



Innovators of the memory loop recording technology

# Genesis™

ECG Memory Loop Recorder

## Physician's Manual



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## Specifications

**Physical & Environmental**

Size	2.25" x 3.125" x .575"
Weight (with battery)	3 oz.
ECG connector	4-position, in-line safety
Operational temperature	0-45°C

**General Electrical**

Battery type	One Lithium CR2450
Battery life	30 days typical

**ECG Amplifier**

Number of channels	1 or 2 (menu selected)
Frequency response	0.05 to 30 Hz
Input impedance	>10 Meg Ohms
Input dynamic range	± 2.2mV
CMMR	60dB @ 60Hz
Minimum feature size	30 micro Volts
Direct currents to electrodes	0.1 micro Ampere
A/C risk currents	N/A - No A/C connection

**Digital System**

A/D converter resolution	8 bits
Sampling rate	120 samples/second
Storage memory	128K Bytes, 16 minutes

**Transmission System**

Transmission media	Voice grade telephone lines
Coupling	Acoustic
Modulation type	FM
Center frequency	1900 Hz - 100 Hz/mV sensitivity
Transmission speeds	1x or 3x (times real time)

**Functional Features**

Maximum number of events	16
Pre-button memory	Programmable — 0:30 to 15:30 min.
Post-button memory	Programmable — 30 or 60 seconds
Low battery detection	Yes (audible and visual alert)
Memory full detection	Yes (audible and visual alert)
Electrode integrity monitor	Yes (audible and visual alert)
Baseline centering	Yes - Automatic
Status information	Yes - Visual display

Not in compliance with AAMI EC38-1994 section 3.2.5.2. Recorder will fail to operate after being subjected to external defibrillator shock and may absorb greater than 10% of the energy delivered from such a shock.

## Genesis™ Accessory Parts List

PART NAME	PART NUMBER
Circuit Board Assembly, Part Populated	BOO-200-0011B
Hole Covering Label	LAB-000-0002A
Battery Bracket	MEN-000-0014A
Top Housing	MEN-000-0015A
Bottom Housing	MEN-000-0016A
Save Button	MEN-000-0017A
Belt Clip	MEN-000-0018A
Break-Away Neck Lanyard	CSB-001-0005
Lanyard Clip with Split Ring	MEN-000-0019A
Speaker Mounting Adhesive	MEN-000-0021A
1/4" #2 Plastite Screw	MFS-PLS-0001A
3/8" #2 Plastite Screw	MFS-PLS-0002A
Top Label	PLA-000-0023A
Top Label Spacer Disc	LAB-000-0028A
Serial Number Label	PLA-000-0024A
Customization Label	PLA-000-0025A
Speaker	XDC-AUD-0003A
LCD	XDC-VIS-0016A
Elastomeric Strip for LCD	XDC-VIS-0017A
4-Wire Patient Cable	CON-CAB-0068C
3-Wire Patient Cable	CON-CAB-0070C
2-Wire Patient Cable	CON-CAB-0069C
3-Volt Lithium Battery, #2450	SUP-BAT-2450

For part replacement or inquiries, contact Lechnologies at:  
262.246.7374 or 866.700.9905

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Caution: Federal (USA) law restricts this device  
to sale by or on the order of a physician.

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Genesis Manual 7-04.indd

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## INTRODUCTION

The Retrospective Genesis™ is an ECG event recorder that stores pre- and post-symptom data. The saved ECG data is then transmitted by phone to a central Receiving Center for interpretation.

This recorder may be used by both children and adults, but is not recommended for use on pediatrics (less than 22 pounds). A Holter is recommended in these cases.

### Features of the Genesis™ include:

- User-selectable single- or dual-channel recording
- Simultaneous recording of new ECG data, even while old memory data is being transmitted
- Automatic baseline centering
- Transtelephonic transmission to any standard single-channel receiver using a 1900Hz center frequency
- Either 1x or 3x transmission speeds
- Digital transmission of time stamps and recorder status
- Digital display of recorder modes and functionality
- Automatic battery monitor — alerts the patient to change battery when it is low (although usually not necessary during a 30-day monitoring period)
- Automatic memory full detection — warns the patient when only one memory bank remains, indicating that the patient should make a transmission to the Receiving Center as soon as possible
- Automatic detection of electrode or patient cable failure — alerts the patient to correct the problem or call for assistance
- Storage of up to 16 events and 16 minutes of data (8 minutes with two channels of data)

## Program Option Table

MENU MODE	PROGRAM SELECTIVITY	OPTIONS
1	Warning Tones	On or Off (O or F)
2	Number of ECG Channels	1 or 2 (1 or 2)
3	Length of Events	For one channel — 1, 2, 4, 8 or 16 minutes  For two channels — 1, 2, 4 or 8 minutes
4	Post-Symptom Recording Time	30 or 60 seconds (3 or 6)
5	Instromedix® King of Hearts® Emulation	On or Off (O or F)
6	Transmit Direct	On or Off (O or F)
7	Transmission Speed	1x or 3x  1 or 3 times real time, with fallback to 1x when problems occur  Fallback is 3 pushes of SEND button within 10 seconds total time
8	FSK Data	On or Off (O or F)

**Menu Options (Continued)****Menu 7: Transmission Speed**

The transmission of the ECG data can be done at “real time” (1x) or three times real time (3x). If it is set for 3x, then the FSK is automatically turned on.

**7 = 1****Transmission at 1x****7 = 3****Transmission at 3x****Menu 8: FSK Data**

FSK can be turned ON or OFF, as desired. When transmitting to an Instromedix® or Paceart® receiver, it should be turned ON. It will be automatically ON whenever 3x speed is turned ON.

**8 = O****FSK is ON****8 = F****FSK is OFF****PRINCIPLES OF OPERATION**

In the occasionally symptomatic patient, it is impractical and costly to order multiple 24-hour Holters to capture the transient offending arrhythmia. Thus, 30-day event recording has been proven to effectively document the patient’s transient symptomatic episodes at a cost lower than conventional Holter recording.

The Genesis™ is a continuously worn memory loop recorder, typically used by the patient for 30 days. It continuously records data from two, three or four surface electrodes.

When a symptom is felt, the patient presses the STORE button. The recorder automatically saves the ECG data 90 seconds\*\* prior to the press of the button (pre-symptom) and 30 seconds after the press of the button (post-symptom). The patient then telephones the Receiving Center and transmits the ECG data for interpretation.

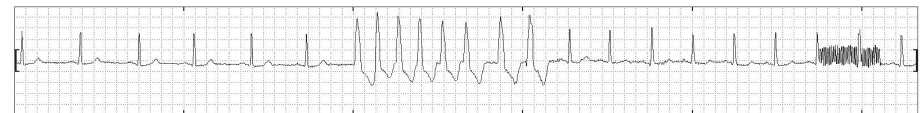
The recorder is completely digital; i.e., the analog ECG data is digitized and stored in digital form. No magnetic storage media or moving parts are used. When the digitized ECG is transmitted, it is reconstructed into an analog frequency modulated (FM) signal, which is transmitted over standard telephone lines to a receiver.

The Genesis™ allows one or two channels of ECG data to be recorded, depending upon physician preference. Two wires are needed for single-channel recording, and either three or four wires can be used for dual-channel recording (the latter providing better backup in the event of electrode or wire failure).

Multiple events can be stored in the memory. This allows storage of additional events if another symptom should occur before the patient is able to reach a phone and transmit the original event.

To provide compatibility with existing receivers, Genesis™ is configured to transmit ECG data serially, one channel at a time. If two channels of data have been recorded, Channel 1 is transmitted first, followed immediately by Channel 2.

\*\* programmable



**Pre-symptom data captured in the memory loop**

## RECORDER OVERVIEW

- STORE Button** The STORE button has two uses during normal operation:
- To store a symptom, press the button once to store the ECG data in memory. After 30 seconds, you can press it again to store additional symptoms (up to sixteen events, depending on the program settings).
  - To erase stored data after it has been transmitted, press and hold the STORE button for five (5) seconds, or until the reboot/erase tones — which is a series of tones — are heard.
- SEND Button** The SEND Button has one use — to activate the process of ECG transmission:
- To transmit data, press the button once to begin sending data (pressing a second time stops the transmission in progress).
- Speaker** The Speaker (under the telephone symbol) emits the tones for transmitting ECG data and warnings. The patient places the mouthpiece of the phone over the telephone symbol when sending data to the Receiving Center.
- Patient Cable** The Patient Cable connects either two, three or four patient electrodes to the recorder.
- LCD Display** The LCD displays the recorder status and programming information.
- In normal mode, the number of “hearts” indicates the number of ECG channels being recorded. In transmission mode, it indicates which channel is being transmitted.
  - A spindle rotates to indicate that the recorder is operating properly.
- Tones** Tones occur with each button push, and automated tones are provided to alert the patient to faults that must be corrected before reliable recording or memory capture can continue. (See page 22 for tone meanings.)

## Menu Options (Continued)

### Menu 4: Post-Symptom Recording Time

The post-button recording time can be set to either 30 or 60 seconds. A “3” indicates a setting of 30 seconds and a “6” indicates a setting of 60 seconds. The 60-second option is not available when the length of an event is set to one minute.

**4 = 3**

**30-second post**

**4 = 6**

**60-second post**

### Menu 5: Instromedix® King of Hearts® Emulation

The recorder can be configured to emulate an Instromedix® King of Hearts® recorder. This configuration makes no operational difference to the patient but uses different markers and an FSK signal compatible with Instromedix® and Paceart® receivers.

**5 = O**

**King of Hearts® is ON**

**5 = F**

**King of Hearts® is OFF**

### Menu 6: Transmit Direct

The recorder can be configured to include or exclude automatic transmission of direct data prior to moving on to the transmission of memory segments.

**6 = O**

**Direct is ON**

**6 = F**

**Direct is OFF**

Instromedix and King of Hearts are registered trademarks of Instromedix. Paceart is a registered trademark of Medtronic, Inc.

**Menu Options (Continued)**

**Menu 2: Number of Channels**

The number of channels of ECG data the recorder is expecting to record is as follows:

**2 = 1**

Channels = 1

**2 = 2**

Channels = 2

**Menu 3: Length of Events**

The recorder can be configured to store event lengths of 16, 8, 4, 2 and 1 minutes. The number of events that the recorder can store is dependent on the length of the events and number of channels the recorder is configured to store.

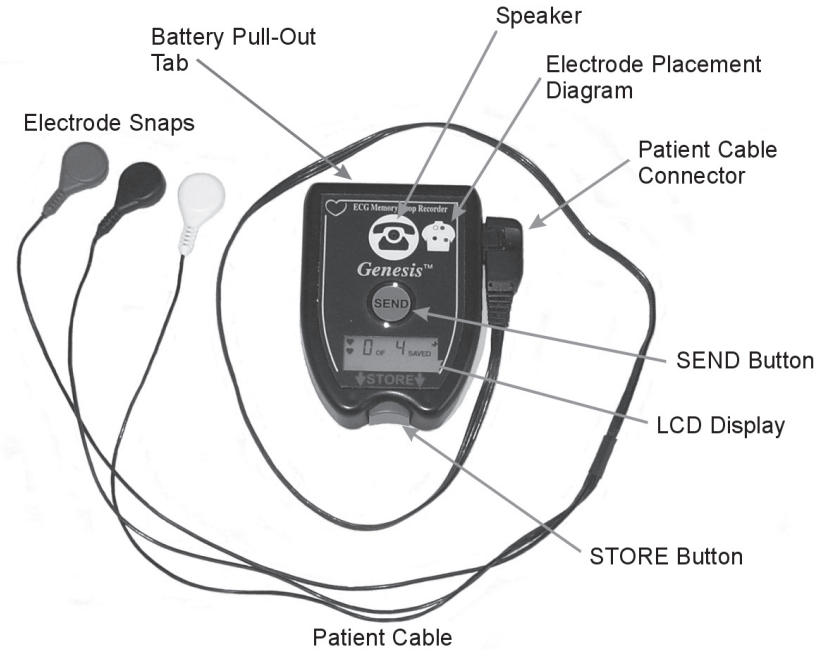
**Single-Channel Mode** (Assumes menu 2 is set at 2=1)

Minutes of Storage	Number of Events	Display Setting
1	16	3 = 1
2	8	3 = 2
4	4	3 = 4
8	2	3 = 8
16	1	3 = 16

**Dual-Channel Mode** (Assumes menu 2 is set at 2=2)

Minutes of Storage	Number of Events	Display Setting
1	8	3 = 1
2	4	3 = 2
4	2	3 = 4
8	1	3 = 8

**RECORDER FEATURE LOCATIONS**



**Genesis™ recorder feature locations**

## SETTING UP THE PATIENT

### Select a Program

The recorder is factory programmed to record dual-channel: four (4) events of 90 seconds of pre-symptom data and 30 seconds of post-symptom data. If another program is desired, turn to page 24 for programming information.

### Select Single- or Dual-Channel Recording

We recommend the four-wire, two-channel configuration for redundancy and greater accuracy. If a configuration change is desired, turn to page 24 for programming information. Following are the advantages of dual-channel data:

#### Redundancy

If an electrode falls off in Channel 1, the second channel retains the data and the symptomatic data is captured rather than lost.

#### Accuracy

In cases of wide QRS tachycardia, having a second ECG channel increases interpretative accuracy. Additionally, two channels virtually eliminate mistaking electrode artifact for sinus arrest or ventricular tachycardia.

#### Patient Compliance

When patients understand that two channels provide a more accurate test, they rarely object to the extra electrodes. Physicians prefer the more accurate two-channel procedure as well.

## Programming the Recorder (Continued)

As can be seen in the first example below, the number to the left of the “equal sign” is the menu item, and the number or letter on the right indicates the mode selected.

To advance the menu item (left digit), press the SEND button.

To advance the selection (right digit), press the STORE button.

To lock a menu item on the desired selection, simply move to the next menu item by pressing the SEND (left digit) button, or press the Program button to save and exit.

## MENU OPTIONS

### Menu 1: Warning Tones

The recorder can be configured to enable or disable the warning tones. An **O** indicates warning tones are on. An **F** indicates that warning tones are off. This menu option is the only one likely to be used by the patient, as it allows the tones to be muted during church, office meetings, etc. However, it is important to stress that these tones should not be left OFF on a continuous basis because they provide an important ongoing monitor of recorder status and potential problems (defective battery, cable or electrodes).



Tones are ON



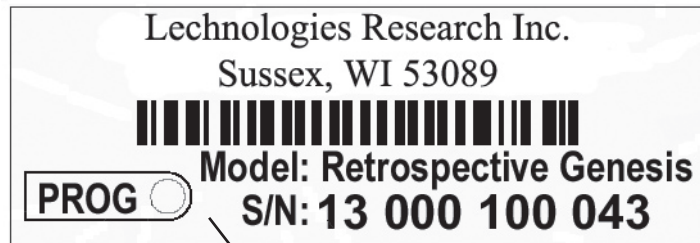
Tones are OFF

## PROGRAMMING THE RECORDER

Programming the recorder is accomplished through a series of menus displayed on the LCD. The user must enter the program mode and advance through the menus, selecting the desired mode as you move along.

**NOTE THAT THIS ERASES ANY EVENTS THAT HAVE BEEN SAVED.**

To enter the programming mode, insert a pointed object into the “PROG” hole on the reverse side of the Genesis™ recorder. Use a ball-point pen or paper clip, and press only until you hear the programming tone.



**Program button**

Upon completion of programming, the program button must be pressed to exit and save the program. (Press just enough to alter the display. Thirty seconds of idle will exit the program mode with no changes being made.)

### **Patient hook-up should be done in this order:**

1. Connect the patient cable to the recorder.
2. Apply the patient electrodes and connect patient to the recorder via the patient cable.
3. Insert the battery into the recorder (see page 13).

### **Step 1: Connecting the Patient Cable**

In most instances, the patient cable will already be attached to the recorder. To install the patient cable, align the “key” of the cable and recorder and lightly push in the cable.

To remove the cable, squeeze the tab on the side of the connector and pull straight outward.

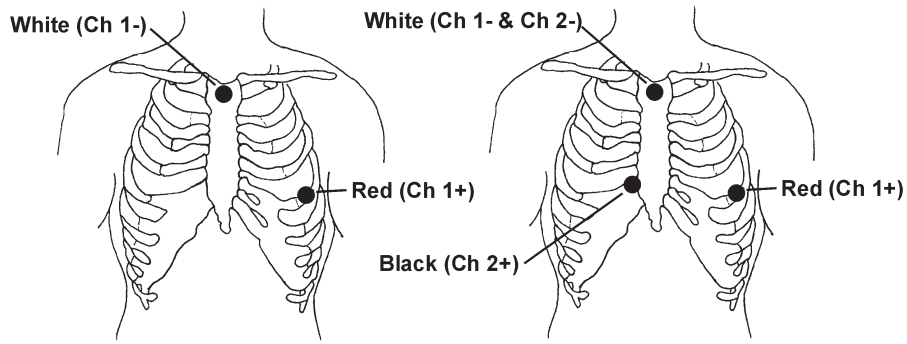
**DO NOT TWIST THE CABLE.**  
It is a straight push in and pull out.

### **Step 2: Applying the Patient Electrodes**

This is no different from normal electrode application techniques:

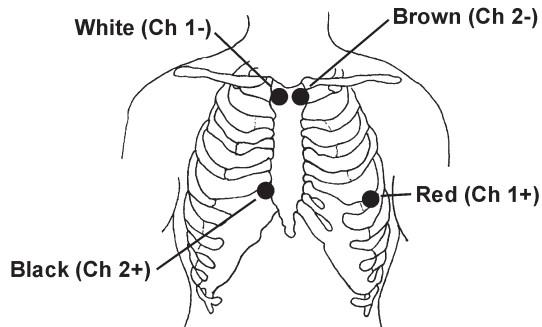
- Referring to the position charts on the next page, clean the skin sites with alcohol and/or an electrode preparation gel, if available.
- Dry the skin by wiping the area with a dry gauze pad or wash cloth. The outermost layer of the skin (epidermis) should be removed to the extent the patient can tolerate it.
- Snap the electrode onto the wire, remove the protective layer from the electrode, and place the electrode onto the skin.

### ELECTRODE POSITION DIAGRAM



**Single-channel  
2-wire configuration**

**Dual-channel  
3-wire configuration**



**Dual-channel  
4-wire configuration**

**NOTE:**  
When positioning the electrodes, choose a site that avoids skin creases, folds or bra lines.

These are guidelines only. Depending on the ECG signal amplitude, you may have to experiment with different positions to maximize R-Wave height.

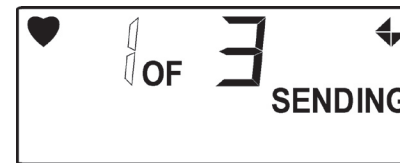
### LCD Display Variations



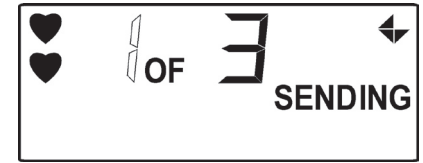
**Immediately after  
insertion of battery**



**Only 1 event left, time to  
call Receiving Center**



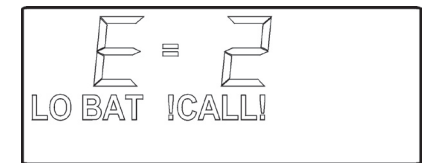
**Sending event 1 of 3,  
Channel 1**



**Sending event 1 of 3  
Channel 2**



**Done sending all 3 events, pick  
up phone**



**An error has occurred,  
call the Receiving Center**

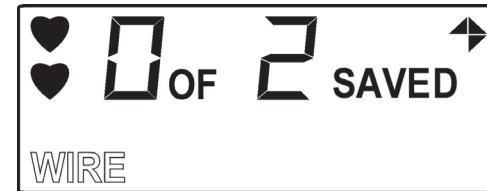
## What the Tones Mean

TONE	MEANING
Low-High	Confirm OK
High-Low	Error
High-High-Low-Low	Low Battery
High-Low-High-Low	Electrode Disabled or Disconnected
High-High	Call Alert
High-High-High-High	Enter Program Mode
High-Low-High-Low	Reboot / Erase

## Electrode Test

During operation, the microprocessor automatically checks the electrode and cable connections to the patient. If a disconnected wire or electrode is detected, a fault tone (High-Low-High-Low) is heard from the speaker and “WIRE” is displayed on the display.

The faulty electrode should be replaced or the cable reattached. If it is left as is, the fault tone will recur every eight seconds until the fault has been corrected. The recorder will, however, continue recording. The channel with the loose connection may have excessive artifact, but (if recording in the dual-channel mode) the other channel may be working properly.



**Electrode off or bad wire indicator**

## Electrode Artifact

Electrode artifact, which is common with ECG and Holter signals, can also occur with memory loop recorders and is always caused by the same thing — *a poor connection between the patient and recorder.*

### Three common factors that cause a poor connection are:

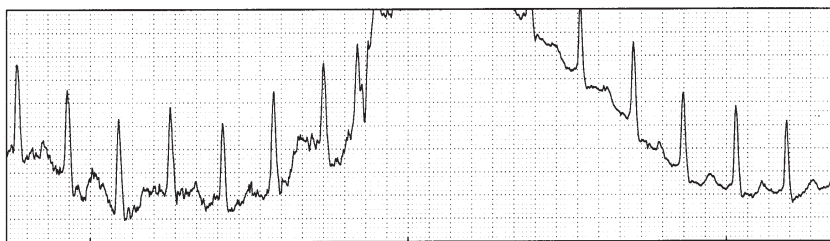
1. The use of defective or dried-out electrodes.
2. The use of a patient cable that has a broken wire(s) or other intermittent problem.
3. The use of a good electrode and good patient cable, but poor preparation of the electrode site or poor site location.

The latter is the most common problem. It results mostly from hook-up personnel being too sensitive about “roughing up” the patient — and that’s an understandable concern.

However, if you tell the patient, “I’m sorry that I have to roughen your skin, but it provides a better connection to the recorder and results in a more accurate test,” most patients will understand and appreciate your concern for better results.

It is also important to tell the patient that they must also prep their skin when they change electrodes during the course of the test.

*NOTE: For consistent results, a trained technician should perform all electrode changes whenever practical, or instruct the patient on proper electrode placement. Patient changing of electrodes may result in improper preparation and placement.*



This is a mild example of what electrode artifact appears like when the electrode connections are bad. Only rigorous cleansing of the skin area will prevent this type of problem.

## Tones

The recorder has several tones to alert the patient to changing conditions within the recorder. While these tones may seem burdensome at times, they have eliminated many failed transmissions because they alert the patient to faults that would negate the next push of the button.

Whenever a tone is heard, the display should be immediately viewed. The tones will continue to sound periodically until the fault condition is corrected. Patients should be advised to call the Receiving Center when they do not understand the situation.

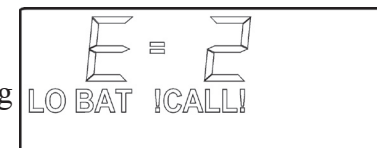
### The tones and conditions that cause tones are:

#### Confirmation

Confirms that the STORE button was properly pushed and an event was properly stored.

#### Fault Conditions

- The STORE button was pushed and the memory is full.
- One or more patient electrodes have fallen off.
- The patient cable has disconnected or become defective.
- The electrode is not connected properly.
- The battery needs replacing. Note that the recorder has two low-battery conditions:
  - (1) a low-battery warning, where the recording continues until the battery totally depletes, and
  - (2) an inoperable low-battery condition where the recorder ceases to function (even though the display continues to display the condition).
- One or no memory bank remains, and the data should be transmitted as soon as possible.
- A general error has occurred and an immediate call to the Receiving Center should be made.



## Transmission Examples

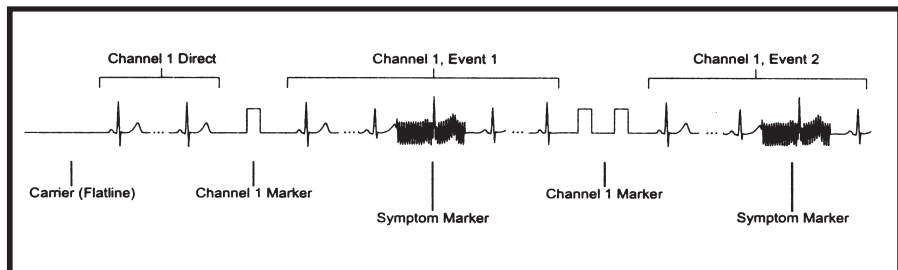


Figure 1 — Single-channel, multi-event transmission

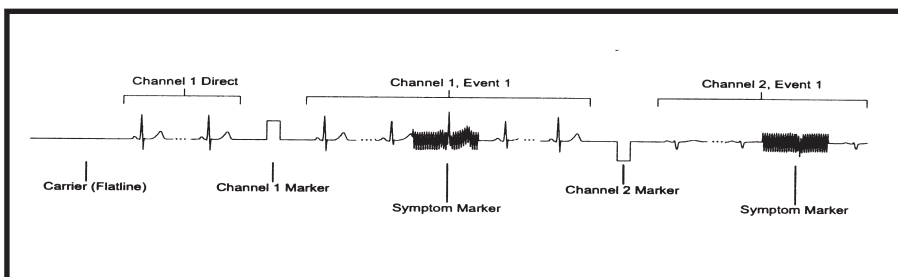


Figure 2 — Dual-channel, multi-event transmission

## Step 3: Inserting the Battery

The Genesis™ utilizes one coin cell battery as its power source.

To insert the battery, flip open the notch on the upper left corner of the recorder, and then insert the battery with the + side UP. This is usually the side of the battery with numbers printed on.



Genesis battery compartment

Note that the compartment will not close if the battery is in upside down. Do not force it closed. Reverse the battery and try again.

Typically, the battery will last over 30 days. But should it deplete prematurely, the recorder will beep and the LO BAT message will appear on the display.



Low battery signal

**IMPORTANT:** If a symptom has been stored in the recorder's memory, the patient must transmit that symptom before changing the battery. Removal of the battery will erase all stored data.

## PATIENT INSTRUCTIONS

The Genesis™ recorder will be worn by the patient for an extended period of time. During this time, the electrodes will need periodic changing. It is therefore suggested that you explain the procedure to the patient as you are connecting him or her for the first time.

Explain the electrode prep and lead placement, how to change the battery and how the recorder works. Show the patient the telephone number of the Receiving Center, located on the back of the recorder. Explain that they should call that number at any time if they have questions concerning the recorder's operation.

As in all tests of this nature, the integrity of the electrode contact with the skin is of greatest concern. The electrode allows the monitor to record the electrical activity of the heart, and needs a good contact with the skin to allow these electrical signals to be transferred to the recorder's memory. Proper preparation by the hook-up personnel and/or patient will maximize the test results.

### Key things for the patient to remember

The two most important instructions the patient must remember are:

- (1) When you feel a symptom, push the STORE button, and
- (2) Call the telephone number provided. Once on the line, the receiving personnel can instruct the patient on any items they may have forgotten.

## Transmission Format

Data is transmitted over normal voice-grade telephone lines using Frequency Modulation (FM). The ECG data is modulated onto a 1900Hz carrier with a sensitivity of 100 Hz/mV. This format allows data to be received by standard single-channel receivers.

The sequence of transmission and other transmission options can be programmed into the recorder.

Immediately preceding the transmission of any stored event, a series of square pulses are sent. The number of pulses sent indicates the number of the stored event that follows, i.e., two pulses indicate the second event. The polarity of the pulse, positive or negative, indicates whether the data is from Channel 1 or Channel 2 (positive is Channel 1 data, negative is Channel 2 data).

In addition to marking the beginning of an event, the recorder also marks the ECG to indicate when the STORE button was pushed. A 32Hz sine wave is superimposed on the ECG channel at the time the STORE button was pressed to differentiate between pre-symptom and post-symptom data.

If two channels of data have been collected, the data will be sent one channel at a time. The Channel 2 marker — a negative direction square pulse wave — is used to separate the two channels. The square channel markers will be 1mV in amplitude. Figure 1 at right shows the format for a single-channel, multi-event transmission. Figure 2 shows a two-channel, multi-event transmission.

**Important:** When transmission is complete, the recorder must be erased (so it is ready to record new events when the patient is released). After the transmission, the recorder will only recognize a prolonged press of the SEND button to resend the data.

## Erasing the Recorder's Memory Data

Once the data has been successfully transmitted, the Receiving Center will ask the patient to erase the data. The patient should not erase until the Receiving Center has acknowledged that the transmission was a success. In rare instances, a repeat transmission is necessary.

Erasing is done by pressing and holding the STORE button (see page 15) for about three (3) seconds, or until the reboot/erase tones are heard. The recorder should return to its normal mode.

The memory data can also be erased by removing and reinserting the battery. However, it is recommended that the STORE button method be used because it provides extra memory safeguards:

If any events in memory have not been transmitted, they cannot be accidentally erased with the STORE button press. If attempted, an error tone will be heard. Only after resending all data successfully will it allow memory to be erased.

After the data has been erased, the LCD display will return to normal.

## Capturing the Event While Transmitting

Note that Genesis™ has a unique ability to record new ECG data even while transmitting old memory data.

Because of their medical condition, it is possible that a patient could pass out during the transmission. With past technology, this data was automatically lost. Genesis™ now provides continuous recording during the transmission process.

If the patient passes out, when they awaken they should be instructed to press the SEND button to terminate the transmission (if still transmitting), and then press the STORE button to save the new event. This will add to the total number of events to be transmitted.

## PATIENT INTERFACE BUTTONS

There are only two buttons that the patient must press during the course of wearing the recorder.

The STORE button is a red tactile button located on the edge of the recorder. This button is pressed immediately upon the patient feeling a symptom.

The green SEND button is located on the front of the recorder and is used to start (and stop) sending ECG data to the Receiving Center.

The STORE button is also used to erase stored ECG data by pressing and holding it for five seconds, or until the reboot/erase tones are heard.

All stored events must be transmitted before they can be erased. A successful erasure will cause the recorder to return to its normal operating mode after going through a 20-second test period.



**Normal operating mode**

## STORING A SYMPTOMATIC EVENT

When a patient feels a symptom, the red STORE button (on the edge of the recorder) should be pressed. The button should be held for one second or until a confirmation tone is heard. The recorder will store pre- and post-event data according to the program selected.

It is not possible to store additional events or send data while the post-symptom data is being recorded. However, if the patient is transmitting an old event and feels a new symptom, the event being transmitted can be terminated with a second push of the SEND button, and the new event may then be STORED.

If the recorder's memory is full, pressing the STORE button will cause the recorder to emit the fault tone indicating that a new event cannot be stored.

The LCD display on the front of the recorder will display how many events have been stored or "saved" (0 of 4, 1 of 4, etc.).

## TRANSMITTING DATA

**Important:** The patient should leave the recorder connected during transmission for the direct data (described below) to be valid.

Immediately after storing an event, or as soon as possible, the patient should call the Receiving Center to transmit their symptomatic ECG data.

Remember that if the patient has a new event before reaching the phone, multiple events may be stored, depending on the selected program.

To transmit data, place the mouthpiece of the phone over the telephone symbol on the front of the recorder and press the SEND button. This will begin the transmission of ECG data. If in the 3x mode and 1x is desired, press SEND three (3) times within 10 seconds.

The recorder starts the transmission by sending 30 seconds of ECG data read directly from the patient's electrodes. This allows the Receiving Center to determine the patient's current status.

**If a life-threatening arrhythmia is transmitted in the direct mode, whether you document the memory data is unimportant at the moment. Preparations for contacting the physician or paramedics can be started even before the memory transmissions are completed.**

At the end of the 30-second direct transmission, the recorder will automatically switch to sending the stored memory ECG data.

During the transmission, the SENDING message will be lit on the display. When the transmission is completed, the tones will cease and the LCD display will read DONE SENDING.



During the transmission



Upon completion of transmission