Welch Allyn®
H12+™
SERVICE MANUAL

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

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

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

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REF ***9516-160-50-ENG REV F (also refer to TDR pages when making revision changes)***
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\# ***901141 HOLTER RECORDER***

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NOTICES

Service Manual Purpose

The purpose of this manual is to provide information to service personnel in order to maintain the H12+ Holter Recorder.
This manual includes parts lists and is intended to function primarily as a guide to preventative and corrective maintenance and electrical repairs considered field repairable.

WARNING: ***No user serviceable parts are inside. Any modification of this device will void any and all Manufacturer's Warranties and/or responsibilities. If you are not able to correct the H12+ Holter Recorder's questionable operating state using the Troubleshooting guide in the Operator's Manual, do not attempt to service it yourself. Contact Welch Allyn Service at 1-888-667-8272.***

Manufacturer's Responsibility

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

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Welch Allyn,

The electrical installation of the relevant room complies with the requirements of appropriate

regulations, and The H12+ Holter Recorder is used in accordance with the instructions for use.

Responsibility of the Customer

The user of this product 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 serial numbers on the back or bottom of the device. Care should be taken so that these numbers are not defaced.

Information pertinent to tracking and manufacturing is found on the product and may be called upon if service of the device is required.

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WELCH ALLYN, INC. (hereinafter referred to as "Welch Allyn") hereby warrants that Welch Allyn products (hereinafter referred to as "Products") shall be free from defects in material and workmanship under normal use, service and maintenance for the warranty period of such Product from Welch Allyn or an authorized distributor or representative of Welch Allyn. Normal use, service and maintenance means operation and maintenance in accordance with appropriate instructions and/or information guides. This Warranty does not apply to damage to the Products caused by any or all of the following circumstances or conditions:

a) Freight damage;

b) Parts and/or accessories of the Products not obtained from or approved by Welch Allyn;

c) Misapplication, misuse, abuse and failure to follow the Product instruction sheets and/or information guides;

d) Accident, a disaster affecting the Products;

e) Alterations or modifications to the Products not authorized by Welch Allyn;

f) Other events outside of Welch Allyn's reasonable control or not arising under normal operating conditions.

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

EXCLUDED FROM THE LIMITED WARRANTY SET FORTH ABOVE ARE CONSUMABLE ITEMS SUCH AS PAPER, BATTERIES, ELECTRODES, PATIENT CABLES, LEAD WIRES AND MAGNETIC STORAGE MEDIUMS.

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

USER SAFETY INFORMATION

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

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

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

Anti-Static equipment should always be worn when working with static sensitive devices and in a static sensitive area.

GENERAL CARE

Periodic Safety Inspections

Follow the recommended maintenance schedule. Inspect the patient cable(s) periodically for fraying or other damage and replace as needed. Broken or frayed wires may cause interference or loss of signal. Pay particular attention to points where wires enter connectors.

Do Not Mount Product above Patient

Do not mount or place the product where it could fall on a patient or where it could be accidentally knocked off a shelf or other mounting arrangement.

Proper Patient Cable

Use only the patient cable specified for this unit.

Recommended Accessories

For the patient's safety and optimum equipment performance, use only the accessories specified by/or that meet Welch Allyn, Inc. specifications.

Sterilizing this Product

Do not sterilize this product or any accessories unless specifically directed by the manufacturer. Sterilization and sterilization environments can seriously damage many components and accessories.

Liquid Spills

Do not set beverages or other liquids on or near the H12+, and/or optional equipment.

Product Information

See Technical Description section of this manual

Disposal

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

EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

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

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

Electrostatic sensitive devices

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

Indicates compliance to applicable European Union directives

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

Medical Device

Model Identifier

Reorder Number

MAINTENANCE AND CLEANING

Introduction

This section provides servicing and maintenance instructions for the H12+ Holter Recorder. Subsequent parts of this section are disassembly, inspection techniques, and cleaning techniques.

Recommended Interior Cleaning Supplies

- Anti-static mat & wrist band, properly grounded
- Clean, lint-free cloth
- Cleaning solvent (isopropyl alcohol, 99% pure)
- DRY, low pressure, compressed air (30 psi)

Note: The equipment and solvent mentioned above are standard shop commodities that are available from commercial sources.

Cleaning and Inspecting Techniques:

This section contains instructions for periodic cleaning and inspection of the instrument as preventative maintenance measures. It also contains specific cleaning procedures to be conducted. Parts having identical cleaning procedures are grouped under common headings. No special tools are required.

WARNING

Ventilate work area thoroughly when using solvents. Observe manufacturers warnings on solvent containers with regard to personnel safety and emergency first aid. Be sure that first aid equipment is available before using chemicals. Observe shop safety and fire precautions. Ventilate all work areas where solvents are used. Store solvents and solvent-soaked rags in approved containers. Refer to manufacturers' instructions on containers for recommended fire-fighting procedures, and make sure that fire-fighting equipment is available.

Metallic and Plastic Parts Cleaning

CAUTION

Do not wipe over surfaces of nameplates or labels with abrasive cleaners or materials, as this will eventually wear away the nameplate information. Do not use solvents to clean plastic parts.

Exterior Cleaning

Use a damp cloth to clean external covers and the patient cable. Do not use alcohol, solvents, or cleaning solutions. These cleaning agents may damage the surfaces of the instrument.

Interior Visual Inspection

Check all connectors for loose, bent or corroded contact points

Check wire, harnesses and cables for signs of wear or

deterioration. Inspect leads for security of mounting, or

deterioration.

Check terminals and connections for proper installation, loss or wear.

Check the identification nameplate and other decals for legibility.

Inspect chassis and covers for warping, bending, surface damage or missing captive hardware.

Check all screws and nuts for tightness or signs of stripped or crossed threads.

Check for any other form of mechanical damage, which may indicate a failure.

Preventative Maintenance Schedule

Maintenance to be Performed	Period	Notes
Clean and inspect unit.	6 mo.	Perform every 3 mo. if unit is in heavy use.

Battery Removal / Installation:

Remove the battery door. Remove the Battery.

Check battery connection terminals for debris and/or corrosion.

CAUTION

Be sure that the polarity of the batteries is correct. Follow diagram in cover.
Use only Welch Allyn approved Alkaline replacement batteries (Welch Allyn part #4800-001).

Re-install the batteries.

TECHNICAL DESCRIPTION

H12+ Overview

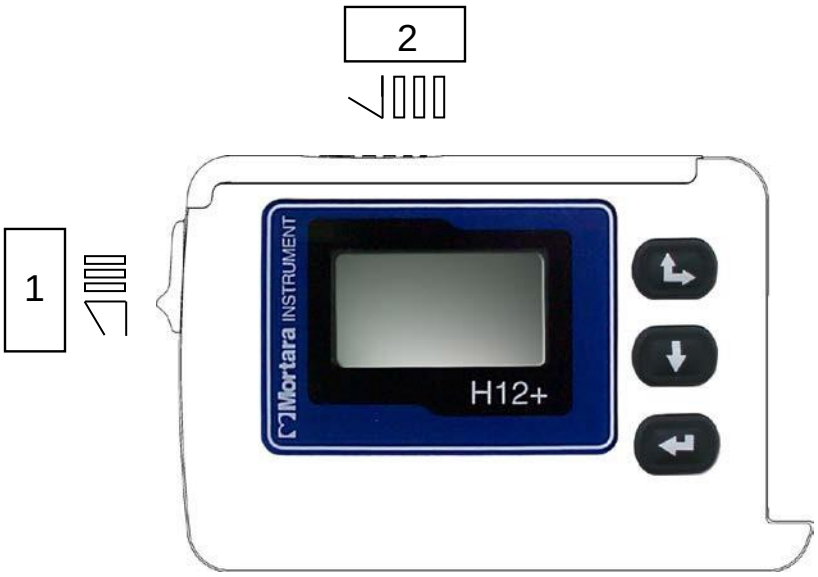
Instrument Type:	12-lead ECG Holter Recorder
Input channels:	Simultaneous acquisition of all leads.
Standard leads acquired:	I,II,III,aVR, aVL, aVF, V1, V2, V3, V4, V5, & V6
Input impedance **Input Dynamic Range** **Electrode Offset Tolerance** **Frequency Response**	Meets or exceeds the requirements of ANSI / AAMI EC38
Digital Sampling:	10,000 s/sec/channel used for pacemaker spike detection. 180 s/sec/channel for recording and analysis.
Special Functions	Pacemaker Detection, ECG Display, Lead Quality Check
A/D Conversion	20 bit
Storage:	Compact Flash Memory
Device Classification	Type CF, Battery operated
Weight:	4 Ounces (125g) without batteries
Dimensions (HxWxD):	2.5 x 3.5 x 0.98 Inches (64 x 91 x 25 mm)
Batteries:	1 AA alkaline required

H12+ Digital Recorder

The compact flash card slot and the battery compartment are accessible via the battery door of the H12+ Recorder.

Opening and Closing the Battery Door

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, place the battery door on the H12+ as shown above and slide the door in the opposite direction of the arrow (2) until the door snaps into place. It is recommended that latch (1) be depressed when closing the battery door to prevent damage to the door and the latch assembly.

Inserting and Removing Flash Cards

To insert or remove a flash card, open the battery door of the H12+. Locate the card slot and the Eject button located to the right of the card slot on the inside of the H12+.

Note: The Eject button has two positions: Up (card properly inserted) and Down (card ejected).

To insert a flash card in an empty card slot, position the card above the card slot with the arrow on the card pointing down. Place the flash card in the card slot and gently push down on the card until it stops. To complete insertion, push down on the top of the card until the Eject button pops up to the full-upright position.

To remove a flash card from the card slot, 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 it out of the card slot.

Inserting the Battery

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

To insert a new battery into the battery compartment, open the battery door of the H12+. If a battery is present in the compartment, remove and discard the 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.

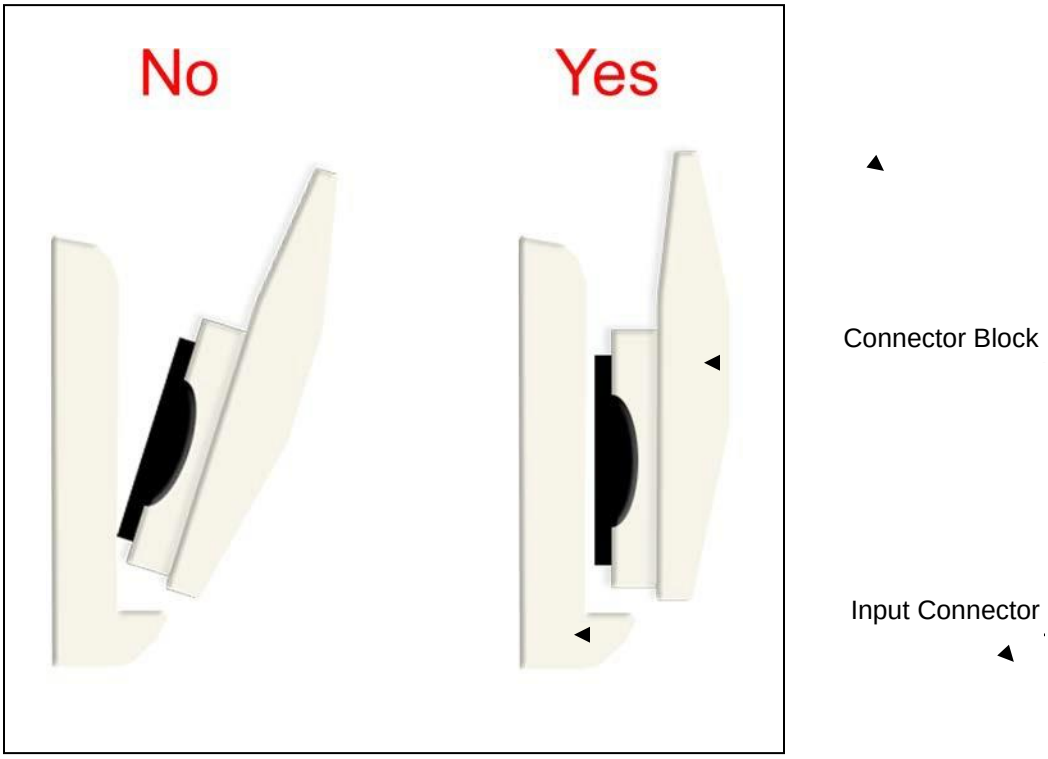
Note: The H12+ recorder requires a fully charged battery to record a 24-hour session. If you are not clear as to the status of a battery's voltage, use a new battery to insure operation for 24 hours.

Attaching the 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.

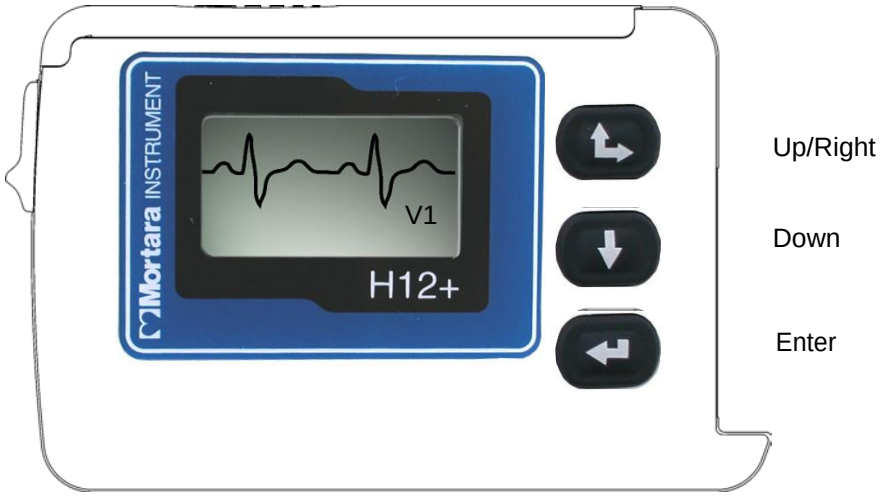
Insert the connector block into the input connector on the side of the H12+.

Note: Be careful to insert the connector block parallel to the input connector of the H12+.



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. These include the **Up/Right**, **Down** and **Enter** keys.



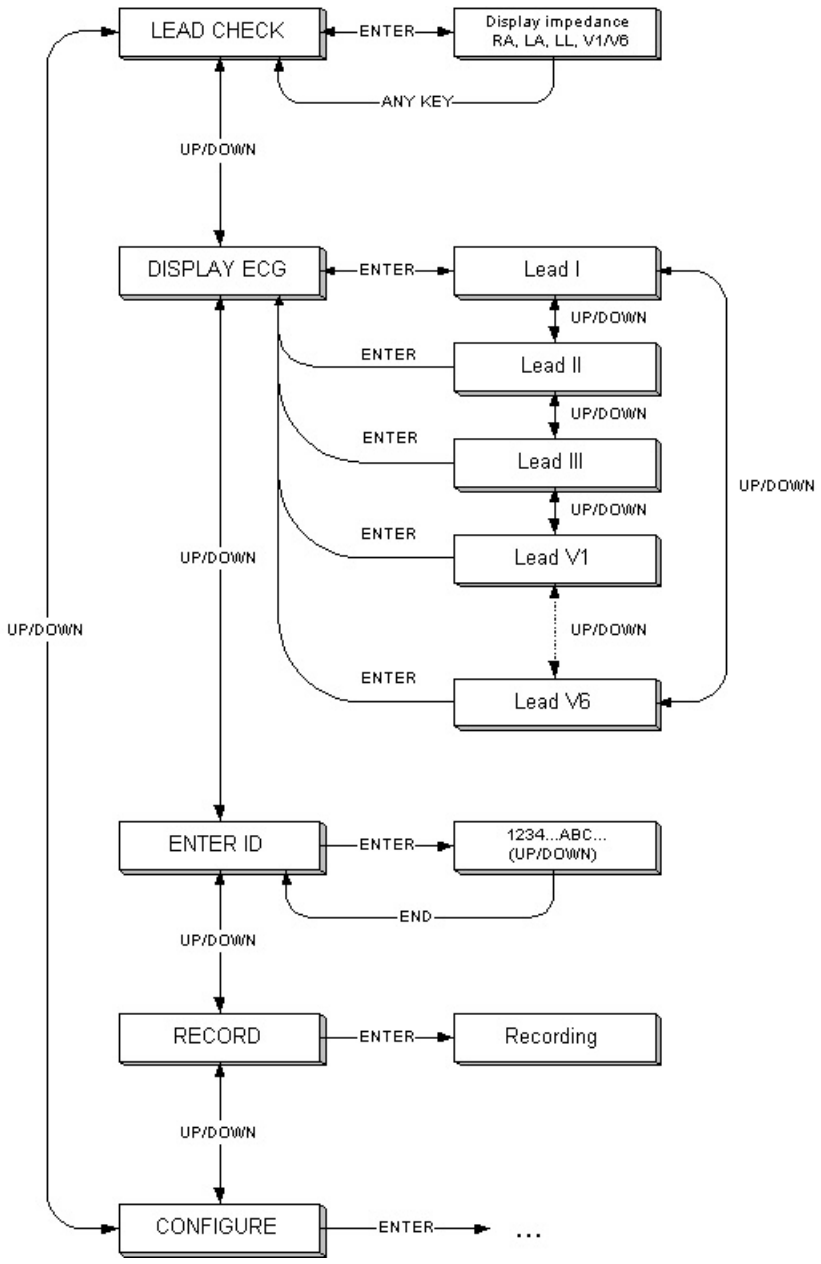
During patient hook-up, the **Down** and **Up** keys are used to scroll through the Main menu options, to enter the Patient ID and to set the date/time and language. The **Enter** key is used to select a Main menu option and sub-menus displayed on the LCD screen and to store the patient ID and configuration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

Main Menu Options

The Main, or top-level, menu includes the following options.

- LEAD CHECK
- DISPLAY ECG
- ENTER ID
- RECORD
- CONFIGURE

On the next page, an operational flowchart of Main menu options depicts the flow of functionality using the **Up**, **Down** and **Enter** keys.



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. If desired, the patient ID may be entered after the patient record is downloaded to the H-Scribe system.

The 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 screen.

Checking Impedances

LEAD CHECK is the first option displayed on the LCD screen after patient hook-up and is a valuable tool for verifying and optimizing signal quality before starting a recording.

From the Main menu, scroll to LEAD CHECK using the **Down** or **Up** key. Press the **Enter** key to select this option.

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.

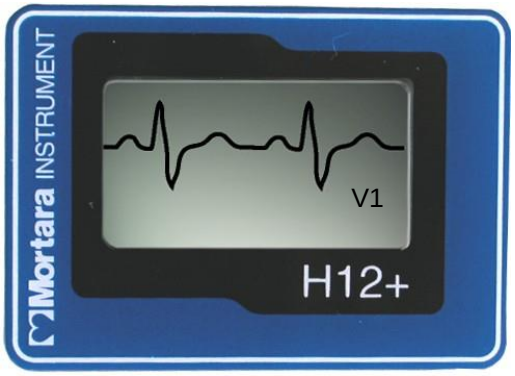
A full-bar graph means optimal high quality and good electrode contact. For good quality recordings, the bars should reach or exceed the horizontal line on the display. A low-bar graph means poor quality and high electrode impedance. The skin preparation should be checked for improvement and, if necessary, the electrode(s) should be replaced.

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

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 lead amplitude for each lead.

From the Main menu, scroll to DISPLAY ECG using the **Down** or **Up** key. Press the **Enter** key to select this option.



Lead I is the first lead displayed on the screen. Use the **Down** or **Up** key to scroll from lead to lead.

After visual verification of all leads, press the **Enter** key to return to the Main menu.

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 using the **Down** or **Up** key. Press the **Enter** key to select this option.

To enter the patient ID, the cursor is moved to the desired letter or digit in the alphanumeric table and then selected by pressing the **Enter** key. The cursor is located initially 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 the **Up** key. 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 the **Down** key. If the cursor is on the bottom line, pressing the **Down** key moves the cursor to the top line.

Note: When entering the patient ID, the Up key is used to move the cursor to the right. The cursor cannot be moved in the Left or Up direction.

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

To delete a letter or digit in the patient ID, position the cursor over Del on the bottom line. Press the **Enter** key to delete the last letter or digit entered in the patient ID.

To end patient ID entry, position the cursor over End on the bottom line. Press the **Enter** key to store the patient ID in the patient record.

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 on the H12+ and do not need to be set on a per patient basis.

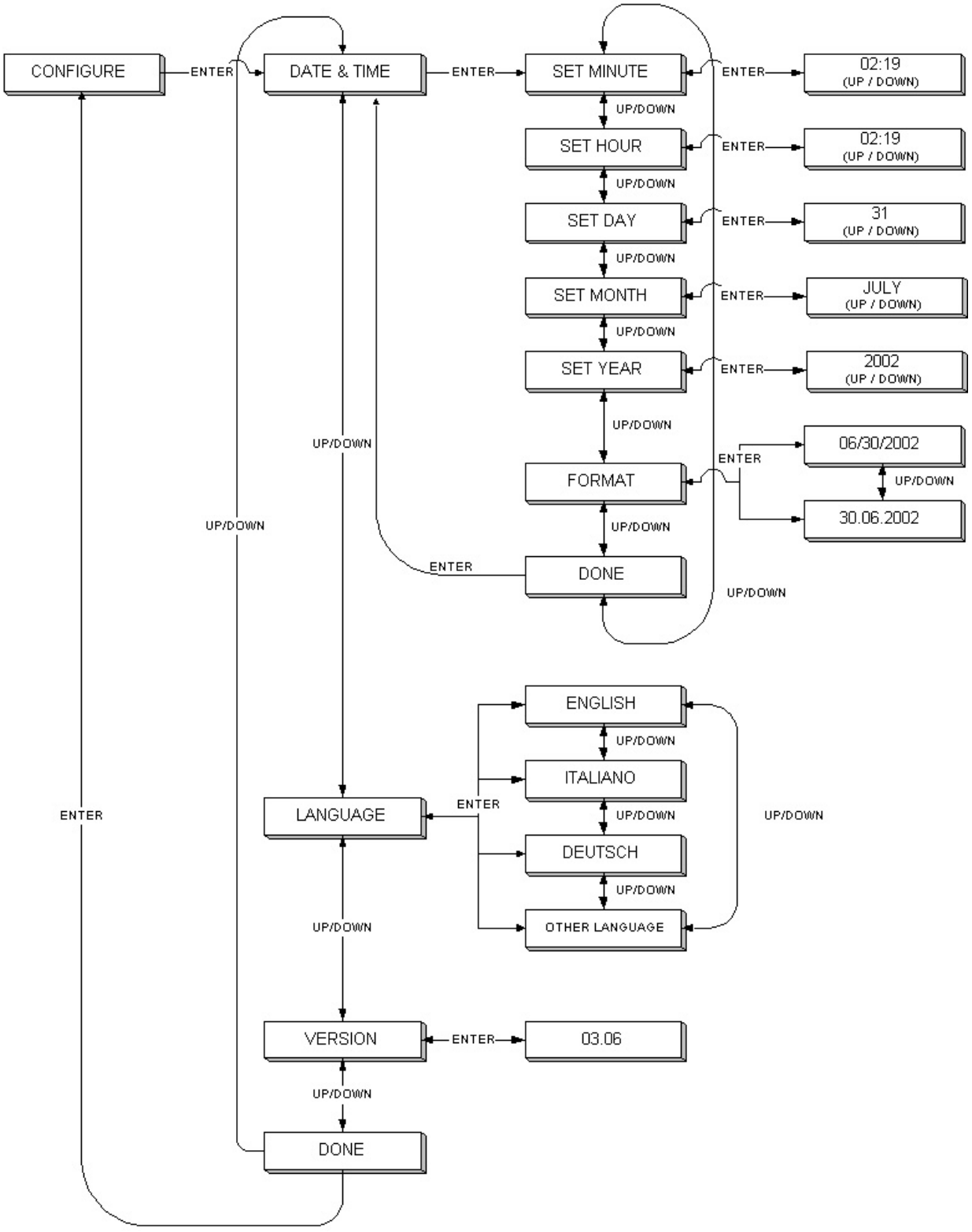
From the Main menu, scroll to CONFIGURE using the **Down** or **Up** key. Press the **Enter** key to select this option.

The Configure menu includes the following options.

- DATE/TIME
- LANGUAGE
- VERSION
- DONE

Use the **Down** or **Up** key to scroll through the Configure menu options. Press the **Enter** key when the desired option is displayed. Select Done and press the **Enter** key to return to the Main menu.

On the next page, an operational flowchart of Configure menu options depicts the flow of functionality via the **Up**, **Down** and **Enter** keys.


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
2002
(UP / DOWN)
UP/DOWN
FORMAT
ENTER
06/30/2002
UP/DOWN
30.06.2002
UP/DOWN
DONE
ENTER
UP/DOWN
UP/DOWN
UP/DOWN
ENGLISH
UP/DOWN
ITALIANO
UP/DOWN
DEUTSCH
UP/DOWN
OTHER LANGUAGE
LANGUAGE
ENTER
UP/DOWN
ENTER
VERSION
ENTER
03.06
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 using the **Down** or **Up** key. Press the **Enter** key to select this option. The Date/Time menu includes the following options.

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

Use the **Down** or **Up** key to scroll to the desired option and press the **Enter** key. The current values for this option are displayed on the LCD screen.

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

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 the Enter key 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 Configuration menu, scroll to FORMAT using the **Down** or **Up** key. Scroll from one option to the other by using the **Down** or **Up** key. Press the **Enter** key to select the desired date format and return to the Configure menu.

To return to the Configure menu, scroll to DONE using the **Down** or **Up** key and press the **Enter** key.

Setting Language

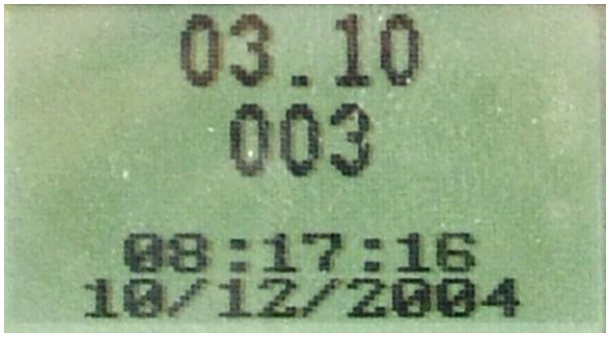
LANGUAGE is used to select a language to view the Main menu and all sub-menu options.

From the Configuration menu, scroll to LANGUAGE using the **Down** or **Up** key. Scroll through the language options using the **Down** or **Up** key. Press the **Enter** key to select the desired language and return to the Configure menu.

Viewing Software Version Number

VERSION displays the current software version installed in the H12+.

From the Configuration menu, scroll to VERSION using the **Down** or **Up** key. Press the **Enter** key to return to the Configure menu.



The top number indicates the software version on the H12+, in this case version 03.10, and the bottom number indicates the bootcode version number, in this case 003.

Starting a Recording Session

1. If necessary, reformat the flash card using the proper utility with H-Scribe software.
2. Remove the battery door of the H12+. Insert the formatted flash card into the card slot.

   Note: The flash card is fully inserted in the card slot when the Eject button is in the full-upright position.

   Insert a new AA battery in the battery compartment.
3. Hook-up the patient.
4. Verify the quality of the hook-up by checking the impedances. Use the **Up** and **Down** keys to scroll through the Main menu until LEAD CHECK is displayed. Press the **Enter** key to select LEAD CHECK.
5. Verify the amplitude and signal quality by displaying each of the leads. Use the **Up** and **Down** keys to scroll through the Main menu until DISPLAY ECG is displayed. Press the **Enter** key to select DISPLAY ECG.
6. If desired, enter the patient ID (or Name). Use the **Up** and **Down** keys to scroll through the Main menu until ENTER ID is displayed. Press the **Enter** key to select ENTER ID.
7. Use the **Up** and **Down** keys to scroll through the Main menu until RECORD is displayed. Press the **Enter** key to select RECORD.

During normal operation, the current time (HH:MM:SS) is displayed in the middle of the screen continuously for the entire 24-hour recording session. The Recording message is displayed below the current time.

If during recording the battery door is removed, the H12+ stops recording. A new formatted flash card must be installed 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..

Entering (Optional) Diary Events

During the recording session, the patient may be instructed to enter event markers on the H12+ for analysis purposes. Once entered, 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+. The Event Stored message is displayed below the current time until a new one 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 recording session, the time is cleared from the LCD screen and the RECORDING COMPLETE message is displayed. To proceed:

1. Remove the battery door of the H12+.
2. Remove the battery. Use the battery only once. After use, dispose of the battery properly.
3. Press down the Eject button and remove the compact flash card.

H12+ DISASSEMBLY

WARNING: ***No user serviceable parts are inside. Any modification of this device will void any and all Manufacturer's Warranties and/or responsibilities. If you are not able to correct the H12+Holter Recorder Module's questionable operating state using the Troubleshooting guide in the Operator's Manual, do not attempt to service it yourself. Contact Welch Allyn Service at 1- 888-667-8272 or via email at mor_tech.support@hillrom.com.***

Parts List

H12+ Digital Recorder Assembly

Item Number	Part Number:	Description:	Qty:
1	8340-002-50	H12+ HOUSING BOTTOM ASSEMBLY	1
2	26025-031-50	H12+ FRONT END PC BOARD ASSEMBLY	1
3	8340-007-01	SPRING DOOR RELEASE H12+	1
4	8340-004-50	H12+ RELEASE LATCH ASSEMBLY	1
5	8340-009-01	FILLER COMPACT FLASH H12+	1
6	26025-030-50	DIGITAL PC BOARD ASSEMBLY	1**
7	8340-001-50	H12+ HOUSING TOP ASSEMBLY	1
8	8312-024-50	BEZEL ASSEMBLY H12+	1
9	4160-025-01	KEYPAD 3 BUTTON H12+	1
10	6021-002	SCREW M2X16MM SLTD CHEESE HD MACH STL	3
11	5400-013	LCD WITH RIBBON CABLE	1
12	7401-003	DOUBLE SIDED FOAM TAPE, 1/2"	2
13	748980	H12+ HILLROM NAMEPLATE LABEL	1
14	8340-003-50	H12+ BATTERY DOOR ASSEMBLY	1
15	6021-003	SCREW M2X16 PHILIPS PNHD PLTD STEEL	3
16	8340-007-01	SPRING DOOR RELEASE H12+	1
17	6020-033-02	SCREW PH PNHD M2X4 DIN 7985 ZP STL CTD	2
18	26025-031-50	H12+ FRONT END PCB ASSEMBLY	1
19	9293-017-50	X-12/H12+ Patient cable AHA (Domestic)*	1
20	9293-017-51	X-12/H12+ Patient cable EC (International)*	1
21	9293-026-50	Large X-12/H12+ Patient Cable AHA (Domestic)*	1
22	9293-026-51	Large X-12/H12+ Patient Cable EC (International)*	1
23	26025-030-51	Digital Board H12+ 24H PC Assembly	1**
24	26025-030-52	Digital Board H12+ 48H PC Assembly	1**

*Note: Only one patient cable is required to operate the H12+. The difference between the 9293-017-5X cable and the 9293-026-5X cable is the length of the cable.

**Note: Depending on the unit any one of these boards can be used.

Opening the Unit

	Anti-Static equipment should always be worn when working with static sensitive devices and in a static sensitive area.

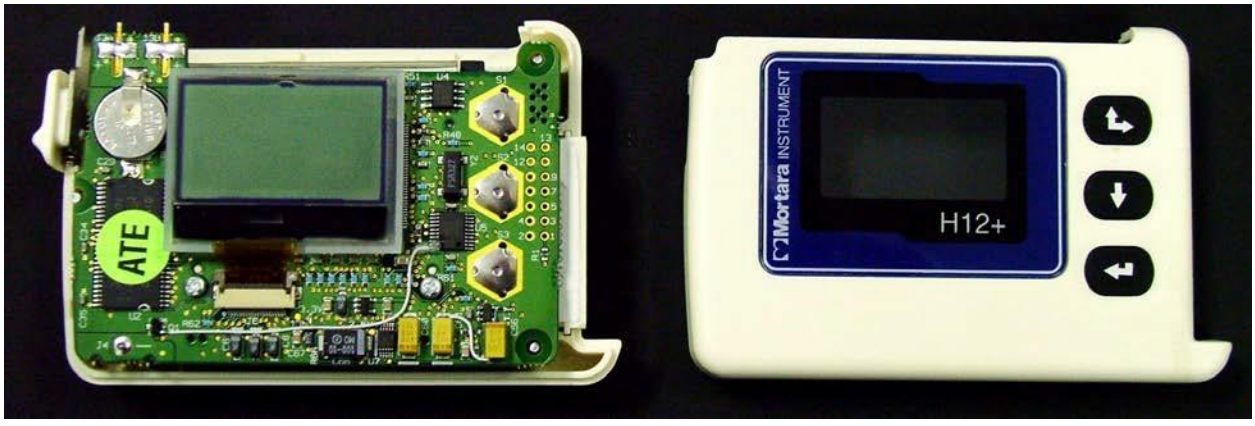
1. Remove the battery from the unit.

2. Remove label, item #13, on back of unit to access the three screws securing the case together.

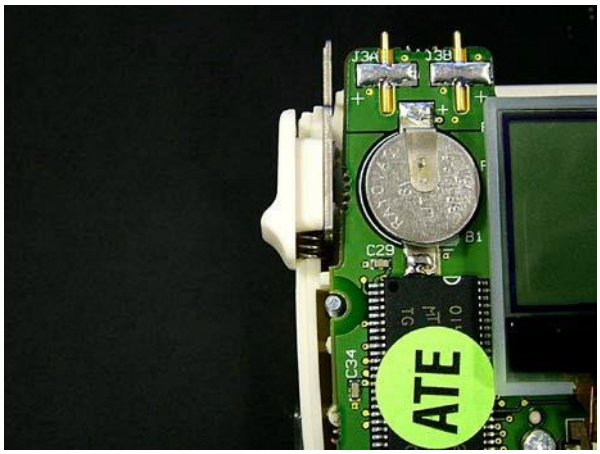
ATTENTION: When removing the back there is the possibility that the serial number label will also be removed. Please document the unit serial number prior to removing the back label of the H12+. If the serial number label is damaged when the back label of the H12+ is removed please contact Welch Allyn for a replacement serial number label. The serial number and the REF number must be supplied.

3. Remove the three screws, item # 16, to open the unit up.

4. Flip the unit over and remove the front cover to expose the boards.



Note: Care should be taken when opening the unit. There is potential for the spring, item # 17, for the battery door latch to pop out.

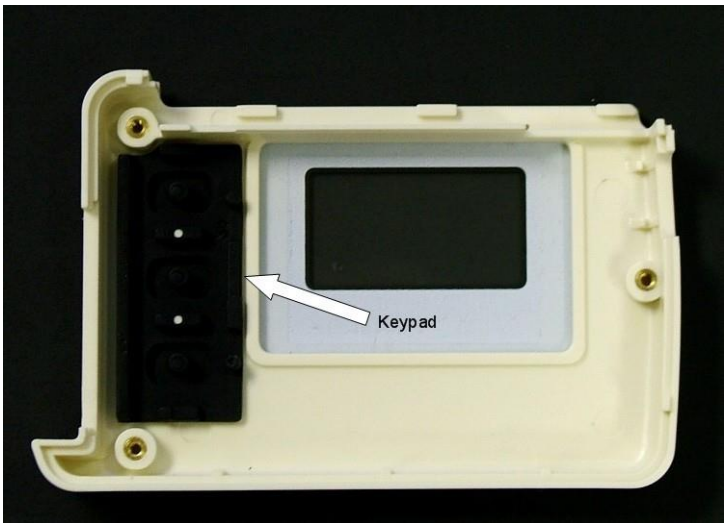


Battery door latch, item #4 and spring, item # 16

Keypad Removal

1. Open the unit (see step above)

2. Flip the top cover over and remove the rubber keypad, item # 9.

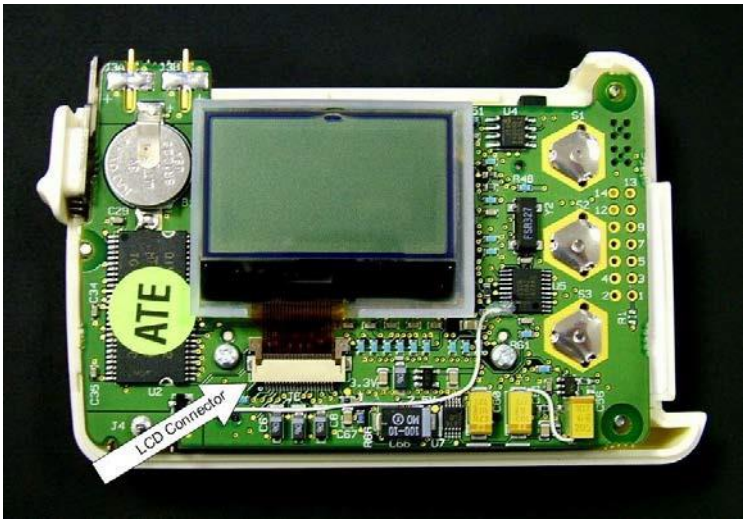


3. Install new keypad.

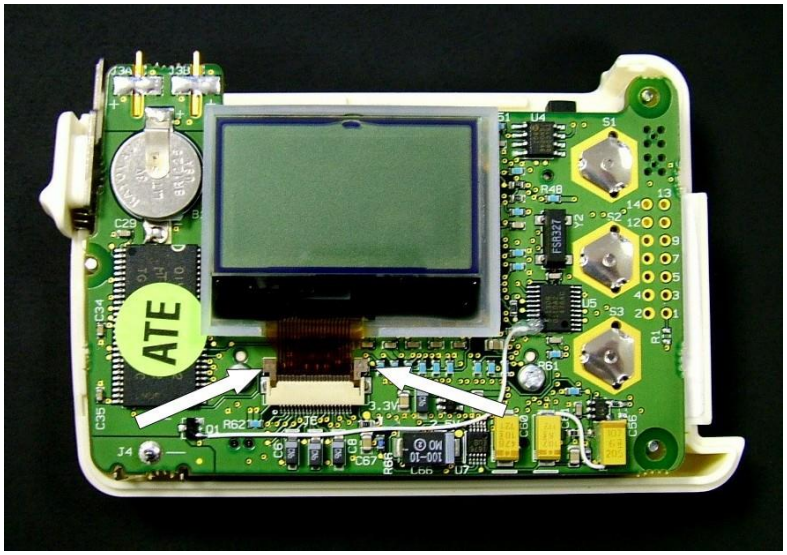
4. Reassemble unit in reverse order using 2.5 in/lbs. torque driver with a 1# Phillip's bit.

LCD Removal & Replacement

1. Open unit as described above.
2. Locate LCD cable on Digital board.
3. Remove the foam tape (item# 12) covering the LCD cable.
4. Locate the LCD Cable connector on the digital board.

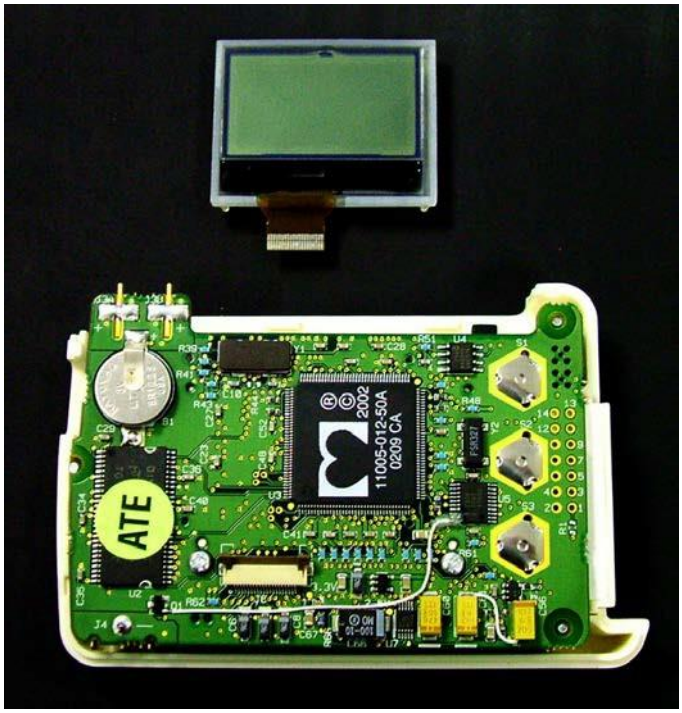


5. Lift the ears of the LCD connector to release the cable from the connector.



6. Lift the LCD, item # 11, and plastic shell off the digital board.

7. Remove and replace the LCD.

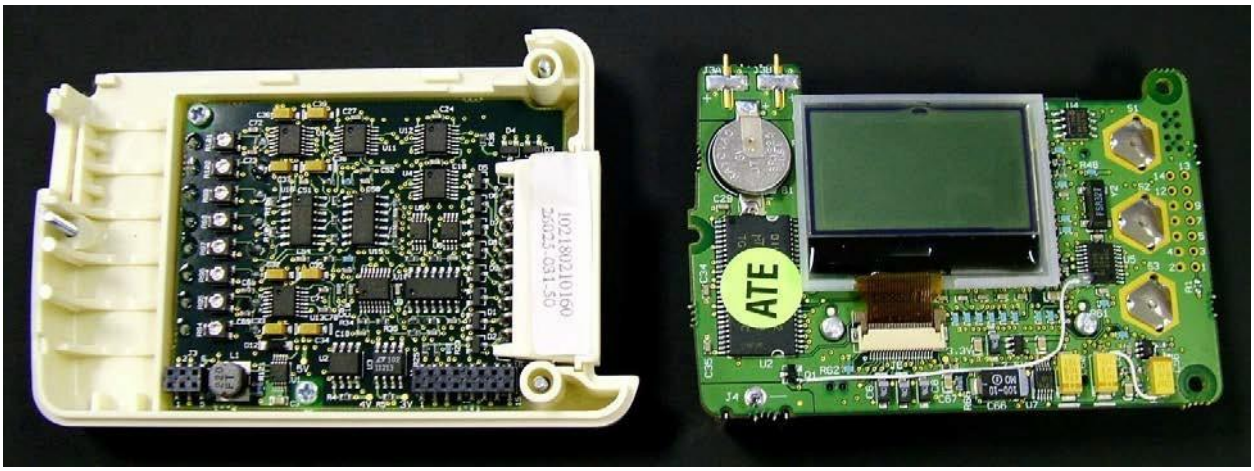


8. Install LCD and reassemble unit in reverse order using 2.5 in/lbs. torque driver (Brown) with a 1# Phillip's bit

Digital Board Removal & Replacement

1. Open unit as described above.

2. With the unit open, lift up on the Digital board (item # 6, 23 or 24) to remove it from its mating connectors.



3. Install digital board in reverse order.

4. Reassemble unit is reverse order using 2.5 in/lbs. torque driver with a 1# Phillip's bit

IMPORTANT

If the digital PCBA is being replaced, be sure to reset the unit serial number (located on the back housing of the unit) into the PCBA memory by utilizing the following process:

- Install a CF card with application software installed into the digital PCBA being processed.
- Install a AA battery into the unit, and hold down the top and bottom buttons simultaneously, as you close the battery door to power up the unit.

  *This will allow access to the **Serial Number Entry** screen.*

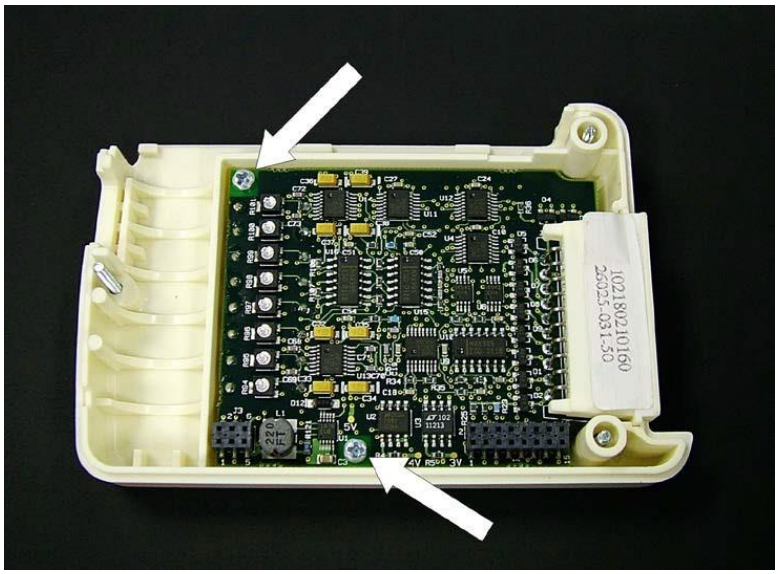
- Once in the serial number screen, press the middle button to allow serial number entry.
- Use the 3 interface buttons to enter the appropriate unit serial number, then select "End" to save the information.

Front End Board Removal & Replacement

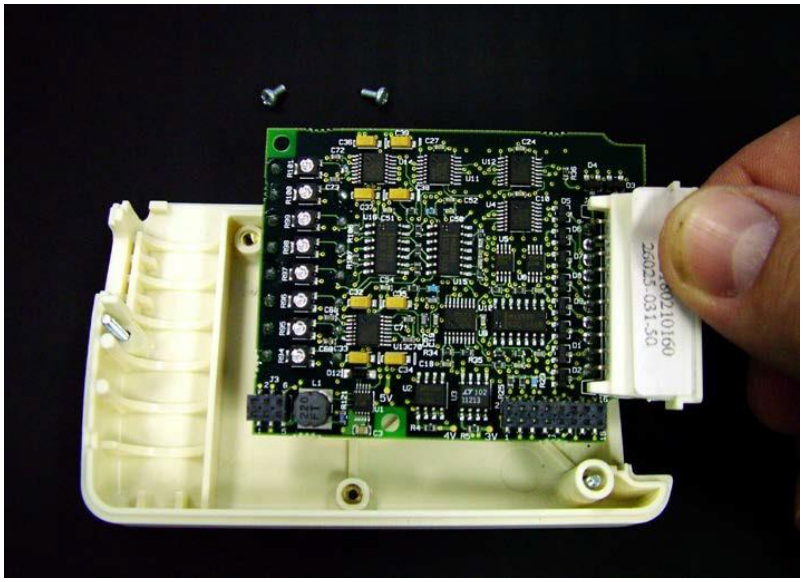
1. Open unit as described above.

2. Remove Digital board, item # 6, as described above. Please note that the LCD does not require removal.

3. Locate the two mounting screws, item # 17, holding the Analog board, item # 18, to the chassis of the unit and remove.



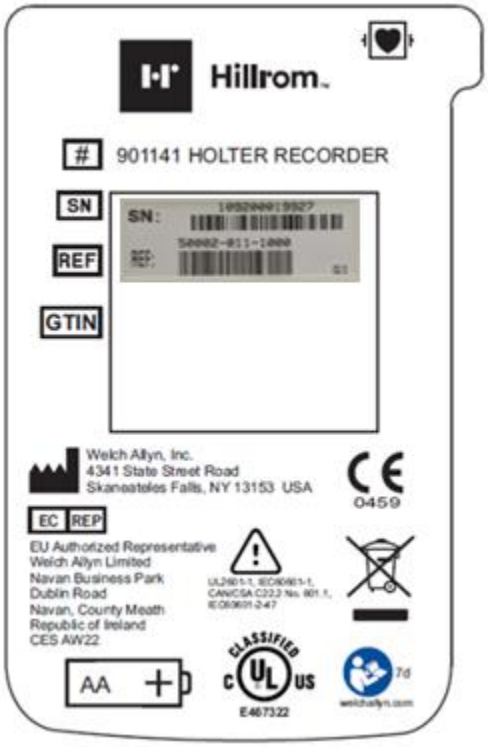
4. Lift the Analog board out of the chassis.



5. Replace/install analog board and reassemble unit in reverse order using 2.5 in/lbs. torque driver with a 1# Phillip's bit.

Serial Number Label Placement / Replacement

Due to changes in H12+ back labels over the life of the product, the serial number label should be placed within the window of the back label (item 13) as shown below.



PRINTED CIRCUIT BOARDS

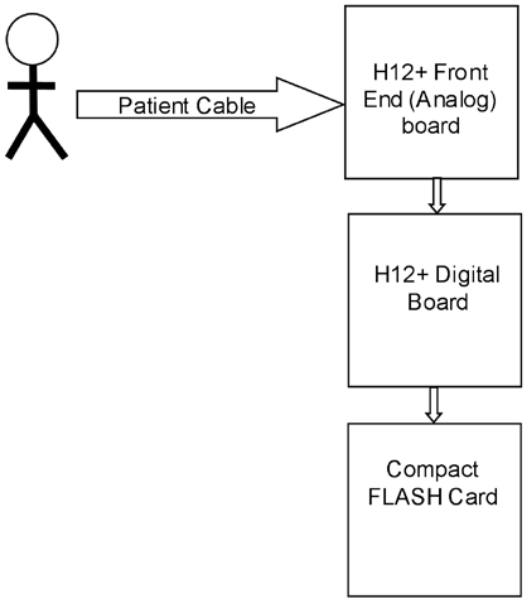
Introduction

This section provides illustrations of the H12+ Holter Recorder Printed Circuit boards. The parts list has not been provided. Boards are to be ordered for replacement as a whole. Refer to Safety Test in the section for Testing and Troubleshooting.

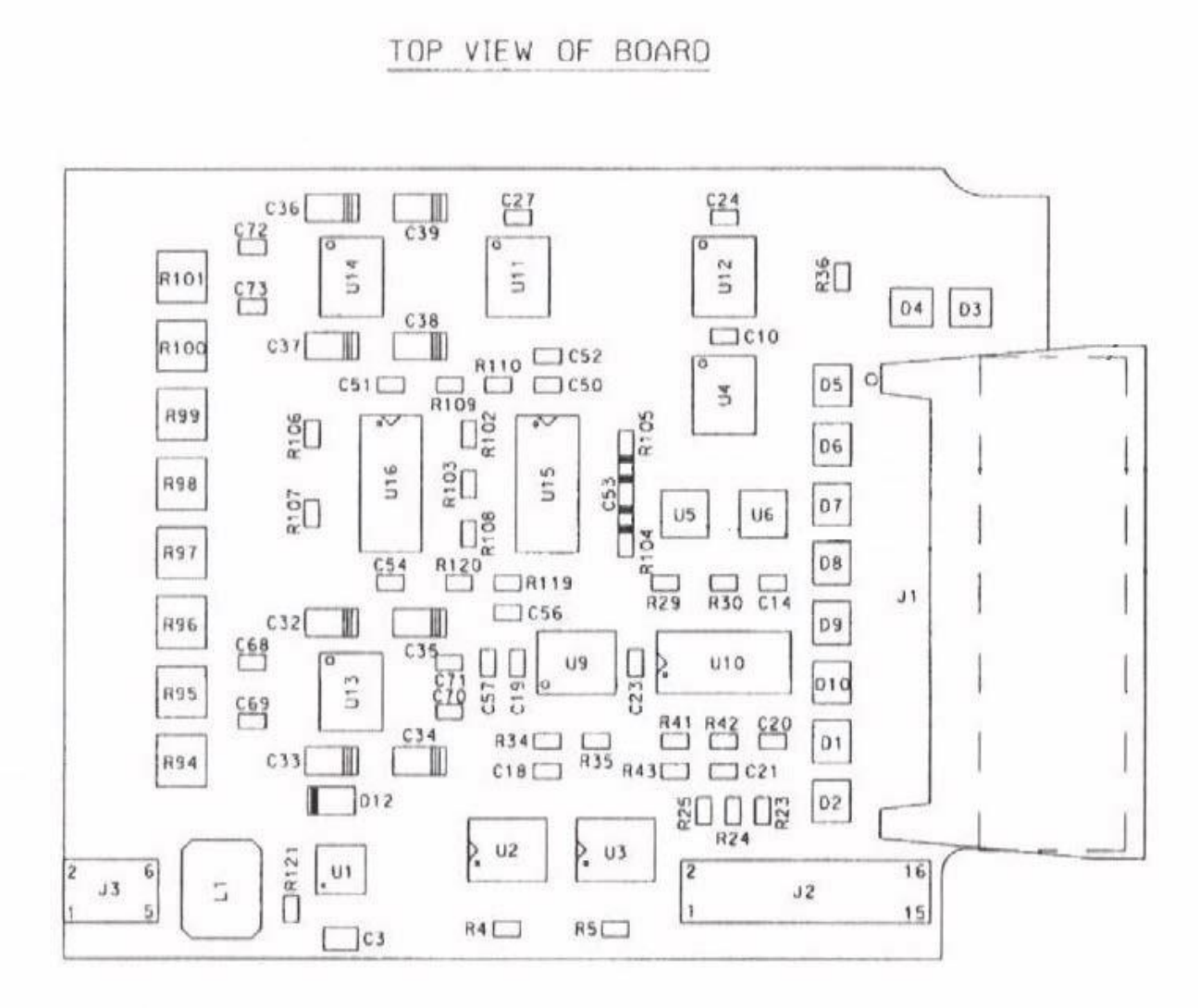
Anti-Static equipment should always be worn when working with static sensitive devices and in a static sensitive area.

Flow chart

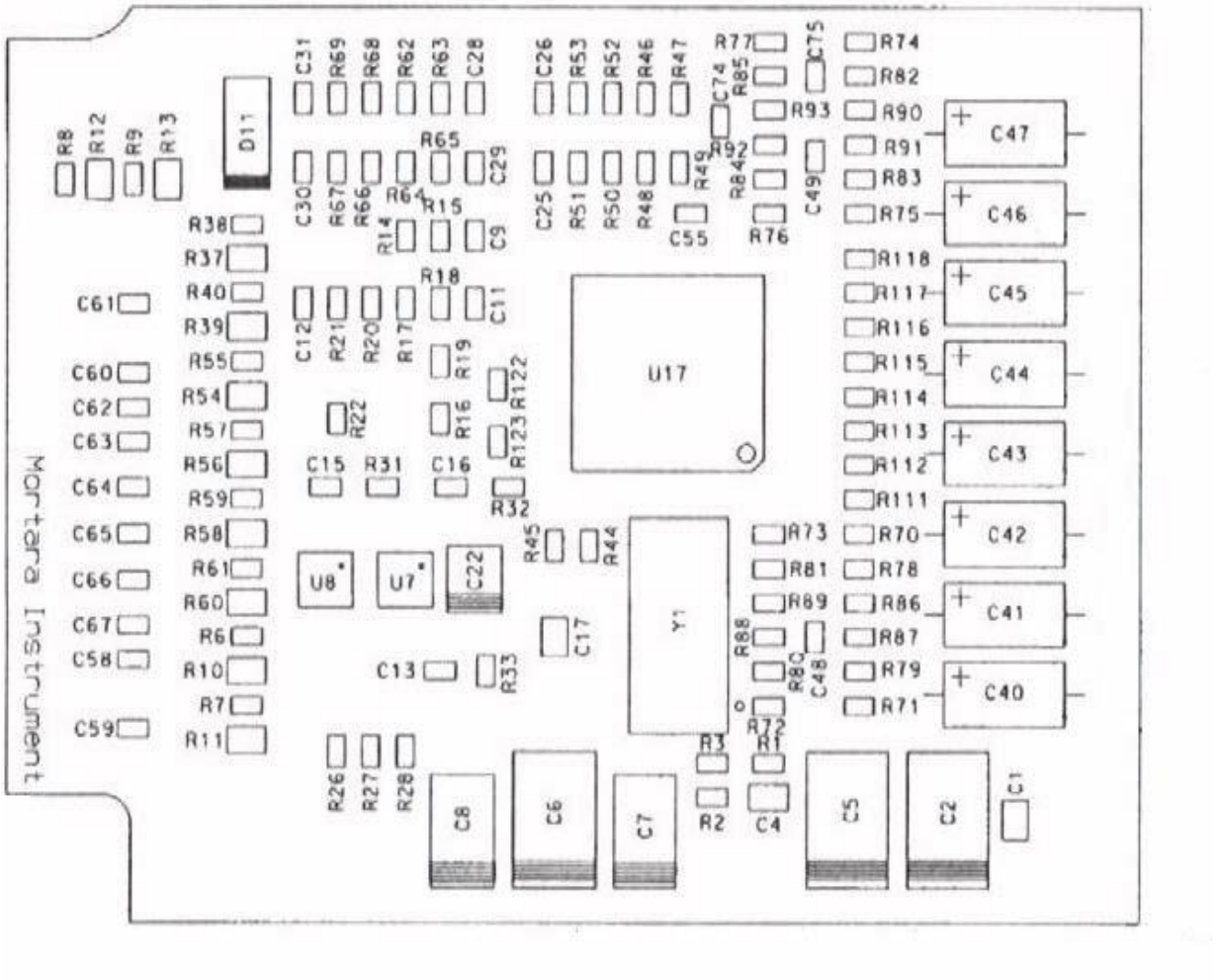
The following flow chart shows the way that the data is received and stored into the H12+



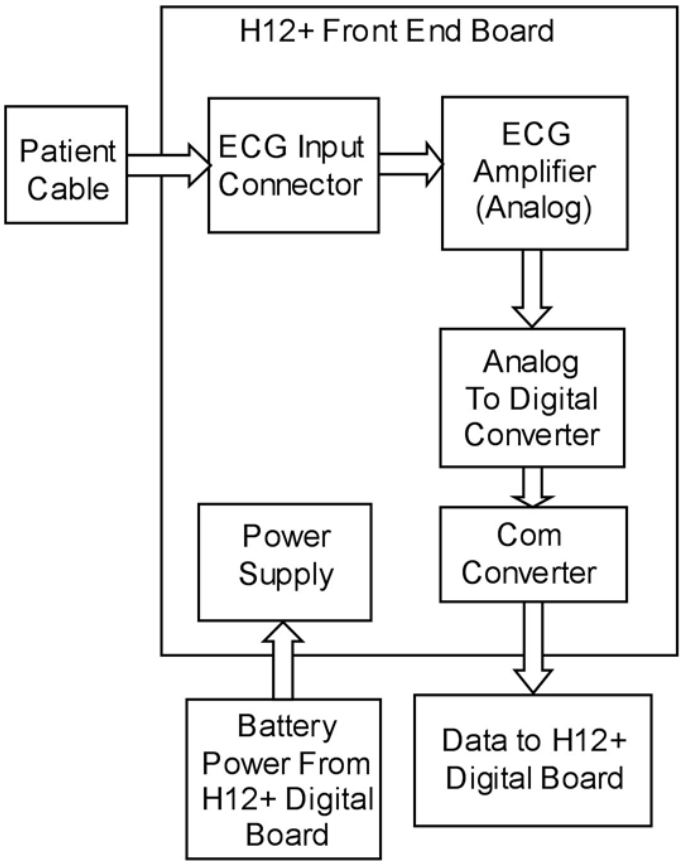
H12+ Front End PC Board Assembly REF: 26025-031-50



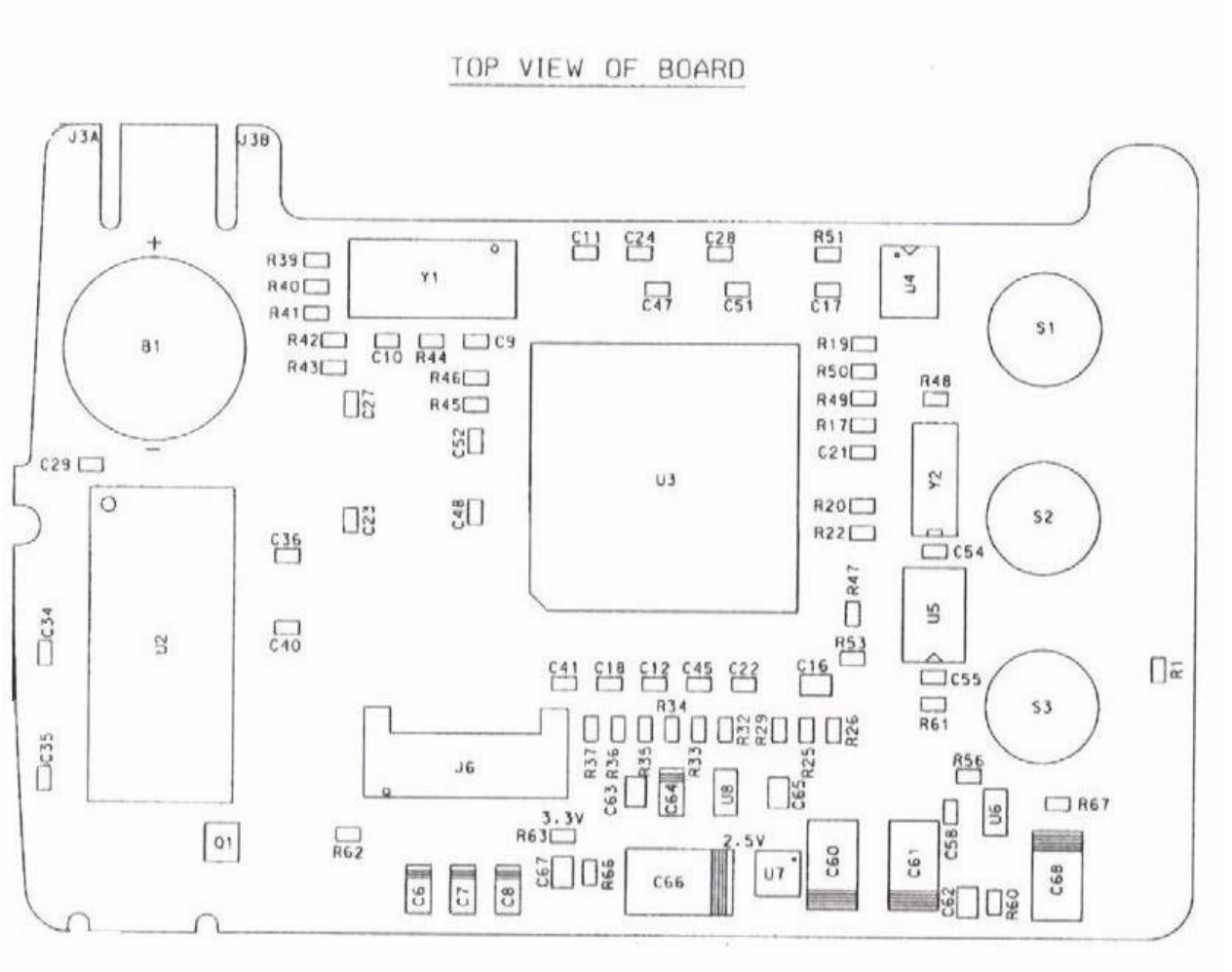
BOTTOM VIEW OF BOARD

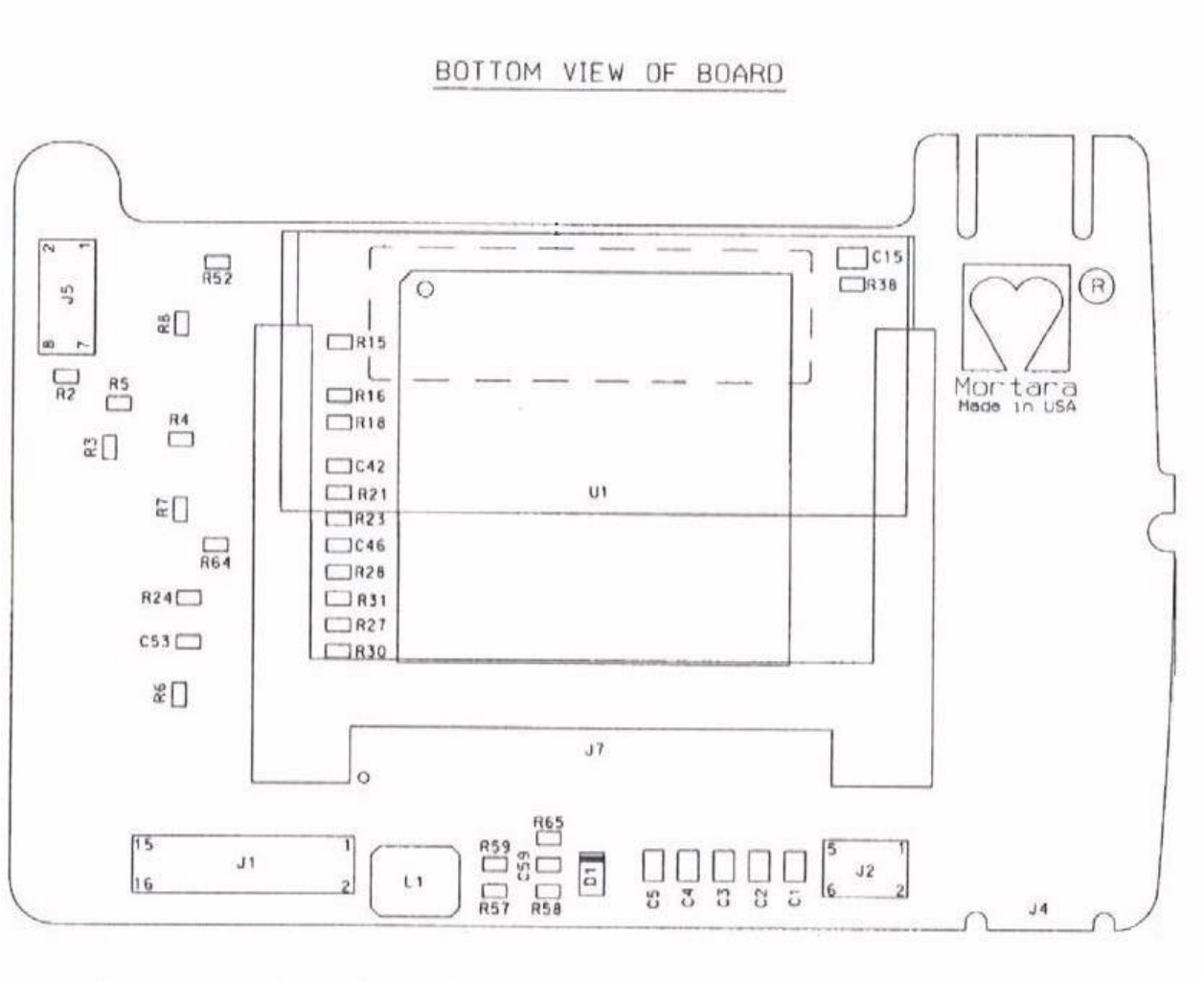


Block Diagram of H12+ Front End Board

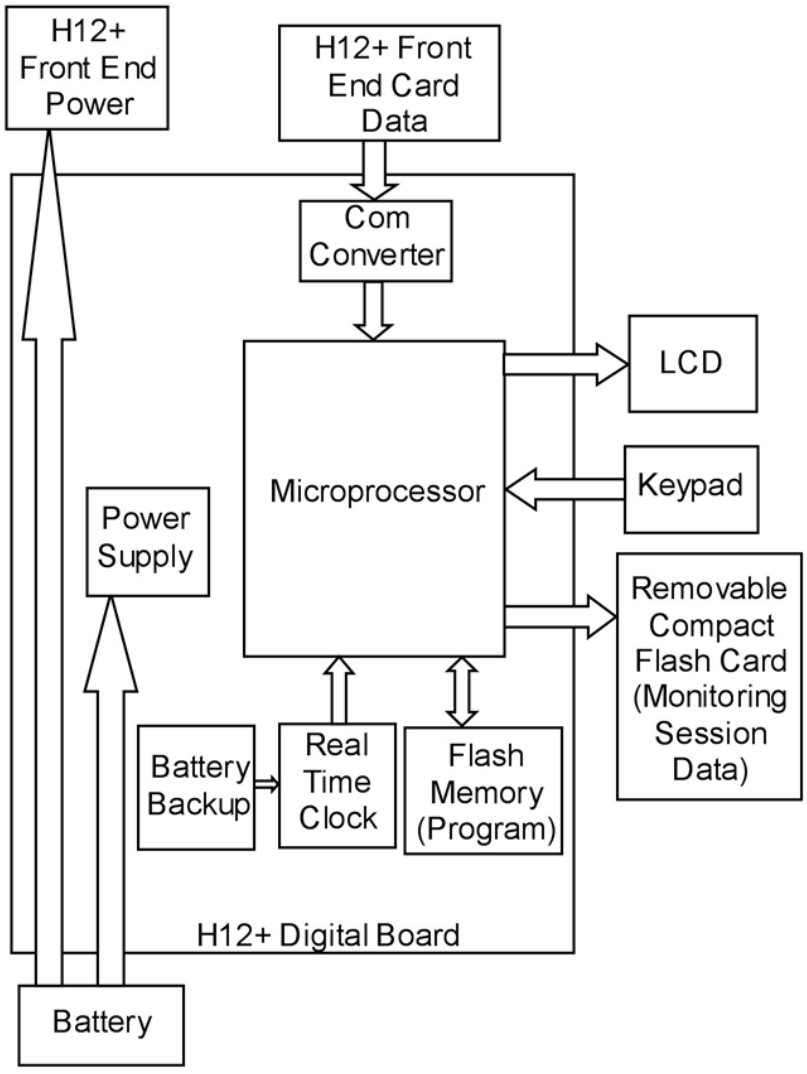


H12+ Digital PC Board Assembly REF: 26025-030-50




BOTTOM VIEW OF BOARD
J5
R52
R8
R2
R5
R4
R3
R7
R64
R24
C53
R6
R15
R16
R18
C42
R21
R23
C46
R28
R31
R27
R30
U1
C15
R38
R
Mortara
Made in USA
J7
J1
L1
R65
R59
C59
R57
R58
D1
C5
C4
C3
C2
C1
J2
J4

Block Diagram of H12+ Digital Board



TESTING AND TROUBLESHOOTING

Introduction

This section contains testing and troubleshooting information and procedures. Repair of the H12+ is limited. Removal of the label on the rear of the H12+ can and will void any and all Manufacturer's Warranties, see Warning.

WARNING: No user serviceable parts are inside. Any modification of this device will void any and all Manufacturer's Warranties and/or responsibilities. If you are not able to correct the H12+ Digital Recorder questionable operating state using the Troubleshooting guide in this manual, do not attempt to service it yourself. Contact Welch Allyn Technical Support if servicing assistance is needed.

Conformance Test

Conformance testing is to be performed by Authorized Welch Allyn Service Representatives to verify the device is functioning correctly after repair operations have been performed. Testing results should be documented on the test data record (TDR) at the end of this section of the manual.

1.0 Test Description

This document describes the steps necessary to functionally test the H12+ Recorder.

2.0 Definition of Terms

UUT	Unit Under Test
DMM	Digital Multi-Meter
LCD	Liquid Crystal Display
CF	Compact Flash

3.0 Required Equipment

Equipment ID	Description / Requirements
N/A	ECG Simulator
TF-0347	H12+ Modified Battery Compartment
TF-0345	H12+ High Lead Quality Test Fixture
TF-0346	H12+ Low Lead Quality Test Fixture
N/A	Digital Multi-Meter
N/A	Variable Power Supply
N/A	Welch Allyn H-Scribe II
TF0553	H12+ Serial number/Date time Compact Flash Card

Initial Set-up

4.0 Set adjustable power supply to 1.35V ± 0.05V.

4.1 Connect adjustable power supply to H12+ Modified Battery Compartment (TF-0347).

4.2 Set the current switch on TF-0347 to bypass.

Special Instructions

5.0 While performing all tests, watch for missing or extra segments on the UUT's LCD. A missing or extra segment on the LCD indicates a failure.

Test Procedure

6.0 Low Battery Test

6.0.1 Connect TF-0347 to UUT.

6.0.2 With the power supply set to 1.35V ± 0.05V, verify "no card" is displayed on the LCD.

6.0.3 Turn variable power supply off.

6.0.4 Insert a compact flash card with the latest released H12+ software and no recorded data on the CF card.

6.0.5 Turn variable power supply on.

6.0.6 Verify "low battery" is displayed on the LCD.

6.0.7 Record result on the TDR.

6.1 Compact Flash Card Test

6.1.1 Adjust the variable power supply to 1.55V ± 0.05V.

6.1.2 Cycle the power on the power supply.

6.1.3 Verify lead check is displayed on the LCD.

6.1.4 Record result on the TDR.

6.2 Real-Time Clock Memory Test

6.2.1 Navigate to the date format setting in the device menu options.

6.2.2 Set the date format to the DD.MM.YYY option and exit the menu.

6.2.3 Cycle the power on the power supply.

6.2.4 Verify the DD.MM.YYYY date format remained.

6.2.5 Record result on the TDR.

6.2.6 Set date format back to MM/DD/YYYY.

6.3 SDRAM / Front End Control Test

6.3.1 With the Serial Number menu option displayed, highlight “end” and press the ↵ button to start the SDRAM test.

6.3.2 Verify the SDRAM test passes.

(Test will indicate pass or fail on LCD. If test passes software indicates pass then continue to front end control test).

6.3.3 Verify the front end control test passes. (Front end control test takes about 11 seconds to run and will start automatically after a passing the SDRAM test. Test must be run with all leads open, NO PATIENT INPUT. If front end control test fails, refer to Appendix A for failure code explanation.)

6.3.4 Press the ↓ button on the UUT to exit self-test.

6.3.5 Record result on the TDR.

6.4 Lead Quality Test

6.4.1 Connect the H12+ High Lead Quality Test Fixture (TF-0345) to the UUT.

6.4.2 Select the lead check menu item on the UUT.

6.4.3 Verify that all of the bars on the LCD are above the horizontal line.

6.4.4 Remove TF-0345 and connect the H12+ Low Lead Quality Test Fixture (TF-0346).

Verify that all of the bars on the LCD are at or below the horizontal line.

Record result on the TDR.

6.6 Current Consumption Test

6.6.1 Leave TF-0346 connected to the UUT.

6.6.2 Connect DMM to TF-0347 and setup meter to read current.

6.6.3 Set the current switch on TF-0347 to measure.

6.6.4 Exit lead quality screen on UUT and enter the display ECG screen.

6.6.5 Verify the current is below 85mA.

6.6.6 Record the current draw on the TDR.

6.7 Recording Test

6.7.1 Remove TF-0347 and TF-0346 from UUT.

6.7.2 Connect the UUT to the simulator.

6.7.3 Put a new AA battery into the UUT and install the battery compartment.

6.7.4 Select the record function on the UUT.

6.7.5 Allow the UUT and simulator to run for approximately 2 minutes.

6.7.6 Remove the compact flash card and review on an H-Scribe system. Verify the UUT properly recorded for the approximate 2 minutes. Record a pass or failure on the TDR.

6.8 Clock Time Retention

6.8.1 Verify the time and date on the UUT are correct.

6.8.2 If incorrect, set them to the correct value and exit the menu option.

6.8.3 Cycle the UUT power and recheck to verify the correct date and time were retained.

6.8.4 Record the result on the TDR.

6.9 LCD Test

6.9.1 Verify that throughout the test no missing or extra segments on the UUT's LCD were observed. Record a pass or failure on the TDR.

APPENDIX A

If the Front End Control Test fails, a failure code will be displayed on the LCD. This failure code will be in decimal. Convert the code to binary and refer to Table 1 to determine which test(s) failed. A binary one indicates that test failed.

Table 1. Fail Codes for Front End Control Test

	Analog Switch Settings							Expected Readings		
Test Bit	LA_W	LL_W	RA_W	RL_DRV	RA_DRV	LA_DRV	LL_DRV	W_S	RL_S	RA_S
MSB 10	1	1	1	0	0	0	0	H	H	H
9	1	0	0	0	0	0	0	H	H	H
8	0	1	0	0	0	1	0	H	H	H
7	1	0	0	0	0	1	0	L	H	H
6	0	1	0	0	0	0	0	H	H	H
5	1	0	0	0	0	0	1	H	H	H
4	0	1	0	0	0	0	1	L	H	H
3	0	0	1	0	0	0	0	H	H	H
2	0	1	0	0	1	0	0	H	H	?
1	0	0	1	0	1	0	0	L	H	L
LSB 0	0	0	1	1	1	0	0	L	L	L

SAFETY TEST

INTRODUCTION:

This procedure describes the safety test for the fully assembled H12+ Recorder. This test can only be done to units which have the back label attached.

REQUIRED EQUIPMENT

High Voltage AC Supply (1.5kV)
H12/X12 Safety Test Fixture (TF-0014)

CAUTION:

DANGEROUS VOLTAGES PRESENT, USE CAUTION AT ALL TIMES

PROCEDURE:

7.0 With power “OFF”, connect AC supply to TF-0014 observing marked polarity.

7.1 Set the AC High Voltage supply to 1.5kV with a high current limit of 50uA.

7.2 Plug the patient cable end on the fixture into the patient input on the UUT. Insert the H12+ into TF-0014, close and latch the fixture.

7.3 Turn “On” the AC Hi-Pot tester and hold for 10 seconds. If the leakage current exceeds the set limit (50uA) at any point in the test, the test fails.

7.4 Turn “Off” the power supply, then remove H12+ unit.

H12+ Test Data Record

Unit Serial #: _____

6.1	**Low Battery Test**	**PASS / FAIL (CIRCLE ONE)**
6.2	**Compact Flash Card Test**	**PASS / FAIL (CIRCLE ONE)**
6.3	**Real-Time Clock Memory Test**	**PASS / FAIL (CIRCLE ONE)**
6.4	**SDRAM / Front End Control Test**	**PASS / FAIL (CIRCLE ONE)**
6.5	**Lead Quality Test**	**PASS / FAIL (CIRCLE ONE)**
6.6	**Current Consumption Test**	**_____ (<85mA)**
6.7	**Recording Test**	**PASS / FAIL (CIRCLE ONE)**
6.8	**Clock Time Retention**	**PASS / FAIL (CIRCLE ONE)**
6.9	**LCD Test**	**PASS / FAIL (CIRCLE ONE)**
7.0	**Safety Test**	**PASS / FAIL (CIRCLE ONE)**

Performed by:_____Date:_____/_____/_____

Required Safety Test for Printed Circuit Boards

NOTE: Any component replacement to PCB assembly, requires a High Voltage Test and it is recommended that the unit be sent back to Welch Allyn Service Department for repair and testing.

Troubleshooting

Trouble Symptoms	Diagnosis
Blank Display	Check battery. Measure battery voltage, should be 1.5 VDC. Clean battery contacts. Check for damaged contacts
Unit Displays Leadfail	Check patient cable. Check input connector pins, if pins are bent or pushed in, replace connector. Use extra care to remove/replace connector to prevent damage to printed circuit board
Unit Display LCD Damaged	Replace LCD.
Keys inoperative	Replace Keypad.
Noisy waveform or no waveform - Bent pins on patient cable interface connector	Contact Welch Allyn Service Department at 1-888-667-8272.
Noisy waveform or no waveform - Poor signal from electrode	Verify good prep before placing electrodes on patient. Verify electrodes are good (not beyond expiration date). Perform lead check test.

LOG FILE INFORMATION

Introduction

The H12+ Holter recorder generates several files when recording a monitoring session. One of these files, the log.txt file, can be useful in determining problems or events that occurred during a monitoring session. This file is accessible after the FLASH card data has been downloaded to the H-Scribe computer system. The log file will be located in the following area on the H-Scribe computer and can be viewed using a text editor:

C:\USR\PAT*XX*
Where *XX* is a number that is equivalent to the slot location of the stored Holter recording.

Below is a sample of the information in a log file:

```
04/05/2004 08:07:32 Power up    Serial Number:  102401428160
04/05/2004 08:07:51 Mode 1
04/05/2004 08:08:08 Impedance 2
Impedance   3
Impedance   8
Impedance   1
Impedance   0
Impedance   1
Impedance   9
Impedance  11
Impedance  17
04/05/2004 08:08:23 Mode  3
04/05/2004 08:09:00 Mode  2
04/05/2004 08:09:13 Mode  2
04/05/2004 08:10:00 Mode  4
04/05/2004 10:02:49 Event
04/05/2004 10:35:30 Lead Fault 638
04/05/2004 10:35:32 Lead Fault 0
04/05/2004 10:36:05 Lead Fault 126
04/05/2004 10:36:07 Lead Fault 0
04/05/2004 10:42:43 Lead Fault 023
04/05/2004 10:42:45 Lead Fault 0
04/05/2004 10:48:51 Lead Fault 023
04/05/2004 10:48:53 Lead Fault 0
```

The log file is separated into several sections, Power up section, Mode section and Fault section.

Section 1 Power up section

The first section of the log file is the power up section. This entry is a 1 line entry that contains the date, time, Power up statement and the H12+ serial number. From the example above this line looks like:

04/05/2004 08:07:32 Power up   Serial Number: 102401428160

Section 2 Mode section

Section 2 of the log.txt file contains information regarding what happens prior to the actual data recording. This will include entries for:

Mode description	Value entered in log.txt file
Main_Menu	0
Impedance	1
Waveform	2
ID	3
Recording	4
Configuration	5
DATETIME Menu	6
Language	7
Version	8
Set Date & Time	9

From the example above the Mode section contains the following information (please note that different recordings will have different information):

04/05/2004 08:07:51 Mode 1
04/05/2004 08:08:08 Impedance 2
Impedance 3
Impedance 8
Impedance 1
Impedance 0
Impedance 1
Impedance 9
Impedance 11
Impedance 17
04/05/2004 08:08:23 Mode 3
04/05/2004 08:09:00 Mode 2
04/05/2004 08:09:13 Mode 2
04/05/2004 08:10:00 Mode 4
04/05/2004 10:02:49 Event

Mode 1 Impedance

Shows the impedance values, in K Ohms, of leads (RA, LA, LL, V1, V2, V3, V4, V5, V6) given during the impedance test. The closer the value is to 0 the better the electrical connection to the patient.

Mode 2 Waveform

An entry of Mode 2 indicated that the Waveform display was accessed.

Mode 3 ID

An entry of Mode 3 (ID) means that the ID screen was accessed.

Mode 4 Recording

An entry of Mode 4 (Recording) means that the Record option was selected and that the monitoring session has begun. The entry after this will be and *Event* indicating the start of the monitoring session.

Mode 5 Configuration

An entry of Mode 5 (Configuration) means that the configuration menus have been accessed.

Mode 6 Date & Time menu

An entry of Mode 6 (Date & Time) means that the Date & Time menus have been accessed.

Mode 7 Language

An entry of Mode 7 (Language) means that the Language menus have been accessed.

Mode 8 Version

An entry of Mode 8 (Version) means that the Version menu has been accessed.

Mode 9 Set Date & Time

An entry of Mode 9 (Set Date & Time) means that the Set Date & Time menus have been accessed.

Section 3 Fault section

The fault section lists faults that the recorder logs during the monitoring session. These are typically lead fail indications or *Events*. Events are logged when the patient presses one of the keyboard buttons during a monitoring session.

Lead faults are recorded in this fashion:

04/05/2004 10:36:05 Lead Fault 126

The number after the Lead Fault text is a decimal number that must be converted to binary in order to determine which lead or leads are in fail. The table below can be used to decode the lead(s) in fail.

Lead	Binary value
LL	00 0000 0001
V6	00 0000 0010
V5	00 0000 0100
V4	00 0000 1000
V3	00 0001 0000
V2	00 0010 0000
V1	00 0100 0000
LA	00 1000 0000
RA	01 0000 0000
RL	10 0000 0000

In the example, 04/05/2004 10:36:05 Lead Fault 126, the value 126 equates to a binary number of 1111110. This number in the scheme listed above equates to 00 0111 1110. This means that leads V1 through V6 were in lead fail (the bits are acting as flags, if the bit is on (1) the lead is in fail and if the bit is off (0) the lead is not in fail.

In the case were the number is 023, a leading 1 must to be added to the beginning of the number so that the number reads 1023. This indicates that all leads were in lead fail because the binary conversion of 1023 is 11 1111 1111.