

OPERATION MANUAL

IQmarkTM
Digital ECG

Version 8.0.1



TABLE OF CONTENTS

A WORD OF THANKS	III
PRECAUTIONS	V
I. GENERAL INFORMATION	1
A. DESCRIPTION	1
B. NECESSARY COMPUTER SKILLS.....	2
C. CONFIGURATIONS	2
<i>Typical PC Configuration.....</i>	2
<i>Thin Client Configurations</i>	2
D. SYSTEM SPECIFICATIONS.....	5
II. SYSTEM INSTALLATION	6
A. COMPUTER REQUIREMENTS.....	6
B. HARDWARE SETUP	6
C. SOFTWARE INSTALLATION.....	7
<i>Windows Taskbar</i>	7
<i>Screen Saver.....</i>	8
<i>Installation Steps for IQmark Diagnostic Workstation.....</i>	8
D. CONNECTING THE IQMARK DIGITAL ECG MODULE	8
<i>Serial-Type ECG module.....</i>	8
<i>USB-Type ECG module</i>	8
E. CONFIGURING THE IQMARK DIGITAL ECG	9
<i>Configuring for Serial-Type ECG Module</i>	10
<i>Configuring for USB-Type ECG Module.....</i>	10
<i>Thin Client Channel Setting.....</i>	10
<i>Database Settings.....</i>	11
<i>List Management.....</i>	11
<i>ECG Settings.....</i>	13
III. OPERATION.....	19
A. INTRODUCTORY NOTES	19
B. PREPARATION	19
<i>Instructions for Performing ECG Acquisition</i>	20
C. STARTING THE PROGRAM	21
D. OPENING SCREEN	21
<i>STAT ECG.....</i>	22
E. TESTING A NEW PATIENT	23
<i>Live ECG</i>	24
F. REVIEWING PATIENT REPORTS.....	26
<i>ECG Report Review</i>	27
<i>Editing Diagnostic Statements</i>	27
<i>ECG Report (Details) Review.....</i>	28

	<i>Serial Comparison</i>	30
	<i>RR Variability Report Review</i>	31
APPENDIX		33
A.	OPERATIONS AT A GLANCE	33
B.	TROUBLESHOOTING GUIDE	34
C.	MAINTENANCE AND STORAGE OF THE ECG MODULE	38
	<i>Preventative Inspection</i>	38
	<i>Cleaning</i>	38
	<i>Storage</i>	38
D.	MAINTENANCE AND STORAGE OF 10-LEAD RESTING ECG PATIENT CABLE	38
	<i>Instructions for Use</i>	38
	<i>Cleaning</i>	39
	<i>Disinfection</i>	39
E.	RADIO AND TELEVISION INTERFERENCE	40
F.	EMC REQUIREMENTS FOR THE IQMARK DIGITAL ECG	40
G.	CUSTOMER SUPPORT	45
	<i>Warranty</i>	45
	<i>Return Materials Authorization</i>	45
	<i>Shipping</i>	45
H.	SAFETY AND INTERNATIONAL SYMBOLS	46
I.	GLOSSARY	47
IV.	IQMARK DIGITAL ECG SERVICE MANUAL	48
A.	INTRODUCTION	48
B.	THEORY OF OPERATION	48
	<i>10-Leadwire Patient Cable</i>	49
	<i>ECG Buffer Amplifiers</i>	49
	<i>Instrumentation Amplifiers</i>	49
	<i>Filters and Gain Amplifiers</i>	50
	<i>Analog to Digital Conversion</i>	50
	<i>Microcontroller</i>	50
	<i>Isolated Serial Interfaces</i>	51
	<i>Lead-Off Detector</i>	51
	<i>Pacemaker Detector</i>	51
	<i>DC-DC Power Converter</i>	51
C.	SYSTEM MAINTENANCE AND OBTAINING SERVICE	52

A Word of Thanks

Thank you for purchasing the IQmark Digital ECG. Midmark has used the latest microelectronic and computer software technology to develop a compact, low-maintenance and high-quality ECG system. Our goal is to enable healthcare professionals to provide quality and efficient patient care. With that in mind, our product is designed with intuitive layouts and features that will enable more physicians to conduct office-based tests, which will result in more timely diagnoses and enhanced patient outcomes.

We believe you will be pleased with the user-friendly operation of our product and with your results. As your partner in healthcare, we look forward to working with you in the coming years as we develop even more sophisticated diagnostic technology for the cardiopulmonary field. Your thoughts, questions, and comments about our product are welcomed.

Midmark Diagnostics Group.
800-624-8950, ext. 2
www.midmark.com

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Physician's Responsibility

The interpretations provided by the Midmark IQmark Digital ECG are for the exclusive use of licensed physicians or personnel under their direct supervision. Not all ECG abnormalities can be detected by computerized / automated ECG analysis algorithm. The suggested interpretation, including numerical and graphical results, should be examined with respect to the patient's overall clinical condition.

It is the responsibility of the physician to ensure proper administration of the test, making a diagnosis, obtaining expert opinions on the results, and instituting the correct treatment.

Notice

The information in this manual is subject to change without notice.

Midmark Diagnostics Group shall not be liable for technical or editorial omissions made herein, nor for incidental or consequential damages resulting from the furnishing, performance, or use of this guide.

This document may contain proprietary information protected by copyright. No part of this document may be photocopied or reproduced in any form without prior written consent from Midmark Diagnostics Group.

IQmark and IQpath are registered trademarks of Midmark Diagnostics Group.

Windows is a registered trademark of Microsoft Corporation.

Pentium is a registered trademark of Intel Corporation.

Precautions

Read the following precautions to ensure proper operation of this instrument.

1. Familiarize yourself thoroughly with the operations and procedures of the instrument prior to use.
2. Installation and maintenance of the instrument:
 - Install and keep the instrument away from splashing water.
 - Do not install the instrument where humidity, ventilation, direct sunlight or air containing dust, salt, sulfur, etc. might affect it.
 - Protect the instrument from shock and vibration while transporting it.
 - Do not install the instrument in a chemical storage area or where gas is generated.
3. Preparation of the instrument prior to operation:
 - Verify proper instrument operation.
 - Check that all cable connections are safe and secured.
 - When in use with additional equipment, such as a computer, request the assistance of personnel familiar with the additional equipment, if needed.
4. Observe the patient and instrument closely during use. If any abnormality is observed, immediate proper action, such as stopping the operation of the instrument, should be taken for the safety of the patient.
5. Keep the instrument clean to ensure trouble-free operation for the next use.
6. In case of a malfunction, call a Midmark Support Services at (800) 624-8950, ext. 2 and describe the problem precisely.
7. Inspect the instrument and accessories regularly.
8. Do not make any modifications to the instrument.
9. Environmental operating limits:

Operation:

 - 59 to 95 °F (15 to 35 °C)
 - 30 to 75% humidity (non-condensing)
 - 760mm Hg +/- 20%.

Storage/Shipping (batteries removed):

 - 4 to 120 °F (-15 to 50 °C)
 - 30 to 95% humidity (non-condensing)
 - 760mm Hg +/- 20%

 **DANGER:** There is a possible explosion hazard if used in the presence of flammable anesthetics.

10. The **IQ**mark Diagnostic Workstation and ECG have been tested for proper function with the Off-The-Shelf (OTS) Operating Systems (OS) specified in this manual. Do not operate the **IQ**mark Diagnostic Workstation and ECG with an operating system

other than the OTS OS specified. Future releases of currently approved operating systems should not be used until Midmark has had an opportunity to test the ECG with them. Before updating your operating system, contact Midmark for the latest OTS operating systems information.

-  **CAUTION:** Replace the patient cable with Midmark patient cables equipped with built-in defibrillation protection. Contact Midmark for cable replacement.
-  **CAUTION:** Contact Midmark for any servicing questions.

I. General Information

A. Description



Figure 1-0 *The IQmark Digital ECG (serial-type - with On/Off switch)*



Figure 1-1 *The IQmark Digital ECG (USB-type - without On/Off switch)*

NOTE: This manual is intended for **IQmark** Diagnostic Workstation users. If you are using your IQmark Digital ECG through an EMR, please contact Midmark Support Services for assistance with installation, setup and operation.

The IQmark Digital ECG is a portable device that converts a supported Microsoft Windows-based personal computer (PC), be it desktop, laptop, notebook or pen-based, to an electrocardiograph with interpretive capabilities. The device is electronically isolated from the PC and connects to it directly through the USB port or serial port.

Together with **IQmark** Diagnostic Workstation, the IQmark Digital ECG makes it easy to record 12-lead ECG, interpret them, archive the reports for future reference and share them with your colleagues via networks or email. As simple to use as a traditional office

ECG device, it features fully integrated PC technology and a host of advanced diagnostic features.

NOTE: There are two types of IQmark Digital ECG acquisition modules: a serial (COM) port type and a USB port type, both are designed for use with a Microsoft-based computer. The serial-type ECG module requires batteries and has a power switch, indicated by ; the USB-type ECG module does not require batteries and does not have a power switch. This manual is written for both types of modules.

B. Necessary Computer Skills

This manual assumes that you are already capable of using Windows-based applications, that you have some understanding of how a PC works, and that you are familiar with the basic operations of Microsoft Windows. If this is true, you will have no problem using the product. However, in the event that you have any technical questions or problems, please refer to *Appendix B, Troubleshooting Guide* for immediate assistance. Support Services information is listed in *Appendix G, Customer Support*.

C. Configurations

Typical PC Configuration

The block diagram below illustrates the standard configuration of the IQmark Digital ECG system. The primary components are a Windows-based PC, a printer, and the IQmark Digital ECG acquisition module. A portable computer is recommended if mobility is a consideration. Please refer to this diagram when setting up your IQmark Digital ECG system.

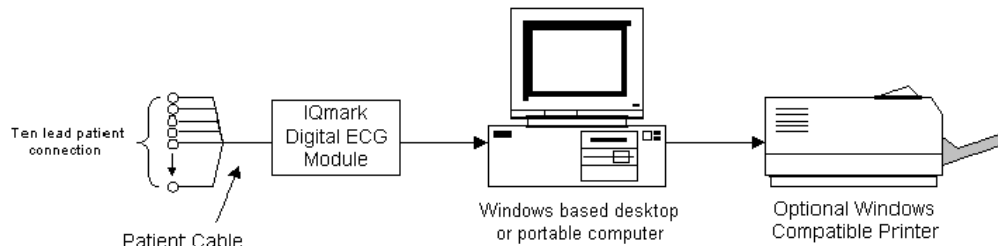


Figure 1-2 *Block Diagram for the IQmark Digital ECG system*

Thin Client Configurations

If you have a thin client environment, you can install the software on the Terminal Server and operate the IQmark Digital ECG through a thin client terminal.

IQmark Diagnostic Workstation supports two thin client configurations: **IQpath Virtual Channel Solution** and **COM port mapping**. **IQpath** uses either USB or serial port versions of the IQmark Digital ECG in high-latency, limited bandwidth network configurations with Windows-based PC clients. For non-Windows thin client devices on low-latency

high-speed networks, use the serial port versions of the IQmark Digital ECG and connect to client devices via COM port mapping.

Setting up any application in a network environment typically requires special access rights and knowledge of the network. Please have your system administrator install and configure the **IQmark** Diagnostic Workstation to your office environment.

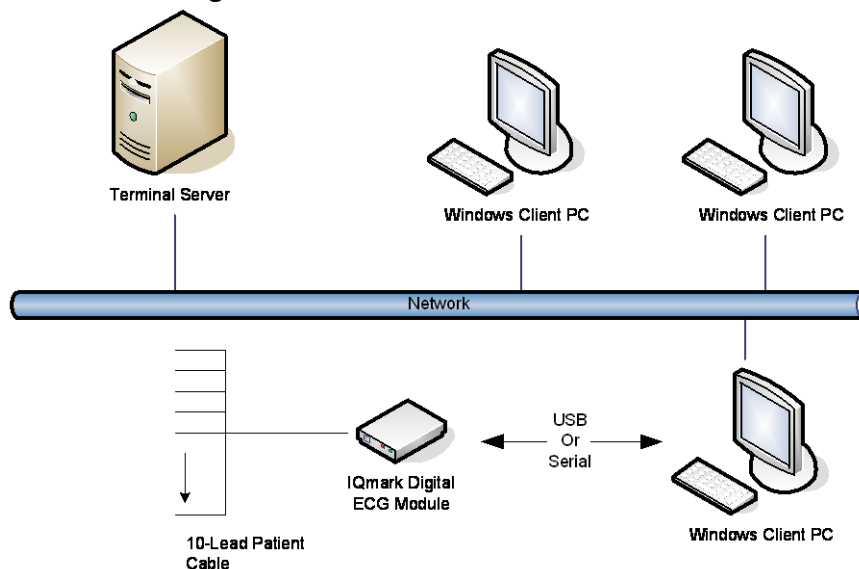
Thin Client Using the IQpath Virtual Channel Solution

IQpath provides the following advantages over COM port mapping:

- Improved performance on high-latency, low-bandwidth, high-loss networks.
 - Microsoft Terminal Services: Improvement is approximately 10-to-1 in latency tolerance.
 - Citrix ICA: Improvement is approximately 40-to-1 in latency tolerance.
- No COM port mapping is required.
- The USB version of the ECG module is compatible.
- Improved device auto-configuration and diagnostics.

NOTE: **IQpath** has specific requirements for computer hardware, software and network performance. System administrators should read *Setup Manual: IQpath Thin Client Virtual Channel Software* before installing, configuring and using this software in a thin client environment.

The following block diagram describes **IQpath**. In this thin client environment, the client computers must be running Windows XP SP2 or Windows Vista:



To use **IQpath**, load **IQmark** Workstation on the terminal server and install one of the following software components on each client PC that you intend to use for data acquisition:

- **IQpath** for Microsoft Terminal Services if you are using Microsoft Terminal Services (Microsoft RDP).

- IQpath for Citrix ICA if you are using Citrix software on your clients and servers.

These software products are provided separately and may be obtained by contacting Midmark at (800) MIDMARK (643-6275).

Once you have installed the software on the server and client computers, you must configure the software for virtual channel operation as described in *Section II-D Connecting the IQmark Digital ECG Module* and *Section II-E Configuring the IQmark Digital ECG*.

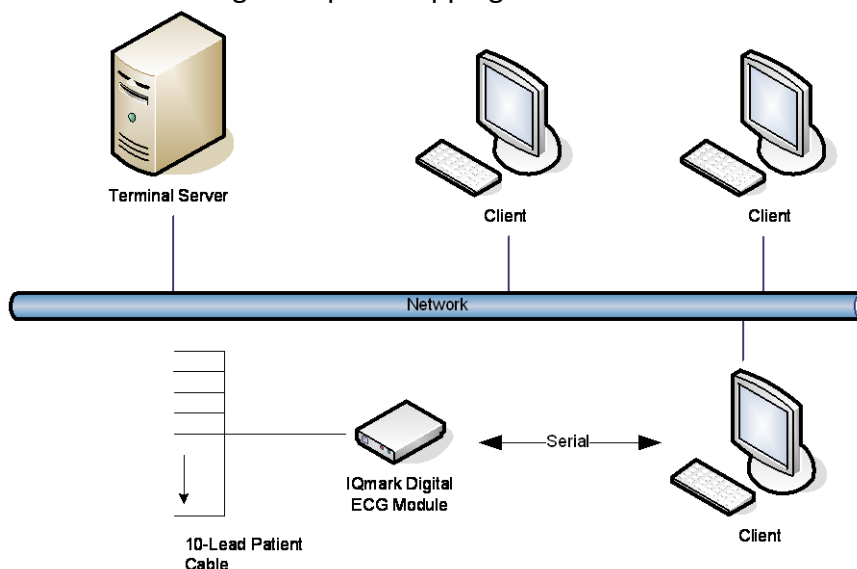
Thin Client Using COM Port Mapping

COM port mapping refers to a configuration in which the ECG device connects to a serial port of the client and the server is configured so that logical COM ports on the terminal server are mapped to the physical COM ports of the client.

If you are using non-Windows-based thin client terminal devices on a low-latency, high-speed network you must use the serial port versions of the ECG device and configure the thin client server for COM port mapping.

NOTE: In order to use the COM port mapping solution in a thin client environment, the computer hardware and software as well as the network must meet stringent performance requirements. System administrators must read the document *Setup Manual: Midmark Products over Thin Client Environments* before installing, configuring and using this software in a thin client environment using COM port mapping.

The following block diagram illustrates the use of the ECG device in a thin client environment using COM port mapping:



To use the ECG device in this configuration, install **IQmark** Diagnostic Workstation on the terminal server and configure the server to map to the COM port on the client terminal.

System administrators should configure the terminal server for COM port mapping as described in the document entitled *Setup Manual: Midmark Products over Thin Client Environments*.

D. System Specifications

The following are the physical and performance specifications for the IQmark Digital ECG:

IQmark Digital ECG Performance Specifications	
Category	Specification
Intended Use	To provide 12-lead resting electrocardiograms, which permit the detection of abnormalities in the transmission of the cardiac impulse through the heart muscle; serves as an important aid in the diagnosis of heart ailments.
Physical Characteristics	• 2.8" (7.1 cm) x 5" (12.7 cm) x .88" (2.3 cm) (W x L x H) • 0.56 lb. (USB-type ECG module without batteries) • 0.66 lb. (serial-type ECG module with batteries) • Two 1.5V AA alkaline batteries (serial-type ECG module only) • 25 hours of "ON" time (serial-type ECG module)
Anatomical Sites	• Noninvasive device, 12-lead electrocardiogram
Safety Parameters	• Patient electrically isolated from main current supply. • Patient leakage current not to exceed 10 uA. • Ground leakage current not to exceed 50 uA.
ECG Acquisition	• 12 leads, simultaneous. • Input impedance > 100 MegaOhm • Frequency response 0.05-150 Hz –3 dB • Sensitivity: 5, 10, 20 mm/mV +/- 10% • Dynamic range: +/- 10 mV • ADC resolution: 13 bits at 2.44 uV/bit • Acceptable electrode offset: +/- 300 mV per AAMI and EC-11 specifications. • A/D 500 samples/sec.
Patient Connection	• 10-lead patient cable with RFI filter, defibrillator protection and patient isolation.
Monitor	• Varies by computer system, minimum 800x600 resolution
ECG Analysis & Measurement	• Midmark 12-Lead Resting Electrocardiogram Analysis Program.
Printer	• Windows-supported ink-jet or laser printer.
Paper	• Plain 8.5" x 11" (Letter size) or 210 mm x 297 mm (A4 size)

II. System Installation

 **NOTE:** Please call Midmark Support Services before installing and setting up your IQmark Digital ECG. Computers today are more complex than ever, coming with wide variations of software and hardware options, making your computer almost unique. Midmark wants to make sure that your ECG device is installed and configured as quickly and easily as possible. Please call 1-800-624-8950, ext. 2, and Support Services will make sure your system is up and running in no time.

A. Computer Requirements

The IQmark Digital ECG system employs 32-bit Windows-based medical software. In order to install and successfully use the ECG system, your computer must meet the following minimum requirements:

- Microsoft Windows-based PC with Windows 2000, XP or Vista
- Hard disk with a capacity of at least 1 GB of free space
- CD-ROM drive
- Intel Pentium IV or compatible microprocessor with 2.0 GHz or faster CPU speed
- VGA display accommodating 1024x768 or higher resolution with 16-bit color; for ease of use, a touch-screen flat-panel 17" or larger display is recommended.
- Minimum 1GB of RAM
- Microsoft Windows-compatible mouse
- Microsoft Windows-compatible keyboard
- One high-speed serial port (115 KB per second) or an USB port

B. Hardware Setup

1. Remove the IQmark Digital ECG from its packaging and verify that you have the following items:
 - IQmark Digital ECG data acquisition module
 - Operation manuals CD
 - Patient cable (10-lead)
 - 10 universal clips
 - Package of electrodes
 - Four (4) AA alkaline batteries (for serial-type ECG module)
 - USB to serial port adapter (for serial-type ECG module)

 **NOTE:** Please call your Midmark rep or Support Services to order an **IQmark** Diagnostic Workstation Installation CD, if needed.

2. For the serial-type ECG module, slide out and remove the battery door underneath the module and install 2 AA batteries. Be sure to follow the battery positions indicated. Replace the battery compartment door.
 - For the USB-type ECG module, no batteries are required.
3. Attach the patient cable to the 15-pin connector on the ECG acquisition module.



Figure 2.0 IQmark Digital ECG Acquisition Module.

C. Software Installation

NOTE: The following software installation information refers to **IQmark** Workstation only. If you are using your IQmark Digital ECG through an EMR, please contact Midmark Support Services for assistance with installation and setup.

The medical diagnostic application, IQmark Digital ECG, uses **IQmark** Diagnostic Workstation to manage patient records. When you install or upgrade the IQmark Digital ECG, **IQmark** Workstation is automatically installed or upgraded accordingly (see **IQmark** Diagnostic Workstation *Operation Manual* for further information).

You can also access other Midmark products, such as the IQmark Digital Holter, IQmark Digital Spirometer, Digital Stress, Vital Signs Interface and Weight/Scale Interface from **IQmark** Diagnostic Workstation. Call Midmark Sales Department for the latest information on available Midmark products.

NOTE: If you already have **IQmark** Diagnostic Workstation installed on your computer and you are now either upgrading or adding a new Midmark product, please **skip** this section and refer to the **IQmark** *Diagnostic Workstation Operation Manual* for installation information.

Before installing **IQmark** Diagnostic Workstation on your computer, it is important that you understand and carry out the following tasks:

Windows Taskbar

IQmark Diagnostic Workstation is designed to run as a full-screen program. For best results, the Windows Taskbar should not be displayed in order to provide maximum

display area. Place the mouse pointer on the blank portion of the Taskbar on the bottom of the screen, then right-click and select **Properties**. Check the *Auto-hide the taskbar* box to hide the taskbar when it is not in use; to display the taskbar when it is hidden, move your mouse cursor over the area where your taskbar is normally set, and it will reappear.

Screen Saver

If a screen saver or any energy saving feature is enabled on the computer, make sure that it does not activate and interfere with data acquisition during patient care. Refer to your computer or software manual for these settings.

Installation Steps for IQmark Diagnostic Workstation

 **NOTE:** Close all Windows programs before installing this software. Do not interrupt the installation program while it is running. The installation should take less than five minutes.

1. Insert the **IQmark** Diagnostic Workstation Installation CD into the CD-ROM or DVD-ROM drive. The installation starts automatically. If the installation does not start automatically, double-click **My Computer** on the desktop and double-click the CD-ROM icon to start.
2. Follow the instructions on the screen. For detailed installation, setup and detailed operation instructions, please refer to the ***IQmark** Diagnostic Workstation Operation Manual*.

D. Connecting the IQmark Digital ECG Module

Serial-Type ECG module

If you have a serial-type ECG module, attach the female end of the 9-pin communication cable to any available serial port on the PC. If you are using a USB port with the serial-type ECG module, install the USB to serial port adapter before you connect the ECG module to the Adapter. Secure the connections with the thumbscrews. Do not over-tighten.

 **NOTE:** Almost all USB to serial port adapters come with specific software drivers that must be installed prior to use. Before connecting the ECG module to any adapter, ensure that all software drivers have been installed according to the manufacturer's instructions.

USB-Type ECG module

If you received a USB-type ECG module, you can connect it to any available USB port on the computer **after** **IQmark** Diagnostic Workstation is installed. As with other USB devices, Windows will attempt to identify the ECG module the first time it connects to it. This may take a few seconds.

E. Configuring the IQmark Digital ECG

Through the **IQmark** Configuration program, you can customize **IQmark** Diagnostic Workstation and the IQmark Digital ECG for your operation. If you are using the database on your local and network computers, the configuration program also enables you to set your default database.

The configuration program can be accessed from the desktop by double-clicking the *IQmark Configuration* icon:



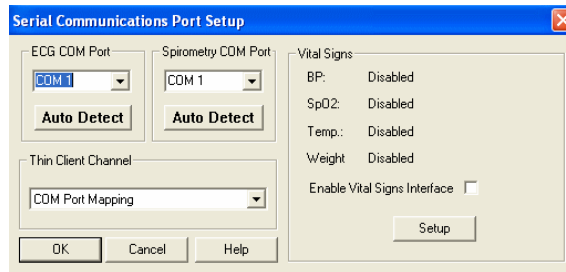
The *IQmark Configuration Settings* dialog box appears:

Complete the *Institution Name* and *Institution Address* boxes with information about your medical practice. The IQmark Digital ECG will display your institution name on each of the procedure screens and on printed reports. Enter a name that describes your practice or operation to enable other medical personnel to identify your reports.

You may choose between Metric and English units of measurement, and between the AC power source frequencies of 50 Hz or 60 Hz. The IQmark Digital ECG uses the latter information to filter out background noise introduced by the power source through its AC filter. In the United States, this frequency is 60 Hz. If you are using this product outside of the United States, please consult with the local power utility company to determine the appropriate frequency.

Configuring for Serial-Type ECG Module

If you have a serial-type ECG module, you can select the serial port for the ECG module in the configuration screen. Click **Serial Port** to open the following dialog box:

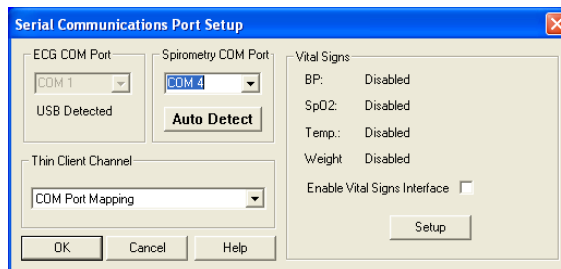


NOTE: The default serial communications port is COM 1.

Click **Auto Detect** to find the port that the ECG module is connected to; the ECG module must be connected to an available serial port on the computer. Confirm that a fresh set of batteries is installed in the ECG module and click **Auto Detect** for ECG COM ports. The result appears on the screen. Some ECG modules may need to be turned on manually for Auto Detect to work; press the  switch to turn on the module.

Configuring for USB-Type ECG Module

If you received a USB-type ECG module and it is already connected to the computer, the *ECG COM Port* setting will be disabled once it is detected.



Thin Client Channel Setting

The *Thin Client Channel* setting applies only if you are using IQmark Diagnostic Workstation in a thin client environment. This setting is ignored when the software is not running in a thin client environment. The drop-down list contains the following selections:

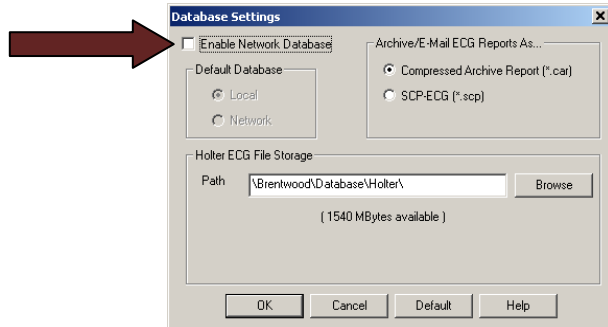
- COM port mapping (default)
- Microsoft RDP
- Citrix

Select *COM port mapping* if you are using IQmark Diagnostic Workstation in a thin client environment and are not using IQpath. If you are using IQpath, select Microsoft RDP or Citrix, depending on what your clients and servers are using. Please refer to the *Setup Manual: IQpath Thin Client Virtual Channel Software* for more information.

Database Settings

IQmark Diagnostic Workstation uses the local database by default. If using a network database, you can set the default to be either the local or network by clicking **Database Settings** on the *IQmark Configuration* screen.

Select a network database as the default by checking the *Enable Network Database* box then clicking **Network**. Refer to the *IQmark Diagnostic Workstation Operation Manual* for more details.



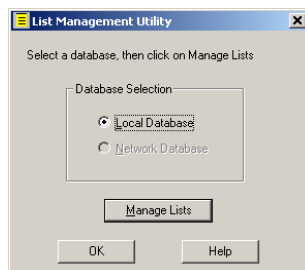
IQmark Diagnostic Workstation allows you to archive the ECG reports from the database as individual files. It also allows you to send the ECG reports using your default email program. The default format for this report is Compressed Archive Report (*.car). The SCP-ECG (*.scp) format is more popular in the European countries.

If you have purchased a Midmark Holter product, you also have the choice to select a different location to store your Holter ECG files.

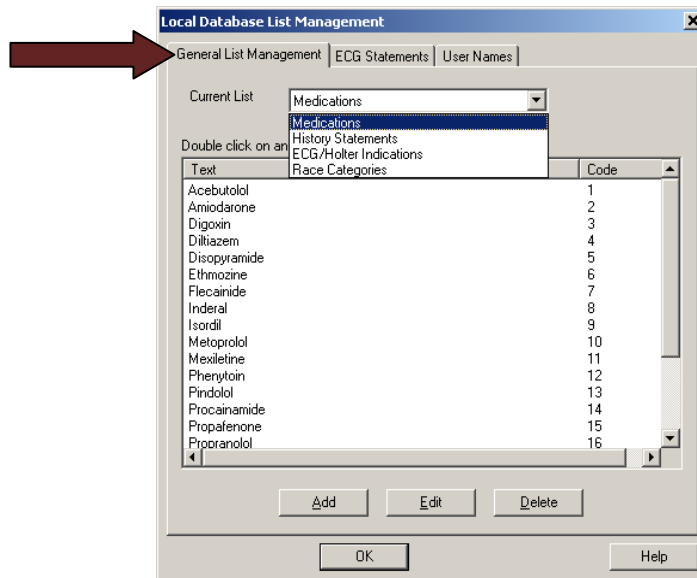
List Management

List Management enables you to add or customize medications, history statements, race categories, ECG/Holter indications and ECG diagnostic statements. You can also enter the doctors and technicians using IQmark Diagnostic Workstation. Once these lists are entered, you can later select them from the appropriate lists in the test without having to retype them.

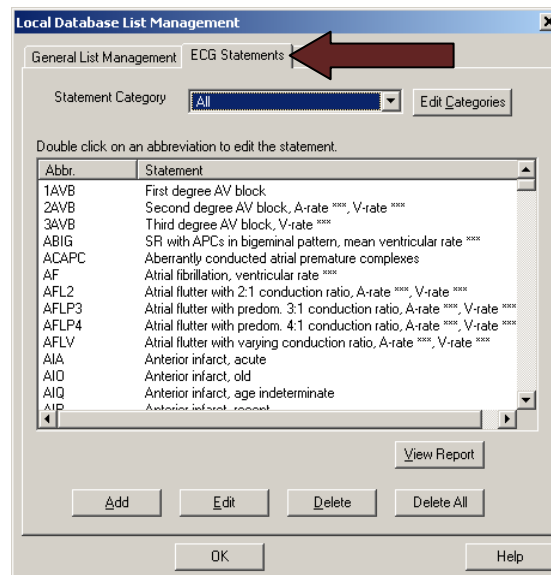
Click **List Management** in the *Configuration* screen and choose to configure the lists for your local database or network database. If the network database is not setup, the *Network Database* selection will be disabled as shown below.



Click **Manage Lists**; you can add, edit, or delete any item in the *Medications*, *History Statements*, *ECG/Holter Statements* and *Race Categories* lists.

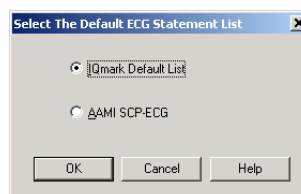


Select the *ECG Statements* tab to view the default ECG statements. These statements will be available when editing the ECG interpretations online.



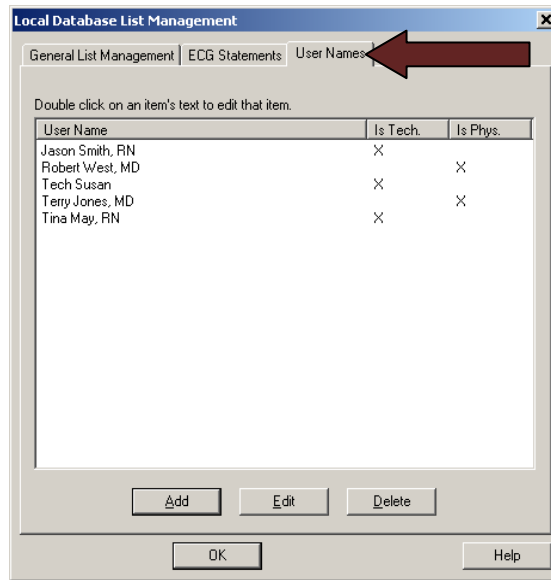
Delete All will delete all the ECG statements to enter your own diagnostic statements from scratch or choose from the two lists available through **Load Default Statements**.

The two ECG statement list options are *IQmark Default List* or *AAMI SCP-ECG*.



The IQmark Default List is the default list installed with IQmark Diagnostic Workstation.

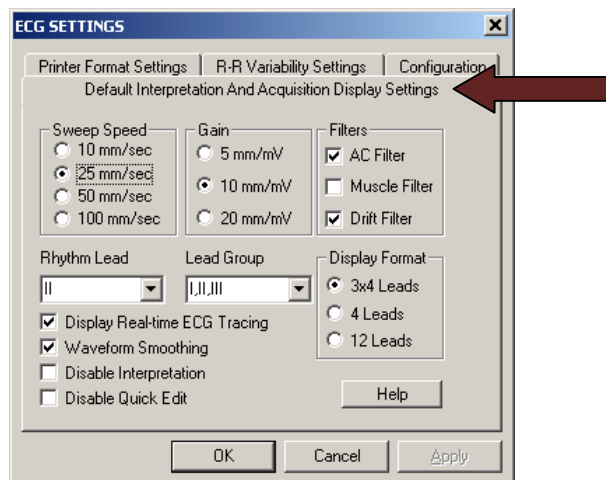
To enter the names of doctors and technicians who use IQmark Diagnostic Workstation, select the *User Names* tab and click **Add**. You can type in a user's name and define the user as a physician, technician, or both.



Click **OK** to close the *List Management* utility.

ECG Settings

Set the default settings to use for ECG tests by clicking **ECG Settings** from the IQmark *Configuration Settings* dialog box. The *ECG Settings* dialog box appears:

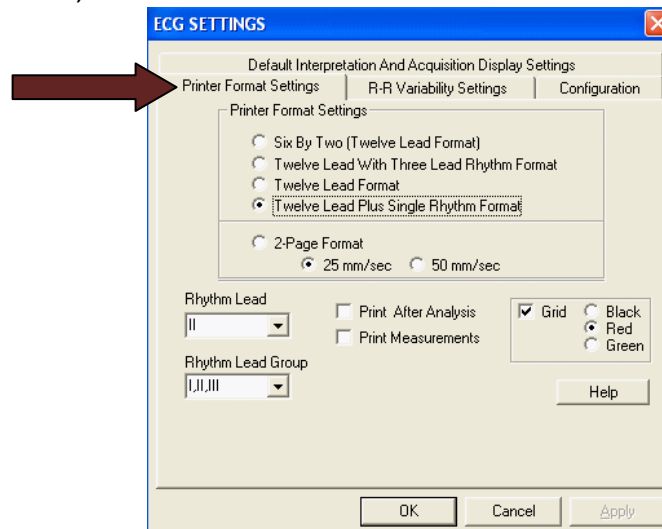


Default Interpretation And Acquisition Display Settings		
Item	Settings	Comments
Sweep Speed	• 10 mm/sec • 25 mm/sec • 50 mm/sec • 100 mm/sec	Default setting is 25 mm/sec. <i>Sweep Speed</i> setting only applies to real time ECG display. The ECG report only prints at 25mm/sec scale, except if a <i>2-Page Format</i> is selected. See <i>Printer Format Settings</i>.
Gain	• 5 mm/mv • 10 mm/mv • 20 mm/mv	½ gain Standard gain (default setting) 2X gain
Filters	• Muscle: On/Off • AC: On/Off • Drift: On/Off	Default settings are MYO: Off, AC: On, Drift: On. See Note following this table.
Rhythm Lead	Select any lead	Default setting is Lead II. This setting applies to both the 3x4 and 4-lead display formats, and to the RR Variability analysis rhythm lead.
Lead Group	• I, II, III • aVR, aVL, aVF • V1, V2, V3 • V4, V5, V6	Default setting is I, II, III. This setting applies to the 4-lead display format.
Display Format	• 3x4 leads plus rhythm • 4 leads • 12 leads	Default setting is 3x4 plus rhythm lead.
Display Real-time ECG Tracings	On/Off	Default setting is <i>On</i> (checked). If this setting is <i>Off</i> (cleared), the live ECG screen will not display real time tracings while acquiring ECG data. Set it to <i>Off</i> only if your computer has problem with displaying real-time ECG.
Waveform Smoothing	On/Off	Default setting is <i>On</i> (checked). Controls how the ECG waveforms are drawn in the real-time display screen. Selecting <i>On</i> produces smoother waveforms. In contrast, selecting <i>Off</i> (cleared) may produce waveforms that appear jagged.  NOTE: If you are using a slow PC or having delayed ECG tracing, set to <i>Off</i>.

Disable Interpretation	On/Off	Default is <i>Off</i> (cleared). If <i>On</i> (checked), the ECG will not produce any diagnostic statements and the interpretation portion of the report, <i>ECG Review and Edit</i> screen will be blank.
Disable Quick Edit	On/Off	Default is <i>Off</i> (cleared) If <i>On</i> (checked), the software defaults to free text entry method for adding any diagnostic statements, instead of the <i>Quick Edit</i> feature of the <i>Add a Statement</i> dialog box. See <i>Editing Diagnostic Statements</i> .

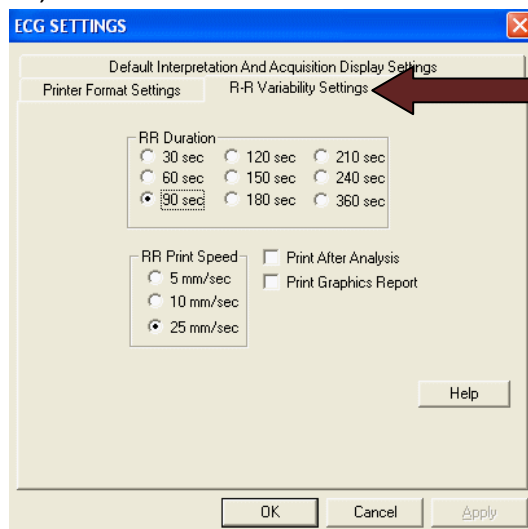
 **NOTE:** For all pacemaker patients, it is **strongly recommended** that the ECG be performed with all filters turned off, particularly the MYO filter. Any artifacts in the ECG should be corrected at the source, i.e., making sure the electrode sites are clean of lotion or body hair, the electrodes are fresh and sticky and are adhering properly on the skin. Refer to *ECG Signal Quality Problems* in the *Troubleshooting Guide* for more details.

Click the *Printer Format Settings* tab of the *ECG Settings* dialog box to select the default ECG report format, as shown below:



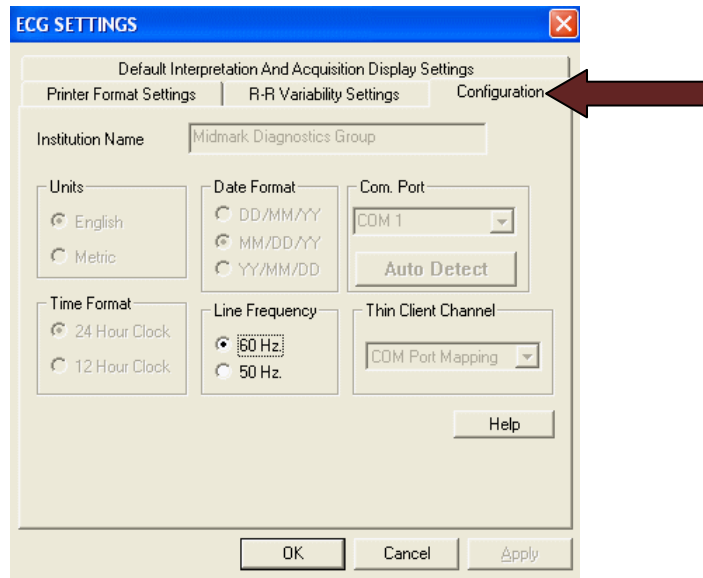
ECG Report Printer Format Settings		
Item	Settings	Comments
Printer Format Settings	• 6 x 2 format • 12-lead with 3-lead rhythm format (3x4+3) • 12-lead format (12x1) • 12-lead plus single rhythm format (3x4+1) • 2-Page Format	Default setting is 12-lead plus single rhythm format. <i>2-Page Format</i> prints leads I, II, III, aVR, aVL, and aVF on the first page and V1-V6 on the second page. You can select the print scale of 25 mm/sec or 50 mm/sec when printing in 2-page format. Other formats will always print at 25mm/sec scale.
Rhythm Lead	Select any lead	Default setting is II. Applies to 12-lead with single rhythm format.
Rhythm Lead Group	• I, II, III • aVR, aVL, aVF • V1, V2, V3 • V4, V5, V6	Default setting is I, II, III. Applies to 12-lead with 3-lead rhythm format above.
Print After Analysis	On/Off	Default setting is <i>Off</i> (cleared). When <i>On</i> , the resting ECG report is automatically printed following analysis. NOTE: For speed, set to <i>Off</i> and print manually.
Print Measurements	On/Off	Default setting is <i>Off</i> (cleared). When <i>On</i> , the detailed measurement matrix report is printed automatically with the ECG report.
Grid	On/Off Black, Red or Green	Default setting is <i>On</i> (checked). When on, the grid is printed in the selected color if a color printer is used.

Click *RR Variability Settings* tab of the *ECG Settings* dialog box to preset the default test duration and report format, as shown below:



RR Variability Settings		
Item	Settings	Comments
RR Duration	• 30 sec • 60 sec • 90 sec • 120 sec • 150 sec • 180 sec • 210 sec • 240 sec • 360 sec	Default setting is 90 sec. This setting defaults the length of the rhythm strip acquired through Start RR test. The rhythm strip is defined in the ECG Settings (Fig. 2.11).
RR Print Speed	• 5 mm/sec • 10 mm/sec • 25 mm/sec	Default setting is 25 mm/sec. This setting defines the print scale of the ECG tracings for RR test.
Print After Analysis	On/Off	Default setting is <i>Off</i> (cleared). When set to <i>On</i> (checked), the RR test report is printed automatically following successful completion of RR test analysis. NOTE: For speed, set to <i>Off</i> and print manually.
Print Graphics Report	On/Off	Default setting is <i>Off</i> (cleared). When set to <i>On</i> (checked), the graphic report, which includes the RR Trend and RR Histogram, is printed automatically with the RR rhythm strip report.

Click the *Configuration* tab of the *ECG Settings* dialog box to access the *ECG Configuration* settings.



Most of the settings on this screen are controlled by the *IQmark Configuration Settings* and therefore cannot be changed, except the line frequency and COM port auto detection for ECG module. You can make changes to these settings on either screen.

Click **OK** on the *ECG Settings* dialog box if you want to save any changes you made. This will return you to the *IQmark Configuration Settings* dialog box. Please refer to the appropriate operation manuals for details on Holter, Spirometry and Stress settings.

Once you are satisfied that the configuration settings are set appropriately, click **OK** on the *IQmark Configuration Settings* dialog box to store the settings. These settings will become effective the next time *IQmark Diagnostic Workstation* is started. If you decide not to make changes to the configuration, click **Cancel**. You can also click **Default** to restore the *IQmark* configuration settings (except *Institution Name*, *Address* and *List Management*) to their default values.

III. Operation

WARNING

The IQmark Digital ECG module has been designed and tested to meet IEC 60601-2-25 and AAMI EC11 defibrillation protection standards. In the event of defibrillation, follow the instructions on your defibrillator and adhere to all warnings and cautions.

A. Introductory Notes

This manual describes how to use the various IQmark Digital ECG features in the operational sequence most new operators will follow. However, this does not mean that you are restricted to following this particular sequence. Many of the features are interconnected and can be accessed from more than one screen. The menu bar, buttons or tabs on each screen lead you to a different screen or feature. To enter any of these screens, click once on the appropriate selection.

Of course, there are certain sequences that must always be followed, such as entering a patient's medical data prior to acquiring an ECG. Overall, we believe that you will find this program to be both user-friendly and flexible.

For your convenience, we have included a condensed guide to the operation of the IQmark Digital ECG with new patients in *Appendix-A, Operations at a Glance*.

B. Preparation

Careful preparation of the patient's electrode sites is a prerequisite for obtaining an interference-free ECG and accurate result. The skin is naturally a poor conductor of electricity and frequently creates artifact that distorts the ECG signal due to dry or dead epidermal cells, oils, sweat and dirt. By performing methodical skin preparation, you greatly reduce the resistive barrier that causes muscle noise and baseline wander, ensuring high-quality signal and test data.

NOTE: The live ECG acquisition screen will show the signal tracings after all limb leads have been connected. When the right-leg (RL) lead becomes detached, the system behaves as if all electrodes were disconnected.

Instructions for Performing ECG Acquisition

NOTE: Please refer to the *Quick Reference User's Guide – Performing a 12-lead Resting ECG Test* for more detailed instructions.

Patient Position

The patient should be placed comfortably in a supine position. Any variation should be noted on the ECG report.

Electrodes

When using disposable electrodes, check to ensure the electrode is fresh and sticky. Always make sure your fingers are clean and free of lotion when handling electrodes.

Skin Prep

Patients with excessive chest hair should be shaved at the electrode site. Abrade these areas with fine sandpaper or an abrasive pad, and then clean with alcohol-saturated gauze. Allow the skin to air dry.

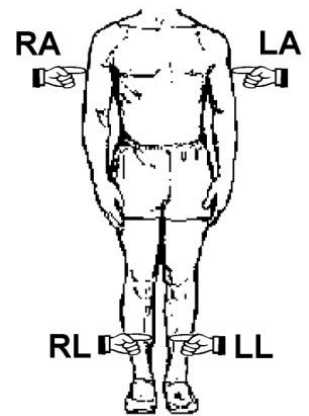
Limb Lead Placement

RA (White) – Right Arm electrode is placed on a distal portion of the right lateral side of the upper arm below the shoulder.

LA (Black) – Left Arm electrode is placed on a distal portion of the left lateral side of the upper arm below the shoulder.

RL (Green) – Right Leg electrode is placed on the inside calf, midway between knee and ankle.

LL (Red) – Left Leg electrode is placed on the inside calf, midway between knee and ankle.



Precordial Lead Placement

V1 (Red) – 4th intercostal place at the right margin of the sternum.

V2 (Yellow) – 4th intercostal place at the left margin of the sternum.

V3 (Green) – Midway between V2 and V4 (on top of the 5th rib).

V4 (Blue) – 5th intercostal place at the left mid-clavicular line.

V5 (Orange) – At the horizontal level of V4, at the left anterior line.

V6 (Purple) – At the horizontal level of V4, at the mid-axillary line.

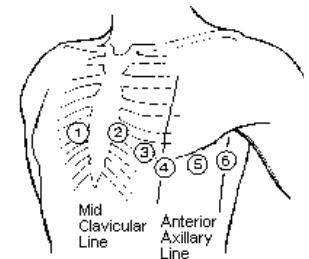


Figure 3-0 ECG Hookup Diagrams

NOTE: Lead placement does affect the ECG waveform. When the limb leads are placed on the torso, waveform changes might be seen in the QRS amplitude, axis shift occurs, Q waves can be seen, and T waves might appear flipped or flattened. These changes are clinically significant in that they are associated with cardiac ischemia. If a non-standard lead placement is used, note the variation in the ECG comment field.

C. Starting the Program

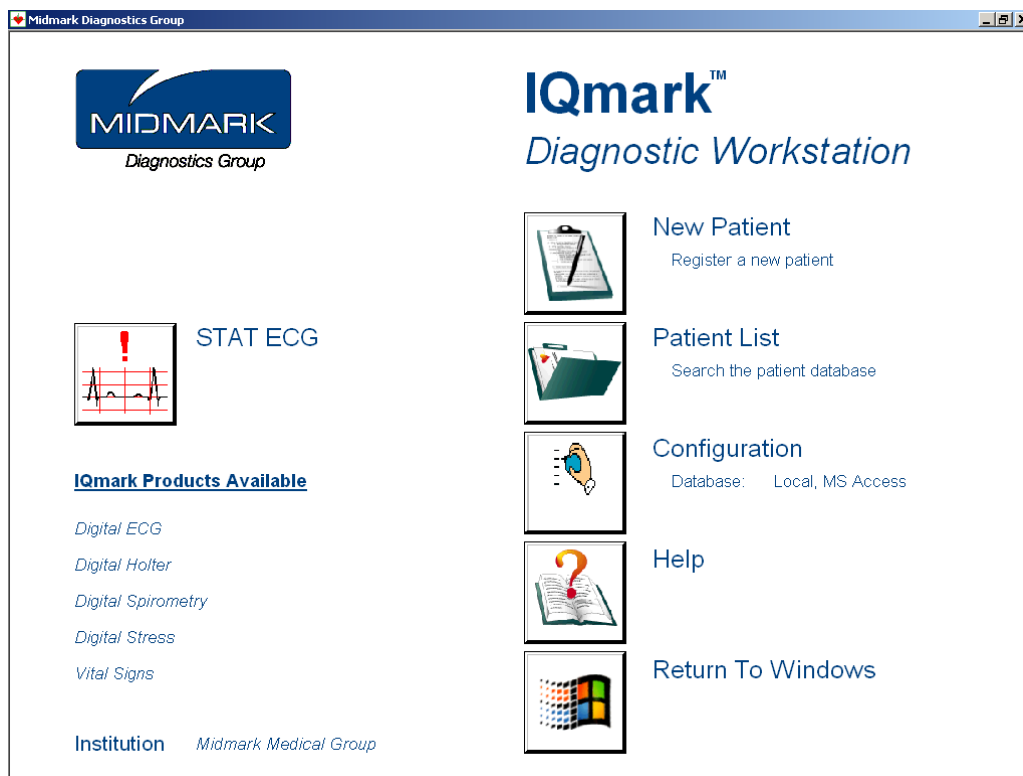
Start the ECG test through IQmark Diagnostic Workstation by double-clicking on the IQmark Workstation icon on the desktop:

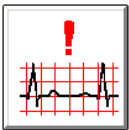


NOTE: For a detailed description of diagnostic functions available through IQmark Diagnostic Workstation, please see the ***IQmark Diagnostic Workstation Operation Manual***.

D. Opening Screen

When you start IQmark Diagnostic Workstation, an opening screen appears:



Opening Screen Buttons	
	Acquire an ECG before entering patient demographics or selecting a patient.
	Register a new patient. Refer to the product's Operation Manual for a description of the patient details required for specific tests.
	View a list of patients previously entered into the database; selecting a patient from the list enables you to access, edit, add and delete data that patient's records and view data from previous tests.
	Display which database is currently selected and enables users to configure the program to meet their needs. See <i>Section II-D, Configuring IQmark Diagnostic Workstation</i> for more information.
	Online assistance regarding the use, operation and troubleshooting of IQmark Diagnostic Workstation and other products.
	Exit the program and returns you to the Windows desktop.

STAT ECG

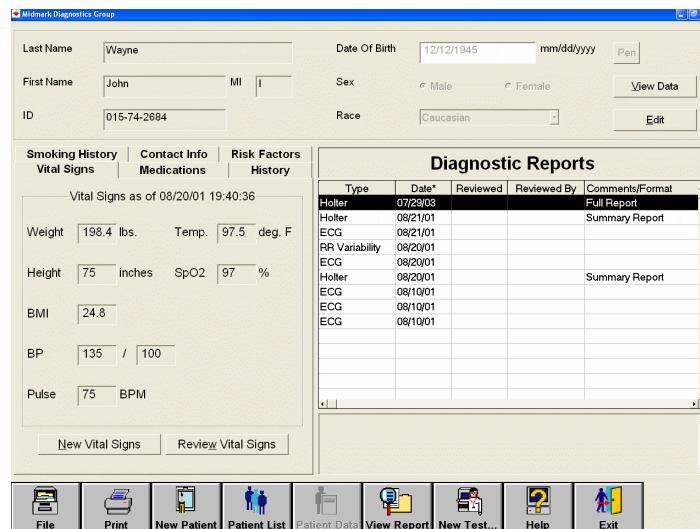
In the event that a stat ECG is required, hook up the patient to the IQmark Digital ECG and click **STAT ECG** to immediately access the live ECG test screen without having to enter the patient information. You can print a live ECG report without saving the patient test or click **Analyze** to have the computer analyze and save the report. You are prompted to enter the patient information when you exit the *Report Review* screen.

NOTE: The green LED on the ECG module will light when the module is on.

- Serial-type ECG module with a power switch: If the module is not on, manually turn it on by pressing .
- USB-type ECG module: **IQmark Diagnostic Workstation** will turn it on as needed.

E. Testing a New Patient

To register new patients, click **New Patient** on the opening screen. The *Patient Data Entry* screen appears, enabling you to enter data that is pertinent to your patient.



NOTE: You must enter a name or ID for the patient to start a new test.

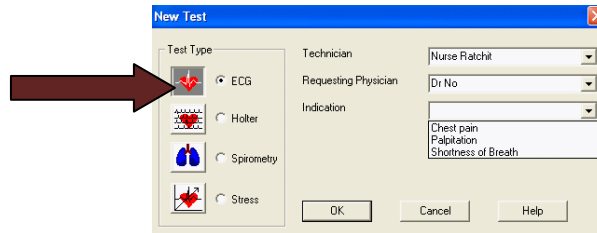
Click in any text box or press the **Tab** key to enter information. Although every field is not essential for the acquisition of an ECG, it is important to complete each of the fields as accurately as possible, particularly *Date of Birth*, *Sex*, and *Medications*, which are used by the *Midmark 12-Lead Resting ECG Analysis Program* to produce diagnostic statements. The blood pressure values entered will be displayed and printed on the ECG report.

The Midmark analysis program is capable of interpreting ECG from infant to adult age by using age-dependent criteria. It automatically calculates the age of the patient based on the date of birth entered on the *Patient Data* screen, and the current date of your computer. Please make sure that the date and time on your computer is current.

Please refer to the *IQmark Diagnostic Workstation Operation Manual* for additional information on the *Patient Data* screen.

Live ECG

When the patient is prepared, calm and comfortable, initiate ECG data acquisition by clicking **New Test** on the menu bar on the *Patient Data* screen. The *New Test* dialog box appears, on which you can select the test type to run. Click the **ECG** icon in the left-hand portion of the dialog box.



Enter the names of the technician conducting the test and the requesting physician. Enter the diagnostic reason for performing the ECG in the *Indication* field. This information is optional.

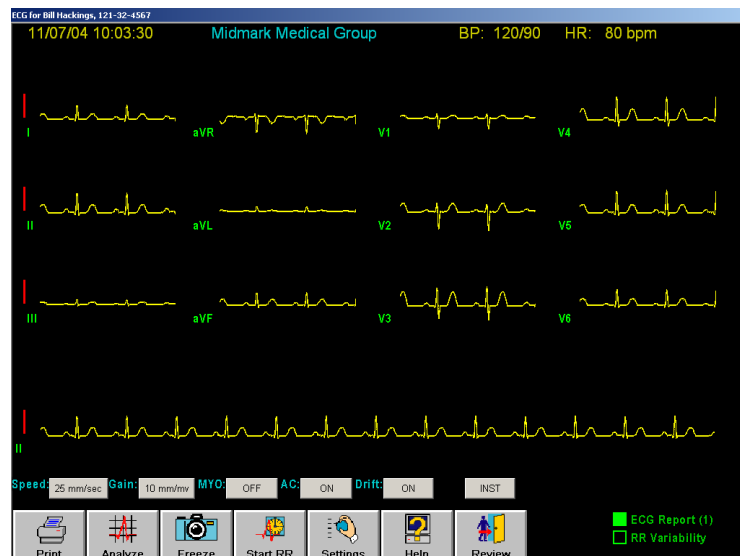
If you have configured the List Management for your practice, you can select these entries from the lists.

Click **OK** to open the live ECG screen.

NOTE: The green LED on the ECG module will light when the module is on.

- Serial-type ECG module with a power switch: If the module is not on, manually turn it on by pressing .
- USB-type ECG module: **IQmark Workstation** turns it on as needed

NOTE: The laptop computer's AC adapter may introduce electrical interference. For best ECG result, do not use the AC adapter while running a live ECG.



The live ECG screen displays the results of the 12-channel ECG in the three-by-four (3x4) leads display format. This format can be changed by using the *Settings* function. Your facility's name, the date, time and the patient's heart rate appear at the top of the screen. The ECG tracings are in the center of the screen moving from left to right.

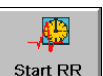
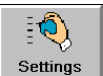
Below the moving tracings are the sweep speed, gain, and filter settings. You can click the appropriate button to modify its setting. Changes to these settings made from this screen are temporary and only apply for as long as you are in this test. You can change and set them as the default settings for all new ECG tests by clicking **Settings**.

Clicking on **INST** resets the ECG module and stabilizes the ECG baselines. If there is no **INST** button on the screen, manually turning the ECG module power off for one second and then turning it on would accomplish the same effect.

In the lower-right corner of the screen are the status indicators for **ECG Report** and **RR Variability**. An empty status indicator means that you have not acquired the specific report since entering the screen. Once a report is created, the indicator next to the test type appears solid. This indicator is not affected by tests that were previously stored or reviewed in the database.

The menu bar at the bottom of this screen provides different options you can take. These available options change according to the settings and the process you have made.

 Print	Prints the last 10 seconds of ECG data being collected. This report contains no measurements or diagnostic statements. If data is not actively being collected, this function prints out the last 10 seconds of data in memory.  NOTE: Clicking Print more than once before the report is printed produces multiple printouts. Exit is disabled until the report is printed. To speed up printing, click Freeze before clicking Print.
 Analyze	Performs resting analysis on the last 10 seconds of data and stores this analysis as an ECG Report, which can be printed from the <i>Report Review</i> screen or by selecting Print After Analysis in the <i>Printer Format Settings</i>.
 Freeze	Freezes the display and copies the last 10 seconds of ECG data into a memory buffer. If there are less than 10 seconds of ECG data collected, the freeze function is delayed until the 10-second buffer is filled. Click this button a second time to unfreeze the display and clear the memory buffer. When the display is frozen, you can also click Print or Analyze.
 Display	This option is only available if the <i>Display Real-time ECG Tracing</i> setting is disabled. Click on this button to display the ECG tracing acquired in the last 10 seconds. Tracings are displayed in static form and are not stored. Click on the Analyze button to analyze and save the ECG displayed.

 Acquire	This option is only available if the <i>Display Real-time ECG Tracing</i> setting is disabled. Click on this button to start new acquisition of ECG data. A message <i>Acquiring ECG</i> will display on the screen.
 Start RR	Collects ECG data for RR Variability analysis. A preset duration between 30 and 360 seconds of ECG data may be collected in 30-second increments. Stop data collection by clicking Start RR again. No RR Variability analysis is performed if less than 30 seconds of data has been collected. Otherwise, the program will automatically analyze the data and store the report. Print RR Variability reports by clicking Exit and selecting Print, or select Print After Analysis in the <i>RR Variability Settings</i> to print reports automatically.
 Setting	Opens a four-tab dialog box for changing the <i>Default Interpretation And Acquisition Display</i> settings, <i>Printer Format</i> settings, <i>RR Variability</i> settings and <i>Configuration</i>, which are similar to those described in <i>Section II-E, Configuring the IQmark Digital ECG</i>.
 Help	Displays the online <i>Help</i> screen.
 Exit	Indicates an ECG or RR Variability Report has not been collected. Click this button to return to the <i>Patient Data</i> screen and terminate ECG acquisition.
 Review	Indicates at least an ECG or RR Variability test has been performed. Click to display the most recent report in the <i>Review Reports</i> screen.

The IQmark Digital ECG collects and stores a test report when you click on **Analyze** or **Start RR** from the *Live ECG* screen. Selecting **Analyze** instructs the program to acquire, analyze and store a resting ECG Report. Selecting **Start RR** instructs the program to begin acquisition for an RR Variability Report. When a minimum of 30 seconds of ECG data has been acquired, the program proceeds to analyze the data and will store an RR Variability report in the **IQ**mark Diagnostic Workstation database. There is no limit to the number of reports you can collect for a given patient using the **Analyze** and **Start RR** functions.

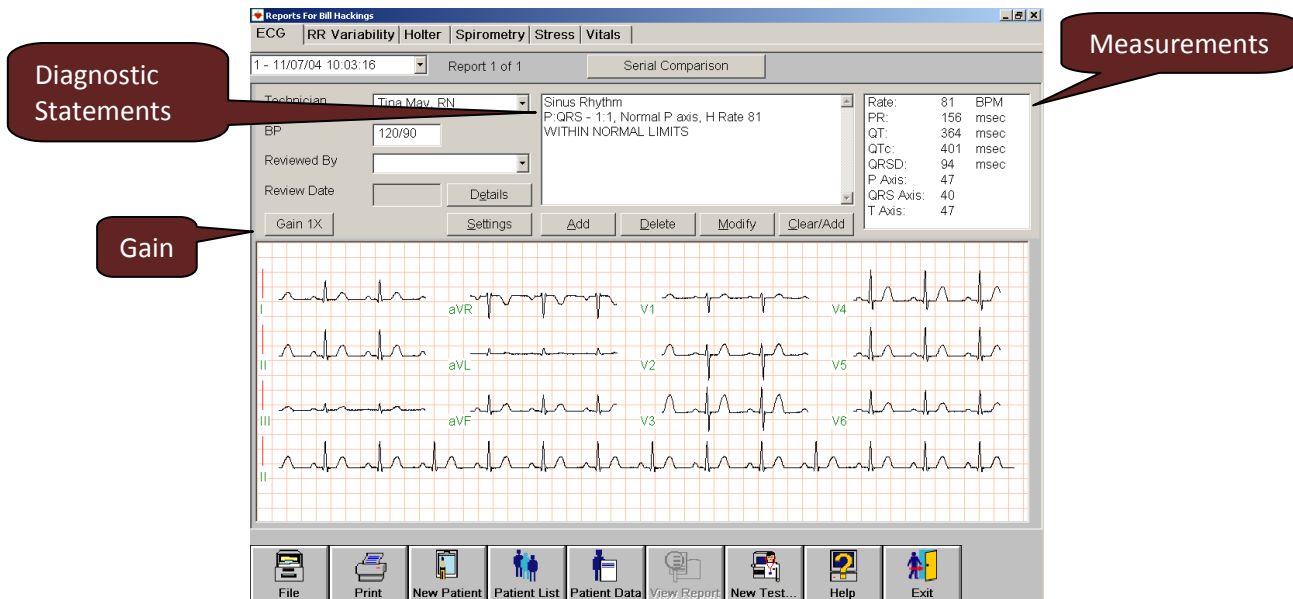
Resting ECG and RR Variability reports are stored in the designated database for future reference, whether locally on your hard drive or remotely in a central database. **IQ**mark Diagnostic Workstation provides many record management features that make it easy for you to retrieve and review this information later.

F. Reviewing Patient Reports

After a report has been collected through **Analyze** or **Start RR**, clicking **Review** on the *Live ECG* screen automatically brings you to the *Report Review* screen. Data from the

latest report collected will be displayed with the format reflecting the method of collection (i.e., **Analyze** or **Start RR**).

ECG Report Review



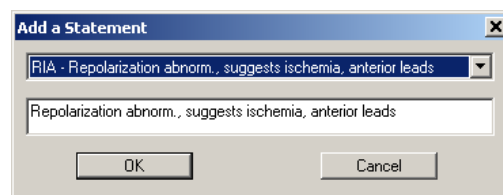
Reports collected using the **Analyze** function are displayed on the *Report Review* screen with ECG data traces from each of the patient leads. You can click on any part of the ECG tracings to zoom in to view in 2X magnification. Click again on the ECG tracings to return to the normal view. In normal and magnified views, move or pan the ECG tracings to view the other leads by holding down the **Shift** key and dragging with the mouse.

If the ECG amplitude is too tall or too short, you can click **Gain 1X** to increase the amplitude gain to 2X (20mm/mv) or decrease to 1/2X (5mm/mv).

The analysis results are displayed in the two text boxes on the upper-right portion of the *Report Review* screen. The attending physician should review and evaluate the diagnostic interpretation and the measurements.

Editing Diagnostic Statements

Some patients have specific physiological profiles that can affect the IQmark Digital ECG interpretation of their test results. If the physician believes there are any discrepancies in the diagnostic statements, the statements can and should be edited.



To modify diagnostic statements, either edit the statements directly in the text box, or click **Add** (enter new diagnostic statements) or **Clear/Add** (clear all statements and add new ones from a pre-established list); clicking either will open the *Add a Statement* dialog box:

In the top box, begin typing the abbreviation of a statement and the statement itself (e.g., RBBB - Right bundle branch block) or select a statement from the list by clicking the down arrow; the statement appears in the box below, where it can be edited.

NOTE: If the statement list is empty, no default ECG statement list is selected in List Management. Refer to *Section II-E Configuring the IQmark Digital ECG* for how to load the default statements through List Management.

If *Disable Quick Edit* is checked on the *Default Interpretation and Acquisition Display Settings* dialog box, the cursor is placed in the lower edit box by default for free text entry.

You can also edit the diagnostic statements through the *Details* screen.

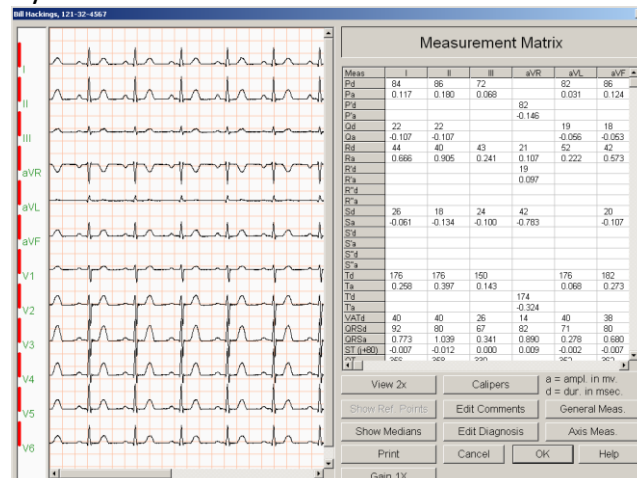
The measurements displayed in the text box on the right can be changed by double-clicking the label of the item to be changed and entering the new value into the pop-up dialog box that appears.

NOTE: If *Disable Interpretation* is checked on the *Default Interpretation and Acquisition Display Settings* dialog box, no interpretive statement appears in the *ECG Report Review* screen and the top center box is blank. The top right box, however, still displays the measurements.

NOTE: If a stat ECG was run, *STAT ECG* is displayed in the ECG window above Lead I.

ECG Report (Details) Review

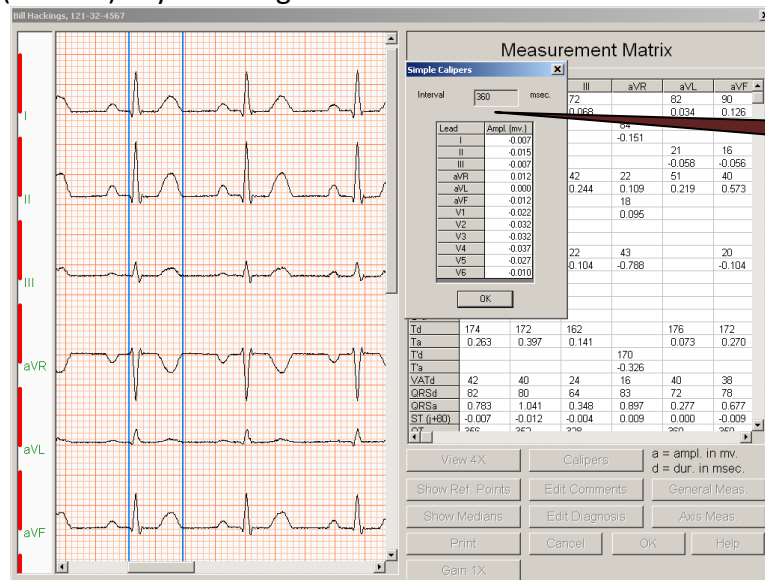
Click **Details** to display a detailed measurement screen like the one shown below:



Click **View 2x** in the *ECG Report Review (Details)* screen to magnify the 12-lead ECG tracings on the left to 2x zoom. Click the same button again and ECG tracings are displayed with 4x magnification.

Click **Calipers** to select between *Simple Calipers* or *P-QRS-T Calipers*. These electronic calipers allow you to measure the amplitude (mv) and duration (ms) of any part of the ECG waveform, making it easy to over read ECG tests online without printing them.

The *Simple Calipers* are shown on the following screen shot. To move the pair of Simple Calipers together with a fixed interval, place the mouse on one of the calipers, hold down the **Ctrl** (Control) key and drag to a desired location.



Simple Calipers

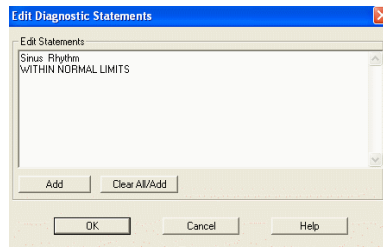
Edit Comments displays a text box for entering and editing report comments that are printed at the top of the ECG report.

General Meas. displays a dialog box showing the general measurements, which are also displayed on the previous *ECG Review* screen and on the ECG report, if printed.

Axis Meas. displays a dialog box showing the axes (frontal, horizontal and sagittal) for the P, QRS and T waves.

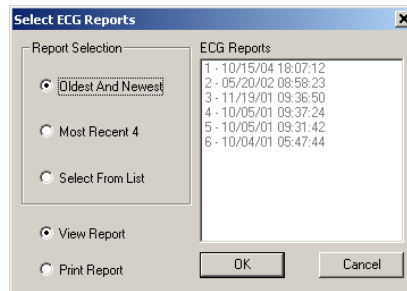
Show Medians switches the ECG display between the median beats (representative beats) or the 10-second ECG tracings. While displaying the *Show Medians* beats, clicking **Show Ref. Points** displays the reference points for onsets and offsets of the P-QRS-T component waves of the median (representative) beats.

You can view and edit the diagnostic statements from this screen by clicking **Edit Diagnosis**. The *Edit Diagnostic Statements* dialog box appears; refer to *Editing Diagnostic Statements* section above for details.



Serial Comparison

This feature enables you to compare up to four ECGs from the same patient. If the patient has more than one ECG report, click **Serial Comparison** on the *Report Review* screen and the *Select ECG Reports* dialog box appears. Choose the test selections you want and click **OK**.



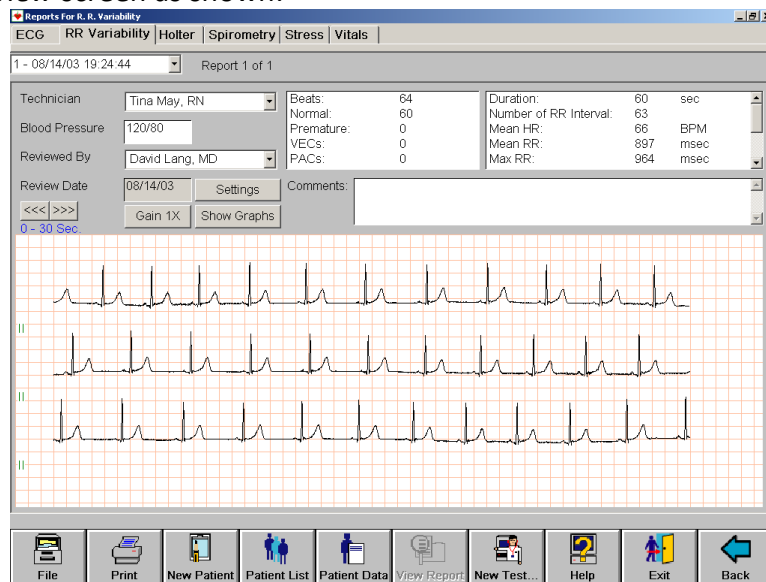
The following sample *Serial Comparison* screen shows two ECG reports simultaneously. Summaries of each ECG report are displayed at the top-right section. Each report is given a report number, shown to the left of the date. ECG tracings are color-coded to identify different reports, as indicated at the lower left corner. Clearing a report check box turns off the median beats for that report, displayed on the left side of the screen. Median beats are superimposed so that subtle differences can be viewed easily. Rhythm strips from each report are also displayed in the lower right section together with the report number and lead label. You can view different rhythm leads by clicking the down arrow button next to the *Rhythm Lead* indicator.

You can click inside the median beat or the rhythm strip area to zoom in on the ECG tracings. Click again and ECG views return to the previous scale.



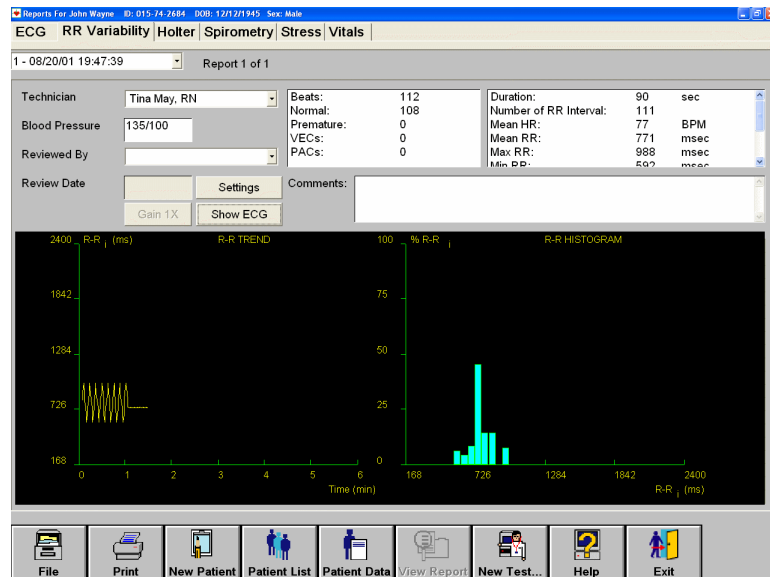
RR Variability Report Review

If a report was collected using the **Start RR** function, then the ECG data is displayed on the *Report Review* screen as shown:



The diagnostic results for the RR Variability analysis are displayed in text boxes on the upper-right portion of this screen and cannot be edited. You can view the patient's ECG tracing from the entire data collection period (30-360 seconds) by clicking the <<< | >>> arrows above the traces. Click **Gain 1X** if the amplitude of the ECG is too tall or too short; clicking the same button circulates through 2X (20mm/mv), 1/2X (5mm/mv) and 1X (10mm/mv) amplitudes.

You can also review the data collected during the RR Variability analysis in RR Trend and RR Histogram formats by clicking the **Show Graphs** button.



On both the resting *ECG* and *RR Variability Report Review* screens, there are fields labeled *Technician* and *Reviewed By*. Ensure that the name of the technician doing the ECG is entered in the *Technician* field, and that the name of the doctor performing the ECG review and confirmation is entered in the *Reviewed By* field. These names are important as they serve to document the ECG collection process and will assist people reviewing these reports in the future.

Click the **Print** button to print the report displayed on the screen.

When you have finished reviewing the patient's reports, you can exit the *Report Review* screen by clicking the appropriate button on the bottom of the screen. If you edited the diagnostic statements, or filled in blank fields, you will be prompted to save your changes prior to exiting the screen. You are allowed to proceed to the appropriate screen regardless of whether you save your changes or not.

Appendix

A. Operations at a Glance

A condensed guide to using the Midmark IQmark Digital ECG with new patients.

- 1) Start **IQ**mark Diagnostic Workstation.
- 2) Select **New Patient** from the opening screen. For returning patient, select **Patient List** and search by patient's last name or ID.
- 3) Complete the fields on the *Patient Data* screen as accurately as possible. You must enter a name or ID number to perform a test. Enter the date of birth and sex of the patient. Enter the patient's vital signs. If the patient has a cardiac history, or is taking prescription medications, make sure you enter them on the appropriate tabs.
- 4) When the *Patient Data* screen is complete, prepare the patient for the resting ECG test. Refer to the enclosed *Quick Reference User's Guide* for a standard 12-lead hookup.
- 5) If the ECG module has an *On/Off* switch, you may need to turn it on by pressing the  symbol. The green LED on the module will light when the ECG module is on.
- 6) Select **New Test** on the menu bar, select the **ECG** test type and enter relevant information. Click **OK** when the patient is prepared and comfortable.
- 7) Adjust the sweep speed and gain as necessary. If artifacts or noise occur in the ECG signal, please refer to *ECG signal quality problems* in the *Troubleshooting Guide* for corrective actions. Do NOT turn the MYO filter on for pacemaker patients.
- 8) Wait for the ECG tracings to pass the screen twice (about 20 seconds) to verify that the signal quality is good and the baselines are stable.
- 9) To acquire a test report, click either **Analyze** or **Start RR** on the menu bar.
 - **Analyze** instructs the program to acquire, analyze and store a resting ECG test.
 - **Start RR** instructs the program to acquire a preset duration of the rhythm strip and prepare a RR Variability report.
- 10) Reports are automatically saved and can be viewed upon exiting the ECG screen by the **Review** button.
- 11) Reports on the *Report Review* screen are in chronological order for the patient being tested, and are displayed on the ECG or RR Variability tabs.
- 12) You can review reports from other patients by clicking **Patient List**.

B. Troubleshooting Guide

This *Troubleshooting Guide* provides a list of solutions and recommendations to problems you might encounter with the IQmark Digital ECG. Before calling Midmark Support Services, please refer to the following table for help. Error messages are displayed at the center or at the bottom right corner of the screen.

 **NOTE:** For errors that occur during the analysis or management of ECG files, please refer to *Troubleshooting* section in the ***IQ**mark Diagnostic Workstation Operation Manual*.

Troubleshooting Guide	
Error Message/Problem	Recommendation/Possible Solution
DATA FORMAT ERROR Message appears after starting a new ECG.	A format error has occurred in the ECG data collected. - This error message can be cleared by clicking on Settings, then Cancel. - Verify that the <i>Low Battery</i> LED on the ECG Module is not blinking. If it is, install new batteries. - Switch to 4 leads display format. Refer to section on <i>Live ECG</i> for <i>Display</i> setting change instructions. - Turn off Waveform Smoothing. Refer to section on <i>Live ECG</i> and <i>Default Interpretation and Acquisition Display</i> settings. If an error message appears consistently at the beginning of a new ECG, verify that the ECG module is connected to the correct serial port. Refer to <i>Sections II-B</i> and <i>II-D</i> .
DISPLAY DIAGNOSTICS: Delays in the ECG display have been detected. Click <i>Help</i> to diagnose this problem. Message appears while running an ECG.	A. The graphics display adapter in the computer is too slow displaying the live ECG for the current display settings. B. The computer might also be too slow or too busy running other programs in the background. C. If you are running live ECG in a thin-client environment, your bandwidth maybe too low. - Click Help and follow the recommendations on the <i>Help</i> screen. - Verify that the <i>Waveform Smoothing</i> option is off and set to display in 4 leads display format. This is found under <i>Default Interpretation and Acquisition Display Settings</i> tab on <i>Settings</i> function. - Verify that you do not have any other tasks or programs running. Exit IQmark Diagnostic Workstation and close all running programs. Restart IQmark Diagnostic Workstation without restarting the computer. - If the above fails to correct the problem, disable the <i>Display Real-time ECG Tracing</i> under <i>Default Interpretation and Acquisition Display Settings</i> tab on <i>Settings</i> function.

Troubleshooting Guide	
Error Message/Problem	Recommendation/Possible Solution
ECG MODULE NOT RESPONDING! Message appears after starting a new ECG test. No ECG tracing is displayed on the screen.	The program cannot communicate with the ECG module because it is not on, not connected to the computer, or is connected to the wrong port.  NOTE for PDA users: If you are using the same COM or USB port for the ECG module and the PDA, exit the syncing program before running the IQmark Digital ECG program.  NOTE for Touchscreen Display users: If you are using the same COM or USB port for the ECG module and the touchscreen display, close or disable the touchscreen driver before running the IQmark Digital ECG program. • Verify that the ECG module is connected to the correct serial port. Refer to <i>Sections II-B</i> and <i>II-D</i>. • For Valentine ECG module: Verify that the <i>ON</i> LED on the ECG module is lit. If not, push the power button. • For Valentine ECG, verify that the <i>Low Battery</i> LED is not blinking. If it is, install new batteries. • For IQmark Digital ECG module: Verify that the LED on the top cover is green. If the LED is red, install new batteries. If there is a  symbol on the module, you may need to press it to turn on its power.
ECG SECURITY KEY NOT FOUND Message appears after clicking Analyze. This message only appears when using the Valentine PC-ECG module and not with the IQmark Digital ECG module.	IQmark Diagnostic Workstation cannot find the Security Key for the Valentine PC-ECG because it is either not installed or there is a conflict with the parallel port. • Verify that the Security Key is installed directly on the parallel (printer) port of the computer and that the printer cable is connected to the back of the Security Key. Ensure that the printer is on and ready (or online). • Print from Windows Notepad or any text file to verify the parallel port is working properly with the Security Key installed.
ERROR: THERE MUST BE AT LEAST 2 REPORTS FOR SERIAL COMPARISON /TRENDING. Message appears after clicking the Serial Comparison button.	<i>Serial Comparison</i> in ECG requires at least 2 ECG reports completed under the same patient. • Click OK. Perform additional test if needed.

Troubleshooting Guide	
Error Message/Problem	Recommendation/Possible Solution
SERIAL PORT ERROR! EXIT. Message appears after starting a new ECG. No ECG trace is displayed on the screen.	The ECG module cannot communicate with the ECG Acquisition module; it is either connected to the wrong serial port or the configuration is incorrect. ⚠️ NOTE for PDA users: If you are using the same COM or USB port for the ECG module and the PDA, exit the syncing program before running the IQmark Digital ECG program. ⚠️ NOTE for Touchscreen Display users: If you are using the same COM or USB port for the ECG module and the touchscreen display, close or disable the touchscreen driver before running the IQmark Digital ECG program. Refer to <i>Sections II-B</i> and <i>II-D</i> for COM port selection and setup. Use Auto Detect to find the correct COM port.
Details button does not work in the <i>ECG Report Review</i> screen.	- Exit the IQmark Digital ECG application. - Start MS-DOS Prompt. - Change directory to c:\windows\system (if Windows NT, c:\winnt\system32) - Type regsvr32 msflxgrd.ocx and press Enter - Type regsvr32 oleaut32.dll and press Enter - Exit MS-DOS Prompt and restart the IQmark Digital ECG application.
Incorrect diagnostic interpretation.	- Refer to <i>ECG signal quality problems</i> above. - Patient's <i>Date of Birth</i>, <i>Sex</i> and <i>Medications</i> must be accurately entered. Refer to <i>Section III-E, Testing a New Patient</i>. - Edit the diagnostic statements accordingly. Refer to <i>Section III-F, ECG Report Review</i>.
No error message and no ECG trace on <i>Live ECG</i> screen.	- Refer to <i>ECG MODULE NOT RESPONDING</i> above. - Refer to <i>SERIAL PORT ERROR</i> above.
Prints slowly when printing live ECG tracing or printing automatically after analysis.	Depending on your computer, print jobs may be slower if the ECG module is still actively collecting live ECG data. - Click Freeze before printing the ECG tracing displayed on the screen. Refer to <i>Section III-E, Live ECG</i>. - Verify that Print after Analysis is not checked. Refer to <i>Settings</i> section, <i>Printer Format Settings</i> and <i>RR Variability Settings</i>. - Uncheck Grid setting. Printing ECG reports without the grid will expedite the print jobs.

Troubleshooting Guide	
Error Message/Problem	Recommendation/Possible Solution
ECG signal quality problems such as a low amplitude, wandering baseline, noisy signal, etc.	- For a good signal quality, the patient must be properly prepped; the lead placements correct and the electrodes and lead wires firmly secured. See <i>Section III-B, Preparation</i> for best practices. - For the Valentine ECG: Verify that the <i>Low Battery</i> LED on the ECG module is not blinking; if it is, install new batteries. - For the IQmark Digital ECG: Verify that the LED is not red nor the <i>Low Battery</i> message displayed. If it is, install new batteries. - Verify that the electrodes are fresh, moist, and sticky, not dry or hard. Check electrode expiration date on package. - Verify that the patient lead wires and cables are not damaged or worn out. - Inspect connections between the electrodes, clips, lead wires, lead cable and the ECG module. - The exam room should not be too cold; patient may shiver, causing a noisy signal. - If any I, II, III, aVR, aVL and aVF leads on the screen are noisy or flat-lined, check the <i>limb lead</i> electrodes for proper contact in this order: RL, LL, RA and LA. If a precordial lead is noisy or flat-lined, check the limb lead electrodes first, and then check the corresponding chest lead electrode for proper contact. Once identified, discard and replace the used electrode. Prepare the problem site again or try a new electrode site in close proximity to the original site. Note any site variance on test report. - Test the filter settings on the ECG screen. Turn AC filter ON if you see 50/60Hz noise. Turn <i>MYO</i> filter ON if patient produces muscle tremor. Turn <i>Drift</i> filter ON if the ECG baseline is drifting. While these digital filters can improve signal quality, they cannot correct hookup problems. NOTE: As with any ECG measuring device, turning on the <i>MYO</i> filter may alter measurements, which may affect the diagnostic statements. Do NOT turn on the <i>MYO</i> filter for pacemaker patients. - Click INST to reset the baselines or manually restart the ECG module. - Verify patient's bed is properly grounded. - Verify patient or examination room is not susceptible to energy interference such as electromagnetic fields from high-power equipment like X-ray machines, power generators, power compressors, etc.
All other operational problems.	- Click Help found on all screens for the online help. - Additional troubleshooting covering ECG diagnostics is available in the <i>IQmark Diagnostic Workstation Operation Manual</i>. - For technical support, please see the contact information at the end of this manual.

C. Maintenance and Storage of the ECG Module

Preventative Inspection

A preventative inspection should occur prior to each use of the ECG module to verify that there is no visible damage to the unit that may cause it to malfunction.

Visual inspection should include the module and all cables for signs of damage and deterioration, including but not limited to cracks, cuts, discoloration or oxidation. If a cable or other accessory exhibits any of these symptoms, replace it prior to using the ECG module.

Cleaning

Clean the outside of the ECG module with a mild solution of detergent and water using a soft cloth. Avoid using excessive amounts of solution, which may infiltrate the connectors, battery compartments or ECG module. If necessary, use a mild sterilizing detergent with low alcohol content, such as those generally used in hospitals. **Verify that all equipment, including accessories, are completely dry before using.**

⚠CAUTION: Do not use aromatic hydrocarbons, rubbing alcohol, or chlorinated solvents for cleaning the ECG module.

Storage

To prevent damage to the IQmark Digital ECG module due to battery leakage or oxidation, remove all batteries if the IQmark Digital ECG module is not to be used for a long period of time. Avoid extreme humidity and heat during storage.

⚠CAUTION: To prevent damage to the cables, do not hang the IQmark ECG module by the interface cable or the patient cable.

D. Maintenance and Storage of 10-Lead Resting ECG Patient Cable

Instructions for Use

- Check the cable integrity before each use. In case of damage of any kind, do not use and do not attempt to repair cable. Contact Midmark Support Services for a replacement cable. If cable is found to be contaminated, clean and disinfect it according to instructions below before reusing.
- Plug the 10-Lead Resting ECG Patient Cable to the ECG module as described in the *IQmark Digital ECG Operation Manual*. Make sure the connection is tight. Check the connection before each use.
- Plug the metal post of each lead of the patient cable into an ECG clip. Make sure each ECG clip is pushed all the way in.

- In case you experience signal disturbance, distortion or interruptions, stop the procedure and localize the source of the problem and correct before continuing.
- At the end of the procedure, gently disconnect the ECG clips from the electrodes.
 - Do not remove the patient cable from the ECG module.
- All cables should be stored in big loops. Tight coiling must be avoided. Also avoid heat sources and direct sunlight.

Cleaning

Cables are supplied non-sterile and are reusable. For cleaning and disinfection the following substances and procedures must be used:

- Disconnect cable. Wipe plastic parts with a cloth moistened in lukewarm water with alcohol-free neutral soap. Always wipe towards the patient connectors/ECG clips.
- Proceed carefully as to not damage the cable through excessive stretching, bending or kinking of the wires.
- Remove the cleaning agent by wiping the cable with a cloth moistened in water. Wipe or air dry before use.
- Remove adhesive residues only with the alcohols listed below. Never use other organic solvents (acetone or toluol will damage the cable jacket).

Disinfection

Clean cable before each disinfection as described above. Perform wipe disinfection using products with the following substances as active ingredients:

- Ethyl or Isopropyl alcohol 70 – 80%
- Glutaraldehyde 2 % (pH 7.5 - 8) (e.g. Cidex[®])
- Quaternary ammonium compounds (e.g. Sanicloth HB wipes)

Remove the disinfectant immediately after the recommended contact time by wiping the cable with a cloth moistened with water.

⚠ CAUTION:

- The ECG patient cable is not suitable for autoclave or UV sterilization!
- Never immerse or soak the cable!
- Prolonged alcohol exposure can negatively affect the mechanical properties of the cable jacket.
- N-propyl alcohol or sodium hypochlorite (bleach, Chlorox) should be avoided for the disinfection of the cables!

E. Radio and Television Interference

This equipment generates and uses radio-frequency energy. If not installed and used properly in strict accordance with the manufacturer's instructions, it may cause interference to radio and television reception.

This equipment has been tested and proved to be in compliance with the standards for medical devices and in accordance with the IEC 601-1 rules, which are designed to provide reasonable protection against such interference in a medical or hospital environment.

F. EMC Requirements for the IQmark Digital ECG

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section.

Portable and mobile RF communications equipment can affect the operation of medical electrical equipment. The IQmark Digital ECG is medical electrical equipment.

The following is a list of the IQmark Digital ECG cables and other accessories that are used as part of the IQmark Digital ECG that comply with sections 36.201 and 36.202 of the EMC Standard IEC60601-1-2 (E):

- ECG Model(s) **IQmark Digital ECG**
- Patient cables: **Approved IQmark cables with 4mm banana connectors or pinch leads**

Use of cables, cable extensions or accessories other than those specified, with the exception of cables and accessories sold by the manufacturer of the IQmark Digital ECG as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the IQmark Digital ECG.

Guidance and manufacturer's declaration – electromagnetic emissions		
The IQmark Digital ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the IQmark Digital ECG should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The IQmark Digital ECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class B	IQmark Digital ECG is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	Battery operated device
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	Battery operated device

Guidance and manufacturer's declaration – electromagnetic immunity			
The IQmark Digital ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the IQmark Digital ECG should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A ±1 kV for input/output lines	Battery-operated device
Surge IEC 61000-4-5	±1 kV differential mode	N/A	Battery-operated device
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (<95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (<95% dip in U_T) for 5 sec	N/A	Battery-operated device
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The IQmark Digital ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the IQmark Digital ECG should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF Communications equipment should be used no closer to any part of the IQmark Digital ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from the fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1- -At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IQmark Digital ECG is used exceeds the applicable RF Compliance level above, the IQmark Digital ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the IQmark Digital ECG.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the IQmark Digital ECG

The IQmark Digital ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IQmark Digital ECG can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IQmark Digital ECG as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

G. Customer Support

For immediate help diagnosing problems with this product, refer to the online *Help* or *Appendix B, Troubleshooting Guide*. Otherwise, contact Midmark Support Services at (800) 624-8950, ext. 2 between 6:30 AM- 4:30 PM, Pacific Standard Time.

Warranty

All Midmark products are warranted to be free from manufacturing and material defects for 12 months from the date of purchase, except for the ECG clips, which are warranted for the initial 30 days. Any misuse or abuse of a Midmark product voids all applicable warranties.

Return Materials Authorization

To return any product for repair, an RMA (Return Materials Authorization) number must be obtained from a Midmark Support Services representative. Mark this number on all the packaging containing the items to be returned and in any correspondence regarding the return.

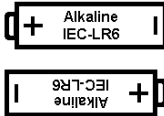
Shipping

Before shipping any unit to Midmark, be certain that an RMA number has been issued and that all guidelines regarding this authorization are followed. We highly recommend that you follow all guidelines for the shipment of medical products set forth by the shipping company you choose to use. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for your RMA number. It is ultimately the responsibility of the customer when shipping a product to ensure that all packages and their contents get to Midmark safely. **Midmark will not assume responsibility for damage incurred by improper packaging, shipment, or product use. Such actions will void all applicable warranties.**

Midmark Diagnostics Group
1125 West 190th Street
Gardena, CA 90248
Tel: (310) 516-6050
USA: (800) 624-8950, ext. 2
Fax:(310) 516-6517

H. Safety and International Symbols

The following symbols are used on Midmark products. These symbols appear on products when applicable. Refer to this directory for details concerning the symbols used on equipment.

Symbol	Description
	ATTENTION Refer to manual for instructions
	Year manufactured
	Battery Orientation This device uses 2 AA alkaline batteries. The icon indicates the orientation of batteries to be installed.
	DC Voltage This device uses 3 Volt power and consumes 30mA when in use.
	CE Mark. Equipment displaying this symbol has passed specific safety tests and adheres to international quality standards established by the European Community.
	IEC-601 Defibrillator-proof Type CF equipment. Equipment displaying this symbol contains an F-type isolated (floating) applied part that provides a high degree of protection against electrical shock, and is suitable for use during defibrillation.
	ETL Listing Mark. Equipment displaying this symbol has been tested and complies with the following safety standards: • Conforms to UL STD 2601-1 • Certified to CAN/CSA STD C22.2 No. 601.1

I. Glossary

ARCHIVING	Moving either an original file or a copy into storage where it can be accessed at a later date for review.
DATABASE	A collection of data arranged into methodically organized categories. In this manual, the term refers to the collection of reports that are stored on your hard drive.
DIALOG BOX	An on-screen form you complete to provide IQmark Diagnostic Workstation with information used to accomplish tasks.
ECG	See ELECTROCARDIOGRAM .
ELECTROCARDIOGRAM	A graphic recording that displays the electrical activities of the heart. Promotes the detection of abnormalities in the transmission of the cardiac impulse through the heart muscle and serves as an important aid in the diagnosis of heart ailments. During an electrocardiogram, the heart's electrical impulses are typically measured through electrodes placed on the chest and limbs.
ELECTRODES	A device used as an interface between an electrical conductor and an organism.
IQMARK DIAGNOSTIC WORKSTATION	The name of the software application installed on a Windows-based computer in order to use Midmark instruments.
IQMARK DIGITAL ECG	Midmark Diagnostics Group's portable ECG device for converting a Microsoft Windows-based PC into an electrocardiograph with interpretive capability. The IQmark Digital ECG operates using IQmark Diagnostic Workstation .
PORT	A place where data is passed in and out of a computer. Windows-based PCs typically have several ports on the computer. The IQmark Digital ECG communicates the data it collects from patients through a serial or USB port.
SERIAL PORT	A 9- or 25-pin port that is used by computers to communicate serial data. These ports are typically labeled in the convention COM[number] (i.e., COM1, COM2). Hardware components that typically use these ports include the mouse, modem and printer. The serial port version of the ECG module connects to a 9-pin serial port or a 25-pin serial port with an adapter. Consult your computer's manual for more information on configuration and capabilities.
UNIVERSAL SERIAL BUS (USB) PORT	A high-speed communication port with plug-and-play support.

IV. IQmark Digital ECG Service Manual

A. Introduction

The Midmark IQmark Digital ECG is a PC-based diagnostic instrument that converts any Windows-based personal computer to a 12-lead electrocardiograph with interpretative and data storage capabilities. A complete IQmark Digital ECG system consists of the ECG data acquisition module, the PC system, including a monitor and printer, Microsoft Windows operating systems (Windows 2000, XP and Vista), and **IQ**mark Diagnostic Workstation software program.

This manual is provided to assistance primarily with service of the IQmark Digital ECG data acquisition module. For information regarding the operation of the IQmark Digital ECG, please consult the *IQmark Digital ECG Operation Manual*; for information about the service and operation of the PC system, please consult your PC's documentation.

B. Theory of Operation

The IQmark Digital ECG data acquisition module is an improved version of previous hardware modules.

Some new features for the IQmark Digital ECG data acquisition module include:

- Built-in defibrillation protection circuit
- Hardware lead-off detection circuit
- Hardware pacemaker detection circuit
- Analog bandwidth from 0.05Hz to 150 Hz
- Digital sample rate of 500 Hz
- USB computer interface (model-specific)
- RS-232/COM port interface (model-specific)
- Pocket PC compatible interface (model-specific)

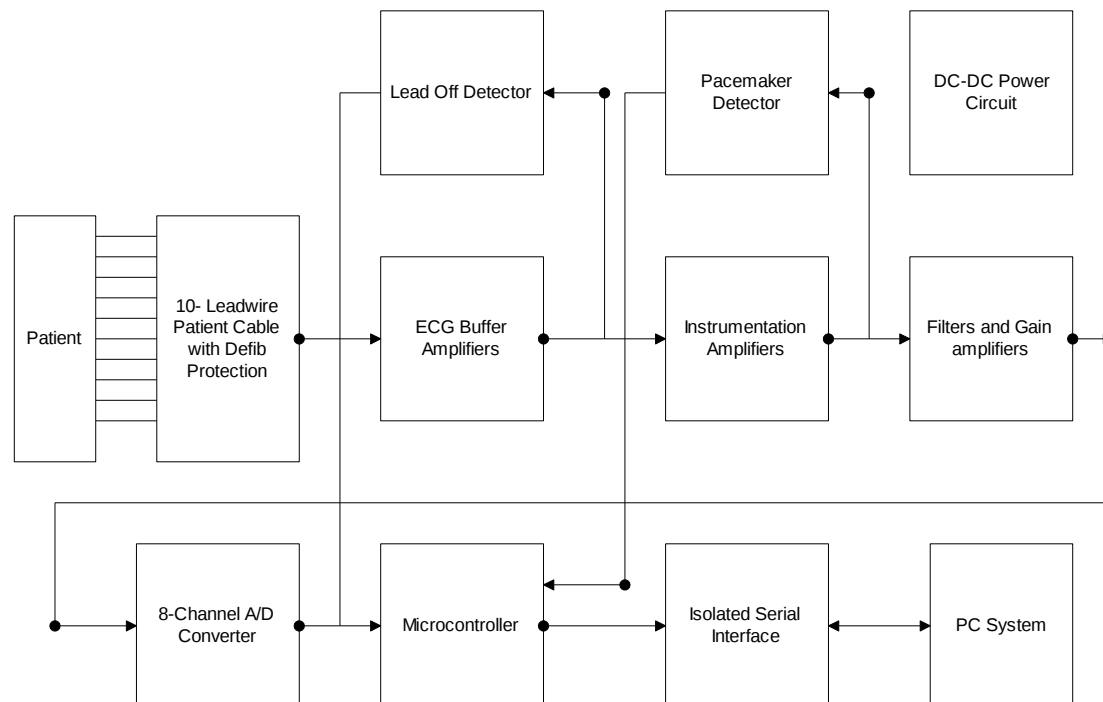


Figure 5-1 System Block Diagram

10-Leadwire Patient Cable

The IQmark Digital ECG uses the special Midmark 10-Leadwire patient cable for its 12-lead ECG data acquisition. The patient cable has 10 conductor shielded lead wires. There is a 1Kohm ($\pm 10\%$) resistor embedded inside each lead wire. Together with the voltage clamping circuit built into the ECG front end, the IQmark Digital ECG provides the built-in defibrillation protection capability required by AAMI EC-11 and IEC-60601.

ECG Buffer Amplifiers

The patient ECG signals are first fed to the 8 ECG buffer amplifiers. These buffer amplifiers provide high input resistance for the patient interface with low output resistance to the instrumentation amplifiers.

Instrumentation Amplifiers

There are eight differential instrumentation amplifiers used in the IQmark Digital ECG, providing eight output signals from CH0 to CH7. Each differential amplifier has two inputs, one positive and one negative.

The following table lists the positive and negative inputs for each channel.

Channel Number	Positive Input	Negative Input
CH0	LA	RA
CH1	LL	RA
CH2	V6	Wilson Center
CH3	V5	Wilson Center
CH4	V4	Wilson Center
CH5	V3	Wilson Center
CH6	V2	Wilson Center
CH7	V1	Wilson Center

The Wilson Center is a reference point combined with the three limb leads. The purpose of the instrumentation amplifier is to provide a high Common Mode Rejection Ratio (CMRR), rejecting common mode signals such as 60 Hz line noise.

Filters and Gain Amplifiers

After the instrumentation amplifiers, the 8-channel ECG signals are passed into two stages of filters. The first stage consists of eight first-order high-pass filters with a cutoff frequency of 0.048Hz. The second stage consists of eight low-pass filters with a cutoff frequency of 159Hz. The ECG signals are also amplified to match the AD converter input dynamic range of 0-2.5V.

There are eight test points provided on the PCB board. The test points are labeled as CH0, CH1, CH2, CH3, CH4, CH5, CH6 and CH7. The signals measured on these test points are amplified with a gain of 125 and DC offset to 1.25Volt.

Analog to Digital Conversion

The AD converter used is ADC12138 from National Semiconductor. The AD converter is 12-bit plus sign serial I/O A/D converter with MUX and Sample/Hold. The amplified and filtered 8-channel ECG signals are passed to the 8-channel inputs of the AD converter. The sampling rate for each channel is 500Hz. The digitized ECG data are sent to the microcontroller through the serial interface.

Microcontroller

The microcontroller is a PIC16LC67 chip from Microchip Technology. This chip has 8Kx14 OTP, 33 I/O lines and built-in serial interfaces for A/D converter and RS232. The microcontroller receives the digitized ECG data from the AD converter and encodes the data with packets and sends out to the PC through serial interface circuitry. The setting for the RS232 is 8 bit data, 1 bit stop, no parity, and 115,000-baud rate and is usually handled automatically. Settings for USB are automatic and are not user selectable.

Isolated Serial Interfaces

To provide the maximum safety for the patient, the IQmark Digital ECG hardware and the PC are isolated with an optical coupler and/or isolated DC to DC converters. The serial signal sent out by the PIC microcontroller is coupled optically to the PC system either through the RS232 or USB interface. There is no electrical connection between the patient and the PC system. The isolation circuit can withstand up to 1000Volts.

Lead-Off Detector

The IQmark Digital ECG has a built in lead off detection circuit. The lead-off circuit senses the lead off condition and reports to the PIC microcontroller. The PIC microcontroller sends out the lead off condition to the PC through the serial interface.

Pacemaker Detector

The pacemaker detection circuit in the IQmark Digital ECG ensures the device's capability of printing the ECG signal in the presence of pacemaker pulses with amplitudes between 2 and 250 mV, duration between 0.1 and 2.0 ms recommended by AAMI EC-11.

DC-DC Power Converter

The IQmark Digital ECG (42 Series / RS232) uses two AA batteries to supply its power.

The IQmark Digital ECG (43 Series / USB) does not require the use of batteries. The USB port of the host computer provides the operating power. A step up DC-DC converter is used to provide a 4.5Volt power source. Two 3.3Volt regulators are used to provide two 3.3Volts power source for the analog circuits and digital circuit for the unit. There is also a negative voltage converter used to generate a 3.3Volt power source for the analog circuit. A Linear Technology 1.25Volt micropower shunt reference regulator provides precision 1.25Volt reference voltage.

The IQmark Digital ECG (42 Series / RS232) power is switched on or off via the switch marked **I/O** on the top label. The IQmark Digital ECG (43 Series / USB) power is switched on or off by the ECG program through the USB port. Isolation is provided for signals entering the ECG module and can withstand up to 1000Volts.

C. System Maintenance and Obtaining Service

The IQmark Digital ECG is a portable device and requires little maintenance. To ensure the best performance of the device, the following procedures are recommended:

1. Keep the patient cable clean.
2. Do not unplug the patient cable from the IQmark Digital ECG hardware.
3. When the device LED turns red or the computer screen displays low battery, (42 Series / RS232 version only) replace the batteries inside the unit *before* continuing.

The IQmark Digital ECG acquisition module contains no user adjustable or serviceable parts. For repair or technical support, refer to the information below.

 **NOTE:** Return authorization is required prior to the return of the device. Midmark Diagnostics Group Support Services will issue a Return Materials Authorization (RMA) number prior to shipment.

Midmark Diagnostics Group
Support Services/Technical Support
Tel: (800) 624-8950, ext. 2

Midmark Diagnostics Group
1125 W. 190th Street
Gardena, California 90248
Technical Support: 1-800-624-8950, Option 2
www.midmark.com
©Midmark Corporation 2009

