# MEDTRUM

# A6 TOUCHCARE SYSTEM

User Guide

# A6 TouchCare®

## *Insulin Management System*

User Guide

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

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This product complies with Directive 93/42/EEC (MDD) and Directive 1995/5/EC (R&TTE).

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# Contents

# Introduction

## Before You Begin

Check with your healthcare provider regarding your individual training needs. Do NOT attempt to use the A6 TouchCare® System before you have been properly trained.

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

The A6 TouchCare® Pump is designed to use U-100 insulin. The following insulin analogs have been tested and found to be safe for use with the A6 TouchCare® Pump: Humalog®, NovoLog®, and Apidra®. Before using different insulin with this Pump, check the insulin label to make sure it can be used with your Pump. Use of any insulin with lesser or greater concentration can result in serious injury or death. Your Pump is not intended to deliver any other substance.

The A6 TouchCare® Continuous Glucose Monitoring (CGM) System incorporates a Glucose Sensor and a Transmitter. The Glucose Sensor measures the glucose level of interstitial fluid. The Transmitter wirelessly transmits your real-time sensor glucose information to your Personal Diabetes Manager (PDM).

Not all devices or accessories are available in all countries where the A6 TouchCare® System is approved. To order supplies, contact your local representatives.

## Indications

The A6 TouchCare® System is indicated for use in people (ages 2 and older) with diabetes. The system is intended for single patient use and should be used under the guidance of a healthcare provider.

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

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

## Contraindications

The A6 TouchCare® System is not recommended for people who are unwilling or unable to:

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

# User Safety

## Warnings and Precautions

### General

Make sure that you have read and are familiar with the *User Guide* before using the A6 TouchCare® System. Failure to follow the instructions may result in pain or injury and may also affect the system's performance. If you do not understand something or have questions, ask your healthcare provider, call customer support, or contact your local Medtrum distributor.

The A6 TouchCare® System has many different settings and features. It is best to talk with your healthcare provider to determine which settings and features are right for you. Some features require great knowledge of insulin pumping and advanced self-care skills. Do NOT use the A6 TouchCare® System until you have specific information for your treatment plan and have had specific training on each feature from your healthcare provider or local Medtrum distributor.

No modification of this system is allowed.

Do NOT use the A6 TouchCare® System if you have delicate skin or if you are allergic to acrylic adhesives.

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

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

Do NOT operate your A6 TouchCare® System in the presence of flammable anesthetics or explosive gases.

The A6 TouchCare® System includes active medical devices. When you dispose of any device in the A6 TouchCare® System, follow the local waste disposal regulations.

We recommend that you have someone around you (family, friends, etc.) who understands diabetes and the A6 TouchCare® System, so that in case of an emergency, they can help you. Make sure they are familiar with any information given by your healthcare provider.

## Patch Pump

In case the A6 TouchCare® System is unable to properly deliver insulin you must be prepared to give yourself an injection of insulin. Knowing how to do this will help to avoid the risk of diabetic ketoacidosis (DKA) or very high blood glucose (BG).

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

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

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

## CGM System

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

the old Sensor and insert a new one.

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

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

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

## Personal Diabetes Manager (PDM)

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

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

If you drop your PDM or if it has been hit against something hard, inspect it to be sure it is still working properly. Check that the display screen is working and is clear, and that the battery compartment door is properly in place. Call customer support or your local Medtrum distributor if you identify or suspect your PDM has been damaged.

Your PDM is designed to achieve optimum performance and battery life with an AAA battery (1.5 V). Use of anything other than a 1.5 V battery could permanently damage your PDM and voids its warranty. Do NOT use rechargeable batteries.

**Operating Temperature Range**

Your A6 TouchCare® System is designed to operate between 5°C (41°F) and 40°C (104°F). Do NOT expose the system to temperatures outside that range. Do NOT expose the system to direct sunlight for a long period of time.

**Cleaning**

Do NOT use household cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your PDM, Pump Base, or Transmitter. Small amounts of rubbing alcohol can be used to clean the surface of your PDM, Pump Base, and Transmitter. Never put your PDM, Pump Base or Transmitter in the dishwasher or use very hot water to clean it.

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

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

**X-rays, MRIs and CT Scans**

The A6 TouchCare® System may be affected by strong radiation or magnetic fields. If you are going to have an X-ray, MRI, CT scan or other type of exposure to radiation, remove your Patch Pump and CGM system, and put them outside the treatment area with your PDM. Change the Reservoir Patch and Sensor after the test or procedure is completed.

The A6 TouchCare® System is designed to tolerate common electromagnetic and electrostatic fields, including airport security systems and cellular phones.

## Consumables

- **Reservoir Patch**— The Pump Base (MD-JN-012) is only used with the

200-unit Medtrum Reservoir Patch (MD-JN-011). Change your Reservoir Patch every 2-3 days or as directed by your healthcare provider.

- **Glucose Sensor** — The Transmitter (MD-TY-012) is only used with the Medtrum Glucose Sensor (MD-JY-006). Change your Glucose Sensor every seven days.

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

## Radio Frequency (RF) Communication

The A6 TouchCare® System complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and

- This device must accept any interference received, including interference that may cause undesired operation.

Note: The A6 TouchCare® System has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The A6 TouchCare® System can generate, use, and radiate radio frequency energy, and may cause harmful interference to radio communications. There are no guarantees that interference will not occur in a particular installation. If the A6 TouchCare®

System does cause harmful interference to radio or television reception, you are encouraged to try to correct the interference by one of the following measures:

- Move or relocate the A6 TouchCare® System.
- Increase the distance between the A6 TouchCare® System and the other device that is emitting/receiving interference.

Common consumer electronic devices that transmit in the same frequency band used by the A6 TouchCare® System may prevent communication between the PDM and your Patch Pump or Transmitter. This interference, however, does not cause any incorrect data to be sent and does not cause any harm to your device.

RF communication between your Patch Pump and PDM works up to a distance of 4 meters (13 feet). RF communication between your Transmitter and PDM works up to a distance of 10 meters (33 feet).

## Emergency Kit

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

This kit should include but is not limited to:

- Fast-acting glucose tablets or gel
- BG monitoring supplies
- Urine ketone testing supplies
- Insulin syringe
- Rapid-acting U-100 insulin

- Extra Medtrum 2.0 mL Reservoir Patches
- Extra AAA alkaline batteries
- Instructions from your healthcare provider about how much insulin to inject if pump delivery is interrupted
- Alcohol wipes
- Glucagon emergency kit
- Emergency contact phone numbers

## Water

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

**Warning:** Do NOT expose your Patch Pump or Sensor (including the installed Transmitter) to water at depths greater than 2.5 meters (8 feet) or for more than 1 hour. Check often to make sure the devices are securely attached and in place.

**Warning:** The PDM is not waterproof. Do NOT spill fluids on it or drop it into fluids.

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

## Storage

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

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

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

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

# Warranty Information

## Warranty

Personal Diabetes Manager (PDM)

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

**The warranty is valid only if the PDM is used in accordance with Medtrum's instructions and will not apply:**
• If damage results from changes or modifications made to the PDM by the user or third persons after the date of manufacture;
• If damage results from service or repairs performed to any part of the PDM by any person or entity other than Medtrum;
• If a battery other than an AAA battery (1.5 V) is used with the PDM;
• If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or
• If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

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

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR

SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

# Warranty

Pump Base

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

**The warranty is valid only if the Pump Base is used in accordance with Medtrum's instructions and will not apply:**
• If damage results from changes or modifications made to the Pump Base by the user or third persons after the date of manufacture;
• If damage results from service or repairs performed to any part of the Pump Base by any person or entity other than Medtrum;
• If a non-Medtrum Reservoir Patch is used with the Pump Base;
• If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or
• If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

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

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

# Warranty

Transmitter

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

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

• If damage results from changes or modifications made to the Transmitter by the user or third persons after the date of manufacture;

• If damage results from service or repairs performed to any part of the Transmitter by any person or entity other than Medtrum;

• If a non-Medtrum Glucose Sensor is used with the Transmitter;

• If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or

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

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

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.
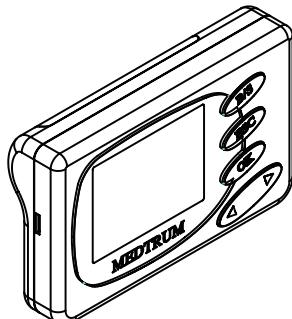
# Your A6 TouchCare® System

## Personal Diabetes Manager (PDM)

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

When conditions or distance cause RF communication to be lost or interrupted, you will not be able to use your PDM to control or monitor your Patch Pump or Glucose Sensing System. The Patch Pump can continue to deliver basal insulin based on your programmed settings, perform safety checks and automatically stop delivery when serious conditions happen. The Transmitter can continue to record sensor glucose readings. The PDM is designed to sense and notify you about a lost connection. As soon as the problem is resolved, RF communication will resume.
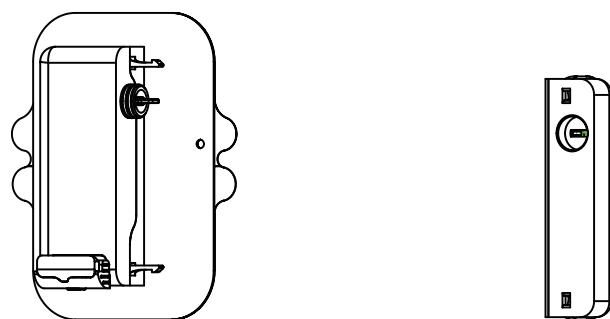
*Note*: We recommend that your PDM is only used by an intended and qualified operator.

✓ Personal Diabetes Manager (PDM) (MD-FM-011)

## Patch Pump
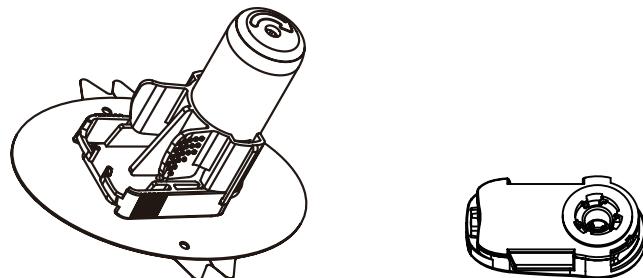
The Patch Pump is a small, lightweight, self-adhesive device worn directly on your body to deliver precise, personalized doses of insulin into your body through a needle. The Patch Pump is composed of a reusable Pump Base and a disposable Reservoir Patch. The reusable Pump Base holds the electronics and stores all of your Pump settings. The disposable 200 unit Reservoir Patch incorporates a precise dispensing screw, a plunger, a driver, a needle, a buzzer and a battery to power your Pump. The delivery system and enclosure of the Reservoir Patch are applied parts of the Pump system.
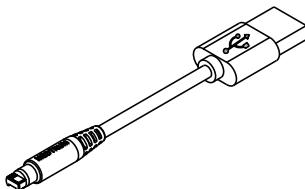
✓ Reservoir Patch
(MD-JN-011) (Consumable)

✓ Pump Base
(MD-JN-012)

## Glucose Sensing System

The Glucose Sensing System is composed of a disposable Glucose Sensor and a reusable Transmitter. The Glucose Sensor is inserted under the skin to measure your glucose level in interstitial fluid. The Sensor is the applied part of the CGM System. The Transmitter records sensor data and sends data to a display device via wireless RF communication. The Transmitter's USB charging cable is also included in the package as an accessory.



✓ Glucose Sensor

(MD-JY-006) (Consumable)

✓ Transmitter
(MD-TY-012)

✓ USB charging cable

# How to Use the PDM

## Basics of the PDM

### Battery Installation

The PDM is designed for 1.5 V AAA alkaline batteries, size E92, type LR03 (we recommend Energizer brand).
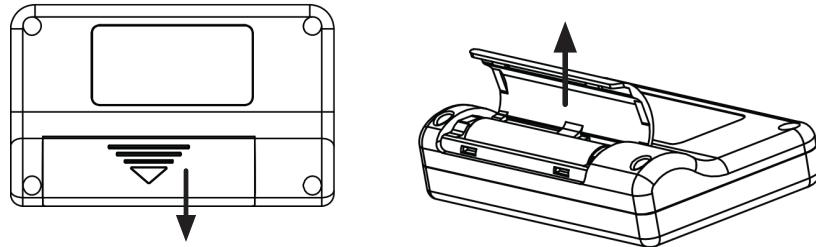
*Note:* Do NOT use any type of batteries other than AAA alkaline batteries to power the PDM. Never use old or used batteries because the PDM may not work properly.

As a safety measure, if you install a battery that does not have full power, the **PDM BATTERY LOW** alert or **REPLACE BATTERY** alarm may sound. If you receive a **PDM BATTERY LOW** alert, respond to the alert and continue. The PDM will still operate normally, but with a decreased battery life.
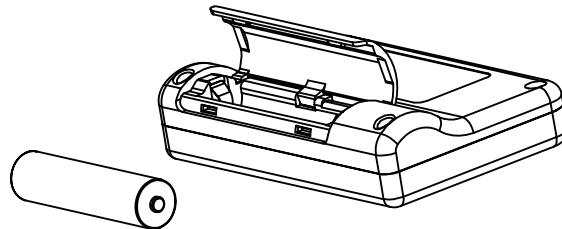
1. Make sure all of the following apply:

   - Clear (**ESC** then **OK**) any alarms and/or alerts before removing and replacing the battery.

- Make sure the PDM is at the **HOME** screen when you remove the battery.

- Do NOT remove the battery during a bolus or a patch change process.

2. Open the battery compartment on the back of the PDM by pushing the compartment latch in the direction of the arrow and lifting upward.
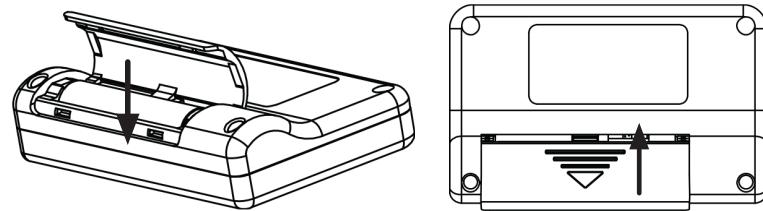


3. Remove the old battery and dispose of it via the disposable requirements of your state or country. Put a new battery in the PDM. Check the diagram inside the compartment to make sure the battery is inserted correctly.



*Note:* Do NOT use batteries that have been in cold storage, such as in the refrigerator or in your car during winter in cold climates.

*Note:* If the PDM will not be used for a long time, please remove the battery.

4.  Close the battery door by pushing the compartment latch in the direction of the arrow.
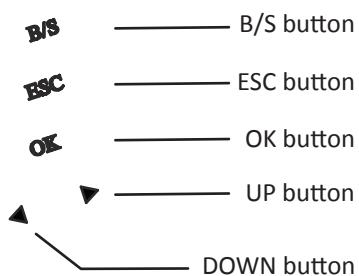


5.  Turn the PDM face-up. The PDM will power on automatically. It will show one or more screens until the **HOME** screen appears.

    If the **HOME** screen does not appear:

    a.  Check that the battery is inserted correctly. If the battery has been installed improperly, remove the battery and install it properly.

    b.  If your PDM displays a **REPLACE BATTERY** alarm, remove and replace the battery with a new one.

    c.  If the PDM is still not on, call customer support or your local Medtrum distributor.

6.  Check to make sure the time and date are correct. If more than 3 minutes have passed since you removed the battery, you will be prompted to set the time and date.

## Buttons



| Names of Buttons | Function Description (From the HOME screen) |
|---|---|
| **UP** | Go to the **EVENT** screen. |
| **DOWN** | Turn on the screen backlight. |
| **OK** | Go to the **MAIN MENU**. |
| **ESC** | Go to the **SENSOR TREND** screen. |
| **B/S** | Go to the **NORMAL BOLUS** or **FOOD BOLUS CALCULATOR** screen. |

| Names of Buttons | Function Description (From the SENSOR TREND screen) |
|---|---|
| UP | Move the cursor right. |
| DOWN | Move the cursor left. |
| OK | Go to the **MAIN MENU**. |
| ESC | Go to the **STATUS** screen. |
| B/S | Press and hold **B/S** and press **DOWN** to turn on/off the screen backlight. |

| Names of Buttons | Function Description (From the STATUS screen) |
|---|---|
| UP | Page up |
| DOWN | Page down |
| OK | Go to the **MAIN MENU**. |
| ESC | Go to the **HOME** screen. |
| B/S | Press and hold **B/S** and press **DOWN** to turn on/off the screen backlight. |

| Names of Buttons | Function Description (From the menus and programming screen) |
|---|---|
| UP | • Increase the value of an item.<br>• Scroll up the items in a list. |
| DOWN | • Decrease the value of an item.<br>• Scroll down the items in a list. |
| OK | Accept a selected menu item or activate a selected setting. |
| ESC | • Return to the previous screen.<br>• Cancel settings if the **OK** button has not been pressed yet. |
| B/S | • Press and hold **B/S** and press **DOWN** to turn on/off the screen backlight.<br><br>• Press and hold **B/S** and press **OK** to access certain menus. |
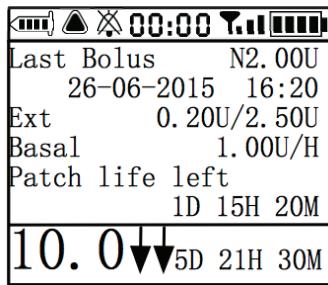
## HOME Screen

The **HOME** screen is the starting point to access the programming screens. When no buttons are pressed for a set period, the PDM returns to this screen. The first line shows icons including reservoir volume, alert/alarm, audio off, time, pump RF signal and battery. The last eight lines show your real-time insulin pump status and sensor status.

```
┌─────────────────────────────┐
│ ⊞) ▲ ✕ 00:00 ▼.ıl ▥▥▥      │
│ Last Bolus       N2.00U     │
│     26-06-2015   16:20      │
│ Ext         0.20U/2.50U     │
│ Basal          1.00U/H      │
│ Patch life left             │
│              1D 15H 20M     │
│ 10.0▼▼5D 21H 30M            │
└─────────────────────────────┘
```

Press the **OK** button from the **HOME** screen to open the **MAIN MENU**.

## Screen Icons

### Battery

The battery icon indicates the remaining battery life. There are four segments in the icon. Each segment represents approximately 25% of the total battery life. If there is only one segment left, make sure that you have a new battery available.

▮▮▮▮    At least 75% left

▭    Low battery

### Time

You can select the current time displayed in a 12-hour or 24-hour format. The

AM or PM is displayed for the 12-hour format. For instructions on setting the time on your PDM, see *Time/Date setup* in Chapter *Utilities*.

**00:00**<sup>AM</sup>   12-hour format

**00:00**   24-hour format

## Audio Off Icon
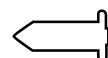
The audio off icon appears only when the audio alert is turned off.

## Reservoir Volume

The reservoir volume icon shows the current amount of insulin in the Reservoir Patch. The icon is divided into four segments.

More than 150 U of insulin left

Empty reservoir

## Alert and Alarm Icons

An empty triangle (alert) or a solid triangle (alarm) appears only when there is an alert or alarm condition in your insulin management system. For more information, see Chapter *Safety System and Alarms*.

Alert icon

 Alarm icon

**Pump RF Signal Icon**

An RF icon appears only when there is an active Patch Pump.
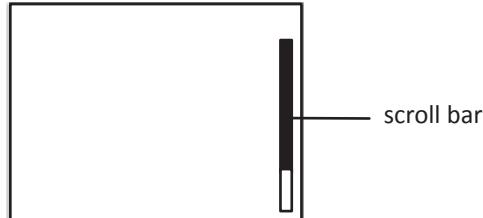
 Patch Pump is active and RF communication is good

 Patch Pump is active but RF communication is lost or interrupted

# Scroll Bar

If there is more text than the screen can show, a scroll bar appears on the right side of the screen. Press the **UP**/**DOWN** button to view any additional text.

 scroll bar

# Screen Backlight

At the **HOME** screen, the backlight can be turned on/off by pressing the **DOWN** button.

On other screens, the backlight can be turned on/off by pressing the **B/S** button and the **DOWN** button together.

The backlight cannot be turned on in a **PDM Battery Low** condition.

## Beep/Vibrate
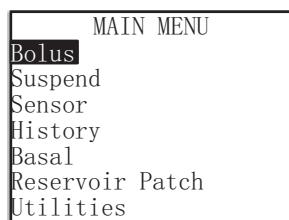
The PDM beeps and/or vibrates to notify you of a condition. See *Audio Options* in Chapter *Utilities* for setup instructions.

## Menus

### MAIN MENU
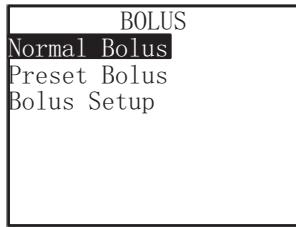
The **MAIN MENU** provides access to various features of the A6 TouchCare® System. It consists of seven submenus: **Bolus**, **Suspend**, **Sensor**, **History**, **Basal**, **Reservoir Patch,** and **Utilities**.

Press the **OK** button from the **HOME** screen to open the **MAIN MENU**.

```
           MAIN MENU
Bolus
Suspend
Sensor
History
Basal
Reservoir Patch
Utilities
```
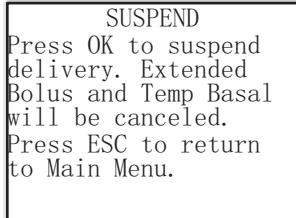
### BOLUS

The **BOLUS** menu contains the settings and functions for bolus deliveries. See *Bolus* in this chapter for more bolus information, and the chapter *Advanced Pump Features* for advanced bolus settings.

```
              BOLUS
Normal Bolus
Preset Bolus
Bolus Setup
```

*Note*: Pressing **B/S** button from the **HOME** Screen allows direct access to **NORMAL BOLUS** or **FOOD BOLUS CALCULATOR** (if the calculator is turned on) without having to navigate through the menus.
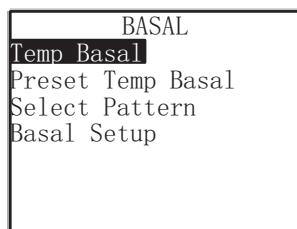
## SUSPEND

From the **SUSPEND** screen you can suspend all current insulin deliveries (basal and bolus) or resume insulin delivery programs. *Suspend and Resume* in this chapter contains more information.

```
             SUSPEND
Press OK to suspend
delivery. Extended
Bolus and Temp Basal
will be canceled.
Press ESC to return
to Main Menu.
```

## BASAL

The **BASAL** menu allows you to set or deliver your basal insulin. *Basal* in this chapter and the chapter *Advanced Pump Features* contain more information.

```
           BASAL
Temp Basal
Preset Temp Basal
Select Pattern
Basal Setup

```
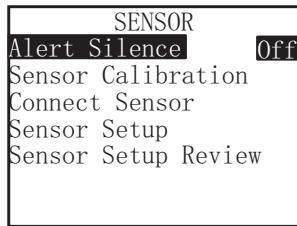
## RESERVOIR PATCH

The **RESERVOIR PATCH** menu helps you when changing your Reservoir Patch.
The chapter *How to Change Reservoir Patch* contains more information.

```
     RESERVOIR PATCH
Change/New Patch

```

## SENSOR

The **SENSOR** menu contains the settings and functions of the Glucose Sensor.
The chapter *CGM Features* contains more information.

```
          SENSOR
Alert Silence        Off
Sensor Calibration
Connect Sensor
Sensor Setup
Sensor Setup Review

```
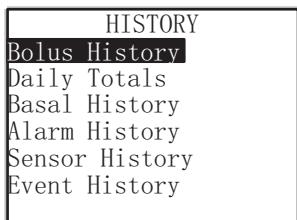
## UTILITIES

The **UTILITIES** menu allows you to edit personal settings of your system. The chapter *Utilities* contains more information.

```
              UTILITIES
Time/Date
Username
Alerts
Lock Keypad
Display
Device Options
Alarm Clock
Glucose Units
Language
Diagnostics
User Settings
```
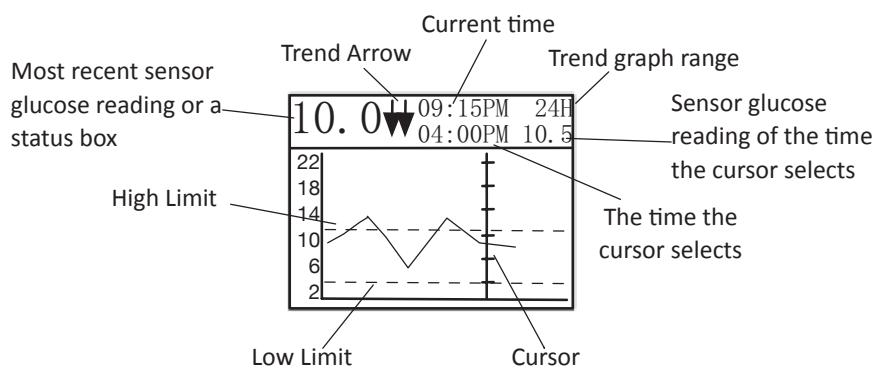
## HISTORY

The **HISTORY** menu is used to review insulin delivery, alarm history, sensor history and event history. *History* in this chapter contains more information.

```
               HISTORY
Bolus History
Daily Totals
Basal History
Alarm History
Sensor History
Event History
```

## SENSOR TREND Screen

Press **ESC** from the **HOME** screen to open the **SENSOR TREND** screen.

Most recent sensor glucose reading or a status box

Trend Arrow

Current time

Trend graph range

Sensor glucose reading of the time the cursor selects

High Limit

The time the cursor selects

Low Limit

Cursor

10.0  09:15PM  24H
       04:00PM  10.5

22
18
14
10
6
2
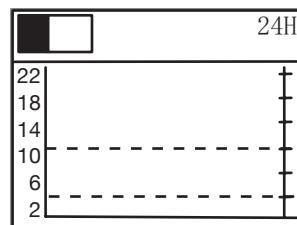
The trend arrow shows the speed and direction of your sensor glucose readings.

→ Constant

↗ Slowly rising

↑ Rising

↑↑ Rapidly rising

↘ Slowly falling

↓ Falling

↓↓ Rapidly falling

No arrow  No rate of change information

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Under normal sensor conditions, the most recent glucose reading is displayed at the top-left corner.
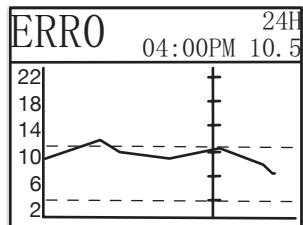
When the Sensor is warming up, a progress bar is displayed at the top-left corner. It takes 120 minutes for each Sensor to warm up.



| | |
|---|---|
| ▰ | The Sensor has been warming up for less than 30 minutes. |
| ▰▯ | The Sensor has been warming up for 30 to 60 minutes. |
| ▰▯ | The Sensor has been warming up for 60 to 90 minutes. |
| ▯ | The Sensor has been warming up for 90 to 120 minutes. |

When the Sensor is under calibration, another progress bar ▬ is displayed at the top-left corner. The black part indicates the progress of calibration.

Under some special conditions, the sensor status is displayed at the top-left corner.

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**ERR0** - the Sensor needs to be recalibrated after 15 minutes.

**ERR1** - the Sensor needs to be recalibrated after 1 hour.

**BG** - the Sensor needs calibration now.

**???** - Sensor signal error.

**LOST** - Sensor signal is lost for more than 2 minutes.

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

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

## STATUS Screen

The **STATUS** screen lists the system's current operating status. Press **ESC** twice from the **HOME** screen to open the **STATUS** screen.

To view more text on **STATUS** screens, press **UP/DOWN** to scroll from 01 to 06 and view all of them.

Press **ESC** from the **STATUS** screen to go back to the **HOME** screen. Press **OK** from the **STATUS** screen to open the **MAIN MENU**.

```
STATUS - ALERTS    01   STATUS - BASAL     02   STATUS - BOLUS     03
29-09-2015 Tuesday       Pattern: Standard        Active Ins: 1.70U
Last Alert: LowRes       24-Hr Total: 24.00U      Last Bolus: N4.00U
   29-09-2015 18:53      Basal: 1.00 U/H             29-09-2015 16:12
Alert Type: Vibrate      Temp Basal: Active       Combo Bolus: 5.00U
Alert Silence: Off         Start 29-09 11:00        CN: 2.50U
Alarm Clock: Off           End 29-09 12:00          CE: 0.20U/2.50U
BolusReminder: 19:00       Rate 200% 2.00 U/H       Time Left: 00:25


STATUS - DEL./TODAY04   STATUS - MISC. INFO05   STATUS - VER. INFO 06
Insulin Type: U100       SensorSignal:15.20nA     PDM: 1.0.0
Temp Basal: Yes          Transmtr Batt: Normal    Transmitter: 1.05
Suspend: No              PDM SN: 101000020        Pump Base: 1.04
Bolus: 16.20U            PumpBase SN:106000011
Basal: 19.00U           Transmtr SN:103000013
Total: 35.20U
Insulin Left: 90.90U
```

## EVENT Screen

Press **UP** from the **HOME** screen to go to the **EVENT** screen.

The **EVENT** screen allows you to record different events including: blood glucose, insulin injection, carbohydrates, exercise, health, and other information.
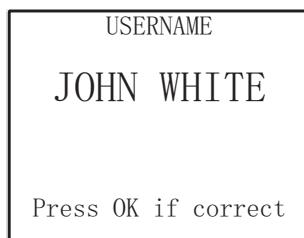
*Record Events* in this chapter contains more information.

```
            EVENT
BG
Injection
Carbs
Exercise
Health
Others
```

### USERNAME Screen

The PDM displays the **USERNAME** screen every time you turn it on to help you identify your own PDM. You must always confirm the username is correct before using the PDM.

You can customize this screen by editing your username. *Set Your Username* in the chapter *Utilities* contains more information.

```
┌─────────────────────────┐
│       USERNAME          │
│                         │
│     JOHN WHITE          │
│                         │
│                         │
│   Press OK if correct   │
└─────────────────────────┘
```

## Setting up the PDM
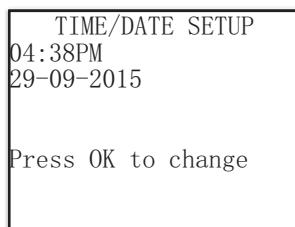
### Time and Date

When you first install a battery in your PDM, you need to set the time and date. Setting the correct time and date in your PDM is necessary for accurate basal insulin delivery and allows you to keep an accurate record of your insulin delivery and sensor readings.
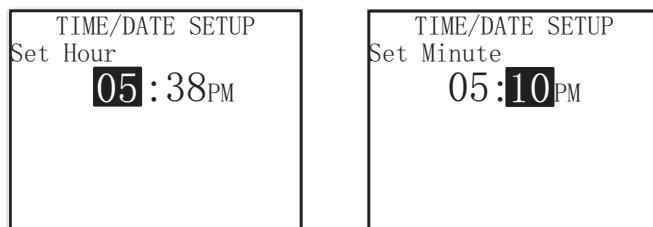
1.   Select **12-Hour** format or **24-Hour** format and press **OK**.
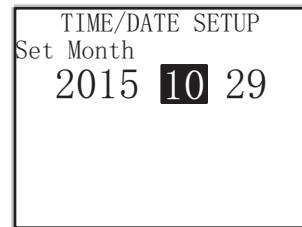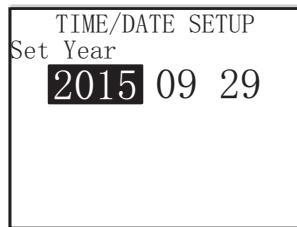
```
        TIME/DATE SETUP
12 Hour
24 Hour
```

2.    Press **OK** again to change the settings.

```
        TIME/DATE SETUP
04:38PM
29-09-2015


Press OK to change
```

3.    Time setup: Press **UP/DOWN** to change the hour; then press **OK**. Press **UP/DOWN** to change the minute; then press **OK**.

```
    TIME/DATE SETUP
Set Hour
        05:38PM
```

```
    TIME/DATE SETUP
Set Minute
        05:10PM
```
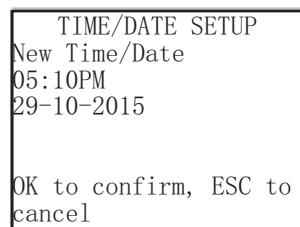
*Note:* AM and PM appear only when the set time format is 12-Hour.

4.    Date setup: Press **UP/DOWN** to change the year; then press **OK**. Press **UP/DOWN** to change the month; then press **OK**. Press **UP/DOWN** to change the day; then press **OK**.

```
       TIME/DATE  SETUP              TIME/DATE  SETUP
Set Year                       Set Month
     2015 09  29                    2015 10  29
```

```
       TIME/DATE  SETUP
Set Day
     2015  10  29
```

5. Press **OK** to accept new date and time, or press **ESC** to cancel the settings.

```
       TIME/DATE  SETUP
New Time/Date
05:10PM
29-10-2015


OK to confirm,  ESC to
cancel
```

## Select a Language

1. Go to the **UTILITIES** screen, select **Language** and press **OK**.

   MAIN MENU➜UTILITIES➜LANGUAGE

2. Press **UP/DOWN** to select your language, press **OK** to confirm and exit to

the **UTILITIES** screen.

```
         LANGUAGE
中文简体
English
Deutsch
Fran Çais
Italiano
Español
```
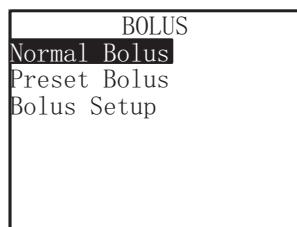
# Bolus

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

Your A6 TouchCare® System provides three bolus types: Normal bolus, Extended bolus, and Combo bolus. This section gives instructions for a Normal bolus. The chapter *Advanced Pump Features* contains more information about Extended bolus and Combo bolus.

Go to the **BOLUS** screen.

MAIN MENU➔BOLUS

```
          BOLUS
Normal Bolus
Preset Bolus
Bolus Setup

```

## Normal Bolus

1. To deliver a normal bolus, go to the **NORMAL BOLUS** screen.

MAIN MENU➔BOLUS➔NORMAL BOLUS

```
       NORMAL BOLUS
Set Bolus


        0.00 U


OK continue, ESC exit
```
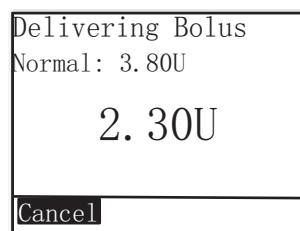
2. Enter your bolus amount by pressing **UP/DOWN** to increase/decrease and press **OK**.
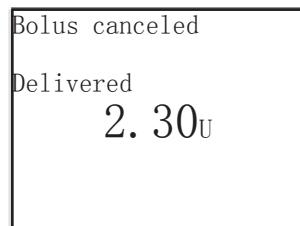
*Note:* The **BG REMINDER DURATION** screen will appear if you have BG reminder turned on. It allows you to accept or modify the time before you are reminded to check your blood glucose after a bolus. *BG Reminder* in this chapter contains more information about this feature.

```
 BG REMINDER DURATION
Duration
        02:00



OK continue, ESC exit
```

3. Press **OK** to accept and deliver the bolus. The normal bolus will start. As the bolus delivers, the amount shown on the screen will increase until the entire bolus has been delivered.

```
Delivering Bolus
Normal: 3.80U

        2.30U


Cancel
```

You can cancel an active normal bolus (one that is currently being delivered) even after insulin delivery has started. Press **OK** to cancel the bolus. An on-screen message tells you how much insulin was delivered before you canceled the bolus. Press **ESC** to go back to the **HOME** screen.

```
Bolus canceled

Delivered
        2.30U
```
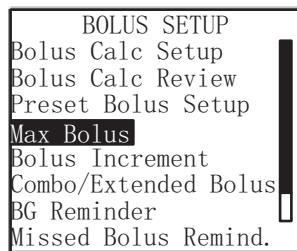
## Maximum Bolus Limit

The maximum bolus (max bolus) is a safety feature that limits the amount of insulin that can be delivered in a single bolus. The factory setting is 10 units. You can set the limit from 0 to 25 units. Please set the maximum bolus with the help of your healthcare provider.

1.  Go to the **MAX BOLUS SETUP** screen.

    MAIN MENU➔BOLUS➔BOLUS SETUP➔MAX BOLUS

```
          BOLUS SETUP
Bolus Calc Setup
Bolus Calc Review
Preset Bolus Setup
Max Bolus
Bolus Increment
Combo/Extended Bolus
BG Reminder
Missed Bolus Remind.
```

2.  Press **UP/DOWN** to change to the desired setting, press **OK** to confirm
    and return to the previous menu.

```
     MAX BOLUS SETUP



        3.70U
```
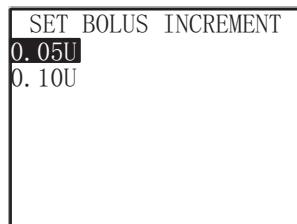
## Bolus Increment Value

1.  Go to the **SET BOLUS INCREMENT** screen.

    MAIN MENU➔BOLUS➔BOLUS SETUP➔BOLUS INCREMENT

2. Press **UP/DOWN** to select the step, press **OK** to confirm and return to the previous menu. The factory setting is 0.10 U.

```
┌──────────────────────────────┐
│  SET BOLUS INCREMENT         │
│ ▐0.05U▌                      │
│ 0.10U                        │
│                              │
│                              │
│                              │
│                              │
└──────────────────────────────┘
```
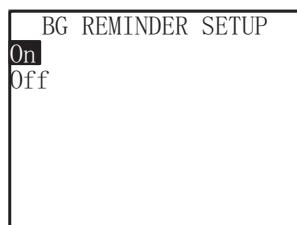
## BG Reminder

After you deliver a bolus, you may want to check your BG. The BG reminder is an optional feature that makes your PDM beep or vibrate to remind you to check your BG after a bolus.

1. Go to the **BG REMINDER SETUP** screen.

    MAIN MENU➔BOLUS➔BOLUS SETUP➔BG Reminder

2. Press **UP/DOWN** to select On or Off, press **OK** to confirm and return to the previous menu.

```
┌──────────────────────────────┐
│   BG REMINDER SETUP          │
│ ▐On▌                         │
│ Off                          │
│                              │
│                              │
│                              │
│                              │
└──────────────────────────────┘
```
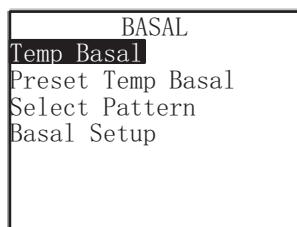
# Basal

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

A basal pattern contains at least one basal rate for a 24-hour period. A selected basal pattern is repeated daily. You can set up to 5 basal rates for a Standard basal pattern, and up to 48 basal rates for all the other patterns. *Basal Patterns* in the chapter *Advanced Pump Features* contains more information.

Go to the **BASAL** screen.

MAIN MENU➔BASAL

```
          BASAL
Temp Basal
Preset Temp Basal
Select Pattern
Basal Setup

```
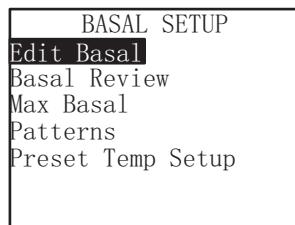
## Your Basal Settings

You must program your basal settings before you can deliver basal insulin. Keep a written record of your basal settings.

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

1. Go to the **BASAL SETUP** screen.

MAIN MENU➜BASAL➜BASAL SETUP

```
        BASAL SETUP
Edit Basal
Basal Review
Max Basal
Patterns
Preset Temp Setup
```

## Edit Your Standard Basal Pattern

If you are new to insulin pumps, we recommend that you first become comfortable with the Standard basal pattern before using multiple basal patterns.

1. Go to the **EDIT BASAL** screen.

MAIN MENU➜BASAL➜BASAL SETUP➜EDIT BASAL

```
        EDIT BASAL
■ Standard      0.00U
□ Exercise      0.00U
□ Holiday       0.00U
□ Pattern A     0.00U
□ Pattern B     0.00U
```

2. Press **OK** to select the Standard pattern and start editing.

```
┌─────────────────────────┐         24-hour Total
│ STANDARD    0.00U ───────┼────
│   Start     U/H         │
│  00:00     ▐0.00▌       │
│  - -:- -                │
│                         │
│                         │
│                         │
└─────────────────────────┘
```

- The **U/H** field is indicated by a highlighted cursor. Press **UP**/**DOWN** to set a desired basal rate. Press **OK** to confirm and enter the next **Start** time field.

*Note:* The next available empty basal segment will appear automatically as you program the previous segment. If the next empty basal segment does not appear, all five possible segments have been programmed.

*Note*: The first basal rate always starts at 12 a.m. or 00:00.

- Press **UP**/**DOWN** to change the next **Start** time as desired. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight. Press **OK** to confirm and enter the next **U/H** field.

- Continue until basal segments have been set as recommended by your healthcare provider.

- When finished, press **OK** while leaving the next **Start** time empty to exit the edit mode and return to the previous menu.

*Note:* As a safety feature, the system will suspend basal delivery when you edit an active basal pattern. The system will resume delivery after the edits are made. You cannot edit a selected basal pattern while a temporary basal is in

process.

## Check the Current Basal Rate

The **HOME** screen and the second **STATUS** screen show the information of the current basal rate.

```
Last Bolus     N2.00U
     26-06-2015  16:20
Ext        0.20U/2.50U
Basal          1.00U/H
Patch life left
             1D 15H 20M
10.0▼▼5D 21H 30M
```

```
STATUS - BASAL     02
Pattern: Standard
24-Hr Total: 24.00U
Basal: 1.00 U/H
Temp Basal: Inactive
```

## Review Your Basal Patterns

The **BASAL REVIEW** screen shows your daily basal rates of all patterns.

1.    Go to the **BASAL REVIEW** screen.

MAIN MENU➜BASAL➜BASAL SETUP➜BASAL REVIEW

```
      BASAL REVIEW
■ Standard    22.70U
□ Exercise    20.00U
□ Holiday     25.00U
□ Pattern A    0.00U
□ Pattern B    0.00U
```

2.    Press **UP**/**DOWN** to choose the basal pattern that you want to review. Press **OK** to review your programmed settings.
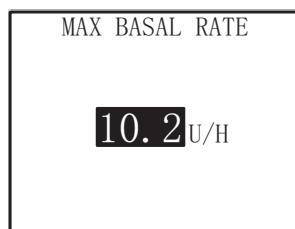
## Maximum Basal Rate

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

1.  Go to the **MAX BASAL RATE** screen.

    MAIN MENU➜BASAL➜BASAL SETUP➜MAX BASAL

2.  Press **UP/DOWN** to change the rate, press **OK** to confirm and return to the previous menu.

```
┌─────────────────────────┐
│   MAX  BASAL  RATE      │
│                         │
│                         │
│     10.2 U/H            │
│                         │
│                         │
└─────────────────────────┘
```

# Suspend and Resume

## Suspend Insulin Delivery

Sometimes you may need to briefly suspend insulin delivery. This **SUSPEND**

feature stops all insulin including the current basal and any bolus that is in progress. Your PDM will beep and/or vibrate every 15 minutes, reminding you that insulin delivery is suspended.

1. Go to the **SUSPEND** screen.

MAIN MENU➔SUSPEND

```
        SUSPEND
Press OK to suspend
delivery. Extended
Bolus and Temp Basal
will be canceled.
Press ESC to return
to Main Menu.
```
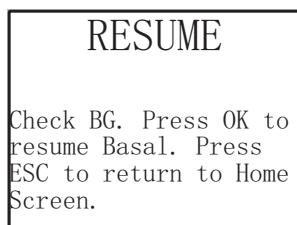
*Note*: When you suspend insulin delivery, Extended Bolus and Temp Basal will be canceled and cannot be resumed.

2. Press **OK** to confirm that you want to suspend all insulin delivery (basal and bolus). The PDM beeps and an on-screen message appears to let you know that insulin delivery is indeed suspended.

```
        SUSPEND


     SUSPENDED

```

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## Resume Insulin Delivery

After insulin delivery is suspended, press **OK** from the **HOME** screen, and the following screen appears.

```
RESUME

Check BG. Press OK to
resume Basal. Press
ESC to return to Home
Screen.
```

Press **OK** to resume basal delivery, or press **ESC** to return to the **HOME** screen.

*Note*: Only basal rate can be resumed, Extended Bolus and Temp Basal cannot be resumed.

## Record Events

The A6 TouchCare® System allows you to record different events including blood glucose, insulin injection, carbs, exercise, health condition, and others. This information can help you and your healthcare provider make better decisions about your diabetes management plan.
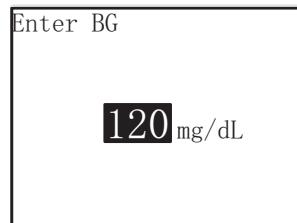
Press the **UP** button from the **HOME** screen to open the **EVENT** screen.

```
                    EVENT
BG
Injection
Carbs
Exercise
Health
Others
```

## BG Measurement

The default blood glucose is 120 mg/dL (or 6.5 mmol/L). The input range is 40 – 400 mg/dL (or 2.2 – 22.2 mmol/L).

1.  Select **BG** in the **EVENT** screen and press **OK**.

```
Enter BG



    120 mg/dL


```

2.  Press **UP**/**DOWN** to enter blood glucose level. Press **OK** to confirm.

3.  Select **Cancel** or **Save**. Press **OK** to confirm and return to the **EVENT** screen.
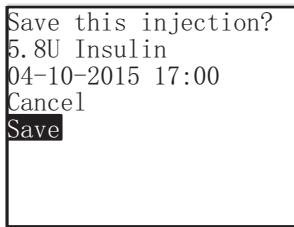
```
Save this BG?
120 mg/dL BG
29-09-2015 16:00
Cancel
Save
```

## Insulin Injection

1.  Select **Injection** in the **EVENT** screen and press **OK**.

2.  Press **UP/DOWN** to enter the amount of insulin you use. Press **OK** to confirm.
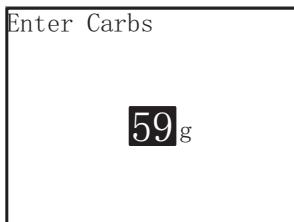
```
Enter Insulin


    5.8 U
```

3.  Select **Cancel** or **Save**. Press **OK** to confirm and return to the **EVENT** screen.

```
Save this injection?
5.8U Insulin
04-10-2015 17:00
Cancel
Save
```
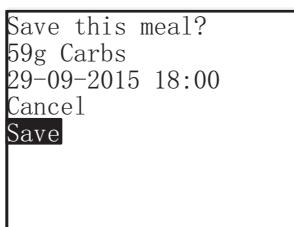
## Carbohydrates Information

1.  Select **Carbs** in the **EVENT** screen and press **OK**.

2.  Press **UP/DOWN** to enter the carbohydrates you eat or drink. Press **OK** to confirm. The input range is 0-200 grams.
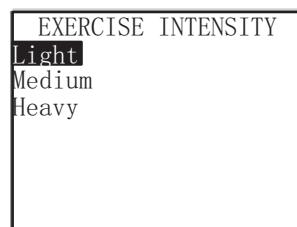
```
Enter Carbs



          59 g
```

3.  Select **Cancel** or **Save**. Press **OK** to confirm and return to the **EVENT** screen.

```
Save this meal?
59g Carbs
29-09-2015 18:00
Cancel
Save
```
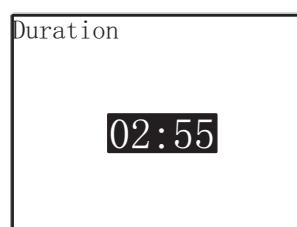
## Physical Exercise Information
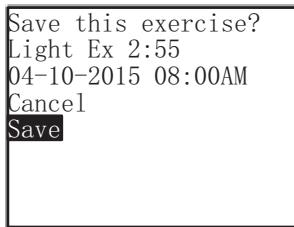
1. Select **Exercise** in the **EVENT** screen and press **OK**.

2. Press **UP**/**DOWN** to select the intensity of physical exercise. Press **OK** to confirm, or press **ESC** to cancel.

```
┌─────────────────────┐
│  EXERCISE  INTENSITY │
│ Light               │
│ Medium              │
│ Heavy               │
│                     │
│                     │
└─────────────────────┘
```

3. Press **UP**/**DOWN** to change the duration of physical exercises. Press **OK** to confirm, or press **ESC** to cancel. The range is 5 minutes to 8 hours and increases in 5 minute increments.

```
┌─────────────────────┐
│ Duration            │
│                     │
│                     │
│      02:55          │
│                     │
│                     │
└─────────────────────┘
```

4. Select **Cancel** or **Save**. Press **OK** to confirm and return to the **EVENT** screen.

```
Save this exercise?
Light Ex 2:55
04-10-2015 08:00AM
Cancel
Save
```
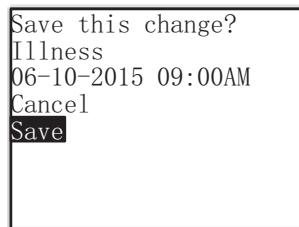
## Health Information

1. Select **Health** in the **EVENT** screen and press **OK**.

2. Press **UP/DOWN** to select the physical condition. Press **OK** to confirm, or
   press **ESC** to cancel.

```
         HEALTH
Illness
Stress
High Symptoms
Low Symptoms
Menstruation
Alcohol
```

3. Select **Cancel** or **Save**. Press **OK** to confirm and return to the **EVENT**
   screen.

```
Save this change?
Illness
06-10-2015 09:00AM
Cancel
Save
```
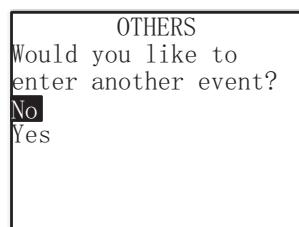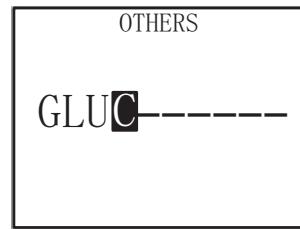
## Other Events

This section shows you how to enter other markers.
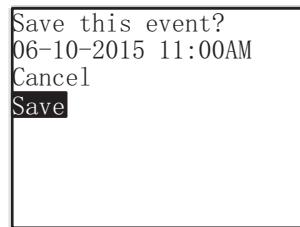
1. Select **Others** in the **EVENT** screen and press **OK**.

2. Select **Yes** or **No**. Press **OK** to confirm, or press **ESC** to cancel.

```
          OTHERS
Would you like to
enter another event?
No
Yes
```

3. Use no more than 10 characters to describe an event. Use **UP/DOWN** to scroll through the list of characters. A space is the first and last option in the scrolling list. Press **OK** to move the highlighted cursor to the next character. When finished, press **OK** while leaving the next — empty to proceed to the next step.

```
            OTHERS

      GLU█──────
```

4.   Select **Cancel** or **Save**. Press **OK** to confirm and return to the **EVENT** screen.

```
Save this event?
06-10-2015 11:00AM
Cancel
Save
```
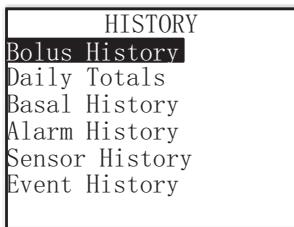
# History

Your PDM stores records of insulin delivery history, sensor history, alarm history and event history to help you manage diabetes.

Go to the **HISTORY** screen.

MAIN MENU➜HISTORY

```
        HISTORY
Bolus History
Daily Totals
Basal History
Alarm History
Sensor History
Event History
```

## Bolus History

1.  Go to the **BOLUS HISTORY** screen.

MAIN MENU➜HISTORY➜BOLUS HISTORY

The screen displays the summary of the last bolus. Record 1 indicates the most recent record.

The summary information includes:

-   The start time of this bolus
-   Bolus type and amount of bolus programmed
-   Amount of bolus delivered if the bolus type is combo bolus or extended bolus
-   Status of bolus
-   Bolus Calculator information if applicable

```
   BOLUS HISTORY 001
06-05-2015 01:12PM
Combo Bolus: 5.60U
 CN: 2.80U
 CE: 2.80U
Completed  00:30
```

**CN** represents the normal portion of a Combo Bolus. **CE** represents the extended portion of a Combo Bolus. The chapter *Advanced Pump Features* contains more information.

2.  Press **UP/DOWN** to change the record number and view other records. Press **OK** to view more detailed information.

```
001 BOLUS DETAIL
Time & Date:
  06-05-2015  01:12PM
Type: Combo
  Delivered: 5.60U
Normal Bolus: 2.80U
Extended Bolus: 2.80U
  Duration: 00:30
```

## Daily Totals

1.  Go to the **DAILY TOTALS** screen.

MAIN MENU➔HISTORY➔DAILY TOTALS

```
    DAILY TOTALS  001
Date        06-03-2015
Temp Basal        Yes
Suspend           Yes
Basal (48%)    22.30U
Bolus (52%)    23.90U
Total          46.20U
```

The screen displays the summary of the Daily Total. Record 1 indicates the most recent record.

2.  Press **UP/DOWN** to change the record number and view other records.

3. Press **OK** to view more information.

```
        06-03-2015
Carbs              20g
TotalInsulin 46.20U
Basal(48%)     22.30U
Bolus(52%)     23.90U
FoodBolus   9.00U #2
CorrBolus   3.90U #1
Food+Corr   1.00U #1
ManualBo   10.00U #2
Bolus Total  23.90U
04:11PM E3.00U 0:30
01:20PM N4.90U
01:15PM C7.00U 2:00
11:36AM E4.00U 2:00
09:25AM N5.00U
```

**FoodBolus 9.00U #2** means there are two food bolus doses in the selected day with a total amount of 9.00U.

**Food+Corr 1.00U #1** means there is a bolus dose that both covers carbs and corrects glucose in the selected day with an amount of 1.00U.

**ManualBo 10.00U #2** means there are two manual bolus doses in the selected day with a total amount of 10.00U.

**N** represents Normal Bolus. **E** represents Extended Bolus. **C** represents Combo Bolus.

The chapter *Advanced Pump Features* contains more information.

## Basal History

1. Go to the **BASAL HISTORY** screen.

MAIN MENU➜HISTORY➜BASAL HISTORY

```
        BASAL HISTORY  001
Date           03-08-2015
Basal           2.15U/H
Suspend             Yes
Temp Basal          Yes
Change/New Patch     No
Delivery Stop        No
Basal Total      30.60U
```

This screen displays the summary of basal delivery. Record 1 indicates the most recent record.

2.   Press **UP/DOWN** to change the record number and view other records.

3.   Press **OK** to view more information.

```
        03-08-2015
*03:35PM 1.00U/H
 03:10PM Suspend
 01:00PM 2.30U/H
 06:18AM 1.55U/H
 05:23AM Temp Basal
    80% 1.60U/H
 03:00AM 2.00U/H
 01:00AM 1.50U/H
 12:00AM 1.00U/H
```

## Alarm History

1.   Go to the **ALARM HISTORY** screen.

MAIN MENU➜HISTORY➜ALARM HISTORY

```
       ALARM HISTORY  001
PDM Battery Low
 06-02-2015  13:36
Reason: PDM battery
is low. Do not sleep
before replacing
battery.
```

This screen displays the summary of the last alarm. Record 1 indicates the most recent record.

2.   Press **UP/DOWN** to change the record number and view other records.

3.   Press **ESC** to return to the previous menu.


## Event History

1.   Go to the **EVENT HISTORY** screen.

MAIN MENU➔HISTORY➔EVENT HISTORY

```
        EVENT HISTORY
06-02-2015 11:36AM
BG 120mg/dL
05-02-2015 01:30PM
Light Ex 01:00
03-02-2015 10:00AM
Injection 4.7U
```

2.   Press **UP/DOWN** to scroll up/down the screen to view more records.


*Sensor History* in the chapter *CGM Features* contains more information.

# How to Change the Reservoir Patch

The Reservoir Patch requires replacement and is not to be reused. The Reservoir Patch should be replaced approximately every 2-3 days or as directed by your healthcare provider. Refer to the insulin labeling and follow the direction of your healthcare provider to know how often you should replace the Reservoir Patch.

**Warning:** Do NOT attempt to apply or use a Patch Pump until you have been trained by your healthcare provider. Use of the device with inadequate training or improper setup could put your health and safety at risk. Your healthcare provider will help you set up and apply your first Patch Pump if you are a first-time A6 Patch Pump user.

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

1. wash your hands

2. clean the insulin vial with an alcohol wipe

3. clean the infusion site with an alcohol wipe

4. keep sterile items away from any possible germs

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

# Before Changing the Reservoir Patch

You will need these items before you begin:

- Vial of U-100 insulin

- An unopened Reservoir Patch

- A Pump Base

- An alcohol wipe(s)

- A 2 mL disposable sterilized syringe with a capped needle

**Warning:** Failure to use U-100 insulin, or using insulin that is expired or inactive, may lead to hyperglycemia or diabetic ketoacidosis (DKA). Do NOT use insulin that is cloudy because it may be old or inactive.
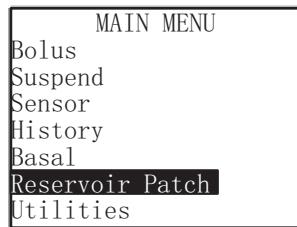
***Note*:** The syringe provided by Medtrum matches the fill port on the Reservoir Patch. Other syringes and needles which meet the following specifications are also permitted.

*Specifications of syringe:*

- *Reservoir volume: 2 mL*
- *Needle size: 26G*
- *Needle length: 3/8''*
- *Make sure the syringe with fill needle has been properly sterilized.*

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

1.  Enter the **MAIN MENU**, press **UP/DOWN** to select **Reservoir Patch** and press **OK**.

```
        MAIN  MENU
Bolus
Suspend
Sensor
History
Basal
Reservoir Patch
Utilities
```
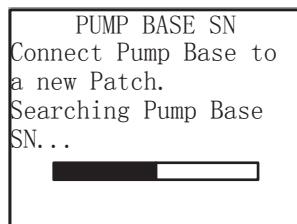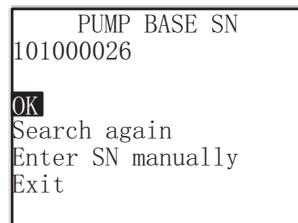
2.  Select **Change/New Patch** and press **OK**.

```
     RESERVOIR PATCH
Change/New Patch
Deactivate Patch
```
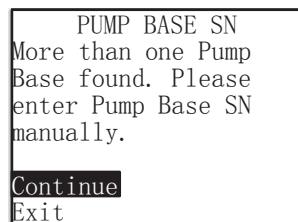
3.  If you haven't set the Pump Base SN, you will see the following message.
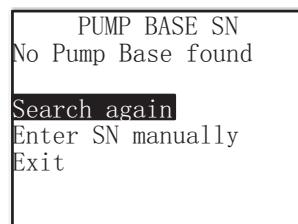
```
       PUMP BASE SN
Connect Pump Base to
a new Patch.
Searching Pump Base
SN...
    ▄▄▄▄▄▄▄▄
```

If your PDM finds one Pump, the Pump Base SN appears on the screen. You can confirm it if it matches the SN printed on your Pump Base.

```
      PUMP  BASE  SN
101000026

OK
Search again
Enter SN manually
Exit
```

If your PDM finds multiple Pumps, the SNs won't be displayed to prevent you from selecting the wrong SN. You need to enter the SN printed on your Pump Base manually.

```
      PUMP  BASE  SN
More than one Pump
Base found. Please
enter Pump Base SN
manually.

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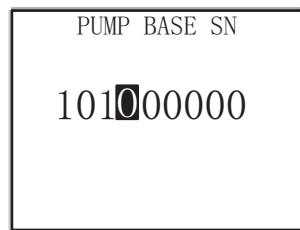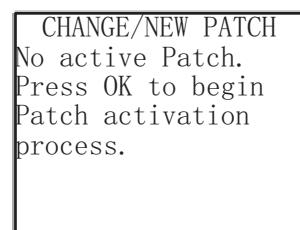
If your PDM does not find a Pump, make sure your Pump Base is connected to a new Reservoir Patch, move the PDM closer to your Pump, and search again or enter the SN manually.

```
      PUMP  BASE  SN
No Pump Base found

Search again
Enter SN manually
Exit
```
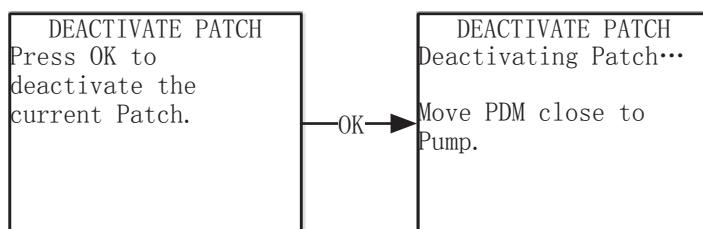
To enter the Pump Base SN manually, use **UP/DOWN** to select from 0 to 9, and press **OK** to move the highlighted cursor to the next digit.

```
        PUMP BASE SN

       101000000



```
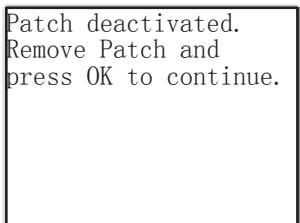
4.   If you have set the Pump Base SN, you will see the following message if
     there is no active Reservoir Patch.

```
   CHANGE/NEW PATCH
No active Patch.
Press OK to begin
Patch activation
process.


```

5.   If there is an active Reservoir Patch, you will see the following message.
     Press **OK** to deactivate the current Reservoir Patch.

```
  DEACTIVATE PATCH            DEACTIVATE PATCH
Press OK to                 Deactivating Patch···
deactivate the
current Patch.              Move PDM close to
                 ─OK──▶     Pump.


```

6.   Several seconds later, you will see the following message.

```
Patch deactivated.
Remove Patch and
press OK to continue.
```

## Deactivate the Current Reservoir Patch Without Changing

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

If you want to deactivate the current Reservoir Patch without activating a new one, follow these steps:

1. Enter the **MAIN MENU**, press **UP/DOWN** to select **Reservoir Patch** and press **OK**.

```
        MAIN MENU
Bolus
Suspend
Sensor
History
Basal
Reservoir Patch
Utilities
```
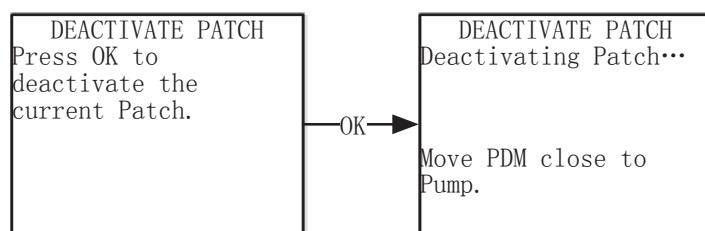
2. Select **Deactivate Patch** and press **OK**.

```
        RESERVOIR PATCH
Change/New Patch
Deactivate Patch
```

3.  Select **Yes**, and then press **OK**.

```
       DEACTIVATE PATCH
No
Yes
```

4.  Press **OK** to deactivate the current Reservoir Patch.

```
    DEACTIVATE PATCH                    DEACTIVATE PATCH
Press OK to                         Deactivating Patch···
deactivate the
current Patch.
                     ─OK─▶
                                    Move PDM close to
                                    Pump.
```
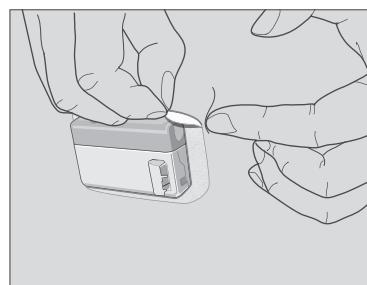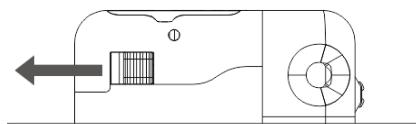
5.  Several seconds later, you will see a message that the Patch has been deactivated.

```
Patch deactivated.
Remove Patch and
press OK to continue.
```

## Remove the Current Reservoir Patch
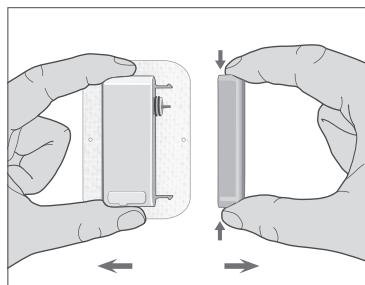
1. After the Reservoir Patch is deactivated, keep pressing the needle release button on the side of the Reservoir Patch, and slide it along with the direction of the arrow to retract the needle. Put the button cover back on. Gently lift the edge of the adhesive tape from your skin and remove the entire Reservoir Patch.



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

**Warning:** Check the infusion site for signs of infection.

2. Keep pressing the two yellow release buttons on two opposite sides of the Pump Base, and pull the Pump Base outward to remove it from the old Reservoir Patch. Discard the old Reservoir Patch according to your local waste disposal regulations.



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

## Connect the Pump Base to a New Reservoir Patch

1. Press **OK** on your PDM and you will see the following message on the screen.
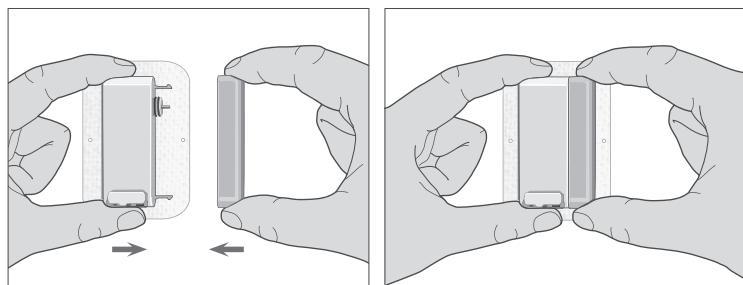
```
     CHANGE/NEW PATCH
Connect Pump Base to
a new Patch. Fill
Patch with insulin.

DO NOT CONNECT TO
BODY. Press OK to
start priming.
```

**Warning**: Do NOT connect the Patch Pump to your body until priming is finished.

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

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



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



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

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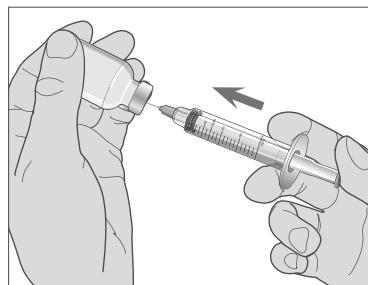
## Fill the New Reservoir Patch

**Warning:** If your insulin is stored in the refrigerator, wait till the insulin reaches room temperature before you fill your reservoir. Using cold insulin can
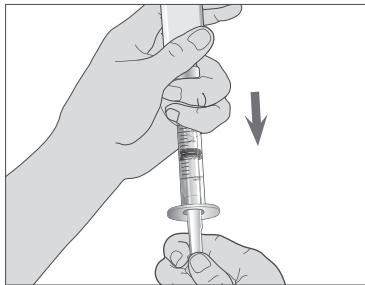
cause air bubbles in the reservoir. When filling the reservoir, take care to remove air bubbles.

Take the following steps to fill a new Patch:

1. Clean the top of the insulin vial with an alcohol wipe.

2. Remove the protective cap from the needle and save it.

3. With the help of your healthcare provider, determine the amount of insulin (70 U-200 U) you need to insert into the Reservoir Patch.

4. Draw air into the syringe up to the amount of insulin you need.

5. Insert the needle into the insulin vial and push down on the plunger to pressurize the vial.
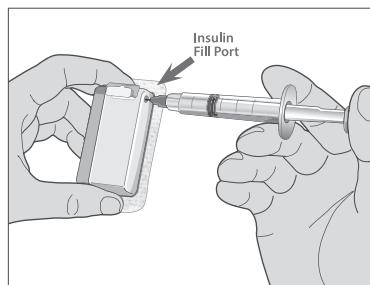


6. While still holding the plunger rod, flip the vial over so the vial is up, and then slowly pull down on the plunger to withdraw insulin from the vial into the syringe. Gently tap the side of the syringe to make any air bubbles rise to the top of the syringe. Slowly push up on the plunger just enough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

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

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



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

8. Press the syringe plunger to empty insulin into the Reservoir Patch.

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

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

or interrupted insulin delivery.

**Warning:** Do NOT insert the syringe into the fill port more than once.

9.   Remove the needle from the self-sealing insulin fill port.

10.  Place the protective cap back on the needle. Safely dispose of the syringe in a waste container according to local waste disposal regulations.

**Warning:** Use your Reservoir Patch right after you fill it. Do NOT store it filled.

11.  After you fill the Reservoir Patch, the reservoir volume icon on your PDM screen will indicate the current reservoir volume. Press OK to continue.
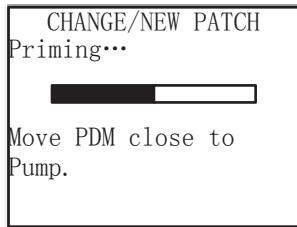
*Note:* Call customer support if you have filled the Reservoir Patch with more than 70 units and the reservoir volume icon is empty.

*Note:* After filling the Reservoir Patch with insulin, you should complete the Reservoir Patch change process within 3 hours. As a reminder that the Reservoir Patch has been filled, it will beep and/or vibrate every 10 minutes to indicate that time is passing. If you do not set up the Reservoir Patch within 3 hours, you must deactivate and discard it.
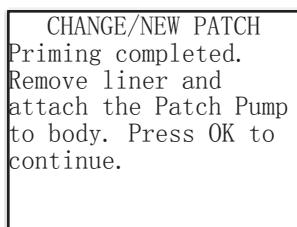
*Note:* Once a Reservoir Patch (assembled with a Pump Base) is activated and communicates with a PDM, it can only receive commands from that PDM, not from any other.

## Prime the Pump

After your Reservoir Patch is filled with insulin, press **OK** on your PDM to prime the Pump.

```
      CHANGE/NEW PATCH
Priming···

  ████████
  
Move PDM close to
Pump.
```

Once complete, the next screen appears, and the Pump vibrates three times.

```
      CHANGE/NEW PATCH
Priming completed.
Remove liner and
attach the Patch Pump
to body. Press OK to
continue.
```

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

# Select and Prepare the Infusion Site

The place on your body where you attach the Pump is important for the success of your therapy. Discuss the best location for you with your healthcare provider.
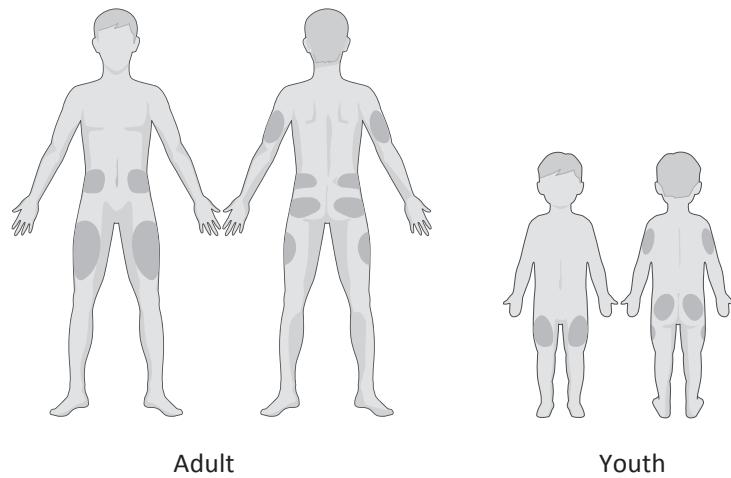
When choosing the location for the Pump, consider the following:

-   That you can comfortably reach the Pump.

-   That you apply the Pump to a flat area of skin, not on a fold of the skin, muscle, or bone.

-   That the area is flat when you are sitting down, standing up, or lying down.

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

- The belt line or waistline, or areas where clothing may rub the Pump.

- Areas with excessive hair. You may need to shave the area to properly attach the Pump.

- Curved or rigid areas due to muscle or bone.

- Areas within a 5.0 cm (2-inch) circle around the belly button or surgical scars.

- Areas of skin that are irregular for any reason.

Shown here are some body areas (shaded) suitable for infusion sites.



Adult                    Youth

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

If you choose an infusion site on your upper arm or thigh, apply the Patch Pump vertically.
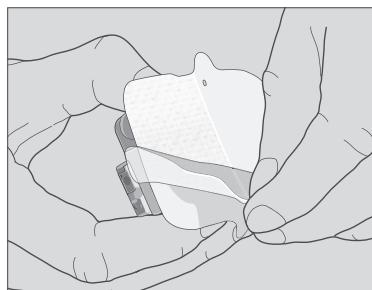
**Warning:** Change the site each time you apply a new Reservoir Patch. Be sure to rotate the infusion sites so that they do not become overused. A new infusion site should be at least 2.5 cm (1 inch) away from the last site.

Practice using an aseptic technique as described at the beginning of this chapter. Clean the area with an alcohol wipe where you will attach the Pump. Let the area dry before applying the Pump.
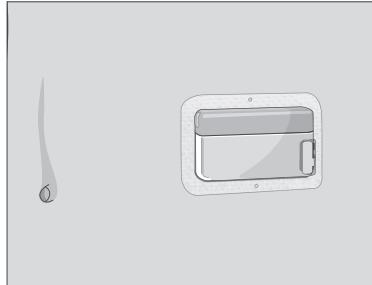
*Note:* If you have sensitive skin or your skin becomes irritated, contact your healthcare provider.

## Attach the Patch Pump
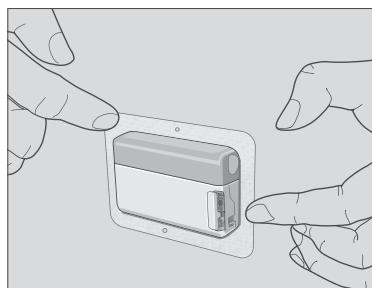
1.  Peel off the adhesive liner from the bottom of the Reservoir Patch. Removing the liner exposes the adhesive.



2.  Without touching the adhesive pad, press the Pump against the skin at the selected infusion site.

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



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

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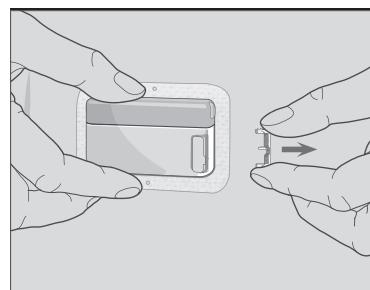
## Start Insulin Delivery

1. Press **OK** on the PDM, and you will see the following message on the
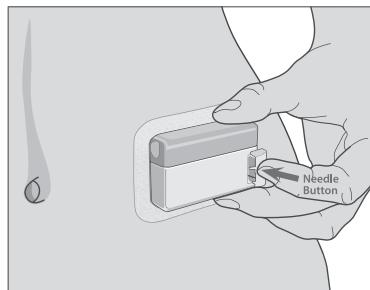
screen.

```
    CHANGE/NEW PATCH
Remove the button
cover, press the
needle button to
insert the needle.
Press OK to continue.
```

2.  After you securely attach the Patch Pump, hold the Pump with one hand and pull the button cover away with the other hand. Save the button cover, you will need it when you remove the Reservoir Patch.



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

**Warning:** The Patch Pump must be placed in a place that has a lot of fatty tissue. If you do not have an area of skin with a lot of fatty tissue, pinch the skin around the Patch Pump before you press the needle button, then hold it until the needle inserts. Occlusions may result if you do not use this technique.

4.  Press **OK** after you insert the needle, and the following screen appears.

```
    CHANGE/NEW PATCH
Check infusion site.
If needle is properly
inserted, press OK to
continue, otherwise
press ESC to
deactivate Patch.
```

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

5.  Press **OK** to activate basal delivery if the needle is properly inserted, or press **ESC** if you see a problem with the needle. The PDM will instruct you to deactivate the Reservoir Patch.

```
    CHANGE/NEW PATCH
Activating Basal…

Move PDM close to
Pump.
```

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

6.  Now your new Reservoir Patch is activated.

```
┌─────────────────────────┐
│    CHANGE/NEW PATCH     │
│ Patch is active.        │
│                         │
│                         │
│ The active Basal        │
│ pattern is Standard.    │
│                         │
│                         │
└─────────────────────────┘
```

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

**Warning**: Check the infusion site frequently for improper placement and leaks that can result in under-infusion. You can also check blood glucose level to ensure normal infusion. Change the Reservoir Patch if the needle becomes fully or partially dislodged from the skin.

# Advanced Pump Features

## Bolus Calculator

This feature allows you to enter the number of carbs eaten and your current (actual) BG value. Your Pump will then automatically calculate your Food Bolus and Correction Bolus, based on your Insulin-to-Carbohydrate ratio (I:C ratio), Insulin Sensitivity Factor (ISF), BG Target and the amount of active insulin for the current time stored in the Pump. Consult your healthcare provider for your personal I:C ratios, Insulin Sensitivity Factor (ISF), BG Target ranges and active insulin time.

## How the Bolus Calculator Works

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

*Note:* As a safety feature, the system only allows you to give a bolus at or below the maximum bolus limit you have set. The chapter *How to Use the PDM* contains more information on resetting your maximum bolus limit. Consult your healthcare provider before changing this setting.

## How to Set up the Bolus Calculator

The **BOLUS CALCULATOR SETUP** screen allows you to program personal settings that will be used with the bolus calculator feature.

After you program all of your settings, review them on the **BOLUS CALCULATOR REVIEW** screen to make sure that they are set correctly.

Instructions for programming the bolus calculator feature settings are in the following paragraphs. Program your settings in the order described to make sure you program all the settings.

## Bolus Calculator Feature on/off

1.  Go to the **BOLUS CALC SETUP** screen.
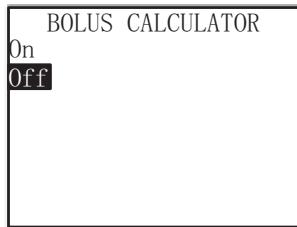
    MAIN MENU➔BOLUS➔BOLUS SETUP➔BOLUS CALC SETUP

2.  Select **Bolus Calculator** and press **OK**.

```
    BOLUS CALC SETUP
Bolus Calculator  Off
IC Ratios          *
Insulin Sensitivity *
BG Target          *
Active Ins Time    6
```

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

3.  Select **On** or **Off** and press **OK** to save your setting and return to the **BOLUS CALC SETUP** screen.

```
        BOLUS  CALCULATOR
On
Off
```

## Insulin to Carb (I:C) Ratios

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

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

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

In the **BOLUS CALC SETUP** screen, select **IC Ratios** and press **OK**.

1. The first segment always starts at midnight. The **Carbs** field is indicated by the highlighted cursor. Press **UP/DOWN** to set the desired value. Press **OK** to confirm and enter the next **Start** time field.

```
        IC  RATIOS
Start  Insulin  Carbs
00:00    1U     100 g
05:30    1U      90 g
13:00    1U     110 g
--:--
```

*Note:* The next available empty ratio segment will appear automatically as you program the previous segment. If the next empty ratio segment does not appear, you have programmed all 8 possible segments.

2.   Press **UP/DOWN** to change the next **Start** time as desired. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight. Press **OK** to confirm and enter the next **Carbs** field.

3.   Continue until ratio segments have been set as recommended by your healthcare provider.

4.   When finished, press **OK** while leaving the next **Start** time empty to exit edit mode and return to the **BOLUS CALC SETUP** screen.

## Insulin Sensitivity

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

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

In the **BOLUS CALC SETUP** screen, select **Insulin Sensitivity** and press **OK**.

1.   The first segment always starts at midnight. The **BG** field is indicated by the highlighted cursor. Press **UP/DOWN** to set the desired value. Press **OK** to confirm and enter the next **Start** time field.

```
 INSULIN  SENSITIVITY
Start  Insulin    BG
00:00   1U   6.5mmol/L
05:30   1U   7.8mmol/L
13:00   1U   8.1mmol/L
--:--
```

*Note:* The next available empty ISF segment will appear automatically as you program the previous segment. If the next empty ISF segment does not appear, you have programmed all 8 possible segments.

2.  Press **UP/DOWN** to change the next **Start** time as desired. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight. Press **OK** to confirm and enter the next **BG** field.

3.  Continue until ISF segments have been set as recommended by your healthcare provider.

4.  When finished, press **OK** while leaving the next **Start** time empty to exit the edit mode and return to the **BOLUS CALC SETUP** screen.

## BG Target

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

If your current BG is above the BG Target Range, the bolus calculator feature will calculate a correction dose. If your current BG is below the BG Target

Range, the bolus calculator will calculate a negative correction and subtract it from your food bolus.

On the **BOLUS CALC SETUP** screen, select **BG Target** and press **OK**.

1. The first segment always starts at midnight. The **BG Range** field is indicated by the highlighted cursor. Press **UP/DOWN** to set the desired value. Press **OK** to confirm and enter the next **Start** time field.

```
            BG  TARGET
    Start  BG  Range  mmol/L
    00:00    4.0 - 9.0
    13:00    4.6 - 11.5
    --:--
```

*Note:* The next available empty BG target segment will appear automatically as you program the previous segment. If the next empty BG target segment does not appear, you have programmed all 8 possible segments.

2. Press **UP/DOWN** to change the next **Start** time as desired. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight. Press **OK** to confirm and enter the next **BG Range** field.

3. Continue until the BG Target segments have been set as recommended by your healthcare provider.

4. When finished, press **OK** while leaving the next **Start** time empty to exit the edit mode and return to the **BOLUS CALC SETUP** screen.
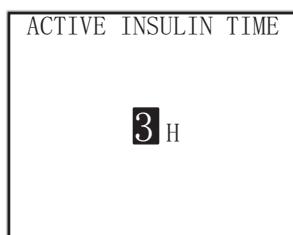
## Active Insulin Time

The active insulin feature helps you calculate how much insulin might still be active in your body from a previous bolus dose. The actual amount of insulin

left in your body is determined by the rate at which your body uses insulin, your infusion site, your activity level, and other factors. Your PDM uses a curvilinear algorithm that mimics the way insulin is metabolized to track active insulin. The active insulin time setting lets the PDM know which active insulin time to use in calculating the amount of active insulin to subtract before estimating a bolus. Your healthcare provider may only have you program the active insulin time that is best for you when you first start using the bolus calculator feature.

In the **BOLUS CALC SETUP** screen, select **Active Ins Time** and press **OK**.

1. Use **UP/DOWN** to change your active insulin time. Press **OK** to save and return to the **BOLUS CALC SETUP** screen.

```
┌─────────────────────────────┐
│  ACTIVE INSULIN TIME        │
│                             │
│                             │
│           3 H               │
│                             │
│                             │
└─────────────────────────────┘
```

## Review Your Bolus Calculator Settings

Check your bolus calculator settings in the **BOLUS CALC REVIEW** screen.

MAIN MENU➔BOLUS➔BOLUS SETUP➔BOLUS CALC REVIEW

In the **BOLUS CALC REVIEW** screen, you can enter the **IC Ratios** screen, **Sensitivity** screen, and **BG Target** screen to view more information.

```
    BOLUS CALC REVIEW
Bolus Calculator    On
Active Ins Time     3h
IC Ratios            *
Sensitivity          *
BG Target            *

```

## Normal Bolus Using Food Bolus Calculator

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

1.  In the **BOLUS** screen, select **Food Bolus Calculator** and press **OK**.

```
         BOLUS
Food Bolus Calculator
Corr Bolus Calculator
Normal Bolus
Preset Bolus
Bolus Setup

```

2.  Use **UP**/**DOWN** to enter your BG value (mmol/L or mg/dL) and press **OK**.

```
FOOD BOLUS CALCULATOR
Enter BG


    8.3 mmol/L


OK continue,ESC exit
```

*Note:* If you are not entering a BG, and want a bolus for food, select the dashes in the **Enter BG** screen, the bolus calculator feature will calculate an estimate of insulin for your food entry without considering your BG level.

3.   Use **UP/DOWN** to enter the amount of carbs. Press **OK**.

```
FOOD BOLUS CALCULATOR
Enter Carbs


         60 g


OK continue,ESC exit
```

4.   The following screen appears with the calculated bolus amount in the **Suggested** field. Press **OK** to continue.
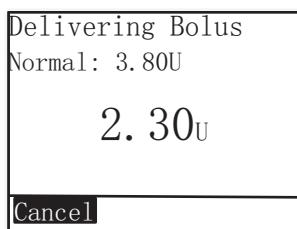
```
FOOD BOLUS CALCULATOR
Suggested: 3.80U
Carbs: 60g
BG: 8.3mmol/L
Food Bolus: 3.75U
Corr Bolus: 0.15U
Active Ins: 0.10U
OK continue,ESC exit
```

5.   You can use **UP/DOWN** to adjust the **Set Bolus** as needed and press **OK**.

```
FOOD BOLUS CALCULATOR
Suggested: 3.80U
Active Ins: 0.10U
Set Bolus: 3.80 U
Type: Normal Bolus


OK continue,ESC exit
```

*Note:* If you have BG Reminder turned on, the **BG REMINDER DURATION** screen appears.

6. Press **OK** to begin the bolus delivery. As the normal bolus delivers, the amount shown on the screen will increase until the entire bolus has been delivered.

```
┌────────────────────────┐
│Delivering Bolus        │
│Normal: 3.80U           │
│                        │
│      2.30ᴜ             │
│                        │
│                        │
│▐Cancel▌                │
└────────────────────────┘
```
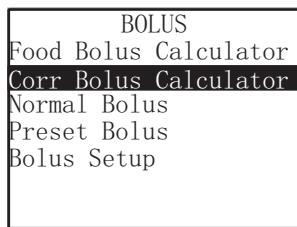
You can cancel an active normal bolus (one that is currently being delivered) even after insulin delivery has started. Press **OK** to cancel the bolus. An on-screen message tells you how much insulin was delivered before you canceled the bolus. Press **ESC** to go back to the **HOME** screen.

## Normal Bolus Using Correction Bolus Calculator

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

1. In the **BOLUS** screen, select **Corr Bolus Calculator** and press **OK**.

```
┌────────────────────────┐
│         BOLUS          │
│Food Bolus Calculator   │
│▐Corr Bolus Calculator▌ │
│Normal Bolus            │
│Preset Bolus            │
│Bolus Setup             │
│                        │
│                        │
└────────────────────────┘
```

2.   Enter your BG value (mmol/L or mg/dL) and press **OK**.

```
┌─────────────────────────┐
│CORR BOLUS CALCULATOR    │
│Enter BG                 │
│                         │
│     ▐10.5▌mmol/L        │
│                         │
│                         │
│OK continue,ESC exit     │
└─────────────────────────┘
```

3.   The  following  screen  appears  with  the  calculated  bolus  amount  in  the **Suggested** field. Press **OK** to continue.

```
┌─────────────────────────┐
│CORR BOLUS CALCULATOR    │
│Suggested: 3.70U         │
│BG: 10.5mmol/L           │
│Corr Bolus: 3.80U        │
│Active Ins: 0.10U        │
│                         │
│OK continue,ESC exit     │
└─────────────────────────┘
```
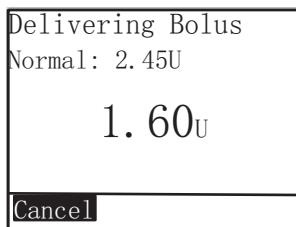
4.   You can use **UP/DOWN** to adjust the **Set Bolus** as needed and press **OK**.

```
┌─────────────────────────┐
│CORR BOLUS CALCULATOR    │
│Suggested: 2.40U         │
│Active Ins: 0.10U        │
│Set Bolus:▐2.45U▌        │
│                         │
│                         │
│OK continue,ESC exit     │
└─────────────────────────┘
```

*Note:* If  you  have  BG  Reminder  turned  on,  the  **BG  REMINDER  DURATION** screen appears.

5.   Press **OK** to begin the bolus delivery. As the normal bolus delivers, the amount shown on the screen will increase until the entire bolus has been

delivered.

```
Delivering Bolus
Normal: 2.45U

      1.60U


Cancel
```
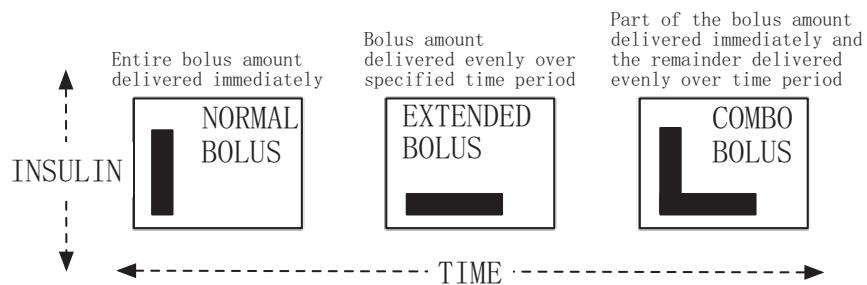
You can cancel an active normal bolus (one that is currently being delivered) even after insulin delivery has started. Press **OK** to cancel the bolus. An on-screen message tells you how much insulin was delivered before you canceled the bolus. Press **ESC** to go back to the **HOME** screen.

## Combo/Extended Bolus

The combo/extended bolus feature is useful for consumption of high carb/high fat meals such as pizza, which has prolonged carb absorption. It is also useful if you will be eating ("grazing") over a few hours or if you have gastroparesis, which means food remains in the stomach for a longer period than normal.

See the following graphic for a description of the different bolus types.
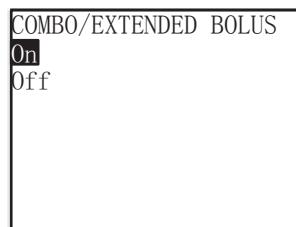
## Turn on the Combo/Extended Bolus Feature

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

To set up a combo bolus, you must first turn on the **Combo/Extended Bolus** option.

1.  Go to the **COMBO/EXTENDED BOLUS** screen.

    MAIN MENU➔BOLUS➔BOLUS SETUP➔COMBO/EXTENDED BOLUS
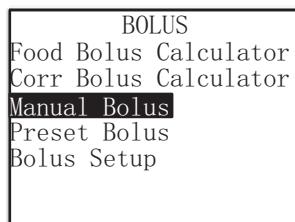


2.  Select **On** and press **OK**.
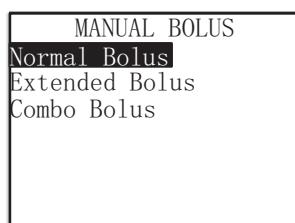
## Combo/Extended Bolus Without Bolus Calculator

*Note*: To deliver a combo bolus or extended bolus, the **Combo/Extended Bolus** option must be on.

1.  Make sure the **Combo/Extended Bolus** option is on.

2.  Calculate your food and/or correction bolus amount.

3.  In the **BOLUS MENU** screen, select **Manual Bolus** and press **OK**.

```
            BOLUS
Food Bolus Calculator
Corr Bolus Calculator
Manual Bolus
Preset Bolus
Bolus Setup
```

4.  The **MANUAL BOLUS** screen appears.

```
       MANUAL  BOLUS
Normal Bolus
Extended Bolus
Combo Bolus
```

### Extended Bolus

To set an Extended bolus, follow these steps:

a.  Select **Extended Bolus** and press **OK**. The **EXTENDED BOLUS** screen appears.

b.   Enter the desired amount for extended bolus units and press **OK**.

```
       EXTENDED  BOLUS
Set Bolus


        5.00 U


OK continue,ESC exit
```

c.   Enter the amount of time you want the extended bolus to last and press **OK**.
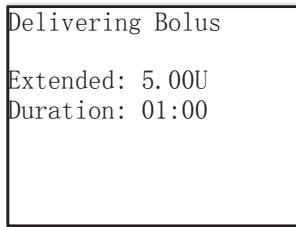
```
       EXTENDED  BOLUS
Extended Bolus: 5.00U
Duration:
        01:00


OK continue,ESC exit
```

d.   Details of the extended bolus will be displayed, press **OK** to start delivery.

```
       EXTENDED  BOLUS
Start Bolus?
Normal:          0U
Extended:     5.00U
(01:00)      _____
Total:        5.00U

OK continue,ESC exit
```

*Note:* If you have BG Reminder turned on, the **BG REMINDER DURATION** screen appears.

e.   This screen indicates the start of bolus delivery.

```
Delivering Bolus

Extended: 5.00U
Duration: 01:00


```
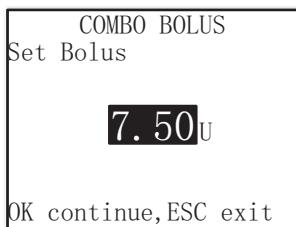
## Combo Bolus

To set a Combo bolus, follow these steps:

a.   Select **Combo Bolus** and press **OK**. The **COMBO BOLUS** screen appears.

b.   Enter the desired amount for the total combo bolus units and press **OK**.

*Note:* The number of units you enter for the combo bolus is a total of normal bolus and extended bolus units.

```
     COMBO BOLUS
Set Bolus


      7.50 U


OK continue,ESC exit
```

c.   Press **UP**/**DOWN** to change the number. When the setting is correct, press **OK** to continue.

```
        COMBO  BOLUS
Set Bolus: 7.50U
Normal: 67% 5.00U
Extended: 33% 2.50U



OK continue,ESC exit
```

d.   Enter the amount of time you want the extended bolus to last and press
     **OK**.

```
        COMBO  BOLUS
Extended Bolus: 2.50U
Duration:

      01:30


OK continue,ESC exit
```
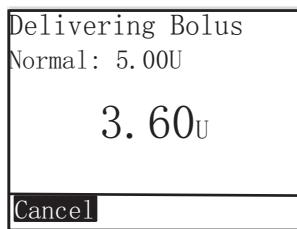
e.   Details of the combo bolus will be displayed. Press **OK** to start delivery.

```
        COMBO  BOLUS
Start Bolus?
Normal:         5.00U
Extended:       2.50U
(01:30)        ──────
Total:          7.50U

OK continue,ESC exit
```

*Note:* If you have BG Reminder turned on, the **BG REMINDER DURATION**
screen appears.

f.    This screen indicates bolus delivery.

```
┌─────────────────────────────┐
│ Delivering Bolus            │
│ Normal: 5.00U               │
│                             │
│          3.60ᴜ              │
│                             │
│                             │
│ Cancel                      │
└─────────────────────────────┘
```
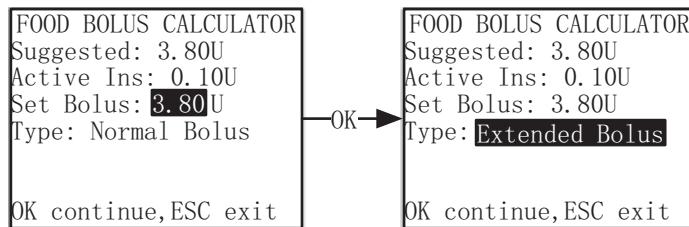
## Combo/Extended Bolus Using Bolus Calculator

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

1.  The bolus calculator feature must be turned on and the settings must be programmed. Also, make sure the combo/extended option is turned on.

2.  After you enter your BG and/or carbs, the calculated bolus amount appears in the **Suggested** field. Press **OK** to continue to step 3. If you need to make any changes, press **ESC** to return to the **Enter BG** screen, make changes as necessary.

3.  You can use **UP**/**DOWN** to adjust the **Set Bolus** as needed and press **OK**.

4.  Scroll to the **Type** field, press **UP**/**DOWN** to select a bolus type (Normal Bolus, Extended Bolus, or Combo Bolus).

```
FOOD BOLUS CALCULATOR          FOOD BOLUS CALCULATOR
Suggested: 3.80U               Suggested: 3.80U
Active Ins: 0.10U              Active Ins: 0.10U
Set Bolus: 3.80U               Set Bolus: 3.80U
Type: Normal Bolus             Type: Extended Bolus


OK continue,ESC exit          OK continue,ESC exit
```

—OK→
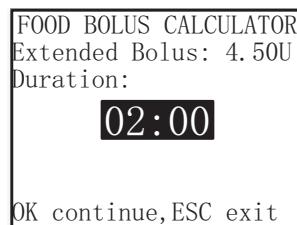
*Note:* If there is an active extended bolus, the extended or combo bolus will not be available until the active extended bolus finished.
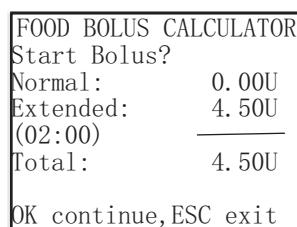
## Extended Bolus

To set an Extended bolus, follow these steps:

a.  The extended duration screen appears. Enter the amount of time you want the extended bolus to last and press **OK**.
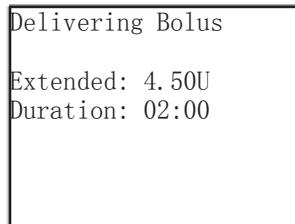
```
FOOD BOLUS CALCULATOR
Extended Bolus: 4.50U
Duration:
        02:00


OK continue,ESC exit
```

b.  Details of the extended bolus will be displayed, press **OK** to start delivery.

```
FOOD BOLUS CALCULATOR
Start Bolus?
Normal:          0.00U
Extended:        4.50U
(02:00)          ─────
Total:           4.50U

OK continue,ESC exit
```

*Note:* If you have BG Reminder turned on, the **BG REMINDER DURATION** screen appears.

c.  This screen indicates the start of bolus delivery.

```
Delivering Bolus

Extended: 4.50U
Duration: 02:00
```
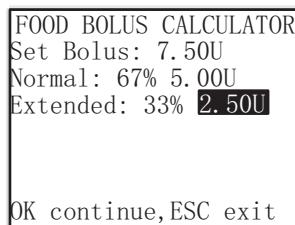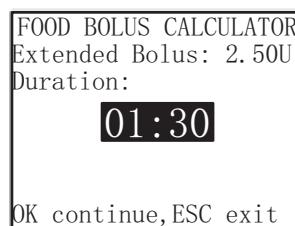
## Combo Bolus

To set a Combo bolus, follow these steps:

a.  Press **UP/DOWN** to change the number. When the setting is correct, press **OK** to continue.

```
FOOD BOLUS CALCULATOR
Set Bolus: 7.50U
Normal: 67% 5.00U
Extended: 33% 2.50U


OK continue,ESC exit
```

b.  Enter the amount of time you want the extended bolus to last and press **OK**.

```
FOOD BOLUS CALCULATOR
Extended Bolus: 2.50U
Duration:
      01:30


OK continue,ESC exit
```

c.  Details of the combo bolus will be displayed, press **OK** to start delivery.

```
┌─────────────────────────┐
│FOOD BOLUS CALCULATOR    │
│Start Bolus?             │
│Normal:         5.00U    │
│Extended:       2.50U    │
│(01:30)                  │
│Total:          7.50U    │
│                         │
│OK continue,ESC exit     │
└─────────────────────────┘
```

*Note:* If you have BG Reminder turned on, the **BG REMINDER DURATION** screen appears.

d.  This screen indicates bolus delivery.

```
┌─────────────────────────┐
│Delivering Bolus         │
│Normal: 5.00U            │
│                         │
│        0.90U            │
│                         │
│                         │
│Cancel                   │
└─────────────────────────┘
```

# Preset Bolus

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

## Preset Bolus Setup

1.  Go to the **PRESET BOLUS SETUP** screen.

MAIN MENU➜BOLUS➜BOLUS SETUP➜PRESET BOLUS SETUP

```
PRESET  BOLUS  SETUP
■ Breakfast      4.65U
□ Lunch          3.20U
□ Dinner
□ Snack
□ Bolus  1
□ Bolus  2
□ Bolus  3
```

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

3. Choose a bolus type. For a normal bolus, set the bolus amount. For an extended bolus, set the bolus amount and duration. For a combo bolus, set the bolus amount, normal/extended percentages, and duration.

*Note*: The **BOLUS TYPE** screen only appears when the Combo/Extended Bolus feature is turned on.

4. Press **OK** to save the settings.

*Note*: If the Combo/Extended Bolus feature is turned off later, your existing preset bolus settings are still available for use.

## Deliver a Preset Bolus

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

1. Go to the **PRESET BOLUS** screen.

MAIN MENU➜BOLUS➜PRESET BOLUS

```
          PRESET  BOLUS
■ Breakfast      4.65U
□ Lunch          3.20U
□ Bolus 1        2.40U
```

The existing preset bolus settings are displayed on this screen. If you have not set up any preset bolus, this screen is blank.

2.    Select the preset bolus you want to deliver.

3.    Verify your preset bolus settings.

4.    Start bolus delivery.

# Missed Bolus Reminder

Missed Bolus Reminder feature is used to alert you if you do not deliver a carb bolus manually or using the bolus calculator within a given period of time. If you do not deliver a bolus within the Missed Bolus Reminder time period, the **MISSED BOLUS REMINDER** appears.
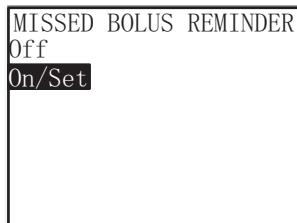
## Add, Delete and Review Reminders

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

1.    Go to the **MISSED BOLUS REMINDER** screen.

2.   Select **On/Set**. Press **OK**.

```
MISSED BOLUS REMINDER
Off
On/Set
```

3.   Go to the **SET BOLUS REMINDER** screen.

## Add Reminder

a.   Select **Add Reminder** and press **OK**.

```
  SET BOLUS REMINDER
Add Reminder
Delete Reminder
Review Reminders
```

*Note:* If reminders are full, **Add Reminder** will be invalid.

b.   Set the start time, and press **OK**. Set the end time, and press **OK**.

```
        ADD  REMINDER
     Start        End
     07:00       07:30
     11:30       12:00
     18:00       19:00
     ──:──
OK  to  confirm,  ESC  to
cancel
```

*Note:* You can program up to four missed bolus reminders.

c.    Press **OK** to save your settings and return to the previous menu.

## Delete Reminder

a.    Select **Delete Reminder** and press **OK**.

```
   SET  BOLUS  REMINDER
Add  Reminder
Delete  Reminder
Review  Reminders



```
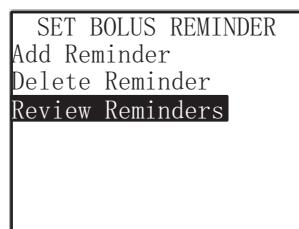
*Note:* If reminders are empty, **Delete Reminder** will be invalid.

b.    Select the bolus reminder you want to delete and press **OK**.

```
      DELETE  REMINDER
    Start        End
    07:00       07:30
    11:30       12:00
    18:00       19:00

OK to confirm, ESC to
cancel
```
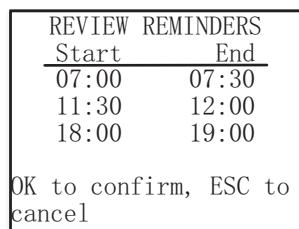
## Review Reminders

a.  Select **Review Reminders** and press **OK**.

```
   SET  BOLUS  REMINDER
Add Reminder
Delete Reminder
Review Reminders



```

b.  Review your Missed Bolus Reminders

```
   REVIEW  REMINDERS
    Start        End
    07:00       07:30
    11:30       12:00
    18:00       19:00

OK to confirm, ESC to
cancel
```
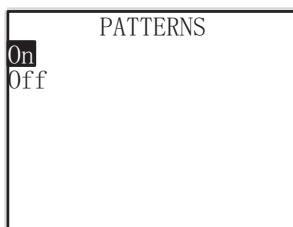
# Basal Patterns

You can program up to 5 basal patterns with the A6 TouchCare® System. Having more than one pre-set basal pattern makes it easy for you to switch patterns based on your different needs such as weekends, weekdays, shift work, and menstruation.

- **Standard:** Your normal basal pattern that supports your usual day-to-day activity. When the **PATTERNS** feature is turned off, only your Standard basal pattern is available.

- **Exercise:** Your exercise basal pattern that supports your exercise activity.

- **Holiday:** Your holiday basal pattern that supports your holiday activity.

- **Pattern A/B:** Basal patterns that support activity levels that are not part of your day-to-day routine, but are normal in your lifestyle, such as menstruation, etc.

## Turn on Multiple Basal Patterns

1. Go to the **PATTERNS** screen.

MAIN MENU➜BASAL➜BASAL SETUP➜PATTERNS

```
        PATTERNS
On
Off
```

2.  Select **On** and press **OK** to save your setting and return to the previous menu. The multiple basal patterns feature is now on.

*Note:* If a basal pattern other than **Standard** is active, you cannot turn off the multiple basal patterns feature.

## Set a Basal Pattern

You can set up to 5 basal rates for a Standard basal pattern, and up to 48 basal rates for all the other patterns.

1.  Go to the **EDIT BASAL** screen.

    MAIN MENU➔BASAL➔BASAL SETUP➔EDIT BASAL

2.  Select the basal pattern you want to edit and press **OK**.

```
           EDIT BASAL
      ■ Standard       0.00U
      □ Exercise       0.00U
      □ Holiday        0.00U
      □ Pattern A      0.00U
      □ Pattern B      0.00U
```

3.  The edit screen appears. The **U/H** field is indicated by a highlighted cursor. Press **UP/DOWN** to set a desired basal rate. Press **OK** to confirm and enter the next **Start** time field.

```
┌─────────────────────────────┐
│  STANDARD   0.00U           │
│  Start        U/H           │
│   00:00      [0.00]         │
│   - -:- -                   │
│                             │
│                             │
│                             │
└─────────────────────────────┘
```

*Note:* The next available empty basal segment will appear automatically as you program the previous segment. If the next empty basal segment does not appear, you have programmed all possible segments.

4.  Press **UP/DOWN** to change the next **Start** time as desired. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight. Press **OK** to confirm and enter the next **U/H** field.

5.  Continue until basal segments have been set as recommended by your healthcare provider.

6.  When finished, press **OK** while leaving the next **Start** time empty to exit the edit mode and return to the previous menu.

```
┌─────────────────────────────┐
│  STANDARD   24.20U          │
│  Start        U/H           │
│   00:00      0.80           │
│   03:30      1.20           │
│   08:00     [1.00]          │
│   - -:- -                   │
│                             │
└─────────────────────────────┘
```

*Note:* As a safety feature, the system suspends basal delivery when you are editing an active basal pattern, and resumes delivery after the edits are made. When a temporary basal is in process, the selected pattern will not program.

## Select a Basal Pattern

Before you try to select a basal pattern to be active, make sure the multiple basal patterns feature is turned on.

1. Go to the **SELECT PATTERN** screen.

    MAIN MENU➜BASAL➜SELECT PATTERN

2. Select the desired pattern, press **OK** to activate it.

```
        SELECT PATTERN
  ■ Standard      24.20U
  □ Exercise      20.00U
  □ Holiday       26.00U
  □ Pattern A      0.00U
  □ Pattern B      0.00U
```

# Temp Basal

A temp basal rate allows you to adjust your basal rate for a short period of time to manage glucose during temporary activities or different conditions. For example, you might want to increase basal rate on sick days, or decrease during exercise. You can set the duration of a temp basal rate up to 24 hours in half-hour increments.
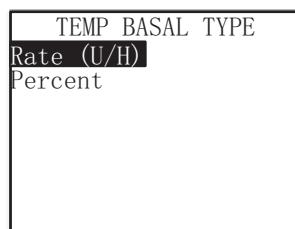
*Note:* During a temp basal delivery, the basal pattern is temporarily overridden. After the temp basal delivery is completed or canceled, your system will return to the selected basal pattern.

## Activate a Temp Basal
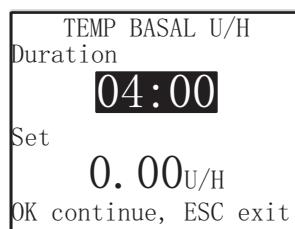
1. Go to the **TEMP BASAL** screen.

   MAIN MENU➜BASAL➜TEMP BASAL
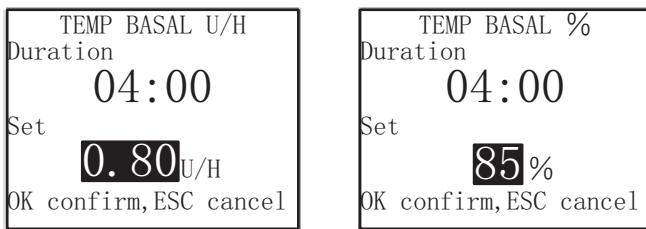
2. Select a temp basal type.

```
      TEMP  BASAL  TYPE
Rate  (U/H)
Percent
```

3. Press **UP/DOWN** to set desired temp basal duration. Press **OK** to continue.

```
     TEMP  BASAL  U/H
Duration
        04:00
Set
     0. 00 U/H
OK continue, ESC exit
```

4. Press **UP/DOWN** to set desired temp basal rate or percentage. Press **OK** to start temp basal delivery.

```
┌─────────────────────────┐   ┌─────────────────────────┐
│     TEMP BASAL U/H      │   │     TEMP BASAL %        │
│ Duration                │   │ Duration                │
│        04:00            │   │        04:00            │
│ Set                     │   │ Set                     │
│      [0.80]U/H          │   │      [85]%              │
│ OK confirm,ESC cancel   │   │ OK confirm,ESC cancel   │
└─────────────────────────┘   └─────────────────────────┘
```
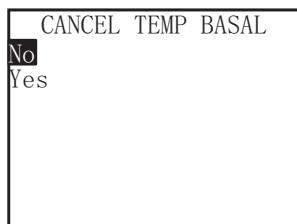
## Cancel a Temp Basal

1.  Go to the **CANCEL TEMP BASAL** screen.

    MAIN MENU➜BASAL➜CANCEL TEMP BASAL

2.  Select **Yes**.

```
┌─────────────────────────┐
│   CANCEL  TEMP  BASAL   │
│ [No]                    │
│ Yes                     │
│                         │
│                         │
│                         │
└─────────────────────────┘
```

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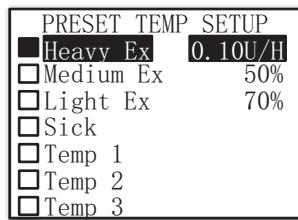
# Preset Temp Basal

The preset temp basal feature allows you to 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, Temp 2, and Temp 3.

## Preset Temp Basal Setup

1.  Go to the **PRESET TEMP SETUP** screen.

    MAIN MENU➜BASAL➜BASAL SETUP➜PRESET TEMP SETUP

    ```
     PRESET  TEMP  SETUP
    ■Heavy Ex    0.10U/H
    □Medium Ex       50%
    □Light Ex        70%
    □Sick
    □Temp 1
    □Temp 2
    □Temp 3
    ```

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. Press **OK** to save settings.

## 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

```
┌─────────────────────────────────┐
│ PRESET  TEMP  BASAL             │
│ ■Heavy Ex    0. 10U/H          │
│ □Medium Ex        50%          │
│ □Light Ex         70%          │
│                                 │
│                                 │
│                                 │
└─────────────────────────────────┘
```

The programmed preset temp basals are displayed on this screen. If you have not set up any preset temp basal rate, this screen is blank.

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

3.  Verify your preset temp basal settings.

4.  Start basal delivery.

# How to Change the Sensor
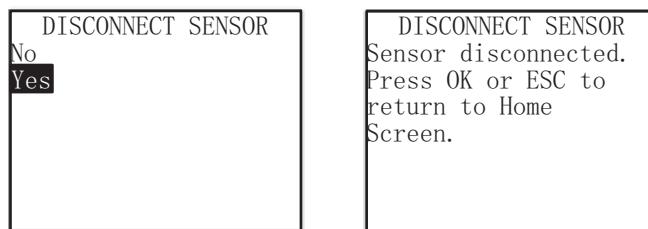
## Disconnect Sensor from Your PDM

Your Sensor gives glucose readings for up to seven days. After a Sensor expires or fails, your sensor session will end automatically, and glucose readings won't be displayed on the PDM. You must remove the Sensor and disconnect the Transmitter.

If you want to remove a Sensor before its expiration, you must disconnect it from your PDM first; otherwise a **Sensor Failure** alert may occur when you connect a new Sensor.

Go to **DISCONNECT SENSOR** screen, select **Yes** and press **OK**.
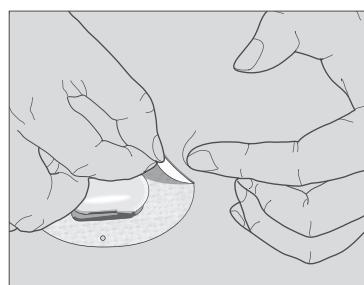
MAIN MENU➜SENSOR➜DISCONNECT SENSOR

```
    DISCONNECT SENSOR
No
Yes
```

```
    DISCONNECT SENSOR
Sensor disconnected.
Press OK or ESC to
return to Home
Screen.
```
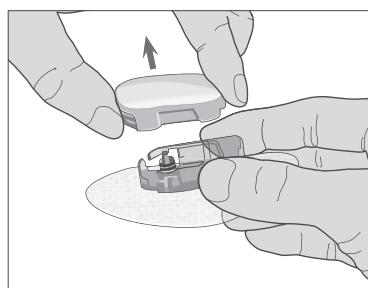
*Note*: The **Disconnect Sensor** option is only available when a Sensor is currently connected to the PDM.

# Remove the Current Sensor and Disconnect the Transmitter

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



2. Pinch the center of 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.

# 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 DC5V and a rated current higher than DC100mA. 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 using the Transmitter, which may take up to 5 hours. It is recommended to recharge the Transmitter after each sensor use. If you recharge the Transmitter battery after each sensor session (7 days), it may take you up to 40 minutes to fully recharge the Transmitter battery. If you recharge the Transmitter battery after two sensor sessions (14 days), it may take you about 90 minutes to fully recharge the Transmitter battery. 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 green when the Transmitter is charging.

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

# Insert a New Sensor
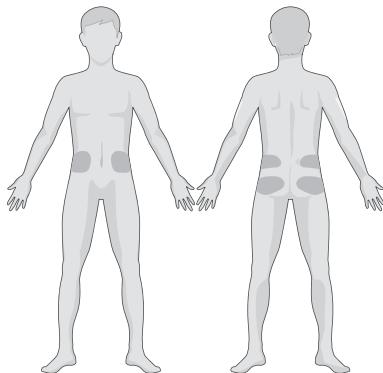
## Select an Insertion Site

When inserting the Senor, choose an area with adequate subcutaneous fat. This area should stay flat during normal daily activities without bending or creasing. The Sensor site should be at least 7.5 cm (3 inches) away from an insulin Pump infusion site or manual injection site. The insulin might affect

sensor performance, and you might miss a low or high blood glucose value.

Avoid inserting the Sensor into areas of skin with scarring, tattoos, or irritation. Do not place the Sensor in areas that are constrained by clothing, such as the belt line or waist. Also do not place the Sensor in areas that involve rigorous movement during exercise. Avoid sites 5 cm (2 inches) around navel. Avoid areas with excess hair, or consider shaving the area.

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

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. Select a new insertion site at least 5 cm (2 inches) from the previous site.

## Prepare the Insertion Site

1.  Wash your hands thoroughly with soap and water, and let them dry.

2.  Wipe the selected insertion area with rubbing alcohol, and allow the area to dry. This may help prevent infection. Do NOT insert the Sensor until the

cleaned area is dry. This will allow the sensor adhesive to stick better.

**Warning:** If the Sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable or no results. Improper site selection and improper site preparation may cause poor adhesion.

## Remove the Glucose Sensor from the Package

Remove the Glucose Sensor from its sterile package by peeling off the paper on the back of the package.
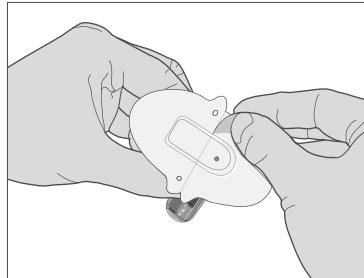
**Warning:** Do NOT use a Sensor if its sterile package has been damaged or opened, or the Sensor has expired, or the Sensor is damaged in any way.

*Note:* Wash your hands with soap and water, and let them dry before opening the Sensor package and handling Sensor. After opening the package, avoid touching any Sensor surface that will come in contact with the body, i.e., adhesive surface. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the Sensor.

## Remove the Protective Liner from the Sensor Support Mount
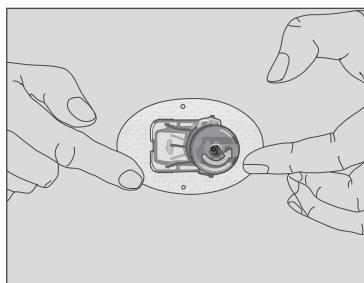
Bend the two-piece protective liner slightly so you can see the seam between the two pieces. Remove the liner from the sensor support mount one half at a time, using the white tabs on the backing. Hold the Sensor by the inserter, and try not to touch the adhesive surface.

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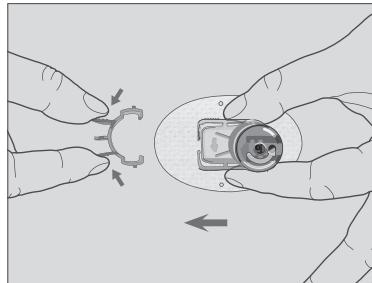
If you are inserting the Sensor on your abdomen or lower back, place the Sensor horizontally on your skin.

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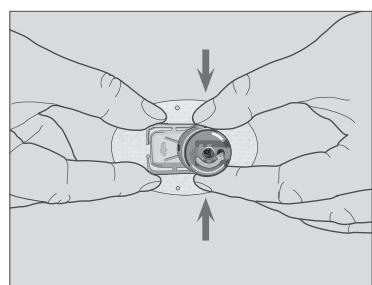


## Remove the Safety Lock

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. Save the safety lock, you will need it later.
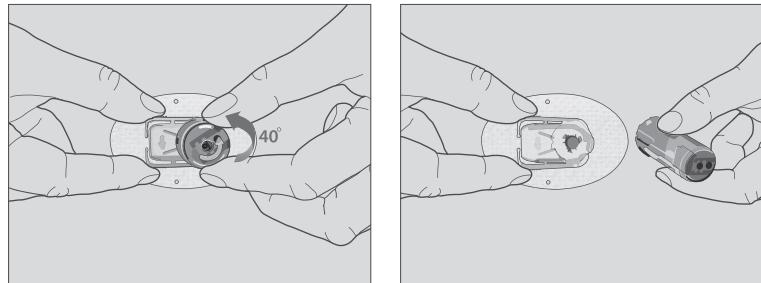
## Insert Sensor

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



## Remove Inserter

Twist the inserter about a 40° turn in the direction shown, and lift the inserter away from the mount. Only the sensor support mount will be left on your body.

## Check the Sensor Support Mount

Confirm 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 does not stop, 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.

## Discard the Sensor Inserter Safely

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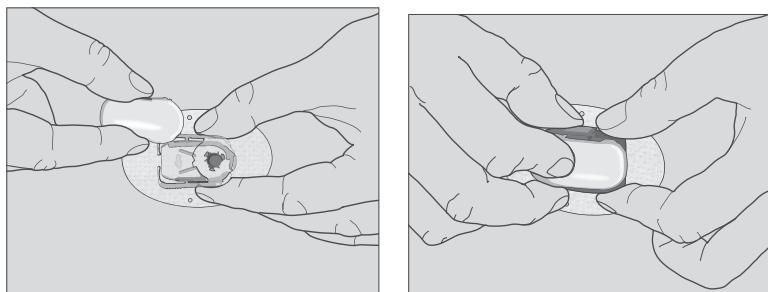
puncture-proof container with a tight lid.

## Attach Your Transmitter

Before attaching the Transmitter to the Sensor, you must have the Transmitter battery fully charged and the PDM set up. After the Sensor is inserted, follow these steps to attach your Transmitter:

1.  Wipe the bottom of the Transmitter with an alcohol wipe and let it dry before every use.

2.  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.

*Note:* Make sure you hear a click when you snap the Transmitter in place. If it is not fully snapped in, poor electrical connection and compromised waterproof performance may result, which can lead to inaccurate sensor glucose readings.



## Tape the Sensor Support Mount (Optional)
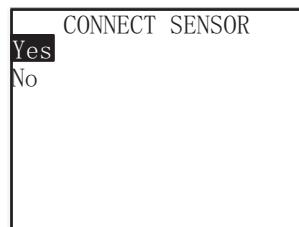
The sensor support mount should stay on your skin using its own adhesive. But,

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 patch on all sides for even support. Do NOT tape over the Transmitter or any of the plastic parts on the sensor support mount.

# Connect Sensor to Your PDM
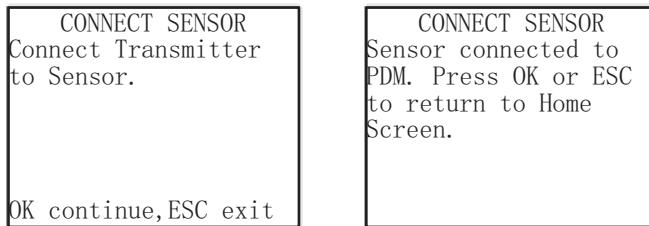
1.  Go to **CONNECT SENSOR** screen, select **Yes** and press **OK**.

<p align="center">MAIN MENU➔SENSOR➔CONNECT SENSOR</p>

```
        CONNECT  SENSOR
  Yes
  No



```

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

2.  Make sure your Transmitter is connected to a Sensor and that your Transmitter SN is found or entered, and then continue to connect the Sensor to your PDM.

```
      CONNECT  SENSOR
  Connect Transmitter
  to Sensor.




  OK continue,ESC exit
```

```
      CONNECT  SENSOR
  Sensor connected to
  PDM. Press OK or ESC
  to return to Home
  Screen.


```
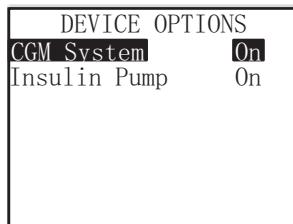
# CGM Features

## CGM Feature on/off

### Turn on/off the CGM Feature
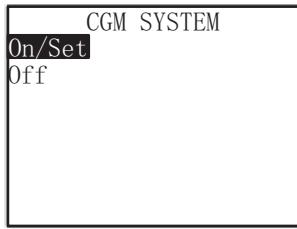
The CGM feature must be turned on to receive sensor data.

1. Select **Device Options** in the **UTILITIES** menu, hold down **B/S** and press **OK** to go to the **DEVICE OPTIONS** screen.

   MAIN MENU➔UTILITIES➔DEVICE OPTIONS

   ```
        DEVICE OPTIONS
   CGM System        On
   Insulin Pump      On
   ```
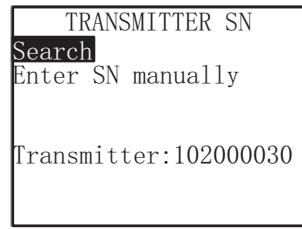
2. Use **UP/DOWN** to choose **CGM System**, and then press **OK** to go to the **CGM SYSTEM** screen. Select **On/Set** to turn on the CGM feature, or select **Off** to turn off the CGM feature.
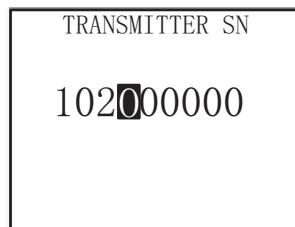
```
        CGM  SYSTEM
On/Set
Off
```

## Set the Transmitter SN

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

1.  After you turn on the CGM System, the **TRANSMITTER SN** Screen appears. Your current Transmitter SN shows on the bottom.

```
      TRANSMITTER  SN
Search
Enter  SN  manually


Transmitter:102000030
```
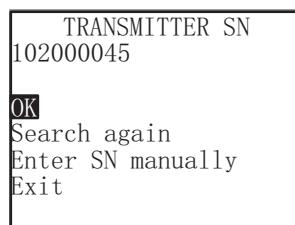
2.  You can enter your new Transmitter SN manually. Use **UP**/**DOWN** to select from 0 to 9. Press **OK** to move the highlighted cursor to the next digit.

```
          TRANSMITTER  SN

          102000000
```
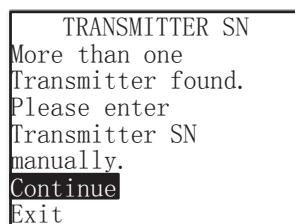
3.    You can also use your PDM to search for your Transmitter.

    If your PDM finds one Transmitter, the Transmitter SN appears on the
    screen. You can confirm it if it matches the SN printed on your
    Transmitter.

```
        TRANSMITTER  SN
    102000045

    OK
    Search again
    Enter SN manually
    Exit
```
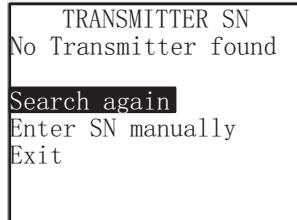
    If your PDM finds multiple Transmitters, the SNs won't be displayed to
    prevent you from selecting the wrong SN. You need to enter the SN
    printed on your Transmitter manually.

```
        TRANSMITTER  SN
    More than one
    Transmitter found.
    Please enter
    Transmitter SN
    manually.
    Continue
    Exit
```

    If your PDM does not find a Transmitter, make sure your Transmitter is

fully charged, move the PDM closer to your Transmitter, and search again
or enter the SN manually.

```
┌─────────────────────────────┐
│      TRANSMITTER SN         │
│ No Transmitter found        │
│                             │
│ ███████████                 │
│ Search again                │
│ Enter SN manually           │
│ Exit                        │
│                             │
└─────────────────────────────┘
```
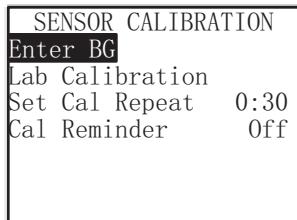
## Calibrate Your Sensor

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. Continuous Glucose Monitoring will begin after you have completed
the first calibration after the Sensor warmup.

Go to the **SENSOR CALIBRATION** screen.

MAIN MENU➔SENSOR➔SENSOR CALIBRATION

```
┌─────────────────────────────┐
│    SENSOR CALIBRATION       │
│ ██████                      │
│ Enter BG                    │
│ Lab Calibration             │
│ Set Cal Repeat     0:30     │
│ Cal Reminder       Off      │
│                             │
│                             │
└─────────────────────────────┘
```

*Note*: Calibration should be done at least once every 12 hours. Calibrating less
than every 12 hours may cause sensor glucose readings to be inaccurate, and
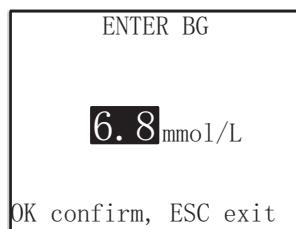
you might miss a low or high blood glucose value.

## 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➔ENTER BG

```
       ENTER BG


       6.8mmol/L

OK confirm, ESC exit
```
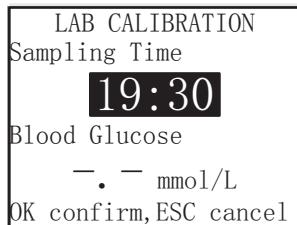
2. Press **UP/DOWN** to choose a correct BG value, and press **OK** to confirm.

## Lab Calibration

If your venous blood sample was collected and analyzed by healthcare providers, you can use the laboratory blood glucose value to calibrate your Sensor 8 minutes to 2 hours after blood sampling.

Go to the **LAB CALIBRATION** screen.

MAIN MENU➜SENSOR➜SENSOR CALIBRATION➜LAB CALIBRATION

```
       LAB CALIBRATION
Sampling Time
         19:30
Blood Glucose
        ⎯.⎯  mmol/L
OK confirm,ESC cancel
```

1. Press **UP/DOWN** to choose a sampling time. Press **OK** to confirm and enter the next **Blood Glucose** field.

2. Press **UP/DOWN** to choose a correct BG value, and press **OK** to confirm.

## Set Calibration Repeat

Go to the **SET CAL REPEAT** screen.

MAIN MENU➜SENSOR➜SENSOR CALIBRATION➜SET CAL REPEAT

```
       SET CAL REPEAT
Repeat
        00:25
```

Here you can set the repeat time of **METER BG NOW** alert from 5 minutes to 1 hour. The alert repeats until you enter a new meter blood glucose measurement.
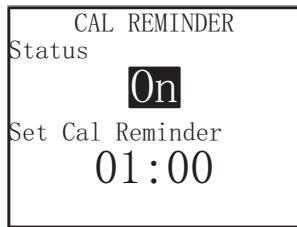
## Calibration Reminder

You can use the Cal Reminder feature to remind you to calibrate the Sensor.

1. Go to the **CAL REMINDER** screen.

   MAIN MENU➔SENSOR➔SENSOR CALIBRATION➔CAL REMINDER

2. Press **UP**/**DOWN** to turn Cal Reminder on/off. Press **OK** to confirm. Press **UP/DOWN** to change the time the Calibration Reminder appears before a new meter BG must be entered. Press **OK** to confirm.

```
         CAL REMINDER
Status
            On

Set Cal Reminder
         01:00
```

## Set Your Sensor

Go to the **SENSOR SETUP** screen.

MAIN MENU➔SENSOR➔SENSOR SETUP

```
        SENSOR SETUP
Glucose Alerts      On
Glucose Limits       *
Snooze               *
Predictive Alerts    *
Rate Alerts          *
Graph Range        12H
```

## Glucose Alerts

You must turn the glucose alerts on so the system can send you an alert when the sensor glucose reading reaches or exceeds your limits.

1.  Go to the **GLUCOSE ALERTS** screen.

    MAIN MENU➔SENSOR➔SENSOR SETUP➔GLUCOSE ALERTS

```
      GLUCOSE  ALERTS
On
Off
```

2.  Select **On** and press **OK** to turn the glucose alerts on.

## Glucose 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, so your PDM allows you to set up to eight pairs.

1. Go to the **GLUCOSE LIMITS** screen.

MAIN MENU➜SENSOR➜SENSOR SETUP➜GLUCOSE LIMITS

```
GLUCOSE LIMITS mmol/L
  Start    Low    High
 00:00    4.0    9.0
 07:30    4.5    11.0
 13:00    4.6    12.2
 --:--
```

The start time for your first pair of Glucose Limits is midnight (00:00) and cannot be changed.

2. The first segment always starts at midnight. The **Low** field is indicated by the highlighted cursor. Press **UP/DOWN** to set desired value. Press **OK** to confirm and enter the next **High** field. Press **UP/DOWN** to set desired value. Press **OK** to confirm and enter the next **Start** time field.

*Note:* The next available empty Glucose Limits segment will appear automatically as you program the previous segment. If the next empty Glucose Limits segment does not appear, you have programmed all 8 possible segments.

Press **UP/DOWN** to change the next **Start** time as desired. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight. Press **OK** to confirm and enter the next **Low** field.

Continue until Glucose Limits segments have been set as recommended by your healthcare provider.

3. When finished, press **OK** while leaving the next **Start** time empty to exit the edit mode and return to the **SENSOR SETUP** screen.

## Snooze

You can set the amount of time between alerts after the first alert. After you receive and clear a **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.

1.  Go to the **SNOOZE** screen.

    MAIN MENU➔SENSOR➔SENSOR SETUP➔SNOOZE

    ```
              SNOOZE
    Type  Status  Repeat
    High   On      00:20
    Low    Off     --:--
    ```

2.  The **Status** field of the **High** segment is indicated by the highlighted cursor. Press **UP/DOWN** to set **On** or **Off**. Press **OK** to confirm and enter the next **Repeat** field. Press **UP/DOWN** to set a desired value. Press **OK** to confirm and enter the next **Status** field of the **Low** segment. Continue until the **Low** segment has been set as desired.

3.  When finished, press **OK** to exit the edit mode and return to the **SENSOR SETUP** screen.

## Predictive Alerts

The predictive alerts calculate when you will 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 selected.

1. Go to the **PREDICTIVE ALERTS** screen.

   MAIN MENU➜SENSOR➜SENSOR SETUP➜PREDICTIVE ALERTS

```
┌─────────────────────────┐
│   PREDICTIVE  ALERTS     │
│ Type   Status    Time    │
│ High   On        00:20   │
│ Low    Off       --:--   │
│                          │
│                          │
│                          │
└─────────────────────────┘
```

2. The **Status** field of the **High** segment is indicated by the highlighted cursor. Press **UP/DOWN** to set **On** or **Off**. Press **OK** to confirm and enter the next **Time** field. Press **UP/DOWN** to set desired value. Press **OK** to confirm and enter the next **Status** field of the **Low** segment. Continue until the **Low** segment has been set as desired.

3. When finished, press **OK** to exit the edit mode and return to the **SENSOR SETUP** screen.

## 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

1. Go to the **RATE ALERTS** screen.

MAIN MENU➜SENSOR➜SENSOR SETUP➜RATE ALERTS

```
        RATE  ALERTS
  Type    Status   Rate
  Rise     On      0.220
  Fall     Off     -.-
          (mmol/L/Min)
```
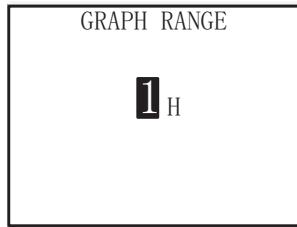
2. The **Status** field of the **Rise** segment is indicated by the highlighted cursor. Press **UP/DOWN** to set **On** or **Off**. Press **OK** to confirm and enter the next **Rate** field. Press **UP/DOWN** to set a desired value. Press **OK** to confirm and enter the next **Status** field of the **Fall** segment. Continue until the **Fall** segment has been set as desired.

3. When finished, press **OK** to exit the edit mode and return to the **SENSOR SETUP** screen.

## Graph Range

You can see Trend Graphs of your glucose information for the past 1-hour, 3-hour, 6-hour, 12-hour, and 24-hour periods. These Glucose Trend Graphs show you where your glucose levels have been and where your glucose levels are headed.

1. Go to the **GRAPH RANGE** screen.

MAIN MENU➜SENSOR➜SENSOR SETUP➜GRAPH RANGE

```
┌─────────────────────────┐
│      GRAPH  RANGE        │
│                         │
│         █ H             │
│                         │
│                         │
│                         │
└─────────────────────────┘
```

2. Press **UP**/**DOWN** to select the number as desired. Press **OK** to confirm.

## Alert Silence

**Warning:** Muting the alarms is not recommended during times 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 buttons and viewing the screen.

The Alert Silence feature allows you to keep glucose alerts silent for a specified time of 30 minutes to 24 hours.

There are five Alert Silence options:

- **Off**— This means all alerts are 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.

- **Hi and Lo** — 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.

1. Go to the **ALERT SILENCE** screen.

    MAIN MENU➔SENSOR➔ALERT SILENCE

```
        ALERT SILENCE
Type
          Off
Duration
         01:00
```
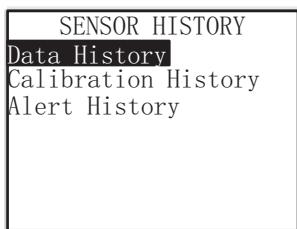
2. The **Type** field is indicated by the highlighted cursor. Press **UP/DOWN** to select an alert silence option. Press **OK** to confirm and enter the next **Duration** field. Press **UP/DOWN** to set the time as desired.

## 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

```
        SENSOR HISTORY
Data History
Calibration History
Alert History
```

## Data History

1.  Select **Data History** in the **SENSOR HISTORY** screen and press **OK**.

    The **DATA HISTORY** screen shows you 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 19-06-2015 6/12/17 means the sensor was started on 19-06-2015 and has been used for 6 days 12 hours and 17 minutes.

```
        DATA HISTORY
19-06-2015 6/12/17
12-06-2015 6/23/30
05-06-2015 7/0/0
11-02-2015 7/0/0
04-02-2015 6/22/10
01-01-2015 6/23/0
20-12-2014 7/0/0
```

2.  Select a sensor session and you will see a list of days within that session.

```
┌─────────────────────────┐
│  SENSOR  TREND  GRAPH   │
├─────────────────────────┤
│█25-06-2015█████████████ │
│24-06-2015               │
│23-06-2015               │
│22-06-2015               │
│21-06-2015               │
│20-06-2015               │
│19-06-2015               │
└─────────────────────────┘
```

3.　　Select a day and you will see the 24-hour sensor trend graph of that day.

## Calibration History

Select **Calibration History** in the **SENSOR HISTORY** screen and press **OK**.

The **CALIBRATION HISTORY** screen displays up to 90 days' calibration history.
Press **UP/DOWN** to scroll up and down.

```
┌─────────────────────────┐
│   CALIBRATION HISTORY   │
├─────────────────────────┤
│19-06-2015 08:17AM    ██ │
│  6.0 mmol/L          ██ │
│18-06-2015 09:15PM    ██ │
│  6.5 mmol/L          ██ │
│18-06-2015 09:30AM    ██ │
│  6.8 mmol/L          ██ │
│17-06-2015 10:00PM    ▯  │
└─────────────────────────┘
```

## Alert History

1.　Select **Alert History** in the **SENSOR HISTORY** screen and press **OK**.

　　The **ALERT HISTORY** screen shows you all of the sensor alerts that have

145

recently occurred. Each line shows the alert date and time, and the alert type.

```
      ALERT  HISTORY
17-06-2015 12:17PM
   SenEx6
16-06-2015 02:17AM
   LosSen
14-06-2015 12:00PM
   LoGluc
11-06-2015 08:15AM
```

2.    Select an alert record to view the details.

```
      ALERT  HISTORY
Sensor Exp in 6 Hours
   17-06-2015 12:17PM
Reason: Current
sensor session has 6
hours left until 7-
day period ends.
```

# Utilities

## Time/Date Setup

Setting the correct time and date in your PDM is necessary for accurate basal insulin delivery and allows you to keep an accurate record of your insulin delivery and other functions. You can select a 12-hour or 24-hour clock. Occasionally, you need to change the date and time settings (for example, to adjust for daylight saving time or after resetting the PDM).
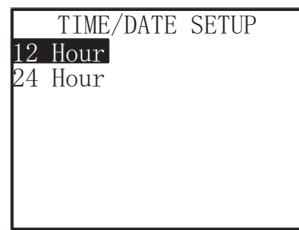
*Note:* As a safety feature, you can only change the date and time when there is no active Reservoir Patch or connected Sensor.

1.  Go to the **TIME/DATE SETUP** screen.
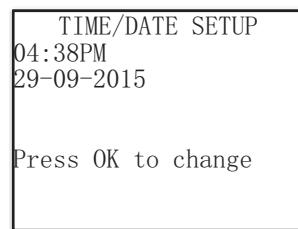
    MAIN MENU➔UTILITIES➔TIME/DATE
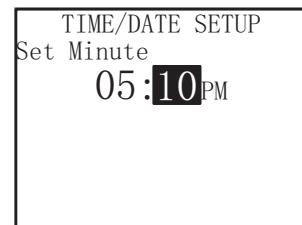
```
          UTILITIES
Time/Date
Username
Alerts
Lock Keypad
Display
Device Options
Alarm Clock
```

2.  Select **12-Hour** format or **24-Hour** format and press **OK**.

```
        TIME/DATE SETUP
12 Hour
24 Hour
```

3.  Press **OK** again to change the settings.

```
        TIME/DATE SETUP
04:38PM
29-09-2015


Press OK to change
```

4.  Time setup: Press **UP/DOWN** to change the hour; then press **OK**. Press **UP/DOWN** to change the minute; then press **OK**.

```
    TIME/DATE SETUP            TIME/DATE SETUP
Set Hour                   Set Minute
      05 : 38PM                  05:10PM
```
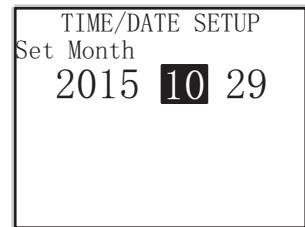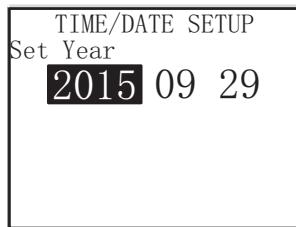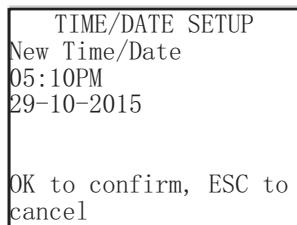
*Note:* AM and PM appear only when the set time format is 12-Hour.

5.  Date setup: Press **UP/DOWN** to change the year; then press **OK**. Press **UP/DOWN** to change the month; then press **OK**. Press **UP/DOWN** to change the day; then press **OK**.

```
   TIME/DATE  SETUP
Set Year
       2015  09  29
```

```
   TIME/DATE  SETUP
Set Month
       2015  10  29
```

```
   TIME/DATE  SETUP
Set Day
       2015  10  29
```

6.    Press **OK** to accept new date and time, or press **ESC** to cancel the settings.

```
   TIME/DATE  SETUP
New Time/Date
05:10PM
29-10-2015


OK to confirm, ESC to
cancel
```

# Set Your Username

1.    Go to the **USERNAME** screen.

MAIN MENU➔UTILITIES➔ USERNAME

2. Use **UP/DOWN** to scroll through the list of characters. A space is the first and last option in the scrolling list. Press **OK** to move the highlighted cursor to the next character.

3. When finished, press **OK** while leaving the next — empty to exit the edit mode and return to the **UTILITIES** screen. You can set up to ten characters.

```
┌──────────────────────────┐
│         USERNAME         │
│                          │
│      JOHN  W█---          │
│                          │
│                          │
└──────────────────────────┘
```

## Alert Settings

### Audio Options

You can choose one of the four audio options: audio, vibrate, audio and vibrate, or both off. The factory setting is audio and vibrate.

1. Go to **AUDIO OPTIONS** screen.

   MAIN MENU➔UTILITIES➔ALERTS➔AUDIO OPTIONS

2. Use **UP/DOWN** to scroll to your selection and press **OK**.

```
         AUDIO OPTIONS
Audio
Vibrate
Audio and vibrate
Both off


```

## Patch Expiration

Go to the **PATCH EXPIRATION** screen.

MAIN MENU➜UTILITIES➜ALERTS➜PATCH EXPIRATION

```
      PATCH EXPIRATION
Status
      All On

Advisory Before Exp
       12H

```

Here you can turn on/off **PATCH EXPIRED** alarm, **PATCH EXP ADVISORY** alert, and **PATCH EXP IN 1 HOUR** alert. When the alerts are turned on, if you don't remove a Reservoir Patch after 72 hours' use, the **PATCH EXPIRED** alarm repeats every hour until the system automatically deactivates the current Reservoir Patch after 80 hours' use.

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

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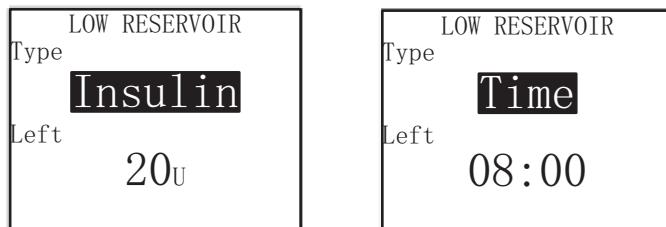
The **LOW RESERVOIR** alert allows you to program the PDM to sound an alert when insulin in the Reservoir Patch reaches a certain level, so you can plan ahead to change the Reservoir Patch. You can select one of these warning types:

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

1. Go to **LOW RESERVOIR** screen.

    MAIN MENU➜UTILITIES➜ALERTS➜LOW RESERVOIR

2. Select **Insulin** or **Time** and press **OK**. Select a desired number and press **OK**.

```
  LOW RESERVOIR          LOW RESERVOIR
Type                   Type
   Insulin                 Time
Left                   Left
    20u                   08:00
```

*Note:* If a bolus is delivered which causes a **LOW RESERVOIR** alert, your remaining insulin may be less than the value on the alert screen.

## Auto Off
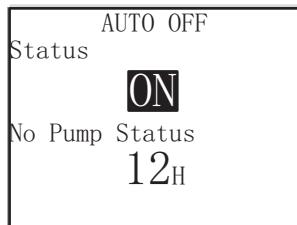
You may program your PDM to automatically suspend basal delivery and

sound an alarm if the PDM does not receive a pump status in a user-selected number of hours. This feature can be used as a safeguard in case you are unconscious. The factory setting for this feature is off. You may choose to program this feature into your PDM based on the number of hours that you usually sleep. Discuss what uses and settings are best for you with your healthcare provider.

1.   Go to the **AUTO OFF** screen.

    MAIN MENU➔UTILITIES➔ALERTS➔AUTO OFF

2.   Press **UP/DOWN** to turn Auto Off **ON** or **OFF**. Press **OK** to confirm. Press **UP/DOWN** to set the time. Press **OK** to confirm.

```
            AUTO OFF
Status
              ON

No Pump Status
             12H
```

## Confidence Reminders

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

1.   Go to the **CONFIDENCE REMINDERS** screen.

    MAIN MENU➔UTILITIES➔ALERTS➔CONFIDENCE REMINDERS

2.   Select **On** or **Off** and press **OK** to confirm.

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```
 CONFIDENCE REMINDERS
On
Off
```
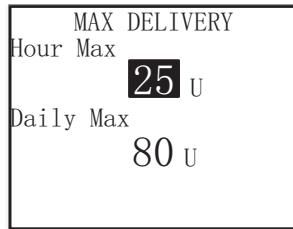
## Max Delivery

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

1.  Go to the **ALERTS** screen, select **Max Delivery**, hold down **B/S** and press **OK** to enter the **MAX DELIVERY** screen.

    MAIN MENU➜UTILITIES➜ALERTS➜ MAX DELIVERY

2.  Press **UP/DOWN** to change the **Hour Max**. Press **OK** to confirm and enter the **Daily Max** field. Press **UP/DOWN** to change the **Daily Max**. Press **OK** to confirm.

```
         MAX DELIVERY
Hour Max
            25 U
Daily Max
            80 U
```

## Audio Off Reminder

If you choose **Vibrate** in the **AUDIO OPTIONS** menu, you can set an audio off reminder to remind you that audio is turned off. The factory setting for this reminder is On.

1.  Go to the **AUDIO OFF REMINDER** screen.

    MAIN MENU➔UTILITIES➔ALERTS➔ AUDIO OFF REMINDER

2.  Press **UP/DOWN** to turn the audio off reminder **On** or **Off**. Press **OK** to confirm. Press **UP/DOWN** to change the reminder repeat time as needed. Press **OK** to confirm.

```
   AUDIO OFF REMINDER
Status
           On
Repeat
         01:00
```

## Low Suspend

When the real-time Continuous Glucose Monitoring (CGM) system is active,

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the Low Suspend alarm can take effect. You may program your PDM to automatically suspend insulin delivery and sound an alarm if your sensor glucose is at or below the low suspend limit. This feature can be used as a safeguard in case the user delivers excessive insulin. The factory setting for this feature is off. You may choose to program this feature into your PDM based on the lowest acceptable sensor glucose. Discuss what uses and settings are best for you with your healthcare provider.

1.  Go to the **LOW SUSPEND** screen.

    MAIN MENU➔UTILITIES➔ALERTS➔LOW SUSPEND

2.  Press **UP/DOWN** to turn Low Suspend **ON** or **OFF**. Press **OK** to confirm. Press **UP/DOWN** to change the low suspend limit. Press **OK** to confirm.

```
        LOW  SUSPEND
Status
           On
Low
        3. 3mmol/L
```

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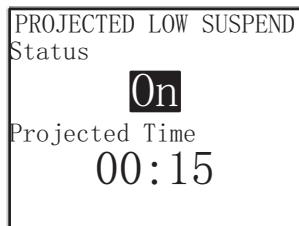
## Projected Low Suspend

The Projected Low Suspend determines when you will reach your Low Suspend Limit, then sends you an alarm before you reach that limit and automatically suspends pump delivery. A Projected Low Suspend alarm informs you that if your sensor glucose measurements keep falling at the current rate, you will reach your low suspend limit in the number of minutes you selected. This feature can be used as a safeguard in case you deliver excessive insulin. The factory setting for this feature is turned off. You may choose to program this

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feature into your PDM based on the lowest acceptable blood glucose and your desired projected time. Discuss what uses and settings are best for you with your healthcare provider.

*Note:* The Projected Low Suspend feature is available when you turn your Low Suspend alarm on.

1. Go to **PROJECTED LOW SUSPEND** screen.

    MAIN MENU➔UTILITIES➔ALERTS➔PROJECTED LOW SUSPEND

2. Press **UP/DOWN** to turn Projected Low Suspend **ON** or **OFF**. Press **OK** to confirm. Press **UP/DOWN** to change the projected time. Press **OK** to confirm.

```
┌─────────────────────────┐
│ PROJECTED LOW SUSPEND   │
│ Status                  │
│          On             │
│                         │
│ Projected Time          │
│       00:15             │
│                         │
└─────────────────────────┘
```

## Lock Keypad

Lock keypad prevents accidental PDM keypad presses.

1. Go to the **LOCK KEYPAD** screen.

    MAIN MENU➔UTILITIES➔LOCK KEYPAD

2. Press **OK** to lock the keypad.

```
Press OK to lock the
keypad.


Press ESC to cancel.
```

3.    After the keypad is locked, you can press **B/S** and **UP** to unlock.

```
Keypad locked.
Press B/S and UP to
unlock.
```

# Display Settings

1.    Go to the **DISPLAY SETTINGS** screen.

MAIN MENU➔UTILITIES➔DISPLAY
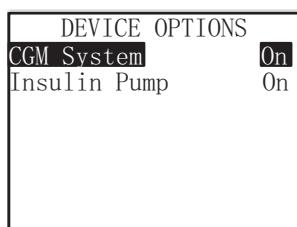
2.    Choose a time interval to set the screen timeout and backlight timeout.
      Press **OK** to confirm.

```
 DISPLAY  SETTINGS
 Screen   Backlight
 60s         30s
 30s         15s
 15s         15s
```

# Device Options

Select **Device Options** in the **UTILITIES** menu, hold down **B/S** and press **OK** to go to the **DEVICE OPTIONS** screen.

MAIN MENU➜UTILITIES➜DEVICE OPTIONS

```
       DEVICE OPTIONS
CGM System             On
Insulin Pump           On



```

You can turn on/off each device here. If you turn **CGM System** off, only the Insulin Pump features will be available on your PDM. If you turn **Insulin Pump** off, only the CGM features will be available on your PDM. You cannot turn them both off.
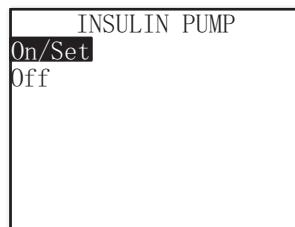
## Set the Transmitter SN

Any time you switch to a new Transmitter and/or a PDM you must set the Transmitter SN. See *CGM Feature on/off* in the chapter *CGM Features* for more information.
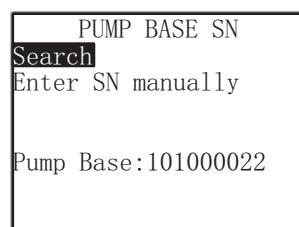
## Set the Pump Base SN

Any time you switch to a new Pump Base and/or a PDM you must set the Pump Base SN.
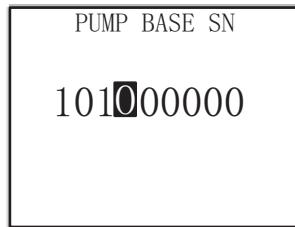
1. Go to the **INSULIN PUMP** screen. Select **On/Set** to turn on the pump features.

```
        INSULIN PUMP
On/Set
Off
```

2. After you turn on the pump features, the **PUMP BASE SN** Screen appears. Your current Pump Base SN shows on the bottom.

```
        PUMP BASE SN
Search
Enter SN manually


Pump Base:101000022
```
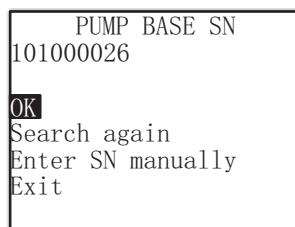
3. You can enter your new Pump Base SN manually. Use **UP**/**DOWN** to select from 0 to 9. Press **OK** to move the highlighted cursor to the next digit.

```
        PUMP  BASE  SN

          101000000
```
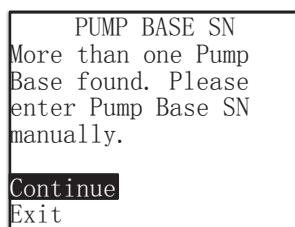
4. You can also use your PDM to search for your Pump.

   If your PDM finds one Pump, the Pump Base SN appears on the screen. You can confirm it if it matches the SN printed on your Pump Base.

```
        PUMP  BASE  SN
   101000026

   OK
   Search again
   Enter SN manually
   Exit
```

   If your PDM finds multiple Pumps, the SNs won't be displayed to prevent you from selecting the wrong SN. You need to enter the SN printed on your Pump Base manually.

```
        PUMP  BASE  SN
   More than one Pump
   Base found. Please
   enter Pump Base SN
   manually.

   Continue
   Exit
```
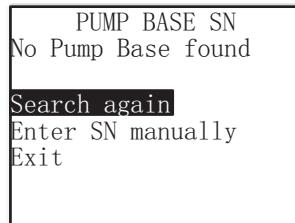
   If your PDM does not find a Pump, make sure your Pump Base is connected to a Reservoir Patch with enough battery power, move the

PDM closer to your Pump, and search again or enter the SN manually.

```
     PUMP BASE SN
No Pump Base found

Search again
Enter SN manually
Exit
```

# Alarm clock

The factory setting for this feature is off. The alarm clock can be useful to remind you when to check your blood glucose, eat, bolus, etc.
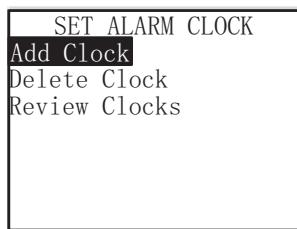
1.  Go to the **ALARM CLOCK** screen.

    MAIN MENU➔UTILITIES➔ALARM CLOCK

2.  Select **On/Set** and press **OK**.

3.  Go to the **SET ALARM CLOCK** screen.

## Add Alarm Clock

a.  Select **Add Clock** and press **OK**.

```
      SET ALARM CLOCK
Add Clock
Delete Clock
Review Clocks
```

b.  Set the time, and press **OK**. Set the **Repeat** mode, and press **OK**.

```
      ADD CLOCK
   Time       Repeat
   07:00      Daily
   08:55      Once
   19:00      Daily
   --:--
```

c.  When finished, press **OK** to save your settings and return to the previous menu.

## Delete Alarm Clock

a.  Select **Delete Clock** and press **OK**.

```
      SET ALARM CLOCK
Add Clock
Delete Clock
Review Clocks
```

b.  Select the alarm clock you want to delete and press **OK**.

```
          DELETE CLOCK
     Time          Repeat
     07:00         Daily
     08:55         Once
     19:00         Daily
```

c.  Delete the selected alarm clock and return to the previous menu.

# Review Alarm Clocks

a.  Select **Review Clocks** and press **OK**.

```
        SET ALARM CLOCK
   Add Clock
   Delete Clock
   Review Clocks
```

b.  The **REVIEW CLOCKS** screen appears.

```
        REVIEW  CLOCKS
    Time       Repeat
    07:00      Daily
    08:55      Once
    19:00      Daily
```

c.    Press **OK** or **ESC** to return to the previous menu.

# Glucose Units
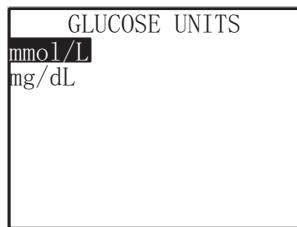
You can set glucose units to mmol/L or mg/dL.

1.    Go to the **GLUCOSE UNITS** screen.

MAIN MENU➔UTILITIES➔GLUCOSE UNITS

```
          UTILITIES
    Display
    Device Options
    Alarm Clock
    Glucose Units
    Language
    Diagnostics
    User Settings
```

2.    Select **mmol/L** or **mg/dL** and press **OK** to confirm.

```
       GLUCOSE  UNITS
mmol/L
mg/dL
```

## Language

1.  Go to the **UTILITIES** screen, select a language and press **OK**.

    MAIN MENU➜UTILITIES➜LANGUAGE

2.  Press **UP/DOWN** to select your language, press **OK** to confirm and exit to the **UTILITIES** screen.

```
          LANGUAGE
中文简体
English
Deutsch
Français
Italiano
Español
```
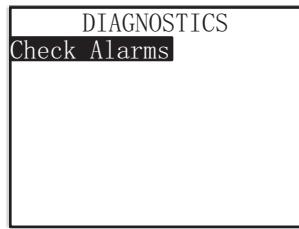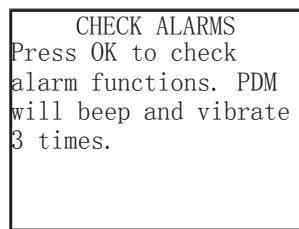
## Diagnostics

The **DIAGNOSTICS** screen allows you to check if the PDM beeps and vibrates properly.

1.  Go to the **DIAGNOSTICS** screen.

MAIN MENU➔UTILITIES➔ DIAGNOSTICS

```
        DIAGNOSTICS
Check Alarms
```

2.    Select **Check Alarms**; Press **OK**.

```
      CHECK ALARMS
Press OK to check
alarm functions. PDM
will beep and vibrate
3 times.
```

3.    Press **OK** again. The PDM beeps and vibrates three times.

**Warning**: If the PDM fails to beep or vibrate, call customer support. Continuing to use the PDM may put your health at risk.
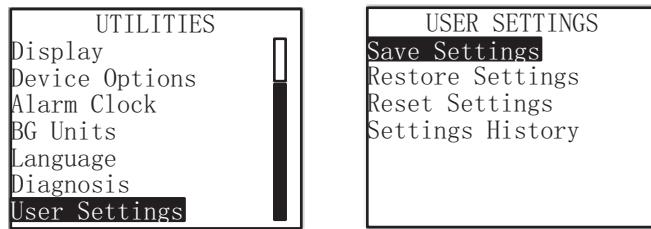
*Note*: Your PDM uses battery power to beep and vibrate. Checking alarms often will result in reduced battery life and the **REPLACE BATTERY** alarm screen may appear sooner than expected.

# User Settings

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

Go to the **UTILITIES** menu and select **User Settings**. Hold down **B/S** and press **OK** to enter the **USER SETTINGS** screen.

MAIN MENU➔UTILITIES➔USER SETTINGS

```
       UTILITIES
Display
Device Options
Alarm Clock
BG Units
Language
Diagnosis
User Settings
```

```
     USER SETTINGS
Save Settings
Restore Settings
Reset Settings
Settings History
```
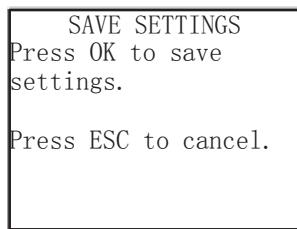
*Note:* If there is an active Reservoir Patch, **Reset Settings** and **Restore Settings** will be disabled.

## Save Settings
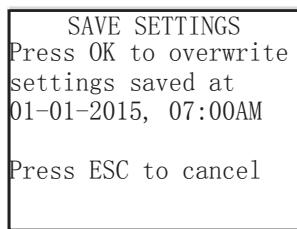
Take these steps to save your current PDM settings:

1.    Select **Save Settings** in the **USER SETTINGS** screen and press **OK**.

If this is the first time saving your PDM settings, this screen appears:

```
     SAVE SETTINGS
Press OK to save
settings.

Press ESC to cancel.
```
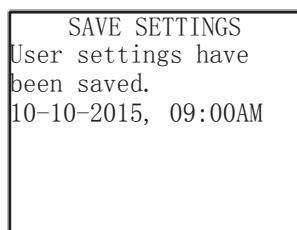
If you have saved PDM settings, this screen appears:

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```
          SAVE SETTINGS
Press OK to overwrite
settings saved at
01-01-2015, 07:00AM

Press ESC to cancel
```

Read the instructions on the screen; then press **OK** to save your current settings (or press **ESC** to cancel the save).

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

```
          SAVE SETTINGS
User settings have
been saved.
10-10-2015, 09:00AM
```
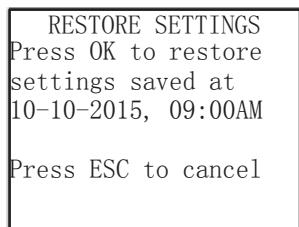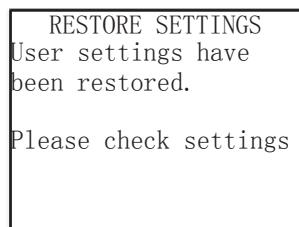
## Restore Settings

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

*Note:* **Restore Settings** always sets the active basal pattern to **Standard**.

1.   Select **Restore Settings** in **USER SETTINGS** screen and press **OK**.

2.   Read the instructions on the screen, and then press **OK** to restore the settings (or press **ESC** to cancel the restore).

```
     RESTORE SETTINGS
Press OK to restore
settings saved at
10-10-2015, 09:00AM

Press ESC to cancel
```

3.   This screen indicates that your user settings have been restored. Exit the
     menu and check your pump settings.

```
     RESTORE SETTINGS
User settings have
been restored.

Please check settings
```
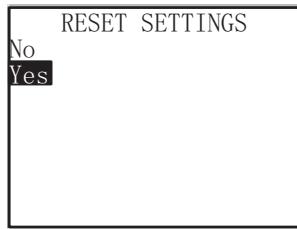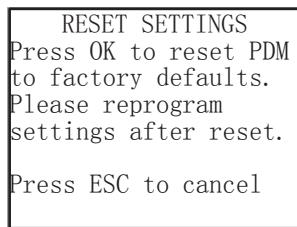
## Reset Settings

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

Take the following steps to reset PDM settings:

1.   Select **Reset Settings** in the **USER SETTINGS** screen and press **OK**.

2.   Select **Yes** and press **OK**.

```
            RESET SETTINGS
No
Yes
```

3. Press **OK** again, the PDM will be reset to the factory default settings and restart.

```
            RESET SETTINGS
Press OK to reset PDM
to factory defaults.
Please reprogram
settings after reset.

Press ESC to cancel
```

## Settings History

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

1. Select **Settings History** in **USER SETTINGS** screen and press **OK**.

2. Press **UP/DOWN** to scroll up/down to view the entire settings history. Press **OK** or **ESC** to exit.

```
        SETTINGS HISTORY
12-01-2015 05:16PM
    Reset Settings
09-01-2015 12:30AM
    Restore Settings
20-12-2014 10:20AM
    Save Settings
```

# Passcode Lock
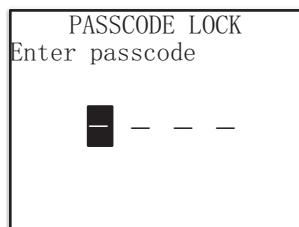
With the Passcode Lock feature turned on, only the **HOME** screen is displayed. You have to enter the correct passcode before accessing any other screens.

Go to the **MAIN MENU** screen and select **Utilities**. Hold down **B/S** and press **OK** to enter the **Passcode Lock** menu.

```
        UTILITIES
Passcode Lock
Set Passcode
```
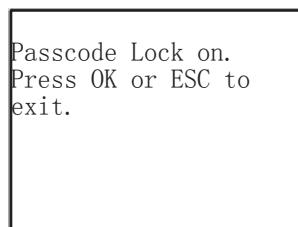
# Passcode Lock

Select **Passcode Lock** and press **OK**. Enter the correct passcode to turn Passcode Lock feature on. Use **UP/DOWN** to select from 0 to 9. Press **OK** to move the highlighted cursor to the next digit. Continue until all four digits have been entered.

```
           PASSCODE LOCK
Enter passcode


        ▌ —  —  —
```
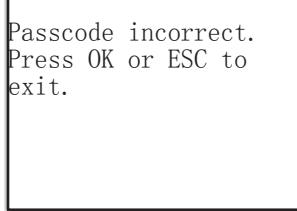
*Note*: The default passcode is 6666.

a.    If the passcode is correct, this message appears indicating that Passcode Lock is on. Press **OK** or **ESC** to return to the **HOME** screen.

```
Passcode Lock on.
Press OK or ESC to
exit.
```
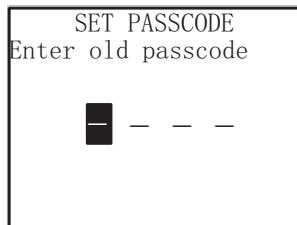
*Note:* If the Passcode Lock has been turned on, you have to enter the correct passcode to unlock your PDM. After your PDM is unlocked, the Passcode Lock is automatically turned off.

b.    If the passcode is incorrect, this message appears. Press **OK** or **ESC** to return to the **Passcode Lock** screen.

```
Passcode incorrect.
Press OK or ESC to
exit.
```
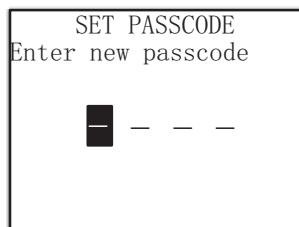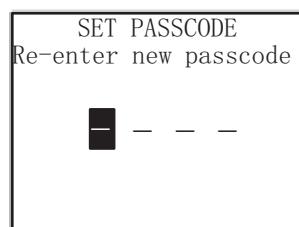
## Set Passcode

1.  Select **Set Passcode** and press **OK**. Enter the old passcode. Use **UP/DOWN** to select from 0 to 9. Press **OK** to move the highlighted cursor to the next digit. Continue until all four digits have been entered.

```
      SET PASSCODE
Enter old passcode


    █ — — —
```

2.  If the old passcode entered is correct, you can set a new passcode. Use **UP/DOWN** to select from 0 to 9. Press **OK** to move the highlighted cursor to the next digit. Continue until all four digits have been entered.

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```
         SET PASSCODE
    Enter new passcode


         ▋ — — —



```

3.    You need to re-enter the new passcode to confirm.

```
         SET PASSCODE
    Re-enter new passcode


         ▋ — — —


```

# Safety System and Alarms

## Safety System

Your A6 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 a condition that is outside normal system activity.

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

All of your alarm settings and alarm history are stored in the PDM if the battery is removed and are restored once a new battery is installed. However, the period of powering down cannot be captured in the alarm history.

*Note*: Do NOT set alarm outside the thresholds or in a way that makes the alarm system useless. Talk with your healthcare provider to see which settings are best for you.

*Note*: Your PDM uses battery power to notify you of alerts, alarms, and reminders. If you do not acknowledge a notification, your PDM will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life and the **Replace Battery** Alarm screen will appear sooner than expected.

## Safety Checks

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

# Alarms

Alarms are triggered by serious or potentially serious conditions. You must address the alarm by taking appropriate action in order to clear the alarm condition. For your safety, if there is no response, the alarm sound escalates to a siren after ten minutes. The siren continues until the alarm is cleared.

When an alarm occurs:

**Display**: The PDM displays an alarm message with instructions and a solid triangle icon ▲.

**Indicator light**: The indicator light on the pump flashes red once per second until the alarm is cleared except for the two alarms generated by the PDM: **PDM ERROR** and **REPLACE BATTERY**.

**Audio/vibration**: Depending on your selected audio option, your PDM emits three beeps and/or three-pulse vibration every minute. Your pump emits three beeps and/or three-pulse vibration every minute except for the two alarms generated by the PDM: **PDM ERROR** and **REPLACE BATTERY**.

| PDM Message | Reason | Actions to Take |
|---|---|---|
| OCCLUSION DETECTED<br><br>Delivery stopped. Change Patch now. ESC, OK to clear. | Pump occlusion is detected. | Press ESC then OK to clear.<br><br>Change Patch.<br><br>Check blood glucose. |

| PDM Message | Reason | Actions to Take |
|---|---|---|
| **AUTO OFF**<br><br>Delivery suspended. No status received. ESC, OK to clear. | The PDM has not received a pump status during the time limit set. | Press ESC then OK to clear.<br><br>Resume basal delivery.<br><br>Check blood glucose and treat as necessary.<br><br>Check Pump history. |
| **PATCH EXPIRED**<br><br>Delivery will stop. Change Patch now. ESC, OK to clear. | The current Reservoir Patch has reached the end of its 3-day operating life. | Press ESC then OK to clear.<br><br>Change Patch.<br><br>Check blood glucose. |
| **PATCH ERROR**<br><br>Delivery stopped. Change Patch now. ESC, OK to clear. | A Reservoir Patch error is detected. | Press ESC then OK to clear.<br><br>Change Patch.<br><br>Check blood glucose. |
| **PATCH BATT DEPLETED**<br><br>Delivery stopped.<br>Change Patch now.<br>ESC, OK to clear. | The Reservoir Patch battery is depleted. | Press ESC then OK to clear.<br><br>Change Patch.<br><br>Check blood glucose. |
| **PUMP RESTARTED**<br><br>Patch changed? For help call the CC. ESC, | Pump restarted without Patch deactivation. | Press ESC then OK to clear.<br><br>Check if a new Patch is connected, and follow the instructions in this *User* |

| PDM Message | Reason | Actions to Take |
|---|---|---|
| OK to clear | | *Guide*.<br><br>Call customer support if you have any questions. |
| **EXCEEDS MAX TDD**<br><br>Exceeds max TDD. Delivery stopped. ESC, OK to clear. | You have attempted to deliver more insulin than expected based on your Daily Max setting. | Press ESC then OK to clear.<br><br>Check blood glucose.<br><br>Resume basal delivery.<br><br>Check bolus history and reevaluate your need for insulin.<br><br>Continue to monitor blood glucose. |
| **EXCEEDS MAX 1HR DELIVERY**<br><br>Exceeds 1 hour max. Delivery stopped. ESC, OK to clear. | You have attempted to deliver more insulin than expected based on your Hour Max setting. | Press ESC then OK to clear.<br><br>Check blood glucose.<br><br>Resume basal delivery.<br><br>Check bolus history and reevaluate your need for insulin.<br><br>Continue to monitor blood glucose. |
| **PUMP BASE ERROR**<br><br>Remove Pump. Call customer support. ESC, OK to clear. | A Pump Base error is detected. | Press ESC then OK to clear.<br><br>Remove Pump.<br><br>Contact customer support |

| PDM Message | Reason | Actions to Take |
|---|---|---|
| | | immediately. Check blood glucose. |
| **EMPTY RESERVOIR** Delivery stopped. Change Patch now. ESC, OK to clear. | There is no insulin in the reservoir. | Press ESC then OK to clear. Change Patch. Check blood glucose. |
| **PDM ERROR** Remove device. Call customer support. ESC, OK to clear. | A PDM error is detected. | Press ESC then OK to clear. Remove Pump and Sensor. Contact customer support immediately. Check blood glucose. |
| **REPLACE BATTERY** Change PDM battery now. ESC, OK to clear. | The PDM battery is depleted. | Press ESC then OK to clear. Replace PDM battery. |
| **PROJECTED LOW SUSPEND** Delivery suspended. Projected low gluc. ESC, OK to clear. | The sensor glucose may reach Low Glucose Suspend Limit in the length of time set. | Press ESC then OK to clear. Check blood glucose and treat as necessary. |

| PDM Message | Reason | Actions to Take |
|---|---|---|
| **LOW SUSPEND**<br><br>Delivery suspended. Low glucose. ESC, OK to clear. | The last sensor glucose reading is at or below Low Glucose Suspend Limit set. | Press ESC then OK to clear.<br><br>Check blood glucose and treat as necessary. |

## Alerts

Alerts are triggered by conditions that may require your attention. Alerts are less serious than alarms. You must acknowledge an alert by pressing buttons and/or take action to address the alert.

When an alert occurs:

**Display**: The PDM displays an alert message with instructions and an empty triangle icon △.

**Indicator light**: For the alerts generated by the Pump: **END OF SUSPEND**, **LOW RESERVOIR**, **AUTO OFF ALERT**, **PATCH EXP ADVISORY**, **PATCH EXP IN 1 HOUR**, and **PATCH BATTERY LOW**, the indicator light on the Pump flashes yellow once every two seconds until the alert is cleared. When a **TRANSMITTER ERROR** occurs, the indicator light on the Transmitter flashes red.

**Audio/vibration**: Depending on your selected audio option, your PDM emits three beeps and/or three-pulse vibration every three minutes. For the alerts

generated by the Pump: **END OF SUSPEND**, **LOW RESERVOIR**, **AUTO OFF ALERT**, **PATCH EXP ADVISORY**, **PATCH EXP IN 1 HOUR**, and **PATCH BATTERY LOW**, your Pump emits one beep and/or one-pulse vibration every three minutes.

| PDM Message | Reason | Actions to Take |
|---|---|---|
| **STUCK BUTTON**<br><br>Button pressed for more than 3 min. ESC, OK to clear. | A button on your PDM has been pressed for more than 3 minutes. | Press ESC then OK to clear.<br><br>Check the buttons. Press the stuck button to unstick it. |
| **END OF SUSPEND**<br><br>Delivery suspended at [ ]. ESC, OK to clear. | Insulin delivery has been suspended for more than 15 minutes. | Press ESC then OK to clear.<br><br>Resume basal delivery. |
| **LOW RESERVOIR**<br><br>[ ] remaining. Change Patch. ESC, OK to clear. | The insulin level in the Reservoir Patch has reached the set low limit. | Press ESC then OK to clear.<br><br>Change Patch soon. |
| **AUTO OFF ALERT**<br><br>Delivery stops if not cleared in 15 min. ESC, OK to clear. | The PDM did not receive a Pump status during the time limit set. | Press ESC then OK to clear.<br><br>Check blood glucose.<br><br>Check Pump history. |

| | | |
|---|---|---|
| **PATCH EXP ADVISORY**<br><br>Patch expiration in [ ] hours. ESC, OK to clear. | The Reservoir Patch will expire within the set time limit. | Press ESC then OK to clear.<br><br>Change Patch soon. |
| **PATCH EXP IN 1 HOUR**<br><br>Patch expiration in 1h. Change Patch soon. ESC,OK to clear | The Reservoir Patch will expire in less than 1 hour. | Press ESC then OK to clear.<br><br>Change Patch soon. |
| **PDM BATTERY LOW**<br><br>Low PDM battery. Change battery soon. ESC, OK to clear. | The PDM battery is low. | Press ESC then OK to clear.<br><br>Change PDM battery soon. |
| **LOST PUMP**<br><br>Move PDM close to Pump. ESC, OK to clear. | The PDM has not received a signal from the Pump for 5 minutes. | Press ESC then OK to clear.<br><br>Move PDM close to Pump. |
| **PATCH BATTERY LOW**<br><br>No bolus allowed. Change Patch soon. ESC, OK to clear. | The Patch battery is running low. No bolus can be delivered. Basal delivery can only last about 30 minutes. | Press ESC then OK to clear.<br><br>Change Reservoir Patch soon. |
| **LOST SENSOR**<br><br>Move PDM close to | The PDM has not received a signal from the Transmitter for 2 | Press ESC then OK to clear. |

| | | |
|---|---|---|
| Transmitter. ESC, OK to clear. | minutes. | Move PDM close to Transmitter. |
| **TRANSMITTER BATTERY LOW**<br><br>Charge Transmitter soon. ESC, OK to clear. | The Transmitter battery is close to running out of power. | Press ESC then OK to clear.<br><br>Charge Transmitter soon. |
| **CHARGE TRANSMITTER**<br><br>Charge Transmitter now. ESC, OK to clear. | The Transmitter battery is depleted. | Press ESC then OK to clear.<br><br>Charge Transmitter. |
| **TRANSMITTER ERROR**<br><br>Call customer support. ESC, OK to clear. | A Transmitter error is detected. | Press ESC then OK to clear.<br><br>Call customer support. |
| **SENSOR ERROR**<br><br>Check or change Sensor. ESC, OK to clear. | The Sensor signals are either too high or too low. | Press ESC then OK to clear.<br><br>Check or change Sensor. |
| **SENSOR EXPIRED**<br><br>Sensor session ended. Change Sensor. ESC, OK to | The current Sensor has reached its 7-day operating life. | Press ESC then OK to clear.<br><br>Change Sensor. |

| clear. | | |
|---|---|---|
| **SENSOR FAILURE**<br><br>Sensor session ended. Change Sensor. ESC, OK to clear. | The Sensor is not functioning properly. | Press ESC then OK to clear.<br><br>Change Sensor. |
| **SENSOR CAL REMINDER**<br><br>Enter a new meter BG for CAL by [ ]. ESC, OK to clear. | A meter BG must be entered by the time shown to calibrate Sensor. | Press ESC then OK to clear.<br><br>Enter new meter BG soon. |
| **METER BG NOW**<br><br>Enter a new meter BG for calibration. ESC, OK to clear. | A meter BG is needed immediately to calibrate the Sensor. | Press ESC then OK to clear.<br><br>Enter new meter BG for calibration. |
| **SENSOR CAL ERROR 0**<br><br>Enter a meter BG after 15 minutes. ESC, OK to clear. | The Sensor hasn't been calibrated properly. | Press ESC then OK to clear.<br><br>Enter meter BG after 15 minutes. |
| **SENSOR CAL ERROR 1**<br><br>Enter a meter BG after 1 hour. ESC, OK | The Sensor hasn't been calibrated properly. | Press ESC then OK to clear.<br><br>Enter meter BG after 1 hour. |

| | | |
|---|---|---|
| to clear. | | |
| **LOW GLUCOSE**<br><br>Glucose level below Low Limit. ESC, OK to clear. | The last sensor glucose reading is at or below Low Glucose Limit set. | Press ESC then OK to clear.<br><br>Check blood glucose and treat as necessary.<br><br>Continue to monitor blood glucose. |
| **HIGH GLUCOSE**<br><br>Glucose level above High Limit. ESC, OK to clear. | The last sensor glucose reading is at or above High Glucose Limit set. | Press ESC, OK to clear.<br><br>Check blood glucose and treat as necessary.<br><br>Continue to monitor blood glucose. |
| **LOW PREDICTED**<br><br>Glucose may reach Low Limit in [ ] min. ESC, OK to clear. | The sensor glucose may reach Low Glucose Limit in the length of time Set. | Press ESC then OK to clear.<br><br>Check blood glucose and treat as necessary.<br><br>Continue to monitor blood glucose. |
| **HIGH PREDICTED**<br><br>Glucose may reach High Limit in [ ] min. ESC, OK to clear. | The sensor glucose may reach High Glucose Limit in the length of time Set. | Press ESC then OK to clear.<br><br>Check blood glucose and treat as necessary.<br><br>Continue to monitor blood glucose. |
| **RAPID RISE**<br><br>Sensor glucose is | The sensor glucose is rising at a rate that is faster than the set Rise | Press ESC then OK to clear.<br><br>Monitor trend and |

| | | |
|---|---|---|
| rising rapidly. ESC, OK to clear. | limit. | glucose level.<br><br>Follow instructions from your healthcare provider. |
| **RAPID FALL**<br><br>Sensor glucose is falling rapidly. ESC, OK to clear. | The sensor glucose is falling at a rate that is faster than the set Fall limit. | Press ESC then OK to clear.<br><br>Monitor trend and glucose level.<br><br>Follow instructions from your healthcare provider. |
| **BELOW 3.1 mmol/L**<br><br>Sensor glucose below 3.1 mmol/L. ESC, OK to clear.<br><br>(**BELOW 56 mg/dL**<br><br>Sensor glucose below 56 mg/dL. ESC, OK to clear.) | The last sensor glucose reading is at or below 3.1 mmol/L.<br><br>(The last sensor glucose reading is at or below 56 mg/dL.) | Press ESC then OK to clear.<br><br>Check blood glucose and treat as necessary.<br><br>Continue to monitor blood glucose. |
| **SENSOR EXP IN 6 HOURS**<br><br>Change Sensor in 6 hours. ESC, OK to clear. | The current sensor session has 6 hours left until 7-day period ends. | Press ESC then OK to clear.<br><br>Change Sensor in 6 hours. |
| **SENSOR EXP** | The current sensor session has 2 hours left | Press ESC then OK to clear. |

| IN 2 HOURS<br><br>Change Sensor in 2 hours. ESC, OK to clear. | until 7-day period ends. | Change Sensor in 2 hours. |
|---|---|---|
| SENSOR EXP IN 30 MIN<br><br>Change Sensor in 30 minutes. ESC, OK to clear. | The current sensor session has 30 minutes left until 7-day period ends. | Press ESC then OK to clear.<br><br>Change Sensor in 30 minutes. |
| ALERT SILENCE<br><br>Alerts have occurred. Check sensor history. ESC, OK to clear. | Sensor alerts have occurred during silence mode. | Press ESC then OK to clear.<br><br>Check the Sensor Alert History.<br><br>Take action based on the alert occurred. |

# Reminders

Reminders are automatically displayed to remind you of a function that you have set or a condition that exists. A reminder requires you to press buttons to clear it and/or to take action as necessary.

When a reminder occurs:

**Display**: The PDM displays a message with instructions.

**Audio/vibration**: Your PDM emits a beep and/or vibration every three minutes,

three times in total.

| Condition | PDM Message | Reason |
|---|---|---|
| HIGH BG | Treat high BG. Monitor BG. ESC, OK to clear. | The blood glucose entered is higher than 13.9 mmol/L (250 mg/dL). |
| LOW BG | Treat low BG. Monitor BG. ESC, OK to clear. | The blood glucose entered is lower than 3.9 mmol/L (70 mg/dL). |
| CHECK BG | Check your BG. ESC, OK to clear. | BG Reminder is turned on to remind you to check meter BG after a bolus. |
| MISSED BOLUS REMINDER | Bolus not delivered in specified period. ESC, OK to clear. | Missed Bolus Reminder is turned on to remind you to deliver a bolus within a specific period. |
| ACTIVE BASAL EMPTY | Your active Basal is 0.00 U/H. ESC, OK to clear. | The selected basal rate or temp basal rate is 0.00 U/H. |
| BASAL RESUMED | Check BG. [ ] Basal active. ESC, OK to clear. | The previously automatically suspended basal rate is resumed. |
| AUDIO OFF | Audio turned off. ESC, OK to clear. | The audio option is set to Vibrate. Audio off reminder is set on. |

| Condition | PDM Message | Reason |
|---|---|---|
| CHECK SETTINGS | Check all settings. ESC, OK to clear. | An error might have occurred to your settings. |
| ALARM CLOCK | Alarm Clock. ESC, OK to clear. | An alarm clock is set at this time. |
| CALL EMERGENCY AID | Low Suspend not responded. Basal resumed. ESC, OK clear. | A **Low Suspend** alarm occurred and was not cleared. Basal rate is automatically resumed after 2 hours of suspension. |

# Manufacturer's Declaration

The A6 TouchCare® System (consisting of the MD-FM-011 PDM, MD-JN-012 Pump Base, MD-JN-011 Reservoir Patch, MD-TY-012 Transmitter and MD-JY-006 Glucose Sensor) is intended for use in the electromagnetic environment specified below. The customer or the user of A6 TouchCare® System should make sure that it is used in such an environment.

## Electromagnetic Emissions

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

## Electromagnetic Immunity

| Immunity Test | IEC 60601 Test Level | Compliance Level |
|---|---|---|
| Electrostatic | ±2.0 kV, ±4.0 kV, | ±2.0 kV, ±4.0 kV, |

| discharge (ESD)<br><br>IEC 61000-4-2 | ±6.0kV, ±8.0 kV contact discharge<br><br>±2.0 kV, ±4.0 kV, ±8.0 kV, ±15.0 kV air discharge | ±6.0 kV, ±8.0 kV, 56% RH<br><br>±2.0 kV, ±4.0 kV, ±8.0 kV, ±15.0 kV air (56% RH) |
|---|---|---|
| RF electromagnetic field immunity test<br><br>IEC 61000-4-3 | 10 V/m | 10 V/m |
| Power frequency magnetic fields<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m |

# Appendix I: Symbols and Icons

## 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 |

| Symbol | Meaning | Symbol | Meaning |
|--------|---------|--------|---------|
|  | 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 |

## PDM Icons

| Icon | Meaning | Icon | Meaning |
|------|---------|------|---------|
|  | Insulin left |  | Alarm |
|  | Alert |  | Audio Off |

| | | | |
|---|---|---|---|
| 00:00 ᴬᴹ | Time | 📶 | Pump RF signal |
| 🔋 | Battery | | |

# Appendix II: Technical Information

## Patch Pump Specifications

**Model**:
   **Pump Base**: MD-JN-012
   **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 cell batteries (1.5 V)

**Wireless Communication Distance**: 4 m

**Waterproof Rating**: IPX8 (2.5 m, 60 min)

**Limited Warranty of Pump Base**: 1 year

**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**:   0.05~ 10 U/h (increment: 0.05 U/h)

**Bolus Range**: 0.05 ~ 25 U (increment: 0.05 or 0.1 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
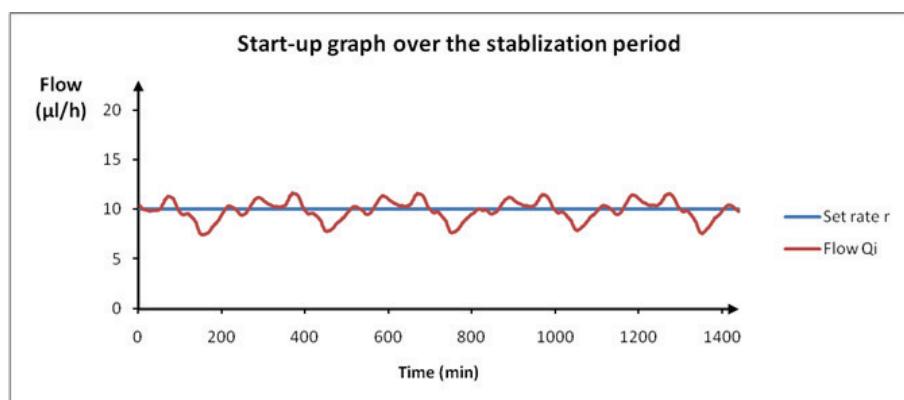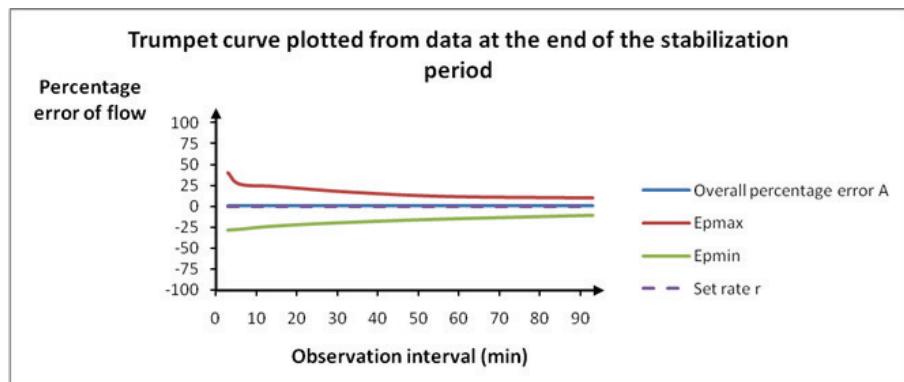
**Bolus Volume after Occlusion Release**: < 3 U

**Delivery Accuracy**:

**Basal**: +/- 5% (at rates: 0.1~ 10 U/h)

**Bolus**: +/- 5% (for all set values: 0.05 ~ 25 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.

## PDM Specifications

**Model**: MD-FM-011
**Size**: 80 mm x 50 mm x 18.5 mm
**Weight**: 43 g
**Screen**: 1.8 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**: Powered by 1 AAA alkaline battery (1.5V)
**Battery Life**: Approximately 3 weeks
**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

# Transmitter Specifications

**Model**: MD-TY-012
**Size**: 36.1 mm x 19.4 mm x 12 mm
**Weight**: 4.8 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)
**Category**: Type BF equipment, Continuous operation
**Data Storage**: Automatically stores the previous 15 days' data
**Wireless Communication Distance**: 10 m
**Limited Warranty**: 1 year

# Glucose Sensor Specifications

**Model**: MD-JY-006
**Storage Temperature Range**: +2°C ~+30°C
**Storage Relative Humidity Range**: 20%~90%RH
**Storage Atmospheric Pressure**: 700~1060 hPa
**Glucose Range**: 2.2~22.2 mmol/L (40~400 mg/dL)
**Sterilization Method**: By radiation
**Sensor Life**: Up to 7 days

# 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 7-day 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 (>=) 75 mg/dL (4.2 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 (<) 75mg/dL (4.2 mmol/L).

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

| Number of Matched Pairs CGM-YSI | ±20%/20 | ±30%/30 | ±40%/40 |
|---|---|---|---|
| 1734 | 90% | 96% | 99% |

# Glossary

| | |
|---|---|
| **Active Insulin** | Bolus insulin delivered by the Pump that is still working to lower your blood glucose levels. |
| **Active Insulin Time** | A Bolus Calculator setting that lets you set the length of time that bolus insulin is tracked as active insulin. |
| **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. |
| **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. |
| **C** | Abbreviation for Combo Bolus. See *Combo Bolus.* |
| **Calibration** | The process of using a meter blood glucose |

| | reading to calculate sensor glucose values. |
|---|---|
| **CE** | The normal portion of a *Combo Bolus*. |
| **CGM** | Abbreviation for Continuous Glucose Monitoring. See *Continuous Glucose Monitoring (CGM)*. |
| **CN** | The extended portion of a *Combo Bolus*. |
| **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. |
| **E** | Abbreviation for Extended Bolus. See *Extended Bolus.* |
| **Extended Bolus** | Bolus amount delivered evenly over specified time period. |
| **Food Bolus** | Bolus used to cover an expected rise in glucose levels from carbohydrates. |
| **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*. |
| **Low Limit** | The value you set to determine when the system will alert you of a low sensor glucose condition. |
| **Manual Bolus** | Allows you to manually deliver a dose of insulin. |
| **Max 1h Delivery** | Allows you to set the maximum insulin amount that can be delivered in one hour. |
| **Max Bolus** | Allows you to set the maximum bolus amount that can be delivered in one dose. |
| **Max Total Daily Dose (TDD)** | Allows you to set the maximum insulin amount that can be delivered in one day. |
| **Missed Bolus reminder** | A reminder that a bolus was not delivered during time periods that you specified, often set around meal times. |
| **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** | Allows you to set up and save a bolus for specific meals or snacks that you frequently eat or drink. |
| **Preset Temp Basal** | Allows you to set up and save temporary basal rates for repeated use. |
| **Sensitivity** | See *Insulin Sensitivity Factor*. |
| **Sensor Glucose (SG)** | The amount of glucose that is present in the interstitial fluid and is measured by a glucose sensor. |

| | |
|---|---|
| **Sensor Session** | The 7-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)** | Allows you to temporarily increase or decrease your current basal rate for a specific amount of time. |
| **Warning** | A warning notifies you of a potential hazard. |

**MEDTRUM**

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