triplejump

Triple Jump Insulin Delivery System

User Manual

Preface

Copyright Notice

The Triple Jump User Manual contains proprietary information of Triple Jump (Israel) Ltd. This information is supplied solely for the purpose of assisting authorized users of Triple Jump products. The instructions presented in this manual should in no way supersede established medical protocol concerning patient care and diagnosis.

No part of the contents of this manual may be used for any other purposes, disclosed to any person or firm, or reproduced by any means, without the express prior written permission of Triple Jump (Israel) Ltd.

The figures in this guide are for the purposes of illustration and reference only. The specifications on which they are based are subject to change without notice.

Trademarks

need details.... Triple Jump trademark? registered trademark?

NovoLog® and NovoRapid® are registered trademarks of Novo Nordisk A/S; Humalog® is a registered trademark Eli Lilly. [maybe we need to show Bluetooth here too?]

Other company and brand, product and service names are for identification purposes only and may be trademarks or registered trademarks of their respective holders.

This product is covered by Triple Jump (Israel) Ltd. patents. [patents pending?]

About this Manual   [Lidar - all my wording]

The Triple Jump User Manual is designed to serve as an accompanying document to the Triple Jump system. It is not intended to take the place of Triple Jump Training, which must be completed by the user before using the system.

Important — **This manual is not intended to provide medical or healthcare advice or any other recommendations to be used for diagnosis, or treatment. Moreover, it does not provide a substitute for medical or healthcare advice, recommendations and/or services from a qualified healthcare provider.**

The information provided in this document should not be relied upon in any way in connection with your personal healthcare, and related decisions and treatment. All such decisions and treatment should be discussed with a qualified healthcare provider who is familiar with your individual needs.

It is recommended to work closely with your healthcare professional when starting insulin pump therapy.

This guide is designed to help you understand the operation of your Triple Jump system, and contains valuable information regarding use of your new Triple Jump insulin pump and accessories.

For easy reference, and to help you find the information you need, each chapter contains relevant topics, arranged in accordance with typical workflow tasks and the system's controls and screens. Step-by-step instructions are grouped in accordance with the type of task you will need to perform; helpful notes, warnings, and cautions are added along the way.

For on-screen use, the electronic version of this document provided in your Triple Jump Starter Kit (shown in Figure 2-1 on page 2-2) has hyperlinked references, a search function, and navigation buttons - all features designed to facilitate seamless navigation and quick, easy access to the information.

⚠ **CAUTION** — **Screen images shown in this manual are examples only and are not suggestions for user settings. Consult with your clinician/healthcare professional to determine the appropriate settings for you.**

Intended Use

The Triple Jump system treatment population is patients who manage their diabetes through continuous subcutaneous insulin injection (CSII) using an insulin pump. The device is intended for independent adults only.

The Triple Jump system is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of insulin-dependent diabetes mellitus. The Triple Jump Pump is able to communicate with the Triple Jump Controller reliably and securely - and to receive, execute, and confirm commands. The system is intended for single patient, home use and must be prescribed for a user by a healthcare provider [or this: a qualified medical professional?].

The Triple Jump Pump is a miniature, portable, programmable, insulin patch pump which adheres to the user's skin, and is therefore intended for ambulatory use. The user is required to wear the Pump at all times.

The Triple Jump system is intended to be used with the following types of legally-marketed, rapid-acting, insulin solution U-100:

- Insulin Aspart (Novolog® / NovoRapid®)
- Insulin Lispro (Humolog®)

The Triple Jump system may be used only after receiving guidance from a Triple Jump Product Trainer and while the user maintains contact with his/her healthcare provider throughout the use period to receive relevant clinical instructions and guidance. All therapy adjustments should be based on measurements obtained using a home glucose monitor.

After training by a Triple Jump Product Trainer, the user can independently perform the Switch Pump flow, and any other task needed for the Triple Jump system use, including delivering a bolus, making changes to the basal profile, suspend delivery, history viewing, notifications handling, and so on.

The Triple Jump Pump is intended for use only with the provided Triple Jump Controller.

⚠ **CAUTION** **In the event of any Controller malfunction, the user is instructed to remove the Pump and discontinue its use. Immediately thereafter the user is required to contact Triple Jump Customer Services for assistance.**

Indications for Use

Lidar- section pending discussion

The Triple Jump System is indicated for Adult use only (i.e., those who more than 21 years old).

Note *The system has not be tested for Pediatric use.*

Contraindications

The Triple Jump System is contraindicated for people who are unable to:

- Perform at least four (4) blood glucose checks per day.
- Maintain contact with their healthcare provider.
- Use the system according to the instructions.

Suggest these additions (people who are).... please check wording and/or advise, as applicable:

- Younger than 21 years.
- Blind, or visually impaired.
- Have hearing loss, or have difficulty hearing.
- Have a physical disability of such nature that would preclude proper use of the system components.

Prescription Notice

⚠ **CAUTION** Federal (USA) law restricts this device to sale by or on the order of a physician. In addition, the user should be properly trained in use of the system.

Triple Jump Training

Important Triple Jump Training must be completed by the user - prior to using the Triple Jump system and its accessories.

Training is given by a Triple Jump Product Trainer. *Lidar - my wording*

Note *You are required to prepare the appropriate Settings List (Basal Profile, Max Bolus, Max Basal rate) prior to your meeting with the Triple Jump Product Trainer.*

Responsibility of the Manufacturer

The manufacturer considers itself responsible for the effects on safety, reliability, and performance of the equipment only if:

- Service and repair of the Triple Jump system components are carried out by Triple Jump personnel, or anyone authorized by Triple Jump (Israel) Ltd.
- The equipment is used in accordance with the instructions for use.

⚠ **CAUTION**   **Users should always adhere to the following precautions:**

- Refrain from modifying the system hardware or software in any way.
- Users are prohibited from changing, adding, removing or disassembling any system parts. The Warranty shall not apply to any defects, failure or damage caused by improper use and/or improper or inadequate care.
- In the event of system malfunction, always report to Triple Jump (Israel) Ltd. authorized representatives only.

Conventions Used in this Manual

Warnings

Warnings are used to identify conditions or actions for which there is a known risk, which may cause serious (or even fatal) injury or other serious adverse reactions if the instructions are ignored. See the example below.

⚠ **WARNING**	**Before filling the Reservoir with insulin, make sure there are no air bubbles or pockets of air in the Filling Syringe.** **Air transferred from the Filling Syringe into the Reservoir could result in interrupted insulin delivery.**

Cautions

Cautions are used to identify conditions or actions for which a potential hazard may exist, which will or can cause minor personal injury or equipment damage, if the instructions are ignored. These will alert you to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunctions, device failure, damage to the device or damage to other property.

Cautions are also used to highlight a procedure or step needing particular care or consideration, as shown in the example below.

⚠ **CAUTION**	**Do not apply the Triple Jump Insulin Pump to skin that is not intact or that shows signs of infection, allergic conditions, burns,** *etc.*

Notes

Notes are used to provide additional information for the purpose of clarification, or to stress details of particular importance. An example is shown below.

Note *The Battery Chargers are interchangeable and can be used for the Engine battery or the Controller battery.*

Important notes are used to stress important information, or to identify procedures or steps that must be performed to ensure normal or optimal system performance. An example is shown below.

Important **When not in use, the Engine should always be placed in the Docker to keep it clean and protect it from damage or entry of dust particles** *etc.*

Procedure Instructions

For easy identification, procedure instructions are preceded by a symbol, as shown in this example:

➼ **To Suspend Insulin Delivery**

Numbered procedure steps then follow.

Terms and Abbreviations

Terms and Abbreviations

Term or Abbreviation	Definition
Note: table now sorted alphabetically - (normal search method) - will add the groups "Interfaces" etc if preferred	
Active Engine	The Engine last chosen by the user during the Pump Switch procedure.
Adhering	Fixating the Pump onto the user's body, using the adhesive base of the Inserter.
Alarm	A high-priority notification indicating that immediate response is required.
Attachment	Physical connection between the two Pump parts (Engine and Reservoir).
Charger	A unit for charging the Controller's or Engine's battery or this: A unit for recharging the battery (Controller or Engine).
Connection	Wireless communication between the Pump and Controller.
Controller	A handheld unit which is used to control the Pump using wireless communication.
CUT	Continuous Use Time (time between Reservoir changes).
DIA	Duration of Insulin Action
Disposable Pack	Loaded Inserter inside blister
Docker	A unit for covering the Engine when it is not in use and for connecting the Engine to the Charger suggest this: A dual-purpose unit used for covering the Engine when not in use and also for connecting the Engine to the Battery Charger.

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Terms and Abbreviations (continued)

Term or Abbreviation	Definition
Engine	A reusable part which includes the motor, battery and electronics. or this: [A reusable part that includes a motor, rechargeable battery and electronics].
EOR	End of Insulin Reservoir
Filling Device	A syringe and needle used for filling the Reservoir with insulin. suggest this: A disposable Filling Syringe and Filling Needle used for drawing insulin from a vial and filling the Reservoir with that insulin.
Inserter	Cannula inserter alone
Loaded Inserter	Inserter attached to a Reservoir
Long Bolus	A dose on insulin delivered at a constant rate, over a set period of time. For example, 2U of insulin over 2 hours.
MFV	Minimal Filling Volume
Non-active Engine	The Engine currently not chosen by the user (typically being charged).
Pairing	Initial connection between the Pump and the Controller, after which the Pump is invisible to other devices and only the Controller can communicate with it. (Pairing process not performed by the user) - should we add this?
Powered Docker	The Docker connected to an electrical power source via USB cable and the Charger which is used for charging the Engine battery. suggest this: Docker state when connected (via USB cable) to both an electrical power source and the Battery Charger - in order to recharge the Engine battery.

Terms and Abbreviations (continued)

Term or Abbreviation	Definition
Pump	Insulin infusion device that comprises the Engine attached to Reservoir.
Pump Switch	A procedure in which the Pump is removed from the user's body and replaced by a new Pump, made of the second (freshly charged) Engine, and a new Reservoir. or this: A procedure in which the Pump is removed from the user's body and replaced by another Pump, comprising the second (freshly-charged) Engine, and a new Reservoir. During this procedure, the placement site (Cannula site) is also changed to avoid possible tissue scarring and/or damage.
Quick Bolus	A single dose of insulin delivered at once [at once, immediately?].
Reminder	An optional periodic signal that reminds the user of something. [An optional periodic signal given to the user as a reminder of action required?].
~~Requirement~~	~~A feature or specification which the product MUST include, and which must be verified. Requirements use the word "shall" to define the required features~~
Reservoir	A disposable part that includes the insulin Reservoir, delivery conduits and Cannula.
Ship Mode	A feature that keeps the Engine in a low-power state. During ship mode, Engine communication is Off. The end-user can exit ship mode and reactivate the Engine by plugging it into the charger. IS THIS FOR THE USER MANUAL? If so, must we add procedure instructions?
Specifications Type:	Not for UM... correct?

Terms and Abbreviations (continued)

Term or Abbreviation	Definition
~~Stretch goal~~	~~A feature or specification which would be nice to have but is not required~~ ~~Stretch goals use the word "should" to define the desired features~~
System/ Triple Jump (TJ) System	Triple Jump's Pump (Engine+ Reservoir), Controller, Inserter, Filling Device, Docker and Charger suggest this: The Triple Jump Pump (Engine + Reservoir), Triple Jump Controller, disposable Inserter, disposable Filling Device (syringe and needle), Docker and Battery Charger.
Tip Protector	A silicone cap used to cover the cannula after removal form body, to eliminate finger pricking from cannula suggest this: A silicone cap used to cover the Cannula after removal of the Pump from your body. This is to eliminate the risk of the sharp Cannula tip pricking your fingers.

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Chapter 1 – Safety Information

General Safety Considerations

The Triple Jump system is designed and manufactured to ensure maximum safety of operation. The system should be used and maintained in accordance with Triple Jump recommended guidelines and in strict compliance with the safety precautions, warnings, and operating instructions contained in this User Manual.

⚠ **CAUTION**   Only users who have been trained in its use may operate the Triple Jump system.

General Warnings and Cautions

Before using the Triple Jump system, it is important to read the instructions provided in this User Manual in order to fully understand use of the system components and its supporting accessories.

Always maintain the strict practice of frequent blood glucose testing procedures and monitor your blood glucose with the guidance of your healthcare provider.

⚠ **CAUTION**   Improper monitoring risks the possibility of undetected hyperglycemia or hypoglycemia!

⚠ **CAUTION**   Do NOT use any system component or accessory if impaired functionality is suspected.

Personal Heath Considerations

It is recommended for users of the Triple Jump system to be aware of the following personal health considerations:

- The Triple Jump system is not recommended for individuals with hearing loss. Always verify your ability to hear system alarms and notifications.

- If you are unable to use the System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the System properly.

- The used Reservoir is considered biohazardous and can potentially transmit infectious diseases.

⚠ **CAUTION** **The Reservoir should be disposed of in accordance with national laws for disposal of bio-hazardous needles**

- The Triple Jump system is intended for one-person use ONLY.
  Do not share the device with anyone - including other family members.

- Although the Triple Jump Pump has multiple safety alarms, it cannot notify you if the Pump is leaking or the insulin with which it is filled has lost its potency. Therefore, it is essential to test your blood glucose levels **at least four times per day**. If your blood glucose is out-of-range, check the Pump to ensure that the necessary amount of insulin is being delivered.

⚠ **WARNING** **If you are having symptoms that are inconsistent with your blood glucose test results and have followed all instructions provided in this User Manual, call your healthcare provider.**

⚠ **WARNING**   Do not use another automated insulin delivery system while using the Triple Jump system.

⚠ **WARNING**   Do NOT use the Triple Jump system until you have been trained by Triple Jump Product Trainer, who will help you initialize the system based on your individual needs.
Inadequate training or improper setup could compromise your health and safety, putting you at risk.

Environments to Avoid

The following outlines various environments to be avoided when using the Triple Jump system:

- The Triple Jump system should NOT be used at low atmospheric pressures.
  For details and specifications, see Appendix B - System Specifications and Technical Information.

- The Triple Jump system should NOT be used in oxygen-rich environments.
  For details and specifications, see Appendix B - System Specifications and Technical Information

- The Triple Jump system should NOT be used in extreme temperatures.
  For details and specifications, see Appendix B - System Specifications and Technical Information

⚠ **CAUTION**   Do not attempt to steam, sterilize or autoclave your Pump or Controller!

⚠ **WARNING**   The Triple Jump system may be affected by strong radiation or magnetic fields.
Always remove your Pump and leave it - together with your Controller - outside the treatment area if ever you are required to undergo imaging examinations (X-ray, MRI, or CT scans), or similar tests.
Magnetic fields in the immediate vicinity of these scanning environments could cause damage to your Triple Jump system - possibly resulting in impaired insulin delivery, or even over-delivery and severe hypoglycemia!

⚠ CAUTION In the event that your Triple Jump Pump is inadvertently exposed to a strong magnetic field, discontinue use immediately - then contact Triple Jump Customer Services (24-hour service) for assistance.

⚠ CAUTION In the event that your Triple Jump Pump is inadvertently exposed to a strong magnetic field, discontinue use immediately - then contact Triple Jump Customer Services (24-hour service) for assistance.

⚠ CAUTION Your Pump can be used while showering, bathing and swimming - however, it is NOT suitable for use when SCUBA diving. (The Pump is water-resistant for depths of up to 1 meter for 30 minutes) For full details and specifications, see Appendix B - System Specifications and Technical Information

⚠ CAUTION When wearing your Pump, always take care to protect it from any external force knocking on the infusion site - for example when playing sports, in crowds, etc.

Travel and International Use

Important When traveling, it is important to be aware of the safety issues detailed below.

- Before air travel, ask your healthcare provider for a written note to present to airport/security personnel stating that you must wear your Triple Jump Pump at all times - and that your Controller and Pump communicate wirelessly using BLE technology, causing no interference to security screening devices.

- When you are wearing your Pump, the Controller MUST be turned ON. Do not turn it OFF during flights.

- Discuss your plans to travel with your healthcare provider and ask if any of your Treatment Settings (Basal rate) should be modified.

Note *You may need a power adapter when using the Battery Charger in different countries.*
Lidar: "Battery charger provided is american charger. any adaptor should do"... don't we need to provide specs?

Changing Date and Time Settings

When traveling to a different time zone, it will be necessary to change the date and time settings on your Triple Jump Controller.

For instructions, see

Emergency Kit

⚠ **CAUTION** **Always keep an Emergency Kit with you at all times for quick response in the event of a diabetic emergency!**

Note The Emergency Kit is not supplied by Triple Jump (Israel) Ltd.

Contents of the Emergency Kit should include the following items:

- Several new Triple Jump Sterile Disposable Packs.
- The inactive, fully-charged Engine (covered by the Docker).
- Triple Jump Battery Charger.
- A vial of U-100 insulin (Humalog® or NovoLog®/NovoRapid®).
- Syringes (or insulin pens) for injecting insulin
- Blood glucose meter and test strips
- Ketone test strips
- Glucose tablets - or other source of fast-acting carbohydrate
- Alcohol prep swabs
- Instructions from your healthcare provider regarding the amount of insulin to inject if for any reason delivery from the Triple Jump system stops
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Triple Jump system
- Emergency phone numbers - including that of your healthcare provider
- Glucagon kit and written instructions for giving an injection in case you are unconscious.

Safety Features

Pump Priming

Every time you switch your active Pump, once you have filled the Pump's insulin cartridge with insulin, it is necessary for the system to perform a Pump priming process to prevent any air bubbles from entering your body - along with the insulin.

⚠️ **WARNING** **Priming MUST be performed BEFORE attaching the Pump to your body and will take only a few seconds.**

Cannula Insertion

Safe insertion of the Cannula is performed by pressing the safety and trigger buttons, simultaneously. These are located on the Loaded Inserter - shown in Figure 2-10 on page 2-14.

When removing the Pump from the body, the Cannula should be covered with the Tip Protector, before removing the Reservoir from the Engine - see Figure 2-11 on page 2-15. For the purpose of safety, this provides safe protection, eliminating the risk of the sharp point causing you injury.

Alarms, Alerts and Notifications

For your safety, the Triple Jump system provides a range of alarms, alerts and notifications to tell you that your attention is needed - or to warn you of hazardous situations.

Note *A detailed explanation of the various system Alarms and Alerts is provided in Chapter 8 – Alarms and Alerts.*

System Safety Checks

The Triple Jump system constantly performs safety checks on your active Pump. If it detects any problems in the Pump, in the Controller, or in the communication between them, the system informs you through on-screen messages, beeps and vibrations from the Controller. Moreover, if Controller is unavailable for use, the system will inform you of any problem with beeps from the Pump.

Compatible Insulin Types

The Triple Jump System has been designed and tested to operate with the following insulin types and strengths, which are suitable for continuous subcutaneous infusion (Insulin Pump):

- Humalog® U100
- NovoLog® U100 / NovoRapid® U100

⚠ **WARNING**

Use of other insulins, or different concentrations, may compromise insulin delivery to your body leading to inaccurate treatment. This poses the risk of out-of-range Blood Glucose levels and possible injury.

Do not use any type of insulin other than those listed above.

Consult your healthcare provider for more information, if necessary.

Lidar... is the following to be added here:

Encoder Sensor, Reservoir Sensor.... Sharps Injury Protection, etc?

Equipment Classification

Lidar.... will explain later

Compliance with International Standards

TBD

Electrical Safety

For details of the electrical safety standards to which the Triple Jump system complies, refer to the information provided in Compliance with International Standards.

⚠ WARNING **Do not open Reservoir or Controller covers!**
The Triple Jump system has no user-serviceable parts.

Note Should technical assistance be required, contact Triple Jump Technical Support.
For contact details, see rear cover of this manual.

Battery Safety

⚠ CAUTION **When recharging either the Controller or Engine batteries, use only the Battery Chargers and USB cables supplied with the Triple Jump system.**

Note For details, see Battery Charger on page 2-16.

Battery Status Indicators

Battery Status indicators for both the Triple Jump Controller and the Engine are displayed on the Controller screens. See detailed explanations in Welcome to the Controller Screens on page 3-1.

Battery Capacity Low

TBD

Protection Against Ingress of Liquids

TBD

Electromagnetic Compatibility (EMC)

TBD

Biocompatibility

TBD

FCC Compliance

FCC Notice:

The Triple Jump system, Model TJ0010 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.

Note *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 separation between the equipment and receiver.
- Connect the equipment into 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.

Triple Jump Engine unit: FCC ID: 2AUPA-TJENG
Triple Jump Controller unit: Contains FCC ID: WAP3028

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

Changes or modifications to this equipment not expressly approved by the party responsible for compliance (Triple Jump Israel Ltd.) could void the user's authority to operate the equipment.

System Safety Labels

TBD

Location of Safety Labels on System Components

TBD

Safety Labels on Accessories and Disposables

TBD

General Guidelines for Comfort and Safe Handling

Environmental Requirements

Infection Control

TBD

System Software

General note about software upgrades not currently supported.

Also, somewhere to add something about backup of system data not currently supported

Q. are data files deleted after a period of time? FIFO? [add to History section?]

Chapter 2 – Introduction to the Triple Jump System

System Overview

The Triple Jump system comprises a compact, fully-portable, battery-operated miniature Insulin Pump and hand-held Controller - together with supporting accessories and sterile, single-use disposables.

Utilizing patented [yes?] Triple Jump technology, the computer-controlled system enables continuous subcutaneous delivery of insulin, at set and variable rates. Communication between the Controller and the Pump utilizes Bluetooth®technology. Active transmission provides real-time instructions, alerts and alarms as well as feedback of a range of parameters that are important (and sometimes critical) for the control and monitoring of diabetes mellitus in persons requiring insulin.

Important	Always work closely with your healthcare professional when starting insulin pump therapy. The Triple Jump system is supplied for your personal use and will require input of your personalized settings in accordance with your prescribed treatment parameters (as determined by your clinician).

To understand the system components and basic features, it is recommended to read this chapter which gives you an overview of the following:

- What's in the Triple Jump Starter Kit?
- System Components

Important	Before using your Triple Jump Pump to deliver insulin, training and an initial setup procedure are required. This is performed (with you) by a Triple Jump Product Trainer, as described in Chapter 4 – Getting Started.

What's in the Triple Jump Starter Kit?

The Triple Jump Starter Kit is supplied in a convenient carry case, containing the items illustrated below.

Legend	
1	Engine covered by Docker (two)
2	Triple Jump Controller
3	Battery Charger (two)
4	USB Cable for use with Battery Charger (two)
5	Triple Jump Sterile Disposable Pack (two). Contents are detailed on page 2-11.

Note: Supplied but not illustrated - Triple Jump User Manual (printed); USB memory stick containing electronic version (PDF file); one pack containing two Tip Protectors.

Figure 2-1   Triple Jump Starter Kit

Note   Additional Sterile Disposable Packs (supplied in a box of 10) are available for order, as required. For catalog numbers and re-ordering information, see Parts List on page 9-4

System Components

Triple Jump Pump

The Triple Jump Pump comprises an assembly of the Engine and Reservoir components (described below). When connected together, this unit can be described as the "heart" of the delivery system by which commands are received from the Triple Jump Controller and insulin is delivered to the body - in accordance with the personalized settings programmed by the user.

Reservoir   Engine   Pump Assembly
                                  (with adhesive base)
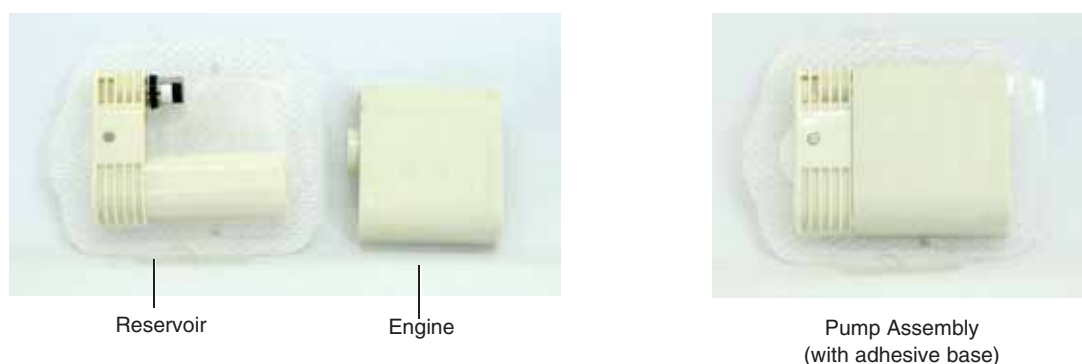
Figure 2-2   Triple Jump Pump

Attachment of the Pump to your body is by way of its strong, adhesive base (shown in Figure 2-2).

Important   The miniaturized Triple Jump Pump is uniquely designed to be unobtrusive and worn easily under your clothing. Moreover, both the Pump and adhesive base are water-resistant, enabling you to shower or use a hot tub, as desired.
Your Pump can be used while swimming - however, it is NOT suitable for use when SCUBA diving.
(The Pump is water-resistant for depths of up to 1 meter for 30 minutes).

Engine

The Triple Jump system is supplied with two Engines (both of which have been paired to the Controller). Each is a small-sized unit that houses the Triple Jump Pump electronic components, a motor, and a rechargeable Lithium Ion Polymer battery (3.7V 25mAh). One end of the Engine is custom-shaped for insertion into either the Reservoir (see Figure 2-3), or to the Docker (when not in use, or when charging the battery).

⚠ **CAUTION**   **Each Engine is intended for single-patient use only.**

The active Engine receives insulin delivery instructions from the Controller, delivering insulin into your body in accordance with your personalized settings (programmed by you).
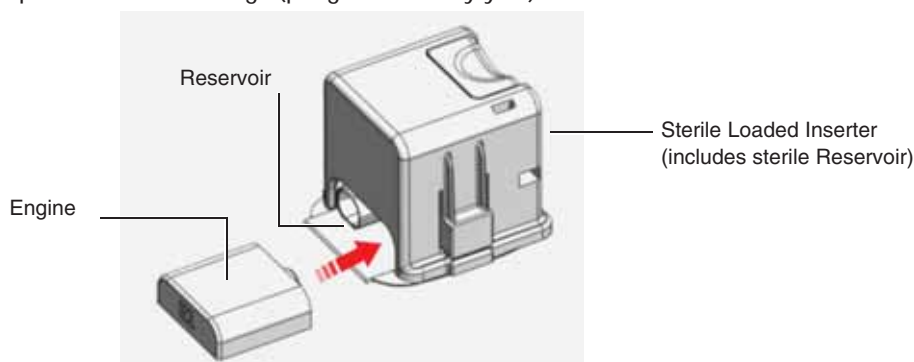
Figure 2-3   Orientation of Engine when Inserting into Reservoir

Note   *For battery-charging instructions, see Charging the Engine Battery on page 4-3.*

Important   **The Controller communicates with only one Engine at a time (the active Engine). When not in use, the inactive Engine should always be kept covered by the Docker to keep it clean and provide protection from the entry of dust particles** *etc.*

Note *The Engine is a reusable component; typically it has a usable life of up to 2 years, before requiring replacement. When replacement is necessary, contact Triple Jump Customer Services for assistance.*

Reservoir

The Reservoir, a single-use disposable component, includes an insulin cartridge and a 27G Cannula (shown in Figure 2-4).
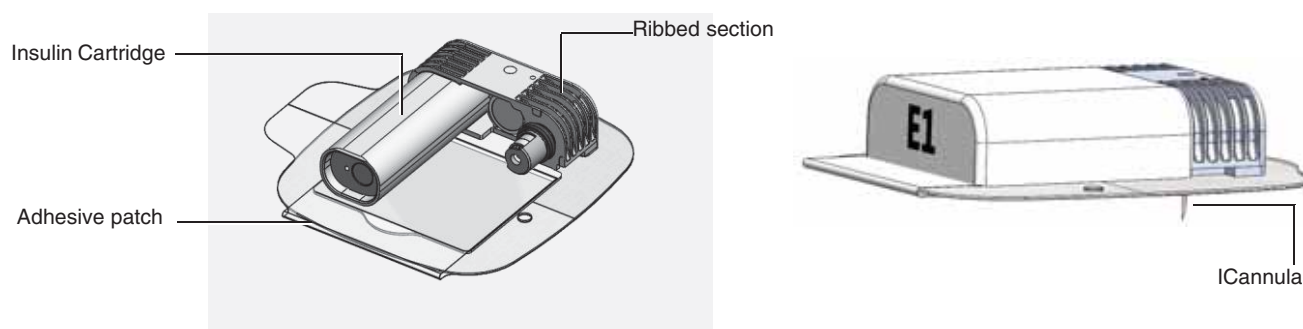
Figure 2-4   Reservoir

The Reservoir is supplied sterile, pre-assembled inside the Cannula Inserter (sterile Loaded Inserter).

Important   The Reservoir has a maximum capacity of 200 insulin units (2.0ml).
Typical use-time of the Reservoir will depend on your insulin requirements and skin tolerance.
However, the user will receive an Alert after 72 hours and an Alarm at 96 hours (when insulin delivery stops).

The Reservoir is attached to the Engine and to your body using adhesive tape.

The Reservoir is ready-mounted onto a strong adhesive patch (shown in Figure 2-4), used to attach the Triple Jump Pump to your body.

A portion of the Reservoir body has ribbed sections (also illustrated). When removing the Pump from the body, gripping this area serves to provide leverage.

⚠ WARNING	**Do not attempt to refill the Reservoir when the insulin cartridge is empty!** The Pump must be removed from your body, and replaced (i.e. using a new Reservoir and an Engine with a fully-charged battery). Refer to the step-by-step instructions provided in Chapter 6 – Switching the Active Pump.

⚠ CAUTION	After use, the Reservoir must be disposed of in a designated container - and in accordance with local safety regulations.

Docker

The dual-purpose Docker is used to dock the Engine when not in use, and also for charging the Engine battery.

| Position for Docking of Engine | Position for Battery Charging |

LED Indicator

USB Port

Figure 2-5   Docker

The base of the Docker is flat and is equipped with a USB port, used for connection of the USB cable when charging the Engine battery. One side of the Docker has an LED indicator; during battery charging, this illuminates to indicate charging status.

Note *For battery-charging instructions, see* *Charging the Engine Battery* *on page 4-3.*

Important   When not in use, the Engine should always be placed in the Docker to keep it clean and protect it from damage or entry of dust particles *etc*.

Triple Jump Controller

The Controller is a rechargeable, hand-held smart device (similar in appearance to that of a smartphone).

All Pump operations are programmed and controlled through the Controller, which receives and transmits information to your Pump via wireless (Bluetooth®) communication.
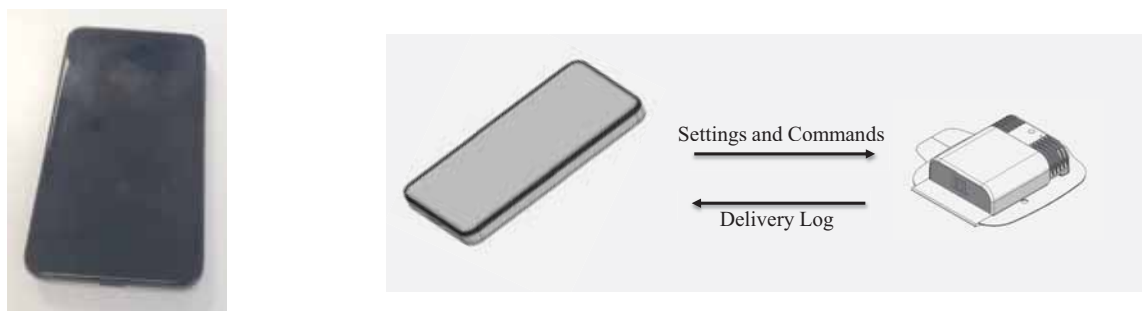
Figure 2-6   Triple Jump Controller

⚠ **CAUTION**   The Controller is intended for single-patient (personalized) use only.

The Controller is operated via its specially-designed touch screen. This is turned On by pressing the On/Reset button located on the *upper right* side. Commands or operations are selected and/or set by tapping the screen on indicated areas, or scrolling to the required selection, as appropriate. The wizard-type display of instructions helps to guide the user in performing specific tasks, as required. See Chapter 3 – Welcome to the Controller Screens for illustrations and explanations of the various Controller screens and controls.

Important   During treatment, the Controller MUST remain ON and always be located close by - within 1.5 meters (5 feet) of the Pump - to enable active communication and successful transmission of data between the two units.

Note *The Controller's Reset button is used in the event that the screen display appears blank. This will restart the application and return to the Home screen (without the loss of any settings).*

The Controller operates on an Android-based platform running patented [check] Triple Jump software. This application is used to program Basal and Bolus insulin deliveries and to change the Triple Jump system and treatment settings.

Information from the Pump (*status of: Engine battery, Reservoir, insulin delivery*) is received by the Controller, where it is stored and displayed in real time on the touch screen (see Status Bar Icons on page 3-6).

The Controller has an internal, rechargeable Lithium Ion Polymer battery (3.7V 1700mAh); power is typically sustained for 2 days before the battery will require charging.

Note *A fully-depleted battery will required approximately 3 hours for a complete recharge. For instructions, see Charging the Controller Battery on page 4-2.*

⚠️ **CAUTION** | **When recharging the battery, use ONLY the Battery Charger and USB cable supplied with the Triple Jump system.**

Note *For Controller and battery specifications, see Appendix B - System Specifications and Technical Information.*

The Controller in the Triple Jump Starter Kit is supplied ready-paired to the two Engines. No further pairing by the user is required.

⚠️ **WARNING** | **Always take care not to lose your Controller!**
Although it is capable of communicating with the Triple Jump Engine, the Controller itself cannot be paged.

⚠ **CAUTION** Avoid exposing the device to extreme temperatures or moisture. For example, do not leave the Controller in your car or outdoors for extended periods of time.

Disposables and Accessories

Triple Jump Sterile Disposable Pack

The Triple Jump Sterile Disposable Pack is a blister pack, supplied sterile and ready-to-use.

Figure 2-7 Triple Jump Sterile Disposable Pack

⚠️ **CAUTION**   The Triple Jump Sterile Disposable Pack is intended for single-use ONLY.
Do NOT attempt to re-sterilize and/or re-use the contents under any circumstances.

Note For an explanation of package symbols, see Safety Labels on Accessories and Disposables *on page 1-13.*

The disposable pack contains a plastic tray with compartments for the following sterile disposable items:

- **Loaded Inserter**
  This is preloaded with a Reservoir, containing a 27G Cannula and an Insulin Cartridge. The Inserter unit is supplied ready-mounted onto an adhesive base (patch) covered by a protective Tyvec film. For more details, see Loaded Inserter on page 2-14.

- **Filling Syringe**

- **Filling Needle**

Note *The single-use, disposable Filling Syringe and Needle are used to draw insulin from an insulin vial - in order to fill the insulin cartridge located in the Reservoir.*
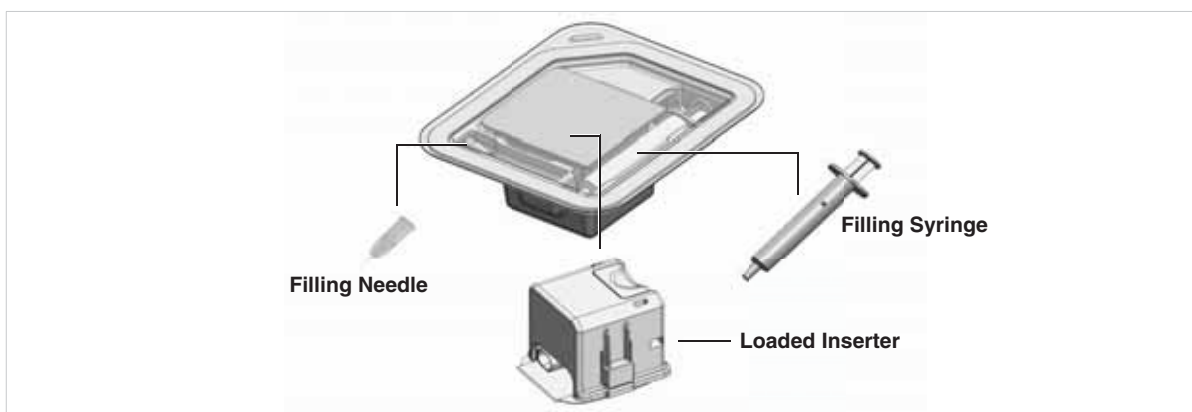
Figure 2-8   Sterile Disposable Blister Pack Contents

Important Before opening a Triple Jump Sterile Disposable Pack, check the expiration date and inspect the packaging for signs of damage or tampering.

Step-by-step procedure instructions for use of the pack contents are provided in Chapter 6 – Switching the Active Pump.

Note *In the unlikely event that it becomes necessary to release the Pump from the Inserter before the Cannula has actually been inserted into the body, the disposable pack tray may be turned upside-down and safely used as a "dummy" for Cannula insertion (in order to release the Pump). For example, this could be required if you had pre-filled the Reservoir prior to attachment to the Engine*

Additional Triple Jump Sterile Disposable Packs are available for order and supplied in a box of 10 units, together with a pack of 10 Tip Protectors.

Figure 2-9   Triple Jump Sterile Disposable Packs in Bulk Box

Note *For reordering details, refer to Parts List on page 9-4*

Loaded Inserter

The disposable Loaded Inserter is designed for safe, quick and easy insertion of the Cannula into your chosen body site by simultaneously pressing the Trigger (located on the top of the Inserter) and each of the two Safety buttons (one on either side) - illustrated in Figure 2-10.

After Cannula insertion, the Inserter is removed from the Pump, then disposed of. This removal process is facilitated by releasing the two Safety buttons (located one on either side of Inserter).

— Trigger

— Safety Button
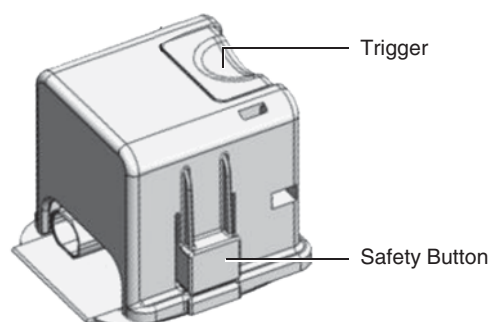
Figure 2-10   Loaded Inserter

⚠ **CAUTION**   After use, all disposable items must be disposed of in a designated container - and in accordance with local safety regulations.

Tip Protectors

The cone-shaped Tip Protector is designed for use when removing the Pump from the body.

Made of strong rubberized? material, this provides protection by being placed over the tip of the Cannula to safely prevent the risk of the sharp point causing you injury.

Figure 2-11   Tip Protector Placed over Cannula

Note   For procedure instructions, see Removing the Pump from Your Body on page 6-6.

Battery Charger

Two Battery Chargers are supplied with the system, each with a USB cable. These are used for recharging the Triple Jump Engine battery, or the Controller battery, as and when required.

Note   *The Battery Chargers are interchangeable and can be used for either unit.*

The Battery Charger connects to a mains power wall outlet and is equipped with a USB port (shown in Figure 2-12).

USB Port

Figure 2-12   Battery Charger and USB Cable

Each USB cable has a USB connector (type C)] on one end, used for connection to the Battery Charger. The other has a micro [yes?] USB connector for connection to either the Controller, or the Docker (when charging the Triple Jump Engine battery).

⚠ **CAUTION**   **Use ONLY the Battery Charger and USB cable supplied with the Triple Jump system. Failure to do so will void the warranty.**

Note   *For charging instructions, see Battery Charging on page 4-2.*
For Battery Charger and USB cable specifications, see Appendix B - System Specifications and Technical Information.

Chapter 3 – Welcome to the Controller Screens

General Overview

Touch Screen Terminology

The explanations in Table 3-1 will help you understand the Triple Jump Controller touch screen, and how to navigate and use the menus, buttons, commands, instructions, and options available.

Table 3-1   Controller Screen Terminology

Term	Explanation
Screen	Area of the Controller that displays menus, instructions, and messages.
Menu	List of options; choosing the appropriate option enables you to perform a specific task.
Button	On-screen button - generally used to confirm or cancel a command, or used as navigation (Next/Back) - see Command and Navigation Buttons.
Tap	Using one finger, tap the screen on a specific area to perform the required action.
Swipe	Swipe the scroll control *up* or *down* to view available options. In the Bolus screen, horizontal swiping is also used. [may change - TBD]
Scroll	A control feature used to view or select an option by swiping it *up* or *down*.
Pop-up	A screen that hovers over the Main screen, partially covering it. When a pop-up is active, the screen beneath it is inactive and appears grayed-out.
Message	A screen that opens to reveal a message. This could be an instruction, or a specific warning.
Wizard	A series of screens, displayed consecutively, to guide you through a specific procedure or task.

Introduction to the Controller Screens

The Triple Jump Controller display is designed for easy operation. Screens are logically grouped and presented in accordance with the respective workflow tasks.

Information below describes the main Screen groups; the illustrations provided are intended to help you become familiar with the screen areas and the main controls and settings available in each screen category.

Note *For reference, an explanation of the typical use of the various screen categories is outlined in Table 5-1 on page 5-1.*

Lock Screen

During your first-time training session together with your Triple Jump Product Trainer, you perform initial setup of your Controller. You are required to enter a passcode pattern and a user name. Refer to Setting a Screen Lock Passcode on page 4-7.

The passcode pattern you set enables you to unlock the Controller when it is locked.

Note *Your Controller automatically locks after 30 seconds of no use.*
During the Pump Switch procedure, the Controller locks after 2 minutes of no use.

Unlocking the Controller will take you to Home Screen. However, note the following:

- Whenever an Alarm is presented, or during the Switch Pump procedure, you will be returned to the same screen in which you were working before the Controller entered sleep mode.

- If you enter your passcode incorrectly for more than 3 times, you are required to enter the recovery password you set in the initial setup. After 3 tries, the screen will remain locked.
  In this event, you will need to contact Triple Jump Customer Services for assistance.

Home Screen

By default, the Home screen is displayed after completion of the first-time Controller setup (procedure described in Chapter 4).
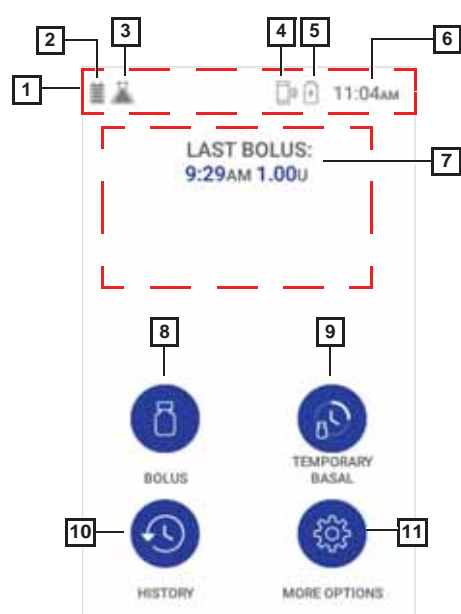
Legend	
1	Status Bar (Pump, *left* side; Controller, *right* side). See Table 3-2.
2	Engine battery status.
3	Volume of insulin in Reservoir (graphic representation)
4	Controller battery status
5	Controller-to-Engine Communication status. Active shows grey icon; inactive shows red.
6	Current time
7	Delivery area - displays real-time update of actual Insulin delivery. Example shows Last Bolus - time delivered and Bolus amount.
8	Bolus icon. Used to access Bolus Settings screens - see page 5-9.
9	Temporary Basal icon. Used to access Temporary Basal Settings screens - see page 5-15.
10	History icon. Used to access History Screen screens - see page 7-2.
11	More Options icon. Used to access More Options screens - see page 3-12.

Figure 3-1   Home Screen

Note   *The Home screen does not have options to deliver Quick Bolus, Long Bolus, or Suspend Insulin Delivery. (The Resume insulin delivery option is available, when applicable).*

After the Controller has been setup during your first-time setup training, and you have programmed more treatment settings, the Home screen display will show more detailed information regarding the Active Insulin Delivery. This will include delivery *mode, status, number of units delivered, time of supply, insulin suspended* - as applicable. See an example below.
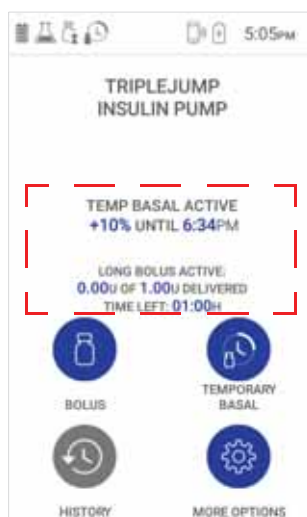

Figure 3-2   Home Screen - Active Insulin Delivery Status
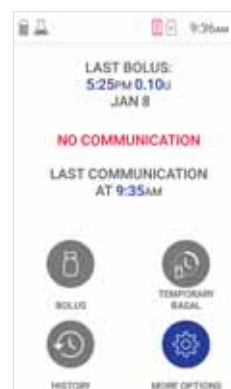
Figure 3-3 illustrates further examples of information presented in this area of the Home screen.

| Last Bolus - Temp Basal Active | Insulin Delivery Suspended | No Communication |

Figure 3-3   Home Screen - Examples of Insulin Delivery Area

Status Bar Icons

Table 3-2 explains the status indicated by each of the Status Bar icons.

Note *Icons pertaining to the Engine are displayed top left; those of the Controller are seen top right.*

Table 3-2   Status Bar Icons

Icon	Status Indicated
(battery icon)	Battery very low - needs charging
(battery icon)	Battery empty
(battery icon)	Battery charged status (from Low to Fully-charged)
(battery icon)	
(battery icon)	
(battery icon)	
(battery icon)	Controller battery low (charging in progress)
(battery icon)	Controller battery very low (charging in progress)
(battery icon)	Controller battery empty (charging in progress)
(alarm icon)	Active alarm

Table 3-2 Status Bar Icons (continued)

Icon	Status Indicated
⚠	Active alert
🧪	Reservoir low
🧪	Reservoir empty
🧪 🧪 🧪 🧪	Reservoir filled status (from Low to Full)
✋	Suspend Insulin command has been activated by user
🕐	Temp basal active
🧪	Long bolus active
☐!	No communication between the Controller and Engine for more than 5 (TBD) minutes. Alternatively, for 30 seconds during user-initiated command (*Time change, Bolus, etc.*)
📱»	Active communication between the Controller and Engine

System Status Screen

The System Status screen is accessed by swiping *down* from the Status bar at the top of the Controller display. This provides a "birdseye view" of the current system status in real time.

Status	Status Indicated
Date & Time	Current date & time.
Basal Rate	Currently delivered Basal rate.
Long Bolus	Currently-delivered Long Bolus. If the Bolus is not active, the item will not be displayed.
Reservoir	Reservoir status – the number of insulin units remaining in Reservoir.
Engine Battery	Charged status of Engine battery.
Controller Battery	Charged status of Controller battery.

Figure 3-4   System Status Screen

Note   Any currently-suspended insulin delivery activity is reflected accordingly:
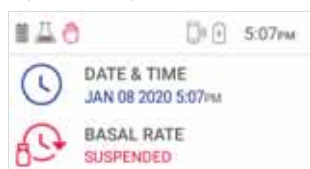
The Status Bar (top of screen) provides an indication of the current connectivity status. This will either show active connectivity between the Controller and the Pump - or, if there is no active communication, the *Last* connection time.

Command and Navigation Buttons

The area at the bottom of each screen displays Command and/or Navigation buttons in accordance with the option currently available. Figure 3-5 illustrates some of the buttons more commonly used. These are used for either accepting or canceling a command, or for navigating to the next screen (and in some cases, back to a previous screen). For an explanation of button colors, see Table 3-3.

Not all buttons are shown at the same time. When displayed, a button has either an *enabled* or *disabled* appearance - depending on the currently-active state of the task being performed.

Note   *A greyed-out button is not currently available.*

Buttons displayed in this area
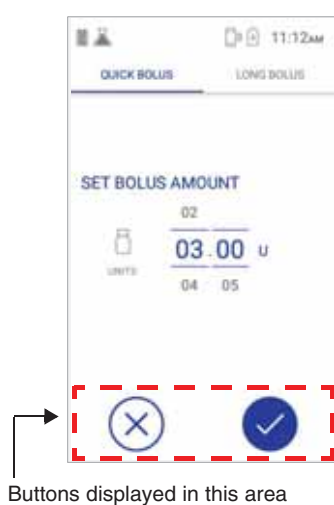
Button	Available Command or Navigation Option
✓	Accept
✕	Exit screen without making a change
→	Next (forward)
←	Back (returns to a previous screen or the Home screen, as applicable).
+	Add Segment (period of time)
−	Delete Segment

Figure 3-5   Command and Navigation Buttons

Note   *Additional buttons displayed in this area are explained in the instructions for performing a specific task, as applicable.*

Additionally, these color-coded buttons give a clear visual indication of the type of command to which you are responding - see examples in Table 3-3.

Note   *See also System Notifications, where the same logic is applied.*

Table 3-3   Command and Navigation Buttons - Color Coding

Color	Button	Type
Red	✓	Alarm
Yellow	✓	Alert
Blue	✓	Confirm

Pop-up Windows and Messages

When using the Controller, a pop-up window or message could be displayed at any stage - as and when applicable. Figure 3-6 shows typical examples.

The type of message presented could be any of the following:

- Alarm
- Alert
- Informative message
- Message asking a question
- Message prompting for confirmation of a command
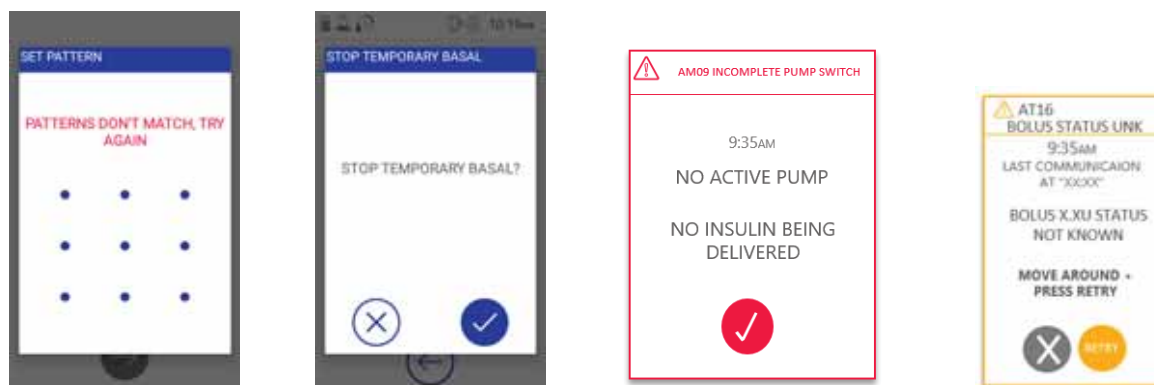
Figure 3-6   Pop-up Windows and Messages - Examples

Note   *When a pop-up window is displayed it hovers over the main screen, partially covering it. The screen beneath is inactive and appears greyed-out.*

More Options

Tapping the More Options icon opens the More Options screen. Here, available options (blue icon) may be accessed as required.

Note   *A grey icon indications the Option is not currently available.*

Figure 3-7   More Options

This screen will be displayed with either a Suspend Insulin icon (Figure 3-7, *left*) or a Resume Insulin icon (*right*), depending which option is currently available.

Use of the individual icons is explained below.

Basal

This feature allows you to view your Basal Profile and make any required adjustments.

- See Table 4-2 on page 4-11 for explanation of insulin delivery terminology.
- For instructions, see Basal Profile Settings on page 5-18.

Suspend Insulin

Used to Suspend delivery of insulin, as and whenever necessary.

- For instructions, see Suspend Insulin Delivery on page 5-4.

Resume Insulin

Used to resume delivery of insulin, as and whenever necessary.

- For instructions, see Resume Insulin Delivery on page 5-6.

Switch Pump

Used when performing the Pump Switch procedure.

- For instructions, see Chapter 6 – Switching the Active Pump.

Date and Time

Used to update current Date/Time time settings, in accordance with your current local Date/Time.

- For instructions, see Setting Current Date and Time on page 4-10.

UM - Draft 3

Treatment

Used to access the Treatment Settings screen (refer to Figure 4-9 on page 4-13) in order to set or adjust your Max Bolus and Max Basal settings.

Once treatment parameters have been set, the screen shows the latest-programmed settings accordingly.

■ For instructions, see

Advanced

Used to access the Advance screen, providing the options outlined below.

Figure 3-8   Advanced Screen

Page Engine

Used for identification - to page either Engine 1 or Engine 2, as required.
The relevant Engine emits a single audible buzz sound. yes?

Info

Used to access the System Status Information screen. This displays a visual summary of the current system status - showing details regarding your Triple Jump Controller and the two Engines (explained in Table 3-4).

Figure 3-9   System Status Information Screen

Table 3-4   Information Screen - System Status Details

Information	Details	Definition
Engine	Serial	Serial number - displayed for Engine 1 and Engine 2.
	Expiration	Expiration date - displayed for Engine 1 and Engine 2. Indicates the last date each Engine can be used as part of the Pump. After Expiration date has been exceeded, the Engine cannot be used.
	Firmware	Firmware version - displayed for Engine 1 and Engine 2.
Controller	Version	Indicates hardware version currently installed
	Android	Indicates software version currently installed
	IHE	need details
	Expiration	Expiration date. Indicates the last date the Controller can be used as part of the Triple Jump system. After Expiration date has been exceeded, the Controller cannot be used.

Switch to Another Controller

need details - when do you use this? we only have one Controller!

Shut Down

Used to shutdown the Controller from the software application.
(Unlike a smartphone, the Controller does not have a physical button for shutdown).

The Shut Down function must ONLY be used when use of the Triple Jump system is no longer required. Do we want to give an example? when?

⚠ WARNING	During use of the Triple Jump system, DO NOT attempt to perform Controller Shut Down. Although the Pump will remain operational even if power to the Controller is OFF, in the event that one or more audible Alarms sound, YOU WILL NOT HEAR IT!! Moreover, Alerts or important messages WILL NOT BE SEEN!!

System Notifications

The Controller provides important (and sometimes critical) information to the user in the form of system notifications, of which there are three types. As shown in the examples below, these are color-coded to give an immediate indication of their importance:

- **Alarm** - Red
- **Alert** - Yellow
- **Confirm** - Blue

ALARM   ALERT   CONFIRM
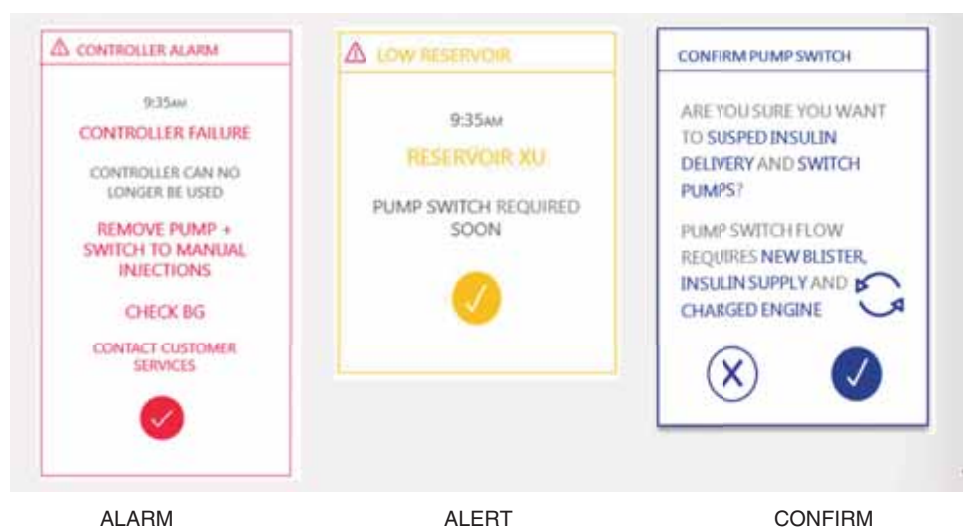
Figure 3-10   System Notifications

Note   For more details, see Chapter 8 – Alarms and Alerts.

Chapter 4 – Getting Started

First-Time Controller Setup - Overview

⚠ **CAUTION** In preparation for the first-time Controller setup and training session, you are required to ask your healthcare provider to write down all your prescribed disease-related parameters (Basal Profile, Max Basal, Max Bolus, *etc.*) and bring them to the session.
The Triple Jump Product Trainer will NOT be able to conduct initial setup without that information.

The first-time setup of your Triple Jump Controller is performed, together with you, by a Triple Jump Product Trainer. In this session you will prepare the Controller for your personalized use, including programming of your initial customized insulin delivery settings in accordance with the parameters prescribed for you by your Clinician.

After this, you will learn the tasks required for assembling and using the Triple Jump Pump and its supporting accessories. Once the Pump has successfully been attached to your body (at your chosen infusion site) you will commence treatment - then monitor insulin delivery and verify successful operation of the system and your competency in its use.

Important To prepare for this initial session with a Triple Jump Product Trainer, make sure the Controller battery and each of the two Engine batteries are fully-charged. For instructions, see Battery Charging on page 4-2.

Battery Charging

⚠ **CAUTION**   When charging the Controller or Engine batteries, use ONLY the Battery Charger and USB cable supplied in the Triple Jump Starter Kit. See Figure 2-1 on page 2-2.

Charging the Controller Battery

To Charge the Controller Battery

1. Attach one end of the USB cable to the Controller.

2. Connect the other end to the USB port on the Battery Charge.
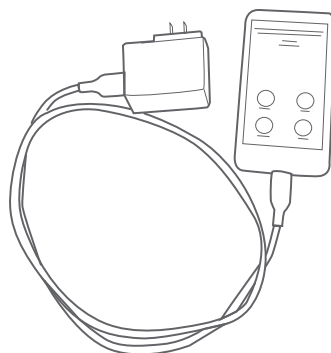
Figure 4-1   Controller Connected to Battery Charger

3. Plug the Charger into a mains power wall outlet (socket).

4. Place the Controller on a flat, stable surface while charging in progress.

Note *While charging is in progress.... what do you see? LED indicator on Controller?*
When the battery is fully-charged.... what do you see? indicator illumination shows?

Charging the Engine Battery

⚠️ **CAUTION** **Use ONLY the Battery Charger and USB cable supplied in the Triple Jump Starter Kit. See Figure 2-1 on page 2-2.**

🔌 To Charge the Engine Battery

1. Place one of the supplied Engines into a Docker.

2. Connect the Battery Charger USB cable to the USB port on the base of the Docker.
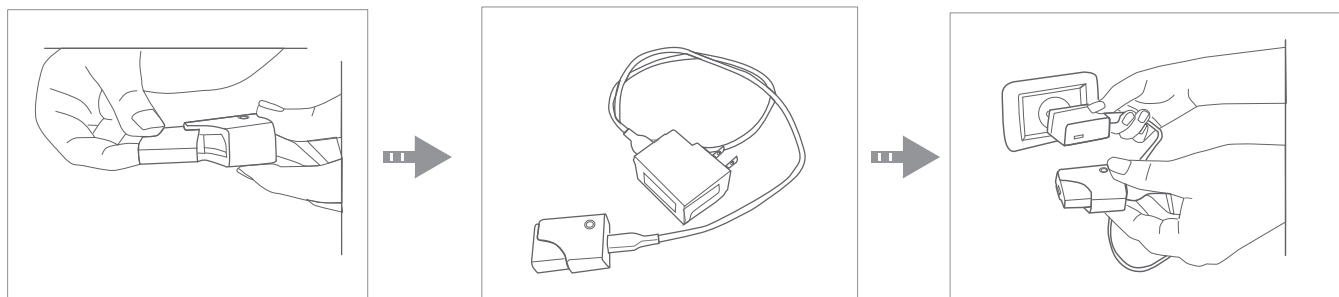
Figure 4-2   Docker Connected to Battery Charger

3. Lay the Docker flat on a clean, stable surface.
   Make sure the LED indicator on the side of the Docker is facing *upwards*.

4. Plug the Charger into a mains power wall outlet (socket).

   Battery charging commences; the LED indicator is now illuminated orange - see Table 4-1.

Figure 4-3   Battery Charging in Progress

Table 4-1   Battery Charger - Status Indicator

LED Indicator		Status
🔴	Red	Battery charging required
🟠	Orange	Charging in progress
🟢	Green	Battery fully charged

5. When charging is complete:
   Disconnect the Battery Charger from the wall outlet, then from the Docker.

6. Repeat the procedure to charge the second Engine battery.

Turning On the Controller

➥ **To Turn On Power to the Controller**

1. Press-and-hold the On button on the *upper right side* of the Controller, then release it.

   An initial screen stating INSULIN PATCH PUMP will be displayed for approx. 5 seconds. The Activation screen then opens (Figure 4-4).

2. The Triple Jump Product Trainer will now provide you with an Activation key (a 6-digit serial number).

Entering the Activation Key

➥ **To Enter an Activation Key**

1. Using the virtual keyboard? Enter the 6-digit Activation Key number.
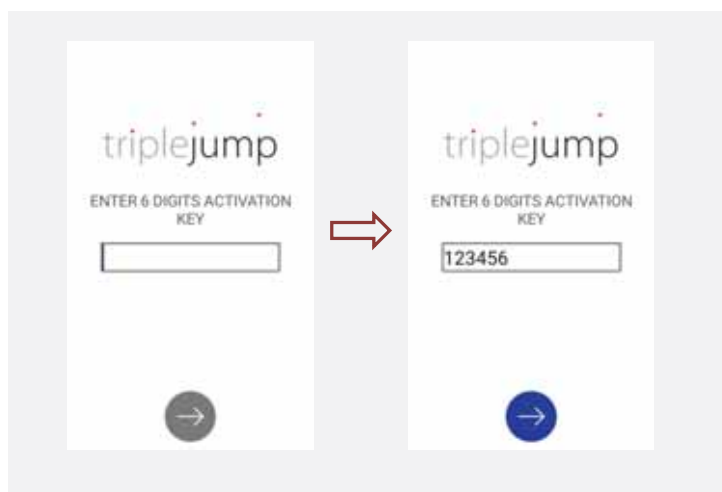
Figure 4-4   Activation Screen

2. Tap Next.

   The Screen Lock Passcode screen opens.

Setting a Screen Lock Passcode

➥ **To Set a Screen Lock Passcode**

    1. Tap **Set Passcode**.
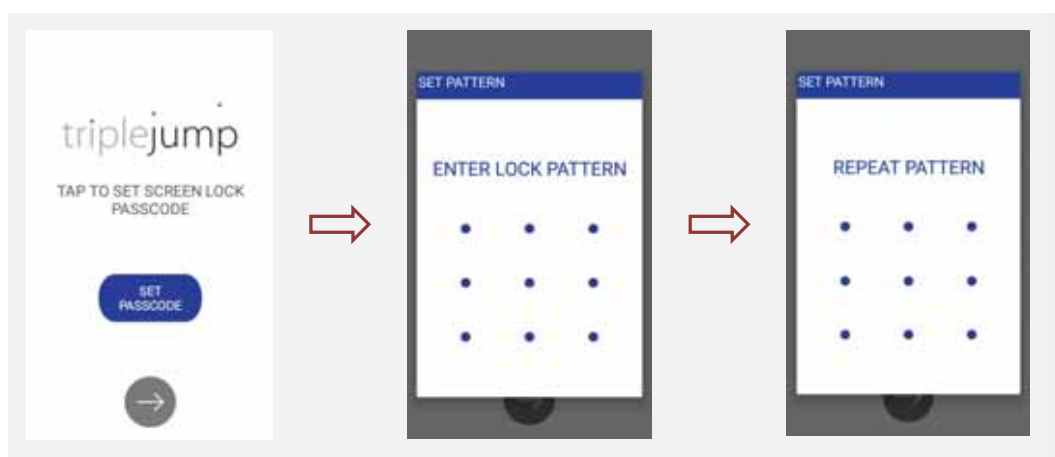
Figure 4-5   Screen Lock Passcode Screen

    2. To set a Passcode, swipe one finger across the dots using a simple pattern (for example, one row horizontally, then one row vertically - alternatively, swipe diagonally).
The pattern you choose to use should be one that you will remember easily.

    3. When prompted, repeat the *same* pattern.
Then, tap Next.

Now you will move to setting a Passcode Recovery hint, then setting the Passcode - see Figure 4-6.

Setting a Passcode Recovery Hint

➥ **To Set a Passcode Recovery Hint**

1. Using characters or digits, enter a suitable Hint (that you will remember easily).

Figure 4-6   Entering Passcode Recovery Hint and Setting Passcode

Note   *At least 3 and no more than 6 characters or digits are required.*
Letters may be uppercase or lowercase. Do not add spaces.

2. Tap **Set Passcode**

3. Tap Next.

   The Controller Name screen opens - Figure 4-7.

Setting a Personalized Controller Name

To Set a Personalized Controller Name

1. Enter a name for your Controller, only to be used by you - see example below.
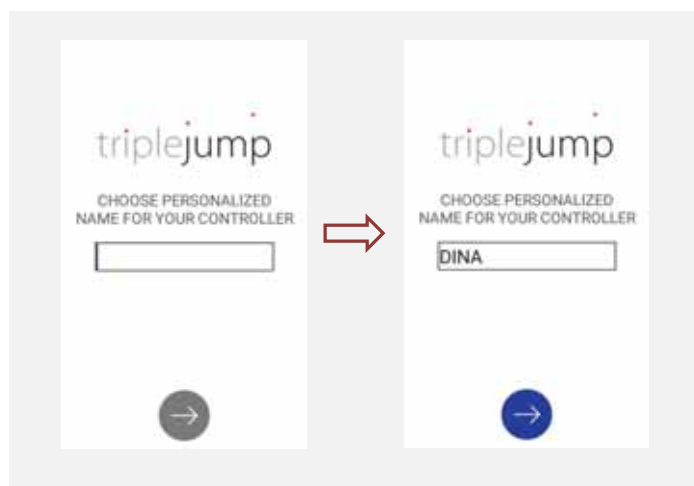
Figure 4-7   Setting a Personalized Controller Name

Note   After tapping Next, the Name you have set will identify this specific Controller as yours - only for your own personal use.

2. Tap Next.

The Date and Time screen opens -Figure 4-8.

Setting Current Date and Time

➥ **To Set the Current Date and Time**

1. Observe the Date and Time initially displayed, then proceed to the following steps (as necessary) to select the correct settings, as appropriate.

2. Set the correct Date by scrolling up/down the options to pick the relevant month, day and year.

3. Tap Next.
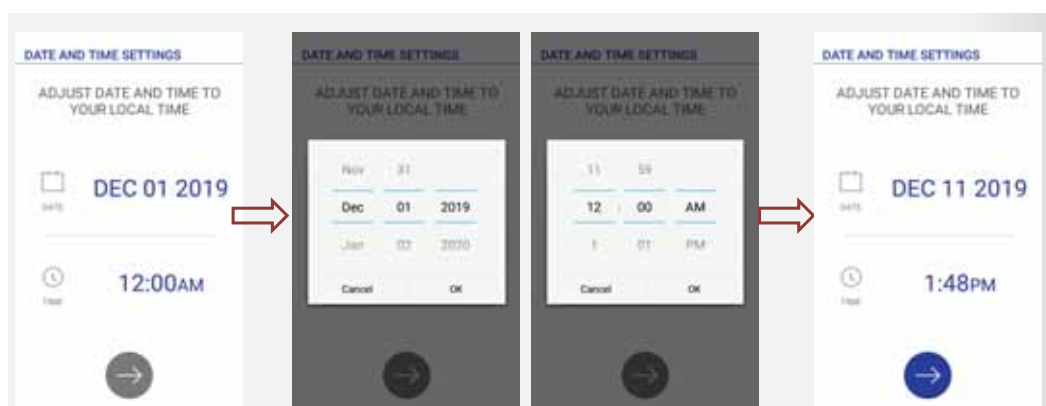
Figure 4-8   Setting the Current Date and Time

4. Set the correct Time by scrolling up/down the options to pick the relevant hour, minute, AM/PM.

5. Tap Next.

6. Check the displayed information is correct with your local time, then tap Next to confirm.

   The Treatment Settings screen is displayed (shown in Figure 4-9).

Programming Your Personalized Settings

For the next stage of the first-time setup session with your Triple Jump Product Trainer, you will now proceed to program your personalized initial treatment settings. The information below is provided for easy reference.

Understanding Insulin Delivery Parameters

Table 4-2 explains the various insulin delivery parameters and related terminology. A full understanding of these terms is paramount for your use of the Triple Jump system to successfully control and manage delivery of insulin to your body.

Table 4-2   Insulin Delivery Parameters - Terminology

Term	Explanation
Basal	The Basal rate is a Pump setting that provides a continuous infusion of insulin to keep the blood glucose stable between meals and during the night. Basal insulin mimics pancreatic insulin delivery which meets all the body's non-food related insulin needs.
Basal Profile	At the initial setup of the Triple Jump system, you are required to set a Basal Profile, according to the prescription you received from your healthcare provider. The Basal Profile includes entries with specified hours, that cover all 24 hours of the day.
Max Basal	The Max Basal setting is a safety feature intended to limit the amount of basal insulin that can be delivered per hour. Note: You will not be able to set a rate in the Basal Profile or Temporary Basal settings that is *higher* than the Max Basal.

Table 4-2   Insulin Delivery Parameters - Terminology (continued)

Term	Explanation
Temporary Basal	Temporary Basal is a feature that enables you to set a Temporary Basal rate in order to manage blood glucose levels during any short-term activities you may undertake - or alternatively, during conditions that require a Basal Rate different from that of your current setting. This could be required for example during an illness or during any temporary change you may make to your physical activity. It is possible to make an immediate change to your Basal insulin supply for a set period of time. Your programmed Basal Profile resumes after the Temporary Basal rate delivery is completed (or canceled by you). The Basal change can be set for as low as 15 minutes and up to 8 hours. Temporary Basal rates can be set to deliver from -95% to +100% of your scheduled Basal rate. Setting a negative rate (below 0%) reduces your Basal insulin supply by a defined rate, while setting a rate above 0% increases your Basal insulin supply by a defined rate. The Temporary Basal rate is limited by the programmed setting of your Max Basal rate.
Bolus	The bolus is a dose of insulin given to cover a rise in blood glucose (such as the rise after a meal) or to lower a high blood glucose down to the target range. The Bolus is supplied in addition to your regular daily Basal supply of insulin.
Max Bolus	A safety feature intended to limit the amount of insulin that can be delivered in a single Bolus, according to the maximum Bolus you set in the initial setup. The Max Bolus value can be 1-30 insulin units.
Quick Bolus	A dose of insulin given at once.
Long Bolus	A dose of insulin delivered at a constant rate, over a set period of time. For example, 2U of insulin over 2 hours.

In this table, pse double-check what is **actually** written in the GUI - sometimes Max, sometimes Maximum?

Programming Your Initial Treatment Settings

Treatment settings are programmed using the Treatment Settings screen. By default, this initially displays the Maximum Bolus amount and Maximum Basal rate with nil values (Figure 4-10, left). Once treatment parameters have been set, the screen shows the latest-programmed settings accordingly (see right).

Initial Display   Programmed Settings
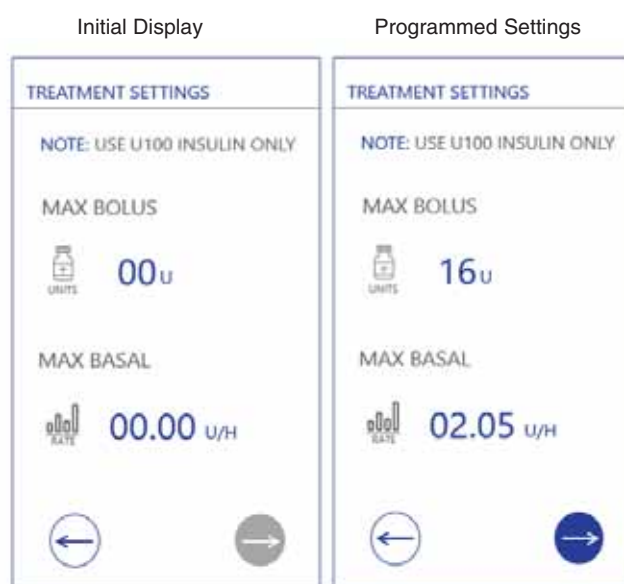
Figure 4-9   Treatment Settings Screen

Setting a Max Bolus Amount

➡ **To Set the Max Bolus Amount**

1. In the Treatment Settings screen, tap the Max Bolus unit value line.

   The MAX BOLUS Setting screen opens.

2. Scroll to select your prescribed Max Bolus amount (insulin Unit value).
   Check the **correct** amount is displayed, then tap Accept to confirm.

   The MAX BASAL Setting screen opens... or goes back to Treatment Settings Screen?.
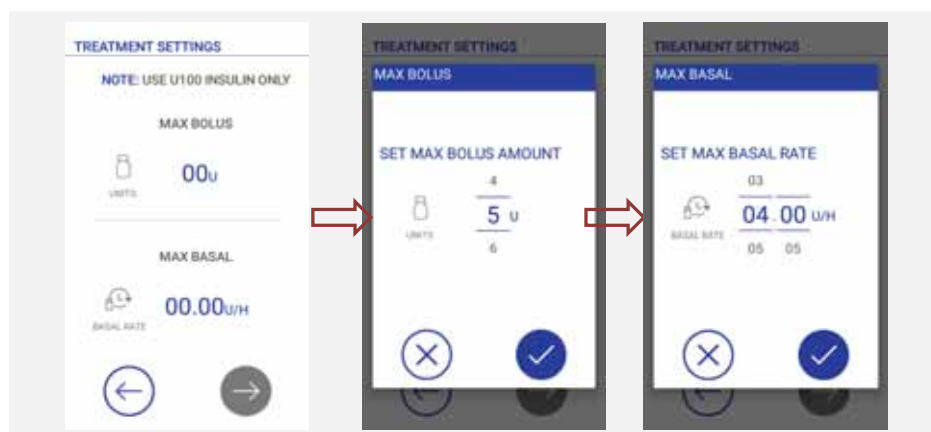
Figure 4-10   Setting Max Bolus Parameters

Setting a Max Basal Rate

➼ **To Set the Max Basal Rate**

1. In the Treatment Settings screen, tap the Max Basal unit value line.

    The MAX BASAL RATE Setting screen opens.

2. Scroll to select the required Unit/H value - see Figure 4-10.
    Check the **correct** value is displayed, then tap Next to confirm.

    The Basal Profile screen opens.

Lidar.... not sure if Max Basal and Rate should be just one procedure? (i.e. if they lead on from one to the next) - or do you go back to Home screen first?

Setting a Basal Profile

The Basal Profile defines your daily schedule for continuous delivery of insulin.

Note *By default, at this initial setup stage, the Basal Profile screen displays a Segment covering the full 24-hour period (midnight to midnight) - shown in Figure 4-11, left).*

➡ To Set Your Basal Profile

1. Tap the displayed Segment to edit it

2. Set the **Basal Rate** (no. of Units/Hr) using the scroll control.
   The rate must NOT exceed the Max Basal rate.
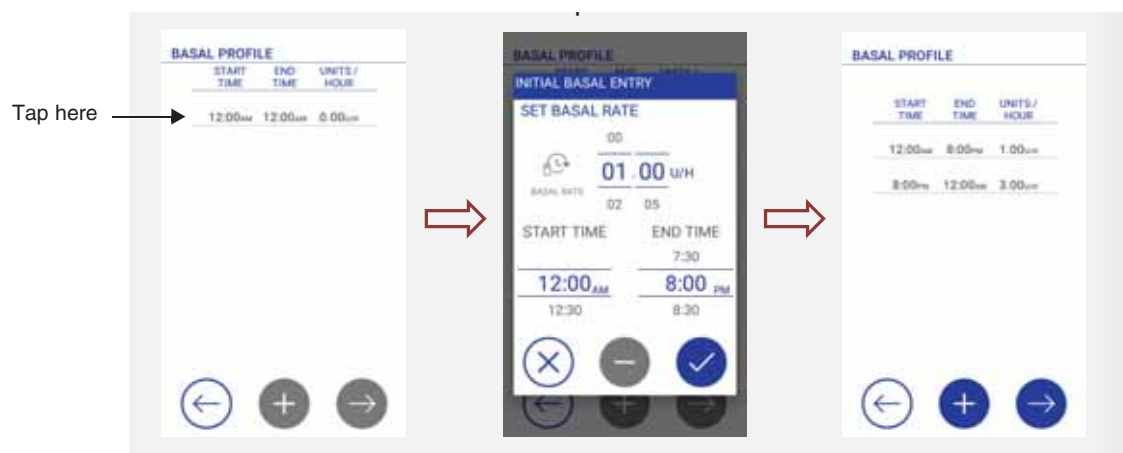
Figure 4-11   Setting the Basal Profile

3. Set the **Start Time** and **End Time** using the scroll control.

4. Check the **correct** values are displayed, then tap Confirm.

   The Basal Profile screen opens, showing the newly-saved setting.

5. Tap Add Entry ⊕ to add additional Segments required.

Note   *To delete a Segment: tap to select it, then tap Delete Entry* ⊖
The Segment is now deleted; the previous segment will have been updated to compensate for the deleted time frame.

6. Continue as required, setting rates for different time periods, and tapping to Confirm.

Important   The End Time for the LAST rate you set must be 12:00AM.

7. Check the **correct** values are displayed for all Segments, then tap Confirm.

Attaching Your Insulin Pump and Starting Treatment

For the last stages of the your first-time setup session, your Triple Jump Product Trainer will teach you the correct techniques for using the Triple Jump disposables, assembling the Pump and attaching it to your body - then finally commencing insulin delivery and monitoring treatment.

Initial setup now proceeds to

⚠ **WARNING**

During use of the Triple Jump system, DO NOT attempt to perform Controller Shut Down.

Although the Pump will remain operational even if power to the Controller is OFF, in the event that an audible Alarm sounds, YOU WILL NOT HEAR IT!!

Moreover, Alerts or important messages WILL NOT BE SEEN!!

Chapter 5 – Managing Insulin Delivery

Typical Workflow

After completion of the Controller initial setup procedure (described in Chapter 4), the default display is the Home Screen from where many tasks and activities are commenced. To help you manage and control your treatment, the various screen groups and controls are outlined in Table 5-1, together with an explanation of their typical frequency of use.

Table 5-1   Controller Screen Categories and Usage Frequency

Screen Category	Typical Frequency of Use	Comments
Initial Setup	Once - at Initial Setup	A Triple Jump Product Trainer performs this procedure with you. See Chapter 4 – Getting Started.
Quick Bolus	Daily: 4-5 times per day	Control used as a reaction to food intake and/or to blood sugar testing. See Quick Bolus on page 5-9.
Long Bolus	Daily: once per day	Control used after eating a heavy meal (when food takes a long time to digest). See Long Bolus on page 5-12.

Table 5-1   Controller Screen Categories and Usage Frequency (continued)

Screen Category	Typical Frequency of Use	Comments
Temporary Basal	Daily, or once every 2 days	Control used when you need to lower or raise insulin delivery for a while. For example, if you have a low blood sugar reading. Alternatively, if you are going running and wish to lower insulin delivery for that period. See Long Bolus on page 5-12.
Suspend	Daily, or once every 2 days	Control used to Suspend insulin delivery, whenever necessary. Always used when performing the Pump switching procedure (see below). See Suspend Insulin Delivery on page 5-4.
Pump Switch	Once every 3 days	Whenever performing the Pump switching procedure. See Chapter 6 – Switching the Active Pump.
History	Once every week	Used for personal tracking of your treatment.
	Every few months	Reviewed by your Clinician at treatment follow-up visits. Refer to Treatment History - Overview on page 7-1.
Treatment Settings	Every few months	Reviewed by your Clinician at treatment follow-up visits. Refer to Treatment History - Overview on page 7-1.

Table 5-1   Controller Screen Categories and Usage Frequency (continued)

Screen Category	Typical Frequency of Use	Comments
Basal Profile	Every few months	Reviewed by your Clinician at treatment follow-up visits. Refer to Treatment History - Overview on page 7-1.
Date and Time	Periodic	Required for Daylight Savings time changes, or when traveling to a different time zone. See Changing the Controller Date and Time Settings on page 9-3.

Controlling Insulin Delivery

Suspend Insulin Delivery

⚠ **WARNING**

The Suspend Insulin command will immediately STOP all [currently-active?] insulin delivery.

If there is no communication between the Controller and the Active Engine for more than 1 min, this function is NOT available.

✋ ➻ **To Suspend Insulin Delivery**

1. Access the **Suspend Insulin** command from Home screen > **More Options**.

   A Suspend Insulin? message opens.

2. Tap Accept to confirm.

   The message now displayed will depend on the insulin delivery parameters currently set.
   Tap to confirm the message, as appropriate - see examples below.
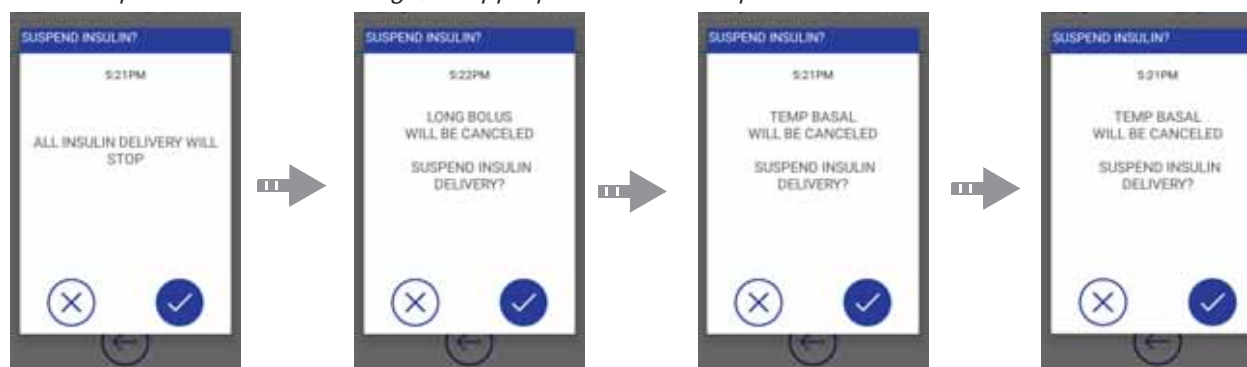
Figure 5-1   Suspend Insulin Messages
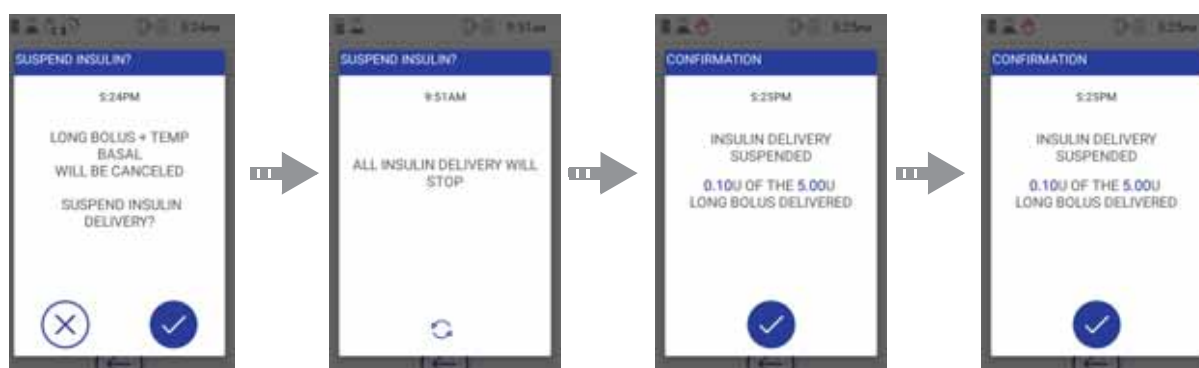
Figure 5-2   Final Confirmation to Suspend Insulin

Once the final confirm command is acknowledged by the Engine, a message confirms that insulin delivery has been suspended.

✋ *In the Home screen status bar, the Insulin Suspended icon is now displayed.*

Resume Insulin Delivery

➥ To Resume Insulin Delivery

1. Access the **Resume Insulin** command from Home screen > **More Options**.

   A Resume Insulin? message opens.
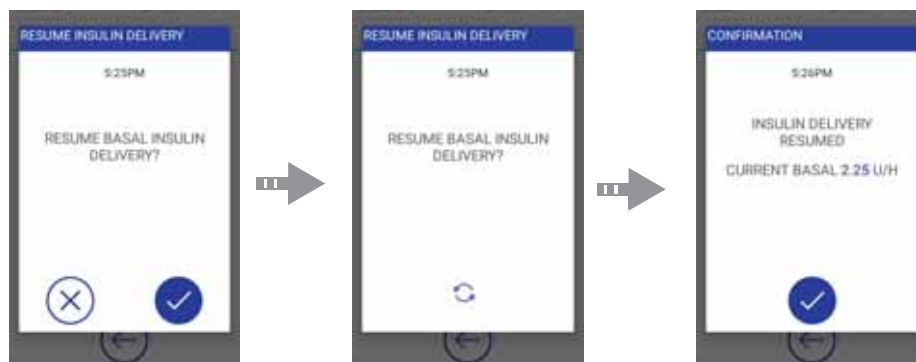
   Figure 5-3   Resume Insulin Messages

2. Tap Accept to confirm.

   A processing screen is displayed until the command is accepted by the Engine. A final message confirms that insulin delivery has been resumed.

> ⚠ **CAUTION** The Resume Insulin command will resume the Basal supply ONLY. It will not resume any Bolus delivery or Temp Basal mode (if those were active prior to the insulin suspension).
>
> If you need to reset a Long Bolus or Temp Basal mode, see instructions for Long Bolus or Temporary Basal Settings, as required.

Adjusting Your Treatment Settings

Important   The Triple Jump system cannot deliver insulin at a rate that exceeds that of your Max Bolus or Max Basal settings.

Max Bolus

Max Bolus is the maximum number of insulin units to be supplied as the Bolus treatment in a single bolus. The value can be set to between 1 and 30 insulin units.

➦ To Set Max Bolus

1. In the Treatment Settings screen, tap the Max Bolus unit value line.

    The MAX BOLUS Setting screen opens.
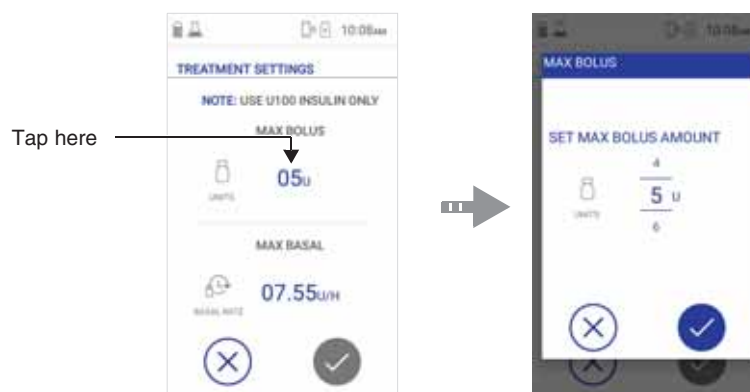
Figure 5-4   Setting Max Bolus Insulin Delivery Unit

2. Scroll to select your prescribed Max Bolus amount (Unit value).
   Check the **correct** amount is displayed, then tap Accept to confirm.

   The display returns to the Treatment Settings screen.

Max Basal

Max Basal is the maximum number of insulin units per hour to be supplied as the Basal treatment.
The value can be set to between 0.05-30.00 units per hour (U/H).

➥ To Set Max Basal

1. In the Treatment Settings screen, tap the Max Bolus unit value line.

   The MAX BOLUS Setting screen opens.

Tap here
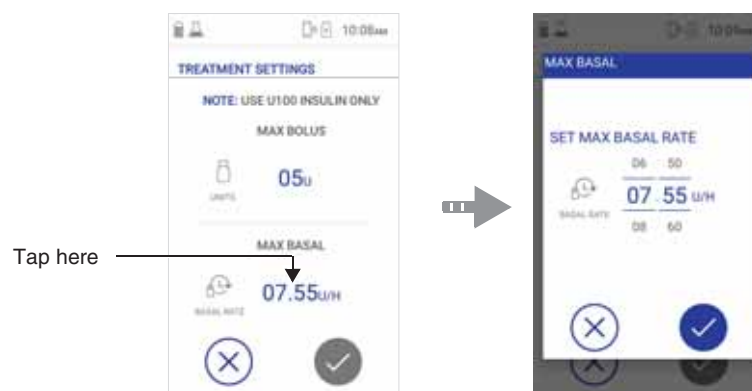
Figure 5-5   Setting Max Basal Insulin Delivery Unit/Hour

2. Scroll to select your prescribed Max Basal amount (Unit/H values).
   Check the **correct** amount is displayed, then tap Accept to confirm.

   The display returns to the Treatment Settings screen.

Bolus Settings

In the Home screen, tap the Bolus icon to access the Bolus Selection screen.

Quick Bolus

➥ To Set a Quick Bolus

1. Tap the **Quick Bolus** icon.

2. Scroll to select your required Quick Bolus amount (Unit value).
   Check the **correct** amount is displayed, then tap Accept to confirm.
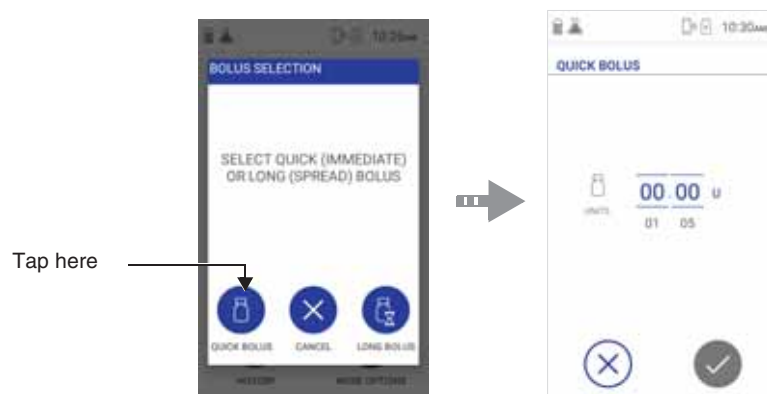
Figure 5-6   Setting Quick Bolus

3. When prompted, tap Accept to confirm delivery of the Quick Bolus.

Figure 5-7   Quick Bolus Delivery Workflow

The Quick Bolus is processed, and the Quick Bolus is supplied to you by the Triple Jump system.

Note   *If you want to cancel the Quick Bolus delivery, tap the Stop Quick Bolus icon.*
Pop-up screens will notify you of the amount of insulin units that have currently been delivered and confirm that Quick Bolus delivery has been canceled - see Figure 5-8.
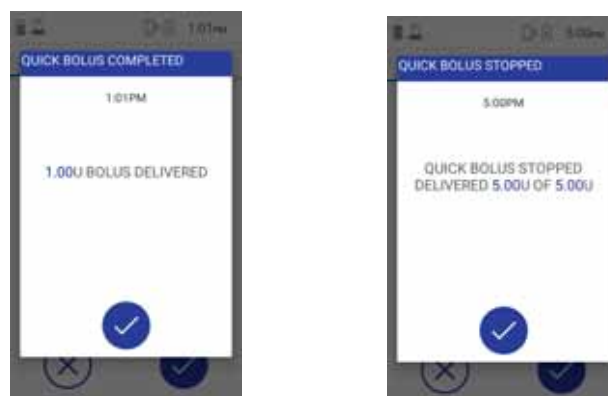
Figure 5-8   Quick Bolus Delivery Canceled

Long Bolus

➦ **To Set Long Bolus Parameters**

1. Tap the **Long Bolus** icon.

2. Scroll to select your required Long Bolus Units (amount) and Duration (time - hrs/min). Check the **correct** values are displayed, then tap Accept to confirm.

Tap here
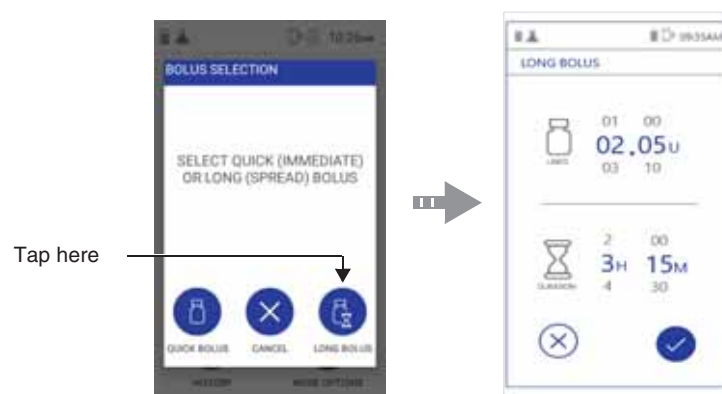
Figure 5-9   Setting Long Bolus

3. When prompted, tap Accept to confirm required settings.

   A series of messages are displayed - see Figure 5-10.

Figure 5-10   Long Bolus Delivery Activated

4. When prompted, tap Accept to confirm.

   The Long Bolus is prepared, and activated to be delivered accordingly.

5. Tap Accept again to confirm.

   The display returns to the Home screen.

Note *Delivery of the Long Bolus can be canceled at any stage, as required - see the following instructions.*

To Cancel Long Bolus Delivery

1. In the Bolus Selection screen, tap the **Stop Long Bolus** icon - see Figure 5-11.

   A message will notify you of the amount of insulin units that have currently been delivered and the remaining delivery time.

2. When prompted, tap Accept to confirm.

   Long Bolus delivery has been canceled

Figure 5-11   Canceling Long Bolus Delivery

3. Tap Accept to confirm.

   The display returns to the Home screen.

Temporary Basal Settings

Setting a Temp Basal rate enables you to manage blood glucose levels during any short-term activities, or during conditions that would require a Basal Rate different from that of your current setting.

- Temp Basal rates can be set to deliver from -95% to +100% of your scheduled Basal rate.
- The duration of the Temp Basal rate may range between 15 minutes and 8 hours

Setting a Temporary Basal Rate

➦ **To Set a Temporary Basal Rate**

1. In the Home screen, tap the Temporary Basal icon.

   The Temporary Basal screen opens.

2. Scroll to select your required Percentage Rate and Duration.
   Check the **correct** values are displayed, then tap Accept to confirm.

Adjust here →

Adjust here →

Figure 5-12 Adjusting Temporary Basal Rate

3. When prompted, tap Accept to confirm the adjusted rate.

Your programmed Temporary Basal pattern resumes - see Figure 5-13.

Figure 5-13   Adjusted Temporary Basal Rate and Duration Activated

4. When prompted, tap Accept to confirm and save the adjusted Temporary Basal rate.

Note *After confirming the Temp Basal rate, it will be calculated for all the affected segments*
A confirmation screen informing the adjusted basal rate will be displayed. If any of the segments are now programmed with a Basal Rate that exceeds the Max Basal rate, the confirmation screen will state that the rate will be limited to the Max Basal rate. If any of the segments have a Basal Rate that is below 0.05 activate AT012 (too low temp basal rate)
Don't understand... help!!

Your Temp Basal rate continues for the Duration you set.

During Temp Basal delivery there is an indication on the Home Screen

A Temp Basal   icon is seen in the Status Bar.

Canceling a Temporary Basal Rate

➡ To Cancel a Temporary Basal Rate

1. In the Home screen, tap the Temporary Basal icon.

   The Temporary Basal screen opens.

2. Tap the Stop Temp Basal icon.

3. When prompted, tap Accept to Confirm.

Figure 5-14   Canceling a Temporary Basal Setting

Important Stopping a programmed Temporary Basal pattern will remove all Temp Basal indications from the system (Home screen and Status Screen/Bar).

Viewing Your Basal Insulin Delivery

To view your active Basal insulin delivery, swipe the Status Screen and view the displayed information. If there are no details about active Temp Basal, this mode is not active.

Basal Profile Settings

The Basal rate is a Pump setting that provides a continuous infusion of insulin to keep your blood glucose stable between meals and during the night.

Your Basal Profile was set during initial Controller setup - refer to Programming Your Initial Treatment Settings on page 4-130. These settings may be updated and adjusted as described below.

Note *The Basal Profile must include entries with specified hours, that are covering all hours of the day. If there are missing values for some hours of the day, you will not be able to leave this page until you set the Basal values that will cover all hours of the day.*

Editing a Basal Profile

➻ To Edit a Basal Profile

1. Access the **Basal Profile** option from Home screen > **More Options**.
2. Tap on a segment to edit it.
3. Set the Basal Rate (no. of units) using the scroll control.

Important The rate cannot exceed the Max Basal that was set in the initial setup.
To change the Max basal rate, go to: Home screen > More Options > Treatment Settings.

4. Set the Start Time and End Time using the scroll control.
5. Tap Accept to confirm and save the new entry.

Note *To return to the Basal Profile screen without saving the entry, tap Exit (X).*

6. To add another segment, tap **Add Entry** and repeat the instructions above.

7. To confirm the Basal Profile, tap Accept.

Important The End Time for your last rate must be 12:00AM

Note *If the starting time conflicts with other segments you will not be able to set this time (Accept will be disabled). You will therefore have to delete the conflicting segment first and then set the new one.*

Deleting a Segment

➥ To Delete a Basal Profile Segment

1. Tap on the Segment to be deleted to select it.

2. Tap **Delete Entry**.

   The Segment is deleted.

Note *When the Segment is deleted, the previous Segment will update to compensate for the deleted time frame.*

Chapter 6 – Switching the Active Pump

Overview

This chapter will guide you in the process of changing your active Triple Jump Pump.

The Pump-switching procedure will be required after every 3 days of use. In some cases, an earlier Pump change will be necessary - for example, low-capacity or depleted Engine battery, failed communication between the Pump and the Controller - or any issue or system malfunction affecting normal insulin delivery.

Before you Start

⚠ **CAUTION**

For this procedure, it is necessary to use an Engine with a fully-charged battery — this will be the replacement Engine. The Controller battery indicator should show at least 2 bars.

Always check battery status before commencing the procedure.

If necessary, recharge either or both batteries - see Battery Charging on page 4-2.

Performing the Pump Switch procedure requires approximately 5 mins. Therefore, make sure you choose a convenient time that will be sufficient to allow you to complete the process.

Note *If the Pump switch procedure is not be completed, an alarm will sound every 30 minutes thereafter to warn you to complete the process.*

Important

During the Pump Switch procedure, insulin delivery is suspended.

Before commencing, ensure your Blood Glucose level is normal, and an immediate Bolus is not required.

It is recommended to perform a Blood Glucose check, if necessary.

Before commencing the procedure, always make sure the following are readily at hand:

- Your Controller
- Pump Engine - fully-charged and in its Docker
- Vial of your prescribed insulin
- Triple Jump Sterile Disposable Pack
- Tip Protector (for covering Cannula tip)

Important **If your Controller battery is insufficiently charged, it will be detected by the system and you will not be able to perform this procedure. An Alarm message will be displayed, as shown below.**

<div align="center">

CHARGE CONTROLLER

CONTROLLER BATTERY
TOO LOW

YOU MUST CHARGE THE
CONTROLLER BEFORE
STARTING PUMP SWITCH

✓

</div>
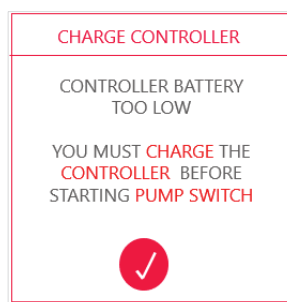
Procedure Workflow

For quick reference, the order in which the required procedure tasks are performed is outlined below.
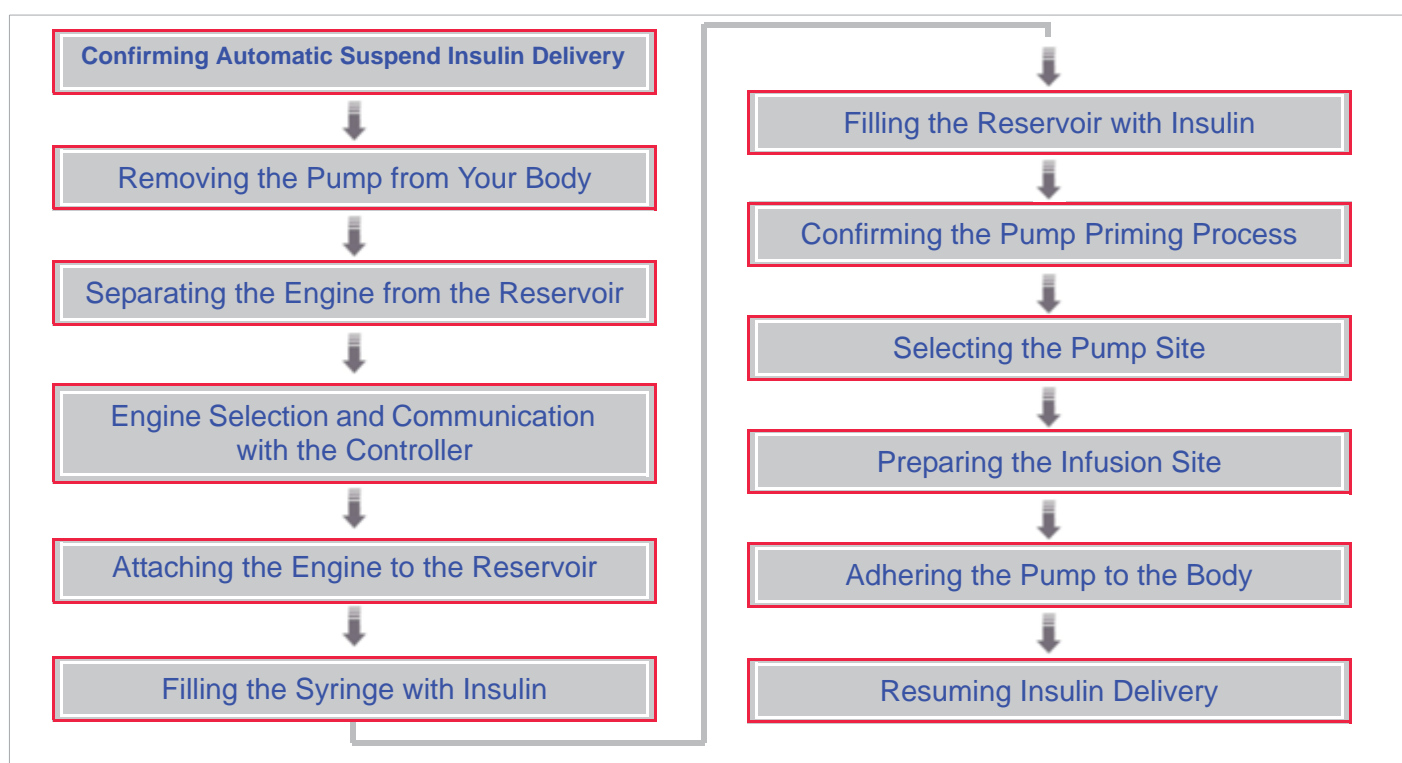
Figure 6-1   Switching the Active Pump - Workflow Order and Tasks Required

⚠ **CAUTION**	Before commencing this workflow, ensure the following:

- This is a convenient time to perform the Pump Switch procedure, so you will be able to complete it.
- Your Blood Glucose level is currently normal.
- The immediate delivery of a Bolus is not required.

Note   During the Switch Pump procedure, the display will NOT show the Status Bar or any Suspended Insulin Delivery icons.

Confirming Automatic Suspend Insulin Delivery

➥ **To Confirm Automatic Suspension of Insulin Delivery**

1. From the Home screen, tap the **More Options** icon, then **Switch Pump**.

    A message opens prompting for confirmation of Suspend Insulin command.
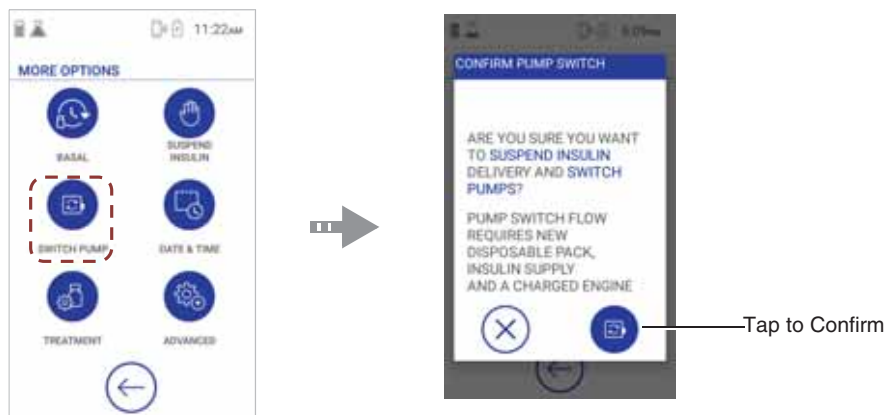
Figure 6-2   Switch Pump - Confirm Insulin Suspension

2. Tap the **Confirm Pump Switch** icon to confirm.

Insulin delivery is now suspended; the display now shows the following Instructions:
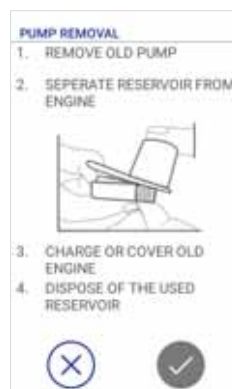
Removing the Pump from Your Body

➥ To Remove the Pump from Your Body

1. At the infusion site, gently ease the edges of the adhesive base away from your skin.

2. Using one hand, place your fingers over the top and each side of the Pump, as shown in Figure 6-3.

3. To provide leverage, make sure you grasp the ridged portions firmly.
    Then, starting at the top, carefully (but strongly) pull the Pump with its adhesive base away from your body.
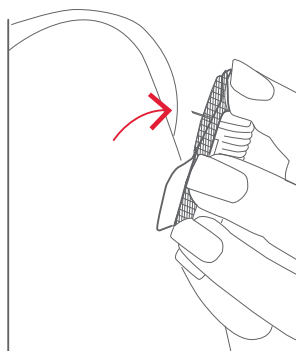
Figure 6-3   Removing the Pump from your Body

⚠ **CAUTION**   The Cannula tip is now exposed - holding the Pump correctly will avoid the risk of pricking a finger!

4. When the Pump is released from your body, peel the adhesive partially away from the base as follows:

a. Hold the patch between your finger and thumb, near the plastic tab shown in Figure 6-4.

b. Peel the adhesive down and away from the Pump base until partially removed - see note.

Plastic tab

Figure 6-4   Removing Adhesive Base

Note   Partial removal is required to allow easy access for separating the Engine from the Reservoir.

5. Lay the Pump flat then carefully place a disposable Tip Protector over the Cannula tip.
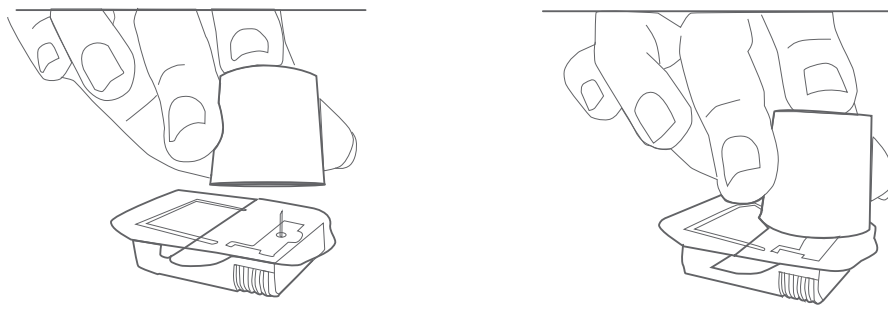
Figure 6-5   Covering the Cannula Tip with the Tip Protector

Important   The Cannula must be covered in this way to avoid the risk of the sharp point causing injury and, for the purpose of hygiene, to prevent any further body contact.

6. Clean the insertion site with? to remove any traces of adhesive residue. yes?

7. Proceed to the instructions for Separating the Engine from the Reservoir.

Separating the Engine from the Reservoir

➡ **To Separate the Engine from the Reservoir**

1. Hold the Pump in one hand with your thumb on top of the Tip Protector.

2. Using the other hand, tilt the Engine to an angle of approx. 15 degrees *downward*, then pull it *backward* to detach it from the Reservoir - see Figure 6-6.

Figure 6-6   Separating Engine from Reservoir

Note   Instructions for Disposing of the Used Reservoir are provided on page 6-10.

Docking the Removed Engine and Charging the Battery

➡️ **To Dock the Engine and Charge the Battery**

1. Place the Engine into a Docker.

2. Follow the instructions for Charging the Engine Battery on page 4-3.

Important | Charging the battery of the removed Engine at this stage is important to ensure you will have a second fully-charged battery available if in any event it should be required during the Pump Switch procedure.

Disposing of the Used Reservoir

Important | Make sure the Cannula remains covered with the Tip Protector.

Discard the used disposable Reservoir, together with the adhesive base and the Tip Protector and dispose correctly.

⚠️ **CAUTION** | After use, all disposable items must be disposed of in a designated container - and in accordance with local safety regulations.

Engine Selection and Communication with the Controller

Note *In the procedure below, Engine 1 is used as the example engine.*

➥ **To Select the Engine and Establish Communication with the Controller**

1. Tap Accept to confirm removal of the previously-active Pump.

2. Select an Engine to be used as the Active Engine, tap Next.

Figure 6-7   Engine Selection and Communication with the Controller

The Engine should now emit a buzzing sound, indicating it is operable.

3. If you hear the buzzing, tap **Engine Operable**.
   If not, tap **Page Again** - when you hear a single buzz, tap **Engine Operable**.

Instruction displayed:

PUMP SWITCH

1. OPEN NEW INSERTER PACK

2. ATTACH ENGINE 1
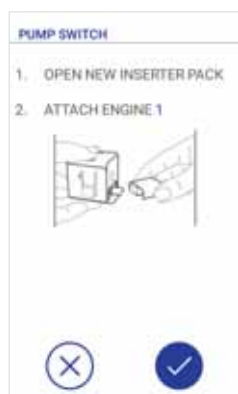
Note When performing *Step 2* above, in the event that an Engine was not detected, the battery was not fully-charged, or an Engine was unusable, a message is displayed with appropriate instructions:

SELECT ENGINE

NO USABLE ENGINES.

FOLLOW INSTRUCTIONS TO RESOLVE

ENGINE 1   NOT DETECTED.
CHARGE MAY
BE REQUIRED

ENGINE 2   NOT ENOUGH
BATTERY
CHARGE TO
REUSE

Opening the Triple Jump Sterile Disposable Pack

⚠ **CAUTION**
- Before proceeding, make sure you have washed your hands and that you are in a clean environment (not surrounded by dust, debris or fumes).
- Do not open the Pack until you are ready to use it.

☛ **To Open the Triple Jump Sterile Disposable Pack**

1. Check the expiration date marked on the pack label.
   (If the date has been exceeded, do not use - take a fresh pack).

2. Make sure the outer pack is not damaged and shows no signs of tampering.

3. Holding the pack in one hand, carefully open it by peeling back the cover to expose the inner tray containing the sterile items.

4. Remove the contents of the tray and place on a flat, clean surface.

Important

It is recommended to keep the tray aside and do not dispose of it at this stage.

If for any reason it later becomes necessary to abort the Pump Switch procedure (for example, a system error that has detected Pump malfunction), the tray may be helpful for use in performing a "mock" Cannula insertion, making it easier to remove the Inserter and then detach the Engine from the Reservoir.

Attaching the Engine to the Reservoir

❧ To Attach the Engine to the Reservoir

1. Remove the Loaded Inserter from the tray.

Important At this stage, do NOT remove the protective film covering the adhesive base!

2. Holding the Loaded Inserter in one hand, use the other hand to hold the selected Engine. Make sure the Engine is correctly orientated for insertion into the Reservoir - see Figure 6-8.

3. Align the Engine with the opening of the Reservoir, then push the two together until you hear a click. This will indicate the Engine is now firmly attached to the Reservoir.

Figure 6-8   Attaching Engine to Reservoir

Filling the Syringe with Insulin

➡ To Fill the Syringe with Insulin

1. Clean the top of your insulin vial with an alcohol prep swab.

2. Remove the disposable Filling Syringe from the tray, then attach the Filling Needle (twist to secure it onto the syringe tip).

Note *Keep the needle cap - you will need it later.*

Important For the next step, you will need to know the amount of insulin with which the Reservoir should be filled. Your healthcare provider can help you determine the correct amount.

3. Draw air into the Filling Syringe up to the amount of insulin you need.

4. Insert the needle into the insulin vial and inject the air.

Note *Injecting air makes it easier to withdraw insulin from the vial.*

5. Holding the vial of U-100 insulin and the syringe together, turn them *upside-down*.

6. Pull *down* on the plunger to withdraw the required amount of insulin into the Filling Syringe.

7. With the needle still in the vial, flick the side of the syringe with your fingertips to dislodge any air bubbles (these will collect at the top of the syringe).

8. Push in the plunger to expel any air bubbles out of the syringe and into the insulin vial. If necessary, pull down the plunger again to refill the syringe to the required insulin amount.

Important Fill the syringe with the amount of insulin you require - but no less than 60 units. The system requires a minimum of 60 units of U-100 insulin to begin operation. The Reservoir has a maximum capacity of 200 units.

9. Remove the needle from the vial.

Filling the Reservoir with Insulin

⚠ WARNING	Before filling the Reservoir with insulin, make sure there are no air bubbles or pockets of air in the Filling Syringe. Air transferred from the Filling Syringe into the Reservoir could result in interrupted insulin delivery.

➦ To Fill the Reservoir with Insulin

1. Holding the Loaded Inserter at an angle, insert the Filling Syringe needle tip into the Reservoir filling port on the base of the Inserter -see Figure 6-9.

Filling Port

Figure 6-9   Filling Reservoir with Required Insulin Amount

Figure 6-10   Filling Reservoir with Insulin

Note   *While in progress, a graphic representation of the Reservoir-filling process is displayed (on-screen icons, top left), as shown in Figure 6-10.*

2. Slowly inject the measured insulin amount into the Reservoir, observing the status of the icons as you do so.

3. Once the required amount of insulin amount has been filled, remove the needle from the Reservoir filling port.

4. Replace the cap (previously removed) on the Filling Needle.

⚠ **WARNING**   Before continuing, DO NOT attempt to adhere the Pump to your body.
First, proceed to the instructions for Confirming the Pump Priming Process.

Confirming the Pump Priming Process

WARNING	Pump Priming must be confirmed BEFORE attaching the Pump to your body; the system priming process will take approx. 20 seconds.

CAUTION	In the event that you had erroneously adhered the Pump to your body at this stage, it would be necessary to abort the Pump Switch procedure (see Aborting the Pump Switch Procedure). This would necessitate discarding the Loaded Inserter (with its filled Reservoir) and starting the procedure again. Moreover, it would require use of another Triple Jump Sterile Disposable Pack.

➥ /To Confirm Pump Priming

1. Once you have filled the Reservoir with the required amount of insulin, tap Accept to confirm.
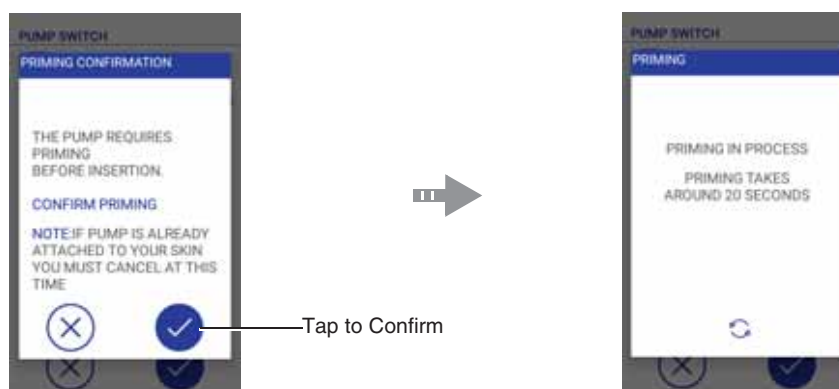   *The system commences the Pump Priming process and displays a message accordingly.*

Tap to Confirm

Figure 6-11   Confirming the Pump Priming Process

2. On completion, proceed to the instructions for Selecting the Pump Site on page 6-21.

Aborting the Pump Switch Procedure

The Abort Pump Switch feature enables you to abort the Pump Switch procedure at any stage, should it become necessary. For example, an error detected by system (such as battery not fully-charged, failed Controller communication with the Engine, Pump malfunction); the system will display error messages accordingly - see examples in Figure 6-12.

Moreover, aborting the Pump Switch procedure would **always** be required if the Pump was already adhered to your body BEFORE confirming the Pump Priming process.

☞ /To Abort the Pump Switch Procedure

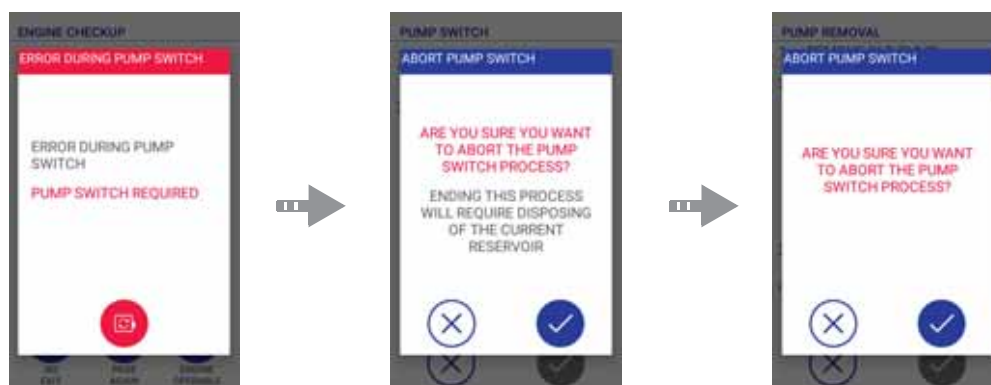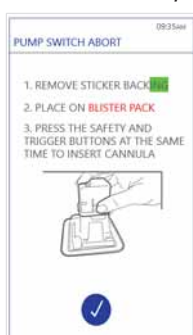1. Respond to the displayed series of error messages, tapping Accept as required.

Figure 6-12   Abort Pump Switch - Messages

Instruction displayed:

2. Remove the protective film from the Loaded Inserter adhesive base - see Figure 6-14.

3. Turn the disposable pack tray upside-down, then adhere the Loaded Inserter to the tray surface. Simultaneously press the Trigger and Safety buttons to perform a "mock" Cannula insertion, then remove the Inserter.

4. Remove the Pump, then separate the Engine from the Reservoir.
   Refer to relevant steps in the following:

   - Removing the Pump from Your Body on page 6-6
   - Separating the Engine from the Reservoir on page 6-9

⚠ CAUTION   **After use, all disposable items must be disposed of in a designated container - and in accordance with local safety regulations.**

5. On the Controller, tap Accept to confirm.

   The screen shown in Figure 6-7 opens - ready for you to select an Engine to use and re-start the Pump Switch procedure (using a fresh Triple Jump Sterile Disposable Pack).

Selecting the Pump Site

It is advisable to discuss suitable options for placement of the Pump on your body with your healthcare provider. General guidelines are outlined below; Figure 6-13 illustrates infusion site options.

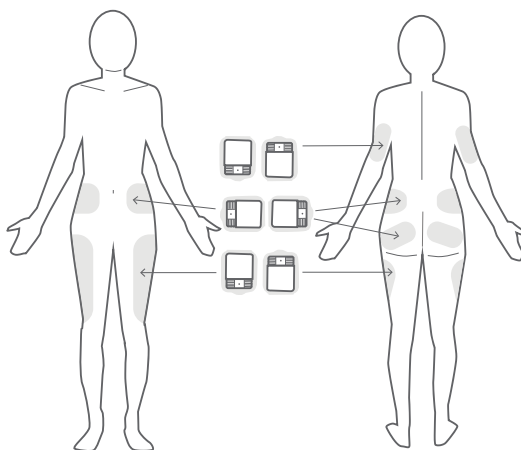**Figure 6-13   Pump Placement on the Body - Recommended Infusion Site Options**

⚠ **CAUTION**   Do not apply the Triple Jump Insulin Pump to skin that is not intact or that shows signs of infection, allergic conditions, burns, *etc.*

General Guidelines

The following are recommendations for placement of your Pump:

- Easily accessible
- Not close to a previous site (to avoid possible irritation)
- Located at least 5 cm (2 ins) from your naval
- Preferably an area with a layer of fatty tissue.

Sites to be Avoided

The following sites should be avoided:

- Any area with cuts, scars, signs of infection, allergic conditions, burns *etc.*
- Any area with moles or tattoos (insulin absorption may be reduced).
- Sites where tight clothing, belts, or waistbands may cause rubbing against the Pump. (This will avoid the risk of dislodging it during treatment).
- Bony areas - or areas with folds of skin.

Preparing the Infusion Site

⚠ **CAUTION** **Before commencing this procedure, wash your hands with soap and water - then dry well. This is important in order to reduce the risk of infection at the infusion site.**

➡ To Prepare the Infusion Site

1. Wash your selected infusion site with soap and water.

Note *When washing the infusion site, it is not recommended to use antibacterial soap since this may cause irritation.*

2. Dry the site with a clean towel.

3. Using an alcohol prep swab, disinfect the site.
    It is preferable to start at the center of the site - then gently rub *outward* in a circular motion.

4. Allow the site to air-dry thoroughly.

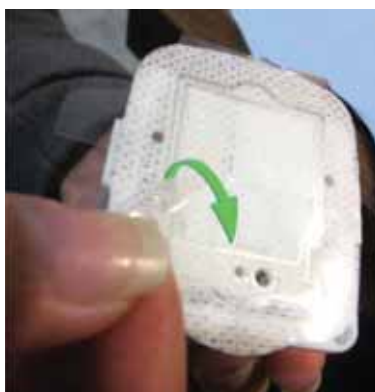**Important**   **Do not blow on the site to dry it as this will contaminate the area and possibly cause infection.**

When dry, the site is ready for Adhering the Pump to the Body.

Adhering the Pump to the Body

➡ To Adhere the Pump to the Body

1. Holding the Loaded Inserter upside-down, carefully peel off the protective plastic film covering the adhesive base.

Figure 6-14   Removing the Protective Film from Adhesive Base

The adhesive surface is now exposed.

2. Turn the Loaded Inserter upright again, then approximate the exposed adhesive area over your required infusion site.

Note   Orientation of the Pump is not critical - choose the placement angle you feel most comfortable.

Important   Once in position, the Pump cannot be relocated at a different site.

3. Press down firmly to secure the adhesive base to your skin.
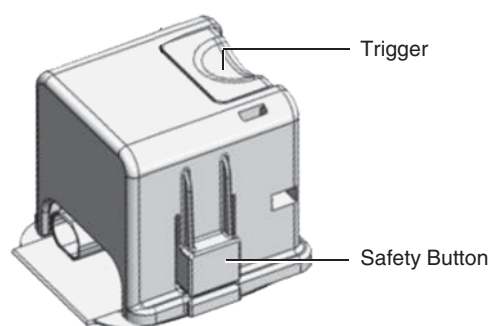
Figure 6-15   Pump and Inserter Located at Infusion Site

4. To perform Cannula insertion, simultaneously press the Trigger button (on top of the Inserter) and the two Safety buttons (one each side).
   See illustration Figure 6-15, *right*.

   You will feel the Cannula tip penetrating your skin.

5. Lift and remove the Inserter.

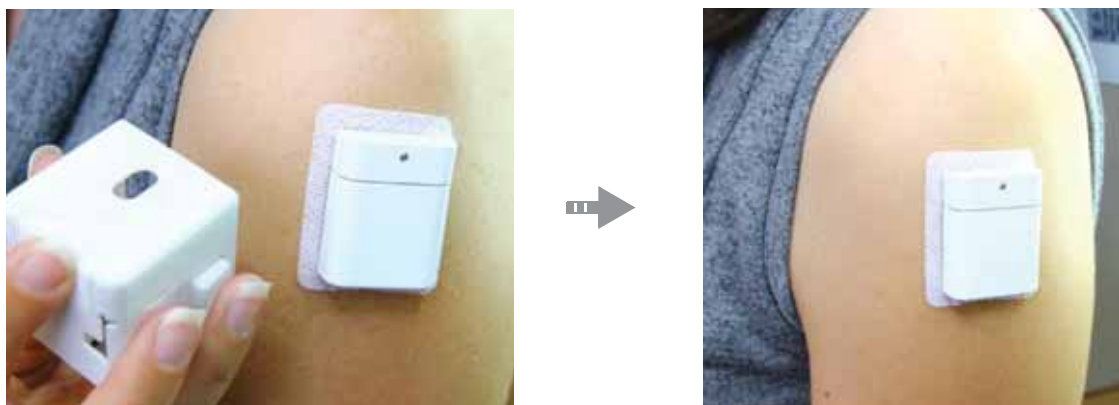   *The Pump now remains adhered to your body at the chosen site - see Figure 6-16.*

Figure 6-16   Lifting Inserter - Pump Adhered to Infusion Site

6. Make sure the Cannula was inserted properly into your body.
Then, press the Pump against your body manually to verify that it is adhered securely.

Proceed to resume (or commence) insulin delivery, as applicable - as described in the next section.

⚠ WARNING   Once you resume insulin delivery, DO NOT attempt to perform Controller Shut Down.

Although the Pump will remain operational even if power to the Controller is OFF, in the event that one or more audible Alarms sound, YOU WILL NOT HEAR IT!!

Moreover, Alerts or important messages WILL NOT BE SEEN!!

Resuming Insulin Delivery

Note *If this is the first-time you are using your Pump, you will perform the steps below to commence your treatment.*

➥ **To Resume (or Commence) Insulin Delivery**

1. Using your Controller, confirm completion of the Cannula insertion process by tapping the Accept button -see Figure 6-17.
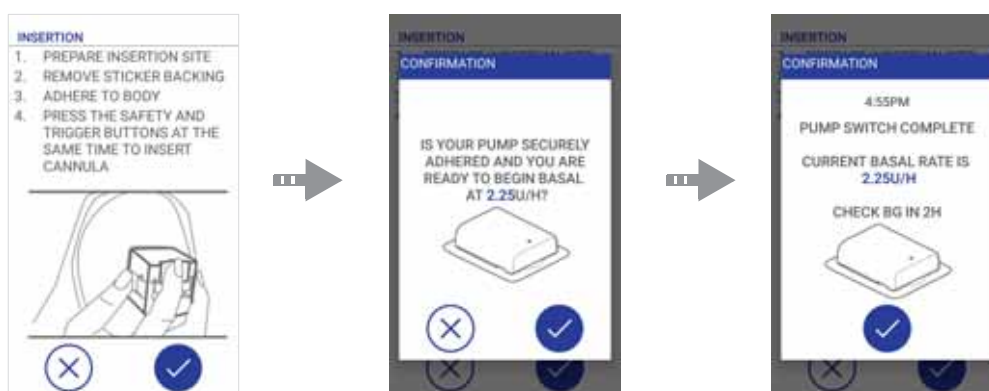

Figure 6-17   Completing Cannula Insertion and Commencing Insulin Delivery

2. In the displayed messages, confirm again.

Insulin delivery commences in accordance with your currently-set parameters.

Important The Pump Switch procedure is now complete.
In 2 hours from now, it is important to check your Blood Glucose level to ensure correct insulin delivery and to continue monitoring your treatment - paying attention to any audible Alarms or displayed Alerts.

Chapter 7 –   Tracking Treatment - Clinician Visits

Treatment History - Overview

The Triple Jump Controller includes a History feature whereby all treatment actions are continuously tracked and saved automatically. This information is presented in the History screen - see Figure 7-1.

Using this feature, you are able to track and monitor your treatment history yourself. It is recommended that you do this on a regular basis - typically once per week.

When attending follow-up visits, this information is readily accessible for your clinician - who can review and monitor your Treatment History, then adjust your treatment parameters as required.
Refer to the following:

- Reviewing Treatment History
- Adjusting Treatment Parameters

Reviewing Treatment History

History Screen

Your Treatment History is accessed from Home screen (**History** icon).

The display presents a sequential log of all actions made in the system. Each action is time-stamped, the most-recent being displayed at the top of the list.

Figure 7-1   History Screen

By default, the screen opens at the current date (displayed at the top of the screen).
To scroll through the list, use the *next* and *back* arrows (adjacent to the date), as required.

Adjusting Treatment Parameters

During your treatment follow-up visits, after reviewing your Treatment History your clinician may decide it necessary to adjust some of your Triple Jump system treatment parameters, or to add additional settings. Refer to the following:

- Adjusting Your Treatment Settings on page 5-7
- Basal Profile Settings on page 5-18

Chapter 8 –   Alarms and Alerts

Introduction

When using the Triple Jump system, active communication between the Controller and the Engine provides the user with constant feedback on the current insulin delivery status and monitors a range of important (and sometimes critical) parameters.

In addition to displayed messages and instructions, the user is notified in real time to warn of any hazardous situation - or of something that may need immediate or close attention - by way of Alarms and Alerts.

These notifications are color-coded to give and immediate indication of their importance.
Alarms are colored red; Alerts are shown in yellow.

⚠ WARNING **ALWAYS respond to an Alarm or Alert as soon as possible.**
Failing to do so could result in inaccurate delivery of insulin - or even failure to deliver insulin!

For examples of the various Alarms and Alerts you could encounter, refer to the following:

- Alarms on page 8-2
- Alerts on page 8-6

Alarms

Controller Alarms

Engine Uncovered Alarm

Incomplete Pump Switch Alarm

Suspend Alarm

No Communication Alarm

Occlusion Alarm

In the event that the Engine detected an irrecoverable occlusion, an Occlusion Alarm is displayed.

The Occlusion Alarm has three variations, depending on the currently-running deliveries (Bolus, Temp Basal *etc.*)

If two boluses are running concurrently, the Occlusion Alarm includes both Bolus amounts.
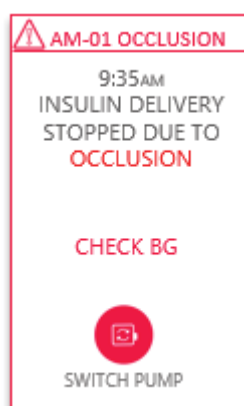

Figure 8-1   Occlusion Alarm

The alarm has one button: Pump Switch (this starts the Pump Switch flow).

Empty Reservoir Alarm

Engine Battery Alarm

AM05 – Detach Detection – Not during priming

AM05 – Detach Detection – During priming

AM06 – Engine Error

AM07 – Reservoir problem – Not during priming

AM07 – Reservoir problem - during priming

AM09 - Incomplete Pump Switch

Alerts

Communication Timeout Alert

Bolus Status Unknown Alert

Low Reservoir Alert

Low Engine Battery Alert

Low Controller Battery Alert

Switch Alert

Chapter 9 – Care and Maintenance

General Care and Maintenance Guidelines

Cleaning Procedures

Battery Care

Changing the Controller Date and Time Settings

This procedure is required whenever the local time changes (Daylight Savings). It will also be necessary when traveling to a different time zone.

For procedure instructions, refer to Setting Current Date and Time on page 4-10.

Parts List

TBD

Appendix A - Troubleshooting Guide

General Troubleshooting Guidelines

TO BE ADDED - specific Troubleshooting Instructions for main problems that may be encountered

Appendix B - System Specifications
and Technical Information

System Specifications

Technical Information

Appendix C - Warranty Information

Pending - if you decide to keep

triplejump

Triple Jump (Israel) Ltd.
5 HaCarmel St. Industrial Park South
Yokneam 2069203, Israel.

Tel: +972 (0)73-7079070
Fax: +972 (0)73- need details - or REMOVE?
email: info@triplejumpmed.com (Website pending Lidar)

Triple Jump Customer Services: Tel #? email?