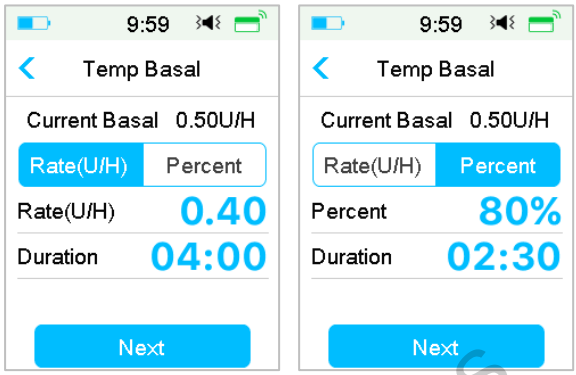
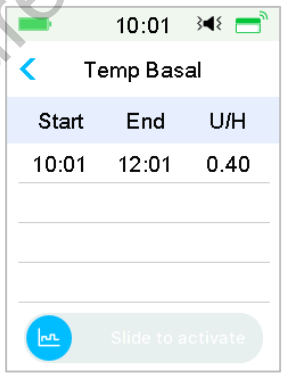
2. Select a temp basal type, temp rate or percent and duration, then Tap **Next** to review the temporary basal rates set.



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

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

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



5.5.2 Cancel a Temp Basal

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

Main Menu➔Basal➔Cancel Temp Basal

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

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

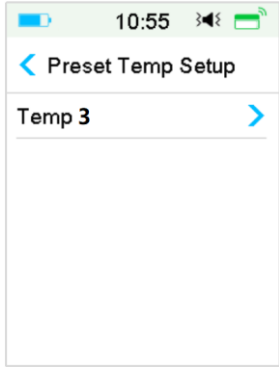
5.6 Preset Temp Basal

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

5.6.1 Preset Temp Basal Setup

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

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



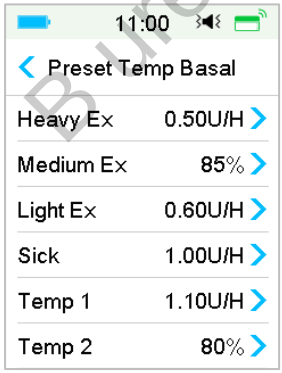
2. Select a preset temp basal you want to edit. Choose the temp basal type (rate or percent).
3. Set the duration and rate/percentage of the preset temp basal. Tap **Save** to save settings.

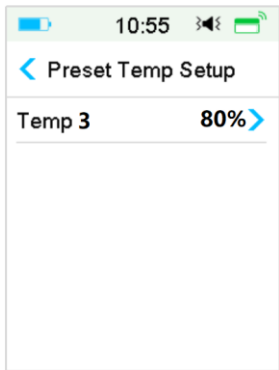
5.6.2 Activate a Preset Temp Basal

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**.

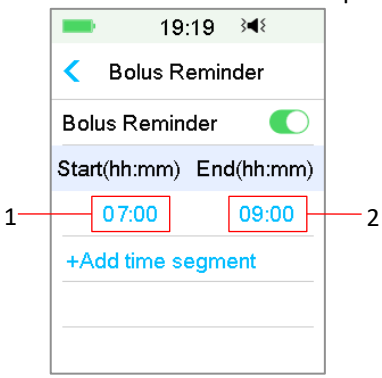
2. Select the preset temp basal you want to activate.

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.

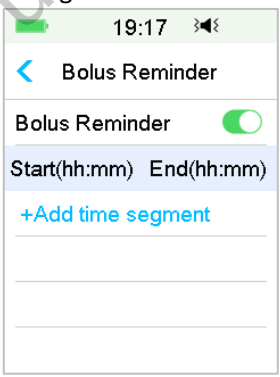


1. Time Point A
2. Time Point B

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

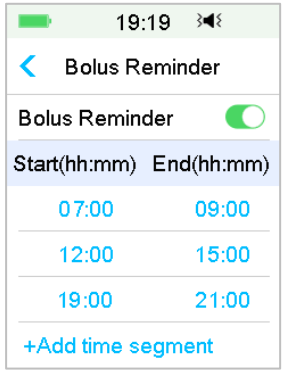
Go to the **Bolus Reminder** screen.

Main Menu➔Settings➔Reminders➔ Bolus Reminder



Add Reminder

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



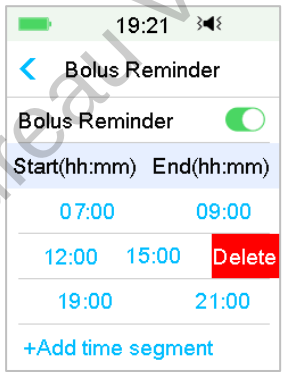
Note:

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

(2) The Reminders will be saved automatically.

Delete Reminder

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

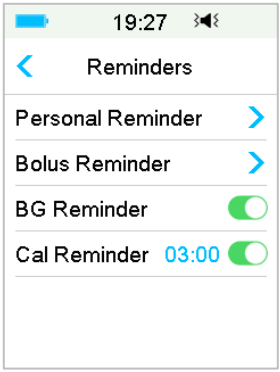


5.7.2 BG Reminder

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

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

Main Menu ➔Settings➔Reminders➔BG Reminder

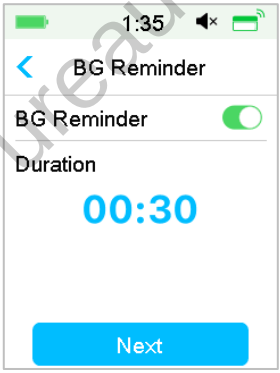


If you have BG Reminder turned on, the **BG REMINDER DURATION** screen appears when you set Bolus.

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

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

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



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

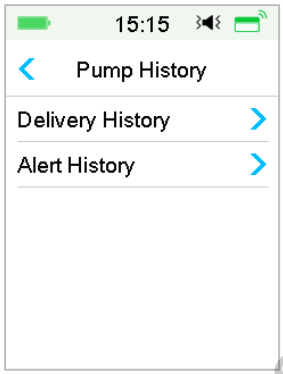
5.8 Pump History

5.8.1 Pump History

The **Pump History** displays the delivery history (bolus, basal and total daily

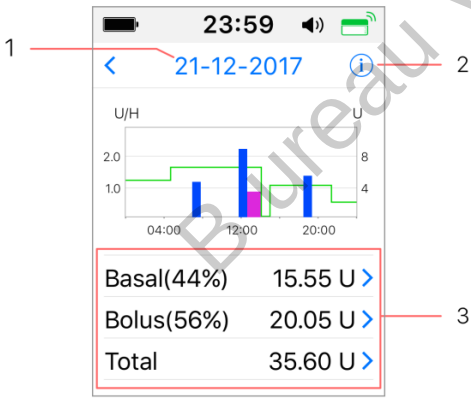
delivery history) and alert history (pump alerts and alarms).
Go to the **Pump History** screen.

Main Menu➔History➔Pump History



5.8.1.1 Delivery History

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

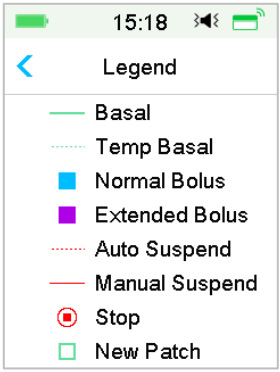


1. Tap the date to switch between records of different dates

2. Tap the info icon to review legend meanings.

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

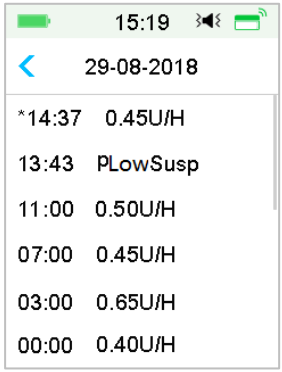
(1) The legend



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

(2) Basal History

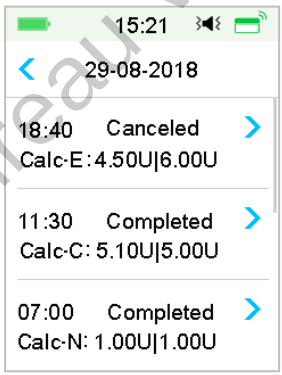
This screen displays most detailed Basal information.



(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:

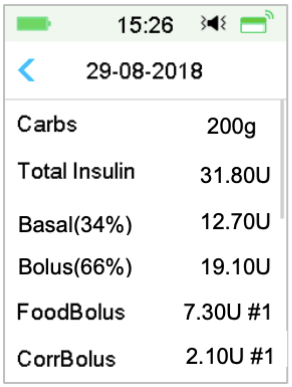
- ✧ N: Normal Bolus
- ✧ E: Extended Bolus
- ✧ C: Combo Bolus
- ✧ Normal: Normal Bolus by Manual Bolus
- ✧ Extended: Extended Bolus by Manual Bolus

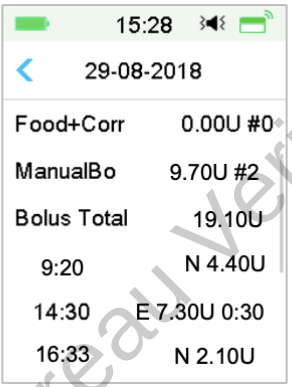
- ✧ Combo: Combo Bolus by Manual Bolus
- ✧ Calc-N: Normal Bolus by Bolus Calculator
- ✧ Calc-E: Extended Bolus by Bolus Calculator
- ✧ Calc-C: Combo Bolus by Bolus Calculator

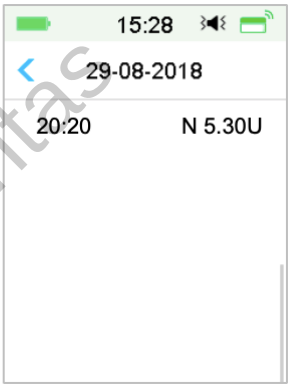
Tap record line to view more detailed information. *See Chapter "Advanced Pump Features" for more information.*

(4) Daily Totals

This screen displays most detailed Daily Totals information.





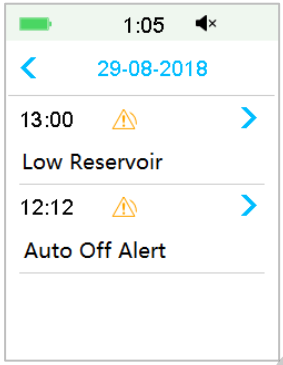


- ✧ **N** represents Normal Bolus.
- ✧ **E** represents Extended Bolus.
- ✧ **C** represents Combo Bolus.
- ✧ **FoodBolus 7.30U #1** means that there is one food bolus doses in the selected day with a total amount of 7.30U.
- ✧ **CorrBolus 2.10U #1** means that there is one correction bolus doses in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

5.8.1.2 Alert History

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

Main Menu➔History➔Pump History➔Alert History



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

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

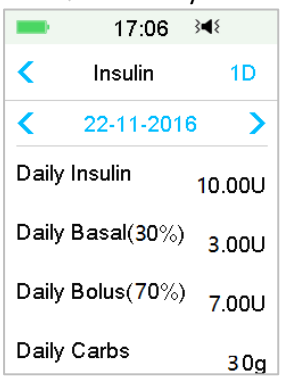
5.8.2 Pump Summary History

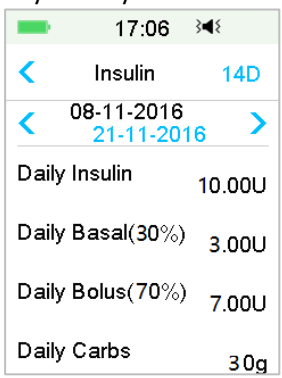
5.8.2.1 Summary History: Insulin History

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.

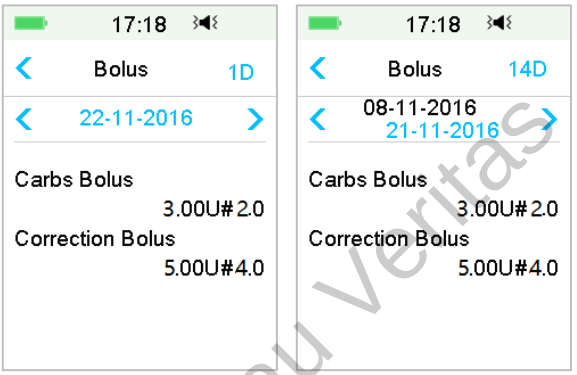
Daily Bolus: Average daily dose and percentage of insulin delivered as Bolus.

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°C ~ +40°C.

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

Can I dive with a Patch Pump on?

No.

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

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

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

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

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

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

If one of the following alerts happened, the PDM would beep/vibrate and display a message first, and if you missed that alert, later when you checked 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 How to use CGM system (Optional)

6.1 Glucose Alerts

Set your Low and High glucose alerts before using the sensor. See Section "Glucose Alerts" in Chapter "How to use (P)LGS" for more information.

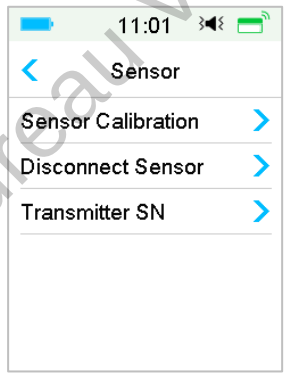
6.2 Change Sensor

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.

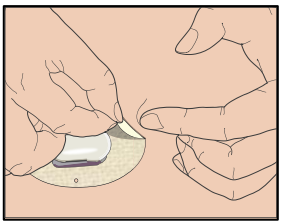
Main Menu➔Sensor➔Disconnect Sensor



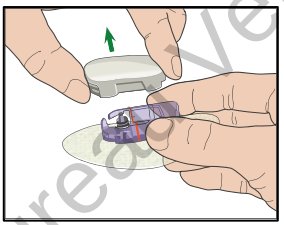
Note: The **Disconnect Sensor** option is only available when a Sensor is currently connected to the PDM.

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.

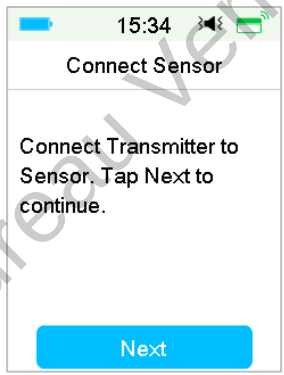
Note: We recommend that your Transmitter is only charged by an intended and qualified operator.

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

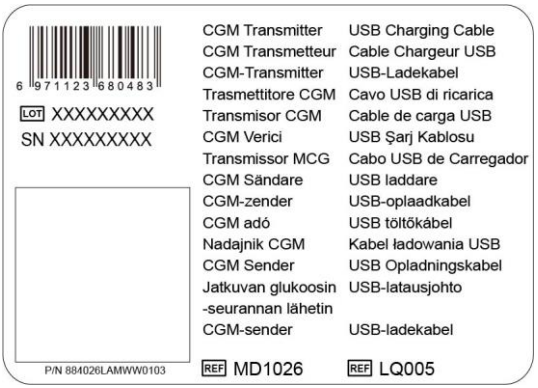
1. Tap **Connect Sensor** if you have set the Transmitter SN.

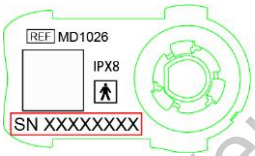


Note: Don't forget to update the SN if you change to a new Transmitter.

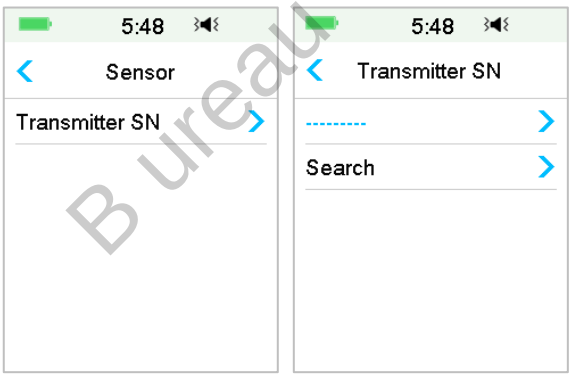
Note: You can only change the Transmitter SN when there is no Sensor connected.

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

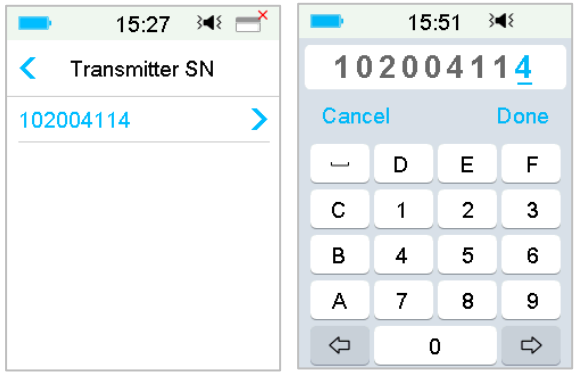




2. You can either enter SN manually or search for the SN if it is the first time you enter the SN.

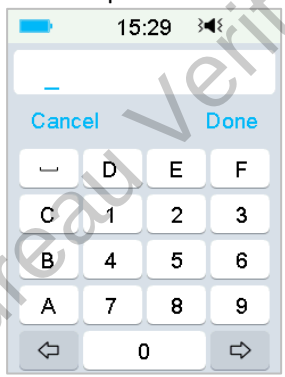


3. You can only enter SN manually if you want to update the SN.



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**.



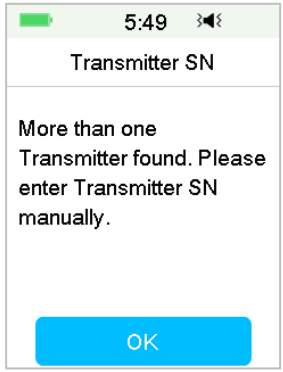
Search for the SN

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.

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

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



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

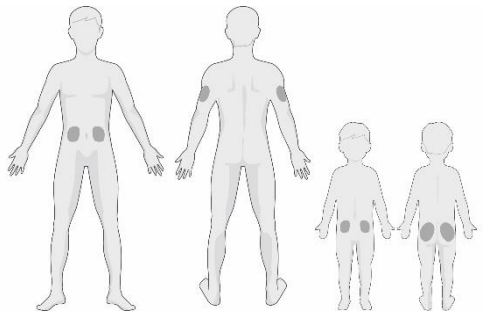
When choosing the location for the Sensor, consider the following:

- 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.



Front Back Front Back

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:

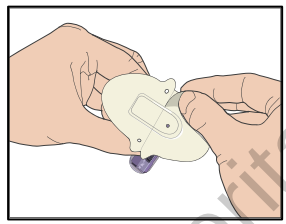
Warning: Do NOT use a Sensor if its sterile package has been damaged or opened, or the Sensor has expired, or the Sensor is damaged in any way.

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.

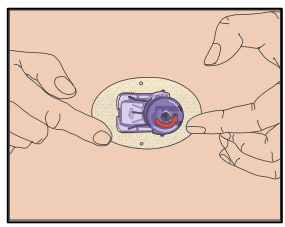


6.2.5.5 Locate the Sensor Support Mount

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

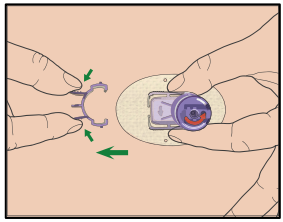
If you are inserting the Sensor on your upper arm or thigh, place the Sensor vertically on your skin.

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



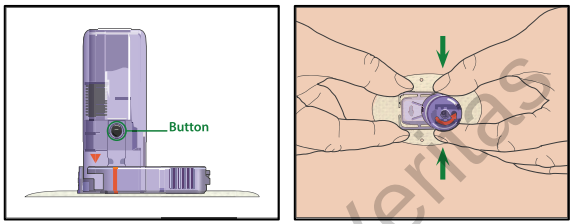
6.2.5.6 Remove the Safety Lock

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.



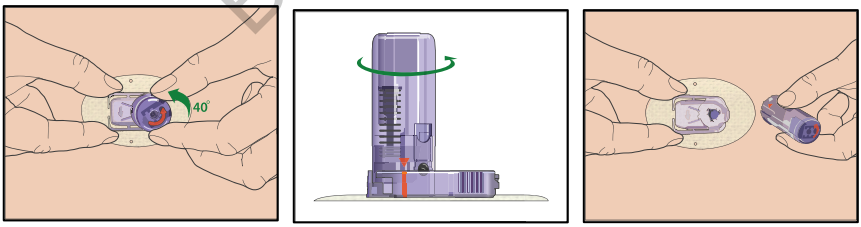
6.2.5.7 Insert the Sensor

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

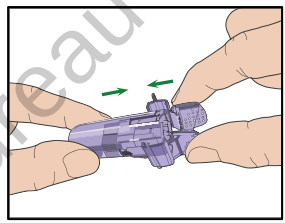
Confirm that the Sensor support mount remains tightly adhered to your skin by sliding your finger along the edges of the adhesive pad and examine for any gaps in adhesion.

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

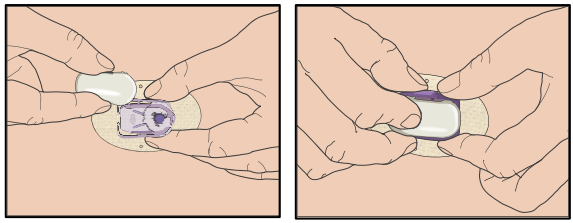
Note: If you are changing Sensor, make sure that your Transmitter was disconnected from the old Sensor at least one minute before being connected to the new Sensor.

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

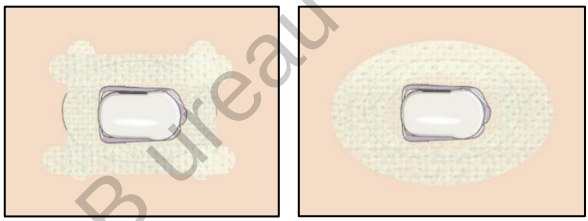
successful connection, three times after properly connected and another six times after successful system check.

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)

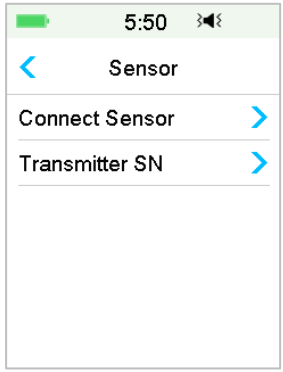
The Sensor support mount should stay on your skin using its own adhesive. But, if you find that the Sensor support mount is not adhering well during daily activities, you can use medical tape for extra support. Only tape over the white adhesive pad on all sides for even support. Do NOT tape over the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



6.2.7 Connect Sensor to Your PDM

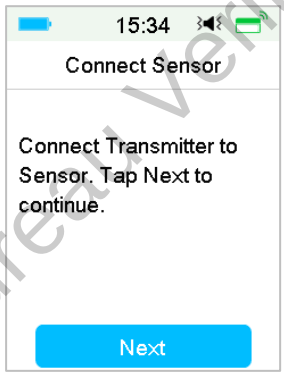
1. Go to **Connect Sensor** screen.

   Main Menu➔Sensor➔Connect Sensor



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

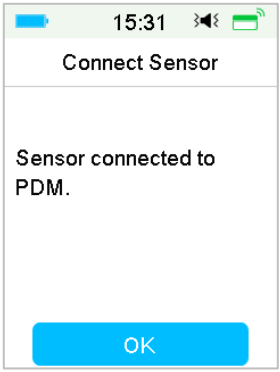
2. Make sure that your Transmitter is connected to a Sensor and that your Transmitter SN is found or entered, and then continue by tapping Next.



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.

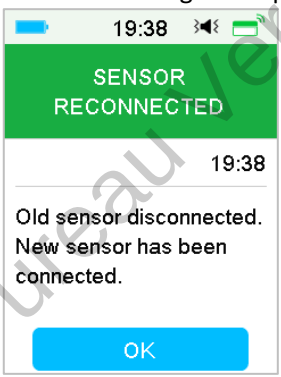
   Or, skip the sensor code input step and go to Connection screen. The sensor need to be calibrated twice (once every 12 hours) on the first day and then once every 24 hours since the second day.

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.

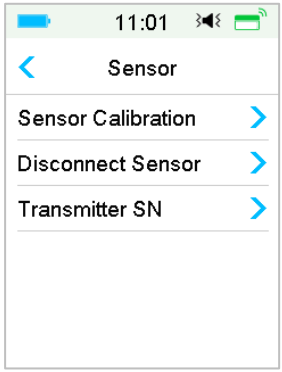


6.3 Calibrate Your Sensor

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



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:

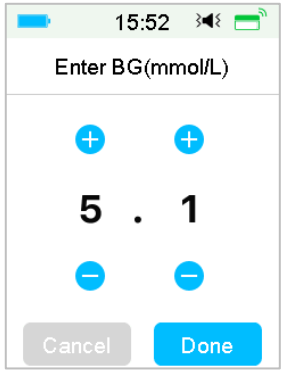
- Sensor disconnected from the PDM
- Sensor warm-up
- Within 15 min after the alert SENSOR CAL ERROR
- Poor RF communication between the Transmitter and the PDM
- No Readings

6.3.1 Enter Your Meter BG

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

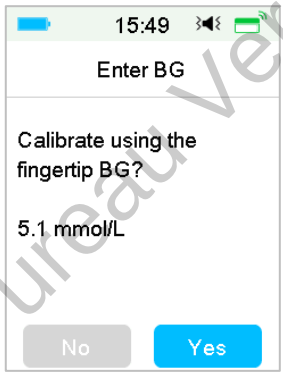
1. Go to the **Enter BG** screen.

Main Menu➔Sensor➔Sensor Calibration

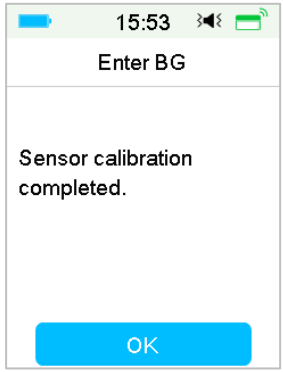


Note: Please enter the exact blood glucose value of a carefully performed fingerstick displayed on your blood glucose meter within five minutes.

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



3. When finished, the following screen appears.



6.3.2 Set Calibration Repeat

Go to the **Cal Repeat** screen.

Main Menu➔Settings➔CGM System➔Cal Repeat

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

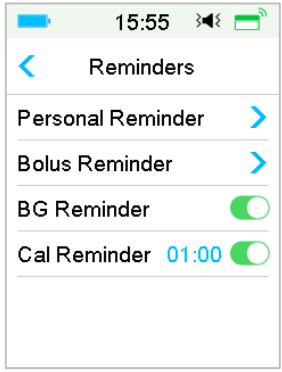
You can turn **Cal Repeat** on/off. If **Cal Repeat** is on, you can set the repeat time of “METER BG NOW” alert from 5 min to 1h with an increment of 5 min.

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.

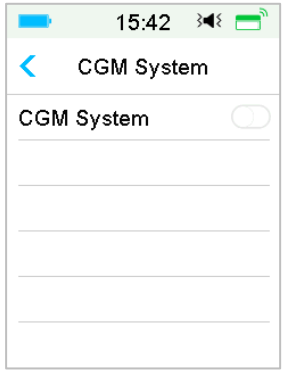
Main Menu➔Settings➔CGM System

6.4.1 CGM Feature on/off

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

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

Main Menu➔Settings➔CGM System



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

6.4.2 Set the Transmitter SN

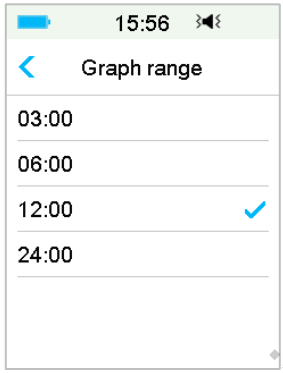
Tap **Settings** on the Main Menu to enter the **Settings** screen. Tap **CGM System** to enter the CGM settings screen. Turn the CGM System feature on.

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

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

6.4.3 Graph Range

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



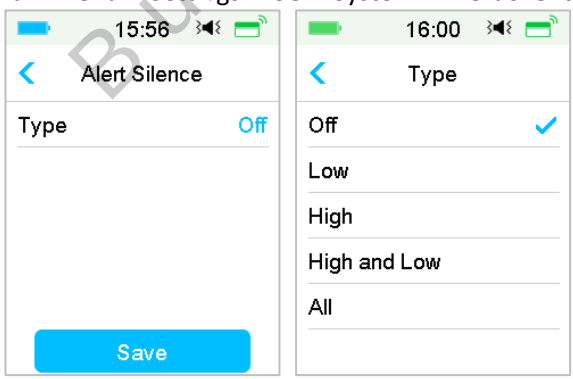
6.4.4 Cal Repeat

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

6.4.5 Alert Silence

Go to the **Alert Silence** screen.

Main Menu➔Settings➔CGM System➔Alert Silence



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

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

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

There are five Alert Silence options:

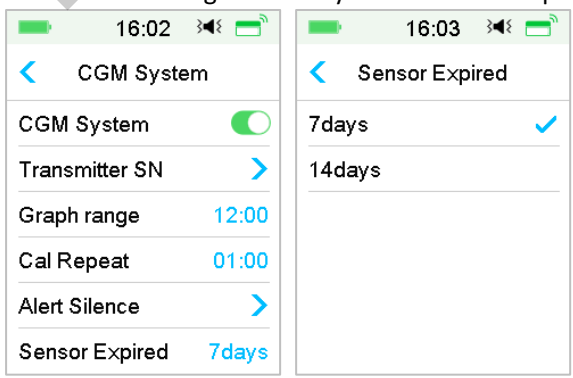
- **Off**— This means all glucose alerts are turned on: the PDM will beep or vibrate if any Sensor alert occurs.
- **Low** — The PDM will not beep or vibrate if a low alert (LOW GLUCOSE, RAPID FALL or LOW PREDICTED) occurs during the specified time.
- **High** — The PDM will not beep or vibrate if a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

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.

In both settings, “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.

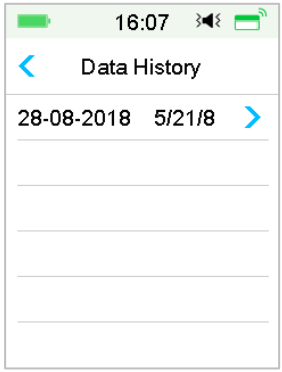
Go to the **Sensor History** screen.

Main Menu➔History➔Sensor History

6.5.1.1 Data History

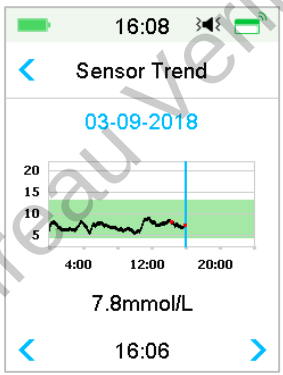
1. Select **Data History** in the **Sensor History** screen.

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



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

The Y-axis of the Sensor graph is featured by four values: 5, 10, 15, 20 mmol/L (90, 180, 270, 360 mg/dL). The X-axis of the Sensor graph presents a period of 24 hours.



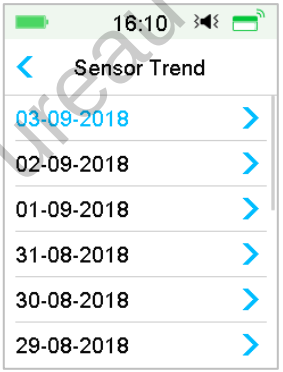
The Sensor graph can be switched to a landscape screen display. Long tap the Sensor graph for 1 second and the display will turn horizontal.

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.
- 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".

- 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).
- After the warm-up phase, the values before the first calibration are marked as “BG“.
- When the Sensor calibration expires, the reading values will be underlined.
- Calibration will be marked with a red dot “•”.
- In the landscape screen display, tap the Home Key to return to the Home Screen.
- 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.

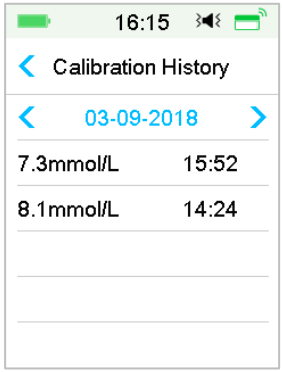
3. Tap the date and you will see a list of dates within that session.



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

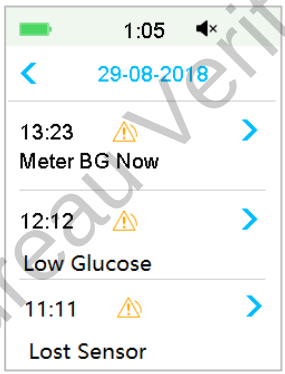
6.5.1.2 Calibration History

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



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 < to return to the previous menu.

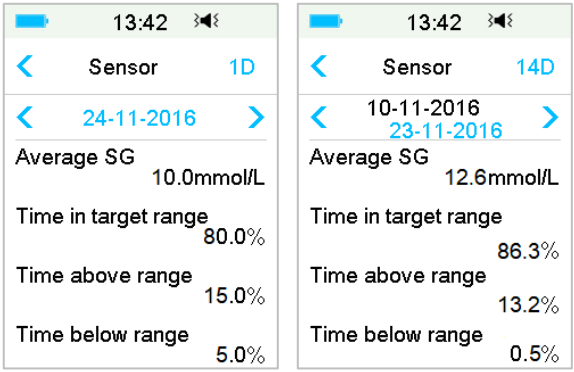
See Section "Alert Icons" and Chapter "Safety System and Alarms/Alerts" for more information about how to address the alarms and alerts.

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°C ~ +40°C.

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

Can I dive with a Sensor on?

No.

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

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

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

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

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

1. LOW GLUCOSE
2. HIGH GLUCOSE
3. LOW PREDICTED
4. HIGH PREDICTED
5. RAPID RISE
6. RAPID FALL
7. ALERT SILENCE
8. SENSOR ERROR
9. BELOW 3.1 mmol/L (56 mg/dL)
10. LOST SENSOR

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

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

Charging the Transmitter

We recommend that you charge the Transmitter after each Sensor session, or make sure that at least 1 minute 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.

7 How to use (P)LGS (Optional)

7.1 (P)LGS settings

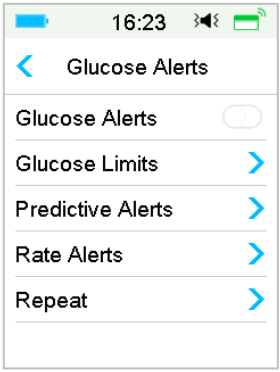
The **Glucose Alerts** and **Low Glucose Suspend/Predictive Low Glucose Suspend** (**Low Suspend/ Pre Low Suspend**) functions are included under the **EasyLoop** Menu. The (Pre) Low Suspend function is available when CGM and Insulin Pump systems are both online. The glucose limits for alerts of Low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

Tap **EasyLoop** on the Home Menu Screen to enter the **EasyLoop** screen.

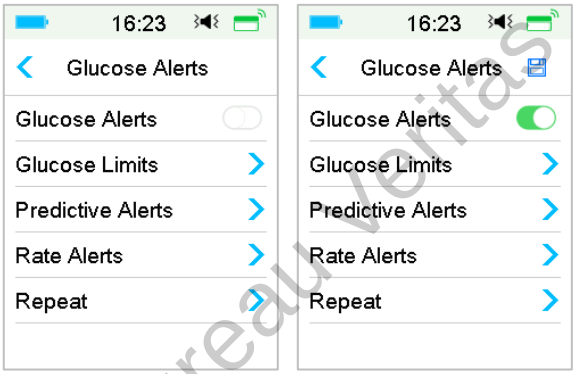
7.1.1 Glucose Alerts

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

Main Menu➔EasyLoop➔Glucose Alerts



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



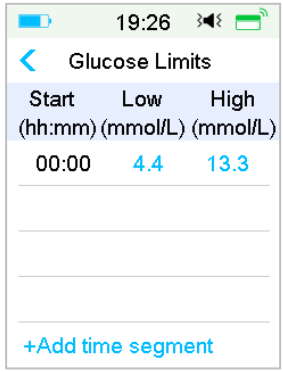
2. Tap to save the settings.

7.1.1.1 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



1. Add segments

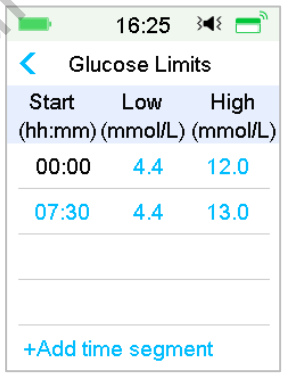
The starting time of the first segment is fixed to be 00:00 or 12:00A.

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.



Note:

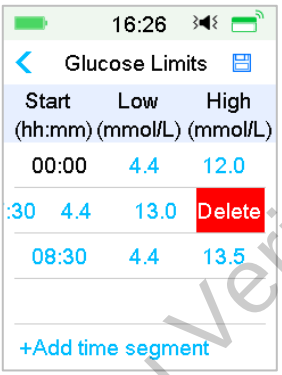
- In the time segments, only the segment starting from 0:00 cannot be deleted. You can always edit the input in each segment. The Low Limit

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.

- In the first segment, the default Low Limit is 4.4mmol/L, the default High Limit is 13.3mmol/L.

2. Delete Segments

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



3. Tap to save the settings.

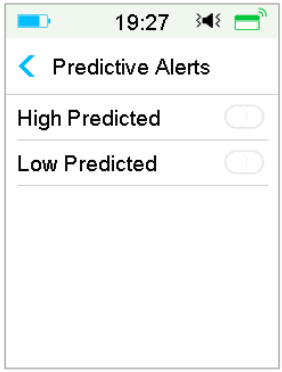
7.1.1.2 Predictive Alerts

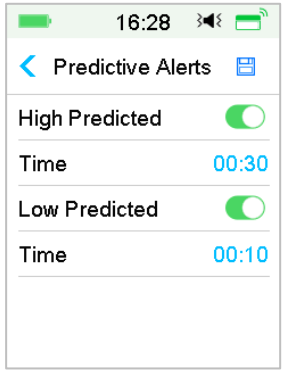
The predictive alerts calculate when you are going to reach your Low or High Glucose Limits, and then send you an alert before you reach those limits. A predictive alert informs you that if your Sensor glucose keeps falling or rising at the current rate, you will reach your Glucose Limit in the number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

Go to the **Predictive Alerts** screen.

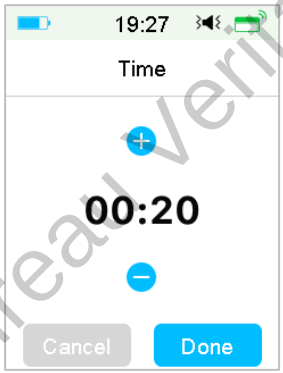
Main menu➔EasyLoop➔Glucose Alerts ➔Predictive Alerts

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





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



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

3. Tap to save the settings.

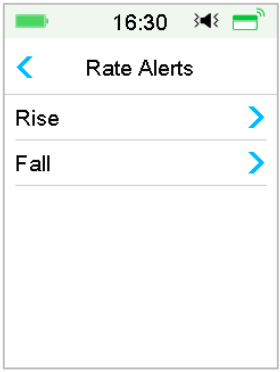
7.1.1.3 Rate Alerts

There are two types of rate alerts:

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

Go to the **Rate Alerts** screen.

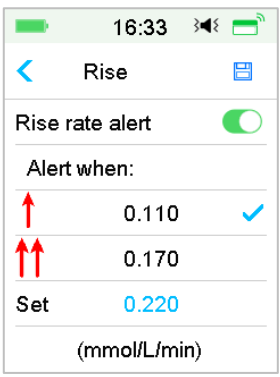
Main menu➔EasyLoop➔Glucose Alerts ➔Rate Alerts



Go to the **Rise** screen.

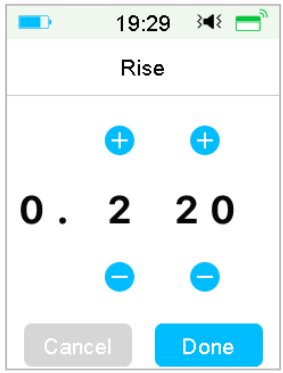
1. You can tap to turn on/off the Rise Alerts.

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



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).

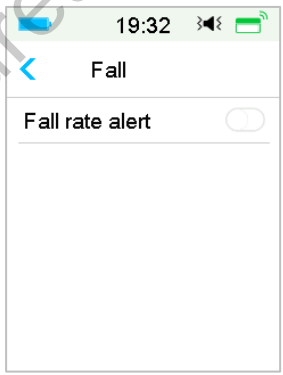
Tap the blue plus/minus sign to set the rise alert. You will be reminded when your SG is rising rapidly.



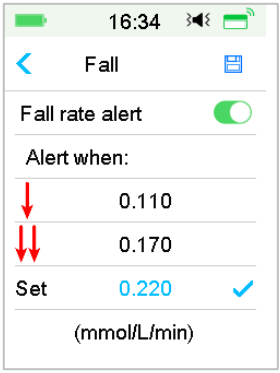
4. Tap to save the settings.

Go to the **Fall** screen.

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

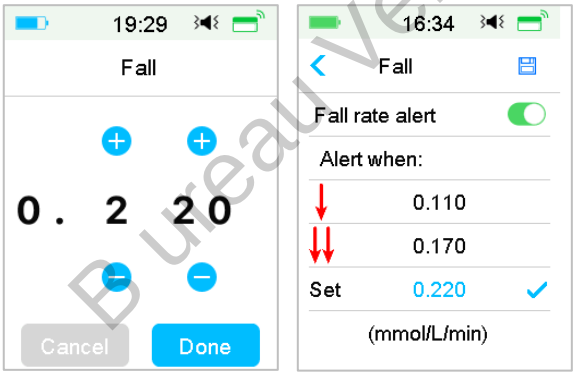


2. You can choose a relative mild or an acute falling rate. *See Section "Sensor Status" for more information.*



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

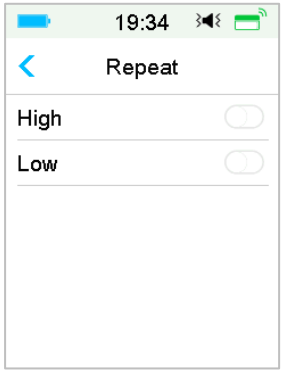
Tap the blue rate value to set the fall alert time. You will be reminded when your SG is falling rapidly.

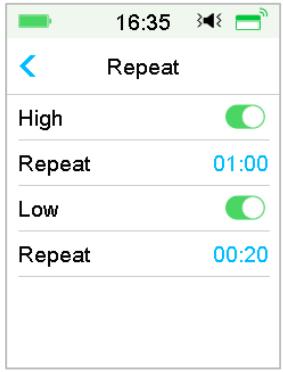


3. Tap to save the settings.

7.1.1.4 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.





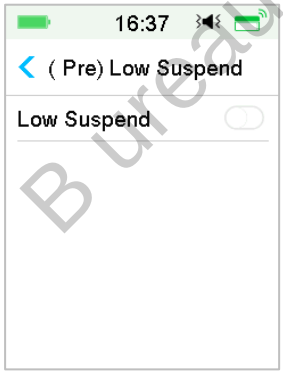
Note: You can turn on or off alert.

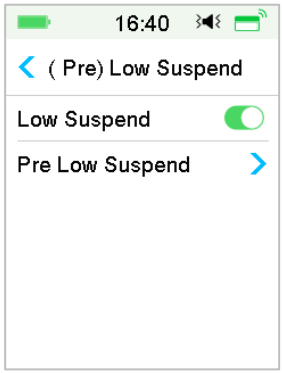
Note: You can set the **Repeat** time between 5 min and 3h with an increment of 5 min.

7.1.2 (Pre) Low Suspend

Go to the **Low Suspend** screen.

Main menu➔EasyLoop➔(Pre) Low Suspend





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

7.1.2.1 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" 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.

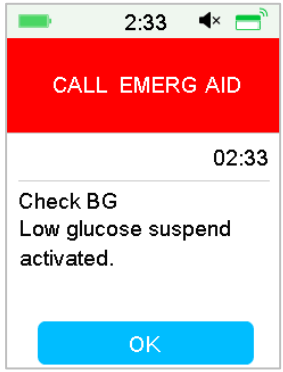
Triggering Conditions for Automatic Resumption of Basal (from 30 min to 2 h after suspension)

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

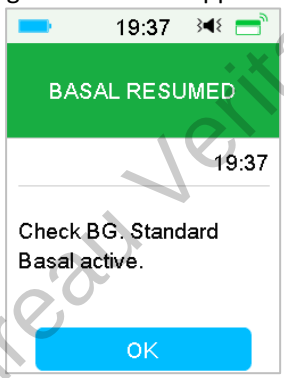
- The Sensor glucose value is at least 0.8 mmol/L (15 mg/dL) higher than the low suspend limit.
- The Sensor glucose value is predicted to be at least 1.7 mmol/L (30 mg/dL) higher than the low suspend limit in half an hour.

Alarm Response

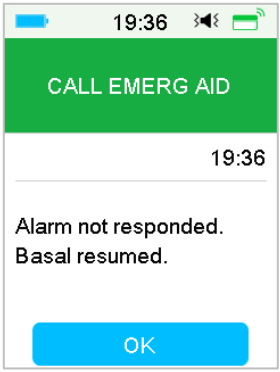
If the Low Suspend alarm is not cleared within 10 minutes, a siren will sound with the following Reminder.



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



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



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

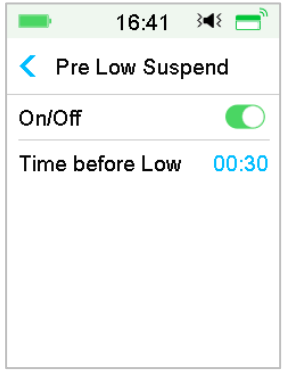
For information on when the Low Suspend feature is unavailable, refer to "Predictive Low Suspend".

7.1.2.2 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

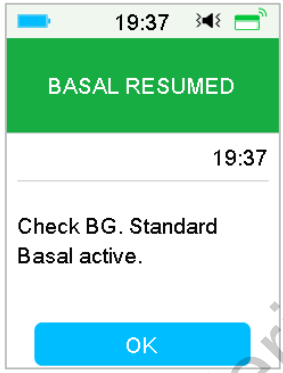
Both of the following two conditions must be met for the system to resume basal insulin automatically.

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

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

Reminder of Resumption

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



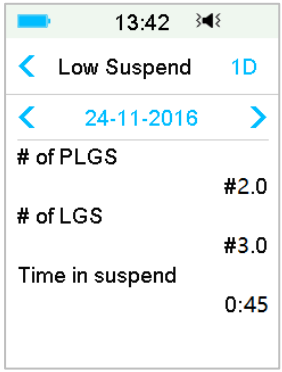
When the Low Suspend Feature and Predictive Low Suspend feature are Unavailable

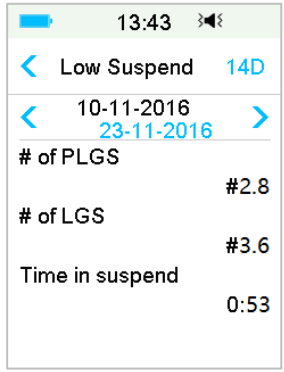
After insulin delivery is resumed from Low Suspend or Predictive Low Suspend, the Low Suspend feature and Predictive Low Suspend feature will be unavailable for 30 minutes.

7.2 Summary History: Low Suspend History

Go to **Low Suspend History** screen.

Main Menu➔History➔Summary History➔Low Suspend History





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

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

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

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

7.3 Troubleshooting Low Suspend issues

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

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

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

8 Safety System and Alarms/Alerts

8.1 Safety System

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

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

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

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

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

8.2 Safety Checks

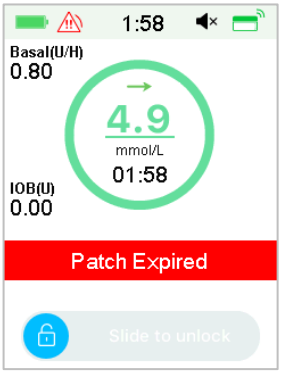
A single fault condition will cause the pump to suspend insulin delivery. Maximum infusion with a single fault condition is 0.05U.

8.3 Alarms

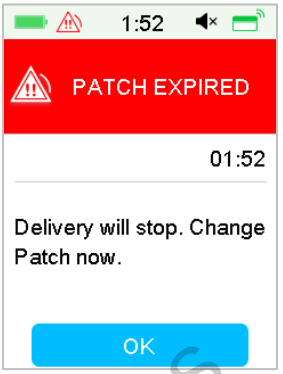
Alarms are triggered by serious or potentially serious conditions. You must respond to the alarm by taking appropriate action in order to clear the alarm condition.

For example:

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



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:

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

8.3.1 PDM Alarms

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

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

8.3.2 Pump Alarms

When a Pump alarm occurs:

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

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

The following table lists high priority alarm messages.

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

The following table lists medium priority alarm messages.

PDM Message	Priority	Reason	Actions to Take
AUTO OFF Delivery suspended. No status received.		The PDM has not received a pump status during the time limit set.	Tap to clear it. Resume basal delivery. Check blood glucose and treat it as necessary. Check Pump history.

PDM Message	Priority	Reason	Actions to Take
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.
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.

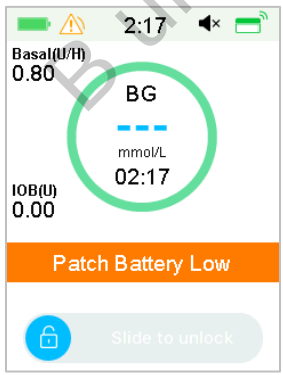
If the following alarm is not cleared within 10 minutes, only your PDM will make a siren sound until the alarm is cleared.

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.

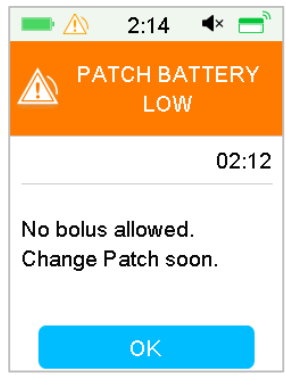
8.4 Alerts

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.



Alert in Lock Screen



Alert after unlock in Alert screen

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

CGM Alerts and PDM Alerts in different audio modes:

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

Patch Pump Alerts in different audio modes:

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

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

The sound wave of every alert beep:

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

8.4.1 PDM Alerts

The following table lists alert messages for PDM.

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

8.4.2 Pump Alerts

When a Pump alert occurs:

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

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.

PDM Message	Priority	Reason	Actions to Take
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.

The response mode of the following alert is same as PDM alert.

PDM Message	Priority	Reason	Actions to Take
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.

8.4.3 CGM Alerts

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

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

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

The following table lists alert messages for CGM.

PDM Message	Priority	Reason	Actions to Take
TRANSMITTER BATTERY LOW Charge Transmitter soon.		The Transmitter battery is close to running out of power.	Tap to clear it. Charge Transmitter soon.
CHARGE TRANSMITTER Charge Transmitter now.		The Transmitter battery is depleted. (MD1026)	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.
SENSOR FAILURE Sensor session ended. Change Sensor.		The Sensor is not functioning properly.	Tap to clear it. Change Sensor.

PDM Message	Priority	Reason	Actions to Take
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.

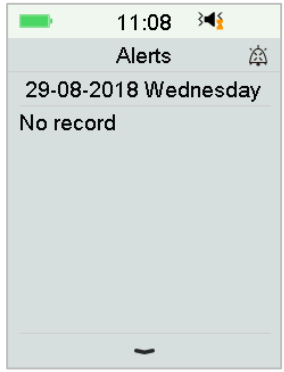
If Alert Silence is turned on, the PDM gives no beep or vibration when an alert occurs. The ALERT SILENCE message will be displayed on your PDM screen instead, and you can check the alert in Sensor alert history. *See Chapter "How to use CGM system" for more information.*

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:

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"🔕"will appear in the top right corner of this screen.

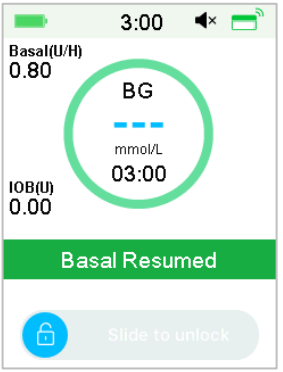


If the Audio is off, the audio off icon” ”will appear in the top right corner of this screen.

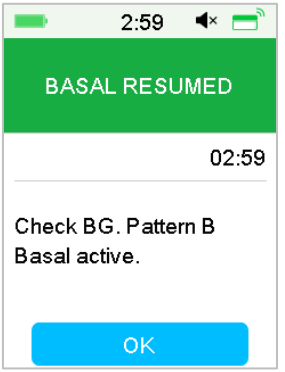
8.5 Reminding messages

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

For example:
When Message “BASAL RESUMED” occurs, the Lock Screen and Message screen display the following screen.



Message in Lock Screen



Message after unlock in Alert screen

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

8.5.1 PDM reminding messages

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

8.5.2 Pump reminding messages

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

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

8.5.3 CGM reminding messages

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

9 Manufacturer's Declaration

9.1 Electromagnetic Emissions

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

9.2 Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.			
IEC 61000-4-4:2012	for AC power port	operate as intended	commercial or hospital environment.
Surge IEC 61000-4-5:2005	±0.5kV, ±1kV (different mode) ±0.5kV, ±1kV, ±2kV (common mode)	During the test, the EUT can operate as intended	The network power supply should have the quality used in a typical commercial or hospital environment.
GB/T 17626.11 Votage dips and interruptions to AC Power Port IEC 61000-4-11:2014	0%UT；0.5T (0°， 45°，90°， 135°，180°，225°， 270° and 315°) 0%UT；1T(0°) 70%UT；20T(0°)； 0%UT；250T(0°)	0.5T(10ms); 1T (20ms); 25T(500ms) ; 250T(5s)	The network power supply should have the quality used in a typical commercial or hospital environment. If the A7+ user needs continuous operation during a power outage, it is recommended that the A7+ be powered by an uninterruptible power supply or battery.
Power Frequency	Table 4 of IEC 60601-1-2:2014 30A/m,	30A/m	Suitable for most environments, if there is no industrial magnetic

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.			
magnetic fields IEC 61000-4-8	50HZ and 60HZ		equipment nearby, the magnetic field strength will not exceed 400A/m
Proximity fields from RF wireless communication equipment IEC 61000-4-3:2006+A1+A2	Table 9 of IEC 60601-1-2:2014	During the test, the EUT can operate as intended	Recommended separation distance d = [12/E1] P 80 MHz to 800 MHz d = [23/E1] P 800 MHz to 6 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is there commended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance
RF electromagnetic field immunity test IEC 61000-4-3:2006+A1+A2	IEC 61000-4-3:2006+A1+A2 10V/m (for home healthcare environment and professional healthcare facility environment) 80 MHz~2.7 GHz	10V/m (for home healthcare environment) 3V/m (for professional healthcare facility environment) 80 MHz~2.7 GHz	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
The A7+ TouchCare® System is intended for use in the electromagnetic environment specified below. The customer or user of the A7+ TouchCare® System should assure that it is used in such an electromagnetic environment.			
			level in each frequency range. 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®

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

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

Electrostatic discharge

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

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

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

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® System			
The A7+ TouchCare® System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the A7+ TouchCare® System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the A7+ TouchCare® System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz~80 MHz $d = 1.2\sqrt{P}$	80 MHz~800 MHz $d = 1.2\sqrt{P}$	800 MHz~2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. ***Note:*** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. ***Note:*** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Warning:

1. EMC (Electromagnetic Compatibility) information in this guide should be referred before installing and using the A7+ TouchCare® System.

2. The A7+ TouchCare® System is not designed to be used in an environment with high voltage, high-intensity magnetic field, where the intensity of EM DISTURBANCES is high.

3. Portable RF Communications equipment should be used no closer than 30 cm (12 inches) to any part of the Medtrum products. Otherwise, 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 Appendix I: Symbols and Icons

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
	Use by: (yyyy-mm-dd)		Follow instructions for use
	Caution: See Instructions for use		Radio communication
	Storage temperature	IPX8	Waterproof to 2.5 m for 1 hour
	Do NOT reuse	SN	Device serial number
CE 0197	CE mark by notified body		Type BF equipment (Protection from electrical shock)
	Waste Electrical and Electronic Equipment	EC REP	Authorized representative in the European Community

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

10.2 PDM Icons

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

11 Appendix II: Technical Information

11.1 PDM Specifications

Model: FM-018
Size: 76.2 x 48.4 x 9.375mm
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: 5.0VDC, 1.0A
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

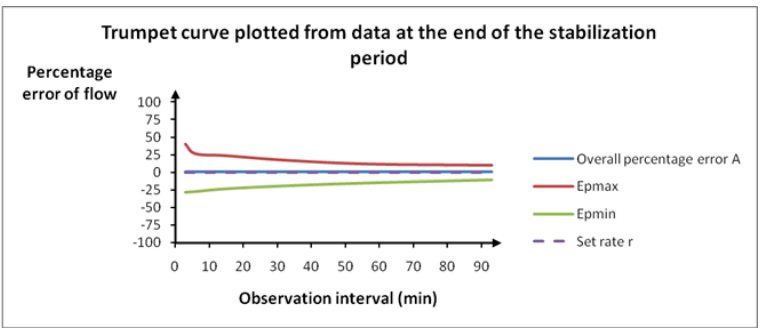
Model:
- **Pump Base**: JN-022
- **Reservoir Patch**: MD-JN-011

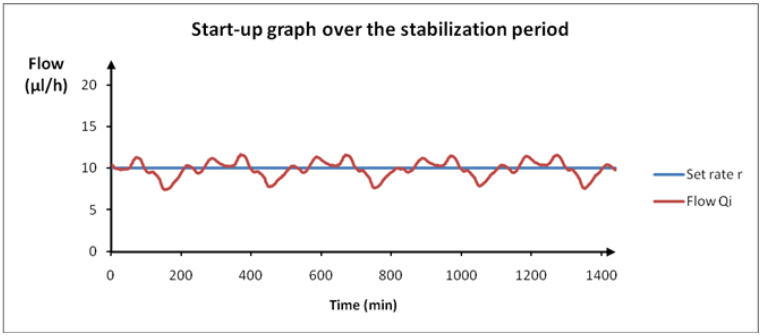
Size: 56.5mm x 33.3mm x 13.3 mm
Weight: 21.5 g (without insulin)
Operating Temperature Range: +5 °C ~ +40 °C
Operating Relative Humidity Range: 20%~90%RH
Operating Atmospheric Pressure: 700~1060 hPa

Storage Temperature Range: -10°C ~ +55°C
Storage Relative Humidity Range: 20%~90%RH
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: 2.2~22.2mmol/L (40~400mg/dL)
SterilizationMethod: By radiation
Sensor Life: Up to 14 days

11.5 CGM System Accuracy

A multi-center, randomized clinic study is designed to determine the Sensor accuracy in adults with Type 1 or Type 2 diabetes. In-clinic testing consisted of frequent venous blood sample testing (by Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer, YSI) on a random day in the Sensor life. The accuracy is based on the percentage of CGM glucose readings that are within ± 20%, 30% or 40% of YSI values at glucose values at or above (>=) 100 mg/dL (5.6

mmol/L), or within ±20 mg/dL (1.1 mmol/l), 30 mg/dL (1.7 mmol/L) or 40 mg/dL (2.2 mmol/L) of YSI values at glucose values below (<) 100 mg/dL (5.6 mmol/L).

Table. Percentage of CGM Glucose Readings within ±20%/20 mg/dL , ±30%/30 mg/dL, or ±40%/40 mg/dL of the YSI; Calibrating every 12 hours, Abdomen insertion site.

Number of Matched Pairs CGM-YSI	±20%/20 mg/dL	±30%/30 mg/dL	±40%/40 mg/dL
1678	91%	97%	99%

12 Glossary

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

Combo Bolus	Part of the bolus amount delivered immediately, and the remainder delivered evenly over time period.
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 *Extended Bolus.*
EasyLoop	Safety functions including Glucose Alerts, Low Suspend and Predictive Low Suspend.
Extended	Bolus amount delivered evenly over specified time period.
Extended Bolus	
Food Bolus	Bolus used to cover an expected rise in glucose levels from carbohydrates.
Food+Corr	Means that a bolus that both covers carbs and corrects glucose.
High Limit	The value you set to determine when the system will alert you of a high Sensor glucose condition.
IC Ratio	Abbreviation for Insulin-to-Carb Ratio. See *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)*.
IOB	Bolus insulin delivered by the Pump that is still working to lower your blood glucose levels.
IOB Time	A Bolus Calculator setting that lets you set the length of time that bolus insulin is tracked as IOB.
Low Limit	The value you set to determine when the system will alert you of a low Sensor glucose condition.
Manual-Bo	Manually deliver a dose of insulin.
Manual Bolus	

Max 1h Delivery	Set the maximum insulin amount that can be delivered in one hour.
Max Bolus	Set the maximum bolus amount that can be delivered in one dose.
Max Total Daily Dose (TDD)	Set the maximum insulin amount that can be delivered in one day.
N	Abbreviation for Normal Bolus. See *Normal Bolus.*
Normal Bolus	Entire bolus amount delivered immediately.
Note	A **Note** provides helpful information.
Occlusion	A blockage or interruption in insulin delivery.
Preset Bolus	You can set up and save a bolus for specific meals or snacks that you frequently eat or drink.
Preset Temp Basal	You can set up and save temporary basal rates for repeated use.
Sensitivity	See *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.

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