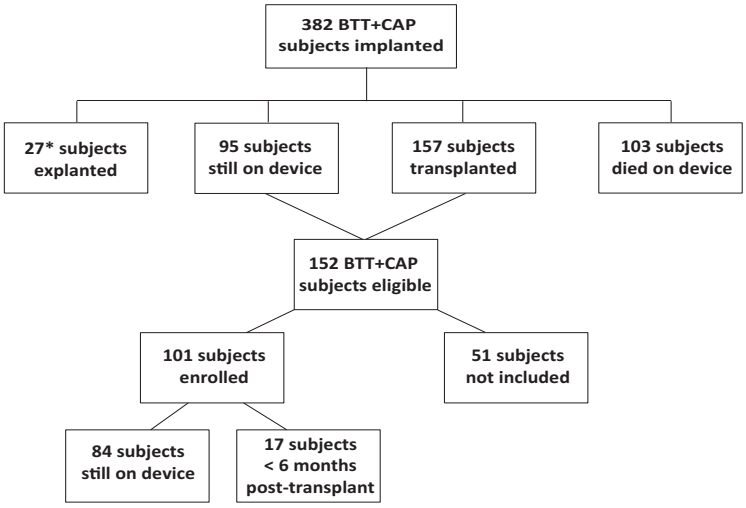
**Summary of Study Progress**

HW-PAS-03 protocol approval was received on November 20, 2012.

Enrollment into the study started on January 23, 2013 and was completed on May 23, 2013. A total of 101 BTT and CAP subjects from 25 sites were enrolled. The study collected its final data and was closed on December 20, 2017.

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Figure 217: Flowchart for Enrollment into HW-PAS-03 Trial**




*2 subjects had withdrawn consent.

### Number of Eligible Site

All 30 sites that participated in BTT and CAP were eligible for participation in HW-PAS-03 . Twenty-five of those sites enrolled at least one eligible subject and participated in HW-PAS-03.

The remaining five centers did not participate in HW-PAS-03. The most frequent reason for not participating was lack of center resources.

### Study visits and length of follow-up

Assessments were conducted at enrollment into HW-PAS-03 and at visits according to the following schedule:

- Subjects enrolled on device (either original device or HeartWare device exchange): every six months until outcome or five years post-initial implant of the original device.
- Subjects who were enrolled after being explanted for transplant or recovery: until six months post-explant to record subject status only, at which point participation in the study was considered complete.

### Summary of the Post Approval Study Results

A total of 152 subjects were eligible for participation in the HW-PAS-03 study. Of those, 101 (66%) were enrolled; 84 subjects enrolled while still on the HeartWare device, and 17 enrolled post-transplant. Subjects in the All Enrolled cohort (N=101) had rates of complete study visit follow-up between 90.9% - 100%.

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

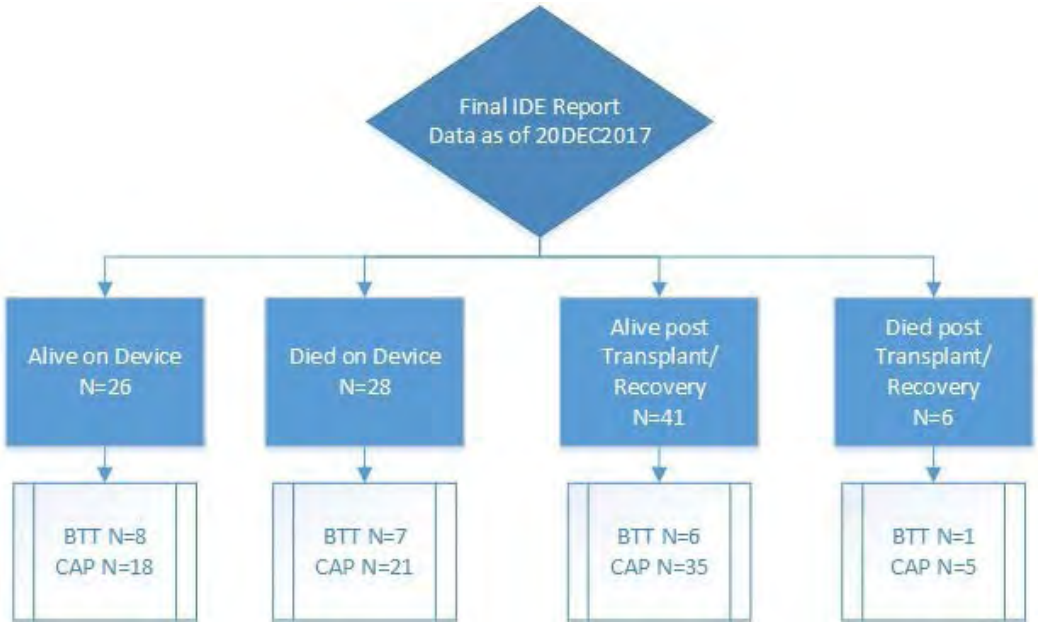
**Table 37:Subject Baseline Demographics**

| Demographics | All Enrolled (N=101) | On Device (N=84) | Off Device (N=17) |
|---|---|---|---|
| **Age at enrollment into PAS03 (years)** | 54.4 ± 12.62 (101)<br>(22.0, 57.0, 74.0) | 54.8 ± 12.35 (84)<br>(24.0, 56.0, 74.0) | 52.3 ± 14.08 (17)<br>(22.0, 58.0, 67.0) |
| **Gender** | | | |
| Male | 73.3% (74/101) | 69.0% (58/84) | 94.1% (16/17) |
| Female | 26.7% (27/101) | 31.0% (26/84) | 5.9% (1/17) |
| **Ethnicity** | | | |
| Hispanic or Latino | 5.9% (6/101) | 6.0% (5/84) | 5.9% (1/17) |
| Non-Hispanic or Non-Latino | 94.1% (95/101) | 94.0% (79/84) | 94.1% (16/17) |
| **Race** | | | |
| White | 58.4% (59/101) | 54.8% (46/84) | 76.5% (13/17) |
| Black/African American | 36.6% (37/101) | 40.5% (34/84) | 17.6% (3/17) |
| Asian | 1.0% (1/101) | 1.2% (1/84) | 0.0% (0/17) |
| American Indian/Native Alaskan | 1.0% (1/101) | 0.0% (0/84) | 5.9% (1/17) |
| Other | 3.0% (3/101) | 3.6% (3/84) | 0.0% (0/17) |

**Note:** Data is from the original ADVANCE and CAP trials for gender, ethnicity and race. Age is as of consent into the HW-PAS-03 study.

For the All Enrolled cohort, 67 subjects (66%) were alive at the time of completion/exit; 26 (26%) were still implanted with an HVAD (21 on original and 5 post-exchange). 41 (41%) subjects were alive after being explanted for transplant. 34 (34%) subjects had died. On Device subjects spent 42.7 months on average implanted with the device through completion of study follow up **(Table 39).**

**Figure 218: Subject Status**



# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Table 38: Subject Disposition (all enrolled through 5 years)**

| Disposition | HW-PAS-03 (N=101) | BTT Cohort (N=22) | CAP Cohort (N=79) |
|---|---|---|---|
| **Alive** | **67 (66.3%)** | **14 (63.6%)** | **53 (67.1%)** |
| On Original Device | 21 (20.8%) | 5 (22.7%) | 16 (20.3%) |
| Post-Exchange | 5 (5.0%) | 3 (13.6%) | 2 (2.5%) |
| Post-Explant for Transplant | 41 (40.6%) | 6 (27.3%) | 35 (44.3%) |
| Post-Explant for Recovery | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| **Dead** | **34 (33.7%)** | **8 (36.4%)** | **26 (32.9%)** |
| On Original Device | 22 (21.8%) | 4 (18.2%) | 18 (22.8%) |
| Post-Exchange | 6 (5.9%) | 3 (13.6%) | 3 (3.8%) |
| Post-Explant for Transplant | 6 (5.9%) | 1 (4.5%) | 5 (6.3%) |
| Post-Explant for Recovery | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |

**Table 39: Summary of Duration on Device and In Study (all enrolled)**

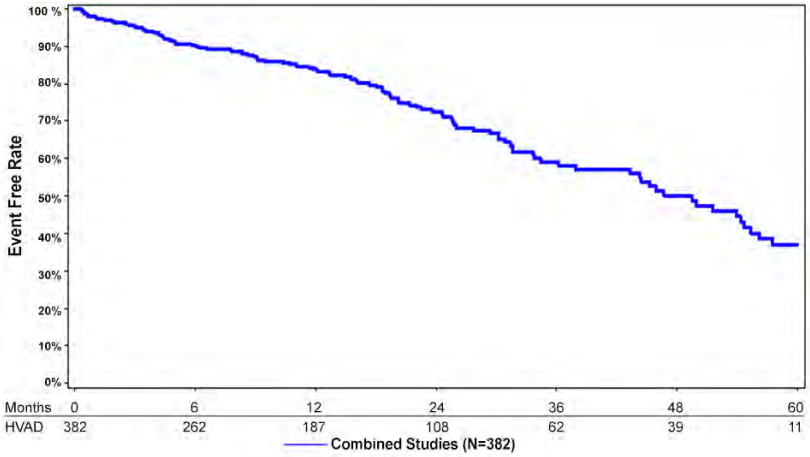
| Parameter | HW-PAS-03 (N=101) | BTT Cohort (N=22) | CAP Cohort (N=79) |
|---|---|---|---|
| Duration on Original Device[a] (months)[a] | 33.6 ± 19.0 (0.1, 31.6, 62.1) | 39.9 ± 20.0 (0.2, 45.2, 61.5) | 31.8 ± 18.4 (0.1, 30.3, 62.1) |
| Duration on Device (months)[b] | 38.1 ± 18.3 (2.5, 41.5, 62.4) | 53.5 ± 6.9 (41.7, 56.9, 62.4) | 33.8 ± 18.2 (2.5, 31.6, 62.1) |
| Duration in Study (months)[c] | 40.5 ± 17.1 (7.8, 44.4, 65.4) | 55.2 ± 6.6 (43.4, 57.1, 63.4) | 36.4 ± 16.8 (7.8, 33.6, 62.1) |

**Note:** Numbers are mean ± SD (min, median, max).
[a] Duration on Original Device (months) = date of first explant/transplant/exchange or last follow up – date of original implant + 1
[b] Duration on Device (months) = date of last explant/transplant or last follow up – date of original implant + 1
[c] Duration on Study (months) = date the subject exited from the study – date of original implant +1

The Kaplan-Meier survival estimates at 5 years for all implanted BTT and CAP subjects (N=382) was 37.1%.

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Figure 219: Kaplan-Meier Survival on device**

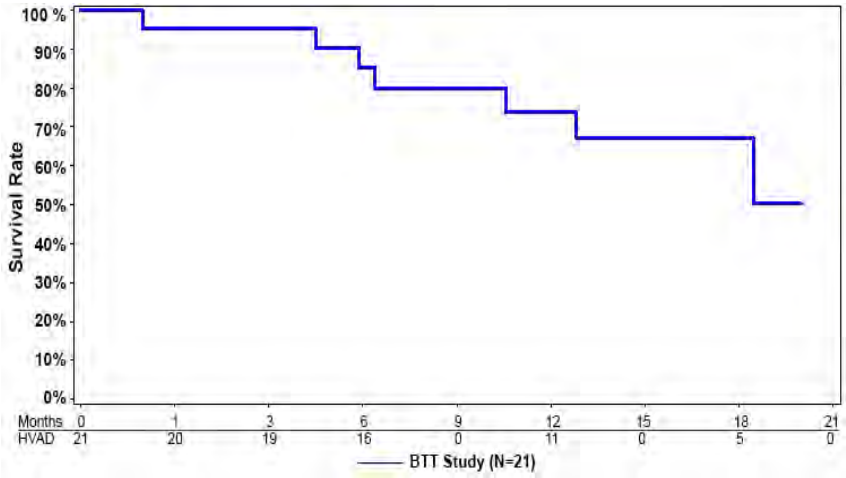



**Note:** Of the 51 subjects who did not rollover into the HW-PAS-03 trial from **Table 36**, 26 subjects were still eligible to participate in the post market study at the time exit from the original trials (did not die or complete 6 months post-transplant). Their follow up was censored at the time of last follow up from the pre-market trials.

There was no statistically significant difference in survival between the BTT and CAP Cohorts, between males and females, or between white and non-white patients when analyzing the All Enrolled (N=101) cohort, which only includes subjects who enrolled into the HW-PAS-03 trial. The two most common causes of death were device malfunction (seven subjects) and neurological dysfunction (four subjects).

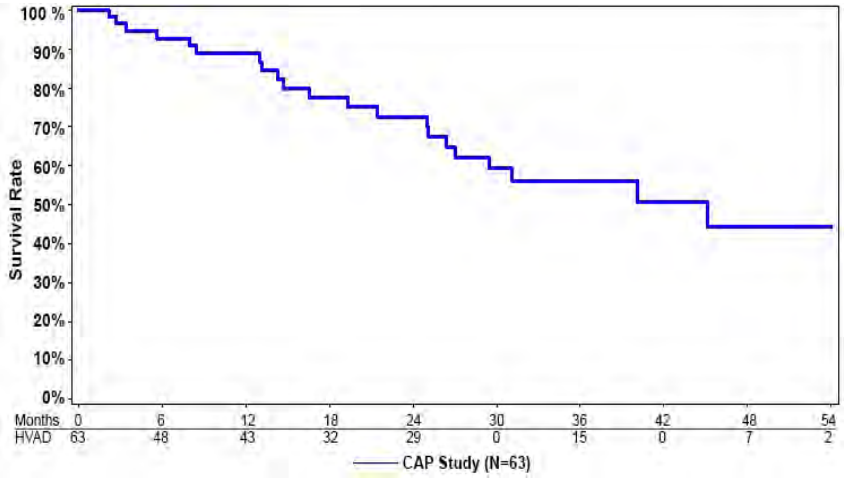
Survival on device from time of consent into HW-PAS-03 for the On Device subjects (N=84) is presented for the subjects who were from the BTT cohort (N=21) and CAP cohort (N=63) separately, as all subjects were enrolled into HW-PAS-03 after implant and given the difference between implant times prior to enrollment. Time 0 was the date of consent for the HW-PAS-03 trial and subjects were censored at the earlier time of their last follow up or the end of LVAD support.

**Figure 220: Kaplan-Meier Survival on device from enrollment into HW-PAS-03, BTT cohort**



# **Appendix F:** Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Figure 221: Kaplan-Meier Survival on device from enrollment into HW-PAS-03, CAP cohort**




Quality of life and functional status assessments demonstrated sustained improvements over time. The overall summary score for KCCQ had an average improvement of at least 20 points from baseline at all follow up visits, and the average EQ-5D-5L Visual Analog Scale was greater than 65 at all visits. The 6-minute walk test showed an average increase of at least 90 meters from baseline at all follow-up timepoints. At most timepoints for NYHA, over 80% of the subjects who completed the assessment were improved to a NYHA classes I or II.

For the On Device subjects in this PAS (n=84), the three most common adverse events were infection, device malfunction/failure and bleeding.

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

**Table 40:INTERMACS adverse events while on a HeartWare device during PAS03* (On Device Subjects)**

| INTERMACS Category Adverse Events | HW-PAS-03 (N=84) | | | BTT Cohort (N=21) | | | CAP Cohort (N=63) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Subjects with Event (%) | No. of Events | Event Rate per PY (137.22) | Subjects with Event (%) | No. of Events | Event Rate per PY (21.22) | Subjects with Event (%) | No. of Events | Event Rate per PY (115.99) |
| Total Adverse Events | 75 (89.3%) | 503 | 3.67 | 19 (90.5%) | 120 | 5.65 | 56 (88.9%) | 383 | 3.30 |
| UADE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Bleeding | 21 (25.0%) | 38 | 0.28 | 5 (23.8%) | 9 | 0.42 | 16 (22.2%) | 29 | 0.25 |
| Re-Hospitalization | 16 (19.0%) | 31 | 0.23 | 4 (19.0%) | 8 | 0.38 | 12 (17.5%) | 23 | 0.20 |
| Re-Operation | 1 (1.2%) | 1 | 0.01 | 1 (4.8%) | 1 | 0.05 | 0 | 0 | 0 |
| GI | 16 (19.0%) | 24 | 0.17 | 3 (14.3%) | 5 | 0.24 | 13 (20.6%) | 19 | 0.16 |
| Cardiac Arrhythmia | 18 (21.4%) | 23 | 0.17 | 5 (23.8%) | 5 | 0.24 | 13 (20.6%) | 18 | 0.16 |
| Ventricular | 8 (9.5%) | 11 | 0.08 | 1 (4.8%) | 1 | 0.05 | 7 (11.1%) | 10 | 0.09 |
| Supraventricular | 7 (8.3%) | 7 | 0.05 | 0 | 0 | 0 | 7 (11.1%) | 7 | 0.06 |
| Device Malfunction/ Failure | 36 (42.9%) | 49 | 0.36 | 10 (47.6%) | 12 | 0.57 | 26 (41.3%) | 37 | 0.32 |
| Hemolysis | 3 (3.6%) | 4 | 0.03 | 2 (9.5%) | 3 | 0.14 | 1 (1.6%) | 1 | 0.01 |
| Hepatic Dysfunction | 2 (2.4%) | 3 | 0.02 | 0 | 0 | 0 | 2 (3.2%) | 3 | 0.03 |
| Hypertension | 2 (2.4%) | 5 | 0.04 | 1 (4.8%) | 1 | 0.05 | 1 (1.6%) | 4 | 0.03 |
| Infection | 43 (51.2%) | 89 | 0.65 | 14 (66.7%) | 23 | 1.08 | 29 (46.0%) | 66 | 0.57 |
| Localized Non-Device | 12 (14.3%) | 17 | 0.12 | 3 (14.3%) | 4 | 0.19 | 9 (14.3%) | 13 | 0.11 |
| Sepsis | 9 (10.7%) | 12 | 0.09 | 3 (14.3%) | 4 | 0.19 | 6 (9.5%) | 8 | 0.07 |
| Driveline Exit Site | 27 (32.1%) | 35 | 0.26 | 6 (28.6%) | 9 | 0.42 | 21 (33.3%) | 26 | 0.22 |
| Myocardial Infarction | 1 (1.2%) | 1 | 0.01 | 1 (4.8%) | 1 | 0.05 | 0 | 0 | 0 |
| Neurological Dysfunction | 16 (19.0%) | 23 | 0.17 | 5 (23.8%) | 7 | 0.33 | 11 (17.5%) | 16 | 0.14 |
| Ischemic CVA | 6 (7.1%) | 7 | 0.05 | 2 (9.5%) | 2 | 0.09 | 4 (6.3%) | 5 | 0.04 |
| Hemorrhagic CVA | 9 (10.7%) | 12 | 0.09 | 3 (14.3%) | 3 | 0.14 | 6 (9.5%) | 9 | 0.08 |
| TIA | 4 (4.8%) | 4 | 0.03 | 2 (9.5%) | 2 | 0.09 | 2 (3.2%) | 2 | 0.02 |
| Pericardial Fluid Collection | 1 (1.2%) | 1 | 0.01 | 0 | 0 | 0 | 1 (1.6%) | 0 | 0.01 |
| Psychiatric | 8 (9.5%) | 8 | 0.06 | 1 (4.8%) | 1 | 0.05 | 7 (11.1%) | 7 | 0.06 |

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

| INTERMACS Category Adverse Events | HW-PAS-03 (N=84) | | | BTT Cohort (N=21) | | | CAP Cohort (N=63) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Subjects with Event (%) | No. of Events | Event Rate per PY (137.22) | Subjects with Event (%) | No. of Events | Event Rate per PY (21.22) | Subjects with Event (%) | No. of Events | Event Rate per PY (115.99) |
| Renal Dysfunction | 7 (8.3%) | 7 | 0.05 | 3 (14.3%) | 3 | 0.14 | 4 (6.3%) | 4 | 0.03 |
| Acute | 7 (8.3%) | 7 | 0.05 | 3 (14.3%) | 3 | 0.14 | 4 (6.3%) | 4 | 0.03 |
| Chronic | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory Dysfunction | 14 (16.7%) | 15 | 0.11 | 4 (19.0%) | 4 | 0.19 | 10 (15.9%) | 11 | 0.09 |
| Right Heart Failure | 8 (9.5%) | 9 | 0.07 | 5 (23.8%) | 6 | 0.28 | 3 (4.8%) | 3 | 0.03 |
| Inotropic Therapy | 7 (8.3%) | 8 | 0.06 | 4 (19.0%) | 5 | 0.24 | 3 (4.8%) | 3 | 0.03 |
| RVAD | 1 (1.2%) | 1 | 0.01 | 1 (4.8%) | 1 | 0.05 | 0 | 0 | 0 |
| Inhaled Nitric Oxide | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Arterial Non-CNS Thromboembolism | 1 (1.2%) | 1 | 0.01 | 0 | 0 | 0 | 1 (1.6%) | 1 | 0.01 |
| Venous Thromboembolism | 3 (3.6%) | 3 | 0.02 | 0 | 0 | 0 | 3 (4.8%) | 3 | 0.03 |
| Wound Dehiscence | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other | 61 (72.6%) | 224 | 1.63 | 16 (76.2%) | 45 | 2.12 | 45 (71.4%) | 179 | 1.54 |

**Note:** Percentages are based on the number of subjects in the group. Subjects are counted once within each INTERMACS defined adverse event term. Summarized AEs include emergent AEs, and AEs that occurred while on any HeartWare device (including pre and post-exchange AEs).
*Adverse Events that occurred and were not ongoing in the Premarket duration of the BTT and CAP studies are not included in this table.

Neurological dysfunction in subjects on a HeartWare device included 16 subjects (19.0%) who had 23 events. Of those, 6 subjects (7.1%) had 7 CT-confirmed ischemic cerebrovascular event's, 9 subjects (10.7%) had 12 CT-confirmed hemorrhagic cerebrovascular event's, and 4 subjects (4.8%) had 4 TIAs. The proportion of On Device subjects who experienced neurological dysfunction adverse events was higher in the BTT cohort (23.84%) than the CAP cohort (17.5%).

A total of 89 infection events occurred in 43 subjects (51.2%) while on a HeartWare device. Of those, driveline infections occurred in 27 subjects (32.1%) who had 35 events and 9 subjects (10.7%) experienced 12 sepsis events.

A total of 49 device malfunctions/failure events occurred in 35 subjects (42.9%) while on a HeartWare device during HW-PAS-03 follow up. The most frequent events were related to the pump, including outflow graft and inflow cannula issues (18 events, 23.1%) and suspected/confirmed pump thrombus (9 events, 11.5%). The second most common event type was controller faults and damage (17 events, 21.8%). Less frequent events included power disconnection, connector issues, electrical faults, and battery issues.

Eight subjects (9.5%) had nine exchanges, with one subject having two exchanges, during HW-PAS-03 follow up.

# Appendix F: Post Approval Study Follow-up of the Pivotal US Clinical Study: Bridge-to-Transplant (continued)

Most subjects had at least one re-hospitalization, with more than half having three or more re-hospitalizations. The mean cumulative LOS was 45.8 days. The two most common primary reasons for re-hospitalization were adverse event (23 subjects, 77.4%) and explant (8 subjects, 27.4%).

**Final safety findings (key endpoints)**

This post approval study followed the long-term safety and effectiveness of IDE trial subjects up to five years post original implant. All subjects had at least one re-hospitalization during the HW-PAS-03 study. The longer term follow up for these subjects (more than three years on average) were associated with, with infections, device malfunctions/failures and bleeding events as the most common type of adverse event.

**Final effectiveness findings (key endpoints)**

Of the 101 enrolled subjects, about two-thirds (67 subjects, 66.3%), were still alive at the time of their study exit or HW-PAS-03 study completion/exit. Of those, 41 subjects were alive post-transplant (40.6% of the enrolled subjects) and 26 were alive on support (25.7% of those enrolled). Fewer than 10% of subjects had an exchange during the HW-PAS-03 trial (8 subjects, 9.5%), 27.7% died while on the device (28 subjects), and 5.9% (6 subjects) died less than 6 months post-transplant. Quality of life and functional status measurements improved over time.

**Study Strengths and Limitations**

There were several strengths to this study. It provided continued follow-up for patients who had received an HVAD System, allowing observation of long-term outcomes in an initial bridge to transplant approach. Additionally, the final data demonstrated consistent results regarding adverse event rate outcomes. A limitation of the study was that only subjects who were still alive on a HeartWare device or post-transplant for less than 6 months were eligible for the HW-PAS-03 trial. Subjects also had varying follow up times prior to enrollment into HW-PAS-03. Additionally, of the 152 eligible subjects, 33% (51/152) of those who potentially could have enrolled into HW-PAS-03 did not (e.g., site declined participation, subject declined participation, lost to follow up, etc.). These factors limit the interpretability of longer-term survival and adverse event results, as the potential for selection bias and the influence of competing risks must be considered.

# Appendix G: US Clinical Study: Destination Therapy

## A. Study Design

Patients in the ENDURANCE trial were enrolled between August 4, 2010 and May 8, 2012. The database for this Panel Track Supplement reflected data collected through June 06, 2016, as well as some additional updated data from March 27, 2017, and included 451 subjects enrolled at 48 investigational sites.

The trial was a prospective, randomized, controlled, multicenter clinical trial. Subjects were randomly assigned using a permuted block, central randomization scheme, in a 2:1 ratio, to receive either the study (HVAD) or control (HeartMate II) device.

The objective of the trial was to compare the safety and effectiveness of HVAD for destination therapy to the HeartMate II, which is legally marketed in the U.S. for destination therapy, in patients with end-stage heart failure who are ineligible for heart transplantation.

The sample size for formal hypothesis testing was to be determined adaptively. Subjects were to be randomized until 450 subjects were randomized and implanted.

It was pre-specified that after the first 300 randomized subjects reached the two-year primary endpoint, the success rate from the control subjects would be assessed. If the observed control success rate was at least 55%, then the data from the first 300 subjects would be analyzed. If the observed control success was less than 55%, then no interim analysis would be performed and the full 450 subjects would be subsequently analyzed. This adaptive sample size for statistical analysis provides at least 90% power to establish non-inferiority.

The ENDURANCE trial was conducted under the oversight of an independent Clinical Events Committee, which adjudicated all the adverse events according to the Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS) definitions; and an independent Data Safety Monitoring Board reviewed study compliance and monitored adverse events and outcomes.

### 1. Clinical Inclusion and Exclusion Criteria

Enrollment in the ENDURANCE trial was limited to patients who met the following inclusion criteria:

- Patients ≥18 years old with chronic, advanced left ventricular failure with New York Heart Association (NYHA) functional class IIIB or IV limitations despite optimal medical therapy and were transplant ineligible at the time of enrollment in whom informed consent was obtained.

Patients were not permitted to enroll in the ENDURANCE trial if they met any of the following exclusion criteria:

- Patients eligible for cardiac transplant or with prior cardiac transplant.
- Patients with recent (within 14 days) acute myocardial infarction or stroke within 180 days.
- Patients with a mechanical heart valve.
- Patients with severe right heart failure in whom right ventricular support is anticipated.
- Patients who might be unwilling or unable to comply with the study criteria.
- Additional exclusion criteria available in the Clinical Study Report.

### 2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 3, 6, 12, 18, and 24 months with a window of ± 7 days, and at 30, 36, 42, 48, 54, and 60 months with a window of ± 14 days postoperatively.

Preoperative baseline assessments included demographics, medical history, physical examination, concurrent medications, laboratory tests, electrocardiogram (ECG), New York Heart Association (NYHA) classification, The National Institutes of Health (NIH) stroke scale, neurocognitive exam, quality of life, and functional status. Postoperative assessments included LVAD parameters, hemodynamics, concurrent medications, laboratory tests, neurocognitive exam, six-minute walk test, NYHA classification, and health status.

### 3. Clinical Endpoints

The primary endpoint was a composite of two-year survival free of disabling stroke (i.e., modified Rankin score ≥ 4 assessed 24 weeks post-event), while alive on the originally implanted device, electively transplanted or explanted due to left ventricular recovery. Success in meeting the primary endpoint was tested for non-inferiority of the experimental group against the control device. The non-inferiority margin of 15% was based on the observed success rate of the control device at >55%. Estimates of stroke-free survival were performed for each treatment using Kaplan-Meier non-inferiority log-rank methodology, comparing study device to control using a one-sided alpha of 0.05; that is, non-inferiority will be established if the one-sided upper confidence limit on the difference in proportions is less than the non-inferiority margin. Analysis of the primary endpoint was conducted on the Per Protocol (PP) population.

Patients were considered a success if at 730 days post-implantation, the subject was alive, did not have a stroke of mRS ≥ 4 assessed 24 weeks post-stroke, and remained on the originally implanted device, unless the device was removed due to heart recovery, or the subject was electively transplanted. Patients were considered a failure if at 730 days post-implantation, they expired, had a stroke with a modified Rankin score ≥ 4 assessed 24 weeks post-stroke, or were urgently transplanted or had surgery for LVAD removal or replacement due to failure of the original device.

There were seven (7) secondary endpoints, of which the following three (3) were to be assessed inferentially to test for superiority in a fixed-sequence procedure if non-inferiority was established for the primary endpoint: incidence of bleeding (per INTERMACS definition), incidence of major infections (per INTERMACS definition), and overall survival (time to death). In addition, a number of subgroup analyses were pre-specified, including gender and BSA (<1.5 $m^2$ vs. ≥1.5 $m^2$).

## B. Accountability of PMA Cohort

### Pre-Specified Interim Analysis

Per the pre-specified analysis plan, the interim analysis cohort (N=300) was to serve as the principal analysis cohort if the Control group success rate for the primary endpoint was at least 55%; as shown below, the observed success rate for the Control group was 59%. A total of 451 patients (inclusive of the initial 300 patients) were enrolled, of which 445 were implanted with a device. This summary presents the ENDURANCE trial results using both the pre-specified interim analysis and full enrollment cohorts. FDA considered the interim analysis to be the principal analysis of the ENDURANCE trial, but considered all analyses when evaluating the safety and effectiveness of the HVAD. The analyses from the full enrollment cohort are included in the Other Results section.

At the time of database lock for the interim analysis, 100% of the pre-specified interim analysis cohort (300 patients) had been followed through the 2-year primary endpoint time point. The disposition of the patients is shown in **Figure 222**.

# Appendix G: US Clinical Study: Destination Therapy (continued)

The Randomized population (HVAD N=200 and Control N=100) included all subjects who were consented (Intent-to-Treat (ITT)) and then enrolled in the study.

The Anesthetized Population (AP) included all randomized subjects who receive induction of anesthesia for implantation.

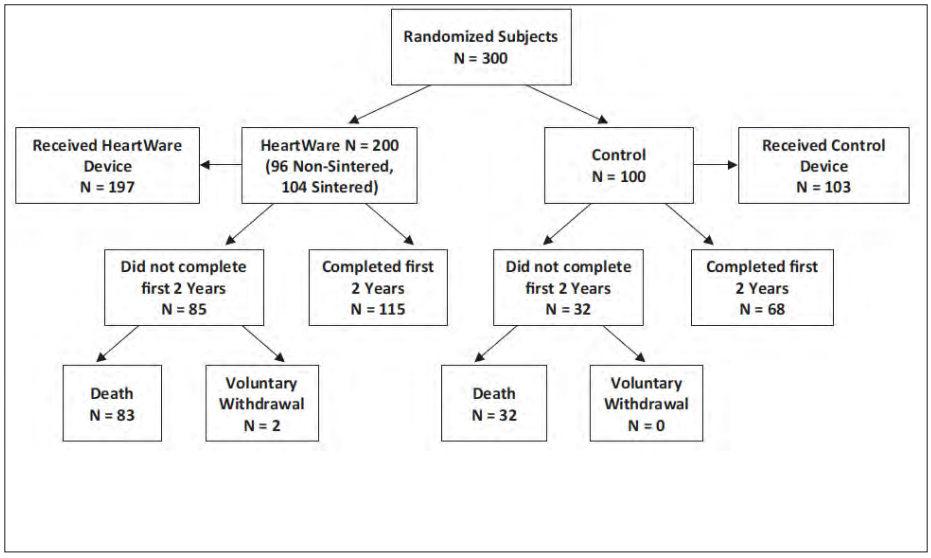
The Anesthetized and Implanted Population (AIP) population, equivalent to an As Treated population, consisted of all randomized subjects who received induction of anesthesia for implantation and received an implant of an LVAD. In the full cohort (N=445), four (4) patients crossed over from HVAD to Control and three (3) patients crossed over from Control to HVAD after randomization but before receiving a device, and one (1) patient in the Control arm did not receive any device. As such, the AT population for the interim analysis consists of 300 patients, 197 in the HVAD arm and 103 in the Control arm.

The Per Protocol (PP) population included all subjects in the AIP population analyzed according to the LVAD to which they were randomized. This definition is more consistent with the ICH definition of what a modified ITT population would be.

The Inclusion Compliant (IC) population included all randomized subjects who received the LVAD to which they were randomized and who did not violate certain inclusion and exclusion criteria that would likely have an effect on outcome.

The primary analysis was performed on the Per Protocol (PP) population. All safety analyses were performed on the AIP population.

**Figure 222: Disposition of First 300 Subjects in the ENDURANCE Trial**



### C. Study Population Demographics and Baseline Parameters

The demographics and baseline characteristics, as summarized in **Table 41**, are typical for an LVAD study performed in the U.S. The HVAD and Control groups did not differ significantly.

**Table 41: Patient Demographics and Baseline Characteristics in the first 300 Subjects in the ENDURANCE Trial**

| Demographics and Baseline Characteristics | HVAD (N=200) | Control (N=100) | P-value |
|---|---|---|---|
| Age (years) | 64.4 ± 12.0 | 66.1 ± 10.4 | 0.25 |
| Male gender (%) | 77.5% | 80.8% | 0.66 |
| Race (%) | | | 0.37 |
| White | 79.5% | 75.0% | |
| Black or African American | 19.5% | 25.0% | |
| Other | 1.0% | 0.0% | |
| Height (cm) | 173.5 ± 9.8 | 175.2 ± 9.3 | 0.15 |
| Body Surface Area ($m^2$) | 2.0 ± 0.3 | 2.0 ± 0.3 | 0.98 |
| INTERMACS Profile (%) | | | 0.17 |
| 1 | 3.5% | 1.0% | |
| 2 | 27.5% | 38.0% | |
| 3 | 39.5% | 41.0% | |
| 4 | 21.5% | 13.0% | |
| 5-7 | 8.0% | 7.0% | |
| Ischemic Etiology of Heart Failure | 59.5% | 59.0% | > 0.99 |

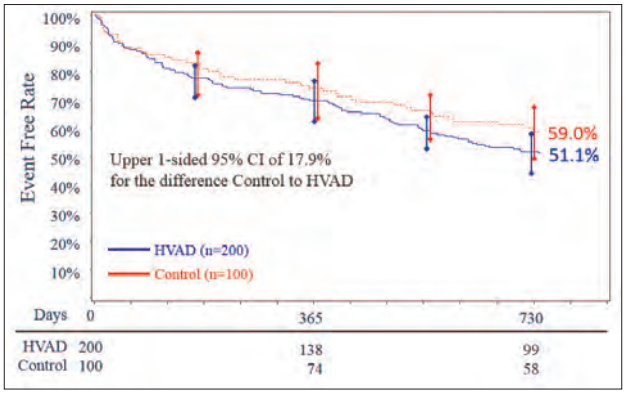
### D. Safety and Effectiveness Results

#### 1. Primary Endpoint

The pre-specified interim analysis was conducted on the first 300 patients to reach two (2) years post-implantation. The Kaplan-Meier estimate for stroke-free success at 2 years for the Control arm was 59.0%; as such, the interim analysis represented the primary analysis for the ENDURANCE trial. The Kaplan-Meier estimate for stroke-free success at 2 years for the HVAD arm was 51.1%. The results of the interim analysis are shown in **Figure 223**. The upper limit of the confidence interval around the difference exceeded the 15% non-inferiority margin (17.9%), resulting in a p-value of 0.1219. The interim analysis showed that the trial failed to demonstrate non-inferiority of the HVAD to the Control.

# Appendix G: US Clinical Study: Destination Therapy (continued)

**Figure 223: ENDURANCE Trial Primary Endpoint. Survival at 2 years free from disabling stroke (mRS ≥ 4) and alive on the originally implanted device, or transplanted or explanted for recovery.**




A binary analysis from the pre-specified interim analysis is presented in **Table 42**.

**Table 42: Binary Analysis of the Primary ENDURANCE Endpoint and its Components for Subjects Receiving Study or Control Device**

| Event Free Survival at 2 years | HVAD (N=200) | Control (N=100) |
|---|---|---|
| Success | 51.5% (103) | 59 (59.0%) |
| Failure | 48.5% (97) | 41.0% (41) |
| **If Failure, reason:** | | |
| Patient dies | 35.5% (71) | 25.0% (25) |
| Device malfunction or failure requiring exchange, explant or urgent transplant | 11.0% (22) | 16.0% (16) |
| Exchange | 9.5% (19) | 14.0% (14) |
| Explant | 0.0% (0) | 0.0% (0) |
| Urgent Transplant | 1.5% (3) | 2.0% (2) |
| Disabling stroke (mRS ≥ 4 at 24 weeks) | 1.5% (3) | 0.0% (0) |
| Imputed failure* | 0.5% (1) | 0.0% (0) |

A subject may have multiple reasons for not completing the first two (2) years, only the first failure type for each subject is specified.
*Patient experienced a stroke prior to their 2-year endpoint, and died beyond the 2-year endpoint, but before the 24-week mRS assessment.

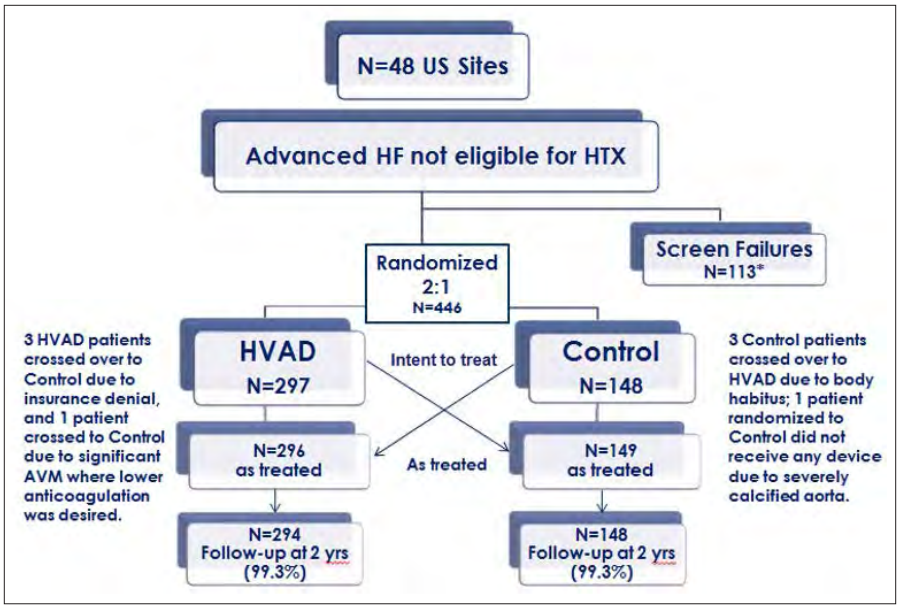
### 2. Secondary Endpoints

Because the primary endpoint was not met per the pre-specified interim analysis, the hypotheses associated with the secondary endpoints of incidence of bleeding (per INTERMACS definition), incidence of major infections (per INTERMACS definition), and overall survival (time to death) could not be tested. As such, the secondary endpoints were not reported.

### 3. Other Results - Adjunctive analysis: Primary Endpoint Using Expanded Dataset

Following the interim analysis at 300 patients, the trial was expanded to enroll additional patients to further investigate various device, procedural, and clinical changes introduced during the trial. A total of 451 patients (inclusive of the initial 300 patients) were enrolled, of which 445 were implanted with a device. The patient disposition is summarized in **Figure 224**. The results of the expanded dataset are summarized below.

**Figure 224: Disposition of Subjects in the ENDURANCE Expanded Dataset**




The demographics and baseline characteristics of the ENDURANCE expanded dataset is summarized in **Table 43**. The demographics and baseline characteristics are typical for an LVAD study performed in the U.S. The HVAD and Control groups did not differ significantly with respect to severity of illness, baseline hemodynamic characteristics, or treatment with evidence-based therapy for heart failure at the time of enrollment. However, subjects in the control group were slightly older (66.2 versus 63.9, control versus HVAD, P=0.04).

# Appendix G: US Clinical Study: Destination Therapy (continued)

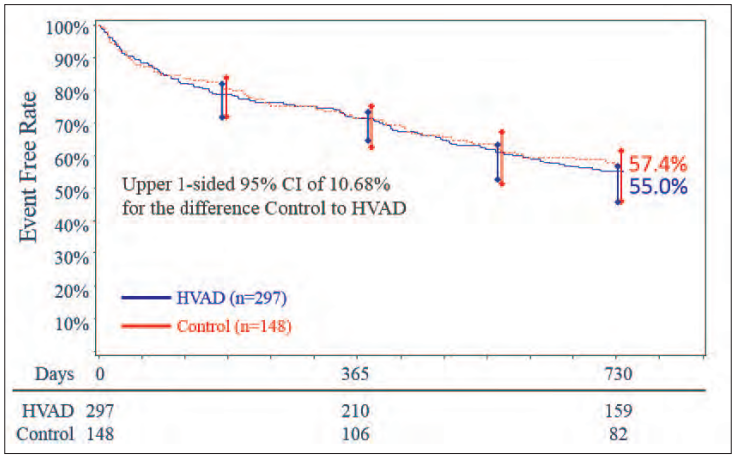
**Table 43: Patient Demographics and Baseline Characteristics of the ENDURANCE Expanded Dataset**

| Demographics and Baseline Characteristics | HVAD (N=297) | Control (N=148) | P-value |
|---|---|---|---|
| Age (years) | 63.9 ± 11.6 | 66.2 ± 10.2 | 0.044 |
| Male gender (%) | 76.4% | 82.4% | 0.178 |
| Race (%) | | | 0.962 |
| White | 76.8% | 77.7% | |
| Black or African American | 22.2% | 21.6% | |
| Other | 1.0% | 0.7% | |
| Height (cm) | 173.8 ± 9.4 | 175.5 ± 9.1 | 0.068 |
| Body Surface Area ($m^2$) | 2.0 ± 0.3 | 2.0 ± 0.3 | 0.615 |
| INTERMACS Profile (%) | | | 0.989 |
| 1 | 3.4% | 3.4% | |
| 2 | 29.0% | 31.1% | |
| 3 | 40.4% | 40.5% | |
| 4 | 19.9% | 18.2% | |
| 5-7 | 7.4% | 6.8% | |
| Ischemic Etiology of Heart Failure | 57.9% | 60.1% | 0.684 |
| Smoker | 68.0% | 62.2% | 0.243 |
| Diabetic | 44.4% | 43.9% | > 0.999 |
| Previous Stroke/TIA | 19.2% | 16.2% | 0.515 |
| Hypertension requiring medication | 65.3% | 70.9% | 0.241 |
| Serum creatinine (mg/dL) | 1.5 ± 0.5 | 1.4 ± 0.5 | 0.760 |
| Severe tricuspid valve insufficiency | 12.0% (N=292) | 5.5% (N=146) | 0.040 |
| Left ventricular ejection fraction (LVEF, %) | 17.1 ± 4.6 | 16.2 ± 4.8 | 0.055 |

Survival free from disabling stroke (mRS ≥4) and alive on the originally implanted device, or transplanted or explanted for recovery for the complete ENDURANCE population is shown below in **Figure 225**. The expanded dataset includes a higher proportion of HVAD devices having titanium-sintered inflow cannulae, a device modification that was introduced during ENDURANCE and designed to decrease thromboembolic adverse event rates. Post hoc one-year comparisons of all sintered HVADs (pooled from both ENDURANCE and ENDURANCE Supplemental) to pooled Control subjects were also performed, as shown in **Figure 225**.

# Appendix G: US Clinical Study: Destination Therapy (continued)

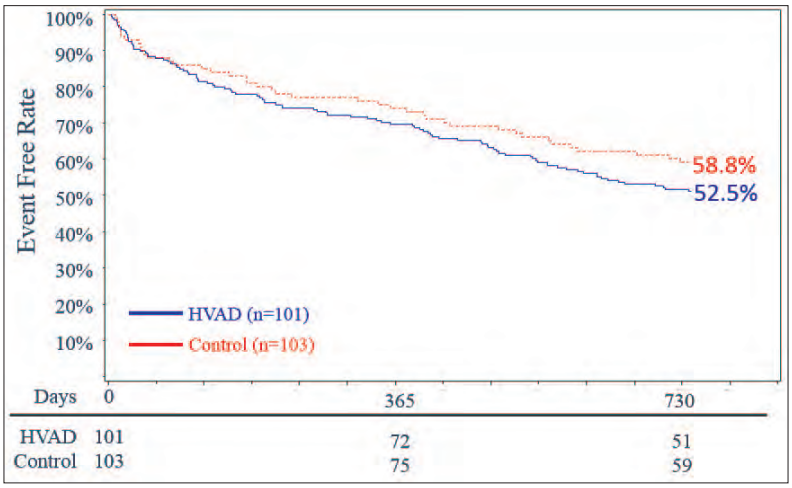
**Figure 225: ENDURANCE Trial Expanded Dataset: Survival free from disabling stroke (mRS ≥4) and alive on the originally implanted device, or transplanted or explanted for recovery in the overall study dataset.**




The post hoc comparison of sintered and non-sintered HVAD Pumps in the interim analysis cohort did not demonstrate markedly different results (See **Figure 226**A, **Figure 226**B).

**Figure 226: Comparison of Outcomes from the Interim analysis of Subjects with Sintered Pumps Compared to Control: Survival free from disabling stroke (mRS ≥4) and alive on the originally implanted device, or transplanted or explanted for recovery in A) the subset of subjects receiving a sintered HVAD Pump, compared to Control, and in B) the subset of subjects receiving the non-sintered HVAD Pump. This analysis is based on the as-treated population.**

**A) Sintered:**



# Appendix G: US Clinical Study: Destination Therapy (continued)

**B) Non-Sintered:**

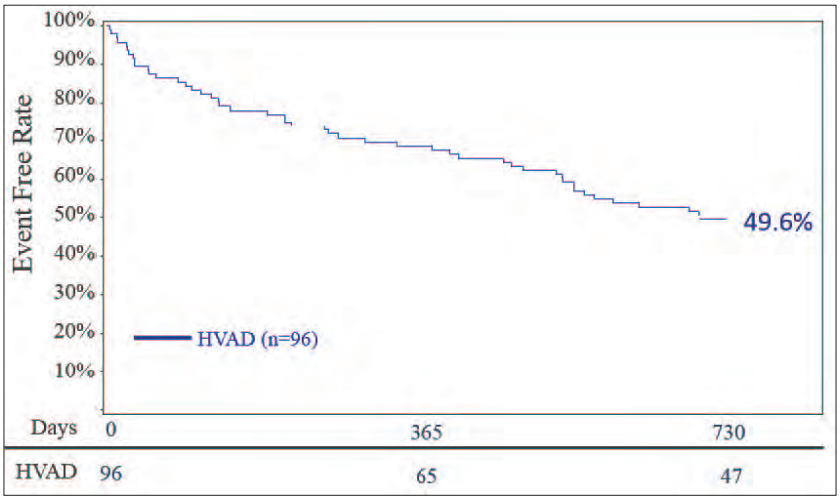



**Table 44: Binary Analysis of ENDURANCE Expanded Dataset: Survival at 2 years free from disabling stroke (mRS ≥4) and alive on the originally implanted device, or transplanted or explanted for recovery.**

| Event Free Survival at 2 years | HVAD (N=297) | Control (N=148) |
|---|---|---|
| Success | 55.2% (164) | 57.4% (85) |
| Failure | 44.8% (133) | 42.6% (63) |
| **If Failure, reason:** | | |
| Patient dies | 34.7% (103) | 26.4% (39) |
| Device malfunction or failure requiring exchange, explant or urgent transplant | 8.8% (26) | 16.2% (24) |
| Exchange | 7.7% (23) | 13.5% (20) |
| Explant | 0.0% (0) | 0.7% (1) |
| Urgent Transplant | 1.0% (3) | 2.0% (3) |
| Disabling stroke (mRS ≥ 4 at 24 weeks) | .0% (3) | 0 |
| Imputed failure* | 0.3% (1) | 0 |

A subject may have multiple reasons for not completing the first two (2) years, only the first failure type for each subject is specified.
*Patient experienced a stroke prior to their 2-year endpoint, and died beyond the 2 year endpoint, but before the 24 week mRS assessment.

# Appendix G: US Clinical Study: Destination Therapy (continued)

In the analyses presented on the entire ENDURANCE trial cohort, the secondary endpoints were analyzed and descriptive data include the following:

- The incidence of bleeding was 60.1% for the HVAD compared to 60.4% for the Control.
- The incidence of major infections was 69.3% for the HVAD and 62.4% for the Control.
- Overall survival was 60.2% for the HVAD and 67.6% for the Control.

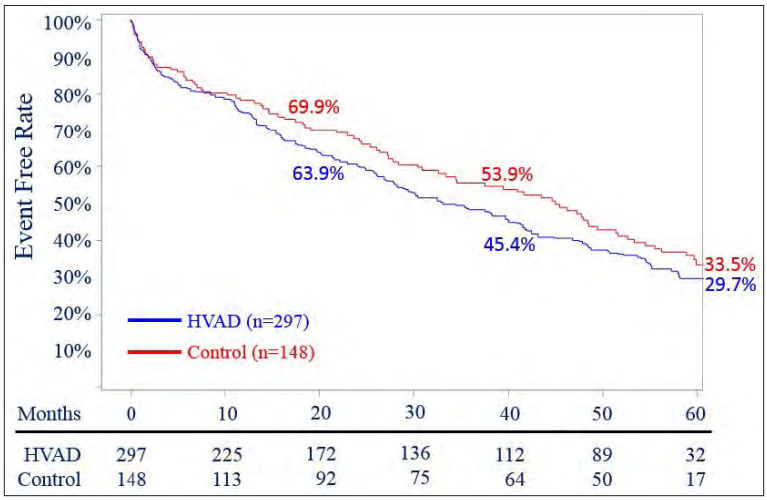
The CEC-adjudicated causes of death for the entire ENDURANCE trial cohort are shown in **Table 45**.

**Table 45: ENDURANCE Expanded Dataset Cause of CEC-Adjudicated on Device Death within 730 days (AIP as Received)**

| Cause of Death | HVAD (N=296) | Control (N=149) |
|---|---|---|
| Total | 38.5% (114) | 30.9% (46) |
| Bleeding | 0.3% (1) | 0.7% (1) |
| Cardiovascular procedure | 1.4% (4) | 1.3% (2) |
| Heart failure | 16.2% (48) | 14.8% (22) |
| Infection | 3.0% (9) | 2.7% (4) |
| Malignancy | 1.4% (4) | 0.7% (1) |
| Multisystem organ failure | 0.0% (0) | 0.7% (1) |
| Respiratory failure | 0.0% (0) | 0.7% (1) |
| Stroke | 8.4% (25) | 6.0% (9) |
| Sudden death | 3.7% (11) | 2.0% (3) |
| Trauma | 0.7% (2) | 0.0% (0) |
| Other cardiovascular | 2.7% (8) | 1.3% (2) |
| Other non-cardiovascular | 0.7% (2) | 0.0% (0) |

Overall survival for the ENDURANCE trial expanded dataset beyond the two (2) year timepoint is included below in **Figure 227**. Aggregate 5-year mortality results for all ENDURANCE subjects were similar.

**Figure 227: Kaplan Meier Survival (Time to Death) in ENDURANCE through 5 years (PP, Per Protocol).**



# Appendix G: US Clinical Study: Destination Therapy (continued)

## Adverse events

The key safety/adverse event outcomes for the ENDURANCE trial expanded dataset are presented in **Table 46** below. Patients in the HVAD arm had a higher rate of ischemic and hemorrhagic stroke, sepsis, and right heart failure compared to control. An analysis of the patient-level data indicated that elevated blood pressure appeared to be a risk factor for stroke, particularly hemorrhagic stroke.

**Table 46: Summary of INTERMACS Adverse Events Occurring Through 2 Years in Subjects in the ENDURANCE Trial Expanded Dataset**

| Adverse Event | HVAD (N=296) | Control (N=149) |
|---|---|---|
| Overall Bleeding events | 60.1% (178) | 60.4% (90) |
| GI Bleed | 35.1% (104) | 34.2% (51) |
| Cardiac Arrhythmia | 37.8% (112) | 40.9% (61) |
| Hepatic Dysfunction | 4.7% (14) | 8.1% (12) |
| Hypertension | 15.9% (47) | 16.8% (25) |
| Sepsis | 23.6% (70) | 15.4% (23) |
| Driveline Exit Site Infection | 19.6% (58) | 15.4% (23) |
| Stroke | 29.7% (88) | 12.1% (18) |
| Ischemic Cerebrovascular Event | 17.6% (52) | 8.1% (12) |
| Hemorrhagic Cerebrovascular Event | 14.9% (44) | 4.0% (6) |
| TIA | 8.4% (25) | 4.7% (7) |
| Renal Dysfunction | 14.9% (44) | 12.1% (18) |
| Respiratory Dysfunction | 29.1% (86) | 25.5% (38) |
| Right Heart Failure | 38.5% (114) | 26.8% (40) |
| Need for RVAD* | 2.7% (8) | 3.4% (5) |
| Pump Replacement | 7.8% (23) | 13.4% (20) |
| Exchange due to Pump Thrombosis | 6.4% (19) | 10.7% (16) |
| Device Malfunction or Failure | 31.4% (93) | 25.5% (38) |

*Event reported by site.
Abbreviations: GI - gastrointestinal; RVAD=right ventricular assist device; TIA= transient ischemic attack (<24 hours).
**Note**: The event of device thrombosis reported is not an INTERMACS-defined event.

## Stroke-related Deaths

Per CEC-adjudication, among the full AIP population 12.5% (37/296) of HVAD patients and 6.7% (10/149) of Control patients had stroke-related deaths (data lock date of May 30, 2017, all patients with follow-up > 4 years or censored). HVAD subjects in the ENDURANCE trial had a risk of death from stroke that was 87% greater than the risk of Control patients. The rate of stroke-related death within 2 years of implantation was 8.4% (25/296) for HVAD patients and 6.0% (9/149) for Control patients. The rate of later-onset stroke-related death (i.e., stroke occurring after 2 years of LVAD support) was 3.7% (11/296) for HVAD patients and 0.7% (1/149) for Control patients. The majority of HVADs which were involved with stroke-related deaths had sintered inlet cannulae

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# Appendix G: US Clinical Study: Destination Therapy (continued)

## Device Failures and Malfunctions

The incidence of device failures and device malfunctions within 730 days was 31.4% in the HVAD arm vs. 25.5% in the Control arm. The rates of pump thrombosis were similar in both arms, though sintering of the HVAD did appear to decrease this event. Device malfunctions related to controller faults were substantially more frequent in the HVAD arm.

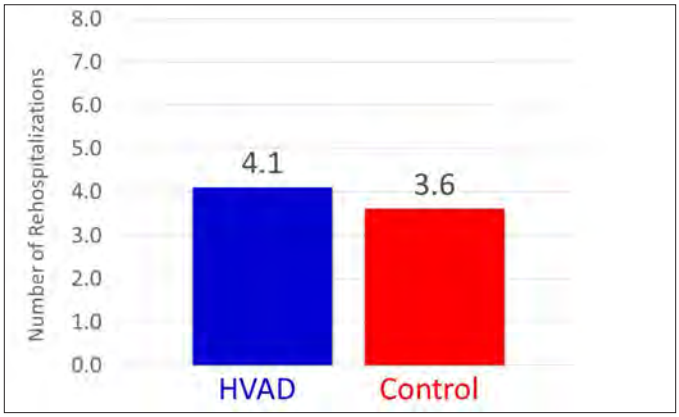
**Table 47: Device Failure or Malfunctions in the ENDURANCE Trial Expanded Dataset**

| Parameter | HVAD Sintered (N=200) | HVAD Non-Sintered (N=96) | Control (N=149) |
|---|---|---|---|
| **Based on CEC-Adjudication Data** | | | |
| Device Failure | 30.5% (61) | 33.3% (32) | 25.5% (38) |
| **Type of Device Malfunction** | | | |
| Controller fault | 10.0% (20) | 7.3% (7) | 2.7% (4) |
| Critical low battery | 0.0% (0) | 1.0% (1) | 0.7% (1) |
| Damaged battery | 1.0% (2) | 0.0% (0) | 0.0% (0) |
| Damaged cable | 2.5% (5) | 3.1% (3) | 4.0% (6) |
| Damaged controller | 2.0% (4) | 3.1% (3) | 0.0% (0) |
| Electrical fault | 2.0% (4) | 0.0% (0) | 0.0% (0) |
| Iatrogenic/Recipient-Induced Failure | 0.5% (1) | 0.0% (0) | 0.7% (1) |
| Insufficient battery charging | 1.5% (3) | 1.0% (1) | 0.0% (0) |
| Power disconnect | 2.5% (5) | 0.0% (0) | 1.3% (2) |
| Pump | 0.0% (0) | 0.0% (0) | 2.7% (4) |
| Pump Thrombosis | 10.0% (20) | 22.9% (22) | 11.4% (17) |
| Other | 4.5% (9) | 1.0% (1) | 3.4% (5) |

## Re-hospitalizations

The average number of re-hospitalizations within 730 days after the initial hospitalization was similar between the HVAD arm and the Control arm, as shown in **Figure 228**. For the AIP population, the HVAD subjects were re-hospitalized on average 4.1 times, compared to 3.6 times in the Control group.

**Figure 228: Average Number of Re-hospitalizations over Two Years in the ENDURANCE Trial Expanded Dataset**



# Appendix G: US Clinical Study: Destination Therapy (continued)

## Functional Status

Functional status was assessed by the NYHA classification and the 6-minute walk test (6MWT), as shown in **Figure 229** and **Figure 230**. Following LVAD implant, approximately 70-80% of subjects in both arms improved to NYHA classification I or II by Month 12. The median baseline 6-minute walk distance (6MWD) was 0 meters for both study and control subjects. At 3 months following LVAD implant, 6MWD increased to a median of 210 meters and 201 meters for study and control subjects, respectively. These improvements were sustained through two (2) years.

**Figure 229: ENDURANCE Trial Expanded Dataset Six-Minute Walk Test**

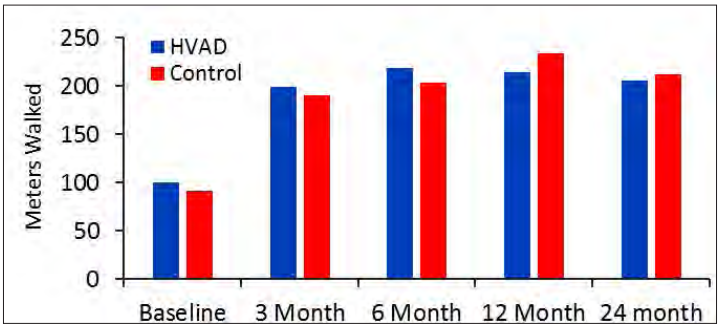
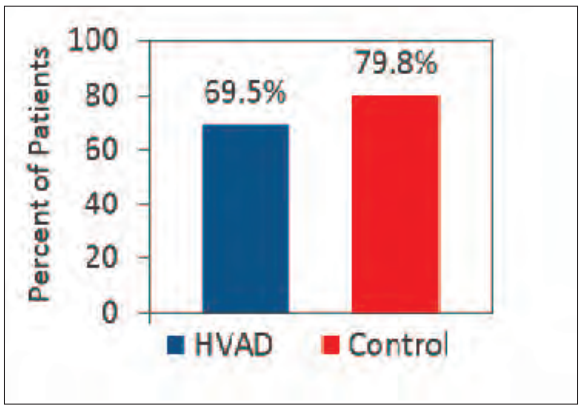



**Figure 230: ENDURANCE Trial Expanded Dataset NYHA Classification Improvement**

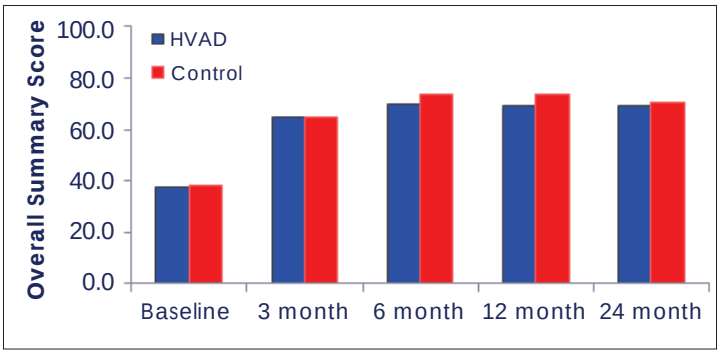



## Quality of Life

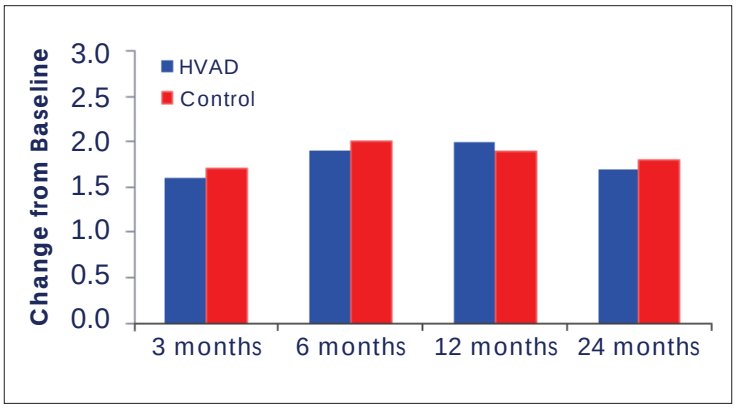
The quality of life was assessed by the EQ-5D-5L and the KCCQ questionnaires, as summarized in **Figure 231**. At baseline, subjects in both cohorts had poor quality of life and health status assessed by KCCQ and EuroQOL EQ-5D. At 3 months, median KCCQ score had improved by 27.3 points and 24.2 points for study and control subjects, respectively. EuroQOL EQ-5D VAS improved an average of 1.6 points at 3 months for subjects in the study arm and 1.7 points at 3 months for subjects in the control arm. Improvements in KCCQ and EuroQOL EQ-5D were sustained during the follow-up period.

**Figure 231: Improvements in Quality of Life and Functional Capacity in the ENDURANCE Trial Expanded Dataset. A) Change over time of the KCCQ Overall Summary Score. B) Change over baseline in the EQ-5D Visual Analog Scale.**

**A. KCCQ**




**B. EQ-5D**




## Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: gender, and BSA (< 1.5 $m^2$, ≥ 1.5 $m^2$). The pre-specified sub-group analyses showed no major clinical differences in outcomes based on gender or BSA.

### Conclusions from the ENDURANCE Destination Therapy Trial

The ENDURANCE trial did not meet its pre-specified primary endpoint, a demonstration of noninferiority of the HVAD to the control device for patients alive on original device at two (2) years free from disabling stroke (mRS ≥4). However, an adjunctive analysis using the full-enrollment dataset demonstrated similar endpoint results, with 57.4% success for control and 55% success for HVAD. Following LVAD implant, approximately 80% of subjects in both arms improved to NYHA classification I or II symptomatology. At 3 months following LVAD implant, median 6 minute walk distance increased in both arms (210 meters and 201 meters for study and control subjects, respectively). Patients in both arms also showed comparable improvement in quality of life from baseline to 3 months as measured by EQ-5D-5L and KCCQ, and the results were sustained through 2 years.

# Appendix H: Destination Therapy Supplemental Study (continued)

## A. Study Design

The objective of the ENDURANCE Supplemental trial was to evaluate the safety and effectiveness of a prospective blood pressure management strategy in HVAD DT patients. The purpose of implementing the prospective blood pressure management strategy was to investigate its effect on the stroke rates in HVAD subjects. The trial was a prospective, randomized, controlled, un-blinded, multicenter clinical study. Subjects were randomly assigned using a permuted block, central randomization scheme, in a 2:1 ratio, to receive either the study (HVAD) or control (HeartMate II) device. All HVAD subjects, in addition to receiving standard of care management, were required to adhere to a blood pressure management protocol that aimed to maintain mean arterial pressure (MAP) ≤ 85 mmHg (automated pneumatic cuff method) or < 90 mmHg (Doppler cuff method). Control patients were not managed with a blood pressure management protocol.

Patients in the ENDURANCE Supplemental trial were enrolled between October 25, 2013 and August 7, 2015. 475 subjects were randomized, with 465 patients implanted at 47 investigational sites.

Similar to the ENDURANCE trial, the ENDURANCE Supplemental trial was conducted under the oversight of an independent Clinical Events Committee (CEC) and monitored by an independent Data Safety Monitoring Board.

The Modified Intent-to-Treat Population (mITT; Total N=465; HVAD, N=308 and Control, N=157) included all subjects who received a device. It was analyzed according to the device to which the subjects were randomized.

All safety analyses were performed on the safety population (SAF), which assigned subjects to the device they actually received. The SAF was equivalent to the mITT population.

The Complete Case Population includes all subjects in the mITT population except those who withdraw, are lost to follow-up, or have missing outcomes (any subject with missing post-event mRS) on original device. It differs for each objective. For the primary endpoint, the Complete Case Population was defined as the mITT population excluding any subjects who withdrew or were lost to follow-up, and any subjects who were missing CEC-adjudicated mRS scores (both day of event and 24 weeks post-event) for the latest stroke event on original device. For the secondary endpoint of stroke/TIA incidence at 12 months on the originally implanted HVAD, the Complete Case Population was defined as the mITT population excluding the subjects who withdrew or were lost to follow-up. For the secondary endpoint of stroke-free success (mRS < 4 at 24 weeks post-stroke) at 12 months, the Complete Case Population was defined as the mITT population excluding subjects who withdrew or were lost to follow-up, and those subjects who were missing a 24 week mRS score for their last stroke on original device (within 1 year post original implant).

### 1. Clinical Inclusion and Exclusion Criteria

Enrollment in the ENDURANCE Supplemental trial was limited to patients who met the same inclusion and exclusion criteria as in the ENDURANCE trial.

### 2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 3 and 6 months with a window of ± 7 days, at 12 months with a window of + 7 days, and at 18, 24, 30, 36, 42, 48, 54, and 60 months with a window of ± 14 days postoperatively.

The pre- and post-operative assessments were the same as in the ENDURANCE trial.

### 3. Clinical Endpoints

The primary endpoint was the incidence of neurologic injury at 12 months. Neurologic injury was defined as an ICVA or HCVA with mRS > 0 at 24 weeks post-stroke, or a TIA, or as a spinal cord infarct (SCI).

# Appendix H: Destination Therapy Supplemental Study (continued)

The HVAD was to be considered non-inferior to the HeartMate II if the upper bound of the two-sided 90% exact binomial confidence interval of the difference in the primary endpoint between the HVAD arm and the control arm was less than 6%.

There were two secondary endpoints. The first secondary endpoint was incidence of HVAD stroke or TIA by 12 months on the originally implanted HVAD. Unlike the primary endpoint, this secondary endpoint included those strokes that were classified as mRS=0 at 24 weeks post-stroke. This endpoint was to be tested by comparison to a performance goal of 17.7%; the performance goal was equivalent to the lower 95% confidence interval of the one-year stroke or TIA rate among sintered HVAD patients in the ENDURANCE trial.

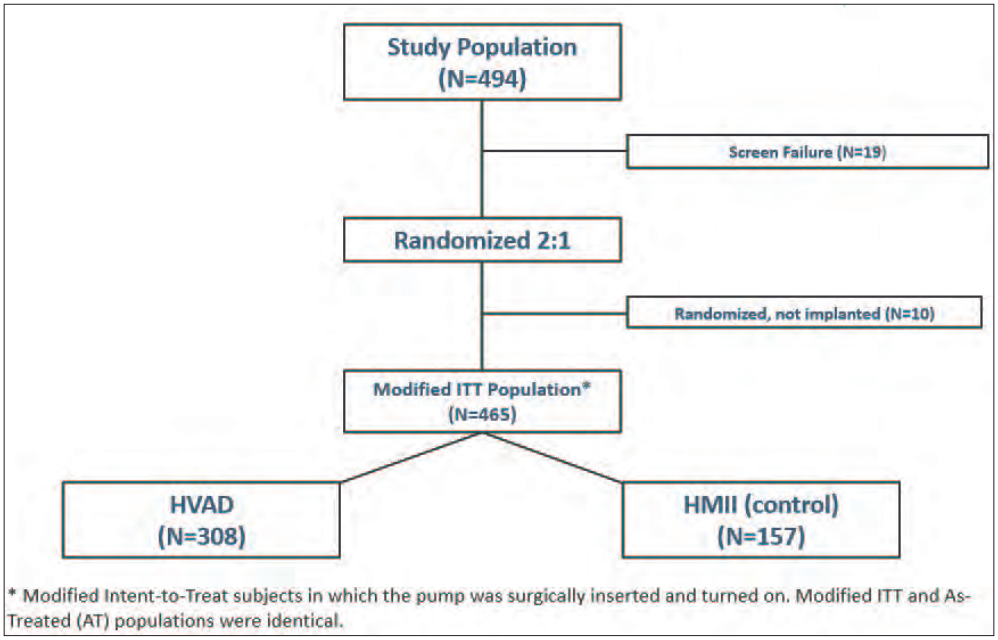
The second secondary effectiveness endpoint was analogous to the ENDURANCE trial's primary endpoint, in that it compared the composite of stroke-free (mRS < 4 at 24 weeks post-stroke) survival while on the original device between HVAD and Control arms; however, the time point for this endpoint was one year, unlike the ENDURANCE trial's 2-year endpoint. This endpoint was to test for non-inferiority of the HVAD to the control device, with a non-inferiority margin of 15%.

Additional endpoints included adverse events, device malfunctions and failures, as well as health status and functional improvements.

### B. Accountability of PMA Cohort

At the time of database lock, of the 494 patients enrolled in the ENDURANCE Supplemental trial, 93.7% (463) patients were available for analysis of the primary objective at the completion of the study, the 12-month post-operative visit. The disposition of the patients is shown in **Figure 232**.

**Figure 232: Disposition of Subjects in the ENDURANCE Supplemental Trial**




The Modified Intent-to-Treat Population (mITT; Total N=465; HVAD, N=308 and Control, N=157) included all subjects who received a device. It was analyzed according to the device to which the subjects were randomized.

All safety analyses were performed on the safety population (SAF), which assigned subjects to the device they actually received. The SAF was equivalent to the mITT population.

# Appendix H: Destination Therapy Supplemental Study (continued)

The Complete Case Population includes all subjects in the mITT population except those who withdraw, are lost to follow-up, or have missing outcomes (any subject with missing post-event mRS) on original device. It differs for each objective. For the primary endpoint, the Complete Case Population was defined as the mITT population excluding any subjects who withdrew or were lost to follow-up, and any subjects who were missing CEC-adjudicated mRS scores (both day of event and 24 weeks post-event) for the latest stroke event on original device. For the secondary endpoint of stroke/TIA incidence at 12 months on the originally implanted HVAD, the Complete Case Population was defined as the mITT population excluding the subjects who withdrew or were lost to follow-up. For the secondary endpoint of stroke-free success (mRS < 4 at 24 weeks post-stroke) at 12 months, the Complete Case Population was defined as the mITT population excluding subjects who withdrew or were lost to follow-up, and those subjects who were missing a 24 week mRS score for their last stroke on original device (within 1 year post original implant).

**C. Study Population Demographics and Baseline Parameters**

The demographics and baseline characteristics of the study population, as summarized in **Table 48**, are typical for an LVAD study performed in the U.S. The baseline characteristics of the two (2) arms were similar; there was no clinically significant difference in the severity of illness or treatments at the time of enrollment.

# Appendix H: Destination Therapy Supplemental Study (continued)

**Table 48: Patient Demographics and Baseline Characteristics in the ENDURANCE Supplemental Trial.**

| Demographics and Baseline Characteristics | HVAD (N=308) | Control (N=157) | P-value |
|---|---|---|---|
| Age (years) | 63.3 ± 11.4 | 64.2 ± 11.1 | 0.39 |
| Female gender (%) | 18.2% | 20.4% | 0.62 |
| Race (% White) | 71.8% | 75.2% | 0.51 |
| Height (cm) | 175.0 ± 9.4 | 175.1 ± 9.8 | 0.91 |
| Body Mass Index (kg/m$^2$) | 28.2 ± 5.5 | 27.4 ± 5.2 | 0.13 |
| INTERMACS Profile (%) | | | 0.90 |
| 1 | 3.9% | 2.5% | |
| 2 | 32.8% | 32.5% | |
| 3 | 43.3% | 43.3% | |
| 4 - 7 | 20.0% | 21.7% | |
| Ischemic Etiology of Heart Failure | 55.2% | 58.0% | 0.62 |
| History of smoking | 68.2% | 65.6% | 0.60 |
| Diabetic | 49.4% | 48.4% | 0.92 |
| Previous Stroke | 10.4% | 8.3% | 0.51 |
| Hypertension requiring medication | 75.0% | 72.0% | 0.50 |
| Atrial Fibrillation | 50.6% | 51.0% | > 0.99 |
| Mean arterial blood pressure (mmHg) | 78.9 ± 11.5 (N=296) | 77.6 ± 11.1 (N=153) | 0.23 |
| Tricuspid regurgitation (≥ moderate) | 40.4% (N=302) | 44.2% (N=154) | 0.48 |
| Left ventricular ejection fraction (LVEF, %) | 17.3 ± 5.1 | 18.2 ± 4.5 | 0.07 |
| Previous intervention (%) | | | |
| ICD | 80.8% | 82.2% | 0.80 |
| CRT | 28.9% | 28.7% | > 0.99 |
| IABP | 19.2% | 15.9% | 0.45 |

Abbreviations: CRT=cardiac resynchronization therapy; ICD=implantable cardioverter defibrillator; LVEF=left ventricular ejection fraction.

**Note**: P-values are post-hoc and are included for information purposes only.

P-values comparing categorical values are from the Fisher's Exact Test. P-values comparing continuous values are from a two-sample t-test.

# Appendix H: Destination Therapy Supplemental Study (continued)

## D. Safety and Effectiveness Results

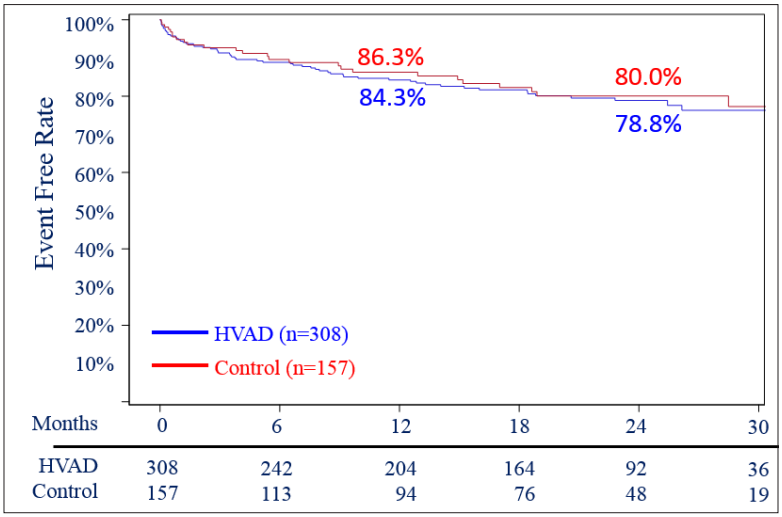
### 1. Primary Endpoint

The outcome and analysis of the primary endpoint are shown in **Table 49** and **Figure 233**. The results show that 14.7% of the HVAD subjects experienced endpoint-defined neurologic injury as compared to 12.1% of the control subjects, with a difference of 2.6% between the two arms. The upper bound of the two-sided 90% exact binomial confidence interval of the difference in the neurologic injury incidence was 10.7%, which was above the pre-specified non-inferiority margin of 6%. Thus, the primary endpoint of the ENDURANCE Supplemental trial was not met.

**Table 49: Analyses of the Primary Endpoint**

| | HVAD (N=308) | Control (N=157) |
|---|---|---|
| Number of subjects who had a stroke/TIA at 12 months | 58 | 24 |
| Number of subjects who had a stroke at 12 months | 51 | 23 |
| Number of subjects who had a TIA at 12 months | 13 | 1 |
| Number of subjects who had mRS > 0 at 24 weeks post-stroke | 38 | 18 |
| Number of subjects who had spinal cord infarction at 12 months | 0 | 0 |
| Number of subjects with endpoint-defined neurologic injury events at 12 months | 45 (14.7%) | 19 (12.1%) |
| Difference of neurologic injury incidence | 2.6% | |
| Two-sided 90% confidence interval | [-5.5%, 10.7%] | |
| Non-inferiority criteria | Fail | |
| p-value | 0.1444 | |

**Figure 233: ENDURANCE Supplemental Trial Primary Endpoint Survival**

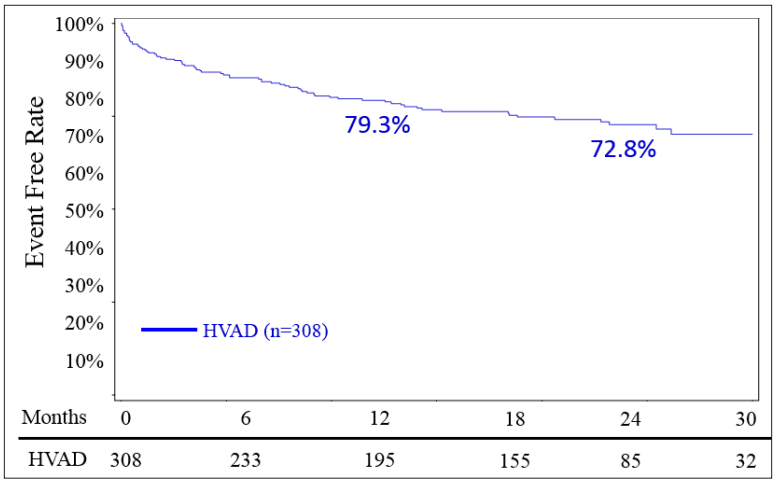


# Appendix H: Destination Therapy Supplemental Study (continued)

### 2. Secondary Endpoints

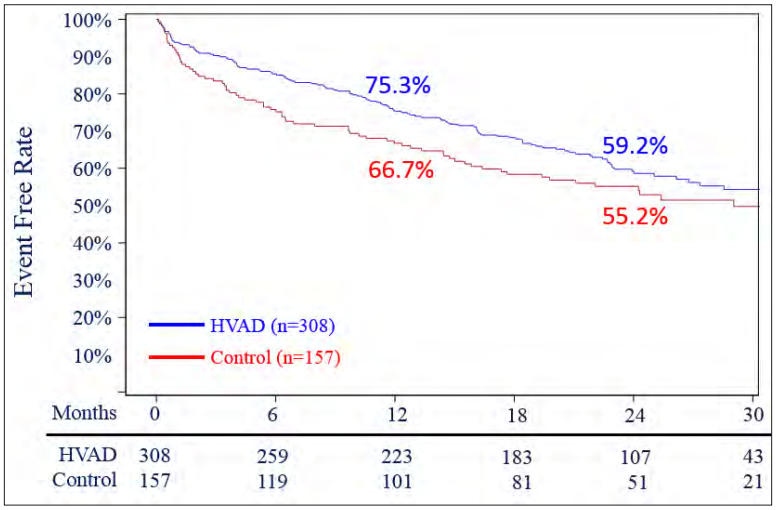
Because the primary endpoint was not met, the hypotheses associated with the secondary endpoints of stroke/TIA incidence and stroke-free success rate could not be tested. Thus, only descriptive data are presented for the two secondary endpoints. The incidence of stroke/TIA (inclusive of strokes with mRS = 0 at the 24 week time point) in HVAD patients was 19.2% at 12 months. The Time to event curve is shown in **Figure 234**.

**Figure 234: ENDURANCE Supplemental Trial Survival Free from Stroke or TIA**




The proportion of subjects who survived to one year on the original device in the absence of "disabling" stroke (mRS ≥4), death, device exchange or urgent transplantation was 75.3% in the HVAD arm and 66.7% in the Control arm. A freedom from event analysis is shown in **Figure 235**, using data from March 27, 2017. The magnitude of the rate differential for this composite decreased with follow-up more analogous to the ENDURANCE trial's 2-year endpoint time frame.

**Figure 235: ENDURANCE Supplemental Trial Survival Free from Death, Disabling Stroke or Device Malfunction/ Failure Requiring Exchange**



# Appendix H: Destination Therapy Supplemental Study (continued)

In the ENDURANCE Supplemental trial, freedom from ischemic stroke was numerically greater in the Control arm, as shown in **Figure 236**; freedom from hemorrhagic stroke was similar in HVAD and Control, as shown in **Figure 237**.

**Figure 236: ENDURANCE Supplemental Trial Survival Free from Ischemic Stroke**

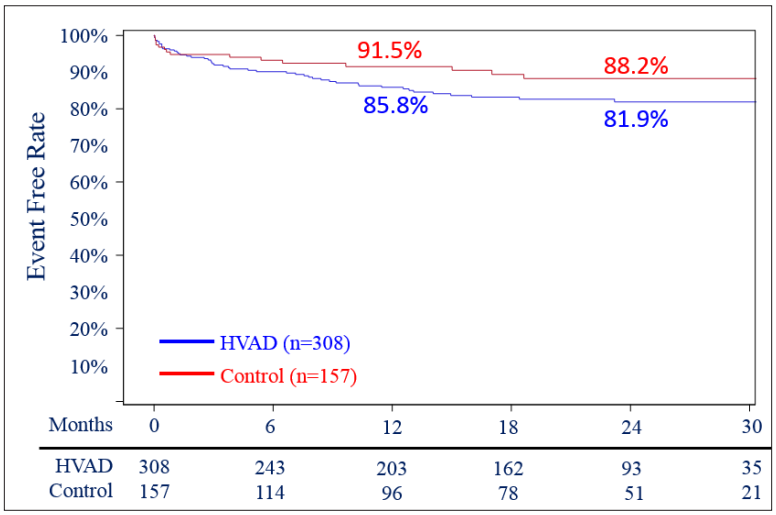
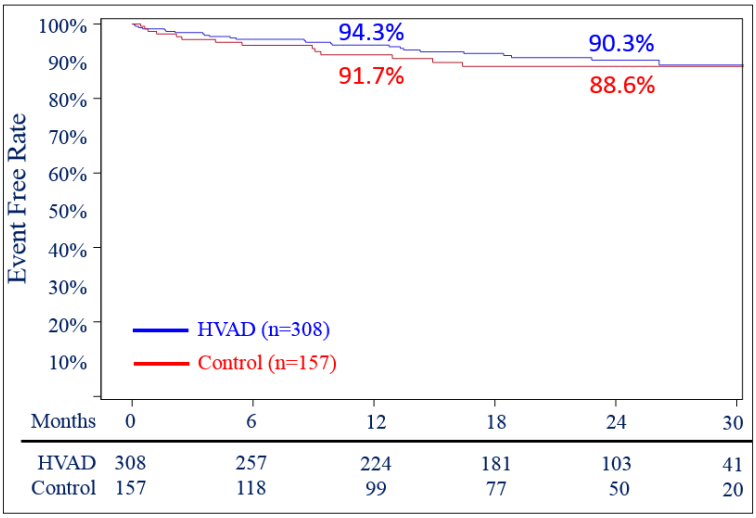



**Figure 237: ENDURANCE Supplemental Trial Survival Free from Hemorrhagic Stroke**



# Appendix H: Destination Therapy Supplemental Study (continued)

### 3. Adverse Events

**Table 50** lists all the adverse events that occurred in the safety cohort.

**Table 50: Summary of Adverse Events at 1 Year in the ENDURANCE Supplemental Trial.**

| Adverse Event | HVAD (N=308) | Control (N=157) |
|---|---|---|
| Major Bleeding | 51.6% (159) | 56.7% (89) |
| Cardiac Arrhythmia | 34.1% (105) | 31.2% (49) |
| Hepatic Dysfunction | 3.9% (12) | 3.8% (6) |
| Hypertension | 13.0% (40) | 12.7% (20) |
| Major Infection | 53.9% (166) | 59.2% (93) |
| Driveline Exit Site Infection | 16.2% (50) | 12.1% (19) |
| Device Malfunction/Failure | 24.0% (74) | 24.2% (38) |
| Hemolysis | 1.3% (4) | 5.7% (9) |
| Stroke | 16.9% (52) | 14.6% (23) |
| Ischemic Cerebrovascular Event | 13.0% (40) | 7.6% (12) |
| Hemorrhagic Cerebrovascular Event | 5.2% (16) | 7.0% (11) |
| TIA | 4.2% (13) | 0.6% (1) |
| Renal Dysfunction | 10.4% (32) | 14.6% (23) |
| Respiratory Failure | 19.8% (61) | 19.7% (31) |
| Right Heart Failure | 35.4% (109) | 38.2% (60) |
| Pump Replacement | 5.2% (16) | 11.5% (18) |
| Exchange for Pump Thrombosis | 4.5% (14) | 10.2% (16) |

## Stroke-related Deaths

Within the mITT population, the CEC-adjudicated rate of stroke-related death within 1 year of implantation was 3.2% (10/308) for HVAD patients and 2.5% (4/157) for Control patients.

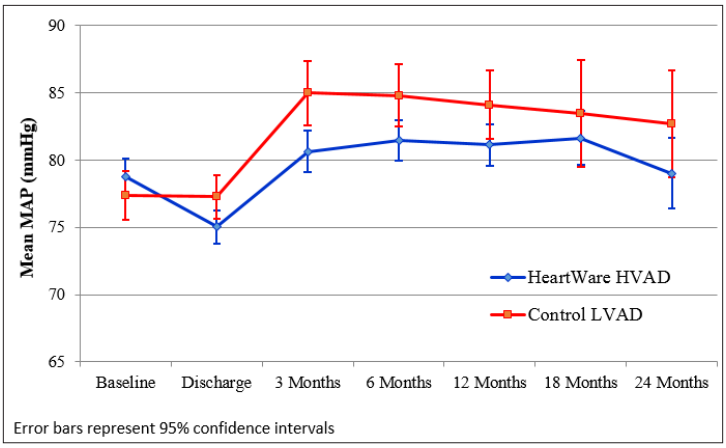
Comparing the results of ENDURANCE and ENDURANCE Supplemental, the rates of stroke-related death decreased by the same proportions (approximately 58%) for both HVAD and Control arms; only the HVAD arm was exposed to the trial's investigational intervention of a blood pressure management protocol. The stroke-related deaths are compared in **Table 51**. The mean arterial pressure (MAP) over time from the ENDURANCE Supplemental trial for the HVAD compared to the Control is shown in **Figure 238**.

**Table 51: Stroke-related Deaths in ENDURANCE and ENDURANCE Supplemental Trials**

| | ENDURANCE Within 2 years of implant (AIP) | ENDURANCE Supplemental Within 1 year of implant (mITT) |
|---|---|---|
| HVAD | 25/296 (8.4%) | 10/308 (3.2%) |
| HMII (control) | 9/149 (6.0%) | 4/157 (2.5%) |

# Appendix H: Destination Therapy Supplemental Study (continued)

**Figure 238: ENDURANCE Supplemental Trial MAP over Time**

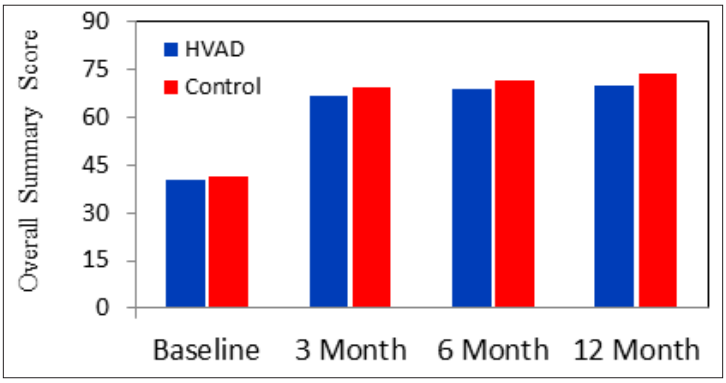



## Health Status and Functional Improvements

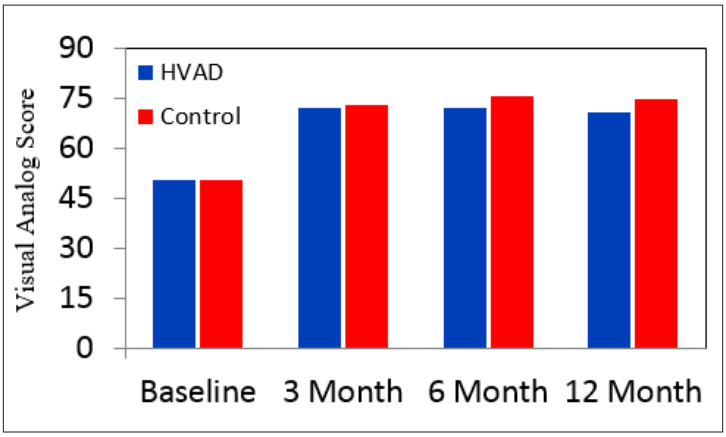
The improvements in quality of life, as measured by the KCCQ and EQ-5D-5L, and functional capacity, as measured by the 6 minute walk test and NYHA Classification improvement, in the ENDURANCE Supplement trial patients are presented in **Figure 239**.

**Figure 239: Improvements in Quality of Life and Functional Capacity in ENDURANCE Supplemental Subjects. A) Change over time of the KCCQ Overall Summary Score. B) Change over time in the EQ- 5D Visual Analog Scale. C) Change over time of total distance walked in the Six Minute Walk Test. D) Percent of patients with a classification increase of 2 or more in NYHA Classification at 12 months compared to baseline.**

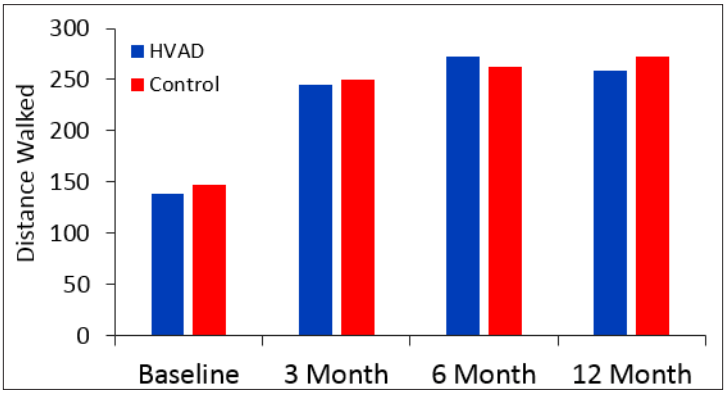
**A. KCCQ**



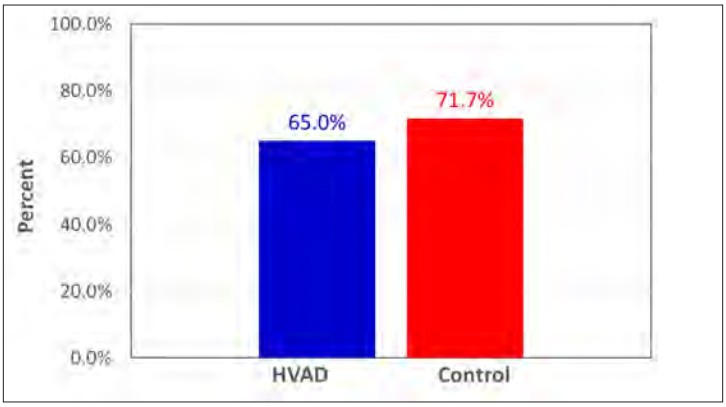
**B. EQ-5D**




**C. Six-Minute Walk**

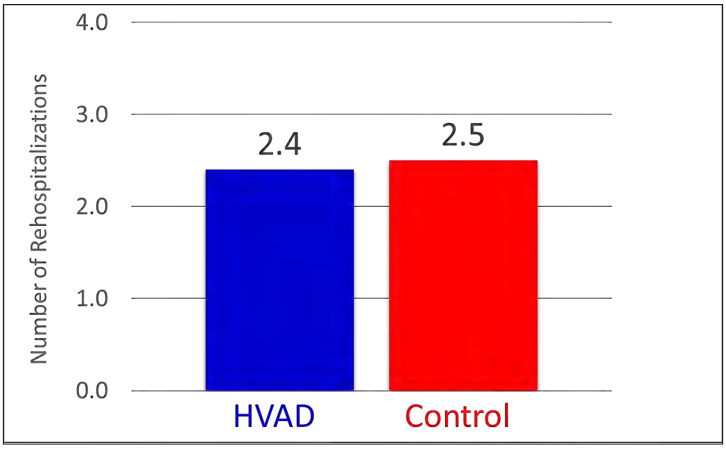



**D. NYHA Classification Improvement**



# Appendix H: Destination Therapy Supplemental Study (continued)

**Figure 240: Average Number of Re-hospitalizations in the First-Year Post-Implant in the ENDURANCE Supplemental Trial**




## Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: gender, BSA (<1.5 $m^2$, ≥1.5 $m^2$). No associations to outcomes of the primary and secondary endpoints were found for these two preoperative characteristics.

**Conclusions from the ENDURANCE Destination Therapy Supplemental Trial**

The ENDURANCE Supplemental trial did not meet its pre-specified primary endpoint, a demonstration of non-inferiority of the HVAD to the control device for freedom from neurologic injury (stroke with mRS >0 at 24 weeks post stroke or a transient ischemic attack) at 12 months (HVAD: 14.7% vs control: 12.1%). The combined rate of stroke and TIA in HVAD patients at one year did not meet a performance goal derived from the rate observed in ENDURANCE. Survival at 1 year free from the composite of disabling stroke or device exchange favored the HeartWare HVAD System (HVAD: 75.3% vs control: 66.7%), though the trend diminished in magnitude over time (at 2 years, HVAD: 59.2% vs Control: 55.2%). The HVAD System and Control both demonstrated sustained improvements in quality of life, functional capacity, and NYHA classification. Finally, although the HVAD failed to demonstrate non-inferiority compared to Control for incidence of neurological injury at one year, the implementation of a blood pressure management strategy for HVAD recipients did demonstrate a reduction in the overall stroke rates in patients receiving an HVAD System in the ENDURANCE Supplemental trial as compared to the first ENDURANCE trial.

# Appendix H: Destination Therapy Supplemental Study (continued)

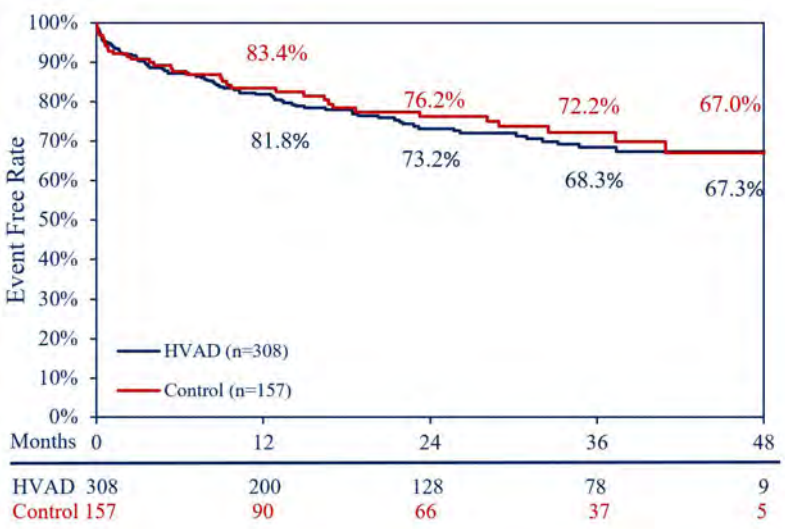
**Additional long-term follow-up from the ENDURANCE Destination Therapy Supplemental Trial**

As of July 30, 2018 additional long-term data from the ENDURANCE Supplemental trial showed the comparative incidences and event-rates for adverse events between the HVAD and Control groups remained similar to those observed in the initial data analysis. The incidence of TIA in the HVAD cohort (9.1%) is significantly higher than the Control cohort (3.8%). However, the overall myocardial infarction event rate was statistically higher in the Control group, while the overall ICVA event rate was statistically higher in the HVAD group. So, while it appears that the number of subjects having ICVA events is similar, HVAD subjects are more frequently having multiple occurrences of these events.

There was no statistically significant difference between treatments for freedom from thrombus on original device, freedom from exchange, freedom from stroke on original device, freedom from ICVA on original device, or freedom from HCVA on original device.

The Kaplan-Meier estimates for freedom from CEC adjudicated stroke, ICVA and HCVA on original device are shown in **Figure 241, Figure 242,** and **Figure 243**, below. The log-rank p-values show no significant differences between HVAD and Control for stroke, ICVA, or HCVA.

**Figure 241: ENDURANCE Supplemental Trial Freedom from Stroke on Original Device**



# Appendix H: Destination Therapy Supplemental Study (continued)

**Figure 242: ENDURANCE Supplemental Trial Freedom from ICVA on Original Device**

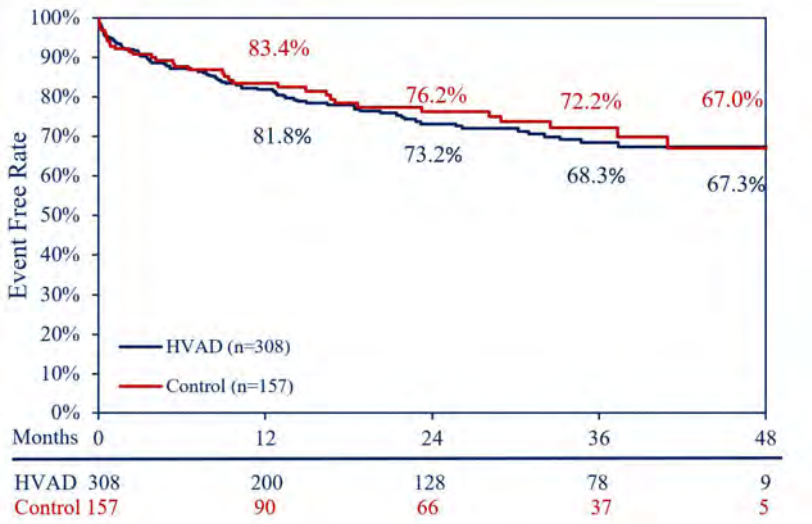



**Figure 243: ENDURANCE Supplemental Trial Freedom from HCVA on Original Device**

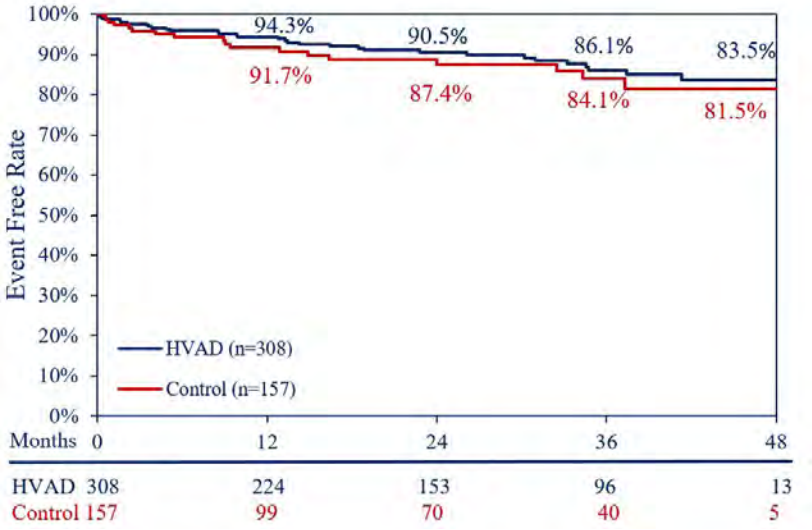
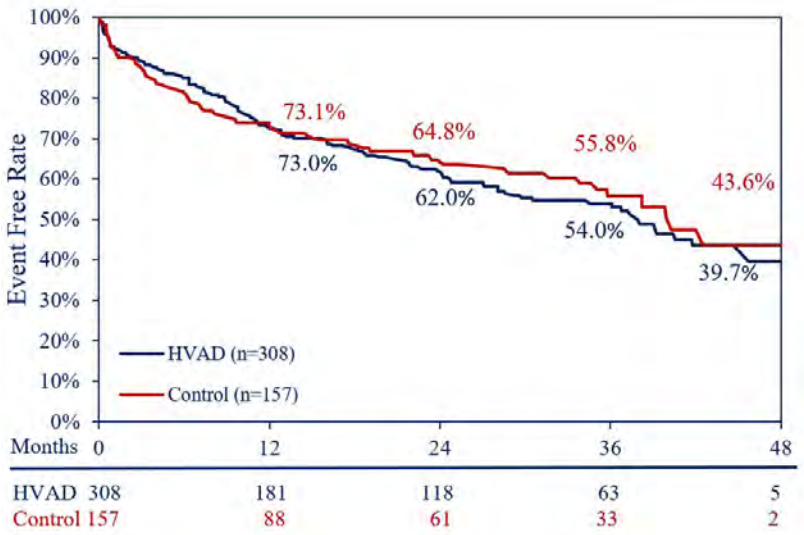
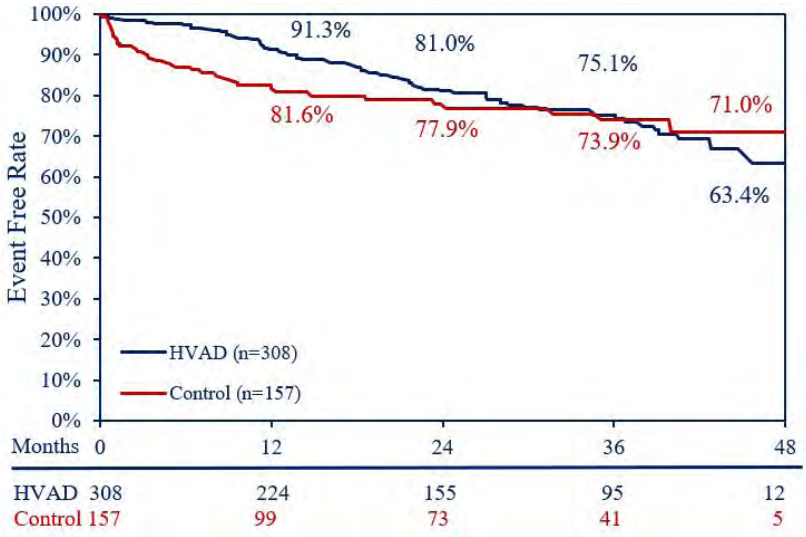


**Figure 244: ENDURANCE Supplemental Trial Time to Device Malfunction**



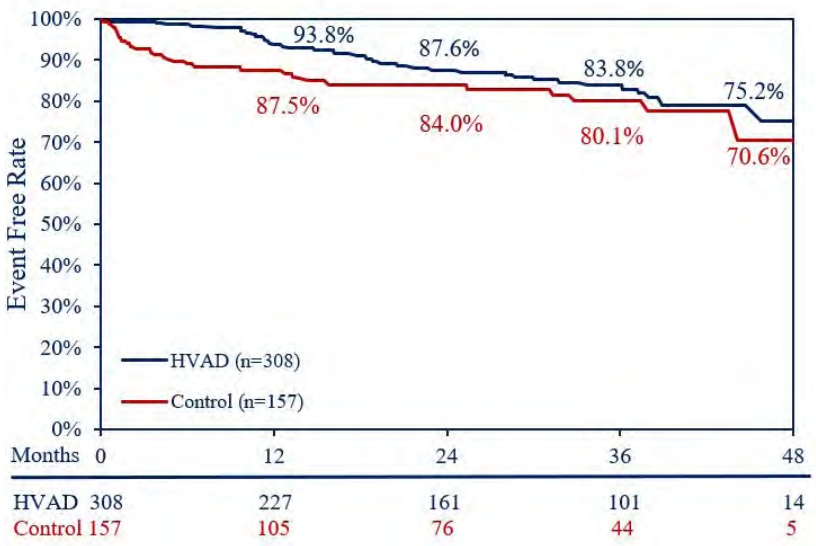

While the incidence of device malfunction/failure was numerically higher in the HVAD group (39.9% vs. 36.9%), the incidence of pump thrombosis and pump replacement was numerically higher in the Control group (21.0% vs. 20.1%, and 17.2% vs. 13.3%, respectively). Kaplan-Meier estimates for freedom from thrombus on original device are presented in **Figure 245** below. There is no significant difference between the two groups.

**Figure 245: ENDURANCE Supplemental Trial Freedom from Thrombus on Original Device**



# Appendix H: Destination Therapy Supplemental Study (continued)

**Figure 246: ENDURANCE Supplemental Trial Freedom From Exchange**




Overall, the incidences of the adverse events still appear similar between the two groups.

**Table 52: Summary of Adverse Events on Original Device in the ENDURANCE Supplemental Trial**

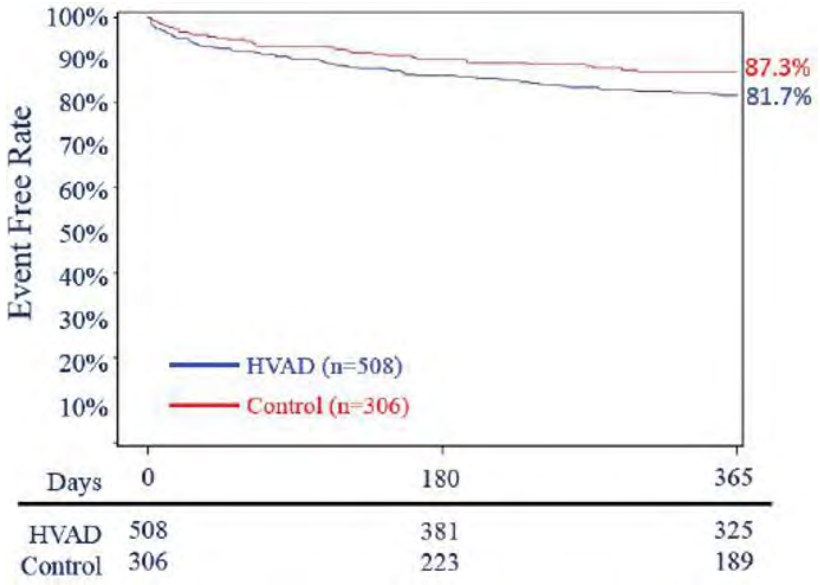
| Adverse Event | HVAD (N=308) | Control (N=157) |
|---|---|---|
| Major Bleeding | 63.6% (190) | 66.2% (104) |
| Cardiac Arrhythmia | 39.% (122) | 36.3% (57) |
| Hepatic Dysfunction | 5.8% (18) | 5.1% (8) |
| Hypertension | 14.3% (44) | 15.9% (25) |
| Major Infection | 73.7% (227) | 73.2% (115) |
| Device Malfunction/Failure | 39.9% (114) | 36.9% (58) |
| Pump Thrombosis | 20.1% (62) | 21.0% (33) |
| Hemolysis | 7.1% (22) | 6.4% (10) |
| Stroke | 25.3% (78) | 22.3% (35) |
| Ischemic Cerebrovascular Event | 17.5% (54) | 12.7% (20) |
| Hemorrhagic Cerebrovascular Event | 10.4% (32) | 11.5% (18) |
| TIA | 9.1% (28) | 3.8% (6) |
| Renal Dysfunction | 14.6% (45) | 20.4% (32) |
| Respiratory Failure | 24.0% (74) | 28.7% (45) |
| Right Heart Failure | 36.7% (113) | 40.8% (64) |
| Pump Replacement | 12.3% (38) | 17.2% (27) |

# **Appendix H:** Destination Therapy Supplemental Study (continued)

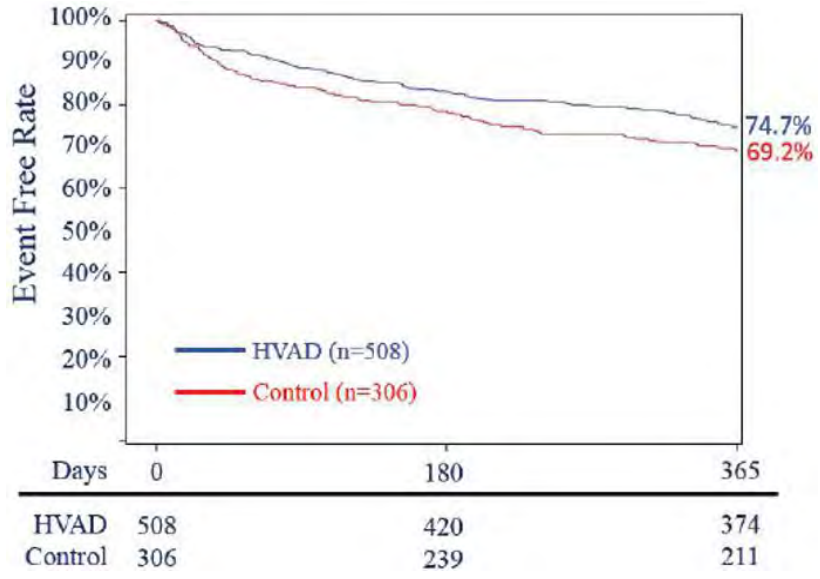
Additional post hoc one-year comparisons of all sintered HVADS (pooled from both ENDURANCE and ENDURANCE-Supplemental) to pooled Control subjects were also performed, and analyzed against the primary endpoint definition of the ENDURANCE Trial (at one year, **Figure 247B**) and against the primary endpoint of the ENDURANCE Supplemental Trial **(Figure 247A).**

An Analysis of Patients Receiving Sintered HVAD® Pumps (Pooled ENDURANCE and ENDURANCE Supplemental) Compared to Control. A) the Primary Endpoint of the ENDURANCE Supplemental Trial, and B) the Primary Endpoint of the ENDURANCE Trial at 1 year.

**Figure 247: A:** Survival on Original Device Free from Neurologic Events (Strokes with mRS>0, TIA or SCI)




**B:** Survival on Original Device Free from Disabling Stroke (mRS ≥4)



# Appendix H: Destination Therapy Supplemental Study (continued)

**Overall Conclusions**

The overall safety comparisons in both the ENDURANCE and ENDURANCE Supplemental trials resulted in similar mortality rates and adverse event profiles. Pump thrombosis rates for the sintered HVAD and the Control LVAD were similar, but a higher proportion of Control pump thrombosis events resulted in device exchange. The incidence of stroke was 2.5 times higher in the patients receiving an HVAD compared to control in the ENDURANCE trial. The ENDURANCE Supplemental trial, which included implementation of a blood pressure management strategy for HVAD recipients, demonstrated a reduction in the overall stroke rates in patients receiving an HVAD System, although a reduction in overall stroke rates was also demonstrated in Control patients who were not subject to the blood pressure management strategy. In ENDURANCE Supplemental, the HVAD failed to demonstrate non-inferiority compared to Control for incidence of neurological injury at one year.

The data supports the reasonable assurance of safety and effectiveness of the HeartWare HVAD System for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a bridge to cardiac transplantation (BTT), myocardial recovery, or as destination therapy (DT) in patients for whom subsequent transplantation is not planned.

# **Appendix I:** North American Clinical Study: LATERAL

## HeartWare HVAD System Clinical Trial Overview: LATERAL Trial

This was a multi-center, prospective, open-label non-randomized single arm trial conducted in collaboration with the InterAgency Registry for Mechanically Assisted Circulatory Support (INTERMACS®) to Evaluate the Thoracotomy Implant Technique of the HVAD System in Patients with Advanced Heart Failure. Enrollment in the study is complete, subjects have all reached the primary endpoint as described and specified in the protocol, but follow-up of subjects is ongoing.

### A. Study Design

Patients were enrolled between January 15, 2015 and April 26, 2016. The study data was collected through June 15, 2017 and included 144 subjects treated per protocol who were enrolled at 26 investigational sites.

The study was a prospective, single arm, multi-center clinical study in collaboration with the InterAgency Registry for Mechanically Assisted Circulatory Support (INTERMACS®) to evaluate the thoracotomy implant technique of the HeartWare HVAD System in patients with advanced heart failure. The study device was the HVAD (HeartWare Ventricular Assist Device) System. The treatment was open-label.

Following implantation, device performance, follow-up visits and visit windows for the LATERAL Study are dictated by the INTERMACS protocol.

Adverse events (AE) were reported through INTERMACS, according to the INTERMACS AE definitions. An independent Data Safety Monitoring Board monitored and reviewed study compliance, adverse events and outcomes.

An NHLBI-appointed (independent) Observational Study Monitoring Board (OSMB) was established in 2006 and meets, at minimum, on an annual basis. The principal role of the OSMB is to monitor data from the Registry, review and assess the performance of its operations, assure patient safety, and make recommendations to the NHLBI and INTERMACS co-investigators.

### 1. Clinical Inclusion and Exclusion Criteria

Enrollment in the LATERAL Study was limited to subjects who met the following inclusion criteria:

-- Subjects >19 years old with chronic, advanced left ventricular failure who were transplant eligible at the time of enrollment in whom informed consent was obtained.

Subjects were not permitted to enroll in the LATERAL Study if they met any of the following exclusion criteria:

- Subjects with a body surface area < 1.2 $m^2$
- Subjects with prior cardiac transplant
- Subjects with a mechanical heart valve
- Subjects with severe right heart failure or receiving biventricular or the device as a right ventricular assist device
- Subjects with a planned concurrent procedure
- Subjects with known LV thrombus
- Additional exclusion criteria are available in the Clinical Study Report.

# Appendix I: North American Clinical Study: LATERAL (continued)

### 2. Follow-up Schedule

Preoperative baseline assessments included demographics, medical history, concurrent medications, laboratory tests, echocardiogram, NYHA, neurocognitive status, quality of life, and functional status.

All patients were scheduled to return for follow-up examinations at Week 1 ± 3 days, Month 1 ± 7 days, Month 3 ± 30 days, Month 6 ± 60 days (primary endpoint), and every 6 months ± 60 days through 5 years of follow-up.

Week 1 and Month 1 visits included clinical laboratory tests for hematology, chemistry and INR, LVAD parameters, concurrent medications, echocardiogram, and assessments of NYHA. Months 3, 6 and onward also included health status, six-minute walk and an assessment of neurocognitive status.

Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

### 3. Clinical Endpoints

The primary endpoint was a composite of six-month survival free of disabling stroke (i.e., modified Rankin score ≥ 4 assessed 12 weeks post-event), while alive on the originally implanted device, transplanted or explanted due to left ventricular recovery.

Success in meeting the primary endpoint was tested comparing to a performance goal (77.5%) using a one-sided exact binomial test. Success will be met if the lower bound of the one-sided exact 95% confidence limit is greater than 77.5%. Success at six months is estimated to be 86% compared to a performance goal of 77.5%. The target success estimate was based on the primary endpoint observed in the ADVANCE BTT+CAP Trial, post-approval data on HVAD outcomes from the INTERMACS Registry (through Q2 2014), and the INTERMACS report from Q1 2014 indicating an 85% survival estimate with LVAD support. Using an exact binomial test, with a one-sided alpha of 0.05, and 80% Power, a sample size of 145 implanted subjects was planned.

The prespecified secondary endpoint is an improvement in the mean length of initial hospital stay as compared to a performance goal of median sternotomy subjects. The mean length of initial hospital stay is estimated to be 26.1 days with a standard deviation of 22.8 days and a median of 20 days based on data from the Bridge-to-Transplantation Continued Access Protocol (BTT CAP) population (N=242). Using a one sample t-test, with a one-sided alpha of 0.05, a sample of 145 implanted subjects with an average value of 21.3 days or less will result in Power greater than 80%.

Other secondary endpoints included the incidence of major adverse events (classified according to the INTERMACS definitions), overall survival, changes in quality of life and health status as assessed by the KCCQ and the EQ-5D VAS, and functional status, as measured by NYHA functional classification and 6-minute walk distance. The safety analysis focused on adverse events. Survival analysis was performed using the Kaplan-Meier method.

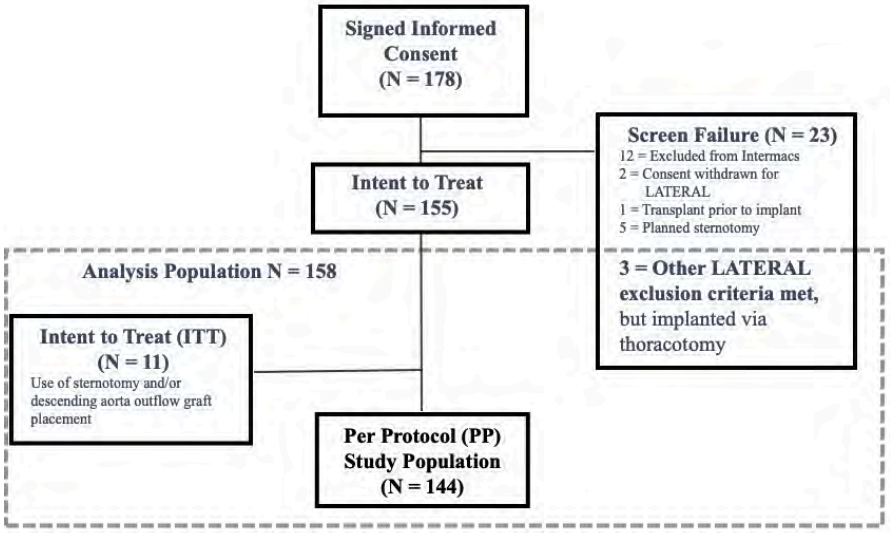
With regards to safety, predetermined secondary endpoints included the incidence of bleeding, major infections, and overall survival. Additionally, incidence of device malfunctions/failures, quality of life and health status changes, as well as major adverse events (classified according to the INTERMACS definitions) were analyzed.

### B. Accountability of Cohort

At the time of the data cut-off for this analysis (June 15, 2017), of the 178 patients enrolled in the LATERAL study, with 158 subjects qualifying for the analysis population, 98.7% (156) subjects were available for analysis of the primary objective at the completion of the study, the 6-month post-operative visit. The disposition of patients is shown in **Figure 248**.

The primary analysis population is the Per Protocol (PP) population, including a total of 144 subjects implanted with an HVAD via a thoracotomy approach and meeting all inclusion criteria without violating any exclusion criteria. The mean duration of subjects on original device in the PP population is 12.1 months. Eleven (11) additional subjects were included in the intent-to-treat population. Of the 23 screen failures, 3 subjects were implanted via a thoracotomy and were thus included in additional secondary endpoint analyses.

**Figure 248: Subject Enrollment and Study populations in the LATERAL study**




The purpose of the LATERAL Study was to evaluate the safety and effectiveness of the implanting the HeartWare HVAD System by a thoracotomy approach, therefore patients in whom an implant via sternotomy was planned were screen failed from the study. Additionally, subjects in whom thoracotomy was planned, but then were implanted via a sternotomy, or those in whom the outflow was implanted in the descending aorta rather than the ascending aorta were included in the intent to treat population. Finally, those patients who violated one or more of the exclusion criteria, but in whom a thoracotomy implant was still completed, were included in the analysis population. All thoracotomy implant procedures were also recommended to be completed on cardiopulmonary bypass.

### Study Population Demographics and Baseline Parameters

The demographics of the primary study population are typical for an advanced heart failure with LVAD therapy study performed in the US. The subjects in the trial had advanced heart failure associated with a substantial risk of death, as evidenced by over 80% of subjects classified as INTERMACS Profile 1-3, almost 20% with chronic renal disease, and more than 60% with ejection fractions lower than 20%. (See **Table 53**).

# Appendix I: North American Clinical Study: LATERAL (continued)

**Table 53: Baseline Demographics and Parameters in LATERAL**

| Demographics and Baseline Characteristics | Study Device N =144 |
|---|---|
| Age (years) | 54.2 ± 11.5 |
| Male gender (%) | 77.1% |
| Race (%) | |
| White | 62.5% |
| Black or African American | 20.8% |
| Asian | 4.9% |
| American Indian or Alaskan Native | 2.1% |
| Other, none of the above | 4.9% |
| Unspecified, Undisclosed | 7.6% |
| Height (cm) | 175.2 ± 8.8 |
| Body Surface Area ($m^2$) | 2.0 ± 0.3 |
| Intended use | |
| Bridge -to-Transplant | 73.6% |
| Possible Bridge-to-Transplant | 26.4% |
| INTERMACS Profile (%) | |
| 1 | 3.5% |
| 2 | 31.3% |
| 3 | 47.2% |
| 4 | 15.3% |
| 5-7 | 2.8% |
| Ischemic Etiology of Heart Failure | 32.6% |
| Prior Cardiac Surgery | 22.9% |
| Previous Major Stroke | 4.9% |
| Chronic Renal Disease | 18.8% |
| History of Atrial Arrhythmias | 30.6% |
| Serum creatinine (mg/dL) | 1.3 ± 0.74 |
| Mean Arterial Blood Pressure (mmHg) | 79.5 ± 10.5 |
| Left ventricular ejection fraction <20% (LVEF, %) | 61.1% |
| Cardiac Index (L/min/$m^2$) | 2.1 ± 0.54 |

### C. Safety and Effectiveness Results

#### 1. Primary Endpoint

The outcome and analysis of the primary endpoint are shown in **Table 54**. The primary endpoint success in the LATERAL Study was defined as alive on original device, transplanted or explanted for recovery without a stroke with an mRS score of ≥ 4 (assessed ≥ three months post-stroke event). One subject had missing data for this endpoint, which resulted in 143 evaluable subjects. The results show that 88.1% of the HVAD subjects treated per protocol achieved primary endpoint success, which was significantly greater than the 77.5% performance goal (P=0.0012). The most common reason for primary endpoint failure was death on original device, seen in 7.7% (11/143) of subjects (**Table 54**). Protocol-mandated stroke assessments were not carried out in all subjects who experienced a stroke. In addition, 6 patients were reported as having a stroke within the first 6 months of implant. 3 of these 6 patients do not have sufficient data on mRS scores and the severity of their strokes could not be determined. The Primary Endpoint for these 3 patients are based upon post hoc imputation of mRS scores.

**Table 54: Primary Endpoint at Six Months***

| Thoracotomy (N=143) | N (%) | 95% CI * |
|---|---|---|
| **Primary Endpoint Success** | 126 (88.1%) | 0.0012<br>82.7%, NA) |
| Alive on original device | 97 (67.8%) | |
| Transplanted | 29 (20.3%) | |
| Explanted for Recovery | 0 (0.0%) | |
| **Primary Endpoint Failure** | 17 (11.9%) | |
| Death on original device | 11 (7.7%) | |
| Stroke with mRS>=4<br>(as assessed >=3 Months post event) | 4 (2.8%) | |
| Exchange | 1 (0.7%) | |
| Explanted (not for recovery) | 1 (0.7%) | |

*Table is summarized by subjects' first failure event and includes all subjects with an endpoint event prior to 6 months or known to be alive on original device at 6 months.
**P-value of one-sided Binomial Exact test comparing to a performance goal of 77.5%
*** Subject considered a success if all strokes have day-of and follow-up mRS scores <4.

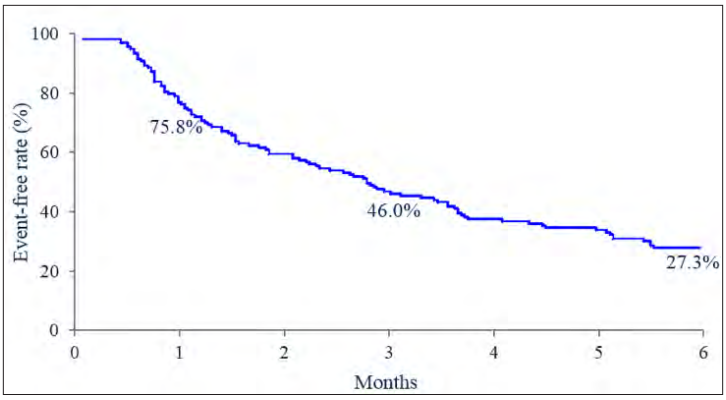
#### 2. Secondary Endpoints

For the PP population, the mean length of initial hospital stay (initial recovery and step down unit) after the implant procedure (date of implant to first discharge) was 18 ± 12.36 days, which is significantly less than the 26.1 day performance goal estimate for median sternotomy subjects. (P<0.0001). Additionally, the mean length of stay in the intensive care unit (ICU) was 8 ± 9.82 days. Results in the ITT population were similar.

Re-hospitalization in the PP population was documented in 70.1% of subjects within 6 months of initial hospitalization. The most common reasons for re-hospitalization were transplant (27.7%), anticoagulation adjustment (19.8%), and major bleeding (17.8%). A freedom from re-hospitalization is presented in **Figure 249**.

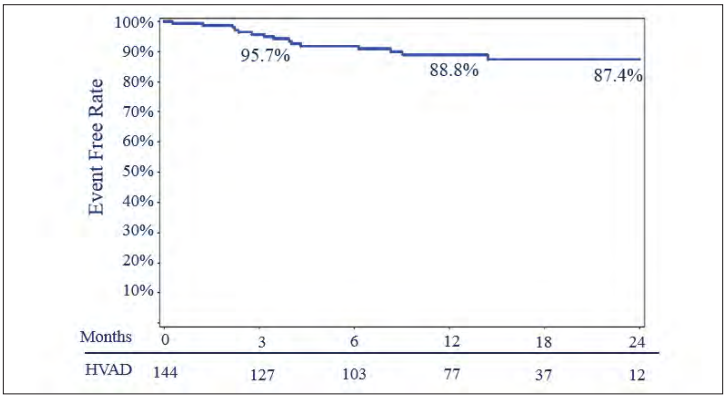
# Appendix I: North American Clinical Study: LATERAL (continued)

**Figure 249: Time to Rehospitalization in LATERAL (PP Population, N=144)**




Overall survival on the HVAD System was also assessed. A Kaplan-Meier estimate for freedom from death on original device for the PP population was 91.8% at 6 months, 88.8% at one year, and 87.4% at two years (**Figure 250**). The Kaplan-Meier estimates in the ITT population were similar.

**Figure 250: Kaplan Meier Survival Analysis in the LATERAL Study (N=144)**




Six of 11 deaths occurring within the first 6 months post-implant were related to circulatory causes, with two due to right heart failure (1.4%) and two due to sudden unexplained death (1.4%). The most common non-cardiovascular cause of death was neurological dysfunction, which occurred in three subjects (2.1%). Additionally, one subject died of multi-system organ failure and another after withdrawal of life support.

# Appendix I: North American Clinical Study: LATERAL (continued)

## Health Status and Functional Improvements

The improvements in quality of life, as measured by the KCCQ and EQ-5D-5L, and functional capacity, as measured by the 6-Minute Walk Test and NYHA Classification improvement, in the LATERAL Study subjects are presented in **Figure 251**A-D.

**Figure 251: Improvements in Quality of Life and Functional Capacity in ENDURANCE Supplemental Subjects.**

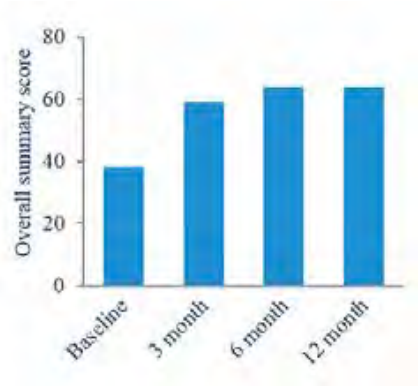
**A) Change over time of the KCCQ Overall Summary Score.**

**B) Change over time in the EQ-5D Visual Analog Scale.**

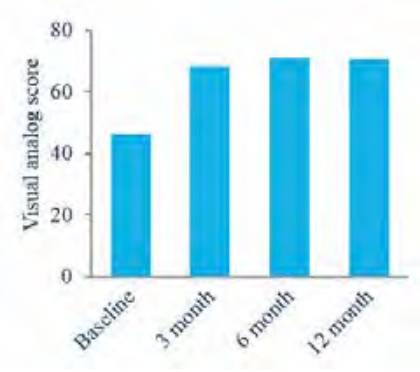
**C) Change over time in subjects' NYHA Classification.**

**D) Change over time of total distance walked in the Six Minute Walk Test.**

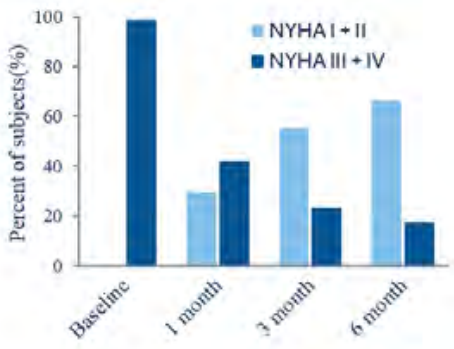
**A. KCCQ**



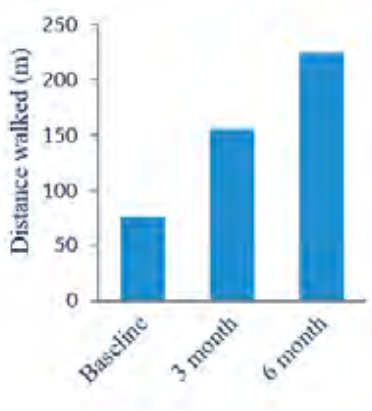

**B. EQ-5D**




**C. NYHA Classification Improvement**




**D. Six-Minute Walk**




### 3. Adverse Events

The analysis of safety was based on the per protocol cohort of 144 patients analyzed through the primary endpoint. A Clinical Events Committee (CEC) was not utilized in this study for adverse event adjudication. A total of 537 INTERMACS adverse events were reported within 6 months on original device. Adverse events were most often reported within the first 30 days post-implant, with 87.5% (126/144) subjects having at least one INTERMACS-defined adverse event.

The most common adverse events were cardiac arrhythmia, bleeding, and infections. Adverse events are summarized in **Table 55**

# Appendix I: North American Clinical Study: LATERAL (continued)

**Table 55: Summary of INTERMACS Adverse Events Occurring Through 6 Months**

| | <=30 Days (N=143) | > 30 Days – 6 Months (N=140 |
|---|---|---|
| **INTERMACS Category Adverse Events** | **Patients with Event (%)** | **Patients with Event (%)** |
| Total Adverse Events | 126 (87.5) | 89 (63.6) |
| Bleeding | 15 (10.4) | 20 (14.3) |
| Re-Hospitalization | 5 (3.5) | 14 (10.0) |
| Re-Operation | 5 (3.5) | 3 (2.1) |
| Transfusion: >=4 within 7 days | 13 (9.0) | 16 (11.4) |
| GI | 6 (4.2) | 11 (7.9) |
| Cardiac Arrhythmia | 32 (22.2) | 13 (9.3) |
| Ventricular | 20 (13.9) | 9 (6.4) |
| Supraventricular | 13 (9.0) | 2 (1.4) |
| Device Malfunction/Failure | 9 (6.3) | 10 (7.1) |
| Hepatic Dysfunction | 1 (0.7) | 0 (0.0) |
| Infection | 20 (13.9) | 32 (22.9) |
| Line Sepsis | 0 (0.0) | 1 (0.7) |
| Driveline Exit Site | 2 (1.4) | 7 (5.0) |
| Myocardial Infarction | 0 (0.0) | 0 (0.0) |
| Neurological | 12 (8.3) | 12 (8.6) |
| Ischemic cerebrovascular accident (CVA) | 3 (2.1) | 3 (2.1) |
| Hemorrhagic CVA | 3 (2.1) | 3 (2.1) |
| TIA | 1 (0.7) | 4 (2.9) |
| Psychiatric | 3 (2.1) | 2 (1.4) |
| Renal Dysfunction | 8 (5.6) | 6 (4.3) |
| Respiratory Dysfunction | 11 (7.6) | 2 (1.4) |
| Arterial non-CNS Thromboembolism | 0 (0.0) | 0 (0.0) |
| Venous Thromboembolism | 4 (2.8) | 1 (0.7) |
| Wound Dehiscence | 1 (0.7) | 2 (1.4) |
| Other | 20 (13.9) | 22 (15.7) |

Abbreviations: GI - gastrointestinal; TIA= transient ischemic attack (<24 hours).

# **Appendix I:** North American Clinical Study: LATERAL (continued)

Nineteen of 143 subjects were reported to have experienced a stroke within six months post-implant, of which two were severely disabling with a mRS ≥ 4 at three months post-stroke. Functional assessment of stroke was specified in the protocol; degree of follow-ups is shown in **Table 56**.

**Table 56: Summary of Stroke Events**

| Patient ID | Primary Endpoint Popula-tion (Y/N) | Primary Endpoint Success (Y/N) | Endpoint Type | mRS at Stroke Event | Time to Stroke Event (Months) | 1 Week Post Implant Followup mRS | 1 Month Post Implant Followup mRS | 3 Months Post Implant Followup mRS | 6 Months Post Implant Followup mRS | 12 Months Post Implant Followup mRS | 18 Months Post Implant Followup mRS | 24 Months Post Implant Followup mRS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 102899 | N | | | | 2.726955 | | | | | | | |
| 103374 | Y | N | Stroke with mRS >= 4 | 5 | 0 | 5 | 4 | 4 | 4 | 4 | 4 | 4 |
| 103481 | Y | Y | Alive Original Device | | 21.74993 | | 0 | | 0 | | | |
| 103573 | Y | N | Death | 5 | 3.876876 | | | | | | | |
| 103799 | Y | Y | Alive Original Device | 4 | 0.032855 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| 103825 | Y | Y | Alive Original Device | | 6.340993 | | | | | 0 | 0 | |
| 103984 | Y | N | Stroke with mRS >= 4 | 5 | 0.032855 | 5 | | | | | | |
| 105103 | Y | Y | Transplanted | 1 | 0.032855 | 1 | 2 | 0 | | | | |
| 105184 | Y | N | Stroke with Missing mRS | 0 | 3.646892 | | | 0 | 0 | | | |
| 105534 | Y | Y | Alive Original Device | 1 | 13.99618 | | | | | | | |
| 105799 | Y | N | Stroke with Missing mRS | | 4.928233 | | | | 1 | | | |
| 106048 | N | | | | 4.041151 | | | | | | | |
| 106239 | Y | Y | Explanted for Recovery | 2 | 16.72314 | | | | | | | |
| 106358 | Y | N | Stroke with mRS >= 4 | | 2.529826 | | | | 2 | 3 | | |
| 106667 | Y | Y | Alive Original Device | 2 | 0.427113 | | 1 | 1 | 1 | 1 | | |
| 107394 | Y | N | Death | | 0.919937 | | | | | | | |
| 107558 | Y | Y | Alive Original Device | | 15.11325 | | | | | | | |
| 108106 | Y | Y | Alive Original Device | | 10.97353 | | | | | | | |
| 108131 | Y | N | Death | | 2.89123 | | | | | | | |
| 108257 | Y | Y | Alive Original Device | | 7.688043 | | | | | | | |

# Appendix I: North American Clinical Study: LATERAL (continued)

INTERMACS data collection methods for hemolysis, hypertension and right heart failure (RHF) adverse events differ from other adverse events. Specifically, events were triggered based on data entered at each patient visit rather than site-reporting of specific events as they occur. This method results in a potential difference in reporting of event frequency. These events are no longer site-reported events per se.

A major hemolysis event was triggered in 11.2% (16/143) of subjects at one-week post-implant based on INTERMACS-defined criteria, and to date this value has not changed substantially over the follow-up period. Severe hemolysis incidence appears greater than previously reported in HVAD studies, however, these are not site-reported events so comparisons cannot be made.

Moderate and severe right heart failure (RHF) events were triggered in 69.9% (100/143) and 0.7% (1/143) of subjects, respectively, at one-week post-implant based on INTERMACS-defined criteria. Though the incidence of severe RHF was low, the incidence of moderate or severe RHF appears to be greater than RHF adverse events previously reported in HVAD studies. However, once again it should be noted that these are triggered events and not site- reported, so comparisons to previous reports cannot be appropriately made.

No unanticipated adverse device effects were reported in the Lateral Study.

The prevalence of device failure/malfunction in the per protocol population was 12.5%. In a majority of these cases, no cause was identified. There were 5 cases of suspected or confirmed pump thrombosis identified by hemolysis (2/5) and/or abnormal pump parameters (4/5). One case was confirmed as pump thrombosis.

**Table 57: Device Malfunction/Failure or Pump Thrombosis within 6 months**

| Adverse Event | N=144 % (N) |
|---|---|
| Device Malfunction/Failure and/or Pump Thrombus | 12.5% (18) |
| Outcome | |
| Death | 0% (0) |
| Serious Injury | 0% (0) |
| Urgent Transplantation | 0% (0) |
| Explant without Replacement | 0% (0) |
| Exchange | 2.8% (4) |
| Breach of Integrity of Driveline that Required Repair | 0% (0) |
| None of the Above | 9.7% (14) |
| Causative or Contributing Factors | |
| Patient Accident | 0.7% (1) |
| Patient Non-Compliance | 0% (0) |
| Sub Therapeutic Anticoagulation | 0.7% (1) |
| Prothrombotic States | 0% (0) |
| End of Component Expected Life | 0% (0) |
| Technical/Procedural Issues | 2.8% (4) |
| No Cause Identified | 9.0% (13) |
| Thrombus (Suspected or Confirmed) | 3.5% (5) |

# Appendix I: North American Clinical Study: LATERAL (continued)

### 4. Subgroup Analyses

Subgroup analyses were planned for analysis of the primary endpoint analysis using stratification factors site, on- vs. off-cardiopulmonary bypass pump, and outflow graft location. An analysis of site homogeneity found that the primary endpoint results were significantly different by site (P = 0.035). Further analyses found no predictive factors.

Across all populations, only one ITT subject had alternative outflow location. The subject is currently alive on original device. Similarly, only one subject had no indication in his records regarding use of cardiopulmonary bypass, and that subject was transplanted. Due to the sparse nature of these data, no additional analyses were performed.

### Overall Conclusions from the LATERAL Trial

The LATERAL Trial was a multi-center, prospective, contemporaneous controlled Study. The purpose of this study was to evaluate the safety and effectiveness of HVAD implantation via the thoracotomy approach. The analysis of the primary endpoint suggested success of the HVAD System implanted via thoracotomy compared to the performance goal. The most common reason for primary endpoint failure was death on original device, seen in 7.7% (11/143) of subjects.

An improvement in mean length of initial hospital stay was also observed, with a mean length of stay of 18 ± 12.36 days as compared to the 26.1 day performance goal.

HVAD implantation via thoracotomy appears to be safe, with adverse event rates that are comparable to previous HVAD studies, with the exception of hemolysis and right heart failure which may be partially related to data collection methods.

Overall, HVAD implantation via the thoracotomy approach appears to be effective, with the achievement of statistical significance in the LATERAL primary and secondary endpoints. Additionally, overall quality of life and functional capacity were meaningfully improved in LATERAL subjects.

# Appendix J: Symbol Definitions

| | |
|---|---|
|  | Attention, consult accompanying documents |
|  | Operating Instructions |
|  | Follow instructions for use |
|  | Batch code |
|  | Catalog number |
|  | Serial number |
|  | Class II equipment |
|  | Protected against vertically falling water drops |
|  | Protected against vertically falling water drops when enclosure tilted up to 15 degrees. |
|  | Protected against dust; protected against splashing water in any direction for 5 minutes |
|  | Protected against solid foreign objects of 12.5 mm diameter or greater; protected against vertically falling water drops |
|  | Protected against solid foreign objects of 12.5 mm diameter or greater; protected against vertically falling water drops when enclosure tilted up to 15 degrees |
|  | Temperature limit |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |
|  | Date of manufacture |

| | |
|---|---|
|  | Manufacturer |
|  | Sterilized with ethylene oxide |
|  | Do not reuse |
|  | Do not use if package is damaged |
|  | Separate collection of waste batteries |
|  | Properly dispose of Li-ion battery |
|  | Waste of electrical and electronic equipment |
|  | Use by date |
|  | Direct current |
|  | Non-pyrogenic |
|  | Pump connection |
|  | Defibrillation proof type CF Applied Part |
|  | Not made with natural rubber latex |
|  | CE Mark |
|  | Authorized representative in the European Community |
|  | The UL Recognized Component certification mark |
|  | UL Classification Mark |
|  | MR unsafe |

| | |
|---|---|
|  | Prescription only |
|  | No battery |
|  | TÜV SÜD Certification Mark |
|  | Alternating currents |
|  | Rechargeable battery |
|  | Rechargeable Lithium Ion battery |
|  | Diameter |
|  | Monitor connection |
|  | Usable length |
|  | Clinician Contact |
|  | Doctor or Health Care Center |
|  | Medical Device |
|  | Unique Device Identifier |
|  | Consult IFU at this website |
|  | Implant Date |
|  | Patient Information Website |

# **Appendix J:** Symbol Definitions (continued)

| | |
|---|---|
|  | Package Contents |
|  | PAL™ Controller for HeartWare™ HVAD™ Pump |
|  | PAL™ Single Battery |
|  | PAL™ Dual Battery |
|  | PAL™ Cap |
|  | PAL™ AC Adapter |
|  | PAL™ DC Adapter |
|  | PAL™ Battery Charger |
|  | MCS Patient Power Cord |
|  | PAL™ Sport Pack |
|  | PAL™ Accessories Bag |
|  | PAL™ Data Cable |
|  | PAL™ Internal Battery Replacement Kit |

# Notes

**Customer Service:**
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E-mail: rs.mcscustomerservice@medtronic.com
Website: www.heartware.com

**24-Hour Clinical Support:**
Toll free (888) 494-6365 or (888) HW INFO 5

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