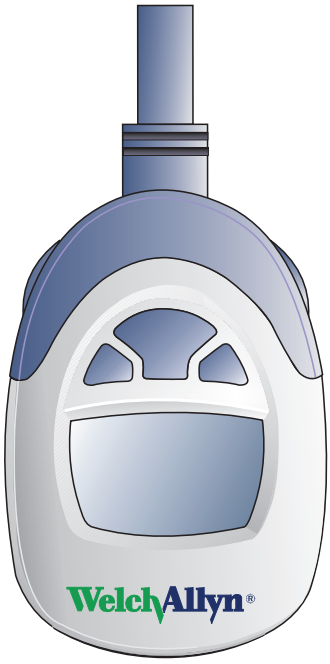
Holter Recorders
HR100/300/1200

HR100
Recorder



HR300 or HR1200
Recorder

Directions for Use

Welch Allyn®

Advancing Frontline Care™

Welch Allyn assumes no responsibility for any injury to anyone, or for any illegal or improper use of the product, that may result from failure to use this product in accordance with the instructions, cautions, warnings, or statement of intended use published in this manual.

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

Manual Material No. 704556

Global Instrumentation part number 004-700-0046 Ver. C

Manufactured for:

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

Manufactured by:

Global Instrumentation, LLC
8104 Cazenovia Road
Manlius, NY 13104

EC REP

Contract Medical International GmbH
Zur Wetterwarte 50, House 302
01109 Dresden
Germany
Tel.: +49 (0) 351 213 88 88
Fax: +49 (0) 351 213 88 99
Contact: European Regulatory Manager
E-mail: tlenihan@contract-medical.com

www.welchallyn.com

Printed in USA

Welch Allyn®

Contents

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 over a minimum 24-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.

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.

Indications for Use

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

Symbols

Warning. Read Carefully.

Caution / Notices. Read Carefully.

Attention: See instructions for use.

Patient Activated Event.

Meets or exceeds Council Directive 93/42/EEC, MDD, Class IIb

Type BF Medical Equipment.

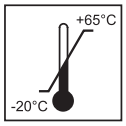
Battery Polarity. Use AA (LR6) Alkaline batteries.

Single use. Use materials labeled with this symbol once only.

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.



Temperature range. (see Technical Specifications)

Keep dry. (see Technical Specifications)

This end up.

Fragile, glass.

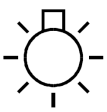
Serial Number.

Reference Number.

No Latex.

No PVC.

Keep from direct sunlight.



LED light.

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 Safety—Discard electrodes after one use.

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.

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 device 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.

Introduction

This manual is written for clinical professionals familiar with 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 for clinical applications
- setting up, configuring, troubleshooting, or servicing the recorder

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: LED (HR 100) or LCD window (HR 300 & HR 1200).
- Removable Secure Digital Memory Card for a minimum of 24-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.

HR 300 & HR 1200:

- Navigational keypad — enter, cancel, up, down, right, and left keys.
- LCD window provides ECG waveform views to ensure proper electrode connection.
- Time of day display.

Recorder Illustrations

Figure 1. HR 100 Holter Recorder

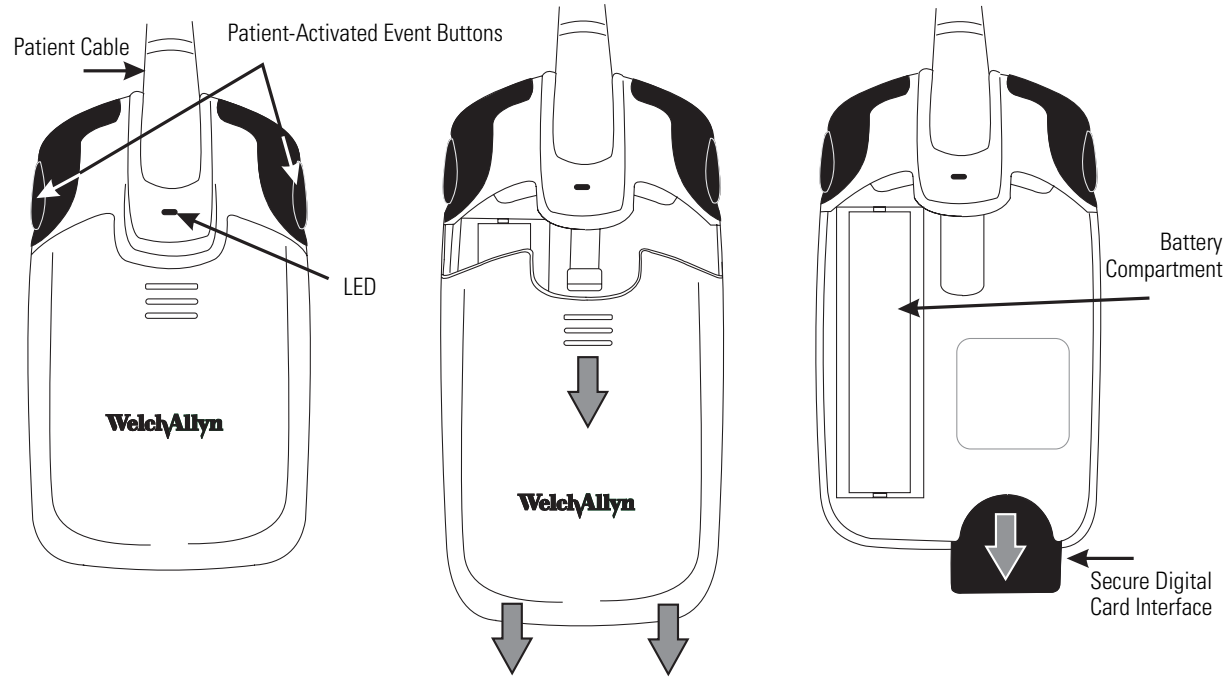
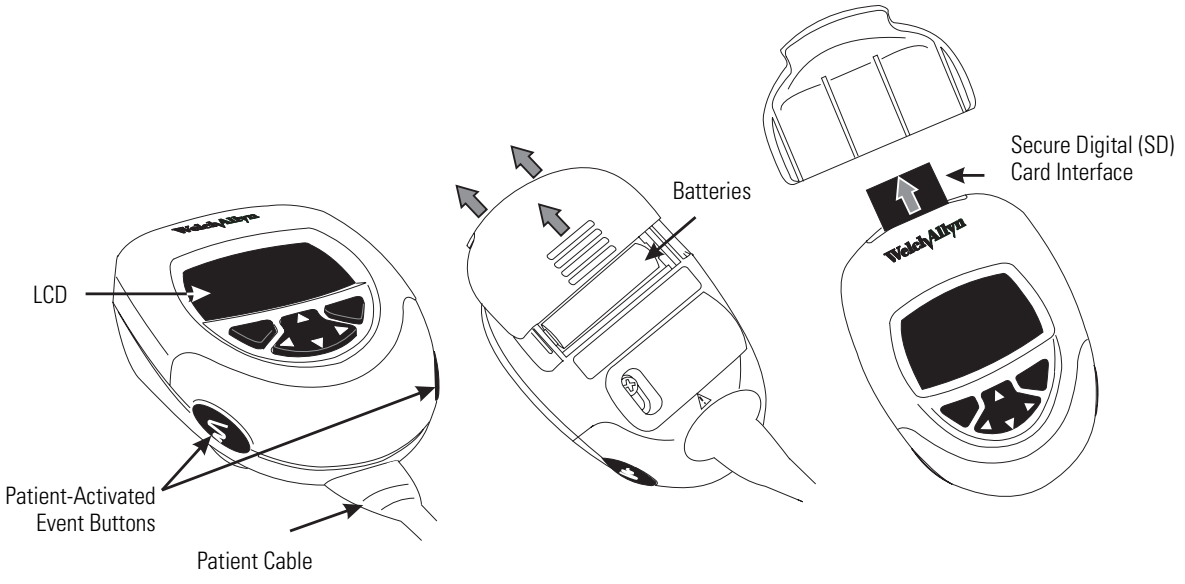


Figure 2. HR 300 & HR 1200 Holter Recorder



Operation

To Set the Time (HR 300 & HR 1200 only)

1. Remove the battery cover from the recorder (see Figure 2 on page 7).
2. Remove the Secure Digital Card from the Secure Digital port located at the rear of the device (see Figure 2 on page 7).
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 the hour digit is blinking.
5. 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 the hour and minute display. Once the time displays, remove the batteries.

To Start a Test

Use this procedure for SD Card only. For wireless operation, refer to the Holter System manual.

WARNING Inspect patient cable, patient leads wires, LED or LCD window, and enclosure for cracks or breaks before each use. See "Maintenance" on page 17 for more information.

1. Prepare the patient according to "Patient Preparation" on page 10.
2. Initialize the Secure Digital Card. Refer to the Holter System Application Directions for Use for the Secure Digital Card initialization procedure.
3. Remove the battery cover from the recorder (see "Recorder Illustrations" on page 7).
4. Insert the Secure Digital Card into the recorder's Secure Digital port located at the rear of the device (see figure 1).
5. Insert new AA alkaline (LR 6) battery or batteries. Note the polarity.
6. 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 26.
   - 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 26.
7. Place the recorder into the carrying case. Secure the carrying case and recorder on the patient.

8. 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 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.

Data transfer to the Workstation

Refer to the Holter System Application operating instructions for transferring the Holter procedure data to the Holter PC.

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

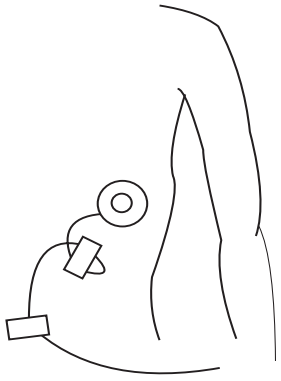
Caution Always ensure that the appropriate electrode placement is employed for the lead configuration selected.

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.

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 12 for 5-lead placement, Figure 5 on page 13 for 7-lead placement, Figure 8 on page 15 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). 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)

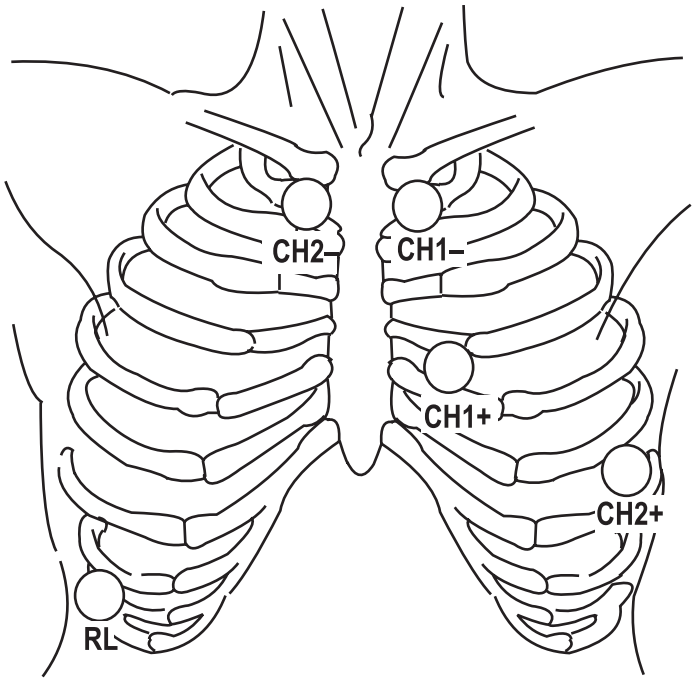


Table 3. 7-Lead Placement (all models)

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 midclavicular line
Ch3-	Blue	Blue	Manubrium sternum
RL	Green	Black	Lowest rib on right side of chest

Figure 5. 7-Lead Placement (all models)

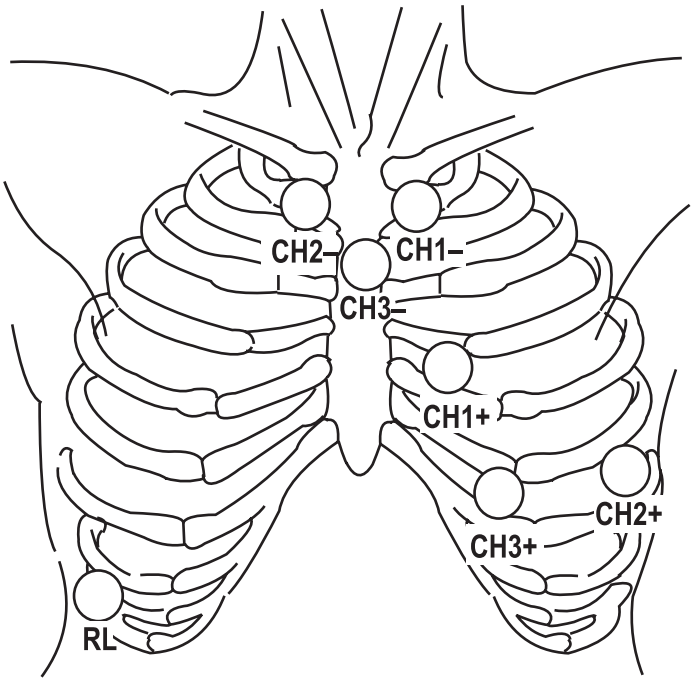
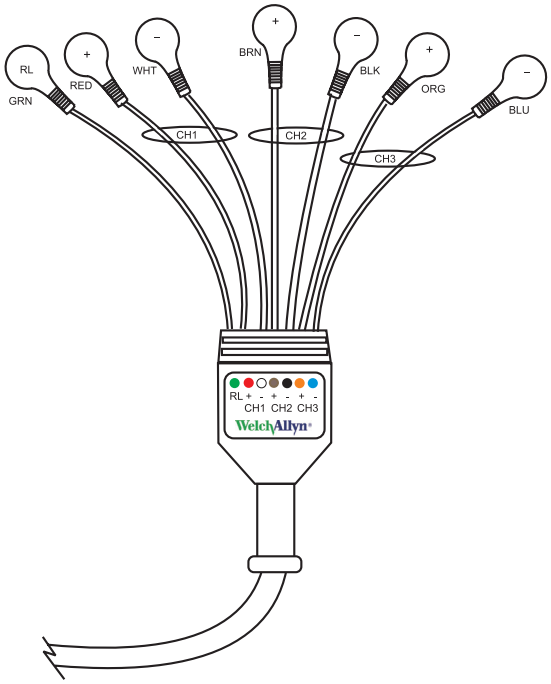


Figure 6. AHA lead cables



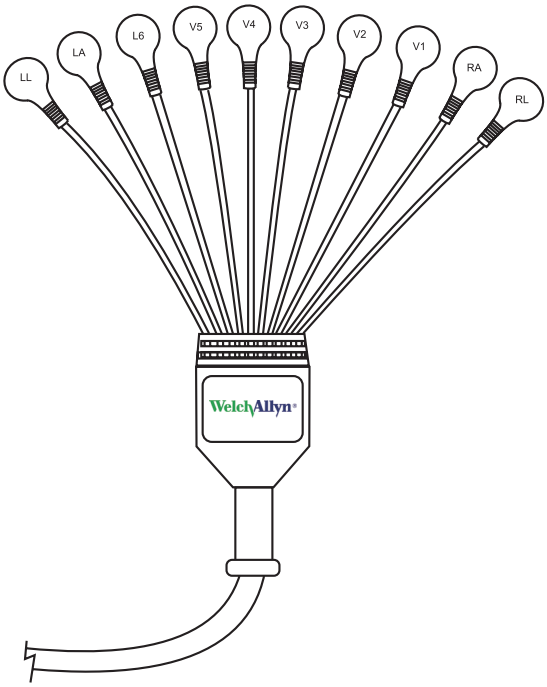
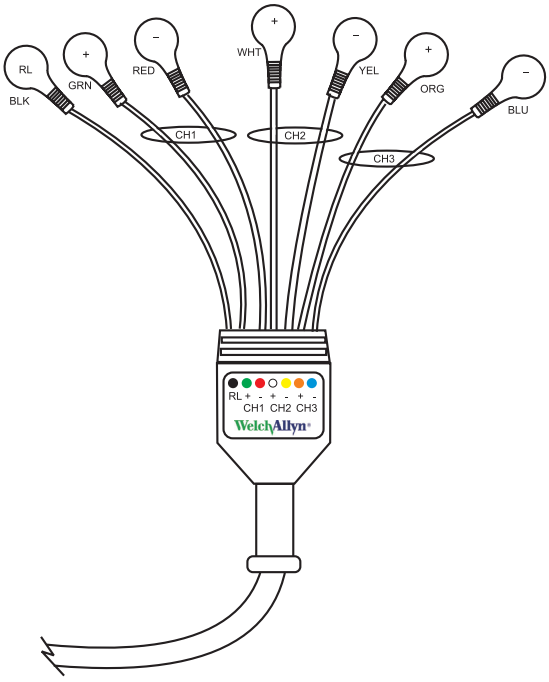


Figure 7. IEC lead cables



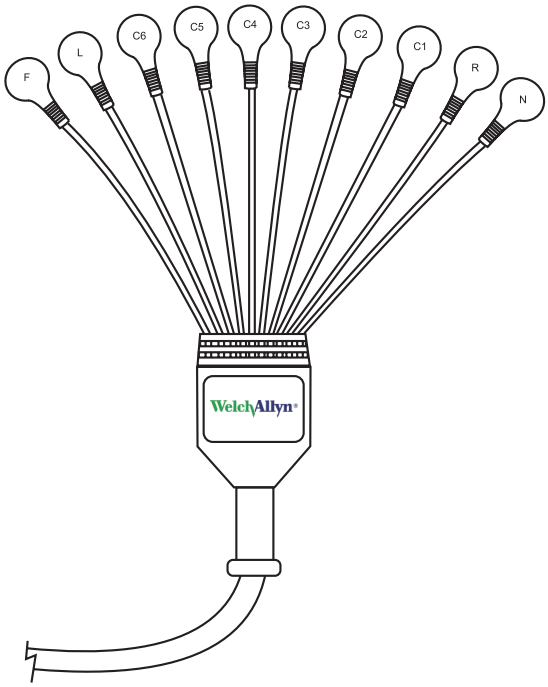
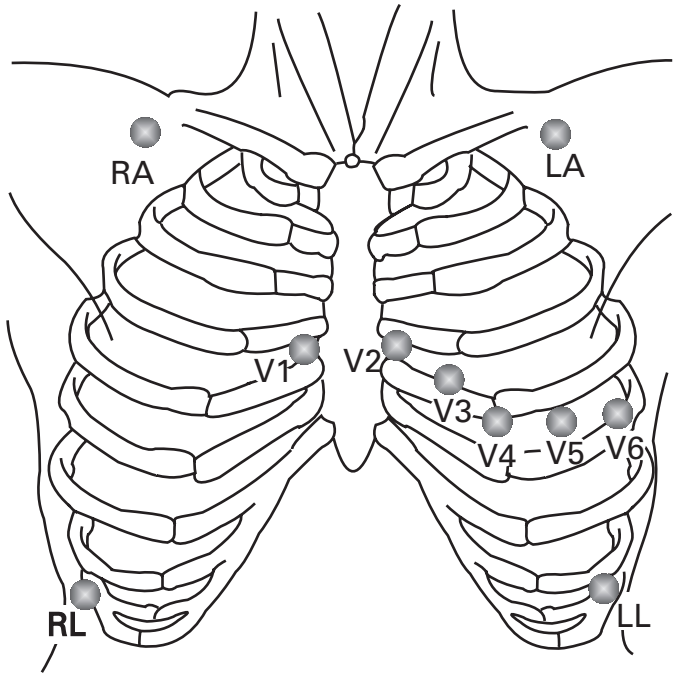


Table 4. 12-Lead Placement (HR1200 only)

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)



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

Cleaning the Recorder and Patient Cable

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.

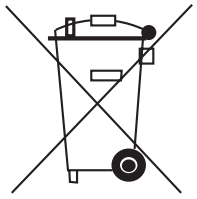
Storing the Recorder

Remove the batteries before storing the recorder. Observe the environmental storage conditions. See "Technical Specifications" on page 19.

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 5. 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)	10 oz. (283 g)

Table 6. Operation

Power source	AA (size LR6) Alkaline battery or batteries
Recording period	Minimum 24 hours continuous
Storage capacity	SanDisk® 256 MB Secure Digital (SD) card for 200 sps (HR100, HR300, HR1200) SanDisk® 1 GB Secure Digital (SD) card for 200, 500, 1000 sps (HR300, HR1200)
Storage period	Data remains valid for >5 years or until SD card is initialized
Battery Life	Minimum 24 hours
Pacemaker Detection	ANSI/AAMI EC38-1998
Effective A/D bit Resolution	0.5 uV
Dynamic Range	+/-330 mV
Frequency Response	0.05 Hz to 100 Hz
Sampling Rate	HR100 200 sps HR300/HR1200 200, 500, 1000 sps

Table 7. 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 8. Protection against ingress of water—compliant with IEC 60529

Holter recorder	IPX0
Patient Cable	IPX0

Table 9. Device Classification

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

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 EC38-1998 (Device is not defibrillator protected. This device does not support Defibrillator Protection requirements defined in section 4.2.5.2 of the requirement.)

Australian Electromagnetic Compatibility

- AZ/NZS 3200-1-0

Accessories

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

Table 10. 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
Holter electrodes, 500/case	45002-0000
Disposable Holter Pouch	08240-0000
5 Lead Patient Cable, AHA, HR 100	704545
5 Lead Patient Cable, IEC, HR 100	704546
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
HR 100 Carrying Case and straps	704553
HR 300 & HR 1200 Carrying Case and straps	704554
HR 100, HR 300, HR 1200 Belt/Shoulder Strap	704710
Holter operator's manual on CD	704556

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.

	Separation Distance According to Frequency of Transmitter (m)		
Rated Max. Output Power of Transmitter (W)	**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.

This device contains FCC ID: ED9LMX9820ASM.

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 unit malfunctions, use the tables below.

Table 11. Patient Preparation Errors

Patient Preparation Error	Probable Cause and Solution
No signal or low amplitude signal on the Holter System Preview ECG	Date Code on Hook-up kit expired. Check the expiration date on the Hook-up kit packaging. Poor skin preparation. Remove sensor(s), repeat skin prep, select new position (see hookup procedure), and apply new electrodes.

Table 12. Holter Recorder Acquisition Errors displayed on the LED (HR 100 only)

Recorder LED will flash yellow several times, pause two seconds, and repeat. Remove the battery to repeat power-up diagnostics.

Flashes on LED	Description
1	Not used
2	Configuration error – recorder SD card contains data or awaiting Bluetooth initialization
3	Low/weak battery
4	Secure digital card not detected
5	Internal data processing error
6	Power on self test failed
7	Wireless data link error
8	Error writing file to secure digital card
9	Error reading file from secure digital card

Table 13. Holter Recorder Acquisition Errors displayed on the LCD (HR 300/1200 only)

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

Limited Warranty

HR 100, HR 300, HR 1200 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.

Welch Allyn's sole and exclusive obligation, and buyer's sole and exclusive remedy under the above warranties, is limited to repairing or replacing, free of charge, a product which is reported to Welch Allyn customer service as listed on page ii. Welch Allyn shall not be otherwise liable for any damages including, but not limited to, incidental, consequential, or special damages.

There are no express or implied warranties which extend beyond the warranties in this document. Welch Allyn makes no warranty of merchantability or fitness for a particular purpose.

CE 0050

4341 State Street Road, PO Box 220, Skaneateles Falls, NY 13153-0220 USA
800 535 6663 www.welchallyn.com

Welch Allyn®

Advancing Frontline Care™

Manual Material No. 704556