Holter System

Directions for Use

WelchAllyn®

Advancing Frontline Care™

For information about any Welch Allyn product, call Welch Allyn Technical Support:

USA	+1 800 535 6663 +1 315 685 4560	Australia	+61 2 9638 3000 +800 074 793
Canada	+1 800 561 8797	China	+86 21 6327 9631
European Call Center	+353 46 90 67790	France	+33 1 55 69 58 49
Germany	+49 7477 9271 70	Japan	+81 3 3219 0071
Latin America	+1 305 669 9003	Netherlands	+31 157 505 000
Singapore	+65 6419 8100	South Africa	+27 11 777 7555
United Kingdom	+44 207 365 6780	Sweden	+46 85 853 6551

REF

Reorder Number: 705874

Global Instrumentation part number 006-700-0035 Version H

Refer to WEB Site "www.WelchAllyn.com" for device directions for use and supporting documentation. To obtain a paper copy of the device directions for use, please contact Welch Allyn.

Manufactured for: Welch Allyn
                                           4341 State Street Road
                                           Skaneateles Falls, NY 13153 USA

Manufactured by: Global Instrumentation, LLC
Manufacturer: 8104 Cazenovia Road
                                           Manlius, NY 13104 USA

CE 0050

EC	REP

                                           Contract Medical International GmbH
                                           Lauensteiner Strasse 37
                                           01277 Dresden
                                           Germany
                                           Tel: +49 (0) 351 213 88 88
                                           Fax: +49 (0) 351 213 88 99
                                           Contact: European Regulatory Manager
                                           Email: tlenihan@contract-medical.com

WelchAllyn®

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Directions for Use

Intended Use

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

The Welch Allyn Holter System is intended to be used as a Holter ambulatory electrocardiograph system for the purpose of screening for ECG rhythm disturbances up to a 48-hour period. The Welch Allyn Holter System is intended for use under the supervision of a physician or those knowledgeable in all aspects of ECG morphology, rhythm, and arrhythmia.

This procedure is known as a Holter procedure and captures infrequent or activity provoked ECG rhythm abnormalities outside of the physician's office.

The Welch Allyn Holter System is comprised of the Welch Allyn Holter Recorder and the Welch Allyn Holter System Application.

As the patient wears the recorder component of the system, it records ambulatory electrocardiograph data. The Welch Allyn Holter System Application analyzes the recorder data.

The Welch Allyn Holter System is not intended for infants weighing less than 10 Kg (22 lbs).

The Welch Allyn Holter System acquires ambulatory ECG waveforms from patients. The recorder and associated accessories provide signal acquisition for up to three channels (HR100 and HR300) or up to eight channels (HR1200) of patient ECG waveforms through surface electrodes adhered to the body.

The subject devices provide the following diagnostic functions:

- Acquire, view, store, and print ambulatory ECG waveforms from patients. The recorder and associated accessories provide signal acquisition for up to 12 leads of patient ECG waveforms through surface electrodes adhered to the patient.
- Using optional Holter algorithms to generate measurements, data presentations and graphical presentations on an advisory basis for patients. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.
- Using optional interpretive algorithms to generate measurements, data presentations, graphical presentations, and interpretive statements on an advisory basis for patients. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.

Indications for Use

⚠️ **WARNING** Safety—Computer assisted ECG data acquisition and interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable and a qualified physician shall review the interpretations before treatment, or non-treatment, of any patient.

The Welch Allyn Holter System is intended for acquiring ambulatory ECG signals from patients. Patients are people with coronary problems or people with suspected coronary problems. This ambulatory electrocardiograph, and associated analysis system, can be used on patients without any limitation on patient age or gender.

The Holter Recorder procedure is one of the many tools that clinicians use to capture infrequent or activity provoked ECG rhythm abnormalities outside of the physician's office. Indications for conducting Holter recording are:

- Arrhythmias
- Chest pain
- Unexplained syncope
- Shortness of breath
- Palpitations
- Evaluation of a pacemaker
- Regulation of anti-arrhythmic drugs
- Evaluation of a patient after myocardial infarction
- Family history of heart disease

Contraindications

Computer assisted ECG data acquisition and interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable and interpretations should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

The Welch Allyn Holter System is not intended for infants weighing less than 10 Kg (22 lbs).

Using optional interpretive algorithms to generate measurements, data presentations, graphical presentations, and interpretive statements on an advisory basis for patients.

Warnings and Cautions

Familiarize yourself with these warnings. Specific warnings and cautions are also found throughout this manual.

Warnings

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

WARNING   Safety—For patients with a pacemaker, maintain a minimum of 6 inches between the recorder and pacemaker. Turn the recorder off immediately and provide appropriate patient care if you suspect the recorder affected the pacemaker.

WARNING   Safety—Remove electrodes, patient lead wires, and recorder from patient before defibrillation.

WARNING   Safety—The conductive parts of electrodes and associated connectors for type BF or CF applied parts, including neutral electrode, should not contact other conductive parts including earth.

WARNING   Safety— Inspect recorder and accessories before each use.

WARNING   Safety—Peripheral equipment and accessories that touch the patient must comply with all appropriate safety, EMC, and regulatory requirements.

WARNING   Safety— System is not designed for use with high-frequency (HF) surgical equipment and does not protect against hazards to the patient.

WARNING   Explosion hazard—Do not use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

WARNING   Fire hazard— Replace batteries using AA (LR6) alkaline batteries. Note polarity.

WARNING   Using non-approved cables and accessories may affect the EMC performance.

WARNING   Stacking of devices or storage near other equipment is not recommended.

Cautions

A caution statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.

Caution US Federal law restricts this system to sale by or on the order of a physician.

Caution   Do NOT use acetone, ether, freon, petroleum derivatives, or other solvents to clean the recorder.

Caution Do NOT let soap or water come into contact with the battery contacts or patient connector pins.

Caution   DO NOT submerse, autoclave, or steam clean the recorder or the patient cabling.

Caution Welch Allyn-certified components are required.

Symbols

⚠	Warning. Read Carefully.
⚠	Caution / Notices. Read Carefully.
⚠	Attention: See instructions for use.
⌇	Patient Activated Event.
CE 0050	Meets or exceeds Council Directive 93/42/EEC, MDD, Class IIb
🧍	Type BF Medical Equipment.
+ AA (LR6)	Battery Polarity. Use AA (LR6) Alkaline batteries.
⊘	Single use. Use materials labeled with this symbol once only.
SD	Secure Digital Memory Card Interface.
❈	Blue Tooth Wireless Communication Technology
🗑	Recycling Symbol - Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. See www.welchallyn.com/weee.
+65°C / -20°C	Temperature range. (see Technical Specifications)
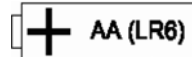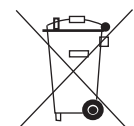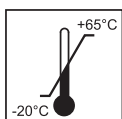
Keep dry. (see Technical Specifications)
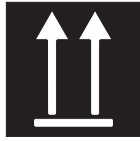
This end up.

Fragile, glass.

SN Serial Number.

REF Reference Number.

No Latex.

No PVC.

Keep from direct sunlight.

LED light.

Non-ionizing radiation.

Temperature range. (see Technical Specifications).

Pressure range. (see Technical Specifications).

Serial Number.

Introduction

This manual is written for clinical professionals with a working knowledge of medical procedures and terminology as required for monitoring cardiac patients. You must read and understand this manual and all other information accompanying the ambulatory electrocardiograph and related options or accessories before:
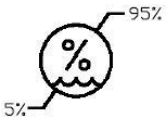
- using the Welch Allyn Holter Recorder and the accompanying Welch Allyn Holter software for clinical applications
- before setting up, configuring, troubleshooting, or servicing the recorder

Inspection upon Delivery

Your new Holter System Application was carefully inspected before shipment. Please inspect all components upon delivery for any damage which may have occurred in transit. If you notice any damage, please contact your shipping agent. If items are missing, contact technical support.

Before you begin

Your system must meet the recommended requirements to function properly. Please review the System Requirements before attempting to install or use the system.

System Requirements

- 300MHz Pentium class processor or faster
- Windows XP (32-Bit), Windows Vista (32-Bit/64-Bit), Windows 7 (32/64-Bit) with all major service pack updates, Windows 8 (32/64-Bit)
- 256Mb RAM minimum
- 40GB hard drive minimum
- Mouse and keyboard
- Compact Disc (CD) Reader
- Secure Digital Card Reader
- Printer with resolution greater than 300 dpi
- Monitor with screen resolution set to 1024 x 768

Hard Drive Space Required

Hard drive space required for program installation:

30Mb for Holter System Application

8Mb for electronic manuals (optional)

Typical Hard Drive Usage

⚠️ **Caution** Windows® requires a minimum 250Mb of free hard drive space available at all times for virtual memory, print spooling and caching. Failing to comply will degrade system performance or crash the system.

- 1Gb for sixteen 24-hour patient reports @ 200 samples per second with full disclosure

Storage requirements examples

- 24-hour patient report @ 200 samples per second with full disclosure requires 64Mb of hard drive space
- 48-hour patient report @ 200 samples per second with full disclosure requires 128Mb of hard drive space

Optional Requirements

Requirements for backup

⚠️ **Caution** Backup on Windows Vista or Windows 7 cannot be restored on Windows XP.

- CD Writer to write Holter report files to CD

Requirements for Bluetooth Communications

⚠️ **Caution** Welch Allyn-certified components are required.

- Support for Universal Serial Bus (USB) 1.1 or 2.0
- Bluetooth Communications Device (Welch Allyn Part Number 704555)

  ⚠️ **Caution** The PCH100 and PCH200 application will not run under any Windows Compatibility Modes (ie. Windows 95, 98, NT 4.0, 2000).

Operator Requirements

Operator of the PCH100 and PCH200 Holter System application shall have the following level of experience:

- Knowledge of operating a Windows based PC system, including mouse and keyboard.
- For the reviewer of the analysis information - operator shall be proficient in reviewing ECG's and understanding various beat classifications. Refer to the physicians guide.
- For operators performing subject hookup to the HR100 and HR300 recorders shall have experience on how to properly perform an electrode preparation.
- For operators performing maintenance operation on the software, database and data files should have previous experience in those specific operations

Features

All models:

- Lightweight and small size provides comfort for the patient.
- Either of two patient-activated event buttons enables patients to mark times they feel are significant. (Both event buttons have the same function.)
- System status feedback: LCD and LED (HR 100) or LCD (HR 300 & HR 1200).
- Removable Secure Digital Memory Card up to 48-hours of ECG storage and transferring ECG data.
- Holter Analysis system provides real-time ECG data via Bluetooth Wireless Communication to verify patient electrode placement and electronic transfer of ECG recordings.
- Operates on AA alkaline (LR6) batteries: one (HR 100) or two (HR 300 & HR 1200).
- Removable patient cable.
- LCD window provides ECG waveform views to ensure proper electrode connection.
- Time of day display.
- Navigational keypad - enter, cancel, up, down, right, left keys (HR300 & HR1200).

Holter System Application Directions for Use

Activating the Welch Allyn Holter Software

You must activate your Holter software within 30 days, or the software will lock itself. The activation message displays each time you launch the software until you activate. The best way to activate your software is through the Internet.

Activating through the Internet

1. Click the Holter icon. The activation message displays.

2. Select **Yes** or **No**.

- If you select **No**, a message displays reminding you that you must activate within 30 days. (**Caution**: after 30 days, the software will not launch.)

- If you select **Yes**, the system automatically activates itself and the activation screen will not display again. This completes the activation requirement.

Activating Manually (No Internet Connection)

If the software cannot detect an Internet connection, you must activate the application manually.

1. Launch the Holter System software. The activation message displays.

2. Select **Yes** or **No**.

- If you select **No**, a message displays reminding you that you must activate within 30 days. (Caution: after 30 days, the software will not launch.)

- If you select **Yes**, the Manual Activation dialog displays. Click the Print button. Contact Welch Allyn Technical Support (see page ii). You will be asked to provide the information displayed on the printout:

  - User name
  - Password
  - PC Serial Number 1
  - PC Serial Number 2

3. Once you receive the Activation Code, type it into the Activation Code box and click Activate. The application launches and the activation screen will not display again. This completes the activation requirement.

Recorder Illustrations

Figure 1. HR 100 Holter Recorder

Patient Cable

Patient-Activated Event Buttons

LED

Battery Compartment

Secure Digital Card Interface

Welch Allyn
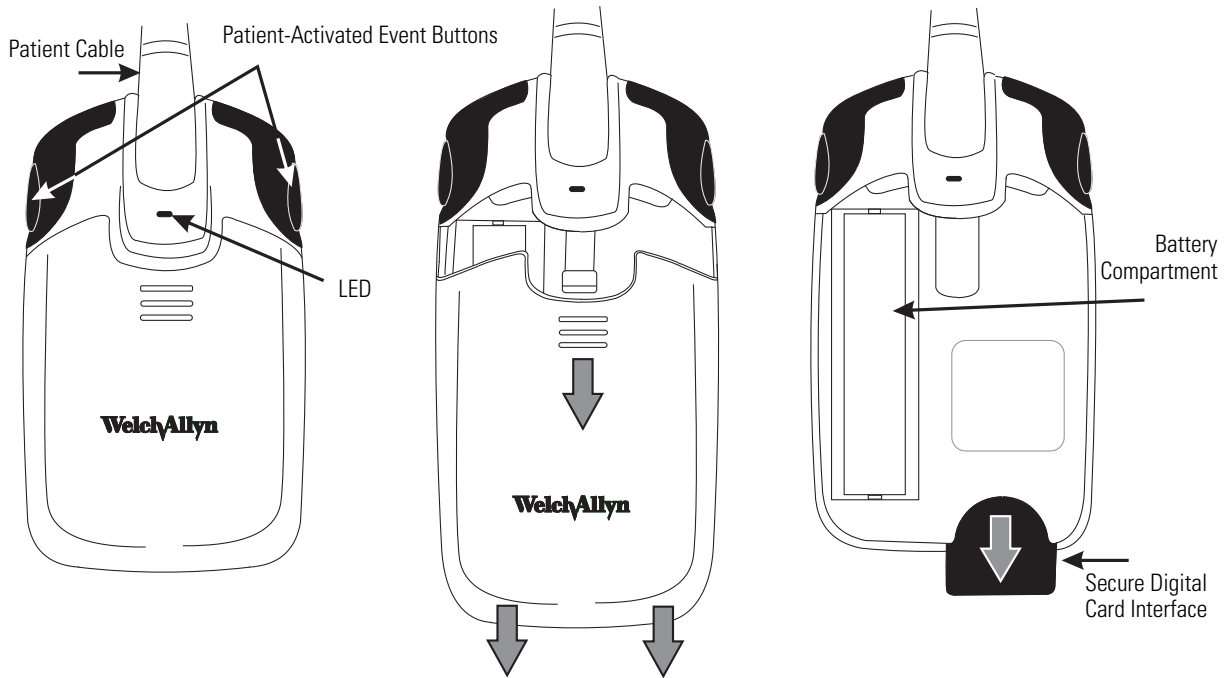
Figure 2. HR 300 & HR 1200 Holter Recorder

Batteries

Secure Digital (SD) Card Interface

LCD

Patient-Activated Event Buttons

Patient Cable

Welch Allyn
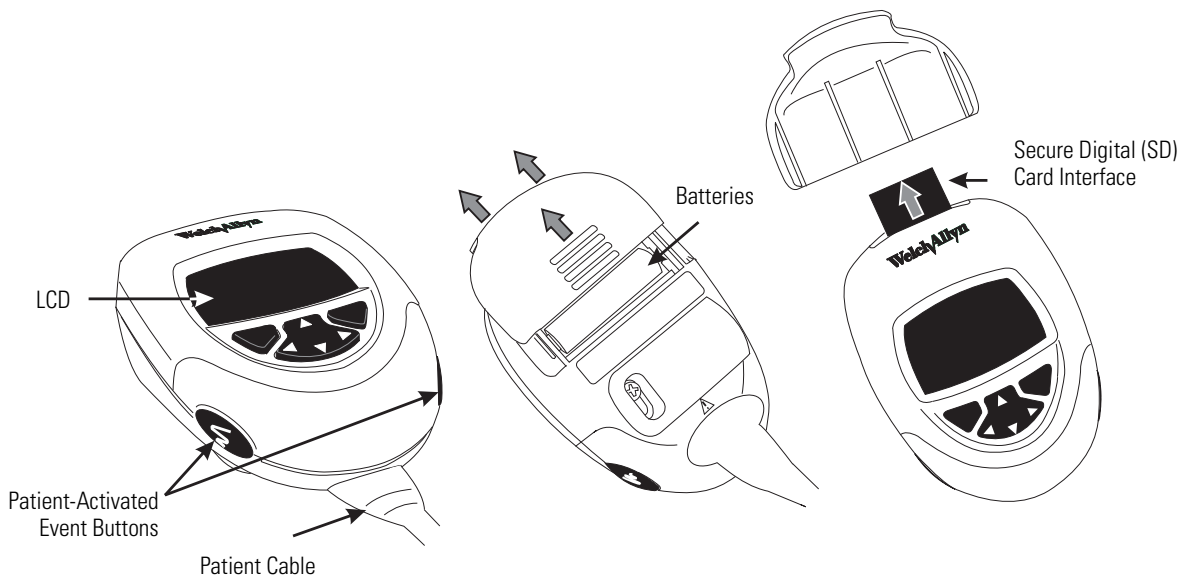
Caution Inserting the Secure Digital Card in backwards or up side down may damage Secure Digital Card Interface.

Operation

To Set the Time (HR100)

Batteries must to stay in the recorder for a minimum of 10-minutes to charge the clock backup cell.

1. Remove the battery cover from the recorder (see Figure 1 on page 11).

2. Remove the Secure Digital Card from the Secure Digital port located at the rear of the device (see Figure 1 on page 11).

3. Insert one new, AA alkaline (LR 6) batteries into the recorder battery compartment. Note the polarity.

4. The LCD window shows the time after the recorder self-diagnostics is complete (approximately 10 seconds). Time is displayed in 24-hour time format and Date is shown in Year Month Day format.

5. Enter time set mode by pressing the Top and Bottom Event switches simultaneously for 2-seconds.,the hour digit starts blinking

6. Increase the value shown with the Top Event switch. Use the Bottom Event switch to toggle between Hours, Minutes, Year, Month and Day.

7. Press the Top and Bottom Event switches to save time and date shown. Remove the batteries.

To Set the Time (HR 300 & HR 1200)

Batteries must to stay in the recorder for a minimum of 10-minutes to charge the clock backup cell.

1. Remove the battery cover from the recorder (see Figure 2 on page 11).

2. Remove the Secure Digital Card from the Secure Digital port located at the rear of the device (see Figure 2 on page 11).

3. Insert two new, AA alkaline (LR 6) batteries into the recorder battery compartment. Note the polarity.

4. Slide and secure the battery cover onto the recorder. The LCD window shows the time after the recorder self-diagnostics is complete (approximately 10 seconds). Time is displayed in 24-hour time format and Date is shown in Year Month Day format.

5. Press the <Right> function key, the hour digit starts blinking

6. Increase the hour shown with the up arrow key or decrease the hour shown with the down arrow key. Use the right and left arrow keys to toggle between Hours, Minutes, Seconds, Year, Month and Day.

7. Press the <Right> function key to save time and date shown. Remove the batteries.

Patient Preparation

Holter Procedure Patient Preparation

When making the appointment, tell the patient:

- Do not remove any electrodes or disconnect lead wires.

- Do not swim, bathe, or shower during the recording period.

- Do wear loose fitting, comfortable clothing to the appointment (shirt-and-pants or blouse-and-skirt combinations are better than one-piece garments.)

Preparing for Electrode Placement on Patient

WARNING Safety—Leave 5 feet (1.5 meters) of open area around the patient during recorder hookup and removal.

WARNING Safety—Do not connect external devices to the recorder. Connect patient lead wires only to the patient electrodes.

WARNING Safety—Keep the recorder and patient cable clean, especially the components that touch patients.

Caution Verify that dates on applicable accessories have not expired.

Table 1. Recommended accessories

Accessory	Quantity
Electrodes	5 or 7
AA Alkaline Batteries (LR6)	1 for HR 100 2 for HR 300 & HR 1200
Disposable Safety Razor	1
Abrading pad	1
Alcohol Prep Pads	2
Pouch	1
Patient Diary	1

**To Prepare the Patient and Place Electrodes**

⚠️ **Caution**   Always ensure that the appropriate electrode placement is employed for the lead configuration selected.

Caution   ECG electrodes can cause skin irritation. Examine the skin for signs of irritation or inflammation and avoid placement of the electrode in those areas. If skin irritation occurs during the procedure advise the patient to remove the electrodes and contact the health service provider as soon as possible.

Help the patient get comfortable. Patient preparation is important for a successful Holter procedure.

1. Describe the procedure to the patient.

2. Prepare electrode locations. See Figure 4 on page 15 for 5-lead placement, Figure 5 on page 16 for 7-lead placement, Figure 8 on page 18 for 12-lead placement.

3. Shave the area for electrode placement, if necessary.

4. Clean electrode sites with alcohol.

5. Allow electrode site to dry.

6. Attach the electrodes to the lead wires before attaching to patient.

7. Secure each lead wire. Loop each lead wire into a 1- to 2-inch diameter loop, position it approximately two inches from each sensor site, and tape it to the skin (see Figure 3 on page 14). This reduces movements that cause signal artifact.

Figure 3. Patient Lead Wire Stress Loop
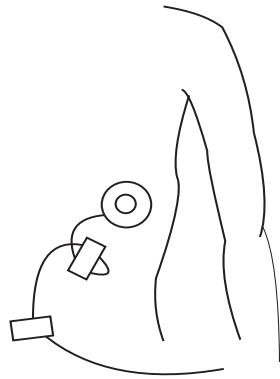
Evaluating the Signal Quality from Each Lead

Refer to the Holter System Application Directions for Use.

Clinician tasks

Explain to the patient:

- the recording procedure
- how to record information in the patient diary
- how to use the Patient Event Button
- to avoid contact with water

Table 2. 5-Lead Placement (HR100 only)

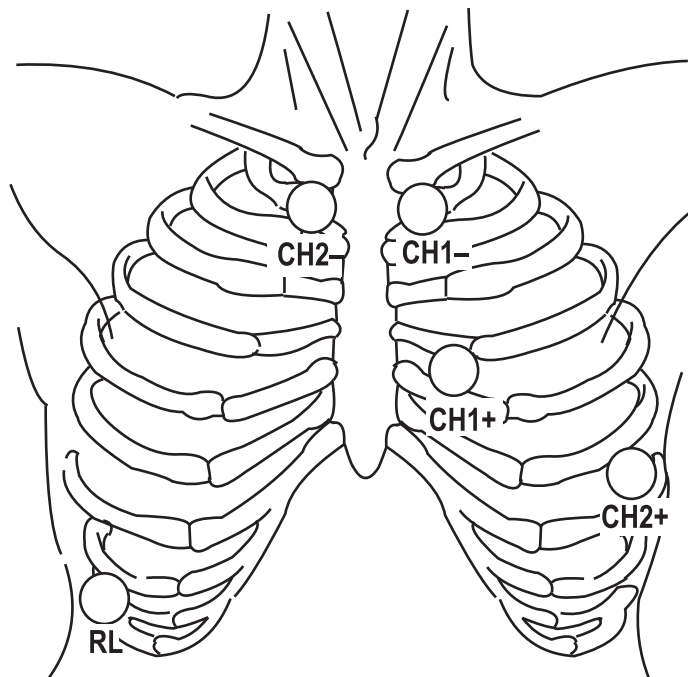| Lead	AHA Color	IEC Color	Placement
Ch1+	Red	Green	4th intercostal space at left border of sternum
Ch1-	White	Red	Left clavicle, lateral of sternum border
Ch2+	Brown	White	6th intercostal space at the anterior axillary's line
Ch2-	Black	Yellow	Right clavicle, lateral to the mid-clavicle line
RL	Green	Black	Lowest rib on right side of chest

Figure 4. 5-Lead Placement (HR100 only)

Table 3. 7-Lead Placement (all models)

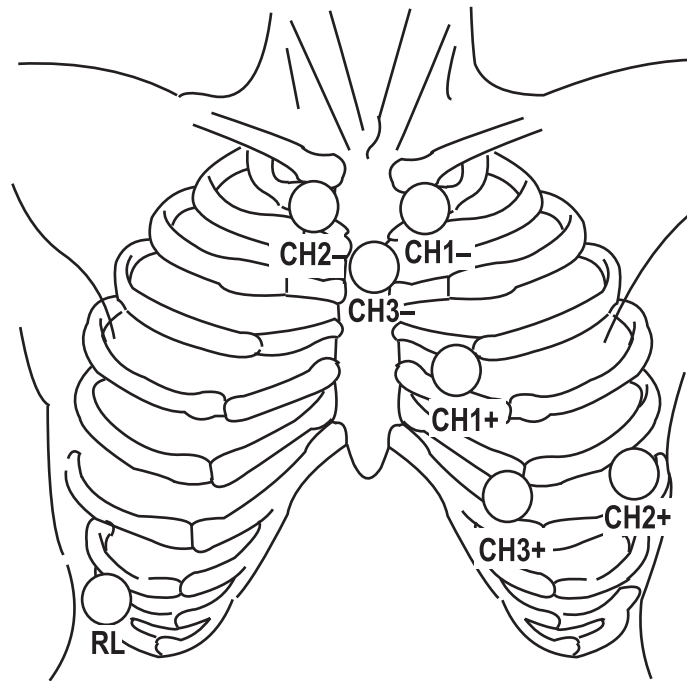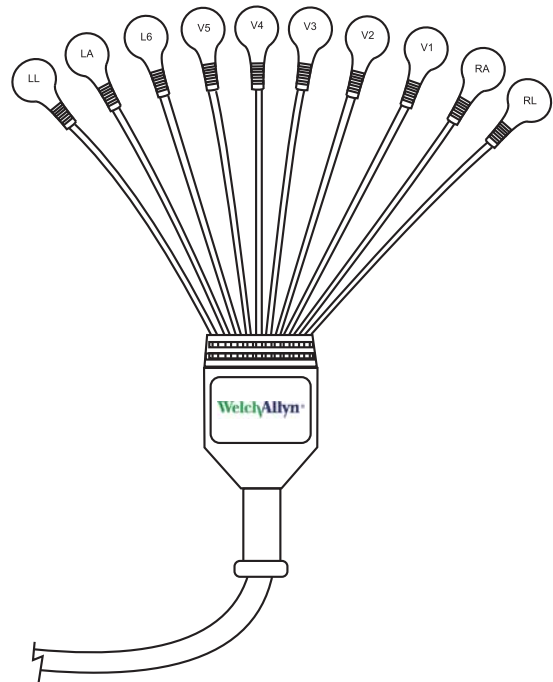| Lead	AHA Color	IEC Color	Placement
Ch1+	Red	Green	4th intercostal space at left border of sternum
Ch1-	White	Red	Left clavicle, lateral of sternum border
Ch2+	Brown	White	6th intercostal space at the anterior axillary's line
Ch2-	Black	Yellow	Right clavicle, lateral to the mid-clavicle line
Ch3+	Orange	Orange	6th intercostal space on left mid-clavicular line
Ch3-	Blue	Blue	Manubrium sternum
RL	Green	Black	Lowest rib on right side of chest

Figure 5. 7-Lead Placement (all models)
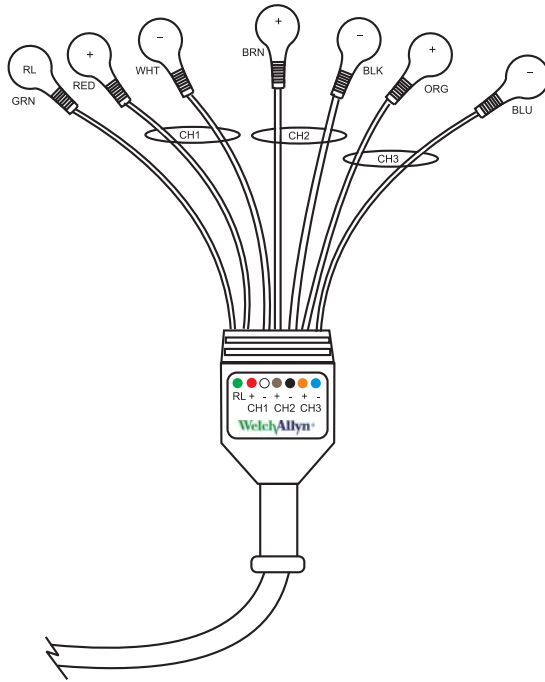
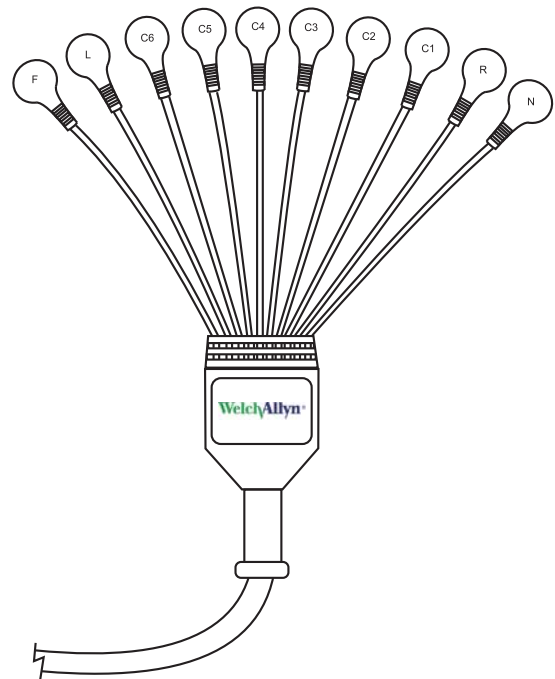**Figure 6. AHA lead cables**
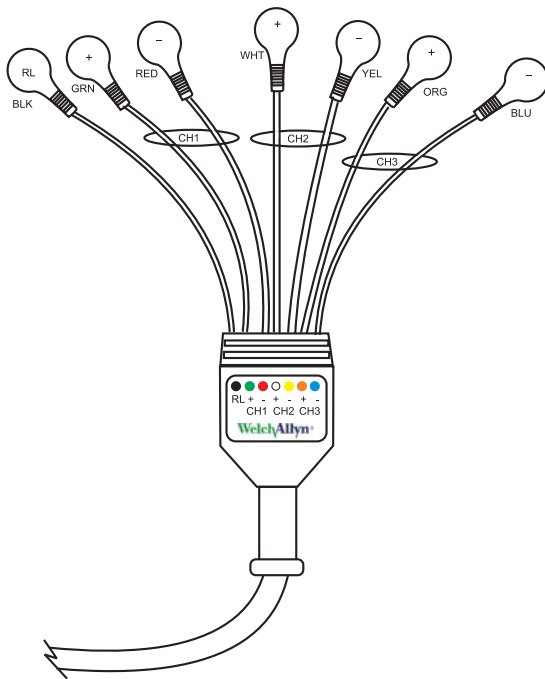

Figure 7. IEC lead cables

Table 4. 12-Lead Placement (HR1200 only)

AHA Lead	AHA Color	IEC Lead	IEC Color	Placement
RA	White	R	Red	Right clavicle, lateral of sternum border
LA	Black	L	Yellow	Left clavicle, lateral of sternum border
LL	Red	F	Green	Lowest rib on left side of chest
V1	Brown/Red	C1	White/Red	4th intercostal space on right border of sternum
V2	Brown/Yellow	C2	White/Yellow	4th intercostal space on left border of sternum
V3	Brown/Green	C3	White/Green	Midway between Lead V2 and Lead V4.
V4	Brown/Blue	C4	White/Brown	5th intercostal space on left midclavicular line
V5	Brown/Orange	C5	White/Black	Left anterior auxiliary line at the horizontal level of V4
V6	Blue/Violet	C6	White/Violet	Left mid-auxiliary line at the horizontal level of V4
RL	Green	N	Black	Lowest rib on right side of chest

Figure 8. 12-Lead Placement (HR1200 only)
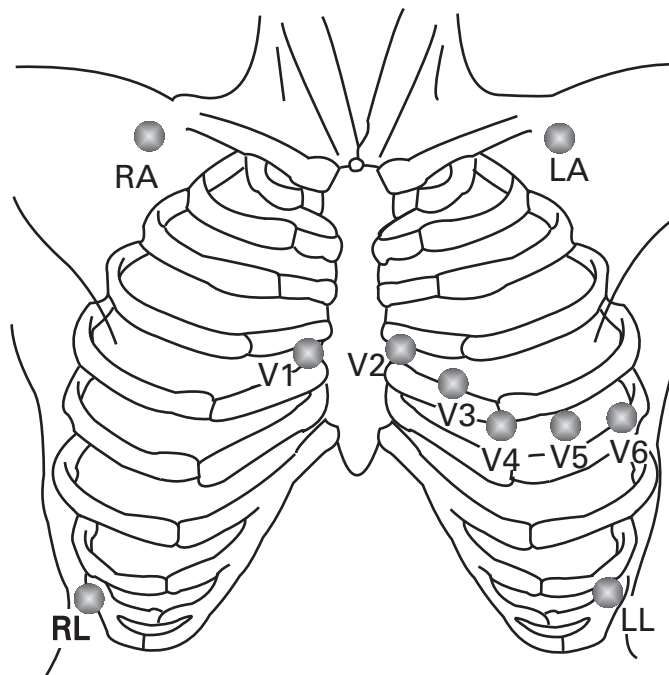
Starting the Welch Allyn Holter System Application

Starting the Welch Allyn Holter System Application

1. Click the Holter System Application icon. The **Main Menu** displays.
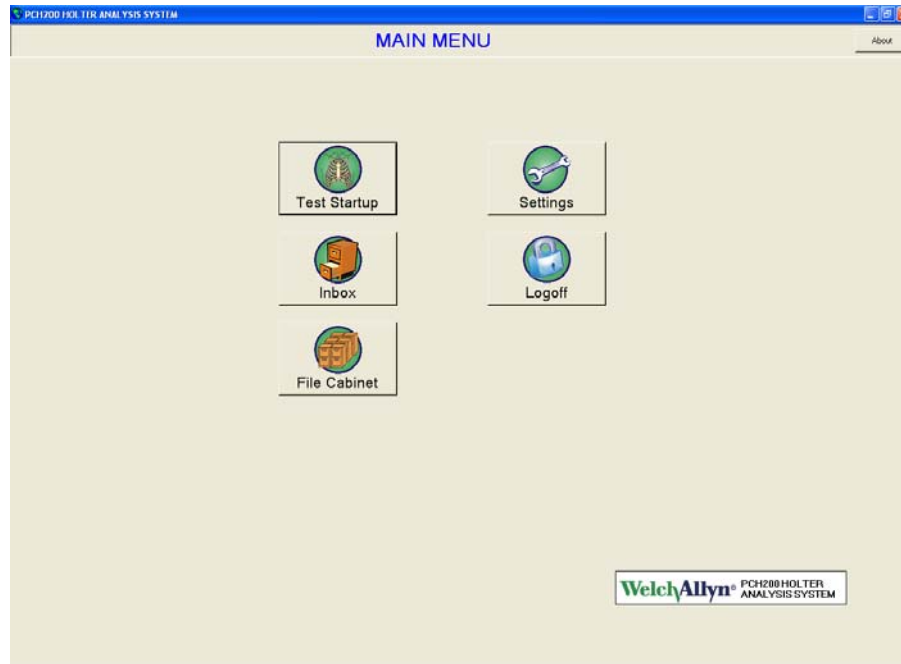
Table 5. Main Menu options

Button	Purpose
Test Startup	Configures the Holter recorder.
Inbox	Displays unprocessed tests.
File Cabinet	Displays processed tests.
Settings	Set system options, such as print formats.
Log Off	Log Off.

Starting a Test

⚠ **Caution** FAT file format recommended for SD Card sizes 2 GB and less.

Wireless Initialization - (ECG Preview on Holter System)

1. Prepare the patient according to "Patient Preparation" on page 13.

2. Remove the battery door.

3. Insert an SD card into the recorder.

4. Insert a new battery (HR100) or batteries (HR300/1200). Note the polarity.

5. Start the Holter software application and select **Test Startup**.

6. If the patient has a previous recording, click **Search**. A patient list displays.

    • Use the fields at the top of the patient list to filter your search.

    • Select a patient.

7. Type or select all appropriate information.

⚠ **Caution** Inserting the Physician, Technician or Ordering Physician information may require multiple attempts.

8. Click **Next**. The **Recorder Selection** window will display.

9. Wait for approximately 20 seconds for the serial number of the recorder to appear in the **Recorders in Range** window.

10. Click **Next**. (If no number displays, click **Troubleshooting**.)

⚠ **Caution** In Windows Vista and Windows 7 operating systems, previously paired recorders can appear in the Recorders in Range list even if the device is off.
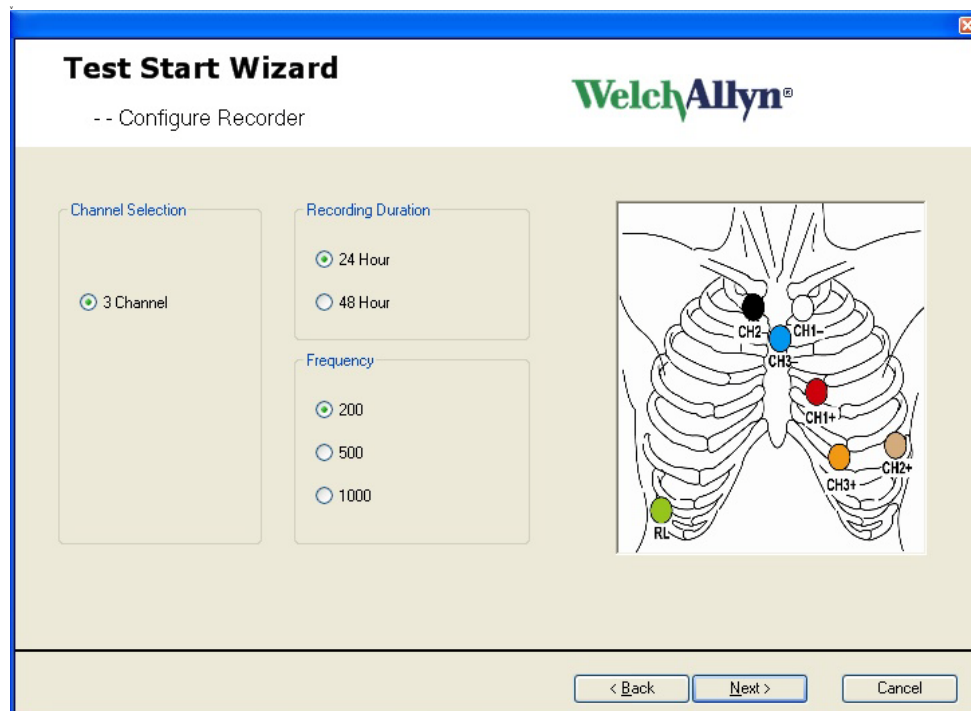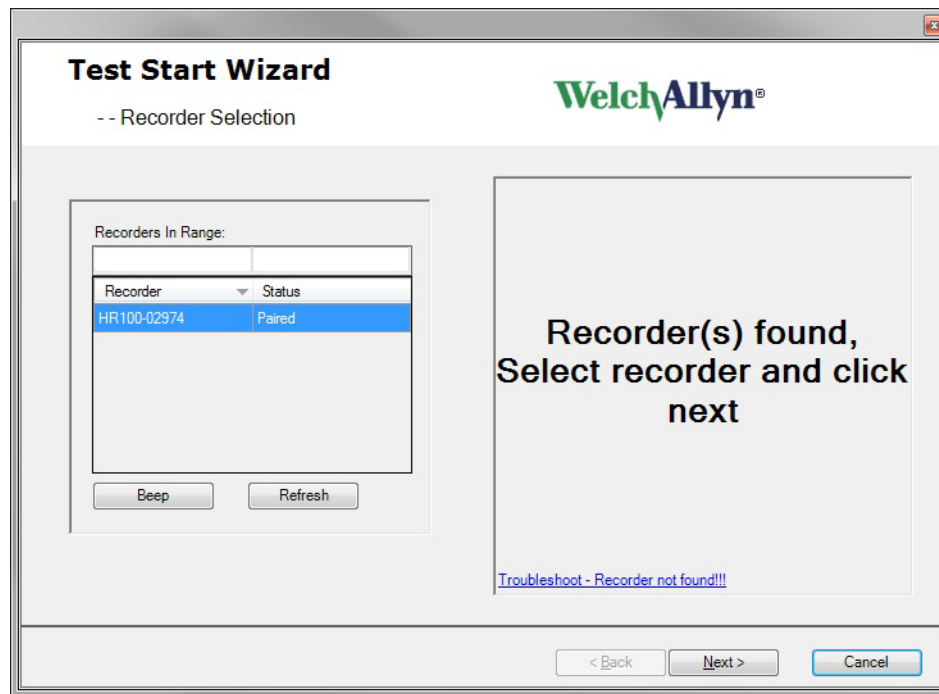
11. Select: 2 or 3 channel and 24 or 48 hour recording duration. Connect patient and click **Next**.

12. The following message indicates that the previously recorded test on this SD card has not been downloaded.

    • If you want to retrieve the data, click **No** and go to "Retrieving data when Patient Returns with Holter Recording Completed" on page 25.

    • If you want to overwrite the data, click **Yes**.
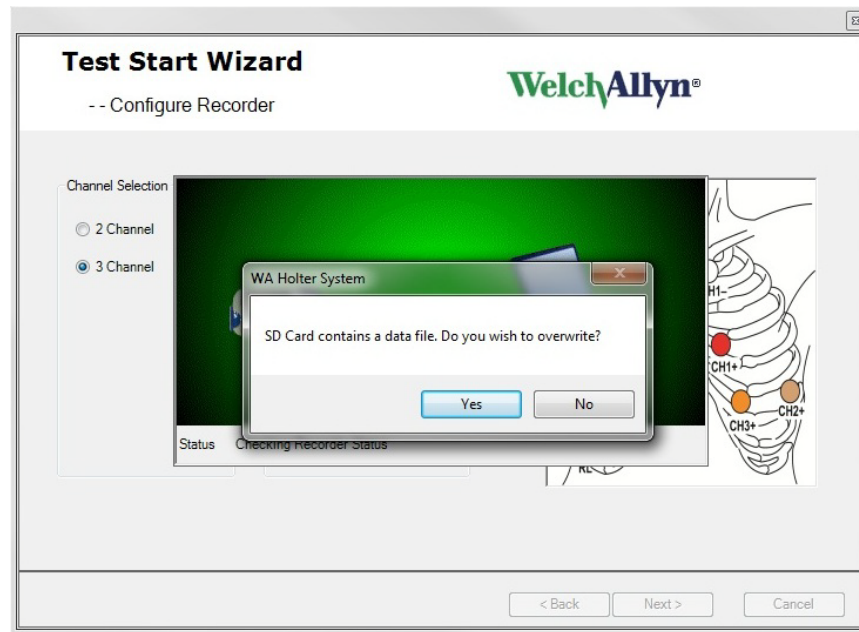
13. Verify signal quality (i.e. amplitude and artifact).QRS signal amplitude should be two boxes peak to peak. Select **Finish**. Test Startup is complete.
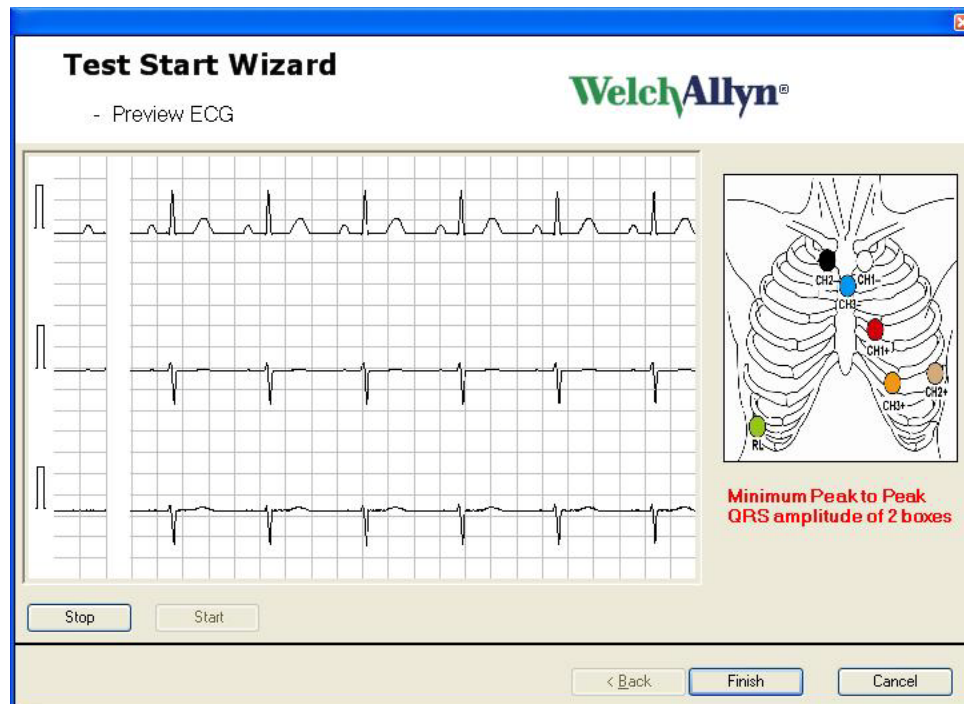
14. Place the recorder into the carrying case. Secure the carrying case and recorder on the patient.

15. Write the start time, date, and patient data in the patient diary.

SD Card Initialization - (ECG Preview on Recorders that have an LCD)

1. Prepare the patient according to "Patient Preparation" on page 13.

2. Remove the battery door.

3. Remove the SD card from the recorder.

4. Start the Holter software application and select **Test Startup**.

5. Enter patient information as desired. If this test has a previous recording, use search to find the patient information. Select **Next**.

6. If the SD card has not been inserted into the reader, the window displays an animation until the card is inserted.

7. Select channels and recorder.

8. Select **Finish**.

9. Insert the configured SD card into the recorder.

10. Insert a new battery (HR100) or batteries (HR300/1200). Note the polarity.

11. Slide and secure the battery cover onto the recorder.

• HR 100 — The LED flashes green in a sequence of two flashes, pause, three flashes, pause, four flashes, pause, then flashes once approximately every three seconds when operating. If the LED flashes yellow (any sequence) see "Troubleshooting" on page 57.

• HR100, HR 300 & HR 1200 — The LCD window shows the time of day after the recorder self-diagnostics are complete (approximately 10 seconds). The recorder is collecting ECG data and functioning properly. After the self test, the recorder will display ECG on the display for 5 minutes and then display the current time. If the recorder does not display time or displays an error code, see "Troubleshooting" on page 57

12. Place the recorder into the carrying case. Secure the carrying case and recorder on the patient.

13. Write the start time, date, and patient data in the patient diary.

Recorder Manual Initialization - (Supported on HR100 Recorders that have an LCD)

1. Prepare the patient according to "Patient Preparation" on page 13.

2. Remove battery door.

3. Insert an SD card into the recorder.

4. Insert a new battery. Note the polarity.

5. After a few seconds the LCD will display E2 – Initialize.

6. Enter manual initialization by pressing both event buttons simultaneously for 2 seconds.

7. Manual initialization allows entering of a four digit Patient ID, Duration and number of Channels.

8. Enter a four digit Patient ID, press the top event button to increment value of Patient ID field and press bottom event button to accept the value and proceed to the next field..

9. Select the duration of 24-hours or 48-hours by pressing the top event button to toggle between 24 & 48 and press the bottom event button to accept the value and proceed to next field. The Duration selected is stored as the default for the next manual initialization.

10. Select the number of channels 2-channel or 3-channel by pressing the top event button to toggle between 2 & 3 and press the bottom event button to accept and proceed to the next field. The Channels selected is stored as the default for the next manual initialization.

11. When complete with setup, start ECG acquisition by pressing both event buttons simultaneously for 2 seconds.

12. A progress indicator will display on the LCD.

13. Once acquisition starts Channel 1 (Ch1) will display on the LCD,

•   Scroll through the channels 2 and 3 by pressing one of event buttons.

•   ECG is displayed on the LCD for a period of 20-minutes then displays current time. To exit ECG preview prior to the 20-minute default, press both event buttons simultaneously for 2 seconds.

14. Place the recorder into the carrying case. Secure the carrying case and recorder on the patient.

15. Write the start time, date, and patient data in the patient diary.

To Shut Down the Recorder (if the recorder does not stop automatically)

⚠ **WARNING**   Discard electrodes after one use.

1. Press and hold both EVENT buttons and count the "beeps." Release the buttons at the start of the seventh beep. The HR100, HR300, HR1200 LCD will display a + sign indicating successful shutdown. The HR100 green LED will stop flashing.

2. Press the EVENT button again. Did the recorder beep?

•   If the recorder does not beep, the recorder was successfully shut down.

•   If the recorder beeps, repeat the shutdown procedure.

•   Remove the battery and SD card.

•   Remove the leadwires and electrodes from the subject.

Retrieving data when Patient Returns with Holter Recording Completed

1. Open recorder door and remove battery.

2. Remove SD card from recorder.

3. Be sure the Holter software application is running and insert an SD card into the SD card reader connected to the computer.

4. The Holter software application will upload and analyze the recorded test information automatically. Monitor the progress in the lower right hand corner of your screen.

Test Report Review, Editing and Printing

1. Open the Inbox.

2. Highlight the desired test. Click **Open**. (If necessary, use the area immediately above the header description to search by Patient ID, Last Name, or First name.)
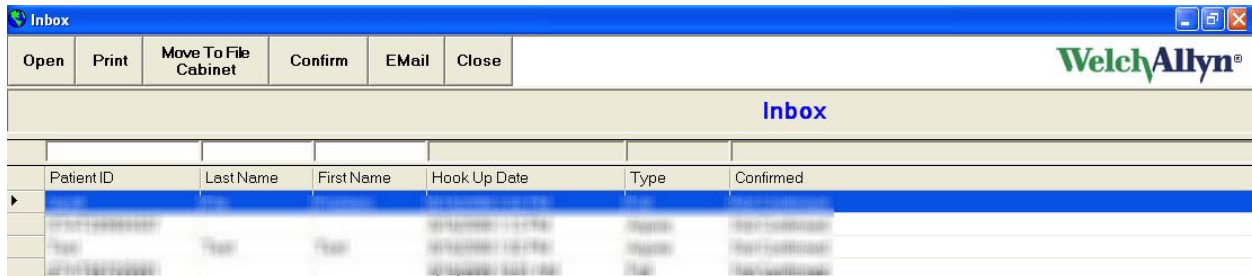
3. Select Summary Preview, Forms, Arrhythmia Review or Full Disclosure modes.
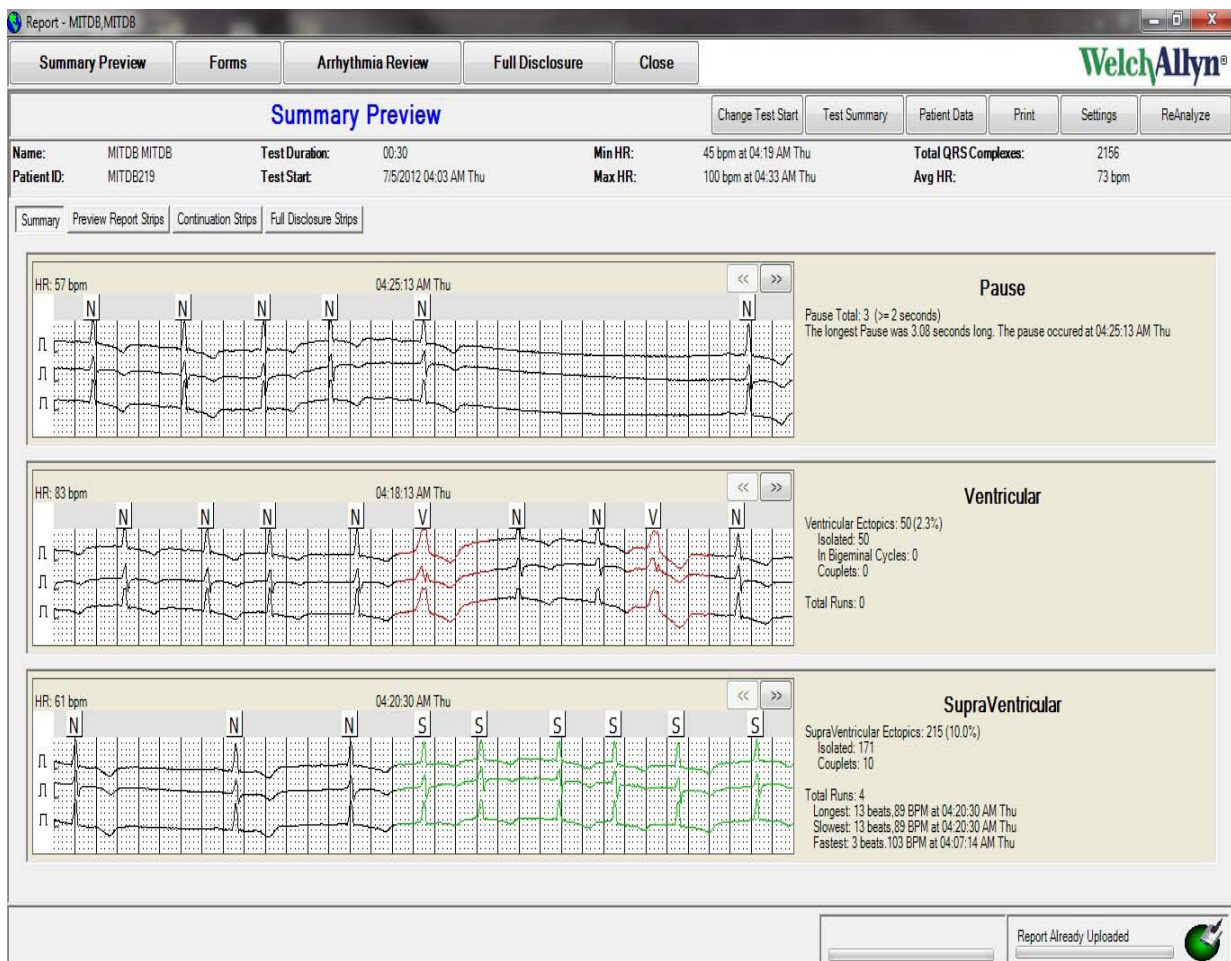
These additional functions are available throughout this review process.

Table 6. Additional Functions

Function	Actions
Change Test Start	Adjust test start time if necessary.
Physician Interpretation	Provides a window for entering a report interpretation which is part of the report cover page. The interpretation can be updated using acronyms (PCH200 only).
Patient Data	Make changes/additions to the patient demographics as desired.
Print	Print the report.
Settings	Change Clinical settings and report format from default values for this test only.
Re-analyze	Turn off channels that exhibit persistent quality problems and re-analyze Note: Any previous edits are lost.

Summary Preview

The Summary tab provides a comprehensive overview of key episodes detected during the recording.

The Preview Report Strips tab includes all the automatically-selected and user-inserted ECG strips which will be printed as part of the report. This includes:

• Baseline ECG strips taken in the first 5 minutes of the recording
• Samples of pauses
• Samples of ventricular ectopy
• Samples of supraventricular ectopy
• Min and Max HR
• Tachy and Brady Min and Max RR
• Max ST elevation and depression

The report includes all the continuation strips inserted by the user that will be printed as part of the report. Use marker mode to select an area in Full Disclosure to create a continuation strip. A continuation strip is limited to 4-14 seconds of sequential data.

The report includes all the Full Disclosure strips inserted by the user that will be printed as part of the report. The strips can be inserted in real time by marking an area in Full Disclosure.

Forms

Forms categorize QRS morphologies into four groups, Normal (N), Ventricular (V), Paced Beats (P) and Artifact (X), (the latter facilitates user review of false negatives).

Normal (N) forms will display SVE's belonging to the form by selecting **SVE Only**.

Each form includes the category label, form number (assigned by the total number of beats in a cluster across all categories) that match this morphology.

Selecting a form provides an accompanying 7-second ECG strip that includes the first QRS from the form. By clicking **Next**, each QRS in the form can be seen in the context of an ECG strip.

Right click the form header to re-categorize the form to the new desired category. All changes will be updated when moving to another category.
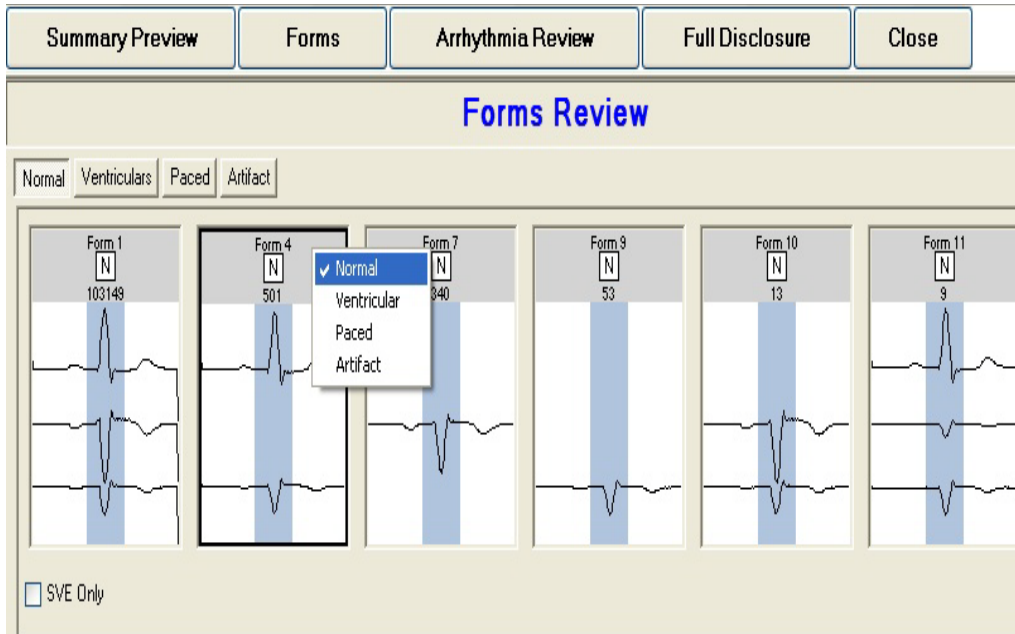
To view all beats in a particular form, double-click the form (PCH200 only).
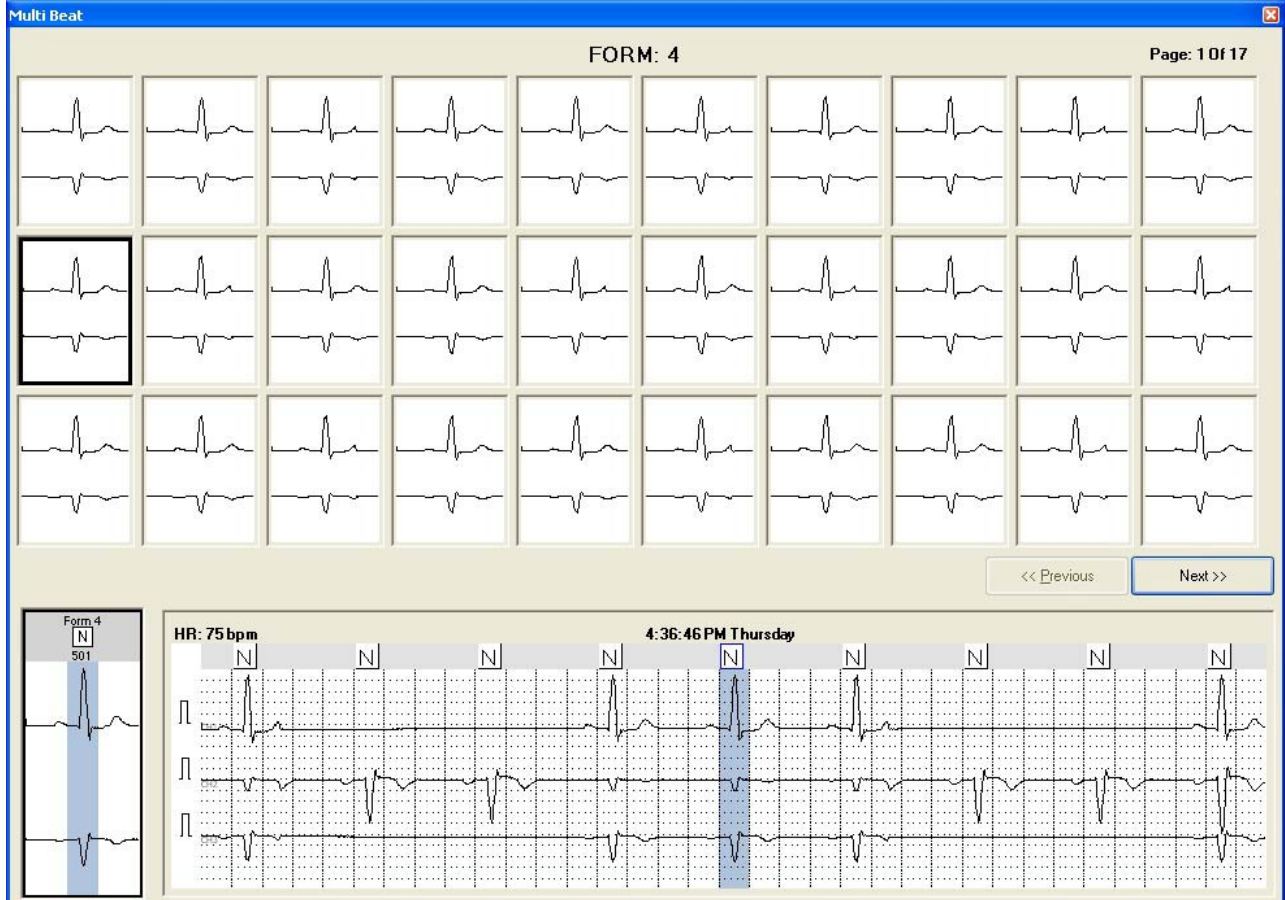
Arrhythmia Review

The display for Pause episodes, Ventricular ectopy, and Supraventricular ectopy includes a histogram of the episodes, a sample 7-second strip (of the worst case occurrence) and a form associated with the highlighted QRS.

In addition for the Ventricular and Supra Ventricular ectopy a chronological histogram can be viewed. The Rate tab displays Heart rate graphs for "Beat to Beat" or "HR Minute".

The R-R Tab displays graphs for "R-R Beat to Beat" or "R-R Histogram"

View any of the events by selecting the respective bar on the histogram and using **Next** to view ECG strips for all occurrences.

The individual beats and/or the form may be edited at any time.

Right-click any ECG strip to delete or add to the final report (all beats within the strip are labeled as artifact or added).

Right-click any ECG strip to print (7-second diagnostic strip will be printed out to the selected printer).
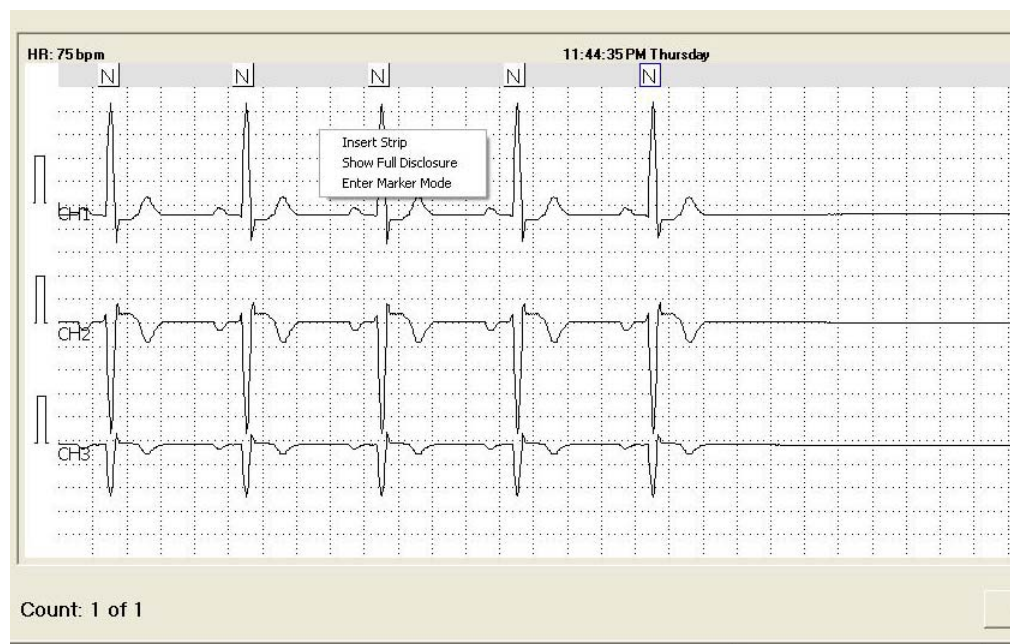
Options to view the strip in Full Disclosure include:

- Right-click the strip and select from the pull-down.
- Double-click the strip.
- Select the **Full Disclosure** tab on the tool bar.

The Rate tab provides Heart Rate information, specifically tachy, brady, min/max HR, and min/max R to R intervals. The top graph includes a 24 hour HR plot with user selected periods presented in 1-hour intervals immediately below.

Select any of the radio buttons to display a representative ECG strip. Or manually select areas (for example, max HR) and manually insert into the report.

HRV (PCH200 Only)

This tab displays time domain heart rate variability information for the report. The computations are available for the procedure. Awake, Asleep and Hourly Epochs. In addition the user can insert HVR Epochs from the full disclosure.

A graph for each Epoch is displayed based on the configuration.

Full Disclosure

This selection allows you to review the entire recording. Abnormal events are color-coded to make it easy to verify report accuracy.

Options for the review include:

- Auto Paging, i.e. automatically scrolling through the test and adjustable speed
- The number of lines displayed - 3, 5, 7, and 10
- The number of seconds per line - 10, 15, 20, 25, 30, 35, and 40
- Channels to be displayed

Use the 7-second window to move to any area to enlarge to diagnostic size for viewing and to insert and label for the final report. Delete areas of artifact using the Delete key. The ECG window moves to the next 7 seconds.

Use the marker to mark a fashion area of interest in full disclosure and print.
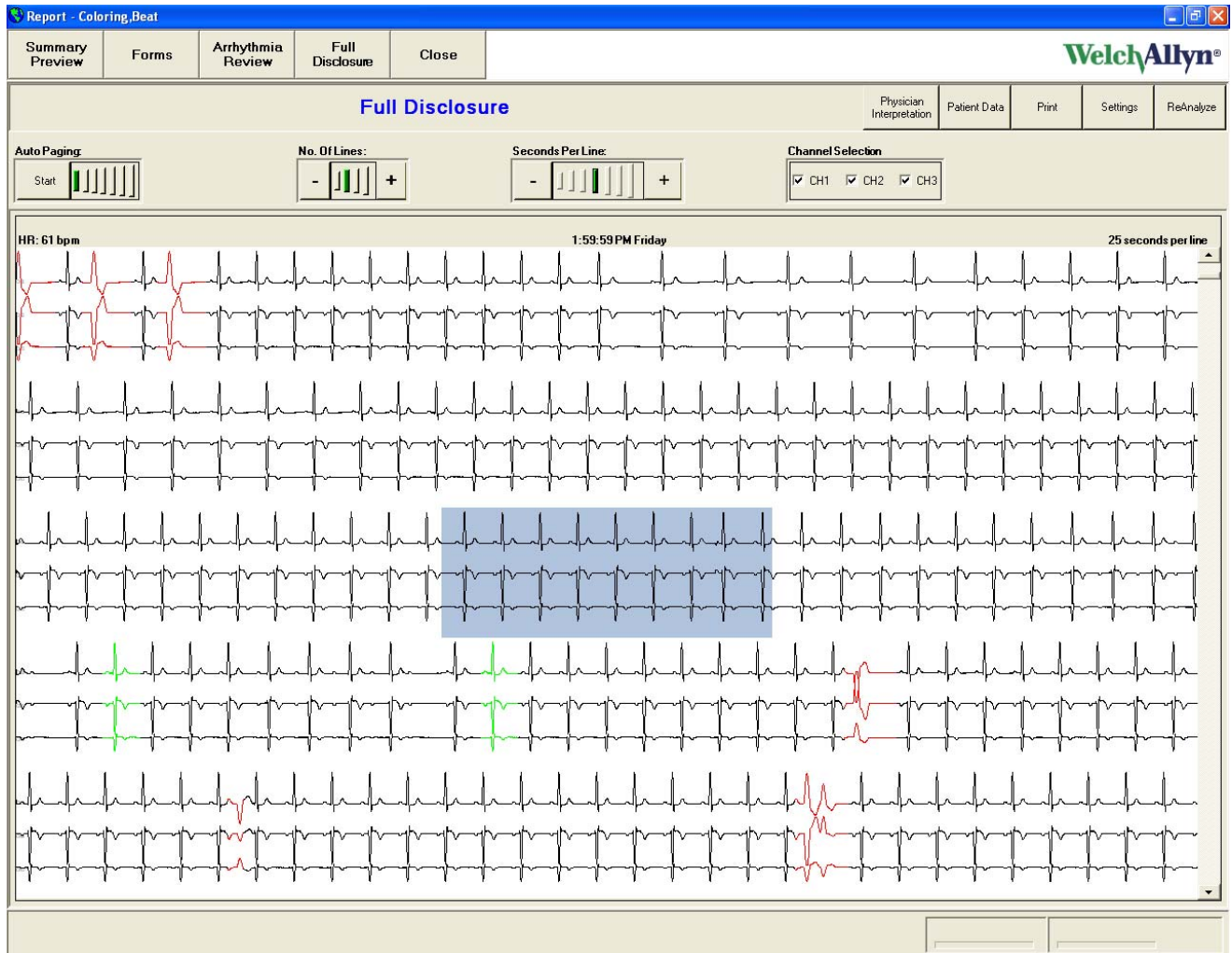
Final Preview of Report Before Printing

Under Summary Preview, the Preview Report Strips provides a review of all the ECG strips selected to be included in the report. Add additional comments or delete strips as required.

Under Summary Preview, the summary provides a review of the strips selected to be included on the summary page. All strips selected within Preview Report Strips are available based on the category for selection under this tab.

Confirm the final report using the Confirm tab. Using the Confirm tab changes the status of the record.

Settings

Report Format screen options

Print format

Select report pages for the standard report.

To print the report immediately after the test data has been transferred from the recorder, check **Auto Print Report on Download**.

To print the report in color check Print In Color.

To print RR intervals on a diagnostic strip check Show RR on Diagnostic Strip.

To print narrative summary on the summary page check Show Narrative Summary, if this is unchecked the summary information will be printed in a tabular format.

Other Strip Settings

Select the number of automatically generated strips.

Manage pre-defined user strip labels.

To sort the strips according to strip times check Strip Time Order Sorting.

ECG Data format

Select Strips - Mini (8 strips per printed page) or Diagnostic (2 per printed page).

Select Beat label annotations, i.e., N, S, P, X for display and printouts.

Select Channels included on a full disclosure printout

Select 10, 30, or 60 seconds per line on a full disclosure printout.

Patient demographics required

Set mandatory entries required by the Test Start Wizard.

Strip setting

Set desired gain per channel.

Facility

Set name and logo to be printed on the top left and right of the cover page.

Clinical Settings

See the Physician's Guide for more information.

Table 7. Clinical Settings specifications

Clinical Settings	Range	Default
Pause	1.0 – 5.0 seconds	2.0 seconds
Tachycardia	80 – 250 BPM	100 BPM

Table 7. Clinical Settings specifications

Clinical Settings	Range	Default
Bradycardia	20 – 119 BPM	60 BPM
ST Depression	0.1 – 5.0 mm	1.0 mm
ST Elevation	0.1 – 5.0 mm	3.0 mm
ST Duration	1 - 180 seconds	60 seconds
ST Reset	1 – 180 seconds	60 seconds
SVE Prematurity	10-100 percent	25 percent
SVE Atrial Tachy	30-150 BPM	80 BPM

User Administration options

Setup user logins and authority levels here.

New	Add new user (user first and last name). Limit 40 characters. Maximum of 20 users are allowed. The system prompts when max number is reached.
User ID	Limit 20 characters.
Edit	Edit user selected in list.
Disable/Enable User	Turn user access off or on for user selected in list.
Reset Password	Reset user selected password for user selected in list. The new password generated will be the same as your user name and requires change upon login.
Enable Administration	Check box "unchecked" allows access without user login.

System Settings Tab

Select:

- Medications and indications
- Recorders to be used
- Filters

Summarize settings

⚠️   **Caution**   Using report summarization deletes the full report and raw data.

To reduce file size, summarization converts a report (not including full disclosure) to a pdf (4 to 6 MB typical). A list of summarized reports displays in the Inbox (PCH100) or the File Cabinet (PCH200) with a summarized status.

Available triggers used to automatically summarize a report include:

- Customer Initiated – Summarize button available from the Inbox for the PCH100, and from the filing cabinet in the PCH200.

- Automatically by a programmable age threshold

- Automatically when confirmed

- Check boxes allow user to configure which report pages to send and select strip format
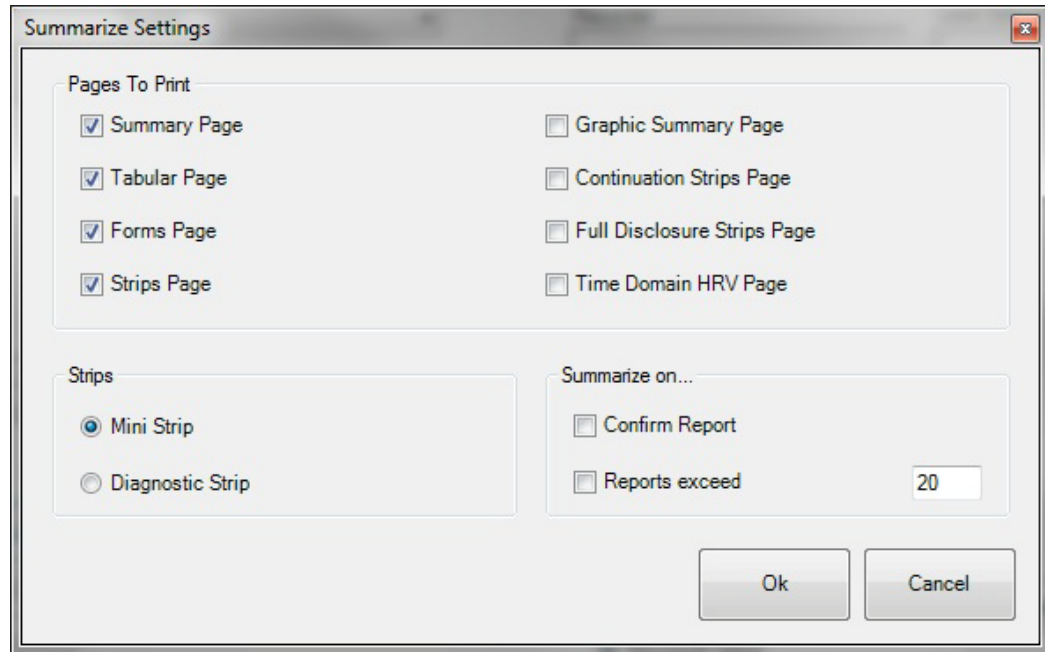
Export for EMRs

This feature exports a pdf of the final report to an Electronic Medical Records (EMR) system.

- Export for EMRs Settings Dialog
    - Define output directory
    - Remove Image Output directory
    - Add Page selection check boxes
- "Test Date" is set on the creation of a new Test
- "Interp Date" is set on "New Interpretation," and "Update to a test"
- The exported file name is a concatenation of substrings, where each substring is separated by a delimiter. The substrings used to build the exported file's name is configured by selecting which items from the list below will be used. The delimiter used to separate each substring can also be configured:
    - Test Type
    - Patient ID
    - Last Name
    - Test Date and Time
    - Test ID
    - Interpretation Date and Time
    - The file delimiter character

- Triggers

  - Initial report upload

  - Automatically when confirmed

  - Automatically if the report has been changed or interpretation modified

- Check boxes allow user to configure which report pages to send and select strip format.

- Check box allow user to enable/disable Cardio perfect work station communications.

Email configuration functionality

This feature provides a mechanism to Email a PDF of a final report.

- EMAIL Setting Dialog

  - Outgoing Email Server: (SMTP address for example; "smtp-server.twcny.rr.com")

  - Outgoing User Name: (Only required if SMTP servers requires user authentication—leave blank if not required.)

  - Outgoing User Password: (same as User name)

  - Check boxes allow user to configure which report pages to send and select strip format

  - **Send Test Email Message** sends an email to a specified user. This can be used to make sure email settings are working properly.

- Email activation in Inbox or File Cabinet

The Email dialog box includes standard **TO**, **CC**, **Subject**, and **Attachment** fields.The attachment: name for the attached PDF file automatically includes the patient ID.

Backup and Recovery.

For the PCH100, a Backup and Restore feature is provided through the System Settings. The backup allows the database, and optionally the data files, to be copied into a separate folder that is time stamped. The restore process can be used in the case of an error or a corrupted database. The restore process will restore information from previous backup.

It is highly recommended that Backups are performed on a regular basis to prevent lost of data. (Note: backups should be performed by those with suitable maintenance and software knowledge).

To perform the backup, first select a directory that the files will be copied to (by default the folder path is the ApplicationInstallFolder\Data\Backup where Application InstallFolder is the folder location of the application). Database files will always be backed up but optionally the "Backup Data Files" can be chosen to also copy all of the data files in the system (Note: data files take up a large amount of space so it is important to choose a sizable hard drive for this operation). Once all the options are selected hit the Backup button and the lower "Status" region will show progress until the process has completed.

To Restore from a backed up database and/or data files begin by browsing to the folder location chosen for the backup. After a folder is selected, the "Database" list will be updated with all databases it finds in the folder. Select the correct database from the list then choose whether to restore the database, the data files or both. Complete the process by clicking the Restore button. Progress will be shown in the lower "Status" region prompting the user with successes or failures. After the restoring a database, close the window and the application will automatically shut down and will need to be restarted for changes to take affect.

Physician's Guide

Overview

The Welch Allyn Holter System performs analysis up for to 48-hour of ECG digital data as a continuous segment of data. The analysis processing consists of the following sub-processing components:

- Signal Conditioning.
- QRS Detection and Feature Extraction.
- Clustering.
- Beat Classification.
- Heart Rate Calculation.
- ST Measurement.
- Pattern Determination.
- Strip Determination.

The analysis program consists of two major stages. The first stage, main analysis, is responsible for QRS detection, classification, feature extraction, and clustering.
The second stage is responsible for pattern, tabulation, and strip determination.
This stage is commonly referred to as a re-compile process. During a full analysis, both the main analysis and re-compile stages are executed. The full analysis will typically take two minutes to analyze a 3-channel, 24-hour recording. The Re-compile typically takes only seconds. The Re-Compile occurs multiple times, usually after the clinician has performed edits. For instance, if the clinician changes the hookup time to a different hour or minute, the recompile process would re-tabulate the results based on the new time. Other edits that could trigger a re-compile include:

- ST Episode threshold changes.
- SVE prematurity threshold changes.
- Pause threshold changes.
- Brady and Tachy threshold changes.
- Form Edits.
- Beat Edits.

Signal Conditioning

The signal processing performed during the analysis is used to remove some of the noise and artifacts normally found during an ambulatory recording. The following types of noise and artifacts may occur:

- Drift - gradual baseline wander usually caused by respiration.
- Shift - sudden baseline changes in electrode skin impedance or external contact to electrode site.
- Rail - amplitude saturation of the signal.
- Continuous noise of a single frequency- usually associated with high electrode impedance and mains 50 or 60 Hz interference.
- Burst of noise- usually several frequencies mixed together due to electrical signals from active muscles.
- Spikes- large amplitude shifts of a short duration.

The analysis program applies a collection of several filters to correct for these types of issues. These filters are optimized for the specific sub-process requirements.

QRS Detection and Feature Extraction

The analysis program detects each QRS for each channel. Each detected QRS has several locations identified including Isoelectric, Q, R, S and ST points. From these locations, additional measurements are made for the width, height, morphology, ST Level, and noise assessment.

Clustering

The analysis program groups beats based on morphology related information. The clusters created are based on which channels are active. For instance, a single channel event in Ch 1 would only be grouped with other single channel events.

Beat Classification

The beat classification is performed by evaluating QRS detections, features, R-R intervals, clustering information and noise assessment. The outcome of the classification results in the following beat types:

- Normal
- Ventricular
- Supraventricular
- Artifact

Heart Rate Calculation

The analysis program assigns an R-R interval to each detected QRS based on the time interval to the last labeled QRS. A QRS can be assigned with an unknown R-R interval if the region between the last detected QRS and current QRS contains artifact classifications. Artifact regions can be automatically classified by the analysis program or labeled through clinician editing.

The heart rate calculation is reported on each beat. The heart rate for a specific beat is based on the average of 9 R-R intervals centered on the specific beat. This would require the 4 previous R-R intervals, the current beat R-R interval and the next 4 R-R intervals. A valid heart rate will require at least 5 out of 9 valid R-R intervals. If the heart rate cannot be calculated, it will be assigned as an unknown heart rate.

The heart rate errors associated with one false positive detection (interpolated noise) would be a +12.5% increase in reported heart rate. A false negative detection (missed beat) would result in a -10% error in reported heart rate. The duration of time required to correct the heart rate calculation would be 9 beats.

The HR is displayed for each strip and it represents the HR for the beat closest to the center of the strip. If the clinician selects another beat in the strip, its HR values will be displayed. If the HR cannot be calculated, it will be displayed as a --- value.

The HR displayed in Full Disclosure refers to the HR value found for the highlighted strip. This HR value is based on the HR of the beat closest to the center of the strip. Refer to Strip HR above.

ST Measurement

The ST Level is measured on normal beats with a width less than 110 msec. The ST level is measured on each channel based on the delta between the isoelectric point and ST Level point. The Isoelectric point is defined as an average of points between P and Q. The ST Level point is a rate sensitive offset relative to the R-wave.

ST Episodes are determined by summing the average ST level over a period of time. Once the average ST Level exceeds the clinician selectable threshold, a ST Episode will be started. The end point of the ST Episode is determined when the average level falls below the clinician selectable threshold. A valid ST episode is reported when the length of the ST episode exceeds the clinician selectable threshold. If a second ST episode starts within the ST Reset threshold, the second ST episode is considered as part of the previous episode.

The clinician has separate ST Elevation and ST Depression thresholds. During each ST episode, the location of the maximum average values is maintained. The analysis program does not identify ST slope levels. The clinician can review the ST strip examples to determine if the ST segment slope is up, down or flat.

ST episodes are determined for each channel and for Elevation and Depression. These ST episodes are sorted based on maximum level of depression or elevation and automatically presented as strips within the report. The strip time reflects the time of maximum depression or elevation. The duration of the ST episodes, ranges of displacement, or heart rates are not reported.

Pattern Determination

The analysis program detects the following ventricular pattern types. N represents any normal beat including S beats.

Table 8. Ventricular events patterns

Ventricular Event Type	Pattern
Isolated	N-V-N
Couplets	N-V-V-N
Runs (three or more Ventriculars)	N-V-V-V-N
Bigeminy	N-V-N-V-N-V-N

Supraventricular detection is based on normal beats only. The normal beat must be premature to the previous normal beat or to the running NN average rate. The prematurity threshold is configurable. The analysis program detects the following supraventricular pattern types:

Table 9. Supraventricular events patterns

Supraventricular Event Type	Pattern
Isolated	N-S-N
Couplets	N-S-S-N
Runs (three or more Supraventriculars)	N-S-S-S-N

The analysis program detects the following Rate related patterns:

Table 10. Rate related patterns

Event	Definition
Tachy Episodes	15 seconds or more of heart rate that exceeds the Tachy Threshold (user configurable)
Brady Episodes	15 seconds or more of heart rate that exceeds the Brady Threshold (user configurable)
Pauses	any valid R-R interval that exceeds the Pause Threshold (user configurable)
Min HR	time of minimum heart rate reported for entire procedure
Max. HR	time of maximum heart rate reported for entire procedure
Min R-R	beat with the shortest R-R coupling interval reported for entire procedure
Max R-R	beat with the longest R-R coupling interval reported for the entire procedure

The analysis program does not automatically:

- **Detect Atrial Fibrillation and Flutter.** View Pause Review, Supraventricular Review, Rate Graphs Review, and Full Disclosure as an aid to identify these types of Arrhythmia patterns.

- **Detect Ventricular Fibrillation and Flutter.** View Arrhythmia Review and Full Disclosure as an aid to identify these types of Arrhythmia patterns.

- **Detect and classify any Intraventricular conduction defects.** View Forms Review, Arrhythmia Review, and Full Disclosure as an aid to identify these types of Ventricular conduction defects.

- **Measure P-R interval or produce any automatic classifications of any Atrio-Ventricular (AV) blocks.** View Pause Review, Supraventricular Review, Rate Graphs Review and Full Disclosure as an aid to identify these types of AV conduction defects.

- **Identify Paced beat.** A green pacer mark is provided by the program to identify the presence of a pacer firing detected within the recorder. The clinician may reclassify beat or forms as Paced.

Strip Determination

The analysis program selects automatic strip examples based on the following categories:

- Ventricular Isolated (2)
- Ventricular Couplets (2)
- Ventricular Runs - selected based on longest run (4)
- Supraventricular Isolated (2)
- Supraventricular Couplets (2)
- Supraventricular Runs - selected based on longest run (4)
- Pauses - selected based on longest pause (4)
- Tachy - selected based on highest Tachycardia Rate (2)
- Brady - selected based on slowest Bradycardia Rate (2)
- Max. Heart Rate - selected on maximum Heart Rate (1)
- Min Heart Rate - selected on minimum Heart Rate (1)
- ST Elevation per channel - selected on maximum average ST Elevation found (2 per channel)

- ST Depression per channel - selected on maximum average ST Depression found (2 per channel)

Report Content

The Analysis program provides results in several different formats. The application provides a sample report (MIT 219) you may print to help you understand the report content described below. Each report contains a header and footer that describes patient, date and time of procedure, current clinical settings, and other data. Each report page is sequentially numbered.

Summary Page

The Summary page contains a section with Patient detail information. This page contains examples of the most severe arrhythmia categories. Pauses, Ventricular and Supraventricular examples are presented as a mini strip format. Adjacent to each strip is some numerical information relative to that pattern category. Both Ventricular and Supraventricular Runs present numerical information for the Longest, Slowest and Fastest Run. The Longest refers to the ventricular run with the largest number of ventricular beats. Slowest and Fastest refer to Runs that contain the highest and lowest Ventricular or Supraventricular Heart Rate. The Ventricular Heart Rate is based on the average Heart Rate of all ventricular beats within the run. Supraventricular heart Rate is based on the Heart Rate of all Supraventricular beats within the run.

Tabular

The tabular page(s) contains hourly information as well as procedure total related information. It contains 25 hours to allow for a partial hour at the beginning and end of the recording. The tabular contains hourly counts for:

- Minimum Heart Rate
- Average Heart Rate
- Maximum Heart Rate
- Total QRS count
- Ventricular Run Count
- Ventricular Couplet Count
- Ventricular Isolate Count
- Total Ventricular Count
- Ventricular /1000
- Supraventricular Run Count
- Supraventricular Couplet Count
- Supraventricular Isolated Count
- Total Supraventricular Count
- Total Pause Count

Strips

The hard copy strips are presented in two different formats including diagnostic and mini format. The diagnostic page contains two strips that are full scale. The Mini strips are organized as 4 rows of two columns. Calibration marks are provided at the left side of the strip. This calibration mark represents a 1-millivolt amplitude signal in the strip.
The clinician can select different scaling factors of x0.25, x0.5, x1.0, x2.0 and x4.0.

The calibration width represents a 100 msec marker. Diagnostic strips contain additional tick marks that are 3 seconds apart. These markers are located at the top of each diagnostic strip presentation. Each strip contains the time of day, day of the week, strip type and heart rate at a minimum. For some types of strips, additional information is presented such as Pause duration, ST Level and Run length with Run heart rate.

Forms

The Forms Page represents the form or clusters that were created. Each form indicates a form count, form classification, and the number of beats in the form. A representative example is shown for each form. Forms can be based on any combination of channels processed.

Full Disclosure

The Full Disclosure can be printed out in several different formats of 10, 30 and 60 seconds per line. Channel indicators are displayed in the lower right footer to indicate which channels are used.

Welch Allyn Service Policy

All repairs on products under warranty must be performed or approved by Welch Allyn. Unauthorized repairs void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by Welch Allyn certified service personnel.

If the product fails to function properly—or if you need assistance, service, or spare parts—contact the nearest Welch Allyn Technical Support Center. For phone numbers, see page ii.

Before contacting Welch Allyn, try to duplicate the problem, and check all accessories to ensure that they are not causing the problem. When calling, please be prepared to provide:

- Product name and model number and complete description of the problem.
- Serial number of your product (if applicable).
- Complete name, address and phone number of your facility.
- For out-of-warranty repairs or spare parts orders, a purchase order (or credit card) number.
- For parts orders, the required spare or replacement part numbers.

If your product requires warranty, extended warranty, or non-warranty repair service, please call first the nearest Welch Allyn Technical Support Center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary returns.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) number, as well as the appropriate return address. An RMA number must be obtained prior to any return.

If you have to return goods for service, follow these recommended packing instructions:

- Remove all cables, sensors, and ancillary products (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible use the original shipping carton and packing materials.
- Include a packing list and the Welch Allyn Return Material Authorization (RMA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

Maintenance

The PCH100 and PCH200 Holter software requires no calibration.

Please note for the maintenance and cleaning instructions in the documentation for your computer.

For maintenance of the computer on which the PCH100 or PCH200 Holter system is installed, the following programs are regularly carried out:

- Virus protection software
- Software to detect spyware
- Microsoft Windows updates
- Backup (see "System Settings")

Cleaning the Recorder and Patient Cable

Note: The HR100 / HR300 / HR1200 Holter Recorders do not require calibration.

For maintenance and cleaning procedures, refer to the documentation that came with your computer.

WARNING   Keep the recorder and patient cable clean, especially the components that touch patients.

Caution   Do NOT use acetone, ether, freon, petroleum derivatives, or other solvents to clean the recorder.

Caution   Do NOT let soap or water come into contact with the battery contacts or patient connector pins.

Caution   DO NOT submerse, autoclave, or steam clean the recorder or the patient cabling.

Cleaning Instructions

1. Remove the battery or batteries and close the battery cover.
2. Wipe the Holter recorder exterior and accessories with a damp cloth. Use mild detergent diluted in water.
3. Dry with a clean, soft cloth or paper towel.
4. Reconnect the patient cable to the recorder.
5. Clean the Patient Cable in the same manner before each procedure.

Inspecting the Recorder

WARNING   Inspect patient cable, patient leads wires, LED or LCD window, and enclosure for cracks or breaks before each use.

Before performing a Holter procedure:

1. Inspect the patient cable, patient lead wires, LED or LCD window, and enclosure.

2. Verify that the patient cable is fully inserted.

Testing the Recorder

Whenever the recorder is serviced or problems are suspected, perform these test procedures:

1. Verify that the recorder is working properly, using an ECG simulator to acquire a standard ECG of known amplitude (7-lead for HR100 and HR300, 12-lead for HR1200).

2. Upload the ECG data to the workstation and verify the waveforms appear normal, with proper amplitude, and without distortion or excessive noise.

Storing the Recorder

Remove the batteries before storing the recorder. Observe the environmental storage conditions. See "Technical Specifications" on page 49.

Discarding the Equipment

Discard the recorder and accessories according to local laws.

Please follow the state's recycling laws or your facility's recycling policy to ensure proper disposal of the recorder and accessories. For more information on recycling, call the Environment Protection Agency or local authorities.
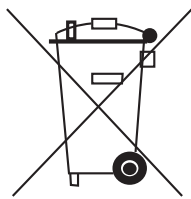
Attention: Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. See www.welchallyn.com/weee.

Technical Specifications

Deviations from the range of specifications stated below may result in device performance degradation.

Table 11. Holter Recorder Characteristics

Characteristic	HR 100	HR 300 & HR 1200
Length	3.8 in (96.5 mm)	4.4 in (112 mm)
Width	2.2 in (56 mm)	3.1 in (78 mm)
Height	0.7 in (18 mm)	1.4 in (36 mm)
Weight with battery (or batteries) and patient cable	7 oz. (198 g)	14 oz. (396 g)

Table 12. Operation

Power source	AA (size LR6) Alkaline battery or batteries
Recording period	up to a 48-hours continuous Minimum 5 days (HR300-XXXXX R only)
Storage capacity	SanDisk® 256 MB Secure Digital (SD) card for 200 sps (HR100, HR300, HR1200) SanDisk® 1 GB ULTRA II SD card for 200 sps (HR100) SanDisk® 1 GB ULTRA II SD card for 200, 500, 1000 sps (HR300, HR1200) SanDisk® 2 GB ULTRA II SD card for 200, 500, 1000 sps (HR1200) FAT file format recommended for SD Card sizes 2 GB and less
Storage period	Data remains valid for >5 years or until SD card is initialized
Battery Life	minimum of 24-hours
Pacemaker Detection	ANSI/AAMI EC38-1998
Effective A/D bit Resolution	0.5 uV
Dynamic Range	+/-300 mV
Frequency Response	0.05 Hz to 100 Hz
Sampling Rate	HR100 200 sps HR300 128 sps (HR300-XXXXX R only) HR300/HR1200 200, 500, 1000 sps
User Adjustable Parameters	None
Applied Currents	HR100 None HR300 None HR1200 Lead connection failures are detected by a 0.4 V bias, which is applied to each patient electrode connection through a 40 Mohm ohm resistor with respect to the reference electrode.

Table 13. Environmental Specifications

Operating Temperature	32° F to +113° F (0° to 45° C)
Storage Temperature	-4° F to +149° F (-20° to +65° C)
Operating Humidity	5 to 95% non-condensing
Storage Humidity	5 to 95% non-condensing
Operating Altitude	-500 to 15,000 ft (-150 to 4500 m)
Storage Altitude	-500 to 50,000 ft (-150 to 15500 m)
Operating Shock	2.95 in (75 mm) drop to hard surface on any axis
Storage Shock	31.5 in (0.8 m) drop to hard surface on any axis
Operating Vibration	0.0002 G2/Hz from 5 to 350 Hz, ramping to 0.0001 G2/Hz from 350 to 500 Hz, random vibration spectrum, 10 minutes in each of three orthogonal axes.
Storage Vibration	Packaged recorder and accessories survived standard drop and vibration procedure published by the National Safe Transit Association, pre-shipment test procedure, March 1977.

Table 14. Protection against ingress of water

Holter recorder	No protection against water ingress
Patient Cable	No protection against water ingress

Table 15. Device Classification

AECG Device Type	Type I
EMC	Class IIb
IEC Type	Type BF

Table 16. Software Technical Specifications

Specification	Value
Rate	30 to 250 BPM
QRS Detection amplitude	≥ 0.5 mV
Analysis Channels	any combination of up to three channels
Report Durations	up to 48 hours
Pacemaker Detection	ANSI/AAMI EC38-1998
A/D bit Resolution	0.5 µV
Sampling Rate	200 sps, 500 sps, 1000 sps
Mains Filter	50, 60 Hz, off (default=60Hz)
Muscle Filter	35, 60 Hz, off (default=off)
Baseline Filter	0.5 Hz, off (default=off)

Table 17. Bluetooth Protocol

FREQUENCY RANGE	2402-2480 MHZ
PEAK OUTPUT POWER	-11dBm (EIRP)
EMISSION DESIGNATOR	864K F1D
RATED POWER	0 dBm
MODULATION	GMSK

Conformance to Regulatory Standards

International Electrotechnical Commission

- CAN/CSA C22.2 No. 601.1-M90

- IEC 60601-2-47, 2001

- USA: UL60601-1

- IEC 601-1-2, conforms to EN 55011

- EN 61000-4-2:1999

- EN 61000-4-3, 1995

- EN 61000-4-5, 1995

American Advancement of Medical Instrumentation

- ANSI/AAMI EC38-2007

Accessories

To order accessories, call Welch Allyn Technical Support as listed on page ii.

Table 18. Accessories

Item	Part Number
3-channel Holter hook-up kit (including two (2) 1.5 V AA batteries, patient diary, razor, abrading pad, alcohol prep pads, 7 disposable Holter electrodes and Disposable Pouch)	08113-0002
5 Lead Patient Cable, AHA, HR 100	704545
5 Lead Patient Cable, IEC, HR 100	704546
5 Lead Patient Cable, IEC, HR300 (HR300-XXXXX R only)	711059
7 Lead Patient Cable, AHA, HR 100	704547
7 Lead Patient Cable, IEC, HR 100	704548
7 Lead Patient Cable, AHA, HR 300 & HR 1200	704549
7 Lead Patient Cable, IEC, HR 300 & HR 1200	704550
10 Lead Patient Cable, AHA, HR 1200	704551
10 Lead Patient Cable, IEC, HR 1200	704552

Electromagnetic Emissions and Immunity Information

Electromagnetic Emissions

The Welch Allyn Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn Holter Recorder should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 2	The Welch Allyn Holter Recorder must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Welch Allyn Holter Recorder is suitable for use in all establishments, including domestic establishments. The recorder has no connection to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity

The Holter recorder is intended for use in the electromagnetic environment specified below. The customer or user of the Holter 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	Not applicable.	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable.	
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 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	Not applicable.	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable.	

Note: U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic Immunity

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

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

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

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

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

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Holter recorder

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

Rated Max. Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = (1.17)\sqrt{P}$	**80 MHz to 800 MHz** $d = (1.17)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (2.33)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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.

FCC information

⚠️ **WARNING** For patients with a pacemaker, maintain a minimum of 6 inches between the recorder and pacemaker. Turn the recorder off immediately and provide appropriate patient care if you suspect the recorder affected the pacemaker. The Health Industry Manufacturers Association recommends a minimum 6-inch distance between a wireless radio and a pacemaker, which is consistent with the recommendations of Wireless Technology Research. The wireless radio is active for the first 15 minutes of the procedure only.

The HR100/HR300 device contains FCC ID: ED9LMX9820ASM or FCC ID: POOWML-C40.

The HR1200 device contains FCC ID: POOWML-C40.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

- This device may not cause harmful interference.

- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communication. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

Troubleshooting

If the Holter System Application malfunctions, you may be able to resolve the issue with little loss of time and expense. We suggest following the troubleshooting guidelines below before returning the unit for servicing.

Contact Welch Allyn Customer Support (see page ii).

Table 19. Lead Quality Problems

Condition	Cause	Actions
General Poor Waveform quality	1, 2, 3, 4, 5	See Table 20 .
AC interference (even-peaked, regular voltage superimposed on the waveforms). May resemble or coincide with muscle-tremor interference.	1, 2, 3, 4, 5	See Table 20 . If AC interference persists, turn AC Filter on. See "System Settings Tab" on page 36.
Muscle tremor interference (random irregular voltage superimposed on the waveforms). May resemble or coincide with AC interference	1, 2, 3, 4,	See Table 20 . If muscle tremor interference persists, turn Muscle Filter on. See "System Settings Tab" on page 36.
Wandering baseline (an upward and downward fluctuation of the waveform)	1, 2, 3, 4,	See Table 20 . If wandering baseline persists, turn baseline filter on. See "System Settings Tab" on page 36.

Table 20. Lead Quality Problems Causes and Actions

	Cause	Action
1	Electrodes positioned on a bony area.	Reposition electrodes.
2	Date Code on Hook-up kit expired. Check the expiration date on the Hook-up kit packaging.	Apply new electrode.
3	Insufficient or dried electrode gel	Apply new electrode.
4	Oily Skin or body lotions	Clean Skin with alcohol or acetone
5	Excessive hair on chest	Shave hair from chest prior to hookup
6	Poor skin preparation.	Remove sensor(s), repeat skin prep, select new position (see hookup procedure), and apply new electrodes.
7	Faulty patient cable	Replace patient cable.

Table 21. Analysis Errors

Condition	Cause	Action
Pause errors	Low Amplitude signal causing misdetection creating long coupling interval Pause threshold set too low Artifact prevents QRS detections creating long coupling interval.	Reposition electrode to increase signal amplitude. Check that Pause threshold set to desired threshold. See "Clinical Settings" on page 33.
Ventricular errors	Form Incorrectly classified Excessive noisy trace causes false interpolated beats Excessive noisy trace causes distortion of original QRS signal	Confirm that Form Classifications are correct and edit any that are not. Improve patient hookup prep. Perform beat edit to correct beat classification

Condition	Cause	Action
Supraventricular errors	Excessive noisy trace causes false interpolated beat Prematurity threshold in clinical settings set too low.	Confirm that Form Classifications are correct and edit any that are not. Improve patient hookup prep. Perform beat edit to correct beat classification
Incorrect Heart Rate	Excessive noisy trace causes false interpolated beat artificially elevating Heart Rate Low amplitude signal cause no detection - thus creating an artificially low Heart Rate	Improve patient hookup prep. Perform beat edit to correct beat classification.
Brady errors	Low amplitude signal causes no detection Brady threshold set too high	Improve patient hookup prep. Perform beat edit to correct beat classification. Check that Brady threshold set to desired threshold. See "Clinical Settings" on page 33.
Tachy errors	Excessive noisy trace causes false interpolated beat Tachy threshold set too low	Improve patient hookup prep. Perform beat edit to correct beat classification. Check that Tachy threshold set to desired threshold. See "Clinical Settings" on page 33.
ST Episodes errors	Isoelectric Point positioned on P-wave ST Level point positioned on T-wave	Delete Incorrect ST Episode strips from report.
Excessive Form Count	Excessive noisy traces causes distortion to QRS creating different clusters	Improve patient hookup prep. Evaluate whether a specific channel has a high degree of artifact and if so re-analyze turning off that channel. Note: re-analysis will lose any previous performed editing.

Table 22. Miscellaneous Problems

Condition	Cause	Action
Failure to upload report from recorder	SD Card Reader not plugged in SD Card Reader location has changed SD Card is corrupt SD Card upload was terminated before completion	Insert SD Card reader into USB port. Double-click over SD Card icon with question mark. This launches a dialog to search for SD card drive. Using Windows Explorer, format the SD using FAT and make sure no volume label is included. Restart the application to allow the report to be re-uploaded.
Test Startup (Wireless) - Cannot find recorder	USB Dongle not plugged in Recorder out of range > 5 feet Recorder does not have fresh batteries Radio Interferences from other signal sources Wireless Stack incorrectly configured.	Insert USB Bluetooth dongle. Recorder needs to be within 5 feet of the USB dongle. Replace battery in the recorder. For Windows 2000 Operating system confirm that the Wireless Stack is set to Widcomm. See **Service Personnel Only** section under "System Settings Tab" on page 36. For Windows XP with no other Bluetooth drivers installed, confirm that Wireless stack is to set to Microsoft. For Windows XP systems that have Bluetooth drivers installed confirm that wireless stack is set to Widcomm.
Test Startup (Wireless) - Fails to enter preview mode	Communication failed with recorder. Recorder out of range > 5 feet	Click Start button to try to connect again. Move recorder to within 5 feet of the USB dongle.
Project activation fails (Internet)	Internet access is blocked	Request temporary internet access from your IT staff. (Only required during activation.)
Project activation fails (Manual)	Invalid Manual release codes	Carefully re-type release code. Contact Welch Allyn customer support.

Condition	Cause	Action
Failed to print	Printer Off-line Printer out of paper Printer not connected	Confirm that printer is online. Confirm printer has paper. Confirm printer connected. Using another application, test the printer. Make sure proper printer is selected with application.
Failure during File transfer	Loss of network connection	User prompted to "Retry" or "Abort" "Retry" will attempt to reestablish network connection and continue to transfer file. "Abort" will lose all unsaved changes and exit the Holter Application.

Table 23. Holter Recorder Acquisition Errors

Recorder LCD displays the error code and Yellow LED (HR100) flashes the error code, pause for two seconds, and repeats. Remove the battery to repeat diagnostic tests.

Code LCD and LED	Description
E1	Not used
E2 - Initialize	Configuration error – recorder SD card contains data or awaiting Bluetooth initialization
E3 - BATT	Low/weak battery
E4 - SD Card	Secure digital card not detected
E5 - Call Service	Internal data processing error
E6 - Call Service	Power on self test failed
E7 - Call Service	Wireless data link error
E8 - SD Card	Error writing file to secure digital card
E9 - SD Card	Error reading file from secure digital card

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7. Governing Law. This License Agreement shall be construed and governed in accordance with the laws of the State of New York, USA.

8. No Waiver. The failure of either party to enforce any rights under this License Agreement or to take action against the other party in the event of any breach hereunder shall not be deemed a waiver by that party as to the subsequent enforcement of such rights.

Limited Warranty

Holter System Application, HR100, HR300 and HR1200 Holter Recorder and Accessories.

This product is sold by Welch Allyn under the warranties set forth in the following paragraphs. These warranties are extended only to the end user with respect to the purchase of this product directly from Welch Allyn or Welch Allyn's authorized distributors as new merchandise.

For a period of 1 year from the date of original delivery to the buyer, the recorder, software, and hardware components are warranted to be free from functional defects in materials and workmanship and to conform in all material respects to the description of the product contained in the Directions For Use and accompanying labels and/or inserts. For a period of 3 months this same warranty is made for accessories (including patient cables) provided by Welch Allyn. Warranty of accessories purchased separately from listed suppliers will be the responsibility of the listed suppliers.

This warranty is valid only if (a) all equipment is approved for use with the recorder by Welch Allyn and are installed according to instructions provided by Welch Allyn or its authorized distributors; (b) the product is properly operated under conditions of normal use in accordance with applicable safety and regulatory requirements; (c) replacements and repairs are made in accordance with the instructions provided by Welch Allyn; (d) only recorder or other software authorized by Welch Allyn is used on the workstation; (e) the product has not been configured, modified, adjusted or repaired other than by Welch Allyn or by persons expressly authorized by Welch Allyn, or in accordance with written instructions provided by Welch Allyn; (f) the product has not been subject to misuse, negligence or accident.

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