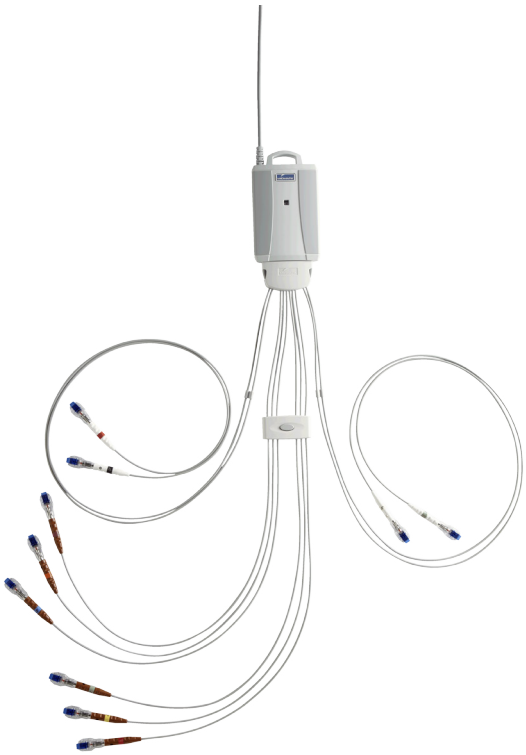
midmark®

IQecg
Version 10.0



Operation Manual

48-78-0002 Rev AB2

Notice

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

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Part number for this operation manual: 48-78-0002 Rev AB2

RxOnly	*Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.*

Table of Contents

Important Information

Safety Symbols

	***Warning*** *Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.*
	***Caution*** *Indicates a potentially hazardous situation that may result in minor or moderate injury. It may also be used to alert against unsafe practices.*
NOTICE	**Notice** *Indicates practices not related to physical injury.*

NOTICE **Notice**

This manual is intended for IQmanager® Diagnostic Workstation software users. If you are using the IQecg® through an EMR, please contact Midmark Technical Services for assistance with installation, setup and operation.

Physician's Responsibility

The interpretations provided by the Midmark IQecg® are for the exclusive use of licensed physicians or personnel under their direct supervision. Not all electrocardiogram (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.

Caution

Federal law restricts this device to sale by or on the order of a physician.

Caution

The automated ECG analysis algorithm assumes standard 12-lead ECG placement. Any deviation from the standard 12-lead ECG placements may affect the accuracy of the automated interpretation..

Caution

Follow standard 12-lead ECG placement when performing a STAT ECG.

Related Documents

The following documents may be needed in order to operate Midmark diagnostic devices and software products with the IQecg® Digital ECG:

- IQecg® Quick Reference User's Guide – Performing a 12-lead Resting ECG Test (Part number: 48-79-0002)
- IQmanager® Software Operation Manual (Part number: 62-78-0001)
- Setup Manual: Midmark Products over Thin Client using IQpath™ or COM port mapping (Part number: 61-78-0001)

French translations of this Operation Manual and the Quick Reference Guide listed above are available on the product page at: https://technicallibrary.midmark.com/ExamTools/CM/IQEcgPlus-CM-00001.htm?Highlight=IQECG

- Midmark IQecg® Operation Manual – French (Part number: 48-78-0001)
- Quick Reference Guide – IQecg® – French (Part number 48-79-0003)

All product Operation Manuals can also be downloaded from midmark.com. For additional information, contact Midmark Technical Service.

Precautions

Read the following precautions to ensure proper operation of the IQecg®.

1. Installation and maintenance of the instrument:
    - Install and keep the instrument away from splashing liquids such as water (device is rated IPX0).
    - 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.
2. 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.
3. 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.
4. Keep the instrument clean to ensure trouble-free operation for the next use.
5. In case of a malfunction, contact Midmark Technical Services and describe the problem precisely.
6. Inspect the instrument and accessories regularly.
7. Do not make any modifications to the instrument.

8. Environmental operating limits:

   Operation:

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

   Storage/shipping:

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

9. The IQmanager® Diagnostic Workstation software and the IQecg® have been tested for proper function with the Off-the-Shelf (OTS) Operating Systems (OS) specified in this manual. Do not operate the IQmanager® Diagnostic Workstation and the IQecg® 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 IQecg® with them. Before updating your operating system, contact Midmark Technical Service for the latest OTS operating systems information.

DANGER

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

Caution

Replace the patient cable with Midmark patient cables equipped with built-in defibrillation protection. Contact Midmark Technical Services for cable replacement.

Caution

Electronic devices can be damaged by exposure to liquids. Do not use or store the IQecg® near any type of liquids.

Caution

Contact Midmark Technical Services for any servicing questions.

Contents Checklist

The IQecg® kit contains the items listed in the following table. Open the package and account for each item. Inspect the items for any signs of damage, such as dents, cracks, tears, or scratches. If an item is missing or damaged, contact Midmark Technical Service for replacement.

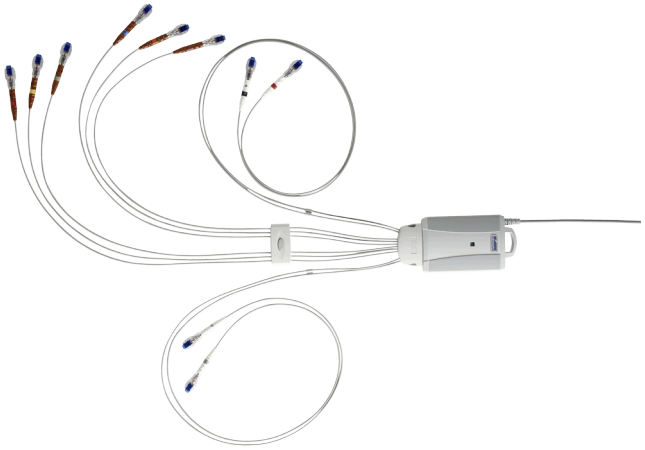
Quantity Each	Description
1	IQecg® Device (data acquisition module)
1	10-Lead Patient Cable
1	10-pack Clear ECG Clips
1	100-pack Disposable ECG Electrodes
1	Mouse Pad
1	IQecg IFU QR code sheet
1	Quick Reference Guide
1	Warranty Card
1	Carrying Case

General Information

Introduction

The IQecg® 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.

Together with IQmanager® Diagnostic Workstation software, the IQecg® makes it easy to record 12-lead ECGs, interpret them, archive the reports for future references and share them with 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.



The information in this Operation Manual is provided for users of Midmark IQecg®. Future references of IQecg® in this document may include the following part numbers:

Model	Connection	Device Part Number	Kit Part Number
Midmark IQecg® (48 series, Gray)	USB	1-100-1330	4-000-0062
Midmark IQecg® (46/47 series, Blue)	USB	1-100-1325*	4-000-0061*

*No longer in production

> ***Notice***
>
> **NOTICE** *This manual is intended for IQmanager® Diagnostic Workstation software users. If you are using the IQecg® through an EMR, please contact Midmark Technical Services for assistance with installation, setup, and operation.*

Necessary Computer Skills

This manual is intended for a user capable of using Microsoft® Windows applications, who has some understanding of PC operations, and who is familiar with the basic operations of Windows®.

This Operation Manual is designed as a comprehensive guide to educate the user on the operation and functions of the IQecg® device. The information in this manual includes options currently available with IQecg®.

Configurations

Typical PC Configuration

The following block diagram illustrates the standard configuration of the IQecg® system. The primary components are a Windows® -based PC, a printer and the IQecg® acquisition module. A portable computer is recommended if mobility is a consideration. Please refer to figure 1 when setting up your IQecg® system.

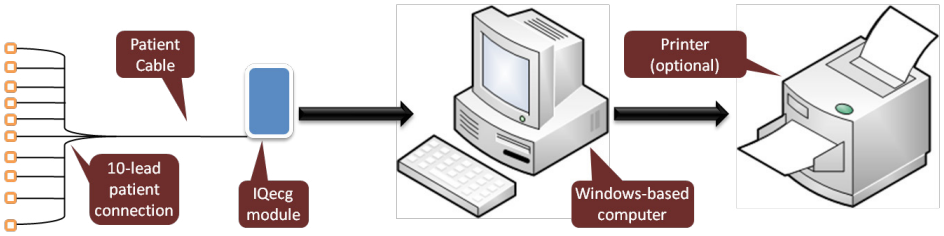


Figure 1 Block Diagram for the IQecg® system

Thin Client Configurations

If you are working in a thin client environment, install the software on the Terminal Server and operate the IQecg® through a thin client terminal.

IQmanager® supports the following thin client configuration: IQpath™ Software Solution. IQpath™ works with the USB port version of the IQecg® in high-latency, limited-bandwidth network configurations with Windows® -based PC clients.

Setting up any application in a network environment typically requires special access rights and knowledge of the network. Please have the system administrator install and configure IQmanager® to the office environment.

Thin Client Using the IQpath™ Software Solution

IQpath™ utilizes a dedicated flow control scheme to provide the following advantages over COM port mapping:

- Improved operation over high-latency, low-bandwidth, high-loss networks:
  - Microsoft® terminal Services: Improvement is approximately 10-to-1 in latency tolerance.
  - VMware® VDI: Improvement is approximately 10-to-1 in latency tolerance.
  - Citrix® ICA® protocol: 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.

NOTICE

Notice

IQpath™ has specific requirements for computer hardware, software and network performance. System administrators should read Setup Manual: Midmark Products over Thin Client using IQpath™ (61-78-0001) before installing, configuring, and using this software in a thin client environment.

The following block diagram describes IQpath™ (figure 2). In this thin client environment, the client computers must be running Windows®: see Minimum Computer Specification #99-99-00741011.

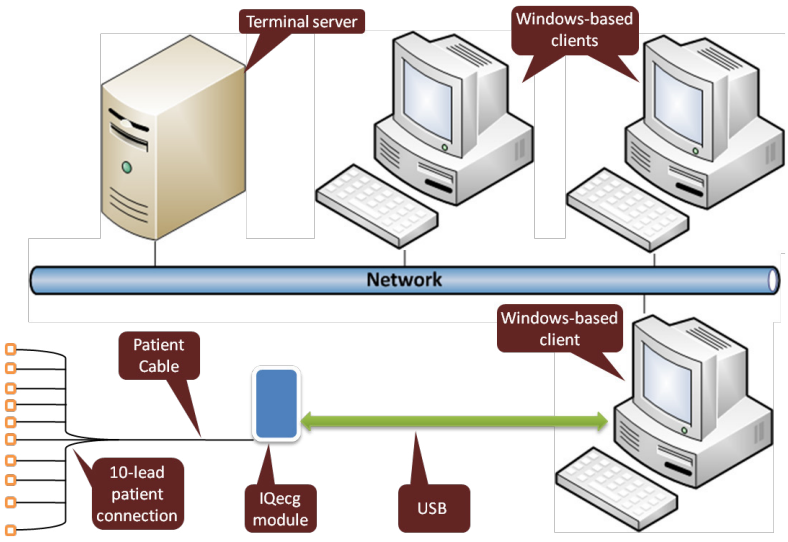


Figure 2. Block diagram of IQpath™

To use IQpath™, load IQmanager® on the terminal server and install one of the following software components on each client PC to be used for data acquisition:

- **IQpath™ for Microsoft Terminal Services:** If using Microsoft Terminal Services (Microsoft RDP).
- **IQpath™ for Citrix ICA:** If using Citrix® software on the clients and servers.
- **IQpath™ for VMware:** If using VMware® VDI software on the clients and servers.

These software products are provided separately and may be obtained by contacting Midmark Technical Service.

Once the software is installed on the client server network and computers, IQmanager® must be configured for thin client operation as described in Connecting the IQecg® Module and Configuring IQecg®, or refer to the IQmanager® Operation Manual, Configuring Client Server Networks.

System Specifications

The following are the physical and performance specifications for the IQecg®:

IQecg® Performance Specifications	
Category	**Specifications**
Intended Use	To provide standard 12-lead resting electrocardiogram recordings.
Physical Characteristics (IQecg acqusition module)	3.5” (88 mm) x 5.7” (145 mm) x 1.2” (30 mm) (W x L x H) 10.2 oz.
Anatomical Sites	Noninvasive device, 12-lead electrocardiogram
Safety Parameters	Patient electrically isolated from mains power supply Patient leakage current not to exceed 10 µA Ground leakage current not to exceed 50 µA

ECG Acquisition	12 leads, simultaneous. Input impedance: > 2.5 MΩ Frequency response: 0.05-150 Hz Gain sensitivity: 5, 10, 20 mm/mV Dynamic range: +/- 5 mV ADC resolution: 2.42 µV/LSB Acceptable electrode offset: +/- 300 mV Sampling rate: 500 samples/sec Channel-to-Channel skew: 65 µs Pacemaker detection: per IEC 60601-2-25 **Note:** For IQecg devices with serial numbers beginning with “L” to be IEC 60601-2-25 compliant, they must have software plug-in v10.0.10.9 or above.
Patient Connection	10-lead patient cable with RFI filter, defibrillator protection and patient isolation.
Monitor	Varies by computer system, minimum 1024 x 768 resolution
ECG Analysis & Measurement	Midmark 12-Lead Resting Electrocardiogram Analysis Program
Printer	Windows®-supported inkjet or laser printer
Paper	Plain 8.5” x 11” (Letter size)
Interpretation Algorithm	Midmark ECG Analysis Program. The duration measurement of Q-wave, R-wave or S-wave does not include the iso-electric segments within the global QRS complex.

Modulating Effects

The digital sampling techniques used by this device, and the asynchronism between the sample rate and the signal rate, may produce a noticeable modulating effect from one cycle to the next. This variation may be particularly noticeable in pediatric recordings. This phenomenon is not entirely physiologic.

System Installation

NOTICE

Notice

Contact Midmark Technical Service before installing and setting up the IQecg® to help ensure that your IQecg® device is installed and configured as quickly and easily as possible. With more software and hardware options available, each computer can be unique and the installation may be complex.

Minimum Computer Requirements

Refer to the Minimum Computer Requirements document at http://www.midmark.com, or contact Midmark Technical Services.

The Minimum Computer Requirements document describes the minimum computer resources and hardware components needed when using new Midmark devices and software. As is the nature of technology to change often, these requirements will be evaluated and modified periodically. We suggest that you always refer to the most recent Minimum Computer Requirements document at http://www.midmark.com or contact Midmark Technical Services for additional information.

NOTICE

Notice

If updating existing computer systems currently being used with older Midmark devices and software, please contact Midmark Technical Services before doing so.

NOTICE

Notice

The Minimum Computer Requirements are the specifications for operating the IQecg® through IQmanager®. A faster CPU and/or more memory may be required *if planning to operate the IQecg® through an EMR or install additional software.*

NOTICE

Notice

USB ports/contacts can become worn with repeated use. The IQecg® test may not function with a worn USB port.

Software Installation

NOTICE

Notice

The following software installation information refers to IQmanager® only. If using the IQecg® through an EMR, please contact Midmark Technical Services for assistance with installation and setup.

The medical diagnostic application IQecg® uses IQmanager® to manage patient records. When installing or upgrading the IQecg®, IQmanager® may also need to be installed or upgraded accordingly (refer to the IQmanager® Operation Manual for further information (48-78-0002)).

Other Midmark products can also be accessed from IQmanager®, such as, IQholter®, Midmark Digital Spirometer, Midmark Digital Vital Signs Device, IQvitals® Zone, and Weight/Scale Interfaces. Contact the Midmark Sales Department, https://www.midmark.com/contact-us/contact-sales for the latest information on available Midmark products or visit http://midmark.com.

NOTICE

Notice

*If IQmanager® is already installed on the computer and you are now either upgrading or adding a new Midmark product, please **skip** this section and refer to the IQmanager® Operation Manual (48-78-0002) for installation information.*

Before installing IQmanager® on a computer, it is important to understand and carry out task described on the following pages:

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 IQmanager®

NOTICE

Notice

The Midmark IQecg® requires software to operate. The following instructions use the IQmanager® software. Please contact Midmark Technical Service to purchase the required software license.

NOTICE

Notice

Do not connect any devices to the computer before running the software installation.

NOTICE

Notice

Close all Windows® programs before running this software installation.
Do not interrupt the installation program while it is running.

For any questions on the installation please refer to the *IQmanager® Operation Manual (48-78-0002)*.

Connecting the IQecg® Module

Patient Cable Installation

To attach the Patient Cable to the IQecg® with Lead Management, hold the patient cable with the Midmark embossed logo facing the same direction as the logo on the IQecg® device.

Align the patient cable connector to the cable clip on the module, as shown in Figure 3, and push it to ensure that the cable clip locks on both sides of the patient cable connector. This will ensure a secured connection between the patient cable and the IQecg® device.

Figure 3. Patient cable and Lead Management

Attach a Clear ECG Clip to the banana plug of all 10 patient leads.

If you have a mobile cart with an equipment pole, you can hang the IQecg® on the hook of the pole. Press the button on the patient lead separator and move it all the way down to keep the leads straight and untangled between uses (see Figure 4).

Figure 4. Hanging IQECG

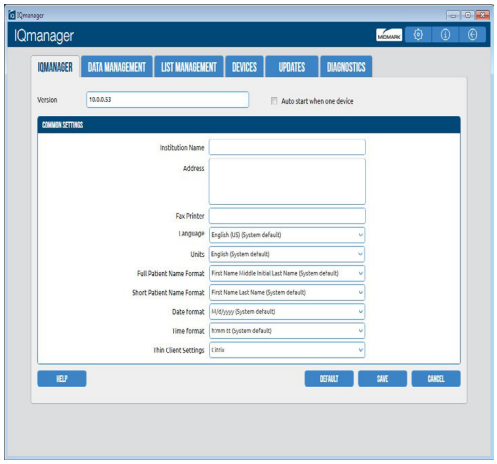
Connecting the IQecg® Module

Connect the IQecg® module to any available USB port on the computer after IQmanager® is installed. As with other USB devices, Windows® will attempt to identify the IQecg® module the first time it connects to it. This may take a few seconds. IQecg® does not require batteries as it receives its power from the computer.

Configuring IQecg®

IQmanager® and the IQecg® can be customized by using the configuration settings. To access the

Configuration Settings click the settings icon  in the upper right corner of the IQmanager® opening screen, see screenshot below. The *IQmanager® Configuration Settings* dialog box appears:



Complete the ***Institution Name*** and ***Institution Address*** boxes with information about the medical practice. This information will also be displayed on printed reports. Enter a name that describes the practice/location to enable other medical personnel to recognize the origin of the reports.

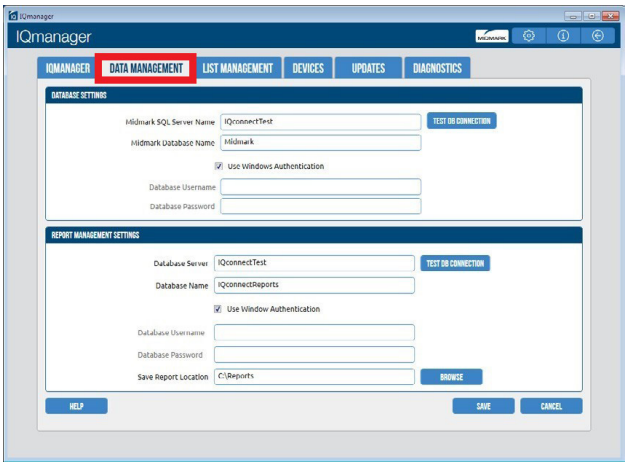
Thin Client Channel Setting

The *Thin Client Channel* setting is no longer applicable for the IQecg®. The ECG software will ignore the Thin Client Channel setting and automatically search all channels (RDP, Citrix®, VMware®) to find an IQecg® device connected over thin client.

Database Settings

IQmanager® uses the local database by default. If you are using a network database, you can set the path by clicking the *Data Management* tab on the *IQmanager Configuration* screen and changing the value for *Midmark SQL Server Name* and *Database Server* as shown in the following screenshot. For further information

on the database settings, refer to the IQmanager® operation manual (48-78-0002).



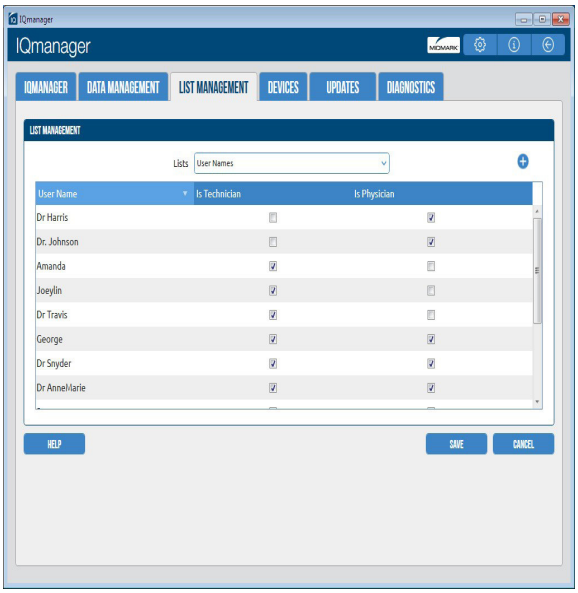
List Management

The *List Management* configuration option customizes the lists used in IQmanager®, including:

- Medications
- Indications
- Race Categories
- Health Networks
- User Names *(the names of doctors and technicians can be entered here)*

Modifying these lists saves time when you are using them in the appropriate testing screens. Follow these steps:

1. To access List Management, click the *List Management* tab in the IQmanager settings (see screenshot below).
2. Select the item that you want to modify from the pull-down list.



You can make the following changes:

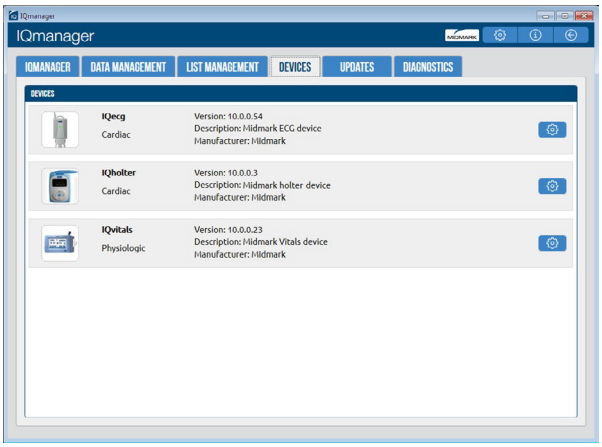
- **Add:** Scroll to the bottom of the list to type the new value or select the plus icon next to the drop-down list to jump to the bottom of the list. After typing the value, press Enter to save the settings.
- **Edit:** To edit an existing item, select the statement, and then begin typing to edit the value.

- **Delete:** To Delete an existing item, highlight the statement with the cursor, and then click the X button.

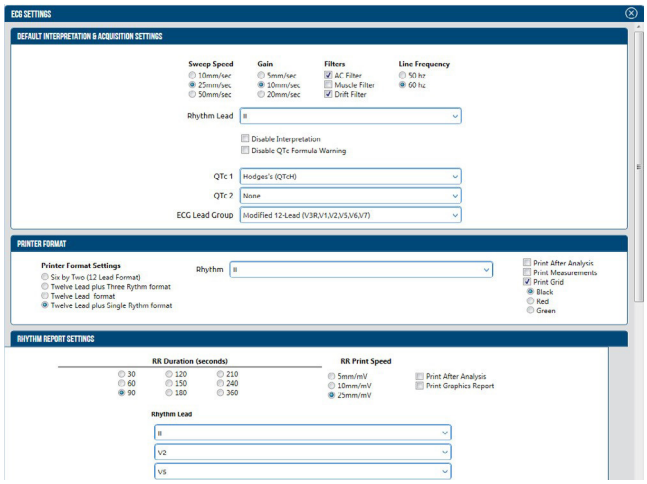
> **NOTICE**
>
> ***Notice***
>
> Selecting Delete All *will delete all the ECG statements.*

ECG Settings

Set the default settings to use for ECG tests by clicking the **Devices** tab in the *IQmanager* settings (see screenshot below). Click the settings icon to customize the settings. All of the common settings for ECG tests are inherited from the application.



The *ECG Settings* dialog box appears (see screenshot below):



> **NOTICE**
>
> ***Notice***
>
> *AC Power source frequencies of 50 Hz or 60 Hz.*
>
> *The IQecg® uses the information to filter out background noise through its AC filter. In the United States, the frequency is 60 Hz. If you are using the device outside of the United States, please consult the local power utility company to determine the appropriate frequency.*

Default Interpretation and Acquisition Display Settings		
Item	**Settings**	**Comments**
Sweep Speed	• 10 mm/sec • 25 mm/sec • 50 mm/sec	Default setting is 25 mm/sec. Sweep Speed setting only applies to real-time ECG display.
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 **Muscle**: Off, **AC**: On, **Drift**: On. See Note following this table.
Line Frequency	• 50 Hz • 60 Hz	Default setting is 60 Hz. If using this product outside of the United States, please consult with the local power utility company to determine the appropriate frequency.
Rhythm Lead	Select any lead I,II,III, aVR, aVL, aVF, V1,V2,V3(V3R),V4(V7),V5,V6	Default setting is Lead II. This setting applies to the 3x4 display format and to the RR Variability analysis rhythm lead.
The Rhythm Lead V3 (V3R) specifies lead V3 if Standard 12-Lead (V1,V2,V3,V4,V5,V6) is selected when a new ECG test is started; it specifies lead V3R if Modified 12-Lead (V3R,V1,V2,V5,V6,V7) is selected. V4 (V7) has a similar definition.		
The Lead Group V1, V2,V3 (V3R,V1,V2) specifies V1,V2,V3 if Standard 12-Lead is selected; it specifies V3R,V1,V2 if Modified 12-Lead is selected. The Lead Group V4, V5,V6 (V5,V6,V7) has a similar definition.		
Disable Interpretation	On/Off	Default is *Off* (cleared). If *On* (checked), the ECG will not produce any diagnostic statements and the interpretation portion of the report, *ECG Review and Edit* screen will be blank. **NOTE:** Modified 12-Lead ECG lead group does not provide automatic interpretation statements.

Default Interpretation and Acquisition Display Settings		
Item	**Settings**	**Comments**
Disable QTc Formula Warning	On/Off	Default is *Off* (cleared). If *On* (checked), the software will not display a warning message that the QTc formula on the report will be changed, based on new QTc1 and QTc2 settings, when the report is edited and saved.
QTc 1 QTc 2	• None • Bazett (QTcB) • Framingham (QTcFh) • Fridericia (QTcFd) • Hodges (QTcH)	QTc 1 default is Hodges (QTcH). QTc 2 default is None. These settings determine what QTc equation(s) to include in the report. *Bazett:* "**QTcB** = QT/√RR," where RR is in seconds; *Framingham:* "**QTcFh** = QT + 0.154 (1000 – RR)," where RR is in milliseconds; *Fridericia:* QTcB = QT/√RR, where RR is in seconds; *Hodges:* "**QTcH** = QT + 1.75 (HR – 60), Where RR is the R-R interval and HR is the averaged heart rate in beats per min. QTc is expressed in milliseconds. **NOTE:** Any changes to QTc 1 and QTc 2 settings will apply to the ECG report if the report is edited.
ECG Lead Group	• Standard 12-Lead (V1,V2,V3,V4,V5,V6) • Modified 12-Lead (V3R,V1,V2,V5,V6,V7)	Default is Standard 12-Lead. Select one of the two choices to be the default resting ECG lead group. **NOTE:** This setting does not affect STAT ECG. STAT ECG assumes the standard 12-lead ECG placement. **NOTE:** Modified 12-Lead ECG lead group does not generate automatic interpretations.

NOTICE

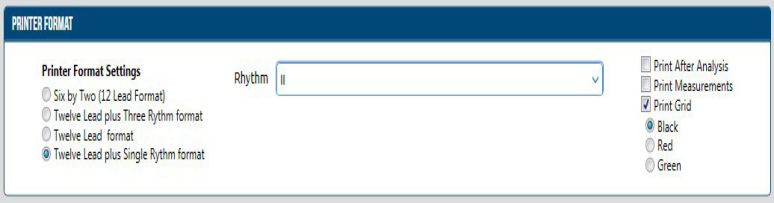
Notice

For all pacemaker patients, all filters should be turned OFF to detect pacer spikes.

Any artifacts in the ECG should be corrected at the source (i.e. ensure the electrodes sites are clean of lotion or body hair and the electrodes are fresh, sticky and properly adhere to the skin). The patient should be supine, relaxed and not talking. Refer to "ECG Signal Quality Problems" in the Troubleshooting Guide for more details.

Printer Settings

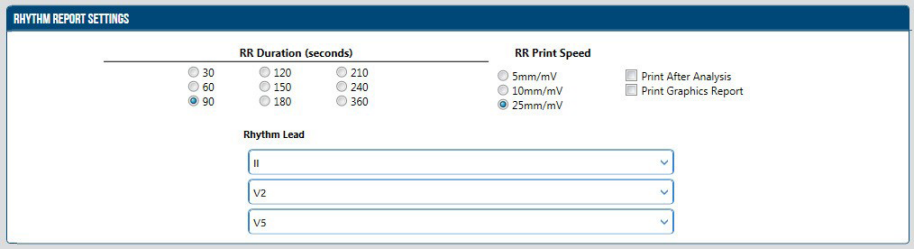
In the *Printer Format Settings* section of the *ECG Settings window*, you can select the default ECG report format (see screenshot below).



ECG Report Printer Format Settings		
Item	**Settings**	**Comments**
Printer Format Settings	• 6 x 2 format • 12-lead format (12x1) • 12-lead plus single rhythm format (3x4+1)	Default setting is 12-lead plus single rhythm format.
Rhythm Lead	Select any lead I, II, III, aVR, aVL, aVF, V1, V2, V3(V3R), V4(V7), V5, V6	Default setting is II. Applies to 12-lead plus single rhythm format (3x4+1) as described above.
*The Rhythm Lead V3 (V3R) specifies Lead V3 if **Standard 12-Lead** (V1,V2,V3,V4,V5,V6) is selected when a new ECG test is started; it specifies Lead V3R if **Modified 12-Lead** (V3R,V1,V2,V5,V6,V7) is selected. V4 (V7) has a similar definition.*		
*The Rhythm Lead Group V1, V2, V3 (V3R, V1,V2) specifies V1, V2, V3 if **Standard 12-Lead** is selected; it specifies V3R, V1, V2 if **Modified 12-Lead** is selected. The Rhythm Lead Group V4, V5, V6 (V5, V6, V7) has a similar definition.*		
Print After Analysis	On/Off	Default setting is *Off* (cleared). When *On* (checked), the resting ECG report is automatically printed following analysis. **NOTE:** For speed, set to *Off* and print manually.
Print Measurements	On/Off	Default setting is *Off* (cleared). When this is *On* (checked), the detailed measurement matrix report is printed automatically with the ECG report.
Grid	On/Off Black, Red, or Green	Default setting is *On* (checked). When this is set to *On*, the grid is printed in the selected color if a color printer is used.

Rhythm Settings

In the *Rhythm Settings* section of the *ECG Settings* window, you can preset the default test duration and report format. *Rhythm Lead* provides choices for the three rhythm leads from all available leads (see screenshot below).

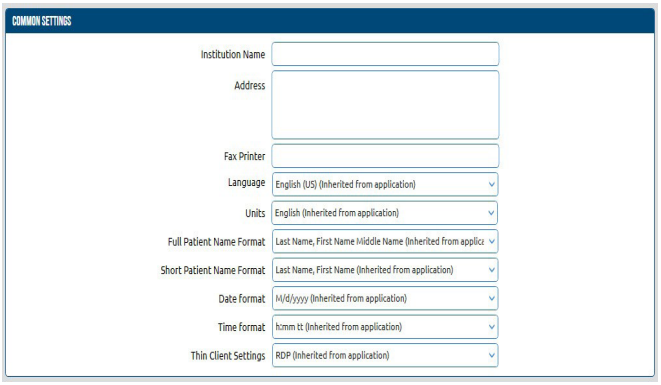


Rhythm Settings		
Item	**Settings**	**Comments**
RR Duration (seconds)	• 30 sec • 60 sec • 90 sec • 120 sec • 150 sec • 180 sec • 210 sec • 240 sec • 360 sec	Default setting is 90 sec. The default setting is the length of the rhythm strip acquired through Start RR test. The rhythm strip is defined in the ECG Settings.
RR Print Speed	1. 5 mm/sec 2. 10 mm/sec 3. 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 *Off* (cleared). When set to *On* (checked), the RR test report is printed automatically following successful completion of RR test analysis. **NOTE:** For speed, set to *Off* and print manually.
Print Graphics Report	On/Off	Default setting is *Off* (cleared). When set to *On* (checked), the graphic report, which includes the RR Trend and RR Histogram, is printed automatically with the RR rhythm strip report.
Rhythm Lead	Select any three leads I, II, III, aVR, aVL, aVF, V1, V2, V3(V3R), V4(V7), V5, V6	Default settings are II, V2 and V5.

Common Settings

Common settings on this screen are inherited from the *IQmanager® Configuration Settings* and can be overridden. To change back and inherit from IQmanager®, select the option that states “inherited from application” in the drop-down menu. Changes to these settings can be made from either screen.

Click **OK** on the *ECG Settings* dialog box to save any changes made (see screenshot below).



Operation

WARNING

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

Notice

NOTICE

For IQecg devices with serial numbers beginning with "L" to be IEC 60601-2-25 compliant, they must have software plug-in v10.0.10.9 or above.

Introductory Notes

This section describes how to use the various IQecg® features and the operational sequence most users will follow. This does not mean that a user is restricted to following this particular sequence. There are certain sequences that must always be followed, such as entering a patient's medical data prior to acquiring an ECG. However, this program is designed to be both user-friendly and flexible.

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 the user to a different screen or feature. To enter any of these screens, click once on the appropriate selection.

For user convenience, a condensed guide to the operation of IQecg® with new patients is included in "Appendix A – Operations at a Glance – Standard 12-lead ECG".

Patient Preparation

Careful preparation of the patient's electrode sites is important for obtaining an interference-free ECG and accurate result. The skin is naturally a poor conductor of electricity and frequently creates artifacts that distort the ECG signal due to dry or dead epidermal cells, oils, sweat and dirt. Well-managed skin preparation will reduce the resistive barrier that causes muscle noise and baseline wander, helping to ensure high-quality signal and test data.

Patient Position

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

Prepare Patient Skin

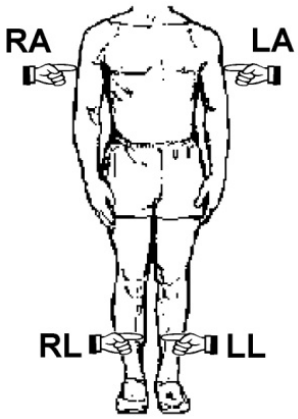
- Shave hair from electrode sites, if necessary. (Reference diagrams below.)
- Rub skin with alcohol wipes. Allow the skin to air dry.

Electrodes

Check to ensure that the electrodes are fresh and sticky. The technician's fingers must be clean and free of lotion when handling electrodes:

- Adhere the electrodes to the electrode sites on the patient.
- Attach the ECG clips from the patient cable to the electrodes according to the lead wire labels or color coding.

Limb Lead Placement



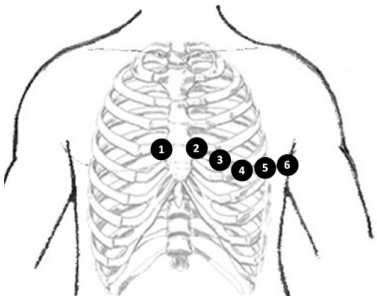
RA (White) – Place the Right Arm (RA) electrode ona distal portion of the right lateral side of the upper arm below the shoulder.

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

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

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

Standard 12-Lead Placement (Precordial)



Standard 12-Lead ECG Hookup

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

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

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

V4 (Blue) – 5th intercostal, left midclavicular line.

V5 (Orange) – Horizontal level of V4, at the anterior axillary line.

V6 (Purple) – Horizontal level of V4, at the midaxillary line.

> ***Caution***
>
> *Follow the standard 12-Lead ECG Placement when performing a STAT ECG. The automated ECG analysis algorithm assumes standard 12-lead ECG placement. Any deviation from the standard 12-lead ECG placements may affect the accuracy of the automated interpretation.*

Modified 12-Lead Placement (Precordial and Posterior)

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

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

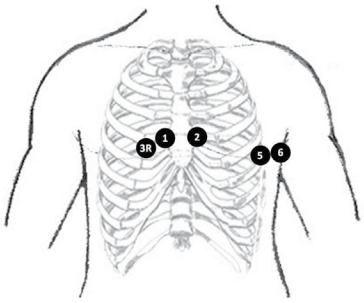
V5 (Orange) – Horizontal level of V4, at the anterior axillary line

V6 (Purple) – Horizontal level of V4, at themidaxillary line.

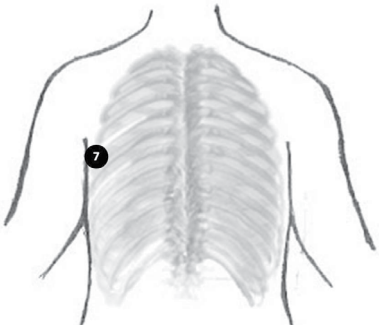
V7 (Blue) – Horizontal level of V4, at the posterior axillary line.

V3R (Green) – Corresponds to V3 on the right side.

Modified 12-Lead ECG Hookup



Precordial



Posterior

NOTICE

Notice

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.

Caution

Do not use a modified 12-lead ECG placement when performing a STAT ECG. The automated ECG analysis algorithm assumes the standard 12-lead ECG placement. Any deviation from the standard 12-lead ECG placements may affect the accuracy of the automated interpretation.

NOTICE

Notice

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.

Operation of IQecg® with IQmanager®

Starting the Program

The software application for operating the IQecg® is called IQmanager® and is located on the computer desktop as a shortcut icon. Double-click this icon to start IQmanager®:

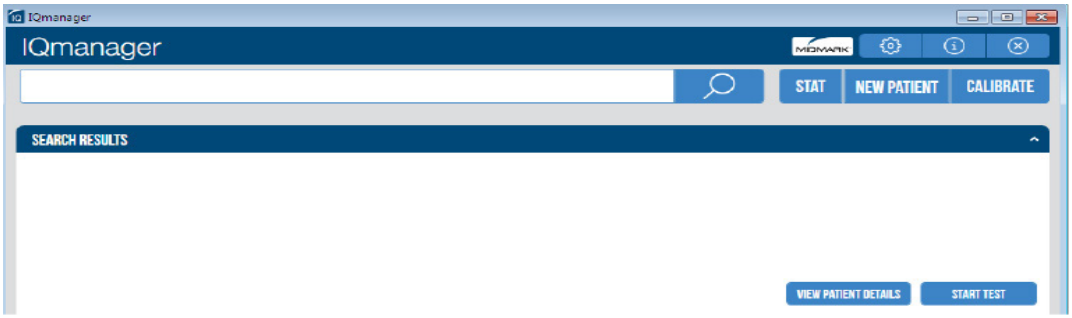
NOTICE

Notice

For a detailed description of diagnostic functions available through IQmanager®, refer to the IQmanager® Operation Manual (48-78-0002).

Opening Screen

When starting IQmanager®, the opening screen appears (see screenshot below):



Opening Screen Buttons	
Button	**Description**
	Search for patients previously entered into the database; selecting a patient from the list allows access to edit, add and delete data from that patient's records and view data from previous tests.
	Acquire vital signs and ECG or any other test that supports STAT workflow before entering patient demographics or selecting a patient.
	Register a **New Patient**. Refer to the appropriate device Operation Manual for a description of the patient details required for specific tests.
	Initiate the calibration check process for specific devices.

Opening Screen Buttons	
	View patient details from a patient selected from the *Search Results* screen.
	Go directly to the test selection screen for the selected patient, bypassing the Patient Data screen.
	Enable users to configure the program to meet their needs. This will also display the current version of IQmanager® software and device software. (See "Configuring IQecg®" for more information.)
	Receive assistance regarding the use, operation and troubleshooting of IQmanager® and other Midmark products.
	Exit the program, and return to the Windows desktop.

STAT ECG

WARNING

Follow the standard 12-lead ECG placement when performing a STAT ECG. The automated ECG analysis algorithm assumes the standard 12-lead ECG placement. Any deviation from the standard 12-lead ECG placements may affect the accuracy of the automated interpretation.

In the event that a STAT ECG is required, hook up the patient using a **STANDARD 12-lead** hook-up to the IQecg® and click **STAT ECG** to immediately access the live ECG test screen without having to enter the patient information. A live ECG report can be printed without saving the patient test, or you can click **Analyze** to have the computer analyze the data and save the report. The system will prompt the user to enter the patient information when exiting the Report Review screen.

Notice

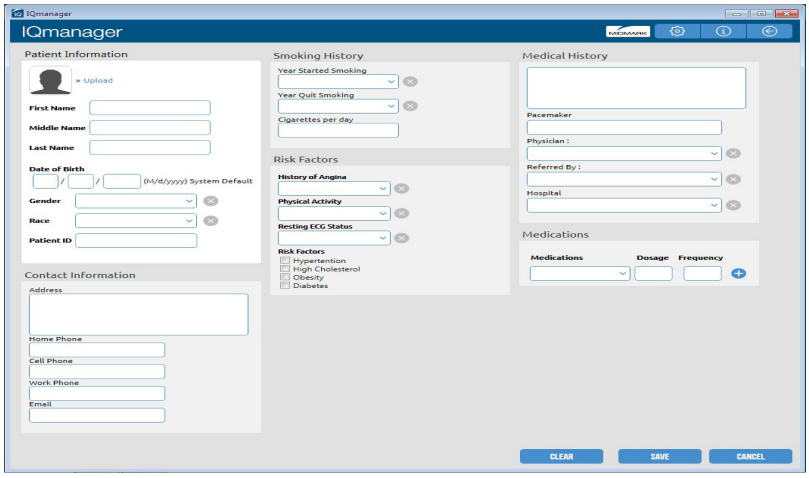
NOTICE *The green LED on the ECG module will light when the module is on.*

Notice

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

Testing a New Patient

To create a new patient file, click the **New Patient** icon on the *Opening* screen. This opens the *Patient Data Entry* screen, where you can enter the patient's specific data (see screenshot below):



Notice

NOTICE *A patient name or ID must be entered to start a new test. It is highly recommended to enter all available information, including an ID.*

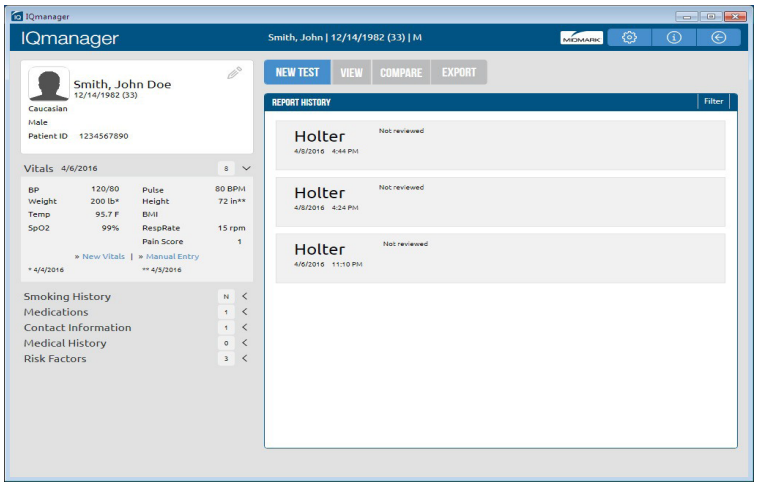
Click in any text box or press the **Tab** key to enter information. This information may not be essential for the acquisition of an ECG; however, it is important to complete each of the fields as accurately as possible, particularly *Date of Birth*, *Sex*, and *Medications*, which are used by the *Midmark 12-Lead Resting ECG Analysis Program* to produce diagnostic statements.

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

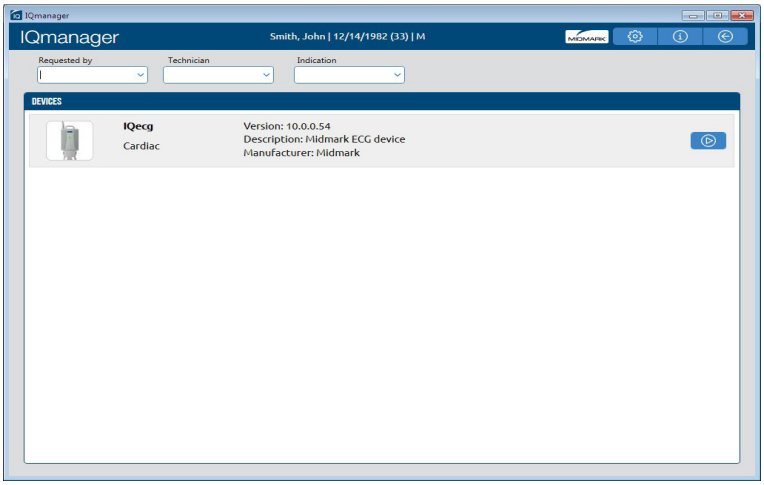
Refer to the *IQmanager® Operation Manual* for additional information on the *Patient Data* screen.

Live ECG Screen

When the patient is properly prepared, is calm, and is comfortable, select a new test by clicking **New Test** on the menu bar on the *Patient Data* screen (see screenshot below):



The *New Test* screen appears (see screenshot below). Select a name from the pull-down list or enter the names of the technician conducting the test and the requesting physician. Enter the diagnostic reason for the ECG test in the Indication field, as necessary. Click the **Start Test** icon in the right-hand portion of the IQecg® device (see screenshot below).



The live **ECG** screen will be displayed (see screenshot below):

The live ECG screen displays the results of the 12-channel ECG in the three-by-four (3x4) leads display format.

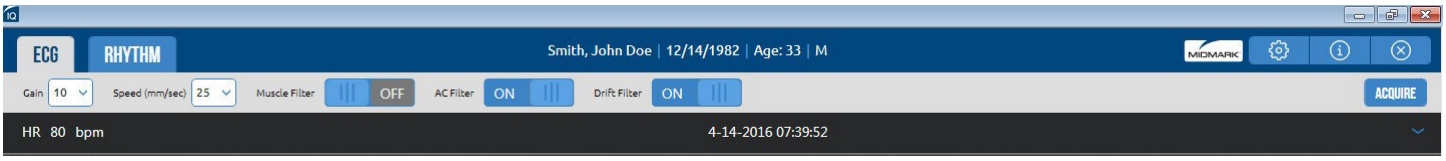
If a modified 12-lead (V3R, V1, V2, V5, V6, V7) is selected:

- The live ECG screen displays a message: “place V3 lead on V3R, V4 lead on V7” at the top right corner of the screen.
- The chest leads on the live ECG screen are arranged in the following order V3R, V1, V2, V5, V6, V7.

> ***Caution***
> *Follow the standard 12-lead ECG placement when performing a STAT ECG. The automated ECG analysis algorithm assumes the standard 12-lead ECG placement. Any deviation from the standard 12-lead ECG placements may affect the accuracy of the automated interpretation.*

> ***Notice***
> NOTICE *The modified 12-lead ECG lead group does not generate automatic interpretations.*

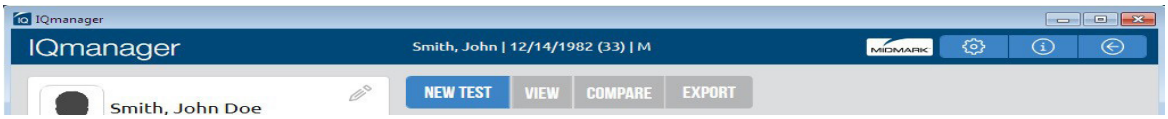
The gain, speed, and filter settings are displayed above the moving tracings. Click the appropriate drop- down item or toggle to modify its setting. Changes to these settings made from this screen are temporary and only apply for as long as the test is active. Make changes and set them as the default settings for all new ECG tests by clicking **Settings**. The patient’s name is displayed at the top center of the screen with the heart rate display on the left of the screen. Lead offs and any error messages will be displayed on the right top corner of the screen (see screenshot below). Wait for the ECG tracings to pass the screen twice and verify the signals are clean and baselines are stabilized. Click the **Acquire** button to capture an ECG test, which will open in the Report Review screen so that the technician can review the quality of the test before saving the report.



Live ECG Screen Buttons	
Button Icon	**Function(s)**
ACQUIRE	Click this button to acquire ECG data.
ECG	Switches to the Resting ECG acquisition screen.
RHYTHM	Switches to the Rhythm screen. A preset duration between 30 and 360 seconds of ECG data may be collected.
⚙	Opens a dialog box for changing the *Default Interpretation* and *Acquisition Display* settings, *Rhythm* settings, and *Configuration*, which are similar to those described in Section II-E, Configuring the IQecg®.
ⓘ	Displays the *Help* screen.
⊗	Click this button to return to the *Patient Data* screen. ECG or Rhythm Reports will not be saved.

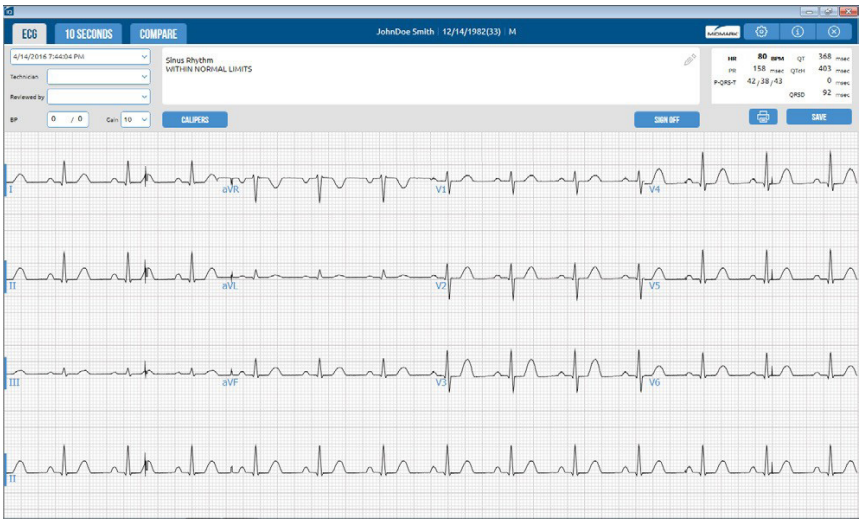
Reviewing Patient Reports

In the Patient Data screen, click **View** to review a selected resting ECG report (see screenshot below):



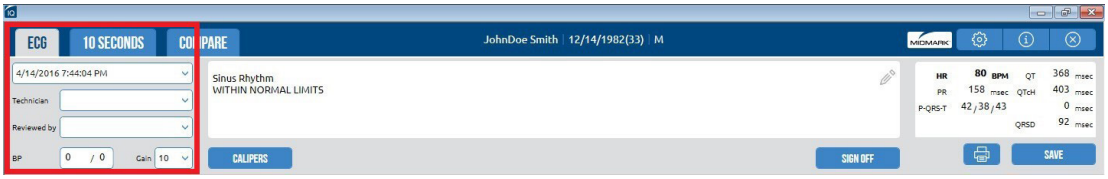
ECG Report Review Screen

The *Report Review* screen displays the 12-Lead ECG tracings of the ECG report (see screenshot below).

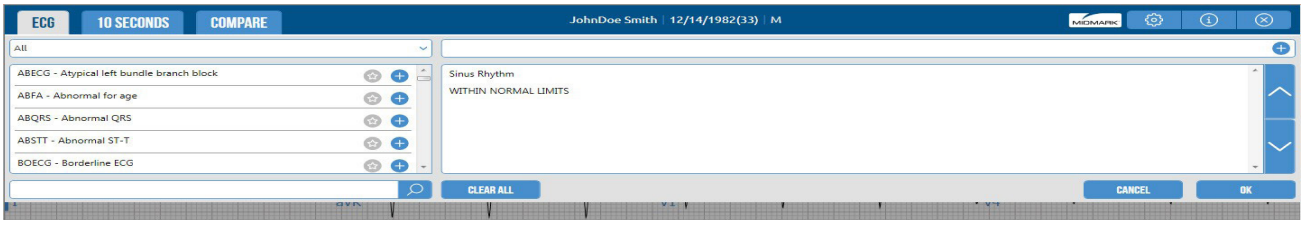


NOTE: Interpretation algorithm: Midmark ECG Analysis Program. The duration measurement of Q-wave, R-wave or S-wave does not include the iso-electric segments within the global QRS complex.

The date and time of the selected report, name of the technician conducting the test, name of the requesting physician, and the patient's blood pressure appear at the top left of the screen (see screenshot below).



Edit or enter an Interpretation by typing directly in the Interpretation field. All diagnostic statements must be reviewed by a qualified physician. You can also make changes to the interpretation and enter customized statements by selecting the pencil icon (see screenshot below).

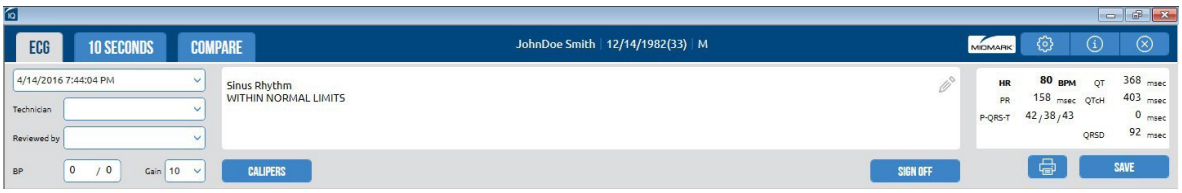


- Click on the top left drop-down arrow for the appropriate category and click the **Plus** (Add) button to add the desired selection. The selected interpretations will be displayed in the right window. Click the
- **Favorite** button to add frequently used interpretations to the *Favorites* list.
- Use the *Search* field to search through all of the pre-set interpretations configured from **List Management**.
- Use the top-right text field to type an interpretation.
- Click the up and down arrows to reorganize the selected interpretations.
- Click **Clear All** to remove all the selected interpretations.

- Click the **X** button next to a selected interpretation to remove it.
- Click **OK** to add the selected interpretations to the *Review Report screen.*
- Click **Cancel** to discard the selected interpretations and return to the *Review Report* screen without saving any interpretations.

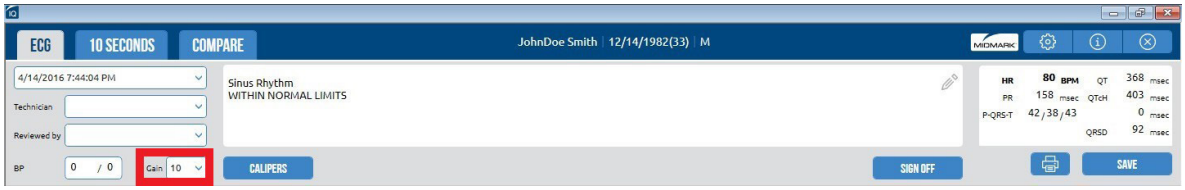
> ***WARNING***
>
> *The computerized interpretation is not a substitute for physician interpretation.*
>
> *All ECGs must be examined with respect to the patient's overall clinical condition.*

The general measurements are displayed on the upper-right portion of the Report Review screen. It is strongly recommended that the physician review and evaluate the diagnostic interpretation and the measurements before signing off on the ECG report. Measurements can be manually overridden by clicking in the field (see screenshot below).

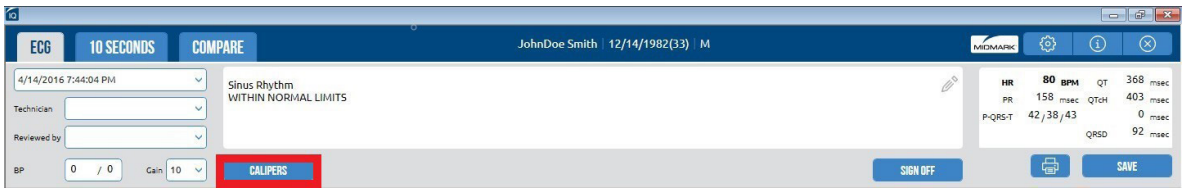


> ***WARNING***
>
> *The computerized calculation of QTc is not a substitute for the physician interpretation of the ECG.*
>
> *It is the responsibility of a qualified physician to review the ECG to determine the accuracy of QTc calculation before using the QTc to make a diagnosis.*

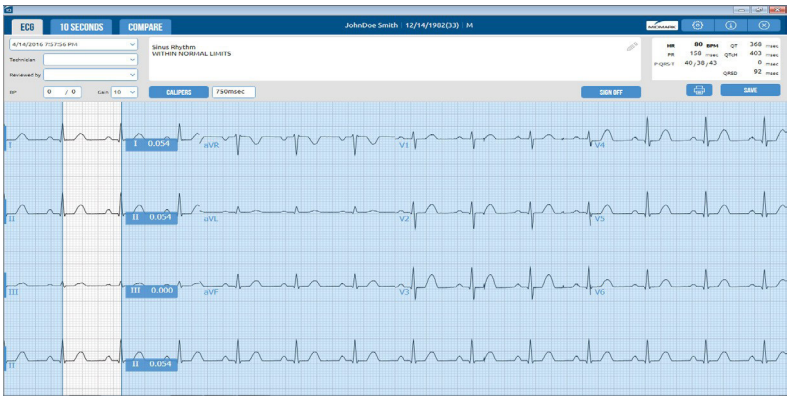
If the ECG amplitude is too short or too tall for viewing, click the **Gain** drop-down to increase the amplitude gain to 20mm/mv or to decrease it to 5 mm/mv (see screenshot below).



Click **Calipers** to measure the amplitude (mv) and duration (ms) of any part of the ECG waveform, making it easy to read over ECG tests online without printing the report (see screenshot below).



Clicking and dragging on a specific caliper will move only that one caliper. Clicking and dragging in the middle of the calipers will move both calipers together. You can adjust the calipers range for longer periods of time by clicking and moving the right or left caliper (see screenshot below).



The **Sign off** button is used for signing off on the report after the physician's name is entered. If the **Sign off** button is clicked, it indicates that the report has been signed by a physician and the screen then becomes read-only. The date the report is signed, the name of the reviewing physician and the user name are recorded (see screenshot below).

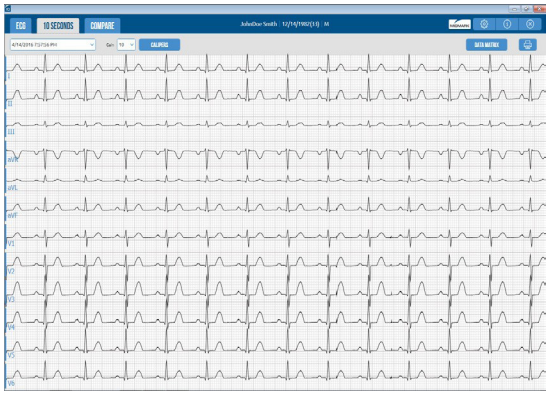
To edit a signed report, first review the report and then click the **Unlock** button.

The **Print** button is used to print the current report. A dialog box will appear after selecting **Print** to specify printing options.

> **NOTICE**
>
> ***Notice***
>
> *Select* **Actual Size** *from the dialog box to ensure grids on the report print in actual size.*

10 Second Screen

The **10 Second** tab will display all 10 seconds from each of the 12 leads on one screen, which is the full disclosure of a 12-lead resting ECG test (see screenshot below).



The menu bar displays the date and time of the selected **report** and the **Gain** drop-down lists.

Click **Calipers** to select the Calipers to measure the amplitude (mv) and duration (ms) of any part of the ECG waveform.

Clicking and dragging on a specific caliper will move only that one caliper. Clicking and dragging in the middle of the calipers will move both calipers together. You can adjust calipers for a different duration by clicking and moving the right or left caliper.

Click **Data Matrix** to display the *Measurement Matrix* window.

If Standard "12-Lead (V1, V2, V3, V4, V5, V6)" is selected, the chest leads and measurement columns are

arranged in the following order: V1, V2, V3, V4, V5, V6.

If “Modified 12-Lead (V3R, V1, V2, V5, V6, V7)” is selected when acquiring a new ECG report, the chest leads of ECG tracings and measurement columns are arranged in the following order: V3R, V1, V2, V5, V6, V7.

Compare Screen

Click the **Compare** tab to compare two ECGs from the same patient (see screenshot below).

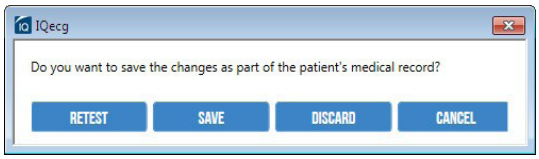
The current test report will be displayed in the top window. The previous test report, by default, will be displayed in the bottom window. You can select other tests by using the drop-down menu, or by using the right or left arrows.

The ECG tracings for each report will be displayed on the left side. The date and time of the report, the **Gain** drop-down, the *ECG Data* fields, and the *Interpretation* field will be displayed on the right side.

The Printer button will print the report that is displayed on screen.

Exiting Report Review

Click the Save button to save the report, or the  (Exit) button for more options through the following dialog box (see screenshot below):



- Click **Retest** to return to the *Acquisition* screen and discard the current ECG test. The retest option is only available after the initial test acquisition.
- Click **Save** to save the ECG test.
- Click **Discard** to delete the ECG test.
- Click **Cancel** to return to the ECG test without saving.

Rhythm Screen

Click the **Rhythm** tab in the Live ECG screen to open the live Rhythm screen for acquiring a *Rhythm* report (see screenshot below).

The gain, speed and filter settings are displayed above the moving tracings. Click the appropriate drop- down item, or toggle to modify its setting. Use the drop-down list on the left-side of each tracing to change the rhythm leads. Changes to these settings made from this screen are temporary and only apply for as long as the test is active. You can make changes and set them as the default settings for all new ECG tests by clicking **Settings**.

The patient's name is displayed at the top center of the screen, with the heart rate display on the left of the screen with the heart rate display on the left of the screen. Lead offs and any error messages are displayed on the top right of the screen (see screenshot below).

Click **Start** to begin the Rhythm test and start recording three rhythm leads.

The time scale is displayed at the bottom of the screen. A colored bar moves across the time scale to indicate the current 10-second window. Note the following details:

- The gray bar indicates that data collected has not reached the 30-second minimum required for a rhythm report (see screenshot below).

- The bar changes to blue once the 30-second minimum has been reached.
- The light blue bar indicates the current data that has been collected.

- The dark blue bar indicates the current 10 seconds of data that is displayed on the screen (see screenshot below).

No test data is recorded during the first 30 seconds. After 30 seconds, the **Cancel** button will change to an **End button**. This is indicated on the screen by a gray bar on the time scale.

Click **Cancel** to stop the test during the first 30 seconds.

Click **End** to manually stop the test and review the data. When the time limit (from settings) has been reached, the software will automatically display the review screen. The data is saved only after you click **Save** in the

review screen (see screenshot below).

Rhythm Review

The *Rhythm Review* screen is displayed after a Rhythm test has ended (see screenshot below).

The *Rhythm Review* screen displays the following data:

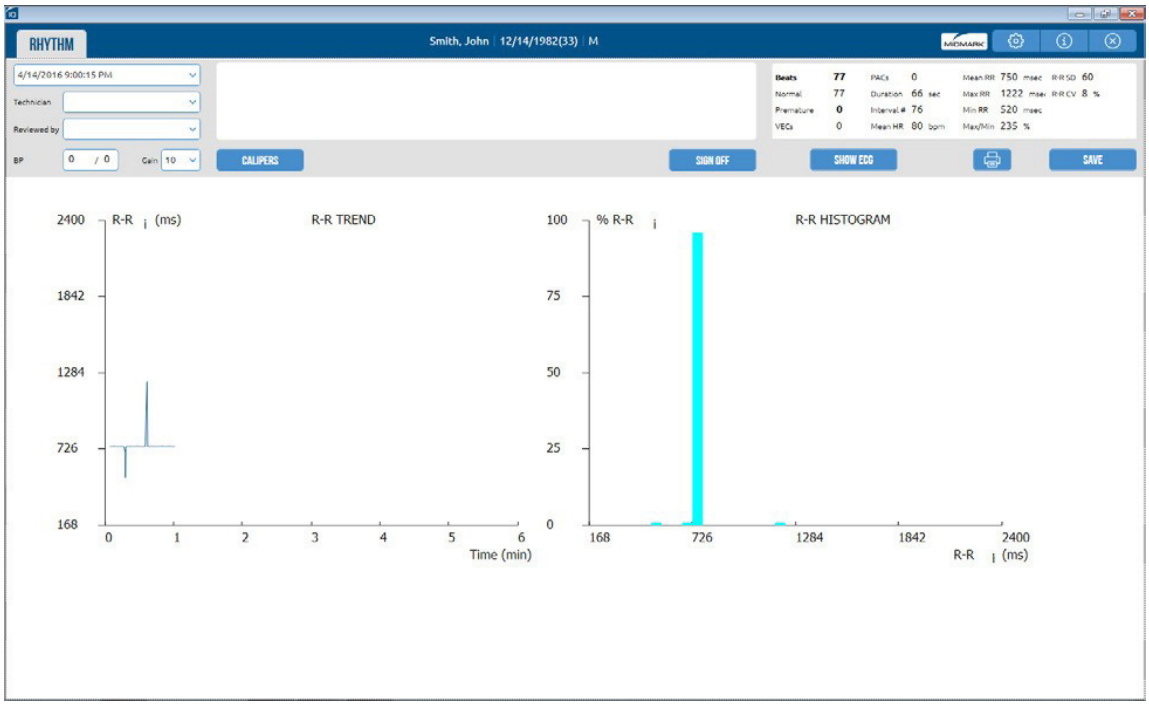
- Test date and time
- Technician
- Physician
- Blood Pressure
- Test data

The *Rhythm Review* screen has the following functionality:

- **Report** selection drop-down menu
- **Gain** drop-down menu
- **Calipers** toggle
- **Print** button
- **Save** button

Click the 10-second markers at the bottom of the *Rhythm Review* screen to move between 10-second intervals of the test. Alternatively, drag the blue section of the time bar to change the ten second portion of the strip shown in the window.

Rhythm data collected can also be reviewed in Rhythm Trend and Rhythm Histogram formats by clicking the **Show Graphs** button (see screenshot below).



Accessories for IQecg®

The following table shows the accessories approved by Midmark for use with the IQecg®.

WARNING

Use only approved accessories with the IQecg®. Substitution of a component different from that supplied could result in measurement error.

Item	Part Number
Universal ECG Clips (3 mm and 4 mm) 10/pack	3-047-0001
Clear ECG Clips (4 mm and Snap) 10/pack	3-047-0005
Patient Cable, Standard, IQecg®	3-100-0203
Disposable ECG Electrodes (box of 1000)	2-100-0208
Disposable ECG Electrodes (case – 4 boxes)	2-100-0209

The disposal of Midmark Diagnostic Devices and their accessories should be carried out according to local medical waste disposal policies and procedures. Do not discard these items in unsorted municipal waste. Contact your local waste disposal agency for guidance on proper recycling or disposal.

Appendices

Appendix A – Operations at a Glance – Standard 12-lead ECG

This appendix provides a condensed guide to using the IQecg® to acquire a standard 12-lead ECG:

1. Start IQmanager®.
2. Select **New Patient** from the opening screen. For a returning patient, search by the patient's last name or ID.
3. Complete the fields on the Patient Data screen as accurately as possible. 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 to 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 Quick Reference User's Guide included with the IQecg® kit, for a standard 12-lead hookup; or refer to "Patient Preparation" of this operation manual.
5. Select New Test on the menu bar, and then select the ECG test after entering the relevant information.
6. 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. For pacemaker patients, all filters should be turned OFF to detect pacer spikes.
7. 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.
8. To acquire a test report, click Acquire on the ECG tab, or Start on the Rhythm tab, as follows:

   - **Acquire** instructs the program to acquire, analyze, and store a resting ECG test.
   - **Start** instructs the program to begin acquiring a preset duration of the rhythm strip, and then prepare a Rhythm report.

9. Reports can be automatically viewed after acquisition, and they can be saved or redone from the review screen.

Appendix B – Operations at a Glance – Modified 12-lead ECG

This appendix provides a condensed guide to using the IQecg® to acquire a modified 12-lead ECG .

> **NOTICE**
>
> ***Notice***
>
> *The modified 12-lead ECG provides the clinician the tool to acquire V3R and V7 using the IQecg® device and its 10-lead patient cable in a way that supplements the standard 12-lead ECG. We recommend performing a standard 12-lead ECG on the patient prior to performing a modified 12-lead ECG.*

10. Perform and acquire a standard 12-lead ECG test. (Refer to "Appendix A – Operations at a Glance – Standard 12-lead ECG" for information on performing a standard 12-lead ECG test.)
11. While in the *Report Review* screen, prepare the patient data for the modified 12-lead resting ECG test as follows:

    a. Prepare the V3R and V7 electrode sites according to best practice.

    b. Apply the new electrodes on V3R and V7 sites.

    c. Remove the V3 lead and attach it to the V3R electrode.

d. Remove the V4 lead and attach it to the V7 electrode.

   Refer to "Patient Preparation " of this operation manual for additional information.

12. Select the ECG test after entering the relevant information.
13. 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. For pacemaker patients, all filters should be turned OFF to detect pacer spikes.

14. 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.
15. To acquire a test report, click **Acquire** on the **ECG** tab, or click **Start** on the **Rhythm** tab as follows:

    - **Acquire** instructs the program to acquire, analyze, and store a resting ECG test.
    - **Start** instructs the program to begin acquiring a preset duration of the rhythm strip, and prepare a Rhythm report.

16. Reports can be automatically viewed after acquisition, and can be saved or redone from the review screen.

Appendix C – Upgrading IQmanager® software version 8.5 and earlier

The following describes the changes to the original QTc data in the ECG reports with previous versions of IQmanager® software after this upgrade:

- Information on the old ECG reports will remain the same as long as no changes are made to the report.
- The original QTc information will no longer be editable. This value will be fixed.
- Add up to two of the four available QTc data to include in the ECG report. See "ECG Configuration Setting".
- Changes made to the ECG report that have the original QTc information may remove it from the report. The general rules of thumb are as follows:

  1. Changing the interpretation statement or general measurement values, other than heart rate or QT, will retain the original QTc data. This is to preserve the original QTc value to support the physician's interpretation. Additional QTc information will be added to the report based on the current selections in QTc 1 and QTc 2 settings.
  2. Changing the heart rate or QT value will remove the original QTc data and replace it with the current selection in QTc 1 and QTc 2 settings. The original QTc value is redundant in this case since QTc will be recalculated based on the new heart rate or QT values.
  3. If the report already has the QTc 1 and/or QTc 2 data, any changes to the report will update the QTc 1 and QTc 2 information based on the current selection in these settings.

- A warning message will appear to inform the user of the changes in QTc data when you begin to edit the report. Accept the change in order to edit the report.
- Optional: Check "Do not show any New QTc Formula Update message again" to disable the warning message.
- The original QTc data in the Measurement Matrix will be removed and replaced by the new QTc 1 and QTc 2 information.
- Accessing the P-QRS-T Calipers will display the QTc information based on the current QTc 1 and QTc 2 settings. Moving the calipers that measure the QT interval will automatically update the new QTc values

according to the specific formula.

- Similar to the original QTc information, the system does not allow the user to change the new QTc data directly. However, changing the heart rate or QT value will automatically update the new QTc data according to the specific formula.

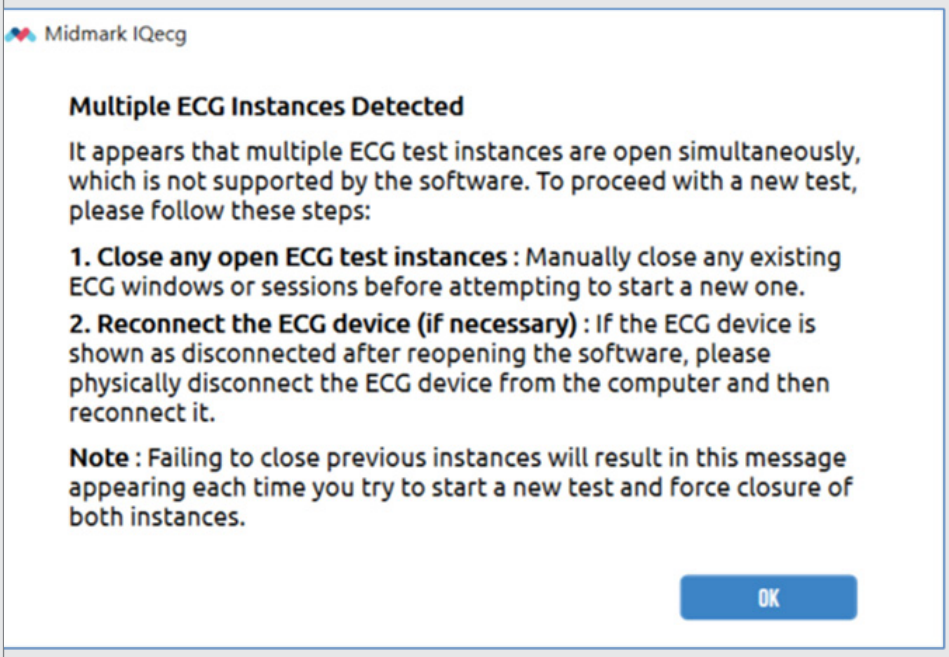
Appendix D – Troubleshooting Guide

This *Troubleshooting Guide* provides a list of solutions or recommendations to situations that may be encountered with IQecg®. Before calling Midmark Technical Service, please refer to the following table for help. Error messages may be displayed at the center or at the bottom-right corner of the screen.

> **NOTICE** ***Notice***
> *For errors that occur during the analysis or management of ECG files, please refer to Troubleshooting section in the IQmanager® 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. 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 "Software Installation" and "Configuring IQecg®".
DISPLAY DIAGNOSTICS: Delays in the ECG display have been detected. Click Help 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 a running live ECG in a thin-client environment, the bandwidth maybe too low. • Click **Help** and follow the recommendations on the Help screen. • Verify that no other tasks or programs are running. Exit IQmanager® and close all running programs. Restart IQmanager® without restarting the computer.
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 **Touchscreen Display** users: If you are using the same COM or USB port for both the ECG module and the touchscreen display, close or disable the touchscreen driver before running the IQecg® program.
Incorrect diagnostic interpretation.	• Refer to ECG signal quality problems above. • The patient's Date of Birth, Sex, and Medications must be accurately entered. Refer to Section III-E, Testing a New Patient. • Edit the diagnostic statements accordingly. See Section III-E, Reviewing Patient Reports/ ECG Report Review.

No error message and no ECG trace on Live ECG screen.	• Refer to ECG MODULE NOT RESPONDING above.
Prints slowly when printing live ECG tracing or printing automatically after analysis.	Depending on the computer, print jobs may be slower if the ECG module is still actively collecting live ECG data. • Verify that Print after Analysis is not checked. Refer to ECG Settings, Section II-D, Configuring IQecg/Printer Settings and RR Variability Settings. • Uncheck the Grid setting. Printing ECG reports without the grid will expedite the print jobs.
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 must be correct, and the electrodes and lead wires firmly must be secured. See Section III-B, Patient Preparation for best practices. • Verify that the electrodes are fresh, moist, and sticky, not dry or hard. Check the electrode expiration date on package. • Verify that the patient lead wires and cables are not damaged or worn out. • Inspect the connections between the electrodes, clips, lead wires, lead cable, and the ECG module. • The exam room should not be too cold; if it is, the 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 limb lead 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 the problem is 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 the test report. • Test the filter settings on the ECG screen. Turn the AC filter to ON if you see 50/60Hz noise. Turn the Muscle filter to ON if the patient produces muscle tremor. Turn the Drift filter to ON if the ECG baseline is drifting. While these digital filters can improve the signal quality, they cannot correct hookup problems. • NOTE: As with any ECG measuring device, turning on the Muscle filter may alter measurements, which may affect the diagnostic statements. For pacemaker patients, all filters should be turned OFF to detect pacer spikes.

	• Verify that the patient's bed is properly grounded. • Verify that the 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.
Running multiple ECG instances	
All other operational problems.	• Click **Help** on all screens to access the online help. • Additional troubleshooting that covers ECG diagnostics is available in the *IQmanager® Operation Manual*. • Contact Midmark Technical Services.

Appendix E – 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 ECG 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, 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, is completely dry before using.

Caution

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

Storage

Avoid extreme humidity and heat during storage.

Caution

To prevent possible damage, do not hang the IQecg® module by the interface cable or the patient cable. The module is constructed with a sturdy, built-in hanger to accommodate safe storage when not kept in the carrying case.

Caution

Electronic devices can be damaged by exposure to liquids. Do not use or store the IQecg® near any type of liquids.

Appendix F – Maintenance and Storage of the 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 the cable, and do not attempt to repair the cable. Contact Midmark Technical Services for a replacement cable. If the cable is found to be contaminated, clean and disinfect it according to the instructions below before reusing it.
- Plug the 10-Lead Resting ECG Patient Cable into the IQecg® module, as described in Section II of this IQecg® Operation Manual. Make sure that 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.
- If you are experiencing signal disturbance, distortion, or interruptions, stop the procedure and localize the source of the problem, and correct the problem 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 in a non-sterile condition and are reusable. For cleaning and disinfection of the cables, the following substances and procedures must be used:

- Disconnect the cable. Wipe the plastic parts with a cloth moistened in lukewarm water with alcohol-free neutral soap. Always wipe towards the patient connectors/ECG clips.
- Proceed carefully and make sure 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 the cable before use.
- Remove adhesive residues only with the alcohols listed in the following section. Never use other organic solvents (acetone or toluol will damage the cable jacket).

Disinfection

Clean the cables before each disinfection as described in the preceding section. 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. Sani-Cloth® 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) should be avoided for the disinfection of the cables

Appendix G – 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 general safety standard IEC 60601-1 for medical devices and in accordance with the EMC standard IEC 60601-1-2 rules, which are designed to provide reasonable protection against electromagnetic interferences in a medical or hospital environment.

Appendix H – EMC Requirements for the IQecg®

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 IQecg® is medical electrical equipment.

The following is a list of the Midmark cables and other accessories that are used as part of the IQecg® that comply with the EMC Standard IEC60601-1-2 :

- ECG Model(s) IQecg®
- Patient cables: **Approved Midmark 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 IQecg® as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the IQecg®.

Guidance and manufacturer's declaration – electromagnetic emissions		
The IQecg® is intended for use in the electromagnetic environment specified below. The customer or the user of the IQecg® should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR11	Group 1	The IQecg® 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 equipment.
RF emissions CISPR11	Class B	The IQecg® 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	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The IQecg® is intended for use in the electromagnetic environment specified below. The customer or the user of the IQecg® 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	±8 kV contact ±2 kV, ± 4 kV, ±8 kV, ±15 kV air	±8 kV contact ±15 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 AC mains ±1 kV for input/ output lines 100kHz repetition frequency	±1 kV for input/ output lines	USB device
Surge line-to-line Surge line-to-ground IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line ±0.5 kV, ±1 kV, ±2 kV line-to-ground	N/A	USB 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	USB device
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	8 A/m @ 30 kHz 65 A/m @ 134.2 kHz 7.5 A/m @ 13.56 MHz	8 A/m @ 30 kHz 65 A/m @ 134.2 kHz 7.5 A/m @ 13.56 MHz	
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The IQecg® is intended for use in the electromagnetic environment specified below. The customer or the user of the IQecg® should assure that it is used in such an environment.			
			Portable and mobile RF Communications equipment should be used no closer to any part of the IQecg®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance d = 1.2 √ P 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	d = 1.2 √ P 80 MHz to 800 MHz d = 2.3√ P 800 MHz to 2.7 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 IQecg® is used exceeds the applicable RF Compliance level above, the IQecg® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the IQecg®.

[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 IQecg®

The IQecg® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IQecg® can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IQecg® 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 $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	*0.73*
1	1.2	1.2	2.3

Recommended separation distances between portable and mobile RF communications equipment and the IQecg®

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

10	3.8	3.8	7.3
100	12	12	23

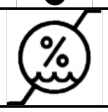
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

Appendix I – 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
	Refer to instruction manual/ booklet
	IEC 60601-1 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.
	Manufacturer
	Date of Manufacture
	DC VOLTAGE – (USB CONNECTION DEVICES) This device uses 5 Volt power and consumes 80mA when in use.
	Warning
	Caution
	Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician
	Batch code
	Catalogue (model) number
	Serial Number
	Temperature limits to which the medical device can be safely exposed
	Range of humidity to which the medical device can be safely exposed
	Consult instructions for use
	Keep dry
	Do not dispose of this product as unsorted municipal waste For more disposal information see Displosal.

IQecg® Service Manual

Introduction

The Midmark IQecg® 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 IQecg® system consists of the ECG data acquisition module; the PC system, including a monitor and printer; Microsoft Windows operating systems (see Minimum Computer Specifications 99-99-00741011); and the IQmanager® software program.

System Maintenance and Obtaining Service

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

- Keep the patient cable clean.
- Do not unplug the patient cable from the IQecg® hardware.

The IQecg® Digital ECG acquisition modules contain no user adjustable or serviceable parts and are designed to operate without adjustment for the lifetime of the product.

However, electronic equipment can be subject to wear and damage that can cause malfunctions. A certification policy is the responsibility of the end user, and is subject to the end user's business practices, which may require it. Certification provides peace of mind that the device continues to work within factory specifications. Certifications can be purchased directly from Midmark. In the event that something unexpected would happen to your device, Midmark also offers repair services for the IQecg Digital ECG.

Please contact Midmark Technical Services with questions or to make arrangements for the certification or repair of an IQecg® Digital ECG device.

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

Disposal

The disposal of Midmark Diagnostic Devices and their accessories should be carried out according to local medical waste disposal policies and procedures. Do not discard these items in unsorted municipal waste. Contact your local waste disposal agency for guidance on proper recycling or disposal.

Customer Support and Warranty Information

For immediate help diagnosing problems with this product, refer to the online Help or "Appendix D – Troubleshooting Guide".

For help diagnosing problems by phone with this product, contact Midmark Technical Services.

Warranty

Midmark warrants IQecg® to be free from manufacturing and material defects for 12 months from the date of purchase. Accessories and patient cables for IQecg® are warranted for 90 days. Any misuse or abuse of a Midmark product voids all applicable warranties.

Please refer to midmark.com for the full and current Warranty Terms and Conditions.

Return Materials Authorization

To return any product for repair, a Return Materials Authorization (RMA) number must be obtained from Midmark Support Services. This RMA number should be referenced on the package(s) containing the items to be returned and in any correspondence regarding the return.

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 following all guidelines for the shipment of medical products set forth by the shipping company used. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for an 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 due to improper packaging, shipment or product use. Such actions will void all applicable warranties

Contact Information

Technical Support is available Monday through Friday (except holidays), 6:00 am to 4:00 pm Pacific Standard Time.

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