P/N 9515-164-50-ENG

Mortara INSTRUMENT

X12+ User Manual

CAUTION: Federal law restricts this device for sale to and use 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 (Ambulatory X12+) 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, 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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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 the warranty period of such Product from Mortara or an authorized distributor or representative of Mortara. The warranty period is defined as twelve (12) months following the date of shipment from 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:

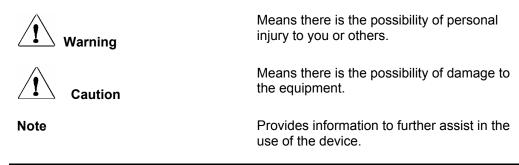
- a) Freight damage;
- b) Parts and/or accessories of the Products not obtained from or approved by Mortara;
- c) Misapplication, misuse, abuse and failure to follow the Product instruction sheets and/or information guides;
- d) Accident, a disaster affecting the Products;
- e) Alterations or modifications to the Products not authorized by Mortara;
- f) Other events outside of Mortara's reasonable control or not arising under normal operating conditions.

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User Safety Information



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



- Device (Ambulatory X12+) 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 <u>not</u> 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.
- 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 equipment.
- 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 mixtures with air, oxygen or nitrous oxide.
- 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.



- 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, and 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 X12+ 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 X12+ will only work with electrocardiographs that are equipped with the appropriate option.
- No user serviceable parts are inside. <u>Any</u> 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.
- To prevent possible damage to the device during transport and storage (while in original packaging) the following environmental conditions must be adhered to:

Ambient Temperature Range: -20°C to 65°C (-4°F to 149°F)

Relative Humidity Range: 5% to 95% (non-condensing)

Atmosphere Pressure: 700 hPa to 1060 hPa

• Allow the device to stabilize within its intended operating environment for a minimum of two hours prior to use. The allowable operating environment is as follows:

Ambient Temperature Range: 0°C to 45°C (32°F to 113°F)

Relative Humidity Range: 5% to 95% (non-condensing)

Atmosphere Pressure: 700 hPa to 1060 hPa

Warning(s)

In some countries the use of the X12+ transmitter (2400 MHz version) has been limited as follows:



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

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

The channel setting of the X12+, when used in the above listed countries, must be set accordingly, as explained in this manual at section 2.

FCC Compliance Statement

In the United States, use of the X12+ transmitters is regulated by Federal Communications Commission (FCC).

FCC ID: HJR-X12-600-15 FCC ID: HJR-X12P-2500

These devices comply with Part 15 of the FCC rules.

Operation is subject to the following conditions:

- 1. This device may not cause harmful interference, and
- 2. This device must accept any interference received, including interference that may cause undesired operation.
- The X12+ (600) must be used solely on the premises of health care facilities (see Part 15, section 15.242a).
- A health care facility operating the X12+ (600) 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 X12+ (Part 15, section 15.242d,e).

Industry Canada Compliance Statement

In Canada, use of the X12+ (600) transmitter is regulated by Industry Canada.

Canada ID: 3758104616

This device complies with RSS-210 of the Industry Canada rules.

This telemetry device is only permitted for installation in hospitals and health care facilities. Devices shall not be operated in mobile vehicles (even ambulances and other vehicles associated with health care facilities). The installer/user of this device shall ensure that it is at least 80 km from the Penticton radio astronomy station (British Columbia latitude: 49o 19' 12" N, longitude: 118o 59'56" W). For medical telemetry systems not meeting this 80 km separation (e.g. the Okinagan valley, British Columbia) the installer/ user must coordinate with and obtain the written concurrence of the Director of the Penticton radio astronomy station before the equipment can be installed or operated. The Penticton contact is Tel: 250-493-2277/ fax: 250-493-7767.

Note

- 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 their 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 mixtures with air, oxygen or nitrous oxide
 - Continuous operation
- The X12+ is a UL classified device:



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 IEC60601-2-25.

5P35

Equipment Symbols

Symbol Delineation







Attention, consult accompanying documents

Attention, consult accompanying documents. Compliance with Directive 1999/5/EC

Defibrillator-proof type CF input



Battery

Indicates compliance to applicable EEC Directives Electromagnetic Compatibility (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the X12+ Transmitter.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the X12+ Transmitter 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 X12+ Transmitter should not be used adjacent to, or stacked on top of other equipment. If the X12+ Transmitter must be used adjacent to or stacked on top of other equipment, verify that the X12+ Transmitter 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 Table X-4 for recommended separation distances between the radio equipment and the X12+ Transmitter.

Accessories and Cables Warning

The use of accessories and cables other than those specified below, may result in increased emissions or decreased immunity of the X12+ Transmitter.

Description	Part Numbers
10-wire LeadForm Patient Cable/ DomesticStandardLarge	9293-017-50 9293-026-50
 10-wire LeadForm Patient Cable/ International Standard Large 	9293-017-51 9293-026-51

Table X-1 Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The X12+ Transmitter is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the X12+ Transmitter should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment: guidance
RF Emissions CISPR 11	Group 2	The X12+ Transmitter must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The X12+ Transmitter is suitable for use in all establishments, including domestic establishments and
Harmonic Emissions IEC 61000-3-2	Not Applicable	those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Table X-2 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The X12+ Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the X12+ Transmitter should assure 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	+/- 2 kV for power supply line +/- 1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	Not Applicable	
Power frequency (50./60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the a.c. mains voltage prior to application of the test level.

Table X-3 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: guidance
Conducted RF IEC 61000-4-6	3 <i>Vrms</i> 150 kHz to 80 MHz	3 <i>Vrms</i> 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the X12+ Transmitter, 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 <i>Vrms</i> 80 MHz to 2.5 GHz	3 <i>Vrms</i> 80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{3V/m}\right]\sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}$
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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: $(((\bullet)))$

The X12+ Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the X12+ Transmitter should assure that it is used in such an environment.

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 X12+ Transmitter is used exceeds the applicable RF compliance level above, the X12+ Transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the X12+ Transmitter.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Table X-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the X12+ Transmitter.

The X12+ Transmitter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X12+ Transmitter can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X12+ Transmitter as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W			
	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.

Table of Contents

1 Introduction

Manual Purpose	1-1
Audience	1-1
System Description	1-1
Equipment Included	1-1
X12+ Front View	1-2
LeadForm Patient Cable	1-2
X12+ Transmitter in Carrying Pouch	1-3
X12+ Ambulatory Transmitter Part Numbers	1-4
Supplies Contact	1-4
Ambulatory X12+ Specifications	1-5

2 Operation

Read Instructions2	2-1
Battery Installation/Removal/Battery Door2	2-2
Furning the Ambulatory X12+ ON2	
Furning the Ambulatory X12+ OFF2	2-3
CD Display Battery Voltage Indicator2	2-3
Attaching the Patient Cable	2-4
Patient Hook-Up	2-4
Skin Preparation2	2-4
Positioning the Electrodes2	2-5
Jsing the Keypad2	2-6
Main Menu	2-6
Fop Level Menu Options2	2-7
Lead Check2	2-8
Checking Impedances	2-8
Displaying ECG Leads2	
Configuring the Ambulatory X12+ Transmitter2	
Setting the Transmission Channel Number2	!-11
Setting the Number of Patient Cable Leadwires2	!-11
Setting Language2	
Viewing Software Version Number2	<u>'-12</u>
Viewing Battery Voltage2	!-12
Starting a Patient Transmission Session2	
Sending (Optional) Call Signals2	<u>'-13</u>
Ending a Transmission Session2	:-13

3 Maintenance

Cleaning the Ambulatory X12+ Transmitter and Patient Cable	3-	1
Periodic Maintenance	3-	1
Disposal of Waste Material	3-	1

Appendix A Messages and Information

Table of Messages	.A-1
System Information Log	.A-2
Serial Number and Part Number Location	

Appendix **B** Channel Assignments

600MHzB-1	
2500MHzB-2	

Appendix C Translations

Table of TranslationsC-1

Glossary	G-1
Index	

Introduction

X12+ Overview

Manual Purpose

The X12+ User Manual explains how to operate the Ambulatory X12+ Transmitter. It shows how to

- Acquire and transmit 12-Lead ECG signals to a receiving device
- Setup device configurations

Audience

1

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.

Conventions

Keys, such as Enter, appear in bold Arial font.

Text on the LCD screen of the X12+ appears in regular Arial font.

System Description

The Mortara Instrument Ambulatory X12+ 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 X12+ 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 X12+ affords the patient complete freedom of movement. Unlimited range can also be obtained with addition of the Mortara Antenna Network Box(s).

The X12+ Transmitter uses a single AA alkaline battery.

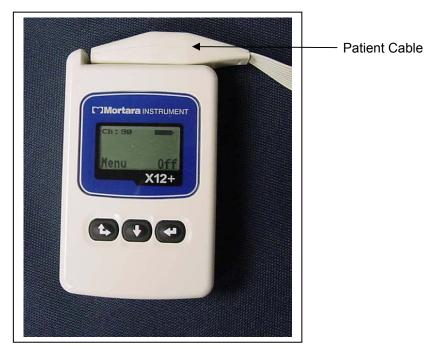
Equipment Included

The following equipment is necessary to use the Ambulatory X12+ Telemetry Module:

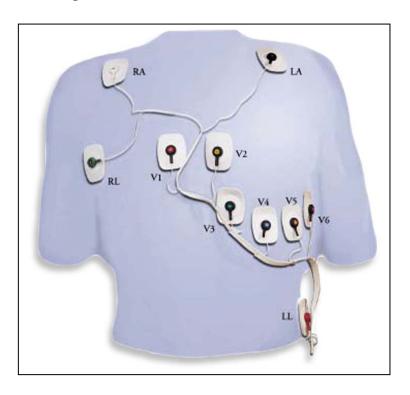
- Ambulatory X12+ (transmitter),
- One AA battery, 1.5V,
- Mortara Receiver Module with Antennas,
- Patient cable
- Antenna Network (optional)

X12+ Transmitter with Patient Cable

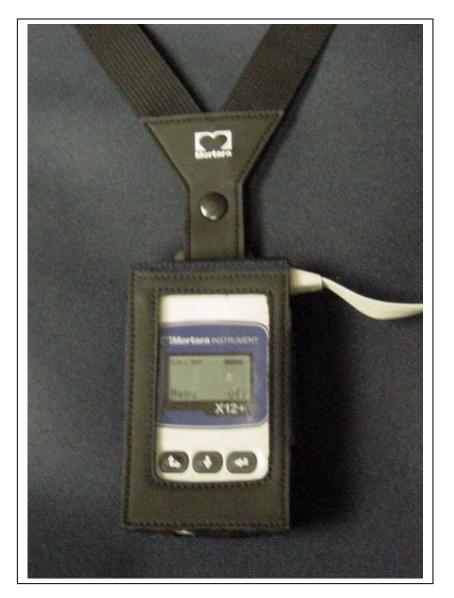
Front View, Figure 1-1



LeadForm Patient Cable, Figure 1-2



X12+ Transmitter in Carrying Pouch, Figure 1-3



Carrying Pouch with Neck Strap

	X12+ Transmitter
Description	Part Numbers
X12+ Transmitter	X12PLUS-XXX-XXXXX
X12+ Battery Door	8346-003-50
X12+ Carrying Pouch with Belt and Neck Strap	8485-020-50
10-wire LeadForm Patient Cable/ DomesticStandardLarge	9293-017-50 9293-026-50
 10-wire LeadForm Patient Cable/ International Standard Large 	9293-017-51 9293-026-51
X12+ User Manual / English	9515-164-50-ENG
X12+ Short Form Instruction Card / English	NEW
 Monitoring Hook-up Kit 10 Monitoring Electrodes 1 Abrasive Pad 1 4x4 Gauze wipe 1 Razor 2 Alcohol Prep Pads 	9294-009-50

Mortara Part Numbers/ X12+ Ambulatory Transmitter

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

	X12+ Ambulatory Transmitter
FEATURE	Specifications
INTRUMENT TYPE	12-Lead ECG Transmitter
INPUT CHANNELS	Continuous 12-lead signal acquisition and transmission
STANDARD LEADS TRANSMITTED	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6
FREQUENCY RANGE*	608.48 MHz to 631.52 MHz or 2400.96 MHz to 2482.56 MHz
SPECIAL FUNCTIONS	Lead Impedance Check, ECG Display, Lead Fail, Low Battery Notification, multi-purpose Call, 10- wire, 5-wire and 4-wire options
DEFIBRILLATOR PROTECTION	In compliance with AAMI standards and IEC 601-2-25
NUMBER OF CHANNELS	256, User Selectable
FUNCTION KEYS	Up/Right, Down and Enter keys for ON, menu navigation and CALL
DEVICE CLASSIFICATION	Type CF, battery-operated
WEIGHT	4 Ounces (125 g) without battery
DIMENSIONS	2.5 x 3.5 x .98 inches (64 x 91 x 25 mm)
BATTERY	1 AA Alkaline, 30 hour typical life

Mortara Specifications/ X12+ Ambulatory Transmitter

Notes: Manufacturer does not supply accessories for direct Cardiac Applications. *Operating frequency range is dependent on the X12+ part number. Operating range performance is 15 meters with no barriers.

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

- 1. This device may not cause harmful interference, and
- 2. This device must accept any interference received, including interference that may cause undesired operation.
- The X12+ (600) must be used solely on the premises of health care facilities (see Part 15, section 15.242a).
- A health care facility operating the X12+ (600) 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 X12+ (Part 15, section 15.242d,e).

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

FCC ID: HJR-X12-600-15 FCC ID: HJR-X12P-2500

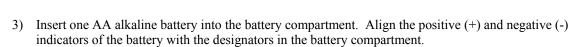
This device is defibrillator-protected in compliance with AAMI standards and IEC 601-2-25.

2-2

Battery Installation / Removal and Opening / Closing the Battery Door

The battery compartment is accessible via the battery door of the Ambulatory X12+ Transmitter.

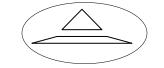
- 1) Position the X12+ Transmitter with its back facing you to open the battery door.
- 2) Press down on the battery door arrow symbol and slide the battery door out.



- 4) To close the battery door, place the battery door on the X12+ as shown above and slide the door in until it snaps into place.
- *Notes:* AA alkaline batteries are recommended. The typical life of one AA alkaline battery is 30 hours.







Turning the Ambulatory X12+ ON

The X12+ will power up as soon as a battery with a minimum of 1.0 Volts has been inserted into the battery compartment. If the X12+ was turned off after its last use, the user has two options to power the X12+ ON:

- 1) Remove and re-insert the AA alkaline battery, or
- 2) Press the Up/Right arrow key on the front of the X12+ Transmitter



The X12+ will power up and display the Main LCD Menu within three seconds.

Turning the Ambulatory X12+ OFF

When the Ambulatory X12+ is not in use, the user has two options to power the X12+ transmitter OFF:

- 1) Remove the battery, or
- 2) Press and hold the Enter key on the front of the X12+ Transmitter for a period of three seconds



- a) A prompt will appear in the LCD display
- b) Press the Up/Right arrow key to highlight YES; or skip this step if NO is desired
- c) Press the Enter key to select

LCD Display Battery Voltage Indicator

The X12+ Transmitter is powered with a single AA alkaline battery that requires a minimum of 1.0 Volts to operate.

When the battery contains sufficient voltage the X12+ LCD Main Menu will display a picture representing the current battery voltage in increments of 100%, 75%, 50% and 25%. If a battery with unknown voltage is inserted and the LCD menu does not appear, insert a new battery.



An option to display the actual battery voltage is also available in the Config menu and will be explained later in this chapter.

Note: In the event that the battery voltage is below 1.0 Volts, the X12+ transmitter will not power on. Insert a new AA alkaline battery to continue operation.

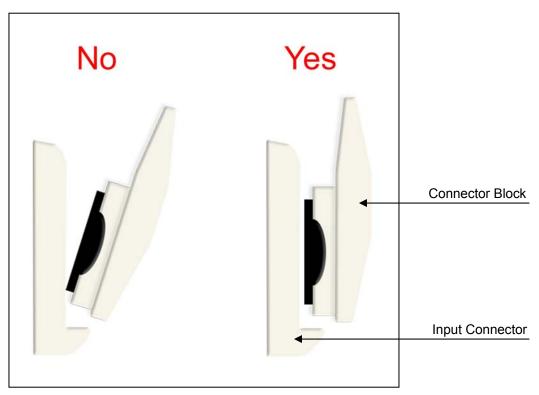
When the battery indicator shows a voltage of 25%, the battery should be discarded and a new battery should be inserted into the battery compartment.

Attaching the Patient Cable

The LeadForm Patient Cable consists of a connector block, main cable and leadwires connected to the main cable. Each leadwire terminates in a snap connector. The leadwires are positioned on the main cable to follow the contour of the torso.

Insert the connector block into the input connector on the top of the X12+ Transmitter.

Note: Be careful to insert the connector block parallel to the input connector of the X12+.



Patient Hook-Up

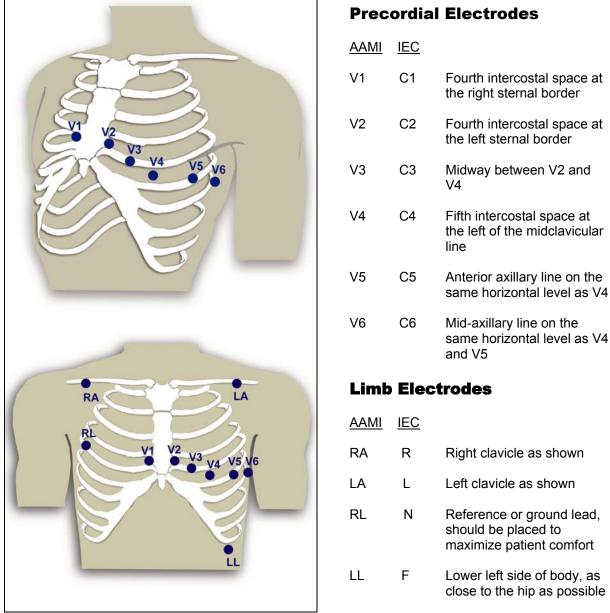
Skin Preparation

Skin preparation is important to perform before electrode attachment to help insure good signal quality when transmitting patient data. Poor skin-electrode contact may cause noise or artifact which can affect the analysis of the ECG data. Low amplitude signals may also be the result of poor skin-electrode contact.

To prepare the skin

- 1. Identify the electrode sites on the torso by referring to the next section on <u>Positioning the</u> <u>Electrodes</u>.
- 2. Remove any hair from the electrode sites using a razor.
- 3. Wipe oils from the electrode sites with an alcohol prep pad.
- 4. Remove any dead skin from the electrode sites with an abrasive pad. Two to three moderate rubs at each site should be sufficient.

Positioning the Electrodes



Lateral View, Precordial Electrode Placement (top)

Front View, Limb and Precordial Electrode Placement (bottom)

When the 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.

To connect the leadwires, begin with connecting the LL leadwire (Red – labeled LL) to the LL electrode. Connect the next leadwire on the cable (Fuchsia – labeled V6) to the V6 electrode. Continue connecting the snap connectors to the electrodes as positioned on the main cable.

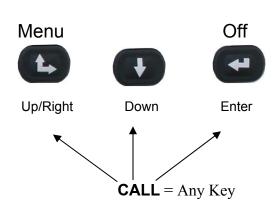
Note: QRS morphology may be slightly different from the standard 12-Lead ECG due to modification of limb electrode placement.

Using the Keypad

The keypad is located on the front, lower portion of the Ambulatory X12+ Transmitter. Three keys are available for navigating through the LCD Menu screens, for powering the X12+ ON/OFF and for sending calls during transmission.

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





Main Menu

The X12+ Transmitter Main LCD menu displays the following information.

- CH: XX = Transmission Channel
- BATTERY SYMBOL = 100%, 75%, 50% or 25% Battery Charge
- Menu = label over the Up/Right key for access to Menu Options
- Off = label over the Enter key to power the X12+ Off
- RL, RA, LL, RL, V1, V2, V3, V4, V5 and/or V6 = Leads in Fail
- CALL = a Call signal has been transmitted

To send a CALL signal, press any one of the three keypad keys. A CALL indicator will appear on the LCD display to notify the user that a call signal has been transmitted.

To turn the X12+ transmitter off, press and hold the **Enter** key for approximately three seconds. A menu will appear prompting the user to select YES or NO. If a selection is not made within three seconds the prompt menu will be replaced by the Main Menu.

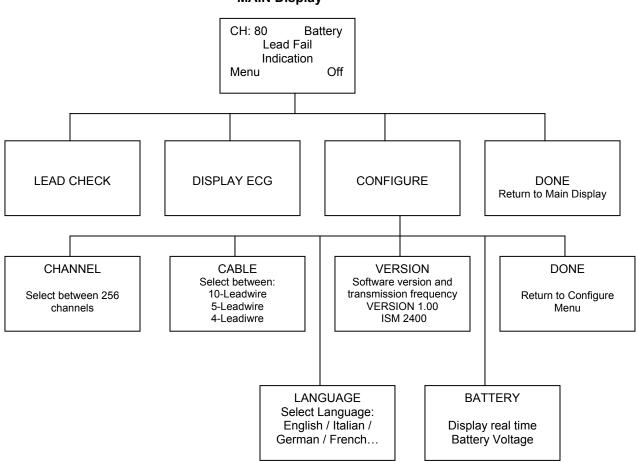
Top Level Menu Options

To select Menu options, press and hold the **Up/Right** arrow key for approximately three seconds. Use the **Up/Right** and **Down** arrow keys to scroll and the **Enter** key to select. The top level menu includes the following options.

- LEAD CHECK
- DISPLAY ECG
- CONFIGURE
- DONE

An operational flowchart of Menu options depicts the flow of functionality using the **Up/Right**, **Down** and **Enter** keys.

Operational Flow Chart



MAIN Display

Lead Check

The LEAD CHECK, DISPLAY ECG and CONFIGURE tasks are performed prior to starting a new patient. LEAD CHECK, DISPLAY ECG and DONE are typically selected prior to each new session.



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 patient session.

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.



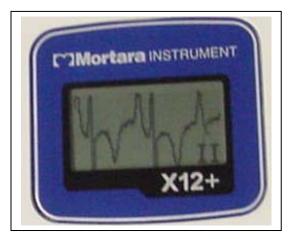
A full-bar graph (6 bars) means optimal high quality and good electrode contact. For good quality transmissions, the bars should be at least 4 bars high. A low-bar graph means poor quality and high electrode impedance. The skin preparation should be checked for improvement and, if necessary, the electrode(s) should be replaced.

Once acceptable impedance levels are verified, press any of the three keys to return to the Top Level Options 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 transmission session. Check the signal quality and lead amplitude for each lead.

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



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

After visual verification of all leads, press the **Enter** key to return to the Top Level Menu Options.

Use the **Down** or **Up/Right** keys to scroll to **Exit** and select the **Enter** key to return to the main menu.

Configuring the Ambulatory X12+ Transmitter

CONFIGURE is used to set the transmitter channel number, the number of patient cable lead wires and language defaults. This menu is also used to display the software version number and current battery voltage. These settings are typically set before the initial patient session on the X12+ and do not need to be set on a per patient basis.

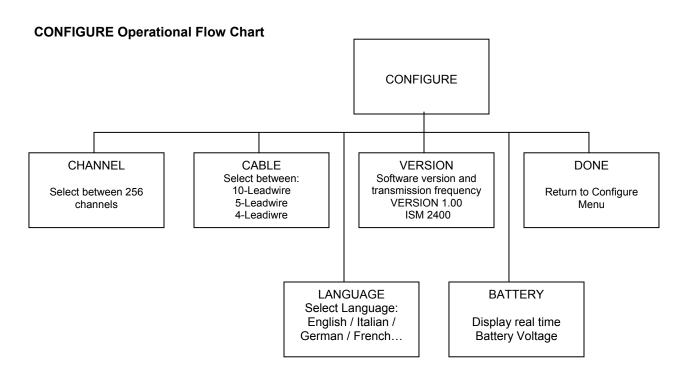
From the Main menu, scroll to CONFIGURE using the **Down** or **Up/Right** key. Press the **Enter** key to select this option.

The CONFIGURE menu includes the following options.

- CHANNEL
- CABLE
- LANGUAGE
- VERSION
- BATTERY
- DONE

Use the **Down** or **Up/Right** 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 Top Level Menu Options. Scroll to 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/Right**, **Down** and **Enter** keys.



Setting the Transmission Channel Number

The X12+ transmits the patient's cardiac signals to the electrocardiograph using a specific channel number. CHANNEL is used to enter the optimal transmission channel number before starting a patient session. The user may choose from any of 256 channels. If ECG signal loss occurs, the transmission channel can be changed.

From the Main menu, scroll to CHANNEL using the **Down** or **Up/Right** keys. Press the **Enter** key to select this menu option.



To enter the channel number, the cursor is moved to the right or left alphanumeric character field by pressing the **Up/Right** arrow key.

To move the cursor one letter or digit at a time, press the **Down** arrow key. When the cursor reaches the end of the characters, the cursor wraps to the beginning of the characters.

When finished, press the **Enter** key to Exit the Channel menu.

Note: When entering the Channel number, the Down arrow key is used to change the characters. The cursor cannot be moved in the Up direction.

Setting the Number of Patient Cable Leadwires

CABLE is used to set the number of leadwires for the patient cable.

From the CONFIGURE menu, scroll to CABLE using the **Down** or **Up/Right** keys. Press the **Enter** key to select this option. The CABLE menu includes the following options.

- 4-Leadwire
- 5-Leadwire
- 10-Leadwire

Use the **Down** or **Up/Right** key to scroll to the desired option and press the **Enter** key.

When finished, press the **Enter** key to Exit the Cable menu

Note: When a 4-wire or 5-wire cable is selected, only the limb leads (and a V label with the 5-wire cable) will appear in LEAD CHECK, DISPLAY ECG and lead fail messages.

Setting Language

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

From the CONFIGURE menu, scroll to LANGUAGE using the **Down** or **Up/Right** keys. Scroll through the language options using the **Down** or **Up/Right** keys. Press the **Enter** key to select the desired language.

When finished, press the Enter key to Exit the Language menu

Viewing Software Version Number

Version displays the current software version installed in the X12+ Transmitter.

From the CONFIGURE menu, scroll to VERSION using the **Down** or **Up/Right** keys. Press the **Enter** key to select VERSION and view the current software.

When finished, press the **Enter** key to Exit the VERSION menu.

Viewing Battery Voltage

BATTERY displays the voltage of the battery currently installed in the X12+ Transmitter.

From the CONFIGURE menu, scroll to BATTERY using the **Down** or **Up/Right** keys. Press the **Enter** key to select BATTERY and view the current battery voltage.

When finished, press the **Enter** key to Exit the **BATTERY** menu.

Starting a Patient Transmission Session

- 1. Hook-up the patient.
- 2. Ensure that there is an AA alkaline battery in the battery compartment (see note below).
- 3. Press the **Up/Right** arrow key to turn on the X12+ Transmitter (if not already powered ON by insertion of the battery).
- 4. Verify the quality of the hook-up by checking the electrode to skin impedances. Press the Up/Right key for approximately three seconds to open the Top Level Menu options. Press the Enter key to select LEAD CHECK. When finished, press any key to exit the LEAD CHECK menu.
- 5. Verify the amplitude and signal quality by displaying each of the ECG leads. Use the Up/Right and Down keys to scroll through the top level menu options until DISPLAY ECG is displayed. Press the Enter key to select DISPLAY ECG. Press the Up/Right key to scroll through all leads for quality verification and then select DONE using the Enter key to return to the top level menu options.
- 6. Select the **Up/Right** and **Down** keys to scroll through the Top Level Menu until DONE is displayed. Press the **Enter** key to select DONE and return to the Main Menu.

Note: In the event that the battery voltage is below 1.0 Volts, the X12+ transmitter will not power on. Insert a new AA Alkaline battery to continue operation.

During normal operation, the following information is displayed in the LCD continuously. The Ch: xx (Channel Number) and (battery indicator) display the transmission channel and current battery power range.



If the battery is removed during a transmission session, the X12+ stops transmitting. A battery must be inserted to continue operation.

Notes: In the event of a lead fail condition occurring during operation, the appropriate lead fail indicator(s) is displayed in the center of the LCD display.

Refer to <u>Appendix A Messages and Information for information on lead fail messages</u>.

Sending (Optional) Call Signals

During the patient data transmission session, the patient may be instructed to transmit call signals from the X12+ to a receiving device for monitoring purposes.

To send a call signal, press any one of the three keys on the X12+. The CALL message is displayed in the Main Menu on the LCD display to inform the user that a call was sent.

Ending a Transmission Session

At the end of the patient session, the X12+ Transmitter can be turned off by:

- 1. Opening the battery door and removing the battery, or
- 2. Pressing and holding the Enter key for approximately three seconds
 - a. Select the **Up/Right** arrow key to highlight YES
 - b. Press the Enter key to Select YES

3 Maintenance

Cleaning the Ambulatory X12+ and Patient Cable

Turn off the Ambulatory X12+, and clean the outside with a damp cloth. Dry the equipment completely before use.

WARNING: The Ambulatory X12+ is not water-proof. Prevent liquid from penetrating, and avoid submerging the Ambulatory X12+ in any liquid. Sterilization is not allowed.

Periodic Maintenance

Check the Ambulatory X12+ and patient cable everyday to be sure they are not damaged or broken.

Disposal of Waste Materials

The Ambulatory X12+ needs one alkaline battery and disposable monitoring electrodes. Their disposal must be in accordance with the following procedures:

Battery: chemical waste Electrodes: normal waste

Appendix A Messages and Information

The following table describes messages that are displayed on the X12+ during patient hook-up and Transmission.

Message	Solution
	Battery power is low. Replace existing battery with a fully charged battery.
	Battery power is at 50%.
	Battery power is at 75%.
	Battery power is at 100% (fully charged).
CALL	A Call signal has been transmitted.
CH:XX	The transmission channel that has been set for this unit.
Menu	Label over the Up/Right arrow key that indicates access to Menu options
Off	Label over the Enter key that indicates powering the unit off.
'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.
A combination of 'RA/…/LL'	More than one limb lead fail or all leads fail. Check the lead wires and electrodes.
'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.
A combination of 'V1//V6'	More than one chest lead fail. Check the lead wires and electrodes.

Table of Messages

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 battery, in the battery compartment on the backside of the unit similar to the one pictured below.



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

Notes:

Appendix

B Channel Assignments

X12+-600 Channel Assignments (FCC Part 15 Compliant) Includes reference to UHF TV channel occupying the same frequency range.

·····p	<u>TV37</u>		<u>TV38</u>		<u>TV39</u>		<u>TV40</u>
<u>CH#</u>	MHz	<u>CH#</u>	MHz	<u>CH#</u>	MHz	<u>CH#</u>	MHz
00	608.48	40	614.48	80	620.48	C0	626.48
01 02	608.56 608.64	41 42	614.56 614.64	81 82	620.56 620.64	C1 C2	626.56 626.64
03	608.72	43	614.72	83	620.72	C3	626.72
04	608.8	44	614.8	84	620.8	C4	626.8
05	608.88	45	614.88	85	620.88	C5	626.88
06	608.96	46	614.96	86	620.96	C6	626.96
07	609.04	47	615.04	87	621.04	C7	627.04
08 09	609.12 609.2	48 49	615.12 615.2	88 89	621.12 621.2	C8 C9	627.12 627.2
03 0A	609.28	40 4A	615.28	8A	621.28	CĂ	627.28
0B	609.36	4B	615.36	8B	621.36	CB	627.36
0C	609.44	4C	615.44	8C	621.44	CC	627.44
0D	609.52	4D	615.52	8D	621.52	CD	627.52
0E 0F	609.6 609.68	4E 4F	615.6 615.68	8E 8F	621.6 621.68	CE CF	627.6 627.68
10	609.76	50	615.76	90	621.76	D0	627.76
11	609.84	51	615.84	91	621.84	D1	627.84
12	609.92	52	615.92	92	621.92	D2	627.92
13	610	53	616	93	622	D3	628
14	610.08	54	616.08	94	622.08	D4	628.08
15 16	610.16 610.24	55 56	616.16 616.24	95 96	622.16 622.24	D5 D6	628.16 628.24
17	610.32	57	616.32	90	622.32	D0 D7	628.32
18	610.4	58	616.4	98	622.4	D8	628.4
19	610.48	59	616.48	99	622.48	D9	628.48
1A	610.56	5A	616.56	9A	622.56	DA	628.56
1B 1C	610.64 610.72	5B 5C	616.64 616.72	9B 9C	622.64 622.72	DB DC	628.64 628.72
10 1D	610.72	5D	616.8	9C 9D	622.8	DD	628.8
1E	610.88	5E	616.88	9E	622.88	DE	628.88
1F	610.96	5F	616.96	9F	622.96	DF	628.96
20	611.04	60	617.04	A0	623.04	E0	629.04
21	611.12	61	617.12	A1	623.12	E1	629.12
22 23	611.2 611.28	62 63	617.2 617.28	A2 A3	623.2 623.28	E2 E3	629.2 629.28
24	611.36	64	617.36	A4	623.36	E4	629.36
25	611.44	65	617.44	A5	623.44	E5	629.44
26	611.52	66	617.52	A6	623.52	E6	629.52
27 28	611.6 611.68	67 68	617.6 617.68	A7 A8	623.6 623.68	E7 E8	629.6 629.68
28 29	611.76	69	617.76	A0 A9	623.76	E9	629.08 629.76
2A	611.84	6A	617.84	AA	623.84	EĂ	629.84
2B	611.92	6B	617.92	AB	623.92	EB	629.92
2C	612	6C	618	AC	624	EC	630
2D 2E	612.08 612.16	6D 6E	618.08 618.16	AD AE	624.08 624.16	ED EE	630.08 630.16
2E 2F	612.24	6F	618.24	AF	624.24	EF	630.24
30	612.32	70	618.32	B0	624.32	F0	630.32
31	612.4	71	618.4	B1	624.4	F1	630.4
32	612.48	72	618.48	B2	624.48	F2	630.48
33	612.56	73	618.56	B3	624.56	F3	630.56
34 35	612.64 612.72	74 75	618.64 618.72	B4 B5	624.64 624.72	F4 F5	630.64 630.72
36	612.72	75	618.8	B5 B6	624.8	F6	630.72
37	612.88	77	618.88	B7	624.88	F7	630.88
38	612.96	78	618.96	B8	624.96	F8	630.96
39	613.04	79	619.04	B9	625.04	F9	631.04
3A 3B	613.12 613.2	7A 7B	619.12 619.2	BA BB	625.12 625.2	FA FB	631.12 631.2
3C	613.28	7C	619.28	BB	625.28	FC	631.28
3D	613.36	7D	619.36	BD	625.36	FD	631.36
3E	613.44	7E	619.44	BE	625.44	FE	631.44
3F	613.52	7F	619.52	BF	625.52	FF	631.52

X12+-2500 Channel Assignments

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	35	2421.12		2441.0	I	DF	2402.00	l	ГĒ	2402.30

Appendix C Translations

Table of Translations

English	Italian ITALIANO	Spanish ESPAÑOL	German DEUTSCH	Dutch HOLLAND
CH:	CH:	C:	KAN:	CH:
Menu	Menu	Menu	Menu	Menu
CALL	CHIAMA	LLAMAR	RUF	OPROEP
Off	Off	Off	Aus	Uit
POWER OFF?	SPEGNERE?	¿APAGAR?	AUSSCHALTEN?	SPANNING UIT?
NO	NO	NO	NEIN	NEE
YES	Sľ	SI	JA	JA
LEAD CHECK	DERIVAZIONI	TEST ELECT	ABL.TEST	AFL. TEST
DISPLAY ECG	MOSTRA ECG	MOSTRAR ECG	EKG-ANZEIGE	TOON ECG
CONFIGURE	CONFIGURA	CONFIGURAR	EINSTELLUNG	CONFIGUREER
CHANNEL	CANALE	CANAL	KANAL	KANAAL
CABLE	CAVO	CABLE	KABEL	KABEL
4-Leadwire	4 Elettrodi	4 Electrodos	4-Elektroden	4 Electroden
5-Leadwire	5 Elettrodi	5 Electrodos	5-Elektroden	5 Electroden
10-Leadwire	10 Elettrodi	10 Electrodos	10-Elektroden	10 Electroden
VERSION	VERSIONE	VERSION	VERSION	VERSIE
BATTERY	BATTERIA	BATERIA	BATTERIE	BATTERIJ
Battery Voltage	Livello Batteria	Voltaje Bateria	Batterie-Spannung	Batterij spanning
DONE	FINE	ок	FERTIG	KLAAR
LANGUAGE	LINGUA	IDIOMA	SPRACHE	TAAL

English	French FRANÇAIS	Polish POLSKI	Portuguese PORTUGUES
CH:	CH:	KAN:	CANAL:
Menu	Menu	Menu	Menu
CALL	APPEL	Dzwonek	Chamar
Off	Off	Wyłącz	Off
POWER OFF?	ETEINDRE?	Wyłączyć zasilanie?	Desligar?
NO	NON	NIE	NÃO
YES	OUI	ТАК	SIM
LEAD CHECK	DÉRIVATIONS	ELEKTRODY	DERIVAÇÕES
DISPLAY ECG	AFFICH. ECG	EKG	MOSTRAR ECG
CONFIGURE	CONFIGURER	USTAWIENIA	CONFIGURAR
CHANNEL	CANAL	KANAŁ	CANAL
CABLE	CÀBLE	KABEL	САВО
4-Leadwire	4 Électrodes	4-ŻYŁOWY	4-eléctrodos
5-Leadwire	5 Électrodes	5-ŻYŁOWY	5-eléctrodos
10-Leadwire	10 Électrodes	10-ŻYŁOWY	10-eléctrodos
VERSION	VERSION	WERSJA	VERSÃO
BATTERY	BATTERIE	BATERIA	BATERIA
Battery Voltage	Capacité Batt.	Napięcie baterii	Voltagem Bateria
DONE	FIN	GOTOWE	ок
LANGUAGE	LANGUAGE	JĘZYK	IDIOMA

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.

Index

Α

Ambulatory X12+ Transmitter 1-2 Ambulatory X12+ Specifications 1-5 Attaching the Patient Cable 2-4 Audience 1-1

В

Back View 2-2 Battery Installation 2-2

С

Call 2-6, 2-13 Channel Settings 2-6, 2-9, 2-11 Configuring the X12+ 2-9

D

Displaying ECG 2-9 Done Menu 2-7, 2-9, 2-11, 2-12

Е

Ending a Transmission Session 2-13

I

Introduction 1-1

Κ

Keypad 2-6

L

Leads 2-5 Lead Check 2-8

Μ

Maintenance 3-1 Manual Purpose 1-1 Menu 2-6, 2-7, 2-10

0

Operation 2-1

Ρ

Patient Hook-Up 2-4 Pouch 1-3 Positioning Electrodes 2-5

S

Specifications 1-5 Starting a Patient Transmission Session 2-12 Supplies 1-4 System Description 1-1

т

Turning the X12+ ON 2-3 Turning the X12+ OFF 2-3, 2-13