equil

Patch Insulin Pump System
Instruction Manual

Contents

1 Foreword

Thank you for choosing the Equil patch insulin pump system. We believe that the system will help you gain better control of your diabetes and will help you live a healthy and active life.

This user guide is designed to help you understand insulin pump therapy and the operation of your Equil patch insulin pump system. We strongly recommend that you work closely with your healthcare professional to ensure you understand the pump functions and can begin therapy safely and effectively.

You can visit our website at any time to browse or download the latest electronic manual of this product: https://microtechmd.com/support/download/83/148

2 Introduction

2.1 Intended Purpose

Ambulatory Insulin Infusion Pump:

The Ambulatory Insulin Infusion Pump is indicated for the subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Portable Diabetes Assistant:

The Portable Diabetes Assistant is intended to control the Ambulatory Insulin Infusion Pump for the subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. Additionally, the PDA is interoperable with continuous glucose monitoring system to receive and display blood glucose measurements.

2.2 Intended Patients

Type 1 and type 2 diabetes patients aged 3

and above requiring insulin pump therapy.

2.3 Intended Users

From device operation perspective, this device is intended to be operated by professional users and lay users with age of 18 and above.

Requirement for professional users:

- Graduate from medical school or graduate with related major
- With normal touch, visual and hearing ability
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Requirement for Lay users:

- With elementary school or above education background
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Note

Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your learning needs. Your healthcare provider can help you to coordinate and set up appropriate training. For pediatric patients, 'lay person' refers to caregiver, parent, or legal guardian.

2.4 Intended Environment

Hospital setting and Home setting.

2.5 Indications

Indications for patch insulin pump system:

(1) Patients with type 1 diabetes mellitus or type 2 diabetes mellitus who require insulin pump therapy.

(2) Patients with type 1 diabetes who are

motivated to improve glycemic control following a trial of multiple daily insulin injection (MDI) therapy and who can show the level of self-care required for adherence.

(3) Patients with type 2 diabetes on MDI who can use the device safely (either by themselves or with a caregiver).

2.6 Contraindications

Contraindications for patch insulin pump system:

(1) Diabetic patients unwilling to perform insulin pump treatment

(2) Patients who do not want to or do not have access to self-monitoring of blood glucose levels

(3) Patients with alcohol addiction, drug abuse, or with severe mental disorders (e.g. depression, schizophrenia)

(4) Allergies, including insulin allergies and severe skin allergies

(5) People who are unconscious or disoriented

(6) People who are intellectually impaired and unable to understand or master the instructions for use

(7) People with severe visual or hearing impairments

(8) Elderly diabetics living alone

(9) Children with diabetes who are too young to take care of themselves

(10) The pump system has not been evaluated in:

- Pregnant woman
- Children below 3 years

(11) Diabetic patients who do not require insulin therapy

(12) Patients with granulomatous nodules, which are tiny lumps or nodules beneath the skin, should not use this product.

(13) Patients with any of the following conditions should not use this product:

- Blood albumin level lower than 90 g/L (may indicate poor nutrition or liver problems);
- White blood cell count lower than 4.0 × 10^9/L (weakened immunity, higher risk of infection);

- Platelet count lower than 90 × 10^9/L (reduced clotting ability, higher risk of bleeding).

(14) Patients in the acute phase of diabetic ketoacidosis or hyperosmolar coma.

(15) Hyperglycemic patients with severe circulatory disorders.

(16) Diabetic patients allergic to subcutaneous infusion sets or adhesive tapes.

(17) Patients and family members lacking relevant knowledge and still unable to use the device correctly after training. Diabetic patients unwilling to perform insulin pump treatment.

2.7 Before Use

Before starting to use your Equil patch insulin pump system, consult with your healthcare provider to determine the appropriate settings (therapeutic regimen) for you. Healthcare and treatment are complex subjects requiring the services of qualified healthcare providers.This User Guide is for information purposes only and not intended as medical or healthcare advice or recommendations to be used for diagnosis, therapy or for any other individual need.

Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your leaning needs. Your healthcare provider can help you to coordinate and set up appropriate training.

The following provides a preliminary introduction to the professional information that frequently appears in the subsequent content.If you have further questions regarding this information, please contact your healthcare professional for more guidance.

1 Basal Rate

Basal insulin is administered to maintain target blood glucose levels when not eating. You can configure up to eight basal programs with Equil patch insulin pump system, which can help you adapt to different situations(for example, workdays,

weekends, and sick days). Each basal program can be configured with up to 48 scheduled basal rate changes within one day. However, if you are new to using an insulin pump, you may decide to only use one or two basal rates during the day.

❷ Active Insulin Time

The length of time that insulin remains active and available in your body after a correction bolus. Quick acting U 100 Insulin should be used in the pump.

❸ Target Blood Glucose Level

Insulin pump therapy requires a target blood glucose level. The purpose of an insulin pump is to keep the patient's blood glucose within a target blood glucose level range (reference range in the software: 70-180 mg/dL).

Note

The target glucose range may vary depending on the type of diabetes, time of day (e.g., fasting or postprandial), and individual patient factors. Please follow the specific recommendations provided by your healthcare provider for personalized settings.

❹ Insulin Sensitivity Factor

How much one unit of insulin can decrease blood glucose level. This number is used to calculate bolus injection amounts.

❺ Carbohydrate Ratio

The number of grams of carbohydrates that can be covered or disposed by 1 unit of insulin.

2.8 How to Use This Guide

We recommend that you read this user guide thoroughly. Your healthcare professional can help you understand the usage in even greater detail.

Please read this user guide in the correct order. In many cases subsequent sections refer to information detailed in previous sections.

Please note that throughout the rest of the instruction manual, "PDA" refers to the portable diabetes assistant.

Note

This user guide shows sample screens only. Your portable diabetes assistant (PDA) screen may be slightly different.

2.9 Getting Help

This user guide describes the insulin pump system in great detail. However, you should still consult your healthcare professional for guidance. New users should consult a healthcare professional to help with first-time setup and training of the insulin pump system.

Please seek help from your healthcare professional if you encounter problems. The manufacturer and Microtech Medical can provide technical support for the device, but cannot provide treatment advice for your medical condition.

Any serious incident that has occurred concerning the device should be reported to the manufacturer and the competent authority of the Member State.

2.10 Prepare for Emergencies

Patients with diabetes should always carry an emergency kit to quickly respond to any diabetes emergencies. Your emergency kit should include the following items:

- Blood glucose test supplies
- Ketone test supplies
- 1-2 sets of pump disposables(reservoirs, infusion sets, etc.)
- PDA and Pump battery chargers
- Alcohol prep swabs
- Backup pump battery
- U-100 insulin that is approved for your pump
- Insulin for manually injecting insulin should the pump malfunction
- Glucose tablets or another fast-acting source of carbohydrates
- Instructions from your healthcare professional regarding the amount of insulin to administer if the pump is interrupted, as well as your healthcare professional's contact phone number in case of emergency

- Emergency card: the emergency card should include name, date of birth, insulin/ medications, allergies, emergency contact, and doctor/clinic.

2.11 Warning

(1) This system is not a closed-loop or partial closed-loop insulin delivery system. It does not automatically adjust insulin delivery based on glucose measurements.

(2) After replacing a new CGMS Sensor, manual reconnection with the PDA is required.

(3) Use only accessories and disposables that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.

(4) DO NOT allow small children access to small parts, such as the Pump and its accessories. Small parts could be swallowed and pose a choking hazard. If ingested or swallowed, these small parts could cause internal injury or infection.

(5) The included adapterr can be used in wall outlets rated at AC 100V-240V 50/60Hz. Connection to outlets that are outside this range can cause damage.

(6) Please keep the charging cable away from children, the charging cable may wrap around the neck and cause strangulation.

(7) Do not touch any metal part of the charger when plugged into a power outlet as it is a potential shock hazard.

(8) Before continuing, please make sure you are familiar with frequently used pump setup operations such as installing/ removing an infusion set, filling a new reservoir, and assembling/disassembling the reservoir.

(9) Do not use any organic solvents or lubricants to clean the insulin pump! Because they can make the pump malfunction, causing minor damage. When cleaning the pump, be sure to keep the reservoir dry and avoid getting it damp.

(10) Cleaning the PDA with any organic solvents or lubricants may make the PDA malfunction, causing damage.

2.12 Ambulatory Insulin Infusion Pump Precautions

(1) The pump is used to administer insulin for people with diabetes. If it is used incorrectly, it could cause life-threatening situations.

(2) Before using the pump, please read the user guide carefully. Patients must be trained by a healthcare professional provider and should only use the pump after they have mastered the operation.

(3) Your healthcare professional should develop a customized insulin delivery protocol for you. Your healthcare professional will adjust the settings and observe the effectiveness, possibly monitoring your blood glucose four times a day until the therapy is stable.

(4) You should keep in frequent contact with your healthcare professional. Basic pump adjustments should be made under close supervision with a qualified healthcare professional.

(5) You should have sufficient knowledge of diabetes, and how to regulate your blood glucose level using insulin delivery and diet. You should understand the effects of hyper and hypoglycemia and how to prevent these conditions.

(6) If the pump fails to deliver your needed insulin, immediately stop using the system and consider using your emergency kit to supplement insulin. Contact your healthcare professional and/or local distributor.

(7) Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions may result in unsafe practices. Microtech Medical is not liable for any related legal obligations arising from misuse.

(8) This product can only be used to administer U-100 insulin. The following U-100 rapidacting insulin analogs have been tested and found to be safe for use in the pump: NovoLog®/NovoRapid® (insulin aspart), Humalog® (insulin lispro). NovoLog®/ NovoRapid® and Humalog® are compatible with the Equil patch insulin pump system for use up to 72 hours (3 days).

(9) Only MicroTech Medical disposable supplies should be used with the pump.

(10) Unauthorized modification of medical electrical equipment may result in danger.

(11) Avoid immersing the product in water for extended periods. For the patch insulin pump system that is not paired with a reservoir, please avoid proximity to water sources. If it accidentally comes into contact with water, perform a self-test to check if the product can operate normally. If it cannot operate, please contact service.

(12) To maintain good battery performance during long periods of non-use, it is recommended to fully charge the pump and PDA at least once a year.

(13) The Ambulatory insulin infusion pump and PDA have a wireless communication range of 2 meters. The distance and surrounding environment have a large effect on the wireless signal integrity. The connection may be affected by distance or objects between the devices. Keep the pump and PDA close to each other to ensure proper operation.

(14) A fully charged battery can be used for 96 hours in typical usage scenarios.

(15) The product may contain small parts that can be dangerous if swallowed.

2.13 Portable Diabetes Assistant(PDA) Precautions

The PDA is the main interface for the entire system. Please note the following precautions:

- Do not let others handle your portable diabetes assistant (PDA) except your qualified healthcare professional.
- Please keep the battery charged.
- Do not drop or get wet as this could cause a malfunction.
- The compatible CGMS models of Microtech Medical are shown in the table:

Product Name	Continuous Glucose Monitoring System		
Model	G7	G7-A	G7-B

Product Name	Continuous Glucose Monitoring System Sensor			
Model	GX-01S	GX-02S	GX-01F	GX-02F

Warning

After replacing a new CGMS Sensor, manual reconnection with the PDA is required.

2.14 Important Safety Information

2.14.1 Waterproof Capabilities

MTM-1\MTM-2\MTM-H2: IPX4

Do not fully submerge the pump and portable diabetes assistant (PDA) in water. If you plan to bathe, swim, or participate in other water activities, please suspend insulin delivery and remove the pump from the base. After you finish your activities, you may re-apply the pump to the base and continue pump therapy.

If the pump is accidentally dropped in water, use a soft clean towel to dry the pump as soon as possible. If you believe that water has entered the pump, or if you observe any other possible pump malfunction, please remove the pump from the base, check your blood glucose level and take precautions as necessary. Symptoms of high blood glucose include fatigue, excessive thirst and nausea. You should always contact your healthcare professional if you experience excessively high or low blood glucose levels, or if you have any questions about your care.

MTM-H1: IPX8

It is protected against the effects of being under water to a depth of up to 2 meters(6.56 feet) for up to 30 minutes.

2.14.2 Static Electricity

The patch insulin pump system is resistant to normal levels of static electricity (ESD)but high levels of shock may cause a software reset which can interrupt insulin delivery.

ESD are more likely in situations where the relative humidity is very low, such as inside a heated building during the winter in areas where it is cold outside.

2.14.3 Extreme Environmental Usage

When the device is used outside the intended operating environment, it may face various risks. For example, in an environment with extreme temperatures (below 5°C or above 40°C), the infusion accuracy of the device may decrease, and the battery performance may significantly deteriorate. In severe cases, it may even cause the insulin to become ineffective, thus affecting the treatment effect and potentially posing a serious threat to the patient's health. In an environment with strong electromagnetic interference (such as an industrial workshop), the key electronic components of the device may be disturbed, resulting in abnormal functionality or complete failure, which in turn affects the continuity and reliability of the treatment. Additionally, in an environment with congested wireless signals (such as an area where multiple Bluetooth or Wi-Fi devices are operating simultaneously), the wireless communication of the device may become unstable, leading to interruptions or failures in data transmission, and further affecting the device's performance and the user experience.

2.14.4 Data Backup and Restoration

To ensure the integrity and security of key treatment parameters, the PDA does not have the function of deleting configuration settings. In terms of data backup, this product supports one-way data transmission via the USB cable and network to the Pancares platform. Users can export the treatment data (such as infusion records, blood glucose data, etc.) in the PDA to an external device for backup through a USB cable.

2.14.5 Security Measures

- In order to ensure the safety of medical devices when they are integrated into health information systems, strict quality management processes are followed to guarantee the reliability and safety of the devices. The specific steps include design verification and validation, production verification, and deployment preparation.
- The device enhances its security through

a variety of security configuration measures to ensure effective resistance against potential security threats both at the network and physical levels. Firstly, the device employs the AES encryption algorithm to protect the confidentiality and integrity of all network communications and sensitive data. Secondly, the device enables a detailed logging function, recording all critical operations and security incidents, and it can detect potential threats in real-time by setting security event parameters.

- The patch insulin pump system captures various types of log files through its built-in logging function, including security event logs, operation logs, and system logs. The log files are stored in the device's local non-volatile memory (NVM) and are in an encrypted format to ensure the confidentiality and integrity of the data. If users need to export the log files, they should contact the manufacturer to obtain technical support.
- The insulin pump software can ensure that after the insulin delivery is initiated, the pump will adjust the basal rate according to the pre-settings. Even if there is a long - term interruption in the wireless communication between the PDA and the pump, it will not affect the execution of the delivery plan. When the network security is under threat, it can still protect key functions to ensure the safety of patients and the continuity of treatment.

2.15 Special Considerations for Pediatric Use

When using the insulin pump system for children aged 3 and above, the following should be considered:

- Infusion Site Selection: Choose sites with adequate subcutaneous tissue and rotate regularly. Avoid areas prone to irritation or dislodgment due to activity.
- Dose Adjustments: Insulin requirements may change frequently due to growth, activity, and dietary intake. Close monitoring and frequent adjustments are essential.

- Device Security: Ensure the pump and infusion set are securely attached to prevent accidental removal. Use additional adhesive patches or securing products if needed.
- Supervision: Children should be supervised by a trained adult during device operation, including bolus delivery and site changes.

2.16 Responsibilities of Lay Users (Caregivers)

Lay users operating the device on behalf of a pediatric patient must:

- Complete structured training and demonstrate competency in device use.
- Maintain a log of blood glucose readings, insulin doses, and notable events.
- Monitor for signs of hypoglycemia, hyperglycemia, or infusion site issues.
- Ensure the device is functioning properly and respond promptly to alarms.
- Communicate regularly with the healthcare team and report any concerns or changes in the patient's condition.

3 Component Descriptions

3.1 Pump System Components

1 PDA

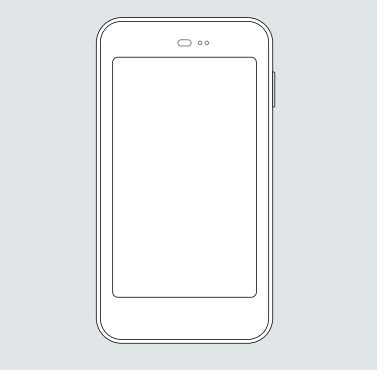


Figure 1

❷ Ambulatory Insulin Infusion Pump

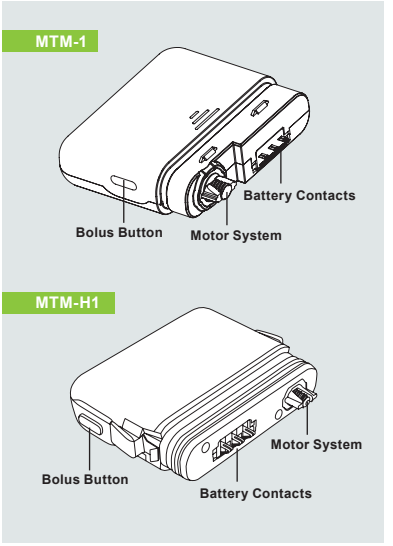


Figure 2

❸ Cannula Inserter

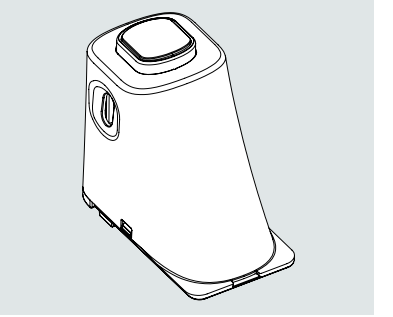


Figure 3

3.2 Accessories

❶ Pump Battery

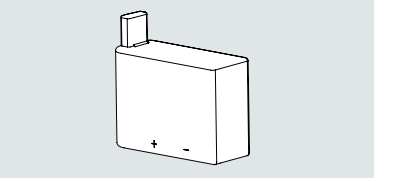


Figure 4

❷ Pump Battery Charger

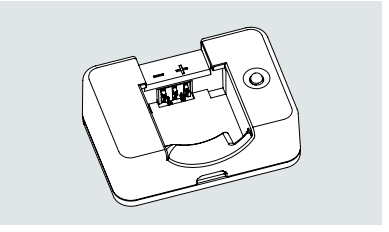


Figure 5

Warning

Use only accessories and disposables that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.
DO NOT allow small children access to small parts, such as the Pump and its accessories. Small parts could be swallowed and pose a choking hazard. If ingested or swallowed, these small parts could cause internal injury or infection.

❸ PDA Adaptor

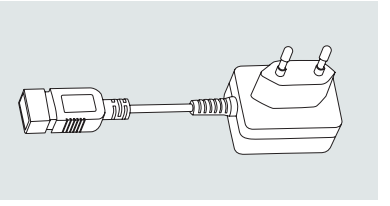


Figure 6

Note

The adapter plug is only used to disconnect the power and does not affect the placement of the ME equipment or make unplugging the power difficult.

Warning

The included adapterr can be used in wall outlets rated at AC 100V-240V 50/60Hz. Connection to outlets that are outside this range can cause damage.

4 PDA Charging Cable

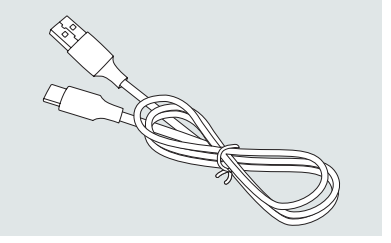


Figure 7

Note

Only use MicroTech's electrical components and accessories. Other accessories may lead to safety problems, including inaccurate insulin delivery.

Warning

Please keep the charging cable away from children, the charging cable may wrap around the neck and cause strangulation.

CRITICAL: PACKAGING INSPECTION BEFORE USE

Always inspect the packaging of all system components and disposables before use.

If the outer packaging is damaged or unintentionally opened before use, you should carefully inspect the external surfaces of all components and accessories inside the package for any damage, cracks, or deformation. If the devices or its accessories are found to be non-functional under these circumstances, contact customer service for assistance.

Summary of components and accessories included with the Equil patch insulin pump system:

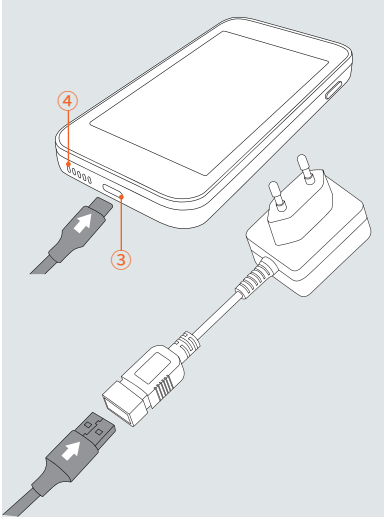
Name	Model Number		Service Life
Ambulatory insulin infusion pump	MTM-1	MTM-H1	Reusable, 4 years
Portable Diabetes Assistant (PDA)	MTM-2	MTM-H2	Reusable, 4 years
Cannula Inserter	MTM-5		Reusable, 4 years
Pump Battery	1001-RMTL-009		Reusable, 4 years
Pump Battery Charger	1001-RMTL-160		Reusable, 4 years
PDA Adaptor	1001-RMTL-163		Reusable, 4 years
PDA Charging Cable	1001-RMTL-164		Reusable, 4 years

Disposable components not included with this system, that need to be purchased separately:

Name		Model Number	Note	Service Life
Equil Insulin Infusion Pump Reservoirs		MTM-3	Suitable for MTM-1 pump	Single-Use
		MTM-R10		Single-Use
		MTM-3WP	Suitable for MTM-H1 pump	Single-Use
		MTM-10WP		Single-Use
Equil Insulin Infusion Sets	Insulin Pump Base	MTM-4	Suitable for MTM-H1 &MTM-1 pump	Single-Use
	Cannula	HRN-S-60		Single-Use
		HRN-S-90		Single-Use

4 Getting Started

4.1 PDA at A Glance



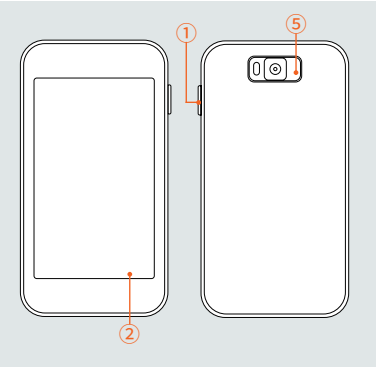


Figure 8

① (Power Button)

Power On: Press and hold this key and the PDA will vibrate, begin the startup process, and enter the home screen.

Screen Off: If the PDA display is on, pressing the Power Button will switch the LCD display off and the PDA will enter standby mode.

Note

The PDA display will also switch off and enter standby mode after a preset time.

Screen On: When on standby, pressing the power button will switch the display and present the lock screen.
Power Off: If the display is on, press and hold the power button to open a dialogue box to confirm that you would like to turn off the device.

② Display

4-inch color display with touchscreen.

③ Charger/Data Port

Connect the PDA charging cable to this port to replenish the battery. This port can also be used to transfer data to a personal computer using a data cable.

④ Speaker

Alerts play sounds through the built-in speaker.

⑤ Camera

The camera can be used to scan the QR codes of CGM and pump.

4.2 Charging the Batteries

The Ambulatory insulin infusion pump should be fully charged before use.

Note

Use only batteries and chargers from MicroTech Medical. Use of third-party accessories may cause unexpected behavior and will void your warranty.

4.2.1 PDA Charger

1. The PDA may be on or off during the charging process however and will charge faster if the controller is off.
2. Insert the small end of the cable into the PDA, and the large end of the cable into the PDA adapter as shown in Figure 9.

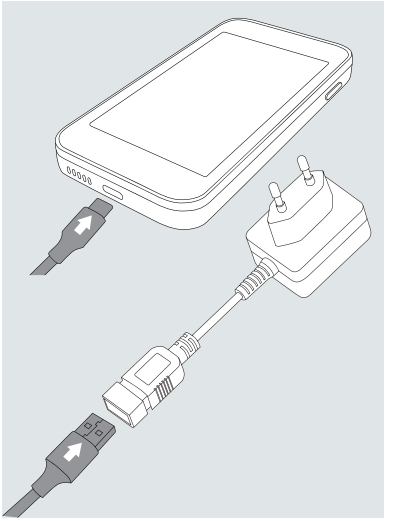


Figure 9

3. Connect the PDA adapter to a power outlet. If the PDA is on, the battery icon will change to the charging icon. If the PDA is off, a charging animation will appear.

Note

If the PDA charger does not work, do not try to repair it. Please contact your local supplier for a replacement.

Warning

Do not touch any metal part of the charger when plugged into a power outlet as it is a potential shock hazard.

4.2.2 Ambulatory insulin infusion pump Battery Charger

1. Insert the small end of the cable into the pump battery charger as shown in Figure 10. The large end of the cable should be inserted into the PDA adapter.

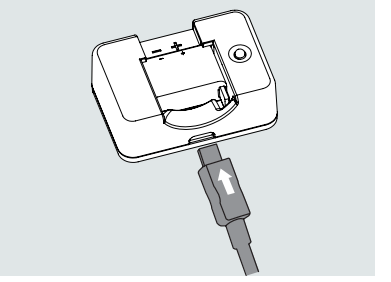


Figure 10

2. The Ambulatory insulin infusion pump battery is inserted into the charger as shown in Figure 11.

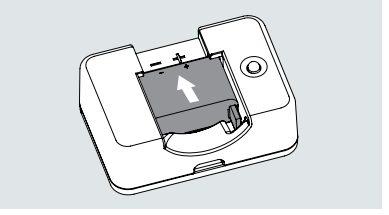


Figure 11

3. Plug the PDA adapter into a power outlet, and the blue LED will turn on, indicating that the battery is charging. The indicator will flash if the charger is faulty.

4. When the battery is fully charged, the blue LED will turn off and you can disassemble the cable, pump battery charger, and PDA charger.

5. Remove the pump battery as shown in Figure 12: lift the battery from the charger groove.

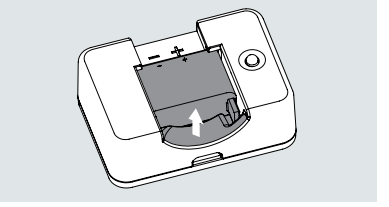


Figure 12

Note

A full battery should be stored properly inside an insulated package. Storing a battery with metal objects may cause a short circuit, resulting in a decrease in capacity or even battery damage.

5 Therapy Setup

5.1 Infusion Set Setup

1. Firstly wash your hands. Then use an alcohol wipe to clean the infusion site area, removing any oils/dirt. Allow it to air dry. Remove the pump base from its packaging and place it on one of the suggested areas shown in Figures 13 and 14(abdomen, upper arm, thigh, lower back), where Figure 13 is a schematic diagram of application sites for children and Figure 14 is for adults. Avoid sites that may rub against other objects like belts, waistbands or tight clothing. Also, make sure that your infusion site is at least 2-3cm away from your navel.

Note

If both the Ambulatory Insulin Infusion Pump and CGMs are used simultaneously, the sensor and the infusion site should keep at least 3 inches (8cm) apart to avoid the influence of insulin injections on the sensor readings.

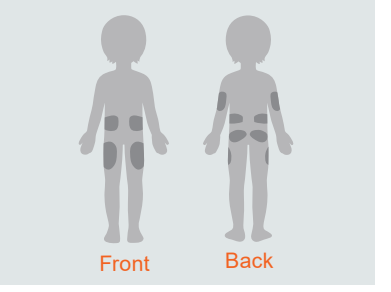


Figure 13

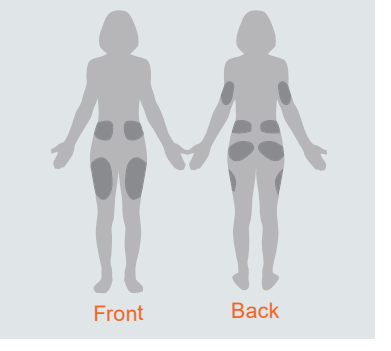
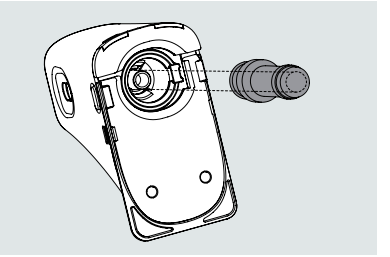


Figure 14

2. Open the cannula pack as indicated on the packaging. Push the cannula assembly into the cannula inserter as shown in Figure 15 until the cannula assembly is in the cocked position and you hear two “click” sounds. You should see that the cannula assembly is connected firmly to the cannula inserter and the inserter is held firmly in the cocked position.



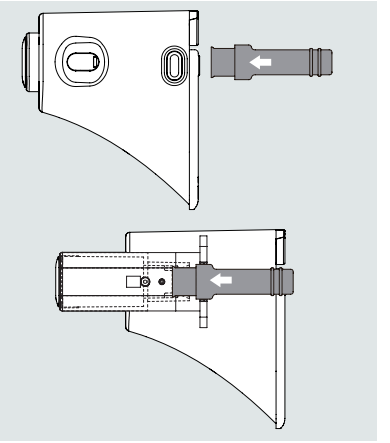


Figure 15

Note

Infusion sets are comprised of a cannula pack and base. Be sure to use only infusion accessories from MicroTech such as HRN-S-60 and HRN-S-90.

Note

When applying the infusion set to a child, ensure the skin is clean, dry, and free of lotions or oils. Use gentle pressure during insertion and monitor for signs of discomfort or skin irritation. Consider using topical anesthetic creams if approved by the healthcare provider.

Note

Soft Cannula are Sterilized using ethylene oxide. Do not use if the cannula and pump base packaging are broken.

3. Remove the protective sleeve as shown in Figure 16.

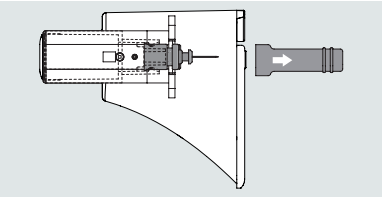
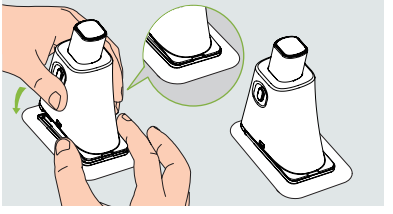


Figure 16

4. Hold the cannula inserter and align the front end with the bottom plate of the pump base as shown in Figure 17. Press down, until you hear a “click” securing it in place. Press the release button on both sides of the cannula inserter at the same time, then the cannula will be inserted into the base and infusion site.



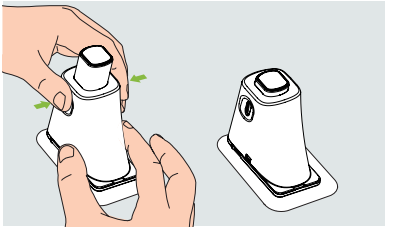


Figure 17

Note

When pressing the release button, the other hand must be pressed against the bottom of the cannula inserter and the base plate cannot be lifted.

5. Release the inserter from the pump base by pressing the button on the lower end of the cannula inserter as shown in Figure 18. If the inserted needle or needle base remains in the pump base, carefully remove it from the infusion site. Place the protective sleeve back onto the cannula assembly.

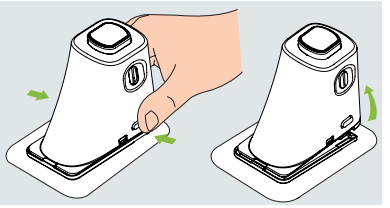


Figure 18

6. If the needle remains in the inserter, place the protective sleeve back onto the needle hub. Firmly push the top of the inserter to eject the needle hub (Fig. 19) and dispose of it properly.

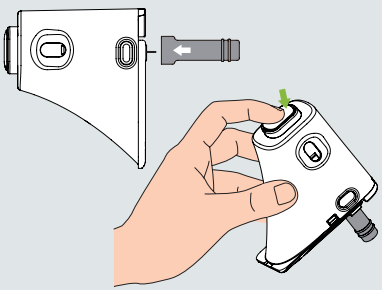


Figure 19

Note

Dispose of the insertion needle properly in a medical sharps container.

5.2 Removing the Infusion Set

Peel away one end of the tape from the skin as shown in Figure 20 and continue until the entire infusion set has been removed.

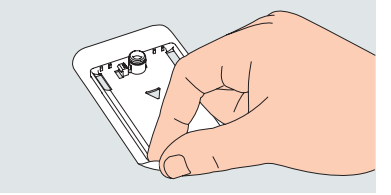


Figure 20

5.3 Filling the Reservoir

Note

This section takes the MTM-3 as an example. There are slight differences in the operation of filling different models of reservoirs. Please see Reservoir Instruction for more details.

Note

Insulin Infusion Pump Reservoir are Sterilized using ethylene oxide.
Do not use if reservoir package is broken.

1. Remove the new reservoir from the packaging.
2. Use an alcohol wipe to clean the insulin vial or cartridge and then attach it to the fill adapter as in Figure 21.

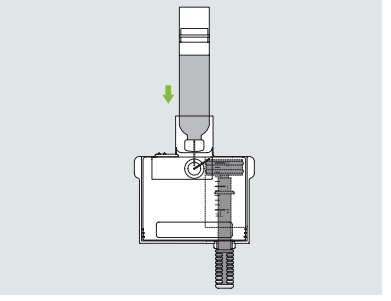


Figure 21

3. With the insulin vial or cartridge on top, slowly pull the pullrod and draw insulin into the reservoir as in Figure 22.

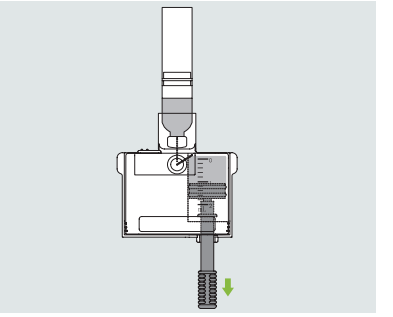


Figure 22

4. Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 23).

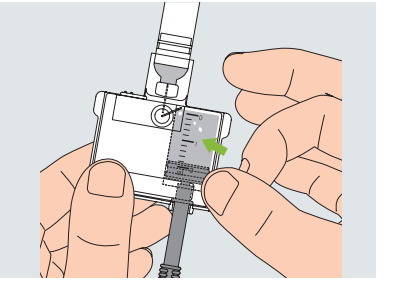


Figure 23

As for the operation of the 10ml reservoir, please refer to the reservoir IFU for more details.

5. Push the pullrod slowly to eject the bubbles back into the vial or cartridge, and then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir has enough insulin and there are no visible air bubbles (Figure 24).

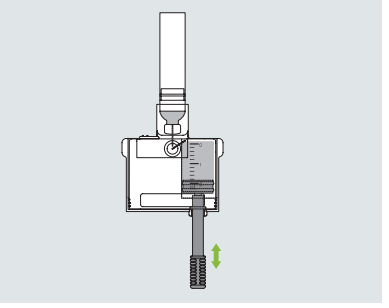


Figure 24

6. Remove the insulin vial or cartridge from the fill adapter (Figure 25).

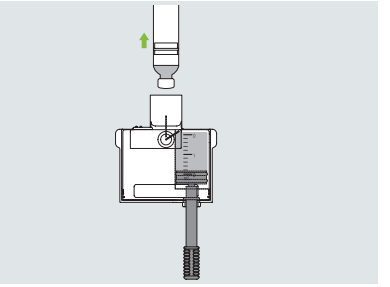


Figure 25

7. Pull the two release tabs (shown in Figure 26) away from the reservoir to release the fill adapter.

Note

The fill adapter contains a needle, please dispose of it properly.

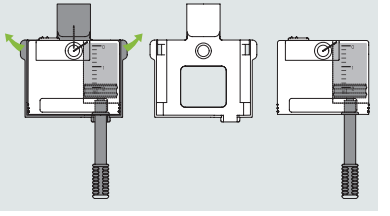


Figure 26

8. Remove the pullrod by unscrewing it counterclockwise (Figure 27).

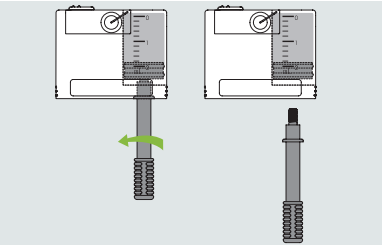


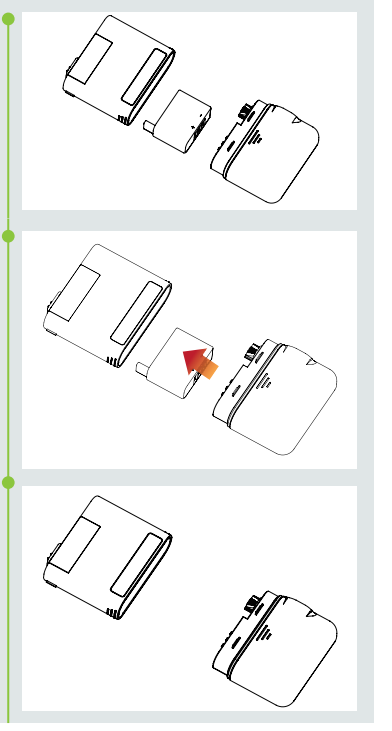
Figure 27

5.4 Assembling Reservoir to Pump

Figure 28 illustrates the sequence to attach the reservoir and battery to the pump. Always install a fully charged battery with a newly filled reservoir.

Note

The image shown here is indicative only. If there is inconsistency between the image and the actual product, the actual product shall govern.



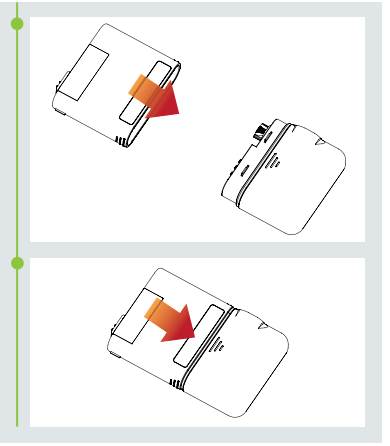


Figure 28

Be sure that the battery is inserted in the orientation shown in Figure 29.

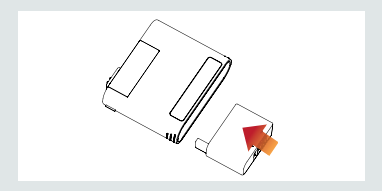


Figure 29

5.5 Disassembling the Reservoir

For MTM-1

Holding the pump and reservoir in the orientation shown in Figure 30, bend the assembly along the seam line as shown until the reservoir separates from the pump. Be sure to recharge the battery immediately to make sure that a fresh battery is always installed with a new reservoir. Dispose of the used reservoir in a medical sharps container.

Note

Pay close attention to the orientation of the pump during disassembly. Incorrect disassembly may cause damage.

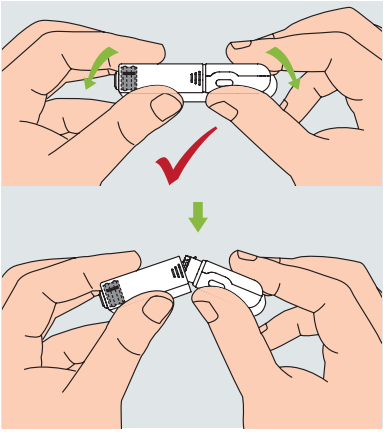


Figure 30

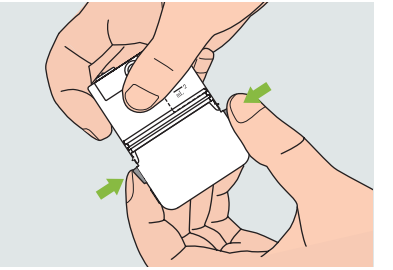


Figure 31

For MTM-H1

According to the method indicated in figure 31, after the pullrod is reset, pinch the side buttons on both sides of the pump with one hand, and at the same time hold the reservoir with the other hand, and pull it out in a parallel direction until it is completely out of the pump.

6 Replacing the Ambulatory insulin infusion pump

Note

The image shown here is indicative only. If there is inconsistency between the image and the actual product, the actual product shall govern.

Warning

Before continuing, please make sure you are familiar with frequently used pump setup operations such as installing/removing an infusion set, filling a new reservoir, and assembling/ disassembling the reservoir.

This section explains how to connect a new Ambulatory insulin infusion pump to the PDA or replace an old one.

1. From the Home Screen, Go to ☰ > Replace Pump and then enter the Replace Pump Wizard.

a) Remove the pump and reservoir from the pump base as shown in Figure 33. Remove the old infusion set, apply a new one, and press "NEXT" (Figure 32). The next page will prompt you to deactivate your old pump.

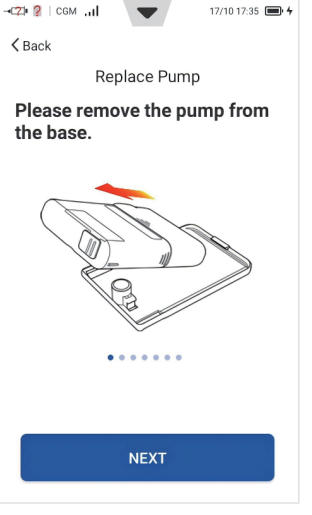
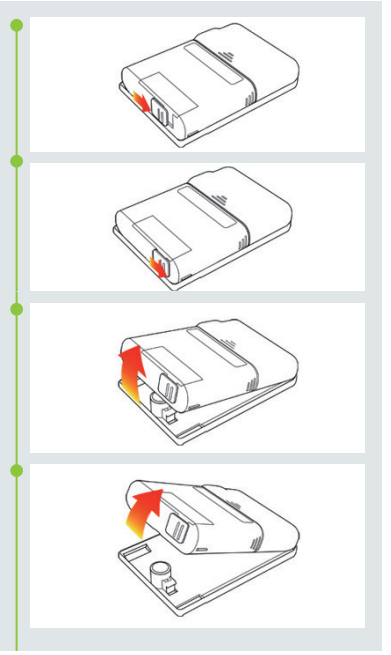


Figure 32



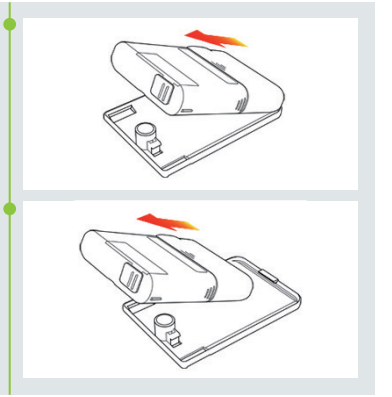


Figure 33

b) Press "REWIND" and a confirmation window will appear. Click "Yes" and wait for the pump to rewind.

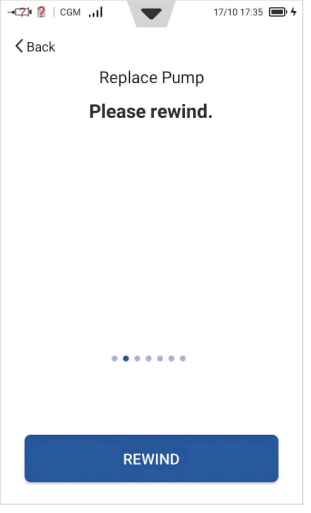


Figure 34

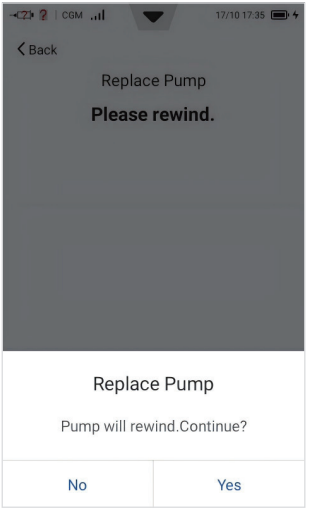


Figure 35

c) After pressing "NEXT", a confirmation window will appear, and then click "Yes".

Figure 36

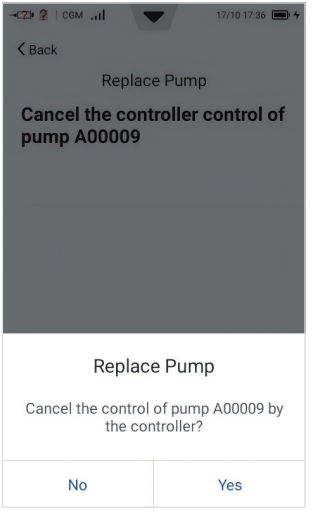


Figure 37

d) Press "OK" and separate the used reservoir from the pump, dispose of the old reservoir and then assemble a filled reservoir and a charged battery to the pump as shown in Figure 38 on the previous page.

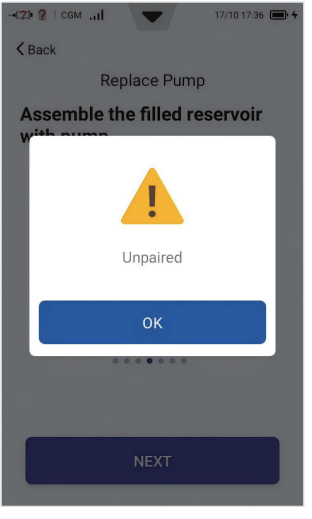
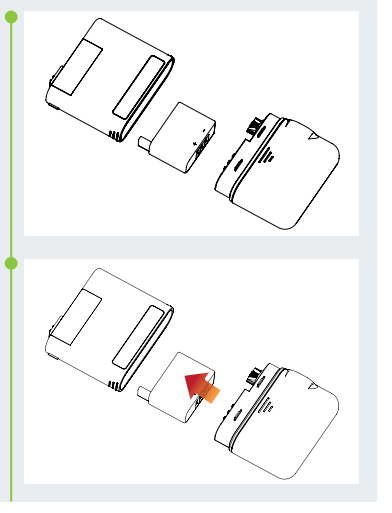


Figure 38

e) Assemble a filled reservoir and a charged battery to the pump as shown in Figure 39. Press "NEXT" to go to the next page.



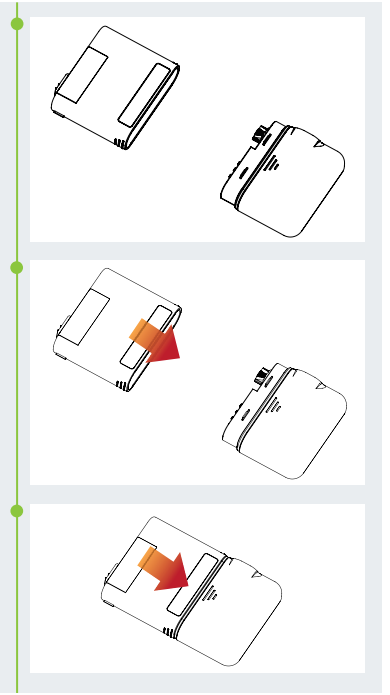


Figure 39

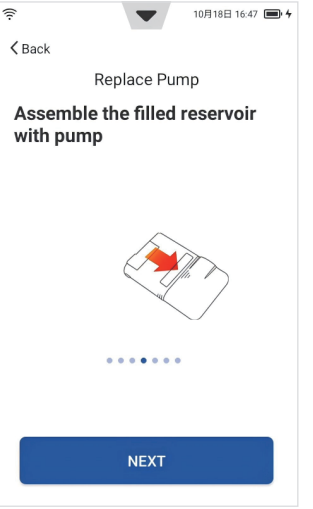


Figure 40

Note

Applied parts: Amubulatoy Insulin Infusion Pump.

Note

Be sure to use a fully charged battery. A low battery may require you to change reservoirs more frequently, resulting in wasted insulin.

2. Enter the New Pump Serial Number or scan the QR code on the pump, and then press "NEXT" in the space provided (Figure 41) using the onscreen keyboard. The PDA will attempt to connect to the new pump. After the new pump has been activated, the PDA will show a confirmation screen (Figure 43).

Figure 41

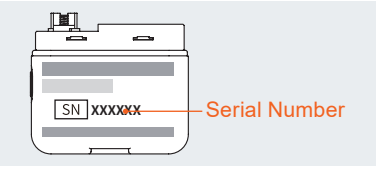


Figure 42

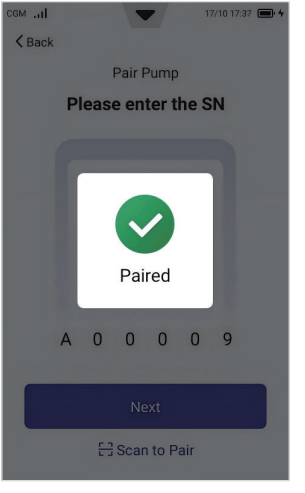


Figure 43

3. Holding the pump in the orientation shown in Figure 45, press "PRIME" button (Figure 44). The plunger will begin to move slowly. Continue to press the button until you see a drop of insulin on the needle tip (Figure 45). Now press "NEXT".

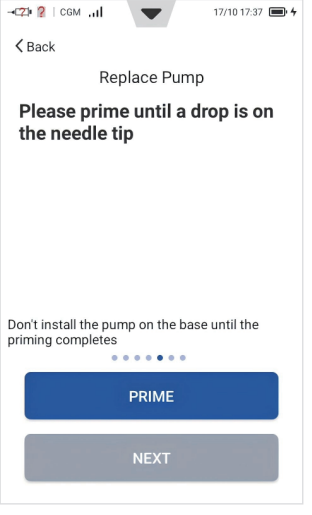


Figure 44

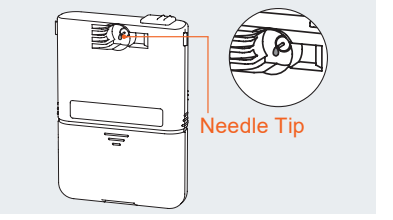
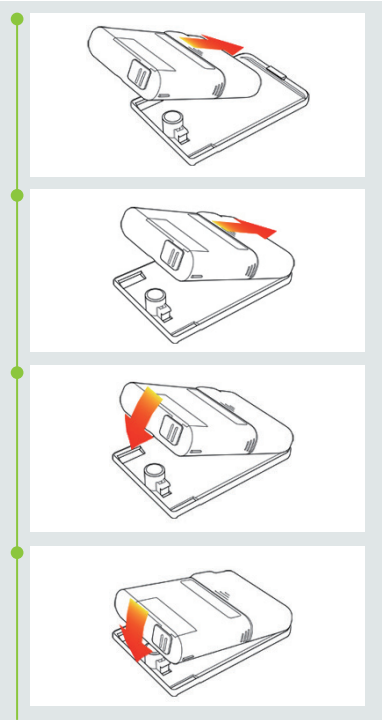


Figure 45

4. Connect the pump to the infusion set as shown in Figure 46 and press "NEXT".

Figure 46



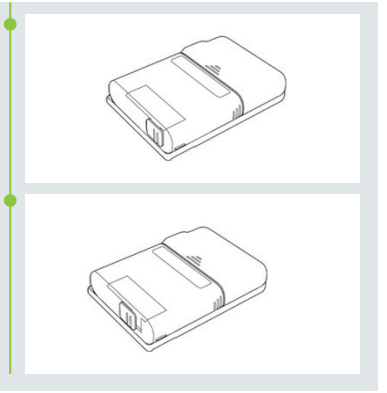


Figure 47

5. Now choose whether or not to prime the cannula (Figure 48). Upon completion, the pump will be ready to deliver.

Note

Skip only if the infusion set was not replaced (and thus the cannula doesn't need to be filled).

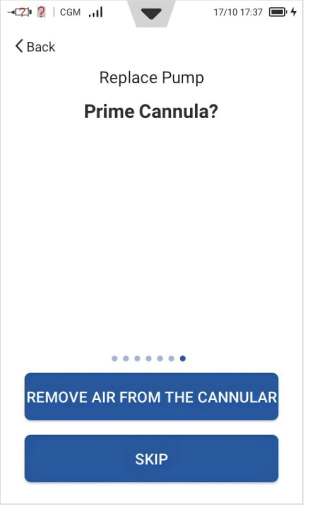


Figure 48

7 Replacing the Reservoir

7.1 Setup

Warning

Before continuing, please make sure you are familiar with frequently used pump setup operations such as installing/removing an infusion set, filling a new reservoir, and assembling/disassembling the reservoir.

If the insulin reservoir connected to your pump is empty, you should replace the reservoir.

1. From the Home Screen, Go to ☰ > Replace Reservoir and Battery, and then enter the Replace Reservoir and Battery Wizard. Remove the pump and reservoir from the infusion set as shown in Figure 49. Press "NEXT" and then click "REWIND". After clicking "Yes" in the confirmation window as shown in Figure 51, the pump will rewind. Before proceeding to the next step, you should prepare a new insulin reservoir.

Figure 49

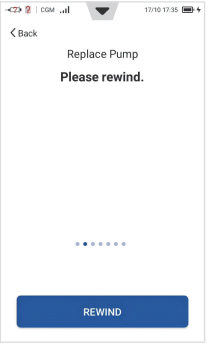


Figure 50

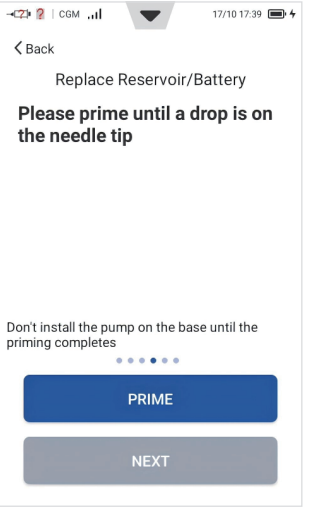
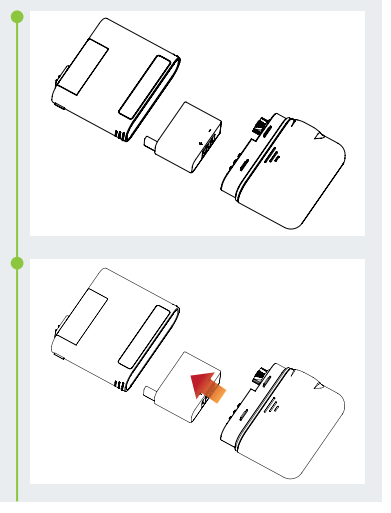


Figure 51

2. Separate the used reservoir from the pump, dispose of the old reservoir, and then assemble a filled reservoir and a charged battery to the pump as shown in Figure 52. Press "NEXT" to go to the next page.

Note

Be sure to use a fully charged battery. A low battery may require you to change reservoirs more frequently, resulting in wasted insulin.



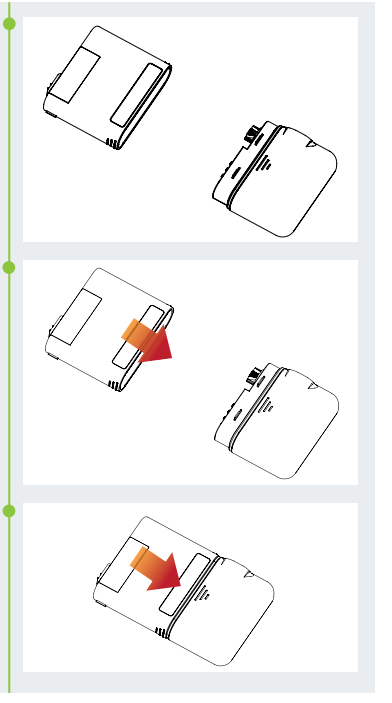


Figure 52

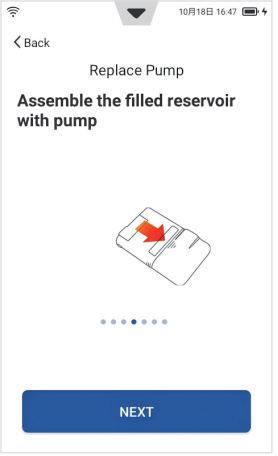


Figure 53

3. Holding the pump in the orientation shown in Figure 54, press “PRIME” (Figure 55). The plunger will begin to move slowly. Continue to press the button until a confirmation window appears as shown in Figure 56 and you see a drop of insulin on the needle tip (Figure 54). Press "OK" and the background of the "NEXT" button will be enabled when it changes from grey to blue. Press "NEXT" to go to the next step.

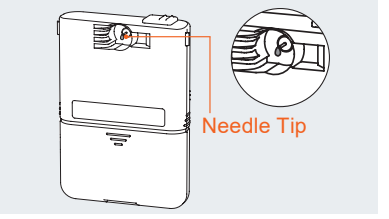


Figure 54

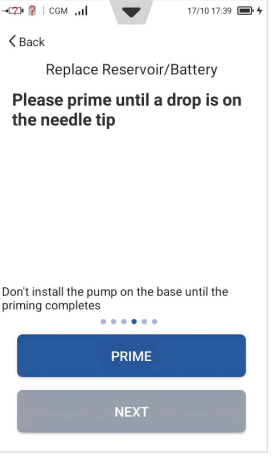


Figure 55

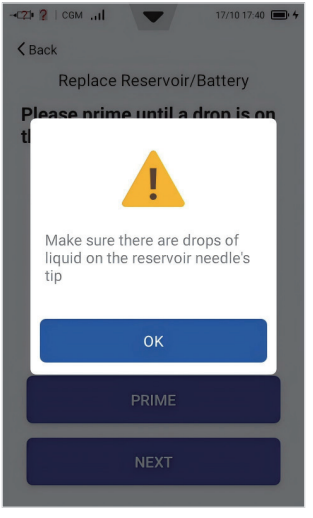
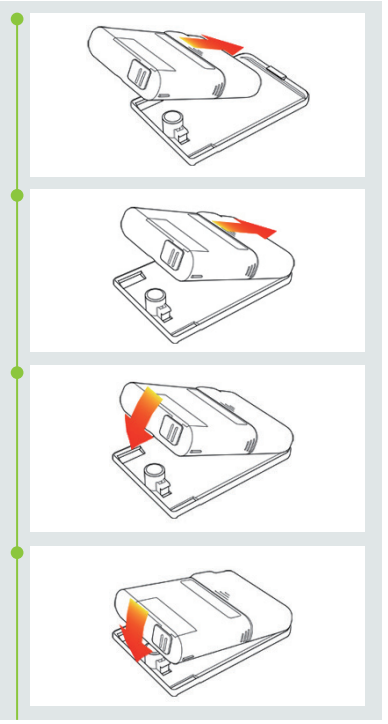


Figure 56

4. Connect the pump to the infusion set as shown in Figure 58 and press "NEXT".

Figure 57



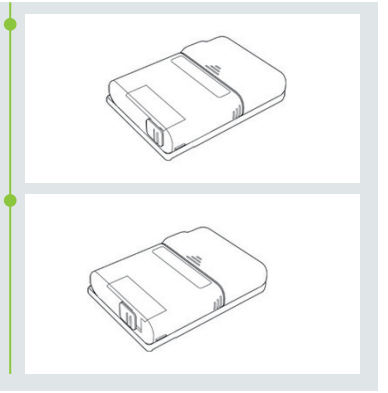


Figure 58

5. Now choose whether or not to prime the cannula (Figure 59). Upon completion, the pump will begin to deliver.

Note

Skip only if the infusion set was not replaced (and thus cannula doesn't need to be filled).

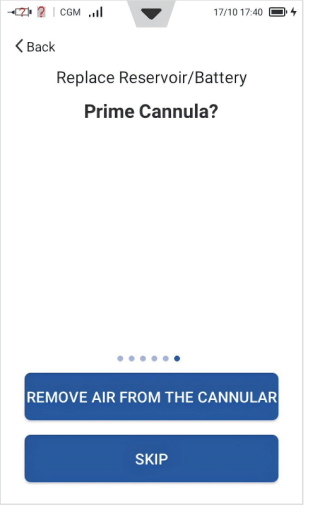


Figure 59

8 Settings Wizard

Turn on the PDA by pressing the power button. The first time you switch the PDA on, you will see the Settings Wizard which will guide you through basic setup options.

8.1 Pair Pump

The first step after turning on the PDA is to pair the pump. Please enter your pump SN or scan the QR code shown in Figure 60.

Figure 60

8.2 Date and Time Settings

The second screen in the Settings Wizard shows the date and time settings (Figure 61).

Note

If 24-Hour Format is checked, the time and history data will be displayed in 24hour format.

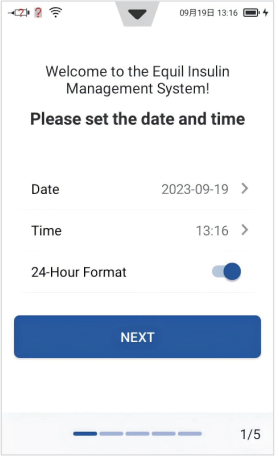


Figure 61

8.3 Basal Settings

The third screen in the Settings Wizard shows the Basal Settings (Figure 62).

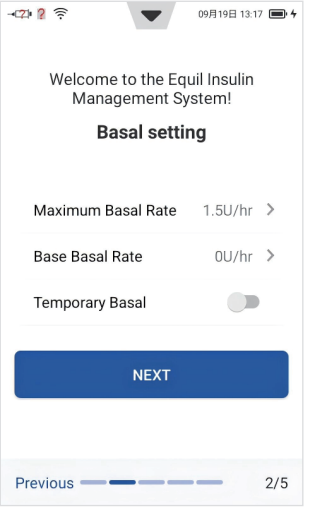


Figure 62

Note

For a more detailed description of basal rates, see Section 10.

a) Choose the Maximum Basal Rate to open a dialog box (Figure 63) that can be used to input the maximum basal rate.

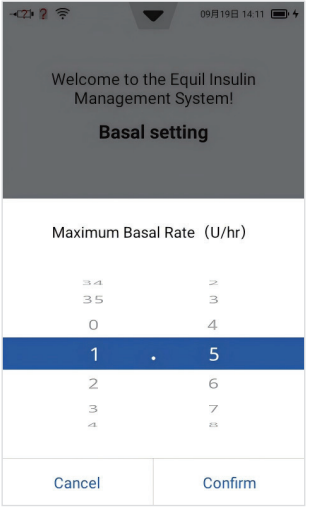


Figure 63

Note

This feature is used to limit the maximum amount of basal delivery that can be administered by accident or misoperation.

b) Choose the Base Basal Rate to open a dialog box (Figure 64) that can be used to input your base basal rate.

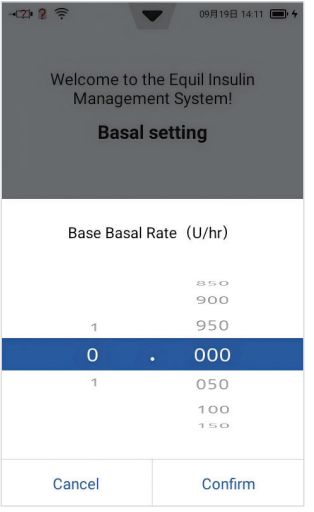


Figure 64

Note

This value is the most frequently used basal rate, and all other rates will be calculated based on this base rate.

c) Temporary Basal can be activated or inactivated (Figure 65).

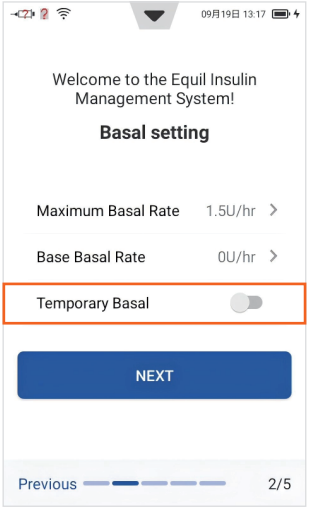


Figure 65

After you have finished choosing the Basal settings, choose NEXT to enter the fourth Settings Wizard screen, or Previous to enter the previous setting screen.

8.4 Bolus Settings

The fourth screen in the Settings Wizard shows the Bolus settings (Figure 66).

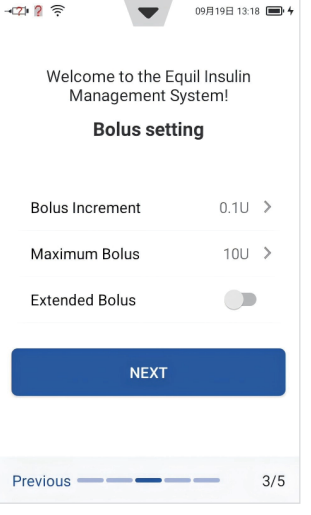


Figure 66

Note

For a more detailed description of boluses, see Section 11.

a) The Bolus Increment setting (Figure 67) allows you to set the interval used when increasing or decreasing bolus amounts.

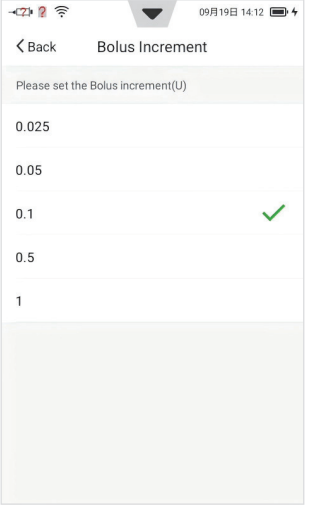


Figure 67

b) The Maximum Bolus allows you to set an upper limit on the amount of insulin given in a single bolus (Figure 68).

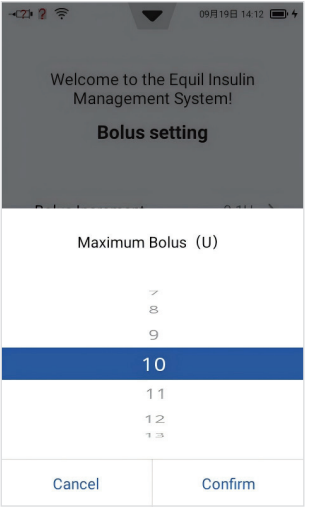


Figure 68

Note

This feature is used to limit the maximum amount of bolus delivery that can be administered by accident or misoperation.

c) Extended Bolus can be activated or inactivated (Figure 69).

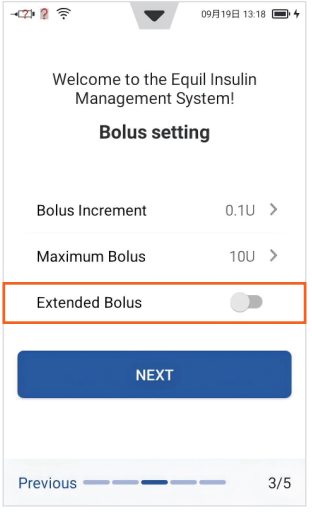


Figure 69

After you have finished choosing the Bolus setting, choose NEXT to enter the fifth Settings Wizard screen, or Previous to enter the previous setting screen.

8.5 Advanced Bolus

The fifth screen in the Settings Wizard shows the Advanced Bolus Settings (Figure 70).

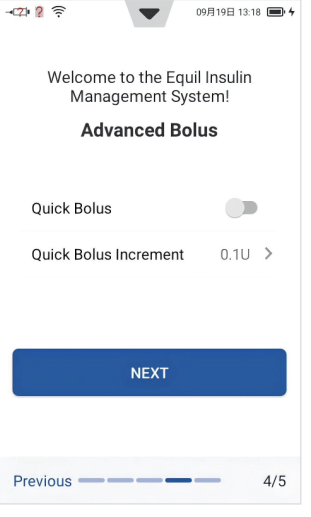


Figure 70

a) The Quick Bolus function allows the user

to administer a bolus using only one button. For more detailed information about this feature, see Section 11.4.

b) The Quick Bolus Increment allows you to set the interval used when increasing or decreasing bolus amounts.

Note

These two features are relatively advanced and MicroTech recommends proper training and practice before using these features.

After you have finished choosing the Advanced Bolus settings, choose NEXT to enter the sixth Settings Wizard screen, or Previous to enter the previous setting screen.

8.6 Alert Settings

The sixth screen in the Settings Wizard shows the Alert Settings (Figure 71).

Note

The operator accesses the operator alarm system log through the history interface. When the alarm system loses power, all alarm information will be saved, but the time and duration of the power loss are not recorded in the log.
After the alarm system experiences a complete power loss (main power and/ or internal power) and a limited period of time, the log content will not change.

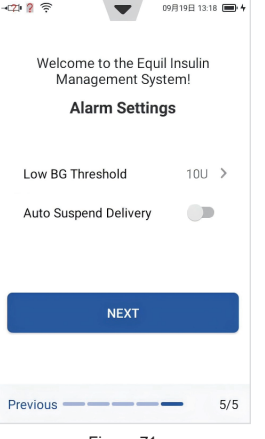


Figure 71

a) Low BG Threshold allows the device to give you an alert warning when your blood glucose level is low.

b) Auto Suspend Delivery can be enabled by clicking the grey button.

After you have completed the Settings Wizard, choose NEXT to finalize your settings and return to the Home Screen. To continue modifying settings on previous screens, choose Previous.

Note

After you complete the Settings Wizard, you can use all of the basic functions of the pump system. However, please read the additional sections of this user guide as they describe the features in greater detail.

9 Home Screen

Notification and Status Icons

Menu bar	
Pull-down Menu	
Remaining Insulin	
CGM Paired	CGM
4G Network Connected	
Settings	
Pump Battery Level	
PDA Battery Level	
PDA Charging	
Wi-Fi Network Connected	

9.1 Display Mode

Home screen has two display modes, including Pump mode and CGM mode.

On your PDA, go to Settings > General Settings > Display mode, and choose Pump mode or CGM mode.

CGM mode is shown in the following figure.

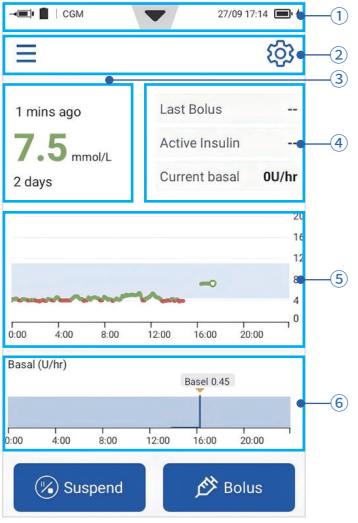


Figure 72

- ①: Status Bar
- ②: Menu Bar and Settings
- ③: CGM Information Display Area
- ④: Pump Information Display
- ⑤: Sensor Glucose Chart Area
- ⑥: Infusion Chart Area

Pump mode is shown in the following figure.

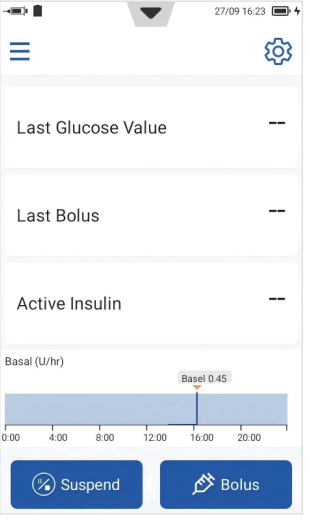


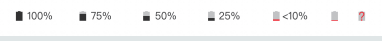
Figure 73

9.2 Status Bar

The Status Bar contains icons that describe the status of the pump, PDA and CGM. The icons shown on the left are generally related to the pump and CGM, and the icons on the right are generally related to the PDA. Each icon in the Status Bar is described below:

Insulin Remaining: This shows how much insulin remains by varying degrees; if PDA wireless link is poor it displays .

Pump Battery Level: Shows the pump battery level status in varying degrees; if PDA wireless link is poor, it displays .



PDA Battery Level: This shows the PDA battery level status in varying degrees. If the PDA is charging, it displays .

Press the button at the middle of the Status Bar and it will enlarge as in Figure 74.

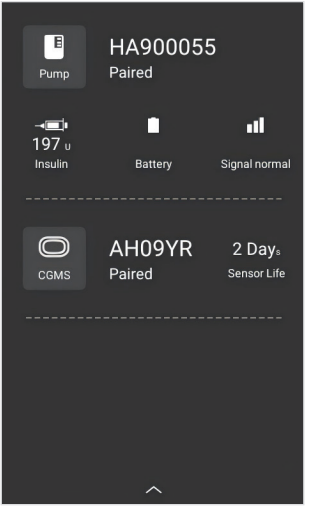


Figure 74

9.3 Unlock Screen

Unlock the device by swiping from left to right in this area.

Note

If your PDA remains inactive for a while, it will automatically lock the screen to save power.

Figure 75

9.4 Unlock the Screen with Password

For security, choose “Password Unlock" to force the user to enter a password during power-on and wake up.

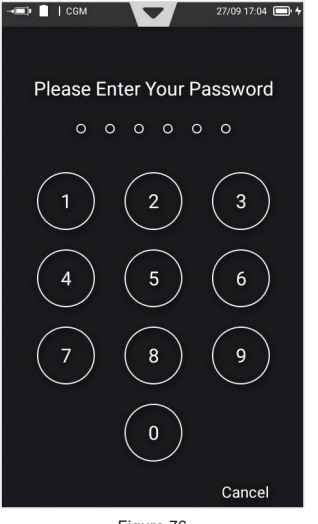


Figure 76

Go to Settings > General Settings > User, click “Edit”, then type your password. The password must be 6 characters, which can be any combination from the number "0-9".

Note

Once the factory settings have been restored, all saved settings will be lost (except for time). Please make a note of all important settings before restoring factory settings.

9.5 Menu Bar

The menu bar contains all common functions, and the various functions included will be described in detail in subsequent chapters. Click ☰ on the home screen to pop up the menu bar, as shown in Figure 77.

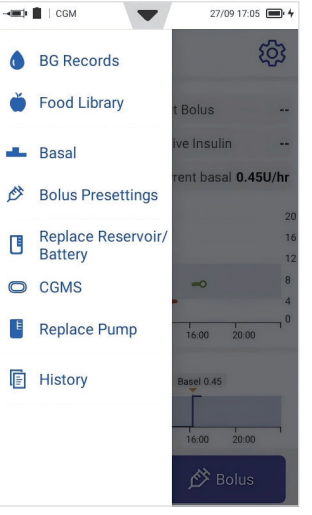


Figure 77

10 Base Basal Rate Adjustment

10.1 Basal Rate Adjustment

We have already set up the base basal rate which is the default basal rate for your basal programs. If you need to set up Basal Rate, Go to ☰ > Basal > Change Settings. In this screen, the name, daily infusion volume and segments can be edited. After setting, PDA will automatically assign segment and basal per segment.

- **Edit Segment:** Go to ☰ > Basal > Change Settings > ✎.
- **Delete Segment:** Go to ☰ > Basal > Change Settings > ✕, and the deleted segment will automatically revert to the base basal rate.
- **Save:** Click “Save” after finishing all basal settings.
- **Add new basal rate:** Go to ☰ > Basal > ⊕. (You can add up to 8 settings.)

Note

After deleting a basal period, the PDA may merge adjacent basal segments if the basal rates are the same.

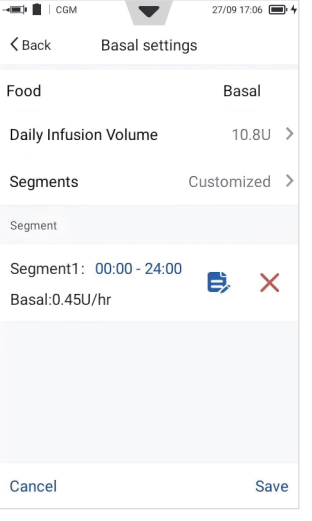


Figure 78

10.2 Activating a Basal Program

There are three default Basal programs and activating a new basal program will stop any programs that were previously running.

- **Select basal:** Click Basal name, as shown in Figure 79.
- **Activate basal:** Click Activate Basal.

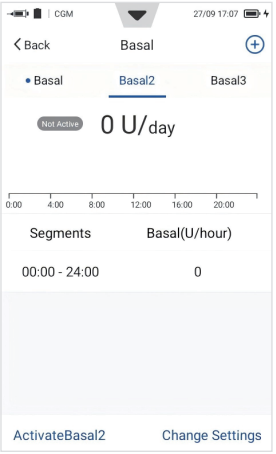


Figure 79

10.3 Temporary Basal Rate

Your basal insulin requirements might change during periods of exercise, sick days and traveling. Climate changes, hormonal changes, menstruation medication, alcohol and certain foods might also require an adjustment to the basal insulin rate. Your healthcare professional will be able to advise you on when and how to set a temporary basal rate.

Normally, your basal rate does not require frequent changes, but in certain circumstances, you may want to temporarily administer a different basal rate to avoid low or high blood glucose levels.

Go to ☰ > Temporary Basal, enter the temporary basal rate and segment, and then click “Activate”, as shown in Figure 80. After activation, the home screen will display the running status of the current temporary basal rate. (If there is no “Temporary Basal” in the ☰, please go to ⚙ > Insulin Delivery Settings, and then turn on “Temporary Basal”.)

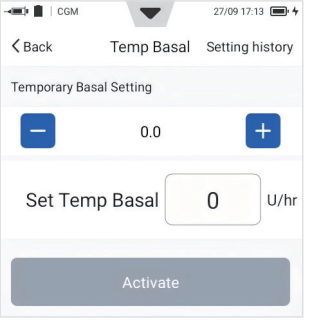


Figure 80

10.4 Basal Infusion Suspend

Click “Suspend” on the home screen to temporarily stop insulin delivery, as shown in Figure 81.

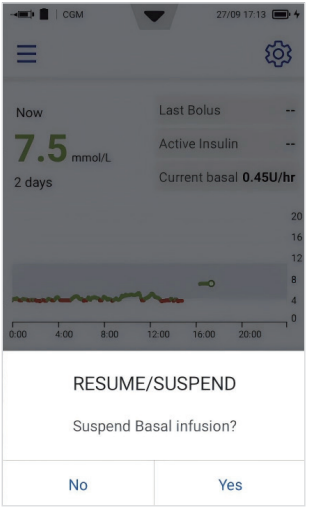


Figure 81

10.5 Basal Infusion Resume

The home screen will display the paused time after stopping the insulin delivery, as shown in Figure 82. You can click “Resume” to resume the insulin delivery.

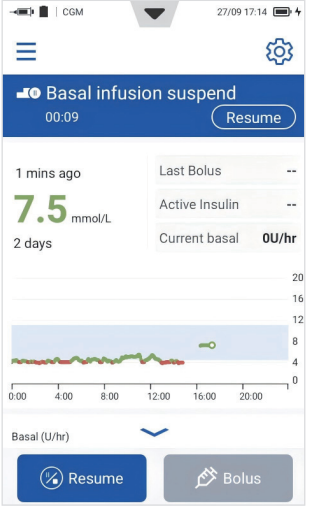


Figure 82

11 Bolus

11.1 Start Bolus

Click “Bolus” on the home screen, as shown in Figure 83. You can enter the bolus value or select preset bolus, and then click “START” to activate bolus delivery.

Note

Before the bolus delivery, the previous bolus delivery (time and infusion volume) will be displayed in a dialog box to prevent you from repeating the delivery due to forgetting or other reasons. Please carefully confirm and choose whether to start bolus.

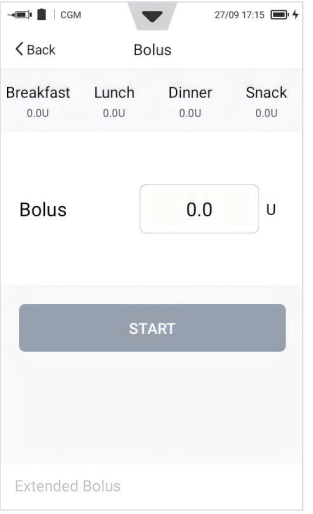


Figure 83

11.2 Suspend Bolus

The home screen displays the rate of progress for infusing before finishing the bolus delivery, as shown in Figure 84.

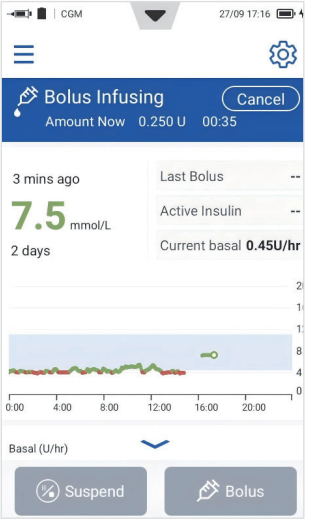


Figure 84

You can click “cancel” and confirm in the dialog box to cancel the bolus infusing.

11.3 Extended Boluses

An Extended Bolus can be useful when you eat meals with both rapidly and slowly absorbed carbohydrates including meals with a high fat content such as some fast foods.

After entering bolus, click “Extended Bolus”, and then enter amount now, extend amount and extend time. Finally, click “OK” to start delivery, as shown in Figure 85.

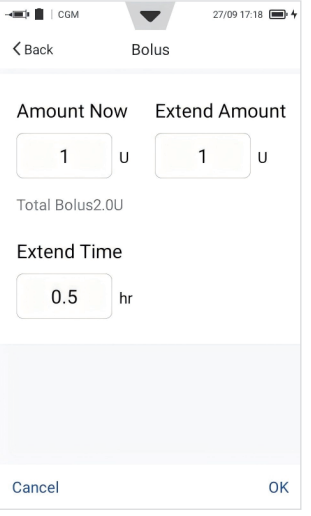


Figure 85

Note

This feature requires a detailed understanding of one's carbohydrate absorption rate. Please consult with your professional healthcare provider before using this feature.

Note

By default, the Extend Bolus function is off.

11.4 Quick Bolus

The Quick Bolus feature allows the user to administer a bolus without using the touchscreen or looking at the PDA Display. This feature can be handy if you forget your PDA, or would like to administer a bolus discretely.

1. Press and hold the Bolus button for three seconds on the Ambulatory insulin infusion pump. The pump will give an audible alert which indicates that you can enter a quick bolus amount.
2. With each subsequent button press, the tone will ascend in pitch (up to 5, and then repeat) to help you remember the number of times you have pressed the button.

Note

If there is no activity for 10 seconds, the PDA will revert to the Lock Screen.

3. After you have set the correct bolus amount, wait for 3 seconds and the pump will repeat the audible tones back for you to confirm the correct number of bolus increments. If the number of tones is correct, press the pump button one last time, and the bolus will be administered.

Note

By default, the Quick Bolus function is off. To enable, be sure to activate the function using the settings menu.

Note

When an audible alert is issued, the pump vibrates.

11.5 Bolus Calculator

The PDA contains a bolus calculator that can suggest a bolus size based on your input. Once the settings are configured properly, the bolus calculator can make a bolus size suggestion after you test your blood glucose level and enter the amount of carbohydrates that you will be eating. The bolus calculator

can also take into account the amount of insulin that is currently being used in your body and make corrections to the suggested bolus size.

The Bolus Calculator requires the following information:

(1) Current blood glucose level

(2) Target blood glucose level (user setting-confirmed by your healthcare professional)

(3) Carbohydrate ratio (confirmed by your healthcare professional)

(4) Carbohydrate intake (user input)

(5) Insulin sensitivity factor (confirmed by your healthcare professional.)

(6) Negative/Reverse correction (user setting-confirmed by your healthcare professional)

(7) Active insulin time (confirmed by your healthcare professional.

The Bolus Calculator suggestion is calculated as follows:

Bolus Suggestion =

Meal Bolus + (Correction Bolus – Active Insulin)

Note

If Correction Bolus < Active Insulin, Correction Bolus - Active Insulin= 0

Meal bolus is used to compensate for increased blood sugars due to eating:

$$\text{Meal Bolus (U)} = \frac{\text{Carb Intake (g)}}{\text{Carb Ratio}}$$

Correction Bolus is used to bring your current BG level to the target BG level:

$$\text{Correction Bolus (U)} = \frac{\text{Current BG Level-Target BG Level (mmol/L)}}{\text{Insulin Sensitivity Factor (mmol/L/U)}}$$

Active Insulin: Insulin is normally absorbed in the body within about 4-6 hours. If you have recently taken a bolus there could still be active insulin in your body. The Bolus Calculator automatically subtracts the

amount of active insulin based on your last bolus and the Active Insulin Time you enter in the settings.

Note

The Bolus Calculator is disabled by default. Please enable this feature in the Settings menu.

Note

For pediatric and caregiver use: The bolus calculator should be used with caution in pediatric patients due to varying insulin sensitivity and smaller dose requirements. All settings (carb ratio, insulin sensitivity factor, active insulin time) must be reviewed and approved by a healthcare professional. Caregivers should double-check calculations before administering bolus doses.

11.5.1 Using the Bolus Calculator

After turning on the Bolus Calculator in Bolus Calculator Settings, Click “Bolus Calculator” at the bottom right of the page, as shown in Figure 86.

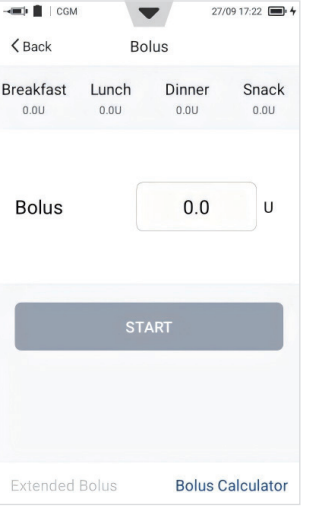


Figure 86

1. If a continuous glucose monitoring product has been paired, it will be asked whether to conduct bolus calculator based on the current glucose value, as shown in Figure 87. Select "Yes" to enter step 2, and "No" to edit the finger-stick blood glucose value.

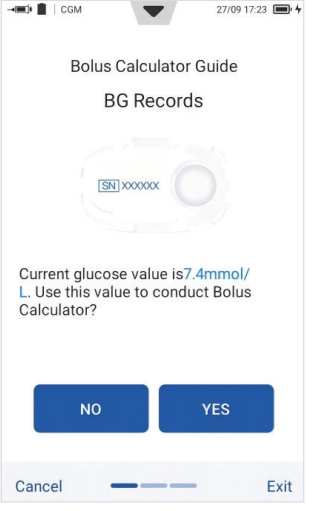


Figure 87

2. In this step, the calculator will ask if you will be eating now (Figure 88). Choosing "No" will only calculate the Correction Bolus, proceed to step 4, and choosing "Yes" will proceed to step 3.

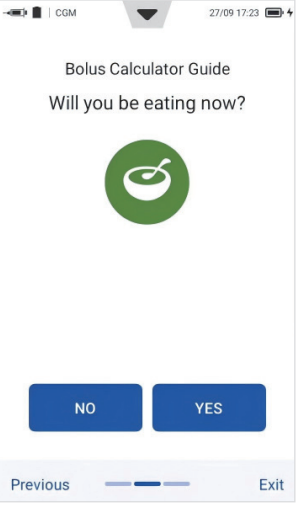


Figure 88

3. Enter your Carbohydrate intake and click "√" as shown in Figure 89.

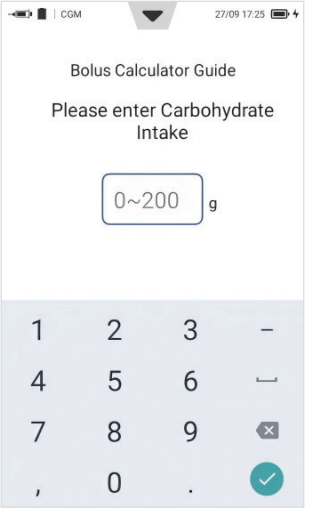


Figure 89

4. Finally, the recommended bolus will be displayed (Figure 90). Click "USE THIS BOLUS" will redirect you to the bolus infusion interface and you can still manually adjust the bolus value.

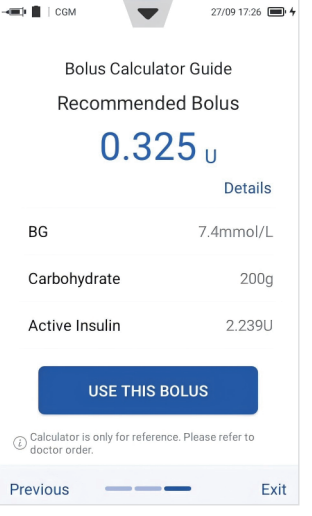


Figure 90

Note

The Bolus Calculator calculates a suggested bolus value. Please discuss this with your healthcare professional before using this function.

Note

Your blood glucose reading is only valid for 10 minutes. If you do not issue a bolus within 10 minutes of your test, please test again to calculate a new bolus value.

Note

Carbohydrate Ratio is defined as the amount of carbohydrates that can be broken down per unit of insulin and is used to calculate the meal boluses. Since everyone has a different metabolism, set this value under the guidance of your healthcare professional.

Note

If the recommended bolus value exceeds the maximum bolus value, the system will choose the maximum bolus value automatically.

11.5.2 Bolus Calculator Settings

Go to > Bolus Calculator Settings, as shown in Figure 91.

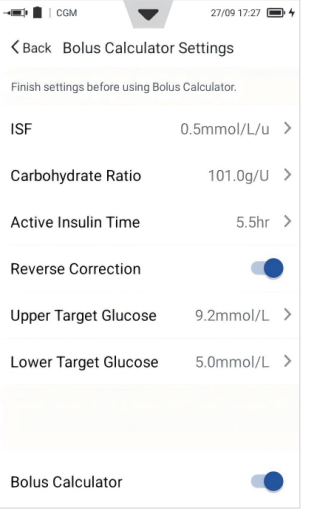


Figure 91

Note

The bolus calculator can only be enabled after all parameters are set. The accuracy of bolus calculator depends on the setting parameters. Please discuss this with your healthcare professional before using this function.

11.5.3 Bolus Presettings

Go to ☰ > Bolus Presettings, as shown in Figure 92. The Bolus Screen contains four preset boluses.

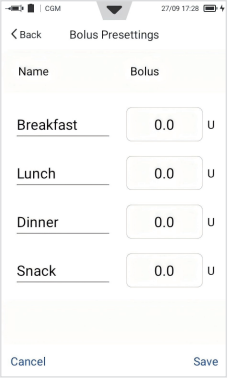


Figure 92

12 Continuous Glucose Monitoring

Note

- Continuous Glucose Monitoring Sensor are Sterilized using radiation. Do not use if sensor package is broken.
- This insulin pump system and the CGMS are not a closed-loop system.

12.1 Pairing

If the CGMS is not paired, "unpaired" will be displayed, as shown in Figure 93. Click “Go to pairing” or go to ☰ > CGMS, and then complete the pairing.

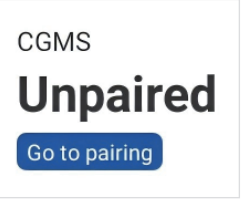


Figure 93

Input the SN (Serial Number) code manually or scan the QR code on the CGMS package. When you have successfully paired the CGMS, the countdown of warm-up will be displayed. The real-time SG data will be displayed after the countdown ends (Figure 94).

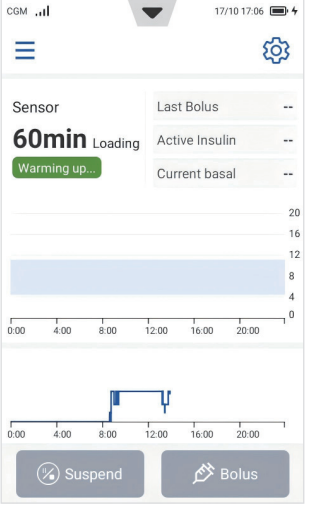


Figure 94

12.2 Alert Settings

Go to > Alert Settings

- Pattern
- Pump Signal Loss
- High/Low Glucose Alert
- High/Low Alert Threshold
- High/Low Alert Setting
- Glucose Rising/Falling Fast
- Pump Signal Loss
- No Signal Alert
- Sensor Life Reminder

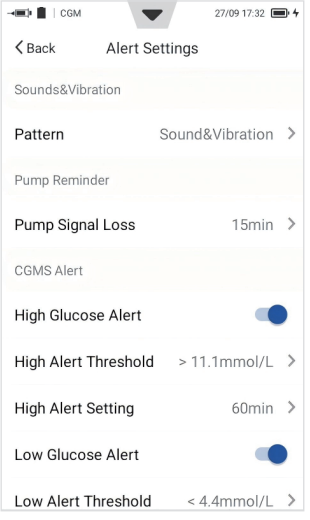


Figure 95

12.3 Device Information

Go to ☰ > CGMS, and then view CGMS's serial number, sensor life and software version (Figure 96). If you want to unpair CGM, choose "Unpair" or "Delete".

Note

CGM is not allowed to pair with other devices after choosing "Delete".

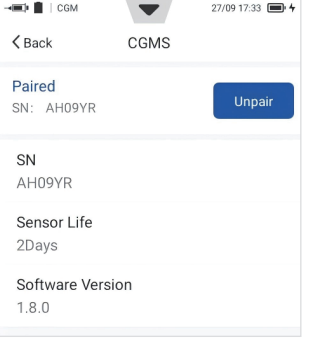


Figure 96

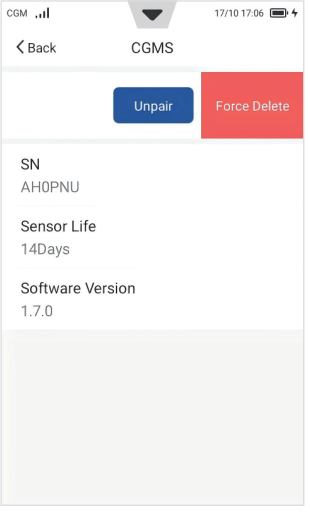


Figure 97

13 Upload data to Pancares

Expand the side menu bar on the main interface and click the "Pancares" function (Figure 98). Enter the Pancares account and password, and tick the privacy agreement to log in to this function (Figure 99). After successful login, you can see your Pancares account shown on the page(Figure 100). On this page, you can manually or automatically upload data to Pancares .

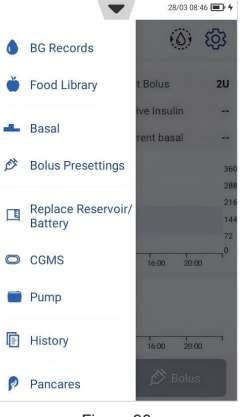


Figure 98

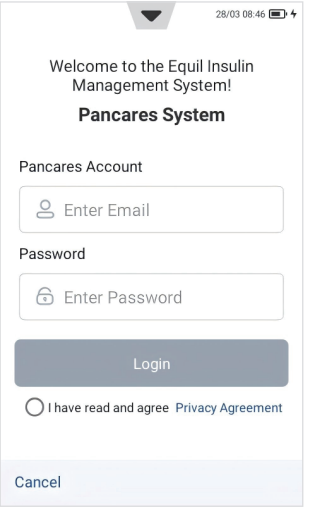


Figure 99

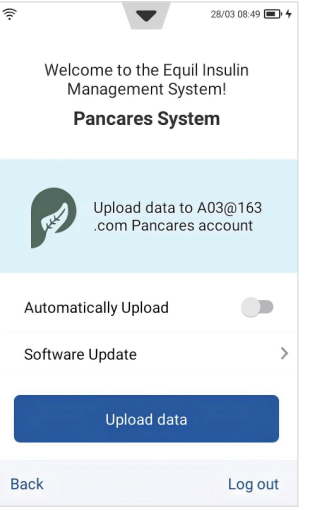


Figure 100

Manually upload: Click the "Upload date" button. When the prompt "Success!" appears, it means the upload is successful.

Automatically upload: Click to turn on "Automatically Upload", and the PDA will

automatically upload the operation data once every five minutes.

Note

The Pancares function needs to be used when the network (Wi-Fi) is available.

14 Others

14.1 BG Records

BG Records is used to record your finger-stick blood glucose results, which can be used for data analysis or bolus calculator.

Go to ☰ > BG Records, slide the ruler to enter your BG value, and then click “RECORD” to save your results in history (Figure 101).

Note

When the deviation range between the blood glucose value you entered and the blood glucose value monitored by the CGMS is greater than 20% and the new sensor warms up for 6 hours or more, a confirmation window will prompt the user whether to optimize.

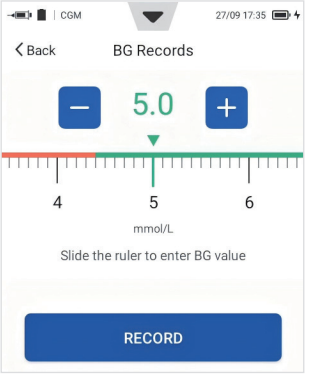


Figure 101

14.2 History

14.2.1 Daily Details

Note

Users can set a password to restrict access, and the storage will not be altered.
During its lifespan, the log capacity will not reach its limit.

Go to ☰ > History.

In Daily Details, you can browse your historical records and view insulin delivery graphs and other statistics. Pressing the can select the date or press the button ◀ ▶ to scroll to the previous or next day. If you click the graph, daily information will be displayed in a Graph, including glucose value, basal rate, bolus and other data (Figure 102).

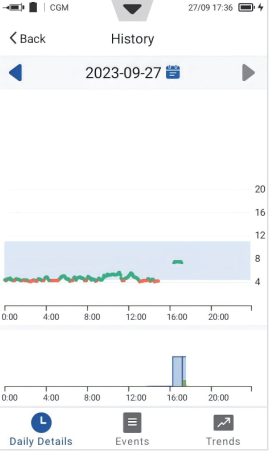


Figure 102

14.2.2 Events

In Events, you can view the average BG, carbohydrate intake, the amount of injected insulin and bolus, as well as alerts, reminders, user actions, and other events on a certain day. Pressing the can select the date or press the button to scroll to the previous or next day.

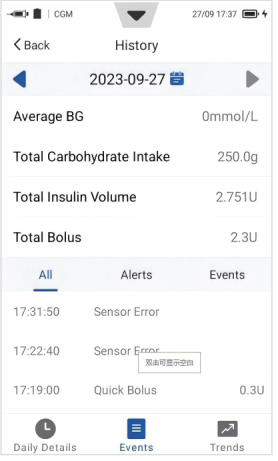


Figure 103

14.2.3 Trends

As shown in Figure 104, Trends is divided into four parts from top to bottom:

- Select a date range
- Display estimated HbA1c and MGB
- Display TIR over a period of time
- Display the average daily insulin infusion volume and the proportion of bolus

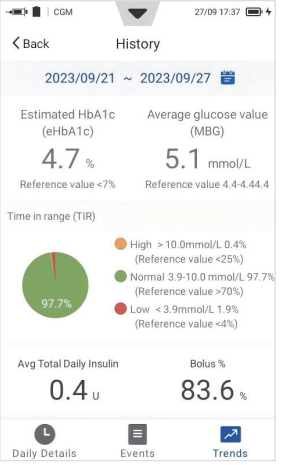


Figure 104

14.3 Food Library

The food library is an extra function that can provide carbohydrate content data for various foods. Go to ☰ > Food Library, and you can search for carbohydrate content data for various foods or manually add, edit, or delete food data in Figure 105.

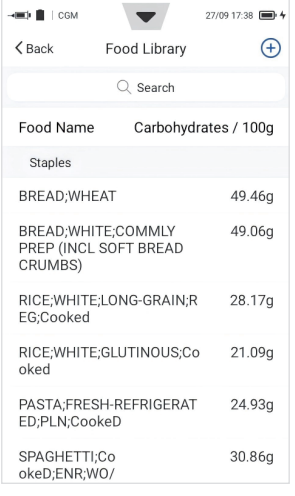


Figure 105

14.4 Replace Reservoir

Go to ☰ > Replace Reservoir/Battery, remove the pump and reservoir from the infusion set as shown in Figure 106, and then click “NEXT”.

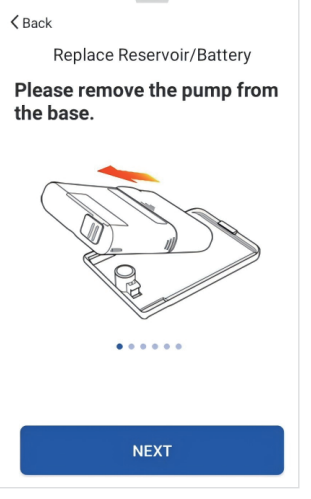


Figure 106

Press “Rewind” and the pump will rewind in Figure 107.

Note

Before proceeding to the next step, you should remove and replace the infusion set and prepare a new insulin reservoir.

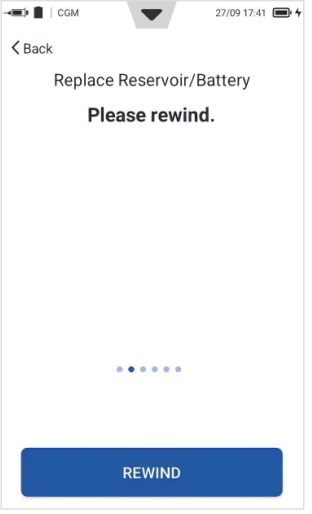


Figure 107

Separate the used reservoir from the pump, dispose of the old reservoir, and then assemble a filled reservoir and a charged battery to the pump as shown in Figure 108. Press “NEXT” to go to the next page.

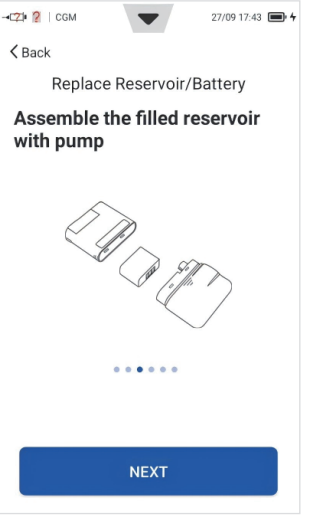


Figure 108

Holding the pump in the orientation shown in Figure 109, press the “Prime” button. The plunger will begin to move slowly. Continue to press the button until you see a drop of insulin on the needle tip. The background of the "NEXT" button will be enabled and press “NEXT” to go to the next step.

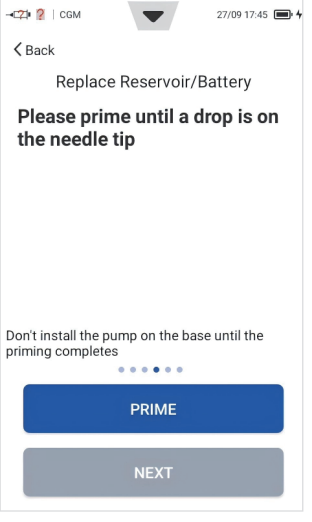


Figure 109

Connect the pump to the infusion set as shown in Figure 110 and press “NEXT”.

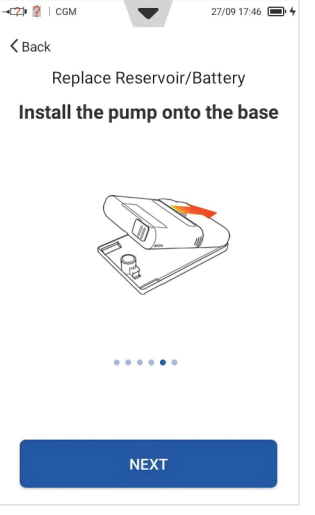


Figure 110

Now choose whether or not to prime the cannula (Figure 111). Skip only if the infusion set was not replaced (and thus cannula doesn't need to be filled). Upon completion, the pump will begin to deliver.

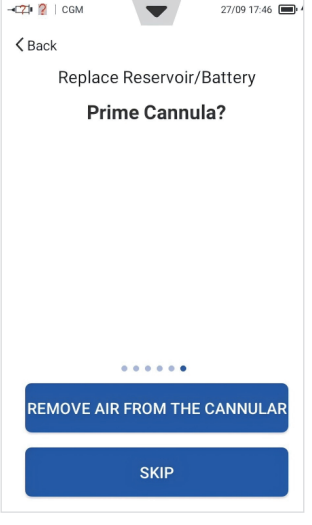
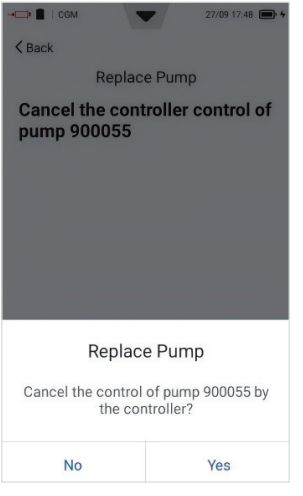


Figure 111

14.5 Replace Pump

Go to ☰ > Replace Pump. Its steps are similar to replacing the reservoir, but the difference is that it provides the reminder of pairing and unpairing the pump, as shown in Figure 112.



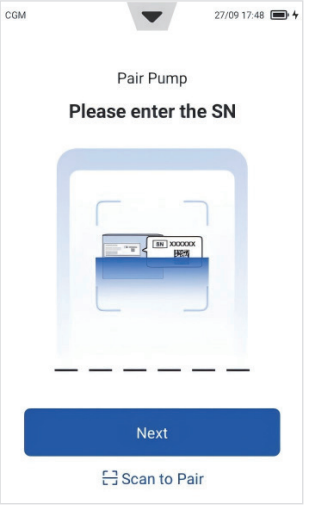


Figure 112

14.6 Auto Suspend Delivery

Go to > Insulin Delivery Settings, and then turn on “Auto Suspend Delivery” in Other Settings.

After Auto Suspend Delivery has been activated, if the user doesn’t operate the PDA and pump within the set time, the pump will stop infusion and issue an alert.

15 General Settings

Go to > General Settings.

15.1 User

Go to > General Settings > User. Username, Password Unlock and Contacts can be edited as shown in Figure 113.

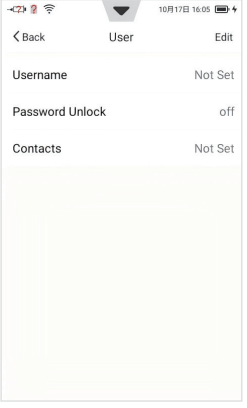


Figure 113

15.2 Date and time

Go to > General Settings > Date and time.

Note

Modifying the date and time will directly affect the accuracy of basal infusion and history records. The date and time can only be modified after all infusions have been stopped.

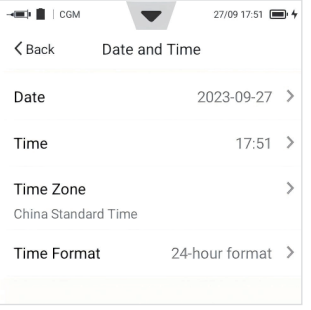


Figure 114

15.3 Language

Click “Language” to set up the PDA language.

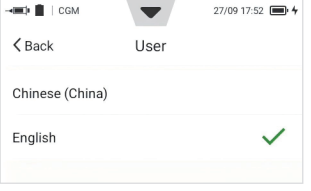


Figure 115

15.4 Screen

Go to > General Settings > Auto-Brightness, then drag the slider. If Auto-Brightness is on, PDA adjusts the screen brightness for current light conditions. You can also adjust the brightness in the Control Center.

Click “Screen Timeout” to select screen timeout.

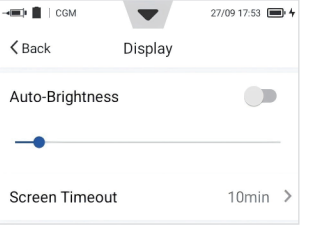


Figure 116

15.5 Display Mode

Display mode provides two modes, including Pump mode and CGMS mode.

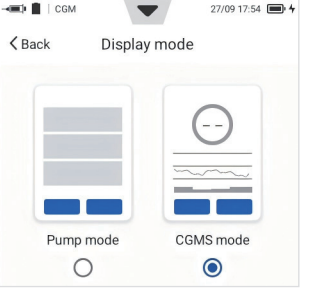


Figure 117

15.6 About the System

From General Settings, choose “About the System”.

- **Model:** Shows the model of the PDA
- **Software version:** Shows the software version of PDA
- **PDA SN:** Shows the serial number of the PDA.
- **Paired Pump SN:** Shows the serial number of the pump that is currently being controlled by the PDA.
- **Pump Software version:** Shows the software version of the paired pump.
- **Pump Shutdown**

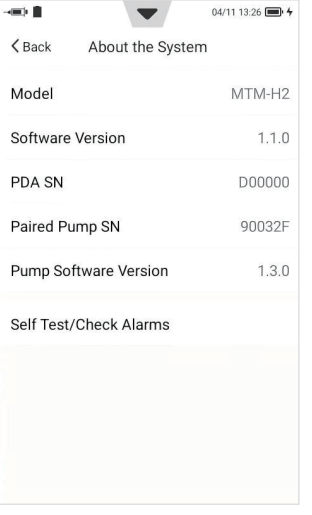


Figure 118

15.7 Factory Data Reset

Factory Data Reset: All settings reset to the factory defaults.

Note

Once the factory settings have been restored, all saved settings will be lost except for time. Please make a note of all important settings before restoring factory settings.

Note

Before resetting to the factory defaults, a reminder that the pump will be unpaired is issued by the PDA.

15.8 Network Setting

The network is used to upload data.

16 Alarms and Troubleshooting

Note

The operator accesses the operator alarm system log through the history interface. Additional guidance for caregivers:

- Familiarize yourself with all alarm types and responses.
- Keep the emergency kit accessible at all times.
- Have a written action plan for pump failure, occlusion, or loss of communication.
- Practice regular alarm drills to ensure timely response.

Alarm type: Technical Alarm Conditions

The patch insulin pump system has a comprehensive safety system to check if abnormal situations require immediate attention. The system will send notification alarms using sound, LEDs, or vibrations as well as provide information on the PDA display.

The patch insulin pump system contains two parts – the Ambulatory insulin infusion pump

detects and sends the alarms, and the PDA receives the alarms and notifies the user.

The patch insulin pump system contains highpriority alarms and low-priority alarms (as defined by ISO standards).

High priority alarms occur when the delivery function has stopped due to technical failure, requiring the user to intervene in the operation of the pump,change of the pump, or possibly injecting insulin manually to control BG levels.

Low priority alarms alert the user that something will occur in a short period of time but insulin delivery continues normally. Users should be aware of this information and make plans in advance to ensure that treatment continues reliably.

PDA Alarm Priority Levels

Alarm Level	Visual Signal	Audio Signal	Vibration Signal
High Priority	Flashing Red Light	Yes	Yes
Low Priority	Steady Yellow Light	Yes	Yes

Ambulatory Insulin Infusion Pump Alarm Priority Levels

Alarm Level	Visual Signal	Audio Signal	Vibration Signal
High Priority	Flashing Red Light	None	Yes
Low Priority	Steady Yellow Light	None	Yes

Audio Alarm Volume

Device	Sound Pressure Level(dB)	Measurement radius (meter)
Ambulatory insulin infusion pump	None	None
PDA	60-90	1

16.1 Patch Pump Alarms

Alarm Description	Priority Level	Alarm Signal	Solution/Action
Out of insulin Delivery stopped!!!	High	Light, Vibration	There is no more insulin and delivery has stopped. The pump will automatically rewind. Replace the reservoir and check your blood glucose level.
Occlusion detected Delivery stopped!!!	High	Light, Vibration	Insulin delivery has stopped.Replace the reservoir/infusion set and check your blood glucose level.
Unexpected Delivery stop!!!	High	Light, Vibration	Insulin delivery has stopped and the pump will automatically rewind. Check your blood glucose level and restart the infusion.
Out of battery Delivery stopped!!!	High	Light, Vibration	Insulin delivery has stopped.The pump will automatically rewind.Please replace the depleted battery with a fully charged one.
Pump error Delivery stopped!!!	High	Light, Vibration	Insulin delivery has stopped. The pump will automatically rewind.Please replace the reservoir. If this error remains, contact your local distributor, or use a new pump.
Auto Suspend Delivery is activated. Delivery stopped!!!	High	Light, Vibration	Insulin delivery has stopped. The pump will automatically rewind. Please check your blood glucose and resume delivery accordingly.
Reservoir Low!	Low	Light, Vibration	The amount of insulin remaining in the reservoir is lower than the low Reservoir Alert Threshold. Prepare a new reservoir to be used after the old one is empty.
Pump Battery Low!	Low	Light, Vibration	The pump battery level is below 5%. Please prepare a fully charged battery for replacement.

16.2 PDA Alarms

Alarm Description	Priority Level	Alarm Signal	Solution/Action
Out of insulin Delivery stopped!!!	High	Light, Auditory, Vibration	The reservoir is empty and insulin delivery has stopped. The Ambulatory insulin infusion pump will automatically rewind. Replace the reservoir and check your blood glucose level.
Occlusion detected Delivery stopped!!!	High	Light, Auditory, Vibration	Insulin delivery has stopped. Replace the reservoir/infusion set and check your blood glucose level.
Unexpected Delivery stop!!!	High	Light, Auditory, Vibration	Insulin delivery has stopped and the pump will automatically rewind. Check your blood glucose level and restart the infusion.
Out of battery Delivery stopped!!!	High	Light, Auditory, Vibration	Delivery has stopped.The Ambulatory insulin infusion pump will automatically rewind.Please replace the depleted battery with a fully charged battery.
PDA Error	High	Light, Auditory, Vibration	Restart the PDA. If the problem persists, contact your distributor for repair or replacement.
Pump error Delivery stopped!!!	High	Light, Auditory, Vibration	Insulin delivery has stopped. The pump will automatically rewind. Please replace the reservoir. If this error remains, contact your local distributor, or use a new pump.
Auto Suspend Delivery is activated. Delivery stopped!!!	High	Light, Auditory, Vibration	Insulin delivery has stopped. The pump will automatically rewind. Please check your blood glucose and resume delivery accordingly.
Reservoir Low!	Low	Light, Auditory, Vibration	The amount of insulin remaining in the reservoir is lower than the low Reservoir Alert Threshold.Prepare a new reservoir to be used after the old one is empty.
PDA Battery Low!	Low	Light, Auditory, Vibration	The PDA battery level is below 5%. Connect to charger.
Pump Battery Low!	Low	Light, Auditory, Vibration	The pump battery level is below 5%. Please prepare a fully charged battery for replacement.
Pump Signal Lost Alert!	Low	Light, Auditory, Vibration	Check connection between PDA and the pump; Change Pump battery.

16.3 Alert

Alert	Resolution
High BG Alert	High glucose threshold reached. Check your blood glucose if your CGM reading keeps rising.
Low BG Alert	Low glucose threshold reached. Check your blood glucose if your CGM reading keeps falling.
Glucose Rising Fast	Glucose rising fast. Check your blood glucose if your CGM reading keeps rising.
Glucose Falling Fast	Glucose falling fast. Check your blood glucose if your CGM reading keeps falling.
Continuous High BG	CGM readings is kept high. Check your blood glucose.
Infusion has been suspended for %s minutes!	Delivery has been stopped, please check if you need to resume delivery.
No basal program running!	Set and activate Basal program.
CGMS has no signal	PDA is not receiving CGM signal, please move PDA closer to CGM or check if the CGM is working properly.
Expired after %s hours	Prepare a new CGM sensor and start the new sensor after the current sensor expires.
Sensor expired	Start a new CGM sensor.
Sensor Error	Start a new CGM sensor.
Sensor detected	If this is a new sensor, choose "new sensor".
Strong magnetic field was detected. Pump may fail!	Leave your current location and check if the pump is working properly.
The pump will stop infusion automatically	When auto off is turned on, the system will remind 15 minutes before insulin delivery stops.

16.4 Alarm System Delay

The alarm system has an inherent delay between the two components, as shown in Figure 119:

- **T2-T1:** The time it takes for a safety sensor in the Ambulatory insulin infusion pump to detect an alarm ≤0.1s.
- **T3-T2:** The amount of time between detecting an alarm and issuing an alarm signal within the Ambulatory insulin infusion pump ≤0.1s.
- **T4-T3:** The time it takes for the pump to send the alarm information wirelessly to the PDA ≤ 4s.
- **T5-T4:** The amount of time between when the PDA receives the alarm to issuing the alarm signal ≤0.1s.

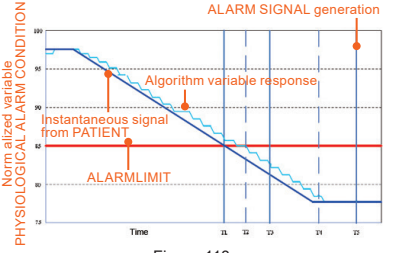


Figure 118

The alarm system is distributed – if a pump sensor detects a problem it will issue an alarm within 0.2 seconds. The PDA will receive the information and issue an alarm within 4 seconds.

16.5 Self Test

When the pump is paired with the PDA, on the PDA homepage, tap "Settings" →"General Settings" → "About System" → "Self Test". Tapping "Self Test" will trigger pump vibration alarm, and PDA auditory alarm and vibration alarm. The user can confirm whether the signal is received and finish the product self-test. If there's something wrong, you can try again or contact the after-sales service.

17 Maintenance

Your Ambulatory insulin infusion pump and PDA are precision instruments. Improper use and maintenance will result in decreased accuracy or even pump failure. Please read this chapter carefully to learn how to properly care for your patch insulin pump system.

Note

Maintenance of the instrument is not allowed during use the device.

17.1 Cleaning

17.1.1 Pump

1. Use alcohol wipes to clean the pump's outer surface thoroughly until there are no obvious dust particles and stains left by visual inspection.
2. It is recommended to clean every 3 days.

Warning

Do not use any organic solvents or lubricants to clean the insulin pump! Because they can make the pump malfunction, causing minor damage. When cleaning the pump, be sure to keep the reservoir dry and avoid getting it damp.

17.1.2 PDA

1. Use alcohol wipes to clean the PDA's outer surface thoroughly until there are no obvious dust particles and stains left by visual inspection.
2. It is recommended to clean every 3 days.

Warning

Cleaning the PDA with any organic solvents or lubricants may make the PDA malfunction, causing damage.

17.1.3 Cannula Inserter

1. Use alcohol wipes to clean the cannula inserter's outer surface thoroughly until there are no obvious dust particles and stains left by visual inspection.
2. It is recommended to clean every 3 days.

17.2 Avoid Extreme Temperatures

1. Avoid exposing the pump and PDA to temperatures above 104°F(40°C) and below 32°F(0°C).
2. Insulin Insulin solutions freeze near 32°F(0°C) and degrade at high temperatures. If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool.
3. Do not steam sterilize or autoclave your storage temperature to normal infusion status is 8mins from 55°C to 20°C, 1min from -40°C to 20°C.

17.3 X-Ray, MRI, CT Scans and Strong Magnetic Field

If you are going to have an X-ray, CT Scan, MRI or other type of radiation exposure, remove your pump and PDA before entering the room that contains this equipment. In addition, stay away from strong magnetic fields which may fail the pump.

17.4 Wireless Connection

The Ambulatory insulin infusion pump and PDA communicate wirelessly, and when the PDA sends instructions to the pump, they must be within an acceptable distance. The Ambulatory insulin infusion pump and PDA have a wireless communication range of 2 meters. The distance and surrounding environment have a large effect on the wireless signal integrity.

Please follow the suggestions below to maximize the wireless signal.

1. Avoid obstructions between the PDA and pump, such as walls, floors, metal plates, people, etc.
2. Avoid wearing clothing that contains metallic substances around the pump.
3. Avoid strong electromagnetic radiation.
4. Keep other wireless devices away from the pump and PDA, even if the devices comply with national emission requirements. Wireless interference can still occur.

If the signal strength between the Ambulatory insulin infusion pump and PDA is good, information will travel more quickly between the two. Always observe the wireless signal strength on the status bar before using the PDA. If the signal is weak or there is no signal, the PDA will not be able communicate with the pump.

Note

If the signal is weak or there is no signal, check that you are avoiding the above four situations. If the signal is still weak, move the PDA closer to the pump. If the situation persists, please contact customer service.

Note

The infusion accuracy is not affected under the interference of wireless power transmission, cellular 5G ,Electronic security system detection and RFID signal (spacing is less than 0.15m).

17.5 Disposal

When you replace the pump, PDA and its attachments, please do not throw them away. Take them to an electronics recycling facility or return them to your supplier.

Do not discard damaged or expired batteries. Please dispose of batteries according to local recycling laws.

Please do not throw away consumables such as reservoir and infusion set after use. Please follow local laws and regulations regarding the disposal of medical devices.

17.6 Transportation

Avoid placing heavy objects on top of the Ambulatory insulin infusion pump and PDA.

Avoid direct sunlight and rain. Transport according to the transportation conditions.

17.7 Storage

If you are temporarily not using the pump system, store the components in a cool, dry, clean and well-ventilated area.

If you decide not to use the pump for a prolonged period, the battery should be stored separately.

Always keep your Pump and PDA port free of debris and liquids. Lint, dirt, dust, and liquids can impair the functionality of your device or damage it.

17.8 Other Considerations

When dealing with potentially contagious substances (such as blood or reagents), use protective gloves or other protective coverings if skin exposure is likely.

17.9 Pediatric Safety and Monitoring

- Regularly inspect the infusion site for redness, swelling, or leakage.
- Monitor the child's behavior for signs of hypoglycemia (e.g., irritability, drowsiness, pallor).
- Ensure the pump is not exposed to extreme temperatures or physical impact during play.
- Use protective cases or clips to secure the PDA and pump.

18 Specifications

18.1 General Specifications

	Ambulatory insulin infusion pump	PDA
Model Number	MTM-1; MTM-H1	MTM-2; MTM-H2
Size	MTM-1: 59.5x40x11.1mm(LxWxD) MTM-H1: 59.5x40x11.1mm(LxWxD)	MTM-2/MTM-H2: 65*120*12mm
Weight	MTM-1: 23g(without batter or insulin) MTM-H1: 24g(without batter or insulin)	MTM-2/MTM-H2: 142g
Reservoir Capacity	2ml	/
Operating Temperature	41-104°F (5-40°C)	41-104°F (5-40°C)
Operating Humidity	10-93% (noncondensing)	10-93% (noncondensing)
Storage Temperature	-40-131°F (-40°C-55°C)	-40-131°F (-40°C-55°C)
Storage Humidity	5-95% (noncondensing)	5-95% (noncondensing)
Ingress protection level	MTM-1: IP24 MTM-H1: IP28	MTM-2: IP54 MTM-H2: IP54
Alarm Prompts	Light, Vibration	Sound, Light, Vibration
History Storage	Automatically Syncs to PDA	Browse by screen
Display	None	4-inch color touchscreen
Battery	Nominal Capacity: 70mAh Type: Li-ion battery	Nominal Capacity: 2500mAh Type: Li-ion battery
Low Reservoir Alarm Threshold	10-50U, in increments of 5U, 10U by default	
Auto-Off	Enable/Disable – Disabled by default	
Auto-Off Time Range	1-24 hours, 1-hour increments, 1 hour by default	
Memory Behavior During Power Off	All settings and records retained after power off	
Wireless Frequency	2.402GHz~2.480 GHz	2.402GHz~2.480 GHz, 5.150GHz~5.850GHz
Bandwidth	1MHz	1MHz for Bluetooth 20/40/80MHz for Wi-Fi
Modulation Type	GFSK	GFSK for Bluetooth, DSSS and OFDM for Wi-Fi
Maximum RF Output Power	-4dBm	18dBm
Use life for Device and accessories	4 Years	
Operating air pressure range	70kPa-106kPa	
Storage air pressure range	50kPa-106kPa	

18.2 Delivery

Attribute	Specification
Basal Rate	0 - 35 U/hr
Basal Increment	(0.025/0.05/0.1) U/hr
Basal Programs	8 Basal Programs, each with 48 time segments
Maximum Basal Rate	0.1-35 U/hr, default: 1.5 U/hr
Base Basal Rate	0-35 U/hr, default: 0 U/hr
Temporary Basal Rate	U/hr or % of basal rate, last 3 basal rates remembered, default: Off
Temporary Basal Time	0.5-24 hours
Bolus Size	0.025U-35U, 4 Presets
Bolus Increment	(0.025/0.05/0.1/0.5/1)U
Max Bolus Size	1-35U, programmed in 1U increments, default: 10U
Extended Bolus	Programmed in U or % of total bolus, default: Off Extend time：0.5-12 hours in increments of 0.5 hr
Quick Bolus	On/Off, default: on
Quick Bolus Increment	0.1-2U in 0.1U increments, default: 1U
Bolus rate	1.5/3 U/min

18.3 Bolus Calculator

Attribute	Specification
Bolus Calculator	On/Off, default is off
Carb Ratio	1-200 g carb/U in 1 g carb/U increment
Insulin Sensitivity Factor	1.8-300 mg/dL(0.01 -22.20mmol/L/U) in 0.01 steps
Negative Correction	On/Off, default: On
Active Insulin Time	2-8 hours in 0.5hr increment
Target blood glucose range	3.3 mmol/L-13.9 mmol/L

18.4 Bolus Delivery

Bolus Steps	Volume per Step	Time Interval Between Steps	Infusion Speed per Minute
0.05 U	0.5 μL	default 1s	default 3 U
0.05U	0.5μL	2S	1.5U

18.5 Infusion Precision

The pump shall deliver basal and bolus infusions accurately.

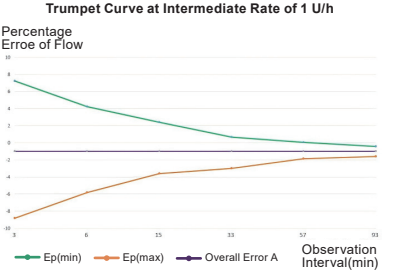
Basal rate ≥1.0U/h, bias≤±5%; basal rate<1.0U/h, bias≤±10%.

Bolus ≥0.1U, bias≤±5%; Bolus<0.1U, bias≤±20%.

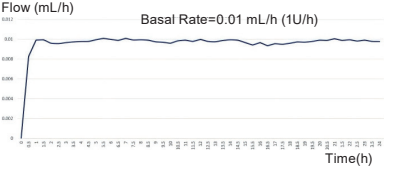
At 1U/h delivery rate, the error was measured at 0.4%.

The following images are representative delivery accuracy curves.

The Trumpet Curve represents the maximum percentage change from the expected insulin dosage for a given time interval, known as the observation window, during the infusion of insulin. The upper curve corresponds to positive changes, and the lower curve corresponds to negative changes.



The Flow Curve represents the delivery amount at 0.1U/h Basal Rate.



The above Trumpet Curve and Flow Curve are created by:

Pump SN: 800012; PDA SN: C00010; Reservoir Lot: AK23D001; Infusion Set Lot: AE23D003.

18.6 Occlusion Detection

The occlusion pressure and maximum infusion pressure during the fill tubing process are 32 psi (220 kPa).

18.7 Occlusion Alert Time

When a fluid obstruction is detected, an occlusion alarm occurs. The occlusion alarm is triggered by an average of 2.5u of missed insulin. (The pump system has a moderate rate of 1 U/h, and the insulin dose that triggers blockage is 1-6 U)

The Table below shows three delivery speeds and the respective occlusion alarm delays using U100 insulin.

Rate	Minimum Time Before Alarm	Maximum Time Before Alarm
Fast Rate (3U/min)	20 sec	100 sec
Medium Rate (1U/h)	1h	6h
Slow Rate (0.025U/h)	60h	197h (Pump battery exhausted)

Note

Certain factors, such as ambient temperature changes or the presence of air in the infusion set or the reservoir, can delay an occlusion alarm. When the occlusion is detected, pump system will initiate an occlusion alarm, and the nut will backward to release occlusion pressure.

18.8 Overdose/Underdose

The pump contains sensors that verify the infusion's accuracy.

If the actual amount of delivery is more or less than the requested amount, this is called an overdose or underdose. The sensors in the pump can detect overdose or underdose situations and compensate automatically, or issue an alarm.

The maximum amount of bolus that can be delivered in a single fault is 0.25U.

18.9 Network Data Streams

Protocol Type	Data Flow Source	Data Flow Destination	Data Flow Direction	Addressing Scheme	Function Description
Bluetooth	PDA	Ambulatory insulin infusion pump	Bidirectional (PDA ↔ Pump Body)	Bluetooth MAC Address	The PDA sends infusion instructions (such as bolus dose, basal rate) to the pump body via Bluetooth.
Bluetooth	Ambulatory insulin infusion pump	PDA	Unidirectional (Pump Body → PDA)	Bluetooth MAC Address	The pump body sends historical information (such as basal rate changes, low battery) to the PDA via Bluetooth.
Bluetooth	Continuous Glucose Monitoring System (CGMS)	PDA	Unidirectional (CGMS → PDA)	Bluetooth MAC Address	The PDA receives the real - time blood glucose information from the CGMS via Bluetooth and displays it.
Wi-Fi	PDA	Pancares Platform	Unidirectional (PDA → Pancares)	IP Address + Port Number (such as 443/HTTPS)	The PDA uploads infusion records, alarm events and blood glucose reminders to the Pancares platform via Wi - Fi.

18.10 Network Ports

Port 443 (https)

Function: Communicate with Pancares and transmit patient data and logs.

Data Flow: Unidirectional

Status: Enabled

18.11 Software Bill of Materials

Name of software	Version	Supplier
mbedTLS	3.1.0	Trusted Firmware
nRF5 Software Development Kit	17.0.2	Nordic Semiconductor
XLog	1.6.1	Open Source Software
MPAndroidChart	3.1.0	Open Source Software
Objectbox	2.5.1	Open Source Software

18.12 Quality of Service

PDA:

1. You can lock PDA containing private data by setting the lock password to prevent unauthorized access.
2. PDA avoids potential risks to your privacy and information security by security check and communication encrypting.
3. Access Control, Data Storage and Transmitting Encryption.

Pump:

1. Pump provides a safe scheme for protecting private key and communication protocols.
2. Pump avoids potential risks to your privacy and information security by security check and communication encrypting.
3. The pump casing uses strong adhesive and cannot be easily removed.

18.13 Electromagnetic Compatibility

Please use 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 devices are intended for use in the electromagnetic environment specified in this section. The user of the device should ensure that the device is used in such an environment.

Portable and mobile RF communication

interference may have an impact on the device.

The cable information is as follows:

#	Item	Length (m)	Cables Shielded	Notes
1	PDA Charge Cable	1.0m	Yes	EUT DC 5V

The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

The basic performance is described in the table below:

Performance	Specific Description
The pump shall deliver basal and bolus infusions accurately	Basal rate ≥1.0U/h, bias ≤±5%; basal rate <1.0U/h, bias ≤±10% Bolus ≥0.1U, bias ≤±5%; Bolus <0.1U, bias ≤±20%.
The pump shall activate a high priority alarm upon detection of delivery occlusion	Occlusion bolus: 1-5U; Maximum infusion pressure: 220KPa; Time for activation of the occlusion alarm: a)Fast rate 3U/min: 20-100s; b)Medium rate 1U/h: 1-6h; c)slow rate 0.025U/h:60h-197h(Pump battery exhausted)
Alarm signal of high priority shall include Auditory and Vibration.	/

Guidance and manufacturer's declaration-electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment-guidance**
RF Emissions CISPR 11	Group 1	The device users RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The device is suitable for use in aircraft and in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration -electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) IEC 60601-4-2	±8 kV Contact ± 15 kV Air	±8 kV Contact ±15 kV Air	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Electrical fast transient burst IEC 61000-4-4	±2 kV power supply lines	±2 kV power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential mode	± 1 kV Differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	70% UT(30% dip in UT) for 25/30 cycles 0% UT(100% dip in UT) for 1 cycle at 0 degrees 0% UT(100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment -guidance**
Conducted RF IEC 61000-4-6	3V(Vrms) 150kHz~80MHz 6V in ISM and amateur radio bands between 150 KHz and 80 MHz	3V(Vrms) 6V(Engineering medical frequency band)	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the device.
Radiated RF IEC 61000-4-3	10 V/m 80MHz~2.7GHz	10 V/m	

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communication equipment. The frequencies and services listed in the trable are representative examples in various locations where the System may be used.

Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]
385	380-390	TETRA 400	Pulse modulation [b] 18Hz
450	430 – 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine
710	704 – 787	LTE Band 13,17	Pulse modulation [b] 217Hz
745			
780			
810	800 – 960	GSM 800/900, TETRA 800. ODEM 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18Hz
870			
930			
1720	1700-1990	G GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulatio n 217 Hz
1845			
1970			
2450	2450- 2570	Bluetooth WLAN, 802.11b/g/ n, RFID 2450, LTE Band 7	Pulse modulation [b] 217Hz
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz
5500			
5785			

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal .
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be worst case.

This table lists the immunity levels at speciffc test frequencies for Proximity Magnetic Fields Range of 9 kHz to 13.56 MHz.

Frequency (MHz)	Modulation	Immunity Test Level (A/m)
134.2 kHz	Pulse modulation [a] 2.1 kHz	65 [b]
13.56 MHz	Pulse modulation [a]	7.5 [b]

a) The carrier shall be modulated using a 50% duty cycle square wave
b) RMS before modulation is applied

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

Note:

If electromagnetic interference causes a loss or degradation of basic performance, the product will be unusable.

Note:

1. Ambulatory insulin infusion pump were tested according to the recommendations of IEC TS 60601-4-2:2024, Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

2. The performance in relation with the intended use of Ambulatory insulin infusion pump is delivering basal and bolus infusions accurately, activating a high priority alarm upon detection of delivery occlusion, alarm signal of high priority shall include Auditory and Vibration.

19 Appendix

Symbols

CE Mark	CE 0197	European Representative	EU REP
Consult instructions for use		Temperature limit	
Use by date		Type BF Applied Part	
Manufacturer		Model Number	#
Lot Number	LOT	Date of manufacture	
Serial Number	SN	Medical Device	MD
Direct current		Waste Electrical and Electronic Equipment (WEEE)	
Non-Ionizing Radiation		Operating temperature limitation	
Caution		Operating humidity limitation	
Importer		Operating atmospheric pressure limitation	
The level of protection against ingress of solid foreign objects is 2 (Protected against solid foreign objects of 12,5 mm ∅ and greater). The level of protection against ingress of water with harmful effects is 4 (Protected against splashing water).	IP24	5: Dust-protected The level of protection against ingress of solid foreign objects is 5 (Protected against dust). The level of protection against ingress of water with harmful effects is 4 (Protected against splashing water).	IP54

The level of protection against ingress of solid foreign objects is 2 (Protected against solid foreign objects of 12,5 mm ∅ and greater). The level of protection against ingress of water with harmful effects is 8 (Protected against the effects of continuous immersionin water).	IP28	Do not use if package is damaged and consult instructions for use	
Unique device identifier	UDI	Refer to Instruction Manual	
Catalogue number	REF		

Potential Risks:

(1) Under delivery or excessive delivery of Insulin leading to severe hypoglycemia or diabetic ketoacidosis

(2) Infusion site problems

- Pruritus (Skin redness), Swelling and other skin allergies

(3) Hyperglycemia or hypoglycaemia

(4) Hardware defects

- Adhesion issues, difficulty peeling off the device, cannula deformation, etc.

(5) Failure to follow the instructions may lead to risks of hyperglycemia or hypoglycemia, and diabetic ketoacidosis (DKA). Both DKA and hypoglycemia can potentially lead to death.

Expected Clinical Benefits:

- Improved management of A1C and TIR for tighter glycemic control
- Reduction in Hypoglycemia events
- Reduction in Total Daily Dose of insulin

20 Applied Countries

Currently, our product's target market is only Ireland. In the future, corresponding language versions of the user manual will be provided based on the target markets.

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