Hillrom™

Welch Allyn®
H3+™
Digital Holter Recorder
User Manual

CE 0459

Manufactured by Welch Allyn. Inc., Skaneateles Falls, NY USA

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

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901142 HOLTER RECORDER

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Hillrom™

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.

The device product label is applied showing the unique identification numbers along with other important information printed on the label.

The serial number format is as follows:

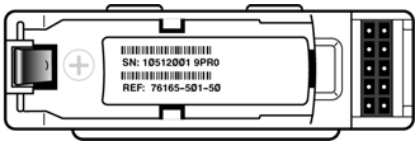
YYYWWSSSSSSS

YYY = First Y is always 1 followed by two-digit Year of manufacture

WW = Week of manufacture

SSSSSSS = Sequence number of manufacture

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.



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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.
- The following Warning is applicable only for the factory configured 7-day recorder, ordered as H3PLUS-CXX-XXXXX:

  Holter analysis system requirements: Your Holter software must be at Version 5.14 or later in order to perform multiday H3+ recorder analysis greater than 48-hours in duration. All H3+ recorders are factory configured to a recording duration of 168 hours (7 days). An H3+ programming tool is provided on the H3+ User Manual CD (9515-165-50-CD) in a folder titled H3Prog to support backward compatibility. Refer to H3+ Recorder Programming Tool instructions in the Introduction section of this manual.
- **For US only:** HScribe Holter analysis software is intended for use for up to 48 hours only. Reference Indications for Use section in the US version of the HScribe user manual (9515-213-70-ENG) for further information.
- This product complies with relevant electro-magnetic interference, mechanical safety, performance, and biocompatibility standards. However, the product cannot completely eliminate potential patient or user harm from the following:
  - Harm or device damage associated with electro-magnetic hazards,
  - Harm from mechanical hazards,
  - Harm from device, function, or parameter unavailability,
  - Harm from misuse error, such as inadequate cleaning, and/or
  - Harm from device exposure to biological triggers that may result in a severe systemic allergic reaction
- The H3+ Holter recorder is not intended for use on infants weighing less than 10 kg (22 lbs).
- Carefully route cables to reduce any possibility of patient entanglement or strangulation.

Caution(s)

- The H3+ recorder is not waterproof. Care should be taken to protect it from water or any other fluids.
- 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/repaired 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:	5° 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 while wearing the device. 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 HScribe 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 is UL classified:

E467322

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

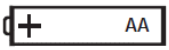
EQUIPMENT SYMBOLS AND MARKINGS

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

Indicates compliance to applicable European Union directives

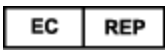
Indicates a separate waste collection is required for Waste of Electrical and Electronic Equipment (WEEE).

Refer to instruction manual / booklet..

Medical Device

Reorder Number

Model Identifier



Authorized representative in the European Community

EU Importer

Manufacturer

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.

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)

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this *User Manual.*
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the device in the presence of high-frequency surgical equipment or MRI.
- However, it is good practice to avoid using the device in extremely close proximity to other equipment.

WARNING Avoid using the device adjacent to or stacked with other equipment or medical electrical systems because it could result in improper operation. If such use is necessary, observe the device and other equipment to verify that they are operating normally.

WARNING Use only accessories recommended by Welch Allyn for use with the device because they have been assessed for EMC compatibility. Replacing any accessories which are not recommend by Welch Allyn could adversely affect the EMC emissions or immunity.

WARNING Maintain a minimum separation distance of 30 cm (1 foot) between the device and portable RF communication equipment. Device performance may degrade if a proper distance is not maintained between equipment.

This device complies to IEC 60601-1-2 (EMC international standard, 4th Edition). Refer to the proper Guidance and Manufacturer's Declaration and Recommended Separation Distance tables based on which standard the device meets.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

IEC 60601-1-2 (EMC International Standard, Edition 4.1)

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 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and 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 Distortion IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

IEC 60601-1-2 (EMC International Standard, Edition 4.1)

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 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 IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Enclosure Port Immunity to Proximity Magnetic Fields IEC 61000-4-39	Reference: Test Specifications for Enclosure Port Immunity to Proximity Magnetic Fields	Reference: Test Specifications for Enclosure Port Immunity to Proximity Magnetic Fields	Compliant including the Home Healthcare environment

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

IEC 60601-1-2 (EMC International Standard, Edition 4.1)

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 80% AM at 1 kHz 6 Vrms in ISM and amateur bands between 0.15 MHz to 80 MHz 80% AM at 1 kHz	3 Vrms 80% AM at 1 kHz 6 Vrms 80% AM at 1 kHz	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. **Recommended separation distance** $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ 150 kHz to 80 MHz where V1 is the compliance level in Vrms.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	$d = \left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz where E1 is the compliance level in V/m.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Reference Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment	Reference Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment	$d = 0.3m$

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level 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 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.

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 H3+ Holter Recorder 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.

Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

IEC 60601-1-2 (EMC International Standard, Edition 4.1)

Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800-900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4,25, UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFUD 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

Test Specifications for Enclosure Port Immunity to Proximity Magnetic Fields

IEC 60601-1-2 (EMC International Standard, Edition 4.1)

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz	CW	8
134.2 kHz	Pulse modulation [a)] 2.1 kHz	65 [b)]
13.56 MHz	Pulse modulation [a)] 50 kHz	7.5 [b)]
a) The carrier shall be modulated using a 50% duty cycle square wave signal.		
b) r.m.s. before modulation is applied		

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the H3+ Holter Recorder

IEC 60601-1-2 (EMC International Standard, Edition 4.1)

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 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 1.2\sqrt{P}$	$d = 0.35\sqrt{P}$	$d = 0.7\sqrt{P}$
0.01	0.1 m	0.04 m	0.07 m
0.1	0.4 m	0.11 m	0.22 m
1	1.2 m	0.35 m	0.7 m
10	4.0 m	1.11 m	2.21 m
100	12.0 m	3.5 m	7 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 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 the absorption and reflection from structures, objects, and people.*

TABLE OF CONTENTS

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

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.

Indications for Use

The H3+ Holter recorder is intended to acquire, record and store continuous ECG data as directed by a clinician from adult, adolescent, pediatric, infant and neonate patient populations for a maximum recording time of 7 days in a hospital, clinic or home environment. The H3+ is intended to be used with a compatible ambulatory ECG (Holter) analysis system which will analyze the recorded data. The H3+ data and the data analysis are then reviewed by trained medical personnel for the purpose of forming a clinical diagnosis.
The H3+ Holter Recorder is not a life-supporting device.

System Description

The H3+ provides three channels of continuous ECG data typically recorded over a 24-hour, 48-hour, or 7-day period (dependent on recorder configuration ordered).
Note(s):

- 48-hour period is available with factory configured 48-hour recorder, ordered as H3PLUS-BXX-XXXXX.
- 7-day period is available with factory configured 7-day recorder, ordered as H3PLUS-CXX-XXXXX.
- For the factory configured 7-day recorder, 24-hour and 48-hour periods are only available as programable options. Reference section H3+ Programming Tool for 7-day recorder.

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.

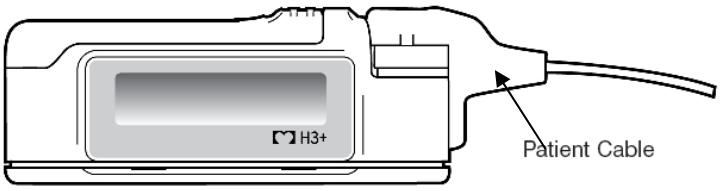
Stored ECG data will be downloaded for analysis to the Holter system with a USB interface cable after the H3+ has been disconnected from the patient cable. After the data is downloaded, the memory is then erased and the H3+ is ready for use on the next patient.

Essential Performance

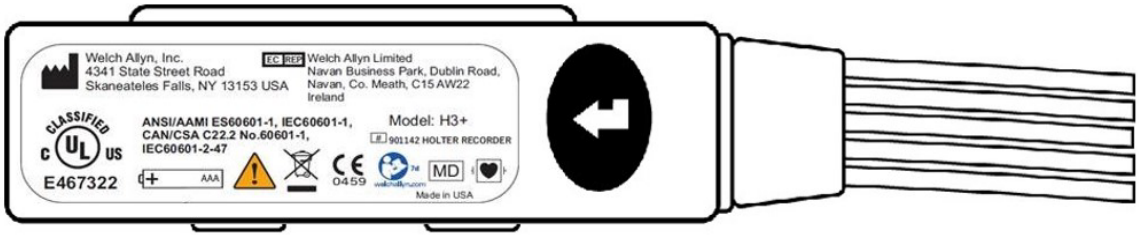
H3+ achieves the essential performance defined by IEC 60601-2-47:2012 when it is used in conjunction with HScribe. A risk analysis has been performed and there is no additional essential performance identified per the definition provided in IEC 60601-1:2020.

H3+ with Patient Cable and Accessories

Front view with LCD display

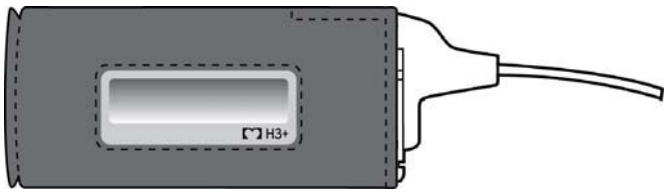


Bottom view with labeling and Event button



H3+ in Carrying Case

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



Part Numbers

Description	Part Numbers
H3+ Digital Holter Recorder factory configured as 7-day recorder	H3PLUS-CXX-XXXXX
H3+ Digital Holter Recorder factory configured as 48-hour recorder	H3PLUS-BXX-XXXXX
H3+ USB Download Cable	25019-006-60
Battery Door	8348-003-70
Reusable carry case with clip	775906
Patient Cable 69 cm H3+ 5-wire AHA Snap Gray	9293-036-52
Patient Cable 69 cm H3+ 5-wire IEC Snap Gray	9293-036-53
Patient Cable 38 cm H3+ 5-wire AHA Snap Gray	9293-036-62
Patient Cable 38 cm H3+ 5-wire IEC Snap Gray	9293-036-63
Monitoring Snap Electrode Pack of 10	419722
Monitoring Snap Electrode Case of 300	108070
Web Direct Card for IFUs	777580

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; 48-hours or 7-days
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

H3+ Programming Tool for 7-day recorder

Note: *This tool is only for use with factory configured 7-day recorder, ordered as H3PLUS-CXX-XXXXX.*

Your H3+ recorder (model H3PLUS-CXX-XXXXX only) is configured to a recording duration of 7-days upon delivery. The H3+ recorder programming tool is used to program this H3+ recorder to a different maximum recording duration when a change is needed. The H3+ recorder will automatically stop recording when the maximum duration is reached.

The programming tool has been tested for compatibility on computers with Microsoft® Windows® 7 Professional with 32-bit or 64-bit and Microsoft Windows 8.1 Professional 64-bit operating systems.

There are three choices for maximum recording duration:

- 24 H (24 hours),
- 48 H (48 hours), or
- 7 Day (7 days or 168 hours)

WARNING: *When using any HScribe software version prior to V5.14, a recording greater than 48-hours in duration is not compatible. Your 7-day recorder must be programmed to a 24-hour or 48- hour recording duration when data is to be acquired at software versions 5.13 and earlier.*

WARNING: For US only, *HScribe Holter analysis software is intended for use for up to 48 hours only. Reference Indications for Use section in the US version of the HScribe user manual for further information.*

NOTE: *Welch Allyn recommends that you program all recorders to the same recording duration to prevent uncertainty when connecting and sending a patient home, only to find that the recording stopped at an unexpected duration when the patient returns.*

To program an H3+ Holter recorder:

1. Open the programming tool or copy it to a location on your computer and then open the tool. A graphical window will display.
2. Connect the H3+ recorder and H3+ USB interface cable to your computer.
3. Select the Get Status button to retrieve and display information. The current set recording duration is displayed with its radio button selected.
4. Select the preferred recording duration radio button to reprogram the H3+ recorder.
5. When complete, a success message is displayed.

6. Close the program and disconnect the H3+ recorder when finished.

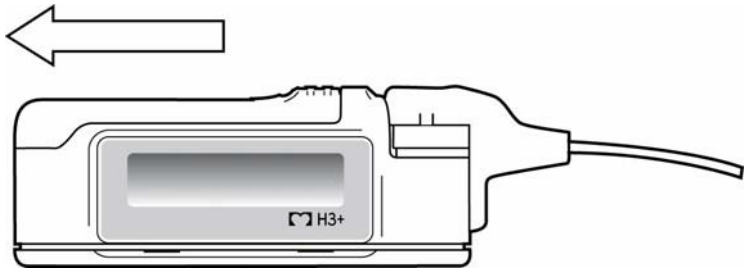
OPERATION

Entering Patient ID and Setting the Date/Time

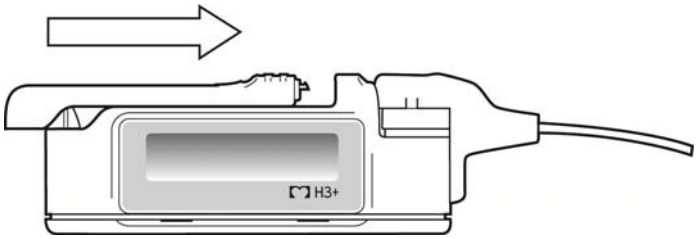
Patient ID information is entered at the Holter analysis system and then transferred to the H3+ using the USB cable. The Holter analysis system automatically sets the H3+ recorder current date and time when the recorder is connected prior to starting a new recording. Refer to the Holter analysis system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

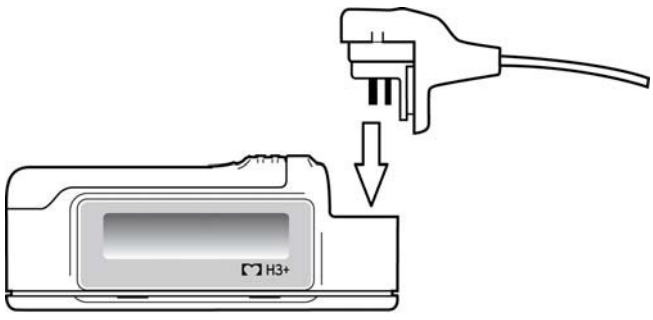


To close the battery door, place the battery door on the H3+ as shown below and slide the door in the opposite direction until the door snaps into place.



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+

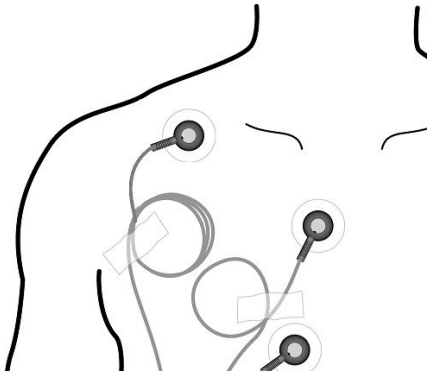
Skin preparation is essential to perform before electrode attachment to ensure good signal quality when recording patient data. Poor skin-to-electrode contact may cause noise to be included in the recording or loss of signal which can affect the analysis of the ECG data. Low amplitude signals may also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

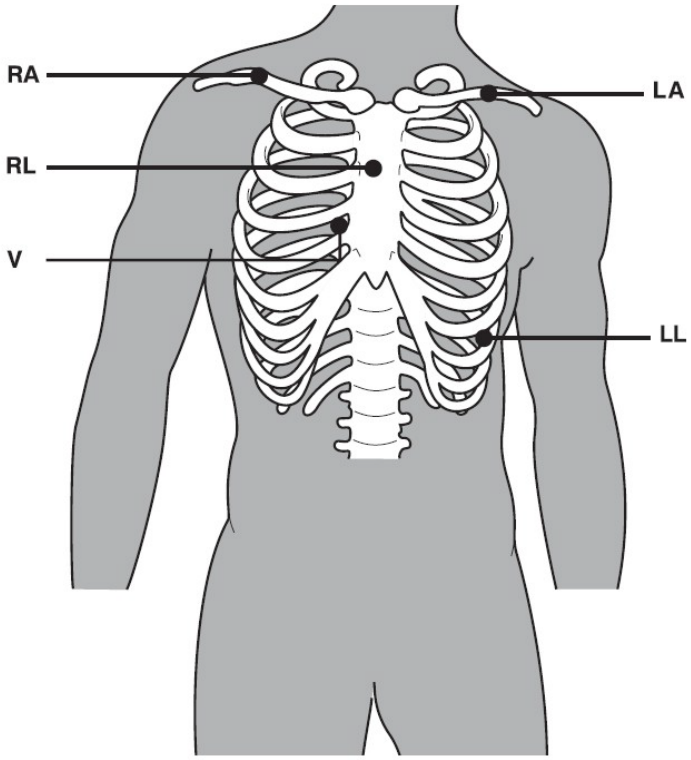
5. Attach the patient cable lead wires to the electrodes before applying them to the patient.
6. Apply an electrode to each of the 5 sites. Secure each electrode by exerting slight pressure around the outer edge and inner ring of the electrode.
7. Any excess lead wire length should be formed into stress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

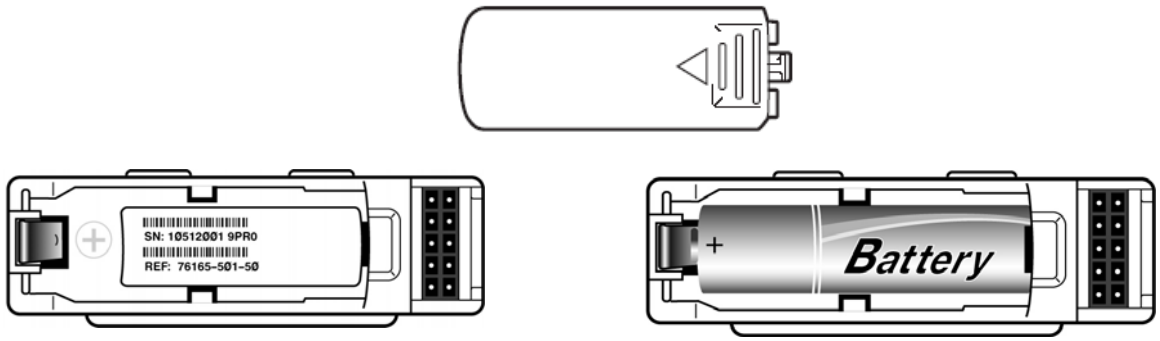
AHA	IEC	
RA	**R**	Right clavicle as shown.
LA	**L**	Left clavicle as shown.
RL	**N**	Reference or ground lead. Should be placed to maximize patient comfort.
LL	**F**	Lower left side of the rib cage or body.
V	**C**	Precordial exploring lead.

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

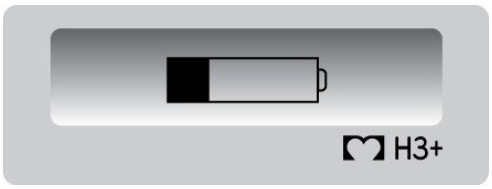
The H3+ is powered with a single AAA alkaline battery for up to 7 days.

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.

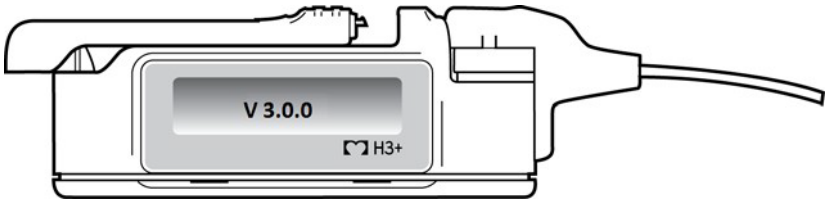


NOTE: *The H3+ requires a fully-charged battery to record a 24-hour, 48-hour, or 7-day session. Always use a new battery to ensure operation.*

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)

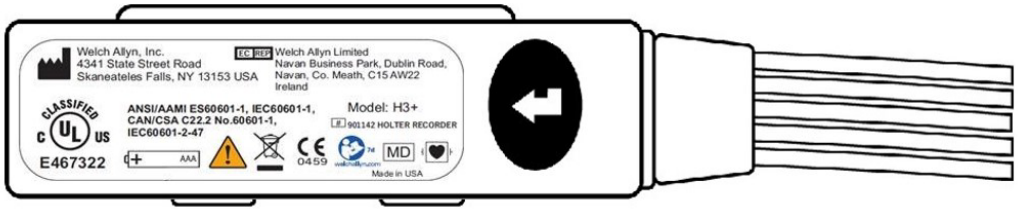
Once the patient cable is connected the H3+ 3-channel mode and the recording duration in hours will display:

- 3-CH xxxHR

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.*

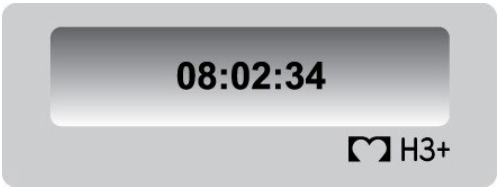
Using the Event Button for Menu Navigation

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.

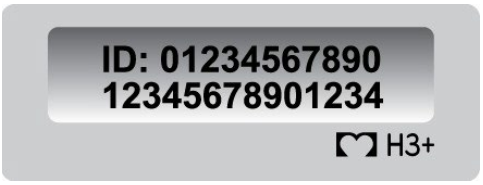


The **Event** button is used to move to the next menu item.

- 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.*

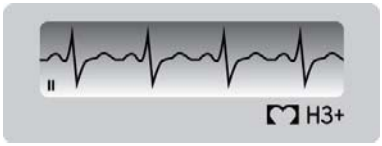
With each single **Event** button push, the H3+ set time and ECG waveform display for each channel will cycle in the following order:

- 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.*

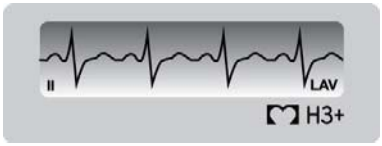
Displaying ECG Channels

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.*

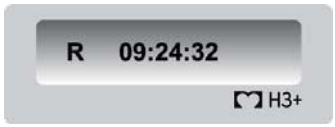
Starting a Recording Session

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.



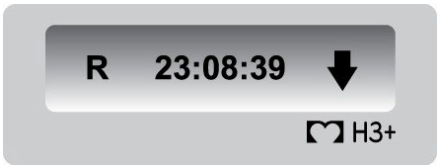
If during recording the battery is removed, the H3+ will stop recording and the LCD will be blank. The recorded data is stored and must be downloaded or erased at the Holter analysis system to begin recording again. Insertion of a battery will display the recorded data **ID**.

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

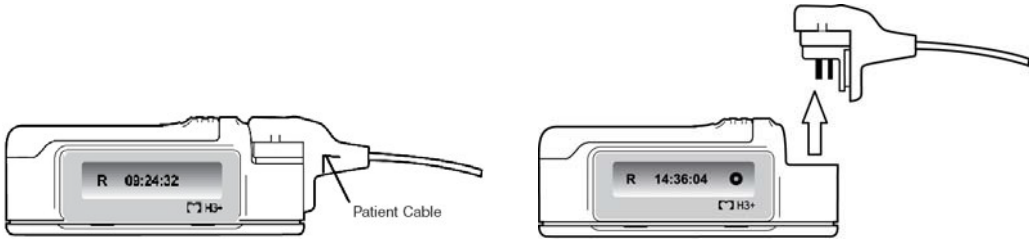
The H3+ recorder is not waterproof. Care should be taken to protect it from water of any other fluids.

If the H3+ recorder shuts down during the recording process, contact your local healthcare professional.

If the H3+ recorder gets wet to the point that the display shuts down, contact your local healthcare professional

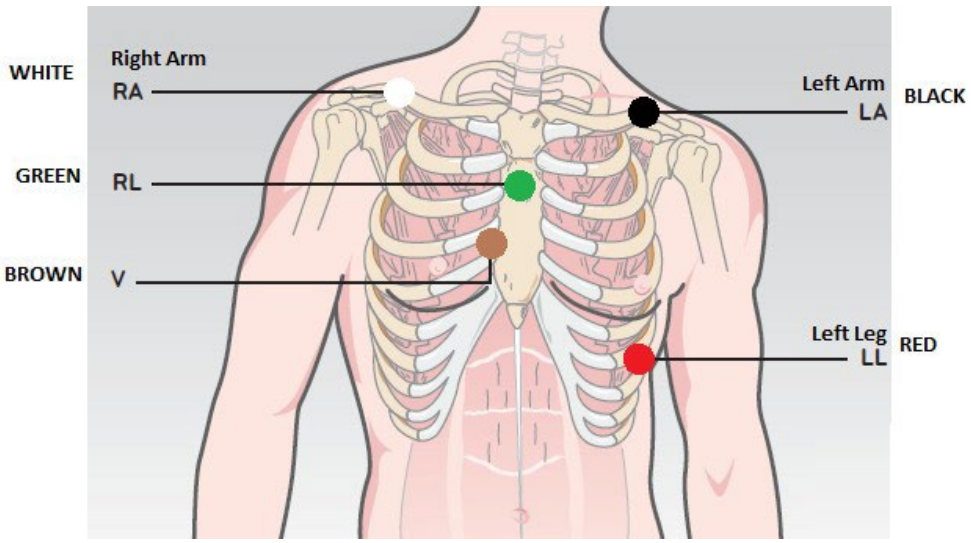
Ensure that the electrodes (sticky patches) are adhering well to your skin. At times, you may need to remove and replace the electrodes with fresh ones should they become disconnected or you wish to bathe. To do this, use the following steps:

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.

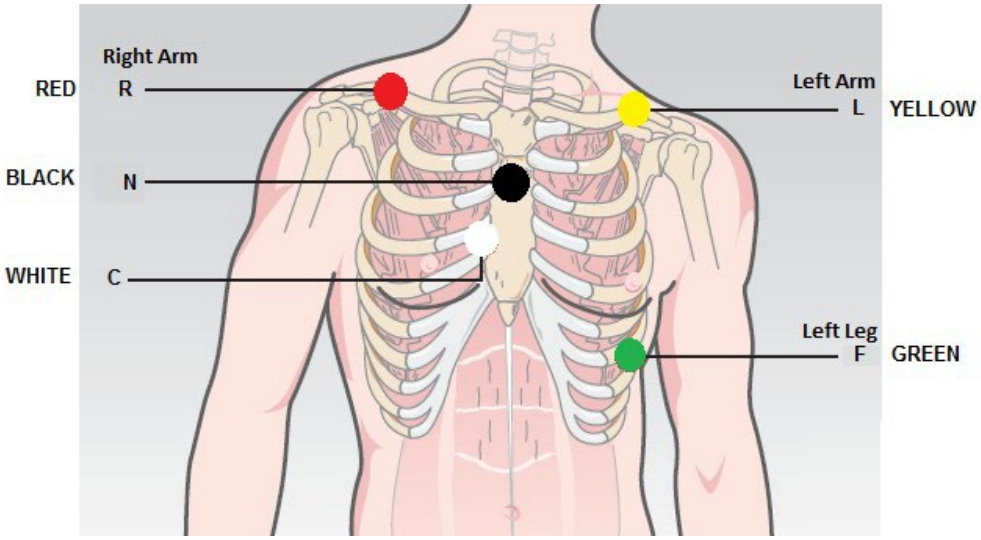


2. Carefully peel the electrodes from your skin and remove the lead wires from the electrodes. Then discard the used electrodes.
3. Snap the lead wires onto fresh electrodes.
4. Apply the electrodes to your clean and dry skin (no lotions, oils, or powder) in the lead locations shown below.

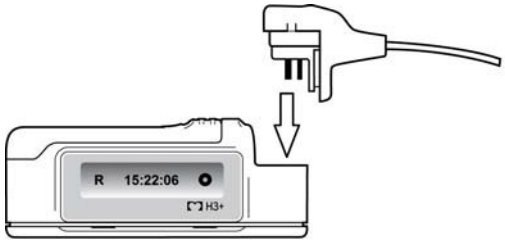
Electrode Placement (AHA colors)



Electrode Placement (IEC 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.
    - Use a clean, lint-free cloth
    - Do not use solvents
    - Do not use abrasive cleaners or materials

4. For disinfecting the exterior surface of the device, cables and lead wires, wipe exterior using:

    - Clorox Healthcare ® Bleach Germicidal Wipes (use according to instructions on product label), or
    - A soft, lint-free cloth with 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. Use caution with excess liquid as contact with metal parts may cause corrosion.

6. Do not immerse cable ends or lead wires; immersion can cause metal corrosion.

7. 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**: 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.

Product Life

The H3+ has a defined product life of 5 years excluding accessories, cables and batteries. As required, product service, accessories and spare parts are available through Welch Allyn or its authorized partners. Using the Holter recorder or its accessories and components beyond their defined life may lead to damage to the equipment or a safety hazard to the user.

Disposal of Waste Materials

Disposal must be in accordance with the following steps:

1. Follow cleaning and disinfection instructions per instructions in this user manual section.
2. Delete all existing data related to patients/hospital/clinic/doctor. Data backup may be performed prior to deletion.
3. Segregate material in preparation for the recycling process
    - Components are to be disassembled and recycled based on type of material
        - Plastic to be recycled as plastic waste
        - Metal to be recycled as Metals
            - Includes loose components containing more than 90% metal by weight
            - Includes screws and fasteners
        - Electronic components, including the power cord, to be disassembled and recycled as Waste of Electrical and Electronic Equipment (WEEE)
        - Batteries to be dismantled from the device and recycled as per WEEE

Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact Hillrom Technical Support for guidance on safe disposal protocols.

Waste of Electrical and Electronic Equipment (WEEE)

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:XXXXXXXXXXX XXXXXXXXXXXXX	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: 1.888.667.8272

Name of Unit/Product: _____

Product Information:

Date of Purchase:_____/_____/_____

Purchased Unit From: _____

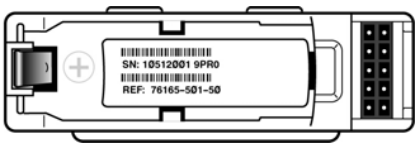
Serial Number: _____

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.



APPENDIX

IEC 60601-1-2 (EMC International Standard, 3rd Edition)

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.

<table>
<tr><th>Emissions Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment: Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to
80 MHz</td><td>3 Vrms
150 kHz to
80 MHz</td><td rowspan="2">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.

Recommended separation distance

$d = \left[\frac{3.5}{3V_{rms}}\right]\sqrt{P}$

$d = \left[\frac{3.5}{3V_{rms}}\right]\sqrt{P}$ 80 MHz to 800 MHz

$d = \left[\frac{3.5}{3V_{rms}}\right]\sqrt{P}$ 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 meters (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:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to
2.5 GHz</td><td>3 V/m
80 MHz to
2.5 GHz</td></tr>
</table>

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.*