

A7+ TouchCare[®] Insulin Management System

User Guide



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Simplifying Diabetes

Medtrum

A7+ TouchCare®
Insulin Management System

User Guide



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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

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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

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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

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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

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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 may 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,

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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,

Introduction

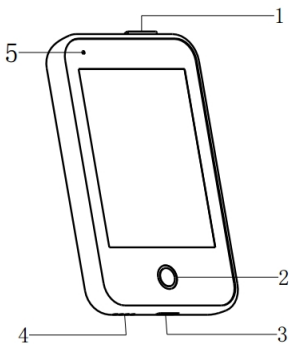
rental or other transfer or use of the Transmitter covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Transmitter and does not apply to other products or accessories.

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.

2.1 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

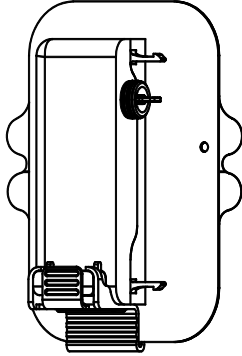
✓ Personal Diabetes Manager (PDM) (FM-018)

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

Your A7+ TouchCare® System

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)



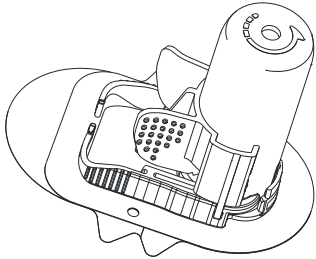
✓ Pump Base (JN-022)

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.

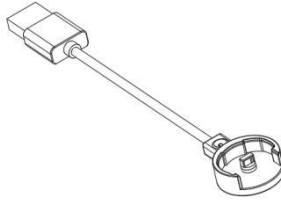
Your A7+ TouchCare® System



- ✓ **Glucose Sensor**
(MD3026, Consumable)



- ✓ **Transmitter**
(MD1026, Chargeable)



- ✓ **USB charging cable**
(LQ005)

3.1 Basics of the PDM

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

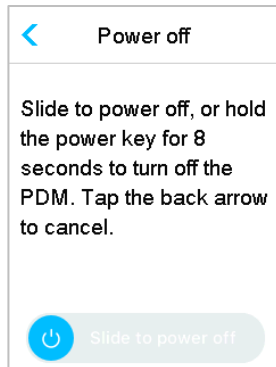
3.1.1 Turn on/off the PDM

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.

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.

How to use the PDM

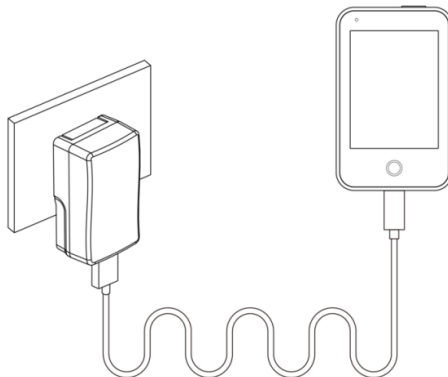
The PDM requires an AC adapter with an output of DC 5.0V that complies with IEC 60601-1 and IEC 60950 such as UES06WNCPU-050 100SPA, (input: 100-240V, 50/60Hz, 0.2A; output: 5.0V DC, 1.0A). The adapter is designed as a part of the ME system.

Note:

- 1) Do not use other types of chargers. Otherwise the PDM may not work normally.
- 2) 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.
- 3) No settings will be lost if the PDM power is depleted or PDM error happens.
- 4) 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.
- 5) Usually, when the PDM is fully charged, it is available for use of one week (7 days).
- 6) Blue light flashes when PDM is charging, and the green light is always on indicates full charge.
- 7) 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:

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.

- The activated basal, temporary basal and all bolus functions will not be changed.
- The screen will be locked after screen backlight timeout.
- Press Power button, and the screen lights up, the PDM displays the Lock Screen.

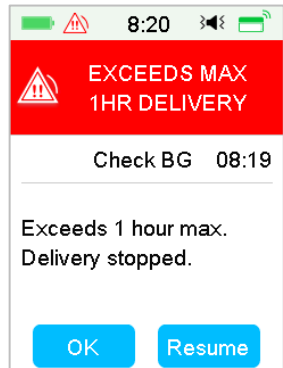
Awake Mode

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

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

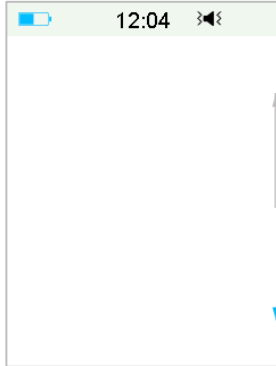


An Alarm occurs when the screen is not locked.

How to use the PDM

3.1.4 Scroll Bar

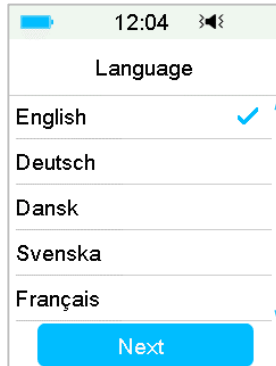
If there is excessive text length for the screen, a scroll bar appears on the right side of the screen. You can view any additional text by scrolling up and down.



3.2 Setting up the PDM

3.2.1 Select language and country/region

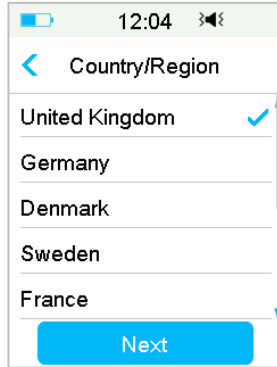
1. Select your language, then tap Next.



You can change language. See “Language” in Section “Settings” for setup instructions.

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

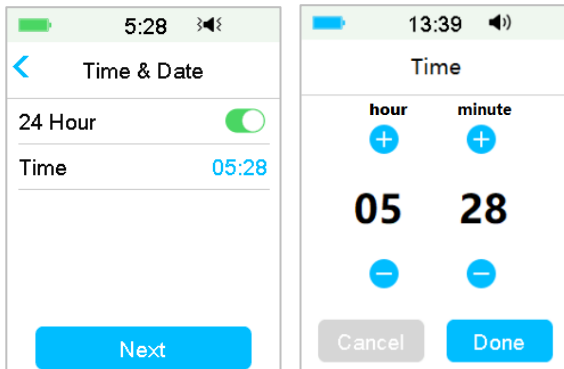
How to use the PDM



3.2.2 Time and Date

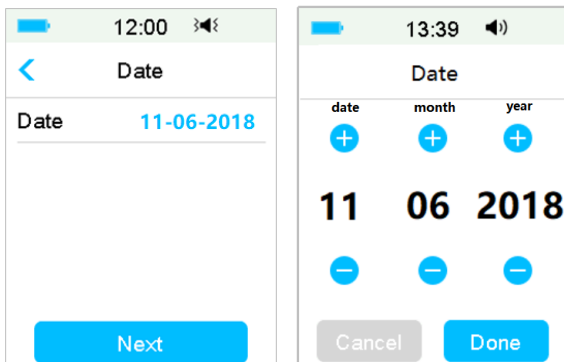
When starting PDM for the first time, you need to set the time and date. Setting the correct time and date in your PDM is necessary for accurate basal insulin delivery and enables you to keep a correct record of your insulin delivery and Sensor readings. You can select a 12-hour or 24-hour clock format.

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**.

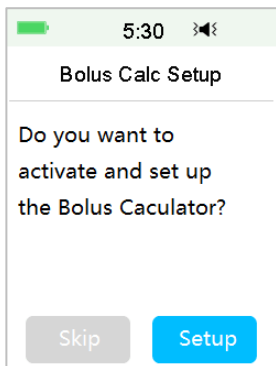
How to use the PDM



- (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.

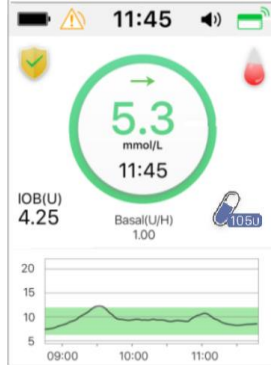


If you choose **Setup**, the Bolus Calculator function will be forced to turn on; If you choose **Skip**, the Bolus Calculation function will stay turned-off.

3.3 Home Screen

How to use the PDM

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 Delivery Status and Glucose 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

How to use the PDM

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 exclamation mark (alert), a red triangle with two red exclamation marks (medium priority alarm) or a red triangle with three red exclamation marks (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 Delivery Status
3. IOB (Insulin on Board)
4. Pump RF Signal
5. Insulin left

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

Insulin Delivery 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.

How to use the PDM

	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.

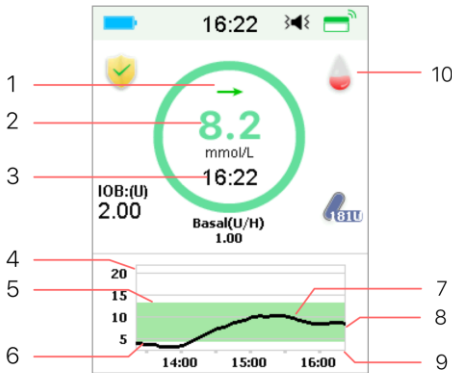
The status information is indicated by text below:

- ✧ 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 Glucose Status

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

CGM feature on:



1. Trend Arrow
2. The last sensor 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

CGM feature off:







1. BG
2. Time of the last BG
3. The scope of glucose limit
4. High Limit of glucose limit
5. Low Limit of glucose limit
6. BG
7. The scope of time

Trend arrow

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








How to use the PDM

-  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.

How to use the PDM



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.




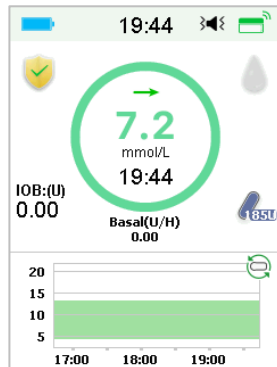
The next calibration is due in 0 to 2 hours.



A calibration is needed now.

Data recovery status icon

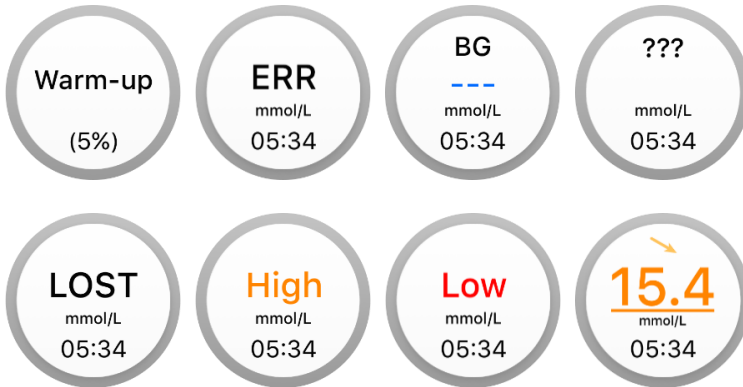
If you disconnect the Sensor for a while and reconnect it, it takes some time to recover the data. The icon  indicates that data is being recovered. It disappears when data-recovery is completed.



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.

How to use the PDM



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.

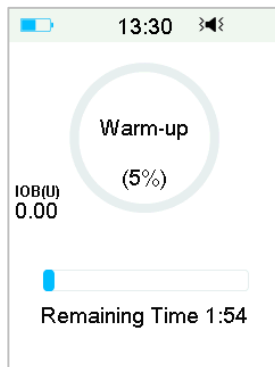
High - Sensor glucose is above 22.2 mmol/L (400mg/dL).

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

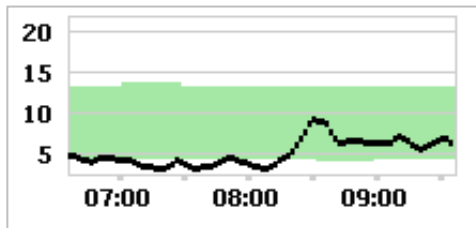
When you turn on Low Suspend or Predict Low switch in **EasyLoop** Menu, the system will be on EasyLoop Icon Mode. The Patch Pump will perform safety checks and automatically stop delivery when the CGM reading triggers the suspend function. There are two kinds of EasyLoop Icon. If Low Suspend or Predict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

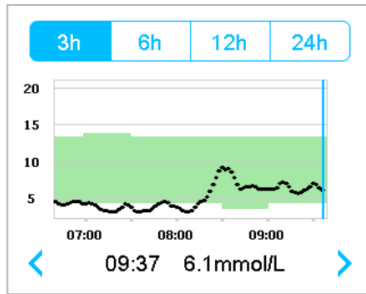
3.3.5 Sensor Graph

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.

How to use the PDM



- 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 “•”.

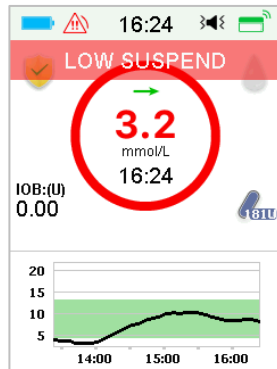
3.3.6 Alarm Status

How to use the PDM

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:

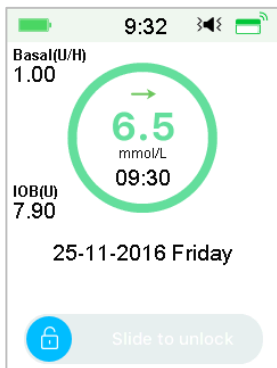


3.4 Lock Screen

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.

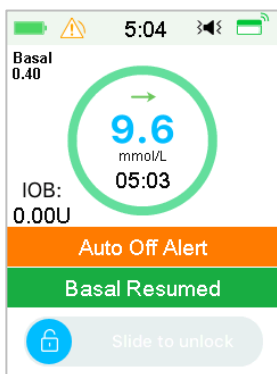
1. Lock Screen without Alarm, Alert and Reminder

How to use the PDM



See “Pump Status” for more information about delivery status.

2. Lock Screen when Alarm, Alert and Reminder occurs



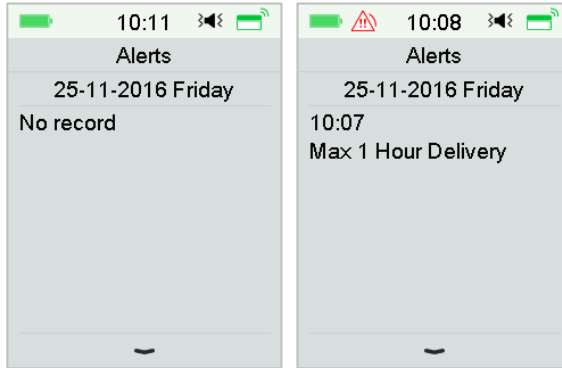
See Chapter “Safety System and Alarms/Alerts” for more information about Alarm, Alert or Reminder status.

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.

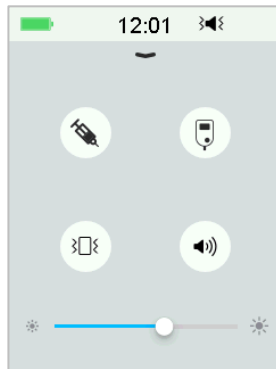
- (1) If there is no daily Alert and Alarm notification, the screen displays No Record.
- (2) If there is Alert and Alarm notification, only the still existing Notifications will be displayed.


- (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 or BG 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 “  ”.

How to use the PDM

(4) Vibration Option icon

There are two icons of Vibration Option, each changing after one tap:

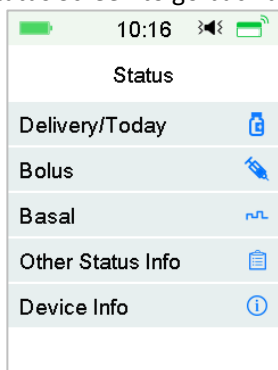
Vibration off “”, Vibration on “”.

(5) Brightness adjustment icon “”

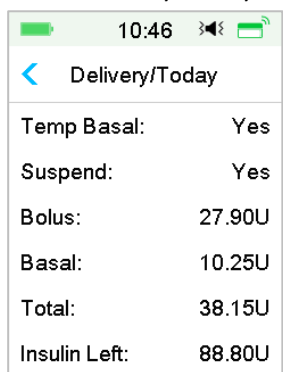
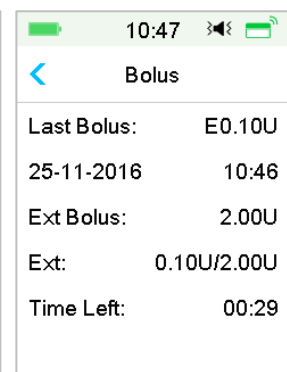
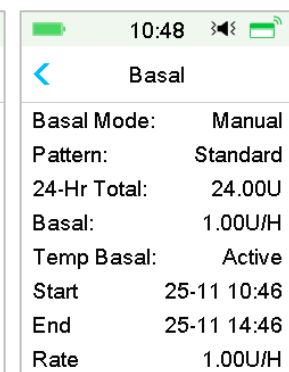
There are ten brightness levels, which are increased from left to right.

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
 <p>10:46</p> <p>Delivery/Today</p> <p>Temp Basal: Yes</p> <p>Suspend: Yes</p> <p>Bolus: 27.90U</p> <p>Basal: 10.25U</p> <p>Total: 38.15U</p> <p>Insulin Left: 88.80U</p>	 <p>10:47</p> <p>Bolus</p> <p>Last Bolus: E0.10U</p> <p>25-11-2016 10:46</p> <p>Ext Bolus: 2.00U</p> <p>Ext: 0.10U/2.00U</p> <p>Time Left: 00:29</p>	 <p>10:48</p> <p>Basal</p> <p>Basal Mode: Manual</p> <p>Pattern: Standard</p> <p>24-Hr Total: 24.00U</p> <p>Basal: 1.00U/H</p> <p>Temp Basal: Active</p> <p>Start 25-11 10:46</p> <p>End 25-11 14:46</p> <p>Rate 1.00U/H</p>

How to use the PDM

Other Status Info	Device Info
11:45	10:49
< Other Status Info	< Device Info
Patch Life Left 0day1hour26min	PDM SN: 067F3586
Sensor Life Left 2day2hour56min	Version 1.67.169
Transmitter Battery Normal	Pump SN: 106000674
Next calibration 6hour24min	Version 1.70.170
Sensor Status Monitoring	Transmitr SN: 102005219
	Version 1.68.181

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.

11:50	12:48
 Bolus	 Bolus
 Basal	 Basal
 Suspend	 Resume
 Patch	 Patch
 Sensor	 Sensor
 History	 History
 Events	 Events
 EasyLoop	 EasyLoop
 Settings	 Settings

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.

How to use the PDM

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 Section “Glucose Alerts” in Chapter “How to use CGM system” and Chapter “How to use (P)LGS” for more information.*

3.8.9 Settings

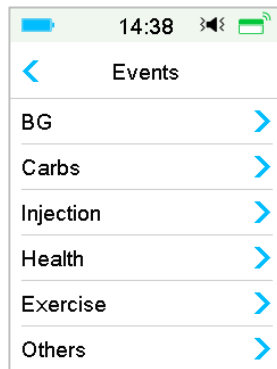
On the **Settings** menu you can edit personal settings of your system. *See Section “Settings” in this chapter for more information.*

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.

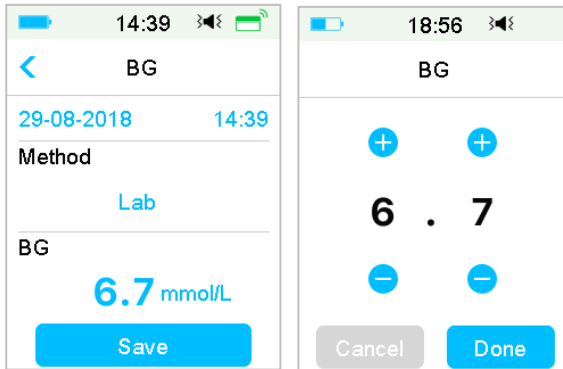
Note: The time refers to blood sampling time.


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 6.7 mmol/L). The input range is 40 - 400 mg/dL (or 2.2 - 22.2 mmol/L).

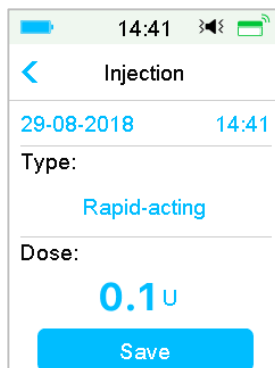
How to use the PDM



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.



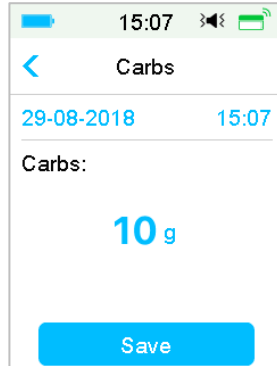
5. When finished, tap **Save** to confirm input. Or press  to cancel.

3.9.3 Carbohydrates Information

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

How to use the PDM

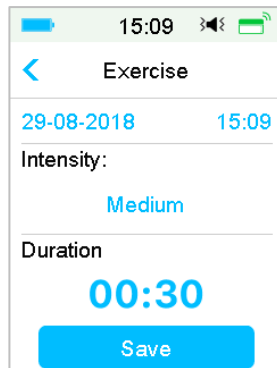
2. Choose the date and time for carbohydrate intake.
3. Tap **Carbs** value to select the carbohydrates you eat or drink. The input range is 0-300 grams.



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.

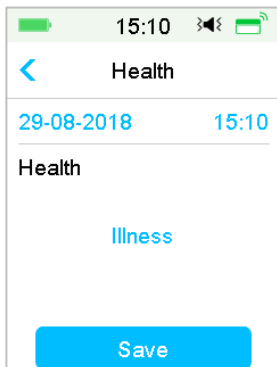


5. When finished, tap **Save** to confirm input. Or press **<** to cancel.

How to use the PDM

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.

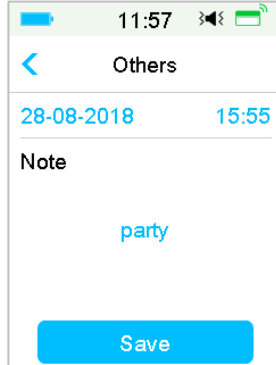


How to use the PDM

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.

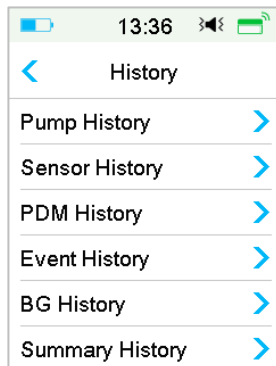
5. When finished, tap **Save** to confirm input. Or press **<** to cancel.

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



How to use the PDM

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.

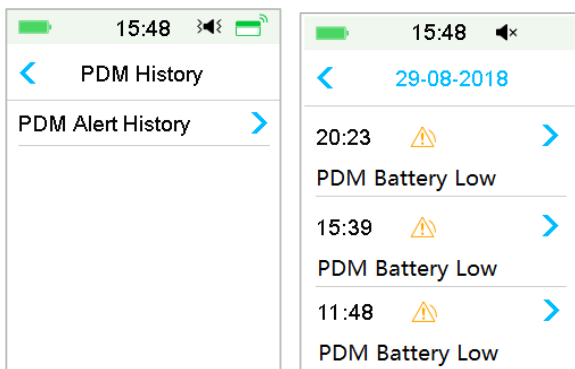
3.10.2 Sensor History

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.

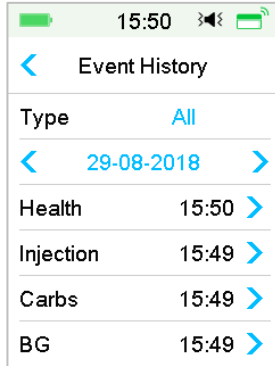
See “Alert Icons” for more information about how to address alarms and alerts and the meanings of different alarm/alert icons.

3.10.4 Event History

Go to the **Event History** screen.

Main Menu → History → Event History

How to use the PDM

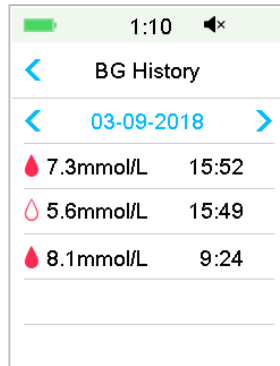





Tap **Type** option to select event type for viewing records accordingly. Tap the date or **<** , **>** to switch between records of different dates. Select an event record to view the details.

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.

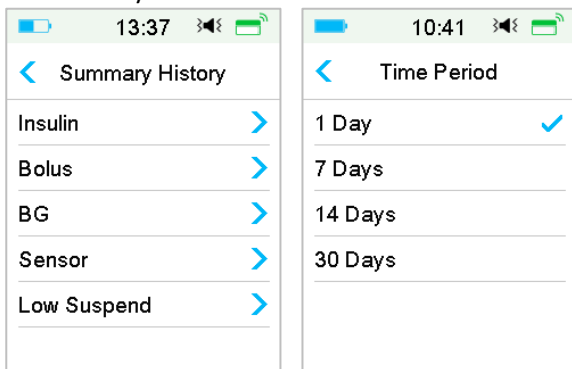
3.10.6 Summary History

How to use the PDM

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

How to use the PDM

Left Panel (24-11-2016)	Right Panel (23-11-2016)
13:41	13:41
BG 1D	BG 14D
24-11-2016	10-11-2016 23-11-2016
BG Test #3.0	BG Test #3.4
Average BG 7.6mmo/L	Average BG 9.6mmo/L
High BG 13.8mmol/L	High BG 13.8mmol/L
Low BG 3.5mmol/L	Low BG 5.5mmol/L

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

Left Panel (13:48)	Right Panel (13:51)
Settings	Settings
CGM System	Diagnostics
Insulin Pump	About Us
General	
Reminders	
Username	
Telephone	

How to use the PDM

3.11.1 CGM System (Optional)

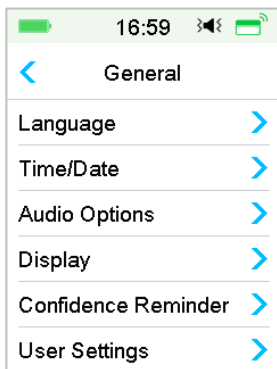
Tap **CGM System** on the **Settings** screen to enter the **CGM System** screen. You can set your Sensor in CGM System Screen. You can turn CGM System on or off, set Transmitter SN, set calibration alert repeat time, set alert silence, set Sensor expiration alert on or off. *See Chapter “How to use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

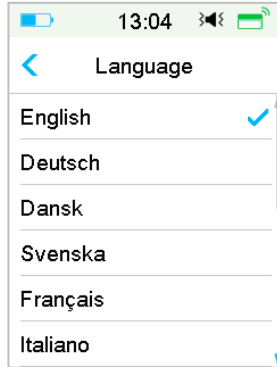
The **General Settings** menu contains: Language, Time/Date, Audio Options, Display, Confidence Reminder, User Settings.



3.11.3.1 Language

You can change your PDM Language.

Main Menu → Settings → General → Language



3.11.3.2 Time/Date

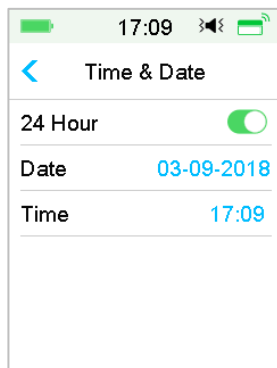
Setting the correct time and date in your PDM is essential to accurate basal insulin delivery and keeping an accurate record of your insulin delivery and other events. You can select a 12-hour or 24-hour clock. Occasionally when you need to change the date and time settings (for example, to adjust for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

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

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

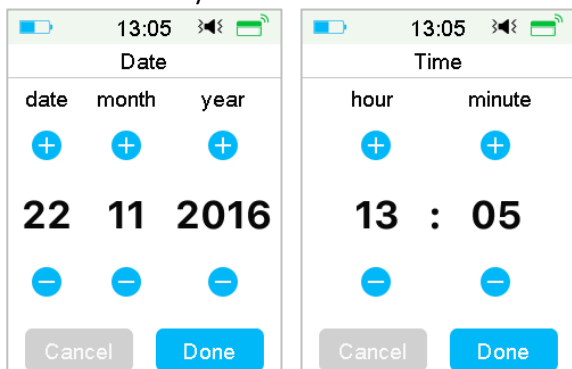
Main Menu → Settings → General → Time/Date

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



How to use the PDM

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.

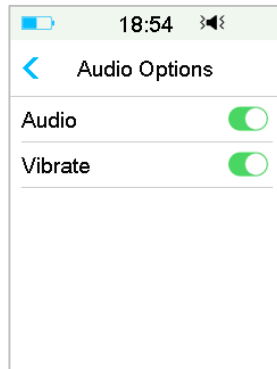
See "Audio Icons" for significance of different audio icons.

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

Go to **Audio Options** screen.

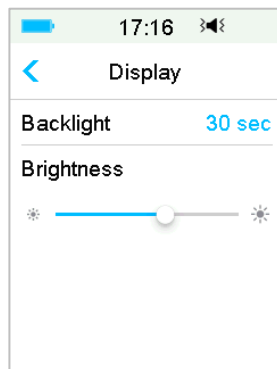
How to use the PDM

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:

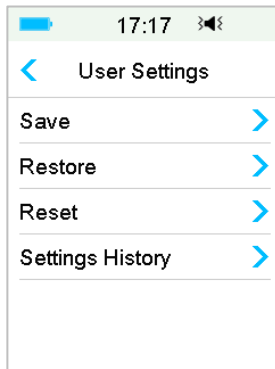
- The beginning and end of a bolus
- The beginning and end of a temp basal
- Basal pattern changed
- Basal edit completed

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- 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.



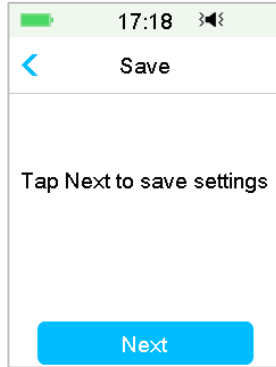
Note: If there is an active Reservoir Patch, **Reset Settings** and **Restore Settings** will be disabled.

Save

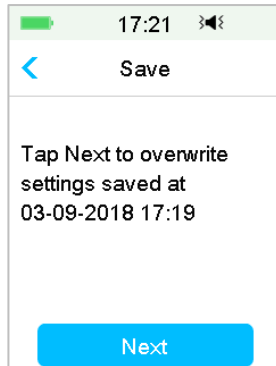
Take these steps to save your current PDM settings:

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

How to use the PDM



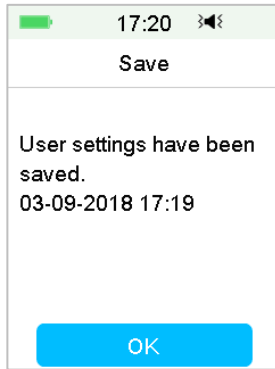
If you have saved PDM settings, this screen appears:



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.

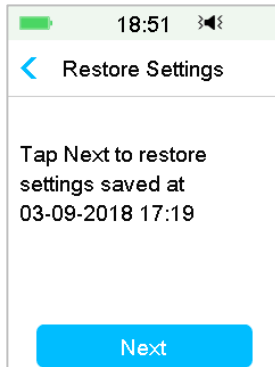
How to use the PDM



Restore

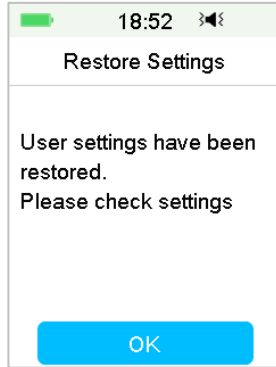
Take these steps to restore the most recent PDM settings you have saved to your PDM.

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.

How to use the PDM

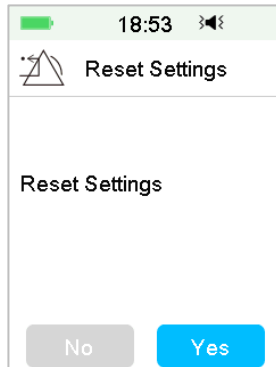


Reset

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.

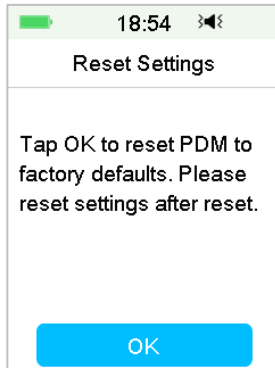
Take the following steps to reset PDM settings:

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.

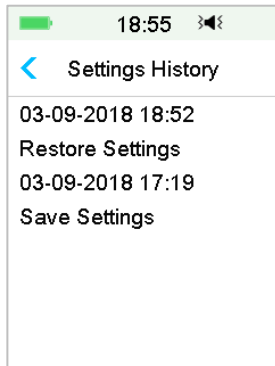
How to use the PDM



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.

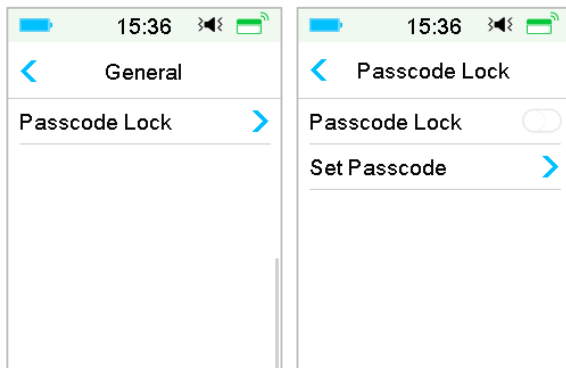


3.11.3.7 Passcode Lock

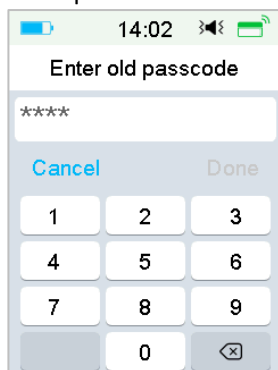
The passcode lock function is a safety feature that prevents improper operation by unintended user.

Main Menu → Settings → General → Passcode Lock

How to use the PDM

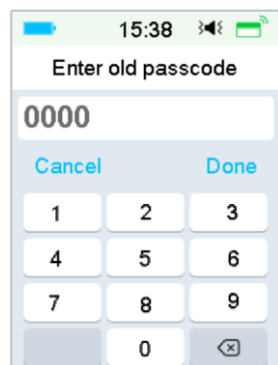


Tap **Set Passcode**, enter the old passcode and then set a new one.



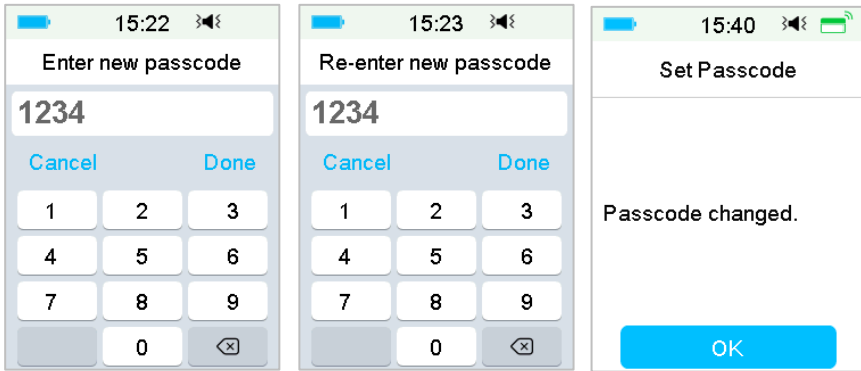
Enter the 4-digit passcode.

Note: The default passcode is 0000.

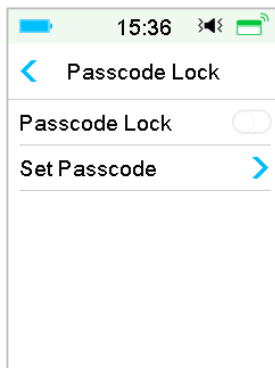


Enter the new passcode twice.

How to use the PDM



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.

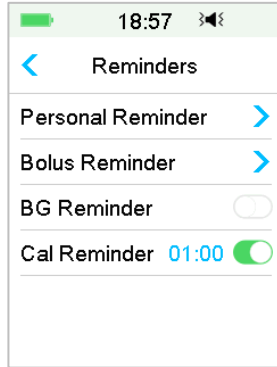


With the Passcode Lock feature turned on, only the Lock Screen is displayed. You have to enter the correct passcode after you slide to unlock the PDM. Once you unlock the PDM, the Passcode Lock is automatically deactivated.

3.11.4 Reminders

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

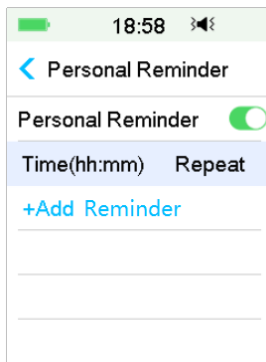
How to use the PDM



3.11.4.1 Personal Reminder

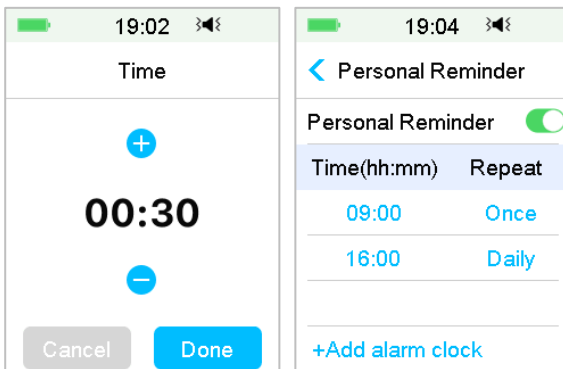
The factory setting for this feature is off. The personal Reminders can be useful to remind you when to check your blood glucose, eat, bolus, etc. You can add, delete, or review Reminders when the Personal Reminder option is turned on. Go to the **Personal Reminder** screen.

Main Menu → Settings → Reminders → Personal Reminder



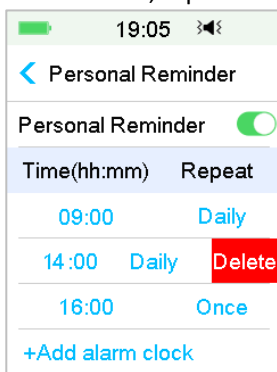
Tap **+ Add Reminder** to add a reminder, choose the time and tap **Done**.

How to use the PDM



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.

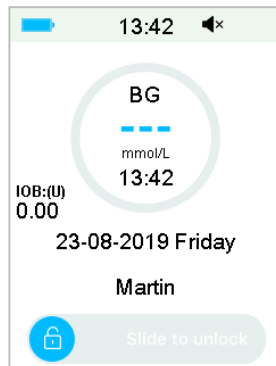
For example, when you want to enter “a”, tap **abc** key, “a”, “b”, “c” appear on the top of the keyboard, then select “a”.

(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.



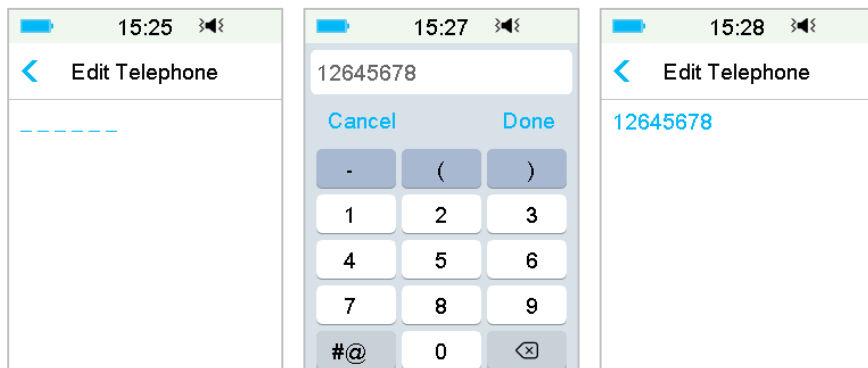
How to use the PDM

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**.

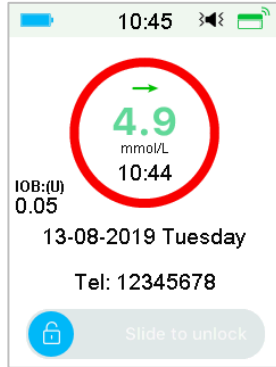
(3) Tap the number in blue to edit telephone number again.

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).



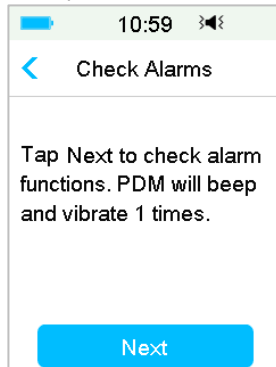
3.11.7 Diagnostics

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

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

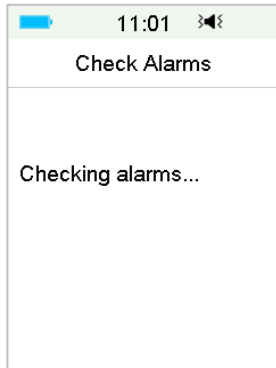
Main Menu → Settings → Diagnostics

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

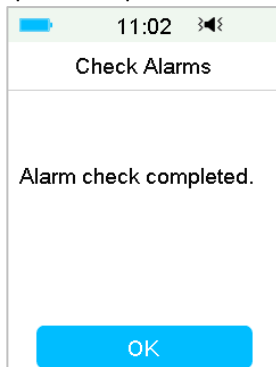


3. The PDM will beep three times and vibrate one time while the screen suggests checking alarms.

How to use the PDM



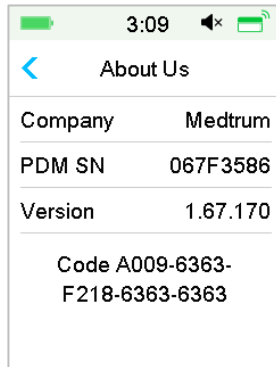
4. When checking is completed, tap **OK** to return to the last menu.



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.

When I should charge my PDM?

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

How to use the PDM

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.

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

How to use Patch Pump

also permitted.

Specifications of syringe:

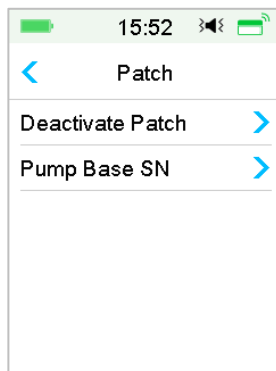
- Reservoir volume: 2.0 mL
- Needle size: 26G
- Needle length: 8 mm (0.31")
- Make sure that the syringe with fill needle has been properly sterilized.


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

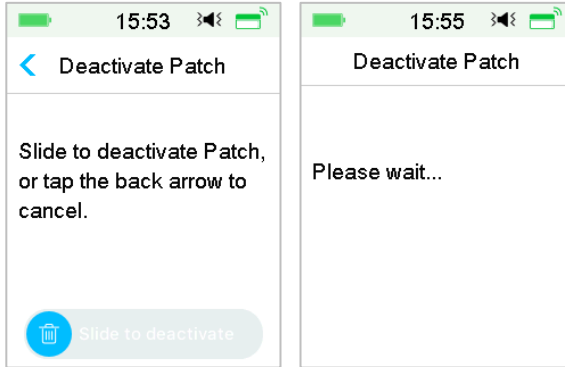
Warning: You must deactivate the current Reservoir Patch before you remove it from your body and disconnect the Pump Base from the Reservoir Patch.

Main Menu → Patch → Deactivate Patch.



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

How to use Patch Pump

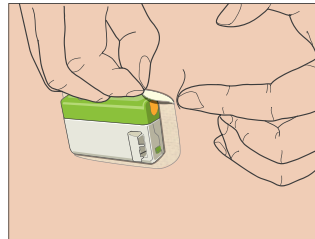
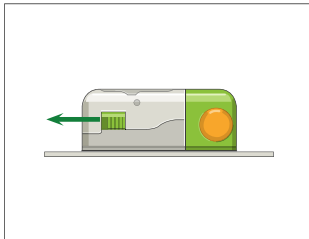


2. Several seconds later, you will see a message showing that the Patch has been deactivated.



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.

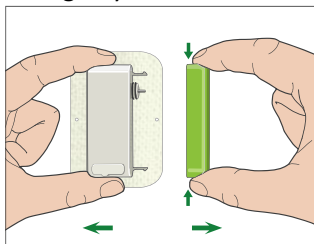


How to use Patch Pump

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.

MEDTRUM

A7+ TouchCare System
Insulin Management System - mmol/L

REF SY-018

Pump Base (xxxxxxxx1x) SN XXXXXXXXX
Personal Diabetes Manager (Black 1x) SN XXXXXXXXX

6 497 1123 680629

CE 0197

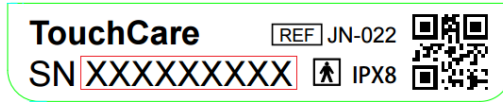
LOT XXXXXXXXX 000

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

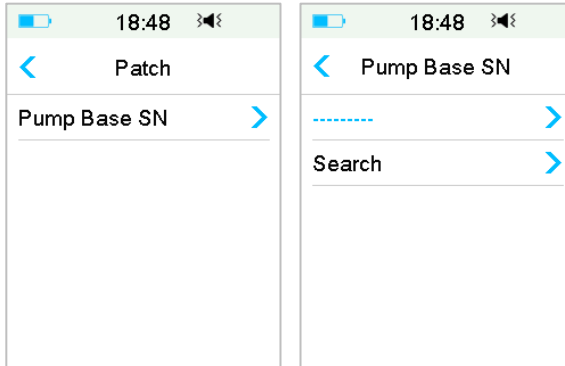
Medtrum B.V.
Nijverheidsweg 17, 5683 CJ Best, The Netherlands
Tel: +31 (0) 499745037

P/N 882022LAMEU0100

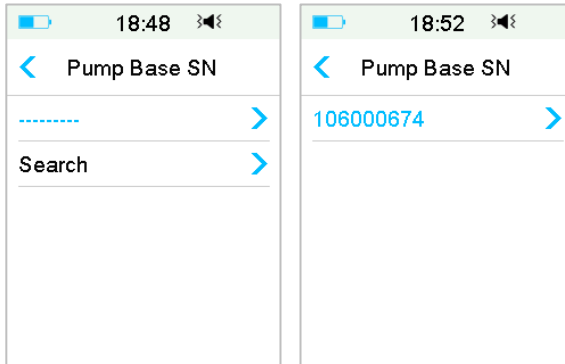
How to use Patch Pump



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

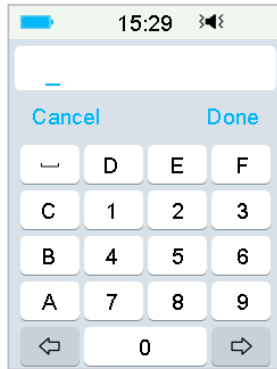


2. You can only enter SN manually if you want to update the SN.
Enter SN manually



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

How to use Patch Pump

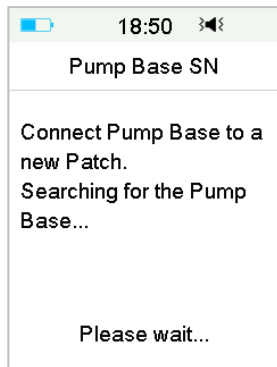


Note: If it is an 8-digit SN, enter space " " at the end.

Search for the SN

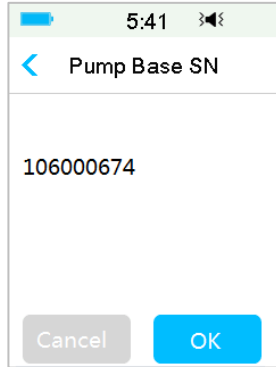
You can select **Search** to search for the SN if it is the first time you enter the SN.

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.



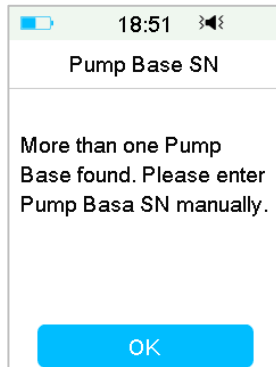
If your PDM finds one Pump, the Pump Base SN appears on the screen. Check if it matches the SN printed on your Pump Base. If it is correct, tap **OK**.

How to use Patch Pump



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.



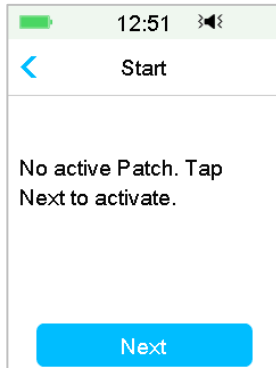
If your PDM does not find a Pump, make sure that your Pump Base is connected to a new Reservoir Patch, move the PDM closer to your Pump, and search again or enter the SN manually.

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.

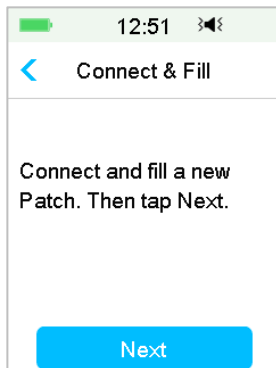
Main Menu → Patch → New Patch

How to use Patch Pump



4.1.3 Connect the Pump Base to a New Reservoir Patch

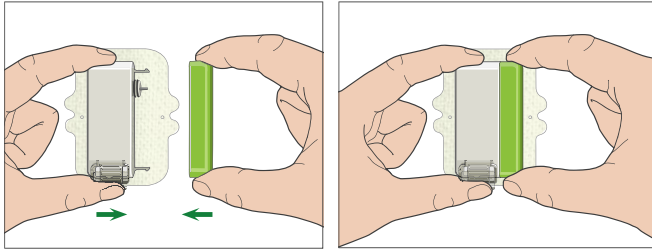
1. Tap **Next** on your PDM and you will see the following message on the screen.



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 connector on the Reservoir Patch all the way into the slots of the Pump Base.

How to use Patch Pump



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.

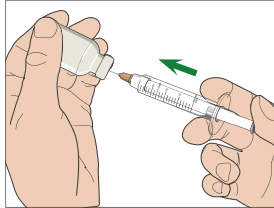
Warning: When you are filling the Reservoir Patch, make sure that it is at least 30 cm (12 inches) from any magnetic objects, such as magnets, mobile phones, and other Reservoir Patches. The Patch Pump will detect the volume of insulin in the reservoir once it is filled, and if the Patch Pump is in a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

Take the following steps to fill a new Patch:

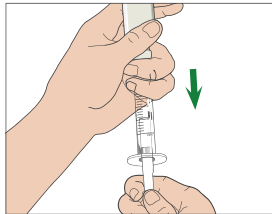
1. Clean the top of the insulin vial with an alcohol wipe.
2. Remove the protective cap from the needle. Keep the cap.
3. With the help of your healthcare provider, decide on the amount of insulin (70 U-200 U) you need to insert into the Reservoir Patch.

How to use Patch Pump

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.



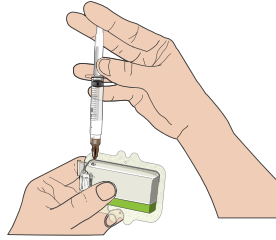
Warning: Avoid using insulin from more than one vial because this may introduce air into the syringe.

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.

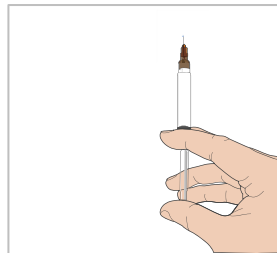
Warning: Make sure that you insert the syringe perpendicularly rather than at an angle into the insulin fill port.

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.

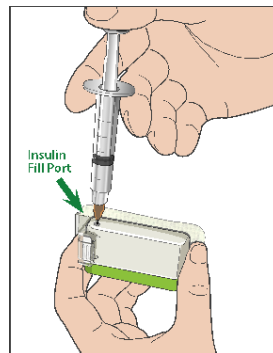
How to use Patch Pump



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.



How to use Patch Pump

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 Remind 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

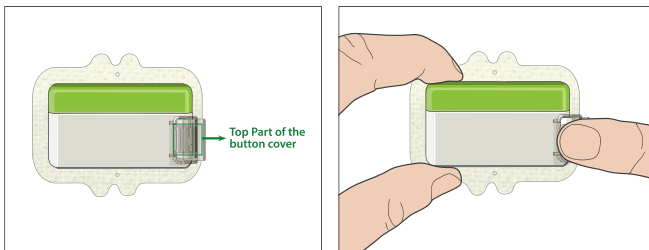
Once the Reservoir Patch is filled with an appropriate amount of insulin (70 U-200 U), tap **Next** on your PDM and you will see the following message on the screen.

How to use Patch Pump

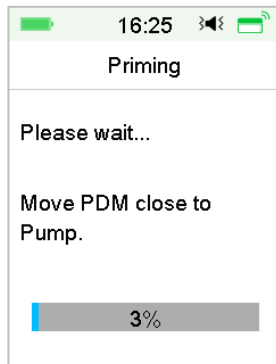


Hold the Patch Pump on a clean flat surface with one hand, and with the other hand, press the top square part of the button cover all the way until you hear a click, indicating the needle button is locked in place by the two hooks on the button cover.

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



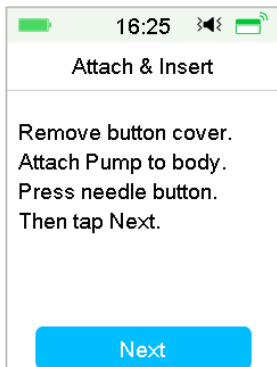
After that, tap **Next** on your PDM to prime the Pump.



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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:

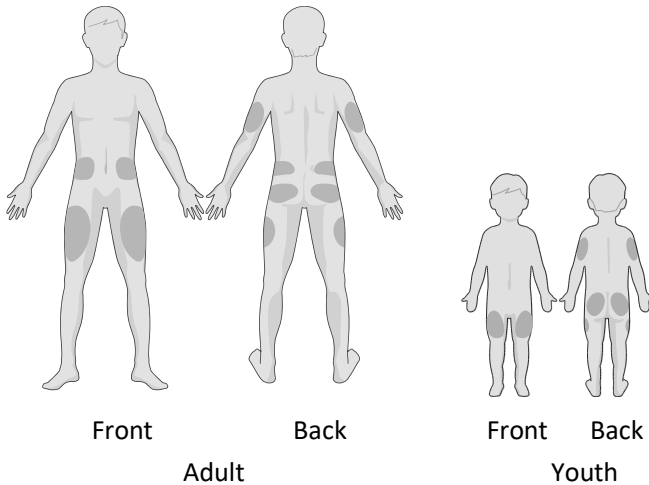
- You can comfortably reach the Pump.
- You apply the Pump to a flat area of skin with adequate subcutaneous fat.
- The area stays flat during normal daily activities without bending or creasing.

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:

How to use Patch Pump



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.

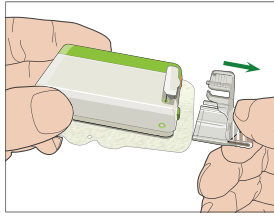
Practice using an aseptic technique as described at the beginning of this chapter. Clean the area with an alcohol wipe where you will attach the Pump. Let the area dry before applying the Pump.

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

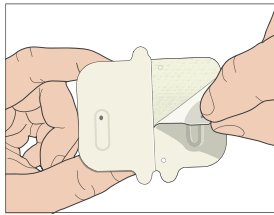
4.1.7 Attach the Patch Pump

1. Remove the button cover.

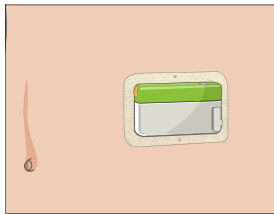
How to use Patch Pump



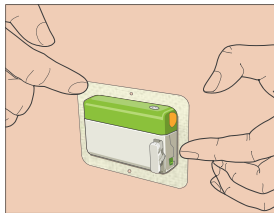
2. Peel off the adhesive liner from the bottom of the Reservoir Patch. Remove the liner and expose the adhesive.



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.



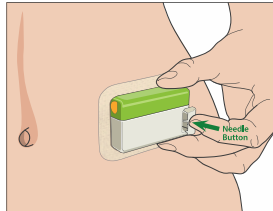
How to use Patch Pump

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.

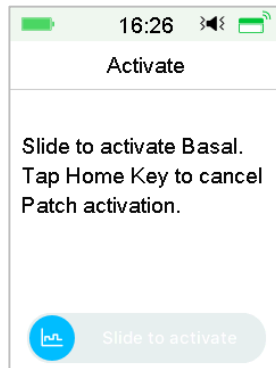
Note: The adhesive is designed for one-time use. Once removed, a Reservoir Patch cannot be reapplied.

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.



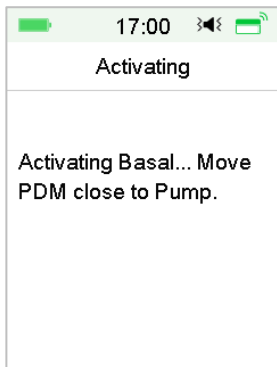
2. Press **Next** after you insert the needle, and the following screen appears.



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.

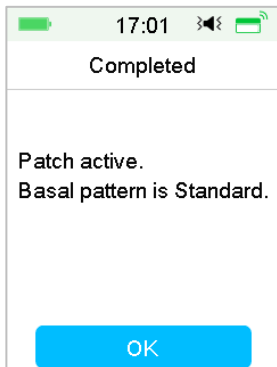
How to use Patch Pump

- 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.

- 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.

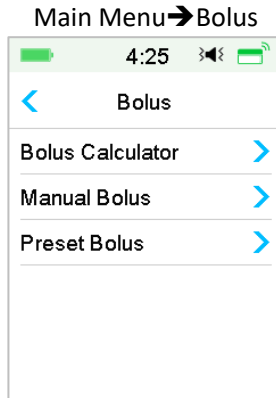
How to use Patch Pump

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.



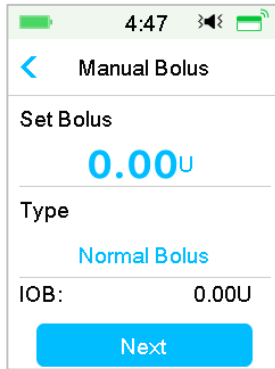
Note: When the Bolus Calculator is switched off in the Settings, Bolus Calculator will not appear in the Bolus menu. *See Chapter “Advanced Pump Features” for more information.*

4.2.1 Normal Bolus

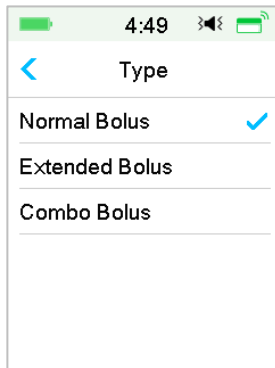
1. To deliver a Normal Bolus, go to the **Manual Bolus** screen.

Main Menu → Bolus → Manual Bolus

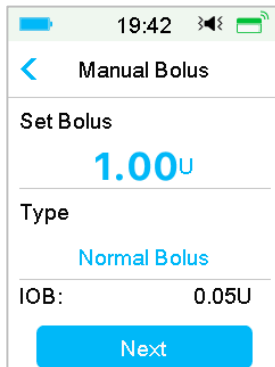
How to use Patch Pump



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



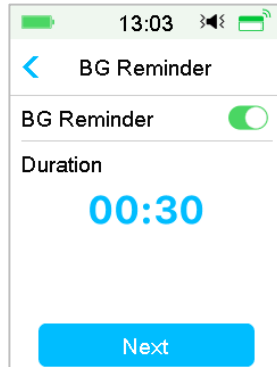
4. Tap **Next** to confirm if the bolus setting is correct.



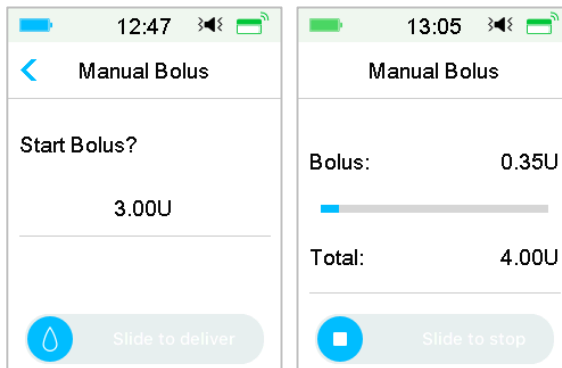
How to use Patch Pump

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.

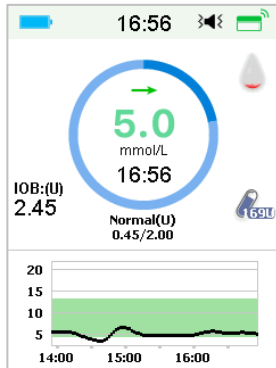


5. **Slide to deliver** the bolus. As the Normal Bolus is being delivered, the amount shown on the screen will add up to the actual bolus amount which is delivered.

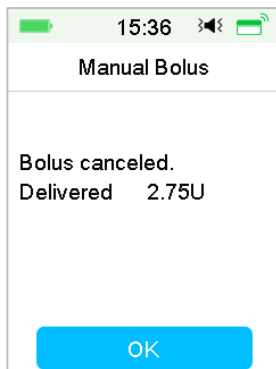


Note: As the bolus is being delivered, you can tap Home Key to return to the Home Screen. The circular progress bar indicating that a bolus is being delivered is displayed on the Home Screen.

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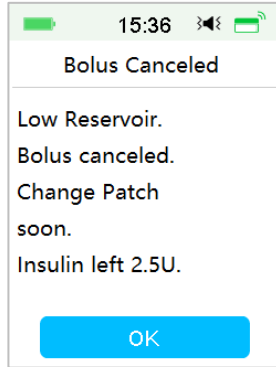


6. You can cancel an active Normal Bolus in the **Suspend** Menu even after insulin delivery has started. **Slide to Stop** to cancel the bolus. An on-screen message will tell you how much insulin has been delivered. Tap **OK** to go back to the Home Screen.

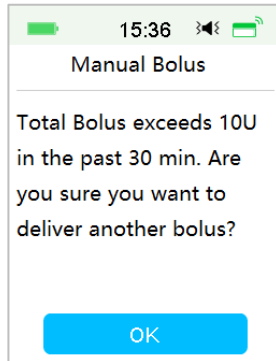


7. If the delivery value given exceeds the remaining insulin amount in the Reservoir, the screen will show the following reminder:

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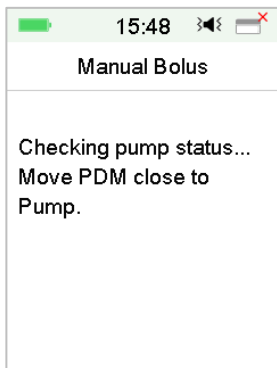


8. If the total Bolus in the last 30 minutes has already exceeded 10 U, the screen will show the following reminder:



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

How to use Patch Pump



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

How to use Patch Pump



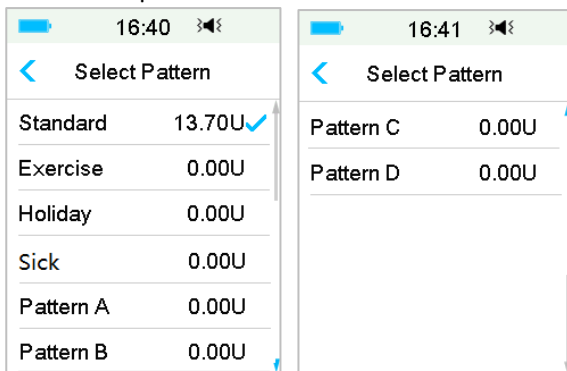
4.3.2 Edit Your Standard Basal Pattern

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

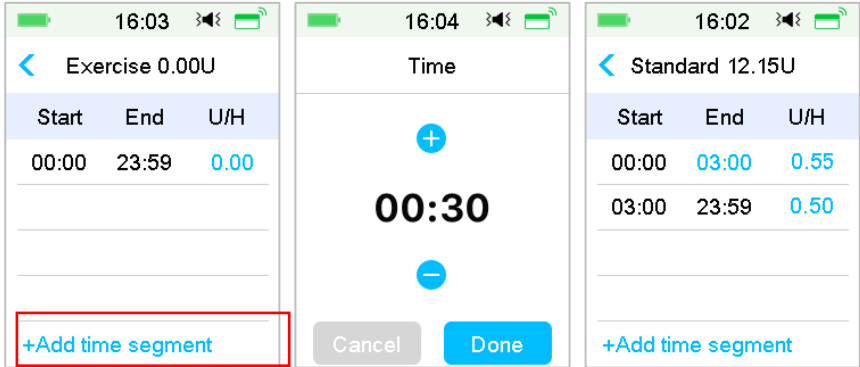
1. Select the **Standard** pattern to edit it.



Note: The active basal pattern is check-marked.

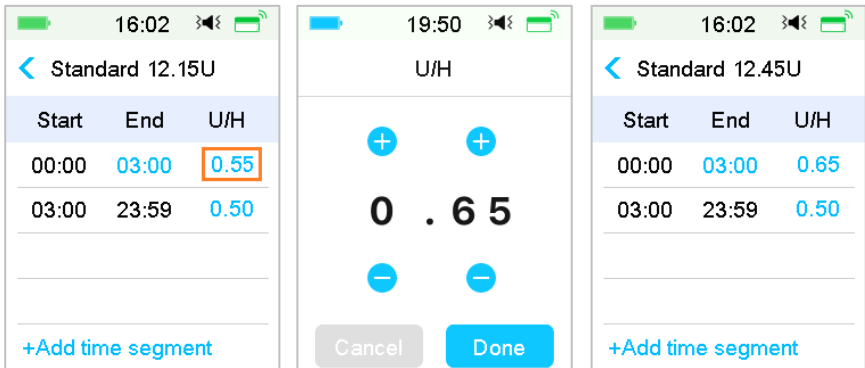
2. The edit screen appears. Tap **+Add time segment** to add a new segment. Enter the end time for this segment. Then tap **Done**.

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Note:

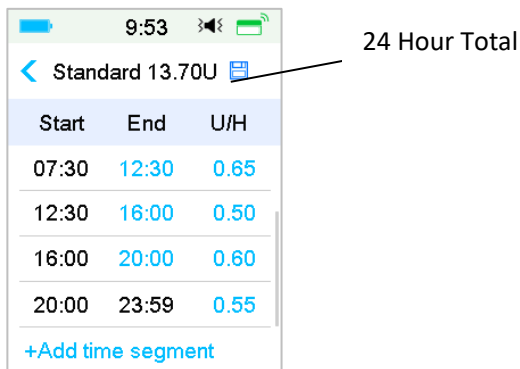
- 1) The first basal segment always starts at 00:00 (12:00 am).
- 2) The last basal segment always ends at 24:00 (12:00 pm).
- 3) Segments can start since each hour or each half-hour. The end time point of the last time segment is always set to be midnight.
- 4) Tap **+Add time segment** to create and 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.

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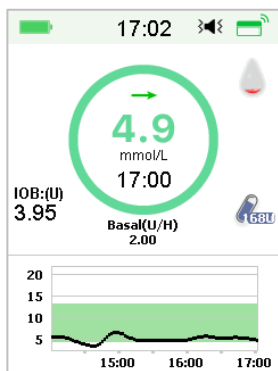


Note: If all 48 basal segments were added, the **+Add time segment** button disappears automatically. Set your basal segments as recommended by your healthcare provider.

4.3.3 Check the Current Basal Rate

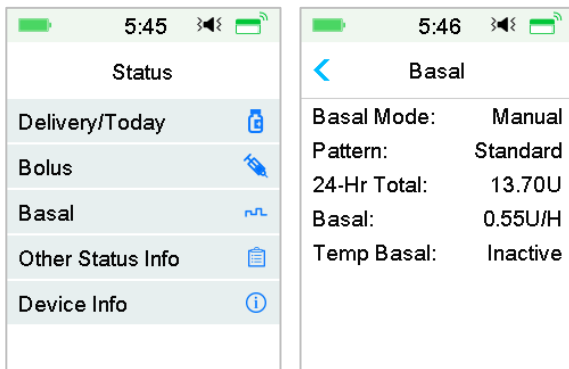
The **Home Screen** and the **Status Screen** show the information of the current basal rate.

1. Home Screen



2. Status → Basal

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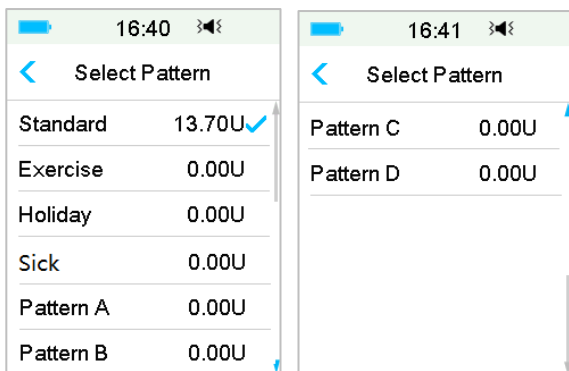


4.3.4 Review Your Basal Patterns

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

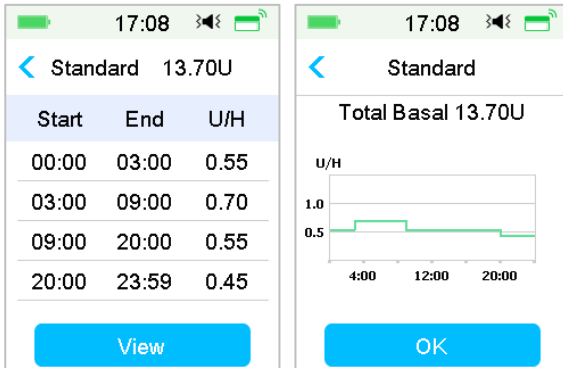
1. Go to the **Basal Review** screen.

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



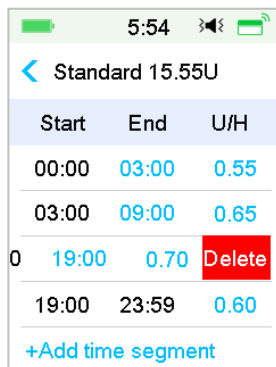
2. Choose the basal pattern that you want to review. Tap it to review your programmed settings.

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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).

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	Start	End	U/H
0	03:00	03:59	0.55
	03:00	23:59	0.65

	Start	End	U/H
	00:00	23:59	0.55

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:

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Start	End	U/H
00:00	12:00	0.70
12:00	13:00	0.65
13:00	15:00	0.50
15:00	23:59	0.60

Start	End	U/H
00:00	15:00	0.70
15:00	23:59	0.60

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.

Start	End	U/H
00:00	12:00	0.70
12:00	13:00	0.65
13:00	15:00	0.50
15:00	23:59	0.60

Start	End	U/H
00:00	12:00	0.70
12:00	23:59	0.65

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

How to use Patch Pump

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

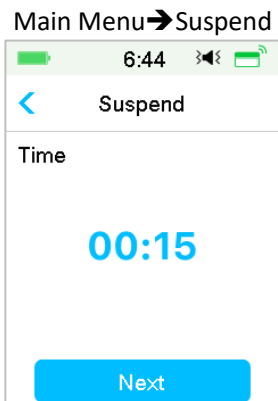
Sometimes you may need to suspend insulin delivery. When no bolus is being delivered, you can suspend basal insulin delivery for a set period of time.

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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.

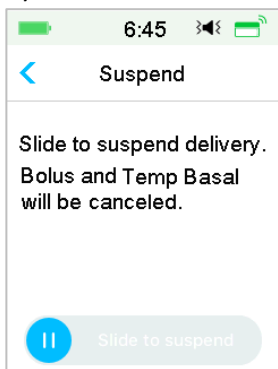
a. When no bolus is being delivered:

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



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

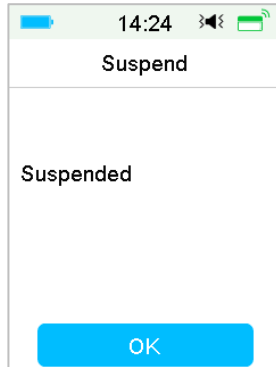
2. The following message will appear. **Slide to suspend** if you want to suspend insulin delivery.



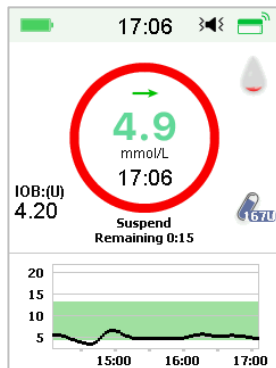
Note: When you suspend insulin delivery, Bolus and Temp Basal will be canceled and cannot be resumed.

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



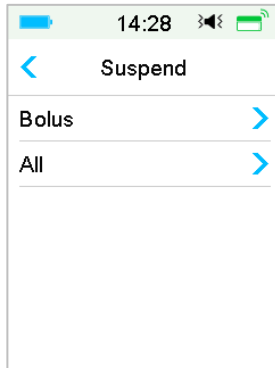
4. The remaining suspend time can be found on **Home Screen**.



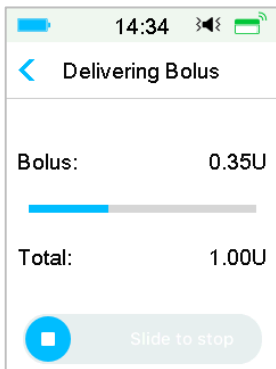
- b. When a Normal/Extended/Combo Bolus is being delivered.
 1. You can choose to suspend all insulin delivery or only the bolus.

Main Menu → Suspend

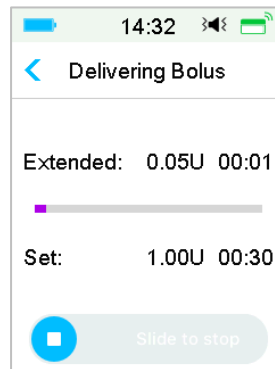
How to use Patch Pump



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

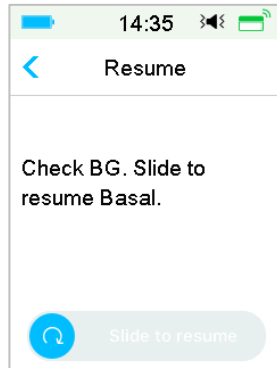


Stop Extended Bolus

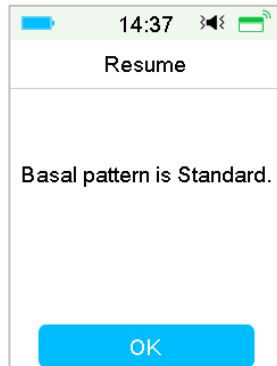
4.4.2 Resume Insulin Delivery

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

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Slide to resume Basal delivery.

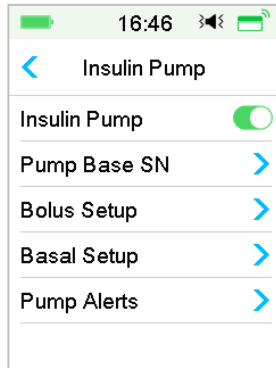


Note: Only basal pattern can be resumed, Bolus and Temp Basal cannot be resumed.

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.

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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.

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Bolus Calculator

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

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.

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.

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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.

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.

Preset Temp Basal

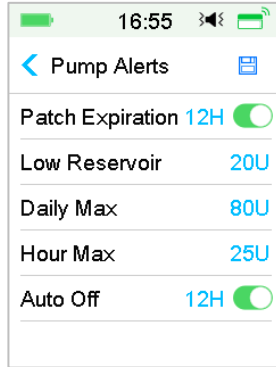
See Section “Preset Temp Basal” in Chapter “Advanced Pump Features” for more information. You can set up to seven preset temp basal rates: Heavy Ex, Medium Ex, Light Ex, Sick, Temp 1, Temp 2 and Temp 3.

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.

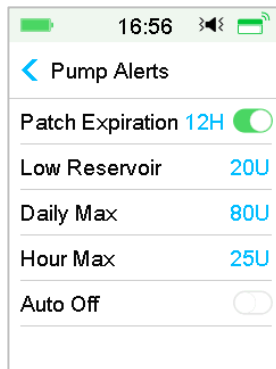
4.5.4 Pump Alerts

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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.

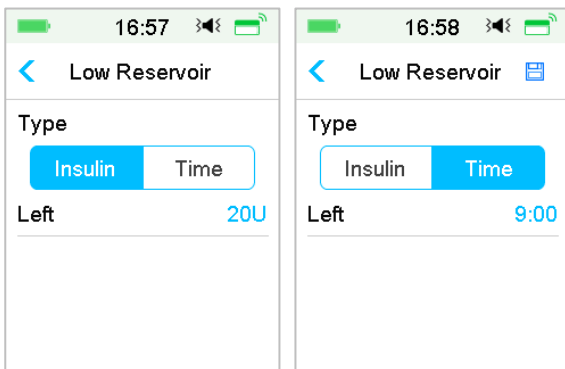
2. Low Reservoir

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

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- 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

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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.

How to use Patch Pump

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.

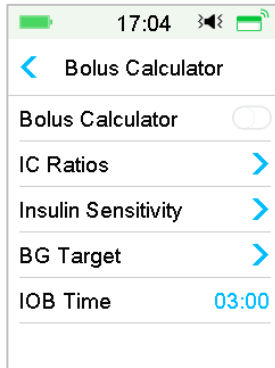
Instructions for programming the bolus calculator feature settings are in the following paragraphs. Program your settings in the order as describe in the following to make sure you have programmed all the settings.

Bolus Calculator Feature on/off

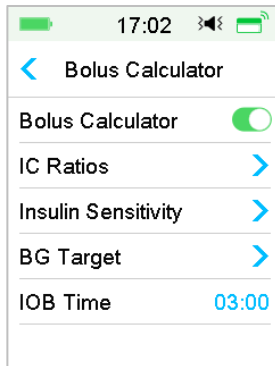
1. Go to the **Bolus Calc Setup** screen.

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

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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.

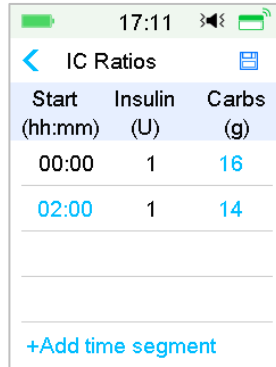
Note: If you set only one Insulin-to-Carb ratio, it will be used for the entire 24-hour period.

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.



Start (hh:mm)	Insulin (U)	Carbs (g)
00:00	1	16
02:00	1	14
+Add time segment		

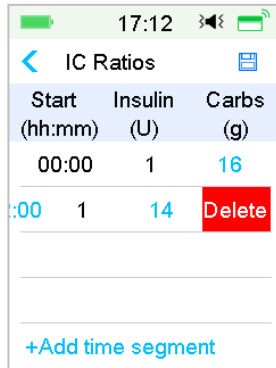
Note: Add time segments by choosing from 00:30-23:30 or 12:30A-11:30P, with an increment of 00:30.



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.

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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.

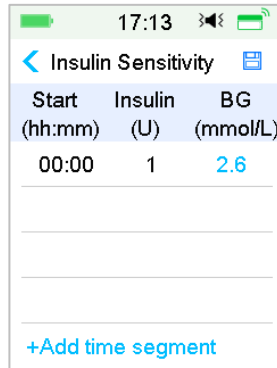
Note: If you only set one insulin sensitivity factor, it will be used for the entire 24-hour period.

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.

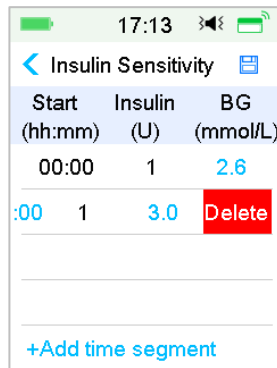




Note: Add time segments by choosing from 00:30-23:30 or 12:30A-11:30P, with an increment of 00:30.

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

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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.

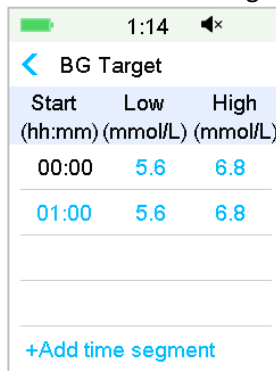
If your current BG is above the BG Target Range, the bolus calculator feature will calculate a correction dose. If your current BG is below the BG Target Range, the bolus calculator will calculate a negative correction and thus subtract it from your food bolus.

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.



Start (hh:mm)	Low (mmol/L)	High (mmol/L)
00:00	5.6	6.8
01:00	5.6	6.8
+Add time segment		

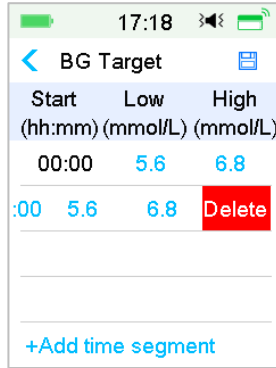
Note: Add time segments by choosing from 00:30-23:30 or 12:30A-11:30P, with an increment of 00:30.

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.

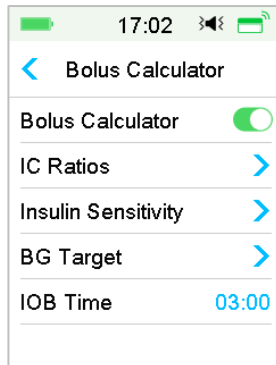


- When finished, press to exit the edit mode and press to save settings.

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.



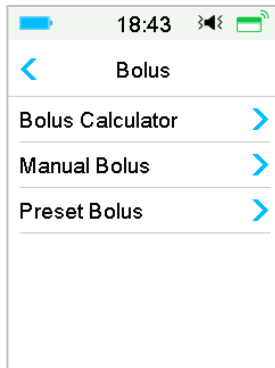
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Note: You can set the IOB Time between 2h and 8h with an increment of 0.5h. The factory default is 3 Hours (03:00).

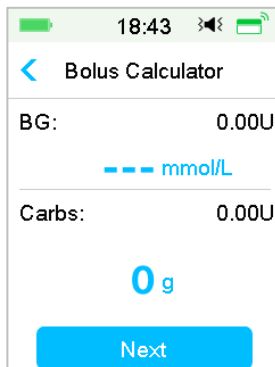
5.1.3 Normal Bolus Using Bolus Calculator

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

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- 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:

18:45

< Bolus Calculator

BG: 0.65U

7.8 mmol/L

Carbs: 7.10U

40 g

Next

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**.

18:48

< Bolus Calculator

Set Bolus:

2.65 U

Type

Normal Bolus

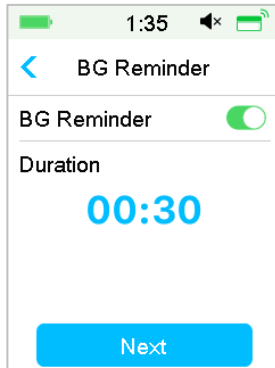
Suggested: 2.65U

IOB: 0.00U

Next

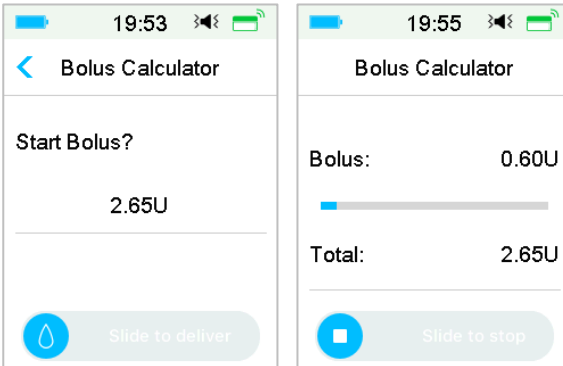
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Note: The **BG Reminder** screen will appear if you have BG Reminder turned on. You can accept or modify the time before you are reminded to check your blood glucose after a bolus.



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.



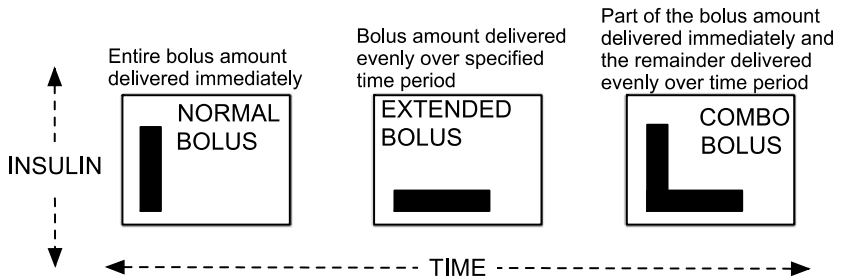
Note: You can cancel an active Normal Bolus (one that is currently being delivered) even after insulin delivery has started. **Slide to Stop** to cancel the bolus.

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.

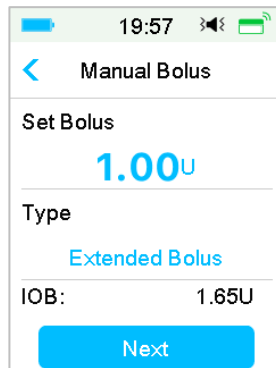
See the following graphic for a description of the different bolus types.



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

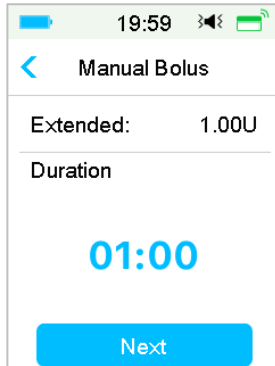
To set an Extended Bolus, follow these steps:

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

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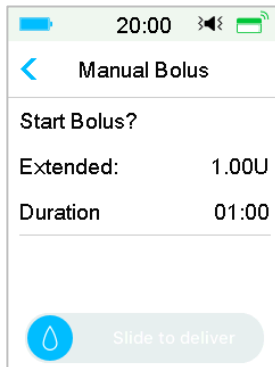
Note: You can set a bolus dose between 0 and the Max Bolus.

- 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

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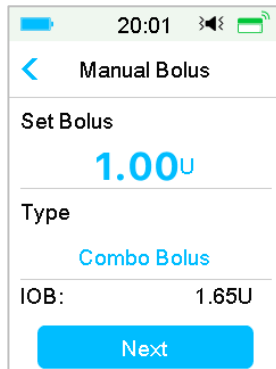
To set a Combo Bolus, follow these steps:



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

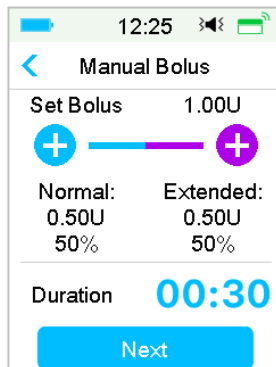
Note: You can set a bolus dose between 0 and the Max Bolus.

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

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



- Tap the blue icon  to increase Normal Bolus. Tap the purple icon  to increase Extended part.
- Enter the amount of time you want the Extended Bolus to last and tap Next to continue.



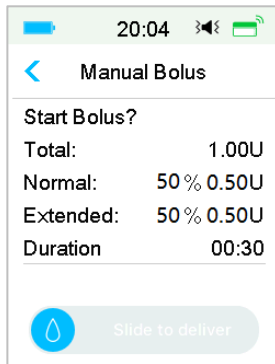
Note: You can set the duration between 30 min and 8h with an increment of

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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.

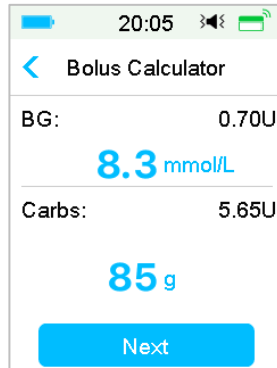
- e. Details of the Combo Bolus will be displayed. **Slide to Deliver** to start delivery.



5.2.2 Combo/Extended Bolus Using Bolus Calculator

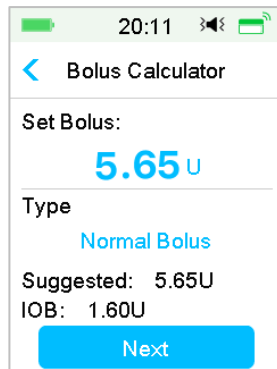
If you are using the bolus calculator feature to calculate your extended or Combo Bolus amounts, you will be prompted to enter your BG reading and/or carb intake. The bolus calculator feature will use this input to calculate your suggested bolus amount. You can also change the estimated bolus if desired.

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.

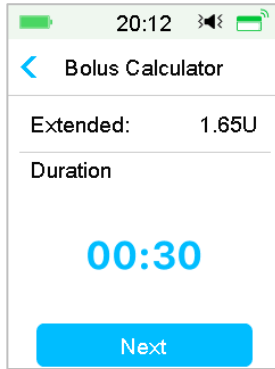
Note: If there is a correction part in the suggested bolus dose, the correction part can only be delivered as a Normal Bolus or the normal part of a Combo Bolus. In other words, the Extended Bolus option will become unavailable in that case.

Extended Bolus

To set an Extended Bolus, follow these steps:

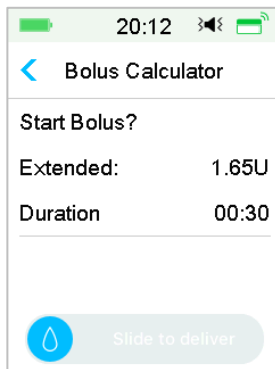
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- a. The extended duration screen appears. Enter the amount of time you want the Extended Bolus to last and tap **Next**.



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.

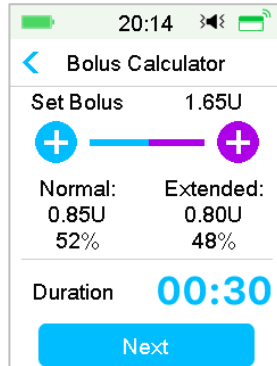
Combo Bolus

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.

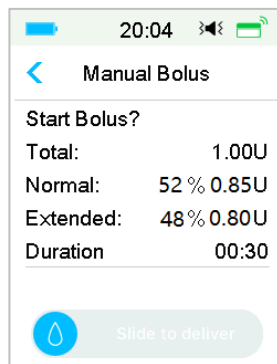
b. Enter the amount of time you want the Extended Bolus to last and tap **Next** to continue.



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

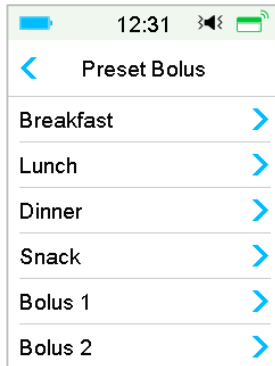
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The preset bolus feature enables you to program bolus deliveries for frequent use. You can set up to seven preset bolus amounts: Breakfast, Lunch, Dinner, Snack, Bolus 1, Bolus 2, and Bolus 3.

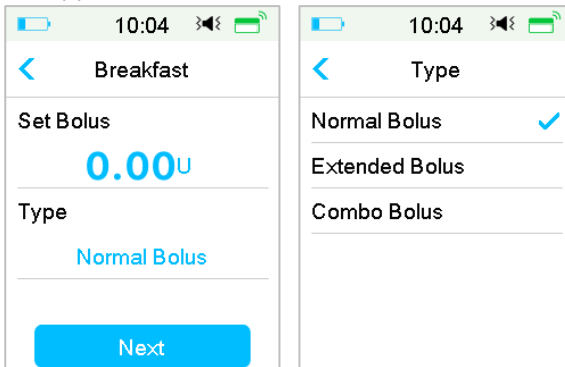
5.3.1 Preset Bolus Setup

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

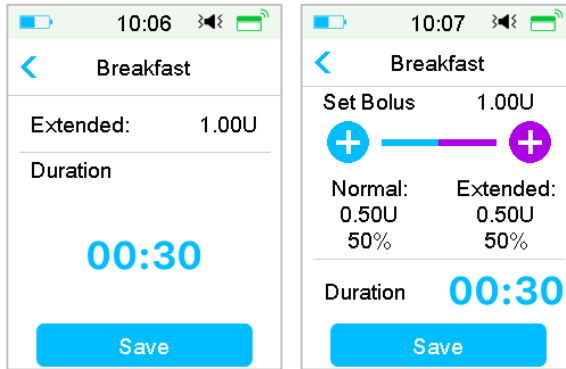
Main Menu → Settings → Insulin Pump → Bolus Setup → Preset Bolus Setup



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.



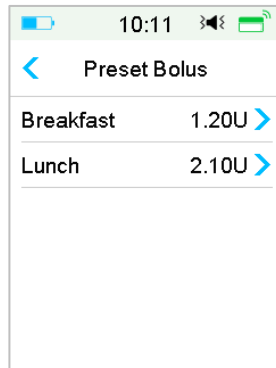
4. Tap **Save** to save the settings. Tap or Home button and tap **No** to quit the settings.

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.

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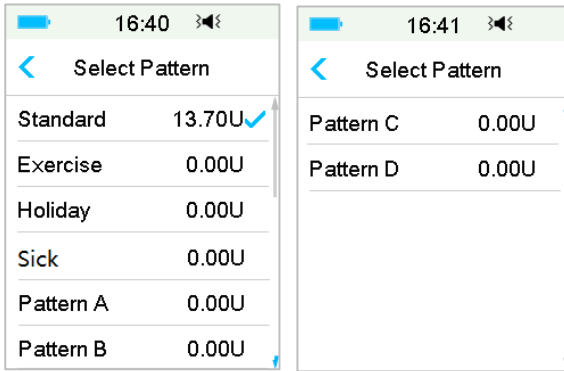
4. Start bolus delivery.

5.4 Select a Basal Pattern

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

Main Menu → Basal → Select Pattern

2. Select the desired pattern and slide to activate it.



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.

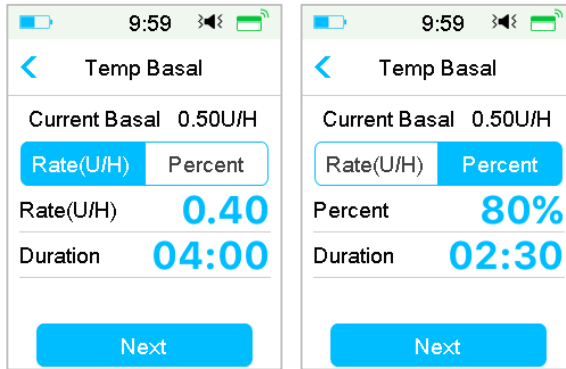
Note: During a temp basal delivery, the basal pattern is temporarily overwritten, thus not available. After the temp basal delivery is completed or canceled, your system will return to the selected basal pattern.

5.5.1 Activate a Temp Basal

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

Main Menu → Basal → Temp Basal

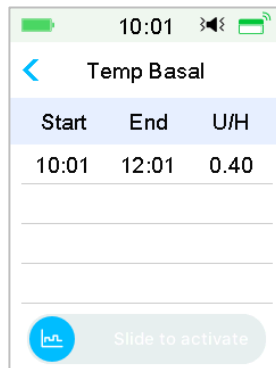
2. Select a temp basal type, temp rate or percent and duration, then Tap **Next** to review the temporary basal rates set.



Note: If **Percent** is selected, you can set the temp basal rate, not exceeding the Max Basal Rate, between 0 and 200% with an increment of 1%. If **Rate (U/H)** is selected, you can set the temp basal between 0 and the Max Basal Rate with an increment of 0.05 U/H.

Note: You can set the duration between 30 min and 24h with an increment of 30 min.

3. Make sure that the temp basal is correct in this Temp Basal Review, then **Slide to activate**.

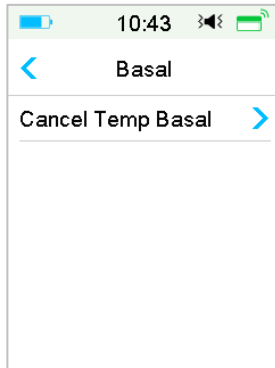



5.5.2 Cancel a Temp Basal

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

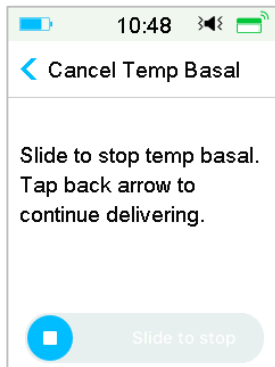
Main Menu → Basal → Cancel Temp Basal

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- Slide to stop temp basal delivery, or tap  to continue delivering.

Note: If you suspend insulin delivery while a temp basal rate is active, the temp basal rate will be canceled.



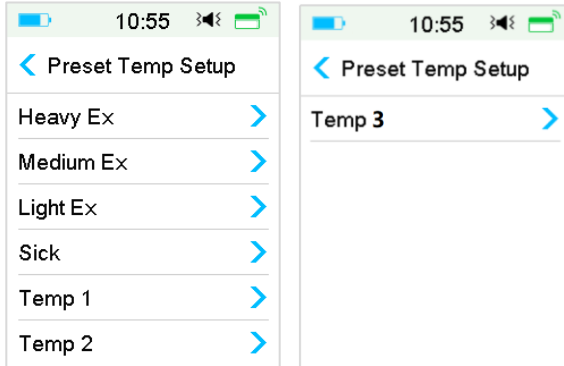
5.6 Preset Temp Basal

With the preset temp basal feature, you can program temp basal rates for recurring short-term situations. You can set up to seven preset temp basal rates: Heavy Ex, Medium Ex, Light Ex, Sick, Temp 1, and Temp 2 and Temp 3.

5.6.1 Preset Temp Basal Setup

- Go to the **Preset Temp Setup** screen.

Main Menu → Settings → Insulin Pump → Basal Setup → Preset Temp Setup



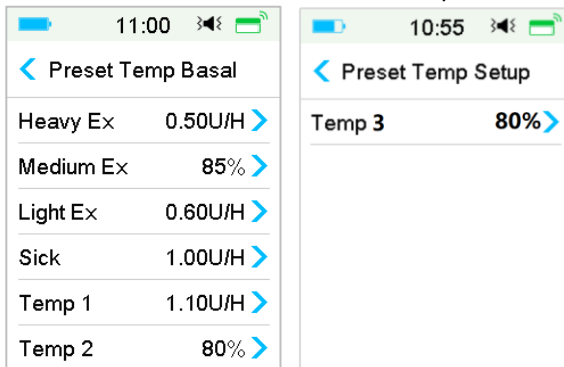
2. Select a preset temp basal you want to edit. Choose the temp basal type (rate or percent).
3. Set the duration and rate/percentage of the preset temp basal. Tap **Save** to save settings.

5.6.2 Activate a Preset Temp Basal

You must set up a preset temp basal before you can activate it.

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

Main Menu → Basal → Preset Temp Basal



The programmed preset temp basal types are displayed on this screen. If you have not set up any preset temp basal rate, this screen shows **No Presets**.

2. Select the preset temp basal you want to activate.
3. Confirm your preset temp basal settings.

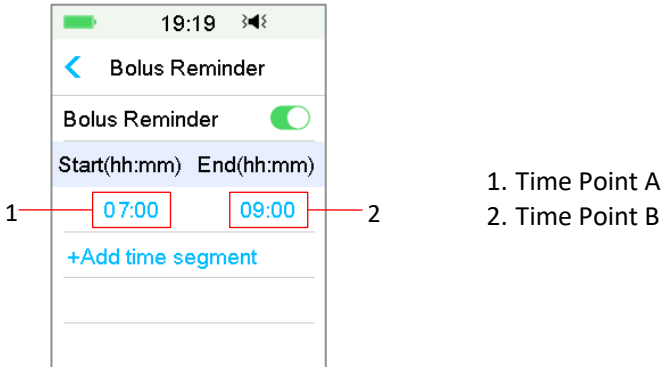
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4. Slide to activate.

5.7 Reminder

5.7.1 Bolus Reminder

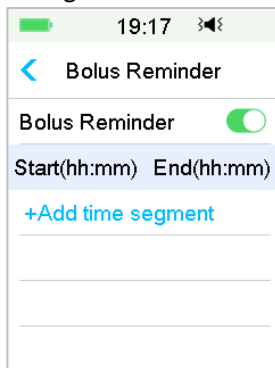
When you fail to deliver a Bolus at between time point A and time point B, you will receive a Reminder at time point B.



You can add, delete, or review Reminders when the Bolus Reminder option is turned on.

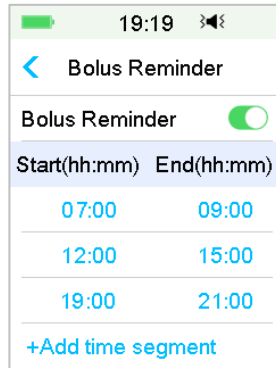
Go to the **Bolus Reminder** screen.

Main Menu → Settings → Reminders → Bolus Reminder



Add Reminder

Tap **+ Add time segment** to add one Reminder, setting the start and end time.

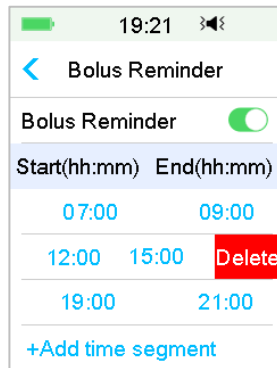


Note:

- 1) The end time should be at least 30 min later than the start time. You can program up to four bolus Reminders.
- 2) The Reminders will be saved automatically.

Delete Reminder

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



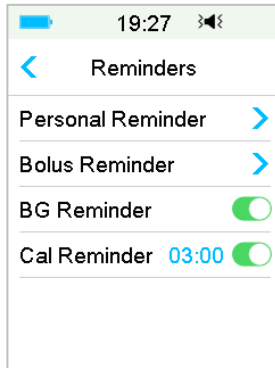
5.7.2 BG Reminder

After you deliver a bolus, you may want to check your BG. The BG Reminder is an optional feature that reminds you to check your BG after a bolus.

Go to the **BG Reminder Setup** screen.

Main Menu → Settings → Reminders → BG Reminder

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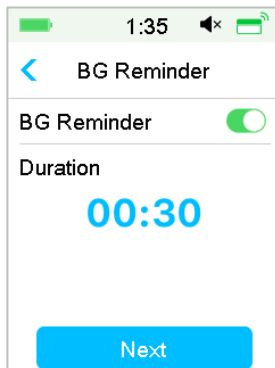


If you have BG Reminder turned on, the **BG REMINDER DURATION** screen appears when you set Bolus.

It allows you to set the time before you are reminded to check your blood glucose after a bolus.

The time ranges from 00:30 to 05:00 with an increment of 30 minutes. The default time is 00:30.

You can also turn off the BG reminder after each bolus.



You can accept or modify the time before you are reminded.

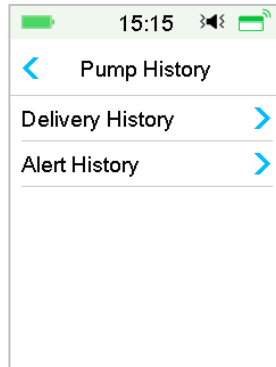
5.8 Pump History

5.8.1 Pump History

The **Pump History** displays the delivery history (bolus, basal and total daily delivery history) and alert history (pump alerts and alarms).

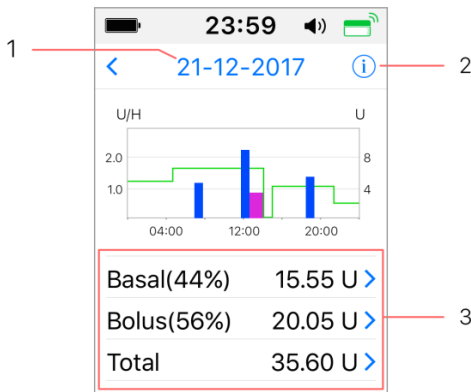
Go to the **Pump History** screen.

Main Menu → History → Pump History



5.8.1.1 Delivery History

You can select one day to review its delivery graph. It displays the summary of basal, bolus and total delivery for one day.



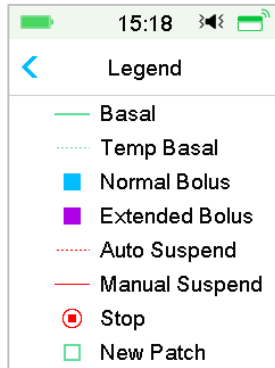
1. Tap the date to switch between records of different dates

2. Tap the info icon to review legend meanings.

3. Tap the “Basal, Bolus, Total” summary chart at the bottom of Delivery History screen to see details.

(1) The legend

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Legend	Abbreviation	Significance
	Basal	Basal Rate infusion curve
	Temp Basal	Temp Basal Rate infusion curve
	Normal Bolus	Normal Bolus delivery icon
	Extended Bolus	Extended Bolus delivery icon
	Auto Suspend	This tag appears when any of the following alarms occurs: AUTO OFF, PREDICTIVE LOW SUSPEND, LOW SUSPEND, EXCEEDS MAX TDD, EXCEEDS MAX 1HR DELIVERY ALARM.
	Manual Suspend	Manually suspend all insulin delivery
	Stop	Including deactivate patch, discard patch, and alarms: OCCLUSION DETECTED, PATCH EXPIRED, PATCH ERROR, PATCH BATT DEPLETED, PUMP BASE ERROR, EMPTY RESERVOIR.
	New Patch	When you activate a new patch, this icon appears.

(2) Basal History

This screen displays most detailed Basal information.

Time	Amount
*14:37	0.45U/H
13:43	PLowSusp
11:00	0.50U/H
07:00	0.45U/H
03:00	0.65U/H
00:00	0.40U/H

(3) Bolus history

The summary information includes:

- The start time of this bolus;
- Status of bolus: completed, canceled, delivering;
- Bolus type;
- Amount of bolus delivered | Amount of bolus programmed.

Time	Status	Calc	E	C	N
18:40	Canceled	4.50U	6.00U		
11:30	Completed	5.10U	5.00U		
07:00	Completed	1.00U	1.00U		

Bolus Type:

- ◇ N: Normal Bolus
- ◇ E: Extended Bolus
- ◇ C: Combo Bolus
- ◇ Normal: Normal Bolus by Manual Bolus
- ◇ Extended: Extended Bolus by Manual Bolus

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- ✧ Combo: Combo Bolus by Manual Bolus
- ✧ Calc-N: Normal Bolus by Bolus Calculator
- ✧ Calc-E: Extended Bolus by Bolus Calculator
- ✧ Calc-C: Combo Bolus by Bolus Calculator

Tap record line to view more detailed information. See Chapter “Advanced Pump Features” for more information.

(4) Daily Totals

This screen displays most detailed Daily Totals information.

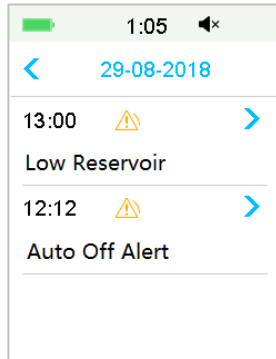
15:26 29-08-2018		15:28 29-08-2018		15:28 29-08-2018	
Carbs	200g	Food+Corr	0.00U #0	20:20	N 5.30U
Total Insulin	31.80U	ManualBo	9.70U #2		
Basal(34%)	12.70U	Bolus Total	19.10U		
Bolus(66%)	19.10U	9:20	N 4.40U		
FoodBolus	7.30U #1	14:30	E 7.30U 0:30		
CorrBolus	2.10U #1	16:33	N 2.10U		

- ✧ **N** represents Normal Bolus.
- ✧ **E** represents Extended Bolus.
- ✧ **C** represents Combo Bolus.
- ✧ **FoodBolus 7.30U #1** means that there is one food bolus doses in the selected day with a total amount of 7.30U.
- ✧ **CorrBolus 2.10U #1** means that there is one correction bolus doses in the selected day with a total amount of 2.10U.
- ✧ **Food+Corr 0.00U #0** means that there is no bolus dose that both covers carbs and corrects glucose in the selected day.
- ✧ **ManualBo 9.70U #2** means that there are two manual bolus doses in the selected day with a total amount of 9.70U.

5.8.1.2 Alert History

Go to the pump **Alert History** screen.

Main Menu → History → Pump History → Alert History



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

See Section “Alert Icons” in Chapter “How to use the PDM” for more information about how to address alarms and alerts and the meanings of different alarm/alert icons.

5.8.2 Pump Summary History

5.8.2.1 Summary History: Insulin History

This screen displays the insulin delivery summary history.

Go to the **Insulin History** screen.

Main Menu → History → Summary History → Insulin History

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17:06	
Insulin 1D	
22-11-2016	
Daily Insulin	10.00U
Daily Basal(30%)	3.00U
Daily Bolus(70%)	7.00U
Daily Carbs	30g

17:06	
Insulin 14D	
08-11-2016 21-11-2016	
Daily Insulin	10.00U
Daily Basal(30%)	3.00U
Daily Bolus(70%)	7.00U
Daily Carbs	30g

Daily Insulin: Total daily dose of insulin delivered per day.

Daily Basal: Average daily dose and percentage of insulin delivered as Basal.

Daily Bolus: Average daily dose and percentage of insulin delivered as Bolus.

Daily Carbs: Average daily amount of carbs.

5.8.2.2 Summary History: Bolus History

This screen displays the Bolus summary history.

Main Menu → History → Summary History → Bolus History

17:18	
Bolus 1D	
22-11-2016	
Carbs Bolus	3.00U#2.0
Correction Bolus	5.00U#4.0

17:18	
Bolus 14D	
08-11-2016 21-11-2016	
Carbs Bolus	3.00U#2.0
Correction Bolus	5.00U#4.0

Carbs Bolus Only: Average daily dose and the number of times of Food Bolus only on the selected days.

BG Correction Only: Average daily dose and the number of times of BG correction Bolus only on the selected days.

5.9 Troubleshooting Pump issues

Can I take a sauna with a Patch Pump on?

No.

Firstly, the operating temperature range for the Patch Pumps is +5°C ~ +40°C.

Secondly, if you take a sauna, insulin will be absorbed faster into your body, and your blood glucose can fluctuate.

Can I dive with a Patch Pump on?

No.

Your Patch Pump is waterproof to a depth of 2.5 meters (8 feet) for up to 60 minutes (IPX8).

It means the maximum pressure the device can tolerate equals the pressure in 2.5m deep in STILL water instead of flowing water.

It is OK to take a shower or go swimming with the devices on, but if you go diving, the water pressure may be too high for the devices.

I didn't see an alert message, but it appeared in History.

If one of the following alerts happened, the PDM would beep/vibrate and display a message first, and if you missed that alert, later when you checked the PDM, the condition that triggered the alert had changed (for example, your glucose level returned to the target range), then you wouldn't see any message on the screen, you would only find it in History.

Alert	Alert change
EXCEEDS MAX TDD	After insulin delivery automatically starts again, alert is switched to BASAL RESUMED.
EXCEEDS MAX 1HR DELIVERY	After insulin delivery automatically starts again, alert is switched to BASAL RESUMED.

If one of the following alerts happened, the PDM would beep/vibrate and display a message first, and if you missed that alert, later when you checked

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the PDM, the alert may have escalated to another alert/alarm, and you will ONLY see the message of the escalated alert/alarm. The first alert will appear in History.

Alert	Alert escalation
LOW RESERVOIR	EMPTY RESERVOIR
PATCH EXP ADVISORY	PATCH EXP IN 1 HOUR, then PATCH EXPIRED
AUTO OFF ALERT	AUTO OFF

Lights on the Patch Pump

Once you connect the pump base with a new Reservoir Patch, you will see the indicator light flashing in the order of blue, green, yellow, and red. When you are activating the new patch, you will see the green light flashing until the basal pattern is activated.

A yellow (orange) light indicates an alert, while a red light indicates an alarm.

If the PDM is away from the Patch Pump, how will the basal rate be delivered?

The selected basal pattern is stored in the pump base, which means that even if the PDM is away, the basal pattern will continue as planned.

Can I fill the patch with insulin when the patch is on body?

NO. NEVER DO THAT. Insulin can go directly into your body, which is very dangerous.

No magnetic objects around when activating (priming)

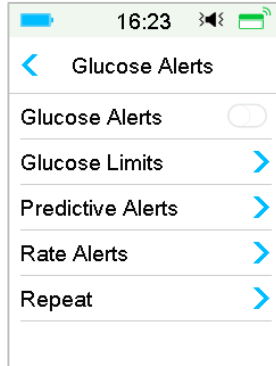
When you are filling the Reservoir Patch, make sure that it is at least 30 cm (12 inches) from any magnetic objects, such as magnets, mobile phones, tablets, other Reservoir Patches, TVs, refrigerators, and sound options. The Patch Pump will detect the volume of insulin in the reservoir once it is filled,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

How to use CGM system (Optional)

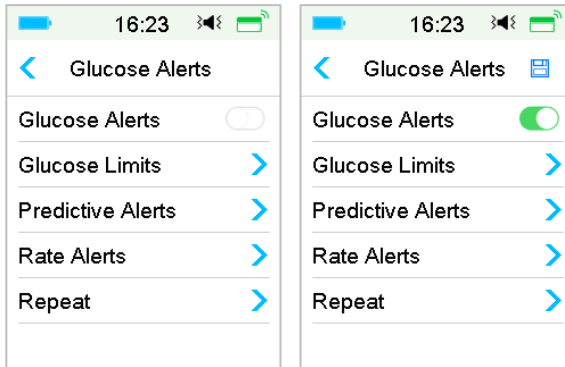
6.1 Glucose Alerts

Set your Low and High glucose alerts before using the sensor. When the glucose alerts feature is turned on, the system can send you glucose alerts including **High/Low Glucose**, **High/Low Predicted** and **Rate Alerts**.

Main Menu → EasyLoop → Glucose Alerts



1. You can turn on or off the Glucose Alerts.



2. Tap  to save the settings.

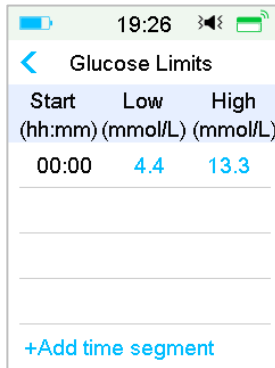
6.1.1 High/Low Limits

You need to set the high and low Glucose Limits recommended by your healthcare provider after you turn the glucose alerts On. Your recommended glucose limits may vary throughout the day, you can set up to eight pairs for different time periods.

How to use CGM system (Optional)

Go to the **Glucose Limits** screen.

Main menu → EasyLoop → Glucose Alerts → Glucose Limits



1. Add segments

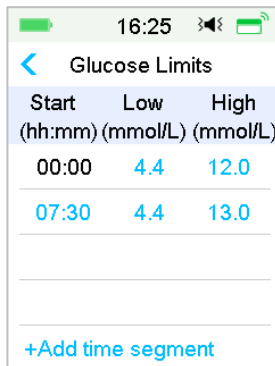
The starting time of the first segment is fixed to be 00:00 or 12:00A.

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

You will be reminded if the time segment to be set already exists. When the time segments are successfully set, they will be listed chronologically.

If you only set one segment, the glucose limits of this segment will be applied for 24 hours.

You can set up to 8 segments with the Low and High limits for each during real-time monitoring.



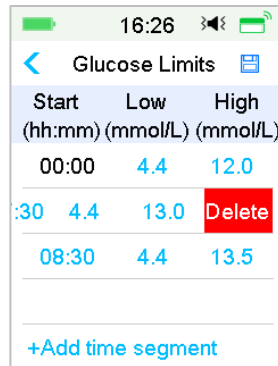
How to use CGM system (Optional)

Note:

- 1) In the time segments, only the segment starting from 0:00 cannot be deleted. You can always edit the input in each segment. The Low Limit range is 2.8-5.0mmol/L (50-90 mg/dL), the High Limit range is 5.5-22.2mmol/L (100-400 mg/dL), both with an increment of 0.1mmol/L (1mg/dL). The High Limit value is always larger than the Low Limit value.
- 2) In the first segment, the default Low Limit is 4.4mmol/L, the default High Limit is 13.3mmol/L.

2. Delete Segments

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



3. Tap  to save the settings.

6.1.2 Predictive Alerts

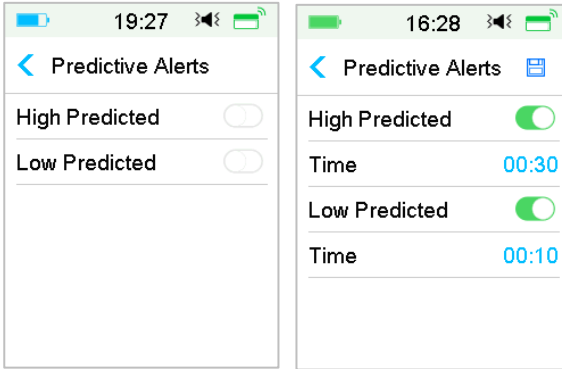
The predictive alerts calculate when you are going to reach your Low or High Glucose Limits, and then send you an alert before you reach those limits. A predictive alert informs you that if your Sensor glucose keeps falling or rising at the current rate, you will reach your Glucose Limit in the number of minutes you set before.

Go to the **Predictive Alerts** screen.

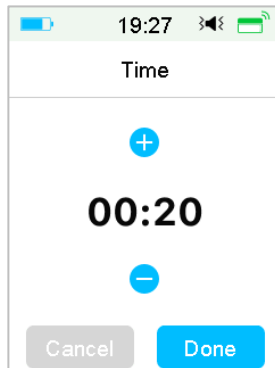
Main menu → EasyLoop → Glucose Alerts → Predictive Alerts

1. You can tap to turn on/off the Predictive Alerts

How to use CGM system (Optional)



2. Tap the blue plus/ minus sign to set the predictive alert time. You will be reminded of a predicted high or low glucose value some time (the predictive alert time) in advance.



Note: You can set the time between 5 min and 30 min with an increment of 5 min.

3. Tap  to save the settings.

6.1.3 Rate Alerts

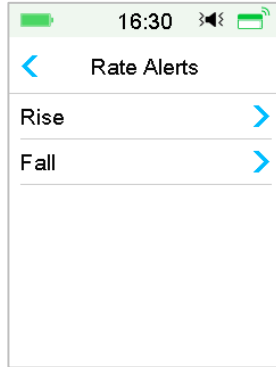
There are two types of rate alerts:

- **Rapid Fall** for Sensor glucose decreasing at or faster than your pre-selected rate
- **Rapid Rise** for Sensor glucose increasing at or faster than your pre-selected rate

Go to the **Rate Alerts** screen.

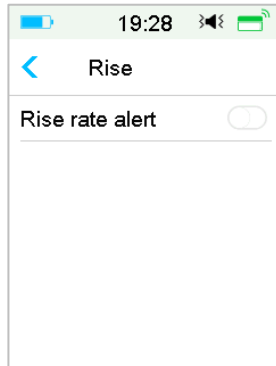
Main menu → EasyLoop → Glucose Alerts → Rate Alerts

How to use CGM system (Optional)

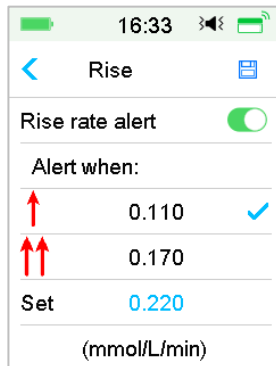


Go to the **Rise** screen.

1. You can tap to turn on/off the Rise Alerts.



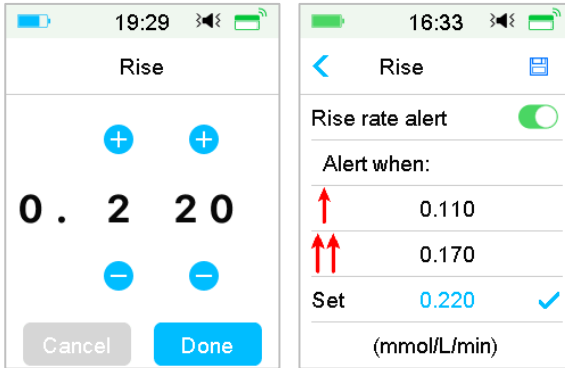
2. You can choose a relative mild or an acute rising rate. *See Section "Glucose Status" for more information.*




How to use CGM system (Optional)

3. You can also set the rate between 0.065 mmol/L/min and 0.275 mmol/L/min (1.1 mg/dL/min and 5.0 mg/dL/min) with an increment of 0.005 mmol/L/min (0.1 mg/dL/min).

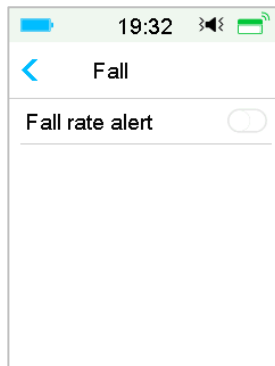
Tap the blue plus/minus sign to set the rise alert. You will be reminded when your SG is rising rapidly.



4. Tap  to save the settings.

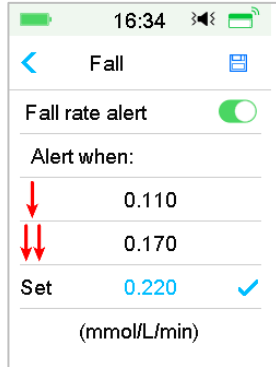
Go to the **Fall** screen.

1. You can tap to turn on/off the Fall Alerts.



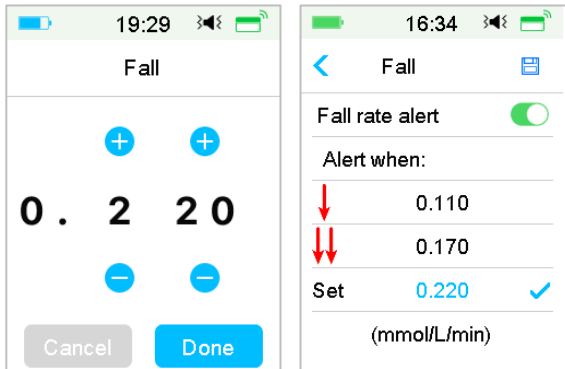
2. You can choose a relative mild or an acute falling rate. See Section *“Glucose Status”* for more information.

How to use CGM system (Optional)



You also can set the custom rate between 0.065 mmol/L/min and 0.275 mmol/L/min (1.1 mg/dL/min and 5.0 mg/dL/min) with an increment of 0.005 mmol/L/min (0.1 mg/dL/min).

Tap the blue rate value to set the fall alert time. You will be reminded when your SG is falling rapidly.

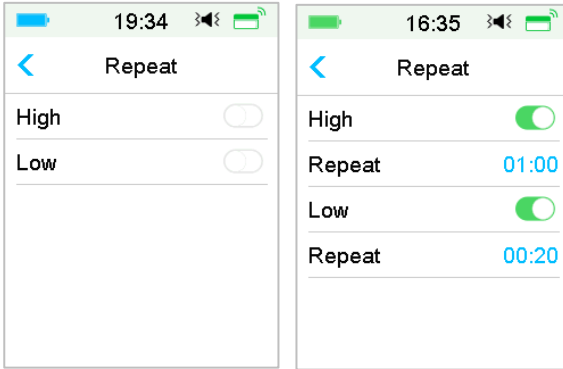


3. Tap  to save the settings.

6.1.4 Repeat

You can set the amount of time between alerts after the first alert. After you receive and clear “HIGH/LOW GLUCOSE”, “RAPID RISE/FALL” or “HIGH/LOW PREDICTED”, the alert will repeat in accordance with your settings until the condition that caused the alert is resolved.

How to use CGM system (Optional)



Note: You can turn on or off alert.

Note: You can set the **Repeat** time of High Alerts (High Glucose, Rapid Rise and High Predicted) between 5 min and 3 h, and Low Alerts (Low Glucose, Rapid Fall and Low Predicted) between 5 min and 1 h with an increment of 5 min.

6.2 Change Sensor

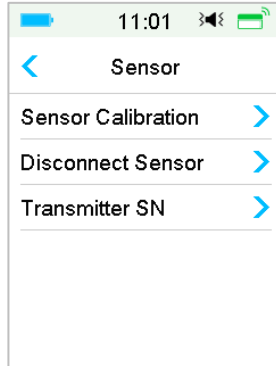
Your Sensor gives glucose readings for up to fourteen days. When a Sensor expires or fails, your Sensor session ends automatically, and PDM displays no more glucose readings. You must remove the Sensor and disconnect the Transmitter.

6.2.1 Disconnect Sensor from Your PDM

Go to **Disconnect Sensor** screen.

Main Menu → Sensor → Disconnect Sensor

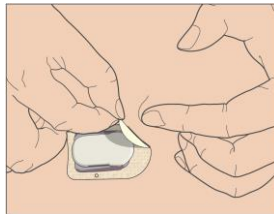
How to use CGM system (Optional)



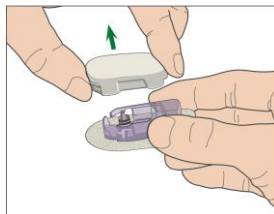
Note: The **Disconnect Sensor** option is only available when a Sensor is currently connected to the PDM.

6.2.2 Remove the Current Sensor and Disconnect the Transmitter

1. Gently peel the adhesive pad off your skin in one continuous movement to remove the Sensor and Transmitter.



2. Pinch the ribbed release tabs on the sides of the Sensor support mount, and gently pull the Transmitter away from the Sensor support mount.



3. Discard the Sensor support mount and reuse the Transmitter.

Note: Do Not discard your Transmitter. It is reusable and rechargeable.

How to use CGM system (Optional)

Note: Make sure that you completely disconnect the Transmitter from the Sensor when you do. Do NOT store the Transmitter connecting a Sensor or a USB charging cable on which may kill the Transmitter battery.

6.2.3 Charge the Transmitter

The Transmitter is charged via a USB charging cable which is plugged into a USB 2.0/3.0 port or a power adapter with a rated voltage of DC 5V and a rated current higher than DC 1000mA. The device with the USB port and the power adapter must comply with EN 60950-1 or EN 60601-1.

The battery must be fully charged the first time you use the Transmitter, which may take up to 2 hours. It is recommended to recharge the Transmitter after each Sensor session. If a Transmitter is stored for two months, you must fully charge the Transmitter battery to ensure it works properly.

The indicator light will flash when the Transmitter is being charged, and go off when the Transmitter is fully charged.

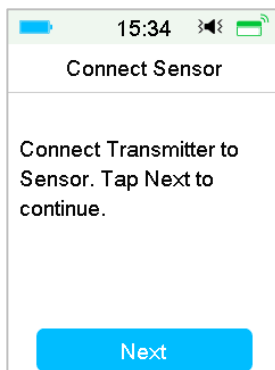
Note: We recommend that your Transmitter is only charged by an intended and qualified operator.

6.2.4 Add the Transmitter SN

Any time when you switch to a new Transmitter and/or a PDM you must add the Transmitter SN.

Main Menu → Sensor → Transmitter SN

1. Tap **Connect Sensor** if you have set the Transmitter SN.

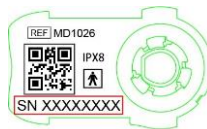


Note: Don't forget to update the SN if you change to a new Transmitter.

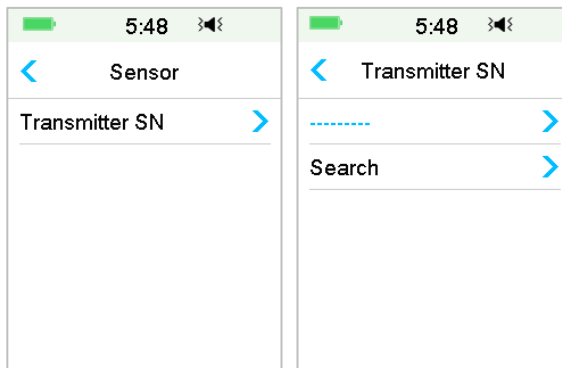
How to use CGM system (Optional)

Note: You can only change the Transmitter SN when there is no Sensor connected.

You can find the Transmitter SN on the product box or on the back of the Transmitter.

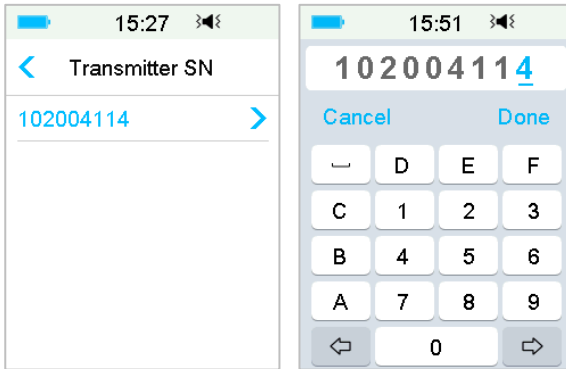


2. You can either enter SN manually or search for the SN if it is the first time you enter the SN.



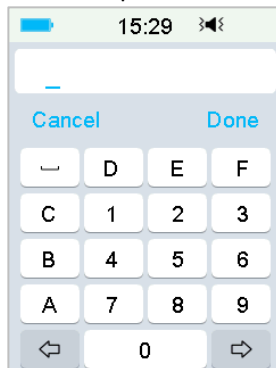
3. You can only enter SN manually if you want to update the SN.

How to use CGM system (Optional)



Enter SN manually

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

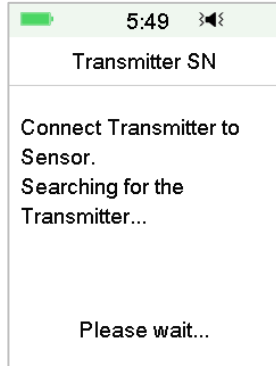


Search for the SN

If you select Search, make sure that your Transmitter is connected to a new Sensor and move the PDM closer to your CGM before searching. See Section "Insert a New Sensor" for more information.

If you tap **Search** in **Sensor**, you will see the following message when you search for the SN.

How to use CGM system (Optional)

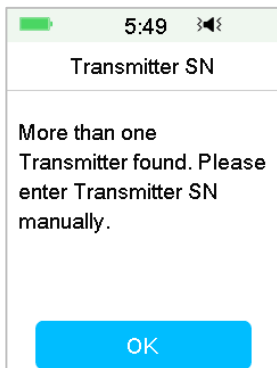


If your PDM finds one Transmitter, the Transmitter SN appears on the screen. Confirm it once it matches the SN printed on your Transmitter. If it is correct, tap **OK**.



If your PDM finds multiple Transmitters, tap **OK** to go back to Sensor Menu, then select “-----” to enter the SN manually.

How to use CGM system (Optional)



If your PDM does not find a Transmitter, make sure that your Transmitter is connected to a new Sensor, move the PDM closer to your CGM, and enter the SN manually.

6.2.5 Insert a New Sensor

6.2.5.1 Select an Insertion Site

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

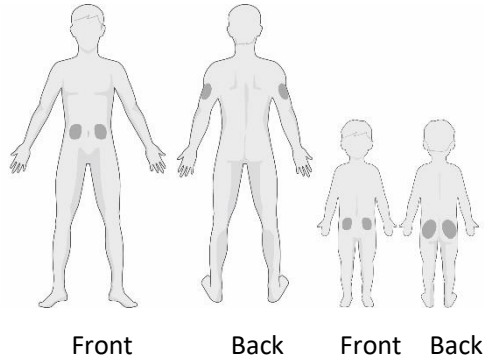
- That you can comfortably reach the Sensor.
- That you apply the Sensor to a flat area of skin with adequate subcutaneous fat.
- That the area stays flat during normal daily activities without bending or creasing.

When choosing the location for the Sensor, 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.
- Within 7.5 cm (3 inches) of an insulin pump infusion site or manual injection site.

Shown here are the best body areas (shaded) for Sensor insertion.

How to use CGM system (Optional)



If you choose an insertion site on your abdomen (buttock for children), apply the Sensor horizontally. If you choose an insertion site on your upper arm, apply the Sensor vertically.

Have a rotation schedule for choosing a new site. Using the same site too often might not allow the skin to heal and can possibly cause scarring or skin irritation.

6.2.5.2 Prepare the Insertion Site

1. Wash your hands thoroughly with soap and water and wait for them dry up.
2. Wipe the selected insertion area with rubbing alcohol and wait for the area to dry up. This may help prevent infection. Do NOT insert the Sensor until the cleaned area is dry. This will make the Sensor adhesive stay on the skin more firmly.

Warning: If the Sensor dislodges because the Sensor support adhesive fails to adhere to the skin, you may get false or no readings. Improper site selection and improper site preparation may result in poor adhesion.

6.2.5.3 Unpack the Glucose Sensor

Open the Sensor package by peeling off the paper on the back of the package. Pay attention to the following:

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

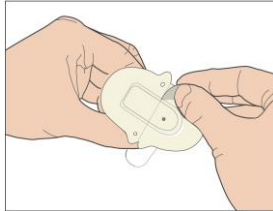
Note: Wash your hands with soap and water and let them dry before

How to use CGM system (Optional)

opening the Sensor package and handling the Sensor. After opening the package, avoid touching any Sensor surface that will be in contact with the body, i.e., adhesive surface. You may contaminate the insertion site and suffer an infection if you have unclean hands while inserting the Sensor.

6.2.5.4 Remove the Protective Liner from the Sensor Support Mount

Bend the two-piece protective liner slightly on the edge so you can see the seam between the two pieces. Hold the inserter part of the Sensor, and try not to touch the adhesive surface. Remove the liners from the Sensor support mount one after another.

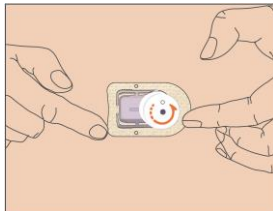


6.2.5.5 Locate the Sensor Support Mount

If you are inserting the Sensor on your abdomen or lower back, place the Sensor horizontally on your skin.

If you are inserting the Sensor on your upper arm or thigh, place the Sensor vertically on your skin.

Move your fingers around the adhesive pad to secure it to your skin.

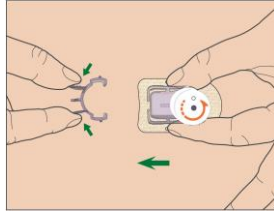


6.2.5.6 Remove the Safety Lock

Hold the Glucose Sensor with one hand. Firmly squeeze the two release tabs of the safety lock with your thumb and index finger of the other hand, as you lift the safety lock away from the inserter. Keep the safety lock, you will need

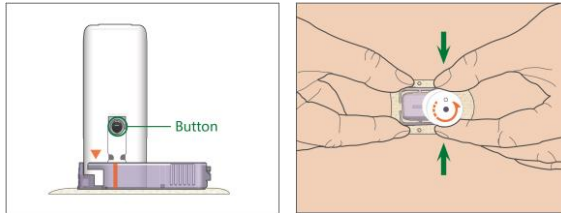
How to use CGM system (Optional)

it later.



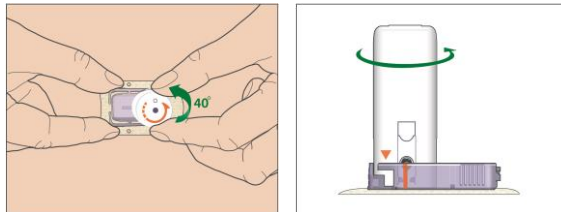
6.2.5.7 Insert the Sensor

Hold the inserter as shown below and press the two buttons at the same time. You might feel a slight pinch as the Sensor is placed just under your skin.

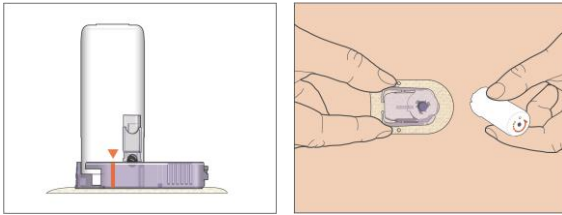


6.2.5.8 Remove the Inserter

Pinch and hold the ribbed release tabs on the sides of the Sensor support mount with one hand, twist the inserter about 40° in the direction (anticlockwise) shown with the other hand, until the orange triangle marked on the inserter lines up with the orange line on the Sensor support mount, and then lift the inserter vertically away from the mount. Only the Sensor support mount will be left on your body.



How to use CGM system (Optional)



6.2.5.9 Check the Sensor Support Mount

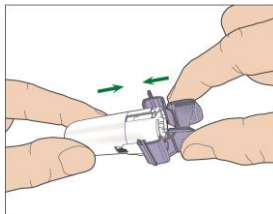
Confirm that the Sensor support mount remains tightly adhered to your skin by sliding your finger along the edges of the adhesive pad and examine for any gaps in adhesion.

Warning: If bleeding occurs at the insertion site, do not attach the Transmitter to the Sensor. Apply steady pressure using a sterile gauze or clean cloth for up to 3 minutes. If bleeding stops, attach the Transmitter to the Sensor. If bleeding continues, remove the Sensor, treat the site as necessary, and insert a new Sensor at a different site.

Warning: Check the insertion site frequently for infection or inflammation redness, swelling or pain. Remove the Sensor and seek professional medical help if one of these conditions occurs.

6.2.5.10 Discard the Sensor Inserter Safely

Attach the safety lock on the inserter to cover its opening and conceal the needle inside. Follow local waste disposal regulations when discarding the inserter. We recommend discarding the Sensor inserter into a sharps container or a puncture-proof container with a tight lid.



6.2.6 Attach Your Transmitter

Note: If you are changing Sensor, make sure that your Transmitter was disconnected from the old Sensor at least one minute before being connected

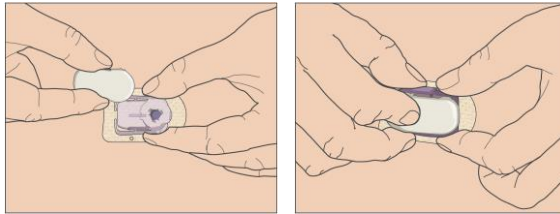
How to use CGM system (Optional)

to the new Sensor.

Before attaching the Transmitter to the Sensor, you must have the Transmitter battery fully charged and the PDM set up.

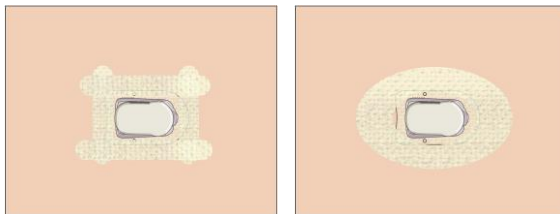
Snap the Transmitter into the Sensor support mount until the two flexible arms fit into the notches on the Transmitter. The indicator light will flash green after successful connection, three times after properly connected and another six times after successful system check.

Note: Make sure that you hear a click when you snap the Transmitter in place. If it is not fully snapped in, electrical connection and waterproof can be compromised, which can lead to inaccurate Sensor glucose readings.



Tape the Sensor Support Mount (Optional)

The Sensor support mount should stay on your skin using its own adhesive. But, if you find that the Sensor support mount is not adhering well during daily activities, you can use medical tape for extra support. Only tape over the white adhesive pad on all sides for even support. Do NOT tape over the Transmitter or any of the plastic parts on the Sensor support mount.

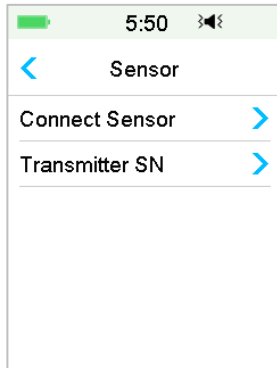


6.2.7 Connect Sensor to Your PDM

1. Go to **Connect Sensor** screen.

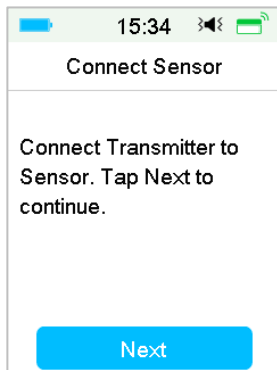
Main Menu → Sensor → Connect Sensor

How to use CGM system (Optional)



Note: The **Connect Sensor** option is only available when no Sensor is currently connected to the PDM.

2. Make sure that your Transmitter is connected to a Sensor and that your Transmitter SN is found or entered, and then continue by tapping Next.

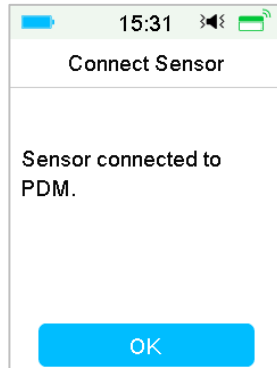


3. If the sensor is calibration-free, enter the sensor code on the sensor label which is unique for each sensor. Once the sensor code is entered successfully, the calibrations aren't required.

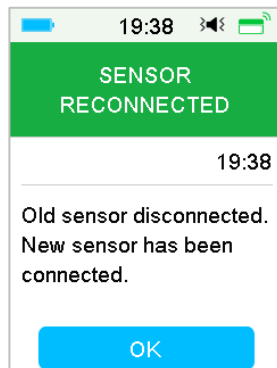
Or, skip the sensor code input step and go to Connection screen. The sensor need to be calibrated twice (once every 12 hours) on the first day and then once every 24 hours since the second day.

4. When finished, the following screen appears.

How to use CGM system (Optional)



Note: If you want to remove a Sensor before its expiration, disconnect it from your PDM first before you connect a new Sensor. When you connect a new Sensor directly, a “SENSOR RECONNECTED” message will appear on your PDM.



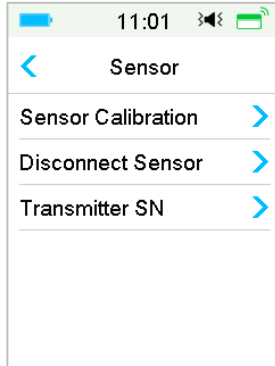
6.3 Calibrate Your Sensor

Each time the PDM prompts you with the message “METER BG NOW” or “SENSOR CAL REMINDER”, you must enter a BG measurement to calibrate your Sensor.

Go to the **Sensor Calibration** screen.

Main Menu → Sensor → Sensor Calibration

How to use CGM system (Optional)



Note: If your sensor is not a calibration-free sensor, or you skip the sensor code input step, you must calibrate your sensor at least twice (once every 12 hours) on the first day and then once every 24 hours since the second day. If you have entered sensor code successfully, the system won't require calibration. But you can calibrate the sensor if you want.

Note: Calibration is unavailable under the following circumstances:

- Sensor disconnected from the PDM
- Sensor warm-up
- Within 15 min after the alert SENSOR CAL ERROR
- Poor RF communication between the Transmitter and the PDM
- No Readings

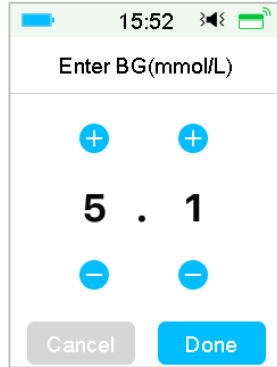
6.3.1 Enter Your Meter BG

Here you can enter your present blood glucose measured by a finger prick blood glucose meter.

1. Go to the **Enter BG** screen.

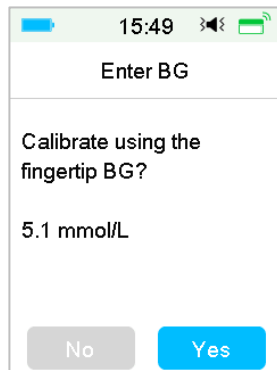
Main Menu → Sensor → Sensor Calibration

How to use CGM system (Optional)



Note: Please enter the exact blood glucose value of a carefully performed fingerstick displayed on your blood glucose meter within five minutes.

2. Tap **Done** to confirm your fingerstick, then tap **Yes** button to start calibration.



6.3.2 Set Calibration Repeat

Go to the **Cal Repeat** screen.

Main Menu → Settings → CGM System → Cal Repeat

How to use CGM system (Optional)



After you receive and clear a “METER BG NOW” alert, PDM will repeat the alert until you enter a new blood glucose measurement.

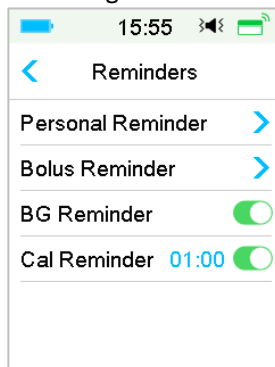
You can turn **Cal Repeat** on/off. If **Cal Repeat** is on, you can set the repeat time of “METER BG NOW” alert from 5 min to 1h with an increment of 5 min.

6.3.3 Calibration Reminder

Calibration reminder enables you to get reminded a certain time before the due time of next calibration.

1. Go to the **Cal Reminder** screen.

Main Menu → Settings → Reminders → Cal Reminder



2. You can turn **Cal Reminder** on/off.

Note: If Cal Reminder is on, you can set the time between 5 min and 6 h with an increment of 5 min.

How to use CGM system (Optional)

6.4 CGM System settings

Go to the **CGM System** screen.

Main Menu → Settings → CGM System

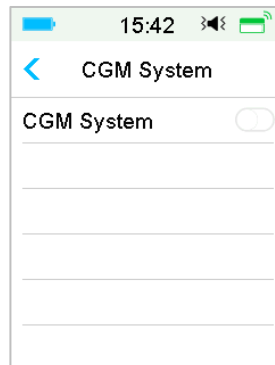


6.4.1 CGM Feature on/off

The CGM feature must be turned on to receive Sensor data.

1. Select **CGM System** in the **Settings** menu.

Main Menu → Settings → CGM System



2. You can turn on or off the CGM feature.
3. After you turn on the CGM System, the Transmitter SN menu appears.

How to use CGM system (Optional)



6.4.2 Set the Transmitter SN

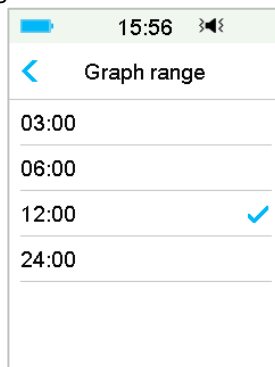
Tap **Settings** on the Main Menu to enter the **Settings** screen. Tap **CGM System** to enter the CGM settings screen. Turn the CGM System feature on.

Tap **Transmitter SN** to add this Transmitter to your PDM. You can use your PDM to search for your Transmitter (only for the first time), or you can enter the SN printed on your Transmitter manually.

You can also enter your new Transmitter SN in CGM System menu. See “Add the Transmitter SN” for more information.

6.4.3 Graph Range

You can set the time range of sensor graph in horizontal screen as 3, 6, 12, 24 hours. The default range is 12 hours.



6.4.4 Cal Repeat

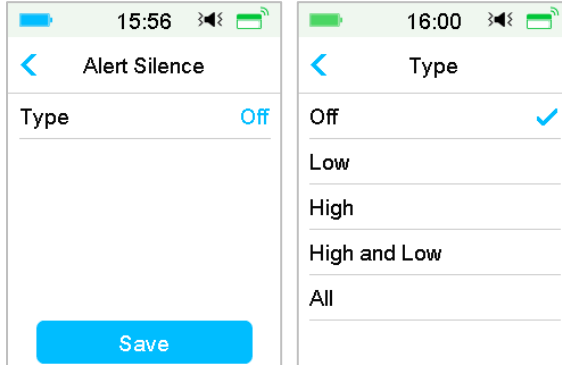
See Section “Calibrate Your Sensor” in this chapter for more information.

How to use CGM system (Optional)

6.4.5 Alert Silence

Go to the **Alert Silence** screen.

Main Menu → Settings → CGM System → Alert Silence



Warning: Muting the alarms is not recommended when you are unable to interact with your PDM (for instance, when you are asleep).

Interacting with your PDM includes activities such as pressing the power button and checking the screen.

With the Alert Silence feature you can keep glucose alerts silent for a specified time of 30 minutes to 24 hours.

There are five Alert Silence options:

- **Off**— This means all glucose alerts are turned on: the PDM will beep or vibrate if any Sensor alert occurs.
- **Low** — The PDM will not beep or vibrate if a low alert (LOW GLUCOSE, RAPID FALL or LOW PREDICTED) occurs during the specified time.
- **High** — The PDM will not beep or vibrate if a high alert (HIGH GLUCOSE, RAPID RISE or HIGH PREDICTED) occurs during the specified time.
- **High and Low** — The PDM will not beep or vibrate if a high/low alert (HIGH/LOW GLUCOSE, RAPID RISE/FALL, HIGH/LOW PREDICTED) occurs during the specified time.
- **All** — The PDM will not beep or vibrate if “LOST SENSOR”, “SENSOR CAL REMINDER”, “METER BG NOW”, “SENSOR EXP IN 6 HOURS”, “SENSOR EXP IN 2 HOURS”, “SENSOR EXP IN 30 MINS”, “SENSOR EXPIRED”, or any of the high/low alert occurs during the specified time.

How to use CGM system (Optional)

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

6.4.6 Sensor Expired

Go to the **Sensor Expired** screen.

Main Menu → Settings → CGM System → Sensor Expired



For MD1026, the expiration date is fixed as 14 days.

“SENSOR EXP IN 6 HOURS” alert, “SENSOR EXP IN 2 HOURS” alert, “SENSOR EXP IN 30 MIN” and “SENSOR EXPIRED” alert will respectively appear.

6.5 Sensor History

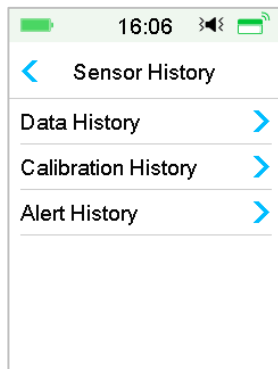
6.5.1 Sensor History

Your PDM stores detailed Sensor history to help you keep track of your glucose readings and Sensor conditions.

Go to the **Sensor History** screen.

Main Menu → History → Sensor History

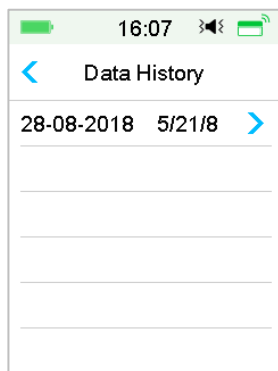
How to use CGM system (Optional)



6.5.1.1 Data History

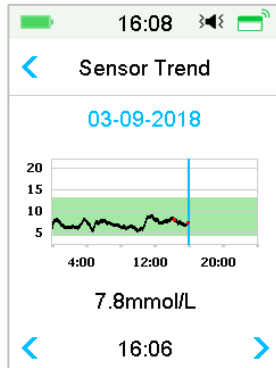
1. Select **Data History** in the **Sensor History** screen.

The **Data History** screen shows all of the Sensor sessions that have recently occurred. Each line shows the Sensor session start date and duration (day/hour/minute). For example, the record 28-08-2018 5/21/8 means the Sensor was started on 28-08-2018 and has been used for 5 days 21 hours and 8 minutes.



2. Select a Sensor session and you will see the last day's Sensor history data. 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 24 hours.

How to use CGM system (Optional)



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.

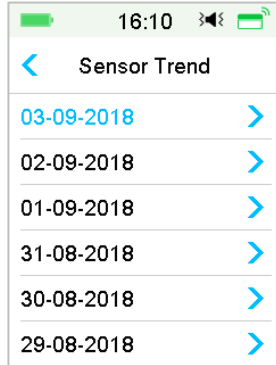
Note:

- 1) Tap the Sensor graph and move the cursor to spot the glucose values. Use the left and right arrow button to do fine adjustment for choosing the time. The time interval between two values is 2 minutes.
- 2) The time 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”.
- 3) 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 or 400mg/dL (HIGH) and Sensor glucose is below 2.2 mmol/L or 40mg/dL (LOW).
- 4) After the warm-up phase, the values before the first calibration are marked as “BG”.
- 5) When the Sensor calibration expires, the reading values will be underlined.
- 6) Calibration will be marked with a red dot “•”.
- 7) In the landscape screen display, tap the Home Key to return to the Home Screen.
- 8) In the following situations, you cannot enter landscape screen by long-

How to use CGM system (Optional)

pressing the graph

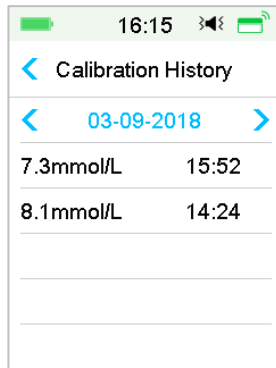
- when no Sensor is connected.
 - when the data is being recovered after reconnection.
3. Tap the date and you will see a list of dates within that session.



4. Select a date and you will see the 24-hour Sensor trend graph of that day.

6.5.1.2 Calibration History

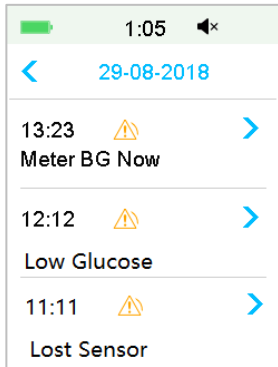
Select **Calibration History** in the **Sensor History** screen. The **Calibration History** screen displays the calibration history.



6.5.1.3 Alert History

Select **Alert History** in the **Sensor History** screen. The **Alert History** screen shows you all of the Sensor alerts that have recently occurred.

How to use CGM system (Optional)



Select an alert record to view the details. Tap < to return to the previous menu.

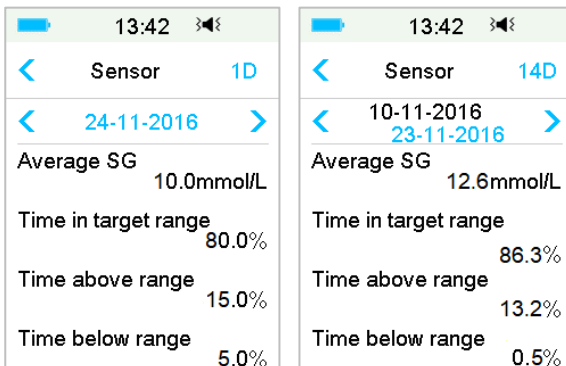
See Section “Alert Icons” and Chapter “Safety System and Alarms/Alerts” for more information about how to address the alarms and alerts.

6.5.2 Summary History: Sensor History

This screen displays the SG readings summary history.

Go to **Sensor History** screen.

Main Menu → History → Summary History → Sensor History



Average SG: Average SG readings of the selected days.

Time in target range: The percentage of the duration in which SG reading is in the target range (3.9 - 10.0 mmol/L or 70 - 180 mg/dL).

Time above range: The percentage of the duration in which SG reading is

How to use CGM system (Optional)

above the target range (10.0 mmol/L or 180 mg/dL).

Time below range: The percentage of the duration in which SG reading is below the target range (3.9 mmol/L or 70 mg/dL).

6.6 Troubleshooting CGM issues

Can I take a sauna with the CGM System on?

No.

Firstly, the operating temperature range for the Transmitter is +5°C ~ +40°C.

Secondly, if you take a sauna, your blood glucose can fluctuate.

Can I dive with a Sensor on?

No.

Your Sensor (including the installed Transmitter) is waterproof to a depth of 2.5 meters (8 feet) for up to 60 minutes (IPX8).

It means the maximum pressure the device can tolerate equals the pressure in 2.5m deep in STILL water instead of flowing water.

It is OK to take a shower or go swimming with the devices on, but if you go diving, the water pressure may be too high for the devices.

I didn't see an alert message, but it appeared in History.

If one of the following alerts happened, the PDM would beep/vibrate and display a message first, and if you missed that alert, later when you checked the PDM, the condition that triggered the alert had changed (for example, your glucose level returned to the target range), then you wouldn't see any message on the screen, you would only find it in History.

1. LOW GLUCOSE
2. HIGH GLUCOSE
3. LOW PREDICTED
4. HIGH PREDICTED
5. RAPID RISE

How to use CGM system (Optional)

- 6. RAPID FALL
- 7. ALERT SILENCE
- 8. SENSOR ERROR
- 9. BELOW 3.1 mmol/L (56 mg/dL)
- 10. LOST SENSOR

If the following alert happened, the PDM would beep/vibrate and display a message first, and if you missed that alert, later when you checked the PDM, the alert may have escalated to another alert/alarm, and you will ONLY see the message of the escalated alert/alarm. The first alert will appear in History.

Alert	Alert Escalation
SENSOR EXP IN 6 HOURS	SENSOR EXP IN 2 HOURS, then SENSOR EXP IN 30 MIN, at last SENSOR EXPIRED

When I should charge my Transmitter?

We recommend that you charge the Transmitter after each Sensor session, or make sure that at least 90 seconds has passed before you attach the Transmitter to a new Sensor.

Green lights after installing the Transmitter

After you install the Transmitter, the green light on the Transmitter will flash 3 times immediately indicating that the Transmitter is properly connected with the Sensor, and flash another 6 times within one minute indicating that the system check has completed.

Some Sensor readings missing on the Sensor Trend Screen

If the PDM is too far away from the Transmitter, or the Bluetooth communication between the Transmitter and the PDM is temporarily interrupted, some Sensor readings might be missing in the Sensor Trend Graph screen.

Solution: Move the PDM close to the Transmitter, and wait for a while. The data will be recovered automatically.

How to use CGM system (Optional)

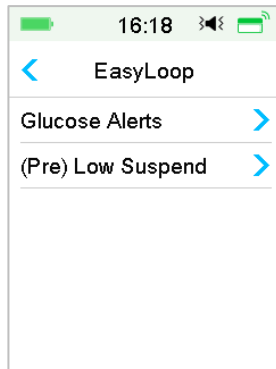
What to do when a “Lost Sensor” alert happens

Move the PDM closer. If the PDM cannot connect with the Transmitter in 10 minutes, keep the Sensor in, disconnect the Sensor from the PDM menu, and connect again.

How to use CGM system (Optional)

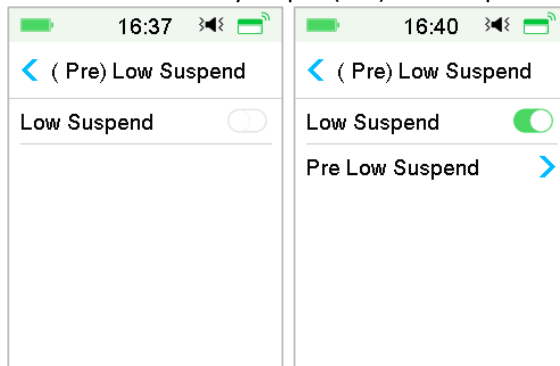
7.1 (P)LGS settings

The **Glucose Alerts** and **Low Glucose Suspend/Predictive Low Glucose Suspend (Low Suspend/ Pre Low Suspend)** functions are included under the **EasyLoop** Menu. The (Pre) Low Suspend function is available when CGM and Insulin Pump systems are both online. The glucose limits for alerts of Low Suspend and Pre Low Suspend are the same.



Go to the **Low Suspend** screen.

Main menu → EasyLoop → (Pre) Low Suspend



Note: If you turn the Low Suspend on, the Predictive Low Suspend feature will appear.

How to use (P)LGS (Optional)

7.1.1 Low Suspend

The Low Glucose Suspend feature is only available when both a Patch Pump and a Glucose Sensor are in use. The factory setting for this feature is off. If you turn it on, your PDM will automatically suspend insulin delivery and give an alarm when your Sensor glucose is at or below the low suspend limit, and resume basal insulin when the risk of low glucose no longer exists. This feature can be used as a safe guard against excessive insulin delivery. You may choose to program this feature based on the lowest acceptable Sensor glucose. Discuss what settings are best for you with your healthcare provider.

Note: The low suspend limit between 2.8 mmol/L and 5.0 mmol/L (50 mg/dL and 80 mg/dL) based on the **Glucose Low Limit** settings. See Section “High/Low Limits” in Chapter “How to use CGM system” for more information.

Triggering Conditions for Low Suspend

The Sensor glucose value is at or below the low suspend limit.

Time of Suspension

Once Low Suspend is triggered, the period of suspension will last for at least 30 minutes unless you manually resume basal insulin. The maximum suspension time is 2 hours. After 2 hours of suspension, basal insulin will be resumed unconditionally.

Triggering Conditions for Automatic Resumption of Basal (from 30 min to 2 h after suspension)

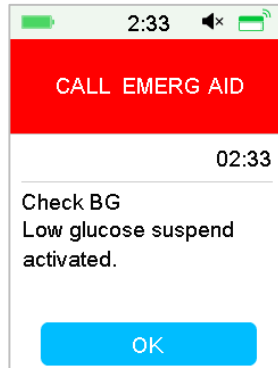
Both of the following two conditions must be met for the system to resume basal insulin automatically.

- The Sensor glucose value is at least 0.8 mmol/L (15 mg/dL) higher than the low suspend limit.
- The Sensor glucose value is predicted to be at least 1.7 mmol/L (30 mg/dL) higher than the low suspend limit in half an hour.

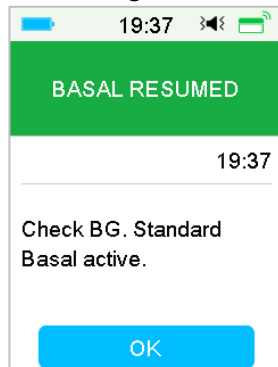
Alarm Response

If the Low Suspend alarm is not cleared within 10 minutes, a siren will sound with the following Reminder.

How to use (P)LGS (Optional)

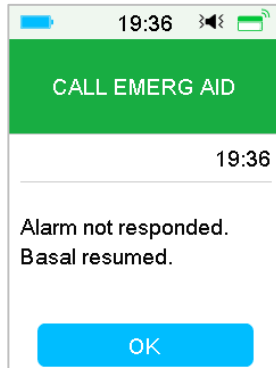


If the Low Suspend alarm is not cleared during suspension and insulin is resumed within 2 hours, the following Reminder will appear.

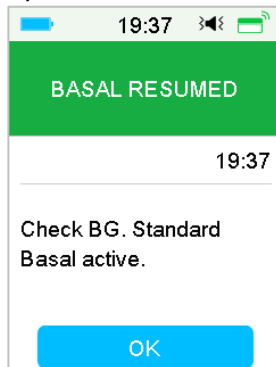


If the Low Suspend alarm is not cleared during suspension and insulin is automatically resumed after 2 hours, the siren will continue, and the following emergency message will appear.

How to use (P)LGS (Optional)



If the Low Suspend alarm is cleared during suspension, a Reminder will appear when insulin is automatically resumed.



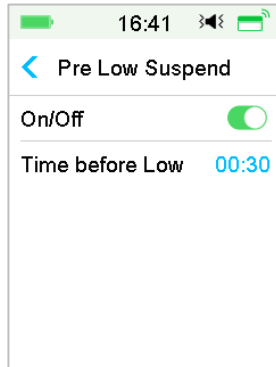
For information on when the Low Suspend feature is unavailable, refer to "Predictive Low Suspend".

7.1.2 Predictive Low Suspend

The Predictive Low Glucose Suspend feature is available only when the Low Suspend feature is turned on and available. The factory setting for the Predictive Low Suspend feature is turned off. If you turn it on, your PDM will automatically suspend insulin delivery and give an alarm when your Sensor glucose is predicted to reach the low suspend limit in a set period of time, and resume basal insulin when the risk of low glucose no longer exists. This feature can be used as a safeguard against excessive insulin delivery. Discuss what settings are best for you with your healthcare provider.

Go to **Pre Low Suspend** screen.

Main Menu → EasyLoop → (Pre) Low Suspend



Note: You can set the Time before Low between 5 min and 40 min with an increment of 5 min. The factory default is 30 min.

Triggering Conditions for Predictive Low Suspend (from 30 min to 2 h after suspension)

Both of the following two conditions must be met to start Predictive Low Suspend.

- The Sensor glucose value is at or within 3.9 mmol/L (70 mg/dL) above the low suspend limit.
- The Sensor glucose value is predicted to fall at or within 0.8 mmol/L (15 mg/dL) above the low suspend limit in the set period of time and the rate of glucose change is negative.

Time of Suspension

Once Predictive Low Suspend is triggered, the period of suspension will last for at least 30 minutes unless you manually resume basal insulin. The maximum suspension time is 2 hours. After 2 hours of suspension, basal insulin will be resumed unconditionally.

Triggering Conditions for Automatic Resumption of Basal

Both of the following two conditions must be met for the system to resume basal insulin automatically.

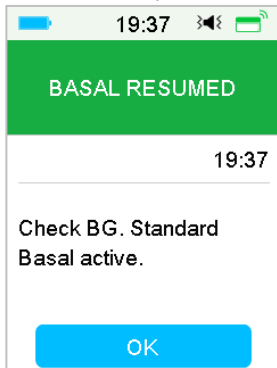
- The Sensor glucose value is at least 0.8 mmol/L (15 mg/dL) higher than the low suspend limit.

How to use (P)LGS (Optional)

- The Sensor glucose value is predicted to be at least 1.7 mmol/L(30 mg/dL) higher than the low suspend limit in half an hour.

Reminder of Resumption

Whether a Predictive Low Suspend alert is cleared or not, the same Reminder will appear when insulin is automatically resumed.



When the Low Suspend Feature and Predictive Low Suspend feature are Unavailable

After insulin delivery is resumed from Low Suspend or Predictive Low Suspend, the Low Suspend feature and Predictive Low Suspend feature will be unavailable for 30 minutes.

7.2 Summary History: Low Suspend History

Go to **Low Suspend History** screen.

Main Menu → History → Summary History → Low Suspend History

How to use (P)LGS (Optional)

Time	Summary	# of PLGS	# of LGS	Time in suspend
13:42	Low Suspend 1D	#2.0	#3.0	0:45
13:43	Low Suspend 14D	#2.8	#3.6	0:53

This screen displays the (Pre) Low Suspend summary history.

of LGS: Average daily number of Suspend due to LGS.

of PLGS: Average daily number of Suspend due to PLGS.

Time in suspend: Average daily duration suspended due to LGS or PLGS.

7.3 Troubleshooting Low Suspend issues

I didn't see an alert message, but it appeared in History.

If one of the following alerts happened, the PDM would beep/vibrate and display a message first, and if you missed that alert, later when you checked the PDM, the condition that triggered the alert had changed (for example, your glucose level returned to the target range), then you wouldn't see any message on the screen, you would only find it in History.

Alert	Alert change
LOW SUSPEND	After insulin delivery automatically starts again, alert is switched to BASAL RESUMED.
PRE LOW SUSPEND	After insulin delivery automatically starts again, alert is switched to BASAL RESUMED.

How to use (P)LGS (Optional)

8.1 Safety System

Your A7+ TouchCare® System automatically performs a series of safety checks. The PDM sounds an alert or alarm and displays an on-screen message to let you know of an abnormal condition.

If you have more than one notification, you need to clear the first notification to see the next one.

Your alarm settings and alarm/alert history of the last 90 days are stored in the PDM even if the battery is depleted and will be restored once the PDM is properly charged. When the PDM battery is empty, new alarm/alert might not be successfully recorded.

Note: Do NOT set alarm (time point, limit value etc.) beyond the thresholds or in a way that makes the safety system useless. Talk with your healthcare provider to see which settings are best for you.

Note: Your PDM and Pump consumes battery power when notifying you of alerts, alarms, and reminders. If you do not acknowledge a notification, the PDM battery power drops fast as the notifications repeat and progress. This will result in reduced battery life and the “CHARGE PDM NOW/PATCH BATT DEPLETED” Alarm or “PDM BATTERY LOW/PATCH BATTERY LOW” alert will appear sooner than expected.

8.2 Safety Checks

A single fault condition will cause the pump to suspend insulin delivery. Maximum infusion with a single fault condition is 0.05U.

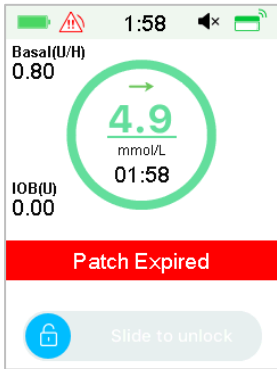
8.3 Alarms

Alarms are triggered by serious or potentially serious conditions. You must respond to the alarm by taking appropriate action in order to clear the alarm condition.

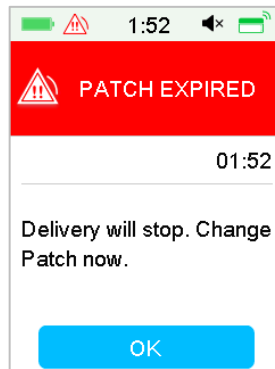
For example:

When Alarm “**PATCH EXPIRED**” occurs, the Lock Screen and Alarm screen display the following screen.


Safety System and Alarms/Alerts




Alarm on the Lock Screen




Alarm on the unlocked screen

If it is a high priority alarm, the PDM will display an alarm message with instructions and icon  (a red triangle with three exclamation marks) in Alarm screen.



If it is a medium priority alarm, the PDM will display an alarm message with instructions and icon  (a red triangle with two exclamation marks) in Alarm screen.



PDM Alarms in different audio modes:

Audio Mode	 medium priority alarm
Audio	PDM emits ten beeps every twenty seconds.
Vibrate	PDM emits one-pulse vibration every twenty seconds
Audio and Vibrate	PDM emits three beeps and one-pulse vibration every twenty seconds
Audio off / Vibrate off	PDM emits one-pulse vibration every twenty seconds

Safety System and Alarms/Alerts









Patch Pump Alarms of different priorities in different audio modes:

Audio Mode	 high priority alarm	 medium priority alarm
Audio	PDM emits ten beeps every ten seconds.	PDM emits ten beeps every twenty seconds.
Vibrate	PDM emits one-pulse vibration every ten seconds	PDM emits one-pulse vibration every twenty seconds
Audio and Vibrate	PDM emits ten beeps and one-pulse vibration every ten seconds	PDM emits three beeps and one-pulse vibration every twenty seconds
Audio off / Vibrate off	PDM emits ten beeps every ten seconds	PDM emits one-pulse vibration every twenty seconds

Audio Mode	 high priority alarm	 medium priority alarm
Audio	Patch Pump emits three beeps every one minute.	Patch Pump emits three beeps every one minute.
Vibrate	Patch Pump emits three-pulse vibration every one minute.	Patch Pump emits three-pulse vibration every one minute.
Audio and Vibrate	Patch Pump emits three beeps and three-pulse vibration every one minute.	Patch Pump emits three beeps and three-pulse vibration every one minute.
Audio off /Vibrate off	Patch Pump emits three-pulse vibration every one minute.	Patch Pump emits three-pulse vibration every one minute.




Safety System and Alarms/Alerts

Alarm sound wave:

Icon	Sound wave	Significance
		PDM emits ten beeps/vibrations each time.
		PDM emits Three beeps/vibrations each time.
		Patch Pump emits Three beeps/vibrations each time.
		Patch Pump emits Three beeps/vibrations each time.

8.3.1 PDM Alarms

If a PDM alarm is not cleared within 10 minutes, your PDM will make a siren sound until the alarm is cleared.

PDM Message	Priority	Reason	Actions to Take
PDM ERROR Remove device. Call customer support.		A PDM error is detected.	Tap to clear it. Remove Pump and Sensor. Contact customer support immediately. Check blood glucose.
PDM ERROR The PDM has restarted. Change patch.		A PDM software error is detected and the PDM has restarted, but no settings have been changed.	Tap to clear it. Remove the Patch Pump and change a Reservoir Patch. If the problem occurs repeatedly, please contact customer support.
CHARGE PDM NOW Charge PDM now.		The PDM battery is depleted.	Tap to clear it. Charge PDM battery.




8.3.2 Pump Alarms

When a Pump alarm occurs:



Indicator light: The indicator light on the pump flashes red once per second until the alarm is cleared.

Note: If a Pump alarm is not cleared within 10 minutes, both your PDM and Patch Pump will make a siren sound until the alarm is cleared.






The following table lists high priority alarm messages.

PDM Message	Priority	Reason	Actions to Take
OCCLUSION DETECTED Delivery stopped. Change Patch now.		Pump occlusion is detected.	Tap to clear it. Change Patch. Check blood glucose.
PATCH ERROR Delivery stopped. Change Patch now.		A Reservoir Patch error is detected.	Tap to clear it. Change Patch. Check blood glucose.
PUMP BASE ERROR Remove Pump. Call customer support.		A Pump Base error is detected.	Tap to clear it. Remove Pump. Contact customer support immediately. Check blood glucose.



The following table lists medium priority alarm messages.

PDM Message	Priority	Reason	Actions to Take
AUTO OFF Delivery suspended. No status received.		The PDM has not received a pump status during the time limit set.	Tap to clear it. Resume basal delivery. Check blood glucose and treat it as necessary. Check Pump history.
PATCH EXPIRED Delivery will stop. Change Patch now.		The current Reservoir Patch has reached the end of its 3-day operating life.	Tap to clear it. Change Patch. Check blood glucose.

Safety System and Alarms/Alerts

PDM Message	Priority	Reason	Actions to Take
PATCH BATT DEPLETED Delivery stopped. Change Patch now.		The Reservoir Patch battery is depleted.	Tap to clear it. Change Patch. Check blood glucose.
EXCEEDS MAX TDD Exceeds max TDD. Delivery stopped.		You have attempted to deliver more insulin than expected based on your Daily Max setting.	Tap to clear it. Check blood glucose. Resume basal delivery. Check bolus history and reevaluate your need for insulin. Continue to monitor blood glucose.
EXCEEDS MAX 1HR DELIVERY Exceeds 1 hour max. Delivery stopped.		You have attempted to deliver more insulin than expected based on your Hour Max setting.	Tap to clear it. Check blood glucose. Resume basal delivery. Check bolus history and reevaluate your need for insulin. Continue to monitor blood glucose.
EMPTY RESERVOIR Delivery stopped. Change Patch now.		There is no insulin in the reservoir.	Tap to clear it. Change Patch. Check blood glucose.
LOW SUSPEND Low glucose suspend activated.		The last Sensor glucose reading is at or below the Low Glucose Suspend Limit set.	Tap to clear it. Check blood glucose and treat it as necessary.

If the following alarm is not cleared within 10 minutes, only your PDM will make a siren sound until the alarm is cleared.

PDM Message	Priority	Reason	Actions to Take
<p>PUMP OUT OF RANGE Low Suspend failed. Move PDM close to Pump. Pre Suspend failed. Move PDM close to Pump.</p>		<p>Low Suspend or Predictive Low Suspend failed because the PDM had lost communication with the Patch Pump.</p>	<p>Tap to clear it. Move PDM close to Pump.</p>
<p>PUMP RESTARTED Patch changed? For help call the CC.</p>		<p>Pump restarted without Patch deactivation.</p>	<p>Tap to clear it. Check if a new Patch is connected, and follow the instructions in this User Guide. Call customer support if you have any questions.</p>

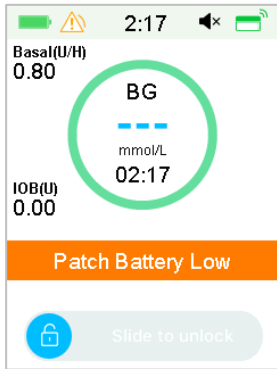
8.4 Alerts

Alerts are triggered by conditions that may require your attention. Alerts are less serious than alarms. You must respond to an alert by pressing buttons and/or taking actions.

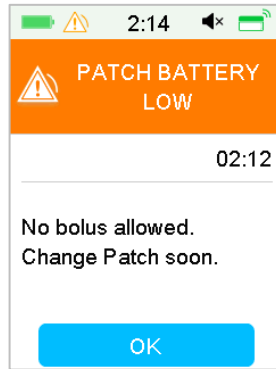
For example:

When Alert “PATCH BATTERY LOW” occurs, the Lock Screen and Alert screen display the following screen.


Safety System and Alarms/Alerts




Alert in Lock Screen




Alert after unlock in Alert screen

The PDM displays an alert message with instructions and icon  (an empty triangle with exclamation mark) in Alert screen.

CGM Alerts and PDM Alerts in different audio modes:


Audio Mode	 Alert
Audio	PDM emits two beeps every three minutes.
Vibrate	PDM emits one-pulse vibration every three minutes.
Audio and Vibrate	PDM emits two beeps and one-pulse vibration every three minutes.
Audio off /Vibrate off	no beeping, no vibration

Patch Pump Alerts in different audio modes:



Audio Mode	 Alert
Audio	PDM emits two beeps every three minutes.
Vibrate	PDM emits one-pulse vibration every three minutes.

Safety System and Alarms/Alerts

Audio and Vibrate	PDM emits two beeps and one-pulse vibration every three minutes.
Audio off /Vibrate off	no beeping, no vibration


Audio Mode	 Alert
Audio	Patch Pump emits three beeps every three minutes.
Vibrate	Patch Pump emits three-pulse vibration every three minutes.
Audio and Vibrate	Patch Pump emits three beeps and three-pulse vibration every three minutes.
Audio off /Vibrate off	Patch Pump emits three-pulse vibration every three minutes.

The sound wave of every alert beep:

Icon	Sound wave	Significance
		Your PDM emits two beeps every time.

8.4.1 PDM Alerts

The following table lists alert messages for PDM.

PDM Message	Priority	Reason	Actions to Take
PDM BATTERY LOW Low PDM battery. Charge battery soon.		The PDM battery is low.	Tap to clear it. Charge PDM battery soon.








8.4.2 Pump Alerts

When a Pump alert occurs:

Indicator light: The indicator light on the Patch Pump flashes yellow once every two seconds until the alert is cleared.

Safety System and Alarms/Alerts

The following table lists alert messages for Patch Pump.

PDM Message	Priority	Reason	Actions to Take
END OF SUSPEND Delivery suspended at [].		Insulin delivery has been suspended for more than 15 minutes.	Tap to clear it. Resume basal delivery.
LOW RESERVOIR [] remaining. Change Patch.		The insulin level in the Reservoir Patch has reached the set low limit.	Tap to clear it. Change Patch soon.
AUTO OFF ALERT Delivery stops if not cleared in 15 min.		The PDM did not receive a Pump status during the time limit set.	Tap to clear it. Check blood glucose. Check Pump history.
PATCH EXP ADVISORY Patch expiration in [] hours.		The Reservoir Patch will expire within the set time limit.	Tap to clear it. Change Patch soon.
PATCH EXP IN 1 HOUR Patch expiration in 1h. Change Patch soon.		The Reservoir Patch will expire in less than 1 hour.	Tap to clear it. Change Patch soon.
PATCH BATTERY LOW No bolus allowed. Change Patch soon.		The Patch battery is running low. No bolus can be delivered. Basal delivery can only last about 30 minutes.	Tap to clear it. Change Reservoir Patch soon.
PRE LOW SUSPEND Delivery suspended. Predictive low glucose.		The Sensor glucose may reach the Low Glucose Suspend Limit in the length of time set.	Tap to clear it. Check blood glucose and treat it as necessary.






8.4.3 CGM Alerts

If you set audio option to **Audio off/Vibrate off**, your PDM will neither beep nor vibrate for all CGM alerts, except:








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

When “TRANSMITTER ERROR”, “CHARGE TRANSMITTER”, “SENSOR EXPIRED”, or “SENSOR FAILURE” occurs, your PDM emits three-pulse vibration every three minutes.







The following table lists alert messages for CGM.

PDM Message	Priority	Reason	Actions to Take
TRANSMITTER BATTERY LOW Charge Transmitter soon.		The Transmitter battery is close to running out of power.	Tap to clear it. Charge Transmitter soon.
CHARGE TRANSMITTER Charge Transmitter now.		The Transmitter battery is depleted.	Tap to clear it. Charge Transmitter.
TRANSMITTER ERROR Call customer support.		A Transmitter error is detected.	Tap to clear it. Call customer support.
NO READINGS Check or change Sensor.		The Sensor signals are abnormal.	Tap to clear it. Check if the Sensor gets bumped or dislodged, make sure that the Sensor is inserted correctly or change Sensor.
SENSOR EXPIRED Sensor session ended. Change Sensor.		The current Sensor has reached its 14-day operating life.	Tap to clear it. Change Sensor.


Safety System and Alarms/Alerts

PDM Message	Priority	Reason	Actions to Take
SENSOR FAILURE Sensor session ended. Change Sensor.		The Sensor is not functioning properly.	Tap to clear it. Change Sensor.
METER BG NOW Enter a new meter BG for calibration or tap OK to clear the alert.		A meter BG is needed immediately to calibrate the Sensor.	Tap to clear it. Enter new meter BG for calibration or tap OK to clear the alert.
SENSOR CAL ERROR Enter a meter BG after 15 minutes.		The Sensor hasn't been calibrated properly.	Tap to clear it. Enter meter BG after 15 minutes.
LOW GLUCOSE Glucose level below Low Limit.		The last Sensor glucose reading is at or below the Low Glucose Limit.	Tap to clear it. Check blood glucose and treat it as necessary. Continue to monitor blood glucose.
HIGH GLUCOSE Glucose level above High Limit.		The last Sensor glucose reading is at or above the High Glucose Limit.	Tap to clear it. Check blood glucose and treat it as necessary. Continue to monitor blood glucose.
LOW PREDICTED Glucose may reach Low Limit in [] min.		The Sensor glucose may reach Low Glucose Limit in the length of time.	Tap to clear it. Check blood glucose and treat it as necessary. Continue to monitor blood glucose.
HIGH PREDICTED Glucose may reach High Limit in [] min.		The Sensor glucose may reach High Glucose Limit in the length of time.	Tap to clear it. Check blood glucose and treat it as necessary. Continue to monitor blood glucose.


Safety System and Alarms/Alerts

PDM Message	Priority	Reason	Actions to Take
RAPID RISE Sensor glucose is rising rapidly.		The Sensor glucose is rising at a rate that is faster than the set Rise limit.	Tap to clear it. Monitor trend and glucose level. Follow instructions from your healthcare provider.
RAPID FALL Sensor glucose is falling rapidly.		The Sensor glucose is falling at a rate that is faster than the set Fall limit.	Tap to clear it. Monitor trend and glucose level. Follow instructions from your healthcare provider.
BELOW 3.1 mmol/L Sensor glucose below 3.1 mmol/L. (BELOW 56 mg/dL Sensor glucose below 56 mg/dL.)		The last Sensor glucose reading is at or below 3.1 mmol/L. (The last Sensor glucose reading is at or below 56 mg/dL.)	Tap to clear it. Check blood glucose and treat it as necessary. Continue to monitor blood glucose.
SENSOR EXP IN 6 HOURS Change Sensor in 6 hours.		The current Sensor session has 6 hours left until its period ends.	Tap to clear it. Change Sensor in 6 hours.
SENSOR EXP IN 2 HOURS Change Sensor in 2 hours.		The current Sensor session has 2 hours left until its period ends.	Tap to clear it. Change Sensor in 2 hours.
SENSOR EXP IN 30 MIN Change Sensor in 30 minutes.		The current Sensor session has 30 minutes left until its period ends.	Tap to clear it. Change Sensor in 30 minutes.

Safety System and Alarms/Alerts

PDM Message	Priority	Reason	Actions to Take
LOST SENSOR Move PDM close to Transmitter.		The PDM has not received a signal from the Transmitter for 10 minutes.	Tap to clear it. Move PDM close to Transmitter.


If Alert Silence is turned on, the PDM gives no beep or vibration when an alert occurs. The ALERT SILENCE message will be displayed on your PDM screen instead, and you can check the alert in Sensor alert history. *See Chapter “How to use CGM system” for more information.*

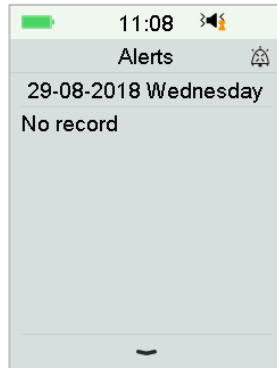
PDM Message	Priority	Reason	Actions to Take
ALERT SILENCE Alerts have occurred. Check Sensor history.		Sensor alerts have occurred during silence mode.	Tap to clear it. Check the Sensor Alert History. Take action based on the alert occurred.

Note:

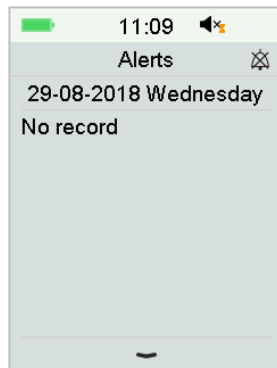
- 1) If the Audio is on and the Alert Silence is off, the audio off icon will not appear in the top right corner of this screen.



- 2) If the Audio and Alert Silence are on, the temporary audio off icon  will appear in the top right corner of this screen.



- 3) If the Audio is off, the audio off icon "🔕" will appear in the top right corner of this screen.



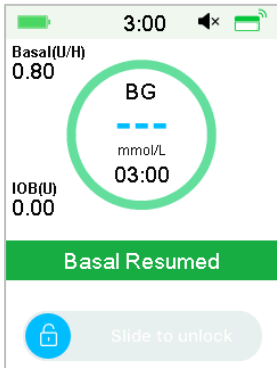
8.5 Reminding messages

Reminding messages are automatically displayed to remind you of a condition, function or event. Reminding messages include the notifications you get after setting reminders and the low-priority reminding notifications. A Message requires you to press buttons to clear it and/or to take action if necessary.

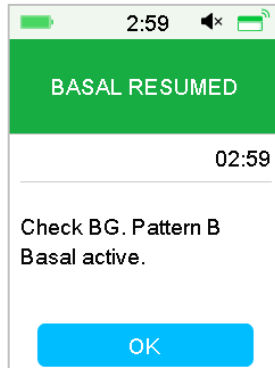
For example:

When Message "BASAL RESUMED" occurs, the Lock Screen and Message screen display the following screen.

Safety System and Alarms/Alerts



Message in Lock Screen



Message after unlock in Alert screen

Audio/vibration: Your PDM emits two beep and/or one vibration every three minutes, three times in total.

8.5.1 PDM reminding messages

Condition	PDM Message	Reason
CHECK SETTINGS	Check all settings.	An error might have occurred to your settings.
ALARM CLOCK	Alarm Clock.	An alarm clock is set at this time.
HIGH BG	Treat high BG. Monitor BG.	The blood glucose entered is higher than 13.9 mmol/L (250 mg/dL).
LOW BG	Treat low BG. Monitor BG.	The blood glucose entered is lower than 3.9 mmol/L (70 mg/dL).

8.5.2 Pump reminding messages

Condition	PDM Message	Reason
CHECK BG	Check your BG.	BG Reminder is turned on to remind you to check meter BG after a bolus.
BOLUS REMINDER	Bolus is not delivered in specified period.	Bolus Reminder is turned on to remind you to deliver a bolus within a specific period.

Condition	PDM Message	Reason
ACTIVE BASAL EMPTY	Your active Basal is 0.00 U/H.	The selected basal rate or temp basal rate is 0.00 U/H.
BASAL RESUMED	Check BG. [] Basal active.	The previously suspended basal rate is automatically resumed.

8.5.3 CGM reminding messages

Condition	PDM Message	Reason
SENSOR CAL REMINDER	Enter a new meter BG for CAL by [].	A meter BG must be entered by the time shown to calibrate Sensor.
SENSOR CAL FAILED	Sensor calibration failed. Please retry to calibrate later.	A meter BG is needed a few minutes later to calibrate the Sensor.
SENSOR RECONNECT ED	Old sensor disconnected. New sensor has been connected.	The old sensor is disconnected and a new sensor is directly connected.

9.1 Electromagnetic Emissions

Emissions Test	Compliance
RF emissions EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007, CISPR 11:2009+A1:2010 and IEC 60601-1-2:2014	Group 1
RF emissions EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007, CISPR 11:2009+A1:2010 and IEC 60601-1-2:2014	Class B

9.2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
<p>The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.</p>			
Electrostatic Discharge IEC 61000-4-2	±2kV, ±4kV, ±8kV contact discharge ±2kV,±4kV,±8kV , ±15kV air discharge	±2kV, ±4kV, ±8kV contact discharge ±2kV,±4kV,±8kV , ±15kV air discharge	For home healthcare environment and professional healthcare facility environment
Power Port, Signal and Interconnecting Cable IEC 61000-4-4:2012	Table 5 of IEC 60601-1:2014 ±2Kv, 100Hz, for AC power port	During the test, the EUT can operate as intended	The network power supply should have the quality used in a typical commercial or

Manufacturer's Declaration

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
<p>The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.</p>			
			hospital environment.
Surge IEC 61000-4-5:2005	±0.5kV, ±1kV (different mode) ±0.5kV, ±1kV, ±2kV (common mode)	During the test, the EUT can operate as intended	The network power supply should have the quality used in a typical commercial or hospital environment.
GB/T 17626.11 Voltage dips and interruptions to AC Power Port IEC 61000-4-11:2014	0%UT; 0.5T (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0%UT; 1T(0°) 70%UT: 20T(0°); 0%UT; 250T(0°)	0.5T(10ms); 1T (20ms); 25T(500ms); 250T(5s)	The network power supply should have the quality used in a typical commercial or hospital environment. If the A7+ user needs continuous operation during a power outage, it is recommended that the A7+ be


Manufacturer's Declaration

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
<p>The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.</p>			
			powered by an uninterruptible power supply or battery.
Power Frequency magnetic fields IEC 61000-4-8	Table 4 of IEC 60601-1-2:2014 30A/m, 50HZ and 60HZ	30A/m	Suitable for most environments, if there is no industrial magnetic equipment nearby, the magnetic field strength will not exceed 400A/m
Proximity fields from RF wireless communication equipment IEC 61000-4-3:2006+A1+A2	Table 9 of IEC 60601-1-2:2014	During the test, the EUT can operate as intended	Recommended separation distance $d = [12/E1] P$ 80 MHz to 800 MHz $d = [23/E1] P$ 800 MHz to 6 GHz
RF electromagnetic field	IEC 61000-4-3:2006+A1+A2 10V/m (for	10V/m (for home healthcare	Where P is the maximum

Manufacturer's Declaration

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
<p>The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.</p>			
<p>immunity test IEC 61000-4-3:2006+A1+A2</p>	<p>home healthcare environment and professional healthcare facility environment) 80 MHz~2.7 GHz</p>	<p>environment) 3V/m (for professional healthcare facility environment) 80 MHz~2.7 GHz</p>	<p>output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is there commended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p>

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Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
<p>The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.</p>			
			<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note: UT means to the AC network voltage before the test voltage is applied.</p> <p>Note: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.</p> <p>Note: The table is per IEC (EN) 60601-1-2 Edition 3.</p>			

Field strengths

A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the A7+ TouchCare® System

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is used exceeds the applicable RF compliance level above, the A7+ TouchCare® System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the A7+ TouchCare® System.

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

Electrostatic discharge

Although your A7+ TouchCare® System is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in reset of the A7+ TouchCare® System. If PDM restarts, please verify the PDM settings to ensure all settings are set to the desired values. If Pump Restarted occurs, please change a new patch. If CGM restarts, please recharge the transmitter and change a new sensor.

For more information on changing a new patch, see Chapter "How to use Patch Pump".

For more information on changing a new sensor, see Chapter "How to use CGM system".

For more information on re-entering your PDM settings, see Section "Settings" in Chapter "How to use the PDM".

If you are unable to re-enter your PDM settings, change a new patch or sensor, or otherwise believe there is a problem with your device, contact your local representative.

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Recommended separation distances between portable and mobile RF communications equipment and the A7+ TouchCare® System

The A7+ TouchCare® System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the A7+ TouchCare® System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the A7+ TouchCare® System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz~80 MHz $d = 1.2\sqrt{P}$	80 MHz~800 MHz $d = 1.2\sqrt{P}$	800 MHz~2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warning:

- 1) EMC (Electromagnetic Compatibility) information in this guide should be referred before installing and using the A7+ TouchCare® System.
- 2) The A7+ TouchCare® System is not designed to be used in an environment with high voltage, high-intensity magnetic field, where the intensity of EM DISTURBANCES is high.
- 3) Portable RF Communications equipment should be used no closer than 30 cm (12 inches) to any part of the Medtrum products. Otherwise,

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degradation of the performance of this equipment could result.

- 4) It should be avoided to use this equipment adjacent to or stacked with other medical equipment, because it could result in improper operation. If such use is necessary, this equipment and the other medical equipment should be observed to verify that they are operating normally.
- 5) Other cables and accessories may negatively affect EMC performance.

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10.1 Product Label Symbols

Symbol	Meaning	Symbol	Meaning
	Lot number		Do NOT use if package is damaged
	Reference number		Sterilized using ethylene oxide
	Manufacturer		Sterilized using radiation
	Use by: (yyyy-mm-dd)		Follow instructions for use
	Caution: See Instructions for use		Radio communication
	Storage temperature	IPX8	Waterproof to 2.5 m for 1 hour
	Do NOT reuse	SN	Device serial number
CE 0197	CE mark by notified body		Type BF equipment (Protection from electrical shock)
	Waste Electrical and Electronic Equipment		Authorized representative in the European Community

Appendix I: Symbols and Icons

Symbol	Meaning	Symbol	Meaning
IP22	Protection Against Insertion of Large Objects and Dripping Water IEC 60529		

10.2 PDM Icons

Icon	Meaning	Icon	Meaning
	High priority alarm		Medium priority alarm
	Alert		Audio off
	Audio temporary off	00:00 a	Time
	Pump RF signal		Battery
	Charging		Charged

Appendix I: Symbols and Icons

11.1 PDM Specifications

Model: FM-018

Size: 76.2 mm x 48.4 mm x 9.375 mm

Weight: 42.4 g

Screen: 2.4 in

Operating Temperature Range: +5°C ~ +40°C

Operating Relative Humidity Range: 20%~ 90%RH

Operating Atmospheric Pressure: 700~1060 hPa

Storage Temperature Range: -10°C ~ +55°C

Storage Relative Humidity Range: 20%~ 90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Classification: Internally powered, Continuous operation

Battery: Built-in 3.8 V polymer lithium ion battery

Power: 5.0 VDC, 1.0 A

Battery Life: Approximately 1 week once fully charged.

Data Storage: Automatically stores the previous 90 days' data

Wireless Communication Distance: 10 m with the Transmitter, 4 m with the insulin pump

Alarm Type: Visual, audible and vibratory

Volume: 52.3 dB(A) measured from 1 m distance

Limited Warranty: 4 years

Dust-proof and Waterproof Rating: IP22

11.2 Patch Pump Specifications

Model:

Pump Base: JN-022

Reservoir Patch: MD-JN-011

Size: 56.5 mm x 33.3 mm x 13.3 mm

Weight: 21.5 g (without insulin)

Operating Temperature Range: +5 °C ~ +40 °C

Operating Relative Humidity Range: 20%~90%RH

Operating Atmospheric Pressure: 700~1060 hPa

Storage Temperature Range: -10°C ~ +55°C

Storage Relative Humidity Range: 20%~90%RH

Appendix II: Technical Information

Storage Atmospheric Pressure: 700~1060 hPa

Classification: Internally powered, Type BF applied parts, Continuous operation

Battery: Powered by two button batteries (1.5 V)

Wireless Communication Distance: 4 m

Waterproof Rating: IPX8 (2.5 m, 60 min)

Limited Warranty of Pump Base: 1 year

Shelf Life of Reservoir Patch: 2 years

Sterilization Method of Reservoir Patch: By EO gas

Reservoir Volume: 200 U (2 mL) (1 U=10 μ L)

Insulin Type Used: U-100

Basal Rate Range: 0.00~ 25 U/h (increment: 0.05 U/h)

Bolus Range: 0.05 ~ 30 U (increment: 0.05 U)

Bolus Delivery Rate: 0.05 U/2 s

Maximum Infusion Pressure and Occlusion Pressure Threshold: 15 psi

Maximum Time to Occlusion Alarm:

Basal Delivery (0.1 U/h): < 30 h

Basal Delivery (1 U/h): < 3 h

Bolus Delivery (3 U at 1.5 U/min): < 120 s

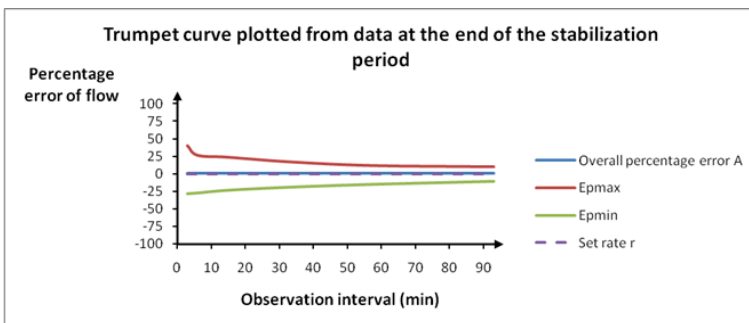
Bolus Volume after Occlusion Release: < 3 U

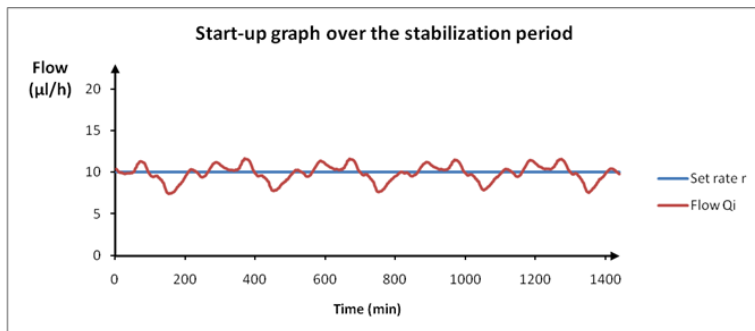
Delivery Accuracy:

Basal: +/- 5% (at rates: 0.1~ 25 U/h)

Bolus: +/- 5% (for all set values: 0.05 ~ 30 U)

Accuracy Test Results (test cycle: 29 H, delivery rate: 1.0 U/H, average error: 0.40%):





Note: The Patch Pump may not be able to achieve the above measurement accuracy under certain circumstances such as vigorous exercise, or abnormal operating conditions.

11.3 Transmitter Specifications

Model: MD1026

Size: 36.1 mm x 19.4 mm x 7.2 mm

Weight: 3.57 g

Operating Temperature Range: +5°C ~+40°C

Operating Relative Humidity Range: 20%~90%RH

Operating Atmospheric Pressure: 700~1060 hPa

Storage Temperature Range: -10°C~+55°C

Storage Relative Humidity Range: 20%~90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Battery: Built-in 3.7 V polymer lithium ion battery

Waterproof Rating: IPX8 (2.5 m, 60 min)

Classification: Type BF equipment, Continuous operation

Data Storage: Automatically stores the previous 14 days' data

Wireless Communication Distance: 10 m

Limited Warranty: 1 year

11.4 Glucose Sensor Specifications

Model: MD3026

Storage Temperature Range: +2°C~+30°C

Appendix II: Technical Information

Storage Relative Humidity Range: 20%~90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Glucose Range: 2.2~22.2 mmol/L (40~400 mg/dL)

Sterilization Method: By radiation

Sensor Life: Up to 14 days

11.5 CGM System Accuracy

A clinical study was designed to determine the sensor accuracy in adults with Type 1 and Type 2 aged eighteen and older. In-clinic testing consisted of frequent venous blood sample testing using the Yellow Spring Instrument Life Sciences 2300 STAT Plus™ Glucose Analyzer (YSI) on a random day in the sensor life. The accuracy was based on the percentage of CGM glucose readings that are within $\pm 20\%$, $\pm 30\%$ and $\pm 40\%$ for reference values 100 mg/dL (5.6 mmol/L) and above, and ± 20 mg/dL (1.1 mmol/L), ± 30 mg/dL (1.7 mmol/L) and ± 40 mg/dL (2.2 mmol/L) for reference values below 100 mg/dL (5.6 mmol/L).

Table. Percentage of CGM Glucose Reading within $\pm 20\%$ / ± 20 mg/dL, $\pm 30\%$ / ± 30 mg/dL and $\pm 40\%$ / ± 40 mg/dL of the YSI.

Number of Matched Pairs CGM-YSI	Within $\pm 20\%$ / ± 20 mg/dL	Within $\pm 30\%$ / ± 30 mg/dL	Within $\pm 40\%$ / ± 40 mg/dL
13116	89.0%	97.8%	99.4%

Basal Pattern	A set of one or more basal rates that covers a 24-hour period.
Basal Rate	The amount of continuous basal insulin that is automatically delivered every hour.
BG	Abbreviation for blood glucose. See <i>Blood Glucose</i> .
BG Target	The high and low values to which your blood glucose is corrected when using the Bolus Calculator.
Blood Glucose (BG)	The amount of glucose present in the blood, often measured by a blood glucose meter.
Blood Glucose Meter/Meter/BG Meter	A medical device used to measure the amount of glucose in the blood.
Bolus Calculator	A feature that calculates an estimated bolus amount based on the BG values and carbs that you enter.
Bolus Dose	The amount of insulin used to cover an expected rise in glucose levels from carbohydrates, or to lower a high blood glucose value down to your target range.
Bolus Reminder	A Reminder that a bolus was not delivered during time periods that you specified, often set around meal times.
C	Abbreviation for Combo Bolus. See <i>Combo Bolus</i> .
Calibration	The process of using a meter blood glucose reading or a venous blood glucose value to calculate Sensor glucose values.
Calc-C	Combo Bolus by Bolus Calculator
Calc-E	Extended Bolus by Bolus Calculator
Calc-N	Normal Bolus by Bolus Calculator
C-Ext.	The extended portion of a <i>Combo Bolus</i> .
C-E	
CGM	Abbreviation for Continuous Glucose Monitoring. See <i>Continuous Glucose Monitoring (CGM)</i> .
C-N	The normal portion of a <i>Combo Bolus</i> .
C-Normal	
Combo	Part of the bolus amount delivered immediately, and the remainder delivered evenly over time period.
Combo Bolus	

Glossary

Continuous Glucose Monitoring (CGM)	A Sensor is inserted under the skin to check glucose levels in interstitial fluid. A Transmitter sends Sensor glucose readings to a display device.
Correction Bolus	Bolus used to lower a high blood glucose value down to your target range.
Audio off /Vibrate off	Both vibration and beep are turned off in Audio Options
E	Abbreviation for Extended Bolus. See <i>Extended Bolus</i> .
EasyLoop	Safety functions including Glucose Alerts, Low Suspend and Predictive Low Suspend.
Extended	Bolus amount delivered evenly over specified time period.
Extended Bolus	
Food Bolus	Bolus used to cover an expected rise in glucose levels from carbohydrates.
Food+Corr	Means that a bolus that both covers carbs and corrects glucose.
High Limit	The value you set to determine when the system will alert you of a high Sensor glucose condition.
IC Ratio	Abbreviation for Insulin-to-Carb Ratio. See <i>Insulin-to-Carb Ratio</i> .
Insulin Sensitivity Factor (ISF)	The amount that blood glucose is reduced by one unit of insulin.
Insulin-to-Carb Ratio	The number of grams of carbohydrates covered by one unit of insulin.
ISF	Abbreviation for Insulin Sensitivity Factor. See <i>Insulin Sensitivity Factor (ISF)</i> .
IOB	Bolus insulin delivered by the Pump that is still working to lower your blood glucose levels.
IOB Time	A Bolus Calculator setting that lets you set the length of time that bolus insulin is tracked as IOB.
Low Limit	The value you set to determine when the system will alert you of a low Sensor glucose condition.
Manual-Bo	Manually deliver a dose of insulin.
Manual Bolus	
Max 1h Delivery	Set the maximum insulin amount that can be delivered in one hour.
Max Bolus	Set the maximum bolus amount that can be delivered in one dose.

Max Total Daily Dose (TDD)	Set the maximum insulin amount that can be delivered in one day.
N	Abbreviation for Normal Bolus. See <i>Normal Bolus</i> .
Normal Bolus	Entire bolus amount delivered immediately.
Note	A Note provides helpful information.
Occlusion	A blockage or interruption in insulin delivery.
Preset Bolus	You can set up and save a bolus for specific meals or snacks that you frequently eat or drink.
Preset Temp Basal	You can set up and save temporary basal rates for repeated use.
Sensitivity	See <i>Insulin Sensitivity Factor (ISF)</i> .
Sensor Glucose (SG)	The amount of glucose that is present in the interstitial fluid and is measured by a glucose Sensor.
Sensor Session	The 14-day monitoring period after inserting a new Sensor. During this time frame, your glucose is being monitored and reported every two minutes, with data being sent to your display device(s).
SG	Abbreviation for Sensor glucose. See <i>Sensor Glucose (SG)</i> .
Suspend	This stops all insulin delivery until you resume it. Only the basal insulin restarts when delivery is resumed.
Temp Basal Rate (Temporary Basal Rate)	You can temporarily increase or decrease your current basal rate for a specific amount of time.
Warning	A warning notifies you of a potential hazard.

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