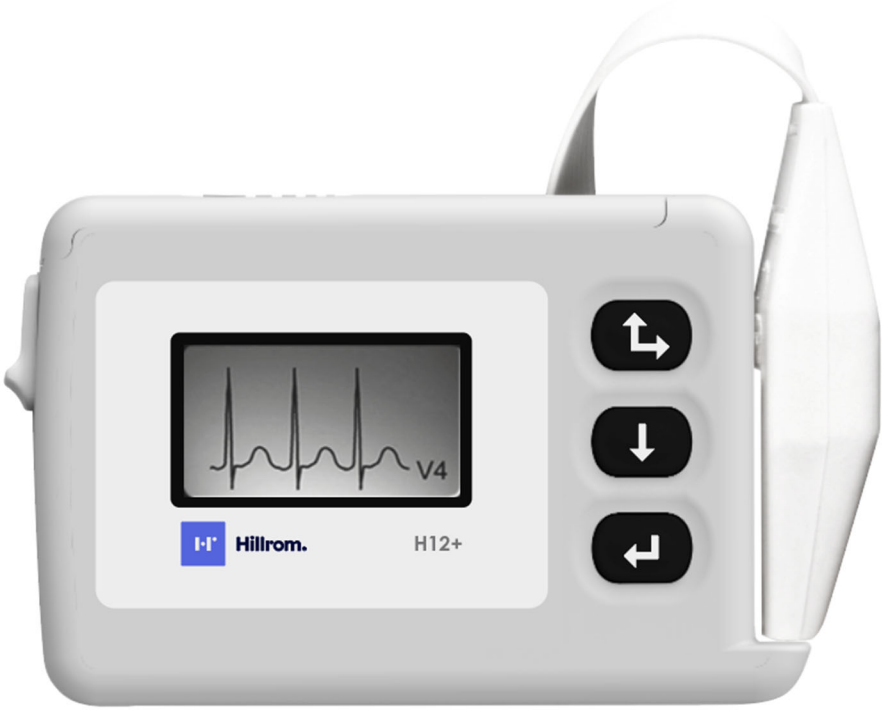
Hillrom™

Welch Allyn®
H12+™
12-lead Holter

User Manual



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

CE 0459

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All changes will be in compliance with regulations governing manufacture of medical equipment.

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
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901141 HOLTER RECORDER

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EC REP EU IMPORTER

Welch Allyn Limited
Navan Business Park, Dublin Road,
Navan, Co. Meath C15 AW22
Ireland

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SERVICE AND SPARE PARTS

Assistance and Parts

If the product fails to function properly or if assistance, service or spare parts are required, contact the nearest Welch Allyn Technical Support Center.

USA	1-800-535-6663	Canada	1-800-561-8797
Latin America	(+1) 305-669-9003	South Africa	(+27) 11-777-7555
European Call Center	(+353) 46-90-67790	Australia	(+61) 2-9638-3000
Italy	(+39) 051-298-7811	Singapore	(+65) 6419-8100
United Kingdom	(+44) 207-365-6780	Japan	(+81) 42-703-6084
France	(+33) 1-55-69-58-49	China	(+86) 21-6327-9631
Germany	(+49) 695-098-5132	Sweden	(+46) 85-853-65-51
Netherlands	(+31) 202-061-360		

When calling, please be prepared to provide:

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

Repairs

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

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

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

Packing Instructions:

Remove patient cable, battery, and Secure Digital memory card (as appropriate) prior to packing, unless you suspect they are associated with the problem.

Whenever possible, use the original shipping carton and packing materials.

Include a packing list and the Welch Allyn Return Material Authorization (RMA) number.

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

NOTICES

Manufacturer's Responsibility

Welch Allyn 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.
- 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 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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WARRANTY INFORMATION

Limited Warranty Statement

Welch Allyn warrants that the Welch Allyn H12+ Holter recorder you have purchased meets the labeled specifications of the product and will be free from defects in materials and workmanship that occur within 1 year after the date of purchase. Accessories used with the Product are warranted for 90 days after the date of purchase.

The date of purchase is: 1) the date specified in our records, if you purchased the Product directly from us, 2) the date specified in the warranty registration card that we ask you to send to us, or 3) if you don't return the warranty registration card, 120 days after the date on which the Product was sold to the dealer from whom you bought the Product, as documented in our records.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

You assume all responsibility for the use of the Product with any accessory that does not meet the requirements described in the Product documentation.

If a product or accessory covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Welch Allyn will, at its discretion, repair or replace the defective Product or accessory free of charge.

You must obtain a return authorization from Welch Allyn to return your Product before you send it to Welch Allyn's designated service center for repair.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.

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.

Any serious incident that has occurred in relation to the H12+ should be reported to Welch Allyn and the competent authority of the Member State in which the user or patient is established.

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.

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 60601-1, IEC 60601-1, and IEC 60601-2-47. Only use parts and accessories supplied with the device and available through Welch Allyn.

- Patient cables intended for use with the device include series resistance (9 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.

- ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation.

- 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.

- Defibrillation protection is guaranteed only if the original patient cable is used. Any modification of this device may alter defibrillator protection.

- 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.

- Carefully route cables to reduce any possibility of patient entanglement or strangulation.

- Simultaneous connection to other equipment may increase leakage current.

- 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.

- A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.

- 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)

- The H12+ recorder is not waterproof. It may be placed in an optionally available sealed, clear pouch that will protect it from moisture, but should not be submerged in water.
- To prevent possible damage to the device, do not use sharp or hard objects to depress buttons, only use fingertips.
- To prevent pinching, press down on the battery door latch when removing and replacing the battery door.
- Do not attempt to clean the device or patient cables by submersing 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.
- The device and patient cable should be cleaned between 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.
- Do not format the SD Card using standard Microsoft Windows formatting conventions on the computer. This will cause the SD card to be non-functional for Holter recording.
- When removing the SD card from the system card reader, it is recommended to use the “Safely Remove Hardware and Eject Media” feature on the computer to reduce the possibility of SD card errors.
- No user-serviceable parts are inside. Damaged or suspected inoperative equipment must be immediately removed from 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.
- AA 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:	-40° to +70°C
Relative Humidity:	10 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.

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 for the lead(s) where the condition is present.

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.
- Complete lead fail will cause a greater draw on battery power which may cause the recording period to end early due to low-battery voltage.
- If during power up the battery voltage is below 1.45V, the recorder will display a low battery message and will not continue.

The device will automatically turn off (blank screen) if the batteries have been severely discharged.

- 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.
- The device conforms to the following standards:

IEC 60601-1: Edition 3.1 2012-08	General requirements for basic Safety and essential performance
IEC 60601-2-47: Edition 2.0 2012-02*	Particular requirements for safety, including essential performance, of ambulatory electrocardiographic systems
IEC 60601-1-2: Third Edition 2007-03	Electromagnetic Compatibility
IEC 62304:2006/A1:2015	Software life-cycle processes
IEC 62366:2015	Application of usability engineering
93/42/EEC	Medical Device Directive (MDD)
2012/19/EU	Waste Electrical and Electronic Equipment
ISO 10993-1:2009/Cor. 1:2010	Biological evaluation of medical devices

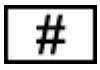
* Pacemaker spikes < 0.1 milliseconds may not always be detected.

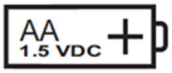
- The device is UL classified:

MEDICAL — PATIENT-MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), IEC 60601-1 (2012), CAN/CSA C22.2 No. 60601-1 (2014) AND IEC 60601-2-47 (2012).

- The H12+ Holter recorder may be used on infants weighing less than 10 kg (22 lbs).

EQUIPMENT SYMBOLS AND MARKINGS

	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.
	Warning: Do not use this equipment in the MRI scan room.
	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.
	Defibrillator-proof type CF applied part
	Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements.
	Device Manufacturer
	Device is UL classified.
	Indicates compliance to applicable EEC directives.
	Model Identifier
	Reorder Number
	Serial Number

	Global Trade Item Number
	Battery orientation and size
	Medical Device

GENERAL CARE

Precautions

- Turn off the device before inspecting or cleaning.
- The H12+ recorder is not waterproof. It may be placed in an optionally available sealed, clear pouch that will protect it from moisture, but should not be submerged 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 Maintenance for proper cleaning and disinfection procedures.

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 appropriate EMC table for recommended separation distances between the radio equipment and the device.

The use of accessories 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: Electromagentic 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.

Immunity 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>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagentic 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

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

$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz

$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 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.*

INTRODUCTION

Manual Purpose

This manual explains how to operate the 12-lead H12+™ digital Holter recorder. It shows the user how to:

- Prepare the patient
- Use the recorder
- Configure the recorder
- Troubleshoot

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.

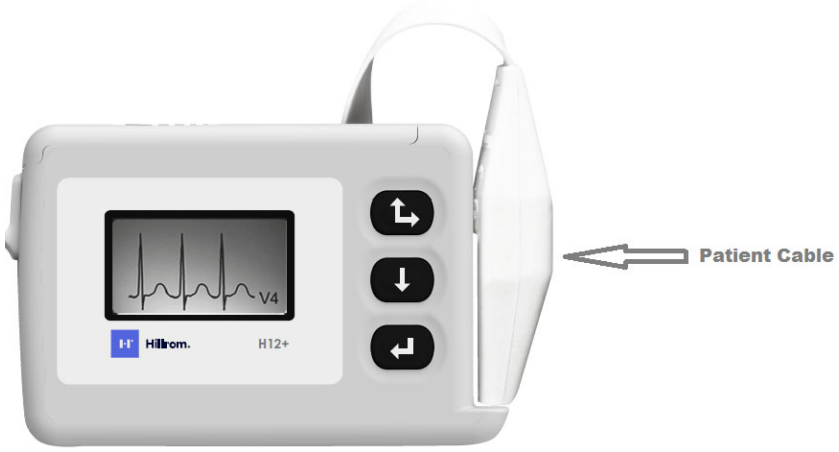
Indications for Use

The H12+ Holter recorder is intended to acquire, record and store ECG data of patients that have been connected to the H12+ recorder and are undergoing Holter monitoring. The H12+ acquires, digitizes and stores data to be analyzed by the HScribe Holter system.

- The H12+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of symptomatic patients requiring ambulatory (Holter) monitoring of up to 48 hours.
- The H12+ does not perform cardiac analysis by itself and is intended to be used with the HScribe™ Holter analysis system. ECG data pre-recorded by the H12+ is acquired and analyzed by the HScribe Holter analysis system.

H12+ Recorder Description

An LCD screen allows for checking the settings for recording duration, ECG sampling rate, impedance and lead quality during patient hook-up; a keypad allows for entering of patient ID, setup of configuration parameters, and starting of recording. The keypad can also be used to enter event markers in the patient record during recording. The H12+ recorder utilizes the patented LeadForm patient cable.



The H12+ recorder uses a single AA alkaline battery to provide continuous 12-lead data recorded and a removable secure digital (SD) card for data storage.

- A removable standard SD card can be dedicated for use with a particular H12+ recorder. Along with a fresh AA battery, this will provide continuous 12-lead data recorded at a 180 Hz sampling rate. A maximum recording duration of 24 hours or 48 hours is a feature of the SD card selected.
- A removable high-fidelity SD card can be dedicated for use with a particular H12+ recorder. Along with a fresh AA battery, this will provide continuous 12-lead data recorded at a 1,000 Hz sampling rate. A maximum recording duration of 24 hours or 48 hours is a feature of the SD card selected.

NOTE: High-fidelity data requires a special orderable option for the HScribe system software to export the 1,000 samples per second data.

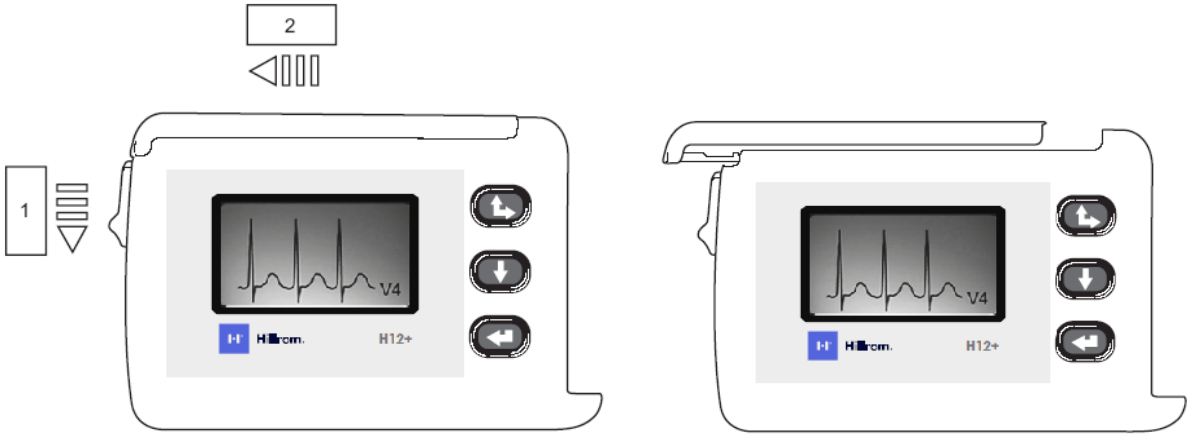
NOTE: The H12+ Holter recorder may be used on infants weighing less than 10 kg (22 lbs).

Recorder Setup

Opening and Closing the Battery Door

The SD card slot and the battery compartment are accessible via the battery door of the H12+ recorder. To open the battery door, hold the latch (**1**) down and then depress and slide the battery door (**2**) until it stops. Lift and remove the battery door.

To close the battery door, replace the battery door halfway, matching the grooves on the H12+ recorder as shown in the diagram, and slide in the opposite direction of the arrow (**2**) until the door latches into place.



Inserting the Battery

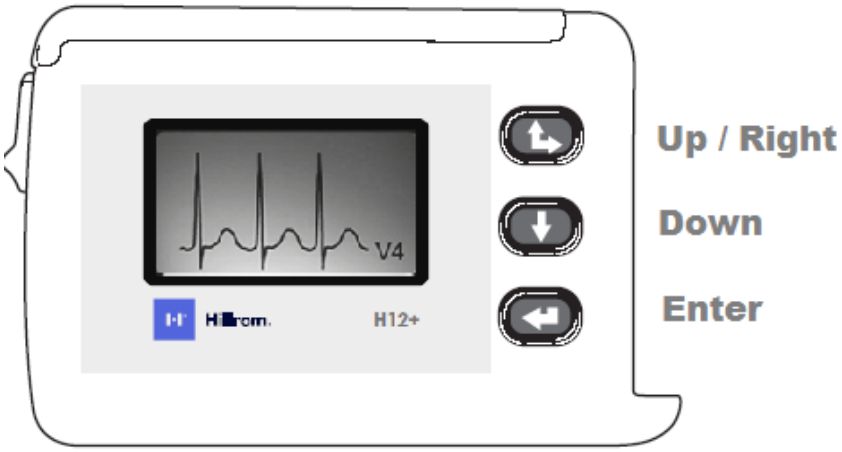
The H12+ recorder is powered with a single AA alkaline battery.

Open the battery door of the H12+ recorder. If needed, remove and discard the old battery. Insert a new battery with the '+' end aligned with the top of the recorder, as indicated on the back label. Close the battery door of the recorder.

> ***NOTE**: The H12+ recorder requires a full capacity battery to record a 24-hour or 48-hour session. The H12+ recorder will test battery voltage upon start up and will not allow the recording to begin if there is insufficient voltage. Always use a new battery to ensure operation.*

Using the Keypad

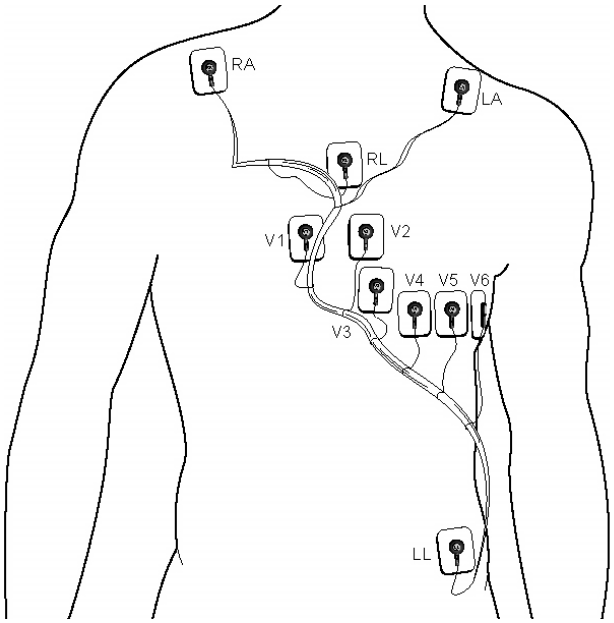
The keypad is located on the front, right side of the H12+ recorder. Three keys are available for navigating through the LCD screens and for entering the patient ID and event markers during the recording: **Up/Right, Down,** and **Enter**.



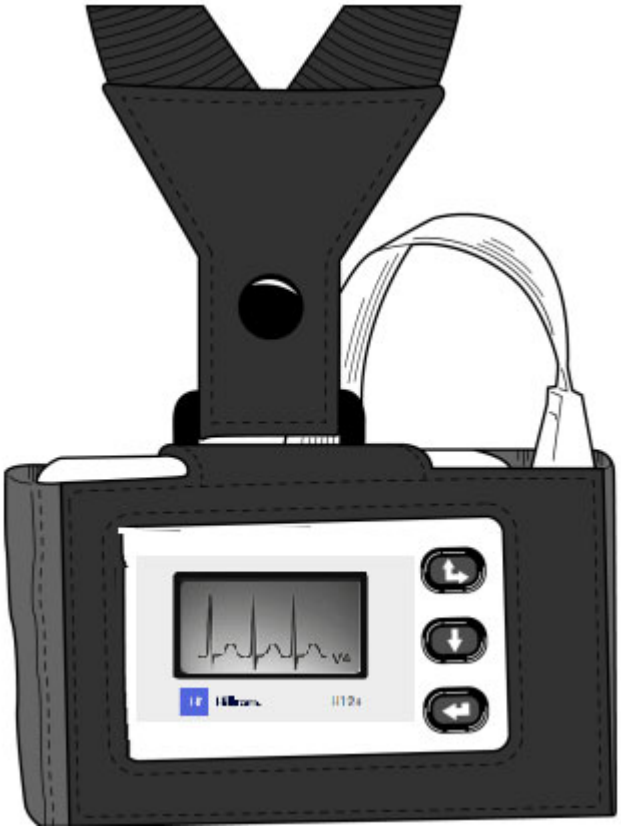
During patient hook-up, **Down** and **Up/Right** are used to scroll through the main menu options to enter the patient ID and to set the date/time and language. **Enter** is used to select main menu and sub-menu options displayed on the LCD screen, and to store the patient ID and configuration parameters for recorder operation.

LeadForm Patient Cable

The LeadForm patient cable consists of a connector block, main cable, and ten lead wires connected to the main cable. Each lead wire terminates in a snap connector. The lead wires are positioned on the main cable to follow the contour of the torso.



H12+ Recorder in Carrying Case



Part Numbers

Description	Part Numbers
H12+ 24-Hour Recorder with Standard SD Card	H12PLUS-LXX-XXXXX
H12+ 48-Hour Recorder with Standard SD Card	H12PLUS-MXX-XXXXX
H12+ 24-Hour Standard SD Card	107503
H12+ 48-Hour Standard SD Card	107505
H12+ 24-Hour Recorder with High-Fidelity SD Card	H12PLUS-NXX-XXXXX
H12+ 48-Hour Recorder with High-Fidelity SD Card	H12PLUS-OXX-XXXXX
H12+ High-Fidelity 24-Hour SD Card	107504
H12+ High-Fidelity 48-Hour SD Card	107506
H12+ Battery Door	413502
H12+ Carrying Case with Strap and Belt	8485-020-51
LeadForm Patient Cable/Domestic (AHA) • Standard • Large	9293-017-50 9293-026-50
LeadForm Patient Cable/International (IEC) • Standard • Large	9293-017-51 9293-026-51
H12+ User Manual – English	9515-160-51-CD
H12+ Quick Reference Guide – English	9515-160-51-CD
H12+ Holter Hookup Kits 24H – case of 24	9294-010-51
H12+ Holter Hookup Kits 48H – case of 24	9294-011-51
Single Patient Use Clip-on Pouch – case of 100	107179

Specifications

Feature	Specifications
Instrument Type	12-lead digital Holter recorder
Input Channels	Simultaneous acquisition of all leads
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
Input Dynamic Range	+/- 300 mV with a resolution of 2.5 µV/LSB
Frequency Response	0.05 to 60 Hz for standard recording 0.05 to 300 Hz for high fidelity recording
Digital Sampling Rate	32,000 s/sec/channel used for pacemaker spike detection 180 s/sec/channel used for standard recording and storage 1,000 s/sec/channel is used for high fidelity recording and storage
Special Functions	Pacemaker detection, ECG display, and lead quality check
A/D Conversion	20 bits
Storage	Secure Digital (SD) memory card
Device Classification	Type CF, battery operated
Weight	4 oz. (125 g) without battery
Dimensions	2.5” x 3.85” x .98” (64 mm x 98 mm x 25 mm)
Batteries	(1) AA alkaline

Environment	Specifications
Operating Temperature	+10˚ to +45˚C
Storage Temperature	-40˚ to +70˚C
Operating Humidity	10% to 95%, non-condensing
Storage Humidity	10% to 95%, non-condensing
Operating Altitude (Pressure)	H12+ will operate normally from 700 to 1060 millibars
Storage Altitude (Pressure)	500 to 1060 millibars
Water Ingress	IPX0

PATIENT PREPARATION

Patient Hookup

Skin Preparation

Good skin preparation prior to electrode attachment is very important to ensure good signal quality when recording patient data. Poor electrode-to-skin contact may cause artifact (noise) to be included in the recording which can affect the analysis of the ECG data. Low-amplitude signals may also be the result of poor electrode-to-skin contact.

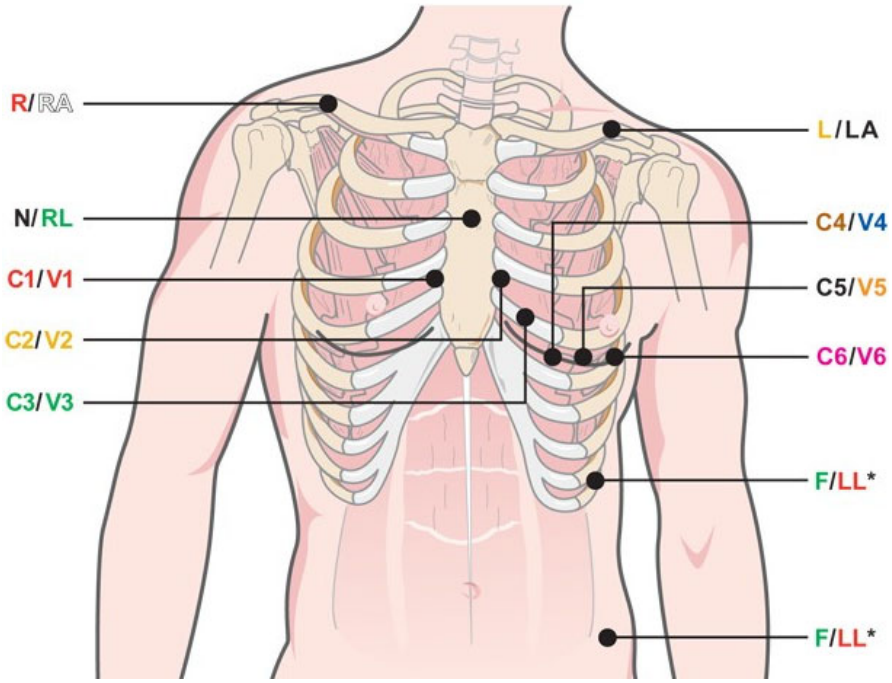
1. Identify the (10) electrode sites on the torso (refer to the Positioning the Electrodes diagram).
2. Use a clipper or razor to remove any hair from the electrode sites.
3. Clean the skin with soap or alcohol to remove any body oils, lotion, or powder.
4. Use gauze to dry the skin and remove any alcohol residue if used.
5. Use an abrasive pad to gently abrade, but not break, the skin where the center of each electrode will be applied. This removes dead skin cells that may impede heart signal conduction.

Positioning the Electrodes

6. Attach the electrodes to the lead wires on the patient cable before attaching electrodes to the patient.
7. Firmly attach each lead wire to an electrode.
8. Place the gel area of the electrode over the center of the prepared area using the positioning illustrated on the next page; press the adhesive ring into place. Avoid pressing the center of the gel area.
9. Place right arm (RA/R) and left arm (LA/L) leads close to the shoulder on the clavicle bone.
10. Place right leg (RL/N) and left leg (LL/F) leads on the lower portion of body, as close to the hip as possible, on the iliac crest (original Mason-Likar position), or on the lowest rib on each side of the chest (modified Mason-Likar position).
11. Ensure electrodes are securely attached to the skin. To test electrode contact, lightly tug the lead wire to check adhesion. If the electrode moves freely, the site should be prepped again. If the electrode does not move easily, a good connection has been obtained.

***NOTE AND CAUTION**: Proper skin preparation is very important. Poor ECG signal quality is the main cause for incorrect beat and arrhythmia detection. RA and LA are susceptible to muscle interference. RL and LL leads are susceptible to interference from clothing, a belt, and movement.*

Choose the best locations for limb lead placement according to body type. Avoid muscular and loose, flabby skin locations.



***NOTE AND CAUTION**: Placement of the Left Leg (LL) electrode in the original Mason-Likar position increases the similarity of the acquired ECG with a standard 12-lead ECG and is therefore recommended; however, clothing may interfere with this position and increase the amount of artifact. The modified position may decrease the sensitivity of inferior ECG leads and cause axis shift with respect to the standard 12-lead ECG. Accurate skin preparation and suitable clothing are the most important factors in excessive artifact prevention.*

Limb Electrode		
AAMI	*IEC*	*Placement*
RA	*R*	**On or below the right clavicle as shown**
LA	*L*	**On or below the left clavicle as shown**
RL	*N*	**Reference or ground lead, should be placed in a stable location of the body**
LL	*F*	**Lower-left side of body in a stable location, as close to the hip as possible**

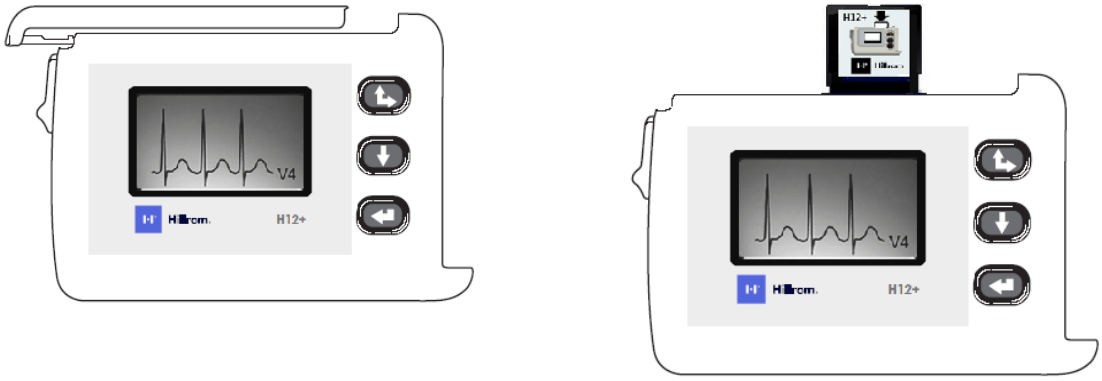
Precordial Electrode		
AAMI	*IEC*	*Placement*
V1	*C1*	***Fourth intercostal space at the right sternal border***
V2	*C2*	***Fourth intercostal space at the left sternal border***
V3	*C3*	***Midway between V2 and V4***
V4	*C4*	***Fifth intercostal space at the left of the midclavicular line***
V5	*C5*	***Anterior axillary line on the same horizontal level as V4***
V6	*C6*	**Mid-axillary line on the same horizontal level as V4 and V5**

USING THE RECORDER

Inserting and Removing SD Cards

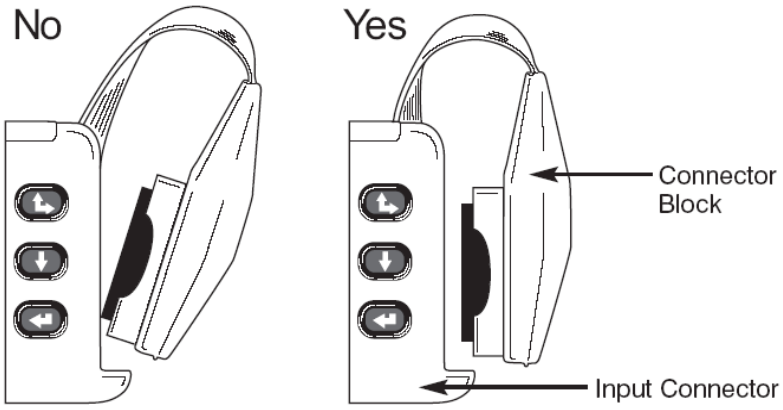
To insert an SD card, open the battery door of the recorder. Position the card above the empty card slot with the label facing front as shown below. Place the SD card in the slot and **gently** push down on the SD card until it is firmly engaged and can move no further.

To remove an SD card, gently push down on the SD card to disengage and eject. The internal card carrier is spring loaded. Once ejected, grasp the top of the card and lift to remove.



Attaching the Patient Cable

Insert the connector block into the input connector on the side of the H12+ recorder.



NOTE: **Be careful to insert the connector block parallel to the input connector.**

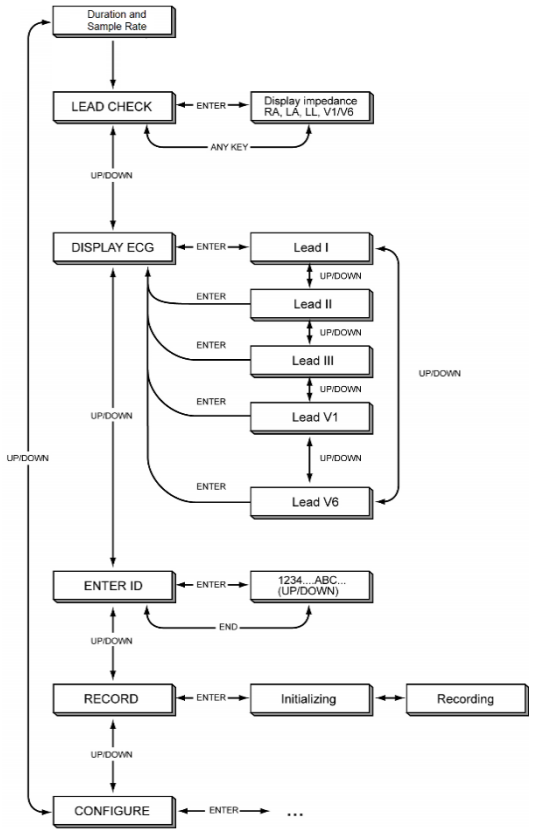
Main Menu Options

The recording set duration from 1 to 48 hours (or 1 to 24 hours) and the Holter ECG sampling rate are initially displayed upon insertion of the SD card and AA battery once the battery door closed and initialization has completed. Selection of the Down-arrow key moves to the Lead Check. Selection of the Up/Right arrow moves to Configure.

The main menu includes the following options:

- TARGET RATE / DURATION SETTINGS (view only, changes made in CONFIGURE)
- LEAD CHECK
- DISPLAY ECG
- ENTER ID (or ID# if card is already prepared)
- RECORD (see Using the Recorder)
- CONFIGURE

The following operational flowchart of menu options depicts the flow of functionality using **Up/Right**, **Down**, and **Enter**.



The LEAD CHECK, DISPLAY ECG, ENTER ID, and CONFIGURE tasks are performed prior to starting a new patient recording. With the exception of CONFIGURE, the other tasks are typically reviewed for each recording.

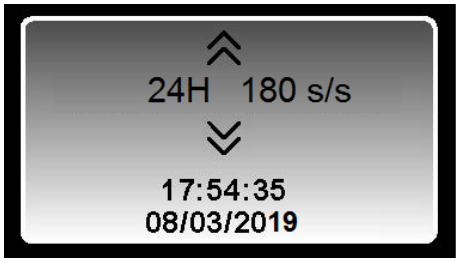
> ***NOTE**: Patient ID entry (ENTER ID) is optional and can be entered during recorder preparation at HScribe or after the patient record is downloaded to the HScribe system.*

Starting a Recording Session

1. Insert a proprietary Welch Allyn SD card and a new AA battery.

2. After the battery door is closed, H12+ will power up and perform software and battery tests. This takes a few seconds while the Hillrom splash screen is displayed. When finished, the duration and sample rate are displayed.

3. Verify the set duration and sample rate.
   a. If necessary, navigate to the CONFIGURE menu to change the set duration and sample rate (see Changing Duration and Changing Sample Rate).



4. Hookup the patient (see Patient Preparation).

5. Verify the quality of the hookup by checking the impedances. Scroll through the main menu until LEAD CHECK is displayed, press **Enter**.

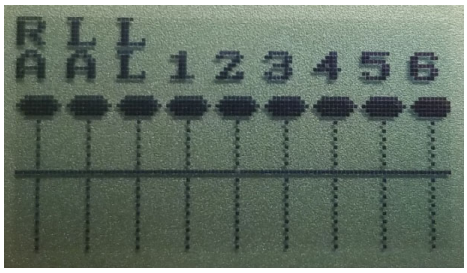
Note: Main menu options are displayed in the middle of the screen with Up '▲' and Down '▼' indicators above and below the option to indicate how to scroll to the next option. The current time and date are displayed at the bottom of the LCD screen.

Checking Impedances

LEAD CHECK is a valuable tool for verifying and optimizing signal quality after patient hookup and before starting a recording.

From the main menu, scroll to LEAD CHECK, press **Enter**.

A graph depicting the impedance measured at the right arm (RA), left arm (LA), left leg (LL), and V1 through V6 electrodes is displayed from left to right in vertical columns on the screen. The higher the solid black oval indicator, the better the contact is between the skin and the electrode.



An oval indicator positioned at the top the vertical line means optimal high quality and good electrode contact. For good-quality recordings, the bars should reach or exceed the horizontal line on the display. A low bar graph means poor electrode-to-skin contact and high-electrode impedance. The skin preparation should be repeated, and the electrode(s) replaced.

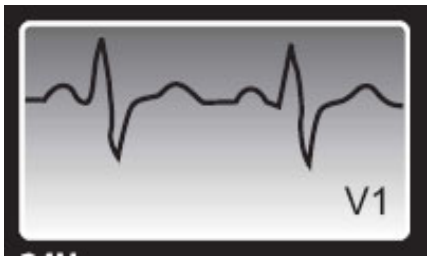
Once acceptable impedance levels are verified, press any of the three keys to return to the main menu.

6. Verify the amplitude and signal quality by displaying each of the leads. Scroll through the main menu until DISPLAY ECG is displayed, press **Enter**.

Displaying ECG Leads

DISPLAY ECG is used to visually inspect leads I, II, III, V1, V2, V3, V4, V5, and V6 before starting a recording. Check the signal quality and ECG amplitude for each lead.

From the main menu, scroll to DISPLAY ECG, press **Enter.**



Lead I is the first lead displayed on the screen. Scroll from lead to lead. After visual verification of all leads, press **Enter** to return to the main menu.

7. To enter the patient ID, scroll through the main menu until ENTER ID is displayed, press **Enter**.

   ***NOTE**: When Patient ID entry has been performed at the HScribe system and saved to the SD card, you will not be prompted with "Enter ID". The patient ID number will be displayed.*

   ***NOTE**: Unsupported characters are displayed as a question mark (?)*

Entering Patient ID

ENTER ID is used to enter the patient ID in the patient record before starting a recording. Press **Enter** to select.

To enter the patient ID, the cursor is moved to the desired letter or digit in the alphanumeric table and then selected by pressing **Enter**.

The cursor is initially located in the upper-left corner of the screen over the number '0'. To move the cursor one letter or digit to the right on a line, press **Up/Right**. When the cursor reaches the end of the line, the cursor wraps to the beginning of the line.

To move the cursor down one line, press **Down**. If the cursor is on the bottom line, pressing **Down** moves the cursor to the top line.

To enter a space, move the cursor to the last line and position the cursor over the blank space following the last letter. Press **Enter**.

To delete a letter or digit, position the cursor over Del on the bottom line. Press **Enter** to delete the last letter or digit entered. To end entry, position the cursor over End on the bottom line, press the **Enter** to end and save.

***NOTE**: When entering the patient ID, the* **Up/Right** *key is used to move the cursor to the right. The cursor cannot be moved in the left or up direction.*

8. To begin recording, scroll through the main menu until RECORD is displayed, then press **Enter**. An initializing message will be displayed for up to 3 seconds; "Recording" and the current time appear when the recording actually begins.

During normal operation of a recording, the current time (HH:MM:SS) is displayed near the middle of the screen for the entire recording session. Total hours recorded is displayed below the current time. The Recording message is displayed below the number of total hours recorded; the patient ID number is displayed at the bottom of the LCD screen.

NOTE: *If the battery door is removed during recording, the H12+ recorder stops recording. A new proprietary Welch Allyn SD card and fresh battery must be inserted to continue recording.*

NOTE*: In the event of a lead fail condition occurring during recording, the appropriate lead fail indicator(s) is displayed below the Recording message and will replace the displayed patient ID number until resolved. See Appendix A, Troubleshooting, for information on lead fail messages.*

Entering (Optional) Diary Events

During the recording session, the patient may be instructed to enter event markers on the H12+ recorder for analysis purposes. Once entered on the recorder, the patient is instructed to document the time and symptom in the patient diary. Typical diary events may include symptomatic occurrences, such as shortness of breath or palpitations, or any event deemed valuable for analysis purposes.

To enter an event after the first minute of recording, press any of the three keys on the H12+ recorder. An "Event Stored" message is displayed below the current time and will replace the patient ID number until a new event can be entered.

NOTE*: In the event of a simultaneous lead fail event, the Event Stored message replaces the lead fail message for the one-minute period. If lead fail persists after the one-minute period, the lead fail message is displayed.*

Ending a Recording Session

At the end of the set recording duration, the time is automatically cleared from the LCD screen and a "Recording Complete" message is displayed. To proceed:

1. Remove the battery door of the H12+ recorder.
2. Remove battery and dispose of properly. (Batteries should only be used once.)
3. Gently press down on the SD card to eject and then remove the SD card.

Ending a Recording Session Early

The recording session can be stopped at any time by performing the following steps:

1. Simultaneously press and hold **Up/Right** and **Down** for a period of 5 seconds. The LCD screen will prompt you with a "Stop Recording" message; "No" is set as the default.
2. Press **Up/Right** to move the highlight to "Yes".
3. Press **Enter** to stop recording.
4. A "Recording Complete" message is displayed.

***NOTE**: A message is added to the SD card service log indicating that the recording was manually ended.*

CONFIGURING THE RECORDER

Configuration

CONFIGURE is used to set the current date and time, the date format, the recording duration from 1 to 48-hours or 1 to 24-hours, language defaults, and to display the software version number.
Note: A maximum recording duration of 24 hours or 48 hours is a feature of the SD card selected.

Also, when a High-Fidelity SD card is used, the Holter ECG sampling rate can be set at 1000 samples per second or 180 samples per second.

These settings are typically set before the initial patient recording and do not need to be set on a per patient recording basis.

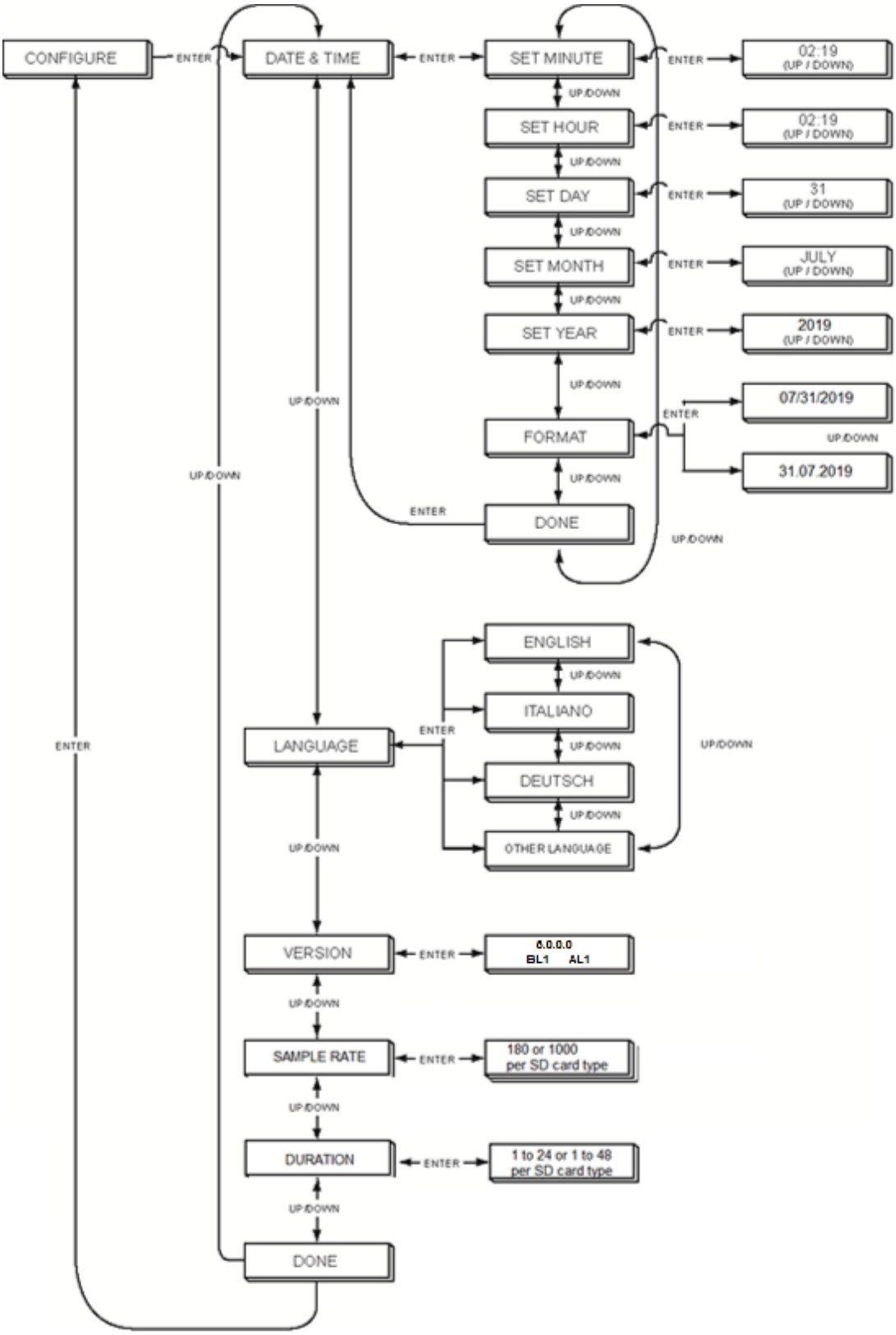
From the main menu, scroll to CONFIGURE, press **Enter**.

The CONFIGURE menu includes the following options.

- DATE/TIME
- LANGUAGE
- VERSION
- SAMPLE RATE
- DURATION
- DONE

Scroll through the CONFIGURE menu options; press **Enter** when the desired option is displayed. Select DONE and **Enter** to return to the CONFIGURE menu.

The following operational flowchart of CONFIGURE menu options depicts the flow of functionality using **Up/Right**, **Down**, and **Enter**.


CONFIGURE
ENTER
DATE & TIME
ENTER
SET MINUTE
ENTER
02:19
(UP / DOWN)
UP/DOWN
SET HOUR
ENTER
02:19
(UP / DOWN)
UP/DOWN
SET DAY
ENTER
31
(UP / DOWN)
UP/DOWN
SET MONTH
ENTER
JULY
(UP / DOWN)
UP/DOWN
SET YEAR
ENTER
2019
(UP / DOWN)
UP/DOWN
FORMAT
ENTER
07/31/2019
UP/DOWN
31.07.2019
UP/DOWN
DONE
ENTER
UP/DOWN
UP/DOWN
UP/DOWN
ENTER
LANGUAGE
ENTER
ENGLISH
UP/DOWN
ITALIANO
UP/DOWN
DEUTSCH
UP/DOWN
OTHER LANGUAGE
UP/DOWN
UP/DOWN
VERSION
ENTER
6.0.0.0
BL1 AL1
UP/DOWN
SAMPLE RATE
ENTER
180 or 1000
per SD card type
UP/DOWN
DURATION
ENTER
1 to 24 or 1 to 48
per SD card type
UP/DOWN
DONE

Setting Date and Time

DATE/TIME is used to set the current date and time and to set an alternative format for the displayed date.

From the configuration menu, scroll to DATE/TIME, press **Enter**. The DATE/TIME menu includes the following options:

- SET MINUTE
- SET HOUR
- SET DAY
- SET MONTH
- SET YEAR
- FORMAT
- DONE

Scroll to the desired option, press **Enter**. The current values for this option are displayed on the LCD screen.

When setting the date or time, increase the value by pressing **Up/Right**. To decrease the value, press **Down**. When the correct value is displayed on the screen, press **Enter**.

> ***NOTE**: A SET SECONDS option does not exist because seconds are reset each time a value is changed. If you want to reset the seconds, set the minutes first. Press* **Enter** *at the instant you want the seconds to be reset.*

FORMAT provides two options for the date format: month/day/year or day.month.year.

From the DATE/TIME menu, scroll to FORMAT**,** press **Enter**. Scroll from one option to the other; press **Enter** to select the desired date format and return to FORMAT menu. Scroll to DONE, press **Enter.**

To return to the CONFIGURE menu, scroll to DONE, press **Enter**.

Setting Language

LANGUAGE is used to select a language to view the main and sub-menu options.

From the CONFIGURE menu, scroll to LANGUAGE, press **Enter**. Scroll through the language options; press the **Enter** key to select the desired language and return to the LANGUAGE menu. Scroll to DONE, press **Enter.**

Viewing Software Version Number

VERSION displays the current software version installed on the H12+ recorder.

From the CONFIGURE menu, scroll to VERSION using **Up/Right** or **Down;** press **Enter** to view software version. Press **Enter** to return to VERSION, scroll to DONE, and press **Enter** to return to CONFIGURE menu.

Changing Sample Rate (High-Fidelity SD card only)

The sample rate is selectable only when using the High-Fidelity SD card which can be set to 1000 or 180 samples per second.

From the CONFIGURE menu, scroll to SAMPLE RATE, press **Enter**. Scroll to the sample rate desired; press the **Enter** key to select and return to the SAMPLE RATE menu. Scroll to DONE, press **Enter.**

Changing Duration

Duration is used to select recording duration in hour intervals. The maximum selectable recording duration of 24 hours or 48 hours is a feature of the SD card being used.

From the CONFIGURE menu, scroll to DURATION, press **Enter**. Scroll to select the desired duration in hours as value of 1 to 48 or 1 to 24 as dependent on the SD card being used; press the **Enter** key to select and return to the DURATION menu. Scroll to DONE, press **Enter.**

MAINTENANCE

Cleaning and Disinfecting

This section describes the procedures for cleaning and disinfecting the H12+ and accessories.

***WARNING**: Follow these instructions to clean and disinfect the H12+ and its accessories. Improper cleaning may cause damage that is not immediately apparent, leading to possible safety hazards, device malfunction, and/or spread of infectious agents between persons.*

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.

***WARNING: Do not immerse the H12+ in water or any other fluids**. The H12+ is not designed to be immersed in liquid and doing so may result in liquid entering the device leading to possible safety hazards and/or device malfunction.*

***CAUTION**: **Do not steam autoclave, gas sterilize, or irradiate** the H12+ as these may result in damage to the device.*

***WARNING**: **Ensure the battery door is securely in place** when cleaning the H12+ to avoid risk of liquid entering into the device which may lead to a possible hazard and/or device malfunction.*

Disinfecting Agents for the H12+

The H12+ is compatible with the following disinfectants:

- Clorox Healthcare® Bleach Germicidal Wipes (use according to instructions on product label), or
- a soft, lint-free cloth dampened 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.

***CAUTION**: Disinfecting or cleaning agents that contain **Quaternary Ammonium Compounds (Ammonium Chlorides)** have been identified as having negative effects if used to disinfect the product. Use of such agents may result in discoloration, cracking, and deterioration of the external housing of the device.*

To clean the H12+

1. Remove carry case and disconnect ECG cable from the device.
2. Disconnect power source by removing AA. Reinstall the battery door.
3. Thoroughly wipe the surface of the H12+ with a clean, lint-free cloth dampened with a mild detergent and water for general cleaning or use one of the above recommended agents for disinfection.

***WARNING**: **Do not oversaturate the cleaning cloth**. Liquid pooling on the device may enter into the device possibly leading to a safety hazard and/or device malfunction.*

4. Dry the device with a clean, soft, dry, lint-free cloth.

Cleaning and Disinfecting Accessories

ECG Cables	**Approved Cleaning Agents** • Enzymatic detergent such as ENZOL (US) or CIDEZYME (outside the US). • Distilled water. • Disinfectant solution (such as CIDEX OPA, or a 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water). • Soft, lint-free cloths and/or soft-bristled brushes. • Protective gloves and eyewear. **Procedure** 1. Remove the ECG cable from the recorder. 2. Put on gloves and protective eyewear. 3. Prepare the detergent according to the manufacturer's instructions, and also the disinfectant solution, in separate containers. 4. Apply detergent to product using a soft, lint-free cloth. If material is dried on, allow to sit for 1 minute. Do not immerse cable ends or lead wires in liquid as it can cause corrosion. 5. Wipe smooth surfaces with the cloth. 6. Use a soft-bristle brush on visibly soiled areas and irregular surfaces. 7. Remove detergent from product using cloth dampened in distilled water. 8. Repeat as necessary. 9. Apply disinfectant solution on affected area using a soft cloth. Allow product to sit for 5 minutes. 10. Wipe excess solution and clean product again with cloth dampened in distilled water. 11. Allow 2 hours for drying.

Carry case: Wash the carry case by hand with fabric detergent and then air dry. Do not machine dry the case.

The H12+ is compatible with a number of other accessories, each with unique cleaning and disinfecting needs. Follow the cleaning and disinfecting instructions provided in the directions for use shipped with those items.

***WARNING**: **Always clean and/or disinfect accessories** between patients to reduce the risk of spreading infectious agents between persons.*

***WARNING**: **Do not reuse accessories indicated as single-patient use**; as this may facilitate the spread of infectious agents between persons.*

***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.*

***CAUTION**: Use caution with excess liquid as contact with metal parts may cause corrosion.*

***CAUTION**: Do not immerse cable ends or lead wires; immersion can cause metal corrosion.*

***CAUTION**: Do not use excessive drying techniques such as forced heat.*

Periodic Maintenance

Check the H12+ and the ECG 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
    - Clean the cable with a germicidal solution that does not contain alcohol
    - Alcohol will cause hardening and can introduce cracks
    - Don't use tape on the patient cable; tape residue 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 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

3. Calibration:
    - H12+ is functionally tested during the manufacturing process and is not designed to require field calibration or annual recertification.

Product Life

The H12+ 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

The H12+ uses one AA battery and disposable monitoring electrodes. Disposal must be in accordance with the following procedures:

Battery: applicable disposal or recycling standards

Electrodes: normal waste

TROUBLESHOOTING

The following table describes error and lead fail messages that are displayed on the H12+ recorder during patient hookup and recording.

Table of Messages

Message	Solution
'LOW BATTERY'	Replace existing battery with a fully charged battery.
'CHECKSUM ERROR'	If checksum does not match the stored checksum at power up. Contact Welch Allyn Technical Support Group.
'CARD ERROR'	SD card error. SD card product capabilities identification file is missing. Contact Welch Allyn Technical Support Group.
'No card'	SD card not detected in the card slot. Install a formatted SD card.
'CARD NOT Hillrom FORMATTED'	SD not properly formatted. Contact Welch Allyn Technical Support Group.
'CARD NOT ERASED'	Data detected on SD card. Erase the card using HScribe system software.
'RATE_DUR.TXT error'	Rate/Duration file is not properly formatted or is set to exceed the limits. Press any key to continue the powerup sequence.
'PATINFO4.TXT error"	Patient information file is not properly formatted. Reformat the SD card at HScribe.
'RA'	RA fail. Check if the lead wire is off or the electrode needs to be replaced.
'RL'	RL fail. Check if the lead wire is off or the electrode needs to be replaced.
'LA'	LA fail. Check if the lead wire is off or the electrode needs to be replaced.
'LL'	LL fail. Check if the lead wire is off or the electrode needs to be replaced.
'V1'	V1 fail. Check if the lead wire is off or the electrode needs to be replaced.
'V2'	V2 fail. Check if the lead wire is off or the electrode needs to be replaced.
'V3'	V3 fail. Check if the lead wire is off or the electrode needs to be replaced.
'V4'	V4 fail. Check if the lead wire is off or the electrode needs to be replaced.
'V5'	V5 fail. Check if the lead wire is off or the electrode needs to be replaced.
'V6'	V6 fail. Check if the lead wire is off or the electrode needs to be replaced.
Any combination of 'RA, LA, RL, LL, V1, V2, V3, V4, V5, V6'	More than one lead is in fail. Check the lead wires and electrodes.

TRANSLATIONS

Table of Translations

English	Italian ITALIANO	Spanish ESPAÑOL	German DEUTSCH	Dutch NETHERLANDS
RECORD	INIZIO	GRABAR	AUFNAHME	OPNAME
DURATION	DURATA	DURACIÓN	DAUER	DUUR
LEAD CHECK	DERIVAZIONI	TEST ELECT	ABL.TEST	LEAD
DISPLAY ECG	MOSTRA ECG	MOSTRAR ECG	EKG-ANZEIGE	TOON ECG
ENTER ID	ID PAZIENTE	INTRO ID	PATIENT ID	ID PATIENT
DATE & TIME	DATA & ORA	FECHA/HORA	DATUM/ZEIT	DATUM/TIJD
CONFIGURE	CONFIGURA	CONFIGURAR	EINSTELLUNG	CONFIGUREER
VERSION	VERSIONE	VERSION	VERSION	VERSIE
SAMPLE RATE	FREQ. ACQ.	MUESTRAS/S	SAMPLE-RATE	SAMPLE RATE
SET HOUR	ORA	HORA	STUNDE	UUR
SET MINUTE	MINUTI	MINUTO	MINUTE	MINUUT
SET DAY	GIORNO	DIA	TAG	DAG
SET MONTH	MESE	MES	MONAT	MAAND
SET YEAR	ANNO	AÑO	JAHR	JAAR
FORMAT	FORMATO	FORMATO	FORMAT	DATANOTATIE
DONE	FINE	OK	FERTIG	GEREED
LANGUAGE	LINGUA	IDIOMA	SPRACHE	TAAL
Recording	Registrazione	Grabacion	Aufnahme	Opname
Event Stored	Evento mem.	Evento mem.	Ereignis gesp.	Event
RECORDING COMPLETE	REGISTRAZIONE TERMINATA	GRABACION FINALIZADA	AUFNAHME FERTIG	EINDE OPNAME
LOW BATTERY	SCARICA BATTERIA	BAJA BATERIA	LEER BATTERIE	LEEG BATTERIJ
CARD NOT FORMATTED	CARD NON FORMATTATA	TARJETA NO FORMATEADA	KARTE NICHT FORMATIERT	KAART NIET GEFORMATEERD
CARD NOT ERASED	CARD NON CANCELLATA	TARJETA NO BORRADA	KARTE NICHT GELÖSCHT	KAART NIET GEWIST
DEL (DELETE)	CANC	Borr	ENTF	DEL
END	FINE	Fin	ENDE	OK
Stop Recording	Fine Registrazione	Salir Grabacion	Ende Aufnahme	Exit Opname
No	No	No	Nein	Nee
Yes	Si	Si	Ja	Ja

Table of Translations (continued)

English	French FRANÇAIS	Polish POLSKI	Finnish SUOMI	Portuguese PORTUGUES
RECORD	ENREGISTRER	START	TALLENNUS	REGISTO
DURATION	DURÉE	CZAS_TRWANIE	KESTO	DURAÇÃO
LEAD CHECK	DÉRIVATIONS	ELEKTRODY	ELEKTRODIT	DERIVAÇÕES
DISPLAY ECG	AFFICH. ECG	EKG	NÄYTÄ EKG	MOSTRAR ECG
ENTER ID	ID PATIENT	OPIS	SYÖTÄ ID	INTRO ID
DATE & TIME	DATE/HEURE	DATA/CZAS	PÄIVÄYS/AIKA	DATA & HORA
CONFIGURE	CONFIGURER	USTAWIENIA	KONFIGUROI	CONFIGURAR
VERSION	VERSION	WERSJA	VERSIO	VERSÃO
SAMPLE RATE	ECH/S	PRÓBKOWANIE	SPS	FREQ AMOSTRA
SET HOUR	HEURE	GODZINA	TUNTI	HORA
SET MINUTE	MINUTE	MINUTA	MINUUTTI	MINUTO
SET DAY	JOUR	DZIEN	PÄIVÄ	DIA
SET MONTH	MOIS	MIESIAC	KUUKAUSI	MÊS
SET YEAR	ANNÉE	ROK	VUOSI	ANO
FORMAT	FORMAT	FORMAT DATY	PÄIVÄYS	FORMATO
DONE	FIN	ZATWIERDZ	VALMIS	OK
LANGUAGE	LANGUAGE	JEZYK	KIELI	IDIOMA
Recording	Enregistr.	Badanie trwa	Tallentaa	A registar
Event Stored	Évèn.mèm	Znacznik	Tapahtuma	Evento mem.
RECORDING COMPLETE	ENREGISTR. COMPLET	REJESTRACJA ZAKONCZONA	TALLENTAA VALMIS	REGISTO COMPLETO
LOW BATTERY	BATTERIE DÉCHARGÉE	SLABA BATERIA	AKKU TYHJENEE	BATERIA FRACA
CARD NOT FORMATTED	CARTE NON FORMATTÉE	KARTA NIE SFORMATOWANA	DATAKORTTI FORMATOIMATON	CARTA NAO FORMATADA
CARD NOT ERASED	CARTE NON EFFACÉE	KARTA NIE KASUJ	DATAKORTTI TUHOTA	CARTA NAO APAGADA
DEL (DELETE)	EFF	KAS	POISTA	APAGAR
END	FIN	KON	LOPETA	FIM
Stop Recording	Fin Enregistr.	Stop Rejestracja	Exit Tallentaa	Fim A registar
No	Non	Nie	Ei	Não
Yes	Oui	Tak	Kylla	Sim

Table of Translations (continued)

English	Swedish SVENSKA	Danish DANSK
RECORD	SPELA IN	OPTAG
DURATION	VARAKTIGHET	VARIGHED
LEAD CHECK	LEDN.KONTR.	AFLED CHECK
DISPLAY ECG	VISA EKG	DISPLAY EKG
ENTER ID	ANGE ID	INDTAST ID
DATE & TIME	DATUM/TID	DATO/TID
CONFIGURE	KONFIGURERA	KONFIGURER
VERSION	VERSION	VERSION
SAMPLE RATE	SAMPL.FREKV	PRØVEFREKV
SET HOUR	ANGE TIMME	INDSTIL TIME
SET MINUTE	ANGE MINUT	INDSTIL MIN
SET DAY	ANGE DAG	INDSTIL DAG
SET MONTH	ANGE MÅNAD	INDSTIL MD
SET YEAR	ANGE ÅR	INDSTIL ÅR
FORMAT	FORMATERING	DATOFORMAT
DONE	KLAR	FÆRDIG
LANGUAGE	SPRÅK	SPROG
Recording	Inspelning	Optagelse
Event Stored	Händ. Lagrad	Begivenh gemt
RECORDING COMPLETE	INSPELNING SLUTFÖRD	OPTAGELSE FÆRDIG
LOW BATTERY	SVAGT BATTERI	LAV BATTERI
CARD NOT FORMATTED	KORTET HAR EJ FORMATERATS	KORT IKKE FORMATERET
CARD NOT ERASED	KORTET HAR EJ RADERATS	KORT IKKE SLETTET
DEL (DELETE)	RADERA	SLET
END	SLUT	SLUT
Stop Recording	Stoppa Inspelning	Stop Optagelse
No	Nej	Nej
Yes	Ja	Ja