

Welch Allyn®

H3+™

DIGITAL HOLTER RECORDER
USER MANUAL



Manufactured by Welch Allyn, Inc. Skaneateles Falls, NY U.S.A



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

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For patent information, please visit www.welchallyn.com/patents

For information about any Welch Allyn product, visit: <https://www.welchallyn.com/en/about-us/locations.html>

Customer Service and Technical Support: <https://www.welchallyn.com/en/other/contact-us.html> 1.888.667.8272, mor_tech.support@hillrom.com



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NOTICES

Manufacturer's Responsibility

Welch Allyn, Inc. is responsible for the effects on safety and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Welch Allyn, Inc.
- The device is used in accordance with the instructions for use.

Responsibility of the Customer

The user of this device is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

Welch Allyn, Inc. equipment is identified by a serial and reference number on the back of the device. Care should be taken so that these numbers are not defaced.

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Other Important Information

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Notice to EU Users and/or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

WARRANTY INFORMATION

Your Welch Allyn Warranty

WELCH ALLYN, INC. (hereafter referred to as “Welch Allyn”) warrants that components within Welch Allyn products (hereafter referred to as “Product/s”) will be free from defects in workmanship and materials for the number of years specified on documentation accompanying the product, or previously agreed to by the purchaser and Welch Allyn, or if not otherwise noted, for a period of twelve (12) months from the date of shipment.

Consumable, disposable or single use products such as, but not limited to, PAPER or ELECTRODES are warranted to be free from defects in workmanship and materials for a period of 90 days from the date of shipment or the date of first use, whichever is sooner.

Reusable product such as, but not limited to, BATTERIES, BLOOD PRESSURE CUFFS, BLOOD PRESSURE HOSES, TRANSDUCER CABLES, Y-CABLES, PATIENT CABLES, LEAD WIRES, MAGNETIC STORAGE MEDIUMS, CARRY CASES or MOUNTS, are warranted to be free from defects in workmanship and materials for a period of 90 days. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

- a) Freight damage;
- b) Parts and/or accessories of the Product/s not obtained from or approved by Welch Allyn;
- c) Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;
- d) Accident; a disaster affecting the Product/s;
- e) Alterations and/or modifications to the Product/s not authorized by Welch Allyn;
- f) Other events outside of Welch Allyn’s reasonable control or not arising under normal operating conditions.

THE REMEDY UNDER THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT WITHOUT CHARGE FOR LABOR OR MATERIALS, OR ANY PRODUCT/S FOUND UPON EXAMINATION BY WELCH ALLYN TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Welch Allyn of any alleged defects promptly after discovery thereof within the warranty period. Welch Allyn’s obligations under the foregoing warranty will further be conditioned upon the assumption by the purchaser of the Product/s (i) of all carrier charges with respect to any Product/s returned to Welch Allyn’s principal place or any other place as specifically designated by Welch Allyn or an authorized distributor or representative of Welch Allyn, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Welch Allyn is limited and that Welch Allyn does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Welch Allyn is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence therefrom relating to the Product/s. If Welch Allyn should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Welch Allyn shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

EXCEPT AS SET FORTH HEREIN WITH RESPECT TO REIMBURSEMENT OF LABOR CHARGES, A PURCHASER'S SOLE EXCLUSIVE REMEDY AGAINST WELCH ALLYN FOR CLAIMS RELATING TO THE PRODUCT/S FOR ANY AND ALL LOSSES AND DAMAGES RESULTING FROM ANY CAUSE SHALL BE THE REPAIR OR REPLACEMENT OF DEFECTIVE PRODUCT/S TO THE EXTENT THAT THE DEFECT IS NOTICED AND WELCH ALLYN IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL WELCH ALLYN BE LIABLE FOR INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY OTHER LOSS, DAMAGE, OR EXPENSE OF ANY KIND, INCLUDING LOSS OF PROFITS, WHETHER UNDER TORT, NEGLIGENCE OR STRICT LIABILITY THEORIES OF LAW, OR OTHERWISE. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

USER SAFETY INFORMATION



WARNING: Means there is the possibility of personal injury to you or others.



Caution: Means there is the possibility of damage to the device.

Note: Provides information to further assist in the use of the device.



WARNING(S)

- This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.
- Caretakers must closely supervise an infant or child who is wearing a Holter recorder to ensure the recorder is intact and the patient cable is properly secured. A patient cable with short lead wires is recommended for pediatric patients.
- Device stores data reflecting a patient's physiological condition to a properly equipped analysis system that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.
- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Welch Allyn service for additional training options.
- To maintain designed operator and patient safety, peripheral equipment and accessories that can come in direct patient contact must be in compliance with UL 2601-1, IEC 60601-1, and IEC 60601-2-47. Only use parts and accessories supplied with the device and available through Welch Allyn, Inc.
- Patient cables intended for use with the device include series resistance (7 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.
- Conductive parts of the patient cable, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrodes, should not come into contact with other conductive parts including earth ground.
- To avoid the possibility of serious injury or death during patient defibrillation, do not come in contact with device or patient cables. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
- A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.

- Defibrillation protection is guaranteed only if the original patient cable is used. Any modifications of this device may alter defibrillator protection.
- Simultaneous connection to other equipment may increase leakage current.
- This device was designed to use the electrodes specified in this manual. Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or other adverse reactions.
- ECG electrodes should be changed routinely for recordings extending beyond 24-hour duration, depending on quality and type of electrodes used.
- To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.
- FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.
- The device has not been designed for use with high-frequency (HF) surgical equipment and does not provide a protective means against hazards to the patient.
- The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillators and ultrasound machines.
- There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.
- Operations may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.
- The device is restricted to use on one patient at a time.
- The performance of the device may be compromised by excessive motion.
- Use only recommended battery cells. Use of other cells may present a risk of fire or explosion.



Caution(s)

- To prevent possible damage to the device, do not use sharp or hard objects to depress buttons, only use fingertips.
- Do not attempt to clean the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device. Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas.
- Wipe the exterior surface of the device and patient cable with a non-alcohol sterilizing disinfectant; dry with a clean cloth.
- Conductive parts of the patient cable, electrodes, and associated Type CF connections, including the neutral conductor of the patient cable and electrodes, should not come into contact with other conductive parts, including earth ground.
- The device and patient cable should be cleaned after each use. Inspect cable and connection for damage or excessive wear prior to each use. Replace cable if damage or excessive wear is noted.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after forming them into a loose loop.
- The device will only work with devices that are equipped with the appropriate option.
- No user-serviceable parts are inside. Damaged or suspected inoperative equipment must be immediately removed for use and must be checked/repared by qualified service personnel prior to continued use.
- This device is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.
- When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- AAA batteries are known to leak their contents when stored in unused equipment. Remove battery from device when not used for an extended period of time.
- To prevent possible damage to the device, the following environmental conditions must be adhered to:

Operating Temperature:	10° to +45° C
Storage Temperature:	-20° to +65° C
Relative Humidity:	5 to 95%, non-condensing
Ambient Air Pressure:	700 to 1060 millibars

Note(s)

- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- It is the responsibility of the medical facility to provide the patient with instructions during use. Refer to the “Patient Instructions” section within this user manual.
- If electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, display will indicate a lead fault condition.
- The device is set to the U.S. Central Time Zone when shipped from the factory. If a change is required, set the correct date and time prior to using the recorder. Refer to the instructions within this user manual.
- The patient cable life expectancy is six months continuous use with proper care.
- The device will automatically turn off (blank screen) if the batteries have been severely discharged.
- When the H3+ has not been used over a period of several months, the date and time may be lost. The following sequence of steps should be performed to recharge the recorder’s internal lithium battery.
 - Insert an AAA alkaline battery into the recorder battery compartment and let it power the recorder for a minimum period of 24 hours.
 - Connect the H3+ recorder to the H3+ interface cable and connect it to H3scribe or a Welch Allyn Web Upload client computer to set the time and date.
- No preliminary or ongoing scheduled periodic calibration by the user or Welch Allyn personnel is required. The design for the device is such that the system contains no elements requiring calibration.
- As defined by IEC 60601-1 and IEC 60601-2-47, this device is classified as follows:
 - Internally powered
 - Type CF defibrillator-proof applied parts
 - Ordinary equipment
 - Not suitable for use in the presence of flammable anesthetics
 - Continuous operation
- The device conforms to the following standards:

IEC 60601-1	General Requirements for Safety
IEC 60601-2-47	Particular Requirements for Safety, including Essential Performance
IEC 60601-1-2	Electromagnetic Compatibility
93/42/EEC	Medical Device Directive
- The device is UL classified:



Medical Equipment

WITH RESPECT TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, CAN/CSA C22.2 No. 601.1 AND IEC60601-2-47

EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. In addition, when used on a patient applied part, this symbol indicates defibrillation protection is in the cables. Warning symbols will appear with a grey background in a black and white document..



CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.



Defibrillator-proof type CF applied part



Battery



Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements



Indicates compliance to applicable European Union directives



Follow instructions/directions for use (DFU) -- mandatory action. A copy of the DFU is available on this website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days



Medical Device



Model Identifier



Reorder Number

GENERAL CARE



Precautions

- Turn off the device before inspecting or cleaning.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces.

Inspection

Inspect your equipment daily prior to operation. If you notice anything that requires repair, contact an authorized service person to make the repairs.

- Verify that all cables and connectors are securely seated.
- Check the case for any visible damage.
- Inspect cables and connectors for any visible damage.
- Inspect buttons and controls for proper function and appearance.

Cleaning and Disinfection

Refer to section 3 for proper cleaning and disinfection procedures.

Sterilization

EtO sterilization is not recommended but may be required for cables and lead wires. Frequent sterilization will reduce the useful life of cables and lead wires. If required, sterilize with ethylene oxide gas (EtO) at a maximum temperature of 50°C/122°F. After EtO sterilization, follow the recommendations from the sterilizer manufacturer for required aeration.



Cautions

Improper cleaning products and processes can damage the device, produce brittle lead wires and cables, corrode the metal, and void the warranty. Use care and proper procedure whenever cleaning or maintaining the device.

Disposal

This product and its accessories must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste. For more specific disposal information see www.welchallyn.com/weee.

ELECTROMAGNETIC COMPATIBILITY (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the device.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The device should not be used adjacent to, or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See applicable EMC table for recommended separation distances between the radio equipment and the device.

The use of accessories, transducers, and cables other than those specified by Welch Allyn may result in increased emissions or decreased immunity of the device.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	Compliance	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	Not Applicable	Not Applicable	
Surge IEC 61000-4-5	Not Applicable	Not Applicable	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable	Not Applicable	
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *UT is the AC Mains voltage prior to application of the test level.*

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{3V_{rms}} \right] \sqrt{P}$ <p>$d = \left[\frac{3.5}{3V/m} \right] \sqrt{P}$ 80 MHz to 800 MHz</p> $d = \left[\frac{7}{3V/m} \right] \sqrt{P}$ 800 MHz to 2.5 GHz <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.
- 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 Equipment

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

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter (m)	
	150 KHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4.0 m	7.0 m
100	12.0 m	23.0 m

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 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 the absorption and reflection from structures, objects, and people.

INTRODUCTION

Manual Purpose

The H3+™ digital Holter recorder user manual explains how to operate the H3+ recorder. It shows the user how to:

- Start and end a patient recording
- Prepare device configurations
- Instruct the patient on electrode replacement

***NOTE:** This manual may contain screen shots. Any screen shots are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording.*

Audience and Indications for Use

This manual is written for clinical professionals who are expected to have a working knowledge of medical procedures and terminology as required for monitoring cardiac patients.

The H3+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of up to 48 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. Holter analysis is appropriate for the indications below:

- Evaluation of adult patients with symptoms suggesting arrhythmia
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Clinical and epidemiological research studies
- Infant patient evaluation is limited to QRS detection only

System Description

The H3+ provides three channels of continuous ECG data typically recorded over a 24-hour or 48-hour period. An LCD screen and event button allow for checking the lead quality during patient hookup and starting the recording.

The 5-wire patient cable allows display of ECG leads I, II, and V during patient hookup. Either a standard 27-inch (69 cm) or short 15-inch (38 cm) 3-channel patient cable can be connected depending on clinician preference.

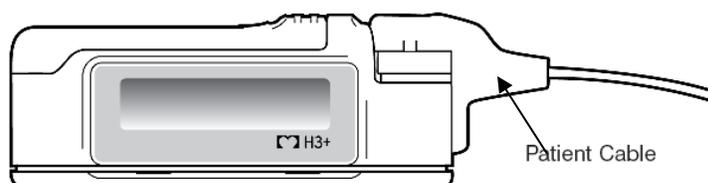
During recording, the LCD will display R and the time of day as HH:MM:SS indicating that the H3+ is in the recording mode. The event button can be used to mark time points within the recorded ECG data.

The H3+ uses a single AAA alkaline battery and stores acquired ECG data in internal memory. The recording will continue and automatically end when the H3+ factory-set duration is reached, the H3+ is connected to the Holter analysis system via USB interface cable, or the battery is removed. The recorded data will remain in memory when the battery is removed.

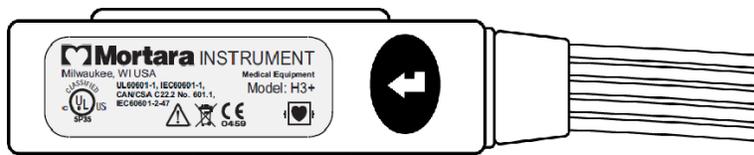
Stored ECG data will be downloaded for analysis to the Holter system with a USB interface cable after the H3+ has been disconnected from the patient cable. After the data is downloaded, the memory is then erased and the H3+ is ready for use on the next patient.

H3+ with Patient Cable and Accessories

Front view with LCD display

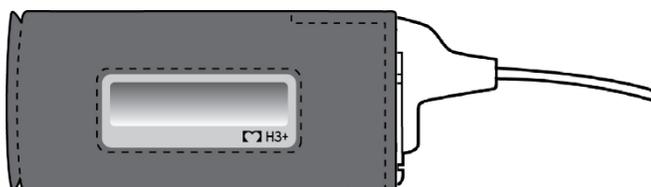


Bottom view with labeling and Event button



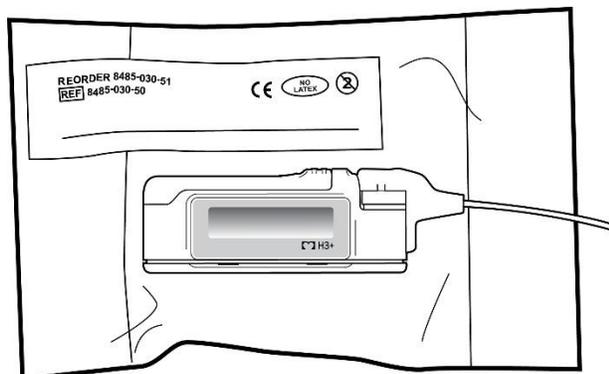
H3+ in Carrying Case

With LCD window and patient cable; clip on back secures the carry case to clothing



H3+ in Single-use Pouch

Adhesive strips secure the pouch to skin or clothing; sealed edges protect H3+ from moisture



Part Numbers

Description	Part Numbers
H3+ Digital Holter Recorder	H3PLUS-XXX-XXXXX
H3+ USB Download Cable	25019-006-50
Battery Door	8348-003-70
Reusable carry case with clip	8485-022-50
Single-use adhesive pouches, pack of 100	8485-031-51
3-Channel 69 cm Patient Cable – AHA Snap	9293-036-50
3-Channel 69 cm Patient Cable – IEC Snap	9293-036-51
3-Channel 38 cm Patient Cable – AHA Snap	9293-036-60
3-Channel 38 cm Patient Cable – IEC Snap	9293-036-61
User Manual – English	9515-165-60-ENG
Short-Form Instruction Card – English	9503-165-02-ENG
Patient Diaries, Pack of 100	881712-50
Holter Prep Kit	XKTHOLT5LA

To order additional supplies, contact a Welch Allyn customer service representative.

Specifications

Feature	Specifications
Instrument Type	Digital Holter Recorder
Input Channels	Simultaneous acquisition of 3 channels
Leads Acquired	Modified I, II, III, aVR, aVL, aVF, and V
Input Impedance Input Dynamic Electrode Offset Tolerance Frequency Response	Meets or exceeds the requirements of IEC 60601-2-47
Digital Sampling Rate	180 s/sec/channel used for standard recording and storage
Special Functions	Pacemaker detection; ECG display during hookup
A/D Conversion	12 bits
Data Storage and Capacity	Internal, non-volatile memory; up to 48-hours
Device Classification	Type CF defibrillator-proof applied parts, internally powered
Weight	1 ounce (28 g) without battery
Dimensions	2.5 x 1.0 x .75 inches (64 x 25 x 19 mm)
Battery	1 AAA alkaline required

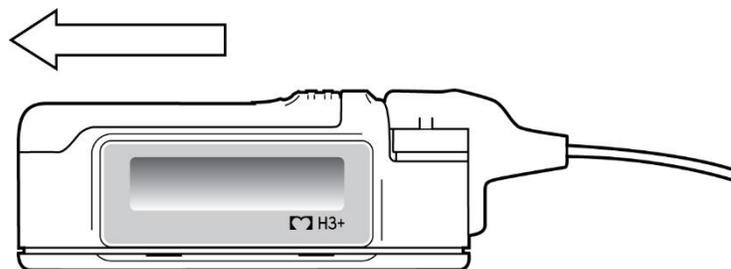
OPERATION

Entering Patient ID and Setting the Date/Time

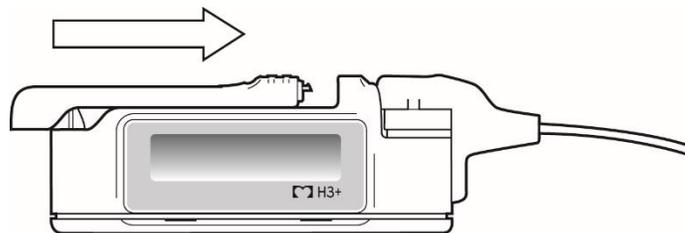
Patient ID information is entered at the Holter analysis system and then transferred to the H3+ using the USB cable. The Holter analysis system automatically sets the H3+ recorder current date and time when the recorder is connected prior to starting a new recording. Refer to the Holter analysis system user manual for instructions on entering patient ID information and setting the date and time.

Opening and Closing the Battery Door

The battery compartment is accessible via the battery door of the H3+. To open the battery door, depress and slide the battery door until it is free. Lift and remove.

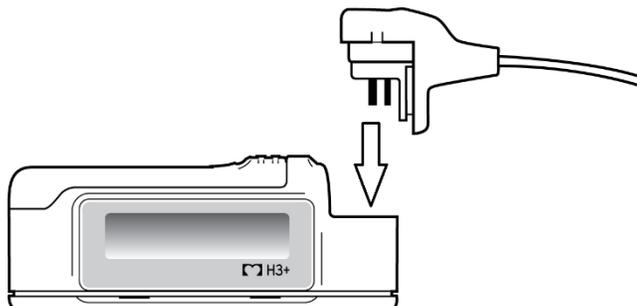


To close the battery door, place the battery door on the H3+ as shown below and slide the door in the opposite direction until the door snaps into place.



Attaching the Patient Cable

The H3+ patient cable consists of a connector block, main cable, and five lead wires connected to the main cable. Each lead wire terminates in a snap connector. Carefully insert the connector block into the input connector on the side of the H3+.



Patient Hookup

Skin Preparation, Electrode Application, and Securing the H3+

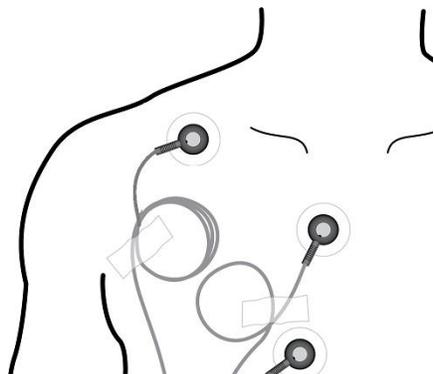
Skin preparation is essential to perform before electrode attachment to ensure good signal quality when recording patient data. Poor skin-to-electrode contact may cause noise to be included in the recording or loss of signal which can affect the analysis of the ECG data. Low amplitude signals may also be the result of poor skin-to-electrode contact.

To prepare the skin:

1. Identify the (5) electrode sites on the torso by referring to the Positioning the Electrodes diagram in this section.
2. Remove any hair from the electrode sites using a razor or shaver.
3. Wipe oils from the electrode sites with an alcohol prep pad or soap and water. Then, wipe the skin dry.
4. Gently exfoliate skin at the electrode site centers where the gel will make contact using an abrasive pad or gel. Two to three moderate rubs at each site is usually sufficient.

NOTE: This step requires evaluation of the patient's skin type. DO NOT break or tear the patient skin.

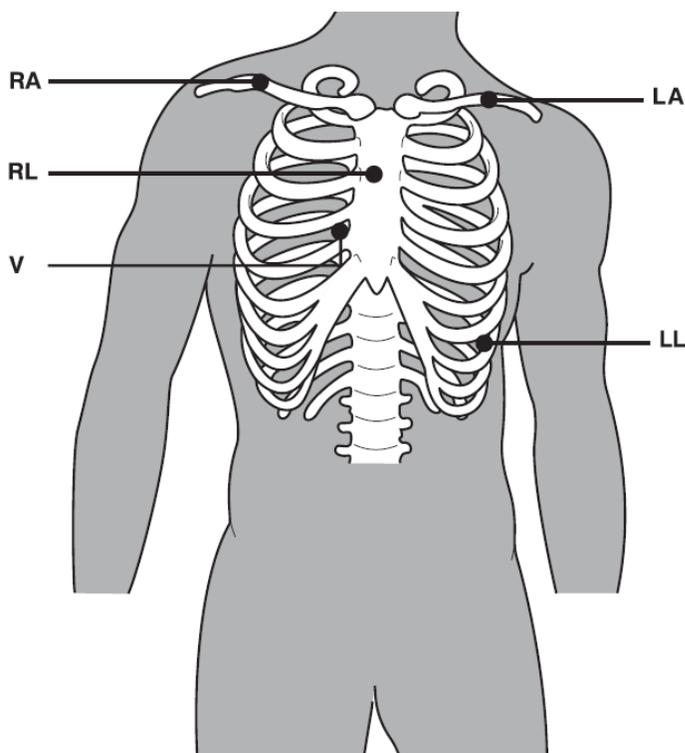
5. Attach the patient cable lead wires to the electrodes before applying them to the patient.
6. Apply an electrode to each of the 5 sites. Secure each electrode by exerting slight pressure around the outer edge and inner ring of the electrode.
7. Any excess lead wire length should be formed into stress loops and secured with adhesive skin tape to prevent direct pulling at the electrode sites.



8. Connect the patient cable to the recorder, insert a new AAA battery, confirm good ECG signal quality, and then start the recording as instructed on the following pages.
9. Secure the H3+ to the patient in its carry case or adhesive pouch in a location that is least subject to movement (e.g. clip the carry case to clothing neckline or a woman's bra instead of the belt area; position the adhesive pouch on the clothing chest area or on the skin; etc.).

Positioning the Electrodes

Electrode Placement: Bipolar – Bipolar - Unipolar



The neutral Right Leg (RL) lead may be positioned in any location least subject to motion artifact. (Shown in mid-sternum position.)

The V lead can be positioned in any of the precordial (V1 – V6) positions according to clinician preference. (Shown in V1 location.)

The left leg (LL) lead positioned on lower left rib cage may ensure the least amount of artifact; however, to be comparable with a standard 12-lead ECG lead II, the LL lead should be placed on the lower left side of the body, as close to the hip as possible.

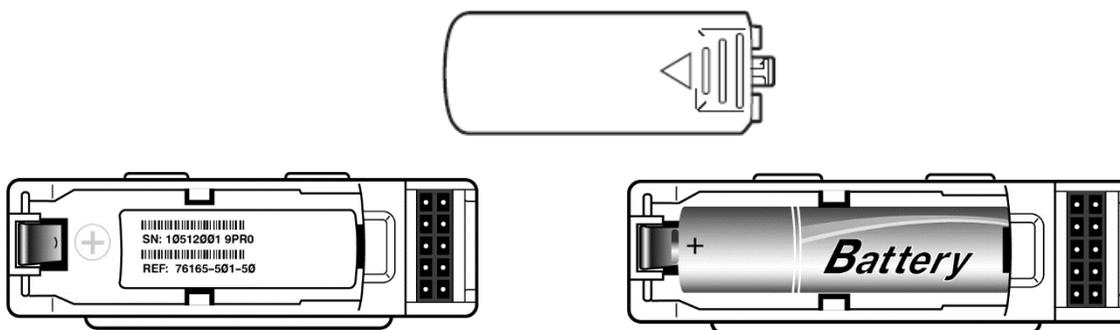
AHA	IEC	
RA	R	Right clavicle as shown.
LA	L	Left clavicle as shown.
RL	N	Reference or ground lead. Should be placed to maximize patient comfort.
LL	F	Lower left side of the rib cage or body.
V	C	Precordial exploring lead.

AHA	IEC
RA = White	R = Red
LA = Black	L = Yellow
RL = Green	N = Black
LL = Red	F = Green
V = Brown	C = White
RA and LA = channel 1 is Bipolar lead I RA and LL = channel 2 is Bipolar lead II V and RA/LA/LL = channel 3 is a Unipolar chest lead	R and L = channel 1 is Bipolar lead I R and F = channel 2 is Bipolar lead II C and R/L/F = channel 3 is a Unipolar chest lead

Inserting the Battery

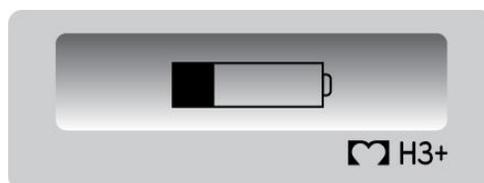
The H3+ is powered with a single AAA alkaline battery for up to 48 hours.

To insert a new battery into the battery compartment, remove the battery door of the H3+. If a battery has been left in the compartment, remove and discard. Insert a new battery with the '+' end aligned as indicated inside the battery compartment.

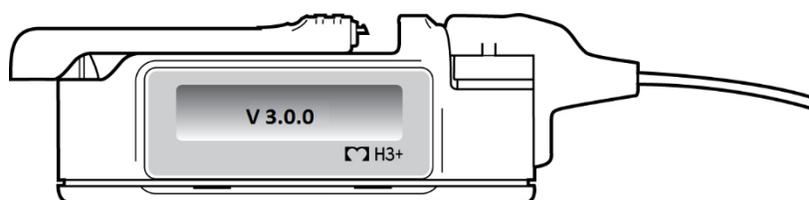


NOTE: The H3+ requires a fully-charged battery to record a 24-hour or 48-hour session. Always use a new battery to ensure operation.

A new battery is required if the Low Battery indicator appears as shown below.



Close the battery door of the recorder.



Upon insertion of the battery the LCD will display:

- SOFTWARE VERSION (e.g., V 3.0.0)

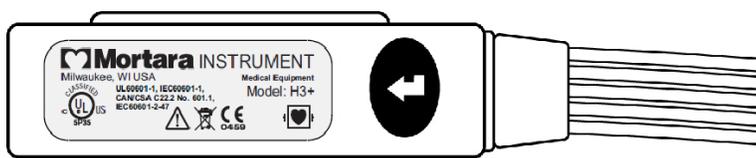
Once the patient cable is connected the H3+ 3-channel mode and the recording duration in hours will display:

- 3-CH xxHR

NOTE: A warning symbol is displayed if an incorrect 2-channel patient cable is connected. Recording cannot proceed until the proper 3-channel patient cable is connected.

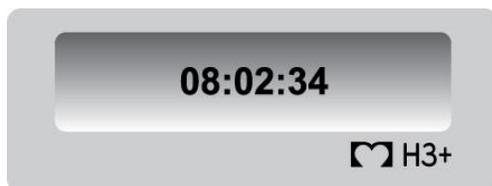
Using the Event Button for Menu Navigation

The **Event** button is located on the bottom side of the H3+. One button is available for navigating through the LCD screens, for starting the recording, and for selecting event markers during the recording.



The **Event** button is used to move to the next menu item.

- CURRENT TIME (HH:MM:SS)



- ID CONFIRMATION



NOTE: If an ID was not entered via the Holter analysis system, this display will be shown as ID: only.

With each single **Event** button push, the H3+ set time and ECG waveform display for each channel will cycle in the following order:

- I -> II -> V -> Time -> I -> II -> V -> Time -> I -> II -> V -> ...

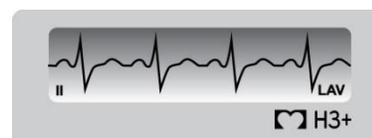
NOTE: If the time and/or the ID are not set properly, refer to the Holter analysis software user manual for instructions on using the USB cable to set time/date and ID. When this is necessary, remove the battery and begin again.

Displaying ECG Channels

This function is used to visually inspect all ECG channels before starting a recording to ensure good signal quality. New electrode sites may be prepped and leads repositioned at this time if necessary.

After the first channel is displayed on the LCD, use the **Event** button to move to the next channel I, II, and V.

If any lead is in fail, the LCD will show the lead label(s) in the lower right area of the LCD as one or a combination of RALALLV.



NOTE: The waveform is shown at 4 mm/mV gain for full representation of the ECG in the LCD display.

NOTE: At least one or more of the three leads should optimally show adequate ECG amplitude with the QRS signal greater than that of the P and T waves. Repositioning leads may be necessary.

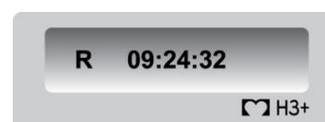
Starting a Recording Session

1. If necessary, erase the memory using the H3+ USB cable with Holter system software.
2. Perform patient skin preparation and hookup.
3. Attach the patient cable to the H3+.
4. Remove the battery door of the H3+.
5. Insert a new AAA battery in the battery compartment.
6. Verify that the correct time and ID have been entered.
7. Verify the amplitude and signal quality by displaying each of the leads or channels using the **Event** button to cycle through the menu.
8. To begin recording, press and hold the **Event** button for a period of 3 seconds. The following information will be displayed in the LCD indicating that H3+ is in the recording mode.

NOTE: Recording will automatically start in 15-minutes once the Event button has been depressed to ensure the recording begins if the Event button was not held for 3-seconds.

During the Recording Session

During H3+ normal operation, R and the current time (HH:MM:SS) are displayed in the LCD continuously for the entire recording session.



If during recording the battery is removed, the H3+ will stop recording and the LCD will be blank. The recorded data is stored and must be downloaded or erased at the Holter analysis system to begin recording again. Insertion of a battery will display the recorded data **ID**.



In the event of a lead fail condition during recording, a lead fail indicator is displayed to the right of the time.

The lead fail indicator is also displayed when the patient cable is disconnected from the recorder. Patient cable disconnection is recommended for the purpose of changing to fresh electrodes during extended recordings.



Entering (Optional) Diary Events

During the recording session, the patient may be instructed to mark a period in time on the H3+ for analysis purposes. Once entered, the patient may be instructed to document the time and symptom in the patient diary.



To enter an event after the first minute of recording, press the **Event** button on the H3+. A **↓** indication message is displayed at the right of the current time until a new one can be entered.

***NOTE:** In the event of a simultaneous lead fail, the **↓** indicator replaces the lead fail indicator. If lead fail persists, the lead fail indicator is displayed again after the event period.*

Ending a Recording Session

At the end of the recording session, the time is cleared from the LCD screen and the ID is displayed in reversed color to indicate the recording period has ended.



To end recording early, the battery may be removed from the recorder to stop recording. Reinsertion of the battery will display the ID in reversed color as shown above.

To proceed:

1. Remove the battery door of the H3+.
2. Remove the battery and dispose of the battery properly.
3. Replace the battery door.
4. Remove the patient cable from the recorder.

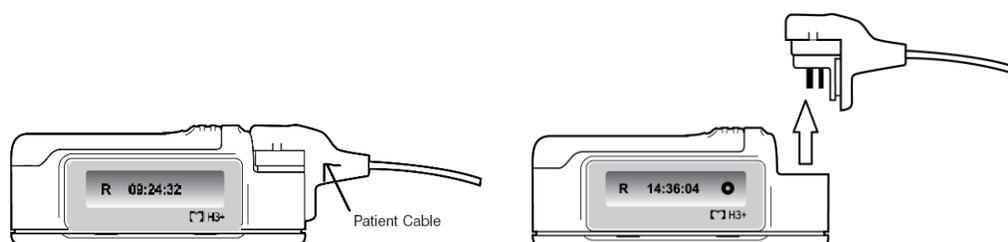
The H3+ data can then be acquired at the Holter analysis system through connection of the H3+ USB interface cable. Once the data is acquired, the memory will be erased by the user and the H3+ is ready to prepare for the next patient recording session.

Patient Instructions

The H3+ recorder is not water proof. It may be placed in a sealed, clear pouch that will protect it from moisture, but should not be submerged in water.

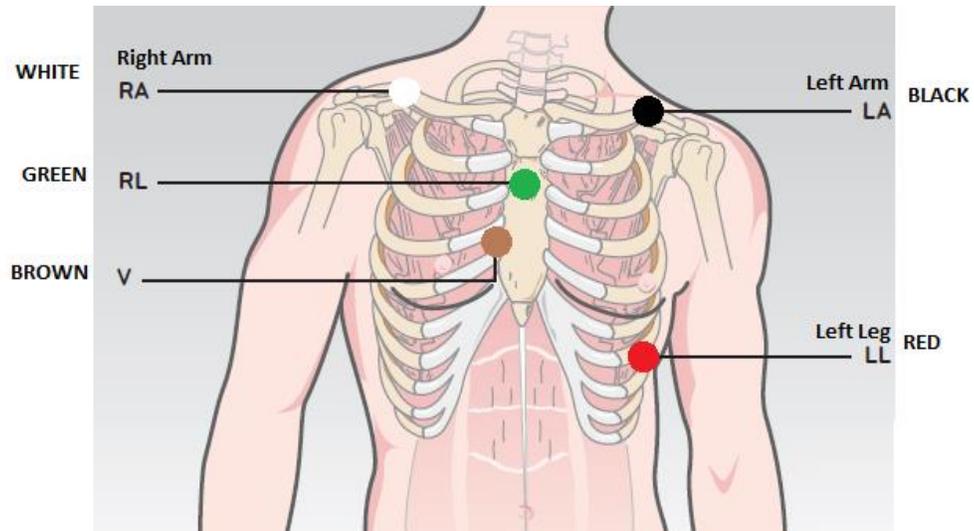
Ensure that the electrodes (sticky patches) are adhering well to your skin. At times, you may need to remove and replace the electrodes with fresh ones should they become disconnected or you wish to bathe. To do this, use the following steps:

1. ECG Recording will continue during this process. Remove the recorder from its pouch or carry case and disconnect the patient cable from the recorder by pulling it straight up BEFORE disconnecting electrodes and lead wires.



2. Carefully peel the electrodes from your skin and remove the lead wires from the electrodes. Then discard the used electrodes.
3. Snap the lead wires onto fresh electrodes.
4. Apply the electrodes to your clean and dry skin (no lotions, oils, or powder) in the lead locations shown below.

Electrode Placement (AHA colors)



5. Reconnect the patient cable to the recorder.
6. Insert the recorder in its carry case or adhesive pouch and secure it to your clothing.

MAINTENANCE

Cleaning the H3+ and Accessories

1. Remove cables and disconnect power source from device before cleaning.
2. Wash the reusable carry case by hand with fabric detergent and then air dry. Do not machine dry the case.
3. For general cleaning, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry.
 - Do use clean, lint-free cloth
 - Don't use solvents
 - Don't use abrasive cleaners or materials
4. For disinfecting the device, wipe exterior with a soft, lint-free cloth using a solution of Sodium Hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants.
5. For disinfecting the cables and leadwires, wipe exterior with a soft, lint-free cloth using the same solutions as for the device.
6. Use caution with excess liquid as contact with metal parts may cause corrosion.
7. Do not immerse cable ends or lead wires; immersion can cause metal corrosion.
8. Do not use excessive drying techniques such as forced heat.



WARNING: Prevent liquid from penetrating the device and do not attempt to clean/disinfect the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning. Never expose cables to strong ultra-violet radiation. Do not sterilize the device or ECG cable with Ethylene Oxide (EtO) gas.



WARNING: Use of unspecified cleaning/disinfecting agents or failure to follow recommended procedures could result in increased risk of harm to users, patients and bystanders, or damage to the device.

NOTE: Welch Allyn does not endorse any specific off-the-shelf wipes or liquids. However, products that only contain the disinfecting agents mentioned above are likely to be compatible with the device. Some products contain a mixture of agents and may have a detrimental effect if used intensively and frequently. Check the Material Safety Data Sheet of the product used for the list of ingredients.

Periodic Maintenance

Check the H3+ and patient cable before each use to ensure they are not damaged or broken.

1. Patient Cable Maintenance: Check patient cables for cracks or breakage prior to use
 - Disinfect the cable with a recommended germicidal solution
 - Alcohol will cause hardening and can introduce cracks
 - Patient cables should be stored by looping them loosely. Don't pull or stretch the cables; don't wrap cables tightly
 - Replace patient cables periodically (depending on frequency of use and care)
2. Exterior Visual Inspection:
 - Check connectors for loose, bent, or corroded contact points
 - Inspect covers for warping, surface damage, or missing hardware
 - Check for any other form of damage

When the H3+ has not been used over a period of several months, the date and time may be lost. The following sequence of steps should be performed to recharge the recorder's internal lithium battery.

- Insert an AAA alkaline battery into the recorder battery compartment and let it power the recorder for a minimum period of 24 hours.
- Connect the H3+ recorder to the H3+ interface cable and connect it to HSCRIBE or a Welch Allyn Web Upload client computer to set the time and date.

Disposal of Waste Materials

The H3+ uses one AAA alkaline battery and disposable monitoring electrodes. Their disposal must be in accordance with the following procedures:

Battery: applicable disposal or recycling standards

Electrodes: normal waste

MESSAGES AND INFORMATION

The following table describes error and lead fail messages and symbols that are displayed on the H3+ LCD during power up, patient hookup, recording, and during connection to the Holter analysis system.

Table of Messages

Message	Description/Solution
	Replace existing battery with a fully charged battery.
ID:XXXXXXXXXX XXXXXXXXXXXXXX	Displayed prior to start of recording to confirm the ID has been entered. If the field after the ID: is blank, no ID has been loaded to the H3+. Reverse color (white on dark background) indicates that the recording period is complete and recording has stopped. A new recording cannot begin until the memory is erased.
	Wrong 2-channel patient cable connection. Recording cannot proceed until the proper 3-channel cable is connected.
	Lead fail indication during recording. Check that all lead wires and electrodes are connected. Check that the patient cable is connected to the recorder.
R	Recording indication.
↓	Event marker indication.
USB	Indicates that the H3+ USB download cable is connected to the H3+.
'RA'	RA in fail during hookup. Check if the lead wire is off or the electrode needs to be replaced.
'LA'	LA in fail during hookup. Check if the lead wire is off or the electrode needs to be replaced.
'LL'	LL in fail during hookup. Check if the lead wire is off or the electrode needs to be replaced.
'V'	V in fail during hookup. Check if the lead wire is off or the electrode needs to be replaced.
A combination of 'RA.../V'	More than one lead in fail or all leads in fail during hookup. Check the lead wires and electrodes.

Device Log Files

Service log files containing information for Welch Allyn technical support personnel are written to the recorder and available by opening the H3+ recorder using Windows Explorer. The files, DEVICE.LOG and RECORD.LOG can be copied and e-mailed to Welch Allyn for troubleshooting purposes. These files are erased when the recorded ECG data is erased in preparation for the next recording.

The following system information log is provided for your convenience. You need this information if the H3+ needs servicing. Be sure to update the information log when your device has been serviced.

Record the model and serial number of all components, dates of removal, and/or replacement of components, and the name of the vendor from whom the component was purchased and/or installed.

In addition to having records of this information, the system information provides a warranty record of when your device was placed in service.

System Information Log

Manufacturer:

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

Telephone Numbers:

Domestic: 800.231.7437
 European: +39.051.298.7811

Sales Department: 800-231-7437

Service Department: 888-667-8272

Product Information:

Name of Unit/Product: _____

Date of Purchase: ____/____/____

Purchased Unit From: _____

Serial Number: _____

Software Version: _____

Serial Number and Part Number Location

When calling with questions or for service information, have the serial number and part number available.

The serial number and part number (REF) are found under the battery, in the battery compartment of the unit similar to the one pictured below.

