OPERATION MANUAL
MODEL 950-12LR-HHC

Overview

The Memtec model 950-12LR-HHC is a battery operated ECG monitoring device that provides true 12-lead, high-resolution, clinical/research-grade recordings with wireless transmission in the 2.4Ghz ISM band for ECG machine function. The device has a resolution of 12 bits, with data viewed and stored uncompressed on a PC. The data is transmitted wirelessly to a PC in real-time for use as an ECG machine. Data integrity is provided through a unique patent-pending technique that includes data, time and patient ID stamps along with a CRC-16 check on the recording every 2 minutes, ensuring usable recordings while preventing patient data mix-ups. A large LCD provides real-time patient ECG signals to confirm lead placement during patient hook-up. One "AA" alkaline battery provides power for up to a month of use.

The model 950-12LR-HHC over-samples the input signal at a rate of 6,000 samples/second to support hardware pacemaker detection on all channels.

Patient Hookup

Once the cardiologist has specified the desired type of patient hookup, the specific location and method of attachment of the electrodes to the body is crucial to achieving the best signal. The following recommendations enable the user to obtain the highest quality signals and recording:

1. Connect the electrodes to the bony area over a rib or sternum to reduce muscle noise interference. Placing the electrode over large muscle areas or in the intercostal spaces can cause high frequency artifacts that degrade the

signal significantly. Electrode placement over fatty areas will also cause signal degradation. Always refer to the ANSI/AAMI Standard EC12-1991 for safety, performance, and labeling requirements for the disposable electrodes, and guidelines for reliable patient connections.

2. Any body hair around the electrode site must be removed by dry shaving. The electrode site must be thoroughly cleaned to remove surface skin oil and dirt. Use a gauze pad moistened with alcohol to properly clean the area. Gauze should be used rather than alcohol prep pads because of its superior abrasive quality.

3. The center of the electrode site where the pad of the electrode will make contact with the skin should be wiped 3 or 4 times with a small piece of extra fine sandpaper or similar abrasive material to remove the dead superficial layer of skin. This will significantly improve the electrical contact between the skin surface and the electrode to provide a quality signal.

4. Finally, proper patient hookup of all channels/leads should be thoroughly tested by using the built in hook-up review feature to verify that the appropriate amplitude signal is being obtained from each channel/lead without noise or artifacts.

Typical Electrode Placement

The Model 950-12LR-HHC has two major modes of operation:

1. Standard 12-Lead mode
2. Optional 3-channel mode.

The cable used on the unit determines the device mode of operation. Changing the mode requires insertion of the appropriate cable. The cable options are:

- 10-wire cable for 12-lead recordings
- 7-wire cable for 1, 2 or 3-channel recordings

The standard patient electrode connections to this device use a 12-Lead/10-Wire cable that conforms to the standard AHA electrode color code system as specified in ANSI/AAMI EC11:1991/(R)2001.   See Figure 1- Hookup for 12-Lead/10-Wire.

For special applications an optional cable is available to allow viewing and recording of 1, 2, or 3 individual channels. This is a seven lead cable that uses the standard AHA electrode color code system as specified in ANSI/AAMI EC13:2007. See Figure 2 - Hookup for 3-Channel 7-Wire.

Variations on the electrode placement sites may be chosen by the cardiologist depending on the type of arrhythmia the patient is suspected of having and other factors.

| 12-Lead (10-Wire) Electrode Placement			
Wire #	Electrode Identifier	Color Code	Position on body
1	RA	White	Right arm
2	LA	Black	Left arm
3	LL	Red	Left leg
4	V1	Brown/red	4th intercostals (IC) space at right border of sternum
5	V2	Brown/yellow	4th IC space at left border of sternum
6	V3	Brown/green	Midway between V2 and V4
7	V4	Brown/blue	5th IC space on left midclavicular line
8	V5	Brown/orange	Left anterior axillary line at the horizontal level of V4
9	V6	Brown/violet	Left midaxillary line at the horizontal level of V4
10	RL	Green	Right leg
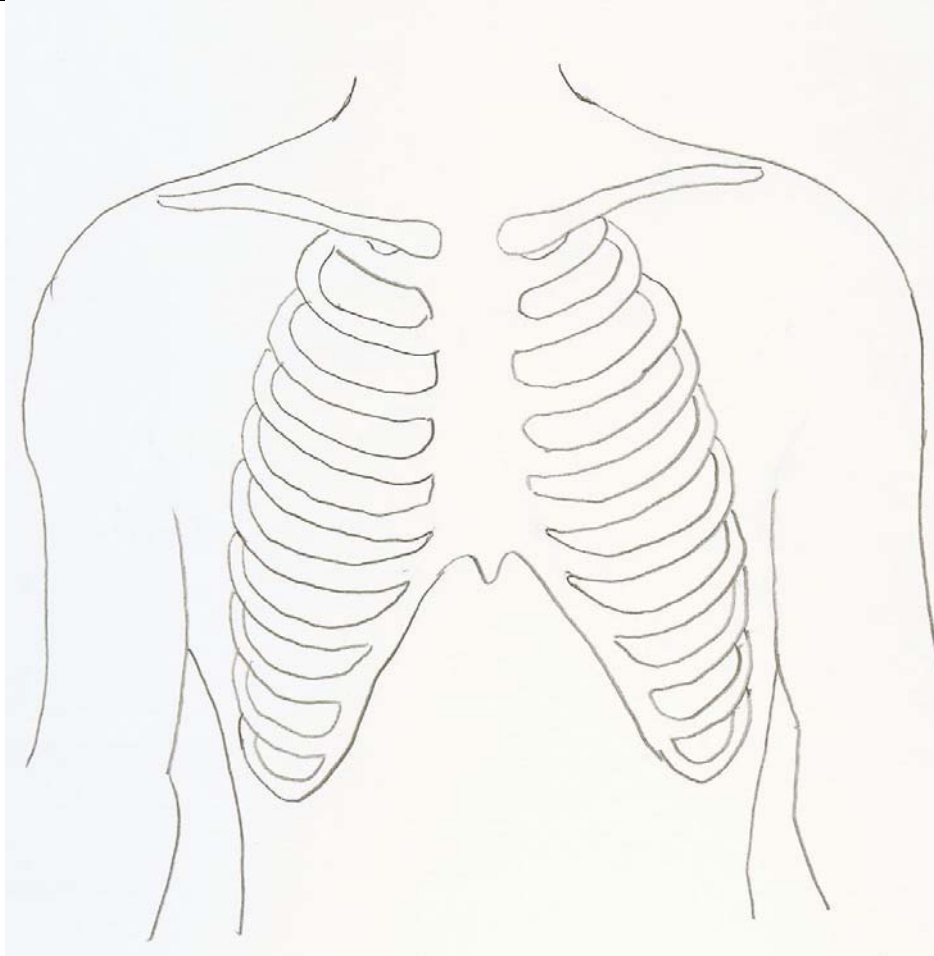
Figure 1- Hookup for 12-Lead/10-Wire Sessions

3-Channel (7-Wire) Electrode Placement			
Wire #	Channel	Color Code	Position on body
1	1 +	Red	Left anterior axillary line 6th rib
2	1 -	White	Right manubrial border of the sternum
3	2 +	Brown	Approximately 1 inch right of Xiphoid process on the rib
4	2 -	Black	Left manubrial border of the sternum
5	3 +	Orange	Left Mid-clavicular line 6th rib
6	3 -	Blue	Center of the manubrium
7	Reference	Green	Lower right rib margin over bone
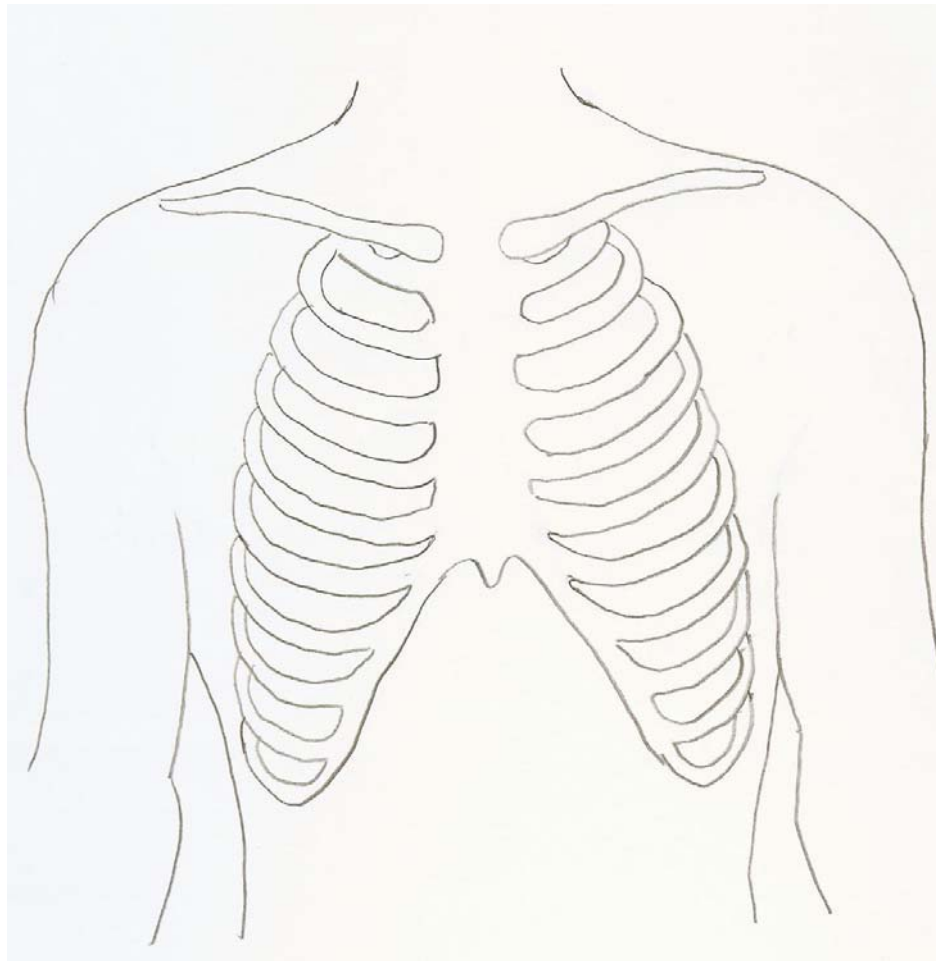
Figure 2 - Hookup for 3-Channel 7-Wire Sessions

3-Channel (5-Wire) Electrode Placement			
Wire #	Channel	Color Code	Position on body
1	3 -	White	Below right clavicle, just lateral to the midclavicular line
2	1 -, 2 -	Red	Top of the sternum
3	2 +, 3+	Black	8th rib at the left midclavicular line
4	1+	Brown	5th rib at the left anterior axillary
5	Reference	Green	8th rib at the right midclavicular line
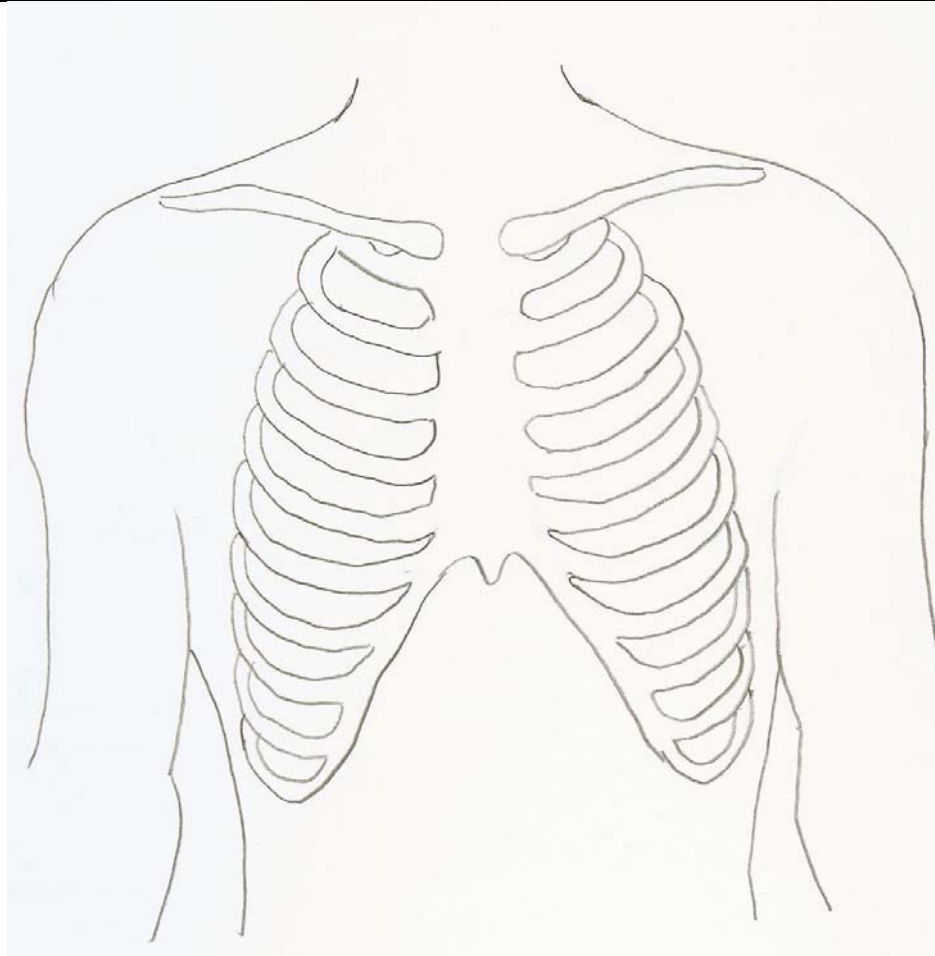
Figure 3 – Hookup for 3-Channel 5-Wire Sessions

Cautions for the operator:

- Do not get the recorder wet

- Keep away from waterbed heaters

- Keep away from heating pads and electric blankets

- Avoid pulling on electrodes

Recording Procedure

Once the patient preparation and surface electrode attachment has been performed as outlined earlier, the Holter ECG recording procedure is ready to begin. It is assumed that trained medical personnel who are familiar with ECG recording procedures will perform this task. The procedure involves the following steps:

- Prep patient and apply electrodes

- Connect the color coded cables to the patient electrodes

- Install the AA battery observing polarity indicators

- Install battery cover

- Start the Unit (see next section)

- Insert holter monitor into carrying case

- Enter start time in diary

- Review patient instructions with patient

Detailed Recorder Operation

Follow the *User Interface Screen* diagrams Figures 1 and 2 to assist with screen navigation.

While observing the correct polarity, insert a fresh battery to start the unit.

Screen and Key Navigation Information

The first screen to appear is the *About This Unit* screen. This screen stays on for only about 3 seconds after battery insertion and contains unit vital information. On first use the unit proceeds to the *Unit Settings* screen enabling the user to set their user preferences. These preferences are then stored internally in non-volatile storage for use during future sessions. On subsequent uses the *Unit Settings* and *Preferences* have already been stored, so the unit jumps forward to the *Review & Start* screen. The user should note that they can navigate back to prior screens using the ***<left>*** key to make configuration changes at almost any time. The user generally navigates using the ***<left>, <right>, <up>,*** and ***<down>*** keys. The ***<enter>*** key typically enables modification of a field or parameter and then accepts that modification.

The *About This Unit* screen displays the following information:

- Software Version
- Model
- Serial Number
- Hardware Version
- Battery Condition
- Date & Time

Press ***<right>*** to advance to **Unit Settings** screen

The *Unit Settings* screen displays the following information:

- Date
- Time
- Contrast
- Language
- Factory Defaults

To change the adjustable parameters:

- Use ***<up>*** and ***<down>*** keys to navigate to and select the parameter to be changed

- To change the <u>date</u> navigate until the arrow points to the date and press *<enter>* to enable modification
  - Adjust month using *<up>* and *<down>* then press *<right>*
  - Adjust first digit of day using *<up>* and *<down>* then press *<right>*
  - Adjust second digit of day using *<up>* and *<down>* then press *<right>*
  - Adjust the year using *<up>* and *<down>* then press *<enter>* to accept your

- To change <u>time</u> navigate to time and press *<enter>*
  - Adjust hour with *<up>* and *<down>* then press *<right>*
  - Adjust first digit of minute with *<up>* and *<down>* then press *<right>*
  - Adjust second digit of minute with *<up>* and *<down>* then press *<right>*
  - Adjust the AM/PM indicator with *<up>* and *<down>* then press *<enter>*

- To change <u>contrast</u> navigate to contrast and press *<enter>*
  - Adjust contrast with *<up>* for darker and *<down>* for lighter then press *<enter>*

- In multi-lingual units, to change the <u>language</u> navigate to Language and press *<enter>*
  - Adjust language selection with *<up>* and *<down>* then press *<enter>*

- To restore the unit to the <u>factory defaults</u>, navigate to Factory Defaults and press *<enter>*

- Press *<right>* to advance to *Preferences* screen

The *Preferences* screen displays the following information:

- MyName
- ID Style
- Template
- Cable

To change the adjustable parameters:

- Use *<up>* and *<down>* keys to select the parameter to be changed

- To change <u>MyName</u> navigate to MyName and press *<enter>*

- o Press *<up>* and *<down>* to select the desired character for the first position of the myname field then press *<right>*
- o Repeat the previous operation until all desired character positions have been filled with the desired data. After the last character is selected press *<enter*

- • To select the Patient ID Style navigate to ID Style and press *<enter>*
  - o Select Numeric or Alpha/Num character style using *<up>* and *<down>* then press *<enter*

Tip: The user should set the Patient ID style first then proceed with setting up a Patient ID template.

- • To enter a Template for the Patient ID navigate to Template and press *<enter>*
  - o Press *<up>* and *<down>* to select the desired character for the first position of the Template field then press *<right>*
  - o Repeat the previous step for each character in the template then press *<enter>*

Note: Each time a new Patient ID is to be entered, the template will be preloaded as a starting point for your data entry. Changing the field style will invalidate the template and force you to create a new template.

- • To change the Cable type
  - o The cable used on the unit determines the device mode of operation. Changing the mode requires insertion of the appropriate cable.
  - o 10-wire cable for 12-lead recordings
  - o 7-wire cable for 1, 2 or 3-channel recordings

Press *<right>* to advance to *Radio Settings* screen

The *Radio Settings* screen displays the following information:

- MyName

- Host

- PanID

- Channel

- Power

To change the adjustable parameters:

 Press ***<right>*** to advance to ***Review & Start*** screen.

The *Review & Start* screen displays the following information:

- Patient

- D.O.B

- Review Leads

- Start Transmitting

To change the adjustable parameters:

- Use ***<up>*** and ***<down>*** keys to navigate to the parameter to be changed. **Tip:** You can make setup easier by selecting the style first, either numeric only or alpha numeric. Next, set your template up so that you can minimize data entry on subsequent sessions. Then, proceed to setting the patient ID and date of birth (D.O.B.).

- To enter a <u>Patient</u> ID navigate to Patient ID and press ***<enter>***
    - o Press ***<up>*** and ***<down>*** to select the desired character for the first position of the ID field then press ***<right>***
    - o Repeat the previous operation until all desired character positions have been filled with the desired data. After the last character is selected press ***<enter>***. **Tip:** This task can be made less tedious by setting up a template and using this as the starting point to enter a Patient ID.

- To enter a <u>Date of Birth</u> navigate to D. O. B. and press ***<enter>***
    - o Adjust month using ***<up>*** and ***<down>*** then press ***<right>***
    - o Adjust first digit of day using <up> and <down> then press <right>
    - o Adjust second digit of day using with ***<up>*** and ***<down>*** then press ***<right>***

- o Adjust the year using *<up>* and *<down>* then press *<enter>*

- To <u>review the leads</u> and verify electrode connectivity navigate to Review Leads then press *<enter>*
  - o View each lead to verify a good signal and press *<right>* to advance to the next lead
  - o After all leads have been verified press *<enter>*

- To <u>Start Transmitting</u> the ECG signal navigate to Start Transmitting, verify the Patient ID and press *<enter>*

Upon pressing *<enter>* on the start transmitting item the unit will begin the data transmitting operation.

Recording Termination

Normal Termination

Disconnect the patient electrode leads

When the recording has completed, simply disconnect the patient electrode leads. The recorder is now free from the patient and the data stored in the PC can be retrieved and analyzed.

Retrieving Recording Data

Recorder Maintenance

Use a mild detergent and water on a soft cloth to clean the recorder and pouch. Remove any adhesives from the patient lead wires with an adhesive tape remover solution or swab. Use a mild disinfectant.

DO NOT use alcohol or acetone on the lead wires since they could stiffen and crack the insulating plastic.

DO NOT leave a battery in the recorder while not in use. Damage from battery leakage and corrosion could result.

FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE:
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
• Consult the dealer or an experienced radio/TV technician for help

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.