medela

Invia® Ease

Negative Pressure Wound Therapy system

EN Clinician Instructions for Use

Precious life,
progressive care

For Clinician Use Only

Please read all instructions before using this product.
Keep these instructions for future reference.

– Misuse or failure to follow the instructions in this manual may result in serious or fatal injury to the patient.
– Clinician Instructions for Use are intended for healthcare professionals only.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Medela Customer Service phone: 1-800-435-8316

Table of contents

EN

1 Introduction

The Invia Ease NPWT system is designed to provide Negative Pressure Wound Therapy (NPWT), to help promote wound healing. The Invia Ease system includes the Invia Ease pump, an Invia Ease canister and tubing in a range of sizes (300 ml, 500 ml and 1000 ml) and an Invia Ease charger.
Invia Ease NPWT system is intended to be used in conjunction with the Invia dressings only.

2 Intended use

2.1 Intended user

– The Invia Ease NPWT system is intended to be used by clinicians or by adequately trained lay users (patients or caregivers).
– Medical situations must be addressed by a physician. Therapy changes should only be done as prescribed by a physician.
– To ensure safe use of the Invia Ease NPWT system, clinicians are responsible to train lay users (patients and caregivers) according to the **Patient Instructions for Use** and explain all related safety information.

2.2 Intended patient population

– The Invia Ease NPWT system is intended to be used only on patients exhibiting conditions as described in the Indications for Use.
– Appropriate patient selection according to Indications for Use is important to prevent complications and help ensure the efficacy and successful treatment with NPWT.
– The Invia Ease NPWT system has not been studied on pediatric patients.
– The lay user (patient or caregiver) must have the visual and hearing acuity to appropriately:
  – respond to notifications displayed by the pump
  – understand directions from a clinician
  – follow the instructions provided in the Patient Instructions for Use

2.3 Intended use environment

The Invia Ease NPWT system is intended for use in acute, extended and home care settings.

3 Indications for use

The Invia Ease Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as when used on open wounds it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudates and infectious material.

When used on closed surgical incisions, the Invia Ease NPWT system is also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of Negative Pressure Wound Therapy.

The Invia Ease NPWT system is appropriate for use for the following indications:
– Acute or subacute wounds
– Chronic wounds
– Dehisced wounds
– Pressure ulcers
– Diabetic/Neuropathic ulcers
– Venous insufficiency ulcers
– Traumatic wounds
– Partial thickness burns
– Flaps and grafts
– Closed surgical incisions

4 Contraindications

The Invia Ease NPWT system is contraindicated in the presence of:
– Necrotic tissue with eschar present
– Untreated osteomyelitis
– Non-enteric and unexplored fistulas
– Malignancy in the wound (with exception of palliative care to enhance quality of life)
– Exposed vasculature
– Exposed nerves
– Exposed anastomotic site of blood vessels or bypasses
– Exposed organs

5 Safety information

⚠ WARNING

Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION

Indicates a potentially hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

Can lead to material damage (not related to personal injury).

i INFORMATION

Useful or important information that is not related to safety.

When using electrical products, especially when children are present, basic safety precautions must always be followed.

5.1. ⚠ WARNING

1. **Therapy interruption:** The recommended application of the therapy with Invia Ease NPWT system is 24 hours without interruption. If therapy is interrupted for more than 2 consecutive hours (120 minutes), the dressing should be changed and therapy restarted by a clinician in order to avoid the risk of infection or sepsis.
2. **Bleeding:** Patient with an increased risk of bleeding complications must be closely monitored and should be treated in the appropriate care settings (e.g. hospital). If sudden or increased bleeding is observed, immediately stop the use of the pump, apply pressure on wound dressing and seek immediate Emergency Medical Attention. Patients with an increased risk for bleeding include:
   – Patients who have been administered anticoagulants or platelet aggregation inhibitors
   – Patients with inadequate wound hemostasis
   – Patients who are more likely to experience vascular anastomosis
   – Patients with friable vessels, infected blood vessels or organs in or around the wound as a result of but not limited to suturing of the blood vessels or organs, infection, trauma, radiation.
3. **Canister size:** Do NOT use the 1000 ml canister on patients with an increased risk of bleeding complications or patients, who should not be permitted to lose a large amount of fluid. Assess patient's physical condition and wound type prior to choosing the canister. The 1000 ml canister is recommended for acute care (hospital) setting only.
4. **Patient monitoring:**
   – A patient undergoing NPWT therapy requires frequent supervision. Signs of possible infection or any complication must be addressed immediately.

- Small adults and elderly patients as well as patients with highly exudating wounds should be closely monitored for fluid loss and dehydration. When needed, fluid output in the canister and tubing should be compensated accordingly to avoid excess fluid loss and dehydration.
- Monitor the patient status and patient comfort level, the exudate collected in the canister, the wound, and the surrounding skin frequently to ensure efficient and safe treatment as well as patient comfort. Non-observance can cause pain, injury or lead to considerable danger to the patient
- Y-Connector: The use of NPWT with single-lumen drain or with the curved arm of the Invia Y-Connector may increase the risk of exudate accumulation, infection, maceration, or loss of NPWT while blockage occurs in the vacuum system. These conditions may only be detected by frequent monitoring and may require more frequent dressing changes.

5. **Wound assessment:** Observe wound/periwound tissue and exudate for signs of infection or other complications. Most common signs of infection include redness, tenderness, swelling, pain, itching, increased warmth in the wound area, strong odor or purulent discharge. Additional symptoms to be noted in patient include nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membranes, disorientation, high fever (>102 °F, >38.8 °C), refractory hypotension, orthostatic hypotension, or erythroedema (a sunburn like rash).
   More serious complications include infection gangrene, toxic or septic shock.
   If more serious complications of infection occur, discontinue therapy and consult a physician immediately.
6. **Osteomyelitis:** Do NOT use Invia Ease NPWT system on wounds with untreated osteomyelitis. In the presence of osteomyelitis, thoroughly debride all necrotic or infected bone tissue and start systemic antibiotic therapy prior to initiating NPWT.
7. **Autonomic hyperreflexia/spinal cord injury:** Special care is required when NPWT is used near vagus nerve (bradycardia) or on patients with a history of spinal cord injury (stimulation of sympathetic nervous system). Should a patient with a spinal cord injury experience autonomic hyperreflexia in response to stimulation of the sympathetic nervous system (characterized by a sudden elevation in blood pressure and one of the following signs/symptoms: bradycardia, headache, flushing, and/or profuse sweating above the lesion level), discontinue treatment with the Invia Ease NPWT system and consult a physician immediately.
8. **Defibrillation:** In the event that defibrillation is required, clamp the tubings and disconnect the Invia Ease pump from the wound dressing before the patient is defibrillated.
9. **Hyperbaric Oxygen Therapy (HBOT):** Do not take the pump into the hyperbaric oxygen chamber (HBO). When going into the hyperbaric oxygen chamber, clamp the canister tubing and disconnect the Invia Ease pump prior to patient entering the hyperbaric oxygen chamber. Note: Do not clamp the dressing tubing and protect the end of the dressing tubing at the Quick-Connector.
10. **Magnetic Resonance Imaging (MRI):** The Invia Ease pump is Magnetic Resonance unsafe. Do not take the Invia Ease pump into MRI environment. When going into MR environment, clamp the canister tubing and disconnect the Invia Ease pump prior to patient entering the MR environment. Note: Do not clamp the dressing tubing and protect the end of the dressing tubing at the Quick-Connector.
11. **Risk of fire, electric shock, or serious burns:**
    - Due to the fire hazard the Invia Ease pump is not for use in potentially explosive environments including oxygen enriched environments and in areas of flammable anesthetics.
    - Only use the charger that comes with the pump. An inadequate power source may result in a fire hazard, electric shock or malfunction of the pump.

- Prior to charging, always inspect the charger and the cord for damage. If damage is found, immediately disconnect the charger and call the Medela Customer Service or the system provider.
- Never operate the pump if it is not working properly, if it has been damaged or dropped into water.
- Do not take the pump into a bathtub or shower.
- Never place or drop the pump into water or other liquids.
- If the pump has been exposed to water or other liquids, do not touch it. Disconnect the pump from electrical outlet port, turn the pump off and contact the manufacturer.
- This pump contains **lithium-ion batteries**, which bears risk of fire, explosion and burns.
- Do not disassemble, crash, or heat the Invia Ease pump above 212 °F (100 °C), do not incinerate or dispose of in fire.

12. **System modification:** Do not modify the Invia Ease pump or any of the system components without authorization from the manufacturer.
13. **Magnet:** The Invia Ease pump contains a magnet, which may interfere with other medical devices. Keep a distance of 00xx between the pump and other medical devices
14. **Sterile products:** Do not use the sterile products if the sterile packaging is damaged, was opened prior to use or has expired.
15. **Dressing application:**
    - For detailed dressing application information, indications, contraindications, warnings and precautions consult the appropriate Invia dressing Instructions for Use.
    - Wound dressing to be applied and changed by clinicians only.
    - Perform a thorough wound cleansing per physician's orders or facility protocol prior to performing a dressing application.
    - Always count the number of dressing filler pieces used in the wound and document that number on the Transparent Film and in the patient's chart. Make sure all pieces are removed when a dressing is changed.
    - Document the dressing change date on the Transparent Film and in the patient's chart.
    - Sharp edges/bone fragments must be eliminated from the wound area or covered to prevent puncturing blood vessels or organs.
    - Do not place dressing filler into blind and/or unexplored tunnels.
    - Do not force dressing fillers into any area of the wound, as this may damage tissue, alter the delivery of negative pressure, or hinder exudate and dressing filler removal.
    - Do not place the dressing filler directly on exposed blood vessels, organs, nerves, tendons, bones or ligaments. When using the Invia Ease NPWT system in close proximity to these structures, a protective barrier such as a non-adherent wound contact layer must be used.
    - Avoid circumferential dressing application.
    - Consider the use of a protective barrier on skin that may come in contact with the tubing, especially in patients with fragile skin.
    - When treating infected wounds or wounds more susceptible to tissue in-growth into wound filler material, more frequent dressing changes or a non-adherent wound contact layer may be needed. The frequency of dressing changes should be based on an evaluation of the wound characteristics rather than standard recommendations.
    - For closed surgical incision the recommended pressure level is –125 mmHg at constant mode.

5.2 ⚠ CAUTION

1. Incorrect use of the Invia Ease NPWT system may cause pain or injury to the patient.
2. Routinely check that therapy is running and that the negative pressure level and therapy mode are at the prescribed setting.
3. The patient should be monitored regularly according to the physician instructions and facility guidelines. Monitor patient comfort, signs of wound infection, integrity of the dressing, volume of fluid in the canister and therapy compliance.
4. Wounds that involve a fistula may require special care.
5. Excessive negative pressure, a too tight adhesive film dressing, or an infection of the wound may cause pain to the patient. In each case, the dressing must be removed and the wound assessed.
6. Constant versus intermittent pressure: use continuous pressure over unstable structures (such as unstable chest wall or non-intact fascia) in order to help minimize movement and stabilize the wound bed. Continuous pressure is also recommended for patients with increased risk of bleeding, flaps and grafts, highly exudating wounds and when used on closed surgical incisions.
7. Infection control: To reduce the risk of cross contamination, apply universal precautions for infection control per institutional protocol. Use gloves and other protective equipment if exposure to body fluids is likely.
8. Protect the canister tubing from coming in direct contact with the wound area.

5.3 Safety measures

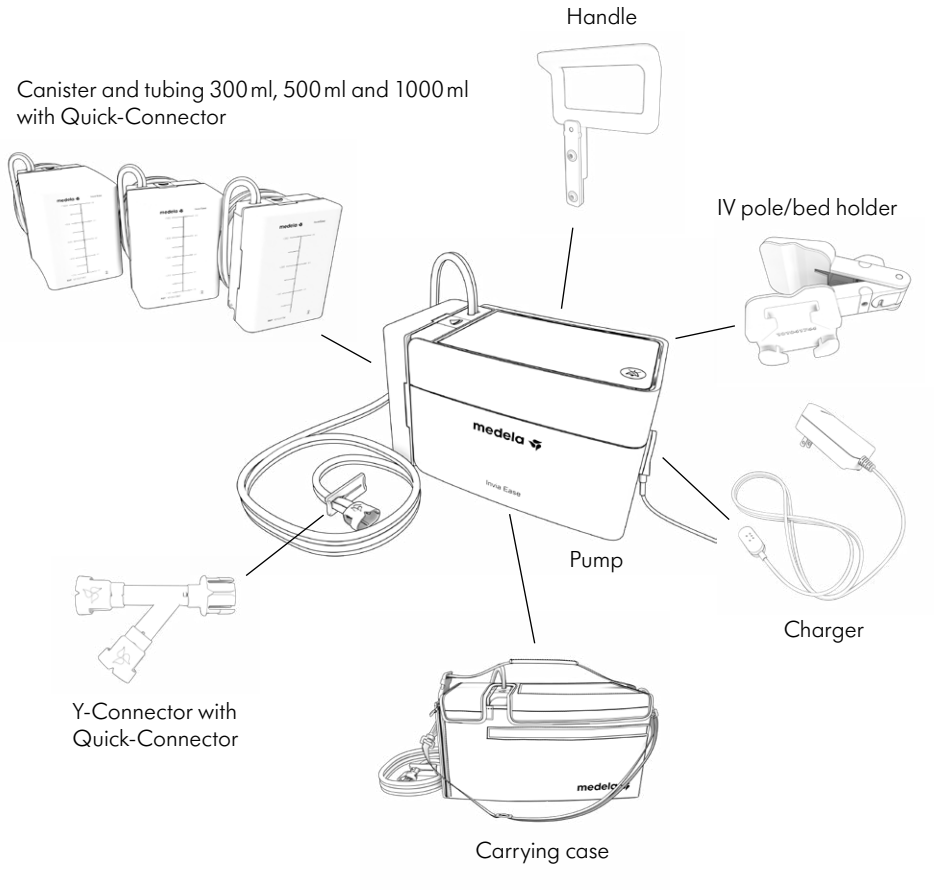
1. Only use products specified in these Instructions for Use.
2. Do not modify the Invia Ease pump or any of the system components without authorization from the manufacturer.
3. The Invia Ease pump is verified within the scope of conformity evaluation and is only to be used with products included in the Invia Ease NPWT system and distributed by Medela. Medela can only guarantee the effective performance of the system with these products.
4. Before you plug in the Invia Ease pump, please check that your local power supply is the same as the voltage given on the specification type plate located at the base of the pump.
5. Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can interfere with the Invia Ease pump and should be kept at a minimum distance of 1 foot (30 cm) away from the Invia Ease pump.
6. Supervision is necessary when the Invia Ease pump is used in the vicinity of children.
7. Do not use the Invia Ease pump if:
   – The power cord or charger are damaged
   – The pump is damaged
   – The pump is not functioning properly
   – The pump has apparent safety defects
8. Do not use the Invia Ease products if they are damaged.
9. Never pull the plug out of the main socket by pulling on the connecting cord.
10. Keep the Invia Ease pump and the associated products away from hot surfaces.
11. Never place the Invia Ease pump or charger in water or other liquids and keep the charger connector away from moisture or immersion in water.
12. The Invia Ease pump must not be used for suctioning explosive, easily flammable or corrosive liquids.

5.4 Physician's orders

A physician must assess each wound when applying this therapy and determine an appropriate negative pressure setting according to the wound characteristics. Changes to the therapy should only be done as prescribed by a physician.

6 Invia Ease NPWT system and accessories

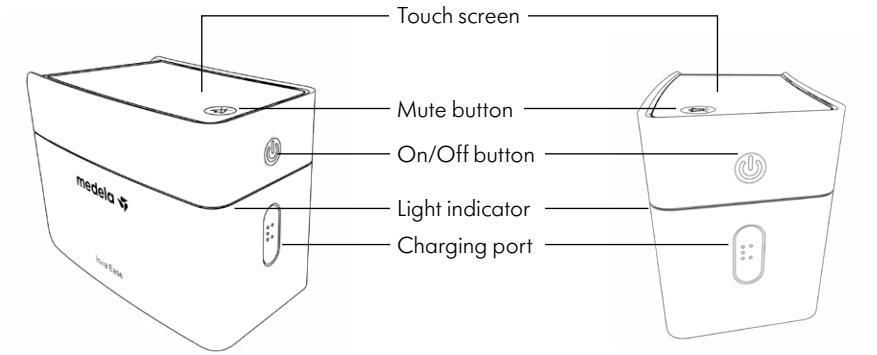
For ordering information refer to chapter 26.



6.1 Invia Ease pump

The Invia Ease pump is a reusable suction pump that provides adjustable negative pressure, constant and intermittent therapy modes, and an electronic measuring and monitoring system. The Invia Ease pump is compact, portable and includes a long-lasting rechargeable battery. The light indicator conveniently shows the therapy status and is easily visible from a distance. The user-friendly touch screen guides the user through troubleshooting steps to help resolve audio and visual alarms as well as provides instructions on how to change a canister and to detach the patient from the pump. The complete history file can be accessed via the touch screen throughout the therapy. The pump dynamically regulates the air flushing cycles to help prevent clogging of the tubing.

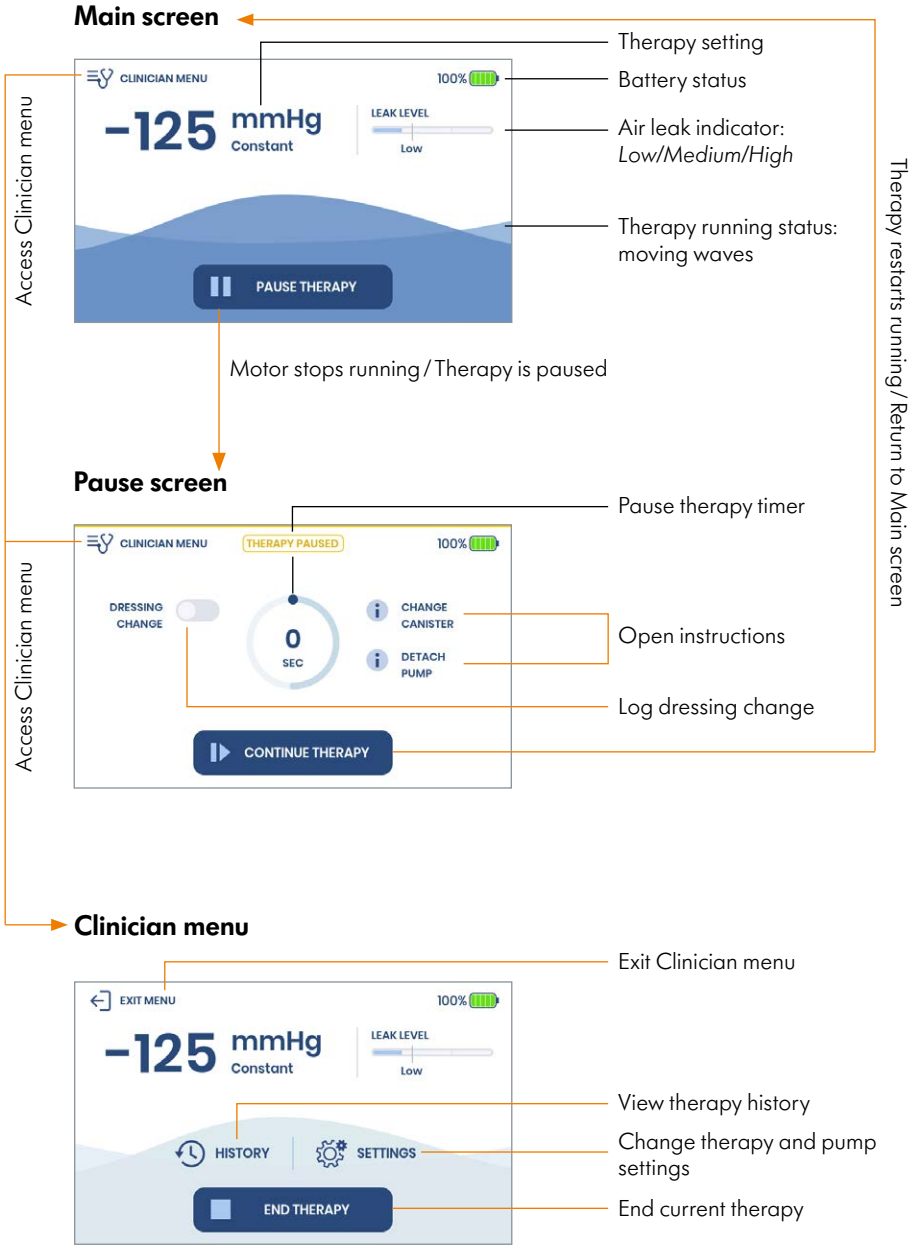
Therapy mode	Default setting	Pressure range
Constant	–125 mmHg	–40 to –200 mmHg
Intermittent	–125 mmHg for 5 min / –40 mmHg for 2 min	High values: –40 to –200 mmHg Low values: 0 to –175 mmHg



6.2 Light indicator status

Green	Therapy is running
Yellow	– Therapy is paused – Alarm state i For instructions, refer to chapter "Alarms and troubleshooting" on page 41.

6.3 Touch screen navigation

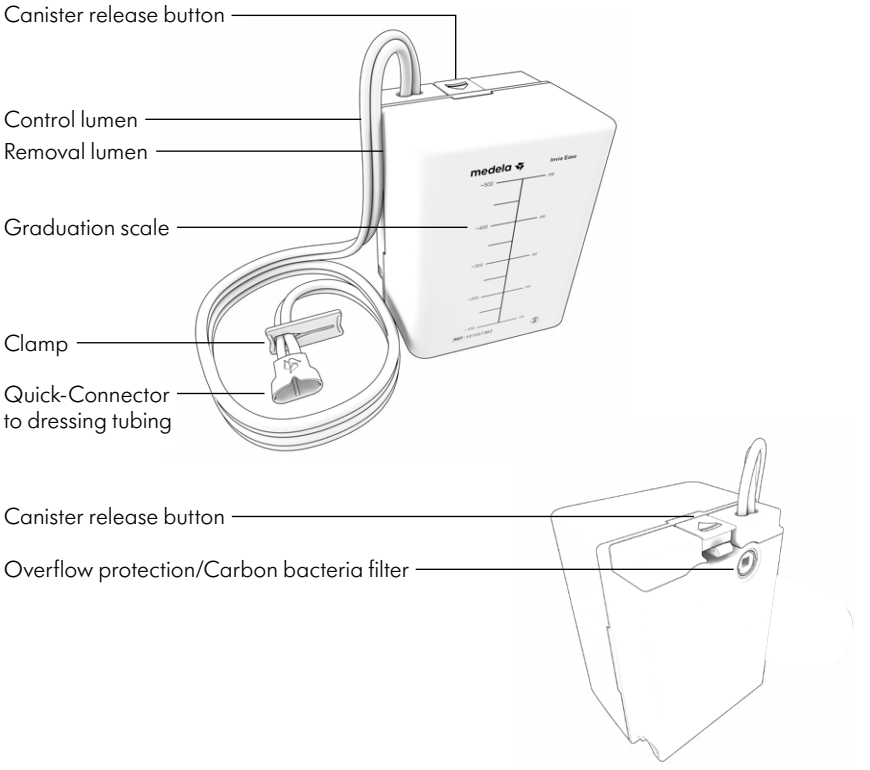


6.4 Invia Ease canister and tubing

NOTICE

Select the appropriate canister size depending on the wound type.

Canister sizes:	300 ml, 500 ml and 1000 ml
Tubing length:	1.5 m
Tubing inner diameter:	2.0 mm/3.0 mm

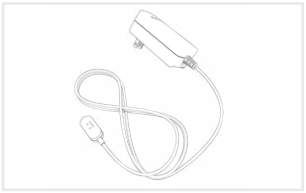


– Canister release button disconnects the canister from the pump with one touch
– Control lumen (smaller tubing) regulates the pressure between the pump and the wound site
– Removal lumen (larger tubing) removes the fluid from the wound into the canister
– Graduation scale shows the amount of fluid in the canister
– Clamp closes the tubing to prevent fluid from spilling out
– Quick-Connector securely attaches canister tubing to the dressing tubing
– Overflow protection/carbon bacteria filter automatically clogs when it comes in contact with fluids to prevent any fluids from entering the pump
– Solidifier is activated when exposed to fluids

6.5 Invia Ease charger

⚠ WARNING

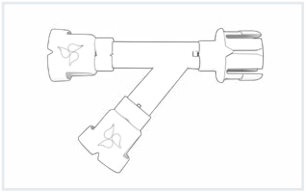
- Only use the charger that comes with the pump. An inadequate power source may result in a fire hazard, electric shock or malfunction of the pump.
- Prior to connecting the charger, always inspect the charger and the cord for damage. If damage is found, immediately disconnect the charger and call the Medela Customer Service or the system provider.



The pump operates when the pump battery is sufficiently charged or when the pump is connected to an electrical outlet port via the charger provided with the pump.

6.6 Accessories

Invia Y-Connector with Quick-Connector

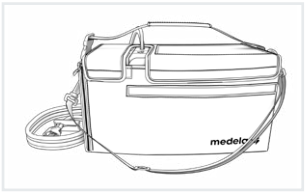


NOTICE

For warnings and cautions of the Invia Y-Connector with Quick-Connector consult the Invia Y-Connector with Quick-Connector Instructions for Use.

Invia Y-Connector with Quick-Connector is intended to connect two dressing tubings to a single Invia Ease pump.

Invia Ease carrying case



NOTICE

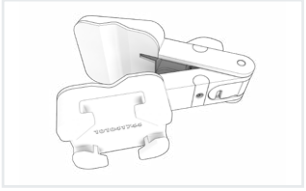
The carrying case is for a single patient use only.

The carrying case is designed to more conveniently carry around a pump, which does not include a handle. The carrying case is compatible with the 300 ml and 500 ml canisters and includes a removable shoulder strap for easier transport. Canister exchange and battery charging can be done while the pump is in the carrying case. The outer pocket of the carrying case should be used to store the quick reference card.

Invia Ease handle

The Invia Ease pump is designed with an option to attach a handle to the pump to more conveniently carry around the pump. The handle should be affixed to the pump via two screws, which are supplied with the handle.

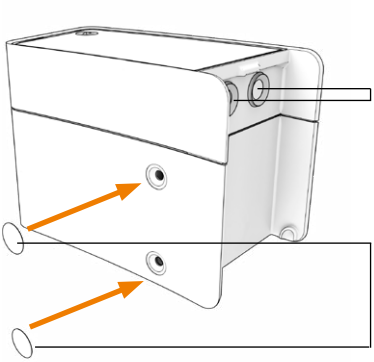
Invia Ease IV pole/bed holder

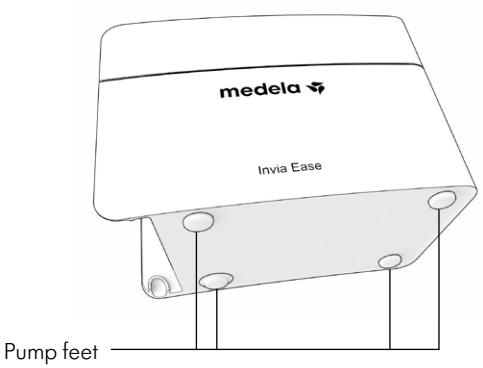


The IV pole/bed holder is designed to be used with the Invia Ease pumps, which include a handle. The IV pole/bed holder allows for easy attachment and removal of the pump to the IV pole or the bed board.

6.7 Spare parts

For ordering information refer to chapter 26.





7 Initial pump setup: first time the pump is turned on

⚠ WARNING

Never operate the pump if it is not working properly, if it has been damaged or dropped into water. If damage is found, immediately disconnect the charger and call the Medela Customer Service or the system provider.

NOTICE

Medela recommends to fully charge the pump battery before its first use.

i INFORMATION

For instructions, refer to chapter “Battery status and charging” on page 20.

To carry out the initial pump setup:

Turn on the pump by pressing the “On/Off” button ⏻

The light indicator will illuminate yellow and the start-up screen will appear.

Click › to begin the initial setup.

Select the preferred language from the list.

Click › to continue.

Program the date and time:
– Choose between AM / PM or 24H format
– To set date (day, month, year) and time (hours, minutes) press + or −

Click › to continue.

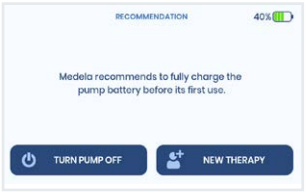
Select the method to access the Clinician menu. This prevents patients from changing any settings. Choose between a Disclaimer or a Code.

Click › to continue.

Disclaimer
Access the clinician menu with a swipe.

Code
Access the Clinician Menu by entering a code:
– The default code is programmed as 1111.
– To set an additional code refer to chapter "Pump settings/Clinician menu access" on page 36.

OR



The Invia Ease pump setup is now complete.
To proceed either:

Turn pump off
Turn the pump off by clicking TURN PUMP OFF

Start therapy
Start a new therapy by clicking NEW THERAPY

8 Operating instructions

⚠ WARNING

Never operate the pump if it is not working properly, if it has been damaged or dropped into water. If damage is found, contact the Medela Customer Service or the system provider.

The Invia Ease NPWT system is intended to be used by clinicians or by adequately trained lay users (patients or caregivers).

8.1 Pump positioning

– The Invia Ease pump should remain in an upright position or can be placed on its front or its back during use.

– If the Invia Ease pump is placed in an inappropriate position (upside-down or on its side), it will lead to the "Pump in the wrong position" alarm.
i For troubleshooting instructions refer to chapter "Alarms and troubleshooting/Pump in the wrong position" on page 42.

– If the canister filter becomes clogged because the pump is in an inappropriate position for too long, it will lead to the "Canister full" alarm. The canister must then be replaced.
i For troubleshooting instructions refer to chapter "Alarms and troubleshooting/Canister full" on page 44.

8.2 Battery status and charging

⚠ WARNING

- This product contains lithium-ion batteries, which bear risk of fire, explosion and burns.
- Only use the charger that comes with the pump. An inadequate power source may result in a fire hazard, electric shock or malfunction of the pump.
- Prior to charging, always inspect the charger and the cord for damage. If damage is found, immediately disconnect the charger and call the Medela Customer Service or the system provider.

NOTICE

- Medela recommends continuous charging while the pump is running overnight to ensure a full charge.
- If the pump is not being used, the battery must be charged approximately once every 6 months to ensure optimum function.

The battery level (as a percentage of fully charged) and the battery symbol are displayed at the top of the touch screen:

Battery status/battery level and symbol

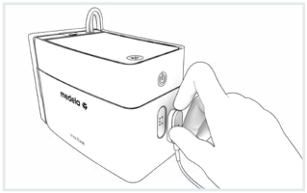
Additional battery symbols/status


Battery is charging

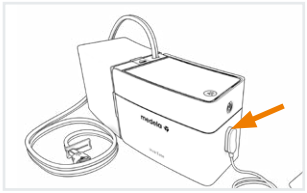

Battery fault


Charging is not possible at this time

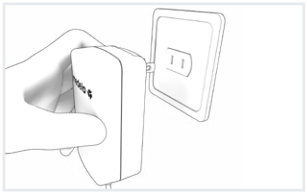
To charge the pump battery:



1. Connect the charger to the charging port.



The LED light on the charger will illuminate white when the charger is correctly connected to the pump's charging port.



2. Plug the charger into an electrical outlet port.

When the pump begins to charge:

Therapy is running

– The touch screen lights up and the battery symbol indicates that the pump is charging.

– If there is no user interaction after 1 minute, the touch screen will enter sleep mode.

Pump is turned off

– The touch screen will display that the pump is charging.

– If there is no user interaction after 1 minute, the touch screen will enter sleep mode.

– The pump is fully charged after approximately 4 hours.

– A fully charged pump should work for at least 20 hours. If there is an air-leak in the system, the pump motor may need to work harder to maintain the target level of negative pressure. Under these circumstances, the pump may need to be recharged more frequently.

– When the battery charge drops to 20%, an acoustic alarm will sound and the "Battery low" alarm will appear on the touch screen. This alerts the user to recharge the battery.

i For troubleshooting instructions refer to chapter "Alarms and troubleshooting/Battery low" on page 42.

– When the battery charge drops below 5%, an acoustic alarm will sound, the "Battery empty" alarm will appear on the touch screen and therapy will be automatically paused.

i For troubleshooting instructions refer to chapter "Alarms and troubleshooting/Battery empty" on page 43.

8.3 Attach canister to the pump

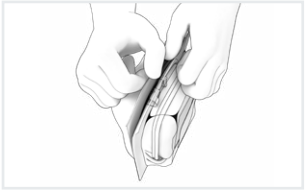
⚠ WARNING

Sterile products: Do not use the sterile products if the sterile packaging is damaged, was opened prior to use or has expired.

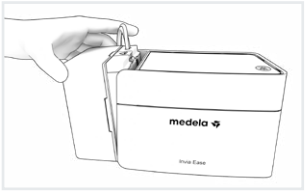
NOTICE

- Wear gloves for all operations and apply universal precautions.
- Canisters are designed for single patient use only and cannot be reused.

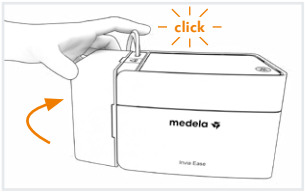
1. Select the appropriate canister size depending on the wound type (300 ml, 500 ml, 1000 ml).



2. Unpack a new sterile canister.

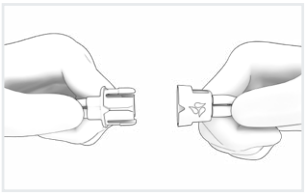


3. Slip the pegs at the bottom of the canister to secure into the slots at the base of the pump.

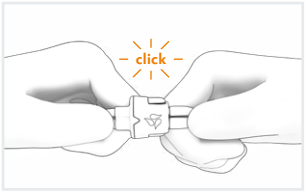


4. Push the canister towards the pump until it clicks into place.

8.4 Connect canister tubing to dressing tubing



1. Align both parts of the Quick-Connector and push the Quick-Connector together until you hear a click.



8.5 Turn pump ON

1. Turn on the pump by pressing the "On/Off" button

2. The light indicator will illuminate yellow and the start-up screen will appear.

8.6 Start new therapy

NOTICE

- New therapy should only be started by a clinician.
- The default therapy setting of the Invia Ease pump is –125 mmHg in constant mode.

1. Turn the pump ON.

i For instructions, refer to chapter "Turn pump ON" on page 24.

2. To start new therapy:

In default settings
Click START THERAPY

Change settings first
Click SETTINGS

i For instructions on how to change therapy settings refer to chapter "Change therapy settings" on page 34. For instructions on how to change pump settings refer to chapter "Change pump settings" on page 35.

Click START THERAPY

3. The light indicator will illuminate green when therapy is running and the target level of negative pressure is reached.

8.7 Activate the display during running therapy

Touch anywhere on the touch screen to activate the display.
The touch screen will automatically activate in the event of an alarm.

8.8 Dim the display/sleep mode during therapy

The touch screen will dim and go into sleep mode 1 minute after the last user interaction.

8.9 Pause therapy

⚠ WARNING

Therapy interruption: The recommended application of the therapy with Invia Ease NPWT system is 24 hours without interruption. If therapy is interrupted for more than 2 consecutive hours (120 minutes), the dressing should be changed and therapy restarted by a clinician in order to avoid the risk of infection or sepsis.

The pump may be paused for a variety of reasons including:
– To change the wound dressing. For detailed information regarding dressing applications, consult the appropriate Invia dressing Instructions for Use.
– To change the cannister.
– To temporarily detach the patient from the pump.

The pump allows the therapy to be paused for up to 30 minutes. After therapy has been paused for 30 minutes, the "Pause reminder" alarm will appear on the touch screen.

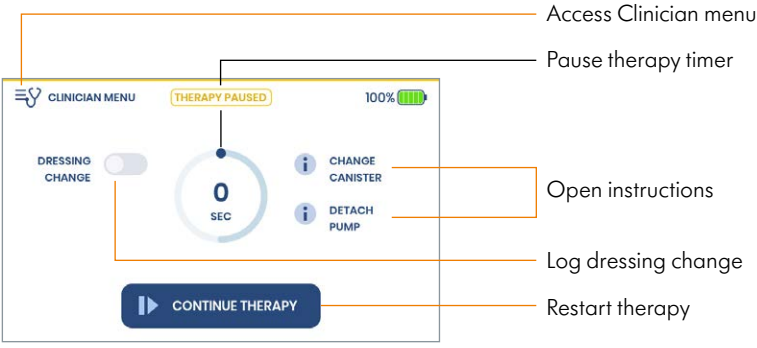
i For troubleshooting instructions refer to chapter "Alarms and troubleshooting/Pause reminder" on page 43.

To pause therapy:

Click and hold PAUSE THERAPY for 3 seconds.

Pause screen will appear, the pump motor will stop working and the light indicator will switch from green to yellow.

Pause screen



8.10 Change a canister

⚠ WARNING

Sterile products: Do not use the sterile products if the sterile packaging is damaged, was opened prior to use or has expired.

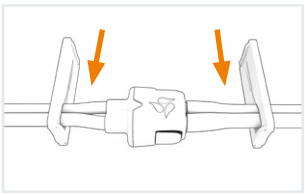
NOTICE

- To change a canister, therapy must be paused.
- Canisters are designed for single patient use only and cannot be reused.
- Change the canister a minimum of once a week or when:
  – The canister appears full
  – "Canister full" alarm appears on the touch screen

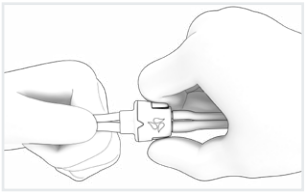
1. Click and hold PAUSE THERAPY for 3 seconds on the Main screen.

i For instructions to change the canister click CHANGE CANISTER on the Pause screen

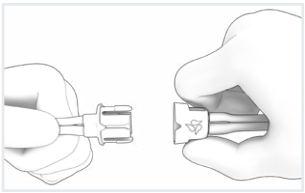
i To exit the instructions at any time, click ✕

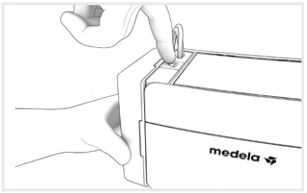


2. Position the clamps next to the Quick-Connector and close clamps on the canister tubing and the dressing tubing.



3. Disconnect the canister tubing from the dressing tubing by pressing the sides of the Quick-Connector.
Prevent the end of the dressing tubing from becoming contaminated.





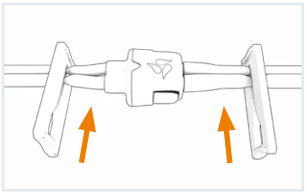
4. Press the canister release button on top of the canister to release and remove the used canister.

5. Unpack a new sterile canister and attach it to the pump.

i For instructions, refer to chapter "Attach canister to the pump" on page 23.

6. Connect canister tubing to the dressing tubing.

i For instructions, refer to chapter "Connect canister tubing to dressing tubing" on page 24.



7. Open the clamp on the dressing tubing and make sure the canister tubing is unclamped.

8. To resume the therapy click CONTINUE THERAPY on the Pause screen.
The pump motor will start to work, the Main screen will appear and the light indicator should switch from yellow to green when the target level of negative pressure is reached.

9. Discard the used canister in accordance with local environmental guidelines.
For instructions, refer to chapter "Disposal" on page 50.

8.11 Detach the pump from the patient

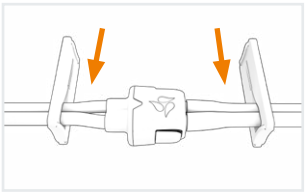
NOTICE

To detach the pump from the patient, therapy must be paused.

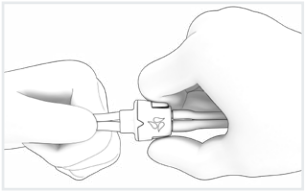
1. Click and hold PAUSE THERAPY for 3 seconds on the Main screen.

i For instructions to detach from the pump click DETACH PUMP on the Pause screen

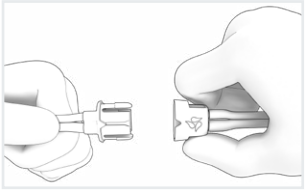
i To exit the instructions at any time, click ✕



2. Position the clamps next to the Quick-Connector and close clamps on the canister tubing and the dressing tubing.



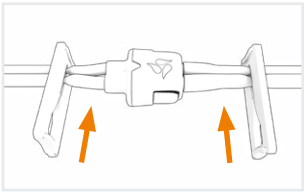
3. Disconnect the canister tubing from the dressing tubing by pressing the sides of the Quick-Connector. Prevent the end of the dressing tubing from becoming contaminated.



4. The patient can perform the activity while being disconnected from the pump, such as taking a shower.

5. When the activity is completed, re-connect the canister tubing to the dressing tubing.

i For instructions, refer to chapter "Connect canister tubing to dressing tubing" on page 24.



6. Open the clamps on the dressing tubing and the canister tubing.

7. To resume the therapy click CONTINUE THERAPY on the Pause screen.
The pump motor will start to work, the Main screen will appear and the light indicator should switch from yellow to green when the target level of negative pressure is reached.

8.12 Change a dressing

NOTICE

To change a dressing, therapy must be paused.

i For detailed information regarding dressing applications, consult the appropriate Invia dressing Instructions for Use.

1. Click and hold PAUSE THERAPY for 3 seconds.

2. Log the dressing change by moving the toggle bar from left to right.

When the DRESSING CHANGE toggle is activated:
– The "Pause reminder" alarm is suspended
– The pump will provide an acoustic sound every 15 min
– A dressing change is logged in the pump's History

3. Perform the dressing change according to the facility guidelines.

4. To resume the therapy click CONTINUE THERAPY on the Pause screen.
The pump motor will start to work, the Main screen will appear and the light indicator should switch from yellow to green when the target level of negative pressure is reached.

8.13 Turn the pump off to temporarily interrupt therapy

⚠ WARNING

Therapy interruption: The recommended application of the therapy with Invia Ease NPWT system is 24 hours without interruption. If therapy is interrupted for more than 2 consecutive hours (120 minutes), the dressing should be changed and therapy restarted by a clinician in order to avoid the risk of infection or sepsis.

i For instructions on how to end therapy refer to chapter "End therapy" on page 40.

To turn the pump off either:

1. Press the "On/Off" button ⏻

OR

1. Press and hold the "On/Off" button ⏻ for 3 seconds

2. Click TURN PUMP OFF

8.14 Resume existing therapy (after the pump was turned off)

1. Press the "On/Off" button to turn the pump on.

2. Click CONTINUE THERAPY to resume existing therapy.

i To start new therapy click NEW THERAPY

i For instructions, refer to chapter "Start new therapy" on page 25.

NOTICE

New therapy should only be started by a clinician.

9 Access the Clinician menu

EN

NOTICE

- The Clinician menu should be used by clinicians only.
- The pump automatically switches to the Main screen 1 minute after the last interaction in the Clinician menu.

The Clinician menu can be accessed during running therapy or while therapy is paused.

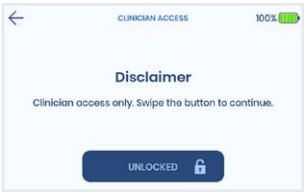
From the Clinician menu it is possible to:
– Change therapy settings
– Change pump settings
– Check the history and log file of the existing therapy
– End therapy

To access the Clinician menu:

1. Select CLINICIAN MENU at the top of the Main screen.

2. Acknowledge that you are a clinician:

Disclaimer
Read the disclaimer and swipe right to unlock.



Code
Enter the code (default code **1111** or a pre-set personal code).

3. To exit the Clinician menu click EXIT MENU

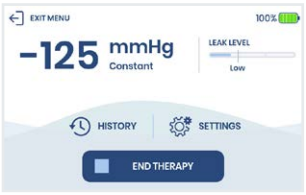
10 Change therapy settings

NOTICE

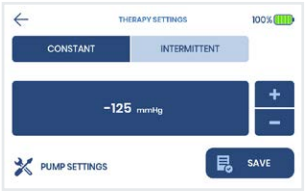
- Changes to therapy settings should only be made as prescribed by a physician.
- The default therapy setting of the Invia Ease pump is –125 mmHg in constant mode.

1. Access the Clinician menu.

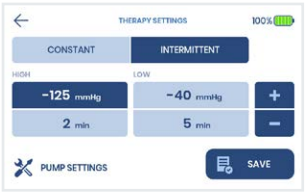
i For instructions, refer to chapter "Access the Clinician menu" on page 33.



2. Click SETTINGS



3. Select between CONSTANT or INTERMITTENT therapy modes.



4. Select the field that needs to be changed and then use + or – to adjust:
- Pressure between –40 and –200 mmHg in increments of 5 mmHg
- Time between 2 and 60 minutes (in the intermittent mode only)

5. Click SAVE to save the new therapy settings.
If the new therapy settings are not saved, the pump will revert to the previous therapy settings.

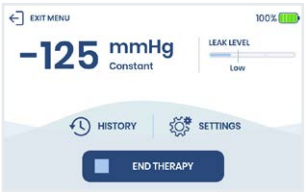
6. Click ← to return to the Clinician menu.

11 Change pump settings

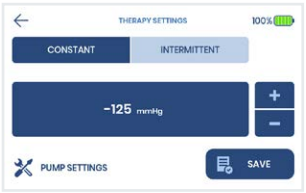
The following settings can be changed from the pump settings menu:
– Date and time
– Clinician access
– Alarm volume
– Vacuum intensity
– Language
– Bluetooth on/off
– Reset factory settings

1. Access the Clinician menu.

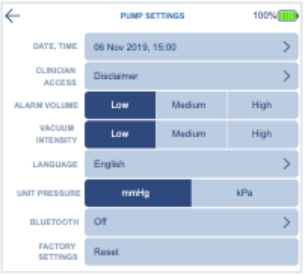
i For instructions, refer to chapter “Access the Clinician menu” on page 33.



2. Click SETTINGS



3. Click PUMP SETTINGS



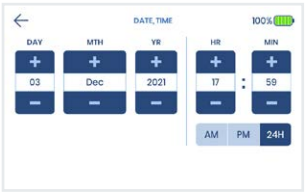
4. Select the field that needs to be changed per instructions on the following pages.

5. Click ← to return to the Clinician menu.

11.1 Date and time

1. Choose between AM / PM or 24H format.

2. Click + or − to set date (day, month, year) and time (hours, minutes).



3. Click ← to return to the pump settings menu.

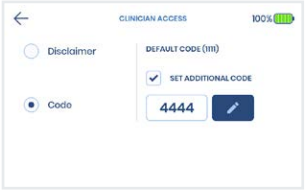
11.2 Clinician menu access

1. Choose between a disclaimer or a code.

Disclaimer
Access the clinician menu with a swipe.

Code
Access the Clinician menu with a default code **1111** or set an additional code.

To set an additional code:
– Check the box "Set additional code"
– Enter a four digit code
– Click ← to return to the pump settings menu.



To change an additional code:
– Click ✎ and enter a new four digit code.

– Click ← to return to the pump settings menu.

11.3 Alarm volume

Select the sound of the acoustic alarm. The sound always starts low and continues to get louder until it reaches its maximum volume. The default alarm volume setting is Medium.

11.3 Vacuum intensity

Select the speed at which the negative pressure is applied and the dressing compresses. The Low vacuum intensity requires the longest time to apply the target negative pressure while the High vacuum intensity is the quickest to apply the target negative pressure at the dressing. The default vacuum intensity setting is Medium.

11.5 Language

1. Select the language from the list.

2. Click ← to return to the pump settings menu.

11.6 Bluetooth

– Bluetooth functionality is presently inactive regardless of Bluetooth setting (On or Off).
– Default setting of the Invia Ease pump is Bluetooth Off.
– Bluetooth interface is used by the Medela service centers only.

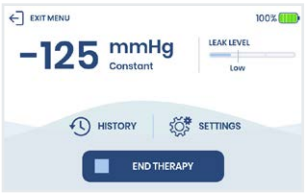
11.7 Factory settings reset

The Invia Ease pump can be reset to the default factory settings:
– Therapy setting is constant mode in –125 mmHg
– Language is English
– Clinician access is Disclaimer
– Alarm volume is medium
– Vacuum intensity is medium
– Unit pressure is mmHg
– Bluetooth is Off

12 View therapy history

1. Access the Clinician menu.

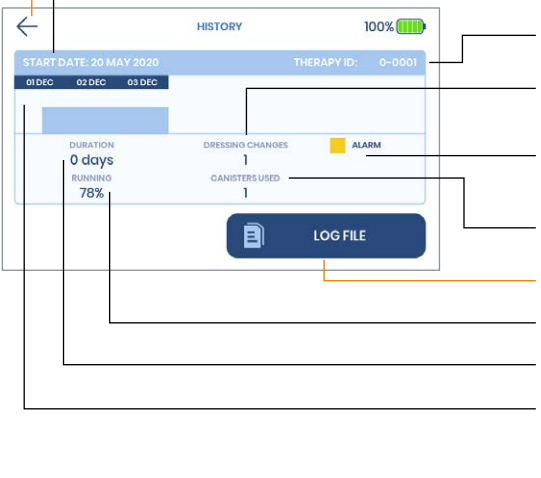
i For instructions, refer to chapter "Access the Clinician menu" on page 33.



2. Click HISTORY

3. To check the detailed therapy events , click LOG FILE

History screen



Exit history screen

Therapy start date

Therapy ID number

Number of dressing changes performed during therapy

Indicates an alarm on the therapy graph

Number of canisters used during therapy

Check detailed therapy events

Therapy run rate

Therapy duration

Therapy graph showing dates, pressure setting(s), alarm(s) and pause(s)

4. Scroll down to view the log file. To filter the events recorded in the log file, click to select the respective fields

Alarm | Dressing | Canister | Pause

and scroll down to view the full list. Filterable events include alarms, dressing changes, canister changes and therapy pauses.

5. Click ← to return to the Clinician menu.

13 End therapy

EN

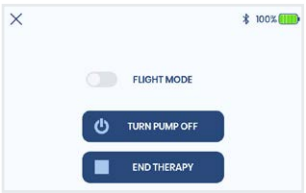
NOTICE

- The therapy history of the current therapy will be erased once therapy is ended and the pump is turned off.
- Therapy should only be ended by a clinician.

i If you wish to temporarily interrupt therapy, please refer to chapter "Turn pump off to temporarily interrupt therapy" on page 31.

To end existing therapy either:

1. Press the "On/Off" button 



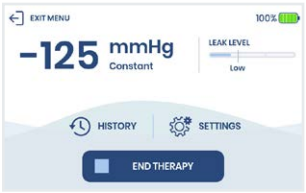
2. Click and hold END THERAPY for 3 seconds.

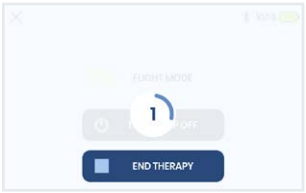
3. Acknowledge you are a clinician via a disclaimer or a code to confirm the end of therapy.

OR

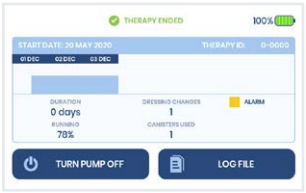
1. Access the Clinician menu.

i For instructions, refer to chapter "Access the Clinician menu" on page 33.





2. Click and hold END THERAPY for 3 seconds.



3. Therapy history of the current therapy will be shown on the touch screen.

4. To see the detailed log file, click LOG FILE

5. To turn the pump off, click TURN PUMP OFF

14 Alarms and troubleshooting

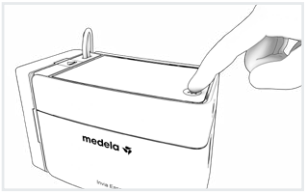
⚠ WARNING

Therapy interruption: The recommended application of the therapy with Invia Ease NPWT system is 24 hours without interruption. If therapy is interrupted for more than 2 consecutive hours (120 minutes), the dressing should be changed and therapy restarted by a clinician in order to avoid the risk of infection or sepsis.

When the pump detects a fault, an acoustic alarm sounds, troubleshooting instructions appear on the touch screen and the light indicator illuminates yellow. The pump differentiates between "Low Priority" and "Medium Priority" alarms (IEC 60601-1:2005, 3rd edition and IEC 60601-1-8:2006):

"Low priority" alarms:
– Battery low
– Temperature high
– No canister detected
– Pump in wrong position

"Medium priority" alarms:
– Pause reminder
– Battery empty
– Internal temperature exceeded
– High leakage
– Blockage
– Canister full
– Defective charger
– Pump error



To resolve an alarm:

1. Press the Mute button to silence the alarm.

The mute symbol will appear on the screen to indicate that the pump has been silenced. The acoustic alarm will resume in 5 minutes if the problem has not been resolved.

2. Follow the instruction shown on the touch screen or refer to the chapter "Alarm table" on page 42.

3. If the problem cannot be resolved, turn the pump off and contact the Medela Customer Service or the system provider for further instructions. For instructions, to turn the pump off refer to chapter "Turn pump Off to temporarily interrupt therapy" on page 31.

Alarm table

"Low priority" alarms:
– Therapy continues to run
– Status indicator illuminates yellow

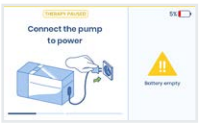
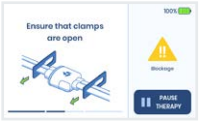
NOTICE

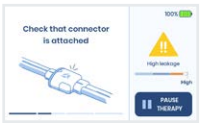
"Low Priority" alarms that are not resolved will lead to "Medium Priority" alarms.

To close the instructions after acknowledging the alarm and to return to the Main screen click ACCEPT

Alarm type	Potential cause	Troubleshooting instructions	Notes
Battery low 	• Battery charge has fallen to 20 % • Alarm will repeat if the battery charge drops to 15 % and subsequently to 10 %	Charge the pump battery i For instructions, refer to chapter "Battery status and charging" on page 20.	If battery charge drops to 5 %, it will lead to the "Battery empty" alarm and therapy will be automatically paused.
Temperature high 	The pump is next to a heat source or is under a cover	Remove the pump from the heat source or uncover the pump	The pump is at risk of overheating. If the pump is not cooled, it will lead to "Temperature exceeded" alarm and therapy will be automatically paused.
No canister detected 	The pump does not detect a canister	• Attach a canister to the pump • Release and reposition the canister if needed	If a canister is missing or is not correctly attached, it will lead to "High leakage" alarm.
Pump in wrong position 	The pump is positioned on its side or is upside down	Place the pump in the upright position	If the pump is in a wrong position for too long, it could lead to "Canister full" alarm.

"Medium priority" alarms:
– Therapy may automatically pause
– Status indicator illuminates yellow and flashes

Alarm type	Potential cause	Troubleshooting instructions	Notes
Pause reminder 	The therapy has been paused for 30 minutes or longer	• To resume the therapy click CONTINUE THERAPY • To remain in the pause therapy mode, click +10 MIN	After 90 minutes in the pause therapy mode, the "Pause reminder" alarm will display an additional warning regarding dressing change 
Battery empty 	Battery charge is 5 % or below	Charge the pump battery i For instructions, refer to chapter "Battery status and charging" on page 20.	Therapy is automatically paused. Resume the therapy once the pump is charging by clicking CONTINUE THERAPY
Internal temperature exceeded  	The pump has overheated	• Remove the pump from the heat source or uncover the pump • Wait a minimum of 30 minutes for the pump to cool down	• Therapy is automatically paused. • To acknowledge the instructions and switch to the Pause screen click ✕ • Resume the therapy after the pump is cooled off by clicking CONTINUE THERAPY
Blockage  	• Tubing may be twisted • Clamp may be closed	• Check the tubing to make sure it is not twisted • Make sure that both clamps are open	If the tubing is blocked or the blockage cannot be identified, the canister and/or the dressing should be changed.

Alarm type	Potential cause	Troubleshooting instructions	Notes
High Leakage   	The pump detects an air leak in the system and cannot maintain the target level of negative pressure	• Inspect the dressing for an air leak • Press firmly around the edges of the dressing and around the Invia FitPad • Apply additional film around the dressing if needed to seal the leak • Check that the Quick-Connector is securely attached • Check that canister is fully connected to the pump • Release and reposition the canister if needed • Ensure that the two filter gasket orange O-rings on the canister side of the pump are not missing  Filter gasket with orange O-ring	• If the leakage is not resolved in the first five minutes, the pump will switch into pause therapy mode.  • If the therapy has been automatically paused, click CONTINUE THERAPY to check if the leakage has been resolved or continue to look for the leak by following the troubleshooting instructions. • If an air leak cannot be identified or resolved, the dressing should be changed.
Canister full 	• Canister is full • Canister filter is clogged	Change the canister i For instructions, refer to chapter "Change a canister" on page 27.	If the pump is not positioned upright, it may cause the canister filter to clog.
Defective charger 	The charger may be damaged	• Unplug the charger immediately • Inspect the charger for damage • Replace the charger	If the charger is not unplugged immediately, it may cause damage to the pump.
Pump error 	The pump has an internal error	• Click TURN PUMP OFF to turn the pump off • Press the "On/Off" button ⏻ on the side of the pump to restart the pump	If the problem cannot be resolved, turn the pump off and contact the Medela Customer Service or the system provider for further instructions.

15 Accessories setup

15.1 Invia Ease carrying case

To place the pump inside the carrying case:

1. Open the Velcro on the top of the carrying case.

2. Slide the pump with canister attached into the designated slot.

3. Close the Velcro over the pump and over the canister. Make sure that the canister tubing is not kinked and the status indicator is visible.

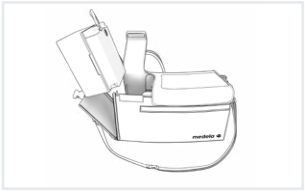
4. Secure additional tubing with a Velcro on the side of the pump.

To exchange a canister from the carrying case:

1. Detach the handle strap on the side of the canister.

2. Open the Velcro over the canister.

3. Unzip the carrying case from the canister side.



4. Change the canister.

i For instructions, refer to chapter "Change a canister" on page 27.

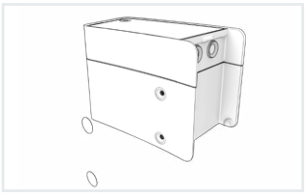
5. Zip up the carrying case from the canister side.

6. Close the Velcro over the canister.

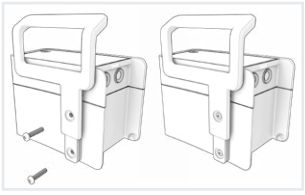
7. Re-attach the handle strap on the side of the canister.

15.2 Invia Ease handle

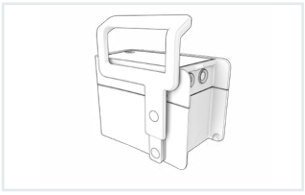
To affix the carrying handle to the pump:



1. Remove the two hole covers from the back of the pump.



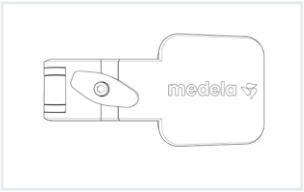
2. Align the two handle parts and fixate the screws inside the two holes.



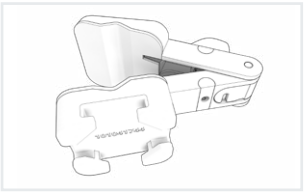
3. Cover the screws with the two hole covers from the pump.

15.3 Invia Ease IV pole/bed holder

To attach the IV pole/bed holder to an IV pole or a bed board (up to 50 mm):



1. Turn the knob left to open the IV pole/bed holder.

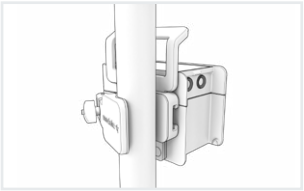


2. Position the open holder in the center of the IV pole or over the bed board.

3. Turn the knob to the right to firmly secure the holder onto the IV pole or the bed board.

To mount the Invia Ease pump onto the IV pole/bed holder:

1. Hold the pump by the handle and position the base of the handle over the IV pole/bed holder.
2. Slide the pump down along the handle until the IV pole/bed holder is secured to the pump handle.



To remove the Invia Ease pump from the IV pole or the bed board:

1. Hold the pump by the handle and lift the pump up to release it from the IV pole/bed holder.

16 Safety-related checks

– The Invia Ease pump is a device in protection class II (EN IEC 60601-1), the safety-related checks are confined to visual inspection of the housing and charger for damage. This check must be performed prior to each use.
– If any damage or safety defects are observed, contact the Medela Customer Service or the system provider.
– Devices of protection class II do not have a protective earth conductor therefore there is no need to check the earth leakage current.
– The Invia Ease pump enclosure is made entirely of insulated material. Tests of the enclosure leakage current using common measuring instruments will therefore not reveal measurable values.
– Even when suctioning a conductive fluid until the overflow protection device activates, measurements of the patient leakage current using common measuring instruments will not reveal measurable values.
– The Invia Ease pump does not have patient circuits or functional earth connections.

17 Maintenance and service

– The Invia Ease pump and charger should be maintained and repaired throughout its service life in compliance with the Medela service procedures.
– Service work may only be carried out by Medela's authorized personnel.
– To request maintenance service contact the Medela Customer Service.

18 Sterility requirements

⚠ WARNING

Sterile products: Do not use the sterile products if the sterile packaging is damaged, was opened prior to use or has expired.

Invia Ease pump, charger, handle, IV pole/bed holder and carrying case cannot be sterilized.

The following products are sterile and single use only:
Invia Ease canister and tubing

These are single use products that should be disposed of after use.
Do not reuse.
If reused, the performance of the product may deteriorate, cross-contamination may occur.

19 Cleaning, disinfection and storage

Reusable devices and components from Medela are delivered non-sterile and are intended for reuse. Prior to use, clean and reprocess the product by following the procedure in the Cleaning and Disinfection instructions below.

Materials and equipments:
– Personal Protective Equipment (PPE: disposable gloves, proper protective gear)
– Lint free nonwoven wipes
– Clean water (<104 °F, <40 °C)
– Common household cleaner

NOTICE

- Never use steel brushes or steel wool for cleaning.
- Invia Ease pump and accessories (charger, handle and IV pole fixation) should be cleaned and disinfected after every use.

⚠ WARNING

- Never place or drop the pump into water or other liquids.
- Before cleaning/disinfecting the pump or the charger, disconnect the charger from the electrical outlet port.

19.1 Cleaning

– The Invia Ease pump and the accessories (charger, handle, IV pole fixation and carrying case) can be wiped with a damp cloth using a common household cleaner throughout the therapy.
– The carrying case can be washed in the washing machine if needed.

19.2 Disinfection

The Invia Ease pump and the accessories (charger, handle and IV pole fixation) should be disinfected after every therapy with a disinfectant containing alcohol to avoid cross-contamination.

NOTICE

- Do not spray disinfectants directly into openings as this may harm electronic components.
- Immersion disinfection, thermal disinfection and ultrasound cleaning are not permitted.

To disinfect the Invia Ease pump and the accessories (charger, handle and IV pole fixation):

1. Wear suitable protection (clothing, gloves, face mask and goggles) according to the facility guidelines.
2. Apply the disinfectant agent in accordance with instructions from the manufacturer. Pay particular attention to the edges, narrow corners, and bottom side.
3. Leave the disinfection agent on for the time recommended by the manufacturer.
4. Thoroughly clean the surface, all edges, housing niches, corners, and bottom side.
5. Wipe dry or air dry according to the instructions from the manufacturer.
6. If needed, repeat step 2–5.
7. Dispose contaminated material in accordance with local environmental guidelines.

For detailed cleaning instructions contact the Medela Customer Service.

19.3 Drying

After the manual disinfection, store the product on a clean dry cloth and let it dry. Alternatively, follow the instructions provided by the disinfectant manufacturer.

19.4 Inspection

After reprocessing according to the steps described above, the device and its components must be inspected for signs of degradation that may limit the useful life and/or performance of the device, such as the following: visible corrosion, mechanical wear, abrasion, damage, or deformation. Furthermore, check if the silicone O-ring is still in place (if applicable). Discard the device if any signs of degradation are evident.

19.5 Storage

Store the product dry and dust-free.

20 Disposal

NOTICE

- Invia Ease products should be handled and disposed of in accordance with the local environmental guidelines.
- The Invia Ease pump or the accessories must not be disposed of with the household refuse.

– The Invia Ease pump is made from various metal and plastic parts, which should be disposed of in accordance with the local environmental guidelines.
– Before disposal of the pump, the rechargeable battery and electronics must be removed. For instructions, contact the Medela Customer Service.

21 International regulations

21.1 Electromagnetic compatibility (EMC)

The Invia Ease pump is intended to be used in the professional healthcare facility environment and home healthcare environment and is EMC tested in conformity with the requirements of the standard IEC 60601-1-2:2014 4th Edition according to clause 7 and 8.9.
The pump needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these instructions for use. Portable and mobile RF communications can affect the pump.

NOTICE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

⚠ WARNING

To prevent malfunction resulting from electromagnetic interference:

- The Invia Ease pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Invia Ease pump should be observed to verify normal operation in the configuration in which it will be used.
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, RFID can affect the Invia Ease pump and should be kept at a distance of at least 30 cm away from the device.
- Use of accessories or cables other than those provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
This Invia Ease pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Invia Ease pump should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The Invia Ease pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	The Invia Ease pump 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 5 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV Line-to-line	± 0,5 kV, ± 1 kV Line-to-line	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25 cycles at 50 Hz at 0° for 30 cycles at 60 Hz at 0° 0 % U_T for 250 cycles at 50 Hz at 0° for 300 cycles at 60 Hz at 0°	0 % U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25 cycles at 50 Hz at 0° for 30 cycles at 60 Hz at 0° 0 % U_T for 250 cycles at 50 Hz at 0° for 300 cycles at 60 Hz at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Invia Ease pump requires continued operation during power mains interruptions, it is recommended that the Invia Ease pump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	It may be necessary to position the Invia Ease pump further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

This Invia Ease pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Invia Ease pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM band	3 Vrms	Except as indicated in the table on the next page, portable and mobile RF communications equipment should be used no closer to any part of the Invia Ease pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommend separation distance $d = 1.2\sqrt{P}$
	6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands	6 Vrms	$d = 2.0\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol. 

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Invia Ease pump is used exceeds the applicable RF compliance level above, the Invia Ease pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Invia Ease pump.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table of frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 inches):

Band (MHz)	Service
380–390	TETRA 400
430–470	GMRS 460, FRS 460
704–787	LTE Band 13, 17
800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5
1 700–1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS
2 400–2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7
5 100–5 800	WLAN 802.11 a/n

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Invia Ease pump including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

21.2 Radio transmission

FCC (USA) statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the 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.

22 Technical specifications

EN

vacuum range
–40 to –200 mmHg
–5 to –27 kPa

low flow
5 l/min.

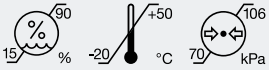
without canister
1.1 kg
2.4 lbs

H x W x D
125 x 175 x 90 mm
4.92 x 6.89 x 3.54 inch

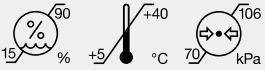
max. noise level
35 dBA
(250 ml/min; 125 mmHg)

alarm noise level
62/68/74 dBA

Switching adapter AC
Model: MSA-C2500IS12.0-30C-ZZ
IEC: 60601-1
Input: 100–240 VAC, max 0.8 A, 50/60 Hz
Output: 12 VDC, 2.5 A



Transport/Storage Conditions



Operating Conditions

IP22

§
ISO 13485

23 Material

Item description	Raw material description	Raw material information
Invia Ease pump (base unit)	Pump housing (upper and lower part) is made of ABS material. The silicone seal in between is made of silicone material.	Housing: ABS Housing seal: MQ Elastosil
Invia Ease charger	Charger housing is made of PC material, plug is made of ABS.	PC and ABS material, heat resistant
Invia Ease canister and tubing 300 ml, 500 ml, 1000 ml	The canister is made of polypropylene material, the tube is made of silicone and the Quick-Connector is made of ABS material.	Canister: PP Tubing: MVQ, silicone Quick-Connector: ABS
Invia Ease carrying case	Body of carrying case is made of microfiber material.	Polyester microfibre with thermoplastic elastomer backing
Invia Ease handle	Handle is made of PA with 30 % glass fiber, seal between pump and handle is made of silicone material.	
Invia Ease IV pole/bed holder	Plastic parts are made of PA with 30 % glass fiber, silicone pads are made of silicone material, and metal parts are stainless steel and aluminum.	Plastic parts: PA Pad: silicone Metal parts: aluminium and inox material

24 Warranty

Warranty period is for 2 years after date of delivery. The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage as well as use by unauthorized persons.

25 Service life

The service life of the device is five years; the internal batteries life included.

26 Meaning of symbols

The following tables explain the meaning of the symbols found on the product parts and its packaging.

Symbols used in these instructions

General safety alert symbol, points to information related to safety. [1]

Symbols on the motor unit

REF Indicates the part number of the device. [7]	MD This symbol indicates the item is a medical device. [X]	SN Indicates the serial number of the device. [8]	 Defines a temperature range (e.g. for operation, transport or storage). [2]
 Defines a relative humidity range (e.g. for operation, transport or storage). [3]	 Read and follow the instructions for use. [12]	Rx only This symbol indicates a Prescription Device U.S. Federal law restricts this device to sale by or on the order of a physician (for US only). [X]	 Identifies the manufacturer. [5]
 Indicates the compliance with the requirements of the Federal Communications Commission. [13]	 Contains fragile goods. Handle with care. [14]	 Keep away from rain. Keep in dry conditions. [16]	 Keep away from sunlight. [15]
 XXX	 Indicates that the package is capable of being recycled. [17]	# XXX	 Indicates the compliance with additional USA and Canada safety requirements for medical electrical equipment. [11]
 Indicates that this device contains Bluetooth wireless technology. (Trademarks of Bluetooth Special Interest Group (SIG))	 XXX	 Indicates compliance with international requirements for protection from electric shock (Type BF applied parts). [9]	 Do not dispose of electric/ electronic devices together with unsorted municipal waste (dispose of the device in accordance with local regulations). [10*]
 Indicates the location of the On/Off button. [4]	 Indicates the location of the mute button. [4‡]		

Symbols on the power adapter

Indicates the compliance with additional USA and Canada safety requirements for medical electrical equipment. [11]

The CE mark indicates conformity with the European low voltage and electromagnetic compatibility directive.*

Indicates alternating current. [17]

Do not dispose of electric/ electronic devices together with unsorted municipal waste (dispose of the device in accordance with local regulations). [10*]

Identifies the manufacturer. [5]

Indicates the part number of the device. [7]

Indicates the date of manufacturing. [6]

This symbol indicates manufacturer's batch code. [X]

Symbols on the canister/tubing

Indicates the part number of the device. [7]

Indicates the quantity (x) of individual devices in pack. [X]

Quick reference of the canister size.

This symbol indicates the item is a medical device. [X]

This symbol indicates manufacturer's batch code. [X]

This symbol indicates that the device should not be used after the date shown. [X]

This symbol indicates a single use device. Do not reuse the device. [X]

This symbol indicates the device is sterilized using ethylene oxide. [X]

XXX

This symbol indicates a Prescription Device U.S. Federal law restricts this device to sale by or on the order of a physician (for US only). [X]

XXX

Identifies the manufacturer. [5]

Contains fragile goods. Handle with care. [14]

Keep away from rain. Keep in dry conditions. [16]

Keep away from sunlight. [15]

XXX

Indicates that the package is capable of being recycled. [17]

Single sterile barrier system with protective packaging inside. [X]

Single sterile barrier system. [X]

Symbols on the handle and IV pole/bed holder

 Indicates the part number of the device.[7]	 Indicates the date of manufacturing.[6]	 Identifies the manufacturer.[5]	 Indicates that the package is capable of being recycled.[17]
 Contains fragile goods. Handle with care.[14]	 Keep away from rain. Keep in dry conditions.[16]	 This symbol indicates a carton package.[X]	

References

1 IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.2 Symbol 2 General Warning sign
2 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.7 Temperature Limit/ISO 7000-0632, Graphical symbols for use on equipment, Temperature Limit
3 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.8 Humidity Limit/ISO 7000-2620, Graphical symbols for use on equipment, Humidity Limit
4 IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.1 Symbol 29 Stand-by
5 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.1 Manufacturer
6 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.3 Manufacturing Date/ISO 7000-2497, Graphical symbols for use on equipment, Date of manufacture
7 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.6 Article number/ISO 7000- 2493, Graphical symbols for use on equipment, Catalogue number
8 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.7 Serial number/ISO 7000-2498, Graphical symbols for use on equipment, Serial number
9 IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.1 Symbol 20 Type BF applied parts
10 EN 50419, Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).
11 TÜV (Technical Inspection Association) mark indicates that the product is manufactured in compliance with UL safety requirements for USA and Canada (USA: UL60950-1, CAN: CSA C22.2 NO. 60950-1).
12 IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Table D.2 Symbol 10 Refer to instruction manual/booklet
13 Code of Federal Regulations, Title 47, Part 15b/15 c
14 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.1, Fragile, handle with care/ISO 7000-0621, Graphical symbols for use on equipment, Fragile, handle with care
15 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.2 Keep away from sunlight/ISO 7000-0624, Graphical symbols for use on equipment, Keep away from sunlight
16 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.4, Keep away from rain/ISO 7000-0626, Graphical symbols for use on equipment, Keep away from rain
17 ISO 7000-1135, Graphical symbols for use on equipment, General symbol for recovery/recyclable

***** These symbols are not applicable for the US, Canada, Mexico market.

27 Ordering information

Product	REF number
Invia Ease NPWT system (pump and charger)	101037357
Invia Ease canister and tubing 300 ml (5pcs)	101037361
Invia Ease canister and tubing 500 ml (5 pcs)	101037362
Invia Ease canister and tubing 1000 ml (3 pcs)	101037363
Invia Ease carrying case	101037360
Invia Ease handle	101037364
Invia Ease IV pole/bed fixation	101041744
Invia Ease charger US	101041939
Filter gasket with orange O-ring	
Pump feet	
Handle attachment covers	

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