



IQholter[®], EX/EP

Version 10.0



Operation Manual

39-78-0001 Rev. B

Notice

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Part number: 39-78-0001 Rev B

Table of Contents

Related Documents	6
Precautions	7
I. General Information	8
A. <u>Recorder Description</u>	8
B. <u>Recorder Specifications</u>	10
C. <u>Holter System Description</u>	11
D. <u>Necessary Computer Skills</u>	11
E. <u>Product Features</u>	12
F. <u>Contents Checklist</u>	13
II. Installation	14
A. <u>Minimum Computer Requirements</u>	14
B. <u>System Components</u>	15
C. <u>Set Up</u>	15
D. <u>Software Installation</u>	17
E. <u>Configuring IQholter®</u>	18
III. Patient Preparation	27
A. <u>Electrode Site Preparation</u>	27
B. <u>Three Channel ECG Recording</u>	29
IV. Recorder Operation	31
A. <u>Recorder Set-Up and Configuration</u>	31
B. <u>Confirm Operation and Start Recording</u>	36
C. <u>Before the Patient Leaves the Office</u>	38
D. <u>Early Termination of Recording</u>	39
E. <u>When patient returns with the IQholter® recorder</u>	39
V. Creating a Holter Report	40
A. <u>Starting IQmanager®</u>	40
B. <u>Reviewing and Editing Holter Tests</u>	49
VI. Appendices	85
A. <u>Appendix A - Operations at a Glance</u>	85
B. <u>Appendix B - Troubleshooting Guides</u>	87
C. <u>Appendix C - Maintenance and Storage</u>	89
D. <u>Appendix D - Radio and Television Interference</u>	91
E. <u>Appendix E - Programming the IQholter® Recorder 24+</u>	95
F. <u>Appendix F - Safety and International Symbols</u>	96
G. <u>Appendix G - Accessories and Supplies</u>	97

VII. Customer Support and Warranty Information 98

VIII. Contact Information 99

Physician's Responsibility

The statistical results provided by the Midmark IQholter[®], IQholter[®] EX, or IQholter[®] EP are for the exclusive use of licensed physicians or personnel under their direct supervision. The numerical and graphical results should be examined with respect to the patient's overall clinical condition, recording preparation quality, and general recorded data quality, which can affect the accuracy of reported data.

Proper administration of the test is the physician's responsibility, as is making a diagnosis, obtaining expert opinions on the results, and implementing the correct treatment, if indicated.



Caution

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

Related Documents

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

- *IQmanager® Software Operation Manual* (Part number: 62-78-0001)
- *IQholter® Quick Reference Guide – Patient Preparation* (Part number: 39-79-0004)

All documents referenced above are located on the Midmark Operation Manuals CD (part number: 3-100-2000), included with every device. All product Operation Manuals can also be downloaded from midmark.com. For additional information contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2.

Precautions

Read the following to ensure the proper operation of this instrument:

1. Become familiar with the operational procedures of the IQholter® recorder prior to use.
 - Disconnect the recorder from patients during defibrillation.
 - The recorder is not designed for sterile use.
 - The recorder is not intended for use with rechargeable batteries.
 - Recorder maintenance:
 - Keep the recorder away from splashing water.
 - Do not store or use the recorder where humidity, ventilation, direct sunlight or air containing dust, salt or sulfur might affect it.
 - Prevent the recorder from slipping and protect it from the possibility of vibration, shock or drop; be particularly careful during transport
 - Do not store or use the recorder in a chemical storage area, or where gas is generated.
 - Preparation of the recorder prior to operation:
 - Verify proper recorder operation.
 - Check that cable connections are secure.
 - Precautions while using the recorder:
 - Avoid activities that could affect the quality of recorded signals. Do not sleep under an electric blanket.
 - Patients should not shower, take baths, use hot tubs or perform similar activities while wearing the recorder.
 - Keep the recorder and electrode sites dry while in use.
 - **Do not tamper with the recorder. Do not remove the secure digital (SD) card or battery until the recording is complete.**
 - Precautions after using the recorder:
 - Remove the battery and SD card.
 - Download patient data to computer as soon as possible to preserve patient data.
 - Do not reinstall battery into the recorder with the SD card installed. Patient data will be lost.
 - Keep the recorder clean to ensure trouble-free operation during next use.
 - Perform routine inspection of the recorder and accessories.
 - Do not make any modifications to the recorder.



DANGER

Possible explosion hazard if used in the presence of flammable anesthetics.



Caution

Refer servicing to qualified service personnel.

I. General Information



IQholter® Recorder

A. Recorder Description

The IQholter® recorder is a lightweight, compact, digital Holter recorder designed for reliability and ease of use in ambulatory ECG applications. Because the digital design has no moving parts, the IQholter® recorder records cleaner ECG quality and has lower maintenance cost when compared to tape-based Holter recorders.

The IQholter® recorder can be configured as a 5-lead/3-channel or 7-lead/3-channel recorder by changing the patient cable.

7-lead/3-channel recording is recommended to attain best signal quality.

OLED

An Organic Light Emitting Diode (OLED) display assists Holter technicians in the verification of proper patient hookup on the spot, eliminating the need for expensive test cable interfaces with ECG machines or connecting to a computer.

Five-Way Navigation Button and Patient Event Button

A five-way (up, down, left, right, center/enter) button provides intuitive access to the options and menus within the IQholter® recorder. The center button also acts as a momentary Event button, providing a convenient means of marking and storing event times. Once the Holter data is downloaded and analyzed, ECG strips correlate to the Event (center) button being pressed can be access easily.

Storage Media

Data is conveniently stored on a removable and reusable SD card, eliminating the need for cassette tapes. Digital technology also eliminates tape-based variables such as tape-head frequency, speed variations, distortion and tape brand inconsistencies.

Removable SD card frees up the IQholter® recorder for next patient without waiting for the recorded data to download.

Note

Midmark only recommends using SD cards issued by Midmark. Using other SD cards may cause recording or download errors and potential loss of test data.

Belt Clip

A repositionable belt clip is available on the back of the IQholter® recorder. For better patient comfort the clip is mounted to the recorder so the recorder rests in a horizontal orientation when attached to a belt.

5-Lead or 7-Lead Cable

Depending on the model purchased, a color-coded 5-Lead or 7-Lead cable comes with the IQholter® recorder.

Note

The 5-Lead and 7-Lead cables require different Holter prep kits. Please contact a Midmark sales representative or call Midmark Technical Service for more information.

7-lead/3-channel recording is recommended to attain best signal quality.

24 Hour Mode or 24, 48, 72 Hour Mode

The IQholter® recorder indicated by 24+ on the serial number label is capable of being upgraded to record 24, 48, or 72 hours in “Hi-Def” mode. See table below. Upgrade kit (1-370-0020) will provide this capability.

Attribute	Standard Mode (Default)	“Hi-Def” Mode (Upgrade kit needed)
Hours of Recording	24	24, 48, or 72
Patient ID	Not Available	AlphaNumeric (up to 21 characters)
Sample Rate	128 samples/sec	256 samples/sec
Resolution	8 bits	12 bits
Data Size (per 24 hours)	33 Mbytes	132 Mbytes
Upload Time (per 24 hours)	2 minutes	2 minutes

Note

Use electrodes that are rated for the timeframe (24, 48, 72 hours) for the patient tests.

Note

Use a lithium battery for 72 hour patient tests.

B. Recorder Specifications

IQholter® Recorder Performance Specifications	
Category	Specification
Intended Use	The IQholter® recorder is intended for the recording of ECG data collected from ambulatory patients. The recorder can collect data in the presence of implanted pacemaker pulses, and can detect and record the occurrence of signals characteristic of pacemaker pulses. The recorder is used under the order of a physician, who reviews the data after downloading and processing by IQholter® program.
PHYSICAL	
Weight	2.8 ounces
Dimensions	3.7" x 2.6" x 1.25" (with belt clip) / 1.06" (without clip)
Operating Temperature	0 to 40 degrees Celsius (32 to 104 degrees Fahrenheit)
Storage Temperature	0 to 70 degrees Celsius (32 to 162 degrees Fahrenheit)
Non Operating Shock	1 meter drop (39 inches)
Operating Position	Any orientation
Humidity	0% to 90% (non-condensing)
Storage Media	Secure digital media card (64MB – 2GB)
FUNCTIONAL	
Recording Time	24 hours (Optional 48, 72 hours)
Channels	3
Sample Rate	128 samples per channel/sec (Optional 256 samples per channel/sec)
Resolution	8 bits (Optional 12 bits)
Bandwidth	0.05 to 60Hz -3dB
Input range	+/- 5.0 mV
Battery	1 AA, IEC-LR6 – Alkaline for 24, 48; Lithium for 72
Patient Input	5- or 7-lead configuration
CMRR	60 dB
PACE DETECTION SPECIFICATION	
Pulse Amplitude (at skin)	+/- 2 mV to +/- 500 mV
Pulse Width (at skin)	2ms to 0.1ms

C. Holter System Description

Note

This manual is intended for IQmanager® users. If using the IQholter® or IQholter® EX/EP through an EMR, please contact Midmark Technical Service for assistance with installation, setup and operation.

IQholter®, IQholter® EX, and IQholter® EP (IQholter® EX/EP) is seamlessly integrated with IQmanager® software, the portal to all of Midmark's medical diagnostic utilities, including ECG, Spirometry, and Vital Signs. It is designed to scan ECG waveform digitally stored on a secure digital (SD) card by the IQholter® recorder, and to produce an analytical report on arrhythmic cardiac activity. It is a computer-based medical diagnostic instrument designed for use on Microsoft® Windows® 10, 8, or 7, operating systems.

The IQholter® is intuitive and simple to operate. It is designed for clinics that do not see patients with atrial fibrillations or pacemakers. The IQholter® EX/EP is developed to allow more interactions from the clinician. The feature differences between the IQholter®, IQholter® EX, and IQholter® EP are shown in the IQholter® Product Matrix table below.

Holter monitoring is performed for mean heart rate, minimum and maximum heart rates, isolated premature arrhythmia, interpolated ventricular arrhythmia (VE), pairs (VE Pairs), runs of three or more VEs (VE Runs), premature supraventricular isolated ectopic beats (SVE), coupled SVEs (SV Pairs), supraventricular runs of three or more SVEs (SV Runs), pause, R on T, bigeminy, trigeminy, atrial fibrillation and ST segment depressions and elevations for channels 1, 2, and 3. Ventricular Tachycardia (V Tach) episodes are included in the VE Runs category. Color-coded beat identification enhances the operator's ability to scrutinize and validate the computer analysis of the Holter test. Important values are presented in tables and graphics for easy overview.

After the patient's demographics and recording information are entered in IQmanager®, the Holter program can scan the recorded ECG and automatically generate preselected reports with minimum operator intervention. The clinician can then review the data, perform editing as needed, produce a final report, archive test results for future reference, and share them with colleagues via networks or email.

Note

The IQholter® and IQholter® EX/EP system is designed to scan only ECG data recorded with the IQholter® recorder.

D. Necessary Computer Skills

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

This Operation Manual is a comprehensive guide, designed to educate the user on the operation and functions of the IQholter®, EX, and EP devices. The information in this manual includes all options that are available with IQholter®, IQholter® EX, and IQholter® EP.

E. Product Features

The following table indicates the features available in the IQholter®, IQholter® EX and IQholter® EP.

IQholter® Product Matrix			
Feature	IQholter®	IQholter® EX (With A-Fib Analysis)	IQholter® EP (With Pacemaker Analysis)
Patient Management Software (Patient Search, Report Sorting, Vitals Trending, etc.)	√	√	√
Network Editing and Reviewing	√	√	√
Pacemaker Analysis with Paced Beat Template Editing			√
Atrial Fibrillation Analysis		√	√
Template Editing for all Categories		√	√
User Defined Templates		√	√
Individual Beat Editing for All QRS Beats	√	√	√
Group Editing for All QRS Beats	√	√	√
Inserting or Deleting QRS Beats		√	√
HR Variability Analysis - Time and Frequency Domains		√	√
HRV Analysis Graphical and Tabular Reports		√	√
Output HRV Frequency Analysis Results to Text Files		√	√
Automatic 3-Channel QT/QTc Interval Analysis		√	√
QT/QTc Trend and Tabular Reports		√	√
Automatic 3-Channel ST-Segment Analysis	√	√	√
ST Trend and Tabular Reports	√	√	√
Page Scan functions	√	√	√
Smart Page Scan by Selected Events		√	√
Sample Strip Viewing and Editing	√	√	√
Heart Rate Trend	√	√	√
RR Interval/Ratio Graphs	√	√	√
3-Channel Full Disclosure Preview Before Analysis		√	√
Automatic Downloading of Patient Events	√	√	√
Patient Diary Viewing and Editing with ECG Strip	√	√	√

IQholter® Product Matrix			
Feature	IQholter®	IQholter® EX (With A-Fib Analysis)	IQholter® EP (With Pacemaker Analysis)
Simultaneous 3-Channel Arrhythmia Analysis	√		
Automatic Color-Coded Arrhythmia	√		
Automatic Narrative Summary Report	√	√	√
Automatic Artifact Rejection	√	√	√
Automatic Printing of Pre-selected Reports	√	√	√
Print Selected Hours of Full Disclosure	√	√	√
Print ECG strips with colored grid	√	√	√
Automatically Saves All Results and Full Disclosure	√	√	√
On-line Help	√	√	√

Note

For the rest of this manual, unless otherwise specified, all features and functionalities described for IQholter® also apply to both IQholter® EX and IQholter® EP.

F. Contents Checklist

The IQholter® kit (including part numbers: 4-000-0110, 4-000-0113, and 4-000-0116) contains the items listed below. Open the package and account for each item. Inspect them for any signs of damage such as dents, cracks, tears or scratches. If an item is missing or damaged, contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2, for replacement.

Quantity Each	Description
1	IQholter® Recorder
1	Patient Cable
1	SD Card
1	Secure Digital Card Reader
1	Reusable IQholter® Recorder Pouch and Belt
1	Software Security Key, USB Version
4	Holter Prep Kits
1	Mouse Pad
1	Training DVD
1	Operation Manual CD
1	Quick Reference Guide
1	Warranty Card

II. Installation

Note

Contact Midmark Technical Service before installing and setting up the IQholter®. 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 IQholter® system is installed and configured as quickly and easily as possible.

Midmark Technical Service can be reached at 1-800-624-8950.

A. Minimum Computer Requirements

This section describes the minimum computer resources and hardware components needed when using new Midmark devices and software. As is the nature of technology to change often, these requirements will be evaluated and modified periodically. We suggest always referring to the most recent *Minimum Computer Requirements* document at www.midmark.com, or contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2, for additional information.

Note

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

The IQholter® is a Windows-based medical software program. For successful installation and use of the Holter system, make sure that the host computer meets the minimum requirements and follow the installation instructions carefully.

IQholter® Computer Minimum Requirements	
Item	Requirement
Operating Systems	Windows® 10, Professional and Enterprise, 32-bit and 64-bit
	Windows® 8, Professional and Enterprise, 32-bit and 64-bit
	Windows® 7, Professional and Enterprise, 32-bit and 64-bit
Hardware Requirements	Windows® compatible personal computer. Desktop model strongly recommended.
CPU	Intel® Core™ 2 Duo Processor E4300 (2M Cache, 1.80 GHz, 800 MHz FSB) (x86) or 64-bit (x64) processor or faster
Disk	2 GB of free disk space or greater
Memory	Minimum 2GB of system memory

IQholter® Computer Minimum Requirements	
Item	Requirement
Input/Output Ports	One (1) USB port: One Universal Serial Bus (USB) port for the external flash card reader The flash card reader is required for new test downloads only. An additional USB port is required if a printer is used.
Pointing Device	Windows® compatible mouse.
Keyboard	Windows® compatible keyboard.
Display	1024x768 or higher resolutions for the real time acquisition screen. 16-bit color. Wide-screen (1680x1050) is highly recommended.
Printer	Microsoft Windows® compatible inkjet or laser printer. Note: A high-speed laser printer is highly recommended specially for continuous rhythm strip printing.

The above is the minimum computer requirement specification for operating the IQholter® through IQmanager®. A faster CPU and/or more Memory may be required if planning to operate the IQholter® through an EMR or install additional software.

B. System Components

Figure 1-1 illustrates a general configuration of the IQholter® system. The primary components are a Windows-based computer, a printer, and the IQholter® recorder.

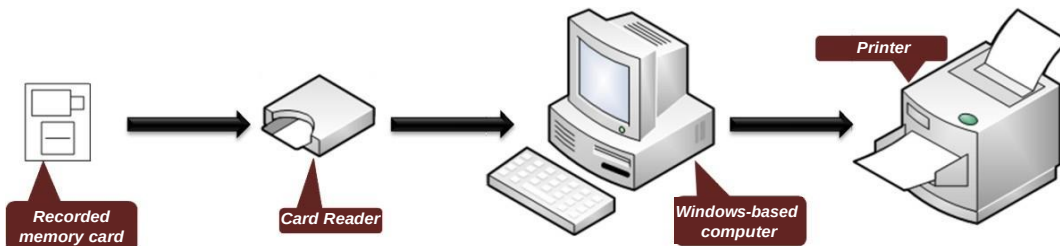


Figure 1-1 Configuration of the IQholter® System

C. Set Up

1. Remove the IQholter® from its packaging, and verify that all the items are present. See [Section I-F, Contents Checklist](#).

Note

If using an electronic medical record (EMR) system that does not interact with the IQholter®, the IQmanager® software will need to be installed. Contact Midmark Technical Service to order an IQmanager® software, if needed.

Note

A Sentinel Security Key will be included with the device kit. **This is NOT a flash drive!** Do NOT lose this security key! Contact Technical Service at 1-800-624-8950, for any questions about the Security Key.

Note

If using with IQmanager, IQiC, IQiA v.10 or above, or any EMR powered by IQconnect™, please contact Technical Service at 1-800-624-8950, to discuss exchanging your key for a software security license.



Figure 2-0 Holter Sentinel Security Key

2. If the host computer does not have a SD card reader, install the external USB SD card reader according to the installation instructions included.
3. If using a software security license, add the license to your license server. If using the Sentinel Security Key (dongle), unpack the key and connect it directly to a USB port on the computer.

Note

Contact Technical Service at 1-800-624-8950, for any questions about the Security Key or Software Security License

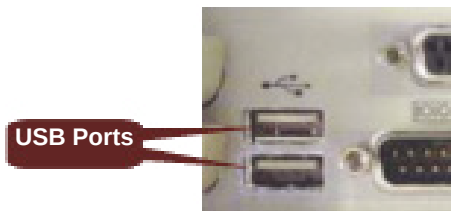


Figure 2-1 Example of USB ports on a computer.

D. Software Installation

Note

The following software installation information refers to IQmanager® Diagnostic Workstation Software users only. If using the IQholter® through an EMR, please contact Midmark Technical Service for assistance with installation and setup.

Note

If IQmanager® is installed on the computer and are upgrading or adding a new Midmark product, please skip this section and refer to the IQmanager® Operation Manual for detailed information on the installation.

Note

Setting up any application in a network environment typically requires administrator privileges, special access rights, and knowledge of the network. Contact the network administrator if you do not have Administrator privileges. The IQmanager® installation program grants all users on the local machine read/write permissions to the Brentwood folder.

Windows® Taskbar

IQmanager® is designed to run as a full-screen program. For best results, the Windows Taskbar should not be displayed in order to provide maximum display area. Place the mouse pointer on the blank portion of the Taskbar on the bottom of the screen, then right-click and select **Properties**. Check the *Auto-hide the taskbar* box to hide the taskbar when it is not in use; to display the taskbar when it is hidden, move the mouse cursor over the area where the taskbar is normally set, and it will reappear.

Installation Steps

Note

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

Note

The Midmark IQholter® requires software to operate. The following instructions use the IQmanager® software. Please contact Midmark at 1-800-624-8950 to purchase the required software license.

1. Double-click the IQmanager® Isetup file. The installation starts automatically. For any questions on the installation please refer to the *IQmanager® Operation Manual*.
2. Follow the instructions on the screen. For detailed installation, setup and detailed operation instructions for IQmanager® software, please refer to the *IQmanager® Operation Manual*.
3. If there are any new licenses, add them to the licensing server. For any questions on adding licenses please refer to the IQmanger® operation manual.

E. Configuring IQholter®

IQmanager® and the IQholter® can be customized by using the configuration settings. Access the **Configuration Settings** by using the following steps:

- Click on the **SETTINGS** button in the upper right side of the IQmanager® opening screen



The *IQmanager Settings* window appears:

Complete the *Institution Name* and *Address* boxes with information about your medical practice. The IQholter® will print the institution name on the *Analysis Summary* cover page of the reports. Enter a name that describes the practice or operation to enable other medical personnel to identify the reports.

Choose between Metric and English units of measurement, which affect how some of the patient data (e.g., weight and height) is displayed. The IQholter® uses both *Date* and *Time Format* settings, but part of the Holter screen will always be in 24-hour format.

The other settings on this screen are irrelevant to Holter. When done, press **Save**.

Database Settings

Note

Refer to the *IQmanager® Operation Manual* for customizing the database settings.

The screenshot shows the IQmanager software interface. At the top, there's a navigation bar with tabs: IQMANAGER, DATA MANAGEMENT, LIST MANAGEMENT, DEVICES, UPDATES, and DIAGNOSTICS. The 'DATA MANAGEMENT' tab is selected. Below it, there are two main sections: 'DATABASE SETTINGS' and 'REPORT MANAGEMENT SETTINGS'. The 'DATABASE SETTINGS' section includes fields for 'Midmark SQL Server Name' (set to 'IQconnectTest'), 'Midmark Database Name' (set to 'Midmark'), a checked 'Use Windows Authentication' checkbox, and empty fields for 'Database Username' and 'Database Password'. A 'TEST DB CONNECTION' button is to the right. The 'REPORT MANAGEMENT SETTINGS' section includes fields for 'Database Server' (set to 'IQconnectTest'), 'Database Name' (set to 'IQconnectReports'), a checked 'Use Window Authentication' checkbox, and empty fields for 'Database Username' and 'Database Password'. A 'Save Report Location' field is set to 'C:\Reports' with a 'BROWSE' button next to it. At the bottom, there are 'HELP', 'SAVE', and 'CANCEL' buttons.

The *Save Report Location* setting determines where the full disclosures and report files will be stored. Each 24-hour Holter ECG file requires 33MB or 132MB (Optional 24, 48, 72) of storage.

List Management

The *List Management* configuration option customizes the lists used in IQmanager®, including Indications and User Name, which may be used for Holter tests.

Note

Refer to the *IQmanager® Operation Manual* for information on customizing List Management.

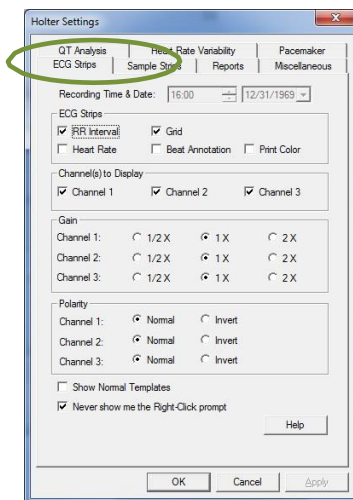
Holter Settings

Change the default settings for Holter tests by clicking **Holter Settings** from the *Devices* tab or by clicking **Holter Settings** inside the Holter program. Both methods provide similar options.



ECG Strips

The *ECG Strips* tab specifies how to view or print ECG strips.



If *RR Interval* is checked, each interval value, in millisecond (ms), will appear on top of the ECG strip between every two RR. If *Heart Rate* is checked, an instantaneous heart rate value, in BPM, will appear on top of the ECG strip between every two RR.

The *Grid* option affects the display only; sample strip printouts always have gridlines.

If *Beat Annotation* is checked, a letter code will appear above each QRS complex indicating its classification. If using a color printer and the *Print Color* box is checked, the diagnostic ECG strips will be printed with a red grid and all ECG beats will be printed with the following designated color codes:

Beat Category	Display Color	Beat Annotation
Normal beats	Black	N
Ventricular beats	Red	V
Supraventricular beats	Blue	S
Pause beats	Pink	P
Artifacts	Dark yellow	?

Note

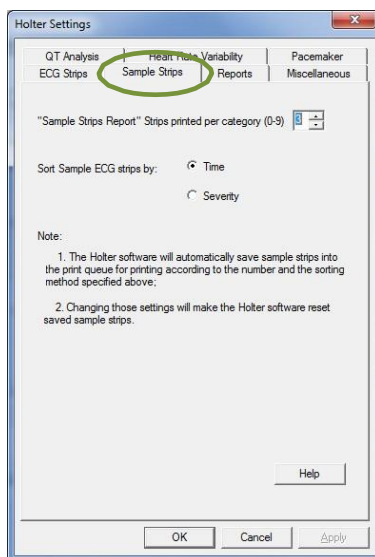
Print Color checkbox only affects the printout if a color printer is used.

Sample Strips

The *Sample Strips* tab sets the maximum number of sample strips (up to 9) per category for printing, and selects to sort sample ECG strips by time or severity.

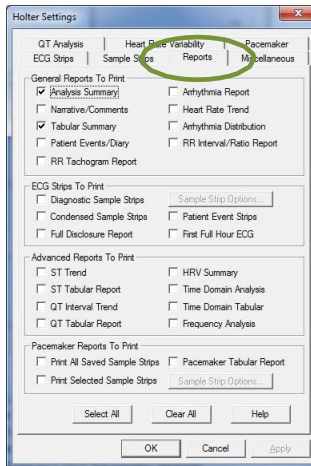
Note

High Heart Rate, Low Heart Rate and ST Segment sample strips will be sorted by severity only.



Reports

The *Reports* tab of the *Holter Settings* dialog box selects the default reports for printing.

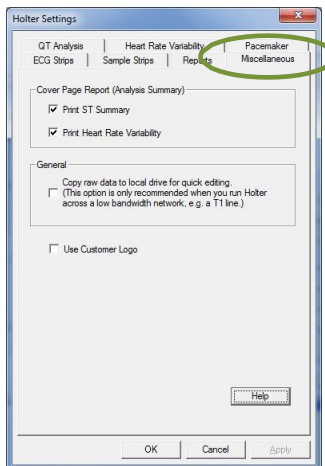


Note

The following reports are only applicable to the IQholter® EX: RR Tachogram, QT Interval Trend, QT Tabular, HRV Summary, Time Domain Analysis, Time Domain Tabular and Frequency Analysis. IQholter® EP offers all reports options including Pacemaker Reports.

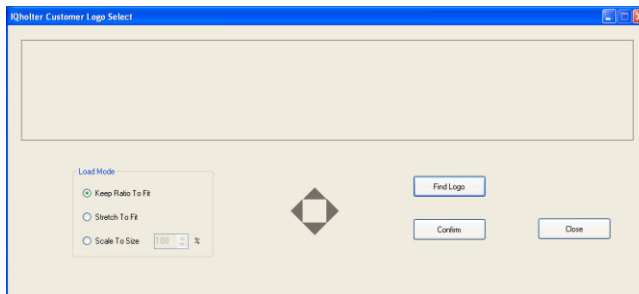
Miscellaneous

The *Miscellaneous* tab provides the option to print *ST Summary* and *Heart Rate Variability* summary results on the cover page of Holter report.



If working on a network and the Holter full disclosure is stored on a network drive, check the *General* box to speed up data access during reviewing and editing. This is useful when operating Holter on a relatively low-bandwidth network, such as a T1 network.

The IQholter® report can be customized to include a logo to the top of cover page. Before clicking on the *Use Customer Logo* checkbox, first prepare a digital image of the logo in jpeg format. Then execute the LogoSelect application in Brentwood\Program folder and click *Find Logo* button to pick the logo image.



The logo window is about 7.3" (W) x 1.1" (H). The options available are to keep the original ratio of the image to fit, stretch to fit, or scale to a desired size. Use the four grey arrows in the middle to position the logo inside the window. Click *Confirm* to save, then *Close* to exit.

Check the *Use Customer Logo* box.

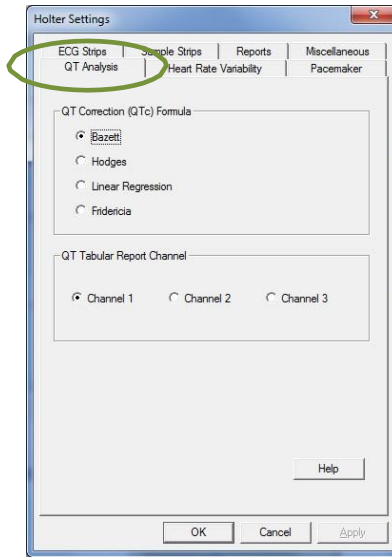
QT Analysis

Note

These settings apply only for IQholter® EX and IQholter® EP.

The *QT Analysis* tab specifies how the Holter software analyzes QTc intervals. Apply one of the available formulas for QTc analysis; Bazett's formula is selected by default.

Determine which channel the QT Tabular Report to be based on. This setting will affect online viewing and report printout.



WARNING

Computerized calculation of QTc is not a substitute for physician interpretation of the Holter. It is the responsibility of a qualified physician to review the ECG to determine the accuracy of QTc calculation before using QTc to make a diagnosis.

Heart Rate Variability

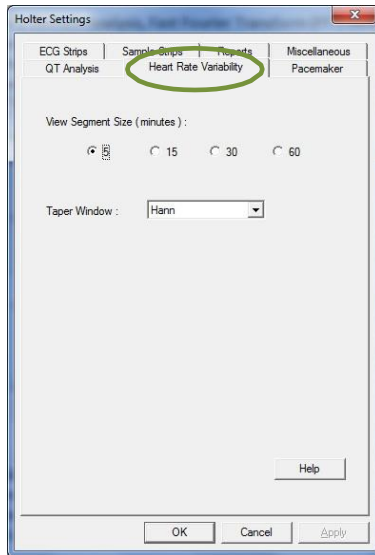
Note

These settings apply only for IQholter® EX and IQholter® EP.

Only normal RR intervals are used for in the Heart Rate Variability (HRV) analysis. A normal RR interval is when the current, the previous, and the next QRS waves are classified as normal (i.e. they are not noise or ectopic beats).

IQholter® provides two HRV analysis domains, Time Domain Analysis and Frequency Domain Analysis. In Time Domain Analysis, the segment size used for calculation is 5 minute.

In the Frequency Domain Analysis, Fast Fourier Transform (FFT) based algorithm is used to estimate the power spectral density (PSD). The segment size for PSD estimation is always 5 minutes, although a longer segment size can be selected for viewing in the setting. If 15 minutes of View Segment Size is selected, the HRV frequency analysis results display will use the average PSD values of three 5-minute segments. For 30 or 60 minutes view segments, the average PSD values of six or twelve 5-minute segments, respectively, will be used.



The *Taper Window* option determines the windowing formula (Blackman, Exact Blackman, Hamming or Hann) used to calculate power values in different ranges of the frequency domain analysis.

If more than 50 percent of the intervals are invalid in a 5-minute segment, then that segment will be marked as invalid and displayed as “-”.

Pacemaker

Note

These settings apply only for IQholter® EP (Pacemaker Analysis) option.

The *Pacemaker* tab enables the user to enter or edit pacemaker parameters and settings for analysis and display. At the start of a Holter test, these settings may be customized for each pacemaker patient. All values are optional; the software assigns default values if the parameters are not manually reset. If the *Restore pacemaker spikes* on ECG box is checked, a red vertical line will appear for each pacemaker spike on the ECG tracing.

The screenshot shows the 'Holter Settings' dialog box with the 'Pacemaker' tab selected. The 'Miscellaneous' tab is circled in green. The 'Pacemaker Data (Optional)' section includes a 'Pacing Mode (Type)' dropdown menu, 'LRL (Lower Rate Limit): 60 ppm', and 'URL (Upper Rate Limit): 120 ppm'. The 'Analysis Parameters (Optional)' section includes 'A-V Interval (AVI): 150 msec', 'A-R Interval (ARI): 180 msec', 'Undersensing Percentage: 20 %', and 'Oversensing Percentage: 15 %'. There is a 'Reanalyze Pacing Data' button. The 'Pseudo-Pulse Annotation' section has a checked box for 'Restore pacemaker spikes on ECG'. At the bottom are 'OK', 'Cancel', and 'Apply' buttons.

Tab	Section	Parameter	Value	Unit
Miscellaneous (Pacemaker)	Pacemaker Data (Optional)	Pacing Mode (Type)		
		LRL (Lower Rate Limit)	60	ppm
		URL (Upper Rate Limit)	120	ppm
	Analysis Parameters (Optional)	A-V Interval (AVI)	150	msec
		A-R Interval (ARI)	180	msec
Undersensing Percentage		20	%	
Oversensing Percentage		15	%	
Pseudo-Pulse Annotation	Restore pacemaker spikes on ECG	checked		

III. Patient Preparation

Required Materials

Before beginning the patient preparation, be sure to have a Midmark Holter Patient Preparation Kit or a similar high-quality Holter preparation kit available.

The Midmark Holter Patient Preparation Kit contains:

- 5 or 7 silver chloride disposable electrodes designed for Holter monitoring
- Abrasive pad
- Patient diary
- Isopropyl alcohol wipes
- Razor
- Two (2) AA alkaline batteries

Note

Use one (1) Energizer® brand lithium battery for 72 hour recording to ensure adequate capacity for duration of patient test. This battery is not included in the Midmark Holter Patient Preparation Kit.

Note

Do not use 12-lead resting ECG electrodes. We recommend using the Midmark Holter Patient Preparation Kit for consistent quality ECG data. Use electrodes that are rated for the timeframe (24, 48, 72 hours) for the patient tests.

A. Electrode Site Preparation

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



Caution

Poor site preparation, improper electrode placement or use of inferior electrodes may lead to unusable data or an inaccurate analysis.

Note

Refer to the IQholter® Quick Reference Guide – Patient Preparation (included in the product kit) for more detailed instructions.

The following steps are *essential* in obtaining usable ECG data:

1. Select the electrode placement configuration from a reliable clinical reference source. Two typical configurations are illustrated in *Figures 3-2* and *3-3*.
2. Select electrode sites located over bony areas where reduced tissue movement will minimize the amount of signal artifact. Electrode sites should be over a rib rather than an intercostal space.
3. Shave electrode placement areas, as needed.
4. Gently scrub the skin with an abrasive pad, lint-free gauze pad or fine sandpaper enclosed in the preparation kit. This loosens and removes deadskin.
5. Wipe the scrubbed area with a clean alcohol pad and ensure the entire electrode site is free of oil. Repeat for all sites. Allow these areas to air dry naturally before attaching electrodes.
6. Follow the electrode manufacturer's application instructions when applying snap leads to the electrodes. To simplify this process, first apply the lead wire snaps to the electrodes then apply the electrodes to the patient.
7. Remove the backing from a pre-gelled disposable electrode and place an electrode on each of the prepared electrode sites, make certain that the right colored lead is placed on the proper site. Ensure that the gel in the center of each electrode maintains contact with the prepared skin surface and the electrode is not wrinkled.
8. Form a stress loop with each electrode lead then tape the loop to the skin. This reduces artifacts caused by snap rotation when leads are pulled or tugged by normal patient movements.

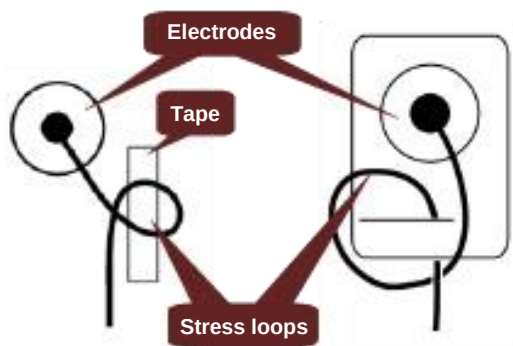


Figure 3-1 Examples of stress loops

B. Three Channel ECG Recording

- 5-lead Holter recordings
Utilize a bipolar lead system that shares either positive or negative leads between the channels and a recorder ground.
- 7-lead Holter recordings
Utilize a bipolar lead system where there is one positive and one negative lead for each channel, plus a recorder ground.

Five Lead Wire Configuration	
Lead Color	Placement
Red	Channel 1 (-), Channel 2 (-) Place at center of manubrium and top of sternum.
White	Channel 3 (-) Place on the right side, below the V1 or V3R position, at the bottom of the rib cage.
Brown	Channel 1 (+) Place on the left side at or below the V3 position, on a rib.
Black	Channel 2 (+), Channel 3 (+) Place on the left side at or below the V5 position, on a rib.
Green	Ground Place on the right side, opposite and below the V5 position.

Note

RED (-) BROWN (+) = CHANNEL 1
RED (-) BLACK (+) = CHANNEL 2
WHITE (-) BLACK (+) = CHANNEL 3

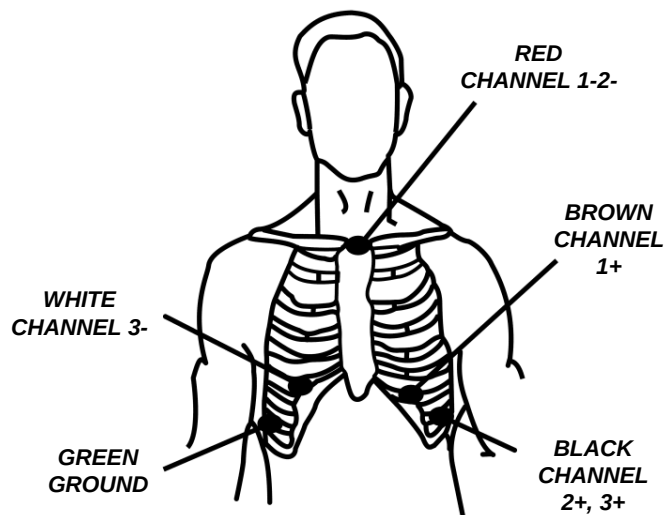


Figure 3-2 Typical three channel five lead electrode placement configuration

Seven Lead Wire Configuration	
Lead Color	Placement
White	Channel 1 (-) Place at top of sternum.
Red	Channel 1 (+) Place on the left side at or below the V3 position, on a rib.
Black	Channel 2 (-) Place at top of sternum, adjacent to white lead.
Brown	Channel 2 (+) Place on the left side at or below the V5 position, on a rib.
Blue	Channel 3 (-) Place at top of sternum, adjacent to white lead.
Orange	Channel 3 (+) Place on the right side at or below the V1 or V3R position, on a rib.
Green	Ground Place on the right side, opposite and below the V5 position.

Note

WHITE (-)	RED (+)	=	CHANNEL 1
BLACK (-)	BROWN (+)	=	CHANNEL 2
BLUE (-)	ORANGE (+)	=	CHANNEL 3

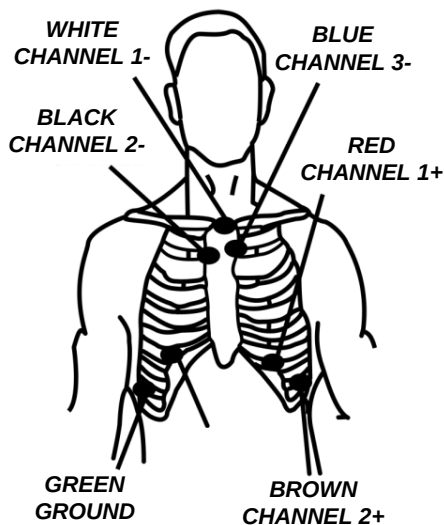


Figure 3-3 Typical three channel, seven lead electrode placement configuration

IV. Recorder Operation

Required Materials

- One SD memory card

Note

Only a Midmark issued SD memory card (P/N: 1-370-0010) should be used.

- Midmark Holter Patient Preparation Kit

Note

Use electrodes that are rated for the timeframe (24, 48, 72 hours) for the patient tests.

Note

For 72 hour recording, DO NOT USE alkaline battery from prep kit. Use Lithium battery.

- IQholter® recorder
- Patient cable

A. Recorder Set-Up and Configuration

Patient Cable

1. Remove the color-coded patient cable from the shipping package.
2. Attach cable to the patient cable connector on top of the recorder.
 - a. Ensure proper alignment of the connector before pressing the cable into the recorder.



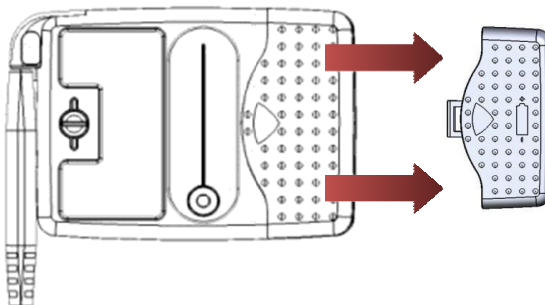
Recorder input configuration is automatically selected by the attachment of the appropriate patient cable. The options are 5-lead/3-channel or 7-lead/3-channel. Please see **Figures 3-2** and **3-3** for proper lead placement.

Remove Battery Door

Open the recorder battery door by gently pressing down on the triangular marking. The door will slide open by itself.

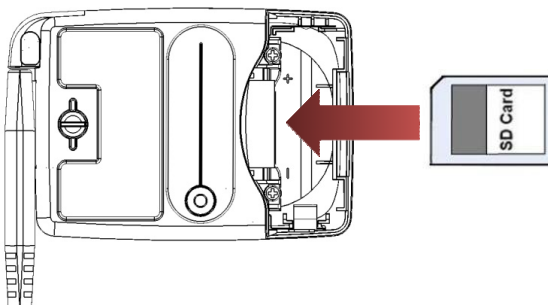
Note

Do not apply excessive pressure to the battery door. Pressing down and sliding the door at the same time may result in damage.



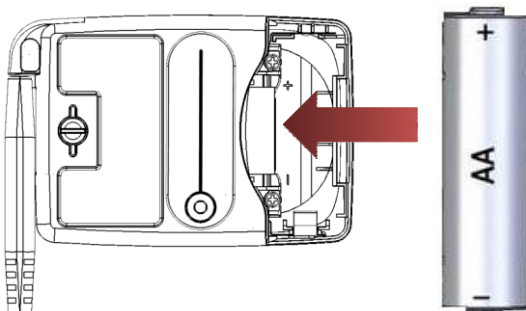
SD Card Insertion and Removal

1. Insert SD card as shown below.
2. The SD card can be removed by pressing the card gently; it will pop out for retrieval.



Battery Installation

After inserting the SD card, install a new AA battery.



Note

It is not recommended to install the SD card after the battery, as the SD card access port is located in the battery compartment.

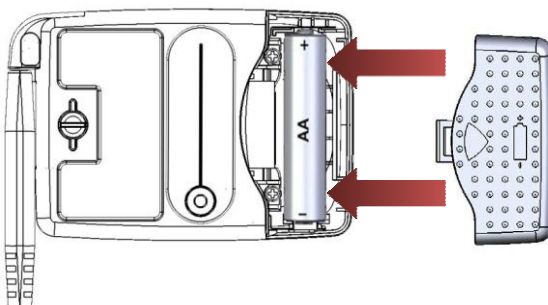


Caution

All previously recorded ECG data stored on the SD card will be erased once the new battery is installed.

Replace the Battery Door

Gently slide the battery door on to the recorder as shown.



Setting Patient ID, Length of Recording, and Date/Time

1. After installing the SD card and battery, the recorder turns on automatically.

Note

Slightly different start-up process for 24 ONLY and Upgraded 24, 48, 72 hour program.



Upgraded 24, 48, 72 hour menu



Standard 24hour only menu

2. For Upgraded 24, 48, 72 hour ONLY – Scroll down to Patient ID.



3. For Upgraded 24, 48, 72 hour ONLY – Use recorder arrow keys to navigate the AlphaNumeric characters (up to 21 characters), press center button to Select character, select DONE when complete.



4. For Upgraded 24, 48, 72 hour ONLY - Scroll down to recording length (default is 24 HOURS).



5. For Upgraded 24, 48, 72 hour ONLY – Use arrow keys to navigate to recording length, press center button to select.

Note

Recorder returns to 24 hour mode each time the battery is replaced.



6. Press the down arrow to scroll to the time or date.



7. Press **Enter** (the center button) to go to the change screen.



8. Use the up and down arrows to scroll through the numbers.
9. Use the right and left arrows to move between fields.



- a. Time fields, from left to right: Hour, Minute, AM/PM



- b. Date fields, from left to right: Month, Day, Year



10. Press the center button to save changes and return to the main screen.

Note

Recorder has an internal clock battery that will last about 3 years. Date and time settings are saved.

B. Confirm Operation and Start Recording

Note

*The recorder emits a continual tone and the OLED displays **FLASHCARD NOT INSERTED** if the SD card is inserted improperly.*

Note

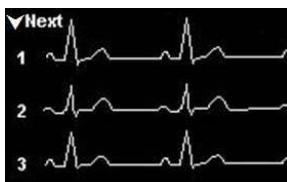
*The recorder tests the battery, sounds warning beeps and displays **LOW BATTERY** if the battery is not suitable for a 24 or 48 hour recording. Replace the AA battery with a fresh battery.*

Note

Use a lithium battery for 72 hour recordings.

Recorder should beep once and the OLED will activate. If not, verify if:

- The above sequence was followed
- The battery is correctly installed
- The recorder is operating properly
- To confirm the ECG signal, the recorder displays the three channels of the patient's ECG on the readout.



- Press the center button to display an enlarged single-channel display or press the down-arrow to rotate through the channels. The top left corner of the screen indicates the channel displayed and color of the lead wires used for that channel.



- The recorder will automatically start recording in approximately eight (8) minutes. If more time is needed to complete or correct the patient hookup, remove the battery and replace it when ready to continue.

Note

After confirming the ECG signal quality, the recording mode may be started immediately by pressing and holding the event button for five seconds or until the ECG display turns off.

- Document the recording start time in the patient diary.

Note

The IQholter® recorder displays the start time in real time. See [Section IV-A, Recorder Set-Up and Configuration](#) for more information.

C. Before the Patient Leaves the Office

1. Secure the recorder to the patient with one of the following:
 - Reusable pouch (each recorder is shipped with one)



- Disposable pouch



2. Verify that the patient or caregiver understands the following:
 - How to use the event button and patient diary (see [Section I-A, Recorder Description](#) for more information).
 - Keep the recorder away from moisture.
 - Keep electrode sites dry: do not shower, take baths, use hot tubs or perform similar activities while wearing the recorder.
 - Refrain from placing the recorder in a backpocket.
 - Do not tamper with the recorder, battery or SD card.
 - Do not remove or reposition any electrodes.
 - Do not use an electric blanket while using the recorder.
 - Avoid environment that has strong electrical or electromagnetic interference. See [Appendix D - Radio and Television Interference](#).

D. Early Termination of Recording

The recorder automatically stops at the predetermined recording length. To terminate the recording early, remove the battery and the SD card. A loss of up to six (6) minutes of data is normal if the recording is terminated early.



Caution

Removal of the SD card during the first thirty (30) minutes of recording will result in a SD card with no data stored on it.

E. When patient returns with the IQholter® recorder

- Remove and discard the battery. (Follow instructions described in [Section IV-A, Remove Battery Door.](#))
- Remove the SD Card and keep with the Patient's Diary until it has been analyzed.
 - SD card can be removed by pressing the card gently; it will pop out for retrieval.

V. *Creating a Holter Report*

This section is written to help the user get started and become familiar with the IQholter® system.

While this manual describes features of the IQholter® in the operational sequence that most new operators will follow, the user is not restricted to following this particular sequence. Many of the features are interconnected and can be accessed from more than one screen. The *Holter Main Buttons Bar* appears at the bottom of each screen, with shortcut buttons to other screens. On each screen, there may be tabs and buttons that can be used to access different functions.

Because of the extensive list of the Holter features and the flexibility of the program, not every possibility is described here. A more comprehensive explanation of the features and functionalities of each screen are available through the online help system installed within the program. Once familiar with the basic operation of this product, the user can operate the Holter program in different ways to meet specific purposes.

Of course, there are certain sequences that must be followed, such as entering a patient's medical data before performing the Holter scan. However, this program is designed to be both user-friendly and flexible.

We have included a condensed guide to operating the IQholter® with new patients. See [Appendix A - Operations at a Glance](#).

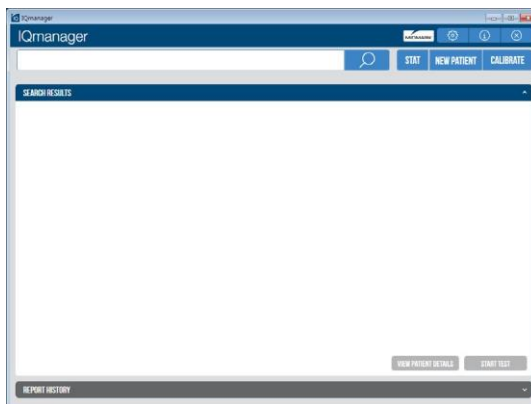
A. *Starting IQmanager®*

Follow this section to get started with a new Holter scan quickly and obtain a standard Holter report printout with minimal involvement in the various screens and functions.

Open IQmanager® software by double-clicking on the IQmanager® icon on the desktop:



Midmark IQmanager



The IQmanager® opening screen appears. Click **New Patient** or Search for a patient.

Entering Patient Data

In the *Patient Data* screen, enter all necessary information regarding the patient. A name or an ID is required to start a Holter test.

The screenshot shows the IQmanager interface for a patient named John D. Smith. The patient's information includes a silhouette icon, name, date of birth (12/14/1982, 33 years old), ethnicity (Caucasian), gender (Male), and Patient ID (1234567890). Below this, the 'Vitals' section for 4/6/2016 displays a grid of vital signs: BP (120/80), Weight (200 lb), Temp (95.7 F), SpO2 (99%), Pulse (80 BPM), Height (72 in), BMI (27.1), RespRate (15 rpm), and Pain Score (1). At the bottom, a list of medical history items with counts and arrows is shown: Smoking History (N), Medications (0), Contact Information (1), Medical History (0), and Risk Factors (3).

Vitals 4/6/2016			
BP	120/80	Pulse	80 BPM
Weight	200 lb	Height	72 in
Temp	95.7 F	BMI	27.1
SpO2	99%	RespRate	15 rpm
		Pain Score	1

» New Vitals | » Manual Entry

Smoking History	N	<
Medications	0	<
Contact Information	1	<
Medical History	0	<
Risk Factors	3	<

Note

For upgraded IQholter recorders only: If the patient ID does not match the ID entered on the recorder the program will display a warning message when downloading the Holter data for analysis. See [Section V-A, Starting IQmanager®/Completing the Holter Scan](#).

Starting a New Holter Test

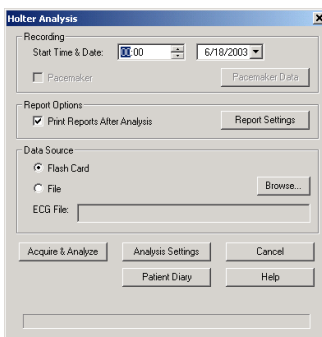
To start a test, click **New Test** from the *Patient Data* screen. Click on the play icon next to IQholter.



If desired, select the Technician's name and the Physician's name from the pull-down list. The reason for testing the patient can also be selected from the *Indication* list as shown in the *New Test Selection Screen*. This information is optional.

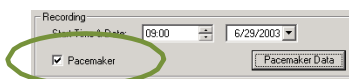
If the List Management has been configured for the practice, these entries can be selected from the lists.

Click **OK**. The *Holter Analysis* dialog box appears:



The software automatically enters the recording start time and date from the IQholter® recorder. Time is in 24-hour format: 1:00 p.m. is entered as 13:00.

The *Pacemaker Analysis* option is enabled for IQholter® EP only. If the patient has an electronic pacemaker, check the *Pacemaker* box to obtain pacemaker analysis results. If the Holter data was recorded using a non-upgraded standard 24hour recorder, the program will check the recording for pacemaker spikes detected during the monitoring period and prompt if the *Pacemaker* box is not checked.



Note

*If the Holter application does not include the Pacemaker Analysis option, this box and the **Pacemaker Data** button will be disabled.*

Pacemaker Data

The *Pacemaker Settings* dialog box will appear if **Pacemaker Data** is selected, which provides the specific parameters of the pacemaker device. For example, the type of pacemaker that the patient is wearing (i.e., DDD, DVI, VDD, VVI), can be selected from a list.

The screenshot shows the 'Holter Settings' dialog box with the 'Pacemaker' tab selected. The 'Pacemaker Data (Optional)' section contains a 'Pacing Mode (Type):' dropdown menu, which is circled in green. Below it are 'LRL (Lower Rate Limit):' and 'URL (Upper Rate Limit):' fields, both set to 60 ppm. The 'Analysis Parameters (Optional)' section includes 'A-V Interval (AVI):' (150 msec), 'A-R Interval (ARI):' (180 msec), 'Undersensing Percentage:' (20 %), and 'Oversensing Percentage:' (15 %). A 'Reanalyze Pacing Data' button is located below these fields. The 'Pseudo-Pulse Annotation' section has a checked box for 'Restore pacemaker spikes on ECG'. At the bottom are 'OK', 'Cancel', 'Apply', and 'Help' buttons.

Report Options

To have the Holter software to print reports automatically when the scan is finished, select the *Print Reports After Analysis* box on the *Holter Analysis* dialog box. View or select which reports to be printed by clicking **Report Settings**.

The screenshot shows the 'Holter Settings' dialog box with the 'Reports' tab selected. The 'General Reports To Print' section includes checkboxes for 'Analysis Summary' (checked), 'Narrative/Comments', 'Tabular Summary' (checked), 'Patient Events/Diary', 'RR Tachogram Report', 'Arrhythmia Report', 'Heart Rate Trend', 'Arrhythmia Distribution', and 'RR Interval/Ratio Report'. The 'ECG Strips To Print' section includes checkboxes for 'Diagnostic Sample Strips', 'Condensed Sample Strips', 'Full Disclosure Report', 'Patient Event Strips', and 'First Full Hour ECG', along with a 'Sample Strip Options...' button. The 'Advanced Reports To Print' section includes checkboxes for 'ST Trend', 'ST Tabular Report', 'QT Interval Trend', 'QT Tabular Report', 'HRV Summary', 'Time Domain Analysis', 'Time Domain Tabular', and 'Frequency Analysis'. The 'Pacemaker Reports To Print' section includes checkboxes for 'Print All Saved Sample Strips', 'Print Selected Sample Strips', 'Pacemaker Tabular Report', and another 'Sample Strip Options...' button. At the bottom are 'Select All', 'Clear All', 'Help', 'OK', 'Cancel', and 'Apply' buttons.

Note

The following reports are only applicable to the IQholter® EX: RR Tachogram, QT Interval Trend, QT Tabular, HRV Summary, Time Domain Analysis, Time Domain Tabular and Frequency Analysis. IQholter® EP offers all report options including Pacemaker Reports.

Note

Available for IQholter® EP only, the Pacemaker Reports choices are disabled if the Pacemaker box on the Holter Analysis dialog box is not checked.

Note

Verify that the default printer is on and ready with enough paper for the report. At least 24 sheets of paper (for each 24 hours) will be needed if the Full Disclosure Report is selected in the Report Settings.

Analysis Settings

To view or change the analysis criteria, click **Analysis Settings** in the *Holter Analysis* dialog box. The default analysis settings are shown below:

Analysis Settings

Supraventricular Prematurity Percentage: 40 %

Tachycardia Limit: 120 bpm

Bradycardia Limit: 50 bpm

Lower Limit of Asystole/Pause: 2.5 second

Upper Limit of Asystole/Pause: 7.5 second

ST Point, milliseconds after the J point: 80 msec

ST Segment Threshold

Depression (mm): -1.0 Elevation (mm): 4.0

Analyzed Channels

Channel	Analyze?	Primary
1	☒	☐
2	☒	☐
3	☒	☐

☐ Tall Pacing Artifact ("Pacer Spikes")

A-Fib

Enable A-Fib Detection: ☐

A-Fib Duration Limit: Beats

Non A-Fib Duration Limit: Beats

Irregularity: %

Mark All as A-Fib: ☐

OK Cancel Save As Default Help

IQholter® Analysis Settings screen



IQholter®, EX, EP Analysis Settings screen

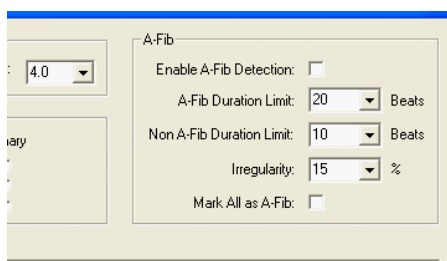
These criteria can be changed to best fit the office or users needs. For example, some offices may choose to use 60bpm as bradycardia limit or 2.0 seconds as the lower asystole/pause limit. The upper pause limit is set to 7.5 seconds as the default to avoid possible false detection caused by lead disconnect or excessive artifact. If the patient has pause(s) that is longer than 7.5 seconds, use the dropdown menu to change the Upper Limit of Asystole/Pause to a desired length.

Under **Analyzed Channels**, select one or more of the available channels to analyze and select one of those channels as the primary channel. By default, all three channels are selected and Channel 1 is the primary channel.

For IQholter®, EX, or EP, the bottom window displays the raw ECG data from the recording. Drag the slider bar below the ECG strip to view the entire length of the recorded ECG before the analysis starts. This provides an overview of the patient's ECG and the quality of the recording, helping to determine if whether or not to change the default settings for this test.

Note

To obtain a preliminary Holter report with better accuracy, do not analyze channel(s) that is very noisy and select the channel that has the best signal quality, least artifacts and tall amplitude as the primary channel.



For IQholter®, EX, or EP, select the *Enable A-Fib Detection* box to perform automatic atrial fibrillation analysis. Any episodes of A-Fib can be manually reclassified, regardless if this box is enabled.

If automatic A-Fib analysis is enabled, the following parameters are used to adapt the algorithm to suit different ECG tracings for better results:

- **A-Fib Duration Limit** sets the minimum run of beats of an atrial fibrillation episode. Select a value from the drop-down list or enter a number between 5 and 1000; the default value is 20.

Note

Since the A-Fib Duration Limit determines the minimum length requirement for the qualification of an A-Fib episode, the smaller it is, the more easily a sequence of beats is identified as positive A-Fib episode, assuming that the other two parameters are fixed. While this may increase the true positive detection if the ECG is really atrial fibrillation with great RR irregularity even in a short period, it can also increase the false positive detection if the ECG is just sinus arrhythmia without any real A-Fib episodes. The true positive detection does not always increase proportionally with the decrease of this setting. For a particular atrial fibrillation ECG, there is a lower bound, below which the true positive detection will decrease because the RR intervals may not be able to change too much. The optimal value of A-Fib Duration Limit is heavily dependent on the particular ECG itself. There is no fixed optimal value for all Holter tests.

- **Non A-Fib Duration Limit** sets the minimum run of beats of a non-atrial fibrillation rhythm. Select a value from the drop-down list or enter a number between 5 and 1000; the default value is 10.

Note

The Non A-Fib Duration Limit determines the minimum length requirement for the qualification of a non-atrial fibrillation rhythm. The smaller it is set to, the more easily a sequence of beats is identified as a non-atrial fibrillation rhythm if the other two parameters are fixed. Consequently, a short sequence of relatively regular RR intervals embedded in a true atrial fibrillation rhythm may be mistakenly identified as non-atrial fibrillation. Thus, a true atrial fibrillation rhythm lasting for a long period could be broken into many short episodes of atrial fibrillation with those regular RR atrial fibrillation beats missed. On the other hand, a smaller value does increase the identifying power to find any short period of non-atrial fibrillation beats. Like A-Fib Duration Limit, there is no one optimal value of Non A-Fib Duration Limit for all Holter tests.

- **Irregularity** sets the percentage of RR interval variation for an atrial fibrillation episode. Select a value from the drop-down list or enter a number between 2 and 100; the default value is 15.

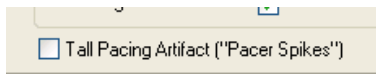
Note

Irregularity has a relatively simple relation with positive detection for atrial fibrillation rhythm. The smaller the value, the more likely a sequence of beats will be identified as atrial fibrillation. While this increases the true positive detection if the ECG is truly atrial fibrillation, it may also increase the false positive detection if the ECG is sinus arrhythmia, but not atrial fibrillation.

The default settings are biased for low false positive detection taking into consideration that non-atrial fibrillation patients are more than atrial fibrillation patients.

If working with a patient with chronic A-Fib, check the **Mark All as A-Fib** box. This setting is the equivalence of zero percent variability.

For IQHolter® EP, the **Tall Pacing Artifact** (“Pacer Spikes”) box is only available if the *Pacemaker* box is checked on the *Holter Analysis* dialog box. Selecting *Tall Pacing Artifact* would produce more accurate pacemaker analysis results for typical unipolar pacemakers, which produce tall spikes.



Note

Do not check the Tall Pacing Artifact (“Pacer Spikes”) box if the amplitude of the spikes is small.

Click **OK** to save any changes and return to the *Holter Analysis* dialog box.

Patient Diary

If the patient has written notes in their patient diary, enter them in the Holter software. On the *Holter Analysis* dialog box, click **Patient Diary** to open the *Patient Diary* dialog box. If the patient has pushed the event button on the recorder during the recording, the Holter software automatically tabulates each event as a *Recorder Event*.

Enter any times, symptoms and comments as recorded on the patient's diary. Once finished, click **Save** to save the entries. Click **Close** to return to the *Holter Analysis* dialog box.

No.	Time	Activity	Symptoms	Comments
1	11:15:14	Recorder Event		
2	13:18:52	Recorder Event		
3	19:02:36	Recorder Event		
4	23:51:27	Recorder Event		
5	06:26:09	Recorder Event		
6				
7				
8				
9				
10				

Save Insert Flow Clear Row Clear All Help Close

Completing the Holter Scan

In the *Holter Analysis* dialog box, click **Acquire & Analyze**. The Holter program acquires the ECG data recorded on the SD card and analyzes it.

Note

For upgraded IQholter® recorders only. If the selected patient ID does not match the ID entered on the recorder, the program will display a warning message as shown below. Click **No** if this is not the right patient or not the correct SD card.



Warning: Patient ID Mismatch

Current selected patient ID is 850000001
ID recorded in Holter data is 08072011

Do you want to continue and assign this report to the selected patient?

Yes

No

Note

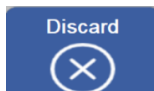
If **Yes** is selected, the ID entered in the Holter data will not be used. The Holter analysis will continue under the current selected patient ID.

Depending on the speed of the computer, it will take about one to two minutes for the Holter to complete the analysis. The Holter reports are then printed automatically if *Print Reports After Analysis* is checked. Printing time varies with the type of printer being used, the type of reports selected, and the Holter analysis results.

Note

If Print Reports After Analysis was not checked before the analysis, the Analysis Results screen will appear for review and edit. See [Section V-B, Reviewing and Editing Holter Tests](#).

The Holter scan for the patient is now completed. IQmanager® automatically launches the full disclosure editing screen. During this session, the Holter test can be discarded by clicking on the **Discard** button.

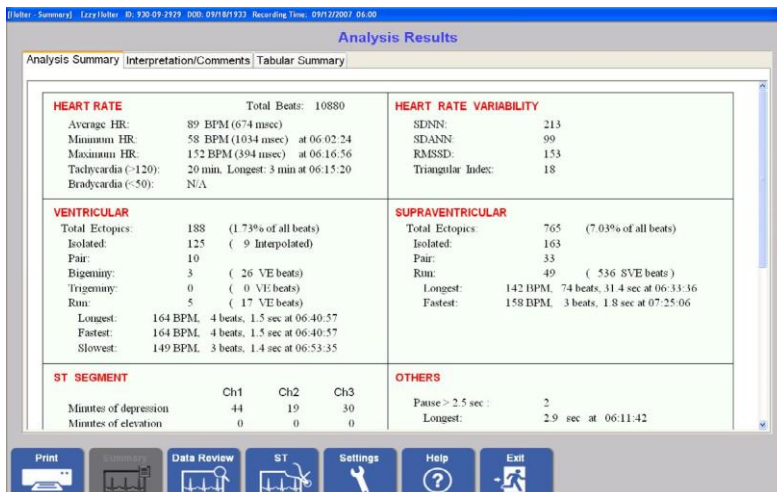


Note

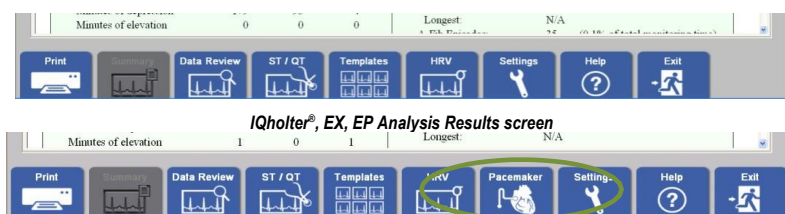
The average Full Report occupies about 35 MB of hard-disk space if acquired from the standard 24-hour IQholter® recorder; 135 MB for each 24 hour if acquired from the upgraded 24, 48, 72 hour IQholter® recorder. A Summary Report takes up about 3MB for each 24 hour. The number of Holter reports that can be stored depends on the hard-disk space available on the computer.

B. Reviewing and Editing Holter Tests

The full Holter analysis results are available for review and edit by clicking **Edit** on the *Report Review* screen. Summary results of the data analyzed during a Holter scan are displayed on the *Analysis Results* screen:



IQholter® Analysis Results screen



IQholter[®], EX, EP Analysis Results screen with pacemaker analysis

The layout of each Holter screen is designed for ease of use. Access the major functions by clicking on one of the buttons at the bottom of the screen. In the *Summary*, *Data Review*, *ST/QT*, *Templates* or *HRV* screens, more information is available with the tabs indicated at the top of the screen.

Functions of the Holter Main Buttons Bar		
Button	Tab/Sub-menu	Functions
Print	Print Current Page	Print the report(s) currently displayed.
	Preview Current Page	Preview the printout(s) currently displayed.
	Print Setup	Set or change default printer settings.
	Print All Selected Pages	Print all reports selected in the report settings.
	Preview All Selected Pages	Preview all printout(s) selected in the report settings.
	Select Report Pages & Print	Select individual reports for printing; changes made here will affect the default report settings.
Summary	Analysis Summary	- View a numerical summary of the analysis results and the doctor's interpretation. - The results are updated automatically when changes are made in the other screens.
	Interpretation/ Comments	- View and edit interpretation, narrative results and comments. - Editing is saved automatically when leaving this screen unless Cancel is clicked. - Any text entered in the <i>Interpretation</i> box is transferred to the bottom page of the <i>Analysis Summary</i> screen.
	Tabular Summary	- View and edit a tabulated summary of all events and various statistics in an hourly breakdown of the ECG recording. - Edit any numeric result that appears in black, but this is not recommended; editing the <i>Tabular Summary</i> does not update the rest of the reports. - In order to maintain consistency with other parts of the Holter reports, edit these results only in the <i>Sample Strips</i> and <i>Page Scan</i> screens.

Functions of the Holter Main Buttons Bar		
Button	Tab/Sub-menu	Functions
Data Review	Sample Strips	• View and edit sample strips for all events, including events that have been selected. • Save sample strips for printing. • Choose condensed or diagnostic-sized printouts.
	Page Scan NOTE: Not available if the report is converted to a Summary Report format	• View the original continuous ECG waveforms (Full Disclosure). • Select channel(s) to view. • Select Auto Scan or manual scan. • SetAuto Scan direction and interval. • Print all or selected hours of Full Disclosure. • Adjust view to 8/30/60/120 seconds per line. • Search a time to view. • Print current strip. • Print continuous strips of 8 to 96 seconds.
	Patient Events/Diary	View and edit a diary of patient-recorded events.
	Heart Rate	• View heart rate trends (maximum, minimum, average) over the recording. • View an 8-second strip of the maximum and minimum heart rate.
	RR Interval/Ratio	View various beat quantity vs. heart rate/RR intervals and beat quantity vs. RR interval ratio histograms; presenting the distribution of heart rate, either by the RR intervals (ms) or by RR(i)/RR(i+1) ratio, over the recorded period.
	Events Distribution	View hourly bar charts of various events
ST/QT NOTE: QT is available for IQholter®EX/EP only.	ST Trend	• View average heart rate, ST level and ST slope trends over the recording. • Select which channel to view. • Click on trend graphs to view specific ECG sample strips.
	ST Tabular	View and edit heart rate and ST statistics in an hourly breakdown.
	QT Trend	• View average heart rate, QT and QTc interval trends over the recording. • Select which channel to view. • Click on trend graphs to view specific ECG sample strips.
	QT Tabular	View and edit heart rate, QT and QTc statistics in an hourly breakdown.

Functions of the Holter Main Buttons Bar		
Button	Tab/Sub-menu	Functions
Templates NOTE: Available for IQholter®EX/EP only.	Arrhythmia Templates NOTE: Not accessible to individual templates if the report is converted to a Summary Report format	View and edit templates automatically classified by the Holter program from the recorded ECG: • VE • Asystole/Pause • Borderline • SVE • Normal • Artifact
	Normal Templates	View and edit templates for Borderline, Normal and Artifact. • This tab is hidden by default; to show, click on <i>Settings</i> and check <i>Show Normal Templates</i> in the ECG Strips tab.
HRV NOTE: Available for IQholter®EX/EP only.	HRV Analysis Summary	View a summary of HRV analysis.
	Time Analysis	View the time-domain analysis results for HRV.
	Frequency Analysis	• View the frequency domain analysis results for HRV. • Print the frequency tabular report to a text (.txt) file, which can be imported into other commercial software and used for customized charts.
Pacemaker NOTE: Available for IQholter®EP only. Not displayed if Pacemaker Analysis was not done.	Pacemaker Templates NOTE: Not accessible to individual templates if the report is converted to a Summary Report format	View and edit templates automatically generated from the pacemaker detection data recorded on the Holter recorder. • Atrial Paced • Ventricular Paced • Dual-Chamber Paced • Non-Capture • Undersensing • Oversensing, • Event 1 and 2 (user-defined events)
	Pacemaker Tabular Summary	View and edit a tabulated statistical summary of all pacemaker events in an hourly breakdown of the ECG recording. • Edit any numeric result that appears in black as a quick fix (not recommended). • In order to maintain consistency with other parts of the Holter reports, edit the pacemaker events only in the <i>Pacemaker Templates</i> screen.

Functions of the Holter Main Buttons Bar		
Button	Tab/Sub-menu	Functions
Settings NOTE: See Section II-E Configuring iQholter®/Holter Settings	ECG Strips	• Display the recording start time and date of the Holter. • Correct the time/date of the recording. • View and print RR Interval, heart rate, grid, and beat annotation in color. • Select channel(s) to display. • Select 1/2X, 1X or 2X gain for each channel • Select polarity for each channel. • Disable the right-click prompt; by default, the right-click prompt appears when the mouse is moved over any ECG strips.
	Sample Strips	• Set maximum number of sample strips per category for printing. • Sort sample ECG strips by time or severity.
	Reports	Select and set various reports to print. • If the <i>Print Reports After Analysis</i> option in the <i>Holter Analysis</i> dialog box is checked, selected reports are printed.
	Miscellaneous	• Select to print ST and HRV summary results on <i>Cover Page Report</i>. • Copy raw data to local drive in a low bandwidth network environment for quick editing. • Select to use Customer Logo.
	QT Analysis	Select a QTc formula. Default is Bazett. Other options are Hodges, Linear Regression and Fridericia. Select the channel for generating QT Tabular Report.
	Heart Rate Variability	Select View Segment Size and Taper Window method for frequency domain HRV analysis.
	Pacemaker	Select the pacing mode and analysis parameters. These entries are optional and should only apply to individual patient with pacemaker. Enable <i>Restore pacemaker spikes on ECG</i> especially when the pacer spikes are very small.
	Criteria	NOTE: Changing the Criteria settings may affect any editing previously done. The criteria settings can be changed in this tab after the computerized analysis is completed. The results will be updated immediately without manually re-analyzing the entire Holter data. See figure following this table.
Help	Multiple Topics	View and print help on various screen topics. This is a useful tool that explains the features of the screen being viewed.
Exit		Exit the Holter program and return to IQmanager®.

Holter Settings

ECG Strips | Sample Strips | Reports | Miscellaneous

QT Analysis | Heart Rate Variability | **Criteria**

Warning:

1. If you change SVE criteria and click OK, your manual editing result of SVE may be lost.
2. If you change Pause criteria and click OK, your manual editing result of pauses may be lost.

Supraventricular Prematurity Percentage %

Tachycardia Limit bpm

Bradycardia Limit bpm

Asystole/Pause Lower Limit second

Asystole/Pause Upper Limit second

Help

OK Cancel Apply



WARNING

Always change the Criteria settings, if needed, before starting any manual editing. Any editing done before changing the Criteria settings may be lost.

The IQholter® software is designed with a lot of flexibility to meet many clinicians' needs. Different clinicians may operate the software in different order depending on available software options and the patient's indication. The following sections describe the software in a workflow order for editing a new Holter test, however, a clinician may use the software in a different order. For example, when reviewing a finalized report, it can be read from left to right beginning with the **Summary** button, then **Data Review** button, etc.

Correcting the Time and Date of the Holter Recording

The IQholter® recorder automatically records the recording start time and date. After the recorded data is acquired, the IQholter® software will have the correct time and date information. If the recording time and date of the Holter test needs to be changed, first open the desired test and click **Settings**.

Holter Settings

ECG Strips | Sample Strips | Reports | Miscellaneous | Criteria

Recording Time & Date: 07:50 11/10/2008

ECG Strips

☒ RR Interval ☒ Grid ☐ Heart Rate ☐ Beat Annotation ☐ Print Color

Channel(s) to Display

☒ Channel 1 ☒ Channel 2 ☒ Channel 3

Gain

Channel 1: ☐ 1/2 X ☒ 1 X ☐ 2 X
 Channel 2: ☐ 1/2 X ☒ 1 X ☐ 2 X
 Channel 3: ☐ 1/2 X ☒ 1 X ☐ 2 X

Polarity

Channel 1: ☒ Normal ☐ Invert
 Channel 2: ☒ Normal ☐ Invert
 Channel 3: ☒ Normal ☐ Invert

☒ Never show me the Right-Click prompt

Help

OK Cancel Apply

Correct the recording time and date as necessary. Changing the recording time and date does not reanalyze the Holter results. All edited results are retained and adjusted appropriately according to the new recording time. Any entry in the *Interpretation* field will remain as before, except in the *Narrative Results/Comments* box.

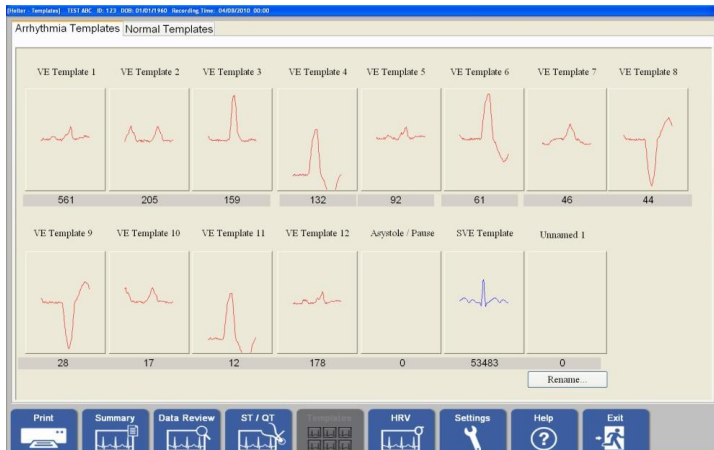
Note

Any changes made in the Narrative Results/Comments box will be discarded, as the Holter software will regenerate the Narrative Results.

Working with Templates

[Available in IQholter®, EX and EP]

All arrhythmias and events identified by the Holter software are grouped into 19 templates. Editing and reclassifying arrhythmias in these templates provides the quickest and easiest way to adjust the Holter analysis results; all Holter analysis results are updated automatically as the changes are made. Click **Templates** to view all templates.



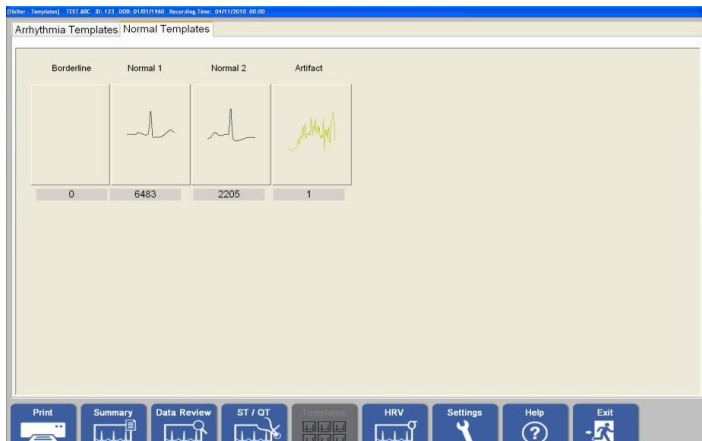
15 templates appear on the *Arrhythmia Templates* tab:

- Ventricular Ectopics (VE) (12 templates)
- Asystole/Pause (1 template)
- Supraventricular Ectopics (SVE) (1 template)
- Unnamed 1 (1 template)

Four other templates are not shown by default:

- Borderline (1 template)
- Normals (2 templates)
- Artifact (1 template)

To show these templates, click **Settings** and check *Show Normal Templates on the ECG* tab. The templates will appear on a separate tab next to the *Arrhythmia Templates* tab.

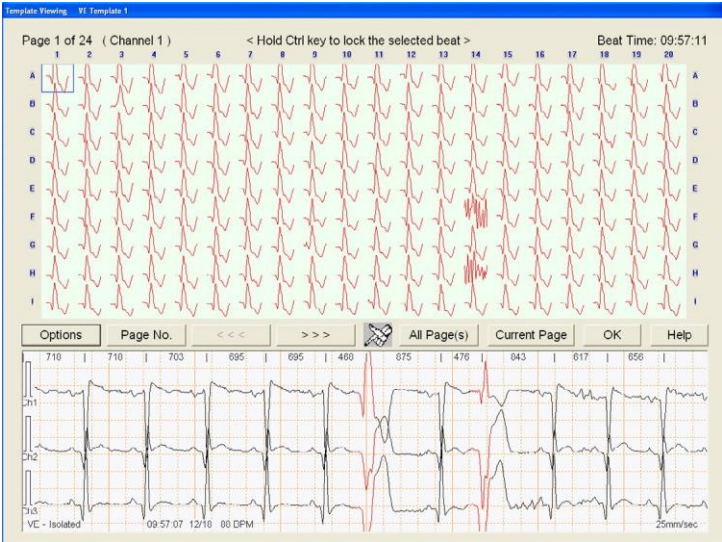


Template *Unnamed 1* can be classified to any event by clicking **Rename**; any beat can be reclassified into this user-defined category.

To view or edit any of these templates, click the desired template button. An example of VE Template 1 is shown below.

Note

When a test is converted to a Summary Report, no template editing can be performed. The Templates Viewing screens are not available.



The *Template Viewing* screen displays the QRS beats that are identified and grouped by the software for a particular arrhythmia. The top-left corner indicates the page displayed, the number of pages in the current template, and the channel displayed. The QRS beats are arranged in rows and columns in the QRS complexes review area, where they are displayed in different colors according to their categories:

Normal beats	Black
Ventricular beats	Red
Supraventricular beats	Blue
Pause beats	Pink
Artifact beats	Dark Yellow
Unnamed 1	Teal

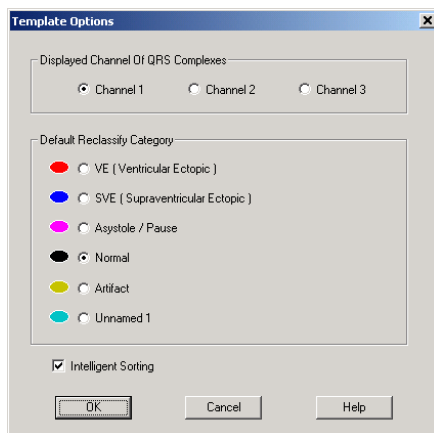
A blue box follows the mouse from beat to beat. The time of the 'boxed' beat is indicated in the upper-right corner of the screen. The viewer underneath the review window displays the corresponding standard

8-second diagnostic strip with the selected QRS beat in the middle, directly under the pointing-hand icon. The time displayed at the bottom of the strip indicates the beginning of this 8-second diagnostic strip.

Click on a beat in the QRS complexes review area to reclassify it according to the *Default Reclassification Category* settings.

Template Options

Click **Options** to view *Template Options*. The *Template Options* dialog box sets which analyzed channel is displayed in the *Template Viewing* screen. By default, the channel displayed in the QRS complexes review area is the primary channel selected before the analysis. Sometimes a different channel may have clearer morphology, higher amplitude, or a cleaner ECG signal that can make editing easier.

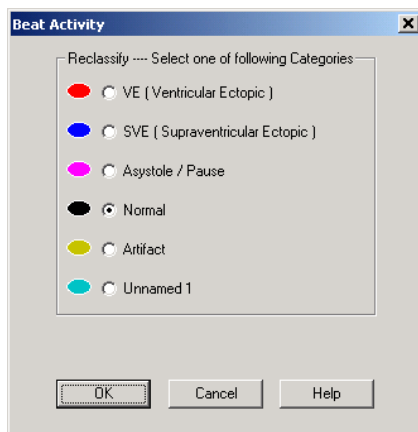


The *Default Reclassify Category* is the category assigned to the left-mouse click; click on any beat to reclassify it into this category. *Intelligent Sorting* sorts all QRS beats in the template according to similarities in their shapes and morphologies. By default it is enabled. If *Intelligent Sorting* is disabled, the beats are arranged chronologically.

Other Templates Viewing Operations

Use **Page No.** to jump to the desired page if the template has more than one page. Click the <<< or >>> buttons to move back or forward one page in the template.

All Page(s) and **Current Page** open the *Beat Activity* dialog box so that either all the pages or just the current page can be reclassified to a selected category.



Click **OK** to save changes and exit the current template view.

Click **Help** for further information on this topic.

Reclassifying Beats

In addition to the methods listed above, there are several methods for reclassifying or changing the category of the heartbeats in a template. These editing functions are the same in all the templates. When finished editing in all templates, move to other functions through the *Holter Main Buttons Bar*.

Reclassifying Mouse Operations on the <i>Template Viewing</i> Screen	
Reclassification	Mouse Action
Reclassify a single beat, column, or row to the category defined in the <i>Default Reclassify Category</i> .	Click a beat, column number or row letter in the QRS complexes review display.
Reclassify a single beat, column, or row to any category of choice.	Right-click a single beat, column number or row letter then pick a category from the <i>Beat Activity</i> dialog box.
Reclassify a group of beats to any category of choice.	Select a group of beats by dragging the mouse across these beats while holding the left mouse button; the <i>Beat Activity</i> dialog box appears when the mouse button is lifted.

Use the keyboard to navigate and reclassify the 'boxed' beat on the *Template Viewing* screen using the following hot keys:

Reclassifying Keyboard Operations on the <i>Template Viewing</i> Screen	
Key	Function
↑	Move to the beat above the current beat
←	Move to the beat to the left of the current beat

Reclassifying Keyboard Operations on the <i>Template Viewing</i> Screen	
Key	Function
→	Move to the beat to the right of the current beat
↓	Move to the beat below the current beat
Home	To the beginning of the current page
End	To the end of the current page
Ctrl + G	Go to a specific available QRS page
X	Mark the current beat as <i>Artifact</i>
N	Mark the current beat as <i>Normal</i>
P	Mark the current beat as <i>Pause</i>
S	Mark the current beat as <i>Supraventricular</i>
U	Mark the current beat as <i>Unnamed</i>
V	Mark the current beat as <i>Ventricular</i>

Note

The mouse pointer must remain inside the upper-window of the Template Viewing screen when using hot keys.

To lock the blue selection box onto any beat in the QRS complexes review display, freeing the mouse for other operations, hold the **Control** (Ctrl) key and move the mouse out of the display area. This allows the user to perform tasks in the lower ECG strip view without losing the selected beat.

Working with Pacemaker Templates

[Available in IQholter® EP]

Note

This is only available if the Pacemaker Analysis option is enabled in IQholter® EP.

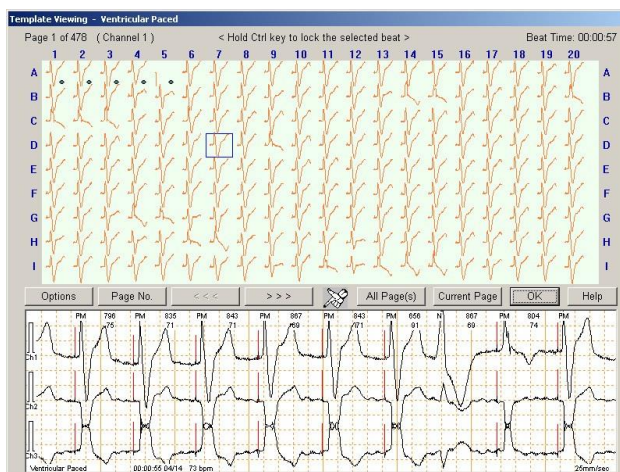
The *Pacemaker* feature contains *Pacemaker Templates* and *Pacemaker Tabular Summary* of all pacemaker categories.

Click **Pacemaker** to view the *Pacemaker Templates* screen as shown below. This button is available only if the *Pacemaker Analysis* was enabled before clicking **Acquire & Analyze**.



The *Pacemaker Templates* screen lists the following categories: *Atrial Paced*, *Ventricular Paced*, *Dual-chamber Paced*, *Non-Capture*, *Undersensing*, *Oversensing* and two custom event categories, *Event 1* and *Event 2*.

To view or edit any of these templates, click the desired template button. An example of *Ventricular Paced* detail screen is shown below.

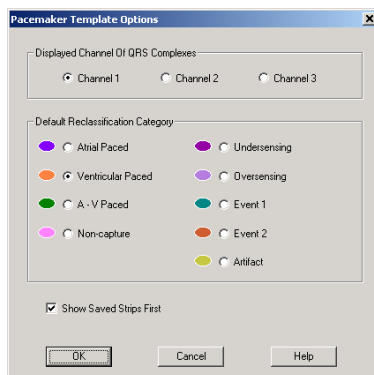


The *Pacemaker Templates Viewing* screen provides the same aspect and very similar operations as the *Template Viewing* screen, see [Section V-B, Reviewing and Editing Holter Tests/Working with Templates](#) for more information.

Template Options

Click **Options** to open the *Pacemaker Template Options* dialog box. This is where which channel to be displayed in the *Templates Viewing* screen was selected. The *Default Reclassification Category* is the category into which the software will default any event that is classified without specifying a category name.

The *Show Saved Strips First* option enables or disables the display sorting for the current category events. If selected, the software will display ECG strips that are saved for printing first so that users can quickly review these sample strips.



Reclassifying Events

To reclassify pacing events, the software provides the same methods as in arrhythmia templates. See [Section V-B, Reviewing and Editing Holter Tests/Working with Templates](#). The difference here is that the classification names are pacing event categories instead of arrhythmia categories. The *Pacing Event Categories* screen shown below lists all event names for pacing events.



The hot keys for navigating and reclassifying beats are as follows:

Reclassifying Keyboard Operations on the <i>Template Viewing</i> Screen	
Key	Function
↑	Move to the beat above the current beat
←	Move to the beat to the left of the current beat
→	Move to the beat to the right of the current beat
↓	Move to the beat below the current beat
Home	To the beginning of the current page
End	To the end of the current page
Ctrl + G	Go to a specific available QRS page
A	Mark the current beat as <i>Atrial Paced</i>
V	Mark the current beat as <i>Ventricular Paced</i>
D	Mark the current beat as <i>A-V Paced</i>
N	Mark the current beat as <i>Non-Capture</i>
U	Mark the current beat as <i>Undersensing</i>
O	Mark the current beat as <i>Oversensing</i>
1	Mark the current beat as <i>Event 1</i>
2	Mark the current beat as <i>Event 2</i>
X	Mark the current beat as <i>Artifact</i>

Note

The mouse pointer must remain inside the upper-window of the Template Viewing screen when using hot keys.

Viewing Pacemaker Tabular Statistics

Note

This is only available if the Holter program has the Pacemaker Analysis option.

Click **Pacemaker**, and then click **Pacemaker Tabular Summary** to view the hourly-tabulated statistics of pacing events.

The Tabular Summary displays the statistical results for each hour of pacing events. For multiple day formats, a new 'shade' will denote the transition from chronological days.

Note

Only the numerical values displayed in black in the Tabular Summary can be edited. However, this editing is not generally recommended, as the Holter program does not automatically update all other sections of the Holter report to reflect these changes.

Editor: Pacemaker 1011AOC R-121 908 01/01/1980 Recording Time: 01/01/2010 13:20

Pacemaker Templates: Pacemaker Tabular Summary

Save Cancel

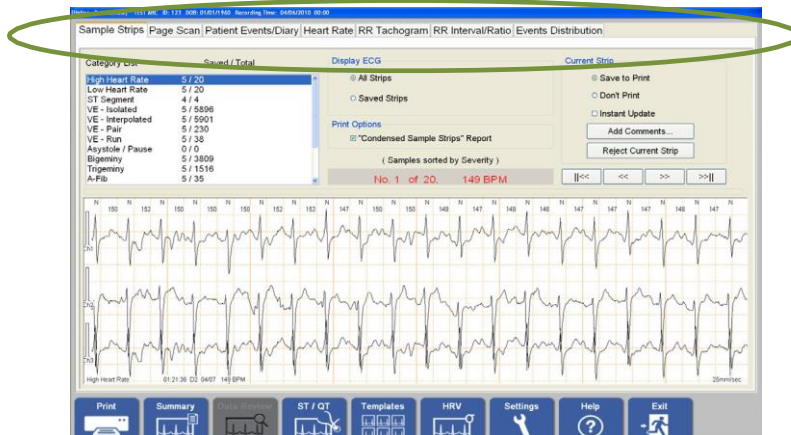
Time	Aug	Min	Max	QRS	Paced	%	Rate	Abtcl	Vent	A-V	Nonspk	Undersen	Overennl	Event 1	Event 2
D1 17:23	75	74	76	8002	8000	99.9	75	0	0	8000	0	0	0	0	0
18:00	75	75	75	4501	4501	100.0	75	0	0	4501	0	0	0	0	0
19:00	74	73	76	4502	4502	100.0	75	0	0	4502	0	0	0	0	0
20:00	74	74	76	4501	4502	100.0	75	0	0	4502	0	0	0	0	0
21:00	74	74	76	4502	4501	100.0	75	0	0	4501	0	0	0	0	0
22:00	74	74	75	4501	4502	100.0	75	0	0	4502	0	0	0	0	0
23:00	74	74	75	4502	4501	100.0	75	0	0	4501	0	0	0	0	0
00:00	74	74	76	4502	4500	100.0	75	0	0	4500	0	0	0	0	0
01:00	74	74	76	4501	4501	100.0	75	0	0	4501	0	0	0	0	0
02:00	75	75	75	4502	4502	100.0	75	0	0	4502	0	0	0	0	0
03:00	74	74	75	4501	4502	100.0	75	0	0	4502	0	0	0	0	0
04:00	74	74	75	4502	4501	100.0	75	0	0	4501	0	0	0	0	0
05:00	74	73	76	4501	4502	100.0	75	0	0	4502	0	0	0	0	0
06:00	74	74	76	4502	4501	100.0	75	0	0	4501	0	0	0	0	0
07:00	74	74	76	4502	4502	100.0	75	0	0	4502	0	0	0	0	0
08:00	75	74	76	4501	4501	100.0	75	0	0	4501	0	0	0	0	0
09:00	75	75	75	4502	4502	100.0	75	0	0	4502	0	0	0	0	0
10:00	74	74	76	4501	4500	100.0	75	0	0	4500	0	0	0	0	0
11:00	75	74	76	4502	4501	100.0	75	0	0	4501	0	0	0	0	0
12:00	75	75	76	4502	4502	100.0	75	0	0	4502	0	0	0	0	0
13:00	74	74	76	4501	4501	100.0	75	0	0	4501	0	0	0	0	0
14:00	74	74	75	4502	4502	100.0	75	0	0	4502	0	0	0	0	0
15:00	74	74	75	4501	4501	100.0	75	0	0	4501	0	0	0	0	0
16:00	74	74	75	4502	4502	100.0	75	0	0	4502	0	0	0	0	0
D2 17:00	74	74	75	4501	4502	100.0	75	0	0	4502	0	0	0	0	0
18:00	75	75	75	4502	4501	100.0	75	0	0	4501	0	0	0	0	0

Print Summary Data Review ST / QT Templates HRV Settings Help Exit

Viewing and Editing Sample Strips

[Available in IQholter®, EX and EP]

Select the *Sample Strips* tab of the *Data Review* screen. Select to view any category in the *Category List*. The numbers in the right column indicate the number of saved strips and total number of beats or runs in each category, except for *High Heart Rate*, *Low Heart Rate*, and *ST Segment* categories, which show a maximum of 20 strips.



- Under *Display ECG*, select whether to display all strips or only the saved strips in the selected category, displayed at the bottom of the screen. The program automatically saves 3 strips from each category to print.

Note

When a test is converted to a Summary Report, only the strips saved to print are retained. All strips not saved for printing are discarded. This does not alter the analysis result.

- If “*Condensed Sample Strips*” Report is checked, up to 30 condensed strips can be printed per page. If the check box is cleared, all sample strips are printed in diagnostic size (25mm/sec) with a maximum of three strips per page.
- In the *Current Strip* control group, *Save to Print* and *Don't Print* indicators show whether the displayed strip is saved; select one of these options to save or save to print. If *Instant Update* is checked, any single change made to the current displayed strip (e.g., *Save to Print/Don't Print*, **Add Comments** or reclassification) will be updated instantly and the next strip in the category will automatically be displayed. If making multiple changes to the current strip, clear the *Instant Update* box.
- **Add Comments** enters a selected or custom comment to the bottom center of the ECG strip.
- Use the arrow buttons on the screen to move the view from strip to strip within the selected category.
- **Reject Current Strip** is available for the *High Heart Rate*, *Low Heart Rate* and *ST Segment* categories; use to quickly reject the current strip if it is incorrectly classified as high or low heart rate, probably due to excessive movement artifacts or low ECG amplitude.

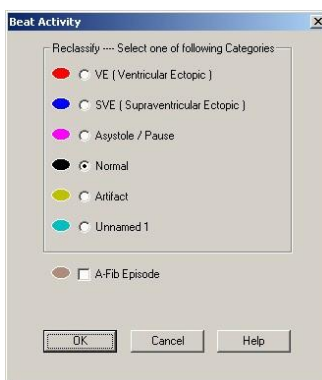
Specific arrhythmia events are displayed in different colors. The sample strips can be printed in color if using a color printer and if the *Print Color* option is selected on the *ECG Strips* tab of the *Holter Settings* dialog box. The diagnostic size ECG strips will be printed on red grid. The category code can be displayed above each beat by checking the *Beat Annotation* box.

Beat Category	Color Code	Beat Annotation
Normal beats	Black	N
Atrial fibrillation beats	Brown	N
Supraventricular beats	Blue	S
Ventricular beats	Red	V
Pause beats	Pink	P
Artifacts	Dark yellow	?

Note

Atrial fibrillation beat category and atrial fibrillation analysis are available in IQholter® EX and EP.

Reclassify any beat in the 8-second strip by double-clicking the QRS complex of the beat to be changed. Reclassify the beat to VE, SVE, Pause, Normal, Artifact, Unnamed 1 (user-define) or Atrial Fibrillation beat via the *Beat Activity* dialog box.



The *A-Fib Episode* box is a tri-state check box. When it is not checked, the selected beat is not part of an A-Fib episode. To add the selected beat to an A-Fib episode, check the A-Fib Episode box once and click **OK**. The selected beat will be reclassified as part of the A-Fib episode.

Note

VE beat will need to be reclassified to Normal beat before it can be reclassified as an A-Fib beat.

If the selected beat is already part of an A-Fib episode, this check box will be grayed and checked. Exclude the current beat from the A-Fib episode by clearing the box. Reclassify the current beat to any other categories at the same time by selecting the appropriate box.

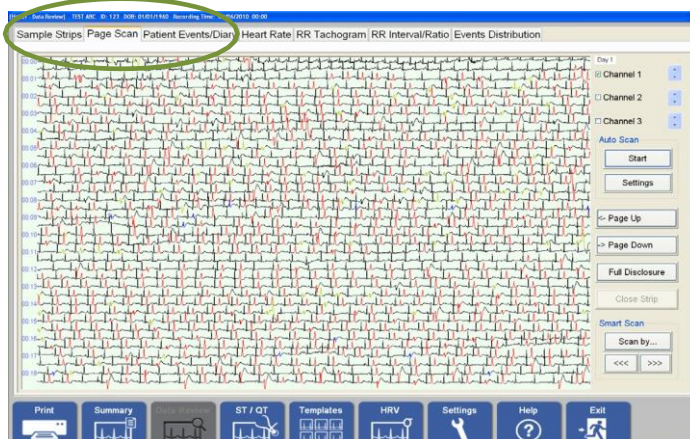
If using group editing to reclassify a series of beats to an A-Fib episode, checking the A-Fib episode box will classify only beats with the normal beat morphology, i.e. Normal, Pause and SVE, into A-Fib beats.

If using group editing to remove a section or an episode of A-Fib event, un-checking the A-Fib episode box and clicking OK will restore selected beats into Normal or SVE beats. VE beats will remain unchanged.

For group editing, see [Section V-B, Reviewing and Editing Holter Tests/Using the Right-Click Menu Options](#) and read the Begin Group and End Group descriptions.

Viewing Full Disclosure in Page Scan

The *Page Scan* tab enables the user to review the full disclosure of the Holter recording. By default, the screen shows the primary channel with 30 seconds per line. To adjust the density from the menu that appears, right-click the strip. See [Section V-B, Reviewing and Editing Holter Tests/Using the Right-Click Menu Options](#).



As the mouse is moved, a redline cursor shows the current position in the *Page Scan* screen. Click on the screen to display a diagnostic ECG strip either at the top or bottom of the display, depending on where the screen is clicked. A green rectangle in the page view indicates which 8-second period is being displayed.

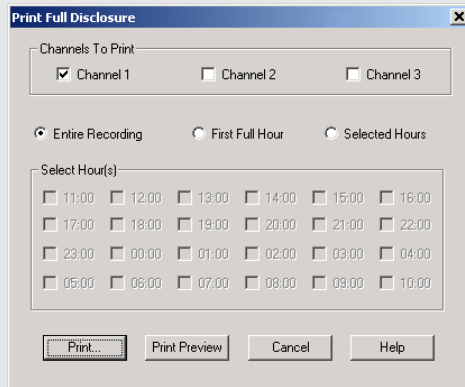


Functions Available on the Page Scan Screen	
☒ Channel 1 ☐ Channel 2 ☐ Channel 3	Check a channel box to show the ECG for that channel in the page view. By default, only the primary channel ECG is shown. Use the arrows to adjust the amplitude of the ECG by increments of 15%, which affects printouts of the full disclosure only.
	Display the previous page; the ECG strip view will close.
	Display the next page; the ECG strip view will close.
	Click Start to browse the ECG. By default, the full-disclosure view is refreshed every three seconds. To stop Auto Scan, click the button again. Auto Scan stops whenever the <i>Page Scan</i> screen is clicked and a diagnostic strip appears; resume Auto Scan by clicking Start again. Click Settings to adjust the direction of the scan and the Auto Scan Interval (in seconds).

Functions Available on the Page Scan Screen

Full Disclosure

Print a full-disclosure report; the *Print Full Disclosure* dialog box will appear. By default, only the primary channel is selected and the entire recording is set to print. Optionally, select *Selected Hours* and check the hours to print.



Print Full Disclosure

Channels To Print

☒ Channel 1 ☐ Channel 2 ☐ Channel 3

☒ Entire Recording ☐ First Full Hour ☐ Selected Hours

Select Hour(s)

☐ 11:00 ☐ 12:00 ☐ 13:00 ☐ 14:00 ☐ 15:00 ☐ 16:00
☐ 17:00 ☐ 18:00 ☐ 19:00 ☐ 20:00 ☐ 21:00 ☐ 22:00
☐ 23:00 ☐ 00:00 ☐ 01:00 ☐ 02:00 ☐ 03:00 ☐ 04:00
☐ 05:00 ☐ 06:00 ☐ 07:00 ☐ 08:00 ☐ 09:00 ☐ 10:00

Close Strip

Close the ECG strip view.

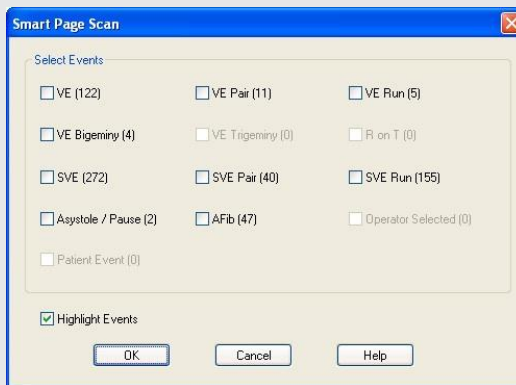
Smart Scan

Scan by...

<<< >>>

NOTE: Available for IQholter® EX and EP only.

Use *Smart Scan* to select one or more arrhythmia events to automatically browse in the *Page Scan* view. Click **Scan by** to display the *Smart Page Scan* dialog box:



Smart Page Scan

Select Events

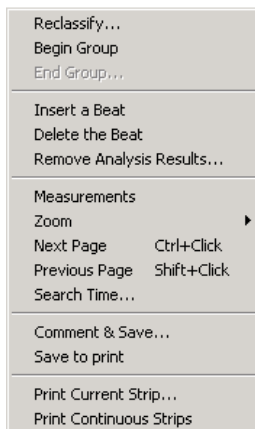
☐ VE (122) ☐ VE Pair (11) ☐ VE Run (5)
☐ VE Bigeminy (4) ☐ VE Trigeminy (0) ☐ R on T (0)
☐ SVE (272) ☐ SVE Pair (40) ☐ SVE Run (155)
☐ Asystole / Pause (2) ☐ AFib (47) ☐ Operator Selected (0)
☐ Patient Event (0)

☒ Highlight Events

The number of strips for each event category is shown in parentheses. Events that contain no strips are not available. If *Highlight Events* is checked, selected events are highlighted in the page scan view.

Using the Right-Click Menu Options

Right-click a waveform in the *Page Scan* view or *ECG Strip* view to access additional features. The following menu appears:



Reclassify	Reclassify the beat to which the cursor is pointing. This option is available only when the cursor is pointing to a beat in the ECG strip view.
Begin Group	Specify the beginning of a group. This is used for reclassifying a group of continuous beats.
End Group	Specify the ending of a group. This is used for reclassifying a group of continuous beats. The <i>Beat Activity</i> dialog box appears automatically when the <i>End Group</i> menu is selected.
Remove Analysis Results	Quickly remove the analysis results of a specific period that has excessive artifacts. For example, if the patient removed the hookup 20 minutes before the end of the recording and it is full of artifacts, right-click on the last of the good ECG beats, select <i>Remove Analysis Results</i> then <i>To the end of the recording</i> . The analysis result and the beat information of the selected period will be deleted, but the full disclosure will not be changed.
Measurements	Use the mouse to measure the current ECG strip to get the interval between two measurement lines and the amplitudes for all available channels. Measurements are given numerically at the bottom of the screen. To move both measurement lines together with a fixed interval, hold down the Ctrl (Control) key then click and drag one of the lines. Click <i>Close</i> to exit <i>Measurements</i> .
Insert a Beat NOTE: Available for IQholter® EX and EP only.	Insert at the cursor position a QRS beat that the Holter program might have missed. By default, it is a normal beat; reclassify it into another category if needed.
Delete the beat NOTE: Available for IQholter® EX and EP only.	Delete the QRS beat at the cursor position. The program automatically adjusts the RR interval to remove the deleted beat.

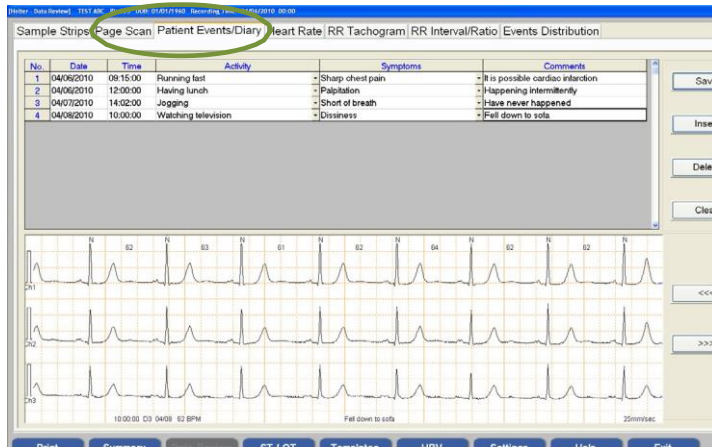
Zoom	Specify the number of seconds of ECG strip to display in each line of the ECG strip view. • 8 seconds per line (default for diagnostic ECG strips) • 30 seconds per line (default for page scan review) • 60 seconds per line • 120 seconds per line
Next Page	Display the next page of the ECG strips. The page size is determined by the length of the ECG strips in the current view. Page Down performs the same function.
Previous Page	Display the previous page of the ECG strips. The page size is determined by the length of the ECG strips in the current view. Page Up performs the same function.
Search Time	Open the <i>Search Time</i> dialog box to search and view the ECG by time.
Comment & Save	Set the label for the current ECG strip and save the ECG strip to the print queue for batch printing later.
Save to print	Save the current ECG strip to the print queue for batch printing.
Print Current Strip	Print the current ECG strip or current report.
Print Continuous Strips	Print continuous ECG strips. Diagnostic-size strips from 8 seconds (1 ECG strip) to 96 seconds (12 ECG strips) long. Print up to 3 strips per page.

Viewing and Editing the Patient Diary

- To enter or update patient diary entries, click **Data Review** then select the *Patient Events/Diary* tab.
- Click **Insert** to insert a blank row for each new diary entry.
- Click **Delete** to erase the selected row.
- When entering a Date (if applicable) and a time in the *Time* column, the corresponding ECG strip is displayed. After the diary entries are entered, click **Save** before continuing.

Note

Time entered must be in 24-hour format. Enter 0945 for 09:45:00 (9:45:00 a.m.) or 132522 for 13:25:22 (1:25:22 p.m.).



Viewing the Heart Rate Trend



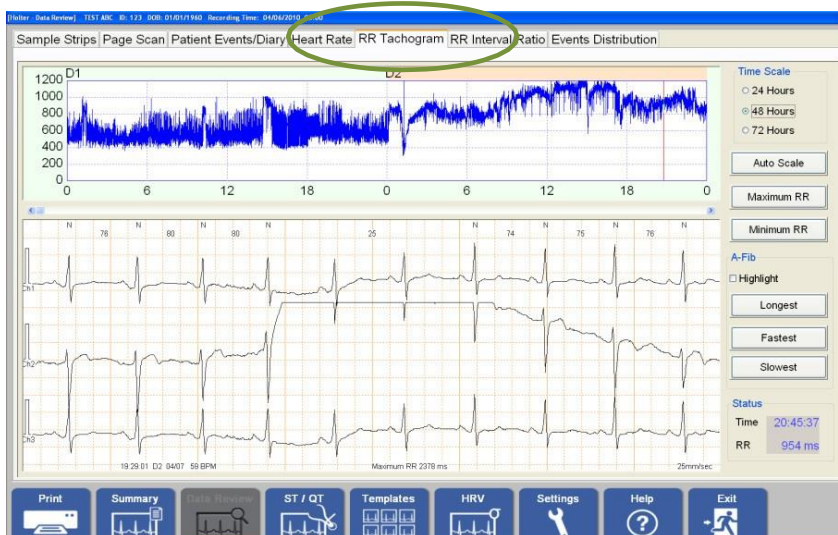
The upper part of the screen displays the heart-rate trend curves while the lower part displays the ECG Strip view. A redline cursor appears as the mouse over the heart-rate trend curves, indicating the current minute. The time indicated by the cursor on the trend curves is displayed in the *Status* box at the lower-right corner, with the maximum, minimum and average heart rates of that minute.

The Heart Rate Trend will also automatically indicate if a 24, 48, or 72 hour format. All days will be displayed.

When clicking on the heart-rate trend curves, the ECG strip beginning from the first second of the current minute appears in the ECG Strip view. Zoom in on the heart-rate trend curves by right-click and drag across the specific section of the graph. To return to full view of the trend graph, click **Auto Scale**.

Viewing the RR Tachogram

[Available in IQholter® EX/EP]



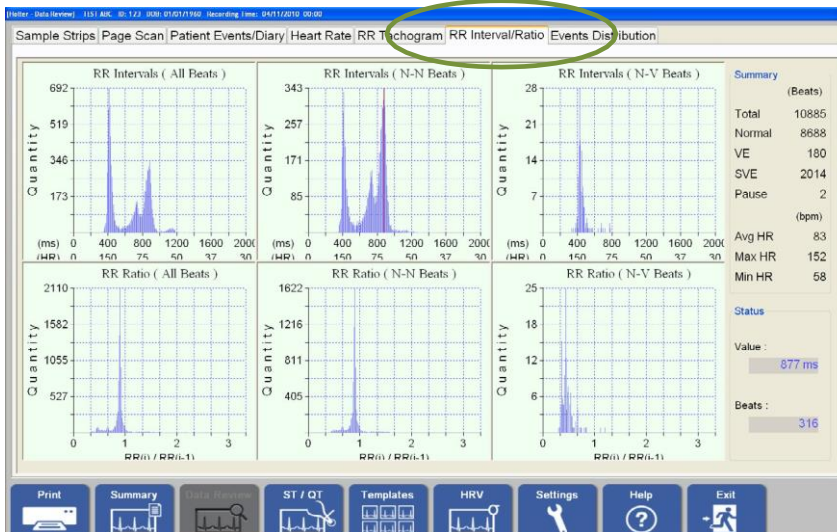
The upper part of the screen displays the RR trend curve while the lower part displays the ECG Strip view. A redline cursor appears as the mouse is moved over the trend curve, indicating the current minute. The time indicated by the cursor on the trend curves is displayed in the *Status* box at the lower-right corner.

The *Maximum RR* and *Minimum RR* strips are based on instantaneous RR intervals between two successive normal beats. By this definition, the *Maximum RR* strip has the longest instantaneous RR interval that is not classified as *Pause*.

The brown highlights on the RR trend curve indicate occurrence of A-Fib episodes if the *Highlight* box is enabled. **Longest**, **Fastest** and **Slowest** show the middle 8-seconds of the corresponding A-Fib episode.

Zoom in on the RR trend graph by right-click and dragging across the specific section of the graph. To return to full view of the trend graph, click **Auto Scale**.

Viewing the RR Interval and RR Ratio Graphs



The *RR Interval/Ratio* view displays six histograms showing the relationships between the number of heartbeats and the RR intervals or the RR interval ratio.

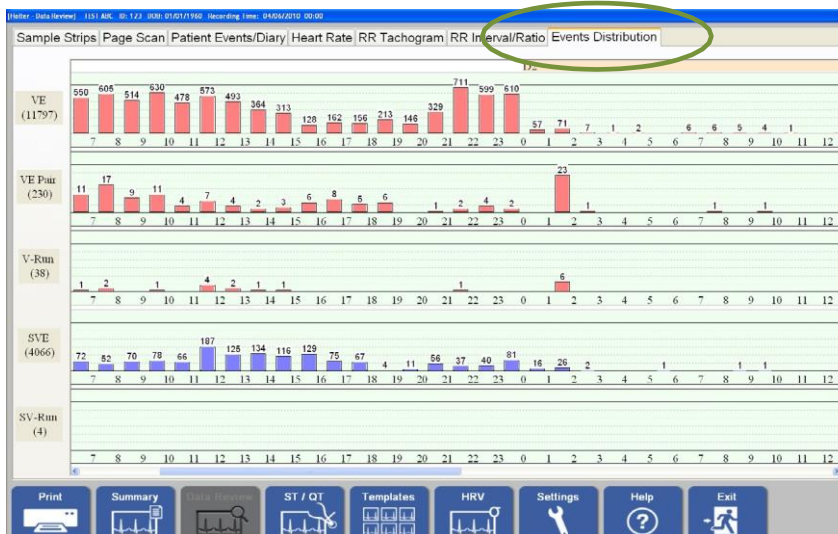
The three upper histograms represent the distribution of the number of heartbeats versus the RR intervals (in milliseconds) and heart rate (in bpm).

The three lower histograms represent the distribution of the number of heartbeats and the RR ratio, which is the ratio of two consecutive RR intervals.

The position of the redline cursor on the histograms affects the status information shown on the lower-right side of the screen.

Viewing the Events Distribution

The *Events Distribution* view displays bar charts showing the hourly distribution of the following arrhythmia events: VE, VE Pair, VE Run, SVE, and SVE Run. VE Runs include V Tach episodes.



Viewing ST and QT Results

[QT analysis is available in IQholter® EX and EP]

To view ST or QT trends or tabular results, click **ST/QT** then select the appropriate tab.

In the *ST Trend* view, the upper part of the screen displays the average heart rate trend curve, ST segment level curves and ST segment slope curves, while the lower part shows the ECG Strip view.

The Status box on the lower-right side of the screen displays information that pertains to the position of the redline cursor on the trend curves. Click on the trend curves and the full-size strip beginning at the first second of the selected minute will be displayed.

To zoom in on the *ST Trend* view, click and drag the right mouse button inside the chart area. Click **24 Hour Scale**, **48 Hours**, or **72 Hours** or **Auto Scale** to return to the full-scale curve.

Select one of the available channels from the *Channel* pull-down menu to view its corresponding ST level curve and the ST slope curve.

The default channel is the primary channel, specified when the Holter data is analyzed.



To view the ST tabular results, click on the *ST Tabular* tab. The table displays the heart rate and ST information for each hour of the Holter monitoring.

The *QT Trend* view enables the user to review the average heart rate trend curve, QT interval curves, and QT correction (QTc) curves.



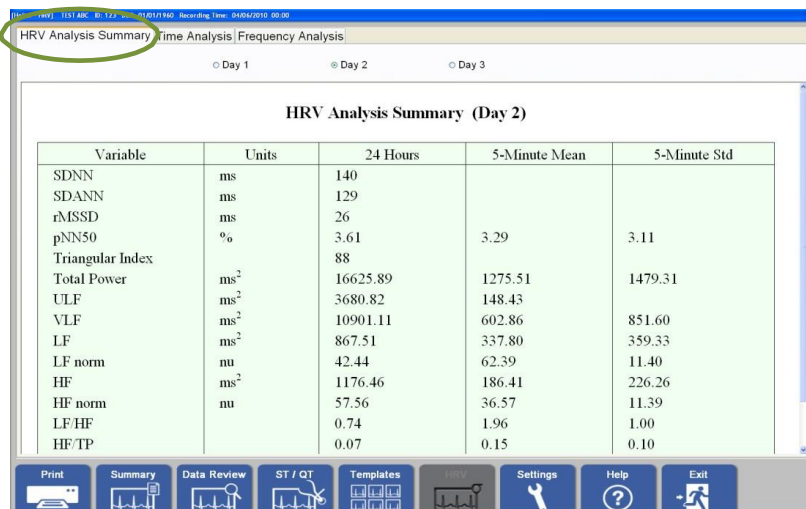
As in the *ST Trend* view, zoom in on the QT Trend graphs by clicking and dragging the right mouse button inside the chart area. Click **24 Hour Scale**, **48 Hours**, or **72 Hours** or **Auto Scale** to return to the full-scale curve.

Apply one of the available formulas for the QTc analysis; Bazett's formula is selected by default. Click **Settings** then select the *QT Analysis* tab. The QTc values are updated automatically once **OK** is selected in the *Holter Settings* dialog box.

Viewing Heart Rate Variability (HRV) Results

[Available in IQholter® EX and EP]

To view heart rate variability (HRV) analysis results, click **HRV**. The *HRV Analysis Summary* screen appears:

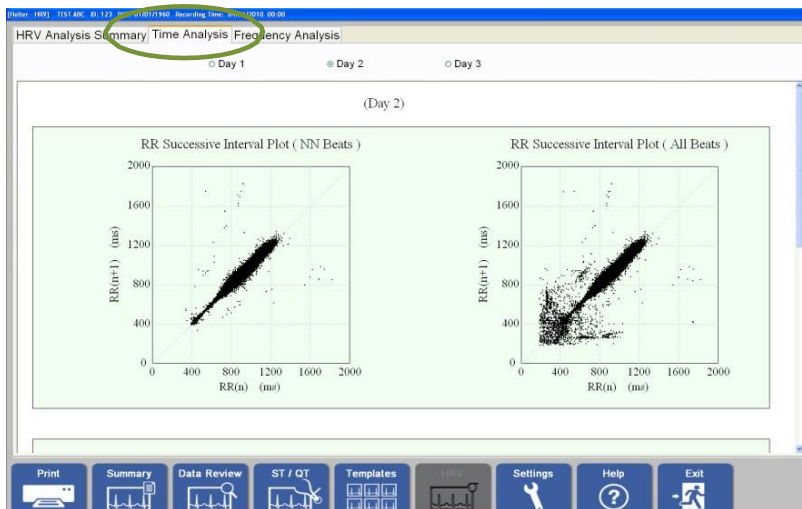


The *HRV Analysis Summary* displays 14 statistics, covering time and frequency domain: SDNN, SDANN, rMSSD, pNN50, Triangular Index, Total Power, ULF, VLF, LF, LF norm, HF, HF norm, LF/HF and HF/TP.

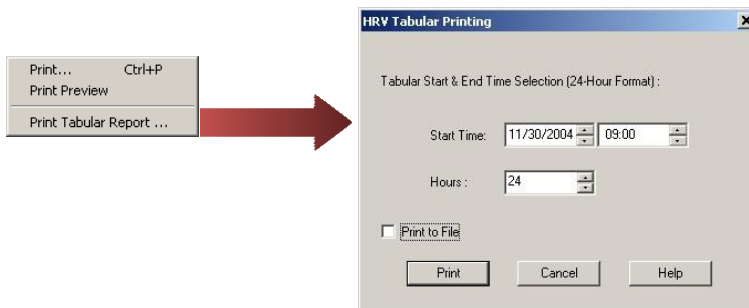
Statistics Shown in Heart Rate Variability Analysis	
SDNN	Standard deviation of all normal RR intervals in the entire ECG recording.
SDANN	Standard deviation of the average normal RR intervals for all 5-minute segments of entire ECG recording.
rMSSD	Root-mean-square successive difference (the square root of the squared differences between adjacent normal RR intervals).
pNN50	The number of times in which the change in consecutive N-N intervals exceeds 50 milliseconds, measured as a percentage of total NN pairs for the unit time.
Triangular Index	Total number of all NN intervals divided by the height of the histogram of all NN intervals measured on a discrete scale with bins of 7.8125 ms.
Total Power	The variance of NN intervals over the selected segment (<= 0.4 Hz).
ULF	Power in the ULF range (<= 0.003 Hz) not defined for 5-minute segments
VLF	Power in the VLF range (5-minute: <= 0.04Hz, 24-hour: 0.003 - 0.04 Hz).
LF	Power in the LF range (0.04 - 0.15 Hz).
LF norm	LF power in normalized units $100 \cdot \text{LF} / (\text{total power} - \text{VLF})$.
HF	Power in the HF range (0.15 - 0.4 Hz).

Statistics Shown in Heart Rate Variability Analysis	
HF norm	HF power in normalized units $100 \times \text{HF} / (\text{total power} - \text{VLF})$.
LF/HF	Ratio LF/HF.
HF/TP	Ratio HF/Total Power

View the HRV results based on time domain analysis by selecting the *Time Analysis* tab:



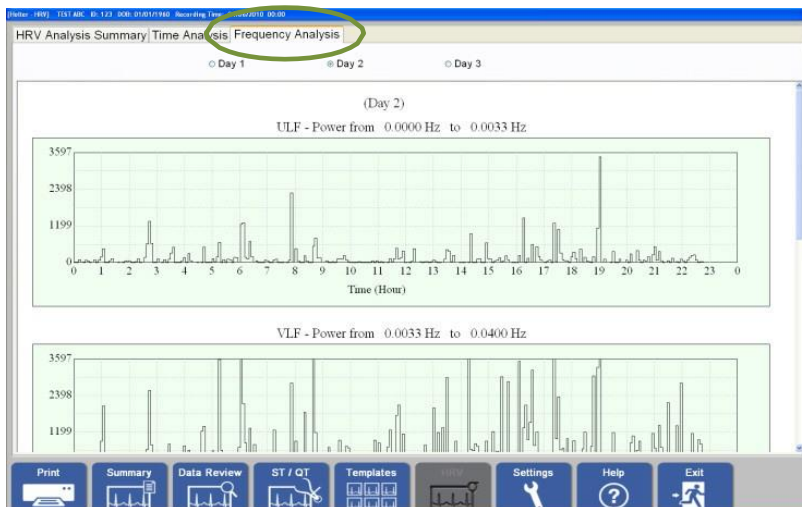
To perform any editing or create customized charts, export the Time Analysis results in a tabulated text format readable by most commercial spreadsheet programs; right-click inside the *Time Analysis* screen and select *Print Tabular Report*.



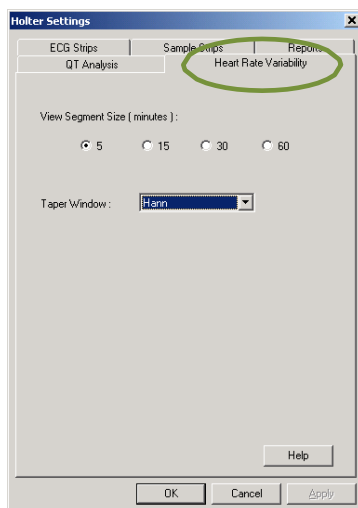
The *HRV Time Analysis Tabular Printing* dialog box appears:

To export the Time Analysis Tabular Report into a text file, check the *Print to File* box. Enter a filename and location for saving the file. To print, click **Print**.

The frequency domain analysis results are provided via the *Frequency Analysis* tab.

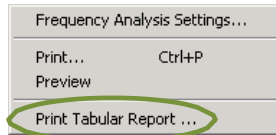


Change the *View Segment Size* and *Taper Window* settings for the HRV analysis by clicking **Settings** and selecting the *Heart Rate Variability* tab.

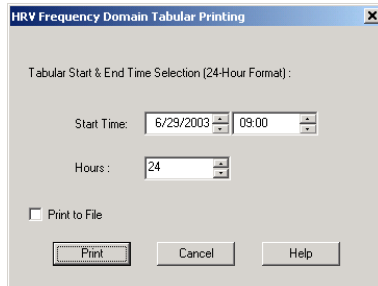


Changing these settings automatically updates the HRV analysis summary and frequency analysis results.

To perform any editing or create a customized chart, export the frequency analysis results in a tabulated text format read by most commercial spreadsheet programs; right-click inside the *Frequency Analysis* screen and select *Print Tabular Report*.



The *HRV Frequency Domain Tabular Printing* dialog box appears:



To export the Frequency Analysis Tabular Report to a text file, check *Print to File*. Enter a filename and location for saving the file. To print, click **Print**.

Viewing the Tabular Summary

The Tabular Summary displays the Holter analysis results for each hour. Click **Summary** and select the *Tabular Summary* tab.

Note

Limited editing is allowed in the Tabular Summary tab. Only the numerical values displayed in black can be edited. However, this editing is not generally recommended, as the Holter program does not automatically update all other sections of the Holter report to reflect these changes.

Analysis Results

Analysis Summary/Interpretation/Comments: **Tabular Summary**

Save Cancel Zero Column

Time	Avg	Min	Max	QRS	VE	V.Pair	V.Run	SVE	SV.Par	SV.Run	Pause	Begin	Trigem	ResT	STD	NA	AF
12:00	83	69	100	6381	490	4	2	126	0	0	0	257	42	0	-0.9(2)	0	0
13:00	75	60	95	6054	384	2	1	104	0	0	0	293	40	0	-0.9(2)	0	0
14:00	66	58	100	5172	313	3	1	116	0	0	0	120	31	0	-1.1(2)	0	0
15:00	67	59	94	5036	128	6	0	129	0	0	0	80	3	0	-1.0(2)	0	0
16:00	79	63	94	5928	162	8	0	76	0	0	0	74	23	0	-0.7(2)	0	0
17:00	79	62	102	5585	156	5	0	67	0	0	0	85	10	0	-0.9(2)	0	0
18:00	78	65	93	5557	218	6	0	4	0	0	0	21	72	0	-0.7(2)	0	0
19:00	68	62	105	5797	146	0	0	11	0	0	0	67	69	0	-1.6(2)	0	0
20:00	83	64	110	5854	329	1	0	56	0	0	0	49	48	0	-1.5(1)	0	0
21:00	92	70	114	6267	711	2	1	37	0	0	0	58	88	0	-0.8(1)	0	0
22:00	83	72	102	6253	599	4	0	40	1	0	0	101	121	0	-0.7(1)	0	0
23:00	84	69	105	6132	810	2	0	81	0	0	0	146	89	0	-0.7(2)	0	0
02:00:00	70	63	84	4440	57	0	0	16	0	0	0	27	1	0	-0.7(2)	0	0
01:00	90	69	149	6159	71	29	6	26	3	0	0	0	0	0	-0.4(1)	0	0
02:00	73	60	84	4470	7	1	0	2	1	0	0	0	0	0	-0.9(1)	0	0
03:00	68	57	87	4152	1	0	0	0	0	0	0	0	0	0	0.4(1)	0	0
04:00	74	62	89	4490	2	0	0	0	0	0	0	0	0	0	0.8(1)	0	0
05:00	76	59	96	4906	0	0	0	1	0	0	0	0	0	0	0.1(1)	0	0
06:00	73	61	92	4442	6	0	0	0	0	0	0	0	0	0	0.2(3)	0	0
07:00	75	62	91	4548	6	1	0	0	0	0	0	0	0	0	0.3(3)	0	0
08:00	67	55	95	4086	5	0	0	1	0	0	0	0	0	0	0.4(3)	0	0
09:00	61	55	88	3746	4	1	0	1	0	0	0	0	0	0	0.5(1)	0	0
10:00	58	52	72	3582	1	0	0	0	0	0	0	0	0	0	0.6(3)	0	0

Print Data Review ST / QT Templates HRV Settings Help Exit

Viewing and Entering Interpretation/Comments

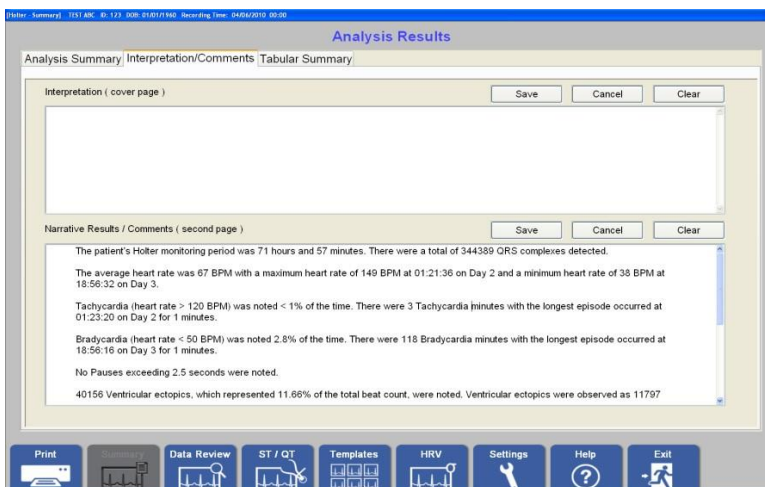
When the Holter analysis has been reviewed, enter the interpretations or comments by clicking **Summary** and selecting the *Interpretation/Comments* tab.

Interpretations entered in the top box also appear in the *Interpretation* section at the bottom of the *Analysis Summary* tab.

Narrative results and comments in the lower box are generated automatically by the Holter program and are editable on this tab.

Note

Any changes made in the Analysis Results screen are saved automatically when the screen is exited. If performing re-analysis of the current Holter test, any changes made in this screen will be lost.

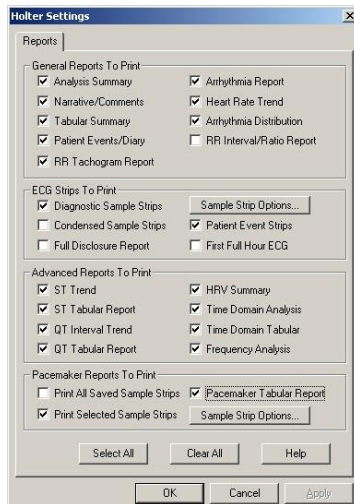


Printing Reports

Once the Holter test is complete, print or preview reports pre-selected in *Holter Settings*. Click **Print** then click **Print All Selected Pages** or **Preview All Selected Pages**.

To print any selected reports: click **Print** and click **Select Report Pages & Print**. The *Holter Settings* dialog box appears.

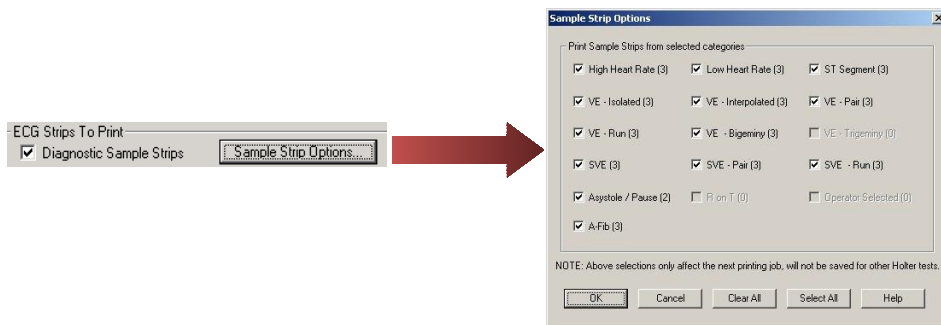
Select or clear any reports as desired, click **OK**, and the selected reports will be printed.



Note

*These are the same selections for the **Print Reports After Analysis** function. If any changes were made in this setting, remember to readjust the selections to reflect the original report preferences after the report has printed.*

Under *ECG Strips To Print*, if the *Diagnostic Sample Strips* is checked, **Sample Strip Options** is available for selecting categories of sample strips for printing.



Exiting the Holter program

Once the Holter test has been completed and reviewed, click **Exit** to return to the *Report Review* screen. Enter the reviewer's name in the *Reviewed by* box. The *Review Date* is entered automatically when and changes are saved when the report is exited. The *Review by* and *Date* on the Analysis Summary Report are updated by the software accordingly.

Converting a Full Report to a Summary Report Format

Depending on the number of arrhythmic events, an average 24-hour Holter Full Report format requires about 35MB of hard-disk space if acquired from the standard 24-hour IQholter® recorder; 135 MB for each 24hour if acquired from the upgraded 24, 48, 72 hour IQholter® recorder. Without the full disclosure, a *Summary Report* takes up about 3MB for each 24hour. Manually convert a full Holter report to a summary Holter report by clicking **Delete ECG** when viewing the Holter report.

Note

Converting to a Summary Report format deletes the full disclosure, i.e. the recorded raw ECG for that Holter test. This action is NOT reversible.

Full editing, printing, and viewing options are available with the full report, however, some operations are not available with the summary report format, as listed below:

Operations Restricted in Summary Report Format		
Buttons	Tabs/Submenu	Remark
Summary	Tabular Summary	No editing available.
Data Review	Sample Strips	View only strips that have been saved to print. By default, only 3 sample strips from each category are saved. Others are discarded.
	Page Scan	Not available. No full-disclosure printing.
	Patient Diary/User Events	No additional entry. Saved event strips are retained.
	Heart Rate	Only the first high heart rate strip is displayed. No other strips are available from the <i>Heart Rate Trend</i> screen.
	RR Tachogram	Only ECG strips for maximum RR and minimum RR are available.

Operations Restricted in Summary Report Format		
Buttons	Tabs/Submenu	Remark
ST/QT	ST Trend	Only the first ST Segment sample strip is displayed. No other ECG strips are available when clicking in the ST Trend graph.
	ST Tabular	No editing available.
	QT Trend	No ECG strip view when clicking in the QT Trend graph.
	QT Tabular	No editing available.
Settings	ECG Strips	<i>Recording Time</i> and <i>Date</i> cannot be changed.
	Sample Strips	Settings disabled.
	Reports	Arrhythmia Report, Full Disclosure Report and First Full Hour ECG Report are not available.
Templates	All Templates	No editing available.
Pacemaker	Pacemaker Templates	No editing available.
	Pacemaker Tabular Summary	No editing available.

VI. *Appendices*

A. *Appendix A - Operations at a Glance*

A quick guide to using the IQholter® on a new patient.

1. Obtain the recorded SD card from the IQholter® recorder.
2. Insert the SD card into the SD card reader in the computer.
3. Start IQmanager®.
4. Choose **New Patient** from the opening screen.
 - For an established patient, search by the patient's name or ID number.
5. Enter as much information as possible on the *Patient Data* screen. The patient's name or ID number is required.
6. Select **New Test** on the menu bar.
7. Click **Holter** after entering relevant information, by clicking the play icon in the Holter section.
8. The software automatically enters the recording start time and date from the recorder.
9. Check *Print Reports After Analysis* to print a preliminary report if needed.
10. Click **Patient Diary** to enter the patient's notes from his or her diary, if available.
11. Click **Acquire & Analyze** to start the Holter analysis.
12. Reports are automatically saved and printed.
13. Click **Exit** to return to the IQmanager® opening screen.

A quick guide to using the IQholter® EX/EP on a new patient.

1. Obtain the recorded SD card from the IQholter® recorder.
2. Insert the SD card into the SD card reader in the computer.
3. Start IQmanager®.
4. Choose **New Patient** from the opening screen.
 - For an established patient, search by the patient's name or ID number.
5. Enter as much information as possible on the *Patient Data* screen. The patient's name or ID number is required.
6. Select **New Test** on the menu bar.
7. Select **Holter** after entering relevant information, by clicking the play icon in the Holter section.
8. The software automatically enters the recording start time and date from the recorder.
9. Check the *Pacemaker* box for pacemaker analysis on the recorded data.
10. Check the *Print Reports After Analysis* box to print a preliminary report if needed.
11. Click **Analysis Settings** to preview the raw ECG or change the analysis settings.
12. Select *Enable A-Fib Detection* to perform automatic atrial fibrillation analysis.
13. Click **Patient Diary** to enter the patient's notes from his or her diary, if available.
14. Click **Acquire & Analyze** to start the Holter analysis.
15. Review and edit the Holter analysis results through the *Templates* functions.
16. Review and edit Pacemaker analysis results using *Pacemaker* functions.
17. Click **Data Review**. Enter final interpretations and comments on the *Interpretation/Comments* tab of the *Analysis Results* screen.
18. Click **Exit** to return to the IQmanager® *Holter Report Review* screen.
19. Enter the reviewer's name in *Reviewed by* and click **Exit**.

B. Appendix B - Troubleshooting Guides

These *Troubleshooting Guides* provide a list of solutions and recommendations to issues that may be encountered with the IQholter® EX/EP software and IQholter® Recorders. Before calling Midmark Technical Service, please refer to the following table for help. Error messages appear at the center or at the bottom right of the computer screen.

Note

For errors that occur during analysis or management of test files, refer to the Troubleshooting Guide in the IQmanager® Operation Manual.

Software Troubleshooting Guide	
Error Message or Issue	Solution or Recommendation
Can't analyze non-Midmark format ECG files. Message appears after clicking Acquire & Analyze .	The IQholter® EX/EP analyzes only ECG data recorded from the IQholter® recorder. • Please contact Technical Service for more information.
Can't find Holter data, please make sure the flash card is inserted into the reader properly Message appears after clicking Acquire & Analyze .	The SD is not inserted or not making proper contact. • Verify that the correct SD card is inserted in the SD card reader. • Eject and reinsert the SD.
Can't successfully save raw ECG data! Message appears after clicking Acquire & Analyze .	The IQholter® EX/EP program cannot copy the raw ECG data file to the required location. • Verify that the holter data folder exists. • Create the required folder or call Technical Service.
All other operational problems.	• Refer to the online help by clicking Help on anyscreen. • Refer to the <i>IQmanager® Operation Manual</i> for additional troubleshooting covering IQmanager®. • For support services information, please see Section VII. Customer Support and Warranty Information.

Recorder Troubleshooting Guide	
Error Message/Issue	Possible Solution or Recommendation
No tone or display following initial battery installation	- Battery is very weak - Battery is incorrectly installed
OLED displays ' SD CARD NOT INSERTED ' and the unit emits a continuous tone following battery installation.	Incomplete SD card installation: - REMOVE BATTERY - INSTALL SD CARD - Reinstall battery
Unit emits a continuous single-tone beeping alarm	SD card did not initialize correctly, reinstall battery
One or more channel has low amplitude, excessive artifact or a wandering baseline.	- Bad lead wire set - Poor connection
ECG data is not observed after recording session is complete	- Poor battery - Unit operated for less than ten minutes prior to battery or SD card removal - SD card or recorder has malfunctioned
SD CARD ERROR	- SD card busy - Bit timeout - SD card too slow - SD card incorrect type - SD card defective - Replace defective SD card
WARNING PATIENT CABLE HAS NOT BEEN DETECTED	- Cable has not been inserted into recorder - The cable is not inserted completely (loose) Press in securely.
LOW BATTERY	- Battery voltage is below the usable threshold. - Appears before controlled shut down - If on startup, use a fresh battery.
ERROR SD CARD IS TOO SLOW	- RAM BUFFERS OVERFLOW BEFORE DATA HAS BEEN WRITTEN TO THE DISK. - SD card too slow - SD card incorrect type, worn or lower quality than necessary. - SD card defective.
WARNING SD CAPACITY IS TOO SMALL FOR RECORD LENGTH	SD card capacity is not large enough for the recording length / quality selected.
WARNING BATTERY IS NOT CAPABLE OF RECORDING FOR SELECTED LENGTH	- Battery failed start up test - Battery is of incorrect capacity to perform length of recording selected - Lithium battery required for 72 hour recordings.

C. Appendix C - Maintenance and Storage

Preventative Inspection

Perform a periodic preventative inspection prior to each use of the recorder. Visual inspection should include the inspection of the recorder and all cables for signs of damage and deterioration, including but not limited to: cracks, cuts, discoloration and oxidation. If a cable or other accessory exhibits any of these symptoms replace it immediately prior to use of the recorder.

Cleaning the Recorder



Caution

Do not use aromatic hydrocarbons, rubbing alcohol or chlorinated solvents for cleaning the Holter recorder. Do not use alcohol or acetone on lead wires or cables, since they could stiffen and crack the insulating plastic.

Clean the outside of the IQholter® recorder with a soft cloth dampened with a mild household soap. Avoid using excessive amounts of solution, which may infiltrate the connectors, battery compartments or recording module. **Verify that all equipment and accessories are completely dry before using.**



Caution

Do not immerse the Holter recorder in any kind of liquid.

Cleaning the Patient Cable

Clean the cables following a hospital approved cleaning procedure, such as those recommended by AAMI or AORN. Wiping the cables with a solution of soap and water followed by a rinse with water is a simple yet effective method for cleaning the cables.

Do not immerse the cables in water. The cables may be disinfected by wiping with a 1:10 solution of chlorine bleach and water, or a 2% glutaraldehyde solution such as Cidex™. The cables should then be rinsed and wiped dry.

Note

Worn or damaged patient cables are the most common cause of poor quality recordings. Successive poor ECG tracings may indicate the patient cable needs to be replaced.

Bad Weather Conditions

In rain or snow conditions, instruct patients to protect the recorder from the elements by wearing the recorder inside a coat.

Storage

To prevent damage to the recorder due to battery leakage or oxidation, the battery should be removed whenever the recorder is not in use or prior to storage for a long period of time. Avoid extreme humidity and heat during storage.

Although the SD card is very durable, it should be stored within the recorder or its original case when not in use. This reduces the possibility of it being damaged by dust or moisture.

D. 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, it may cause interference with radio and television reception.

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

EMC Requirements for the IQholter® Recorder

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Addendum. Portable and mobile RF communications equipment can affect the operation of medical electrical equipment. The IQholter® recorder is medical electrical equipment.

The following is a list of the lead wires and SD cards that are used as part of the IQholter® recorder that comply with sections 36.201 and 36.202 of the EMC Standard IEC60601-1-2 (E). Electromagnetic compatibility testing has not been conducted using lead wires longer than 40 inches (101.6 cm).

Lead Wires

5-Lead 3-Channel Lead Wires

7-Lead 3-Channel Lead Wires

Memory Cards

Secure Digital (SD) Memory Cards: Standard length up to 2GB, conforming to SD Specification 2.0 as issued by the SD Association. Class 6 SD cards, or higher, should be used for optimal performance.

Use of lead wires, SD cards, or accessories other than those specified, with the exception of lead wires, SD cards, and accessories sold by the manufacturer of the IQholter® recorder as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the IQholter® recorder.



Caution

THE IQholter® RECORDER SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE IQholter® RECORDER SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

Guidance and manufacturer's declaration – electromagnetic emissions		
The IQholter® recorder is intended for use in the electromagnetic environment specified below. The customer or user of the IQholter® recorder should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR11	Group 1	The IQholter® recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The IQholter® recorder is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
RF emissions CISPR11	Class B	
Harmonic Emissions CISPR11	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The IQholter® recorder is intended for use in the electromagnetic environment specified below. The customer or user of the IQholter® recorder should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	N/A	N/A
Surge IEC 6100-4-5	+/- 1kV line(s) to lines(s) +/- 2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	N/A	N/A
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic if a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity

The IQholter® recorder is intended for use in the electromagnetic environment specified below. The customer or user of the IQholter® recorder should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 6100-4-3	 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	 N/A 3 Vrms 80 MHz to 6.0 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the IQholter® recorder, including cables, than the recommended separation distance calculated for the equation applicable to the frequency of the transmitter. Recommended separation distance. $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.33 \sqrt{P} \text{ 800 MHz to 6.0 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level on each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

^aField 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 access 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 IQholter® recorder is used exceeds the applicable RF compliance level above, the IQholter® recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IQholter® recorder.

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

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

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	(m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 5 GHz
	$d = 1.17 \sqrt{P}$	$d = 1.17 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.77
1	1.17	1.17	2.33
10	3.69	3.69	7.37
100	11.67	11.67	23.3

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 and 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.

E. Appendix E - Programming the IQholter® Recorder 24+

ONLY update recorders with the “24+” symbol indicated on the back of the recorder. The same process is to be followed to change from 24 hour ONLY to 24, 48, 72 hour or change 24, 48, 72 hour to 24 hour ONLY.

Programming the 24+ recorder will affect file size and downloading time.

Attribute	24 Hour Only Mode	24, 48, 72 Hour Mode
Patient ID	Not Available	AlphaNumeric (up to 21 characters)
Sample Rate	128 samples/sec	256 samples/sec
Resolution	8 bits	12 bits
Data Size (per 24 hours)	33 Mbytes	132 Mbytes
Upload Time (per 24 hours)	2 minutes	2 minutes

1. Install the SD card with the Red or Green dot into the IQholter® recorder 24+ and then install a fresh AA battery.
2. When the IQholter® recorder 24+ detects the program, a screen will display: “WARNING...YOU ARE ABOUT TO PROGRAM THIS DEVICE (.) TO CONTINUE, OR REMOVE BATTERY AND SD CARD TO CANCEL”.
3. Press and hold the center (enter) button when ready. This begins the programming process for the IQholter® recorder 24+. The programming will take approximately 7 minutes to complete.
4. When the programming is complete, follow the instructions on the screen: “PROGRAMMING COMPLETE REMOVE BATTERY AND SD CARD”.

Note

Once the IQholter® recorder 24+ is programmed, the SD card will be erased and become a blank SD card.

Note

Use electrodes that are rated for the timeframe (24, 48, 72 hours) for the patient tests.

Note

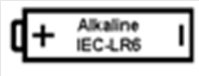
For 72-hour recording, a Lithium battery is required.

To program the IQholter® 24+ recorder, order the following:

- 24 ONLY (Red dot) Part Number: 1-370-0021
- 24, 48, 72 (Green dot) Part Number: 1-370-0020

F. Appendix F - Safety and International Symbols

The following symbols are used on the IQholter® recorder. Refer to this directory for details concerning symbols used on the instrument.

Symbol	Description
	Follow instructions for use.
	Year of manufacture.
	Battery Orientation This device uses 1 AA alkaline or lithium (72 hour) battery. The icon indicates the proper orientation of battery to be installed.
	Device is compliant with IEC 60601-1 as a Type BF, internally powered device.
	“Ordinary” enclosure IPX0: Keep the instrument away from splashing water.
	Conforms to UL Std. 60601-1 Certified to CAN/CSA Std. C22.2 No. 601.1
	Do not dispose of this product as unsorted municipal waste. Dispose this product in accordance with national requirements per EC Directive 2002/96.

G. Appendix G - Accessories and Supplies

Contact a local distributor for reordering supplies for Holter monitoring.

Midmark Part Number	Description
1-370-0010	SD Memory Card
2-100-0080	Prep Kit – Midmark IQholter®, 5-lead, 2AAs (each)
2-100-0081	Prep Kit – Midmark IQholter®, 5-lead, 2AAs (case – 30 kits)
2-100-0090	Prep Kit – Midmark IQholter®, 7-lead, 2AAs (each)
2-100-0091	Prep Kit – Midmark IQholter®, 7-lead, 2AAs (case – 30 kits)
90-30-0205	Lead Wire, 5-lead, IQholter® recorder
90-30-0206	Lead Wire, 7-lead, IQholter® recorder
2-100-0060	Holter Snap Electrodes (box of 50)
2-100-0050	Disposable IQholter® Recorder Pouches (pack of 25)
2-100-0051	Reusable IQholter® Recorder Pouch with Belt

VII. Customer Support and Warranty Information

For help diagnosing problems by phone with this product, contact Midmark Technical Service at (800) 624-8950 or (844) 856-1230, option 2, between 5:00 AM to 5:00 PM, Pacific Standard Time.

To contact Midmark Technical Service via email: techsupport@midmark.com

Self-help knowledge base and live chat can be accessed at: kb.midmark.com

Warranty

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

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

Return Materials Authorization

To return any product for repair, a Return Materials Authorization (RMA) number must be obtained from Midmark 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. We highly recommend following all guidelines for the shipment of medical products set forth by the shipping company you choose to use. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for your RMA number. It is the responsibility of the customer when shipping a product to ensure that all packages and their contents get to Midmark safely. Midmark will not assume responsibility for damage due to improper packaging, shipment or product use. Such actions will void all applicable warranties.

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VIII. Contact Information

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