Guardian® REAL-Time

Continuous Glucose Monitoring System

User Guide

Terms	Meaning
WARNING	A potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
Menu item selections	The items on a menu you need to select to go to another menu or a screen. Each menu item is separated by the (>) symbol. For example: **MAIN MENU > Utilities > Alarm** The actual steps used to complete menu item selection shown above are: 1 Open the MAIN MENU. 2 Select **Utilities** and press ACT. 3 Select **Alarm** and press ACT. To make the steps for getting to a specific menu or screen easier to follow, the menu item selections do not include the steps for pressing the **ACT** button.

User safety

This section includes important safety information such as indications, contraindications, safety warnings, potential adverse reactions, and how to protect the system from damage due to exposure to radiation.

Indications

The Guardian REAL-Time system (pediatric version) consists of the model CSS7100K monitor, the MMT-7002 or MMT-7003 glucose sensor and the MMT-7701 transmitter. This system is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, in children and adolescents (ages 7 through 17) with diabetes mellitus, for the purpose of improving diabetes management. The monitor provides an alert 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 meter blood glucose measurement may be required. All therapy adjustments should be based on measurements obtained using a home glucose meter and not on Guardian REAL-Time system values. The Guardian REAL-Time system provides real-time glucose values that allow users to track patterns in glucose concentrations and to possibly identify episodes of low and high blood glucose. It also stores the data so that it can be analyzed to track patterns. Glucose data can be further downloaded to PC software for analysis of historical glucose values.

Contraindications

Glucose monitoring therapy is not recommended for people who are unwilling or unable to perform a minimum of **two** (2) meter blood glucose tests per day and to maintain contact with their healthcare professional. Successful monitor therapy requires sufficient vision or hearing to allow recognition of the monitor signals and alarms.

Safety Warnings

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

Precautions

Although the monitor has multiple safety alarms, it cannot notify you of all potential problems. It is essential that you test your blood glucose levels at least two times per day. If your blood glucose is out of range, check your blood glucose using your blood glucose meter.

Avoid extreme temperatures

1 Avoid exposing the system to temperatures above 42°C (108°F) or below 1°C (34°F).

2 Do not steam, sterilize, or autoclave your monitor, transmitter, or sensor.

Sensor

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

CAUTION: Any changes or modifications to the devices not expressly approved by Medtronic could impair the functioning of the system and could void your warranty.

Adverse reactions

Use of the sensor and transmitter can cause the following potential adverse reactions. Contact your healthcare professional and your local Medtronic representative in the event of any adverse reaction.

Accuracy of the glucose sensor readings provided by the Guardian REAL-Time CGM System was not evaluated in patients with medical conditions, such as insulin resistance and cystic fibrosis. Also, the impact of medications was not specifically evaluated; therefore, device performance may vary in these situations.

Sensor

To use the glucose monitoring features, you must insert 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.

Transmitter

The transmitter should be removed if irritation or reaction to the transmitter tape develops. The transmitter should be disconnected from the sensor while traveling on an aircraft, or if it interferes with another transmitting device.

NOTE: If you experience irritation or have a reaction to the transmitter tape (or other tapes), please contact the Medtronic 24 Hour HelpLine.

Damage due to radiation

If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, TAKE OFF YOUR MONITOR, TRANSMITTER, and SENSOR and remove them from the area.

NOTE: The Guardian REAL-Time CGM System monitor and transmitter are designed and tested to withstand common electromagnetic interference, including airport security systems.

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Performance results in adults

The performance of the Guardian RT in adults was evaluated in a clinical study[3]. 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 Paradigm Link blood glucose meter. YSI measurements were taken every thirty minutes.

Users and their healthcare professionals 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.

3. See Note 1, on page 139.

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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[a]	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%

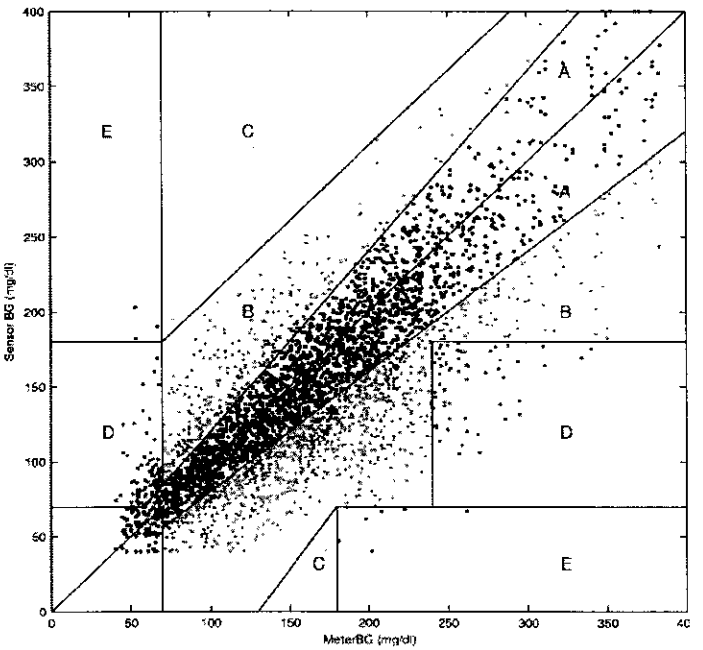
a. For the Low glucose range, 40-80 mg/dl (2.2-4.4 mmol/l), the value shown is the percent within 20 mg/dl (1.1 mmol/l).

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. See following table.

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.



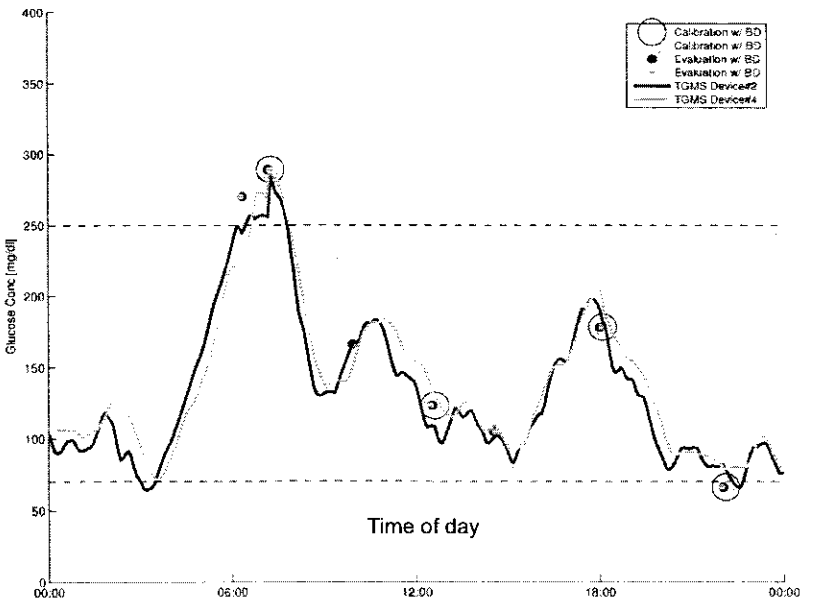
The percent of Guardian RT readings in the previous graph are presented in the following table according to the percentage of points falling within each zone (A-E). Results are further broken down (stratified) according to the range of glucose concentrations.

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.



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 in Adults

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% (see the following table).

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 following table 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 following table).

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. Table 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 above (Table 5.4), 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. This 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 mg/dl and 30 mg/dl of YSI readings from 40-80 mg/dl was analyzed according to time after Sensor insertion and according to the glucose-concentration range (as determined by the YSI analyzer).

	Percentage of Guardian RT values within 20 mg/dl of YSI laboratory readings		Percentage of Guardian RT values within 30 mg/dl 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%	78-91%	67%

The percentage of Guardian RT readings within 20% and 30% of YSI readings from 81-120 mg/dl was analyzed according to time after Sensor insertion and according to the glucose-concentration range (as determined by the YSI analyzer).

	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
81-120	57-66%	48%	72-84%	66%

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.

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Effects of calibration frequency

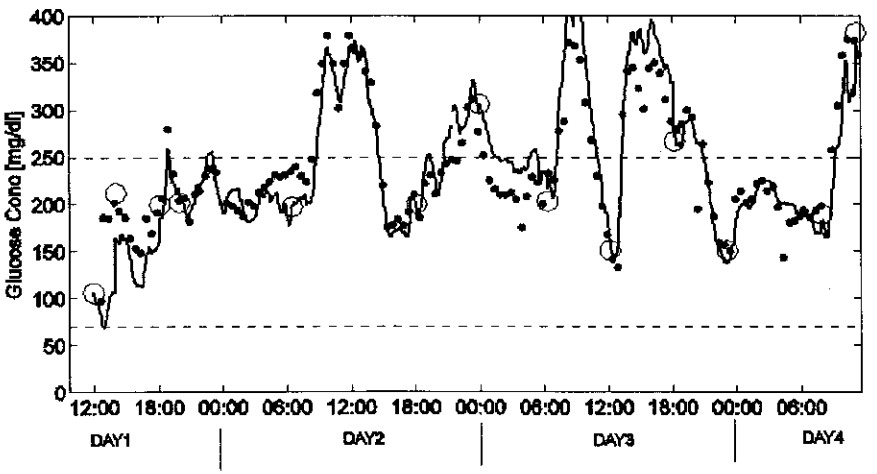
The average bias when Guardian RT was calibrated ~ 3.5 times a day was -20.5 ± 41 mg/dl (LL: -22.40 mg/dl and UL: -18.63 mg/dl). In those calibrated ~ 5 times a day, the bias was -10.2 mg/dl ± 36 mg/dl (LL: -11.74 mg/dl and UL: -8.66 mg/dl). When comparing Guardian RT units that were calibrated less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

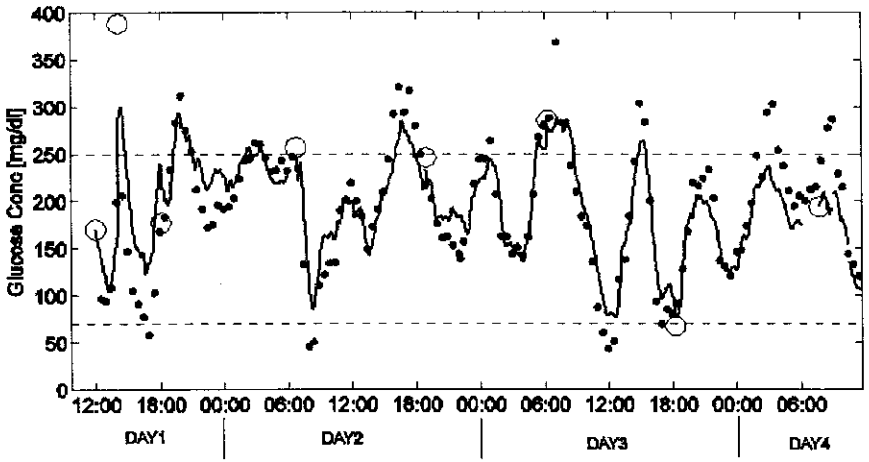
Stratified error grid analysis also shows better performance in the hypoglycemic range when fewer calibrations are performed, i.e., 62% of data points are in Zone A when fewer calibrations were performed, whereas 58% were in Zone A when more calibrations were performed.

Time-Elapsed Plots

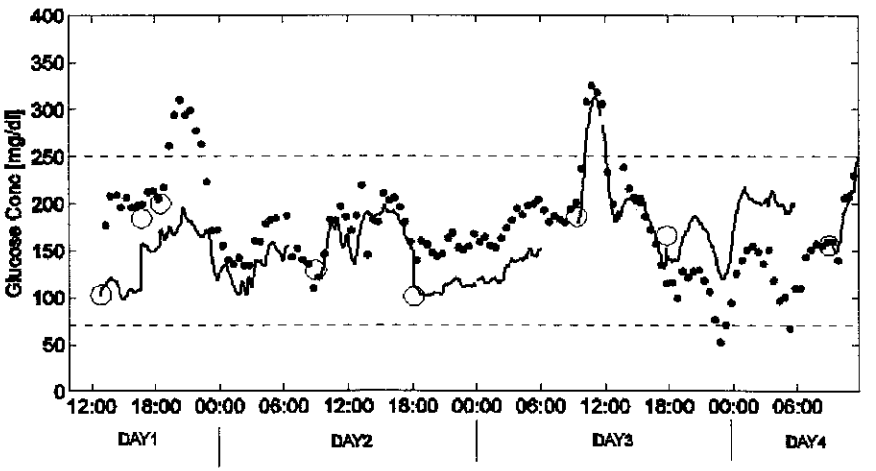
The plot graph below is a representative example of continuous sensor tracing vs. reference blood glucose reading, where sensor showed excellent performance. The open circles (o) on the graph represent the meter calibration readings. The closed circles (•) represent the reference blood glucose readings,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



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Performance Results in Children and Adolescents

The performance of the Guardian RT in Children and Adolescents was evaluated in a clinical study[4]. Guardian RT results were compared to capillary blood glucose measured by a OneTouch® Ultra® meter. Sixty subjects with Type I diabetes participated in a three-site out-patient study. Subjects ranged in age from 7 to 17 years old. Each subject wore a Guardian RT system, which records a sensor glucose value every 5 minutes. Subjects were instructed to perform at least seven (7) blood glucose meter measurements each day.

Accuracy of Guardian RT Readings

In this study, each blood glucose meter measurement was 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 blood glucose meter 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 blood glucose meter measurement. The difference between them was calculated as a percentage of the blood glucose meter measurement (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 blood glucose meter values. The paired glucose measurements are summarized in the following table.

Number of Paired Glucose Measurements	2599
Mean Absolute Percent Difference (± SD)	19.0 ± 19.7%
Bias	-6.0 mg/dl (-0.3 mmol/l)

4. See Note 2, on page 139.

The accuracy of the Guardian RT was also evaluated by calculating the percentage of Guardian RT readings within 20% and within 30% of the blood glucose meter reading (or within 20 mg/dl (1.1 mmol/l) in the low glucose range). Results are shown in the following table.

Plasma Glucose Range (mg/dl)	Plasma Glucose Range (mmol/l)	Number of Paired Readings	Percent Within 20%	Percent Within 30%
Overall		**2599**	**68%**	**82%**
40-80*	2.2-4.4	360	51%	----
>80-120	>4.4-6.7	482	60%	77%
>120-240	>6.7-13.3	1055	74%	90%
>240	>13.3	702	75%	89%

* 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 blood glucose meter measurements. The Clarke Error Grid divides a correlation plot into 5 zones. See the following table.

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

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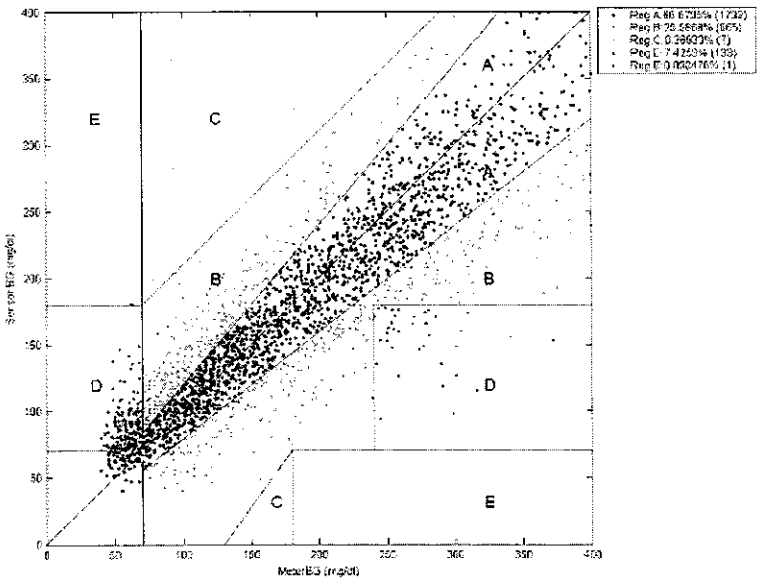
The following figure is a correlation plot of Guardian RT readings versus readings from the reference method, the blood glucose meter. It is overlaid with the Clarke Error Grid. The total number of paired data points is 2599.



The percent of Guardian RT readings in the above graph are presented in the table on the next page 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.

Stratified Clarke Error Grid Analysis

Range of Comparative Glucose Readings (mg/dL)	Total count	Clarke Error Grid Zones					
		A + B	A	B	C	D	E
40-80	360 (13.9%)	201 (55.8%)	141 (39.2%)	60 (16.7%)	1 (0.3%)	157 (43.6%)	1 (0.3%)
81-120	482 (18.5%)	478 (99.2%)	287 (59.5%)	191 (39.6%)	4 (0.8%)	0 (0%)	0 (0%)
121-240	1055 (40.6%)	1053 (99.8%)	782 (74.1%)	271 (25.7%)	2 (0.2%)	0 (0%)	0 (0%)
240-400	702 (27.0%)	666 (94.9%)	523 (74.5%)	143 (20.4%)	0 (0%)	36 (5.1%)	0 (0%)
Overall	2599 (100.0%)	2398 (92.3%)	1733 (66.7%)	665 (25.6%)	7 (0.3%)	193 (7.4%)	1 (0.0%)

Low and High Alerts in Children and Adolescents

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 blood glucose meter. As a reference, with the Low Glucose Alert set at 70 mg/dl (3.8 mmol/l), 24% (59/244) 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 24% to 70% (see the following table).

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, 48% 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	24%	48%
80	4.4	52%	46%
90	5.0	70%	52%
100	5.6	85%	57%

* 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 blood glucose meter. As a reference, with the High Glucose Alert set at 250 mg/dl 13.8 mmol/l), 64% (404/632) 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 64% to 94% (see the following table).

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, 13.1% 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 following table 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	94%	40%
200	11.1	91%	36%
225	12.5	81%	21%
250	13.8	64%	13%

* 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 Patient Labeling

F

Emergency kit

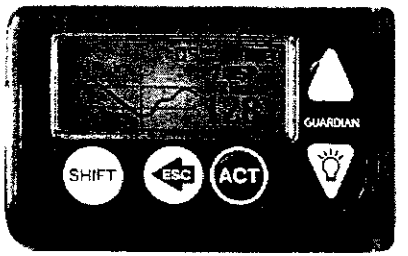
As a person with diabetes, you should keep an emergency kit with you at all times to make sure that you always have necessary supplies. Inform a family member, co-worker, or friend where this emergency kit is kept. Please see *User safety, on page 6* for more information on monitor safety. Your emergency kit should include these items:

- Fast-acting glucose tablets
- Urine ketone monitoring supplies
- Insulin syringe and insulin (with dosage instructions from your healthcare professional)
- Guardian REAL-Time CGM System Wallet Card
- Transparent dressing and adhesive transmitter pads
- Blood glucose monitoring supplies
- Glucagon Emergency Kit®
- Extra AAA alkaline batteries for your monitor (Energizer® brand is recommended)

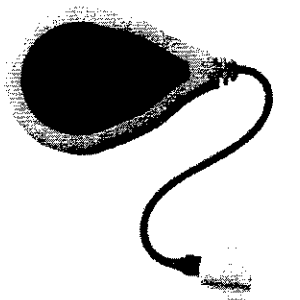
Your system

This section describes the items in your Guardian REAL-Time CGM System.

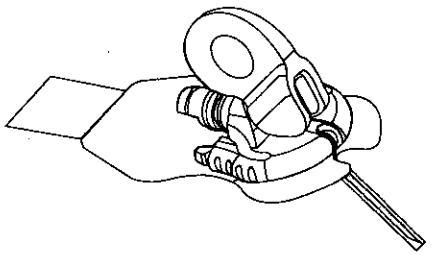
- **Monitor** – The monitor displays real-time glucose measurements, notifications about fluctuations and excursions, and historical information. It also displays information to alert you of potential issues, such as a low battery.



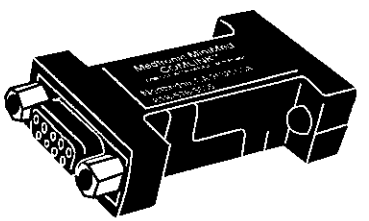
- **Transmitter** — The transmitter is a small oval disk that connects to the sensor and adheres to the skin with tape. Under proper conditions, the transmitter periodically transmits sensor glucose data to the monitor using a radio signal.



- **Sensor** — The sensor is a membrane encased electrode that 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 reading on your pump screen.



- **ComLink™** — The Medtronic ComLink is a serial communication cable used to upload the Guardian REAL-Time CGM System data to the Medtronic CareLink® Therapy Management Software using a serial communications interface cable installed on your computer.



Options

Your system can be used with the optional Paradigm Link® Blood Glucose Monitor (meter). You can program your monitor to automatically receive your blood glucose measurements from this meter.

To order this option, call 800-646-4633 (1-800-MiniMed) or visit our online store at www.minimed.com.

Accessories

Medtronic offers the following accessories that provide convenient ways to wear your monitor, while keeping it protected and hidden.

- **Holster** – Used to wear the monitor on your belt.
- **Monitor clip** – Used to wear the monitor underneath your clothing.
- **Leather case** – Fine leather lined with nylon. Styling complements business and formal wear. Velcro flap provides easy access to monitor for programming. Wear it vertically with the built-in belt clip.

To order any of these accessories, call 800-646-4633 (1-800-MiniMed) or visit our online store at www.minimed.com.

Conventions used in this guide

The conventions used in this guide are defined in the following table.

Terms	Meaning
"Press"	To push and release the button.
"Hold"	To press and keep pressure on the button.
"Press **ESC, ACT**"	To press the **ESC** button, then press the **ACT** button. When two buttons are separated by a comma (,) it means to press the first button, then press the next button.
"Select"	To choose an item or a value from a menu or screen. You use the △ and ▽ buttons to make your selections.
Button names	Always bold and uppercase (for example, **UP, DOWN, ACT**).
Screen and menu names	Always uppercase; for example, MAIN MENU, STATUS screen.
Menu items	Always bold; for example, **12-Hour Setup, On, Off**
NOTE	Additional helpful information.
CAUTION	A potential hazard which, if not avoided, may result in damage to your Guardian REAL-Time CGM System.

The basics

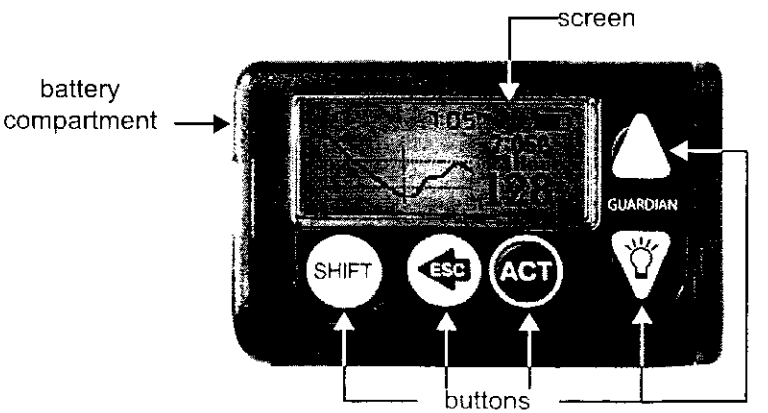
2

What's in this chapter:

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

The monitor

Take a look at your monitor. The screen displays important information, such as your real-time sensor glucose measurements, alarm messages, your current settings, and statuses. You use the buttons to select menu items, enter values, and perform actions.



Installing the battery

CAUTION: Do not use a rechargeable or carbon zinc battery in your monitor. For best results, a new AAA Energizer alkaline battery is recommended.

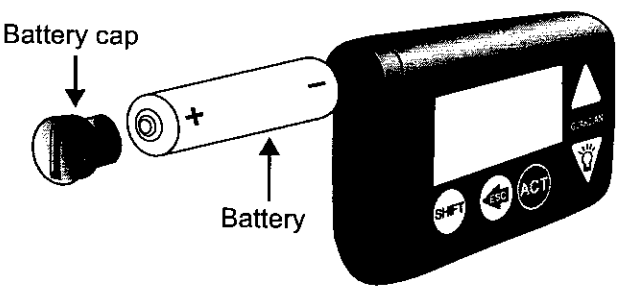
Medtronic has designed the monitor to only accept a NEW battery. As a safety measure, if you install a battery that does not have full power, one of the following alarms may occur:

- **WEAK BATTERY** – If this alarm occurs, clear it. You can continue installing the same battery, or install another new battery. If you continue installing the same battery, the monitor will work properly, but with a decreased battery life.
- **FAILED BATT TEST** – If this alarm occurs, clear it and install a new battery.
- **BATT OUT LIMIT** – This alarm may occur if the battery is removed from the monitor, and more than 10 minutes passes before the new battery is inserted. If this alarm occurs, continue installing the new battery. See *page 98* for information about what you need to do when you receive this alarm.

NOTE: Do not use batteries that have been in cold storage (i.e., in the refrigerator or your car in the winter). Allow the batteries to return to room temperature before use.

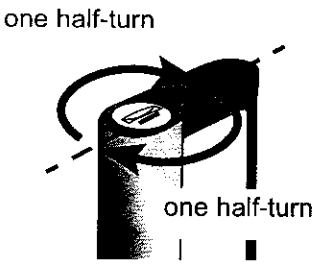
To install the battery:

1. Make sure that you clear any alarms (**ESC**, **ACT**), and that the monitor is at the HOME (idle) screen when you remove the battery.
2. Use the edge of a coin to remove the battery cap. Turn the cap in a counter-clockwise direction.
3. Remove the old battery and dispose of it per the disposable requirements of your state or country. Put the new battery in the monitor with the negative end [(-) symbol] going in first, as shown here. Check the label on the back of the monitor to make sure the battery is inserted correctly.



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

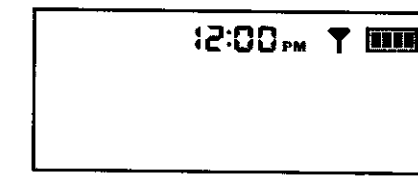
Do NOT apply force when you turn the cap.



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

As the monitor turns on, a sequence of screens appear, the version number is displayed, and then the HOME screen appears.

NOTE: If you are replacing a battery for a monitor that has very recently been in use, the only screen you will see before the HOME screen is the one displaying the version number.



HOME screen

5 If the HOME screen appears, skip to the next step. If the HOME screen does not appear:

   a. Check that the battery is inserted correctly. If not, remove the battery and install it properly as described in the previous steps.

   b. If the monitor still does not turn on or if you receive a FAILED BATT TEST alarm, then remove the battery and replace it with a new one.

   c. Call the 24 Hour HelpLine.

6 Make sure the time showing on the HOME screen is correct. If more than **10** minutes have passed since you removed the battery, you will be prompted to check the time and date. See *Setting the time and date, on page 22* for details.

7 Press **ESC** until the STATUS screen appears. Make sure no alarms are active. If an alarm is active, follow the instructions on the screen to clear the alarm.

The monitor buttons

This section describes how you use the different buttons on your monitor.

Button	Description
 UP	You use this button to: • **Scroll up** through menus when selecting menu items. • **Increase the value** of a setting when entering or changing settings. • **Select** different graphs when viewing the sensor glucose graphs. • **Move the cursor to the right** in the graph when viewing the sensor glucose graphs.
 DOWN	You use this button to: • **Scroll down** through menus when selecting menu items. • **Decrease the value** of a setting when entering or changing settings. • **Move the cursor to the left** in the graph when viewing the sensor glucose graphs. • **Turn the backlight on** when the HOME screen is showing. • **Turn the backlight on** when viewing screens other than the HOME screen (hold down **SHIFT** and press **DOWN**).
 ACT	You use this button to: • **Accept** the selected menu item • **Choose a setting** when entering or changing settings • **Open the MAIN MENU** from the HOME screen. • **Clear alarms** (press **ESC**, then press **ACT**).

 ESC	You use this button to:
	• **Return** to previous screen or menu.
	• **Open** the following screens and graphs from the HOME screen:
	  • The SENSOR DEMO screens (if the feature is turned On).
	  • The sensor glucose graphs.
	  • The STATUS screen and SENSOR STATUS screen.
	• **Move the cursor to the far right** side of the graph when viewing the sensor glucose graphs.
	• **Clear alarms** (press **ESC**, then press **ACT**).

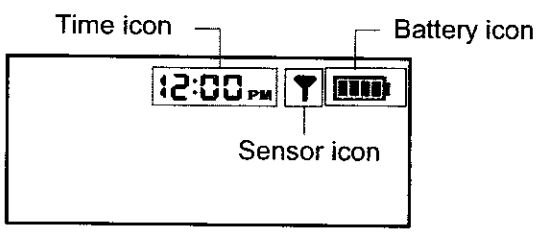
Button	Description
SHIFT SHIFT	You use this button to: • Turn the backlight on when viewing screens other than the HOME screen (hold down **SHIFT** and press **DOWN**). • Access the User Settings (hold down **SHIFT** and press **ACT**).

The monitor screen

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

The HOME screen

The HOME screen serves as the starting point to access the menus and screens you use to set up the system. You use the HOME screen to view the time and the Sensor Icon, which tells you whether the transmitter and monitor are communicating. If you do not press any buttons for about 30 seconds, the monitor automatically returns to the HOME screen.



When the monitor is on, the time and battery icons always appear across the top of the HOME screen. The Sensor icon will not appear until you start the sensor and establish communication between the monitor and transmitter.

NOTE: If the time and battery icons do not appear, the monitor is not working.

Icons

The different types of icons that appear on the monitor screen are described below.

Sensor icon

If an antenna icon displays, the monitor and transmitter are communicating. If the antenna colors are reversed, the Sensor feature is on, but there is no communication. For information about the Sensor, *Chapter 4, Setting up your sensor and transmitter.*


Sensor On and communicating with the transmitter.

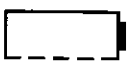

Sensor On, but not communicating with the transmitter.

Battery icon

This icon appears when a battery is installed in the monitor. There are four segments in the icon. Each segment represents approximately 25 percent of the usable battery life you have left until you reach Low Battery point. If you only have one segment left, make sure that you have a new battery available.

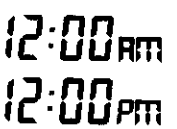
NOTE: You use the STATUS screen to check the status of the battery. This is described on page 77.

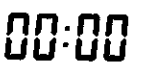

At least 75 percent left


Low battery.

Time of day icon

The current time of day is displayed across the top of the monitor screen in the format you select —12-hour or 24-hour. The AM or PM only appears when you are using the 12-hour format. See *page 22* for details on setting the time.


12 hour


24 hour

Alarm icons

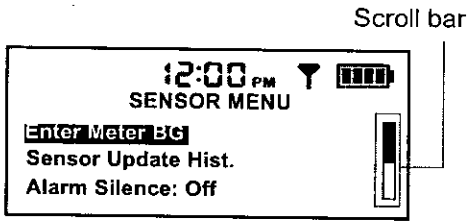
An open circle icon or a closed circle icon appear when an alarm occurs. The icon that appears depends on the alarm that occurred. See *Chapter 6, Troubleshooting and alarms* for information on the different alarms.


open circle


closed circle

Scroll bar

If there is more information on the screen than the monitor can show at the same time, a scroll bar appears in the right side of the screen. Press  to view any additional information.



Screen backlight

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

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

Alert types

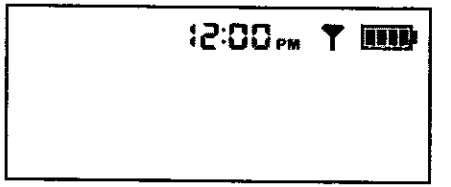
You can set up your monitor to either beep or vibrate when an alarm occurs. See *Setting your alert type, on page 24* for details on setting the alert type.

Operating modes

The screen lets you know when a special feature is active or if there is a condition that needs your attention. The monitor status will determine the operating mode. The screens for the different modes are shown below.

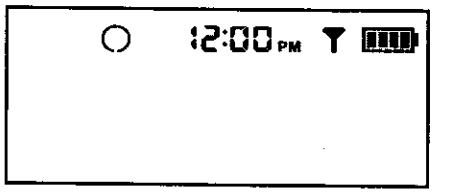
Normal mode

This mode indicates that no alarms are active.



Special mode

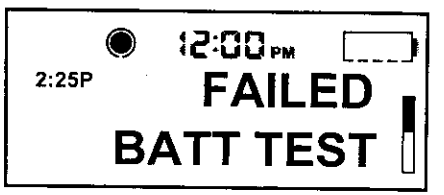
This mode indicates that a special feature is active or that a certain alarm condition exists. Special mode does not restrict any of the monitor functions. When the monitor is in Special mode, an open circle appears at the top of the screen and it will beep or vibrate periodically to remind you of the condition. All sensor alarms will begin to siren if they are not cleared within 10 minutes. The special features and alarm conditions that put the monitor in Special mode are:



- Block feature is turned on (special feature)
- Low Battery alarm
- Sensor alarms

Attention mode

This mode means that an alarm is active or an alarm condition exists that needs immediate attention. A solid circle appears at the top of the screen and the monitor will beep or vibrate periodically until the condition is cleared. How often the monitor beeps or vibrates changes depending on the condition that put the monitor in Attention mode.



The screen shows the name of the alarm and information about how to clear it (press to see the information on clearing the alarm). In this example, the alarm is the FAILED BATTERY TEST alarm.

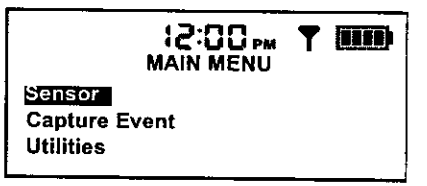
See *Chapter 6, Troubleshooting and alarms* for information on the alarm conditions that can cause Attention mode.

Menus

There are four menus in the system. Each menu contains different menu items that you select to set up the system and to view information.

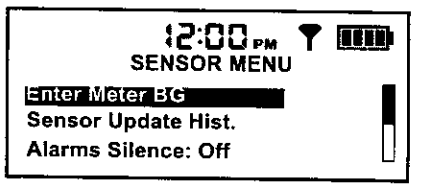
MAIN MENU

This is the highest menu in the system. It contains the SENSOR MENU, CAPTURE EVENT, and UTILITIES MENU. To open the MAIN MENU, press **ACT** from the HOME screen.



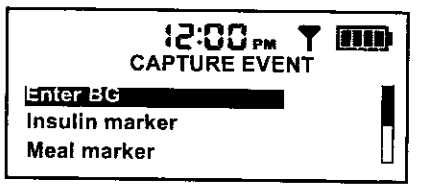
SENSOR MENU

This menu contains the options you use to set up the interface between the sensor and the monitor and to access to the monitor's sensor features. See *Chapter 3, Entering your settings* for details on how to enter your glucose monitoring settings. See *Chapter 4, Setting up your sensor and transmitter* for details on how to set up your sensor.



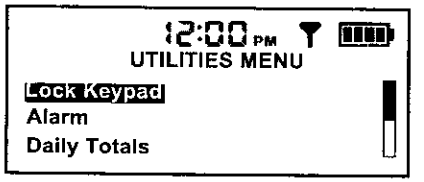
CAPTURE EVENT

This menu contains the options you use to log information about different events into the system. Some examples of events are the amount of insulin used for injections and carbohydrates eaten during meals or snacks. See *Chapter 5, Using your system* for details on how to log event information.



UTILITIES MENU

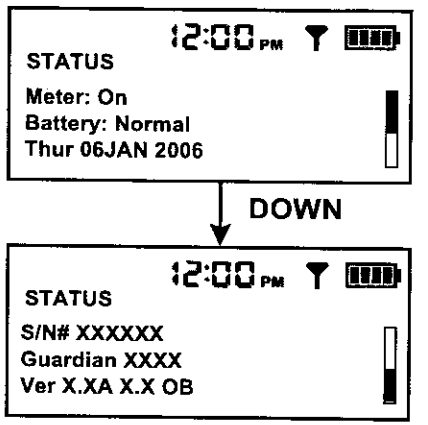
This menu contains the options you use for safety features, convenience, and to view information on system alarms. Some examples of when you use this menu include locking the keypad (buttons), viewing system alarms, turning the meter option on and off, and running the Selftest diagnostic test. See *Chapter 7, Utilities* for details on using this menu.



The STATUS screen

You use the STATUS screen to view any recent activity, the condition of the monitor battery, and to see if any special features are active.

- To open the STATUS screen from the HOME screen, press **ESC** until the STATUS screen appears.
- To view additional information, press  .
- To return to the HOME screen, press **ESC** until the HOME screen appears.



For details on the type of information shown in the STATUS screen, see *page 131*.

*NOTE: Do NOT try to open the STATUS screen when you are entering settings into the monitor. If you press the **ESC** button when you are entering settings, you may cancel the settings.*

Entering your settings

3

What's in this chapter:

NOTE: Before you can begin entering your glucose settings, make sure you have installed the battery in your monitor. If not, return to Installing the battery, on page 12 and install the battery.

Basic steps

There are a few basic steps you need to complete to enter your settings into the system. You should perform the steps in the order shown.

1. Make sure you have the information you need to begin.
2. Set the time and date.
3. Set the alert type.
4. Enter your glucose monitoring settings.
5. Review your settings.
6. Save your settings.
7. Modify your settings as needed.

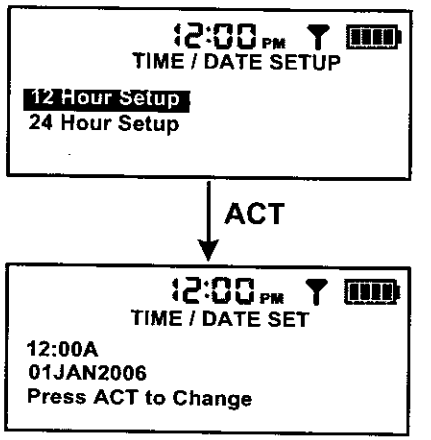
Setting the time and date

Setting the correct time and date in your monitor is necessary for the system to have accurate information about your glucose monitoring. You can select a 12-hour or 24-hour clock. You must reset the time and date if you receive a CHECK SETTINGS alarm or if you clear your settings.

1 From the HOME screen, open the TIME/DATE SETUP screen.

MAIN MENU > Utilities > Time/Date

The TIME/DATE SETUP screen appears.

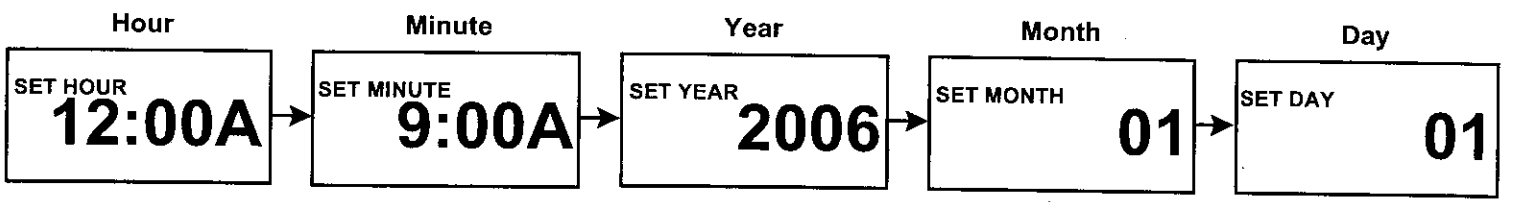


2 Select **12-Hour Setup** or **24-Hour Setup**, then press **ACT**. The TIME/DATE SET screen appears with the time and date that is currently set on your monitor.

3 Press **ACT**. The SET HOUR screen appears.

4 Using △ / ▽ to select the values, set the correct time and date as follows:

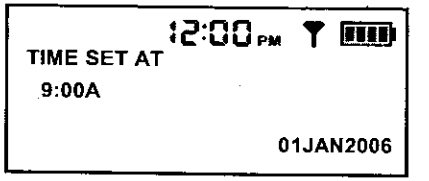
a. Set the correct hour, then press **ACT**.
b. For 12-hour setups, you must also select **A** (am) or **P** (pm), then press **ACT**.
c. Set the correct minutes, then press **ACT**.
d. Set the correct year, then press **ACT**.
e. Set the correct month, then press **ACT**.
f. Set the correct day, then press **ACT**.



5 Depending on whether you are resetting the time or setting the time when first setting up your monitor, the TIME SET AT or the TIME/DATE CORRECT screen will appear.

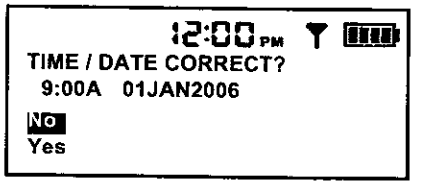
If the TIME SET AT screen appears:

a. Make sure the time and date shown on the screen is correct.
b. If the time and date is correct, press **ACT**. If it is not correct, press **ESC** until the HOME screen appears and repeat the procedure to enter the correct information.



If the TIME / DATE CORRECT? screen appears:

a. Make sure the time and date shown on the screen is correct.
b. If the time and date is **correct**, select **Yes**, then press **ACT**. If it is **not correct**, press **ACT**. The TIME/DATE SETUP screen reappears. Repeat the procedure to enter the correct information.



6 To return to the HOME screen, press **ESC** until it appears.

You are now ready to set your alert type.

Setting your alert type

You can select the type of notice the system will give you when an alarm occurs. Here are some examples of the types of things that cause an alarm:

- The sensor glucose measurement reaches or exceeds your High or Low Glucose Limits.
- Your battery is low and needs to be replaced.
- One or more parts of the system are not communicating, and you are losing important glucose monitoring information (such as your current sensor glucose levels).

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

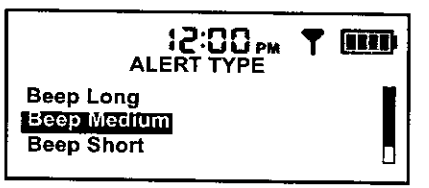
NOTE: Vibrate uses more battery power than the beep alert type and may shorten battery life. If your alert type is set to vibrate and you get a LOW BATTERY alert, your monitor will use the beep alert type instead to conserve battery power.

To set the alert type:

1 Open the ALERT TYPE screen.

MAIN MENU > Utilities > Alarm > Alert Type

The ALERT TYPE screen appears with **Beep Medium** selected (the default alert type).



2 Select your alert type. The available alert types are:
- Beep Long
- Beep Medium
- Beep Short
- Vibrate

3 Press **ACT**. The alert type is set. Any alarms you receive will have the alert type (beep or vibrate) you selected.

4 To return to the HOME screen, press **ESC** until it appears.

Entering your glucose monitoring settings

This section describes how you will enter the settings that are used for glucose monitoring, such as your glucose limits, turning on the sensor, turning on glucose alarms, setting glucose alarm limits, and entering the transmitter number.

You should enter the glucose monitor settings in the exact order they appear in this section, as some of the settings are dependent upon other settings being made first. As you complete each setting, your monitor will automatically display the screen for the next setting in the sequence.

Before you begin

If a screen item is flashing (blinking) during programming, press △ or ▽ to change the value of the flashing item.

Turning on the sensor

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

1 Open the EDIT SETTINGS screen.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

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

2 Press **ACT**. The SENSOR ON/OFF screen appears with **Off** selected.

3 Select **On**, then press **ACT**. The EDIT SETTINGS screen appears showing the sensor is now turned **on**.

You are now ready to select the blood glucose units.

Selecting the system blood glucose units

You must select the blood glucose units (BG units) for the system (either **mg/dL** or **mmol/L**). All blood glucose values will be displayed in the unit type you select.

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **BG Units**, then press **ACT** (BG Units is near the bottom of the screen). The BLOOD GLUCOSE UNITS screen appears.

3 Select **mg/dL** or **mmol/L**, then press **ACT**. The EDIT SETTINGS screen appears showing the blood glucose units you selected.

You are now ready to turn on the Glucose Alarms.

Turning on the Glucose Alarms

In order for the system to send you an alarm when the sensor glucose measurements reach or exceed your Glucose Limits, Glucose Alarms must be turned on.

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Glucose Alarms**, then press **ACT**. The GLUCOSE ALARMS screen appears with **Off** selected.

3 Select **On**, then press **ACT**. The EDIT SETTINGS screen appears showing the glucose alarms are now turned **on**.

You are now ready to set your Glucose Limits.

Setting the Glucose Limits

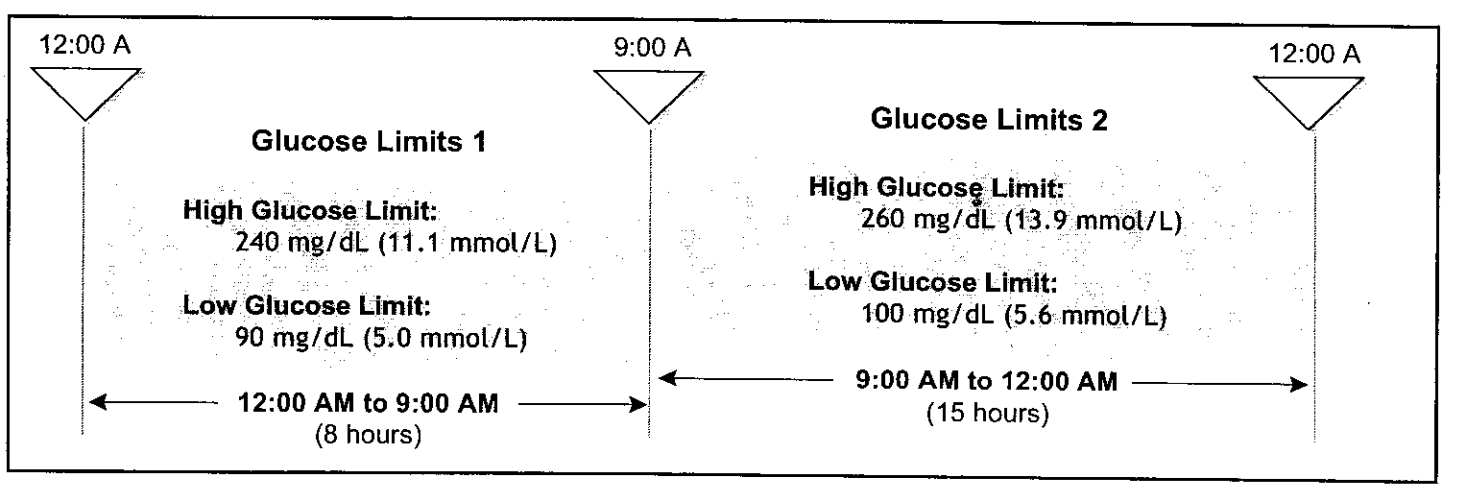
If you turned the Glucose Alarms **on**, you need to set up the high and low Glucose Limits recommended for you by your healthcare professional. Because your recommended glucose limits may vary throughout the day, your monitor allows you to set up to eight (8)settings.

A Glucose Limit setting includes one High Glucose Limit and one Low Glucose Limit, as shown in the following example.

Glucose Limit setting		Alarms you would receive
Low **High**	90 mg/dL (5.0 mmol/L) 280 mg/dL (15.6 mmol/L)	• A **Low Glucose Limit** alarm when the sensor glucose measurement **reaches or goes below** 90 mg/dL (5.0 mmol/L). • A **High Glucose Limit** alarm when the sensor glucose measurement **reaches or goes above** 280 mg/dL (15.6 mmol/L).

Setting the Glucose Limits start time

If your healthcare professional recommends that you set more than one set of Glucose Limits, you must enter a start time for each. For example, you may use one set of Glucose Limits during the day and another set at night. The example below shows two sets of Glucose Limits. The first set begins at 12:00 AM, and the second set begins at 9:00 AM.



To set up your Glucose Limits:

NOTE: To switch either the Low or High Glucose Limits OFF (independently of each other), scroll to select the value of OFF for step 3 and step 5 below.

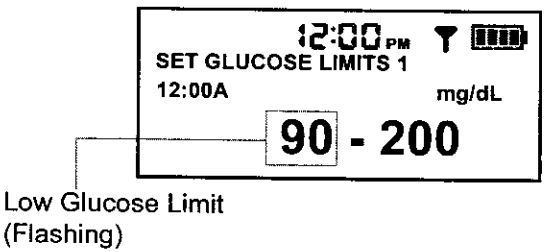
1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Glucose Limits**, then press **ACT**. The SET GLUCOSE LIMITS 1 screen appears. The Low Glucose Limit is flashing 90 mg/dL (5.0 mmol/L).

The start time for your first set of Glucose Limits is midnight (12:00A) and cannot be changed.

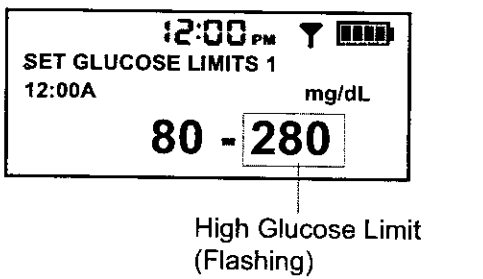
3 Select your Low Glucose Limit. The value must be between 90 and 390 mg/dL (5.0 and 21.6 mmol/L).



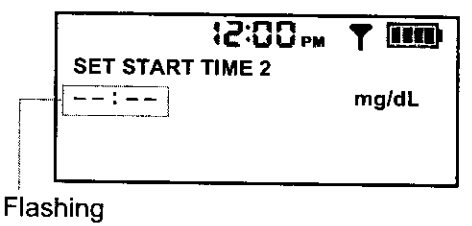
4 Press **ACT**. The High Glucose Limit is flashing 280 mg/dL (15.6 mmol/L).

5 Select your High Glucose Limit. The value must be between 100 and 400 mg/dL (5.6 and 22.2 mmol/L).

NOTE: Your High Glucose Limit must be at least 10 mg/dL (0.6 mmol/L) above your Low Glucose Limit.



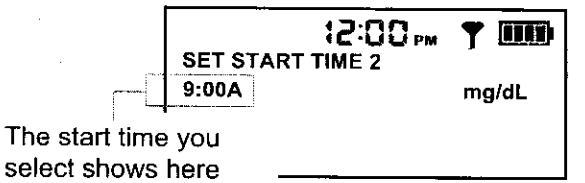
6 Press **ACT**. The SET START TIME 2 screen appears. The dashes under the screen name are flashing. The first pair of Glucose Limits are now set.



*NOTE: If you want to set up a second pair of Glucose Limits, follow step 7 through step 13 below. If you do not need a second set of Glucose Limits, press **ESC**.*

7 If you are setting a second set of Glucose Limits, select the time of day you want this set to become active.

For example, if you select 9:00A, this pair of Glucose Limits will become active at 9:00 A.M.



8 Press **ACT**. The SET GLUCOSE LIMITS 2 screen appears.

9 The default Low Glucose Limit is flashing (**OFF**).

10 Select your Low Glucose Limit. The value must be between 90 and 390 mg/dL (5.0 and 21.6 mmol/L).

11 Press **ACT**. The default High Glucose Limit is flashing (**OFF**).

12 Select your High Glucose Limit, then press **ACT**. The value must be between 100 and 400 mg/dL (5.6 and 22.2 mmol/L).

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

NOTE: You are done setting up the second pair of Glucose Limits (Glucose Limits 2). If you want to set more Glucose Limits, repeat step 7 through step 13 above. The maximum number of Glucose Limits you can set up is eight (8).

You are ready to set up your High Snooze.

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Setting the High Snooze

Once you receive and clear a High Glucose, Rise Rate of Change, or High Predictive alarm, the monitor will repeat the alarm for as long as the condition that caused the alarm exists. The High Snooze feature enables you to set how frequently you want the alarm to repeat after you clear it.

NOTE: If it typically takes one to two hours for your glucose values to fall after a correction bolus, you may want to set the High Snooze to one or two hours to avoid nuisance alarms.

Example

Suppose you set your High Snooze to 15 minutes. You receive an alarm at 1:00 P.M. and immediately clear it; however, the condition that caused the alarm still exists. In this case, you will receive a second alarm at 1:15 P.M. (15 minutes after you cleared the first alarm). If you immediately clear the alarm again, the alarm will repeat at 1:30 P.M. This will continue until you resolve the condition that caused the alarm. The example also applies to the Low Snooze.

To set up your High Snooze:

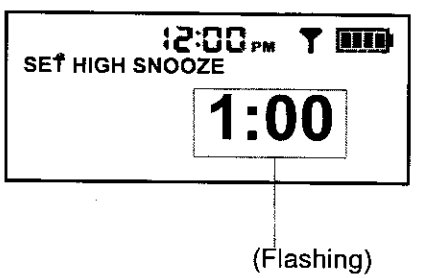
1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **High Snooze**, then press **ACT**. The SET HIGH SNOOZE screen appears. The screen shows the default High Snooze time of 1 hour (1:00) flashing.

3 Select your High Snooze time. The time must be between 5 minutes (0:05) and 3 hours (3:00).

4 Press **ACT**. The EDIT SETTINGS screen appears showing the High Snooze is set.



You are now ready to set up your Low Snooze.

Setting the Low Snooze

Once you receive and clear a Low Glucose, Fall Rate of Change, or Low Predictive alarm, the monitor will repeat the alarm for as long as the condition that caused the alarm exists. The Low Snooze feature enables you to set how frequently you want the alarm to repeat after you clear it. See *page 30* for an example of how the High Snooze and Low Snooze alarms work.

NOTE: If it typically takes one to two hours for your glucose values to rise after a correction bolus, you may want to set the Low Snooze to one or two hours to avoid nuisance alarms.

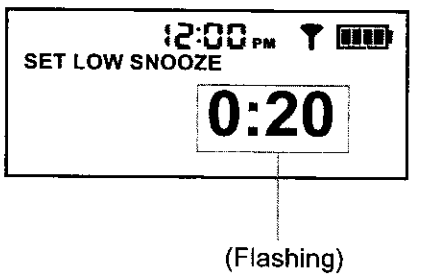
1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Low Snooze**, then press **ACT**. The SET LOW SNOOZE screen appears. The screen shows the default Low Snooze time of 20 minutes (0:20).

3 Select your Low Snooze time. The time must be between 5 minutes (0:05) and 1 hour (1:00).

4 Press **ACT**. The EDIT SETTINGS screen appears showing the Low Snooze is set.



You are now ready to set up the Predictive Alarm.

Setting the Predictive glucose alarm

The system predicts when you will reach your Glucose Limits, and sends an alarm according to preset time values. A Predictive alarm is telling you that **if your sensor glucose measurements keep falling or rising at the current rate**, the measurements will reach your Glucose Limit in your personal predefined number of minutes.

The example below shows how the system predicts when the sensor glucose measurements will reach your high and low Glucose Limits.

Example 1: The Predictive Alarm calculation

This example is using the High Glucose Limit.

If:	• Rate of change (per minute)	**3.0** mg/dL
	• Current sensor glucose measurement	**160** mg/dL
	• High Glucose Limit	**220** mg/dL
	• **[High Glucose Limit] – [Current sensor glucose]**	**220** mg/dL - **160** mg/dL = **60** mg/dL
Calculation:	Your sensor glucose measurements will reach your High Glucose Limit in **20 minutes**, if the rate of change continues.	**60** mg/dL **3.0** mg/dL per minute = **20 minutes**

Example 2: Understanding the Time Sensitivity Settings

Time Sensitivity is the amount of time (in minutes) you want to be notified before your High or Low Glucose Limit is reached. If you set the Time Sensitivity settings at Low = 25 minutes and High = 20 minutes, the Predictive alarms would occur when:

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

32 Entering your settings

To set up the Predictive alarms:

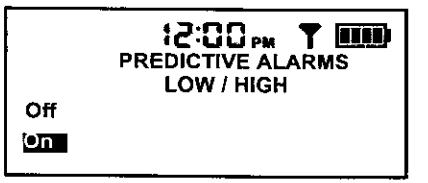
NOTE: The Predictive Alarms are switched On or Off from the Predictive Alarm screen, as shown in the procedure below. To switch either the Low or High Predictive Alarm OFF independently, select the Time Sensitivity value of Off (see step 4 and step 6 below).

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

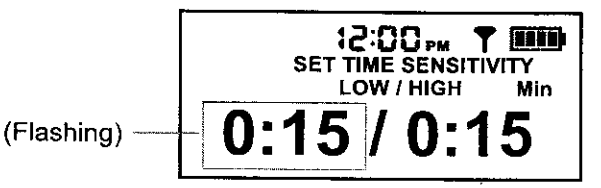
2 Select **Predictive Alm**, then press **ACT**. The PREDICTIVE ALARMS LOW/HIGH screen appears showing the alarms are turned **off**.

3 Select **On**, then press **ACT**. The SET TIME SENSITIVITY LOW/HIGH screen appears. The time setting for the Low Predictive alarm is flashing.



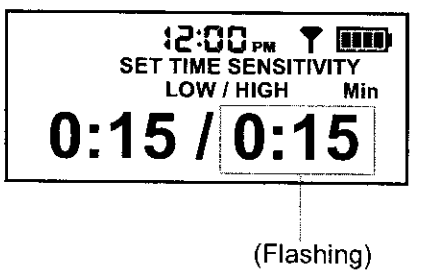
4 Select the Time Sensitivity, which is the amount of time you want to be notified before the Low Glucose Limit is reached (default is **15 minutes**).
- Range: **5 to 30 minutes (0:05 to 0:30)**
- Increments: **5 minutes**

5 Press **ACT**. The time setting for the High Predictive alarm begins flashing.



6 Select the Time Sensitivity, which is the amount of time you want to be notified before the High Glucose Limit is reached (default is **15 minutes**).
- Range: **5 to 30 minutes (0:05 to 0:30)**
- Increments: **5 minutes**

7 Press **ACT**. The EDIT SETTINGS screen appears.



You are now ready to set up the Rate of Change alarms.

Setting the Rate of Change alarms

The system detects if the sensor glucose measurements change too rapidly and sends an alarm, based on preset values. There are two Rate of Change alarms:

- **Falling Rate** for rapid **decreases** in sensor glucose measurements
- **Rising Rate** for rapid **increases** in sensor glucose measurements

You can set one or both of the alarms. The default value is **4.0** mg/dl/min (**0.220** mmol/L/min).

The example below provides further explanation of how the settings work.

If the value is set	Then
Lower than the default (4.0 mg/dl/min (0.220 mmol/L/min))	• The system is **more sensitive** to rapid changes • Alarms are **more frequent** than if you use a higher value
Higher than the default (4.0 mg/dl/min (0.220 mmol/L/min))	• The system is **less sensitive** to rapid changes • Alarms are **less frequent** than if you use a lower value

To set up the Rate of Change alarms:

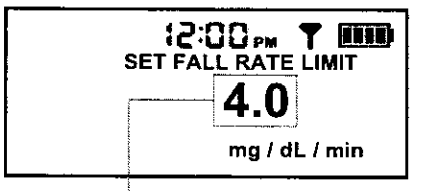
1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Rate Alarms**, then press **ACT**. The SET FALL RATE LIMIT screen appears showing the alarms are turned **off**.

3 Select the Fall Rate Limit you want to use. The default rate is flashing.

- Range: mg/dL/min from **1.1** to **5.0**
  mmol/L/min from **0.065** to **0.275**
- Increments: mg/dL/min **0.1**
  mmol/L/min **0.005**

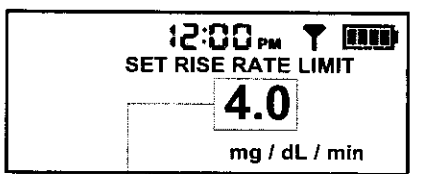


(Flashing)

4 Press **ACT**. The SET RISE RATE LIMIT screen appears showing the alarm if turned **off**.

5 Select the Rise Rate Limit you want. The range and increments are the same as the Fall Rate Limit (see *step 3* above).

6 Press **ACT**. The system will now use your new settings for the Rate of Change alarms.



(Flashing)

You are now ready to set up the AUC Limits.

Setting the AUC Limits

The AUC (Area Under the Curve) Limits feature measures the extent and duration that your sensor glucose measurements are above the predefined AUC High Limit or below the predefined AUC Low Limit.

The AUC Limits are different than your Glucose Limits. The AUC Limits are used to analyze the sensor glucose measurement data that is stored in the system's memory. The AUC Limits are not high and low glucose alarms.

NOTE: You should check with your healthcare professional to determine the AUC settings that are best for you.

The default AUC Limits are:

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

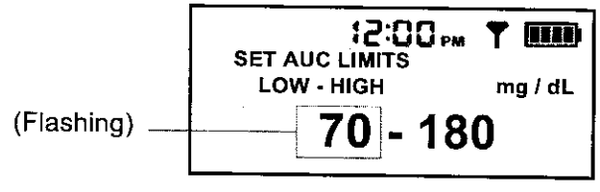
To set the AUC Limits:

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **AUC Limits**, then press **ACT**. The SET AUC LIMITS screen appears. The default Low AUC Limit is flashing 70 mg/dL (3.9 mmol/L).

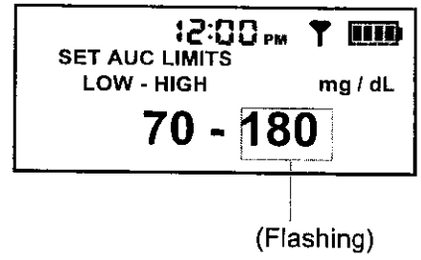
3 Select your Low AUC Limit. The value must be between 40 and 400 mg/dL (2.2 and 22.2 mmol/L).



4 Press **ACT**. The default High AUC Limit is flashing

5 Select your High AUC Limit. The value must be between 40 and 400 mg/dL (3.9 and 22.2 mmol/L).

NOTE: The AUC High Limit can be equal to, but not lower than the AUC Low Limit.



6 Press **ACT**. The EDIT SETTINGS screen appears showing the AUC Limits you selected.

You are now ready to set up the Alarm Snooze.

Setting the Alarm Snooze

Once you receive and clear a Meter BG Now alarm, the monitor will repeat the alarm until you enter a new meter blood glucose measurement. See *Meter BG now, on page 90* for more information. The Alarm Snooze feature enables you to set how frequently you want the alarm to repeat after you clear it.

1 Make sure the EDIT SETTINGS screen is open.

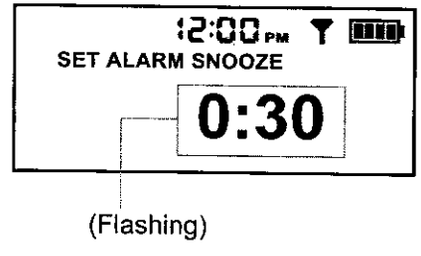
MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Alarm Snooze**, then press **ACT**. The SET ALARM SNOOZE screen appears. The default Alarm Snooze time is flashing.

3 Select your Alarm Snooze time. The amount of time must be between 5 minutes (0:05) and one hour (1:00).

4 Press **ACT**. The EDIT SETTINGS screen appears showing the Alarm Snooze time you selected.

You are now ready to set your Cal Reminder.



Setting the Cal Reminder

Once you calibrate your system, you must continue to calibrate it every twelve (12) hours. If you miss a calibration, the system will send you a Meter BG Now alarm. The Cal Reminder feature allows you to set a reminder to calibrate your system. For example, if you set your reminder to 4 hours you will receive a Cal Reminder 4 hours before the next meter BG entry is due, which is 8 hours after your last successful sensor calibration was done. For more information on calibration, see *Calibrating your system, on page 58.*

The system comes to you with the Cal Reminder feature turned on, with a default setting of one hour (1:00).

To set up the Cal Reminder:

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

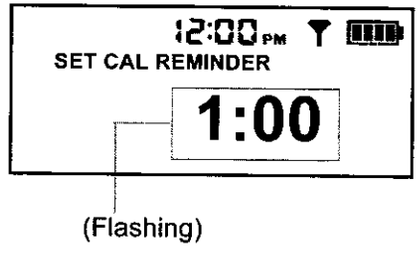
2 Select **Cal Reminder**, then press **ACT**. The CAL REMINDER screen appears with **On** selected.

3 Press **ACT**. The SET CAL REMINDER screen appears. The default Cal Reminder time is flashing.

4 Select your Cal Reminder time. The time you select must be between 5 minutes (0:05) and 6 hours (6:00).

5 Press **ACT**. The EDIT SETTINGS screen appears showing the Cal Reminder time you selected.

You are now ready to enter the identification number of your transmitter.



Entering the transmitter identification number

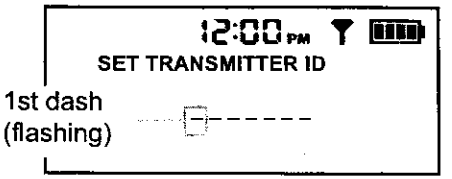
You must enter the identification number of the transmitter so that the transmitter and monitor can communicate with each other. The Transmitter ID is found on the front of your transmitter.

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

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Transmitter ID**, then press **ACT**. The SET TRANSMITTER ID screen appears. The screen shows 7 dashes for the Transmitter ID. The first dash (on the left of the screen) is flashing. If your transmitter ID has less than seven numbers, add zeros in front of the ID so that there are seven.



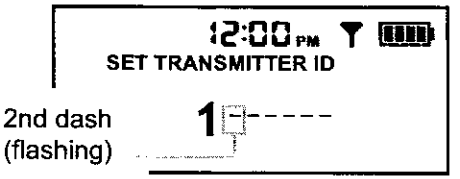
3 Select the first number of the Transmitter ID (the number on the screen must match the first number of the Transmitter ID).

4 Press **ACT**. The second dash is flashing.

5 Select the next number of the Transmitter ID, then press **ACT**.

6 Repeat *step 5* until all 7 digits of the Transmitter ID have been selected.

A message appears telling you that the Transmitter ID has been changed. After about 30 seconds, the HOME screen appears.



NOTE: If you are entering the Transmitter ID for the first time, you do not need to restart the sensor right now. If you entered the Transmitter ID for a new transmitter, you need to restart the sensor. See Starting the sensor, on page 53 for details.

You are now ready to set up the Missed Data option.

Setting up the Missed Data option

Missed Data notifies you of the amount of the time (in minutes) that the communication between the transmitter and the monitor is disrupted, based on your predefined values.

NOTE: The transmitter has 40 minutes of memory.

To set up the Missed Data option:

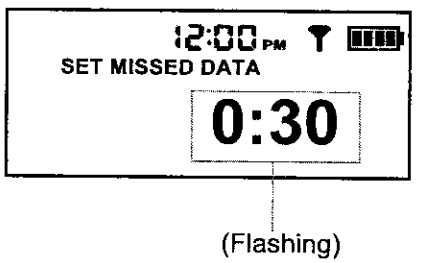
1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Missed Data**, then press **ACT**. The SET MISSED DATA screen appears. The default MISSED DATA time is flashing 30 minutes (0:30).

3 Select your Missed Data time. The time you select must be between 5 minutes (0:05) and 40 minutes (0:40).

4 Press **ACT**. The EDIT SETTINGS screen appears showing the amount of time you entered for the Missed Data option.



You are now ready to set up the sensor glucose graph timeout.

Setting the sensor glucose graph timeout

The sensor glucose graph timeout is the amount of time that the graphs are displayed on the monitor screen before the HOME screen automatically appears. The default is two (2) minutes, and begins from the last time you select an event or graph to view.

You also have the option of having a continuous graph display where no timeout is used (choose option NONE). In this case, the monitor screen will display your graph until you open another screen or menu.

Using a continuous graph display

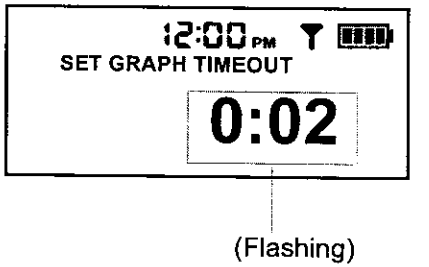
You have the option of setting up the system to continuously display the graphs. If you choose NONE to select this option, the HOME screen will not automatically reappear. Rather, the sensor graphs will remain constant and will not time out until another screen or menu is accessed, or an alarm occurs. Setting up your monitor for a continuos graph display will significantly increase the battery power required. To return to the HOME screen from the sensor glucose graphs, press **ESC** until the HOME screen appears.

To set the sensor glucose graph timeout:

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

2 Select **Graph Timeout**, then press **ACT**. The SET GRAPH TIMEOUT screen appears. The default Graph Timeout is flashing 2 minutes (0:02).



3 Select your Graph Timeout. The time you select must be:

- 2 minutes
- 4 minutes
- 6 minutes
- NONE

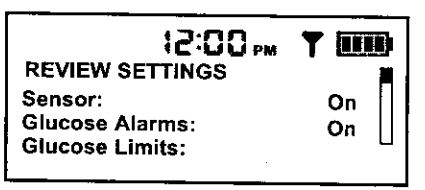
4 Press **ACT**. The EDIT SETTINGS screen appears showing the Graph Timeout you selected. You are now ready to review your sensor glucose monitoring settings.

Reviewing your settings

To make sure all the settings you have made are correct before you begin using the system, use the following procedure to review your settings.

1 Open the REVIEW SETTINGS screen.

MAIN MENU > Sensor > Sensor Setup > Review Settings



2 View all of the settings on the screen to make sure they are correct.

Press  to view all of the settings.

3 To change any of the settings, return to the EDIT SETTINGS menu.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

4 Once your settings are set up as desired, you should save them. This way, if you receive an alarm or error that resets your settings, you can restore the settings that you have saved. See *Save settings, on page 114.*

Using the Sensor Demo

The Sensor Demo is primarily used as a training tool. It shows you demonstrations of the sensor graphs and the Sensor Status screen. In order to view the demo screens, you must first turn on the Sensor Demo feature.

Turning on the Sensor Demo feature

1 Make sure the EDIT SETTINGS screen is open.

MAIN MENU > Sensor > Sensor Setup > Edit Settings

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

2 Press **ACT**. The SENSOR DEMO ON/OFF screen appears with **Off** selected.

3 Select **On**, then press **ACT**. The EDIT SETTINGS screen appears showing that SENSOR DEMO is now turned **on**.

Viewing the Sensor Demo screens

1 From the HOME screen, press ESC. The screen will briefly display "SENSOR DEMO," then the first Sensor Demo graph appears.

2 You can move the cursor through the graph to see examples of how the real-time graphs appear. For more information on viewing the graphs, see *Reading the sensor glucose graphs, on page 67*.

Setting up your sensor and transmitter 4

What's in this chapter:

NOTE: Before you can begin setting up your sensor and transmitter, you must have already set up your monitor. If you have not done this yet, go back to Chapter 3, Entering your settings and finish setting up your monitor.

Basic steps

There are a few basic steps you need to complete to set up your sensor and transmitter so you are ready to begin using the system. You should perform these steps in the order below.

1 Inserting the sensor into your body.
2 Attaching the transmitter to your body.
3 Connecting the sensor to the transmitter.
4 Starting the sensor.
5 Entering your first meter blood glucose.

Inserting the sensor

This section shows you how to insert the sensor into your body correctly so that the sensor can measure the glucose in your body. You insert the sensor into the fatty layer under the skin. You can insert the sensor using the Sen-serter® insertion device that came with your system, or you can insert the sensor manually. However, it is highly recommended that you use the Sen-serter® to make sure that the sensor is placed in the tissue correctly.

The sensor produces a signal that reflects the amount of glucose in the fatty layer under the skin at the insertion site. This signal is sent to the transmitter, which is then sent to the monitor. The monitor translates the signal and displays a sensor reading on your monitor screen.

WARNING:

The sensor may create special needs regarding your medical conditions or medications. Please discuss these conditions and medications with your healthcare professional 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.

Before you begin

This section contains important information on making sure your sensor is ready to be inserted, where you should and should not insert the sensor, and how to prepare the insertion site.

Make sure the sensor is ready to be inserted

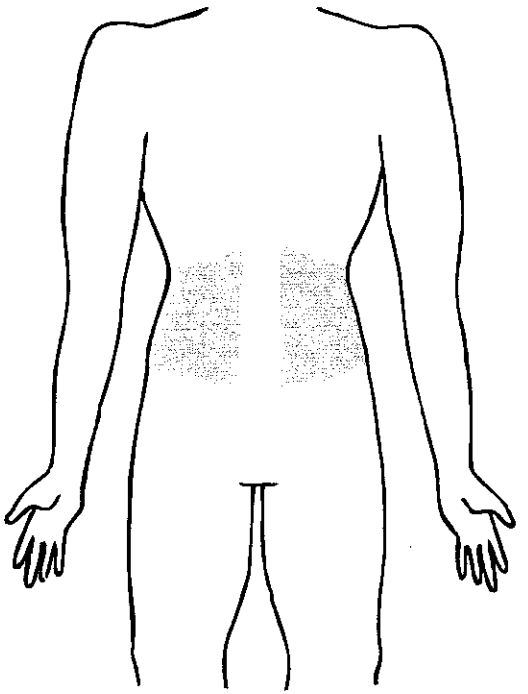
Be sure you allow the sensor package to reach room temperature before you open the sensor package (approximately 10 to 15 minutes).

Where you should insert the sensor

CAUTION: Never insert the sensor within 2 inches (5.0 cm) of an insulin pump infusion site, or within 3 inches (7.5 cm) of a manual insulin injection site.

Be sure you choose a site (place) on your body that has enough of a fatty layer to insert your sensor. This diagram shows the areas of the body that are the best sites to use to insert the sensor. **You should use a different site each time you insert a new sensor.**

NOTE: Be sure to rotate (change) the sensor sites so that the areas you use to insert the sensor do not become overused.



Rotating sensor sites
New sensor = new site

Where you should NOT insert the sensor

- Frequently used injection or infusion sites
- The 2 inches (5.0 cm) area around your navel
- Sites (areas) where clothing will rub your skin or where it constricts movement
- Scarred or atrophied tissue
- Areas of your body that you move frequently
- Areas of your body without enough fatty tissue

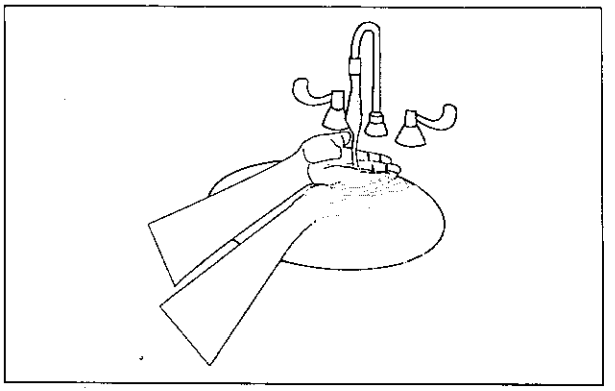
How to prepare the insertion site

- Be sure you prepare the insertion site with alcohol and that the site is dry before you insert the sensor.
- Do NOT use sticky skin preparation solutions before you insert the sensor.
- A sticky intravenous (I.V.) preparation solution can be used after you insert the sensor, and before you apply a sterile dressing to help the dressing stick to your skin.

To insert the sensor:

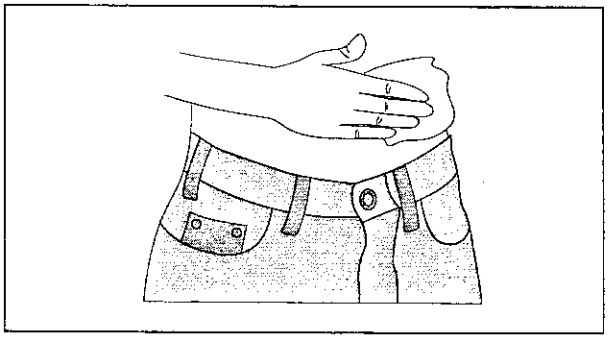
Always refer to the instructions that shipped with your glucose sensor.

1 Wash your hands.

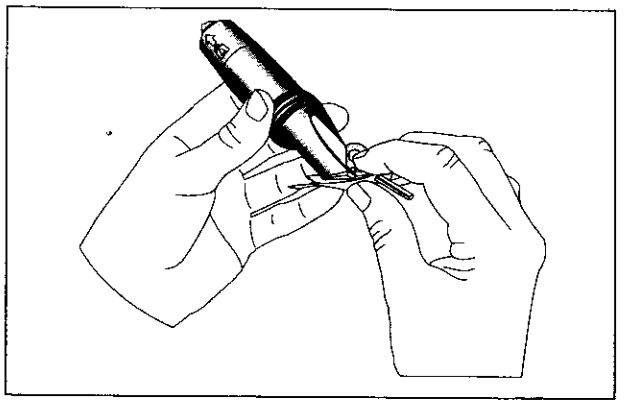


2 Prepare the insertion site with alcohol, then allow the site to dry.

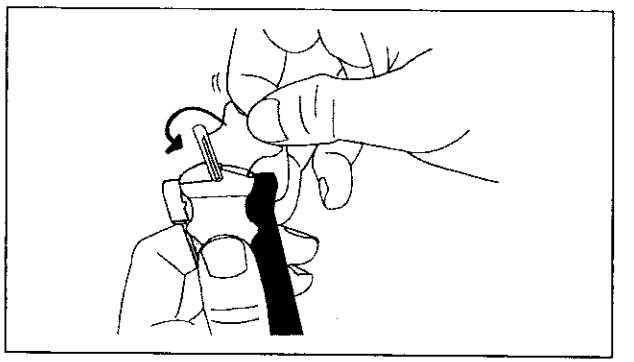
3 Remove the sensor from the package. Be sure you hold the base of the sensor or the tape. Do not hold the sensor by the introducer needle handle.



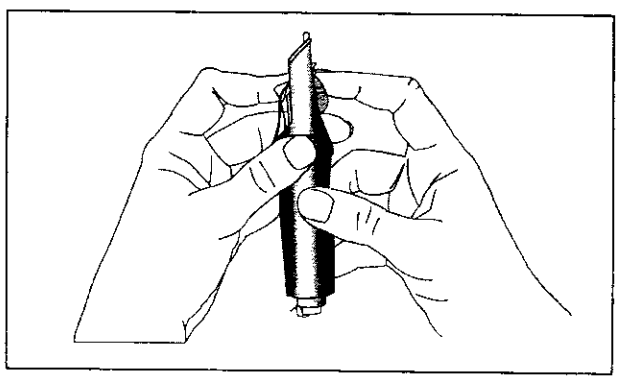
4 Place the sensor in the Sen-serter until it fits snugly.



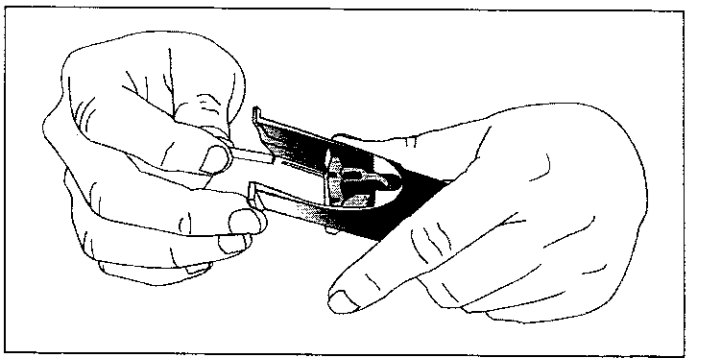
5 Holding the white tape as shown, remove the clear tape.



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

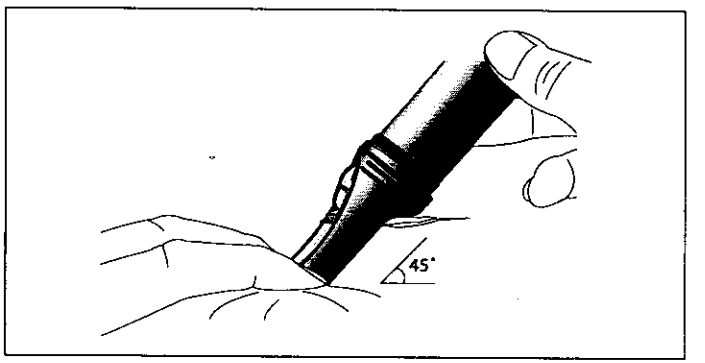


7 Turn the lock on the Sen-serter and remove needle guard from introducer needle.



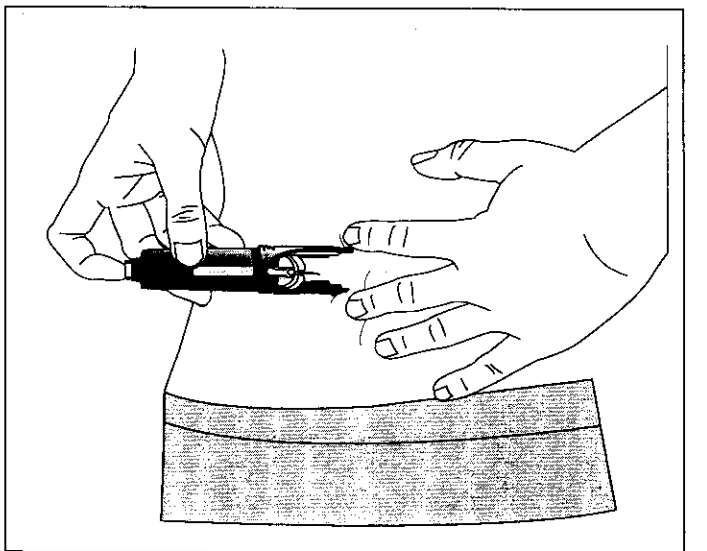
8 With one hand, rest the Sen-serter legs flat on your skin so that the Sen-serter is at a 45 degree angle (or more) to the insertion site. Place two fingers of your other hand on the Sen-serter legs to maintain the correct angle.

NOTE: Bleeding can occur if you insert the sensor at too shallow of an angle (less than 45 degrees).

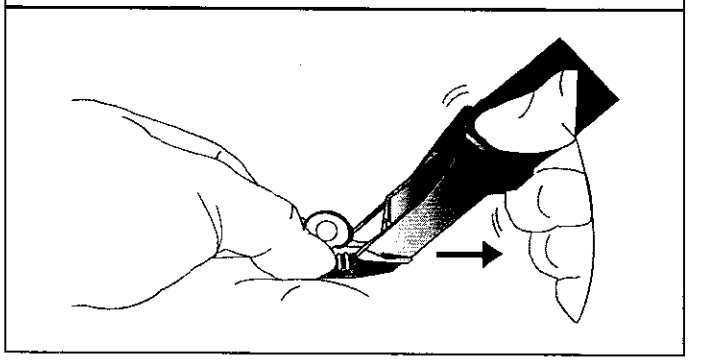


9 Unlock the Sen-serter and then press the white button to insert the sensor. If the sensor tube is not fully inserted, it can be manually pushed into place before removing the introducer needle.

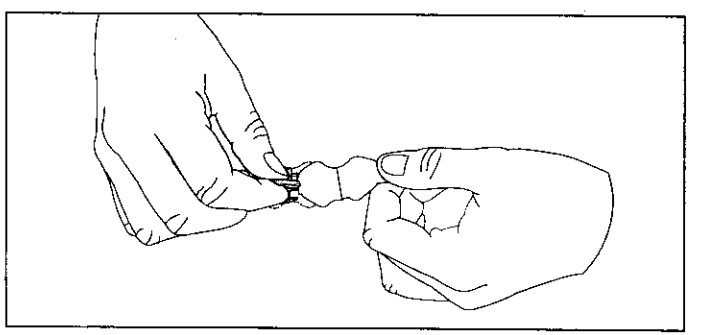
10 Make sure the sensor is inserted and flush with your skin.



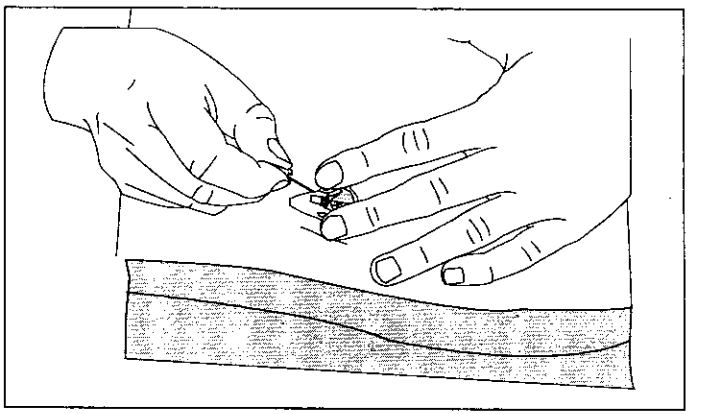
11 While holding the sensor in place, gently slide the Sen-serter away from the sensor. Do not twist, bend or lift the Sen-serter.



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 at a 45-degree angle. Do NOT rotate the introducer needle when removing it. Dispose of the needle in a sharps container.



CAUTION: DO NOT connect the sensor to the transmitter until it has been inserted for about five (5) minutes and is allowed enough time to be wetted with interstitial fluid. Make sure that the site is not bleeding. If you connect the sensor to the transmitter and the site begins to bleed, you will have to disconnect the sensor and transmitter and insert a new sensor in a different site.

14 Wait five (5) minutes 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.

If the bleeding stops after applying pressure using the gauze, go to *Attaching the transmitter to your body, on page 51.*

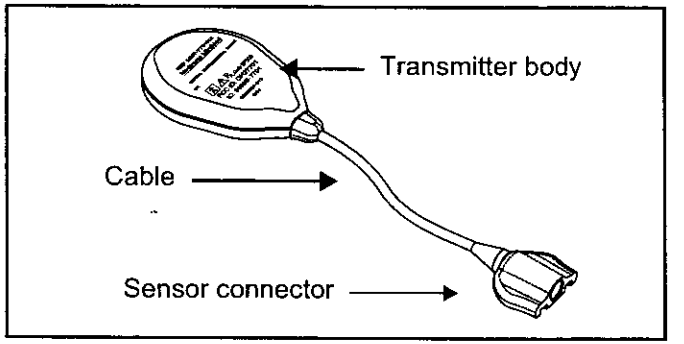
If the bleeding does NOT stop after applying pressure using the gauze, follow *step a* through *step d* below:

a. Remove the sensor and discard it.
b. Check the site for redness, bleeding, irritation, pain, tenderness or inflammation.
c. Insert a new sensor in a different location.
d. Check to make sure you are not bleeding from the new site. If bleeding occurs, apply pressure using a sterile gauze or clean cloth for 3 minutes.

Attaching the transmitter to your body

This section shows you how to attach the transmitter to your body. You attach the transmitter body to your skin using an adhesive pad.

The transmitter must be connected to the sensor so that it can receive the glucose measurements from the sensor. Once the transmitter receives the glucose measurements from the sensor, it sends them to the monitor so you can see the glucose measurements on the monitor screen.



Before you begin

Make sure you have the following items before you attach the transmitter to your skin:

- Unscented soap and water
- A clean towel to clean your skin
- Adhesive pad

To attach the transmitter to your skin:

CAUTION: Always hold the transmitter by its body, not the cable.

1. Find a comfortable, protected area of your body near the sensor you just inserted that is within cable reach (3 inches or 7.5 cm) of the sensor you just inserted.
2. Clean the area with a unscented soap and water, and allow the area to dry.
3. Peel the paper labeled as "1" from the adhesive patch.
4. Stick the adhesive pad to the side of the transmitter that is not labelled.
5. Peel the paper labeled as "2" from the skin side of the adhesive patch and firmly press the transmitter against your skin within three (3) inches from the sensor site.

NOTE: If you experience irritation or have a reaction to the transmitter tape (or other tapes), please contact the Medtronic 24 Hour HelpLine.

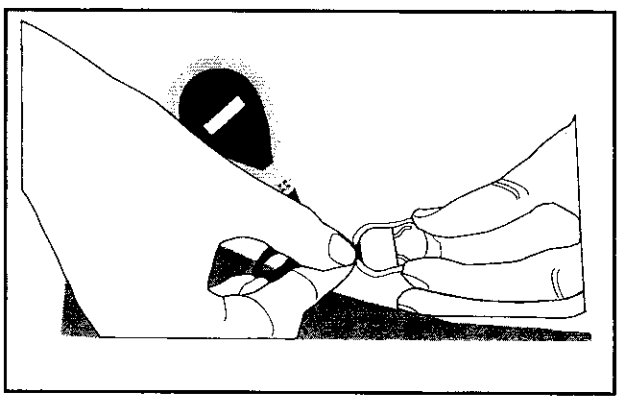
Connecting the sensor to the transmitter

This section shows you how to connect the sensor to the transmitter. You connect the sensor to the transmitter using the sensor connector that is at the end of the cable. The diagram below shows the cable and the sensor connector.

The transmitter must be connected to the sensor so that it can receive the glucose measurements from sensor. Once the transmitter receives the glucose measurements from sensor, it sends them by radio frequency to the monitor.

CAUTION: To avoid damaging the sensor or the sensor connector, make sure the sensor and the cable are level against the skin when you connect them.

To connect the sensor to the transmitter:



1 Hold the base of the sensor while you connect it to the cable. Do not squeeze the clips on the sides of the sensor. You should hear a 'click' when the cable and sensor become connected. You will also hear a click and an audible beep that confirm the sensor and transmitter are connected.

2 A prepping agent, such as an I.V. prep can be used to strengthen the adhesion before applying the dressing. Make sure the smooth side is down and the transmitter serial number is visible, as shown.

3 If you need to secure the transmitter more firmly, you can apply a sterile transparent dressing over the sensor and transmitter if desired.

Starting the sensor

This section shows you how to 'start' the sensor. Starting the sensor prepares it for taking glucose measurements and sending them to the transmitter. You use the monitor to start the sensor.

To start the sensor:

1 Open the SENSOR START MENU.

MAIN MENU > Sensor > Sensor Start

The SENSOR START MENU appears with **New Sensor** selected.

2 Press **ACT**. The NEW SENSOR screen appears with a message reminding you to connect the sensor to the transmitter.

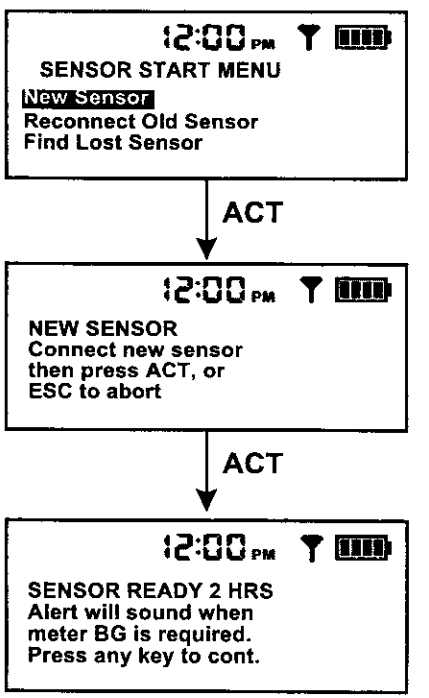
3 If you have not connected them already, do so now (see *page 52* for the steps to use).

NOTE: If the New Sensor screen times out and the HOME screen appears, DO NOT connect the sensor. Go to step 1 and start the procedure again.

4 Press **ACT**. The SENSOR READY 2 HRS screen appears.

5 Press any button. The sensor is started.

After two hours, your monitor will prompt you to enter the first meter BG to calibrate the sensor.



Entering the first meter blood glucose

NOTE: If you have just started the sensor, do NOT enter a meter blood glucose measurement until at least two hours after you started the sensor.

After the two hour initialization period, a Meter BG Now alarm will appear to prompt you to enter a blood glucose (BG) reading into the monitor to calibrate the sensor. This calibration will be successful only if the blood glucose entry is in the range of 40-400 mg/dL (or 2.2 to 22 mmol/L).

To enter the first meter blood glucose:

1 Press **ESC**, then **ACT** to clear the METER BG NOW alarm.

2 Check the sensor icon on the screen to make sure the monitor and the transmitter are communicating properly.

- The communication is **good.** You can go to *step 3* to continue entering your first meter blood glucose measurement.
- The communication is **lost**. Do **not** continue entering your first meter blood glucose measurement. Check the following:
  - The sensor is connected correctly to the transmitter.
  - The sensor is turned on. See *Turning on the sensor, on page 25.*
  - The sensor has been started. See *Starting the sensor, on page 53.*
  - The monitor is not too far from transmitter.
  - If the communication is still lost, see *Chapter 6, Troubleshooting and alarms* for information on how to restore the communication between the monitor and the transmitter.

3 Take a meter blood glucose measurement. **Immediately enter the meter blood glucose measurement into your monitor** by following *step 4* through *step 6* below.

If you are using the Paradigm Link meter, your blood glucose measurement is automatically sent to your monitor to calibrate the system. In this case, you should skip *step 4* through *step 6* below.

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4 Open the ENTER BG screen.

MAIN MENU > Sensor > Enter Meter BG

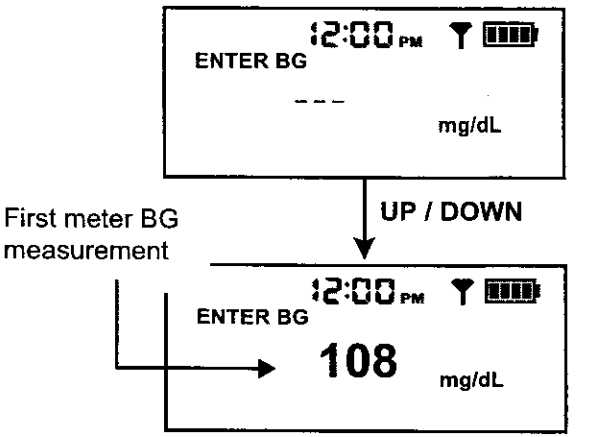
The ENTER BG screen appears showing three dashes.

5 Select the value from your meter (the value on the screen must match the measurement from your meter).

NOTE: Values below 40 mg/dL or above 400 mg/dL cannot be used for calibration.

6 Press **ACT**. The system is calibrated.

Once you have entered your first meter blood glucose measurement, you are ready to begin using your system. You must calibrate your system regularly. *Chapter 5, Using your system* for further information.



CAUTION: Many different types of events can cause the glucose levels in your body to change rapidly. Blood glucose measurements that are taken during rapid changes are not the best measurements to use to calibrate your system. It is recommended that you only use blood glucose measurements to calibrate your system that are taken when your blood glucose is the most stable. Some examples of times of the day when your blood glucose is most stable include before meals, at least two hours after a meal or snack, and before going to bed. Avoid calibrating two to three hours after a meal, two hours after a correction (insulin or carbohydrate), if rapid change arrows appear on your monitor, or if you have recently received a Rate of Change alarm. These are all times when your glucose may be rapidly changing.

Using your system

5

What's in this chapter:

NOTE: Before you can begin using the system, you must have already set up your monitor, sensor, and transmitter. If you have not set up your monitor already, go back to Chapter 3, Entering your settings to finish setting up the monitor. If you have not set up the sensor and transmitter already, go back to Chapter 4, Setting up your sensor and transmitter to finish setting up the sensor and transmitter.

Calibrating your system

Calibrating your system is very important because it helps to make sure that the glucose readings from the sensor are as accurate and reliable as possible. Calibrating your system involves periodically entering meter blood glucose measurements into your system.

NOTE: If you have just inserted and started a new sensor, do NOT enter a meter blood glucose measurement to calibrate the system until at least two hours after you started the sensor.

Guidelines for calibrating the system

The sections below contain important recommendations and information you need to know about calibrating the system.

When should I calibrate the system?

You should calibrate the system in all of the following circumstances. The monitor will display a Meter BG Now Alarm to notify you when you need to calibrate.

- Each time you insert a new sensor, after the two-hour warm-up period.
- Within six (6) hours of the initial calibration of a new sensor, a failed calibration, or an invalidated calibration factor. An invalidated calibration factor can occur, for example, if the battery is removed for more than ten minutes.
- After the above two circumstances, at least **twice** a day (once every 12 hours).

NOTE: When you are first learning to use the system, it is best to calibrate three to four times per day: when you wake up, before meals, and before you go to bed.

What are the best times to calibrate the system?

In order to calibrate the system using meter blood glucose measurements that are as accurate and reliable as possible, it is recommended that you calibrate your system when your blood glucose is **not** changing rapidly. For example:

- Before meals
- At least two hours after a meal or snack
- Before going to bed

What happens if I do not calibrate it often enough?

This example assumes that you are using the default Cal Reminder setting of 1 hour.

Time since last calibration	What happens
At least **11 hours**	If you have **not changed the default** Cal Reminder setting (one hour), the system reminds you to calibrate the system by sending a CAL REMINDER alarm one hour before your next calibration is due. You can change the CAL REMINDER alarm setting so that you receive an alarm earlier than the default. See *Setting the Cal Reminder, on page 38* for details.
At least **12 hours**	• The system sends you a METER BG NOW alarm. • The system stops taking real-time glucose measurements. • The system stops sending alarms when you reach your High/Low Glucose limits. *NOTE: Once you receive the METER BG NOW alarm, you must enter a new meter blood glucose measurement before the system will start taking glucose measurements again.*

To calibrate your system:

1 Check the sensor icon on the screen to make sure the monitor and the transmitter are communicating properly.

- The communication is **good**. You can go to *step 2* to continue calibrating your system.
- The communication is **lost**. Do **not** continue entering your first meter blood glucose measurement. Check the following:
  - The sensor is connected correctly to the transmitter.
  - The sensor is turned on. See *Turning on the sensor, on page 25*.
  - The sensor has been started. See *Starting the sensor, on page 53*.
  - The monitor is not too far from transmitter.
  - If the communication is still lost, see *Chapter 6, Troubleshooting and alarms* for information on how to restore the communication between the monitor and the transmitter.

2 Take a meter blood glucose measurement. **Immediately enter the meter blood glucose measurement into your monitor**, by following *step 3* through *step 5* below.

If you are using the Paradigm Link meter, your blood glucose measurement is automatically sent to your monitor to calibrate the system. In this case, you should skip *step 3* through *step 5* below.

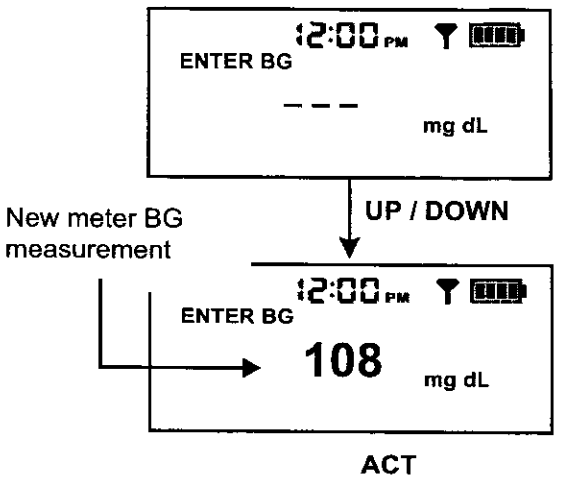
3 Open the ENTER BG screen.

Main > Sensor > Enter Meter BG

The ENTER BG screen appears showing three dashes.

4 Select the value from your meter (the value on the screen must match the measurement from your meter).

NOTE: Values below 40 mg/dL or above 400 mg/dL cannot be used for calibration. If your measurement is below 40 mg/dL or above 400 mg/dL, treat according to your health care provider's instructions. Calibrate when your meter blood glucose level is between 40 mg/dL and 400 mg/dL.



5 Press **ACT**. The calibration has been successfully entered. It takes 10 to 15 minutes after entering your meter blood glucose value for the measurement to be accepted as a valid calibration, and for the system to begin displaying those values.

If you enter an incorrect calibration value:

If you accidentally enter an incorrect calibration value, you should immediately re-enter the correct value. If two values are entered within 15 minutes of one another, the system will use the most recently entered value.

Capturing Events

The Capture Event feature may help you manage your diabetes therapy by electronically logging certain types of information. The system creates a "marker" for each type of event you log. Some examples of the information you might log include:

- Non-calibration meter blood glucose measurements (measurements that **are used to manage your diabetes therapy**, but are not used to calibrate the system)
- The type and amount of insulin you are using
- The amount of carbohydrates you eat with your meals and snacks
- The type and amount of exercise
- Other (this can be used for anything else as needed)

This information can then be uploaded to Medtronic CareLink® Therapy Management software, where it can be used to generate treatment reports that you can share with your healthcare professional.

NOTE: The Capture Events feature allows you to manually log information. The system automatically logs the following information, which can also be uploaded to Medtronic CareLink® Therapy Management software.

- *Sensor glucose measurements*
- *Sensor glucose alarm settings*
- *Sensor glucose limit alarms*
- *Meter blood glucose measurements that are **used to calibrate the system***

Logging non-calibration meter BG measurements

Non-calibration meter blood glucose measurements include those measurements that are taken after eating, between calibration meter blood glucose measurements, or when your blood glucose is rising or falling rapidly.

NOTE: Although this procedure is for taking a non-calibration meter blood glucose readings, the system gives you the option of using the reading you enter for calibration purposes.

1 Make a note about the non-calibration meter blood glucose measurement.

2 Open the ENTER BG screen.

Main > Capture Event > Enter BG

The ENTER BG screen appears with the most recent meter blood glucose measurement you entered flashing.

3 Enter your new measurement, then press **ACT**. A message appears asking you if you want to save the new measurement that is displayed on the screen. The **Yes** option is selected.

4 Make sure the number shown on the screen is correct.

- If the information is correct, press **ACT**.
- If the information is **not** correct, select **No**, then press **ACT**. The CAPTURE EVENT menu reappears with **Enter BG** selected. Repeat the procedure to enter the correct information.

NOTE: For the Update Sensor screen to appear as described below, you must have the sensor turned on, started and initialized, and have successful communication between the sensor and transmitter. Your BG measurement must be between 70 mg/dL and 250 mg/dL.

5 The Update Sensor screen appears. This allows you to use this meter BG reading to calibrate your sensor.

- To update the sensor with this meter BG reading, select **Yes**.
- If you do not want to updated the sensor with this reading, select **No**.

The Capture Event menu reappears.

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Logging insulin injection information

Follow these steps to log the type and amount of insulin you are injecting.

1 Make a note about the amount and type of injection you are taking.

2 Open the INSULIN TYPE screen.

Main > Capture Event > Insulin Marker

The INSULIN TYPE screen appears. The system automatically selects the type of insulin you entered the last time you logged information.

3 Select the correct insulin type for the injection. The insulin types are:

- Fast Acting
- Short Acting
- Intermediate Acting
- Long Acting
- Mixed 70/30
- Mixed 50/50

4 Press **ACT**. The ENTER INSULIN screen appears with the amount of insulin you entered the last time you logged information flashing.

5 Enter the amount of the injection then press **ACT**. A message appears asking you if you want to save the new information that is displayed on the screen. The **Yes** option is selected.

6 Make sure the type and amount of insulin shown on the screen is correct.

- If the information is correct, press **ACT**. The information you entered is saved to the system and can now be used in reports.
- If the information is **not** correct, select **No**, then press **ACT**. The CAPTURE EVENT menu reappears with **Enter BG** selected. Repeat the procedure to enter the correct information.

Logging information about carbohydrates consumption

This section shows you how to log the amount of carbohydrates you consume with meals or snacks.

Before you begin

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

To set the carbohydrate units:

1 Open the CARB UNITS screen.

Main > Capture Event > Carb Units

The CARB UNITS screen appears with **Grams** selected.

2 Select either **Grams** or **Exchanges**, then press **ACT**. The CAPTURE EVENT menu appears showing the carbohydrate unit you selected.

3 You are now ready to log your carbohydrates.

To log amount of carbohydrates information:

1 Determine the total number of grams of carbohydrates in the meal or snack you plan to consume.

2 Open the ENTER MEAL screen.

Main > Capture Event > Meal Marker

The ENTER MEAL screen appears with **Breakfast** selected.

3 Select the correct meal type for the meal or snack. The meal types are:

- Breakfast
- Lunch
- Dinner
- Snack

4 Press **ACT**. The ENTER FOOD screen appears with the number of carbohydrate grams or exchanges you entered the last time you logged information flashing.

5 Enter the carbohydrate grams or exchanges for the meal or snack, then press **ACT**. A message appears asking you if you want to save the information that is displayed on the screen. The **Yes** option is selected.

6 Make sure the number shown on the screen is correct.
   - If the information is correct, press **ACT**. The information you entered is saved to the system and can now be used in reports.
   - If the information is **not** correct, select **No**, then press **ACT**. The CAPTURE EVENT menu reappears with **Enter BG** selected. Repeat the procedure to enter the correct information.

Logging exercise information

Follow these steps to log information about the exercise you do.

1 Make a note about the intensity (how difficult or hard the exercise was), and how long you exercised.

2 Open the EXERCISE INTENSITY screen.

   Main > Capture Event > Exercise Marker

   The EXERCISE INTENSITY screen appears with the intensity type you selected the last time you logged information flashing.

3 Select the intensity type. The intensity types are:
   - High difficult
   - Medium some difficulty, but not too hard
   - Low not difficult, easy

4 Press **ACT**. The EXERCISE DURATION screen appears with the amount of time (duration) you entered the last time you logged information flashing.

5 Enter the amount of time you exercised, then press **ACT**. A message appears asking you if you want to save the information that is displayed on the screen. The **Yes** option is selected.

6 Make sure the number shown on the screen is correct.
   - If the information is correct, press **ACT**. The information you entered is saved to the system and can now be used in reports.
   - If the information is **not** correct, select **No**, then press **ACT**. The CAPTURE EVENT menu reappears with **Enter BG** selected. Repeat the procedure to enter the correct information.

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Logging Other markers

This section shows you how to log Other markers, which include any kind of activity that does not fit with the following marker types:

- Enter BG (non-calibration meter blood glucose measurements)
- Insulin marker (the type and amount of insulin you are using)
- Meal marker (the amount of carbohydrates eaten)
- Exercise marker (the type and amount of exercise)

When you log Other markers, you only record the type of marker and the time. A couple examples of Other markers include recording when you take medications or if you feel dizzy. In the reports you create, these markers appear with the name of the marker (Other) and the time you logged the marker.

To log Other markers:

1 Go to the OTHER screen.

Main > Capture Event > Other

A message appears on the screen asking you "Do you want to enter an Other marker?"

2 To log an Other marker, make sure **Yes** is selected, then press **ACT**. The CAPTURE EVENT screen appears.

Reading the sensor glucose graphs

Your monitor displays an updated glucose value every five (5) minutes. The signal is sent from the sensor to the transmitter, and then to the monitor, where it is converted to a glucose value. There are four graphs you can use to view the real-time sensor glucose measurements, depending on the number of hours you wish to review.

- **3** hour
- **6** hour
- **12** hour
- **24** hour

Each graph displays the following information. The time period represented in the graph depends on which graph you view.

- The most recent sensor glucose or the reason a sensor glucose value is not displayed.
- The historical sensor glucose measurements taken for the last 3, 6, 12 or 24 hours. This includes the value and the time the sensor glucose measurement was taken, or the reason it is not displayed.
- Arrows that give a relative indication of the rate at which the most recent sensor glucose levels are rising or falling.

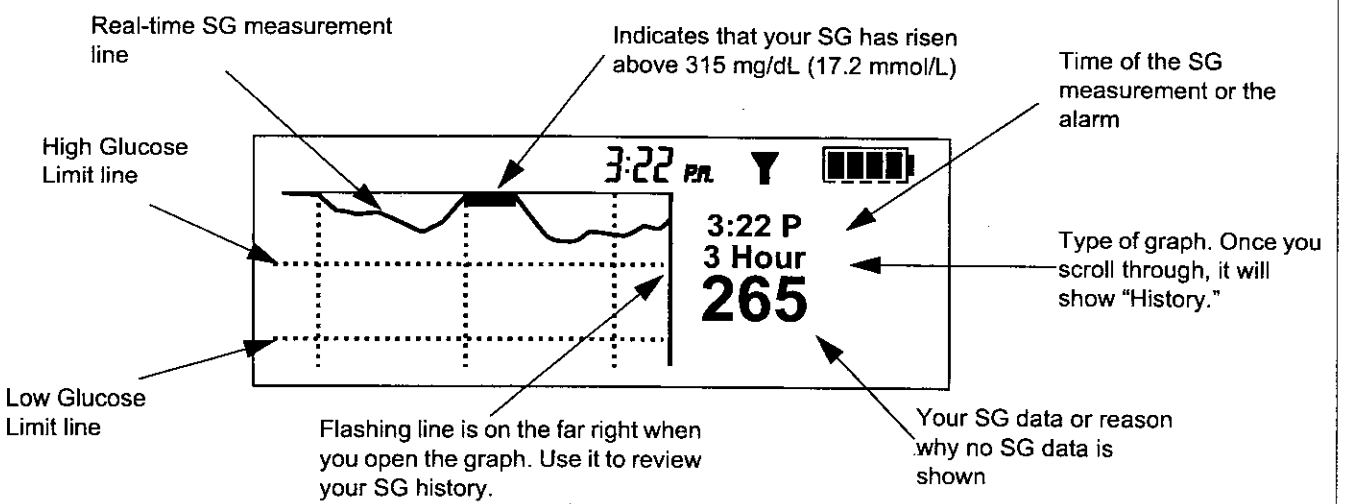
The following conditions can prevent a real-time sensor glucose measurement from being taken. If this occurs, your graph will include this information.

- A LOST SENSOR alarm.
- A new sensor you just inserted is being initialized and has not yet started taking sensor glucose measurements.
- After a Cal Error alarm occurs.
- More than 12 hours has passed since the last system calibration.

The graphs

When you open any of the graphs, the latest event (sensor glucose measurement or sensor alarm) is always shown, and the cursor (flashing line) is always on the right edge of the graph. You use the cursor to select the event you want to view details about. For information on how to open the graphs and use the cursor, see *Opening and viewing the graphs, on page 69.*

Top of the graph: The largest reading that can be displayed is 315 mg/dL (17.2 mmol/L)



Bottom of the graph: The smallest reading that can be displayed is 40 mg/dL (2.2 mmol/L)

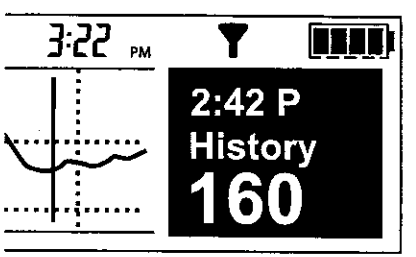
Opening and viewing the graphs

The following table describes how to work within the graphs.

If you want to:	Do the following:
Open the graphs	From the HOME screen, press **ESC**. The last graph you viewed (3 hour, 6 hour, 12 hour or 24 hour) appears showing the details for your most recent event.
View information in a graph	In most cases you will use the graphs to select and view a real-time sensor glucose measurement. If a sensor alarm has occurred, the graph will show the name of the alarm. No sensor glucose measurement is shown with an alarm. • When you open the graphs, the cursor is always on the right edge of the graph. • Press ▽ to move the cursor to the left and select an event to view. • To return to more recent events, press △ to move the cursor to the right.
View different graphs	• With the cursor at the far right edge of a graph, you can press △ to open the next graph. • If the cursor is anywhere but the far right of a graph, press **ESC** to move it to the right, then press △ to open the next graph.

How you know you are viewing earlier events

Once you select an earlier event, the event details area of the screen becomes shaded, and the graph name changes to "History," as shown here.

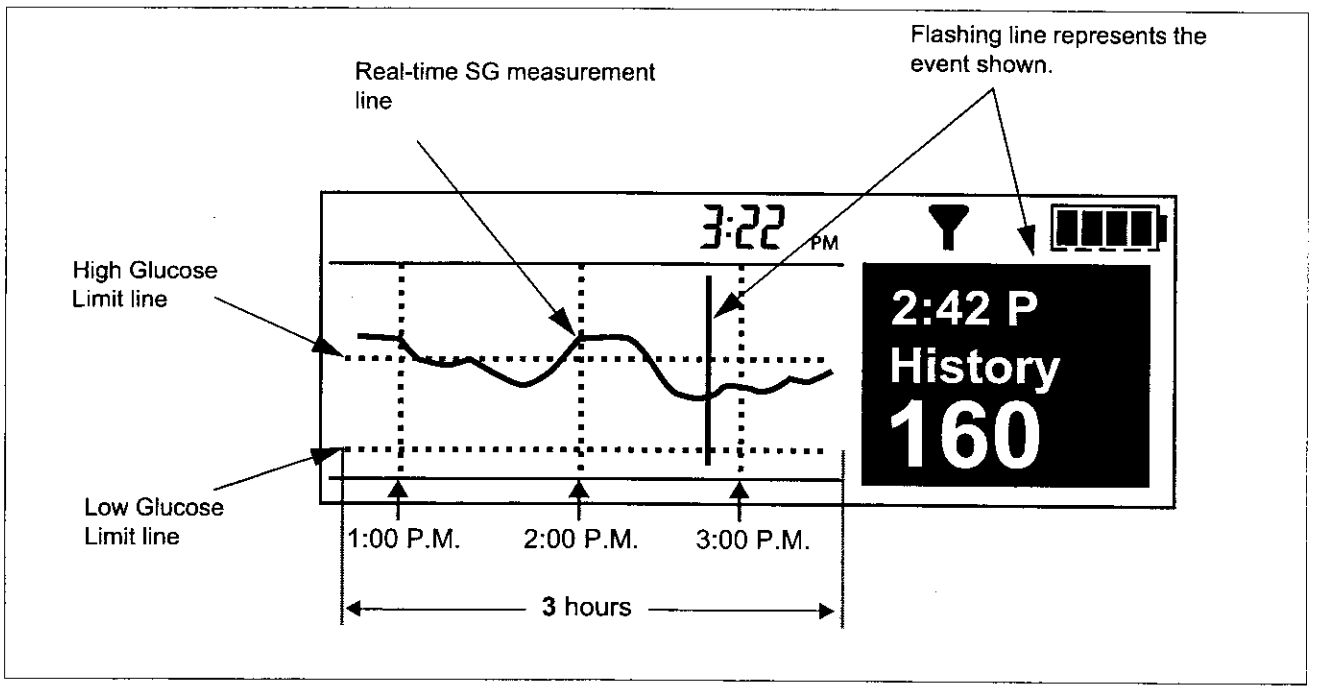


Examples of real-time sensor glucose graphs

The following pages show examples of the different graph types.

3 hour graph

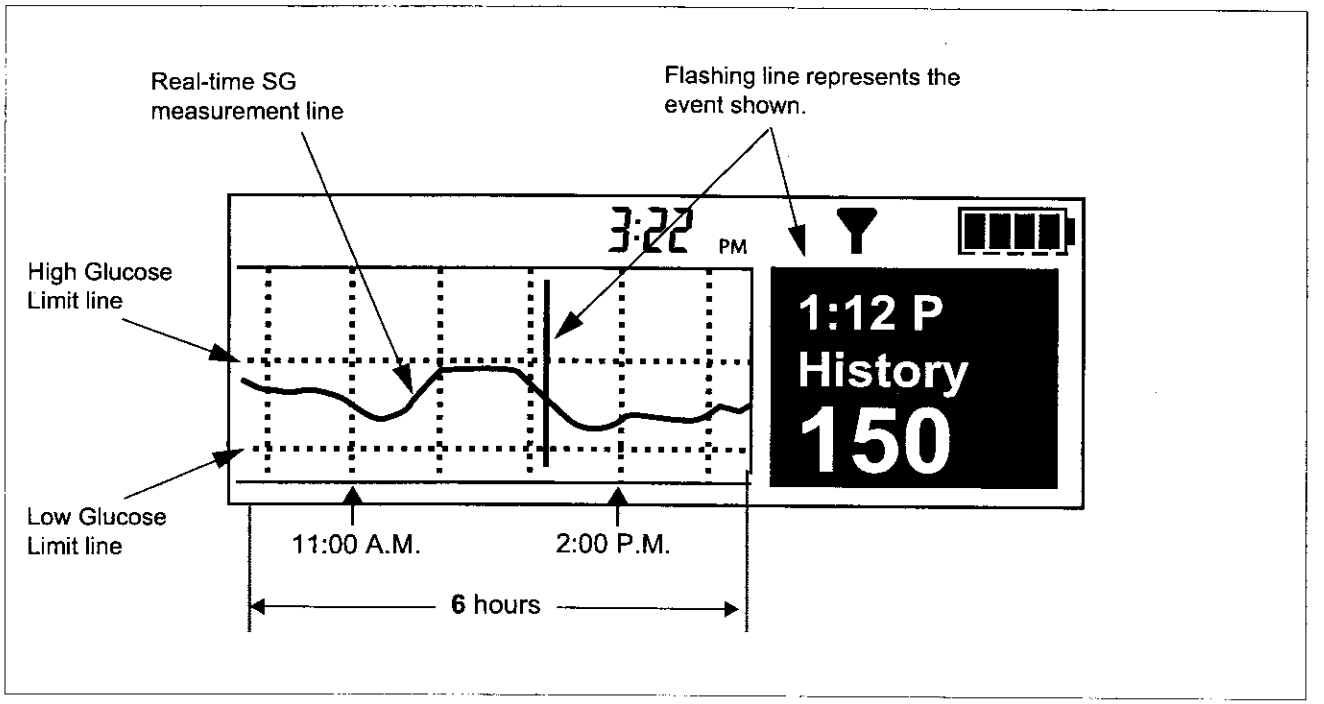
This picture shows an example of the 3 hour graph. Each part of the graph between the vertical dashed lines represents one hour. In this example, the selected event is a real-time sensor glucose measurement. It was taken at 2:42 P.M., and the value was 160.



Q11

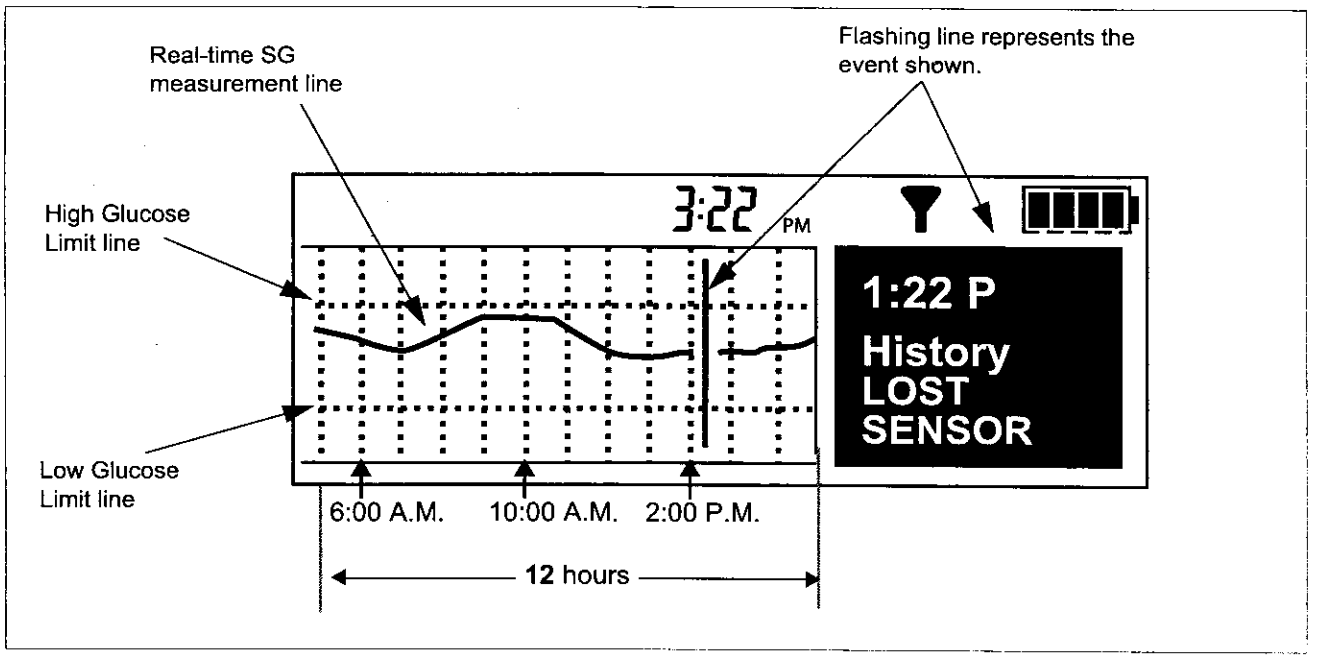
6 hour graph

This picture shows an example of the 6 hour graph. Each part of the graph between the vertical dashed lines represents one hour. In this example, the selected event is a real-time sensor glucose measurement. It was taken at 1:12 P.M., and the value was 150.



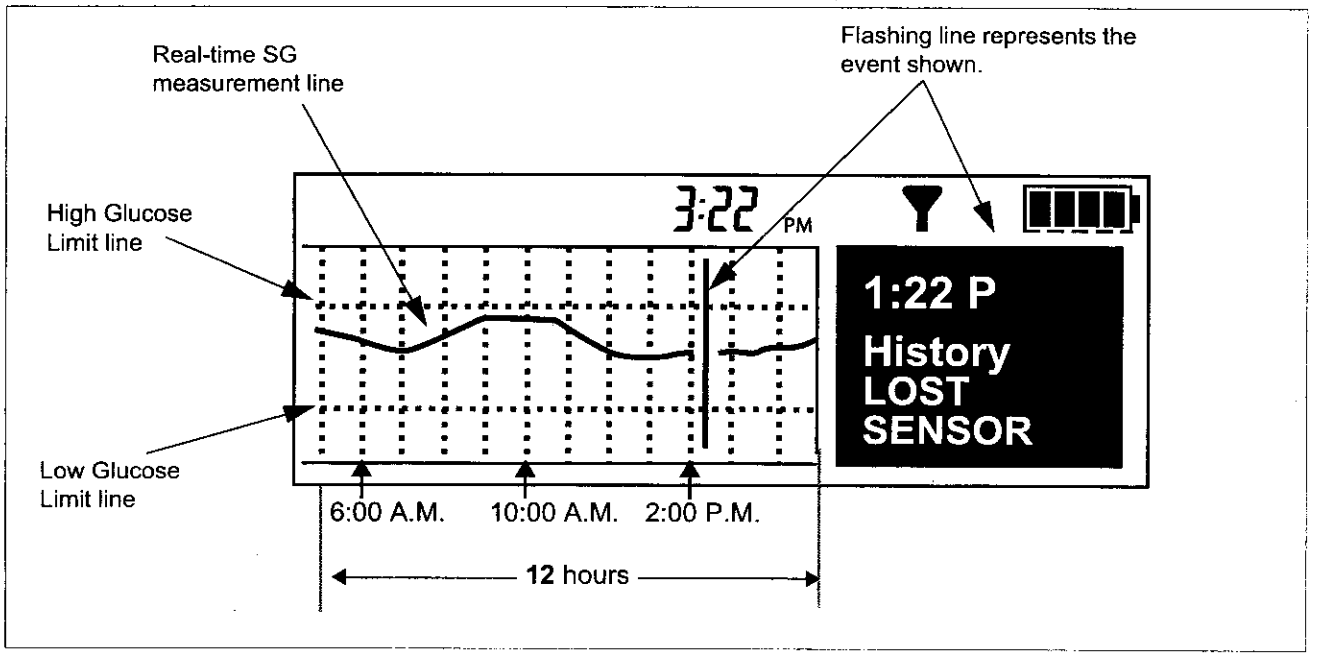
12 hour graph

This picture shows an example of the 12 hour graph. Each part of the graph between the vertical dashed lines represents one hour. In this example, the selected event is a sensor alarm (LOST SENSOR alarm). The alarm occurred at 1:22 P.M.



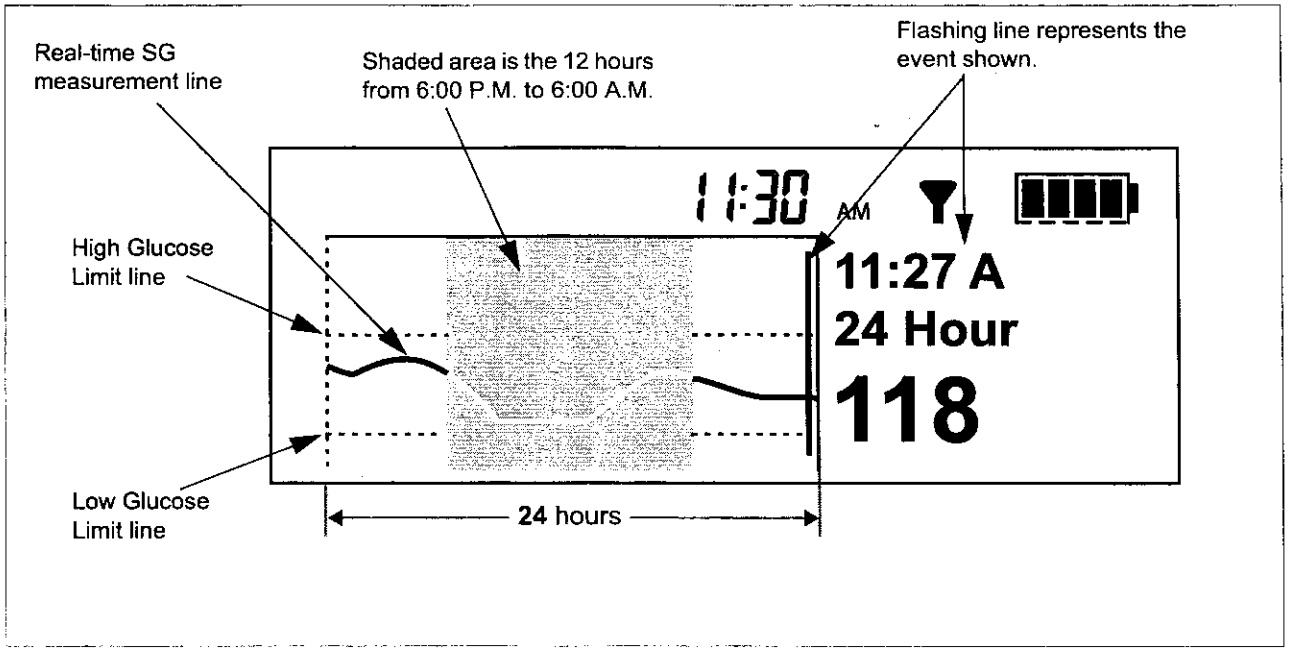
12 hour graph

This picture shows an example of the 12 hour graph. Each part of the graph between the vertical dashed lines represents one hour. In this example, the selected event is a sensor alarm (LOST SENSOR alarm). The alarm occurred at 1:22 P.M.



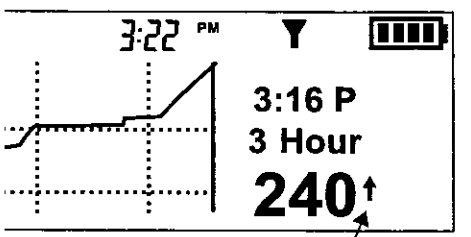
24 hour graph

This picture shows an example of the 24 hour graph. Each part of the graph between the vertical dashed lines represents six hours. The shaded area helps you easily see the sensor glucose measurements for the previous night. In this example, the selected event is a real-time sensor glucose measurement. It was taken at 11:27 A.M. and the value was 118.



How to check for rapid changes

If the sensor glucose measurements are rapidly rising or falling, the Rapid Change arrows automatically appear in the graphs next to the sensor value, as shown here.



Upward arrow indicates that your sensor glucose is rising rapidly.

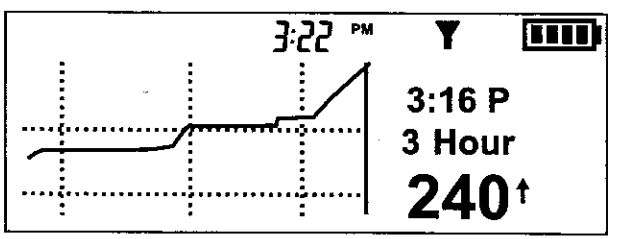
NOTE: You can also use the Rate of Change alarm to help you know if your sensor glucose measurements are changing rapidly (see page 34 for details). If they are, you should not calibrate until they have stabilized.

The rapid change arrows

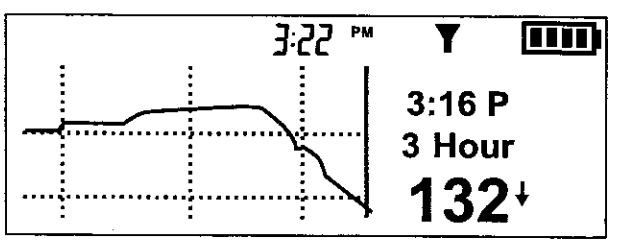
The following examples show the how the system uses the rapid change arrows to tell you when your sensor glucose measurements are rising or falling rapidly.

The direction of the rapid change arrows indicate whether the sensor glucose measurements are rising or falling, and the number of arrows (one or two) indicates how rapidly the change is occurring.

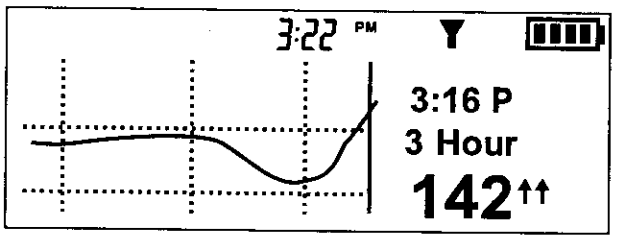
- One up arrow ↑ indicates that your sensor glucose has risen between **1.0** and **2.0** mg/dL (**0.06** and **0.11** mmol/L) each minute for the last 20 minutes. Your sensor glucose has risen between **20.0** and **40.0** mg/dL (**1.11** and **2.22** mmol/L) in the last 20 minutes.



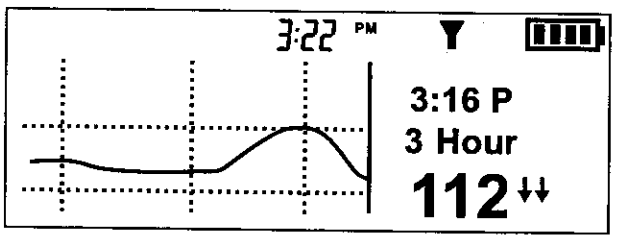
- One down arrow ↓ indicates that your sensor glucose has dropped between **1.0** and **2.0** mg/dL (**0.06** and **0.11** mmol/L) each minute for the last 20 minutes. Your sensor glucose has dropped between **20.0** and **40.0** mg/dL (**1.11** and **2.22** mmol/L) in the last 20 minutes.



- Two up arrows ↑↑ indicate that your sensor glucose has risen more than **2.0** mg/dL (**0.11** mmol/L) each minute for the last 20 minutes. Your sensor glucose has risen more than **40.0** mg/dL (**2.22** mmol/L) in the last 20 minutes.



- Two down arrows ↓↓ indicate that your sensor glucose has fallen more than **2.0** mg/dL (**0.11** mmol/L) each minute for the last 20 minutes. Your sensor glucose has fallen more than **40.0** mg/dL (**2.22** mmol/L) in the last 20 minutes.



Adjusting the sensitivity to rapid changes

You can make the system more sensitive or less sensitive to rapid changes in sensor glucose measurements by changing the settings for the Rate of change alarms. You do this by changing the value of the Fall Rate Limit or the Rise Rate Limit. Here are some guidelines to follow when changing the settings for the Rate of change alarms.

Changes you make	Changes in sensitivity and number of alarms
Decrease the value of the **Fall Rate Limit** or the **Rise Rate Limit**	• The **higher** the sensitivity • You will receive **more** alarms than if you entered a higher value
Increase the value of the **Fall Rate Limit** or the **Rise Rate Limit**	• The **lower** the sensitivity • You will receive **fewer** alarms than if you entered a lower value

NOTE: The procedure below is only for making adjustments to the Rate of Change alarm. See Setting the Rate of Change alarms, on page 34 to set up the Rate of change alarms.

To change the Rate of change alarms:

1 From the HOME screen, open the EDIT SETTINGS screen.

Main > Sensor > Sensor Setup > Edit Settings

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

2 Select **Rate Alarms**, then press **ACT**. The SET FALL RATE LIMIT screen appears showing your current setting.

3 To change the Fall Rate setting, enter the new Fall Rate Limit you want.
   - Range: mg/dL/min from **1.1** to **5.0**
     mmol/L/min from **0.065** to **0.275**
   - Increments: mg/dL/min **0.1**
     mmol/L/min **0.005**

4 Press **ACT**. The SET RISE RATE LIMIT screen appears showing your current setting.

5 To change the Rise Rate setting, enter the new Rise Rate Limit you want. The range and increments are the same as the Fall Rate Limit (see *step 3* above).

6 Press **ACT**. The system will now use your new settings for the Rate of change alarms.

Checking the status of the system

The system allows you to check its status in the following areas:

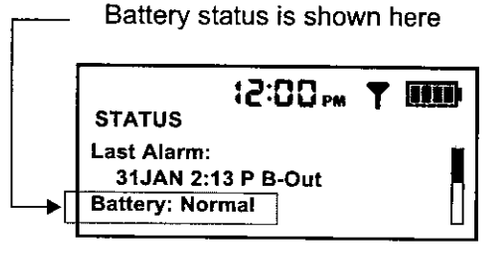
- Condition of the batteries and age of the sensor.
- Connection and communication between the sensor and transmitter, and the transmitter and monitor.
- When the next meter blood glucose measurement is needed to calibrate the system.

Checking the monitor battery status

The battery status shows you the level of energy remaining in the battery.

1 Make sure the HOME screen is showing. If it is not, press **ESC** until it appears.

2 Press the **ESC** button until the STATUS screen appears.



One of the following statuses is displayed:

Status	Description
Normal	The battery has enough energy to run the features of the system.
Low	The battery is running low on energy. Some features may not work properly. The battery should be replaced soon.
Off	The battery is out of energy. The system shuts down automatically. The battery should be replaced as soon as possible (see *page 15* for details).

Checking the sensor status

The sensor status tells you when your next calibration is due, how long the sensor has been used, and more.

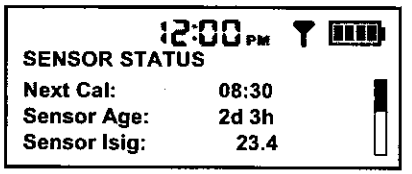
Before you begin

The sensor and transmitter must be connected, and the sensor must be turned on before you can check the sensor status.

To check the sensor status:

1 From the HOME screen, press **ESC** until the SENSOR STATUS screen appears.

The following statuses are displayed:



Status	Description
Next Cal	Indicates the time that your next calibration is due. See *Calibrating your system, on page 58* for instructions.
Sensor Age	The total number of days and hours the sensor has been used.
Sensor Isig	*NOTE: This information is not about the status of the sensor, it is about the signal of the sensor. It is only used by Medtronic's 24 Hour HelpLine for diagnostics purposes.*

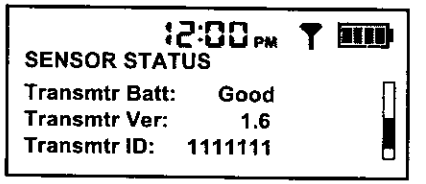
Checking the transmitter status

The transmitter status tells you whether the transmitter is connected to the sensor, and the status (condition) of the transmitter battery.

To check the transmitter status:

1 From the HOME screen, press ESC until the SENSOR STATUS screen appears.

2 Press  to view the transmitter status information, which is described below.



Status	Description	
Transmtr Batt	The status (condition) of the transmitter battery. The possible values are:	
	Good	The transmitter battery has adequate energy to run all features of the transmitter.
	Low	The transmitter battery is close to running out of energy. Some transmitter features may not work properly. The transmitter should be replaced within 24 hours.
	Bad	The transmitter battery is out of energy. The transmitter shuts down automatically, and no sensor data is sent to the monitor. The transmitter should be replaced as soon as possible.
Transmtr Ver	The version number of the transmitter.	
Transmtr ID	The serial number of the transmitter.	

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How to make glucose alarms silent

The Alarm Silence feature allows you to make glucose alarms silent, so that they will not beep or vibrate for a preset amount of time. An example of when you might use this feature would be while watching a movie in a theater.

NOTE: Information about any glucose alarms that occur during the time you have made them silent is not lost. The system still records the information about any glucose alarms that occur, including when they occurred, and the glucose measurement for each alarm.

You can choose from one of the following options when silencing alarms:

- **Off** – The monitor will beep or vibrate when any sensor glucose alarm occurs.
- **High BG** – The monitor will not beep or vibrate when the High Glucose Limit alarm occurs during the specified time.
- **Low BG** – The monitor will not beep or vibrate if the Low Glucose Limit alarm occurs during the specified time.
- **High and Low BG** – The monitor will not beep or vibrate if the High Glucose Limit or Low Glucose Limit alarm occurs during the specified time.
- **All** – The monitor will not beep or vibrate if **any** sensor glucose alarm occurs during the specified time, including the High and Low BG, Cal Reminder, and BG Now alarms.

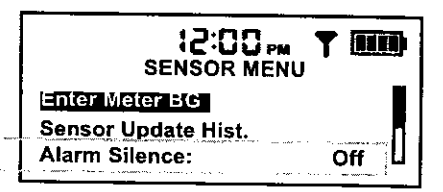
The amount of time that you can make glucose alarms silent is:

- Minimum 30 minutes
- Maximum 24 hours

To make alarms silent:

1 Open the SENSOR MENU.

Main Menu > Sensor



2 The SENSOR MENU appears, showing you the current status of the Alarm Silence feature. In this example, the feature is turned **Off**.

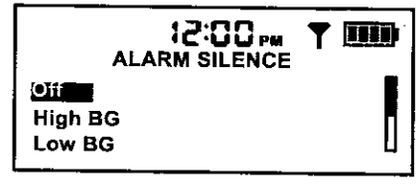
*NOTE: The **Alarm Silence** option **always** appears directly under the **Sensor Update Hist.** option.*

3 Depending on your current settings, one of the following **Alarm Silence** options will appear in the SENSOR MENU.

- Alarm Silence: Off
- Hi BG Alarm: Silent
- Lo BG Alarm: Silent
- Hi/Lo BG Alarm: Silent
- All Alarms: Silent

4 To change your current Alarm silence settings, select **Alarm Silence**, then press **ACT**.

The ALARM SILENCE screen appears with the alarm (or alarms) that are set to be silent already selected. In this example, **Off** is selected.



5 Select the alarm silence option you want, then press **ACT**. The SET DURATION screen appears showing one of the following:

- A set of dashes (if this is the first time you have used the Alarm Silence feature, or you just cleared your settings).
- The amount of time that you entered the last time you set an alarm to be silent.

6 Select your alarm silence time, then press **ACT**. The amount must be between 30 minutes (minimum) and 24 hours (maximum).

The SENSOR MENU appears showing the new alarm you selected to be silent.

7 Press the **ESC** button until the MAIN MENU appears.

Viewing the sensor update history

A sensor update is a meter blood glucose value that is entered into the system to calibrate the system.

Your system automatically records the meter blood glucose values you enter manually **and** the blood glucose values that are automatically sent from your Paradigm Link meter to the monitor. The last **28** sensor updates can be reviewed. The **date**, **time**, and **meter blood glucose measurement** is recorded for every meter blood glucose that was used to successfully calibrate the system. Note that it takes about 20 minutes from the time your meter blood glucose measurement is entered and accepted until it appears in the Sensor Update History screen.

To review the Sensor Update History:

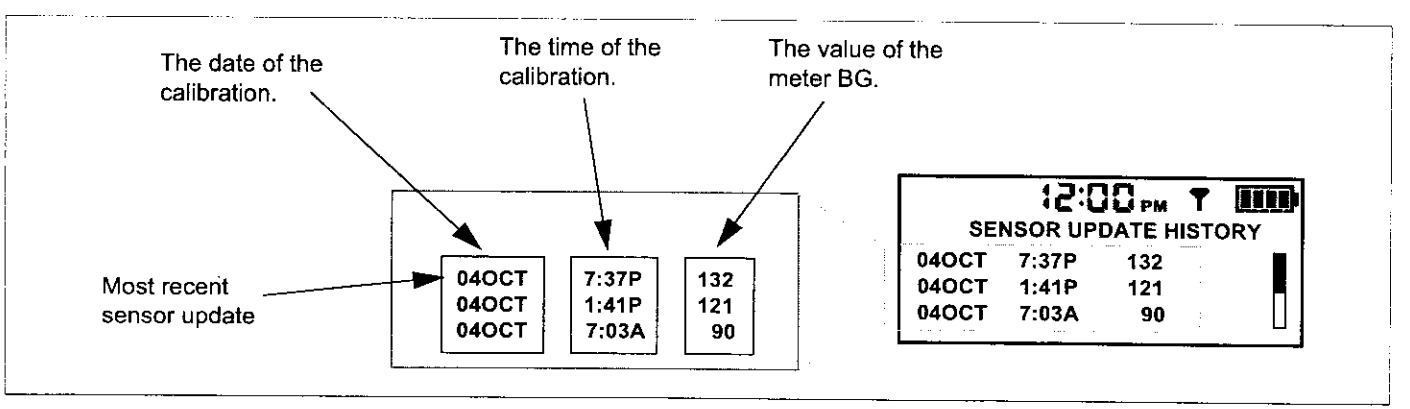
1 Open the SENSOR UPDATE HISTORY screen.

Main Menu > Sensor > Sensor Update History

The SENSOR UPDATE HISTORY screen appears showing the recent meter blood glucose measurements that were used to calibrate the system.

2 Use the △ or ▽ buttons to view the information on the screen. Your most recent sensor update is displayed at the top of the list. If a calibration was not successful, it will not display in the Sensor Update History screen.

NOTE: The date and time of the calibration occurs 15 minutes after the meter blood glucose measurement is entered.



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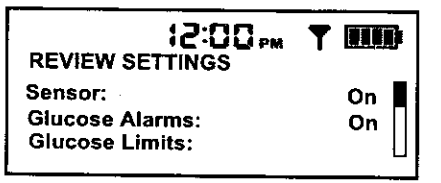
Viewing your current settings

You can review your current settings at any time, including your High and Low Glucose Alarm Limits, and the blood glucose units (BG Units). This is useful for making sure that you are using the correct settings, when performing troubleshooting activities, and for checking a setting prior to changing it.

1 From the HOME screen, open the REVIEW SETTINGS screen.

Main Menu > Sensor > Sensor Setup > Review Settings

The REVIEW SETTINGS screen appears.



2 Press the △ and ▽ buttons to scroll through all of your settings.

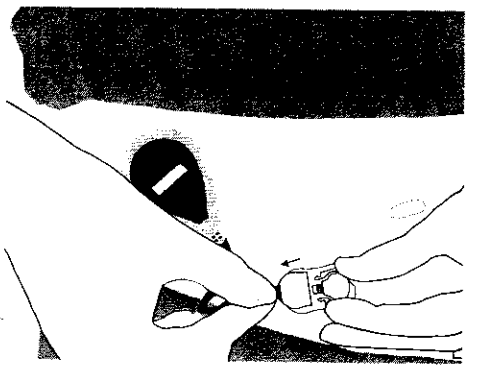
NOTE: If you did not switch on at least one of the following alarms, then the High Snooze setting will not appear: High Glucose, Rise Rate, or High Predictive alarms. Likewise, if you did not switch on one of the following alarms, then the Low Snooze will not appear: Low Glucose, Fall Rate, or Low Predictive alarms.

Removing the transmitter and sensor

This section shows you how to remove the transmitter and sensor.

Disconnecting the sensor from the transmitter

While pinching the sides of the sensor connector, gently pull the sensor connector away from the sensor assembly.



Removing the transmitter

Gently pull on the transmitter. Do not pull the sensor connector wire. You may use an adhesive remover, if desired.

NOTE: If you experience irritation or have a reaction to the transmitter tape (or other tapes), please contact the Medtronic 24 Hour HelpLine.

Removing the sensor

Peel up the outer tape from under the sensor. Then, gently pull the sensor from your body. When removed, place the sensor in a Sharps container.

Using your system in water

Your monitor 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. Tightly attach the occlusive dressing to the skin covering the sensor and the transmitter connector.
2. Remove your monitor before entering the water.
3. You can enter the water. Avoid submerging the sensor in hot water as this may significantly reduce its life or accuracy.
4. Once out of the water, put the monitor back on.
5. Check your transmitter tapes and replace these if waterlogged.

Troubleshooting and alarms

6

What's in this chapter:

About alarms

For the Guardian REAL-Time CGM System to continue to work well, all parts of the system need to function properly. The system also needs to be calibrated regularly so that your sensor glucose measurements are as close as possible to your meter blood glucose measurements.

The system is designed to let you know whenever something happens that could impact your diabetes management. The alarms the system uses can be separated into the following categories:

- Calibration
- Glucose status
- Part replacement
- Communication

NOTE: The STATUS screen shows the last alarm that you cleared. If there is a low battery, this condition will also display in the STATUS screen for as long as the battery is working or until you change the battery.

Why alarms are important

Alarms are important because they let you know that you need to take an action. Here are some examples of the different alarms that help you maintain your system:

- Reminder to enter a meter blood glucose measurement

  This helps you to keep your system calibrated so that the sensor glucose measurements are as accurate as possible.

- Alarm letting you know you need to replace your transmitter or sensor

  This helps you to continue using your system with as little interruption as possible.

- Alarm letting you know you need to replace a battery

  This helps give you time to replace your monitor battery with a new one so you can continue using your system without interruption.

- Alarm letting you know your sensor glucose measurement has reached or exceeded your Glucose Limits

  This helps let you know that you may need to take action to correct your blood glucose. You should take a meter blood glucose measurement to verify the sensor glucose reading, then respond appropriately to the meter blood glucose level based on instructions from your health care professional.

Your system notifies you if there is an unusual monitor status or your attention is required.

What to do when you get an alarm

When an alarm occurs, the monitor goes into Attention mode, and an alarm message appears on the screen. The monitor then defaults to the HOME screen.

Alarms gradually become higher in volume (louder and louder) until you clear them. 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 monitor will alarm with a siren and/or a vibration every minute until the alarm is cleared.

Follow these steps when you get an alarm:

To view the alarm:

1 From the HOME screen, review the alarm by pressing any button to see the alarm message.

2 **Read the entire alarm message,** pressing ▽ to scroll if the message is longer than your screen allows. The message includes instructions on how to fix the alarm condition.

3 Clear the alarm by pressing **ESC**, then press **ACT** after you read the alarm instructions. The HOME screen appears.

4 **Follow the instructions** in the alarm message to fix the alarm condition.

5 **Check your settings** (for example, time and date and Glucose Limits) to make sure they are correct.

821

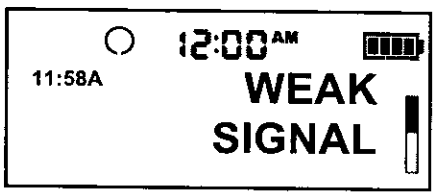
Sensor alarms

Listed below are the alarms that you may encounter while using the system, along with information on how to resolve the alarm condition.

Weak signal

Alerts you when the monitor does not receive data from the transmitter for a predefined period of time, as set in Missed Data.

Move the monitor closer to the transmitter or move the transmitter and the monitor to a new location on your body.



DOWN

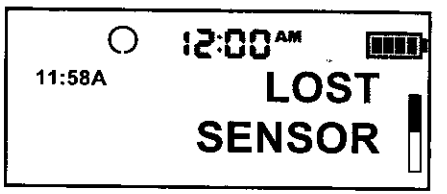
Move device closer to sensor
See user guide
ESC, ACT to clear

Lost sensor

The monitor has not received a signal from the transmitter for more than 40 minutes.

Make sure the transmitter and sensor are connected. **Do NOT disconnect.** To find your sensor use the **Find Lost Sensor** function:

MAIN MENU > Sensor > Sensor Start > Find Lost Sensor



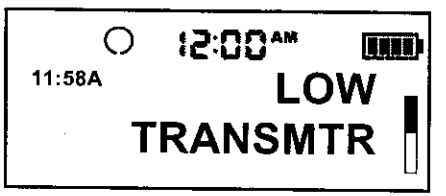
DOWN

Sensor values not available:
go to Find Lost Sensor
See user guide
ESC, ACT to clear

Low transmtr

Occurs when the transmitter battery is low. The transmitter will continue sending sensor signals until the battery becomes depleted.

Replace the transmitter as soon as possible. Call 800.MiniMed to order a new transmitter if your 6 month transmitter warranty has expired.

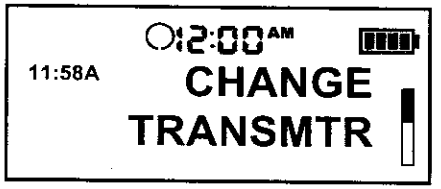


DOWN

Replace transmitter now
ESC, ACT to clear

Change transmtr

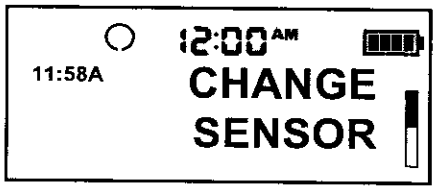
The transmitter battery is depleted. You need to change (replace) your transmitter. Call 800.MiniMed to order a new transmitter if your 6 month transmitter warranty has expired.



DOWN
ESC, ACT to clear

Change sensor

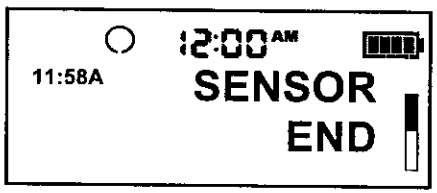
The transmitter has detected a sensor that needs to be changed (replaced). You must replace your sensor.



DOWN
See user guide
ESC, ACT to clear

Sensor end

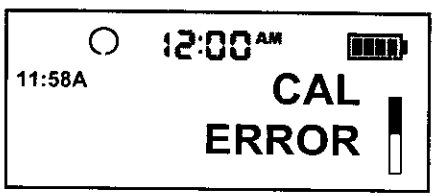
The sensor has reached the end of its life. Replace sensor. The sensor has a maximum life of 72 hours (3 days). The 72 hour life span of the sensor begins at the time of the first accepted calibration after initialization.



DOWN
Replace sensor
See user guide
ESC, ACT to clear

Cal error

An error occurred when entering a new meter blood glucose measurement to calibrate the system. Some possible causes for the error are:



DOWN
Invalid sensor data
or invalid BG value
See user guide
ESC, ACT to clear

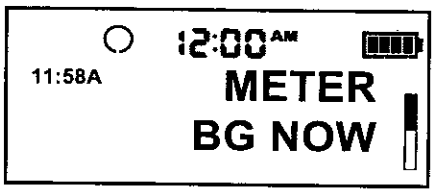
- An incorrect blood glucose value was entered from the meter into the monitor.
- You entered your blood glucose value too late after selecting the Meter BG option.

- 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.

If you receive a Cal Error, wait at least 10 to 15 minutes and try calibrating the system again with a new meter blood glucose measurement. If you receive the error again on your second calibration attempt, a Change Sensor alarm will occur. **If your glucose is changing rapidly, it is best to wait 30 to 60 minutes before calibrating the system again. Call the 24 Hour Helpline if you have questions.**

Meter BG now

A meter blood glucose measurement is needed right away to calibrate the system so that you can continue receiving sensor glucose measurements.

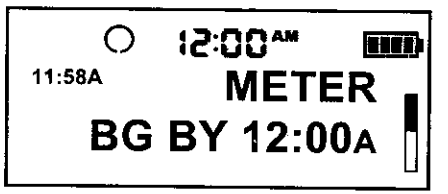


DOWN

Sensor values not available:
enter a new BG now
ESC, ACT to clear

Meter BG by

A meter blood glucose measurement entry is required by the time that is shown to calibrate the system. The Meter BG by alarm is also known as the Cal Reminder Alarm.

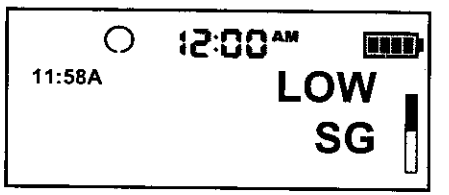


DOWN

This is a reminder to enter meter BG soon
ESC, ACT to clear

Low glucose

The sensor glucose value is equal to or lower than your Low Glucose Limit. If you do not set a Low Glucose Limit and set the Glucose Alarms ON, then you will not get a Low sensor glucose alarm.

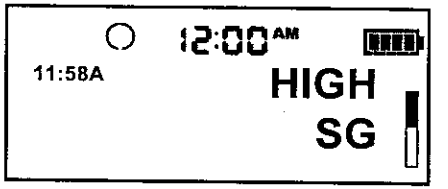


DOWN

Glucose is lower than or equal to user specified limit
ESC, ACT to clear

High glucose

The glucose value is higher than or equal to the high glucose limit set. If you do not set a High Glucose Limit and set the Glucose Alarms ON, then you will not get a High sensor glucose alarm.

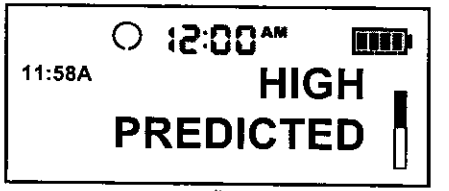


DOWN

Glucose is higher than or equal to user specified limit
ESC, ACT to clear

High Predictive

The sensor glucose measurements will **reach or go above** your High Glucose Limit in a certain amount of time. The amount of time is the time you selected for the High Predictive alarm. See *Setting the Predictive glucose alarm, on page 32* for details.

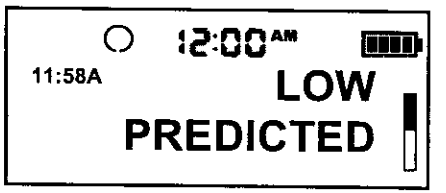


DOWN

Glucose may be higher or equal to user specified limit at specified time.
ESC, ACT to clear

Low Predictive

The sensor glucose measurements will **reach or go below** your Low Glucose Limit in a certain amount of time. The amount of time is the time you selected for the Low Predictive alarm. See *Setting the Predictive glucose alarm, on page 32* for details.

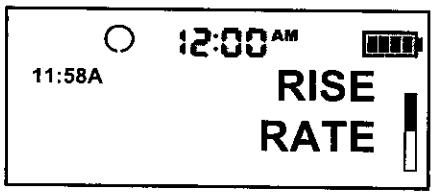


DOWN

Glucose may be lower or equal to user specified limit at specified time.
ESC, ACT to clear

Rise Rate

The sensor glucose measurements are rising at a rate that is equal to or faster than the Set Rise Rate Limit you selected for the alarm. See *Setting the Rate of Change alarms, on page 34* for details.

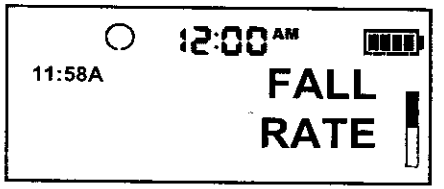


DOWN

Glucose rising rate of change is equal or higher than specified rate.
ESC, ACT to clear

Fall Rate

The sensor glucose measurements are falling at a rate that is equal to or faster than the Set Rise Rate Limit you selected for the alarm. See *Setting the Rate of Change alarms, on page 34* for details.

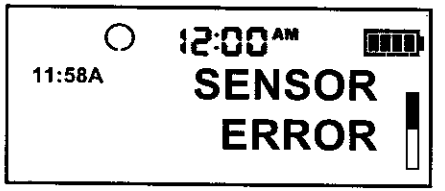


DOWN

Glucose falling rate of change is equal or higher than specified rate.
ESC, ACT to clear

Sensor error

The sensor data is invalid. Clear the alarm. You do not need to change the Sensor yet. If the alarm repeats, you should check that the sensor is inserted properly, and that the sensor and transmitter are connected correctly. If the alarm still persists, you will need to replace the sensor.



DOWN

Sensor failed Selftest
See user guide
ESC, ACT to clear

Viewing sensor alarm history

Your system lets you easily view all of the sensor alarms that have recently occurred using the SENSOR ALARM HISTORY screen. The type of sensor alarm history information includes the date and time the alarm occurred, the type of alarm, and the sensor glucose measurement that was taken when the alarm occurred.

The SENSOR ALARM HISTORY screen lists all of the sensor alarms that have occurred, up to a maximum of 36 alarms.

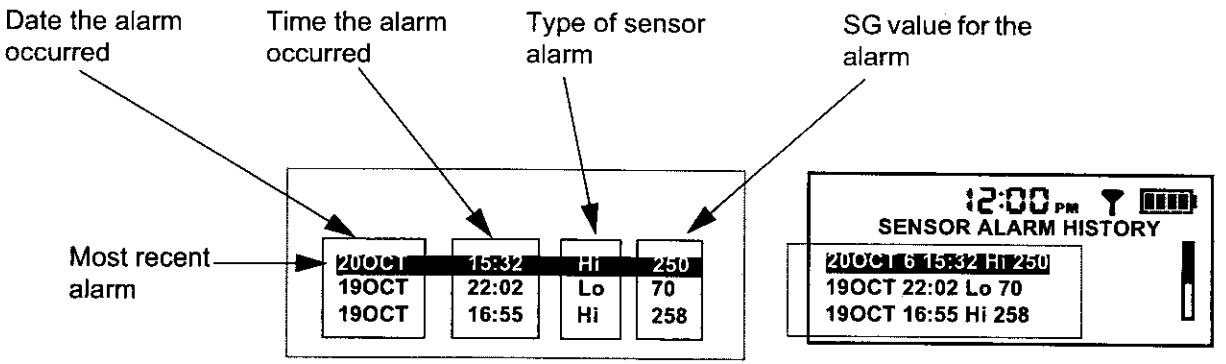
To view the sensor alarm history:

1 Open the SENSOR MENU.

MAIN MENU > Sensor

The SENSOR MENU appears.

2 Select **Sensor Alarm History**, then press **ACT**. The SENSOR ALARM HISTORY screen appears showing recent sensor alarms. The most recent (last) sensor alarm is selected and appears at the top of the list.



Troubleshooting

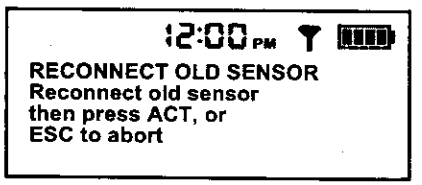
Reconnect old sensor

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

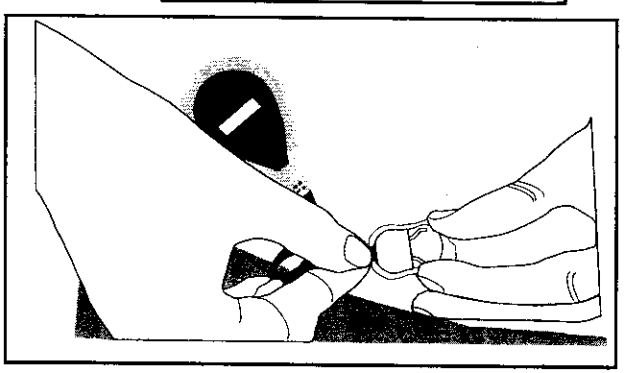
1 Open the RECONNECT OLD SENSOR screen.

MAIN MENU > Sensor > Sensor Start > Reconnect Old Sensor

The RECONNECT OLD SENSOR screen appears.



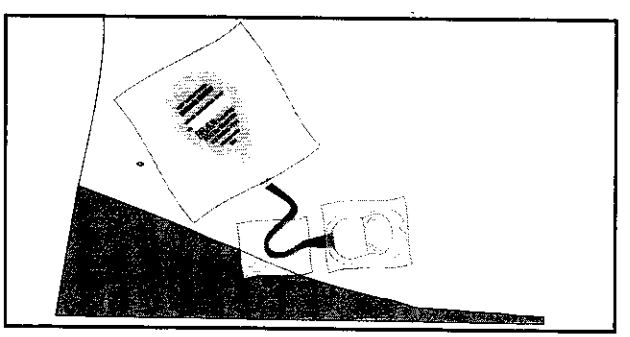
2 Hold the sensor base while connecting the cable. Do not squeeze clips. You should hear a click when the cable and sensor connect. You will also hear a short beep from the transmitter.



3 A prepping agent, such as an I.V. prep can be used to strengthen the adhesion before applying sterile dressing. Make sure the smooth side is down. The cable can be looped under the tape (see the picture) to make sure the cable does not pull on the sensor. Apply a sterile, transparent tape over the site.

4 From the RECONNECT OLD SENSOR screen, press **ACT**. The SENSOR READY 2 HOURS screen appears.

5 Press any key (button). The sensor is reconnected.



Find lost sensor

You can use this feature if you receive a LOST SENSOR alarm, or if the communication between the transmitter and the monitor is lost.

1 From the HOME screen, open the SENSOR START MENU.

MAIN MENU > Sensor > Sensor Start

The SENSOR START MENU appears with **New Sensor** selected.

2 Select **Find Lost Sensor.**

3 Press **ACT**. A message appears to let you know that your sensor will be ready in 15 minutes.

What happens if I leave the monitor battery out too long?

If you leave the battery out too long (more than 10 minutes) you may receive a BATT OUT LIMIT alarm message when you install the new battery. Do the following steps:

1 Set your monitor clock to the correct time, date, and year. See *Setting the time and date, on page 22* for details.

2 Make sure that all your settings are correct. If need be, reapply your last saved settings to the monitor by using the Restore Settings option under User Settings in the UTILITIES MENU as described in *Chapter 7, Utilities* (you can only use this option if you have previously saved your monitor settings).

3 Check the ALARM HISTORY screen and the STATUS screen for any alarms and/or alerts that may still need attention.

4 Perform the previous procedure, *Find lost sensor*.

Why doesn't my monitor battery last very long?

- A short battery life does not necessarily mean something is wrong with your monitor.
- Battery life in your monitor varies, based on the conditions below.
  - The brand of battery you use (we recommend Energizer).
  - The way the battery was stored and/or handled before use (avoid high or low temperatures).
  - How you use your monitor. For example: how often the buttons are pushed, the number of alarms that occur, and if you keep your graphs on continuous display.
  - Use of some features. The backlight, vibrate, and meter options decrease battery life.

What is a CHECK SETTINGS alarm?

This alarm is a reminder for you to make sure that all your settings are correct. A CHECK SETTINGS alarm occurs after:

- The user settings were cleared automatically by the system (set back to their defaults) because there was an E-error alarm.
- You cleared your settings manually using the Clear Settings feature.

My screen appears distorted

- The screen may appear distorted or have a "rainbow" appearance if you are wearing polarized sunglasses, are in bright sunlight, or in extreme high or low temperatures. If your screen appears distorted:
  - Take off your sunglasses.
  - Move into the shade.
  - Make sure your monitor is not in direct heat (i.e., next to a heater) or cold (worn on the outside of your clothing on a very cold day).

NOTE: Do not return the monitor: this is a normal property of this type of screen on any device.

I dropped my monitor

Take care to protect your monitor from being dropped.

1. Check that all connections are still tightly in place.
2. Check the LCD, keypad and monitor case for cracks or damage.
3. Review the **STATUS** screen and your monitor settings.
4. Run the Selftest to make sure the system is working properly.
5. Call the 24 Hour HelpLine for assistance.

I submerged my monitor in water

Your monitor is designed to resist accidental contact with water. Do not submerge the monitor in water during bathing, swimming, or other water activities.

1 Pat the outside of the case until dry.
2 Do not use hot air to dry your monitor. This may damage your monitor's internal electronics.
3 Check the battery compartment and the battery. If either of them are wet, let them dry completely before using the monitor.
4 Run the Selftest to make sure the system is working properly.

I cannot get to the User Settings screen

If you do not hold down **SHIFT** and press **ACT** when you have User Settings highlighted, you will see the following screen:

This feature is not normally accessible. To access, consult your User Guide.

To access the User Settings screen, do the following:

1 Go to the UTILITIES MENU.

Main Menu > Utilities

2 Select **User Settings**. Then, hold down **SHIFT** and press **ACT**.
3 See *User settings, on page 113* for information about the menu options.

My monitor won't display my Paradigm Link meter blood glucose measurement

1 Check that the following conditions are true:
- You are using the Paradigm Link blood glucose meter. Your system monitor will only communicate with the Paradigm Link meter.
- Your meter is on (set to "snd") and working correctly.
- The meter option in your monitor is set to "on" and you have set the meter ID number correctly on the monitor.
- Your monitor does not have a low battery alert condition.
- The meter is within 4 feet (1.2 meters) of the monitor without anything in between such as another person, a wall, etc.

- There is no RF (radio frequency) interference from other electronic devices that could prevent communication. These devices can include some cell phones, cordless phones, televisions, computers, radios, other Paradigm® monitors, meters, and remote controls. To restore communication, move away from these other types of devices, or turn them off.
- That your monitor will not show another measurement. Check that the monitor is idle and the HOME screen is blank.

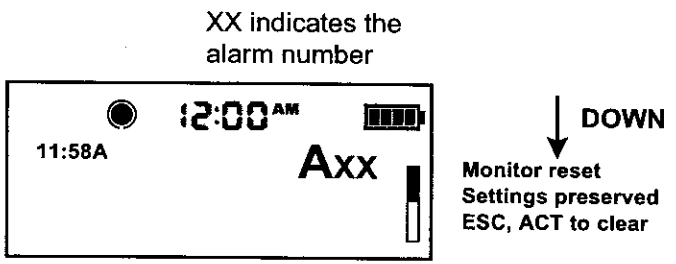
2 If your monitor still does not receive your blood glucose measurement from the Paradigm Link meter, use the △ or ▽ buttons to manually enter your blood glucose (in the ENTER BG screen).

System alarms

Alarms put the monitor in "Attention" mode.

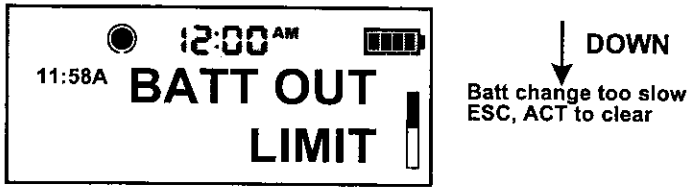
A (Alarm)

This alarm shows an "A" followed by two numbers. A-alarms cause the monitor to be reset. If this alarm repeats often, call the 24 Hour HelpLine for assistance.



Batt out limit

This alarms occurs if the battery is removed from the monitor and more than ten (10) minutes passes before a battery is inserted. This alarm can happen when you remove and reinsert a monitor battery.



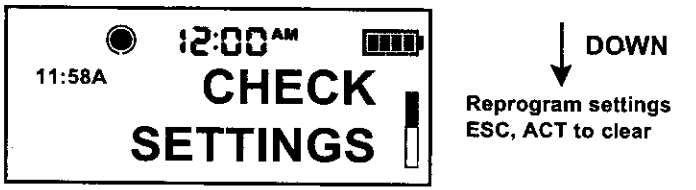
You must go to the UTILITIES menu and reset the date and time (see *page 22*). Then, **Find Lost Sensor** to re-establish communication from the sensor, as described on *page 95*.

Button error

Occurs if a button has been continually pressed for more than 3 minutes.

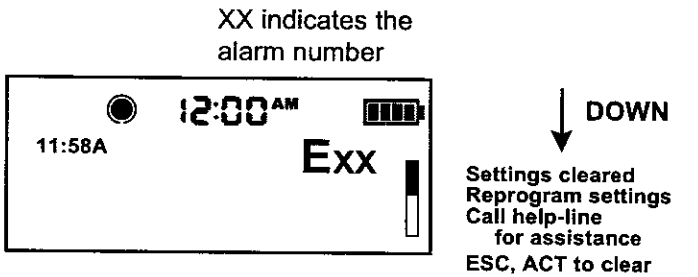
Check settings

When this alarm is active, you should check and or reprogram your settings as need (including the time and date).



E (Error)

After receiving this alarm, note the error number then call the 24 Hour HelpLine for assistance. An error alarm will show an "E" followed by two numbers. E-alarms cause the monitor to be reset and all your monitor settings are cleared. You must reset your monitor settings after an E-alarm occurs. You must also turn on the sensor.



and do a Find Lost Sensor to reestablish communication.

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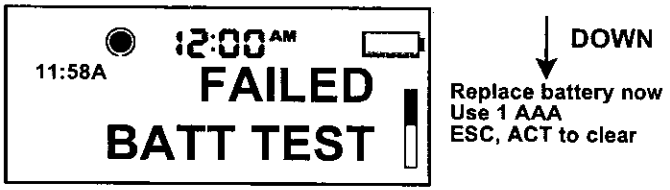
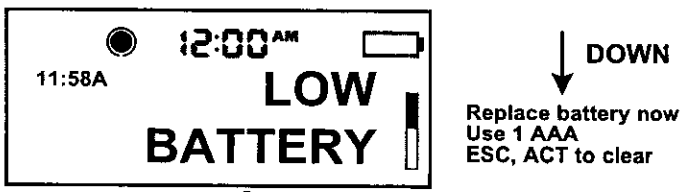
Failed batt test

The monitor tests the voltage of each battery installed. This test ensures a battery with low voltage is not used. If the battery does not have enough voltage, this alarm will occur. The monitor will not function and the battery must be replaced. Always make sure that you install a NEW battery into the monitor.



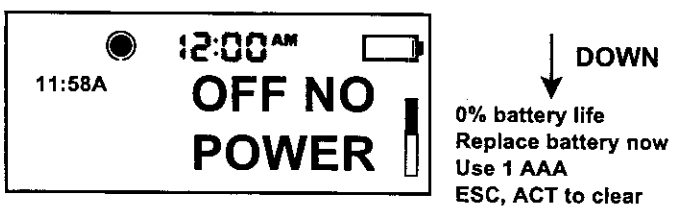
Low battery

If you get this alarm, DO NOT go to sleep without replacing the battery. The backlight and the Paradigm Link meter functions are disabled during a LOW BATTERY condition. If the alert type is set to "vibrate," the monitor will change to the audio alert "beep-medium." Clear (**ESC**, **ACT**) this alarm before you replace your battery.



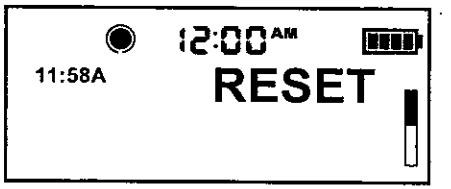
Off no power

The battery is dead. Replace battery immediately. Follow the directions on the screen. Check to make sure that the time is correct on the screen. Reset the time if necessary.



Reset

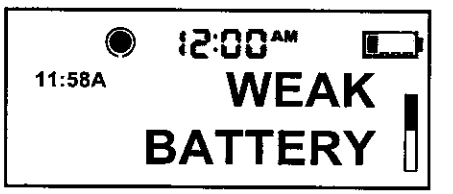
The Reset alarm triggers when monitor settings are cleared because of one of these reasons:



- Your settings were cleared using the Clear Settings feature, and the settings have not been reprogrammed.
- A download attempt from the PC is incomplete. (The download function is applicable to the optional Medtronic CareLink® Therapy Management software. Refer to the software's user guide for more information.)

Weak Battery

The monitor tests the voltage of each battery installed. If the battery voltage is less than full strength, this alarm may occur. The monitor will operate normally, but the battery life will be shorter than expected.



Always make sure to install a NEW battery in the monitor.

Utilities

7

What's in this chapter:

Viewing your system alarm history

The system allows you to view information on previous system alarms you have received, including the name of the alarm, and the date and time it occurred. This is done using the ALARM HISTORY screen. You can view up to 36 of your most recent alarms.

1 Open the ALARM HISTORY screen.

MAIN MENU > Utilities > Alarm > Alarm History

2 Press  to view previous alarms.

3 To view further information about an alarm, select the alarm and press **ACT**. The details for that alarm appear on the screen.

4 Press **ESC** to return to the ALARM HISTORY screen.

5 You can continue viewing alarms repeating *step 2* through *step 4* above, or return to the HOME screen by pressing **ESC** until it appears.

The data management feature

The system keeps a daily record of the following types of information for up to 31 days:

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

Both the sensor glucose information and meter blood glucose information includes daily totals and averages, as described in the following sections.

Sensor glucose information

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

Item	Description
SG Average	The **average** sensor glucose measurement.
Above Hi Limit	The percentage of the sensor glucose measurements that were **above** your High Glucose Limit.
Within Limits	The percentage of the sensor glucose measurements that were **between** your Low Glucose Limit and your High Glucose Limit.
Below Low Limit	The percentage of the sensor glucose measurements that were **below** your Low Glucose Limit.
SG Std. Dev.	The standard deviation of the sensor glucose measurements.
AUC Hi/Lo.	The High AUC Limit and Low AUC Limit. These values are shown in mg/dL or mmol/L, depending on your BG Unit setting.
#Hi/Lo Alarm	The **total number** of Glucose Alarms. The number to the **left** is the total number of High Glucose alarms. The number to the **right** is the total number of Low Glucose alarms.

Meter blood glucose information

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

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

To view data for a single day:

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

1 Open the DAILY TOTALS screen.

MAIN MENU > Utilities > Daily Totals

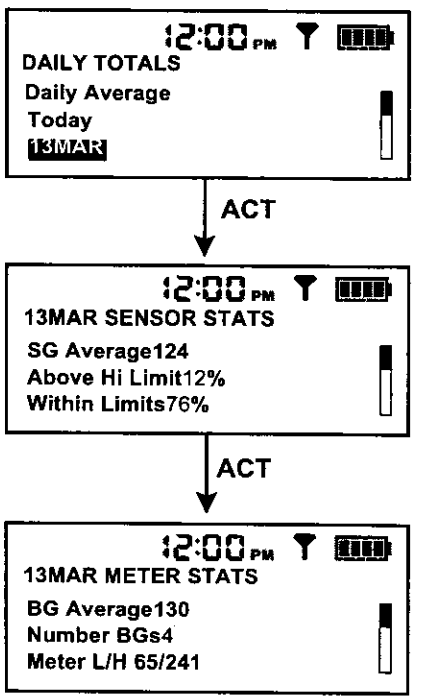
2 Select the day you want to view.
- To view totals for today, select **Today**.
- To view totals for a previous day, select the date. In the example shown here, the date selected is **March 13.**

3 Press **ACT**. The SENSOR STATS screen appears showing the sensor glucose information for the day you selected (the day you selected is shown on the screen).

4 Press  to view more information.

See *page 104* for descriptions of the sensor glucose information.

5 To view meter blood glucose measurement information for the same day you have selected in *step 2*, press **ACT** from the SENSOR STATS screen. The METER STATS screen appears showing the meter blood glucose information for the day you selected (the day you selected is shown on the screen).



NOTE: The ACT button allows you to toggle between the SENSOR STATS and METER STATS screens. Pressing ESC from the METER STATUS screen will take you to the SENSOR STATUS screen.

6 Press  to view all of the information in the SENSOR STATS or METER STATS screen.

See *page 105* for descriptions of the sensor glucose information.

7 Continue viewing daily totals by following the previous steps, or return to the HOME screen by pressing **ESC** until it appears.

To view data over a number of days:

This procedure shows you how to view sensor glucose data and meter blood glucose data for a specified number of days.

1 Open the DAILY TOTALS screen.

MAIN MENU > Utilities > Daily Totals

The DAILY TOTALS screen appears with **Daily Average** selected.

2 Press **ACT**. The DAYS TO AVERAGE screen appears. The number of days you chose the last time you used this feature is flashing.

3 Select the number of days you want to average. For example, if you want to see the averages for the last 10 days, select 10.

4 Press **ACT**. A message appears telling you the system is calculating the averages.

Then the SENSOR STATS screen appears showing the sensor glucose information for the number of days you selected. The number of days is shown on the screen.

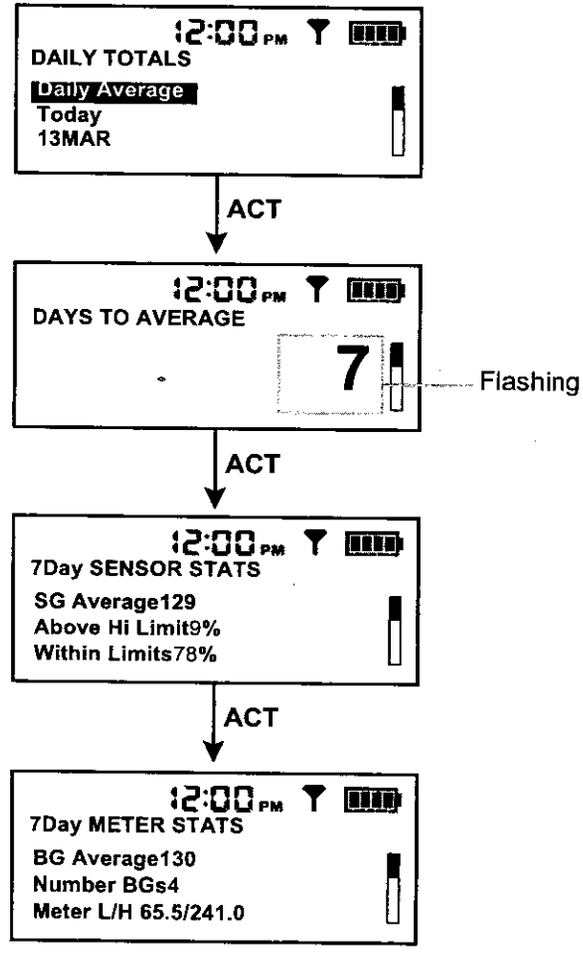
5 Press to view more information.

See *page 104* for descriptions of the sensor glucose information.

6 To view meter blood glucose measurement information for the same days you selected in *step 3*, press **ACT**. The METER STATS screen appears showing the meter blood glucose information.

7 Press to view more information.

See *page 105* for descriptions of the meter blood glucose information.



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The Alarm Clock feature

This feature enables you to set up daily Alarm Clock reminders to help you remember to check your blood glucose, eat, calibrate the system, or any other activity you use to manage your diabetes therapy. This feature is turned off by default.

When you set up an Alarm Clock reminder, you enter the time you want the system to send you the reminder. When the Alarm Clock reminder occurs, the monitor beeps or vibrates just like an alarm, and ALARM CLOCK appears on the screen. After the reminder occurs, press **ESC** then **ACT** to clear it.

Each Alarm Clock reminder you set up occurs at the same time every day. The system allows you to set up a total of 8 daily reminders. When the alarm clock reminder occurs, the message "ALARM CLOCK" appears on the screen.

To set up daily Alarm Clock reminders:

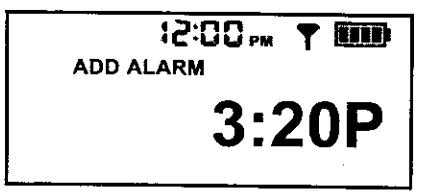
1 Open the ALARM OPTION screen.

MAIN MENU > Utilities > Alarm Clock

2 Select **On/Set**, then press **ACT**. The ALARM CLOCK screen appears.

3 Select **Add Alarm**, then press **ACT**. The ADD ALARM screen appears showing a default time of 12:00 A.M.

4 Enter the time you want for the reminder. You will receive an ALARM CLOCK reminder at the time you enter. In this example, the time entered was 3:20 P.M.



NOTE: If you are using the 12 hour time setting, check the ADD ALARM screen to make sure that the A.M. or P.M. setting is what you want (A is A.M., and P is P.M.).

5 Press **ACT**. The reminder is set.

6 Repeat these steps to set up additional Alarm Clock reminders.

7 Press **ESC** until the HOME screen appears.

Reviewing your current Alarm Clock reminders

This procedure shows you how to view all of your current Alarm Clock reminders.

1 Open the ALARM OPTION screen.

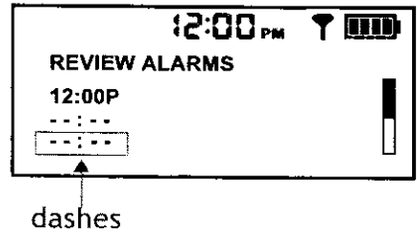
MAIN MENU > Utilities > Alarm Clock

The ALARM OPTION screen appears.

2 Select **On/Set**, then press **ACT**. The ALARM CLOCK screen appears.

3 Select **Review Alarms**, then press **ACT**. The REVIEW ALARMS screen appears showing all of your current Alarm Clock reminders.

NOTE: The dashes shown in this example indicate that there are available 'slots' to set up additional reminders. The maximum number of reminders you can set up is 8.



4 Press **ESC** until the HOME screen appears.

Deleting Alarm Clock reminders

This procedure shows you how to delete Alarm Clock reminders.

1 Open the ALARM OPTION screen.

MAIN MENU > Utilities > Alarm Clock

The ALARM OPTION screen appears.

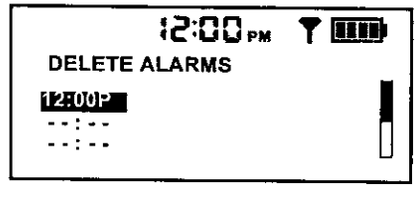
2 Select **On/Set**, then press **ACT**. The ALARM CLOCK screen appears.

3 Select **Delete Alarms**, then press **ACT**. The DELETE ALARMS screen appears with the first Alarm Clock reminder selected (highlighted).

4 Select the reminder you want to delete, and press **ACT**. The reminder is deleted.

5 Repeat these steps to delete additional Alarm Clock reminders.

6 Press **ESC** until the HOME screen appears.



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The Block feature

This feature enables you to prevent (block) others from entering or changing any of your settings. This is an important safety feature if you need someone else to maintain complete control of monitor operation. When this feature is turned on, anyone else with access to your monitor cannot enter or change any of your settings. The only features that can be used are the ones that you use to view information. Discuss what uses and settings are best for you with your healthcare professional.

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

To turn the Block feature on:

1 Open the BLOCK OPTION screen.

MAIN MENU > Utilities > Block

2 Select **On** and press **ACT**. The Block feature is now turned **on**. The HOME screen will appear with an open circle to indicate you have a special feature turned on.

To turn the Block feature off:

1 Open the BLOCK OPTION screen.

MAIN MENU > Utilities > Block

2 Select **Off** and press **ACT**. The Block feature is now turned **off**. The HOME screen will appear (without the open circle).

The Lock keypad feature

Lock keypad prevents accidental keypad presses. When the keypad is locked, you can still press **ESC** to view the STATUS screen, the SENSOR STATUS screen, and the sensor graphs.

A locked keypad is automatically unlocked during the following:

- Battery insertion
- Alarms

To lock the keypad:

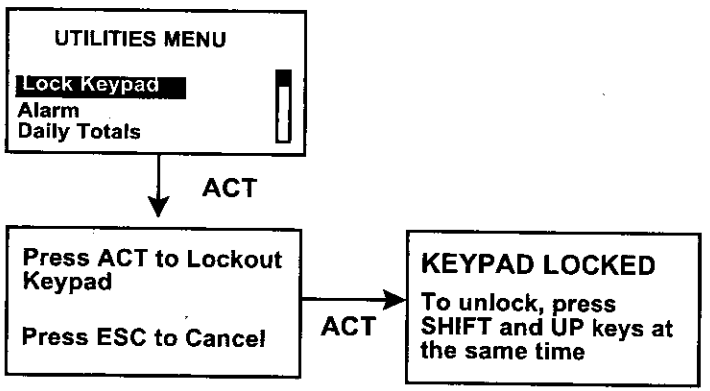
1 Open the LOCK KEYPAD screen

MAIN MENU > Utilities > Lock Keypad

2 Select **Utilities**, then press **ACT**.

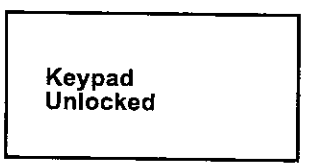
3 Select **Lock Keypad**, then press **ACT**.

4 Press **ACT** to lock the keypad.



To unlock the keypad:

Hold down **SHIFT** and press the △ button. A message appears that the keypad is now unlocked.



Running the Selftest

Selftest is a safety utility that allows you to check if your monitor is operating properly. During selftest, your monitor will automatically run internal tests, including a check for proper operation of the beep and vibrate modes. The selftest is additional to the routine tests that run independently while the monitor operates.

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

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

1 Open the UTILITIES MENU.

MAIN MENU > Utilities

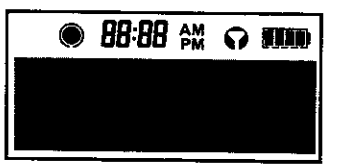
2 Select **Selftest.**

3 Press **ACT**. The system automatically runs the selftest.

NOTE: As the test runs, the monitor will beep and vibrate and different screens will appear.

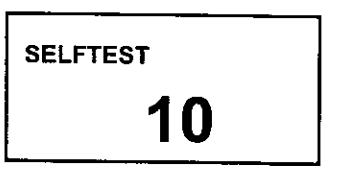
a. Screen Test:

The screen will appear all black as shown here.



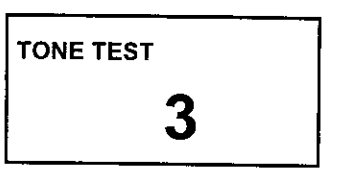
b. Selftest:

The monitor will count down from 10.



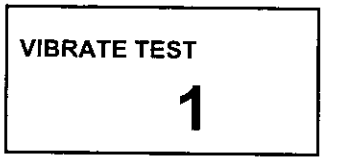
c. Tone Test:

You should hear beeps.

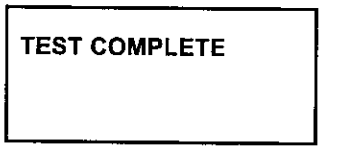


d. Vibrate Test:

You will feel vibrations.



4 After the selftest is finished, TEST COMPLETE will appear on the screen. The screen will return to the UTILITIES MENU, then to the HOME screen.



User settings

The user settings feature allows you to save your current settings, restore previously saved settings, and clear your current settings. You can also check the history of your use of the feature. This history information includes the date and time that you used the feature, and whether you saved, restored, or cleared the settings.

The Save Settings feature lets you save a set of system settings. Once the settings are saved, you can restore them at a later time as needed. When you restore a set of settings, you make those settings the active, current settings. Using the Save Settings and Restore Settings features enables you to easily change your current settings as needed without having to re-enter them.

When you clear your system settings, all your current settings are reset to the default settings (the settings that came with your system). Once you clear your current settings, you must do one of the following before you can begin using your system:

- Restore previously saved settings using the Restore Settings feature
- Enter your settings into the monitor manually

Save settings

Use this procedure to save you current settings.

1 Open the UTILITIES MENU.

MAIN MENU > Utilities

2 Select **User Settings**. Then, hold down **SHIFT** and press **ACT**. The USER SETTINGS screen is displayed with **Save Settings** selected.

3 Press **ACT**. If you have saved your settings before, a message appears showing the last time you saved your settings, and asking you if you want to write over them.

4 Read the instructions on the screen, then do one of the following:

- Press **ACT** to save your current settings. The SETTINGS SAVED message displays to confirm that your current monitor settings have been saved.
- Press **ESC** if you do not want to save your current settings.

5 To return to the HOME screen, press **ESC** until it appears.

Restoring your settings

This procedure shows you how to restore the most recent monitor settings you saved. You must have saved your monitor settings in order to restore them.

1 Open the UTILITIES MENU.

MAIN MENU > Utilities

2 Select **User Settings**. Then, hold down **SHIFT** and press **ACT**. The USER SETTINGS screen appears.

3 Select **Restore Settings**, then press **ACT**. A message appears showing you your options.

4 Do one of the following:

- To restore your settings you saved on the date shown, press **ACT**. The SETTINGS RESTORED message appears, confirming that your settings have been restored.
- If you do not want to restore the settings, press **ESC**.

5 Press **ESC** until the HOME screen appears.

6 Check your monitor settings to make sure that your settings were restored correctly. See *Viewing your current settings, on page 83* for the steps to use to check your settings.

Clear settings

Take the following steps only if you want to clear your current monitor settings, and restore the factory default settings.

CAUTION: Do not clear your monitor settings unless directed by your healthcare professional or by a Medtronic representative. If you clear your monitor settings, you will have to re-enter them manually or restore a previous saved version of your settings.

To clear your monitor settings:

1 Open the UTILITIES MENU.

MAIN MENU > Utilities

2 Select **User Settings**. Then, hold down **SHIFT** and press **ACT**. The USER SETTINGS screen appears.

3 Select **Clear Settings**, then press **ACT**. The CONFIRM message displays asking you to confirm that you want to clear your current settings.

4 Do one of the following:

- If you do not want to clear your current settings, press **ESC**.
- To clear your current settings, select **Yes**, then press **ACT**.

NOTE: At this point the RESET alarm automatically occurs to make sure you reset your system.

5 Press  to view the RESET alarm message.

6 Clear the RESET alarm by pressing **ESC**, then press **ACT**.

Various screens will appear (this happens automatically when you clear a RESET alarm). Then, the TIME/DATE SETUP screen appears.

7 Reset the time and date. You cannot begin using the system again until you reset the time and date. See *Setting the time and date, on page 22* for details.

8 Once you reset the time and date, you must enter settings before you can begin using the system. You have two options:

- You can manually re-enter settings (just like you did when you set up the system the first time). See *Chapter 3, Entering your settings* for details.
- You can restore the last settings you saved. See *Restoring your settings, on page 114*.

9 Do do one of the following:

- If you are using a new sensor, you must turn on and start the sensor. See *Turning on the sensor, on page 25* and *Starting the sensor, on page 53*.
- If you are using the same sensor, you must do a **Find Lost Sensor** to reestablish communication. See *Find lost sensor, on page 95*.

Viewing your User Settings history

This feature allows you to view your most recent User Settings operations. There are three User Settings operations:

- **Save** – When you save your current settings.
- **Restore** – When you restore previously saved settings.
- **Clear** – When you clear your current settings.

The system can store up to 20 User Settings operations for you to review.

To view the User Settings history:

1 Open the UTILITIES MENU.

MAIN MENU > Utilities

2 Select **User Settings**. Then, hold down **SHIFT** and press **ACT**. The USER SETTINGS screen appears.

3 Select **History**, then press **ACT**. The SETTINGS HISTORY screen appears. The screen shows a list of your most recent User Settings operations, including the type of User Setting operation you performed, and the date and time it occurred.

4 To view more history information, press ▽.

5 To return to the HOME screen, press **ESC** until it appears.

Language setting

You can select the language you want used for all the monitor screens and menus and the system information. When you select a language, all of the information (text) on the monitor screens and menus will appear in the language you select. The information that is recorded by the system (for example, alarms, sensor updates, meter blood glucose measurements, and sensor glucose measurements), will also be in the language you select.

NOTE: Some languages will not be available on all monitors.

To change the language setting:

1 Open the LANGUAGE MENU.

MAIN MENU > Utilities > Language

2 Select the language you want to use.

3 Press **ACT**. The language setting is changed.

4 To return to the HOME screen, press **ESC** until it appears.

System maintenance

8

What's in this chapter:

NOTE: As part of your normal system maintenance, you need to replace the monitor battery with a new battery. See Installing the battery, on page 12 for all of the steps to follow to replace the monitor battery, including what to do if you receive an alarm after you insert the new battery.

Storing the system

This section shows you how to store the monitor, transmitter, sensor, and Sen-Serter.

Storing the monitor

If you need to remove and store your monitor for short periods of time, do not remove the battery. For longer-term storage, removing the battery is recommended.

NOTE: To preserve battery life, make sure you turn off the RF options (meter).

Storing the transmitter

If you need to remove your transmitter, make sure to disconnect it from the test plug. This will help avoid draining energy from the transmitter battery.

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Storing the sensor

Make sure you store your sensors in a refrigerator (or another refrigerated location) within the following temperature range:

- Low + 36° Fahrenheit (2° Celsius)
- High + 50° Fahrenheit (10° Celsius)

CAUTION: Do not freeze your sensors. If you accidentally freeze a sensor, do not use it. Once a sensor is frozen, it can not be used. Be sure to dispose of any frozen sensors.

Any sensors that you remove from refrigeration must be kept at or below + 75° Fahrenheit (24° Celsius), and must be used **within one week (7 days) after being removed from refrigeration** to make sure the sensor works correctly.

Storing the Sen-serter

Store the Sen-serter in the released position. This will make sure that it lasts as long as possible and works properly.

Cleaning the system

This section shows you how to clean the different parts of your system.

Be sure you read the "CAUTION" section below for important information about cleaning your system. This information will help you avoid accidentally damaging the your system.

CAUTION:

- **Only use a damp cloth and mild liquid soap to clean your system.**
- **Never use organic solvents such as lighter fluid, nail polish remover, or paint thinner to clean your system.**
- **Never use lubricants of any kind to clean your system.**

Before you begin

Make sure you have the following items before you begin cleaning your monitor:

- Clean cloths
- Clean water
- Mixture of clean water and mild liquid soap
- 70 percent alcohol wipes
- An antibacterial hand sanitizer

Cleaning the monitor

This procedure shows you how to clean your monitor.

CAUTION:

- **Never place your monitor directly in water.**
- **Keep the battery compartment dry and away from moisture.**
- **Never try to clean the inside of your monitor.**

To clean the monitor:

1 Wash your hands thoroughly.
2 Dampen a clean cloth with mild liquid soap and warm water, and wipe the outside of the monitor.
3 Dampen a clean cloth with clean water.
4 Rinse your monitor by wiping it with the dampened part of the cloth.
5 Dry your monitor by wiping it with the dry part of the cloth.
6 Disinfect your monitor by wiping it with 70 percent alcohol wipes.
7 Place the monitor on a clean dry cloth and allow to air dry for 2 to 3 minutes.

Cleaning the transmitter

This section contains the steps you use to clean your transmitter.

CAUTION: Make sure water does not get on the inside of the connector when cleaning your transmitter (see the drawing below).

To clean the transmitter:

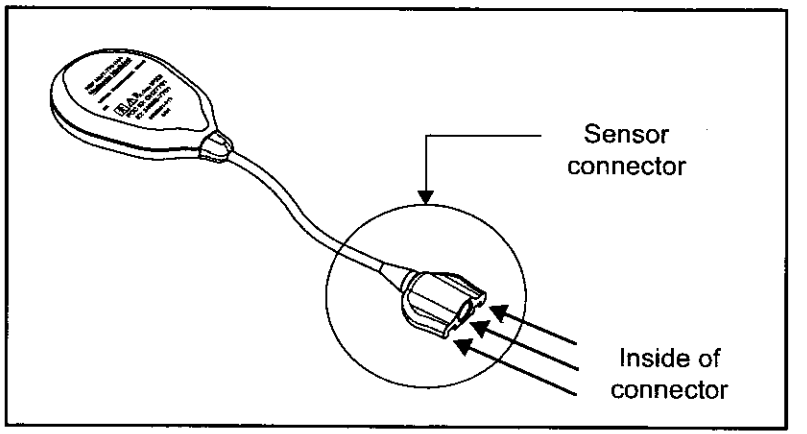
1 Wash your hands thoroughly.

2 Dampen a clean cloth with mild liquid soap and warm water, and wipe the outside of the transmitter, cable, and connector.

3 Holding the end of the transmitter, rinse it under warm tap water.

4 Disinfect the transmitter, cable, and connector by doing the following:
   - Apply some antibacterial hand sanitizer to a clean, dry cloth.
   - Wipe the transmitter, cable, and connector with the cloth.

5 Place the transmitter on a clean dry cloth and allow to air dry for 2 to 3 minutes.



Cleaning the Sen-serter

This section contains the steps you use to clean your Sen-serter.

To clean the Sen-serter:

1 Wash your hands thoroughly.

2 Dampen a clean cloth with mild liquid soap and warm water, and wipe the Sen-serter.

3 Holding the end of the Sen-serter, rinse it under warm tap water.

4 Disinfect your Sen-serter by wiping it with 70 percent alcohol wipes.

5 Place the Sen-serter on a clean dry cloth and allow to air dry for 2 to 3 minutes.

System specifications

9

What's in this chapter:

Alert types

- **Audible tone (beep)** – To make sure you are aware of the alarm, the sound goes from a beep to a siren until you respond to the alarm.
- **Vibration** – The system vibrates.

Alarm messages and codes

- Alarm information appears on the monitor screen
- Types of alarm information:
  - alarm name
  - alarm message (what to do when you receive the alarm)
  - alarm code (not for all alarms)

Alarm history

- Maximum number of recent alarms recorded: 36

Backlight

- Type of display: LCD (Liquid Crystal Display)

Screen and menu timeout

- Default: 30 seconds

Sensor glucose graph timeout

- Default: 2 minutes
- Options
  - 2 minutes
  - 4 minutes
  - 6 minutes
  - no timeout (NONE)

High and low Glucose Limits

- Maximum number of Glucose Limits: 8
- **Low** Glucose Limit
  - Default 90 mg/dL (5.0 mmol/L)
  - Range 90 to 390 mg/dL (5.0 to 21.6 mmol/L)
  - Increments 1 mg/dL (0.1 mmol/L)
- **High** Glucose Limit
  - Default 280 mg/dL (15.6 mmol/L)
  - Range 100 to 400 mg/dL (5.6 to 22.2 mmol/L)
  - Increments 1 mg/dL (0.1 mmol/L)

Daily totals

- Maximum number of daily totals recorded: 31 days

Default screen

- The HOME screen. The time always appears at the top of the HOME screen.
- The monitor automatically returns to the HOME screen if no buttons are pressed for 30 seconds for most screens.

Default settings

Feature	Options	Factory Setting	Limits, Range of Values
Alarm Clock	• On • Off	Off	Possible values: On Off (You can set up to 8 daily reminders)
Alarm Snooze	(Always on - cannot be turned off)	On 30 minutes	Range: Shortest 0:05 (5 minutes) Longest 1:00 (1 hour)
Alarm Silence	• Off • High BG • Low BG • Hi and Lo BG • All	Off	Possible values: Off High BG Low BG Hi and Lo BG All
Alert Type	• Beep • Vibrate	Beep Medium	Possible values: Beep Beep Long Beep Medium Beep Short Vibrate
AUC Limits	Always on	Low Limit 70(mg/dL) 3.9(mmol/L) High Limit 180(mg/dL) 10.0(mmol/L)	Low Limit range: [a] Lowest 40 (mg/dL) 2.2 (mmol/L) Highest 400 (mg/dL) 22.2(mmol/L) High Limit range: [b] Lowest 40 (mg/dL) 2.2 (mmol/L) Highest 400 (mg/dL) 22.2(mmol/L)
Block	• On • Off	Off	Possible values: On Off

Feature	Options	Factory Setting	Limits, Range of Values
Blood Glucose Units (BG Units)	• mg/dL • mmol/L	mg/dL	Possible values: mg/dL mmol/L
Cal Reminder	• On • Off	On 1 hour	Range: Shortest 0:05 (5 minutes) Longest 6:00 (6 hours)
Glucose Alarms	• On • Off	Off	You set the thresholds (limits) for the Glucose Alarms using the Glucose Limits settings.
Glucose Limits	• Maximum of 8 Glucose Limits. • One pair of Glucose Limits (Glucose Limits 1) is already set up for you, with a default High Glucose Limit and Low Glucose Limit. • Glucose Limits 2 through 8 can be set up as needed.		
Glucose Limits 1	• Low: Off or valid range from 90 to 390 mg/dL (5.0 mmol/L to 21.6 mmol/L) • High: Off or valid range from 100 mg/dL to 400 mg/dL (5.6 mmol/L to 22.2 mmol/L)	Low On 90 (mg/dL) 5.0 (mmol/L) High On 280 (mg/dL) 15.6 (mmol/L)	Low Glucose Limit range [c]: Lowest 90 (mg/dL) 5.0(mmol/L) Highest 390 (mg/dL) 21.6(mmol/L) High Glucose Limit range [d]: Lowest 100 (mg/dL) 5.6 (mmol/L) Highest 400 (mg/dL) 22.2(mmol/L)
Glucose Limits 2 through Glucose Limits 8	• Low Off On • High Off On	Low Off High Off	

Feature	Options	Factory Setting	Limits, Range of Values
High Snooze	• On • Off (Set to On when High Glucose, High Predictive, or Rising Rate of Change Alarm is on)	On 1 hour	Range: Shortest 0:05 (5 minutes) Longest 3:00 (3 hours)
Language	• English • Español • Français	English	Possible values: English Español Français
Lock Keypad	• On • Off	Off	Possible values: On Off
Low Snooze	• On • Off (Set to On when Low Glucose, Low Predictive, or Falling Rate of Change Alarm is on.)	On 20 minutes	Range: Shortest 0:05 (5 minutes) Longest 1:00 (1 hour)
Meter Option	• On • Off	Off	Possible values: On Off
Missed Data	(Always on - cannot be turned off)	30 minutes	Range: Shortest 0:05 (5 minutes) Longest 0:40 (40 minutes)
Predictive Alarm	• On • Off	Off Default time sensitivity: Low 15 minutes High 15 minutes	Range: Off Shortest 0:05 (5 minutes) Longest 0:30 (30 minutes)

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Feature	Options	Factory Setting	Limits, Range of Values
Rate of Change Alarms	• On • Off	Fall Rate Limit Off Rise Rate Limit Off	Fall Rate Limit range: Lowest 1.1(mg/dL/min) 0.065(mmol/L/min) Highest 5.0(mg/dL/min) 0.275(mmol/L/min) Rise Rate Limit range: Lowest 1.1(mg/dL/min) 0.065(mmol/L/min) Highest 5.0(mg/dL/min) 0.275(mmol/L/min)
Sensor	• On • Off	Off	Possible values: On Off
Sensor glucose graph timeout	• 2 minutes • 4 minutes • 6 minutes • NONE [e]	2 minutes	Possible values: Shortest 0:02 (2 minutes) 0:04 (4 minutes) 0:06 (6 minutes) No timeout NONE
Time/Date setup	• 12 Hour • 24 Hour	12 Hour	Possible values: 12 Hour 24 Hour

a. The AUC Low Limit can be equal to, but not higher than the AUC High Limit.
b. The AUC High Limit can be equal to, but not lower than the AUC Low Limit.
c. Your Low Glucose Limit must be at least 10 mg/dL (0.6 mmol/L) below your High Glucose Limit. For example, if your High Glucose limit is 200 mg/dL (11.1 mmol/L), then your Low Glucose limit cannot be higher than 190 mg/dL (10.5 mmol/L).
d. Your High Glucose Limit must be at least 10 mg/dL (0.6 mmol/L) above your Low Glucose Limit. For example, if your Low Glucose limit is 90 mg/dL (5.0 mmol/L), then your High Glucose limit cannot be lower than 100 mg/dL (5.6 mmol/L).
e. If you select this option the sensor glucose graphs will show continuously on the monitor screen.

ENTER BG meter values

- Expiration: 12 minutes
- Supported value range:
  - from 20 to 600 (mg/dL)
  - from 1.1 to 33.3 (mmol/L)
- Appears in the STATUS screen (RF only)

Meter ID entries

- Maximum meter ID entries: 3

Power supply

- Standard 1.5 V AAA alkaline battery
- Energizer brand is recommended

System safety checks

- Over 50 independent checks
- Regular and periodic checking of system functions

Monitor size

- Inches
  - Height — approximately 2.0 inches
  - Width — approximately 3.2 inches
  - Depth (thickness) — approximately 0.77 inches
- Centimeters (cm)
  - Height — approximately 5.1 cm
  - Width — approximately 8.1 cm
  - Depth (thickness) — approximately 2.0 cm

Monitor weight

- Approximately 79 grams (with battery installed)

TIME/DATE SET screen

- 12-hour or 24-hour formats
- You set the time/date (including the year, month and day)

STATUS screen

Screen item	Description
Last Alarm:	The most recent alarm that occurred within the past 24 hours. Alarms that occurred more than 24 hours ago are not displayed.
SENSOR DEMO: On	Indicates whether the Sensor Demo feature is turned **on** or **off**. This only appears when the Sensor Demo feature is turned **on**.
Meter: On	Indicates whether the meter option is turned **on** or **off**. This only appears when the meter option is turned **on**.
Meter: On, Low Batt	Indicates that the meter option is turned **on** and the monitor battery is low or dead. This only appears when the meter option is turned **on** and the monitor battery is low or dead.
Battery:	Indicates the condition of the battery (how much energy is left in the battery). This always appears.
BG meter value:	Indicates the most recent meter blood glucose value you entered within the past 24 hours, and when it was entered (date and time). Meter blood glucose values that were entered more than 24 hours ago are not displayed. This only appears when the meter option is turned on.
Date:	Indicates the current date. This always appears.
S/N# XXXXXX	The serial number of the monitor. This always appears.
Guardian XXXX	The model number of the monitor. This always appears.

Screen item	Description
Software version:	The version number of the system software. This always appears.
Status of system	Always appears (for example, Set Time).

Guidance and manufacturer's declaration

Guidance and Manufacturers Declaration - Electromagnetic Emissions		
The Guardian REAL-Time CGM System consisting of the CSS7100 Receiver and MMT-7701 Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the Guardian REAL-Time CGM System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Guardian REAL-Time CGM System uses RF energy only for system communication functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Guardian REAL-Time CGM System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. *NOTE: The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. However, since the Guardian REAL-Time CGM System is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.*
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturers Declaration - Electromagnetic Immunity

The Guardian REAL-Time CGM System consisting of the CSS7100 Receiver and MMT-7701 Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the Guardian REAL-Time CGM System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Not applicable ±30 kV air (<5% relative humidity)	The Guardian REAL-Time CGM System should not be affected by electrostatic discharge that might be encountered under normal conditions of use.
Electrical fast transient/burst IEC 61000-4-5	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable Not applicable	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Not applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 seconds	Not applicable Not applicable Not applicable Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturers Declaration - Electromagnetic Immunity

The Guardian REAL-Time is intended for use in the electromagnetic environment specified below. The customer or user of the Guardian REAL-Time should assure that it is used in such an environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 60601-4-3	10V/m 80MHz to 2.5GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Guardian REAL-Time system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.70\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, "should be less than the compliance level in each frequency range." Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.

Guidance and Manufacturers Declaration - Electromagnetic Immunity
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Guardian REAL Time is used exceeds the applicable RF compliance level above, the Guardian REAL Time should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Guardian REAL Time.

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Recommended separation distances between portable and mobile RF communications equipment and the Guardian REAL-Time system

This section provides information on the recommended separation distance between portable and mobile RF communications equipment and the Guardian Real Time. The Guardian Real Time is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Guardian Real Time system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Guardian Real Time as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)	
	80MHz to 800MHz $d = 0.35\sqrt{P}$	800MHz to 2,5GHz $d = 0.70\sqrt{P}$
0.01	0.035	0.07
0.1	0.11	0.11
1	0.35	0.7
10	1.1	2.2
100	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

Symbol table

Do not reuse:	
Attention: See Instructions for Use	
Date of manufacture (year - month):	
Manufacturer	
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)	
Conforms to IEC60601-1 sub-clause 44.6 and IEC60529 standard.	IPX7
Recycle:	
Radio communication:	

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Sensor accuracy

A

NOTE: You should have the information in this section reviewed by your healthcare professional.

The Guardian REAL-Time CGM System uses a glucose sensor to continuously monitor your glucose levels. The Guardian REAL-Time CGM System utilizes the same algorithm as the Guardian RT®. The Guardian RT was evaluated using two clinical studies and the following information describes the findings. The remainder of this section discusses the results of these pivotal studies, and uses the term Guardian RT.

NOTE: The Guardian RT is not an abbreviation for the Guardian REAL-Time CGM System. The Guardian RT is a continuous glucose monitoring system that was developed before the Guardian REAL-Time CGM System. The Guardian RT was originally named TGMS II, and the name was changed to Guardian RT.

The Medtronic 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 two clinical studies.[1,2]

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 section.

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.
2. Medtronic MiniMed, An Accuracy Evaluation of the Medtronic Diabetes Guardian RT Glucose Monitoring System in Pediatric Subjects with Type 1 Diabetes Mellitus, February, 2006.

Paradigm®
522K and 722K Sensor Features

Chapter 1

Introduction

Thank you for choosing Medtronic MiniMed as your partner in helping you gain better control of your diabetes. The Paradigm® 522K and 722K insulin pumps combine the technology of the Guardian® Continuous Glucose Monitoring system as well as the Paradigm Link™ Blood Glucose Monitor powered by BD Logic™ Technology 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:** Your pump can be used with the optional Paradigm Link Blood Glucose Monitor powered by BD Logic Technology. You can program your pump to automatically receive your blood glucose (BG) readings from this 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 all data stored in the pump to a computer.
- **Transmitter:** The transmitter (MMT-7701) is a small oval disk that connects to the sensor and is adhered to the skin with a medical dressing. It contains a battery, sensor electronics and a radio frequency transmitter. When a sensor is attached to the transmitter, it automatically initializes the sensor and begins to periodically transmit glucose data 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 the pump data to the diabetes management software installed in your computer via a serial communications interface cable.

User safety

Indications

Pump

The Paradigm MMT-522K and MMT-722K insulin infusion pumps are 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 Paradigm REAL-Time system (pediatric version) consists of the Paradigm MMT-522K or MMT-722K insulin infusion pumps, the MMT-7002 or MMT-7003 glucose sensor and the MMT-7701 transmitter. Use of the MMT-522K and MMT-722K insulin pumps with the optional sensor and transmitter components is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, and possible low and high blood glucose episodes in children and adolescents (ages 7 through 17). The system provides an alert if glucose levels fall below or rise above preset values. Glucose values provided by the system are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the sensor glucose readings provided by the Paradigm REAL-Time system.

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

The transmitter should be removed if irritation or reaction to the transmitter tape 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 transmitter should be removed if irritation or a reaction to the transmitter tape develops. Contact your doctor and the Medtronic MiniMed 24 Hour HelpLine in the event of any adverse reaction.

Accuracy of the glucose sensor readings provided by the Paradigm 522K or 722K pump was not evaluated in patients with medical conditions, such as insulin resistance and cystic fibrosis. Also, the impact of medications was not specifically evaluated; therefore, device performance may vary in these situations.

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, Paradigm Link meter, transmitter and remote control comply with the United States Federal Communications Commission and international standards for Electromagnetic Compatibility.

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

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

The Paradigm Link 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 cable orientation. 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.

Chapter 2

Programming your sensor

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.

Sensor icons

Refer to the Pump User Guide (Paradigm 522/722 Insulin Pump User Guide) to learn how to navigate through the pump screens. 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 3 for how to start 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.

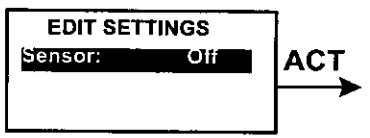
Programming the sensor

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

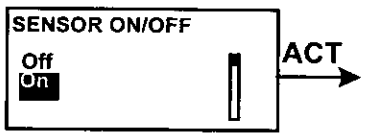
NOTE - The sensor features are programmed in the order described in this chapter.

Main Menu > Sensor> Sensor Setup > Edit Settings

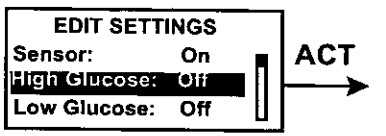
1 Press **ACT**.



2 Select **On** and press **ACT**.



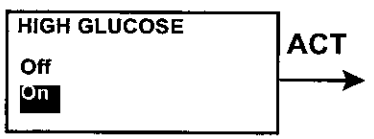
3 The **EDIT SETTINGS** screen will appear. Press **ACT** to program your High Glucose limit.



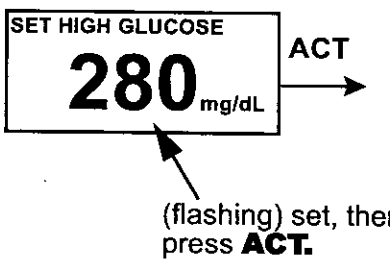
High glucose alarm

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 goes high.

4 Select **On** and press **ACT**.



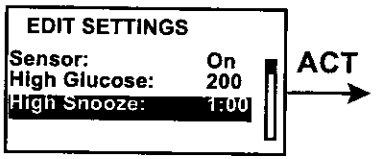
5 In the **SET HIGH GLUCOSE** screen, use the up and down arrow buttons to set your limit. Press **ACT**.



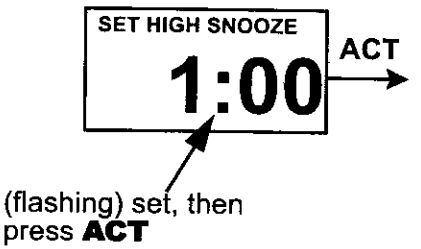
High snooze

Once you get a High Glucose Alarm, the pump is set to alarm every 1 hour while the high glucose condition exists. The High Snooze setting can be set anywhere from 5 minutes to 3 hours to increase or reduce the frequency of alarms until your glucose level goes below the set High Glucose level.

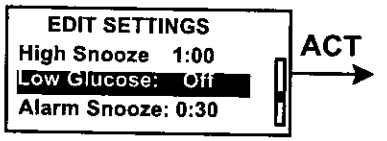
6 **High Snooze** will be highlighted. Press **ACT**.



7 Use the up and down arrow buttons to select your High Snooze alarm time. Press **ACT**.



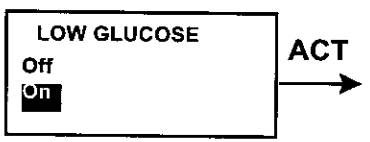
8 Press **ACT** to program your Low Glucose limit.



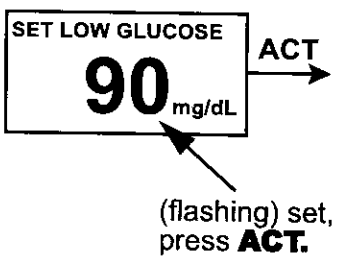
Low glucose alarm

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 goes low.

9 Select **On** and press **ACT**.

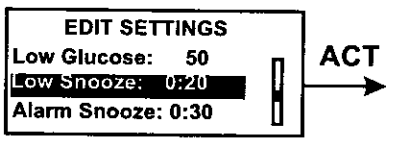
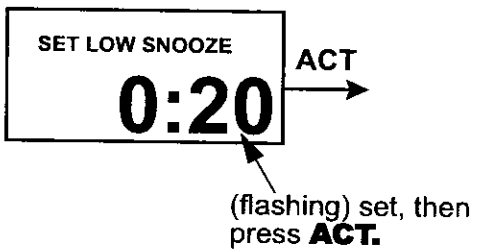


10 Use the up and down arrow buttons to set your Low Glucose limit. Press **ACT**.



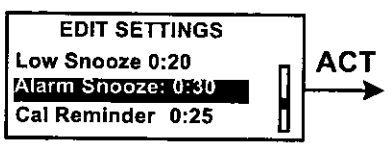
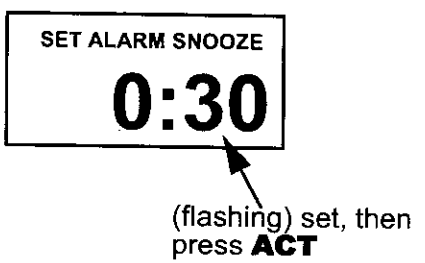
Low snooze

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 settings 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**.
	

Alarm snooze

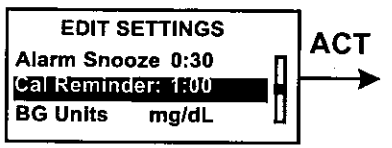
This option allows you to set an alarm snooze for the Meter BG Now alarm (see Chapter 5, Troubleshooting and Alarms for more information). So, instead of alarming every 5 minutes, the pump will alarm at the time interval you set here. For example, if you set an Alarm Snooze of 20 minutes for the Meter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

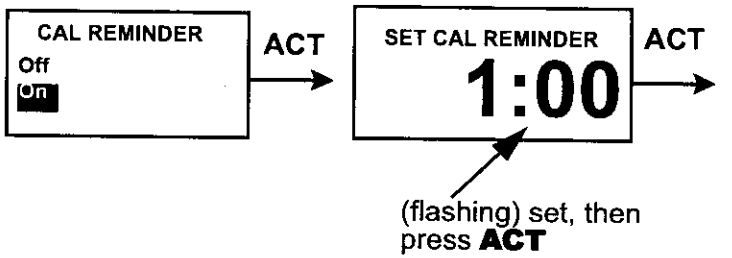
Cal reminder

Once you enter a meter BG you have to do another BG within 12 hours otherwise you will receive a Meter BG Now alarm. 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 Cal Reminder 4 hours before the next meter BG entry is due, which is 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**.

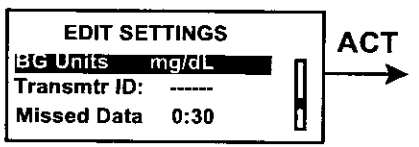


BG units

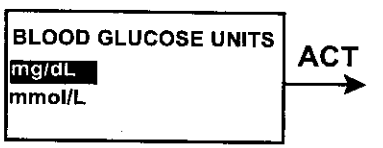
You can select **mg/dL** or **mmol/L** as your Blood Glucose Unit (measurement type).

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

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



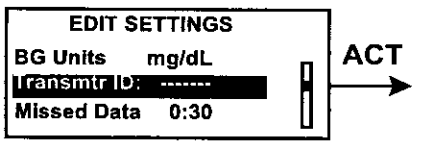
18 Select **mg/dL** or **mmol/L** and press **ACT**.



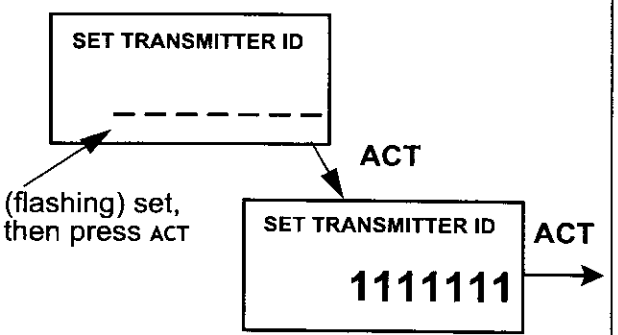
Transmitter ID

The transmitter ID is found on the front of your transmitter. You need to enter your transmitter ID so the transmitter and pump can communicate with each other.

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

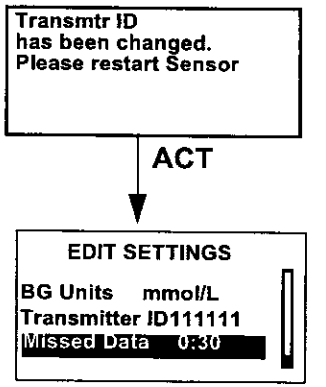


20 Use the up and down arrow buttons to select each of the seven ID numbers. If this ID has less than seven numbers, add zeros in front of the ID so that there are seven numbers. Press **ACT** after each entry. Press **ESC** when you are done.



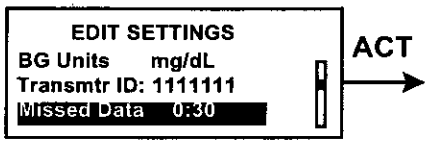
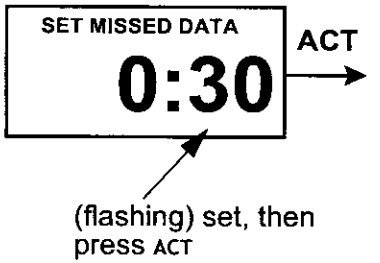
Tip - To remember your transmitter ID, write it here _____.

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.

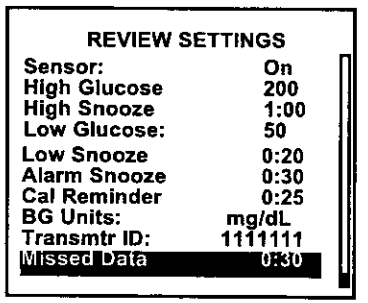
22 Select **Missed Data** and press **ACT**.	23 Use the arrow buttons to select your Missed Data time. Press **ACT**.	24 When you have completed the sensor setup, press **ESC** until the HOME screen appears.
		

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.



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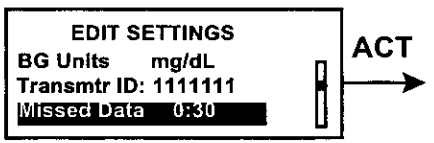
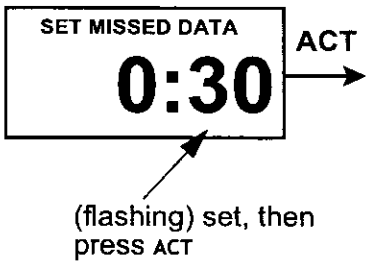
22 Select **Missed Data** and press **ACT**.	23 Use the arrow buttons to select your Missed Data time. Press **ACT**.	24 When you have completed the sensor setup, press **ESC** until the HOME screen appears.
		

Review settings

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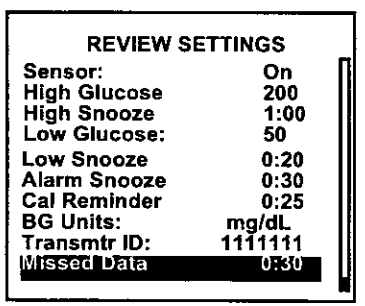


Default settings

Menu	Item	Default Setting	Limits
Sensor Menu:	Sensor:	Off	
	High Glucose:	Off	Low to 400 mg/dL (Low to 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	90 mg/dL to Hi (5.0 mmol/L to 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 90 mg/dL (5.0 mmol/L) then you cannot set your High limit lower than 100 mg/dL (5.6 mmol/L).

Chapter 3

Starting the sensor

Introduction

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

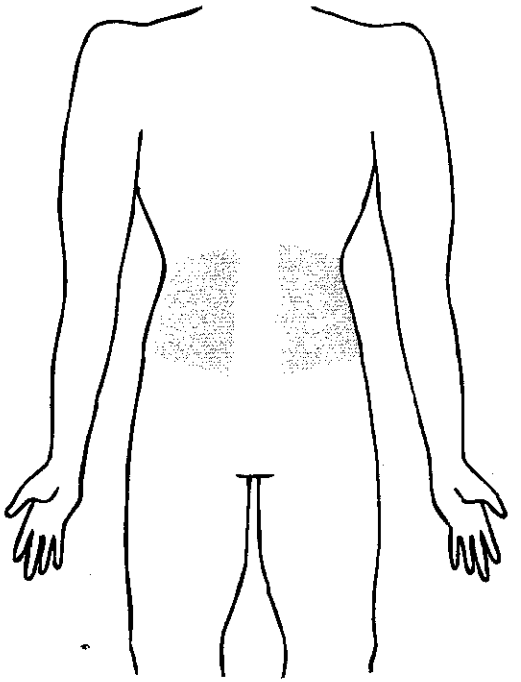
- Insert the sensor
- Apply the transmitter
- Connect the sensor to the transmitter
- Perform "Sensor Start" on the pump

Inserting the sensor

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 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 are the body areas (shaded) that are best 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.**

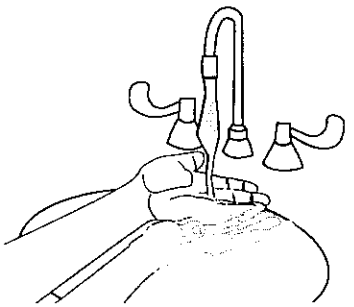
Areas to avoid:

- Frequently used injection or pump/sensor sites
- 2-inch area around navel
- Site where clothing will rub or constrict
- Scarred or atrophied 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.

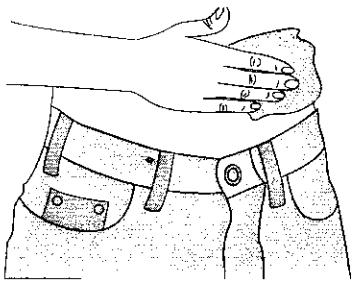
NOTE *- Clean site with alcohol, making sure site is dry before inserting the sensor. Do NOT use skin-preparation solutions prior to insertion. However, I.V. Prep may be used after insertion and before applying a sterile dressing. Lift back of tape slightly to apply I.V. Prep.*

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

1 Wash your hands.

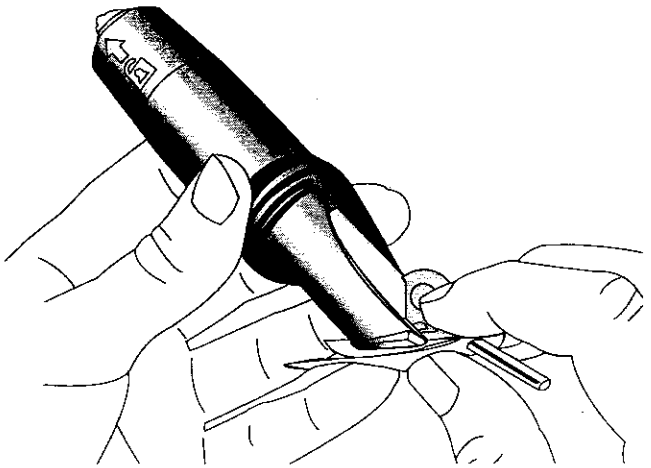


2 Clean with alcohol and then dry the sensor site.

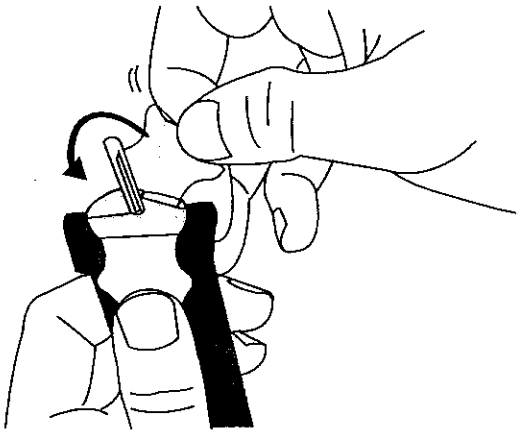


3 Remove the sensor from package by holding base or tape. Do not hold the sensor by the introducer needle handle.

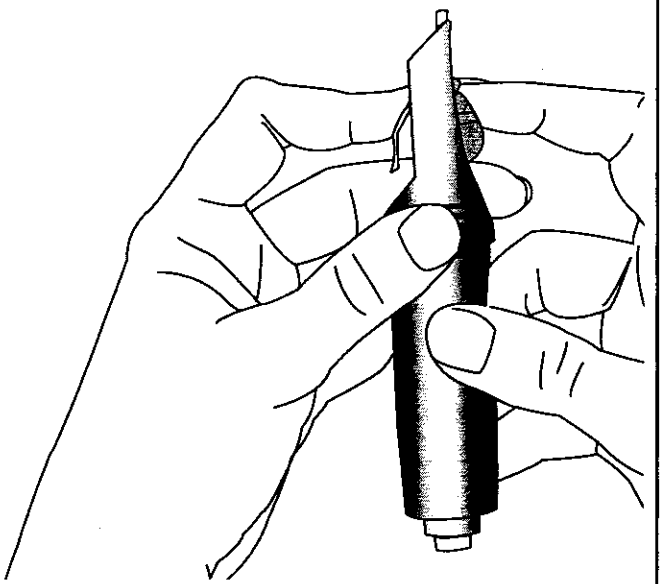
4 Place the sensor in the Sen-serter until it fits snugly.



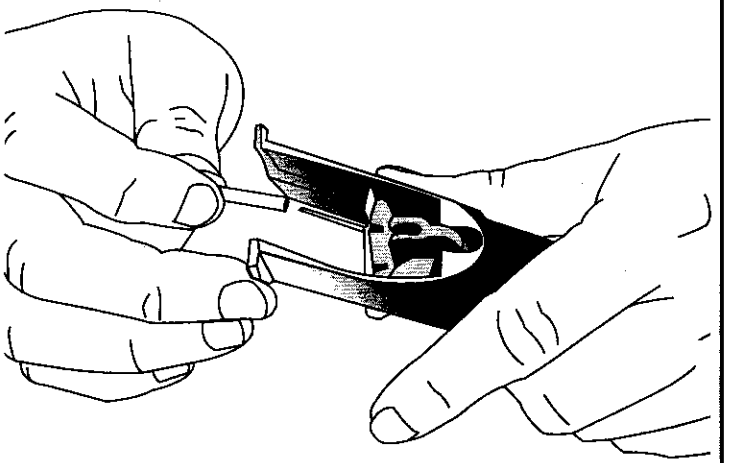
5 Holding the white tape as shown, remove the clear tape using a counterclockwise motion.



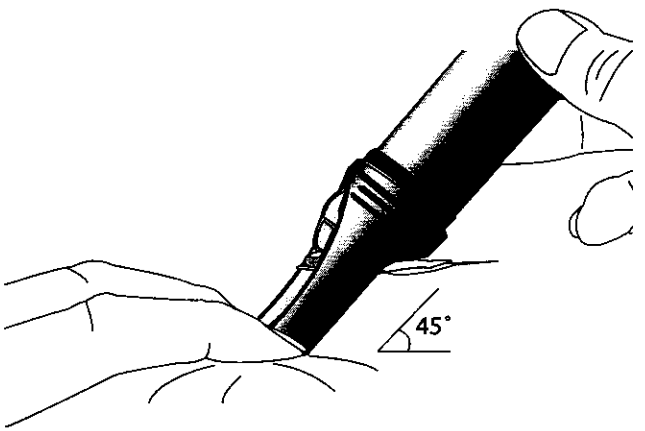
6 Place fingers on the back of the white tape and push the carrier down until it clicks into place.



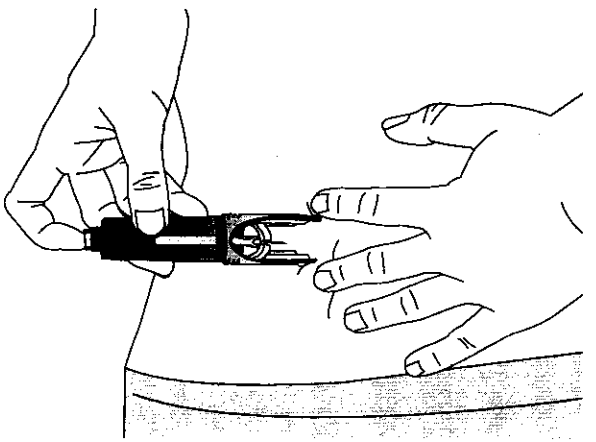
7 Turn the lock on the Sen-serter and remove needle guard from introducer needle.



8 Rest the Sen-serter legs flat on skin so the Sen-serter is at a 45 degree angle, placing two fingers of opposite hand on the Sen-serter legs to maintain angle.

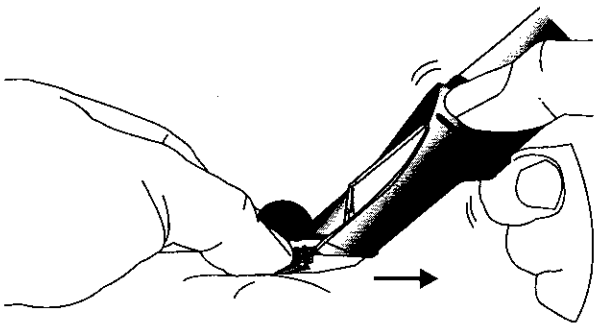


9 Unlock the Sen-serter and then press the white button to insert the sensor.

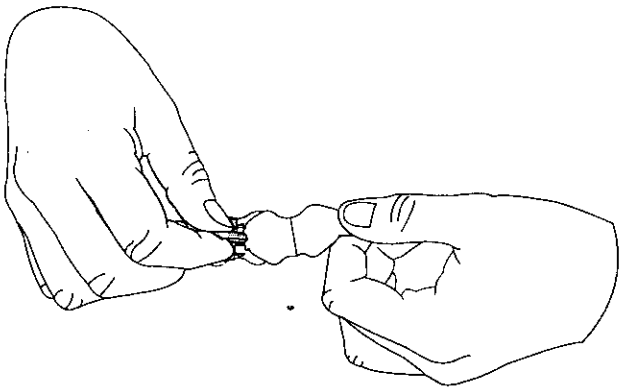


10 Make sure the sensor is inserted and flush with your skin.

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.

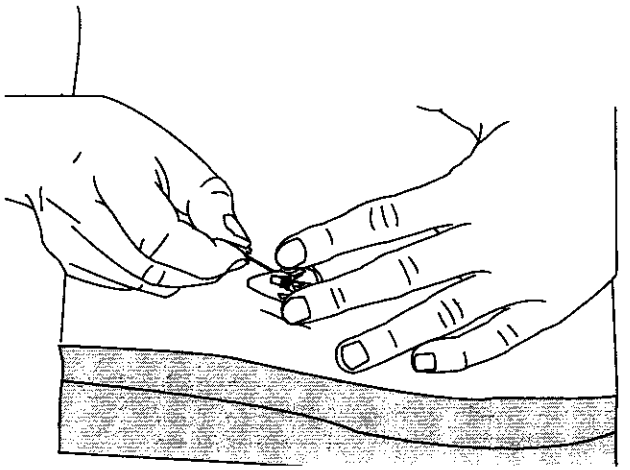


12 Holding the sensor in place, remove the white paper from the adhesive pad. Press adhesive against your skin.



1999

13 Hold the sensor with two fingers on the base, and gently remove the introducer needle at 45-degree angle. Do NOT rotate introducer needle when removing. Dispose of needle in sharps container.



14 After insertion, wait 5 minutes before attaching the transmitter, in case any bleeding occurs. If bleeding occurs apply pressure using a sterile gauze or clean cloth for 3 minutes. If bleeding stops:

a. Attach the sensor to the system connector.

If bleeding does NOT stop:

Caution: DO NOT connect the sensor to the system connector.

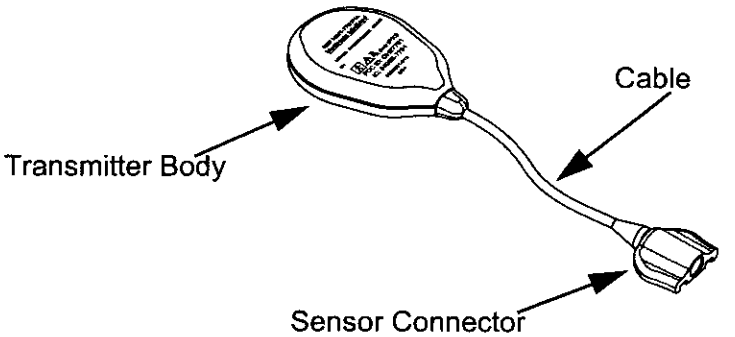
a. Remove the sensor and discard.

b. Check the site for redness, bleeding, irritation, pain, tenderness or inflammation.

c. Insert a new sensor in a different location.

The transmitter

The Medtronic MiniMed Transmitter (MMT-7701) is a device that takes electronic signals generated by the glucose sensor and sends them by radio frequency to the pump. The transmitter is connected to the sensor by a sensor connector.



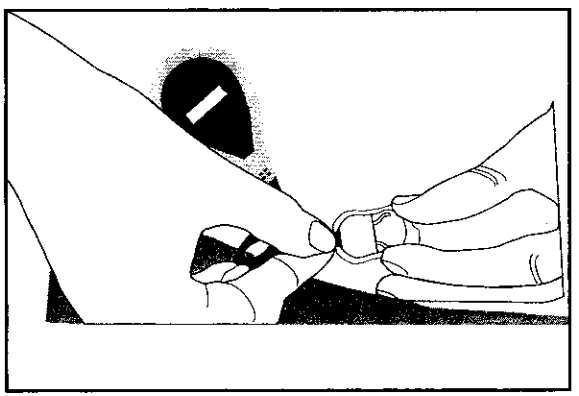
Attaching the transmitter

1. Find a comfortable, protected area on the abdomen that is within cable reach to the sensor.
2. Clean the area with isopropyl alcohol and allow to dry.
3. Peel the paper from the transmitter side of the adhesive pad.
4. Stick the adhesive pad to the back of the transmitter.
5. Peel the paper from the skin side of the adhesive pad. Apply to skin by pressing firmly.

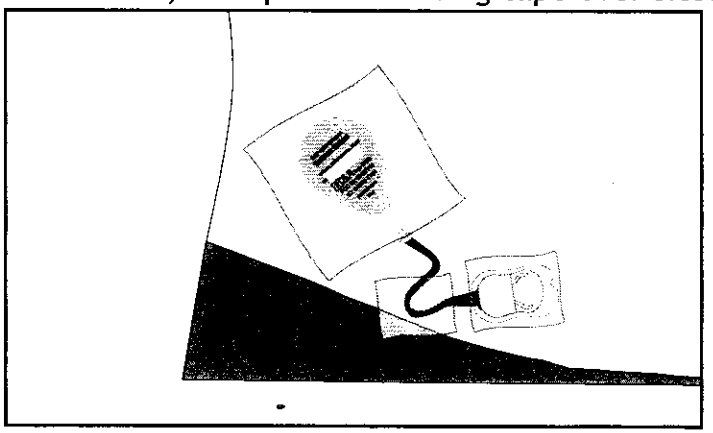
Connecting the sensor to the transmitter

CAUTION: In order to avoid damage, make sure the sensor and the cable are leveled against the skin when attaching.

1 Hold the sensor base while connecting the cable. Do not squeeze clips. You should hear a click when the cable and sensor connect. You will also hear a short beep from the transmitter.



2 A prepping agent, such as an I.V. Prep may be used to strengthen adhesion before applying sterile dressing. The cable may be looped under tape for strain relief. Apply a sterile, transparent dressing tape over site.

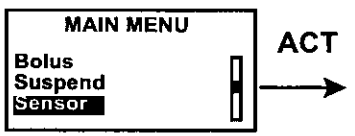


Starting the sensor

You are now ready to start your sensor so the sensor and the pump can communicate with each other. To do this, follow the steps below:

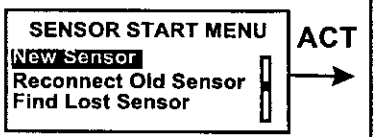
203

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



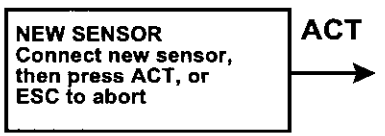
2 Select **Sensor Start** and press **ACT**.

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

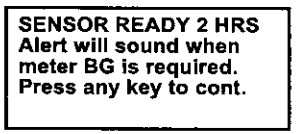


NOTE - If screen times out, start again. DO NOT disconnect sensor.

4 Connect your sensor now if you have not already done so. Press **ACT**.



5 Press **ANY KEY**.



Enter meter BG

After the two hour initialization period you must enter a blood glucose (BG) reading into the pump to calibrate the sensor. This 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 to enter a BG value:

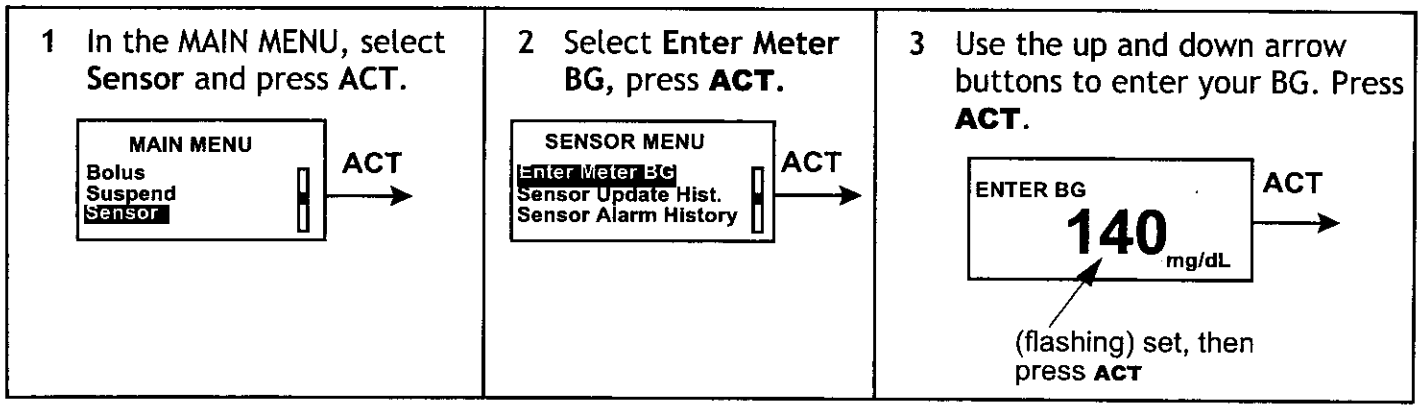
1 To enter a BG value manually in the Bolus Wizard press the **Express Bolus Wizard** button on your pump, or go to the ENTER BG screen from the MAIN MENU:

Bolus > Use Bolus Wizard

Enter the BG value by using the up and down arrow buttons on your pump. Press **ACT**.

2 To enter a BG value automaticaly through the Paradigm Link Blood Glucose Monitor, test your BG with a fingerstick. The value will be automatically sent from the Paradigm Link Monitor to your pump. Make sure that your pump and the Paradigm Link Monitor are properly programmed for communication.

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



Chapter 4

Using your sensor

Two hours after you insert your sensor, your pump will alert you to enter a meter BG (Meter BG Now). A meter BG reading should be entered 3-4 times a day, however, a minimum of one meter reading must be entered every 12 hours. If you fail to enter a meter reading after 12 hours your pump will alarm with the Meter BG Now alarm and your pump will stop calculating glucose values. Avoid calibrating the system during times of rapid glucose change such as after eating or exercise. Always use clean dry fingers when you check your blood glucose. Do not use alternate sites; always use fingertips to obtain blood samples for calibration.

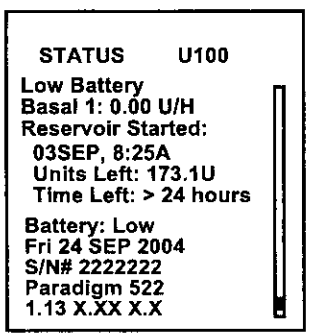
NOTE - For best results, enter a Meter BG reading 3 to 4 times a day.

Status screens

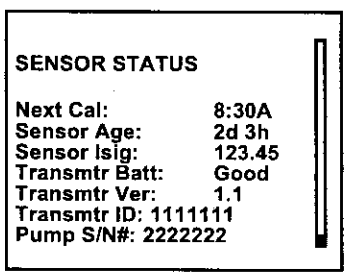
Your STATUS screens tell you what is going on in your pump. In the SENSOR STATUS screen you can check the status of sensor information including when your next calibration will be needed, your sensor's age, and the state of your transmitter battery.

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.

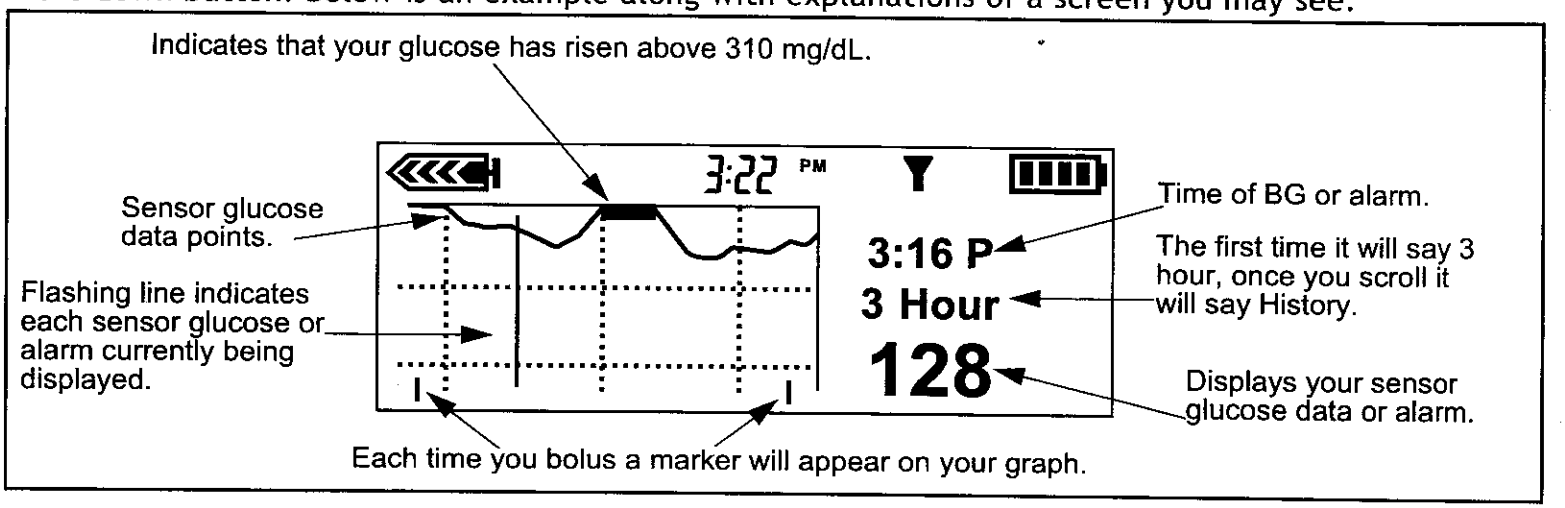


Reading your graphs

Once the sensor is calibrated you can view your sensor glucose values in real-time. To view your current 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.

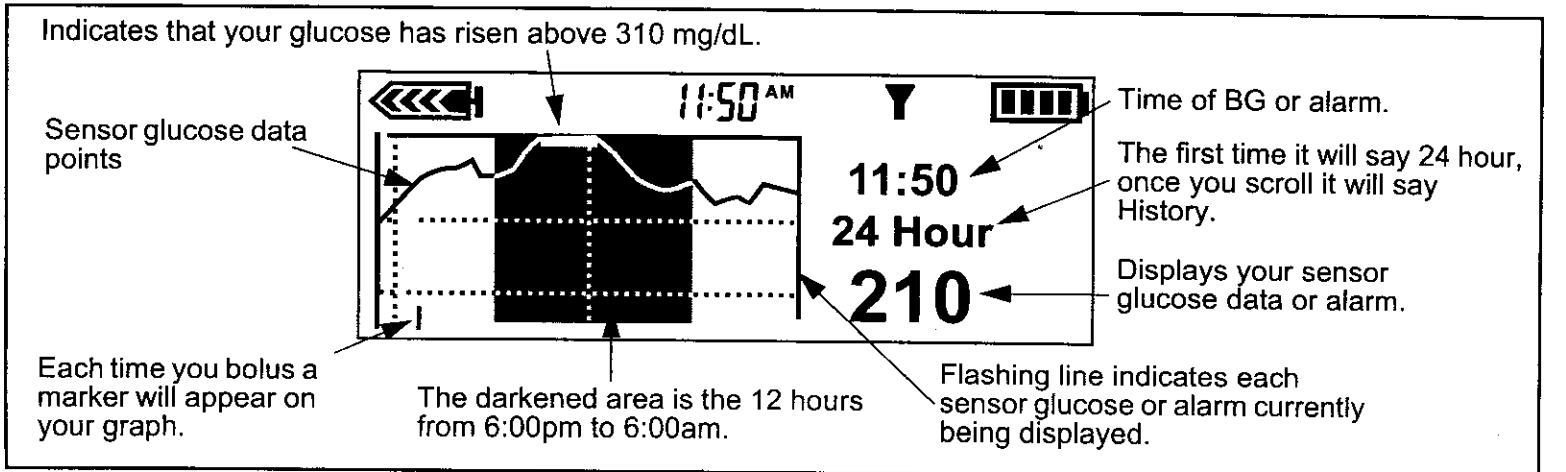
3 hour graph

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

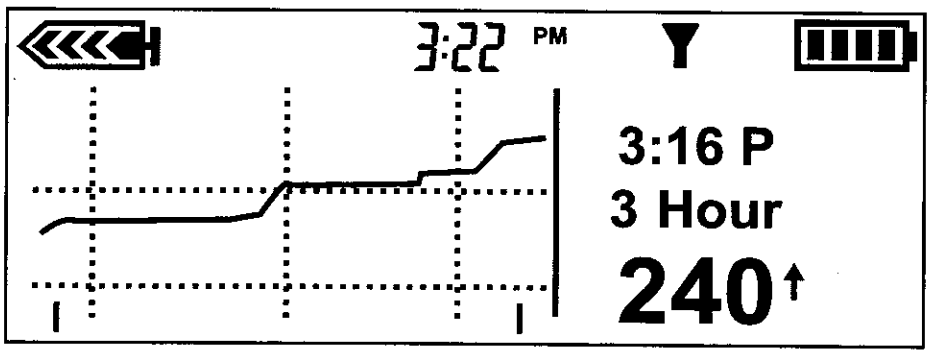
To view the current glucose and a graph of the most recent 24 hours of data, press **ESC** twice from the HOME screen:



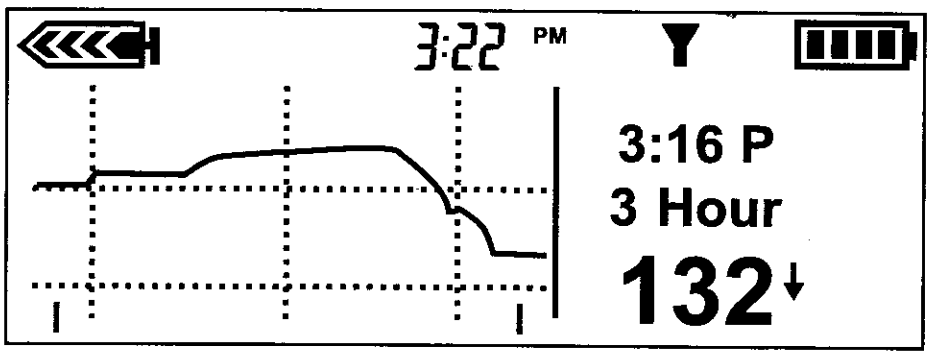
Your glucose values

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

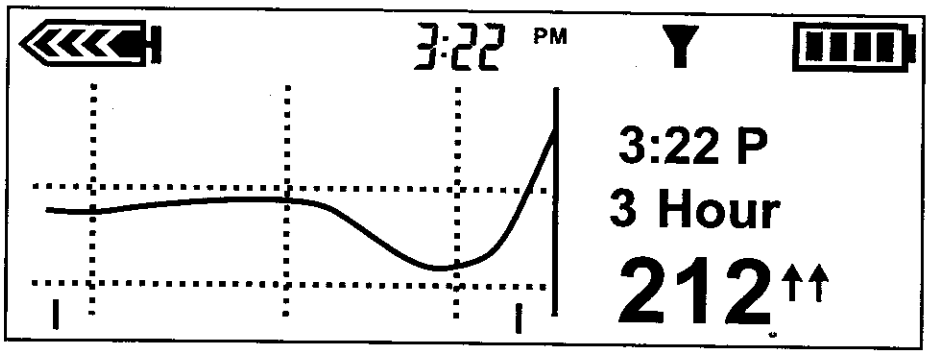
- An up arrow ↑ next to your glucose indicates that your glucose is rising at a rate of 1 to 2 mg/dL per minute for the last 20 minutes. Your glucose has changed by 20-40 mg/dL in the last 20 minutes.



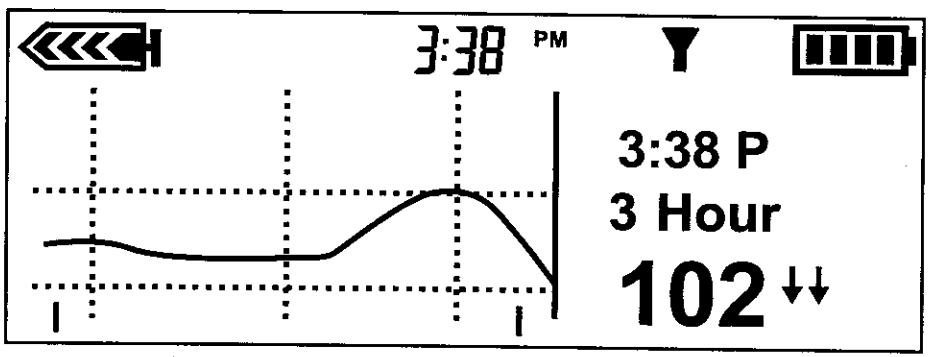
- A down arrow ↓ next to your glucose indicates that your glucose is dropping at a rate of 1 to 2 mg/dL per minute for the last 20 minutes. Your glucose has changed by 20-40 mg/dL in the last 20 minutes.



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



- Two down arrows ↓↓ next to your glucose 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 also 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	➠ Sensor End	➠ Sensor Error	➠ Lost Sensor
➠ Cal Error	➠ Bad Sensor	➠ Weak Signal	

For further information on these alarms, go to Chapter 5, Troubleshooting and Alarms.

Sensor alarm history

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

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

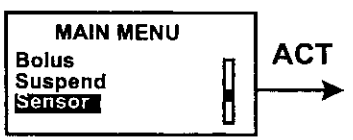
2 Select **Sensor Alarm History** and press **ACT**.

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

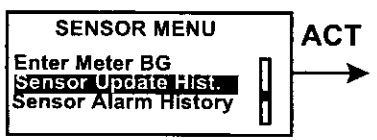
Sensor update history

Lists all your calibration values entered into the pump. To view your Sensor Update History:

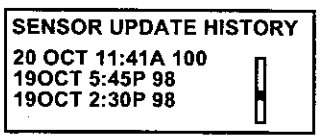
1 In the MAIN MENU, select **Sensor** and press **ACT**.



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



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

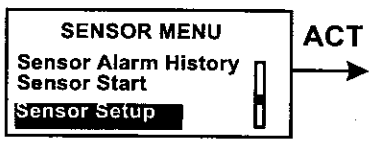


Review settings

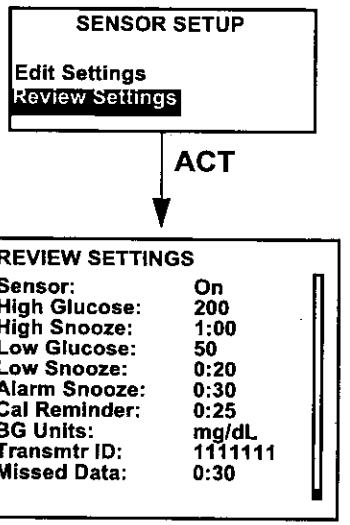
To review your sensor settings:

1 In 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 then you will not see High Snooze or Low Snooze listed under Review Settings.

Removing transmitter and sensor

Disconnecting the sensor from the transmitter

Remove the tape covering the sensor. Hold the glucose sensor assembly in one hand and the sensor connector in the other hand. While squeezing the snap arms on the sides of the glucose sensor assembly together, gently pull the glucose sensor assembly away from the sensor connector.

Removing the transmitter

Remove the outer tape covering the transmitter and the wire. Remove the transmitter by pulling gently on its end. Do not pull off by the sensor connector wire. Remove the adhesive pad from the skin by gently pulling on its end.

Removing the sensor

Gently pull the sensor from your body. When removed place in a sharps container.

Storage and handling

Store sensors in refrigerator at +2 to +10°C (+36 to +50° F). Do not freeze.

Prior to opening, allow the sensor package to reach room temperature and 5% to 95% humidity to prevent condensation.

Sen-serter maintenance

Cleanse Sen-serter with soapy water, using liquid detergent or other household soaps. Allow to dry.

Disinfect Sen-serter by wiping with 10% bleach solution or 70% isopropyl alcohol.

Store Sen-serter in the released position to maintain optimum product performance and life.

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 Tightly attach the occlusive dressing to the skin covering the sensor and the transmitter connector.

2 Disconnect the infusion set from the pump and remove the pump. The pump is not watertight.

3 You can enter the water. Avoid submerging the sensor in hot water as this may significantly reduce its life.

4 Once out of the water, put the pump back on and reconnect the infusion set.

5 Check your infusion set and transmitter tapes and replace these if waterlogged.

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Alarms

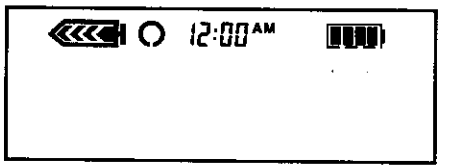
Your pump has a sophisticated network of safety checks and systems. If the safety network detects anything unusual, your pump notifies you of conditions that require your immediate attention. The backlight illuminates the pump screen, and the alarm message displays on the screen. Sensor alarms put the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

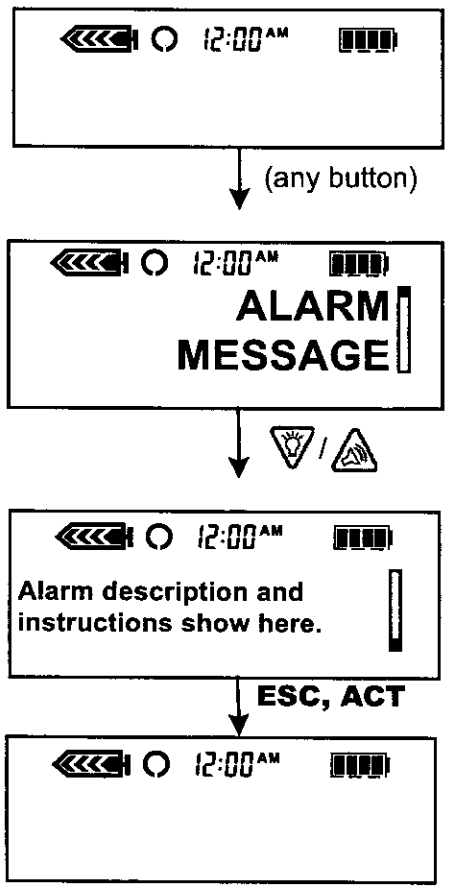
2 **Read all of the alarm text.** There are instructions on how to fix the alarm condition. (Press the down button to read more text, if available.)

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.

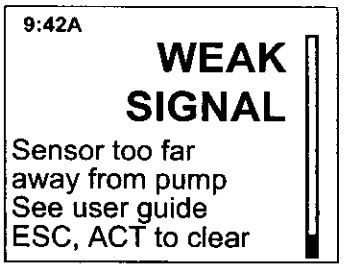


Sensor alarm conditions

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

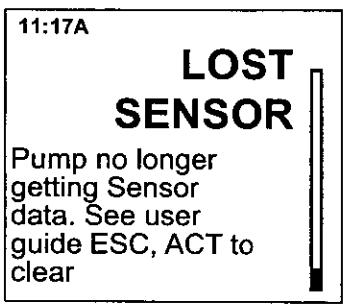
Alerts you when the pump does not receive data for a period of time, as set in Missed Data. Move the pump closer to the transmitter or move the transmitter and the pump to a new location on your body.



Lost sensor

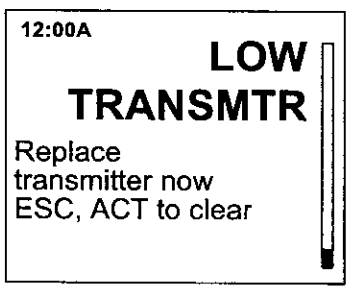
The pump has not received a signal from the transmitter for more than 40 minutes. Make sure the transmitter and sensor are connected. If you hear a beep you will have to recalibrate. **Do NOT disconnect.** To find your sensor use the **Find Lost Sensor** function:

Main Menu > Sensor > Sensor Start > Find Lost Sensor



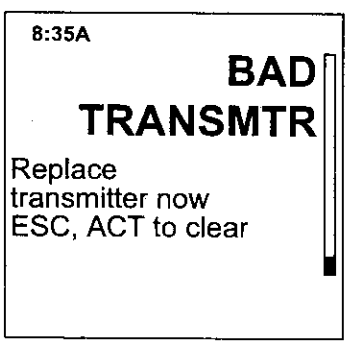
Low transmtr

Occurs when the transmitter battery is low. The transmitter will continue sending sensor signals until the battery becomes depleted. Replace the transmitter as soon as possible. Call 800.MiniMed to order a new transmitter if your 6 month transmitter warranty has expired.



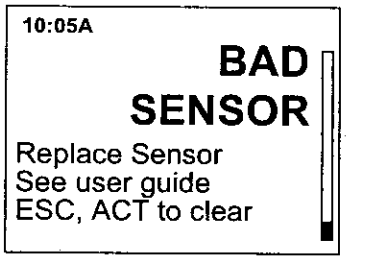
Bad transmtr

The transmitter battery is depleted. Replace your transmitter. Call 800.MiniMed to order a new transmitter if your 6 month transmitter warranty has expired.



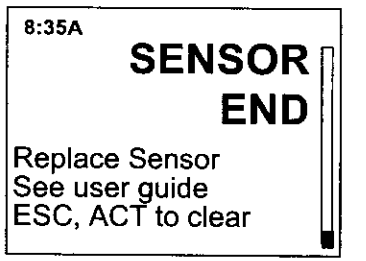
Bad sensor

The transmitter has detected a bad sensor. Replace the sensor.



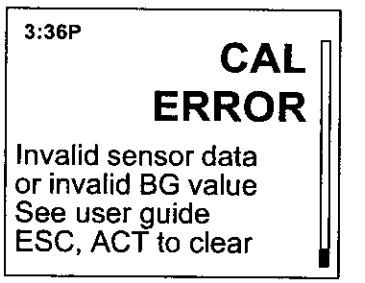
Sensor end

The sensor has reached the end of its life. Replace the sensor. The sensor has a maximum life of 72 hours.



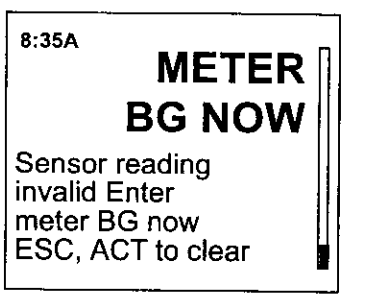
Cal error

Enter a new meter BG and try again. If error repeats, wait 10-15 minutes and try again. If error repeats, you will get a Bad Sensor alarm and you will need to replace the sensor.



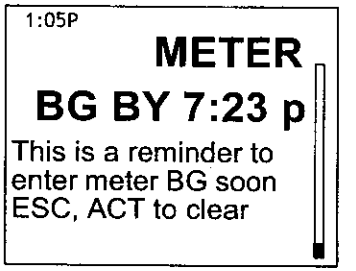
Meter BG now

A meter BG is needed right away to update sensor and to keep receiving sensor glucose data.



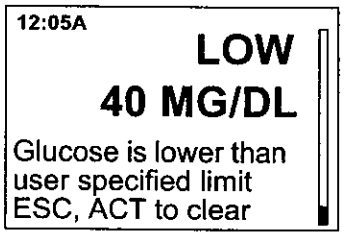
Meter BG by

A meter BG entry is required by the time that is shown to update sensor and to keep receiving sensor glucose data.



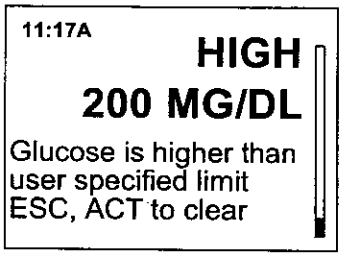
Low glucose

The glucose value is lower than or equal to the low glucose limit set. If you do not set a Low sensor glucose then you will not get a Low sensor glucose alarm.



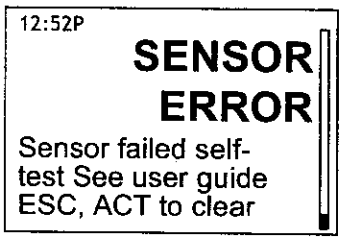
High glucose

The glucose value is higher than or equal to the high glucose limit set. If you do not set a High sensor glucose then you will not get a High sensor glucose alarm.



Sensor error

Sensor failed self-test. You do not need to change the Sensor.



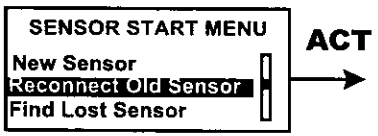
Troubleshooting

Reconnect old sensor

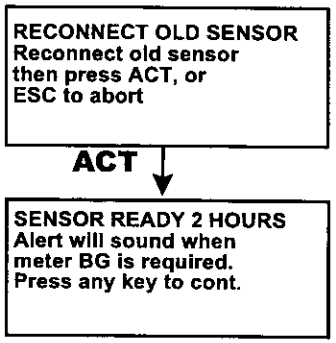
You should only use this feature if you have disconnected the sensor from the transmitter and have to reconnect. For example, when you are flying on an aircraft.

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

2 Select **Reconnect Old Sensor** and press ACT.



3 The **Reconnect Old Sensor** screen will appear. Follow instructions and press ACT.



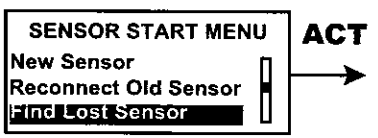
Find lost sensor

If you receive a Lost Sensor alarm:

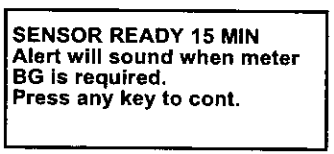
Sensor > Sensor Start

1 Relocate the pump closer to the sensor, select **Sensor Start** and press ACT.

2 Select **Find Lost Sensor**, press ACT.



3 Your sensor will be ready in 15 minutes.



Cleaning

Cleaning the transmitter

1 Wash your hands thoroughly.

2 Dampen a clean cloth with mild liquid soap and warm water. Wipe the outside of the transmitter, cable and connector. Do not wet the inside of the connector.

CAUTION:	Do not place the transmitter into the soap and/or water.

3 Hold by the transmitter end, and rinse the transmitter under warm tap water, being careful not to get the inside of the connector wet.

4 Using an antibacterial hand sanitizer (readily available at your local drugstore), wipe down the transmitter, cable and connector with a clean dry cloth. Make sure the inside of the connector does not get wet.

5 Place the transmitter on a clean dry cloth and allow to 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
Transmitter: Protected Against the Effects of Continuous Immersion in Water.	IPX8
Recycle:	
Radio communication:	
Manufacturer:	
Configuration:	CONF

Chapter 6

Sensor accuracy

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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 two clinical studies and the following information explains the findings.

NOTE - The Guardian RT is not an abbreviation for the Guardian REAL-Time CGM System. The Guardian RT is a continuous glucose monitoring system that was developed before the Guardian REAL-Time CGM System. The Guardian RT was originally named TGMS II, and the name was changed to Guardian RT.

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 two clinical studies[1,2].

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.*
2. *Medtronic MiniMed, An Accuracy Evaluation of the Medtronic Diabetes Guardian RT Glucose Monitoring System in Pediatric Subjects with Type 1 Diabetes Mellitus, February, 2006.*

Performance results in adults

The performance of the Guardian RT in adults was evaluated in a clinical study[3]. 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.

3. *See Note 1, on page 41.*

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%

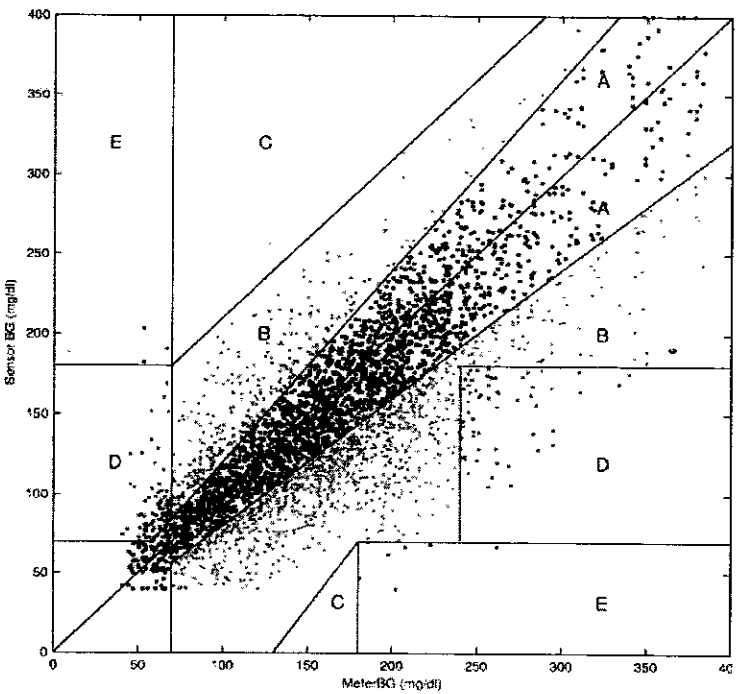
**For the Low glucose range, 40-80 mg/dL (2.2-4.4 mmol/L), the value shown is the percent within 20 mg/dL (1.1 mmol/L).*

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.



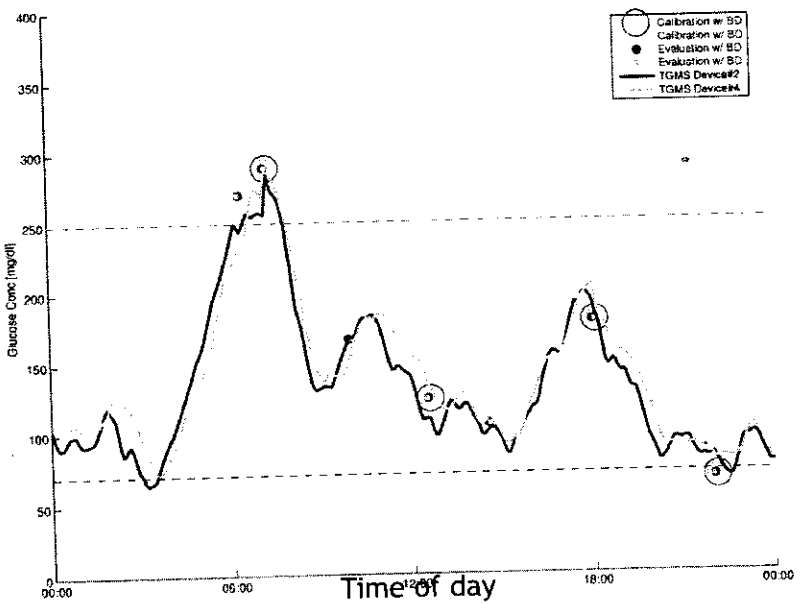
The percent of Guardian RT readings in the above graph are presented in the following table according to the percentage of points falling within each zone (A-E). Results are further broken down (stratified) according to the range of glucose concentrations.

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 in Adults

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.

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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 46, 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 mg/dl and 30 mg/dl of YSI readings from 40-80 mg/dl was analyzed according to time after Sensor insertion and according to the glucose-concentration range (as determined by the YSI analyzer).

	Percentage of Guardian RT values within 20 mg/dl of YSI laboratory readings		Percentage of Guardian RT values within 30 mg/dl 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%	78-91%	67%

The percentage of Guardian RT readings within 20% and 30% of YSI readings from 81-120 mg/dl was analyzed according to time after Sensor insertion and according to the glucose-concentration range (as determined by the YSI analyzer).

	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**
81-120	57-66%	48%	72-84%	66%

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

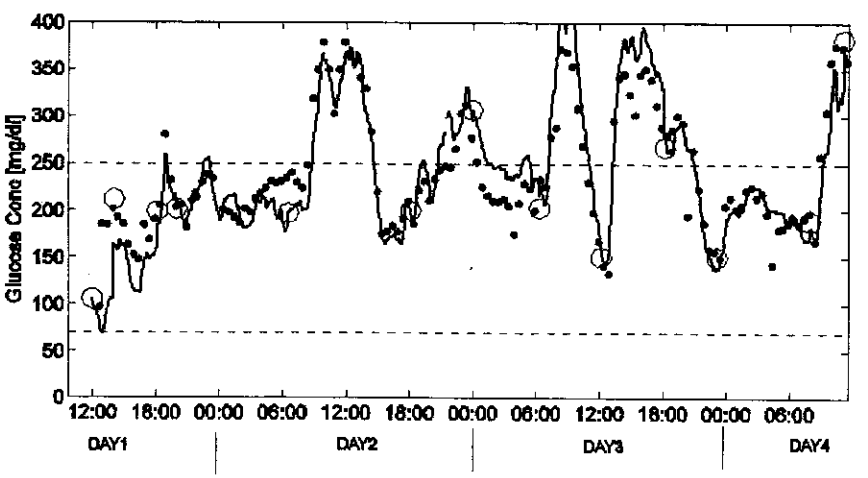
The average bias when Guardian RT was calibrated ~ 3.5 times a day was -20.5 ± 41 mg/dL (LL: -22.40 mg/dL and UL: -18.63 mg/dL). In those calibrated ~ 5 times a day, the bias was -10.2 mg/dL ± 36 mg/dL (LL: -11.74 mg/dL and UL: -8.66 mg/dL). When comparing Guardian RT units that were calibrated less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

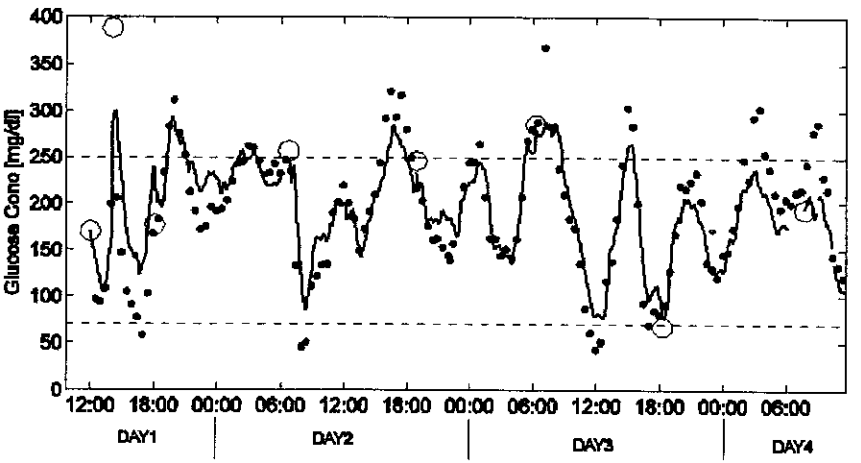
Stratified error grid analysis also shows better performance in the hypoglycemic range when fewer calibrations are performed, i.e., 62% of data points are in Zone A when fewer calibrations were performed, whereas 58% were in Zone A when more calibrations were performed.

Time-Elapsed Plots

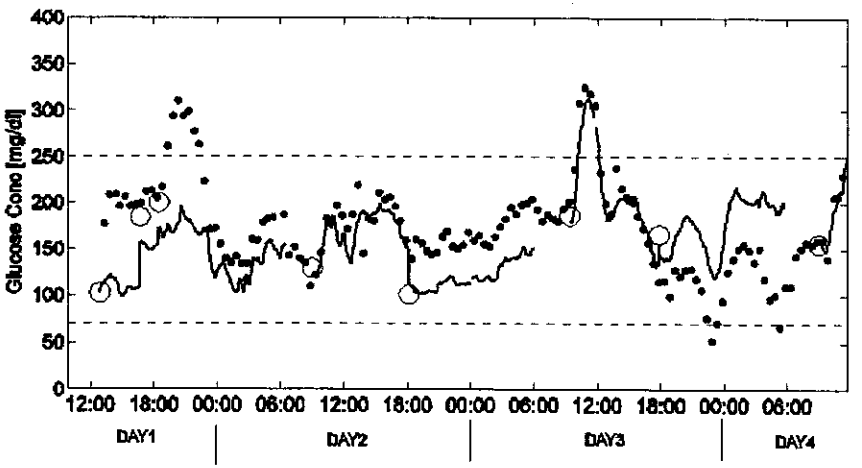
The plot graph below is a representative example of continuous sensor tracing vs. reference blood glucose reading, where sensor showed excellent performance. The open circles (o) on the graph represent the meter calibration readings. The closed circles (•) represent the reference blood glucose readings,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



Performance Results in Children and Adolescents

The performance of the Guardian RT in Children and Adolescents was evaluated in a clinical study[4]. Guardian RT results were compared to capillary blood glucose measured by a OneTouch® Ultra® meter. Sixty subjects with Type I diabetes participated in a three-site out-patient study. Subjects ranged in age from 7 to 17 years old. Each subject wore a Guardian RT system, which records a sensor glucose value every 5 minutes. Subjects were instructed to perform at least seven (7) blood glucose meter measurements each day.

Accuracy of Guardian RT Readings

In this study, each blood glucose meter measurement was 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 blood glucose meter 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 blood glucose meter measurement. The difference between them was calculated as a percentage of the blood glucose meter measurement (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 blood glucose meter values. The paired glucose measurements are summarized in the following table.

Number of Paired Glucose Measurements	2599
Mean Absolute Percent Difference (± SD)	19.0 ± 19.7%
Bias	-6.0 mg/dl (-0.3 mmol/l)

4. *See Note 2, on page 41.*

The accuracy of the Guardian RT was also evaluated by calculating the percentage of Guardian RT readings within 20% and within 30% of the blood glucose meter reading (or within 20 mg/dl (1.1 mmol/l) in the low glucose range). Results are shown in the following table.

Plasma Glucose Range (mg/dl)	Plasma Glucose Range (mmol/l)	Number of Paired Readings	Percent Within 20%	Percent Within 30%
Overall		**2599**	**68%**	**82%**
40-80*	2.2-4.4	360	51%	----
>80-120	>4.4-6.7	482	60%	77%
>120-240	>6.7-13.3	1055	74%	90%
>240	>13.3	702	75%	89%

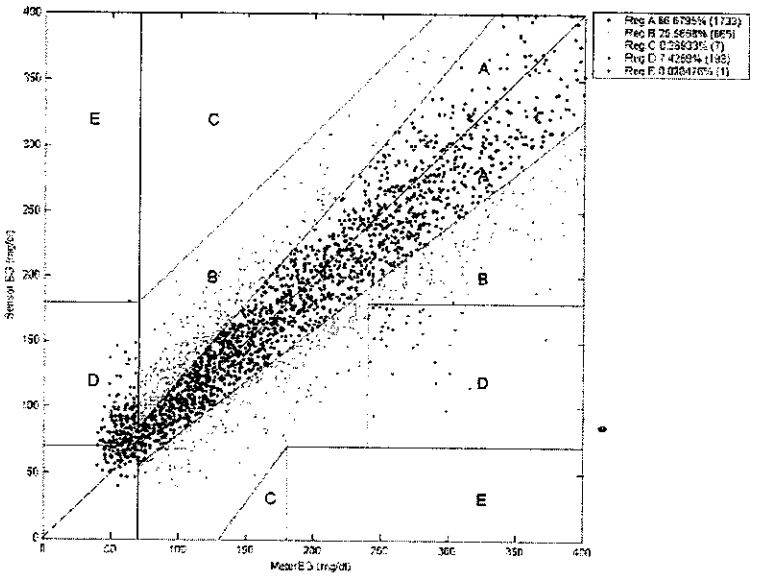
*For the Low glucose range, 40-80 mg/dl (2.2-4.4 mmol/l), the value shown is the percent within 20 mg/dl (1.1 mmol/l).

The Clarke Error Grid was used to assess the clinical relevance of the differences between the Guardian RT readings and the comparative blood glucose meter measurements. The Clarke Error Grid divides a correlation plot into 5 zones. See the following table.

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 following figure is a correlation plot of Guardian RT readings versus readings from the reference method, the blood glucose meter. It is overlaid with the Clarke Error Grid. The total number of paired data points is 2599.



The percent of Guardian RT readings in the above graph are presented in the table below 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.

Stratified Clarke Error Grid Analysis

Range of Comparative Glucose Readings (mg/dL)	Total count	Clarke Error Grid Zones					
		A + B	A	B	C	D	E
40-80	360 (13.9%)	201 (55.8%)	141 (39.2%)	60 (16.7%)	1 (0.3%)	157 (43.6%)	1 (0.3%)
81-120	482 (18.5%)	478 (99.2%)	287 (59.5%)	191 (39.6%)	4 (0.8%)	0 (0%)	0 (0%)
121-240	1055 (40.6%)	1053 (99.8%)	782 (74.1%)	271 (25.7%)	2 (0.2%)	0 (0%)	0 (0%)
240-400	702 (27.0%)	666 (94.9%)	523 (74.5%)	143 (20.4%)	0 (0%)	36 (5.1%)	0 (0%)
Overall	2599 (100.0%)	2398 (92.3%)	1733 (66.7%)	665 (25.6%)	7 (0.3%)	193 (7.4%)	1 (0.0%)

Low and High Alerts in Children and Adolescents

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 blood glucose meter. As a reference, with the Low Glucose Alert set at 70 mg/dl (3.8 mmol/l), 24% (59/244) 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 24% to 70% (see the following table).

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, 48% 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	24%	48%
80	4.4	52%	46%
90	5.0	70%	52%
100	5.6	85%	57%

* 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 blood glucose meter. As a reference, with the High Glucose Alert set at 250 mg/dl 13.8 mmol/l), 64% (404/632) 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 64% to 94% (see the following table).

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, 13.1% 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 following table 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	94%	40%
200	11.1	91%	36%
225	12.5	81%	21%
250	13.8	64%	13%

** 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.

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.

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.

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.

P

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

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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