Mortara

Ref 9515-XXX-XX-ENG Rev A1

WIRELESS ACQUISITION MODULE

WAM™

USER MANUAL

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

CE 0459

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

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Notices

Manufacturer's Responsibility

Mortara Instrument, Inc. is responsible for the effects on safety and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Mortara Instrument, Inc.
- The device is used in accordance with the instructions for use.

Responsibility of the Customer

The user of this device is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

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

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 ñMortaraò) hereby warrants that Mortara products (hereinafter referred to as ñProduct/sò) shall be free from defects in material and workmanship under normal use, service, and maintenance for the warranty period of such Product/s from Mortara or an authorized distributor or representative of Mortara. The warranty period is defined as twelve (12) months for the patient module following the date of shipment from Mortara. Normal use, service, and maintenance mean operation and maintenance in accordance with appropriate instructions and/or information guides. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

a) Freight damage;

b) Parts and/or accessories of the Product/s not obtained from or approved by Mortara;

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

d) Accident; a disaster affecting the Product/s;

e) Alterations and/or modifications to the Product/s not authorized by Mortara;

f) Other events outside of Mortaraôs reasonable control or not arising under normal operating conditions.

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

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

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User Safety Information

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

 **Caution:** Means there is the possibility of damage to the device.

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

 **Warning(s)**

- This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.

- Device transmits data reflecting a patientôs physiological condition to a properly equipped receiving device that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patientôs diagnosis.

- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical application, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device.

- 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 60601-1, IEC 60601-1 and IEC 60601-2-25. Only use parts and accessories supplied with the device and available through Mortara Instrument, Inc.

- Patient cables intended for use with the device include series resistance (7 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.

- Conductive parts of the patient cable, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrodes, should not come into contact with other conductive parts including earth ground.

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

- To avoid the possibility of serious injury or death during patient defibrillation, do not come 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.

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

- This device was designed to use the electrodes specified in this manual. Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or

other adverse reactions. Electrodes are intended for short term use and should be removed from the patient promptly following testing.

- FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

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

- The device has not been designed for use with high-frequency (HF) surgical equipment and does not provide a protective means against hazards to the patient.

- The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillators and ultrasound machines.

- There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.

- Operations may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.

- The battery operated device transmits data reflecting a patient's physiological condition to a receiving device. During operation failure, data transmission and LCD information will cease to occur. In mission critical conditions, it is advisable to have a backup device available.

- Use only recommended battery cells. Use of other cells may present a risk of fire or explosion.

Caution(s)

- To prevent possible damage to the device, do not use sharp or hard objects to depress buttons, only use fingertips.

- Do not attempt to clean the device or patient cables by submersing into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device. Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas. Refer to section 3 for proper cleaning and disinfection instructions.

- The device and lead wires should be cleaned between each use. Inspect connections for damage or excessive wear prior to each use. Replace lead wires if damage or excessive wear is noted.

- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Lead wires should be stored after forming them into a loose loop.

- The device will only work with receiving devices that are equipped with the appropriate option.

- No user-serviceable parts are inside. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.

- This device is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.

- The following equipment may cause interference with the RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.

- When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.

- AA batteries are known to leak their contents when stored in unused equipment. Remove battery from device when not used for an extended period of time.

- To prevent possible damage to the device 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:	500 hPa to 1060 hPa

- This device is intended to be used in a hospital or doctorôs office setting, and should be used and stored according to the environmental conditions specified below:

Ambient Temperature Range:	0°C to 45°C (32°F to 113°F)
Relative Humidity Range:	5% to 95% (non-condensing)
Atmosphere Pressure:	500 hPa to 1060 hPa

FCC Compliance Statement

In the United States use of this device is regulated by the Federal Communications Commission (FCC). The device with its antenna complies with FCCôs RF exposure limits for general population/uncontrolled exposure.

FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the userôs authority to operate the device.

WAM FCC ID: HJR-WAM2500

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.

Industry Canada Compliance Statement

These devices comply with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

1. This device may not cause interference, and

2. This device must accept any interference, including interference that may cause undesired operation of the device.

WAM IC: 3758B-WAM2500

The term **"IC:"** before the certification/registration number only signifies that the Industry Canada technical specifications were met.

Note(s)

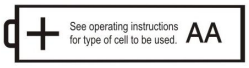
- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- If an electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, display will indicate a lead fault for the lead(s) where the condition is present.
- For additional instructions and warnings, refer to the user manual of the receiving device.
- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
  - Class I equipment or internally powered
  - Type CF (ECG) defibrillation-proof applied parts
  - IPX1 with regards to the harmful ingress of water
  - Equipment not suitable for use in the presence of a flammable anesthetic mixture
  - Continuous operation
- The device will automatically start flashing LEDôs if the batteries have been discharged below 1.0 volts.
- The device will automatically turn off (LEDôs off) if the battery has been severely discharged.

The device is UL classified:

Medical Equipment
WITH RESPECT TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY, IN ACCORDANCE WITH UL 60601-1, CAN/CSA C22.2 No. 601.1, IEC60601-1 AND IEC60601-2-25.

Equipment Symbols

Symbol Delineation

	Attention, consult accompanying documents
	Defibrillator-proof, type CF applied part
	Acquire 12 Lead ECG
	Acquire Rhythm Print
	On / Off button
	Battery with notification: See operating instructions for type of cell to be used
	Indicates compliance to applicable EEC directives
	Do not dispose as unsorted municipal waste. Per EC Directive 2002/96, requires separate handling for waste disposal according to national requirements
IPX1	Rated IPX1 with regards to the harmful ingress of water

General Care

Precautions

- Turn off the device before inspecting or cleaning.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces.

Inspection

Inspect your equipment daily prior to operation. If you notice anything that requires repair, contact an authorized service person to make the repairs.

- Verify that all cables and connectors are securely seated.
- Check the case for any visible damage.
- Inspect cables and connectors for any visible damage.
- Inspect buttons and controls for proper function and appearance.

Cleaning and Disinfection

Refer to section 3 for proper cleaning and disinfection procedures.

Sterilization

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

Cautions

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

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the device.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The device should not be used adjacent to, or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See Table X-4 for recommended separation distances between the radio equipment and the device.

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

Description	Part Number
LEAD SET WAM 10 WIRE BANANA AHA	9293-046-50
LEAD SET WAM 10 WIRE BANANA IEC	9293-046-51
REPLACEMENT LEAD SET WAM LIMBS BANANA AHA	9293-046-52
REPLACEMENT LEAD SET WAM LIMBS BANANA IEC	9293-046-53
REPLACEMENT LEAD SET WAM V1-V3 BANANA AHA	9293-046-54
REPLACEMENT LEAD SET WAM C1-C3 BANANA IEC	9293-046-55
REPLACEMENT LEAD SET WAM V4-V6 BANANA AHA	9293-046-56
REPLACEMENT LEAD SET WAM C4-C6 BANANA IEC	9293-046-57
LEAD SET WAM 10 WIRE CLIPS AHA	9293-047-50
LEAD SET WAM 10 WIRE CLIPS IEC	9293-047-51
REPLACEMENT LEAD SET WAM LIMBS CLIPS AHA	9293-047-52
REPLACEMENT LEAD SET WAM LIMBS CLIPS IEC	9293-047-53
REPLACEMENT LEAD SET WAM V1-V3 CLIPS AHA	9293-047-54
REPLACEMENT LEAD SET WAM C1-C3 CLIPS IEC	9293-047-55
REPLACEMENT LEAD SET WAM V4-V6 CLIPS AHA	9293-047-56
REPLACEMENT LEAD SET WAM C4-C6 CLIPS IEC	9293-047-57
COMBINER REPLACEMENT WAM LEADS 5 POSITION	9293-046-01

BATTERY CAP ASSEMBLY WAM	8356-008-51

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

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

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

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

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

Emissions Test	Compliance	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 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 AC Mains voltage prior to application of the test level.*

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

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

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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

Table X-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Equipment

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

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter (m)**	
	150 KHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4.0 m	7.0 m
100	12.0 m	23.0 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: *At 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.*

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