



M12A Enterprise Holter System

Study Management

- M12A supports multiple independent studies
- User login selects which study to access
- Study centric configuration setting for monitoring modes
- Study centric demographic entry rules
- Study centric QT Epoch requirements

Acquisition Station

- Simple Acquisition wizard
- Bluetooth or SD card device initialization
- Patient/Subject demographic entry or search central site for information.
- Provides a list of active recording devices allowing immediate connection
- Monitored ECG data segments can be printed, reviewed and analyzed locally, then saved to central site
- Epoch Acquisition mode connects when required to active device storing ECG data for each QT Epoch
- Each epoch of data or the entire recording can be saved to the central site
- Acquisition station exchanges data with central site via the internet

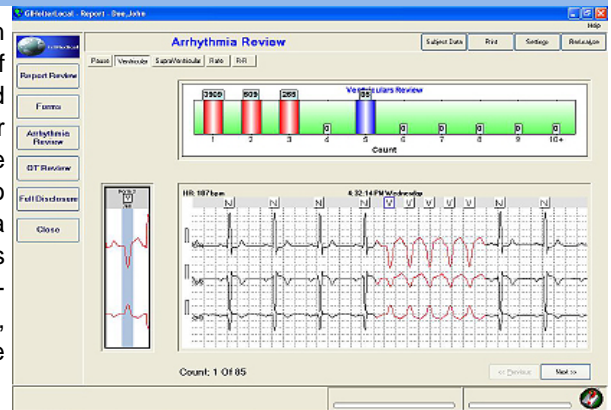
Data Reviewer Station

- Includes all acquisition station features
- Provides site centric list of subjects
- Review/Editing tool allows access to all the ECG data
- Traditional Arrhythmia Holter Analysis program
- QT Analysis program
- Full report including 12-lead standard
- Export FDA HL7 XML QT information
- Data reviewer station exchanges data with central site via the internet

Central Site Data Management

- Back-end application for collecting information from remote sites
- SQL database
- User security management
- Remote Client Software versioning management

The M12A is a Clinical Research System that provides a suite of data management, analysis and acquisition software modules for Drug Study applications. The M12A provides the capability to manage the data acquisition, data analysis, data storage functions required for Clinical Research/Drug Study applications, and is scalable to support multiple drug studies.



The Clinical Research System software architecture allows for multiple remote sites to exchange data over the internet to a central site (including full support of wireless internet connectivity options). The remote site application is intended to operate with the M12R 12-lead ECG system and Holter monitor device. The M12A Clinical Research System supports several models including central site Study Management Stations, Data Acquisition Stations and Data Reviewer Stations. The central site Study Management Stations provide the back-end support for collection of data from the remote sites/stations, security management and other administrative features.

The M12A Data Acquisition Station and Data Reviewer Station software run on a PC or Laptop and uses internet connection to transfer data to the central site Study Management Stations.

The principal function of the M12A Data Acquisition Station is to manage the initialization, monitoring and upload of data to the central site. For initializing the device the Data Acquisition Station can use an SD card or Bluetooth wireless interface. During actual acquisition the station can connect to the active device using a wireless interface to collect and present ECG data in real-time on the PC display. This ECG data can be locally reviewed, analyzed, printed and saved to the central site. Epoch acquisition modes sequence the station to automatically connect to the appropriate device to collect data continuously, or periodically, at specified times from the data recording device. The collected data can be reviewed, locally and/or remotely, and saved to the central-site for further analysis.

Data Reviewer Stations enable review, analysis, storage and printing of the data at local and remote sites. This provides multiple users with the ability to view and analyze the data per the user/system configurations that have been established by the Study Management Station. The system supports connections to additional data analysis modules and provides the ability to use third party data analysis and processing modules for custom applications.

The M12A software system is modular, enabling each system component to be run on different PC's at different locations throughout the world to support worldwide collaborative applications. It is also possible to run the entire system on a single PC at a single location for specific isolated study applications. This modular configurability enables the M12A to support requirements for virtually any Clinical Research/Drug Study.

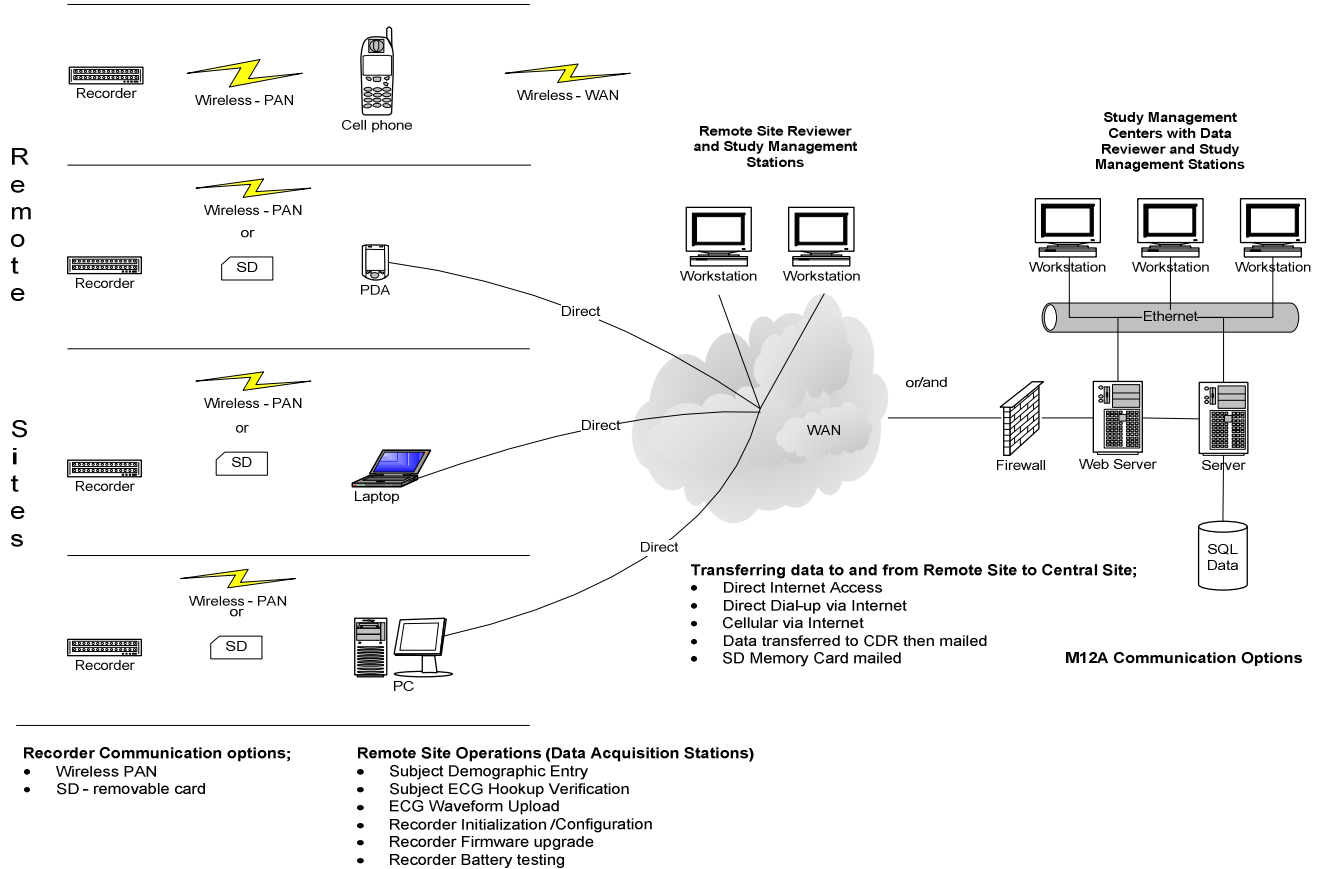
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System Architecture Example



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:

Study Management Station
Data Acquisition Station
Data Reviewer Station
QT analysis module

Analysis Options:

QT
Arrhythmia

External Data Interfaces:

Internet Connectivity (wired and wireless options)
Bluetooth Wireless interface
SD Memory Card interface
Compatible with 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, CMDCAS, FDA 510K, GMP-QSR, CE Mark, FCC, ICC

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