

Telemetered Glucose Monitoring System

User Manual

PRELIMINARY DRAFT

MMT-7600
GMP9190066-011
July 25, 2000
Revision 4X



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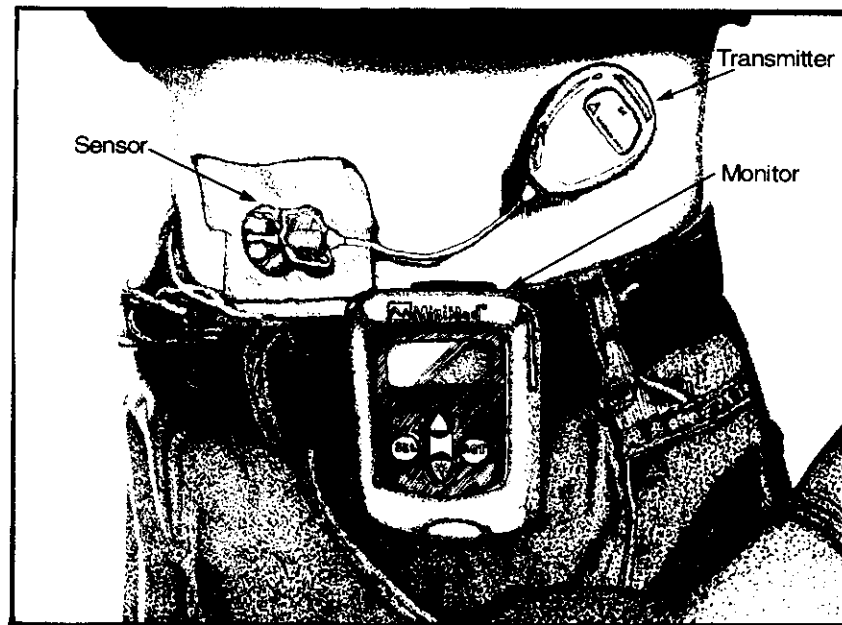
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CHAPTER 1

Before You Begin

Thank you for using the MiniMed Telemetered Glucose Monitoring System (TGMS). You will need this manual to set-up and operate your TGMS.

The TGMS is comprised of the following system components: The Monitor, the Transmitter, and the Sensor.



MiniMed help line

MiniMed provides a 24 hour help line for assistance in the United States. The toll free number is: 800.826.2099. The help line is staffed with Clinical Service personnel, who are trained in the set-up and operation of the Monitor and are able to answer Monitor-related questions. When calling, have the Monitor and this manual with you.

Department	Telephone Number
Clinical Services Help Line	800.826.2099 818.678.5555
Main Number	800.933.3322
Sales Order	800.843.6687 818.362.5958
Sales Order (Fax)	888.268.0200
MiniMed web site	www.minimed.com

For your records

The Monitor serial number is located on the back of your Monitor. Please enter the serial number and purchase date in the table below.

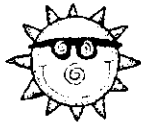
Serial Number	Purchase Date

Availability

U.S. law restricts the TGMS and system components to sale by or on the order of a physician. The TGMS and its components are available through MiniMed and from authorized MiniMed distributors.

Conventions

The following paragraphs explain the conventions used in this manual to describe the TGMS.



This symbol indicates an important note.



This symbol indicates a Caution statement.

- ☒ Bolded letters in all capital, such as **ACT**, indicate a button on the actual Monitor.
- ☒ Words that are in all capital letters, such as **EVENT**, indicate a word on the Monitor screen.

Unpack the TGMS

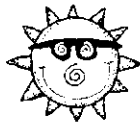
Carefully unpack the TGMS, saving all packing materials for possible future use. The original packing materials provide the safest way to ship the Monitor should factory maintenance or repairs be necessary. If any part of the system appears damaged in shipment, do not attempt to use it. Call the MiniMed Clinical Services Help Line immediately at 800.826.2099.

Check to make sure that the shipping box contains all of the following items:

- ☒ Monitor (1 each)
- ☒ Transmitter (1 each)
- ☒ AAA Batteries (2 each)
- ☒ Belt Clip (1 each)
- ☒ Registration Card (1 each)

Registration and warranty

- ☒ MiniMed Standard Warranty Card (1 each)
- ☒ Test Plug (1 each)
- ☒ Leather Case (1 each)
- ☒ Screwdriver (1 each)



Glucose Sensors, MiniMed Solutions Software, Com-Stations, Shower Paks, and medical tapes are sold separately.

Registration and warranty

Please fill out the registration card enclosed with the Monitor and mail it to MiniMed, so we can activate your warranty. If you choose to add your name to our mailing list, you will receive MiniMed newsletters along with important product update information. Please read the enclosed terms of the warranty carefully, as it specifies what repairs are covered during the warranty period. Call MiniMed Sales and Information Services at 800.843.6687 if you did not receive a registration card or terms of the warranty.

CHAPTER 2 **User Safety**

Indications for use

The TGMS is indicated for continuous or periodic monitoring of interstitial glucose values in persons with diabetes mellitus. Glucose values collected by the TGMS can be viewed real-time on the Monitor. The TGMS also stores at least 14 days of data that can be downloaded to a personal computer using a MiniMed Com-station and MiniMed TGMS Solutions 7315 to identify patterns and optimize diabetes management.

The TGMS is especially useful for the monitoring of diabetic patients at risk of developing hypoglycemia or hyperglycemia. The TGMS contains a settable feature that triggers an alarm if the real-time glucose value and the alarm trigger is exceeded. User should confirm symptoms of hypoglycemia and hyperglycemia or alarms with a FDA cleared home glucose meter. (See page 8 for detailed description of symptoms.)

Contraindications

Successful operation of the TGMS requires some visual and auditory acuity. Use of the TGMS is not recommended for persons whose impaired vision or hearing does not allow full recognition of the Monitor signals and alarms.

Warnings

- ☒ Operation of the TGMS requires the insertion of a Sensor into the skin. Infection, inflammation, or bleeding at the Sensor insertion location are possible risks of glucose sensing. The Sensor should be removed if redness, pain, tenderness, unexplained fever, or swelling develop at the insertion location.
- ☒ You should confirm symptoms of hypoglycemia and hyperglycemia or alarms with a FDA cleared home glucose meter.
- ☒ Calibration of the TGMS is accomplished using FDA cleared home glucose meter values, entered by the user at least once a day. At least twice a day is recommended.
- ☒ Some persons may be allergic to glucose oxidase or bovine serum albumin (BSA). The Sensor is manufactured using these two biological reagents.

Precautions

- ☒ You should be trained to program and operate the Monitor, and respond to alarm conditions prior to attempted use of the system.
- ☒ Always wash hands with soap and water before opening the Sensor package. After opening the package, avoid touching any Sensor surfaces that will come in contact with the body (i.e., sensor, needle, connector adhesive surfaces and bandage).
- ☒ If you also wear an insulin pump, make sure that the Sensor insertion location is at least two (2) inches away from the insulin infusion location. Users who inject insulin should administer injections at least three (3) inches away from the Sensor insertion location.

- ☒ The Sensor is sterile in its unopened, undamaged package. Do not use any Sensor if its sterile package has been previously opened or damaged. Always inspect packaging for damage prior to use.
- ☒ Before inserting the Sensor, always aggressively clean the skin at the sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol.
- ☒ After inserting the Sensor and attaching the Transmitter, dress the sensor site with occlusive dressing.
- ☒ After Sensor insertion, check the insertion site often for redness, bleeding, pain, tenderness, and swelling, especially before going to bed in the evening and after waking up in the morning.
- ☒ Establish a rotation schedule for choosing each new Transmitter and Sensor location. Avoid sites that are constrained by clothing, accessories or subjected to rigorous movement during exercise.
- ☒ Monitors should be set aside or placed in Shower-Paks™ prior to engaging in activities in which the monitor would be expected to get wet. Do not submerge the Monitor.
- ☒ Contact sports or other activities which may damage the Monitor should be avoided. Prior to exercising, TGMS users should make sure that the Sensor, Transmitter, and Monitor are securely fastened to their bodies.
- ☒ If the Monitor shows a NO POWER alarm on the display for more than one hour, the setup information in the memory will be lost; however, stored glucose data will be unaffected. If this occurs, all program information will return to the manufacturer's default settings after the batteries are replaced. Users must first reprogram the Monitor and then initialize and calibrate the Sensor before returning to normal operation.
- ☒ Although the TGMS is tested and complies with the applicable standards, the use of the TGMS in close proximity to strong electromagnetic sources such as medical imaging equipment, television transmitters, high voltage power lines, or high power radio transmitters is not recommended.
- ☒ Keep the Monitor in its leather case to protect against electrostatic discharges that are common in cold and dry climates.

Symptoms of hypoglycemia

Hypoglycemia (too little glucose in the blood) is a frequent symptom of persons with diabetes mellitus. Never ignore these symptoms, no matter how mild they are, even if the system does not indicate hypoglycemia. If you have any of the following symptoms, treat per the advice of your physician.

The symptoms are: sweating, dizziness, palpitation, tremor, hunger, anxiety, nausea, shivering, confusion, headache, speech impairment, drowsiness, weakness, and blurred vision.

Symptoms of hyperglycemia

Hyperglycemia (too much glucose in the blood) may develop if you have do not have enough insulin. Never ignore these symptoms, no matter how mild they are, even if the system does not indicate hyperglycemia.. If you have any of the following symptoms, treat per the advice of your physician.

The symptoms are: a drowsy feeling, flushed face, thirst, loss of appetite, and fruity odor to the breath.

Adverse reactions

Operation of the TGMS requires the insertion of a sensor into the skin. Infection, inflammation or bleeding at the sensor insertion location are possible risks of sensor use. The sensor should be removed if redness, pain, tenderness, or swelling develop at the insertion location.

FCC notice for the monitor and 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 and
- (2) This device must accept any interference received, including interference that may cause undesirable operation.

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

- ☒ Reorient or relocate the monitor and/or Transmitter
- ☒ Increase the separation between the Transmitter and Monitor from the device that is receiving/sending interference
- ☒ Consult the MiniMed Clinical Services Help Line at 1.800.826.2099 if you have any questions.



CAUTION:

Any changes or modifications to the devices not expressly approved by MiniMed could void your ability to operate the equipment.

How Does the System Work?

The TGMS takes periodic measurements of your glucose levels in interstitial fluid. Interstitial fluids, under most circumstances, closely approximate blood glucose levels. The three system components that are used to do this are: the Monitor, the Transmitter, and the Sensor.

Monitor

The Monitor is the data collection unit for the Sensor. The Transmitter sends radio signals to the Monitor which interprets and stores the information. These radio signals are received, and stored, approximately every five minutes from the Transmitter. The Monitor and Transmitter need to be kept within 3 to 4 meters (10 to 15 feet) of each other to make sure that communication is not interrupted.

The Monitor is calibrated by entering a glucose value manually. These glucose values are from the normal fingerstick method using a blood glucose meter. A single measurement is used to calibrate the Monitor.

A minimum of one blood glucose value must be entered within a 24 hour period into the Monitor. For optimal performance, it is recommended that a glucose value is entered every 12 hours. If a glucose value is not entered at the 12 hour mark, the Monitor will beep

and the letters CAL will appear on the screen. The CAL reminder will remain until a calibration value has been entered. If a blood glucose value is not entered for 24 hours, an alarm is generated.

Control buttons

The Monitor operation is controlled by pressing five (5) buttons. To program and operate the Monitor, always press the required buttons slowly and firmly. The word “press” in the instructions implies “press and release,” unless otherwise specified. A slight snap can be felt when a button is pressed correctly. Refer to the following figure for button locations.

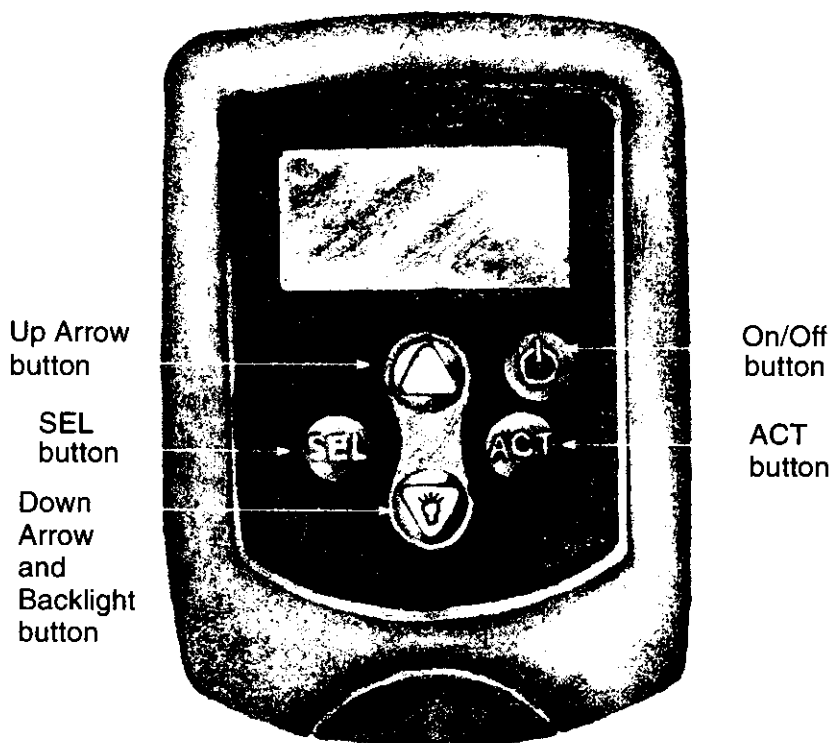
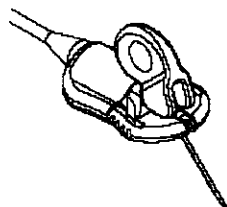


TABLE 1. Button Functions

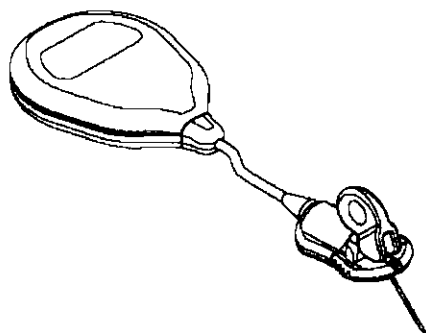
 <i>On/Off</i>	Turns the Monitor on or off.
 <i>Up and Down</i>	Changes the preset values in the Monitor. Pressing the arrows once will select the next highest or lowest value. Holding down either button will scroll through the list of the preset values. Holding down either button for more than 5 seconds will accelerate the speed of the scrolling. When the desired value is displayed, it will blink until it is confirmed by pressing ACT .
 <i>Backlight</i>	From the Normal Operation screen, press the Backlight button to turn On or Off the illumination of the screen, allowing operation at night or in dim lighting conditions. The light will stay on until approximately 15 seconds after the last button press.
ACT <i>Activate</i>	The ACT button allows changes to be made when programming the Monitor with new information, saving information to Monitor memory, and acknowledging alarms.
SEL <i>Select</i>	The SEL button steps through each of the screens. Press SEL and then ACT acknowledges an alarm.

Sensor



The Sensor generates a signal from the chemical reaction in the interstitial fluid at the insertion site. This signal is processed by the Transmitter, which in turn transmits the signals to the Monitor which interprets the data and displays the current glucose value on the History screen.

Transmitter



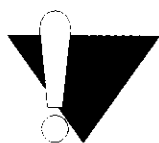
The Transmitter is a small oval disk which connects to the Sensor and is adhered to the skin with a medical dressing. The Transmitter contains a battery, sensor electronics, and a radio frequency (RF) transmitter. Attaching the Sensor to the Transmitter automatically initializes the Sensor and begins to periodically transmit glucose data to the Monitor using a radio signal. When the Sensor is disconnected, the Transmitter is turned off and stops transmitting data.

Install the batteries

The Monitor uses two (2) AAA alkaline batteries. Under normal use conditions, these batteries will provide power to the Monitor for up to two (2) months.

Batteries should be installed immediately after unpacking the Monitor. Replacement of batteries more frequently than every two months is recommended, to avoid LOW BATT or NO POWER alarms.

1. Batteries are included when receiving a system from MiniMed, but not installed. If replacing the old batteries, obtain two new AAA alkaline batteries.
2. Press the  On/Off button and then ACT to confirm, to turn off the Monitor.



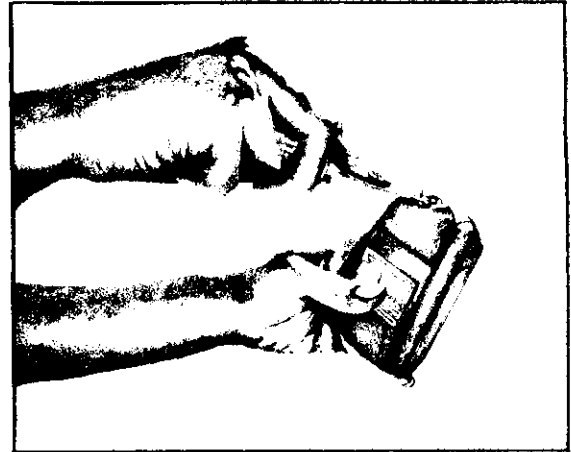
CAUTION

Always turn off the Monitor before changing the battery or the memory inside the Monitor could be damaged.

3. Locate the battery compartment at the lower back side of the Monitor.

4. Remove the belt clip per the procedure on the following page.

5. With the screwdriver provided, loosen the screw holding the battery compartment lid to the Monitor. Do not attempt to fully remove the screw; it is intended to remain attached to the lid.



6. Remove the battery compartment lid.

7. If you are changing batteries, remove the old batteries by pulling on the ribbon to unseat and then pull out the batteries with your fingers



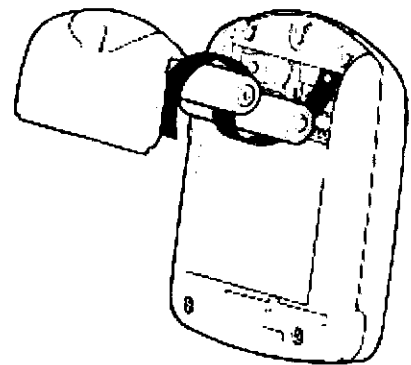
CAUTION

The batteries, if installed opposite of the polarity diagram, will become very warm. The Monitor will not operate. Use caution when reorienting the batteries to the correct positions.

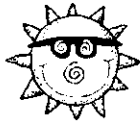
8. Install two new batteries, taking care to align the batteries correctly per the diagram on the bottom of the compartment.

9. Orient the battery strap around the new batteries as shown on the diagram on the inside of the battery compartment lid.

10. Place the battery compartment lid back into place, taking care to align it properly against the compartment seal.



11. With the screwdriver, tighten the screw to seal the battery compartment and hold the lid in place. Do not over-tighten the lid.
12. Reinstall the belt clip.



After installing new batteries, time and date should be checked and adjusted if needed.

Accessories

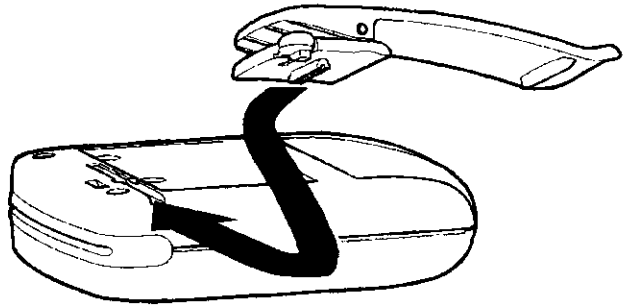
The following items also are in the shipping box with the Monitor. The belt clip ships installed on the Monitor.

Belt clip

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

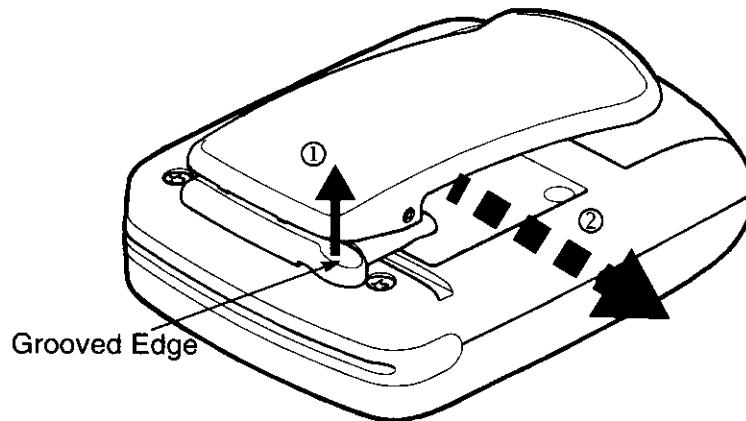
Installation

The Belt Clip is attached to the back of the Monitor by sliding the triangular-shaped ridge on the back of the clip into its corresponding groove on the back of the Monitor. Push the clip until it stops and clicks into place.



Removal

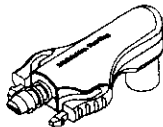
Using your finger, lift up on the grooved edge of the Belt Clip and then gently slide the clip out of its groove.



Leather case

The Leather Case is provided to help protect the Monitor against moisture, dirt, debris and electrostatic discharge.

Test plug



The Test Plug is used for troubleshooting the components of the TGMS (Sensor, Transmitter, and Monitor).

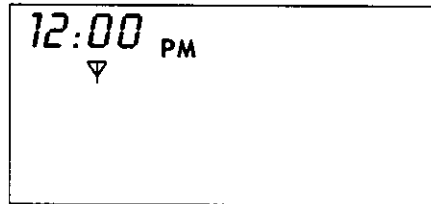
Turn the monitor on

Every time the Monitor is turned On, an automatic diagnostic test is performed on the Monitor. If a problem is detected during the test, you will receive an audible alarm and an error message. (Refer to Chapter 5: *Alarms and Troubleshooting*.)

1. Press the On/Off (⏻) button once.
2. The Monitor will beep and vibrate once, display the software version being used, and the time will appear in the upper left hand corner of the screen. This screen is referred to as the Normal Operation Screen.

Normal operation screen

The Normal Operation Screen for the Monitor shows the current time in the upper left-hand corner of the screen. The antenna icon indicates that the Monitor is synchronized with the Transmitter. This screen is displayed if no buttons have been pressed or no alarms have been activated.



When the Monitor screens are chosen using the **SEL** and **ACT** buttons, you have approximately 15 seconds to respond before the Monitor returns to the Normal Operation Screen. The Monitor will then return to the Normal Operation Screen, and you can then attempt to program the Monitor again.



If the ACT button has not yet been pressed, mistakes in programming often can be reversed by simply waiting about 15 seconds without pressing any buttons.

Turn the monitor off

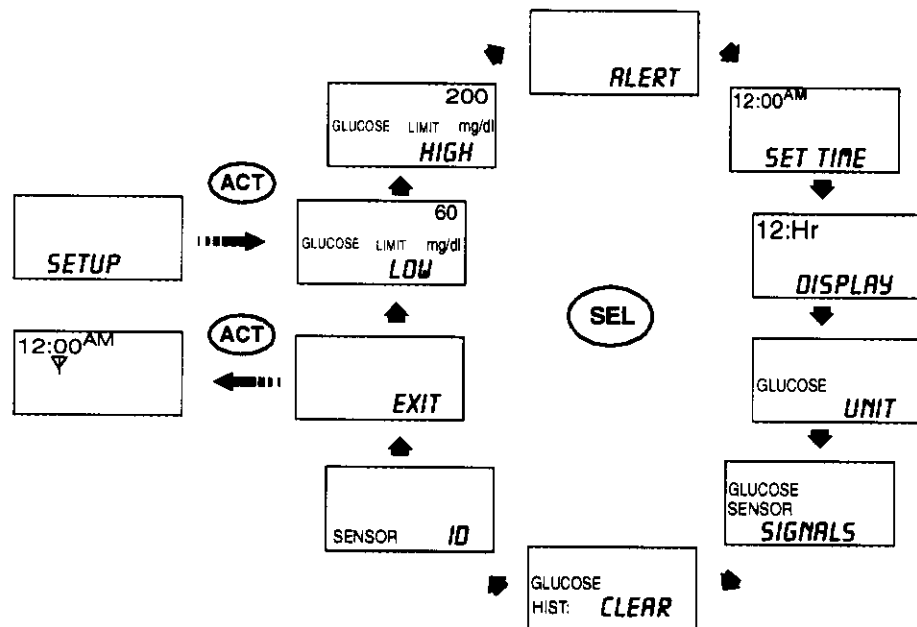
While the Monitor is off, the Sensor is ready to operate and previously recorded glucose data and set-up information will remain in Monitor memory. However, the operating and alarm functions of the Monitor will be disabled and no new glucose data will be recorded into memory.

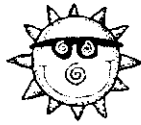
1. Press the **On/Off** (⏻) button.
2. The Monitor will beep and CONFIRM will blink on the screen.
3. Press the **ACT** button to confirm that you do wish to turn the Monitor off. (If you do not press the **ACT** button the Monitor will return to the Normal Operation screen.)
4. The screen will go blank.

Getting Started

Program your monitor

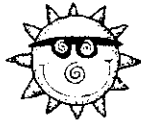
This section explains how to program your Monitor. There are nine (9) Setup screens to choose from. All of the Setup screens can be reached from the Normal Operation Screen, by pressing **SEL** until the SETUP screen appears, and then pressing **ACT**. After finding the first Setup screen, press the **SEL** button once to advance to the next Setup screen. The Setup screens are displayed in the following diagram:





Perform the following procedures in the order provided.

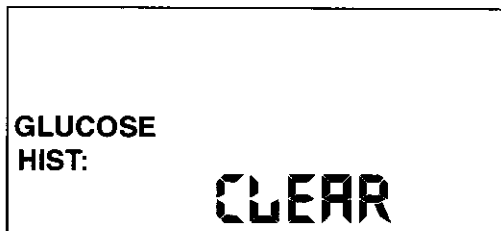
Clear the glucose history



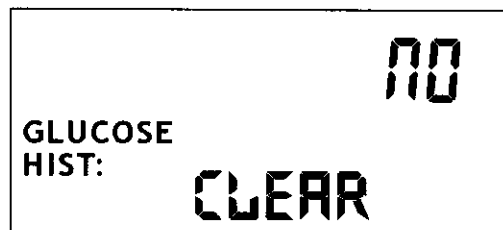
If there is data in the Monitor, that you wish to save, download the data using a Com-Station connected to a personal computer.

The Monitor glucose history should be cleared before use to ensure the Monitor memory is free of all unwanted information.

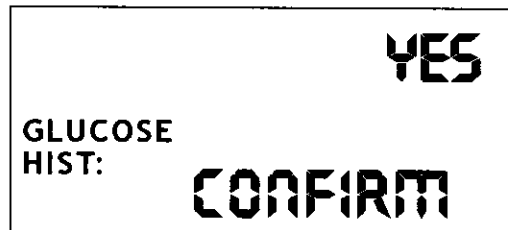
1. From the Normal Operation Screen, press the **SEL** button until the **SETUP** screen appears.
2. Press the **ACT** button once to access the Setup screens.
3. Press the **SEL** button until the **CLEAR** screen appears.



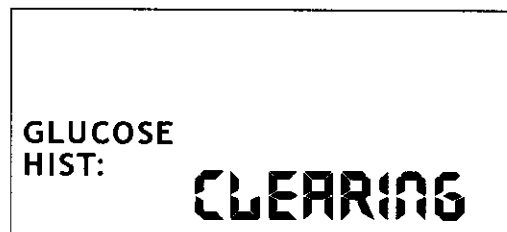
4. Press **ACT** once. The Monitor will beep, and the words **CLEAR** and **NO** will appear on the screen blinking.



5. Use the ▲ and ▼ buttons to select between YES and NO. Select YES to clear the Monitor memory.
6. With YES displayed on the screen, press **ACT** once. The Monitor will display YES with CONFIRM blinking.



7. Press **ACT** once. The Monitor will beep and the work **CLEARING** will be displayed for two to five seconds. The Monitor will then advance to the Sensor ID Screen. The memory will now be cleared.

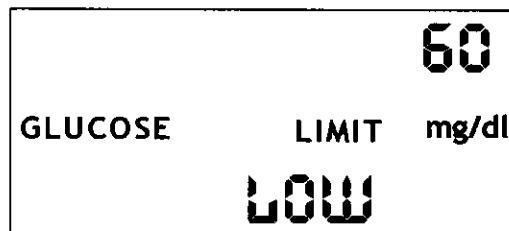


8. If NO is selected, the Monitor memory will NOT be cleared, and the Monitor will advance to the Sensor ID Screen.

Set hypoglycemia alarm

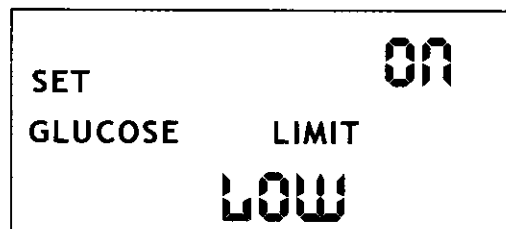
Enter the glucose value that will trigger a hypoglycemia alarm. For this feature to operate, you must select both ON, a value, and CONFIRM to save the value in memory.

1. From the Normal Operation Screen, press the **SEL** button until the **SETUP** screen appears.
2. Press the **ACT** button once to access the Setup screens.
3. Press the **SEL** key until the **LOW** screen appears.



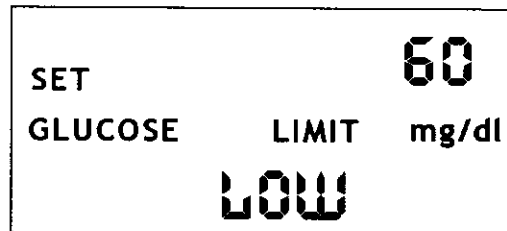
60
GLUCOSE LIMIT mg/dl
LOW

4. Press the **ACT** button and the following screen appears. ON is the default value and will be blinking.

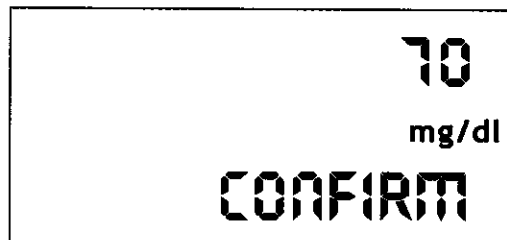


ON
SET
GLUCOSE LIMIT
LOW

5. Press the ▲ and ▼ buttons to select either ON or OFF. If you do not wish to use this feature, select OFF and the hypoglycemia alarm feature will be disabled.
6. Press the **ACT** button.
7. If ON is entered, the current value will begin blinking. If OFF is entered, go to step 10.



8. Use the ▲ and ▼ buttons to select the desired value to trigger a hypoglycemia alarm. The range for mg/dl units is 40 to 100. The range for mmol/l units is 2.2 to 5.6. The value 70 mg/dl has been entered in this example.

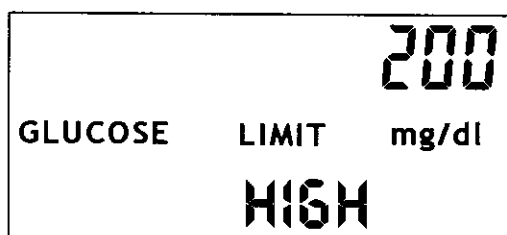


9. CONFIRM will appear blinking, press the **ACT** button to confirm the selected value. Pressing the **ACT** button will place you into the HIGH or hyperglycemia alarm setting screen.
10. Press the **ACT** button to CONFIRM OFF. Pressing the **ACT** button will place you into the HIGH or hypoglycemia alarm setting screen.

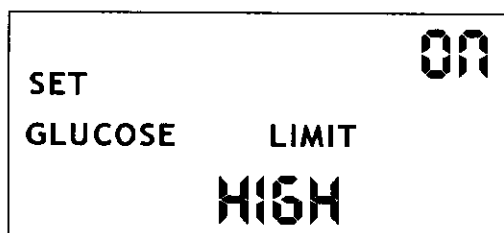
Set hyperglycemia alarm

Enter the glucose value that will trigger a hyperglycemia alarm. For this feature to operate, you must select both ON, a value, and CONFIRM to save the value in memory.

1. After pressing the **ACT** button to save the value for the Low alarm the **HIGH** screen appears.

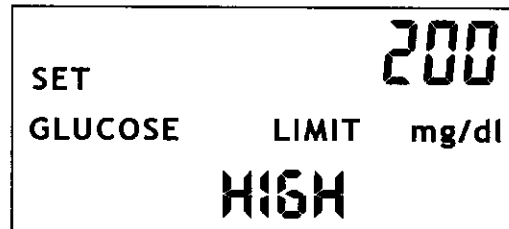


2. Press the **ACT** button and the following screen appears with **ON** blinking.

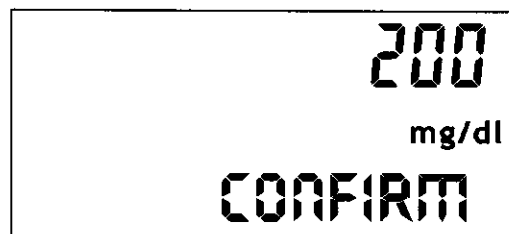


3. Press the **▲** and **▼** buttons to select either **ON** or **OFF**. If you do not wish to use this feature, select **OFF** and the hypoglycemia alarm feature will be disabled. This procedure assumes that **ON** has been selected.

4. Press the **ACT** button and the value will be blinking. The default value is 200 mg/dl or 11 mmol/l depending on the units selected.



5. Use the ▲ and ▼ buttons to select the desired value to trigger a hyperglycemia alarm. The range for mg/dl units is 105 to 400. The range for mmol/l units is 5.8 to 22.2.
6. Press the **ACT** button to save the selected value. The following screen will appear with CONFIRM blinking.



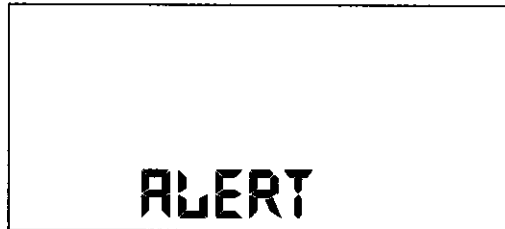
7. Press the **ACT** button to confirm the selected value.

Set alert

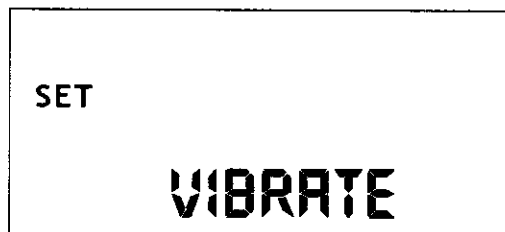
The Set Alert feature gives the option of either an audible BEEP, VIBRATE, or BOTH whenever an alarm is triggered. If this section is not completed, the default setting for the Monitor is the audible BEEP.

1. From the Normal Operation Screen, press the **SEL** button until the SETUP screen appears.
2. Press the **ACT** button once to access the Setup screens.

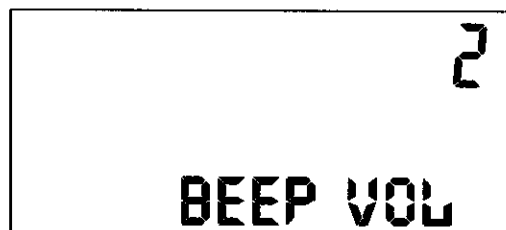
3. Press the **SEL** button until **ALERT** is displayed.



4. Press the **ACT** button once and the word **BEEP** will appear blinking. Use the **▲** button to select **BEEP**, **VIBRATE**, or **BOTH**, as desired.
5. Press the **ACT** button again to save your choice in the Monitor memory. If the **VIBRATE** alert has been chosen, the Monitor will vibrate briefly and advance to the Set Time and Date Screen.



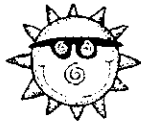
6. If you select the **BEEP** or **BOTH** alert, a number 2 (default) will appear blinking above the words **BEEP VOL**. You can choose between three different beep durations: 1=short, 2=medium, and 3=long. Use the **▲** and **▼** buttons to select either 1, 2, or 3. (While scrolling, corresponding beep tones will sound.)



7. Press **ACT** to save your choice. The Set Time and Date screen will appear.

Set time and date

Program the current time and date into the Monitor. The following example displays the Monitor default when turned on the first time before programming.

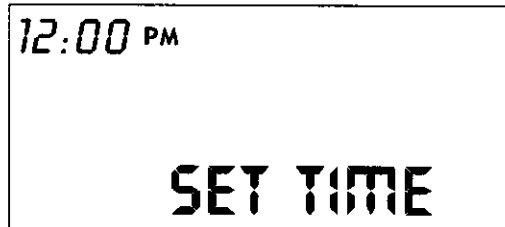


The entire sequence of Time and Date steps must be completed or the time and date will not be saved.

If you are programming your Monitor for the first time, you will already be at the SET TIME screen, consequently steps 1 through 3 do not need to be performed.

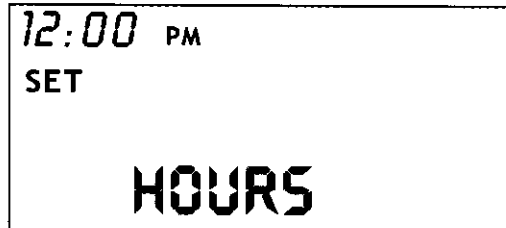
Set the time

1. From the Normal Operation Screen, press the **SEL** button until the SETUP screen appears.
2. Press the **ACT** button once to access the Setup screens.
3. Press the **SEL** button until the SET TIME screen appears.



Set current hour

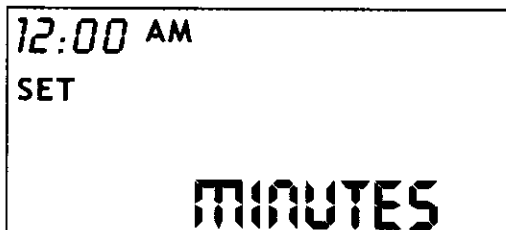
4. Press the **ACT** button once and the word **HOURS** will appear. The first two digits, will be blinking and the word **SET** will be displayed.



5. Use the **▲** and **▼** buttons to select the correct hour. If using the 12 hour format, make sure that the screen shows the correct AM or PM symbol. For example: AM is displayed, and you need PM, press the **▲** and **▼** buttons to scroll through the times until the correct time with PM is displayed.
6. If using the 24 hour time format, select hours between 0 and 23.
7. Press the **ACT** button and the **MINUTES** screen will appear.

Set current minute

1. The word **MINUTES** will now appear with the last two digits of the time blinking.

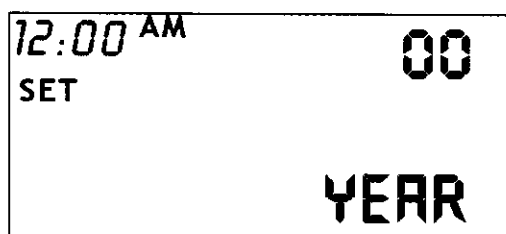


2. Use the **▲** and **▼** buttons to select the current minute from "00" to "59."

3. Press the **ACT** button once and the YEAR screen will appear.

Set the current year

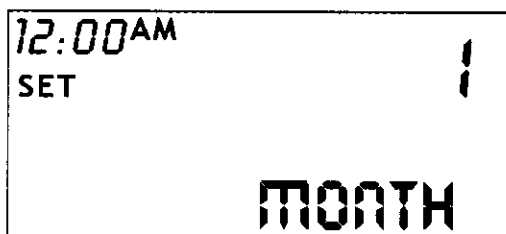
4. The YEAR will now appear with the number “00” blinking in the upper right-hand corner of the screen. The starting year is 2000.



5. Use the ▲ and ▼ buttons to select the last two digits of the current year. For example: “00” is entered for the year 2000 and “01” is entered for the year 2001, etc.
6. Press the **ACT** button once and the MONTH screen will appear.

Set the current month

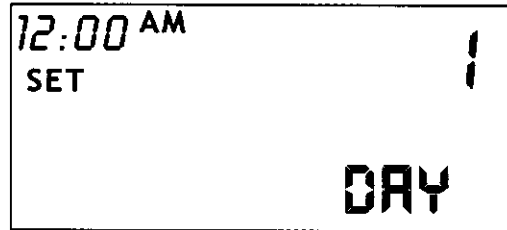
7. The word MONTH will now appear with the number “1” blinking in the upper right-hand corner of the screen. Use the ▲ and ▼ buttons to select the digits for the current month. For example: “1” is entered for the month of January, “2” is entered for the month of February, “3” is entered for the month of March, etc.



8. Press the **ACT** button once and the DAY screen will appear.

Set the current day

9. The word DAY will now appear with the number “1” blinking in the upper right-hand corner of the screen.

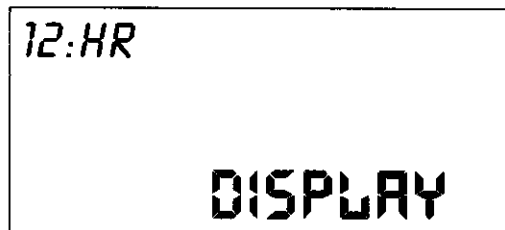


10. Use the ▲ and ▼ buttons to select the digits for the current day of the month.
11. Press the **ACT** button once to save and start using the day, time, and date values selected.
12. The current time and date will be displayed briefly, before advancing to the TIME FORMAT Screen.

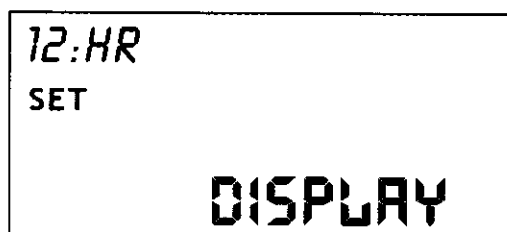
Time format

The Monitor offers a choice of reporting the time in either 12 hour or 24 hour formats.

1. From the Normal Operation Screen, press the **SEL** button until the SETUP screen appears.
2. Press the **ACT** button once to access the Setup screens.
3. Press the **SEL** button until the DISPLAY screen appears.



4. Press the **ACT** button and the upper left-hand corner of the screen will appear blinking. The word **SET** will appear under the blinking number. Use the **▲** and **▼** buttons to select either 12 or 24, indicating the time format to be used.

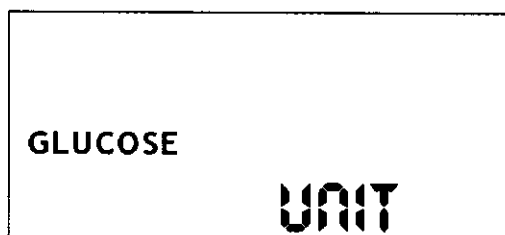


5. Press the **ACT** button to enter the desired time format into the Monitor memory and advance to the **GLUCOSE UNIT** screen.

Glucose unit

The TGMS offers a choice of reporting glucose data in either mg/dl or mmol/l.

1. From the Normal Operation Screen, press the **SEL** button until the **SETUP** screen appears.
2. Press the **ACT** button once to access the Setup screens.
3. Press the **SEL** button until the **UNIT** screen appears.



4. Press the **ACT** button once and use the ▲ and ▼ buttons to select either mg/dl or mmol/l to report glucose units.

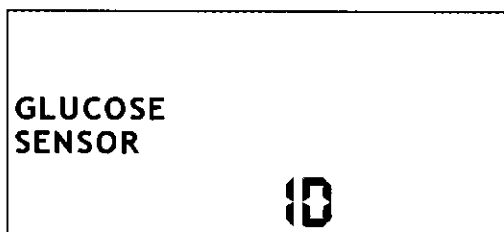


5. Press the **ACT** button again to save the desired units into the Monitor memory and advance to the SIGNALS screen.

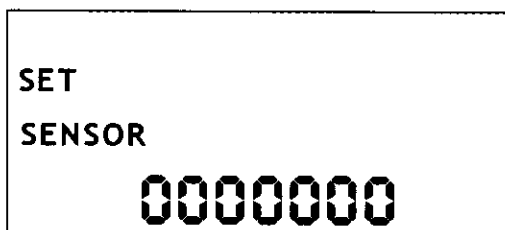
Transmitter ID

Each Transmitter is given a unique identification number in the factory, from 0000001 to 9999999. (This is the serial number on the Transmitter.) This number must be entered into the Monitor before glucose data sent from the Transmitter can be received and stored. This will limit the Monitor to receive data from the Transmitter with that specific ID number only. If a different Transmitter is to be used, the new Transmitter ID must be entered.

1. From the Normal Operation Screen, press the **SEL** button until the **SETUP** screen appears.
2. Press the **ACT** button once to access the Setup screens.
3. Press the **SEL** button until the ID screen appears.



4. Press the **ACT** button and a seven (7) digit number will appear with the first digit blinking. Use the ▲ and ▼ buttons to select the first digit on your left in your Transmitter ID number.
5. Press **ACT** again to advance to the second digit.



6. The second digit from the left will now be blinking. Use the ▲ and ▼ buttons to select the second digit in your Transmitter ID number.
7. Press **ACT** once again to advance to the third digit.
8. Continue using the ▲ and ▼ buttons to assign numbers for each of the remaining digits and then press **ACT** to the next digit.
9. Press **ACT** after the seventh digit has been entered and the ID will be accepted by the Monitor.

Sensor initialization



Prior to performing sensor initialization, make sure that the Transmitter ID number has been entered.

Every time a Sensor has been inserted properly into the subcutaneous tissue and then connected to the Transmitter, the system needs to initialize the Sensor before beginning to record glucose data. It takes approximately two hours to initialize a Sensor.

1. Insert the Sensor into the site per the instructions that came with the Sensor.

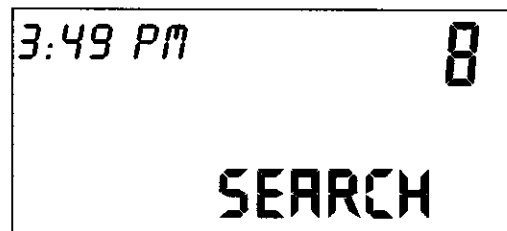
2. Tape the Transmitter to your body as described in the instructions that came with your transmitter. **DO NOT CONNECT** to the Sensor at this time.

Search for transmitter

3. From the Normal Operation Screen, press the **SEL** button (3 times) until **SEARCH** screen is displayed.



4. Press **ACT** and the Monitor will beep and **CONFIRM** will be blinking on the screen.
5. Press **ACT** again to begin a Search. The screen will display **SEARCH**. Also appearing is the number "8" in the upper right-hand corner, which counts down from 8 minutes.



6. To trigger the initialization, make sure that the Monitor is in the Search mode, and then connect the Sensor to the Transmitter.
7. The Monitor will listen for the Transmitter. The eight (8) in the upper right-hand corner will count down for 8 minutes.

If the Transmitter is not identified by the Monitor, an alarm code will

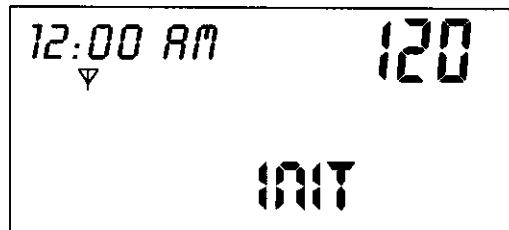
appear. Refer to the Alarms and Troubleshooting chapter for detailed information on Alarm codes.

8. When the Transmitter is identified by the Monitor, the screen will briefly display SUCCESS and change to the initialization screen.



Initialization Screen

1. The following screen will appear. Initialization lasts up to 120 minutes. The countdown during initialization is to zero (0) or until complete, whichever occurs first.



2. The initialization is complete when the screen returns to the Normal Operation Screen.

Sensor calibration and sensitivity check

When the Sensor has been initialized, an alarm will prompt you to calibrate the Sensor prior to operation. Until an initial calibration value (fingerstick glucose reading using a meter) has been entered into the Monitor memory, the TGMS will not record or display any glucose values. The hyperglycemia and hypoglycemia alarm feature also will not operate until calibration has been completed. Calibration is required to assure that the Monitor is able to convert the electronic signals from the Sensor into glucose values.

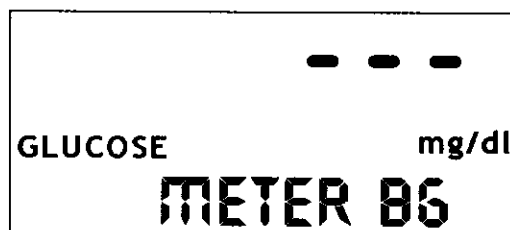
The calibration value, for each sensor, is used as a sensitivity check and should be performed by entering one glucose meter reading into the Monitor. A calibration value should be entered into the monitor every 12 hours. If you have not entered a calibration value, a CAL alert will notify you to do so. The CAL icon will remain on the Monitor screen until a calibration value has been entered. A minimum of one meter reading should be entered over a 24 hour period, however, two or more readings will optimize your results in determining your daily glucose levels.

Calibration prompt

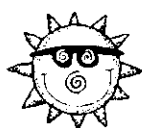
At the completion of the initialization, the Monitor will display a CAL alert to remind you to calibrate the sensor.

Enter a glucose measurement

1. From the Normal Operation Screen, press **SEL**. When the METER BG screen appears, a glucose value of mg/dl or mmol/l will be shown on the screen. (Dashes will be displayed if no entry has been made.)

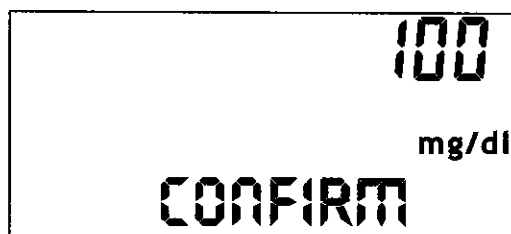


2. Press the **ACT** button once and the glucose value will begin to blink. Use the **▲** and **▼** buttons to scroll through the values until the correct meter value is displayed in increments of 1 mg/dl or 0.1 mmol/l, then press **ACT** to save the desired value in the Monitor. Holding down either button will scroll through the list of the values. Holding down either button for more than 5 seconds will accelerate the scrolling. The METER BG feature allows only values from 40 to 400 mg/dl or 2.2 to 22.2 mmol/l to be entered into the Monitor.



The Monitor will only accept meter values between 40 and 400 mg/dl or 2.2 to 22.2 mmol/l. If your glucose value is outside this range, treat as appropriate per your physician's advice and enter a meter value into the Monitor once your glucose value is between 40 and 400 mg/dl or 2.2 to 22.2 mmol/l.

3. Press **ACT** again to confirm the blood glucose entry.



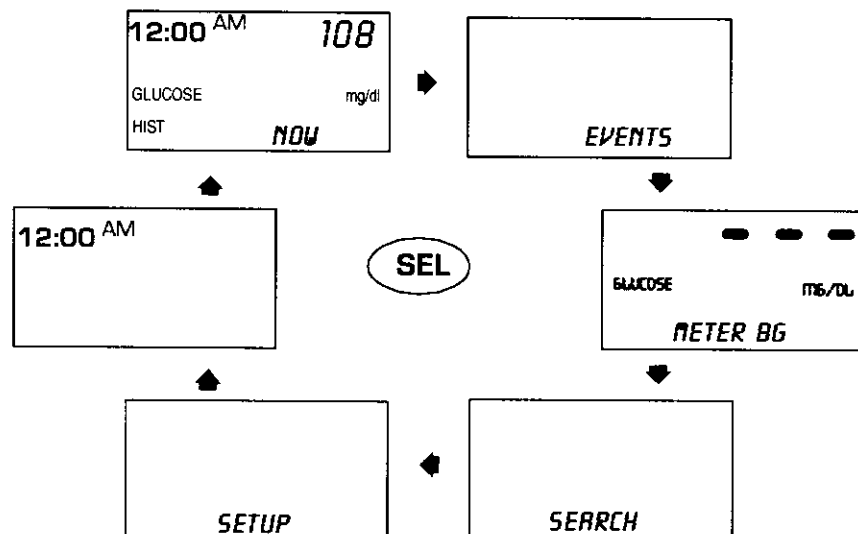
Sensor calibration and sensitivity check

4. The Monitor will perform calibration and sensitivity check using the Meter BG value entered and a corresponding sensor value.
5. The Monitor will return to the Normal Operation Screen.

CHAPTER 5 Using Your System

This section explains how to operate the system after it has been set up. There are five operating screens to choose from: GLUCOSE HISTORY, EVENTS, METER BG, SEARCH, and SETUP. From the Normal Operation Display, pressing the **SEL** button once will advance to the next operating screen. Notice that pressing **SEL** from the SETUP screen will return the user back to the Normal Operation Display.

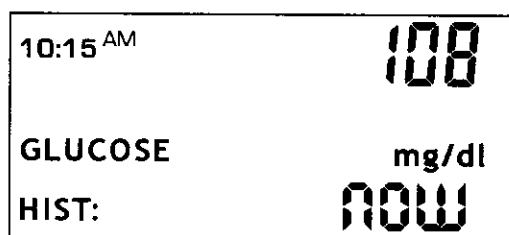
The following screens are used to operate the Monitor:



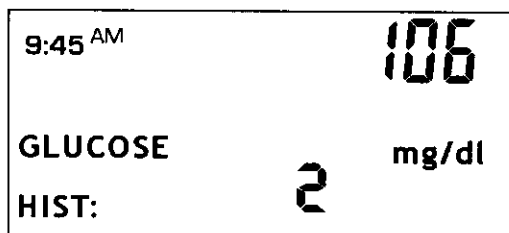
Glucose history

The Glucose History screen allows you to review the glucose measurements from the last eight hours. Dashes will be displayed in the place of a measurement, if no measurement is available. The ACT button is disabled when you are in the Glucose History screen. A maximum of seventeen values are stored in history.

1. From the Normal Operation Display, press the **SEL** button (1 time) and the GLUCOSE HISTORY screen appears.



2. The NOW screen displays the value of the most recent glucose measurement and the time it was obtained.
3. Use the ▲ and ▼ arrow buttons to scroll through the values.



4. Notice that the time is now 30 minutes earlier than the previous screen and the "2" is blinking. The "2" means that this is the second most recent glucose history record.

5. Press the **SEL** button to go to the METER BG screen or allow the screen to time-out to the Normal Operation Display.

Record important events

The Event screens are used to record information that might affect glucose values. These Events are designed to be entered one after the other, however an event can be skipped if desired. There are four types of events that can be recorded into the Monitor:

- ☒ Units of insulin taken
- ☒ Amount of carbohydrates eaten
- ☒ Duration of exercise
- ☒ Other.

Find the events screen

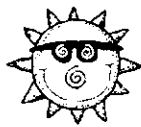
1. From the Normal Operation Display, press the **SEL** button (2 times) until the EVENTS screen appears.



2. Press the **ACT** button once to activate the Event screen. Use the ▲ and ▼ buttons to scroll between the following Event options: Insulin, Meal Cho, Exercise, and Other.

Enter an insulin dose

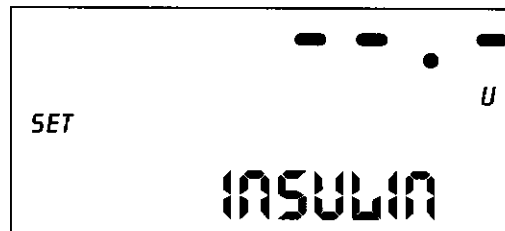
1. Press **ACT** and the screen will change to SET and INSULIN, with “INSULIN” blinking.



If the patient is an insulin pump user, the dose refers to their bolus, not basal insulin.

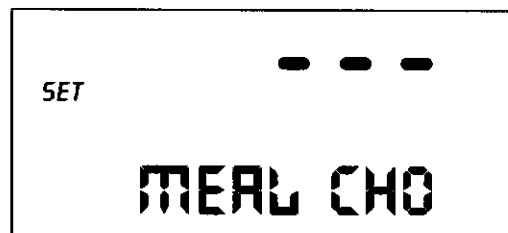
If your bolus amounts are in the hundredth of a unit, round to the nearest tenth or whole number of units.

2. Press **ACT** once again, and then use the **▲** and **▼** buttons to enter units of insulin taken, from 0.1 to 99 units.



Enter meal carbohydrate eaten

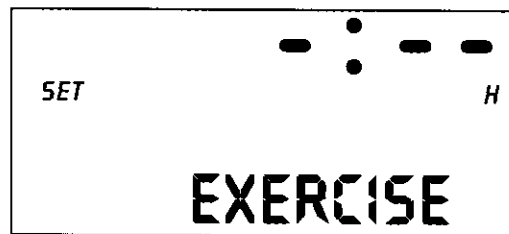
1. Press **ACT** and the screen will change to SET and MEAL CHO, with "MEAL CHO" blinking.
2. Press **ACT** once again, and then use the **▲** and **▼** buttons to enter amount of carbohydrate eaten. Units are chosen by user. The range is from 1 to 300. If you are not familiar with how to estimate amount of carbohydrates eaten, consult with your physician to learn how.



3. Press **ACT** again to save the carbohydrate value in the Monitor memory.

Enter duration of exercise

1. From the Normal Operation Display, press the **SEL** button two times. The EVENTS screen will appear.
2. Press **ACT** once. The screen will change to SET and INSULIN, with “INSULIN” blinking.
3. Use the ▲ and ▼ buttons to select the exercise Event option. The screen will change to SET and EXERCISE, with “EXERCISE” blinking.
4. Press **ACT** once again, and then use the ▲ and ▼ buttons to enter the duration of exercise in 10 minute increments, from 10 minutes to 4 hours.



Enter other events

1. Any other important events can be entered using the OTHER screen. From the Normal Operation Display, press the **SEL** button two times. The EVENTS screen will appear.
2. Press **ACT** once. The screen will change to SET and INSULIN with “INSULIN” blinking.
3. Press the ▼ button, and the screen will change to SET and OTHER with “OTHER” blinking.

4. Press **ACT** again to enter a marker on the daily glucose graph for the OTHER event.



5. Press **ACT** to return to the Normal Operation Display.

Alarms and Troubleshooting

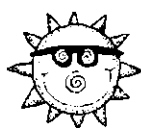
This chapter describes the Monitor alarms and how to respond to alarm conditions to keep the Monitor operating smoothly. This chapter also covers troubleshooting the alarm conditions.

If an alarm is triggered, the Monitor will either beep, vibrate, or both depending on the Alert setting. All Monitor alarms are acknowledged by pressing in sequence **SEL**, followed by **ACT**. If an alarm is not acknowledged within 10 minutes, a continuous audible tone will be triggered.

Errors prefixed with an “F” are system errors. Follow the procedure under System Errors in this chapter to troubleshoot your alarms.

If multiple alarms exist, alarm conditions will be shown sequentially on the display screen starting from the most recent. The type of each alarm and when it occurred is stored in the Monitor memory.

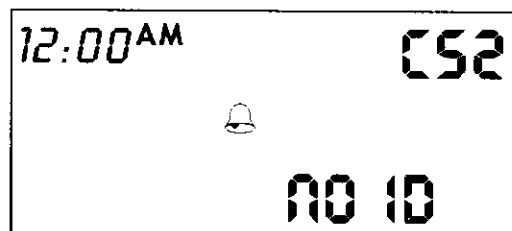
Troubleshooting alarms



A calibration must be performed following the resolution of certain alarm conditions by entering a METER BG value. No TGMS glucose values will be calculated after these alarms occur until the calibration is performed.

The following list describes the error messages for the Alarms and actions that must be taken to correct the condition.

NO ID

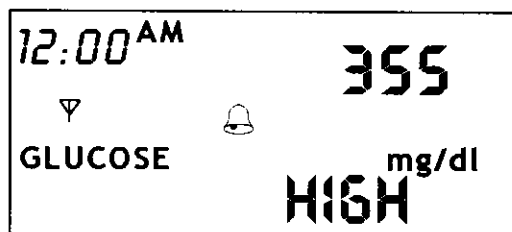


Error Message: *NO ID C52*

Cause: Transmitter ID in memory is 0000000. No non-zero transmitter ID has been entered in the Monitor.

Action: Press **SEL** and then **ACT** to acknowledge the alarm. Enter the Transmitter ID into the Monitor.

HIGH



Error Message: The glucose value that triggered the alarm, with HIGH in text area.

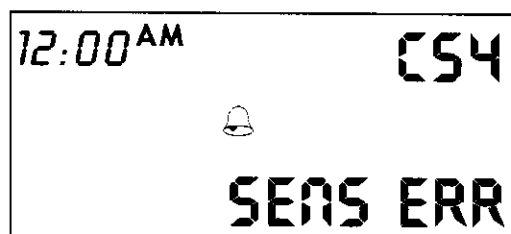
Cause: Glucose value is higher than the hyperglycemia limit set.

Action: (1) Press **SEL** and then **ACT** to acknowledge the alarm. The alarm will turn off and the Normal Operation Display will reappear. The alarm will repeat every 20 minutes until the condition has been corrected.

(2) Take a fingerstick glucose meter measurement. If the measurement corresponds with reading on Monitor, treat per physician's instructions.

(3) If the fingerstick reading does not confirm the alarm, enter the fingerstick glucose meter reading and recalibrate. If the fingerstick reading is still above the hyperglycemic limit, treat per physician's instructions.

SENS ERR



Error Message: *SENS ERR C54*

Cause: The Monitor detected a sensor current (ISIG) that is either higher or lower than expected. This alarm can also be triggered by excessive electronic noise or interference.

Action: (1) Press **SEL** and then **ACT** to acknowledge the alarm. The alarm will turn off and the Normal Operation Display will reappear. The alarm will repeat until the condition has been corrected.

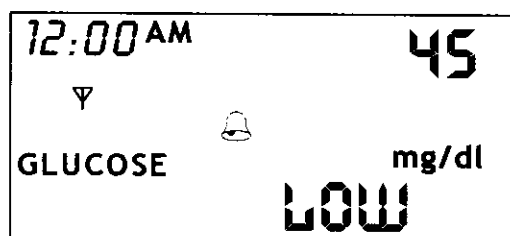
(2) Make sure that the insertion site and sensor appear to be connected and normal in appearance. **DO NOT REMOVE CONNECTOR.**

(3) If the alarm is triggered a second time. Remove the sensor. Before inserting a new sensor, perform the Test Plug procedure in

this chapter.

(4) If transmitter is bad, a new transmitter must be used. If good, insert a new sensor. Perform initialization and calibration.

LOW



Error Message: *Glucose value that triggered the alarm with LOW in the text field.*

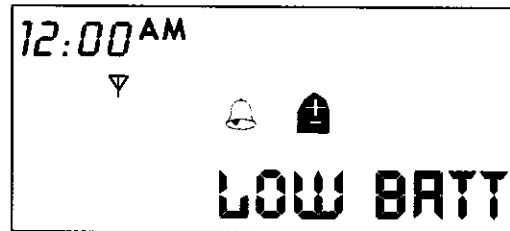
Cause: Glucose value is lower than the hypoglycemic limit set.

Action: (1) Press **SEL** and then **ACT** to acknowledge the alarm. The alarm will turn off and the Normal Operation Display will reappear. The alarm will repeat every 20 minutes until the condition has been corrected.

(2) Take a fingerstick glucose meter measurement. If the measurement corresponds with monitor reading, treat per physician's instructions.

(3) If the fingerstick reading does not confirm the alarm reading, enter the fingerstick glucose meter reading and recalibrate. If the fingerstick reading is still below the hypoglycemic limit, treat per physicians's instructions.

LOW BATT



Error Message: *LOW BATT*

Cause: The AAA batteries in the Monitor are low.

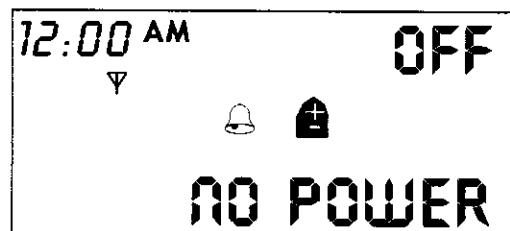
Action: Press **SEL** and then **ACT** to acknowledge the alarm. When this alarm first occurs, the batteries have about eight hours of normal operating life remaining. The time of the initial alarm is recorded into the Monitor memory. The Battery icon will be displayed on the Normal Operation Display.

(1) Change the batteries. Refer to *Chapter 1: Before You Begin*.

(2) Turn On the Monitor.

(3) Perform the Search procedure. Refer to *Chapter 4: Getting Started*.

NO POWER



Error Message: *NO POWER*

Cause: There is less than one (1) hour left of battery life in the AAA batteries in the Monitor. Press **SEL** and then **ACT** to acknowledge the alarm. The Monitor will turn off.

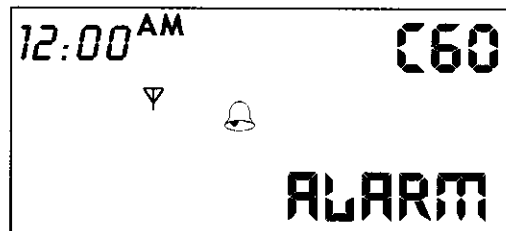
If the Monitor is turned on again, the alarm will repeat until the batteries are changed or all power is lost.

Action: CHANGE THE BATTERIES IMMEDIATELY!

Follow steps in Low Battery Alarm (C58) on the previous page to change the batteries.

Perform the Search procedure. See *Chapter 4: Getting Started*.

ALARM C60/61



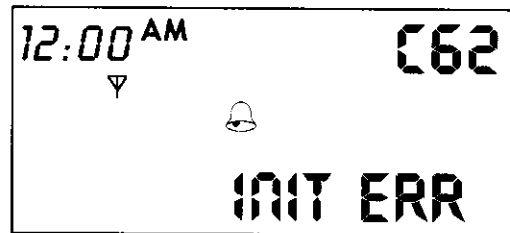
Error Message: *ALARM C60*

Cause: The Transmitter battery is low when C60 appears. The C60 alarm will repeat once a day. Alarm C61 indicates that the Transmitter battery has been depleted.

Action: Press **SEL** and then **ACT** to acknowledge the alarm. The battery cannot be changed in the Transmitter. The battery life is approximately one year. Replace Transmitter immediately.

After the Transmitter is replaced, the TGMS must be reprogrammed with the new Transmitter ID number. Refer to *Chapter 4: Getting Started*.

INIT ERR



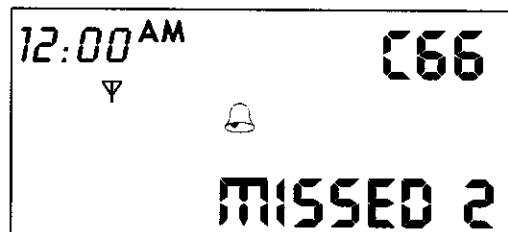
Error Message: *INIT ERR C62*

Cause: The Monitor did not receive needed information from Transmitter.

Action: Press **SEL** and then **ACT** to acknowledge the alarm. Disconnect the Sensor from the Transmitter. Perform Search and Initialization. Refer to *Chapter 4: Getting Started*.

If alarm reappears, insert a new sensor and perform Initialization.

MISSED 2

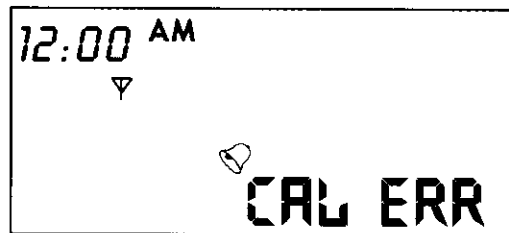


Error Message: *MISSED 2 C66*

Cause: The Monitor has missed the last two sensor readings from the Transmitter. This can be caused by: Monitor being too far away from Transmitter, static, or interference from cell phones or other electronic devices.

Action: Press **SEL** and then **ACT** to acknowledge the alarm. When you acknowledge the alarm, the system will automatically search for the next data packet from the Transmitter. During the searching process the Monitor will display the SEARCH screen with the countdown value.

CAL ERR



Error Message: *CAL ERR*

Cause: Calibration cannot be performed successfully due to out of range calibration values or calibration parameters cannot be found.

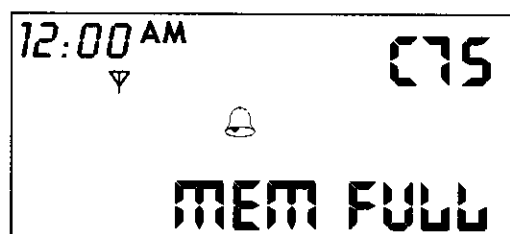
Action: (1) Press **SEL** and then **ACT** to acknowledge the alarm. The alarm will turn off and the Normal Operation Display will reappear. The alarm will repeat until the condition has been corrected.

(2) Check to make sure that the antenna icon is displayed. If not displayed, the telemetry link between the Transmitter and the Monitor has not been established.

(3) Check to make sure the most recent glucose value entered in the METER BG screen is correct. If an incorrect value has been entered by mistake, enter the correct glucose value.

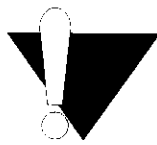
(4) If the glucose value is correct, replace the sensor. Perform Initialization.

MEM FULL



Error Message: *MEM FULL C75*

Cause: This alarm occurs when the history buffer has less than 15 percent of the memory allocated remaining. The alarm will be repeated when there is less than 10 percent and 5 percent of memory remaining.



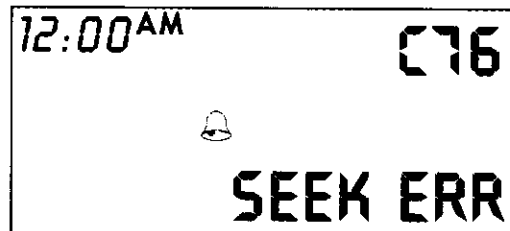
If the memory becomes completely filled, memory will be automatically cleared.

Action: (1) Press **SEL** and then **ACT** to acknowledge the alarm. The alarm will turn off and the Normal Operation Display will reappear. The alarm will repeat until the condition has been corrected.

(2) Download the Monitor data to a personal computer using the Com-Station and MiniMed Solutions Software, within 24 hours of receiving the first message.

(3) After downloading the data successfully, perform the CLEAR procedure in Chapter 4.

SEEK ERR

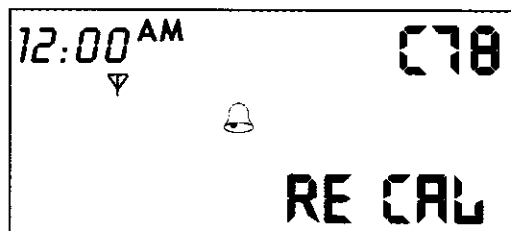


Error Message: *SEEK ERR C76*

Cause: The search for the Transmitter has failed.

Action: Press **SEL** and then **ACT** to acknowledge the alarm. Is the Transmitter ID entered correctly? If not, reenter Transmitter ID number and retry SEARCH procedure.

RE CAL

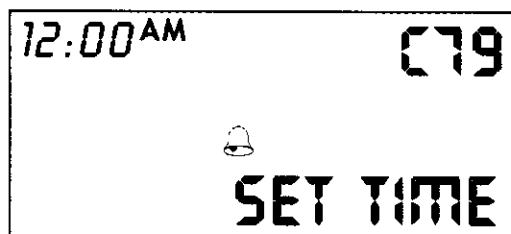


Error Message: *RE CAL C78*

Cause: Calibration is required. No new glucose values will be reported.

Action: Press **SEL** and then **ACT** to acknowledge the alarm. Perform Calibration Sensitivity Check procedure. Until calibration is performed, this alarm will repeat hourly.

SET TIME



Error Message: *SET TIME C79*

Cause: The batteries have expired. They were left unchanged for an extended time period and the clock no longer has the correct time.

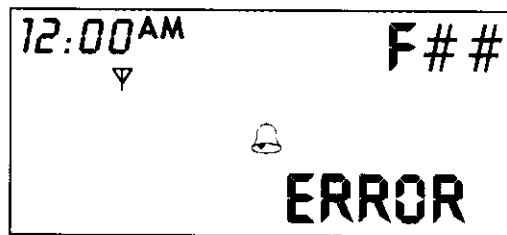
Action: Press **SEL** and then **ACT** to acknowledge the alarm. Replace batteries and perform and reprogram your Monitor per the instructions in *Chapter 4: Getting Started*.

Antenna icon blinking

If the icon is blinking slowly the Monitor has missed a data packet from the Transmitter. Make sure that the Monitor and Transmitter are within 3 to 4 meters (10-15 feet).

System errors

A diagnostic test has detected an error in the Monitor Memory. If an error appears prefixed with an F and followed by two digits (example shown below) perform the following procedure.



1. Write down the error code number to report to the MiniMed Help Line to troubleshoot the error.
2. Acknowledge the alarm by pressing **SEL** and **ACT**. The Monitor will default to factory defaults, except for time and glucose history. All other information will need to be reprogrammed after conferring with MiniMed Clinical Services.
3. Download data into a personal computer immediately if a Com-Station is available.
4. After successfully or unsuccessfully downloading the data, call the MiniMed Clinical Services at 800.826.2099.

Test plug procedure

1. Disconnect the Sensor from the Transmitter connector.
2. Perform Sensor Initialization in *Chapter 4: Getting Started*. **When the SEARCH screen appears**, connect the Cable Connector end of the Test Plug to the Transmitter. Press the parts together until the snap arms on the Cable Connector engage with a click.
3. If the Monitor recognizes the Transmitter the Monitor will enter the Initialization mode. The Monitor will display INIT and the number 120.
4. To check the correct ISIG values, you must wait until the INIT screen countdown number is at 100 or less. This ensures that the reading is stable from the Transmitter.
5. If the ISIG value remains between 24 and 29 for 15 minutes, the Transmitter and Monitor are operating properly. Replace the Sensor. Initialize and calibrate the new Sensor before returning to Normal Operation. Refer to *Chapter 4: Getting Started*.
6. If the ISIG value is outside the range of 24 to 29, the Transmitter, Monitor, or both may have a problem. Replace the Transmitter and use the Test Plug again to diagnose the system.
7. If the problem remains, call MiniMed Clinical Services: 800.826.2099 for assistance.

CHAPTER 7 **System Maintenance**

Protection from water

Although the Monitor, Transmitter, and Sensor are designed to be water resistant, prolonged direct contact with water or other fluids should be avoided.

1. The TGMS should not be used while swimming.
 2. The Monitor should always be set in a dry location before taking a shower.
 3. The Monitor should never be submerged.
 4. Check to make sure that the occlusive dressing covering the Sensor and Transmitter connector is tightly adhered to the skin when showering.
 5. Any moisture that comes in contact with the Monitor should be dried with a soft towel.
-

Protection from impact

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

1. The Monitor should be protected from mechanical damage such as a fall or impact. If the Monitor is dropped, inspect for damage before continuing use.
2. The Monitor should be placed inside the leather case provided when it is worn. The case will absorb many of the bumps and scratches from sharp objects during every day use.
3. During exercise, if an alarm should occur, you should stop exercising and follow the directions in Chapter 6, Alarms and Troubleshooting.

Protection from high temperatures

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

1. If outside during freezing weather, the Monitor should be kept underneath clothing to keep it warm.
2. Avoid using or storing the Monitor in any environments in which temperatures would be expected to exceed 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.
3. Do not steam sterilize or autoclave the Monitor.

Cleaning the monitor

1. Use a damp cloth and mild cleaning solution to clean the outside of the Monitor. Cleaning solutions may include tap water, 409[®], Windex[®], Liquid Joy[®], Betadine[®], 10% bleach solution, 3% hydrogen peroxide solution and 70% isopropyl alcohol. Do not spray solutions directly onto the Monitor.
2. Never use organic solvents, such as paint thinner or lighter fluid to clean the Monitor. Organic solvents will damage the Monitor surface and may affect its water resistance.
3. Keep the battery compartment dry at all times.

X-rays, MRI and CT scans

The Monitor is designed to comply with IEC standards for electromagnetic interference, and should withstand all common electrostatic and electromagnetic interference including airport security systems, cell phones and microwave ovens. However, using the Monitor in close proximity to strong electromagnetic sources such as medical imaging equipment, television and radio transmitters and high voltage power lines is not recommended.

1. Keep the Monitor in its leather case to protect against electrostatic discharges, that are common in cold and dry climates.
2. 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 the Monitor off. After the procedure, put the monitor back on and return to normal operation.

Ordering supplies

For your convenience, MiniMed stocks an extensive supply of components and disposables for the Monitor, including Glucose Sensors, Glucose Transmitters, leather cases, belt clips, dressings, and other accessories. MiniMed supplies are available online at www.minimed.com, or call 800.843.6687 during MiniMed's normal business hours: Monday through Friday, 8:00 AM to 5:00 PM Pacific time. You may also Fax your order to us at 888.268.0200. Please allow 10 business days for processing your order.

Product	Model Number
Glucose Sensor (box of 10)	MMT-7002
Continuous Glucose Monitor	MMT-7600
Glucose Transmitter	MMT-7700
Com-Station™	MMT-7301
MiniMed Solutions™ Software	MMT-7315

Accessory	Model Number
Belt Clip	MMT-7402
Test Plug	MMT-7400
Leather Case	MMT-7401
IV Prep (50/box)	MMT-173
IV 3000 (100/box)	MMT-174
Polyskin (50/box)	MMT-134

Product specifications

Component	Performance Specification
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 War- ranty	1 year
System Memory	Stores up to 14 days of data
Alarms	Audible (50 decibels @ 1 meter) Vibrate (Counter Weight: 2.6 grams) Axial Shaft Displacement:1.5 mm Torque Generated at Nominal Motor Speed:25 N•cm min. (Equivalent to the vibration mode on a per- sonal pager.)
Backlight	Electroluminescent (EL) Panel
Power Supply	2 AAA alkaline batteries
Battery Life	Approximately 2 months
Case Material	High impact ABS/polycarbonate composite
Safety Checks	Diagnostic signals verify proper sensor and measurement system operation, every 10 sec- onds.
Operating Conditions	Temperature: 0 to +50 degrees Celsius (32 to 122 degrees Fahrenheit) Relative Humidity: 10% to 95% with no condensation

Component	Performance Specification
Storage Conditions	Temperature: -20 to +55 degrees Celsius (-4 to 131 degrees Fahrenheit) Relative Humidity: 10% to 100% with condensation
Approved Cleaners and Disinfectants	Compatible with common cleaning solutions, including tap water, 10% bleach solution, 3% hydrogen peroxide solution, Windex®, 409®, Betadine®, Liquid Joy®, and 70% isopropyl alcohol

Legend of symbols

The Legend of Symbols table describes each of the symbols located on the TGMS.

TABLE 2. Legend of Symbols

	Please Read The Instructions for Use
 1994-12	Manufacture Date (year - month)
S N	Device Serial Number
-20C  +50C	Storage Temperature Range
	Type BF (Protection from electric shock)
	On / Off
▲	Change Value Up
▼	Change Value Down
	Backlight

TABLE 2. Legend of Symbols

(1x)	One Per Container / Package
ACT	Activate
SEL	Select

If you require additional information regarding use of this Telemetered Glucose Monitoring System, contact your health care professional or the Clinical Services Department at 800.826.2099.

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