# A7+ TouchCare® Insulin Management System User Guide

Medtrum

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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Pump: Humalog<sup>®</sup>, NovoRapid<sup>®</sup>, and Apidra<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> System is approved. To order supplies, contact your local representatives.

## **1.2 Indications**

The A7+ TouchCare<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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

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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<sup>®</sup> System, contact customer support.

The A7+ TouchCare<sup>®</sup> System includes active medical devices. When you dispose of any device in the A7+ TouchCare<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> System is designed to tolerate common electromagnetic and electrostatic fields, including airport security systems and mobile phones.

#### 1.4.2 Consumables

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

*Warning:* For your protection the Pump Base and Transmitter have undergone extensive testing to confirm appropriate operation when used

with consumables manufactured or distributed by Medtrum. We recommend using Medtrum Reservoir Patches and Glucose Sensors as we cannot guarantee appropriate operation if the system is used with consumables offered by third-parties and therefore we are not responsible for any injury or malfunctioning of the system that may occur in association with such use.

## 1.4.3 Radio Frequency (RF) Communication

*Note:* The A7+ TouchCare<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> System may prevent communication between the PDM and your Patch Pump or Transmitter. This interference, however, does not cause any incorrect data to be sent and does not cause any harm to your device.

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

### 1.4.4 Emergency Kit

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

This kit should include but is not limited to:

- Fast-acting glucose tablets or gel
- BG monitoring supplies
- Urine ketone testing supplies

- Insulin syringe
- Rapid-acting U-100 insulin
- Extra Medtrum 2.0 mL Reservoir Patches
- Power Bank
- Instructions from your healthcare provider about how much insulin to inject if pump delivery is interrupted
- Alcohol wipes
- Glucagon emergency kit
- Emergency contact phone numbers

#### 1.4.5 Water

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

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

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

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

*Note:* Hot water may decrease Sensor life.

#### 1.4.6 Storage

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

Store the Sensor at temperatures between 2°C (36°F) and 30°C (86°F), and at humidity levels between 20% and 90% relative humidity for the length of the Sensor's shelf life. For temperatures greater than 30°C (86°F), the Sensor will require cooled storage at temperatures no lower than 2°C (36°F). You may store the Sensor in the refrigerator if it is within this temperature range. The

Sensor should not be stored in the freezer. Wait for the Sensor to warm to room temperature before usage to prevent condensation. Storing the Sensor improperly may cause the Sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

Store the Transmitter at temperatures between  $-10^{\circ}C$  ( $14^{\circ}F$ ) and  $55^{\circ}C$  ( $131^{\circ}F$ ), 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,

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
 ✓ Pump Base (JN (MD-JN-011, consumable)
 022)

## 2.3 Glucose Sensing System (Optional)

The Glucose Sensing System is an optional part of the A7+ TouchCare<sup>®</sup> 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)

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## **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.

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.

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

#### Awake Mode

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

- a. You can turn Sleep Mode to Awake Mode by pressing power button.
- b. In the Sleep Mode, all Alerts and Alarms regarding the Pump and CGM will immediately wake the screen to enter Lock Screen. The Alerts and Alarms shall be manually cleared after sliding to unlock.





An Alarm occurs when the screen is locked.

An Alarm occurs when the screen is not locked.

#### 3.1.4 Scroll Bar

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



## 3.2 Setting up the PDM

### 3.2.1 Select language and country/region

1. Select your language, then tap Next.

	12:04	3∎8
	Languag	e
English		* 1
Deutsch	1	
Dansk		
Svenska	a	
Français	S	
	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

	12:04	3∎{
<	Country/Reg	jion
Unit	ed Kingdom	~
Geri	many	
Den	mark	
Swe	eden	
Frar	nce	
	Next	

#### 3.2.2 Time and Date

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

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

		-	5:28	3∎{	-	13:39	<b>∢</b> ))	
	Time & Date			Time				
		24 Ho	our		hou	'n	ninute	
		Time		05:28	<b>•</b>			
					05	2	28	
					•		•	
			Next		Cancel		Done	
(1)	Choo	se the	time.					
(2)	Tap t	he blu	ue button	to i	increase a	nd 🧲	to decr	rease hour on
	the le	eft.						
	Tap t	he blu	e button	🕂 to ir	crease and	9 😑	to decrea	ase minute on
	the ri	ight.						
(3)	Whe	n finis	h, tap <b>Dor</b>	ne.				

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

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.





No battery left

When the PDM is charging
There are six icons, indicating different battery conditions.

- Less than 10% charged
- ļ 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  $\triangleright$
- 14.00 24-hour format  $\triangleright$

#### 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 and Vibrate
- **▲**×
  - Audio off /Vibrate off
- **4** Alert Silence + Audio Reminder
- 3 Alert Silence + Vibrate Reminder
- }∎≨ Alert Silence + Audio and Vibrate
- Alert Silence + Audio off /Vibrate off

#### 3.3.1.4 Pump RF Signal Icon

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

- Patch Pump is active and RF communication is good
  - Patch Pump is active but RF communication is lost or interrupted

#### 3.3.1.5 Alert Icons

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



Alert icon

Medium priority alarm icon



High priority alarm icon

### 3.3.2 Pump Status



- 1. EasyLoop Icon
- 2. Insulin Pump 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
$\bigcirc$	Grey ring	Grey ring indicates that there is no activated Pump.
$\bigcirc$	Green ring	Green ring represents the basal delivery.

$\bigcirc$	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.
$\bigcirc$	Blue and dark blue ring	Blue ring represents the Normal Bolus, the dark blue part indicates the progress of delivery.
$\bigcirc$	Purple and dark purple ring	Purple ring represents the extend Bolus, the deep purple part indicates the progress of delivery.
$\bigcirc$	Red ring	Red ring represents the delivery suspend status.

The status information is indicated by text below:

 $\diamond$  Basal(U/H) 1.00: The current basal rate is 1.00U/H.

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

 $\diamond$  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).

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

 $\diamond~$  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.

 $\diamond$  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:



#### CGM feature off:



1. Trend Arrow

2. The last senor reading or status

3. Time of the last sensor reading

- 4. The scope of glucose limit
- 5. High Limit of glucose limit
- 6. Low Limit of glucose limit
- 7. CGM Curve
- 8. Last Glucose point
  - 9. The scope of time
  - 10. Calibration
    - 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.



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.
- ۲
- The next calibration is due in 4 to 8 hours.
- .

The next calibration is due in 0 to 4 hours.

A calibration is needed now.

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

The next calibration is due in 10 to 12 hours.

The next calibration is due in 8 to 10 hours.

The next calibration is due in 6 to 8 hours.

The next calibration is due in 4 to 6 hours.

The next calibration is due in 2 to 4 hours.

The next calibration is due in 0 to 2 hours.

A calibration is needed now.

#### Data recovery status icon

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



#### **Special conditions**

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



Warm-Up- the Sensor is warming up.

ERR - the Sensor shall be recalibrated after 15 minutes.

BG- the Sensor shall be recalibrated now.

??? - No readings.

LOST - Sensor signal has been lost for more than 10 minutes.

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

Low - Sensor glucose is below 2.2 mmol/L (40mg/dL).

<u>Underlined reading</u> - 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.

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

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

### 3.3.5 Sensor Graph

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



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



- Tap the Sensor graph and move the cursor to spot the glucose values. Use the left and right arrow button to choose the time. The time interval between two values is 2 minutes.
- The time point when a new Sensor is applied will be marked with a green square tag "
  . Readings during warm-up phase will not be displayed but marked as "warm-up".
- Glucose value or special status will always be shown in the area below, between the left and right arrow button. Special status includes: calibration error (ERR), no readings (???), warm-up phase (Warm-up), Sensor glucose is above 22.2 mmol/L (400mg/dL). (HIGH) and Sensor glucose is below 2.2 mmol/L (40mg/dL). (LOW).
- After the warm-up phase, the values before the first calibration are replaced by "BG".
- When the Sensor calibration expires, the reading values will be underlined.
- Calibration will be marked with a red dot "•".
- The green square blocks in the graph background represent the Low and High limits of glucose.
- In the landscape screen display, tap the Home Key to return to the Home Screen.
- When data is being recovered after sensor-reconnection, you cannot enter landscape screen by long-pressing the graph.
- When you are only using the insulin pump as stand-alone system, the sensor graph displays the blood glucose recorded, and BG inputs will be displayed as red dots "•".

## 3.3.6 Alarm Status

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

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

For example:



## 3.4 Lock Screen

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

1. Lock Screen without Alarm, Alert and Reminder



See "Pump Status" for more information about 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 " ◄ ".

#### (4) Vibration Option icon

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

Vibration off " 🕸 ", Vibration on " 💷 ".

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.

-	10:16	3∎{	=
	Status		
Delivery	Today		ē
Bolus			1
Basal			<sub>κ</sub> π.
Other Sta	atus Info		Ê
Device Ir	nfo		í

The Status Screen displays the following information.

Delivery/Today		Bolus		Basal			
10:46	}∢₹ 📑 ੈ	-	10:47	}∎≀ =	-	10:48	348 📑
< Delivery/To	day	<	Bolus		<	Basal	
Temp Basal:	Yes	Last Bo	olus:	E0.10U	Basal N	lode:	Manual
Suspendi	Vaa	25 11 2	016	10.46	Pattern:	Si	tandard
Suspend.	res	20-11-2	2010	10.40	24-Hr T	otal:	24.00U
Bolus:	27.90U	Ext Bol	us:	2.00U	Basal:	1	.00U/H
Basal:	10.25U	Ext:	0.10	00/2.000	Temp B	asal:	Active
Totol	20 1511	Time	- <del>A</del> .	00.20	Start	25-1	1 10:46
TOLAI.	36.150	Time Lo	en.	00.29	End	25-1	1 14:46
Insulin Left:	88.80U				Rate	1	.00U/H

Other Status Info	Device Info
= 11:45 ◄ =	= 10:49 承 =
<ul> <li>Other Status Info</li> </ul>	< Device Info
Patch Life Left 0dav1hour26min	PDM SN: 067F3586
Sensor Life Left	Version 1.67.169
2day2hour56min Transmitter Battery	Pump SN: 106000674
Normal	Version 1.70.170
Next calibration 6hour24min	Transmitr SN: 102005219
Sensor Status Monitoring	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.



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

## 3.8.1 Bolus

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

### 3.8.2 Basal

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

### 3.8.3 Suspend

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

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

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

### 3.8.4 Patch

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

### 3.8.5 Sensor

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

### 3.8.6 History

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

### 3.8.7 Events

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

### 3.8.8 EasyLoop

The **EasyLoop** menu is used to set "Glucose Alerts" and "(Pre) Low Suspend" functions. See 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<sup>®</sup> 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.

Main Monu - Events

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

Ivianni		LVCIICS
-	14:38	}∢{ 📑
<	Events	
BG		>
Carbs		>
Injection	I	>
Health		>
Exercise		>
Others		>

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).



5. When finished, tap **Save** to confirm input. Or press  $\checkmark$  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 "Rapidacting", "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  $\leq$  to cancel.

### 3.9.3 Carbohydrates Information

1. Select Carbs in the Events screen.

2. Choose the date and time for carbohydrate intake.

3. Tap **Carbs** value to select the carbohydrates you eat or drink. The input range is 0-300 grams.

-	15:07	}∢{ 📑
<	Carbs	
29-08-3	2018	15:07
Carbs:		
	<b>10</b> g	
	Save	

4. When finished, tap **Save** to confirm or press  $\leq$  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  $\sim$  8 hours, the input increment is 5 minutes.

-	15:09	348 📑
<	Exercise	e
29-08-	2018	15:09
Intensi	ty:	
Medium		
Duration		
00:30		
Save		

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

#### 3.9.5 Health Information

- 1. Select Health in the Events screen.
- 2. Choose the date and time for health information
- 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  $\leq$  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.

8:38		3∎१
Cancel		Done
a	b	C
abc	def	ghi
jkl	mno	pqr
stu	vwx	yz
ABC	space	$\otimes$

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.

-	11:57	}∎₹ 🚍
<	Others	
28-08-3	201 <b>8</b>	15:55
Note		
	party	
	Save	

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

5. When finished, tap **Save** to confirm input. Or press  $\checkmark$  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.

	13:36	3∎{	=
<	History		
Pump H	History		>
Sensor History			>
PDM History			>
Event History			>
BG History			>
Summary History		>	

#### Main Menu→History

### 3.10.1 Pump History

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

## 3.10.2 Sensor History

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

## 3.10.3 PDM Alert History

PDM History stores PDM Alert history.



Main Menu→History→PDM History→PDM Alert History

Tap the date to switch between records of different dates. Tap each Alert to view alert detail information. Tap  $\leq$  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

-	15:50 🔌 💳	
Κ Ε	vent History	
Туре	e All	
<b>&lt;</b> 2	29-08-2018	
Health	15:50 >	
Injection	n 15:49 <b>&gt;</b>	
Carbs	15:49 >	
BG	15:49 >	

Tap **Type** option to select event type for viewing records accordingly. Tap the date or  $\lt$ , > 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

	-	1:10	) <b>∢</b> ×			
	<	BG Hist	tory			
	<	03-09-2	018	>		
	<b>6</b> 7.3	mmol/L	15:52	2		
	0 5.6	mmol/L	15:49	)		
	<b>6</b> 8.1ı	mmol/L	9:24			
BG History contains BG fror	m Cali	ibration	🌢 , E	Even	t BG 🔇	$\bigcirc$
during Bolus delivery throu	igh Bc	olus Calo	ulator	$\bigcirc$		
Tap the date or < , > to	switc	h betwe	een rec	ord	s of dif	ffe

# 3.10.6 Summary History

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

Go to Summary History screen.

Main Menu→History→Summary History

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

■ 13:37 🔌 🚍	= 10:41 承 =
< Summary History	< Time Period
Insulin >	1 Day 🗸
Bolus >	7 Days
BG >	14 Days
Sensor >	30 Days
Low Suspend	

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

-	13:41 →	٩٤	-	13:41	348
<	BG	1D	<	BG	14D
<b>&lt;</b> 24	4-11-2016	>	<	10-11-201 23-11-20	6 <b>&gt;</b>
BG Test		#3.0	BG 1	Fest	#3.4
Average	BG		Aver	age BG	
	7.6m	nmo/L		9	.6mmo/L
High BG	13.8m	mol/L	High	BG 13. BG	8mmol/L
200000	3.5m	mol/L	2000	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



# 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.

-	16:59	}∢{ =
<	General	
Langua	ge	>
Time/D	ate	>
Audio C	ptions	>
Display		>
Confide	nce Remir	nder >
User Se	ettings	>

#### 3.11.3.1 Language

You can change your PDM Language.

Main Menu → Settings → General → Language

	13:04	}∢₹ 📑
<	Language	e
Englis	h	~
Deuts	ch	
Dansk	ĸ	
Svens	ska	
Franç	ais	
Italian	o	

#### 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.

-	17:09 🛯 🕬 💳
<	Time & Date
24 Hoi	ır 💽
Date	03-09-2018
Time	17:09

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 threepulse vibration every three minutes. If not cleared within 9 minutes, your PDM will make a siren until the alert is cleared.

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

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

Go to Audio Options screen.

Main Menu→Settings→General→Audio Options



#### 3.11.3.4 Display

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



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

#### 3.11.3.5 Confidence Reminder

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

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

- Suspend alarm setting takes effect
- Max delivery setting takes effect
- Sensor connected
- Insulin delivery has been suspended
- Basal insulin has been resumed
- Glucose alert set
- Pump alert/alarm set
- Tapping the HOME key

#### 3.11.3.6 User Settings

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

-	17:17 →	4
<	User Settings	
Save	•	>
Rest	ore	>
Rese	ət	>
Setti	ngs History	>

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

Save

Take these steps to save your current PDM settings:

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



If you have saved PDM settings, this screen appears:



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

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



#### Restore

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

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



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



Reset

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

Take the following steps to reset PDM settings:

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



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



#### **Settings History**

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

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



#### 3.11.3.7 Passcode Lock

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

Main Menu → Settings → General → Passcode Lock



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

	14:02	}∢≀ 📑					
Enter	Enter old passcode						
****							
Cancel							
1	2	3					
4	5	6					
7	8	9					
	0	$\otimes$					

Enter the 4-digit passcode.

*Note:* The default passcode is 0000.

-	15:38	}∢{ 📑				
Enter	Enter old passcode					
0000						
Cancel		Done				
1	2	3				
4	5	6				
7	8	9				
	0	$\otimes$				

Enter the new passcode twice.

-	15:22	} <b>∢</b> {	-	15:23	} <b>∢</b> {		■ 15:40 🕬 🚍
Enter	new pas	scode	Re-en	ter new pa	asscode		Set Passcode
1234			1234				
Cancel		Done	Cance	əl	Done		
1	2	3	1	2	3	Pa	asscode changed.
4	5	6	4	5	6		
7	8	9	7	8	9		
	0	$\otimes$		0	$\otimes$		ок

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.

-	15:36	}∢≀ 📑
< 1	Passcode L	ock
Pass	code Lock	
Set P	asscode	>

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.

-	18:57 🛛 🛤	۶
<	Reminders	
Perso	onal Reminder	>
Bolus	Reminder	>
BG R	leminder	
Cal R	eminder 01:0	0

#### 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

18:58	3 }4⊱
Personal Reminder	
Personal Reminder 🛛 🌔	
Time(hh:mm)	Repeat
+Add 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.

-	19:05	} <b>∢</b> {
< Perso	onal Rem	inder
Persona	l Remind	er 💽
Time(hh	:mm) F	Repeat
09:0	0	Daily
14 :00	Daily	Delete
16:0	0	Once
+Add alarm clock		

#### 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.

19:32 ऄ◀१	-	19:35	<b>}</b> ¶{	= 19:36 ≩4∜
< Edit Username	Martin			< Edit Username
	Cancel		Done	Martin
	a	b	c	
	abc	def	ghi	
	jkl	mno	pqr	
	stu	vwx	yz	
	ABC	space	$\overline{\mathbf{x}}$	

(1) Use the keyboard to enter the username.

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

(2) When finish, tap Done.

(3) Tap the name in blue to edit Username again.

*Note:* You can enter as many as 18 letters including spaces. Your username will be displayed on the Lock Screen.

The PDM displays the username on Lock Screen to help you identify your own PDM. You can always confirm that the username is correct before using the PDM.



### 3.11.6 Telephone

1. Go to the Telephone screen.

Main Menu→Settings→ Telephone

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

■ 15:25 3	-	15:27	3∎{	<b>15:28 ∢</b> ₹
< Edit Telephone	1264567	78		< Edit Telephone
	Cancel		Done	12645678
	•	(	)	
	1	2	3	
	4	5	6	
	7	8	9	
	#@	0	$\propto$	

- (1) Use the keyboard to enter the telephone number .
- (2) When finish, tap **Done**.
- (3) Tap the number in blue to edit telephone number again.

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

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

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

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



### 3.11.7 Diagnostics

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

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

Main Menu→ Settings → Diagnostics

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



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



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

-	11:02	} <b>≼</b> {
c	heck Aları	ms
Alarmo	check com	pleted.
	ОК	

*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

-	3:	09	∎×	=
<	Abou	ut Us	\$	
Compa	any		Med	trum
PDM SN		0	67F3	8586
Version			1.67	.170
Co F2	de A0 218-63	09-6 63-6	363- 363	

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  $+5^{\circ}C \sim +40^{\circ}C$ .

#### When I should charge my PDM?

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

#### PDM DOES NOT POWER ON AFTER YOU PRESS THE POWER BUTTON:

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

2. PDM is outside of its operating temperature range. Move the PDM to a temperature between  $+5^{\circ}C \sim +40^{\circ}C$  and then try to power it on.

# How to use the PDM

### 4.1 Change the reservoir patch

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

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

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

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

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

#### 4.1.1 Before Changing the Reservoir Patch

You will need these items before you begin:

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

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

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

#### also permitted.

#### Specifications of syringe:

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

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

#### 4.1.1.1 Deactivate the Current Reservoir Patch

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

Main Menu  $\rightarrow$  Patch  $\rightarrow$  Deactivate Patch.



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



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

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De	eactivate P	atch
Deacti	vated	
	ок	

#### 4.1.1.2 Remove the Current Reservoir Patch

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



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

Warning: Check the infusion site for signs of infection.

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



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

#### 4.1.1.3 Enter Pump Base SN

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

Main Menu→Patch →Pump Base SN

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

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

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





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



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



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



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

#### Search for the SN

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

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

■⊃ 18:50 348
Pump Base SN
Connect Pump Base to a new Patch. Searching for the Pump Base
Please wait

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**.

-	5:41	} <b></b> ₹
< Ρι	ımp Bas	e SN
106000	0674	
Canc	el	ОК

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

-	12:51 ऄ◀१	
<	Start	
No acti Next to	ive Patch. Tap o activate.	
	Next	

#### 4.1.3 Connect the Pump Base to a New Reservoir Patch

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



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

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



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



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

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

#### 4.1.4 Fill the New Reservoir Patch

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

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

Take the following steps to fill a new Patch:

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

- 4. Draw air into the syringe up to the amount of insulin you need.
- 5. Insert the needle into the insulin vial and push down on the plunger to pressurize the vial.



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



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

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

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

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



- 9. Make sure that the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position, but it will NOT push any air back inside the reservoir.
- 10. Withdraw the needle from the fill port. Turn the syringe upright and pull on the plunger. Flick the syringe to make sure that any air bubbles rise to the top. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle.



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



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

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

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

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

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

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

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

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

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

#### 4.1.5 Prime the Pump

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

-	16:23	}∢≀ 📑
	Prime	
Press b tap nex	utton cov t to start p	er. Then rime.
	Next	

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

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



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



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

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



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

### 4.1.6 Select and Prepare the Infusion Site

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

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

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

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

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

Body areas (shaded) suitable for infusion sites:



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

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

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

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

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

#### 4.1.7 Attach the Patch Pump

1. Remove the button cover.



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



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



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



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

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

#### 4.1.8 Start Insulin Delivery

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



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



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

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



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

4. Now your new Reservoir Patch is activated.



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

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

## 4.2 Bolus

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

Your A7+ TouchCare<sup>®</sup> 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.

	5	
<ul> <li>Bolus</li> <li>Bolus Calculator</li> </ul>		
Bolus Calculator		
	>	
Manual Bolus		
Preset Bolus		

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

#### 4.2.1 Normal Bolus

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

Main Menu→Bolus→Manual Bolus

-	4:47 अब्≮ 🚍 े
<	Manual Bolus
Set E	Bolus
	<b>0.00</b> U
Туре	•
	Normal Bolus
IOB:	0.00U
	Next

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



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



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

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

-	13:03 斗 💳		
<	BG Reminder		
BGF	Reminder 🛛 🌔		
Duration			
00:30			
	Next		

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.

= 12:47 承 =	= 13:05 承 :=			
< Manual Bolus	Manual Bolus			
Start Bolus?	Bolus: 0.35U			
3.00U				
	Total: 4.00U			
Slide to deliver	Slide to stop			

*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.

		5
	16:56 🛛	(¥ 🚍 )
юв:(U) 2.45	5.0 mmol/L 16:56 Normal(U) 0.45/2.00	La contraction of the second s
20		
15		
10		
5	$\sim$	·
14:00	15:00 16:00	

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



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



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



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



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

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

#### 4.2.2 Max Bolus

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

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

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



### 4.3 Basal

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

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

#### 4.3.1 Your Basal Settings

You must program your basal settings before you deliver any basal insulin. Keep a written record of your basal settings. You can program up to 8 basal patterns with the A7+ TouchCare<sup>®</sup> 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

-	15:53	}∎≀ =			
<	Basal Setup				
Edit Basal					
Basal Review					
Preset Temp Setup >					
Max E	Basal	2.00U/H			

### 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.

<b></b> 16:	40 ∛¶∛	<b>—</b> 16:4	41 ≩¶≷		
< Select Pattern		< Select Pattern			
Standard	13.70U	Pattern C	0.00U		
Exercise	0.00U	Pattern D	0.00U		
Holiday	0.00U				
Sick	0.00U				
Pattern A	0.00U				
Pattern B	0.00U <mark>,</mark>				

*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**.

-	16:03	}∎⊱ =	-	16:04	}∢≀ 📑	-	16:02	}∎≀ ]
< Exercise 0.00U			Time			<ul> <li>Standard 12.15U</li> </ul>		
Start	End	U/H		_		Start	End	U/H
00:00	23:59	0.00				00:00	03:00	0.55
				00:30	0	03:00	23:59	0.50
+Add time segment		Canc	el	Done	+Add time segment			

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.


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

### 4.3.3 Check the Current Basal Rate

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

1. Home Screen



#### 2. Status → Basal



### 4.3.4 Review Your Basal Patterns

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

1. Go to the Basal Review screen.

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

<b>-</b> 16:	40 }◀⊱	<b>1</b> 6:	41 ∛¶∛
< Select	Pattern	< Select F	Pattern
Standard	13.70U	Pattern C	0.00U
Exercise	0.00U	Pattern D	0.00U
Holiday	0.00U		
Sick	0.00U		
Pattern A	0.00U		
Pattern B	0.00U		

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

-	17:08	}∎⊱ 📑	■ 17:08 348 🚍
< Stand	lard 13	.70U	< Standard
Start	End	U/H	Total Basal 13.70U
00:00	03:00	0.55	U/H
03:00	09:00	0.70	1.0
09:00	20:00	0.55	0.5
20:00	23:59	0.45	4:00 12:00 20:00
	View		ОК

### 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.

•	•	5:54	}∢€ 🚍		
	<ul> <li>Standard 15.55U</li> </ul>				
	Start	End	U/H		
	00:00	03:00	0.55		
	03:00	09:00	0.65		
0	19:00	0.70	Delete		
	19:00	23:59	0.60		
	+Add time segment				

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).

-	5:56	}∢{ =	-	5:56	}∢{ =
< Stand	dard 15.3	0U 💾	< Stand	dard 13.2	20U 🗎
Start	End	U/H	Start	End	U/H
0 03:00	0.55	Delete	00:00	23:59	0.55
03:00	23:59	0.65			
+Add tir	ne segm	ent	+Add tin	ne segm	ent

### 4.3.6 Change the time of the Basal Pattern

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

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

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

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

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



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

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

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

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

-	13:58	<b>▲</b> ×		-	14:02	<b>∢</b> ×
< Stand	dard 15.4	5U 💾		< Stan	dard 16.2	0U 💾
Start	End	U/H		Start	End	U/H
00:00	12:00	0.70		00:00	12:00	0.70
12:00	13:00	0.65	$\Box$	12:00	23:59	0.65
13:00	15:00	0.50				
15:00	23:59	0.60				
+Add tin	ne segme	ent		+Add tir	ne segme	ent

### 4.3.7 Maximum Basal Rate

Maximum (Max) basal rate is a safety limit for the amount of basal insulin to be delivered within an hour. This maximum rate applies to every basal rate

that is set, including a temporary basal. Once your basal rates have been set, you cannot set a maximum basal rate that is less than any of the programmed basal rates. The factory default is 2.00 U/H. The setting range is:  $0.00U/H^{25U}/H$ . Please set the maximum basal rate with the help of your healthcare provider.

1. Go to the Max Basal screen.

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

-	6:42	348 📑
<	Basal Se	tup
Edit	Basal	>
Basal Review		
Pres	et Temp Se	etup >
Max	Basal	2.00U/H

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

-	6:43	}∢₹ 📑		
N	Ma× Basal			
G	) (	•		
2	. 0	0		
•		•		
Cance		Done		

### 4.4 Suspend and Resume

### 4.4.1 Suspend Insulin Delivery

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

When the Bolus is being delivered, you can choose to suspend all insulin deliveries (basal and bolus) for a set period of time or to just stop the bolus currently being delivered.

- a. When no bolus is being delivered:
- 1. Go to the **Suspend** screen. Set a suspension time and tap **Next** to continue.



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

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



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

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



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



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

Main Menu→Suspend

-	14:28	}∎⊱ ]
<	Suspend	
Bolus		>
All		>

- 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.



### 4.4.2 Resume Insulin Delivery

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



Slide to resume Basal delivery.

-	14:37	}∢₹ 📑
	Resume	
Basal p	attern is S	Standard.
	ОК	

*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.

Insulin Pun	np
Pump	
Base SN	>
Setup	>
Setup	>
Alerts	>
	Insulin Pur Pump Base SN Setup Setup Alerts

### 4.5.1 Add/Change the Pump Base SN

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

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

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

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

### 4.5.2 Bolus Setup

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

-	16:47	3∎{	=
<	Bolus Set	qu	
Bolu	s Calc Setup	)	>
Pres	et Bolus Set	up	>
Max	Bolus	10.	000

### **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.

-	16:52	}∢{ 📑
<	Basal Set	tup
Edit B	Jasal	>
Basal Review		
Prese	et Temp Se	tup >
Max B	2.00U/H	

#### **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

-	16:55	¥ =
< Pum	p Alerts	
Patch E	×piratior	12H 💽
Low Re	servoir	20U
Daily M	ax	80U
Hour M	ax	25U
Auto Of	f	12H 🌑

#### **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.

-	16:56	}∢≀ 📑
< Pum	p Alerts	
Patch E	×piration	12H 💽
Low Re	servoir	20U
Daily Ma	ax	80U
Hour Ma	ax	25U
Auto Off	-	

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

#### 2. Low Reservoir

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

• A specified number of units that remain in the Reservoir Patch

• A specified maximum amount of time that remains before the Reservoir Patch will be empty



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

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

#### 3. Max Delivery

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

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

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

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

*Note:* If you resume insulin delivery manually after the hourly/daily max was exceeded, the previously delivered amount in this hour/day will be cleared

and the PDM will record the hourly/daily amount from zero.

#### 4. Auto Off

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

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

## **5.1 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

17:04	348 📑	
Bolus Calcula	ator	
us Calculator		
IC Ratios >		
lin Sensitivity	>	
Target	>	
Time	03:00	
	Bolus Calculator Ratios Iin Sensitivity Target Time	

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

-	17:02	}∢{ 📑
<	Bolus Calcula	ator
Bol	us Calculator	
IC F	Ratios	>
Insi	ulin Sensitivity	>
BG	Target	>
IOP	Time	03:00

*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.

-	17:11	}∢₹ 📑
	atios	=
Start (hh:mm)	Insulin (U)	Carbs (g)
00:00	1	16
02:00	1	14
+Add tin	ne segm	ent

*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.

-		17:12	∢ <b>4</b> ⊱ <u>=</u> "
Sta (hh:r	irt nm)	Insulin (U)	Carbs (g)
00	:00	1	16
00	1	14	Delete
+Ac	ld tin	ne segm	ent

4. When finished, press  $\equiv$  to save settings. Or Press  $\leq$  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.

-	17:13	}∢₹ 📑
< Insulir	n Sensiti	vity 💾
Start (hh:mm)	Insulin (U)	BG (mmol/L)
00:00	1	2.6
+Add tin	ne segm	ent

*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.

-		17:13	∢∎ ≀∎
<b>&lt;</b> Ii	nsulir	n Sensiti <sup>,</sup>	vity 💾
Sta (hh:i	art mm)	Insulin (U)	BG (mmol/L)
00	00:00	1	2.6
:00	1	3.0	Delete
+Ac	dd tin	ne segm	ent

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

#### **BG Target**

A BG Target is your personal goal for keeping your BG levels under control. A

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

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

On the Bolus Calc Setup screen, select BG Target.

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

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

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



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

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

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

Note: Select segment, slide to left on each and a delete button will appear.

Tap **Delete** to delete the selected segment. The first segment cannot be deleted and the starting time of first segment cannot be changed.



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

#### **IOB Time**

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

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

-	17:02	∢∎ ≀∎
< Bo	lus Calcul	ator
Bolus C	alculator	
IC Ratio	os	>
Insulin \$	Sensitivity	>
BG Tar	get	>
IOB Tin	ne	03:00

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

### 5.1.3 Normal Bolus Using Bolus Calculator

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

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



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



#### Note:

1) If you are not entering a BG and want a bolus for food, enter only your carbohydrate amount, the bolus calculator feature will calculate an

estimate of insulin for your food entry without considering your BG level.

- 2) You can enter a BG value between 1.1 mmol/L and 33.3 mmol/L (20 mg/dL and 600 mg/dL) with an increment of 0.1 mmol/L (1 mg/dL). The factory default is 5.6 mmol/L (100 mg/dL).
- 3) You can enter an amount of carbs between 0 g and 300 g with an increment of 1 g.
- 4) You can set a bolus dose between 0 and the Max Bolus with an increment of 0.05 U.
- 3. After BG and Carbs input, the recommended Bolus dose according to the Bolus Calculator appears on the right side of the BG value and carbohydrate amount. For example:



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

■ 18:48 🕬 🗂		
< Bolus Calculator		
Set Bolus:		
<b>2.65</b> U		
Туре		
Normal Bolus		
Suggested: 2.65U IOB: 0.00U		
Next		

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



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

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

= 19:53 ◄ =	= 19:55 → = =	
< Bolus Calculator	Bolus Calculator	
Start Bolus?	Bolus: 0.60U	
2.65U		
	Total: 2.65U	
Slide to deliver	Slide to stop	

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

## 5.2 Combo/Extended Bolus

The Combo/Extended Bolus feature is useful for consumption of high carb/high fat meals such as pizza, which entails prolonged carb absorption. It

is also useful if you will be eating ("grazing") over a few hours or if you have gastroparesis, which means food remains in the stomach for a longer period than it normally does.

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



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

### 5.2.1 Combo/Extended Bolus Without Bolus Calculator

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



#### **Extended Bolus**

To set an Extended Bolus, follow these steps:

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

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

- b. Tap **Type** option to choose **Extended Bolus**. Then tap Next.
- c. Enter the amount of time you want the Extended Bolus to last and tap **Next**.



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

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



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

**Combo Bolus** 

To set a Combo Bolus, follow these steps:

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

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

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

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

-	20:01	348 📑
<	Manual Bo	lus
Set Bolus		
<b>1.00</b> ∪		
Туре		
Combo Bolus		
IOB:		1.65U
	Next	

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



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

30 min.

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

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



### 5.2.2 Combo/Extended Bolus Using Bolus Calculator

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

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

-	20:05	}∎⊱ =	
< Bolus Calculator			
BG:		0.70U	
8.3 mmol/L			
Carbs:		5.65U	
<b>85</b> g			
Next			

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

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



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

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

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

#### **Extended Bolus**

To set an Extended Bolus, follow these steps:

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



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

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



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

#### **Combo Bolus**

To set a Combo Bolus, follow these steps:

a. Tap the blue icon 😌 to increase Normal Bolus. Tap the purple icon 😌

to increase Extended part.

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



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

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

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



# **5.3 Preset Bolus**

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

### 5.3.1 Preset Bolus Setup

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

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

	12:31	}∢₹ 📑
Preset Bolus		
Breakfast		>
Lunch		>
Dinne	ər	>
Snac	k	>
Bolus	s 1	>
Bolus 2		>

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

∎ 10:04 🕬 🚍	∎ 10:04 🝽 🚍
< Breakfast	< Туре
Set Bolus	Normal Bolus 🗸
<b>0.00</b> U	Extended Bolus
Туре	Combo Bolus
Normal Bolus	
Next	

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.

Save	Save
00.00	Duration 00:30
00:30	Normal:         Extended:           0.50U         0.50U           50%         50%
Extended: 1.00U	Set Bolus 1.00U
< Breakfast	< Breakfast
■ 10:06 🕬 🚍	■ 10:07 🝽 🚍

4. Tap **Save** to save the settings. Tap  $\checkmark$  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.



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

2. Select the preset bolus you want to deliver.

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

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

### 5.4 Select a Basal Pattern

1. Go to the Select Pattern screen.

Main Menu→Basal→Select Pattern

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

<b></b> 16	:40 ∛¶∛	<b>1</b> 6:	41 ∛¶⊱
Select Pattern		Select Pattern	
Standard	13.70U	Pattern C	0.00U
Exercise	0.00U	Pattern D	0.00U
Holiday	0.00U		
Sick	0.00U		
Pattern A	0.00U		
Pattern B	0.00U 🖕		v

### 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.

<b>•</b> 9:	59 📧 💳	<b>-</b> 9	:59 🕬 💳	
Temp Basal		< Temp	Temp Basal	
Current Basal 0.50U/H		Current Basal 0.50U/H		
Rate(U/H)	Percent	Rate(U/H)	Percent	
Rate(U/H)	0.40	Percent	80%	
Duration 04:00		Duration	02:30	
Next		N	ext	

**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



2. Slide to stop temp basal delivery, or tap  $\leq$  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

1. 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.

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.

-	19:	:19	} <b>∢</b> {
< Bo	Bolus Reminder		
Bolus R	Bolus Reminder		
Start(hh	:mm)	End	d(hh:mm)
07:	00		09:00
12:	00		15:00
19:	00		21:00
+Add time segment			

#### 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

-	19:27 🕬			
<	Reminders			
Pers	Personal Reminder >			
Bolus Reminder				
BG Reminder 🛛 🌔				
Cal F	Reminder 03:00			

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.



#### 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



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
۲	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.

-	15:19	3∎{	=
<	29-08-201	8	
*14:37	0.45U/H		
13:43	PLowSus	sp	
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.



#### **Bolus Type:**

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

- ♦ 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.

15:20	6 ∢∢ 📑 ື	<b>1</b> 5	:28 🔌 📑	<b>—</b> 1:	5:28 🔌 📑
< 29-08-2	018	< 29-08	-2018	< 29-0	8-2018
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	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

-	1:05 <b>4</b> ×	
<	29-08-2018	
13:00		>
Low R	eservoir	
12:12		>
Auto (	Off Alert	

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

See Section "Alert Icons" in Chapter "How to us 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



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



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  $+5^{\circ}C \sim +40^{\circ}C$ .

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

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.

## **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.

= 16:23 承 =	= 16:23 承 =
Glucose Alerts	🧲 Glucose Alerts 🗎
Glucose Alerts	Glucose Alerts
Glucose Limits	Glucose Limits
Predictive Alerts	Predictive Alerts
Rate Alerts	Rate Alerts
Repeat >	Repeat >

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.

Go to the Glucose Limits screen.

Main menu→EasyLoop→Glucose Alerts→Glucose Limits

	19:26	}∢{ 📑				
< Glu	Glucose Limits					
Start (hh:mm)	Low (mmol/L)	High (mmol/L)				
00:00	4.4	13.3				
+Add time segment						

#### 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.

-	16:25	}∢≀ 📑
< Glu	cose Lin	nits
Start (hh:mm)	Low (mmol/L)	High (mmol/L)
00:00	4.4	12.0
07:30	4.4	13.0
+Add tin	ne segm	ent

#### Note:

- 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 rage 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.

		16:26	}∢{ ➡
<	Gluo	cose Lim	nits 💾
Sta (hh:	art :mm) (	Low mmol/L)	High (mmol/L)
00	00:0	4.4	12.0
:30	4.4	13.0	Delete
0	8:30	4.4	13.5
+Add time 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 \rightarrow EasyLoop \rightarrow Glucose Alerts \rightarrow Predictive Alerts
```

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

■ 19:27 348 🚍	■ 16:28 🕬 🚍
Predictive Alerts	Predictive Alerts 🗄
High Predicted	High Predicted
Low Predicted	Time 00:30
	Low Predicted
	Time 00:10

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.

	19:27	348 📑
	Time	
	•	
00:20		
•		
Cance		Done

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

3. Tap  $\blacksquare$  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 preselected rate
- **Rapid Rise** for Sensor glucose increasing at or faster than your preselected rate

Go to the Rate Alerts screen.

Main menu  $\rightarrow$  EasyLoop  $\rightarrow$  Glucose Alerts  $\rightarrow$  Rate Alerts

-	16:30 🔌 💳	
<	Rate Alerts	
Rise	>	•
Fall	>	

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.

-	16:33	}∢≀ 📑
<	Rise	
Rise		
Aler	t when:	
1	0.110	~
11	0.170	
Set	0.220	
(mmol/L/min)		

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.

	16:34	348 📑
<	Fall	
Fallr	ate alert	
Aler	when:	
¥	0.110	
₩	0.170	
Set	0.220	~
	(mmol/L/min	)

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.

= 19:29 承 =	16:34 🝽 💳	
Fall	< Fall 🗎	
	Fall rate alert	
••••	Alert when:	
0.220	0.110	
	0.170	
	Set 0.220 🗸	
Cancel Done	(mmol/L/min)	

3. Tap  $\blacksquare$  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.

-	19:34	}∎⊱ ]	-	16:35	}∢{ =
<	Repeat		<	Repeat	
High		$\bigcirc$	High		
Low		$\bigcirc$	Repeat		01:00
			Low		
			Repeat		00:20

*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

11:01	348 📑	
Sensor		
Calibratio	on >	
Disconnect Sensor		
Transmitter SN		
	11:01 Sensor Calibratic nect Sens hitter SN	

*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.

*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.

*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.



#### **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**.

-	15	:29 3	4٤
_			
Canc	el		Done
_	D	E	F
С	1	2	3
В	4	5	6
Α	7	8	9
$\Leftrightarrow$		)	⇔

#### 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.

-	5:49	} <b></b> ₹
Tra	ansmitter	SN
Connect Sensor. Searchir Transmi	t Transm ng for the tter	itter to
PI	ease wa	it

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**.

-	12:47	} <b></b> ₹
Transmitter SN		
1020028	392	
Cano	el	ОК

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



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.



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

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 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.





#### 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

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


*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.



*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.

-	19:38	}∎{	-
RE	SENSOF	R TED	
		19	9:38
Old ser New se connec	nsor disco ensor has sted.	nnect been	ed.
	ОК		

## 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

-	11:01 →	18 🚍
<	Sensor	
Sensor	Calibration	>
Discon	nect Sensor	>
Transn	nitter SN	>

*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



*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

-	16:35	3∎{
< (	CGM Syste	em
CGMS	System	
Transn	nitter SN	>
Graph	range	12:00
Cal Re	peat <mark>0</mark>	1:00 🚺
Alert Silence		
Sensor	r E×pired	14 days

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.

## 6.4 CGM System settings

Go to the CGM System screen.

Main N	/lenu•	→Settings	s→CGN	/I System
	-	16:35	}∎{	
	<	CGM Syst	em	
	CGM	System		$\geq$
	Trans	mitter SN	2	>
	Grap	h range	12:0	0
	Cal R	epeat 0	1:00 🗨	2
	Alert	Silence	2	
	Sens	or E $ imes$ pired	14 day	s

## 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.

-	16:35	3∎{
< c	GM Syste	em
CGM S	ystem	
Transmi	itter SN	>
Graph ra	ange	12:00
Cal Rep	oeat <mark>0</mark> ′	1:00 🚺
Alert Sil	ence	>
Sensor	Expired	14 days

## 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.

<b>-</b>	15:56	} <b>∢</b> {
<	Graph rang	ge
03:00		
06:00		
12:00		~
24:00		

### 6.4.4 Cal Repeat

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

### 6.4.5 Alert Silence

Go to the Alert Silence screen.

💶 15:56 斗∛ 🚍	■ 16:00 🔫 🚍
< Alert Silence	< Туре
Type Off	Off 🗸 🗸
	Low
	High
	High and Low
	All
Save	

*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.

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

-	16:06	}∎{	=
<	Sensor Hist	ory	
Data	History		>
Calib	ration Histor	у	>
Alert	History		>
Alert	History		)

### 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.

-	16:	07	3∎{	=
< [	)ata⊦	listo	ry	
28-08-2	2018	5/2	1/8	>

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.



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:

- 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-

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.

-	16:1	5 }¶≀	=
< Ca	libration	History	,
<	03-09-2	2018	>
7.3mn	nol/L	15:5	2
8.1mn	nol/L	14:2	4

### 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.



Select an alert record to view the details. Tap  $\checkmark$  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

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  $+5^{\circ}C \sim +40^{\circ}C$ .

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

RAPID FALL
 ALERT SILENCE
 SENSOR ERROR
 BELOW 3.1 mmol/L (56 mg/dL)
 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.

### 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.

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# 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.



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

### 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 exits. 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.

-	19:37	}∢₹ 📑
BAS	SAL RESU	JMED
		19:37
Check Basal a	BG. Stanc active.	lard
	ок	

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)

-	19:36	}∢{ 📑	
CAL	LEMERO	9 AID	
		19:36	
Alarm not responded. Basal resumed.			
	ок		

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

-	19:37	¥ =
BASA	LRESI	JMED
		19:37
Check B Basal ac	G. Stand tive.	dard
	ок	

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 exits. 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.

BASAL RESUMED
19:37
Check BG. Standard Basal active.
ок

# 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)



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	After insulin delivery automatically starts again, alert is
SUSPEND	switched to BASAL RESUMED.

## 8.1 Safety System

Your A7+ TouchCare<sup>®</sup> 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.





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

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.

Alarm sound wave:

lcon	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.

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

The following table lists high priority alarm messages.

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.

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	
PUMP OUT OF RANGE Low Suspend failed. Move PDM close to Pump. Pre Suspend failed. Move PDM close to Pump.		Low Suspend or Predictive Low Suspend failed because the PDM had lost communication with the Patch Pump.	Tap to clear it. Move PDM close to Pump.	
PUMP RESTARTED Patch changed? For help call the CC.		Pump restarted without Patch deactivation.	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.	

## 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.

<b>•• (</b>	2:17	٩×	=		1
Basal(U/H)					
0.00	BG				4
<b>(</b>					
	mmol/L				
10B(U) 0.00					
					1
Patch	n Battery	/ Low	1		1
					L
Alert	in Lock	Scre	een	A	le



Alert after unlock in Alert screen

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

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

CGM Alerts and PDM Alerts in different audio modes:

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.

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:

lcon	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.

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 threepulse 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.

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.

The following table lists alert messages for CGM.
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.

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.

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.



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



 If the Audio is off, the audio off icon "<sup>A</sup>" 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.



Message in Lock Screen Mess

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.

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### 9.1 Electromagnetic Emissions

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

## 9.2 Electromagnetic Immunity

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

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

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

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

Immunity Test	IEC 60601 Test	Compliance	Electromagnetic
	Level	Level	Environment
The A7+ TouchCa	are <sup>®</sup> System is inte	nded for use in the	electromagnetic
environment sp	ecified below. T	he customer or	user of the A7+
TouchCare <sup>®</sup> Sys	stem should assu	re that it is ι	used in such an
electromagnetic	environment.		
			Interference may
			occur in the
			vicinity of
			equipment
			marked with
			the following
			symbol:
			(((•)))

*Note:* UT means to the AC network voltage before the test voltage is applied.

*Note:* At 80 MHz and 800 MHz, 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.

*Note:* The table is per IEC (EN) 60601-1-2 Edition 3.

#### **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

is used exceeds the applicable RF compliance level above, the A7+ TouchCare<sup>®</sup> System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the A7+ TouchCare<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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. Recommended separation distances between portable and mobile RF communications equipment and the A7+ TouchCare<sup>®</sup> System

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

Rated maximum	Separation distance according to the frequency of transmitter (m)		
output	150 kHz~80 MHz	80 MHz~800 MHz	800 MHz~2.5 GHz
transmitter	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
(W)			
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<sup>®</sup> System.
- The A7+ TouchCare<sup>®</sup> 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.
- Portable RF Communications equipment should be used no closer than 30 cm (12 inches) to any part of the Medtrum products. Otherwise,

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.

## **10.1 Product Label Symbols**

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

# Appendix I: Symbols and Icons

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

#### 10.2 PDM Icons

lcon	Meaning	lcon	Meaning
	High priority alarm		Medium priority alarm
	Alert	$\bigotimes$	Audio off
À	Audio temporary off	00:00 a	Time
	Pump RF signal		Battery
•	Charging		Charged

#### **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 µL) 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 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) SterilizationMethod: 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<sup>™</sup> 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 ±20%, ±30% and ±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  $\pm 20\%$  /  $\pm 20$  mg/dL,  $\pm 30\%$  /  $\pm 30$  mg/dL and  $\pm 40\%$  /  $\pm 40$  mg/dL of the YSI.

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

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hour period.Basal RateThe amount of continuous basal insulin that is automatically delivered every hour.BGAbbreviation for blood glucose. See Blood Glucose.BG TargetThe 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 Meter/Meter/BG MeterA medical device used to measure the amount of glucose in the blood.Bolus CalculatorA feature that calculates an estimated bolus amount based on the BG values and carbs that you enter.Bolus DoseThe 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 ReminderA Reminder that a bolus was not delivered during time periods that you specified, often set around meal times.CAbbreviation for Combo Bolus. See Combo Bolus.Calc-CCombo Bolus by Bolus CalculatorCalc-NNormal Bolus by Bolus CalculatorCalc-NNormal Bolus by Bolus CalculatorC-EThe extended portion of a Combo Bolus.C-NThe normal portion of a Combo Bolus.C-NThe normal portion of a Combo Bolus.C-NPart of the bolus amount delivered immediately, and the remainder delivered evenly over time period.	Basal Pattern	A set of one or more basal rates that covers a 24-	
Basal RateThe amount of continuous basal insulin that is automatically delivered every hour.BGAbbreviation for blood glucose. See Blood Glucose.BGThe 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 Meter/Meter/BG MeterA medical device used to measure the amount of glucose in the blood.Bolus CalculatorA feature that calculates an estimated bolus amount based on the BG values and carbs that you enter.Bolus DoseThe 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 ReminderA Reminder that a bolus was not delivered during time periods that you specified, often set around meal times.CAbbreviation for Combo Bolus. See Combo Bolus.Calc-CCombo Bolus by Bolus CalculatorCalc-NNormal Bolus by Bolus CalculatorC-EThe extended portion of a Combo Bolus.CGMAbbreviation for Continuous Glucose Monitoring (CGM).C-NThe normal portion of a Combo Bolus.Combo BolusPart of the bolus amount delivered immediately, and the remainder delivered evenly over time period.		nour period.	
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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 Extended Bolus	Bolus amount delivered evenly over specified time period.
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 Insulin-to-Carb Ratio.
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 Insulin Sensitivity Factor (ISF).
ЮВ	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 Manual Bolus	Manually deliver a dose of insulin.
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.

# Glossary

Max Total Daily Dose (TDD)	Set the maximum insulin amount that can be delivered in one day.	
N	Abbreviation for Normal Bolus. See Normal Bolus.	
Normal Bolus	Entire bolus amount delivered immediately.	
Note	A <b>Note</b> 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 Insulin Sensitivity Factor (ISF).	
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 Sensor Glucose (SG).	
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.	

# Glossary



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