Guardian® RT

Continuous Glucose Monitoring System

REF MMT-7900

User Guide

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The Guardian RT System is covered by the following Patent Nos: 5,390,671; 5,391,250; 5,568,806; 5,586,533; 5,586,553; 5,777,060; 5,779,665; 5,786,439; 5,851,197; 5,882,494; 5,954,643; 6,093,172; 6,248,067; 6,293,925; 6,368,141; 6,418,332; 6,424,847; 6,462,162; 6,520,326; 6,607,509; DES 433,755.

The Guardian RT System is covered by other/pending patents.

Medtronic
MINIMED

Medtronic MiniMed
Northridge, CA 91325
USA
800-646-4633 (800-MiniMed)
818-576-5555

E.U. Representative
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
31 (0) 45 566 8000
www.minimed.com

CE 0459/0976

℞ Only

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Chapter 5

Performance Characteristics

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

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

Although presentations to characterize performance of the Guardian RT are given below, there is no commonly accepted statistical approach for capturing the performance of continuous glucose monitors such as the Guardian RT. Performance may be best characterized by viewing graphs called time-elapsed plots. In these plots, the values from Guardian RT for one subject over time are overlaid with values at the same time from the glucose reference method. The three days of data for clinical trial subjects can be viewed at: **www.minimed.com.**

Time-elapsed plots are also available in a paper format by submitting a written request for "Guardian RT time-elapsed plots" with your name and address to:

attn: Marketing—Guardian RT Time-Elapsed Plots
Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325

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

Performance Results

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

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

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

Accuracy of Guardian RT Readings

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

Agreement between the matched pair was estimated by evaluating the difference between the Guardian RT reading and the YSI measurement. The difference between them was calculated as a percentage of the YSI (Mean Absolute Percent Difference). The bias was also calculated, and it is defined as the overall difference between the Guardian RT glucose values and the YSI values. The paired glucose measurements are summarized in Table 5.1.

Table 5.1

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 in Table 5.2

Table 5.2

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. See Table 5.3.

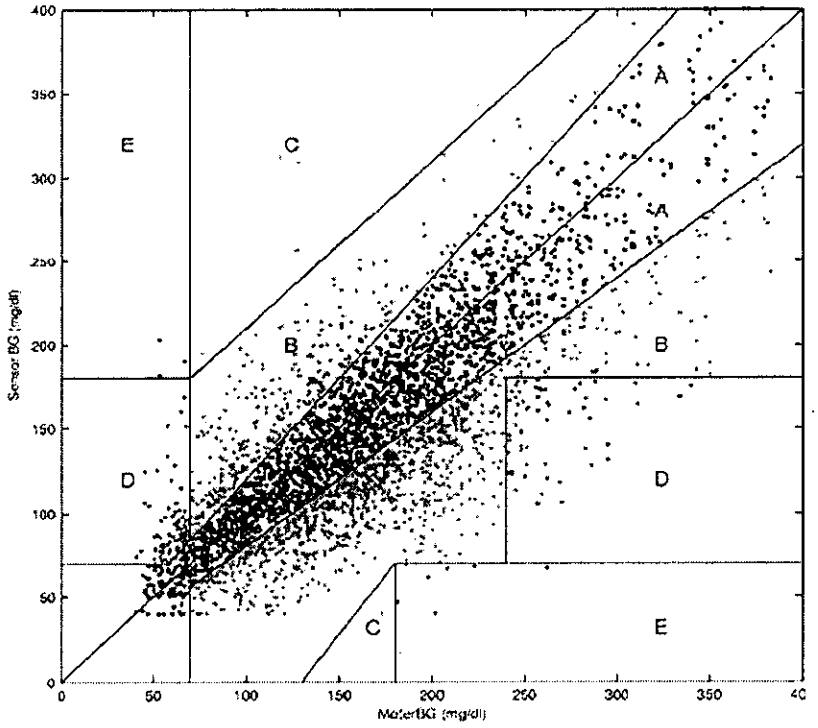
Results in zones A and B are considered clinically acceptable, while results in zones C, D, and E are potentially dangerous and, therefore, clinically significant errors. The Clarke Error Grid zones are labeled on the correlation plot.

Table 5.3

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

Figure 5.1 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.

Figure 5.1



The percent of Guardian RT readings in the above graph are presented in Table 5.4 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.

Table 5.4: Stratified Clarke Error Grid Analysis

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.

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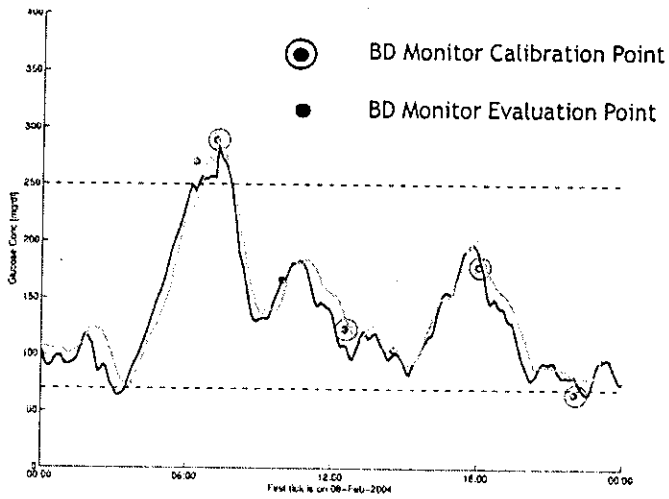
Precision of Guardian RT Readings

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%. **Figure 5.2 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.

Figure 5.2



In Figure 5.2, Guardian RT device #1 is represented by a solid line, and the Guardian RT device #2 by a light-gray line.

Low and High Alerts

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

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

The Low Glucose Alert

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

Sometimes the Guardian RT will alert when the blood glucose levels are not low. When the Guardian RT Low Alert was set at 70 mg/dl (3.9 mmol/l) in this study, 43% of the results were considered false alerts (actual blood glucose values are greater than 85 mg/dl (4.7 mmol/l)). This percentage may be exaggerated because blood glucose may be dropping when the Guardian RT alerts. Table 5.5 shows the percent of Low Glucose readings correctly identified by the Guardian RT for specific settings.

Table 5.5

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 rate.

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 Table 5.6).

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 5.6 shows the percent of High Glucose readings correctly identified by the Guardian RT for specific settings.

Table 5.6

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 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 rate.

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.

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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. Table 5.7 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.

Table 5.7

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 Table 5.8 below. Both data sets are pooled together in this data.

Table 5.8: Performance As a Function of Sensor-Insertion Time

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 (Table 5.9), and the percentage of readings within 20% and 30% of YSI readings from 81-120 mg/dl (Table 5.10), was analyzed according to time after Sensor insertion and according to the glucose-concentration range (as determined by the YSI analyzer).

Table 5.9

	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%

Table 5.10

	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.

Affects 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.

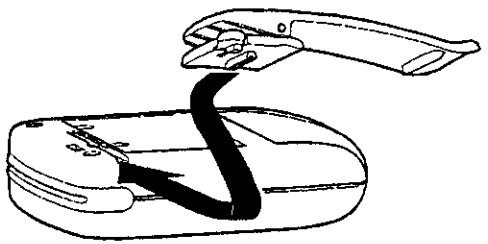
Belt Clip

The Belt Clip is used to attach the Monitor to a belt or to clothing.

Installation

The Belt Clip is attached to the back of the Monitor by sliding the triangular-shaped ridge on the back of the clip into a groove on the back of the Monitor. Push the clip until it stops and clicks into place. (See Figure 6.1.)

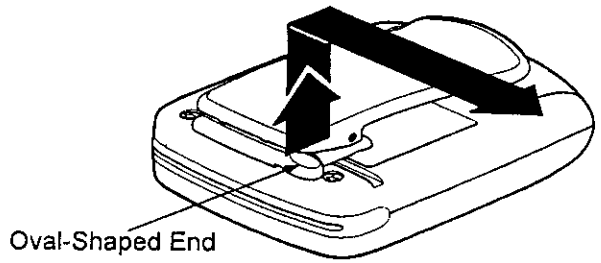
Figure 6.1



Removal

Using your finger, lift up on the oval shaped end of the Belt Clip. Gently slide the clip out of its groove. (See Figure 6.2.)

Figure 6.2



Leather Case

The Leather Case helps protect the Monitor against moisture, dirt, debris and electrostatic discharge.

Protection from Water

Although the Transmitter and Sensor are water resistant, repeated direct contact with water or other liquids should be avoided.

- The Monitor should never be placed under water.
- The Monitor should always be set in a dry place before showering, bathing or swimming.
- Any moisture that comes in contact with the Monitor should be dried with a soft towel.
- It is possible to shower, bathe and swim with the Sensor and Transmitter. However, please ensure that:
    - The occlusive dressing covering the Sensor and Transmitter connector is tightly attached to the skin.
    - You avoid submerging the Sensor in hot water, as this might significantly reduce its life.

Protection from Impact

The Monitor has been designed to be rugged and resistant to wear during everyday use. However, users should avoid rough sports or other activities that could damage the Monitor, the Transmitter, or the Sensor.

- The Monitor should be protected from mechanical damage, such as a fall or impact. If the Monitor is dropped, check for damage before using.
- The Monitor should be placed inside the leather case when it is worn. The case will absorb many of the bumps and scratches from sharp objects during everyday use.
- During exercise, if an alarm is triggered, you should stop exercising. Follow the directions in *Chapter 4: Troubleshooting and Alarms.*

Protection from High and Low Temperatures

The Monitor was designed to operate in a temperature range of 0 to +50 degrees Celsius (+32 to +122 degrees Fahrenheit).

- If outside during freezing weather, the Monitor should be kept underneath clothing to keep it warm.
- Avoid using or storing the Monitor in any environment where temperatures would be expected to rise above +50 degrees Celsius (+122 degrees Fahrenheit). This may include in a car on a hot summer day, or near a fire or other radiant heat source.
- Do not steam sterilize or autoclave the Monitor.

Cleaning the Monitor

1. Use only a damp cloth and mild detergent mixed with water to clean the outside of your Monitor.
2. Wipe excess soap from the Monitor with a clean, damp cloth.
3. Dry with a separate clean cloth.
4. Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your Monitor.
5. Keep the reservoir and battery compartments dry and away from moisture.
6. Do not use any lubricants with your Monitor.
7. Disinfect the Monitor by wiping the outside with an isopropyl alcohol wipe.

Cleaning the Transmitter

For single-patient use

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. Do not wet the inside of the connector.

CAUTION: **Do not place the Transmitter into the liquid soap solution.**

3. Hold by the Transmitter end and rinse the Transmitter under warm tap water. Be careful not to get the inside of the connector wet.
4. Using an antibacterial hand sanitizer (readily available at your local drugstore) on a clean, dry cloth, wipe down the Transmitter, cable and connector. 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.

For multiple-patient use

1. Wash your hands thoroughly.
2. Dampen a clean cloth with a mild liquid soap solution.

CAUTION: Do not place the Transmitter into the liquid soap solution.

3. Wipe the outside of the Transmitter, cable, and connector. Make sure the inside of the connector does not get wet.
4. Hold by the Transmitter end and rinse the Transmitter under warm tap water. Be careful not to get the inside of the connector wet.
5. Apply 3-4 drops of a quaternary ammonium compound disinfectant (e.g., CaviCide®) on a clean dry cloth. Wipe the Transmitter, cable, and connector, making sure the inside of the connector does not get wet.
6. Holding it by the Transmitter end, rinse the transmitter with 70% Isopropyl alcohol, being careful not to get the inside of the connector wet.
7. Place the Transmitter on a clean, dry, non-shedding cloth and allow to air dry.
8. Once the Transmitter is dry, place it in a sealed bag, labeled with the cleaning date. (See the example below.)
9. If there is any blood inside the connector, the Transmitter must be disposed of. Cut off the connector portion and discard in a Sharps or other medical waste container. Discard the Transmitter portion according to the local regulations for battery disposal (non-incineration).

CAUTION: It is important to NOT discard the Transmitter portion in a medical waste container or otherwise subject it to incineration. The Transmitter contains batteries which may explode upon incineration.

Example: Multiple-use cleaning label

Device:
Date:
Method of Decontamination
Wash:
Disinfectant:

Cleaning the Sen-serter

For single-patient use

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

For multiple-patient use

1. Dampen a clean cloth with mild liquid soap and warm water, and wipe the Sen-serter.
2. Rinse with warm tap water.
3. Apply 3-4 drops of quaternary ammonium compound disinfectant (e.g., CaviCide®) on a clean, dry cloth. Wipe down the sen-serter.
4. Using 70 percent isopropyl alcohol, or isopropyl alcohol wipes, wipe down the sen-serter.
5. Place the sen-serter on a clean dry cloth and allow to air dry.
6. Once the sen-serter is dry, place it in a sealed bag, labeled with the cleaning date. (See example below.)

Example: Multiple-use cleaning label

Device:
Date:
Method of Decontamination
Wash:
Disinfectant:

Interference from Electrical Equipment

The Monitor is designed to meet all IEC standards for electromagnetic interference. The Monitor should withstand common electrostatic and electromagnetic interference. However, using the Monitor in close distance to strong electromagnetic sources, such as MRIs, X-rays, CT scans, television sets, cell phones, cordless phones, hand-held and mobile two-way radios, radio transmitters, high-voltage power lines, and store anti-theft security devices, is not recommended.

- Keep the Monitor in its leather case to protect against electrostatic discharges that are common in cold and dry climates.
- Do not place the Monitor in direct contact with X-rays or other medical or industrial imaging equipment. If a user is scheduled to have an X-ray, CT or MRI scan, take off Sensor, Transmitter and Monitor. Put in new Sensor after procedure.
- The Monitor is designed to withstand interference from airport X-rays or metal detectors and store anti-theft security devices. Nevertheless, always check the Monitor after it has passed through these devices to make sure the system is still synchronized and working properly.
- The Monitor listens for radio signals from the Transmitter via a 418 MHz (U.S. and Canada) or 433.92 MHz (International) radio receiver with a 400 KHz bandwidth. This receiver can be interfered with by other electrical/electronic equipment, even if that equipment complies with IEC or FCC standards. This interference may result in a C76/No Sync alarm.

Ordering Supplies

Medtronic MiniMed stocks a wide range of Guardian RT supplies, including Glucose Sensors, Transmitters, leather cases, belt clips, dressings, and other accessories. (See Tables 6.1 and 6.2.) U.S. and Canadian customers, place orders by calling 800-MINIMED (800-646-4633) or 818-576-5555. All other international customers please contact your local sales office. Orders can be placed online at *www.minimed.com*.

Table 6.1: Products

Product	Model Number
Glucose Sensor	MMT-7002
Monitor	MMT-7901
Transmitter	MMT-7700
Guardian Solutions Software	MMT-7315

Table 6.2: Accessories

Accessory	Model Number
Com-Station	MMT-7301
Sen-serter®	MMT-7500
Belt Clip	MMT-7402
Test Plug	MMT-7400
Leather Case	MMT-7401
I.V. Prep	MMT-173
IV3000®	MMT-174
Polyskin®	MMT-134
Detachol®	HMS-051304
Screwdriver	ACC-129
Transmitter Adhesive Pads	MMT-7006
Shower-Pak	MMT-117

Product Specifications

The following tables list Monitor, Test Plug and Transmitter performance specifications. (See Tables 6.3, 6.4 and 6.5.)

Table 6.3: Monitor

Component	Performance Specification
Glucose Measurement Range	40-400 mg/dl (2.2-22.2 mmol/l)
Typical Operating Range	6 feet (2 meters)
Display	Liquid crystal display (LCD)
Display Window	Length: 1.40 inches (3.56 centimeters) Height: 0.70 inches (1.78 centimeters)
Dimensions	Length: 3.56 inches (9.04 centimeters) Height: 2.77 inches (7.04 centimeters) Width: 0.86 inches (2.18 centimeters)
Weight	4 ounces (114 grams)
Limited Warranty	1 year
System Memory	Stores up to 21 days of data
Alarms	Audible (50 decibels @ 1 meter) Vibrate (similar to the vibrational power of a personal pager)
Backlight	Electroluminescent (EL) Panel
Power Supply	2 AAA alkaline batteries

Table 6.3: Monitor

Component	Performance Specification
Battery Life	Exceeds one month under anticipated normal use
Case Material	High impact ABS/polycarbonate composite
Safety Checks	Diagnostic signals verify proper Sensor and measurement system operation
Operating Conditions	Temperature: 0 to +50 degrees Celsius (+32 to +122 degrees Fahrenheit). Relative Humidity: 10% to 95% with no condensation
Storage Conditions	Temperature: -20 to +55 degrees Celsius (-4 to +131 degrees Fahrenheit) Relative Humidity: 10% to 100% with condensation
Approved Cleaners	A mild household liquid detergent diluted with water, a quaternary ammonia solution, or isopropyl alcohol on a wipe.
Approved Disinfectants	10% bleach solution, 3% hydrogen peroxide solution, or 70% isopropyl alcohol.

Table 6.4: Test Plug

Component	Performance Specifications
Operating Conditions	Temperature: 0 to +50 degrees Celsius (+32 to +122 degrees Fahrenheit) Relative Humidity: 15% to 95% with no condensation
Storage Conditions	Temperature: -20 to +55 degrees Celsius (-4 to +131 degrees Fahrenheit) Relative Humidity: 10% to 100% with condensation
Approved Cleaners	A mild household liquid detergent diluted with water, a quaternary ammonia solution, or isopropyl alcohol on a wipe. (DO NOT place liquids into either connector.)
Approved Disinfectants	Tap water, 10% bleach solution, 3% hydrogen peroxide solution, 70% isopropyl alcohol.

Table 6.5: Transmitter

Component	Performance Specifications
Biocompatibility	Complies with ISO 10993-1 for long-term body contact
Operating Conditions	Temperature: 0 to +50 degrees Celsius (+32 to +122 degrees Fahrenheit) Relative Humidity: 10% to 95% with no condensation
Transmitter Life	1 year under anticipated normal use conditions
Transmitter Frequency	418 MHz (U.S. and Canada) or 433.92 MHz (International), 1mWerp, 20k5A1D Modulation

Table 6.5: Transmitter

Storage Conditions	Temperature: -20 to +55 degrees Celsius (-4 to +131 degrees Fahrenheit) Relative Humidity: 10% to 100% with condensation
Approved Cleaners	A mild household liquid detergent diluted with water, a quaternary ammonia solution, or isopropyl alcohol on a wipe. (DO NOT place liquids into either connector.)
Approved Disinfectants	Tap water, 10% bleach solution, 3% hydrogen peroxide solution, 70% isopropyl alcohol.

FCC Notice for the Monitor

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

- Reposition the Monitor and/or Transmitter.
- Increase the distance between the Transmitter and Monitor from the device that is receiving/sending interference.
- U.S. and Canadian customers, please contact the Product Help Line at 800-MINIMED (800-646-4633) or 818-576-5555. All other international customers please contact your local sales office.

FCC Notice for the Transmitter

This device complies with Part 15 of the U.S. Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Icon Table

Table 6.6: Icons

	Attention: See Instructions for Use
	Date of Manufacture (year - month)
$R_{X\ Only}$	CAUTION: U.S. law restricts the Guardian RT and system components to sale by or on the order of a physician.
SN	Serial Number
	Storage Temperature Range
	Type BF Device (Protection from electrical shock)
	On/Off
	Backlight
LOT	Batch Number
REF	Catalogue Number
	Fragile Product
	Protect Against Moisture
	Open Here
	Recycling Symbol
STERILE R	Sterilized Using Irradiation
	Do Not Re-Use; Single use only
	Radio Communication

Table 6.6: Icons

CE 0459	CE Mark By Notified Body As a Medical Device
CE 0459/0976	CE Mark With a Radio Transmitter Under The R&TTE1999/5/EC Directives
IPX1	Monitor: Protected Against the Effects of Vertically Falling Water Drops.
IPX8	Transmitter and Sensor: Protected Against the Effects of Continuous Immersion in Water.

Fixed Elements Table

Table 6.7: Fixed Elements

CAL	Displayed as a reminder or warning to the user to enter a BG value for glucose sensor calibration.
GLUCOSE	Displayed on screens related to glucose readings. Not used on Alarm History Screen but on the Alarm History Selection screen.
GLUCOSE HIST	Displayed on screens used for viewing or clearing glucose history values. Not used on the NOW screen.
GLUCOSE LIMIT	Displayed on screens showing hypoglycemia or hyperglycemia alarm limits.
GLUCOSE SENSOR	Displayed on screens showing raw glucose Sensor values or status.
SET	Displayed during parameter value selection.
SET GLUCOSE	Displayed when setting glucose measurement unit (mg/dl or mmol/l).
SET GLUCOSE LIMIT	Displayed when setting glucose limit values (hypoglycemia/hyperglycemia setting).

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Electromagnetic Compatibility Compliance Information

In accordance with IEC 60601-1-2, the following information on electromagnetic compatibility compliance has been provided. Also refer to the section "Interference from Electrical Equipment" in *Chapter 6: System Maintenance.*

Table A1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Guardian RT is intended for use in the electromagnetic environment specified below. The user of the Guardian RT should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Guardian RT Monitor uses RF energy only for its internal function. 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 RT is suitable for use in all establishments, including domestic establishments, and those directly connected to the public, low-voltage, power-supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	Not Applicable
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not Applicable	Not Applicable

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Table A2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Guardian RT is intended for use in the electromagnetic environment specified below. The user of the Guardian RT 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 ± 8 kV air	> ± 8 kV > ± 30 kV air	Typical commercial, hospital, or home environment. Synthetic materials may be present. The relative humidity may be as low as 10%.
Electrical Fast Transient/Burst IEC 61000-4-4	Not Applicable	Not Applicable	Not Applicable
Surge IEC 61000-4-5	Not Applicable	Not Applicable	Not Applicable
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	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.

Table A2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Guardian RT is intended for use in the electromagnetic environment specified below. The user of the Guardian RT should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	Not Applicable 3 V/m 80 MHz - 2.5 GHz	Not Applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Guardian RT than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** Not Applicable d = 1.2 x square root[P] 80 - 800 MHz d = 2.3 x square root[P] 800 MHz - 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: ((•))

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
Note 1: At 80 MHz and 800 MHz the higher frequency range applies. *Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*
[a] *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Guardian RT is used exceeds the applicable RF compliance level above, the Guardian RT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Guardian.*

Table A3

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Guardian RT

The Guardian RT is intended for use in an electromagnetic environment in which RF disturbances are controlled. The user of the Guardian RT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Guardian RT as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)	
	80 MHz - 800 MHz d = 1.2 x square root [P]	800 MHz - 2.5 GHz d = 2.3 x square root [P]
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

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

Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Glossary

Alarm - An audible tone or physical vibration that lets the user know of an important event.

Calibration - The process of adjusting how the Guardian RT turns electronic signals from the Sensor into glucose values. The Sensor is calibrated by entering fingerstick meter values into the Guardian RT memory.

Com-Station - A device that lets a personal computer (PC) communicate with the Guardian RT to download data.

Diabetes Mellitus - A medical condition in which the body cannot properly process glucose.

Download - The process of sending data from one electronic device to another. The Guardian RT can download glucose data to a PC (personal computer).

False Alert - When the Guardian RT alarms for low or high glucose, even though the alert is not confirmed by a blood glucose meter value beyond the limit.

Fingerstick Glucose Meter Measurement - Blood glucose measurement by which the tip of a finger is pricked, a drop of blood is placed on a test strip, and the strip is placed into a meter that reports blood glucose.

Glucose - A type of sugar found in the blood, and it is the chief energy source for living organisms.

Glucose Sensor - A device that can monitor glucose levels in the body by sending out electronic signals proportional to those levels.

Guardian RT Monitor - A medical device developed by Medtronic MiniMed that continuously monitors glucose levels and sends out high and low glucose alerts.

Hyperglycemia - Abnormally high levels of glucose in the blood.

Hypoglycemia - Abnormally low levels of glucose in the blood.

Infection - A possible side effect of medical-device usage where bacteria may cause symptoms of local pain, redness, tenderness and swelling.

Initialization (INIT) - The process of stabilizing the electronic signal s sent out by the Sensor after insertion.

Insulin - A hormone that controls glucose levels in the body.

Interstitial Fluid - Fluid found just under the skin into which a Sensor is inserted to measure glucose levels.

ISIG - Electrical current that the Sensor sends to the Guardian, measured in nanoamperes (nA).

Memory - A component of the Guardian RT that stores Sensor data and programming information.

Sen-serter - Automatic device used to insert the glucose Sensor.

Test Plug - A device that can troubleshoot problems with the Monitor, Sensor or Transmitter.

Transmitter - A device that receives and processes signals from the Glucose Sensor and sends them to the Monitor.

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