When should I calibrate?

▲ top

It is best to calibrate when your blood sugar is not changing rapidly. We recommend that you calibrate on a routine schedule, for instance when you first wake up, before a meal, or before your bedtime snack. Try to find a time during the day when your blood sugar is stable. Make sure you do not calibrate when your blood sugar is changing rapidly, like within the first hour after a meal.

It is important to calibrate when glucose values are not changing rapidly. (For example, glucose is more stable before a meal. After a meal, it is more likely that glucose will change rapidly to adjust for the food being digested).

Pediatric Indication

Are insulin pumps and continuous glucose monitoring indicated for children?

▲ top

Yes! Our insulin pumps are indicated for persons of all ages requiring insulin. Our REAL-Time Continuous Glucose Monitoring (CGM) technology is indicated for patients age 7 and older. For children and teens ages 7-17 who are using CGM, separate pediatric models are indicated.

The pediatric model MiniMed Paradigm 522K/722K Insulin Pump is for children and teens 7-17 who will be using continuous glucose monitoring. (If continous glucose monitoring will not be used, the standard model 522/722 Insulin Pump can be used.)

There is also a pediatric model of the Guardian REAL-Time system.
Please see our Safety Information page for more details.

What are the differences between the pediatric model 522K/722K Insulin Pumps and the standard 522/722 models?

▲ top

The main difference is that the pediatric models feature a minimum low glucose alert threshold of 90 mg/dL for added safety, as part of the REAL-Time continuous glucose monitoring functionality. In the standard models, the minimum low glucose alert threshold is 40 mg/dL. There are two other differences:

- The high glucose alert threshold default setting is 280 mg/dL in the pediatric model instead of 200 mg/dL in the standard model.
- The pediatric model insulin pumps are not supported by Paradigm PAL™ software. This software is used by some customers to program and back-up insulin pump settings. Instead of using Paradigm PAL software, pediatric model users can use CareLink™ software. Although CareLink software cannot be used to program insulin pump settings, it can be used to document the settings, as well as generate treatment reports integrating insulin pump, CGM, meter and logbook data to help you understand how insulin dosage, eating habits, and exercise routine affect glucose levels.

What are the differences between the pediatric model Guardian REAL-Time System and the standard model?

▲ top

The main difference is that the pediatric model features a minimum low glucose alert threshold of 90 mg/dL for added safety. In the standard model, the minimum low glucose alert threshold is 40 mg/dL. Additionally, the pediatric model's default setting for the high glucose alert threshold is 280 mg/dL, instead of 200 mg/dL in the standard model.

CareLink Therapy Management Software

Why should I use CareLink Personal software?

▲ top

Understanding the effects of insulin dosage, eating habits, exercise routine, and medication on glucose levels is the key to improving your diabetes control. Seeing this cause-and-effect relationship in chart, graph, and table formats allows you to better identify patterns and problems that will help you figure out the root cause of your low and high blood glucose levels. With CareLink Personal software, you are empowered to effectively maximize your therapy by working with your healthcare professional to reach your individual goals.

How much does CareLink Personal software cost?

▲ top

While CareLink Personal software is provided at no additional cost, separate purchase of a connectivity device may be required:

Customers	Connectivity Devices	Cost
MiniMed Paradigm® Insulin Pump Customers	Paradigm Link Blood Glucose Monitor	Free
	BD USB Cable (available on the online store)	$29.99
Guardian® REAL-Time CGM System Customers	ComLink device with serial cable [1]	Free

How do I access CareLink Personal software?

▲ top

Go to http://carelink.minimed.com

What do I need in order to get started using CareLink Personal software?

▲ top

- Access to a personal computer running Windows® 98SE, ME, 2000, XP, or Vista
- A reliable Internet connection

- Microsoft® Internet Explorer version 5.5 (SP2) or higher
- Adobe® Reader™ version 5.0 or higher
- A connectivity device, such as a Paradigm Link® Blood Glucose Monitor or ComLink™ device, with an appropriate cable

What if I have more questions about using the software or the connectivity devices? top

- Refer to "Getting Started" guide to CareLink Personal software (PDF)
- Contact the Medtronic Diabetes 24-Hour HelpLine at 1-800-MINIMED (1-800-646-4633) Option 1.

Is my medical and personal information secure? top

CareLink Personal software complies with the strictest privacy regulations in the world, including HIPAA guidelines. The system also uses Secure Sockets Layer (SSL), a data encryption technology, which ensures that data is unreadable during the transfer.

Storing data in CareLink Personal software is often safer than storing it on a home computer system that is connected to the Internet. We use a three-tier architecture that puts the data behind three separate firewalls.

How long does it take to upload data? top

Frequent data uploading (i.e. every two-four weeks) will provide uploads in about 2-4 minutes depending upon frequency of use of the insulin pump and CGM features.

How do I create reports? top

From the main Reports page, select a report from the menu on the left-hand side of the screen. Select the date or date range for the report and click the Go button. Your report is displayed as a PDF file in a separate window.

Can I still use CareLink Personal software even if I don't use the MiniMed Paradigm REAL-Time System? top

Yes, CareLink Personal software supports a number of third-party meters.

Travel and Environmental Exposure

Will MRI or X-ray equipment interfere with the system? top

If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, please take off your insulin pump, transmitter, and sensor and remove them from the area.

Is the MiniMed Paradigm REAL-Time System affected by computers, cell phones or airport detectors? top

The MiniMed Paradigm REAL-Time System is designed to withstand common electromagnetic interference, including airport security systems.

The Paradigm Link monitor and MiniLink REAL-Time Transmitter send information to the insulin pump using radio frequency. If other devices that use radio frequency are in use, such as cell phones, cordless phones or wireless networks, they may prevent communication between the insulin pump and the meter. This interference will not cause incorrect data to be sent and will not cause any harm to your insulin pump or meter. Moving away from or turning off these other devices may allow communication.

Can I use the MiniMed Paradigm REAL-Time System on an airplane? Must I turn off the radio frequency during flight? top

International standards and U.S. Federal Communications Commission (FCC) regulations require that devices using radio frequency capabilities should not be used on an aircraft. As a result, you must disconnect the transmitter from the glucose sensor while traveling on an airplane; however, you can continue using the insulin pump. It is not sufficient to simply turn the continuous glucose monitoring (CGM) feature off on the insulin pump, the transmitter will continue to transmit on the RF frequency and must be disconnected from the glucose sensor to stop.

While in flight, you need to manually test your glucose levels using a standard meter (i.e. the Paradigm Link monitor). When downloading data and reviewing

historical reports, you will notice "data gap" where information is missing during this period of time.

How do you turn off the transmission from the transmitter to the insulin pump? ▲ top

The transmitter starts to transmit as soon as a sensor is connected to it. The transmitter will transmit even if the continuous glucose monitoring (CGM) feature is turned off on the insulin pump. Patients should physically disconnect the glucose sensor from the transmitter. If convenient, it is possible to leave the glucose sensor inserted in the skin.

For additional Travel Tips: ▲ top

http://www.minimed.com/help/pumptips/traveltips.html

Availability...Colors...Price

Will my insurance cover the entire MiniMed Paradigm REAL-Time System? ▲ top

The MiniMed Paradigm REAL-Time System consists of the MiniMed Paradigm 522 or 722 Insulin Pump and the REAL-Time Continuous Glucose Monitoring (CGM) System. For insurance purposes, the components are handled separately. Insulin pump therapy has a 20-year history and insurance companies are familiar with this technology. Therefore, there is an established process for authorization and payment for insulin pumps. Medtronic Diabetes will verify coverage with your insurance company and will help process claims for your insulin pump and on-going insulin pump supplies.

However, because REAL-Time CGM is a brand new therapy, it is not yet covered by insurance companies. At this time the REAL-Time CGM components—the transmitter and glucose sensors, are an out-of-pocket expense. Medtronic Diabetes will continue to build the clinical evidence and work with insurance companies to obtain coverage for this exciting technology.

How can I get the MiniMed Paradigm Platform? ▲ top

The MiniMed Paradigm REAL-Time System, consisting of the MiniMed Paradigm 522 and 722 Insulin Pumps with the optional continuous glucose monitoring system component, is available now by prescription for purchase in the U.S. Please check with your local representative or distributor for prices and availability. Call us at 800-MINIMED (800-646-4633), extension 4776, if you would like a referral to an insulin pump prescriber in your area.

What is the price of the MiniMed Paradigm Platform? Will my insurance cover it? ▲ top

The MiniMed Paradigm 522 and 722 Insulin Pumps have a list price of $6,195.* An optional starter kit for the continuous glucose monitoring components has a list price of $999. It is important to remember that most insurance plans provide coverage for insulin pump therapy and diabetes testing supplies. Medtronic Diabetes Insulin Pump Specialists are available to assist with insurance verification weekdays from 6 a.m. to 5 p.m., Pacific Standard Time, at 800-MINIMED (800-646-4633), extension 4776. Medtronic Diabetes has a long and successful history of negotiating coverage for insulin pump therapy, and we have the largest contract network of any insulin pump company.

* U.S. only. Prices outside the U.S. may vary.

Government insurance plans – including Medicare and Medicaid – do provide coverage for Medtronic Diabetes insulin pump therapy. Specifically, the MiniMed Paradigm model 515R and 715R insulin pumps are available to government insurance plan members.

I have a model 508 insulin pump still under warranty. Can I purchase a MiniMed Paradigm 722 Insulin Pump with a larger reservoir? ▲ top

Generally speaking, if your insulin pump is still under warranty, your insurance plan would not cover this purchase. While you have the option of paying out-of-pocket, it may be in your financial interest to wait until your insulin pump is no longer in warranty.

Does the MiniMed Paradigm Insulin Pump come with a remote? ▲ top

The remote control is an accessory available for purchase separately, and it is compatible with both the MiniMed Paradigm model 522 and 722 Insulin Pumps.

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1 USB-to-serial converter available (if applicable)

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MiniMed Paradigm® REAL-Time System
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How to Learn More
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Important Safety Information
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Features

Type Size + –

Download the full features overview (Adobe PDF, 42kb) and specifications for the MiniMed Paradigm® 522 or 722 Insulin Pump and Continuous Glucose Monitoring System.

Some of the features of the MiniMed Paradigm 522 or 722 Insulin Pump include [1]:

Exclusive capability of integrating with continuous glucose monitoring technology

When used with the available glucose sensor and MiniLink™ Transmitter components, the MiniMed Paradigm 522 or 722 Insulin Pump displays on-screen REAL-Time data to help you understand more about your glucose control

- Displays updated glucose values every five minutes.
- Displays 3-hour and 24-hour glucose trend graphs, as well as arrows that indicate how fast, and in what direction, glucose is moving.
- Designed to alert patients to potentially dangerous low blood sugar and high blood sugar episodes by sounding an alarm or vibrating.
- Requires a minimum of two calibrations each day (one every 12 hours). A confirmatory fingerstick using a standard blood glucose meter is required prior to making self-management or therapy decisions.

Small size and Lightweight

Model 522 2 x 3 x 0.8 inches, 100 grams.

Model 722 2 x 3.6 x 0.8 inches, 108 grams.

Four color choices

All models are available in clear, blue, smoke, and purple.

Exclusive optional remote control [2]

The Bolus Wizard® Calculator

Patented bolus dosing calculator suggests a bolus dose based on personal settings, food intake, and current blood glucose value.

Adjustable active insulin curves

Active insulin curves selectable between 2 and 8 hours in duration. Defaults to six hours, which most closely represents the published scientific data. [3]

Choice of two reservoir capacities

Model 522: 176 units.

Model 722: 300 or 176 units.

CareLink™ Personal Therapy Management Software for Diabetes

This web-based system transforms data from your MiniMed Paradigm Insulin Pump, blood glucose meters, and online logbook into meaningful treatment information that you and your healthcare provider can use to better manage your diabetes. Uncover problems and patterns not visible with meter software and logbooks.

The ParadigmPAL™ software [4]

Review, modify and/or back up settings for the MiniMed Paradigm Insulin Pump using your computer. [5]

The only wireless connection to a monitor, uses RF technology

The Paradigm Link® Blood Glucose Monitor.

What should you look for in an insulin pump?

Choosing the right insulin pump is an important decision. To help you and your healthcare provider, here are factors recommended by the American Diabetes Association (ADA) [6] for you to consider:

- Cosmetic attractiveness
- Clinically desirable features
- Ease of use
- Safety features
- Durability

- Availability of service and training
- The Truth About Watertight

Get Started Today

Learn more about the MiniMed Paradigm Brand of Insulin Pumps and the REAL-Time Continuous Glucose Monitoring System by calling one of our Insulin Pump Therapy Consultants at 1-800-MINIMED (646-4633), ext. 4776. They can answer your questions and help begin your insurance paperwork. Or request a free therapy and product brochure.

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1 The pediatric model has a few features that are different from the standard model. For additional details, see the Pediatric Model page.

1 Mudaliar SR, et al. "Insulin aspart (B28 asp-insulin): a fast-actin analog of human insulin: absorption kinetics and action profile compared with regular human insulin in healthy nondiabetic subjects." *Diabetes Care*. 1999;22(9):1501-6.

2 Not all commercially available meters are currently supported by this system. Requires the Paradigm Link Interface Cable, which is included with the MiniMed Paradigm 522 or 722 Insulin Pump.

3 Subject to state and federal laws and/or regulations.

4 Requires the Paradigm Link Blood Glucose Monitor and the Paradigm Link Interface Cable, which are included with the MiniMed Paradigm 522 or 722 Insulin Pump.

5 American Diabetes Association. "Position Statement: Continuous Subcutaneous Insulin Infusion." *Diabetes Care*. 2002; 25:S116.

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MiniMed Paradigm® REAL-Time System
- Components
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MiniMed Paradigm® REAL-Time Insulin Pump and Continuous Glucose Monitoring System

Type Size + −

REQUEST INFORMATION >

The MiniMed Paradigm REAL-Time System is the world's only system to integrate an insulin pump with REAL-Time continuous glucose monitoring, taking diabetes management to a level you just can't achieve with other insulin pumps.

Now you can free yourself from multiple daily injections and:

- Know your glucose levels around the clock
- Discover the effects of your diet, exercise, and medication on your glucose levels
- Help prevent lows and highs

New MiniLink™ REAL-Time Transmitter smaller and more comfortable >

DID YOU KNOW...

The MiniMed Paradigm 522 or 722 model Insulin Pump can be purchased and used by itself.

Or, you can get the REAL-Time Continuous Glucose Monitoring Starter Kit to complete the system and maximize its benefits!

Component Overview

View the major components and their functionality (requires Macromedia Flash Player).

The MiniMed Paradigm 522 or 722 Insulin Pump and the optional REAL-Time continuous glucose monitoring components are sold separately.

Demonstration

Play this video (requires Macromedia Flash Player) to see how the system empowers "Caroline" to understand her blood sugar levels and make better, more confident self-management decisions throughout her day.

This demonstration is not for instructional purposes.

Who Can Use the MiniMed Paradigm® REAL-Time System?

- The insulin pump is indicated for adults and children of all ages who require insulin.
- The REAL-Time glucose monitoring components are indicated for persons ages seven and older, with type 1 and type 2 diabetes. A separate pediatric model is indicated for patients ages 7-17.

Get started on the MiniMed Paradigm REAL-Time System.

THE MINIMED Paradigm® REAL-Time
INSULIN PUMP AND CONTINUOUS GLUCOSE MONITORING SYSTEM
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Alleviating Pain · Restoring Health · Extending Life

SEARCH

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Home | Insulin Pump Therapy | Product Information | Help & Support | Healthcare Professionals | About Us

A REAL Breakthrough - the world's only insulin pump with REAL-Time Continuous Glucose Monitoring

THE MINIMED Paradigm® REAL-Time
INSULIN PUMP AND CONTINUOUS GLUCOSE MONITORING SYSTEM
Now I Can

REQUEST INFO

New smaller MiniLink™ transmitter >

Enjoy greater control >

MiniMed Paradigm® REAL-Time

Insulin Pumps: Now I can live in my target zone >

Guardian® REAL-Time System

Continuous Monitoring: Glucose confidence at all times >

CareLink™ Personal Software

Therapy Management: Start solving the puzzle today.

News & Information

- **Medtronic Diabetes to Bring New Meter Option to its U.S. Customers in 2008**
- ParadigmPAL™ DST Patch
- Now Available: REAL-Time CGM for kids
- Update on BD Products
- MiniLink™: Smaller CGM transmitter now available

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EXHIBIT B

https://web.archive.org/web/20071030065834/http://www.medtronicdiabetes.com/pdf/dtc_features_glance.pdf

Medtronic
Alleviating Pain · Restoring Health · Extending Life

FACT SHEET

Features and Benefits
MiniMed Paradigm®
REAL-Time System*

Now i Can
get the best
features for
REAL diabetes control

REAL-Time Continuous Glucose Monitoring System

REAL insights help you take action sooner to improve your glucose control[1-3]

Feature	Specification	Benefit
Glucose Sensor	The glucose sensor is inserted, virtually painlessly, through the skin, usually in the stomach area. The glucose sensor sends an electronic signal measuring the amount of glucose in your interstitial fluid. Replace the glucose sensor every three days.	Measures your glucose levels continuously, as an addition to fingerstick measurements. Displays a five-minute average, 24 hours a day. Numerous studies have proven the accuracy of the sensor.[4-6]
Calibration	Calibrate your MiniMed Paradigm REAL-Time System at least once every 12 hours. In addition, make sure you always confirm with a fingerstick before making any adjustments in your therapy.	Simple and easy.

MiniLink™ REAL-Time Transmitter

Wireless communication gives you REAL comfort

Feature	Specification	Benefit
Small	1.4" x 1.1" x 0.3".	Less noticeable.
Lightweight	Less than 1/4 of an ounce.	Exceptionally comfortable.
Ergonomically Shaped	Rounded, no hard edges.	Won't tug, pull, or pinch with movement.
Thin Profile	Approximately 1/3" thick.	Easy to hide under clothing.
Wireless	Receives and processes signals from the glucose sensor and sends glucose values to the insulin pump through radio frequency (RF).	Provides flexibility to place in different locations of the body.
Waterproof	To a depth of 8 feet for 30 minutes.	Can be worn while swimming, bathing, or showering.
Rechargeable	Quick 20-minute recharge lasts up to three days of continuous use and a full recharge lasts up to 14 days of continuous use.	Allows for long-term use and convenience.

*Information contained in this fact sheet refers to the MiniMed Paradigm 522 and 722 Insulin Pump models. For more information about other models, please visit www.minimed.com.

THE MINIMED Paradigm® REAL-Time
INSULIN PUMP AND CONTINUOUS GLUCOSE MONITORING SYSTEM
Now i Can

Medtronic

MiniMed Paradigm® 522/722 Insulin Pump

REAL-Time features give you insights you need to take action

Feature	Specification	Benefit
REAL-Time Trend Graphs	Your insulin pump displays glucose trend graphs for 3-hour and 24-hour periods.	Shows you the effects of meals, exercise, insulin, and medication on your glucose control.
REAL-Time Readings	Monitors your glucose every minute and displays a five-minute average, 24 hours a day.	Continuous glucose monitoring is proven to improve glycemic control,[1-3] which reduces your risk of long-term complications including eye, nerve, kidney, and heart disease.[7,8]
REAL-Time Alarms	Audible or vibrating alarms occur when glucose levels go out of your preset target range. Personalize alarms to meet your specific needs and preferences. You also can turn off your alarms, if you prefer.	Warns you of high or low glucose levels. Use of continuous glucose monitoring is proven to detect highs and lows that fingersticks and A1C testing alone may miss.[1-3,9]
REAL-Time Trend Arrows	Single and double arrows point up and down to show the degree and direction of glucose trends. One arrow indicates that glucose has risen or fallen 20-40 mg/dL during the last 20 minutes. Two arrows indicate that glucose has risen or fallen >40 mg/dL during the last 20 minutes.	Up arrows reveal increases in glucose levels. Down arrows reveal decreases in glucose levels. Double arrows suggest a more rapid increase or decrease. Use of continuous glucose monitoring helps reduce the duration of high and low blood glucose and A1C. [1-3,9]

Software

Better data management for better diabetes management

Feature	Specification	Benefit
On-Board Data Management	Your insulin pump shows data—blood glucose, insulin delivered, and bolus details—viewable by individual day or as an average of up to 31 days.	Delivers the personalized information you need to make informed decisions about your treatment.
CareLink™ Personal Therapy Management Software for Diabetes	FREE Web-based system transforms data from your insulin pump, glucose sensor, meters, and logbook into meaningful treatment information that you and your healthcare professional can use.	Helps you and your health care provider more effectively optimize therapy.

Small, light, discreet

Feature	Specification	Benefit
Small	Model 522: 2 x 3 x 0.8 inches. (5.08 x 7.62 x 2.03 centimeters) Model 722: 2 x 3.6 x 0.8 inches. (5.08 x 9.14 x 2.03 centimeters)	Easy and comfortable for you to wear under clothing.
Lightweight (with full reservoir)	Model 522: 3.53 ounces (100 grams). Model 722: 3.81 ounces (108 grams).	Easy to wear.
4 Color Choices	Clear, Blue, Smoke, Purple.	Pick a color to match your style.
Exclusive Remote Control	Available for all MiniMed Paradigm Insulin Pumps.	More privacy with one-touch bolus delivery.

Infusion Sets and Serters

A complete line of convenient and comfortable sets for REAL reliability

Feature	Specification	Benefit
Quick-set®	- 90° angle insertion - At-site disconnection - Soft cannula - Quick-serter® auto-insertion device	Features built-in adhesive (no over-taping needed) and a "self-capturing" introducer needle for safe disposal after insertion. Available in two cannula lengths and two tubing lengths.
Silhouette®	- Variable angle insertion - At-site disconnection - Soft cannula - Sil-serter® auto-insertion device	Features built-in adhesive (no over-taping needed). Variable angled insertion allows you to choose the precise insertion depth. Available in two cannula lengths and two tubing lengths.
Sof-set® Ultimate QR® and Sof-set Micro QR®	- 90° angle insertion - Quick Release® disconnection - Four inches away from site - Soft cannula - Sof-serter® auto-insertion device	Easy insertion, connection, and disconnection. Available in two tubing lengths and two cannula lengths.
Polyfin QR®	- Bent surgical steel needle with 35° angled insertion - Quick Release® disconnection four inches away from site - Available with or without built-in adhesive wings	Easy-to-use, smooth bent needle. Available in two tubing lengths.
Sure-T™	- 90° angle insertion - Fine steel needle - Low-profile, virtually unnoticeable design - Two hypoallergenic adhesive pads help prevent needle from dislodging	Offers you an alternative to cannula infusion sets.

Advanced performance for superior diabetes control

Feature	Specification	Benefit
Bolus Wizard® Calculator	Recommends a bolus dose based on your personal settings, food intake, and the amount of active insulin in your body. Includes carbohydrate ratios, insulin sensitivities, and blood glucose targets.	Eliminates the guesswork and complicated diabetes math to make dosing easier and more accurate[10]
Adjustable Active Insulin Curves	Select between two and eight hours.	Automatically defaults to six hours, which most closely represents the published scientific data.[11]
Blood Glucose Target Ranges	Program ranges into your insulin pump. Recommends correction doses when your blood glucose goes outside the range.	Helps keep your blood glucose levels within your personalized target range by recommending necessary correction doses.
High and Low Blood Glucose Alerts	When your insulin pump receives high or low results, it automatically displays helpful management tips.	Help you stay on target for maximum glucose control.
Choice of Reservoir Sizes	Model 522: 176 units. Model 722: 176 or 300 units.	Larger reservoir is for people who require more than 50 units of insulin per day; smaller reservoir makes the insulin pump even more discreet and lightweight.
Accurate Delivery	+ or - 5%.	Precise dosing with controlled, steady insulin delivery.
3 Bolus Delivery Options	Normal, Square Wave,® Dual Wave.®	More closely matches your insulin delivery to the food you eat.
Basal Rates and Patterns	Three patterns, 48 rates each.	Set the pattern and rate to match your day's activities.
Basal Rate Range	0.05 to 35 units per hour.	Precise insulin dosing to meet your specific needs.
Temporary Basal Rate	Increase or decrease by % or set the insulin pump at any rate for 30 minutes, up to 24 hours.	Adjust insulin "on the fly" in response to stress, illness, or changes in your activity levels.
Blood Glucose Testing Reminders	Built into your bolus menus; set to remind yourself 30 minutes to five hours after eating.	Even if you forget, your insulin pump won't. Helps ensure your peace of mind.
Memory	90 days.	Download data to your personal computer; or, for immediate review, view up to 31 days of your personal history on your insulin pump screen.

Safe and durable for your peace of mind

Feature	Specification	Benefit
Keypad Lock-out	Locks, like a cell phone, to prevent unintended programming from accidentally pressing keypad.	Helps protect your therapy control and quality of life by protecting against accidental system settings. Also helpful for parents and caregivers to block children from tampering with settings.
Save/Restore Settings	Save current settings as a backup; restore saved settings if cleared or lost.	Lets you keep your individualized settings for consistent control.
Low Reservoir Alert	Set up automatically in units or time remaining.	For your peace of mind, keeps track of your insulin usage and tells you when it's time to change your infusion set.
Safety Checks	Millions per day, automatically.	Reliable performance.
Alert Modes	Beep or vibrate.	Vibrate mode adds privacy.
Water-Resistant	Protects against splashes or a temporary dunk in water.	Gives you more freedom and flexibility with less worries about system performance and reliability.

Easy to learn, easy to use

Feature	Specification	Benefit
Onscreen icons for battery level, reservoir level, and time of day	Icons appear on every screen.	Helps simplify proper, effective use.
Alarms	Up to eight customizable reminders per day.	Helps you remember the action to take to keep your diabetes in control.
Display	Large font, with backlit screen.	Easy to read, especially at night.
Menus	E-Z PATH™ programming.	Easy to learn, easy to use, with menus that guide you through each step.
Power Source	One AAA alkaline battery.	Cost-effective and widely available.

Support

Expert training and REAL help for all your diabetes management needs

Feature	Specification	Benefit
Education	Training with a Certified Product Trainer.	Smooth transition from multiple daily injections to insulin pump therapy.
Live Help Line	24/7/365 product support.	Around-the-clock support.
Warranty	Four years, including a 30-day money-back guarantee.	Your wise investment is protected.
Supply Ordering	Easy process.	Convenient and reliable for you.
Proven Experience	More than 20 years of leadership from the pioneer in insulin pump therapy and continuous glucose monitoring.	Trust the performance of your insulin pump and the support you'll get from the leader in insulin pump therapy.

1. Kaufman FR, et al. *Diabetes Care*. 2001;24(12):2030.
2. Bode BW, et al. *Diabetes Research and Clin Practice*. 1999;46:183-90.
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4. Steil GM, et al. *Diabetes*. 2000;49(Suppl 1):510.
5. Gross TM, et al. *Diabetes Technol Ther*. 2000;2(Suppl 1):S19-26.
6. Caplin NJ, et al. *Diabet Med*. 2003;20:238-41.
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Confirmatory fingersticks required prior to treatment adjustments.

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THE MINIMED

Paradigm® REAL-Time

INSULIN PUMP AND CONTINUOUS GLUCOSE MONITORING SYSTEM

Sensor Features User Guide

Medtronic

Paradigm®
522 and 722 Sensor Features

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This product is covered by U.S. Patent Nos. 6,551,276; 6,554,798; 6,872,200; 6,936,029; 6,979,326; 6,997,920 and 7,025,743. Other U.S. and/or foreign patents may be pending.

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Introduction

Thank you for choosing Medtronic MiniMed as your partner in helping you gain better control of your diabetes. The Paradigm® 522 and 722 insulin pumps combine the technology of the Guardian® Continuous Glucose Monitoring system to provide not only insulin delivery but real-time glucose sensor values as well.

This user guide is designed to help you understand the sensor features of your pump. We strongly recommend that you work closely with your healthcare professional for a safe and complete pump start, and for ongoing support of your pump therapy experience.

Assistance

Medtronic MiniMed provides a 24 Hour HelpLine for assistance. The HelpLine is staffed with professionals 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 MiniMed 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 and Canada)	800.646.4633 (800.MiniMed)
24 Hour HelpLine (calls outside the United States)	818.576.5555
Web site	www.minimed.com

Accessories

- **Meter:** You can program your pump to automatically receive your blood glucose (BG) readings from your meter. When a BG reading is taken, the value is automatically transferred to the pump and stored in its memory as a calibration point. The calibration point is used to calculate the real-time sensor glucose values that are displayed. The meter can also be used to download data stored in the pump to a computer.
- **Transmitter:** The transmitter (MMT-7703) is a small device that connects to the sensor. It comes with a blue tester and a charger. When connected to a sensor that is inserted in the body, the transmitter automatically initializes the sensor and begins to periodically transmit sensor glucose readings to the pump using a radio signal.

- **Sensor:** The glucose sensor (MMT-7002) is a device that continuously measures glucose from your subcutaneous tissue as an electronic signal, the strength of which is proportional to the amount of glucose present. An introducer needle allows for subcutaneous insertion of the sensor.
- **ComLink:** The Medtronic MiniMed ComLink (MMT-7304), if available, is used to download pump data to diabetes management computer software via a serial communications interface cable.

User safety

Indications

Pump

The Paradigm 522/722 pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Sensor and transmitter

The sensor and transmitter components are 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). It alerts if a glucose level falls below or rises above preset values. Values 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 Paradigm 522/722 pump system values.

Contraindications

Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four (4) 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.

Warnings

Sensor

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

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 PUMP, METER, TRANSMITTER, and SENSOR, and remove them from the area.

NOTE - The Paradigm pump and transmitter are designed and tested to withstand common electromagnetic interference, including airport security systems.

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 dressing develops.

The transmitter should be disconnected from the sensor while traveling on an aircraft, or if it interferes with another transmitting device.

Precautions

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, transmitter, or sensor.

Sensor

Prior to exercising, make sure the sensor is firmly attached.

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 dressing develops. Contact your doctor and the Medtronic MiniMed 24 Hour HelpLine in the event of any adverse reaction.

Notice

CAUTION:	**Any changes or modifications to the devices not expressly approved by Medtronic MiniMed could void your warranty.**

Insulin pump and Radio Frequency (RF) accessories

The pump, transmitter and remote control comply with the United States Federal Communications Commission and international standards for Electromagnetic Compatibility.

Do not use the RF meter to send your BG reading to the pump while on an aircraft. Manually enter your BG.

Do not use your pump's remote control to operate your pump while on an aircraft. Use the pump buttons instead.

The transmitter should be disconnected from the sensor while traveling on an aircraft, or if it interferes with another transmitting device.

These devices comply 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 undesirable operation. It does not interfere with any radio frequency signals transmitted from outside sources.

These standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference. Operation is subject to the following two conditions:

1. This device has been tested and found to comply with the regulations governing such devices in your area. For the specific regulation and test results for your area, please contact the Medtronic MiniMed 24 Hour HelpLine.
2. This device generates, uses, and can radiate radio frequency energy and, if installed and used in accordance with the instruction, may cause 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:

- Reorient or relocate the insulin pump/remote control/meter/transmitter
- Increase the separation between the insulin pump/remote control/meter/transmitter and the device that is receiving/emitting interference.

The meter and transmitter send information to the pump using radio frequency. If other devices that use radio frequency are in use, such as cell phones, cordless phones and wireless networks, they may prevent communication between the pump and the meter and/or the pump and transmitter. This interference will not cause any incorrect data to be sent and will not cause any harm to your pump, transmitter or meter. Moving away from or turning off these other devices may allow communication. Refer to, “Troubleshooting and alarms” in the pump user guide to correct interference problems you may have.

Wireless transmission between the pump and transmitter within the six-feet operating range may be interrupted due to the transmitter orientation and the pump position on the body. Move the pump closer to the transmitter or to another position. If a Lost Sensor alarm has occurred retry:

Sensor > Sensor Start > Find Lost Sensor.

If you have questions, please contact the Medtronic MiniMed 24 Hour HelpLine.

Sensor set-up

Introduction

This chapter describes how to program your pump to get it ready to accept sensor data. To understand how to navigate through these screens refer to your Pump User Guide (Paradigm 522/722 Insulin Pump User Guide).

Sensor icons

There are various icons that appear at the top of your pump screen, such as the time, battery and reservoir icons. The following two icons appear if you are using the sensor.

The sensor icon appears once you start your sensor. (Refer to Chapter 4 for starting your sensor.)

The sensor icon changes when the sensor is connected to the transmitter and communicating with the pump.

When your sensor and transmitter are connected, and communication is lost this icon will re-appear.

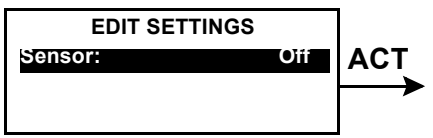
Setting up the sensor features

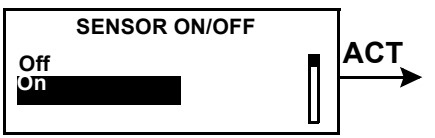
To set up the sensor feature, from the Home screen, press **ACT**, and do the following steps:

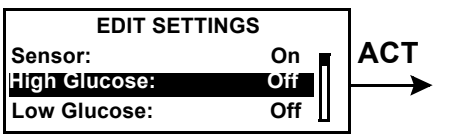
NOTE - The sensor features should be programmed in the order described in this chapter.

Main Menu > Sensor> Sensor Setup > Edit Settings

1 Press **ACT**.	2 Select **On** and press **ACT**.	3 The **EDIT SETTINGS** screen will appear. Press **ACT** to program your High Glucose limit.



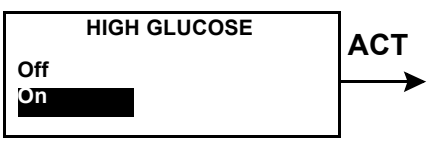


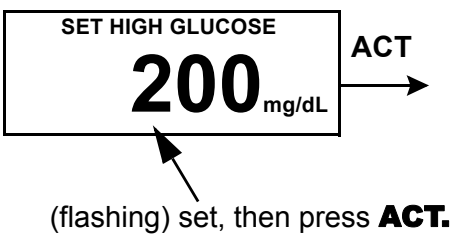


High glucose alarm

Your pump will alarm if your sensor glucose reaches or goes above what you set here. If you do not turn on the High Glucose Alarm, your pump will not alarm when your sensor glucose readings are high.

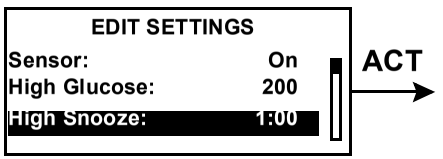
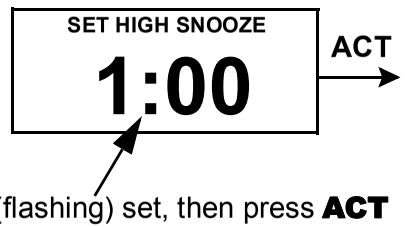
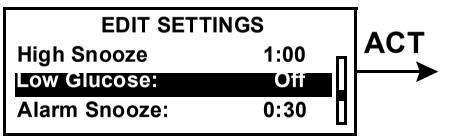
4 Select **On** and press **ACT**.	5 In the **SET HIGH GLUCOSE** screen, use the up and down arrow buttons to set your limit. Press **ACT**.





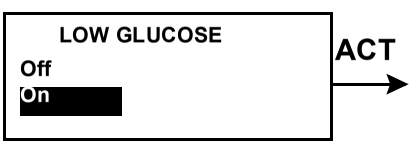
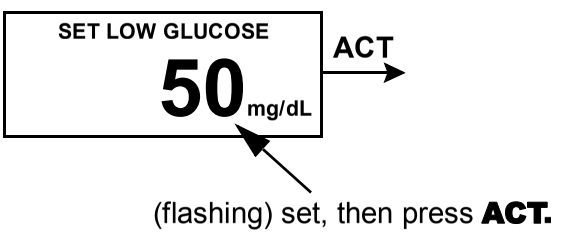
High snooze

Once you get a High Glucose Alarm, the pump is set to alarm every hour while the high glucose condition exists. The High Snooze feature can be set (5 minutes to 3 hours) to increase or reduce the frequency of alarms until your glucose level goes below the set High Glucose level.

6 **High Snooze** will be highlighted. Press **ACT**. 	7 Use the up and down arrow buttons to select your High Snooze alarm time. Press **ACT**. 	8 Press **ACT** to program your Low Glucose limit. 

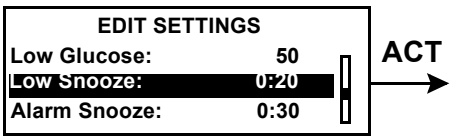
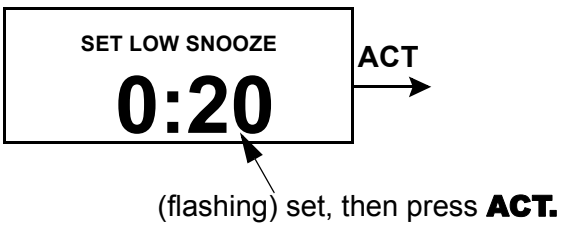
Low glucose alarm

Your pump will alarm if your sensor glucose reaches or goes below what you set here. If you do not turn on the Low Glucose Alarm, your pump will not alarm when your sensor glucose readings are low.

9 Select **On** and press **ACT**. 	10 Use the up and down arrow buttons to set your Low Glucose limit. Press **ACT**. 

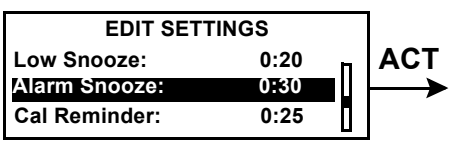
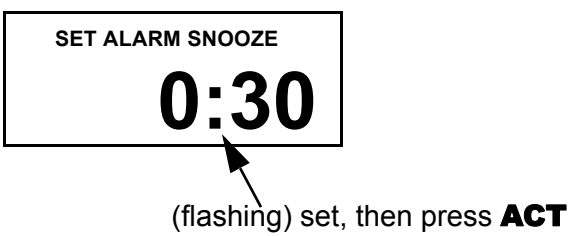
Low snooze

Once you get a Low Glucose Alarm, the pump is set to alarm every 20 minutes while the low glucose condition exists. The Low Snooze feature can be set anywhere from 5 minutes to 1 hour to increase or reduce the frequency of alarms until your glucose level goes above the set Low Glucose level.

11 **Low Snooze** will be highlighted, press **ACT**. 	12 Use the up and down arrow buttons to select your Low Snooze alarm. Press **ACT**.  (flashing) set, then press **ACT.**

Alarm snooze

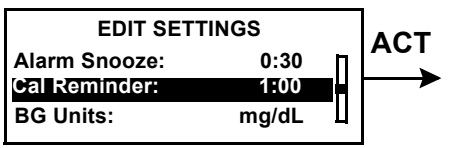
This option allows you to set an alarm snooze for the Meter BG Now alarm (see Chapter 5, Troubleshooting and Alarms for more information). So, instead of alarming every 5 minutes, the pump will alarm at the time interval you set here. For example, if you set an Alarm Snooze of 20 minutes for the Meter BG Now alarm, the alarm will only repeat every 20 minutes until you enter a Meter BG.

13 **Alarm Snooze** will be highlighted, press **ACT**. 	14 Use the up and down arrow buttons to select your Alarm Snooze time. Press **ACT**.  (flashing) set, then press **ACT**

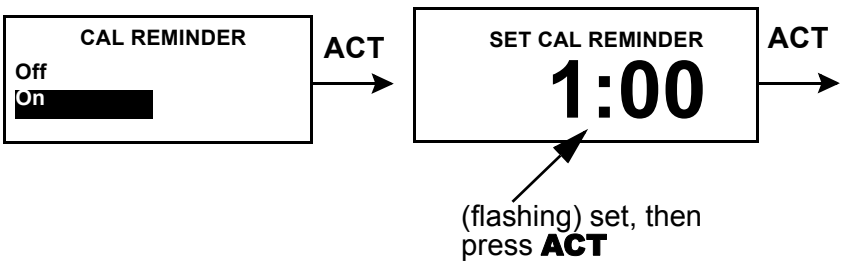
Cal reminder

Once you enter a meter BG, you will have to enter another BG within 12 hours. Otherwise, you will receive an alarm stating when your meter BG is due (Meter BG By X:XX). To help you remember to enter your meter BG readings for sensor calibration, you can set the Cal Reminder feature. For example, if you set your reminder to 4 hours, you will receive a Meter BG By X:XX alarm 4 hours before the next meter BG entry is due (8 hours after your last successful sensor calibration was done). To set your Cal Reminder:

15 **Cal Reminder** will be highlighted. Press **ACT**.



16 Use the up and down arrow buttons to select your Cal Reminder time. Press **ACT**.

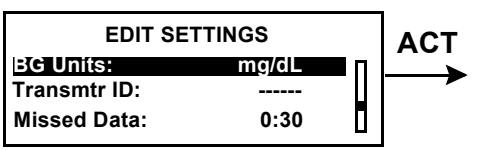


BG units

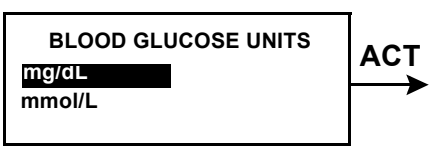
You can select **mg/dL** or **mmol/L** as your Blood Glucose Unit (measurement type).

NOTE - Once the Bolus Wizard® feature is turned on, the BG Units will no longer appear in the sensor menu, but can be set through the Bolus Wizard menu.

17 **BG Units** will be highlighted. Press **ACT**.



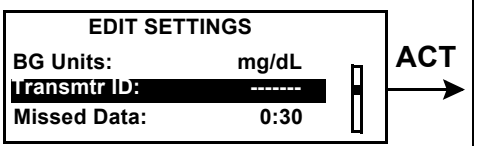
18 Select **mg/dL** or **mmol/L** and press **ACT**.



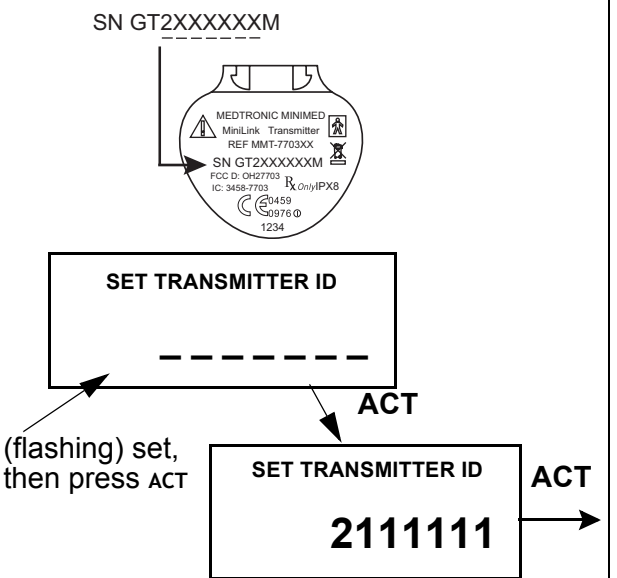
Transmitter ID

The transmitter ID (SN) starts with 2 and is found on the flat side of your transmitter. You need to enter your transmitter ID so the transmitter and the pump can communicate with each other.

19 Select **Transmtr ID** and press **ACT**.

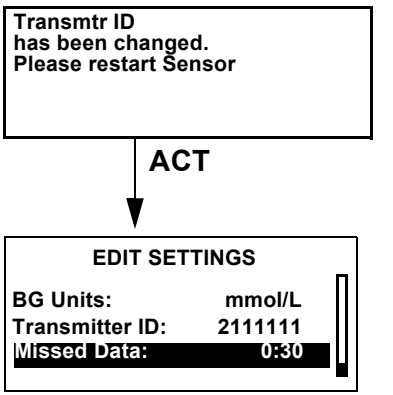


20 Use the up and down arrow buttons to select each of the seven ID numbers. Press **ACT** after each entry. Press **ESC** when you are done.



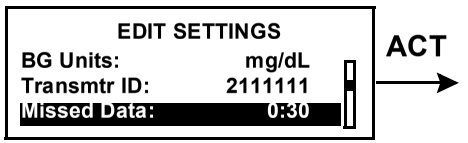
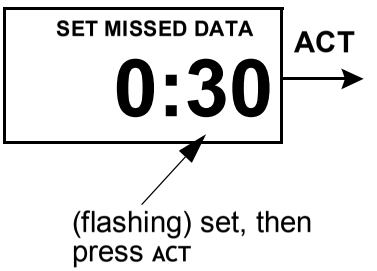
Tip - To remember your transmitter ID, write it here: 2_____.

21 The **EDIT SETTINGS** screen will appear. Your Transmitter ID will be displayed.



Missed data

The Missed Data option allows you to set the period of time the pump will wait to alert you of a failed reception of sensor data from the transmitter to the pump.

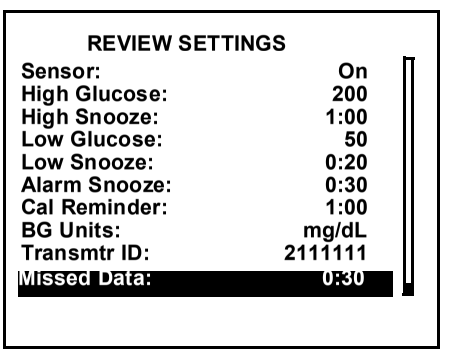
22 Select **Missed Data** and press **ACT**. 	23 Use the arrow buttons to select your Missed Data time. Press **ACT**. 	24 When you have completed the sensor setup, press **ESC** until the HOME screen appears.

Review settings

Main Menu > Sensor > Sensor Setup > Review Settings

The Review Settings feature allows you to review your settings to verify that they have been set as you intended.

Select Review Settings now and verify that your settings are correct.



Default settings

Menu	Item	Default Setting	Limits
Sensor Menu:	Sensor:	Off	
	High Glucose:	Off	Low-400 mg/dL (Low-22.2 mmol/L)* **Note:** Your high limit will always be at least 10 mg/dL (0.6 mmol/L) above your low limit.**
	Low Glucose:	Off	40 mg/dL-Hi (2.2 mmol/L-Hi)* **Note:** Your low limit will always be at least 10 mg/dL (0.6 mmol/L) lower than your high limit.**
	Alarm Snooze:	0:30	0:05-1:00
	Cal Reminder	1:00	0:05-4:00
	BG Units	mg/dL	
	Missed Data	0:30	0:05-0:40
	Low Snooze	0:20	0:05-1:00
	High Snooze	1:00	0:05-3:00

* Depending on your settings for High and Low Glucose, your limit ranges will vary.

** If you set your High Glucose limit at 100 mg/dL (5.6 mmol/L) then you cannot set your Low limit greater than 90 mg/dL (5.0 mmol/L). If you set your Low Glucose limit at 50 mg/dL (2.8 mmol/L) then you cannot set your High limit lower than 60 mg/dL (3.4 mmol/L).

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 a blue tester (MMT-7706) and a charger (MMT-7705).

MiniLink Transmitter

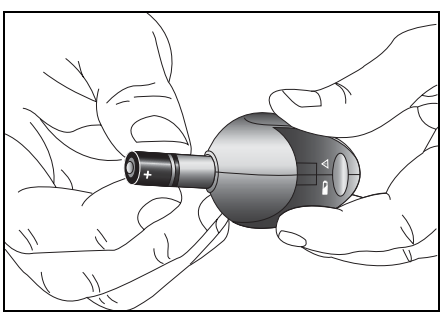
MiniLink Tester

MiniLink Charger

Transmitter 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 “Understanding your transmitter, tester and charger” on page 42. The charger needs a AAA battery to operate.

Installing a new charger battery



1. Unscrew 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 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.
3. If the battery is installed incorrectly or is low, the charger will not work. Repeat the steps above using a new battery.

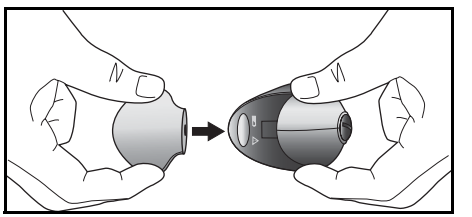
NOTE - A new AAA battery contains enough power to recharge the transmitter more than 40 times.

Charging the transmitter

Before using your transmitter for the first time, you must fully charge the transmitter battery which may take up to 8 hours. It is recommended to recharge the transmitter after each sensor use. A fully charged transmitter battery will generally work more than 14 days without recharging.

NOTE - When connecting the transmitter to the charger, always allow at least one minute before disconnecting or the transmitter will not work. If you disconnect your transmitter before one minute, reconnect it to the charger for at least one minute.

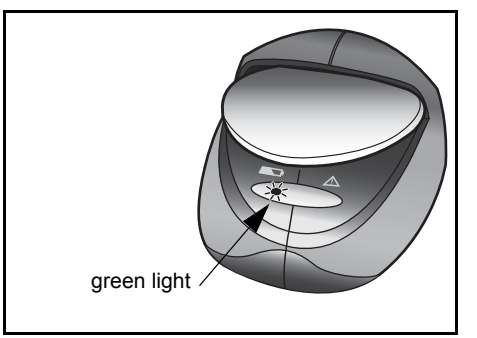
1 Insert the transmitter into the charger by lining up the transmitter connector (flat side down) with the charger. Push the two components together fully.



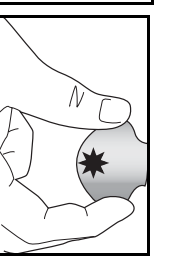
NOTE - If a green light on the transmitter is lit or flashing, do not connect the transmitter to the charger. The transmitter will not charge with its green light on. Wait for the green light to turn off (about 30 seconds), then connect it to the charger.

2 Within 10 seconds after the transmitter is connected to the charger, a green light on the charger will flash for 1-2 seconds as the charger powers on. For the rest of the charging time, the charger's green light will flash on and off every second.

3 When charging is complete, the green light on the charger will stay on, without flashing, for 15-20 seconds and then turn off.



4 After the green charger light turns off, disconnect the transmitter from the charger. The green light on the transmitter will flash for about 5 seconds and then turn off. Your transmitter is now ready to use. See the picture on the right.



Starting the sensor

Introduction

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

- Insert a battery into the transmitter's charger. See "Installing a new charger battery" on page 15.
- Charge the transmitter battery. See "Charging the transmitter" on page 16.
- Set up the sensor features. See "Setting up the sensor features" on page 8.
- Insert the sensor (see page 19). Wait five minutes.
- Connect the transmitter to the sensor. See "Connecting the transmitter to the sensor" on page 23.
- Start the sensor. Wait two hours. See "Preparing the sensor for communication" on page 23.
- Enter your first meter BG. See "Entering meter BG" on page 26.

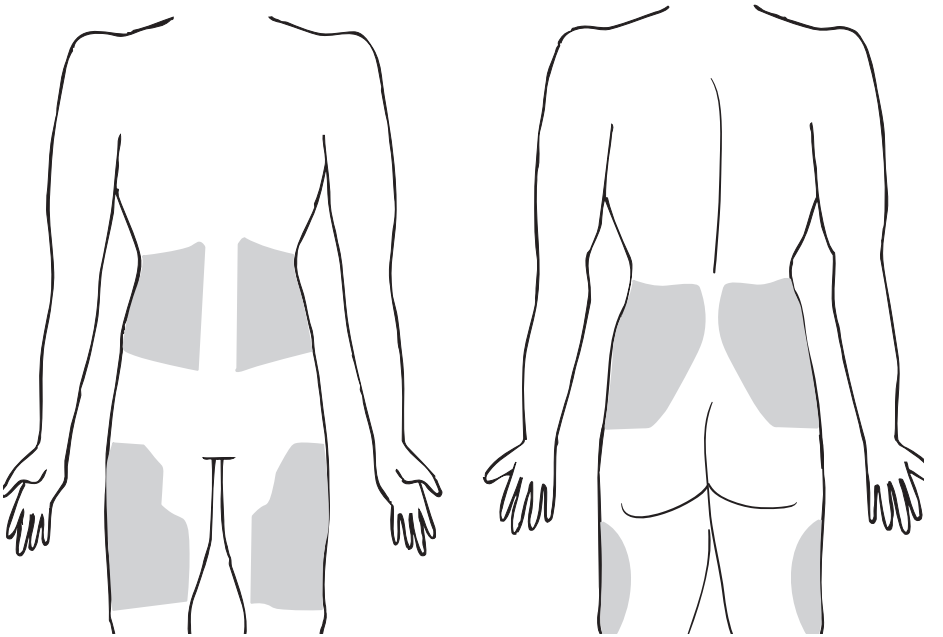
Inserting the sensor

Before inserting the sensor, you must fully charge (see "Charging the transmitter" on page 16) and set up (see "Transmitter ID" on page 12) the transmitter. Also, if the sensor has been refrigerated, remove the sensor package from refrigeration. To avoid condensation, make sure that you allow the sensor package to reach room temperature before opening.

The sensor is inserted through the skin with an insertion device called the Sen-serter® and placed in the fatty layer under the skin. The sensor produces a signal that reflects the amount of glucose in the interstitial fluid at the insertion site. This signal is sent to the transmitter, which is then sent to the pump. The pump translates the signal and displays a sensor glucose reading on your pump screen.

WARNINGS:	**The sensor may create special needs regarding your medical conditions or medications. Please discuss these conditions and medications with your doctor before using the sensor.** **Bleeding, swelling, irritation and/or infection at the insertion site are possible risks associated with inserting the sensor and sometimes results from improper insertion and maintenance of insertion site.**

Choose a site with an adequate fatty layer for sensor insertion. Shown here are the best body areas (shaded) for sensor insertion.



CAUTION: Never insert the sensor within 2 inches from the pump infusion site or within 3 inches from the manual injection site.

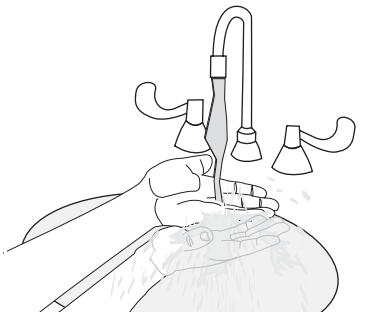
Areas to avoid:

- Frequently used injection or pump/sensor sites
- 2-inch area around navel
- Site where clothing will rub or constrict
- Scarred or hardened tissue
- Areas subjected to a lot of movement
- Never insert the sensor within 2 inches from the pump infusion site or within 3 inches from the manual injection site.
- Be sure to rotate the sensor sites so that they do not become overused.

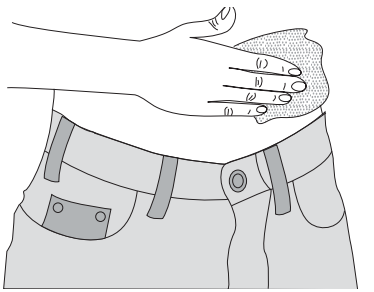
NOTE *- Clean site with alcohol, making sure site is dry before inserting the sensor. Do NOT use skin-preparation solutions prior to insertion. However, I.V. Prep may be used after insertion and before applying a sterile dressing. Lift back of tape slightly to apply I.V. Prep.*

Always refer to the instructions that shipped with your glucose sensor.

1 Wash your hands.

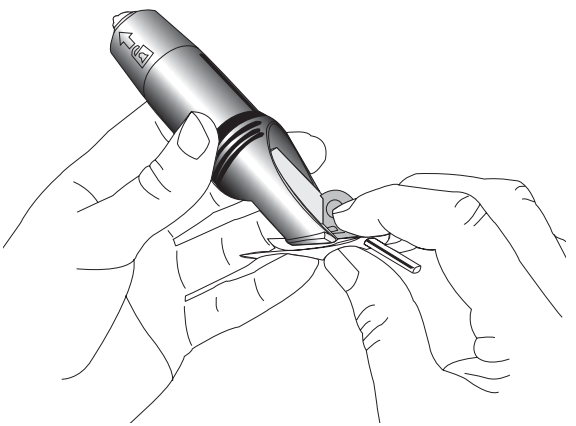


2 Clean with alcohol and then dry the sensor site.

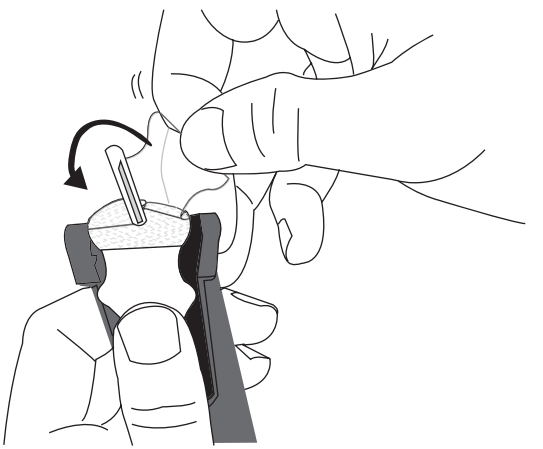


3 Remove the sensor from package by holding base or tape. Do not hold the sensor by the introducer needle handle.

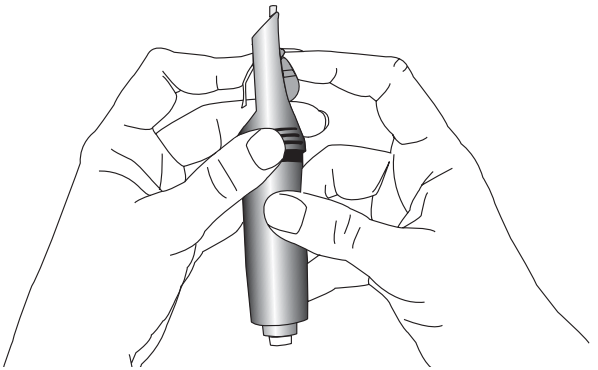
4 Place the sensor in the Sen-serter until it fits snugly.



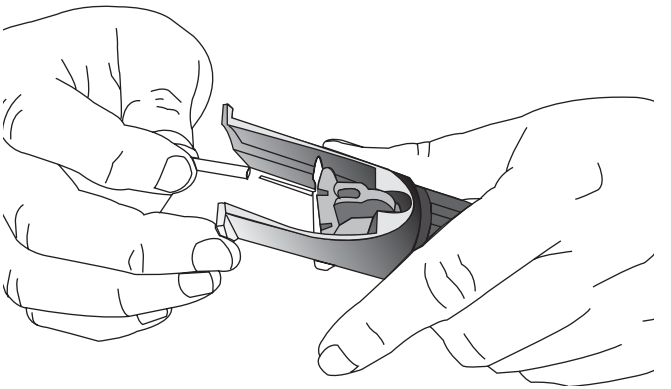
5 Holding the white tape as shown, remove the clear tape using a counterclockwise motion.



6 Place fingers on the back of the white tape and push the carrier down until it clicks into place.

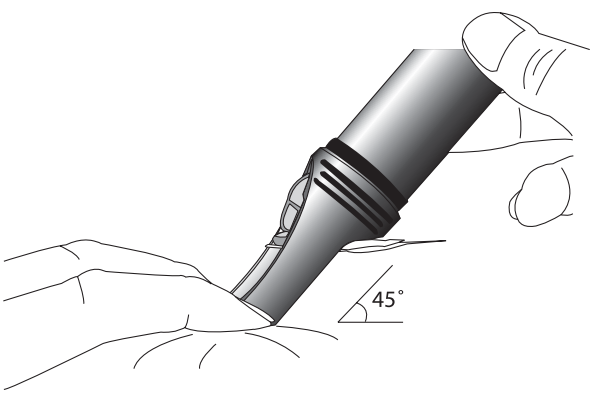


7 Turn the white button to lock the Sen-serter. Remove needle guard from introducer needle.

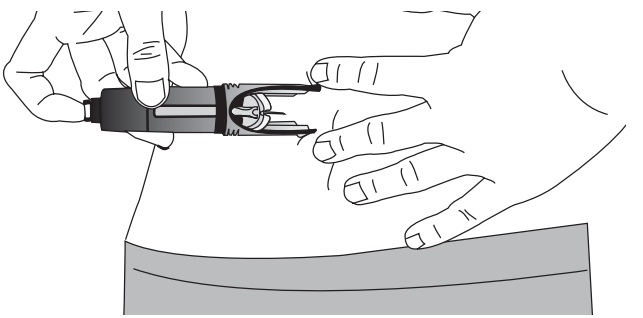


8 Rest the Sen-serter legs flat on skin so the Sen-serter is at a *45 degree angle or more* to the insertion site. Place two fingers of your other hand on the Sen-serter legs to maintain the correct angle.

NOTE *- Bleeding can occur if you insert the sensor at an angle less than 45 degrees.*

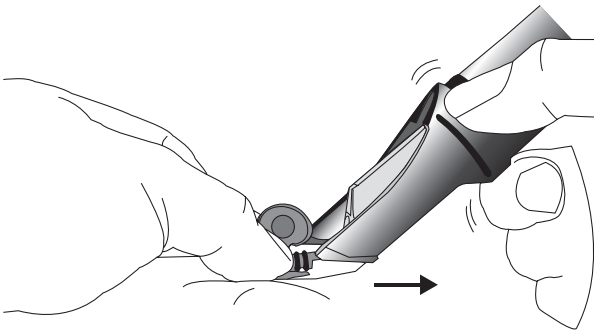


9 Turn the white button to unlock the Sen-serter. Press the white button to insert the sensor. If the sensor is not fully inserted, it can be manually pushed into place before removing the introducer needle.

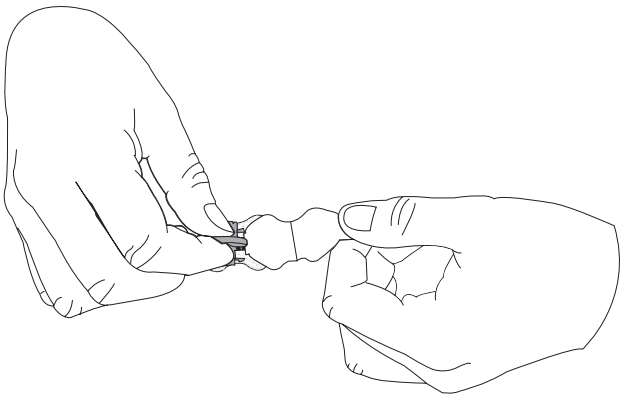


10 Make sure the sensor is inserted and flush with your skin.

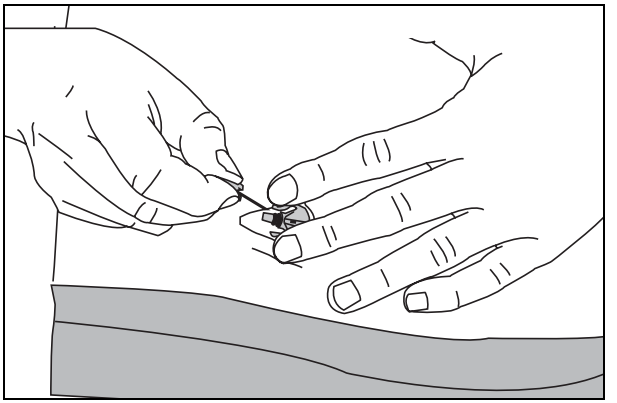
11 While holding the sensor in place, gently slide the Sen-serter away from the sensor. Do not twist, bend or lift the Sen-serter while removing from the sensor.



12 Holding the sensor in place, remove the white paper from the adhesive pad. Press adhesive against your skin.



13 Hold the sensor with two fingers on the base, and gently remove the introducer needle. Do NOT rotate the introducer needle when removing. Dispose of the needle in sharps container.



14 Wait 5 minutes after insertion before connecting the transmitter to the sensor. Make sure that the site is not bleeding before connection. If bleeding occurs apply pressure using a sterile gauze or clean cloth for 3 minutes.
When bleeding stops, attach the transmitter to the sensor.

Caution: If bleeding does NOT stop, DO NOT connect the transmitter to the sensor.

a. Remove the sensor and discard.

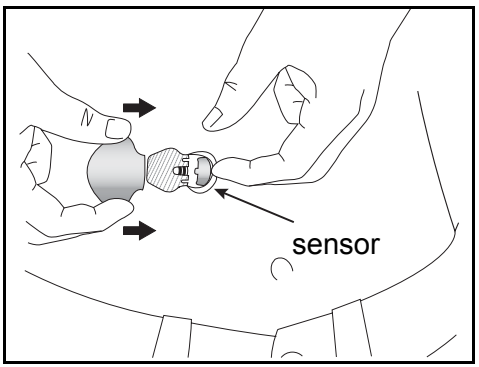
b. Reapply pressure using a sterile gauze or a clean cloth until the bleeding stops.

c. Insert a new sensor in a different location.

Connecting the transmitter to the sensor

Before connecting the transmitter to the sensor, you must have the transmitter fully charged (see "Charging the transmitter" on page 16) and set up (see "Transmitter ID" on page 12). You must also have the sensor inserted (see the instructions on page 19 and those provided with your sensor).

1. After the sensor is inserted, wait 5 minutes before connecting the transmitter. Check for bleeding. Make sure that any bleeding has stopped (see page 22), then connect the transmitter to the sensor.
2. Touch the inserted sensor at back of assembly to prevent movement.
3. Hold the transmitter as shown to line up the two notches on both sides with the flexible side arms of the sensor. The transmitter's flat side with the label should face the skin.
4. Slide the transmitter onto the sensor and push in firmly until the flexible side arms of the sensor "click" into the notches on both sides of the transmitter. In the next 20 seconds the transmitter light will flash green for about 10 seconds with a proper connection.

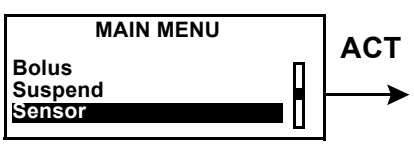


5. After the transmitter light flashes green, use your pump to start communicating with the sensor and to start the sensor initialization. The pump will notify you with a Meter BG Now alarm when the sensor is ready for calibration. See "Preparing the sensor for communication" on page 23.
6. After the transmitter successfully sends signals to the pump, you may choose to put an occlusive dressing over the transmitter and the sensor.

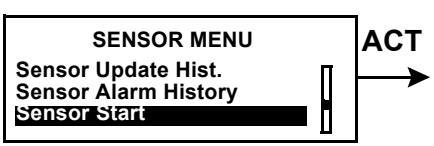
Preparing the sensor for communication

You are now ready to use your pump to start communicating with the sensor and start sensor initialization. The pump will start a timer and notify you when the sensor is ready to use. To do this, use your pump to follow the steps below:

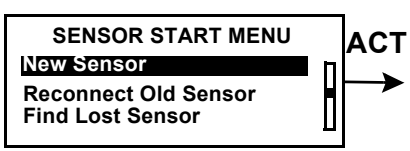
1. Press **ACT** from the HOME screen. In the MAIN MENU, select **Sensor** and press **ACT**.



2. Select **Sensor Start** and press **ACT**.



3. **New Sensor** will be highlighted. Press **ACT**.



NOTE - If screen times out, start again. DO NOT disconnect sensor.

4 Connect the transmitter to your sensor now if you have not already done so. After it is connected, press **ACT**. **NEW SENSOR** **Connect new sensor,** **then press ACT, or** **ESC to abort** **ACT** →	**5** The sensor will enter a two hour initialization period. Press **ANY KEY** to continue. After this period is completed, you will be alerted to enter a meter BG to calibrate your sensor. **SENSOR READY 2 HRS** **Alert will sound when meter BG** **is required.** **Press any key to cont.** *NOTE - Your blood glucose must be stable at the time you enter your first meter BG after initialization. See calibration guidelines on page 25.*

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 10-15 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 will alarm with the Meter BG Now alarm. 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 3-4 times spread throughout the day.
- Avoid calibrating your sensor during times of rapid glucose change such as after eating or exercise.
- Enter a 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 fingertips to obtain blood samples for calibration.

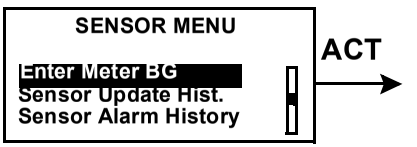
Entering meter BG

Sensor calibration will be successful only if the BG entry is in the range of 40-400 mg/dL (or 2.2 to 22 mmol/L). There are three ways listed below to enter a meter BG value. Use one of these ways for all the calibrations throughout the sensor's life, including the first calibration after the initialization.

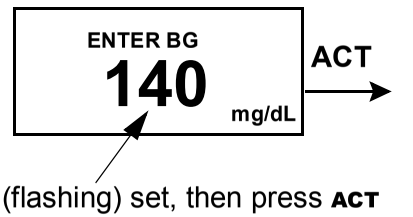
1 To enter a meter BG value manually, perform the following steps:

a. From the MAIN MENU, select **Sensor** and press **ACT**.

b. Select **Enter Meter BG,** press **ACT.**



c. Use the up and down arrow buttons to enter your meter BG. Press **ACT**.



2 If at the time of sensor calibration you also need to perform a bolus using the Bolus Wizard, you can use the meter BG for both calibrating the system and bolusing. To enter a meter BG value manually in the Bolus Wizard, go to the ENTER BG screen by pressing the **Express Bolus** button on your pump, or by using the MAIN MENU:

Main Menu > Bolus > Use Bolus Wizard > Enter BG

Use the up and down arrow buttons on your pump to enter the meter BG. Press **ACT.** Select **Yes** when **BG to update Sensor** screen comes up.

3 To enter a BG value automatically through your meter, test your BG with a fingerstick. The BG value will be automatically sent from the meter to your pump. Make sure that your pump and the meter are properly programmed for communication.

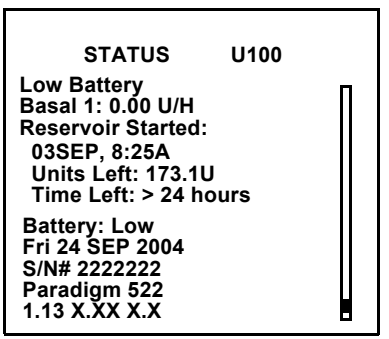
NOTE – You should calibrate 3-4 times spread throughout the day for optimal results. During times of rapid glucose change, turn the automatic send feature off on your meter.

Status screens

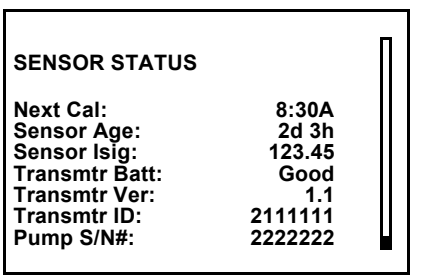
Your STATUS screens tell you what is going on in your pump. In the SENSOR STATUS screen you can check the status of sensor information including when your next calibration will be needed, your sensor's age, and the state of your transmitter battery.

To get to your status screens:

1. From the HOME screen, press the **ESC** button three times. 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.

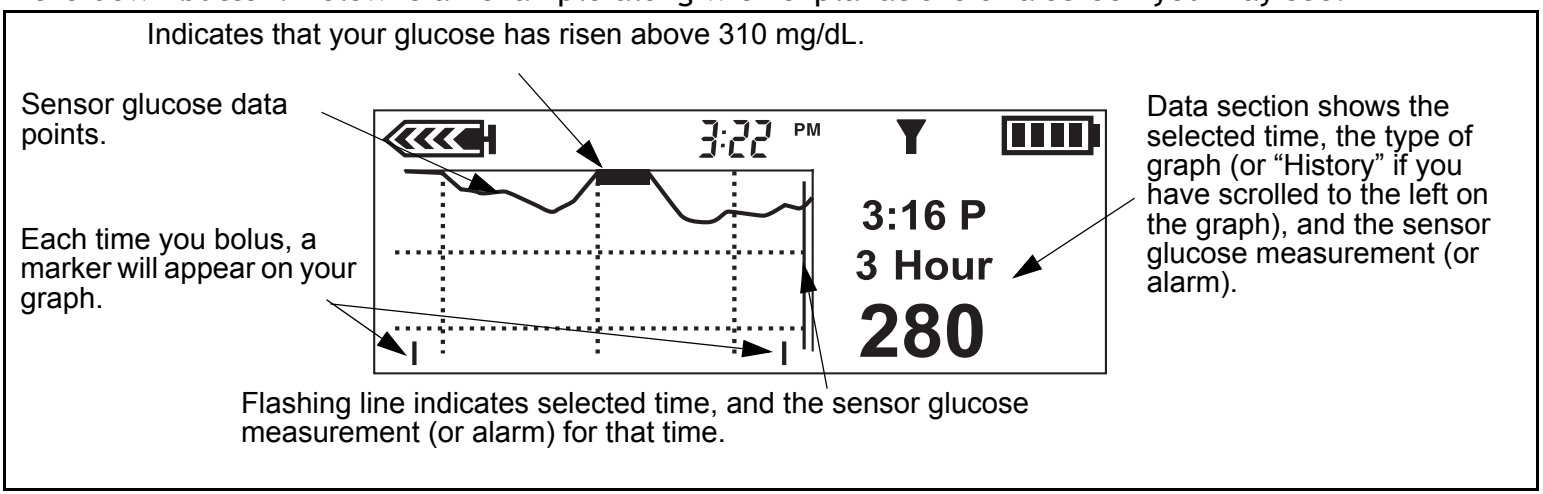


Reading your graphs

Once the sensor is calibrated you can view your sensor glucose values in real time. To view your current sensor glucose and the most recent three hours of data, press **ESC** once from the HOME screen. To view the most recent 24 hours of data, press **ESC** twice from the HOME screen.

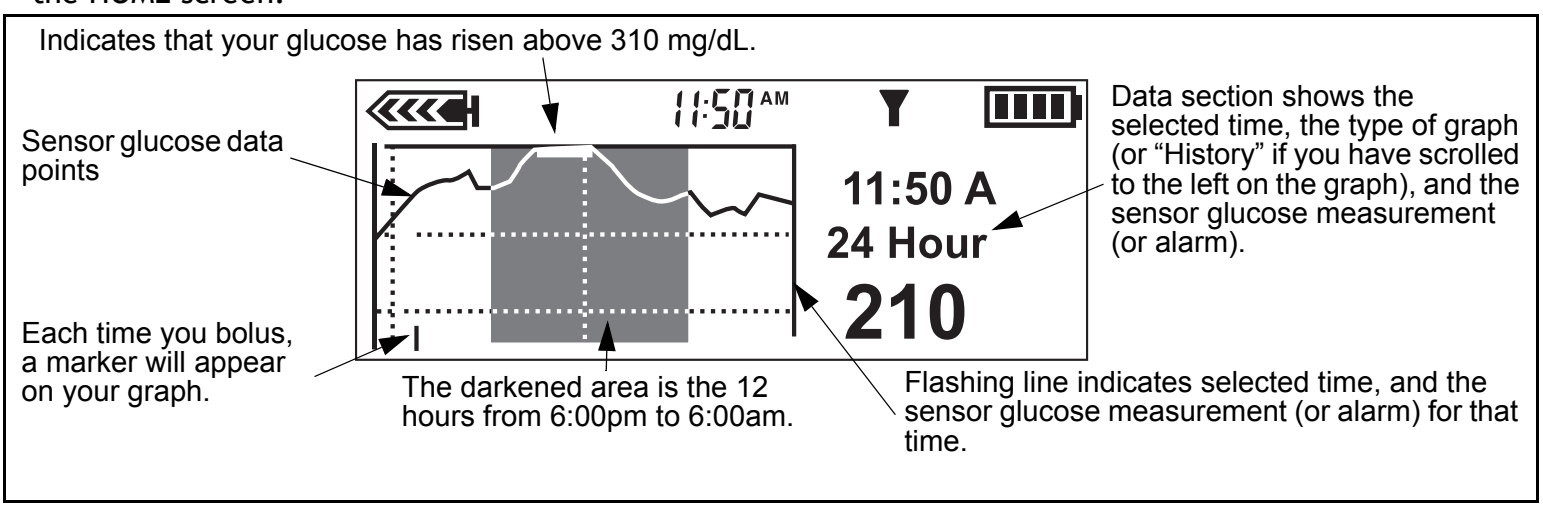
3 hour graph

To scroll through your sensor glucose data points and any alarms that you may have received, press the down button. Below is an example along with explanations of a screen you may see.



24 hour graph

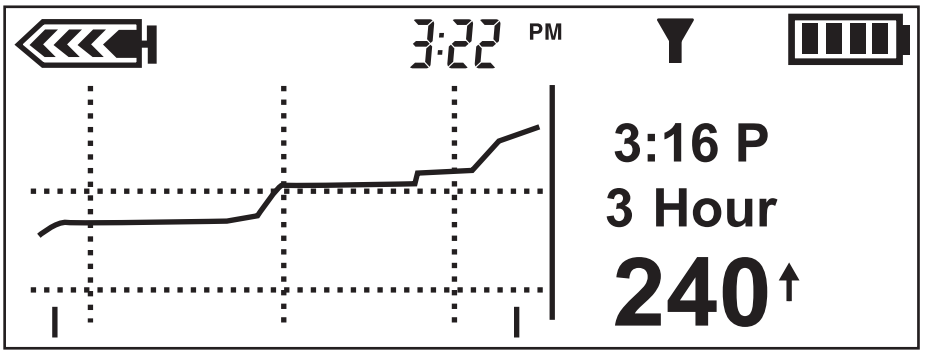
To view the current glucose and a graph of the most recent 24 hours of data, press **ESC** twice from the HOME screen:



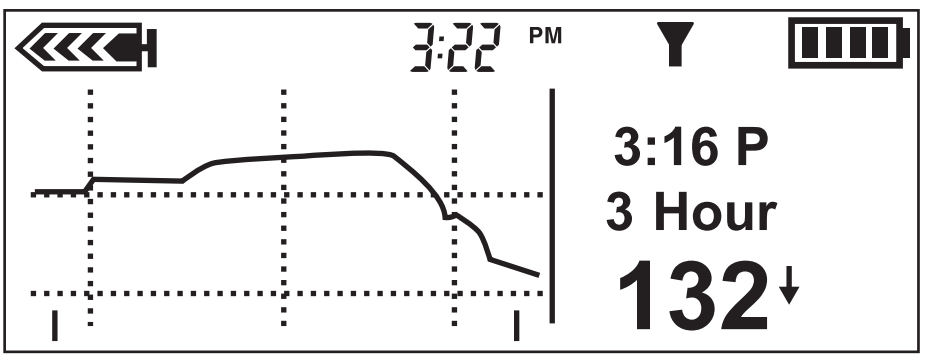
Your glucose values

Your glucose value will be shown on your graph. Each data point on the graph indicates your sensor glucose reading at that time. If an arrow is next to your sensor glucose data:

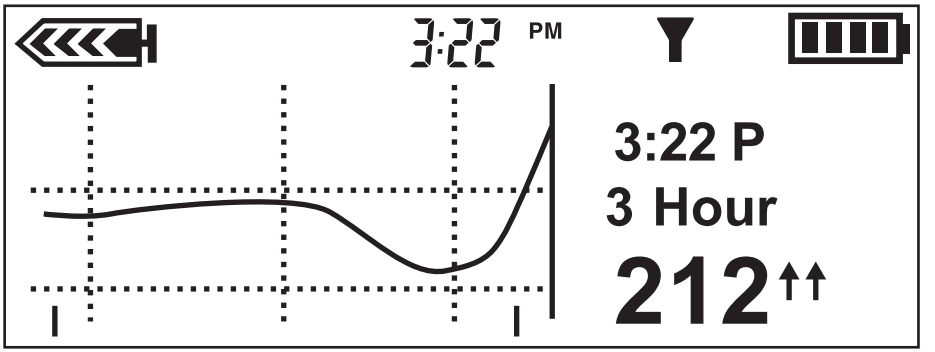
- An up arrow ↑ next to your glucose measurement indicates that your glucose has been rising at a rate of 1 to 2 mg/dL per minute for the last 20 minutes. Your glucose has changed by 20-40 mg/dL in the last 20 minutes.



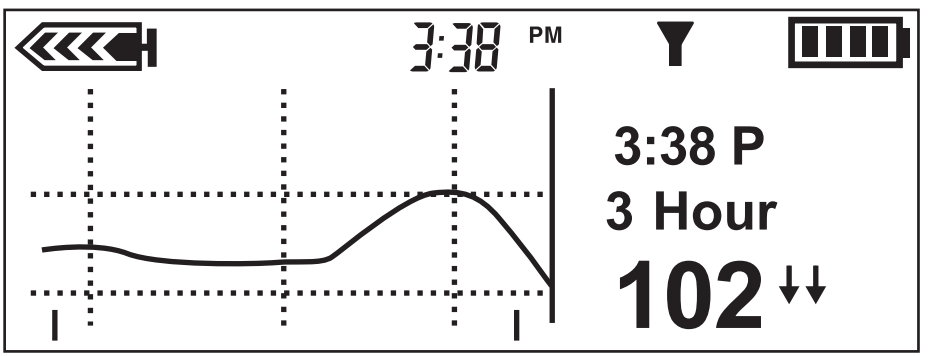
- A down arrow ↓ next to your glucose measurement indicates that your glucose has been dropping at a rate of 1 to 2 mg/dL per minute for the last 20 minutes. Your glucose has changed by 20-40 mg/dL in the last 20 minutes.



- Two up arrows ↑↑ next to your glucose data indicate that your glucose has been rising at a rate of more than 40 mg/dL over the last 20 minutes.



- Two down arrows ↓↓ next to your glucose data indicate that your glucose has been dropping at a rate of more than 40 mg/dL over the last 20 minutes.



Your alarms

The graph will show any alarms that you received along with the time of the alarm. The alarms you will see in your graph screens are:

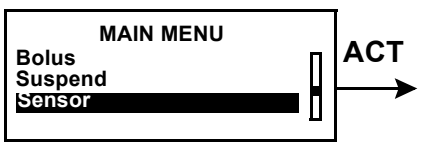
➠ Meter BG ➠ Cal Error	➠ Sensor End ➠ Bad Sensor	➠ Sensor Error ➠ Weak Signal	➠ Lost Sensor

For further information on these alarms, go to Chapter 6, Troubleshooting and Alarms.

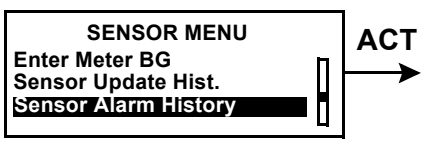
Sensor alarm history

Lists all of the sensor alarms that have occurred, displaying up to 36 alarms. To view your Sensor Alarm History:

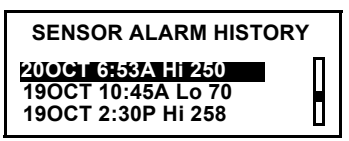
1. From the MAIN MENU, select **Sensor** and press **ACT**.



2. Select **Sensor Alarm History** and press **ACT**.



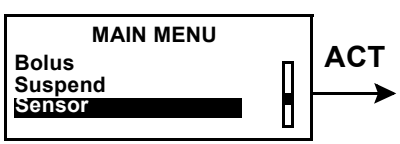
3. The **SENSOR ALARM HISTORY** screen will appear.



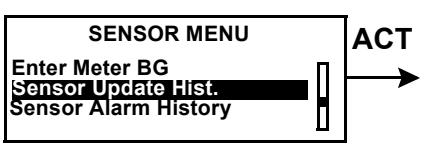
Sensor update history

Lists all of the successful sensor calibration BG values that were entered into the pump more than 15 minutes ago. To view your Sensor Update History:

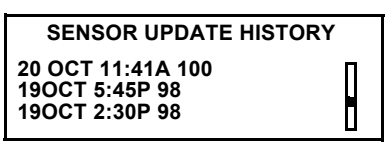
1. From the MAIN MENU, select **Sensor** and press **ACT**.



2. Select **Sensor Update Hist.** Press **ACT**.



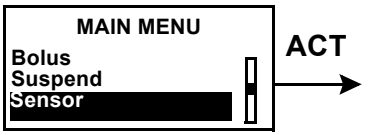
3. The **SENSOR UPDATE HISTORY** screen will appear.



Review settings

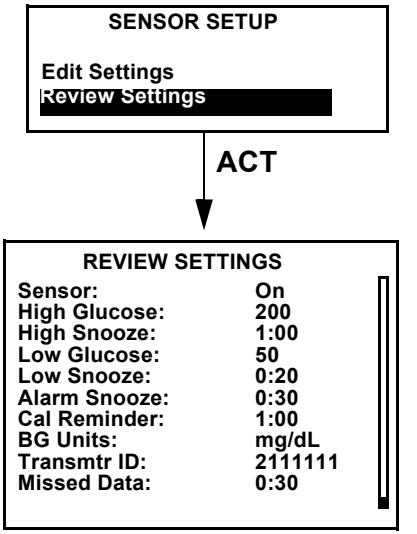
To review your sensor settings do the following:

1 From the MAIN MENU, select **Sensor** and press **ACT**.



2 Select **Sensor Setup** and press **ACT**.

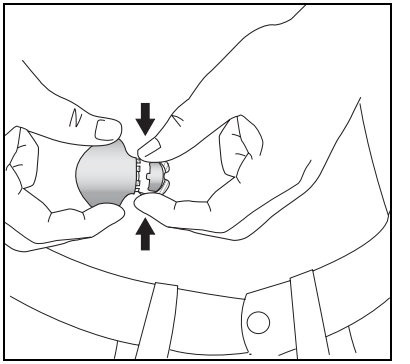
3 Select **Review Settings** and press **ACT.**



NOTE - If you do not turn on the High Glucose or the Low Glucose alarms, you will not see High Snooze or Low Snooze listed under Review Settings.

Disconnecting the transmitter and removing the sensor

Disconnecting the sensor from the transmitter



NOTE - If you are not going to replace the sensor, turn off the Sensor feature on the pump to avoid getting a Lost Sensor alarm.

1. Hold the transmitter as shown, and pinch the flexible side arms of the sensor between your thumb and forefinger.
2. Gently pull the transmitter away from the sensor assembly.

Removing the sensor

Gently pull the sensor from your body to remove it. Place it in a sharps container.

Storage

If you do not plan to use your transmitter in the next 30 days, connect it to the charger for storage.

Using your system in water

Your pump must not be used in water and needs to be removed if planning water activities. You should shower, bathe and swim with the transmitter and the sensor by following the guidelines below:

1. Disconnect the infusion set from the pump and remove the pump. The pump is not water-tight.
2. After the transmitter and sensor are connected, they form a water-tight seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them. Avoid taking extremely hot baths as this may significantly reduce the sensor's life.
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.

Alarms

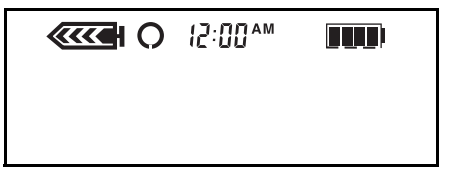
Your pump has a sophisticated network of safety checks and systems. If the safety network detects anything unusual, your pump notifies you of conditions that require your immediate attention. Sensor alarms put the pump in “Special” mode displaying an alert icon ○ on the screen, and the backlight illuminates the pump screen.

NOTE - The STATUS screen shows any alarms that are active.

➠ Why are alarms important?

Your pump monitors activities and notifies you if there is an unusual pump status or your attention is required.

An alarm gradually becomes higher in volume until you turn it off. If the vibrate mode is on, all alarms start as vibrations and then change to beeps. For your safety, if there is no response within ten (10) minutes, the beeps change to a siren. The pump will alarm with a siren and/or a vibration every minute until the alarm is cleared.

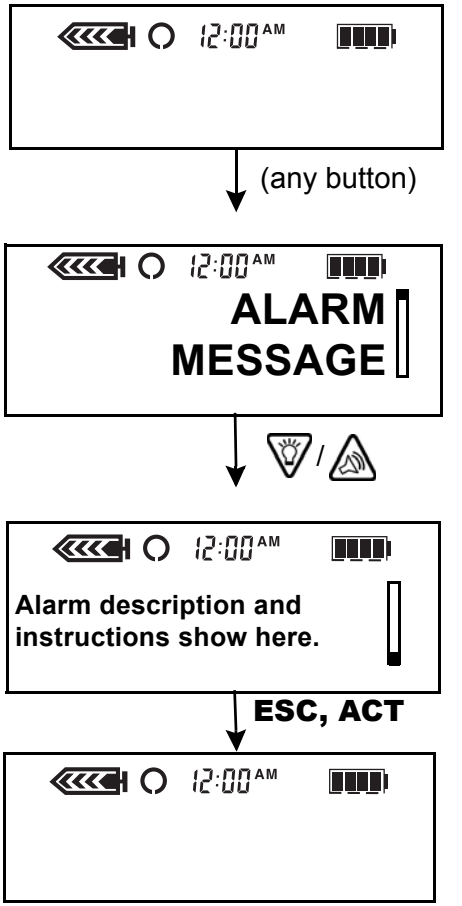


when an open circle appears, follow the instructions on the screen.

What to do

When an alarm is triggered, the pump goes into Special 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 the down button to read more text, if available.)

3 **Clear the alarm:**
Press **ESC** then **ACT** after you read the alarm instructions.

4 The HOME screen appears.

5 **Follow the instructions** that appeared with the alarm to fix the alarm condition.

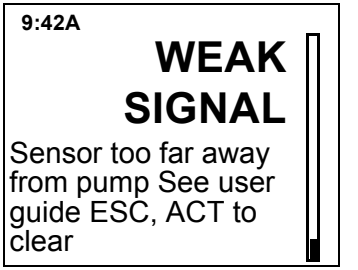
6 **Check your settings** (i.e., time/date, basal, etc.) to make sure they are correct.

Sensor alarm conditions

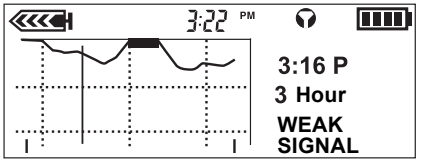
Listed below are the alarms that you may encounter while using the sensor feature of your pump, along with how to resolve the alarm condition.

Weak signal

Alerts you when the pump does not receive data for a period of time, as set in Missed Data. Move the pump closer to the transmitter or move the transmitter and the pump to a new location on your body.

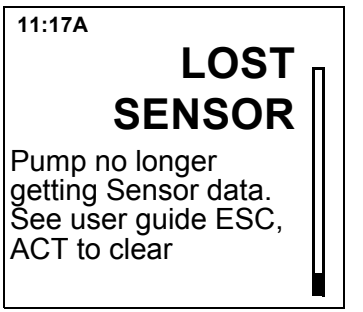


NOTE - You may see a Weak Signal recorded on the sensor graphs without receiving an alert. An alert condition will start once the pump has not received sensor data for the length of time set in Missed data (page 13).



Lost sensor

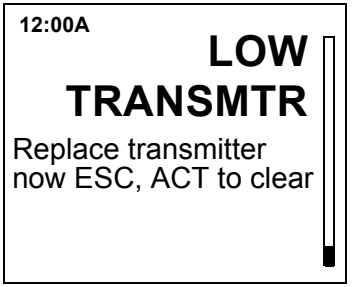
The pump has not received a signal from the transmitter for more than 40 minutes. **Do NOT disconnect.**



1. Check the transmitter and sensor connection. Touch the inserted sensor at back of assembly to prevent movement and push the transmitter firmly:
   a. If you hear a click, wait 20 seconds to see a green light on the transmitter flash for 10 seconds to confirm a good connection. The alarm was due to the transmitter and the sensor not being connected.
   b. If you do not hear a click when you check the connection, the alarm was due to a transmission problem. Bring the pump closer to the sensor and transmitter.
2. Use the **Find Lost Sensor** function to continue (see page 41):

   Main Menu > Sensor > Sensor Start > Find Lost Sensor

Low transmtr

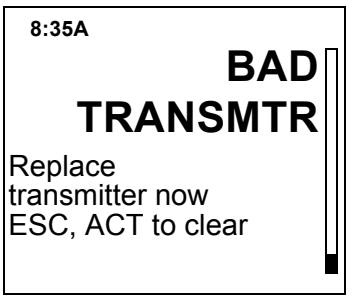


Occurs when the transmitter battery is close to running out of power. The transmitter will continue sending sensor signals for several hours and may last for several days until the battery becomes depleted. Be prepared to recharge your transmitter immediately when its battery becomes depleted. See “Bad transmtr” on page 38.

Recharge your transmitter. See “Charging the transmitter” on page 16.

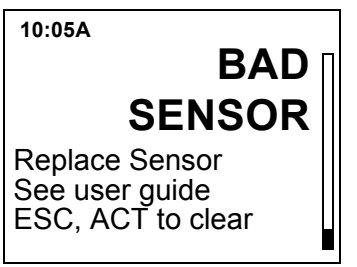
NOTE - This alert will repeat daily at 12:00 while this condition exists.

Bad transmtr



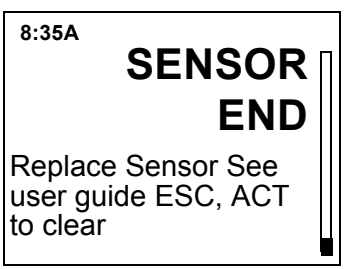
The transmitter battery is depleted. Recharge your transmitter immediately. See “Charging the transmitter” on page 16.

Bad sensor



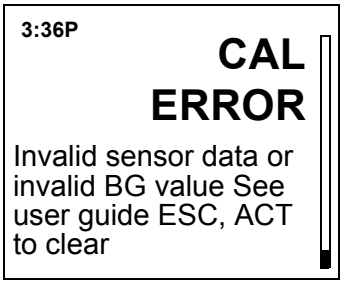
This alarm occurs after two consecutive Cal error alarms. If this alarm occurs during initialization, use the tester to test the transmitter. See “Testing the transmitter” on page 44. The transmitter may not be receiving signals from the sensor.

Sensor end



The sensor has reached the end of its life. Replace your sensor. The sensor has a maximum life of 72 hours (3 days). The 72 hour life span of the sensor begins at the time of the first accepted calibration after initialization.

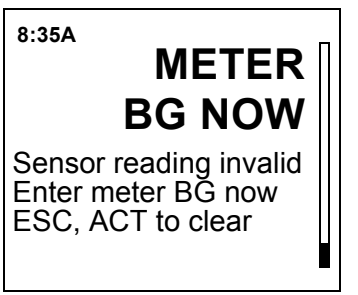
Cal error



If Cal error occurs after entering a meter BG, wait until your BG is stable to enter a new meter BG for calibration. If error repeats, you will get a Bad Sensor alarm and you will need to replace the sensor. Some possible causes for the error are:

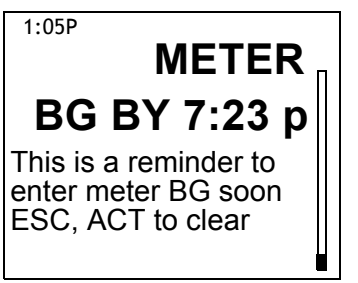
- An incorrect blood glucose value was entered from the meter into the pump.
- You entered your blood glucose value too late after selecting the Meter BG option.
- The blood glucose values are rising or falling very quickly.
- The sensor needs additional time to stabilize after being inserted.
- The sensor is ready to be replaced and is no longer reading glucose values correctly.

Meter BG now



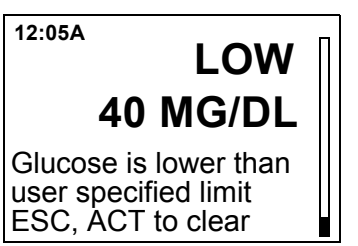
A meter BG is needed right away to calibrate your sensor and to keep receiving sensor glucose readings.

Meter BG by



A meter BG entry is required by the time that is shown to calibrate your sensor and to keep receiving sensor glucose data. This alarm is also known as the Cal Reminder Alarm.

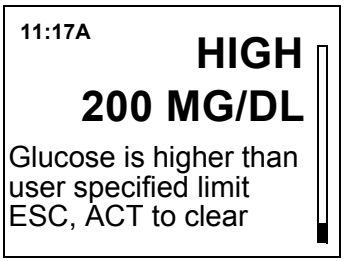
Low glucose



The glucose value is lower than or equal to the set low glucose value. If you do not turn on the Low Glucose Alarm, your pump will not alarm when your sensor glucose goes low.

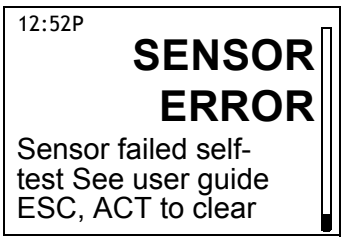
High glucose

The glucose value is higher than or equal to the set high glucose value. If you do not turn on the High Glucose Alarm, your pump will not alarm when your sensor glucose goes high.



Sensor error

This alarm occurs when the sensor signals are either too high or too low. You do not need to change the Sensor. Clear the alarm. If the alarm persists, test your transmitter with the blue tester (see page 44).



Troubleshooting

Reconnect old sensor

You should only use this feature if you have disconnected the sensor from the transmitter and have to reconnect them (for example, when you are flying on an aircraft).

1 Select **Sensor Start** and press **ACT**. SENSOR MENU Sensor Update Hist. Sensor Alarm History Sensor Start ACT →	2 Select **Reconnect Old Sensor** and press **ACT**. SENSOR START MENU New Sensor Reconnect Old Sensor Find Lost Sensor ACT →	3 The **Reconnect Old Sensor** screen will appear. Follow instructions and press **ACT**. RECONNECT OLD SENSOR Reconnect old sensor then press ACT, or ESC to abort ACT ↓ SENSOR READY 2 HOURS Alert will sound when meter BG is required. Press any key to cont.

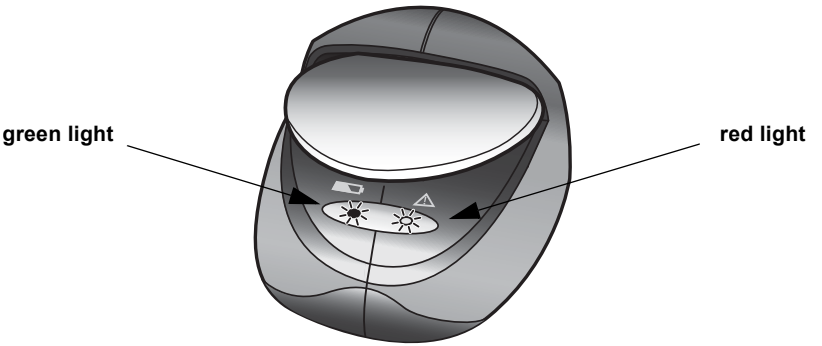
Find lost sensor

If you receive a Lost Sensor alarm:

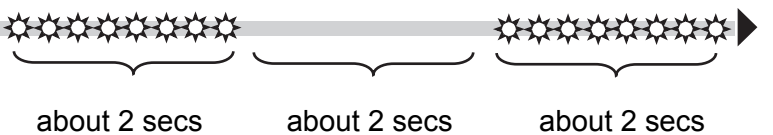
Sensor > Sensor Start

1 Relocate the pump closer to the sensor, select **Sensor Start** and press **ACT**. SENSOR MENU Sensor Update Hist. Sensor Alarm History Sensor Start ACT →	2 Select **Find Lost Sensor**, press **ACT**. SENSOR START MENU New Sensor Reconnect Old Sensor Find Lost Sensor ACT →	3 Your sensor will be ready in 15 minutes. SENSOR READY 15 MIN Alert will sound when meter BG is required. Press any key to cont.

Charger indicator lights

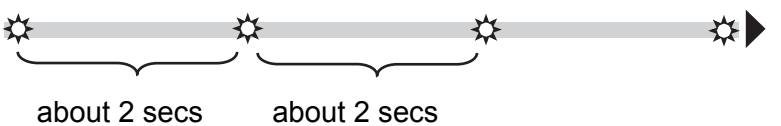


- **Question: Why did the flashing green charger light turn off and a longer flashing red charger light turn on during charging?**



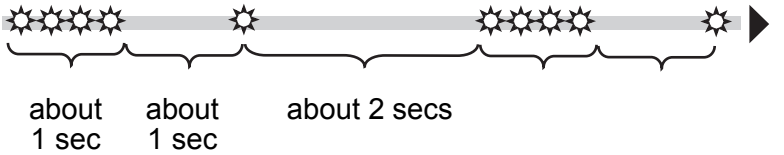
Answer: The transmitter battery is very low. Leave the transmitter on the charger for 8 hours to completely recharge. If the red light is still flashing after 8 hours, call the HelpLine. It may be time to replace your transmitter.

- **Question: Why do I see quick flashing red lights on the charger?**



Answer: Your charger battery is low. Replace with a new AAA 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 battery. If you now get the pattern for very low transmitter battery, leave the transmitter on the charger for 8 hours to recharge. If the red light is still flashing after 8 hours, call the 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's green light did not flash after removing it from the charger?**
  Answer: Reconnect the transmitter to the charger for at least one minute, remove it and watch the transmitter's green light flash and then turn off.

- **Question: What should I do if the transmitter's 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 a monitoring device.

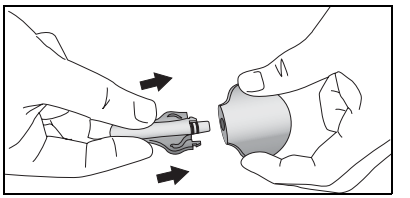
  If the sensor is inserted in the body, you need to disconnect the transmitter from the sensor, wait for at least 30 seconds, and then reconnect. If the green light still does not flash, charge the transmitter.

- **Question: Why didn't I see the transmitter's 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, call the HelpLine. It may be time to replace your transmitter.

Testing the transmitter

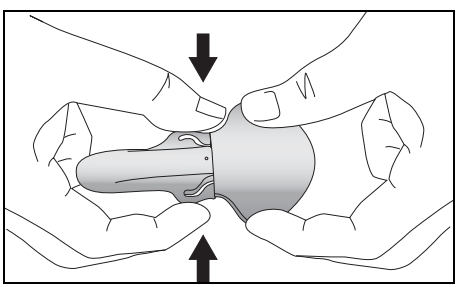
The blue tester acts like a sensor. If you get sensor related alarms, use the tester to make sure that the transmitter is working.

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.
4. The Sensor feature must be turned On on your pump (see page 8). Go to the Sensor Start Menu (see page 23) to start the tester. You should see the sensor icon on the pump which means that the transmitter and the sensor are communicating.
5. Within the next 5 minutes, go to the Sensor Status screen (see page 27) to look for the Sensor ISIG value:
   a. The Sensor ISIG value on this screen should be between 24.00 - 29.00 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 alarm. 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 24.00 nA or more than 29.00 nA, call the 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.

NOTE - To save transmitter battery life, do NOT leave the tester connected after testing.

Cleaning

Cleaning the transmitter

CAUTION:	**The charger and the tester are NOT water-tight. Do NOT immerse in water.** **Do NOT discard the transmitter in a medical waste container or otherwise subject it to incineration. Transmitter contains a battery which may explode upon incineration.**

1. Wash your hands thoroughly.
2. Dampen a clean cloth with mild liquid soap and warm water. Wipe the outside of the transmitter.
3. Rinse the transmitter under warm tap water but do NOT get water inside the connector. If you get water inside the connector, shake the water out and allow to air dry.
4. Using an antibacterial hand-sanitizer (available at a local drugstore) on a clean, dry cloth, wipe the transmitter's surface. Do NOT get any hand-sanitizer inside the connector. Repeated exposure to the hand-sanitizer could damage the connectors and affect the transmitter's performance as a result. If you get hand-sanitizer inside the connector, allow it to air dry.
5. Place the transmitter on a clean, dry cloth and air dry for 2-3 minutes.

Cleaning the Sen-serter

1. Wash your hands thoroughly.
2. Dampen a clean cloth with mild liquid soap and warm water. Wipe the Sen-serter.
3. Rinse with warm tap water.
4. Using an antibacterial hand sanitizer (readily available at your local drugstore), wipe down the Sen-serter.
5. Place the Sen-serter on a clean dry cloth and allow to air dry.
6. Store Sen-serter in the released position to maintain optimum product performance and life.

Icon table

Do not reuse:	
Attention: See Instructions for Use	
Date of manufacture (year - month):	
Batch code:	LOT
Use by: (year - month)	
Catalogue number:	REF
Device serial number:	SN
Storage temperature range:	
Fragile product:	
Type BF equipment: (Protection from electrical shock)	
Pump: Conforms to IEC60601-1 sub-clause 44.6 and IEC60529 standard.	IPX7
Recycle:	
Radio communication:	
Manufacturer:	
Configuration:	CONF

Sensor accuracy

NOTE - Users should have the information in this chapter reviewed by their healthcare professionals.

The Medtronic MiniMed Paradigm 522/722 pump uses a glucose Sensor to continuously monitor your glucose levels. The 522/722 pump uses the same algorithm as the Guardian RT. The Guardian RT was evaluated in a clinical study and the following explains the findings.

The Medtronic MiniMed Guardian RT uses a glucose sensor to continuously monitor your glucose levels. The Guardian RT Sensor is “calibrated” using your home blood glucose meter. Once calibrated, the Guardian RT reports glucose values every 5 minutes. These values were compared to reference laboratory blood glucose measurements to check the Guardian RT’s performance characteristics in a clinical study[1].

Although presentations to characterize performance of the Guardian RT are given below, there is no commonly accepted statistical approach for capturing the performance of continuous glucose monitors such as the Guardian RT. Performance may be best characterized by viewing graphs called time-elapsed plots. In these plots, the values from Guardian RT for one subject over time are overlaid with values at the same time from the glucose reference method. Three representative time-elapsed plots of sensors that exhibited excellent performance, average performance and poor performance are shown at the end of this chapter.

1. *Medtronic MiniMed, A Frequent Sample Accuracy Evaluation of the Medtronic MiniMed Telemetered Glucose Monitoring System II (TGMS II) in Subjects with Type 1 Diabetes Mellitus, August 2004.*

Performance results

The performance of the Guardian RT was evaluated in a clinical study. Guardian RT results were compared to plasma glucose values from a reference method, the YSI 2300 STAT Plus™ glucose analyzer (referred to as YSI). Sixteen subjects with Type I diabetes participated in a single-site in-clinic study. Subjects ranged in age from 18 to 65 years old. Each subject wore 2 Guardian RT systems simultaneously. One Guardian system was calibrated an average of 3.5 times per day, and the other was calibrated approximately 5 times per day using the BD Logic™ meter. YSI measurements were taken every thirty minutes.

Users and their healthcare providers should consider that performance in this study may be idealized, and that performance may be worse when the Guardian RT is used in a less-controlled home setting. For example:

- The mean Hemoglobin A1c among the 16 participants was 8.2%. As hemoglobin A1c levels rise, conditions often occur which are most challenging to test systems measuring glucose in interstitial fluid, i.e., higher glucose levels, more rapid changes in glucose concentrations, and often more hypoglycemic episodes.
- Subjects saw, on average, between 4 and 5 fingerstick values per day. This enables subjects to better manage their diabetes when compared to those who perform less fingersticks per day. Agreement between Guardian RT and YSI values is shown to be closer at mid-range glucose levels, as compared to agreement at low or high glucose concentrations.
- Subjects were more limited in their activities than what may exist in home use, and they were provided with all their meals. Sensors were also inserted by clinic staff rather than the subjects themselves. Subjects who are more active, or with poor eating habits, may create more challenging conditions for the Guardian RT.
- Performance of the Guardian RT may vary depending on the glucose meter used and how well the meter is maintained. It is important to carry out quality-control checks on the meter and code the meter according to the manufacturer's instructions to optimize performance of the Guardian RT.

Accuracy of Guardian RT readings

In this study, YSI measurements (taken every half hour) were paired with the corresponding Guardian RT reading (taken every 5 minutes). Pairing was done by selecting the Guardian RT value closest in time to the YSI test result. Agreement was analyzed by comparing paired glucose measurements.

Agreement between the matched pair was estimated by evaluating the difference between the Guardian RT reading and the YSI measurement. The difference between them was calculated as a percentage of the YSI (Mean Absolute Percent Difference). The bias was also calculated, and it is defined as the overall difference between the Guardian RT glucose values and the YSI values. The paired glucose measurements are summarized below.

Number of Paired Glucose Measurements	3941
Mean Absolute Percent Difference (± SD)	19.7 ± 18.4%
Bias	-15.0 mg/dL (-0.8 mmol/L)

The accuracy of the Guardian RT was also evaluated by calculating the percentage of Guardian RT readings within 20% and within 30% of the YSI reading (or within 20 mg/dL (1.1 mmol/L) in the low glucose range). Results are shown below.

Plasma Glucose Range (mg/dL)	Plasma Glucose Range (mmol/L)	Number of Paired Readings	Percent Within 20%	Percent Within 30%
Overall		3941	62%	79%
40-80*	2.2-4.4	356	68%	68%
>80-120	>4.4-6.7	769	60%	77%
>120-240	>6.7-13.3	2362	62%	81%
>240	>13.3	454	61%	82%

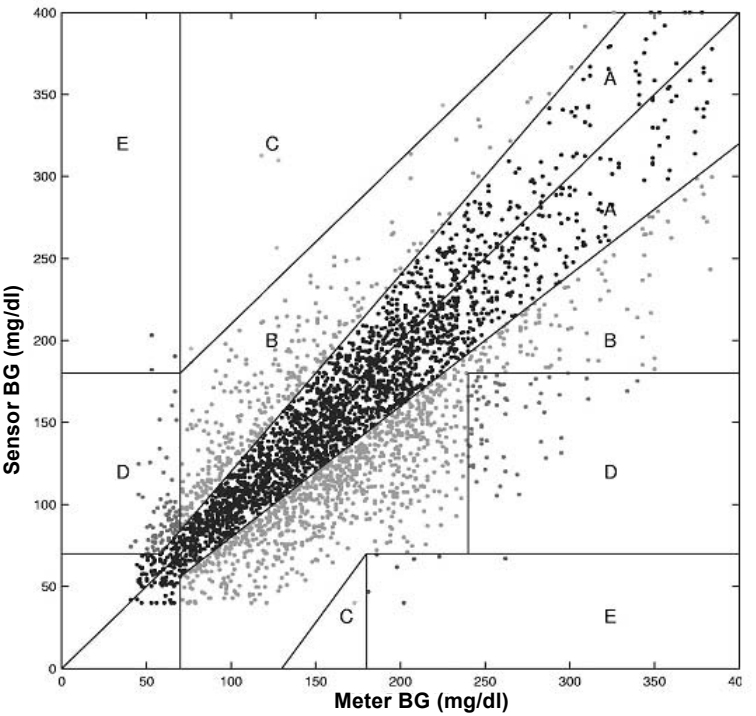
**For the Low glucose range, 40-80 mg/dL (2.2-4.4 mmol/L), the value shown is the percent within 20 mg/dL (1.1 mmol/L).*

The Clarke Error Grid was used to assess the clinical relevance of the differences between the Guardian RT readings and the comparative YSI measurements. The Clarke Error Grid divides a correlation plot into 5 zones, as shown below.

Results in zones A and B are considered clinically acceptable, while results in zones C, D, and E are potentially dangerous and, therefore, clinically significant errors. The Clarke Error Grid zones are labeled on the correlation plot.

Zone	Description
A	Clinically accurate, would lead to correct treatment decisions
B	Would lead to benign decisions or no treatment
C	Would lead to overcorrection of normal glucose levels
D	Would lead to failure to detect and treat high or low glucose levels
E	Would lead to erroneous treatment decisions

The plot below is a correlation plot of Guardian RT readings versus readings from the reference method, the YSI 2300 Glucose Analyzer. It is overlaid with the Clarke Error Grid. The total number of paired data points is 3941.



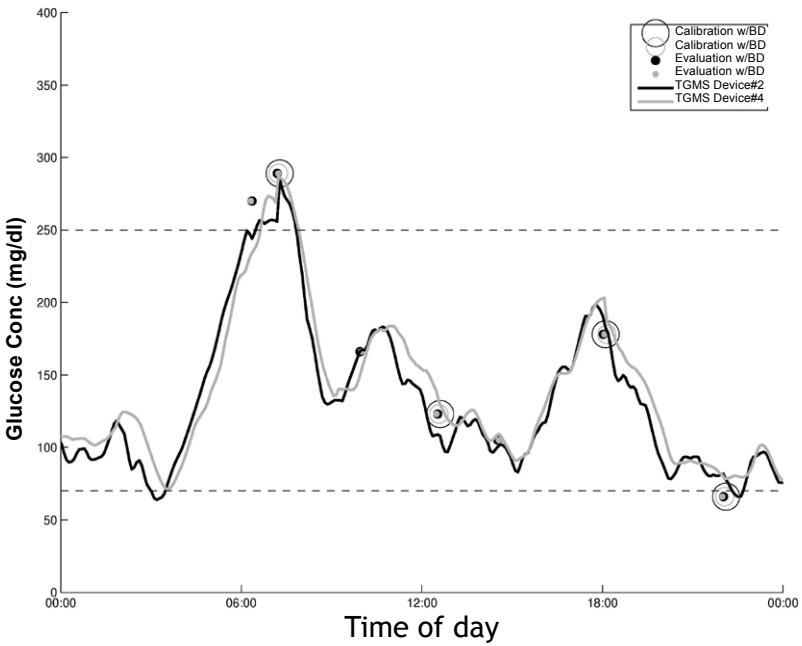
The percent of Guardian RT readings in the above graph are presented in the following table according to the percentage of points falling within each zone (A-E). Results are further broken down (stratified) according to the range of glucose concentrations.

Glucose Range (mg/dl)	Number and (%) of Data Points Evaluated	A+B	A	B	C	D	E
40-80	356 (9)	271 (76.1)	214 (60.1)	57 (16.0)	2 (0.6)	80 (22.5)	3 (0.8)
81-120	769 (20)	768 (99.9)	463 (60.2)	305 (39.7)	1 (0.1)	N/A*	N/A
121-240	2362 (60)	2352 (99.6)	1476 (62.5)	876 (37.1)	4 (0.2)	N/A	6 (0.2)
>240	454 (11)	394 (86.8)	277 (61.0)	117 (25.8)	N/A	59 (13.0)	1 (0.2)
Overall	3941 (100)	3785 (96.0)	2430 (61.7)	1355 (34.4)	7 (0.2)	139 (3.5)	10 (0.2)

**N/A means that the Clarke Error Grid does not consider the possibility of these zones in that concentration range.*

Precision of Guardian RT readings

This study was also designed to look at the reproducibility of two Sensors worn simultaneously at different locations on the body. Precision was estimated by comparing the glucose readings from the two Guardian RT systems. In this study 11,475 paired Sensor Guardian RT values were obtained. On average, they were different by 17.2%. **The following figure is an example of how data was paired in this study.** In the graph there are two tracings of Guardian RT values. Each tracing comes from a different Guardian RT unit worn by one subject during a one-day period.



In the above chart, Guardian RT device #2 is represented by a solid line, and the Guardian RT device #4 by a light-gray line.

Low and High Alerts

The ability of the Guardian RT to detect high and low glucose levels was measured in the same clinical study. Since it is important to set the alert levels in a conservative fashion, the Low Glucose Alert should be set at a value slightly higher than the value of blood glucose you want to detect, and the High Glucose Alert should be set at a value slightly lower than the value of blood glucose you want to detect.

NOTE - Please ask your doctor which low and high alert setting is best for you.

The Low Glucose Alert

The Low Glucose Alert was evaluated for its ability to detect glucose levels at 70 mg/dL (3.9 mmol/L), or below, using the YSI 2300 STAT Plus glucose analyzer. As a reference, with the Low Glucose Alert set at 70 mg/dL (3.8 mmol/L), 49% (100/205) of low glucose events were detected by the Guardian RT. Better detection of low blood glucose can be obtained by setting the Low Glucose Alert level higher. For example, setting the Low Glucose Alert at 90 mg/dL (5.0 mmol/L), instead of 70 mg/dL (3.9 mmol/L), increases the ability to detect low blood glucose levels from 49% to 82% (Table 5.5).

Sometimes the Guardian RT will alert when the blood glucose levels are not low. When the Guardian RT Low Alert was set at 70 mg/dL (3.9 mmol/L) in this study, 43% of the results were considered false alerts (actual blood glucose values are greater than 85 mg/dL (4.7 mmol/L)). This percentage may be exaggerated because blood glucose may be dropping when the Guardian RT alerts. The table below shows the percent of Low Glucose readings correctly identified by the Guardian RT for specific settings.

Guardian RT Low Alert Setting (mg/dL)	Guardian RT Low Alert Setting (mmol/L)	True Alert Rate*	False Alert Rate**
70	3.9	49%	60%
80	4.4	68%	64%
90	5.0	82%	75%
100	5.6	90%	79%

** True Alert Rates are the % of times when the glucose level was at or below the alert setting and the alert sounded.*
*** False Alerts Rates are the % of times when the Guardian RT Sensor alarmed but the blood glucose level was greater than the alert setting.*

Increasing the Low Alert settings will improve the ability to detect low blood glucose events, but it will also increase the frequency of Guardian RT false alerts for blood glucose levels not below the target value. You should consider this trade-off between the improved ability to detect true low blood glucose versus the increased number of false alerts when setting the low alert threshold.

The High Glucose Alert

The High Glucose Alert was evaluated for its ability to detect glucose levels at 250 mg/dL (13.8 mmol/L), or above, using the YSI analyzer. As a reference, with the High Glucose Alert set at 250 mg/dL 13.8 mmol/L), 53% (195/365) of high glucose events were detected by the Guardian RT. Better detection of high blood glucose can be obtained by setting the High Glucose Alert level lower. For example, setting the High Glucose Alert at 190 mg/dL (10.6 mmol/L), instead of 250 mg/dL (13.8 mmol/L), increases the ability to detect high blood glucose levels from 53% to 85% (see the table below).

Sometimes the Guardian RT will alert when the blood glucose levels are not high. When the Guardian RT High Alert was set at 250 mg/dL (13.8 mmol/L) in this study, 7.2% of the results were considered false alerts (actual blood glucose values are less than 225 mg/dL (12.5 mmol/L)). This percentage may be exaggerated because blood glucose may be rising when the Guardian RT alerts. The table below shows the percent of High Glucose readings correctly identified by the Guardian RT for specific settings.

Guardian RT High Alert Setting (mg/dL)	Guardian RT High Alert Setting (mmol/L)	True Alert Rate*	False Alert Rate**
190	10.6	85%	64%
200	11.1	81%	58%
225	12.5	67%	40%
250	13.8	53%	25%

** True Alert Rates are the % of times when the glucose level was at or above the alert setting and the alert sounded.*
*** False Alerts Rates are the % of times when the Guardian RT Sensor alarmed but the blood glucose level was lower than the alert setting.*

Decreasing the High Alert settings will improve the ability to detect high blood glucose events, but it will also increase the frequency of Guardian RT false alerts for blood glucose levels not above the target value. You should consider this trade-off between the improved ability to detect true high blood glucose versus the increased number of false alerts when setting the high alert threshold.

Guardian RT Sensor Performance and Calibration Stability As a Function of Time

The Guardian RT Sensor may be worn for up to 3 days (72 hours) and must be calibrated at least twice a day. Two sets of data, approximately equal in number, were collected during the clinical trial. One data set was generated when the frequency of calibrations averaged 3.5 per day (Data Set A), and the other averaged 5 times a day (Data Set B). During the study, a total of 38 Sensors were evaluated in 16 individuals.

As per the stratified Clarke Error Grid analysis on page 52, agreement between Guardian RT values and YSI values tends to be poorer at low and high glucose concentrations when compared to other concentration ranges.

Guardian RT performance in the hypoglycemic range, as a function of Sensor insertion time, is characterized below. Results from the two different data sets are presented. The two populations were separated according to the number of calibrations per day. The following table represents the percentage of Data Points in the 40-80 mg/dL range that fell within 20 mg/dL. Data is presented in 12-hour increments.

Data Set	0-12 hrs	12-24 hrs	24-36 hrs	36-48 hrs	48-60 hrs	60-72 hrs
A	78%	81%	73%	65%	56%	41%
B	67%	70%	93%	60%	75%	38%

An analysis of the mean percentage of Absolute Relative Error (ARE %) and standard deviations, across 12-hour increments of wear periods, appears in the table below. Both data sets are pooled together in this data.

Hours From Insertion	Mean ARE (%)	Std. Dev.
0-12 hrs	24.84	20.04
12-24 hrs	19.66	16.17
24-36 hrs	16.43	15.62
36-48 hrs	18.23	19.27
48-60 hrs	16.59	14.25
>60 hrs	22.95	23.51

The median Sensor life from Data Sets A and B were 57.5 hours and 72.9 hours, respectively. Twenty-one of the Sensors operated for 72 hours, while the others were removed for a variety of reasons, most often because of calibration errors.

The percentage of Guardian RT readings within 20% and 30% of YSI readings was analyzed according to time after Sensor insertion and according to the glucose-concentration range (as determined by the YSI analyzer). See the following table.

	Percentage of Guardian RT values within 20% of YSI laboratory readings		Percentage of Guardian RT values within 30% of YSI laboratory readings	
Glucose Range (mg/dL)	During first 60 hours of Sensor wear	After 60 hours of Sensor wear	During first 60 hours of Sensor wear	After 60 hours of Sensor wear
40-80*	62-82%	39%	62-82%	39%
81-120	57-66%	48%	72-84%	66%

** Agreement to within ± 20 mg/dL for glucose readings ≤ 80 mg/dL*

Performance of the Guardian RT was evaluated according to the length of time since calibration. This data is not conclusive because of the limited number of data points during the final 3 hours of the 12-hour calibration cycle, i.e., 10. In contrast, 3-hour time bins, earlier in the 12-hour cycle, contained hundreds of data points. This may suggest that calibrations are often required prior to the 12-hour calibration cycle.

Effects of calibration frequency

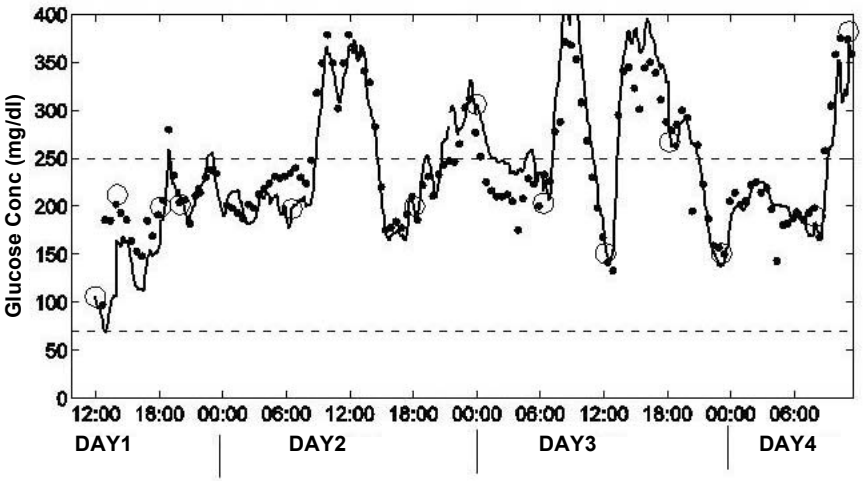
The average bias when Guardian RT was calibrated ~ 3.5 times a day was -20.5 ± 41 mg/dL (LL: -22.40 mg/dL and UL: -18.63 mg/dL). In those calibrated ~ 5 times a day, the bias was -10.2 mg/dL ± 36 mg/dL (LL: -11.74 mg/dL and UL: -8.66 mg/dL). When comparing Guardian RT units that were calibrated less often to those calibrated more often, the following alarm performance was observed:

- Specificity increased 2-4% in the hypoglycemic range and decreased 0-2% in the hyperglycemic range
- Sensitivity increased between 5-9% across the hyperglycemic range, and decreased 7-16% when the alarm was set to 80 mg/dL or below, and decreased 3-7% when set between 85 and 100 mg/dL

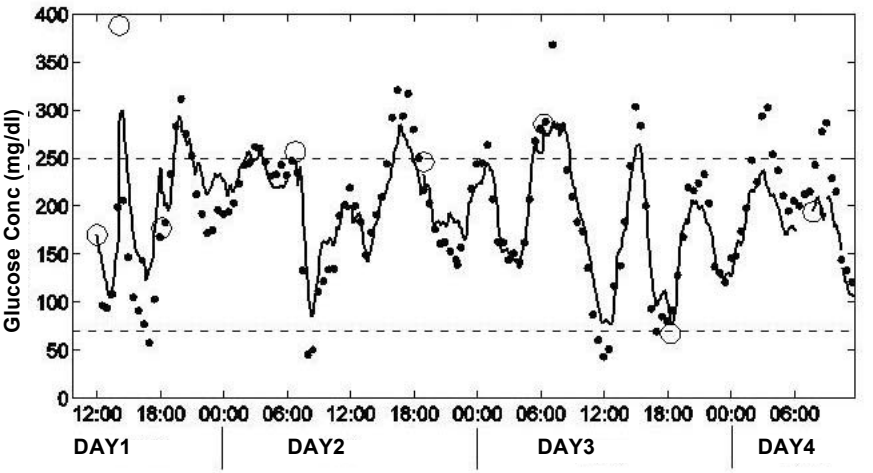
Stratified error grid analysis also shows better performance in the hypoglycemic range when fewer calibrations are performed, i.e., 62% of data points are in Zone A when fewer calibrations were performed, whereas 58% were in Zone A when more calibrations were performed.

Time-Elapsed Plots

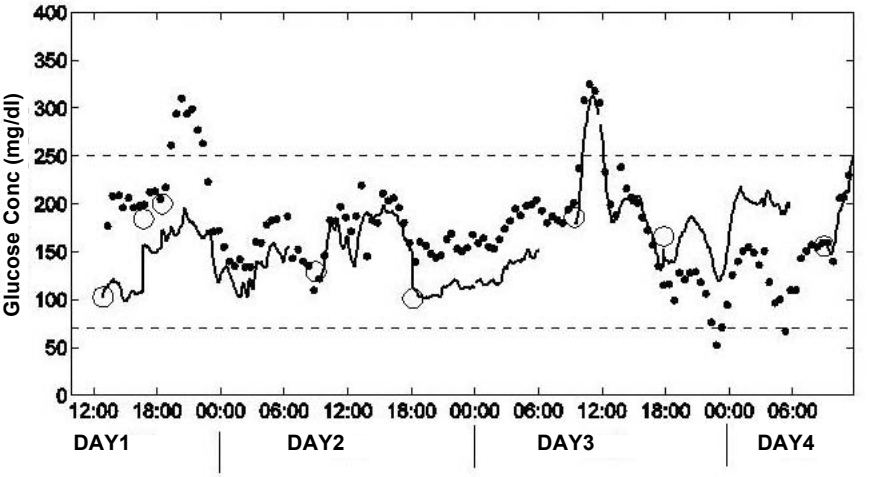
The plot graph below is a representative example of continuous sensor tracing vs. reference blood glucose reading, where sensor showed excellent performance. The open circles (o) on the graph represent the meter calibration readings. The closed circles (•) represent the reference blood glucose readings, and the solid line (—) represents the sensor glucose value.



The plot graph below is a representative example of continuous sensor tracing vs. reference blood glucose reading, where sensor showed average (typical) performance. The open circles (o) on the graph represent the meter calibration readings. The closed circles (•) represent the reference blood glucose readings, and the solid line (—) represents the sensor glucose value.



The plot graph below is a representative example of continuous sensor tracing vs. reference blood glucose reading, where sensor showed poor performance. The open circles (o) on the graph represent the meter calibration readings. The closed circles (•) represent the reference blood glucose readings, and the solid line (—) represents the sensor glucose value.



A

Alarm Snooze - Once a sensor alarm occurs, the pump will not repeat the alarm until after this period of time. This is the setting for the Meter BG Now alarm.

B

BG Units - Blood glucose units used by the pump (mg/dL or mmol/L). The BG units can only be set from the sensor "Edit Settings" screen if the Bolus Wizard is turned off.

C

Cal Reminder - The pump will trigger a Meter BG Now alarm automatically every 12 hours, signaling that the current calibration value is no longer valid. 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 Now alarm. For example, if the Cal Reminder is set to 2 hours, the Meter BG Now alarm will occur 2 hours before the calibration is required.

Cannula - A short, thin, and flexible tubing at the end of an infusion set that is inserted into the subcutaneous tissue to deliver insulin.

H

High Glucose - The pump will alarm if the sensor indicates that the user's sensor glucose is at or above this value. You have the option to turn this feature on or off.

High Snooze - Allows the user to set the delay between the first High Glucose Alarm and any subsequent alarms. This will allow the user to avoid an alarm every five minutes until the condition is corrected.

I

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.

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.

L

Low Glucose - The pump will alarm if the sensor indicates that the user's sensor glucose is at or below this value. You have the option to turn this feature on or off.

Low Snooze - Allows the user to set the delay between the first Low Glucose Alarm and any subsequent Low Glucose Alarms. This will allow the user to avoid an alarm every five minutes until the condition is corrected.

M

Missed Data - The pump will alarm if it has not received data from the sensor for an amount of time that you set.

O

Occlusive dressing - A bandage that seals a wound from air or bacteria.

P

Pump S/N - Pump S/N is the serial number of the pump currently in use.

R

Reservoir - The syringe that holds insulin.

S

Sensor - Indicates whether the sensor feature is On or Off.

Sensor Age - Sensor age is the amount of time, in days and hours, since the sensor was first inserted.

Sen-serter - The Sen-serter is indicated as an aid for insertion of the Medtronic MiniMed glucose sensor.

T

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.

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