



M12A Office Holter System

Data Acquisition

- Simple Acquisition wizard
- Bluetooth or SD card device initialization
- Patient demographic information can be entered on the PC or on the recorder
- Patient demographic entry allows search database for information.
- Bluetooth Preview automatically identifies all active recorders allowing immediate connection
- Bluetooth preview allows for ECG backup verification
- Supports the M3R and M12R Holter recorders

Review and Edit

- Review/Editing tool allows access to all the ECG data
- Arrhythmias organized by severity
- Beat edits performed using mouse or keyboard
- Insert Beat Capabilities
- On Screen Calipers to perform measurement of the ECG
- Automatic Arrhythmia Holter Analysis program
- Full report including optional 12-lead standard
- EMR Export of report in PDF format
- EMAIL of report in PDF format
- Optional QT Analysis program
- Export FDA HL7 XML QT information

Database Management

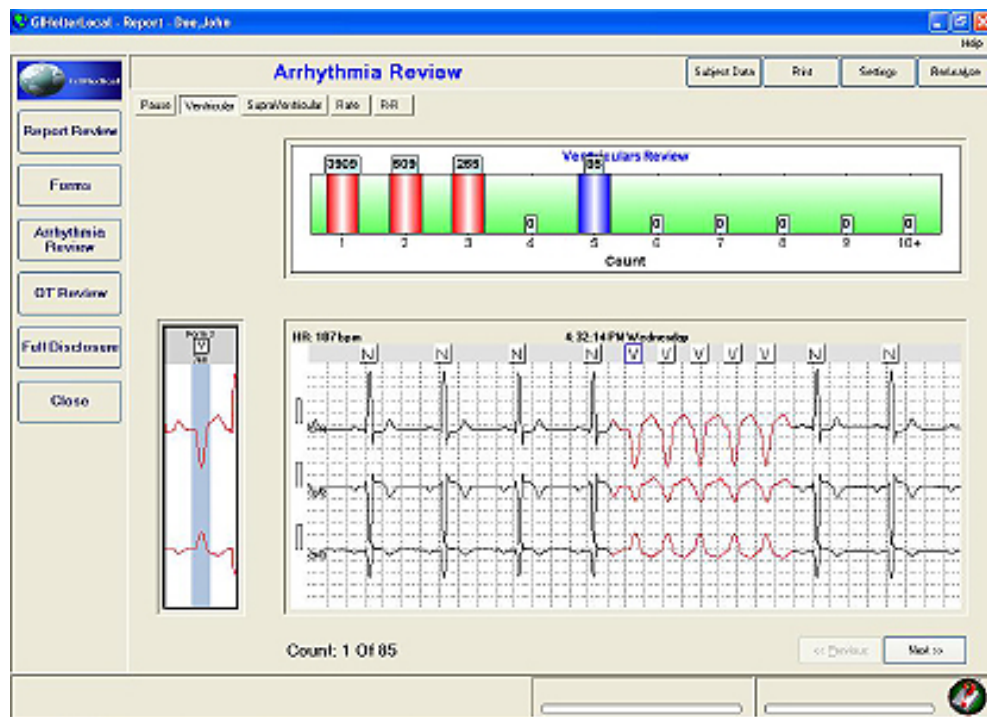
- SQL database
- User security management
- Software versioning management

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The M12A Office Holter System was specifically designed to meet the requirements of the Physician and Cardiology offices. The M12A Office Holter System contains all the features that are required to efficiently and accurately perform Holter ambulatory ECG procedures.

The M12A Office Holter system software installs on a standard PC system using Windows XP and Vista. It contains a full set of editing tools to review all the beats within the recording to ensure the most accurate Holter reports. The system is intended to operate with the M3R and M12R Holter recorders

The principal functions of the M12A Office Holter System are to perform patient hook ups, retrieve data from the recorders and review, analyze, store and print the data

When initializing the device for patient hookups the system can use an SD card or Bluetooth wireless interface. During the patient hook up, the system can connect to the recorder using a wireless interface to preview ECG data in real-time on the PC display. The usage of the SD card interface allows the recorder to be initialized at a remote site. In remote site scenarios the recorder can be configured to enter specific patient demographic information. This demographic information is recorded with the ECG waveform onto the SD card and subsequently uploaded into the M12A Office Holter System.

Recommended PC Requirements

Computers: Laptop, Tower or Desktop PC Configuration

Processor: P4 or higher

Ports: 2 USB

Memory: 1 GB or higher

Monitor: 1280 x 1024 true color, 17" or higher

Hard disk: At least 40 GB with 10 GB available

Operating system: Microsoft Windows XP SP2 or Vista

I/O: CD-R or CD-R/W

Peripherals: Keyboard, mouse and printer

Internet connection: required for product activation, direct software upgrades and on-line technical support.

Note: Installations include a free SQL Express license. This version of SQL allows up to 4 GB of data to be stored (this will accommodate approximately 50,000 Holter tests). Parts of the Holter datasets are stored external to database.

Software License: provides for installation of the application on one personal computer.

Specification Summary

Standards:

Meets applicable sections of ANSI/AAMI EC38-1998 "Ambulatory Electrocardiographs", ANSI/AAMI EC57:1998/(R)2003 "Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms", and IEC 60601-2-47-2001 Particular requirements for the safety, including essential performance of ambulatory electrocardiographic systems

Software Modules:

M12A Office Holter Software
QT analysis module

Analysis Options:

QT analysis is performed on a beat to beat basis for all selected channels

Report Formats:

Summary page, mini or diagnostic strips, tabular page, form page,
12-lead format in 3x4, 3x4R3, 6x2 and 12x1.

External Data Interfaces:

Internet Connectivity (wired and wireless options)
Bluetooth Wireless interface
SD Memory Card interface
Compatible with M3R 3-Channel Holter recorder or M12R 12-lead Holter Recorder

Lead Configurations (cables and operating modes):

7-lead, 12-lead Data Input Channels with 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

Warranty and Service:

GI is dedicated to the highest quality of customer support
Product Maintenance agreements are available for each software module

Approvals/Certifications:

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

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