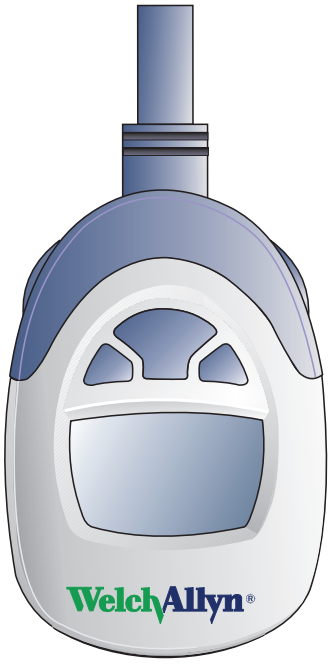
HR100 | HR300

Holter Recorders
HR100/300/1200

HR100
Recorder



HR300 or HR1200
Recorder

Directions for Use

WelchAllyn®

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:

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Manual Material No. 704556

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

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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

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.

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.

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.

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.

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.