



M12R Ambulatory 12 lead Electrocardiograph (Holter Recording and Bluetooth Wireless ECG data transmission functions)

Continuous or Periodic 12-Lead Holter Recording

- True 12-lead or 3-Channel Holter continuous recording
- No data compression
- Standard SD Card (Secure Digital Memory Card) for data storage, SD 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 hookup verification
- Transmit 12-lead or 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

Pacemaker detection

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

Patient Motion Logging

- Proprietary sensors monitor and record Patient / Subject movement position and orientation.

Small, Light, Easy to use

- Ergonomically designed to maximize Patient / Subject comfort

The M12R is a simultaneous realtime 12-lead ECG system and Holter monitor providing a single device which can perform all ECG data acquisition processes required for state-of-the-art ECG research and clinical evaluation applications. The M12R continuously acquires and wirelessly transmits full 12-lead ECG data using industry standard 12-lead electrode configurations. The data is stored and transmitted in full fidelity. The M12R does not use any 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 M12R 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 devices such as PC's, PDA's, and cellular telephones. This provides the ability to perform realtime viewing and processing of the data by remote devices. This capability enables realtime access to the data over the internet, providing users with the capability to monitor and process the data from remote applications around the world. The M12R is much more than a 12-lead Holter recorder – it also simultaneously provides diagnostic ECG data. This provides the clinician with the ability to wirelessly obtain full 12-lead realtime ECG data during the Holter procedure, eliminating the need to use separate devices to obtain Holter and diagnostic ECG data.

The M12R can be configured to record 12-Lead continuous, 3-Channel continuous or a combination of 12-Lead and 3-Channel recording. The sample rates are configurable from 200 samples per second to 1000 samples per second and supports recording periods up to 5-Days 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 M12R has configurable interface buttons to enable users to input Patient / Subject demographics and test procedure related data, and to select customizable operation modes. Includes two large buttons for patient event activation.

The M12R uses state-of-the art signal processing and provides full support of pacemaker pulse detection. M12R also uses a proprietary technology to record Patient / Subject physical activity, including movement and orientation/position. This information can be used to correlate Patient physical activity with ECG results.

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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:
Up to 12-lead ECG at 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 for 12-lead and Holter data

Recording duration:

Up to 5-Days

Recording bandwidth:

0.05 - 100 Hz in 200 samples/second mode
0.05 - 250 Hz in 500 and 1000 samples/second mode

Digital Resolution:

16-bit, 0.5 μ 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, or 2 GByte SD memory card (uses standard FAT16 format)

Sample Rates:

200, 500, 1000 samples/second

Lead Configurations (cables and operating modes):

7-lead, 12-lead
Input Channels Simultaneous acquisition of all leads
Standard Leads Acquired in 12-lead mode include I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

Modes:

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

Accessories:

Host SD card reader
Host Bluetooth Interface
Patient cable (7 & 12 lead versions)
Recorder Carry Case
User Manual
Quick Step Instruction Sheet
Holter Hook-up Kit
M12A Analysis System Software for 12-lead and Holter data

Warranty and Service:

GI is dedicated to the highest quality of customer support
The M12R 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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