REF 9502-036-50

Mortara INSTRUMENT

Ambulatory X-12 Operator's Manual

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

REF 9500-067-01

Technical Support and Service

Following are telephone numbers and addresses for contacting various technical support and service personnel.

Mortara Instrument, Inc.
7865 N. 86th St.
Milwaukee, WI 53224
Telephone Number: 414-354-1600
Toll-free Telephone Number: 800-231-7437
Toll-free Service Number: 888-MORTARA
Fax: 414-354-4760
E-mail address: sales@mortara.com

24 hour technical support
Over 120 trained field service technicians
Same day shipment of replacement parts
Biomedical training classes
Extended warranties/service contracts

Sales Support/Supplies & Accessories

Mortara Instrument, Inc.
7865 N. 86th St.
Milwaukee, WI 53224
Phone: 414-354-1600
Fax: 414-354-4760
Internet: http://www.mortara.com

European Economic Community Representative

Mortara Rangoni
Via Oradour, 7 40016
San Giorgio di Piano
Bologna, Italy
Phone: 39-51-6650-701
Fax: 39-51-6651-012

Additional International Support Offices

Mortara France (France)
Immeubles Burolines - Bat. 2
2 Ter, Rue Marcel Doret
31700 Blagnac
Telephone number: 33-561-164000
Fax number: 33-561-164001

Mortara Instrument, Inc., GMBH (Germany)
Henricistr. 124
45136 Essen
Telephone number: 49-201-268311
Fax: 49-201-268313

Mortara Instrument, Inc., B.V.
(The Netherlands).
H. Dunantplein 6
3731 CL De Bilt
Postbus 131
3720 AC Bilthoven
Telephone number: 31-30-2205050
Fax: 31-30-2201531

Notices

Manufacturer's Responsibility

Mortara Instrument, 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 Mortara Instrument,
- The electrical installation of the relevant room complies with the requirements of appropriate regulations, and
- The Ambulatory X-12 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

Mortara Instrument 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 under the battery compartment of the product and may be called upon if service of the device is required.

Copyright and Trademark Notices

Other Important Information

The information in this document is subject to change without notice.

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Warranty Information

Your Mortara Warranty

MORTARA INSTRUMENT, INC. (hereinafter referred to as "Mortara") hereby warrants that Mortara products (hereinafter referred to as "Products") shall be free from defects in material and workmanship under normal use, service and maintenance for one year of such Product from Mortara or an authorized distributor or representative of Mortara. 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 Mortara;

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 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 PRODUCTS 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 Products (i) of all carrier charges with respect to any Products 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, 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 Products. 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 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 MORTARA 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 MORTARA IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL MORTARA 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.

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

Warning(s)

- Device (Ambulatory X-12) transmits data reflecting a patient's physiological condition to a properly equipped electrocardiograph and 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.
- To maintain designed operator and patient safety, peripheral equipment and accessories used that can come in direct patient contact, must be in compliance with UL 2601-1, IEC 601-1 and IEC 601-2-25.
- To maintain designed operator and patient safety, only use parts and accessories supplied with the device and available through Mortara Instrument, Inc..
- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with device or patient cables. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
- A possible explosion hazard exists, do not use the device in the presence of flammable anesthetics.
- Defibrillation protection is guaranteed only if the original patient cable is used.
- Simultaneous connection to other equipment may increase leakage current.
- Some stimulators may cause interference with the signal.
- ECG electrodes could cause skin irritation and should be examined daily. Reposition and change electrodes every 24 hours, though it may be necessary to do so sooner if signs of irritation or inflammation occur.
- Before attempting to use the device for clinical applications the operator must read and understand the contents of the manual and any documents accompanying the device.

Caution(s)

- To prevent possible damage to the keypad, do not use sharp or hard objects to depress keys, only use fingertips.
- Do not attempt to clean the device or patient cables by submersing into a liquid, autoclaving, or steam cleaning.
- Wipe the exterior surface of the device and patient cables with a sterilizing disinfectant, then dry with a clean cloth.
- Conductive parts of the patient cable, electrodes and associated Type CF connections, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts, including earth ground.
- The Ambulatory X-12 and Patient Cable should be cleaned between each use.
- 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 Ambulatory X-12 will only work with electrocardiographs that are equipped with the appropriate option.
- No user serviceable parts are inside. Any modification of this device may alter defibrillator protection. Any modification to any part of this device is to be performed by qualified service personnel only.
- The following equipment may cause interference with the RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios and government radar.

Warning(s)

In some countries the use of the X-12 transmitter (2400 MHz version) has been limited as follows:

E Spain: use is limited to channels in the range 8B to E6 (inclusive).

F France: use is limited to channels in the range 8E to A5 (inclusive).

The channel setting of the X-12, when used in the above listed countries, must be set accordingly, as explained in this manual at section 2.

In the United States and Canada, use of the X-12 transmitter (600 MHz version) is regulated by Federal Communications Commission (FCC) rules, Part 15.

- The X-12 must be used solely on the premises of health care facilities (see Part 15, section 15.242a).
- A health care facility operating the X-12 must coordinate with the directors of existing nearby TV stations and Radio Astronomy Observatories to ensure compatible use. Minimum separation distances from such facilities may apply. It may be necessary to obtain written authorization from such facilities prior to installation and use of the X-12 (Part 15, section 15.242d,e).

Notes

- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- Patient cables should be checked for cracks or breakage in its exterior properties prior to use.
- As defined by IEC 601-1 and IEC 601-2-25, the device is classified as follows:

  - Internally powered
  - Type CF applied parts
  - Ordinary equipment
  - Not suitable for use in the presence of flammable anesthetics
  - Continuous operation

Equipment Symbols

Symbol Delineation

Attention, consult accompanying documents

Attention, consult accompanying documents.

Compliance with Directive 1999/5/EC

Defibrillator-proof type **CF** input

Battery

Enables lead check test

Toggles through each lead

Indicates compliance to applicable EEC Directives

ON (power)

OFF (power)

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3 Maintenance and Troubleshooting

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1 Introduction

Manual Purpose

The Ambulatory X-12 Operator's Manual explains how to operate the transmitter (Ambulatory X-12). You can use this manual as a learning tool as well as a source of reference information. It explains how to acquire and transmit 12-lead cardiac signals without direct connections to an electrocardiograph:

Audience

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

System Description

The Mortara Instrument Ambulatory X-12 Telemetry Module represents the state-of-the-art in Wireless Electrocardiographic Technology. It provides a means to acquire and transmit 12-lead cardiac signals without direct connections to an electrocardiograph. Design innovations implemented in the Ambulatory X-12 Telemetry Module achieve real-time acquisition, RF transmission of simultaneous 12-lead ECG data with diagnostic quality to the Mortara Receiver Module while allowing the patient to be ambulatory.

In addition, by using a very high monitoring frequency to transmit cardiac signals, the diagnostic bandwidth of the signals is maintained.

The Ambulatory X-12 affords the patient complete freedom of movement. Unlimited range can also be obtained with addition of the Mortara Antenna Network Box(s).

Equipment Included

The following equipment is necessary to use the Ambulatory X-12 Telemetry Module:

- Ambulatory X-12 (transmitter),
- Two AA batteries, 1.5V,
- Mortara Receiver Module with Antennas,
- Patient cable
- Antenna Network (optional)

Features

- Continuous 12-lead signal acquisition and transmission,
- User selectable channel,
- User lead check (LC), nine selections,
- Automatic notification of lead fail,
- AA battery operation,
- Notification of low battery

Using the Ambulatory X-12 in Conjunction With Mortara Electrocardiographs

See the appropriate Mortara operator's manual for electrocardiograph.

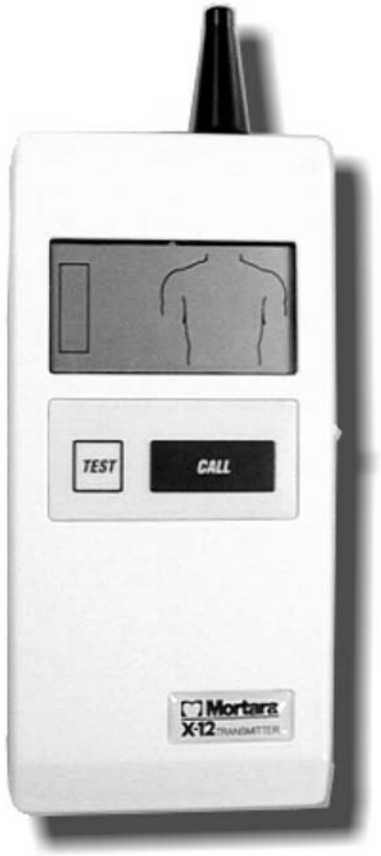


Figure 1-a Ambulatory X-12 Transmitter

Ambulatory X-12 Specifications

Environmental	
Temperature Operating	10° C to 32° C
Temperature Storage	0° C to 45° C
Humidity Operating	20% to 80%
Humidity Storage	10% to 90%
Atmospheric Pressure	700 - 1060 millibars
Dimensions	14 cm x 6.6 cm x 2.5 cm, 5.5” x 2.6” x 1”
Weight, with and without battery	With: 8.3 ounces, (240 grams) Without: 6.7 ounces, (200 grams)
Batteries	2, AA alkaline, 30 hour typical life
Display	LCD of lead fail, lead quality, power ON/OFF, low battery
Frequency range [1)]	608.48 to 631.52 MHz, or 904.76 to 925.16 MHz, or 2400.96 MHz to 2482.56MHz
Function keys (2)	One provides multi-purpose call or activation; the other provides lead quality activation
Leads connector	Single-block, 10 lead
Tunable	Yes
Number of channels	256
Leads transmitted	12

NOTE: Manufacturer does not supply accessories for direct cardiac applications.

15 meters with no barriers	**Operating Range Performance** [2)]

[1)]Operating frequency range is dependent on Ambulatory X-12 part number

[2)]Based on ELI 100 (electrocardiograph) equipped with wireless option

Ambulatory X-12 Supply List

Standard Ambulatory X-12 orders include the following accessories:

- REF 9293-017-XXResting Patient Cable (international or domestic))
- REF 4800-001Two AA Batteries
- REF 9502-036-50 Operator's Manual
- REF 9503-031-01Short Form Instruction Card
- REF 34999-002-50Carrying Case with Strap

Refer to the respective Mortara electrocardiograph's manual for electrode supplies.

To order additional supplies, contact a Mortara Instrument customer service representative at:

Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
Phone: 1-888-MORTARA (667-8272)
Fax: (414) 354-4760
Internet: *http://www.mortara.com*

2 Operation

Please Read Instructions before Operating this Device

The user of this device is cautioned that any changes or modifications not expressly approved by Mortara Instrument, Inc., could void the user's authority to operate the equipment.

This cable complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Operating frequencies are 608.48-631.52 MHz, or 904.76-925.16 MHz, or 2400.96-2452.96 MHz operating frequency range.

FCC ID: HJR-X12-600-15
FCC ID: HJR-X12-915
FCC ID: HJR-X12-2500

This device is defibrillator-protected in compliance with AAMI standards and IEC 601-2-25.

Electrocardiograph

Figure 2-a Electrocardiograph Equipped with Wireless Option

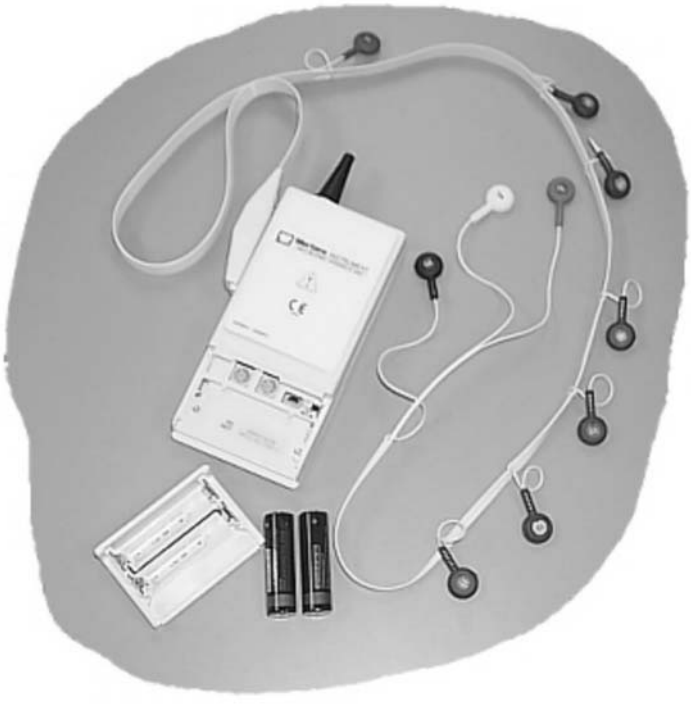


Figure 2-b Ambulatory X-12, Back View Battery Compartment, Inner View

Power Supply

Two disposable AA batteries (industrial AA's), which you insert into the unit's battery compartment, are used to power the Ambulatory X-12. The typical life of two AA batteries is 30 hours.

When you turn the unit on, ON appears on the LCD screen to the lower left of the torso.

NOTE: Alkaline batteries are recommended .

Battery Installation and Ambulatory X-12 Operation

To install the new batteries and operate the Ambulatory X-12:

❶ Position the Ambulatory X-12 with its back facing you. (See the illustration which follows.)

❷ Grasp the device with one hand on each side, placing your right and left thumbs on the back's grooved sections of the battery compartment. Then gently push your thumbs down and away to remove the battery compartment.

❸ Turn the compartment over and insert one new battery in each battery slot. To be sure of correct placement, align the positive (+) and negative (-) locators of each battery with the respective designator in each battery slot. (See the previous illustration, "Ambulatory X-12, Back View, with Battery Compartment Removed."

❹ Push the ON/OFF switch, located next to the channel selectors, to the ON position.

❺ Re-insert the battery compartment.

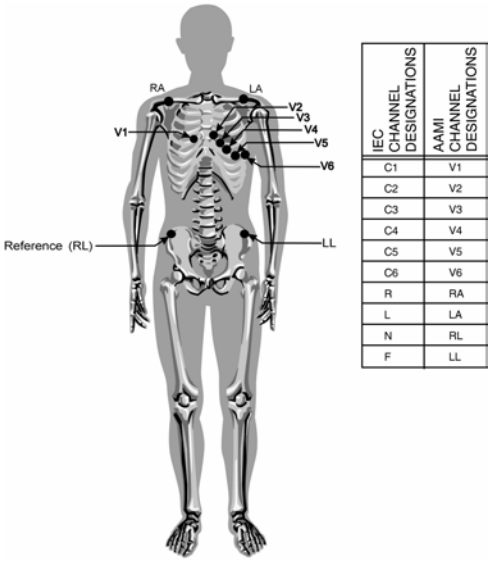
❻ When the Ambulatory X-12 is not in use, push the ON/OFF switch to the OFF position.

Note: If the batteries are not functioning, or the ON/OFF switch is in the OFF position, the message ON will not appear on the LCD screen, and the leads will not flash on the torso.

Patient Preparation

Correct electrode placement is important for acquiring a successful ECG (see *Patient Hookup* below). Although most resting cardiograms are completely successful without patient preparation, consider performing some patient preparation procedures to remove oils, lotions, and hair from the skin, particularly on obese individuals.

Patient Hookup



IEC CHANNEL DESIGNATIONS	AAMI CHANNEL DESIGNATIONS
C1	V1
C2	V2
C3	V3
C4	V4
C5	V5
C6	V6
R	RA
L	LA
N	RL
F	LL

Figure 2-c Patient Hook-Up

The 12-lead patient cable is attached to the patient, and the patient cable input connector is inserted into the receptacle located on the right topside of the Ambulatory X-12.

WARNING: QRS morphology may be slightly different from the standard ECG because of different position of lower limb electrodes. To reduce these differences, try to position LL electrode as low as possible, e.g., iliac crest, leg root.

Lead Fail

A lead in failure is displayed as a blinking lead designator located on the torso. If the patient cable is not attached, the LL, V1, V2, V3, V4, V5, and V6 lead designators blink on the torso.

Lead Check

To check the electrode contact quality, you may review the impedance measured for each of the leads. The Ambulatory X-12 presents this information in the impedance check graph located on the left side of the display in the triangular box on the left of the LCD. To interpret the impedance check graph, read the instructions on the back of the Ambulatory X-12.

NOTE: Ambulatory X-12 is not waterproof. Prevent liquid from penetrating, and avoid submerging in any liquid. Sterilization is not allowed.

The greater the impedance, the more the signal quality is compromised. Increments of impedance are represented as black bars located within the rectangular box. Six black bars represent minimum impedance, or optimal signal quality; one bar represents maximum impedance, poor signal quality, or lead fail.

To check the impedance of each lead:

❶ Press and hold down the Test key located on the front of the Ambulatory X-12 until the message LC (Lead Check) appears on the bottom of the display. The LA (left arm) lead designator appears on the upper right section of the torso. The impedance check graph depicts the value measured for the LA (left arm) lead.

❷ Press the Call key to check the remaining leads: LL (left arm), V1, V2, V3, V4, V5, V6, RA (right arm).

❸ To exit the impedance check mode, continue to press the Call key until the LC message is erased.

Once signal quality is confirmed, you are ready to initiate monitoring on the electrocardiograph.

Transmitting

Refer to the appropriate appendix of the Mortara electrocardiograph operator's manual for setting up the Wireless Patient Cable.

CAUTION: Failure to properly set up the electrocardiograph with the Ambulatory X-12 Telemetry Module will result in poor or non-operation of the Ambulatory X-12.

Miscellaneous

Channel Number

The Ambulatory X-12 transmits the patient's cardiac signals to the electrocardiograph using a specific channel number. The Ambulatory X-12 is preset at the facility with a channel number of 80H. You may, however, choose individually from any of the 256 channels. If you experience ECG signal loss, for instance, you might want to change the transmission channel.

The two-channel selector dials are located on the inside of the battery compartment,

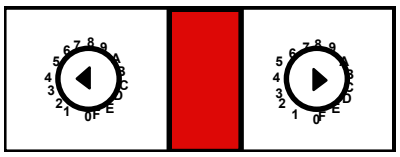


Figure 2-d Channel Selector Dials

By adjusting the slot located on the inside of the inner circle of each dial, you may select a new channel.

Each dial is numbered in a hexadecimal format, beginning with the alphanumeric value of 0 and ending with F (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A, B, C, D, E and F). Select one number from a choice of 16 alphanumeric values for each dial. The left dial represents the first alphanumeric value and the right dial the second. The total number of two alphanumeric combinations is 256.

To change the currently selected channel, insert a small, flat screwdriver in the slot located in the circle of the dial. Turn the screwdriver clockwise, and release when the arrow inside the circle is aligned with the desired number.

Removal and Installation of Antenna

When attached directly to a Electrocardiograph:

❶ To remove an antenna, gently rotate the ridged band counterclockwise while simultaneously pushing in on the band. The small post is released in the diagonal groove, freeing the antenna from the connector.

❷ To install an antenna, position the small post in the groove. Push in the antenna and gently rotate the ridged band, allowing the post to engage and lock in the curved end portion of the groove.

When a Telementry Receiver Processor Card is used:

Antenna should not be removed. If necessary to tighten or clean, the antenna screws on and off in clockwise/counterwise manner.

3 Maintenance and Troubleshooting

Cleaning the Ambulatory X-12 and Patient Cable

Turn off the Ambulatory X-12, and clean the outside with a damp cloth (possibly moistened with alcohol). Dry the equipment completely before use.

WARNING: The Ambulatory X-12 is not water-proof. Prevent liquid from penetrating, and avoid submerging the Ambulatory X-12 in any liquid. Sterilization is not allowed.

Periodic Maintenance

Check the Ambulatory X-12 and patient cable everyday to be sure they are not damaged or broken.

Disposal of Waste Materials

The Ambulatory X-12 needs two alkaline batteries and disposable electrodes. Their disposal must be in accordance with the following procedures:

Batteries: chemical waste
Electrodes: normal waste

Troubleshooting

PROBLEM	POSSIBLE CAUSE	SUGGESTED SOLUTIONS
No or noisy waveform	1. Mismatched frequency setting	1. Ensure frequency setting at electrocardiograph (receiver) is the same as the Ambulatory X-12's.
	2. Frequency channel selected has interference	2. Select a different frequency for both the electrocardiograph (refer to the appropriate manual) and Ambulatory X-12.
	3. Bent pins on patient cable interface connector	3. Contact Mortara Service Department at 1-888-MORTARA (667-8272).
	4. Poor signal from electrode	4a. +Verify good prep before placing electrodes on patient. 4b.Verify electrodes are good (not beyond expiration date). 4c.Perform lead check test.
Blinking lead on torso	1. Cable is not attached	1. Check cable to ensure it is connected to the Ambulatory X-12 and patient electrodes.
	2. Poor lead placement or attachment	2a.Verify good prep before placing electrodes on patient. 2b.Verify electrodes are good (not beyond expiration date). 2c.Perform lead check test.
Display does not show ON	1. Ambulatory X-12 not turned ON	1. Remove battery compartment door batteries and turn switch to ON. 2. Install new batteries.
	2. Dead batteries	3. Install new batteries.
	3. No batteries	
Display shows Lb	Low battery	Replace batteries with new batteries.

WARNING: If you are not able to correct the Ambulatory X-12 Telemetry Module's questionable operating state using the above guide, do not attempt to service it yourself. Contact Mortara Service at 1-888-MORTARA (667-8272).

Appendix A System Information Log

The following system information log is provided for your convenience. You need this information to set up your system if it needs servicing. Be sure to update the information log when you add options or your system has been serviced.

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

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

System Information Log

Manufacturer:

Mortara Instrument, Inc.
7865 N. 86th St.
Milwaukee, WI 53224

Telephone Numbers:

Domestic: 800-231-7437
European: +39-51-6650-701

Sales Department: 800-231-7437

Service Department: 888-MORTARA

Product Information:

Name of Unit/Product: _____

Date of Purchase: ___/___/_____

Purchased Unit From: _____

Serial Number: _____

Software Version: _____

System Information Log

For questions and service information, when calling have serial number and part number available.

(The Serial Number and Part Number (REF) are found under the batteries , in the battery compartment on the back side of the unit.

Similar to the one pictured below.)

Figure A-a Serial Number (SN) Part Number (REF) Location

Notes:

Glossary

TERM	DEFINITION
Limb lead	Bipolar lead that represents the differences of electrical potential between two selected sites (leads I, II, III).
Muscle noise	Grossly uneven baseline caused by patient body tremor or other muscle movement. The artifact may be so large that it overtakes the complex.
Precordial leads	(V1-V6) Unipolar chest leads.

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