GE Healthcare

SEER® Light
Ambulatory Recorder/Controller

Operator's Manual

2040604-012 Revision D

The information in this manual only applies to SEER® Light devices. Due to continuing product innovation, specifications in this manual are subject to change without notice.

CE Marking Information

Compliance

NOTE

This CE mark information is part of the operator manual and is applicable for all products marketed and distributed by GE Medical Systems *Information Technologies* in the European community.

These SEER® Light devices bear the CE mark 0459, notified body GMED, indicating its conformity with the provisions of the Council Directive 93/42/EEC, concerning medical device and fulfills the essential requirements of Annex I of this directive.

The product is in radio-interference protection class A in accordance with EN 55011.

The country of manufacture can be found on the equipment labeling.

The product complies with the requirements of standard EN 60601-1-2 “Electromagnetic Compatibility - Medical Electrical Equipment”.

NOTE

Refer to the SEER Light service manual for additional compliance and exception information.

The safety and effectiveness of this device has been verified against previously distributed devices. Although all standards applicable to presently marketed devices may not be appropriate for prior devices (i.e. electromagnetic compatibility standards), this device will not impair the safe and effective use of those previously distributed devices. Any other directive(s) and all the standards the product complies to are listed in the general information of the operator manual for the product following this page.

Contents

1 Manual Information

2 Equipment Overview

5 Recording Data

6 Transferring Data

A Troubleshooting

B Accessories

1 Manual Information

Manual Information

This manual includes operator's instructions for:

- SEER Light/SEER Light Extend Compact Digital Holter Recorder
- SEER Light Extend Controller
- SEER Light Connect

Revision History

Each page of the document has the document part number followed by a revision letter at the bottom of the page. The revision letter identifies the document's update level.

Revision History PN 2040604-012		
Revision	**Date**	**Comment**
A	30 April 2008	Initial release of this document.
B	11 August 2008	Revised to include the word "Greece" to Greek address on backcover.
C	19 September 2008	Revised manual to reflect Suzuken responsibility and new controller configuration.
D	14 April 2009	Revised to change CF Card part number.

Manual Purpose

This manual contains the instructions necessary to operate the equipment safely in accordance with its function and intended use. These instructions include but are not limited to:

- an explanation of the function of controls and indicators
- the sequence of operation
- connection and disconnection of detachable parts and accessories
- instructions for operator cleaning, preventive inspection and maintenance

Where necessary, the manual identifies additional sources of relevant information and/or technical assistance.

Intended Use

The SEER Light recorder/SEER Light Extend recorders are designed to acquire 2 or 3 channels of ECG signal from the chest surface of pediatric or adult patients. The devices store data along with patient demographic information to on-board flash memory; they do not perform any analysis on the ECG data. These devices are intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional facility.

This device is not intended for use on patients weighing less than 10 kg (22 lbs.).

Intended Audience

This manual is intended for an operator of the SEER Light devices. The SEER Light operator requires some training to become familiar with the capabilities and operations of the devices.

Product References

Regardless of the Holter analysis system (MARS PC workstation or MARS Unity workstation) used, the product will be referred to as SEER Light throughout this document. Instances where functionality differs due to Holter analysis system will be called out specifically.

Conventions

These are the conventions used in this manual.

Styles	
Style	**Definition**
Bold text	Indicates keys on the keyboard, text to be entered, or hardware items such as buttons or switches on the equipment.
Italicized text	Indicates software terms that identify menu items, buttons or options in various windows.

Styles	
Style	**Definition**
Ctrl+Esc	Indicates a keyboard operation. A (+) sign between the names of two keys indicates, you press and hold the first key while pressing the second key once. For example, "Press **Ctrl+Esc**" means to press and hold down the **Ctrl** key while pressing the **Esc** key.
<Space>	Indicates that you must press the spacebar. When instructions are given for typing a precise text string with one or more spaces, the point where the spacebar must be pressed is indicated as: **<Space>**. The purpose of the < > brackets is to ensure you press the spacebar when required.
Enter	Indicates that you must press the "**Enter**" or "**Return**" key on the keyboard. Do not type "**enter**".

Illustrations

All illustrations in the manual are provided as examples only. All patient names and data are fictitious, and any similarity to actual persons is coincidental.

Safety Information

Definitions

The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance.

Hazard is defined as a source of potential injury to a person.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

Messages

Additional safety messages may be found throughout this manual that provide appropriate safe operation information.

Warnings

WARNING
ACCIDENTAL SPILLS — To avoid electric shock or device malfunction, liquids must not be allowed to enter the device.

If liquids have entered a device, take it out of service and have it checked by a technician before it is used again.

WARNING
CARDIAC APPLICATION — This device cannot be used for direct cardiac application.

WARNING
LEAKAGE CURRENT — Electrical shock to patient could result from component failure and lack of power isolation.

In the event this system is used in the patient vicinity/ environment, it must be configured in such a way that it and all of its electrically-connected peripheral devices are isolated from mains power to prevent excessive leakage current to the patient. Use of isolated mains power, or a medical grade isolation transformer (in compliance with UL 60601, CAN/CSA C22.2 No. 601.1, EN/IEC 60601-1) with this system will support compliance with EN/IEC 60601-1-1. All nonmedical peripheral devices shall comply with applicable EN/IEC/ISO and UL safety standards that are relevant to that equipment (i.e., EN/ IEC 60950, UL 60950). The overall system (device and all of its connected peripheral devices) must comply with EN/ IEC 60601-1.

Use of SEER Light Connect device in the patient vicinity requires that these measures are observed.

Patient vicinity/environment defined as:

- Any volume in which intentional or unintentional contact can occur between patient and parts of the system or between patient and other persons touching parts of the system (IEC 60601-1-1).
- A space (volume), within a location intended for the examination and treatment of patients, extending 6 ft (1.83 m) beyond the normal location of the bed, chair, table, treadmill, or other device that supports the patient during examination and treatment and extending vertically to 8 ft 2.4 in. (2.5 m) above the floor.
- Areas where healthcare staff members monitor patients remotely and perform charting and administrative tasks are not considered to be Patient Vicinity/environment areas.

WARNING
PACEMAKER PATIENTS — Take precautions to avoid risks of hazard due to the operation of a cardiac pacemaker or other electrical stimulators.

WARNING
RF INTERFERENCE — Known RF sources, such as cell phones, radio or TV stations, and two-way radios, may cause unexpected or adverse operation of this device.

Consult qualified personnel regarding system configuration.

WARNING
CABLES — Cables present a possible strangulation hazard.

To avoid possible strangulation, route all cables away from patient's throat.

Use short version of cables for pediatric patients.

WARNING
CONDUCTIVITY — Electric shock or device malfunction may occur if electrodes contact conductive materials.

Keep the conductive parts of lead electrodes and associated parts away from other conductive parts, including earth.

WARNING
DEFIBRILLATION — Do NOT contact unit or patient during defibrillation. Serious injury or death could result.

Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and leadwires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

WARNING
ELECTROSURGERY — Take precautions to reduce risks of burns and injury to the patient.

If an electrosurgery device is used, it is necessary to disconnect the patient cable from the SEER Light recorder.

WARNING
OXYGEN RICH ENVIRONMENT — An oxygen rich environment may be flammable.

Do not use device in an oxygen rich environment or around other flammable or explosive gases.

WARNING
SUPERVISED USE — This device is intended for use under the direct supervision of a licensed health care practitioner.

Cautions

CAUTION
BEFORE OPERATION — Check that the instrument operates properly.

See Chapter 5 of the *SEER™ Light Ambulatory Recorder / Controller Service Manual* for proper maintenance practices.

When using with other instruments, request the assistance of a specialist.

CAUTION
DISPOSAL — At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products.

If you have questions concerning the disposal of this product, contact GE or its representatives.

Dispose of the packaging material, observing the applicable waste regulations.

Keep the packaging material out of children's reach.

CAUTION
EQUIPMENT CONFIGURATION — The equipment or system should not be used adjacent to, or stacked with other equipment.

If adjacent or stacked use is necessary, test the equipment or system to verify normal operation.

CAUTION
INTERFERENCE — Electrical emissions from an electric blanket may degrade signal quality.

Do not use in conjunction with an electric blanket.

CAUTION
INSTRUCTIONS FOR USE — For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual IN NO WAY supersede established medical practices concerning patient care.

CAUTION
MODIFICATIONS — Do not make any modifications to the device. You will void the device's warranty. See "Responsibility of the Manufacturer" on page 1-10.

CAUTION
RESTRICTED SALE — U.S. Federal law restricts this device to sale by or on the order of a physician.

Responsibility of the Manufacturer

Suzuken Company, Ltd is responsible for the effects of safety, reliability, and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by Suzuken Company, Ltd.
- The equipment is used in accordance with the instructions for use.

General

To ensure patient safety, use only parts and accessories manufactured or recommended by GE Medical Systems *Information Technologies*, and Suzuken Company, Ltd.

Contact GE Medical Systems *Information Technologies* for information before connecting any devices to this equipment that are not recommended in this manual.

Parts and accessories used must meet the requirements of the applicable EN/IEC/UL 60601 or EN/IEC/UL 60950 series safety standards, and the

system configuration must meet the requirements of the EN/IEC 60601-1-1 medical electrical systems standard.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY/ENVIRONMENT; and
- evidence that the safety certification of the ACCESSORY has been performed in accordance with the appropriate EN/IEC/UL 60601-1 (medical) or EN/IEC/UL 60950 (information technology), and EN/IEC 60601-1-1 safety standard(s).

Classification

The SEER Light Connect is classified according to EN/IEC 60950.

The SEER Light recorders and controllers are classified, according to EN/IEC/UL 60601-1, as:

Type of protection against electrical shock	Internally Powered Equipment
Degree of protection against electrical shock	Type B Equipment
Degree of protection against harmful ingress of water	Ordinary Equipment (enclosed equipment without protection against ingress of water)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable
Mode of operation	Continuous operation

Underwriters Laboratories, Inc.

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical and other specified hazards, only in accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, EN/IEC 60601-1, and IEC 60601-2-47.

Information Technology Equipment

The hardware components supplied by GE for the MARS® Holter analysis workstation, on which the SEER Light Connect application runs, are considered to be Information Technology Equipment (ITE). These individual components have been found to comply with the standard for Safety of Information Technology Equipment, including Electrical Business Equipment EN/IEC/UL 60950.

The software used in the MARS® Holter analysis workstation is considered as medical software. The software has been designed and manufactured to the appropriate medical regulations and controls.

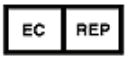
In order for the MARS® Holter analysis workstation to comply with medical equipment leakage current requirements, a medical grade uninterruptible power supply (UPS) must be used (EN/IEC/UL 60601-1) to power all non-medical equipment.

In addition, non-medical electrical equipment must comply with EN/IEC/ UL safety standards that are relevant to that equipment (i.e., IEC 60950, Safety of Information Technology Equipment).

Equipment Symbols

The following symbols may appear on the equipment.

	Attention. Consult accompanying documents.
	Manufacturer name and address.

	European authorized representative.
	Serial Number.
RX Only	USA only. For use by or on the order of a physician, or person licensed by state law.
	Type B applied Part.
	Event.
	This symbol indicates the polarity orientation that each battery should have when you insert it into the unit. This unit requires you to insert the batteries so that the polarities are oriented in alternating directions.
	Power.
	Stop.
	Input connector.

	Output connector.
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Service Information

Requirements

Refer equipment servicing to GE Medical Systems *Information Technologies*' authorized service personnel only. Any unauthorized attempt to repair equipment under warranty voids that warranty.

It is the user's responsibility to report the need for service to GE Medical Systems *Information Technologies* or to one of their authorized agents.

Serial Number

The serial number is a unique number used for identification. The serial number appears on the device label located on the back of the device, similar to the following.

089A

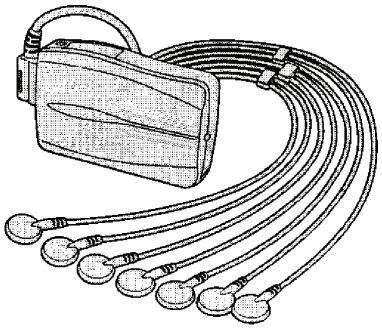
2 Equipment Overview

General Information

For safe and effective operation, read this manual thoroughly prior to use.

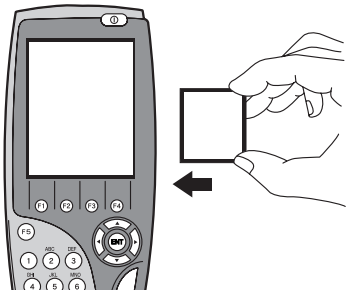
NOTE

It is unsafe to start using the device before reading this entire manual.



1A

SEER Light/SEER Light Extend Compact Digital Holter Recorder



2B

SEER Light Extend Controller with Compact Flash Card

084A

SEER Light Connect

SEER Light Device Compatibility

There are two types of recorders and controllers, with different capabilities: SEER Light and SEER Light Extend.

- The SEER Light recorder acquires, stores and transfers up to 24 hours of ECG data.
- The SEER Light Extend recorder and SEER Light Extend controller acquires, stores and transfers up to 48 hours of ECG data.

CAUTION

DATA TRANSFER — The SEER Light Extend recorder works with the 24-hour SEER Light controller for setup, but not for transferring data. The 24-hour SEER Light controller is no longer available.

Always use the SEER Light Extend recorder with the SEER Light Extend controller when transferring data.

NOTE

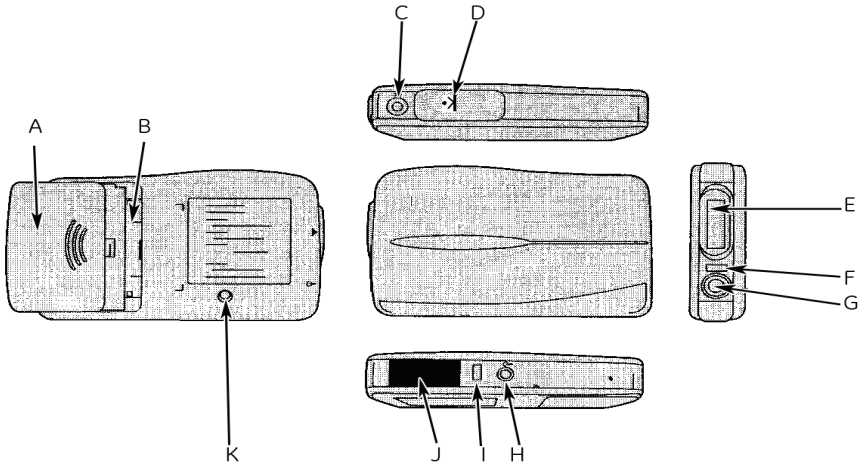
The 24-hour SEER Light recorder can be used with the SEER Light Extend controller.

SEER Light/SEER Light Extend Compact Digital Holter Recorder

The SEER Light/SEER Light Extend Compact Digital Holter Recorder is shown and described below. This device is also referred to as “the recorder” in this document.

NOTE

There are two recorders available: The SEER Light recorder that records up to 24 hours of ECG data, and the SEER Light Extend recorder that records up to 48 hours of ECG data. The stenciled label on each device identifies the recorder name.



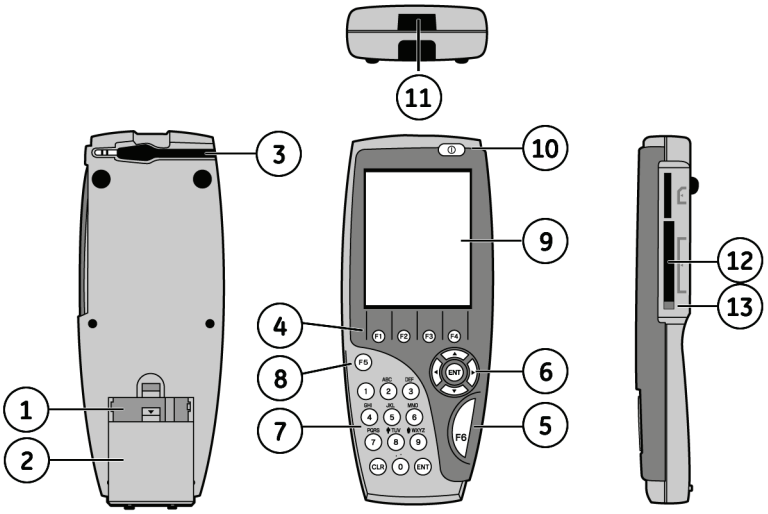
3A

	Name	Function
A	Battery box cover	Slide the cover to open and set the batteries in the battery box. **NOTE** Do not open in patient vicinity.
B	Battery box	Holds the batteries.
C	REC LED	To display operation conditions: ■ After pressing the **Start/Event** button, the LED will flash twice per second for three minutes. During this time data is not recorded. ■ During recording, the LED will flash every second.
D	Start/event button	■ Use to start recording. ■ Use mark events during recording.
E	Patient cable connector	Used to connect patient cable.

	Name	Function
F	DATA LED	The LED lights while transferring data to the SEER Light controller or SEER Light connect.
G	 **A** data output connector	For transfer of data to the SEER Light controller or SEER Light connect.
H	 **B** output connector	Not used. **NOTE** Do not connect to any unauthorized device.
I	Access LED	Will flash during communication with the SEER Light controller.
J	Infrared terminal (IR Window)	■ Used to receive the signal from the SEER Light controller to begin ECG recording. ■ Used to receive patient information and ECG recording starting time. ■ Used to confirm the ECG waveform recorded by the recorder (ECG preview).
K	 Stop button	Push this button with a ball point pen to stop the recording before 24 hours have elapsed (or 48 hours with the SEER Light Extend recorder).

SEER Light Extend Controller

The SEER Light Extend Controller is shown and described below. This device is also referred to as “the controller” in this document.



4A

	Name	Function
1	Battery box	Holds the batteries.
2	Battery box cover	In direction indicated, lift the cover open and place four new alkaline AAA type batteries in the battery box.
3	Data transfer cable	Used to transfer data from the SEER Light recorder. When not in use, store the cable in the guide on the backside panel.
4	Function buttons	Used to enter controller modes. Press **F1** to enter Preview mode to confirm the quality of ECG recording. Press **F2** to enter Data Transfer mode to transmit data to SEER card. Press **F3** to enter Review mode to confirm SEER card contents. Press **F4** to return to SEER mode.
5	**F6** button	Used to start recording of the SEER Light recorder and to start transferring data to a SEER card.
6	Select (ENT) button	Used to select items and navigate around the display panel.
7	Patient information entry keypad	Enter the patient's alphanumeric information.
8	**F5** button	Used to enter Set-up condition mode to change certain settings on the controller and recorder.

	Name	Function
9	LCD (liquid crystal display)	Displays operating conditions.
10	 Power button	Used to turn the power on and off.
11	Infrared terminal (IR Window)	Used to communicate with the SEER Light recorder. ■ Transfer the instructions to a SEER Light recorder before recording. ■ Receive ECG waveform recording data from a SEER Light recorder to preview.
12	SEER card slot	Used to insert a SEER card.
13	Eject button	Used to eject a SEER card.

SEER Light Connect

The SEER Light Connect is used as a direct interface connection between the recorder and the Holter analysis system. This device is also referred to as “the connect” in this document.

WARNING

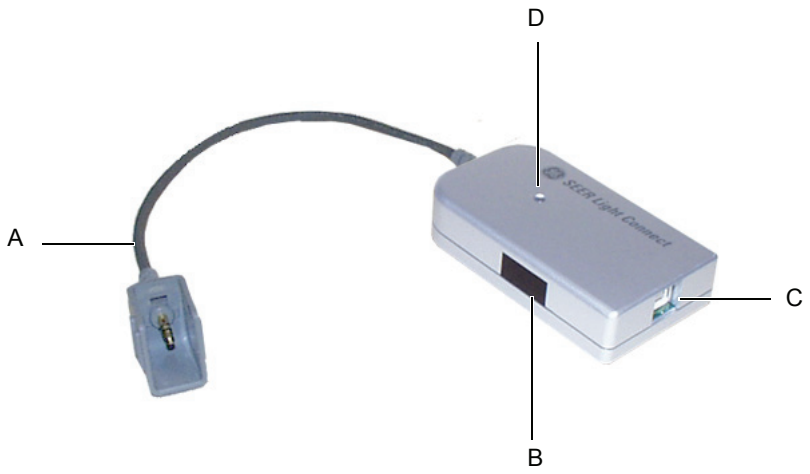
LEAKAGE CURRENT — Electrical shock to patient could result from component failure and lack of power isolation.

In the event this system is used in the patient vicinity/ environment, it must be configured in such a way that it and all of its electrically-connected peripheral devices are isolated from mains power to prevent excessive leakage current to the patient. Use of isolated mains power, or a medical grade isolation transformer (in compliance with UL 60601, CAN/CSA C22.2 No. 601.1, EN/IEC 60601-1) with this system will support compliance with EN/IEC 60601-1-1. All nonmedical peripheral devices shall comply with applicable EN/IEC/ISO and UL safety standards that are relevant to that equipment (i.e., EN/ IEC 60950, UL 60950). The overall system (device and all of its connected peripheral devices) must comply with EN/ IEC 60601-1.

Use of SEER Light Connect device in the patient vicinity requires that these measures are observed.

Patient vicinity/environment defined as:

- Any volume in which intentional or unintentional contact can occur between patient and parts of the system or between patient and other persons touching parts of the system (IEC 60601-1-1).
- A space (volume), within a location intended for the examination and treatment of patients, extending 6 ft (1.83 m) beyond the normal location of the bed, chair, table, treadmill, or other device that supports the patient during examination and treatment and extending vertically to 8 ft 2.4 in. (2.5 m) above the floor.
- Areas where healthcare staff members monitor patients remotely and perform charting and administrative tasks are not considered to be Patient Vicinity/environment areas.



	Name	Function
A	Data transfer cable	Used to transfer data from the SEER Light recorder to the SEER Light Connect.
B	Infrared terminal (IR Window)	Used to communicate with the SEER Light recorder. ■ Receives ECG waveform data from a SEER Light recorder to preview. ■ Transfers patient demographics to the SEER Light recorder. ■ Starts the SEER Light recorder.
C	USB Connection	Uses a USB patch cord to transfer data from the SEER Light Connect to the Holter analysis system.
D	LED indicator	■ Flashes when data is transferring. ■ Lights without flashing when a proper connection exists.

Installing SEER Light Hookup

This software is used in conjunction with the SEER Light Connect device. If you do not have a SEER Light Connect device, you may skip this section.

Before you connect the SEER Light Connect device to your Holter analysis workstation, follow these steps to install the SEER Light Hookup software.

NOTE

You must have administrator privileges to install the SEER Light Hookup software.

1. Insert the SEER Light Hookup software CD in the CD drive of your workstation.

   NOTE

   The computer you install the SEER Light Hookup software must be running Windows 2000, 2000 server, XP or 2003 server.

   The software cannot be installed on Windows NT, 98 or ME.

2. The *SEER Light Hookup InstallShield Wizard* appears. Choose the appropriate language and select *Next*.
3. The *SEER Light Hookup Setup* welcome window appears. Select *Next*.
4. The license agreement window appears. Review the license agreement and select *Yes*.
5. The *Destination Disk* window appears. Highlight the disk in which the SEER Light Hookup application will be installed. Select *Next*.
6. The software is now being installed. When finished, a message appears asking if you would like to view the installation report. Select *Yes* to view the report or *No* to continue.

   If you select *Yes*, the *Installation Report* appears.

   - To print the report, select the *Print* button.
   - To view previous installation reports, select the *View History* button. This button will be grayed out if no prior installations were done on your computer.
7. Select *Next* when finished.
8. At the *InstallShield Wizard Complete* window, select *Yes, I want to restart my computer now*.
9. Select *Finish*. Your computer will restart.
10. Log back in as Administrator.
11. Plug the Universal Serial Bus (USB) cable into the USB port of your computer to load the USB drivers. Connect the USB cable to the SEER Light Connect device.

The *Found New Hardware* window appears.

12. If you are on a Windows 2000 operating system, the *Insert Disk* window will appear. Select *OK*.

    Two additional files need to be loaded: the *WinRTUSB.dll* and the *WinRTUSB.sys*. The *Files Needed* window appears. In the dropdown box, type in **D:\drivers** (or the letter assigned to the CD drive if it is not D). Select *OK*.

    The *Files Needed* window appears again. In the dropdown box, type in **D:\drivers** (or the letter assigned to the CD drive if it is not D). Select *OK*.

13. If you are on a Windows XP system the *Found New Hardware Wizard* window appears. Select the button next to *Install the software automatically*. Select *Next*.

    The *Found New Hardware Wizard* window appears again. Select *Finish*.

The SEER Light Hookup installation is now complete.

Pouch

It is recommended that the recorder be used in combination with the SEER Light pouch (PN 2008596-001) for the entire duration of the recording. The pouch protects the connection between the patient cable and the recorder.

Operating Modes - SEER Light Controller

There are three operating modes for the controller:

- SEER mode
- Transfer mode
- Set-up Condition mode

SEER mode

This is the main user mode of operation; patient information and recording occurs from within SEER mode. Refer to "Entering Patient Data" on page 4-1 and "Recording Data" on page 5-1 for more information.

The controller starts up in *SEER* mode automatically.

Transfer mode

Recorded data is transferred from the recorder to the controller from within *Transfer* mode. Refer to "Transferring Data" on page 6-1 for more information.

Press **F2** to enter *Transfer* mode.

Set-up Condition Mode

Use the *Set-up Condition* mode to configure operating parameters for the recorder and controller. Once configured, the settings will be saved if the power is turned off.

1. Press the **Power** button and the **F5** button simultaneously. Continue to hold the **F5** button while releasing the **Power** button. The *Set-up condition* display mode opens.
2. Press the ▲ ▼ buttons to select a parameter.
3. Press the ◀ ▶ buttons to set the parameter's conditions.
4. Press the **F1** button to exit the *Set-up Condition* mode.

Selecting a Language

Follow these steps to change the language that the SEER Light controller displays.

1. Press the **Power** button and the **F5** button simultaneously. Continue to hold the **F5** button while releasing the **Power** button. The *Set-up condition* display mode opens.
2. Press the **0** button to open the *Language Selection* display.
3. Use the Patient Information Entry keypad or the ▲ ▼ buttons to select the desired language.
4. Press **ENT** to select the language.

Parameter Descriptions and Configuration

The following operating parameters can be configured for the recorder and the controller.

Parameter	Description
Heart rate synchronizing sound (controller)	Heart rate synchronizing (shown as *HR sound*) can be set *ON* or *OFF* during the preview of ECG waveforms. (*OFF* is the initial setting.) Press the ◂ ▸ buttons to turn the selection *ON* or *OFF*.
Heart rate detection channel (controller)	Used to select a recording channel to detect heart rate to calculate the heart rate and the heart rate synchronizing sound during the preview of ECG waveform. Selections are *CH1*, *CH2*, or *CH3* (*CH1* is the initial setting). Press the ◂ ▸ buttons to select *CH1*, *CH2*, or *CH3*.
Auto start (recorder)	If auto start is set to on, the controller will program the SEER Light recorder so it automatically starts 30 minutes after batteries are installed. Once the recorder is setup this way it will always automatically start in this manner unless is it reprogrammed. If auto start is set to off it will program the SEER Light recorder so it does not automatically start 30 minutes after the batteries are installed Press the ◂ ▸ buttons to turn the selection *ON* or *OFF*. **NOTE** The recorder will not Auto start if there is untransferred data in the recorder.

Parameter	Description
Date and Time (controller)	Used to set the date and time of the controller. The start time of the recorder is calculated based on the date and time of the controller. The recorder does not have a time clock. ■ The recorder receives the date and time information from the controller when the recorder is started by the controller. ■ Or, in instances when recording is initiated from the recorder, the recording start time will be calculated from the time clock of the controller when the ECG data is transferred to a SEER card from the recorder using the controller. Setting the Date 1. Press the alphanumeric buttons to enter DD, MON (the 3-letter code for the month), and YYYY in order. The Hungarian language version displays the date using the yyyy-MON-dd format. 2. Press ▼ to confirm the new date. Setting the Time 1. Press the alphanumeric buttons to enter HH and MM in order. 2. Press ▼ to confirm the new time.
Accelerometer Check	Not used

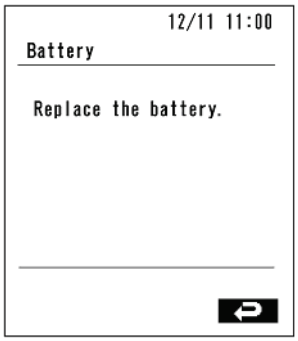
Battery Power

The controller and the recorder use AAA alkaline batteries. Always remove the batteries when storing either device.

SEER Light Controller

According to the battery power level, the battery icon will change.

The following table describes the battery power level icon(s).

Battery Symbol Mark	Battery Power Level
	Sufficient power for normal operation.
	Battery power sufficient for 6 normal recording operations, including preview of the ECG waveform for 5 minutes, start recorder, and data transfer. It is recommended to replace the batteries.
	Battery power sufficient for 3 normal recording operations, including preview of the ECG waveform for 5 minutes, start recorder, and data transfer. Replace with new batteries
	No power for operation. Replace the batteries.

NOTE

The Auto Power OFF function will be activated to save the battery power if no button is pressed for 15 minutes. The Auto Power OFF function will not be activated if any error message is displayed.

SEER Light Recorder

Always remove the batteries when not in use, and replace with new AAA alkaline batteries when ready for use. See "Inserting Batteries in the SEER Light Recorder" on page 5-12 for details.

Battery Disposal

Do not burn the batteries, or dispose of batteries with other medical wastes. Contact your local recycling center for information on proper disposal of used batteries.

Care and Cleaning

Follow these cleaning instructions for the recorder, controller and the connect device.

- Keep the device clean between each use to prevent infection.
- Remove the batteries and disconnect any power and USB cords before cleaning the device.
- Use a piece of cloth dampened with alcohol to clean the device and the patient cable.

  NOTE

  Do not clean and reuse electrodes. Use new electrodes for each use.

- The devices cannot be sterilized.
- Do not immerse the device in any liquid, or allow liquids to enter through connections, ports or buttons.
- Do not use xylene or petroleum-based solvents for cleaning the device.
- In case of a malfunction, call a service technician and precisely describe the problem.
- Check the patient cable and connectors every month by connecting to an ECG simulator.

Storage and Operating Conditions

Follow these guidelines when storing and operating the SEER Light devices.

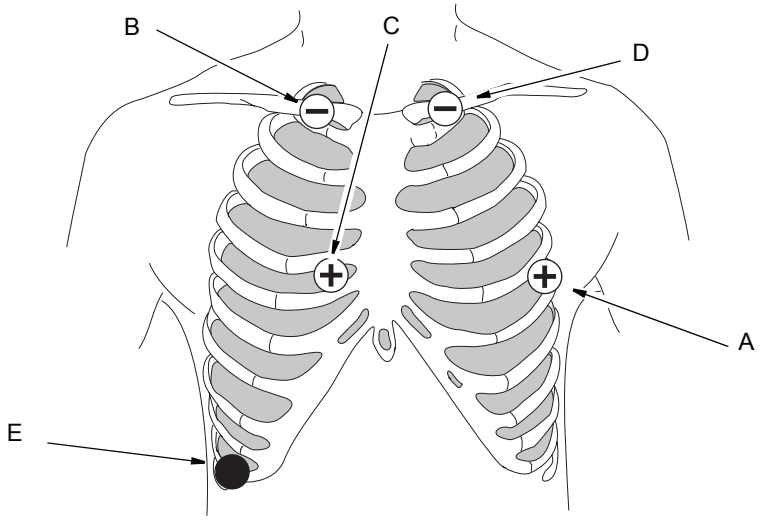
Storage and Operation	Environmental Conditions
Storage Conditions	■ Remove batteries from the recorder and controller ■ Temperature, SEER Light Recorder and SEER Light Connect: -4°F to 149°F (-20°C to 65°C) ■ Temperature, SEER Light Controller: -4°F to 140°F (-20°C to 60°C) ■ Relative Humidity, SEER Light Recorder 5-90% RH non-condensing ■ Relative Humidity, SEER Light Controller 30-90% RH non-condensing
Operating Conditions for SEER Light Controller and SEER Light Connect	■ Temperature 50°F to 95°F (10°C to 35°C) ■ Relative Humidity 30-80% RH non-condensing
Operating Conditions for SEER Light Recorder and SEER Light Extend Recorder	■ Temperature 32°F to 113°F (0°C to 45°C) ■ Relative Humidity 10-95% RH non-condensing

3 Preparing the Patient

Placing Electrodes

Two Channel, Five Electrode

In the two channel, five electrode configuration, two channels of ECG data are bipolar. Red positive (+) is referenced to white negative (–) and brown positive (+) is referenced to black negative (–).



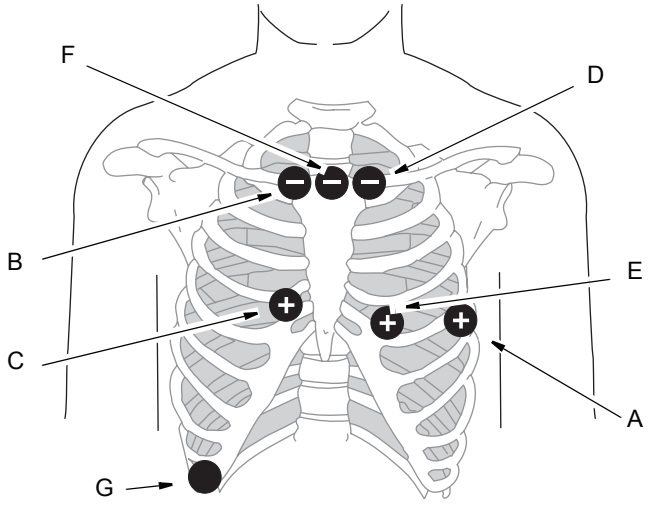
	AHA Color	IEC Color	Channel	Lead	Location
A	Red	Yellow	CH 1(+)	II (+)	Fifth intercostal space, anterior axillary line.
B	White	Red	CH 1 (-)	II (-)	Below the right clavicle, just lateral to the midclavicular line.
C	Brown	Green	CH 2 (+)	mV1 (+)	Fourth intercostal space, right sternal edge.
D	Black	White	CH 2 (-)	mV1 (-)	Below the left clavicle, just lateral to the midclavicular line.
E	Green	Black	Ground		On the lower right chest wall, on a rib.

Three Channel, Seven Electrode

There are three possible electrode configurations for three channel, seven electrode recording.

Modified V3 Leads

A modified V3 lead may be helpful in identifying ST segment changes in ischemic episodes associated with the left anterior descending coronary artery. The following are the recommended electrode locations to record the modified V5 (mV5) on channel 1, the modified V1 (mV1) on channel 2, and the modified V3 (mV3) on channel 3.



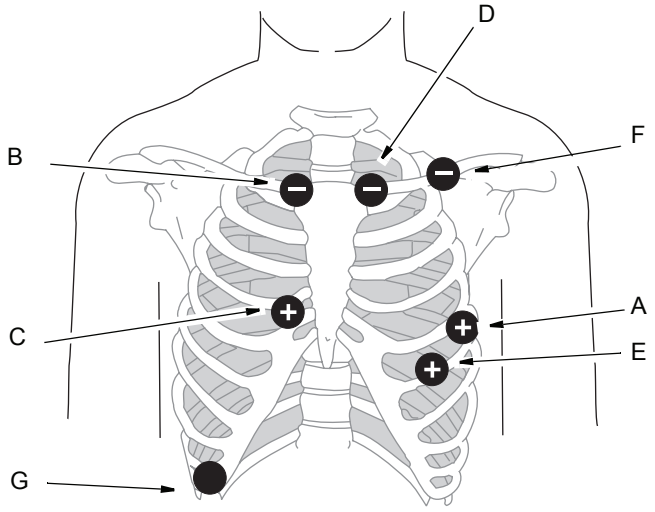
046A

	AHA Color	IEC Color	Channel	Lead	Location
A	Red	Yellow	CH 1(+)	mV5 (+)	Fifth intercostal space at the left axillary line.
B	White	Red	CH 1 (-)	mV5 (-)	Right clavicle, just lateral to the sternum.
C	Brown	Green	CH 2 (+)	mV1 (+)	Fourth intercostal space at the right sternal edge.
D	Black	White	CH 2 (-)	mV1 (-)	Left clavicle, just lateral to the sternum.
E	Orange	Orange	CH 3 (+)	mV3 (+)	Equidistant between the normal locations for precordial leads V2 and V4.

	AHA Color	IEC Color	Channel	Lead	Location
F	Blue	Blue	CH 3 (-)	mV3 (-)	Mid-sternum, at the level of the clavicles.
G	Green	Black	Ground		Lower right chest wall.

Modified aVF Leads

A modified aVF lead may be helpful in identifying ST segment changes in ischemic episodes associated with the right coronary or circumflex arteries. The following are the recommended electrode locations to record the modified V5 (mV5) on channel 1, the modified V1 (mV1) on channel 2, and the modified aVF (maVF) on channel 3.



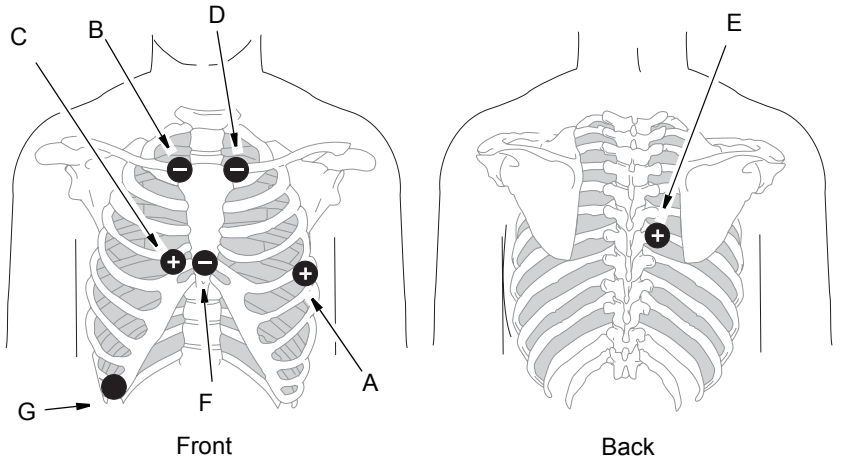
047A

	AHA Color	IEC Color	Channel	Lead	Location
A	Red	Yellow	CH 1(+)	mV5 (+)	Fifth intercostal space at the left axillary line.
B	White	Red	CH 1 (-)	mV5 (-)	Right clavicle, just lateral to the sternum.
C	Brown	Green	CH 2 (+)	mV1 (+)	Fourth intercostal space at the right sternal edge.
D	Black	White	CH 2 (-)	mV1 (-)	Left clavicle, just lateral to the sternum.

	AHA Color	IEC Color	Channel	Lead	Location
E	Orange	Orange	CH 3 (+)	maVF (+)	Sixth rib, at the left mid-clavicular line.
F	Blue	Blue	CH 3 (-)	maVF (-)	Left clavicle, at the mid-clavicular line.
G	Green	Black	Ground		Lower right chest wall.

Modified Z Leads

A modified Z lead (mZ) may be helpful in identifying ST segment changes in ischemic episodes with an anteroposterior axis. The following are the recommended electrode locations to record the modified V5 (mV5) leads on channel 1, modified V1 (mV1) leads on channel 2, and Z leads on channel 3.



048A & 049A

	AHA Color	IEC Color	Channel	Lead	Location
A	Red	Yellow	CH 1(+)	mV5 (+)	Fifth intercostal space at the left axillary line.
B	White	Red	CH 1 (-)	mV5 (-)	Right clavicle, just lateral to the sternum.
C	Brown	Green	CH 2 (+)	mV1 (+)	Fourth intercostal space at the right sternal edge.

	AHA Color	IEC Color	Channel	Lead	Location
D	Black	White	CH 2 (-)	mV1 (-)	Left clavicle, just lateral to the sternum.
E	Orange	Orange	CH 3 (+)	Z (+)	Posterior, just right of the spine, at the same level as the anterior lead.
F	Blue	Blue	CH 3 (-)	Z (-)	Mid-sternum, at the level of the fourth intercostal space.
G	Green	Black	Ground		Lower right chest wall.

Preparing the Skin

Determine electrode placement according to one of the configurations shown in this chapter. Use this procedure to insure good quality ECG data.

CAUTION
ELECTRODES — Make sure that the electrodes conducting elements do not make contact with each other or other metal parts.

Make sure that the device is not subject to disturbances from the electric mains.

Use only the specified electrodes for safety. Any other electrode may not give proper recording and may cause problems with the patient.

1. To minimize electrode problems, be sure to use the proper type of electrode. Check the expiration date on any pregelled electrode before using it. Also, check for dry gel pads on any pregelled electrodes that have been left out of their foil package.
2. Shave hair from each electrode site. This improves conductivity, helps hold the electrode to the skin, and makes the removal of the electrode easier.
3. Rub each electrode site thoroughly with alcohol. This removes oil from the skin.

4. Mark each electrode site with a felt tip pen. This provides an easy way to determine when the epidermis has been sufficiently abraded.
5. Use an abrasive pad to remove the epidermal skin layer at each electrode site. The epidermal skin layer has been removed when the mark left from the felt tip pen has been erased.

WARNING
ELECTRODE CONDUCTIVITY — Keep the conductive parts of lead electrodes and associated parts away from other conductive parts, including earth.

6. Place an electrode on each prepared site.

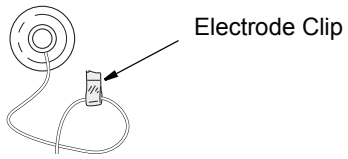
Hooking Up the Patient

Complete patient hookup and prepare the patient for ECG data recording.

NOTE
Use only the 5- or 7-electrode patient cable designed for use with the recorder.

1. Connect each cable lead wire to the correct patient electrode per the electrode placement tables.
2. Use stress loops to reduce the movement of the electrodes caused by tension from the lead wires.

   Form a stress loop in each lead wire using an electrode clip as shown below. This prevents a lead wire from pulling directly on the electrode contact points. Each loop should be about 1 or 2 inches in diameter, about 2 inches from the electrode.



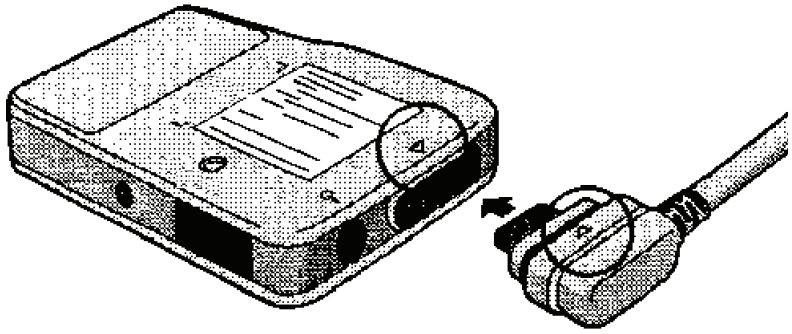
3. Secure the electrodes with tape to prevent movement and maintain electrical contact.

   If you are using wet gel electrodes, apply the tape loosely enough so that no gel squeezes onto the adhesive surfaces of the electrodes.

NOTE

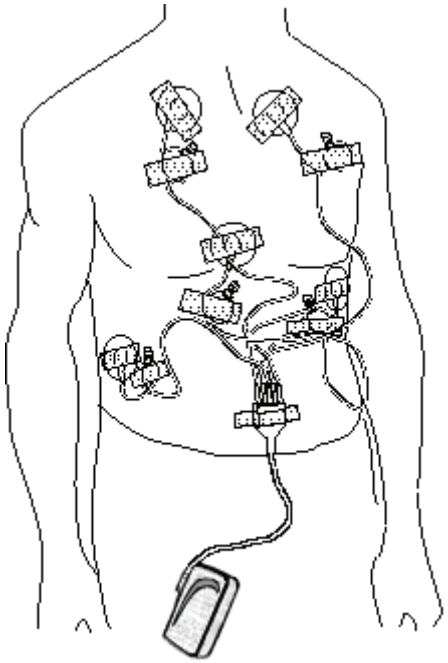
Special T-shirts (PN 9812-011/012/013) are available from GE Medical Systems *Information Technologies* that minimize movement and increase comfort during the data recording period.

4. Connect the patient cable to the connector on the recorder.



21A

An example of the completed hookup is shown below.



51A

Pouch

It is recommended that the recorder be used in combination with the SEER Light pouch (PN 2008596-001) for the entire duration of the recording. The pouch protects the connection between the patient cable and the recorder.

Holter ECG Patient Diary

Setting Up the Patient Diary

Enter the following items in the patient's diary:

- Patient name
- Patient identification number
- Data card number
- Recorder type and number, and
- Hook-up date and time

Instructing the Patient

Inform the patient of the recorder's audible alarms to prevent patient anxiety when alarms sound. The recorder does NOT interfere with the patient's normal routine, but there are a few restrictions while wearing it.

Describe the diary to the patient and emphasize the importance of keeping track of activities and symptoms.

Audible Alarms

The patient must understand that the recorder beeps under normal operation, and is NOT an indication of cardiac problems for the patient. Describe these instances of audible alarms to prevent patient anxiety.

- In case of insufficient battery level, an audible alarm will continuously sound. This indicates that new batteries are required.
- A beep sounds for one minute when beginning a recording.

Activity Restrictions

- Do NOT tamper with the recorder, electrodes, or lead wires.
- Do NOT take the recorder from the case and do not touch the cable or switch unnecessarily during Holter ECG checking.
- Do NOT drop or hit the recorder as the Holter recorder is precision equipment.
- Do NOT use other low frequency medical equipment at the same time.
- Do NOT push the **Stop** button.
- Do NOT take a shower or bath, or get the electrodes or recorder wet.
- Do NOT submerge the recorder in water or other liquids, otherwise you may damage the recorder.
- When wearing the recorder at night, do NOT use an electric blanket. It may interfere with the recording.

Keeping Track

- Record all diary entries with the date and time.
- Record any physical signs and symptoms. When a symptom is felt, press the **(Start/Event)** button, describe it in the diary, and correlate it with the patient's activity and position.
- Press the **(Start/Event)** button for about one second to mark the beginning of an event. For prolonged events, you can also press the button to signal the end of an event.
- Record activities throughout the test period. Make notations about physical activities, rest periods, meals, strong emotional conditions, and sleep.

Shorter Test

If you perform a test shorter than 24 hours (or 48 hours with SEER Light Extend recorder), instruct the patient to disconnect the recorder when the test is complete.

- Make sure the patient understands at what time the recording is complete.
- Instruct the patient how to remove the lead wires from the electrodes and how to remove the electrodes.

NOTE

The recorder continues to record even if you remove the cable or electrodes. Reconnect the patient to continue testing. Noise recorded during disconnection can be handled by the Holter analysis system.

- To stop recording before 24 hours have elapsed (or 48 hours with SEER Light Extend recorder), press the ▽ (**Stop**) button with a ball point pen.

4 Entering Patient Data

Entering Patient Data

Patient data can be entered via the controller or the connect device.

WARNING
MIXING PATIENT DATA — Accidental mixing of patient data can result in misdiagnosis and incorrect treatment.

Always transfer or delete old data before beginning a new recording session, and promptly enter patient demographics.

Using the SEER Light Extend Controller

Be sure that all information from previous patient recordings has been transmitted to the controller.

If data remains on the recorder that has not been transmitted to the controller, the controller will display the message *Recorder still contains untransmitted data. Press F6 to start a new recording.* A beep will sound from the recorder.

Deleting Old Data

Press the **F6** button to delete any old data remaining on the recorder and to begin entering patient data for this test.

Entering Patient Information

The controller displays the patient information screen when you press the **POWER** button. Use this screen to enter the followingpatient information:

- ID number (up to 10 digits)
- Age
- Gender
- Last Name [Displayed as *NAME(L)*]
- First Name [Displayed as *NAME(F)*]

Items can be selected by pressing the ◂ ▴▾ ▸ buttons.

Press **CLR** to correct error input.

Alphanumeric Entry

Each patient information field accepts alphabetic or numeric data. *ID#* and *Age* are numeric-only fields. The bottom of the display panel shows *{1}*. *Name(L)* and *Name(F*), which are alphabetic fields by default, and the bottom of the display planel shows *{A}*. Press **F5** before entering numbers in these fields. Press **F5** again to return to entering letters. The **8** and **9** buttons are used in the *Gender* field.

Choosing a Letter to Enter

Each numbered button represents specific letters listed above the button. Each time you press the button the letter displayed will change in the order they appear, first in UPPERCASE, then in lowercase. For example, if the 

button is pressed three times in the alphabet entry mode, the capital letter “C” will display. If the 

button is pressed four times in the alphabet entry mode, the lowercase letter “a” will be displayed. Pressing **F4** while in an information field will display a hyphen (-).

NOTE

Press the ▸ button to advance the cursor to enter the next letter in the name.

Button	Alphabet	Number
		1
	ABC abc	2
	DEF def	3
	GHI ghi	4

Button	Alphabet	Number
	JKL jkl	5
	MNO mno	6
	PQRS pqrs	7
	TUV tuv	8
	This button is also used to enter gender for male patients.	
	WXYZ wxyz	9
	This button is used to enter gender for female patients.	
	. -	0
	Space	

Using the SEER Light Connect

To enter patient data using the SEER Light Connect device.

WARNING
LEAKAGE CURRENT — Electrical shock to patient could result from component failure and lack of power isolation.

In the event this system is used in the patient vicinity/ environment, it must be configured in such a way that it and all of its electrically-connected peripheral devices are isolated from mains power to prevent excessive leakage current to the patient. Use of isolated mains power, or a medical grade isolation transformer (in compliance with UL 60601, CAN/CSA C22.2 No. 601.1, EN/IEC 60601-1) with this system will support compliance with EN/IEC 60601-1-1. All nonmedical peripheral devices shall comply with applicable EN/IEC/ISO and UL safety standards that are relevant to that equipment (i.e., EN/ IEC 60950, UL 60950). The overall system (device and all of its connected peripheral devices) must comply with EN/ IEC 60601-1.

Use of SEER Light Connect device in the patient vicinity requires that these measures are observed.

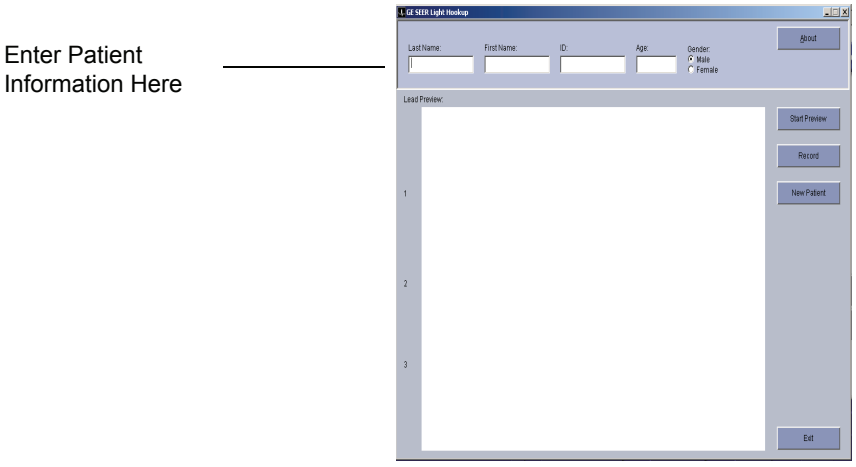
Patient vicinity/environment defined as:

- Any volume in which intentional or unintentional contact can occur between patient and parts of the system or between patient and other persons touching parts of the system (IEC 60601-1-1).
- A space (volume), within a location intended for the examination and treatment of patients, extending 6 ft (1.83 m) beyond the normal location of the bed, chair, table, treadmill, or other device that supports the patient during examination and treatment and extending vertically to 8 ft 2.4 in. (2.5 m) above the floor.
- Areas where healthcare staff members monitor patients remotely and perform charting and administrative tasks are not considered to be Patient Vicinity/environment areas.

1. Select the *SEER Light Hookup* icon on your desktop 

. The *GE SEER Light Hookup* window appears.

2. Enter the patient's information. The *Last Name* and *First Name* fields are limited to a maximum of 14 characters. The *ID* field is limited to a maximum of 10 numeric characters.



080A

3. Refer to "Begin Recording with SEER Light Connect" on page 5-14.

5 Recording Data

Operating

Before Recording

Follow these steps before recording. For information on each operation, see the page(s) indicated.

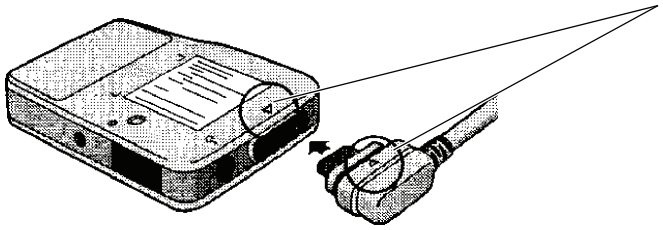
1. Prepare the patient by performing skin preparation and attaching the electrodes. Refer to "Placing Electrodes" on page 3-2 and "Preparing the Skin" on page 3-6 for more information.
2. Prepare the controller by checking the battery status. If necessary, replace the controller's batteries. Install new batteries in the recorder. Refer to "Battery Power" on page 2-14.
3. Connect the electrode lead wires. Refer to "Hooking Up the Patient" on page 3-7 for more information.
4. Do a lead check. Refer to "Checking the Leads" on page 5-3 for more information.
5. Enter patient information. Refer to Chapter 4, "Entering Patient Data" on page 4-1 for more information.
6. Start the recorder. Refer to "Starting the SEER Light Recorder" on page 5-11 for more information.

After Recording

Follow these steps after recording. For information on each operation, see the page indicated.

1. Disconnect the patient from the recorder. Refer to "Disconnecting the SEER Light Recorder" on page 5-15 for more information.
2. Transfer the patient's Holter data from the recorder/controller/ connect to the MARS system for analysis. Refer to Chapter 6, "Transferring Data" for more information.
3. Clean and store the SEER Light devices. Refer to "Care and Cleaning" on page 2-16 and "Storage and Operating Conditions" on page 2-16 for more information.

Connecting the Patient Cable



9A

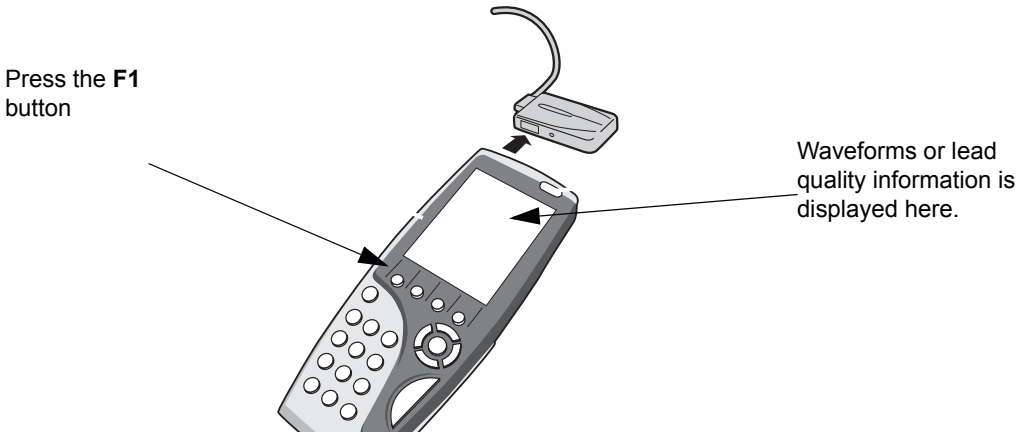
Connect the patient cable to the connector of the recorder with the ▲ mark facing up. Make sure it is connected properly.

Checking the Leads

After the patient is hooked up to the recorder, check the quality of the connections using the controller or the connect.

Check Leads Using the SEER Light Extend Controller

1. Turn the controller's power on. Confirm the date and time; adjust if necessary. Refer to "Set-up Condition Mode" on page 2-12 for more information.
2. Align the infrared terminals on the controller and the recorder.



43A

3. Press the **F1** button on the controller.

The *Preview* screen is displayed on the controller, showing the following elements:

- The patient's heart rate is displayed in the upper right corner
- Two or three channels of waveform data are displayed
- Adjust patient hookup if waveform height/quality are not satisfactory or if messages are displayed instead of waveforms.

CAUTION
WAVEFORM DIAGNOSTIC QUALITY — The ECG waveforms shown on the preview screen are used for assessing the quality of the connections only.

Do not use these preview waveforms for diagnostic purposes.

CAUTION
WAVEFORM DISPLAY — Fluorescent lights in the room may interfere with infrared communication between the recorder and controller. In this case, normal ECG waveform will not be displayed on the LCD.

Keep the device away from fluorescent lights. Turn off fluorescent lights when device is used. Cover the infrared window with a hand to shield the display from the fluorescent lights.

4. Select the **F4** button to exit the *Preview* screen and return to the *SEER* screen.

Checking Leads Using the SEER Light Connect

WARNING
LEAKAGE CURRENT — Electrical shock to patient could result from component failure and lack of power isolation.

In the event this system is used in the patient vicinity/ environment, it must be configured in such a way that it and all of its electrically-connected peripheral devices are isolated from mains power to prevent excessive leakage current to the patient. Use of isolated mains power, or a medical grade isolation transformer (in compliance with UL 60601, CAN/CSA C22.2 No. 601.1, EN/IEC 60601-1) with this system will support compliance with EN/IEC 60601-1-1. All nonmedical peripheral devices shall comply with applicable EN/IEC/ISO and UL safety standards that are relevant to that equipment (i.e., EN/ IEC 60950, UL 60950). The overall system (device and all of its connected peripheral devices) must comply with EN/ IEC 60601-1.

Use of SEER Light Connect device in the patient vicinity requires that these measures are observed.

Patient vicinity/environment defined:

- Any volume in which intentional or unintentional contact can occur between patient and parts of the system or between patient and other persons touching parts of the system (IEC 60601-1-1).
- A space (volume), within a location intended for the examination and treatment of patients, extending 6 ft (1.83 m) beyond the normal location of the bed, chair, table, treadmill, or other device that supports the patient during examination and treatment and extending vertically to 8 ft 2.4 in. (2.5 m) above the floor.
- Areas where healthcare staff members monitor patients remotely and perform charting and administrative tasks are not considered to be Patient Vicinity/environment areas.

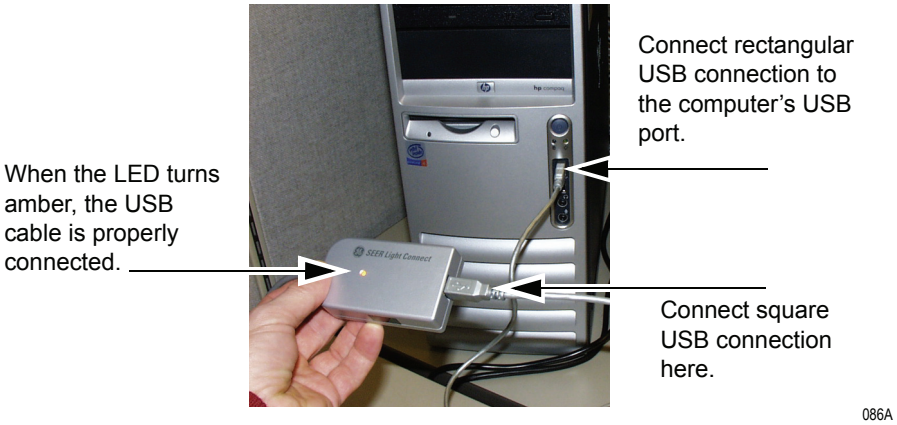
1. Select the *SEER Light Hookup* icon on your desktop. 

The *GE SEER Light Hookup* window appears.

2. Connect the USB cable to the connect and the Holter analysis PC. When properly connected, the LED on the connect turns amber.

NOTE

The following picture shows a USB port on the front of the PC. Some PCs have the USB port(s) located on the back. The connect can be connected to either a front or back USB port.



3. Align the infrared terminals on the connect and the recorder.

4. At the *GE SEER Light Hookup* window, select the *Start Preview* button.

   - Up to three channels of waveform data are displayed.
   - Adjust patient hookup if waveform height/quality are not satisfactory or if messages are displayed instead of waveforms.

CAUTION

WAVEFORM DIAGNOSTIC QUALITY — The ECG waveforms shown on the preview screen are used for assessing the quality of the connections only.

Do not use these preview waveforms for diagnostic purposes.

5. Select the *Stop Preview* button to stop the lead preview.

Confirming ECG Recording

The quality of a Holter ECG recording is very important. To record ECG without artifact, confirm the recording conditions before starting the recording. To improve the ECG quality, adjust the electrode attachments.

Wireless Data Transfer

The controller and the connect use infrared wireless data transfer to confirm the ECG waveform recorded by the recorder. In preview mode, the controller displays two channels of real-time ECG waveforms at a time, and the connect displays up to three channels of real-time ECG waveforms.

Considerations Using the SEER Light Extend Controller

- Insert the batteries in the recorder before entering the preview mode. The ECG waveform cannot be checked without inserting the batteries.
- By entering the preview mode, infrared data transfer will be checked automatically. Point the controller to the infrared terminal of the recorder, and press the **F1** button.
- As the preview mode of the controller consumes battery power, return to the *SEER* mode after checking the ECG waveform.
- Preview mode by remote wireless operation can only be done before starting the recorder (pressing the **F6** button) and during the first three minutes of the recording phase (after pressing the **F6** button). The recorder will beep for the first minute of the recording phase.
- The recorder will enter Power Save mode after setting the batteries.

Confirming ECG Recording Using the SEER Light Extend Controller

1. From the *SEER* screen, point the controller to the infrared terminal of the recorder, and press the **F1** button. The *Preview* screen will display.
2. By pressing the ▲ or **F4** button after checking the ECG waveform, it will return to the *SEER* screen.

Considerations Using the SEER Light Connect

- Insert the batteries in the recorder before entering the preview mode. The ECG waveform cannot be checked without inserting the batteries.
- By entering the preview mode, infrared data transfer will be checked automatically.
- You can only enter preview mode by remote wireless operation before starting the recorder (selecting the *Record* button) and during the first three minutes of the recording phase (after pressing the *Record* button). The recorder will beep for the first minute of the recording phase.
- The recorder will enter Power Save mode after setting the batteries.

Confirming ECG Recording Using the SEER Light Connect

1. At the *GE SEER Light Hookup* window, select the *Start Preview* button.

   NOTE

   Selecting the *Start Preview* button will cause the button text to change to *Stop Preview*.

2. At the *Lead Preview* screen, review the displayed channels for ECG waveform confirmation.

   NOTE

   You may continue to enter patient demographics while the waveform is scrolling.

3. Select the *Stop Preview* button after checking the ECG waveforms.

Interruption of Infrared Communication

Distance, direction, objects, and so on. between the recorder and controller or connect can interrupt the infrared communication, causing the ECG waveform to become a bold line on the LCD display.

CAUTION

SIGNAL QUALITY — If there is a severe muscle interference or artifact on the ECG when you tap the top of the electrodes lightly or when the patient moves, it is possible that the electrodes are not attached properly.

To increase the accuracy of analysis, make sure that the channel has a high amplitude of QRS complex (greater than 10 mV). If the amplitude of QRS is small, shift the electrodes to find a suitable location for electrode attachment.

Confirming Pacemaker Pulses

When viewing the ECGs of pacemaker patients, it can be difficult to see the pacemaker pulses on the ECG waveform. If the pacemaker pulse of CH1 is small, it may not be detected. Verify accurate pace detection before starting to record.

To verify accurate pace detection using the controller:

1. While in *SEER* mode, point the controller to the infrared terminal of the recorder, and press the **F1** button. The *Preview* screen will display.
2. A down pointing arrow mark is displayed above the pacemaker pulse detected by the recorder. If the down pointing arrow mark is not shown on the pacemaker waveform, change CH1 to another lead that produces big pacemaker pulses.
3. By pressing the **F4** button after checking the ECG waveform, it will return to *SEER* mode.

CAUTION

PACEMAKER PATIENTS — Pacemaker pulses are only detected on CH1. Before attaching the recorder, check the patient's ECG to predict which lead will produce a big pacemaker pulse. That is the lead that should be assigned to CH1 (refer to table below).

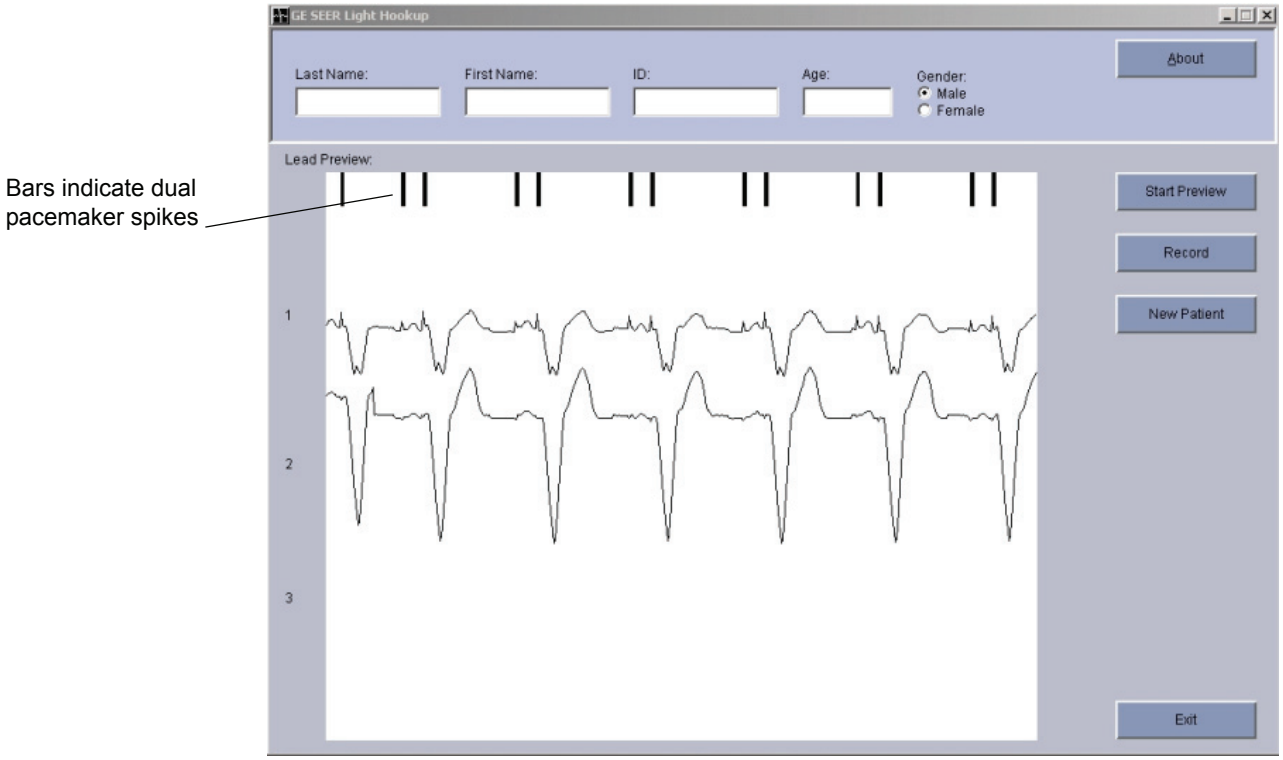
If the pacemaker pulse of CH1 is small, there is a possibility that the pacemaker pulse may not be detected. Change the lead of CH1 to another lead that has a bigger pacemaker pulse.

The down pointing arrow mark of the pacemaker pulse location for the preview mode is only displayed when using the remote method.

Holter ECG Leads	Similar 12-Leads
CM_5, CC_5	V_5
CM_1	II, III, aV_1
NASA	V_1

To verify accurate pace detection using the connect:

At the *Lead Preview* window, the position of the pacemaker spikes are displayed with vertical bars. Refer to the following illustration.



081A

Starting the SEER Light Recorder

There are three ways to start the recorder.

- Startup with the controller:

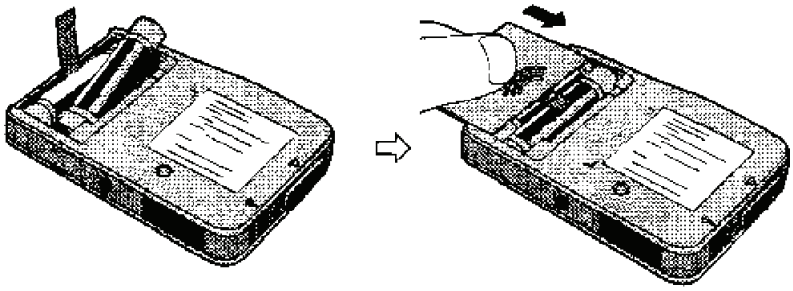
  The recorder can be started remotely by the controller. The controller starts the recorder and at the same time the patient information (ID number, age, gender, and name) and the recording date and time are transmitted to the recorder memory. The recording date and time information remains in the recorder if the batteries are removed before transferring the data. See "Begin Recording with SEER Light Extend Controller" on page 5-13.
- Startup with the connect:

  In the SEER Light Hookup application, you will enter the patient information (ID number, age, gender, and name) and then select the *Record* button to start the recorder. See "Begin Recording with SEER Light Connect" on page 5-14.
- Startup with the recorder button:

The recorder can also be started by pressing the record button. In this case, do not remove the batteries from the recorder. Otherwise, the recording date and time information will be erased from the recorder memory."Begin Recording with SEER Light Recorder Button" on page 5-14.

Inserting Batteries in the SEER Light Recorder

If you are recording up to 24 hours of ECG data, use the SEER Light recorder. If you are recording up to 48 hours of ECG data, use the SEER Light Extend recorder.



8A

1. Slide the battery box cover to open.

NOTE

Install new batteries for each use to prevent loss of power and data.

2. Insert two new AAA type alkaline batteries.
3. Confirm the audible beep sounds for approximately 2 seconds.

   In case of insufficient battery level, an audible alarm will continuously sound. This indicates that new batteries are required.
4. Hold the battery string and slide the battery box cover to close.

CAUTION

BATTERIES — Do not use any battery other than new alkaline batteries. Use of other types of batteries, including manganese, rechargeable, or used alkaline batteries will not ensure ECG recording for the life of the recorder (24 hours for the SEER Light recorder, 48 hours with the SEER Light Extend recorder).

Do not leave the batteries in the recorder for a long time. This may cause leakage of battery liquid.

If the recorder (with batteries inserted) is not started for over one hour when the power is ON, the battery Power Save mode will be activated. In this case, the batteries must be removed to deactivate the Power Save mode. To reset the recorder, leave the recorder without the batteries for 30 seconds.

Make sure the batteries are set in the correct directions. Then begin the recording process again.

Begin Recording with SEER Light Extend Controller

1. Press the **F6** button on the controller to start recording. Refer to "Entering Patient Data" on page 4-1.

   NOTE

   Recording can be started without entering patient information.

   NOTE

   If data remains on the recorder that has not been transmitted to the controller, the message *Recorder still contains untransmitted data. Press F6 to start a new recording.* will be displayed, and a beep will sound from the recorder. Press the **F6** button to delete the data and start recording.

   If the data is needed, transfer the remaining data to the controller. Refer to Chapter 6, "Transferring Data".

2. Confirm that the beep sounds for one minute and that the LED flashes (twice per second) for three minutes.

   The recording date and time will be displayed on the LCD of the controller.

3. Put the recorder in the carrying pouch with the button facing up.

Begin Recording with SEER Light Connect

1. Select the *SEER Light Hookup* icon located on your desktop. The *GE SEER Light Hookup* window appears.

   NOTE

   If data remains on the recorder that has not been transmitted to the connect, the message *Recorder contains untransmitted data. Press the "Record" button to start a new recording* is displayed.

   If the data is needed, transfer the remaining data to the connect. Refer to Chapter 6, "Transferring Data".

2. Point the infrared terminal of the recorder to the connect.

3. At the *GE SEER Light Hookup* window, select *Record*.

   A message appears stating the Holter recording started successfully. Select *OK*.

   NOTE

   If the infrared sensors are not aligned properly, or if the cables are not connected, a message will appear stating *Error occurred while starting the recorder. Check the connections and infrared sensor alignment*.

4. Confirm that the beep sounds for one minute and that the LED flashes (twice per second) for three minutes.

   NOTE

   If you press the *Record* button after the recording has already started, a message appears stating *Holter recording has already started*.

5. Put the recorder in the carrying pouch with the button facing up.

Begin Recording with SEER Light Recorder Button

1. Insert the batteries. Refer to "Inserting Batteries in the SEER Light Recorder" on page 5-12 for more information.

2. Connect the patient cable to the connector of the recorder with the ▲ mark facing up.

3. Press and hold the button on the recorder. Confirm beep sounds for one minute and that the LED flashes (twice per second) for three minutes.

4. Put the recorder in the carry case with the button facing up. Attach the case to the patient belt.

Disconnecting the SEER Light Recorder

NOTE

ECG recording will stop after 24 hours (48 hours if using the SEER Light Extend recorder) and the LED will stop flashing. To stop recording before 24 (48) hours, press the (**Stop**) button with a ball point pen and disconnect the patient cable.

If the batteries are removed from the recorder before recording of 24 (48) hours or before the (**Stop**) button is pressed, the recorder may not transmit data correctly.

1. Disconnect the patient cable from the recorder.
2. Remove the electrodes.
3. Clean the skin with alcohol. Adhesive material remaining on the skin may cause itchiness.
4. After transferring data from the recorder (with controller or connect and Holter analysis system), remove the batteries from the recorder.

NOTE

Do not remove the batteries from the recorder before transferring the data from the recorder, or before analyzing the data with the Holter analysis system as the time will be erased when the battery is removed from the recorder.

The recorder retains the data for about one week after recording. Transfer the data to the Holter analysis system or copy it to a flash card within one week to prevent loss of data.

6 Transferring Data

Transferring Data to the Holter Analysis System

The procedure for transferring data from the recorder to the Holter analysis system depends on which device is used to transfer the data: the controller, or the connect.

- If using the controller, the transfer must undergo a two-step process:
  1. Data is transferred from the recorder to a compact flash card via the controller. See "Transferring to the Flash Card using the SEER Light Extend Controller" on page 6-2.
  2. Data is transferred from the compact flash card to the Holter analysis system. See "Transferring Data to the Holter Analysis System via Flash Card" on page 6-6.
- If using the connect, the data is acquired directly into the Holter analysis system. See "Transferring Data to the Holter Analysis System via Connect" on page 6-7.

Transferring to the Flash Card using the SEER Light Extend Controller

Follow these steps to transfer data from the recorder to a compact flash card via the controller. See the matrix below for SEER Light recorder and controller compatibility.

CAUTION

EQUIPMENT DAMAGE — To avoid equipment damage, follow the considerations below when using a flash card:

- Do not place the patient label over another label.
- Do not touch the connector with your hand, or scratch it with a hard object.
- Do not get the card wet.
- Do not subject the card to any external force or shock.
- Use only the flash card specified by GE Medical Systems *Information Technologies*.

SEER Light Recorder/Controller Compatibility		
	SEER Light Controller (24 Hour)	SEER Light Extend Controller (48 Hour)
SEER Light Recorder (24 Hour)	YES	YES
SEER Light Extend Recorder (48 Hour)	NO	YES

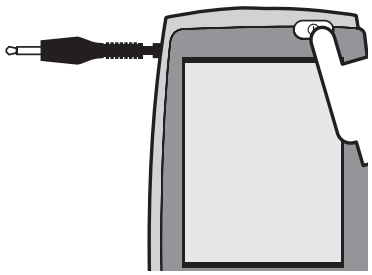
NOTE

The SEER Light Controller (24 hour) is no longer available. The SEER Light Extend Controller is compatible with both SEER Light (24 hour) and SEER Light Extend (48 hour) recorders.

NOTE

The SEER Light Extend Recorder (48 hours) is compatible with MARS v7.x and higher only. It is not compatible with MARS v4, v5, or v6.

1. Remove the data transfer cable from the back side of the controller. Switch on the controller's power supply by pressing the **POWER** button, as in the following graphic.

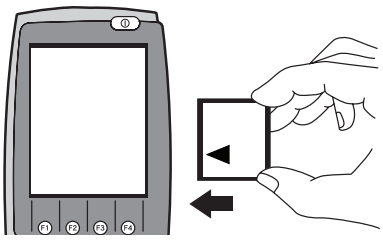


32A

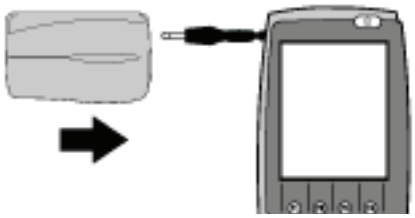
2. Confirm the date and time. Change the date and time if it is not correct. Refer to "Set-up Condition Mode" on page 2-12.

3. Insert flash card with the ▲ mark facing up into the controller. Pivot the **EJECT** button to prevent inadvertent ejection of the flash card.

33Z



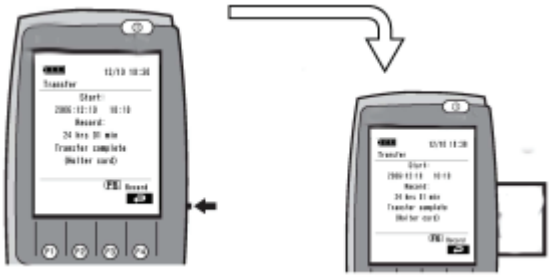
4. Connect the cable to the data output connector of the recorder (⊖→).



5. Press the **F2** button to enter the data transfer mode. Press the **F6** button. The data will be transferred to the flash card.
6. You will be asked to confirm transfers under the following conditions. Refer to "Confirming Flash Card Contents" on page 6-5 if this occurs.
   - The flash card contains any data that has not been analyzed by the Holter analysis system.
   - The recording is stopped by pressing the ▽ button on the recorder with a ball point pen, or removing the recorder's batteries, before recording 24 hours (48 hours if using the SEER Light Extend recorder).

     NOTE

     An error message will appear on the screen if a flash card is not inserted into the controller. Make sure the card is inserted before attempting to transfer.
7. Data transfer is completed when the transfer progress bar on the controller reaches 100%. Confirm the time displayed on the screen.
8. Remove the flash card by pressing the **EJECT** button.



35A

9. Disconnect the data transfer cable from the recorder. Switch off the power supply by pressing the controller's **POWER** button.

Confirming Flash Card Contents

You can confirm that the data transferred to the flash card through the controller. This data includes:

- Patient information (ID, age, gender, and name)
- ECG waveform (close to the event point, close to the starting point, close to the ending point, specific times) copied into the card

By confirming the contents of the flash card, the patient information can be edited.

Confirming Patient Information

1. Insert the flash card into the controller.

NOTE
If the flash card is not inserted into the controller before starting the operation, error messages will appear on the screen.

2. Press the **F3** button to open *Review* mode, where you can confirm the flash card contents.
3. Select *Patient Information*. Press **ENT**.
4. The patient information to be transferred from the recorder will be displayed on the screen of the controller.
   - Patient information can be edited. Refer to "Entering Patient Data" on page 4-1.
   - By pressing the **F4** button after editing the data, a message appears prompting you whether or not to save the edited data.

Press the **ENT** button to save the data and return to the screen in Step 3.

5. Press the **F4** button to return to *SEER* mode.

Displaying the ECG Waveform

1. Insert the flash card into the controller.

NOTE
If the flash card is not inserted into the controller before starting the operation, error messages will appear on the screen.

2. Press the **F3** button under *SEER* mode. It will proceed to the confirmation of flash card contents.
3. Select *ECG Display*. Press **ENT**.
4. Select the ECG waveform that you want to display by using the ▲ and ▼ buttons. Choices are *Event, Start*, *End* and *Time*. Press the **ENT** button.
   - If you select *Time*, the starting time of the recording will be displayed first. By entering the time you want to review in this screen and pressing the **ENT** button, the ECG waveform corresponding to that specified time will be displayed on the screen.
   - Scroll forward through the ECG waveform by pressing the ▶ or **F1** button. You cannot scroll backward through the waveform.
5. Press the ▲ or **F4** button until you are returned to the screen in Step 4. Press the ▲ or **F4** button again to return to *SEER* mode.

Transferring Data to the Holter Analysis System via Flash Card

Follow these steps to transfer data from the flash card to the Holter analysis system.

1. Insert the flash card into the flash card adapter.

NOTE
ECG data recorded by the recorder can only be analyzed by the Holter analysis system.

2. Insert the flash card adapter into the acquisition unit. Proceed with data transfer as outlined in the operator's manual for the Holter analysis system.

Transferring Data to the Holter Analysis System via Connect

Follow these steps to transfer data from the recorder through the connect.

088A

1. Connect the cable on the connect to the USB port of your MARS workstation. (The USB port may be located on the front or the back of the PC.)
2. Remove the lead wires.
3. Connect the recorder to the connect device.
4. Refer to the Holter analysis system Operator Manual for instructions on acquiring the data.

Analyzing Waveforms and Patient Treatment

Refer to the Holter analysis system Operator Manual for instructions on viewing and analyzing waveform data.

CAUTION

PATIENT TREATMENT — Various clinical persons may view, analyze and make recommendations based on patient waveforms, but a plan of treatment requires confirmation from a qualified physician or cardiologist.

A qualified physician or cardiologist MUST confirm all information pertaining to treatment of a patient.

A Troubleshooting

Troubleshooting Chart

Use the chart below to troubleshoot problems.

Trouble	Cause	Recommendation
Alarm sound continues when batteries are inserted. (Recorder)	Battery power is low. Wrong type of batteries, or batteries other than alkaline are inserted.	Replace with new alkaline batteries.
No beeping sound when batteries are inserted. (Recorder)	Battery power is low.	Replace with new alkaline batteries.
	Batteries are reinserted quickly right after completing the data transfer. This may occur because the condenser in the recorder has power reserve function.	Reposition batteries 30 seconds after replacement, and resume the function.
	The damage may be caused by physical shock.	Check with service, or open a service call.
No beep sound for start-up when is pressed. (Recorder)	The button was pressed too rapidly.	Press gently and slowly.
	The recorder is already in the recording process.	Press again 30 seconds after batteries are reset.
	It has been more than 1 hour after batteries are inserted. The recorder automatically cancels start-ready mode in order to reduce battery power loss. This function makes the button inactive.	
The recorder does not start up when the controller sends a start up command through infrared, and *The recording has already started.* is displayed. (Recorder and controller)	The recorder is already in the recording process.	Press **F6** again 30 seconds after batteries are replaced.

Trouble	Cause	Recommendation
The recorder does not start up when the controller sends a start up command through infrared, and *Communication Error* is displayed. (Recorder and controller)	Infrared transfer does not work due to the distance or an obstruction between the recorder and controller.	Adjust the position of the infrared terminal part of the recorder. Set both devices within 1 meter and adjust the direction so that the terminal of infrared between the recorder and controller are aligned. Press **F6** button again.
	It has been more than 1 hour after batteries are inserted. The recorder automatically cancels start-ready mode in order to reduce battery power loss. This function makes the **F6** button not work.	Press the **F6** button again 30 seconds after batteries are replaced.
The SEER Light Hookup window displays a dialog box stating *Holter recording has already started*. when the *Record* button is selected. (Recorder and connect)	The recorder is already in the recording process.	Select *OK*. The dialog box closes and the recording continues.
The *SEER Light Hookup* window displays a dialog box stating *Error occurred while starting the recorder. Check the connections and the infrared sensor alignment*. when the *Record* button is selected. (Recorder and connect)	Infrared transfer does not work due to the distance or an obstruction between the recorder and connect.	Select the *OK* button to close the dialog box. Set both devices within 1 meter and adjust the direction so that the terminal of infrared between the recorder and connect are aligned. Select the *Record* button again.
	Patient data not available because cables are not properly connected.	Select the *OK* button to close the dialog box. Connect the cables. Select the *Record* button again.
The recorder does not start up when the controller sends a start up command through infrared, and *Recorder still contains untransmitted data. Press the F6 button to start a new recording.* is displayed. (Recorder and controller)	Data remains in the recorder and was not transferred to the controller.	If the data is not needed, press the **F6** button. Otherwise, transfer the old data to the controller.

Trouble	Cause	Recommendation
The *SEER Light Hookup* window displays a dialog box stating *Recorder contains untransmitted data. Press the Record button to start a new recording*. when the *Record* button is selected. (Recorder and connect)	The recorder contains untransmitted data.	Select the *OK* button to close the dialog box. If the data is not needed, select the *Record* button again. If the data is needed, transfer the data before beginning a new recording.
The recorder starts using the controller command through infrared. However, the controller displays *Communication Error*. (Recorder and controller)	The controller does not receive a response back to start recording from the recorder.	Align the infrared terminals then repeat the process. If the *Communication Error* condition persists, check with service, or open a service call.
Patient data is not transferring between the recorder and the controller. (Recorder and controller)	An Extend device is used with a non-Extend device.	Always transfer data from the SEER Light Extend recorder to a SEER Light Extend controller.
Beep sound is heard. However, LED does not blink. (Recorder)	The recorder is malfunctioning internally.	Check with service, or open a service call.
LED blinking stops before 24- or 48-hour period. (Recorder)	May be using rechargeable or manganese type batteries.	Use new alkaline batteries.
	The batteries were removed while recording.	Do not touch or remove the batteries while recording.
	Damage to unit caused by physical shock.	Check with service, or open a service call.
When the **F1** button on the controller is pressed for preview through infrared, transfer error occurs. (Recorder and controller)	Infrared transfer does not work due to the distance or an obstruction between the recorder and controller.	Set both devices within 1 meter and adjust the direction so that the terminal of infrared between the recorder and controller are directly facing each other. Press the **F1** button again.
	The **F1** button was pressed 1 hour after the batteries are inserted.	Reset the batteries 30 seconds after the batteries are removed. Press the **F1** button within 1 hour.
	The recorder beeps the first minute after the recording has started. For the remaining 2 minutes of calibration, the recorder's LED flashes twice per second.	After the beeping sound, the controller cannot preview using infrared. Otherwise, the recorder and controller must be connected by the cable.

Trouble	Cause	Recommendation
	The batteries are not inserted in the recorder.	Insert the batteries and press the **F1** button.
	The batteries in the recorder do not have enough power.	Replace the batteries and press **F1** button.
The *SEER Light Hookup Lead Preview* window displays no waveforms when the *Start Preview* button is selected. (Recorder and connect)	Infrared transfer does not work due to the distance or an obstruction between the recorder and connect.	Set both devices within 1 meter and adjust the direction so that the terminal of infrared between the recorder and connect are aligned. Select the *Start Preview* button again.
	Patient data not available because cables are not properly connected.	Connect the cables properly. Select the *Start Preview* button again.
The notched waveform is displayed while using infrared preview. (Recorder and controller/connect)	Infrared transfer does not work due to the distance or an obstruction between the recorder and controller/connect.	Set both devices within 1 meter and adjust the direction so that the terminal of infrared between the devices are aligned.
When the flash card is set in the slot of the controller, *CARD ERROR Insert the SEER card properly* displays. (Controller)	The flash card is inserted upside down.	Place the flash card with ▲ mark facing up on the card into the controller. Press the power switch to on.
	The flash card is not completely inserted into the slot of the controller	Place the flash card all the way into the slot of the controller. Press the power switch to on. If the flash card is correctly positioned, it should not protrude from the side of the controller.
When flash card is set in the slot of the controller, *CARD ERROR Press **F6** to format the card* is displayed on the controller screen. (Controller)	The flash card has not been initialized.	Follow the initialization instructions provided by the flash card manufacturer.
*CARD ERROR Press **F6** to format the card* is displayed on the controller screen when the data transfer starts. (Controller)	A different type of card other than the flash card is inserted.	Insert the correct flash card.
Card contains unanalyzed data. Pressing **F6** *will overwrite this data.* is displayed on the controller screen when the data transfer to the flash card does not start. (Controller)	The data is not transferred to the Holter analysis system, and remains on the flash card.	If necessary, transfer the data to the Holter analysis system. Otherwise, press the **F6** button to overwrite the old data with the new recording.

Trouble	Cause	Recommendation
Data Error No data in the recorder is displayed on the controller screen when the data transfer starts. (Recorder)	The recorder is shut down within three minutes of when recording was started.	No data in the recorder. Record the data again.
Controller/connect transfers the data from the recorder up to 100% (progress bar scans through twice) and completes the transfer. (Recorder)	The batteries are removed before the 24- or 48-hour recording is completed.	The data recorded before the batteries were removed remains. If the data is needed, proceed with the transfer.
DATA ERROR Recorder contains data error(s) is displayed on the controller screen/*SEER Light Hookup* window after the data is transferred from the recorder. (Recorder)	Files are damaged and cannot be transferred from the recorder.	Check with service, or open a service call.
Data LED does not blink while the data is transferred from the recorder. (Recorder)	LED may be broken.	Check with service, or open a service call.
Data LED does not blink while the data is transferred through connect. (Connect)	LED may be broken.	Check with service, or open a service call.
Wrong date and time on the report. (Controller)	Date and time settings are wrong on the controller.	Reset date and time on the controller.
	The backup battery for the clock in the controller is worn out.	Check with service, or open a service call.
Wrong date and time on the report. (Connect)	Date and time setting are wrong on the *SEER Light Hookup* dialog box when starting a recording, stating *Holter recording started successfully. Hook-up date and time are: dd/mm/yyyy hh:mm:ss AM/PM*.	Have the IT department or biomed reset date and time on the MARS PC, or network.

B Accessories

Accessories

The following are accessories that may be included with the system. Information is subject to change without notice.

CAUTION
— Use only the specified accessories. Use of any other accessories may cause problems.

Description	GE Part Number
Electrodes, ECG, SilverTRACE, MULTI P20MO, Ad, Foam Oval, Tab, 300/bx	2014768-001
Electrodes, ECG, SilverTRACE, FIRST P28MO, Ad, Foam Rect, 300/bx	2014775-001
Electrodes, ECG, SilverTRACE, FIRST P28MO,Ad, Foam Rect, 300/bx	2014776-001
Electrodes, ECG, SilverTRACE, SOFT STRESS PS50MO, Ad, Foam Rnd, 300/cs	2014780-001
Electrodes, ECG, SilverTRACE, SOFT STRESS PS50MO, Ad, Foam Rnd, 600/cs	2014781-001
Electrodes, ECG, SilverTRACE, WINDOW P50TR Vinyl Tape Rnd, 30/pch 300/cs	2014783-001
Electrodes, ECG, SilverTRACE, WINDOW P50TR, Vinyl Tape Rnd, 5/strip 300/cs	2014784-001
Electrodes, ECG, SilverTRACE WINDOW P50TR Vinyl Tape Rnd, 7/pch, 350/cs	2014785-001
Electrodes, ECG, SilverTRACE Disposable, Foam Oval, 5/strip, 600/cs	900703-205
Electrodes, ECG, SilverTRACE Disposable, Foam Oval, 30/pch, 300/cs	900703-230
Electrodes, ECG, SilverTRACE Disposable, Ad, Clear Vinyl Tape, 5/strip, 300/cs	9653-305

Description	GE Part Number
Electrodes, ECG, SilverTRACE Disposable, Ad, Clear Vinyl Tape, 7/pch, 350/cs	9653-507
SEER Light Cable/lead wires, 2 Channel, AHA	2008594-001
SEER Light Cable/lead wires, 3 Channel, AHA	2008594-002
SEER Light Cable/lead wires, 2 Channel, IEC	2008594-003
SEER Light Cable/lead wires, 3 Channel, IEC	2008594-004
SEER Light Patient Cable/lead wires 2ch AHA - Short	2008594-005
SEER Light Patient Cable/lead wires 3ch AHA - Short	2008594-006
SEER Light Patient Cable/lead wires 2ch IEC - Short	2008594-007
SEER Light Patient Cable/lead wires 3ch IEC - Short	2008594-008
Holter Kit, 5-Lead, 24 kits/case	400068-026
Holter Kit, 7-Lead, 24 kits/case	400068-027
Prep Razors, Disposable	3704-901
Pre-Cut Tape Strips for Stress Loops, 100/pack	4829-002
SEER Light Carrying Case, Belt and Strap	2008596-001
Holter Patient Diary	90026-902
Holter/Exercise/Stress Vests, Medium	9812-011
Holter/Exercise/Stress Vests, Large	9812-012
Holter/Exercise/Stress Vests, Extra Large	9812-013
SEER Light 64MB Memory Card	2008750-003
SEER Light Memory Card Adapter	2008751-001
Alcohol/Pumice Prep Pads	4828-004
Sandpaper Prep Strips	4828-005
Dry Skin Prep Pads	9386-001

Index

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