MEDTRUM | Simplifying Diabetes

A7+ TouchCare®

Insulin Management System

User Guide

A7+ TouchCare®

Insulin Management System

User Guide

Humalog® is a trademark of Eli Lilly and Company.
NovoRapid® is a trademark of Novo Nordisk A/S.
Apidra® is a trademark of Sanofi S.A.

Medtrum Technologies Inc.
7F, Building 8, No. 200, Niudun Road
Shanghai 201203, China
Tel: +86-21-50274781
Fax: +86-21-50274779
www.medtrum.com

EC REP

Medtrum B.V.
Nijverheidsweg 17
5683 CJ Best
The Netherlands
Tel: +31 (0) 499745037

CE 0197

This product complies with Directive 93/42/EEC (MDD) and Directive 2014/53/EU (RED).

REF SY-018
Version: 1.01
Publication date:
20 August, 2019

UG881116GB
348431

Contents

1 Introduction

1.1 Before you begin

Check with your healthcare provider (diabetes team) regarding your individual training needs. Do NOT attempt to use the A7+ TouchCare® System before you have been properly trained.

As part of your training, your healthcare provider will work with you to establish diabetes management guidelines and settings that best fit your needs. Your healthcare provider can provide you with the initial settings of your insulin Pump and CGM system. After adequate training and practice, you will find it easy to enter and change the system's settings.

The A7+ TouchCare® Pump is designed to use U-100 insulin. The following insulin analogs have been tested and found to be safe for use in with the A7+ TouchCare® Pump: Humalog®, NovoRapid®, and Apidra®. Before you use different insulin with this Pump, check the insulin label to make sure that it can be used with your Pump. Use of any insulin with lesser or greater concentration can result in serious injury or even death. Your Pump is not intended to deliver any other substance.

The A7+ TouchCare® Continuous Glucose Monitoring (CGM) System incorporates a Glucose Sensor and a Transmitter. The Glucose Sensor measures the glucose level of interstitial fluid. The Transmitter wirelessly transmits your real-time Sensor glucose information to your Personal Diabetes Manager (PDM).

Not all devices or accessories are available in all countries where the A7+ TouchCare® System is approved. To order supplies, contact your local representatives.

1.2 Indications

The A7+ TouchCare® System is indicated for use in people (ages 2 and older) with diabetes. The system is intended for single patient use and should be used under the guidance of a healthcare provider.

The Patch Pump is indicated for the continuous subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The CGM System is indicated for continuous monitoring of interstitial fluid glucose levels, and detecting possible low and high glucose episodes. Interpretation of the CGM System results should be based on the glucose trends and several sequential readings.

1.3 Contraindications

The A7+ TouchCare® System is not recommended for people who are unwilling or unable to:

- Maintain contact with their healthcare provider.
- Test their blood glucose levels as recommended by their healthcare provider.
- Maintain sufficient diabetes self-care skills.
- Recognize and respond to alerts and alarms. (Sufficient vision and/or hearing are required.)

1.4 User Safety

1.4.1 Warnings and Precautions

General Statements

Make sure that you have read and are familiar with the User Guide before using the A7+ TouchCare® System . Failure to follow the instructions may result in pain or injury and may also affect the system's performance. If you do not understand something or have questions, ask your healthcare provider, call customer support, or contact your local Medtrum distributor.

The A7+ TouchCare® System has many different settings and features. It is best to talk with your healthcare provider to determine which settings and features are right for you. Some features require great knowledge of insulin pumping and advanced self-care skills. Do NOT use the A7+ TouchCare® System until you have specific information for your treatment plan and have had specific training on each feature from your healthcare provider or local Medtrum distributor.

General Precautions

Do NOT put skin care products on the A7+ TouchCare® System, that might result in damage to the plastic surface of the products. Wipe off the skin care products such as sunscreen by using a clean cloth. If you find a crack in any part of the A7+ TouchCare® System, contact customer support.

The A7+ TouchCare® System includes active medical devices. When you dispose of any device in the A7+ TouchCare® System, follow the local waste disposal regulations.

We recommend that you have someone around you (family, friends, etc.) who understands diabetes and the A7+ TouchCare® System, so that in case of an emergency, they can help you. Make sure that they are familiar with any information given by your healthcare provider.

General Warnings

No modification of this system is allowed.

Do NOT use the A7+ TouchCare® System if you have delicate skin or if you are allergic to acrylic adhesives.

Do NOT use anything other than the accessories specified in this User Guide, which could permanently damage your system and voids its warranty.

Do NOT allow young children to hold the Reservoir Patch, Pump Base, Transmitter or Sensor without adult supervision. The Reservoir Patch, Pump Base, Transmitter and Sensor contain small parts and could pose a choking hazard.

Do NOT operate your A7+ TouchCare® System in the presence of flammable anesthetics or explosive gases.

Patch Pump Precautions

Contact your healthcare provider about lifestyle changes such as starting/stopping your exercise program or significant weight loss/gain because this can affect the way that your body uses insulin.

Patch Pump Warnings

In case the A7+ TouchCare® System is unable to properly deliver insulin you must be prepared to give yourself an injection of insulin. Knowing how to do

this will help to avoid the risk of diabetic ketoacidosis (DKA) or very high blood glucose (BG).

Do NOT stop using your Pump if you are ill unless instructed to do so by your healthcare provider. Even when you are ill, your body still needs insulin.

If failure or damage of your Pump Base is found during usage, please contact customer support or your local Medtrum distributor for replacement.

CGM System Precautions

The Sensor may create special needs regarding your medical conditions or medications. Please discuss these conditions and medications with your healthcare provider before using the Sensor.

If failure or damage of your Transmitter is found during usage, please contact customer support or your local Medtrum distributor for replacement.

CGM System Warnings

Do NOT ignore symptoms of high or low glucose. If you believe your Sensor glucose readings are inconsistent with how you feel, manually measure your blood glucose with a blood glucose meter. If the problem continues, discard the old Sensor and insert a new one.

If you suspect your Sensor is broken during usage, do NOT attempt to remove it yourself. Contact your healthcare provider for assistance in removing the Sensor.

Personal Diabetes Manager (PDM) Precautions

Your PDM is featured by its color touchscreen. Please operate with dry fingers.

Before you put your PDM in your pocket or purse, remember to press the power button to put the PDM on sleep mode, so that you can avoid misoperation resulting from accidental bumps and movements. Press the power button again to wake the screen.

Check your PDM occasionally to make sure that it emits audible beeps that are easily detectable and that the vibrate feature is working properly.

If you return your PDM for service, a replacement PDM will be sent. Do NOT use the replacement PDM until it has been programmed to fit your specific needs.

If you drop your PDM or if it has been hit against something hard, check whether the display screen and the touch screen are working properly, whether the PDM can be charged normally. Call customer support or your local Medtrum

distributor if you identify or suspect your PDM has been damaged. Your PDM is designed to be charged by matching charger. Use of anything other than a charger that does not match could permanently damage your PDM and voids its warranty.

Operating Temperature Range

Your A7+ TouchCare® System is designed to operate between 5°C (41°F) and 40°C (104°F). Do NOT expose the system to temperatures outside that range. Do NOT expose the system to direct sunlight for a long period of time.

Cleaning

Do NOT use household cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your PDM, Pump Base, or Transmitter. Never put your PDM, Pump Base or Transmitter in the dishwasher or use very hot water to clean it.

Do NOT use a hair dryer, microwave oven, or conventional oven to dry your PDM, Pump Base, or Transmitter. Use a soft towel.

Do NOT clean any part of the system while it is in use.

X-rays, MRIs and CT Scans

The A7+ TouchCare® System may be affected by strong radiation or magnetic fields. If you are going to have an X-ray, MRI, CT scan or other type of exposure to radiation, remove your Patch Pump and Glucose Sensing System, and put them outside the treatment area with your PDM. Change the Reservoir Patch and Sensor after the test or procedure is completed.

The A7+ TouchCare® System is designed to tolerate common electromagnetic and electrostatic fields, including airport security systems and mobile phones.

1.4.2 Consumables

- **Reservoir Patch**—The Pump Base (JN-022) is only used with the 200-unit Medtrum Reservoir Patch (MD-JN-011). Change your Reservoir Patch every 2-3 days or as directed by your healthcare provider.
- **Glucose Sensor**—The Transmitter (MD1026) is used with the Medtrum Glucose Sensor (MD3026). Change your MD3026 Glucose Sensor every fourteen days.

Warning: For your protection the Pump Base and Transmitter have undergone extensive testing to confirm appropriate operation when used with consumables manufactured or distributed by Medtrum. We recommend using Medtrum Reservoir Patches and Glucose Sensors as we cannot guarantee appropriate operation if the system is used with consumables offered by third-parties and therefore we are not responsible for any injury or malfunctioning of the system that may occur in association with such use.

1.4.3 Radio Frequency (RF) Communication

Note: The A7+ TouchCare® System can generate, use and radiate radio frequency energy, and may cause harmful interference to radio communications. There are no guarantees that interference will not occur in a particular installation. If the A7+ TouchCare® System does cause harmful interference to radio or television reception, you are encouraged to try to correct the interference by one of the following measures:

- Move or relocate the A7+ TouchCare® System.
- Increase the distance between the A7+ TouchCare® System and the other device that is emitting/receiving interference.

Common consumer electronic devices that transmit in the same frequency band used by the A7+ TouchCare® System may prevent communication between the PDM and your Patch Pump or Transmitter. This interference, however, does not cause any incorrect data to be sent and does not cause any harm to your device.

Based on GFSK modulation, the system communicates at frequencies between 2402 and 2480 MHz with power level 0 dBm. RF communication between your Patch Pump and PDM works up to a distance of 4 meters (13 feet). RF communication between your Transmitter and PDM works up to a distance of 10 meters (33 feet).

1.4.4 Emergency Kit

Keep an emergency kit with you at all times to make sure you have necessary supplies. Inform a family member, co-worker, and/or friend where this emergency kit is kept.

This kit should include but is not limited to:

- Fast-acting glucose tablets or gel
- BG monitoring supplies
- Urine ketone testing supplies
- Insulin syringe
- Rapid-acting U-100 insulin
- Extra Medtrum 2.0 mL Reservoir Patches
- Power Bank
- Instructions from your healthcare provider about how much insulin to inject if pump delivery is interrupted
- Alcohol wipes
- Glucagon emergency kit
- Emergency contact phone numbers

1.4.5 Water

Both your Patch Pump and Sensor (including the installed Transmitter) are waterproof to a depth of 2.5 meters (8 feet) for up to 60 minutes (IPX8). After exposure to water, rinse the devices with clean water and dry them with a towel.

Warning: Do NOT expose your Patch Pump or Sensor (including the installed Transmitter) to water at depths greater than 2.5 meters (8 feet) or for more than 60 minutes. Check often to make sure that the devices are securely attached and in place.

Warning: The PDM is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically dripping water (IP22).

Warning: The Patch Pump may not be able to deliver normally in water. The Transmitter may not be able to send data normally in water.

Note: Hot water may decrease Sensor life.

1.4.6 Storage

Store the Pump Base and Reservoir Patch at temperatures between -10°C (14°F) and 55°C (131°F), and at humidity levels between 20% and 90% relative humidity. Do NOT store the Pump Base and Reservoir Patch in direct sunlight, extreme temperatures, or in very humid areas.

Store the Sensor at temperatures between 2°C (36°F) and 30°C (86°F), and at humidity levels between 20% and 90% relative humidity for the length of the Sensor's shelf life. For temperatures greater than 30°C (86°F), the Sensor will require cooled storage at temperatures no lower than 2°C (36°F). You may store the Sensor in the refrigerator if it is within this temperature range. The Sensor should not be stored in the freezer. Wait for the Sensor to warm to room temperature before usage to prevent condensation. Storing the Sensor improperly may cause the Sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

Store the Transmitter at temperatures between -10°C (14°F) and 55°C (131°F), and at humidity levels between 20% and 90% relative humidity. Keep the USB charging cable and the Transmitter separate when in storage.

Store the Personal Diabetes Manager (PDM) at temperatures between -10°C (14°F) and 55°C (131°F), and at humidity levels between 20% and 90% relative humidity.

1.4.7 FCC Caution

Labelling requirements.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Information to user.

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

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or

television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

RF warning for Portable device.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

1.4.8 IC Caution

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:
(1) This device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

1.5 Warranty Information

Personal Diabetes Manager (PDM)

Medtrum Technologies Inc. ("Medtrum") warrants its PDM against defects in materials and workmanship for the period of 4 years from the original date of shipment of the PDM to the original end use purchaser (the "Warranty Period"). During the Warranty Period, Medtrum will, at its discretion, either repair or replace (with a new or recertified PDM, at Medtrum's discretion) any defective PDM, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the PDM is repaired or replaced, the warranty period shall not be extended.

The warranty is valid only if the PDM is used in accordance with Medtrum's instructions and will not apply:

- If damage results from changes or modifications made to the PDM by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the PDM by any person or entity other than Medtrum;

- If a charger without matching is used with the PDM
- If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or
- If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the PDM covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the PDM and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Pump Base

Medtrum Technologies Inc. (“Medtrum”) warrants its Pump Base against defects in materials and workmanship for the period of 1 year from the original date of shipment of the Pump Base to the original end use purchaser (the “Warranty Period”). During the Warranty Period, Medtrum will, at its discretion, either repair or replace (with a new or recertified Pump Base, at Medtrum’s discretion) any defective Pump Base, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the Pump Base is repaired or replaced, the warranty period shall not be extended.

The warranty is valid only if the Pump Base is used in accordance with Medtrum’s instructions and will not apply:

- If damage results from changes or modifications made to the Pump Base by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the Pump Base by any person or entity other than Medtrum;
- If a non-Medtrum Reservoir Patch is used with the Pump Base;
- If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or

- If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the Pump Base covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Pump Base and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Transmitter

Medtrum Technologies Inc. ("Medtrum") warrants its Transmitter against defects in materials and workmanship for the period of 1 year from the original date of shipment of the Transmitter to the original end use purchaser (the "Warranty Period"). During the Warranty Period, Medtrum will, at its discretion, either repair or replace (with a new or recertified Transmitter at Medtrum's discretion) any defective Transmitter, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the Transmitter is repaired or replaced, the warranty period shall not be extended.

The warranty is valid only if the Transmitter is used in accordance with Medtrum's instructions and will not apply:

- If damage results from changes or modifications made to the Transmitter by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the Transmitter by any person or entity other than Medtrum;
- If a non-Medtrum Glucose Sensor is used with the Transmitter;
- If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or
- If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the Transmitter covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Transmitter and does not apply to other products or accessories.

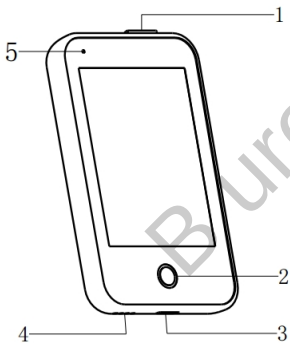
THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

2 Your A7+ TouchCare® System

2.1 Personal Diabetes Manager (PDM)

The Personal Diabetes Manager (PDM) monitors and controls your Patch Pump and Continuous Glucose Monitoring System via wireless RF communication. It stores your Pump and Sensor data of the last 90 days. Keep the PDM with you at all times so that, when needed, you are able to deliver a bolus, change the basal rate, check your glucose level and so on.

When RF communication is lost or interrupted because of adverse conditions or overlong distance, you will not be able to use your PDM to control or monitor your Patch Pump or Continuous Glucose Monitoring System. Yet the Patch Pump is able to continue delivering basal insulin based on your programmed settings, perform safety checks and automatically stop delivery in case of serious conditions. The Transmitter can continue to record Sensor glucose readings. The PDM is designed to detect and notify you about a disconnection. As soon as the problem is solved, RF communication will be resumed.



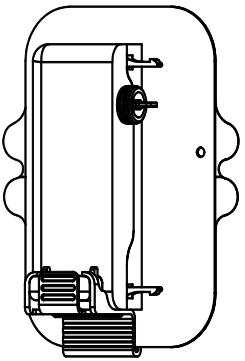
1. Power button
2. Home Key (Software Key)
3. Charging Port
4. Sound Hole
5. Indicator light

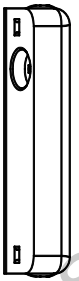
✓ Personal Diabetes Manager (PDM) (FM-018)

2.2 Patch Pump

The Patch Pump is a small, portable, self-adhesive device worn directly on your body to deliver precise, personalized doses of insulin into your body through a needle. The Patch Pump consists of a reusable Pump Base and a disposable Reservoir Patch. The reusable Pump Base holds the electronics and stores all your Pump settings. The disposable 200 Unit Reservoir Patch incorporates a

precise dispensing screw, a plunger, an actuator, a needle, a buzzer and a battery to power your Pump. The delivery system and enclosure of the Reservoir Patch are applied parts of the Pump.





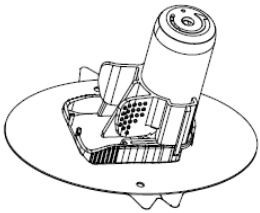
✓ Reservoir Patch (MD-JN-011, consumable)

✓ Pump Base (JN-022)

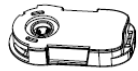
2.3 Glucose Sensing System (Optional)

The Glucose Sensing System is an optional part of the A7+ TouchCare® System which consists of a disposable Glucose Sensor and a reusable Transmitter. The Glucose Sensor is inserted under the skin to measure your glucose level in interstitial fluid. The Sensor is the applied part of the Glucose Sensing System. The Transmitter records Sensor data and sends data to a display device via wireless RF communication. The Transmitter's USB charging cable or charging dock is also included in the package.

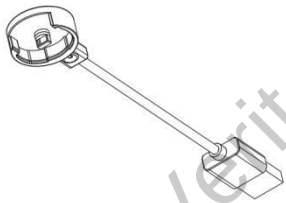
Transmitter MD1026, compatible sensor MD3026 and compatible charging cable LQ005 are as follows.



✓ Glucose Sensor
(MD3026, Consumable)



✓ Transmitter
(MD1026, Chargeable)



✓ USB charging cable
(LQ005)

3 How to use the PDM

3.1 Basics of the PDM

We recommend that your PDM is only used by an intended and qualified operator.

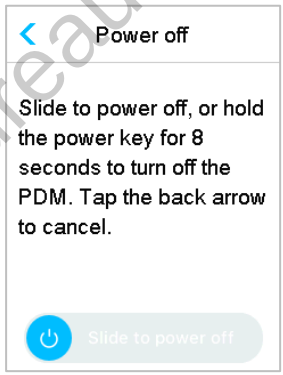
3.1.1 Turn on/off the PDM

1) Turn-on

- When you long-press the power button, a green light will flash, the screen will light up, the PDM is successfully turned on.
- When you short-press the power button, a yellow light will go on for about 8 seconds but the PDM is not turned on.

2) Turn-off

- When you long-press the power button for about 2 seconds, the shutdown screen appears. Then you can slide to power off, a yellow light will last for about 6 seconds, indicating that the shutdown is completed.



- Or you long-press the power button for about 6 seconds, a yellow light will go on for about 2 seconds, indicating that the shutdown is completed.

3.1.2 Charge the PDM

As a safety measure, the PDM will give you “PDM BATTERY LOW” or “CHARGE PDM NOW” alert when you keep the PDM working at a low power level. If you receive a “PDM BATTERY LOW” alert, respond to the alert and continue. Though the PDM will still function normally, the battery life could be decreased.

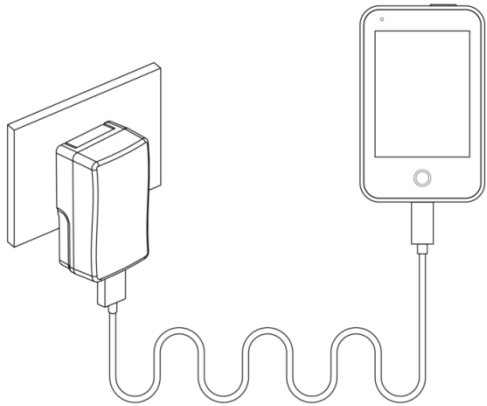
The PDM requires an AC adapter with an output of DC 5.0V that complies with IEC 60601-1 and IEC 60950 such as UES06WNCPU-050 100SPA, (input: 100-240V, 50/60Hz, 0.2A; output: 5.0V DC, 1.0A). The adapter is designed as a part of the ME system.

Note:

- Do not use other types of chargers. Otherwise the PDM may not work normally.
- You must charge the PDM when the battery is low to keep using the PDM. If the battery is exhausted, the PDM will shut down automatically.
- No settings will be lost if the PDM power is depleted or PDM error happens.
- The battery must be fully charged the first time you use the PDM, which usually takes around 2 hours. If the battery is not full after 12 hours of continuous charging as required, please contact customer service.
- Usually, when the PDM is fully charged, it is available for use of one week (7 days).
- Blue light flashes when PDM is charging, and the green light is always on indicates full charge.
- Only person (including patient) with adequate training is permitted to operate the PDM.

Charging process:

1. Connect PDM to adapter.
2. Plug the adapter into a power socket.



3.1.3 Power Mode

The PDM has two power modes:

1. Sleep Mode

   The PDM enters the Sleep Mode after screen backlight timeout and the screen shuts down. You can turn the PDM into Lock Screen of Awake Mode by short-pressing the Power button.

a. The activated basal, temporary basal and all bolus functions will not be changed.

b. The screen will be locked after screen backlight timeout.

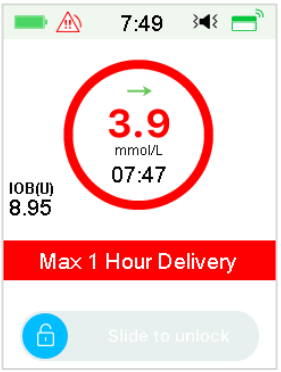
c. Press Power button, and the screen lights up, the PDM displays the Lock Screen.

2. Awake Mode

The PDM is in the Awake Mode when the screen backlight stays on.

a. You can turn Sleep Mode to Awake Mode by pressing power button.

b. In the Sleep Mode, all Alerts and Alarms regarding the Pump and CGM will immediately wake the screen to enter Lock Screen. The Alerts and Alarms shall be manually cleared after sliding to unlock.

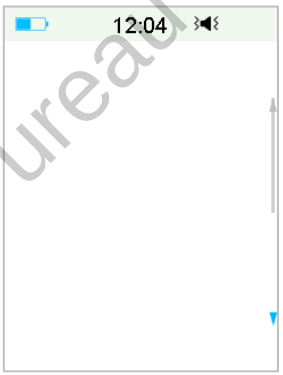


An Alarm occurs when the screen is locked.

An Alarm occurs when the screen is not locked.

3.1.4 Scroll Bar

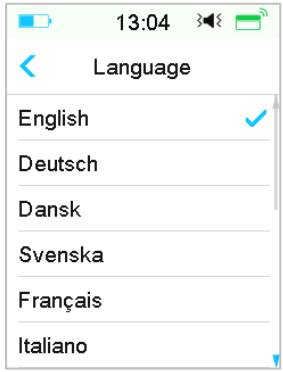
If there is excessive text length for the screen, a scroll bar appears on the right side of the screen. You can view any additional text by scrolling up and down.



3.2 Setting up the PDM

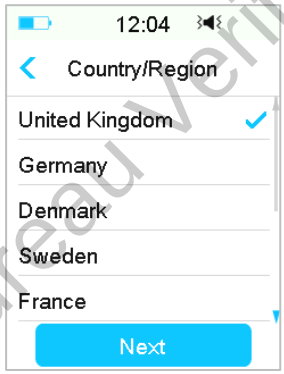
3.2.1 Select language and country/region

1. Select your language, then tap Next.



You can change language. *See "Language" in Section "Settings" for setup instructions.*

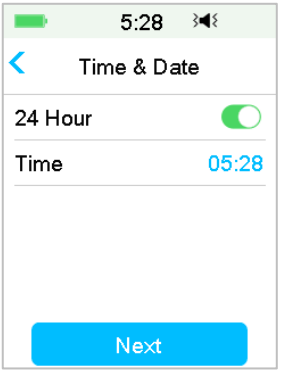
2. Select your country/region, then tap **Next**.

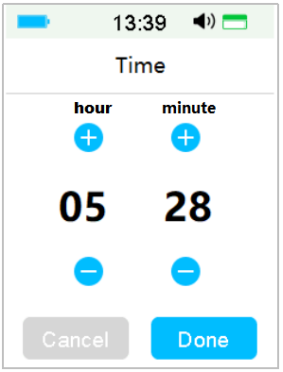


3.2.2 Time and Date

When starting PDM for the first time, you need to set the time and date. Setting the correct time and date in your PDM is necessary for accurate basal insulin delivery and enables you to keep a correct record of your insulin delivery and Sensor readings. You can select a 12-hour or 24-hour clock format.

1. Select your time, then tap **Next**.



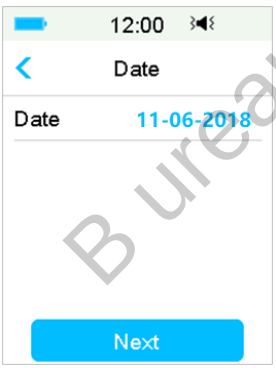


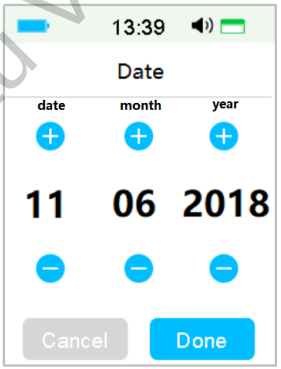
(1) Choose the time.

(2) Tap the blue button ⊕ to increase and ⊖ to decrease hour on the left.
Tap the blue button ⊕ to increase and ⊖ to decrease minute on the right.

(3) When finish, tap **Done**.

2. Select the Date, then tap **Next**.





(1) Choose the date.

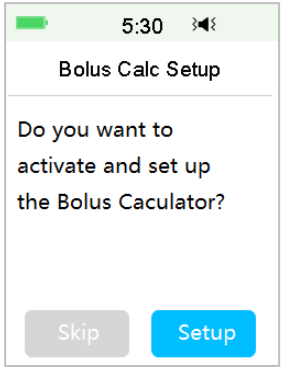
(2) Adjust the day, month and year separately.

(3) When finish, tap Done.

3.2.3 Bolus Calculator

After you finish the settings for date and time, you can choose whether you shall use the Bolus Calculator. Tap **Setup** to enter Bolus Calc Setup. Tap **Skip** to go

directly to Lock Screen. *See "Bolus Calculator" in Chapter "Advanced Pump Feature" for more information.*

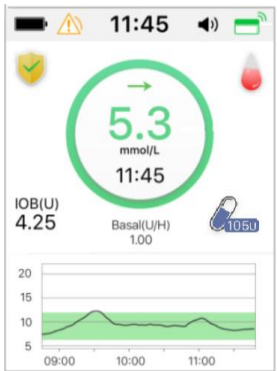


If you choose **Setup**, the Bolus Calculator function will be forced to turn on;

If you choose **Skip**, the Bolus Calculation function will stay turned-off.

3.3 Home Screen

The **Home Screen** is the starting point to access the programming screens. You can return to the Home Screen by tapping the **Home Key**. The first line shows status bar icons including PDM Battery, Alert/Alarm, Time, Audio/Vibration, Pump RF Signal. You can find on the main interface icons including Calibration, IOB (Insulin on Board), EasyLoop Icon, Insulin left and your real-time Insulin Pump Delivering Status and Sensor Status.



Note: At this screen, slide on the screen from right to left, you can open main menu screen. Slide from left to right to open status screen. Slide PDM from top to bottom to open alert notification screen. Slide on the screen from bottom to top to open shortcut screen.

3.3.1 Status Bar Icons

3.3.1.1 Battery Icon

The battery icon shows the remaining battery life.

- When the PDM is not charging

There are five icons, indicating different battery conditions. You need to charge PDM when the battery icon turns red.


At least 80% left


At least 60% left


At least 20% left


At least 10% left


No battery left

- When the PDM is charging

There are six icons, indicating different battery conditions.


Less than 10% charged


At least 10% charged


At least 20% charged


At least 60% charged


At least 80% charged


Fully charged

3.3.1.2 Time Icon

You can select the current time displayed in a 12-hour or 24-hour format. The a or p appears in the 12-hour format. For instructions on setting the time on your PDM. *See "Time and Date" in Section "Settings"*.

- 02:00 p 12-hour format
- 14:00 24-hour format

3.3.1.3 Audio Icon

There are eight kinds of audio icons, indicating different Reminder types, you can set it in the **General Settings** menu and **CGM Settings** menu.

 Audio

 Vibrate

 Audio and Vibrate

 Audio off /Vibrate off

 Alert Silence + Audio Reminder

 Alert Silence + Vibrate Reminder

 Alert Silence + Audio and Vibrate

 Alert Silence + Audio off /Vibrate off

3.3.1.4 Pump RF Signal Icon

A Pump RF icon appears only when there is an active Patch Pump.

 Patch Pump is active and RF communication is good

 Patch Pump is active but RF communication is lost or interrupted

3.3.1.5 Alert Icons

A yellow triangle with one yellow exclamatory mark (alert), a red triangle with two red exclamatory mark (medium priority alarm) or a red triangle with three red exclamatory mark (high priority alarm) appears only when there is an alert or alarm condition in your insulin management system. *See Chapter "Safety System and Alarms/Alerts" for more information.*

 Alert icon

 Medium priority alarm icon

 High priority alarm icon

3.3.2 Pump Status

1. EasyLoop Icon
2. Insulin Pump Delivering Status
3. IOB (Insulin on Board)
4. Pump RF Signal
5. Insulin left

You can view the **Pump Status** on the Home Screen.

Insulin Delivering Status icons in different situations:

Icon	Shape and Color	Description
	Grey ring	Grey ring indicates that there is no activated Pump.
	Green ring	Green ring represents the basal delivery.
	Green and dark green ring	Green ring with dark green part represents Temp Basal, the dark green part indicates the progress of Temp Basal delivery.
	Blue and dark blue ring	Blue ring represents the Normal Bolus, the dark blue part indicates the progress of delivery.

	Purple and dark purple ring	Purple ring represents the extend Bolus, the deep purple part indicates the progress of delivery.
	Red ring	Red ring represents the delivery suspend status.

The status information is indicated by text below:

✧ Basal(U/H) 1.00: The current basal rate is 1.00U/H.

✧ Temp Basal(U/H) 1.00: Temp Basal is activated and the active temp basal rate is 1.00U/H.

✧ Temp Basal(U/H) 1.00 85%: Temp Basal is activated and the active temp basal rate is 1.00U/H (85% of current basal pattern).

✧ Normal(U) 1.00/2.00: Normal Bolus is active and 1.00U of bolus delivered | total bolus programmed: 2.00U.

✧ Extended(U) 1.00/2.00: Extended Bolus is active and 1.00U of bolus delivered | total bolus programmed: 2.00U.

✧ C-Normal(U) 1.00/2.00: Normal Bolus of Combo Bolus is active and 1.00U of Normal Bolus delivered | total Normal Bolus programmed: 2.00U.

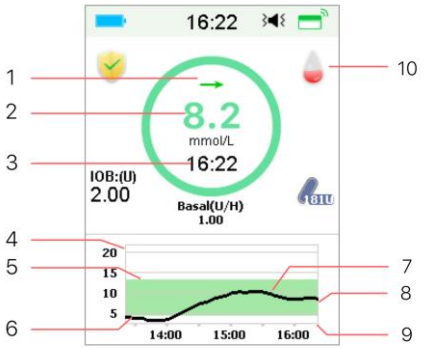
✧ C-Ext.(U) 1.00/2.00: Extended Bolus of Combo Bolus is active and 1.00U of Extended Bolus delivered | total Extended Bolus programmed: 2.00U.

✧ Suspend time remaining 0:15: Suspend is active and basal will resume automatically after 15 minutes.

✧ Insulin left: The actual amount of insulin left in the reservoir.

3.3.3 Sensor Status

You can view the **Sensor Status** on the Home Screen.



1. Trend Arrow
2. The last senor reading or status
3. Time of the last sensor reading
4. The scope of glucose limit
5. High Limit of glucose limit
6. Low Limit of glucose limit
7. CGM Curve
8. Last Glucose point
9. The scope of time
10. Calibration

➢ **Trend arrow**

The trend arrow shows the speed and direction of your Sensor glucose readings.

Stable

Slowly-rising

Rising

Rapidly-rising

Slowly-falling

Falling

Rapidly-falling

No arrow No information

➢ **Calibration Icon**

If your Sensor is on a 24-hour calibration routine, the calibration icon grows fuller as the time for the next calibration.

The next calibration is due in 20 to 24 hours.

The next calibration is due in 16 to 20 hours.

The next calibration is due in 12 to 16 hours.

The next calibration is due in 8 to 12 hours.

The next calibration is due in 4 to 8 hours.

The next calibration is due in 0 to 4 hours.

A calibration is needed now.

If your Sensor is on a 12-hour calibration routine, the calibration icon grows fuller as the time for the next calibration.

The next calibration is due in 10 to 12 hours.

The next calibration is due in 8 to 10 hours.

The next calibration is due in 6 to 8 hours.

The next calibration is due in 4 to 6 hours.

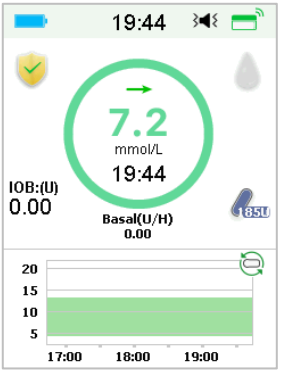
The next calibration is due in 2 to 4 hours.

The next calibration is due in 0 to 2 hours.

A calibration is needed now.

- **Data recovery status icon**

If you disconnect the Sensor for a while and reconnect it, it takes some time to recover the data. The icon indicates that data is being recovered. It disappears when data-recovery is completed.



➢ **Special conditions**

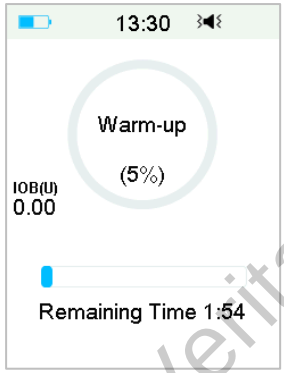
Under normal Sensor conditions, the most recent glucose reading is displayed at the center of the ring on the Home Screen. Under certain conditions, the Sensor reading will be replaced by a Sensor status in the middle of the ring.

Warm-Up- the Sensor is warming up.
ERR - the Sensor shall be recalibrated after 15 minutes.
BG- the Sensor shall be recalibrated now.
??? - No readings.
LOST - Sensor signal has been lost for more than 10 minutes.
High - Sensor glucose is above 22.2 mmol/L (400mg/dL).

Low - Sensor glucose is below 2.2 mmol/L (40mg/dL).
Underlined reading - Calibration overdue. A new meter BG is needed for calibration.

Note:

1) When the Sensor is warming up, a progress bar is displayed at the bottom of Home Screen. It takes 120 minutes for each Sensor to warm up.



2) After you enter a meter BG value to calibrate the Sensor, it may take up to 3 minutes for the Sensor to adjust its readings, with the Sensor glucose reading blinking.

3.3.4 EasyLoop Icon

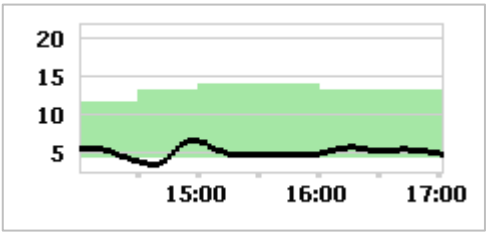
When you turn on Low Suspend or Predict Low switch in **EasyLoop** Menu, the system will be on EasyLoop Icon Mode. The Patch Pump will perform safety checks and automatically stop delivery when the CGM reading triggers the suspend function. There are two kinds of EasyLoop Icon. If Low Suspend or Predict Low happens in different situations, the screen shows different icons.

It will appear when Low Suspend or Predict Low function is available for now or when Low Suspend or Predict Low is triggered and the insulin delivery has been suspended.

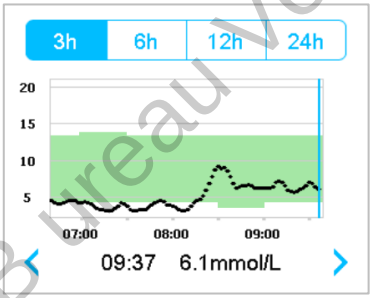
It will appear when Low Suspend or Predict Low function is unavailable for now.

3.3.5 Sensor Graph

The Y-axis of the Sensor graph is featured by four values: 5, 10, 15, 20 mmol/L (90, 180, 270, 360 mg/dL). The X-axis of the Sensor graph presents a period of the last 3 hours.



The Sensor graph can be switched to a landscape screen display. Long tap the Sensor graph for 1 second and the display will turn horizontal. You can see trend graph of your glucose information for the past 3-hour, 6-hour, 12-hour, and 24-hour periods.



- Tap the Sensor graph and move the cursor to spot the glucose values. Use the left and right arrow button to choose the time. The time interval between two values is 2 minutes.
- The time point when a new Sensor is applied will be marked with a green square tag "□". Readings during warm-up phase will not be displayed but marked as "warm-up".
- Glucose value or special status will always be shown in the area below, between the left and right arrow button. Special status includes: calibration error (ERR), no readings (???), warm-up phase (Warm-up),

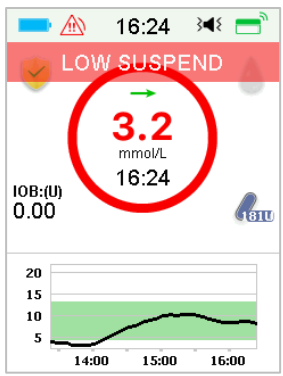
Sensor glucose is above 22.2 mmol/L (400mg/dL). (HIGH) and Sensor glucose is below 2.2 mmol/L (40mg/dL). (LOW).

- After the warm-up phase, the values before the first calibration are replaced by “BG”.
- When the Sensor calibration expires, the reading values will be underlined.
- Calibration will be marked with a red dot “•”.
- The green square blocks in the graph background represent the Low and High limits of glucose.
- In the landscape screen display, tap the Home Key to return to the Home Screen.
- When data is being recovered after sensor-reconnection, you cannot enter landscape screen by long-pressing the graph.
- When you are only using the insulin pump as stand-alone system, the sensor graph displays the blood glucose recorded, and BG inputs will be displayed as red dots “•”.

3.3.6 Alarm Status

Some Alarm status remains even after the alarm is cleared. The following alarms will be displayed on the Home Screen in this case:

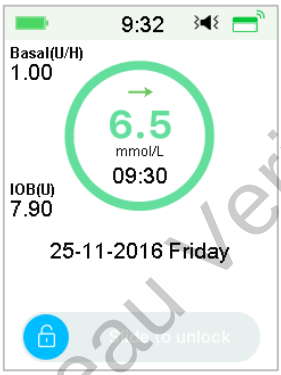
PATCH BATT DEPLETED, PUMP OUT OF RANGE, EMPTY RESERVOIR, PATCH EXPIRED, OCCLUSION DETECTED, PATCH ERROR, AUTO OFF, EXCEEDS MAX TDD, EXCEEDS MAX 1HR, PUMP BASE ERROR, LOW SUSPEND and PRE LOW SUSPEND. For example:



3.4 Lock Screen

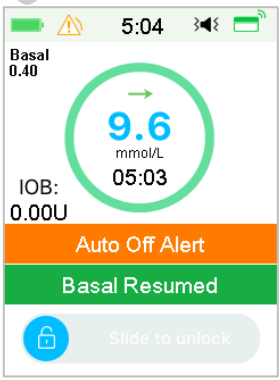
The PDM displays the **Lock Screen** every time you turn it on to view glucose Information, insulin delivery information, alarm/alert information, date and time. You also can customize this screen by editing your username and telephone number. *See "Username" and "Telephone" in Section "Settings" for more information*. The PDM displays the Lock Screen after display timeout. When the screen's gone dark, short press the Power button to activate the Lock Screen.

1. Lock Screen without Alarm, Alert and Reminder



See "Pump Status" for more information about delivering status.

2. Lock Screen when Alarm, Alert and Reminder occurs

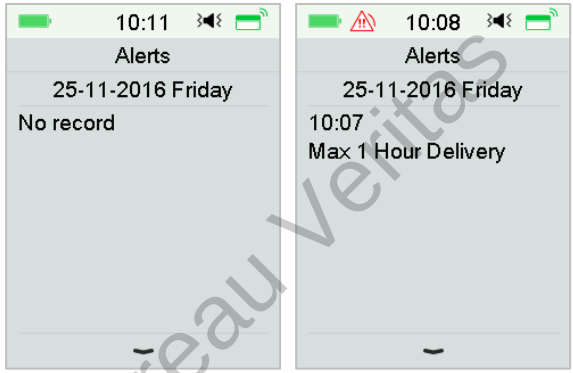


See Chapter "Safety System and Alarms/Alerts" for more information about Alarm, Alert or Reminder status.

3.5 Notification Screen

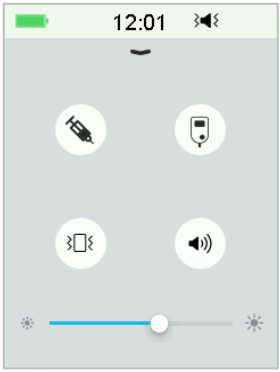
Notification Screen only records alert and alarm notifications which are still effective today. You can slide from top to bottom on Home Screen to call the Notification Screen.

1) If there is no daily Alert and Alarm notification, the screen displays No Record.
2) If there is Alert and Alarm notification, only the still existing Notifications will be displayed.
3) The latest notifications will be displayed on top.



3.6 Shortcut Screen

Shortcut Screen grants you quick access to a few settings including Bolus, Calibration, Audio, Vibration and Brightness. You can slide from bottom to top from Home Screen to call the Shortcut Screen.



1) Calibration Shortcut icon “ ”
2) Bolus Shortcut icon “ ”

- If the Food/Correction Bolus function is turned on, then you’ll enter Food/Correction Bolus by tapping this icon.
- If not, you’ll enter Manual Bolus by tapping this icon.

3) Audio Option icon

There are two icons of Audio Option, each changing after one tap: Audio off “ ”, High volume “ ”.

4) Vibration Option icon

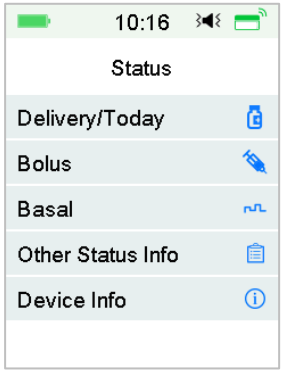
There are two icons of Vibration Option, each changing after one tap: Vibration off “ ”, Vibration on “ ”.

5) Brightness adjustment icon “ ”

There are ten brightness levels, which are increased from left to right.

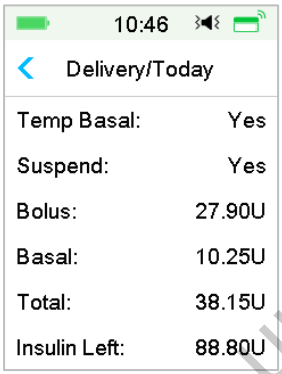
3.7 Status Screen

The **Status Screen** lists the system’s current operating status. Slide from left to right on the Home Screen to open the Status Screen. Slide from right to left or tap Home key on the Status Screen to go back to the Home Screen.

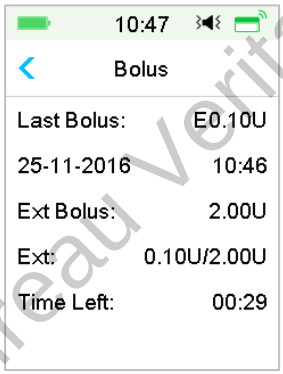


The Status Screen displays the following information.

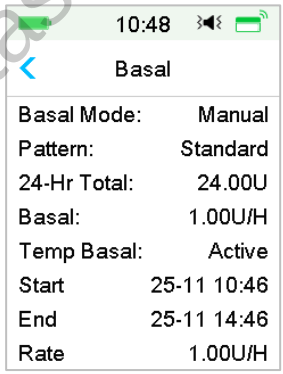
Delivery/Today



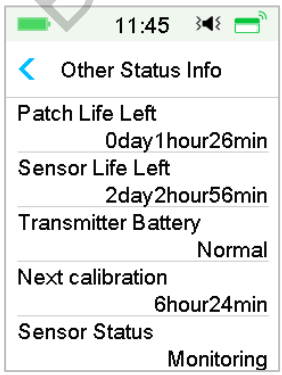
Bolus



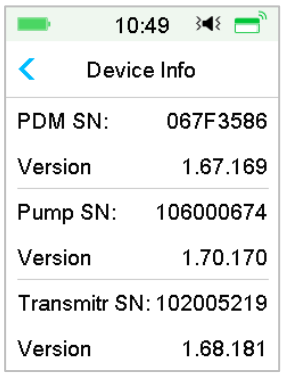
Basal



Other Status Info



Device Info



3.8 Menus

The **Main menu** consists of nine sub-menus: **Bolus**, **Basal**, **Suspend**, **Patch, Sensor**, **History, Events, EasyLoop, Settings.** Slide from right to left on the Home Screen to open Main Menu.

Note: After all insulin delivery is suspended, the **Suspend** icon on the Main Menu turns into **Resume** icon.

3.8.1 Bolus

The **Bolus** menu contains the settings and functions for bolus deliveries. *See Section "Bolus" in Chapter "How to use Patch Pump" for more bolus information, and Chapter "Advanced Pump Features" for advanced bolus settings.*

3.8.2 Basal

On **Basal** menu you can deliver temp basal insulin, select and view different basal pattern. *See Chapter "How to use Patch Pump" and Chapter "Advanced Pump Features" for more information*

3.8.3 Suspend

When no Bolus is being delivered, you can suspend Basal delivery for a set period of time by tapping **Suspend** icon.

When a Bolus is being delivered, with the **Suspend** function you can suspend Bolus or all insulin deliveries (basal and bolus) for a set period of time.

See Section "Suspend and Resume" in Chapter "How to use Patch Pump" for more information.

3.8.4 Patch

You can change your Reservoir Patch and check Pump Base SN on **Patch** menu. *See Chapter "How to use Patch Pump" for more information.*

3.8.5 Sensor

The **Sensor** menu contains calibration and connection functions of the Glucose Sensor. *See Chapter "How to use CGM system" for more information.*

3.8.6 History

On the **History** menu you can review Pump History, Sensor History, PDM History, Event History, BG History and Summary History. *See Section "History" in this chapter for more information.*

3.8.7 Events

The **Events** screen helps you record different events including: blood glucose, insulin injection, carbohydrates, exercise, health, and other information. *See Section "Events" in this chapter for more information.*

3.8.8 EasyLoop

The **EasyLoop** menu is used to set "Glucose Alerts" and "(Pre) Low Suspend" functions. *See Chapter "How to use (P)LGS" for more information.*

3.8.9 Settings

On the **Settings** menu you can edit personal settings of your system. *See Section "Settings" in this chapter for more information.*

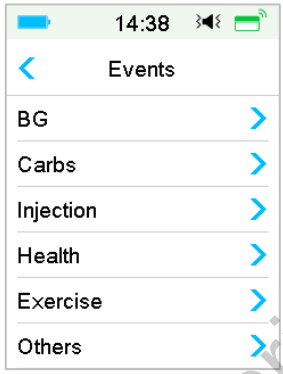
3.9 Events

The A7+ TouchCare® System is able to record different events including blood

glucose, carbs, insulin injection, health condition, exercise and others. This information can help you and your healthcare provider make better decisions about your diabetes management plan.

Go to **Events** Screen. You can select event type you want to record.

Main Menu➔Events



3.9.1 BG Measurement

1. Select **BG** Type in the **Events** screen.

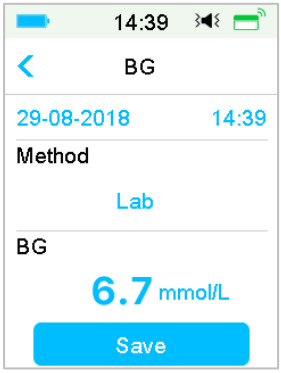
2. Choose the date and time for BG event.

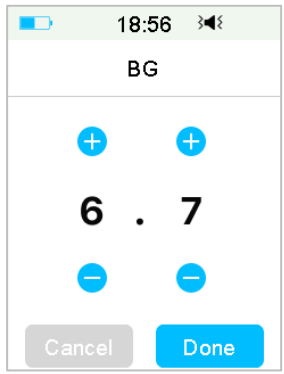
Note: The time refers to blood sampling time.

3. You can choose between BG and Lab Measurements in the **Method** option.

Note: **Lab** is referred to as venous blood glucose tested in laboratory.

4. Tap **BG** to enter BG in the BG row, the default blood glucose is 120 mg/dL (or 6.5 mmol/L). The input range is 40 - 400 mg/dL (or 2.2 - 22.2 mmol/L).

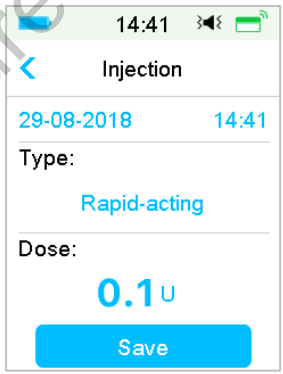




5. When finished, tap **Save** to confirm input. Or press < to cancel.

3.9.2 Insulin Injection

1. Select **Injection** in the **Events** screen.
2. Choose the date and time for insulin injection.
3. Tap **Type** option, you can choose the insulin type between “Rapid-acting”, “Intermediate-acting”, “Long-acting”, “Pre-mixed” and “unselected”.
4. Tap **Dose** value to select the amount of insulin you use. The input range is 0.1-99 units.



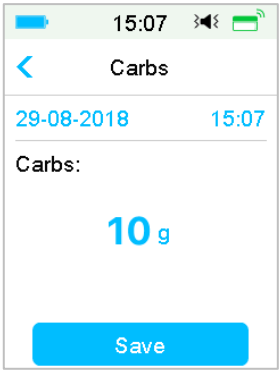
5. When finished, tap **Save** to confirm input. Or press < to cancel.

3.9.3 Carbohydrates Information

1. Select **Carbs** in the **Events** screen.

2. Choose the date and time for carbohydrate intake.

3. Tap **Carbs** value to select the carbohydrates you eat or drink. The input range is 0-200 grams.



4. When finished, tap **Save** to confirm or press < to cancel.

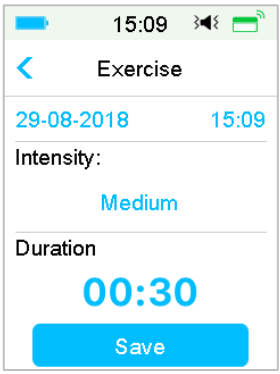
3.9.4 Physical Exercise Information

1. Select **Exercise** in the **Events** screen.

2. Choose the date and time for physical exercise.

3. Tap **Intensity** option to select the intensity of physical exercise. You can choose the intensity between “Light”, “Medium”, and “Heavy”.

4. Tap **Duration** value to select the duration of exercise. The input range is 5 minutes ~ 8 hours, the input increment is 5 minutes.



5. When finished, tap **Save** to confirm input. Or press < to cancel.

3.9.5 Health Information

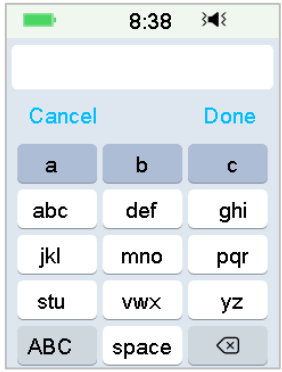
1. Select **Health** in the **Events** screen.
2. Choose the date and time for health information
3. Tap **Health** option to select the physical condition. You can choose the intensity between “Illness”, “Stress”, “High Symptoms”, “Low Symptoms”, “Menstruation” and “Alcohol”.

4. When finished, tap **Save** to confirm input. Or press < to cancel.

3.9.6 Other Events

This section shows how to enter other markers.

1. Select **Others** in the **Events** screen.
2. Choose the date and time for other events
3. Tap **Note** text to enter other event information.



For example, when you want to enter “a”, tap **abc** and select “a”.

Tap **ABC** to switch to capital.

4. Tap and choose the letters for text input.

Note: Use no more than 22 characters to describe an event.

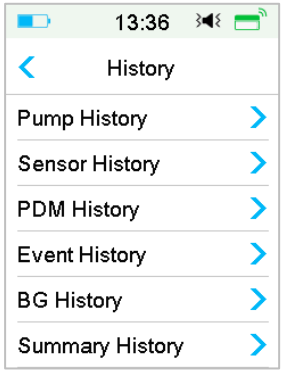
5. When finished, tap **Save** to confirm input. Or press < to cancel.

3.10 History

Your PDM stores insulin delivery history, Sensor history, PDM history, Event history, BG history and Summary history to help you manage diabetes.

Go to the **History** screen.

Main Menu➔History



3.10.1 Pump History

On the **Pump History** menu you can review Pump History. *See Section "Pump History" in Chapter "Advanced Pump Features" for more information.*

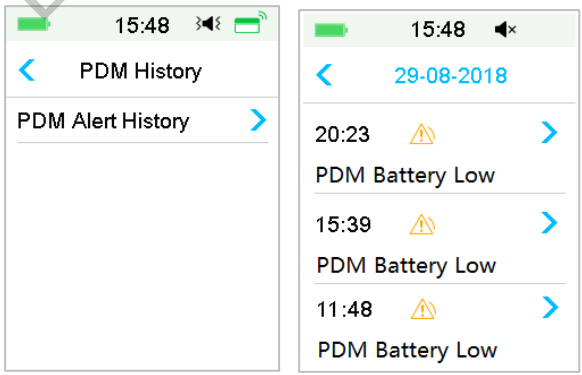
3.10.2 Sensor History

On the **Sensor History** menu you can review Sensor History. *See Section "Sensor History" in Chapter "How to use CGM system" for more information.*

3.10.3 PDM Alert History

PDM History stores PDM Alert history.

Main Menu➔History➔PDM History➔PDM Alert History



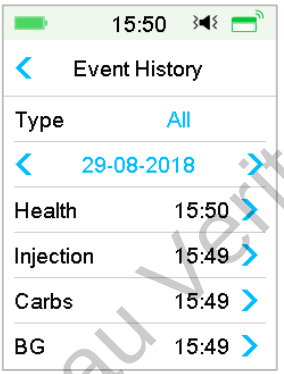
Tap the date to switch between records of different dates. Tap each Alert to view alert detail information. Tap < to return to the previous menu.

See "*Alert Icons*" for more information about how to address alarms and alerts and the meanings of different alarm/alert icons.

3.10.4 Event History

Go to the **Event History** screen.

Main Menu➔History➔Event History

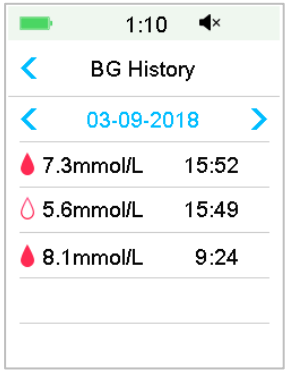


Tap **Type** option to select event type for viewing records accordingly. Tap the date or < , > to switch between records of different dates. Select an event record to view the details.

3.10.5 BG History

Go to the **BG History** screen.

Main Menu➔History➔BG History



BG History contains BG from Calibration , Event BG and BG input during Bolus delivery through Bolus Calculator .

Tap the date or , to switch between records of different dates.

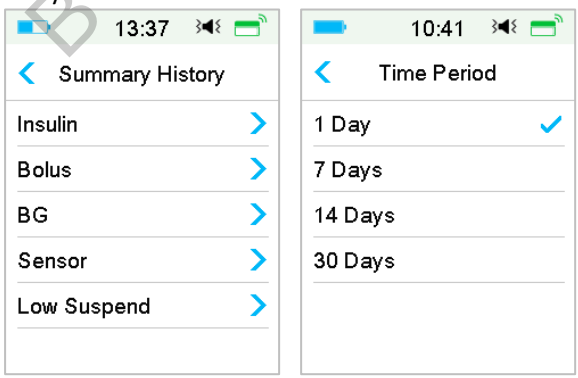
3.10.6 Summary History

The **Summary History** displays a summary of past histories including Insulin History, Bolus History, BG history, Sensor History and Low Suspend History.

Go to **Summary History** screen.

Main Menu➔History➔Summary History

On the top right of each summary screen, select 1 day to view the history data for a single day, or select multiple days (7, 14, 30 days) to view an average result on the selected days .



3.10.6.1 Summary History: Insulin History

See Section "Pump Summary History" in Chapter "Advanced Pump Features" for more information.

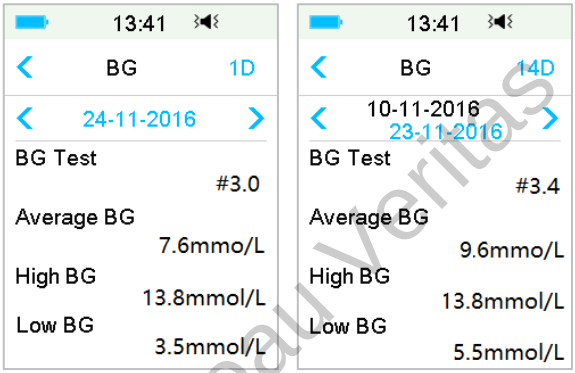
3.10.6.2 Summary History: Bolus History

See Section "Pump Summary History" in Chapter "Advanced Pump Features" for more information.

3.10.6.3 Summary History: BG History

This screen displays the BG result summary history.

Main Menu➔History➔Summary History➔BG



BG Test: Total number of BG readings entered manually on the selected days.

Average BG: Average BG readings on the selected days.

High BG: Highest BG reading on the selected days.

Low BG: Lowest BG reading on the selected days.

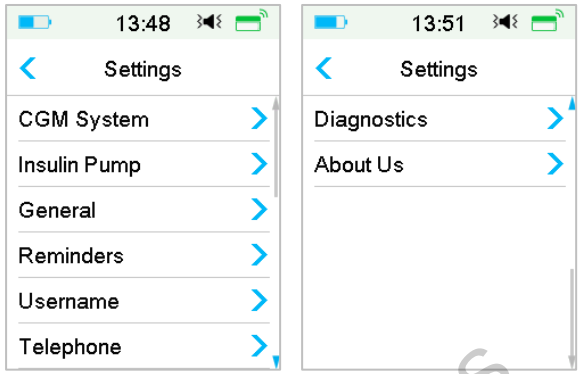
3.10.6.4 Summary History: Sensor History

See Section "Sensor History" in Chapter "How to use CGM system" for more information.

3.10.6.5 Summary History: Low Suspend History

See Section "Low Suspend History" in Chapter "How to use (P)LGS" for more information.

3.11 Settings



3.11.1 CGM System (Optional)

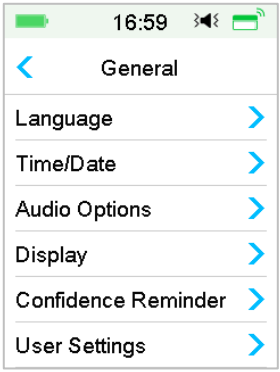
Tap **CGM System** on the **Settings** screen to enter the **CGM System** screen. You can set your Sensor in CGM System Screen. You can turn CGM System on or off, set Transmitter SN, set calibration alert repeat time, set alert silence, set Sensor expiration alert on or off. *See Chapter "How to use CGM system" for more information.*

3.11.2 Insulin Pump

Tap **Insulin Pump** on the **Settings** screen to enter the **Insulin Pump** screen. You can set your Insulin Pump in **Insulin Pump** Screen. *See Chapter "How to use Patch Pump" and Chapter "Advanced Pump Features" for more information.*

3.11.3 General Settings

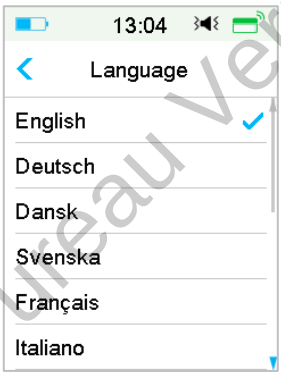
The **General Settings** menu contains: Language, Time/Date, Audio Options, Display, Confidence Reminder, User Settings.



3.11.3.1 Language

You can change your PDM Language.

Main Menu ➔Settings➔General➔Language



3.11.3.2 Time/Date

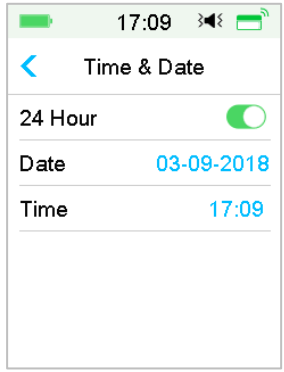
Setting the correct time and date in your PDM is essential to accurate basal insulin delivery and keeping an accurate record of your insulin delivery and other events. You can select a 12-hour or 24-hour clock. Occasionally when you need to change the date and time settings (for example, to adjust for daylight saving time or after resetting the PDM), change the old Reservoir Patch and activate a new patch, disconnect the Sensor and reconnect it.

Note: As a safety feature, you can only change the date and time when there is no active Reservoir Patch or connected Sensor.

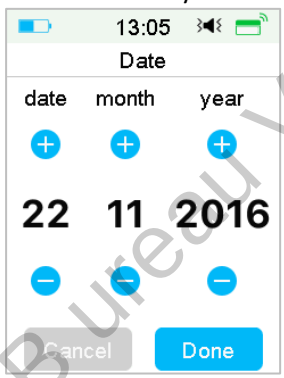
1. Go to the **Time/Date** Setup screen.

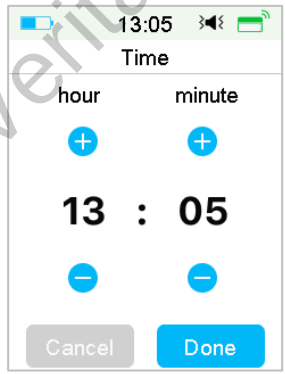
Main Menu ➔Settings➔General➔Time/Date

If you turn the switch on, the time is set as 24-hour-format.



2. Date keyboard and Time keyboard





3.11.3.3 Audio Options

Audio/Vibrate

You can choose one of the four audio options for your alerts and alarms: audio, vibrate, audio and vibrate, or both off. The factory setting is audio and vibrate. Your choice applies to both your PDM and Patch Pump.

If **Audio** is selected, both your PDM and Patch Pump will beep when an alert occurs.

If **Vibrate** is selected, both your PDM and Patch Pump will vibrate when an alert occurs.

If **Audio off/Vibrate off** is selected, your PDM and Patch Pump will not beep or vibrate.

But there are exceptions:

If an alarm is not cleared within 10 minutes, your PDM or/and Patch Pump will make a siren sound until the alarm is cleared.

When “BELOW 3.1mmol/L (BELOW 56mg/dL)” occurs, your PDM emits three-pulse vibration every three minutes. If not cleared within 9 minutes, your PDM will make a siren until the alert is cleared.

See ”Audio Icons” for significance of different audio icons.

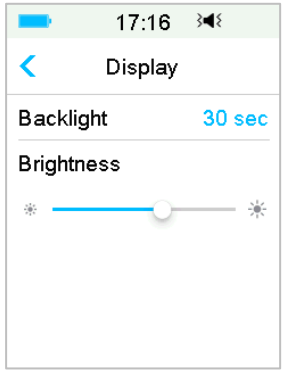
See Chapter “Safety System and Alarms/Alerts” for more information.

Go to **Audio Options** screen.

Main Menu➔Settings➔General➔Audio Options

3.11.3.4 Display

You can set your screen display time between 30 sec, 1 min and 2 min. You can also set the brightness of the screen.



Slide or tap to adjust the brightness, you can choose between 10 brightness levels. Lower level consumes less power.

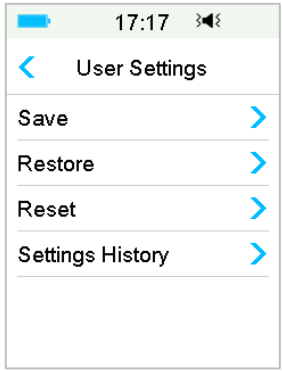
3.11.3.5 Confidence Reminder

If this feature is turned on, the PDM will beep and/or vibrate in response to your instructions, including:

- The beginning and end of a bolus
- The beginning and end of a temp basal
- Basal pattern changed
- Basal edit completed
- Suspend alarm setting takes effect
- Max delivery setting takes effect
- Sensor connected
- Insulin delivery has been suspended
- Basal insulin has been resumed
- Glucose alert set
- Pump alert/alarm set
- Tapping the HOME key

3.11.3.6 User Settings

You can use this feature to save, restore or reset all PDM settings.



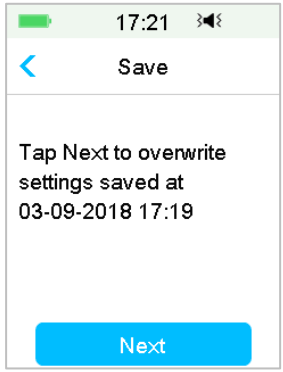
Note: If there is an active Reservoir Patch, **Reset Settings** and **Restore Settings** will be disabled.

- Save

Take these steps to save your current PDM settings:

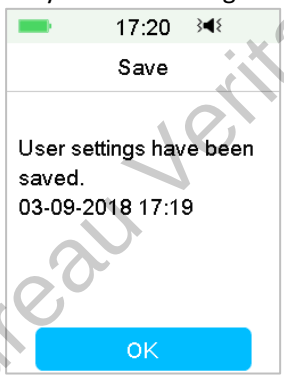
1. Select **Save** in the **User Settings** screen.
2. If this is the first time saving your PDM settings, this screen appears:

If you have saved PDM settings, this screen appears:



Read the instructions on the screen; then tap **Next** to save your current settings.

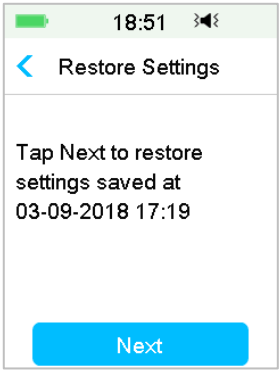
3. This screen indicates that your user settings have been saved.



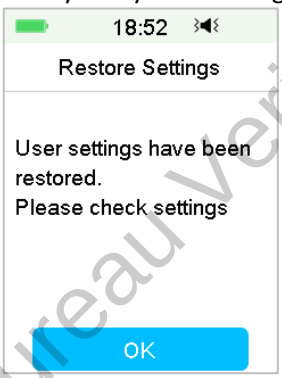
- Restore

Take these steps to restore the most recent PDM settings you have saved to your PDM.

1. Select **Restore** in **User Settings** screen.
2. Read the instructions on the screen, and then tap **OK** to restore the settings.



3. This screen indicates that your user settings have been restored. Tap **OK** to exit the menu and check your system settings.

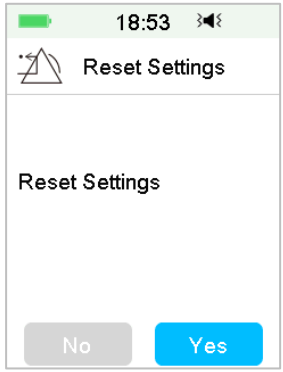


- Reset

Warning: Do NOT reset your PDM settings unless directed by your healthcare provider. If you reset your PDM settings, it will be necessary to reprogram all your personal PDM settings as directed by your healthcare provider.

Take the following steps to reset PDM settings:

1. Select **Reset** in the **User Settings** screen. Then select **Yes**.

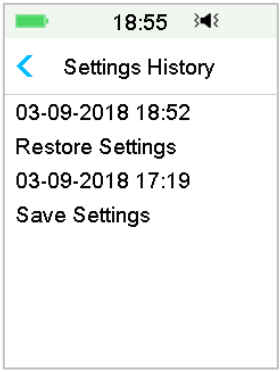


2. Tap **OK**. The PDM will be reset to the factory default settings and restart.

- Settings History

On this screen you can review all recent user settings operation records and the date and time.

1. Select **Settings History** in **User Settings** screen.
2. Slide to scroll up/down to view the entire settings history.

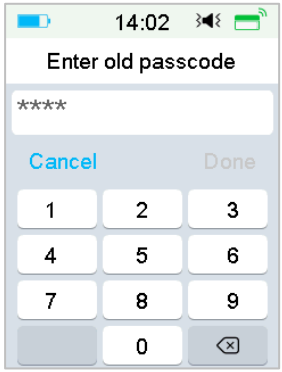


3.11.3.7 Passcode Lock

The passcode lock function is a safety feature that prevents improper operation by unintended user.

Main Menu ➔Settings➔General➔Passcode Lock

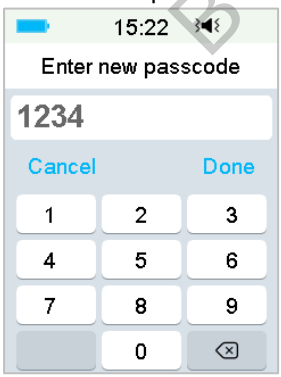
Tap **Set Passcode**, enter the old passcode and then set a new one.

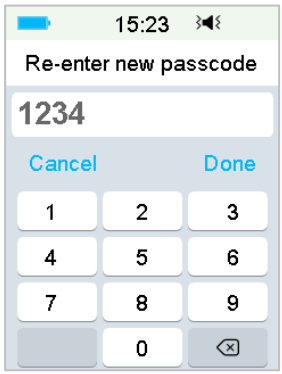


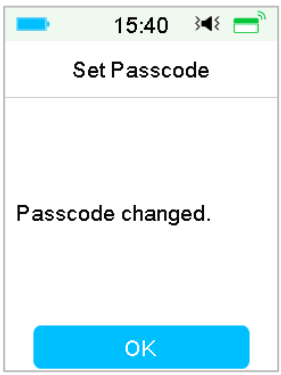
Enter the 4-digit passcode.

Note: The default passcode is 0000.

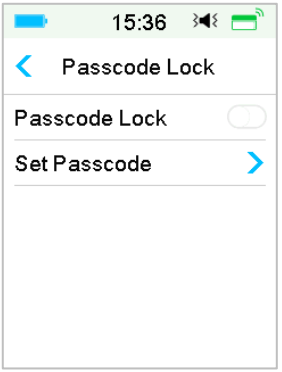
Enter the new passcode twice.







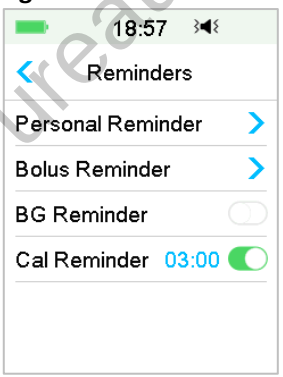
Turn on Passcode Lock and enter the Passcode to activate Lock, the Passcode Lock is only for one-time use, you need to enter the passcode each time you turn on the function.



With the Passcode Lock feature turned on, only the Lock Screen is displayed. You have to enter the correct passcode after you slide to unlock the PDM. Once you unlock the PDM, the Passcode Lock is automatically deactivated.

3.11.4 Reminders

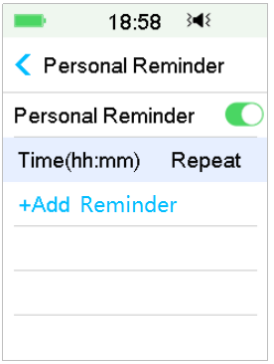
Tap **Reminders** on the **Settings** to enter the **Reminders** screen.



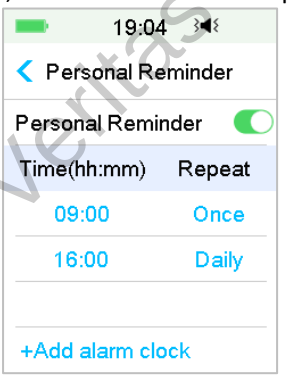
3.11.4.1 Personal Reminder

The factory setting for this feature is off. The personal Reminders can be useful to remind you when to check your blood glucose, eat, bolus, etc.
You can add, delete, or review Reminders when the Personal Reminder option is turned on. Go to the **Personal Reminder** screen.

Main Menu➔Settings➔Reminders➔Personal Reminder



Tap **+ Add Reminder** to add a reminder, choose the time and tap **Done**.

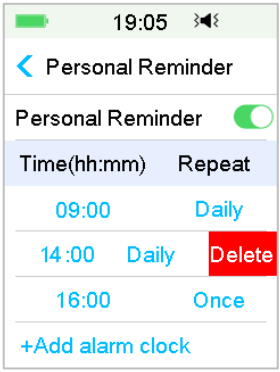


Note:

(1) You can set up to 4 Reminders.

(2) The Reminders will be saved automatically.

Slide from right to left on one reminder, tap **Delete** to delete this segment.



3.11.4.2 Bolus Reminder

See Section "Reminder" in Chapter "Advanced Pump Features" for more information.

3.11.4.3 BG Reminder

See Section "Reminder" in Chapter "Advanced Pump Features" for more information.

3.11.4.4 Cal Reminder

See Section "Calibration Reminder" in Chapter "How to use CGM system" for more information.

3.11.5 Username

1. Go to the **Username** screen.

Main Menu➔Settings➔ Username

2. Tap ------ to enter your username.

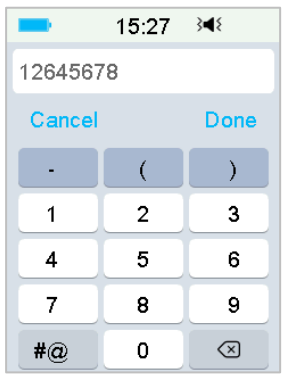
(1) Use the keyboard to enter the username.
For example, when you want to enter “a”, tap **abc** key, “a”,”b”,”c” appear on the top of the keyboard , then select “a”.
(2) When finish, tap **Done**.
(3) Tap the name in blue to edit Username again.
Note: You can enter as many as 18 letters including spaces. Your username will be displayed on the Lock Screen.
The PDM displays the username on Lock Screen to help you identify your own PDM. You can always confirm that the username is correct before using the PDM.

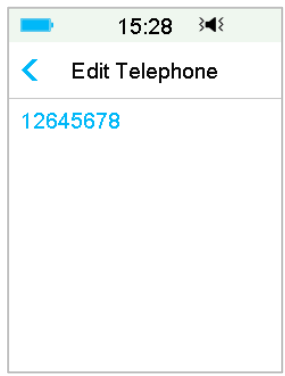
3.11.6 Telephone

1. Go to the **Telephone** screen.

Main Menu➔Settings➔ Telephone

2. Tap ------ to enter your telephone number or emergency-call number.





(1) Use the keyboard to enter the telephone number .

(2) When finish, tap **Done**.

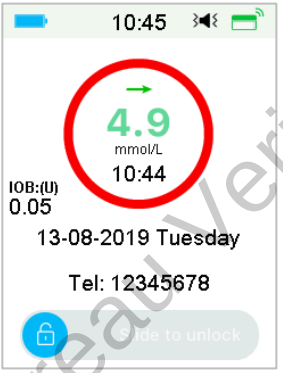
(3) Tap the number in blue to edit telephone number again.

Note: You can enter as many as 18 letters including spaces.

The PDM displays the **Telephone number** on Lock Screen, which works in two optional ways:

1. to help you find your PDM if your PDM is lost.

2. to display your emergency-call number (family members, doctor, healthcare center).



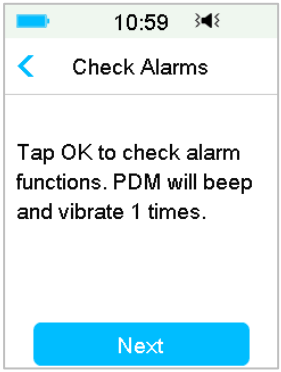
3.11.7 Diagnostics

The function Diagnostics helps you check if the PDM beeps and vibrates properly.

1. Go to the **Diagnostics** screen.

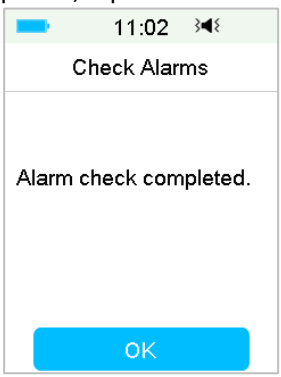
   Main Menu➔ Settings ➔ Diagnostics

2. Select **Diagnostics,** then tap **Next**.



3. The PDM will beep three times and vibrate one time while the screen suggests checking alarms.

4. When checking is completed, tap **OK** to return to the last menu.



Warning: If the PDM fails to beep or vibrate, call customer support. To continue using the PDM may put your health at risk.

Note: Your PDM uses battery power to beep and vibrate. Checking alarms often will result in reduced battery life and the "CHARGE PDM NOW" Alarm may appear sooner than expected.

3.11.8 About Us

Here you can see the Company name, PDM SN, PDM program version, and code.

3.12 Troubleshooting

This section contains procedures and information to help you understand and address conditions that might occur with A7+ TouchCare System. It will give a simple analysis, and some detailed answers, please look for it in the corresponding sections.

What protocol does the A7+ TouchCare System use to communicate?

The Bluetooth protocol.

Bluetooth Low Energy (BLE) in specific.

Can I take a sauna with a PDM?

No.

The operating temperature range for the PDM is +5°C ~ +40°C.

Charging the PDM

We recommend that you charge the PDM when a PDM BATTERY LOW alert happens.

PDM does not power on after you press the Power button:

1. PDM battery is too low. Charge the PDM.

2. PDM is outside of its operating temperature range. Move the PDM to a temperature between +5°C ~ +40°C and then try to power it on.

4 How to use Patch Pump

4.1 Change the reservoir patch

The Reservoir Patch requires replacement and shall not be reused. The Reservoir Patch should be replaced approximately every 2-3 days or as directed by your healthcare provider.

Warning: Do NOT attempt to apply or use a Patch Pump before you have been trained by your healthcare provider. Use of the device with inadequate training or improper setup could put your health and safety at risk. Your healthcare provider will help you set up and apply your first Patch Pump if you are a first-time A7+ Patch Pump user.

Warning: Use an aseptic technique when you are preparing, filling, attaching, or removing a Reservoir Patch. This means to:

1. wash your hands with soap and water
2. clean the insulin vial with an alcohol wipe
3. clean the infusion site with an alcohol wipe
4. keep sterile items away from any possible germs

Warning: Always check BG one to two hours after changing the Reservoir Patch. Remember to check the insulin level in your Reservoir Patch two hours before going to sleep. Change the Reservoir Patch if it doesn't have enough insulin to cover your night time insulin needs.

4.1.1 Before Changing the Reservoir Patch

You will need these items before you begin:

- Vial of rapid-acting U-100 insulin
- An unopened Reservoir Patch
- A Pump Base
- Alcohol wipe(s)
- A 2mL disposable sterilized syringe with a capped needle

Warning: Using an insulin type other than rapid-acting U-100 insulin, or using insulin that is expired or inactive, may lead to hyperglycemia or diabetic ketoacidosis (DKA). Do NOT use insulin that is cloudy because it may be inactive.

Note: The syringe provided by Medtrum matches the fill port on the Reservoir Patch. Other syringes and needles meeting the following specifications are also permitted.

Specifications of syringe:

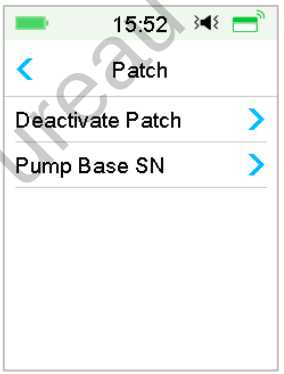
- *Reservoir volume: 2.0 mL*
- *Needle size: 26G*
- *Needle length: 8 mm (0.31")*
- *Make sure that the syringe with fill needle has been properly sterilized.*

Warning: A Reservoir Patch that has not been deactivated properly may continue to deliver insulin as programmed, putting you at risk of over infusion and possible hypoglycemia. Do NOT apply a new Reservoir Patch before you have deactivated and removed the old Reservoir Patch.

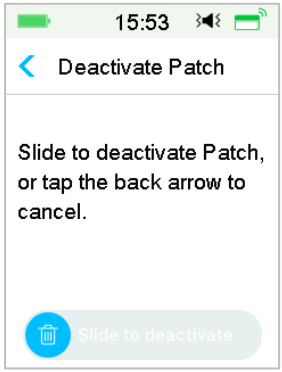
4.1.1.1 Deactivate the Current Reservoir Patch

Warning: You must deactivate the current Reservoir Patch before you remove it from your body and disconnect the Pump Base from the Reservoir Patch.

Main Menu➔ Patch➔ Deactivate Patch.



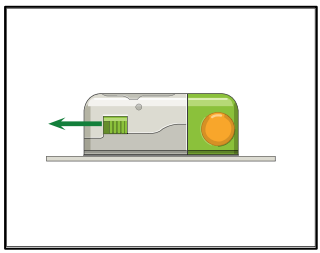
1. Slide to Deactivate current Reservoir Patch. Tap < or Home Key to cancel this operation.

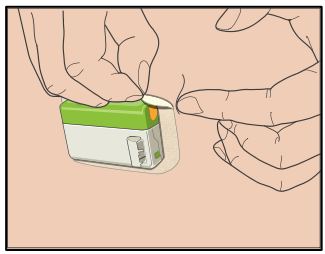


2. Several seconds later, you will see a message showing that the Patch has been deactivated.

4.1.1.2 Remove the Current Reservoir Patch

1. After the Reservoir Patch is deactivated, press the needle release button on the side of the Reservoir Patch, and slide it to the direction of the arrow to retract the needle. Gently lift the edge of the adhesive tape from your skin and remove the entire Reservoir Patch.

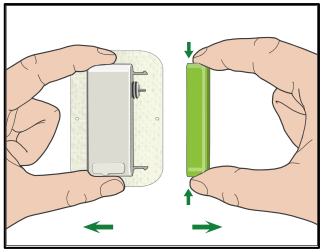




Note: To avoid possible skin irritation, remove the Reservoir Patch slowly and gently. If any adhesive remains on your skin, remove it with soap and water.

Warning: Check the infusion site for signs of infection.

2. Press and hold the two release buttons on both ends of the Pump Base and pull the Pump Base off the old Reservoir Patch. Discard the old Reservoir Patch according to your local waste disposal regulations.



Warning: Do NOT discard your Pump Base. It is reusable.

4.1.1.3 Enter Pump Base SN

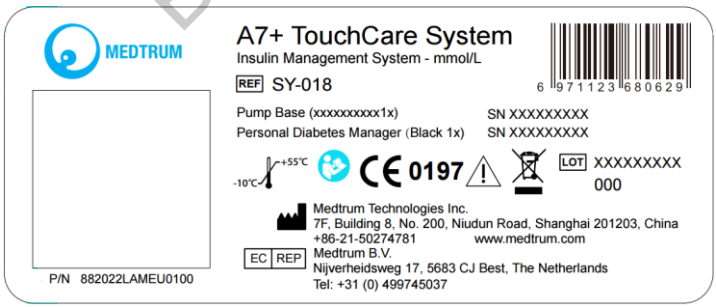
Before activating a new patch, make sure that the pump Base serial number has been entered into your PDM.

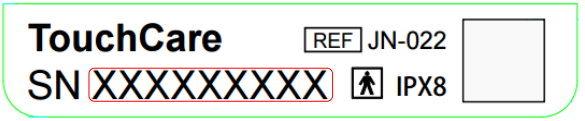
Main Menu➔Patch ➔Pump Base SN

Note: Don't forget to update the SN if you change to a new Pump Base.

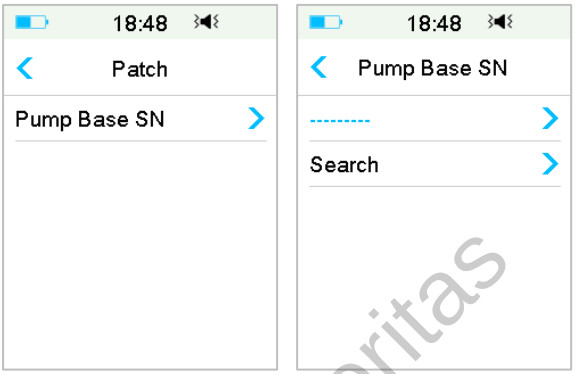
Note: You can only change the Pump Base SN when there is no active Reservoir Patch.

You can find Pump Base SN on the product box or on your Pump Base.



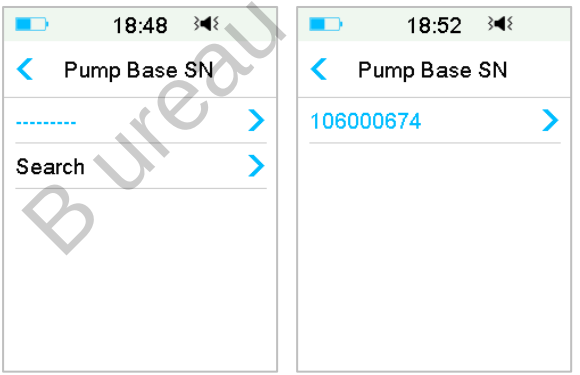


1. You can either enter SN manually or search for the SN if it is the first time you enter the SN.

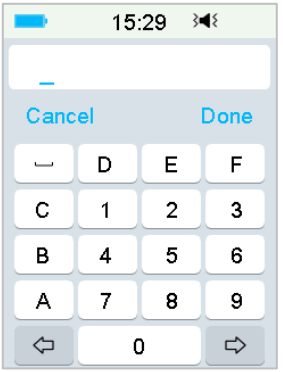


2. You can only enter SN manually if you want to update the SN.

Enter SN manually



Tap --------- or the existing Pump base SN, you will see the following screen. Then enter the SN to your PDM and tap **Done**.

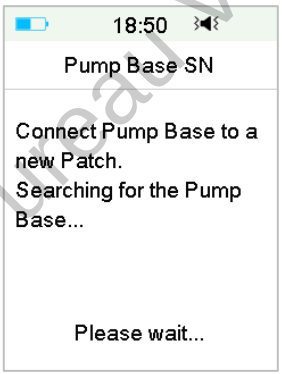


Note: If it is an 8-digit SN, enter space " ␣ " at the end.

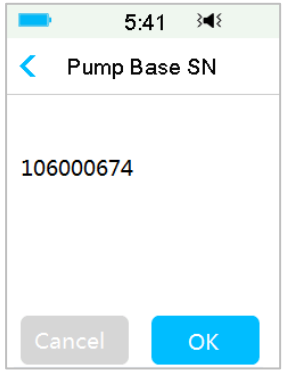
Search for the SN

You can select **Search** to search for the SN if it is the first time you enter the SN.

Make sure that your Pump Base is connected to a new Reservoir Patch and move the PDM closer to your Pump before searching for the SN. *See Section "Connect the Pump Base to a New Reservoir Patch" for more information.*

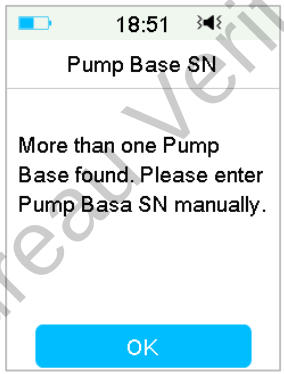


If your PDM finds one Pump, the Pump Base SN appears on the screen. Check if it matches the SN printed on your Pump Base. If it is correct, tap **OK**.



If your PDM finds multiple Pumps, the SNs won't be displayed to prevent you from selecting the wrong SN.

Tap **OK** to go back to Patch Menu, then select "---------" to enter the SN manually.

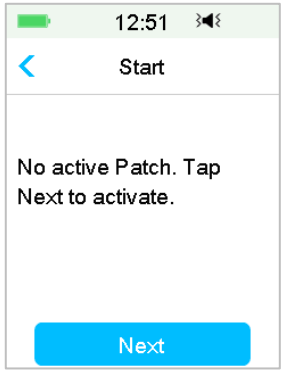


If your PDM does not find a Pump, make sure that your Pump Base is connected to a new Reservoir Patch, move the PDM closer to your Pump, and search again or enter the SN manually.

4.1.2 Activate a New Reservoir Patch

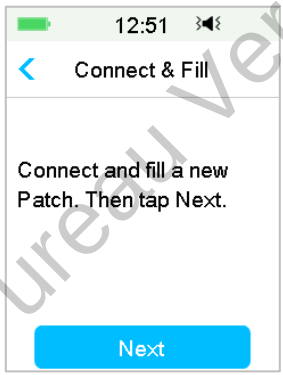
When there is no old Patch activated or when the old Patch has been removed, you can go to Patch Menu to activate a new patch. Make sure that the pump Base serial number has been entered into your PDM correctly.

Main Menu➔Patch➔New Patch



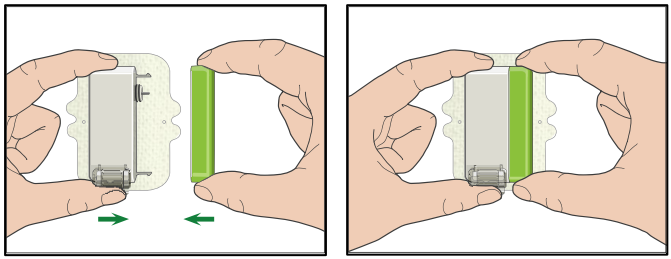
4.1.3 Connect the Pump Base to a New Reservoir Patch

1. Tap **Next** on your PDM and you will see the following message on the screen.



Warning: Do NOT use a Reservoir Patch if its sterile package has been damaged or already opened, or if the Reservoir Patch has expired, or if the Reservoir Patch is damaged in any possible way.

2. Place your thumb and index finger on the Pump Base. Hold the new Reservoir Patch with your other hand. Insert the hooks and connecter on the Reservoir Patch all the way into the slots of the Pump Base.



3. The Pump performs a series of safety checks immediately after the two parts are connected. The safety checks take about twenty seconds. The indicator light flashes in the order of blue, green, yellow, and red, and the Pump beeps four times.

Warning: If the Pump fails to beep or the indicator light fails to flash, call customer support. It may put your health at risk if you continue to use the Pump.

Warning: If a single fault condition occurs, the indicator light flashes red, and the Pump cannot proceed to the next step, call customer service.

4.1.4 Fill the New Reservoir Patch

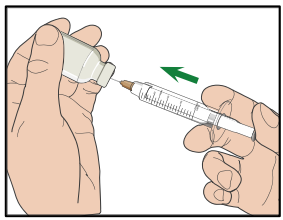
Warning: If your insulin is stored in the refrigerator, wait until the insulin reaches room temperature before you fill the reservoir. Using cold insulin could produce air bubbles in the reservoir. While filling the reservoir, be sure to remove air bubbles.

Warning: When you are filling the Reservoir Patch, make sure that it is at least 30 cm (12 inches) from any magnetic objects, such as magnets, mobile phones, and other Reservoir Patches. The Patch Pump will detect the volume of insulin in the reservoir once it is filled, and if the Patch Pump is in a magnetic field, the volume detected can be inaccurate.

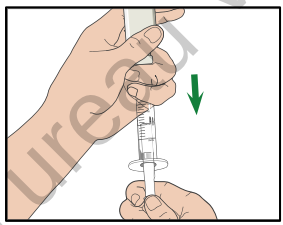
Take the following steps to fill a new Patch:

1. Clean the top of the insulin vial with an alcohol wipe.
2. Remove the protective cap from the needle. Keep the cap.

3. With the help of your healthcare provider, decide on the amount of insulin (70 U-200 U) you need to insert into the Reservoir Patch.
4. Draw air into the syringe up to the amount of insulin you need.
5. Insert the needle into the insulin vial and push down on the plunger to pressurize the vial.



6. While still holding the plunger rod, flip the vial over so the vial is on top, and then slowly pull down on the plunger to fill the syringe with the number of desired units. Gently tap the side of the syringe to make air bubbles rise to the top of the syringe. Slowly push up on the plunger just enough to remove air bubbles from the syringe.

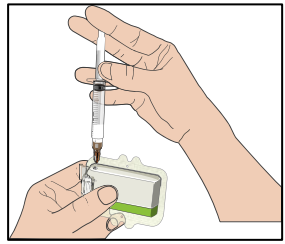


Warning: Avoid using insulin from more than one vial because this may introduce air into the syringe.

7. With the vial down, hold the syringe. Pull straight up to remove the syringe needle from the vial, and then insert it perpendicularly into the insulin fill port on the side of the Reservoir Patch.

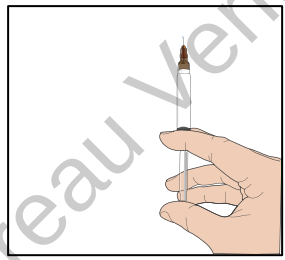
Warning: Make sure that you insert the syringe perpendicularly rather than at an angle into the insulin fill port.

8. Keep the syringe vertical to the Patch Pump, and the needle inside the fill port, pull back on the plunger until it is fully retracted. This will remove any residual air from the reservoir. Bubbles will rise toward the plunger.

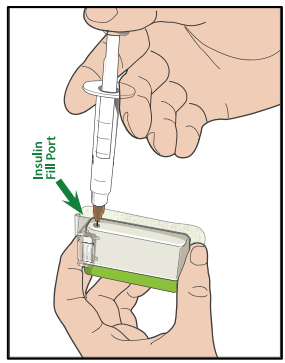


9. Make sure that the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position, but it will NOT push any air back inside the reservoir.

10. Withdraw the needle from the fill port. Turn the syringe upright and pull on the plunger. Flick the syringe to make sure that any air bubbles rise to the top. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle.



11. Re-insert the needle in the fill port and slowly fill the reservoir with insulin. It is normal to feel some back pressure as you slowly press on the plunger.



Warning: Do NOT use a Reservoir Patch if you hear a crackling noise or feel abnormally strong resistance when you press down on the plunger. These conditions can result in not delivering enough insulin.

Warning: Do NOT inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.

Warning: Do NOT fill the Reservoir Patch when you are wearing it. Doing so may cause serious harm to your life and health.

12. Hold the plunger in position while you remove the needle from the reservoir. Place the protective cap back on the needle. Safely dispose of the syringe in a waste container according to local waste disposal regulations.

Warning: Use your Reservoir Patch right after you fill it. Do NOT store a Reservoir Patch filled with insulin. Reservoir Patch shall be used soon after being filled with insulin.

13. After you fill the Reservoir Patch, Press OK to continue.

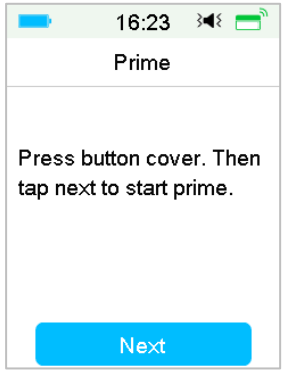
Note: Call customer support if you have filled the Reservoir Patch with more than 70 units but the reservoir volume icon is still empty.

Note: After filling the Reservoir Patch with insulin, you should change the Reservoir Patch within 3 hours. To Reminder that the Reservoir Patch has been filled and shall be used, the PDM will beep and/or vibrate every 10 minutes. If you do not apply the Reservoir Patch on your body within 3 hours, you must deactivate and discard it.

Note: Once a Reservoir Patch (connected with a Pump Base) is activated and communicates with a PDM, it can only receive commands from that PDM, not from any other.

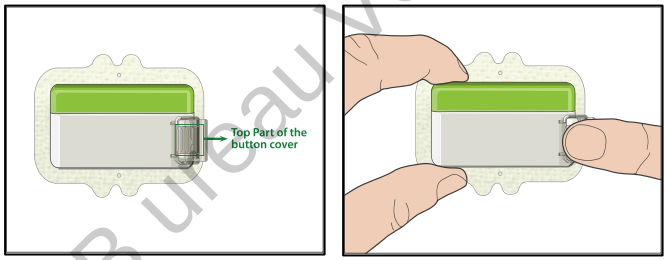
4.1.5 Prime the Pump

Once the Reservoir Patch is filled with an appropriate amount of insulin (70 U-200 U), tap **Next** on your PDM and you will see the following message on the screen.

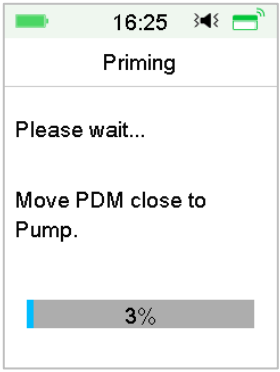


Hold the Patch Pump on a clean flat surface with one hand, and with the other hand, press the top square part of the button cover all the way until you hear a click, indicating the needle button is locked in place by the two hooks on the button cover.

Warning: Do not start priming before the top square part of the button cover is fully pressed.



After that, tap **Next** on your PDM to prime the Pump.



Warning: Do NOT remove the button cover before priming is completed.

Once completed, the next screen "Attach and Insert" appears, and the Pump vibrates three times.

Warning: If the Pump fails to vibrate, call customer support. To continue using the Pump may put your health at risk.

4.1.6 Select and Prepare the Infusion Site

The place on your body where you attach the Pump is important for the success of your therapy. Discuss the best infusion sites with your healthcare provider.

When choosing the location for the Pump, consider the following:

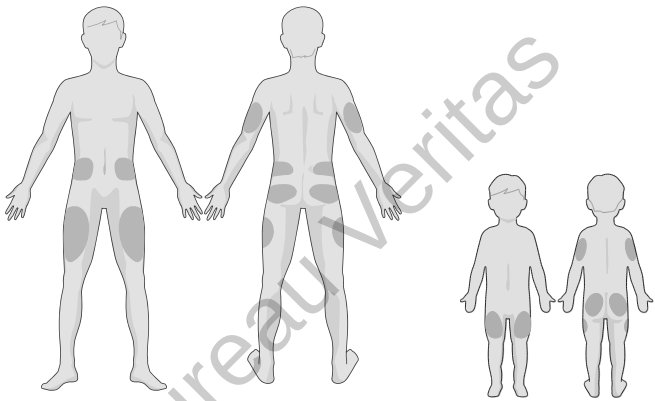
- You can comfortably reach the Pump.
- You apply the Pump to a flat area of skin with adequate subcutaneous fat.

- The area stays flat during normal daily activities without bending or creasing.

When choosing the location for the Pump, avoid the following:

- Areas that are constrained by clothing, such as the belt line or waist.
- Curved or rigid areas due to muscle or bone.
- Areas that involve rigorous movement during exercise.
- Areas of skin with scars, tattoos, or irritation.
- 5.0 cm (2 inches) around the navel.
- Areas with excess hair.

Body areas (shaded) suitable for infusion sites:



If you choose an infusion site on your abdomen, hip, back, or buttocks, apply the Patch Pump horizontally.

If you choose an infusion site on your upper arm or thigh, apply the Patch Pump vertically.

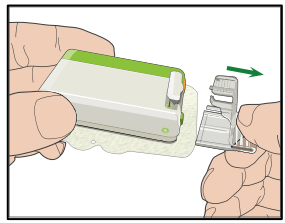
Warning: Change the site each time you apply a new Reservoir Patch. Be sure to rotate the infusion sites so that they are not overused. A new infusion site should be at least 2.5 cm (1 inch) away from the last site.

Practice using an aseptic technique as described at the beginning of this chapter. Clean the area with an alcohol wipe where you will attach the Pump. Let the area dry before applying the Pump.

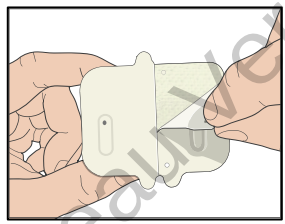
Note: If you have sensitive skin or your skin gets irritated, contact your healthcare provider.

4.1.7 Attach the Patch Pump

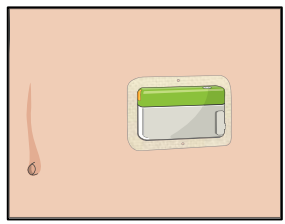
1. Remove the button cover.



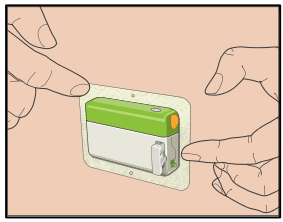
2. Peel off the adhesive liner from the bottom of the Reservoir Patch. Remove the liner and expose the adhesive.



3. Avoid touching the stickiness of the adhesive pad, press the Pump against the skin at the selected infusion site.



4. Hold your Pump in place for 5-10 seconds. Run your finger around the entire edge of the adhesive pad to make sure that it is securely attached to your body.

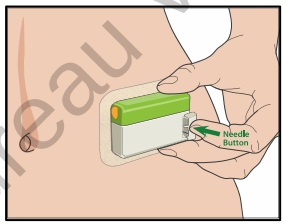


Note: The adhesive of the Reservoir Patch keeps the Patch position secured for up to 3 days. Several products are available to enhance adhesion if necessary. Ask your healthcare provider about these products. Avoid getting body lotion, creams, or oil near the infusion site because it may loosen the adhesive.

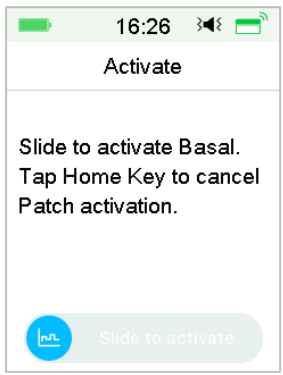
Note: The adhesive is designed for one-time use. Once removed, a Reservoir Patch cannot be reapplied.

4.1.8 Start Insulin Delivery

1. Press the needle button with one quick motion to completely insert the needle below your skin until the button locks in place.

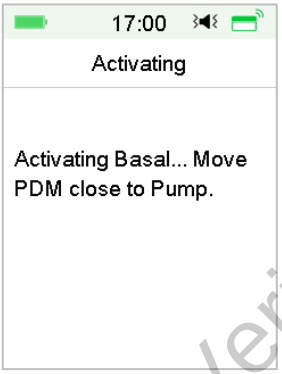


2. Press **Next** after you insert the needle, and the following screen appears.



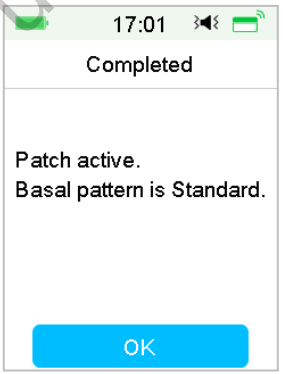
Warning: Check the infusion site and needle after insertion to ensure that the needle has been properly inserted. If the needle is not properly inserted, hyperglycemia may ensue.

3. Slide to activate basal delivery if the needle is properly inserted. Or tap Home Key if you find a problem with the needle, then the PDM will instruct you to discard the Reservoir Patch.



Warning: You should check the area around the Reservoir Patch at regular intervals for possible redness, irritation, and inflammation. If you find infection, immediately remove the Reservoir Patch and apply a new one in a different location.

4. Now your new Reservoir Patch is activated.



Warning: Do NOT disconnect the Pump Base from the Reservoir Patch while the Patch Pump is connected to your body.

Warning: Check the infusion site frequently for improper placement and leaks that can result in inadequate infusion. You can also check blood glucose level to ensure normal infusion.

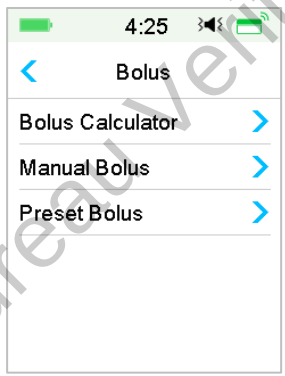
4.2 Bolus

A bolus dose is insulin you deliver to cover meals or snacks, or to correct high blood glucose. Consult your healthcare provider about how to set your bolus dose.

Your A7+ TouchCare® System provides three bolus types: Normal Bolus, Extended Bolus and Combo Bolus. This section gives instructions for a Normal Bolus. *See Chapter "Advanced Pump Features" for more information about Extended Bolus and Combo Bolus.*

Go to the **Bolus** screen.

Main Menu➔Bolus

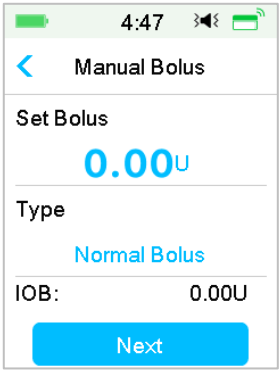


Note: When the Bolus Calculator is switched off in the Settings, Bolus Calculator will not appear in the Bolus menu. *See Chapter "Advanced Pump Features" for more information.*

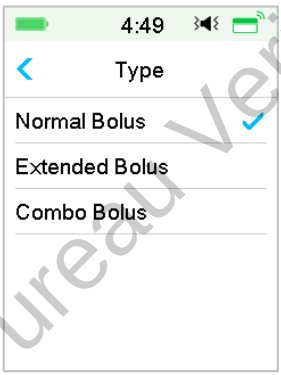
4.2.1 Normal Bolus

1. To deliver a Normal Bolus, go to the **Manual Bolus** screen.

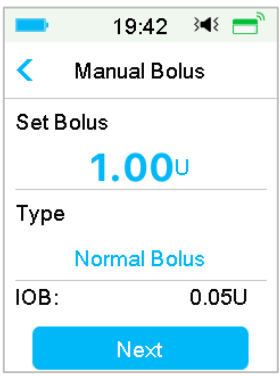
Main Menu➔Bolus➔Manual Bolus



2. Set your bolus amount.
3. Select Normal Bolus type. Bolus type is Normal Bolus, Extended Bolus or Combo Bolus.

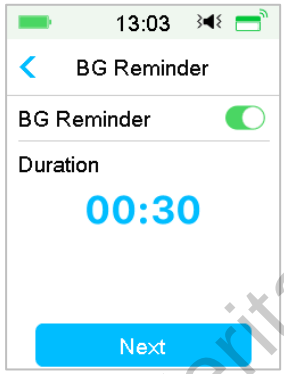


4. Tap **Next** to confirm if the bolus setting is correct.

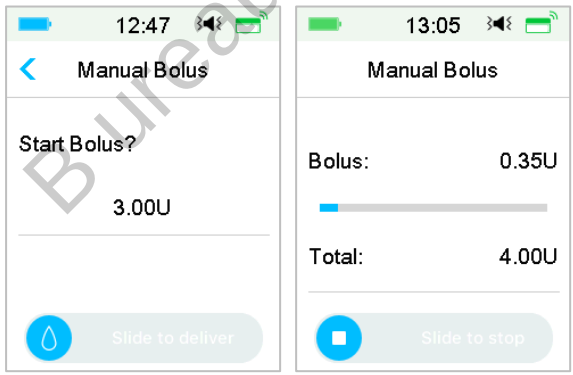


Note: You can set a bolus dose between 0 and the Max Bolus. When an extend Bolus is already being delivered, you can only choose a Normal Bolus.

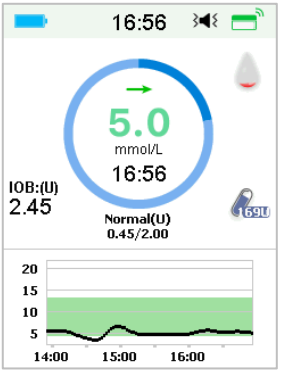
Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. *See Section "BG Reminder" in Chapter "Advanced Pump Features" for more information.*



5. **Slide to deliver** the bolus. As the Normal Bolus is being delivered, the amount shown on the screen will add up to the actual bolus amount which is delivered.

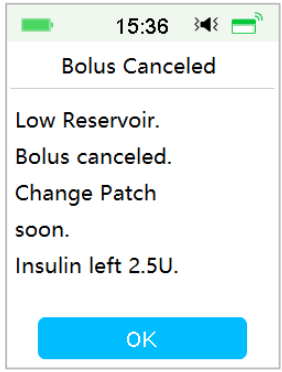


Note: As the bolus is being delivered, you can tap Home Key to return to the Home Screen. The circular progress bar indicating that a bolus is being delivered is displayed on the Home Screen.

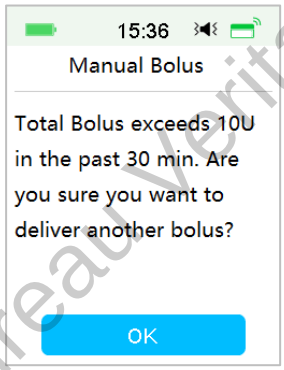


6. You can cancel an active Normal Bolus in the **Suspend** Menu even after insulin delivery has started. **Slide to Stop** to cancel the bolus. An on-screen message will tell you how much insulin has been delivered. Tap **OK** to go back to the Home Screen.

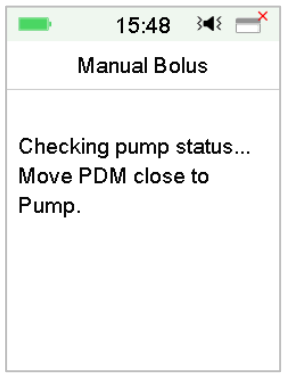
7. If the delivery value given exceeds the remaining insulin amount in the Reservoir, the screen will show the following reminder:



8. If the total Bolus in the last 30 minutes has already exceeded 10 U, the screen will show the following reminder:



9. If connection between PDM and Pump failed during delivery, the screen shows “Checking Pump status”, the delivery cannot be cancelled.



When insulin delivery is completed, PDM display returns to the Home Screen automatically.

10. When a Normal Bolus is being delivered, if the PDM screen goes dark as a result of display timeout, you can slightly shake the PDM to light up the screen again.

4.2.2 Max Bolus

The maximum bolus (Max Bolus) is a safety feature that limits the amount of insulin to be delivered in a single bolus. The factory setting is 10 units. You can set the limit from 0 to 30 units. Please set the maximum bolus with the help of your diabetes team.

Go to the **Max Bolus** screen to set the max bolus.

Main Menu ➔Settings➔Insulin Pump➔Bolus Setup➔Max Bolus

4.3 Basal

Basal rate is the rate at which your Patch Pump infuses small doses of insulin to cover your body's insulin needs between meals. Basal rates usually take up about 50% of the total daily dose (TDD) of insulin.

A basal pattern contains at least one basal rate for a 24-hour period. A selected basal pattern is exercised daily. You can set up to 48 basal rates for any basal pattern. *See "Select a Basal Pattern", "Temp Basal", "Preset Temp Basal" in Chapter "Advanced Pump Features" for more information.*

4.3.1 Your Basal Settings

You must program your basal settings before you deliver any basal insulin. Keep a written record of your basal settings. You can program up to 8 basal patterns with the A7+ TouchCare® System. Having more than one pre-set basal pattern makes it easy for you to switch between patterns to cater to your different needs such as weekends, weekdays, shift work, and menstruation.

- **Standard:** Your normal basal pattern that supports your usual day-to-day activity.
- **Exercise:** Your exercise basal pattern that supports your exercise activity.
- **Holiday:** Your holiday basal pattern that supports your holiday activity.
- **Sick:** Your sick basal pattern that supports your sick day activity.
- **Pattern A/B/C/D:** Basal patterns for you to define, such as menstruation, etc.

We recommend that you set your basal rates with the assistance of your healthcare provider.

Go to the **Basal Setup** screen.

Main Menu➔Settings➔Insulin Pump➔Basal Setup

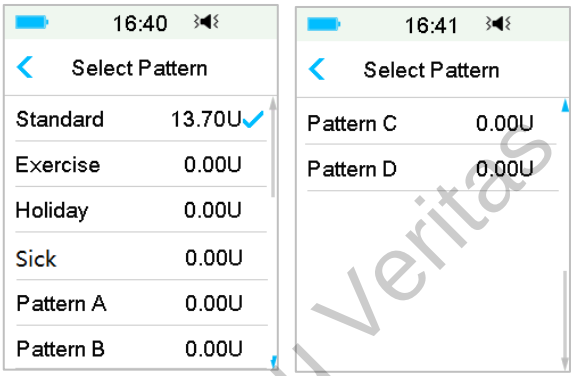
4.3.2 Edit Your Standard Basal Pattern

We recommend that you get acquainted with the Standard basal pattern before using multiple basal patterns. You can set up to 48 basal segments in the Standard basal pattern.

Go to the **Edit Basal** screen.

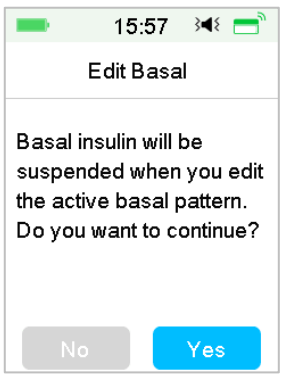
Main Menu➔Settings➔Insulin Pump➔Basal Setup➔Edit Basal

1. Select the **Standard** pattern to edit it.

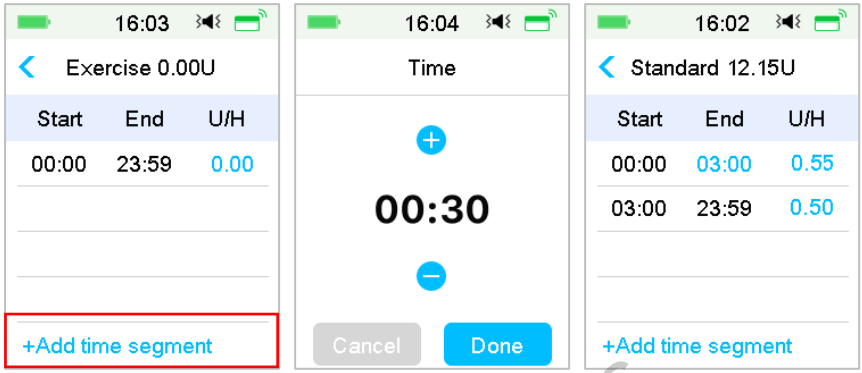


Note: The active basal pattern is check-marked. Select the desired pattern and slide to activate it.

Note: As a safety feature, the system suspends basal delivery when you are editing an active basal pattern, and resumes delivery after the editing is done. When a temporary basal is in process, the check-marked pattern cannot be edited.



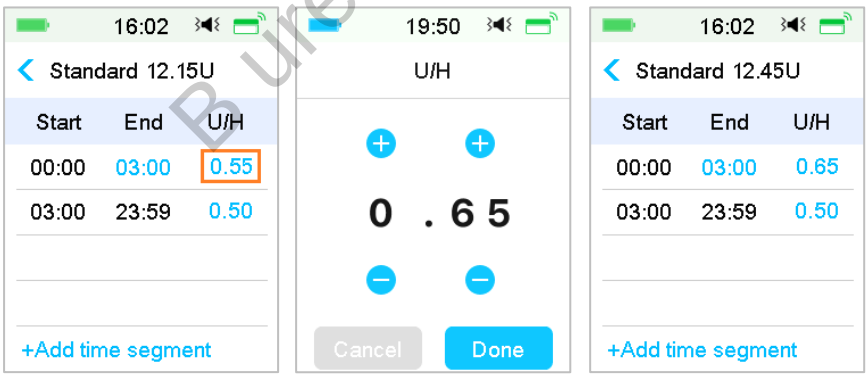
2. The edit screen appears. Tap **+Add time segment** to add a new segment. Enter the end time for this segment. Then tap **Done**.



Note:

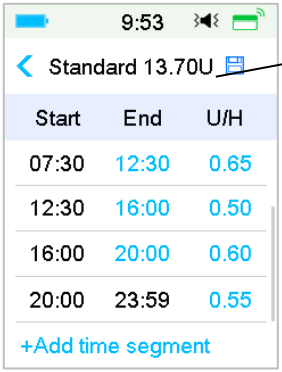
- The first basal segment always starts at 00:00 (12:00 am).
- The last basal segment always ends at 23:59 (11:59 pm).
- Segments can start since each hour or each half-hour. The end time point of the last time segment is always set to be midnight.
- Tap **+Add time segment** to create and edit a new segment.

3. Tap blue font of the **U/H** field to set a desired basal rate value. Then tap **Done**.



Note: You can set a basal rate between 0 and the Max Basal Rate with an increment of 0.05 U/H.

4. When finished, tap to save the basal setup and return to the previous menu.

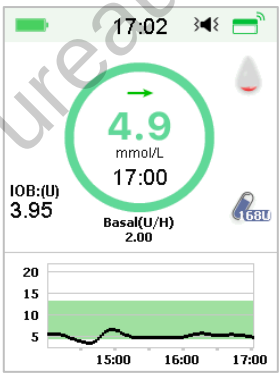


Note: If all 48 basal segments were added, the **+Add time segment** button disappears automatically. Set your basal segments as recommended by your healthcare provider.

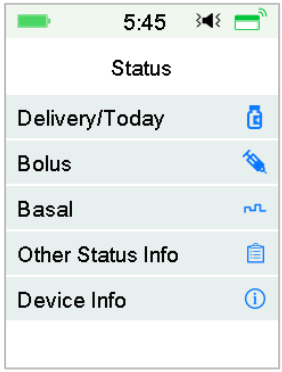
4.3.3 Check the Current Basal Rate

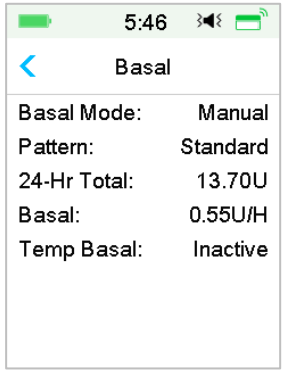
The **Home Screen** and the **Status Screen** show the information of the current basal rate.

1. Home Screen



2. Status➔Basal



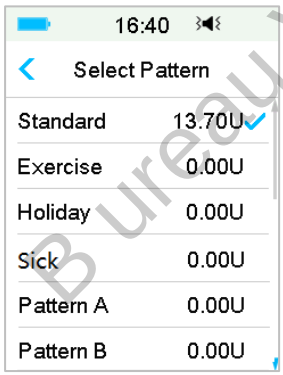


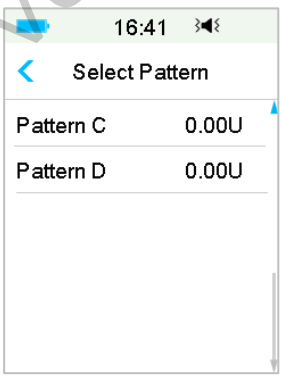
4.3.4 Review Your Basal Patterns

The **Basal Review** screen shows your daily basal rates of all patterns.

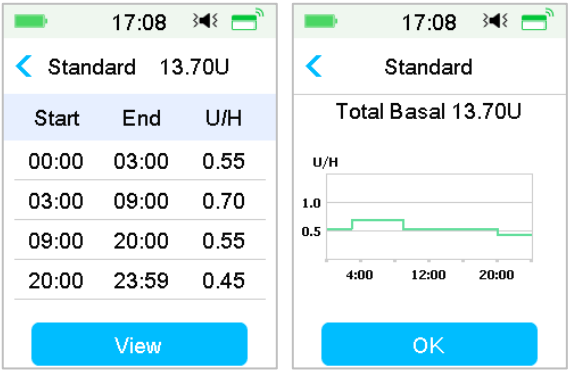
1. Go to the **Basal Review** screen.

   Main Menu➔Settings➔Insulin Pump➔Basal Setup➔Basal Review



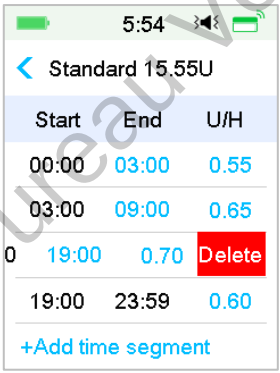


2. Choose the basal pattern that you want to review. Tap it to review your programmed settings.



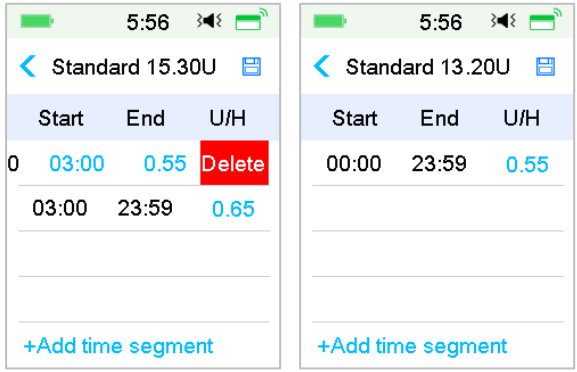
4.3.5 Delete a time segment of Basal Pattern

1. Select segment, slide to left on each and a delete button will appear. Tap **Delete** to delete the selected segment. Slide back to right to close **Delete**.
The last segment cannot be deleted and the starting time of all segments cannot be changed.



2. After the selected segment is deleted, the starting time of the next segment following the deleted segment will change to the ending time of the last segment before the deleted one. The same when you delete more than one segment.

3. When the first segment is deleted, the starting time of the previous second segment (now the new first segment) becomes 00:00 (12:00AM).



4.3.6 Change the time of the Basal Pattern

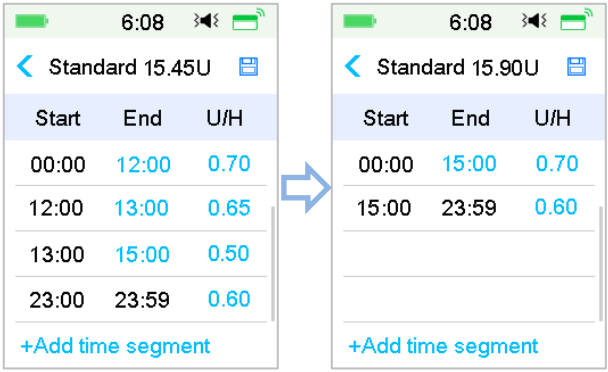
Note: Only the ending time of a segment is editable.

1. Change the ending time point of a segment to a later time point.

When the ending time point A of a segment is changed to a later time point B (for example: 12:00 is changed to 15:00), all previous segments between time point A and time point B will be deleted, leaving only the edited segment featuring a period between its original starting time point and ending time point B.

The ending time Point B equals to the starting time point of the segment that follows. As for the Basal rate, when not edited, the Basal rate of the previous segment covers the Basal rate of the segment in the same period or with overlapping period after editing.

Example: the ending time point of the first segment is changed from 12:00 to 15:00, see following:

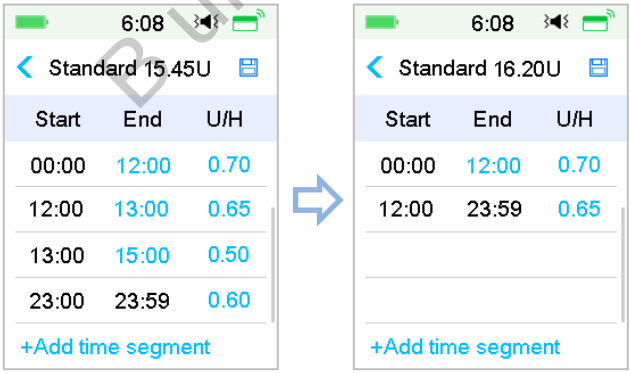


2. Change the ending time point of a segment to an earlier time point

When the ending time point B of a segment is changed to an earlier time point A, all previous segments between time point A and time point B will be deleted, leaving only the edited segment featuring a period between its original starting time point and ending time point A.

The ending time Point A equals to the starting time point of the segment that follows. As for the Basal rate, when not edited, the Basal rate of the previous segment covers the Basal rate of the segment in the same period or with overlapping period after editing.

Example: the ending time point of the third segment is changed from 15:00 to 12:00.



4.3.7 Maximum Basal Rate

Maximum (Max) basal rate is a safety limit for the amount of basal insulin to be delivered within an hour. This maximum rate applies to every basal rate that is set, including a temporary basal. Once your basal rates have been set, you cannot set a maximum basal rate that is less than any of the programmed basal rates. The factory default is 2.00 U/H. The setting range is: 0.00U/H~25U/H. Please set the maximum basal rate with the help of your healthcare provider.

1. Go to the **Max Basal** screen.

Main Menu➔Settings➔Insulin Pump➔Basal Setup➔Max Basal

2. You can modify max basal rate by using the number keyboard.

4.4 Suspend and Resume

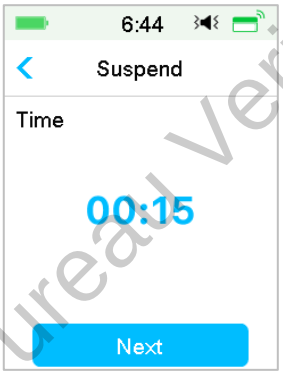
4.4.1 Suspend Insulin Delivery

Sometimes you may need to suspend insulin delivery. When no bolus is being delivered, you can suspend basal insulin delivery for a set period of time. When the Bolus is being delivered, you can choose to suspend all insulin deliveries (basal and bolus) for a set period of time or to just stop the bolus currently being delivered.

a. When no bolus is being delivered:

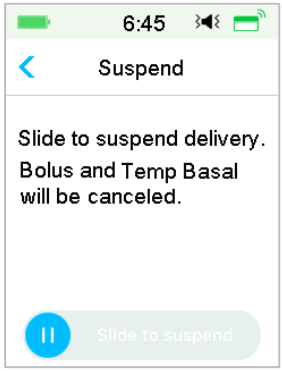
1. Go to the **Suspend** screen. Set a suspension time and tap **Next** to continue.

Main Menu➔Suspend



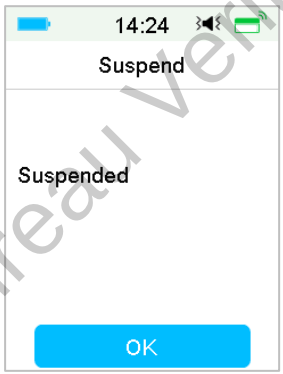
Note: You can set the suspension time between 15 min and 2 hours with an increment of 15 min.

2. The following message will appear. **Slide to suspend** if you want to suspend insulin delivery.

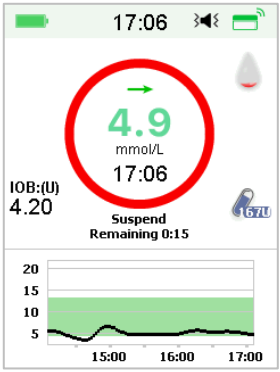


Note: When you suspend insulin delivery, Bolus and Temp Basal will be canceled and cannot be resumed.

3. The PDM will give an on-screen message to let you know that insulin delivery is indeed suspended.



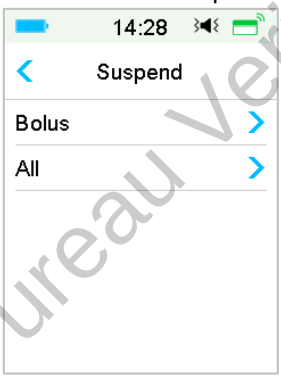
4. The remaining suspend time can be found on **Home Screen**.



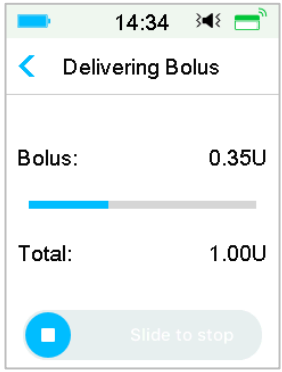
b. When a Normal/Extended/Combo Bolus is being delivered.

1. You can choose to suspend all insulin delivery or only the bolus.

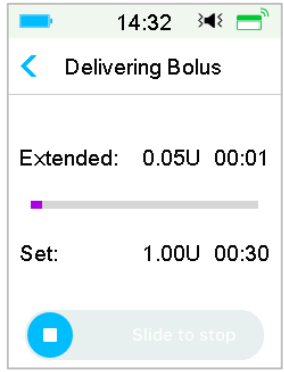
Main Menu➔Suspend



2. If you select **All**, the same to the situation when no bolus is being delivered. The feature can stop all insulin.
3. If you select **Bolus**, the delivery status of respectively a Normal or an Extended Bolus will show following screen. **Slide to stop** to stop bolus insulin.



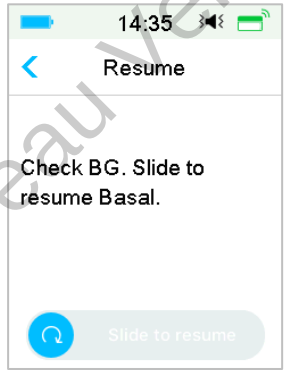
Stop Normal Bolus



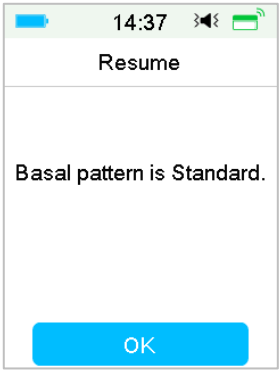
Stop Extended Bolus

4.4.2 Resume Insulin Delivery

After all insulin delivery is suspended, Tap **Resume** on the Main Menu screen, and the following screen appears.



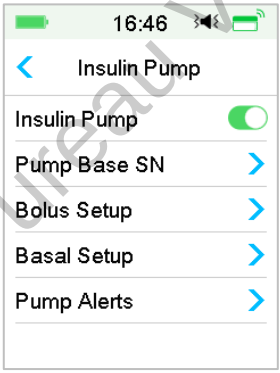
Slide to resume Basal delivery.



Note: Only basal pattern can be resumed, Bolus and Temp Basal cannot be resumed.

4.5 Insulin Pump Settings

Go to Insulin Pump Settings screen. You can turn on or off Insulin Pump, set Pump SN, set Bolus Setup, set Basal Setup and set Pump Alerts.



4.5.1 Add/Change the Pump Base SN

Every time you use a new Pump Base, you need to add the Pump Base SN to your PDM. Your PDM and Pump Base will connect automatically after each Reservoir Patch change process.

Tap **Settings** on the **Main Menu** to enter the **Settings** screen. Tap **Insulin Pump** to enter the Pump Settings screen. Turn the insulin pump feature on.

Tap **Pump Base SN** to edit it. You can use your PDM to search for your Pump Base (only for the first time), or you can enter the SN printed on your Pump Base manually. The Pump Base SN can only be changed when there is no activated Reservoir Patch.

See Section "Activate a New Reservoir Patch" for more information.

4.5.2 Bolus Setup

Tap **Bolus Setup** on the **Insulin Pump** screen to enter the **Bolus Setup** screen. You can set Bolus Calculator, Preset Bolus and Max Bolus in the Bolus Setup.

1. Bolus Calculator

See Chapter "Advanced Pump Features" for more information. Consult your healthcare provider before changing this setting.

2. Preset Bolus Setup

See Section "*Preset Bolus"* for more information. You can set up to seven preset bolus amounts: Breakfast, Lunch, Dinner, Snack, Bolus 1, Bolus 2, and Bolus 3.

3. Max Bolus

The maximum bolus (Max Bolus) is a safety feature that limits the amount of insulin that can be delivered in a single bolus. The factory setting is 10 units. You can set the limit between 0 and 30 units. Please set the maximum bolus with the help of your healthcare provider.

4.5.3 Basal Setup

Tap **Basal Setup** on the **Insulin Pump** screen to enter the **Basal Setup** screen. You can edit basal, check basal review, set preset temp basal and set Max basal.

1. Edit Basal

See Section "Basal" in Chapter "How to use Patch Pump" for more information. You can set up to 48 basal rates for any basal pattern.

2. Basal Review

See Section "Basal" in Chapter "How to use Patch Pump" for more information. The **Basal Review** screen shows your daily basal rates of all patterns.

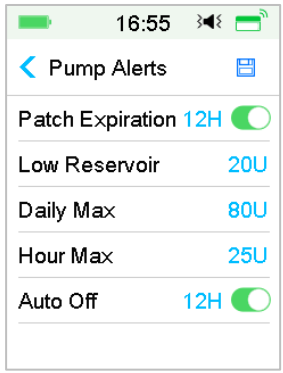
3. Preset Temp Basal

See Section "Preset Temp Basal" in Chapter "Advanced Pump Features" for more information. You can set up to seven preset temp basal rates: Heavy Ex, Medium Ex, Light Ex, Sick, Temp 1, Temp 2 and Temp 3.

4. Max Basal

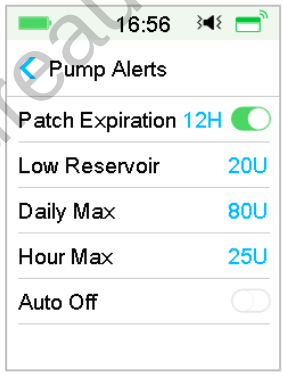
See Section "Basal" in Chapter "How to use Patch Pump" for more information. Maximum (Max) basal rate is a safety limit for the amount of basal insulin to be delivered within an hour. This maximum rate applies to every basal rate that is set, including a temporary basal. Once your basal rates have been set, you cannot set a maximum basal rate that is less than any of the programmed basal rates. Please set the maximum basal rate with the help of your healthcare provider. The factory default is 2.0 U/H.

4.5.4 Pump Alerts



1. Patch Expiration

Here you can turn on/off “PATCH EXPIRED” Alarm, “PATCH EXP ADVISORY” Alert, and “PATCH EXP IN 1 HOUR” Alert. When the alerts are turned on, if you do not remove a Reservoir Patch after 72 hours’ use, the “PATCH EXPIRED” Alarm repeats every hour until the system automatically deactivates the current Reservoir Patch after 80 hours’ use.

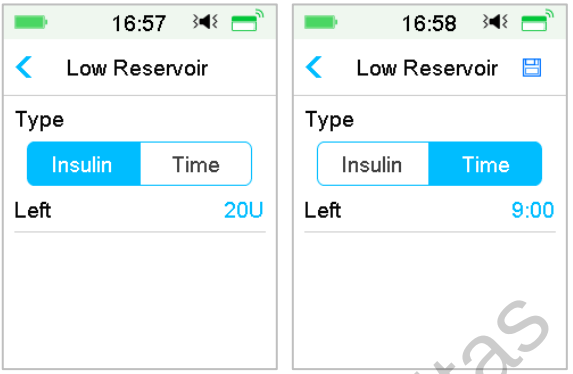


You can set the “PATCH EXP ADVISORY” Alert period from 2 hours to 24 hours before expiration.

2. Low Reservoir

The “LOW RESERVOIR” Alert allows you to program the PDM to give an alert when insulin in the Reservoir Patch reaches a certain level, so you can plan ahead to change the Reservoir Patch. You can select one of these warning types:

- A specified number of units that remain in the Reservoir Patch
- A specified maximum amount of time that remains before the Reservoir Patch will be empty



Note: You can set the amount of insulin between 5 U and 50 U with an increment of 1 U. You can set the time between 2h and 24h with an increment of 30 min.

Note: If a bolus is being delivered when a "LOW RESERVOIR" Alert occurs, your remaining insulin may be less than the value on the alert screen.

3. Max Delivery

This program is designed to instruct the Pump to automatically suspend insulin delivery and give an alarm if you may have delivered excessive insulin in the past hour or within one day. There are two types of delivery limit that you can set, hour max and daily max. The factory setting for hour max is 25 U, and for daily max is 80 U. You may choose to program this feature into your PDM based on the amount of units you usually deliver in 1 hour and within 1 day. Discuss what settings are best with your healthcare provider.

Note: You can set the Daily Max between 20 and 180 U and the Hourly Max between 10 and 40U.

Note: If the Reservoir Patch is changed, the hourly insulin amount will start from 0.

Note: Insulin delivery will be automatically resumed at 0:00 am on the next day if suspension occurs after daily max has been exceeded.

Note: If you resume insulin delivery manually after the hourly/daily max was exceeded, the previously delivered amount in this hour/day will be cleared and the PDM will record the hourly/daily amount from zero.

4. Auto Off

You may program your PDM to automatically suspend basal delivery and give an alarm if the PDM does not receive a Patch Pump status in a set number of hours. Obtain Patch Pump status by pressing any button on your PDM. This feature can be used as a safeguard in case you are unable to operate your PDM (for example, being unconscious). The factory setting for this feature is off. You may choose to program this feature into your PDM based on the number of hours that you usually sleep. Discuss what functions and settings are best for you with your healthcare provider.

Note: You can set the time between 1h and 24h with an increment of 1h.

5 Advanced Pump Features

5.1 Bolus Calculator

With your input of the number of carbs eaten and your current (actual) BG value, this feature can automatically calculate your Food Bolus and Correction Bolus, based on your Insulin-to-Carbohydrate ratio (I:C ratio), Insulin Sensitivity Factor (ISF), BG Target and the amount of IOB for the current time. Consult your healthcare provider for your personal I:C ratios, Insulin Sensitivity Factor (ISF), BG Target ranges and IOB Time.

5.1.1 How the Bolus Calculator Works

Enter your BG reading as a calculation factor of Bolus Calculator. If you are going to eat a meal, enter your food amount in carbs. The bolus calculator will provide a suggested bolus for you.

Note: As a safety feature, the system only allows you to give a bolus at or below the maximum bolus limit you have set. *See Chapter "How to use Patch Pump" for more information on resetting your maximum bolus limit.* Consult your healthcare provider before changing this setting.

5.1.2 How to Set up the Bolus Calculator

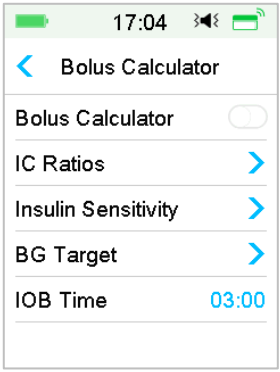
You can do your personal settings in the bolus calculator feature on the **Bolus Calc Setup** screen or when PDM is turned on for the first time.

Instructions for programming the bolus calculator feature settings are in the following paragraphs. Program your settings in the order as describe in the following to make sure you have programmed all the settings.

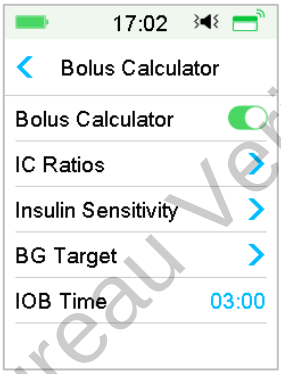
Bolus Calculator Feature on/off

1. Go to the **Bolus Calc Setup** screen.

   Main Menu➔Settings ➔Insulin Pump➔Bolus Setup➔Bolus Calc Setup



2. Turn on or off Bolus Calculator. The factory default is off.



Note: **IC Ratios** is the abbreviation for Insulin-to-Carb Ratios. **BG** is the abbreviation for blood glucose.

Insulin to Carb (I:C) Ratios

An Insulin to Carb (I:C) ratio features the amount of carbs you can cover with one unit of insulin.

Because this ratio may vary throughout the day, you can program up to eight I:C ratios. Your healthcare provider may only have you program one or two carb ratios when you first start using the bolus calculator feature.

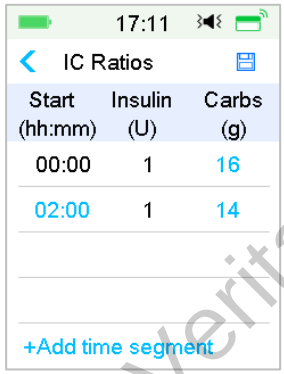
Note: If you set only one Insulin-to-Carb ratio, it will be used for the entire 24-hour period.

In the **Bolus Calc Setup** screen, select **IC Ratios**.

1. The first segment always starts at midnight. The **Carbs** field is indicated by the blue editable digit. You can tap the blue digit to change it.

Note: You can set the carbs between 1.0 g and 200 g. When the carbs is between 1.0 g and 9.9 g, the increment is 0.1 g. When the carbs is between 10 g and 200 g, the increment is 1 g.

2. Tap **+Add time segment** to create a new segment.

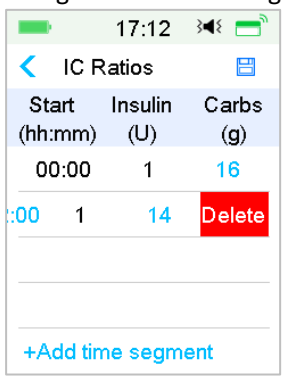


Note: Add time segments by choosing from 00:30-23:30 or 12:30A-11:30P, with an increment of 00:30.

Note: If **+Add time segment** does not appear, you have programmed all possible segments.

3. Continue to set ratio segments as recommended by your healthcare provider.

Note: Select segment, slide to left on each and a delete button will appear. Tap **Delete** to delete the selected segment. The first segment cannot be deleted.



4. When finished, press to save settings. Or Press to cancel setup and exit the edit mode.

Insulin Sensitivity

An insulin sensitivity factor (ISF) evaluates the blood glucose level you can expect to lower with one unit of insulin. This value is used to calculate a suggested insulin dose to correct a high BG. Because this amount may vary throughout the day, you can set up to eight different time slots. Your healthcare provider may only have you program one or two insulin sensitivity factors when you first start using the bolus calculator feature.

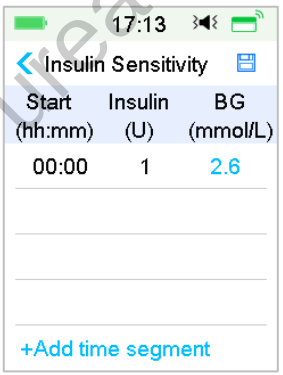
Note: If you only set one insulin sensitivity factor, it will be used for the entire 24-hour period.

In the **Bolus Calculator Setup** screen, select **Insulin Sensitivity**.

1. The first segment always starts at midnight. The **BG** field is indicated by the blue editable digit.

Note: You can set the BG between 0.5 mmol/L and 22.2 mmol/L (10 mg/dL and 400 mg/dL) with an increment of 0.1 mmol/L (1 mg/dL).

2. Tap **+Add time segment** to create a new segment.

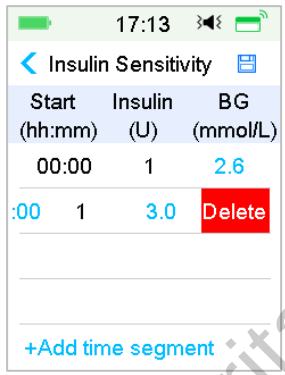


Note: Add time segments by choosing from 00:30-23:30 or 12:30A-11:30P, with an increment of 00:30.

Note: If **+Add time segment** does not appear, you have programmed all possible segments.

3. Continue to set ISF segments as recommended by your healthcare provider.

Note: Select segment, slide to left on each and a delete button will appear. Tap **delete** to delete the selected segment. The first segment cannot be deleted and the starting time of first segment cannot be changed.



4. When finished, press to save settings. Or Press to cancel setup and exit the edit mode.

BG Target

A BG Target is your personal goal for keeping your BG levels under control. A BG Target may be set as an actual range (with a low limit and high limit), or a single value. Because your targets may vary throughout the day, you can set up to eight BG targets. If you want to set just one target value instead of a range, set both the low and high values to the same number.

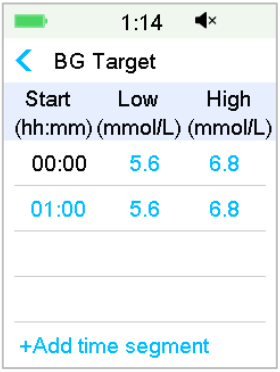
If your current BG is above the BG Target Range, the bolus calculator feature will calculate a correction dose. If your current BG is below the BG Target Range, the bolus calculator will calculate a negative correction and thus subtract it from your food bolus.

On the **Bolus Calc Setup** screen, select **BG Target**.

1. The first segment always starts at midnight. The **BG Range** field is indicated by the blue editable digit.

Note: You can set the low and high limit between 3.3 mmol/L and 13.9 mmol/L (60 mg/dL and 250 mg/dL) with an increment of 0.1 mmol/L (1 mg/dL). The high limit should never be lower than the low limit.

2. Tap **+ Add time segment** to create a new segment.



Note: Add time segments by choosing from 00:30-23:30 or 12:30A-11:30P, with an increment of 00:30.

Note: If **+Add time segment** does not appear, you have programmed all possible segments.

3. Continue to set the BG Target segments as recommended by your healthcare provider.

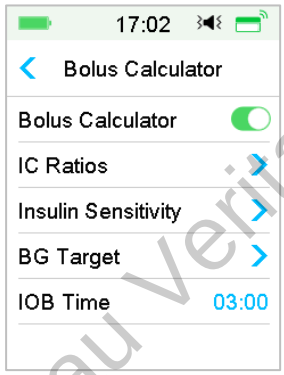
Note: Select segment, slide to left on each and a delete button will appear. Tap **Delete** to delete the selected segment. The first segment cannot be deleted and the starting time of first segment cannot be changed.

4. When finished, press < to exit the edit mode and press to save settings.

IOB Time

The IOB feature shows how much insulin from a previous bolus dose might still be active in your body. The actual amount of insulin left in your body is determined by the rate at which your body utilizes insulin, your infusion site, your activity level, and other factors. Your PDM uses a curvilinear algorithm that mimics the way insulin is metabolized to track IOB. The IOB setting lets the PDM know which IOB to use in calculating the amount of IOB to subtract before estimating a bolus. Please set the IOB time with the help of your healthcare provider.

In the **Bolus Calculator** screen, select **IOB Time** and edit it.

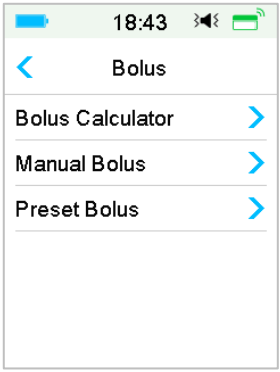


Note: You can set the IOB Time between 2h and 8h with an increment of 0.5h. The factory default is 3 Hours (03:00).

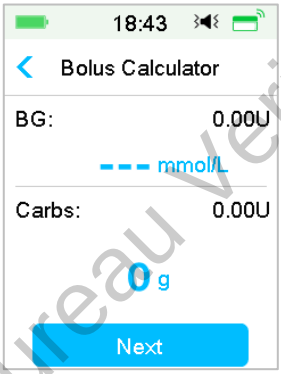
5.1.3 Normal Bolus Using Bolus Calculator

After the bolus calculator is turned on and programmed, this feature can calculate an estimate of insulin you need for your correction bolus or food bolus. You have the option of using the estimated dose or changing it as necessary.

1. In the **Bolus** screen, select **Bolus Calculator**.



2. Tap **BG** value to enter your BG and tap **Carbs** value to enter your carbohydrate amount.



Note:

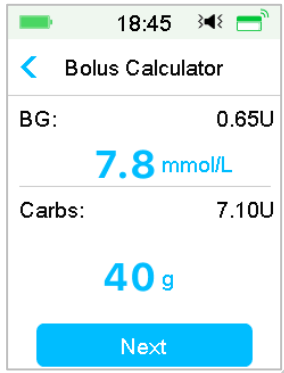
(1) If you are not entering a BG and want a bolus for food, enter only your carbohydrate amount, the bolus calculator feature will calculate an estimate of insulin for your food entry without considering your BG level.

(2) You can enter a BG value between 1.1 mmol/L and 33.3 mmol/L (20 mg/dL and 600 mg/dL) with an increment of 0.1 mmol/L (1 mg/dL). The factory default is 5.6 mmol/L (100 mg/dL).

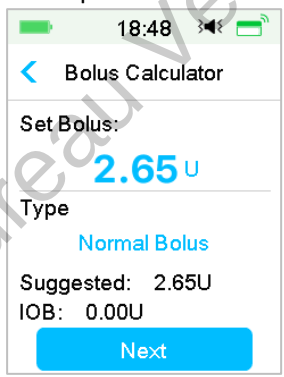
(3) You can enter an amount of carbs between 0 g and 300 g with an increment of 1 g.

(4) You can set a bolus dose between 0 and the Max Bolus with an increment of 0.05 U.

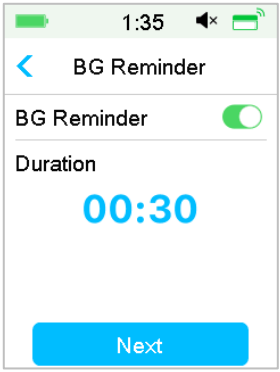
3. After BG and Carbs input, the recommended Bolus dose according to the Bolus Calculator appears on the right side of the BG value and carbohydrate amount. For example:



4. The following screen appears with the calculated bolus amount. You can adjust the recommended Bolus amount for the **Set Bolus** as needed. Then choose the Bolus type and tap **Next**.

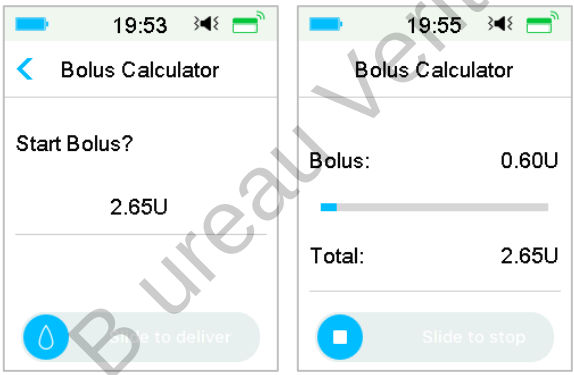


Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. You can accept or modify the time before you are reminded to check your blood glucose after a bolus.



See "BG Reminder" in this chapter for more information.

5. **Slide to Deliver** to begin the bolus delivery. As the Normal Bolus is being delivered, the amount shown on the screen will add up to the actual bolus amount which is delivered.

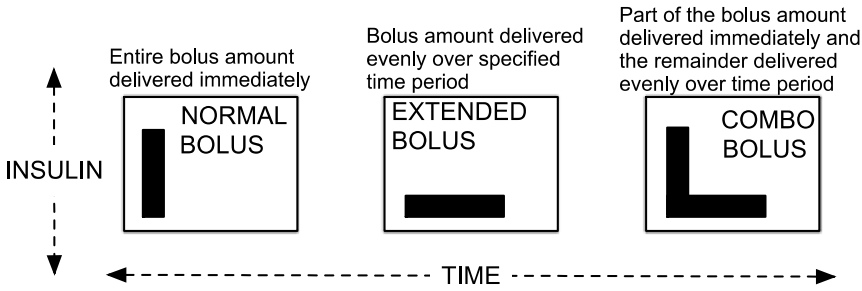


Note: You can cancel an active Normal Bolus (one that is currently being delivered) even after insulin delivery has started. **Slide to Stop** to cancel the bolus.

5.2 Combo/Extended Bolus

The Combo/Extended Bolus feature is useful for consumption of high carb/high fat meals such as pizza, which entails prolonged carb absorption. It is also useful if you will be eating ("grazing") over a few hours or if you have gastroparesis, which means food remains in the stomach for a longer period than it normally does.

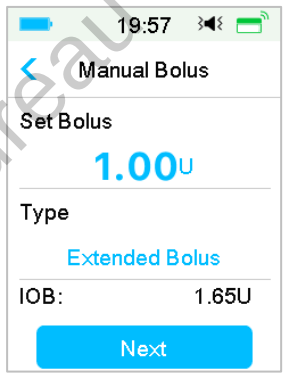
See the following graphic for a description of the different bolus types.



Note: It is important that you consult with your healthcare provider before using a Combo/Extended Bolus. You should be familiar with the basic functions of your PDM before exploring these options.

5.2.1 Combo/Extended Bolus Without Bolus Calculator

1. Calculate your food and/or correction bolus amount.
2. In the **Bolus Menu** screen, select **Manual Bolus**.



Extended Bolus

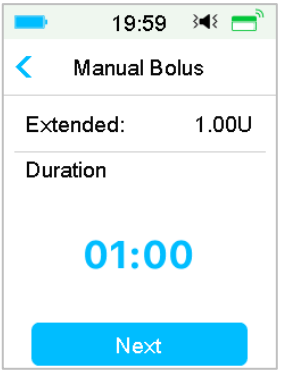
To set an Extended Bolus, follow these steps:

a. Tap **Set Bolus** value to enter the desired amount for Extended Bolus units and tap **Next**.

Note: You can set a bolus dose between 0 and the Max Bolus.

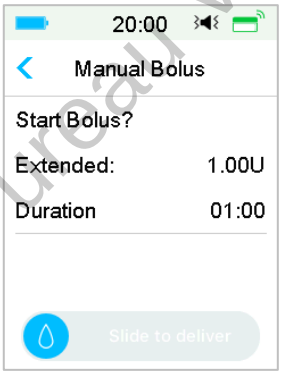
b. Tap **Type** option to choose **Extended Bolus**. Then tap Next.

c. Enter the amount of time you want the Extended Bolus to last and tap **Next**.



Note: You can set the duration between 30 min and 8 h with an increment of 30 min.

d. Details of the Extended Bolus will be displayed, then **Slide to deliver** to start delivery.



Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. You can accept or modify the time before you are reminded to check your blood glucose after a bolus. *See "BG Reminder" in this chapter for more information.*

Combo Bolus

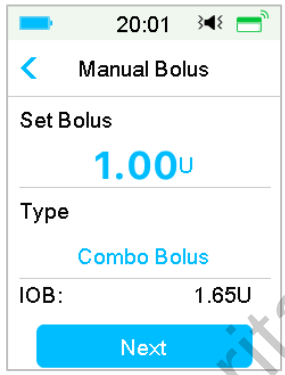
To set a Combo Bolus, follow these steps:

a. Select **Set Bolus** value to enter the desired amount for Combo Bolus units and tap **Next**.

Note: You can set a bolus dose between 0 and the Max Bolus.

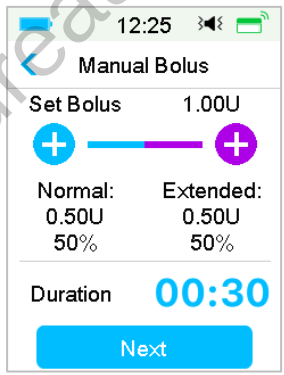
Note: The number of units you enter for the Combo Bolus is a total amount of Normal Bolus and Extended Bolus units.

b. Tap **Type** option to choose **Combo Bolus**. Then tap **Next**.



c. Tap the blue icon to increase Normal Bolus. Tap the purple icon to increase Extended part.

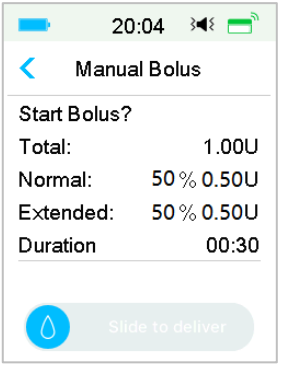
d. Enter the amount of time you want the Extended Bolus to last and tap Next to continue.



Note: You can set the duration between 30 min and 8h with an increment of 30 min.

Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. You can accept or modify the time before you are reminded to check your blood glucose after a bolus. *See "BG Reminder" in this chapter for more information.*

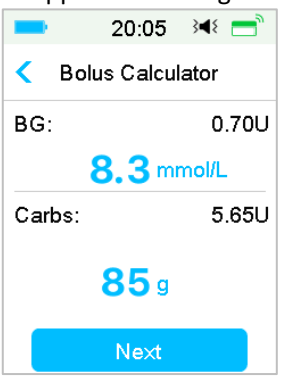
e. Details of the Combo Bolus will be displayed. **Slide to Deliver** to start delivery.



5.2.2 Combo/Extended Bolus Using Bolus Calculator

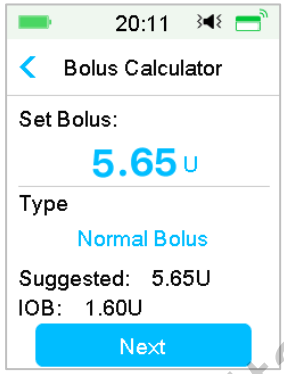
If you are using the bolus calculator feature to calculate your extended or Combo Bolus amounts, you will be prompted to enter your BG reading and/or carb intake. The bolus calculator feature will use this input to calculate your suggested bolus amount. You can also change the estimated bolus if desired.

1. The bolus calculator feature and the Combo/Extended Bolus function must be turned on and the settings must be programmed. *See "Bolus Calculator" for more information.*
2. Enter a bolus calculator process. After you enter your BG and/or carbs, the calculated bolus amount appears in the right. Tap **Next** to continue.



Note: If you need to make any changes in the previous menu, press to return to the previous menu, select Bolus Calculator, and re-enter the values.

3. You can adjust the **Set Bolus** as needed.



Note: You can set a bolus dose between 0 and the Max Bolus.

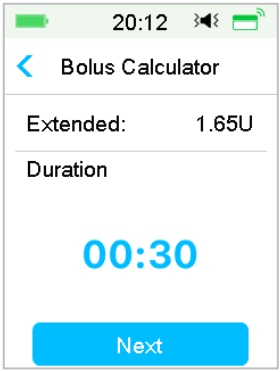
Note: If there is an active Extended Bolus, the extended or Combo Bolus will not be available until the active Extended Bolus finished.

Note: If there is a correction part in the suggested bolus dose, the correction part can only be delivered as a Normal Bolus or the normal part of a Combo Bolus. In other words, the Extended Bolus option will become unavailable in that case.

Extended Bolus

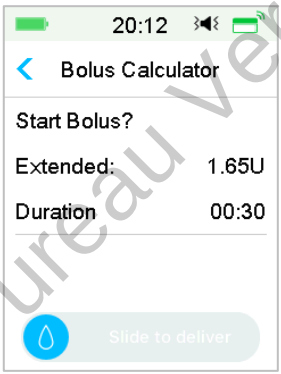
To set an Extended Bolus, follow these steps:

a. The extended duration screen appears. Enter the amount of time you want the Extended Bolus to last and tap **Next**.



Note: You can set the duration between 30 min and 8 h with an increment of 30 min.

b. Details of the Extended Bolus will be displayed, then **slide to deliver** to start delivery.



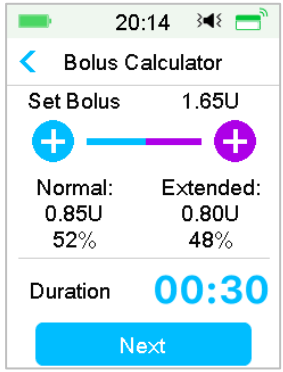
Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. You can accept or modify the time before you are reminded to check your blood glucose after a bolus. *See "BG Reminder" in this chapter for more information.*

Combo Bolus

To set a Combo Bolus, follow these steps:

a. Tap the blue icon ⊕ to increase Normal Bolus. Tap the purple icon ⊕ to increase Extended part.

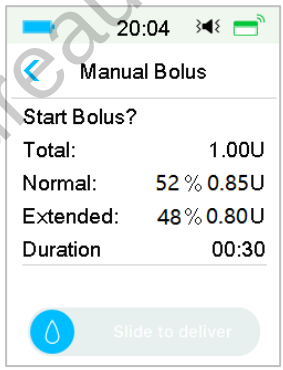
b. Enter the amount of time you want the Extended Bolus to last and tap **Next** to continue.



Note: You can set the duration between 30 min and 8 h with an increment of 30 min.

Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. You can accept or modify the time before you are reminded to check your blood glucose after a bolus. *See "BG Reminder" in this chapter for more information.*

c. Details of the Combo Bolus will be displayed. **Slide to deliver** to start delivery.



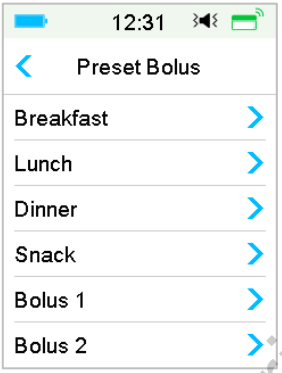
5.3 Preset Bolus

The preset bolus feature enables you to program bolus deliveries for frequent use. You can set up to seven preset bolus amounts: Breakfast, Lunch, Dinner, Snack, Bolus 1, Bolus 2, and Bolus 3.

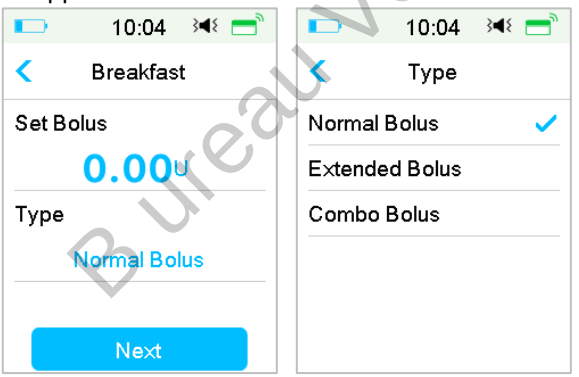
5.3.1 Preset Bolus Setup

1. Go to the **Preset Bolus Setup** screen.

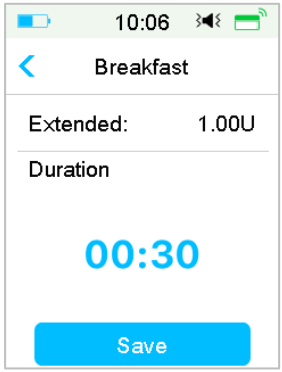
   Main Menu➔Settings➔Insulin Pump➔Bolus Setup➔Preset Bolus Setup

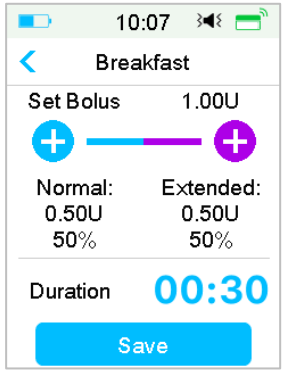


2. Select a preset bolus you want to edit. If it has been edited, the current settings will appear.



3. Choose a bolus type. For a Normal Bolus, set the bolus amount. For an Extended Bolus, set the bolus amount and duration. For a Combo Bolus, set the bolus amount, normal/extended percentages and duration.





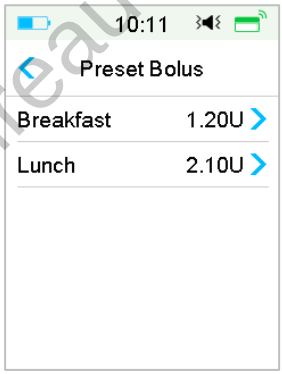
4. Tap **Save** to save the settings. Tap < or Home button and tap **No** to quit the settings.

5.3.2 Deliver a Preset Bolus

You must set up a preset bolus before you can deliver it.

1. Go to the **Preset Bolus** screen.

Main Menu➔Bolus➔Preset Bolus



The existing preset bolus settings are displayed on this screen. If you have not set up any preset bolus, this screen shows **No Presets**.

2. Select the preset bolus you want to deliver.

Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. *See "BG Reminder" in this chapter for more information.*

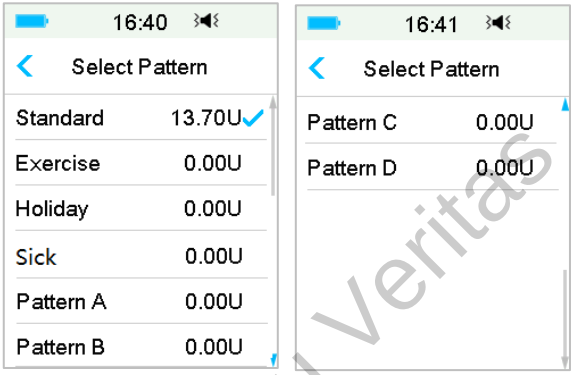
3. Verify your preset bolus settings.
4. Start bolus delivery.

5.4 Select a Basal Pattern

1. Go to the **Select Pattern** screen.

   Main Menu➔Basal➔Select Pattern

2. Select the desired pattern to activate.



5.5 Temp Basal

With a temp basal rate, you can adjust your basal rate for a short period of time to manage glucose levels during temporary activities or different conditions. For example, you might want to increase basal rate on sick days or decrease during exercise. You can set the duration of a temp basal rate up to 24 hours in half-hour increment.

Note: During a temp basal delivery, the basal pattern is temporarily overwritten, thus not available. After the temp basal delivery is completed or canceled, your system will return to the selected basal pattern.

5.5.1 Activate a Temp Basal

1. Go to the **Temp Basal** screen.

   Main Menu➔Basal➔Temp Basal