

# INSTRUCTIONS FOR USE

## MiniMed® Test Plug

REF MMT-7400

SYMBOL	DESCRIPTION
REF	REFERENCE/MODEL NUMBER
(1x)	ONE PER CONTAINER / PACKAGE

### INDICATIONS FOR USE

The MiniMed Test Plug (MMT-7400) is an accessory included with the Continuous Glucose Monitor (MMT-7102). The Test Plug can be used to troubleshoot problems encountered during the operation of the Continuous Glucose Monitoring System (CGMS).

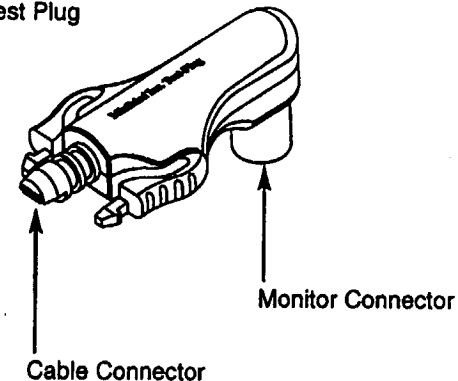
### DESCRIPTION OF THE TEST PLUG

The Test Plug is a device that can simulate a Glucose Sensor (MMT-7002), or both the Glucose Sensor and Cable (MMT-7203) of the CGMS. If an operating problem occurs while the CGMS is being used, the Test Plug provides diagnostic information that can help identify if a Glucose Sensor, Cable or the Continuous Glucose Monitor unit is operating normally. The Test Plug provides and sends a constant electronic signal to the Continuous Glucose Monitor, normally about 27nA, that can be read on the monitor "ISIG" screen.

The Test Plug has the following connections:

- **Cable Connector** - Connects to the CGMS Cable (MMT-7203) in the same manner as the Glucose Sensor (MMT-7002).
- **Monitor Connector** - Connects to the Continuous Glucose Monitor in the same manner as the Cable.

FIGURE 1: Test Plug



If you require additional information regarding use of the Test Plug, contact the Clinical Services Department at 800-826-2099.



USA:  
Sylmar, CA  
818-362-5958 • 800-826-2099 (24-hour Help Line within U.S. & Canada)  
To order supplies:  
800-843-6687 • FAX: 888-268-0200 (within U.S. & Canada)  
FAX: 818-362-3788 (outside U.S.)

The CGMS is covered by the following U.S. patents: [U.S.]5,390,671; [U.S.]5,568,806; [U.S.]5,586,553; [U.S.]5,777,060; and [U.S.]5,786,439. Other U.S. and/or foreign patents may be pending.

## TEST PLUG APPLICATIONS

The CGMS Test Plug can be used to diagnose a number of alarm conditions, including:

- Repeated "Disconnect" alarms; "DISCONN-" appears on the monitor screen.
- Repeated "Too High" alarms; "TOO HIGH" appears on the monitor screen.
- "ISIG" values displayed on the "SIGNALS" screen appear to vary randomly.

## INSTRUCTIONS FOR USING THE TEST PLUG

**NOTE:** Always evaluate the Continuous Glucose Monitor and Cable together first by following the instructions in the following section, "Connecting to the Cable"

**NOTE:** Before using the Test Plug, make sure the Glucose Sensor, Cable and Continuous Glucose Monitor are connected together, the connections are complete and secure, and the Monitor is turned on.

### Connecting to the Cable:

1. Disconnect the Glucose Sensor from the Cable.
2. Connect the Cable Connector end of the Test Plug to the Cable. Press the parts together until the snap arms on the Cable Connector engage with a click.
3. Find the "SIGNALS" menu in the monitor. From the Normal Operation Display,
  - Press the **SEL** button three (3) times to select the "SET UP" menu,
  - Press the **ACT** button once to access the set up menus,
  - Press the **SEL** button two (2) times. The "SIGNALS" screen will be shown.
4. Press **ACT** once to view the "ISIG" screen. The value shown is the electronic current the Test Plug is sending to the Monitor.
5. If the ISIG value remains between 24 and 29 for one minute, the Monitor and the Cable are operating properly. Replace the Glucose Sensor. Initialize and calibrate the new Glucose Sensor before returning to normal operation. Refer to the Continuous Glucose Monitor User's Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on correcting the problem.





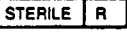

6. If the ISIG value is outside the range of 24 to 29, the Monitor, the Cable or both may have a problem. Proceed to the following section, "Connecting to the Monitor," for instructions on how to evaluate the Monitor separately.

### Connecting to the Continuous Glucose Monitor:

1. Disconnect the Cable from the Continuous Glucose Monitor.
2. Connect the Monitor Connector end of the Test Plug into the Monitor. Rotate the Monitor Connector gently until the pins line up with the sockets in the Monitor port. Then press the Monitor Connector into the Monitor port until it seats snugly into place.
3. Find the "SIGNALS" menu. From the Normal Operation Display,
  - Press the **SEL** button three (3) times to select the "SET UP" menu,
  - Press the **ACT** button once to access the set up menus,
  - Press the **SEL** button two (2) times. The "SIGNALS" screen will be shown.
4. Press **ACT** once to view the "ISIG" screen. The value shown is the electronic current the Test Plug is sending to the Monitor.
5. If the ISIG value remains between 24 and 29 for one minute, the Monitor is operating properly. Replace the Cable and repeat the "Connecting to the Cable" section. Refer to the Continuous Glucose Monitor User's Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on correcting the problem.
6. If the ISIG value is outside the range of 24 to 29, the Monitor may have a problem. Refer to the Continuous Glucose Monitor Users Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on correcting the problem.

**NOTE:** If a problem is found when the Test Plug is connected to the Cable, but the Monitor is found to be operating properly, the Cable is probably faulty. Refer to the Continuous Glucose Monitor Users Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on when to replace the Cable.

**NOTE:** If you are unable to successfully identify the source of the problem using the Test Plug, please call MiniMed Clinical Services at (800) 826-2099 or contact your local MiniMed Sales Representative for additional assistance.

SYMBOL	DESCRIPTION
 1999-12	EXPIRATION DATE (Use by Date) (year - month)
	DO NOT REUSE
	READ INSTRUCTIONS FOR USE
	LOT NUMBER
	STERILIZED WITH RADIATION
REF	REFERENCE/MODEL NUMBER
	STORAGE TEMPERATURE RANGE

If you require additional information regarding use of the Glucose Sensor, contact the MiniMed Clinical Services Department at 800-826-2099.



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G9190021-011 5/99

# INSTRUCTIONS FOR USE

## MiniMed® Glucose Sensor

REF MMT-7002

### STERILE DEVICE

This device is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the sterile package has been opened or damaged.

### INDICATIONS FOR USE

The Glucose Sensor is intended for use with the Continuous Glucose Monitoring System (CGMS) in continuous monitoring of glucose levels in persons with diabetes. After insertion under the skin, the Glucose Sensor generates an electrical current which is proportional to the concentration of glucose in the surrounding interstitial fluid. The Glucose Sensor signal is recorded by the monitor for conversion to glucose concentrations at the time the data is downloaded from the Monitor using CGMS Com-Station.

### CONTRAINDICATIONS

None

### WARNINGS

Infection at the insertion site is a risk which can be minimized with proper skin preparation, insertion technique, and frequent Glucose Sensor changes. Remove the Glucose Sensor if redness or soreness develops.

### PRECAUTIONS

1. Use aseptic technique when inserting the Glucose Sensor.
2. Check the insertion site often for redness, irritation, and inflammation.
3. Select a new insertion site each time the Glucose Sensor is replaced. The new site should be at least two inches from the previously used site.
4. Avoid using insertion sites that can be irritated by clothing or accessories (belts) or by rigorous movements and stretching due to exercise.
5. Infusion or injection of insulin within two inches of the Glucose Sensor insertion site may interfere with the glucose readings.

### PRINCIPLES OF OPERATION

The Glucose Sensor works through an electrochemical reaction with glucose. The enzyme glucose oxidase is used to convert glucose at the sensor surface into electronic signals. The Glucose Sensor sends these signals continuously through a cable to the Monitor. The Monitor samples the signals once every 10 seconds, and a smoothed average of the 10 second values is stored in the Monitor once every five (5) minutes.

## REAGENTS

The Glucose Sensor contains two reactive or biological ingredients:

1. **Glucose oxidase:** The enzyme glucose oxidase is derived from a microorganism *Aspergillus niger*, purified and dried according to Type VII-S guidelines. Less than 0.4 µg of glucose oxidase is used to manufacture each Glucose Sensor, and the enzyme is covalently bonded onto the sensor surface. Therefore the risk of tissue reactions from glucose oxidase is considered to be minimal.
2. **Bovine serum albumin (BSA):** BSA is the purified and dried albumin fraction V, derived from pasteurized bovine serum. Less than 0.7 µg of BSA is used to manufacture each Glucose Sensor. Further, the process used to cross-link glucose oxidase with BSA utilizes glutaraldehyde, a viral inactivating compound. Therefore, the risk of viral transmission is considered to be minimal.

## STORAGE AND HANDLING

Glucose Sensors must be stored within a temperature range +2 and +24 degrees Celsius (+36 to +75 degrees Fahrenheit), and a relative humidity range of 10% to 80%, with no condensation present. Refrigeration is recommended. Do not freeze.

Use the Glucose Sensors before the expiration date shown on the package. Discard and do not use any sensors, in which 1) the packaging is torn or the seal is loose, 2) the temperature indicator on the package is black (not clear), or 3) the sterility indicator on the package is orange (not red).

## ADVERSE REACTIONS

Infection, site irritation, or minor discomfort may result from improper insertion and maintenance of an insertion site.

## IMPORTANT NOTE

Use Glucose Sensors only if:

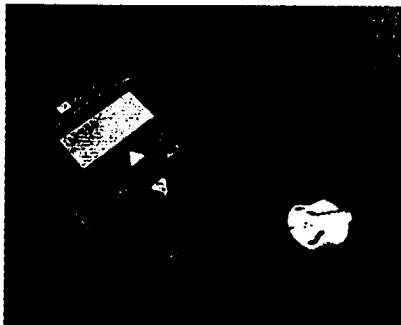
- The sterilization indicator dot (⦿) is red, not orange (⦿).
- The temperature dot (○) is clear, not black (●).

## PRESCRIPTION DEVICE

Caution: U.S. law restricts this device to sale by or on the order of a physician.

## INSTRUCTIONS

These instructions describe how to insert the subcutaneous Glucose Sensor. Please refer to the accompanying illustrations for further assistance. The process is the same regardless of the insertion site.



- Step 8. Hold the Sensor Assembly against the skin by grasping it between the thumb and forefinger. With the other hand, remove the White Release Paper (2) by pulling on the tab which extends out from under the Cable. Press the Adhesive Pad against the skin until it adheres (Figure 9).

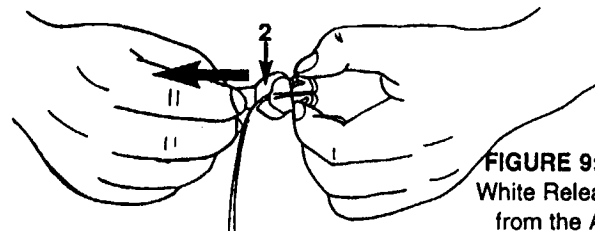


FIGURE 9: Remove the White Release Paper (2) from the Adhesive Pad

- Step 9. While holding onto the Sensor Assembly with one hand, remove the Introducer Needle by pulling the Needle Hub gently away from the Sensor Assembly. Dispose of the Introducer Needle properly (Figure 10).

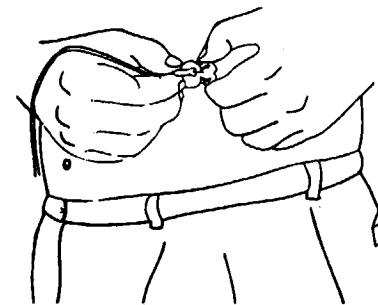


FIGURE 10: Remove the Introducer Needle

- Step 10. Secure the Cable/Sensor Connector to the skin with a sterile transparent moisture permeable dressing such as Polyskin®, OpSite IV 3000® or Tegaderm®. If desired, make a safety loop with the Cable and secure it with a separate piece of tape or bandage (Figure 11).

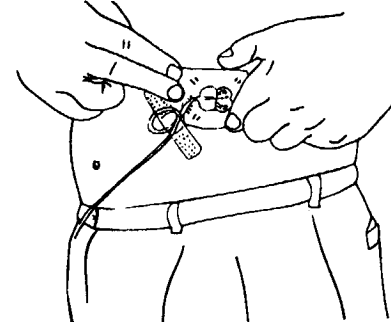


FIGURE 11: Secure with Transparent Dressing and Tape

- Step 5. Being careful not to touch the sterile needle, hold the Sensor Assembly in one hand and then remove the Needle Guard Tube from the Introducer Needle with the other hand (Figure 6).

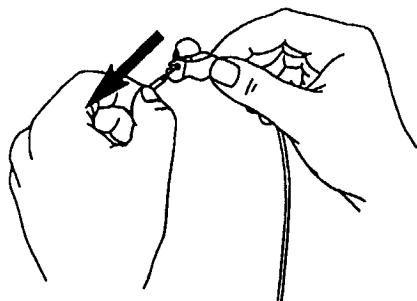


FIGURE 6: Remove the Needle Guard

- Step 6. Check to make sure that the Needle Hub is seated against the Sensor Assembly Base. If there is a gap between the Needle Hub and the Sensor Assembly, push on the hub to slide it back into position (Figure 7).

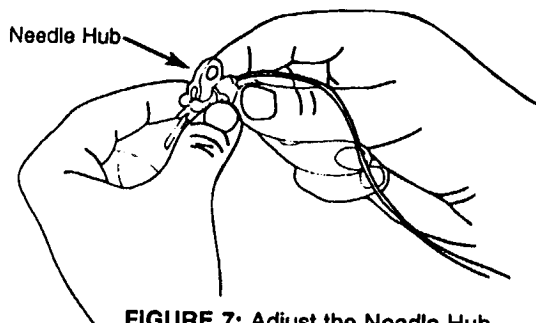


FIGURE 7: Adjust the Needle Hub

- Step 7. Locate the insertion site which has previously been wiped with 70% alcohol. With one hand, stabilize the insertion site by pinching up a large area of skin between the thumb and forefinger. Do not touch either the Adhesive Pad or the sterile needle. Make sure the Needle Hub is pushed all the way forward against the Sensor Assembly. Now hold the Glucose Sensor by the Needle Hub. Slide the needle into the subcutaneous tissue at a 45 degree angle to the skin surface, until the Adhesive Pad touches the surface of the skin. Release the skin fold (Figure 8).

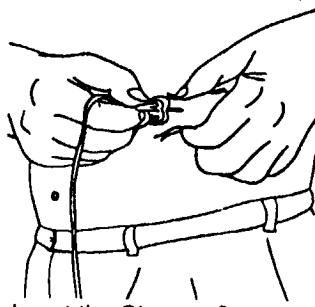


FIGURE 8: Insert the Glucose Sensor

**NOTE:** When replacing a Glucose Sensor, the following procedure is recommended:

1. Disconnect the old Glucose Sensor from the Cable and connect the Test Plug in its place.
2. Find the "SIGNALS" screen and read "ISIG." An "ISIG" value between 24 and 29 nA indicates that the Cable and Monitor are operating normally.
3. Disconnect the Test Plug and proceed with the following instructions to insert a new Glucose Sensor.

#### BEFORE BEGINNING

1. Wash hands thoroughly.
2. Wipe the sensor insertion site on the skin with isopropyl alcohol and allow it to dry.
3. Assemble the CGMS on a clean, dry surface (Figure 1).

#### GLUCOSE SENSOR COMPONENTS

The Glucose Sensor consists of six (6) components:

1. **Sensor** - a tiny electrode that is inserted under the skin. The Sensor continuously converts glucose into an electronic signal which is then transferred to the Continuous Glucose Monitor.
2. **Sensor Assembly** - a plastic "button" adhering to the skin that links the Sensor to the Cable and Continuous Glucose Monitor.
3. **Introducer Needle** - a needle attached to a plastic handle or hub. The Glucose Sensor is packaged with the needle attached to aid in its insertion. Once the Sensor has been inserted under the skin, the Introducer Needle is withdrawn by pulling gently on the hub.
4. **Needle Guard Tube** - a piece of plastic tubing that is placed over the Sensor and needle for protection. The Needle Guard is removed just before the Sensor is inserted.
5. **Adhesive Pad** - the surface of the Sensor Assembly that attaches to the skin.
6. **Release Paper** - protects the adhesive pad until the Sensor has been properly inserted. Two Release Papers are provided with each Glucose Sensor.

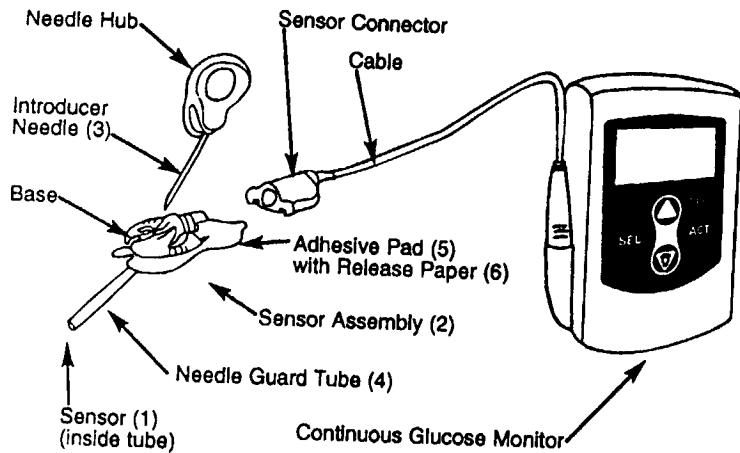


FIGURE 1: Continuous Glucose Monitoring System (CGMS)

### INSTRUCTIONS

Step 1. If it is not already connected, insert the connector end of the Cable into the Continuous Glucose Monitor. Rotate the connector gently until the pins in the Cable line up with the sockets in the monitor port. Advance the connector into the monitor port until it seats snugly into place (Figure 2).

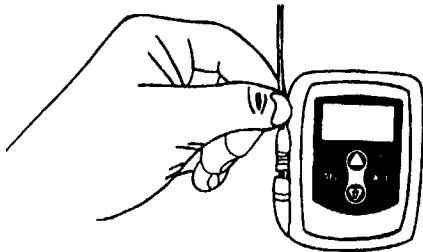


FIGURE 2: Attach the Cable to the Continuous Glucose Monitor

Step 2. Remove the Glucose Sensor from the sterile package. Grasp the package on either side of the top seal and peel it apart (Figure 3). Place the assembly onto a clean/dry surface.

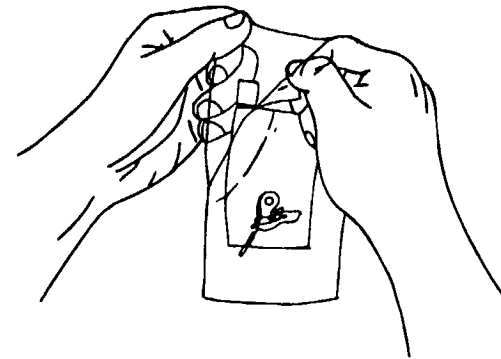


FIGURE 3: Remove Glucose Sensor from Sterile Package

Step 3. Fasten the Sensor Assembly to the Cable. Grasp the Sensor Assembly Base between the thumb and forefinger. Hold the Sensor Connector in the other hand. Plug the Sensor Assembly into the Sensor Connector and press the parts together until the snap arms on the Sensor Assembly engage with a click (Figure 4).

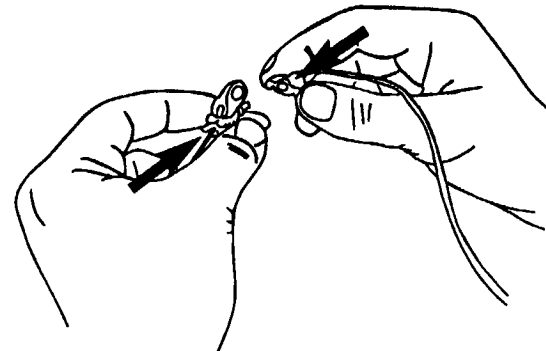


FIGURE 4: Connect Sensor Assembly to the Sensor Connector

Step 4. Holding the Sensor Connector in one hand, remove the Clear Release Paper (1) from the Adhesive Pad taking care to keep the adhesive surface clean and dry. This surface will adhere to skin and help hold the Glucose Sensor in place (Figure 5).

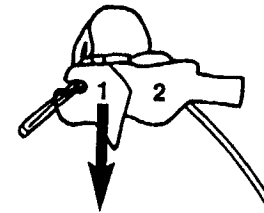


FIGURE 5: Remove Clear Release Paper (1) from the Adhesive Pad

SYMBOL	DESCRIPTION
REF	REFERENCE/MODEL NUMBER
(1x)	ONE PER CONTAINER / PACKAGE

If you require additional information regarding use of the MMT-7203 Cable, contact the MiniMed Clinical Services Department at 800-826-2099.



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# INSTRUCTIONS FOR USE

## MiniMed® Cable

REF MMT-7203

The MiniMed Cable (MMT-7203) is a component of the Continuous Glucose Monitoring System ("CGMS"). The Cable is used to transmit electronic signals generated by the Glucose Sensor (MMT-7002) to the Continuous Glucose Monitor ("Monitor") (MMT-7102).

### DESCRIPTION OF THE CABLE

The Cable is a special wire with two connectors that provide a seamless, continuous transmission of electronic signals from the Glucose Sensor to the Monitor.

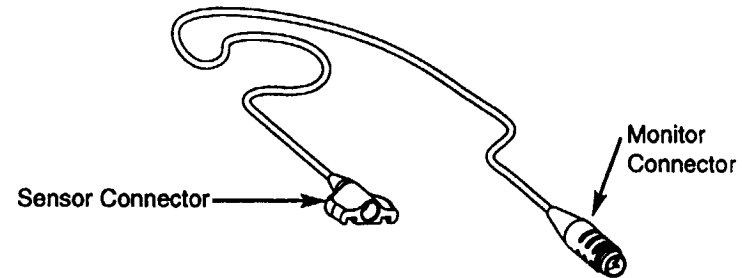


FIGURE 1: Cable

The Cable has the following connectors:

- **Sensor Connector** - A special three-pin connector, designed to be low profile, biocompatible and conform with the surface of the skin. The Sensor Connector holds two latches on the Glucose Sensor Assembly which engage with a click when they are pressed together. The latches help form a tight seal between the two parts.
- **Monitor Connector** - A four-pin snap-in connector that plugs into the side-port of the Monitor, forming a tight seal. The Monitor Connector is designed for a one-way keyed connection to avoid inadvertent connection errors.

## INSTRUCTIONS FOR USING THE CABLE

1. **How to connect the Glucose Sensor to the Cable:** Make sure the Needle Guard remains over the Glucose Sensor to maintain its sterility. Grasp the Sensor Assembly Base between the thumb and forefinger. Hold the Sensor Connector in the other hand. Orient the Glucose Sensor Assembly so that the two connectors align in close proximity. Plug the Glucose Sensor Assembly into the Sensor Connector. Press the parts together until the snap arms on the Glucose Sensor Assembly engage with a click (Figure 2).

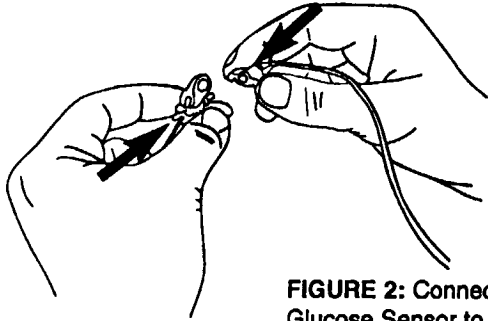


FIGURE 2: Connect the Glucose Sensor to the Cable

2. **How to disconnect the Glucose Sensor from the Cable:** Hold the Glucose Sensor Assembly in one hand and the Sensor Connector in the other hand. While pinching the snap arms on the sides of the Glucose Sensor Assembly together, gently pull the Glucose Sensor Assembly away from the Sensor Connector.
3. **How to connect the Cable to the Monitor:** Hold the Monitor Connector end of the Cable in one hand and the Monitor in the other hand. Place the Monitor Connector just above the Monitor Connector Port until gentle contact is made. Align the pins in the Cable Connector with the sockets in the Monitor Connector Port. Apply firm pressure to advance the Monitor Connector into the Monitor Connector Port until it is firmly seated into place. (Figure 3).

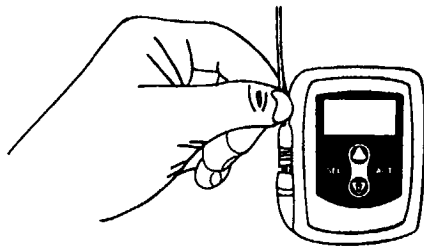


FIGURE 3: Connect the Cable to the Continuous Glucose Monitor

NOTE: The Continuous Glucose Monitor is sold with a Cable pre-connected to the Monitor Side Port. Under normal operating conditions, the Monitor Connector end of the Cable should be left connected to the Monitor.

4. **How to disconnect the Cable from the Monitor:** While holding the Monitor Connector securely, pull it firmly until it separates from the Monitor Connector Port.

NOTE: Never attempt to disconnect the Cable from the Continuous Glucose Monitor by holding onto the Cable wire. Permanent damage to the Cable and a loss of Glucose Sensor signal transmission to the Monitor will result.

NOTE: Never attempt to disconnect the Cable from the Continuous Glucose Monitor, while the Cable is connected to a working Glucose Sensor at the other end unless instructed to do so by your health care professional.

NOTE: Disconnect the Cable from the Continuous Glucose Monitor and Glucose Sensor before wiping it with an approved cleaning solution (see Cable Specifications).

## CABLE SPECIFICATIONS

Component	Performance Specification
Biocompatibility	Complies with ISO 10993-1 for long term body contact.
Length (approximate)	36.0 inches (91.4 centimeters).
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.
Cable Life	1 year
Chemical Resistance	Tap water, 70% isopropyl alcohol, 3% hydrogen peroxide solution, 409®, Windex®, Liquid Joy®, Betadine® and Armor-Aid®

## INDICATIONS FOR USE

The Cable is intended for use only with the MiniMed CGMS.

## CONTRAINDICATIONS

None.



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# INSTRUCTIONS FOR USE

## MiniMed® Test Plug

REF MMT-7400

### INDICATIONS FOR USE

The MiniMed Test Plug (MMT-7400) is an accessory included with the Continuous Glucose Monitor (MMT-7102). The Test Plug can be used to troubleshoot problems encountered during the operation of the Continuous Glucose Monitoring System (CGMS).

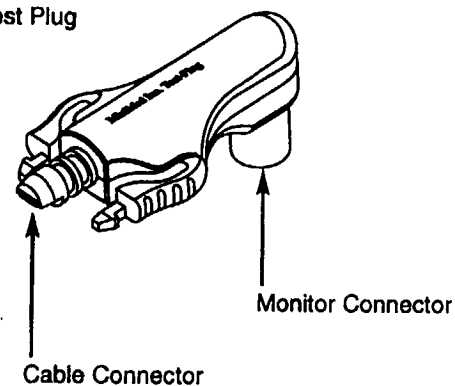
### DESCRIPTION OF THE TEST PLUG

The Test Plug is a device that can simulate a Glucose Sensor (MMT-7002), or both the Glucose Sensor and Cable (MMT-7203) of the CGMS. If an operating problem occurs while the CGMS is being used, the Test Plug provides diagnostic information that can help identify if a Glucose Sensor, Cable or the Continuous Glucose Monitor unit is operating normally. The Test Plug provides and sends a constant electronic signal to the Continuous Glucose Monitor, normally about 27nA, that can be read on the monitor "ISIG" screen.

The Test Plug has the following connections:

- **Cable Connector** - Connects to the CGMS Cable (MMT-7203) in the same manner as the Glucose Sensor (MMT-7002).
- **Monitor Connector** - Connects to the Continuous Glucose Monitor in the same manner as the Cable.

FIGURE 1: Test Plug



## TEST PLUG APPLICATIONS

The CGMS Test Plug can be used to diagnose a number of alarm conditions, including:

- Repeated "Disconnect" alarms; "DISCONN-" appears on the monitor screen.
- Repeated "Too High" alarms; "TOO HIGH" appears on the monitor screen.
- "ISIG" values displayed on the "SIGNALS" screen appear to vary randomly.

## INSTRUCTIONS FOR USING THE TEST PLUG

**NOTE:** Always evaluate the Continuous Glucose Monitor and Cable together first by following the instructions in the following section, "Connecting to the Cable"

**NOTE:** Before using the Test Plug, make sure the Glucose Sensor, Cable and Continuous Glucose Monitor are connected together, the connections are complete and secure, and the Monitor is turned on.

### Connecting to the Cable:

1. Disconnect the Glucose Sensor from the Cable.
2. Connect the Cable Connector end of the Test Plug to the Cable. Press the parts together until the snap arms on the Cable Connector engage with a click.
3. Find the "SIGNALS" menu in the monitor. From the Normal Operation Display,
  - Press the **SEL** button three (3) times to select the "SET UP" menu,
  - Press the **ACT** button once to access the set up menus,
  - Press the **SEL** button two (2) times. The "SIGNALS" screen will be shown.
4. Press **ACT** once to view the "ISIG" screen. The value shown is the electronic current the Test Plug is sending to the Monitor.
5. If the ISIG value remains between 24 and 29 for one minute, the Monitor and the Cable are operating properly. Replace the Glucose Sensor. Initialize and calibrate the new Glucose Sensor before returning to normal operation. Refer to the Continuous Glucose Monitor User's Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on correcting the problem.

6. If the ISIG value is outside the range of 24 to 29, the Monitor, the Cable or both may have a problem. Proceed to the following section, "Connecting to the Monitor," for instructions on how to evaluate the Monitor separately.

### Connecting to the Continuous Glucose Monitor:

1. Disconnect the Cable from the Continuous Glucose Monitor.
2. Connect the Monitor Connector end of the Test Plug into the Monitor. Rotate the Monitor Connector gently until the pins line up with the sockets in the Monitor port. Then press the Monitor Connector into the Monitor port until it seats snugly into place.
3. Find the "SIGNALS" menu. From the Normal Operation Display,
  - Press the **SEL** button three (3) times to select the "SET UP" menu,
  - Press the **ACT** button once to access the set up menus,
  - Press the **SEL** button two (2) times. The "SIGNALS" screen will be shown.
4. Press **ACT** once to view the "ISIG" screen. The value shown is the electronic current the Test Plug is sending to the Monitor.
5. If the ISIG value remains between 24 and 29 for one minute, the Monitor is operating properly. Replace the Cable and repeat the "Connecting to the Cable" section. Refer to the Continuous Glucose Monitor User's Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on correcting the problem.
6. If the ISIG value is outside the range of 24 to 29, the Monitor may have a problem. Refer to the Continuous Glucose Monitor Users Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on correcting the problem.

**NOTE:** If a problem is found when the Test Plug is connected to the Cable, but the Monitor is found to be operating properly, the Cable is probably faulty. Refer to the Continuous Glucose Monitor Users Guide, *CHAPTER TWELVE: Troubleshooting Guide* for tips on when to replace the Cable.

**NOTE:** If you are unable to successfully identify the source of the problem using the Test Plug, please call MiniMed Clinical Services at (800) 826-2099 or contact your local MiniMed Sales Representative for additional assistance.

# **MiniMed Continuous Glucose Monitoring System**

## **Monitor Instructions For Use**

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# I BEFORE YOU BEGIN

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## THANK YOU

Thank You for using the MiniMed Continuous Glucose Monitor ("Monitor"), the latest advance in glucose monitoring equipment. You will need this guide to learn how to set-up and operate the Monitor, and respond to any alarms that may occur.

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## MINIMED HELP LINE

MiniMed provides a 24 hour help line for assistance. The toll free number is: (800) 826-2099. The help line is staffed with Clinical Services personnel, who are trained in the set-up and operation of the Monitor and able to answer Monitor-related questions. When calling, have the Monitor and Instructions for Use in hand.

MiniMed offices are open for business Monday through Friday, 8:00 AM to 5:00 PM Pacific time. For after-hours emergencies, MiniMed's answering service will page a Clinical Services representative. We strive to return your calls within a few minutes. However, there are times when our representatives are busy taking other calls, and it may take longer to get a response. We appreciate your patience.



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## ORDER SUPPLIES

For your convenience, MiniMed stocks an extensive supply of components and disposables for the Monitor, including Glucose Sensors, Cables, leather cases, Shower-Paks, belt clips, dressings and other accessories. To order, please 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 the receipt of your order.

---

## FOR YOUR RECORDS

Serial Number: \_\_\_\_\_  
(Located on the back of your Monitor)

Purchase Date: \_\_\_\_\_

### CONTINUOUS GLUCOSE MONITORING SYSTEM MODEL NUMBERS:

Product	Model No.
Glucose Sensor	MMT - 7002
Continuous Glucose Monitor	MMT - 7102
Cable	MMT - 7203
Com-Station	MMT - 7301
CGMS Com-Station Software	MMT - 7310

### ACCESSORY MODEL NUMBERS:

Accessory	Model No.
Shower Pak	MMT - 117
Belt Clip	MMT - 131C
Test Plug	MMT - 7400
Leather Case	MMT - 7401

### MINIMED TELEPHONE LIST:

Department	Telephone No.
Clinical Services Help Line	(800) 826-2099
Main Number	(800) 933-3322
Sales Order	(800) 843-6687 (818) 362-5958
Sales Order (Fax)	(888) 268-0200

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## REGISTRATION AND WARRANTY

Please fill out the Registration Card enclosed with the Monitor and return it, 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.

## GENERAL DESCRIPTION

The MiniMed Continuous Glucose Monitoring System (CGMS) is a Holter-style sensor system that is designed to continuously and automatically monitor glucose values in subcutaneous tissue fluid within a range of 40-400 mg/dl. Clinical studies have shown that subcutaneous glucose measurements by the CGMS generally follow fingerstick glucose meter measurements and venous blood laboratory values. Up to two (2) weeks of glucose data can be stored in the monitor's memory and then transferred to a personal computer for analysis.

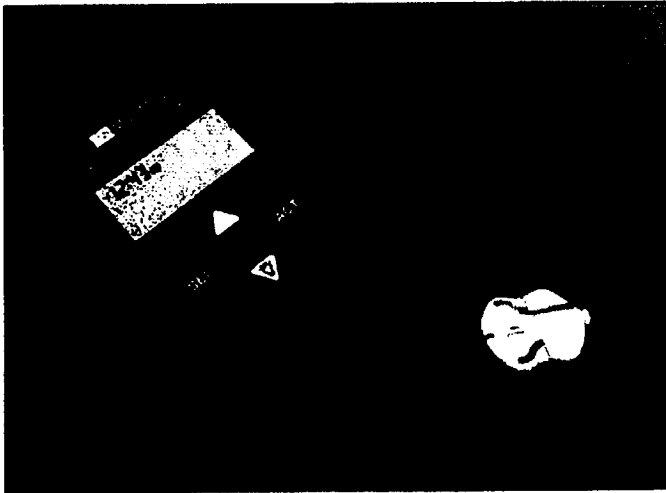


FIGURE 1 - 1: Continuous Glucose Monitoring System

The CGMS has four (4) primary components (See Figures 1 - 2 and 1 - 3):

**1. Continuous Glucose Monitor** - a portable, pager-sized device that serves as a computer operated data collection unit for the Glucose Sensor. The Monitor acquires and stores electronic signals from the Glucose Sensor, and converts these signals into clinical glucose values which are also stored. Using the Com-Station, stored signals and glucose values in the Monitor can then be downloaded to an external personal computer (PC) for analysis. The Monitor requires two (2) off-the-shelf AAA alkaline batteries, which should provide adequate power for two (2) months under conditions of normal use.

**2. Cable** - a special wire with two (2) connectors that provide a seamless, continuous transmission of electronic signals from the Glucose Sensor to the Monitor.

**3. Glucose Sensor** - a small, sterile, flexible electrode containing the enzyme glucose oxidase. The electrode is coated with a biocompatible polyurethane polymer for sensor protection and patient comfort. The electrode is attached to a connector, which adheres to the surface of the skin and forms a tight connection with the Cable. The Glucose Sensor is inserted just under the skin using a rigid Introducer Needle. The Needle is then removed and the connector is secured against the skin with medical dressing. The Glucose Sensor is packaged in a sealed pouch with sterilization and temperature indicators.

**4. Com-Station** - a data downlink communications station which is form-fit for the Monitor. An infrared serial communication port built into the Com-Station and the Monitor enable data to be sent one-way into a personal computer. Data is downloaded into a database file, which can be viewed and graphed using a Microsoft Excel® utility program provided with the Com-Station. The system includes a software diskette, a UL-approved power cord with AC adapter, and a serial data cable that connects the Com-Station to a PC. The Com-Station must be plugged into a standard 110VAC power source.

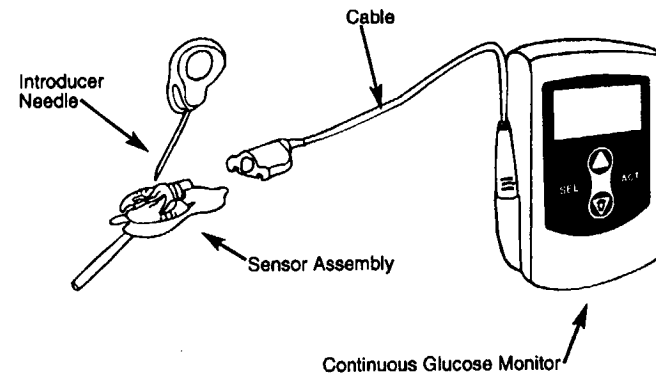


FIGURE 1 - 2: CGMS Components



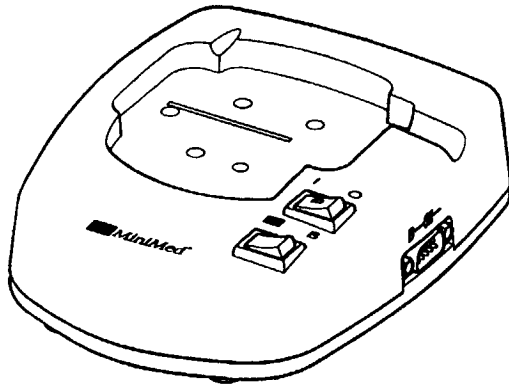


FIGURE 1 - 3: Com-Station

The Monitor records glucose values every five (5) minutes, providing as many as 288 sensor readings in a 24 hour period. Individual Glucose Sensors will be worn for a maximum of three days. Following each patient use, data stored in the monitor is transferred to a personal computer for analysis and interpretation. Up to 14 days of information can be stored in the Monitor.

The CGMS is used by health care professionals as a Holter-style monitor, to periodically record comprehensive glucose profiles and key statistics for their patients. During a typical Holter-style monitor procedure, a patient wears the CGMS for up to three (3) days while continuing to manage their diabetes as prescribed. Data from the Monitor is then transferred into the health care professional's PC for analysis. The health care professional can then assess this information.

---

## SUMMARY AND PRINCIPLE OF OPERATION

The Monitor is connected to a tiny Glucose Sensor that is inserted just under the skin to measure glucose. The Glucose Sensor works through an electrochemical reaction with glucose. The enzyme glucose oxidase is used to convert glucose at the sensor surface into electronic signals. The Glucose Sensor sends these signals continuously through a Cable to the Monitor. The Monitor samples the signals once every 10 seconds, and records an average signal every five (5) minutes. These electrical signals and any fingerstick blood glucose measurements entered into the Monitor are stored in the monitor's memory and can be downloaded later into a computer for analysis. At the time of download, the stored electrical signals are converted to glucose concentrations which may be reviewed in both graphical and tabular formats.

---

## AVAILABILITY

U.S. Law restricts the CGMS and all system components to sale by or on the order of a licensed physician. The CGMS and its components are available through MiniMed and from Authorized MiniMed Distributors.

---

## REFERENCES

Bantle J and Thomas W, Glucose Monitoring Using Interstitial Fluid, *Diabetes*, 46:619(A), 1997.

Fisher U, Continuous *In Vivo* Monitoring in Diabetes: The Subcutaneous Glucose Concentration, *Acta Anaesthesiol Scan*, 39 (Suppl 104):21-29, 1995.

Johnson KW, et. al., *In Vivo* Evaluation of an Electroenzymatic Glucose Sensor Implanted in Subcutaneous Tissue, *Biosens Bioelec*, 7:709-714, 1992.

Sternberg F, et. al., Subcutaneous Glucose Concentration in Humans, *Diabetes Care*, 18:1266-1269, 1995.

Sternberg F, et. al., Does Fall in Tissue Glucose Precede Fall in Blood Glucose?, *Diabetologia*, 39:609-612, 1996.

## II PERFORMANCE CHARACTERISTICS

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### *IN VIVO* PERFORMANCE

*In vivo* performance of the CGMS was evaluated in a multi-center clinical trial that involved a total of 62 subjects who used the system, on average, for a period of 18.6 days. An average of 6.7 Glucose Sensors were used by each subject.

Subjects took frequent blood glucose measurements using a commercially available home glucose meter. System performance was assessed by comparing the glucose meter readings to the glucose values calculated by the CGMS. The data collected during the study was used to calculate intra-day correlation, the average numerical difference between the sensor and meter readings and the categorical agreement between the Glucose Sensor and meter.

### NUMERICAL AGREEMENT

Numerical agreement was assessed by averaging the individual differences between the blood glucose meter readings (reference meter readings) and corresponding sensor glucose concentrations. The average difference between the Glucose Sensor and the reference meter was -5.4 mg/dl with a standard deviation of 44.2 mg/dl.

### INTRA-DAY CORRELATION

Correlation coefficients were calculated for each calendar day of sensor use. The median correlation was 0.92, with 75% of the correlation values above 0.75.

## CATEGORICAL AGREEMENT

The ability of the CGMS to identify periods of glucose excursions above or below the normal range was evaluated by classifying sensor and reference meter readings into one of three categories. These categories were based on defining the range of desired glycemic control as 70 to 180 mg/dl. In order to avoid the potential lack of agreement due to the reference, or the sensor, being near the upper and lower limits of this "In Control" range, only values more than 20% away from each boundary were analyzed.

Based on these boundaries, values less than 56 mg/dl were considered "Low", those between 84 and 144 were considered "In Control" and those above 216 were considered "High. Values between 56 and 84 and between 144 and 216 were not include in the analysis.

Table 1 presents a 3 x 3 cross-tabulation of the number of pairs of data falling into each of the nine sensor-reference category combinations. The three cells on the diagonal represent agreement, with the off-diagonal cells representing varying degrees of disagreement.

Reference Meter Category (mg/dl)	CGMS Category (mg/dl)			Total
	less than 56	84-144	216	
less than 56	50	25	0	75
84-144	117	930	13	1060
216	2	42	372	376
Total	169	997	345	1511

Table 2-1: Categorical Agreement Between CGMS and Reference Meter

Of the 75 reference values in the Low category, 66.7% (50) were identified by the sensor. Of the 169 sensor values in the Low category, 29.6% (50) were confirmed by the reference meter. Of the 376 reference values in the High category, 88.3% (332) were identified by the sensor. Of the 345 sensor values in the High category, 96.3% were confirmed by the meter.

## IN VITRO PERFORMANCE

### ACCURACY

Accuracy of the CGMS was evaluated *in vitro* by calibrating Glucose Sensors in solutions with known glucose concentrations (measured using a Yellow Springs Instruments (YSI) Glucose Analyzer) and then testing the Glucose Sensors in solutions with various concentrations across the range of operation. This testing yielded the following results:

$$y = 0.94x + 9.61$$

slope = 0.94  
intercept = 9.61 mg/dl  
r = 0.978  
range = 0 to 400 mg/dl

### PRECISION

Precision of the CGMS was evaluated *in vitro* by calibrating Glucose Sensors in solutions with known glucose concentrations (measured using a YSI Glucose Analyzer) and then repeatedly performing measurement (at least 10 times) in solution with concentrations across the range of operation. The average coefficient of variation was 5.06%.

**NOTE:** *In vivo* precision studies have not been performed to date and therefore results may differ due to matrix effects.

## INTERFERENCES

*In vitro* and *in vivo* testing suggests that usual pharmacologic levels of acetaminophen and ascorbic acid have a minimal effect on the function of the CGMS. *In vitro* testing suggests that normal physiological levels of uric acid do not affect Glucose Sensor function. The impact of oral hypoglycemic agents, lipids, bilirubin and other potential interfering substances have not been studied.

---

## LIMITATIONS

Since the CGMS requires regular calibration using a blood glucose value obtained from a standard home glucose meter, any inaccuracy in the value obtained from the reference meter will affect the accuracy of the value calculated by the CGMS. In addition, since the sensitivity of the Glucose Sensor is known to decrease over time, **failure to recalibrate the sensor at least twice daily may result in inappropriately low glucose readings.**

*In vitro* testing has indicated that the Monitor may record inaccurate glucose readings during exposure to electromagnetic fields of 3 V/M or stronger. **Therefore, the use of the CGMS in close proximity to strong electromagnetic sources such as medical imaging equipment, television transmitters, high voltage power lines and high power radio transmitters is not recommended.**

---

## SIGNS OF SENSOR DETERIORATION

The expected life of the Glucose Sensor is one to three days. Degradation of Glucose Sensor performance is indicated by an audible alert tone and display of the message "CAL GLUCOSE SENSOR ERROR" following an attempted sensor calibration. If this alert recurs, the Glucose Sensor should be replaced. If the Glucose Sensor's sensitivity drops to very low levels, an audible alert and the message "GLUCOSE SENSOR DISCONN-" will be displayed. If reconnection of the Glucose Sensor to the Monitor does not eliminate this error condition, the Glucose Sensor should be replaced. See *CHAPTER TWELVE: Troubleshooting Guide*:

# III IMPORTANT SAFETY INFORMATION FOR THE CGMS

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## CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed physician.

---

## INDICATIONS FOR USE

The Continuous Glucose Monitoring System (CGMS) is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices. The information collected by the CGMS may be downloaded and displayed on a computer and reviewed by health care professionals. This information may allow identification of patterns of glucose level excursions above or below the desired range, facilitating therapy adjustments which may minimize these excursions.

- The System is intended for prescription use only.
- Will not allow readings to be made available directly to patients in real time.
- Provides readings that will be available for review by physicians only after the entire recording interval (suggested as 72 hours).
- Is currently intended for occasional rather than everyday use, is to be used only as a supplement to, and not a replacement for, standard invasive measurement.
- Is not intended to change patient management based on the numbers generated, but to guide future management of the patient based on response to trends noticed. That is, these trends or patterns may be used to suggest when to take fingerstick glucose measurements to better manage the patient.

---

## CONTRAINDICATIONS

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

---

## WARNINGS

- Operation of the CGMS requires the insertion of a Glucose Sensor into the skin. Infection, inflammation or bleeding at the Glucose Sensor insertion site are possible risks of glucose sensing. The Glucose Sensor should be removed if redness, pain, tenderness or swelling develop at the insertion site.
- The CGMS does not display glucose values and is intended to be used in addition to, not in place of, home glucose monitoring performed using a standard home glucose meter. During use of the CGMS, diabetes treatment should not be modified based solely on CGMS information.

---

## PRECAUTIONS

- CGMS users 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 Glucose Sensor package. After opening the package, avoid touching any Glucose Sensor surfaces that will come in contact with the body (i.e., sensor, needle, connector adhesive surfaces and bandage).
- Before inserting the Glucose Sensor, always clean the skin at the sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol.
- After Glucose Sensor insertion, check the insertion location 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 Glucose Sensor location. Avoid sensor locations that are constrained by clothing, accessories or subjected to rigorous movement during exercise.
- Monitors should be placed in Shower-Paks, prior to taking a shower or engaging in other 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, CGMS users should make sure that the Glucose Sensor and Monitor are securely fastened to their bodies.
- If the Glucose Sensor is disconnected and then reconnected again, the signals it sends to the Monitor may not be stable or accurate. The sensor may need to be recalibrated and reinitialized before returning to normal operation.
- Users who also wear an insulin pump should make sure that the Glucose Sensor insertion site is at least two (2) inches away from the insulin infusion site. Users who inject insulin should administer injections at least three (3) inches away from the sensor insertion site.

- The Glucose Sensor is sterile in its unopened, undamaged package. Do not use any Glucose Sensor if its sterile package has been previously opened or damaged.
- The current and voltage signals shown in the Monitor are to be used only for finding potential problems with the CGMS and do not indicate the current glucose value.
- If the Monitor shows a "NO POWER" alarm on the display for more than one hour, the glucose data and program information in the memory will be lost. 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 reinitialize and calibrate the Glucose Sensor before returning to normal operation.
- 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.
- Keep the Monitor in its leather case to protect against electrostatic discharges, that are common in cold and dry climates.

---

## USE IN SPECIAL PATIENT GROUPS

The Monitor has been clinically tested primarily in adult Caucasian persons with Type I diabetes. This device has not been tested in children. Because of variations in size and the amount of body fat, performance may be different in children relative to that observed when the device is used in adults. Although the system has not been studied in other diabetic patient populations, similar results are expected.

Use of the Monitor may not be applicable for patients who are not motivated to operate it, are physically unable to operate it, have unrealistic expectations about its value and do not have a good support system at home for responding to alarms.

---

## ADVERSE REACTIONS

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



---

## IMPORTANT NOTES

**1. Entering fingerstick glucose measurements into the Monitor.** Patients and/or health care professionals should enter at least four (4) fingerstick glucose measurements each day into the Monitor. Ideally, it is recommended that at least two preprandial and one post prandial measurements be taken to maximize the range of values used for sensor calibration. Measurements should be taken when a patient's blood glucose is not changing rapidly, and entered immediately (within one to two minutes) after obtaining a glucose meter reading.

- If a wrong glucose meter value was entered by mistake, enter the correct blood glucose value as soon as possible. Incorrect blood glucose entries used for calibration will reduce the accuracy of the Monitor.

**NOTE:** For information on how to identify successfully calibrated Glucose Sensors, see pages 29-32 of the Com-Station Instructions for Use.

- The Monitor will alarm and "ERROR" will appear on the screen, if a measurement entered to calibrate the Monitor is outside the expected range. Follow the instructions in *CHAPTER TEN: Understanding and Responding to Alarms* to correct the problem.
- Following any Monitor alarm, a calibration sensitivity check should be performed by entering the average of two meter readings obtained within a five minute period into the Monitor. This value should be designated as a calibration value. The blood samples for the two readings may be obtained from one fingerstick or two separate fingersticks.

**2. Components of the CGMS.** The Monitor, Glucose Sensor and Cable and all accessories are to be used only with the CGMS. Use of system components with other products is not recommended.

**3. Changing the batteries.** Batteries should be replaced within a five (5) minute period, to avoid losing glucose data and program information in the Monitor memory.

**4. Set-up information stored in the Monitor memory.** Set-up information programmed into the Monitor will be stored until either it is changed or the Monitor shows a "NO POWER" alarm for more than two (2) hours.

**5. Clear the glucose history.** If the Monitor memory becomes completely filled, no additional glucose data will be recorded until the memory is cleared using the "CLEAR" set-up menu. After clearing the glucose history, the patient ID number must be reprogrammed into the Monitor memory and then the Glucose Sensor must be recalibrated.

**6. Disconnecting the Glucose Sensor from the Monitor.** For procedures that require the Glucose Sensor to be disconnected from the Monitor for more than 15 minutes, the user must first reconnect the Glucose Sensor, wait 30 minutes and then recalibrate the Glucose Sensor before returning to normal operation.

**7. Establishing event codes.** Users should establish a list of event codes in advance of operating the Monitor. Suggested event codes are:

1 - Meals

2 - Insulin

3 - Exercise

4 to 9 - Other



# IV PRODUCT SPECIFICATIONS

## CONTINUOUS GLUCOSE MONITOR

Component	Performance Specification
Display	Seven (7) segment 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, excluding the cable
System Memory	Stores up to 14 days of data
Alarms	Audible (50 decibels @ 1 meter)
Communications Transfer	Infrared port
Back Light	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 seconds
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



55



## Chemical Resistance

Resistant to common cleaning solutions, including tap water, 10% bleach solution, 3% hydrogen peroxide solution, Windex®, 409®, Betadine®, Liquid Joy® and 70% isopropyl alcohol

# V UNPACKING INSTRUCTIONS

## UNPACKING

Carefully unpack the system, saving all packing materials for possible future use. The original packing materials provide the safest way to transport the Continuous Glucose 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 (see telephone numbers on page 3 of these Instructions for Use).

Check to make sure the box containing the Monitor contains all of the following components:

- Continuous Glucose Monitor (1 each)
- Cable (1 each)
- AAA Batteries (2 each)
- Belt Clip (1 each)
- Registration Card (1 each)
- Terms of Warranty (1 each)
- Important Documents Binder (1 each)
- Programming and Alarm Card (1 each)
- CGMS Test Plug (1 each)
- Leather Case (1 each)
- Screw Driver (1 each)

Find the serial number on the back of the Monitor. Write it on the Registration Card and in the space provided on page 2.

**NOTE:** Glucose Sensors and Com-Stations are sold separately.

---

## INSTALL THE BATTERIES

The Monitor uses two AAA alkaline batteries as a power supply. Under normal use conditions, these batteries will provide power to the monitor for up to two (2) months. Battery life for individual users may vary.

Batteries should be installed immediately after unpacking the Monitor. Thereafter, batteries can be replaced at any time, but should normally be replaced after a **LOW BATT** or **NO POWER** alarm.

1. Obtain two AAA alkaline batteries.
2. If the Monitor screen is not blank, turn off the Monitor by pressing the **ON/OFF** (Ⓛ) button once followed by **ACT**.
3. Locate the battery compartment at the lower back side of the Monitor.
4. With a small flat blade screwdriver, loosen the screw holding the battery compartment lid to the Monitor.
5. Remove the battery compartment lid and then remove the old batteries by pulling on the battery strap.
6. Install two new batteries, taking care to align the batteries correctly in the compartment (see Figure 5 - 1). Orient the battery strap around the new batteries in the same manner it was wrapped around the old batteries.

**NOTE:** If the batteries are not aligned correctly they may get hot. Handle with care.

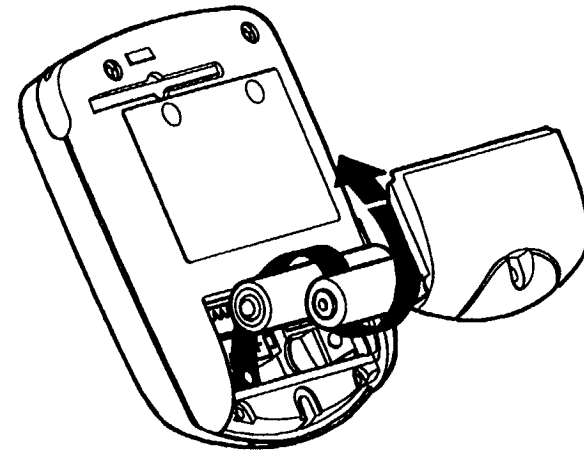


FIGURE 5 - 1: Battery Installation

7. Place the battery compartment lid back into place at the lower back side of the Monitor, taking care to align it properly against the compartment seal.
8. With the screwdriver, tighten the screw to seal the battery compartment and hold the lid in place. Do not over-tighten the lid.

**NOTE:** Batteries should be replaced within 5 minutes to avoid losing glucose data or program information stored in the Monitor.



---

## DESCRIPTION OF ACCESSORIES

**Belt Clip:** 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 (see Figure 5-2). Push the clip until it stops and clicks into place.

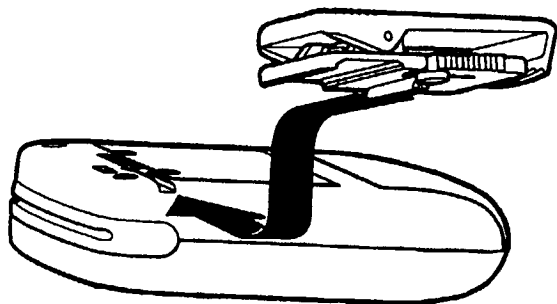


FIGURE 5 - 2: Insert the Belt Clip

**Removal:** Using your thumb, lift up on the grooved edge of the Belt Clip and then gently slide the clip out of its groove (see Figure 5-3).

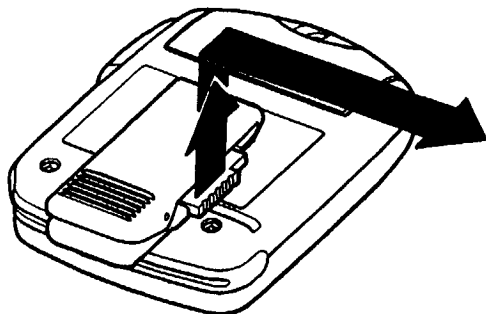


FIGURE 5 - 3: Remove the Belt Clip

**Leather Case:** A special case provided with the Monitor to help protect it against moisture, dirt and debris.

**Shower-Pak:** A waterproof clear plastic pouch designed to keep the Monitor dry during a shower or any other time when the Monitor may become wet.

**Important Documents Binder:** The Important Documents Binder is an important accessory, which contains Instructions for Use for all of the components of the CGMS. The binder also contains a Programming and Alarm Card, a handy reference that describes how to perform important programming functions for the Monitor, how to acknowledge Monitor alarms when they occur and what to do to resolve alarm conditions. The Important Documents Binder should be read thoroughly before operating the Monitor, and referred to often during its operation. Keep the binder handy when calling for assistance.

**CGMS Test Plug:** Useful for testing the components of the Continuous Glucose Monitoring System (Glucose Sensor, Cable, Continuous Glucose Monitor). Problems associated with alarms can be quickly identified and solved.



# VI UNDERSTANDING THE CONTINUOUS GLUCOSE MONITOR CONTROLS

## OPERATING CONTROLS

The Continuous Glucose Monitor is controlled by pressing five (5) control buttons. Figure 6 - 1 shows the Monitor operating control panel and the display window. In order to program and operate the Monitor successfully, always press the buttons slowly and firmly. The word "press" should be taken to mean "press and release" unless otherwise specified. A slight ticking sound can be heard and a depression felt when a button is pressed correctly.

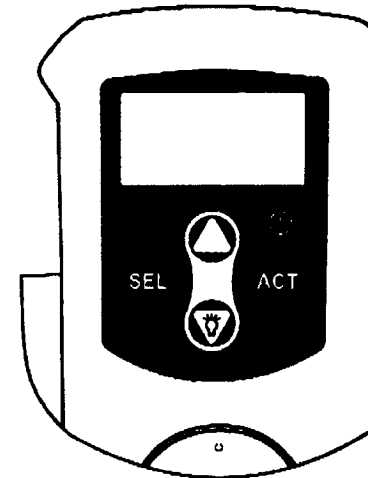


FIGURE 6 - 1: Continuous Glucose Monitor Control Panel

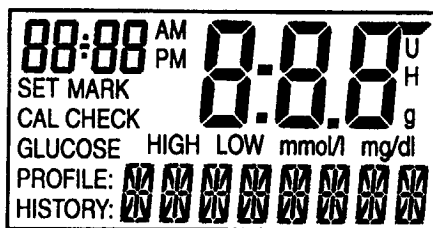
Ⓛ : Turns the Monitor on and off.

**SEL:** **SEL** means **Select**. The **SEL** button steps through each of the displays and menus.

**ACT:** **ACT** means **Activate**. The **ACT** button allows changes to be made in the Monitor programming, new information to be entered into the Monitor memory, and alarms to be turned off.

▲ and ▼: Changes the preset values in the Monitor. Pressing ▲ (**Up Arrow**) once will find the next highest preset value. Pressing ▼ (**Down Arrow**) once will find the next lowest preset 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**.

The Monitor uses a segmented liquid crystal display (LCD). An example of the characters indicated by the display are shown:



---

## TURN THE MONITOR ON

Pressing the **ON-OFF** (Ⓛ) button once while the Monitor is **OFF** turns the Monitor back **ON**. The Monitor will beep once, identify the software being used and then will show the normal operation display.

Every time the Monitor is turned **ON**, it will perform a diagnostic test of its program memory. If a problem is detected during the test, you will receive an alarm and "ERROR" message (see *CHAPTER TEN: Understanding and Responding to Alarms*).

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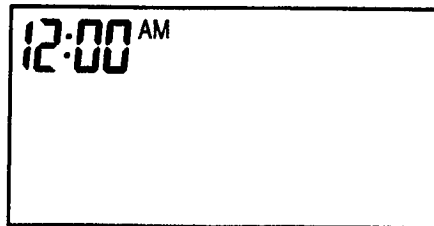
## TURN THE MONITOR OFF

While the Monitor is **ON**, press the **ON-OFF** (Ⓛ) button once. The Monitor will beep and the word "CONFIRM" will appear blinking on the display. Pressing **ACT** will then switch the Monitor **OFF**, and the display screen will go blank.

While the Monitor is **OFF**, the Glucose Sensor will be kept ready to operate and previously recorded glucose data and set-up information will continue to be stored. However, the operating and alarm functions of the Monitor will be turned off, and no new glucose data will be recorded into memory.

## THE NORMAL OPERATION DISPLAY

The Normal Operation Display for the Monitor shows the current time in the upper left-hand corner of the display screen.



When Monitor displays and menus are chosen using the **SEL** and **ACT** buttons, the user has 15 seconds to respond before the Monitor returns to the Normal Operation Display. Mistakes in programming often can be reversed by simply waiting 15 seconds without pressing any buttons. The user will then return to the Normal Operation Display and can attempt to program the Monitor again.

## TURN ON THE DISPLAY BACK LIGHT

The **▼ (Down Arrow)** button has an icon showing a light bulb (☀). A display back light can be turned on while in the Normal Operation Display, "SIGNALS" or "INIT" screens, or when responding to an alarm. Press the **▼** button once to fully illuminate the display, allowing operation at night or in dim lighting conditions. The back light will automatically turn off after 15 seconds to conserve battery power.

# VII PROGRAMMING THE CONTINUOUS GLUCOSE MONITOR

This section explains how to program the Continuous Glucose Monitor. Turn on the Monitor by pressing the **ON-OFF (Ⓢ)** button once. The Normal Operation Display will appear with time shown in the upper left-hand corner of the screen.

The following set-up menus are used to program the Monitor:

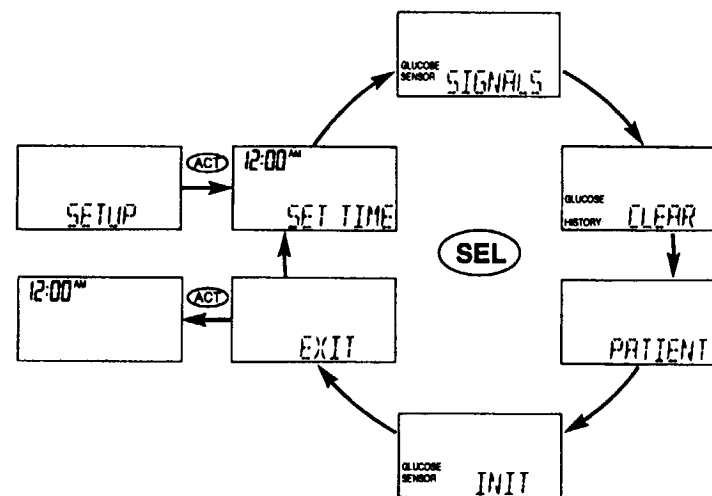


FIGURE 7 - 1: Set-Up Menu Flow Diagram

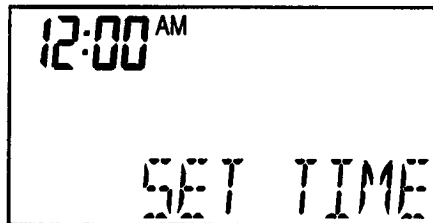
There are six (6) set up menus to choose from: "SET TIME," "SIGNALS," "CLEAR," "PATIENT," "INIT" and "EXIT." All of the set-up menus can be reached from the Normal Operation Display, by pressing **SEL** three (3) times to find the "SETUP" screen and then pressing **ACT**. After finding the first set-up menu, pressing the **SEL** button once will advance to the next set-up menu. Notice that pressing **SEL** from the "EXIT" menu will return to the first set-up menu, "SET TIME." Pressing **ACT** from the "EXIT" menu will return the user back to the Normal Operation Display.

## SET THE TIME AND DATE

Program the current time and date into the Monitor. The following example assumes the time in the Monitor is 12:00 AM and the date is January 1, 1997.

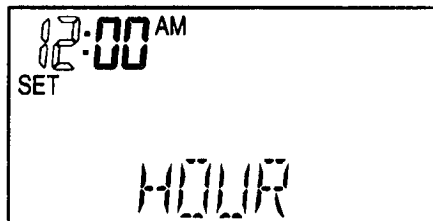
1. Find the **SET TIME** menu: From the Normal Operation Display,

- Press the **SEL** button three (3) times to select the "SETUP" menu.
- Press the **ACT** button once. The "SET TIME" menu will be shown:

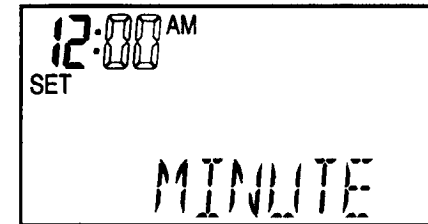


2. Set the current hour: Press the **ACT** button once and the word "HOUR" will appear. The first two digits "12" of the time will be blinking. Use the ▲ and ▼ buttons to select the correct hour between "1" and "12". Make sure that the AM or PM are also correct. Then press the **ACT** button once again to enter the hour value into the Monitor memory.

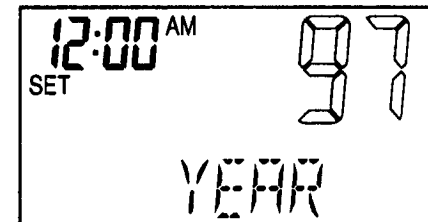
**NOTE:** Numbers that are blinking on the screen can be changed. Blinking numbers in the Instructions for Use are shown in white outlined in black color.



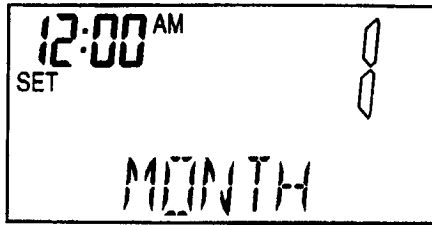
3. Set the current minute: The word "MINUTE" will now appear with the last two (2) digits "00" of the time blinking. Use the ▲ and ▼ buttons to select the current minute from "00" to "59". Then press the **ACT** button once again to enter the minute value into the Monitor memory.



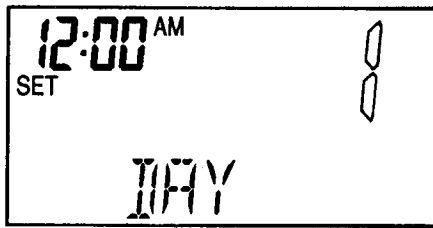
4. Set the current year: The word "YEAR" will now appear with the number "97" blinking in the upper right-hand corner of the display. Use the ▲ and ▼ buttons to select the last two digits of the current year. For example, "97" is entered for the year 1997, "98" is entered for the year 1998, "99" is entered for the year 1999, "00" is entered for the year 2000, etc. Then press the **ACT** button once again to enter the year value into the Monitor memory.



5. Set the current month: The word "MONTH" will now appear with the number "1" blinking in the upper right-hand corner of the display. 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. Then press the **ACT** button once again to enter the month value into the Monitor memory.



6. **Set the current day:** The word "DAY" will now appear with the number "1" blinking in the upper right-hand corner of the display. Use the ▲ and ▼ buttons to select the digits for the current day of the month from "1" to "31". Then press the **ACT** button once again to enter the day value into the Monitor memory. The Monitor will then return to the Normal Operation Display.



**NOTE:** Year, Month and Day must be entered as a group at one time.

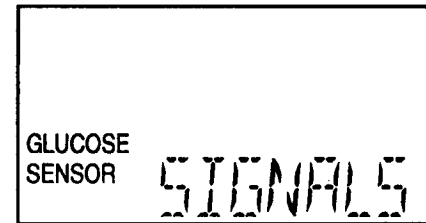
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## READ THE CURRENT AND VOLTAGE SIGNALS

During normal operation, the electronic signals the Glucose Sensor is sending to the Monitor can be viewed. The following example assumes the Glucose Sensor current output (ISIG) value is +28.7 and the Glucose Sensor voltage (VCTR) value is -0.53.

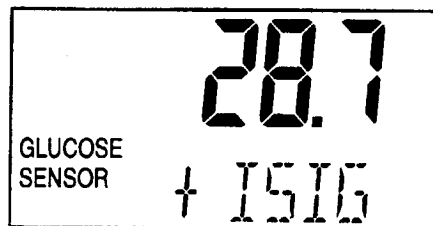
1. **Find the "SIGNALS" menu:** From the Normal Operation Display,

- Press the **SEL** button three (3) times to select the "SET UP" menu.
- Press the **ACT** button once to access the set up menus.
- Press the **SEL** button once. The "SIGNALS" screen will be shown:

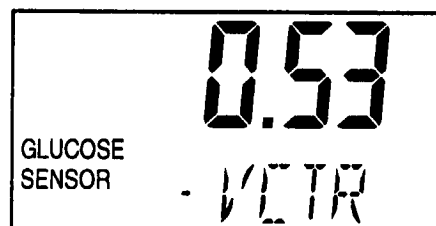




2. **View the Glucose Sensor current:** Press the **ACT** button once and the display will change to "ISIG" with the Glucose Sensor current displayed in nanoamperes in the upper right-hand corner of the screen. Press **ACT** to return to the Normal Operation Display.



3. **View the Glucose Sensor voltage:** Press the **SEL** button and the display will change to "VCTR" with the Glucose Sensor voltage displayed in volts in the upper right-hand corner of the screen. Pressing the **SEL** button once again will return to the "ISIG" display, or press **ACT** to return to the Normal Operation Display.



**PRECAUTION:** The current and voltage signals shown in the Monitor are used for finding potential problems with the CGMS and do not indicate the current glucose value.

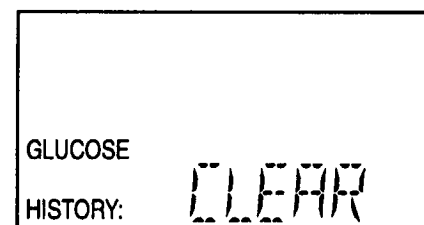
## CLEAR THE GLUCOSE HISTORY

The data in the Monitor should be transferred to a personal computer after each monitoring period. After each successful download, the Monitor memory should be cleared of all glucose history and calibration data using the "CLEAR" function. The patient ID number will also be cleared. The time & date will remain in the Monitor memory.

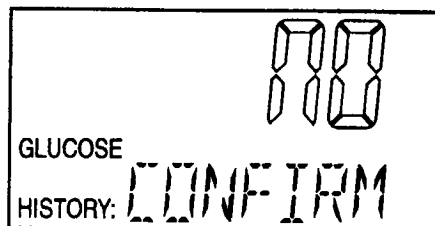
**NOTE:** Before returning the Monitor to normal operation, after clearing the glucose history, the patient ID number must be reprogrammed into the Monitor memory and the Glucose Sensor must be recalibrated. Reprogramming is necessary for this information to be included in the next download of the glucose data.

1. Find the "CLEAR" menu: From the Normal Operation Display,

- Press the **SEL** button three (3) times to select the "SET UP" menu.
- Press the **ACT** button once to access the set-up menus.
- Press the **SEL** button two (2) times. The "CLEAR" menu will be shown:



2. **Clear glucose data from the Monitor memory:** From the "CLEAR" display screen, press **ACT** once. The Monitor will beep and the words "CONFIRM" and "NO" will appear on the display screen. Use the ▲ and ▼ buttons to select between "YES" or "NO." Then press **ACT** to clear the Monitor memory ("YES") or to cancel the clear memory operation ("NO"). The Monitor will then return to the Normal Operation Display.



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## ENTER A PATIENT IDENTIFICATION NUMBER

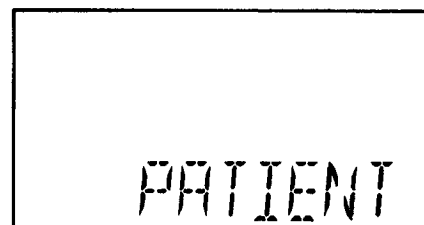
An identification number may be entered into the Monitor memory for each person who uses the Monitor. All glucose data collected will be referenced with this identification number. The monitor provides a seven (7) digit number for identification, divided into two fields: 000-0000.

- The first, three (3) digit field is intended to reference a physician or medical center.
- The second, four (4) digit field is intended to reference a patient medical record number.

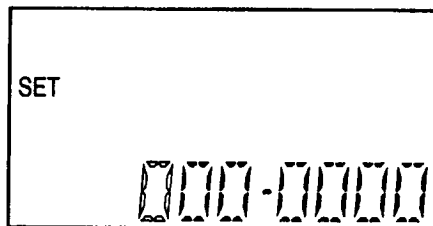
This example assumes the patient ID no. in the Monitor is set at "000-0000".

1. **Find the "PATIENT" menu:** From the Normal Operation Display,

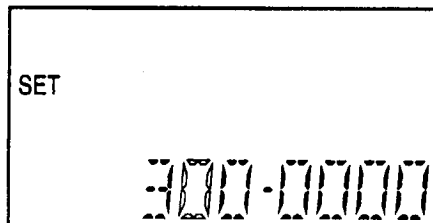
- Press the **SEL** button three (3) times to select the "SET UP" menu.
- Press the **ACT** button once to access the set-up menus.
- Press the **SEL** button three (3) times. The "PATIENT" menu will be shown:



2. **Enter the first digit:** Press **ACT** and the seven (7) digit number will appear with the first digit blinking. Use the **▲** and **▼** buttons to select a number between 0 and 9. Press **ACT** once again to enter this value into the Monitor memory.



3. **Enter the second digit:** The second digit from the left will now be blinking. Use the **▲** and **▼** buttons again to select a number between 0 and 9. Press **ACT** once again to enter this value into the Monitor memory.



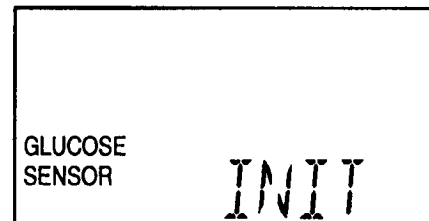
4. **Enter the third to seventh digits:** Continue using the **▲** and **▼** buttons to assign numbers for each of the digits and then press **ACT** to enter each one in sequence into the Monitor memory. After the seventh digit has been entered, the Monitor will return to the Normal Operation Display.

## VIII INITIALIZATION AND CALIBRATION SENSITIVITY CHECK

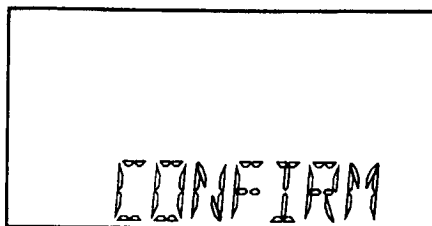
### INITIALIZE THE GLUCOSE SENSOR

After a Glucose Sensor has been properly inserted into the subcutaneous tissue and then connected to the Continuous Glucose Monitor, the following procedure will stabilize the Glucose Sensor in subcutaneous tissue and prepare it to measure glucose.

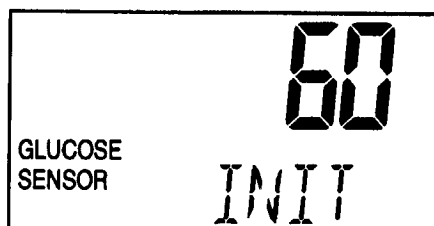
1. **Find the "INIT" menu:** From the Normal Operation Display,
  - Press the **SEL** button three (3) times to select the "SETUP" menu.
  - Press the **ACT** button once to access the set up menus.
  - Press the **SEL** button four (4) times. The "INIT" menu will be shown:



2. **Verify the Glucose Sensor is connected to the Monitor:** From the "INIT" display screen, press the **ACT** button once. The Monitor will beep and the word "CONFIRM" will appear blinking. Make sure the Glucose Sensor is properly inserted and secured, and connected to the Monitor.



- 3. Initialize the Glucose Sensor:** Press **ACT** again to begin the initialization. It takes one (1) hour to initialize a Glucose Sensor. The Monitor screen will again show "INIT" with the number "60" appearing in the upper right-hand corner of the screen. The monitor will count-down the time remaining for the sensor to initialize from 60 minutes.



- 4. Cancel the initialization:** Pressing **SEL** or **ACT** at any time during the initialization will return the user to the "CONFIRM" screen. Pressing **ACT** while "CONFIRM" appears on the screen will cancel the initialization. Otherwise, the initialization will automatically resume after 15 seconds.

**NOTE:** If the Glucose Sensor is not connected properly, the Monitor will beep and return to the Normal Operation Display.

**NOTE:** Disconnecting the Glucose Sensor assembly from its Cable or the Cable from the Monitor for more than two minutes will interrupt the initialization process.

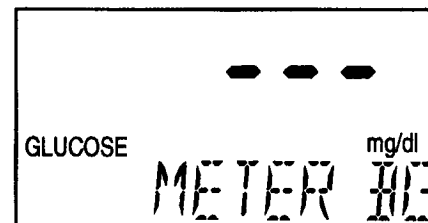
## PERFORMING THE INITIAL CALIBRATION SENSITIVITY CHECK

When the Glucose Sensor has been initialized, the Monitor will prompt the user to calibrate the Glucose Sensor prior to operation. Until an initial calibration value has been entered into the Monitor memory, the CGMS will not provide any glucose information. Calibration is required to assure that the Monitor is able to convert the electronic signals from the Glucose Sensor into glucose values. **Optimal calibration of this instrument requires a minimum of four fingerstick entries for each day of Glucose Sensor use.**

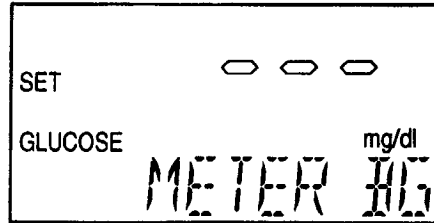
The initial calibration value is used as a calibration sensitivity check and should be performed by entering the average of two meter readings, obtained within a five minute period, into the Monitor. This value should be designated as a calibration value. The blood samples for the two readings may be obtained from one fingerstick or two separate fingersticks. Thereafter, a calibration sensitivity check should be performed at least once each day of Glucose Sensor use.

More details regarding calibration of the Glucose Sensor based on entered meter values is provided on page 27 of the Com-Station Instructions for Use.

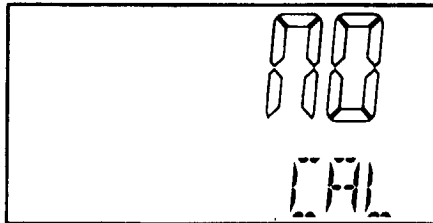
- 1. Automatic prompt:** At the completion of the initialization, the Monitor will beep and "METER BG" will appear for 15 seconds as a reminder to take glucose meter measurements and enter a value into the Monitor. After 15 seconds, the Monitor will return to the Normal Operation Display.



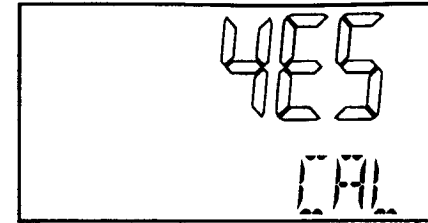
2. **Enter a glucose measurement:** The patient should take two (2) fingerstick glucose meter measurements no sooner than one minute before the end of the initialization period. When the "METER BG" display appears, a glucose value of "--- mg/dl" will be shown on the screen. Press the ACT button once and the glucose value will begin to blink. Use the ▲ and ▼ buttons to select the average meter value in increments of 1 mg/dl, then press ACT to enter. 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.



3. **Use the glucose value for a calibration sensitivity check:** The Monitor will beep, the word "CAL" will appear and the word "NO" will be blinking in the upper right-hand corner of the display.



The glucose measurement may be used to perform a calibration-sensitivity check ("YES") or simply used to update the calibration without performing a sensitivity check ("NO"). Press either the ▲ or ▼ button to select a "YES" response, then press the ACT button. The Monitor will be returned to the Normal Operation Display.



**PRECAUTION:** Each glucose meter value entered into the Monitor will be used for calibration. Once a blood glucose meter measurement is confirmed, it cannot be removed. If a wrong glucose meter value was entered by mistake, enter the correct blood glucose value as soon as possible. **INCORRECT BLOOD GLUCOSE ENTRIES MAY REDUCE THE ACCURACY OF THE MONITOR VALUES.**

**NOTE:** To exit the "SETUP" menu at any time, press the SEL button until "EXIT" appears on the display. Then press ACT to exit "SETUP" and return to the Normal Operation Display.



# IX OPERATING THE CONTINUOUS GLUCOSE MONITOR

This section explains how to operate the Continuous Glucose Monitor. Detailed information for downloading and interpreting Monitor data is provided in the Com-Station Instructions for Use.

Turn on the Monitor by pressing the **ON-OFF** (Ⓢ) button once. The Normal Operation Display will appear with time shown in the upper left-hand corner of the screen.

The following menus are used to operate the Monitor:

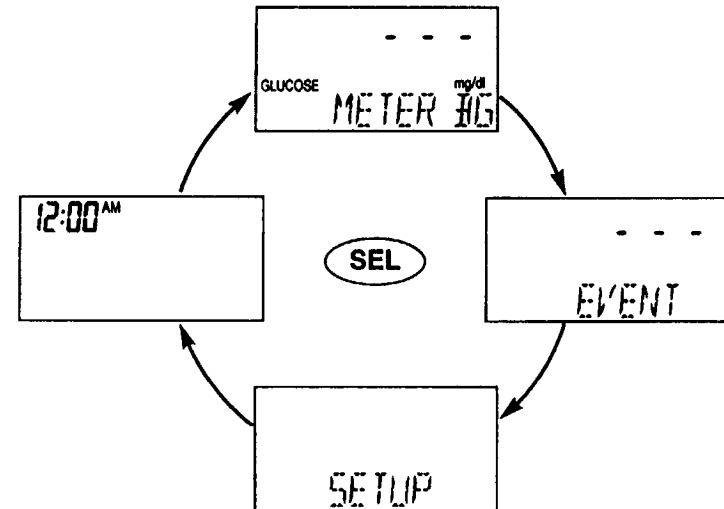


FIGURE 9 - 1: Operating Menus Flow Diagram

There are three (3) operating menus to choose from: "METER BG," "EVENT" and "SETUP." From the Normal Operation Display, pressing the SEL button once will advance to the next operating menu. Notice that pressing SEL from the "SETUP" menu will return the user back to the Normal Operation Display once again.

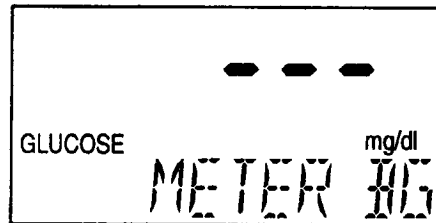
## ENTER METER VALUES FOR GLUCOSE SENSOR CALIBRATION

It is necessary to enter the average of two (2) fingerstick glucose meter measurements into the Monitor's memory each day to perform the real-time calibration sensitivity check by designating the value as "CAL YES". The blood samples for the two readings may be obtained from one fingerstick or two separate fingersticks. In addition, it is recommended that users enter a minimum of three (3) other meter values each day. These additional values can be identified as "CAL NO" values at the time of entry and will not be used for real-time calibration sensitivity checks. All meter values entered in the Monitor will be used at the time of downloading the data to a personal computer to generate the calibration constants required to convert the sensor signals to blood glucose values.

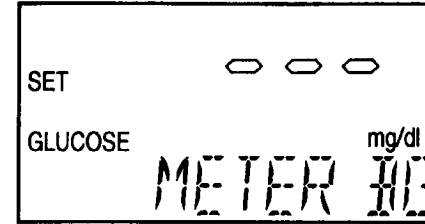
**NOTE:** The Glucose Monitor will only accept meter values between 40 and 400 mg/dl. If the patient's blood glucose is outside this range, treat as appropriate and instruct the patient to enter a meter value into the Monitor once their blood glucose is between 40 and 400 mg/dl.

**PRECAUTION:** It is important that patients attempt to take fingerstick glucose meter measurements when their blood glucose is relatively stable by avoiding times such as immediately following meals, insulin delivery or exercise. Each measurement should be entered into the Monitor within 1-2 minutes after taking a blood sample.

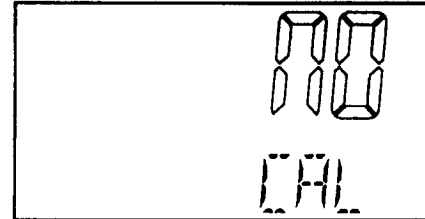
**1. Find the "METER BG" menu:** First, take either one or two glucose meter measurements. Then from the Normal Operation Display, press the **SEL** button once. The "METER BG" menu will be shown:



**2. Enter a glucose measurement:** Press the **ACT** button once and the glucose value will begin to blink. Use the **▲** and **▼** buttons to select a glucose value in increments of 1 mg/dl, then press **ACT** to enter.



**3. Designate how the glucose value will be used:** The Monitor will beep, the word "CAL" will appear and the word "NO" will be blinking in the upper right-hand corner of the display. The glucose value may be used to perform the real-time calibration sensitivity check in addition to being used for calibration ("YES") or simply recorded for calibration purposes only ("NO"). Press the **▲** and **▼** buttons to select either a "YES" or "NO" response, then press the **ACT** button. The Monitor will be returned to the Normal Operation Display.



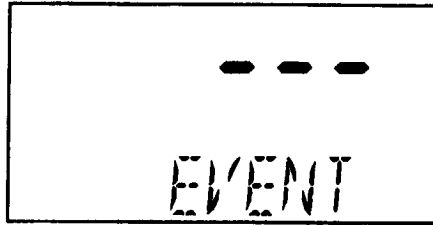
**PRECAUTION:** The Continuous Glucose Monitor will alarm and "ERROR" will appear on the screen, if the glucose value entered to perform the calibration sensitivity check is outside the expected range. Follow the instructions in *CHAPTER TEN: Understanding and Responding to Alarms*.

**PRECAUTION:** Each glucose meter value entered into the Monitor will be used for sensor calibration. Once a blood glucose meter measurement is confirmed, it cannot be removed. If a wrong glucose meter value was entered by mistake, enter the correct blood glucose value as soon as possible. **INCORRECT BLOOD GLUCOSE ENTRIES WILL REDUCE THE ACCURACY OF THE GLUCOSE VALUES CALCULATED BY THE CGMS.**

## RECORD IMPORTANT EVENTS

The Monitor has a menu for recording important daily events. These events include meals and snacks, insulin dosages, exercise and illness, that may affect blood glucose levels.

1. **Find the "EVENT" menu:** From the Normal Operation Display, press the **SEL** button twice. The "EVENT" screen will be shown.



2. **Find the event code:** Find the correct code (1 to 9) for the event to be entered. Suggested event codes are:

- 1 - Meals
- 2 - Insulin
- 3 - Exercise
- 4 to 9 - Other

**NOTE:** CGMS users should establish a list of event codes in advance of operating the Monitor.

3. **Enter the event code:** Press the **ACT** button and either " --- " or the last event code entered will start blinking in the upper right-hand corner of the screen. Use the **▲** and **▼** buttons to select the appropriate code, then press **ACT**. Each event code is automatically time and date stamped at the time of entry into the Monitor memory.

## X UNDERSTANDING AND RESPONDING TO ALARMS

This section describes the Continuous Glucose Monitor alarms and how to respond to alarm conditions to keep the Monitor operating smoothly.

During an alarm, the Monitor will normally beep once and then continue to beep about once every 15 seconds until the alarm is acknowledged. All monitor alarms, except "LOW BATT", "NO POWER" and "ERROR E-0X", must be acknowledged by pressing in sequence **SEL** followed by **ACT**. If an alarm is not acknowledged within 10 minutes, a continuous audible alarm will sound.

Alarm conditions are shown sequentially on the display screen if more than one exists. The most important alarm condition will be shown first. The type of each alarm and when it occurs is stored in the Monitor memory.

**NOTE:** A calibration sensitivity check must be performed following the resolution of any alarm condition by entering a "METER BG" value and selecting "CAL YES". No CGMS glucose values will be calculated after the alarm until the check is performed

**NOTE:** Refer to *CHAPTER TWELVE: Troubleshooting Guide* for specific instructions to diagnose and resolve Continuous Glucose Monitor alarm conditions.

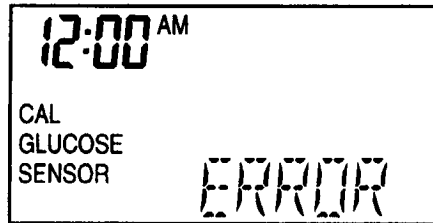
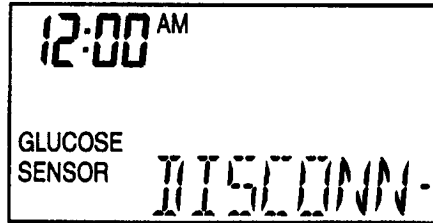


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## GLUCOSE SENSOR DISCONNECTED

An alarm will beep about once every 15 seconds, and "DISCONN-" will appear in response to a possible disconnection of the Glucose Sensor from the Monitor, or the Glucose Sensor may have pulled out of the insertion site.

1. **Acknowledge the "DISCONN-" alarm:** Turn off the alarm by pressing in sequence **SEL** followed by **ACT**. When the "DISCONN-" alarm is acknowledged, the Monitor will continue to beep and "ERROR" will appear on the screen indicating that a calibration sensitivity check should be performed. Press in sequence **SEL** followed by **ACT** again. The "ERROR" screen will change back to the Normal Operation Display. The "DISCONN-" alarm will repeat every five (5) minutes as long as the disconnect condition remains.



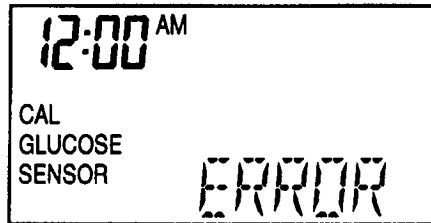
2. Find the "SIGNALS" screen and read "ISIG" for 15 seconds. See the section, "Read the Current and Voltage Signals".
3. **Check the Glucose Sensor-to-Cable and Cable-to-Monitor connections.** Check to make sure that the connections between the Glucose Sensor and Monitor are tight. Watch for any changes in the ISIG value.

4. **Recalibrate the Monitor.** If the ISIG value is more than 5 and remains fairly constant, wait 15 minutes and then recalibrate the Monitor before returning to normal operation.
5. **Check the function of the Cable and Monitor.** If the ISIG value is either less than 5 or highly variable, refer to the Test Plug Procedure in *CHAPTER TWELVE Troubleshooting Guide*.

---

## CALIBRATION ERROR

An alarm will beep about every 15 seconds and "ERROR" will appear. A fingerstick glucose measurement entered into the Monitor is outside the expected range of values.

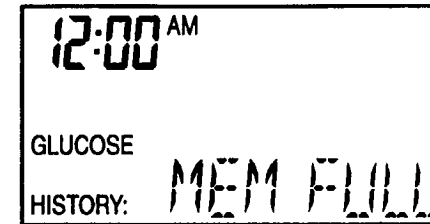


1. **Acknowledge the "ERROR" alarm:** Turn off the alarm by pressing in sequence **SEL** followed by **ACT**. The "ERROR" screen will change back to the Normal Operation Display. The alarm will repeat every five (5) minutes as long as the last fingerstick glucose measurement entered remains outside the expected range.
2. **Find the "METER BG" screen:** Check to make sure the most recent blood glucose value entered into the Monitor memory for calibration is correct. If an incorrect value was entered by mistake, turn off the Monitor, then turn it back on again and enter the correct blood glucose value, see *CHAPTER EIGHT: Initialization and Calibration Sensitivity Check*. Otherwise,
3. **Replace the Glucose Sensor, then:**
4. **Check the function of the Cable and Monitor.** Refer to the Test Plug Procedure in *CHAPTER TWELVE: Troubleshooting Guide*.

---

## MEMORY FULL

An alarm will beep about every 15 seconds and "MEM FULL" will appear. The Monitor memory is 90% filled with recorded glucose data.



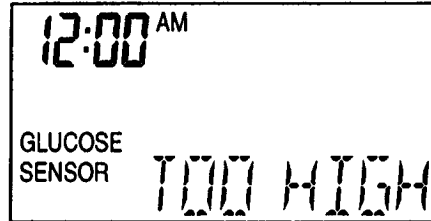
1. **Acknowledge the "MEM FULL" alarm:** Turn off the alarm by pressing in sequence **SEL** followed by **ACT**. The "MEM FULL" screen will change back to the Normal Operation Display. The alarm will repeat every six (6) hours as long as the memory is more than 90% full.
2. **Download glucose data to a personal computer:** Glucose data stored in the Monitor should be downloaded to a computer within 24 hours after the first "MEM FULL" alarm sounds.
3. **Find the "CLEAR" menu:** After successfully downloading the glucose data, clear the Monitor memory of all glucose data. See *CHAPTER SEVEN: Programming the Continuous Glucose Monitor*.

**NOTE:** If the Continuous Glucose Monitor memory becomes completely filled, no additional glucose data will be recorded until the memory is cleared.

---

## GLUCOSE SENSOR CURRENT TOO HIGH

An alarm will beep about every 15 seconds and "TOO HIGH" will appear on the screen. The Monitor has detected an "ISIG" value above "200" for three (3) minutes.

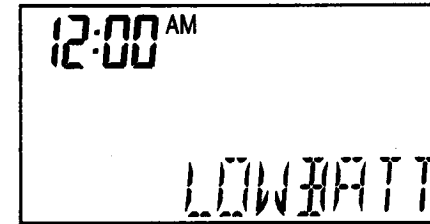


1. **Acknowledge the "TOO HIGH" alarm:** Turn off the alarm by pressing in sequence **SEL** followed by **ACT**. The "TOO HIGH" screen will change back to the Normal Operation Display. The alarm will repeat every three (3) minutes as long as an abnormally high Glucose Sensor current continues to be detected.
2. **Take a fingerstick glucose meter measurement:** If the measurement is greater than 400 mg/dl, treat per physician's instructions and return to normal operation. If the measurement is less than 400 mg/dl but still above normal, treat per the physician's instructions and then,
3. **Replace the Glucose Sensor, then:**
4. **Check the function of the Cable and Monitor.** Refer to the Test Plug Procedure in *CHAPTER TWELVE: Troubleshooting Guide*.

---

## LOW BATTERY

When the two (2) AAA alkaline batteries in the Monitor are depleted, an alarm will beep and "LOWBATT" will appear on the screen. The batteries have about eight (8) hours of normal operating life remaining. The time of the initial alarm is recorded into the Monitor memory.



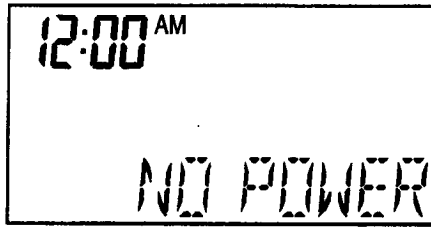
After a "LOWBATT" alarm, the Monitor will continue to operate normally. The "LOWBATT" reminder will remain on the Normal Operation Display. During Glucose Sensor initialization ("INIT") and while viewing the "SIGNALS" screens, the "LOWBATT" reminder will appear briefly every 10 seconds. The alarm will repeat every hour until the batteries are changed.

1. **Turn off the Monitor.** Press in sequence the ON/OFF button followed by **ACT**.
2. **Change the batteries:** Install two (2) new AAA alkaline batteries. Follow the battery replacement procedure described in *CHAPTER FIVE: Unpacking Instructions*.
3. **Press the ON/OFF button once to return to the Normal Operation Display.**
4. **Recalibrate the Glucose Sensor** before returning to normal operation.

---

## No POWER

When the two (2), AAA alkaline batteries in the Monitor are in danger of losing power, an alarm will beep and "NO POWER" will appear on the screen. The batteries are expected to last less than one (1) hour and must be changed immediately to continue normal operation. An interruption in operation is imminent. The time of the initial alarm is recorded into the Monitor memory.



After a "NO POWER" alarm, the Monitor will continue to operate normally as long as there is sufficient power to continue. The "NO POWER" reminder will remain on the normal operation screen. During Glucose Sensor initialization ("INIT") and while viewing the "SIGNALS" screens, the "NO POWER" reminder will appear briefly every 10 seconds. The alarm will repeat until either the batteries are changed or all power is lost and the screen goes blank.

1. **Turn off the Monitor.** Press in sequence the **ON/OFF** button followed by **ACT**.
2. **Change the batteries:** The batteries must be replaced immediately to continue normal operation. Follow the battery replacement procedure described in *CHAPTER FIVE: Unpacking Instructions*.
3. **Press the ON/OFF button** once to return to the Normal Operation Display.
4. **Recalibrate the Glucose Sensor** before returning to normal operation.

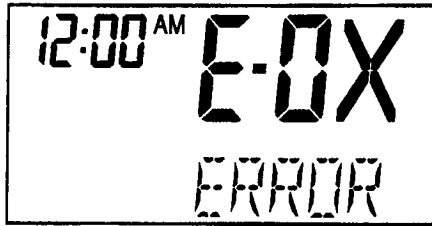
**PRECAUTION:** If the Monitor shows a "NO POWER" alarm for more than one hour, the glucose data and set up information in the Monitor memory will be lost. If this occurs, after replacing the batteries, all set up information will return to the manufacturer's original settings. Reprogram the Monitor and then reinitialize and recalibrate the Glucose Sensor before returning to normal operation. Patients should be instructed to contact their health care professional immediately if this occurs.



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## SYSTEM ERROR

A diagnostic test has detected an error in the Monitor program memory.



1. **Download glucose data into a personal computer:** Glucose data in the Monitor should be downloaded into a personal computer immediately.
2. **After successfully downloading the data, replace the Monitor.** Call the MiniMed Clinical Services Help Line at: (800) 826-2099.

**PRECAUTION:** The Continuous Glucose Monitor must be left on until all data is successfully downloaded into a personal computer. Turning the Monitor off by removing the batteries may result in a loss of this data.

**NOTE:** The "X" in "E-0X" is a number from 1 to 9 that identifies the nature of the error and is useful to MiniMed technicians as a troubleshooting aid.

# XI CARING FOR THE CONTINUOUS GLUCOSE MONITOR

---

## MAINTENANCE OF THE CONTINUOUS GLUCOSE MONITOR

### PROTECTION FROM WATER:

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

1. The Monitor should not be used while swimming.
2. The Monitor should always be placed into a Shower-Pak or other fluid resistant container before taking a shower or bath.
3. The Monitor should never be submerged.
4. Check to make sure that the occlusive dressing covering the Glucose Sensor connector is tightly adhered to the skin.
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 or disconnect the Cable and Glucose Sensor.

1. The Monitor should be protected from mechanical damage such as a fall or impact.
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. The Monitor should be safely secured to the body, and all connections should be checked frequently during exercise.
4. If a "DISCONN-" alarm should occur, the user should stop exercising and follow the directions in *CHAPTER TEN: Understanding and Responding to Alarms*, or in *CHAPTER TWELVE: Troubleshooting Guide*.

#### **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 worn close to the body and under 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 CONTINUOUS GLUCOSE MONITOR**

1. Use a damp cloth and mild cleaning solution to clean the outside of the Monitor. Cleaning solutions may include tap water, 409<sup>®</sup>, Windex<sup>®</sup>, Liquid Joy<sup>®</sup>, Betadine<sup>®</sup>, 10% bleach solution, 3% hydrogen peroxide solution and 70% isopropyl alcohol. Do not spray solution directly onto the Monitor. Do not clean and avoid moisture contact with the Glucose Sensor-to-Cable, or Cable-to-Monitor connectors.
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.

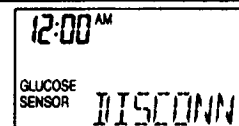
1. Keep the Monitor in its leather case to protect against electrostatic discharges, that are common in cold and dry climates.
2. **Do not** place the Monitor in direct contact with X-rays or other medical or industrial imaging equipment. If a user is scheduled to have an X-ray, CT or MRI scan, either protect the Monitor by placing it under lead shielding or take the Monitor off by gently disconnecting the Cable from the Sensor. After the procedure, the Cable and Sensor should be reconnected, and the sensor recalibrated before returning to normal operation.

**NOTE:** For procedures which require the Continuous Glucose Monitor to be disconnected for more than 15 minutes, reconnect the Cable to the Monitor, wait 30 minutes and then recalibrate the Glucose Sensor before returning to normal operation.

## XII TROUBLESHOOTING GUIDE

### Alarm Message

### What To Do



**Cause:** The Monitor is not detecting a signal from the Glucose Sensor.

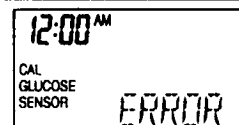
The Glucose Sensor may be disconnected from the Monitor, or may have pulled out of the insertion site.

See *CHAPTER TEN: Understanding and Responding to Alarms*.

**When:** An alarm will beep every 15 seconds until acknowledged.

The alarm will repeat every 5 minutes as long as the Monitor continues not to detect a signal.

1. Turn off the alarm by pressing SEL and then ACT. An ERROR message will appear. Press SEL and then ACT again.
2. Find the SIGNALS screen and read ISIG (see the section "Read the Current And Voltage Signals"). Check the Glucose Sensor-to-Cable and Cable-to-Monitor connections while watching the screen.
3. If the ISIG value is more than 5 and remains fairly constant, wait 15 minutes and then recalibrate the Monitor before returning to normal operation. If the ISIG value is either less than 5 or highly variable, refer to the Test Plug Procedure at the end of this Troubleshooting Guide.

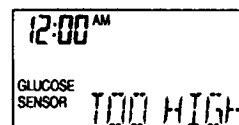


**Cause:** A blood glucose value entered to perform the calibration sensitivity check is either higher or lower than expected.

See *CHAPTER TEN: Understanding and Responding to Alarms*.

**When:** An alarm will beep every 15 sec. until acknowledged. This alarm will always follow a DISCONN alarm, as a reminder to perform the calibration sensitivity check before returning to normal operation.

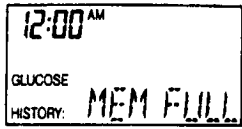
1. Turn off the alarm by pressing SEL and then ACT.
2. If ERROR alarm follows a calibration entry, check the METER BG screen to make sure the blood glucose value entered was correct. If the wrong glucose value was entered by mistake, turn off the Monitor, then turn it back on again and enter the correct blood glucose value. See *CHAPTER EIGHT: Initialization And Calibration Sensitivity Check*.
3. Otherwise, replace the Glucose Sensor.
4. Then, check the Monitor and Cable function by referring to the Test Plug Procedure at the end of this Troubleshooting Guide.



**Cause:** The Monitor detected a sensor current (ISIG) that is higher than expected. See *CHAPTER TEN: Understanding and Responding to Alarms*.

**When:** An alarm will beep every 15 sec. until acknowledged. The alarm will repeat every 3 min. as long as the sensor current (ISIG) remains higher than expected.

1. Turn off the alarm by pressing SEL and then ACT.
2. Take a glucose meter measurement:
  - a. If measurement is greater than 400 mg/dl, treat per physician's instructions.
  - b. If measurement is less than 400 mg/dl but still above normal, treat per physician's instructions and then replace the Glucose Sensor. Refer to the Test Plug Procedure at the end of this Troubleshooting Guide



**Cause:** The memory used to store glucose data is more than 90% full. See *CHAPTER TEN: Understanding and Responding to Alarms*.

**When:** An alarm will beep every 15 seconds until acknowledged. The alarm will repeat every six (6) hours as long as the memory is more than 90% full.

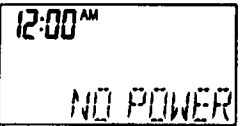
1. Turn off the alarm by pressing SEL then ACT.
2. Download the Monitor glucose data to a PC within 24 hours after the first alarm occurs.
3. After successfully downloading the data, clear all glucose history data from the Monitor memory. See *CHAPTER SEVEN: Programming the Continuous Glucose Monitor*.



**Cause:** The two (2) AAA batteries in the Monitor have about eight (8) hours of power remaining, and need to be changed as soon as possible. See *CHAPTER TEN: Understanding and Responding to Alarms*.

**When:** The Monitor will continue to operate normally. An alarm will beep once and repeat every hour until the batteries are replaced or lose power.

1. Turn off the Monitor.
  2. Install two (2) AAA alkaline batteries. Follow the battery replacement procedure described in *CHAPTER FIVE: Unpacking Instructions*.
  3. Press the ON/OFF button once to return to the Normal Operation Display.
  5. Recalibrate the Glucose Sensor.
- NOTE:** Batteries should be replaced within 5 minutes to avoid losing glucose data and program information in the Monitor memory.



**Cause:** The two (2) AAA alkaline batteries in the Monitor are nearly out of power and an interruption in operation is imminent. See *CHAPTER TEN: Understanding and Responding to Alarms*.

**When:** The Monitor will attempt to operate normally as long as there is sufficient power to continue. The alarm will beep once and repeat every hour until the batteries are replaced or lose power.

1. Turn off the Monitor by pressing the ON/OFF button and then ACT.
  2. The batteries must be replaced immediately to continue normal operation. Follow the battery replacement procedure described in *CHAPTER FIVE: Unpacking Instructions*.
  3. Press the ON/OFF button once to return to the Normal Operation Display.
  4. Recalibrate the Glucose Sensor.
- NOTE:** If the Monitor shows a "NO POWER" alarm for more than one hour, glucose data and program information in the memory will be lost. If this occurs, all setup information will return to the manufacturer's original settings. Reprogram the Monitor, and then reinitialize and recalibrate the Glucose Sensor.

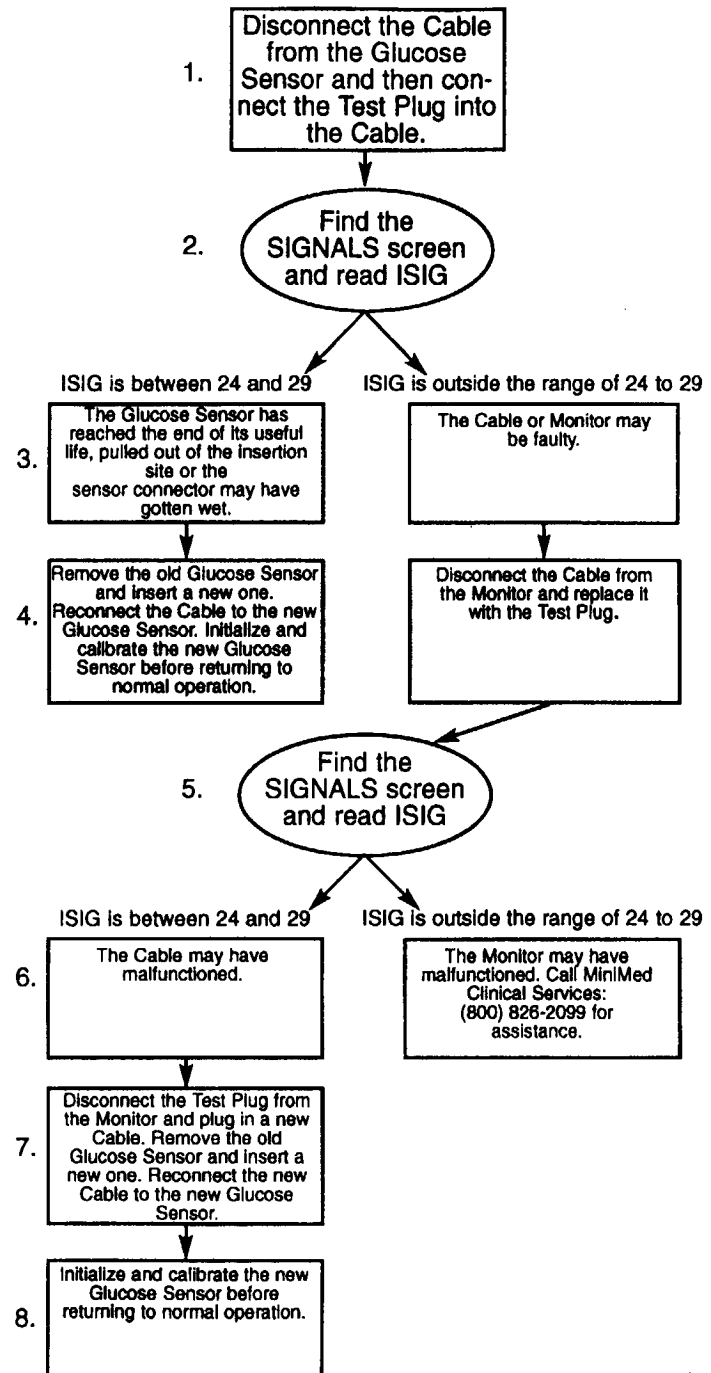


**Cause:** A diagnostic test detected an error in the Monitor program memory. See *CHAPTER TEN: Understanding and Responding to Alarms*.

**When:** An alarm will beep every 10 seconds, until all data is downloaded into a PC.

1. Immediately download all Monitor glucose data to a PC.
  2. After successfully downloading the data, replace the Monitor.
- Note:** The Monitor must be left on until all data is successfully downloaded to a PC. Turning the Monitor off by removing the batteries may result in a loss of this data.

## TEST PLUG PROCEDURE





# GLOSSARY

**Alarm** - An audible tone that alerts the user of an important event. Alarm conditions for the Continuous Glucose Monitor include Monitor alarms and system errors.

**Cable** - A special wire with connectors that transmits electronic signals from the Glucose Sensor to the Continuous Glucose Monitor.

**Calibration** - The process of adjusting how the Continuous Glucose Monitor converts electronic signals from the Glucose Sensor into glucose values. The Monitor is calibrated by entering periodic fingerstick glucose meter measurements into the monitor memory.

**Calibration Sensitivity Check** - If a meter value is entered into the Monitor and the "CAL YES" option is selected, a calibration sensitivity check is performed. A sensitivity ratio is determined by dividing the meter value by the most recent sensor current reading. If the result of this calculation is 15 or greater, the Monitor will display a "CAL ERROR" message, indicating that the Glucose Sensor has reached the end of its useful life.

**Com-Station** - A device that allows a personal computer (PC) to communicate with the Continuous Glucose Monitor, for the purpose of downloading data for analysis and interpretation. The communication link between the Continuous Glucose Monitor and Com-Station is by infrared port. The communication link between the Com-Station and a computer is by RS-232 cable.

**Continuous glucose monitoring** - The method of checking constantly on the level of a patient's physiological glucose and then recording glucose values for periodic analysis.

**Continuous Glucose Monitoring System (CGMS)** - A medical device developed by MiniMed Inc. to perform continuous glucose monitoring on people with diabetes mellitus. The CGMS consists of a subcutaneous Glucose Sensor, a Continuous Glucose Monitor, a Cable connecting the Glucose Sensor and Monitor, and a Com-Station for transferring glucose data to a personal computer.

**CT** - Computed tomography, also called body section roentgenography. A method of medical imaging, whereby a patient is exposed to an X-ray beam. Electronic pulses produced in the body are then transferred to a computer to construct medical images.

**Data link** - The connection of two (2) or more electronic devices together for the purpose of sharing or transferring data. A data link between the Continuous Glucose Monitor and a personal computer (PC) is established by using a Com-Station.

**Diabetic ketoacidosis (DKA)** - A complication of diabetes mellitus, caused by extremely low levels of circulating insulin. Fat cells to breakdown and release ketones into the bloodstream. Elevated ketone levels can cause nausea, vomiting, abdominal pain, rapid breathing, weight loss, frequent urination and dehydration.

**Diabetes Mellitus** - a general medical condition of metabolic and immunological origin, in which the body's ability to metabolize glucose is impaired. Type 1 or insulin-dependent diabetes involves the selective autoimmune destruction of pancreatic beta cells which are responsible for the production and secretion of insulin. Type 2 or adult-onset diabetes is caused by a reduction in insulin secretion combined with the development of a metabolic resistance to endogenous insulin.

**Download** - The process of transferring data from one electronic device to another after a communication link has been established. The Continuous Glucose Monitor can download glucose data to a personal computer (PC).

**Electrode** - An electrical conductor through which an electronic current is transmitted. The Glucose Sensor contains an electrode which continuously transmits electronic signals to the Continuous Glucose Monitor.

**Fingerstick glucose meter measurement** - A diagnostic method for measuring blood glucose, whereby the tip of a finger is lanced, a drop of blood is placed on a test strip, and the strip is placed into a spectrophotometric instrument which reports blood glucose.

**Glucose** - A monosaccharide also known as dextrose. Glucose is found in the normal blood of all animals, and is the chief energy source for living organisms. The use of glucose in the body is controlled by insulin.

**Glucose Sensor** - A device capable of performing glucose monitoring. A sensor responds to glucose levels in the body and generates an electronic signal that can be measured and recorded for analysis.

**Holter-type monitor** - A CGMS application used by health care professionals to collect and store glucose data during periods of 2-3 days for their patients diagnosed with diabetes. Data from the Monitor will then be transferred to a personal computer (PC) for analysis.

**Hyperglycemia** - Abnormally high levels of glucose in the bloodstream.

**Hypoglycemia** - Abnormally low levels of glucose in the bloodstream. Hypoglycemia events usually involve a blood glucose below 60 mg/dl and acute symptoms of weakness, confusion, dizziness, headache, trembling and sweats. Hypoglycemia is considered severe if the diabetes patient requires assistance to regain glycemic control.

**Hypoglycemia unawareness** - People with diabetes who experience frequent hypoglycemia events lose their ability to recognize the early symptoms of hypoglycemia. As a result, hypoglycemia events occur more rapidly, often with severe symptoms of long duration.

**Infection** - A possible side-effect of medical device usage, in which an invasion and multiplication of microorganisms occur in tissues which surround the device. These microorganisms may not be clinically apparent or may cause symptoms of local pain, redness, tenderness and inflammation.

**Initialization** - The process of equilibrating the electronic signal generated by the Glucose Sensor after it has been inserted in the subcutaneous tissue. Sensor initialization for 60 minutes is necessary to make sure the Monitor is receiving signals that are responsive to changes in glucose.

**Insulin** - A double-chain protein hormone, that regulates energy usage in the body in response to glucose and amino acid levels in the bloodstream.

**Intensive insulin therapy** - A method for regulating blood glucose in people with diabetes, recommended by the Diabetes Control and Complications Trial (DCCT). Intensive therapy usually requires 4 daily injections of insulin each day or continuous insulin infusion therapy with an insulin pump. Intensive therapy also requires 4 or more fingerstick glucose meter measurements each day to help establish insulin boluses and schedules.

**Irritation** - A possible side-effect of medical device usage, in which body surfaces contacting a device become inflamed and more sensitive to pain. Irritation may occur at the site of sensor insertion on the skin or in areas in which an occlusive bandage is used.

**ISIG** - Electrical current that the Glucose Sensor sends to the Continuous Glucose Monitor, measured in nanoamperes.

**Memory** - An electronic component of the Continuous Glucose Monitor that can accept and store electronic signals from the Glucose Sensor and retain programming information. This data can be transferred to a personal computer (PC) for analysis and interpretation.

**MRI** - Magnetic Resonance Imaging. A method of medical imaging, whereby a subject is placed into a strong magnetic field. Magnetic changes produced in the body are then transferred to a computer to construct medical images.

**Preprandial** - Before meals.









**Postprandial** - After meals.

**Subcutaneous** - Beneath the skin.

**VCTR** - Electrical voltage that the Continuous Glucose Monitor provides to the Glucose Sensor, measured in volts.

**X-ray** - Also called roentgenography. A method of medical imaging, whereby a patient is exposed to an X-ray beam. Photographic images are developed from the beam after it travels through the patient's body.



Please Read The Instructions for Use	
Manufacture Date (year - month)	 1999-12
Device Serial Number	S N
Storage Temperature Range	-20C  +56C
Type BF (Protection from electric shock)	
On / Off	
Change Value Up	
Change Value Down	
Backlight	
One Per Container / Package	(1x)
Activate	ACT
Select	SEL

If you require additional information regarding use of the Continuous Glucose Monitoring System, contact your health care professional or the Clinical Services Department at 800-826-2099.



USA:  
 Sylmar, CA  
 818-362-5958 • 800-826-2099 (24-hour Help Line within U.S. & Canada)  
 To order supplies:  
 800-843-6687 • FAX: 888-268-0200 (within U.S. & Canada)  
 FAX: 818-362-3788 (outside U.S.)

This product is covered by the following U.S. patent: [U.S.]5,376,070.  
 Other U.S. and/or foreign patents may be pending.

G9190038-011 6/99

# **MiniMed Continuous Glucose Monitoring System**

## **Com-Station Instructions For Use**

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# I BEFORE YOU BEGIN

The MiniMed Com-Station (MMT-7300 & 7301) is designed to retrieve glucose data from the Continuous Glucose Monitor (MMT-7102), and download it to a personal computer (PC) for analysis. This Instructions for Use document provides the user with information about the Com-Station, how to install the CGMS Com-Station Software (MMT-7310), how to download glucose data from the monitor, how to save it in data files in a PC, and how to use the software to analyze the data.

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## UNPACKING INSTRUCTIONS

Carefully unpack the Com-Station, saving all packing materials for possible future use. The original packing materials provide the safest way to transport the Com-Station if service becomes necessary. If any part of the system appears to have been damaged in shipment, do not attempt to use it. Call the MiniMed Clinical Services Help Line between 8:00AM and 5:00PM Pacific Time Monday through Friday at (800) 826-2099. If calling from outside the US, dial +1-818-368-2522 or call your local MiniMed Representative.

Check to make sure the box contains the following parts:

Com-Station (1 each)

MiniMed power cable with AC adapter (1 each)

Communication interface cable (1 each)

Important documents packet (1 each)

contains CGMS Com-Station Software diskette (1 each)

## REGISTRATION AND WARRANTY

Please fill out the Registration Card enclosed with the Com-Station and return it, so we can activate your warranty. Read the enclosed terms of the Warranty carefully, as it specifies what repairs are covered during the warranty period.

## DESCRIPTION OF THE COM-STATION

The Com-Station is an important component of the MiniMed Continuous Glucose Monitoring System (CGMS), allowing communication between the Continuous Glucose Monitor and a PC. The CGMS Com-Station Software provided on a diskette with the Com-Station will retrieve glucose data stored in the monitor and produce a report. The report includes text, graphics and key statistics useful for data analysis and interpretation.

The Com-Station also has a second communication port (Com Port B), that can connect commercially available memory glucose meters to a PC. To download glucose meter data to a PC, connect the glucose meter to Com Port B, press the Device Selector Switch to "B", and use the software provided by the glucose meter manufacturer to transfer the data (see Figure 1-1).

The Com-Station has the following operating components (see Figures 1-1 and 1-2):

- **On/Off Switch** - light illuminates when the Com-Station is ON.
- **Continuous Glucose Monitor "Cradle"** - A depression in the Com-Station where the Continuous Glucose Monitor is placed to download data stored in its memory. The Cradle contains infrared (IR) ports, which provide a communication link between the monitor and a PC and allow a data download to occur.
- **AC Adapter Port** - The power supply connection to the Com-Station.

- **Communication Ports (Com Ports) A and B** - Using a computer cable, provides a data link between the Com-Station and a PC (Port A) or a memory glucose meter (Port B).
- **Device Selector Switch** - Selects a data download from either a Continuous Glucose Monitor (MiniMed Logo) or a memory glucose meter (B).
- **IR Communication Ports** - When the Continuous Glucose Monitor is placed in the Com-Station Cradle, two (2) infrared (IR) ports on the back side of the monitor align with two (2) ports on the Com-Station. Data is then transferred between these IR ports.

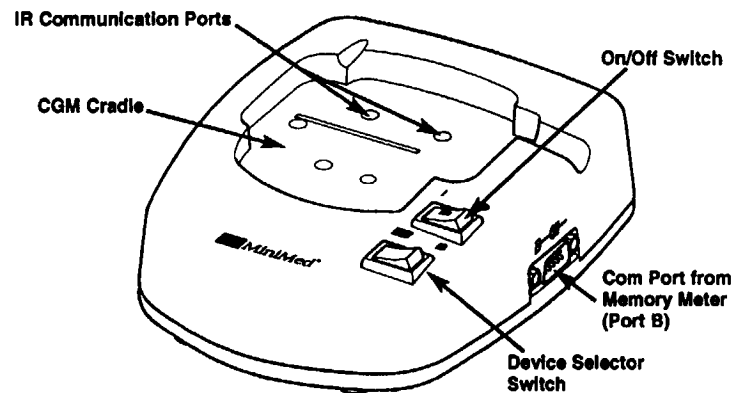


FIGURE 1 - 1: Com-Station Front View

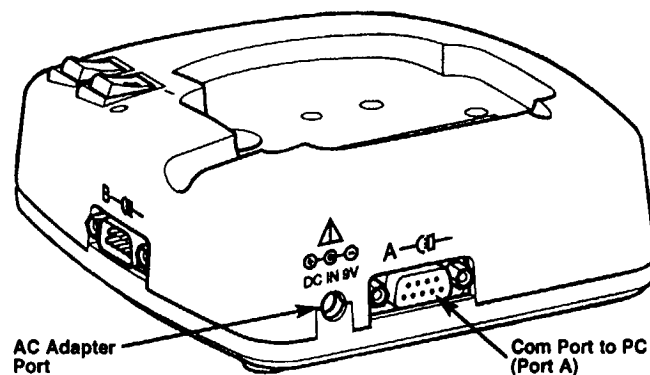


FIGURE 1 - 2: Com-Station Rear View



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## COM-STATION SPECIFICATIONS

Component	Performance Specification
Communication ports (2)	Serial, RS-232 compatible
Power cable (1)	DC power jack with AC adapter Complies with IEC 60601-1 and UL 2601-1 standards
Dimensions (approximate)	Length: 6.2 inches (15.7 centimeters) Width: 5.0 inches (12.7 centimeters) Height: 1.8 inches (4.5 centimeters)
Communications transfer from monitor	Infrared port
Operating Conditions	Temperature: +10 to +40 degrees Celsius (50 to 104 degrees Fahrenheit) Relative Humidity: 30% to 75% non-condensing
Storage Conditions	Temperature: -20 to +55 degrees Celsius (-4 to +131 degrees Fahrenheit) Relative Humidity: 10% to 100% with condensation
Chemical resistance	Resistant to common cleaning solutions, including tap water, 10% bleach solution, 3% hydrogen peroxide solution, Windex®, 409®, Betadine®, Liquid Joy® and 70% isopropyl alcohol

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## INDICATIONS FOR USE

The Com-Station is intended for use as a component of the Continuous Glucose Monitoring System (CGMS) to continuously monitor glucose levels in persons with diabetes.

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## CONTRAINDICATIONS

None.

# II SOFTWARE INSTALLATION

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## INSTALL THE SOFTWARE

Included with the Com-Station packaging is a 3.5 inch diskette containing the CGMS Com-Station Software. This software contains:

- a program that downloads, formats and stores data from the Continuous Glucose Monitor
- a program that generates a summary report and graphs of the stored data.

**NOTE:** The PC software and hardware requirements are:

- Microsoft Windows® 95.
- Microsoft Excel® for Windows 95, version 7.0a. Attempting to use an older version of Excel will result in an error message.
- At least 300 K bytes of memory available on the hard drive.
- For best results, a screen resolution set to a minimum of 800 x 600 pixels (1,024 x 768 pixels or higher is preferred).
- A printer has been set up using the "Printers" icon located in the Microsoft Windows 95 "Control Panel", even if no printer is physically connected to the PC.
- Either the COM1 or COM2 port is available and set to communicate with Microsoft Windows 95.

Windows is a registered trademark of Microsoft Corporation.  
Excel is a registered trademark of Microsoft Corporation.



## TO INSTALL THE SOFTWARE:

1. Before proceeding with the installation, close all active windows on the PC.
2. Insert the CGMS Com-Station Software diskette into the 3.5 inch drive (usually either the "A" or "B" drive) into the PC. The examples below will use the "A" drive.
3. Using the mouse, click once on the "Start" button located in the lower left-hand corner of the Microsoft Windows 95 desktop.
4. Click once on "Run." A dialogue box will appear (see Figure 2-1). Type the message "a:\setup.exe" in the text box:

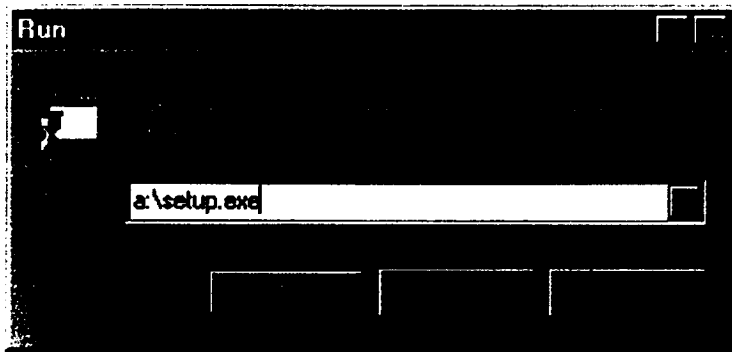


FIGURE 2 - 1: Run Dialog Box

5. Click once on "OK." The "CGMS Com-Station Software Setup Program" will appear (see Figure 2-2). The Setup screen will continue to appear while the CGMS Com-Station Software is being installed.

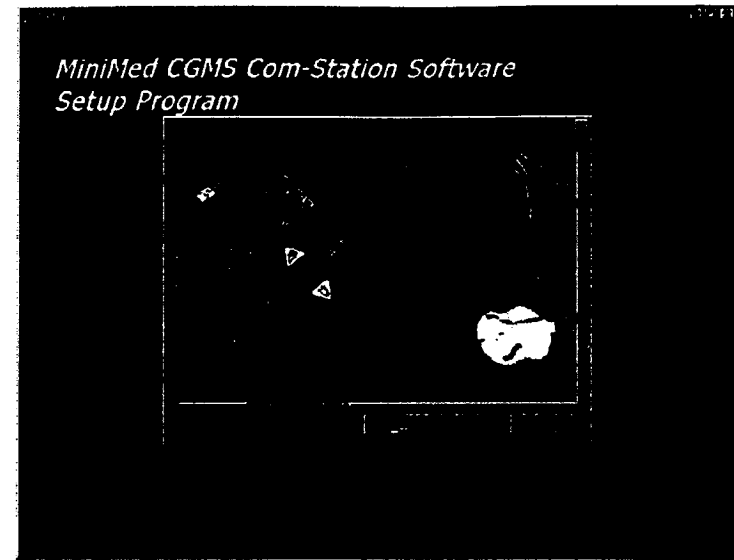


FIGURE 2 - 2: Setup Program Screen

6. Click once on "Next" to continue with the installation. A welcome message will appear on the screen (see Figure 2-3). Read and follow the instructions contained in this message box:

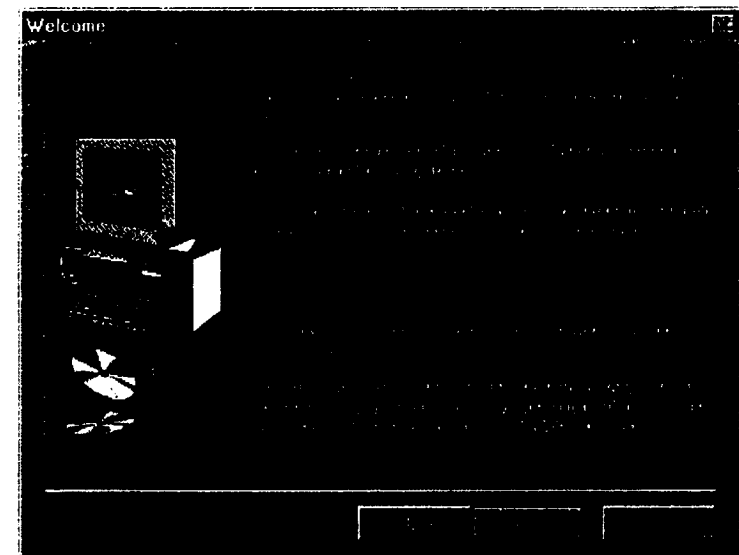


FIGURE 2 - 3: Welcome Screen

7. Click once on "Next" again. The Setup program will now guide the user through the following screens:

- **User Information.** Asks for a user name and company name (see Figure 2-4):

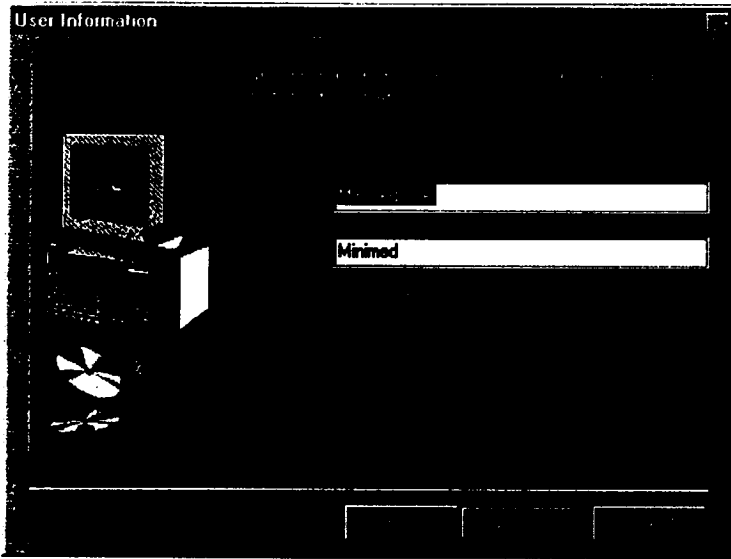


FIGURE 2 - 4: User Information

- **Choose Destination Location.** Selects "CGMS 1.4A Com-Station Software" as the default directory where the software will be located on the PC (see Figure 2-5):

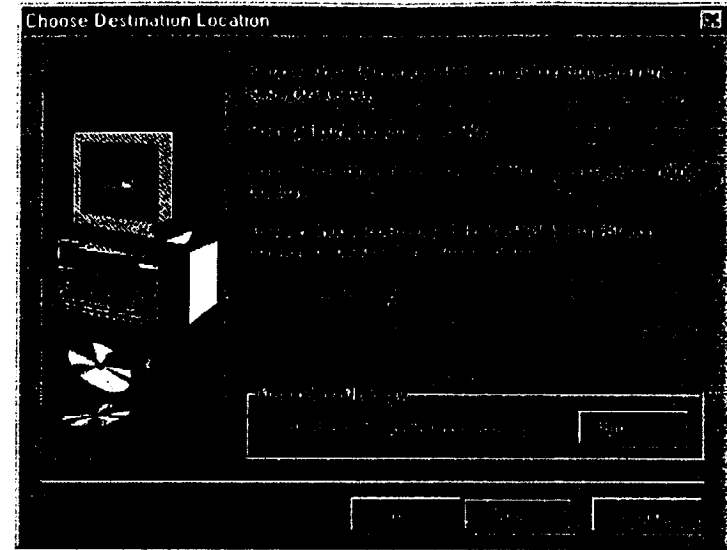


FIGURE 2 - 5: Choose Destination Location

- **Start Copying Files.** Displays the setup information that has just been entered. "MiniMed" is used as the default program folder name. At this time it is possible to go back and change any of the installed selections. If the selections are OK, click once on "Next" and the software installation will continue (see Figure 2-6):

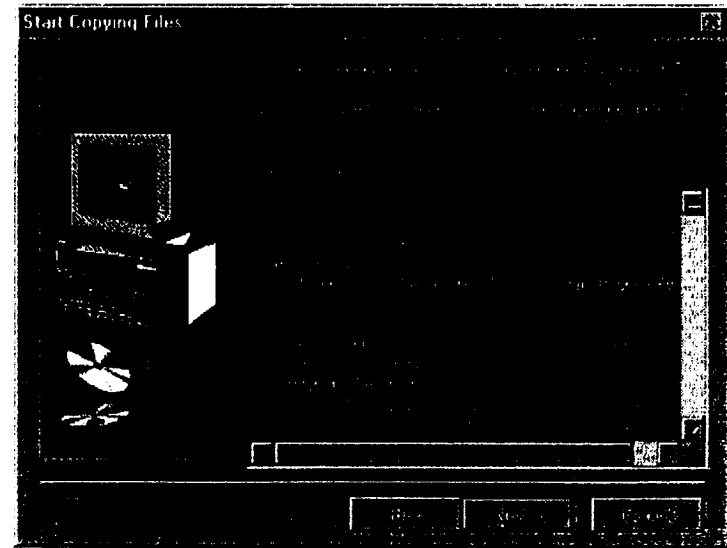


FIGURE 2 - 6: Start Copying Files

- **Setup Complete.** The necessary software installation files will now be copied to the PC hard disk. When the file transfer is completed, the following screen will appear (see Figure 2-7). Click "Finish" to complete the installation setup.

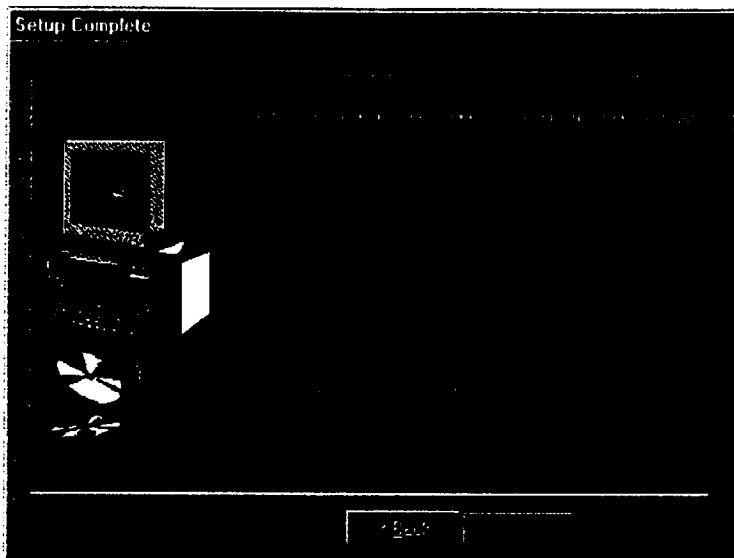


FIGURE 2 - 7: Complete the Installation

The Microsoft Windows 95 desktop screen on the PC should now have two (2) new icons (see Figure 2-8). If these icons are displayed, the software has been successfully installed. The Com-Station can now be set-up and then glucose data can be downloaded to the PC.



FIGURE 2 - 8: CGMS Com-Station Software Icons

**NOTE:** If the software icons do not appear, reinstall the CGMS Com-Station Software from the diskette.

## UNINSTALL THE SOFTWARE

Users may want to remove the MiniMed CGMS Com-Station Software from their PC. The Com-Station Software can be removed using the uninstall feature of the Microsoft Windows 95 desktop:

1. Click once on the "Start" button.
2. Use the cursor to select "Settings" and a list of options will appear.
3. Click once on "Control Panel." A menu of control panel options will appear.
4. Double-click on the "Add/Remove Programs " option.
5. The "Install/Uninstall " menu should be active on the screen. Otherwise click once on the "Install/Uninstall" tab to activate the menu
6. Scroll through the list of software programs and click once on "MiniMed CGMS Com-Station Software" to select it.
7. Click the "Add/Remove" button.
8. Confirm the selection by clicking the "Yes" button.
9. After the software is removed, click on the "OK" button.
10. The MiniMed CGMS Com-Station Software has now been removed.





# III DOWNLOADING TO YOUR PC

## CONNECT THE COM-STATION TO THE PC

1. Connect the Communication Interface Cable, which is supplied with the Com-Station, into either the "COM 1" or "COM 2" connector of the PC. These connectors are usually located in the rear of the PC.
2. Connect the other end of the Communication Interface Cable to the "COM A" port of the Com-Station (see Figure 3-1):

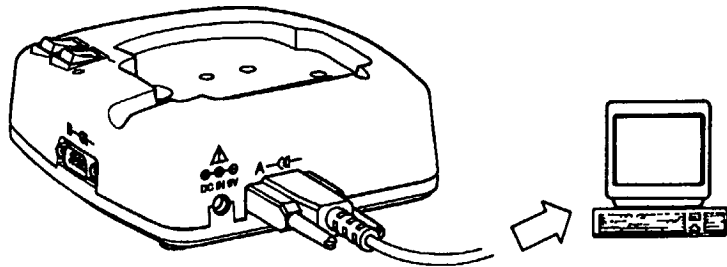


FIGURE 3 - 1: Communication Interface Cable Connection

3. Connect the MiniMed Power Cable with AC Adapter into a power source and connect the other end to the Com-Station (see Figure 3-2):

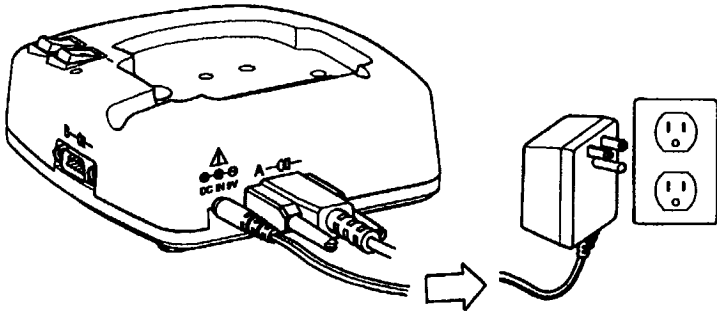


FIGURE 3 - 2: MiniMed Power Cable Connection

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## ESTABLISH A DATA LINK AND DOWNLOAD GLUCOSE DATA

With the connections established, the Com-Station is now ready to download the data stored in the Continuous Glucose Monitor. Follow these steps to download the data:

1. **Turn on the PC.** Wait until the Microsoft Windows 95 desktop is displayed.
2. **Place the Com-Station on a flat surface,** for example on a desk next to the PC.
3. **Turn on the Com-Station.** A green light on the ON/OFF Switch should illuminate indicating the Com-Station is on.
4. **Turn on the Continuous Glucose Monitor.** The monitor must be turned on, otherwise the download will not take place. Find the "PATIENT" screen and verify that the correct Patient ID has been entered (see *CHAPTER SIX* of the CGM Instructions for Use).

**NOTE:** If a "LOWBATT" alarm sounds when the Continuous Glucose Monitor is turned on, replacement of the batteries is recommended before downloading the glucose data. If the monitor gives a "NO POWER" alarm, replacing the batteries before continuing with the download is required (see *CHAPTER FOUR* of the CGM Instructions for Use).

5. **Press the Device Selector Switch on the Com-Station** to the MiniMed logo, to indicate that a MiniMed product will be used.
6. **Place the Continuous Glucose Monitor face up** into the Com-Station Cradle (see Figure 3-3). Make sure that the monitor is lying flat and snugly in the Cradle. This procedure will align the IR communication ports.



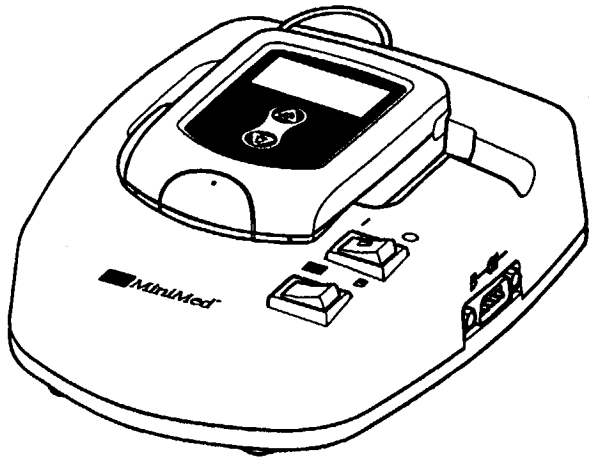


FIGURE 3 - 3: Monitor Placement in the Cradle

7. With the mouse, double-click on the "MiniMed Com-Station" icon on the Microsoft Windows 95 desktop. A MiniMed copyright message will appear for a few seconds (see Figure 3-4). Then, a main user interface screen will appear (see Figure 3-5).

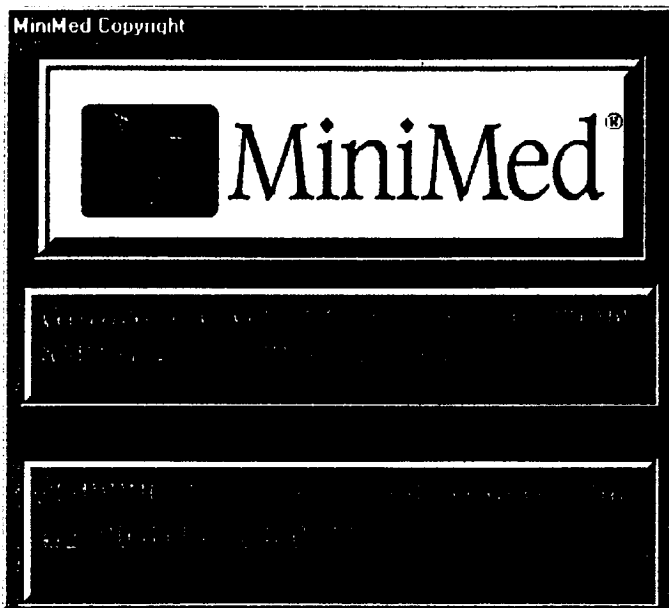


FIGURE 3 - 4: Copyright Message

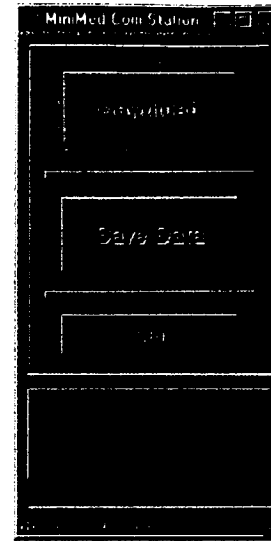


FIGURE 3 - 5: Com-Station Main User Interface

8. With the mouse, click on the "Download" button. The following actions will occur:
  - The status line on the main user interface screen will display "Waiting For Glucose Monitor" (see Figure 3-6):

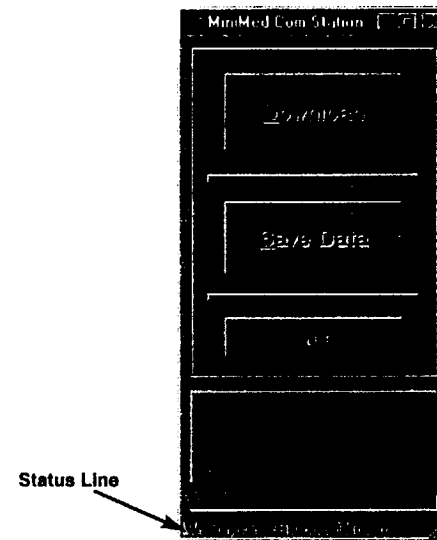


FIGURE 3 - 6: Waiting for Glucose Monitor





**NOTE:** Check to make sure the cable connections between the Com-Station (port A) and PC (Com 1 or Com 2) are correct and complete, the monitor is turned on and the normal operation display is shown, the monitor is placed properly in the Com-Station Cradle, the monitor and Com-Station IR communication ports are clean, and the Com-Station is turned on (green LED on) with the selector switch pressed toward the MiniMed logo. Click "Quit" on the main user interface screen, restart the CGMS Com-Station Software and then repeat step no. 7 of the directions. Refer to the Troubleshooting Guide at the end of these instructions.

- When a communication link is successfully established between the Continuous Glucose Monitor and PC, the status line will display "Receiving Data": indicating that data transfer has begun. The bottom screen on the user interface box will gradually reveal the word "MiniMed," and the progress bar will show how much of the data transfer has been completed (see Figure 3-7):

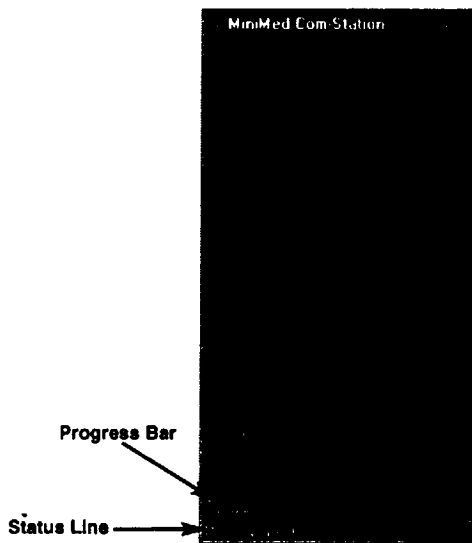


FIGURE 3 - 7: Receiving Data

- A download status screen will also appear, showing the amount of data in the monitor and what was downloaded to the PC (see Figure 3-8):

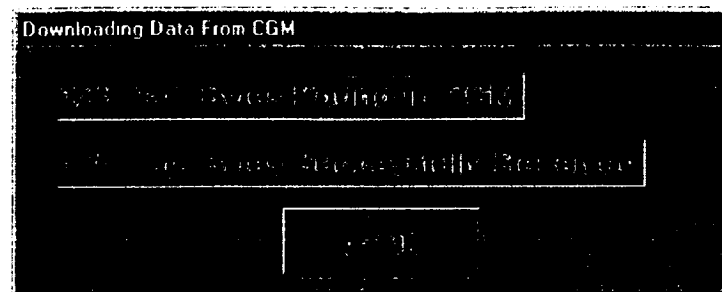


FIGURE 3 - 8: Data Transfer Status

- When the download is completed, the status line will display "Data Received" (see Figure 3-9):

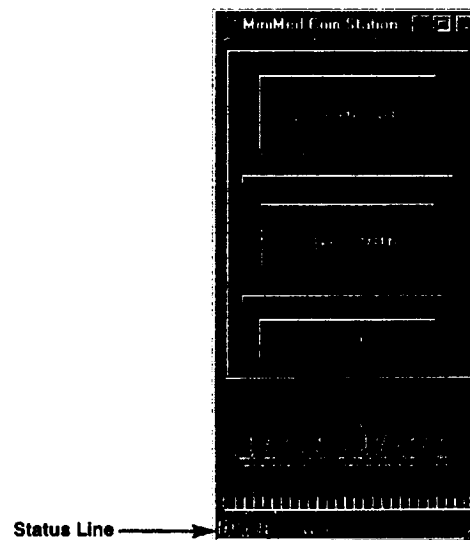


FIGURE 3 - 9: Data Received

- After completing the download, choosing "Download" again before saving the downloaded data will result in the following message (see Figure 3-10):



FIGURE 3 - 10: Previously Downloaded Data Not Saved

- Clicking on "Yes" will start the next download, and will delete all of the previously downloaded (but not saved) data in the PC. Clicking on "No" will return the user to the "Data Received" user interface screen.
- After completing the download, choosing "Quit" will result in the following message (see Figure 3-11):

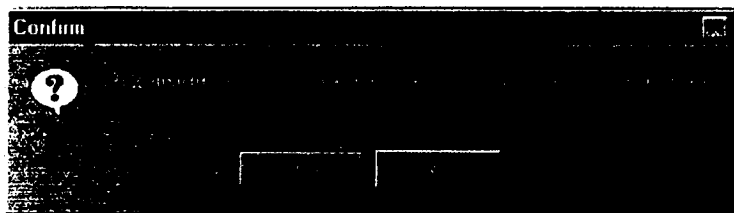


FIGURE 3 - 11: Recent Download Not Saved

- Clicking "No" allows the User to exit the MiniMed Com-Station software without saving the download. If "No" is chosen, the following message will appear (see Figure 3-12):

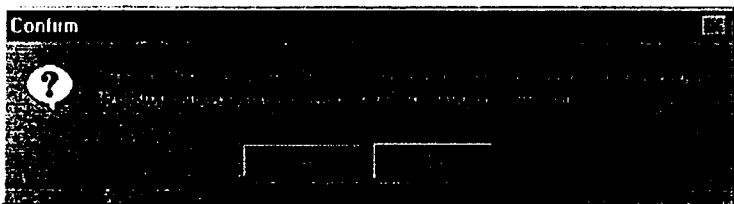


FIGURE 3 - 12: Exit Com-Station Software

- Clicking on "Yes" will exit the Com-Station software and return to the Microsoft Windows desktop. Choosing "NO" will return to the main user interface screen.

**NOTE:** If "Quit" is selected after a data download, data files will not be created or saved in the PC. Data from the same monitor can be downloaded again or new data from additional monitors can be downloaded.

- 9. Save function:** To save the data that was just downloaded, click once on the "Save Data" button. The software will begin generating and saving data files in the PC. The first time the Monitor is downloaded, a new file folder, "MonitorData," is created on the "C" drive. All of the new data files are saved and stored in the "MonitorData" file folder.

- When the data has been saved, the following screens are shown, showing the two new data files that were created in the MonitorData folder and verifying the data was successfully saved (see Figures 3-13 and 3-14):

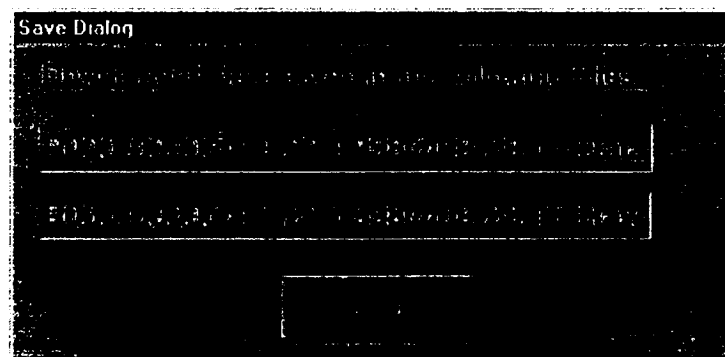


FIGURE 3 - 13: Saved Data Files



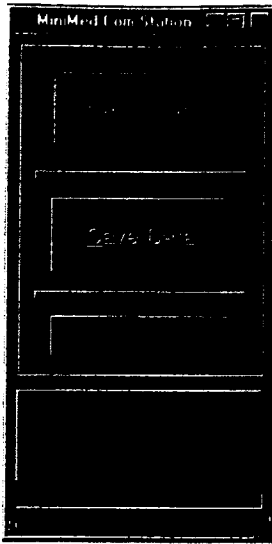


FIGURE 3 - 14: Data Saved

10. **File Name Format:** Data files are generated and saved, using the following name format:

- The patient ID, consisting of the letter "P" followed by seven digits (Pxxx-xxxx)
- The date of the data download in month, day, year format (mm-dd-yyyy)
- The time of the data download in hour, minute, second format (hh-mm-ss)

An example is P000-0008@10-15-1998@12-54-35, where "P000-0008" is the Patient ID, "10-15-1998" is the date, "12-54-35" is the time in 24 hour format, and the symbol "@" is used as a separator.

**File Name Format Example:** The following is an example of the "file tree" for data downloaded from the Continuous Glucose Monitor (see Figure 3-15).

#### A. File Folders

- The first time a monitor is downloaded, a file folder on the "C" drive is created that is called "MonitorData;"
- Every time a monitor with a different patient ID is downloaded and the data is saved, a new file folder for that Patient ID will be created. Each file folder will look like this: "C:\MonitorData\P000-0008". Each file folder contains all of the downloaded data files for a particular Patient ID, making data retrieval by patient very easy.

#### B. Data Folders

- Every time a monitor is downloaded and the data is saved, a new data folder is created. All data folders with the same Patient ID are placed inside the same file folder.
- Each data folder contains the Patient ID and a time and date stamp. For example, data folders will look like this: "P000-0008@10-15-1998@12-54-35"

#### C. Data Files

- Each data folder contains two (2) data files. The data files carry the same data folder name but have different extensions. Using the example below, the two (2) data files are:

P000-0008@10-15-1998@12-54-35.Data

P000-0008@10-15-1998@12-54-35.Raw



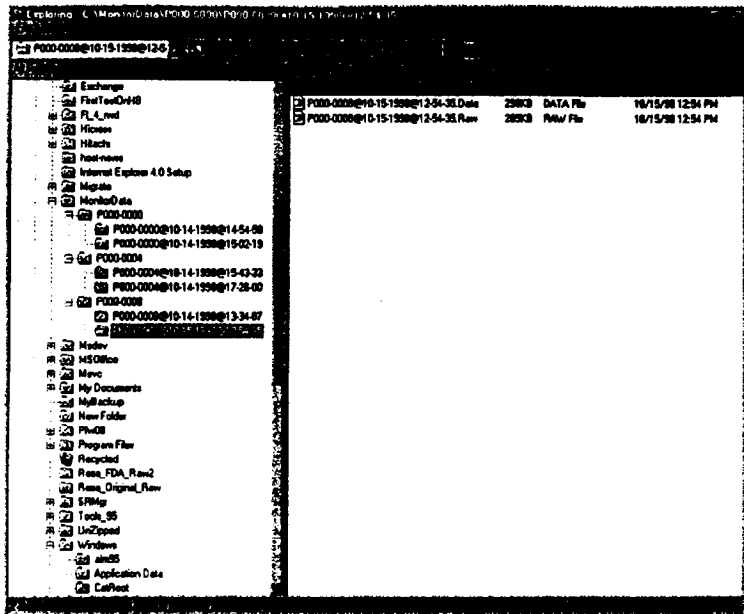


FIGURE 3 - 15: Monitor Data File Tree

- After saving these files, click on "OK" to return to the "Ready to Download" user interface screen. Choose "Download" to begin another data download, or click on "Quit" to return to the Microsoft Windows desktop.

# IV DISPLAYING GLUCOSE DATA

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## DISPLAY THE GLUCOSE DATA

Once glucose data from the Continuous Glucose Monitor has been downloaded, the CGMS Com-Station Software can be used to analyze and display the data. The data can be viewed as graphical data and summary statistics, or as numerical data.

**CAUTION:** The CGMS data should only be viewed using the "MiniMed Graphs" graphing utility. The utility calibrates the CGMS data and tests the accuracy of the calibration. These operations must be performed prior to evaluating the glucose profiles. If the data are viewed using any other program, the integrity of the data cannot be ensured.

**NOTE:** Only data files with the "Data" extension are used to generate glucose displays and reports. Data files with the "Raw" extension are used by MiniMed personnel.

### GRAPHICAL DATA

The "MiniMed Graphs" graphing program allows the data in a "Data" file to be displayed in several graphical formats. The program displays the Continuous Glucose Monitor readings, meter blood glucose values and event codes.

### SELECTING A PATIENT FILE

1. Double click on the "MiniMed Graphs" icon located on the Microsoft Windows 95 desktop. A MiniMed copyright message appears briefly and then the following display is shown (see Figure 4-1):



2. Double click on a patient file folder, for example "P000-0008" (see Figure 4-1). The display will now show a list of data folders stored for patient P000-0008, listed by the date and time of each download. Double click on a data folder, for example "P000-0008@10-16-1998@14-08-56". When the data file "P000-0008@10-16-1998@14-08-56.Data" appears, double click on it.

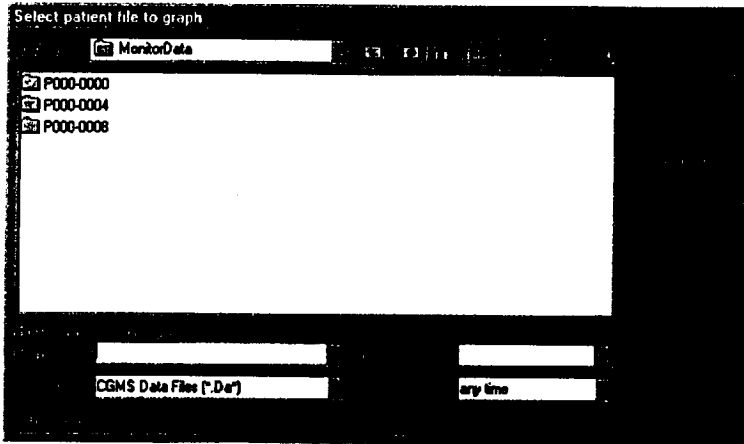
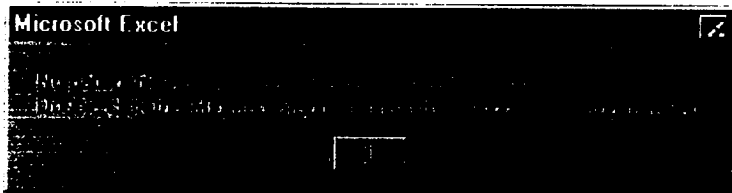


FIGURE 4 - 1: Select patient file to graph

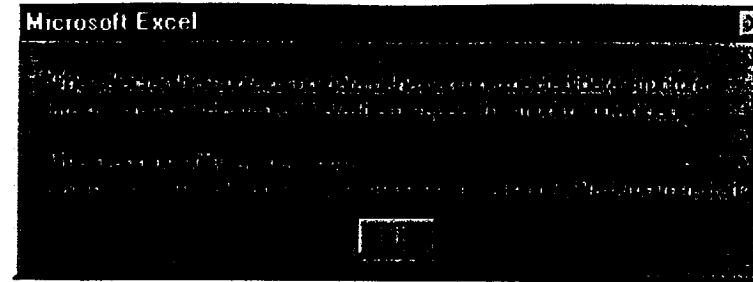
- If the "Cancel" or "ESC" buttons are pressed, a text box will appear (see Figure 4-2). Click on "OK", then return to the Microsoft Windows desktop and double-click the "MiniMed Graphs" icon to restart the graphing utility.

FIGURE 4 - 2: "No Patient File was Selected" Message



- If an incorrect data file is selected, the following message will appear (see Figure 4-3). Click on "OK" to return to the Microsoft Windows desktop, then repeat step 1.

FIGURE 4 - 3: Incorrect Data file Selected



### REGRESSION CALIBRATION

The software will now format the data file that was selected. The first step is to calibrate the CGMS data using the patient's meter readings that were entered into the monitor. A regression analysis that uses each of the meter values, paired with the CGMS signal at the time that the meter value was entered into the monitor, is used to calculate the regression slope that converts CGMS signal (in nano-amperes, nA) into glucose (in mg/dl). The regression is performed using a fixed intercept of zero. If the resulting slope is less than 7 mg/dl per nA, then an offset of 3 nA is subtracted from each CGMS value and the regression slope recalculated, again with a fixed intercept of zero. A separate calibration is calculated for each day the CGMS was worn except on days when one sensor is removed and another sensor inserted. On these days, each sensor is calibrated independently, but then combined on a single graph and in the summary table. The allowable range for the calibration slope is 2 to 10. After the regression analysis is complete, the calibration is applied to each day's data and sensor glucose values are calculated. If the calibration slope for a given day is outside the allowable range of 2 to 10, no sensor glucose values will be calculated for that day.

**NOTE:** The accuracy of this calibration is directly related to the number and accuracy of meter readings entered into the monitor by the patient using the CGMS. Patients must be instructed to enter at least four meter readings each day the sensor is worn, to enter the readings immediately after they are taken and to enter them accurately. Sensors must be inserted early enough in the day to allow at least four meter readings to be performed before midnight. Days with fewer than four meter readings should be interpreted with caution.



**NOTE:** The program will indicate if no meter readings were entered into the monitor on a particular day. A message will appear indicating that: "The following dates have no glucose meter data. No graphs were created for these dates." (see Figure 4-4)

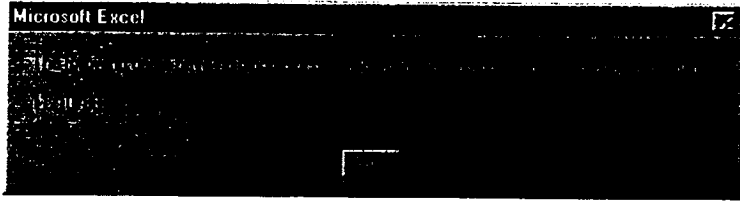


FIGURE 4 - 4: Insufficient Data Message

3. A message will appear asking if you would like to print the summary table and graphs (see Figure 4-5). Turn on your printer and then click "Yes" to print the summary table, the modal day graph and all daily graphs. If you click "No", you will still be able to print the table and graphs manually after the graphing utility is finished.

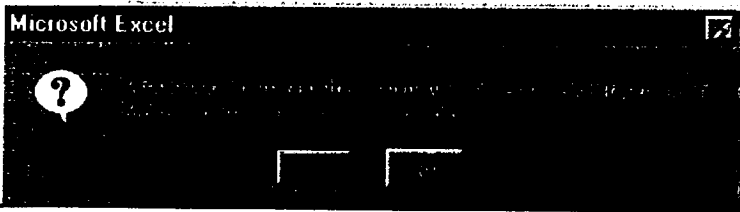


FIGURE 4 - 5: Print Message

4. A message will appear to remind you that all charts and graphs are saved in a Microsoft Excel xls file in the same folder that contains the data and raw files (see Figure 4-6).

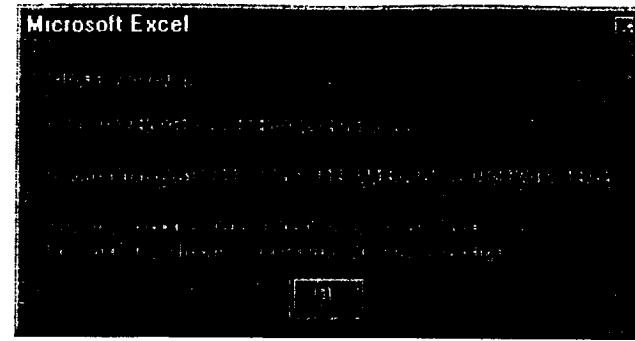


FIGURE 4 - 6: Microsoft Excel File

If this patient file has already been graphed previously, a dialog box will appear asking if you want to overwrite the older file or create a copy of the graphs with a different file name. If you choose to create a copy, the "#2" will be added to the copy's file-name (e.g. P000-0008@10-16-98@14-08-56#2.xls). If there is not enough disk space to save the file or the disk drive is no longer available, a message box will appear with additional information. These messages are explained in more detail in the Troubleshooting Guide.

5. After the glucose values are calculated, several Microsoft Excel worksheet tabs are provided to view different graphing and data options (see Figure 4-6). These options include:
  - Summary Table
  - Modal or Standard Day Graph
  - Glucose Profile Graphs
  - Data Listing Table



## SUMMARY TABLE

This table displays summary statistics for Continuous Glucose Monitor data ("Sensor") and for meter glucose data ("Meter") that was entered into the monitor. It also indicates if the sensor data possesses optimal accuracy. Optimal accuracy requires two criteria be met: 1) a correlation between the meter readings and the sensor values of at least 0.79 and 2) a mean absolute error of no more than 28%. Days that do not satisfy both criteria are marked with an "x" next to the date, and the value(s) that do not meet the criteria are shaded. Days with only 1 or 2 paired meter readings will have the number of readings shaded and "N/A" for the correlation coefficient. Data from these days may still be used, if review of the graph suggests that the sensor data matches the available meter readings. You should use your clinical judgement to determine the utility of days marked with an "x". The Summary Table also lists the number of readings, average, standard deviation and range of readings from the sensor and the meter, for each day and for all days combined (see Figure 4-7).

Data Summary											
Date	Optimal Accuracy Criteria			Sensor				Meter			
	Number of Paired Sensor/Meter Readings	Correlation Coefficient (r)	Mean Absolute Error (%)	Number of Readings	Average (mg/dL)	SD (mg/dL)	Sensor Range (mg/dL)	Number of Readings	Average (mg/dL)	SD (mg/dL)	Meter Range (mg/dL)
11-10-98	3	0.87	10	134	105	49	101-209	3	161	18	129-174
11-11-98	7	0.80	7	295	132	43	41-223	7	130	48	74-226
11-12-98 x	10		28	279	152	46	81-330	10	124	60	90-274
11-13-98 x	8		18	149	156	39	71-278	8	114	28	71-163
All Days	28	0.79	18	659	151	51	41-330	28	142	49	71-274

x: This day does not satisfy the criteria for optimal accuracy as indicated by the shaded entries in the summary table. Please use your clinical judgement in evaluating the graph.  
 -: The calibration slope for this day is outside the allowable range of 2 to 10 or no paired sensor/meter data are available. As a result, no sensor plot is provided.

Worksheet Tabs

FIGURE 4 - 7: Summary Table

## MODAL DAY GRAPH

The Modal Day Graph, also called the Standard Day Graph, presents all of the Continuous Glucose Monitor data, superimposed over a 24-hour period with each day presented as a separate plot line (see Figure 4-8). Up to 288 glucose data points are displayed for each day, beginning at 12:00 A.M. Click on the "Modal Day" tab to view the graph.

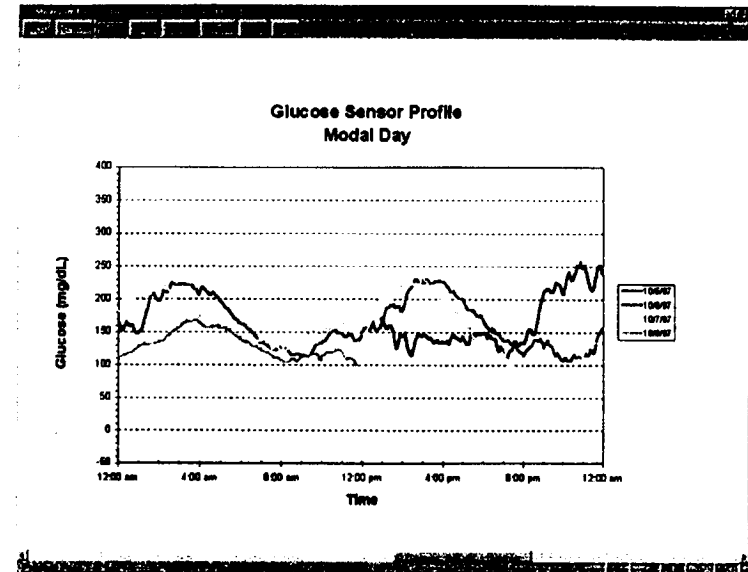


FIGURE 4 - 8: Modal Day Graph



## GLUCOSE PROFILE GRAPHS

Each Glucose Profile Graph shows the daily glucose data over a 24 hour period (see Figure 4-9).

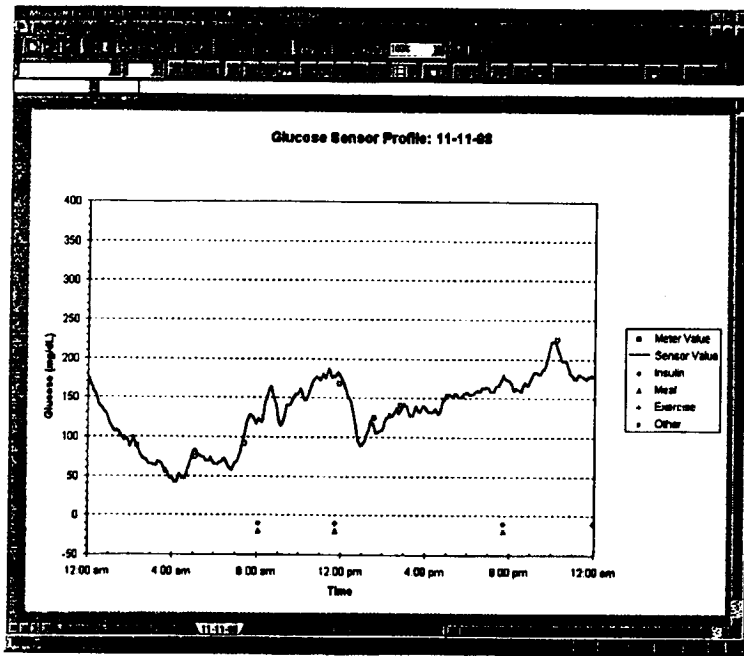


FIGURE 4 - 9: Glucose Profile Graph

Up to 288 glucose data points are used to draw a profile line on the graph. A gap in the profile line indicates that glucose monitoring during that period was interrupted.

The Glucose Profile Graph also shows all meter blood glucose values that were entered into the monitor during each 24 hour period. Event entries are also shown, including meals, insulin dosing, exercise and any other events. Click on the tab for each glucose profile graph desired. In this example, "11-11-98" was selected.

An "x" will appear next to the date in the worksheet tab (e.g. "10-08-97 x") if that day's calibration did not meet the two criteria for optimal accuracy. The shaded entries in the Summary Table for that day indicate the criteria that were not met. The graph for this day will have a message at the top indicating that you should use your clinical judgement in evaluating the profile (see Figure 4-10).

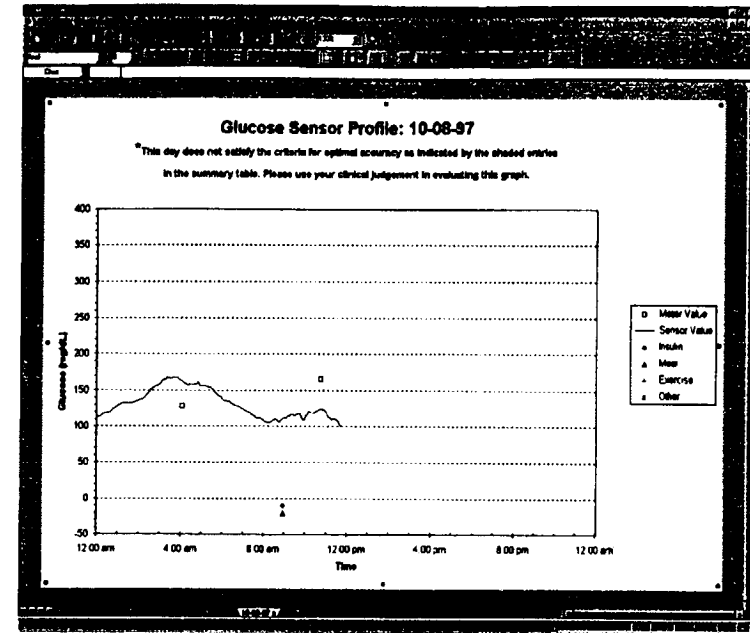


FIGURE 4 - 10: Glucose Profile Where Criteria for Optimal Accuracy Were Not Met

If the calibration slope for a given day is outside the allowable range of 2 to 10 or no paired sensor/meter data are available, no sensor glucose values will be calculated for that day. A "c" will appear next to the date in the Worksheet tab (e.g. "10-23-98c") as well as in the summary table. The daily glucose profile will plot meter values and event markers but will not contain a sensor glucose profile. A message will appear at the top of the graph indicating that the calibration slope is outside of the allowable range (see Figure 4-11). The sensor profile line will also be absent from the graph if no valid sensor signals were obtained on that day and a corresponding message will appear at the top of the graph.

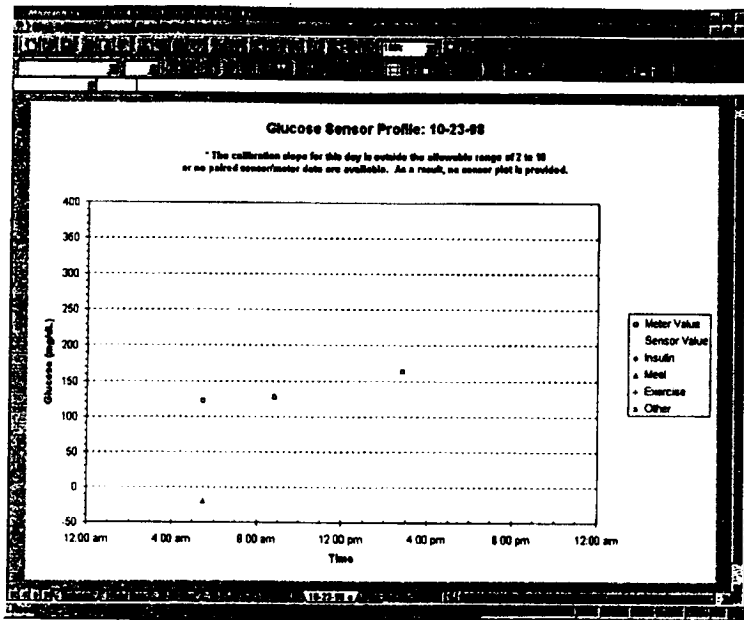


FIGURE 4 - 11: Calibration Slope Outside Allowable Range or No Paired Sensor/Meter Data

#### DATA LISTING TABLE

The Data Listing Table is a computerized log book, that presents all of the data stored in the glucose monitor memory for a particular patient download (see Figure 4-12). Click on the "Data" tab to view the data listing table. The data is presented in a Microsoft Excel spreadsheet, allowing health care professionals to generate custom charts and graphs using their own software of choice. Each data sample is identified in the spreadsheet columns:

- **Patient ID Number**, for example "P000-0008".
- **Data Sample Number** listed in chronological order.
- **Date**, for example "10/07/97".
- **Time** listed in 24 hour format, for example "13:08".
- **ISIG** or the sensor current, measured in nanoamperes (nA).
- **VCTR** or the voltage applied on the sensor, measured in volts (V).
- **Meter Value** from a fingerstick blood glucose measurement, measured in mg/dL. These values are entered by the user and used to calculate the daily calibration.

- **Calibration Constants**, recorded as the **Slope** and **Offset**.
- **Valid ISIG** or sensor current selected for conversion to sensor value in mg/dL.
- **Sensor Value** calculated from the calibration constants, measured in mg/dL glucose.
- **Monitor on and off events**, listed as **Power Up** and **Power Down**.
- **Sensor Initialization** records the time when initialization of a new sensor is completed.
- **Link Event** is the time of a data download.
- **Alarm events**, including **Sensor Disconnect**, **Sensor Reading Out of Range**, **History Memory Full**, **Calibration Error** and **Noise**.
- **Events** including **Meals**, **Insulin**, **Exercise** and **Other**.

FIGURE 4 - 12: Data Listing Table

#### TO GRAPH ADDITIONAL PATIENTS:

Microsoft Excel does not need to be closed to graph another patient's data. Multiple patients may be graphed in a single session. To graph additional Patient files, simply double-click again on the "MiniMed Graphs" icon on the Windows 95 desktop.

#### TO EXIT THE GRAPHING SOFTWARE:

With the mouse, click on "File" and then "Exit." The software will then close and return the user to the Microsoft Windows desktop.



# V TROUBLESHOOTING GUIDE

## ALARM MESSAGE

Information



**Cause:** A communication link cannot be made between the Com-Station and the "Com Port 1" on the PC.

Refer to the section: *"Connect the Com-Station to the PC"*

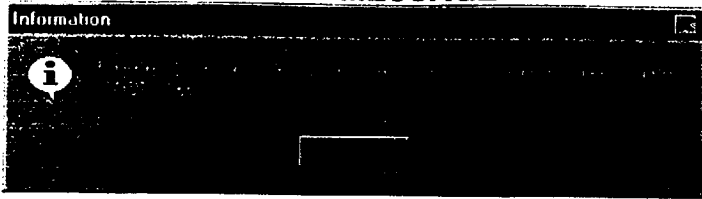
**When:** When attempting to establish a data link between the Glucose Monitor and PC. The error message may appear after the "Download" button is clicked on the main user interface screen.

- What to do:**
- 1) Verify the cable connections between "Com Port A" on the Com-Station and "Com Port 1" on the PC are correct and secure.
  - 2) Verify the Com-Station is turned on. The ON/OFF button light should be illuminated.
  - 3) Verify "Com Port 1" is available on the PC.
  - 4) Click on "OK." Repeat the data download.



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## ALARM MESSAGE



**Cause:** A communication link cannot be made between the Com-Station and the "Com Port 2" on the PC.

Refer to the section: *"Connect the Com-Station to the PC"*

**When:** When attempting to establish a data link between the Glucose Monitor and PC. The error message may appear after the "Download" button is clicked on the main user interface screen.

- What to do:**
- 1) Verify the cable connections between "Com Port A" on the Com-Station and "Com Port 2" on the PC are correct and secure.
  - 2) Verify the Com-Station is turned on. The ON/OFF button light should be illuminated.
  - 3) Verify "Com Port 2" is available on the PC.
  - 4) Click on "OK." Repeat the data download.

## ALARM MESSAGE



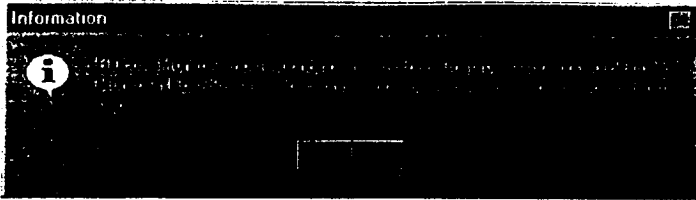
**Cause:** A communication link cannot be made between the Com-Station and either "Com Port 1" or "Com Port 2" on the PC.

Refer to the section: *"Connect the Com-Station to the PC"*

**When:** When attempting to establish a data link between the Glucose Monitor and PC. The error message may appear after the "Download" button is clicked on the main user interface screen.

- What to do:**
- 1) Close all other active programs.
  - 2) Verify "Com Port 1" or "Com Port 2" is available to use with the Com-Station.
  - 3) Enable both ports, using PC Setup or the Microsoft Windows 95 Device Manager.
  - 4) Verify the configuration settings for "Com Port 1" and "Com Port 2" are correct. If necessary, consult with a PC expert for completing steps 2 to 4.
  - 5) Click on "OK." Repeat the data download.

## ALARM MESSAGE



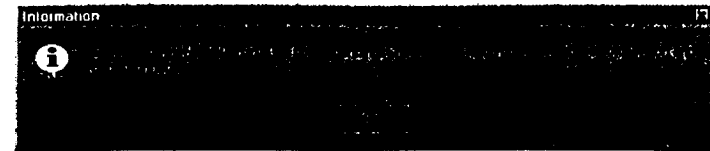
**Cause:** A communication link cannot be made between the Com-Station and Glucose Monitor.

Refer to the section: *"Establish a Data Link and Download Glucose Data"*

**When:** When attempting to establish a data link between the Glucose Monitor and PC. The error message may appear after the "Download" button is clicked on the main user interface screen.

- What to do:**
- 1) Verify the cable connections between the Com-Station and PC are secure, and the "Com Port A" on the Com-Station is used.
  - 2) Verify the Com-Station is turned on. The ON/OFF button light should be illuminated.
  - 3) Verify the Glucose Monitor is turned on and in its normal operation display, and is aligned properly in the Com-Station Cradle.
  - 4) Check to make sure the infrared ports on the Glucose Monitor and Com-Station are clean.
  - 5) Verify the correct PC port is being used.
  - 6) Click on "OK." Repeat the data download.

## ALARM MESSAGE



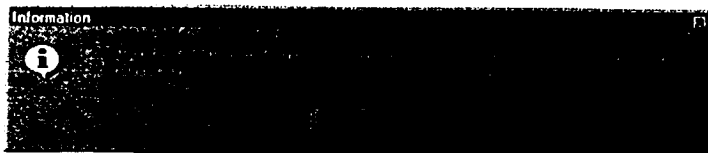
**Cause:** A communication link cannot be made between the Com-Station and Glucose Monitor.

Refer to the section: *"Establish a Data Link and Download Glucose Data"*

**When:** When attempting to establish a data link between the Glucose Monitor and PC. The error message may appear after the "Download" button is clicked on the main user interface screen.

- What to do:**
- 1) Verify the cable connections between the Com-Station and PC are secure, and the "Com Port A" on the Com-Station is used.
  - 2) Verify the Com-Station is turned on. The ON/OFF button light should be illuminated.
  - 3) Verify the Glucose Monitor is turned on and in its normal operation display, and is aligned properly in the Com-Station Cradle.
  - 4) Check to make sure the infrared ports on the Glucose Monitor and Com-Station are clean.
  - 5) Verify "Com Port 1" is being used.
  - 6) Click on "OK." Repeat the data download.

## ALARM MESSAGE



**Cause:** A communication link cannot be made between the Com-Station and Glucose Monitor.

Refer to the section: *"Establish a Data Link and Download Glucose Data"*

**When:** When attempting to establish a data link between the Glucose Monitor and PC. The error message may appear after the "Download" button is clicked on the main user interface screen.

- What to do:**
- 1) Verify the cable connections between the Com-Station and PC are secure, and the "Com Port A" on the Com-Station is used.
  - 2) Verify the Com-Station is turned on. The ON/OFF button light should be illuminated.
  - 3) Verify the Glucose Monitor is turned on and in its normal operation display, and is aligned properly in the Com-Station Cradle.
  - 4) Check to make sure the infrared ports on the Glucose Monitor and Com-Station are clean.
  - 5) Verify "Com Port 2" is being used.
  - 6) Click on "OK." Repeat the data download.

## ALARM MESSAGE



**Cause:** After completing a download, attempting to download another Glucose Monitor without saving the data.

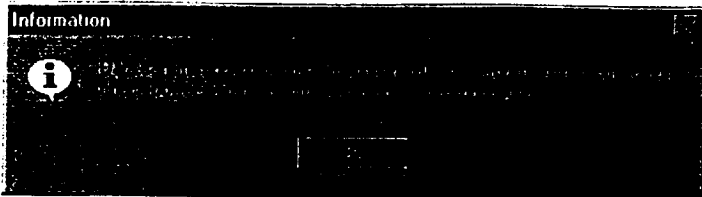
Refer to the section: *"Establish a Data Link and Download Glucose Data"*

**When:** While downloading data from the Glucose Monitor to a PC. The error message appears after the "Download" button is clicked on the main user interface screen for a second time without saving the data from the first download.

- What to do:**
- 1) Click on "No" to return to the main user interface screen.
  - 2) Click on "Save Data" to save the last glucose data download and generate a new data folder in the PC. The PC will then return to the main user interface screen.
  - 3) Begin a second data download.
  - 4) Click on "Yes" to begin the second data download without saving the data from the first download.



## ALARM MESSAGE



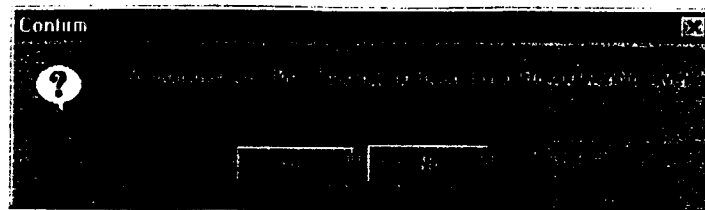
**Cause:** Data transmission was interrupted during a data download.

Refer to the section: *"Establish a Data Link and Download Glucose Data"*

**When:** While downloading data from the Glucose Monitor to a PC. The error message appears after the "Download" button is clicked on the main user interface screen and data transmission is in progress.

- What to do:**
- 1) Verify the cable connections between the Com-Station and PC are secure.
  - 2) Verify the monitor is aligned properly in the Com-Station Cradle.
  - 3) Check to make sure the infrared ports on the Glucose Monitor and Com-Station are clean.
  - 4) Click on "OK." Repeat the data download.

## ALARM MESSAGE



**Cause:** After completing a download, choosing "Quit" without saving the data.

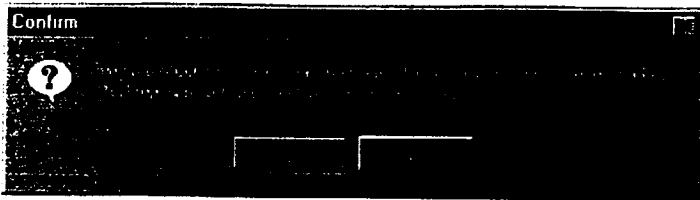
Refer to the section: *"Establish a Data Link and Download Glucose Data"*

**When:** While downloading data from the Glucose Monitor to a PC. The error message appears after the "Quit" button is clicked on the main user interface without saving the data from last download.

- What to do:**
- 1) Click on "Yes" to return to the main user interface screen.
  - 2) Click on "Save Data" to save the last glucose data download and generate a new data folder in the PC. The PC will then return to the main user interface screen.
  - 3) Click on "No" to return to the Microsoft Windows desktop without saving the data from the last download.



## ALARM MESSAGE



**Cause:** Choosing to exit the MiniMed Com-Station Software.

Refer to the section: *"Establish a Data Link and Download Glucose Data"*

**When:** Choosing to exit the MiniMed Com-Station Software through another "Confirm" screen, or by selecting "File" and then either "Close" or "Exit".

- What to do:**
- 1) Click on "Yes" to exit the MiniMed Com-Station Software and return to the Microsoft Windows desktop.
  - 2) Click on the "MiniMed Com-Station" icon to download additional glucose monitor data.
  - 3) Click on "No" to return to the main user interface screen.

## ALARM MESSAGE

**No Message. The Com-Station loses power during operation, even through its power cable remains connected to a wall outlet.**

**Cause:** The Com-Station may be consuming an excessive amount of power during its operation, causing its thermal fuse to interrupt the power supply.

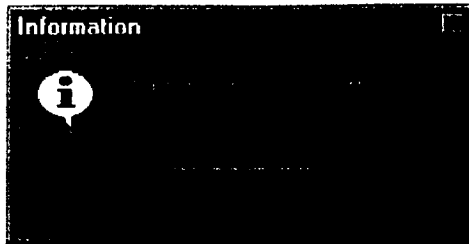
The On/Off light on the Com-Station will be off.

**When:** While attempting to install the MiniMed CGMS Com-Station Software or download glucose data from the CGMS to a PC.

- What to do:**
- 1) Turn the Com-Station off by turning the On/Off Switch to the "O" position.
  - 2) Verify the MiniMed Power Cable connections to the wall outlet and the AC Adapter Port in the Com-Station are complete and secure.
  - 3) Wait 15 minutes.
  - 4) Turn the Com-Station back on and return to normal operation.



## ALARM MESSAGE



**Cause:** An error is detected in the data saved in the monitor memory. Eight (8) different kinds of errors can be reported: ISIG, VCTR, Vset, Event, Alarm, Time, Hypoglycemia Limit, and Calibration.

Refer to the section: *"Connect the Com-Station to the PC"*

**When:** While downloading data from the monitor to a PC. The error message may appear after the "Download" button is clicked on the main user interface screen.

**What to do:**

- 1) Click on "OK." Repeat the data download.
- 2) If the error repeats, please call the MiniMed Clinical Services Help Line at (800) 826-2099 or contact your local MiniMed Sales Representative.

## ALARM MESSAGE

**No Message. After the Download button is clicked, no communication activity is observed within one minute and no error message is displayed.**

**Cause:** A data transmission error of unknown origin has occurred.

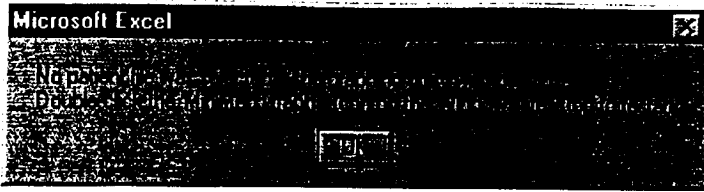
Refer to the section: *"Connect the Com-Station to the PC"*

**When:** While attempting to download data from the monitor to a PC. After the "Download" button is clicked on the main user interface screen, no data is downloaded within one minute and no error message is displayed.

**What to do:**

- 1) Check for the availability of COM1 or COM2 ports on the PC. Make sure one of the ports is free to use with the Com-Station.
- 2) Enable both ports by using the PC Setup screen or the Microsoft Windows 95 Device Manager.
- 3) Verify the configuration settings for COM1 or COM2 are correct. Consult with a PC expert for completing steps 2 and 3.
- 4) Repeat the data download.

## ALARM MESSAGE



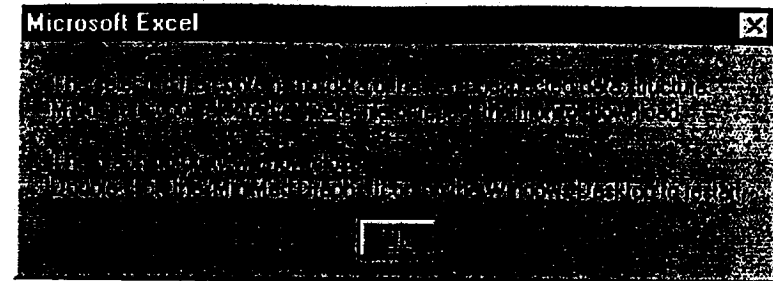
**Cause:** Choosing to "Cancel" or "Esc" from "MiniMed Graphs" without selecting a patient file to graph.

Refer to the section: *"Display the Glucose Data"*

**When:** Choosing to exit the MiniMed Graphs Software by pressing "Cancel" or "Esc" before a patient file is selected.

- What to do:**
- 1) Click on "OK" to exit the MiniMed Graphs Software and return to the Microsoft Windows desktop.
  - 2) Click on the "MiniMed Graphs" icon to graph Glucose Monitor patient files stored in the PC.
  - 3) Select a patient file by looking in the "MonitorData" folder on the "C" drive, and then double clicking on the desired patient folder.

## ALARM MESSAGE



**Cause:** The data file selected for graphing does not contain any monitor or meter data, or its structure does not match that of a ".Data" file.

Refer to the section: *"Display the Glucose Data"*

**When:** After selecting a data file to be graphed.

- What to do:**
- 1) Click on "OK" to exit the MiniMed Graphs Software and return to the Microsoft Windows desktop.
  - 2) Click on the "MiniMed Graphs" icon to graph Glucose Monitor patient files stored in the PC.
  - 3) Select a data file to be graphed by:
    - a) looking in the "MonitorData" folder on the "C" drive
    - b) double clicking on a patient folder
    - c) double clicking on a data folder
    - d) double clicking on a data file, with a "Data" extension at the end of the file name

## ALARM MESSAGE



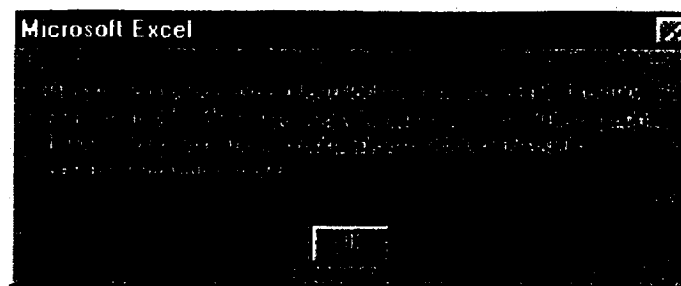
**Cause:** No blood glucose meter data was entered on these days.

Refer to the section: *"Display the Glucose Data"*

**When:** When graphing data from a data file.

- What to do:**
- 1) Click on "OK" to return to the data file report. Notice that worksheet tabs are not included for the days listed in the message.
  - 2) If the data file is believed to be incomplete, repeat the data download from the Glucose Monitor and then select the newly downloaded data file for graphing.

## ALARM MESSAGE



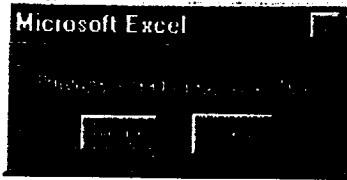
**Cause:** There is less than 5 megabytes of space on disk drive C:. The graphs can still be viewed and printed.

Refer to the section: *"Display the Glucose Data"*

**When:** When the Excel Graphing Utility tries to save the patient graphs at the completion of the utility.

- What to do:**
- 1) Click on "OK" to return to the Window Desktop.
  - 2) Delete unused files on drive C:.
  - 3) Rerun "MiniMed Graphs"

## ALARM MESSAGE



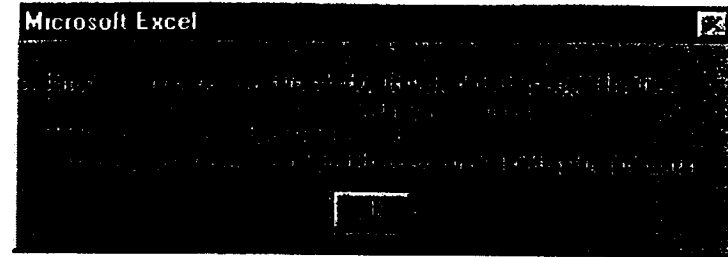
**Cause:** The source drive containing the patient .Data is no longer available.

Refer to the section: *"Display the Glucose Data"*

**When:** When the Excel Graphing Utility tries to save the patient graphs at the completion of the utility.

- What to do:**
- 1) Click "Retry" to attempt to access the drive again.
  - 2) Click "cancel" to skip saving the graphs. The graphs can still be viewed and printed.

## ALARM MESSAGE














**Cause:** Disk space is not available to save the patient graphs as an Excel file on the original source drive. The file is saved in C:/Windows/Temp.

Refer to the section: *"Display the Glucose Data"*

**When:** When the Excel Graphing Utility tries to save the patient graphs at the completion of the utility.

- What to do:**
- 1) Click on "OK" to return to the Window Desktop.
  - 2) Delete unused files on source drive.
  - 3) Rerun "MiniMed Graphs"

Please Read The Instructions for Use	
Manufacture Date (year - month)	 1997-12
Device Serial Number	S N
Storage Temperature Range	-20C  155C
One Per Container / Package	(1x)
DC Voltage	==
Device Language Code	
UL/CSA Approved Device	
Indoor Use Only	
DC Output Connection	+  -
Alternating Current	
Device ON/Device OFF	O
Communications Port	
Recycling Symbol	
Type B (Protection from electric shock)	

If you require additional information regarding use of the Continuous Glucose Monitoring System, contact your health care professional or the Clinical Services Department at:



USA:  
 Sylmar, CA  
 818-362-5958 • 800-826-2099 (24-hour Help Line within U.S. & Canada)  
 To order supplies:  
 800-843-6687 • FAX: 888-268-0200 (within U.S. & Canada)  
 FAX: 818-362-3788 (outside U.S.)

This product is covered by the following U.S. patent: [U.S.] 5,376,070.  
 Other U.S. and/or foreign patents may be pending.

G9190037-011 5/99

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**MiniMed Continuous Glucose Monitoring System**  
**Patient Instructions For Use**

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# I BEFORE YOU BEGIN

**YOUR DOCTOR** has asked you to wear a MiniMed Continuous Glucose Monitoring System (CGMS) to measure your glucose levels. This glucose information may help you and your doctor fine tune your therapy to avoid some of the highs and lows you are experiencing.

This guide can help answer many of the questions you may have:

1. About how the CGMS operates
2. When and how to enter a fingerstick blood glucose value into the CGMS
3. What to do if you get an alarm

If you have a question that the guide cannot answer, please talk to your doctor first. Your doctor knows the most about your medical condition and can give you the best answers to your questions.

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## MINIMED HELP LINE

MiniMed provides a 24 hour help line. The toll free number is (800) 826-2099. The help line is staffed with Clinical Services people, who can answer your questions about the CGMS.

During MiniMed's normal business hours, from 8:00 AM to 5:00 PM Pacific time, Monday through Friday, you can speak to a Clinical Services person within a few minutes. For after-hours emergencies, MiniMed's answering service will page a Clinical Services person to call you back. There are times when our Clinical Services people are very busy taking other calls. Sometimes it may take longer to get a response. We appreciate your patience.

## II GENERAL DESCRIPTION

MiniMed's Continuous Glucose Monitoring System (CGMS) will automatically monitor glucose levels in your subcutaneous tissue located just underneath your skin. Glucose values from 40 to 400 mg/dl are measured once every five minutes. Up to 288 values can be measured each day. Usually, you will wear the CGMS for a maximum of three days.

The CGMS collects and stores all of these glucose values in its memory. Glucose values above 400 mg/dl are recorded as 400 mg/dl. Glucose values below 40 mg/dl are recorded as 40 mg/dl. After returning to your doctor's office, your glucose data will be downloaded into your doctor's personal computer. The computer will print a report of your daily glucose profiles. Your doctor will use this information and your fingerstick glucose values and other data to identify changes in your blood glucose. This information may help you and your doctor manage your diabetes better. The CGMS:

- Is a prescription device.
- Is meant for occasional rather than everyday use. The CGMS is used only to supplement, not replace, standard fingerstick measurements.
- Is meant to identify patterns in your glucose levels. Your doctor may use these patterns to suggest when you should take fingerstick glucose measurements to better manage your diabetes.
- Provides readings that can be reviewed by your doctor only after you return to his or her office.
- Will not show you any glucose values while you are wearing the system.



FIGURE 2 - 1: Continuous Glucose Monitoring System (CGMS)

## PARTS OF THE CGMS

1. **Glucose Sensor** - a tiny flexible electrode that measures your glucose. The Glucose Sensor has an enzyme, glucose oxidase, that changes a small amount of glucose from your subcutaneous tissue into an electrical signal.

The Glucose Sensor is inserted just under your skin inside a needle. When the Glucose Sensor is in place, the needle is removed and disposed of. One end of the Glucose Sensor is attached to a sensor assembly about the size of a small coin. This sensor assembly stays outside your body and is taped onto your skin with clear tape.

Your doctor may give you an extra Glucose Sensor to take home. This Glucose Sensor should be stored in the refrigerator (**not the freezer!**) until it is used.

2. **Continuous Glucose Monitor** - The "Monitor" is a portable device about the size of a pager. The Monitor collects and stores your glucose signals from the Glucose Sensor. This glucose data can be downloaded into your doctor's computer. The Monitor is powered by two AAA alkaline batteries.
3. **Cable** - a special wire that connects the Monitor to the Glucose Sensor. Glucose signals from the Glucose Sensor travel through the Cable into the Monitor.

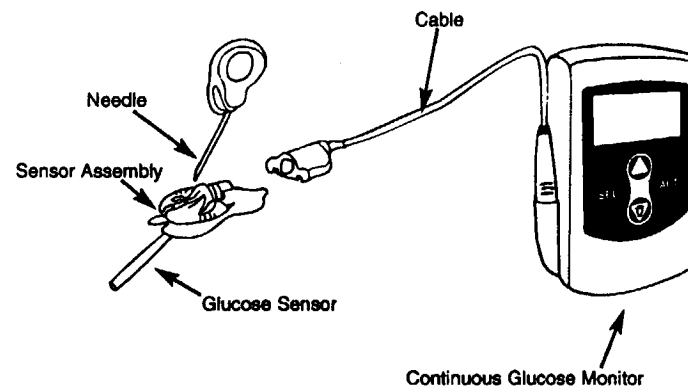


FIGURE 2 - 2: Parts of the CGMS

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## CGMS ACCESSORIES

1. **Belt Clip** - Used to attach the Monitor to a belt or clothing.

Attach the Belt Clip to the back of the Monitor: Slide the ridge on the back of the Belt Clip into the groove on the back of the Monitor. Push the Belt Clip forward until it clicks into place.

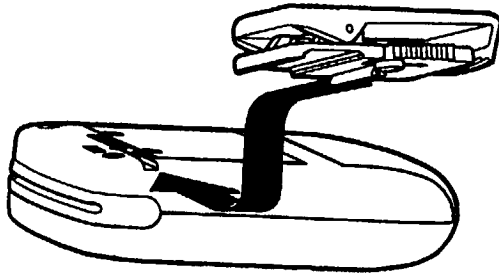


FIGURE 2 - 3: Attach the Belt Clip

Remove the Belt Clip: Using your thumb, lift up on the ridged edge of the Belt Clip and then gently slide the Belt Clip out of its groove on the Monitor.

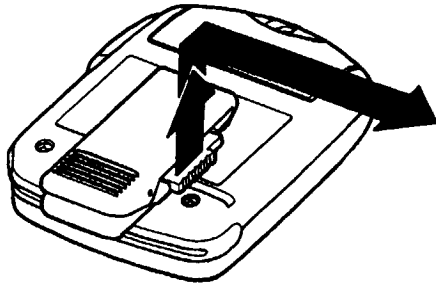


FIGURE 2 - 4: Remove the Belt Clip

2. **Leather Case** - A special case provided with the Monitor to help protect it against moisture, dirt and debris.
3. **Shower-Pak** - A waterproof clear plastic pouch designed to keep the Monitor dry during a shower or any other time when the Monitor may become wet.

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## WEARING THE CGMS

Your doctor will probably want you to wear the CGMS for two or three days. During this time, you will need to follow your normal daily schedule agreed to by you and your doctor. This schedule will probably include:

1. Taking your diabetes medicine
2. Taking several fingerstick blood glucose values each day
3. Following instructions for eating meals and snacks, and exercising
4. Coping with stress or illness

You can carry on most of the daily activities that you normally would. Activities to be aware of while wearing the CGMS:

1. MiniMed provides a Shower-Pak to help protect the Monitor while you are taking a shower. Avoid dunking the Monitor in liquids, for example while swimming or bathing.
2. You can exercise and play most sports. Try to avoid high impact physical activities, like football or martial arts. These activities could damage the Monitor or pull the Glucose Sensor out of your skin.
3. Do not wear the Monitor during medical imaging procedures, like X-rays, CT scans or MRI. Avoid close contact with high power radio or television transmitters, and high voltage power lines. It is all right to wear the Monitor when walking through metal detectors, like those found at airports.

**Let your doctor know at once, if you have any difficulty hearing the Monitor alarms, reading the Monitor screen, or understanding what the Monitor messages mean.**



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## CALIBRATING THE CGMS

The CGMS must be calibrated with blood glucose measurements from a fingerstick glucose meter. You will need to enter at least four (4) fingerstick blood glucose values into the CGMS each day. You should choose one or more of these values each day to perform a calibration check. These calibration checks will help the Monitor alert you if your Glucose Sensor is not working well and needs to be changed.

It is important that you follow your doctor's instructions for taking these fingerstick measurements. Enter each value into the CGMS just as soon as the glucose meter gives you a reading. Make sure each glucose value you enter into the CGMS is correct. If you make a mistake, the CGMS will probably be less accurate.

---

## INSTALLING NEW BATTERIES

The Monitor batteries should last about eight weeks before needing to be changed. If the Monitor alarms and either a "**LOW BATT**" or "**NO POWER**" message is shown, **call your doctor at once for instructions.**

If your doctor instructs you to replace the batteries in the Monitor, follow this procedure:

**NOTE:** You must replace the batteries within 5 minutes. After you remove the old batteries from the Monitor, it will have enough power for 5 minutes to continue to store your glucose data. Taking longer than 5 minutes may erase your glucose data.

1. Before beginning, you should have ready two new AAA alkaline batteries and a small flat blade screwdriver.
2. Turn off the Monitor by pressing the **ON/OFF** (ⓘ) button once.
3. Press the **ACT** button once.
4. Find the battery compartment at the lower back side of the Monitor.
5. Use the screwdriver to unscrew the battery compartment lid from the Monitor.
6. Remove the battery compartment lid, and then remove the old batteries by pulling on the battery strap.
7. Insert the two new batteries, taking care to align the batteries correctly in the compartment (see Figure 2-5). Wrap the battery strap around the new batteries as shown.

**NOTE:** If the batteries are not aligned correctly they may get hot. Handle with care.



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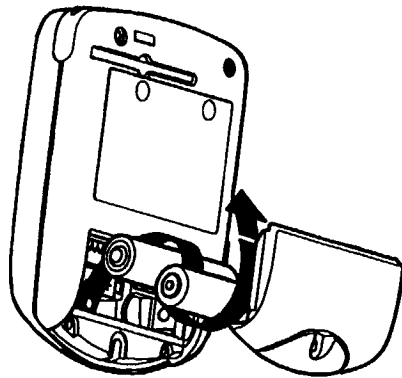


FIGURE 2 - 5: Battery Installation

8. Replace the battery compartment lid onto the Monitor, taking care to align it against the compartment seal.
9. Tighten the screw to seal the battery compartment lid against the Monitor.

### III CHANGING THE GLUCOSE SENSOR

MiniMed's Glucose Sensor was designed to be easily inserted and replaced by diabetes care professionals as well as by people with diabetes who wear the CGMS. This chapter provides you with a simple set of instructions for changing a Glucose Sensor. Only change your Glucose Sensor under the following conditions:

1. You and your doctor agree that your Glucose Sensor needs to be changed
2. Your doctor has provided you with a spare Glucose Sensor
3. Your doctor has instructed you to replace the Glucose Sensor

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### GLUCOSE SENSOR SAFETY

Glucose Sensors are supplied sterile to minimize the risk of a local skin reaction (infection or irritation). If your sensor insertion site becomes red, sore, painful, swollen or irritated, **call your doctor at once for instructions on whether or not to remove or replace your Glucose Sensor.**

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## SIGNS THAT A GLUCOSE SENSOR NEEDS TO BE CHANGED

Glucose Sensors are expected to last one to three days. The Monitor will alarm if a Glucose Sensor is at the end of its useful life. An alarm will alert you with a beep and a message will be shown on the screen:

1. **"CAL GLUCOSE SENSOR ERROR"** alarm is shown right after entering a fingerstick blood glucose value into the Monitor for calibration.
2. **"GLUCOSE SENSOR DISCONN"** is shown again after checking your Cable connections to the Glucose Sensor and Monitor.

If you get an error alarm and think your Glucose Sensor may need to be changed, **be sure to call your doctor at once for instructions.**

---

## CARING FOR A SPARE GLUCOSE SENSOR

Your doctor may give you a spare Glucose Sensor to use in case your first sensor needs to be changed. **Be sure to call your doctor for instructions before trying to change your own Glucose Sensor.**

Your spare Glucose Sensor should be stored in the refrigerator (**not the freezer!**) until just before it is used.

It is acceptable to take the spare Glucose Sensor with you to work or while traveling. The Glucose Sensor can be kept at room temperature, **as long as the temperature is never greater than 75 degrees Fahrenheit (36 degrees Celsius).**

**Do not** use the spare Glucose Sensor if:

1. The expiration date shown on the package has past.
2. The packaging is torn or the seal is loose.
3. The temperature indicator on the package is black (●), not clear (○).
4. The sterility indicator dot is orange (⦿), not red (⦿).

**Let your doctor know if any of these conditions has occurred.**



# INSTRUCTIONS FOR CHANGING A GLUCOSE SENSOR

The Glucose Sensor has several parts. Look at the following drawing (Figure 3-1) when using these instructions:

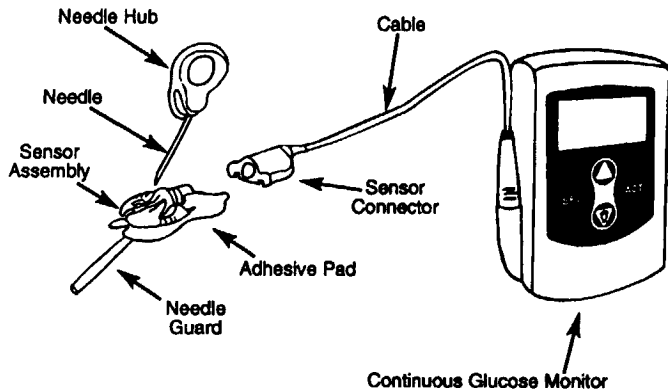


FIGURE 3 - 1: Glucose Sensor Parts

1. Wash your hands with soap and warm water for at least one minute.
2. Remove your old Glucose Sensor. Pull off the clear tape or bandage holding the old Sensor Assembly against your skin. Gently pull the old Sensor Assembly away from your skin at a 45 degree angle until the Sensor has pulled completely out of your skin.
3. Disconnect the Sensor Assembly from the Cable by pressing the sides of the Sensor Assembly together and then pulling it away from the Cable. Dispose of the old Sensor Assembly.
4. Wipe the old sensor insertion site on your skin with alcohol and allow it to dry.
5. Choose a new sensor insertion site on your skin. This site must be at least two inches away from the old insertion site. If you wear an insulin pump, the new sensor insertion site must also be at least two inches away from your insulin infusion site.

6. Wipe the new sensor insertion site on your skin with alcohol and allow it to dry.
7. Remove your spare Glucose Sensor from its package. Grab the top of the package and peel the two sides apart (see Figure 3-2). Place the spare Glucose Sensor on a clean, dry surface.

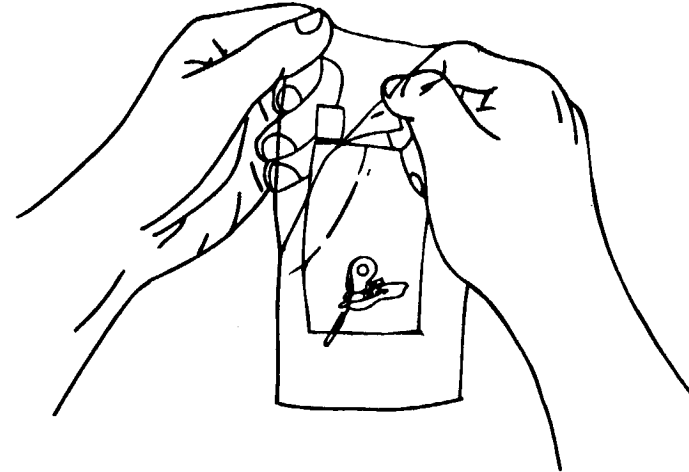


FIGURE 3 - 2: Remove Glucose Sensor from its Package

8. Plug the Sensor Assembly into the Sensor Connector. Press the parts together until they fasten with a click (Figure 3-3).

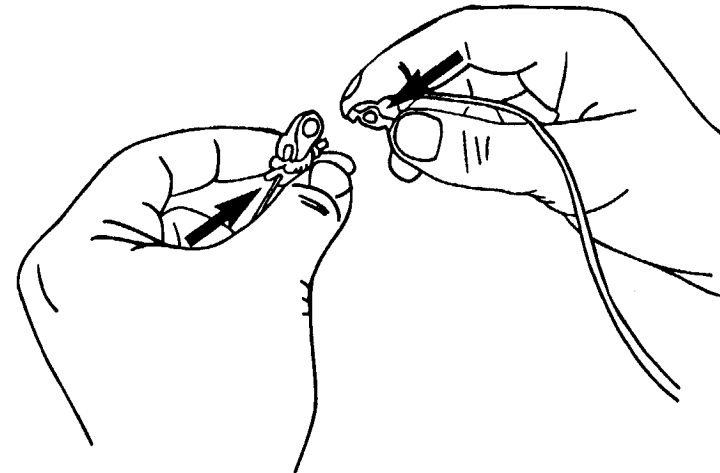


FIGURE 3 - 3: Connect Sensor Assembly to Sensor Connector



9. Remove the Clear Release Paper (1) from the bottom of the Sensor Assembly. This will expose part of the Adhesive Pad underneath (Figure 3-4). The Adhesive Pad will adhere to the skin and help hold the Glucose Sensor in place.

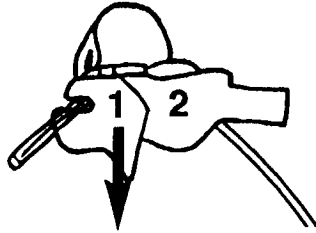


FIGURE 3 - 4: Remove Clear Release Paper (1)

10. Hold the Sensor Assembly in one hand. Use your other hand to remove the Needle Guard. Be sure not to touch the sterile needle inside the Needle Guard (Figure 3-5).

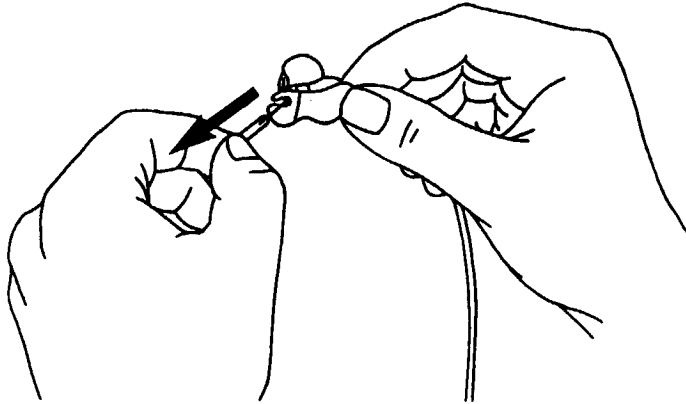


FIGURE 3 - 5: Remove Needle Guard

11. Check to see if the Needle Hub is seated against the Sensor Assembly. If there is a gap between the Needle Hub and Sensor Assembly, push the hub until it touches the Sensor Assembly (Figure 3-6).

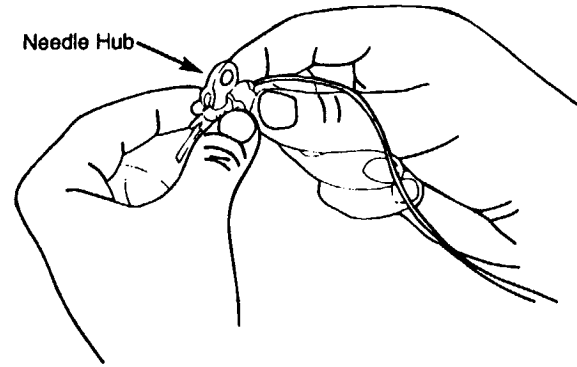


FIGURE 3 - 6: Check the Needle Hub

12. Pinch up the area of skin you have wiped with alcohol between your thumb and forefinger. Grasp the Needle Hub in your other hand. Slide the needle smoothly into your skin at about a 45 degree angle until the Adhesive Pad touches the skin surface (Figure 3-7).

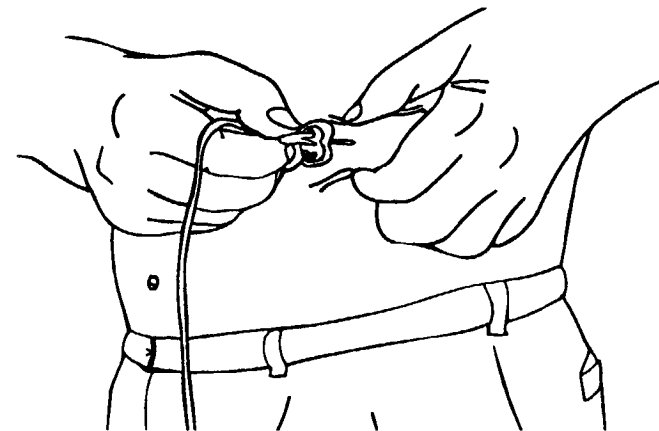


FIGURE 3 - 7: Insert the Glucose Sensor



13. With one hand, hold the Sensor Assembly against your skin. With your other hand, peel off the White Release Paper (2) from the Adhesive Pad. Then press the Adhesive Pad firmly against your skin until it sticks (Figure 3-8).

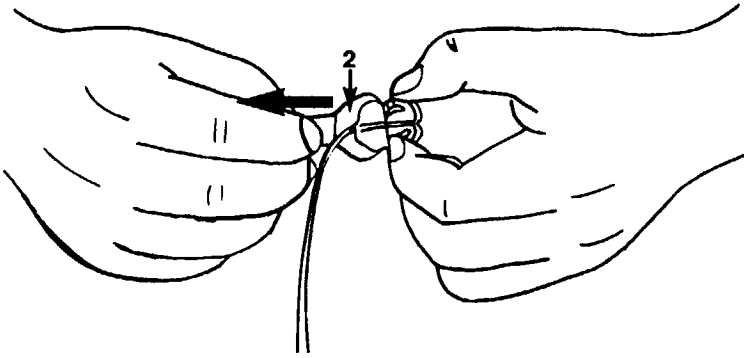


FIGURE 3 - 8: Remove White Release Paper (2)

14. With one hand, hold the Sensor Assembly against your skin. With your other hand, pull the Needle Hub gently away from the Sensor Assembly (Figure 3-9). Dispose of the Needle inside a puncture proof container.

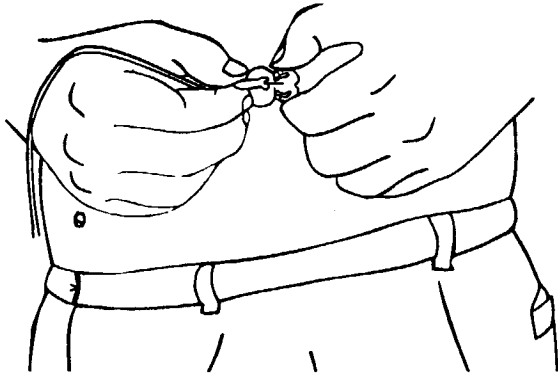


FIGURE 3 - 9: Remove the Needle

15. Put on a clear tape over the Sensor Assembly and Sensor Connector to hold them in place. You can also make a safety loop in the Cable and place a bandage over it (Figure 3-10). If your skin is sensitive to tapes and bandages, discuss which kinds of clear tape and bandages you should use with your doctor.

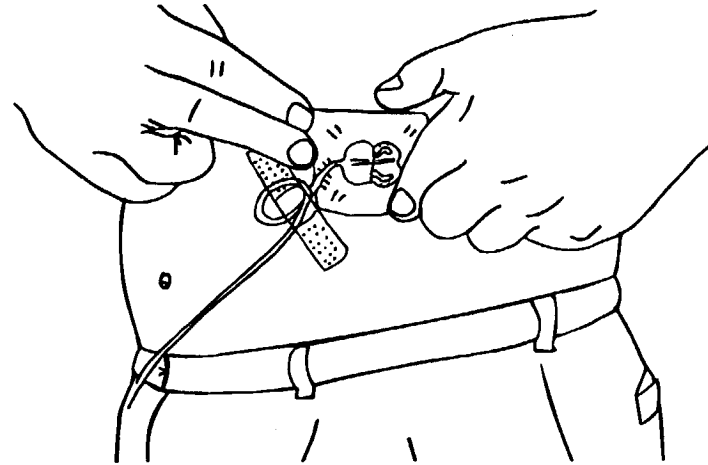


FIGURE 3 - 10: Put on a Clear Dressing and Bandage



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## MANAGING YOUR SENSOR INSERTION SITE

Be sure that your clothing or accessories (waist bands or belts) will not rub against your sensor insertion site. This may cause your insertion site to become irritated.

Keep your sensor insertion site as clean and dry as possible.

Avoid physical activities that may jolt your sensor or move it in your skin.

**If you notice any change in your sensor insertion site, such as redness, soreness, pain, swelling or irritation, call your doctor at once for instructions.**

## IV CONTINUOUS GLUCOSE MONITOR CONTROLS

The Continuous Glucose Monitor is operated by using five buttons (Figure 4-1). Press each button slowly and firmly until you hear a slight ticking sound and the button gives way. Then release the button before pressing another one.

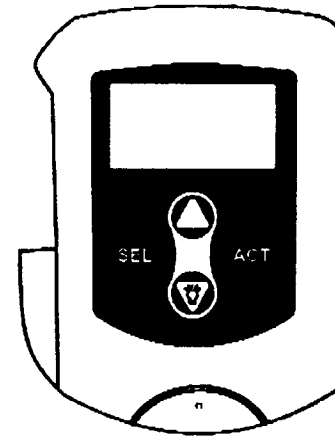


FIGURE 4 - 1: Continuous Glucose Monitor Buttons



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## WHAT THE BUTTONS MEAN

- Ⓛ: Turns the Monitor **ON** and **OFF**.
- SEL**: **SEL** means **Select**. The **SEL** button takes you through each of the operating displays.
- ACT**: **ACT** means **Activate**. Once you have reached a desired operating display, the **ACT** button allows you to make changes. You can program the Monitor, enter new information such as fingerstick blood glucose measurements, and turn off alarms.
- ▲ & ▼: Scrolls through lists of values in the Monitor. Pressing ▲ (**Up Arrow**) once will find the next highest value in the list. Pressing ▼ (**Down Arrow**) once will find the next lowest value in the list. Holding down either button will scroll more rapidly through the list of the values. When the desired value is displayed, it will blink until you press **ACT** to enter it.

---

## HOW TO TURN THE MONITOR ON

Pressing the **ON-OFF** (Ⓛ) button once while the Monitor is **OFF** turns the Monitor back **ON**. The Monitor will beep once and then will show the normal operation display.

Normally, the Monitor will be turned on and programmed for you when see your doctor.

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## HOW TO TURN THE MONITOR OFF

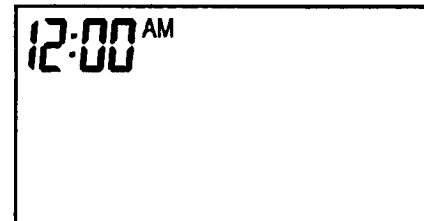
While the Monitor is **ON**, press the **ON-OFF** (Ⓛ) button once. The Monitor will beep and the word "CONFIRM" will appear blinking on the display. Then press **ACT** once to switch the Monitor **OFF**. The display screen will go blank and the Monitor will stop operating.

The Monitor should remain **ON** the whole time you are wearing it. **Do not turn your Monitor off, unless your doctor instructs you to do so. If you believe your Monitor was turned off by mistake, contact your doctor at once for instructions.**

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## THE NORMAL OPERATION DISPLAY

The Normal Operation Display is shown while the Monitor is operating normally. The current time is shown in the upper left-hand corner of the display screen.



If you are entering a fingerstick blood glucose measurement and 15 seconds goes by without a button press, the Monitor will return to the Normal Operation Display. If this happens, try to immediately enter the value again.

---

## HOW TO TURN ON THE DISPLAY LIGHT

The ▼ (**Down Arrow**) button has a picture of a light bulb (💡). A display light can be turned on from the Normal Operation or "INIT" displays, and when answering alarms. Press the ▼ button once to turn on the display light. The display light will turn off after 15 seconds to save battery power.

# V PROGRAMMING THE CONTINUOUS GLUCOSE MONITOR

This section explains how to program the Continuous Glucose Monitor. In most cases, your doctor will set-up and program the Monitor for you. The only set-up display that you probably will use on your own will be the "INIT" display. "INIT" is used after changing a Glucose Sensor.

There are six (6) set-up displays to program the Monitor: "SET TIME," "SIGNALS," "CLEAR," "PATIENT," "INIT" and "EXIT."

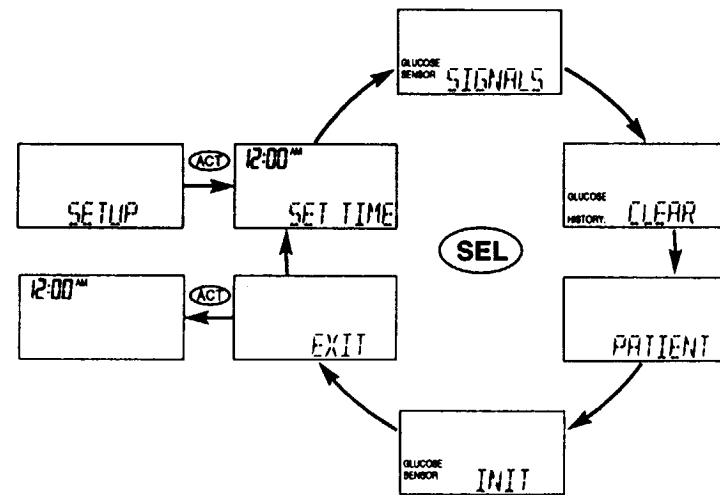


FIGURE 5 - 1: Set-Up Displays

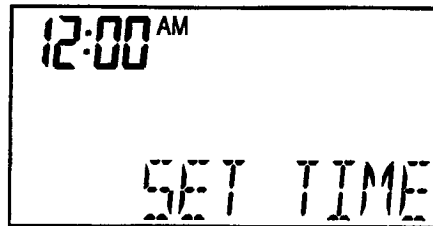
All of these set-up displays can be reached from the Normal Operation Display. Press **SEL** three (3) times to find the "SETUP" screen and then press **ACT** once. After finding the first set-up display, press the **SEL** button once to advance to the next set-up display. Notice that pressing **SEL** from the "EXIT" display will return to the first set-up display, "SET TIME."

To return to the Normal Operation Display, find the "EXIT" display and then press **ACT** once. Or you can simply wait 15 seconds and the Monitor will return to the Normal Operation Display on its own.

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## SET THE TIME AND DATE

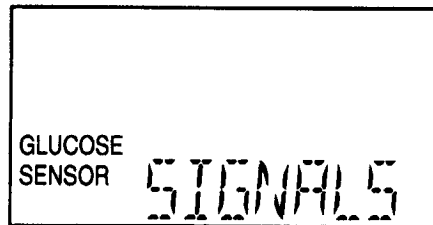
This display is used to set the current time and date. Normally, your doctor will set-up this display for you.



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## READ THE MONITOR SIGNALS

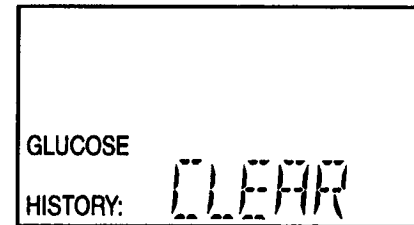
This display should be used only by your doctor. It is used to help diagnose problems that may occur with the Monitor. The numbers displayed are current and voltage signals used for finding problems with the CGMS and do not indicate a glucose value.



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## CLEAR THE GLUCOSE HISTORY

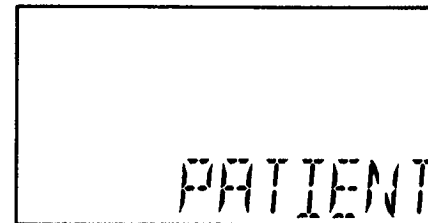
This display should be used only by your doctor. It is used to clear the Monitor of all glucose data and calibration data. Data is normally cleared, after your doctor downloads your glucose data into a personal computer.



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## ENTER A PATIENT IDENTIFICATION NUMBER

This display should be used only by your doctor. When your Monitor is being set-up, your doctor will enter a number into the Monitor which identifies who you are. All of your glucose data will be stamped with this identification number.

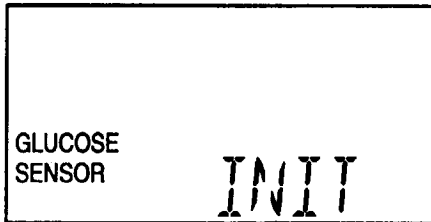


## INITIALIZE THE GLUCOSE SENSOR

If your doctor gives you instructions to change your Glucose Sensor, you will need to use the "INIT" display. "INIT" stands for initialize. First, change the Glucose Sensor following the directions in *CHAPTER THREE: Changing the Glucose Sensor*. Then, use the "INIT" procedure to help prepare the Glucose Sensor to measure glucose in its new location.

### 1. Find the "INIT" display: From the Normal Operation Display,

- Press the **SEL** button three (3) times to select "SETUP".
- Press the **ACT** button once to access the set-up displays.
- Press the **SEL** button four (4) times. The "INIT" display will be shown:

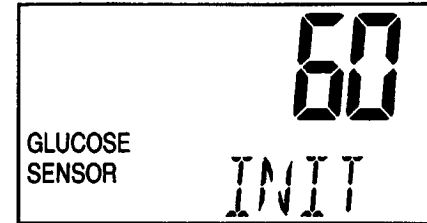


### 2. Verify the Glucose Sensor is connected to the Monitor:

From the "INIT" display, press the **ACT** button once. The monitor will beep and the word "CONFIRM" will appear blinking.



- ### 3. Start the Initialization:
- Press **ACT** once to begin the initialization. The Monitor screen will again show "INIT" with the number "60" appearing in the upper right-hand corner of the screen. It takes 60 minutes to initialize a new Glucose Sensor. The Monitor will count down the time remaining for the Glucose Sensor to initialize from 60 minutes.



- ### 4. Cancel the initialization:
- If you need to cancel the initialization before the 60 minutes have passed, press **SEL** or **ACT** once. The "CONFIRM" display will be shown again. Press **ACT** once again to cancel the initialization procedure.

**NOTE:** If the Glucose Sensor is not connected properly, the Monitor will beep and return to the Normal Operation Display.

**NOTE:** Disconnecting the Glucose Sensor assembly from its Cable, or the Cable from the Monitor for more than two minutes will interrupt the initialization.



# VI OPERATING THE CONTINUOUS GLUCOSE MONITOR

This section explains how to operate the Continuous Glucose Monitor. There are three (3) operation displays to choose from: "METER BG," "EVENT" and "SETUP."

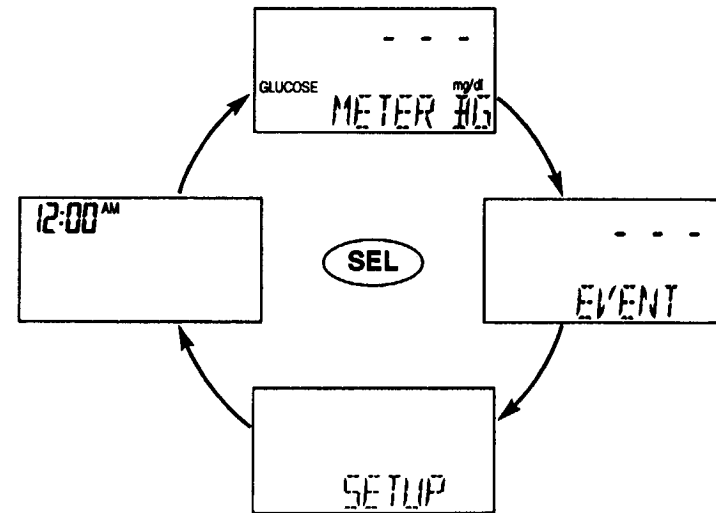


FIGURE 6 - 1: Operating Displays

All of the operation displays can be reached from the Normal Operation Display. Press the **SEL** button once to advance to the next operation Display. Notice that pressing **SEL** from the "SETUP" display will return you to the Normal Operation Display once again.



## HOW TO ENTER FINGERSTICK BLOOD GLUCOSE VALUES AS A GLUCOSE SENSOR CALIBRATION CHECK

**Check the Glucose Sensor for the First Time:** After you have initialized a new Glucose Sensor, a calibration check must be performed. This is done by taking two (2) blood glucose measurements, one right after the other. Only one fingerstick may be needed to take these two measurements. Take the average of the two glucose values and then enter it into the Monitor memory by using the "METER BG" display and selecting the "CAL YES" option.

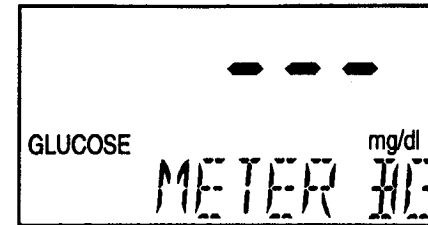
When your Glucose Sensor has been initialized, the Monitor will beep and the "METER BG" display will appear. This will remind you to enter the first meter measurement into the Monitor. After 15 seconds, the Monitor will return to the Normal Operation Display.

**Entering Other Blood Glucose Values Into the Monitor:** When you wear the CGMS, you should take at least four (4) fingerstick blood glucose measurements each day. We recommend that you take these measurements spread throughout the day, obtaining values at least twice before meals and once two hours after a meal.

All of your fingerstick blood glucose measurements should be entered into the Monitor's memory. You should choose at least one of these measurements each day to perform the sensor calibration check. These calibration checks will help the Monitor alert you if your Glucose Sensor needs to be changed. Each calibration check requires entering an average value taken from two (2) blood glucose measurements taken one after the other. Again, only one fingerstick may be needed to take these two measurements.

**PRECAUTION:** It is important that you take your fingerstick blood glucose measurements when you think your blood glucose is relatively steady. Each measurement should be entered into the Monitor within 1-2 minutes after taking the blood sample.

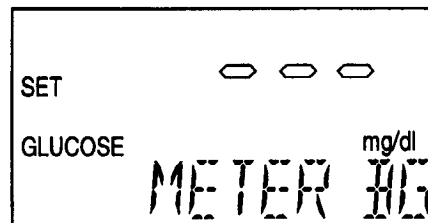
1. Find the "METER BG" display: From the Normal Operation Display, press the SEL button once. The "METER BG" display will be shown. When entering a glucose measurement for the first time, the display will look like this:



- Otherwise, the last glucose measurement that was entered will be shown. For example, if your last entered blood glucose measurement was 126 mg/dl, the following display will be shown:



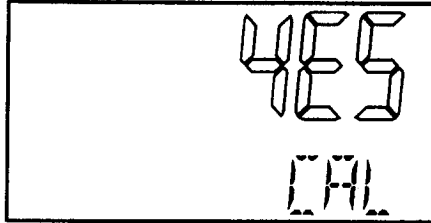
2. Enter a glucose measurement: Press the ACT button once. The glucose value " --- " will begin to blink.



- Use the ▲ and ▼ buttons to select the glucose value you want to enter. Then press ACT once to enter it. Now you must tell the monitor if the entered value should be used for a calibration check.

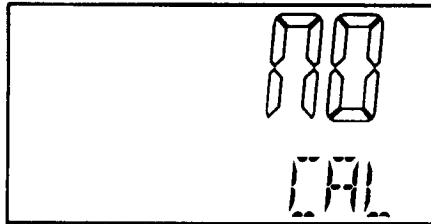
**3. To use the glucose measurement for a calibration check:**

The Monitor will beep, the word "CAL" will appear and the word "NO" will be blinking in the upper right-hand corner of the display. To check the monitor's calibration, press either the ▲ or ▼ button once to select a "YES" response, then press the ACT button once. The Monitor will then return to the Normal Operation Display.



**4. To enter a glucose measurement without a calibration check:**

The Monitor will beep, the word "CAL" will appear and the word "NO" will be blinking in the upper right-hand corner of the display. Simply press the ACT button once. The Monitor will then return to the Normal Operation Display.



**NOTE:** The Glucose Monitor will only accept meter values between 40 and 400 mg/dl. If your blood sugar is outside this range, treat per your doctors instructions then recheck your blood sugar and enter the value into the Monitor once your blood sugar is between 40 and 400 mg/dl.

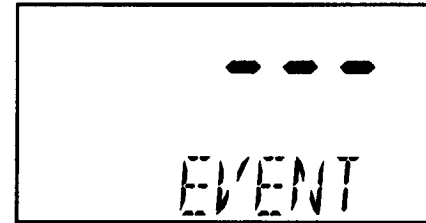
**PRECAUTION:** Once a blood sugar measurement is confirmed by pressing ACT, it cannot be erased. If a wrong blood sugar measurement was entered by mistake, enter the correct value as soon as possible. **INCORRECT BLOOD GLUCOSE ENTRIES MAY REDUCE THE ACCURACY OF THE CGMS VALUES.**

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## RECORD IMPORTANT EVENTS

Your doctor may also instruct you to enter important daily events into the Monitor. These events may include meals and snacks, insulin dosages, exercise, and other conditions that may affect your blood glucose.

1. Find the "EVENT" menu: From the Normal Operation Display, press the SEL button twice. The "EVENT" screen will be shown. When entering an event for the first time, the display will look like this:



2. Find the event code: Find the correct code (1 to 9) for the event to be entered:

- 1 - Meals
- 2 - Insulin
- 3 - Exercise

- 4 to 9 - Other (You should establish a list of additional event codes with your doctor before using the monitor for the first time)

3. Enter the event code: Press the ACT button once and " - - - " will start to blink. Use the ▲ and ▼ buttons to select the right code, then press ACT again to enter it.



## VII UNDERSTANDING AND RESPONDING TO ALARMS

This section describes the Continuous Glucose Monitor alarms and how to respond to alarm conditions to keep the Monitor operating smoothly.

During an alarm, the Monitor will normally beep once and then continue to beep about once every 15 seconds until the alarm is acknowledged. You will normally respond to an alarm by pressing **SEL** once followed by **ACT** once. If you do not respond to an alarm within 10 minutes, you will be reminded with a continuous audible alarm.

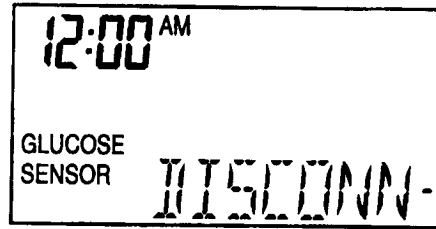
If there is more than one alarm at a time, the most important alarm will be shown first.

**NOTE:** A sensor calibration check must be performed after a alarm condition has been resolved by entering a "METER BG" value and selecting "CAL YES". No CGMS glucose values will be calculated after the alarm until the check is performed.

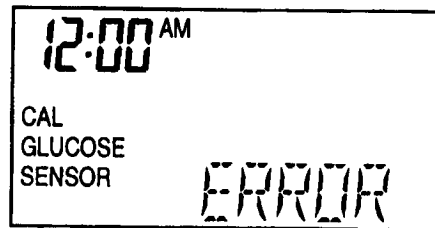
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## GLUCOSE SENSOR DISCONNECTED

This alarm occurs if the Glucose Sensor has disconnected from the Monitor, or the Glucose Sensor has pulled out of its insertion site. The Glucose Sensor will stop taking glucose measurements. However, your glucose data will continue to be stored in the Monitor. The alarm will beep once every 15 seconds, and the "DISCONN-" display will appear.



1. Answer the "DISCONN-" alarm: Turn off the alarm by pressing **SEL** followed by **ACT**.
2. Answer the "ERROR" alarm: The Monitor will now beep and the "ERROR" display will appear. This is a reminder to perform a calibration check before returning to operation. Press **SEL** followed by **ACT** again. The Monitor will then return to the Normal Operation Display.

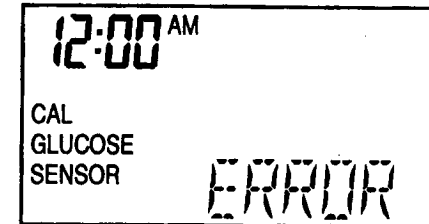


3. Enter a blood glucose value into the Monitor as a calibration check. See *CHAPTER SIX: Operating the Continuous Glucose Monitor* for directions.
4. The "DISCONN-" alarm will repeat every five (5) minutes as long as the disconnect condition remains. If this alarm occurs a second time, call your doctor at once for instructions.

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## CALIBRATION ERROR

This alarm may occur after entering a fingerstick blood glucose measurement into the Monitor. The value you entered is outside the range of values expected by the Monitor. The alarm will beep once every 15 seconds, and the "ERROR" display will appear.

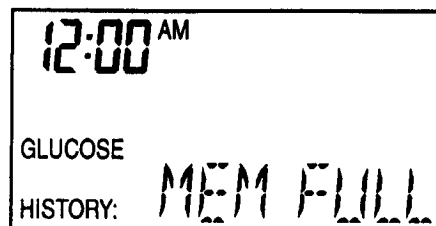


1. Answer the "ERROR" alarm: Turn off the alarm by pressing **SEL** followed by **ACT**. The "ERROR" screen will change back to the Normal Operation Display. The alarm will repeat every five (5) minutes as long as the last fingerstick glucose measurement entered remains outside the expected range.
2. Find the "METER BG" screen: Check to make sure the blood glucose value you just entered into the Monitor was correct. If you entered an incorrect value by mistake, enter the correct blood value as soon as possible (see *CHAPTER SIX: Operating the Continuous Glucose Monitor*).
3. Otherwise if the alarm repeats, call your doctor at once for instructions.

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## MEMORY FULL

The Monitor will store up to two weeks of glucose data in its memory. This alarm will occur when the Monitor memory is 90% full of glucose data. The alarm will beep once every 15 seconds and the "MEM FULL" display will appear.

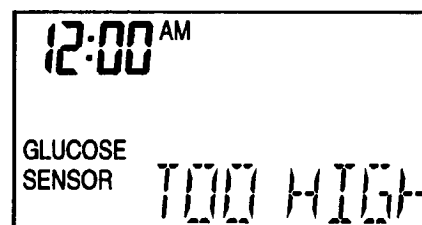


1. **Answer the "MEM FULL" alarm:** Turn off the alarm by pressing **SEL** followed by **ACT**. The "MEM FULL" display will change back to the Normal Operation Display. The alarm will repeat every six (6) hours as long as the memory is more than 90% full.
2. **Call your doctor at once for instructions.**

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## GLUCOSE SENSOR SIGNAL IS TOO HIGH

This alarm will occur when the Monitor has recorded a higher than expected reading from the Glucose Sensor for three (3) minutes in a row. This alarm may be due to either a Glucose Sensor malfunction or to an abnormally high blood glucose value. The alarm will beep once every 15 seconds and the "TOO HIGH" display will appear.

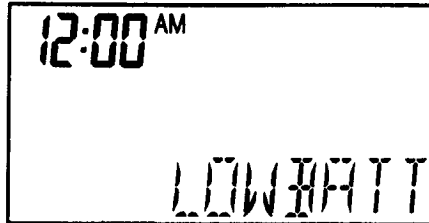


1. **Answer the "TOO HIGH" alarm:** Turn off the alarm by pressing **SEL** followed by **ACT**. The "TOO HIGH" screen will change back to the Normal Operation Display. The alarm will repeat every three (3) minutes as long as an abnormally high Glucose Sensor value continues to be detected.
2. **Take a fingerstick blood glucose meter measurement:** If the measurement is abnormally high, follow your doctor's instructions for treating high blood glucose. If the fingerstick measurement is normal, this suggests there may be a problem with your CGMS. You should contact your doctor for further instructions.
3. If the "TOO HIGH" alarm occurs again, **call your doctor at once for instructions.**

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## LOW BATTERY

This alarm occurs when the Monitor batteries are weak and need to be replaced. The alarm will beep once and the "LOWBATT" display will appear on the screen.



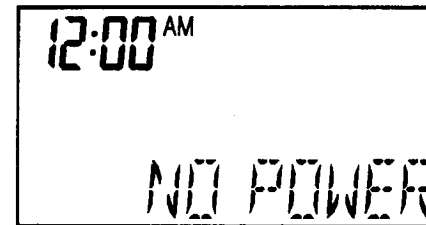
After a "LOWBATT" alarm, the Monitor will continue to operate normally as long as the batteries continue to have power. About eight (8) hours of power is left. The "LOWBATT" display will remain. The alarm will repeat every one (1) hour until the batteries are changed.

1. **Call your doctor at once for instructions.** If your doctor instructs you to change the batteries, follow the instructions in *CHAPTER TWO: General Description*.
2. **Press the ON/OFF button once to return to the Normal Operating Display.**
3. **Check Calibration of the Glucose Sensor** by entering a fingerstick blood glucose measurement and selecting "CAL YES" before returning to normal operation.

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## NO POWER

This alarm occurs when the Monitor batteries are in danger of losing power. The alarm will beep once and the "NO POWER" display will appear. The batteries are expected to last less than one (1) hour and must be changed **immediately** to continue normal operation. An interruption in operation will happen very soon. The time of the initial alarm is recorded into the Monitor memory.



After a "NO POWER" alarm, the Monitor will continue to operate normally as long as the batteries continue to have power. Less than one (1) hour of power is left. The "NO POWER" display will remain. The alarm will repeat until either the batteries are changed or all power is lost and the screen goes blank.

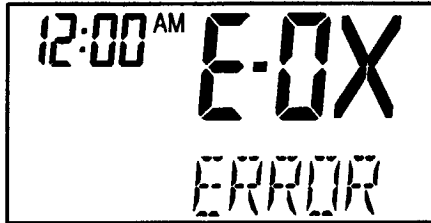
1. **Call your doctor at once for instructions.** If your doctor instructs you to change the batteries, follow the instructions in *CHAPTER TWO: General Description*.
2. **Press the ON/OFF button once to return to the Normal Operating Display.**
3. **Check Calibration of the Glucose Sensor** by entering a fingerstick blood glucose measurement and selecting "CAL YES" before returning to normal operation.

**PRECAUTION:** If the Monitor shows a "NO POWER" alarm for more than one hour, the glucose data other information in the Monitor memory may be lost. **Contact your doctor immediately if this should occur.**

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## SYSTEM ERROR

This alarm occurs when a self-test of the Monitor has found an error in the memory. The alarm will beep once and the following "ERROR" display will appear.



1. Do not turn the Monitor Off!
2. Call your doctor at once for instructions.

## VIII CARING FOR THE CONTINUOUS GLUCOSE MONITOR

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### PROTECTION FROM WATER

Although the Continuous Glucose Monitor, Cable and Glucose Sensor are designed to be water resistant, avoid prolonged direct contact with water or other fluids.

1. The Monitor should not be used while swimming.
2. The Monitor should always be placed into a Shower-Pak or other fluid resistant container before taking a shower or bath.
3. The Monitor should never be submerged.
4. Check to make sure that the clear medical dressing covering the Glucose Sensor connector is tightly adhered to the skin.
5. Any moisture that comes in contact with the Monitor should be dried with a soft towel.

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## PROTECTION FROM IMPACT

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

1. The Monitor should be protected from mechanical damage such as a fall or impact.
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. The Monitor should be safely secured to the body, and all connections should be checked frequently during exercise. If a "DISCONN" alarm occurs, stop exercising and follow the directions in *CHAPTER SEVEN: Understanding and Responding to Alarms*.

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## PROTECTION FROM HIGH TEMPERATURES

The Monitor was designed to operate from 0 to 50 degrees Celsius (32 to 122 degrees Fahrenheit).

1. If you are outside during freezing weather, the Monitor should be worn close to your body and under 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 happen in a car on a hot summer day, or near a fire or other radiant heat source.

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## CLEANING THE MONITOR

1. Use a damp cloth and mild cleaning solution to clean the outside of your Monitor. Cleaning solutions may include tap water, 409<sup>®</sup>, Windex<sup>®</sup>, Liquid Joy<sup>®</sup>, Betadine<sup>®</sup>, 10% bleach solution, 3% hydrogen peroxide solution and 70% isopropyl alcohol. **Do not spray cleaning solution directly onto the Monitor.** Avoid moisture contact with the Glucose Sensor-to-Cable, or Cable-to-Monitor connectors.
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.

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## X-RAYS, MRI AND CT SCANS

The Monitor should withstand all common electrostatic and electromagnetic sources including airport metal detectors, cell phones and microwave ovens. However, using the Monitor near 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 you are scheduled to have an X-ray, CT or MRI scan, either protect the Monitor by placing it under lead shielding or take the Monitor off by gently disconnecting the Cable from the Monitor. After the procedure, the Cable and Monitor should be reconnected, and the Glucose Sensor recalibrated before returning to normal operation.

**NOTE:** For procedures which require the Continuous Glucose Monitor to be disconnected for more than 15 minutes, reconnect the Cable to the Glucose Sensor, wait 30 minutes and then recalibrate the Glucose Sensor before returning to normal operation.



Please Read The Instructions for Use	
Manufacture Date (year - month)	 1999-12
Device Serial Number	S N
Storage Temperature Range	
Type B (Protection from electric shock)	
On / Off	
Change Value Up	
Change Value Down	
Backlight	
One Per Container / Package	(1x)
Activate	ACT
Select	SEL
Do Not Reuse This Device	
Lot Number	 123456
Expiration Date (Use By Date) (Year - Month)	 1999-12
Fragile Product	
Protect Against Moisture	
Open Here	
Watertight	

If you require additional information regarding use of the Continuous Glucose Monitoring System, contact your health care professional or the Clinical Services Department at:



USA:  
 Sylmar, CA  
 818-362-5958 • 800-826-2099 (24-hour Help Line within U.S. & Canada)  
 To order supplies:  
 800-843-6687 • FAX: 888-268-0200 (within U.S. & Canada)  
 FAX: 818-362-3788 (outside U.S.)

This product is covered by the following U.S. patent: [U.S.]5,376, 070.  
 Other U.S. and/or foreign patents may be pending.

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