GALIX
BIOMEDICAL INSTRUMENTATION, INC.

3 Channel Digital Ambulatory
ECG Holter Recorder

Model GBI-3SM
OPERATION MANUAL

2555 Collins Avenue, Suite C-5
Miami Beach, FL 33140, U.S.A.
Tel.: (305) 534-5905   Fax : (305) 534-8222
e-mail: info@galix-gbi.com

TABLE OF CONTENTS

SECTION 1 - INTRODUCTION

1.1 - INTRODUCTION

Ambulatory electrocardiography is the continuous recording of a patient's electrocardiogram for a period of 24 hours (normally). The associated technology is referred to as a Holter system.

The recording is not really a form of continuous monitoring in the sense that the signal is not available immediately. The recording is a representation of past events which permits a detailed analysis of them.

In a routine electrocardiogram, transitory changes may easily be missed due to the short time span over which the recording is made. These intermittent episodes are more reliably detected when the electrocardiogram is recorded continuously over a 24-hour period. This allows a correlation to be made between patient activities and symptoms and transitory abnormalities of cardiac function which are frequently associated with the tensions of daily life.

The Holter method consists of the continuous recording of more than 100,000 heartbeats in patients undergoing their normal life. When the tape is analyzed, any cardiac arrhythmias which appear may then be correlated with symptoms and events noted by the patient in his personal diary.

The patient is therefore instructed as to the enormous importance of his daily diary, in which he must note his activities and the appearance of even the slightest symptoms. The patient is also informed of the completely innocuous nature of the method in order to avoid apprehension on his part, which may generate spurious changes not related to his normal electrocardiographic pattern.

The electrocardiography signal is commonly detected using disposable auto-adhesive electrodes which assure good adhesion and electrode-skin continuity.

The GALIX *GBI – 3SM* unit is an ultra lightweight 3-Channel Digital ECG Holter Recorder using a SD (Secure Digital) Card as ECG data storage media over a 24-48 or 72-hour period, and designed for reliability in ambulatory ECG applications.

The collected information is downloaded, viewed, printed and analyzed using GALIX commercial analysis program such as the WinTer Holter Analysis System. There are different sampling rates, amplitude resolutions and record durations in accordance with the recording nature. No compression scheme is used, thus allowing cleaner ECG signal waveforms.

CAUTION

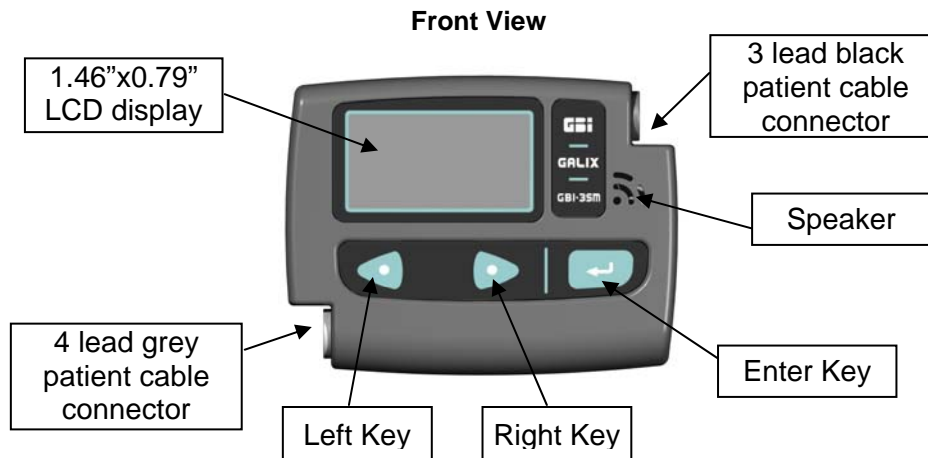**Federal law restricts this device to sale by or on the order of a physician**

1.2 - *GALIX GBI-3SM* SPECIFICATIONS

DIMENSIONS	Length: 3" (76.2 mm), Width: 2.2" (55.88 mm), Height: 0.65" (16.51 mm).
WEIGHT	Less than 2 ounces (55 grams) with battery.
ENCLOSURE	A.B.S., no metal parts exposed.
ADDITIONAL FEATURES	ECG Signals on LCD Screen, Real Time Clock, Digital Filtering
OPERATING TEMPERATURE	0 - 70º C.
DIGITAL DISPLAY	Interactive 1.46in x 0.79in (37 x 20 mm) - 64x128dot graphic LCD.
CHANNELS	Three true ECG channels.
RECORDING METHOD	Digital. <u>Ambulatory:</u> 256 samples/sec - 20uV/step <u>V.H.R.ECG:</u> 1,000 samples/sec - 0.5uV/step (for further Ventricular Late Potential analysis)
STORAGE MEDIA	Standard SD (Secure Digital) memory card.
PATIENT CABLE	Super flexible and durable tinsel wire, seven lead cable.
RECORDING BANDWIDTH	.05 Hz - 100 Hz.
RECORDING DURATION	24-48-72 Hours ECG (Programmable).
EVENT MARKER	Tactile and audible feedback pushbutton.
POWER SUPPLY	1 standard AAA 1.5 Volts alkaline battery.
INPUT IMPEDANCE	>5 Mohms
CMRR	60 dB minimum.
STANDARD ACCESSORIES	One 3 lead patient cable, one 4 lead patient cable, one AAA 1.5V alkaline battery, one SD card, one watertight dustproof shock resistant case, one user's manual and hook-up accessories.
WARRANTY	18 months

SECTION 2 - HOLTER RECORDER SETUP

2.1 - PRODUCT OVERVIEW

Standard features of *GALIX GBI-3SM* Holter Recorder are shown on Figures 2.1a, 2.1b and 2.1c.

Front View

1.46"x0.79" LCD display

3 lead black patient cable connector

Speaker

4 lead grey patient cable connector

Enter Key

Left Key

Right Key

Figure 2.1(a): Front View

Rear View

Plastic holders for lanyards

Battery and SD card compartment
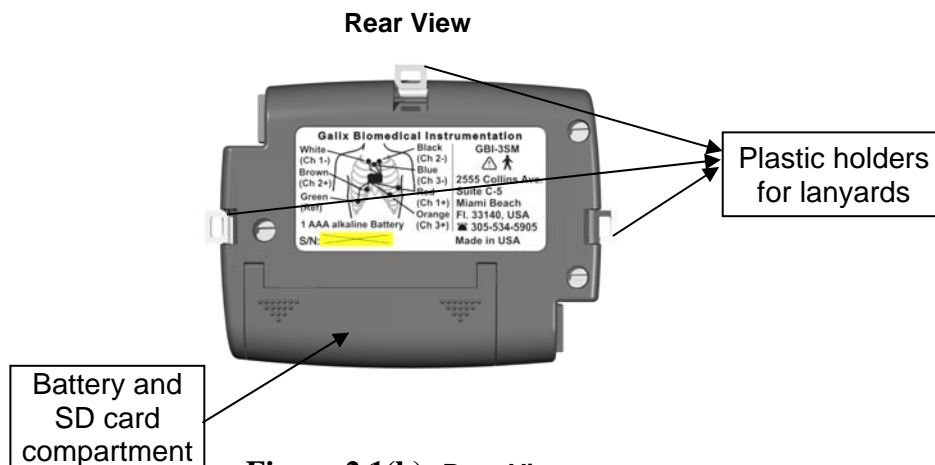
Figure 2.1(b): Rear View

Lateral View

Figure 2.1(c): Lateral View

2.2 - INTERACTIVE SCREENS AND KEYS DESCRIPTION:

The operation of the **GALIX GBI-3SM** Holter Recorder involves a simple sequential procedure comprising: Patient Identification Entry, ECG signal quality Checking, Record Mode Setting, Date & Time Checking or Setting, and Start Recording. The user interacts with the recorder through different LCD screens and three push-buttons. The **GALIX GBI-3SM** offers 3 (three) language options: English, Spanish and Portuguese.

There are:
- 2 (two) Recording Screens:
  - Ambulatory
  - V.H.R.ECG Recording

- 8 (eight) preparation screens:
  - Patient Identification [***ID***]
  - Channel 1 ECG [***CH1***]
  - Channel 2 ECG [***CH2***]
  - Channel 3 ECG [***CH3***]
  - Recording Settings [***Settings***]
  - Date & Time Setting [***Date/Time***]
  - Start Recording [***Start***]
  - Device Information [***About***]

The screen labels are positioned on top of the 64x128-pixels LCD, resembling MS Excel Sheets

All selections and modifications are performed using only three keys (◄ [Left], ► [Right], ● [Enter]). No On-Off key is used to turn on/off the unit. Turn on is performed automatically once the battery is inserted (1 AAA Alkaline battery). Turn off is performed through battery removal.

The selection of a particular Preparation Screen is performed by means of the [Left] and [Right] keys. After selecting a particular Preparation Screen, data entry is enabled by pressing the [Enter] key. A question mark will indicate that the operator can modify a parameter value or select a parameter option.
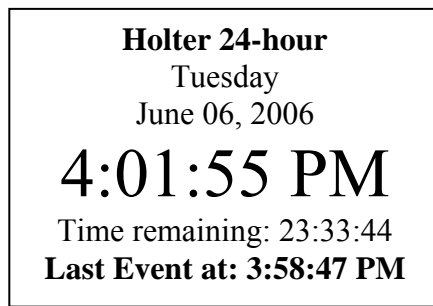
Ambulatory ECG Recording Screen

The information shown on the LCD during the recording of the ambulatory ECG is: Recording Type (Holter 24-48-72-hour), Full Date, Current Time, Remaining Recording Time, Time of the Last Event (See **Figure 2.2**).

```
┌─────────────────────┐
│   Holter 24-hour    │
│        Date         │
│        TIME         │
│   Remaining Time    │
│   Last Event Time   │
└─────────────────────┘
```
Figure 2.2

By pressing any key a Patient Activated Event (PAE) is tagged on the recording. The last LCD line shows the last time the PAE button was pressed. The **GALIX GBI-3SM** can record up to 250 events.

Information is presented Upside Up (See **Figure 2.3a**). When pressing the [Left] and [Right] keys simultaneously, the information is presented Upside Down for 5 seconds to ease the reading by the user (See **Figure 2.3b**).

```
Holter 24-hour
Tuesday
June 06, 2006

4:01:55 PM

Time remaining: 23:33:44
Last Event at: 3:58:47 PM
```

Figure 2.3a

```
Holter 24-hour
Tuesday
June 06, 2006

4:01:55 PM

Time remaining: 23:33:44
Last Event at: 3:58:47 PM
```
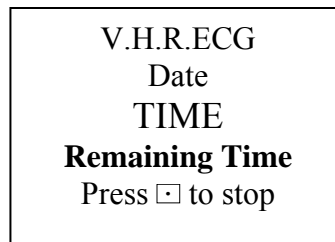
Figure 2.3b

Recording cannot be stopped unless the battery or the memory card is removed. Prior to remove the battery or the memory card it is recommended to press the [Right] and [Enter] key simultaneously. This action will not stop the recording but will indicate the unit that the battery or card will be removed; the message "Please, Remove the Memory Card or the Battery" will appear on the screen for 5 seconds.
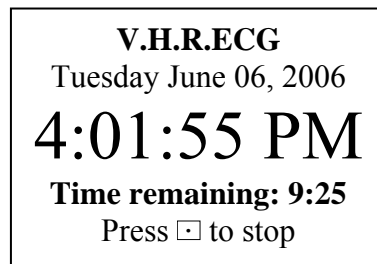
Very High Resolution ECG Recording Screen

During the Very High Resolution ECG (V.H.R.ECG) recording process the information presented on the LCD is: Recording Resolution (V.H.R.ECG-1000 samples/second), Full Date, Current Time, Remaining Recording Time, "*Press [Enter] to stop Recording*" (See *Figure 2.4*).

```
V.H.R.ECG
Date
TIME
Remaining Time
Press ⊡ to stop
```

Figure 2.4

The recording can be stopped by pressing the [Enter] ⊡ Key.

```
V.H.R.ECG
Tuesday June 06, 2006

4:01:55 PM

Time remaining: 9:25
Press ⊡ to stop
```

Figure 2.5

Patient ID Screen

When no Patient ID has been entered, the initial Patient ID Screen looks as shown in *Figure 2.6a*. By pressing the [Enter] key, a numeric data entry screen is accessed (see **Figure 2.6b**). The underscore indicates the field (number or action) to activate.

In the *Figure 2.6b*, the underscore is pointing to the number 3. After pressing the [Enter] key this number, will be copied onto the ID field at the left bottom of the LCD. It is possible to choose another number, such as the one indicated in the *Figure 2.6c* (number 7). Again, by pressing the [Enter] key this number will be copied onto the ID field.

The operator may decide to **cancel** the whole operation, to **resume** one position back withdrawing the latest number entered or to **confirm** the whole ID entered. These operations are performed by placing the cursor (underscore) on the words CANCEL, BACK or OK. After confirming the whole ID entered (OK option) the screen will present the entered Patient ID on the center (see **Figure 2.6d**).

The selection of another Preparation Screen can only be performed from this screen.

Patient ID:
None entered

Press ⊡ to select a Patient ID

Figure 2.6a

0 1 2 <u>3</u> 4 5 6 7 8 9

Cancel   Back   OK

ID: 3

Figure 2.6b

0 1 2 3 4 5 6 <u>7</u> 8 9

Cancel   Back   OK

ID: 37
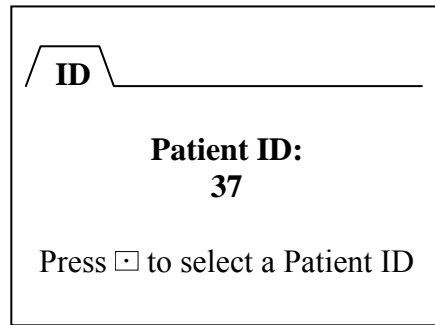
Figure 2.6c

Figure 2.6d

Settings Screen

The Settings screen allows the modification of the recording parameters. The parameters are the following: Mode, Record Time, Pacer Detector, Language, and LCD Contrast.

The Mode, Language and LCD Contrast are independent parameters. This means that the user may select any of the available options independently. On the contrary, the Record Time parameter options will depend on the selected mode. The Pacer Detector parameter is available only for Ambulatory Recording.

The **Mode** options are: **Ambulatory** and **V.H.R.ECG.**

The **Language** options are: **English**, **Español** (Spanish) and **Português** (Portuguese).

The **LCD Contrast** values range from 10 to 90%, in 10% increments

The **Pacer Detector** parameter is only available in the Ambulatory Mode. There are two options: **On** and **Off**.

The **Record Time** options are:
   - <u>Ambulatory Mode:</u> **24-hour**, **48-hour** or **72-hour**
   - <u>V.H.R.ECG Mode:</u> **up to 1 hour.**

The minimum capacity of the Memory Card to use (SD - Secure Digital) will depend on the Sampling Rate, Amplitude Resolution [step size and dynamic range] and Record Time. The ***Table 1*** summarizes this requirement.

When selected the **Holter** Mode, the LCD Screen will look as shown in the ***Figure 2.7***. The default parameters options are:
   - Mode: Holter
   - Record Time: 24 hr   {24hr / 48hr / 72hr}
   - Pacer Detector: Off
   - Language: English   {English, Español, Portuguès}
   - Contrast: 60%   {10% to 90%}

When selected the **V.H.R.ECG** Mode, the LCD Screen will look as shown in the ***Figure 2.8***. The default parameter options are:
   - Mode: High Resolution
   - Record Time: 10 min   {10min / 1hr / 24hr}
   - Language: English   {English, Español, Portuguès}
   - Contrast: 60%   {10% to 90%}

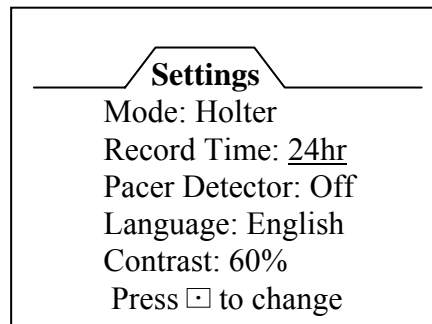| Mode	Record Time (#1)	Sampling Rate [Hz] (#1)	Amplitude Resolution			ECG record length [Bytes] (#1)	Minimum Memory Capacity [MB] (#2,#3)
			Step [uV]	Dynamic Range [mV]	Bytes /Sa /Ch (#1)		
Holter	24 hr	256	20	+/- 2.55	1	66,355,200	64
Holter	48 hr	256	20	+/- 2.55	1	132,710,400	128
Holter	72 hr	256	20	+/- 2.55	1	199,065,600	192
V.H.R.ECG	10 min	1000	0.5	+/- 16.38	2	3,600,000	4
V.H.R.ECG	1 hr	1000	0.5	+/- 16.38	2	21,600,000	24

Notes:

#1: ECG record length calculated as *Recording Time*3*SamplingRate*Bytes/Sa/Ch*

#2: The Memory card also contains patient demographic information, pacemaker detection information and other study data.

#3: 1 Mega Byte is 2^{20} Bytes or 1,048,576 Bytes

Table 1

```
 _____/Settings_____
       Mode: Holter
       Record Time: 24hr
       Pacer Detector: Off
       Language: English
       Contrast: 60%
        Press ⊡ to change
```

Figure 2.7

```
 _____/Settings_____
       Mode: High Resolution
       Record Time: 1 hour

       Language: English
       Contrast: 60%
        Press ⊡ to change
```
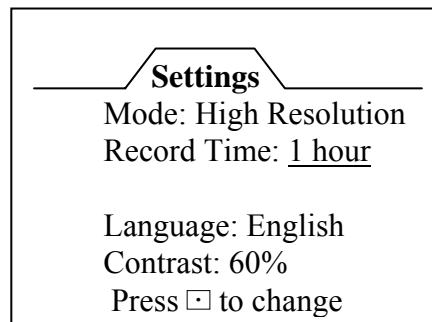
Figure 2.8

The standard SD memory card delivered with the unit is 512 mega bytes.

2.3 – SETTING THE CLOCK

The *GALIX GBI-3SM* Holter Recorder has a Real Time Clock. The actual date and time can be adjusted through the Date/Time Screen by means of the keyboard.

2.4 - INSTALLING BATTERY

The recommended battery for the *GALIX GBI-3SM* Holter recorder is a AAA 1.5V alkaline battery. For proper battery placement first open the compartment pushing the door slightly in the sense of the arrows. The correct polarity is noted at the bottom of the compartment.
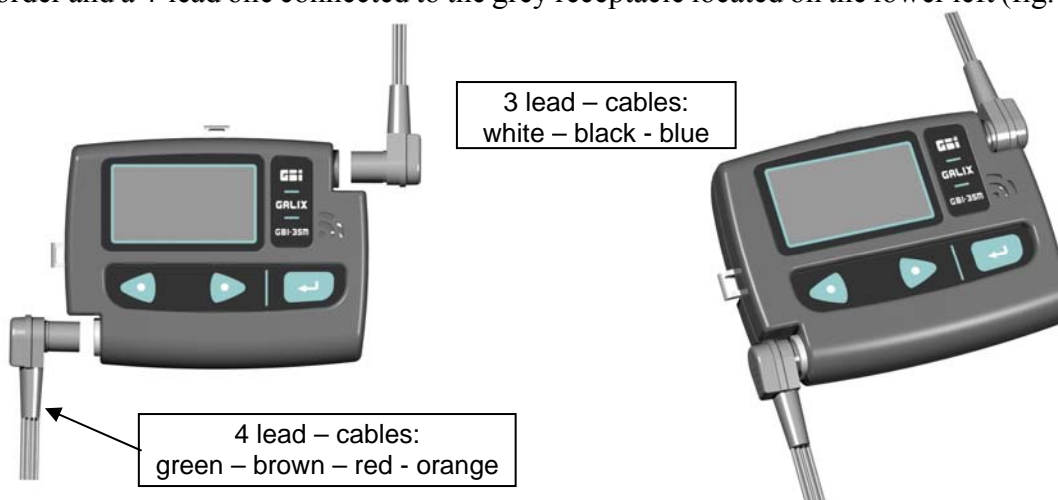

Figure 2.9

NOTE: To insure reliable operation of the recorder, the battery must be replaced every patient recording.

2.5 PATIENT CABLE CONNECTION

There are two patient cables, a 3-lead connected to the black receptacle located on the upper right part of the recorder and a 4-lead one connected to the grey receptacle located on the lower left (fig. 2.10 and 2.11)

3 lead – cables:
white – black - blue

4 lead – cables:
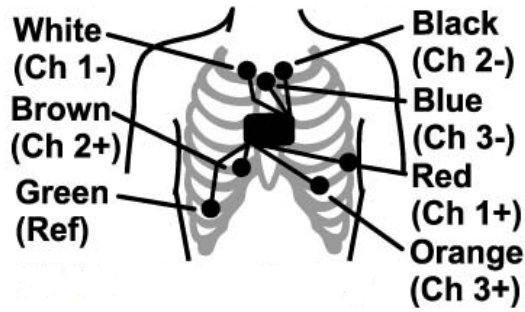green – brown – red - orange

Figure 2.10

Figure 2.11

2.6 - LEAD WIRES ECG CHANNELS QUALITY TEST

In order to check the right functioning of the patient cable, it is not necessary to disconnect it from its receptacle. The procedure is simple and consists of checking the quality of the incoming ECG signal by viewing the screens CH1, CH2 and CH3 when the lead wires are connected to the patient. In case the CH1 ECG signal appears noisy, gently press the red and white electrodes to improve the contact with the patient skin, or move / place the red and white wires to / in other locations. In case the CH2 ECG signal appears noisy, the same actions have to be followed with the brown / black electrodes and wires. Finally, if CH3 ECG signal presents noise, the described actions have to be followed with the orange / blue electrodes and wires.

SECTION 3 - OPERATION

3.1 - PATIENT PREPARATION

Materials needed:
1. Seven silver-silver chloride disposable electrodes designed for 24 hour Holter monitoring.
2. Prep pads.
3. Alcohol

Do not use 12-lead ECG or Stress Test electrodes. Use electrodes designed for long-term monitoring. Proper patient preparation is the key for Holter recording.

3.2 - PATIENT HOOK-UP

In order to achieve a proper patient hook-up, the following steps are recommended:

1. Shave the electrode areas if needed. Wipe the skin in the electrode areas with alcohol prep pads.

2. Wipe the skin in the electrode areas with an alcohol prep pad again.

3. Dry the electrode application areas with a lint free cloth.

4. After preparing the electrode area, connect the electrodes to the ECG leadwires before applying the electrodes to the patient.

5. Remove the backing from the pre-gelled disposable electrode, and place an electrode on each of the seven prepared skin surface sites, carefully placing the gelled electrode firmly in contact with the skin surface.

3.3 - ELECTRODE APPLICATION

Place the electrodes following the color code shown in the following figure:
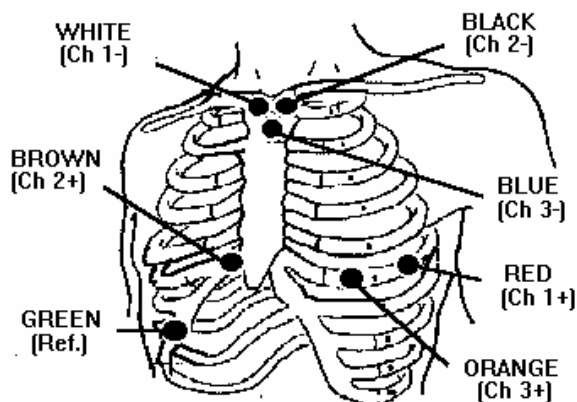
Figure 3.1

Channel 1 = Red (+) - White (-)
Channel 2 = Brown (+) - Black (-)
Channel 3 = Orange (+) - Blue (-)

3.4 - ELECTRODE PLACEMENT CHART

Seven color coded leadwires are utilized for a true three channel ECG recording.

3-Channel electrode placement chart:

White	Channel 1 (-). Place at the top/center of the sternum directly on the right side of the bone.
Red	Channel 1 (+). Place on the left side at the V5 position, on a rib.
Black	Channel 2 (-). Place at the top of the sternum on the left side on the bone.
Brown	Channel 2 (+). Place on the right side at the V1 position on a rib.
Blue	Channel 3 (-). Place at the top of the sternum below the black and white leads on the bone.
Orange	Channel 3 (+). Place on the left side at the V3 position, on a rib.
Green	Reference. Place on right side opposite V5 position on a rib.

3.5 - EDUCATING THE PATIENT

It has been said that one of the greatest advantages of ambulatory monitoring is that you do not have to be with the patient constantly in order to collect diagnostic information. On the other hand, the disadvantages of ambulatory monitoring are that you are not constantly with the patient while the data is being collected.

The moral of this story is that a successful procedure requires a properly educated patient. If the patient is not instructed on what he can or cannot do during the procedure, the results will be totally dependent on luck. Taking this into consideration, we have outlined the important points you should pass along to your patients.

- Do not get the *GALIX GBI-3SM* recorder wet! The recorder must be taken off by the doctor before the patient can shower, take a bath, or swim. The patient would not be harmed if the recorder got wet, but the machine could be severely damaged by any wet exposure.
- Please do not pull or jerk the lead wires.
- Avoid electric blankets.
- In his diary, the patient should record the time, activity, and how he feels during abnormal episodes, in addition to pressing the Event button. Every time the event button is pressed, a beep will sound as an audible feedback.

SECTION 4 - RECORDING PROCEDURE

4.1 - STEP BY STEP PROCEDURE

Materials needed:

- One SD (secure digital) memory card
- One AAA 1.5V alkaline battery
- Patient diary
- *GALIX GBI-3SM* Holter recorder
- Four-lead patient cable
- Three-lead patient cable
- Set of Lanyards
- Seven pre-gelled Holter disposable electrodes.

In order to obtain a 24 hour - 3 channel continuous ECG recording, you have to follow the steps listed below:

1- Insure the patient cables are connected to the *GALIX GBI-3SM* Digital Holter recorder (Figure 2.10).

2- Insert the SD card by pushing it gently into the recorder (Figure 4.1).

3- Install a new AAA 1.5V alkaline battery (see Figure 2.9). The LCD will show the introductory screens and finally the Patient ID screen (Figure 2.6).

4- Enter the Patient ID number as explained in the Section 2.2.

5- Check the signal quality and amplitude of each channel accessing the CH1, CH2 or CH3 screen as explained in the Section 2.2

6- Access the Recording Settings Screen to check the recording mode. Select the recording mode if necessary.

7- The ambulatory ECG recording is ready to begin. Access the Starting Screen. Press <ENTER> to start recording.

8- The LCD will show the Recording Screen indicating the recording mode, the actual time and a count-down timer. Once the recording has begun, any key of the keyboard can be used to mark Patient Events

9- Connect the lanyard or necklace to the recorder and hang it to the patient.

When the patient returns after a 24-hour period:

1. Press the <Right> and <ENTER> keys simultaneously to indicate that the memory card and/or the battery will be removed. Remove the battery and the card from the recorder. The card is now ready to be downloaded to the Holter Analyzer system.

2. Once the ECG download process has been completed in the Holter Analyzer, the memory card will be available to begin a new 24-hour ambulatory ECG recording.

4.2 - MEMORY CARD INSERTION

SD (Secure Digital) memory cards are a tiny and versatile way of storing data.
Insertion of the SD: Holding by the edges, insert memory card into the recorder slot until you fell a click (Do not apply pressure to the center of the card). Memory card can only be inserted one way; the chamfer must be facing the upper right side.
The SD memory card has a mechanical write protection switch (lock), when this switch is enabled no data can be written into the memory card. It is extremely important that this switch is not activated when connecting the recorder to the patient.
To remove the SD memory card first push slightly the card and release it, then you will be able to remove the SD from the recorder.

Precautions:
- Keep memory card away from heat, direct sunlight and moisture.
- To not bend, bend, or drop memory card.
- To prevent data loss and /or damage of a memory card, NEVER remove the card from the GBI-3SM Holter recorder while data is being transferred (Section 4.5).
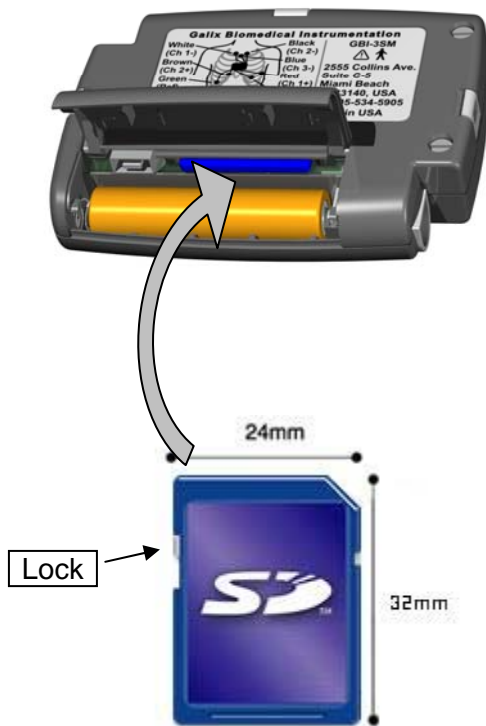
Figure 4.1

Important: Make sure the SD card is not locked before inserting it into the recorder.

4.3 – ECG MONITORING

It is very important to monitor each one of the three ECG channels prior to the beginning of the 24-hour ECG recording, in order to verify the amplitude and quality of each ECG signal. The ECG signal of the 3 channels can be observed on the LCD screen by selecting the CH1, CH2 or CH3 tabs. There is no need to use an external device such a cardiac monitor or an electrocardiograph.

4.4 - PATIENT EVENT BUTTON

Every time the patient wishes to note his activities or symptoms in his diary, he must gently press any key. A beep will indicate that a Patient Activated Event was logged. If necessary, the corresponding time can be taken from the LCD display.

4.5 - STOPPING THE RECORDER

When patient returns to the office the next day, press the <RIGHT> and <ENTER> keys to indicate the recorder that the battery and/or memory card will be removed. A message on the screen will indicate that they can be safely removed; this is a software protection tool in order to prevent data loss and/or damage to the memory card witch could occur if the SD card is removed from the recorder while data is being transferred. Remove the battery and the card. Next, remove the patient cable and electrodes.

In case you wish to stop the ECG recording before the 24-hour recording is completed, you must follow the same procedure. The message allowing the memory card removal will last for 5 seconds. If the card and/or battery are not removed, the equipment will continue the recording procedure until the 24-hour period has elapsed.

SECTION 5 - LATE POTENTIAL ANALYSIS

5.1 - INTRODUCTION

According to the data estimated by the American Heart Association, Sudden Cardiac Death (SCD) is the second leading cause of death in the United States after Cancer. In contrast to other terminal diseases, SCD appears suddenly, causing death within an hour of the initial symptoms. Early detection in potential victims is crucial in the treatment of these patients in order to prevent the SCD.

The micro potentials that appear at the end of the QRS complex represent the fragmented and delayed conduction in damaged or diseased ventricular myocardium, and are indicators of possible ventricular arrhythmia risks. Every pathological process that affects the conduction velocity in any ventricular tissue area, may be studied by means of the Ventricular Late Potential analysis.

5.2 - ECG SIGNAL ACQUISITION

Conventional surface electrocardiography generally cannot detect late potentials. Its main limitation stems from the inability to visualize the low amplitude signals, which may be as low as one microvolt. Amplification of the standard electrocardiogram to detect late potentials results in contamination by amplification of coincident electrical noise. Thus, sophisticated digital signal processing techniques have evolved to detect individuals at risk for the development of sustained ventricular tachyarrhythmia, which may cause marked haemodynamic embarrassment, including sudden death.

These techniques involve the recording, digitalization, averaging, amplification, and filtering of the ECG signal, and enable the late potentials to be amplified, while eliminating undesired electrical signals.

The seven lead shielded patient wires are used to obtain three bipolar recordings. With these orthogonal leads, the heart is viewed from three dimensional perpendicular aspects, referred to as x, y and z. The electrode placement for this scheme is illustrated in **Figure 5.1** and described in **Table II** on the following page.
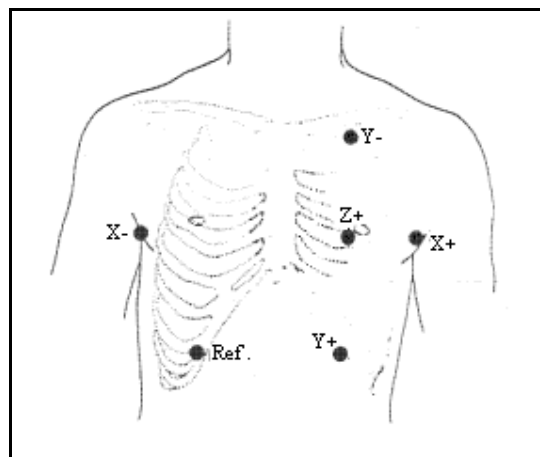
Figure 5.1

Lead	Color	Electrode placement
+X	Red	Left midaxillary line at the fourth intercostal space
-X	White	Right midaxillary line at the fourth intercostal space
+Y	Brown	Standard V3 position / proximal left leg
-Y	Black	Superior aspect of the manubrium
+Z	Orange	Standard V2 position
-Z	Blue	Immediately posterior to +Z position
Ref.	Green	Lower right rib

Table II

5.3 - PROCEDURE TO RECORD V.H.R.ECG

The steps to follow during the acquisition of V.H.R.ECG signals for LP analysis are the following:

1) Prepare the electrode sites and place the electrodes on the patient body as shown on **Figure 5.1**. Remember that good electrode contact is critical to obtaining data with a minimum amount of noise.

2) Insert the SD card by pushing it gently into the recorder (Figure 4.1).

3) Install a new AAA 1.5V alkaline battery (see Figure 2.9). The LCD will show the introductory screens and finally the Patient ID screen (Figure 2.6).

4) Enter the Patient ID number as explained in the Section 2.2.

5) Check the signal quality and amplitude of each channel accessing the CH1, CH2 or CH3 screen as explained in the Section 2.2

6) Access the Recording Settings Screen to check the recording mode. Select the V.H.R.ECG recording mode.

7) The V.H.R.ECG recording is ready to begin. Access the Recording Screen. Press <ENTER> to start the recording.

8) The LCD will show the High Resolution Recording Screen indicating the recording mode, the actual time and a count-down timer. Once the recording has begun, the keyboard can be used to reverse the presentation or to stop the recording.

9) After the programmed V.H.R. Acquisition has elapsed, the unit will stop. Now, take out the memory card and battery and continue with the procedure to perform the VLP analysis.

NOTE: In case you want to stop the ECG data acquisition before the programmed period, press the <RIGHT> and <ENTER> keys simultaneously.

SECTION 6 – SERVICE

6.1 - REPLACEMENT PARTS

To ensure patient safety and proper performance of your Ambulatory Holter Recorder, use only parts and accessories manufactured or recommended by GALIX Biomedical Instrumentation, Inc.

Replacement parts:

Part #	Description
15-03-001	4-lead Patient Cable
15-03-002	3-lead Patient Cable
15-04-001	SD Memory card
15-04-002	One AAA Alkaline Battery
15-04-003	Operating manual CD
15-04-004	Set of lanyards
15-04-005	Shock resistant carrying case

6.2 - MAINTENANCE

The recorder should be cleaned regularly, using a soft cloth moistened with water and mild detergent. Remove any adhesive from the lead wires.

The patient's cable lead wire snap connectors should be cleaned with alcohol and a small brush to eliminate any trace of gel remaining after the use of disposable electrodes.

We suggest that the patient cable be left inserted into the patient cable receptacle. This increases the useful life of the patient cable. It is usually unnecessary to disconnect the patient cable, especially considering that the electrical continuity of the lead wires can be checked in situ.

We also suggest to keep records of every problem or failure during either the recording or download procedure.

SECTION 7 - WARRANTY

GALIX Biomedical Instrumentation, Inc. provides to the original purchaser the following limited warranty from the date of invoice.

All serialized parts: 18 months

GALIX Biomedical Instrumentation, Inc. warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instrument when returned prepaid from the customer's facility. GALIX Biomedical Instrumentation, Inc. will repair any component(s) or part(s) that it find to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser shall first notify GALIX Biomedical Instrumentation, Inc. of the suspected defect. To return your instrument for repair, a return material authorization (RMA) must be provided by GALIX Biomedical Instrumentation, Inc. The instrument should be carefully packaged with receipt as proof of purchase and shipped prepaid to:

> **GALIX Biomedical Instrumentation, Inc.**
> **2555 Collins Avenue Suite C-5**
> **Miami Beach, FL 33140, U.S.A.**
> **Phone: (305) 534-5905 Fax: (305) 534-8222**

Your instrument will be repaired in the shortest possible time and returned by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by Accident, Misuse, Negligence, Act of God, or if the instrument has been serviced or modified by any person not authorized by GALIX Biomedical Instrumentation, Inc.

This limited warranty contains the entire obligation of GALIX Biomedical Instrumentation, Inc. and no other warranties expressed, implied, or statutory are given. No representative or employee of GALIX Biomedical Instrumentation, Inc. is authorized to assume any further liability or grant any further warranties except as set herein.