Mortara

Ref: 9515-160-50-ENG Rev G

H12+

DIGITAL HOLTER RECORDER
USER MANUAL

CE
0459

Manufactured by Mortara Instrument, Inc., Milwaukee, Wisconsin U.S.A.

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

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NOTICES

Manufacturer's Responsibility

Mortara Instrument, 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 Mortara Instrument, 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

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

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WARRANTY INFORMATION

Your Mortara Warranty

MORTARA INSTRUMENT, INC. (hereafter referred to as "Mortara") warrants that components within Mortara 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 Mortara, 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 Mortara;

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 Mortara;

f) Other events outside of Mortara'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 MORTARA TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Mortara of any alleged defects promptly after discovery thereof within the warranty period. Mortara'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 Mortara's principal place or any other place as specifically designated by Mortara or an authorized distributor or representative of Mortara, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Mortara is limited and that Mortara does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Mortara is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence therefrom relating to the Product/s. If Mortara should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Mortara shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

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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.
- 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 Mortara 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 601-1, and IEC 601-2-47. Only use parts and accessories supplied with the device and available through Mortara Instrument, Inc.

- 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.

- 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)**

- 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 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.

- 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:	0° 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.

- 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.

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

- When using the H12+ 48-Hour Digital Recorder, the recording will automatically restart after the first 24-hour period, the recorder will display "Initializing" and then begin the second 24-hour period. There will be an 8 to 10-second delay between periods 1 and 2 where no data is recorded.

- No preliminary or ongoing scheduled periodic calibration by the user or Mortara 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 601-1	General Requirements for Safety
IEC 601-2-47*	Particular Requirements for Safety including Essential Performance
IEC 601-1-2	Electromagnetic Compatibility
ANSI/AAMI EC38*	Ambulatory Electrocardiographs
93/42/EEC	Medical Device Directive

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

- The device is UL classified:

Medical Equipment
WITH RESPECT TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY, IN ACCORDANCE WITH UL 60601-1, CAN/CSA C22.2 No. 601.1, IEC60601-1 AND IEC60601-2-47.

EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

Attention, consult accompanying documents

Defibrillator-proof type CF applied part

Do not dispose as unsorted municipal waste. Per European Union Directive 2002/96, requires separate handling for waste disposal according to national requirements

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 5 for proper cleaning and disinfection procedures.

Sterilization

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

Cautions

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

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 Mortara Instrument 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.

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

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

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

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagentic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	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** $$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P} \quad \text{80 MHz to 800 MHz}$$ $$d = \left[\frac{7}{3V/m}\right]\sqrt{P} \quad \text{800 MHz to 2.5 GHz}$$ 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:

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.*

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INTRODUCTION

Manual Purpose

This manual explains how to operate the 24-hour and 48-hour 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

- 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+ recorder does not perform cardiac analysis by itself and is intended to be used with the H-Scribe™ Holter analysis system. ECG data pre-recorded by the H12+ recorder is acquired and analyzed by the H-Scribe system.

H12+ Recorder Description

An LCD screen allows for checking the 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 24-hour H12+ recorder uses a single AA alkaline battery to provide continuous 12-lead data recorded over a 24-hour period and a removable 24-hour compact flash (CF) card for data storage.

Patient Cable

- The 48-hour H12+ recorder uses a single AA lithium battery to provide continuous 12-lead data recorded over a 48-hour period and a removable 48-hour CF card for data storage. A removable 24-hour CF card with an AA alkaline battery can also be used with the 48-hour recorder for 24-hour recordings.

Patient Cable
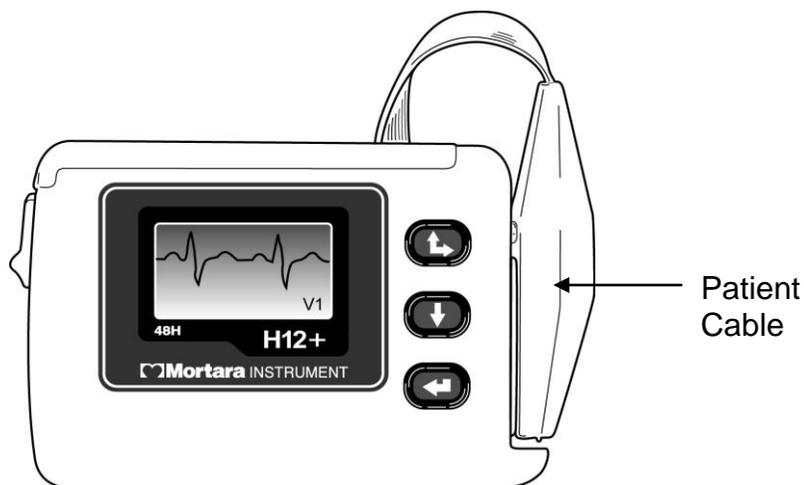
- A removable high-fidelity CF card and an AA lithium battery can be used with either the 24 or 48-hour H12+ recorder. This will provide continuous 12-lead data recorded over a 24-hour period.

- A removable high-fidelity extend CF card and an AA lithium battery can be used with the 48-hour H12+ recorder to provide continuous 12-lead data recorded up to a 30-hour period (requires manual record stop).

    NOTE: High-fidelity CF cards will store waveform files at 1,000 samples per second together with the standard waveform data. High-fidelity data requires a special version of H-Scribe system software to export the 1,000 samples per second waveforms. If you have standard H-Scribe software on your system, you will not benefit from the acquisition of this high-fidelity data.

Recorder Setup

Opening and Closing the Battery Door

The CF 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.
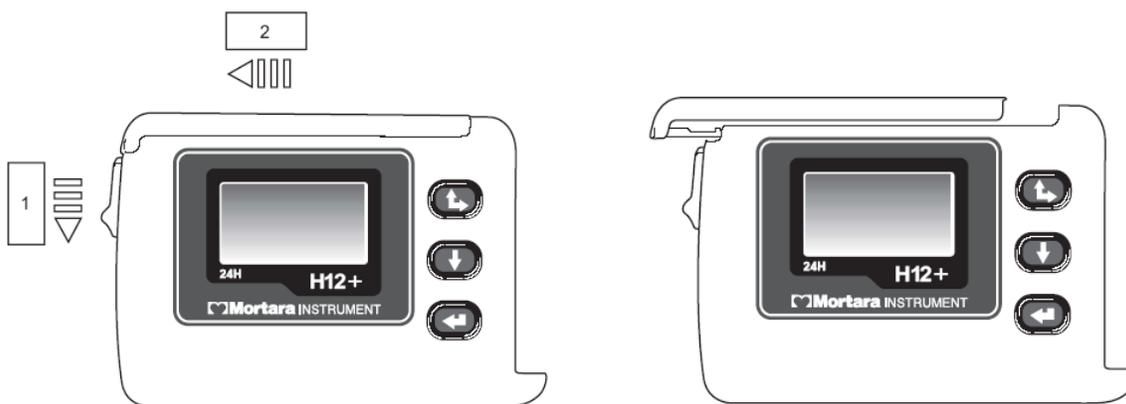
Inserting the Battery

- The H12+ 24-hour recorder is powered with a single AA alkaline battery.
- The H12+ 48-hour recorder is powered with a single AA lithium battery.
- High-fidelity recordings require a single AA lithium 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 fully-charged 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**.
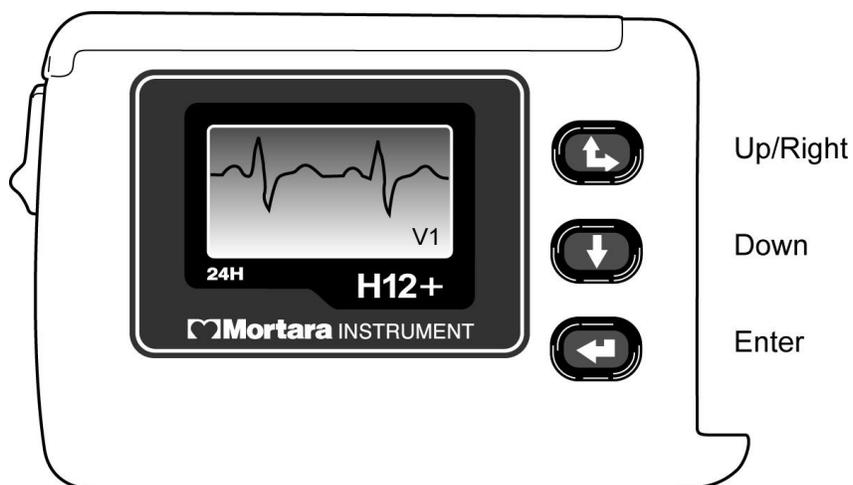
During patient hook-up, **Down** and **Up/Right** are used to scroll through the main menu options to enter the patient ID and to set the date/time and language. **Enter** is used to select main menu and sub-menu options displayed on the LCD screen, and to store the patient ID and configuration parameters 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.
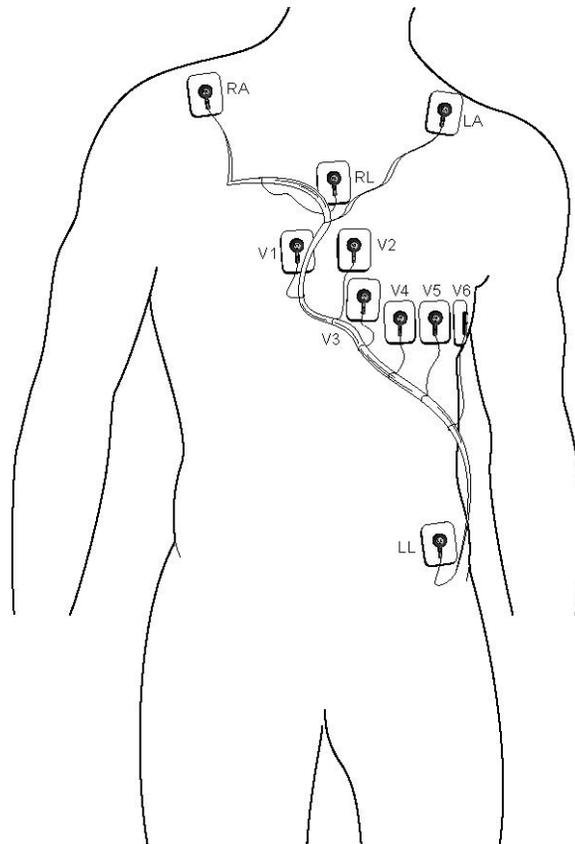
H12+ Recorder in Carrying Case

Part Numbers

Description	Part Numbers
H12+ 24-Hour Recorder	H12PLUS-AXX-XXXXX
H12+ 24-Hour CF Card	11018-001-50
H12+ 48-Hour Recorder	H12PLUS-BXX-XXXXX
H12+ 48-Hour CF Card	11018-001-52
H12+ 24-Hour Recorder with High-Fidelity CF Card (24 Hour)	H12PLUS-CXX-XXXXX
H12+ 48-Hour Recorder with High-Fidelity Extend CF Card (30 Hour)	H12PLUS-HXX-XXXXX
H12+ High-Fidelity CF Card (24 Hour)	11018-002-50
H12+ High-Fidelity Extend CF Card (30 Hour)	11018-001-53
H12+ Battery Door	8340-003-50
H12+ Carrying Case with Strap and Belt	8485-020-50
LeadForm Patient Cable/Domestic • Standard • Large	9293-017-50 9293-026-50
LeadForm Patient Cable/International • Standard • Large	9293-017-51 9293-026-51
H12+ User Manual – English	9515-160-50-ENG
H12+ Short-Form Instruction Card – English	9503-039-01
H12+ 24-Hour Holter Hookup Kits – case of 24	9294-010-51
H12+ 48-Hour with High-Fidelity Holter Hookup Kits – case of 24	9294-011-51
Patient Diaries – Box of 100	5004-008-51

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 Impedance Input Dynamic Range Electrode Offset Tolerance Frequency Response	Meets or exceeds the requirements of ANSI/AAMI EC38
Digital Sampling Rate	10,000 s/sec/channel used for pacemaker spike detection 180 s/sec/channel used for standard recording and storage
HF Digital Sampling Rate	1,000 s/sec/channel used for high-fidelity data storage
Special Functions	Pacemaker detection, ECG display, and lead quality check
A/D Conversion	20 bits
Storage	Compact flash memory card
Device Classification	Type CF, battery operated
Weight	4 oz. (125 g) without battery
Dimensions	2.5" x 3.5" x .98" (64 mm x 91 mm x 25 mm)
Batteries	(1) AA alkaline required for 24-hour recording (1) AA lithium required for 48-hour and high-fidelity recordings

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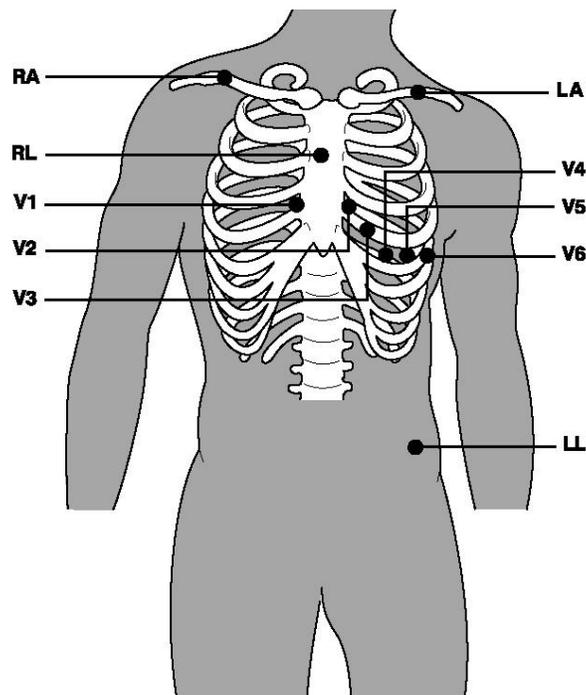
Limb Electrode		
AAMI	IEC	Placement
RA	R	On or below the right clavicle as shown
LA	L	On or below the left clavicle as shown
RL	N	Reference or ground lead, should be placed in a stable location of the body
LL	F	Lower-left side of body in a stable location, as close to the hip as possible

| 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

1. Connect the electrodes to the lead wires prior to applying them to the skin. This will prevent pressure on the center of the electrodes that may cause the gel to interfere with the adhesive part of the electrode.

2. After the skin electrode sites have been identified and prepped, remove the clear electrode covering and apply an electrode to each of the (10) sites. Secure each electrode by exerting slight pressure around the outer edge and inner ring of the electrode.

3. Begin the electrode-to-skin application with the left leg (LL/F). Connect the next electrode on the cable (Fuchsia – labeled V6/C6) to the V6/C6 position. Continue connecting the electrodes as positioned on the main cable.

4. There is no need to tape the electrodes or lead wires to the patient's skin. The LeadForm patient cable has been designed to conform to the body and to maximize patient comfort.

USING THE RECORDER

Inserting and Removing CF Cards

To insert a CF card, open the battery door of the recorder. Position the card above the empty card slot with the arrow on the card pointing down. Place the CF card in the slot and **gently** push down until the eject button (to the right of the card slot) pops up to the full upright position.

To remove a CF card, depress the eject button. When fully depressed, the top of the eject button is flush with the opening of the card slot. Once ejected, grasp the top of the card and lift.
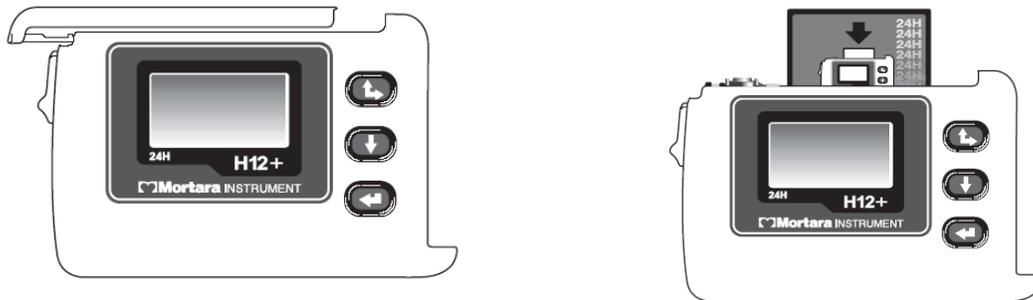
NOTE: *The eject button has two positions:* **Up** *(card properly inserted) and* **Down** *(card ejected).*

Attaching the Patient Cable

Insert the connector block into the input connector on the side of the H12+ recorder.
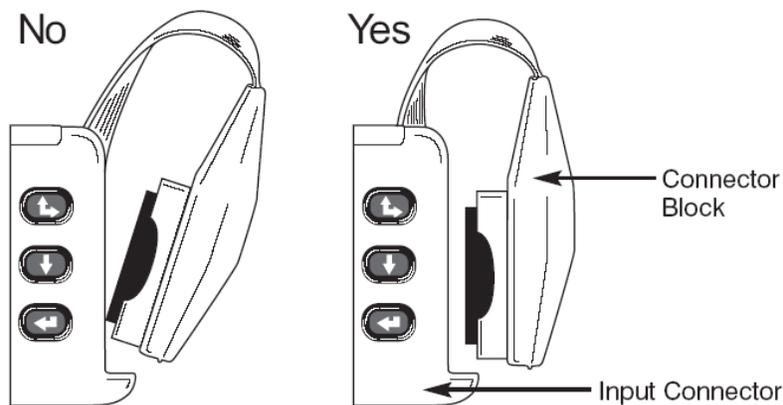
NOTE**: Be careful to insert the connector block parallel to the input connector.**

Main Menu Options

The main menu includes the following options:

- LEAD CHECK
- DISPLAY ECG
- ENTER ID
- RECORD (see Section 3, Using the Recorder)
- CONFIGURE

The following operational flowchart of main menu options depicts the flow of functionality using **Up/Right**, **Down**, and **Enter**.
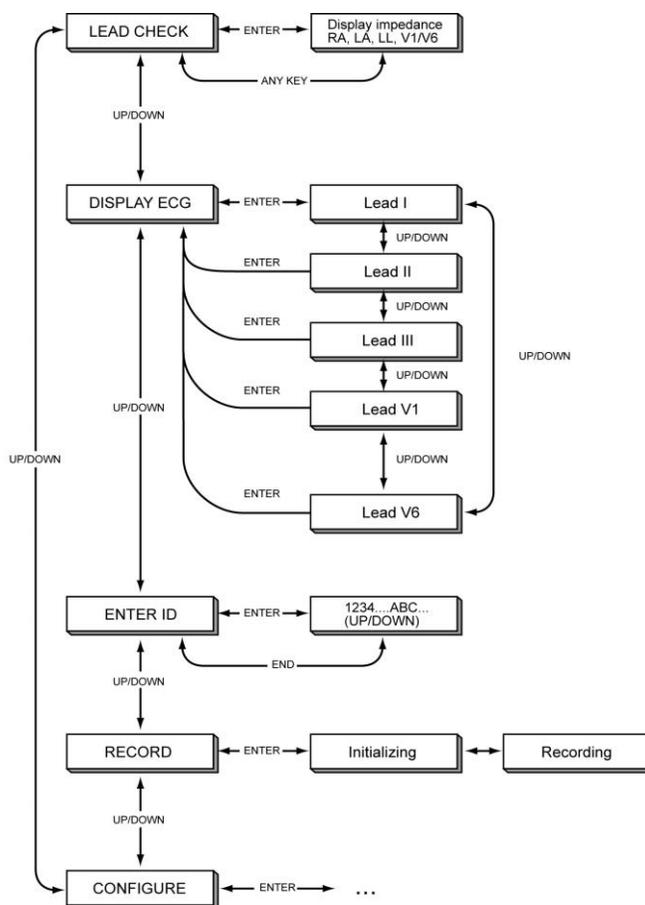
The LEAD CHECK, DISPLAY ECG, ENTER ID, and CONFIGURE tasks are performed prior to starting a new patient recording. With the exception of CONFIGURE, the other three tasks typically are done for each new recording.

> *NOTE: Patient ID entry (ENTER ID) is optional and can be entered after the patient record is downloaded to the H-Scribe system.*

Starting a Recording Session

1. Insert a formatted CF card and a new AA battery. (If necessary, reformat the CF card using the proper utility with H-Scribe system software.)

2. Hookup the patient (see Section 2, Patient Preparation).

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

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 the first option displayed on the LCD screen after patient hookup. It is a valuable tool for verifying and optimizing signal quality 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 bar, the better the contact is between the skin and the electrode.

A full bar graph 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.

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4.   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.**
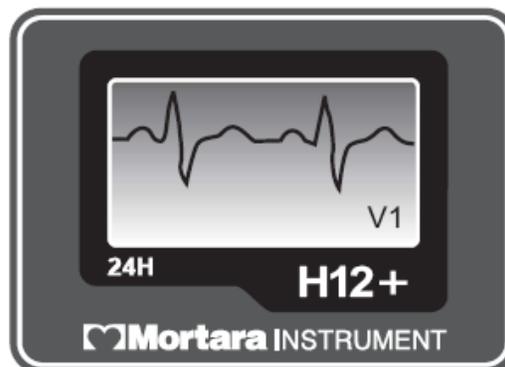
Lead I is the first lead displayed on the screen. Scroll from lead to lead. After visual verification of all leads, press **Enter** to return to the main menu.

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

Entering Patient ID

ENTER ID is used to enter the patient ID in the patient record before starting a recording.

From the main menu, scroll to ENTER ID, press **Enter**.

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.*

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

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6. To begin recording, scroll through the main menu until RECORD is displayed, 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 the 24-hour H12+ recorder, the current time (HH:MM:SS) is displayed in the middle of the screen for the entire recording session. The Recording message is displayed below the current time; the patient ID number is displayed at the bottom of the LCD screen.

During normal operation of the 48-hour H12+ recorder, the current time (HH:MM:SS) is displayed in the middle of the screen for the entire recording session. Total hours recorded (0 to 48 Hrs Tot) 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.

During normal operation of the 24-hour H12+ recorder using a high-fidelity CF card, the current time (HH:MM:SS) is displayed in the middle of the screen for the entire recording session. "HF" is displayed above the current time to indicate that a high-fidelity CF card is being used. The Recording message is displayed below the current time; the patient ID number is displayed at the bottom of the LCD screen.

During normal operation of the 48-hour H12+ recorder using a high-fidelity extend CF card, the current time (HH:MM:SS) is displayed in the middle of the screen for the entire **30-hour** recording session. Total hours recorded (0 to 30 Hrs Tot) 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 formatted CF 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 24-hour or 48-hour recording session, 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. Press down the eject button and remove the CF 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 compact flash card service log indicating that the recording was manually ended.

CONFIGURING THE RECORDER

Configuring Date/Time and Language

CONFIGURE is used to set the current date and time, the date format and language defaults, and to display the software version number. These settings typically are set before the initial patient recording and do not need to be set on a per patient basis.

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

The CONFIGURE menu includes the following options.

- DATE/TIME
- LANGUAGE
- VERSION
- 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→ 2007 (UP / DOWN)

UP/DOWN

FORMAT ENTER 07/31/2007

UP/DOWN

31.07.2007

UP/DOWN

DONE ―ENTER→

UP/DOWN

ENGLISH

UP/DOWN

ITALIANO

LANGUAGE ―ENTER→ UP/DOWN

DEUTSCH

UP/DOWN

OTHER LANGUAGE

UP/DOWN

VERSION ―ENTER→ 03:14
BØ5 FØ7 48 Hr

UP/DOWN

DONE

ENTER

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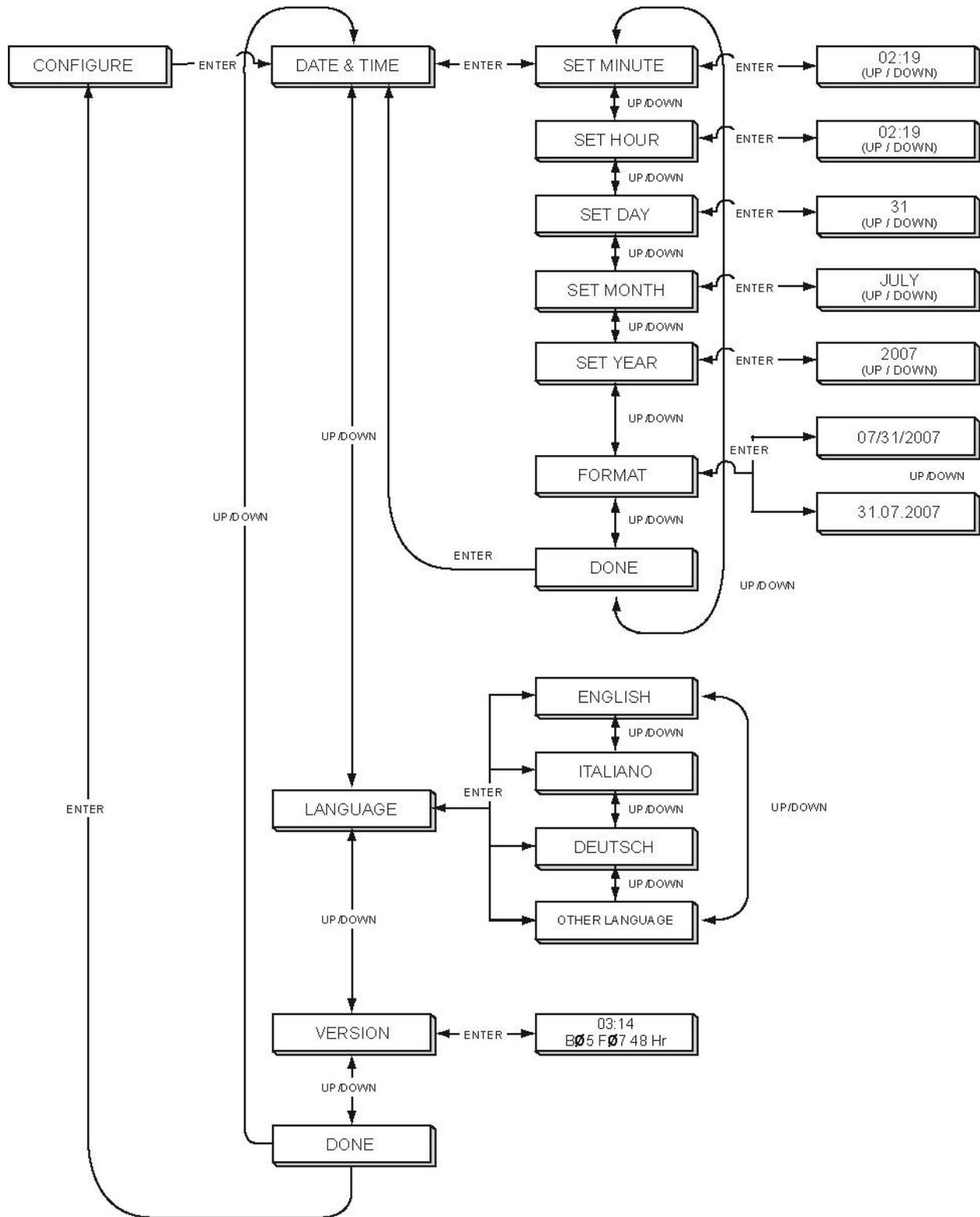
Setting Date and Time

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. "48 Hour" will be displayed when the model is a 48-hour 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.

MAINTENANCE

Cleaning the H12+ Recorder and Accessories

1. Remove cables and disconnect power source from device before cleaning.

2. Wash the 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 alcohol or 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.

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

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' 'LOW BATTERY A'	Replace existing battery with a fully charged battery.
'CARD ERROR' 'CARD ERROR A – E' 'CARD ERROR 1 – 13'	CF card error. Contact Mortara Technical Support Group. Please make note of the letter or number following the CARD ERROR message when present.
'NO CARD'	CF card not detected in the card slot. Install a formatted CF card.
'CARD NOT FORMATTED'	CF not properly formatted. Contact Mortara Technical Support Group.
'CARD NOT ERASED'	Data detected on CF card. Erase the card using H-Scribe system software.
'Reformat card with FAT16 / FAT not FAT32'	CF card has been formatted with unsupported FAT32. Reformat the CF card with FAT16 or FAT. **Using H-Scribe system software to reformat the CF card will not correct the error.** Contact Mortara Technical Support Group for assistance.
'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 HOLLAND
INITIALIZING	INIZIALIZ.	INICIANDO	INITIALISIERUNG	INITIALIZING
RECORD	INIZIO	GRABAR	AUFNAHME	OPNAME
LEAD CHECK	DERIVAZIONI	TEST ELECT	ABL.TEST	LEAD
DISPLAY ECG	MOSTRA ECG	MOSTRAR ECG	EKG-ANZEIGE	TOONT 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
SET HOUR	ORA	HORA	STUNDE	UUR
SET MINUTE	MINUTI	MINUTO	MINUTE	MINUUT
SET DAY	GIORNO	DIA	TAG	DAG
SET MONTH	MESE	MES	MONAT	MAANDEN
SET YEAR	ANNO	AÑO	JAHR	JAAR
FORMAT	FORMATO	FORMATO	FORMAT	DATANOTATIE
DONE	FINE	OK	FERTIG	KLAAR
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
Reformat card with FAT16 / FAT not FAT32	RIFORMATTARE CARD CON FAT16 NON FAT32	REFORMATEAR TARJETA CON FAT16 NO FAT32	REFORMATIERE KARTE MIT FAT16 NICHT FAT32	REFORMAT DE KAART MET FAT16 EN NIET MET FAT32
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

TRANSLATIONS

Table of Translations (continued)

English	French FRANÇAIS	Polish POLSKI	Finnish SUOMI	Portuguese PORTUGUES
INITIALIZING	INITIALISEZ	INICJALIZACJA	ALUSTAA	INICIALIZACAO
RECORD	ENREGISTRER	START	TALLENNUS	REGISTO
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
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
Reformat card with FAT16 / FAT not FAT32	REFORMATEZ LA CARTE AVEC FAT16 PAS AVEC FAT32	FORMATUJ KARTE NA FAT16, A NIE FAT32	ALUSTA KORTTI FORMAATTIIN FAT16 EI FAT32	REFORMATAR A CARTA COM FAT16 E NAO COM FAT32
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