



## M3R Ambulatory 3-Channel Electrocardiograph (Holter Recording and Bluetooth Wireless ECG data transmission functions)

### *Continuous or Periodic 12-Lead Holter Recording*

- True 3-Channel Holter continuous recording
- No data compression
- Standard Secure Digital Memory Card (SD) for data storage, SD Memory Card is removable
- Duration up to 5-Days
- Uses standard AA batteries

### *Real-Time Bluetooth Wireless Data Transmission*

- Internal Bluetooth radio (bi-directional communications)
- Recorder programmable
- Patient / Subject bookup verification
- Transmits 3-Channel ECG continuous with no data compression
- Wireless connectivity to PC's, PDA's or cellular telephones

### *User Interface Display and Data entry keys*

- Display of realtime ECG waveforms, operating status and time of day
- Patient / Subject demographic entry and selection of operating mode
- Dual large event marker buttons for ease of use

### *High quality ECG*

- Data resolution of 0.5 microvolts
- Data is stored at up to 1000 samples / second
- Data is processed and stored without any compression
- Frequency Response of 0.05Hz to 100Hz

### *Pacemaker detection*

- Pacemaker data is sampled at greater than 10,000 samples/second to ensure accurate pacemaker pulse detection

### *Small, Light, Easy to use*

- Ergonomically designed to maximize Patient / Subject comfort

The M3R is a simultaneous realtime 3-channel (7 lead wires) ECG Holter Recorder. The M3R continuously acquires, stores and wirelessly transmits full 3-channel ECG data using industry standard 7 electrode configurations. The data is stored and transmitted in full fidelity. The M3R does not require data compression and does not use any data compromising lead derivation techniques. The data is stored and transmitted at a data sample rate of up to 1000 samples per second with the ultra-high resolution of 0.5 microvolt.



The M3R uses low cost standard SD data storage cards (no need to purchase "custom memory cards"). Use of a removable SD Card enables immediate recorder reuse. The unit can be configured to simultaneously transmit realtime ECG data over a Bluetooth wireless data link to remote personal computers. This provides the ability to perform realtime viewing and processing of the data on the personal computer. This capability enables access to the data over the internet, providing users with the capability to view and process the data from remote applications around the world. The M3R provides the clinician with the ability to wirelessly obtain realtime ECG data during the Holter procedure, eliminating the need to use separate devices to obtain Holter and realtime ECG data.

The M3R can be configured to record 2 channel (5-Lead wires) or 3 channel (7-Lead wires) data. The sample rates are configurable from 200 samples per second to 1000 samples per second and supports multiple day recording periods on a single set of "AA" batteries.

The built-in graphic LCD display provides display realtime of ECG traces, operating modes, and time of day. The M3R has configurable interface buttons to enable users to review and/or input Patient / Subject demographics and test procedure related data. Includes two large buttons for patient event activation.

The M3R uses state-of-the art signal processing and provides full support of pacemaker pulse detection.

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## Specification Summary

### Standards:

Meets applicable sections of ANSI/AAMI EC38-1998 "Ambulatory Electrocardiographs", ANSI/AAMI EC53:1995/(R)2001 "ECG Cables and Leadwires", and IEC 60601-2-47-2001 Particular requirements for the safety, including essential performance of ambulatory electrocardiographic systems

### Data Acquisition Types (types of data recorded and transmitted):

ECG Data:  
3-Channel ECG from 200 samples/second to 1000 samples/second  
Pacemaker detection:  
Samples for pacemaker pulses at greater than 10,000 samples/second  
Patient Movement/Position:  
Uses internal proprietary inertial measurement unit to monitor and record Patient movement and position/orientation  
Recorder status:  
Recorder operational status is internally monitored, stored and transmitted  
Patient Events  
Provisions for additional digital or analog data inputs

### User Interface:

Language independent  
Graphic Liquid Crystal Display (LCD)  
Programmable user interface  
Bluetooth Wireless  
SD card interface  
Dual event buttons

### Usability Enhancements:

Battery tests  
Hookup quality displayed on LCD and via Bluetooth Wireless  
Encoded unique id's embedded within stored and transmitted data

### External Data Interfaces:

Bluetooth Wireless interface  
SD Memory Card interface  
Compatible with M12A Analysis System Software

### Recording duration:

Up to 5-Days

### Recording bandwidth:

0.05 - 100 Hz 0.05 - 150 Hz

### Digital Resolution:

16-bit, 0.5  $\mu$ V/LSB

### Physical:

Size: 4.4 in x 3.1 in x 1.4 in  
Weight: 14 oz, including batteries, memory card, and leadwires  
Power: 2 AA batteries: alkaline, or rechargeable

### Storage capacity:

256 MByte, 1GByte Secure Digital memory card (uses standard FAT16 format)

### Sample Rates:

200, 500, 1000 samples/second

### Lead Configurations (cables and operating modes):

7-lead  
Input Channels Simultaneous acquisition of all leads  
Standard Leads Acquired Channel 1, Channel 2 and Channel 3

### Modes:

Recording – continuous or periodic  
Wireless data transmission – continuous or periodic

### Accessories:

Host SD card reader  
Host Bluetooth Interface  
Patient cable (7 lead)  
Recorder Carry Case  
User Manual  
Quick Step Instruction Sheet  
Holter Hook-up Kit

### Warranty and Service:

GI is dedicated to the highest quality of customer support  
The M3R has a 1 year warranty

### Approvals/Certifications:

ISO 13485, CMDCAS, FDA 510K, GMP-QSR, CE Mark, FCC, ICC

NOTICE: In the U.S.A., Federal Law restricts devices to sale by or on the order of a physician.  
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