midmark®

Midmark Digital ECG

Version 10.0

Operation Manual

003-10563-00 Rev AB3

Notice

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

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Part number for this operation manual: 003-10563-00 Rev AB3

If you have the Midmark IQecg, please refer to manual 48-78-0002 on our online technical library.

℞ ONLY	Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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Important Information

This manual is maintained with the utmost care. Should you find any inaccurate or outdated details in this manual, please inform Midmark, who will proceed to correct such inconsistencies as soon as possible.

The information contained in this manual is subject to change without prior notice. All changes are made in compliance with the regulations governing medical equipment manufacturing.

Safety Symbols

	**Warning** *Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.*
	**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 Midmark Digital ECG through an EMR, please contact Midmark Technical Service for assistance with installation, setup, and operation.

Safety Information

Midmark shall be liable for the safety, reliability and functionality of the devices only if the device is used in compliance with the instructions provided in the relevant Operation Manual.

Warnings

- This manual provides important information on proper use and safety of the device. Failure to comply with the described operating procedure, improper use of the device, or ignoring the provided specifications and recommendations could cause severe physical injuries to the operators, patients, and bystanders, or may damage the device.
- No appliance modification is permitted.
- This device captures data that reflects the physiological condition of the patient; this information can be examined by specialist medical staff and may be useful in providing an accurate diagnosis. In any event, the data must not be used as the only means to make an accurate diagnosis of the patient.
- The intended device operators must have the required skills regarding medical procedures and the treatment of patients. They must also be appropriately trained in using the device. The operator must carefully read and understand the contents of the operation manual and other annexed documents before using the device for clinical applications. Inadequate knowledge or training could cause greater risk for the physical safety of operators, patients and bystanders, or could damage the device. It is recommended to contact Midmark or their Authorized Trainer to schedule an adequate training course.
- For the correct operation of the device and for the safety of the operators, patients and bystanders, the device and the accessories must be exclusively connected as outlined in this manual.
- The safety of the patient and the operator is protected if the peripheral units and the accessories that can come into direct contact with the patient comply with standards IEC 60601-1 and IEC 60601-2-25. Only use spare parts and accessories supplied with the device and available from Midmark. Refer to the Accessories for Midmark Digital ECG section for a list of approved accessories.

- Conductive parts of the patient cable, electrodes and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts, including earth ground.
- To prevent serious personal injuries or death during defibrillation, avoid contact with the device or patient cables. It is also necessary to properly position the defibrillation pads with respect to the electrodes in order to minimize patient skin burns.
- Protection from defibrillation can only occur by using an original patient cable. Any modifications to the device may offset any protection from defibrillation.
- After a defibrillator shock, the device operation may be interrupted for no longer than five seconds, during which essential functions and performance are restored.
- The patient cables to be used with the device are defibrillation-proof. Check the patient cables for ruptures or cracks before use.
- This device is designed to be used only with the electrodes specified in this manual. Strictly follow the correct clinical procedures to prepare the skin before electrode application and monitor the patient in order to avoid any irritation, inflammation or other skin reactions. The electrodes are designed for short-term applications and must be promptly removed once the examination is complete.
- To prevent infection, use the disposable components (e.g., the electrodes) only once. To ensure safety and use efficiency, do not use electrodes after their expiration date. Expiration date can be found on the packaging of the electrodes.
- The device is intended for external use and is not intended for direct cardiac application.
- There is a potential explosion hazard using the device. Do not use the device in the presence of flammable anesthetics.
- The device is not designed for use with high-frequency (HF) surgical equipment and does not provide any protection against related hazards to the patient.
- The signal quality produced by the electrocardiograph may be adversely affected by other medical equipment use such as defibrillators and ultrasound machines.
- The following equipment can cause interferences on the RF channel for data transmission: microwave ovens, diathermy units with LAN (spread spectrum), amateur radio transceivers and radars.
- There is no safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.
- The operation may be adversely affected by the presence of strong magnetic fields such as those produced by electrosurgery equipment.
- Device use is not recommended in the presence of medical diagnostic imaging equipment such as Magnetic Resonance Imaging (MRI) or Computerized Axial Tomography (CAT) in the same environment.
- Do not clean the device or the patient cables by submersing them in liquid, autoclaving or steam cleaning. This may cause serious damage to equipment or reduce its lifespan. Using non-specific detergents/disinfectants, failure to comply with the recommended procedures or contact with non-specific materials may cause additional risks to operators, patients or bystanders, or may damage the device. Do not sterilize the device or the patient cable with ethylene oxide gas (EtO). Refer to Appendix C for instructions on proper cleaning and disinfecting.
- The device has IP4X protection rating against the ingress of solid particles, thus protected against solid particles with diameter larger than 2.5 mm.
- The Silicone Cover accessory (see general overview) has IPX2 protection rating against the ingress of solid particles and water; it therefore protects the device against water drops falling at a maximum angle of 15° when used with the device. Without the Silicone Cover accessory, the device is not protected against liquid penetration.
- Always check the condition of a Silicone Cover before use. The use of a worn or damaged Silicone Cover might impair the degree of protection of the Midmark Digital ECG. If the Midmark Digital ECG needs to be used in situations for which the IPX2 degree of protection is essential to assure correct operation, it is recommended to always keep a Silicone Cover on hand for replacement.
- No risk has been identified from contact or prolonged contact with the material comprising a Silicone Cover. However, it is recommended to avoid direct contact with the skin for periods exceeding 24 hours.

- Using non-specific detergents/disinfectants for cleaning a Silicone Cover, failure to comply with the recommended procedures or contact with non-specific materials may cause additional risks for the physical safety of operators, patients or bystanders, or may damage the device. Do not use strong oxidizing agents. Reference Appendix C.
- Silicone Cover is designed to maintain its features. It is recommended to replace the cover if it is damaged or worn.
- Do not leave the patient cable unattended in the presence of children to avoid accidental strangulation.
- Do not leave the electrodes unattended in the presence of children to avoid suffocation if accidentally swallowed.
- Always store the device in a clean place protected from insects, which might damage it.
- Do not use the USB connector in environments at atmospheric pressure lower than 700 mbar (altitude more than 3,000 m Above Sea Level).
- The device powered via USB must be connected to a PC compliant with IEC 60950-1:2015 or to IEC 62368-1:2018 or to IEC60601-1:2012. Connecting additional equipment to the device could increase leakage current to the chassis and/or patient. To avoid endangering the safety of the operator and patient, keep in mind the requirements of IEC 60601-1:2005+A1 chapter 16 and measure the leakage current to confirm that there is no risk of electric shock.
- The device powered via USB must be connected to a USB 2.0 port, compliant with the electrical and power supply requirements set by the USB 2.0 specifications published by USB-IF (USB Implementation Forum, Inc.)
- Disconnect the patient from the device when inserting or disconnecting the USB connector.

Caution

- To prevent damage, do not use sharp or heavy objects to press the power button, only use your fingertips.
- Clean the device and the patient cable before use if necessary (reference Appendix C). Check the connections for any damage or excessive wear before each use. Replace the patient cable should it present any damage or excessive wear.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Form the patient cables into a loose loop before storing the device.
- The device operates exclusively with a computer having the appropriate Midmark software installed.
- There are no user-serviceable parts inside the device.
- The device does not require any calibration or special instrumentation for correct use.
- When it is necessary to dispose of the device, its components and accessories (e.g., cables, electrodes) and/or packaging material, comply with local standards for waste disposal.
- Handle this device with care, taking all the necessary precautions to prevent and avoid heat sources, liquids and other possible causes of damage.

Notes

- Patient movement can generate excessive noise and affect the quality of the ECG trace or the correct analysis of the ECG tracings.
- Appropriate patient preparation is important to guarantee the proper ECG electrodes application and correct device operation.
- The algorithm attempts to detect the positioning of electrodes based on both normal physiology and the order in which the electrodes are placed. However, it is recommended to check the positioning of the electrodes of the same group (limbs or chest).
- There is no identified safety hazard when using other equipment, such as pacemakers or other stimulators, simultaneously with the device; however, disturbances to the signal may occur.
- If the electrodes are not properly attached to the patient, or one or more patient leads are damaged, the ECG plugin software will indicate which lead is off.
- As defined by the IEC 60601-1 and IEC 60601-2-25 safety standards, the device is classified as follows:
    - Internal power supply or Class II.

- Defibrillation-proof Type CF applied parts.
- Ordinary equipment.
- Not suitable for use in the presence of flammable anesthetics.
- Continuous operation.

- The USB power supply has the following specifications: 5 V - 500 mA.
- The Midmark Digital ECG is a Class II device in compliance with US FDA 21 CFR Part 820.
- To prevent possible damage to the device and/or its accessories during transportation and storage (even if no longer in its original packaging), the following environmental conditions must be complied with:

Environment	Requirements
Temperature conditions:	○ From -40°F to 40°F (-40°C to 5°C) without relative humidity control ○ From 40°F to 104°F (+5°C to 40°C), up to 90 % relative humidity, without condensation ○ From 104°F to 158°F (40°C to 70°C) with water vapor pressure up to 50 hPa
Atmospheric pressure:	○ 540 mbar – 1,060 mbar

- The device and its accessories are intended for use in hospitals or doctor's offices and should comply with the following environmental requirements:

Environment	Requirements
Temperature conditions:	○ 32°F to104°F (0°C - 40°C)
Relative humidity:	○ 15 % - 90 % without condensation, but not requiring a partial water vapor pressure greater than 50 hPa
Atmospheric pressure:	○ USB operation: 700 mbar – 1,060 mbar (up to 3,000 m Above Sea Level)

- The device can be operated at a temperature of 23°F (-5°C) after storing it at an ambient temperature of 68°F (20°C).
- Midmark Digital ECG and its accessories do not require acclimatization time from extreme storage temperatures to ambient temperature 68°F (20°C).
- The Midmark Digital ECG must be connected to the computer's USB port before use.
- In order to be used with the Midmark Digital ECG, the computer must meet the hardware specifications set out by Midmark.
- Refer to System Specification for the performance and accuracy specifications in the analogic/digital conversion of the ECG signal (resolution, amplitude, sampling frequency, etc.)
- **The device's expected service life is five years**.

Physician's Responsibility

The interpretations provided by the Midmark Digital ECG 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 test administration, making a diagnosis, obtaining expert opinions on the results and instituting the correct treatment.

Caution

US Federal Legislation restricts the sale of this device to physicians only.

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 Midmark Digital ECG:

- Quick Reference User's Guide – Performing a 12-lead Resting ECG Test (Part number: 003-10560-00)
- 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)
- Midmark Digital ECG Handling and Use Guide (003-10742-00)

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 Midmark Digital ECG:

1. Installation and maintenance of the device:
    - Protect the device from shock and vibration while transporting it.
    - Do not install the device in a chemical storage area or where gas is generated.
2. Preparation of the device prior to operation:
    - Verify proper device 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 device closely during use. If any abnormality is observed, immediate proper action, such as stopping the operation of the device, should be taken for the safety of the patient.
4. Keep the device clean to ensure trouble-free operation for the next use.
5. In case of a malfunction, contact Midmark Technical Service, and describe the problem precisely.
6. Inspect the device and accessories regularly.
7. Do not make any modifications to the device.
8. The IQmanager® Diagnostic Workstation software and the Midmark Digital ECG 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 Midmark Digital 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 Midmark Digital ECG with them. Before updating your operating system, contact Midmark Technical Service for the latest OTS operating systems information.
9. Do not carry/transport the device via USB cable or Patient Cable.
10. The Midmark Digital ECG is intended to be used with direct connection to a computer's USB port. USB dongles, USB adapters, USB powered hubs, USB extensions, computer monitor USB ports, and other similar 3rd party accessories are NOT supported with the digital ECG.

Caution

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

Caution

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

Caution

Contact Midmark Technical Service for any servicing questions.

Contents Checklist

The Midmark Digital ECG kit contains the following listed items. 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	Midmark Digital ECG (data acquisition module)
1	Patient Cable
1	Silicone Cover
1	USB Cable
1	10-pack Clear ECG Clips
1	100-pack Disposable ECG Electrodes
1	Midmark Digital ECG QR code
1	Quick Reference Guide
1	Warranty Card
1	Proper Use and Storage Guide
1	Midmark Digital ECG Handling and Use Guide

Note: Midmark Digital ECG, Patient Cable, Silicone Cover and USB Cable come pre-assembled.

General Information

This manual is an integral part of the device and should always be available as support material to the clinician or the operator. Strict compliance with the information contained in this manual is an essential prerequisite for a proper and reliable use of the device.

It is intended for the operator to read the manual thoroughly as the information related to the different chapters is only described once.

Should any instructions or assistance be required for device installation, use or maintenance please contact Midmark Technical Service.

Should any unexpected operations or events occur please contact *Midmark Technical Service* immediately.

Introduction

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

Together with IQmanager® Diagnostic Workstation software, the device makes it possible to record 12-lead ECGs, interpret them, archive the reports for future references and share them with colleagues via networks or email. It features fully integrated PC technology and a host of advanced diagnostic features.

Model	Connection	Device Part Number	Kit Part Number
Midmark Digital ECG	USB	1-100-1550	4-000-0080

The information in this Operation Manual is provided for users of Midmark Digital ECG.

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

Intended Use

The function of the Midmark Digital ECG device is the acquisition and transmission of the ECG signal for viewing, processing and presenting the ECG signal to support diagnosis of the patient's conditions.

Midmark Digital ECG is a USB ECG acquisition device intended as a standard PC (Windows) common front-end for resting ECG.

The device implements wired communication via the USB cable. Midmark Digital ECG data goes through an embedded high pass filter to the PC without performing any analysis.

Midmark Digital ECG is not intended for monitoring or analysis of the cardiac function or to diagnose the patient's health condition. The analysis program on the PC is a separate product. The result of the analysis must always be validated by qualified and trained medical personnel.

Midmark Digital ECG is not able to permanently store the acquired data, therefore it does not work unless a connection has been established with a PC with installed Midmark software. Furthermore, Midmark Digital ECG does not collect any of the patient's protected health information (e.g., patient's name, age, previous health conditions).

- Midmark Digital ECG is indicated for the acquisition of ECG signals for resting ECG systems.
- Midmark Digital ECG is suitable for working at high altitudes, with restrictions (see ***Safety Information*** **Notes**).
- Midmark Digital ECG is intended for use on adult and pediatric patients, with no limits of age or gender.
- Midmark Digital ECG is intended for use in medical facilities (hospitals, clinics).
- Midmark Digital ECG is intended for use by a doctor or nurse, or by other skilled clinical personnel who act following orders by a doctor or authorized nurse.
- Midmark Digital ECG is not intended for monitoring vital physiological parameters.

Essential Performance

The purpose of the device is the acquisition of ECG signals for diagnostic purposes, as defined in IEC 60601-2-25.

Midmark Digital ECG meets the following essential performance requirements:

- Defibrillation protection, for cl. 201.8.5.5.1

- Reduction of defibrillation energy, for cl. 201.8.5.5.2
- Frequency response, for cl 201.12.4.107.1
- Linearity and dynamic range, for cl. 201.12.4.107.2
- Sampling and quantization, for cl. 201.12.4.107.3
- Use with cardiac pacemaker, for cl. 201.12.4.109
- Immunity to electrostatic discharges, for cl. 202.6.2.2.1
- Immunity to fast electrical transients and bursts, for cl. 202.6.2.4.1
- Immunity to conducted disturbances, for cl. 202.6.2.6.1

Device Description

Midmark Digital ECG is a portable digital acquisition device that can acquire the physiological 12-lead signal.

Midmark Digital ECG sends the acquired data by USB and, in real time, to a computer with compatible Midmark software installed.

Midmark Digital ECG ensures the acquisition of an ECG signal that meets the strictest standards used in clinical and diagnostic applications (AAMI, ANSI, AHA, ACC).

Midmark Digital ECG is light, compact, convenient to wear and reduces motion artifacts that can be caused by using conventional electrodes and patient cables.

An LED indicator makes it possible to monitor the connection status of the device (off when the unit is off and on when the unit is connected).

General Overview

Front view of the device:

Rear view of the device:

Note: The Midmark Digital ECG is powered by a USB cable and does not require AAA batteries. The USB connects the Midmark Digital ECG to the PC using a computer USB-A (2.0 or 3.0) port. The connector is inserted and provides power to the device via the USB port.

Use of the Power button

- Use the power button to turn on the device.
- Do not use the power button to turn off the device; the device will automatically power down once the USB cable is unplugged from the computer.

LED indicator

The device is equipped with a two-color yellow and blue LED status indicator. The following device statuses correspond to the LED indicators:

LED	Device Status
Off	The Midmark Digital ECG is switched off.
Flashing yellow	Midmark Digital ECG is on, but in error status which prevents its use (e.g., USB connection not established), Midmark USB ECG driver is not installed.
Flashing blue	Midmark Digital ECG is on, connection active, waiting for the software to activate ECG acquisition.
Steady blue	Midmark Digital ECG is connected to the PC, ECG acquisition/ transmission in progress.

Buzzer

The Digital ECG device is fitted with a buzzer to indicate:

Sound	Event
Ascending tone sequence	Switching on
Quick two-tone sequence	PC connection

Silicone Cover

The Silicone Cover for Midmark Digital ECG is a protective shell that allows the device to have enhanced resistance to impacts, falls and water ingress. With Silicone Cover the device reaches degree IP42 protection.

The material and ergonomic shape improves gripping the device, making it even easier to handle when used in emergency situations.

Necessary Computer Skills

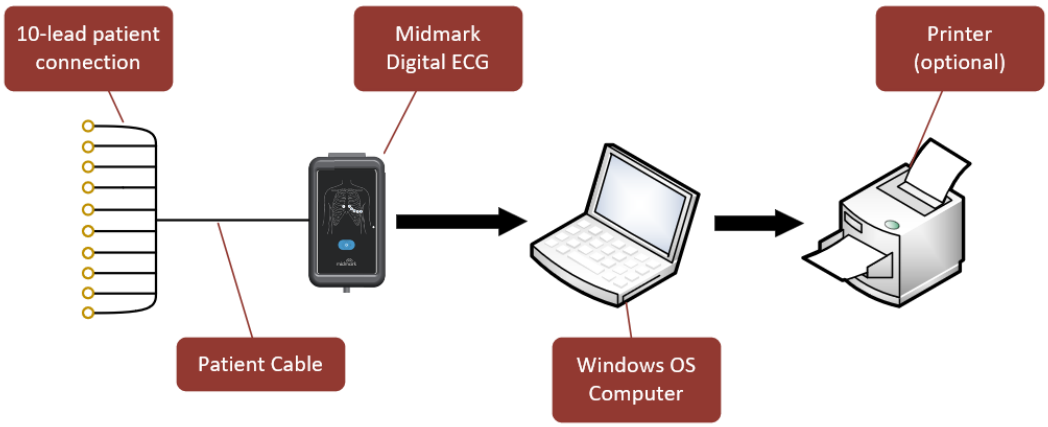
This manual is intended for capable Microsoft® Window® application users who have some understanding of PC operations and is familiar with the basic operations of Windows®.

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

Configurations

Typical PC Configuration

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



Block Diagram of the Midmark Digital ECG system

Thin Client Configurations

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

IQmanager® supports the following thin client configuration: IQpath™ Software Solution. IQpath™ works with the USB port

version of the ECG 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

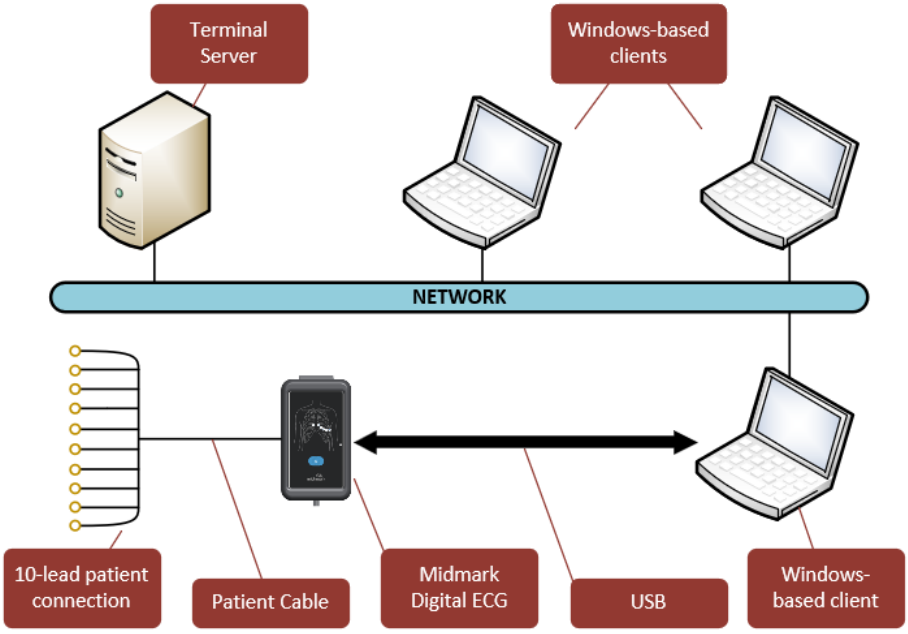
IQpath™ utilizes a dedicated flow control scheme to provide the following advantages over COM port

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.

Note: IQpath™ has specific requirements for computer hardware, software, and network performance. System administrators should read Setup Manual: Midmark Products over Thin Client using IQpath™ 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 align with the Minimum Computer Requirements:



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 Remote Desktop 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 Midmark Digital ECG Module and Configuring Midmark Digital ECG or refer to the IQmanager® Operation Manual, Configuring Client Server Networks.

System Specifications

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

Item	Performance Specifications
ECG leads	12-leads (I, II, III, aVR-L-F, V1-6)
Patient Cable	10 replaceable wire patient lead
Anatomical Sites	Noninvasive device, 12-lead electrocardiogram
CMRR	≥ 100dB
DC input impedance	≥ 100MΩ
Front-end sampling rate	128K c/s per channel
Sampling rate for analysis	500 c/s
A/D conversion	24 bit
Resolution	~2.5 µV/LSB
Gain Error	< 1% Gain sensitivity: 5, 10, 20 mm/mV
Dynamic range	+/- 500 mV
Bandwidth	Performances equivalent to 0,05-150 Hz

Item	Performance Specifications
Pacemaker detection	Software on 128K c/s simultaneous on lead pairs (I, II) and (V4, V5) Impulse duration range: 0.2 ms – 2 ms Impulse width range: 2mV – 250mV Estimate of pacemaker spike duration and amplitude
Defibrillation protection	AAMI/IEC standard
Front-end performance	ANSI/AAMI IEC 60601-2-25
Data transfer	USB
Lead-fail detection	Independent for all leads
Dimensions (W x D x H)	2.5 in. (65 mm) x 0.59 in. (15 mm) x 4.5 in. (115 mm)
Total weight	388 g / 0.85 lb
Protection against accidental ingress of water or substances	IP4X / IP42 (with protective shell)
Mechanical strength and temperature resistance	Compatible with requirements EN 1789 (Ambulances) and EN 60601-1-11 (homecare)
Environmental specifications	Operative: Temperature conditions: 32°F to 104°F (0°C to 40°C) Relative humidity: 15% to 90% (without condensation), but not requiring a partial water vapor pressure greater than 50 hPa Atmospheric pressure: 700 mbar – 1,060 mbar The device can be operated at a temperature of 23°F (-5°C) after storing it at an ambient temperature of 68°F (20°C). Storage from -40°F to 41°F (-40°C to 5°C) without relative humidity control from 41°F to 104°F (5°C to 40°C), up to 90 % relative humidity, without condensation from 104°F to 158°F (40°C to 70°C) with water vapor pressure up to 50 hPa Atmospheric pressure: 540 mbar; 1,060 mbar
Classification of Medical Devices	in compliance with the directive MDD 93/42/EEC.
Printer	Windows-supported inkjet or laser printer.
Paper	Plain 8.5" x 11" (Letter size)

Applied Harmonized Standards

STANDARD	DESCRIPTION
EN ISO 15223-1	Medical devices - Symbols to use in labels of the medical device, in the labelling and in the information supplied - Part 1: General requirements

STANDARD	DESCRIPTION
EN 1041	Information supplied by the manufacturer of medical devices
EN 1789	Medical vehicles and their equipment - Road ambulances
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 62304	Medical device software - Software life-cycle processes
EN 60601-1-6	Medical electrical equipment - Part 1: General safety requirements - Collateral standard: Usability
EN 62366	Medical devices - Application of usability engineering to medical devices
EN 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs

System Installation

Note: Contact Midmark Technical Service before installing and setting up the Midmark Digital ECG. Computers today are more complex, with more software and hardware options than before, making each computer almost unique. Midmark wants to make sure that your device is installed and configured as quickly and easily as possible.

Minimum Computer Requirements

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

The Minimum Computer Requirements document describes the minimum computer resources and hardware components needed when using new Midmark devices and software. As technology changes, these requirements are evaluated and modified periodically. Refer to the most recent *Minimum Computer Requirements* document at www.midmark.com, or contact Midmark Technical Service for additional information.

Note: Contact Midmark Technical Service before updating computer systems involving older Midmark devices and software.

Note: The Minimum Computer Requirements are the specifications for operating the Midmark Digital ECG through IQmanager®. A faster CPU and/or more memory may be required if you plan to operate the ECG through an EMR or install additional software.

Note: USB ports/contacts can become worn with repeated use. The Midmark Digital ECG test may not function with a worn USB port.

Software Installation

Note: The following software installation information refers to IQmanager® only. If using the Midmark Digital ECG through an EMR, please contact Midmark Technical Service for assistance with installation and setup.

The medical diagnostic application Midmark Digital ECG uses IQmanager® to manage patient records. When installing or upgrading the device, IQmanager® may also need to be installed or upgraded accordingly (refer to the IQmanager® Operation Manual for further information).

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 for the latest information on available Midmark products or visit midmark.com.

Note: 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 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

Screen saver or any energy-saving feature should be disabled when installing software.

Installation Steps for IQmanager®

Note: The Midmark Digital ECG requires a PC based software to operate. The following instructions refer to the IQmanager® software. Please contact Midmark Technical Service to purchase the required software license.

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

Note: Do not connect any devices to the computer before completing the software installation.

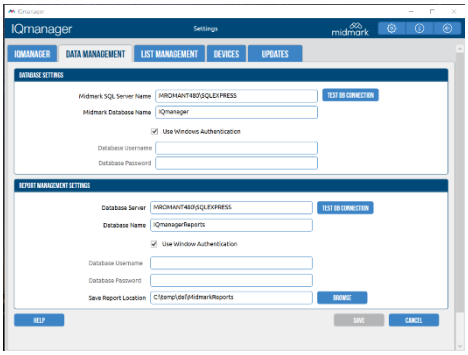
For any questions on the installation, please refer to the IQmanager® Operation Manual part number 62-78-0001.

Connecting the Midmark Digital ECG Device

Connect the Midmark Digital ECG device to any available USB 2.0 port on the computer after IQmanager® is installed. As with other USB devices, Windows attempts to identify the new Midmark Digital ECG connected device. This may take a few seconds. The Midmark Digital ECG does not require batteries as it receives its power from the computer.

Configuring Midmark Digital ECG®

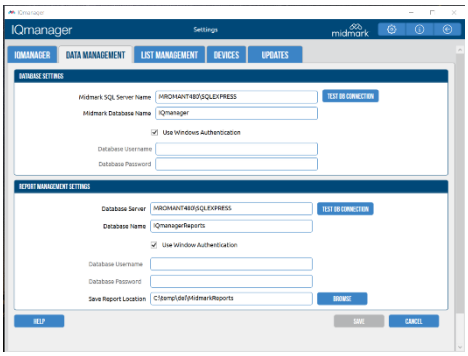
IQmanager® and the Midmark Digital ECG can be customized using the configuration settings. To access the **Configuration Settings**, click  in the upper right side of the IQmanager® opening screen. The *IQmanager® Configuration Settings* dialog box appears:



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

Database Settings

IQmanager® uses the local database by default. If you are using a network database, you can set the path by clicking **Data Management tab** on the *IQmanager® Configuration* screen and changing the value for *Midmark SQL Server Name and Database Server*. For further information on the database settings, refer to the IQmanager® operation manual.



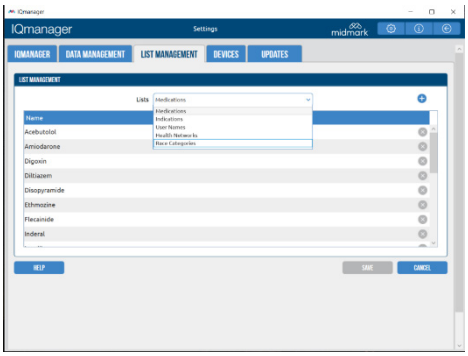
List Management

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

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

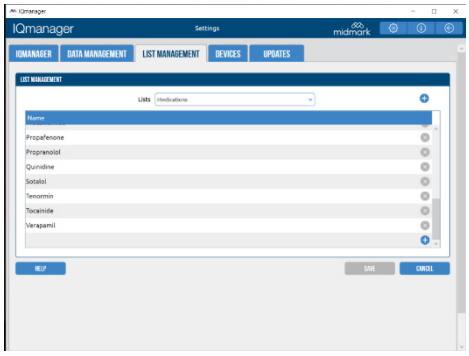
Modifying these lists saves time when you use them in the appropriate testing screens. Follow these steps:

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

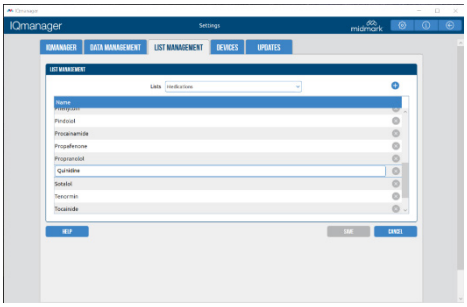


You can make the following changes:

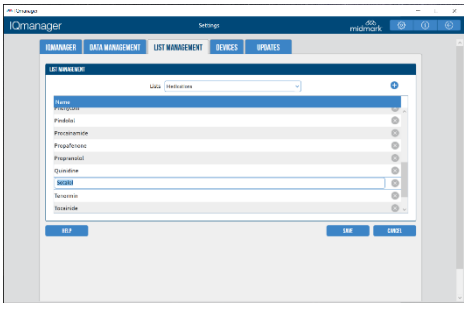
- **Add:** Scroll to the bottom of the list to type the new value or select the plus icon next to the list to jump to the bottom of the list. After typing the value, press keyboard **Enter** to save the settings.



- **Edit:** Edit an existing item. Select the statement, and then begin typing to edit the value.



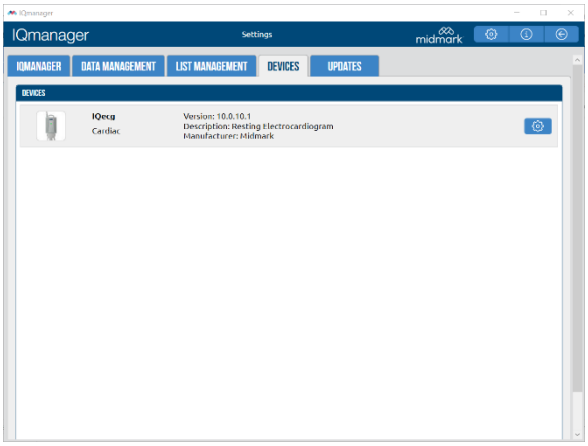
- **Delete:** Delete an existing item. Highlight the statement with the cursor, and then click the X button.



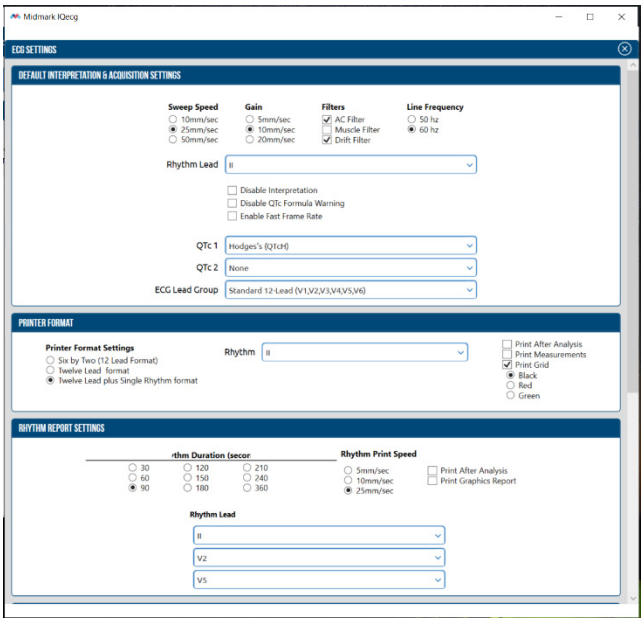
Note: *Delete All removes all the ECG statements from the database.*

ECG Settings

Establish the default settings for ECG tests by clicking the Devices tab in the IQmanager® settings. Click the settings icon  to customize the settings. All common settings for ECG tests are inherited from the application.



The *ECG Settings* dialog box appears:

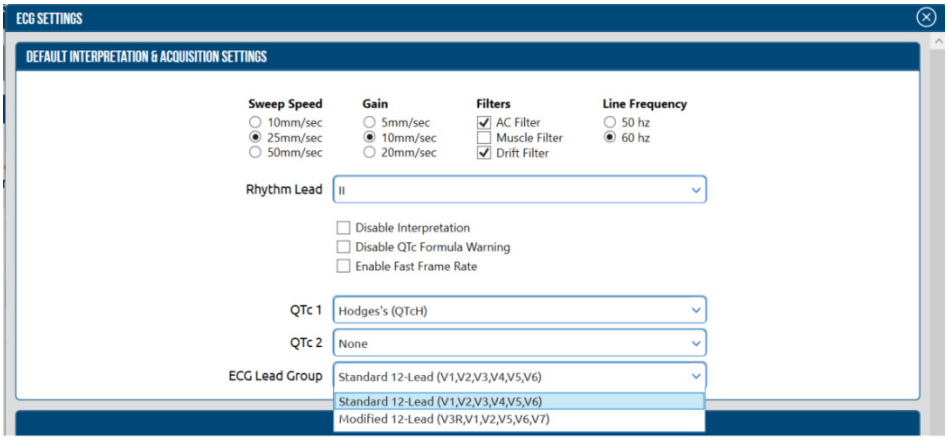


ECG Lead Group

When you are acquiring an ECG report, IQmanager® Version 8.6 and later offers one option:

- Standard 12-Lead ECG lead group

(Refer to "Testing a New Patient" for more information on this option.)

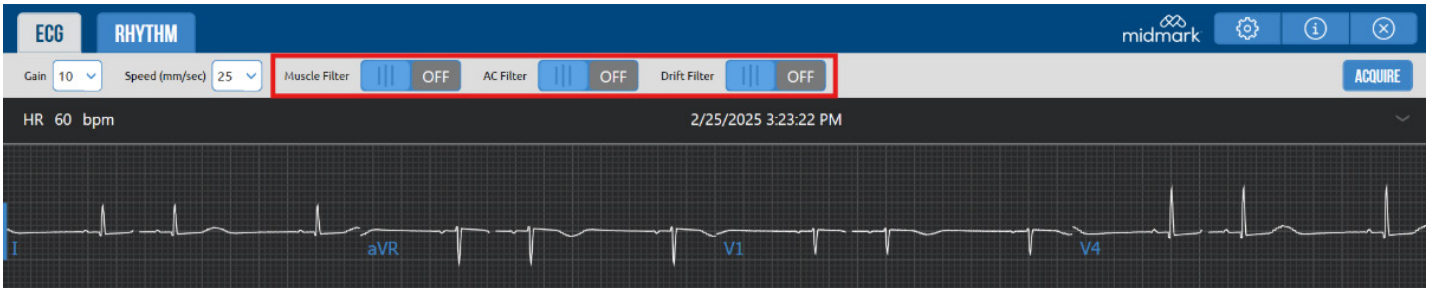


Filters

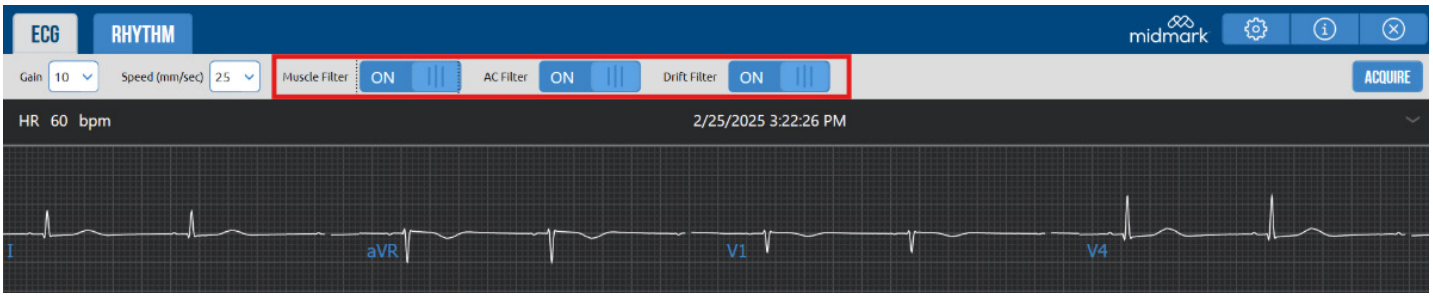
ECG signals are often affected by noises from the environment and filters remove unwanted noise in the ECG signal. Noise may come from an unstable dc offset from electrode/body interface, muscle noise, mains hum (50/60 Hz), electrical noise from equipment in the environment and from within the ECG equipment itself, such as from internal dc/dc converters. Removing these noises is important for improving the quality of the ECG signal.

The filter settings are controlled by toggle switches at the top of the screen. The below images illustrate the appearance of the controls when the filters are all off (top image) and on (bottom image).

Filters all off:



Filters all on:



AC Filter

The AC Filter eliminates disturbance introduced by the electrical mains. The value must correspond to the mains frequency (e.g., 60 Hz in the USA and 50 Hz in Europe).

Muscle Filter

The Muscle Filter reduces higher frequency to eliminate muscle noise.

Drift Filter

The Drift Filter is a high-pass filter that removes low frequency signals to reduce artifacts induced by respiratory movement without introducing distortions on the reproduction of the ST segment.

Note: The Midmark Digital ECG has a high-pass filter embedded in the firmware that is always on.

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 Filter: Off, AC Filter: On, Drift Filter: On. See Notice following this table.
Line Frequency	• 50 Hz • 60 Hz	Default setting is 60 Hz.
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 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. 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. 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.

The Rhythm Lead V3 (V3R) specifies that Lead V3 if Standard 12-Lead (V1,V2,V3,V4,V5,V6) is selected when a new ECG test is started. V4 (V7) has a similar definition.

The Rhythm Lead Group V1, V2, V3 (V3R,V1,V2) specifies that V1, V2, V3 if Standard 12-Lead is selected. The Rhythm Lead Group V4, V5, V6 (V5,V6,V7) has a similar definition.

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)	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: *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., making sure that the electrode sites are clean of lotion or body hair, and that the electrodes are fresh and sticky and are adhering properly on the skin).

The patient should be supine, relaxed, and not talking. Refer to "ECG Signal Quality Problems" in the Troubleshooting Guide for more details.

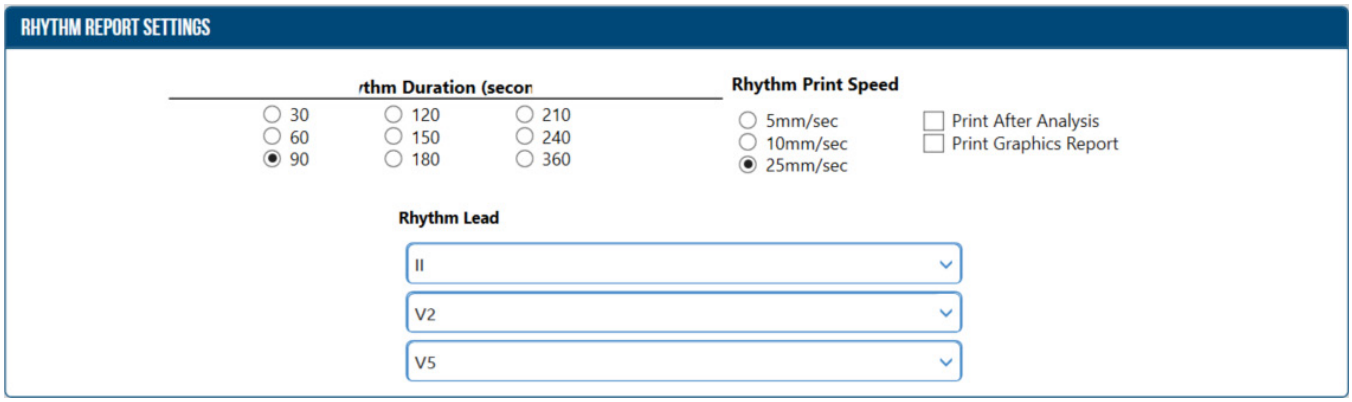
Printer Settings

In the Printer Format Settings section of the ECG Settings window, you can select the default ECG report format.

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. 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. 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, 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, 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 default color, black. If a color printer is used, select red or green.

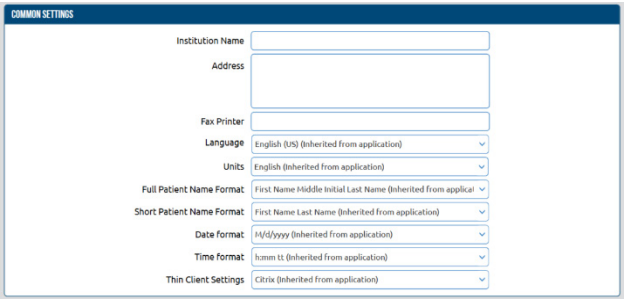
Rhythm Settings

In the Rhythm Settings section of the ECG Settings window, you can preset the default test duration and report format. Rhythm Leads provides choices for the three rhythm leads from all available leads.



Rhythm Settings		
Item	**Settings**	**Comments**
RR Duration (seconds)	• 30 sec	Default setting is 90 sec.
	• 60 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.
	• 90 sec • 120 sec	through Start RR test. The rhythm strip is defined in the ECG Settings.
	• 150 sec	
	• 180 sec	
	• 210 sec	
	• 240 sec	
	• 360 sec	
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 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



Most of the 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.

Operation

WARNING

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

Introductory Notes

This section describes how to use the various Midmark Digital ECG 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, we have included a condensed guide to the operation of the Midmark Digital EG with new patients 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, ensuring high-quality signal and test data.

Ensure that the patient fully understands the procedure and knows what to expect before connecting the electrodes.

- Privacy is important to allow the patient to be relaxed.
- Once the electrodes are connected, ask the patient to remain still and not to talk. Explain that this is important to ensure a good ECG acquisition.

Patient Position

The patient should be placed comfortably in a supine position. Any variation should be noted on the ECG report. If the bed is narrow, place the hands of the patient under their buttocks to ensure the muscles are relaxed.

Prepare Patient Skin

- Shave hair from electrode sites, if necessary. (Reference diagrams below.)
- Clean skin with mild soap and water, not alcohol. Allow the skin to air dry.

Note: *Pay attention not to cause abrasions, discomfort or bruises on the skin. Always observe the utmost clinical discretion when preparing the patient.*

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.

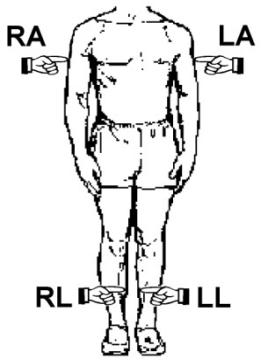
Limb Lead Placement

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

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

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

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



Standard 12-Lead Placement (Precordial)

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

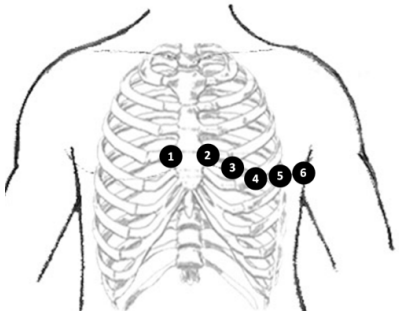
V2 (Yellow) – 4th intercostal, left margin of the sternum.

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.



Standard 12-Lead ECG Hookup

> ***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.*

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

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.*

Note: *Midmark recommends placing the lower extremity leads at the inside calf, halfway between the knee and the ankle. This placement follows the current standard as defined by the American Heart Association.[1] However, in cases where such placement does not render a suitable diagnostic-grade ECG or such placement yields no waveforms, the recommended alternative is to move both of the lower limb leads to the lower abdomen, at least 5 cm below the umbilical line and near the iliac crests. This alternative placement should generate waveforms in all leads that are morphologically equivalent to the standard lower-leg placement.[2] Midmark advises symmetric leads for lower-limb lead placements, either both RL and LL on the lower extremity or both on the lower abdomen, when acquiring an ECG.*

Sources:

1. Recommendations for the Standardization and Interpretation of the Electrocardiogram

2. https://openheart.bmj.com/content/2/1/e000226

Operation of Midmark Digital ECG with IQmanager®

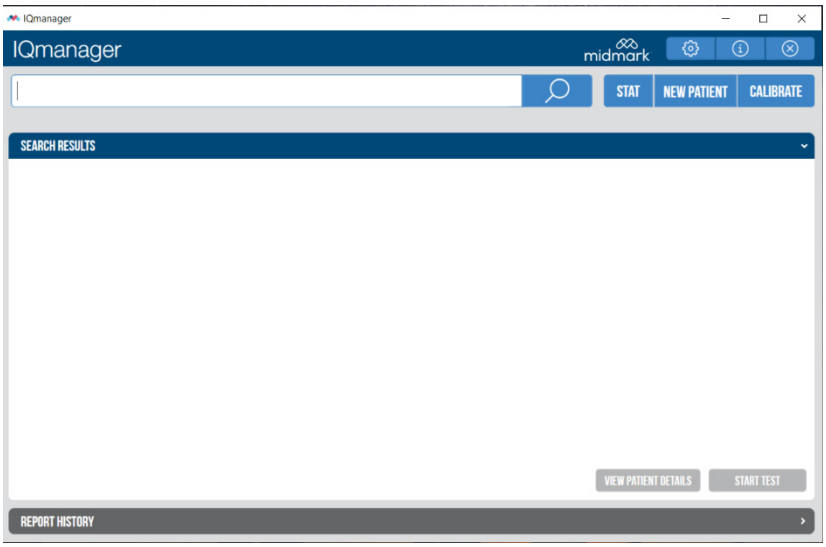
Starting the Program

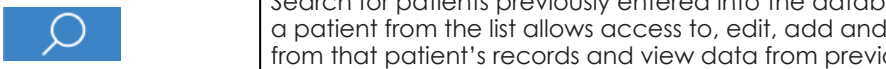
The software application for operating the Midmark Digital ECG is called IQmanager® and is located on the computer desktop as a shortcut icon. Double-click this icon to start IQmanager®.

Opening Screen

Note: *For a detailed description of diagnostic functions available through IQmanager®, refer to the IQmanager® Operation Manual.*

When starting IQmanager® the opening screen appears:



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. The Midmark Digital ECG does not require calibration.
	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 Midmark Digital ECG" 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.

When a STAT ECG is required, hook up the patient using a **STANDARD 12-lead** hook-up to the Midmark Digital ECG 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

When the blue light is flashing, the Midmark Digital ECG is on, the connection is active, and the device is waiting for the software to activate ECT acquisition.

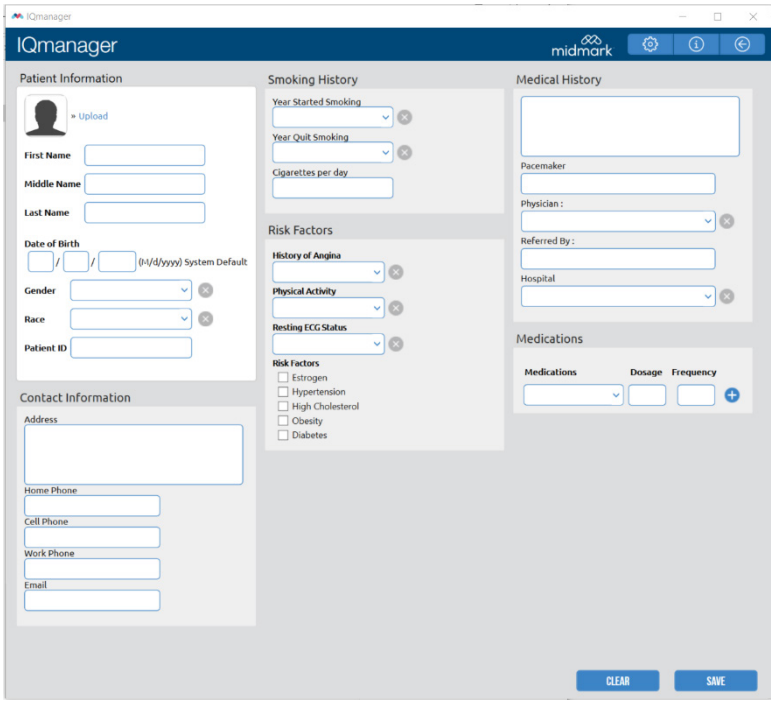
NOTICE

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.



Note: *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 keyboard **Tab** to enter information. This information may not be essential for the acquisition

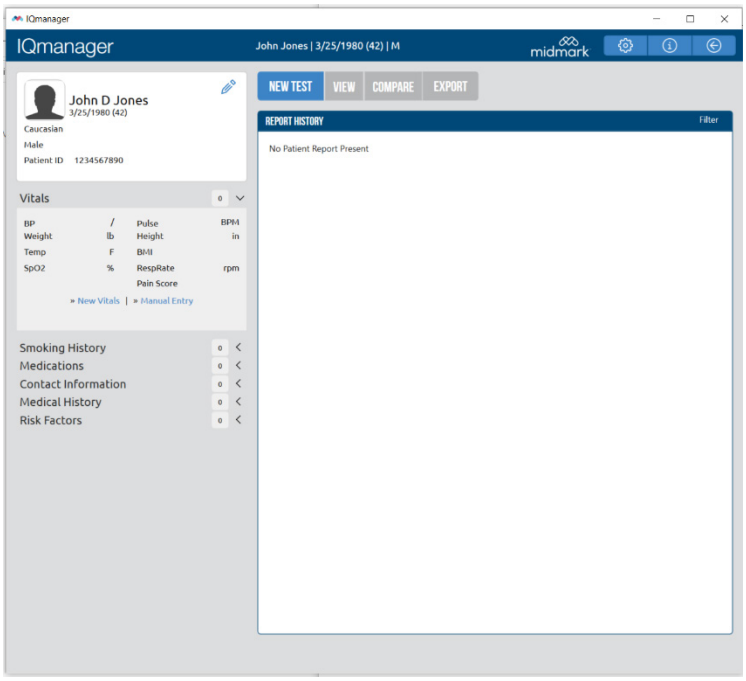
of an ECG; however, it is important to complete each of the fields as accurately as possible, particularly Date of Birth, Sex, and Medications, which are used by the Midmark 12-Lead Resting ECG Analysis Program to produce diagnostic statements.

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

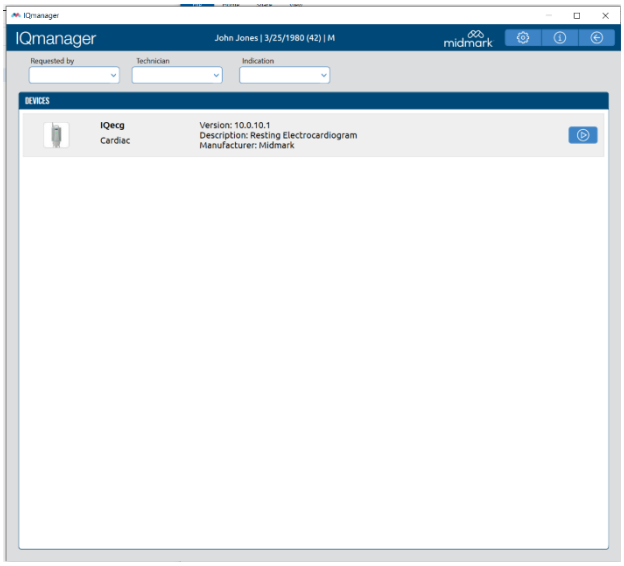
Refer to the IQmanager® Operation Manual for additional information on the Patient Data screen.

Live ECG Screen

1. When the patient is properly prepared and is calm and comfortable, select a new test by clicking **New Test** on the menu bar of the *Patient Data* screen.



2. The New Test screen appears. Select a name from the drop-down list or enter the names of the technician conducting the test and the requesting physician.
3. Enter the diagnostic reason for the ECG test in the Indication field, as necessary.
4. Click the **Start Test** icon in the right-hand portion of the ECG device.



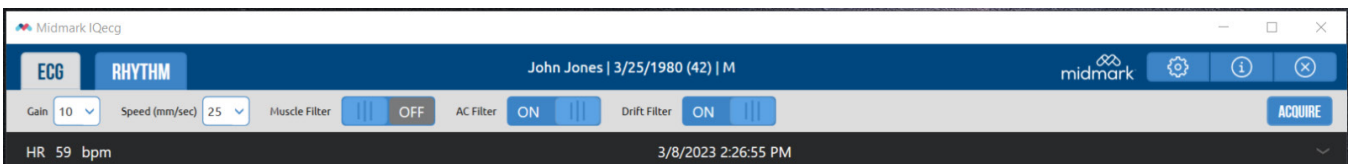
The live **ECG** screen displays.

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

> ***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.*

The gain, speed and filter settings are displayed above the moving tracings.

1. 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 display on the upper-right corner of the screen.



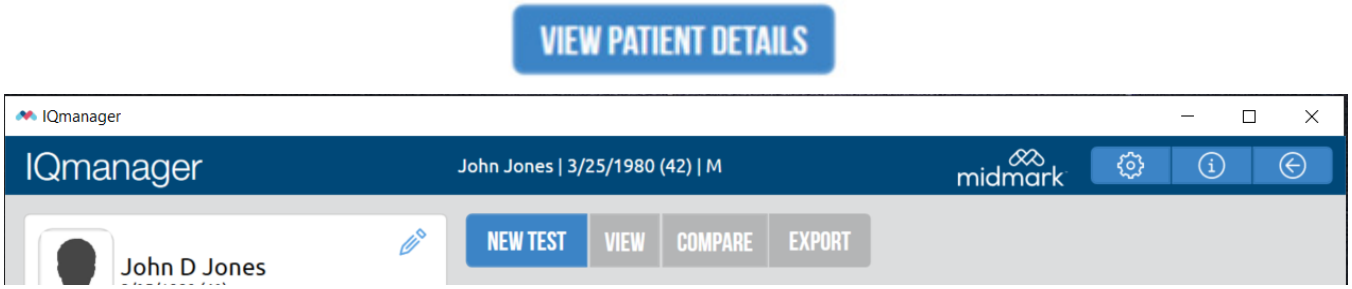
2. Wait for the ECG tracings to pass the screen twice and verify the signals are clean and baselines are stabilized.

3. Click **Acquire** to capture an ECG test, which opens 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 ECG data.
	Switches to the Resting ECG acquisition screen.
	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 the Configuring the Midmark Digital ECG section of this manual.
	Displays the Help screen.
	Return to the *Patient Data* screen. ECG or Rhythm Reports will not be saved.

Reviewing Patient Reports

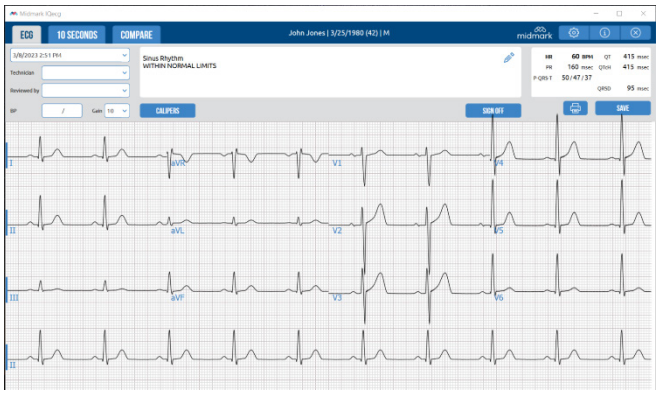
In the Patient Data screen, click View Patient Details to review a selected resting ECG report.



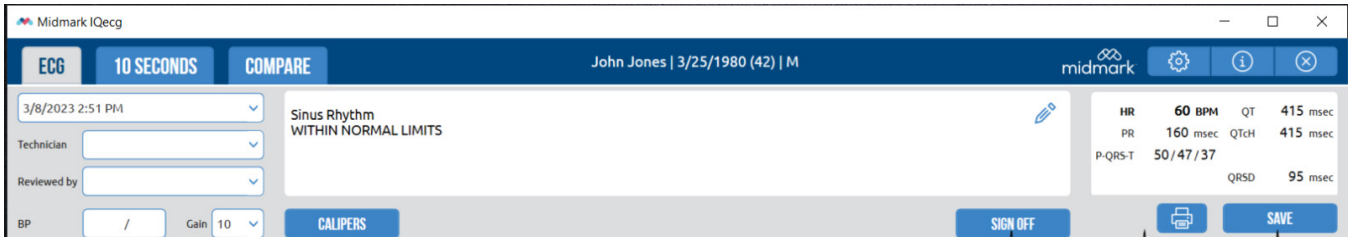
ECG Report Review Screen

Click on the **ACQUIRE** button.

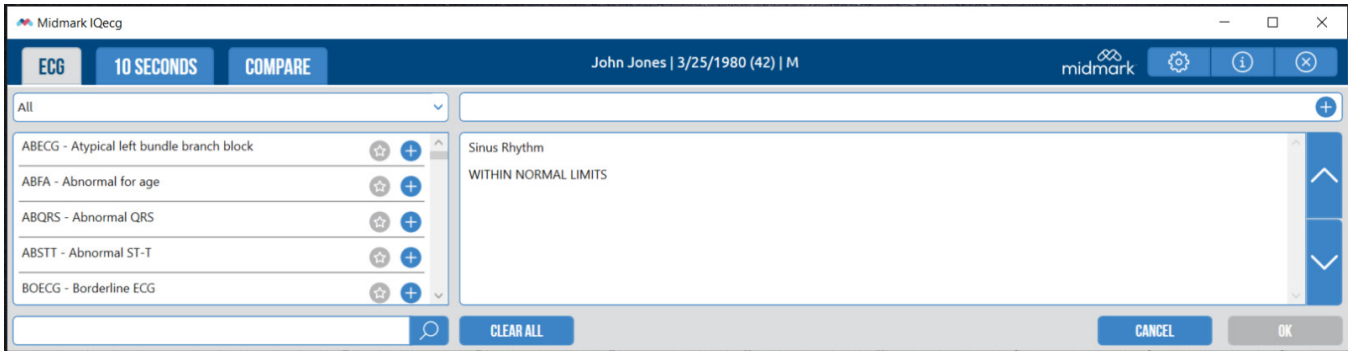
The Report Review screen displays the 12-Lead ECG tracings of the ECG report.



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.



Edit or enter an Interpretation in the Interpretation field 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.



The following revisions are available:

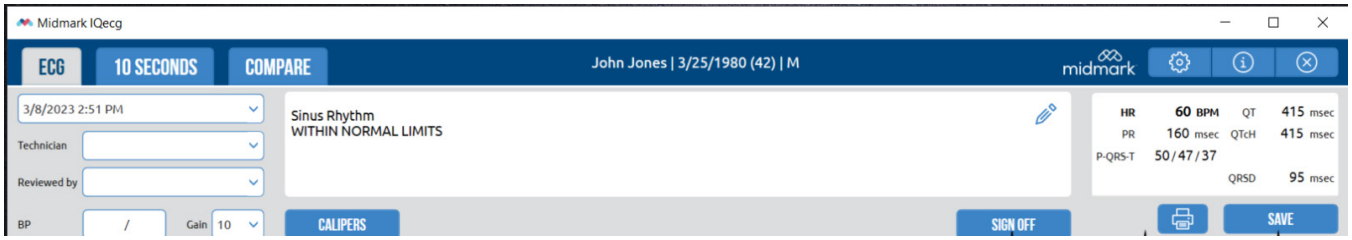
- Click on the top left drop-down arrow for the appropriate category and click **Add** to add the desired selection. The selected interpretations displays in the right window. Click **Favorite** to add frequently used interpretations to the Favorites list.
- Use the Search field to search through all 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 delete icon (**X**) 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

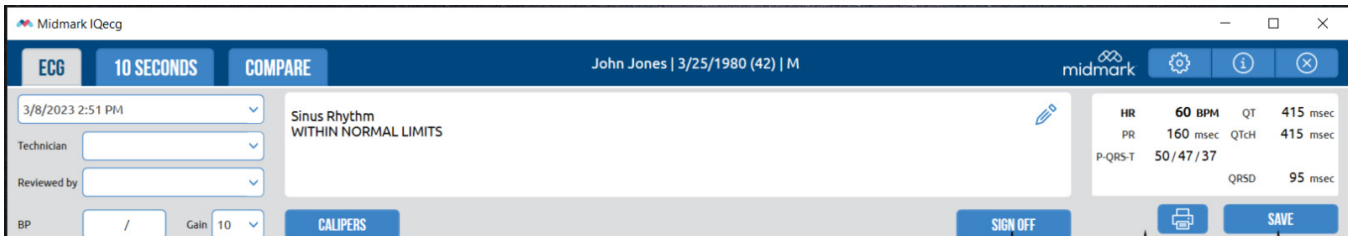
The computerized interpretation is not a substitute for physician interpretation.

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. The physician must 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.



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

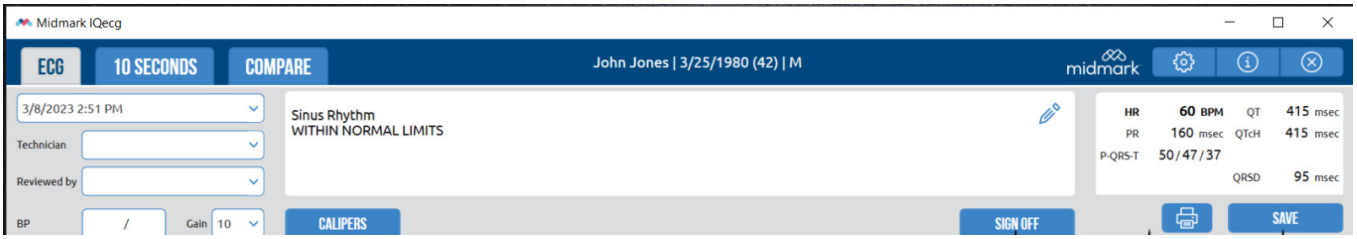


WARNING

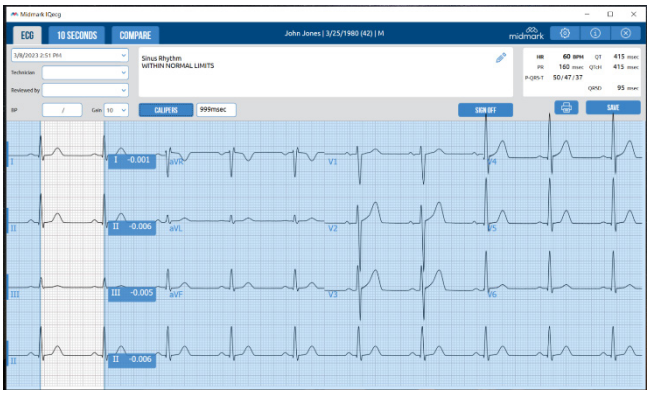
The computerized calculation of QTc is not a substitute for the physician interpretation of the ECG.

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.

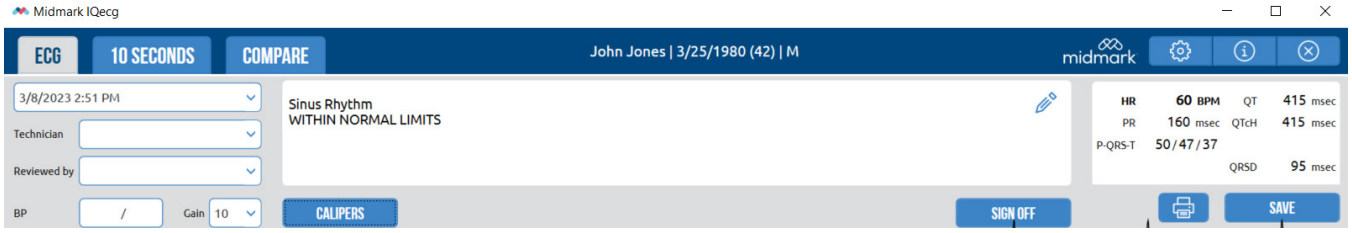
Click **Calipers** to measure the amplitude (mv) and duration (ms) of any part of the ECG waveform, making it easy to read over ECG tests online without printing the report.



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 longer periods of time by clicking and moving the right or left caliper.



Sign off is used for signing off on the report after the physician's name is entered. If **Sign off** 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 username are recorded.

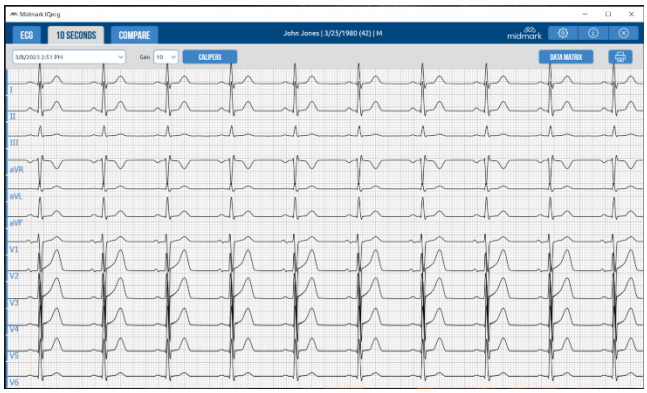


To edit a signed report, first view the report, and the click **Unlock**.

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

Note: *Select **Actual Size** from the dialog box to ensure grids on the report print in actual size.*

10 Second Screen



The **10 Second** tab displays all 10 seconds from each of the 12 leads on one screen, which is the full disclosure of a 12-lead resting ECG test. 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.

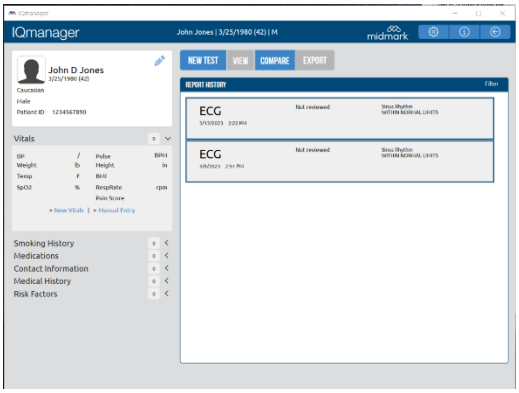
Clicking and dragging on a specific caliper moves only that one caliper. Clicking and dragging in the middle of the calipers moves both calipers together. You can adjust calipers for a different duration by clicking and moving the right or left caliper.

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

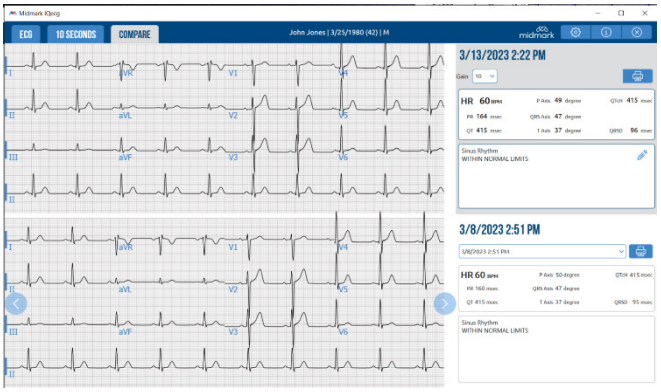
If Standard "12-Lead (V1, V2, V3, V4, V5, V6)" is selected, the chest leads and measurement columns are arranged in the following order: V1, V2, V3, V4, V5, V6.

Compare Screen

To **Compare** two ECGs from the same patient, highlight both saved ECGs:



Click the **Compare** tab to view two ECGs from the same patient side-by-side.



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

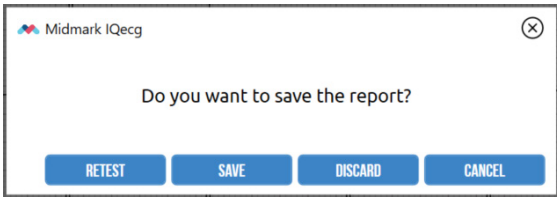
The ECG tracings for each report display on the left side. The date and time of the report, the **Gain**

drop-down, the *ECG Data* fields, and the *Interpretation* field display on the right side.

The Printer button prints 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:



- Click **Retest** to return to the *Acquisition* screen and discard the current ECG test. 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.

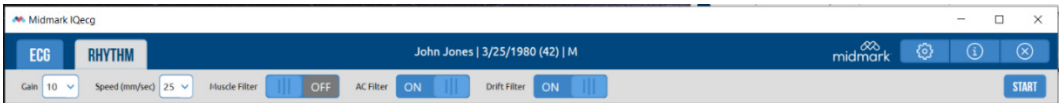
Rhythm Screen

Click the **Rhythm** tab in the Live ECG screen to open the live Rhythm screen for acquiring a *Rhythm* report.

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**.

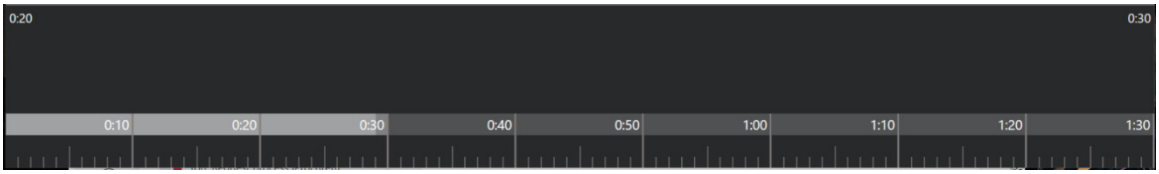
The patient's name is displayed at the top center of the screen, with the heart rate displayed on the left of the screen. Lead offs and any error messages are displayed on the top right of the screen.



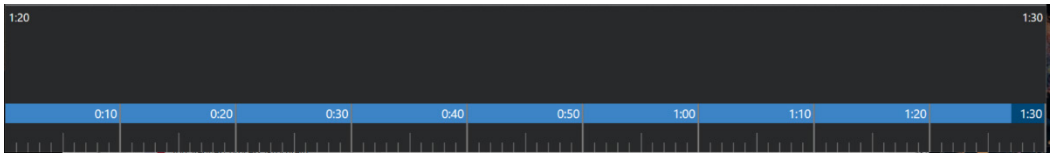
Click **Start** to begin the Rhythm test and start recording three rhythm leads.

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.



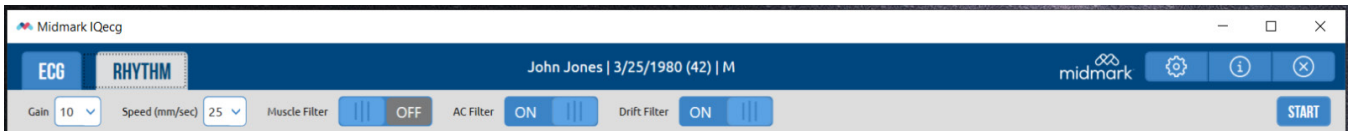
- The bar changes to blue once the 30-second minimum has been reached.
- The light blue bar indicates the current data that has been collected.
- The dark blue bar indicates the current 10 seconds of data that is displayed on the screen.



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

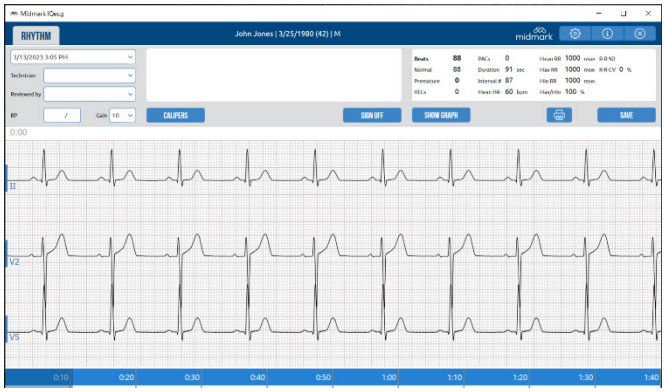
Click **Cancel** to stop the test during the first 30 seconds.

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



Rhythm Review

The *Rhythm Review* screen is displayed after a Rhythm test has ended.



The *Rhythm Review* screen displays the following data:

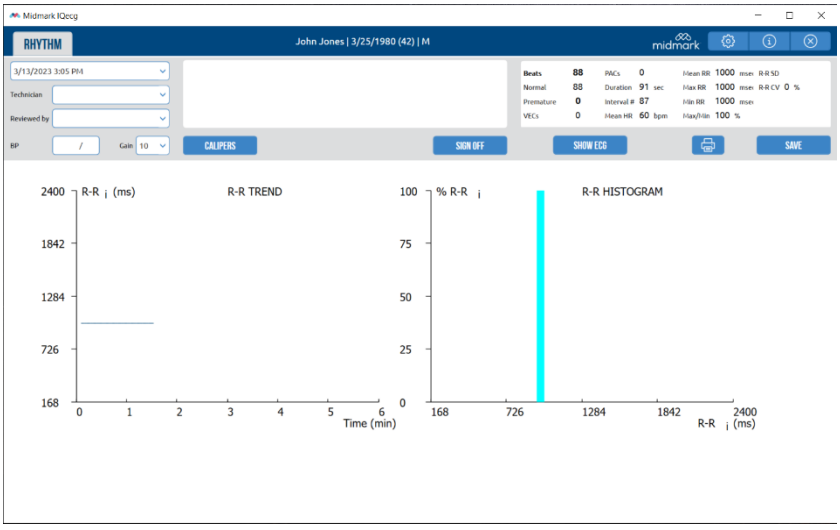
- Test date and time
- Technician
- Physician
- Blood Pressure
- Test data

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.

You can also review Rhythm data collected can also be reviewed in Rhythm Trend and Rhythm Histogram formats by clicking the **Show Graphs** button.



Accessories for Midmark Digital ECG

The following table shows the accessories approved by Midmark for use with the Midmark Digital ECG.

WARNING

Use only approved accessories with the Midmark Digital ECG. Substitution of a component different from that supplied might result in measurement error.

Item	Part Number
Universal ECG Clips (3mmm & 4mm) 10/pack	3-047-0001
Clear ECG Clips (3 mm, 4mm, & Snap) 10/pack	3-047-0005
Disposable ECG Electrodes (box of 1000)	2-100-0208
Disposable ECG Electrodes (case – 4 boxes)	2-100-0209
Silicone Cover for Midmark Digital ECG	002-10937-00
USB Cable for Midmark Digital ECG	015-11877-00
Patient Cable for Midmark Digital ECG	015-11871-00

Appendices

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

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

- Start IQmanager®.
- Select **New Patient** from the opening screen. For a returning patient, search by the patient's last name or ID.
- 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.
- 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 Midmark Digital ECG kit for a standard 12-lead hookup; or refer to "Patient Preparation" of this operation manual.
- Select **New Test** on the menu bar, and then select the **ECG** test after entering the relevant information.
- 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.
- 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.
- 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.
- Reports can be automatically viewed after acquisition, and they can be saved or redone from the review screen.

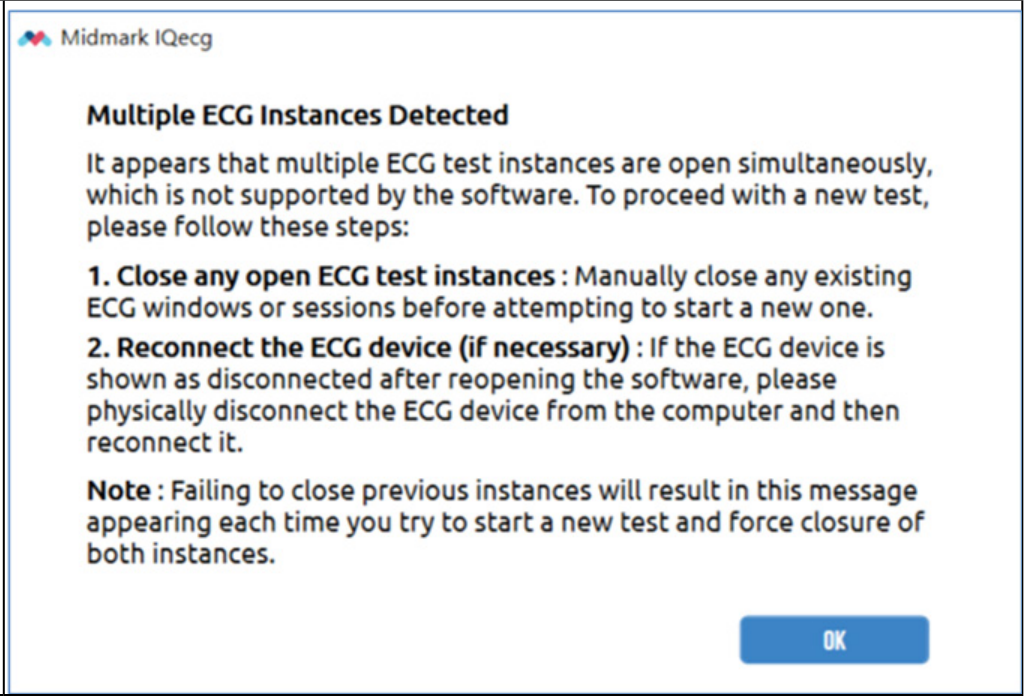
Appendix B – Troubleshooting Guide

This Troubleshooting Guide provides a list of solutions or recommendations to situations that may be encountered with

Midmark Digital ECG. 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.

Note: *For errors that occur during the analysis or management of ECG files, please refer to Troubleshooting section in the IQmanager® Operation Manual.*

Software 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 Midmark Digital ECG".
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 running a live ECG in a thin-client environment, the bandwidth may be 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 Midmark Digital ECG 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, Testing a New Patient. • Edit the diagnostic statements accordingly. See the section, 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, Configuring Midmark Digital ECG/Printer Settings and RR Rythm 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, 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 of the 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 ON if you see 50/60Hz noise. Turn the Muscle filter ON if the patient produces muscle tremor. Turn the Drift filter 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 including X-ray machines, power generators, power compressors, or other.
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 Service.
Running multiple ECG instances	

Hardware Troubleshooting Guide		
Problem	**Cause**	**Solution**
• Flashing yellow LED	• PC connection attempt	The device is attempting to connect to the computer. • If the device cannot connect via USB • Ensure the USB driver is installed • Try disconnecting and reconnecting the USB cable
• By pressing the power On button, the LED remains off, but the device emits an acoustic signal	• The LED is faulty	If upon power-on the LED remains off but an acoustic signal is emitted, the LED is faulty. Contact Midmark Technical Service
• The LED is on, but no acoustic signal is emitted	• The audible warning device is faulty	If upon power-on or when connecting the device to the PC no acoustic signal is emitted but the LED is on, the audible warning device is faulty. Contact Midmark Technical Service
• Noisy or low-quality signal	• Interference with other devices or electrodes need replacing	In the event that the electrodes do not have a good bond or are frayed or in cases where a noisy signal is observed, they must be replaced

Appendix C – Maintenance and Storage

Preventative Inspection

Check the device daily before using.

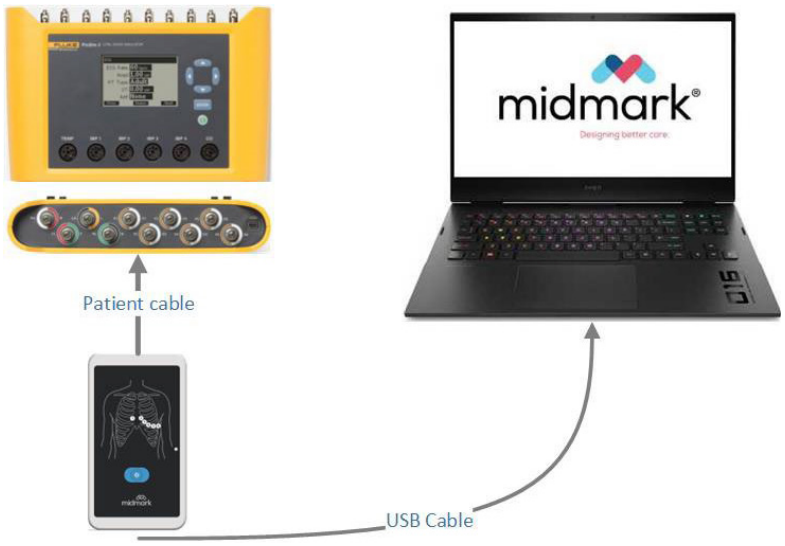
- Ensure the USB Cable and Patient Cable are securely connected.
- Check the casing for any damage.
- Check the USB cable and Patient Cable for visible damage.
- Check that the power button works properly and does not show any signs of deterioration.

Maintenance

Periodically check the status of the patient cables and connectors when necessary and at least once each year using an ECG simulator.

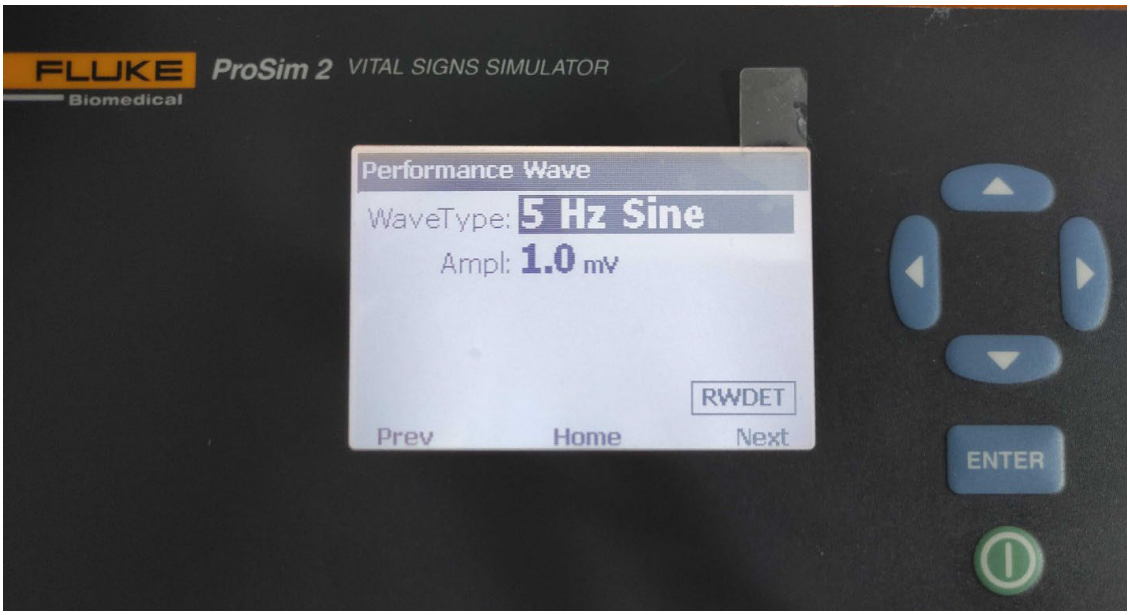
Test Setup

1. Connect the patient cable wires to the ECG simulator.
2. Connect the ECG Device USB cable to the pc and open Midmark IQmanager software application.
3. Disable the "Drift filter", Enable "AC Filter", set "Gain" at 20 mm/mV, set "Speed" at 25 mm/sec.
4. Set the ECG simulator to generate a Sine wave with frequency of 5 Hz and 1 mV amplitude.



Test Verification

Test Step	Acceptance Criteria
Turn on the Midmark Digital ECG	All the V1, V2, V3, V4, V5, V6 and II traces visualized in Midmark IQmanager must have the amplitude of 1mV peak to peak +/-2%
Turn on the ECG simulator and select the sine signal at 1mV peak to peak of amplitude at 5 Hz frequency.	I trace must be 0.7 mVpp +/-2% (Fig 3). III trace must be 0.3 mVpp +/-2% (Fig 3). L trace must be 0.2 mVpp +/-2% (Fig 3). F trace must be 0.65 mVpp +/-2% (Fig 3). The frequency must be 300 bpm/5 Hz (Fig 3). The signals must be visualized without distortions (Fig 3).



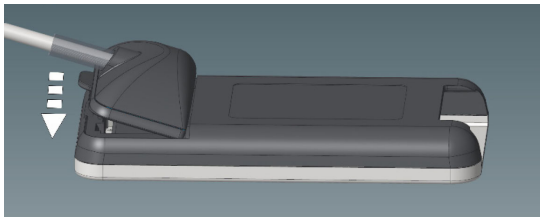
Check the overall functionality of the equipment when necessary or at least once every two years. It is recommended to measure the leakage currents at least once every two years.

This device is not meant to be disassembled unless directed to by Midmark Technical Service.

Attaching Cables and Silicone Covers

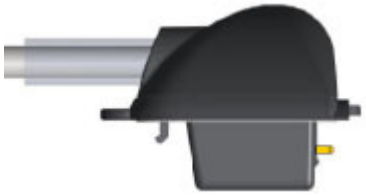
If there is a need to replace components of the device, follow the below assembly instructions.

1. Align and attach the USB cable to the rear housing of the device.

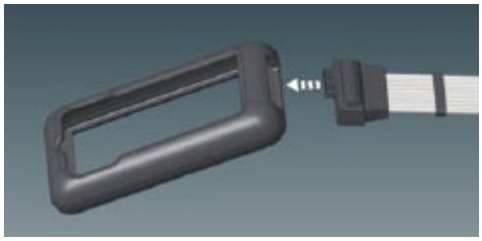


Top view:

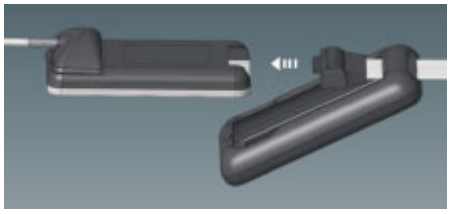
Side view:



2. To connect the patient cable, insert the cable through the opening in the silicone cover.



3. Ensure the opening for the patient cable is aligned with the connector on the device.

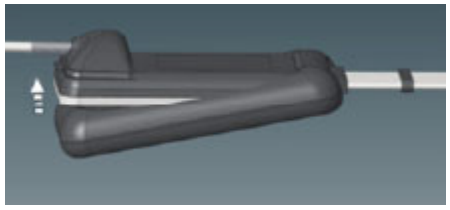


4. Insert the cable into the connector on the device.

   ***Note**: The connector is designed to allow for the insertion of the patient cable in one direction only. Should the plug of the patient cable not go into the connector, do not force it but try to rotate it.*

   ***Note**: When removing the patient cable, to prevent the cable from breaking, remove it by grasping the plug. Avoid straining the terminations.*

5. Attach the silicone cover to the Digital ECG:



Cleaning

Precautions

- Ensure the device is disconnected from computer before cleaning.
- Do not disassemble during cleaning.
- Do not remove cables for cleaning.
- Do not immerse the device in water or other liquid.
- Do not use organic solvents, ammonia-based solutions or abrasive cleaning agents, which could damage the surface of the device.

Patient Cable Cleaning

- For the general cleaning of cables and terminations, use a soft lint-free cloth slightly moistened with a mild soap and water solution. Clean and air dry.
- For cable and termination disinfection, clean the outside with a soft lint-free cloth using a Sodium Hypochlorite solution (water and bleach at 10%): minimum dilution 1:500 (minimum 100 ppm of free chlorine) and maximum dilution: 1:10 in compliance with the APIC guidelines for the Selection and Use of Disinfectants.
- Pay attention to the excess liquid as contact with metal parts may result in corrosion.
- Do not immerse the cable terminations. Immersion may result in metal corrosion.
- Do not dry excessively or use forced heat to dry.

Note: *Avoid immersing the device in the liquid and do not apply a direct stream of liquid. Do not autoclave or steam clean. Protect the leads against strong ultra-violet radiation. Do not sterilize the device or the ECG lead cables with ethylene oxide gas (EO).*

Cleaning the Device

Clean the external surface of the device with a damp lint-free cloth, using a neutral detergent diluted with water. Thoroughly dry with a clean cloth or paper napkin after washing.

The cleaning solutions allowed are:

- 90% ethyl alcohol solution
- 10-12% hydrogen peroxide solution
- 2% sodium hypochlorite solution

Note: *Improper cleaning products and operations may damage the device, render the terminals and cables fragile, corrode the metal and invalidate the warranty. Use caution and adopt the correct procedures when cleaning and checking the device.*

Note: *After cleaning and checking the device, it is possible to verify the correct operation of the device using an ECG simulator to acquire a standard 12-lead ECG of known amplitude. The tracing detected by the receiver must be clear, uniform and consistent with the signal generated by the simulator.*

Cleaning the Accessories

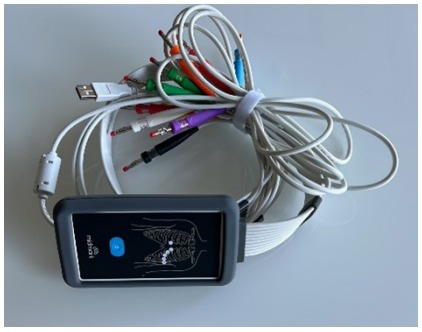
The Silicone Cover may be cleaned with a soft, lint-free cloth slightly moistened with a solution of water and neutral soap. Clean and air dry.

For disinfection, clean with a soft lint-free cloth using a sodium hypochlorite solution (water and 10% bleach): minimum dilution 1:500 (minimum 100 ppm of free chlorine) and maximum dilution 1:10 in compliance with the APIC guidelines for the Selection and Use of Disinfectants.

Storage

- Avoid extreme humidity and heat during storage.
- Do not hang the device by the USB cable or the patient cable.

- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Form the patient cables into a loose loop before storing the device (image below).
- Do not exceed a minimum bend radius of 25 mm (or ~1 inch) on USB and patient cables to prevent damage.



Caution

To prevent possible damage, do not hang the device by the USB cable or the patient cable.

Caution

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

Appendix D – 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, this device 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, which is designed to provide reasonable protection against electromagnetic interferences in a medical or hospital environment.

Appendix E – EMC Requirements for the Midmark Digital ECG

Electromagnetic compatibility during the use of the device is required with the surrounding devices.

An electronic device can generate or receive electromagnetic interferences. The electromagnetic compatibility test (EMC) has been performed on the electrocardiograph in compliance with the international EMC directive for medical equipment (IEC 60601-1-2). This IEC standard has been adopted as a European standard (EN 60601-1-2).

The device must not be used above or next to other devices. If necessary, check the system during normal use, depending on the configuration.

Fixed, portable and mobile equipment for RF communication may affect the protection of the medical equipment. See the **Recommended separation distance** table for the recommended separation distance between the radio equipment and the device.

The use of accessories and cables other than those recommended by Midmark may cause an increase in emissions or a reduction in the protection of the system.

Guidance and manufacturer's declaration of electromagnetic emissions

The device is intended for use in the electromagnetic environment specified in the following table. The customer or the user should ensure that the device is used in the appropriate environment.

Emission test	Conformity	Electromagnetic Environmental Information
Radio frequency emissions (RF) CISPR 11	Group 2	Electromagnetic energy emissions depend on the use of the device. Electronic equipment near the device may be affected.
Radio frequency emissions (RF) CISPR 11	Class B	The device is suitable for use in all establishments other than domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration on electromagnetic emissions

The device is intended for use in the electromagnetic environment specified in the following table. The customer or the user should ensure that the device is used in the appropriate environment.

Emission test	Conformity	Compliance level	Electromagnetic Environmental Information
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact discharge +/- 15 kV air discharge	+/- 8 kV contact discharge +/- 15 kV air discharge	
Electrical Fast Transients/ bursts IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Not applicable	
Surges IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	Not applicable	
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 cycles 40% U_T (60% dip in U_T) for 5 cycles	Not applicable	
Power frequency magnetic field (50/60 Hz) 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 field IEC 61000-4-39	30 KHz, CW, 8 A/m	30 KHz, CW, 8 A/m	RFID generated magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
	134.2 KHz, PM, 65 A/m	134.2 KHz, PM, 65 A/m	
	13560 KHz, PM, 7.5 A/m	13560 KHz, PM, 7.5 A/m	

Note: *UT is the AC mains voltage prior to the application of the test level.*

Guidance and manufacturer's declaration on electromagnetic immunity

The device is intended for use in the electromagnetic environment specified in the following table. The customer or the user should ensure that the device is used in the appropriate environment.

Emission test	IEC 60601 test level	Compliance level	Electromagnetic Environmental Information
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz 6 Vrms in ISM and amateur bands	3 and 6 Vrms 150 kHz - 80 MHz	Portable and mobile RF Communication equipment should be used no closer to any part of the device than 30 cm/1 ft d = 30 cm/1 ft
Radiated R IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz	10 V/m 80 MHz - 2.7 GHz	
Proximity fields from RF wireless communi-cations equipment IEC 61000-4-3	TETRA 400 380 – 390 MHz 27 V/m	27 V/m	d = 30 cm/1 ft
	GMRS 460 FRS 460 430 – 170 MHz 28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz 9 V/m	9 V/m	
	GSM 800/900, **Guidance and manufacturer's declaration on electromagnetic immunity** TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz 28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz 28 V/m	28 V/m	
	Bluetooth®, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz 28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz 9 V/m	9 V/m	

Emission test	IEC 60601 test level	Compliance level	Electromagnetic Environmental Information
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 Midmark Digital ECG is used exceeds the applicable RF Compliance level above, the Midmark 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 Midmark Digital ECG. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Medical electrical equipment requires special precautions regarding EMC and must 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 Midmark Digital ECG is medical electrical equipment.

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

- ECG Model(s) Digital ECG
- Patient cables: **Approved Midmark cables with 4 mm 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 Midmark Digital ECG as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Midmark Digital ECG

Recommended separation distance between portable and mobile RF communications equipment and the Midmark Digital ECG

The Midmark Digital ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Midmark Digital ECG can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Midmark 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 $d = 1.2 \sqrt{P}$	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
10	3.8	3.8	7.3
100	12	12	23

Recommended separation distance between portable and mobile RF communications equipment and the Midmark Digital ECG
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 F – 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 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
	Distributed By
	Warning
	Caution
	Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician
	Lot Number
	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

Symbol	Description
	Keep away from sunlight
IP4X	IP protection rating (degree of protection against the ingress of solids and water) provided by Midmark Digital ECG. Protected against solid foreign objects larger than 0.04 inch in diameter.
IPX2	IP protection rating (degree of protection against the ingress of solids and water) provided by Silicone Cover. Protected against vertically falling water drops when tilted up to 15 degrees.
	Do not dispose of this product as unsorted municipal waste For more disposal information see Disposal

Midmark Digital ECG Service

Introduction

The Midmark Digital ECG is a PC-based diagnostic device that converts any Windows-based personal computer to a 12-lead electrocardiograph with interpretative and data storage capabilities. A complete ECG system consists of the ECG data acquisition module; the PC system, including a monitor and printer; Microsoft Windows operating systems (must align with Minimum Computer Requirements); and the IQmanager® software program.

This manual is provided for assistance primarily with service of the Midmark Digital ECG data acquisition module.

For information about the service and operation of the PC system, please consult your PC's documentation.

System Maintenance and Obtaining Service

Midmark Digital ECG 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 and device clean.
- Do not disconnect USB Cable or Patient Cable from Digital ECG.
- Do not hang Digital ECG from USB Cable and Patient Cable.

The Midmark Digital ECG acquisition module contains no user adjustable or serviceable parts and is designed to operate without adjustment for the lifetime of the product.

The device cannot be repaired. In the event of a failure, contact Midmark to assess the extent of the failure and, possibly, to replace the device. In any case, where a non-compliant operation is suspected, it is recommended to follow procedures in the Appendix C Maintenance section.

Disposal

The disposal of Midmark Diagnostic Devices and their accessories should be performed 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 B - Troubleshooting Guide".

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

Warranty

Midmark warrants Midmark Digital ECG to be free from manufacturing and material defects for 24 months from the date of purchase. Accessories are warranted for 90 days. Any misuse or abuse of a Midmark product will void 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 Technical Service. This RMA number should be referenced on the package(s) 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. Midmark highly recommends 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 does 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), 6:00AM to 4:00PM Pacific Time.

Midmark Corporation

60 Vista Drive

Versailles, OH 45380 USA

Email: techsupport@midmark.com

T: 844.856.1230, option 2

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