

**Paradigm[®] REAL-Time
Revel[™] Insulin Pump**

User Guide

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Important Safety Information Regarding Your Paradigm Insulin Pump (includes all models)

Avoid Immersing Your Pump In Water

The pump was tested and met requirements for IPX7 at time of manufacture. For more information about IPX7, see the *Glossary* on *page 213*. Be aware that drops and bumps that occur over time will affect the integrity of the pump case and make it more vulnerable to damage from water. Lotions, sunscreens and insect repellent can also damage the pump case. It is not known how much water is needed to damage your pump. **You should avoid getting your pump wet. To shower, bathe, swim, or participate in water activities, always disconnect from your pump and reconnect after you are out of the water.**

If you inadvertently submerge your pump in water, dry the pump quickly using a soft, clean towel and verify that it is working properly by selecting **Selftest** from the pump's Utilities menu. If you believe that water has entered your pump or you observe any other possible pump malfunction, please check your blood glucose, treat high blood glucose (if necessary) with an injection and contact our 24 Hour HelpLine at 1 800 646 4633 for further assistance. Symptoms of high blood glucose include fatigue, excessive thirst and nausea. Always contact your healthcare professional if you experience excessively high or low blood glucose levels, or if you have any questions about your care.

Electrostatic Discharge

Although your Paradigm pump is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in a reset of the pump's software with an associated pump error alarm. In most cases, exposure to high levels of ESD will trigger the pump's A-13 alarm although, under certain circumstances, high level ESD exposure can cause A-44, Bolus Stopped or Max Delivery alarms. High levels of ESD are more likely in situations where the relative humidity is very low, such as inside a heated building during the winter in areas where it is cold outside.

If your pump experiences an A-13 or other error alarm, press the **ESC** and **ACT** buttons to clear the alarm. If you are unable to clear the alarm by pressing **ESC** and **ACT**, you may need to remove and replace the pump's battery to clear the alarm. After clearing the alarm, you should always verify that your pump is set to the correct date and time and that all other settings (basal rate, max basal and bolus limits, etc.) are programmed to the desired values, since the software reset could erase your previously programmed settings. Please see the *Alarms and alerts* chapter of this User Guide for more details regarding what to do if your pump displays an error alarm or other alert message.

Please contact our 24 Hour HelpLine at 1 800 646 4633 to report any error alarms or other problems that occur with your pump.

Warranty

Medtronic Diabetes warrants the Medtronic MiniMed Insulin Pump against defects in materials and workmanship for a period of 4 years from the date of purchase.

During the warranty period, Medtronic Diabetes will, at its discretion, either repair or replace (with a new or recertified pump, at Medtronic Diabetes' discretion) any defective pump or motor, subject to the conditions and exclusions stated herein. In the event that a pump is repaired or replaced, the warranty period will not be extended.

This warranty is valid only if the Medtronic MiniMed Insulin Pump is used in accordance with the manufacturer's instructions. This warranty will not apply:

- If damage results from changes or modifications made to the pump by the user or third persons after the date of manufacture.
- If damage results from use of non-Medtronic reservoirs and/or infusion sets.
- If damage results from service or repairs performed by any person or entity other than the manufacturer.
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water or physical abuse, such as dropping or otherwise.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to batteries, infusion sets, reservoirs, and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic Diabetes 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.

Pumps purchased through our Pathway Program will assume the warranty stated in our Pathway Program agreement.

All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

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Introduction

Thank you for choosing Medtronic Diabetes (legally known as Medtronic MiniMed, Inc.) as your partner in helping you gain better control of your diabetes. Whether you are beginning pump therapy for the first time or upgrading from a previous model, we believe that the combination of state-of-the-art technology and the simple, menu-driven programming of the pump will provide many benefits.

This user guide is designed to help you to understand pump therapy and the operation of your Medtronic MiniMed Paradigm® REAL-Time Revel™ insulin pump. We strongly recommend that you work closely with your healthcare professional for a safe and complete pump start.

Assistance

Medtronic Diabetes provides a 24 Hour HelpLine for assistance. The HelpLine is staffed with representatives who are trained in the set-up and operation of the pump and are able to answer pump-related questions. When calling the HelpLine or your local Medtronic Diabetes office, please have your pump and serial number available. The phone number for the 24 Hour HelpLine is also on the back of your pump.

Department	Telephone number
24 Hour HelpLine (calls within the United States)	800 646 4633
24 Hour HelpLine (calls outside the United States)	+1 818 576 5555
Web site	www.medtronicdiabetes.com

Emergency kit

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. Inform a family member, co-worker, and/or friend where this emergency kit is kept. Please refer to the *User safety* section in this chapter for more information on pump safety. Your emergency kit should include these items:

- Fast-acting glucose tablets
- Blood glucose monitoring supplies
- Urine ketone monitoring supplies
- Extra Paradigm® compatible infusion set and Paradigm reservoir
- Insulin syringe and fast-acting insulin (with dosage instructions from your healthcare professional)
- Wallet card
- Dressing and adhesive
- Glucagon Emergency Kit®
- Extra AAA alkaline batteries (Energizer® brand is recommended)

CAUTION: If you give yourself insulin by using a syringe or pen, the Bolus Wizard feature will not be able to correctly determine the active insulin in your system. The Bolus Wizard does not account for manual injections, and could prompt you to deliver more insulin than needed. Too much insulin may cause low BG. Consult with your healthcare professional on how long you need to wait after a manual injection before you can rely on the active insulin calculation of your Bolus Wizard feature.

Consumables

The pumps use disposable reservoirs and infusion sets for insulin delivery. Installation instructions for Paradigm reservoir and Paradigm compatible infusion sets are provided in the *Starting on insulin* chapter.

- **Reservoirs** – For the 523 pump, use the 176-unit Paradigm reservoir (MMT-326A). The 723 pump can be used with either the 300-unit Paradigm reservoir (MMT-332A) or the 176-unit reservoir, depending on your insulin needs.
- **Infusion sets** – Medtronic Diabetes provides a variety of Paradigm-compatible infusion sets to fit your needs. Contact your healthcare professional for help in choosing an infusion set that fits your needs. Change your infusion set every two to three days.

WARNING: For your protection the pump has undergone extensive testing to confirm appropriate operation when used with Paradigm reservoirs and Paradigm compatible infusion sets manufactured or distributed by Medtronic Diabetes. We recommend using Medtronic Diabetes infusion sets and reservoirs as we cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third-parties and therefore we are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.

Accessories

- **Meter** – Your pump can be used with Bayer's CONTOUR® NEXT LINK Wireless Meter, a blood glucose meter powered by MWT1 technology. MWT1 is the wireless Radio Frequency (RF) technology that is used to transmit information from the meter to the pump. You can program your pump to automatically receive your BG reading from this meter. Bayer's CONTOUR® NEXT LINK Wireless Meter can also be used to upload insulin pump data to CareLink® Personal using a USB port on your computer. Refer the *Meter Option* section for information on how to manually or wirelessly transmit blood glucose values from the meter to the pump.
- **Remote control** – The optional Paradigm remote control can be used with the pump to deliver normal boluses and suspend/resume the pump from a distant location. (This user guide provides programming instructions for the remote control. Refer to the remote control user guide for operating instructions.)
- **Medtronic MiniLink® transmitter** – The transmitter (MMT-7703) is a small device that connects to the sensor. It comes with two watertight testers and a charger. When connected to a sensor that is inserted in the body, the transmitter automatically initializes the sensor and begins to periodically send glucose data to the pump using a radio signal.

- **Enlite® sensor** – The sensor (MMT-7008) continuously converts tiny amounts of glucose from your fatty layer under the skin into an electronic signal. This signal is sent to the transmitter.
- **CareLink USB upload device** – The Medtronic Diabetes CareLink USB (MMT-7305) is used to upload the Paradigm 523 or 723 pump data to the diabetes management software using a USB port on your computer.

To order supplies, call 800 646 4633, +1 818 576 5555 (outside U.S.), refer to the contacts list at the beginning of this user guide, or visit our web site at www.medtronicdiabetes.com.

How to wear your pump

There are different ways to wear your pump. Medtronic Diabetes has optional accessories that can hide, protect, and add to the convenience of wearing a pump. Refer to the accessories catalog or the website (www.medtronicdiabetes.com) for more information.

- **Holster** – To wear the pump on your belt.
- **Pump clip** – To wear the pump underneath your clothing.
- **Activity guard** – Children or people who are active in sports can use the guard to protect the pump from disconnecting.
- **Leather case** – Fine leather lined with nylon. Styling complements business and formal wear. A flap with a hook-and-loop fastener provides easy access for programming. Wear it vertically with the built-in belt clip.

Working with your healthcare professional

Always consult your healthcare professional about your diabetes management and insulin pump therapy. Your healthcare professional will prescribe the pump settings that are best for you. Always consult your healthcare professional before changing your pump settings or using advanced features.

This user guide contains some clinical language. Before using your pump and working with this user guide, consult your healthcare professional about how the clinical language in this guide applies to your diabetes management and insulin pump therapy.

How to use this guide

NOTE: *This user guide shows sample screens only. Your pump screens may be slightly different.*

For step-by-step instructions, refer to the appropriate sections in this guide. Refer to the *Glossary* for definitions of terms and functions. The terms and symbols used in this guide are in the table below.

Conventions	Meaning
Press	to push and release the button
Hold	to push and keep pressure on the button
Select	to press  or  to highlight a screen item you want to select
Exit the menus	press ESC until the HOME screen appears
Pump buttons	always bold and uppercase; for example, ESC , ACT
Screen and menu names	always uppercase; for example, MAIN MENU, REWIND screen
Menu selections	always bold; for example, 24 Hour Setup , On , Off
Flashing (blinking) screen item	you can change the value for that item with the  or  buttons
NOTE and TIP	additional helpful information
CAUTION	warns of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment
WARNING	notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards
Go to the...screen.	<p>when a step instructs you to go to a certain screen, the path to that screen is shown. For example: Go to the ALARM MENU.</p> <p>Main > Utilities > Alarm</p> <ol style="list-style-type: none"> 1 From the MAIN MENU, select Utilities and press ACT. 2 In the UTILITIES MENU, select Alarm and press ACT. 3 The ALARM MENU appears.

User safety

Indications

Paradigm REAL-Time Revel insulin pump

The Paradigm REAL-Time Revel insulin pumps (MMT-523/MMT-723) are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The Paradigm REAL-Time Revel system consists of the Paradigm MMT-523/MMT-723 insulin pumps, the Enlite glucose sensor (MMT-7008), and the MiniLink Transmitter (MMT-7703). Use of the Paradigm MMT-523/MMT-723 insulin pumps with the optional sensor and transmitter components is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, and possible low and high blood glucose episodes in adults (ages 18 and older).

Enlite Sensor

The Enlite sensor (MMT-7008) is intended for use with the Paradigm REAL-Time Revel insulin pump systems (MMT-523/MMT-723) to continuously monitor glucose levels in persons with diabetes.

Glucose values provided by the Paradigm REAL-Time Revel system are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the sensor glucose readings provided by the Paradigm REAL-Time Revel system.

Meter

The Paradigm pump can be programmed to receive fingerstick blood glucose values transmitted from Bayer's CONTOUR® NEXT LINK Wireless Meter for use in the Bolus Wizard calculator and for use as calibration values for the glucose sensor. Glucose values from other glucose meters must be manually entered into the pump.

Potential risks

Risks related to insulin pump infusion

General risks related to insulin pump infusion set may include:

- Localized infection
- Skin irritation or redness
- Bruising

- Discomfort or pain
- Bleeding
- Irritation
- Rash

Patients should be instructed to follow the provided user guides for insertions and care of infusion sets. If an infusion site becomes irritated or inflamed, the infusion set should be removed and another placed in a new location.

Risks related to insulin administration and pump use

Due to the use of insulin, there is risk related to the infusion of insulin and the potential interruptions of insulin delivery. These general risks may include:

- Hypoglycemia
- Hyperglycemia

Risks related to sensor use

General risks related to sensor use may include:

- Skin irritation or other reactions
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small "freckle-like" dot where needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive, tape, or both
- Scarring

Specific risks related to sensor use

During the conduct of the Performance Evaluation of the Enlite™ Glucose Sensor to Support a Full 144 Hours (6 Days) of Use¹, the following specific sensor risks were identified:

- Pain at sensor insertion site during sensor wear (1 incident reported)
- Dermatological risks (number of events/number of skin assessments performed):
 - Redness due to device insertion (abdomen, 35/213)
 - Redness in area of adhesive (abdomen, 63/213)
 - Bruising (abdomen, 2/213)
 - Bump (induration) (abdomen, 1/213)
 - Bleeding:
 - Bleeding immediately after insertion (abdomen, 2/213)
 - Bleeding at removal (abdomen, 5/213)
 - Fluid discharge (abdomen, 1/213)
 - Other, including indentation from device, e.g., transmitter (abdomen, 9/213)

Taking medications with acetaminophen while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions.

The Enlite Sensor is not approved for use in children or adolescents aged younger than 16 years, pregnant women, or persons on dialysis.

It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this sensor in the critically ill population is not recommended.

Sensor placement and insertion is not approved for sites other than the belly (abdomen).

1. Medtronic Inc., *A Performance Evaluation of the Enlite™ Glucose Sensor to Support a Full 144 Hours (6 Days) of Use, CER247/ Z25/C, May 2012.*

Risks related to serter use

General risks with serter use may include skin infection around the area where the serter is used.

Risks related to the MiniMed insulin pump system

General risks related to the MiniMed insulin pump system may include:

- Hypoglycemia
- Hyperglycemia

Specific risks related to the MiniMed insulin pump system

During the conduct of the In-Clinic, Randomized, Cross-Over Study to Assess the Efficacy of the Low Glucose Suspend (LGS) Feature in the MiniMed Paradigm® X54 System with Hypoglycemic Induction from Exercise ², the following specific system risks were identified:

- Bruising at sensor site (1 incident reported)
- Bleeding at sensor site (1 incident reported)
- Urine ketones resulting from improper connection of the tubing to the insulin pump (1 incident reported)

Contraindications

Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day and to maintain contact with their healthcare professional. Successful insulin pump therapy requires sufficient vision or hearing to allow recognition of the pump signals and alarms.

Do not expose your insulin pump to MRI equipment, diathermy (heat treatment commonly used during physical therapy to relieve pain), or other devices that generate very strong magnetic fields (for example, motor generator sets, industrial motors, or magnetic machine chucks). The magnetic fields in the immediate vicinity of these devices can damage the part of the pump's motor that regulates insulin delivery, possibly resulting in over-delivery and severe hypoglycemia.

Your pump must be removed and kept outside the room during magnetic resonance imaging (MRI) procedures.

If your pump is inadvertently exposed to a strong magnetic field, discontinue use and contact our 24 Hour HelpLine for further assistance.

2. Medtronic Inc., *An In-Clinic, Randomized, Cross-Over Study to Assess the Efficacy of the Low Glucose Suspend (LGS) Feature in the MiniMed Paradigm® X54 System with Hypoglycemic Induction from Exercise*, CER235/Z25/A, November 2011.

Warnings

Pump

The pump is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Never rely on the pump beeps or vibrations alone to navigate through the pump screens or menus, as this may result in incorrect menu selection or setting. You should always check your pump if you hear any unanticipated beeps or vibrations.

The drive support cap should appear slightly indented at all times (as shown in the image). If you notice that the cap is loose, or sticking out, discontinue use of the pump and contact our 24 Hour HelpLine at 1 800 646 4633 to arrange for your pump to be replaced. **Do not press on the drive support cap if it is sticking out. Pushing on the drive support cap may result in unintended delivery of insulin, which can cause hypoglycemia.** Do not attempt to remove any excess glue that might be present on the drive support cap.



Reservoir and infusion sets

Standard Luer sets are not compatible with the Medtronic MiniMed Paradigm pump. Medtronic Diabetes Paradigm reservoirs and Paradigm-compatible infusion sets are specifically designed for use with the pump. Do not modify your Paradigm reservoir or Paradigm-compatible infusion set.

Do not put any other drugs/medications inside your reservoir to use with this pump. Only insulin that has been prescribed by your physician can be used in this pump.

Sensor

Bleeding, swelling, irritation and/or infection at the insertion site are possible risks associated with inserting the sensor and sometimes result from improper insertion and maintenance of insertion site. Rotate the sensor insertion site so that sites do not become overused.

If you suspect that the sensor has broken and is lodged in your skin, please report the issue to the Medtronic HelpLine and seek guidance from your health care professional.

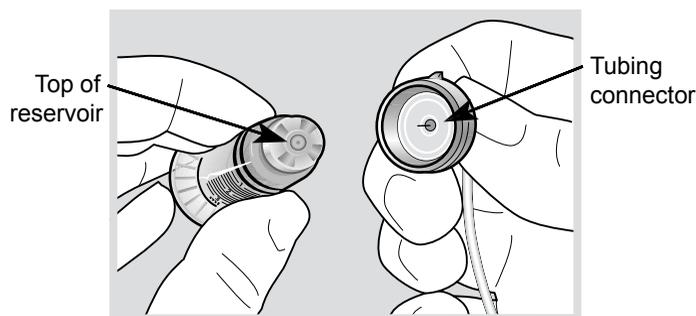
Transmitter

Product contains small parts and may pose a choking hazard for young children.

Optional occlusive dressing should be removed if irritation or reaction to this develops.

Tubing Connector

If insulin, or any liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly prime the infusion set. This may result in the delivery of too little or too much insulin, which can cause hypoglycemia or hyperglycemia. To prevent liquid from getting inside the tubing connector, after you fill the reservoir make sure you hold the insulin vial upright when you remove the reservoir from the transfer guard. If you do not hold the insulin vial upright, insulin can get on the top of the reservoir and could transfer liquid into the tubing connector. If any liquid gets on the top of the reservoir or inside the tubing connector when you change your infusion set, start over with a new reservoir and infusion set. For instructions on setting up your reservoir, see *Setting up the reservoir*, on page 56. For instructions on changing your infusion set, see *Changing your infusion set*, on page 58.



Exposure to magnetic fields and radiation

Warning: Keep the pump away from magnetic fields and avoid direct contact with any magnets.

If you are going to have an X-ray, MRI, diathermy treatment, CT scan, or other type of exposure to radiation, take off your pump, sensor, transmitter, and meter before entering a room containing any equipment of this kind. The magnetic fields and radiation in the immediate vicinity of this equipment can make your devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and severe hypoglycemia.

Do not expose your pump to a permanent magnet, such as pump cases that have a magnetic clasp. Exposure to a permanent magnet may interfere with the motor inside the pump.

Airport security

Important information about airport security systems, and using your insulin pump on an airplane, can be found on the Emergency Card. Be sure to carry the Emergency Card provided when you are traveling.

Precautions

Although the pump has multiple safety alarms, it cannot notify you if the set is leaking or the insulin has lost its potency. It is essential, therefore, that you test your blood glucose levels at least four times per day. If your blood glucose is out of range, check the pump and the infusion set to ensure that the necessary amount of insulin is being delivered.

Avoid extreme temperatures

- 1 Avoid exposure of your pump and remote control to temperatures above 108°F (42°C) or below 34°F (1°C).
- 2 Insulin solutions freeze near 32°F (0°C) and degrade at high temperatures. If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool.
- 3 Do not steam, sterilize, or autoclave your pump or remote control.

Infusion sets and sites

Avoid using an infusion set insertion site that will be irritated by clothing and accessories, or by rigorous stretching and exercise.

Sensor

Prior to exercising, make sure the sensor is firmly attached. Rotate the sensor insertion site so that sites do not become overused.

Adverse reactions

Operation of the sensor feature requires the insertion of a glucose sensor into the skin. Bleeding, swelling, bruising, or infection at the sensor insertion site are possible risks of sensor use. The sensor should be removed if redness, pain, tenderness, or swelling develop at the insertion site. The optional occlusive dressing should be removed if irritation or a reaction to this develops. Contact your doctor and our 24 Hour HelpLine in the event of any adverse reaction.

Notice

Warning: Do not modify this product, as modification could result in a safety hazard.

Radio Frequency (RF) communication

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility.

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

These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.

This device can generate, use, and radiate radio frequency energy and, if installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
- Increase the separation between the transmitter and the device that is receiving/emitting interference.

If other devices that employ radio frequencies are in use, such as cell phones, cordless phones, and wireless networks, they may prevent communication between the transmitter and the insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, please contact the 24 Hour HelpLine.

If the pump and transmitter are not communicating, the devices will attempt to reestablish a lost connection. If a connection cannot be established, the user will be alerted. The pump includes a programmable WEAK SIGNAL alert that notifies you when one or more expected transmissions were not received as expected by the pump. The pump will also issue a LOST SENSOR alert if communication is interrupted for an extended period of time. If you receive a WEAK SIGNAL or LOST SENSOR alert, please see the *Alarms and alerts* chapter.

Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, please contact the 24 Hour HelpLine.

RF interference from other devices

Common consumer electronic devices that transmit in the same frequency band used by the MMT-7703 MiniLink transmitter may prevent the pump from receiving the glucose information sent by the transmitter. Most cellular (mobile) phones and 900 MHz cordless phones, when transmitting or receiving may cause significant interruption of transmitter-receiver communication. It is likely that other devices operating in similar frequency ranges will have a similar effect. This interference, however, will not cause any incorrect data to be sent and will not cause any harm to your transmitter

Communications problems may also occur due to cellular telephone interference. Testing conducted with several different cellular telephones indicates that, while a glucose value is being transmitted, using a cell phone within 12 inches (31 cm) of receiving devices, transmitters or RF glucose meters can interfere with reception of the transmitted values. In the event of such interference, normal communication can be reestablished by:

- turning the cell phone off; or
- keeping the cell phone at least 12 inches (31 cm) away from the receiving device, transmitter or glucose meter when a glucose measurement is being transmitted.

Caution: Changes or modifications to the internal RF transmitter or antenna not expressly approved by Medtronic could void the user's authority to operate this insulin delivery system.

The basics

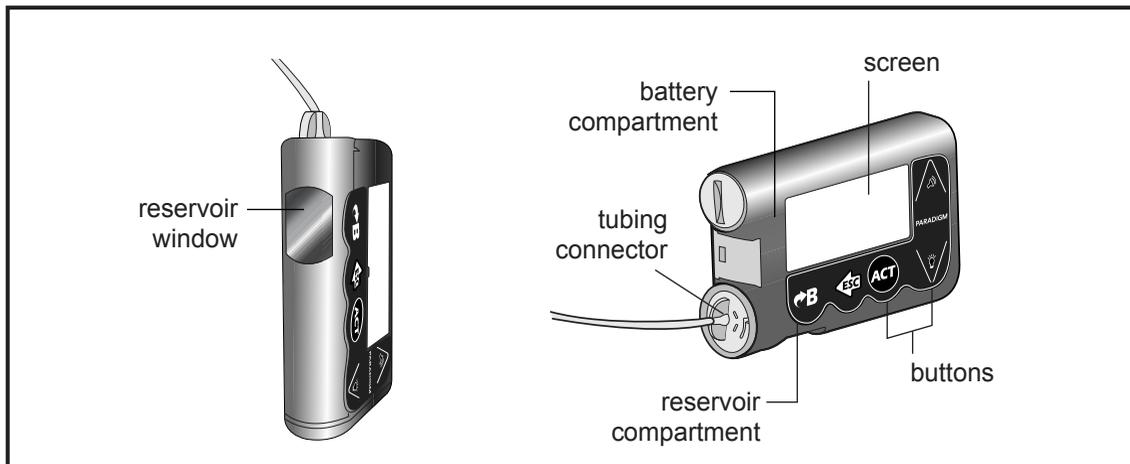
Your pump

WARNING: Never start on insulin until directed by your healthcare professional. Do not use insulin in your pump while you are practicing by either inserting an insulin filled reservoir into your pump, or connecting an insulin filled infusion set to your body. Doing so could result in an infusion of insulin, not prescribed by your healthcare professional, which may cause low or high BG.

CAUTION: Never use sharp objects to press the buttons on your Paradigm pump as this can damage the buttons or compromise the seal of the pump. Some examples of sharp objects that may damage your keypad are fingernail files, pens or pencils, paper clips, knives, scissors, and keys.

NOTE: *If you are practicing, do not select the Rewind or Clear Settings options in the pump menu as these will cancel the practice mode. Make sure the red shipping cap is installed in the reservoir compartment as shipped.*

Take a look at your pump. The reservoir window allows you to view the insulin in the reservoir. The reservoir, with the tubing connector attached, is inserted into the reservoir compartment of the pump.

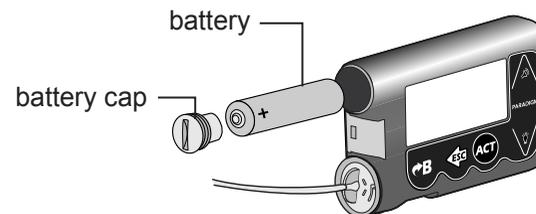


Inserting the battery

CAUTION: Do not remove the battery unless you are inserting a new battery. Insert the new battery within five minutes, or your pump will display the BATT OUT LIMIT or FAILED BATT TEST alarm and you may need to re-enter some pump settings. Follow the instructions in the message and make sure the time and date are set correctly.

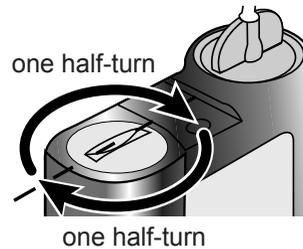
Medtronic Diabetes designed the pump to only accept a new battery. As a safety measure, if you install a battery that does not have full power, the WEAK BATTERY or FAILED BATT TEST alarm may sound. If you receive a WEAK BATTERY alarm, respond to the alarm and continue. The pump will still operate normally, but with a decreased battery life. The pump uses one AAA alkaline battery.

- 1 Make sure all the following apply:
 - Clear (ESC, ACT) any alarms and/or alerts before removing and replacing the battery.
 - Make sure the pump is at the HOME (idle) screen when you remove the battery.
 - Do NOT remove the battery during a bolus or Fill Cannula delivery.
- 2 Use the edge of a coin to remove the battery cap. Turn the cap in a counter-clockwise direction.
- 3 Remove the old battery and dispose of it per the disposable requirements of your state or country. Put the new battery in the pump with the negative end [(-) symbol] going in first. Check the label on the back of the pump 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.

- 4 Place the battery cap in the pump and tighten so the slot is aligned horizontally with the pump as shown here:



CAUTION: Do not over-tighten the battery cap. You should not turn the cap more than four half turns. If you over-tighten the cap you may not be able to remove it, and you can damage your pump.

- 5 While the pump turns on, it will show one or more screens until the HOME screen appears.
If the HOME screen does not appear, do these steps:
 - a. Check that the battery is inserted correctly. If the battery has been installed backwards, remove the battery and install it properly.
 - b. If your pump still does not turn on or you get a FAILED BATT TEST alarm, remove and replace the battery with a new one.
 - c. If the pump is still not on, call our 24 Hour HelpLine.
- 6 Check to make sure the time and date are correct. If more than five minutes have passed since you removed the battery, you will be prompted to check the time and date. Refer to the *Setting the time and date* section in the *Basic programming* chapter for programming instructions.
- 7 Press **ESC** to view the STATUS screen, making sure no alarms are active. If an alarm is active, follow the instructions on the screen.



HOME screen

Pump buttons

The buttons on the pump are used to navigate through the menus and screens, and to program the features of the pump.



The following table describes how to use the buttons on your pump from the **HOME** screen:

Button	Description
	EASY BOLUS™ button - Shortcut to set and deliver an Easy Bolus.
	Turns the backlight on or off.
	Opens the MAIN MENU.
	<ul style="list-style-type: none"> • Opens the pump STATUS screen if the sensor feature is turned off. • Opens the following screens and graphs from the HOME screen if the sensor feature is turned on: <ul style="list-style-type: none"> • 1 press opens the last sensor graph selected. • 2 presses open the pump STATUS screen. • 3 presses open the SENSOR STATUS screen.
	EXPRESS BOLUS button - Shortcut to set any bolus.

The following table describes how to use the buttons on your pump from the menus and programming screens:

Button	Description
	Increases or decreases the value of a flashing item. Scrolls up or down the items in a list.
	Accepts a selected menu item or activates a selected setting.
	<ul style="list-style-type: none"> • Returns to previous screen or exits the menu. • Backs out of unintentional menu selections if the ACT button has not been pressed yet.
	<ul style="list-style-type: none"> • Press simultaneously with  to turn on backlight when in the menus. • Use as a Shift button by pressing it in combination with another button to access certain features.

The pump screen

The screen shows five lines of text at one time. The first is the operating mode. The second is the current open menu or function. The last three lines show either information or text that you can select for the current function.

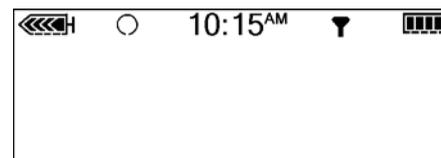
NOTE: The screen text in the examples used in this guide might not exactly match the text on your pump screen. Please follow your pump screen instructions. If you have any questions, contact our 24 Hour HelpLine.

HOME screen

The HOME screen serves as the starting point to access the programming screens. When no buttons are pressed for about 30 seconds, the pump returns to this screen.

When you press **ACT** from the HOME screen, the MAIN MENU will appear.

When the pump is on, the following icons always appear across the top of the screen: reservoir volume icon, the time (12- or 24-hr), and the battery icon. If these do not appear, the pump is not operating.



Screen icons

There are various icons that appear at the top of your pump screen, like the time, battery and reservoir icons mentioned above. The next sections describe what the icons mean.

Battery

The battery icon tells you how much usable life is left in your battery. There are four segments in the icon. Each segment represents approximately 25 percent of the usable battery life you have left until you reach Low Battery point. So if you only have one segment left, make sure you have a new battery available.



At least 75% left



Low battery

Time display

The current time of day is displayed across the top of the pump screen in the format you select—12-hour or 24-hour. The AM or PM is only displayed for the 12-hour format. For instructions on setting the time on your pump, see the *Setting the time and date* section in the *Basic programming* chapter.

00:00 24-Hr

12:00^{AM} 12-Hr

Time Display

Reservoir volume

The reservoir volume icon tells you how much insulin is in your pump. This icon is also divided into four segments. Each segment represents approximately 25 percent of the reservoir volume you have left. This allows you to be aware of how much insulin you have left in your pump. Refer to your STATUS screen to view the number of units left in the reservoir.



Full 176-unit reservoir MMT-723 pump

NOTE: For the Paradigm 723 pump, your reservoir icon will only appear full if using a filled, 300-unit reservoir. This icon will appear as indicated in the illustration above if you are using a 176-unit reservoir.

Alert and alarm icons

An open circle (alert) or a solid circle (alarm) are displayed in the upper part of your pump screen only when there is an alert or alarm condition on your pump. For alarm and alert information, see the *Alarms and alerts* chapter.



Alert icon



Alarm icon

Sensor icons

A dark sensor icon means that the sensor is on and the pump is receiving sensor data. A light-colored sensor icon with a dark circle around it means that the sensor is on, but the pump is not receiving sensor data. For information about the sensor, see the *Sensor features* chapter.



Sensor is on and the pump is receiving sensor data



Sensor is on but the pump is not receiving sensor data

Scroll bar

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



↑
scroll bar

Screen backlight

When you press  from the HOME screen, the light on the screen turns on or off. During programming, the backlight can be turned on by pressing the  and the  together. The light will stay on while you are pressing any of the pump buttons. It will stay on as long as the current screen is active.

To conserve your battery, the backlight will turn off automatically while the pump is vibrating. After the vibration is finished, the light will turn back on. The backlight cannot be turned on in a low or dead battery condition.

Beep/vibrate

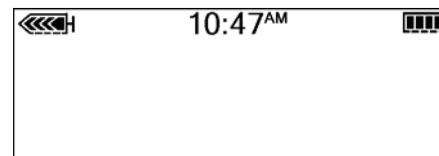
Your pump will beep or vibrate to indicate activity. Refer to the *Setting your alert type* section in the *Utilities* chapter for setup instructions.

Operating modes

The screen lets you know when a special feature is active or if there is a condition that needs your attention. The active features and pump status will determine the operating mode. The screens for the three modes are shown in the following sections.

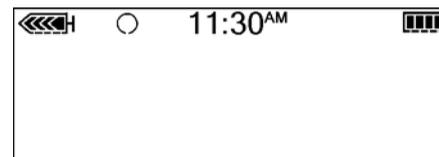
Normal mode

Mode for standard pump operations for normal basal and bolus delivery. No special features are active (such as basal patterns, temp basal, and others). No alarms and no alerts exist.



Special mode

Indicates a special feature is active or an alert condition(s) exists. Special mode does not restrict any of the pump functions. When the pump is in Special mode, an open circle appears at the top of the screen and it beeps or vibrates periodically to remind you of the condition. The conditions and features that put the pump in Special mode are:

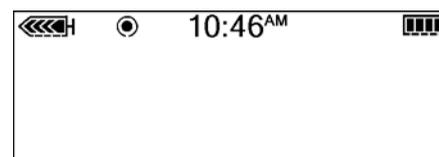


- Low Reservoir condition
- Low Battery condition
- Block feature is on
- Dual or Square Wave bolus delivery
- Basal pattern A or B is active
- Sensor alerts
- Temporary basal delivery
- Alert Silence is active

Attention mode

WARNING: Do not ignore your pump when it is in Attention  mode because all insulin delivery is stopped, which may lead to high blood glucose and ketoacidosis.

Indicates insulin delivery has stopped. This can mean that the pump is in Suspend mode. It can also mean an alarm is active or an alarm condition exists that needs immediate attention for insulin delivery to resume. A solid circle appears at the top of the screen and the pump will beep periodically until either the pump is taken out of Suspend mode or the condition is cleared. The screen will show text describing the condition that put the pump in Attention mode. For example, if the reservoir is empty, EMPTY RESERVOIR will appear on the screen.



When the pump is in Attention mode, it will beep or vibrate periodically to remind you of the condition. The beep or vibrate frequency varies depending on the condition that put the pump in Attention mode. Refer to the *Alarm conditions* section in the *Alarms and alerts* chapter for alarm conditions that will trigger the Attention mode. See the *Stopping your pump* section in the *Basic programming* chapter to learn about Suspend mode.

Menus

The MAIN MENU is the highest level menu. There are submenus, functions, status and programming screens in the lower menu levels. The menus are described in the following paragraphs.

Tip: If a screen item is flashing (blinking), during programming, press  or  to change the value.

MAIN MENU

Highest menu level in the menu system. When you press **ACT** from the HOME screen, the MAIN MENU will appear.

BOLUS MENU

Contains the settings and functions for bolus deliveries. The  button allows direct access to MANUAL BOLUS or to the BOLUS WIZARD feature without having to navigate through the menus. Refer to the *Basic programming* chapter for the manual bolus information or to the *Using the Bolus Wizard feature* chapter for bolusing using the Bolus Wizard feature.

SUSPEND

Stops all current insulin deliveries. Refer to the *Stopping your pump* section in the *Basic programming* chapter for more information.

SENSOR MENU

Contains the functions to setup the interface between the sensor and the pump and access to the pump's sensor features.

CAPTURE EVENT

Contains the options you use to enter information about different events into the system. Examples of events include: the amount of insulin used for injections, and the carbohydrates consumed during meals or snacks. The Capture Event option appears in the MAIN MENU after this feature has been turned on in the UTILITIES MENU. See the *Capturing Events* section in the *Basic programming* chapter for more details.

BASAL MENU

Contains the functions to setup and deliver your basal. Refer to the *Basal* section in the *Basic programming* chapter for more information.

RESERVOIR + SET MENU

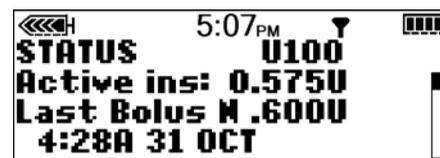
Contains the functions required to change your reservoir and fill the infusion set with insulin. Refer to *Changing your infusion set* section in the *Starting on insulin* chapter for more information.

UTILITIES MENU

Contains features for your safety and convenience. Refer to the *Utilities* chapter for more information.

STATUS screen

The STATUS screen shows information about what your pump is doing. Only check your pump status (press ESC) when you are not programming your pump. If you press ESC during programming, you will cancel the settings you are trying to enter.



The information that shows on the STATUS screen depends on the current activities and conditions of your pump.

- To open the STATUS screen, press **ESC** until the STATUS screen appears.
- To view more text on STATUS screen, press  or  to scroll and view all of the information.
- To exit the STATUS screen, press **ESC** until the STATUS screen disappears.

The screen includes information about:

- Last bolus insulin delivery
- Current basal insulin delivery
- The amount of active insulin, if any

- Special features that are turned on
- Last alarm/alert that was cleared within 24 hours
- Most recent BG meter reading received within 24 hours
- Reservoir status
- Battery status
- Time and date

Refer to the *Pump specifications* chapter for a complete list of the information that is available in the STATUS screen.

If you remove your pump

You may have an occasion when you need or want to remove your pump. If you have to remove and store your pump, it is recommended that you do the following:

- Store your pump with the battery in place
- Keep a record of your current basal rates and use the *Save Settings* feature (see the *Saving the settings* section in the *Utilities* chapter).
- To preserve battery life, reset the basal rates to 0 (zero), turn off the RF options (meter, remote), and set Auto-off to dashes or zeroes.

Remember, your body still needs insulin while your pump is removed.

It is important that you consult with your healthcare professional to determine an alternate method of receiving your insulin. Disconnecting from your pump for less than one hour may not require an insulin adjustment. If you remove your pump for more than one hour, you will have to use another way to take your insulin, as prescribed by your healthcare professional.

Basic programming

Setting the time and date

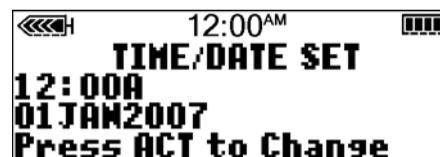
Setting the correct time and date in your pump is necessary for accurate basal insulin delivery and allows you to keep an accurate record of your insulin delivery and other pump functions. You can select a 12-hour or 24-hour clock. You must reset the time and date if you receive a CHECK SETTINGS alarm or you clear your settings (Clear Settings function).

- 1 Go to the TIME/DATE SETUP screen.

Main > Utilities > Time/Date



- 2 Select 12 Hour Setup or 24 Hour Setup and press ACT.



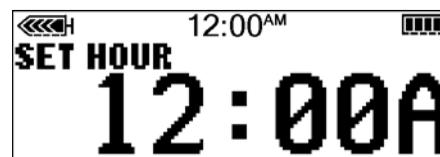
- 3 Press ACT again to change the settings.

- 4 Change each of the settings as follows:

- a. Hour

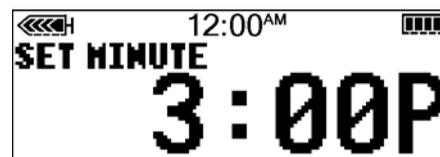
Change the hour. Press ACT.

For 12-hour setups, press  or  until the correct A (am) or P (pm) appears.



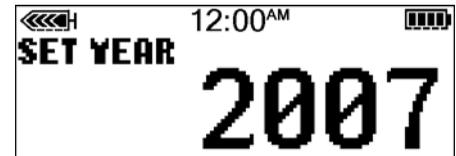
- b. Minutes

Change the minutes. Press ACT.



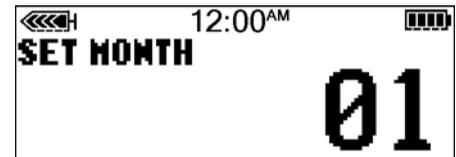
c. Year

Change the year. Press ACT.



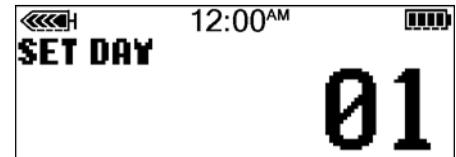
d. Month

Change the month. Press ACT.

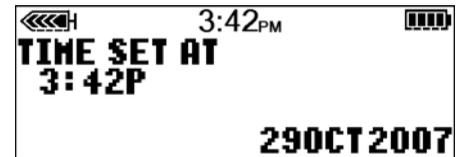


e. Day

Change the day. Press ACT.



- 5 The TIME SET AT screen will show the settings that you programmed. Press ACT and exit the menus. Your time/date settings are complete.



Selecting the language

The language shown on the pump screens can be changed. Some languages may not be available on all pumps. Before you can select another language, you need to set the time using the English screens. Refer to the previous section.

To change the language for your pump:

- 1 Go to the LANGUAGE MENU screen.
Main > Utilities > Language
- 2 Select your language, then press ACT.
- 3 The language setting is now changed. Exit the menus.



Bolus

There are three bolus types: Normal, Square Wave[®], and Dual Wave[®]. This section gives instructions for a Normal bolus using the **EXPRESS BOLUS** button and navigating through the menus. (For information about Square Wave and Dual Wave boluses, refer to the *Optimizing pump therapy* chapter.)

The Normal bolus delivers an immediate food or correction bolus. It can be delivered at any time except during another Normal bolus. During a Normal bolus, most pump features are disabled until after all the bolus has been delivered. The suspend function and the STATUS screen, however, are always available.

Setting the Normal bolus

Normal bolus can be used to cover the carbohydrate in a meal or snack and/or to correct a blood glucose that is higher than your blood glucose target.

The following instructions are for a Normal bolus when the Bolus Wizard feature is turned off.

- 1 Go to the BOLUS MENU.
Main > Bolus

Select **Set Bolus** and press **ACT**. Go to step 2.

You can also use the **EXPRESS BOLUS** button to get to step 2. Press **EXPRESS BOLUS** from your HOME screen.

- 2 a. If the **SET BOLUS** screen appears: (Dual/Square option is off) Go to step 3.
- b. If the **BOLUS TYPE** screen appears: (Dual/Square Wave is on) Select **Normal Bolus** and press **ACT**.
Go to step 3.

- 3 The **SET BOLUS** screen (or **SET NORMAL BOLUS** screen if the Dual/Square option is on) appears with 0.0 unit bolus amount flashing. Enter your bolus amount and press **ACT**.

If some of the bolus insulin delivered by the pump has not been used and is active in your body, the screen will show this amount as Act. Ins. (Active Insulin). This amount is based on the active insulin setting selected in the Bolus Wizard feature. The Active Insulin amount shows even if the Bolus Wizard feature is turned off. Take this amount into consideration to determine your bolus. See *About active insulin*, on page 78 for more information.

NOTE: *If you have BG Reminder turned On, the BG REMINDER DURATION screen displays. It allows you to set the duration before you are reminded to check your blood glucose after a bolus. See the BG Reminder section in this chapter for information about this feature.*

- 4 The **BOLUS DELIVERY** screen appears and the Normal bolus starts. The pump will beep/vibrate at the start of the bolus. As the bolus delivers, the amount shown on the screen will increase until the entire bolus has been delivered. When the bolus is finished, the pump will beep/vibrate again and the HOME screen will appear.

The following practice lessons will help you understand this pump feature.

WARNING: Never start on insulin until directed by your healthcare professional. Do not use insulin in your pump while you are practicing by either inserting an insulin filled reservoir into your pump, or connecting an insulin filled infusion set to your body. Doing so could result in an infusion of insulin, not prescribed by your healthcare professional, which may cause low or high BG.

Normal meal bolus using the exchange system

Normal bolus can be used to cover the carbohydrate in a meal or snack and to correct a blood glucose that is higher than the target that was chosen for you.

Fred has been taught that he needs to take 1 unit of insulin for every carbohydrate exchange that he eats (every milk, every starch or every fruit). For lunch today he will eat:

Turkey sandwich with two slices of bread **2** starches

1 small apple **1** fruit

1 cup of non-fat milk **1** milk

Total carbohydrate exchanges = 4

Fred's lunch has a total of 4 carbohydrate exchanges so he will take a meal bolus of 4 units for his lunch.

Bolus practice:

NOTE: Make sure that you are not connected to your pump while practicing.

Going through the menus, program a 2.0 unit Normal bolus now.

Check here if you were able to program it.

Using the **EXPRESS BOLUS** button , program a 2.0 unit Normal bolus now.

Check here if you were able to program it.

Normal meal bolus practice using exchanges

Choose a meal you might eat and fill in the blanks.

Food: _____ exchange: _____
_____ exchange: _____
_____ exchange: _____
total exchanges: _____

You will take _____ units of insulin for each exchange. Your total bolus is _____ for this meal.

Normal meal bolus using carbohydrate counting

Lydia has been taught that she needs to take 1 unit of insulin for every 10 grams of carbohydrate. This is her insulin to carbohydrate ratio. For dinner she will have:

4 oz. broiled chicken	0 grams
2/3 cup of rice	30 grams
1/2 cup cooked broccoli	5 grams
1 oz. dinner roll	15 grams
1 tsp margarine	0 grams

total grams of carbohydrates = 50 grams

Lydia's dinner totals 50 grams of carbohydrate. Her insulin to carbohydrate ratio is 1 unit to 10 grams. She will take a meal bolus of 5 units for her dinner. She determined this by dividing 50 (total grams of carbohydrate) by 10 (insulin to carbohydrate ratio).

Normal meal bolus practice using carbohydrates

Choose a meal you might eat and fill in the blanks.

Food: _____ grams of carbohydrate: _____
_____ grams of carbohydrate: _____
_____ grams of carbohydrate: _____
total grams of carbohydrate: _____

Your insulin to carbohydrate ratio: 1 unit of insulin for _____ grams carbohydrate.

Divide your total carbohydrates by your insulin to carbohydrate ratio and take _____ units of insulin for your meal.

Meal bolus, correction bolus and insulin sensitivity

Jason is ready to eat his breakfast. He has calculated that he will need 4.0 units for his food.

He tests his blood glucose and finds that it is 200 mg/dL (11.1 mmol/L). Jason knows that his blood glucose level is above his blood glucose target and will need additional insulin before he eats.

Jason's healthcare professional has determined the following for him:

BG Target: 110 mg/dL (6.1 mmol/L)

Insulin sensitivity¹: 36 mg/dL/u (2.0 mmol/L/u)

Jason determines that he will need a correction bolus of 2.5 units insulin to lower his elevated blood glucose. The 2.5 correction bolus will lower his current blood glucose of 200 mg/dL (11.1 mmol/L) to his target of 110 mg/dL (6.1 mmol/L).

- elevated blood glucose: $200 - 110 = 90$ mg/dL ($11.1 - 6.1 = 5$ mmol/L)
- correction bolus: $90 / 36$ mg/dL/u (insulin sensitivity) ($5.0 / 2.0$ mmol/L/u) = 2.5 units

(He will add this 2.5 correction bolus to the 4.0 units of insulin that he will need for his meal bolus. Jason will take a total bolus of 6.5 units.)

1. *Insulin sensitivity is the amount (in mg/dL or mmol/L) by which blood glucose will be lowered after taking 1 unit of insulin. Consult with your healthcare professional to determine your insulin sensitivity.*

Practice: Meal bolus

You have determined your meal bolus as: _____ units.

Your target blood glucose range is: _____ to _____ (average is _____).

Your current blood glucose level is: _____.

Your correction factor is: 1 unit of insulin will drop your blood glucose _____.

You will take _____ unit(s) of insulin to correct your high blood glucose level.

Your total bolus (meal bolus plus correction bolus) is _____.

Review your bolus deliveries

You can view a list of your bolus deliveries in the BOLUS HISTORY screen. This screen shows a list of the dates, times, units, and types for your last 24 boluses. This feature is helpful for record keeping or to check if you bolused for your last meal.

If a bolus was stopped before delivery was complete, the BOLUS HISTORY screen will show only the amount actually delivered. Refer to the *Bolus details* section in this chapter for instructions about viewing bolus details.

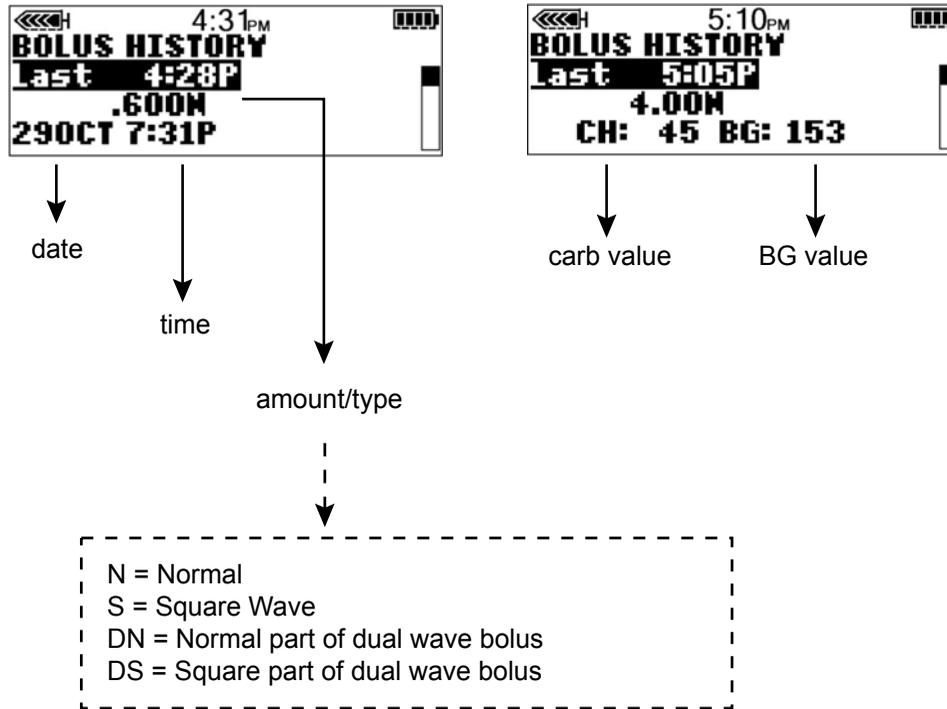
Do the following steps to view the BOLUS HISTORY screen:

- 1 Go to the BOLUS HISTORY screen and scroll through the bolus deliveries.

Main > Bolus > Bolus History

If you used the Bolus Wizard feature to deliver any of these boluses, the BOLUS HISTORY screen shows the carbohydrate/food (CH) and blood glucose values that the Bolus Wizard feature used to calculate the boluses.

(with the Bolus Wizard feature)



2 Refer to the instructions in the *Bolus details* section to see the details for any of these boluses.

Bolus details

You can view the details of any of the deliveries in the BOLUS DETAIL screen. The details include:

- bolus types: normal, square, and dual
- programmed bolus amount

- delivered bolus amount
- Bolus Wizard feature information (if used)

To see the details of any bolus, do these steps:

- 1 In the BOLUS HISTORY screen, select the bolus that you want to review and press ACT.
- 2 The details for that bolus will appear on the screen. Scroll through the details.

Without the Bolus Wizard feature

delivery is active

```

<<<H 12:48PM
BOLUS DETAIL
Type: Normal
User entry: 4.00U
Delivered: 1.40U
  
```

delivery stopped

```

<<<H 12:48PM
BOLUS DETAIL
Type: Normal
User entry: 4.00U
Stopped at: .650U
  
```

delivery completed

```

<<<H 12:48PM
BOLUS DETAIL
Type: Normal
Delivered: 4.00U
  
```

- 3 Exit when you are done.

With the Bolus Wizard feature

If the Bolus Wizard feature calculated your bolus, more information will appear in the BOLUS DETAIL screen.

```

<<<H 5:10PM
BOLUS DETAIL
Type: Normal
Delivered: 4.00U
Bolus wizard:
  
```

Press the down key to see the details

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 10.0 units. You can specify the limit from 0.0 to 25.0 units. Set your Max bolus amount as prescribed by your healthcare professional.

To set the Maximum bolus limit, do these steps:

- 1 Go to the MAX BOLUS SETUP screen.
Main > Bolus > Bolus Setup > Max Bolus
- 2 Set your Max bolus limit and press **ACT**. To change this limit, press **ESC**, and then set a lower Max bolus limit.
- 3 Your Max bolus is set. Exit the menus.

Example 1: Max bolus

Shelby takes very small doses of insulin for her meal boluses. As a safety limit, she and her healthcare professional reset her pump with a Maximum bolus of 5.0 units.

Example 2: Max bolus

David is a growing teenager. He loves to eat big meals and requires very large doses of insulin for his food. David's healthcare professional had him reset his pump with a Maximum bolus of 20.0 units so he can take more insulin when he needs to.

Scroll rate

The scroll rate feature allows you to program bolus insulin delivery in preset increments. These increments are effective on all bolus screens, except for the SET EASY BOLUS screen. See the *Easy bolus setup* section in the *Optimizing pump therapy* chapter for more information on how to set up the steps for your Easy Bolus. The factory setting for the scroll rate feature is 0.10 units, and the available options are 0.025, 0.05, or 0.10 unit increments.

When you set the scroll rate to 0.025, you can use the following increments to program a bolus:

- 0.025 unit increments for a bolus of 0.975 units or less
- 0.05 unit increments for a bolus between 1 unit and 9.95 units
- 0.10 unit increments for a bolus of 10 units or more

When you set the scroll rate to 0.05, you can use the following increments to program a bolus:

- 0.05 unit increments for a bolus of 9.95 units or less
- 0.10 unit increments for a bolus of 10 units or more

When you set the scroll rate to 0.10, the increments will increase or decrease by 0.10 units during bolus programming regardless of the bolus value.

To program your scroll rate:

- 1 Go to the SET SCROLL RATE screen.
Main > Bolus > Bolus Setup > Scroll Rate
- 2 The scroll rate value appears flashing. Change the value and press **ACT**.
- 3 The pump returns to the BOLUS SETUP screen. Your scroll rate is now programmed and ready to use. Exit the menus.

Example: Scroll rate

You have set your scroll rate to 0.025 units. You need to set your pump to deliver a 2.5 unit bolus. The bolus values on the SET BOLUS screen will change in 0.025 unit increments until you reach 1.0 unit. After this the value will change in 0.05 unit increments until you reach 2.5 units in the SET BOLUS screen.

BG Reminder

After you deliver a bolus you may want to check your blood glucose. The BG Reminder is an optional feature that makes the pump beep or vibrate to remind you to check your blood glucose after a bolus. However, this reminder is not available after an Easy Bolus. Your pump is set at the factory with the BG Reminder feature turned off.

When setting a bolus, if the BG Reminder is on, your pump will ask you to set up the BG Reminder Duration. This sets how long after bolus delivery you will be reminded to check your BG. This time can be from 30 minutes to 5 hours, or NONE. The BG Reminder is not available after an Easy Bolus.

1 Go to the BG REMINDER SETUP screen.

Main > Bolus > Bolus Setup > BG Reminder

2 Select **On** and press **ACT**. The BG Reminder is now enabled. Exit the menus.

Now, the next time you program a bolus, your pump will ask you for the amount of time after your bolus before you want to be reminded to check your blood glucose.

When the BG Reminder goes off, your pump will beep or vibrate and **CHECK BG** will appear on the screen. Your pump will beep or vibrate periodically until it is cleared (**ESC**, **ACT**).

When you set a BG Reminder after a bolus, the **STATUS** screen will show the amount of time remaining before the reminder goes off.

Here, the **STATUS** screen indicates that the BG Reminder will go off in 18 minutes.



Capturing Events

The Capture Event feature electronically saves certain types of information. Some examples include:

- Blood glucose (BG) measurements
- The amount of insulin you use
- The amount of carbohydrates you eat or drink
- The exercise you do
- Other (this can be used for anything else as needed)

Make sure that you enter events when they happen since the system records the time of the entry. You cannot change entries after you have put the information into your device. The entered information can be sent to Medtronic CareLink® Personal software. Here it can be used to generate treatment reports that you can share with your healthcare professional. You can view up to 10 of the latest saved events in the **CAPTURE HISTORY** screen.

Turning on the Capture Event feature

The Capture Events option appears in the MAIN MENU after this feature has been turned on in the UTILITIES MENU.

To turn on the Capture Event feature, do these steps:

- 1 Go to the CAPTURE EVENT ON/OFF screen:
Main > Utilities > Capture Option
- 2 Select **On**, then press **ACT**.
You will now have a Capture Event option in the MAIN MENU.

Entering BG measurements

You can save non-calibrating BG readings in device history. Non-calibration meter BG measurements are those that are taken at times when you will not use them for calibration, such as after eating or when your blood glucose is rising or falling rapidly. You also have the option of using the entered reading for calibration purposes. Do **not** calibrate if your sensor is not communicating with your device.

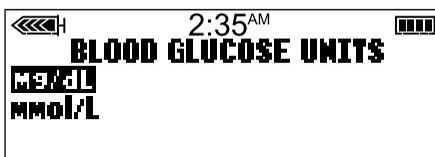
Before you can enter BG readings, you must select the BG units for the Capture Event features. You can set the BG units to mg/dL or mmol/L.

WARNING: Make sure that you select the correct BG units. Standard units in the United States are mg/dL. Selecting the wrong BG units in Capture Events will change the BG units in the Bolus Wizard and Sensor menu. Using the wrong BG units can result in incorrect bolus dosing, incorrect calibration of the sensor, and misinterpretation of glucose information.

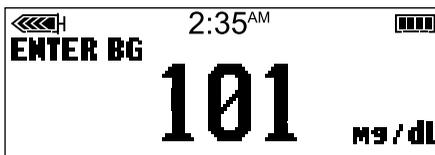
To set the BG units:

- 1 Go to the BLOOD GLUCOSE UNITS screen.

Main > Capture Event > BG Units



- 2 Select either mg/dL or mmol/L, then press ACT. The CAPTURE EVENT menu shows.
- 3 You can now enter your BG reading.



To enter the BG measurement:

- 1 Make a note of the BG measurement.
- 2 Go to the ENTER BG screen.

Main > Capture Event > Enter BG

The ENTER BG screen flashes with dashes or the most recent meter BG measurement you entered.

- 3 Enter your new measurement, then press **ACT**. The BG measurement must be between 20-600 mg/dL (1.1-33.3 mmol/L). A message asks if you want to save the new measurement that is shown on the screen.
- If the information is correct, select **Save BG**, then press **ACT**. Your BG is saved.
 - If the Bolus Wizard feature is off, the CAPTURE EVENT screen appears.
 - If the Bolus Wizard is on and the saved BG is below your BG Target range, the BG Saved screen appears. This screen indicates that your saved BG is below your BG Target set in the Bolus Wizard feature, and the pump beeps three times. See *Setting the BG Targets, on page 77* for more information.
 - If the Bolus Wizard is on, the saved BG is above your BG Target range, and the calculated correction estimate is more than the preset scroll rate increment, the BG Saved screen appears. This screen indicates that your saved BG is above your BG Target set in the Bolus Wizard feature, and the pump beeps three times. Go to the ENTER BG screen of the Bolus Wizard feature to enter a correction bolus. See *Setting the BG Targets, on page 77* for more information.
 - If you want to use the new BG measurement for calibration, select **Save and Calibrate**. This option is available when your sensor is communicating with the pump, and the BG measurement is between 40 mg/dL (2.2 mmol/L) and 400 mg/dL (22.2 mmol/L).
 - If the information is not correct, select **Cancel**, then press **ACT**. The CAPTURE EVENT screen reappears with **Enter BG** selected. Repeat the procedure and enter the correct information.

Entering insulin injection information

Follow these steps to enter the amount of insulin you use.

WARNING: Insulin doses entered under Capture Events are not included in Bolus Wizard calculations of active insulin. Therefore, do not use the Bolus Wizard to calculate a bolus for a period of time after giving a manual injection by syringe or pen. Since the Bolus Wizard does not account for manual injections, it could prompt you to deliver more insulin than needed. Too much insulin may cause low BG. Consult with your healthcare professional for how long you need to wait after a manual injection before you can rely on the active insulin calculation of your Bolus Wizard.

Record your healthcare professional's recommendation here:

- 1 Go to the ENTER INSULIN screen.
Main > Capture Event > Insulin Marker

- The ENTER INSULIN screen flashes with dashes or the insulin amount that you most recently entered.
- 2 Enter the amount of insulin you used, then press **ACT**. A message appears asking you if you want to save this information. The **Yes** option is selected.
 - 3 Make sure that the amount of insulin shown on the screen is correct.
 - If the information is correct, press **ACT**. The information you entered is saved to the system and can now be used in reports.
 - If the information is **not** correct, select **No**, then press **ACT**. The CAPTURE EVENT menu shows. Repeat the procedure to enter the correct information.

Entering carbohydrate information

This section shows you how to enter information about the carbohydrates you eat or drink.

Before you begin

Before you can enter carbohydrate information, you must select the carbohydrate units (Carb Units) for the Capture Event feature. You can set the carbohydrate units to grams or exchanges.

To set the carbohydrate units:

- 1 Go to the CARB UNITS screen.
Main > Capture Event > Carb Units
- 2 Select either **Grams** or **Exchanges**, then press **ACT**. The CAPTURE EVENT menu shows. You are now ready to enter your carbohydrate information.

To enter carbohydrate information:

- 1 Determine the total units of carbohydrates in the meal or snack that you plan to eat.
- 2 Go to the ENTER FOOD screen.
Main > Capture Event > Meal Marker
- 3 The ENTER FOOD screen flashes with dashes or with the number of carbohydrate grams or exchanges you entered last time.
- 4 Enter the carbohydrate grams or exchanges, then press **ACT**. A message asks if you want to save the information that is displayed on the screen. The **Yes** option is selected.

- 5 Make sure the number shown on the screen is correct.
 - If the information is correct, press **ACT**. The information you entered is saved to the system and can now be used in reports.
 - If the information is **not** correct, select **No**, then press **ACT**. The CAPTURE EVENT menu shows. Repeat the steps above to enter the correct information.

Entering exercise information

Follow these steps to enter exercise information. Be consistent and enter the marker either before or after each time you exercise.

- 1 Follow the path below to save your exercise information:
Main > Capture Event > Exercise Marker
- 2 A message asks if you want to save this exercise.
- 3 Make your selection, then press **ACT**.

Entering Other markers

This section shows you how to enter markers other than Enter BG, Insulin Marker, Meal Marker, or Exercise Marker. Examples of Other markers include: when you take medications, when you feel ill, when you are under stress, and so on. The Other marker appears in CareLink Personal reports, and shows at what time you have entered it in the Capture Event feature.

To enter Other markers:

- 1 Follow the path below to save your Other marker:
Main > Capture Event > Other
A message asks if you want to enter this marker.
- 2 Select **Yes**, then press **ACT**. Your pump saves your Other marker and returns to the CAPTURE EVENT screen.

Viewing Capture Event history

You can view up to 10 captured events saved into the device. The most recent event will be displayed at the top of the CAPTURE HISTORY screen.

To view the Capture Event history:

- 1 Go to the CAPTURE HISTORY screen:
Main > Capture Event > History
- 2 The CAPTURE HISTORY screen displays the saved events. Each event has the date and time when it was saved, the name, and any detail associated with that event.

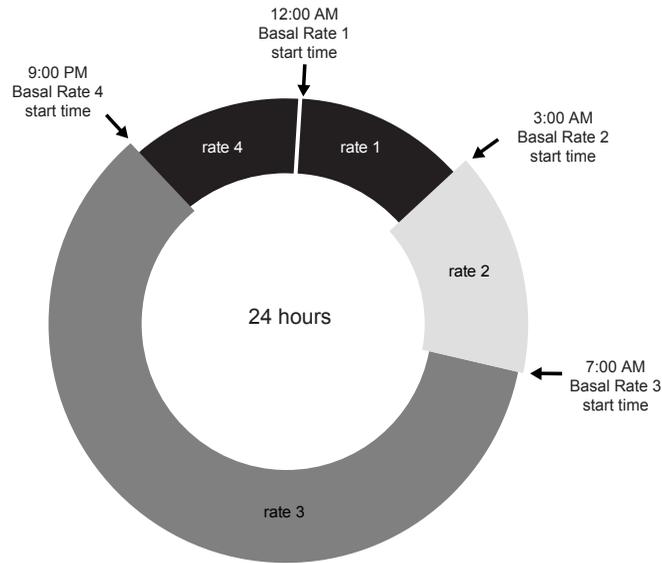
Basal

Basal insulin is required to maintain your target blood glucose values when you are not eating. Your healthcare professional will calculate this rate for you. Your basal insulin accounts for approximately one half of the body's total daily insulin requirements. Your pump mimics your pancreas by delivering insulin continuously over 24 hours.

You can set your insulin pump to change rates during the day to match your needs. Your needs depend on your lifestyle and insulin requirements. Some people only use one rate throughout the day, while others find they need more. Your basal rates are made up of insulin deliveries that have start and stop times. Once set, these rates make up your 24-hour basal pattern and are repeated daily.

Start and stop times

When you set your basal rate(s) in the BASAL MENU, your pump prompts you to set the start time for each basal delivery. The start time of one basal rate is the stop time of the previous rate. This gives you continuous basal insulin through a 24-hour period. For basal rate 1, the start time is midnight (00:00 or 12:00 a.m.) and cannot be changed. See the following sample graph of basal rates.



The start and stop times of basal rates for this example are:

- 12:00 a.m. (00:00) to 2:59 a.m. (2:59) for basal rate 1
- 3:00 a.m. (3:00) to 6:59 a.m. (6:59) for basal rate 2
- 7:00 a.m. (7:00) to 8:59 p.m. (20:59) for basal rate 3
- 9:00 p.m. (21:00) to 11:59 p.m. (23:59) for basal rate 4

If you need one basal insulin that starts before midnight and stops after midnight, you need to set up two basal rates. These basal rates have the same rate but different start and stop times. For example, in this graph a basal rate is needed from 9:00 p.m. to 2:59 a.m. (21:00 to 2:59) at one rate. Basal rate 1 always starts at midnight and should be set to end at 2:59 a.m. (2:59). After setting basal rates 2 and 3, rate 4 is set from 9:00 p.m. (21:00) to 11:59 p.m. (23:59) at the same rate as basal rate 1. This gives continuous basal insulin from 9:00 p.m. to 2:59 a.m. (21:00 to 2:59) at one rate.

You cannot set a start time for one basal rate to overlap the next basal rate. The addition of a new basal rate will erase any basal rates that follow.

Consult your healthcare professional when setting or changing your basal rate(s).

Your basal settings

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

You should set your prescribed basal rates with the assistance of your healthcare professional.

If you plan to take off your pump for an extended period of time, such as more than a day, set the basal rate to 0.000 U/H. This will ensure that the insulin delivery records in your pump are accurate. Refer to the *If you remove your pump* section in *The basics* chapter for more information.

Basal programming and delivery

NOTE: *You cannot make changes to your basal rate settings while a percent temp basal is active.*

To set your basal rates:

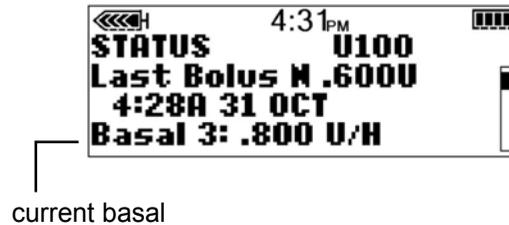
- 1 Go to the SET BASAL RATE 1 screen.
Main > Basal > Basal Setup > Set/Edit Basal
- 2 The SET BASAL RATE 1 screen flashes the basal rate in U/H.
- 3 Enter your first basal rate amount and press **ACT**.
The start time for your first basal rate is midnight and cannot be changed.
- 4 The SET START TIME 2 screen appears. The dashes under the screen name flash. The first basal rate is now set.
If you do not need a second basal rate for the day, press **ESC**. If you need to set up a second basal rate for the day, follow steps 5 and 6.
- 5 In the SET START TIME 2 screen, enter the start time for the next rate.
- 6 Press **ACT**. The SET BASAL RATE 2 screen appears. Enter the rate.
- 7 Press **ACT**. The SET START TIME 3 screen appears. The second basal rate is now set. If you do not need to set up any more basal rates for the day, press **ESC** and skip to step 9. If you need to set up more basal rates, follow steps 5 and 6 for each basal rate.
- 8 After you program your last basal rate, press **ESC**.
- 9 The BASAL RATE screen appears. Your basal rate(s) will now deliver as programmed. Exit the menus.

NOTE: *The pump delivers basal amounts in 0.025 U/H increments for basal rates of less than 1.00 U/H, and in 0.05 U/H increments for basal rates of 1.00 U/H or more.*

- 10 When you have finished programming your pump, you can save your settings. Refer to the *User settings* section in the *Utilities* chapter for instructions.

Current basal delivery

The STATUS screen shows your current basal information.

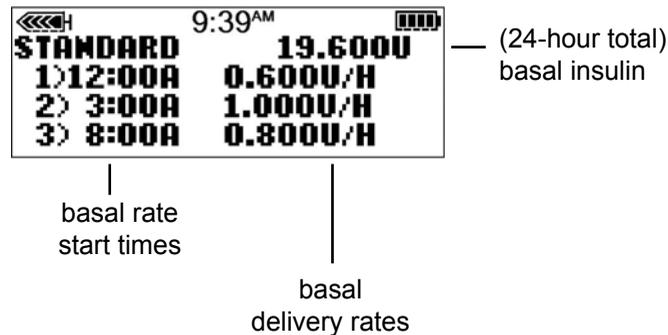


Daily basal rate(s)

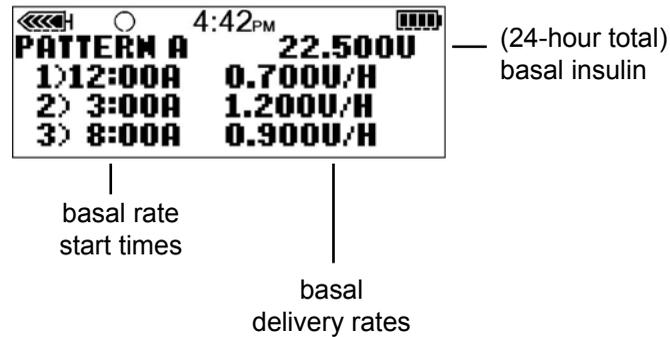
The BASAL REVIEW screen shows your daily basal rates programmed for delivery from midnight to midnight. Compare your daily insulin deliveries to your blood glucose records to help you and your healthcare professional identify your optimal daily basal insulin rate(s).

To review your basal rates, do these steps:

- 1 Go to the BASAL MENU screen.
Main > Basal
- 2 Select **Basal Review** and press **ACT**.
- 3 If you do not use patterns, the STANDARD screen appears.
The delivery details for your standard basal will appear.



If you use patterns, the BASAL REVIEW screen appears.
The current basal pattern will be highlighted. Select the pattern you want to view. Press **ACT**.
The delivery details for that pattern will appear.



4 Exit the menus when you are done.

Setting the Max basal rate

Maximum basal (Max basal) rate is a safety limit for the amount of basal insulin that is able to be delivered per hour. Your pump is sent from the factory with the Max basal set to 2.00 units per hour. It is important to determine your Max basal rates with your healthcare professional. This safety feature will not allow you to program any basal rates, including patterns and temporary basal rates, that are greater than the Max basal rate.

If you are setting your Max basal rate after your basal rates have been set, you **cannot** set a Max basal that is less than any of the programmed basal rates.

To set your Max basal rate, do these steps:

- 1 Go to the MAX BASAL RATE screen. The Max basal rate will be flashing.
Main > Basal > Basal Setup > Max Basal Rate
- 2 Change the rate and press **ACT**.
- 3 Your Max basal rate is now set. Exit the menus.

Example 1: Max basal

Helen has a very low insulin requirement. Her highest basal rate is only 0.400 units per hour. As a safety measure, Helen's healthcare professional set her pump with a Maximum basal rate of 1.00 units per hour.

Example 2: Max basal

Rusty needs large amounts of insulin to control his blood glucose levels. His new pump was delivered from the factory with a Maximum basal rate of 2.00 units per hour, but he needs 2.80 units per hour in the early morning. Rusty will reprogram his Maximum basal rate to 3.00 units per hour to accommodate his needs.

Stopping your pump

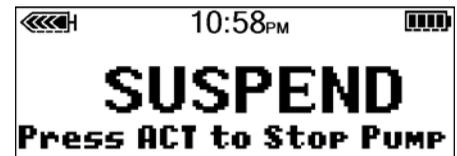
Suspend stops all insulin delivery, including the current basal and any bolus or Fill Cannula deliveries that are in progress. While suspended, your pump will not deliver insulin until you resume your pump. When you resume your pump, the basal delivery will continue.

The pump will beep or vibrate about every 15 minutes on the hour to remind you that it is not delivering insulin. Example: You suspend your pump at 11:20 AM. The pump will beep/vibrate at 11:30 AM, 11:45 AM, 12:00 PM, and so on until you resume your pump (basal resumes).

When suspended, your pump is in Attention mode with a solid circle showing on the pump. When in **Suspend**, you can only resume your basal or view the STATUS screen. If the Sensor feature is turned on, you can also view the sensor graphs and the SENSOR STATUS screen. No other functions are available.

To suspend the pump:

- 1 Select **Suspend** from the MAIN MENU, and press **ACT**.
Main > Suspend
- 2 **SUSPEND** will flash on your screen. Press **ACT** to stop your pump.



- The screen will show that the pump is suspended and the time that it stopped. After less than one minute, the pump will return to the HOME screen with a solid circle. You can verify on your pump STATUS screen that your pump is suspended.



Resume pump delivery

When the pump is suspended, it defaults to the HOME screen with a solid circle.

To resume your pump and basal delivery, do these steps:

- From any screen, press ACT until the RESUME screen appears. Press ACT again.



- Your pump will beep once, then the HOME screen will appear without the solid circle.

CAUTION: A bolus delivery or fill cannula that was suspended does not restart when you resume. To avoid a high BG and ketoacidosis, always check the pump's Bolus History or Reservoir + Set History after you resume insulin delivery to determine the amount that was delivered. If needed, program a new bolus or fill cannula delivery.

Example: Suspend function

Helen is ready to eat her lunch. She has just programmed her pump to deliver a meal bolus when the phone rings. Helen wants to talk on the phone and not eat her lunch right away. She knows that if she lets the bolus continue and she does not eat her lunch soon, she may be at risk for low blood glucose. Helen suspends delivery of her pump to stop the bolus, but then resumes delivery to restart her basal insulin. When she is off the phone and ready to eat, she checks her STATUS screen to see how much insulin she received from the partially delivered bolus before she suspended her pump. She will reprogram a new bolus for the remainder of her bolus amount.

**Practice:
Suspend function**

- 1 **Make sure you are NOT connected to your pump while practicing.**
Program your pump to deliver a Normal bolus of 3.0 units. Once the bolus begins, stop the bolus by suspending your pump.
Remember, when you stop the bolus delivery with SUSPEND, all insulin delivery will stop.
- 2 Now, RESUME delivery, so that your basal insulin will continue.
- 3 Check the STATUS screen.
- 4 How much insulin did the bolus deliver before you Suspended delivery? _____.
- 5 If you wanted to take the rest of the bolus later, how much would you take to equal 3.0 units?
_____.

**Practice:
Resume basal delivery after a suspend**

Make sure you are NOT connected to your pump while practicing.

- 1 Give a 3.0 unit bolus now. While it is delivering, suspend the bolus.
- 2 Check here if you were able to suspend the bolus.
- 3 Now restart the pump.
- 4 Check here if you were able to restart the pump.

Starting on insulin

The Paradigm pump is intended for use with U100 insulin. The following insulins have been tested by Medtronic MiniMed and found to be safe for use in Paradigm REAL-Time insulin pumps (MMT-523/723):

- Humalog®
- Novolog®

Before using different insulin with this pump, check the insulin label to make sure the insulin can be used with the pump.

WARNING: Never start on insulin until directed by your healthcare professional. Do not use insulin in your pump while you are practicing by either inserting an insulin filled reservoir into your pump, or connecting an insulin filled infusion set to your body. Doing so could result in an infusion of insulin, not prescribed by your healthcare professional, which may cause low or high BG.

Prepare your pump for use

Before continuing with the steps in this chapter, we recommend that you watch your pump training CD-ROM and complete your pump start training.

WARNING: Check your time, date, and prescribed settings. If these are not correct when you use your pump, then your insulin will not deliver as prescribed by your healthcare professional.

When you are done practicing and ready to use your pump with insulin, you must make sure the time and date are correct on your pump. You must also program your settings as instructed by your healthcare professional.

You will need these items:

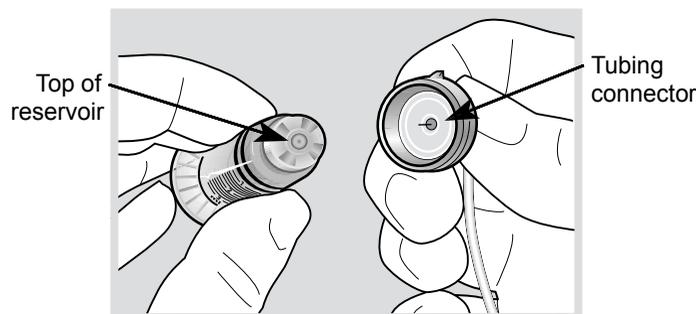
- Pump
- Insulin (U100)
- Paradigm reservoir and user guide
- Paradigm compatible infusion set and user guide

Setting up the reservoir

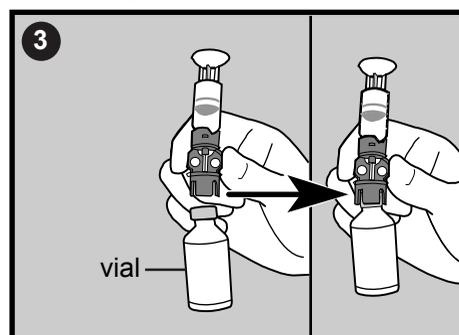
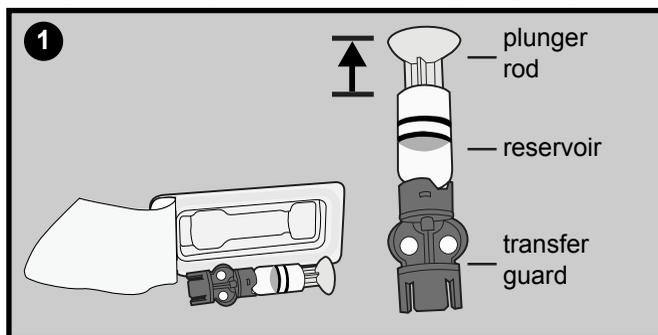
WARNING: Always allow your insulin to reach room temperature before use. Cold insulin can cause air bubbles in the reservoir and tubing, which may result in inaccurate insulin delivery.

Filling the reservoir

Warning: Do not use the reservoir or infusion set if any liquid gets on the top of the reservoir or inside the tubing connector (as shown in the image). Liquid can temporarily block the vents. This may result in the delivery of too little or too much insulin, which can cause hypoglycemia or hyperglycemia. If any liquid gets on the top of the reservoir or inside the tubing connector, start over with a new reservoir and infusion set.

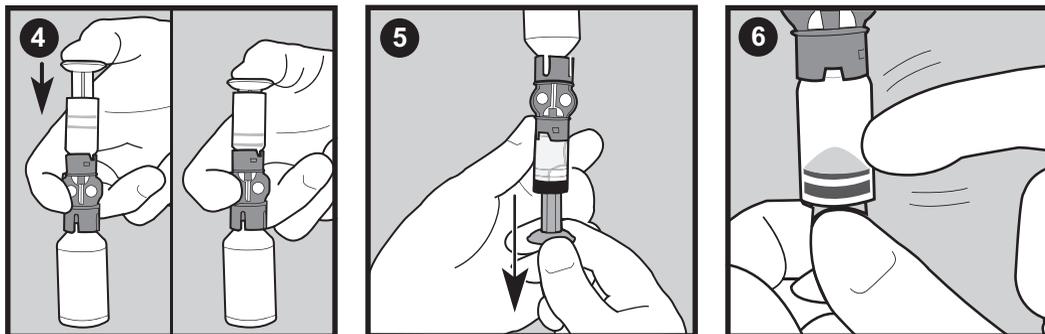


- 1 Remove the reservoir from the package. Make sure the plunger rod is fully extended.
- 2 Swab the vial with alcohol (not shown).
- 3 Making sure you do not push down on the plunger, press the transfer guard onto the vial.

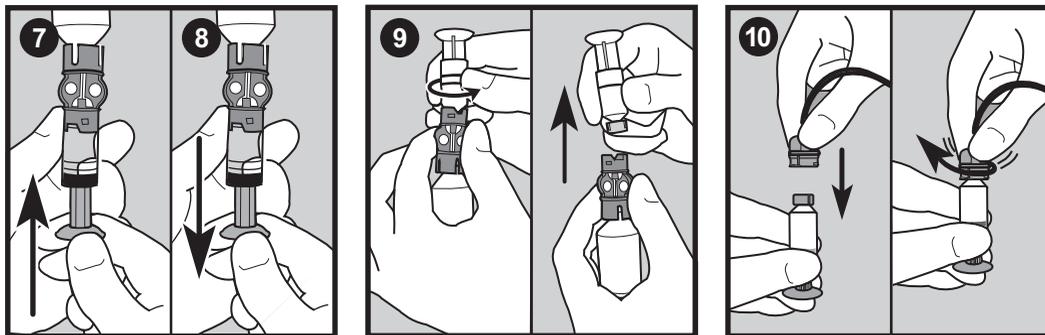


- 4 Push down on the plunger to pressurize the vial. Hold down the plunger rod.

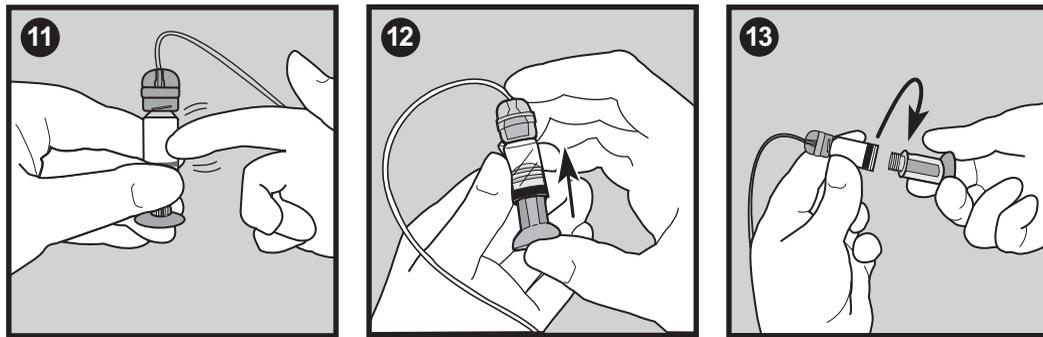
- 5 While still holding the plunger rod, flip the vial over so the vial is on top. Slowly pull down on the plunger to fill the reservoir.
- 6 Gently tap the side of the reservoir to make any air bubbles rise to the top of the reservoir.



- 7 Slowly push up on the plunger just enough to remove any air bubbles from the reservoir.
- 8 Slowly pull down on the plunger to fill the reservoir to the number of units desired.
- 9 To avoid getting liquid on the top of the reservoir, flip the vial over so that it is upright. Turn the reservoir counter-clockwise, then pull straight up to remove the reservoir from the transfer guard.
- 10 Place the tubing connector onto the reservoir. Turn the connector clockwise, pressing gently against the reservoir until you feel it slide in. Push in and continue turning until the reservoir and the connector lock with a click.



- 11 Tap the side of the reservoir to remove any air bubbles.
- 12 To purge air bubbles that have risen to the top of the reservoir, push up on the plunger until you see insulin in the tubing.
- 13 Without pulling, turn the plunger counter-clockwise to remove it from the reservoir.



14 Use your reservoir immediately after you fill it. Do not store it filled.

Changing your infusion set

You must do all the tasks in the following list every time you change your infusion set. Follow the procedures in this section in the order they are presented.

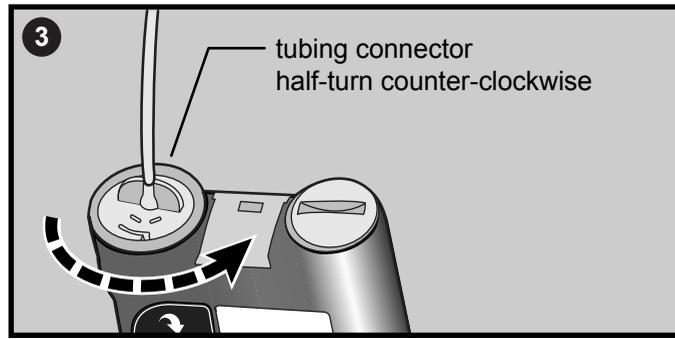
- Remove the old reservoir from your pump.
- Rewind your pump.
- Insert the new filled reservoir into your pump.
- Fill the tubing.
- Insert the infusion set into your body.
- Fill the cannula.

NOTE: You need your filled reservoir to complete the following procedures. If necessary, return to the previous section for instructions on filling your reservoir.

Removing the reservoir

Each time you remove and replace a reservoir in your pump, you have to rewind your pump, and fill the infusion set with insulin.

- 1 Remove the entire infusion set from your body.
- 2 If attached, remove the activity guard.
- 3 Turn the tubing connector half-turn counter clockwise, then pull the reservoir and connector out from the pump.



- 4 Safely dispose of the used reservoir and infusion set item in a sharps container.
- 5 You must now rewind your pump as described in the next section.

Rewinding your pump

Before you continue, make sure the infusion set is NOT connected to your body and the reservoir is NOT in the pump.

WARNING: Make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which may cause low BG.

- 1 If you removed your reservoir and are replacing it, go to the REWIND screen.
Main > Reservoir + Set > Reservoir Setup
- 2 In the REWIND screen, press **ACT** to start the rewind process. The REWINDING screen will appear while the pump rewinds.
- 3 After the pump rewinds the REWIND COMPLETE screen will appear.
If you are practicing:
 - a. Do **NOT** insert the reservoir in your pump. Make sure the red shipping cap is installed in the reservoir compartment as shipped. Consult your healthcare professional before starting on insulin.
 - b. Press **ACT**, then continue with the instructions in the *Filling the tubing* section in this chapter.

If you are **not practicing**, continue to the next section to insert the reservoir in your pump.

Inserting the reservoir in your pump

If your reservoir is already inserted in your pump, continue to the next section.

You must do these steps in the order described. If you are practicing, do not insert the reservoir in your pump.

CAUTION: You must rewind your pump before installing a new reservoir to ensure correct insulin amount.

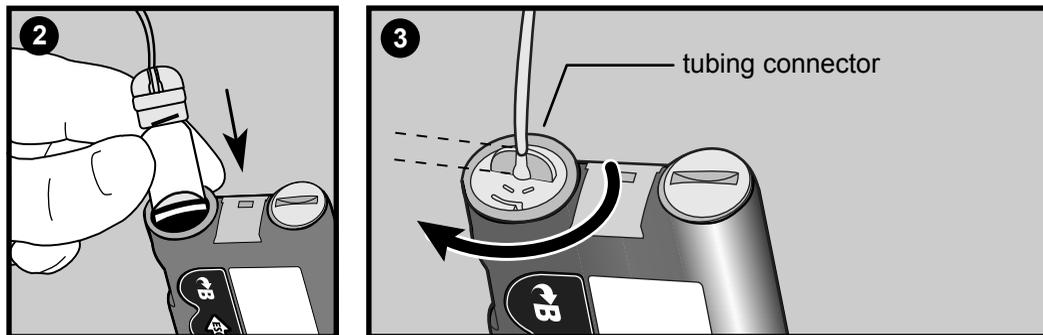
NOTE: A pump rewind is required to start the infusion set change process.

To insert the reservoir in your pump, do these steps:

- 1 If you are using the pump for the first time, remove the red shipping cap from the reservoir compartment.

WARNING: Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which may cause low BG.

- 2 Rewind your pump if you have not done so. See *Rewinding your pump*, on page 59 for instructions.
- 3 Insert the reservoir into the top of the pump case.
- 4 Turn the tubing connector approximately 1/2 -turn clockwise until the connector is seated. The tubing connector should be aligned horizontally with the pump case as shown here.



- 5 Attach the activity guard, if desired.
- 6 If the pump has returned to the HOME screen, press **ACT** to show the REWIND COMPLETE screen. Press **ACT** again to go to the FILL TUBING screen.
- 7 You must now fill the infusion set tubing as described in the next section.

Filling the tubing

You need to fill the infusion set tubing with insulin before you insert the set into the body.

WARNING: Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause low BG.

- 1 After you rewind your pump, the FILL TUBING screen will appear.
 - a. If the infusion set is **NOT** disconnected from your body, press **ACT** to select **No** on the screen. After you disconnect the infusion set from your body, press **ACT** on the next screen to continue.
 - b. If the infusion set is disconnected from your body, select **Yes** on the FILL TUBING screen. Press **ACT** to continue to the next FILL TUBING screen.
- 2 Press and hold **ACT**. The pump will beep six times indicating that the pump is positioning the reservoir.
- 3 After the reservoir is positioned, you need to fill the infusion set tube with insulin. Press and hold **ACT** until insulin droplets form on the tip of the infusion set needle, then release. Follow the instructions on the screen. You will hear beeps as the pump fills the tubing with insulin. Be sure no bubbles are in the tubing.

WARNING: If the FILL TUBING screen does not display, do NOT continue. Do NOT insert the infusion set into your body. Please contact our 24 Hour HelpLine for assistance.

Always check your tubing for air bubbles. Continue to hold ACT until the bubbles have been removed from the tubing. Air bubbles may result in inaccurate insulin delivery.

If you use more than 30 units of insulin to fill the infusion set tubing, the MAX FILL REACHED alarm screen will appear. If you get this alarm, do these steps:

- a. **Make sure that you are not connected to the pump.**
 - b. Read the message on the screen, then press **ESC**, **ACT** to clear.
 - c. To continue filling the infusion set tubing, select **Yes**, **Continue** and press **ACT**. See the next step to continue. If you have made a mistake, select **No**, **Rewind** and press **ACT**. The **REWIND** screen will appear. Refer to the pump rewinding and insulin loading instructions in this chapter to continue.
- 4 A message will appear: **DO YOU SEE DROPS AT END OF TUBING?**

Do **not** press **ESC** because this will trigger a **FINISH LOADING** alarm in 10 minutes. Make sure to complete this **Fill Tubing** step. Select **Yes** or **No**.

- a. If you do **NOT** see drops at the tip of the needle, select **No** and press **ACT**. Make sure your infusion set is **NOT** connected to your body. Follow the instructions on the **FILL TUBING** screens to continue filling the infusion set tubing with insulin.
 - b. If you see drops formed at the tip of the needle, select **Yes** and press **ACT**. The **FILL CANNULA** screen will appear.
- 5 You can now insert the infusion set into your body as described in the next section.

Inserting the infusion set

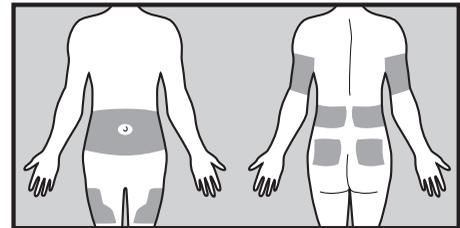
WARNING: Do not remove the reservoir from the pump while the infusion set is connected to your body. Doing so could result in the delivery of too little or too much insulin, which can cause high BG or low BG.

After you complete all of the following, you will be ready to insert the infusion set into your body:

- fill your reservoir
- rewind your pump
- insert the reservoir into pump
- fill the infusion set with insulin

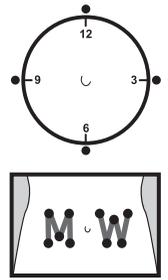
Shown here are the best body areas (shaded) for infusion set insertion. Avoid the 2-inch (5.0 cm) area around the navel.

It is important that you change your infusion set every two to three days. Be sure to rotate the infusion set insertion sites so that they do not become overused. To keep sites healthy, some people find it



helpful to use a visual scheme to help them rotate their insertion sites in an organized way. Here are two commonly used methods for rotating insertion sites around the abdomen. For maximum effectiveness, use both methods, alternating between them:

- Visualize an imaginary clock drawn on your abdomen surrounding your belly button. Rotate infusion set insertion sites by starting at 12 o'clock and then rotate the site clockwise to 3 o'clock, 6 o'clock, and so on.
- Imagine a letter M or a letter W on either side of your belly button. Start at the end of one letter and proceed through the letter, rotating to each intersection in turn.

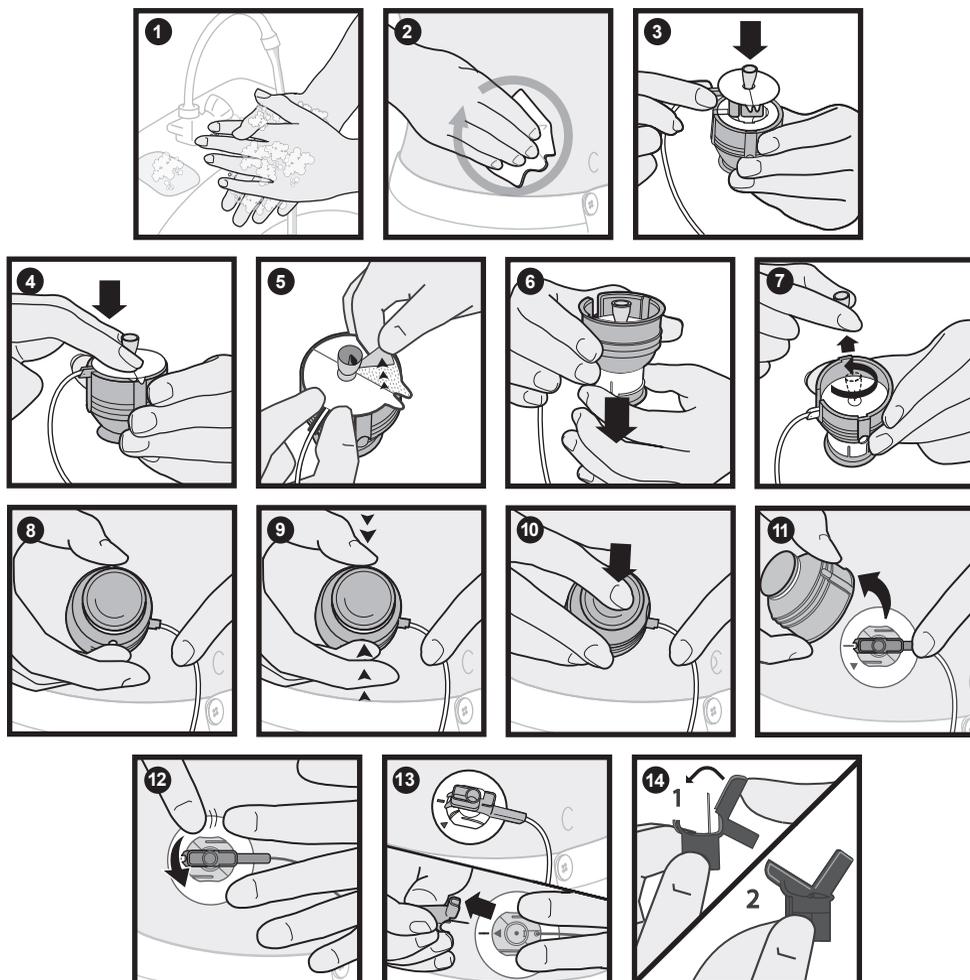


Medtronic Diabetes offers different infusion sets for your pump. Instructions for the Quick-set® begin on the next page as an example. Always refer to the instructions that shipped with your infusion set.

After your infusion set is inserted, see the *Filling the cannula* section in this chapter to fill the infusion set cannula.

Quick-set infusion set (with Quick-serter®)

There are different infusion sets that you can use with your pump. As an example, the following procedure shows how to insert the Quick-set infusion set. Always refer to the instructions that shipped with your infusion set.



Filling the cannula

Filling the soft cannula with insulin is required after the infusion set is inserted into your body and the introducer needle is pulled out. The insulin amounts required to fill the cannula depend on the type of infusion set you are using. Refer to your infusion set instructions for this information. If you are using an infusion set with a needle, press **ESC** to skip this step.

If you do not complete the Fill Cannula steps, your pump triggers a FINISH LOADING alarm. If you need to skip the Fill Cannula step, press **ESC** to avoid getting this alarm.

- 1 After you have filled the infusion set tubing, the FILL CANNULA screen appears. It displays a message to connect the infusion set to your body. Press **ACT** to fill the cannula. To skip this step, press **ESC** until you see the MAIN MENU screen. If you do not complete this step, the RESERVOIR + SET MENU screen appears after 15 minutes. After 10 minutes, your pump triggers a FINISH LOADING alarm.
- 2 Enter the amount for your type of infusion set, then press **ACT**. To skip this step, press **ESC** until you see the MAIN MENU screen. If you do not complete this step, the RESERVOIR + SET MENU screen appears after one minute. After 10 minutes, your pump triggers a FINISH LOADING alarm.
- 3 As the cannula starts filling, the FILLING CANNULA screen will count up the units as they are delivered. The pump will beep or vibrate when the fill cannula delivery is complete.

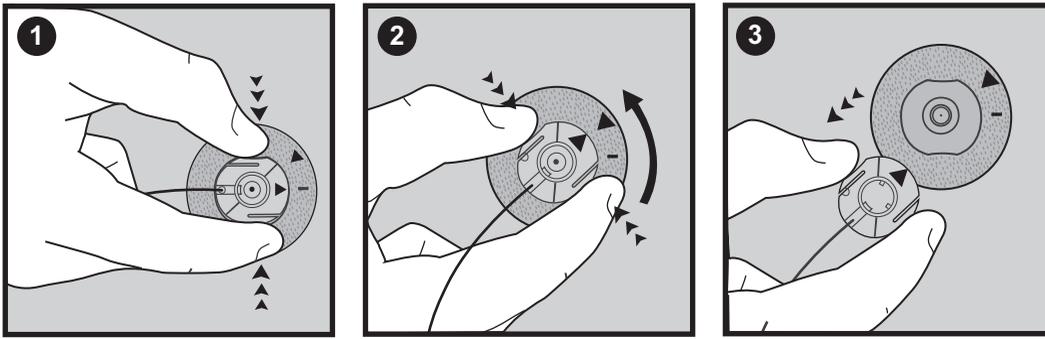
To see how much insulin was delivered to fill the infusion set:

- 1 Go to the HISTORY screen.
Main > Reservoir + Set > History
- 2 Scroll through the list of insulin deliveries. The letter T at the end of the text line indicates that insulin was delivered to fill the tubing. The letter C at the end of the text line indicates insulin was delivered to fill the cannula. Exit the menus.

Disconnecting the Quick-set infusion set

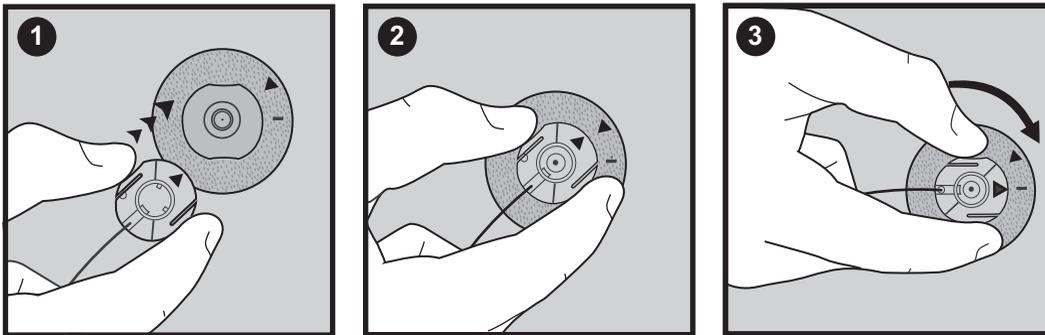
The Quick-set infusion set allows you the freedom to temporarily disconnect from your pump without removing the infusion set from your body.

- 1 Hold the side grips of the connector part with your fingers.
- 2 Twist the connector counter-clockwise.
- 3 Remove the connector from the site.



Reconnecting the Quick-set infusion set

Place the connector part (flat side facing down) on the infusion site until it is fully seated. Do not squeeze the connector part by the flat side grips.



Record keeping for diabetes management

Now that you are using the pump, we will be asking you to test your blood glucose regularly. It is important to test often and write down your blood glucose readings, the food you eat, any exercise you perform and any other notes to explain your blood glucose results.

You must test at the recommended times and any other time that you feel your blood glucose is high or low. Be sure to include your meal boluses, correction boluses, the amount of carbohydrate you eat, basal rate and any other information that will be helpful in assisting your healthcare professional in adjusting your pump settings.

It is very important to look at your blood glucose readings as feedback regarding your diabetes management, not as statements about you or your self-worth. Try not to have an emotional reaction to the numbers and do not judge them too harshly.

Test at least four to six times per day. These are the recommended times to test to determine control:

- Overnight (occasionally, at approximately 2:00-3:00 AM)
- Pre-breakfast (fasting)
- Post-breakfast (approximately two hours after eating)
- Pre-lunch
- Post-lunch (approximately two hours after eating)
- Pre-dinner
- Post-dinner (approximately two hours after eating)
- Bedtime
- Before driving

Determining your pump settings

Your healthcare professional will use your daily blood glucose journal records to program your pump. It is very important to keep good records during the first weeks after you start on pump therapy. Not only must you record your blood glucose readings, but it will be important to eat regularly scheduled meals and to keep your activity as consistent as possible.

Until you and your healthcare professional determine the pump settings that will work best for you, it is important to eat meals for which it is easy to count the carbohydrates. After your correct basal rate is determined, you will be able to experiment with varied food choices and amounts.

After you and your healthcare professional are satisfied with your initial pump settings, you may begin to experiment with different food choices, meal times and exercise schedules.

Using the Bolus Wizard feature

What is it?

Bolus Wizard is a feature that calculates an estimated bolus to support your food intake or to correct a high blood glucose. To use this feature, you need the following information:

Carbohydrate counting

You need to know which foods contain carbohydrates and how to count these.

Your blood glucose reading

You need to know your blood glucose (BG) readings. When using the Bolus Wizard feature, the pump can work with blood glucose meter powered by MWT1 technology to automatically receive your blood glucose reading. MWT1 is the wireless Radio Frequency (RF) technology that is used to transmit information from the meter to the pump. You can program your pump to automatically receive your BG reading from this meter. Bayer's CONTOUR® NEXT LINK Wireless Meter is supported by MWT1 technology. The *Meter option* section has more information. If you are not using this meter, you will manually enter your blood glucose.



Your personal Bolus Wizard feature settings

In addition to your blood glucose reading and/or your food entry, the Bolus Wizard feature uses personal settings that you program into the pump. (For instructions see the *How to program the Bolus Wizard feature* section in this chapter.)

- carb units (grams or exchanges)
- carb ratios (in carbohydrate grams/unit of insulin or insulin units/carb exchanges)
- BG units (mg/dL or mmol/L)
- insulin sensitivity

- target blood glucose range
- active insulin time (hours)

Get this information from your healthcare professional, and, for best results, talk to your healthcare professional before making any changes. Keep a record of your settings in the following *Bolus Wizard feature settings* table:

Bolus Wizard feature settings		
Information	Setting	
Carb units:	_____ grams or _____ exchanges	
<p>Carb ratios: Bolus Wizard feature uses this for your food bolus calculations.</p> <p>If you count carbs, this ratio is the amount of carbohydrate grams covered by one unit of insulin.</p> <p>range: 1-200 grams/unit</p> <p>If you count exchanges, this ratio is the amount of insulin you need to cover one (carb) exchange.</p> <p>range: 0.075-15.0 units/exchange</p> <p>NOTE: <i>Your carb ratios may vary throughout the day. Your pump allows you to program up to eight different carb ratios.</i></p>	<p>Ratio:</p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>6. _____</p> <p>7. _____</p> <p>8. _____</p>	<p>Start time:</p> <p>1. midnight</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>6. _____</p> <p>7. _____</p> <p>8. _____</p>
BG units: (how you measure your blood glucose)	_____ mg/dL or _____ mmol/L	

Bolus Wizard feature settings

Information	Setting	
<p>Insulin sensitivity: This ratio is used for your correction bolus calculations. This ratio is the BG units reduced by 1.0 unit of insulin. range: 10-400 mg/dL/u or 0.5-22.2 mmol/L/u</p> <p>NOTE: <i>Your insulin sensitivity may vary throughout the day. Your pump allows you to program up to eight different insulin sensitivities.</i></p>	<p>Ratio:</p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>6. _____</p> <p>7. _____</p> <p>8. _____</p>	<p>Start time:</p> <p>1. midnight</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>6. _____</p> <p>7. _____</p> <p>8. _____</p>

Bolus Wizard feature settings		
Information	Setting	
<p>BG Target range: If your current blood glucose is above the BG Target range, the Bolus Wizard feature will calculate a correction dose. If your current blood glucose is below the BG Target range, the Bolus Wizard feature will calculate a negative correction and subtract it from your food bolus.</p> <p>range: 60-250 mg/dL or 3.3-13.9 mmol/L</p> <p>NOTE: Your pump will allow you to program up to eight different BG Target ranges.</p>	<p>Range:</p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>6. _____</p> <p>7. _____</p> <p>8. _____</p>	<p>Start time:</p> <p>1. midnight</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>6. _____</p> <p>7. _____</p> <p>8. _____</p>
<p>Active insulin time: The Bolus Wizard feature uses this time to calculate the active insulin in your system (see the <i>About active insulin</i> section in this chapter). Use your healthcare professional's recommendation for the active insulin time that best represents the insulin type you use and your physiological insulin absorption rate.</p> <p>range: 2-8 hours</p>	<p>Number of Hours: _____</p>	

How the Bolus Wizard feature works

- 1 If you want your current blood glucose to be factored in, enter your BG Reading:
 - automatically from the meter (refer to the *Meter option* section)
 - manually by selecting the **↻B** button.
- 2 If you are going to eat, enter your food amount in grams or exchanges.
- 3 The Bolus Wizard feature will calculate a bolus for you. An ESTIMATE DETAILS screen will appear with your estimated total bolus amount.



Bolus Wizard warnings

When using the Bolus Wizard feature, the pump may display a HIGH BG, LOW BG, and MAX BOLUS EXCEEDED warnings.

HIGH BG

If your blood glucose in the ENTER BG screen is above 250 mg/dL (13.9 mmol/L), the Bolus Wizard feature displays a HIGH BG warning. Read the instructions, then press **ACT** or **ESC** to clear the message. You can then continue programming to deliver your bolus.

LOW BG

If your blood glucose in the ENTER BG screen is below 70 mg/dL (3.9 mmol/L), the Bolus Wizard feature displays a LOW BG warning. Read the instructions, then press **ACT** or **ESC** to clear the message. You can then continue programming to deliver your bolus.

MAX BOLUS EXCEEDED

Bolus Wizard feature will not deliver more than the limit set for your maximum bolus. If the Bolus Wizard feature calculates a bolus amount that is larger than your max bolus limit setting, the message, MAX BOLUS EXCEEDED will appear. If this happens, do these steps:

- 1 In the MAX BOLUS EXCEEDED screen, press **ACT** to continue your bolus programming. The EST : MAX screen appears with the estimated and maximum bolus amounts. Continue to the next step. If you do not want to continue, press **ESC** to cancel and the screen will return to the ENTER BG screen.
- 2 In the EST : MAX screen, press **ACT** again to continue your bolus programming.
- 3 The SET BOLUS screen appears with the maximum bolus amount flashing. Enter the bolus amount. This amount cannot be more than the max bolus amount. Press **ACT**.
- 4 The BOLUS DELIVERY screen appears showing the insulin units being delivered.
- 5 The pump will beep/vibrate after it has completed the insulin delivery.

How to program the Bolus Wizard feature

You need your personal settings from the Bolus Wizard feature settings table to setup the Bolus Wizard feature. Your Bolus Wizard feature settings are programmed in the EDIT SETTINGS screen.

Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings

Once the settings are programmed, you do not have to program them again unless the values change. After you program one setting, the screen will automatically go to the next required setting. After you program all your settings, review them as described in this section to make sure they are set correctly.

Instructions for programming the Bolus Wizard feature settings are in the next paragraphs. Program your settings in the order described to make sure you program all the settings. If you have not completed setting up all of the required settings, MISSING INFO screen appears. It lists the required settings for this feature. You must program the listed settings before you can use the Bolus Wizard feature.

Turning on the Bolus Wizard feature

- 1 Go to the EDIT SETTINGS screen.
Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings
- 2 The EDIT SETTINGS screen appears with **Wizard: Off** selected. Press **ACT**.
- 3 The WIZARD ON/OFF screen appears. Select **On**, then press **ACT**.
- 4 The EDIT SETTINGS screen appears, showing that the wizard is now turned on. You are now ready to select your carb units.

Selecting the Carb units

The carb unit setting lets the pump know which way to count your carbohydrates (grams or exchanges).

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings
- 2 Select **Carb Units**, then press **ACT**.
- 3 The CARB UNITS screen appears. Select **Grams** or **Exchanges**, then press **ACT**.
- 4 The EDIT SETTINGS screen shows the carb units you selected. You are now ready to set your carb/exchange ratios.

Setting the Carb/Exch ratios

Your pump allows you to set up to eight Carb/Exch ratios because this ratio may vary throughout the day. Your healthcare professional may only have you program one or two carb ratios when you first start using the Bolus Wizard feature.

To set the Carb/Exch ratios:

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings
- 2 Select **Carb Ratios**, then press **ACT**.
 - **If you use grams as your carb units:** Carb ratio is the number of carb grams that are covered by one (1.0) unit of insulin.
 - **If you use exchanges as your carb units:** Carb ratio is the number of insulin units that are needed to cover one (1.0) carb exchange.
- 3 The SET CARB RATIO 1 (if you are using grams) or SET EXCH RATIO 1 (if using exchanges) screen appears. The default ratio flashes on the screen.
- 4 Set your first ratio, then press **ACT**. Carb ratio values are normally between 5-50 grams/u or 0.3-3.0 u/exch. If your ratio value is outside the range, a warning message will appear on the screen. This message warns that the entered carb ratio is valid but outside the usual range. Press **ESC** to correct or **ACT** to continue.
The start time for your first ratio is midnight and cannot be changed.
- 5 The SET START TIME 2 screen appears. The dashes under the screen name flash. The first Carb Ratio or Exchange Ratio is now set.
If you do not need a second ratio, press **ESC** and skip to the next section. If you need to set up another ratio, follow steps 6 through 9.
- 6 In the SET START TIME 2 screen, enter the time of the day you want this ratio to become active.
- 7 Press **ACT**. The SET CARB RATIO 2 screen (if using grams) or SET EXCH RATIO 2 screen (if using exchanges) appears.
- 8 The default ratio flashes. Select your ratio.
- 9 Press **ACT**. The SET START TIME 3 screen appears. The second carb or exchange ratio is now set.
- 10 If you do not need to set up any more ratios, press **ESC**. If you need to set up more ratios, repeat steps 6 through 9 above for each ratio.
You are now ready to set up the BG units.

Setting the BG units

You can select **mg/dL** or **mmol/L** as your Blood Glucose Unit (measurement type). You can also set these units in the Sensor and Capture Event menus.

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings
- 2 Select **BG Units**, then press **ACT**.
- 3 The BLOOD GLUCOSE UNITS screen displays. Select **mg/dL** or **mmol/L**, then press **ACT**.
- 4 The EDIT SETTINGS screen shows the BG units you selected. You are now ready to set your insulin sensitivity.

Insulin sensitivity

Your insulin sensitivity is the amount your blood glucose (BG) level is reduced by one unit of insulin. This value is used to calculate a suggested insulin dose to correct a high BG. Because this sensitivity may vary throughout the day, your pump lets you set up to eight sensitivity settings. Your healthcare professional may only have you program one or two insulin sensitivities when you first start using the Bolus Wizard feature. Record your settings in the *Bolus Wizard feature settings* table in this chapter.

Insulin sensitivity values are normally between 20-100 mg/dL/u (1.1-5.6 mmol/L/u). If your value is outside this range, a warning message will appear on the screen.

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings
- 2 Select **Sensitivity**, then press **ACT**.
- 3 The INS SENSITIVITY 1 screen appears. The default sensitivity value flashes on the screen.
- 4 Set the value for your first insulin sensitivity setting, then press **ACT**.
The start time for your first insulin sensitivity is midnight and cannot be changed.
- 5 The SET START TIME 2 screen appears. The dashes under the screen name flash. The first insulin sensitivity is now set.
If you do not need a second insulin sensitivity, press **ESC** and skip to the next section. If you need to set up another insulin sensitivity, follow steps 6 through 9.
- 6 In the SET START TIME 2 screen enter the time of the day you want this insulin sensitivity to become active.
- 7 Press **ACT**. The INS SENSITIVITY 2 screen appears.
- 8 The default sensitivity value flashes. Set the value for this insulin sensitivity.

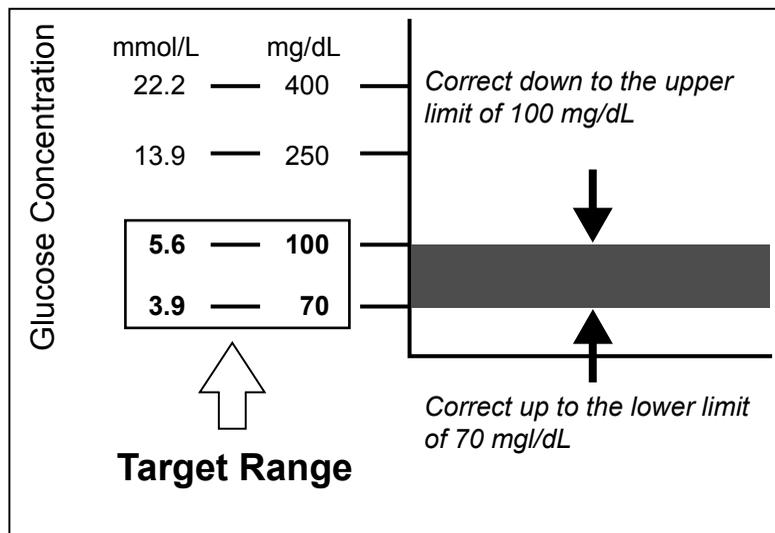
- 9 Press **ACT**. The SET START TIME 3 screen appears. The second insulin sensitivity is now set.
- 10 If you do not need to set up any more insulin sensitivities, press **ESC**. If you need to set up more insulin sensitivities, repeat steps 6 through 9 above for each insulin sensitivity.
You are now ready to set up the BG Target.

Setting the BG Targets

The BG Target setting allows you to set glucose targets. The Bolus Wizard will use these targets to calculate a correction dose. Because the targets may vary throughout the day, your pump allows you to set up to eight BG Targets each day. 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 Wizard feature may calculate a correction dose. The correction dose will deliver enough insulin to bring your BG down to your current high end of the BG Target range. If your current BG is below the BG Target range, the Bolus Wizard may calculate a negative correction and subtract it from your food bolus. This will bring your BG to the low end of the BG Target range.

Example:



Pumps are sent from the factory with default BG Target range of 100-100 mg/dL (5.6-5.6 mmol/L).

- 1 Make sure the EDIT SETTINGS screen is open.

Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings

- 2 Select **BG Target**, then press **ACT**.
- 3 The **TARGET RANGE 1** screen appears. The low end of your BG Target range flashes on the screen.
- 4 Set the BG Target, then press **ACT**.
- 5 The high end of your BG Target range flashes on the screen. Enter the BG Target, then press **ACT**. The start time for your first BG Target is midnight and cannot be changed.
- 6
 - a. If your BG Target is outside of 90-140 mg/dL (5.0-7.8 mmol/L), the pump screen displays a warning that the values are acceptable but outside normal range. Press **ESC** to change your BG Target or press **ACT** to set this range.
 - b. If your BG Target is within 90-140 mg/dL (5.0-7.8 mmol/L), the **SET START TIME 2** screen appears. The dashes under the screen name flash. The first BG Target range is now set. If you do not need a second BG Target range, press **ESC** and skip to the next section. If you need to set up another BG Target range, follow steps 7 through 11.
- 7 In the **SET START TIME 2** screen enter the time of the day you want this BG Target range to become active.
- 8 Press **ACT**. The **TARGET RANGE 2** screen appears.
- 9 The low end of your BG Target range flashes on the screen. Set the BG Target, then press **ACT**.
- 10 The high end of your BG Target range flashes on the screen. Enter the BG Target, then press **ACT**.
- 11 The **SET START TIME 3** screen appears. The second BG Target range is now set.
- 12 If you do not need to set up any more BG Target ranges, press **ESC**. If you need to set up more BG Target ranges, repeat steps 7 through 11 above for each one.
You are now ready to set up the Active insulin time.

About active insulin

Active insulin is the bolus insulin that has already been delivered to your body, but has not yet been used. The pump considers your active insulin time setting in determining any active insulin still in your body from prior boluses. This may help prevent hypoglycemia caused by over-correcting for high blood glucose.

The pump shows the active insulin amount in the **ESTIMATE DETAILS** screen during the Bolus Wizard programming steps, the **STATUS** and the **SET BOLUS** screens. However, the active insulin amount is calculated differently in the **ESTIMATE DETAILS** screen and appears with an asterisk (*Active Insulin). The active insulin amount calculated in the Bolus wizard steps includes the insulin that has already been delivered and insulin that is going to be delivered by the active Square Bolus.

Your Paradigm pump is shipped from the factory with an active insulin time setting of six hours, which most closely matches the published scientific data. If your healthcare professional prescribes a different time for you, the active insulin time setting can be adjusted in the Bolus Wizard menu in one-hour increments from two to eight hours.

For more details about active insulin, see the *Bolus Wizard feature specifications* section in the *Pump specifications* chapter.

CAUTION: If you give yourself insulin by using a syringe or pen, the Bolus Wizard feature will not be able to correctly determine the active insulin in your system. The Bolus Wizard does not account for insulin injections by syringe or pen, and could prompt you to deliver more insulin than needed. Too much insulin may cause low BG. Consult with your healthcare professional on how long you need to wait after a manual injection before you can rely on the active insulin calculation of your Bolus Wizard feature.

Active insulin time

The active insulin time setting lets the pump know which active insulin time to use in calculating the amount of active insulin to subtract before estimating a bolus. Your healthcare professional should determine the active insulin time that is best for you.

To set the Active insulin time, do the following steps:

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Bolus > Bolus Setup > Bolus Wizard Setup > Edit Settings
- 2 Select **Active Ins Time**, then press **ACT**.
- 3 The **ACTIVE INS TIME** screen appears. The default time of 6 hours flashes on the screen.
- 4 Set the number of hours for the active insulin time, then press **ACT**.
- 5 The EDIT SETTINGS screen shows the new Active insulin time setting. You have now completed the Bolus Wizard setup. Press **ESC** or wait to see the message: **Bolus Wizard setup is complete**.

Review your Bolus Wizard feature settings

Check your Bolus Wizard feature settings in the REVIEW SETTINGS screen. If necessary, compare this information with your information in the Bolus Wizard feature settings table.

- 1 Go to the REVIEW SETTINGS screen.
Main > Bolus > Bolus Setup > Bolus Wizard Setup > Review Settings
- 2 Scroll through the text to view your Bolus Wizard settings.
- 3 Exit the menus when you are done.

Normal bolus using Bolus Wizard feature

After the Bolus Wizard feature 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. Additionally, your pump can receive your blood glucose reading from the meter, if they are linked.

Use the **↔B** button to deliver a Normal bolus at any time except during another Normal bolus. A Normal bolus will temporarily interrupt a Square Wave or Dual Wave bolus that is delivering. After the Normal bolus is finished, the Square Wave or Dual Wave bolus delivery will resume.

NOTE: *If you want to use the pump-to-meter link, make sure the meter option is on. Refer to the Meter option section for instructions.*

- 1 If you want a correction bolus, check your blood glucose with your blood glucose meter and go to step 2. If you want to bolus for food, go to step 2.
- 2 Press **↔B** on your pump, or go to the BOLUS MENU, select **Use Bolus Wizard**, and press **ACT**.
- 3 The ENTER BG screen will appear.
 - a. If you are **not** using the meter:
Enter your blood glucose value. Press **ACT** and continue to step 4. If you are not entering a blood glucose and want to bolus for food, select the dashes in the ENTER BG screen. The Bolus Wizard feature will calculate the insulin needed for your food entry without considering your blood glucose level. Press **ACT** and continue to step 4.
 - b. If you are using the meter, you must program your bolus within 12 minutes of the pump receiving the reading from the meter. If more than 12 minutes have passed, the reading will no longer be available from the screen and you must enter your blood glucose manually.

Your pump checks if the entered BG is within your target range. Press **ACT** to accept the blood glucose value. You can also change this blood glucose value, if necessary, then press **ACT**.

- 4 The ENTER FOOD screen appears.
 - a. If this is a food bolus, enter the food value you will eat, then press **ACT**.
 - b. If this is a correction bolus, select 0 (zero) as the value, then press **ACT**.
- 5 The ESTIMATE DETAILS screen appears. Review the information on this screen. If you need to make any changes, press **ESC** to return to the ENTER BG screen (step 3) and make changes as necessary.
- 6 Press **ACT** in the ESTIMATE DETAILS screen. The SET BOLUS screen appears with the estimated bolus amount flashing. Change the amount if desired. Press **ACT** to accept and start delivering your bolus.

NOTE: *If you have BG Reminder turned On, the BG REMINDER DURATION screen displays. It allows you to set the duration before you are reminded to check your blood glucose after a bolus. See the BG Reminder section in the Basic programming chapter for information about this feature.*

- 7 The BOLUS DELIVERY screen appears. The pump will beep or vibrate at the start and end of the bolus. As the bolus is delivered, the screen shows the bolus type and amount until the total units have been delivered. The screen then returns to the HOME screen.

Bolus Wizard feature examples

For the scenarios that follow, Michael has his Bolus Wizard feature turned on with the following settings:

Carb ratio: 15 grams per unit of insulin

Insulin Sensitivity: 40 mg/dL (2.2 mmol/L) per unit of insulin

BG Target: 90-120 mg/dL (5.0-6.7 mmol/L)

Active Insulin Time: 6 hours

NOTE: *If you want to see details of the formulas the Bolus Wizard feature uses to calculate estimate boluses like the ones in the following examples, see the Bolus Wizard feature specifications section in the Pump specifications chapter.*

Example 1: Blood glucose on target (normal blood glucose) and no active insulin

Michael awakens in the morning before school and his mother has breakfast waiting for him. Before he begins eating, he tests his blood glucose with his meter and his blood glucose result of 120 mg/dL (6.6 mmol/L) is automatically sent to his pump.

He estimates that his meal consists of 60 grams of carbohydrates. When prompted by the Bolus Wizard feature, he enters this amount in the ENTER FOOD screen. Based on his Bolus Wizard feature settings, the pump will suggest that he take 4.0 units of insulin.

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

$$60 \text{ g} \div 15 \text{ g/u} = 4 \text{ units}$$

Correction estimate:

Correction is 0 because the current BG reading is within the BG Target range.

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

$$4 \text{ units} + 0 \text{ units} = 4 \text{ units}$$

Example 2: Blood glucose above target (high blood glucose) and no active insulin

The next day, Michael wakes up before school. Before eating the same breakfast, he tests his blood glucose with his meter and finds it to be 200 mg/dL (11.1 mmol/L), which is above his target of 120 mg/dL (6.6 mmol/L). His blood glucose reading is automatically sent to his pump.

When prompted by the Bolus Wizard feature, he enters his carbohydrate amount of 60 grams in the ENTER FOOD screen. Based on his settings, the pump will suggest that he take 6.0 units of insulin.

Food estimate:

Carb grams \div Carb ratio = Units of insulin

$$60 \text{ g} \div 15 \text{ g/u} = 4 \text{ units}$$

Correction estimate:

(Current BG - High BG Target) \div Insulin sensitivity = Units of insulin

$$(200 \text{ mg/dL} - 120 \text{ mg/dL}) \div 40 \text{ mg/dL/u} = 2 \text{ units, or}$$
$$(11.1 \text{ mmol/L} - 6.6 \text{ mmol/L}) \div 2.2 \text{ mmol/L/u} = 2 \text{ units}$$

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

$$4 \text{ units} + 2 \text{ units} = 6 \text{ units}$$

Example 3: Blood glucose below target (low blood glucose) and no active insulin

On another morning, Michael sits down before eating the same breakfast. He tests his blood glucose with his meter and finds it at 70 mg/dL (3.9 mmol/L), which is below his Low BG target of 90 mg/dL (5.0 mmol/L). His reading is automatically sent to his pump.

When prompted by the Bolus Wizard feature, he enters his carbohydrate amount of 60 grams in the ENTER FOOD screen. Based on his settings, the pump will suggest that he only take 3.5 unit of insulin.

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

$$60 \text{ g} \div 15 \text{ g/u} = 4 \text{ units}$$

Correction estimate:

(Current BG - Low BG Target) ÷ Insulin sensitivity = Units of insulin

$$(70 \text{ mg/dL} - 90 \text{ mg/dL}) \div 40 \text{ mg/dL/u} = -0.5 \text{ units, or}$$
$$(3.9 \text{ mmol/L} - 5.0 \text{ mmol/L}) \div 2.2 \text{ mmol/L/u} = -0.5 \text{ units}$$

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

$$4 \text{ units} + (-0.5) \text{ units} = 3.5 \text{ units}$$

Example 4: Blood glucose above target (high blood glucose) with active insulin

Michael is at school and wants to eat a snack in the late morning. He tests his blood glucose with his meter and finds it at 200 mg/dL (11.1 mmol/L), which is above his target of 120 mg/dL (6.6 mmol/L). He estimates that his snack contains 60 grams of carbohydrate, so he enters 60 into the pump when prompted by the Bolus Wizard feature. Based on his settings, and as a result of 1.5 units of active insulin, his pump will suggest that he take 4.5 units.

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

$$60 \text{ g} \div 15 \text{ g/u} = 4 \text{ units}$$

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

$$(200 \text{ mg/dL} - 120 \text{ mg/dL}) \div 40 \text{ mg/dL/u} - 1.5 \text{ units} = 0.5 \text{ units, or}$$

$$(11.1 \text{ mmol/L} - 6.6 \text{ mmol/L}) \div 2.2 \text{ mmol/L/u} - 1.5 \text{ units} = 0.5 \text{ units}$$

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

$$4 \text{ units} + 0.5 \text{ units} = 4.5 \text{ units}$$

Example 5: Blood glucose below target (low blood glucose) with active insulin

Another day at school, Michael is getting ready to eat lunch. He tests his blood glucose with his meter and finds it at 70 mg/dL (3.9 mmol/L), which is below his Low BG target of 90 mg/dL (5.0 mmol/L). His reading is automatically sent to his pump.

When prompted by the Bolus Wizard feature, he enters his carbohydrate amount of 60 grams in the ENTER FOOD screen. Based on his settings, and despite 1.5 units of active insulin, his pump will suggest that he take 3.5 units of insulin.

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

$$60 \text{ g} \div 15 \text{ g/u} = 4 \text{ units}$$

Correction estimate:

(Current BG - Low BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

$$(70 \text{ mg/dL} - 90 \text{ mg/dL}) \div 40 \text{ mg/dL/u} - 0^* = -0.5 \text{ units, or}$$
$$(3.9 \text{ mmol/L} - 5.0 \text{ mmol/L}) \div 2.2 \text{ mmol/L/u} - 0^* = -0.5 \text{ units}$$

NOTE: *When the current BG is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

$$4 \text{ units} + (-0.5) \text{ units} = 3.5 \text{ units}$$

Optimizing pump therapy

WARNING: This chapter contains advanced features. Do not use the features in this chapter until you are completely familiar with the basic pump functions. If you use these features incorrectly, your insulin may not deliver as prescribed by your healthcare professional. Consult your healthcare professional before using advanced features on your pump.

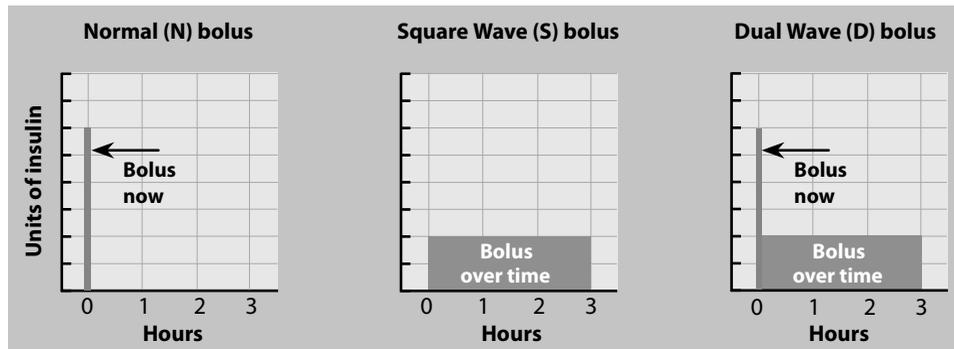
Square Wave and Dual Wave bolus

Square Wave bolus delivers a bolus evenly over a period of time (30 minutes to 8 hours). This bolus can be used for insulin delivery when you have eaten a long meal or extended snacking. It can also be useful if you have delayed food digestion due to gastroparesis or meals high in fat. A Square Wave bolus can be useful if a Normal bolus drops your blood glucose too rapidly. Since the Square Wave portion extends over a period of time, the insulin is more likely to be available to match your individual needs.

NOTE: During delivery of a Square Wave bolus, you will not be able to do the following pump functions: change the max bolus amount, change the scroll rate, disable or deliver Dual and Square Wave boluses, rewind or fill the cannula, change the active insulin time, run the selftest utility, or access the User Settings menu. All other pump functions are still available during the Square Wave bolus.

Dual Wave bolus delivers a combination of an immediate Normal bolus followed by a Square Wave bolus. The Square Wave portion is delivered evenly over a period of time. A Dual Wave bolus is useful for meals with both rapidly and slowly absorbed carbohydrates. For example, a Dual Wave bolus would be appropriate for fruit and crackers followed by pasta. The Dual Wave option meets both immediate and extended insulin needs. A Dual Wave bolus is also useful for correcting elevated blood glucose before a meal.

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



Turning on the Dual Wave/Square Wave option

It is important that you consult with your healthcare professional before using a Square Wave or Dual Wave bolus. You should be familiar with the basic functions of your pump before exploring these options.

To set up a Dual Wave or Square Wave bolus, you must first turn on the dual/square bolus option.

- 1 Go to the DUAL/SQUARE OPTION screen.
Main > Bolus > Bolus Setup > Dual/Square Bolus
- 2 Select **On**, then press **ACT**. The feature is now on. Exit the menus.

Square Wave or Dual Wave bolus without Bolus Wizard feature

- 1 Make sure the dual/square option is on.
- 2 Calculate your food and/or correction bolus amount.
- 3 Go to the BOLUS TYPE screen.
Press **⬅B** on your pump, or follow this path:
Main > Bolus > Set Bolus
- 4 For a Square Wave bolus, do these steps:
 - a. Select **Square Wave Bolus**, then press **ACT**. The SET SQUARE BOLUS screen appears.
 - b. Enter the desired amount for the Square Wave bolus units, then press **ACT**.
 - c. Continue to step 5.

For a Dual Wave bolus, do these steps:

- a. Select **Dual Wave Bolus**, then press **ACT**. The SET DUAL BOLUS TOTAL screen appears.
 - b. Enter the desired amount for the total dual bolus units. This amount is the total of Normal and Square Wave bolus units. Press **ACT**.
 - c. The next screen flashes the amounts of Now (Normal) and Square Wave portions of the Dual Wave bolus. The screen also shows the percentage amount of each portion. Press  or  to change the percentage/number of units. Continue to step 5.
- 5 The SQUARE DURATION screen appears. Enter the amount of time you want the Square Wave bolus to last, then press **ACT**.

NOTE: *If you have BG Reminder turned On, the BG REMINDER DURATION screen displays. It allows you to set the duration before you are reminded to check your blood glucose after a bolus. See the BG Reminder section in the Basic programming chapter for information about this feature.*

- 6 The BOLUS DELIVERY screen appears with an open circle indicating that your pump is in Special mode. The pump beeps/vibrates at the start of the bolus. During bolus delivery, the pump will return to the HOME screen. The pump beeps/vibrates at the end of the bolus and the open circle disappears.

Square Wave bolus practice

Your target pre-meal blood glucose range is _____ to _____.

Check your pre-meal blood glucose. Are you within your target? _____. If yes, continue. If no, wait to try the following test until your pre-meal blood glucose is within your target range:

TEST: Choose a meal that is high in fat (hot dogs, pizza, cheese enchiladas). Determine your meal bolus amount. Set the Square Wave bolus to deliver the determined amount of insulin over two hours. (This duration time is an example. As always, consult with your healthcare professional for guidance.)

Check your blood glucose and record:

Pre-meal	_____
1 hour post meal	_____
2 hours post meal	_____
3 hours post meal	_____
4 hours post meal	_____

Did your blood glucose return to your pre-meal target within 4 hours post meal? _____

If yes, then repeat this test with the same meal on another day to verify your results.

If no, discuss this with your healthcare professional for guidance.

Dual Wave bolus practice

Can you think of any meals where this feature would help you with blood glucose control?

Your target pre-meal blood glucose range is _____ to _____

Check your pre-meal blood glucose. Are you within your target? _____ If yes, continue. If no, try this test when your pre-meal blood glucose is within your target range:

TEST: Choose a meal that has a combination of both rapidly absorbed and slowly absorbed carbohydrates. Determine your meal bolus amount. Set the Dual Wave bolus to deliver the determined amount of insulin. Program your pump to deliver one-half over 2-hours*, and the other half immediately.

(* This duration of time and ratio is an example. As always, consult with your healthcare professional for guidance.)

Check blood glucose and record: Pre-meal _____
1 hour post meal _____
2 hours post meal _____
3 hours post meal _____
4 hours post meal _____

Did your blood glucose return to your pre-meal target within 4 hours post meal? _____*

If yes, repeat this test with the same meal on another day to verify results.

If no, discuss this with your healthcare professional for guidance.

Using the Bolus Wizard feature for a Square Wave or Dual Wave bolus

If you are using the Bolus Wizard feature to calculate your Square Wave or Dual Wave bolus amounts, you will be prompted to enter your blood glucose reading and/or the (gram or exchange) units you will eat. The Bolus Wizard feature will use this input to calculate your suggested correction and/or food bolus amount. If you do not want to use the Bolus Wizard feature estimate, you can change it.

The Bolus Wizard feature must be turned on and the settings must be programmed (see the *How to program the Bolus Wizard feature* section in the *Using the Bolus Wizard* chapter). Also, make sure the dual/square option is turned on (see the *Turning on the Dual Wave/Square Wave option* section in this chapter).

If you want to use the pump-to-meter link, make sure the meter option is on. Refer to the *Meter option* section for instructions.

1 Go to the ENTER BG screen.

Press  on your pump, or use the following path:

Main > Bolus > Use Bolus Wizard

2 Enter your blood glucose value, then press **ACT**.

3 The ENTER FOOD screen appears. Enter your food, then press **ACT**.

4 The ESTIMATE DETAILS screen appears. Scroll down to review the information there. Press **ACT** to continue to step 5.

If you need to make any changes, press **ESC** to return to the ENTER BG screen. Make changes as necessary.

5 The BOLUS EST screen appears with Normal Bolus, Square Wave Bolus, and Dual Wave Bolus options. If your Bolus Wizard feature calculates that your bolus includes a portion to correct your high blood glucose, the Square Wave Bolus option will not be available. This helps you to select a bolus type (Normal or Dual Wave) that has an immediate delivery option to cover your high blood glucose.

6 **To set a Square Wave bolus, do these steps:**

a. In the BOLUS EST screen, select **Square Wave Bolus**, then press **ACT**.

b. The SET SQUARE BOLUS screen flashes the estimated bolus amount. Change the amount if needed. Press **ACT** to accept the bolus amount.

To set a Dual Wave bolus, do these steps:

a. The SET DUAL BOLUS TOTAL screen flashes the estimated bolus amount. This amount is the total of both the Normal and Square Wave bolus units. Change the amount if needed. Press **ACT** to accept the bolus amount.

b. The next screen flashes the amounts of Now (Normal) and Square portions of the Dual Wave bolus. The screen also shows the percentage amount of each portion. Press **ACT** to accept the Bolus Wizard's suggested portions. You can also press  or  to change these portions, then press **ACT**.

The Bolus Wizard feature recommends splitting the food portion of your bolus 50/50 between the Square and Now portions. The entire correction amount is always recommended to the Now portion. In this example the NOW portion consists of half of the food insulin plus the correction amount less the active insulin (1.5U + 2.5U - 1.5U). This gives 2.5U or 62% of total insulin of 4.0U. The Square portion consists of the other half of the food insulin (1.5U), which is 38% of total insulin of 4.0U.

7 The SQUARE DURATION screen appears. Enter the amount of time you want the Square Wave bolus to last, then press **ACT**.

NOTE: If you have BG Reminder turned On, the BG REMINDER DURATION screen displays. It allows you to set the duration before you are reminded to check your blood glucose after a bolus. See the BG Reminder section in the Basic programming chapter for information about this feature.

- 8 Press **ACT** to accept and deliver the bolus. The BOLUS DELIVERY screen appears with an open circle indicating that your pump is in Special Mode. The pump beeps or vibrates at the start of the bolus. During bolus delivery, the pump returns to the HOME screen. If you want to see the progress of the delivery, press **ESC** to see the STATUS screen. The pump beeps or vibrates at the end of the bolus, and the open circle disappears.

Easy bolus

The **EASY BOLUS** button  allows a quick way to deliver a Normal bolus. You will preset the settings for this feature in the EASY BOLUS OPTION screen in the BOLUS MENU. Your pump is sent from the factory with the Easy Bolus feature set to off. If you want to use Easy Bolus, turn it on.

After you set up Easy Bolus, with each  press, you can increase the Normal bolus amount by a fixed amount, called a step. Before you can deliver an Easy Bolus, you must set the amount in the EASY BOLUS ENTRY screen. This amount equals the number of units of insulin for each step. The maximum number of steps can equal up to your maximum bolus limit. When using vibrate mode, EASY BOLUS is limited to 20 steps or maximum bolus, whichever comes first.

After you set your step amount, you can program your Easy Bolus. When you are in the HOME screen, each time you press  the Easy Bolus amount increases by one step. You will hear a beep or feel a vibration for each step increase. Each beep is a different tone. This makes it easy for you to count the beeps while you are programming your Easy Bolus.

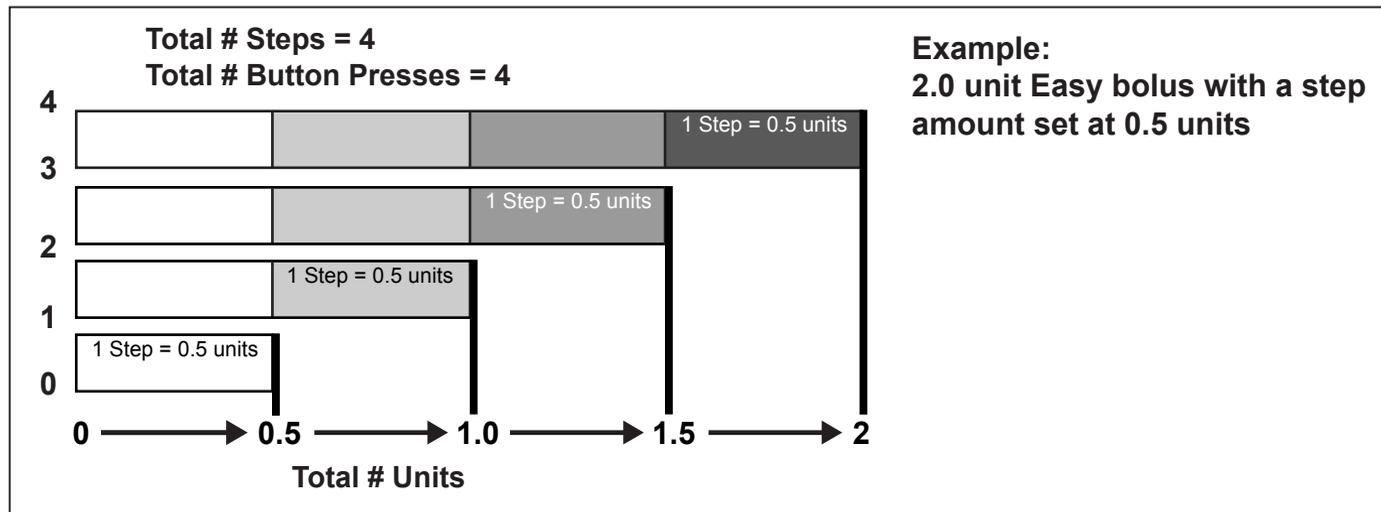
Easy bolus setup

- 1 Go to the EASY BOLUS OPTION screen.
Main > Bolus > Bolus Setup > Easy Bolus
Select **On/Set**, then press **ACT**.

NOTE: If you are using the remote control, the Easy Bolus must be set to on.

Step value setup

You can set the step value from 0.1 to 2.0 units, or to the set maximum bolus limit of less than 2.0 units (factory setting: 0.1). Set the step to a number that is convenient to use and easy to multiply.



- 1 The EASY BOLUS ENTRY screen flashes the step value. Change the value, then press **ACT**. The step value is the increment you will use for your Easy bolus.
- 2 The screen will return to the BOLUS MENU. Your step amount is now programmed and Easy Bolus is ready to use. Exit the menus.

Delivering Easy Bolus

Practice using the Easy Bolus feature while looking at the pump screen as you count the beeps. This feature only works from the HOME screen. After you are familiar with Easy Bolus, you can use the audible tones for bolus delivery without having to look at the screen.

- 1 From the HOME screen, press . The SET EASY BOLUS screen appears with the single step value flashing.
- 2 Press  the number of times needed for your bolus amount. Watch the amount change on the screen with each press. The pump will vibrate or sound a different tone for each  press.

WARNING: Never rely on the pump beeps or vibrations alone to navigate through the pump screens or menus, as this may result in incorrect menu selection or setting. You should always check your pump if you hear any unanticipated beeps or vibrations.

- 3 When your total bolus amount appears on the SET EASY BOLUS screen, press **ACT**. Listen/feel to count the steps without looking at the screen.

For example: You need to deliver a 2.0 unit bolus, and your step size is set to 0.5. Each time you press , the units increase by the step amount of 0.5 units. To deliver 2.0 units, you need to press the  button four times. (4 X 0.5 = 2.0) The screen will show 2.0 units.

NOTE: For your safety, you cannot use the  to select the Easy Bolus values. Pressing  or **ESC** will cancel the Easy bolus.

- 4 If this amount is correct, press **ACT** to start the Easy Bolus delivery. The BOLUS DELIVERY screen will show the units being delivered. When the total bolus is finished, the pump will beep or vibrate.

If this amount is wrong, press **ESC** or  to start over. The pump will return to the HOME screen.

Example 1: Easy bolus

Alexander is a busy executive with an accounting firm. He wears his Paradigm pump on his belt and does not want to take it off to give himself a bolus. Alexander can easily reach down and feel for the Easy Bolus button  to give a bolus.

He previously programmed his pump to deliver an Easy Bolus in steps of 0.5 unit increments. From the HOME screen, with each press of the , the pump will sound a different tone so he can keep track of the number of button presses.

He wants to give himself 2.0 units for a snack, so he will press  4 times (4 presses x 0.5 units/press = 2.0 units) and then press the **ACT** button. The pump counts back 4 beeps because he pressed  4 times. He simply presses **ACT** to confirm the amount, and his pump delivers the 2.0 units.

When Alexander wants to be more discreet, or does not want his pump to beep in an important meeting, he can set the pump to Vibrate mode and feel for vibrations rather than listening for the tones. (See the *Setting your alert type* section in the *Utilities* chapter for details.)

Your turn: Easy bolus practice

The factory default setting for the Easy Bolus feature is 0.1 unit steps. You can change the step level as necessary to a value that is more convenient for you to use and easier to multiply.

Give your next bolus by using the Easy Bolus feature on your pump.

Your step level is _____.

How many units did you give? _____

How many tones did you count? _____

It might be a good idea to look at your pump's screen to see the bolus amount as well as counting the steps the first few times you try this until you become familiar and comfortable with the feature.

Missed Bolus Reminder

Missed Bolus Reminder feature helps you remember to give yourself a meal bolus. It triggers a MISSED BOLUS alert if you do not deliver a bolus during the time periods that you set. Set these time periods for the meals for which you want to receive a reminder. The pump is set at the factory with the Missed Bolus Reminder feature turned Off.

Add, delete, and review bolus reminders

You have to turn on the Missed Bolus Reminder option to add, delete and review the programmed reminders.

- 1 Go to the MISSED BOLUS REMINDER screen.
Main > Bolus > Bolus Setup > Missed Bolus Reminder
- 2 Select **On/Set**, then press **ACT**.

Add

You can set up to four Missed Bolus Reminders.

- 1 Select **Add Reminder** on the MISSED BOLUS REMINDER screen, then press **ACT**.
- 2 The Start Time flashes. Times can be entered in 30 minute increments. Set the Start Time, then press **ACT**.

- 3 After this time is set, the End Time flashes. Set the End Time, then press **ACT**.
If you enter the same Start Time and End Time, you will get one Missed Bolus Reminder in a 24 hour period. If you add a Missed Bolus Reminder with a start time earlier than the current pump time, you will not get this Missed Bolus Reminder until the next day.

Delete

- 1 Select **Delete Reminder** on the MISSED BOLUS REMINDER screen and press **ACT**.
- 2 In the DELETE REMINDER screen, highlight the bolus reminder that you want to delete and press **ACT**.

Review

- 1 Select **Review Reminders** on the MISSED BOLUS REMINDER screen and press **ACT**.
- 2 Review your Missed Bolus reminders.

Basal patterns

The Basal Patterns feature is optional for pump users. You can set your pump to deliver a standard basal and two additional basal patterns to meet your individual daily, weekly, or monthly needs. Keep a paper copy of your programmed patterns with you at all times in case you need to reprogram your pump. To select and use pattern A or pattern B, the patterns option must be turned on and programmed.

NOTE: *You may want to explore this option after you become familiar with the basic pump functions. It is important that you consult your healthcare professional before using a pattern other than your standard pattern.*

- Standard pattern: Your normal basal that supports your usual day-to-day activity. When the Patterns feature is off, the pump uses your standard basal pattern.
- Pattern A/B: Basal pattern that supports activity levels that are not a part of your day-to-day routine, but are normal in your lifestyle. Such activities could be a sport that you do once a week or a change in your sleep pattern over the weekend, extended periods of higher or lower activity, or menses.

Turning on the patterns

Your pump is set at the factory with the basal patterns feature turned off. After you turn on patterns, you still have to program and select a pattern (A or B), as described in the next sections, before the patterns feature is active. If you turn off the patterns feature, your pump will automatically select your standard basal pattern.

- 1 Go to the PATTERNS OPTION screen.

Main > Basal > Basal Setup > Patterns

- 2 Select **On**, then press **ACT**. The patterns feature is now on. Exit the menus.

Programming a pattern

Your pump will keep your pattern settings even when the Patterns option is turned off. However, the patterns feature must be on to program a basal pattern.

To program your patterns, do these steps:

- 1 Go to the EDIT BASAL screen.

Main > Basal > Basal Setup > Set/Edit Basal

- 2 Select the basal pattern you want to program, then press **ACT**.
- 3 The SET BASAL RATE 1 screen appears. The basal rate flashes, indicating that it can be changed. Set your first rate, then press **ACT**.
The start time for your first basal rate is midnight and cannot be changed.
- 4 The SET START TIME 2 screen appears. The dashes under the screen name flash. The first basal rate is now set.
If you want to use the same rate for the whole day, press **ESC** and skip to step 10. If you want to program another basal rate, follow steps 5 through 8.
- 5 In the SET START TIME 2 screen enter the time of the day you want this basal rate to become active.
- 6 Press **ACT**. The SET BASAL RATE 2 screen appears.
- 7 The previously set basal rate or dashes flash on the screen. Select the value for this basal rate.
- 8 Press **ACT**. The SET START TIME 3 screen appears. The second basal rate is now set.
- 9 If you do not need to set up any more basal rates, press **ESC**. If you need to set up more basal rates, repeat steps 5 through 8 above for each rate.

10 After you press **ESC**, the **BASAL RATE** screen appears. The screen will show:

- the current basal pattern and basal rate,
- time it started, and
- the 24-hour basal total.

After you make changes to a pattern, the pump will use that pattern as the current basal. Make sure the basal you want is selected in the **SELECT PATTERN** screen.

Select a pattern

Before you select a pattern to be active, make sure the **Patterns** feature is turned on. After your standard pattern or pattern A or B are set, do these steps to select a pattern to be the active one:

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

Main > Basal > Select Patterns

2 Select the desired pattern, then press **ACT**.

3 The screen will return to the **BASAL MENU**. Your basal pattern is now active. Exit the menus.

NOTE: *If pattern A or B is active, the pump is in Special mode. An open circle appears at the top of the screen.*

Example 1: Basal patterns

Ken has had his insulin pump for about a month. He tests his blood glucose 4-6 times a day and records his results in his logbook. He is happy with his glucose control during the week but on the weekends, he noticed that he has to eat more food to prevent his blood glucose from running too low.

Ken has realized that during the week while he is at work, he is very inactive and sits at a desk most of the time. On the weekends, though, he is busy with yard work, running errands and playing with his kids. He determines that he needs to have lower basal settings to receive less insulin during active times, such as his weekend.

He can use the **Basal Patterns** feature to support his weekend change in activity. During the week, he can set his pump to deliver in the standard setting, and on Saturday morning, he can switch over to **Pattern A**, which he can set with lower basal rates for the weekend. On Monday morning, he can return his pump to the **Standard** setting for his weekday insulin needs.

Example 2: Basal patterns

Cynthia has had diabetes for about 12 years and has been on her Paradigm pump for several weeks. Every Monday, Wednesday and Friday, Cynthia goes on a 3 kilometer walk in the morning. To prevent hypoglycemia on these days, she uses the patterns feature. For those days, she simply switches over to Pattern A, which she has programmed with a lower set of basal rates. Before she learned to use the patterns feature, she would have to eat more food throughout the day to keep her blood glucose at a safe level. Cynthia has also noticed that a few days prior to menstruation, her blood glucose levels seem to rise, requiring more insulin. She has programmed Pattern B on her Paradigm pump with higher basal rates for this time. For her usual schedule, she uses the standard basal pattern.

Your turn:

Can you think of situations where you might require different basal rate settings on different days?

Temp basal rates

Temp basal should be used based on the guidance of your healthcare professional. This feature is useful to manage blood glucose levels during **unusual** short-term activities or conditions. These conditions could be an illness or physical activity.

A temporary basal rate allows an immediate short-term change to your basal insulin for a specified period of time (30 minutes to 24 hours). This rate can be up to your *Maximum* basal rate setting. It offers an easy way to immediately meet short-term insulin needs for temporary activities or situations. When your blood glucose is temporarily high or low, a temp basal rate allows you to set a temporarily higher or lower basal to accommodate your blood glucose. For ongoing periods of increased or decreased activity, the patterns feature may be more suitable.

How does temp basal work?

During a temp basal delivery, all other basal programming is temporarily overridden. After the temp basal delivery is completed, your pump will return to the programmed basal. A temp basal is delivered only once and does not repeat. If you want another temp basal, you must program the temp basal again. This feature may be useful to temporarily increase or decrease basal insulin during illness, exercise or similar unusual situations.

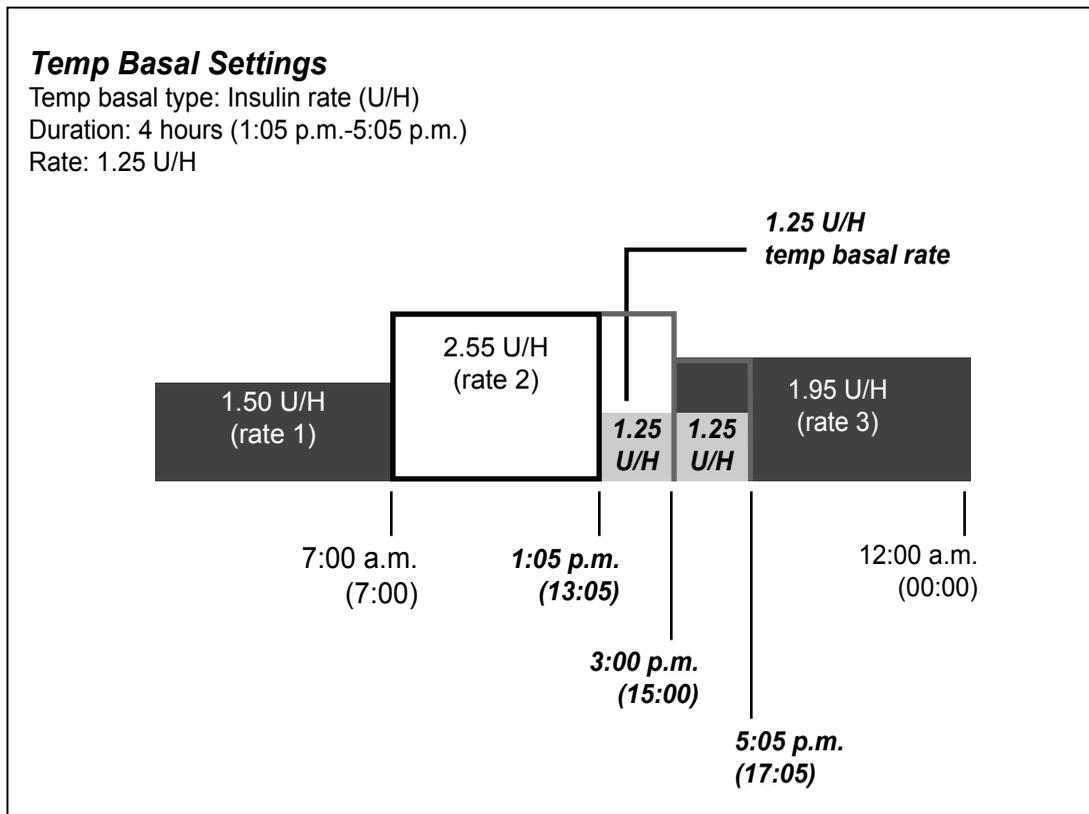
Temp basal types

Based on your preference, you can select either Percent of Basal or Insulin Rate.

Insulin rate (U/H)

Insulin rate is a fixed basal in units per hour (U/H). This temp basal type is independent of your current basal. When you select **Insulin rate (U/H)** for your temp basal type, your pump will deliver the fixed amount you have set for the duration as set. The amount of your temp basal insulin rate can be set up to your Maximum basal rate setting.

If you make changes to your normal basal rate, your U/H temp basal is not affected and will continue to deliver as programmed.



Percent of basal

Unlike insulin rate, the percent of basal is dependent on your current basal rates. Percent temp basal is a percentage of your current basal (0-200 percent limited to your Maximum basal rate setting). The temp basal amount is rounded down to the next 0.025 or 0.05 U/H increment based on the basal rate.

The maximum percent limit is based on the largest basal rate segment with your programmed temp basal rate time.

For example: It is 6:00 AM and your current basal rate is 1.50 U/H. You want to set a temp basal rate of 130 percent for seven hours. The maximum percent temp basal rate you can set is 125 percent. Anything larger would make #2 segment exceed your Maximum basal setting of 2.0 U/H.

Your current basal rates:	Your Maximum basal rate setting: 2.0 U/H
Segment #1: 12:00A	1.50 U/H
Segment #2: 11:00A	1.60 U/H (largest)
Segment #3: 4:00P	1.30 U/H

If your current basal changes (for example, from rate 1 to rate 2), your percent temp basal amount will also change. The pump will deliver the percentage for the duration that you have set.

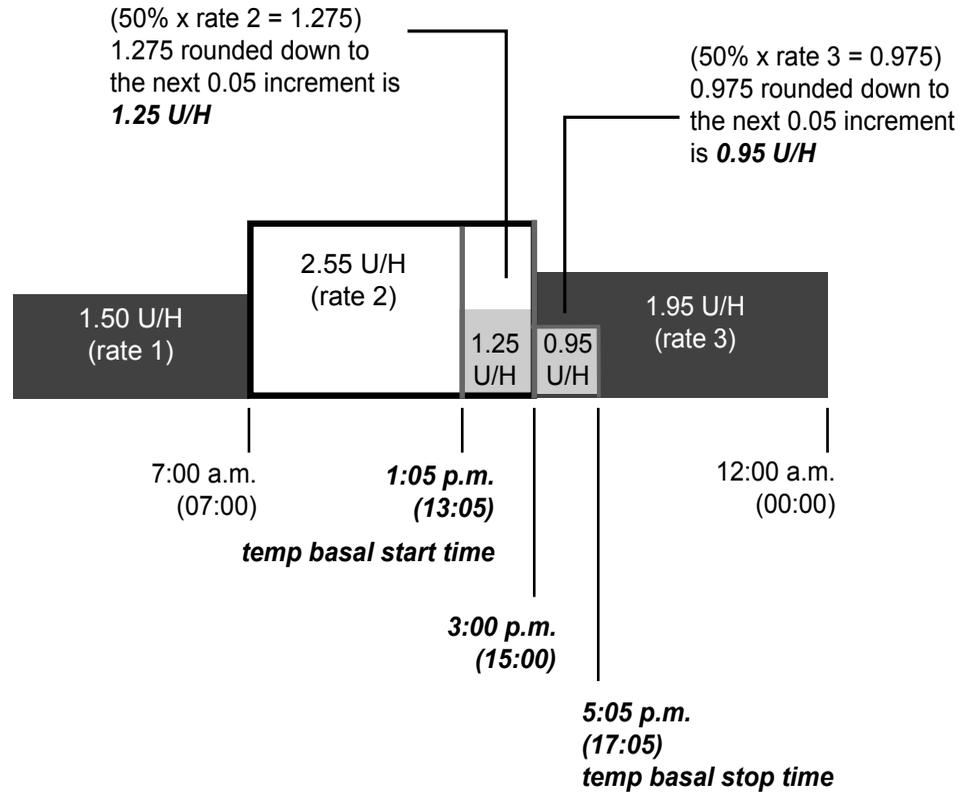
You cannot make changes to your normal basal rate while a percent temp basal is active. You must either wait until the temp basal is finished or cancel the temp basal in order to reprogram your normal basal rate setting(s).

Temp Basal Settings

Temp basal type: Percent of basal

Duration: 4 hours (1:05 p.m. - 5:05 p.m.)

Rate: 50%



Selecting temp basal type

Your pump will remember the temp basal type setting. Once the type is set, you do not have to set it again. To select a temp basal type, do these steps:

- 1 Go to the SET TEMP BASAL AS screen.
Main > Basal > Basal Setup > Temp Basal Type
- 2 The SET TEMP BASAL AS screen appears. Select **Insulin Rate (U/H)** or **Percent of Basal**, then press **ACT**.

- 3 The screen will return to the BASAL SETUP screen. The temp basal type is now set. Exit the menus. If you select **Percent of Basal** as your temp basal type, changes to your basal rate are not allowed until after temp basal is completed or cancelled.

Delivering a temp basal

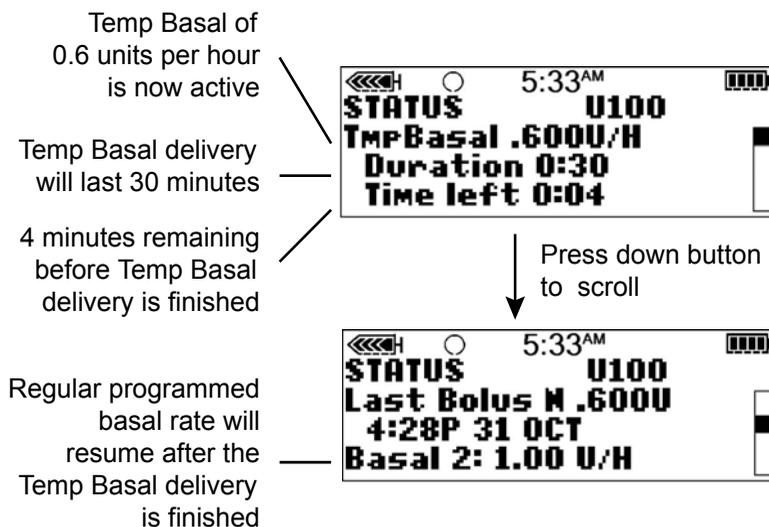
A temp basal cannot exceed your programmed Max basal rate.

- 1 Go to the BASAL MENU.
Main > Basal
- 2 Select **Set/Edit Temp Basal**, then press **ACT**.
- 3 The SET DURATION screen appears. The duration will flash. Duration is the amount of time it will take for the pump to deliver the temporary basal. Enter the desired minutes or hours (30 minutes to 24 hours), then press **ACT**.
- 4 If you have selected insulin rate as your temp basal type, the SET TEMP BASAL U/H screen appears. If you have selected percent of basal as your temp basal type, the SET TEMP BASAL % screen appears. The temporary basal rate will flash. Enter your temp basal rate, then press **ACT**.
- 5 The BASAL MENU screen appears with an open circle at the top of the screen. Your pump is in Special mode; temp basal is now set and delivering. Exit the menus.

Verifying temp basal delivery

Temporary basal information is available in the STATUS screen only.

During a temporary (temp) basal, the pump is in Special mode (an open circle appears). This open circle will remind you that a temp basal is active. Additionally, your pump will beep/vibrate three times on the hour regardless of the starting/ending time for the temp basal. During delivery, go to the STATUS screen to see the current temp basal information.



Canceling a temp basal

Use the Cancel Temp Basal function in the BASAL MENU to cancel a temporary basal. This function immediately stops the temp basal and resumes the regular programmed basal delivery.

To cancel a temp basal, do these steps:

- 1 Go to the BASAL MENU.
Main > Basal
- 2 Select **Cancel Temp Basal**, then press **ACT**.
The screen will return to the BASAL MENU. Your temp basal is cancelled and open circle has disappeared from the top of the screen. The programmed basal is now active again. Exit the menus.

Example 1:**Temp Basal for a decreased temporary basal rate**

Ramon and his friends got together for an unplanned game of soccer. Before using the pump, he was taking shots to manage his diabetes. Ramon experienced frequent low blood glucose reactions sometimes during, and very often after, he played games with his friends. Now that he is using his Paradigm pump, he can use the Temporary Basal Rate feature to help prevent low blood glucose. He simply programs his pump to temporarily deliver less basal insulin during the time that he is playing, and often for several hours after play, as well.

Ramon was able to determine how to set his Temporary Basal rates by frequent blood glucose testing, both during and after activity, and recording his results. The first time he tried using the pump, his healthcare professional advised him to program his pump to deliver one-half of his usual basal rate for the amount of time that he was playing and for an hour after he was done. He made small adjustments of the temporary basal rate and the duration of time, each time he tried to use the feature. After several different attempts with similar activity for the same amount of time, (such as his soccer game that lasted two hours), he found a temporary basal rate that worked well for him.

Example 2:**Temp Basal for an increased temporary basal rate**

Gail has had a cold with a cough for a couple of days. Because she is not feeling well, she tests her blood glucose more frequently. She finds that her blood glucose levels are running above target range before meals and she has needed several correction boluses to keep her blood glucose levels within her normal limits. Gail decides to use the Temporary Basal Rate to increase her basal rate during the day today. As advised by her healthcare professional, she will continue to check her blood glucose more frequently until she is feeling well.

Your turn:

Think of an activity where you might need to use a Temporary Basal Rate.

At what rate is your current basal rate running? _____

What Temporary Basal Rate would you try using at this time? _____

How long will you be active? _____

What duration will you set for the Temporary Basal Rate? _____

Test your blood glucose before and during activity and several times after as well. What are your blood glucose results?

Pre-activity _____

During activity _____

1 hour after activity _____

Several hours after activity _____

What Temporary Basal Rate changes will you make for the next time you try this?

Sensor features

The optional sensor and transmitter can provide continuous glucose measurements to help you control your glucose levels better. The sensor measures the glucose levels in the fluid under your skin. The transmitter receives this measurement from the sensor and sends it wirelessly to the pump. To take advantage of your pump sensor features, call 800 646 4633, +1 818 576 5555 (outside U.S.), or visit our web site at www.medtronicdiabetes.com to purchase your sensor and transmitter.

To learn more about the accuracy of sensor glucose (SG) readings versus blood glucose (BG) readings, see the *Enlite® Sensor Performance for the Paradigm® REAL-Time Revel™ Insulin Pump* document.

WARNING: Do not make therapy treatment decisions based on sensor glucose values because sensor glucose and blood glucose values may differ. If your sensor glucose reading is low or high or if you feel symptoms of low or high glucose, confirm your blood glucose with your BG meter prior to making therapy decisions to avoid severe low or high glucose conditions.

Entering your sensor settings

Enter your pump sensor settings in the order they appear below, as some of the settings are dependent upon other settings being made first. When you complete each setting, your pump will automatically display the screen for the next setting in the sequence. When a screen item flashes, you may change the value of the flashing item by pressing  or .

Turning on the sensor

The sensor must be turned on, started and initialized to report glucose measurements.

- 1 Go to the EDIT SETTINGS screen.

Main > Sensor > Edit Settings

The EDIT SETTINGS screen appears with **Sensor: Off** selected.

- 2 Press **ACT**. The SENSOR ON/OFF screen appears.

- 3 Select **On**, then press **ACT**. The EDIT SETTINGS screen appears showing the sensor is now turned **on**. You are now ready to turn on the glucose alerts.

Turning on the Glucose Alerts

The Glucose alerts must be turned on if you want the system to send you an alert when the sensor glucose measurements reach or exceed your Glucose Limits. For a Low sensor glucose alert, the pump plays four consecutive tones, in falling pitch, if an audible beep has been selected as the alert type. For a High sensor glucose alert, the pump plays four consecutive tones, in rising pitch, if an audible beep has been selected as the alert type.

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Glucose Alerts**, then press **ACT**. The GLUCOSE ALERTS screen appears.
- 3 Select **On**, then press **ACT**. The EDIT SETTINGS screen appears showing the glucose alerts are now turned **On**.

Setting the Glucose Limits

If you turned the Glucose alerts **On**, then you need to set the high and low Glucose Limits recommended by your healthcare professional. Your recommended glucose limits may vary throughout the day, so your pump allows you to set up to eight pairs.

A Glucose Limit pair includes one High Glucose Limit and one Low Glucose Limit, as shown in the following table:

Glucose Limit pair	Alerts
Low: 80 mg/dL (4.4 mmol/L)	A Low Glucose Limit alert occurs when the sensor glucose measurement reaches or goes below the Low Glucose Limit in this table.

Glucose Limit pair	Alerts
High: 240 mg/dL (13.3 mmol/L)	A High Glucose Limit alert occurs when the sensor glucose measurement reaches or goes above the High Glucose Limit in this table.

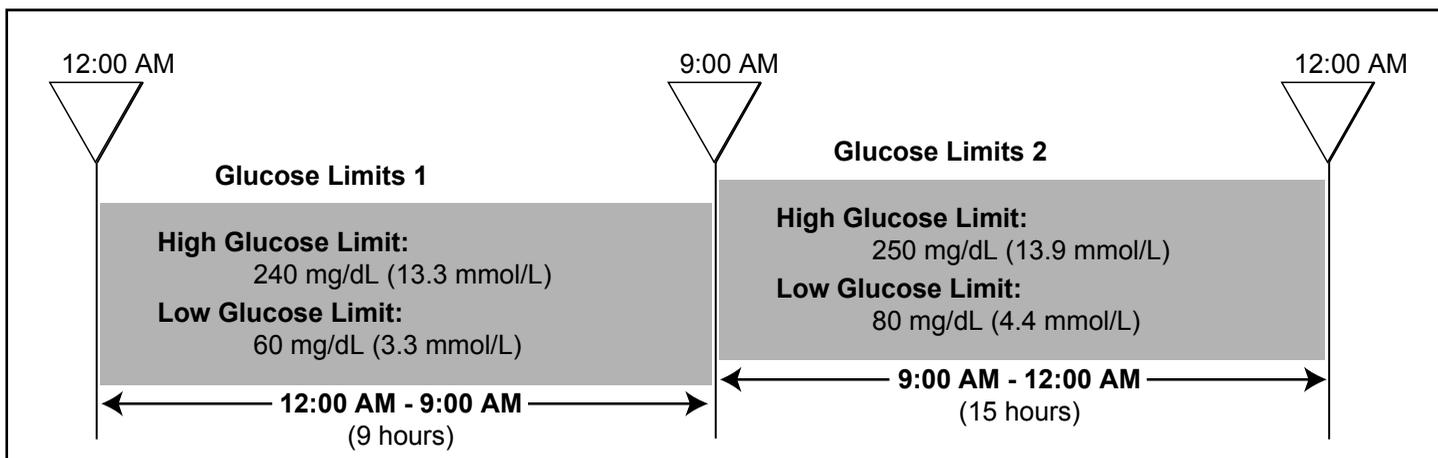
Selecting the BG units

You must select the blood glucose units (BG Units) for the system (either mg/dL or mmol/L). All BG measurements will show in the BG unit type you select.

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **BG Units**, then press **ACT**. The BLOOD GLUCOSE UNITS screen shows **mg/dL** and **mmol/L**.
- 3 Select your BG units.
- 4 Press **ACT**. The EDIT SETTINGS screen shows the BG Units type you selected.
 You are now ready to set up your glucose limits.

Setting the Glucose Limits start time

If your healthcare professional recommends that you set more than one pair of Glucose Limits, you must enter a start time for each. For example, you may use one pair of Glucose Limits during the day and another pair at night. The example below shows two pairs of Glucose Limits. The first pair begins at midnight, and the second pair begins at 9:00 AM.



To set up your Glucose Limits:

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Glucose Limits**, then press **ACT**. The SET GLUCOSE LIMITS 1 screen appears. The Low Glucose Limit flashes 80 mg/dL (4.4 mmol/L).
 The start time for your first pair of Glucose Limits is midnight and cannot be changed.
- 3 Select your Low Glucose Limit. The value must be between 40 and 390 mg/dL (2.2 and 21.6 mmol/L). To switch off the Low Glucose Limit, reduce it below 40 mg/dL (2.2 mmol/L) to select **OFF**.
- 4 Press **ACT** to select your High Glucose Limit. The screen flashes 240 mg/dL (13.3 mmol/L). The limit you select must be between 50 and 400 mg/dL (2.8 and 22.2 mmol/L). Your High Glucose Limit must also be at least 10 mg/dL (0.6 mmol/L) above your Low Glucose Limit. To switch off the High Glucose Limit, reduce the High Glucose Limit below 50 mg/dL (2.8 mmol/L) to select **OFF**.
- 5 Press **ACT**. The SET START TIME 2 screen appears. The dashes under the screen name flash. The first pair of Glucose Limits is now set.
 If you do not need a second pair of Glucose Limits, press **ESC** and skip to the next section. If you want to set up a second pair of Glucose Limits, follow steps 6 through 11 below.
- 6 To set a second pair of Glucose Limits, select the time of day you want this pair to become active.
- 7 Press **ACT**. The SET GLUCOSE LIMITS 2 screen appears. The default Low Glucose Limit flashes (**OFF**).
- 8 Select your Low Glucose Limit. The value must be between 40 and 390 mg/dL (2.2 and 21.6 mmol/L).
- 9 Press **ACT**. The default High Glucose Limit flashes (**OFF**).
- 10 Select your High Glucose Limit. The value must be between 50 and 400 mg/dL (2.8 and 22.2 mmol/L).

11 Press **ACT**. The SET START TIME 3 screen appears.

The second pair of Glucose Limits (Glucose Limits 2) is now set. If you do not need any more Glucose Limits pairs, press **ESC**. If you want to set more Glucose Limits, then repeat steps 6 through 11 above for each pair, up to a maximum of eight.

You are ready to set up your High Repeat.

Setting the High Repeat

After you receive and clear a High Glucose, Rise Rate of Change, or High Predictive alert, the alert will repeat until the condition that has caused the alert is resolved. The High Repeat feature allows you to set how frequently you want the alert to repeat after you clear it the first time. For example, if your blood glucose levels usually take one to two hours to fall after a correction bolus, you may want to set the High Repeat to one or two hours to avoid unnecessary alerts.

Example

You set your High Repeat to 15 minutes. You receive an alert at 1:00 PM and immediately clear it. However, the condition that caused the alert still exists, so you will receive a second alert at 1:15 PM, 15 minutes after you cleared the first alert. If you immediately clear the alert again, then the alert will repeat at 1:30 PM and continue to repeat every 15 minutes until you resolve the condition that caused the alert. (This example also applies to the Low Repeat.)

To set up your High Repeat:

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Hi Repeat**, then press **ACT**. The SET HI ALERT REPEAT screen flashes the default High Repeat time of 1 hour (1:00).
- 3 Select your High Repeat time. The time must be between 5 minutes (0:05) and 3 hours (3:00).
- 4 Press **ACT**. The EDIT SETTINGS screen shows the High Repeat value set.
You are now ready to set up your Low Repeat.

Setting the Low Repeat

After you receive and clear a Low Glucose, Fall Rate of Change, or Low Predictive alert, the alert will repeat until the condition that caused the alert is resolved. The Low Repeat feature allows you to set how frequently you want the above alerts or alarm to repeat after you clear it the first time. The Low Repeat feature works similar to the High Repeat one. See *Setting the High Repeat* section in this chapter for an example.

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Lo Repeat**, then press **ACT**. The SET LO ALERT REPEAT screen flashes the default Lo Alert Repeat time of 20 minutes (0:20).
- 3 Select your Low Repeat time. The time must be between 5 minutes (0:05) and 1 hour (1:00).
- 4 Press **ACT**. The EDIT SETTINGS screen shows the Low Repeat value set. You are now ready to set up the Predictive Alert.

Setting the Predictive glucose alert

The Predictive alerts calculate when you may reach your Low or High Glucose Limits, then send you an alert before you reach those limits. A Predictive alert tells you that **if your sensor glucose measurements keep falling or rising at the current rate**, you may reach your Glucose Limit in the number of minutes you selected. For a LOW PREDICTED alert, the pump plays three consecutive tones, in falling pitch, if an audible beep has been selected as the alert type. For a HIGH PREDICTED alert, the pump plays three consecutive tones, in rising pitch, if an audible beep has been selected as the alert type.

Understanding the Time Sensitivity Settings

To use the Predictive alerts, you need to first set your Low or High Glucose Limits, and then your Time Sensitivities. Time Sensitivity means the length of time, in minutes, you want to be notified before you reach your High or Low Glucose Limit. If you set the Low time sensitivity setting at 25 minutes and the High time sensitivity setting at 20 minutes, then the Predictive alerts will be sent:

- **25 minutes before** the sensor glucose reaches your Low Glucose Limit
- **20 minutes before** the sensor glucose reaches your High Glucose Limit

To set up the Predictive alerts:

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Predict Alerts**, then press **ACT**. The PREDICTIVE ALERTS LOW/HIGH screen shows that the alerts are turned **Off**.
- 3 Select **On**, then press **ACT**. The SET TIME SENSITIVITY LOW/HIGH screen appears and the LOW time setting flashes the default time: 15 minutes (0:15).

- 4 Select the Time Sensitivity (how many minutes before you reach your Low Glucose Limit). To turn off the Low Predictive Alert, reduce the Time Sensitivity to **OFF**.
 - Range: **5 to 30 minutes (0:05 to 0:30)**
 - Increments: **5 minutes**
- 5 Press **ACT**. The HIGH time setting flashes the default time: 15 minutes (0:15).
- 6 Select the Time Sensitivity (how many minutes before you reach your High Glucose Limit). To turn off the High Predictive Alert, reduce the Time Sensitivity to **OFF**.
 - Range: **5 to 30 minutes (0:05 to 0:30)**
 - Increments: **5 minutes**
- 7 Press **ACT**. The EDIT SETTINGS screen appears.
You are now ready to set up the rate alerts.

Setting the Rate of Change Alerts

The Rate of Change alerts tell you when your sensor glucose (SG) changes at, or faster than, the per-minute rate pre-selected by you. There are two alerts:

- **FALL RATE** for SG **decreases** at or faster than your pre-selected rate. The pump plays two consecutive tones, in falling pitch, if an audible beep has been selected as the alert type.
- **RISE RATE** for SG **increases** at or faster than your pre-selected rate. The pump plays two consecutive tones, in rising pitch, if an audible beep has been selected as the alert type.

You can set one or both Rate of Change alerts. The rate of change alert default setting is **OFF**. When you press  or , 4.0 mg/dL (0.220 mmol/L) displays. This value changes up or down with each additional press.

The explanation in the following table shows how the Rate alerts work.

If you set the number	Then
Lower than 4.0 mg/dL/min (0.220 mmol/L/min)	<ul style="list-style-type: none"> • The system is more sensitive to SG changes • Alerts are more frequent than if you use a higher number
Higher than 4.0 mg/dL/min (0.220 mmol/L/min)	<ul style="list-style-type: none"> • The system is less sensitive to SG changes • Alerts are less frequent than if you use a lower number

To set up the Rate of Change alerts:

- 1 Make sure the EDIT SETTINGS screen is open.

Main > Sensor > Edit Settings

- 2 Select **Rate Alerts**, then press **ACT**. The SET FALL RATE LIMIT screen flashes the rate alert default setting: **OFF**.
- 3 Select the Fall Rate Limit.
 - Range: mg/dL/min from **1.1** to **5.0**
 mmol/L/min from **0.065** to **0.275**
 - Increments: mg/dL/min **0.1**
 mmol/L/min **0.005**
- 4 Press **ACT**. The SET RISE RATE LIMIT screen flashes the rate alert default setting: **OFF**.
- 5 Select the Rise Rate Limit. The range and increments are the same as the Fall Rate Limit (see step 3 above).
- 6 Press **ACT**. The Rate of Change alerts will now use the settings you specified. You are now ready to set up the Cal Repeat.

Setting the Cal Repeat

After you receive and clear a METER BG NOW alert, the device will repeat the alert until you enter a new meter blood glucose measurement. The Cal Repeat feature allows you to set how frequently you want the alert to repeat after you clear it.

- 1 Make sure the EDIT SETTINGS screen is open.

Main > Sensor > Edit Settings

- 2 Select **Cal Repeat**, then press **ACT**. The SET CAL REPEAT screen flashes the default Cal Repeat time of 30 minutes (0:30).
- 3 Set your Cal Repeat time between 5 minutes (0:05) and 1 hour (1:00).
- 4 Press **ACT**. The EDIT SETTINGS screen shows the Cal Repeat time you selected. You are now ready to set your Cal Reminder.

Setting the Cal Reminder

The Cal Reminder feature allows you to set a reminder to calibrate your system. For example, if you set your reminder to four hours, then you will receive a METER BG BY alert (Cal Reminder) four hours before the next meter blood glucose (BG) entry is due (eight hours after your last successful sensor calibration).

To set up the Cal Reminder:

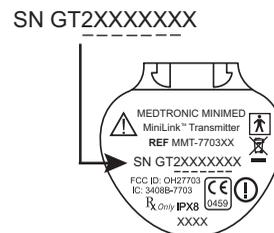
- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Cal Reminder**, then press **ACT**. The CAL REMINDER screen shows **On**.
- 3 Press **ACT**. The SET CAL REMINDER screen flashes the Cal Reminder default time of 1 hour (1:00).
- 4 Select your Cal Reminder time between 5 minutes (0:05) and 6 hours (6:00).
- 5 Press **ACT**. The EDIT SETTINGS screen shows the Cal Reminder time you selected. You are now ready to enter your transmitter ID number.

Entering the transmitter ID

The transmitter ID (serial number) starts with 2 and is found on the flat side of your transmitter. You must enter the transmitter ID so that the transmitter and the pump can communicate with each other.

Write the Transmitter ID of the transmitter you are using here: _____.

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Transmtr ID**, then press **ACT**. The SET TRANSMITTER ID screen appears. The screen shows seven dashes for the Transmitter ID, the first of which (on the left) is flashing.
- 3 Select the first number of the Transmitter ID (the number on the screen must match the first number of the Transmitter ID). The transmitter ID is located on the transmitter label, as shown.
- 4 Press **ACT**. The second dash flashes.
- 5 Select the next number of the Transmitter ID, then press **ACT**.
- 6 Repeat step 5 until all seven digits of the Transmitter ID have been selected.



- 7 A message shows that the Transmitter ID has been changed. After about 30 seconds, the EDIT SETTINGS screen appears. It shows the Transmitter ID you entered.
You are now ready to set up the Weak Signal.

Setting up the Weak Signal feature

The Weak Signal feature allows you to determine how quickly you will receive a Weak Signal alert when there is no communication between the transmitter and the pump. For example, if you set the Weak Signal value to 30 minutes, you will receive a Weak Signal alert 30 minutes after loss of communication.

To set up the Weak Signal feature:

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
- 2 Select **Weak Signal**, then press **ACT**. The SET WEAK SIGNAL screen flashes the default time of 30 minutes (0:30).
- 3 Select your Weak Signal time between 5 minutes (0:05) and 40 minutes (0:40).
- 4 Press **ACT**. The EDIT SETTINGS screen shows the length of time you entered for the Weak Signal option.
- 5 You are now ready to set up the sensor glucose graph timeout.

Setting the sensor glucose graph timeout

The sensor glucose graph timeout is how long the graphs show on the pump screen until the HOME screen automatically appears. The default timeout is two (2) minutes, and you can set it for 2, 4, or 6 minutes.

Using a continuous graph display

You can also select **NONE** to set the sensor graph timeout to display continuously. If you select **NONE**, the sensor graphs will show until another screen or menu is selected, or an alarm/alert occurs. Selecting continuous graph display uses more battery power and decreases battery life. To return to the HOME screen from the sensor glucose graphs, press **ESC** until the HOME screen appears.

To set the sensor glucose graph timeout:

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings

- 2 Select **Graph Timeout**, then press **ACT**. The SET GRAPH TIMEOUT screen flashes the default time of 2 minutes (0:02).
- 3 Select your Graph Timeout. The time you select must be: 2 minutes; 4 minutes; 6 minutes; or NONE.
- 4 Press **ACT**. The EDIT SETTINGS screen shows the Graph Timeout you selected.
You are now ready to review your sensor glucose monitoring settings.

Reviewing your settings

Make sure that all the settings you have made are correct before you use the system. Use the following procedure to review your settings:

- 1 Open the REVIEW SETTINGS screen.
Main > Sensor > Review Settings
- 2 Press  to scroll through all settings to make sure that they are correct.
- 3 To change any settings, return to the EDIT SETTINGS menu.
Main > Sensor > Edit Settings
- 4 Save your settings after you have set your preferences. This will allow you to restore the settings you have saved if you receive an alarm or error that resets your settings.

Using the Sensor Demo

The Sensor Demo shows you a demonstration of a sensor graph. To view the Sensor Demo screen, you must first turn on the Sensor Demo feature. After the Sensor Demo feature is turned on, the first line of the STATUS and SENSOR STATUS screens will show **SENSOR DEMO: On**.

Turning on the Sensor Demo feature

- 1 Make sure the EDIT SETTINGS screen is open.
Main > Sensor > Edit Settings
The EDIT SETTINGS screen shows **Sensor Demo: Off**.
- 2 Press **ACT**. The SENSOR DEMO ON/OFF screen appears with **Off** selected.
- 3 Select **On**, then press **ACT**. The EDIT SETTINGS screen shows that SENSOR DEMO is now turned **On**.

CAUTION: The Sensor Demo feature affects the sensor demonstration graph only. All other features, screens and options are in the normal mode.

Warning: Do not use Sensor Demo to make any decisions related to your therapy. Information seen in the Sensor Demo is not real data. It is an example of the type of information you can access when using the sensor feature. Making treatment decisions based on data that is not real can lead to low or high blood glucose conditions.

Viewing the Sensor Demo screens

- 1 From the HOME screen, press **ESC**. The screen briefly shows **SENSOR DEMO**, then the first Sensor Demo graph appears.
- 2 You can move the cursor (flashing vertical line) through the graph to see examples of how the real-time graphs appear. Press  to move the cursor left, press  to move the cursor right.
- 3 You must turn the Sensor Demo off in order to show your actual, real-time sensor glucose graphs. To turn the Sensor Demo off, follow the above procedure and select **Off**.

The transmitter

The Medtronic MiniLink transmitter (MMT-7703) is a device that takes electronic signals generated by the glucose sensor and sends them by radio frequency to the pump. It has two watertight testers (MMT-7726) and a charger (MMT-7705). For details on how to use your transmitter, charger, and tester, see your transmitter user guide.

Starting the sensor

To start the sensor working, you must complete the following steps in order:

- Insert a battery into the transmitter's charger.
- Charge the transmitter battery.
- Set up the sensor features.
- Insert the sensor.
- Connect the transmitter to the sensor.
- Wait for the transmitter to flash.
- Cover the transmitter with the sensor adhesive tab.
- Start the sensor and wait two hours.
- Enter your first meter BG.

Inserting the sensor

Refer to your serter user guide for information on sensor insertion.

Connecting the transmitter to the sensor

Before connecting the transmitter to the sensor, make sure of the following:

- The transmitter is fully charged.
- The transmitter ID and other sensor settings have been entered into your pump.
- The Enlite sensor has been inserted and the Enlite overtape has been applied.
- The sensor insertion site is not bleeding.

Removing the sensor

When you are ready to change your sensor, disconnect it from the transmitter as described in your transmitter user guide. Gently pull the sensor from your body to remove it. Place it in a sharps container.

Preparing the sensor for communication

Connect your transmitter to your sensor as described in the transmitter user guide. When the green light on the transmitter flashes, use your pump to follow the steps below.

- 1 Go to the LINK SENSOR MENU screen.
Main > Sensor > Link to Sensor
- 2 Select **New Sensor**. Press **ACT**.
- 3 Connect the transmitter to your sensor now if you have not already done so. If the screen times out, do **not** disconnect the sensor. Start from step 1 again.
- 4 After your sensor is connected, press **ACT**. The **SENSOR READY 2 HRS** screen appears.
- 5 The sensor will enter a two hour initialization period. Press any button to continue. After 2 hours your pump will alert you to enter a meter BG to calibrate your sensor.

Calibrating the sensor

Two hours after you use your pump to start the sensor, your pump will alert you to enter a meter BG (METER BG NOW). This meter BG entry will be the **first** calibration for your sensor. You have to wait 10 to 15 minutes after calibration to see the first sensor glucose reading on the pump screen. Six hours after the first calibration, the pump will alert you to enter the second calibration.

After the second calibration, you must calibrate your sensor every 12 hours. If you fail to enter a meter BG reading after 12 hours, your pump displays the METER BG NOW alert. Your pump will then stop calculating glucose values. However, about 20 minutes after you have entered a meter BG, your pump will continue calculating glucose values.

Follow these guidelines for best calibration results:

- Calibrate three to four times spread out throughout the day.
- Avoid calibrating when your glucose is changing rapidly, such as after eating or exercise.
- Enter your meter BG reading into the pump immediately after testing your BG. Do not wait to enter it later.
- Always use clean dry fingers when you check your blood glucose.
- Only use your fingertips to obtain blood samples for calibration.
- Wait at least 15 minutes in between calibration attempts.

After the transmitter successfully transmits signals to the pump, you may choose to put an occlusive dressing over the transmitter and the sensor.

Entering meter BG for calibration

Sensor calibration is necessary for optimal glucose sensor performance. Only BG entries in the range of 40-400 mg/dL (2.2-22.2 mmol/L) are accepted for sensor calibration.

Use any of the following methods for your sensor calibrations, including the first calibration after the initialization. You can enter BG values manually or through your linked meter.

To enter BG values manually:

- 1 You can enter a meter BG value manually in the Bolus Wizard.
 - a. Press the **B** button on your pump, or use the MAIN MENU to go to the ENTER BG screen:
Main > Bolus > Use Bolus Wizard
 - b. Use the up and down arrow buttons on your pump to enter your meter BG. Press **ACT**.
 - c. Select **Yes** to calibrate, or **No** to cancel, when the following screen displays: BG to update Sensor?
- 2 You can enter a meter BG value manually through the Sensor menu.
 - a. Follow this path:
Main > Sensor > Calibrate
 - b. Enter the BG value, and then press ACT. Your sensor is now calibrated with the BG value you entered.
 - If the Bolus Wizard feature is off, the SENSOR MENU screen appears.
 - If the Bolus Wizard is on and the saved BG is below your BG Target range, the Cal Saved screen appears. This screen indicates that your saved BG is below your BG Target set in the Bolus Wizard feature, and the pump beeps three times. See *Setting the BG Targets, on page 77* for more information.
 - If the Bolus Wizard is on, the saved BG is above your BG Target range, and the calculated correction estimate is more than the preset scroll rate increment, the Cal Saved screen appears. This screen indicates that your saved BG is above your BG Target set in the Bolus Wizard feature, and the pump beeps three times. Go to the ENTER BG screen of the Bolus Wizard feature to enter a correction bolus. See *Using the Bolus Wizard feature* section for more information.
 - If the information is not correct, select **Cancel**, then press **ACT**. The SENSOR MENU screen reappears with **Calibrate** selected. Repeat the procedure and enter the correct information.
- 3 You can enter a meter BG value manually through the Capture Event menu. Follow this path:
Main > Capture Event > Enter BG

See *Entering BG measurements, on page 41* for more information.

To enter BG values through your linked meter:

- 1 Test your BG with a fingerstick.
- 2 The BG value is automatically sent from the meter to your pump. This value displays in the following screen: BG to update Sensor. Select **Yes** if you want to calibrate your sensor. Select **No** if you do not want to use your BG value for calibration.
Make sure that your pump and the meter are properly programmed for communication. See *Meter option, on page 155* for more information.

Restarting the sensor after three days

The sensor can be worn for up to six days (144 hours). This procedure must be conducted for each newly inserted sensor to restart that sensor after three days. This will allow you to use your sensor up to its maximum life of six days (144 hours). If this is the second time you have received the SENSOR END alert, replace your sensor and recharge the transmitter.

Use your Daily Journal to record the date and time each sensor is inserted to ensure that you do not restart an individual sensor more than once. To help remind you of this, and to maintain battery life, the transmitter is designed to turn off after seven days (168 hours) of use. After the transmitter turns off, your pump will display a LOST SENSOR alert.

To restart your sensor, do these steps:

- 1 Go to the LINK SENSOR MENU screen.
Main > Sensor > Link to Sensor > New Sensor
- 2 Select **New Sensor**. Press **ACT**.
- 3 Press **ACT** again. The **SENSOR READY 2 HRS** screen appears.
- 4 Press any button to continue. In most cases, your device displays a **METER BG NOW** alert within five minutes.

When you restart the sensor, there is no two-hour wait for your device to prompt you to enter a meter BG. This is because the sensor has already been started, wetted, and has not been disconnected from the transmitter.

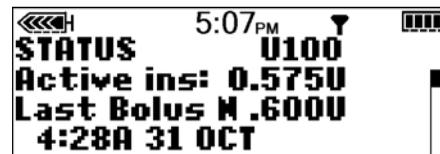
Using your sensor

Status screens

Your STATUS screens tell you what is going on in your pump. In the SENSOR STATUS screen you can check the status of sensor information including when your next calibration will be needed, your sensor's age, and the state of your transmitter battery.

To get to your status screens:

- 1 From the HOME screen, press the ESC button twice. This takes you to your pump status screen.
- 2 To see the Sensor Status screen, press ESC one more time. This screen will only be available if the Sensor feature has been turned On.



Reading the sensor glucose graphs

NOTE: If your graphs say *DEMO* in the upper left corner of your screen, you must turn off the *SENSOR DEMO* mode to see your actual graphs (see the *Using the Sensor Demo* section in the *Sensor features* chapter).

Your pump shows an updated, real-time glucose measurement. This measurement is generated by data sent from the sensor to the transmitter, and then to the pump every five minutes. The pump converts these measurements to glucose graphs that include the following information:

- **The most recent sensor glucose measurement or the reason that one is not displayed.**
- **The historical sensor glucose measurements or the reason that one is not displayed for the last 3, 6, 12 or 24 hours.**
- **Arrows that show the relative rate at which the most recent sensor glucose levels have risen or fallen.**

The following conditions can prevent a real-time sensor glucose measurement from being displayed:

- **A Lost Sensor alert.**
- **A Sensor Error alert.**
- **A Change Sensor alert.**
- **A Cal Error alert.**
- **Find Lost Sensor (15 minutes).**
- **Weak signal.**
- **Reconnect old sensor (two hours).**
- **A meter BG entry is needed for calibration.**

Your pump displays ABOVE 400 when the measured sensor glucose reading is greater than 400 mg/dL, and BELOW 40 when the measured sensor glucose reading is less than 40 mg/dL.

Two other conditions also prevent a real-time SG measurement and generate a WARM UP message on your sensor glucose graphs:

- You started a new sensor, and it has entered a two-hour initialization. The sensor is not ready to take glucose measurements.
- You entered a BG for calibration, and your pump is waiting to receive the first valid SG value.

Opening and viewing the graphs

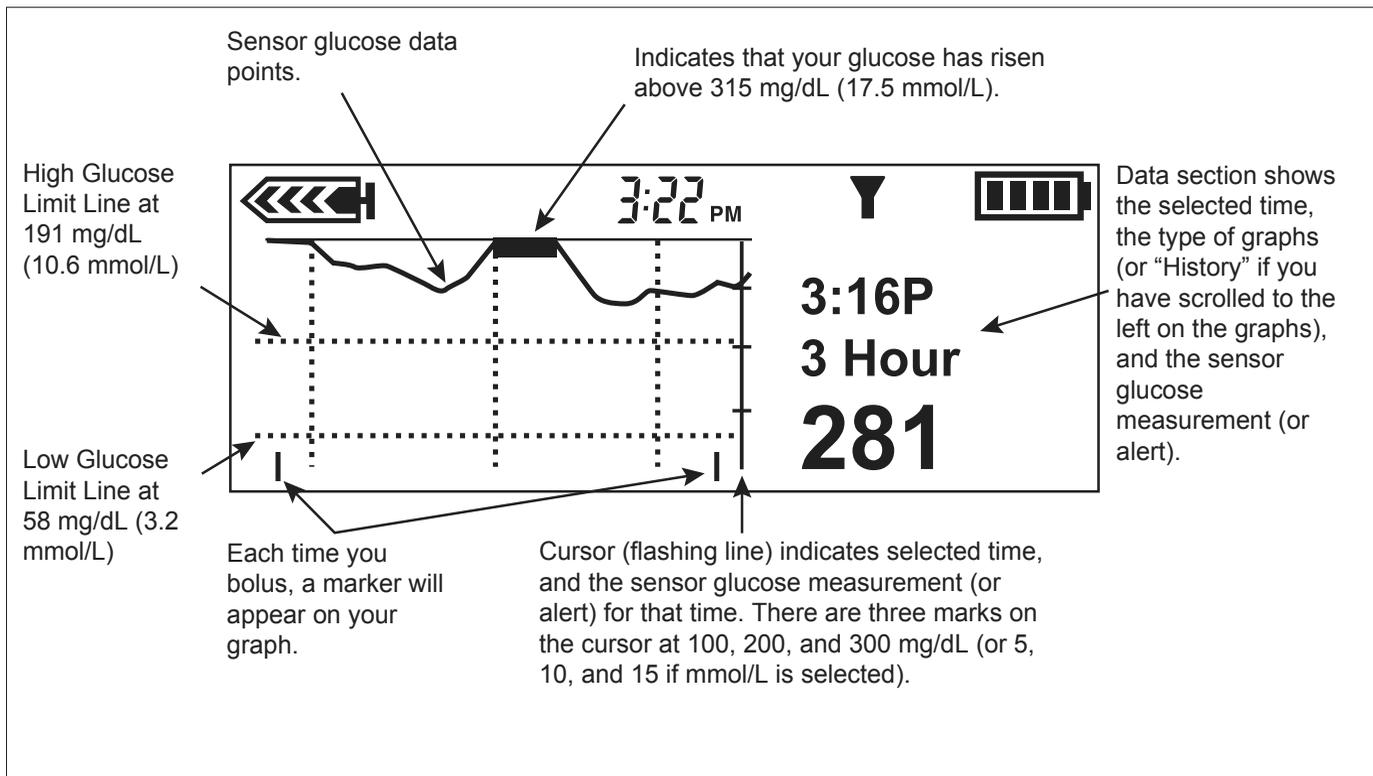
The following table describes how to use the graphs.

If you want to:	Do the following:
Open the graphs	From the HOME screen, press ESC . The last graph you viewed (3-, 6-, 12- or 24-hour) shows the details for your most recent sensor glucose (SG) measurement.
View information in a graph	<p>If there is no SG measurement at the time you select, the reason for the missing measurement will be shown on the right side of the graph (for example, LOST SENSOR).</p> <ul style="list-style-type: none"> • When you open the graphs, the cursor (flashing vertical line) is always on the right edge of the graph and the graph shows the most recent SG measurement. • Press  to move the cursor left to see an earlier SG measurement. • Press  to move the cursor right to return to more recent SG measurements.
View different graphs	<ul style="list-style-type: none"> • With the cursor at the far right edge of a graph, you can press  to open the next graph. • If the cursor is anywhere to the left of the far right edge, press ESC to move it to the right, then press  to open the next graph.

The graphs

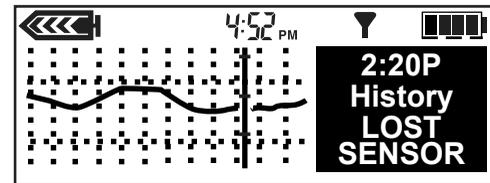
All graphs show High and Low Glucose Limits lines, a real-time SG measurement line, a data section, and the cursor (flashing vertical line).

When you open any graph, the cursor flashes on the right edge of the graph. There are three marks on the cursor at 100, 200, and 300 mg/dL (or 5, 10, and 15 if mmol/L is selected). The data section shows the most recent SG measurement or the reason why no measurement shows, and the time in the data section matches the time at the top of the screen.



When you move the cursor left to select an earlier SG measurement, the data section of the graph turns black, the word History appears here, and the time in the data section changes to show the time when the SG measurement was taken or the reason why no SG measurement shows for that time.

NOTE: *There are many reasons your graphs may not show an SG measurement, but your system does not alert for every one. Therefore, your system’s alarm/alert history may not match the number of times your graphs do not show an SG measurement.*

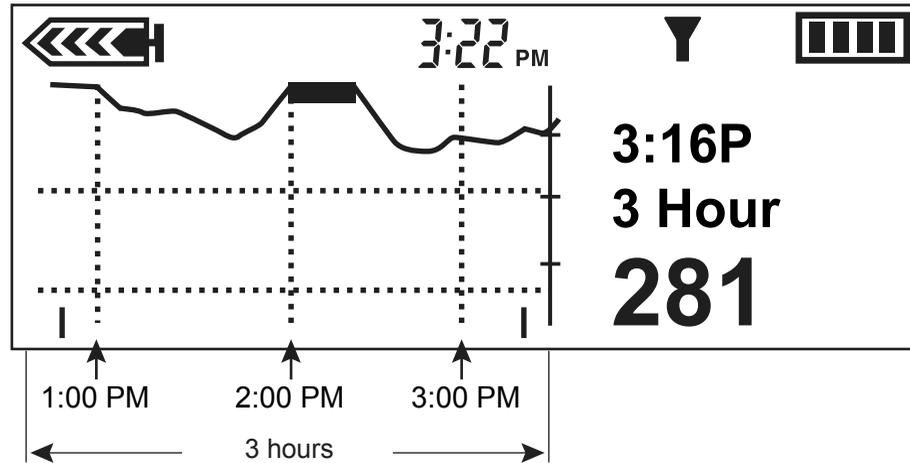


Examples of real-time sensor glucose graphs

The following pages show examples of the different graph types.

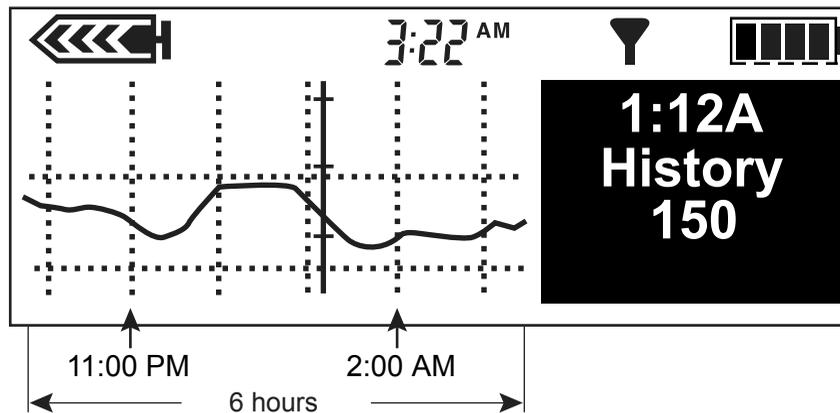
3-hour graph

Each part of the graph between the vertical dashed lines represents one hour. In this example, the selected SG measurement was taken at 3:16 PM, and the value at that time was 281 mg/dL (15.6 mmol/L).



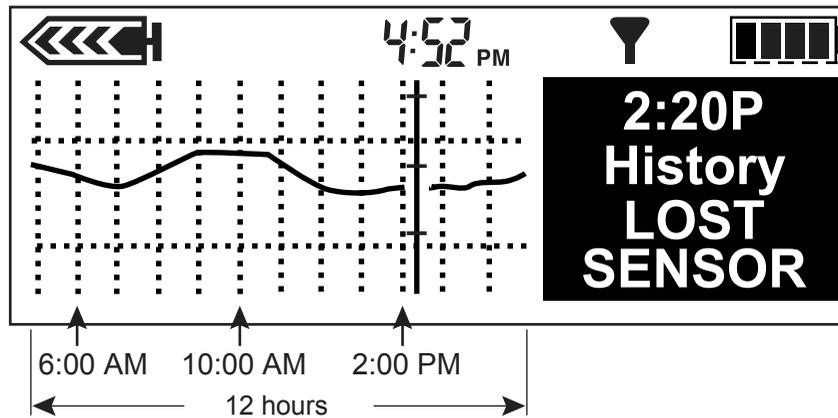
6-hour graph

Each part of the graph between the vertical dashed lines represents one hour. In this example, the selected SG measurement was taken at 1:12 AM, and the value at that time was 150 mg/dL (8.3 mmol/L).



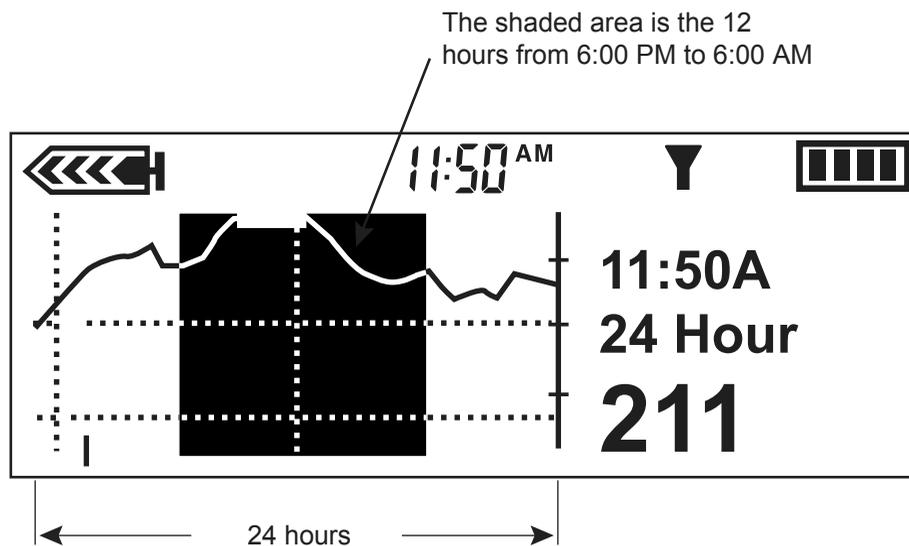
12-hour graph

Each part of the graph between the vertical dashed lines represents one hour. In this example, the reason no measurement is displayed is LOST SENSOR and it occurred at 2:20 PM.



24-hour graph

Each part of the graph between the vertical dashed lines represents 12 hours. The shaded area helps you more easily see the sensor glucose measurements for the previous night. In this example, the selected SG measurement was taken at 11:50 AM and the value at that time was 211 mg/dL (11.7 mmol/L).



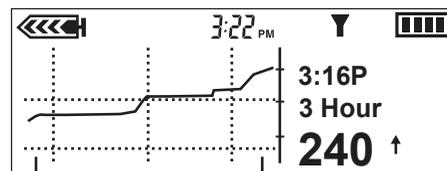
How to check for rapid changes in sensor glucose

If your sensor glucose (SG) rises or falls faster than a certain rate, rapid change arrows automatically appear in the graphs next to the SG measurement, as shown in the following section.

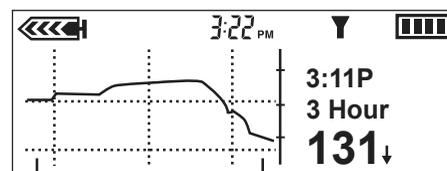
The rapid change arrows

These examples show how the rapid change arrows tell you when your SG rises or falls faster than a certain per-minute rate. The arrow direction shows if your SG measurements are rising or falling. The number of arrows (one or two) shows how rapidly your SG is changing.

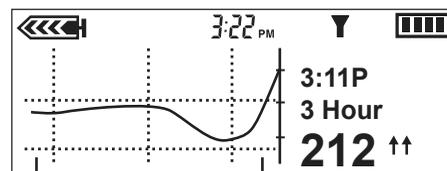
- One up arrow \uparrow shows that your SG has been rising at a rate of 1 to 2 mg/dL (0.05 to 0.11 mmol/L) per minute.



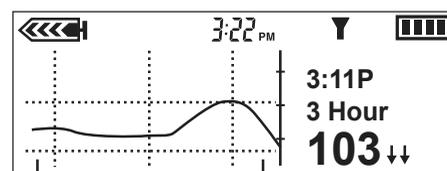
- One down arrow \downarrow shows that your SG has been falling at a rate of 1 to 2 mg/dL (0.05 to 0.11 mmol/L) per minute.



- Two up arrows $\uparrow\uparrow$ show that your SG has been rising at a rate of 2.0 mg/dL (0.11 mmol/L) or more per minute.



- Two down arrows $\downarrow\downarrow$ show that your SG has been falling at a rate of 2.0 mg/dL (0.11 mmol/L) or more per minute.



How to make glucose alerts silent

The Alert Silence feature allows you to silence glucose alerts for a preset amount of time. You may use this feature when you are in a business meeting, watching a movie in a theater, and so on. The system records the time and glucose measurement for each alert during this silent period. You can see this alert information in the SENSOR ALERT HISTORY screen. See the *Sensor alert history* section in this chapter for details.

When one or more glucose alerts occur during the time when the Alert Silence feature is turned on, the pump displays the ALERT SILENCE screen without beeping or vibrating. If this alert is not cleared before the end of the silenced period, the pump beeps or vibrates periodically at the end of the preset time until the alert is cleared. Press **ESC**, then **ACT** to clear the alert.

You can make the glucose alerts silent in the following ways:

- **Off** – This means the Alert Silence feature is **Off** and the alerts are **On**. The pump beeps or vibrates when any sensor glucose alert occurs.
- **Hi Alerts** – The pump does not beep or vibrate if a high or rising sensor related alert occurs during the specified time.
- **Lo Alerts** – The pump does not beep or vibrate if a low or falling sensor related alert occurs during the specified time.
- **Hi and Lo Alerts** – The pump does not beep or vibrate if a high or low, rising or falling sensor related alert occurs during the specified time.
- **All Sensor Alerts** – The pump does not beep or vibrate if any sensor glucose alert occurs during the specified time, including the Hi and Lo glucose alerts, Cal Reminder, and Meter BG Now alerts.

The amount of time that you can make glucose alerts silent is:

- Minimum: 30 minutes
- Maximum: 24 hours

To make alerts silent:

- 1 Open the SENSOR MENU.
Main Menu > Sensor
- 2 The SENSOR MENU shows you the current status of the Alert Silence feature.

- 3 Depending on your current settings, one of the following **Alert Silence** options will appear in the **SENSOR MENU**.
 - Alert Silence: Off
 - Alert Silence: Hi
 - Alert Silence: Lo
 - Alert Silence: Hi/Lo
 - Alert Silence: All
- 4 To change the current alert silence settings, select **Alert Silence**, then press **ACT**.
- 5 Select the alert silence option you want, then press **ACT**. The **SET DURATION** screen flashes a set of dashes or the length of time that you entered the last time you set an alert to silent.
- 6 Select your alert silence length between 30 minutes (minimum) and 24 hours (maximum), then press **ACT**. The pump is in Special mode for the set silenced period. The **SENSOR MENU** shows the new alert that you selected to be silent.
- 7 Press the **ESC** button until the **MAIN MENU** appears.

Calibration history

The **CALIBRATE HISTORY** screen lists the successful sensor calibration BG values that were entered into the pump more than 15 minutes ago.

To view your Calibration History:

- 1 Go to the **CALIBRATE HISTORY** screen.
Main > Sensor > Calibration Hist.
- 2 The **CALIBRATE HISTORY** screen appears. It shows up to 28 calibration values.

Sensor alert history

The **SENSOR ALERT HISTORY** screen lists all of the sensor alerts that have occurred, displaying up to 36 alerts.

To view your Sensor Alert History:

- 1 Go to the **SENSOR ALERT HISTORY** screen.
Main > Sensor > Sensor Alert History

- 2 The SENSOR ALERT HISTORY screen appears. The most recent alert is highlighted. Select the alert you want to get more information on, then press **ACT**.
- 3 A new screen will appear with the alert details.

Using your system in water

WARNING: Do not use your pump in water or wear it during water activities. The pump is not watertight and it may become damaged if it is used in water.

You should shower, bathe and swim with the transmitter and the sensor by following the guidelines below:

- 1 Disconnect the infusion set from your site and remove the pump. The pump is not watertight.
- 2 When the transmitter and sensor are connected, they form a watertight seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them.
- 3 Once out of the water, put the pump back on and reconnect the infusion set.
- 4 Check your infusion set tape and the sensor tape to make sure that they are not damaged.

Utilities

Alarm review

You can review alarms and their details in the ALARM HISTORY screen. This screen shows up to 36 past alarms, errors, or LOW RESERVOIR and LOW BATTERY alerts.

- 1 Go to the ALARM HISTORY screen.
Main > Utilities > Alarm > Alarm History
- 2 Scroll through your past alarms.
- 3 In the ALARM HISTORY screen, select the alarm you want to review and press **ACT**. The details for that alarm will appear on the screen.
- 4 Press **ESC** to return to the ALARM HISTORY screen. Select another alarm to review, or exit the menus if you are done.

Setting your alert type

You can select the type of alert your pump uses (for alarms, special conditions and programming). You can select a vibrate (silent) alert, or an audible beep alert. There are three beep types: long, medium and short tones. The factory setting for this feature is beep-medium.

The vibrate alert type is disabled if you use the block feature, and vibrate must be set again once block is turned off. Vibrate uses more battery power than the beep alert type and may shorten battery life. If your alert type is set to vibrate and you get a LOW BATTERY alert, your pump will use the beep alert type instead to conserve battery power.

- 1 Go to the ALERT TYPE screen.
Main > Utilities > Alarm > Alert Type
- 2 Select your alert type and press **ACT**. That alert type is now active. Exit the menus.

Auto-off

The factory setting for this feature is **Off**. This is a safety feature that stops insulin delivery after a defined time period (from 1 to 24 hours). If the pump detects that no buttons have been pressed for the selected amount of time in Auto-off, insulin delivery will stop and an alarm will sound. You may choose to program this feature into your pump based on the number of hours that you usually sleep at night. Discuss what uses and settings are best for you with your healthcare professional.

- 1 Go to the AUTO OFF DURATION screen.
Main > Utilities > Alarm > Auto Off
- 2 Set the number of hours you want to set and press **ACT**.
If you do not want to use the Auto Off feature, make sure the hour is set to zero (0).
- 3 The screen will return to the ALARM MENU. The Auto Off feature is now set. Exit the menus.

LOW RESV WARNING (Low reservoir warning)

Allows you to program the pump to sound an alert before your reservoir is empty. This warning functions the same for both the 176-unit and the 300-unit reservoirs. You can select one of these warning types:

- a specified number of units that remain in the reservoir
- a specified maximum amount of time that remains before the reservoir will be empty

The factory setting for this feature is 20 insulin units.

If you use **Time** as the low reservoir warning type and you deliver large boluses, the actual time remaining could be less than the warning time. The warning time is based on the basal insulin delivery rate. The **Time** low reservoir warning type is intended to let you know if you will have enough insulin while you are sleeping.

- 1 Go to the RESV WARNING TYPE screen.
Main > Utilities > Alarm > Low Resv Warning
- 2 Select **Insulin Units** or **Time** and press **ACT**.

WARNING: When the pump detects a low reservoir condition during a bolus or Fill Cannula delivery, the LOW RESERVOIR alert displays after the delivery is finished. Check the volume of your reservoir to make sure your pump does not run out of insulin, as this could lead to an under delivery of insulin.

a. For Insulin units:

In the WARNING UNITS screen enter the number of units you want remaining for the first warning, then press **ACT**.

The pump displays a LOW RESERVOIR alert first when the specified units remain, then again when half that remaining amount is used.

b. For Time:

In the WARNING TIME screen enter the amount of remaining time you want the first warning, then press **ACT**.

The pump displays a LOW RESERVOIR alert first when the specified time remains, then again up to one hour before empty or depending on programmed insulin delivery.

Review daily insulin totals

The DAILY TOTALS screen provides a day-by-day history of the total amount of insulin for the last 32 days, including today. This screen includes all bolus and basal amounts delivered midnight-to-midnight for each of the last 32 days. The Today line in the DAILY TOTALS screen shows the amount of insulin you delivered so far that day.

The insulin used to fill the tubing or the cannula is not included in the DAILY TOTALS screen. This amount is counted separately and shown in the HISTORY screen of the RESERVOIR + SET MENU.

Question: Why should I review my daily totals?

Answer: Comparing your daily insulin deliveries to your blood glucose records helps you and your healthcare professional identify your optimal daily insulin rate(s).

Question: What is included in the daily totals?

Answer: Daily totals include all basal and bolus insulin deliveries, sensor glucose, meter blood glucose, and AUC information for that day.

Pump data management

The pump data management feature allows you and your healthcare professional to view and manage your basal and bolus insulin delivery, food intake, BG data, SG data, and AUC data with averages. You can view the details of each day individually or you can average the data over a specified number of days (up to 32 days).

- **Daily totals** – The system automatically tracks certain types of information for you on a day-to-day basis. The daily totals are the totals for a single day.
- **Averages** – The system automatically calculates averages of certain types of information for you. There are two basic types of averages:
 - An average over a number of days (you select the number of days)
 - An average for a single day

The insulin delivery, food intake, sensor glucose information, meter blood glucose information, and AUC data includes daily totals and averages, as described in the following sections.

Insulin delivery information

This table lists the different types of insulin delivery and food intake information that the system automatically records. This information is calculated by using all of the basal, bolus, and food data for that day.

An asterisk (*) next to a date means that the data for that day will not be used for the calculations that are displayed in the Daily Average option. Anything, such as a time or date change, that shortens a day at least one hour and twelve minutes (01:12) will cause the asterisk to be displayed.

Item	Description
Carbs	The total number of carbohydrates entered using the Bolus Wizard and Capture Event (Meal marker) features.
Tot Insulin	The total amount of insulin delivered with the pump.
Basal (first line)	The total amount of insulin delivered as basal .
Basal (second line)	The percent of insulin delivered as basal .
Bolus (first line)	The total amount of insulin delivered as bolus .
Bolus (second line)	The percent of insulin delivered as bolus .

Item	Description
Food Only	The total amount of insulin delivered using the Bolus Wizard feature with food amount only .
#Food Only	The number of times the Bolus Wizard feature delivered a food bolus only .
Corr Only	The total amount of insulin delivered using the Bolus Wizard feature with BG correction amount only .
#Corr Only	The number of times the Bolus Wizard feature delivered a BG correction bolus only .
Food+Corr	The total amount of insulin delivered using the Bolus Wizard feature with food and BG correction amount .
#Food+Corr	The number of times the Bolus Wizard feature delivered a food and BG correction bolus .
Manual	The total amount of insulin delivered manually .
#Manual	The number of manual insulin deliveries .

Sensor glucose information

This table lists the different types of sensor glucose information that the system automatically records. The sensor glucose information is calculated by using all of the sensor glucose measurements that were received by the pump during the day.

Item	Description
SG Average	The average sensor glucose measurement.
Above Hi Limit	The percentage of sensor glucose measurements that were above your High Glucose Limit.
Within Limits	The percentage of sensor glucose measurements that were between your Low Glucose Limit and your High Glucose Limit.
Below Low Limit	The percentage of sensor glucose measurements that were below your Low Glucose Limit.
SG Std. Dev.	The standard deviation of the sensor glucose measurements.
#Hi Alert	The number of High Glucose alerts.
#Lo Alert	The number of Low Glucose alerts.

Item	Description
#Predict Hi	The number of High Predictive Glucose alerts.
#Predict Lo	The number of Low Predictive Glucose alerts.
#Rise Rate	The number of Rise Rate alerts.
#Fall Rate	The number of Fall Rate alerts.
Number SGs	The number of SG measurements received from the transmitter.

Meter blood glucose information

The table below lists the different types of meter blood glucose information that the system automatically records. The meter blood glucose information is calculated by using all of the automatic and manual meter blood glucose measurements that were received by the pump for the day, or number of days. This includes measurements that were manually entered into the pump during that time.

Item	Description
BG Average	The average meter blood glucose measurement.
Number BGs	The total number of meter blood glucose measurements taken.
Meter L/H	The lowest and highest blood glucose measurements sent by the meter (L is the lowest, and H is the highest). These can be used for calibration or non-calibration purposes.
Manual L/H	The lowest and highest manually entered blood glucose measurements (L is the lowest, and H is the highest). These can be used for calibration or non-calibration purposes.

To view data for a single day:

- Go to the DAILY TOTALS screen.
Main > Utilities > Daily Totals
- Select the day that you want to view.
 - To view totals for today, select **Today**.
 - To view totals for a previous day, select the date.
- Press ACT. The DELIVERY STATS screen shows the basal, bolus, and food intake information for the day you selected in step 2. This day is shown on the title line of the screen.
- Press  to view more information. See the table in the *Insulin delivery information* section in this chapter for descriptions of information shown here.

- 5 To view sensor glucose information for the same day you have selected in step 2, press **ACT** from the DELIVERY STATS screen. The SENSOR STATS screen appears, showing the sensor glucose information for the day you selected. The day you selected is shown on the title line of the screen.
- 6 Press  to view more information. See the table in the *Sensor glucose information* section in this chapter for descriptions of the sensor glucose information.
- 7 To view meter blood glucose measurement information for the same day you have selected in step 2, press **ACT** from the SENSOR STATS screen. The METER STATS screen appears, showing the meter blood glucose information for the day you selected. The day you selected is shown on the title line of the screen.
- 8 Press  to view all of the information in the METER STATS screen. See the table in this section for descriptions of the meter blood glucose information shown here.
- 9 Press **ACT** to toggle between the different STATS screens. Press **ESC** from any STATS screen to go to the DAILY TOTALS screen.
Continue viewing daily totals by following the steps above, or press **ESC** until the HOME screen appears.

The following procedure shows you how to view insulin delivery, food intake, sensor glucose and meter blood glucose data for a selected number of days.

To view data over a number of days:

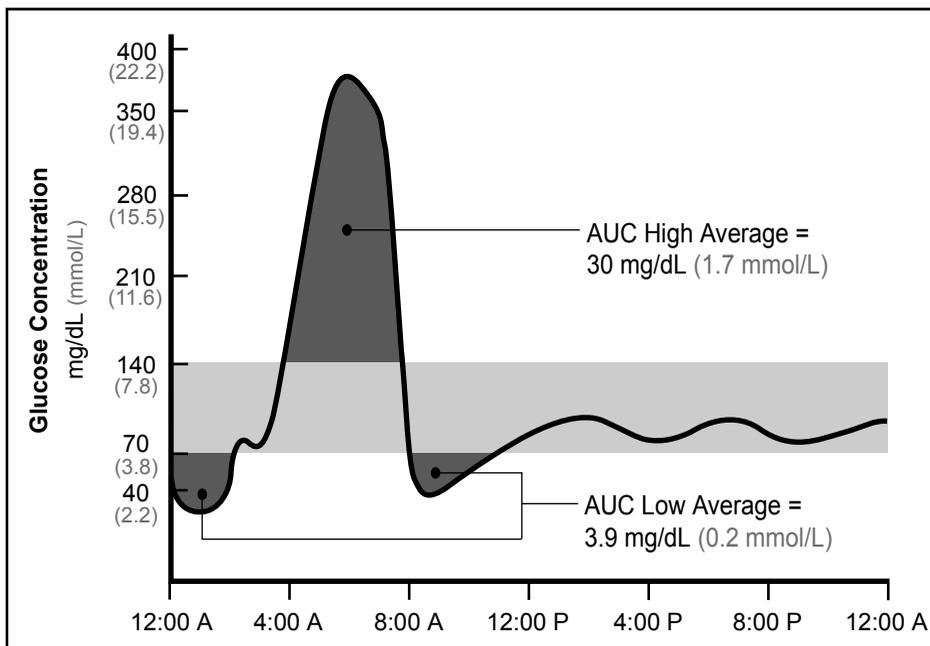
- 1 Go to the DAILY TOTALS screen.
Main > Utilities > Daily Totals
The DAILY TOTALS screen shows **Daily Average** selected.
- 2 Press **ACT**. The DAYS TO AVERAGE screen flashes the number of days you selected the last time you used this feature.
- 3 Select the number of days that you want to average. For example, if you want to see the averages for the last seven days, select 7.
- 4 Press **ACT**. A message tells you that the pump is calculating the averages.
The DELIVERY STATS screen shows the insulin delivery and food intake information for the number of days you selected. The number of days is shown on the title line of the screen.
- 5 Press  to view more information. See the table in the *Insulin delivery information* section in this chapter for descriptions of the information shown here.
- 6 To view sensor glucose information for the same days you selected in step 3, press **ACT**. The SENSOR STATS screen appears, showing the sensor glucose information.

- 7 Press  to view more information. See the table in the *Sensor glucose information* section in this chapter for descriptions of the information shown here.
- 8 To view meter blood glucose measurement information for the same days you selected in step 3, press **ACT**. The **METER STATS** screen shows the meter blood glucose information.
- 9 Press  to view more information. See the table in the *Meter blood glucose information* section in this chapter for descriptions of the information shown here.

AUC calculation

The AUC (Area Under the Curve) feature measures how much and how long your sensor glucose measurements are outside the user-defined AUC Limits. Check with your healthcare professional to determine the AUC settings that are best for you. The AUC Limits are different than the Glucose Limits. The AUC Limits are used to analyze the sensor glucose measurement data that is stored in your system. The closer the AUC values are to zero, the closer your SG values are to your AUC Limits. If your AUC values are zero, then your SG values are within your AUC Limits.

In the following example the AUC Limits are defined as 70 to 140 mg/dL (3.9 to 7.8 mmol/L), and are represented by the light shaded area. The actual AUC is the dark shaded area, between the sensor glucose curves and the defined limits. On average, the SG exceeded the AUC high limit by 30 mg/dL (1.7 mmol/L), and the AUC low limit by 3.9 mg/dL (0.2 mmol/L).



The default AUC Limits are:

- Low AUC Limit: 70 mg/dL (3.9 mmol/L)
- High AUC Limit: 180 mg/dL (10.0 mmol/L)

To set the AUC Limits:

- 1 Go to the AUC MENU.
Main > Utilities > Daily Totals > Calculate AUC
- 2 Select **AUC Limit**, then press **ACT**. The **SET AUC LIMITS** screen appears. The default **LOW AUC Limit** flashes 70 mg/dL (3.9 mmol/L).
- 3 Select your Low AUC Limit. The number must be between 40 and 400 mg/dL (2.2 and 22.2 mmol/L).
- 4 Press **ACT**. The default **High AUC Limit** flashes 180 mg/dL (10.0 mmol/L).
- 5 Select your High AUC Limit. The number must be between 40 and 400 mg/dL (2.2 and 22.2 mmol/L). It can be equal to, but not lower than, the AUC Low Limit.

6 Press **ACT**. The AUC MENU screen shows the AUC Limit you selected.

To view AUC data for a single day:

1 Go to the AUC MENU.

Main > Utilities > Daily Totals > Calculate AUC

2 Select the day that you want to view.

- To view totals for today, select **Today**.
- To view totals for a previous day, select the date.

3 Press **ACT**. AUC High and AUC Low values appear for the selected day.

- **AUC High** is the average of AUC for sensor glucose values above the AUC High Limit for that day.
- **AUC Low** is the average of AUC for sensor glucose values below the AUC Low Limit for that day.

To view AUC data over a number of days:

1 Go to the AUC MENU.

Main > Utilities > Daily Totals > Calculate AUC

2 Select **AUC #Days**, then press **ACT**.

3 The **DAYS TO AVERAGE** flashes the number of days to average. Select the number of days you want. For example, if you want to see the averages for the last seven days, select 7.

4 Press **ACT**. A message tells you that the pump is calculating averages.

5 The Day Average screen shows the data for the number of days you selected. The number of days is shown on the screen. For example, if you have selected seven days, the screen title will be **7Day Average**. AUC High and AUC Low appear below the title.

- **AUC High** is the average value of AUC for sensor glucose values above the AUC High Limit for the number of days selected.
- **AUC Low** is the average value of AUC for sensor glucose values below the AUC Low Limit for the number of days selected.

Personal reminders

Alarm clock

The alarm clock is a feature that allows you to set a maximum of eight daily reminders for various events. 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. However, do not rely on the alarm clock feature as the only reminder for monitoring your diabetes. When the alarm clock goes off, the ALARM CLOCK screen appears. Press **ESC**, then **ACT** to clear the reminder.

- 1 Go to the ALARM OPTION screen.
Main > Utilities > Alarm Clock
- 2 Select **On/Set**. Press **ACT**.
- 3 Select **Add Alarm**. Press **ACT**.
- 4 Enter the hour (flashing). Press **ACT**.
- 5 Enter the minutes (flashing). Press **ACT**.
- 6 Repeat steps 3 through 5 to program additional alarm times. Exit the menus when you are done.

PC connect for change settings

PC Connect for Change Settings option allows you to connect your pump to your computer, permitting a change of settings, by way of RF (radio frequency). At this time, PC software to modify pump programmed settings is not available and therefore the Change Settings option is not functional. If you should accidentally navigate to the **Change Settings** option as shown below, press **ESC** to cancel.

Main > Utilities > Connect Devices > PC Connect

Remote control option

The factory setting for this feature is off. You may want to explore the remote option after you have become completely familiar with the basic functions of your pump. It is important that you consult with your healthcare professional before using this feature. Remote controls can be purchased from Medtronic Diabetes.

Refer to the remote control user guide for operating instructions.

NOTE: *The use of RF (radio frequency) devices with the pump reduces battery life.*

To use the remote control, these pump settings must be programmed:

- Remote Options = On
- Remote control ID code entered in pump (code is on back of remote)
- Easy Bolus = On

Turn on remote control option

WARNING: If there is a LOW BATTERY condition, the pump will not receive signals from the remote. To ensure the pump communicates with the remote control, make sure the pump does not have a low battery. (Replacing the low battery with a new battery will restore remote control function.)

- 1 Go to the REMOTE OPTION screen.
Main > Utilities > Connect Devices > Remotes
- 2 Select **On**, then press **ACT**.
- 3 The REMOTE ID MENU screen appears. Add, delete or review your remote ID as described in the next section. Exit the menus if you are done.

Add, delete, review remote control IDs

Each remote control has its own unique ID. Up to three different remote control IDs can be programmed in your pump. You must turn on the remote option to add, delete or review the remote control IDs programmed in your pump.

- 1 **Adding a remote ID**
 - a. Select **Add ID** from the REMOTE ID MENU screen, then press **ACT**.
 - b. Enter each of the six ID numbers found on the back of the remote control. Press **ACT** after each entry. After you set the last number of the ID, the screen will return to the REMOTE ID MENU.
- 2 **Deleting a remote ID**
 - a. Select **Delete ID** from the REMOTE ID MENU screen, then press **ACT**.
 - b. Select the remote ID that you want to delete, then press **ACT**. The selected ID is now deleted.
- 3 **Reviewing remote IDs**
 - a. Select **Review ID** from the REMOTE ID MENU screen, then press **ACT**.
 - b. The programmed IDs will show in the REVIEW REMOTE ID screen.
- 4 Exit the menus when you are done.

Other Devices option

The factory setting for this feature is **Off**.

Other devices may be available to be linked to your pump. If available, refer to the appropriate device user guide for programming and operating instructions.

NOTE: *The use of RF (radio frequency) devices with the pump reduces battery life.*

WARNING: Do not use accessories that have not been approved for use with the MiniMed Paradigm® REAL-Time Revel™ insulin pump. Use of unapproved devices can have software incompatibility and can result in inaccurate data transfer that may result in harm. Bayer's CONTOUR® NEXT LINK Wireless Meter and the remote control are the only devices that have been approved for use with this system.

Block feature

Block restricts access to pump programming. The factory setting for this feature is off. Block is an important safety feature if the pump user requires someone else to maintain complete control of pump operation. When block is on, the remote control is used to deliver a bolus and suspend/resume the pump. Direct pump programming is limited to suspend, block, and selftest. You can, however, still view status-type screens such as STATUS, BOLUS HISTORY, BASAL REVIEW, and DAILY TOTALS. Discuss what uses and settings are best for you with your healthcare professional. (You can order the remote control from Medtronic Diabetes.)

Turning block on

NOTE: *The vibrate alert-type is disabled when block is on.*

- 1 Go to the BLOCK OPTION screen.
Main > Utilities > Block
- 2 Select **On**, then press **ACT**. The HOME screen will appear with an open circle. The Block option is now on and the pump is in Special mode.

Turning block off

NOTE: The vibrate alert-type is enabled when block is off.

1 Go to the BLOCK OPTION screen.

Main > Utilities > Block

2 Select **Off**, then press **ACT**. The HOME screen will appear without a circle. The Block option is now off and the pump is in Normal mode.

Example: Block

Oscar is an elderly man with diabetes who needs assistance with all of his daily living activities. He needs his caregiver or family member to help him with his pump as well. To be sure that Oscar does not change any pump settings, his family programmed his Paradigm pump with the Block feature turned on. They use the Remote Control to give him his boluses when he needs them.

Caution: This elderly patient can still manually suspend the pump which may result in high blood glucose and ketoacidosis.

Lock keypad feature

Lock keypad prevents accidental pump keypad presses. You can only press the  to view the STATUS screen, and the  button to turn on the backlight. The remote control can be used to give a bolus or put the pump into Suspend.

A locked keypad is automatically unlocked during the following:

- Battery insertion
- Alarms
- Alerts

Locking the keypad

1 Go to the UTILITIES MENU.

2 Select **Lock Keypad**, then press **ACT**.

3 Press **ACT** again to lock the keypad. The KEYPAD LOCKED screen appears with instructions on how to unlock the keypad.

Unlocking the keypad

Press the  button and the  button at the same time. Keypad Unlocked screen appears.

Selftest

Selftest is a safety utility that allows you to check if your pump is operating properly. This self-diagnostic feature can be used for maintenance or to check your pump if it operates unusually. During selftest, your pump will automatically run internal tests, including a check for proper operation of the beep and vibrate modes. The selftest is additional to the routine tests that run independently while the pump operates.

Contact our 24 Hour HelpLine if any of the tests do not occur as described here.

NOTE: *If the pump detects a condition such as low battery, the selftest will not finish. A message will appear to show the condition that caused the test to stop.*

- 1 Go to the UTILITIES MENU.
Main > Utilities > Selftest
- 2 Select **Selftest**, then press **ACT**.
- 3 Periodically, you will hear beeps as different mechanisms in the pump are being tested. As part of the selftest, the pump will do these tests:
 - a. **Screen Test:**
The screen will appear all black.
 - b. **Selftest:**
The pump will count down from 10.
 - c. **Tone Test:**
You should hear beeps.
 - d. **Vibrate Test:**
You will feel vibrations.
- 4 After the selftest is finished, **TEST COMPLETE** screen appears. The screen will return to the UTILITIES MENU, then to the HOME screen.

User settings

The user settings function allows you to save, restore, and clear all pump settings. You can also view a listing of the dates and times of all recent user settings operations you have done. The Save Settings feature lets you keep a set of pump settings that you can restore to your pump if it is cleared or you need to go back to these settings for any reason.

When you clear your pump, the pump settings are restored to the factory defaults, and you must either use Restore Settings, if you have saved a set of pump settings, or reprogram all your settings before you can use your pump again. The pump does not clear the internal pump memory.

WARNING: Do not clear your pump settings while it is connected to your body.

CAUTION: Do not clear your pump settings unless directed by your healthcare professional. If you clear your pump settings, it will be necessary to reprogram all your personal pump settings as directed by your healthcare professional. Additionally, you will have to rewind your pump.

Saving the settings

Do these steps to save your current pump settings:

- 1 Go to the UTILITIES MENU screen and select **User Settings**.
Main > Utilities > User Settings
- 2 Hold down **ⓑ** and press **ACT**.
- 3 The USER SETTINGS screen is displayed with **Save Settings** highlighted. Press **ACT**.
- 4 If this is the first time you have saved pump settings, go to step 5. If you have previously saved pump settings, a message displays, indicating the date of your last pump settings save. Read the instructions on the screen, then press **ACT** to save your current settings. You can press **ESC** if you want to cancel the save.
- 5 The SETTINGS SAVED message displays to confirm that your current pump settings have been saved. Exit the menus.

Restoring the settings

Do these steps to restore the most recent pump settings you have saved to your pump:

- 1 Go to the UTILITIES MENU screen and select **User Settings**.

Main > Utilities > User Settings

- 2 Hold down **↻B** and press **ACT**.
- 3 The **USER SETTINGS** screen is displayed. Select **Restore Settings**, then press **ACT**.
- 4 A message displays, giving you the option of restoring the pump settings that were saved on the given date and erasing the ones currently on your pump. Read the instructions on the screen then press **ACT** to restore the settings. You can press **ESC** if you want to cancel the restore.
- 5 The **SETTINGS RESTORED** message displays to confirm that your current pump settings have been replaced with the pump settings you had saved on the given date. Exit the menus and check your pump settings to verify the restore.

Clearing the settings

Take the following steps only if you want to clear your pump to factory default settings.

WARNING: Do not clear your pump settings while it is connected to your body.

CAUTION: Do not clear your pump settings unless directed by your healthcare professional. If you clear your pump settings, it will be necessary to reprogram all your personal pump settings as directed by your healthcare professional. Additionally, you will have to rewind your pump.

- 1 Go to the **UTILITIES MENU** screen and select **User Settings**.

Main > Utilities > User Settings

- 2 Hold down **↻B** and press **ACT**.
- 3 The **USER SETTINGS** screen is displayed. Select **Clear Settings**, then press **ACT**.
- 4 A **CONFIRM** message displays, giving you the option of clearing your pump settings or not. Select **YES** and press **ACT** to clear the settings. You can press **ESC** if you want to cancel.
- 5 You will see a **RESET** alarm, and then the pump will go through various screens while it restarts. After the pump clears all of your settings, the screen will go to the **TIME/DATE SETUP** screen.
- 6 Reset the time and date as described in *Setting the time and date* section in the *Basic programming* chapter.
- 7 After you set the time and date, you must rewind your pump. Refer to the *Rewinding your pump* section in the *Starting on insulin* chapter for instructions. Remember, all your settings have been cleared and you must either restore or reprogram all your settings.

History

If you want to view a listing of the dates and times of all recent User Settings operations you have done on your pump, such as saves and restores, take the following steps:

- 1 Go to the UTILITIES MENU screen and select **User Settings**.
Main > Utilities > User Settings
- 2 Hold down **↻B** and press **ACT**.
- 3 The USER SETTINGS screen is displayed. Select **History**, then press **ACT**.
- 4 The SETTINGS HISTORY screen displays, giving you a list of all the dates and times of your most recent User Setting operations. Scroll down to view the entire history. When you are done looking at the history, press **ESC** to exit the menu.

Meter option

About meters

You can set up your pump to automatically receive your blood glucose readings from Bayer's CONTOUR® NEXT LINK Wireless Meter. Your pump is set at the factory with the meter option turned off. See the *Add, delete, review meter IDs* section in this chapter to turn the meter option on, and to enter your meter ID. Programming your meter ID links your pump to the meter. Each meter has its own unique ID. You can link up to three meters to your pump. If you do not link the meter to your pump, you must enter your blood glucose readings manually.



When the pump is idle (at the HOME screen), it will beep or vibrate when it receives a blood glucose reading from the meter. The reading will appear on the pump screen. If your BG reading is not within your set BG Target range, the pump beeps three times. For BG readings that are above the set BG Target range, use the Bolus Wizard feature to enter a correction bolus.

NOTE: *The use of RF (radio frequency) devices with the pump reduces pump battery life.*

You have to turn on the meter option to add, delete or review the meter ID(s) programmed in your pump. The meter ID is printed on the back of the meter. See the user guide that came with your meter for detailed information on how to use it.

Meter rules

If you want your pump to communicate with the meter, the following conditions must apply:

- 1 The meter option must be turned on and programmed. Refer to the instructions in this section.
- 2 Your pump must be within 4 feet (1.2 meters) of your meter to receive the blood glucose reading.
- 3 The pump cannot have a LOW BATTERY alert condition.

- 4 When programming a bolus, the blood glucose measurement from the meter will appear as the default blood glucose value on the ENTER BG screen. The pump will not display a reading that is older than 12 minutes on the ENTER BG screen.
- 5 Do not use the RF meter to send your blood glucose readings to the pump while onboard aircraft. Manually enter your blood glucose.

CAUTION: The pump will not receive signals from the meter while it has a LOW BATTERY condition. To ensure the meter communicates with the pump, make sure the pump does not have a low battery. (Replacing the low battery with a new battery will restore meter-pump communication.)

Add, delete, review meter IDs

The meter programming screens are very similar to those for the remote control. Make sure to select **Meters** in the DEVICE OPTIONS screen when programming your meter.

You have to turn on the meter option to add, delete, or review the meter ID(s) programmed in your pump.

To turn on the meter option:

- 1 Go to the METER OPTION screen.
Main > Utilities > Connect Devices > Meters
- 2 Select **On**, then press **ACT**. The METER ID MENU appears.
- 3 Add, delete or review your meter ID(s) as desired.
Adding meter IDs
 - a. Select **Add ID**, then press **ACT**.
 - b. Use the up and down arrow buttons to enter each of the six ID characters. Press **ACT** after each entry.
 - c. After you set the last character of the ID, the screen will return to the METER ID MENU.Deleting meter IDs
 - a. Select **Delete ID**, then press **ACT**.
 - b. Select the meter ID that you want to delete and press **ACT**.
 - c. The selected ID is now deleted.Reviewing meter IDs

If you are not sure that your meter ID is entered in your pump, check the REVIEW METER ID screen.

 - a. Select **Review ID**, then press **ACT**.
 - b. The programmed IDs will show in the REVIEW METER ID screen.
- 4 Exit the menus when you are done.

Therapy management software

Medtronic provides software to optimize your pump use. Contact our 24 Hour HelpLine for more information.

CareLink® Personal Software

Your pump provides real-time glucose values so that you can track glucose concentration patterns and possibly identify episodes of low and high blood glucose. It also stores glucose data so that it can be analyzed to track patterns or downloaded to CareLink Personal for analysis of historical glucose values.

CareLink Personal is a Web-based system designed to help you manage your diabetes. It has many key features:

- It copies (uploads) data from your devices: insulin pump and supported blood glucose meters.
- Device data is stored on a centralized database.
- There is an online logbook where you can record self-reported information, such as how many carbohydrates you consumed.
- Uploaded data and other information stored on the system can be viewed through several different types of treatment reports.
- Access to data and personal information on this system is secure.

Reports

Reports show you data gathered from your device uploads, and from what you directly entered into the system. Examples of the report data you can get include:

- Pump operation, such as alarm settings and maximum allowed bolus amount.
- Insulin delivery rates, types and times.
- Blood glucose reading levels and times.
- Sensor glucose reading levels and times.
- Bolus Wizard or online logbook entry data.

Reports are displayed in PDF format. They can be viewed online, saved, or printed.

You can share your reports with your healthcare professional. These reports can help you and your healthcare professional to discover trends and other information. This can lead to improved therapy management for greater control.

Logbook

The logbook allows you to enter the following self-reported information:

- Carbohydrates consumed
- Exercise activity
- Urine ketone results
- HbA1c results
- Infusion set changes

The data from your logbook is used in the reports you create. You can see how, for example, your carbohydrate intake compares to blood glucose levels for the same day or time. You can also use it as an online diary of your diabetes management.

Insulin pump therapy follow-up

We hope that you are now comfortable using the pump and your blood glucose values have improved through insulin pump therapy. Diabetes management requires much more than blood glucose control. You need to take care of your complete physical and mental health. This includes seeking treatment for any condition both directly related to and not related to diabetes. The following recommendations apply to general diabetes as well as insulin pump therapy follow-up. Remember, your healthcare professional is your best resource for successful diabetes management.

Recommended follow-up

Everyday

- Check blood glucose four to six times a day and always before bed.
- Test before driving and have a fast-acting carbohydrate with you when you drive.
- If your blood glucose is above 250 mg/dL (13.9 mmol/L) twice in a row, take an injection and change the infusion set.

Every month

- Review DKA prevention guidelines.
- Check 3:00 AM blood glucose at least once during the month.
- Check two-hour post-meal blood glucose for all meals on a given day.

Every three months

- Visit your healthcare professional, even if you feel well and your blood glucose values are within target range.
- Review your blood glucose log and insulin pump settings with your healthcare professional.
- Make sure you have an HbA1c test done.

Laboratory tests

- Test for HbA1c every three months
- Test for cholesterol, HDL, LDL, triglyceride yearly
- Test for microalbuminuria yearly

Every visit

- Blood pressure check
- Foot exam
- Review goals for blood glucose, meal plan and exercise

Annually

- Dilated eye exam by a qualified eye care professional
- Annual flu shot
- Regular dental visits
- Nerve function tests
- EKG test over age 35
- Prostate exam for men, breast exam for women
- Diabetes education review
- Replace Glucagon Emergency Kit (new prescription from your healthcare professional)

Alarms and alerts

This chapter is designed to help you understand the messages that your pump is giving you when you get an alarm or an alert message. For help on common conditions that might occur with your pump, see the *Troubleshooting* chapter.

About alarms and alerts

Your pump has a sophisticated network of safety checks and systems. If the safety network detects anything unusual, your pump notifies you of conditions that require your immediate attention. The backlight illuminates the pump screen and the alarm or alert message displays on the screen.

It is important that you understand how your pump behaves when you do not clear an alarm or an alert:

- Alarm – If you do not clear an alarm, insulin delivery remains suspended, and the pump does not display any subsequent alarms or alerts until the first alarm is cleared. After you clear the first alarm, the pump displays any subsequent alarms, followed by any alerts in order of their importance.
- Alert – If you do not clear an alert, the pump does not display any subsequent alerts until the first alert is cleared. However, the pump displays an alarm even if you do not clear the alert. After you clear the first alert or alarm, the pump displays any subsequent alarms or alerts in order of their importance.

Check your pump and test your blood sugar. Follow the guidelines prescribed by your healthcare professional to manage your diabetes as needed.

NOTE: *The STATUS screen shows any alarms and alerts that are active.*

Example:

John's pump displays a BUTTON ERROR alarm, but he does not clear it. During the time that his pump displays the BUTTON ERROR alarm, his pump receives a LOW RESERVOIR alert. A few minutes later, his pump receives a NO DELIVERY alarm. John's pump does not display the LOW RESERVOIR alert or the NO DELIVERY alarm until he clears the first alarm. After John clears the BUTTON ERROR alarm, his pump displays the NO DELIVERY alarm. After he clears the NO DELIVERY alarm, his pump displays the LOW RESERVOIR alert.

Alarms

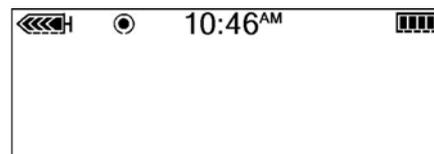
An alarm warns you that the pump detected something that prevents insulin from being delivered. An alarm means that insulin delivery stopped, the pump has been placed in Attention mode, and a solid circle displays on the pump screen. It is important that you respond to an alarm.

WARNING: Do not ignore your pump when it is in Attention  mode because all insulin delivery is stopped, which may lead to high blood glucose and ketoacidosis.

Question: Why are alarms important?

Answer: Your pump monitors activities and notifies you if there is an unusual pump status or your attention is required. When an alarm is active, INSULIN DELIVERY IS STOPPED and immediate operator interaction is required.

If the vibrate mode is on, all alarms and alerts start as vibrations and then change to beeps. For your safety, if there is no response after 10 minutes, the beeps change to a siren. The siren continues every minute until the alarm is cleared.



When a solid circle appears, follow the instructions on the screen

What to do

When an alarm is triggered, the pump goes into Attention mode and an alarm message shows on the screen. The pump then defaults to the HOME screen. Do these steps when you get an alarm:

- 1 **View the alarm.** From the HOME screen, press any button to see the alarm message.
- 2 **Read all of the alarm text.** There are instructions on how to fix the alarm condition. (Press  to read more text, if available.)

- 3 **Clear the alarm.** Press **ESC** then **ACT** after you read the alarm instructions. The HOME screen appears.
- 4 **Follow the instructions** that appeared with the alarm to fix the alarm condition.
- 5 **Check your settings.** Check your time, date, basal and other settings to make sure they are correct.

Alarm conditions

Alarms put the pump in Attention mode.



A (ALARM)

This alarm shows the letter **A** followed by two numbers. A-alarms cause all insulin delivery to stop. Your pump settings are retained. If this alarm repeats often, call our 24 Hour HelpLine for assistance.



AUTO OFF

Alerts you that no buttons were pressed during the time limit you set for the AUTO OFF DURATION feature, and so insulin delivery has been stopped.



BATT OUT LIMIT

Occurs if the battery has been out of the pump for more than five minutes. Verify that the pump time and date are correct. If not correct, go to the UTILITIES MENU and reset the date and time.



BOLUS STOPPED

If this alarm occurs, it is very important to check bolus history to review how much of the bolus was actually delivered. If necessary, reprogram a bolus with the amount not yet delivered.



BUTTON ERROR

Occurs if a button has been continually pressed for more than three minutes.

CHECK SETTINGS

When this alarm is active, you should check and/or reprogram your pump settings, including the time/date.

E (ERROR)

An E-error alarm will show the letter *E* followed by two numbers. E-alarms cause all insulin delivery to stop, the pump resets, and all your settings are cleared. After receiving this alarm, note the error number then call our 24 Hour HelpLine for assistance.

EMPTY RESERVOIR

There is no insulin in the reservoir. Change the reservoir immediately. A NO DELIVERY alarm may prevent the EMPTY RESERVOIR alarm from displaying.

FAILED BATT TEST

The pump tests the voltage of each battery installed. This test ensures a battery with low voltage is not used. If the battery does not have enough voltage, this alarm will occur. The pump will not function and the battery must be replaced. (Always make sure that you install a NEW battery into the pump.)

FINISH LOADING

You have not completed filling the infusion set with insulin. Clear the alarm. This resumes basal delivery. See the *Filling the cannula* section in the *Starting on insulin* chapter to fill the infusion set cannula with insulin. If your infusion set has a needle cannula, press **ESC** to skip this step.

MAX FILL REACHED

If you use more than 30 units of insulin to fill the infusion set tubing, this message appears. Press **ESC**, **ACT** to clear the message. See the *Filling the tubing* section in the *Starting on insulin* chapter for more information.

MAX DELIVERY

This alarm alerts you when you have taken more insulin than expected based on Maximum bolus and Maximum basal rates.

MOTOR ERROR

Insulin delivery has stopped. This alarm occurs if your pump detects a motor error.

NO DELIVERY

Insulin delivery has stopped. This alarm will occur if your pump detects a blockage or if the reservoir is empty. Refer to the Troubleshooting chapter for additional information.

NO RESERVOIR

The reservoir is not inserted correctly or no reservoir has been inserted.

OFF NO POWER

The battery is dead. Replace battery immediately. Follow the directions on the screen. Check to make sure that the time is correct on the screen. Reset the time if necessary.

RESET

The Reset alarm triggers when pump settings are cleared because of one of these reasons:

- Pump settings were cleared (Clear Settings function) and settings have not been reprogrammed.
- A download attempt from the PC is incomplete. (The download function is applicable to the optional software feature. Refer to the software user guide for more information.)



WEAK BATTERY

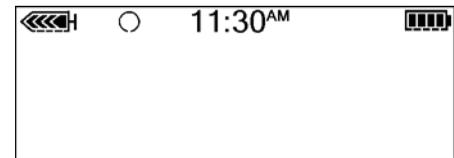
The pump tests the voltage of each battery installed. If the battery voltage is less than full strength, this alarm may occur. The pump will operate normally, but the battery life will be shorter than expected. Always make sure to install a new battery in the pump. See Inserting the battery for more information.

Alerts

An alert makes you aware of a situation that may require your attention. An alert is less serious than an alarm. When an alert condition exists, the pump is placed in Special mode and an open circle displays on the pump screen.

Question: Why are alerts important?

Answer: Your pump monitors activities and will alert you if a Special mode is active. Some alerts are a normal part of pump therapy, such as an active temporary basal. There are alerts that indicate a condition that is outside normal pump activity. For example, your pump notifies you with an alert when you need to replace the reservoir (LOW RESERVOIR) or replace your pump battery (LOW BATTERY).



What to do

When your pump beeps or vibrates notifying you that an alert condition exists:

- 1 Read and follow the instructions on the screen. Press **ESC**, then **ACT** to clear the alert message.
- 2 Check the **STATUS** screen to determine what caused the alert.
- 3 If the condition is due to a low battery, replace the battery.
- 4 If the condition is due to a low reservoir, monitor the reservoir volume frequently and change the reservoir when appropriate. Make sure you have a new reservoir, infusion set and vial of insulin with you.

Pump alert conditions

Listed below are alerts that indicate a condition that is outside normal pump activity.

LOW RESERVOIR

You can program the pump to sound an alert when either a specified number of units remains or a specified amount of time remains before the reservoir will be empty.

LOW BATTERY

If you get this alert, **do not go to sleep** without replacing the battery. The backlight, the remote, and meter functions are disabled during a LOW BATTERY condition. If the alert type is set to Vibrate, the pump will change to the audio alert Beep-medium. Clear (**ESC, ACT**) this alert before you replace your battery.

Sensor alert conditions

Listed below are the alerts that you may encounter while using the sensor feature of your pump, and how to resolve the alert condition.

WEAK SIGNAL

Reason: Occurs when the pump does not receive data from the transmitter for a pre-defined period of time (as set in Weak Signal).

Action: Press **ESC**, then **ACT** to clear the alert message. Move the pump closer to the transmitter or move the transmitter and the pump to the same side of your body.

ALERT SILENCE

Reason: This alert screen displays when one or more glucose alerts occur during the time that the Alert Silence feature is turned on.

Action: Press **ESC**, then **ACT** to clear the alert. Check the **SENSOR ALERT HISTORY** screen for the recorded glucose alert information. See the *Sensor alert history* section in the *Using your sensor* chapter for details.

MISSED BOLUS

Reason: You have not delivered a bolus during the time period you specified in the Missed Bolus Reminder feature.

Action: Set a meal bolus if needed.

LOST SENSOR

Reason: The pump has not received a signal from the transmitter. **Do not disconnect the transmitter from the sensor.**

Action:

- 1 Make sure that the sensor is inserted correctly.
- 2 Check the REVIEW SETTINGS screen to make sure that the transmitter ID entered into the pump matches the ID on your transmitter:
Main > Sensor > Review Settings
- 3 Check the transmitter and sensor connection. Touch the inserted sensor at the back of the assembly to prevent movement and push the transmitter firmly:
 - a. If you hear a click, wait 20 seconds and look for a green light on the transmitter flash for 10 seconds to confirm a good connection. If you see the green light, the alert was due to the transmitter and the sensor not being connected.
 - b. If you hear a click, but do not see a green light on the transmitter, check to make sure that the transmitter is charged.
 - c. If you do not hear a click when you check the connection, the alert was due to a transmission problem. Bring the pump closer to the sensor and transmitter.
- 4 Use the **Find Lost Sensor** function to find your sensor (see the *Troubleshooting sensor features* section):
Main > Sensor > Link to Sensor > Find Lost Sensor

LOW TRANSMTR

Reason: The transmitter battery is close to running out of power. This alert will repeat daily at noon while this condition exists. The transmitter will continue sending sensor signals for several hours and may last for several days until the battery becomes depleted. Be prepared to recharge your transmitter immediately when its battery becomes depleted.

Action: Press **ESC**, then **ACT** to clear the alert message. Recharge your transmitter as soon as possible. See your transmitter user guide for charging instructions.

CHARGE TRANSMTR

Reason: The transmitter battery is depleted.

Action: Recharge your transmitter immediately. See your transmitter user guide for charging instructions.

CHANGE SENSOR

Reason: You may receive this alert after you receive two Cal Errors in a row, without the Cal Errors, or when initializing your sensor.

Action: If the alert resulted from two Cal Errors in a row, replace the sensor. If the alert happened without two Cal Errors, use the transmitter's tester to make sure your transmitter is working properly. If you received this alert during initialization, you may be able to resolve this alert without replacing your sensor. Call our 24 Hour HelpLine for further assistance.

SENSOR END

Reason: Your pump is programmed to automatically stop the sensor after three days (72 hours).

Action: If this is the first time you have received the SENSOR END alert, do not remove the sensor. Follow instructions in *Restarting the sensor after three days, on page 125*. This will allow you to use your sensor up to its maximum life of six days (144 hours). If this is the second time you have received the SENSOR END alert, replace your sensor.

CAL ERROR

Reason: An error occurred when entering a new meter BG measurement to calibrate the system. Some possible causes are:

- An incorrect blood glucose number was entered from the meter into the pump.
- The entered blood glucose measurement was not current.
- Your blood glucose is rising or falling rapidly.
- The sensor needs more time to stabilize after being inserted.
- The sensor is no longer reading the glucose correctly.

Action: Follow the guidelines in the *Calibrating the sensor* section in the *Sensor features* chapter to enter a new meter BG for calibration. If you receive a Cal Error on your second calibration, a CHANGE SENSOR alert will occur. Call our 24 Hour HelpLine if you have questions.

METER BG NOW

Reason: A meter BG measurement is needed immediately to calibrate your sensor so that you can continue receiving sensor glucose readings.

Action: Press **ESC**, then **ACT** to clear the alert message. Take and enter a meter blood glucose measurement. Follow the guidelines in the *Calibrating the sensor* section in the *Sensor features* chapter.

METER BG BY

Reason: A meter BG measurement must be entered by the time that is shown to calibrate your sensor. The METER BG BY alert is also known as the CAL REMINDER alert.

Action: Press **ESC**, then **ACT** to clear the alert message. Enter a blood glucose measurement to avoid a METER BG NOW alert.

LOW XX MG/DL (XX = SG measurement)

Reason: The sensor glucose number is equal to or lower than your low glucose limit. If you do not set a Low Glucose Limit and do not set the glucose alerts ON, then you will not get a Low sensor glucose alert. The pump plays four consecutive tones, in falling pitch, if an audible beep has been selected as the alert type.

HIGH XXX MG/DL (XXX = SG measurement)

Reason: The sensor glucose number is higher than or equal to your high glucose limit. If you do not set a High Glucose Limit and do not set the glucose alerts ON, then you will not get a High sensor glucose alert. The pump plays four consecutive tones, in rising pitch, if an audible beep has been selected as the alert type.

LOW PREDICTED

Reason: The sensor glucose measurements may **reach or go below** your Low Glucose Limit in the length of time you selected for the Low Predictive alert. The pump plays three consecutive tones, in falling pitch, if an audible beep has been selected as the alert type.

HIGH PREDICTED

Reason: The sensor glucose measurements may **reach or go above** your High Glucose Limit in the length of time you selected for the High Predictive alert. The pump plays three consecutive tones, in rising pitch, if an audible beep has been selected as the alert type.

RISE RATE

Reason: The sensor glucose measurements are rising at a rate that is equal to or faster than the Set Rise Rate Limit you selected for the alert. The pump plays two consecutive tones, in rising pitch, if an audible beep has been selected as the alert type.

FALL RATE

Reason: The sensor glucose measurements are falling at a rate that is equal to or faster than the Set Fall Rate Limit you selected for the alert. The pump plays two consecutive tones, in falling pitch, if an audible beep has been selected as the alert type.

SENSOR ERROR

Reason: The sensor signals are either too high or too low.

Action: You do not need to change the sensor. Clear the alert. If the alert persists, test your transmitter with the tester.

Troubleshooting

This chapter contains procedures and information to help you understand and address specific conditions that might occur with your pump. For a complete list of alarms and alerts that may appear on your pump, see the Alarms and alerts chapter.

NOTE: *It is recommended that you read your warranty statement included with your pump for information on what is covered during your warranty period.*

My pump has a NO DELIVERY alarm

When a NO DELIVERY alarm occurs, it means that insulin delivery has stopped. Your pump is not broken, but it has detected that something is preventing insulin from being delivered. Do the following steps:

- 1 Check to see if your infusion set has become dislodged or kinked.
- 2 Check your blood glucose and follow your safety guidelines for treating high glucose if necessary.
- 3 Clear the alarm by pressing **ESC**, then **ACT**. A screen appears with two choices: **Resume** and **Rewind**.
- 4 Make sure that there is insulin in your reservoir.
 - a. If you identified and fixed a kink in your tubing, select **Resume**.
 - b. If the reservoir is empty, select **Rewind** and change your reservoir and infusion set.
- 5 Monitor your blood glucose closely.
- 6 If you have followed these steps and receive another NO DELIVERY alarm, call our 24 Hour HelpLine.

What happens if I leave the pump battery out too long?

If you leave the pump battery out too long (more than five minutes) you may receive a BATT OUT LIMIT alarm message when you install the new battery. Do the following steps:

- 1 Set your pump clock to the correct time, date, and year.
- 2 Check to make sure that all your settings, such as basal rate, are set as desired. If need be, reapply your last saved settings to the pump by using the **Restore Settings** option under **User Settings** in the UTILITIES MENU (you can only use this option if you have previously saved your pump settings). See the *Restoring the settings* section in the *Utilities* chapter.
- 3 Check the ALARM HISTORY screen and the STATUS screen for any alarms and/or alerts that may still need attention.

If you leave the battery out for more than three or four days, you may receive an A17 and A47 alarms when you install a new battery. Do the following steps:

- 1 Clear the A17 and A47 alarms.
- 2 Set your pump clock to the correct time, date and year.
- 3 Check to make sure that all your settings, such as basal rate, are set as desired. If need be, reapply your last saved settings to the pump by using the **Restore Settings** option under **User Settings** in the UTILITIES MENU (you can only use this option if you have previously saved your pump settings). See the *Restoring the settings* section in the *Utilities* chapter.
- 4 Check the ALARM HISTORY screen and the STATUS screen for any alarms and/or alerts.

Why doesn't my pump battery last very long?

A short battery life does not mean that something is wrong with your pump. Battery life in your pump is variable and based on the conditions below:

- The brand of battery you use (Energizer brand is recommended).
- The storage and/or handling of the battery before use (avoid high or low temperatures).
- The usage of pump in cold temperatures; this may shorten the battery life.
- The usage of your pump, such as how often the buttons are pushed, the number of alerts/alarms and set changes.
- The amount of insulin the pump is delivering.
- The usage of some features. The backlight, vibrate, sensor, remote control and meter options decrease battery life.

What is a CHECK SETTINGS alarm?

This alarm occurs after an E-alarm or after you clear your pump. It is advising you to make sure that all your settings are correct. A CHECK SETTINGS alarm occurs after any of these actions:

- All user settings were cleared (set back to their defaults) because there was an E-error alarm.
- The Clear Settings function was performed.
- After you rewind when practicing without a reservoir when you first get your pump. In this case, it is just a reminder to make sure all your settings are programmed before you begin using the pump with insulin.

My screen appears distorted

The screen may appear distorted or have a rainbow-like appearance if you are wearing polarized sunglasses, are in bright sunlight, or in extreme high or low temperatures. If your screen appears distorted:

- Take off your sunglasses.
- Move into the shade.
- Make sure your pump is not in direct heat (next to a heater) or cold (worn on the outside of your clothing on a very cold day).
- **Do not return the pump:** this is a normal property of this type of screen on any device.

The pump is asking me to rewind

This is normal after any of the following:

- Any E-alarms
- The Clear Settings function
- A NO DELIVERY alarm (during the Reservoir + Set sequence)

My bolus stopped

The Bolus Stopped error can occur if the battery cap is loose or the pump was bumped or dropped during a bolus. It can also happen if the pump receives a static shock. As a safety measure, the pump stops the bolus when this happens.

- 1 If you dropped your pump, visually inspect it to make sure that it is not damaged in any way.
- 2 Review your bolus history and reprogram the remaining bolus, if needed.

My pump buttons are not acting right during a bolus

If the ,  or  buttons are pressed and held down while a bolus is being delivered, the screen will freeze on that amount. Once the button is released, the units will ramp up to the amount delivered so far. Pressing and holding down the button will not stop the delivery of a bolus.

My pump will not display my blood glucose reading from my meter

- 1 Make sure you are using the correct meter (a blood glucose meter supported by MWT1 technology). Your pump will communicate with this meter only.
- 2 Make sure your meter's RF (radio frequency) feature is on and working correctly.
- 3 Make sure the meter option in your pump is set to **On** and you have set the meter ID number correctly on the pump.
- 4 Make sure your pump does not have a low battery alert condition.
- 5 Make sure the meter is within 4 feet (1.2 meters) of the pump without anything in between such as another person, a wall, etc.
- 6 Make sure there is no RF (radio frequency) interference from other electronic devices that could prevent communication. These devices can include some cell phones, cordless phones, televisions, computers, radios, other Paradigm pumps, meters and pump remote controls. To restore communication, simply move away from these other types of devices, or turn them off.
- 7 Your pump will not show another reading. Make sure the pump is idle and the HOME screen is blank.
- 8 If your pump still does not receive your blood glucose reading from the meter, use the up/down buttons to manually enter your blood glucose (in the ENTER BG screen).

I dropped my pump

Take care to protect your pump from being dropped.

- 1 Check that all connections are still tightly in place.
If you notice that the drive support cap is loose, or sticking out, discontinue use of the pump. **Do not press on the drive support cap. Pushing on the drive support cap may result in unintended insulin delivery, which can cause hypoglycemia.** See *Warnings* in the *Introduction* chapter for more information.
- 2 Check the LCD, keypad and pump case for cracks or damage.
- 3 Check the infusion set, including the tubing connector and tubing for cracks or damage.
- 4 Review the status screen, basal rates, and other pump settings.

- 5 Perform the Selftest procedure located in the UTILITIES MENU.
- 6 If the selftest does not complete successfully, call our 24 Hour HelpLine for assistance.

I submerged my pump in water

Your pump is designed to resist accidental contact with water. Do not submerge in water during bathing, showering, swimming, or other water activities.

- 1 Pat the outside of the case until dry.
- 2 Open the reservoir compartment and check the compartment and reservoir for water. If wet, dry it completely within 10 minutes of exposure to water. Exposure to liquids, including water or insulin can corrode the mechanism.
- 3 Dry the reservoir completely—do NOT place a wet reservoir in the pump.
- 4 Do not use hot air to dry your pump. This may damage your pump's internal electronics.
- 5 Check the battery compartment and the battery—if wet, dry them completely before using the pump.
- 6 Perform a selftest.

I cannot get to the USER SETTINGS screen

If you press ACT when you have **User Settings** highlighted, the following message appears: This feature is not normally accessible. To access, consult your User Guide.

To get to the USER SETTINGS screen:

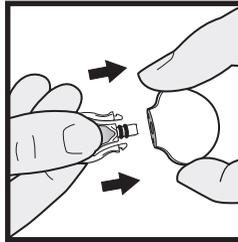
- 1 Go to the UTILITIES MENU screen.
Main > Utilities
- 2 Select **User Settings**. Hold down **⬅B** and press ACT.
- 3 See the *User settings* section in the *Utilities* chapter for information about the menu options.

Testing the transmitter

The tester acts like a sensor. If you get sensor-related alerts, use the tester to make sure that the transmitter is working.

Connecting the tester

- 1 Hold the transmitter and the tester as shown. Line up the flat side of the tester with the flat side of the transmitter.



- 2 Push the tester into the transmitter until the flexible side arms of the tester click into the notches on both sides of the transmitter.
- 3 Within 20 seconds, the green light on the transmitter will flash for about 10 seconds when properly connected. The Sensor feature must be turned **On** on your pump. Go to the RECONNECT OLD SENSOR screen to start your sensor.

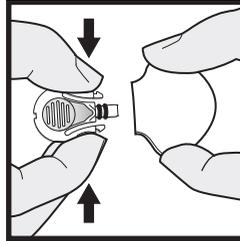
Main > Sensor > Link to Sensor > Reconnect Old Sensor

You should see the sensor icon  on the pump screen, which means that the transmitter and the sensor are communicating.

- 4 Within the next seven to eight minutes, go to the SENSOR STATUS screen to look for the Sensor ISIG value:
 - a. The sensor ISIG value on this screen should be between 48-59 nA. This range of ISIG values means that the transmitter electronics are working properly. Since the transmitter is sending signals correctly, the sensor must have caused the alert. Remove and discard the sensor. Insert a new sensor in a new site.
 - b. If you see a Sensor ISIG value that is less than 48.00 nA or more than 59.00 nA, contact our 24 Hour HelpLine. It may be time to replace your transmitter.

Disconnecting the tester

- 1 Hold the transmitter body as shown and pinch the side arms of the tester.



- 2 With the tester arms pinched, gently pull the transmitter away from the tester. To save transmitter battery life, do not leave the tester connected after testing.

Troubleshooting sensor features

Reconnect old sensor

You should only use this feature if you have disconnected the sensor from the transmitter and have to reconnect them.

To reconnect old sensor:

- 1 Go to the RECONNECT OLD SENSOR screen.
Main > Sensor > Link to Sensor > Reconnect Old Sensor
- 2 Press **ACT** in the RECONNECT OLD SENSOR screen.
- 3 The **SENSOR READY 2 HRS** screen appears. Press any button to continue. An alert will sound in two hours when a meter BG is required for calibration.

Find lost sensor

If you receive a Lost Sensor alert:

- 1 Relocate the pump closer to the sensor, and go to the **LINK SENSOR MENU**.
Main > Sensor > Link to Sensor
- 2 Select **Find Lost Sensor**, then press **ACT**.

-
-
- 3 The SENSOR READY 15 MIN screen appears. Press any button to continue. An alert will sound in 15 minutes when a meter BG is required for calibration.

Maintenance

It is recommended that you read your warranty statement included in this user guide for information about what is covered during your warranty period.

Battery

The Paradigm pump uses a single AAA battery (Energizer brand is recommended). As a safety measure, Medtronic Diabetes has designed the pump to only accept a new battery. If you insert a used battery, the FAILED BATT TEST alarm may be triggered. Refer to the *Install battery* section in *The basics* chapter for instructions.

The use of cold batteries causes erratic pump behavior. To prevent this, do not use batteries that have been in cold storage (such as in the refrigerator or your car in the winter). It takes several hours for these batteries to warm to room temperature.

Certain features on the pump use a lot of battery power. Your battery will need to be replaced more frequently if you use these features:

- Remote control
- Meter
- Backlight
- Vibrate alert type setting

CAUTION: You should use an alkaline battery in the pump (Energizer brand is recommended). Do not use a rechargeable or carbon zinc battery in the pump. Do not remove the battery unless you are changing your battery (installing a NEW battery). Replace it within five minutes. If not replaced within five minutes, the screen may display an alarm message. Follow the instructions in the message and make sure the time and date are set correctly. Check that the battery is inserted correctly. If the battery has been installed backwards, remove the battery and install it properly.

Storage

If you have to remove and store your pump, it is recommended that you store it with the battery in place. Keep a record of your current basal rates. To preserve battery life, set the basal rates to 0 (zero), turn off the remote and meter options, and set the Auto-off to dashes or zeroes.

CAUTION: Always keep the reservoir compartment dry and away from moisture to avoid damaging your pump.

Cleaning your pump

- 1 Use only a damp cloth and mild detergent mixed with water to clean the outside of your pump.
- 2 Rinse the pump with a clean cloth, dampened with clean water.
- 3 Dry with a clean cloth.
- 4 Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your pump.
- 5 Keep the reservoir compartment and battery compartment dry and away from moisture.
- 6 Do not use any lubricants with your pump.
- 7 Use a 70 percent alcohol wipe to disinfect your pump.
- 8 Use a dry clean cotton tip to remove any battery residue from the battery cap.
- 9 Use a dry clean cloth to remove any battery residue from the battery compartment opening.

Cleaning the transmitter

For details on how to clean the transmitter, see your transmitter user guide.

Warning: You must adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*, <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.

The transmitter must be disinfected after use on each patient. This system may only be used for testing multiple patients when Standard Precautions and Medtronic's disinfection procedures are followed.

Cleaning the server

For details on how to clean the server, see your server user guide.

Pump specifications

This section provides detailed information on specifications related to your pump. The safety features of your pump are individually listed and described.

Alarms and error messages

- Indicators: audible tone (beep) or vibration (silent).
- All alarms and errors show messages on the pump's screen and provide instructions on what to do. Unresolved alarms will escalate to siren mode for added safety.

Alarm history

Maximum records shown: 36

Audio frequency

Name	Frequency (+/- 25%)
Alarm	1850 Hz
Escalated alarm (siren)	2.5 kHz, followed by 3.2 kHz
Alert	1.8 kHz, followed by 2.1 kHz and 1.8 kHz
High Glucose alert	2.5 kHz, followed by 2.79 kHz, 2.98 kHz and 3.2 kHz
Low Glucose alert	3.2 kHz, followed by 2.98 kHz, 2.79 kHz and 2.5 kHz
Predictive High Glucose alert	2.5 kHz, followed by 2.98 kHz and 3.2 kHz
Predictive Low Glucose alert	3.2 kHz, followed by 2.98 kHz and 2.5 kHz

Name	Frequency (+/- 25%)
Rising rate of change alert	2.5 kHz, followed by 3.2 kHz
Falling rate of change alert	3.2 kHz, followed by 2.5 kHz

Backlight

- LCD (Liquid Crystal Display) type
- Time-out: 30 seconds

Basal

- Delivery: 0.025-35 units/hour (maximum units: 35/hour)
- Factory maximum setting: 2.0 units/hour
- 3 patterns maximum, each with 48 rates
- Increments:
 - 0.025 units for basal amounts in the range of 0.025 to 0.975 units
 - 0.05 units for basal amounts in the range of 1 to 9.95 units
 - 0.1 units for basal amounts of 10.0 units or larger

BG Target

Maximum targets: 8

- Range: 60-250 mg/dL (3.3-13.9 mmol/L)
- Warning limits: less than 90 or greater than 140 mg/dL (less than 5.0 or greater than 7.8 mmol/L)

Bolus delivery

- Insulin delivered/stroke:
 - 0.025 units for bolus amounts in the range of 0.025 to 0.975 units
 - 0.05 units for bolus amounts larger than 0.975 units
- Fluid delivered/stroke: 0.25 μ L (microliter) for 0.025 unit pump stroke; 0.5 μ L for 0.05 unit pump stroke

Maximum bolus

- Range: 0.0-25.0 units

Bolus history

Maximum records shown: 24

Bolus units

Increments: Based on selected scroll rate

Bolus Wizard feature

See the *Bolus Wizard feature specifications* section in this chapter for information.

Carb ratios

Maximum ratio settings	Range	Warning limits
8	1-200 grams/u	less than 5 or greater than 50 grams/u
	0.075-15.0 u/exch	less than 0.3 or greater than 3.0 u/exch

Carb units

The food entry when using Bolus Wizard feature:

- grams: 0-300 (increments: 1 gram)
- exchanges: 0.0-20 (increments: 0.5 exch)

Daily totals

Maximum records shown: 32 days of data, maximum display: 999.975 units/day. Daily delivery accuracy: 0.025 units.

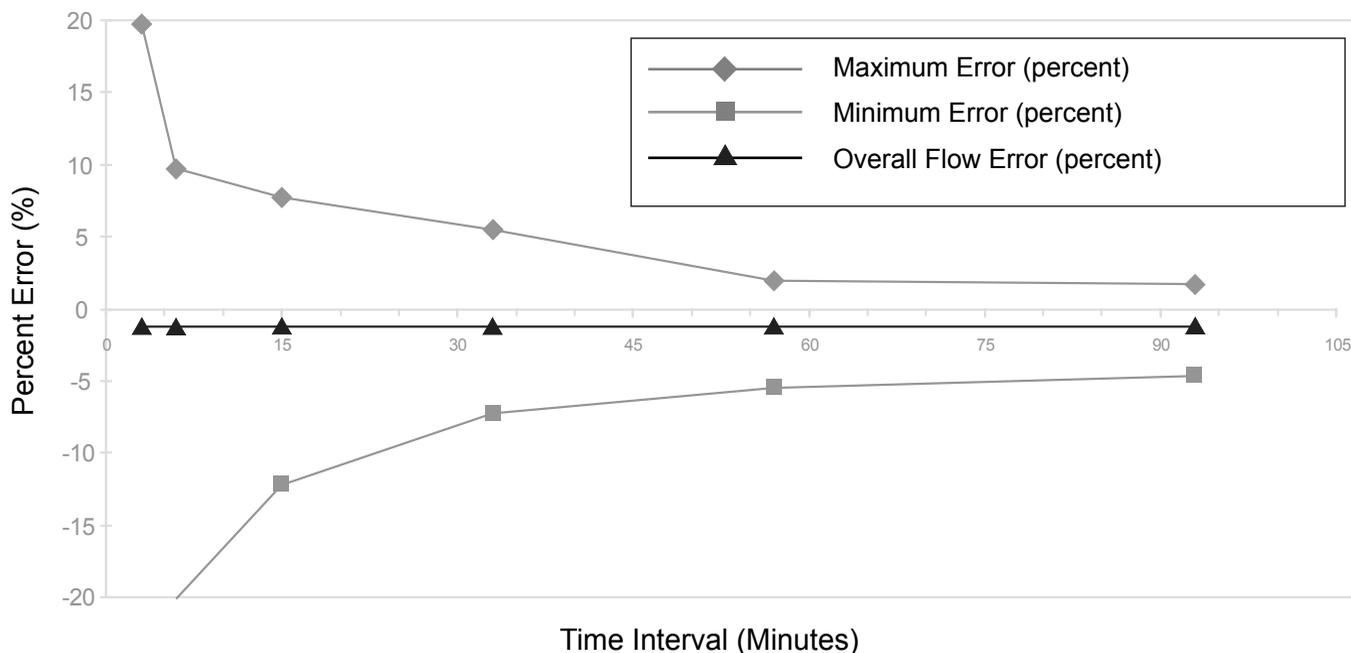
Default screen

The HOME screen. For most screens, if no buttons are pressed for 30 seconds, the pump returns to this screen.

Delivery accuracy

- Testing has confirmed that the delivery accuracy for the maximum/minimum bolus/basal amounts are within the +/-5 percent of the programmed value.
- A maximum bolus of 25 units will be delivered within six minutes.
- Displacement (piston) accuracy: +/-2 percent.

Delivery Volume Accuracy Curve (-1.20%) Overall Error
(MMT-523 Model) QTP6303 Qualification Pump (0.01 ml/hr 10/22/07 S/N: PAR162804U); 23°C,
MMT-326A Reservoir Lot#: WE0107318, MMT-317 Infusion set Lot: 620699



NOTE: The above trumpet curve was generated by a 1.0 Unit per hour basal rate.

Pump motor

The pump motor has a unique, patented design with an integrated safety check system. The system delivers in precise increments.

Dual Wave bolus

Delivers a Normal bolus followed by a Square Wave bolus (limited by maximum bolus).

Easy bolus

- Features programming using audible tones (or vibrate pulses) in user-defined increments.
 - Beep mode range: 0 to maximum bolus
 - Vibrate mode range: 0 to 20 steps or maximum bolus, whichever comes first
- Factory default: off
- Default step increment: 0.1 unit
- Step size \leq maximum bolus.
- Adjustable step size: 0.1 to 2.0 units per step.
- Accessible from the remote control or pump buttons.

Filling the infusion set

- Filling the cannula: up to 10 units (limited by maximum bolus)
- Filling the tubing: warning at 30 units, then at each 10 units thereafter.
- Fill rate: 1 to 5 units/second.
- Insulin used to fill the infusion set is not counted in daily totals but is recorded separately in the Reservoir + Set history.

Infusion pressure

Maximum infusion pressure and occlusion pressure: 13.7 PSI (94.46 kPa).

Insulin sensitivity

- Maximum settings: 8
- Factory default: 50 mg/dL/u (2.8 mmol/L/u)

- Range: 10-400 mg/dL/u (0.5-22.2 mmol/L/u)
- Warning limits: less than 20 or greater than 100 mg/dL/u (less than 1.1 or greater than 5.6 mmol/L/u)

Low resv (reservoir) warning

Values are based on displayed amount, not actual amount. This warning functions the same for both the 176-unit and the 300-unit reservoirs.

time:	2-24-hours, and @ 1:00 hour before empty	08:00 hours (default when time is selected)
units:	5-50 units, and @ half of the remaining amount	20 units (factory default)

Meter value

The BG measurement received from the meter. Appears in the ENTER BG screen during bolus programming. Appears on the screen when the pump is idle at the HOME screen.

- Expiration: 12 minutes
- Range: 20-600 mg/dL (1.1-33.3 mmol/L)
- Maximum meter ID entries: 3

Normal bolus

Range 0.025-25.0 units of insulin (limited by maximum bolus setting).

Occlusion detection

When occlusion is detected, the NO DELIVERY alarm occurs. The occlusion alarm is triggered by an average of 2.77 units of missed insulin. The Paradigm pump is intended for use with U100 insulin. This table shows occlusion detection for three different situations when using U100 insulin.

Rate	Minimum time before alarm	Typical time before alarm	Maximum time before alarm
bolus delivery (10 units at 2 u/min)	28 seconds	49 seconds	72 seconds
basal delivery (1.0 u/h)	1.95 hours	3.26 hours	4.9 hours

Rate	Minimum time before alarm	Typical time before alarm	Maximum time before alarm
basal delivery (0.025 u/h)	27 hours	112.47 hours	179 hours

Percent temp basal

Default value: 100% of basal programming

Power supply

The pump is powered by a standard 1.5 V AAA alkaline battery, size E92, type LR03 (Energizer brand recommended).

Reservoir + Set history

Maximum records shown: 20 (fill tubing and fill cannula)

Program safety checks

Maximum infusion with single fault condition: 0.0 units

Pump size

The dimensions of the pump are approximately:

- 523 pump:
 - 2.0 x 3.3 (2.8 at the battery cap) x 0.82 inches
 - 5.1 x 8.3 (7.1 at the battery cap) x 2.0 cm
- 723 pump:
 - 2.0 x 3.7 (3.5 at the battery cap) x 0.84 inches
 - 5.1 x 9.4 (8.9 at the battery cap) x 2.1 cm

Pump weight

- 523 pump: approximately 95 grams (with battery installed).
- 723 pump: approximately 102 grams (with battery installed).

Remote control

Uses radio signals to allow users to program Normal boluses or to manually suspend/resume their pumps.

Reservoir

- The user-filled reservoir is made from impact-resistant, insulin-compatible polypropylene.
- 523 pump volume: up to 176 units of U100 insulin
- 723 pump volume: up to 300 units of U100 insulin

Square Wave bolus

Delivers bolus insulin over a duration of 30 minutes up to eight hours (limited by the Max bolus setting).

Temporary (temp) basal rate

Allows you to temporarily change the current basal rate for a duration of 30 minutes up to 24 hours (limited by Maximum basal setting). The temp basal rate can be set to either Percent of basal or Insulin rate.

Time and date screen

12-hour or 24-hour formats. Pump users set the time/date, including the year, month and day. The date is included in the STATUS screen. Time always appears on the top of the screen.

Environmental conditions

- Pump operating temperature range:
from 37° F (3° C) to 98.6° F (37° C)
- Air pressure range:
from 700 hPa to 1060 hPa (from 10.2 PSI to 15.4 PSI)
- Operating humidity range of the case: 20% to 95%. This requirement exceeds EN 60601-2-24:1998, Section 10.2.1b (20% to 90%).

Radio frequency (RF) communication specifications

- Pump to transmitter frequency: 916.5 MHz; proprietary Medtronic protocol; range up to 6 feet (1.8 meters)
- Pump to meter frequency: 916.5 MHz; proprietary Medtronic protocol; range up to 4 feet (1.2 meters)
- Pump to remote frequency: 916.5 MHz; proprietary Medtronic protocol; range up to 24 inches (approximately 60 cm)

Quality of service

Common consumer electronic devices that transmit in the same frequency band used by the transmitter may prevent the pump from receiving the glucose information sent by the transmitter. Adherence to the following guidelines will result in a consistent and reliable quality of service:

- Cell phone 12 inches away from pump and meter
- Meter and pump within 4 feet of each other
- Pump and transmitter 6 feet of each other

Data security

The Medtronic MiniMed Paradigm® series insulin pump is designed to only accept radio frequency (RF) communications from recognized and linked devices (you must program your pump to accept information from a specific device).

The Medtronic MiniMed Paradigm® insulin pump and system components (meters and transmitters) ensure data security via proprietary means and ensures data integrity using error checking processes, such as cyclic redundancy checks.

Status screen

Item	When	What
Active Insulin	(if any)	(Active Ins:) the amount of active insulin, displayed to the next 0.025 U
Alarm Clock*	(appears if scheduled to alarm)	Time set is displayed.
Alert Silence	(if active)	Hi, Lo, Hi/Lo, All with time left
Auto-off	(appears if enabled)	X HR

Item	When	What
Basal pattern information	(if active)	Pattern A or B
Battery Status	(always appears)	Normal, Low, Off
BG meter value (most recent BG value received)	(appears if BG meter is enabled)	XXX mg/dL (XX.X mmol/L) time and date received
BG Reminder* (Only if enabled)	Time remaining before BG Reminder is set to go off H:MM h (if less than 1 hour, 0:XXh where XX is minutes remaining)	
Block	(if active)	ON
Current date	(always appears)	
Current temp basal information	(if active)	rate (units per hour), duration, time remaining
Last alarm/alert	(if cleared within 24 hours)	(Last:) with the date, time and abbreviation for the most recently cleared alarm/alert
Last bolus information	(appears if at least one bolus was started)	type and units delivered delivery time and date (S = Square, N = Normal, DN = Normal part of dual wave bolus, DS = Square part of dual wave bolus)
Meter: Disabled	(appears if enabled but battery is low or empty)	
Meter: On	(appears if enabled)	
Missed Bolus Reminder	(if this feature is turned on)	Bolus Before and the time that the reminder is due
Pump model number	(always appears)	
Remote: Disabled	(appears if enabled but battery is low or empty)	
Remote: On	(appears if enabled)	
Reservoir started	(always appears)	date, time, units left, time left
Serial number	(always appears)	

Item	When	What
Sensor Demo	(if Demo Mode is selected for the sensor graphs)	SENSOR DEMO: On
Software version	(always appears)	
Standard basal delivery data	(always appears)	current basal rate (basal 1, basal 2, etc.)
Status of pump	(such as Rewind, Suspended, Low Reservoir, Set Time, and so on)	
Time	(always appears)	
*If all of the Reminders and the Alarm Clock are enabled, only the reminder that is nearest to alarming will appear in the STATUS screen.		

Bolus Wizard feature specifications

There are four different formulas the Bolus Wizard feature uses to estimate a bolus, depending on your current BG. The following formulas apply only when the carb units are in grams.

- 1 If your current BG is greater than your High BG Target, the Bolus Wizard feature subtracts active insulin from the BG correction estimate, then adds this to the food estimate to get the total bolus estimate. However, if the result of subtracting active insulin from BG correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

- 2 If your current BG is less than your Low BG Target, the Bolus Wizard feature adds the BG correction estimate to the food estimate to get the total bolus estimate.

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - Low BG Target) ÷ Insulin sensitivity = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

- 3 If your current BG is between or equal to your High or Low BG Target, the total bolus estimate is based only on the food estimate.

Food estimate:

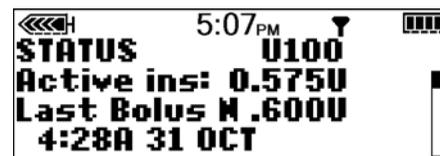
Carb grams ÷ Carb ratio = Units of insulin

Total bolus estimate = Food estimate

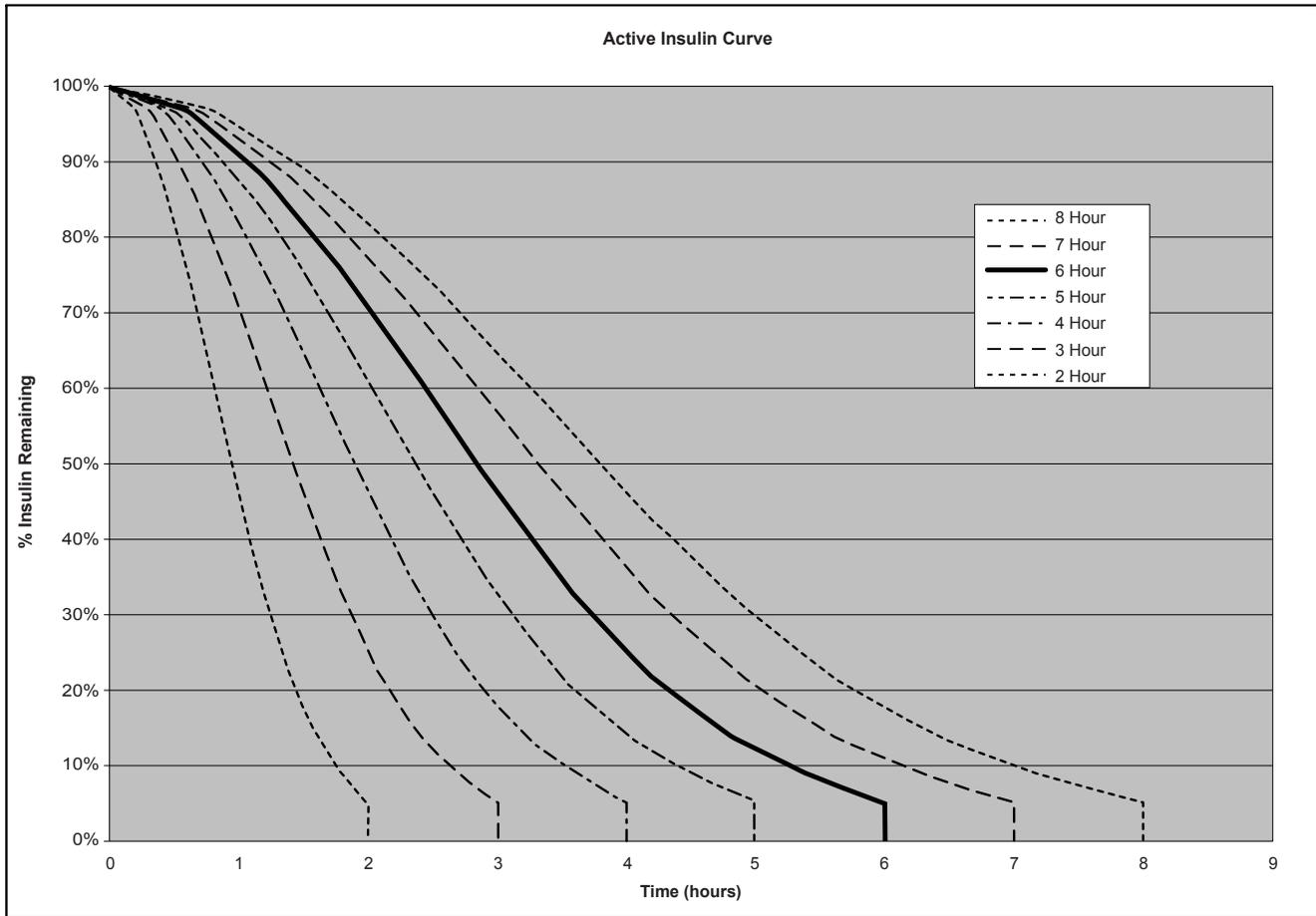
- 4 If you do not enter a BG, the total bolus estimate is based only on the food estimate.

NOTES:

- *If a Dual Wave bolus is less than the estimate due to the max bolus limit or a user change, the square (sq) portion is reduced first.*
- *Based on the Active Insulin Time setting you choose, the pump keeps track of how much insulin is still active in your body. This is shown as Active Ins. or Act. Ins. in the STATUS, SET BOLUS, SET NORMAL BOLUS, SET SQUARE BOLUS, SET DUAL BOLUS TOTAL, and SET EASY BOLUS screens. This prevents stacking of insulin, and lowers the chances of hypoglycemia.*
- *The active insulin amount is also shown in the Bolus Wizard's ESTIMATE DETAILS screen but is calculated differently than in the above screens. The active insulin amount calculated in the ESTIMATE DETAILS screen includes the insulin that has already been delivered and insulin that is going to be delivered by the active Square Bolus. To show this difference in calculation, the active insulin appears with an asterisk (*Active Insulin) in this screen.*



- The Bolus Wizard feature may utilize your current BG measurement, carbohydrate consumption, and active insulin to calculate your estimated bolus.
- Active Insulin Curves



Graph adapted from Mudaliar and colleagues, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

Bolus Wizard feature examples

Settings:

- Carb ratio: 30 grams/unit
- BG Target: 90-120 mg/dL (5.0-6.7 mmol/L)

- Insulin Sensitivity: 40 mg/dL/unit (2.2 mmol/L/unit)
 - Active Insulin Time: 6 Hours
- 1 No active insulin from previous bolus delivery. User inputs 60 grams of carbs and does not enter BG.
Food estimate:
 Carb grams ÷ Carb ratio = Units of insulin
 $60 \text{ g} \div 30 \text{ g/u} = 2 \text{ units}$
Total bolus estimate = Food estimate = 2 units
 - 2 No active insulin from previous bolus delivery. User inputs 60 grams of carbs and a BG of 200 mg/dL (11.1 mmol/L).
Food estimate:
 Carb grams ÷ Carb ratio = Units of insulin
 $60 \text{ g} \div 30 \text{ g/u} = 2 \text{ units}$
Correction estimate:
 (Current BG - High BG Target) ÷ Insulin sensitivity = Units of insulin
 $(200 \text{ mg/dL} - 120 \text{ mg/dL}) \div 40 \text{ mg/dL/u} = 2 \text{ units}$, or
 $(11.1 \text{ mmol/L} - 6.7 \text{ mmol/L}) \div 2.2 \text{ mmol/L/u} = 2 \text{ units}$
Total bolus estimate:
 Food estimate + Correction estimate = Units of insulin
 $2 \text{ units} + 2 \text{ units} = 4 \text{ units}$
 - 3 No active insulin from previous bolus delivery. User inputs 60 grams of carbs and a BG of 70 mg/dL (3.9 mmol/L).
Food estimate:
 Carb grams ÷ Carb ratio = Units of insulin
 $60 \text{ g} \div 30 \text{ g/u} = 2 \text{ units}$
Correction estimate:
 (Current BG - Low BG Target) ÷ Insulin sensitivity = Units of insulin
 $(70 \text{ mg/dL} - 90 \text{ mg/dL}) \div 40 \text{ mg/dL/u} = -0.5 \text{ units}$, or
 $(3.9 \text{ mmol/L} - 5.0 \text{ mmol/L}) \div 2.2 \text{ mmol/L/u} = -0.5 \text{ units}$
Total bolus estimate:
 Food estimate + Correction estimate = Units of insulin
 $2 \text{ units} + (-0.5) \text{ units} = 1.5 \text{ units}$
 - 4 No active insulin from previous bolus delivery. User inputs 60 grams of carbs and a BG of 100 mg/dL (5.6 mmol/L).
Food estimate:
 Carb grams ÷ Carb ratio = Units of insulin
 $60 \text{ g} \div 30 \text{ g/u} = 2 \text{ units}$
Correction estimate:

Correction is 0 because the current BG reading is within the BG Target range.

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2 units + 0 units = 2 units

- 5 Previous bolus activity results in a calculation of 1.5 units unabsorbed (active) insulin. User inputs 60 grams of carbs and a BG of 200 mg/dL (11.1 mmol/L).

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

60 g ÷ 30 g/u = 2 units

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

(200 mg/dL - 120 mg/dL) ÷ 40 mg/dL/u - 1.5 units = 0.5 units, or

(11.1 mmol/L - 6.7 mmol/L) ÷ 2.2 mmol/L/u - 1.5 units = 0.5 units

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2 units + 0.5 units = 2.5 units

- 6 Previous bolus activity results in a calculation of 3.5 units unabsorbed (active) insulin. User inputs 60 grams of carbs and a BG of 200 mg/dL (11.1 mmol/L).

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

60 g ÷ 30 g/u = 2 units

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

(200 mg/dL - 120 mg/dL) ÷ 40 mg/dL/u - 3.5 units = -1.5 units*, or

(11.1 mmol/L - 6.7 mmol/L) ÷ 2.2 mmol/L/u - 3.5 units = -1.5 units*

NOTE: *This negative number indicates that active insulin is sufficient to cover the correction that is needed. Thus, correction is 0 units. Active insulin does not reduce the food portion of the estimate.

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2 units + 0 units = 2 units

Insulin delivery default settings

Menu	Item	Default Setting	Limits	Increments
Bolus Menu:	Bolus Wizard feature:	Off		
	Easy bolus:	Off		
	Easy bolus step:	0.1 u	2.0 u	0.1 u
	Scroll Rate:	0.10 u		0.025 u; 0.05 u; 0.10 u
	Dual/Square bolus:	Off		
	Maximum bolus:	10.0 u	0.0-25.0 u (per single bolus)	
	BG Reminder:	Off	0:00-5:00	0:30
Basal Menu:	Patterns:	Off		
	Maximum basal rate:	2.00 u/h	0.000-35.0 u/h	0.025 u (for 0.025-0.975 u/h); 0.05 u (for 1.00-9.95 u/h); 0.1 u (for rates of 10 u/h or more)
	Basal rate:	0.000 u/h		0.025 u (for 0.025-0.975 u/h); 0.05 u (for 1.00-9.95 u/h); 0.1 u (for rates of 10 u/h or more)
	Temp basal type:	u/h	Max basal rate setting	0.025 u (for 0.025-0.975 u/h); 0.05 u (for 1.00-9.95 u/h); 0.1 u (for rates of 10 u/h or more); (or 1%)
Utilities Menu:	Lock Keypad:	Off		
	(Alarm) History:	(no defaults)		

Menu	Item	Default Setting	Limits	Increments
	Alert type:	audio, beep-med		
	Auto-off:	Off		
	Capture Option:	Off		
	Low reservoir warning:	20 insulin units	if units: 1st @ 5-50 u; 2nd @ half amount remaining if time: 1st @ 2:00-24:00; 2nd @ 1:00 hour before empty	20 u 0:30
	(Time/Date) Time:	12 a.m. (midnight)		
	(Time/Date) Date:	1/1/07		
	(Time/Date) Time format:	12-hour		
	Block:	Off		
	Alarm clock:	Off		
	Remote option:	Off		
	Meter option:	Off		
	User Settings:	(no defaults)		
	Language:	English		

Bolus Wizard feature default settings

Item	Default Setting	Limits	Increments	Warning Limits
carb units:	grams	—	—	—
ins to carb (or exch) ratio:	15 grams/u or 1 unit/exch	1-200 g/u or 0.075-15.0 u/exch	0.1 g/u for 0-9.9 g/u; 1 g/u for ratios of 10.0 g/u or more (or 0.001 u/exch for 0.075-0.099 u/exch;	5-50 g/u or 0.3-3.0 u/exch

Item	Default Setting	Limits	Increments	Warning Limits
			0.01 u/exch for 0.10-9.99 u/exch; 0.1 u/exch for 10.0-15.0 u/exch)	
(insulin) sensitivity:	50 mg/dL/u or 2.8 mmol/L/u	10-400 mg/dL/u or 0.5-22.2 mmol/L/u	1 mg/dL/u or 0.1 mmol/L/u	20-100 mg/dL/u or 1.1-5.6 mmol/L/u
BG Target:	100-100 mg/dL or 5.6-5.6 mmol/L	60-250 mg/dL or 3.3-13.9 mmol/L	1 mg/dL or 0.1 mmol/L	90-140 mg/dL or 5.0-7.8 mmol/L
Active Ins Time:	6 hours	2-8 hours	1 hour	—

Sensor features default settings

Feature	Options	Default Setting	Limits, Range of Values
Sensor	<ul style="list-style-type: none"> On Off 	Off	—
Glucose Alerts	<ul style="list-style-type: none"> On Off 	Off	Set the limits using the Glucose Limits feature.
Glucose Limits	<ul style="list-style-type: none"> Maximum of 8 Glucose Limits. One pair of Glucose Limits (Glucose Limits 1) is already set up for you, with a default High Glucose Limit and Low Glucose Limit. Glucose Limits 2 through 8 can be set as needed. 		

Feature	Options	Default Setting	Limits, Range of Values
Glucose Limits 1	523, 723 <ul style="list-style-type: none"> Low: 80 mg/dL (4.4 mmol/L) High: 240 mg/dL (13.3 mmol/L) 	523, 723 <p>Low: 80 mg/dL (4.4 mmol/L)</p> <p>High: 240 mg/dL (13.3 mmol/L)</p>	Low Glucose Limit range: ^a <ul style="list-style-type: none"> 523, 723: 40-390 mg/dL (2.2-21.6 mmol/L) High Glucose Limit range: ^b <ul style="list-style-type: none"> 523, 723: 50-400 mg/dL (2.8-22.2 mmol/L)
Glucose Limits 2 through Glucose Limits 8	<ul style="list-style-type: none"> Low: Off High: Off 	Low Off High Off	See the Glucose Limits 1 range.
High Repeat	<ul style="list-style-type: none"> On Off (Set to On when High Glucose, High Predictive, or Rising Rate of Change Alert is on)	On 1 hour	Range: 0:05-3:00 (5 minutes to 3 hours)
Low Repeat	<ul style="list-style-type: none"> On Off (Set to On when Low Glucose, Low Predictive, or Falling Rate of Change Alert is on.)	On 20 minutes	Range: 0:05-1:00 (5 minutes to 1 hour)
Predictive Alert	<ul style="list-style-type: none"> On Off 	Off Default time sensitivity: Low 15 minutes High 15 minutes	Range: Off 0:05-0:30 (5 to 30 minutes)

Feature	Options	Default Setting	Limits, Range of Values
Rate of Change Alerts	<ul style="list-style-type: none"> On Off 	Fall Rate Limit Off Rise Rate Limit Off	Fall Rate Limit range: 1.1-5.0 mg/dL/min (0.065-0.275 mmol/L/min) Rise Rate Limit range: 1.1-5.0 mg/dL/min (0.065-0.275 mmol/L/min)
Cal Repeat	(Always on - cannot be turned off)	On 30 minutes	Range: 0:05-1:00 (5 minutes to 1 hour)
Cal Reminder	<ul style="list-style-type: none"> On Off 	On 1 hour	Range: 0:05-6:00 (5 minutes to 6 hours)
Blood Glucose Units (BG Units)	<ul style="list-style-type: none"> mg/dL mmol/L 	mg/dL	—
Weak Signal	(Always on - cannot be turned off)	30 minutes	Range: 0:05-0:40 (5 to 40 minutes)
Sensor glucose graph timeout	<ul style="list-style-type: none"> 2 minutes 4 minutes 6 minutes NONE^c 	2 minutes	—

Feature	Options	Default Setting	Limits, Range of Values
Alert Silence	<ul style="list-style-type: none"> Off Hi Alerts Lo Alerts Hi and Lo Alerts All Sensor Alerts 	Off	If any option other than Off is selected in the ALERT SILENCE screen, the SET DURATION screen displays. The value range is from 00:30 to 24:00.
AUC Limits	Always on	Low Limit 70 mg/dL (3.9 mmol/L) High Limit 180 mg/dL (10 mmol/L)	Low Limit range: ^d 40-400 mg/dL (2.2-22.2 mmol/L) High Limit range: ^e 40-400 mg/dL (2.2-22.2 mmol/L)

- a. Your Low Glucose Limit must be at least 10 mg/dL (0.6 mmol/L) below your High Glucose Limit. For example, if your High Glucose limit is 200 mg/dL (11.1 mmol/L), then your Low Glucose limit cannot be higher than 190 mg/dL (10.5 mmol/L).
- b. Your High Glucose Limit must be at least 10 mg/dL (0.6 mmol/L) above your Low Glucose Limit.
- c. If you select this option the sensor glucose graphs will show continuously on the pump screen.
- d. The AUC Low Limit can be equal to, but not higher than the AUC High Limit.
- e. The AUC High Limit can be equal to, but not lower than the AUC Low Limit.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
<p>The Paradigm 523/723 pump system (consisting of the 523/723 pump and MMT-7703 transmitter) is intended for use in the electromagnetic environment specified below. The customer or the user of the Paradigm 523/723 pump system should make sure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Paradigm 523/723 pump system uses RF energy only for system communication functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Harmonic emissions IEC 61000-3-2 Voltage fluctuations/flicker emissions IEC 61000-3-3	Class B Not applicable Not applicable	The Paradigm 523/723 pump system is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. NOTE: <i>The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. However, since the Paradigm 523/723 pump system is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.</i>

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Paradigm 523/723 pump system (consisting of the 523/723 pump and MMT-7703 transmitter) is intended for use in the electromagnetic environment specified below. The customer or the user of the Paradigm 523/723 pump system should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±30 kV air (<5% relative humidity)	The Paradigm 523/723 pump system should not be affected by electrostatic discharge that might occur under normal conditions of use.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable Not applicable	Not applicable Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Not applicable	Not applicable Not applicable
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	Not applicable	Not applicable
	40% U_T (60% dip in U_T) for 5 cycles	Not applicable	Not applicable
	70% U_T (30% dip in U_T) for 25 cycles	Not applicable	Not applicable
	<5% U_T (>95% dip in U_T) for 5 seconds	Not applicable	Not applicable

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Paradigm 523/723 pump system (consisting of the 523/723 pump and MMT-7703 transmitter) is intended for use in the electromagnetic environment specified below. The customer or the user of the Paradigm 523/723 pump system should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m	400 A/m 4000 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Paradigm 523/723 pump is intended for use in the electromagnetic environment specified below. The customer or user of the Paradigm 523/723 pump system should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Paradigm 523/723 pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance Not applicable

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Paradigm 523/723 pump is intended for use in the electromagnetic environment specified below. The customer or user of the Paradigm 523/723 pump system should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.4 GHz	200 V/m 80 MHz to 6.0 GHz	<p> $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.70 \sqrt{P}$ 800 MHz to 6.0 GHz </p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Paradigm 523/723 pump is intended for use in the electromagnetic environment specified below. The customer or user of the Paradigm 523/723 pump system should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
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NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Paradigm 523/723 pump is used exceeds the applicable RF compliance level above, the Paradigm 523/723 pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Paradigm 523/723 pump.

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Paradigm 523/723 pump system

This section provides information on the recommended separation distance between portable and mobile RF communications equipment and the Paradigm 523/723 pump. The Paradigm 523/723 pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Paradigm 523/723 pump users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Paradigm 523/723 pump as recommended below, according to the maximum output power of the communications equipment.

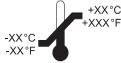
Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)	
	80MHz to 800MHz $d = 0.35 \sqrt{P}$	800MHz to 6.0GHz $d = 0.70 \sqrt{P}$
0.01	0.035	0.07
0.1	0.11	0.11
1	0.35	0.7
10	1.1	2.2
100	3.5	7

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

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

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

Icon table

Refer to instruction manual/booklet before every use . (Appears blue on label.)	
Caution: Specific warnings may not be found on label.	
Manufacturer	
Date of manufacture	
Batch code	
Use by date	
Catalog or model number	
Serial number	
Temperature limit	
MR unsafe: Keep away from magnets and strong electromagnetic fields.	
Fragile, handle with care	
Degree of protection against electric shock: Type BF applied part	
IP Rating: Degree of protection against water and debris under conditions provided by the manufacturer. For more information about IPX7, see the <i>Glossary</i> on page 213.	IPX7
Recycle cardboard, paper, plastic packaging supplies and unwanted written material.	
Non-ionizing electromagnetic radiation (RF communication)	

Glossary

A

A1C (HbA1c) test - A 2-3 month average of blood glucose values expressed in percent. The normal range varies with different labs and is expressed in percent (such as 4 - 6%).

Accept - Pressing the **ACT** button to approve the selection or setting.

Active insulin - Bolus insulin that has been delivered to your body, but has not yet been used.

Adverse reaction - An unexpected, unpleasant or dangerous reaction to a sensor when it is inserted into the body. An adverse reaction may be sudden or may develop over time.

Alarm - Audible or vibrating (silent) notice that indicates the pump is in Attention mode and immediate attention is required. Alarms are prefixed in the alarm history with the letter A.

Alarm clock - Feature you can set to go off at specified times of the day.

ALARM HISTORY - Screen that displays the last 36 alarms/errors that have occurred on your pump.

Alarm icon - a solid circle that shows at the top of the screen and the pump beeps or vibrates periodically until the condition is cleared (see Attention mode).

Alert - Audible or vibrating (silent) indicator that notifies you the pump needs attention soon or that you should be reminded of something. Insulin delivery continues as programmed.

Alert icon - an open circle that appears at the top of the screen and the pump beeps or vibrates periodically to remind you of the condition (see Special mode).

Attention mode - Operating mode that stops all current insulin delivery. This mode indicates an alarm or

condition exists that requires immediate attention.

AUC Limits - The AUC Limits feature allows you to see how long your sensor glucose measurements are outside your target range. Your target range is the area between your Low AUC Limit and your High AUC Limit. When you set the AUC Limits, you select the Low AUC Limit and High AUC Limit you want for your target range.

B

Backlight - Pump screen light. Turns on whenever the  button is pressed or in combination with the  button if not on the HOME screen. The backlight also appears during alarms and alerts, except for LOW BATTERY alert and OFF NO POWER alarm.

Basal patterns - The user can program up to three different basal rate patterns into the

pump for the delivery of basal insulin: Standard, A, and B. For each pattern, there is an option of setting up to 48 basal rates.

Basal rate - The pump setting that provides a continuous infusion of insulin to keep the blood glucose stable between meals and during the night. Basal insulin mimics pancreatic insulin delivery—which meets all the body's non-food related insulin needs.

BASAL REVIEW screen - shows the basal rates programmed in the pump, with the 24-hour total for each rate.

BG - Blood Glucose

BG Reminder - Feature that you can set to remind you to check your blood glucose after a bolus.

BG Target - Normal blood glucose level

BG Units - Blood glucose units used by the pump (mg/dL or mmol/L).

Block - Feature that restricts access to all programming except suspend, selftest and the delivery of a bolus with the remote control.

Blood glucose (BG) - A form of digested sugar in the bloodstream. Glucose is the major source of energy for living cells, and is carried to each cell through the blood

stream. Cells cannot use glucose without the help of insulin.

Bolus - A dose of insulin given to cover an expected rise in blood glucose (such as the rise after a meal) or to lower a high blood glucose down to target range.

BOLUS HISTORY - This screen displays the last 24 boluses delivered by your pump.

Bolus Wizard® feature - Calculates the bolus amount based on personal information of the pump user.

C

Cal Reminder - The value of the Cal Reminder is the amount of time before the current calibration value expires when the user wants to be reminded to calibrate by having the pump issue a METER BG BY alert. For example, if the Cal Reminder is set to two hours, the METER BG BY alert will occur two hours before the calibration is required.

Cal Repeat - Once a METER BG NOW alert occurs, the pump will not repeat the alert until after this selected Cal Repeat time.

Calibrate - Check, adjust, or set to a standard (calibrate your sensor).

Cannula - A short, thin, and flexible tubing at the end of the infusion set that is inserted into the subcutaneous tissue to deliver insulin.

Carb ratio (Carbohydrate ratio) - Used when counting carbohydrates in grams. The amount of carbohydrates covered by one unit of insulin. (Also see exch ratio.)

Carb units - The food entry when using the Bolus Wizard feature. Entered as (carbohydrate) grams or exchanges.

Carbohydrate - One of the three main sources of energy or calories in food. Carbohydrates are mainly sugars found in fruits, milk, and starches that the body breaks down into glucose.

CH - Carbohydrate

Contraindication - A condition that makes a specific treatment or procedure NOT advisable. A contraindication is literally contra- (against) an indication, against something that is indicated as advisable or necessary.

Correction bolus - The amount of insulin needed to return a high blood glucose level back down to target range.

D

Daily totals - Shows the total insulin delivered (basal and bolus) in the last 24-hours. Maximum records: 32 days

Default - A setting or value for your pump that is assigned automatically by your system. Some default settings cannot be changed; other default settings remain in effect until you change them.

Diabetic Ketoacidosis (DKA) - A serious condition that occurs when the insulin levels are low, blood glucose level are elevated, and the body uses fat for energy. This process produces ketones which upset the body's acid-base balance leading to a potentially life threatening situation.

Diathermy - A medical and surgical technique involving the production of heat in a part of the body by high-frequency electric currents, to stimulate the circulation, relieve pain, destroy unhealthy tissue, or cause bleeding vessels to clot.

DKA - Diabetic Ketoacidosis

Dual Wave® bolus - Combination of a Normal bolus that is delivered immediately, then followed by a Square Wave bolus. The Square Wave portion is delivered evenly over a period of time.

Duration - Amount of time it takes to administer a bolus or basal delivery. Also, length of time for an action or condition.

E

Easy bolus™ - Method of delivery for a Normal bolus using the Easy Bolus button .

Electromagnetic compatibility - The condition that exists when systems and devices that use electromagnetic energy operate properly without causing or suffering accidental electromagnetic interference to or from other electromagnetic devices.

Electrostatic discharge - The rapid, spontaneous transfer of electrostatic charge induced by a high electrostatic field. The charge usually flows through a spark, known as static discharge, between two objects at different electrostatic levels as they approach each other (for example, when people touch each other after dragging their feet on a carpet).

Exch ratio - (Exchange ratio) Used when counting carbohydrates as exchanges. The amount of insulin required to cover one (1) carbohydrate exchange. (Also see carb ratio.)

Exchange system - A system of estimating carbohydrate and calorie intake that groups by type. Each exchange group lists similar types of food in serving sizes. A person can exchange, trade, or substitute a food serving in a particular group for another food serving in the same group.

Express bolus - Method of delivery for any bolus type using the **EXPRESS BOLUS** button .

F

Fingerstick - One method used to test blood glucose by taking a sample of blood for testing from a finger using a lancet or automatic finger puncture device.

Food bolus - A dose of insulin given to cover the expected rise in blood glucose that occurs after eating.

G

Gastroparesis - A condition of the digestive system that slows down the emptying of food from the stomach.

Generate - create a result (your pump will generate a graph).

Glucagon Emergency Kit - An injectable form of glucagon that can be used to treat

severe low blood glucose levels (hypoglycemia). A Glucagon Emergency Kit can be obtained in a pharmacy with a prescription.

Glucose tablet - A simple sugar in tablet form, that is taken orally to treat low blood glucose (hypoglycemia). Glucose tablets can be purchased from the Medtronic Diabetes online store at www.medtronicdiabetes.com as well as drug stores and pharmacies.

H

HbA1c - Glycosylated hemoglobin.

HDL - High-density lipoprotein A complex of lipids and proteins in approximately equal amounts that functions as a transporter of cholesterol in the blood.

High Glucose - The pump displays an alert if the sensor indicates that your sensor glucose is at or above this value. You have the option to turn this feature on or off.

High Repeat - For the High Glucose, High Predictive, and Rising Rate of Change alerts, allows the user to set the delay between the first alert and any subsequent alerts. This will allow the user to avoid getting an alert every

five minutes until the condition is corrected.

Hold - Press and continue to press a pump button.

Hyperglycemia - A condition in which blood glucose values are elevated above target. Symptoms may include excessive thirst, frequent urination, dry mouth, headache, fatigue, and blurred vision.

Hypoglycemia - A condition in which blood glucose values are below 70 mg/dL (3.9 mmol/L). Symptoms may include behavioral changes, pale complexion, hunger, sweating, sudden weakness, headache, confusion, drowsiness, non-responsiveness to questions, and the most serious: seizure, convulsion or loss of consciousness.

I

Idle - The pump is at the HOME screen.

Increment - A small increase or decrease in a measurement.

Indication - A condition that makes a specific medical treatment or procedure advisable or necessary.

Infusion set - Flexible tubing with a reservoir connector and an infusion site. This

tubing delivers insulin from the pump to the body.

Infusion site - The end of the infusion set held to the body with a tape. It consists of a cannula and an introducer needle.

Initialize - To set a starting value or prepare your pump, transmitter, or sensor for use.

Insulin - A hormone that helps the body use glucose (sugar) for energy. The beta cells of the pancreas make the insulin.

Insulin sensitivity - The amount by which your blood glucose (BG) level is reduced by one unit of insulin. (Bolus Wizard feature data)

Insulin to carbohydrate ratio - The amount of insulin required to cover a given number of carbohydrates. This ratio helps you estimate what size bolus you should take when eating carbohydrates. Your healthcare professional will determine your insulin to carbohydrate ratio.

Interstitial fluid - The fluid between the cells in the human body.

Introducer needle - This needle allows the insertion of a cannula or a sensor into the subcutaneous tissue. It is removed and discarded after insertion leaving only the

cannula or the sensor in the body.

IPX7 - Protected against water immersion. Immersion for 30 minutes at a depth of up to 1 meter.

K

Ketone - A chemical created by the human body when there is not enough insulin in the blood.

kPa (kilopascal) - A unit of measurement for quantifying force. Used to measure atmospheric pressure. Equivalent to 10,000 dynes per square centimeter.

L

LDL (Low-density lipoprotein) - A complex of lipids and proteins, with greater amounts of lipid than protein, that transports cholesterol in the blood.

Link - To turn on and setup the meter option that allows the pump to receive BG readings from a meter that communicates with your pump.

Log - A record of measurements, alarms or other actions by your pump.

Low Glucose - The pump displays an alert if the sensor

indicates that your sensor glucose is at or below this value. You have the option to turn this feature on or off.

Low Repeat - For the Low Glucose, Low Predictive, and Falling Rate of Change alerts, allows you to set the delay between the first alert and any subsequent alerts. This will allow the user to avoid getting an alert every five minutes until the condition is corrected.

Low resv warning - Programmable warning that notifies you with an alert when either a specified number of units remain in the reservoir or a specified amount of time remains before the reservoir will be empty.

M

Manual bolus - Selectable item available in the BOLUS MENU when the Bolus Wizard feature is active. It is one method of programming a bolus without the Bolus Wizard feature. (see *Set bolus*)

Marker - A measurement of a specific event - such as a BG measurements, exercise, or the amount of insulin used.

Max basal rate - The maximum amount of basal insulin that

the pump can be programmed to deliver per hour. (set by the user)

Max bolus - The maximum amount of bolus insulin that the pump will deliver at one time. (set by the user)

Meter - An optional blood glucose meter powered by MWT1 technology. Your pump can be programmed to receive your BG readings from this meter.

Meter option - Feature that allows the pump to receive BG readings from a meter powered by MWT1 technology.

MWT1 technology - MWT1 is the wireless Radio Frequency (RF) technology that is used to transmit information from the meter to the pump. You can program your pump to automatically receive your BG reading from this meter.

N

Normal bolus - An immediate delivery of a specified unit amount of insulin.

Normal mode - Regular operating mode. No special features are active, no alert or alarm conditions exist. Insulin delivery is normal during this mode.

Now portion - The normal portion of a Dual Wave bolus.

The now portion delivers immediately and is then followed by the Square portion.

O

Occlusive dressing - A bandage that seals a wound from air or bacteria.

P

Pattern A/B - Basal pattern that supports activities that are not a part of your day-to-day routine, but are normal in your lifestyle. Such activities could be a sport that you do once a week or a change in your sleep pattern over the weekend, extended periods of higher or lower activity, or menses.

Predictive alerts - These alerts can be used so that you receive alarms before the sensor glucose measurements reach your glucose limits. This alert predicts when the sensor glucose measurements will reach your glucose limits by using information about your glucose limits and recent sensor glucose measurements.

Press - To push and release a button.

PSI - Pound-force per square inch.

Pump S/N - Pump S/N is the serial number of the pump currently in use.

R

Rate of Change alerts - These alerts can be used to set up the system so that you receive alerts if the sensor glucose measurements change too rapidly for your needs. You can set the limit for these alerts so that you receive an alert whenever the sensor glucose measurements fall or rise faster than the limit.

Reservoir - The syringe that holds insulin.

Reset - To set again, or change the information (reset your glucose values).

Resume - Restarts basal delivery after the pump is suspended.

Rewind - The pump drive moves back to its starting position to prepare the pump for a new reservoir.

RF - Radio frequency

S

Scroll - Press the up or down arrow buttons to move through the screen text.

Select - Pressing the up or down arrow buttons to highlight a desired screen item.

Sensitive - Easily irritated (sensitive skin), or able to measure very slight differences (a sensitive instrument).

Sensor Age - Sensor age is the amount of time, in days and hours, since the sensor was first inserted.

Sensor features - Optional continuous glucose monitoring capabilities.

Sensor (glucose sensor) - The small part of the continuous glucose monitoring system that you insert just below your skin to measure glucose levels in your interstitial fluid.

Sensor glucose (SG) - Glucose levels in the fluid under your skin measured by the sensor.

Sensor icon - An icon on your pump that tells you whether the Sensor feature is On or Off.

Serter - The serter is an aid for the insertion of a Medtronic Diabetes glucose sensor.

Set - To enter or establish a value for your pump (set your BG Reminder).

Set bolus - Selectable item available in the BOLUS MENU when the Bolus Wizard feature is inactive. One method of programming a bolus without the Bolus Wizard feature. (See *Manual bolus*.)

S/N# - Serial number.

Special mode - Operating mode that indicates one or more special functions is active or a condition exists that requires attention.

Square Wave® bolus -

Immediate bolus delivered evenly over a specified time period (30 minutes to 8 hours).

Square Wave portion - (Sq) The second part of a Dual Wave bolus. The Square Wave portion delivers evenly over a period of time after the NOW portion delivers.

Stabilize - To make steady or keep from changing (stabilize your blood glucose).

Standard pattern - Your normal basal that supports your usual day-to-day activity. When the Patterns feature is off, the pump uses your standard basal pattern.

Status - The condition of a part of your system (battery status, alarm/alert status).

Status screen - Displays the current operations of the pump, including active functions, the most recent basal and bolus deliveries, reservoir information, and battery condition.

Step - Measurement of insulin that you set and use for Easy

Bolus and other bolus deliveries.

Sterile - Free from substances or germs that could cause infection.

Sterile gauze - A thin medical bandage with loose weave that is free from substances or germs that could cause infection.

Submerge - To place under water or cover completely with water.

Suspend - Function that stops all current insulin deliveries. The basal delivery is paused until restarted.

T

Temp - Temporary.

Temp basal - (Tmp basal) Temporary one-time basal insulin with a specified amount and duration. Used to support insulin needs for special activities or conditions that are not part of the normal daily routine.

Timeout - If you do not enter information or do something in a specific length of time, your pump automatically stops what it is doing and goes to the HOME screen.

Transmitter - The device that sends a signal to your pump with information from your sensor.

Transmtr Batt - The status of the transmitter battery. Possible values are **Good**, **Low**, or **Bad**.

Transmtr ID - The serial number of the transmitter currently in use.

Transmtr Ver - The software version of the transmitter currently in use.

W

Weak Signal - The pump displays an alert if it has not received data from the sensor for an amount of time that you set.

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Medtronic

ENLITE™

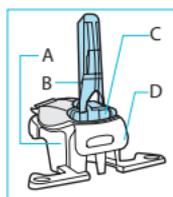
Glucose Sensor
User Guide

RELEASED

RELEASED

Introduction

The Enlite™ glucose sensor (sensor) is part of your Continuous Glucose Monitoring System. The sensor continuously converts tiny amounts of glucose from the fatty layer under your skin into an electronic signal. Your system then uses these signals to provide sensor glucose values.



- A. Pedestal
- B. Needle housing
- C. Sensor
- D. Clear liner

Potential risks

Risks related to sensor use

General risks with sensor use include:

- Skin irritation or reaction to adhesives
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Irritation from tapes used with glucose-sensing products.
- Raised bump
- Appearance of a small “freckle-like” dot where needle was inserted
- Allergic reaction
- Fainting secondary to needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive and or tapes
- Scarring

Specific risks related to sensor use

During the conduct of the Performance Evaluation of the Enlite™ Glucose Sensor to Support a Full 144 Hours (6 Days) of Use¹, the following specific sensor risks were identified:

¹ Medtronic Inc., A Performance Evaluation of the Enlite™ Glucose Sensor to Support a Full 144 Hours (6 Days) of Use, CER247/Z25/C, May 15, 2012.

- Pain at sensor insertion site during sensor wear (1 incident reported)
- Dermatological risks (number of events/number of skin assessments performed):
 - Redness due to device insertion (abdomen, 35/213)
 - Redness in area of adhesive (abdomen, 63/213)
 - Bruising (abdomen, 2/213)
 - Bump (induration) (abdomen, 1/213)
 - Bleeding:
 - Bleeding immediately after insertion (abdomen, 2/213)
 - Bleeding at removal (abdomen, 5/213)
 - Fluid discharge (abdomen, 1/213)
 - Other, including indentation from device, for example, the transmitter (abdomen, 9/213)

When using medications containing acetaminophen some people experience a temporary increase in sensor glucose readings for less than one hour. For some people the sensor readings are not noticeably affected by acetaminophen. Always use BG meter readings to verify your glucose level before making therapy decisions.

Indications for use

The sensor is intended for use with Medtronic Diabetes (Medtronic) glucose sensing systems to continuously monitor glucose levels in persons with diabetes.

Contraindications

None known.

General warnings

Do not make therapy treatment decisions based on sensor glucose values because sensor glucose and blood glucose values may differ. If your sensor glucose reading is high or low, or if you feel symptoms of high or low glucose, confirm your blood glucose with your BG meter prior to making therapy decisions to avoid severe high or low glucose conditions.

Keep an arm's length between you and the patient when removing the needle. A retractable needle is attached to the sensor and minimal blood splatter may occur.

Keep the needle housing within sight at all times to avoid accidental needle stick injury.

Always inspect the packaging for damage prior to use. Sensors

are sterile and nonpyrogenic, unless the package has been opened or damaged. Do not use any of the sensors if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.

Watch for bleeding at the insertion site (under, around, or on top of the sensor). Apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes, if bleeding occurs. The use of unsterile gauze can cause an infection.

Do not attach the transmitter to the sensor, if bleeding does not stop. Blood can get into the transmitter's connector, which can damage the device. Remove the sensor and continue to apply steady pressure until the bleeding stops.

1. Remove the sensor and discard.
2. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation and treat accordingly.
3. Insert a new sensor in a different location.

Keep the sensor away from children. This product contains small parts and may pose a choking hazard.

General precautions

Wash your hands with soap and water before inserting the sensor to help prevent site infection.

Wear gloves when inserting the sensor into someone other than yourself to avoid contact with patient blood.

Do not insert the sensor through tape to ensure proper sensor function and insertion.

Only use alcohol to prepare the insertion site to ensure that residue is not left on the skin.

Rotate the sensor insertion site so that sites do not become overused.

Discard used sensors and needle housings in a sharps container after each use to avoid accidental needle stick injury.

Do not clean, resterilize, or try to extract the needle from the needle housing. An accidental needle stick may occur.

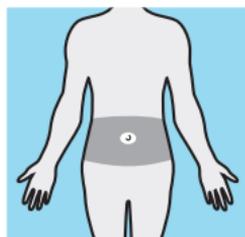
Do not reuse sensors. Reuse of the sensor may cause damage to the sensor surface and lead to inaccurate glucose values, site irritation, or infection.

Where to insert the sensor

WARNING: Always refer to the Enlite Serter User Guide for instructions on inserting the sensor. Failure to follow directions may result in pain or injury.

CAUTION: Avoid the 2 inch (5.0 cm) area around the navel to help ensure a comfortable insertion site, and to help with adhesion.

Choose an insertion site that has an adequate amount of subcutaneous fat. Shown here are the best body areas (shaded) for sensor insertion.



Do not insert the sensor in muscle or areas constrained by clothing or accessories; areas with tough skin or scar tissue; sites subjected to rigorous movement during exercise; or in sites under a belt or on the waistline to avoid chafing or site irritation.

Removing the sensor

When you are ready to change your sensor, disconnect the transmitter from the sensor as described in your transmitter user guide. Gently pull the sensor from your body to remove it. Place it in a sharps container.

Reagents

The sensor contains two biological reagents: glucose oxidase and human serum albumin (HSA). Glucose oxidase is derived from *Aspergillus Niger*, purified and dried according to Type VII-S guidelines and cross-linked to HSA, purified and dried albumin fraction V, derived from pasteurized human serum with glutaraldehyde. Since less than 0.4 μg of glucose oxidase and less than 0.7 μg of HSA is used to manufacture each sensor, the risks of tissue reactions and viral transmission are considered minimal.

Storage and handling

CAUTION: Do not freeze the sensor, or store it in direct sunlight, extreme temperatures, or humidity. These conditions may damage the sensor.

Store sensors at room temperature between +36°F to +86°F (+2°C to +30°C). If the sensor is stored in a cool environment, allow the sensor to warm to room temperature to prevent condensation. Do not store sensors at temperatures lower than +36°F (+2°C).

Discard sensor after “Use by” on label, or if the package is damaged, or the seal is broken.

Specifications

Dimensions	2.46 x 2.50 x 1.87 inches
Weight	6.25 grams

Sensor life of use

The sensor can be used one time, and it has a maximum life of 144 hours (six days). The 144-hour life span of the sensor begins when the insulin pump or monitor receives the first METER BG NOW alert.

Icon table

	Use by
	Do not reuse
	Follow instructions for use
REF	Catalogue number
	Batch code
	Sterilized using irradiation
	Temperature limitation
	Date of manufacture
	Open here
	Manufacturer

RELEASED



Medtronic



Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
USA
800 646 4633
818 576 5555
www.medtronicdiabetes.com

R_x Only

REF MMT-7008A, MMT-7008B
6025676-013_a

MP6026071-011 / 1



MiniLink[®] REAL-Time

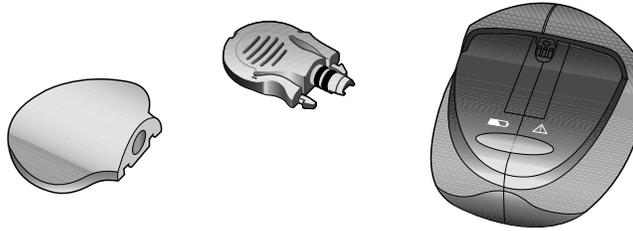
TRANSMITTER



MP6026071-011 / 1

RELEASED

The Medtronic MiniLink® transmitter is a component of a MiniMed® 530G or a MiniMed® Paradigm® REAL-Time Revel™ sensor-augmented system. The transmitter powers the glucose sensor, collects glucose data, and wirelessly sends the data to the sensor-augmented pump.



A complete MiniLink kit includes:

- MiniLink transmitter (MMT-7703)
- Two watertight testers (MMT-7726)
- Sensor insertion device
- Blue charger (MMT-7705)
- AAA or LR-03 alkaline battery(ies)

Indications for use

The transmitter is indicated for use as a component of select Medtronic continuous glucose sensing systems, the MiniMed 530G, or the Paradigm REAL-Time Revel system.

Contraindications

Do not expose your transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. If your transmitter is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

Warnings

Product contains small parts and may pose a choking hazard for young children.

The sensor should be removed if redness, bleeding, pain, tenderness, irritation, or inflammation develops at the insertion site, or if you experience unexplained fever.

The optional occlusive dressing should be removed if irritation or reaction develops.

Bleeding may occur after inserting the sensor. Make sure that the site is not bleeding before connecting the transmitter to the sensor.

- If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.
- If bleeding persists after three minutes, remove the sensor and discard. Insert a new sensor in a different location.

Contact the 24 Hour HelpLine if you experience any adverse reactions associated with the transmitter or sensor.

Magnetic fields

Do not expose your transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. If your transmitter is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

X-rays, MRIs, diathermy devices, and CT scans

If you are going to have an X-ray, diathermy treatment, CT scan, MRI, or other type of exposure to radiation, disconnect your transmitter and remove your sensor before entering a room that contains any of this equipment.

Important information about airport security systems, and using your insulin pump on an airplane, can be found on the Emergency Card. Be sure to carry the Emergency Card provided when you are traveling.

Precautions

Establish a rotation schedule for choosing new sensor sites. Avoid sites that are constrained by clothing, have scar tissue, or are subject to rigorous movement during exercise.

Only use the watertight tester with the transmitter. Do not use any other test plug.

Do not twist the tester while it is attached to the transmitter. This will damage the transmitter.

Do not allow water, or any other liquid, to come in contact with the tester when it is not connected to the transmitter. A wet tester can cause damage to the transmitter.

Do not clean the o-rings on the tester, as this can damage the o-rings.

Notice

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility.

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

The transmitter does not interfere with any radio frequency (RF) signals transmitted from outside sources. These FCC standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference.

Warning: Any changes or modifications to the devices not expressly approved by Medtronic Diabetes could interfere with your ability to operate the equipment, cause injury, and void your warranty.

RF interference from other devices

Common consumer electronic devices that transmit in the same frequency band used by the transmitter may prevent the receiving device (MiniMed 530G or Revel insulin pump) from receiving the glucose information sent by the transmitter. Most cellular (mobile) phones and 900 MHz cordless phones, when transmitting or receiving, may cause significant interruption of transmitter-receiver communication. It is likely that other devices operating in similar frequency ranges will have a similar effect. This interference, however, will not cause any incorrect data to be sent and will not cause any harm to your transmitter.

MiniMed 530G and Revel insulin pumps include a programmable “Weak Signal” alert that notifies you when one or more transmitter transmissions were not received as expected by the receiving device. (The receiving device will also issue a “Lost Sensor” alert if communication is interrupted for approximately 40 minutes.)

Communication problems can typically be resolved by ensuring that the distance between transmitter and receiving device is less than six feet (1.8 meters), and by turning off or moving away from other RF transmitting devices. You can also reorient or relocate the transmitter and/or the receiving device to try to correct the interference. Testing conducted with several different cellular phones suggests that interference will not be a problem if the phone is at least 12 inches (31 cm) from the transmitter or receiving device while it is being used (greater separation distance may be required for certain devices).

Assistance

Medtronic MiniMed provides a 24 Hour HelpLine for assistance. The HelpLine is staffed with representatives who are trained in the set-up and operation of your CGM system. When calling the HelpLine, please have your pump serial number available. Your pump serial number and the 24 Hour HelpLine phone number are listed on the back of your device.

Department	Telephone number
24 Hour HelpLine (calls within the United States)	800 646 4633
24 Hour HelpLine (calls outside the United States)	+1 818 576 5555
Web site	www.medtronicdiabetes.com

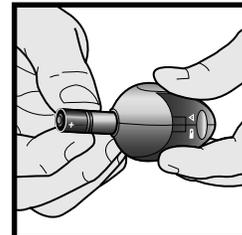
Charger

The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If you see a red light, see the Troubleshooting section. The charger needs one AAA alkaline battery, size E92, type LR03 (Energizer® brand recommended) to operate.

Note: *If the battery is installed incorrectly or is low, the charger will not work. Repeat the battery installation steps using a new battery.*

Installing a battery in the blue charger

- 1 Remove the charger battery cap by turning it counter-clockwise 1/4 turn using a coin in the groove of the cap.
- 2 Insert a new AAA or LR-03 battery with the flat (-) end first. Make sure that you align the small bumps on the battery cap with the small notches in the charger's battery opening. Push in the cap all the way using a coin. Turn the cap clockwise 1/4 turn to close.



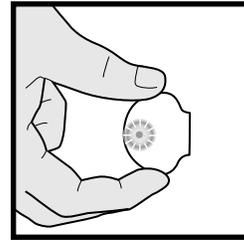
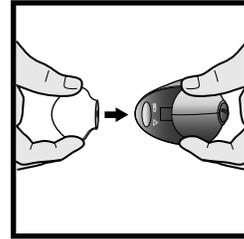
Charging the transmitter

Before using the transmitter for the first time, you must fully charge the transmitter battery. This may take up to eight hours. A depleted transmitter can take up to two hours to recharge.

The transmitter is designed to turn off after seven days (168 hours) of use. This is to maintain battery life, and to remind you to change your sensor. Recharge your transmitter after each sensor use.

To charge the transmitter:

- 1 If the green light on the transmitter is lit or flashing, do not connect it to the charger. The transmitter will not charge with its green light on. Wait until the green light turns off (approximately 30 seconds), and then connect the transmitter to the charger.
- 2 Connect the transmitter to the charger by lining it up, flat side down, with the charger. Push the two components together fully.
- 3 Within 10 seconds after the transmitter is connected, a green light on the charger will flash for one to two seconds as the charger powers on. For the rest of the charging time, the charger's green light will continue to flash in a pattern of four flashes with a pause between the four flashes.
- 4 When charging is complete, the green light on the charger will stay on, without flashing, for 15 to 20 seconds and then turn off.
- 5 After the green charger light turns off, disconnect the transmitter from the charger. The green light on the transmitter will flash for about five seconds and then turn off.



Setting up the transmitter

For instructions on setting up your transmitter, see the user guide for your pump.

Connecting the transmitter to the sensor

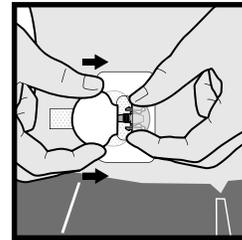
Before connecting the transmitter and sensor, make sure of the following:

- The transmitter is fully charged.
- Consult the user guide for your pump for details on setting up and starting the sensor.
- Insert the sensor.

- The sensor insertion site is not bleeding.

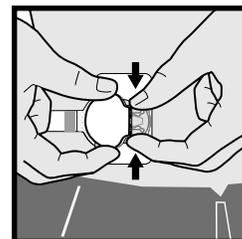
To connect the transmitter to the sensor:

- 1 After the sensor is inserted, apply the Enlite® overtape to the sensor. Consult the user guide for your Enlite Serter for details on applying Enlite overtape.
- 2 Touch the rounded end of the inserted sensor to prevent it from moving during connection.
- 3 Hold the rounded end of the inserted sensor to prevent it from moving during connection.
- 4 Hold the transmitter as shown. Line up the two notches on the transmitter with the side arms of the sensor. The flat side of the transmitter should face the skin.
- 5 Slide the transmitter onto the sensor connector until the sensor's flexible arms snap into the notches on the transmitter. If the transmitter is properly connected, and if the sensor has had enough time to become hydrated, the green light on the transmitter will flash within 10 seconds.
- 6 If the transmitter light does not flash, disconnect it from the sensor, wait for several seconds and then reconnect. If the transmitter light still does not flash, charge the transmitter.
- 7 After the transmitter light flashes green, attach the sensor's adhesive tab to the transmitter.
- 8 Use your pump to communicate with the sensor. For more instructions, see the user guide for your pump.
- 9 [Optional]: Apply occlusive dressing over the transmitter and the sensor.



Disconnecting the transmitter from the sensor

- 1 Carefully remove any occlusive dressing from the transmitter and sensor.
- 2 Remove the sensor's adhesive tab from the transmitter.
- 3 Hold the transmitter as shown, and pinch the flexible side arms of the sensor between your thumb and forefinger.
- 4 Gently pull the transmitter away from the sensor.



Bathing and swimming

After the transmitter and sensor are connected, they form a waterproof seal to a depth of eight feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them. No occlusive dressing is needed.

Watertight tester

The tester is used to test the transmitter to make sure it is working. It is also used as a required component for cleaning the transmitter. Properly connecting the tester to the transmitter will ensure that fluids do not come in contact with the transmitter's connector pins. Fluids can cause connector pins to corrode and affect the transmitter's performance.

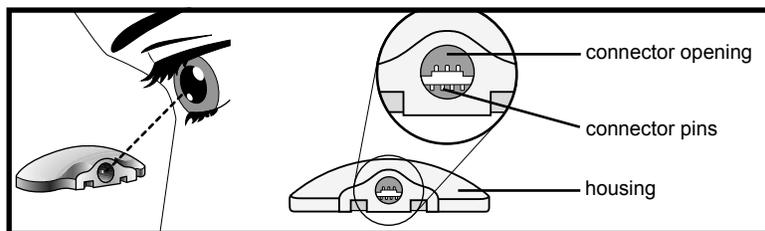
Each tester can be used a total of 30 times. Open and use one tester at a time. Keep track of the tester uses on the supplied log sheet and discard the tester after 30 uses in a bio-waste container. If you continue to use the tester beyond 30 times, the transmitter's connector pins could be damaged, because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see *Inspecting the transmitter connector pins, on page 7*.

Caution: Only use the watertight tester with the transmitter. Do not use any other test plug.



Inspecting the transmitter connector pins

This image is an example of how the connector pins should look.



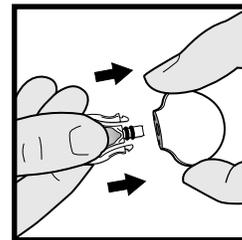
Look inside the transmitter's connector opening to make sure that the connector pins are not damaged or corroded. If the connector pins are damaged or corroded, the transmitter cannot communicate with the charger or pump. Contact the 24 Hour HelpLine. It may be time to replace your transmitter.

Also look for moisture inside the connector opening. If you see any moisture, allow the transmitter to dry for at least one hour. Moisture inside the connector opening could cause the transmitter to not work properly, and could cause corrosion and damage over time.

Connecting the tester for testing or cleaning

To connect the tester:

- 1 Hold the transmitter and the tester as shown. Line up the flat side of the tester with the flat side of the transmitter.
- 2 Push the tester into the transmitter until the flexible side arms of the tester click into the notches on both sides of the transmitter. Within 20 seconds the green light on the transmitter will flash for about 10 seconds when properly connected.
- 3 To test the transmitter, check the sensor icon on the pump or monitor to ensure that the transmitter is sending a signal (see the user guide for your device).
- 4 To clean the transmitter, see *Cleaning/disinfecting the transmitter*, on page 9.
- 5 After testing or cleaning, disconnect the tester from the transmitter.

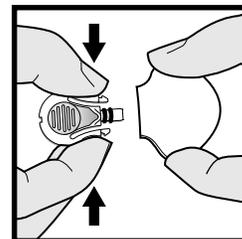


Disconnecting the tester

To disconnect the tester:

- 1 Hold the transmitter body as shown and pinch the side arms of the tester.
- 2 With the tester arms pinched, gently pull the transmitter away from the tester.

Note: To save transmitter battery life, do NOT leave the tester connected after cleaning or testing.



Cleaning/disinfecting the transmitter

The transmitter is intended for personal use at home (single-patient use) or for use in healthcare facilities (multiple-patient use). Single-patient use requires cleaning after each use, while multi-patient use requires cleaning and disinfection after each use. When using the transmitter in a healthcare facility, always follow the cleaning and disinfecting procedure for multiple-patient use.

Caution: Do not discard the transmitter in a medical waste container or otherwise subject it to incineration. The transmitter contains a battery that may explode upon incineration.

Note: The tester is a required component for cleaning and disinfecting the transmitter. For details, see *Watertight tester*, on page 7.

For single-patient use

Always clean the transmitter after each use.

To clean the transmitter, you will need the following materials: Ivory[®] liquid soap, a soft-bristled toddler toothbrush, a container, 70% isopropyl alcohol, and a few clean, dry cloths. You can buy these supplies from retailers such as Walmart, Target, or <http://www.amazon.com>.

Use life

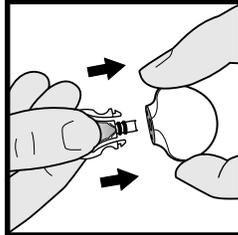
The MiniLink transmitter can be cleaned up to 122 cycles or one year, whichever comes first. Discard the transmitter at this point. If you continue to use the transmitter beyond 122 cycles or one year, the cleaning process may damage the device. Contact Medtronic to order a new transmitter. The transmitter was validated to last 122 cycles, which represents one cleaning cycle every three days for one year.

Warning: Cracking, flaking, or damage of the housing are signs of deterioration and the performance of the device may be compromised. This may affect the ability to properly clean and disinfect the transmitter. If these signs are noted, stop using the device and call the Medtronic Diabetes 24 Hour HelpLine. The device must be discarded according to local regulations for battery disposal (non-incineration).

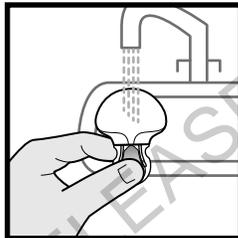
To clean the transmitter:

- 1 Wash your hands thoroughly.

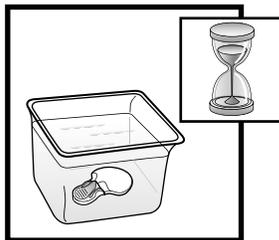
- 2 Attach the tester to the transmitter.



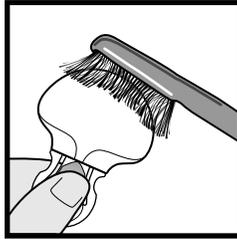
- 3 If optional occlusive dressing was used and there is adhesive residue on the transmitter, follow the instructions in *Removing adhesive residue, on page 17*.
- 4 Rinse the transmitter under cool tap water for at least one minute and until visibly clean. Make sure all hard-to-reach areas are rinsed completely.



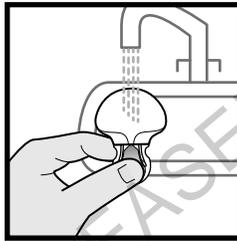
- 5 Prepare a mild liquid soap solution using one (1) teaspoon of Ivory® liquid soap per one (1) gallon of room temperature tap water.
- 6 With tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.



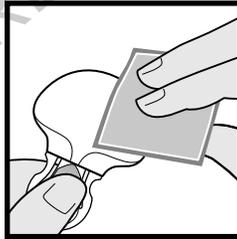
- 7 Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.



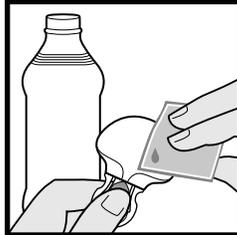
- 8 Rinse the transmitter under running room temperature tap water for at least one minute, and until all visible liquid soap is gone.



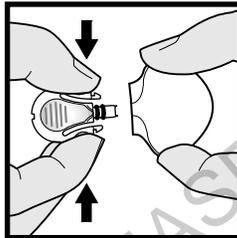
- 9 Dry the transmitter and tester with a clean, dry cloth.



- 10 Holding the tester, wipe the transmitter with 70% isopropyl alcohol.



- 11 Place the transmitter and tester on a clean, dry cloth and air dry them completely.
- 12 Disconnect the tester from the transmitter.



For multiple-patient use

When using the transmitter in a healthcare facility, always clean and disinfect the transmitter after each use.

Warning: You must adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*, <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.

The transmitter must be disinfected after use on each patient. This system may only be used for testing multiple patients when Standard Precautions and Medtronic's disinfection procedures are followed.

To clean and disinfect the transmitter, you will need the following materials: gloves, ENZOL[®] Enzymatic Detergent, a soft-bristled toddler toothbrush, Clorox[®] Regular-Bleach, 70% isopropyl alcohol, two containers, and a few clean, dry cloths. You can buy these supplies from retailers such as Walmart, Target, or <http://www.amazon.com>.

Use life

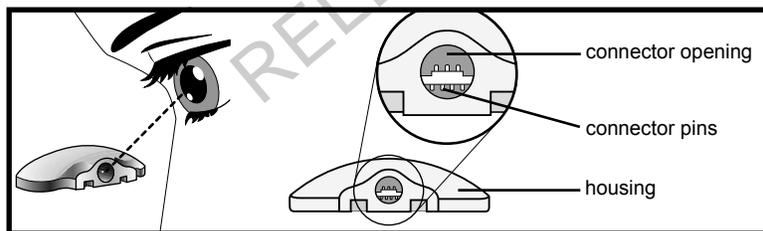
The MiniLink transmitter can be cleaned and disinfected up to 122 cycles or one year, whichever comes first. Discard the transmitter at this point. If you continue to use the transmitter beyond 122 cycles or one year, the cleaning and disinfection process may damage the device. Contact Medtronic to order a new transmitter. The transmitter was validated to last 122 cycles, which represents one cleaning cycle every three days for one year.

To clean and disinfect the transmitter:

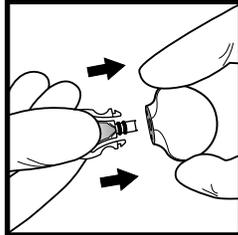
- 1 Wash your hands and put on gloves.
- 2 Inspect the inside of the transmitter's connector opening for any sign of body fluid. For instructions on how to inspect the connector pins, see *Inspecting the transmitter connector pins*, on page 7.

Caution: The person inspecting the transmitter must have sufficient vision that enables him or her to see small drops of body fluid or debris.

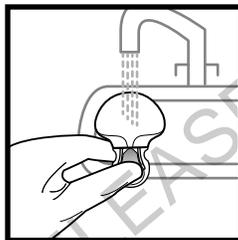
Warning: If you see any body fluid in the connector opening, you must discard the transmitter. Because the transmitter contains a battery, do not discard in a bio-waste container. Instead, continue to clean and disinfect the transmitter, and then discard according to local regulations for battery disposal (non-incineration).



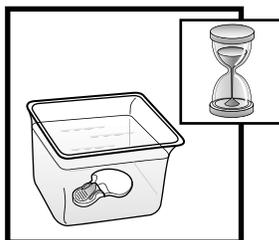
- 3 Attach the tester to the transmitter.



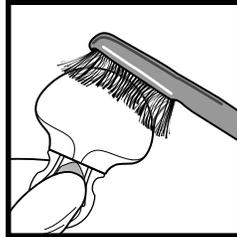
- 4 If optional occlusive dressing was used and there is adhesive residue on the transmitter, follow the instructions in *Removing adhesive residue, on page 17*.
- 5 Rinse the transmitter under cool tap water for at least one minute and until any visible debris is gone.



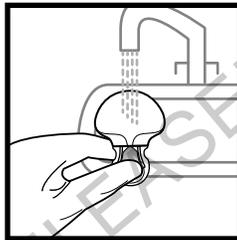
- 6 Prepare an enzymatic solution using two (2) ounces of ENZOL[®] Enzymatic Detergent per gallon of water. Make sure to prepare a fresh solution for each use.
- 7 With the tester still attached, fully submerge the transmitter in the enzymatic solution for one minute.



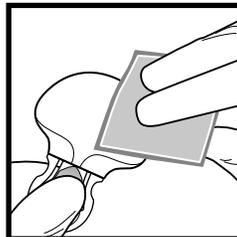
- 8 Holding the tester, remove the transmitter from the solution. Brush the entire surface of the transmitter using a soft-bristled brush, paying close attention to hard-to-clean areas, until visibly clean.



- 9 Rinse the transmitter under room temperature tap water until all visible detergent is gone.

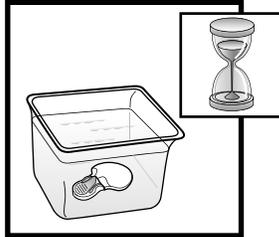


- 10 Dry any excess moisture by wiping the outside of the transmitter with a clean, dry cloth.

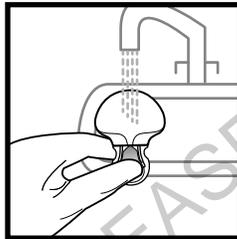


- 11 Prepare a 1:10 bleach solution by using one (1) part 8.25% bleach to nine (9) parts water, for a final concentration of 0.825%. Make sure to prepare a fresh solution for each use.

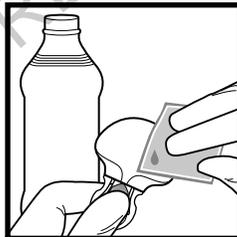
- 12 Make sure that you have completed the previous cleaning steps before disinfection. With the tester still attached, soak the transmitter in the bleach solution for 20 minutes.



- 13 Rinse the transmitter under room temperature tap water for three minutes.



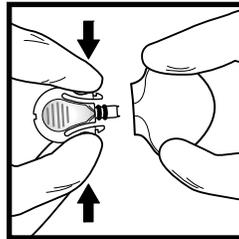
- 14 Holding the tester, wipe the transmitter with 70% isopropyl alcohol.



- 15 Place the transmitter and tester on a clean, dry cloth and air dry them completely.

Warning: If you saw any body fluid inside the connector opening on earlier inspection, you must now discard the transmitter with tester still attached, according to local regulations for battery disposal (non-incineration).

- 16 Disconnect the tester from the transmitter by gently squeezing the arms of the tester.



- 17 Inspect the housing of the transmitter for any signs of cracking, flaking, or damage. If you see any of these signs, you must now discard the disinfected transmitter according to local regulations for battery disposal (non-incineration).

Warning: Cracking, flaking, or damage of the housing are signs of deterioration and the performance of the device may be compromised. This may affect the ability to properly clean and disinfect the transmitter. If these signs are noted, stop using the device and call the Medtronic Diabetes 24 Hour HelpLine. The device must be discarded according to local regulations for battery disposal (non-incineration).

- 18 Discard the used gloves and thoroughly wash hands with soap and water.

Removing adhesive residue

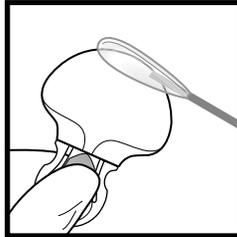
You may need to perform this procedure only if you have used optional occlusive dressing, which may leave adhesive residue on the transmitter. If you visually inspect the transmitter and see adhesive residue on it, follow the instructions below.

To remove adhesive residue, you will need the following materials: Detachol[®] medical adhesive remover and cotton swabs. You can buy Detachol[®] at <http://www.amazon.com/>, <http://www.medtronicdiabetes.com>, or by calling 800 646 4633.

To remove adhesive residue:

- 1 Make sure the tester is attached to the transmitter.

- 2 Holding the tester, saturate a cotton swab in the Detachol solution and gently rub the adhesive residue on the transmitter until it is fully removed.



- 3 Continue with the appropriate single-patient or multiple-patient cleaning procedure above.

Cleaning the charger

The charger cannot be disinfected. This procedure is for general cleaning as required, based on physical appearance.

Caution: The charger is NOT waterproof. Do NOT immerse in water or any other cleaning agent.

Caution: Dispose the charger according to the local regulations for battery disposal (non-incineration).

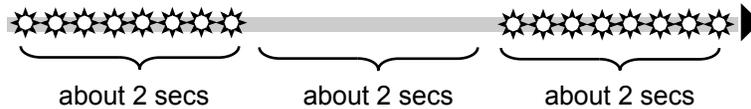
Warning: For multiple-patient use, always clean and disinfect the transmitter after removing it from the patient and before attaching it to the charger. If blood comes in contact with any surface areas of the charger, the contaminated device must be discarded. The charger contains a battery which may explode upon incineration.

To clean the charger:

- 1 Wash your hands thoroughly.
- 2 Use a damp cloth with mild cleaning solution, such as a dishwashing detergent, to clean any dirt or foreign material from the outside of the charger. Never use organic solvents, such as paint thinner or acetone, to clean the charger.
- 3 Place the charger on a clean, dry cloth and air dry for two to three minutes.

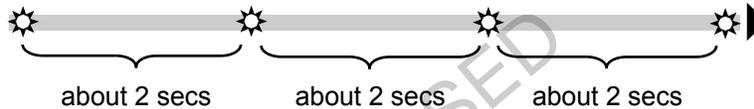
Troubleshooting

Question: Why do I see quick flashing red lights on the charger?



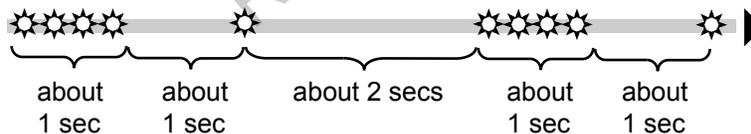
Answer: The transmitter battery is very low. Leave the transmitter on the charger for eight hours to completely recharge. If the red light is still flashing after eight hours, leave your transmitter on the charger for 24 hours. If the red light is still flashing after its been charging continuously for 24 hours, contact the 24 Hour HelpLine. It may be time to replace your transmitter.

Question: Why did the flashing green charger light turn off and a longer flashing red charger light turn on during charging?



Answer: Your charger battery is low. Make sure the transmitter is not connected to the charger and replace the charger battery with a new AAA or LR-03 battery.

Question: Why do I see a mix of quick and long flashing red lights on the charger?



Answer: Your charger AND transmitter batteries are very low. Replace the charger's AAA or LR-03 battery. If you now get the pattern for very low transmitter battery, leave the transmitter on the charger for eight hours to recharge. If the red light is still flashing after eight hours, leave your transmitter on the charger for 24 hours. If the red light is still flashing after its been charging continuously for 24 hours, contact the 24 Hour HelpLine. It may be time to replace your transmitter.

Question: I had my transmitter on the charger for a day. Will this damage my transmitter?

Answer: It will not damage the transmitter. You cannot overcharge it.

Question: What should I do if the transmitter green light does not flash when connected to the sensor?

Answer: Is the sensor inserted in the body? If **it is not inserted**, the transmitter will not flash green or send signals to your pump or monitor.

If the **sensor is inserted** in the body, you need to disconnect the transmitter from the sensor, wait for several seconds and then reconnect. If the green light still does not flash, charge the transmitter.

Question: Why didn't I see the transmitter green light flash after connecting it to the tester?

Answer: Check the connection. If you still do not see a green light flash, fully recharge the transmitter battery. Test the transmitter with the tester. If you still do not see a green light flash, contact the 24 Hour HelpLine. It may be time to replace your transmitter.

Storing the devices

Store the transmitter, charger, and tester in a clean, dry location at room temperature. Although not required, you may store the transmitter on the charger. If the transmitter is not in use, you must charge the transmitter at least once every 60 days.

Specifications

Biocompatibility	Transmitter: Complies with ISO 10993-1 for body contact
Applied parts	Transmitter Sensor
Operating conditions	Transmitter Temperature: +32° to +122°F (0° to 50°C) Caution: When operating the transmitter on a tester in air temperatures greater than 106°F (41°C), the temperature of the transmitter may exceed 109°F (43°C). Transmitter Relative Humidity: 10% to 95% with no condensation Charger Temperature: +50° to +104°F (10° to 40°C) Charger Relative Humidity: 30% to 75% with no condensation
Storage conditions	Transmitter Temperature: -4° to +131°F (-20° to +55°C) Transmitter Relative Humidity: 10% to 100% with condensation Charger Temperature: +14° to +122°F (-10° to +50°C) Charger Relative Humidity: 10% to 95% with no condensation

Battery life	Transmitter: Recharge the transmitter after each sensor use. This maintains the life of the transmitter battery. Charger: Uses one new AAA or LR-03 battery to charge the transmitter.
Transmitter frequency	MMT-7703NA 916.5 megahertz MMT-7703WW 868.35 megahertz
Transmitter size	The dimensions of the transmitter are approximately: 1.13 x 1.41 x 0.38 inches
Transmitter weight	The weight of the transmitter is approximately 5.4 grams.
Charger size	The dimensions of the charger are approximately: 1.71 x 2.29 x 1.08 inches
Charger weight	The weight of the charger is approximately 19.6 grams.

RELEASED

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The MiniLink transmitter (MMT-7703 transmitter) is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniLink transmitter should make sure that it is used in such an environment. The transmitter contains no reparable parts.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The MiniLink transmitter uses RF energy only for system communication functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MiniLink transmitter is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	<p>Note: The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. However, since the MiniLink transmitter is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.</p>
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV indirect ±8 kV air	±6 kV indirect (30-60% relative humidity) ±30 kV air (<5% relative humidity)	The MiniLink transmitter should not be affected by electrostatic discharge that might occur under normal conditions of use.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable Not applicable	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Not applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Not applicable Not applicable Not applicable Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the MiniLink transmitter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 80MHz to 800 MHz $d=2.3\sqrt{P}$ 800MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) tele-phones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MiniLink transmitter is used exceeds the applicable RF compliance level above, the MiniLink transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MiniLink transmitter.</p>			

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Recommended separation distances between portable and mobile RF communications equipment and the MiniLink transmitter (MMT 7703 transmitter)		
This section provides information on the recommended separation distance between portable and mobile RF communications equipment and the MiniLink transmitter. The MiniLink transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MiniLink transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MiniLink transmitter as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)	
	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.74
1	1.2	2.3
10	3.8	7.4
100	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		
NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Warranty

Medtronic MiniMed warrants the Medtronic MiniLink transmitter to the purchaser of the product against defects in material and workmanship for a period of twelve (12) months and the charger for up to six (6) months from the date of purchase.

During the warranty period, Medtronic MiniMed will repair or replace, at its discretion, any defective MiniLink transmitter or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a MiniLink transmitter or charger is repaired or replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic MiniLink transmitter or charger is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the MiniLink transmitter or charger by the user, or third parties, after the date of sale;
- If service or repairs are performed by any person or entity other than the manufacturer;
- If damage results from a *Force Majeur* or other event beyond the control of the manufacturer;
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in fluid, physical abuse (such as dropping); or
- If blood or water has entered the inside of the MiniLink transmitter connector.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to Glucose Sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any defects in material or workmanship in the product. Any statutory rights granted to consumers under any applicable legislation are reserved. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, punitive or special damages of any nature or kind caused by or arising out of a defect in the product.

All other warranties, except any applicable mandatory statutory warranties, expressed or implied, are excluded and specifically disclaimed, including, but not limited to, any warranty of merchantability or fitness for a particular purpose.

Icon table

	Serial number
	Catalogue or Model Number
(1X)	One per container/package
(2X)	Two per container/package
	Date of manufacture
	Manufacturer
	Refer to instructions before each use (appears blue on label).
	Temperature limit

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	Non-ionizing electromagnetic radiation (RF communication).
CONF	Configuration
	Degree of protection against electric shock: Type BF applied part
IPX8	Transmitter: Degree of protection against water and debris under conditions provided by the manufacturer.
	Caution: Specific warnings may not be found on label.
	Humidity limitation

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MMT-7726
MMT-7705



6026071-011_1

Enlite® Sensor Performance for the Paradigm® REAL-Time Revel™ Insulin Pump

CGM performance

The Paradigm® REAL-Time Revel™ insulin pumps (MMT-523/723) are integrated with CGM (Continuous Glucose Monitoring) technology. CGM enables your pump to display sensor glucose readings, glucose trend arrows, glucose trend graphs, as well as sensor glucose alerts (for example, High and Low Limit alerts, High and Low Predicted alerts, and Rise and Fall Rate of Change alerts).

Clinical study description

The performance of the Enlite® sensor was evaluated in a clinical study¹. This inpatient (in-clinic) and outpatient (at home) study included subjects 18 to 75 years in age. The study design was a multi-center, prospective single-sample correlational design without controls. All subjects were assigned to treatment. Each subject was instructed to wear two Enlite sensors (MMT-7008). Bayer's CONTOUR® NEXT LINK Wireless Meter was used as the study meter, and used for all study calibrations. This system has not been tested with other meters. Performance of this system with other blood glucose meters may differ from the performance with Bayer's CONTOUR NEXT LINK Wireless Meter.

A total of 111 subjects previously diagnosed with type 1 or 2 diabetes were enrolled in the study. Twenty subjects failed the screening. Sixty one subjects with abdominal insertions completed the study, and one subject enrolled after the study was completed. Frequent sample testing (FST) was performed on days 1, 3, and 6. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI®) Glucose Analyzer every 5 to 15 minutes and then compared with sensor glucose values. During the FSTs, subjects were instructed to calibrate one sensor three to four times throughout the day. They also calibrated the other sensor once every 12 hours. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times throughout the day.

During each FST, subjects with established insulin sensitivity and insulin carbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge. Subjects were instructed to continue with their current diabetes regimen, independent of their study devices. This included glucose monitoring with their own meter when desired. The meter was used for confirmation of alarms, treatment decisions, and sensor calibrations.

Results

Sensor accuracy

The following information highlights the sensor performance using the Revel algorithm during normal use. Compared to calibrating every 12 hours, the data indicates that calibrating three to four times per day at any time will result in a 0.6% mean absolute relative difference (MARD) improvement within YSI glucose ranges. Additionally, compared to calibrating every 12 hours, the data indicates that calibrating three to four times per day at any time will result in a 1.6% MARD improvement within CGM glucose ranges.

Mean and median absolute relative difference, by number of daily calibrations

The following tables describe the mean/median relative difference and mean/median absolute relative difference of CGM to YSI. These results are shown for comparing the Enlite sensor (CGM readings) and the reference YSI value when calibrating three to four times per day and when calibrating every 12 hours. The overall mean absolute relative difference (MARD) between the Enlite sensor (CGM readings) and the reference YSI values was 15.6% and the median ARD was 11.5%, from inpatient frequent sample testing (FST) during hypoglycemic and hyperglycemic challenges.

Table 1. CGM difference to YSI within YSI glucose ranges, calibrating three to four times per day, abdomen insertion site.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean relative difference (%)	Median relative difference (%)	Mean absolute relative difference (%)	Median absolute relative difference (%)
Overall	7403	6.27	4.49	15.57	11.45
<40*	3	30.85	32.65	30.85	32.65
40-60*	631	12.60	11.65	13.94	11.70

1 Medtronic Inc., A Performance Evaluation of the Enlite® Glucose Sensor to Support a Full 144 hours (6 Days) of Use, CER247/Z25/C, May 2012.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean relative difference (%)	Median relative difference (%)	Mean absolute relative difference (%)	Median absolute relative difference (%)
61-80*	1430	10.37	9.10	14.34	11.40
81-180	3225	5.10	4.68	13.55	10.45
181-300	1640	-1.61	-1.66	11.65	8.91
301-350	318	-6.25	-5.82	10.68	8.59
351-400	135	-12.49	-10.80	13.50	10.86
>400	21	-29.76	-31.04	29.76	31.04

* For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of relative difference (%).

Note: CGM readings are within 40 to 400 mg/dL.

Table 2. CGM difference to YSI within YSI glucose ranges, calibrating every 12 hours, abdomen insertion site.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean relative difference (%)	Median relative difference (%)	Mean absolute relative difference (%)	Median absolute relative difference (%)
Overall	7467	5.24	3.87	16.15	11.36
<40*	3	33.18	33.65	33.18	33.65
40-60*	543	13.43	11.40	15.22	11.85
61-80*	1376	7.77	5.75	13.90	10.40
81-180	3146	5.66	5.56	14.86	11.12
181-300	1885	-1.92	-0.54	12.46	9.13
301-350	345	-6.69	-3.53	12.38	7.96
351-400	136	-11.44	-7.53	12.83	8.44
>400	33	-27.54	-22.91	27.54	22.91

* For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of relative difference (%).

Note: CGM readings are within 40 to 400 mg/dL.

Table 3. CGM difference to YSI within CGM glucose ranges, calibrating three to four times per day, abdomen insertion site.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean relative difference (%)	Median relative difference (%)	Mean absolute relative difference (%)	Median absolute relative difference (%)
Overall	7403	-2.20	-4.29	14.51	11.11
40-60*	406	5.76	4.15	8.60	5.73
61-80*	1178	-3.48	-6.37	11.39	9.60
81-180	3703	-4.12	-5.90	15.43	11.80
181-300	1724	0.66	-0.55	12.31	9.81
301-350	287	-2.55	-2.28	9.50	6.62
351-400	105	-7.58	-6.74	9.63	7.98

* For CGM range ≤ 80 mg/dL, the differences in mg/dL are included instead of relative difference (%).

Table 4. CGM difference to YSI within CGM glucose ranges, calibrating every 12 hours, abdomen insertion site.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean relative difference (%)	Median relative difference (%)	Mean absolute relative difference (%)	Median absolute relative difference (%)
Overall	7467	-0.20	-3.72	16.08	11.05

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean relative difference (%)	Median relative difference (%)	Mean absolute relative difference (%)	Median absolute relative difference (%)
40-60*	436	9.81	7.60	12.07	8.40
61-80*	1077	0.77	-4.15	13.04	8.00
81-180	3575	-2.49	-5.88	17.38	12.50
181-300	1885	-0.44	-2.13	12.11	8.96
301-350	346	-2.19	-1.31	9.83	7.76
351-400	148	-7.37	-6.78	10.68	9.43

*For CGM range ≤ 80 mg/dL, the differences in mg/dL are included instead of relative difference (%).

Percent agreement, by number of daily calibrations

The accuracy of the Enlite sensor (CGM) was evaluated by calculating the percentage of CGM readings within $\pm 15\%$, $\pm 20\%$, $\pm 30\%$, and $\pm 40\%$ of the YSI values (or within ± 15 , ± 20 , ± 30 , or ± 40 mg/dL in the low glucose range of 40 to 80 mg/dL). These results are shown for various YSI glucose ranges when calibrating three to four times per day and when calibrating every 12 hours. For example, 92.1% of all Enlite sensors readings overall were within 30% of the YSI value when calibrating three to four times per day.

Table 5. Agreement (%) of CGM-YSI paired points within YSI Glucose Ranges, abdomen insertion site, calibrating three to four times per day.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7403	66.8	79.4	92.1	96.5	3.5
<40*	3	0	33.3	33.3	66.7	33.3
$\geq 40-60^*$	631	62.9	78	91.4	97.3	2.7
>60-80*	1430	63.1	78.6	91.5	95.5	4.5
>80-180	3225	66	78	91.1	96.1	3.9
>180-300	1640	72.7	83.2	95.1	97.7	2.3
>300-350	318	75.5	86.5	95.3	98.7	1.3
>350-400	135	60.7	74.8	88.9	97	3
>400	21	14.3	23.8	47.6	85.7	14.3

*For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM readings are within 40 to 400 mg/dL.

Table 6. Agreement (%) of CGM-YSI paired points within YSI Glucose Ranges, abdomen insertion site, calibrating every 12 hours.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7467	65.7	77.1	89.4	95.3	4.7
<40*	3	0	33.3	33.3	66.7	33.3
$\geq 40-60^*$	543	61.5	75.3	87.1	95	5
>60-80*	1376	64.1	77	88.7	95.9	4.1
>80-180	3146	63	74.5	88.9	95.1	4.9
>180-300	1885	71	81	91.6	95.8	4.2
>300-350	345	73.9	83.2	90.4	94.2	5.8

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
>350-400	136	71.3	83.1	89.7	94.1	5.9
>400	33	42.4	45.5	69.7	81.8	18.2

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM readings are within 40 to 400 mg/dL.

The accuracy of the Enlite (CGM) sensor was evaluated by calculating the percentage of Enlite sensor readings within $\pm 15\%$, $\pm 20\%$, $\pm 30\%$, and $\pm 40\%$ (or within ± 15 , ± 20 , ± 30 , or ± 40 mg/dL in the low glucose range of 40 to 80 mg/dL) of the YSI values. These results are shown for various CGM glucose ranges when calibrating three to four times per day and when calibrating every 12 hours. For example, 92.0% of all Enlite sensors readings overall were within 30% of the YSI value when calibrating three to four times per day.

Table 7. Agreement (%) of CGM-YSI paired points within CGM glucose ranges, abdomen insertion site, calibrating three to four times per day.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7403	67.1	80.1	92	96.5	3.5
$\geq 40-60^*$	406	81	90.9	96.6	98.8	1.2
$>60-80^*$	1178	76.6	88.7	96.1	97.4	2.6
$>80-180$	3703	60.1	74.2	88.8	95.4	4.6
$>180-300$	1724	69.8	82.9	93.7	97	3
$>300-350$	287	79.1	87.8	96.5	99.7	0.3
$>350-400$	105	76.2	83.8	100	100	0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 8. Agreement (%) of CGM-YSI paired points within CGM glucose ranges, abdomen insertion site, calibrating every 12 hours.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7467	66.3	77.7	89.6	95.4	4.6
$\geq 40-60^*$	436	75	83.5	94	97.7	2.3
$>60-80^*$	1077	76.5	88.7	95.7	97.7	2.3
$>80-180$	3575	57.7	69.5	84.6	93	7
$>180-300$	1885	72	82.7	92.8	96.9	3.1
$>300-350$	346	77.5	89.6	95.4	99.4	0.6
$>350-400$	148	73	86.5	95.9	100	0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Agreement of low and high CGM readings compared to YSI glucose values

The following tables show the number and percentage of YSI values collected when CGM readings displayed 'Low' (less than 40 mg/dL) and 'High' (greater than 400 mg/dL).

Tables 9 and 10. The number and percentage of YSI values collected when CGM readings displayed 'Low' (less than 40 mg/dL) and 'High' (greater than 400 mg/dL), calibrating three to four times per day, abdomen insertion site.

YSI mg/dL							
CGM readings	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	0	0	0	0	0	0
'LOW'	Cumulative %	0%	0%	0%	0%	0%	

YSI mg/dL							
CGM readings	CGM-YSI pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	16	20	23	23	0	23
'HIGH'	Cumulative %	70%	87%	100%	100%	0%	

Tables 11 and 12. The number and percentage of YSI values collected when CGM readings displayed 'Low' (less than 40 mg/dL) and 'High' (greater than 400 mg/dL), calibrating every 12 hours, abdomen insertion site.

YSI mg/dL							
CGM readings	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	0	0	0	3	0	3
'LOW'	Cumulative %	0%	0%	0%	100%	0%	

YSI mg/dL							
CGM readings	CGM-YSI pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	65	79	89	90	0	90
'HIGH'	Cumulative %	72%	88%	99%	100%	0%	

Concurrence of CGM readings to YSI glucose values

The following tables show the percentage of concurring CGM readings with YSI reference values. With ideal performance the CGM readings would match the YSI values, therefore the shaded boxes would be 100 percent.

Table 13. The concurrence of YSI values and CGM readings using YSI glucose ranges, calibrating three to four times per day, abdomen insertion site.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of matched pairs-in each CGM glucose range for each YSI glucose range CGM (mg/dL)										
		<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) <40	3	0.0%	33.3%	66.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >=40-60	631	0.0%	34.1%	53.2%	11.6%	1.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
C) >60-80	1430	0.0%	12.1%	48.1%	37.0%	2.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D) >80-120	1423	0.0%	1.2%	9.5%	63.4%	24.5%	1.3%	0.1%	0.0%	0.0%	0.0%	0.0%
E) >120-160	1265	0.0%	0.0%	1.1%	12.9%	62.5%	21.3%	2.1%	0.2%	0.0%	0.0%	0.0%
F) >160-200	971	0.0%	0.0%	0.2%	1.3%	19.1%	56.0%	22.0%	1.1%	0.2%	0.0%	0.0%
G) >200-250	689	0.0%	0.0%	0.1%	2.0%	3.3%	24.1%	54.6%	13.9%	1.9%	0.0%	0.0%
H) >250-300	518	0.0%	0.0%	0.0%	0.8%	0.2%	2.3%	29.5%	46.1%	16.8%	4.1%	0.2%
I) >300-350	327	0.0%	0.0%	0.0%	0.0%	0.0%	1.2%	8.3%	36.4%	40.7%	10.7%	2.8%
J) >350-400	142	0.0%	0.0%	0.0%	0.7%	0.7%	0.7%	2.1%	26.8%	31.7%	32.4%	4.9%
K) >400	27	0.0%	0.0%	0.0%	0.0%	7.4%	0.0%	3.7%	29.6%	25.9%	11.1%	22.2%

Table 14. The concurrence of YSI values and CGM readings using YSI glucose ranges, calibrating every 12 hours, abdomen insertion site.

YSI glucose ranges (mg/dL)	Percent of matched pairs-in each CGM glucose range for each YSI glucose range CGM (mg/dL)											
	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) <40	3	0.0%	33.3%	33.3%	33.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >=40-60	543	0.0%	30.8%	52.3%	14.9%	2.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
C) >60-80	1379	0.2%	17.8%	46.1%	33.8%	2.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D) >80-120	1292	0.0%	1.3%	10.2%	55.8%	29.6%	2.9%	0.2%	0.0%	0.0%	0.0%	0.0%
E) >120-160	1327	0.0%	0.2%	1.0%	13.5%	61.2%	21.0%	3.1%	0.1%	0.0%	0.0%	0.0%
F) >160-200	991	0.0%	0.3%	0.1%	2.2%	21.3%	52.7%	21.5%	1.6%	0.3%	0.0%	0.0%
G) >200-250	838	0.0%	0.0%	0.0%	2.3%	7.0%	19.1%	53.2%	16.1%	1.7%	0.6%	0.0%
H) >250-300	586	0.0%	0.0%	0.2%	0.9%	1.0%	5.1%	27.1%	43.5%	18.1%	3.6%	0.5%
I) >300-350	372	0.0%	0.0%	0.8%	0.5%	2.2%	2.7%	5.4%	24.5%	41.7%	15.1%	7.3%
J) >350-400	174	0.0%	0.0%	1.1%	0.0%	0.6%	2.3%	4.0%	6.3%	34.5%	29.3%	21.8%
K) >400	55	0.0%	0.0%	7.3%	0.0%	0.0%	3.6%	0.0%	7.3%	14.5%	27.3%	40.0%

Table 15. The concurrence of CGM readings and YSI values using CGM glucose ranges, calibrating three to four times per day, abdomen insertion site.

CGM glucose ranges (mg/dL)	Percent of matched pairs-in each YSI glucose range for each sensor glucose range YSI (mg/dL)											
	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) >=40-60	406	0.2%	53.0%	42.6%	4.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >60-80	1178	0.2%	28.5%	58.4%	11.5%	1.2%	0.2%	0.1%	0.0%	0.0%	0.0%	0.0%
C) >80-120	1699	0.0%	4.3%	31.1%	53.1%	9.6%	0.8%	0.8%	0.2%	0.0%	0.1%	0.0%
D) >120-160	1397	0.0%	0.5%	2.9%	24.9%	56.6%	13.2%	1.6%	0.1%	0.0%	0.1%	0.1%
E) >160-200	1016	0.0%	0.0%	0.0%	1.9%	26.6%	53.5%	16.3%	1.2%	0.4%	0.1%	0.0%
F) >200-250	802	0.0%	0.0%	0.0%	0.2%	3.2%	26.7%	46.9%	19.1%	3.4%	0.4%	0.1%
G) >250-300	513	0.0%	0.0%	0.0%	0.0%	0.4%	2.1%	18.7%	46.6%	23.2%	7.4%	1.6%
H) >300-350	287	0.0%	0.0%	0.0%	0.0%	0.0%	0.7%	4.5%	30.3%	46.3%	15.7%	2.4%
I) >350-400	105	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	33.3%	43.8%	2.9%

Table 16. The concurrence of CGM readings and YSI values using CGM glucose ranges, calibrating every 12 hours, abdomen insertion site.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of matched pairs-in each YSI glucose range for each sensor glucose range YSI (mg/dL)										
		<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) >=40-60	436	0.2%	38.3%	56.2%	3.9%	0.7%	0.7%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >60-80	1077	0.1%	26.4%	59.1%	12.3%	1.2%	0.1%	0.0%	0.1%	0.3%	0.2%	0.4%
C) >80-120	1496	0.1%	5.4%	31.2%	48.2%	12.0%	1.5%	1.3%	0.3%	0.1%	0.0%	0.0%
D) >120-160	1519	0.0%	0.7%	1.9%	25.1%	53.5%	13.9%	3.9%	0.4%	0.5%	0.1%	0.0%
E) >160-200	1043	0.0%	0.0%	0.0%	3.5%	26.7%	50.0%	15.3%	2.9%	1.0%	0.4%	0.2%
F) >200-250	889	0.0%	0.0%	0.0%	0.3%	4.6%	24.0%	50.2%	17.9%	2.3%	0.8%	0.0%
G) >250-300	513	0.0%	0.0%	0.0%	0.0%	0.2%	3.1%	26.3%	49.7%	17.7%	2.1%	0.8%
H) >300-350	346	0.0%	0.0%	0.0%	0.0%	0.0%	0.9%	4.0%	30.6%	44.8%	17.3%	2.3%
I) >350-400	148	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.4%	14.2%	37.8%	34.5%	10.1%

Sensor life

After calibration, 87.3% of sensors operated more than five days and up to the full six days of wear (120 to 144 hours).

Safety

Adverse events related to the study device or procedures were mild. There were no serious adverse events or unanticipated adverse device effects with the use of the Enlite sensor during the study.

Alert performance

Event analysis

The high and low limit alerts let the user know when the sensor glucose is at or above the high limit/at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit. Predictive alerts notify users that their sensor glucose level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their sensor glucose level reaches a high or low limit setting. The earliest warning is 30 minutes before reaching a high or low limit, but users can reduce the amount of warning down to 5 minutes. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A Predictive alert is an estimation of a future sensor glucose level compared to the high or low limit setting. If the predicted sensor glucose value is above the high limit or below the low limit, then a Predictive alert is sounded before the current sensor value has crossed the high or low limit. The predicted sensor glucose level is calculated using the current sensor glucose level, the derivative of previous sensor glucose readings (the trend or slope of the sensor glucose readings) and the amount of early warning duration the user selects.

Hypoglycemic alert performance within ± 30 minutes of event, by number of daily calibrations

The following tables show the percent of YSI hypoglycemic events detected by a CGM alert and the percent of CGM alerts for which the YSI value did not reach the CGM hypoglycemic alert setting (false alerts) within 30 minutes of an event. For example, if the CGM Alert Setting is at 70 mg/dL, 82.9% of YSI hypoglycemic events below 70 mg/dL were detected within 30 minutes of the event, and for 28.4% of the CGM alerts, YSI values were above 70 mg/dL within 30 minutes of the alert (false alerts).

Table 17. Both threshold and Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	68.7	31.3	53.9	46.1
70	82.9	17.1	71.6	28.4
80	91.5	8.5	77.7	22.3
90	95.5	4.5	81.8	18.2
100	97	3	85.3	14.7

Table 18. Only threshold alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	47.7	52.3	75.8	24.2
70	62.1	37.9	85.4	14.6
80	79.7	20.3	88.1	11.9
90	90.7	9.3	91.8	8.2
100	91.8	8.2	94	6

Table 19. Only Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	68.2	31.8	54.8	45.2
70	82.1	17.9	72.2	27.8
80	91.1	8.9	78.4	21.6
90	94.9	5.1	82.1	17.9
100	96.5	3.5	85.5	14.5

Table 20. Both threshold and Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	76.4	23.6	46.7	53.3
70	85.2	14.8	67	33
80	92.1	7.9	76.5	23.5
90	93.8	6.2	81.3	18.7
100	95.5	4.5	82.3	17.7

Table 21. Only threshold alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	47.9	52.1	56.3	43.7
70	66.7	33.3	78.8	21.2
80	80.6	19.4	86.8	13.2
90	88.6	11.4	90.1	9.9
100	90.9	9.1	90.5	9.5

Table 22. Only Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	76	24	47.8	52.2
70	85	15	67.9	32.1
80	91.9	8.1	77.4	22.6
90	93.5	6.5	81.5	18.5
100	95	5	82.7	17.3

Hyperglycemic alert performance within ±30 minutes of event, by number of daily calibrations

The following tables show the percent of YSI hyperglycemic events detected by a CGM alert and the percent of CGM alerts for which the YSI value did not reach the CGM hyperglycemic alert setting (false alerts) within 30 minutes of an event. For example, if the CGM Alert Setting is at 250 mg/dL, 96.5% of YSI hyperglycemic events greater than 250 mg/dL were detected within 30 minutes of the event, and for 14.6% of the CGM alerts, YSI values were below 250 mg/dL within 30 minutes of the alert (false alerts).

Table 23. Both threshold and Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	91.7	8.3	72.9	27.1
250	96.5	3.5	85.4	14.6
220	95.4	4.6	83.3	16.7
180	97.9	2.1	87.3	12.7

Table 24. Only threshold alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	75.4	24.6	85.2	14.8
250	90.5	9.5	93.4	6.6
220	92.7	7.3	91.1	8.9

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
180	94.9	5.1	93.5	6.5

Table 25. Only Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	90.9	9.1	74.6	25.4
250	95.2	4.8	85.7	14.3
220	95.1	4.9	84.4	15.6
180	97.2	2.8	88.6	11.4

Table 26. Both threshold and Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	89.5	10.5	73.3	26.7
250	92.9	7.1	83.5	16.5
220	94.7	5.3	84.1	15.9
180	96.6	3.4	87.1	12.9

Table 27. Only threshold alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	82.4	17.6	83.6	16.4
250	86.2	13.8	91.9	8.1
220	90.5	9.5	92	8
180	93	7	92.9	7.1

Table 28. Only Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	89.1	10.9	75.7	24.3
250	92.4	7.6	84.8	15.2
220	94.1	5.9	85.4	14.6
180	95.8	4.2	88.6	11.4

Hypoglycemic alert performance within ± 15 minutes of event, by number of daily calibrations

The following tables show the percent of YSI hypoglycemic events detected by a CGM alert and the percent of CGM alerts for which the YSI value did not reach the CGM hypoglycemic alert setting (false alerts) within 15 minutes of an event. For example, if the CGM Alert Setting is at 70 mg/dL, 74% of YSI hypoglycemic events less than 70 mg/dL were detected within 15 minutes of the event, and for 41.8% of the CGM alerts, YSI values were above 70 mg/dL within 15 minutes of the alert (false alerts).

Table 29. Both threshold and Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
60	58.1	41.9	37.7	62.3
70	74	26	58.2	41.8
80	85.6	14.4	67.7	32.3
90	91.3	8.7	71.5	28.5
100	93.5	6.5	76	24

Table 30. Only threshold alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
60	43	57	65.9	34.1
70	55.7	44.3	79.3	20.7
80	75.5	24.5	84.7	15.3
90	86.3	13.7	87.9	12.1
100	88.7	11.3	90.2	9.8

Table 31. Only Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
60	55.7	44.3	39.7	60.3
70	72.1	27.9	59.6	40.4
80	83.9	16.1	68.5	31.5
90	89.6	10.4	72.7	27.3
100	91.9	8.1	77.4	22.6

Table 32. Both threshold and Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
60	66.1	33.9	31.8	68.2
70	78.2	21.8	52.6	47.4

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
80	86.7	13.3	64.9	35.1
90	90.7	9.3	71.4	28.6
100	92.6	7.4	74.3	25.7

Table 33. Only threshold alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
60	40.7	59.3	48.3	51.7
70	61.8	38.2	71.9	28.1
80	76.5	23.5	81.6	18.4
90	85.1	14.9	86	14
100	88.4	11.6	87.2	12.8

Table 34. Only Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
60	64.4	35.6	34.5	65.5
70	75.9	24.1	55.2	44.8
80	85.1	14.9	67	33
90	88.6	11.4	73	27
100	91	9	75.7	24.3

Hyperglycemic alert performance within ±15 minutes of event, by number of daily calibrations

The following tables show the percent of YSI hyperglycemic events detected by a CGM alert and the percent of CGM alerts for which the YSI value did not reach the CGM hyperglycemic alert setting (false alerts) within 15 minutes of an event. For example, if the CGM Alert Setting is at 250 mg/dL, 92.9% of YSI hyperglycemic events greater than 250 mg/dL were detected within 15 minutes of the event, and for 22% of the CGM alerts, YSI values were below 250 mg/dL within 15 minutes of the alert (false alerts).

Table 35. Both threshold and Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	84.6	15.4	62.3	37.7
250	92.9	7.1	78	22
220	93	7	77.5	22.5
180	95.5	4.5	81.3	18.7

Table 36. Only threshold alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	68.5	31.5	76.3	23.7
250	86.2	13.8	89.3	10.7
220	89.1	10.9	87.3	12.7
180	92.5	7.5	89.6	10.4

Table 37. Only Predictive alerts turned-on, calibrating three to four times per day, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	81.7	18.3	66.2	33.8
250	89.9	10.1	80.2	19.8
220	91	9	80.2	19.8
180	93	7	84.4	15.6

Table 38. Both threshold and Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	86.1	13.9	66.2	33.8
250	89.7	10.3	77.4	22.6
220	92	8	79.3	20.7
180	93.8	6.2	81.8	18.2

Table 39. Only threshold alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	77.8	22.2	78.3	21.7
250	83.3	16.7	87.6	12.4
220	87.7	12.3	88.7	11.3
180	90.4	9.6	89.6	10.4

Table 40. Only Predictive alerts turned-on, calibrating every 12 hours, abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	84.3	15.7	69.6	30.4
250	87.8	12.2	80.3	19.7

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
220	90	10	81.9	18.1
180	91.5	8.5	84.8	15.2

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Getting Started

with Continuous Glucose Monitoring

Paradigm REAL-Time™
Revel
MINIMED

Congratulations on your decision to use the MiniMed Paradigm® REAL-Time Revel™ system!

A solid understanding of continuous glucose monitoring (CGM) basics is essential to your success. Here's what we'll cover in this guide:

1 UNDERSTANDING CGM

Glucose Readings	Blood glucose (BG) meter and sensor glucose readings come from similar, but different, places in your body
Calibration	A sensor needs BG meter readings to function properly
Settings	Personalize and adjust your settings over time

2 STARTING-UP CGM

- Step 1 – Programming Settings
- Step 2 – Sensor Insertion
- Step 3 – Connecting the MiniLink® Transmitter
- Step 4 – Calibrating
- Step 5 – Reading the Display

2 APPLYING CGM IN YOUR LIFE

- What is CareLink® Therapy Management software?
- How do CareLink software reports help me?
- How do I sign up for CareLink software?

Let's get started!

Your CGM system includes 3 key items:

- 1 Enlite® Glucose Sensor** Measures glucose levels in the body. Each Enlite sensor can be worn for up to 6 days.
- 2 MiniLink® Transmitter** The MiniLink transmitter connects to the glucose sensor and sends glucose readings to your insulin pump. It is recharged and stored in the MiniLink charger when not in use.
- 3 MiniMed Paradigm REAL-Time Reveal Insulin Pump** Delivers insulin and receives and displays glucose readings. Other items include: Enlite sensor and Enlite sensor overtape.



Remember, your healthcare provider and Medtronic Diabetes are here to support you every step of the way.

1 Understanding CGM



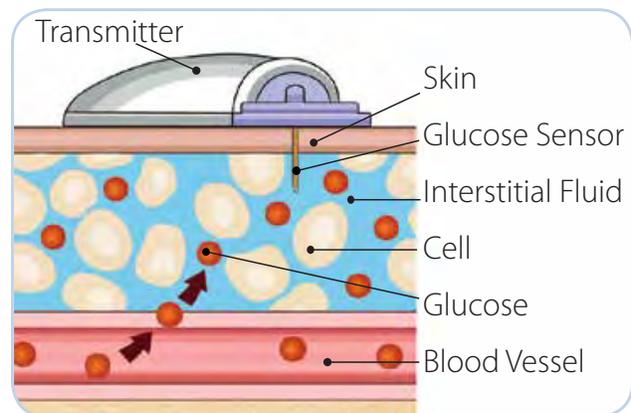
GLUCOSE READINGS

Your BG meter measures glucose (sugar) levels in your **blood**, and your glucose sensor measures glucose levels in the fluid surrounding the cells in your tissue, which is called **interstitial fluid**.

Most of the time, glucose travels first to your blood and then to your interstitial fluid.

Because of how glucose travels, your BG meter readings and sensor readings will rarely match exactly. *This is normal and should be expected.*

Usually your BG meter readings and your sensor readings will be close.



However, when glucose levels are rising or falling quickly, you should **expect** to see a larger difference between your BG meter value and the sensor glucose reading. Examples of times when this may occur include:

- After meals or after insulin
- When ↑ or ↓ arrows appear on your pump screen

Use CGM to understand your glucose trends.



Focus on what matters: the **direction** and the **speed** of the sensor glucose change. Pay less attention to each individual glucose number.

Always rely on BG meter readings for therapy adjustments.



CALIBRATION

Your MiniMed Paradigm® REAL-Time Revel™ system uses BG meter readings to make sure the glucose sensor maintains its accuracy over time. This is called **calibration**.

To calibrate you must check your BG on your meter and enter the value into the pump. The two most common ways to calibrate are through the Bolus Wizard® and the sensor menu. The preferred method is the Bolus Wizard, which may help to prevent the stacking of insulin.

When you calibrate is important.

- On day one of a new sensor, a calibration is needed:
 - approximately 2 hours after you connect the MiniLink® transmitter to your sensor (the system will notify you)
 - again within 6 hours
 - again within 12 hours
- After day one, calibrate **3–4 times a day** for optimal sensor accuracy
- A **minimum** of 1 calibration every 12 hours is required to receive sensor glucose readings

It's easy to remember when to calibrate. Think *Before is best*. The best times to calibrate are when glucose levels are least likely to be changing rapidly, such as:

- **Before** meals
- **Before** insulin
- **Before** bedtime
- When there are **no arrows on your insulin pump screen**

Tip:

Time your calibrations so you will not have to wake up in the middle of the night. Remember, you can calibrate early! For example, if it's 9pm and you know a calibration will be required by 3am, go ahead and calibrate before bed. This will start the 12 hour calibration clock over. To find out when your next calibration is due, press  3 times from the HOME screen.

If you notice a large difference between your BG meter and sensor glucose readings, calibration may be needed to bring them closer together again (remember, only calibrate if there are no arrows on your display).

Calibration is essential for optimal sensor performance. The glucose sensor performs best when calibrated 3–4 times per day.



CGM does **not** eliminate the need for BG meter readings (fingersticks).

You do not need to wait 6 hours (day one) and 12 hours to calibrate. You can calibrate early, as long as your glucose is stable.



SETTINGS

Your MiniMed Paradigm REAL-Time system allows you to customize alerts to help improve your glucose control. Your healthcare provider will work with you and your trainer to determine the initial alert settings that work best for you.



In using CGM, these settings will determine how often you are alerted. You will want to find a balance between the benefit of receiving these alerts and any inconvenience that may be caused by receiving too many.

During the first several weeks on CGM, you and your healthcare provider may consider (i) waiting to turn these alerts on, (ii) turning on only certain alerts, or (iii) setting these alerts very wide. As you learn more about your glucose patterns and how to use CGM, you will be able to adjust your alert settings to meet your individual needs.

2 Starting-Up CGM



STEP 1: PROGRAMMING SETTINGS

Your healthcare provider will work with you and your trainer to determine your initial settings.

To turn the SENSOR feature on, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > Sensor: ON

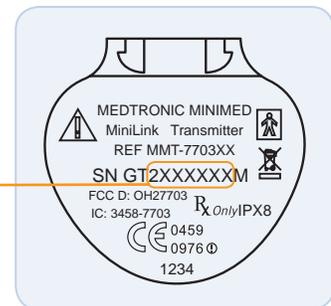
After you have turned your SENSOR feature on, enter your MiniLink® transmitter ID:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > Transmtr ID > SET TRANSMITTER ID

- Use the and buttons to select each digit and press to enter. The seven-digit ID (or serial number) is located on the flat side of the MiniLink transmitter. Be sure to only select the numbers.

Transmitter ID Number

2XXXXXX



Follow these steps to personalize your sensor settings:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS

Two alerts are the HIGH SG and LOW SG alerts, which notify you when your sensor glucose has moved above or below your programmed glucose limits. For example, if your HIGH SG alert is set at 250 mg/dL and your LOW SG alert is set at 70 mg/dL, you will receive an alert every time your glucose goes above 250 or below 70.

You can set up to 8 customizable HIGH SG and LOW SG alert limits for different periods of the day. This is especially helpful, for example, if you would like to set your glucose alert limit differently at night to prevent frequent alerts while you sleep.

To turn your sensor setting on, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > SENSOR: ON

To turn your high and low glucose alert limits on, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > GLUCOSE ALERTS: ON

To set your high and low glucose alert limits, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > GLUCOSE LIMITS

Predictive alerts provide you with a warning that your glucose is trending towards your chosen high and low glucose limits 5-30 minutes before you would otherwise reach these limits. With predictive alerts, you can be made aware of potential highs and lows even before

Remember!

Your High and Low glucose alerts are not the same as your target glucose ranges.

High and Low alerts are useful features of the system that are meant to be adjusted as your knowledge of the system improves.

Successful CGM usage involves optimizing your settings over time.

they occur. Based on your healthcare provider's recommendations, you may set a predictive low, a predictive high, both, or neither.

To set your predictive alerts, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > PREDICT ALERTS: ON

Rate of Change alerts notify you that your glucose levels are rising or falling at a certain rate. They are useful for understanding how quickly your glucose levels are affected by meals and insulin, and to recognize potentially dangerous sensor glucose changes before they become a problem. The **RISE RATE** alert can be helpful if you are prone to forgetting to take insulin, since glucose levels tend to spike significantly at these times. Likewise, the **FALL RATE** alert can be helpful in protecting you when you give yourself too much insulin, or if you skip a meal by accident.

To set your rate of change alerts, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > Rate Alerts

You will be asked first to set a fall rate of 1.1 to 5.0 mg/dL/min, or select to turn it OFF. After your fall rate is selected, you will then be asked to set your rise rate. You may set a rise rate of 1.1 to 5.0 mg/dL/min, or turn it OFF. It's often best to wait until you have adjusted to CGM to set these alerts.

Going to a movie or making a presentation? You can set the volume to VIBRATE if you prefer to not receive audible alerts for any reason. There is also an **Alert Silence** feature which allows you to silence specific sensor alerts in the system. You will still be able to see these alerts on the screen of your insulin pump.

To place your monitor on VIBRATE mode, go to:

HOME Screen > MAIN MENU > UTILITIES > ALERT > ALERT TYPE > Vibrate

To set your **ALERT SILENCE** feature, go to:

HOME Screen > MAIN MENU > SENSOR > Alert Silence

You can then select which alerts you would like to silence.

The **Repeat** setting is the time the system waits after an alert and before it alerts again if the situation is not resolved. Setting the repeat properly will prevent excessive alerts for HIGH SG and LOW SG situations which you have already taken action to correct.

To set your high repeat, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > Hi Repeat

To set your low repeat, go to:

HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > Lo Repeat

Your personalized CareLink® reports will help you and your healthcare provider to see where to best set your alerts over time.

Setting	What It Does	Commonly Used Settings
High Repeat	The amount of time until you are reminded that your sensor glucose is still above your high alert setting	2 hrs – 3 hrs
Low Repeat	The amount of time until you are reminded that your sensor glucose is still below your low alert setting	20 min – 30 min
Cal Repeat	The amount of time after you miss a calibration (Meter BG Now alert) before you are reminded	1 hr
Cal Reminder	The amount of time until your next calibration	30 min – 1 hr
Weak Signal	The amount of time before you are alerted if there is a weak signal	30 min

Remember, alerts are optional and are meant to be personalized and adjusted over time. Start wide and customize your alerts as you use CGM to learn more about your glucose trends and patterns.



You can adjust your alert settings so that they are different during your bedtime hours to ensure that you get a good night's sleep.

CareLink reports help you and your healthcare provider fine tune your settings.



STEP 2: SENSOR INSERTION

Before you insert your sensor, gather all of your supplies:

Enlite® System Components

The diagram illustrates the four main components of the Enlite system. On the left is the Enlite Serter, a grey handheld device. Next is the Enlite Sensor & Pedestal assembly, which includes a blue needle housing (D) inserted into a white pedestal (B) with an adhesive pad (C) and the sensor (A). To the right is the Sensor Overtape, a white adhesive strip with a pre-cut hole (A). Finally, on the far right is the MiniLink Transmitter, a small grey oval device.

Enlite Serter

Enlite Sensor & Pedestal
A – Sensor
B – Pedestal
C – Adhesive pad
D – Needle housing

Sensor Overtape
A – Pre-cut Hole

MiniLink Transmitter

*For more details on the Enlite System Components, consult the User Guides.

Enlite serter is required in order to insert the sensor properly and safely

Enlite sensor is individually packaged and comes attached to a plastic pedestal which is necessary for proper loading into the serter

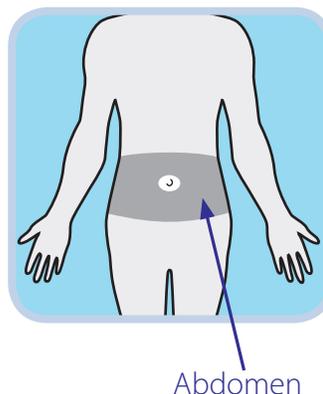
Sensor overtape is required to keep the sensor securely in place

MiniLink transmitter is connected after the sensor is inserted and covered with the overtape

Selecting Your Site

Your sensor should be inserted in the abdomen.**
The sensor insertion site should be at least:

- 2 inches away from your navel
- 1 inch away from your insulin pump infusion site
- 1 inch away from any other insulin needle injection site (syringe, pen)



** Clinical trials for glucose sensors were performed on sensors inserted in the shaded area shown

For best glucose sensor performance, avoid sites:

- Where clothing may rub or constrict (for example, your beltline)
- Where your body naturally bends a great deal which may cause the sensor to pull out
- That are scarred or have hardened tissue or stretch marks
- Where there is a great deal of motion or friction

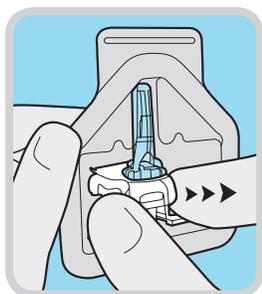
Preparing Your Site

- Wash your hands
- Clean the selected site with an alcohol swab and allow the alcohol to dry. Do not use IV prep or the sensor may not work properly.

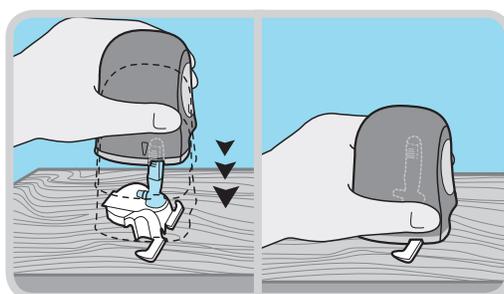
Inserting Your Sensor



1. Open the sensor package.



2. Remove the sensor with attached pedestal by holding the pedestal. Place the sensor and pedestal on a clean, flat surface (such as a table).



3. Hold the serter so the green button is lined up with the arms of the pedestal. To load the serter, carefully push the serter down on the sensor and pedestal until the base of the serter sits flat on the table. Be careful not to force the serter too hard onto the sensor and pedestal or it may not load properly.



4. To detach the pedestal from the sensor, place two fingers on the pedestal arms and slowly pull the serter straight up. This step will also remove the paper backing from the sensor. The sensor will remain inside the serter after detaching the pedestal. **Do not detach the pedestal from the sensor in mid-air as this may damage the sensor.**



5. Place the base of the serter flat against your selected insertion site. The arrow on each side of the serter indicate the location of the sensor and needle.

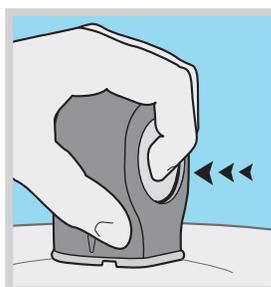
Inserting Your Sensor (Cont.)



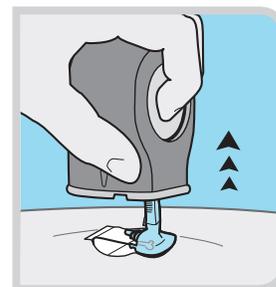
6a. To insert the sensor, press the green button in and then release it. Then keep the inserter flat against your body.



6b. While continuing to hold the inserter against your body, wait 5 seconds in order to allow time for the pressure-sensitive adhesive to stick to your skin.



6c. In order to remove the inserter, a **SECOND BUTTON PUSH** is required. Press and **hold in** the green button. **Do not push the inserter too hard against the skin or doing so may make it difficult to press and hold in the green button.**

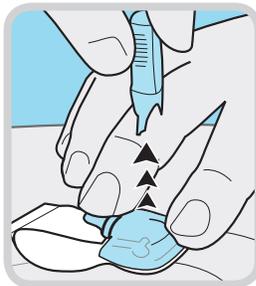


6d. While continuing to hold in the green button, slowly pull the inserter away from your body.

Inserting Your Sensor (Cont.)

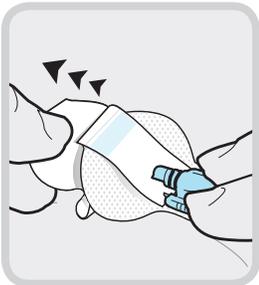


7. With one hand, hold the sensor against your body. With the other hand, hold the needle housing at the tip.



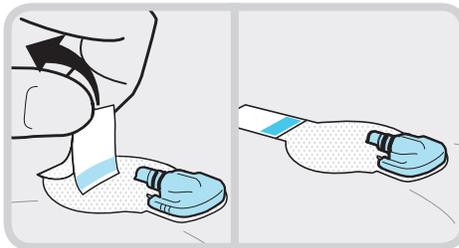
8. Slowly pull the needle housing straight out, away from the sensor.

Warning: If bleeding occurs at your sensor site (under/around/or on top of the sensor), apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. If bleeding does not stop, then remove the sensor and apply steady pressure until the bleeding stops.



9. Carefully, remove the white paper that is located underneath the curved adhesive pad.

Press the adhesive against the skin for several seconds to help ensure that it sticks to your skin.



10. Flip the adhesive tab so that it lies flat, but do not remove the paper backing yet.



REMEMBER:

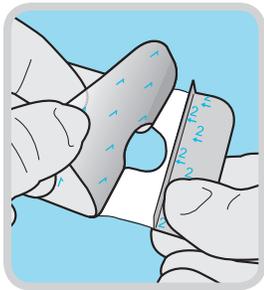
Inserting the sensor requires

2 button presses:

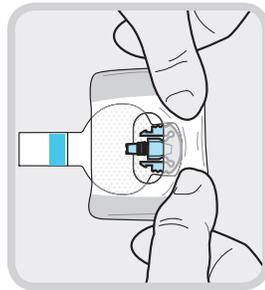
1. To insert the sensor
2. To remove theserter after sensor insertion

Taping Your Sensor

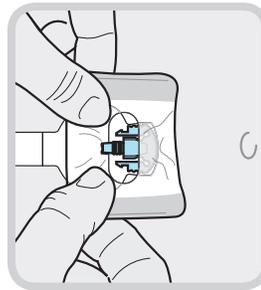
Before you connect the MiniLink transmitter to your Enlite sensor it is very important that you properly secure the sensor against your skin using the sensor overtape.



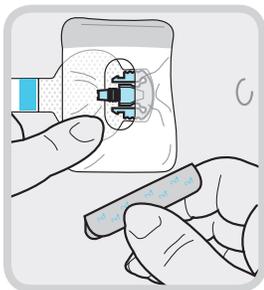
1. Remove the large paper backing from the overtape. Do not remove the two smaller paper tabs on the sides of the overtape.



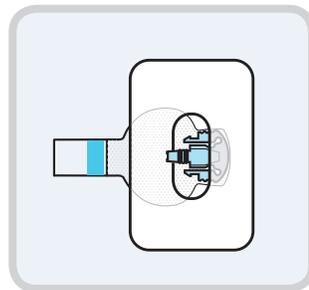
2. **Important:** Attach the overtape to both the rounded part of the sensor and the skin in front of the sensor.



3. Stretch the remaining part of the overtape around the sensor connector so that the tape sticks to the curved adhesive pad and does not block the sensor connector. **Press the overtape to your skin for several seconds to help ensure that it sticks securely.**



4. Remove the two paper tabs from the sides of the overtape and press the adhesive against the skin.



5. This image is an example of the overtape applied correctly.



IMPORTANT

All Enlite tapes and adhesives stick best when you apply pressure for several seconds after putting them on your skin. Doing so helps the Enlite sensor stay securely placed and fully inserted.

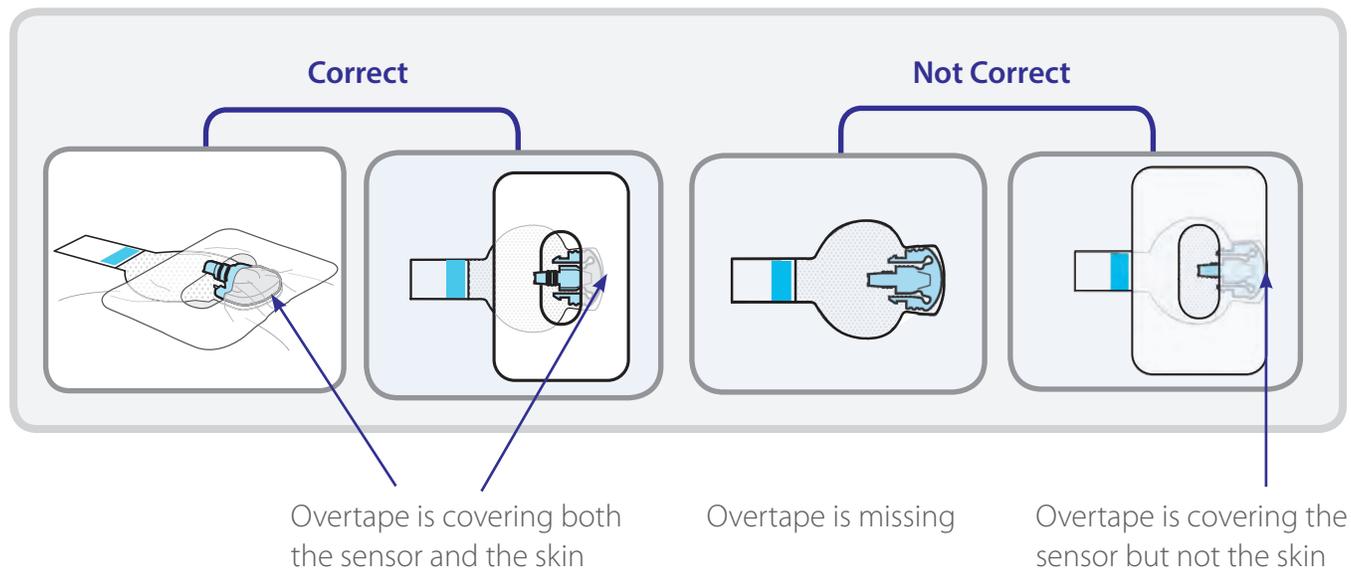


Properly applying the overtape is key to ensuring your success with the Enlite sensor. Due to the sensor's small size and flexible nature, the overtape helps to secure it from body motion or physical activity that can cause it to be pulled out.

Checking Proper Tape Application

It is important to check your sensor site periodically to make sure the sensor is still secure and has not been pulled out. If the sensor has been pulled out, do not try to push it back into place as this will damage the sensor.

Ways to Check Proper Tape Application

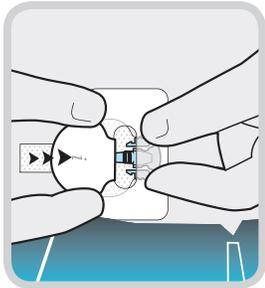




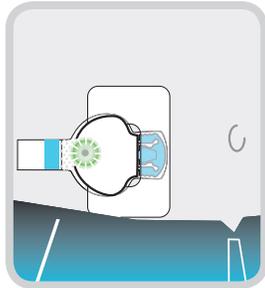
STEP 3: CONNECTING THE MINILINK® TRANSMITTER

After the glucose sensor is inserted, taped securely, and your settings are entered, connect the MiniLink transmitter to the glucose sensor immediately.

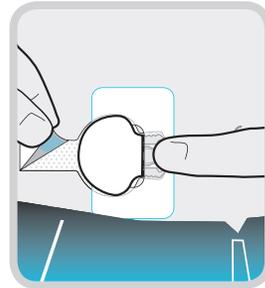
To connect your transmitter to your sensor:



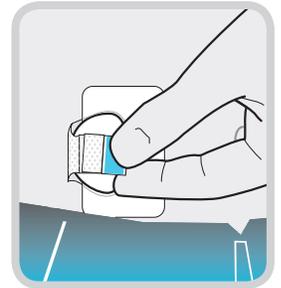
1. With one hand, hold the sensor in place. With the other hand, connect the transmitter to the sensor.



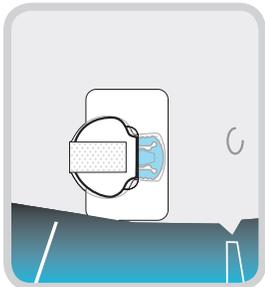
2. You will hear a faint “click” indicating that the two components are connected. Check for a green light to flash on the transmitter.



3. Remove the paper on the adhesive tab.



4. Fold the adhesive tab over and onto the transmitter. **Important:** Be careful not to pull the adhesive tab too tightly or it may cause the transmitter to bend or pull from the sensor connection.



5. Press the adhesive onto the transmitter.



IMPORTANT If you do not see a green light flashing on the transmitter after it is connected to the sensor, then disconnect the transmitter and place it back on the charger to ensure that it is fully charged. Then reconnect the transmitter to the sensor.

Perform the **Sensor Start: HOME Screen > MAIN MENU > SENSOR > LINK TO SENSOR > New Sensor**. The system is ready approximately 2 hours after the MiniLink transmitter is connected to the glucose sensor and the green light flashes. This 2 hour period is called **initialization**.

Note: At the end of the 3 day sensor wear, you will receive a Sensor End alert. Perform the steps for Sensor Start again as the Enlite sensor can be worn for 6 days.



STEP 4: CALIBRATING

METER BG NOW alert will sound when the system is ready for you to enter a BG meter value for initial calibration. Remember, the preferred method is to use the Bolus Wizard.[®] Clear the alert and follow either of these steps to enter a BG meter value:

CB > **ENTER BG** > **BG to update Sensor : YES** or
MAIN MENU > **SENSOR** > **CALIBRATE** > **Enter BG**

After your first calibration, it will take 10–15 minutes for sensor glucose readings to appear on your insulin pump screen.

After your initial calibration, another calibration will be required within 6 hours.

1 calibration every 12 hours is the minimum required to continue to receive glucose sensor readings after the first day.

Calibrate 3–4 times a day thereafter for optimal glucose sensor accuracy.

Remember!

The best times to calibrate the glucose sensor are when your glucose levels are least likely to be changing rapidly. Think *Before*: before meals, before bedtime, before insulin. Also, you do not need to wait until you are alerted to calibrate. You can calibrate at any time when your glucose is stable.

If you get a CAL ERROR on your insulin pump, don't worry. This is a feature of your system intended to ensure good performance.

- To avoid a CAL ERROR make sure you calibrate when your glucose is least likely to be changing rapidly
- If you get a CAL ERROR recalibrate if the BG is stable, otherwise wait at least 15 minutes before calibrating again



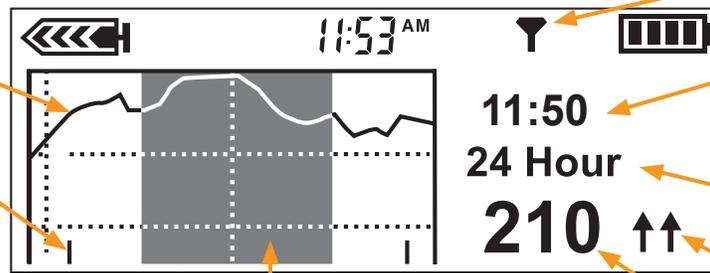
STEP 5: READING THE DISPLAY

Your insulin pump screen displays 3-hour, 6-hour, 12-hour, and 24-hour glucose trend graphs. Press once from the HOME Screen to display the most recently viewed trend graph. Press to display the other graphs.



Glucose sensor graph

Each time you bolus a marker will appear on your graph



Connection icon

Time of most recent sensor glucose reading

11:50

24 Hour

210



24-hour trend graph

Trend arrows

Sensor glucose reading

The darkened area is the 12 hours from 6:00pm to 6:00am

Press to view individual sensor glucose readings on the graph.

What the Sensor Icons Mean

	Glucose has risen or fallen 1-2 mg/dL per minute.
	Glucose has risen or fallen 2.0 or more mg/dL per minute.
	Insulin pump indicates that the MiniLink® transmitter and insulin pump are communicating properly.
	Pump has not received a signal for more than 5–7 minutes. This is okay; the MiniLink transmitter stores up to 40 minutes of data and will send these readings to the insulin pump once a signal is reestablished.

3 Applying CGM in Your Life



WHAT IS CARELINK® SOFTWARE?

CareLink software is a Web-based software that allows you to upload information from your MiniMed Paradigm® REAL-Time system to a secure online (internet) site for viewing.

CareLink software organizes all of your insulin pump and glucose sensor information into reports (charts, tables and graphs) that help you track glucose levels, insulin usage and carbohydrate intake over time.

With CareLink software, you can grant your healthcare provider online access – or just bring a copy of your CareLink reports to your appointments – so you and your provider can work together to determine the best therapy decisions and system settings to improve your outcomes.

Don't have a computer? Your healthcare provider may be able to download the reports at your next visit.



CareLink reports help you and your healthcare provider make decisions that improve your control and fit your lifestyle.

The combination of insulin pump therapy, continuous glucose monitoring and CareLink software provides you with the tools and information you need to **optimize** your therapy.



HOW DO CARELINK® SOFTWARE REPORTS HELP ME?

CareLink software provides you with information you've never had before about your glucose trends and patterns. Take action and make simple changes to optimize your glucose control. CareLink software helps you answer questions like:

- Do I need to adjust my basal rate or use temporary basal rates to avoid going high or low at the same time every day?
- Am I accurately counting my carbs at meals?
- Are my carb ratios correct?
- Do I need to use the Dual Wave® or Square Wave® bolus functions for tighter control?
- Where should I set my high, low, predictive, and rate of change alerts?



CareLink® Software Tips

For best results using CareLink software, Medtronic Diabetes recommends:

- Finding a consistent time once a week to review your CareLink reports.
- Reviewing two CareLink reports to start: the Sensor Daily Overlay Report and the Daily Summary Report.
- Picking one or two simple adjustments to work on at a time when you review the past week's information in CareLink software.

Always remember to review and discuss your CareLink reports when you visit your healthcare provider. Note: some providers may use a different but similar version of CareLink software called CareLink Pro at their office.



HOW DO I SIGN UP FOR CARELINK SOFTWARE?

To sign up for your free CareLink software account visit:
www.medtronicdiabetes.com/carelink

Set up a meeting with your Medtronic Diabetes trainer or your healthcare provider to learn more about how to use this valuable tool.

See the difference that the combination of insulin pump therapy, CGM and CareLink software can make in your life.



CGM and Medtronic – giving you the confidence to live *your* life.

Appendix

- MiniLink® Transmitter Tips
- Other Useful Information

Tape Tips

X-rays, MRIs and CT scans

Air Travel

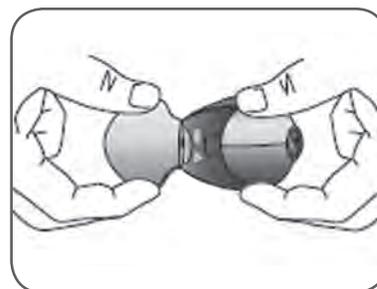
- Alerts
- Notes

MiniLink® Transmitter Tips

Fully charge the MiniLink transmitter before each use.

When the MiniLink transmitter is charging, a green light on the charger will flash.

The green light on the charger will turn off when completely charged.



When you remove the MiniLink transmitter from the charger, a green light should flash on the MiniLink transmitter. This indicates it has enough battery power to last 6 days and is ready to be connected to the sensor.

Charging time:

- For a completely depleted transmitter: up to 8 hours.
- Normal use: less than 20 minutes to fully recharge.

Although optional, you may store the MiniLink transmitter in the charger when not in use.

- To preserve transmitter battery life during periods of infrequent usage, remove the MiniLink transmitter from its charger for at least 1 minute every 1-2 months.



Battery status for charger and MiniLink transmitter:

- The light on the charger will flash red once every 2 seconds if the AAA battery in the charger needs replacement.
- The light on the charger will quickly and repeatedly flash red over 2 second intervals if the MiniLink transmitter battery is depleted. This should rarely happen if the transmitter is recharged after each use.

Other Useful Information

X-rays, MRIs and CT scans

If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, take off your insulin pump, BG meter, MiniLink transmitter and glucose sensor and remove them from the area.

Air Travel

Your transmitter, sensor, and insulin pump are safe for use on U.S. commercial airlines and can be worn during flight. However, if airport security requests that you turn off your CGM device, then you must comply. It is advisable to check with the Transportation Safety Administration (TSA) for updates. International passengers should consult with their individual air carriers for international regulations.

For the flight simply:

- 1) Go to: **HOME Screen > MAIN MENU > SENSOR > Turn Off Sensor**
- 2) Keep the glucose sensor in, but disconnect the MiniLink transmitter from the glucose sensor and store on the charger
Note: During this time you will have to manually check your BG

To reconnect after the flight:

- 1) Reconnect the MiniLink transmitter to the sensor
- 2) Go to: **HOME Screen > MAIN MENU > SENSOR > EDIT SETTINGS > Sensor: ON**
- 3) Go to: **HOME Screen > MAIN MENU > SENSOR > LINK TO SENSOR > Reconnect Old Sensor**

Just like starting a **New Sensor**, there will be a two hour initialization period and a calibration will be needed.

Alerts

To clear an alert screen, press , then .

Alert	What It Means	How to Respond
Weak Signal (WeakSn)	The insulin pump and MiniLink® transmitter are not communicating.	Re-position the insulin pump closer to the MiniLink transmitter.
Lost Sensor (SenLos)	Insulin pump has not received a signal from the MiniLink transmitter for more than 40 minutes.	Ensure the MiniLink transmitter and sensor are connected. Place the insulin pump closer to the transmitter. To restart communication go to Home Screen > Main Menu > Sensor > Link to Sensor > Find Lost Sensor .
Cal Error (CalErr)	BG entry is out of expected BG range.	Wash hands. Re-calibrate if BGs are stable. Wait at least 15 minutes if BG was entered at time of rapid glucose change.
Meter BG By (mBGby)	A BG will be needed for the system to continue providing sensor readings by the time shown on the alert	Clear the alert. You will continue to receive sensor readings until Meter BG Now alert appears.
Meter BG Now (mBGnow)	A BG is needed for the system to continue to provide sensor readings.	Make sure there are no arrows on the pump screen, test your BG and calibrate the system.
High SG (Hi)	Glucose level is higher than or equal to your high glucose alert setting	Treat as instructed by your healthcare provider based on BG meter reading. If this alert becomes frequent, adjust the setting and/or Repeat setting for this alert.
Low SG (Lo)	Glucose level is lower than or equal to your low glucose alert setting.	Treat as instructed by your healthcare provider based on BG meter reading. If this alert becomes frequent, adjust the setting and/or Repeat setting for this alert.

Alert	What It Means	How to Respond
Sensor End (SenEnd)	Sensor has been used for 72 hours.	Perform the Sensor Start to wear current sensor for a total of 6 days: HOME Screen > MAIN MENU > SENSOR > LINK TO SENSOR > New Sensor. Important: Enlite sensor should not be used past a total of 6 days wear.
Sensor Error (SenErr)	Sensor signals are either too high or too low.	Clear the alert and ignore if this happens during initialization. If alert happens more than 3 times in 24 hours, replace the sensor
Change Sensor (ChgSen)	System has detected a sensor that isn't working correctly.	If alert occurs during initialization, wait and perform a sensor start using the same sensor. Otherwise, call our 24-Hour HelpLine.
Rise Rate (UpSlp)	The sensor glucose measurements are rising at a rate that is equal to or faster than the SET RISE RATE LIMIT you selected.	Consider taking corrective action after confirming with a BG meter reading. Follow your healthcare provider's instructions.
Fall Rate (DwnSlp)	The sensor glucose measurements are falling at a rate that is equal to or faster than the SET FALL RATE LIMIT you selected.	Consider taking corrective action after confirming with a BG meter reading. Follow your healthcare provider's instructions.
High Predicted (PrdHi)	Sensor glucose is trending to reach or go above your high glucose limit in the length of time you selected for the high predictive alert.	Consider taking corrective action after confirming with a BG meter reading. Follow your healthcare provider's instructions.
Low Predicted (PrdLow)	Sensor glucose is trending to reach or go below your low glucose limit in the length of time you selected for the low predictive alert.	Consider taking corrective action after confirming with a BG meter reading. Follow your healthcare provider's instructions.

The versions in parentheses above show how the alert will appear in the Sensor Alert History.



Still have questions?
Our 24-Hour HelpLine is here to help.
Call 1.800.646.4633, option 1.

www.MedtronicDiabetes.com

Medtronic, Inc. | Diabetes

18000 Devonshire Street
Northridge, CA 91325
1.800.646.4633



Welcome

Thank you for choosing Medtronic Diabetes as your diabetes care partner! We believe that our state-of-the-art technology and simple, menu-driven programming of the pump will provide many benefits to you in gaining control over your diabetes. We know that you are excited to start using the pump, however, it is important that you do not start using insulin pump therapy before you are instructed to do so by your healthcare provider.

Your pump arrives from the factory in a mode that allows you to practice programming the pump without filling it with insulin. Please do not select the Rewind or Clear Settings options in the pump menu as these will cancel the practice mode. If you accidentally select these functions while practicing, refer to step 3 in the *Rewinding your pump* section in your user guide.

Before using your pump

Meet with your pump trainer after you have completed the following:

- Read and complete the exercises found in the training workbook.
- Change the language setting on your pump so the screens display in your language. Refer to the *Basic programming* chapter in your user guide for instructions on selecting the language.
- Read and complete the exercises in the *Basic programming* chapter in your user guide.
- For questions on how to use Bayer's CONTOUR® NEXT LINK Wireless Meter, please review the user guide that came with your meter.

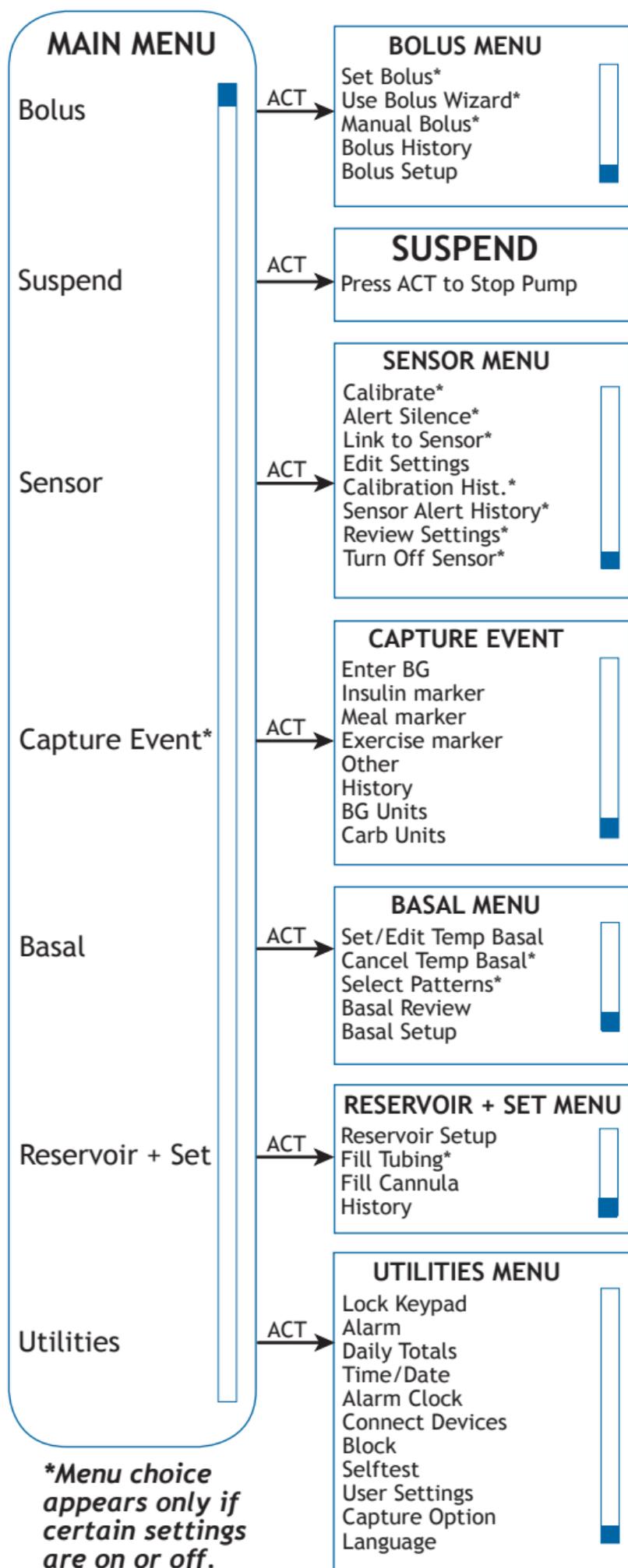
What you will find inside this box

- Pump
- Batteries
- User guide
- Daily journal (log book)
- Holster
- Tubing clamps
- Wallet card
- Pump clip
- Activity guard
- Emergency card

Some items listed here may not be included based on their availability in your region.

Paradigm REAL-Time™ Revel MINIMED

Wallet Card



Pump modes

<p>normal</p>	<p>The pump is in “normal” operation if it does not display an open or closed circle.</p>
<p>special</p>	<p>Indicates:</p> <ul style="list-style-type: none"> dual/square wave bolus basal patterns (a or b) temporary basal low reservoir low battery block sensor alerts alert silence
<p>attention</p>	<p>Indicates:</p> <ul style="list-style-type: none"> suspended rewind filling infusion set alarms
<p>sensor icon</p>	<p>The sensor is on but the pump is not receiving sensor data.</p>
<p>sensor icon</p>	<p>The sensor is on and the pump is receiving sensor data.</p>

Troubleshooting

Read alarm text on your pump screen by pressing the down button. Follow instructions. ESC/ACT to clear. Consult the *Troubleshooting, alerts and alarms* chapter located in your User Guide.

Sensor Alerts

Follow instructions. ESC/ACT to clear.

 Alert	Instructions
METER BG NOW	A meter BG measurement is needed immediately to calibrate your sensor so that you can continue receiving sensor glucose measurements.
CAL ERROR	If Cal error occurs after entering a meter BG, wait until your BG is stable to enter a new meter BG for calibration.
LOW XX MG/DL (X.X MMOL/L)	The sensor glucose measurement is equal to or lower than your low glucose limit.
HIGH XXX MG/DL (XX.X MMOL/L)	The sensor glucose measurement is equal to or higher than your high glucose limit.
SENSOR END	The sensor can be worn for up to six days (144 hours). Follow the <i>Restarting the sensor after three days</i> procedure found in your user guide. This procedure must be conducted for each newly inserted sensor to restart the sensor after three days. This will allow you to use your sensor up to its maximum life of six days (144 hours). If this is the second time you have received the SENSOR END alert, replace your sensor.
SENSOR ERROR	The sensor signals are either too high or too low. You do not need to change the sensor. Clear the alert. If the alert persists, test your transmitter with the tester.
WEAK SIGNAL	The pump has not received data from the transmitter for a predefined period of time (as set in Weak Signal). Move the pump closer to the transmitter or move the transmitter and the pump to the same side of your body.
LOST SENSOR	The pump has not received a signal from the transmitter. Do <i>not</i> disconnect. <ul style="list-style-type: none">• Bring your pump closer to the sensor and transmitter.• Make sure that the sensor is inserted correctly.• Check to make sure that the transmitter ID entered into the pump matches the ID on your transmitter.• Check the transmitter and sensor connection.• Use <i>Find Lost Sensor</i> function to find your sensor.

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Daily Journal



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USING THE DAILY BLOOD GLUCOSE JOURNAL

- Write the Day and Date in the spaces provided on the top of the page.
- Find the time of the entry you are making. Test your blood glucose and enter the value in the space labeled METER BLOOD GLUCOSE.
- If you are eating at this time, write the grams of carbohydrates in the space labeled CARBOHYDRATES.
- If you are taking a correction and/or meal bolus, record it in the space labeled MEAL BOLUS and/or CORRECTION BOLUS. Even if you have added these together to take one bolus, write the separate amounts in the corresponding spaces.
- Record your basal rate in the space labeled BASAL RATE. If you have more than one rate, be sure to record the rate in the space corresponding to the correct time for each rate.
- When you exercise, write the minutes in the space labeled EXERCISE.
- If you test your urine ketones, write the result in the space labeled URINE KETONES. Each time you test your ketones, write the result even if it is negative.

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- If you use different Target Blood Glucose ranges for different times of day, record your current high and low Blood Glucose targets in the space labeled SENSOR TARGETS.
- Use the space labeled SENSOR INSERT to record the date and time each sensor is inserted to ensure that you do not restart an individual sensor on the pump more than once.
- Record the time you change your infusion set in the space labeled SET CHANGE. This notation will help you to evaluate any changes in your blood glucose readings due to changing your infusion set.
- Record the food you eat in the BREAKFAST, LUNCH and DINNER columns provided.
- In the NOTES section, write down any information that may explain your blood glucose values or diabetes management decisions. Use this section as you would a personal journal.
- You will find four graphs for weekly recording in the back section.

Note: The shaded area of the graph represents the acceptable level of blood glucose control for most people with diabetes.

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FOOD JOURNAL	Breakfast	NOTES Exercise, stress, illness, low blood sugar & treatment, alarms, specific foods/CHO
	Snack	
	Lunch	
	Snack	
	Dinner	
	Snack	

RELEASED

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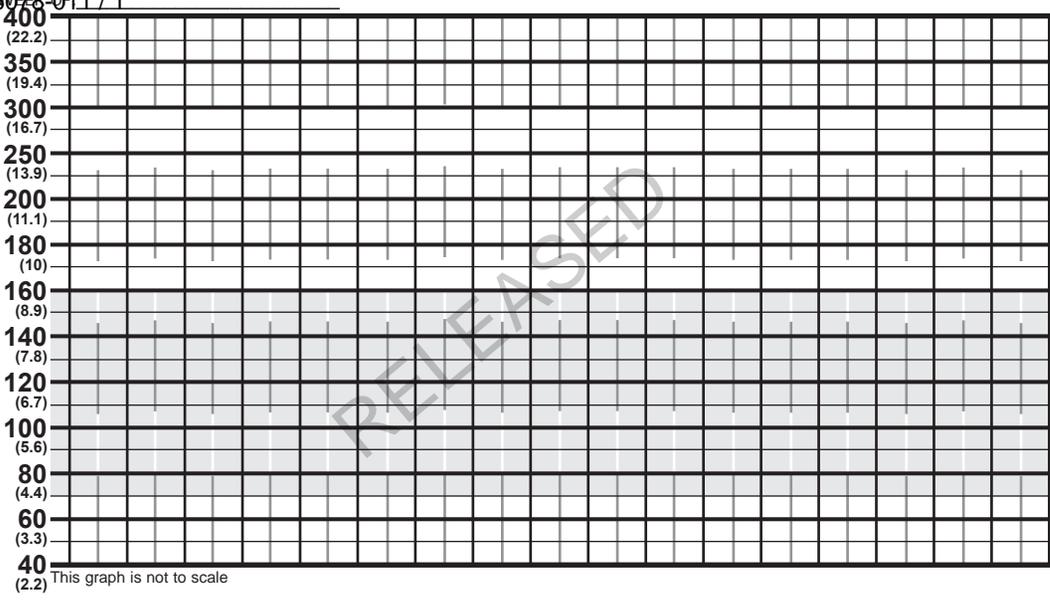
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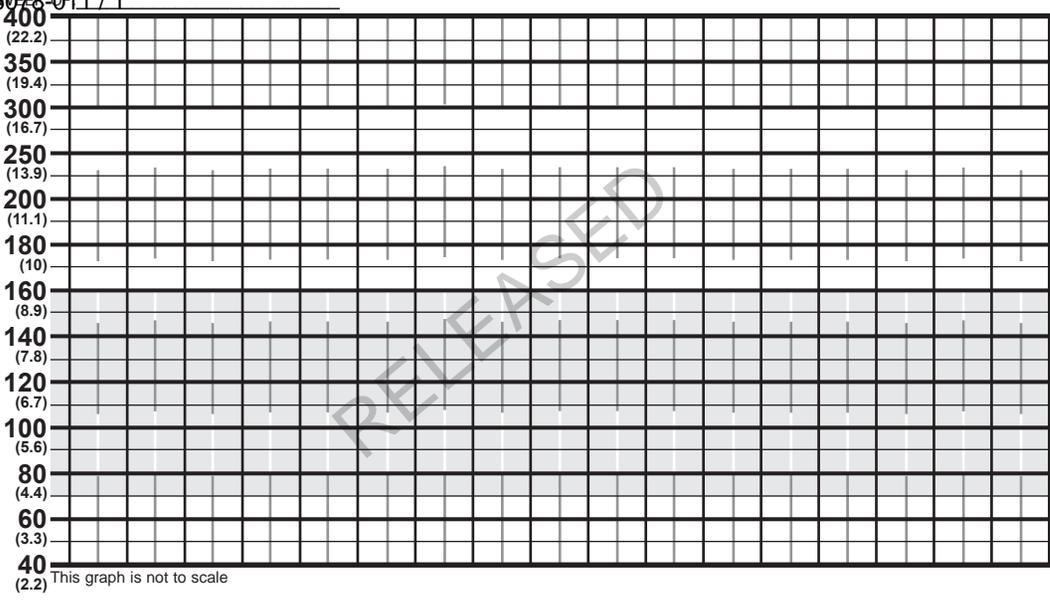
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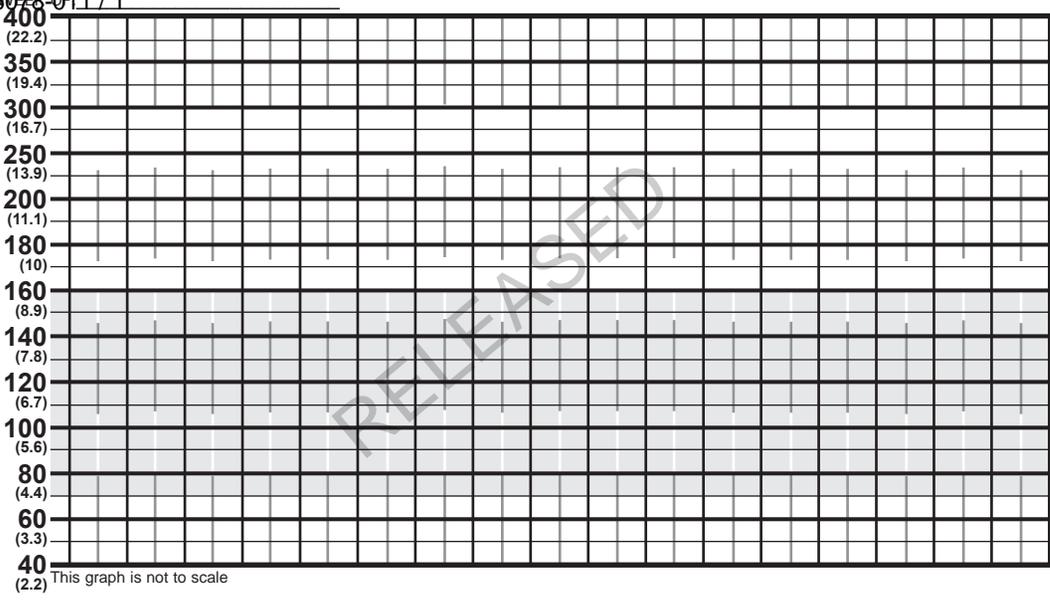
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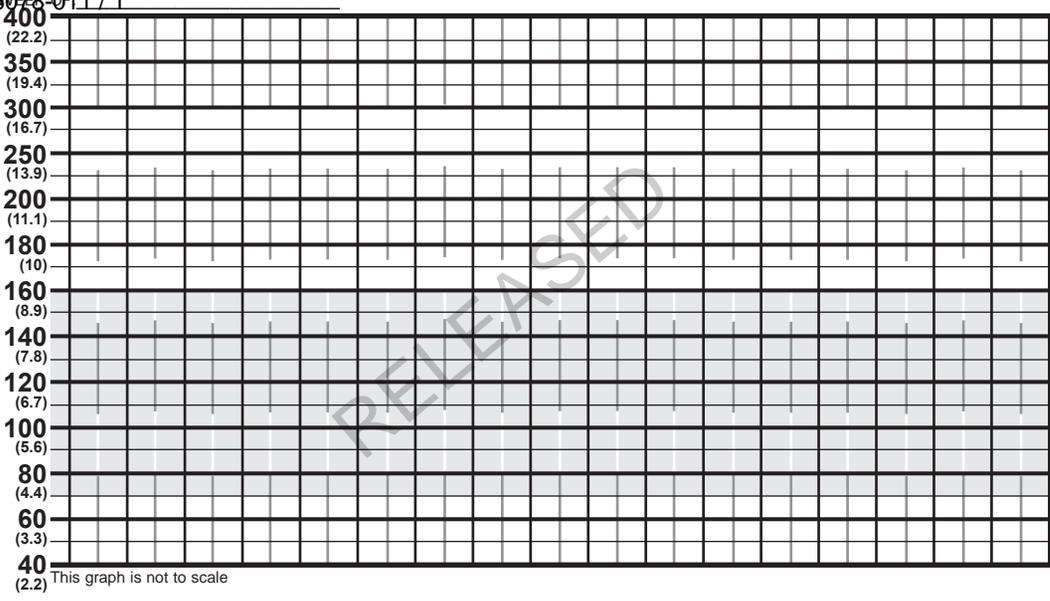
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