Mortara

REF 9515-185-50-ENG Rev C1

XScribe

STRESS EXERCISE TESTING SYSTEM

USER MANUAL

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 by persons authorized by Mortara Instrument, Inc.

• The device is used in accordance with the instructions for use.

• The electrical installation of the relevant room complies with the requirements of appropriate regulations.

Responsibility of the Customer

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

Equipment Identification

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

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WARRANTY INFORMATION

Your Mortara Warranty

MORTARA INSTRUMENT, INC. (hereafter referred to as "Mortara") warrants that components within Mortara products (hereafter referred to as "Product/s") will be free from defects in workmanship and materials for the number of years specified on documentation accompanying the product, or previously agreed to by the purchaser and Mortara, or if not otherwise noted, for a period of twelve (12) months from the date of shipment.

Consumable, disposable or single use products such as, but not limited to, PAPER or ELECTRODES are warranted to be free from defects in workmanship and materials for a period of 90 days from the date of shipment or the date of first use, whichever is sooner.

Reusable product such as, but not limited to, BATTERIES, BLOOD PRESSURE CUFFS, BLOOD PRESSURE HOSES, TRANSDUCER CABLES, Y-CABLES, PATIENT CABLES, LEAD WIRES, MAGNETIC STORAGE MEDIUMS, CARRY CASES or MOUNTS, are warranted to be free from defects in workmanship and materials for a period of 90 days. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

a) Freight damage;

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

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

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

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

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

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

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USER SAFETY INFORMATION

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

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

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

⚠️ **Warning(s)**

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

- The various manufacturers of accessories provide separate user manuals and/or instructions (e.g., monitor, laser printer, X12+, WAM, AM12, patient cables, electrodes). Read these instructions well and refer to them for specific functions. It is recommended to keep all instructions together. Refer to these instructions for a list of approved accessories. When in doubt, contact Mortara Instrument.

- Device (stress test system) captures and presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.

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

- To ensure that electrical safety is maintained during operation from AC (~) power, the device must be plugged into a hospital-grade outlet.

- The device is supplied with a power isolation transformer that must be used to maintain designed operator and patient isolation from power source. The power isolation transformer must be plugged into a hospital-grade outlet.

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

- All signal input and output (I/O) connectors are intended for connection of only those devices complying with IEC 60601-1, or other IEC standards (e.g., IEC 60950), as appropriate to the device. Connecting additional devices to the device may increase chassis and/or patient leakage currents. To maintain operator and patient safety, consideration should be given to the requirements of IEC 60601-1-1, and leakage currents should be measured to confirm no electric shock hazard exists.

- Patient cables intended for use with the device include series resistance (9 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.

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

- The personal computer and all peripheral equipment used should be approved to the appropriate safety standard for nonmedical electrical equipment per IEC 60950, or its national variants.

- If there is a requirement for the personal computer or any peripheral equipment connected to it, including exercise equipment like an ergometer or treadmill to be situated within the patient environment it is the responsibility of the user to ensure the system provides a level of safety that ensures compliance with IEC 60601-1. Non-medical equipment should be powered through a medical grade isolation transformer of sufficient capacity, and a connection to a data network should be made through a medical grade separation device.

- 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.

- 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.

- To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.

- 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.

- When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.

- To maintain designed operator and patient safety when the optional network connection is being used, the network cable must be connected to the device through the Ethernet isolator module provided.

- To maintain designed operator and patient safety, the M12xxx-USB module, TTL-trigger USB module, and conductive portions of connected antennas and cables must be positioned such that they are inaccessible during normal operation.

- An additional Multiple Plug Socket Outlet (MPSO) or extension cord shall not be connected to the system.

- Do not connect any items which are not specified as part of the system.

- To avoid risk of improper electrical isolation the Tango SpO2 probe must only be connected to the proper SpO2 extension patient cable or port on the SunTech Tango blood pressure monitor.

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

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

- The WAM low-battery warning function is designed for alkaline battery cells only. Use of other cells may result in failure of the low battery warning possibly resulting in a malfunction of the device.

⚠ Caution(s)

- Do not use the device as a method for loading or operating commercially available software. Doing so might affect the performance of the device.

- 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. Wipe the exterior surfaces with a warm water and mild detergent solution and then dry with a clean cloth. 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.

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

- Windows compatibility, updates and anti-virus policy: The XScribe software has been fully tested with Windows 7 Professional Service Pack 1. The Modality Manager software has also been tested with Windows Server 2008 R2 Service Pack 1. Although it is unlikely that Windows updates and security patches affect XScribe functionality, Mortara recommends turning automatic Windows update off, and periodically running it manually. A functional test should be executed after update, which includes conducting an exam, as well as importing an order and exporting results, if activated. Compatibility of XScribe with major corporate anti-virus software packages has been verified. Mortara recommends excluding the XScribe database folder (normally C:\ProgramData\MiPgSqlData on a stand-alone system or the server) from the folders to be scanned. In addition, anti-virus patch updates and system scans should be scheduled for time periods when the system is not actively in use or performed manually.

- Exams that are saved to the local or server database on the hard drive will cause the device to fill over a period of time. These exams must be removed from the database by deleting or archiving prior to causing the device to cease to operate. Periodic checks of the device's capacity are recommended; a safe minimum capacity is 3 GB. See Section 8 "Exam Search" for ways to select exams for deletion or archiving.

- The XScribe application will display a warning prompting the user to delete exams when the database reaches a threshold at 3.2 GB of available space. Each stress exam is approximately 40 MB in size and only 30 more exams can be started. When the available storage is at 2 GB, no new stress exams can be started.

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

- No user-serviceable parts are inside the WAM. 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 WAM 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 WAM 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 WAM when not used for an extended period of time.

- Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the WAM or AM12 label.

FCC Compliance Statement for the WAM

In the United States use of this device is regulated by the Federal Communications Commission (FCC). The WAM with its antenna complies with FCC's 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 user's authority to operate the device.

>   WAM FCC ID: HJR-WAM2500
>   UTK FCC ID: HJR-UTK2500

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.

Note(s)

- 8-hour timeout expiration is automatically controlled by the system. Each operation that occurs (e.g. Exam Search, Patient Search, editing exams, starting an exam, etc.) will reset the timeout start time. When there is no interaction with the system for the timeout duration, the user is prompted to enter login information.

- When the server is unavailable in a distributed configuration, the client workstation will notify the user with a prompt to proceed in Offline Mode or cancel. Scheduled orders are not available. An exam can be conducted with manually entered demographics and will be stored locally. When the server comes available, the user is prompted with a list of unsent exams and a selection to send exams to the modality manager database.

- Patient movements may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.

- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.

- 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.

- If electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, display will indicate a lead fault for the lead(s) where the condition is present.

- As defined by IEC 60601-1 the device is classified as follows:
  - Class I equipment
  - Type CF, defibrillation-proof applied parts (ECG inputs)
  - Tango BP monitor type BF, defibrillation-proof applied parts
  - Ordinary equipment
  - Equipment not suitable for use in the presence of a flammable anesthetic mixture
  - Continuous operation

  NOTE: From a safety perspective, per IEC 60601-1 and derivative standards/norms, this unit is declared to be "Class I" and uses a three-prong inlet to ensure an earth connection is made along with mains.

- 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:	-20° C to 65° C (-4° F to 149° F)
Relative humidity:	10% to 95%, non-condensing
Atmospheric pressure:	500 hPa to 1060 hPa

- Allow the device to stabilize within its intended operating environment for a minimum of two hours prior to use. Refer to the computer and peripheral equipment user manuals for allowable environmental conditions. The allowable environmental conditions for the X12+, WAM, and AM12 acquisition module are as follows:

Ambient temperature:	10° C to 40° C (50° F to 104° F)
Relative humidity:	10% to 95%, non-condensing
Atmospheric pressure:	500 hPa to 1060 hPa

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

- In the event of absent waveform presentation on the display while using the AM12, this may be due to an improper auto-calibration. Disconnect and then reconnect the AM12 cable from the USB port, or power cycle the XScribe system to re-calibrate.

- The display of absent waveform while using the WAM wireless acquisition module could be due to the WAM being turned off or having no battery, or the WAM being out of range or experiencing a calibration error. Ensure the WAM is paired correctly and is within recommended proximity of the UTK receiver, and/or power cycle the WAM to re-calibrate. **RF Synch Fail** message will also be displayed.

- A square wave on the display and rhythm printout could be due to the WAM, the AM12, or lead wires not being connected to the patient.

- Proper functioning backup items such as a spare patient cable, front-end device, display monitor, and other equipment are recommended on hand to prevent delayed treatment due to an inoperable device.

- The WAM must be paired to the XScribe system before operation.

- If the WAM battery cover is opened during transmission, the device will stop transmitting. The battery must be reinserted and the cover must be applied to resume operation.

- The WAM will automatically turn off (LEDs off) if the battery has been severely discharged.

- The WAM will automatically power off after the exam has ended.

- The WAM and AM12 Rhythm Print and 12-Lead ECG buttons are non- functional.

- When both WAM and AM12 are present, only the UTK or the AM12 may be connected to the XScribe system during use.

- The WAM is UL classified:

WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
UL2601-1, IEC60601-1, CAN/CSA CC22.2 No. 601.1, IEC60601-2-25,

EQUIPMENT SYMBOLS

Symbol Delineation

Attention, consult accompanying documents

Alternating current

Protective earth

Fuse

Defibrillator-proof type CF applied part

Input

Green light illuminates when power is ON

Green light illuminates when paper is out or an error condition is detected

Advances paper to the next paper perforation and will reset a paper error condition. When depressed for approximately 7 seconds, will reset the device

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

Indicates compliance to applicable European Union directives

NOTE: Refer to the manual(s) accompanying the device that pertain to the computer hardware for additional definitions of symbols that may be present.

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 cords and connectors are securely seated.
- Check the case and chassis for any visible damage.
- Inspect cords and connectors for any visible damage.
- Inspect keys and controls for proper function and appearance.

Cleaning Exterior Surfaces and Patient Cables

1. Remove cables and lead wires from device before cleaning.
2. For general cleaning of cables and lead wires use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry.
3. For disinfecting the cables and lead wires, wipe exterior with a soft, lint-free cloth using a solution of Sodium Hypochlorite (10% household bleach and water solution): minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants.
4. Use caution with excess liquid as contact with metal parts may cause corrosion.
5. Do not immerse cable ends or lead wires; immersion can cause metal corrosion.
6. Do not use excessive drying techniques such as forced heat.

⚠ *WARNING: Do not attempt to clean/disinfect the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning. Never expose cables to strong ultra-violet radiation.*

Cleaning the Device

Disconnect the power source. Clean the exterior surface of the device with a damp, soft, lint-free cloth using a solution of mild detergent diluted in water. After washing, thoroughly dry off the device with a clean, soft cloth or paper towel.

The device carry case can be surface cleaned with a damp cloth or a disinfectant wipe or spray. The carry case may also be machine or hand washed with detergent and air dried. Do not machine dry the carry case. Cosmetic changes may occur during washing. Inspect carry cases for structural damage after each washing cycle and replace when necessary.

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 system 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 (and optional thermal writer) 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 the appropriate table for recommended separation distances between the radio equipment and the device.

The use of accessories, transducers and cables other than those specified by Mortara Instrument may result in increased emissions or decreased immunity of the system.

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 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic 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	Complies	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

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	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery
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.

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
			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**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = \left[\dfrac{3.5}{3Vrms}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \left[\dfrac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\dfrac{7}{3V/m}\right]\sqrt{P}$ 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.

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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MAINTENANCE AND TROUBLESHOOTING APPENDIX A

PROTOCOLS APPENDIX B

TTL/ANALOG OUTPUT APPENDIX C

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Z200+ THERMAL PRINTER AND SUPPLIES APPENDIX E

SUNTECH TANGO+ AND TANGO M2 INTERFACE APPENDIX F

INTRODUCTION

Manual Purpose

This manual is intended to provide the user with information about:
- Using the Schedule/Orders icon. (Section 2)
- XScribe™ stress exercise system setup and installation. (Section 3)
- Using the XScribe system. (Section 4)
- Patient preparation and conducting a stress test. (Section 5)
- Configuring the XScribe. (Section 6)
- Using Worklist. (Section 7)
- Using Exam Search. (Section 8)
- Using Patient Search. (Section 9)
- Final Reports. (Section 10)
- Maintenance and troubleshooting. (Appendix A)
- Protocols. (Appendix B)
- TTL and analog output. (Appendix C)
- Treadmill/ergometer hookup. (Appendix D)
- Configuring and using the Z200+ thermal printer. (Appendix E)
- Configuring the SunTech Tango+ monitor interface (Appendix F)

   NOTE: This manual may contain screen shots. Screen shots are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording.

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.

Intended Use

The device is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data, and creates summary tables, trends, and a final report regarding a variety of cardiac data indices. The cardiac data provided by XScribe is reviewed, confirmed, and used by trained medical personnel to assist in the diagnosis of the electrocardiographic data reflecting the patient's physiological condition during stress exercise testing.

Indications for Use

- The device is indicated for use to acquire, process, record, archive, analyze, and output electrocardiographic data obtained during physiologic stress exercise testing.

- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

- The device is indicated for use on adult populations, typically symptomatic.

- The device is not intended to be used as a vital signs physiological monitor.

System Description

The XScribe is a high-performance, PC-based, dedicated color, stress exercise testing system with an exam database capable of acquiring, viewing, printing, and storing ECG, NIBP, and SpO2 data. The XScribe may be used with a treadmill, ergometer, or pharmacological form of testing. The device is equipped with Mortara Instrument's VERITAS™ resting ECG interpretation algorithm. This feature enables the VERITAS algorithm to provide an over-reading physician with a silent second opinion through diagnostic statements output on the supine and Mason-Likar ECG reports. The interpretive portion of the ECG is available in the pre-exercise portion of the test. For additional information on the VERITAS algorithm, please refer to the *Physician's Guide to VERITAS with Adult and Pediatric Resting ECG Interpretation*. (See Parts and Accessories.)

The XScribe system can function as a standalone workstation or can be set up in a distributed configuration where the database resides on a server supporting a number of networked client workstations.

The XScribe Review software offers users with appropriate permissions at a networked location the ability to schedule new exams when not linked to an external scheduling system, view full disclosure exams, enter conclusions, and generate printed or electronic reports for completed exams.

The XScribe workstation includes:
- PC with keyboard and mouse
- X12+™ transmitter or WAM™ acquisition module for wireless configuration
- M12A patient cable or AM12™ acquisition module for traditional wired connection
- 24" wide-screen color monitor
- Isolation transformer
- ECG lead wires
- Carry case with belt
- Software
- System cart

Optional items include:
- High-speed laser printer
- Z200+ thermal array printer
- Treadmill
- Ergometer
- Multi-modality module for wireless RF transmitter with TTL and analog output
- Multi-modality module for wired M12A with TTL and analog output
- Programmable remote keypad
- Local area network (LAN)
- Integrated non-invasive blood pressure monitoring with or without SpO_2

Miscellaneous System Information

- XScribe is capable of supporting the following video resolutions: 1920 x 1080 and 1920 x 1200.
- XScribe is capable of supporting HP LaserJet printers with 600 dpi and PCL5 capabilities, and Mortara Instrument's Z200+ thermal printer.
- A supplied network isolation device must be installed between the PC and wall network plug. This is to ensure compliance with IEC 60601-1-1 standard.

    NOTE: No user-serviceable parts are inside. Any modification to any part of device is to be performed by qualified service personnel only.

About the XScribe

XScribe documents four phases of a patient's exercise test: pre-exercise (resting ECG), exercise, recovery, and final report (Report Manager). The initial observation phase allows the user to prepare the patient, choose the appropriate exercise protocol, front end type, and enable/disable various settings prior to exam start.

XScribe is based on a Microsoft® Windows® operating system and conforms to common elements to perform tasks. The device keyboard provides an easy means for entering patient ID information at the start of the test, as well as comments in the Final Report phase; test functions are controlled by mouse or by on-screen menu functions using the keyboard. Using the customizable screen formats, operational conditions can be customized to suit specific needs.

Full features include:
- Automatic ST segment analysis and trending on all 12 leads.
- Superimposition comparison of current and reference complexes on both a 4x QRS, and updated 12-lead median complexes.
- Context View during the exam allowing full disclosure review and addition of past ECG events.
- Automatic ventricular ectopic beat detection.
- Up to 100 different exercise protocols.
- Automatic 12-lead ECGs with prompts for manual or automated (optional) blood pressure acquisition.
- Multiple final report formats with custom report sequence capabilities and automated narrative summary.
- Networked export of XML, PDF, HL7, or DICOM® results.
- Networked receipt of XML, HL7, or DICOM orders.
- Archive directories with full disclosure exam data.
- User-defined ST measurement points.
- Analog and TTL output with X12+ or M12A front ends.
- Programmable and fixed protocols, procedures, and final reports.
- Pre-test electrode check (impedance) on X12+ wireless transmitter.
- Automated NIBP and SpO2 readings (with optional device).
- Various text and graphical formats.
- Medications, notes, diagnoses, indications, and procedural comment entries.
- RPE entry during test (Borg Scale).
- Source Consistency Filter (SCF).
- Beat Consistency Filter (BCF) on ECG printouts.
- METs, maximum predicted heart rate, and target heart rate formula selection.
- Various exercise controls with Mortara-approved treadmills, ergometers, and pharmacological studies.
- Ability to select final report segments including Patient Information, Exam Summary, Rate/BP/Work Trends, ST Level Trends, ST Slope Trends, Average QRS, and Events.
- ST level and slope data for lead and worst-case average beat, updated continually during test.
- Editing of final report in Review phase.
- Paperless workflow capability.
- Ability to store exams and final reports in a centralized database.
- Pre-registration and scheduling of patients.
- Health risk assessment based on Duke and Functional Aerobic Impairment (FAI) algorithms.

  NOTE: Arrhythmia detection is provided for the convenience of automatic documentation. The device offers no diagnostic opinion but provides documentation during the exam for which the operator renders their own medical opinion. Documentation is presented and stored for the convenience of and verification by a physician.

XScribe System*

Figure 1-1

XScribe with Z200+ Thermal Printer   **XScribe with Laser Printer**
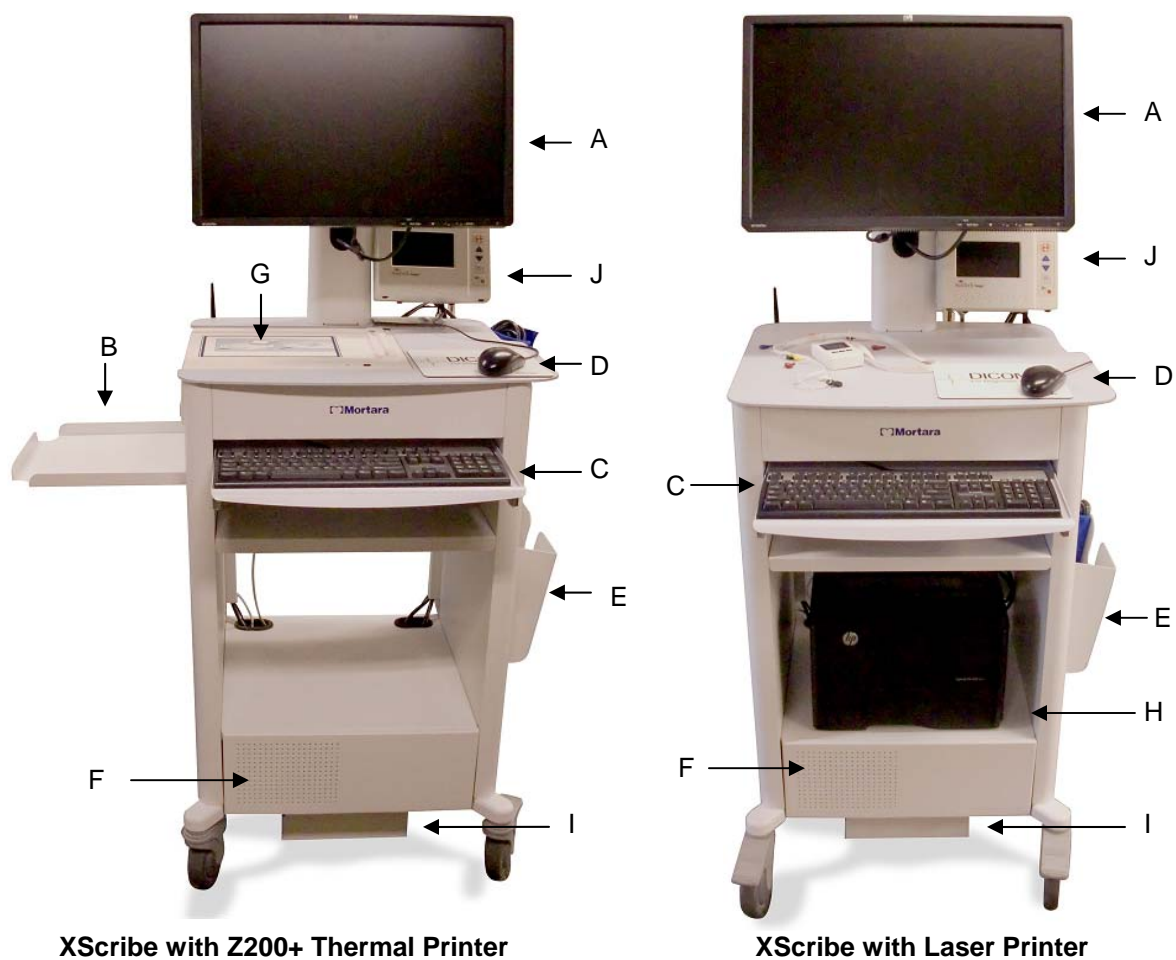
A. Display
B. Paper catch tray
C. Keyboard

D. Mouse
E. Storage bin
F. CPU compartment

G. Z200+ thermal printer
H. Laser printer
I. Isolation Transformer shelf
J. SunTech Tango+ (optional) or
Tango M2 (optional)

* Subject to change without notice.

XScribe Front End Types

There are three front end types for patient connection that can be used with XScribe.

X12+ Digital Transmitter

12-lead telemetry transmitter with Mortara's patented LeadForm patient cable operates in 608 MHz or 2500 MHz frequency. Uses one AA alkaline battery for approximately 24-hours of continuous operation. Includes impedance check and ECG display to ensure good quality patient hookup. The RF Scan tool can be used with this front end for optimal channel selection. Refer to the X12+ user manual and/or the short-form instruction card for detailed information.

M12A Patient Cable

12-lead patient cable together with Mortara's patented LeadForm patient cable for connection to MMM when a wired connection and TTL/analog output is desired.

Multi-modality Module (MMM)

MMM supports both X12+ wireless and M12A wired front ends with TTL/Analog output, required for TANGO BP Monitor interface and ECG signal output for ECHO and other devices. Antennas are connected with 18" cables and must be at least 12" apart when installed for the X12+. Connects to computer through USB.

WAM Wireless Acquisition Module

WAM for wireless ECG acquisition with the USB UTK module incorporates frequency-hopping technology in the 2500 MHz frequency range with 40,000 Hz ECG acquisition. Uses one AA alkaline battery for approximately 8-hours of continuous operation. Uses replaceable lead wires with medi-clip connectors.
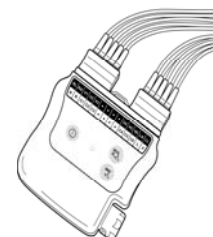
USB Transceiver Key (UTK)

UTK connected to the XScribe USB port receives ECG signals from the paired WAM for presentation of the electrocardiogram. A USB port built into the XScribe cart display mount top is most appropriate for this device. Alternatively, the UTK connected to USB cable (6400-012) from the PC port may be mounted in an unobstructed location.

AM12 Acquisition Module

AM12 for a traditional wired connection allows direct USB connection with 40,000 Hz ECG acquisition. Uses replaceable lead wires with medi-clip connectors.
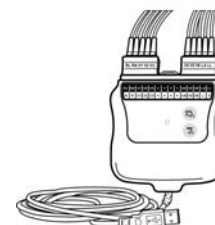
XScribe Software Installation Process

Navigate to the location of the software to be installed and double click on the "Setup" application file.

If asked to allow the program to make changes to the computer, click **Yes.**

The Exam setup window will appear prompting you to install Mortara PDF, click **Install**.
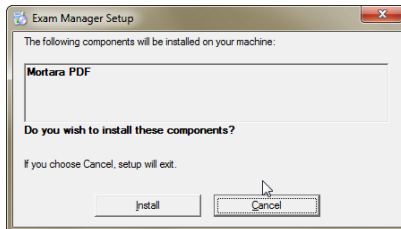
The Modality Manager x86 v5.13 Setup window will appear, click **Next** to continue.
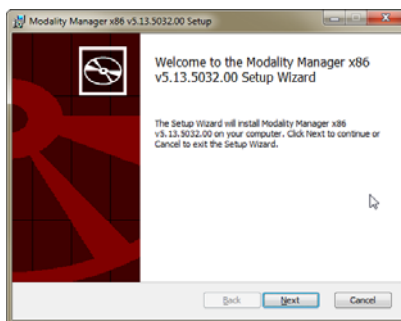
NOTE: If you are upgrading the system from a previous version, the next step will be omitted.

Select the appropriate Setup Type for the installation (see below):

There are 5 installation types to select from that simplify the installation process. The definitions below will assist with making the most appropriate choice. Click Next after the installation type has been selected.
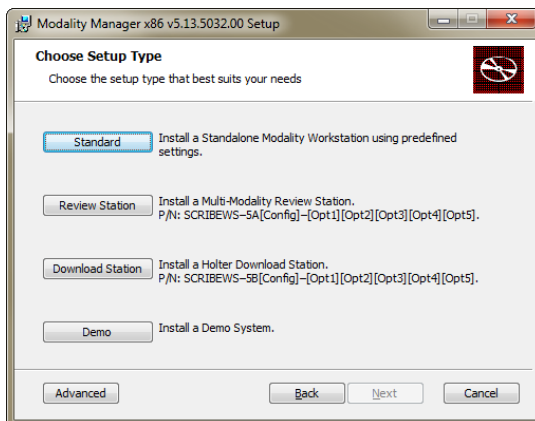
Standard: Choose the standard option if you are loading a single modality with the Database Server functionality included on a single PC.

> *NOTE: Choose the Standard option when loading XScribe <u>and</u> RScribe™ with the Database Server functionality onto a single computer.*
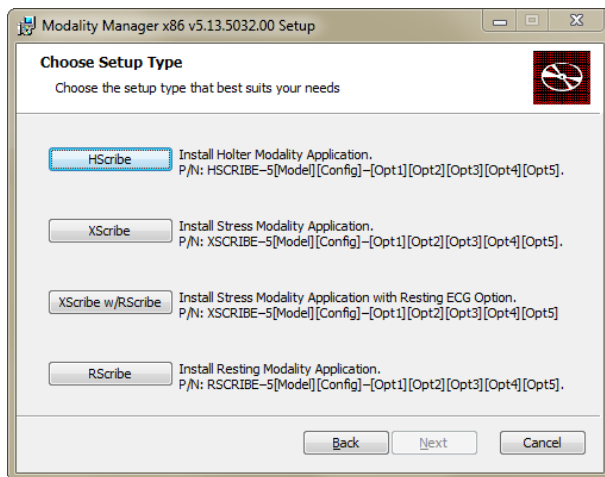
Review: This option should be used if you are loading a modality client ONLY onto a PC, with the Database Server functionality being loaded onto a separate networked PC.

Download: The Download option does not apply to XScribe; it should only be selected when installing the software to an HScribe™ system..

Demo: This option should be used to load a single PC with all modalities and the Database Server functionality onto a single PC for demonstration purposes.

> *NOTE: The demo mode will not allow importing or acquisition of data, it will only operate with the demonstration data included when the software is loaded.*

Advanced: This option should be used for all cases that do not fit into one of the categories above. The advanced option will allow the installer to select an alternate path to install the software, and will also allow for installations using multiple networked PCs with the Database Server functionality being loaded on a separate PC or a Server hardware platform.

The Database Configuration window will appear which will show you the default DB Port number (5432) and an option to enable or disable the Unique Patient ID option.

DB Port: It is recommended that you use the default port number for the installation. If the port is already being used, the installation tool will alert you that the port is already taken and a new port number will need to be entered to continue with the installation.

Unique Patient ID: This option defaults to a YES (checked) condition to configure the system to utilize the Patient ID field as a unique identifier for patient demographic information, which is the most typically used system configuration.
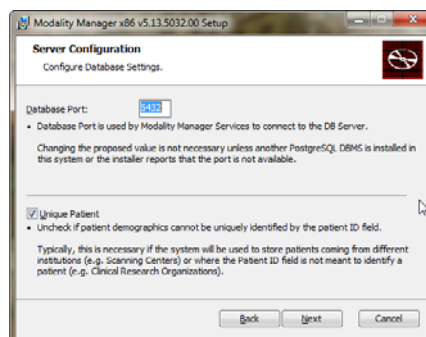
The option box can be UNCHECKED if the system is to be configured without using the Patient ID field as a unique identifier for patient demographics. This type of configuration is used when patients may be entered from different institutions (such as scanning centers) that use different ID schemes; or instances where the Patient ID field is not used to identify a patient (such as clinical research studies).

Once the selections are made, click **Next** and the Installation window will appear.

Click **Install** to continue.

The wizard will now load the software files to the defined location and then present the Modality Manager Configuration window.

> **NOTE**: The Modality Manager Configuration Utility can also be accessed after the installation process is completed if any changes are needed through selection of the Modality Configuration settings from the Windows START menu, under All Programs then Mortara Instrument.
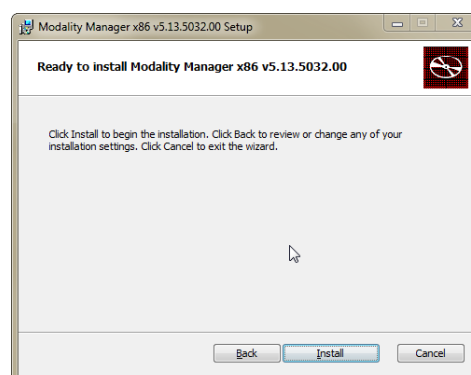
Refer to information below regarding configuration settings:

Language: This setting is always available to select the desired language.

Server Address: This setting is grayed out when the Database Server functionality will be installed on the local PC, but will become an active selection when the modality(s) will be accessing a remote Database Server.

Log Port: This setting is always available to select the port to be used for the event log service. Leave on the default if the port is not occupied for other purposes.

8
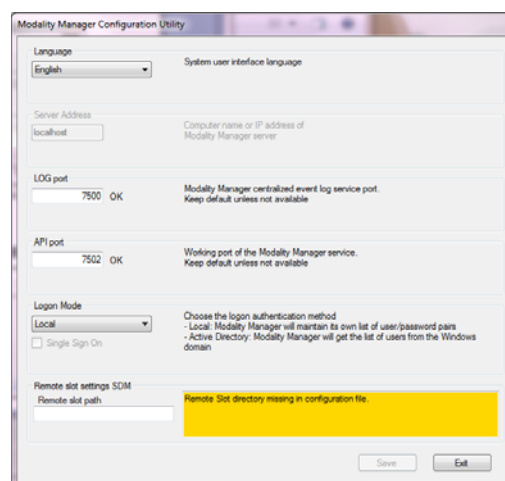
API Port: This setting is always available to select the port to be used for Modality Manager Service.

Remote slot settings SDM (Single Directory Management): This setting is only intended for Server systems. Normally, when an exam is active (selected), all data will be copied from the system database to the local client workstation. If a path is entered here, the temporary data will be copied to a central (local) folder on the server. This method can only be used for Holter workstations and is not applicable to XScribe.

Logon Mode: This setting can be set to either Local or Active Directory depending on the user preference. If Local is selected, the Modality Manager Service will maintain its own local listing of user/password pairs for logging onto the system. If Active Directory is selected, the Modality Manager service will access the list of users from the Windows domain.

The Single Sign On box is grayed out unless the installation is for a "Server Only" installation using Active Directory logon authentication.

Once the settings are correct, select **Save** (if you changed anything), then select **Exit** to continue.

If you exit without saving modified settings, a warning message will appear.

Click **Finish** to complete the installation process.
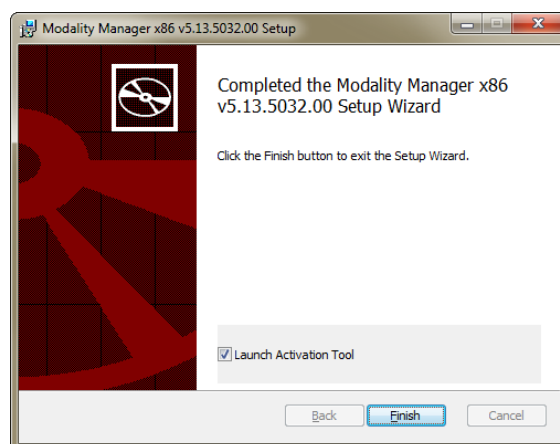
Feature Activation

An activation code is required to permanently operate full XScribe software functions such as start an exam, access stored exams, schedule patients, review exams, store exams, archive exams, export results and other tasks. Without activation, the system will function for a period of fourteen days and will then become invalid.

To prepare for activation, run the Modality Manager Activation Tool accessed from the following menus:
- Start menu
- All Programs
- Mortara Instrument
- Modality Manager Activation Tool (click **Yes** when prompted to allow changes to the computer)

Once your system serial number is entered, this utility generates the site code that is needed for activation by Mortara Technical Support personnel. You can click on the Copy to Desktop or the Copy to Clipboard button to generate a file to be e-mailed to TechSupport@mortara.com.

Mortara Technical Support will return an activation code that can be typed or copied and pasted into the white space above the "Activate License" button. Select the Activate License button to activate the software. You can activate the software at any time after installation with the Modality Manager Activation Tool. Contact Mortara Technical Support personnel for further information.

Starting the XScribe Workstation

The ON/OFF switch is located on the front side of the CPU. When the switch is depressed, the workstation will power on. To turn on the LCD screen, locate the display main switch.

⚠ *CAUTION: Do not run any other applications, including screen savers, when performing a stress test. Once the test has begun, the XScribe application does not allow the user to access other system functions.*

XScribe Login and Main Display

The XScribe application requires user credentials on startup when the program has not been set up with a single sign on. The default factory Username and Password is admin. The password is case sensitive.

Upon successful login, the application will present a screen similar to the one shown at the right. The user name and software version is shown in the bottom left corner. Click on any of the icons representing workflow to perform a specific task.

The XScribe Username and Password are entered then the OK button is selected to open the application main menu. Some of the icons may be grayed or absent depending on the user permissions and system configuration.

Hovering over an icon will display a textual message showing its function. Icons that are not permitted for the logged in user are grayed and unavailable.
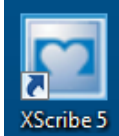
The first time you login, you will need to select the **System Configuration** icon to setup your access to all functions.

1. Select the **User's Database** button and you will see the" IT Admin" user. Double-click on the name to open the role privileges and check desired functions.

2. Click **OK → Exit → Exit** and start up XScribe again. If you don't do this, most all icons are grayed and unavailable.
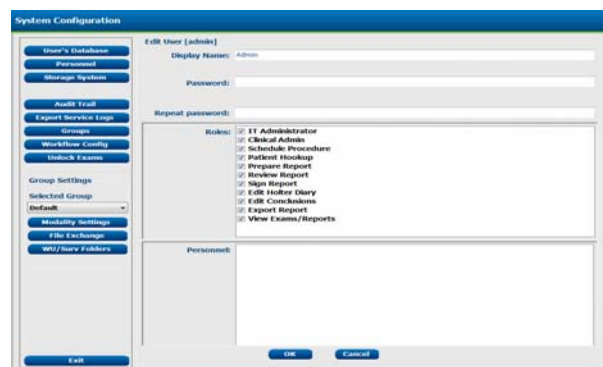
XScribe Icon Descriptions

Icon and Hover Text	Description
XScribe 5	XScribe desktop shortcut icon to launch the Stress modality application.
Schedule/Orders	Opens a window allowing exam scheduling and schedule review. *This icon is only available when XScribe is not linked to an external scheduling system.*
Start a Stress Test	Opens a window presenting scheduled exams or the Search Patient list when no exams are scheduled allowing association of patient demographic data with the exam. The stress hookup display is opened when the Start Exam button is selected.
Worklist	Opens a window displaying exams with a preset filter showing only Acquired, Edited, or Reviewed status according to user preference. Checkboxes in the window allow further filtering.
Exam Search	Opens a window allowing users to search for Stress exams in the database using filters.
Patient Search	Opens a window allowing users to search for patients in the database using filters and editing of the patient demographics.
User Preferences	Opens a window for configuring the user preferences for the Worklist and changing the password.
System Configuration	Opens a window for administrative users to configure the system settings such as creating/modifying users, changing the XScribe default settings and protocols, defining archive directories, and so on.
Exit	Closes the XScribe application and returns the user to the desktop.
	Allows users to Minimize or Exit the application and return to the desktop.

User Roles and Permissions

XScribe supports a workflow oriented setup for defining user roles and controlling user access to the various operations. Role assignments are comprised of a set of permissions for each user type (e.g., IT administrator, clinical administrator, Stress Hookup Tech, and so on).

Each user can be assigned a single role or a combination of roles. Some roles include permissions assigned to other roles where applicable. After installation, a single user is created, with the role of "IT Administrator". Before using XScribe, this user must log in and create required users and roles.

Roles	Permission Assignment
IT Administrator	Manage user permissions; manage personnel lists; export settings; archive settings; workflow configuration; storage system configuration; unlock exams; view audit trail reports; export service logs.
Clinical Administrator	Manage database exams (delete, archive, and restore); export settings; copy exams offline to share with Mortara personnel or other sites; view audit trail reports; modify modality settings (profiles, protocols, and other stress specific settings); reconciliate; export service logs; create and modify groups.
Schedule Procedure	Create new patient orders; associate an order with an existing patient; modify demographics of an existing patient; export service logs. *Scheduling and order entry is only available when XScribe is not linked to an external scheduling system.*
Patient Hookup (Start Stress Exam)	Ability to start a stress test using Start a Stress Test icon. Includes the ability to create a new patient; associate an order with an existing patient; export service logs.
Edit Holter Diary	Not applicable to XScribe application.
View Exams/Reports	Review exams and final reports only. Includes the ability to search exams, view and print reports; export service logs.
Prepare Report	Review and edit exams to move them to the edited state. Includes ability to search exams and view and print reports; export service logs.
Review Report	Review and edit exams to move them to the reviewed state. Includes ability to search exams and view and print reports; modify and create conclusions; export service logs.
Edit Conclusions	Create and modify conclusions. Includes ability to review exams and final reports only; search exams and view and print reports; export service logs.
Sign Report	Ability to move exams to a signed state. Includes ability to review exams and final reports; search exams and view and print reports; export service logs. Requires user authentication.
Export Report	Ability to export a PDF and XML file when features are enabled. Must be assigned in conjunction with another role (e.g. Review, View, or Conclusions).

XScribe Specifications

Feature	Workstation Minimum Specification*
Computer Model	HP rp5800 CPU
Processor	Intel Core i3
Graphics	1920 x 1080 or 1920 x 1200
RAM	4 GB
Operating System	Microsoft Windows 7 Professional 32-bit (required)
Hard Drive Capacity	500 GB
Archive	Network or external USB drive
Input Devices	Standard keyboard and scroll mouse
Software Installation	CD-ROM
Network	100 Mbps connection or better
Front-end ECG Devices	X12+ and M12-USB for wireless ECG acquisition and TTL/analog output M12A and M12-USB for wired ECG acquisition and TTL/analog output WAM for wireless ECG acquisition AM12 for wired ECG acquisition
Printing Devices	HP M401n Laser printer (recommended) Z200+ thermal printer (requires additional network port)
USB Ports	2 free USB 2.0 ports
Serial Ports	2 serial ports required for digital interface
Audio	Required for NIPB and Pharmacological notification
Isolation Transformer Required When Workstation is Used for Stress Testing	
Isolation Transformer Requirement	Known Agency Mark (KAM) Meets IEC 60601-1 requirements Protective Earth conductor for all connected equipment Z200+ only configuration: 300 watts LaserJet printer configuration: 1,000 watts
Feature	Server Minimum Specification*
Processor	Performance equivalent to an Intel Xeon class, Quad-core with hyperthreading
Graphics	1024 x 768
RAM	4 GB
Operating System	Microsoft Windows 2008 server R2, SP1, 64-bit (required)
System Disk	100 GB for OS and product installation (RAID recommended for data redundancy)
Data Disks	550 GB hard drive space available HD controller with 128 MB read/write cache (RAID recommended for data redundancy)
Archive	Network or external USB drive
Software Installation	CD-ROM
Network	100 Mbps connection or better
Input Devices	Standard keyboard and mouse

* Specifications subject to change without notice.

WAM Specifications

Feature	Specification*
Instrument Type	12-lead wireless acquisition module for cardiac stress testing
Input Channels	12-lead signal acquisition and transmission
ECG Leads Transmitted	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
WAM Transmission Protocol	Bidirectional and frequency hopping; beacon and response method links a single acquisition module to a single cardiac stress system
Frequency Range	2400.96 MHz to 2482.56 MHz
WAM and Receiver Distance	Approximately 10 feet (3 meters)
Lead Set	RA, LA, RL, LL, V1, V2, V3, V4, V5, and V6 (R, L, N, F, C1, C2, C3, C4, C5, and C6) with detachable lead wires
Sampling Rate	40,000 samples/second/channel acquisition; 1,000 samples/second/channel transmitted for analysis
Resolution	1.875 microvolt LSB
User Interface	Button operation: ON/OFF; 12-lead ECG and rhythm strip buttons are non-functional with cardiac stress testing
Defibrillator Protection	Complies with AAMI standards and IEC 60601-2-25
Device Classification	Type CF, battery operated
Weight	6.7 oz. (190 g) with battery
Dimensions	4.45 x 4.25 x 1.1" (11.3 x 10.8 x 2.79 cm)
Battery	1 AA alkaline 1.5V battery

* Specifications subject to change without notice.

Parts and Accessories

For more information on parts/accessories or to place an order, contact Mortara Instrument. See Appendix A for contact information.

Part Number	Description
X12PLUS-XXX-XXXXX	X12+ TRANSMITTER with accessories
8346-003-50	X12+ BATTERY DOOR
8485-020-51	CARRY CASE & BELT ASSEMBLY (for the X12+ transmitter)
9293-017-50	PAT CBL 10WIRE LEADFORM AHA SNAP
9293-017-51	PAT CBL 10WIRE LEADFORM IEC SNAP
9293-026-50	PAT CBL 10WIRE LEADFORM XL AHA SNAP
9293-026-51	PAT CBL 10WIRE LEADFORM XL IEC SNAP
30012-016-61	M12RF611-USB w/AUX OUTS INTERFACE ASSY
30012-016-71	M12RF2500-USB w/AUX OUTS INTERFACE ASSY
9293-029-50	M12A FRONT END FOR MULTI-MODALITY MODULE w/o LeadForm Patient Cable
9293-048-54	ACQ MOD (AM12) w/o LEAD WIRES
30012-019-54	WIRELESS ACQUISITION MODULE (WAM) w/o LEAD WIRES
30012-021-51	UTK MODULE (receiver for WAM)
9293-047-70	AHA MEDI-CLIP SHORT CABLE SET (for WAM and AM12)
9293-047-71	IEC MEDI-CLIP SHORT CABLE SET (for WAM and AM12)
8485-026-50*	ECG STRESS BELT (for the WAM, AM12, and M12A options)
9100-026-11	PAPER Z2XX US CUED ZFOLD PACK
9100-026-12	PAPER Z2XX A4 CUED ZFOLD PACK
9300-032-50	ECG MONITORING ELECTRODES CASE 300
9294-009-51	HOOKUP KIT MONITORING KIT 1-10E CASE/24
9515-001-51	PHYS GUIDE ADULT PED V7 INTERP UMs
34000-025-1002	Z200+ THERMAL WRITER Standard/A4
9906-037	CPU w/WINDOWS OS
9970-011-50	REMOTE KEYPAD
9911-020-50	XSCRIBE TRANSPORT CART BASE
9911-020-51	XSCRIBE TRANSPORT CART CUTOUT DESKTOP W/TRAY (for Z200+ model)
9911-020-52	XSCRIBE TRANSPORT CART SOLID DESKTOP (for Laser Printer model)
9911-020-60	SUNTECH TANGO+ and TANGO M2 MOUNTING BRACKET

Support Parts

The following parts can only be ordered by Mortara personnel.

Part Number	Item
Isolation Transformer and Power Cord	
1404-002	TRANSFORMER ISOLATION 1000VA MED DOM
3181-008	POWER CORD US/CAN HOSPITAL 5-15P+320-C13
1404-003	TRANSFORMER ISOLATION 1000VA MED INTN'L
3181-002	POWER CORD INTN'L CEE7/7+IEC320-C13
3181-003	POWER CORD BRIDGE 2m IEC320-C13+C14
Interface Cables and Adapters	
6400-012	CABLE USB TYPE A-TO-B FULL SPD
3601-001	COUPLER TNC FEMALE TO BNC FEMALE
3600-003	ANTENNA TNC 2400MHz 1/2 WAVE LENGTH
7500-008	CLIP WIRE CORD 1x1x.53ID WHITE W/ADHESIV
3510-005	PLUG TO PLUG ADAPTOR BNC
3600-010	ANTENNA 611MHz BNC 1/4 WAVE
25004-003-52	CABLE TRACKMASTER TO CPU XSCRIBE
9912-018	CABLE ERGOMETER INTERFACE ERGOLINE
9912-019	CABLE ERGOMETER INTERFACE LODE CORRIVAL
6400-001	CABLE PWR DC F SR CONN STRPD 10"
8342-007-01	SPACER A4 PAPER ELI 200+
Network and Miscellaneous Items	
9960-051	NETWORK CARD PCI 10/100 FAST ETHERNET
9960-052	ISOLATOR ETHERNET LOW LEAKAGE RJ45/RJ45
6400-010	CABLE ETHERNET CAT5e RJ-45 M SHLD 2FT
6400-008	CABLE ETHERNET RJ-45M TO RJ-45M STR-THRU
6400-018	CABLE LONG CROSSOVER CAT5e RJ-45 M SHLD 6FT

SCHEDULE/ORDERS

The Schedule/Orders icon is only available when the modality is not linked to an external scheduling system. Click on the icon to open a window allowing you to schedule stress exams and view the existing schedule.

Time Filter

Filter the Schedule/Orders list by selecting from the Time Filter drop-down menu:
- All
- Today
- Yesterday, Today and Tomorrow
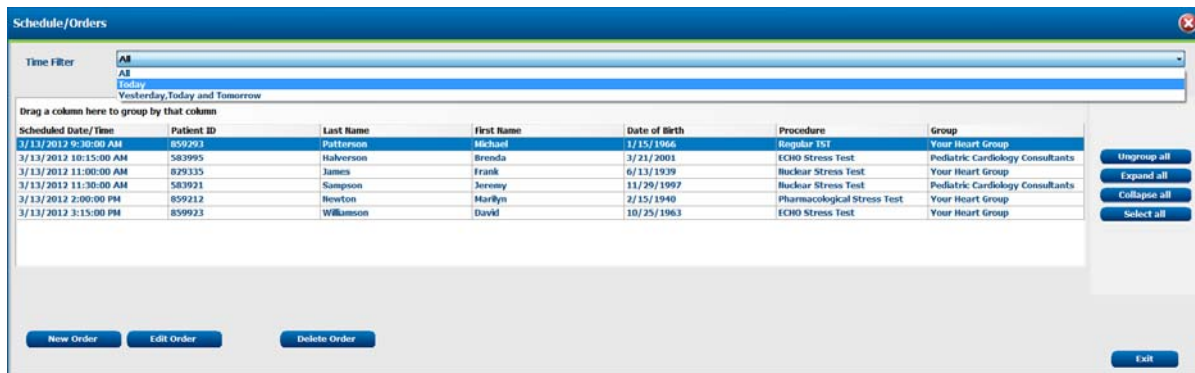
Group by Column Header

Organize the Schedule/Orders list by dragging a column header above the list; use **Ungroup all** to return the column header. **Collapse all** and **Expand all** collapse and expand the grouped orders.
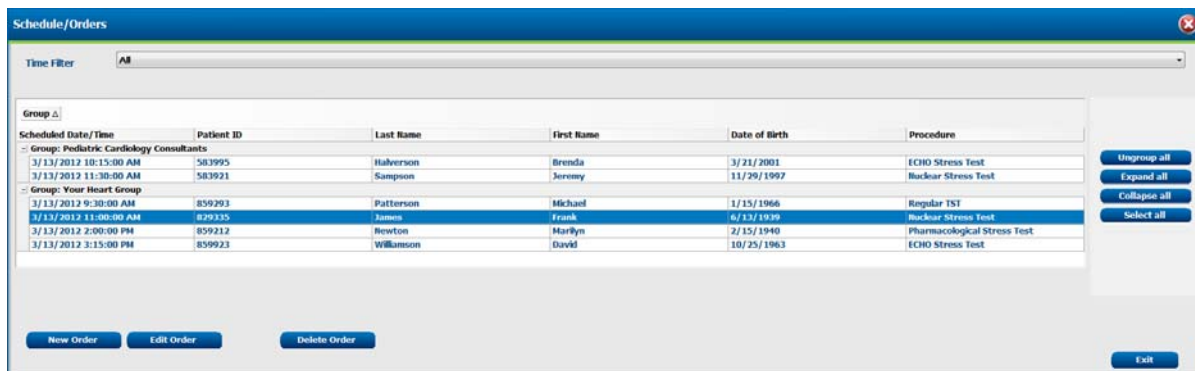
Schedule a New Order

Search for and select an existing patient or enter a patient that does not exist by selecting **New Order**.

Search for existing patients in the database using the drop-down fields. Up to two filters can be selected. Click on **+** to add another set of criteria for the search.

- Patient ID
- Last Name
- First Name
- Exam Date
- Date of Birth

Exam date criteria can be selected by clicking on the calendar icon. When done, click **Search**.

Highlight the desired patient and click on **Select** to open the Exam Data Entry window and add schedule information.

Some of the patient data fields cannot be edited because they are attached to exams in the database. Changes to this information can be made under the Search Patients icon explained in another section of this manual.

Click on **Confirm** when done and the patient will be listed on the schedule with the scheduled date and time. Choose **Cancel** to exit this window without saving changes.

If no match is found, select **New**. The Exam Data Entry window will open allowing for entry of exam demographics.

A single group may be used for all exams or use the **Group** drop-down menu to choose the desired name.

Enter date of birth by typing MM/DD/YY or DD-MM-YY according to the computer regional settings, or by clicking on the calendar icon. Select the decade and the year; use the left/right arrows to scroll the year, the month, and the day to populate the field. Age will be automatically calculated.

XScribe will remember list items such as Indications, Medications, Procedure Type, and Referring Physician as they are entered. The added items will be available for future selection. Enter text or choose items from the drop-down menu and then click on the green checkmark to enter. Use the red **X** to delete the selected item. When there are multiple entries, items can be moved up or down by using the green arrow keys.

Click on **Confirm** when done and the patient will be listed on the schedule with the scheduled date and time. Choose **Cancel** to exit this window without saving changes.

Edit an Existing Order

Select an existing patient order by highlighting the line and then click on **Edit Order**.

The Exam Data Entry window will open allowing editing of the existing schedule information.

Click on **Confirm** when done editing changes and the updated patient order will be listed on the schedule with the scheduled date and time. Choose **Cancel** to exit this window without saving changes.

Delete an Existing Order

Select an existing patient order by highlighting the line and then click on **Delete Order**.

A warning message prompting delete confirmation will appear. Click **Yes** to delete the order or click **No** to cancel and return to the Schedule/Orders listing.
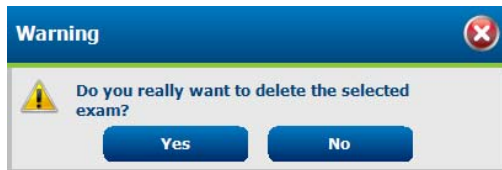
Click on **Exit** when done.

SETUP AND INSTALLATION

XScribe System Setup and Installation

> **NOTE:** Refer to Interconnect diagram, Figure 3-1.

1. Assemble the XScribe system cart and connect all system components according to the instructions included with the cart assembly. Make sure all cables are seated completely onto their respective connectors and that all methods of securing cables to connectors are properly used.

2. Refer to Introduction section for XScribe software installation and activation.

3. Refer to Appendix C for TTL and analog output setup and installation.

4. Refer to Appendix D for XScribe to treadmill or XScribe to ergometer hookup instructions.

5. Refer to Appendix E for configuring and using the Z200+ thermal printer.

6. Refer to Appendix F for SunTech Tango+ and Tango M2 BP monitor interface.

7. Connect all power cords on the CPU and the printer to the isolation transformer; leave the power switches of these components in the ON position. Connect the isolation transformer to an approved hospital-grade AC power outlet and turn the isolation transformer to the ON position.

8. Start the XScribe system by turning on the CPU power button. When the Windows screen appears, log onto the system.

> **NOTE:** After initial equipment installation is complete, the power switch on the isolation transformer will power up the XScribe system. The isolation transformer also supplies power to the Z200+ thermal writer which does not have its own ON/OFF switch.

> **NOTE:** When finished using the XScribe system, a Windows system shutdown should be performed. This will power off the CPU and put the display in standby mode. The isolation transformer will remain powered on.

XScribe Interconnect Diagram
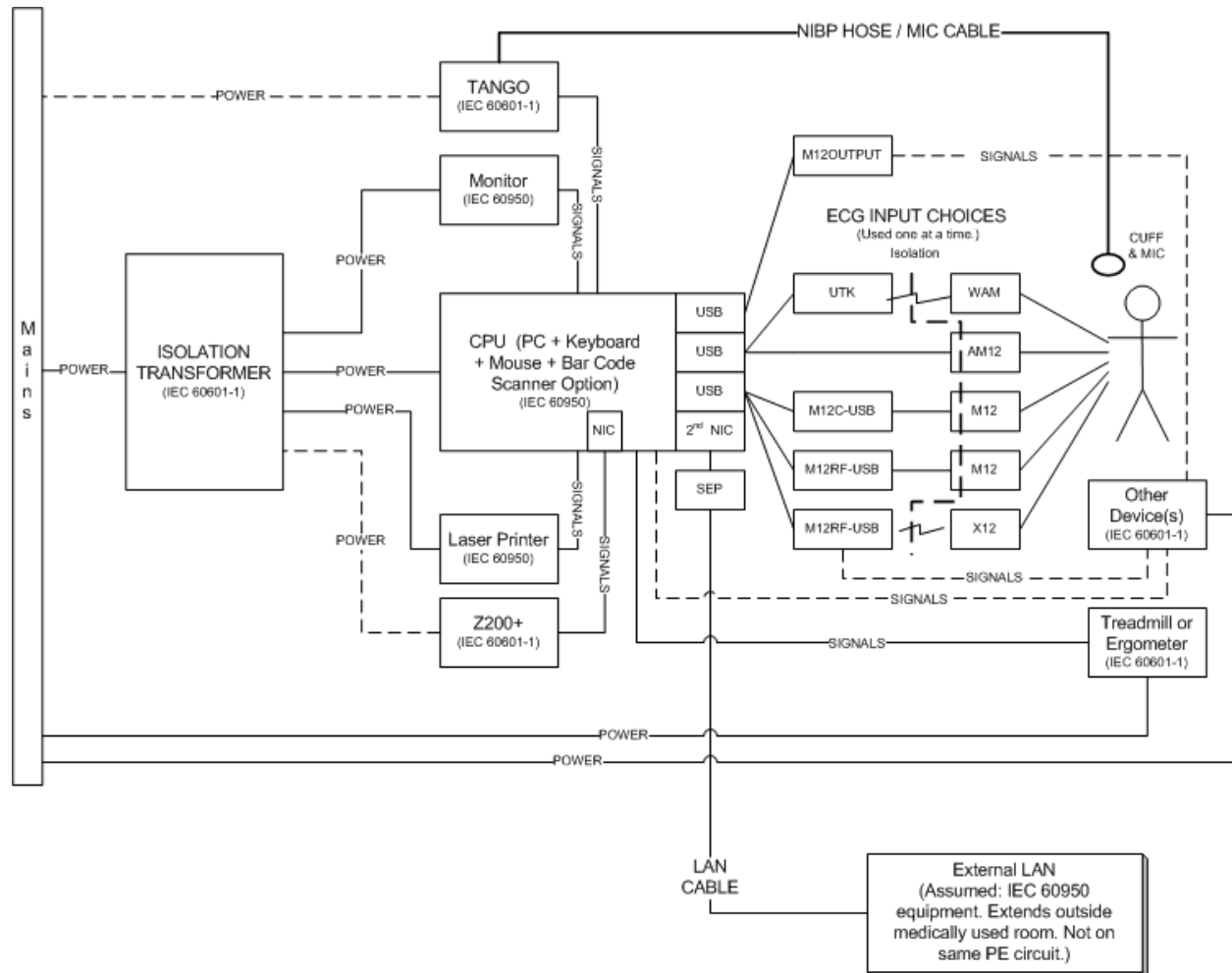
Figure 3-1

Medical Isolation Transformer

Figure 3-2
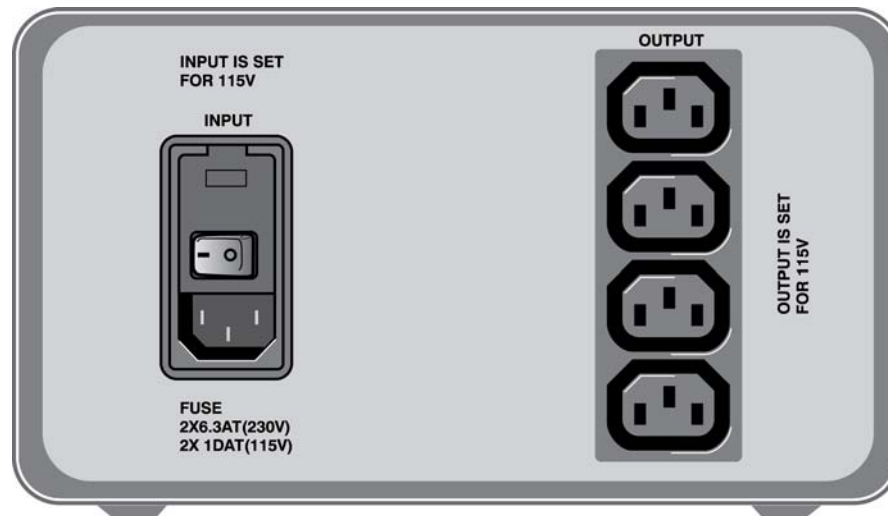
Medical Isolation Transformer Specifications

Frequency: 50/60 Hz
Output Ratings: 115/230V 1000VA
Weight: 22 lbs. (9.98 kg)
Dimensions: Height =   5.1" (130 mm)
                     Width   =   8.0" (203 mm)
                     Depth   =   11.0" (280 mm)

REF: 1404-002   Input 115VAC 50/60 Hz 2x10AT Fused
REF: 1404-003   Input 230VAC 50/60 Hz 2x6.3AT Fused

CAUTION: Before connecting system components to the isolation transformer, ensure the voltage selector (located above the power cord) matches the line voltage.

CAUTION: Risk of electrical shock. Do not remove cover. Refer servicing to qualified service personnel. Grounding reliability can only be achieved when system components are connected to an equivalent receptacle marked "hospital grade."

CAUTION: Use of this transformer with equipment other than originally supplied, or surpassing the ratings, may cause damage, fire, or injury.

WARNING: Possible explosion hazard. Do not use in the presence of flammable anesthetics.

WAM Battery Installation

The WAM is powered with a single AA battery. When the battery contains sufficient voltage to operate and the patient is properly connected, an LED on the front of the WAM will appear solid green indicating proper pairing and communication with the electrocardiograph. A battery with low voltage or a lead fail will result in a flashing green or yellow LED.

To install a new battery, remove the battery cover by twisting the cover in a counterclockwise direction. Removal of the battery cover will automatically turn the power off. Insert one AA battery into the battery compartment aligning the battery's positive (+) and negative (-) indicators with the designators shown on the device's back label. Replace the battery cover by twisting the cover in a clockwise direction. The battery cover will seal the battery compartment and make contact with the battery providing power to the device.

Applying Power to the WAM

Before you apply power to the WAM, make sure that patient lead wires do not touch metal connected to ground (this may happen if reusable electrodes with exposed metal are used); the WAM will auto-calibrate at power-on, and a large amount of noise caused by ground loops may disrupt calibration, in which case the XScribe will not display ECG.

Press the power On/Off button to turn the device on or off. An audible tone will sound indicating power off and RF disconnect.

Attaching the WAM Lead Wire Connector Block

The 12-lead ECG lead wires consist of one connector block with 10 lead wires (5 leads wires to each side). The lead wires are positioned on the WAM to follow the contour of the torso. Each lead wire terminates in a medi-clip.

Securely insert the connector block into the ECG input connector on the top of the WAM.

⚠ *CAUTION: Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the WAM label.*

Pairing the WAM with XScribe

Start the XScribe application. Start a stress test and navigate to the observation phase, then:

- Select **Local Settings** and choose **WAM** as the Front End.
- Select the **PAIR** ^{F8} button.
- Select **OK**.
- Place the WAM (powered off) in close proximity to the UTK receiver connected to the XScribe USB port.
- Turn WAM on**.**
- A successfully paired message will display.
- Select **OK**.

NOTE: Ending the stress exam will automatically cause the WAM to power off. It is not necessary to pair the WAM with the same UTK to use it again.

NOTE: LED indication is not available when using WAM with XScribe.

NOTE: 12-Lead ECG and Rhythm Print buttons are non-functional when using WAM with XScribe.

USING THE XSCRIBE

At the start of a stress exam, XScribe initially acquires a 12-lead dominant QRS complex to build the first QRS template for all 12 ECG leads. The average QRS waveform for each of the 12 leads is updated after every beat. If the dominant QRS morphology changes, it is automatically detected and the new morphology is "learned" as the new dominant beat morphology. This event is labeled as DRC (Dominant Rhythm Change) on the displayed trends.

During the test, 12-lead ECGs can be printed automatically or manually. User-selected ECG format choices are: 6x2, 3x4, 3x4+1, 3x4+1 BCF, 3x4+3, 3x4+3 BCF, or 12x1 leads. These formats can optionally include an expanded average complex at 100 mm/s and 40 mm/mV (4x standard gain) with associated averaged beats on the printed ECG.

> **NOTE:** *Beat Consistency Filter (BCF) provides an averaged ECG printout utilizing the median ECG complexes. Printed lead labels designate 'BCF' next to the lead label (e.g. I BCF, II BCF, III BCF, etc.). The rhythm lead below the 12-lead ECG is real-time and does not reflect the BCF. Real-time ECG is always displayed on the screen during the exam.*

Depending on the parameters defined at setup, XScribe performs the following operations during the exam:

- Documents ventricular ectopy (isolated PVC, ventricular couplets and ventricular runs) as arrhythmias; and dominant rhythm change (DRC) stored in memory for later review, editing and inclusion in the final report.

- Workload changes at specified times with automatic progression of treadmill and ergometer by protocol definition.

- Highlights the BP menu and sounds audible prompts to signify upcoming measurements.

- Displays the expanded average complex of a user-defined lead or lead undergoing maximum ST segment depression, and compares it to a reference complex for that same lead (Auto Compare).

- Displays trends of HR, ST Index, METs, NIBP, and Double Product (HR*BP).

The user can choose from several rhythm display screens:
- **3-LEAD DISPLAY WITH ZOOMED ST ANALYSIS AND TRENDS**
  Three channels consisting of 7.5 seconds of three user-defined leads
- **3-LEAD DISPLAY WITH ZOOMED ST ANALYSIS WITHOUT TRENDS**
  Three channels consisting of 10.5 seconds of three user-defined leads
- **3-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITHOUT TRENDS**
  Three channels consisting of 15 seconds of three user-defined leads
- **3-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITH TRENDS**
  Three channels consisting of 10.5 seconds of three user-defined leads

- **6-LEAD DISPLAY WITH ZOOMED ST ANALYSIS AND TRENDS**
  Six channels consisting of 7.5 seconds of six user-defined leads
- **6-LEAD DISPLAY WITH ZOOMED ST ANALYSIS WITHOUT TRENDS**
  Six channels consisting of 10.5 seconds of six user-defined leads
- **6-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITHOUT TRENDS**
  Six channels consisting of 15 seconds of six user-defined leads
- **6-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITH TRENDS**
  Six channels consisting of 10.5 seconds of six user-defined leads

- **6x2-LEAD DISPLAY WITH ZOOMED ST ANALYSIS AND TRENDS**
  Twelve channels consisting of 3.75 seconds of twelve leads
- **6x2-LEAD DISPLAY WITH ZOOMED ST ANALYSIS WITHOUT TRENDS**
  Twelve channels consisting of 5.25 seconds of twelve leads
- **6x2-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITHOUT TRENDS**
  Twelve channels consisting of 7.5 seconds of twelve leads
- **6x2-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITH TRENDS**
  Twelve channels consisting of 5.25 seconds of twelve leads

- **12-LEAD DISPLAY WITH ZOOMED ST ANALYSIS AND TRENDS**
  Twelve channels consisting of 7.5 seconds of twelve leads
- **12-LEAD DISPLAY WITH ZOOMED ST ANALYSIS WITHOUT TRENDS**
  Twelve channels consisting of 10.5 seconds of twelve leads
- **12-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITHOUT TRENDS**
  Twelve channels consisting of 15 seconds of twelve leads
- **12-LEAD DISPLAY WITHOUT ZOOMED ST ANALYSIS AND WITH TRENDS**
  Twelve channels consisting of 10.5 seconds of twelve leads

Additional parameters displayed during testing may include the following:
- Treadmill speed and grade, or watts if an ergometer is being used
- Protocol name
- Stage hold (if selected)
- Heart rate (HR)/% of target HR, and target watts if ergometer is being used
- ST level in mm or µV and ST slope in mV
- NIBP and SpO2 with time last acquired (optional)
- Stage
- Stage time
- Patient name
- Patient ID number
- Total exercise time
- METs and/or Double Product, and/or ST Index
- One average complex for each of the 12 leads superimposed for comparing current data to reference data
- User-defined, expanded average complex superimposed for comparing current data to reference data
- Running trends of METs with HR, NIBP systolic and diastolic values, and ST level

During the Recovery phase, XScribe will display both a "PATIENT" and a "COMMENTS" button that allow data entry for the final report. At the end of the Recovery phase, Report Manager will display a summary page that allows the user to define and create the final report.

The final report may consist of the following sections that are user enabled or disabled:
- Patient information page
- Exam summary
- Trends for rate, NIBP, workload, ST level, and ST slope
- Average QRS
- ECG Events
  - Automatic 12-lead ECGs per protocol
  - Peak exercise ECG
  - Arrhythmia events
  - User added 12-lead ECG Events (Supine, Standing, Symptoms, Perceived Exertion, etc.)

The patient information page printout includes:
- Patient demographics
- Protocol
- Date and time of exercise start
- Target HR or target watts if ergometer is being used
- Brief medical history
- Indications
- Medications
- Referring physician
- Procedure type
- Location
- Reason for end
- Symptoms
- Diagnosis
- Notes
- Conclusions
- Technician: [name]
- Reviewed by: [name]
- Signed by: [authorized signing physician name]
- Signed date

The exam summary page printout includes:
- Patient name, ID, date and time of exercise start, and protocol
- Summary of exercise time and leads with 100 μV change, and total PVC count
- Risk scoring
  - Duke Score
  - FAI% (Functional Aerobic Impairment percent)
- Max values
- Max ST
- Max ST changes
- Stage summary

The stage summary printout includes tabular data consisting of the following data that may be included:
- Pre-exercise/exercise/recovery times
- Speed/grade or watts
- HR
- BP
- SpO2
- METs
- Double Product (Sys BP*HR)
- ST measurements of all 12 leads

In addition, the user can also print the following:
- One average complex (at one-minute intervals or at stage intervals) from each of the 12 leads in the Exercise and Recovery phases
- A trend of the ST level, ST slope, HR, BP, Double Product, workload and estimated metabolic equivalents (METs)
- Selected 12-lead ECGs

Function Keys

The XScribe display is designed similar to a control panel with buttons. Each command is a button accessible via mouse, keyboard, or optional remote keypad (used for treadmill and automatic BP device control). All main commands are also available by function keys located on the keyboard (**F1** to **F12**). Each command will show the function key associated with it (e.g., **ECG** ^{F11} = print 12-lead ECG).

Left click the function key to activate a command or option. Some commands will open a pop-up window with drop-down menu options. All pop-up windows will time out within 10 seconds if no selection is made. At any time a pop-up window is open and an additional function needs to be selected, simply click on the next selection and the open pop-up window will close and the new function will be activated.

Function Key	Action and Description
F1 Key	Displays 4 different labels during the stress exam depending on the phase: **BEGIN, START EXE, RECOVERY, END**
BEGIN ^{F1}	• Starts the Pre-exercise phase. Select a pre-registered patient or add patient demographics. The pre-exercise clock starts at this time. • Label changes to **Start Exe**.
START EXE ^{F1}	• The total exercise clock replaces the pre-exercise clock and starts counting from 00:00. • A stage clock appears next to the total exercise clock and starts counting from 00:00. A stage number is also displayed. • If a treadmill or ergometer is turned on, the workload as defined by the protocol or manual setting will display in the upper central portion of the screen. • Pre-exercise reference data is superimposed on the current data for each of the 12 leads and the expanded average Auto Compare complex. As HR increases and/or morphological changes occur, there is a separation of color: black is current data; green is reference data used for comparative analysis. • Label changes to **Recovery**.
RECOVERY ^{F1}	• ECG automatically prints. A printout will always generate when going from Exercise to Recovery phase regardless of settings. • Total exercise time freezes. • Stage timer is replaced with a recovery time clock. • Treadmill or ergometer returns to workload specified in protocol or manual setting. • Label changes to **End**.
END ^{F1}	• Recovery display freezes while test information transfers to system storage. • Report Manager loads and displays final report menu options. • TTL and analog output is maintained in Report Manager.
ABORT ^{ESC}	Exits the observation or pre-exercise phase and returns to the Start a Stress Test menu. The patient demographic information will remain available for future use.
LOCAL CONF ^{F2}	Allows selection of the front end type (WAM, AM12, X12+, M12A), exercise equipment, BP equipment, and AC frequency for this exam. Observation phase selection only.

Function Key	Action and Description

TREADMILL ^{F2}
 	
Or
 	
ERGOMETER ^{F2}
	Allows control of the treadmill or ergometer. The pop-up window will appear.
	
	1. To turn the treadmill/ergometer on or off, select **On** or **Off** and click **OK**.
	
	2. To hold an individual stage, select **Hold Stage** and click **OK**. This setting allows the user to monitor a patient at the set workload parameters without leaving the selected protocol. A "Stage Hold" message will display below the protocol. To resume the stage where it left off, select **Stop Hold** from the pop-up window and click **OK**.
	
	3. To advance through the first few stages of the selected protocol or to manually move to the next appropriate stage, select **NEXT STAGE** and click **OK**.
	
	4. To leave the selected protocol and control the workload manually, select **MANUAL** and click **OK**. This allows the user to control the test according to the patient's ability.
	   • Set speed and grade using the arrows located on the pop-up window, or by using the up/down keys on the keyboard.
	   • Select **Increment Stage** to advance the treadmill/ergometer to the next appropriate stage once **OK** is selected.
	
	NOTE: When changing to manual control, the selected protocol cannot be resumed. The test must be completed in manual mode. Once in the Recovery phase, pre-set recovery parameters will automatically return the treadmill/ergometer to baseline.
	
	5. To change to a different protocol, click on the drop-down menu to select the new protocol, and then click on **PROTOCOL** followed by **OK**. This action will:
	   • Move the patient to the beginning of the next stage of the new protocol.
	   • Advance or regress the system to the appropriate speed and elevation for the stage of the new protocol.
	
	NOTE: Reports and reviewed data will be marked with appropriate change and time.
	
	During pre-exercise and recovery, the speed and grade or watts can be changed. Upon moving to exercise, speed and grade or watts will change to the programmed protocol values.

Function Key	Action and Description
BP ^{F3}	Allows entry of a manual BP measurement or an automatic BP measurement from the Tango+ monitor. Background display turns yellow and a beep will sound. BP values are maintained on the display along with a timestamp and the stage in which the BP was acquired. BP values are updated periodically via manual entry or from an automatic, interfaced BP device. BP measurement can be edited by moving the mouse over the BP value on the right side of the display with a left mouse click. The new BP value appears in the pop up window allowing entry of the edited value. To accept the current value, allow the display to clear automatically (5 seconds) or press **OK**. *NOTE: The values for a <u>new </u>BP measurement should be entered using the* **BP** *or* **F3** *key only. Users may edit the existing value for the last BP measurement displayed by placing the cursor in the BP display field, clicking mouse key, and changing the value. When BP values are edited, the existing values for the measurement are erased and overwritten in the system and summary reports.*
EVENT ^{F4}	Displays an Event pop-up window. Select an event name from the drop-down menu or enter free text and click **OK** to generate a 12-lead ECG. The event name text is included on the ECG printout and stored 12-lead ECG. The Event is included in the summary, final report, and minute-by-minute averaged ECG. Bookmark, Supine, Mason-Likar, Standing and Hyperventilation are listed by default and new event labels can be added for drop-down list selection in the modality manager settings. Resting ECG interpretation can be enabled or disabled in Pre-exercise phase during supine or Mason-Likar ECG acquisition. *NOTE: XScribe automatically detects arrhythmia events. Events are stored and can be displayed and printed (if Arrhythmia Printouts is enabled in the Softkey pop-up menu).*
RPE ^{F5}	Defines the patient's rate of perceived exertion level. Either of two user-selectable scales is defined in the modality settings menu. The displayed pop-up list begins with Nothing and ends with Maximal, with various grades of effort in between. Select the specific rating to generate a 12-lead ECG with the selected statement appended to it.

Function Key	Action and Description
SOFTKEY ^{F6}	Defines or selects various soft key options. Options for Gain, AC Filter, Source Consistency Filter, 40 Hz Filter, 50 mm/sec Display Sweep Speed, ECG Print Speed, Continuous Print Speed, Sync Lead, and Arrhythmia Printouts will appear on the Softkey pop-up window. Click **OK** to save changes. *NOTE: Double click anywhere in the gray shaded area of the pop-up window to demonstrate Mortara's paper-like display; double click again to switch this demonstration tool off. Changes in waveform will be evident on the display and printout.* ⚠ *WARNING: When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.* Use the drop-down menu to choose the **Gain** or amplitude for the on-screen ECG display and 12-lead printout. See Section 5 for defining **AC Filter**, **Source Consistency Filter**, and **40 Hz Filter**. Select **50 mm/sec** to change the sweep speed and printout from the default 25 mm/sec to 50 mm/sec. Use the **ECG Print Speed** drop-down menu to choose the paper speed for the printed ECG. The default speed will be reset for each new test. Use the **Continuous Print Speed** drop-down menu to choose the paper speed for continuous rhythm printouts. Use the **Sync Lead** drop-down menu to select the ECG lead used for TTL or analog output. Lead II is the default. Select **Arrhythmia Printouts** to generate an automatic printout when an arrhythmia is detected. At the beginning of each test, this setting is automatically enabled but can be disabled by the user for the current test if desired. All arrhythmia events will continue to be saved and can be reviewed after the test has been completed. Enable the **Manual BP** checkbox when an automatic BP has been selected in the Local Conf/F2 menu and it is necessary to change to manual BP for the remainder of the exam. Once Manual BP is enabled, the user cannot switch back to automatic BP during the exam.

Function Key	Action and Description
FORMAT F7	Allows access to all available screen configurations for the exercise profile display. The Format pop-up window will appear; click **OK** to save changes. Configure rhythm display by using the **Realtime ECG** drop-down menu. Choose to show 3 leads, 6 leads, 12 leads (12x1), or 12 leads (6x2). When 3 leads and 6 leads are selected, a **V1…** lead selection button opens a drop-down menu for lead selection. The **Zoom ST Lead** display consists of one expanded average complex with superimposition of current and reference data. ST level and slope measurements are also displayed. The lead used for the expanded average complex can be defined as any of the 12 leads or dynamic in which the lead with the most significant change in ST is automatically displayed. Uncheck the box to view only rhythm (9 seconds) and average complexes for all 12 leads. The **Context View** displays 1-minute of a single lead when enabled. The phase or stage together with the time is displayed in green text. Choose the displayed lead using the drop-down menu below the selection. A scroll bar in the Context View is used to move back and forward in time from pre-exercise through the recovery phase. When scrolling back in time, the display will return to the current time after 60-seconds when there is no activity. Stored 12-lead ECGs are highlighted with a blue box that can be edited with a single mouse click. The blue box changes to red with an **X** in the upper right corner. Click on the **X** to delete the stored ECG. Double-click the ECG to add an event and choose a label from the Event drop-down list. A bookmark label allows a quick selection that can be edited during post-test review. Configure the running trends display to show **+ Running Trends** only, **+ Last Rhythm Event** only, or **+ Event on Trends** only which will display the last event over the trends for a period of 10 seconds. After 10 seconds the rhythm event disappears and the trends are displayed. The rhythm event is displayed in 3 user-defined leads.

Function Key	Action and Description
ST LEAD [F8]	Used to select a specific lead for the expanded QRS complex and ST display. The ST Lead pop-up window will appear; click **OK** to save changes. • Manually select any of the 12 leads. The lead is displayed until another lead is selected. • Select **Dynamic** and the lead with the most significant ST change is displayed and changes automatically. • Select **Max Depression/Max Elevation** and the lead with the maximum ST depression or elevation is displayed. • Select **Max ST/HR Index** and the lead with the maximum ST/HR index at that moment is displayed. *NOTE: When a lead is selected as the Zoom ST Lead, its ST change trend is also displayed in the trend window.* To change the time interval between the J-point and the ST measurement point, use the **J-ST** up/down arrows to select the desired interval. Adjust the QRS onset and offset any time after the ST is learned. Click **Manual Avg** to change the pop-up window; the current ST lead displays along with adjustment buttons for Isoelectric and J-Point. A spatial magnitude complex is displayed in the expanded average complex window that represents the summation of high-frequency signal magnitudes (vector sum) for all 12 leads. This allows a visual for adjustment of the QRS onset and offset using information from all 12 leads simultaneously. **Isoelectric:** Tick marks are displayed below the QRS onset of the spatial magnitude complex. The amplitude is defined as zero at QRS onset. The ST segment measurement is the amplitude difference between QRS onset and the measurement point after the J-point. To adjust the QRS onset, click on the left arrow to shift the tick marks to the left and click on the right arrow to shift the tick marks to the right. Each click represents a change of two milliseconds. **J-Point:** Tick marks are displayed below the J-point or QRS offset of the spatial magnitude complex. To adjust the QRS offset, click on the left arrow to shift the tick marks to the left and click on the right arrow to shift the tick marks to the right. Each click represents a change of two milliseconds. *NOTE: The interval between QRS offset and the ST measurement point will not be altered when changing the QRS offset.* Once adjustments are made and **OK** is selected, all ST measurements are updated onscreen and a warning symbol ⚠ appears near the displayed ST value in the right border. 12-lead ECGs obtained after a change will reflect the updated measurement points. During the Final Report phase, the QRS onset and/or the QRS offset can be adjusted retrospectively. After the adjustment, XScribe generates the final reports with all ST levels corresponding to the degree of QRS onset/offset adjustment. **Relearn** initiates an automatic relearn of a new dominant QRS complex. This is useful when a patient changes position or the QRS morphology changes. A dominant rhythm change (DRC) is displayed on the trends after a relearn.

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Function Key	Action and Description
COMPARE ^{F9}	Used to modify the measurement location of the J-point on the ST and ST Profile bar graph. The Compare pop-up window will appear allowing relocation of the J-point between 20 and 120 ms post J. Selecting an item from the **Event (F4)** list will increase the number of events that the current ECG can be compared to. Maximum number of compare conditions is six. Select the desired event for comparison reference and click **OK**. The 12 median beats and the zoomed ECG will update in comparison to the selected reference.
RHYTHM ^{F10}	Selected to run a continuous rhythm strip. A continuous 3-channel or 6-channel printout of the leads defined in modality settings. The rhythm button will change to **RHY LEADS.** As an example, clicking **RHY LEADS** switches the printout to the 6-channel frontal leads (I, II, III, aVR, aVL, aVF); a second click changes the printout to the precordial leads (V1, V2, V3, V4, V5, V6). The speed of the continuous rhythm strip is set in the modality settings or can be changed using **SOFTKEY (F6)**. To stop the printout, click on **STOP PRT** or **F12.** Continuous rhythm strips contain the patient's name, date, time, stage time, total exercise time, workload, lead labels, and calibration pulses. Generate continuous rhythm strips during Observation, Pre-exercise, Exercise, Recovery, and Final Report phases. A scheduled automatic 12-lead or manually generated event will interrupt the continuous rhythm strip; printing resumes once the 12 lead or event has printed.

Function Key	Action and Description

ECG [F11]	Selected to generate a 12-lead ECG printout during Observation, Pre-exercise, Exercise, Recovery, and Final Report phases. Printout configurations are based on definitions in modality settings.
	
	• ECG formats:
	    o 6x2 – 3.5 seconds of each lead, with median ST beats on
	    o 3x4 - 1.75 seconds of each lead, with median ST beats on
	    o 3x4+1 – 1.75 seconds of each lead + 7 seconds of one user-defined rhythm lead, with median ST beats on
	    o 3x4+3 – 1.75 seconds of each lead + 7 seconds of three user-defined rhythm leads, with median ST beats on
	    o 3x4+1 BCF – 1.75 seconds of each averaged lead + one real-time rhythm lead, with median ST beats on
	    o 3x4+3 BCF – 1.75 seconds of each averaged lead + three real-time rhythm leads, with median ST beats on
	    Or
	    o 6x2 – 5 seconds of each lead, with median ST beats off
	    o 3x4 – 2.5 seconds of each lead, with median ST beats off
	    o 3x4+1 – 2.5 seconds of each lead + 7 seconds of one user-defined rhythm lead, with median ST beats off
	    o 3x4+3 – 2.5 seconds of each lead + 7 seconds of three user-defined rhythm leads, with median ST beats off
	    o 3x4+1 BCF – 2.5 seconds of each averaged lead + one real-time rhythm lead, with median ST beats off
	    o 3x4+3 BCF – 2.5 seconds of each averaged lead + three real-time rhythm leads, with median ST beats off
	  * One average complex for each of the 12 leads.
	  * Superimposed expanded average complex with reference data (presented as a dotted line for the ST segment and T wave). User selectable as either On or Off.
	
	The patient's name, date, time, stage time, stage number, total exercise time, workload, lead labels, ST values, and calibration pulses.

STOP PRT [F12]	Will stop a continuous rhythm strip printout. Use of Stop Print does not stop any system function.

System Display

Total Exercise Time   **Stage Time/ Stage**   **Protocol Name**   **Treadmill Speed And Grade %**   **Patient Name, Sex, ID and DOB**

Heart Rate, Target HR and Max HR % of Target HR graph

ST Level

Blood Pressure and time/phase acquired

SpO$_2$ Level

METs

ST/Index

Double Product

Notes

Real-Time ECG in 6x2 format   **ECG Averages**   **Zoomed ECG**   **HR Mets BP**

Context View   **ST Profile**   **ST Level**

Total Exercise Time   **Stage Time/ Stage**   **Protocol Name**   **Ergometer Watts/ Target HR/Max HR/ Percent Target**   **Patient Name, Sex, ID and DOB**

The XScribe display is organized to provide the clinician quick access to important and critical information.

Feature	Description
Time Display	• The pre-exercise clock starts upon phase entry. • Time clock resets to zero at the start of the Exercise phase. At Exercise phase end, the exercise time clock freezes. • At Exercise phase end and entry into Recovery, the exercise time clock is frozen and the recovery clock begins.
Stage Display	The exercise and recovery stage numbers are displayed.
Protocol Name	Specific protocol name currently being used for the stress exam is displayed.
Treadmill Speed/Grade %	The MPH or KPH (speed) and percent (elevation/grade) for the current workload settings of the treadmill are displayed when using a treadmill protocol. *NOTE: When the treadmill is off and a printout is made, dashes will print next to MPH and %.*
Watts	The current workload settings of the ergometer are displayed when using an ergometer protocol. Watts is displayed from 0 to 999. *NOTE: If the ergometer is off and a printout is made, dashes will print next to watts.*
Patient Name, Sex, ID, Date of Birth	Entered patient demographics are always displayed.
Heart Rate, Target HR and Max HR, and % of Target HR	Calculates and displays the HR derived from rhythm leads V1 and V5 with lead II as a confirmation lead using a sliding average window of 16 consecutive R to R intervals. Target HR calculation with treadmill and pharmacological testing is based on age and percent of maximum predicted HR using 220 minus age, or 210 minus age, or 210 minus (0.65 x age). Maximum workload with ergometer testing is calculated using the following formula: Max Workload Men = 6.773 + (136.141 * BSA) – (0.064 * Age) – (0.916 * BSA * Age) Max Workload Women = 3.933 + (86.641 * BSA) – (0.015 * Age) – (0.346 * BSA * Age) Where BSA = 0.007184 * (Height $^{0.725}$) * (Weight $^{0.425}$) Age in years / Height in cm / Weight in kg Target HR or Target Workload can be calculated from a range of 75% to 100% in increments of 5%. Clinicians may also manually enter the target value they would like the patient to obtain.

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Feature	Description
ST Level	Displays ST value for the on-screen average complexes. When **BEGIN** or **F1** is selected, XScribe will acquire and analyze the incoming ECG data to develop the dominant beat template. **ST LEARN…** displays during this process and is replaced by the measured ST level once the dominant template is established. *NOTE: When the Source Consistency Filter (SCF) is enabled, it is also learning at the start of the Pre-exercise phase. It is very important that the patient is in the position of exercise, is relaxed, and remains very still during this learning process.*
Heart Rate, METs, BP and ST Level Trends	Trends can be enabled/disabled on display. Continually updated every 10 seconds.
Zoomed ST Lead	One expanded average complex with superimposition of current and reference data. ST level in mm or µV and ST slope measurement in mV are also displayed. The zoomed ECG can be enabled/disabled on display. *NOTE: A click on the Zoomed ECG will display horizontal ST reference lines.*
ST Profile	Displays ST value for the on-screen average in a graph format. When **BEGIN** or **F1** is selected, XScribe will acquire and analyze the incoming ECG data to develop the current ST level at the beginning of the procedure. The graph displays the current ST levels in black and the reference levels in green.
Blood Pressure Display	Displays last entered or acquired BP reading. When value is updated, background display will turn yellow and an audible beep will sound. Once value is displayed on screen, it will be maintained along with a timestamp as to when it was last acquired. Value will not change until next manual or automatic entry. *NOTE: The values for a <u>new</u> BP measurement should be entered using the* **BP** *or* **F3** *key only. Users may edit the existing value for the last BP measurement displayed by placing the cursor in the BP display field, clicking the right mouse key, and changing the value. When BP values are edited, the existing values for the measurement are erased and overwritten in the system and summary reports.*
SpO$_2$ Level	Displays on-screen SpO$_2$ average value in percent. Value is updated every 15 seconds when the unit is attached to a manufacturer approved device.
METs	Displays the estimated metabolic equivalents (METs). Calculation updates every 10 seconds throughout the first two minutes of each stage. At the end of the second minute, maximum METs should be obtained and the value will be maintained until stage completion. At the beginning of the next stage, a linear progression of METs calculations will begin to the completion of the first two minutes of the next stage.
ST/HR Index	Calculates and displays the ST/HR index value in µV/bpm. *NOTE: ST/HR index value displays only when XScribe detects a change in HR with an increase of greater than 10% and ST depression greater than 100 µV.*

Feature	Description
Double Product (DP)	Calculates and displays current Double Product value (systolic BP x HR) once BP is manually or automatically entered. DP value updates dynamically when next BP is obtained and is maintained on display in relation to the BP timestamp. *NOTE: If a DP cannot be calculated due to lack of HR or BP, dashes are displayed.*
Notes	Allows for the entry of free text notes; enter up to 8 lines of 64 characters.
ECG Averages	All 12 averaged ECG complexes are displayed with superimposition of current and reference data. ST level and slope measurements are also displayed.
Real-Time ECG	3 leads, 6 leads, 12 leads (12x1), or 12 leads (6x2) are displayed in real time with their respective lead labels.
Context View	Displays 1-minute of a single ECG lead when enabled. The phase or stage together with the time is displayed in green text. Stored 12-lead ECGs are highlighted with a blue box.

CONDUCTING A STRESS TEST

Patient Preparation

Before attaching the electrodes, ensure the patient fully understands the procedure and what to expect.
- Privacy is very important to ensure the patient is relaxed.
- Explain the method to be taken for skin preparation and electrode application.
- Make sure the patient is comfortable and that the arms and hands are relaxed.
- Once all the electrodes are attached, ask the patient not to talk to assist in good baseline ECG acquisition.

Preparing Patient Skin

Thorough skin preparation is very important. There is natural resistance on the skin surface from various sources such as hair, oil, and dry, dead skin. Skin preparation is intended to minimize these effects.

To prepare the skin:
- Shave chest hair at the electrode sites if necessary.
- Clean skin with alcohol or warm, soapy water to remove body oils, lotion and powder.
- Thoroughly dry the skin.
- Gently exfoliate the skin with an abrasive pad where the gel center of each electrode will be applied.

Patient Hookup

Attach the electrodes to the lead wires on the patient cable or acquisition module before attaching electrodes to the patient.

To Attach the Electrodes

1. Firmly attach each lead wire to an electrode.

2. Place the gel area of the electrode over the center of the prepared area using the positioning illustrated in figure 5-1; press the adhesive ring into place. Avoid pressing the center of the gel area.

3. Place right arm (RA) and left arm (LA) leads close to the shoulder on the clavicle bone.

4. Place right leg (RL) lead on the sternum. This lead can be placed in another stable location for patient comfort.

5. Place left leg (LL) lead on the lower left side of body, as close to the hip as possible, on the iliac crest (original Mason-Likar position), or on the lowest rib on the left side of the chest (modified Mason-Likar position).

6. Ensure electrodes are securely attached to the skin. To test electrode contact, lightly tug the lead wire to check adhesion. If the electrode moves freely, the site should be prepped again. If the electrode does not move easily, a good connection has been obtained.

⚠ *NOTE AND CAUTION: Proper skin preparation is very important. Poor ECG signal quality is the main cause for incorrect beat and arrhythmia detection. RA and LA are susceptible to muscle interference. LL lead is susceptible to interference from clothing, a belt, and movement.*

Choose the best locations for limb lead placement according to body type. Avoid muscular and loose, flabby skin locations.

Depending on front end type, prevent pulling on the lead wires by means of strain relief as needed with use of surgical tape or a stress vest available from most medical supply companies.

Figure 5-1
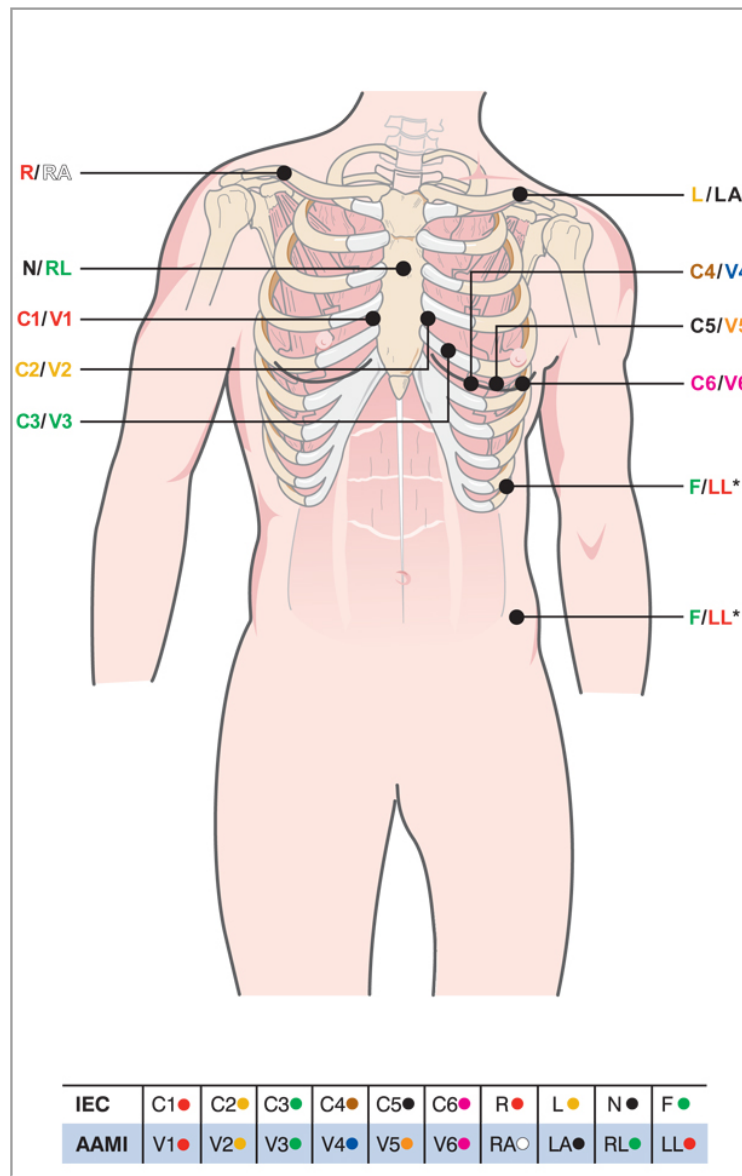
⚠️ *NOTE AND CAUTION: Placement of the Left Leg (LL) electrode in the original Mason-Likar position increases the similarity of the acquired ECG with a standard 12-lead ECG and is therefore recommended; however, clothing may interfere with this position and increase the amount of artifact. The modified position may decrease the sensitivity of inferior ECG leads and cause axis shift with respect to the standard 12-lead ECG. Accurate skin preparation and suitable clothing are the most important factors in excessive artifact prevention.*

NOTE: The Right Leg (RL) electrode may be positioned in any location least subject to motion artifact according to clinician preference and specific test requirements.

Patient Hookup Summary Table

AAMI Lead	IEC Lead	Electrode Position
V1 Red	C1 Red	On the 4th intercostal space at the right sternal border.
V2 Yellow	C2 Yellow	On the 4th intercostal space at the left sternal border.
V3 Green	C3 Green	Midway between V2/C2 and V4/C4 electrodes.
V4 Blue	C4 Brown	On the 5th intercostal space at the left midclavicular line.
V5 Orange	C5 Black	Midway between V4/C4 and V6/C6.
V6 Violet	C6 Violet	On the left midaxillary line, horizontal with V4 electrode.
LA Black	L Yellow	On the left clavicle.
RA White	R Red	On the right clavicle.
LL Red	F Green	Place on lower left side of body, as close to the hip as possible, or on the lowest rib on the left side of the chest; see Note and Caution*.
RL Green	N Black	Place in the area of the upper third of the sternum.

Strain Relief and Artifact

Because the patient is ambulatory and will be exercising, steps must be taken to ensure the best possible ECG quality. The ECG quality may look good at rest but may not when the patient begins to exercise.

Artifact is frequently associated with poor electrode contact, poor skin preparation, and poor lead positioning. Noisy ECG waveform, distortion of ECG complexes, wandering baseline, fuzzy ECG tracing, small ECG complexes, false high heart rate values, and false arrhythmia detection all lead to inaccurate stress testing results.

LeadForm Patient Cable and Strain Relief

Mortara's patented LeadForm patient cable is light in weight, so taping the lead wires should not be necessary. Use of the proper LeadForm patient cable size, standard or XL, will prevent pulling on the electrodes.

> **TIP**: *Provide strain relief where the ribbon cable meets the plug into the X12+ transmitter by creating a loop held in place by the carry case Velcro tab.*

WAM and AM12 Strain Relief

The wireless (WAM) or wired (AM12) acquisition module leadwires may pull on the electrode sites during exercise if not secured properly.

1. Route the upper body leadwires upward, and then curve downward.

2. Creation of a curve in all remaining leadwires will prevent pulling on each electrode.

3. Affix the leadwires with adhesive skin tape as shown that will not leave a residue on the leadwire.
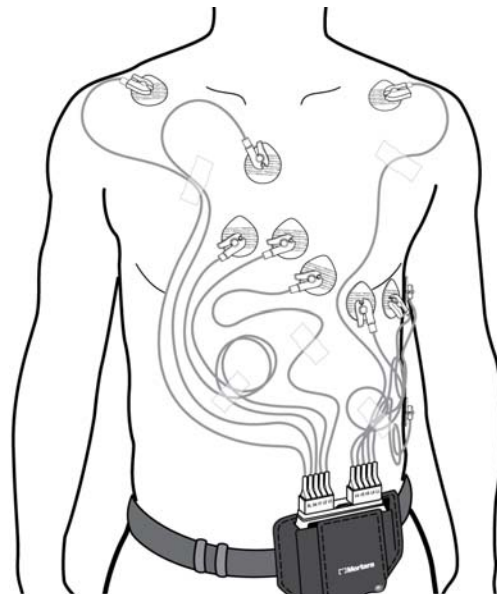
4. As an alternative, a stress vest available from most medical supply companies may be used.

Start a Stress Test

Select the Start a Stress Test icon to open the orders list.
- When scheduled orders exist for today's date, Today's Exam tab will be displayed listing those patients.
- When scheduled orders exist for any day other than today's date, the All Scheduled tab will be displayed listing those patients.
- When no scheduled orders exist, the Search Patient tab automatically opens.

Select **Open Legacy** to review exams that have been archived by previous versions of XScribe. See *Open Legacy Exams* in this section.

Scheduled Order(s)

When there is an existing order for the patient, highlight the patient in the Start a Stress Test window and click on **Start Exam**.

The Exam Data Entry window is displayed populated by the entered patient demographics.

Age is automatically calculated from the date of birth (DOB) if entered. When DOB is not entered, enter the age for Max HR calculation.

Target HR is calculated according to the Max HR and percent selected (75% to 100%) to determine a submaximal HR.

Max Workload and Target Workload are calculated using age, height and weight. These values are used for ergometer exams.

> *NOTE: Max HR, Target HR, Max Workload, and Target Workload values can also be manually entered as desired.*

Click **Confirm** after demographic information is complete and the observation phase of the stress exam is displayed.

No Scheduled Order(s)

When no scheduled orders exist, the Search Patient tab automatically opens.

Search for existing patients in the database using the drop-down fields. Up to two filters can be selected. Click on **+** to add another set of criteria for the search. When done, click on **Search**.

Drop-down one:
- Patient ID
- Last Name
- Acquisition Date/Time
- Technician

Drop-down two:
- Equal To
- Start With
- More Recent Than
  - Acquisition date selection only

When no match is found, select **New Patient**.

The Exam Data Entry window will open allowing for entry of exam demographics.

A single group may be used for all recordings or use the **Group** drop-down menu to choose the desired name.

Age is automatically calculated from the DOB if entered. When DOB is not entered, enter the age for Max HR calculation.

Target HR is calculated according to the Max HR and percent selected (20% to 100%) to determine a submaximal HR.

Max Workload and Target Workload are calculated using age, height and weight. These values are used for ergometer exams.

> *NOTE: Max HR, Target HR, Max Workload, and Target Workload values can also be manually entered as desired.*

Enter date of birth by typing MM/DD/YY or DD-MM-YY according to the computer regional settings, or by clicking on the calendar icon. Select the decade and the year; use the left/right arrows to scroll the year, the month, and the day to populate the field. Age will be automatically calculated.

XScribe will remember list items such as Indications, Medications, Procedure Type, and Referring Physician as they are entered. The added items will be available for future selection. Enter text or choose items from the drop-down menu and then click on the green checkmark to enter. Use the red **X** to delete the selected item. When there are multiple entries, items can be moved up or down by using the green arrow keys.

Some fields are not available (grayed) when patient demographics are attached to existing exams in the database or are ordered by an external system.

Click **Confirm** after demographic information is complete and the observation phase of the stress exam is displayed.

Observation Phase and Local Settings

Users will select the exam settings, profile and protocol within the initial patient hookup and observation display. ECG ^{F11} and continuous Rhythm ^{F10} can be printed during this phase but will not be stored with the exam.

Local Settings

Select **Local Conf** or press **F2**. Choose from the following:

Front End: WAM*, AM12, X12+**, or M12A

Channel: RF channel entry when X12+ is selected

Exer Equipment: Trackmaster 0.5, Trackmaster 1.5, No Sensing; Ergoline Ergometer, or Lode Ergometer

BP Equipment: Manual, Ergoline BP, SunTech BP, or Lode Ergometer BP

AC Frequency: 50 or 60

Selected settings are remembered when the next exam is started.
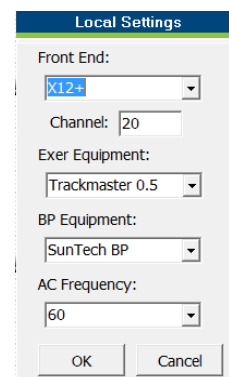
*When WAM is selected as the Front End, **PAIR** ^{F8} button appears. Refer to the WAM user manual for pairing instructions, notes, and warnings.

** When X12+ is selected as the Front End, the RF Channel value entry is enabled.

Softkey and Using Filters

Select **SOFTKEY** or press **F6** to set filters, gain, continuous (Rhythm Strip) print speed, sync lead for ECG output, and arrhythmia printout on or off. A Manual BP checkbox is available when Automatic Blood Pressure is selected at start of test.

Filters listed below may be enabled or disabled at any time during the patient test:
- Source consistency filter (SCF)
- 40 Hz filter
- AC filter

Source Consistency Filter (SCF)

Mortara Instrument's patented Source Consistency Filter (SCF) is an exclusive feature used for reducing noise associated with stress testing. Using the morphology learned during the Pre-exercise phase or during a relearn operation, the SCF distinguishes between noise and the actual signal in each of the 12 leads. This filtering reduces muscle tremor noise, low-frequency and high-frequency noise, and baseline artifact while preserving diagnostic-quality waveforms.

The default state of the filter (enabled or disabled) is determined by the modality settings. When the filter is on, SCF© appears in the lower border of the real-time ECG display. This setting can be changed at any time during a stress exam.

> *NOTE*: *When the SCF is on, attempt to maintain a motionless patient in the position that will be assumed during stress testing while the SCF is learning. This will ensure a clean and clear signal during the stress test. A message will appear at the top right-hand side of the display with notification that the SCF filter is in the process of learning. Once this message disappears the SCF has completed its learning process indicating that it's okay for the patient to move.*

AC Filter

The AC filter removes line frequency noise by removing frequencies in a narrow band around 60 Hz (domestic) or 50 Hz (international). The default state of the filter (enabled or disabled) is determined by the selected profile. When the filter is on, 60 Hz or 50 Hz appears in the lower border of the real-time ECG display. This setting can be changed at any time during a stress exam.

40 Hz Filter

The 40 Hz filter is a plot filter, meaning that it affects only the plotted/printed information similar to a 40 Hz filter on an electrocardiograph. The default state of the filter (enabled or disabled) is determined by the selected profile. When the filter is on, 40 Hz appears in the lower border of the real-time ECG display. This setting can be changed at any time during a stress test.

To enable/disable the filters:

1. Select **SOFTKEY** or press **F6** to display the Softkey pop-up window.
2. To enable the filter, select the filter check box; to disable the filter, clear the check box.
3. Click **OK** to save the change.

⚠️ **WARNING**: *When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.*

Protocol Selection

The appropriate Protocol selection is identified prior to starting the exam using the drop-down menu in the upper left corner of the Observation phase display.
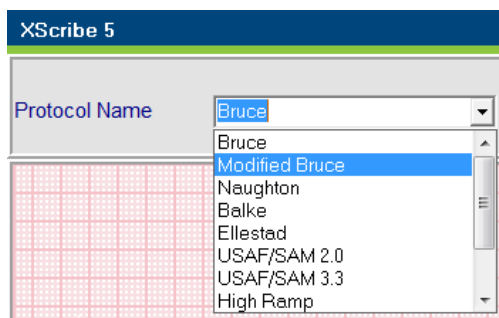
Protocols can be modified using the Modality Settings located in the System Configuration menu. This is explained in the System Configuration section of this user manual.

The observation window displays the lead placement diagram and acquired ECG waveforms. By default, XScribe displays real-time ECG waveforms in a 6x2 format.

- Examine the 12-lead rhythm display for artifact (noise), or baseline drift. Re-prep and replace electrodes as necessary to obtain satisfactory tracings. (See *Patient Preparation* in this section.)

- If a lead fail condition exists in any of the displayed leads, a square wave appears for that lead on the display and the lead in fault displays in red letters in the upper right corner of the screen together with a LEAD FAIL message. In instances of simultaneous, multiple lead fail conditions, XScribe gives display priority to the limb leads, followed by leads V1 through V6.

1. Highlight and select the desired **Protocol**.

   NOTE: Manual control of any exercise protocol during the test is always available; however, this may cause the XScribe to exit the current protocol. Selecting pause will halt the advancement of the current stage. The protocol can be resumed at the stage and time where it was paused. The pause will be documented in the report. An alternate protocol can be selected during any stage allowing entry into a new protocol automatically advancing the test to the <u>beginning</u> of the next stage selected.

   As an example, if the test is in stage three of a Bruce protocol and a pharmacological protocol is preferred, XScribe will advance to the beginning of stage four of the pharmacological protocol.

2. Select **Begin** or press **F1** when ready to enter the Pre-exercise phase.

Conducting a Stress Test

Pre-Exercise Phase

The XScribe acquires ECG data to develop the patient's cardiac template and uses the template for arrhythmia detection. ST learning begins and the SCF filter begins to learn upon entry into Pre-exercise.

> *NOTE: Attempt to maintain a motionless patient in the position that will be assumed during stress testing while the SCF and ST are learning. This will ensure a clean and clear signal during the stress test. A message will appear at the top right-hand side of the display with notification that the SCF filter is in the process of learning. Once this message disappears the SCF has completed its learning process indicating that it's okay for the patient to move.*

The phase time clock starts and the HR and ST level for the expanded lead displays along with the expanded average complex.

During the Pre-exercise phase, the user should:

1. Enter the patient's baseline BP.
   - Entry of three characters in the systolic field automatically advances the cursor to the diastolic field.
   - An automatic timestamp as to when the NIBP was entered will appear below the diastolic pressure.

2. Obtain event documentation (i.e., supine, standing, and hyperventilation 12-lead ECGs) as desired.
3. Instruct patient on the proper technique for using the exercise equipment.
4. If desired, change the exercise display options by selecting **Format** and the preferred display options.

Acquiring a Resting ECG

XScribe allows for the acquisition and printing of a 12-lead resting ECG while the patient is in a supine position. A Mason-Likar labeled ECG may also be acquired as a baseline for comparison throughout the exam. Enable or disable interpretation by checkbox in the Pre-exercise phase of the exam by using **Event** or **F4**.

1. Have the patient rest on a bed or exam table. If the exam table is narrow, tuck the patient's hands under his/her buttocks to ensure arm muscles are relaxed. Click on **EVENT**, select **Supine,** and then click **OK**.
2. After a few seconds, XScribe will print a full 12-lead resting ECG including measurements and interpretation text if so selected. The printout format is defined in the modality settings menu.
3. Have the patient stand and move to the treadmill or ergometer. Click on **EVENT**, select **Standing** or **Mason Likar**, and then click **OK**.

> *NOTE: When using a WAM or an AM12 front end for stress testing, the ECG and Rhythm Strip buttons on the module are not functional.*

Prior to starting the exercise portion of the test it is recommended that the ECG template be re-learned if the patient had been supine when the ST Learning occurred and moves to the standing position.

To avoid ECG template differences caused by postural changes, select **ST LEAD** or **F8**, then **MANUAL AVG/RELEARN**. The process takes approximately forty seconds.

> *NOTE: It is recommended to Abort the exam and Begin again if waiting more than one hour to begin exercise. This prevents unnecessary data storage, however previously stored full disclosure, ECG events, and BP values are not saved when an exam is aborted.*

Before beginning the Exercise phase of the test, instruct the patient to follow the appropriate steps below:

For Treadmill

1. Have the patient straddle the belt. (Turn the treadmill on only when the belt has been safely straddled). Highlight and click on **Treadmill**, and then click **ON** from the pop-up window. The treadmill starts at the pre-selected speed and elevation.

2. Patient should place hands on the handrail for stability and test the speed of the belt with one foot before transferring the other foot to the moving belt.

3. When acclimated to the movement of the belt, remind patient to keep body straight with head up. Wrists can rest over the handrail or arms at their sides as in a normal walking position.

4. Instruct patient to relax, using as little upper-body motion as possible, and stay near the front of the treadmill.

NOTE: When using a treadmill and an emergency occurs, depress the emergency stop button mounted on the handrail to stop the treadmill immediately.

For Ergometer

1. Have the patient sit on the ergometer seat. Highlight and click on **ERGOMETER**, and then click **ON** from the pop-up window. The ergometer starts at the pre-selected watts level.

2. Patient should place hands on the handlebars for stability and test the watts level of the ergometer before proceeding ensuring familiarity with the functional requirements during the test.

3. When acclimated to the ergometer, remind patient to keep their body straight with head up. Wrists can be rested over the handlebars as in a normal riding position.

Exercise Phase, Recovery, and Recovery End

Enter the Exercise phase of the stress test by clicking on **START EXE** or **F1**. The following will occur:

- The stage time clock and the total exercise time clock will start counting from 00:00.
- The treadmill or ergometer advances the workload according to the protocol definitions for the first stage of exercise.

1. Allow the XScribe to acquire ECGs at the defined times set by the current protocol.
2. Allow the automated NIBP device to obtain NIBP readings at the protocol defined times, or manually acquire and enter an NIBP value as required.
3. Enter notes and NIBP values; acquire manual ECGs or rhythm strips as required throughout the test.
4. Select **RECOVERY** or **F1** when the test is completed and the Recovery phase is to begin.
5. Select **END** or **F1** when the Recovery phase is complete.
6. Select **Yes** to confirm end of test or **Cancel** to return to the test. (The Test End confirmation is an optional feature that must be configured in the XScribe.)

About the Recovery Phase

Recovery is manually entered by clicking on **RECOVERY** or **F1**. The treadmill will change to the specified recovery speed and grade or ergometer to the specified watts level, and then turn off once the recovery period has been completed. The treadmill or ergometer can also be manually shut down by clicking on **Treadmill** or **Ergometer**, then **OFF**.

At the start of the Recovery phase, the stage time clock resets to zero, the exercise time clock freezes at the total exercise time amount, and an automatic printout generates (when moving from "Exercise" to "Recovery" a Peak Exercise printout is always generated regardless of settings). Menu items function in recovery as they did in exercise; however, the user can also add or edit the patient data and some final report fields (reasons for test end, symptoms, conclusions, technician, and reviewing physician information) in Recovery. BP values can be entered and acquired, events, and ECGs as they were entered during the Exercise phase of the test. XScribe generates automatic BP prompts and ECGs as programmed. 12-lead ECGs can be printed at any time by clicking on **ECG** or **F11**.   At the end of the Recovery phase, click on **End** to enter the Final Report phase. If configured to, XScribe will ask "Are you Sure?" Select **Yes** to confirm end of test or **Cancel** to return to the test.

Final Report Phase (Report Manager with Summary Statistics)

When the Recovery phase is ended, XScribe advances to the Report Manager display.

- A real-time, 7.5-second ECG channel displays in the lower left-hand portion of the screen.
    - The displayed lead can be changed to a different lead
    - A 12-lead ECG or rhythm strip can be printed
- Summary section presents total exercise time, maximum speed, and maximum grade or watts as well as leads with greater than 100 μV of ST change.
- Max values section presents Max HR, Target HR and METs achieved. Max values are followed by Double Product, maximum systolic and diastolic BP.
- Max ST values section presents elevation, depression, total change, and ST/HR Index.
- Conclusions section allowing entry of Diagnosis, Reasons for End, Symptoms, Conclusions, and Technician using free-text or drop-down lists.

Duke Score and FAI% when applicable:

Percent of Functional Aerobic Impairment, or FAI %, is present only when a Bruce protocol has been conducted.

The Duke Score, a quantitative exercise treadmill score for predicting prognosis at Duke University, is present only when a Bruce protocol has been conducted and the patient presents ST change during the exam. Clinical assessment of the Duke Score can be chosen from a drop-down list with the following selections that will affect the resulting value:

- No angina
- Non-limiting angina
- Exercise-limiting angina

Quick Start: System Selection to Start a Stress Test

Click on this icon to open a window presenting Today's or All Scheduled exams. The Search Patient tab is selected when no exams have been ordered.

Highlight the desired patient and select the Start Exam button.

When the patient is not listed, select the Search Patient tab to see if the patient exists in the database using the search criteria selections.

When the patient is not found, select the New Patient button to open the Exam Data Entry window and then enter the demographics and test information.

Edit or add information as needed and then select the Confirm button. The XScribe observation phase begins.

Quick Start: System Display during the Observation Phase

Protocol Selection

Protocol Name

Patient Name, Sex, ID and DOB

Heart Rate, Target HR and Max HR
% of Target HR graph

ST Level

Blood Pressure and time/phase acquired

SpO₂ Level

METs

ST/Index

Double Product

Abort

Real-Time ECG in 6 x 2 format

Lead Placement Diagram

RF power with wireless options

Protocol Selection and Name

Choose the appropriate protocol from the drop-down list. The selected Protocol Name is displayed to the right.

Functions Keys

BEGIN ^{F1} starts the Pre-exercise phase.

LOCAL CONF ^{F2} allows selection of the front end type (WAM, AM12, X12+, M12A), exercise equipment, BP equipment, and AC frequency for this exam.

PAIR ^{F8} allows pairing with the WAM and only appears when WAM is selected as the front end.

SOFTKEY ^{F6} allows selection of various settings for this exam.

RHYTHM ^{F10}, **ECG** ^{F11}, and **STOP PRT** ^{F12} allow printouts of continuous rhythm, printout of a 10-second 12-lead ECG, and stopping the continuous rhythm printing.

ABORT ^{ESC} cancels the observation phase and returns the user to the Start a Stress Test window.

Quick Start: System Display during the Observation Phase

Protocol Selection

Protocol Name

Patient Name, Sex, ID and DOB

Heart Rate, Target HR and Max HR
% of Target HR graph

ST Level

Blood Pressure and time/phase acquired

SpO₂ Level

METs

ST/Index

Double Product

Abort

Real-Time ECG in 6 x 2 format

Lead Placement Diagram

RF power with wireless options

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SOFTKEY [F6] allows selection of various settings for this exam.

Quick Start: System Display during the Pre-exercise Phase
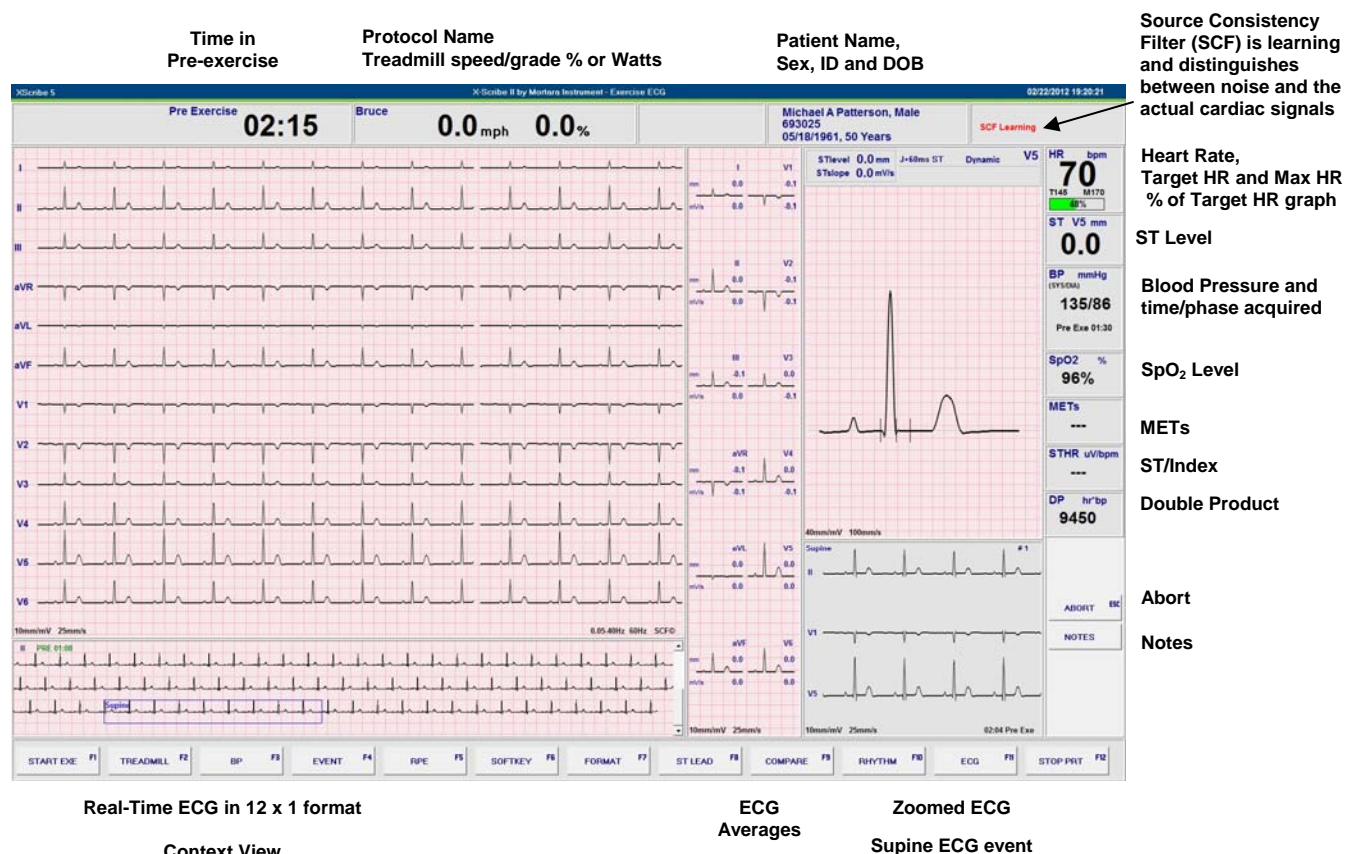
Time in Pre-Exercise, Protocol Name, Treadmill Speed/Grade %

The pre-exercise clock starts and the **ST** and **SCF Learning** processes start upon entry into this window.

NOTES allows free text entry

Functions Keys

START EXE [F1] ends pre-exercise and starts the exercise phase.

TREADMILL [F2] allows control of the treadmill. The Treadmill pop-up window will appear.

BP [F3] allows entry of a manual BP measurement or starts/stops an automatic BP measurement.

EVENT [F4] allows selection of an event from the drop-down menu to print and store a 12-lead ECG.

RPE [F5] allows selection of the patient's rate of perceived exertion level.

FORMAT [F7] allows access to all available screen configurations for the exercise profile display.

ST LEAD [F8] is used to select a specific lead for the expanded QRS complex and ST display.

COMPARE [F9] is used to modify the measurement location of the J-point on the ST and ST Profile bar graph.

Quick Start: System Display during Exercise Phase

Total Exercise Time   Stage Time/Stage   Protocol Name   Treadmill Speed/Grade % or Watts   Patient Name, Sex, ID and DOB

Heart Rate, Target HR and Max HR % of Target HR graph

ST Level

Blood Pressure and time/phase acquired

SpO₂ Level

METs

ST/Index

Double Product

Notes

Real-Time ECG in 6x2 format   ECG Averages   Zoomed ECG   HR Mets BP ST Level

Context View   ST Profile
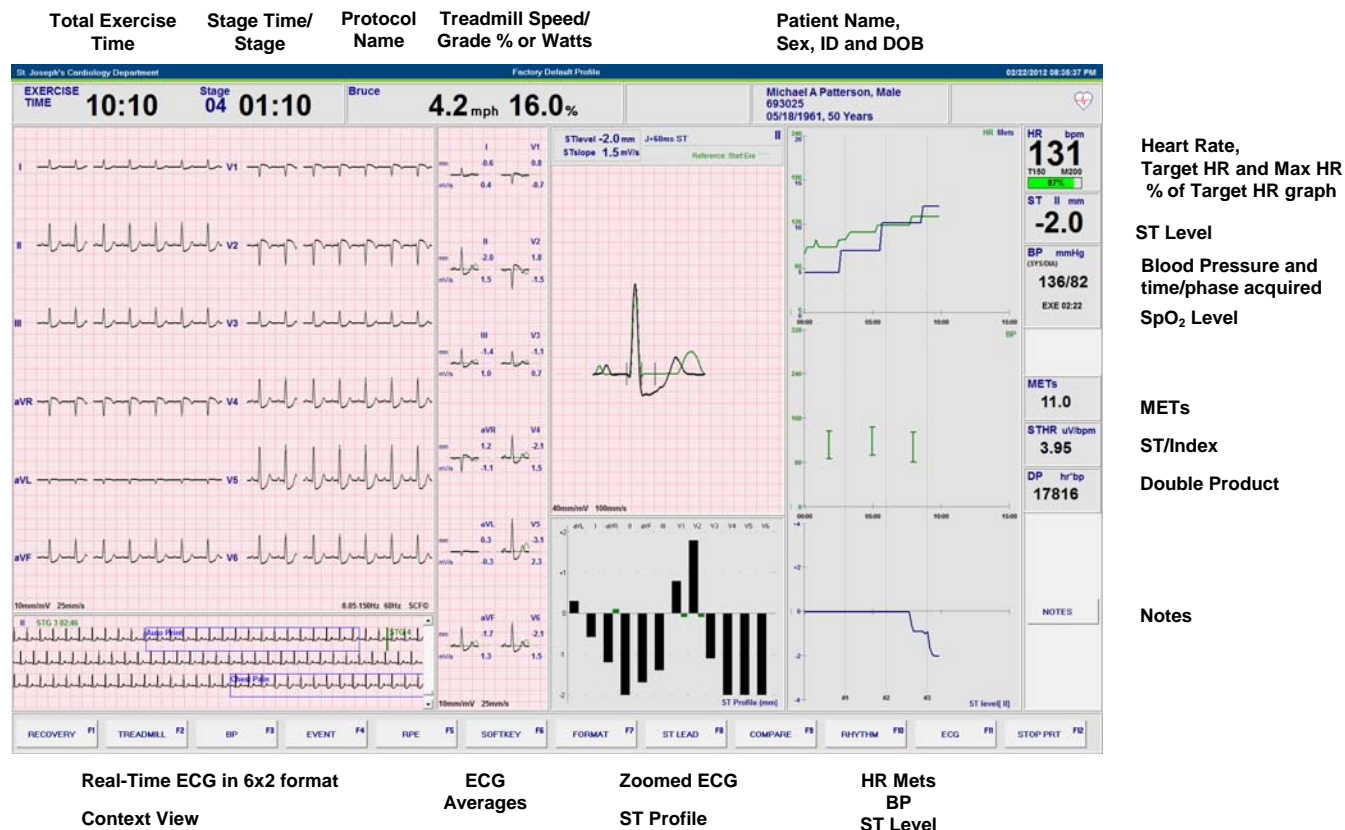
Total Exercise Time

Time clock resets to zero at the start of the Exercise phase. At Exercise phase end, the exercise time clock freezes.

Exercise Stage Time/Stage

Stage time clock starts at zero and resets to zero at the start of each new exercise stage or when workload is manually changed. The exercise stage number is also displayed.

Protocol Name

Specific protocol name currently being used for the stress exam.

Treadmill Speed/Grade %

Displays the MPH or km/h (speed) and percent (elevation/grade) for the current workload settings of the treadmill.

Heart Rate, Target HR and Max HR, and % of Target HR

Displays the target (THR) and maximum heart rate (MHR) calculations. Graph shows percent of achieved THR.

Function Key

RECOVERY ^{F1} ends exercise and starts the recovery phase.

Quick Start: System Display during Recovery Phase

Total Exercise Time	Recovery Time/ Stage	Protocol Name	Treadmill Speed/ Grade % or Watts	Patient Name, Sex, ID and DOB

Real-Time ECG / Context View · ECG Averages · Zoomed ECG / ST Profile · HR Mets / BP / ST Level

Heart Rate, Target HR and Max HR % of Target HR graph · ST Level · Blood Pressure and time/phase acquired · SpO2 Level · METs · ST/Index · Double Product · Patient · Comments
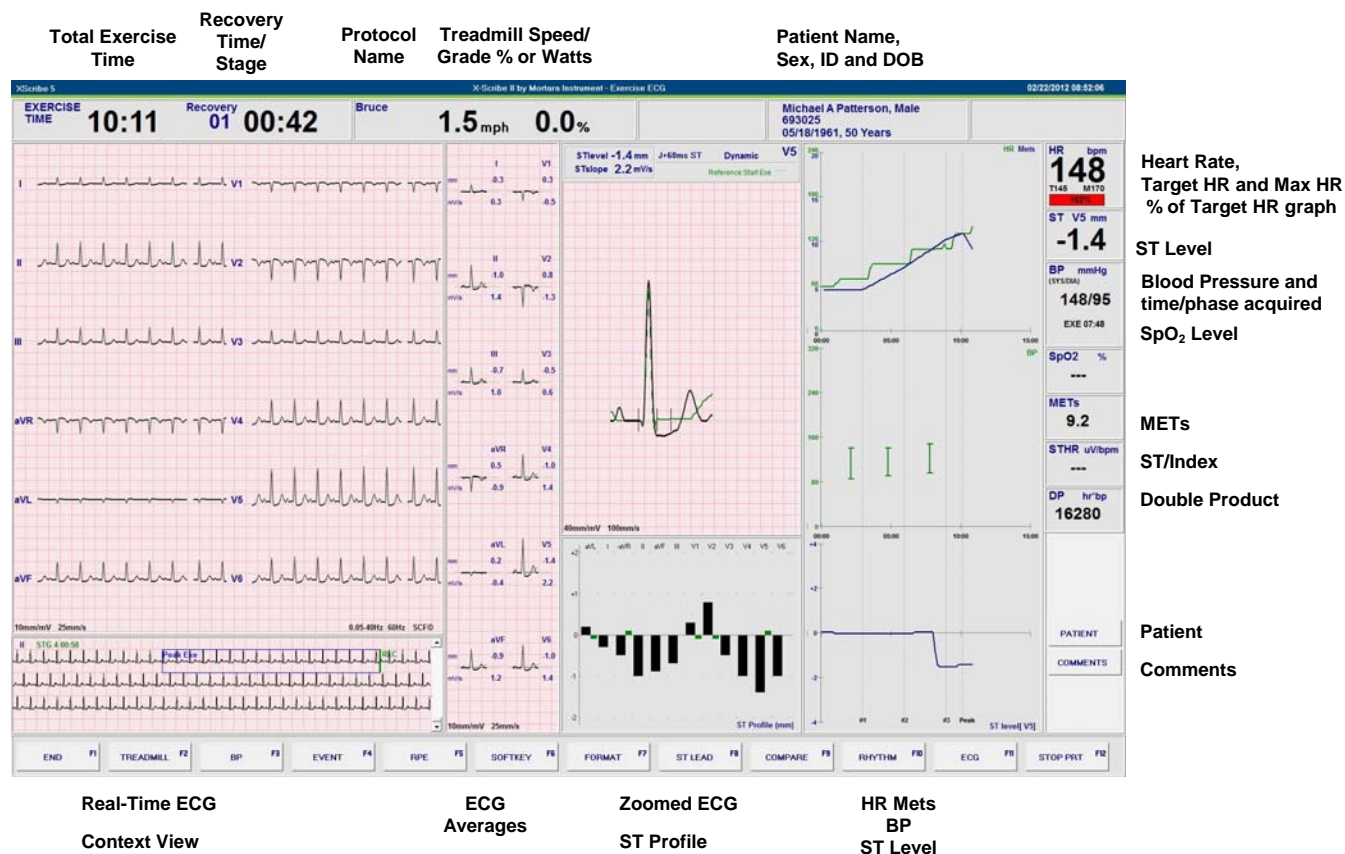
Total Exercise Time

At Exercise phase end, the exercise time clock is frozen.

Recovery Time/Stage

Recovery time clock starts at zero and resets to zero at the start of each new recovery stage. The stage number is also displayed.

Treadmill Speed/Grade %

Displays the MPH or KPH (speed) and percent (elevation/grade) for the current workload settings of the treadmill.

% of Target Heart Rate (THR)

Green colored graph changes from green to red when 100% THR is achieved and exceeded.

Function Key

END [F1] ends the recovery phase and opens the report manager display.

Quick Start: Report Manager Display

Summary   Max Values   Max ST   Conclusions

Patient Data

Print Options

Print Report
(copies)

Quick Print

Post Processing

and

Full Disclosure
Review

Exit

Real-Time ECG   ECG Lead and
                                 Printout

Patient Data

Click to open and edit patient demographics data.

Print Options

Choose desired printer, enable/disable grid (for laser printer), and summary by stage or by minute.

Print Report (copies)

Choose number of desired copies, enable/disable rhythm events, and click Print Report button.

Quick Print

Click selection to print a section of the final report.

Post Processing

Rhythm Events allows review and editing of stored event and arrhythmia snapshots.

J-ST and **ST Modify** allow a rescan using a different ST measurement point.

Review Exam allows playback of full disclosure exam data as if in real-time.

Page Review allows full disclosure event editing and navigation by event, trend click, and paging.

Exit

Closes report manager and prompts for a final exam update status.

Using Report Manager

Patient Data

If patient demographic data has not been entered, enter it now by clicking **Patient Data**. The Patient Demographics pop-up window will appear. Enter changes and then click the **OK** button to save and close.

Print Report

Use the Print Options drop-down menu to choose the desired printer. Check the Grid box to include grid when printing to a laser printer. Using the up/down arrow keys, choose the number of copies for each report (Summary, Trends, Average QRS, 12-Lead ECG, Rhythm Events) and click **Print Report**. Reports can also be printed from the exam database at a later date or time.

> *NOTE: The Grid checkbox, By Stage or By Minute selections, and the Rhythm Events checkbox settings are carried over and used by the Finalize Exam Update for the final report preview, printout, and PDF export.*

Quick Print

Quick Print buttons provide an alternative means for printing the following reports:

- **Patient ID**: Patient demographics.

- **Summary**: Summary report page, plus one average beat per lead from pre-exercise, peak-exercise, the point of maximum ST depression two minutes into recovery, and any documented events.

- **Trends**: Trends of the ST slope, ST level, HR, systolic and diastolic blood pressure, Double Product, speed and metabolic equivalents. Trends of the ST slope and ST level print for all leads defined as valid in the configuration.

- **Average QRS**: One average complex per lead for each minute or stage of exercise and recovery. 12 average complexes for all events, RPE ratings, automatic ECGs, manual ECGs, and arrhythmia episodes are included. Select the printout by stage or by minute using the drop-down menu.

- **12 Lead ECG**: 12-lead ECGs acquired during the Exercise and/or Recovery phase.

- **Arrhythmias** - All acquired arrhythmia events.

Post-Processing

Click **Rhythm Events** to display a snapshot of all events and captured arrhythmias. Use the buttons provided to Print, Re-label, or delete each snapshot. When a snapshot is deleted, a red message is displayed across the snapshot. All deleted snapshots are removed upon exiting. Select **OK** to exit and save all changes or select **Cance**l to exit without saving changes.

To rescan the stress test using a different ST measurement point, use the up/down arrows to define a new **J-ST** value and click **ST Modify**. All ST measurements will be adjusted to reflect the new measurement point.

Review Exam

This replay function allows the user to play back the entire stress test on screen. Exam review may take place immediately after ending the stress test or at a later date by selecting the patient from the directory. From the Report Manager screen, select **Review Exam**. ECG data is displayed at real-time speed and the following commands are available.

- Terminate the review session and return to Report Manager by selecting **END** or **F1**.
- Increase the playback speed up to 4 times the real time (x4) by selecting **FAST** or **F3**.
- Decrease the playback speed down to ¼ the real time (x 0.25) by selecting **SLOW** or **F4**.
- Toggle between play and pause by selecting **PAUSE** or **F5**.

Users can also navigate to a play back time by clicking on the trends graph during review mode. Select or set the test time by clicking on the trends graph; a vertical line indicates the current time into the test and the replay mode is terminated. Replay restarts at the position selected on the graph and represented by the vertical line.

Page Review

This function allows review of saved ECG events as well as the ability to relabel, print, and delete them. New ECG events may also be added. Page review may take place immediately after ending the stress test or at a later date by selecting the exam search icon. From the Report Manager screen, select **Page Review**. ECG data is displayed at the left half of the display and the following commands are available.

- Terminate the review session and return to Report Manager by selecting **END** or **F1.**
- Move the ECG back in 10-second increments by selecting **<<** or **F3.**
- Move the ECG forward in 10-second increments by selecting **>>** or **F4.**
- Add a new event by selecting **EVENT** or **F5** and then choose an event label or free text a new label.
- Change the Gain and Print Speed by selecting **SOFTKEY** or **F6** and choose from the drop-down lists.
- Customize the display by selecting **FORMAT** or **F7** and click on the check boxes and drop-down list.
- Change the ST Lead by selecting **ST LEAD** or **F8** and choose from the drop-down list.
- Enable a reference ECG by selecting **COMPARE** or **F9** and choose from the drop-down list.
- Print the displayed ECG to the default printer by selecting **ECG** or **F11.**

Display an ECG event by clicking on any of the saved events in the Event column to the right of the displayed ECG. Each saved event can be relabeled, printed, or deleted by highlighting it and then clicking on the respective button. Navigate to a specific exam time by clicking on the trend graph displayed through selection of FORMAT [F7]. A vertical dotted line indicates the current time into the test.

Conclusions: Narrative Template

A narrative conclusion can be inserted into the conclusions field though selection of the TEMPLATE1 checkmark button under this section. Additional templates can be created and added when requested from Mortara service personnel allowing their selection in the drop-down list. Upon selecting the desired template, the conclusions window will automatically populate with the appropriate summary data and will be included in the final report.

Conclusions: Acronyms

Click on the acronym icon to open a list of pre-defined acronyms and their statements. When the acronym is known, a forward slash followed by the acronym can be entered into the conclusion field (e.g. **/C10**) followed by a spacebar press.

Exit

Select the **Exit** button to save changes and close the Finalize Exam Update window. A window opens to display the exam information and prompts for selection of the status to **Finalize Exam Update**. The next logical status is displayed and can be changed using the drop-down menu. Select the **Cancel** button to cancel changes and close the Finalize Exam Update window.

Depending on how the modality settings are defined, there are four possible states:

1. Acquired indicates that the exam has been completed and is waiting for the clinician to confirm or modify results.
2. Edited indicates the reviewer has examined the results and prepared the exam for review.
3. Reviewed indicates that an authorized user has confirmed the results are correct.
   - When selected, a Reviewed By field will open for reviewer's name entry.

4. Signed indicates that the exam results are correct and no further processing is necessary.
   - When selected, both a Username and Password field must be completed by a user with signing authority (if Legal Signatures is set to yes in the system settings).

Selecting **Always** or **If Signed** from the Print Option selections will automatically generate a printout of the final report. The report will print to the default Windows printer when the selected state is updated.

Select **Update** to save the next state selection or **Cancel** to exit the window without saving any status change.

Preview opens the final report display.

Final Report Preview

To open a preview of the final report, select **Preview** from the Finalize Exam Update window. A preview is generated and the first report page is displayed.

Icon Tool Bar

Use the printer icon to open a Windows' printer dialog and choose defined printers with properties, print range, and number of copies. To print the final report, select **OK**.

Use the magnifying glass icon to choose Auto to fit the window or a percentage size for display.

Use the page icons to select a single-page, two-page, or four-page preview.

The number of report pages is shown as xx / xx (displayed page number per total pages). The red arrow keys allow you to preview the next page or the previous page, as well as move to the last page or the first page.

Use the settings icon to change the Average ECG Type to by stage or by minute, choose to enable/disable arrhythmia event printouts, and to print ECG with or without grid. Select **OK** to save your changes and update the displayed report.

> *NOTE: The Grid, By Stage or By Minute selections, and the Rhythm Events settings are carried over from the Report Manager dialog settings.*

Use the pink grid icon to toggle the ECG grid background on or off. An X appears when the background is off.

Sections

Use the checkboxes at the left of the display to choose sections for inclusion or exclusion in the final report. Select the arrows in the bottom left corner of the display to refresh the displayed report after a change is made.

Exit the Preview

Click on the red **X** to close the report preview and return to the Finalize Exam Update window.

Open Legacy Exams

Archived exams from XScribe software prior to version 5.xx may be opened, edited and reviewed with the current system software. Click on **Open Legacy** and browse to the directory where the legacy exams are stored. Once selected, all exams at that location are shown in a list.

Highlight the desired patient and double-click to open. The Exam Data Entry window opens displaying the existing demographics attached to the exam.

Click **Confirm** after demographic information is complete and the Report Manager screen is displayed.

Refer to *Using Report Manager* in this section.

Open a Legacy Exam

Legacy Exams List

Path	Exam Date	Last Name	First Name	Patient ID
E:\Archive\EXAM000	07/18/2011 10:13	Halverson	Frederick	715074
E:\Archive\EXAM001	07/13/2011 15:56	Rodriguez	Arnaldo	714824
E:\Archive\EXAM002	07/14/2011 08:42	SCHULZ	Brenda	10879
E:\Archive\EXAM003	07/18/2011 11:40	REYNOLDS	RAYMUND	128592
E:\Archive\EXAM004	07/14/2011 09:53	REYSON	STELLA	120401
E:\Archive\EXAM005	07/14/2011 10:48	ARLING	JENNY	123207
E:\Archive\EXAM006	07/14/2011 11:00	ESSLER	JANE	232072
E:\Archive\EXAM007	07/14/2011 15:41	TO	PENNY	8359
E:\Archive\EXAM008	07/15/2011 08:32	TATRO	FAITH	317152
E:\Archive\EXAM009	07/15/2011 10:10	ARRETTA	ANN	106810
E:\Archive\EXAM010	07/15/2011 10:58	WESTWOOD	ARNOLD	607047
E:\Archive\EXAM011	07/15/2011 11:59	OLSON	JANE	71424
E:\Archive\EXAM012	07/15/2011 14:55	HANSEN	HEDDA	103715
E:\Archive\EXAM013	07/18/2011 15:47	CARSON	ROBERTA	105222
E:\Archive\EXAM014	07/20/2011 12:35	SEXTON	SAMMY	945
E:\Archive\EXAM015	07/20/2011 16:08	LIS	GEORGE	645
E:\Archive\EXAM016	07/21/2011 09:53	NEWTON	RONDA	105242
E:\Archive\EXAM017	09/26/2011 11:31	IST	SAMPSON	87654

Exit

SYSTEM AND USER CONFIGURATION

Administrative Tasks

The IT and Clinical Administrator user will select the **System Configuration** icon to enter the XScribe administrative functions. All other users can enter this menu to access the Export Service Log task only.

A list of administrative tasks is presented to:

- Manage user accounts
- Manage personnel lists
- Manage Groups
- Manage archived exams*
- View audit trail logs
- Export service logs for troubleshooting purposes
- Configure system-wide modality settings
- Configure DICOM data exchange
- Configure XML and PDF data exchange
- Configure workflow
- Unlock exams

Task may not be available when operating with DICOM.
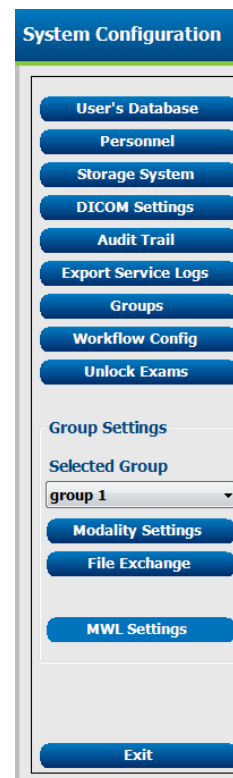
Manage User Accounts

User's Database

The IT administrator will select **User's Database** to create or remove user accounts, reset user passwords, assign permissions and groups for each user, and assign personnel entries for that user's selection. When a single sign-on is used, no user account and password creation is needed.

Personnel

Personnel is selected to add personnel that will be available in the Patient Information, Summary, and the Finalize Exam Update windows. Listed personnel can be assigned to each user account and will appear as selections for the logged-in user and in the appropriate final report fields.

Manage/Create Groups

Groups allow the administrator to group exams according to user access, reporting preferences (modality settings) and file exchange preferences. Any user can be assigned to multiple groups. A group definition can be copied and saved with a new name to create a second group, copying all settings and preferences of the existing group. Select **Groups** to make a change. Highlight a group. If you want to create a new group, enter a New Name and select **Copy Current**. A new group will be created with the settings of the highlighted group. Select the users that may have access to this group. If you want to rename a group without creating a new one, highlight the group, enter a Changed Name and select **Update**. Any created group can be copied, renamed and modified. The Default group (first in the list) can only be renamed. An unlimited number of groups can be created and modified.

XScribe Modality Settings and File Exchange paths can be uniquely defined for each individual group.

Groups, with exception of the Default group, can be deleted. All exams present in the database for the deleted group will be automatically assigned to the default group.

Modality Settings

XScribe modality settings are defined as default by the clinical administrator and are available for the user with editing permissions. The user is able to modify these settings on a per exam basis. Select the tab you wish to modify and click on **Save Changes** or **Discard Changes** to cancel changes before exiting**.**

Profile

The Profile for the factory default group can be modified according to physician and user preferences. A single profile that contains four tabs, described below and on the following page, is defined per group.

Real Time Display

Use the drop-down lists to select the **Waveform** speed, gain, **Lead Layout**, **Lead Mode** and 3 or 6 leads for display.

40 Hz, Source Consistency (SCF), and AC filters are enabled by check box.

⚠ **WARNING:** *When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.*

Choose the **Context View On** check box to enable and select the default lead from the drop-down list.

Standard or **Cabrera** lead mode can be selected.

Enable **ST-Lead** by checkbox and use the drop-down list to select the default for the 4x QRS window. When Dynamic is selected, the lead with the most significant ST change is displayed.

Choose the desired radio button for the **Event Display**. When the Trend Display is enabled, the HR, METs, NIBP, and ST running trends are displayed during the test.

Printout

Use the drop-down lists to select the ECG Print **Speed**, **Format**, and **Printer Type** for 12-lead ECG printouts. Grid can be enabled for windows printers. Choose the Rhythm Lead from the drop down and enable Zoom ST Lead and 12 Lead Average as desired.

Use the drop-down lists to select the Event Print **Speed**, **Format**, and **Printer Type**. Grid can be enabled for windows printers. Choose the Rhythm Lead from the drop down.

Use the drop-down lists to select the Continuous Print **Speed**, **Format**, and **Printer Type** for 12-lead ECG printouts.

Rhythm Events

Use the up/down arrows to select the maximum number of events stored during pre-exercise and PVCs per minute events, maximum couplets per minute, and maximum ventricular runs per minute during exercise.

Use **Add** or **Delete** to modify the Event Labels list.

NOTE: Bookmark, Supine, Mason-Likar, Standing, and Hyperventilation event labels are listed by default and cannot be edited or deleted.

NOTE: XScribe automatically detects an arrhythmia event. It is stored, can be displayed on trends display, and printed if Arrhythmia Printouts is enabled in the Softkey pop-up menu.

⚠ **WARNING:** *Do not insert more than 20 Event Labels.*

Miscellaneous

Use the drop-down lists to select the **Treadmill Speed Units** and **RPE Scale** type.

Choose Automatic or Manual **Blood Pressure** radio buttons.

Choose Normal or Bold **Waveform Print**.

Use checkboxes to enable display of ST/HR Index, Double Product, METS, SpO2, Duke Score and FAI Score.

Use drop-down lists to select Male Max HR formula, Female Max HR formula, and ST Units in mm or µV.

Use up/down arrows to choose ST post-J measurement in milliseconds.

Protocols

Users can **Add Protocol** to create a copy of the selected protocol, **Delete Protocol** and **Reset to Factory Default**. The **Add Protocol** button will create a copy of the selected protocol that can be edited and renamed. All added protocols will be deleted by selection of the **Reset to Factory Default** button.

The Protocols tab selections are related to each selected Protocol Name. Choose from the Protocol Name drop-down list to edit the stage settings for that protocol. Select the **Save Changes** button prior to exiting, or the **Discard Changes** button to cancel your edits.

> **Protocol Name** — Use the drop-down menu to select a specific protocol.

> **Equipment** — Displays the exercise equipment associated with the selected protocol.

> **Pharmacological** — A dose setting is included that when selected prompts the system to display a pop-up window notifying the clinician that a next-dose administration may be required.

> **Add Protocol** — Adds an additional protocol requiring the user to complete fields on the 3 tabs: **Pre-Exercise**, **Exercise**, and **Recovery**.

> - Type a name for the new protocol
> - Select the equipment associated with the new protocol

> *NOTE: Refer to your treadmill/ergometer documentation to check models supported by XScribe, or contact Mortara Technical Support for assistance.*

Pre-Exercise

- Speed/Grade or Power: use the up/down arrows to define treadmill speed and grade, or ergometer power in watts.

Exercise

- Use the **Add Stage** to define the number of exercise stages needed. A maximum of 60 stages at a maximum stage time of 30 minutes per stage and a minimum stage time of 15 seconds per stage may be defined for each protocol.

- Select the **Action** to define ECG Print, BP measurement, and Dose **By Stage** or for the **Entire Exercise** starting at mm:ss every mm:ss independent of stage durations.

To define a stage, highlight and click **Edit Stage**.

- Time/Speed/Grade or Power: use the up/down arrows to define stage length, and treadmill speed/grade, or ergometer power in watts.
  - set Time in increments of five seconds, starting at 10 seconds.
  - set treadmill speed from 0.0 to 12.0 mph, and 0.0 to 19.3 kph.
  - set treadmill grade from 0° to 25° elevation.
  - set ergometer power starting at 10 watts.

- ECG Print/BP Measure: use the drop-down menus to define when to print an ECG and/or prompt for a blood pressure reading.
  - to print/prompt at the beginning of a stage, select Begin.
  - to print/prompt at the end of a stage, select End.
  - select Off for no print/prompt.
  - select Every to manually define the print/prompt time. Use the upper portion of the time selection to define frequency; use the lower portion to define when.

- Dose: use the drop-down menu to define when to administer the next pharmacological stage. Settings available are the same as for ECG Print/BP Measure above.

    NOTE: When using a device to acquire a BP measurement at the beginning of a stage, XScribe will start BP acquisition immediately upon stage start. When acquiring a BP measurement at the end of a stage, XScribe will start acquisition one minute before stage end enabling the BP measurement to be printed on the ECG printout. If XScribe does not receive the BP measurement within the one-minute time period, the BP measurement will not appear on the ECG printout.

Recovery

- Number of Stages: use the up/down arrows to define the number of recovery stages needed. A maximum of 60 stages at a maximum stage time of 30 minutes per stage and a minimum stage time of 15 seconds per stage may be defined for each protocol.

Define individual stages in the same manner as for Exercise.

File Exchange

XScribe supports the ability to import orders from XML files and export PDF and XML results to an external system dependent on the system activated features. Import/Export directories for the selected group are defined in the File Exchange window. The Site Number field is not applicable to XScribe. Refer to the Scribe Data Exchange Administrator Manual (P/N: 9515-185-51-ENG) for external system integration, file name and path details.

> *NOTE: Default Import/Export paths are defined during software installation. PDF files will be exported to C:\CSImpExp\XmlOutputDir until modified by the administrative user. Access to PDF files are based on user account settings. Permission changes to the file or folder may be required.*

DICOM Settings

XScribe supports the ability to exchange information with DICOM systems dependent on the system activated features. A DICOM Modality Worklist (MWL) will be received from the DICOM server. A DICOM encapsulated PDF will be exported to the defined destination. Refer to the Scribe Data Exchange Administrator Manual (P/N: 9515-185-51-ENG) for DICOM connectivity configuration details.

Unlock Exams

XScribe internally tracks transitioning exams preventing the same exam to be processed by two or more users. When a second user attempts to access an exam in use, a message displays with notification that the exam is not currently available.

As a measure for recovering locked exams, administrative users can unlock an exam that resides on the same workstation by selecting **Unlock Exams**. Highlight the listed exam(s) and click on **Unlock**.

Manage Archive Storage

The XScribe administrative user will manage storage system disks through selection of **Storage System**.

Add Archive Location

Select **Mount Remote Disk** to open a window allowing entry of a path to the archive directory destination. Any external disk (e.g. NAS, USB, etc.) accessible from the XScribe central database is a candidate for becoming an archive volume. A Username, Password and Domain must be entered to **Add** the new storage disk to the Available Disks listing. Select **Cancel** button to exit this window without saving changes.

Restore Archived Exams

Administrative users can restore exams from the archive location to the XScribe database through selection of **Archive Recovery**. Once selected, a window will open listing exam archive date and time, archive name, volume name, volume ID, and drive letter of the archive volume. To restore exams, highlight the desired exam(s) in the list and click on **Recovery**. Multiple exams can be restored by highlighting them and then a single Recovery button click.

Search can be used to find exams matching alphanumeric text entry. Column headers can be selected to sort listed exams by that item.

Audit Trail Logs

The XScribe administrative user will select **Audit Trail** to view the audit trail history. A selection of filter criteria is available to sort the listing by date, user, workstation, operation, or target (e.g. User, Patient, Exam, Conclusion, Locked Exams, User and System Settings). One or two filter criteria can be used to find audit trails.

Selection of results will display the differences by comparing the XML statistics data before and after changes. A legend with colored highlighting will point to added, removed, changed, and moved information.

All configuration information, user information, patient demographic information, exam demographic information, textual conclusions, archive operations, and exam download requests are tracked by the audit trail.

Service Logs

All XScribe users have access to **Export Service Logs**. Selection of the button creates a Win-7 zipped file that can be sent to the desktop containing a copy of the system logged events.

The file named EMSysLog.xml.gz can be e-mailed to a Mortara service representative for troubleshooting purposes.

Configure Workflow

The XScribe exam states are designed to follow typical user workflow. There are five possibilities with meanings defined below each state:

1. ORDERED
   The stress exam is either scheduled by a user or an external scheduling system has sent an order.

2. ACQUIRED
   The stress exam is completed at the XScribe system and is ready for editing.

3. EDITED
   The stress exam has been analyzed with or without changes and is ready for review by a physician. Conclusions may be entered at this state.

4. REVIEWED
   The stress exam has been reviewed and confirmed to be accurate by an authorized user (e.g. physician, fellow, clinician, etc.). Conclusions may be entered at this state.

5. SIGNED
   The exam is reviewed and electronically signed by an authorized user. No further workflow processing is required. Conclusions may be entered at this state.

The user with appropriate permissions is prompted with a Final Exam Update dialog to confirm or Update the next logical state when exiting a stress exam. A drop-down menu allows selection of a state in respect to the exam's current state. **Cancel** may be selected to discard any change to the state.

Workflow Config

A Legal Signature can be enabled by selecting **Yes** or disabled by selecting **No**. Administrative users can configure the workflow to include all, or exclude some states through selection of **Workflow Config**.

Legal Signature	Modality Status
⦿ Yes	⦿ All
○ No	○ No REVIEWED
	○ No EDITED/REVIEWED

- Select **All** under Modality Status to enable all five states.
- Select **No REVIEWED** under Modality Status to move the state from EDITED to SIGNED.
- Select **No EDITED/REVIEWED** under Modality Status to move the state from ACQUIRED to SIGNED.

About the Legal Signature

The legal signature requires the user credentials prior to updating a stress exam when changing to a signed state. When enabled, the user is prompted to authenticate with a user name and password when transitioning to the signed state. Authentication can be entered when a different user is currently logged in. When the correct credentials are not entered, the user will be notified with a message that the "Credentials supplied are not valid."

When the signing physician has been set up as an Attending Physician under Personnel, the printed name will appear in the XScribe final report on the signature line following the "Signed By:" field label.

User Preferences

Select the User Preferences icon to open the window. Set selections define the default criteria for the Worklist when the particular user is logged into XScribe. Set selections can be changed when the user enters the Worklist window. The user can also change the password in this window when the system is not set up with a single sign-on.

All users have access to the User Preferences settings but may not have the Worklist available. Those users will only enter this window to change their own password.

There are three possible choices for the Worklist stress exam states that can be enabled or disabled by checkboxes. The choices are dependent on the workflow configuration modality status setting in that Edited or Review may not appear as selections.

1. Acquired
2. Edited
3. Reviewed

There are three choices for the default time filter for orders.

1. All
2. Today
3. Today, Yesterday and Tomorrow

There are also three choices for the default time filter for worklists.

1. All
2. Today
3. Last week

The user's custom lists can also be modified on this page. Some demographic data entry lists also accept free text which will be automatically added to the list for future use. "My Custom Lists" allows deletion of any items you do not wish to use in the future.

The user can change his password on this page, only if "Single Sign On" is not used.

When finished, select **OK** to save changes or **Cancel** to exit the window without saving changes.

XScribe will present the default settings on any of the workstations that the user logs into.

Report Configuration Tool

XScribe final reports should be configured with the practice name prior to using the system. The default sections for final report inclusion are also customizable within this tool.

Click on the XScribe workstation **Start** menu. Choose **All Programs**, **Mortara Instrument, Inc.** followed by **Report Configuration Tool** to open a dialog window prompting a **Group** choice from a drop-down list. Each group that has been defined will have its own report configuration.

Click on the **Start Wizard** button to open the tool. The **Exit** button will close the tool.

Configuring the Final Report

Once the tool is opened, the following can be performed:

1. **Hide** final report sections by checkbox selection in the Report Configuration Tool. When the box is checked, the section is disabled as a default; however, the section can be enabled for printing and export when previewing the final report for each individual exam.

2. Enter institution contact information under the **Practice** section.

When finished, click on **Next >** and then **Finish**.   **<Back** allows you to return to the previous screen; **Cancel** prompts you with an "Are You Sure" message. Select **Yes** to cancel the changes.

Once finished, the Group selection is still available for you to choose the next group to repeat the steps listed above. When done defining all groups, select the **Exit** button.

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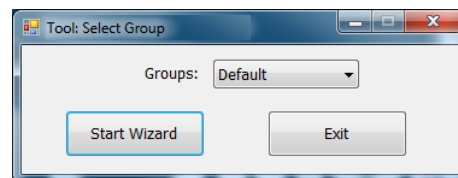
RF Scan for X12+

To reduce the possibility of radio frequency (RF) interference while using the X12+ wireless option, you can use the XScribe to perform an RF Scan for optimal channel selection.

Click on the XScribe workstation **Start** menu. Choose **All Programs**, **Mortara Instrument, Inc.** followed by **RF Scan Tool** to open the Mortara Spectrum Analyzer dialog window. To simplify access, it is recommended to place a shortcut to this tool on the desktop.

The analyzer will scan all channels and display a bar graph showing the RF activity found on each channel. Radio button selections allow choices for each antenna or Best (using both antennas) to search for the channel having the lowest RF activity (smallest graphical bar) and set that channel on both the X12+ transmitter and the XScribe. Channels in the graph can be displayed in Hex or Decimal values using radio button selections as well.

To stop the RF scan, click the **Stop RF Scan** button. To clear the display, click the **Clear** button.

It is recommended to allow the RF Scan to run for a period of time during the times that the possibility for interference is highest. The current RF power is colored amber and the maximum power for each channel is colored red.

The example below shows that the best channel selections would be 16, 32, or 38 for a 608 MHz X12+ transmitter in the WMTS band.
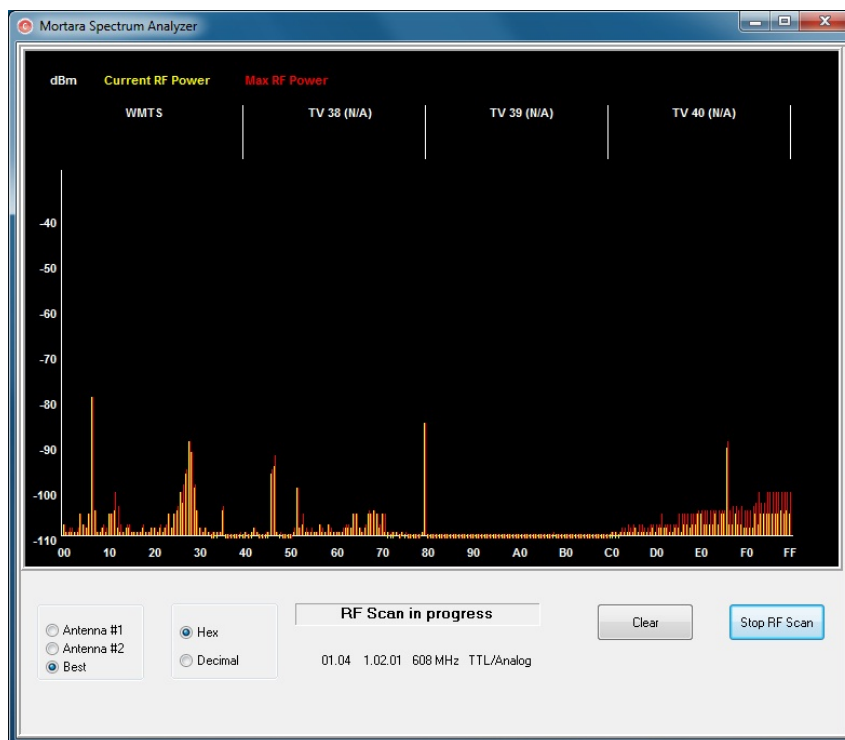
> *NOTE: To change channels on the X12+ transmitter, refer to the device user manual. There are 256 channels available for the 2500 MHz transmitter and 64 channels available for the 608 MHz transmitter in the WMTS band.*

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WORKLIST

Worklist is available for users that will edit, review, and sign stress test exams. Click on the icon to open a window allowing you to view the exams according to their status and your role.

Status Filter

The Worklist can be filtered by enabling or disabling checkboxes. Available checkboxes are dependent on workflow configuration set up by the system administrator.

- Acquired
- Edited
- Reviewed

Time Filter

The Worklist can be filtered by selecting from the Time Filter drop-down menu.

- All
- Today
- Last week
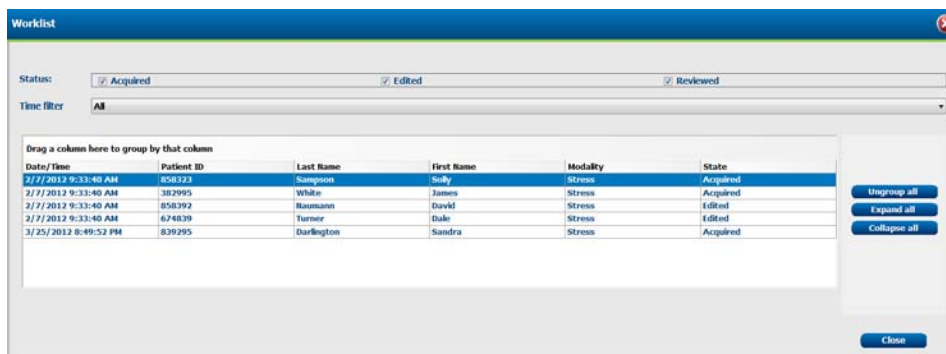
Group By Column Header

Organize the Worklist by dragging a column header above the list; use **Ungroup all** to return the column header. **Collapse all** and **Expand all** collapse and expand the grouped exams.
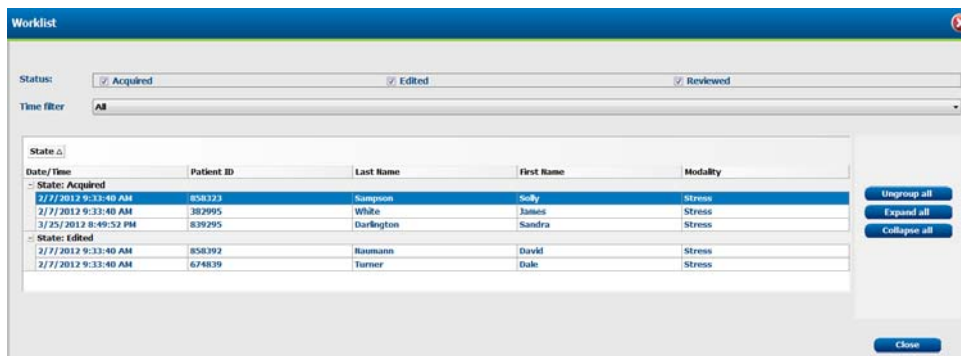
Double click on a patient to open the recording and view or edit the exam data. Select **Close** or use the red **X** to exit the window.

EXAM SEARCH

Exam Search is available for users that will edit, review, print or export reports, archive, delete, copy offline, open offline, and sign stress exams. Click on the icon to open a window allowing you to view a list of the exams according to the filter and your assigned permissions.

Filters and Identifiers

Filter the Exam list by selecting an item from the drop-down menu and then an identifier. The identifier selections are relational to the selected filter and are dependent on your system configuration. Click **Search** after your filter and identifier are selected.

- Patient ID
    - Equal To
    - Start With
- Date
    - Equal To
    - Prior To
    - Later Than
- Last Name
    - Equal To
    - Start With
- First Name
    - Equal To
    - Start With
- Date of Birth
    - Equal To
- Group
    - Equal To
- Admission ID
    - Equal To
    - Start With
- Status
    - Equal To Ordered
    - Equal To Acquired
    - Equal To Edited
    - Equal To Reviewed
    - Equal To Signed
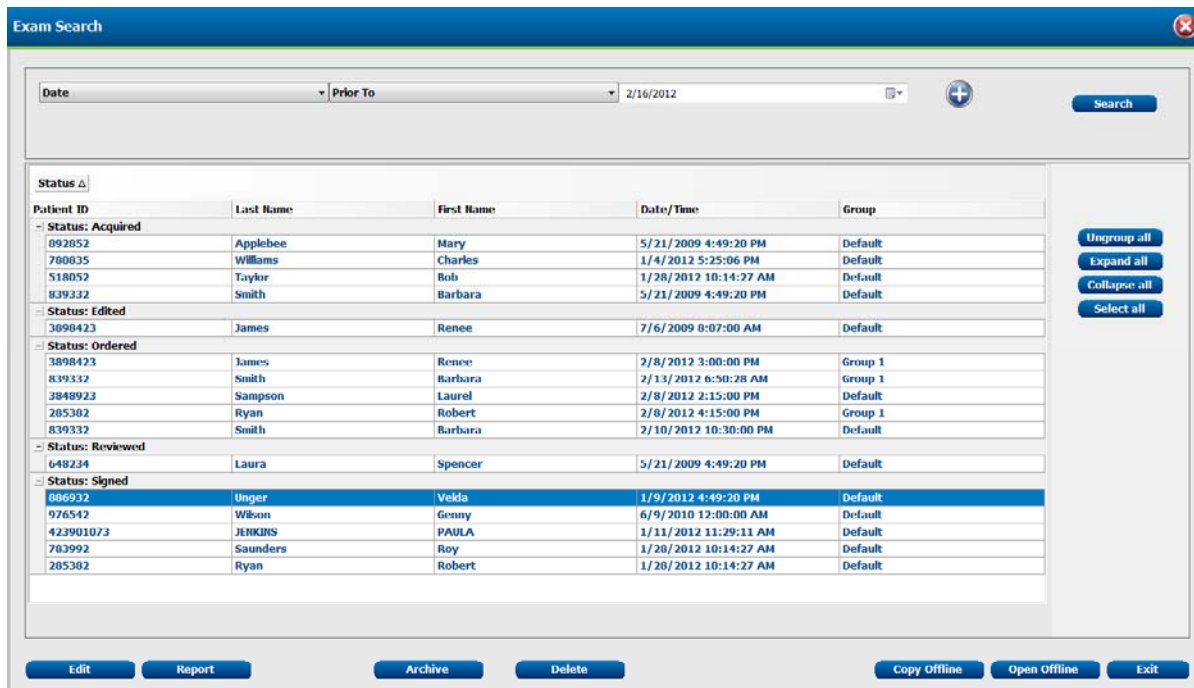
Double click on an exam or highlight the patient and click **Edit** to open an existing exam in the database and view or edit the exam data. Use:

- **Report** to open an existing final report.

- **Archive** to remove the stress exam from the database and send it to the defined archive location.
    o Archive is not available when the DICOM feature is enabled.

- **Delete** to remove the stress exam from the database, or the ordered exams from the exam list.

- **Export** to send the exam data to the defined destination.
    o Export is only available when the export feature is enabled.
    o Export button is only enabled when the exam status is Signed.

Group By Column Header

Organize the Exam list by dragging a column header above the list; use **Ungroup all** to return the column header. **Collapse all** and **Expand all** collapse and expand the grouped exams.

Offline Exam Copies

The offline buttons allow you to send a copy of an exam to another XScribe system and receive copies of exams for read-only review at your XScribe system.

Select **Copy Offline** or **Open Offline** to open a window allowing you to browse to a folder to copy to or read from. After the offline recording folder is selected, the stress exam will open allowing exam review and final report review. Any changes made during review will not be saved upon exiting the stress exam.

Select **Close** or the red **X** to exit the window.

PATIENT SEARCH

Patient Search is available for users that will find, edit, and add new patient demographics. Click on the icon to open a window allowing you to view a list of the patient demographics that exist in the database according to the filter and your assigned permissions. A column named Exam Count designates the number of exams that are associated with the patient demographics.

Filters and Identifiers

Filter the Patient list by selecting an item from the drop-down menu and then an identifier. The identifier selections are relational to the selected filter. Click **Search** after the filter and identifier are selected.

- Patient ID
  - o Equal To
  - o Start With
- Exam Date
  - o Equal To
  - o Prior To
  - o Later Than
- Last Name
  - o Equal To
  - o Start With
- First Name
  - o Equal To
  - o Start With
- Date of Birth
  - o Equal To

Group By Column Header

Organize the Patient list by dragging a column header above the list; use **Ungroup all** to return the column header. **Collapse all** and **Expand all** collapse and expand the grouped patients.

Add a New Patient

Use **New** to open a window and enter a patient that does not exist in the database. Select **OK** when finished or the **Cancel** to exit this window without saving changes.

Delete a Patient

Delete is only available when the selected patient demographics are not associated with any exam. Exams can be deleted within the Exam Search window prior to deletion of the patient demographics.

You may highlight the patient and select **Delete** to remove it from the patient listing only when the Exam Count is 0 (zero).

Duplicate Patient ID

If an entered ID number matches an existing ID in the Patient database, a warning message will notify of the match and demographics cannot be added until a correction is made. Click **OK** to exit the message.

Warning

⚠ Failed to create new patient. ID "976542" is already associated to patient "Wilson, Genny".

OK
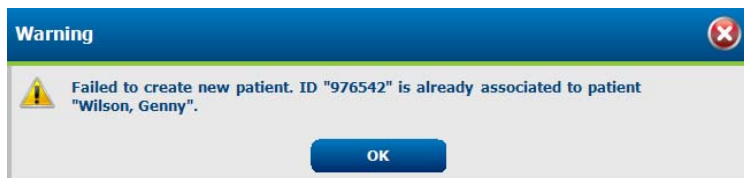
Patient and Exam Reconciliation

Correct a mistake in patient ID entry by associating a different patient demographic data set to an exam with an incorrect ID number or name. Select **Reconciliate** to open a window with the exams at the top and patients at the bottom. Independent filters for a Search are available for each.

Patient/Exams Reconciliation

Exams

| Status | ▾ | Equal To | ▾ | Acquired | ▾ | ➕ | Search |

Drag a column here to group by that column

Patient ID	Last Name	First Name	Modality ▽	Status	Date/Time	Group
389995	White	James	Stress	Acquired	2/7/2012 9:33:40 AM	Default
858323	Sampson	Solly	Stress	Acquired	2/7/2012 9:33:40 AM	Default
839295	Darlington	Sandra	Stress	Acquired	3/25/2012 8:49:52 PM	Default

Ungroup all
Expand all
Collapse all
Select all

Patient

| Last Exam | ▾ | Prior To | ▾ | 3/25/2012 | ▾ | ➕ | Search |

Drag a column here to group by that column

Patient ID	Last Name	First Name	Date Of Birth
385921	Barington	Delores	2/11/1947
839295	Darlington	Sandra	9/12/1962
674839	Turner	Dale	10/15/1976

Ungroup all
Expand all
Collapse all

Reconciliate   Exit

Highlight the exam and the patient you wish to change and then select **Reconciliate** to update the exam with the selected patient demographics.

Select **Exit** or the red **X** to close this window.

FINAL REPORTS

The final report can be previewed and printed during stress exam review. Any of the following sections can be excluded by the user with appropriate permissions. This section explains the information contained in each final report page.

Patient Information

The Patient Information header section includes a patient name, patient ID, exam start date/ time, and protocol. Sections below contain patient ID, secondary ID, admission ID, date of birth, age, gender and race; a patient address, telephone and e-mail section; an indication and medications section; a referring physician, procedure type and location section; a target heart rate, reasons for end, technician, and symptoms section; diagnosis, notes and conclusions sections; fields for the reviewer name and the signing physician name with signing date. A report footer with manufacturer name (Mortara Instrument, Inc.), the XScribe software version, and the institution name are repeated on every page.

The Diagnosis field allows up to three lines of text or approximately 100 alphanumeric characters. The Notes field allows up to approximately 100 alphanumeric characters.   The Conclusions field allows up to approximately 750 alphanumeric characters.

Areas within this page can be customized through use of the Report Configuration Tool.

Exam Summary

The Exam Summary header includes a patient name, patient ID, exam start date/ time, and protocol.

The summary statistics section includes exercise time, leads with 100 μV change, total number of PVCs during the exam, Duke Treadmill Score and FAI% (when a Bruce protocol has been used).

Max Values section includes Speed and Grade or Watts values, METs, HR, SBP, DBP, HR*BP, ST/HR Index, and % Target values.

Max ST Changes lists ST elevation and ST depression change values.

The Stage Summary lists information by user-selected stage or minute for Speed/Grade or Workload (Watts), HR (BPM), BP (mmHg), METs, HR*BP, SpO2 (%), and ST Level (mm) for each period from pre-exercise start through recovery end.

Rate/BP/Work Trends

The Rate/BP/Work page header includes a patient name, patient ID, exam start date/ time, and protocol.

Trends for Heart Rate (BPM), Speed (MPH or KPH)/Grade (%) or Watts, Blood Pressure (mmHg), and METs/Double Product (HR*BP) are included.

ST Level Trends

The ST Level Trends page header includes a patient name, patient ID, exam start date/ time, and protocol. Absolute ST Trends for each of the 12-leads are included.

ST Slope Trends

The ST Slope Trends page header includes a patient name, patient ID, exam start date/ time, and protocol. ST slope trends for each of the 12-leads are included.

Average QRS

The Average QRS page header includes a patient name, patient ID, exam start date/ time, and protocol.

The Average QRS by user-selected stage or minute is included for all 12-leads.

Events

The Events pages include 12-lead ECG pages as they were saved during the exam or added in the Context View or during Page Review.

The XScribe Report Settings icon ⚙ allows the user to include/exclude Arrhythmia Events, grid, and average QRS type by stage or by minute. Click **Ok** to change and the final report is updated.
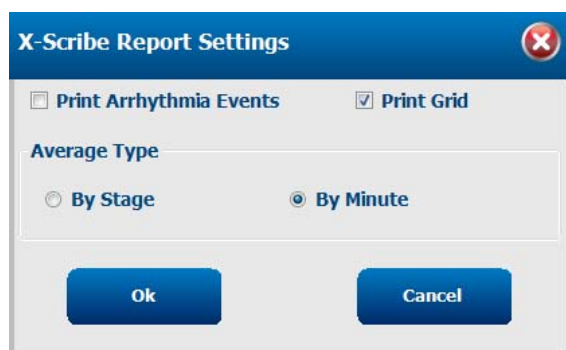
MAINTENANCE AND TROUBLESHOOTING

Routine Maintenance Requirements and Cleaning Instructions

1. Use high-pressured air to blow dust or other particles out of the keyboard.

2. Clean keyboard with a damp cloth as necessary.

3. Clean outside of the computer with a soft cloth lightly moistened with a mild detergent solution. Do not use solvents or abrasive cleaners.

4. Clean the display with an industry-standard screen cleaner (these are typically small anti-static towelettes). Do not use solvents or abrasive cleaners.

5. Clean cart with a damp cloth as necessary. A 10% bleach solution is recommended for contaminated areas.

Troubleshooting Chart

Screen Message or Issue	Possible Cause	Solution
Baseline drift	Poor skin-to-electrode contact.	Re-prep skin and replace faulty electrode(s).
BP Printout and Report discrepancy	Use of BP field to enter new blood pressure values.	BP value entry MUST BE completed through the F3 key. Editing of BP is completed through the selection of the BP value on the right side of display. Edited value will erase previously entered value from summary report.
Squared line(s) display on the multi-lead rhythm display screen or on the screen during the exercise test	Lead fail caused by poor skin-to-electrode contact. Broken lead wire/cable. Channel of transmitter doesn't match channel on XScribe.	Correct faulty lead(s) identified in upper right corner of the screen. Replace patient cable. Match transmitter channel to same channel setting in the Local Conf/F6 pop up window.
Intermittent blank areas in the multi-lead rhythm display screen and in ECG printouts	WAM signal loss.	Check proximity of WAM to UTK device and that there is no obstruction preventing communication.
Muscle noise	Electrode placed over muscle or fatty tissue.	Find stable electrode site, re-prep skin, and apply a new electrode.
No response to keyboard commands	Disconnected keyboard cable. Transposed keyboard/mouse cable.	Turn system OFF. Check keyboard to mouse port connections.
Menu cursor will not move	Disconnected mouse cable. Transposed keyboard/mouse cable.	Turn system OFF. Check mouse port connections.

Troubleshooting Chart (Continued)

Screen Message or Issue	Possible Cause	Solution
Treadmill does not respond to the ON command from XScribe	Equipment powered up in wrong sequence.	Turn treadmill OFF using Softkey menu. Turn power to the treadmill OFF. Wait one minute and turn power back ON. Proceed with test.
	Treadmill power switch is off, or treadmill cable not properly attached.	Secure the treadmill to XScribe cable connections. Turn treadmill main power switch ON. (Switch is located at the base of the treadmill hood, left side.)
	Emergency stop switch is engaged.	Reset emergency stop switch by turning clockwise one-quarter turn. Shutdown and restart XScribe.
	Treadmill settings are incorrect.	Set treadmill to proper setting for corresponding treadmill.
Z200+ writer paper out, light on	Paper jammed.	Open writer cover and remove jammed paper.
Z200+ writer not printing	No paper in tray. Open writer door.	Insert new packet of paper in tray. See if writer door is latched.
Uneven printing of ECGs or reports	Printer head needs cleaning.	Refer to printer head cleaning instructions in Appendix E.
Treadmill belt starts to slip	When loose it can shift.	Tighten adjustment bolts on both sides until slippage stops.
ECG Front-End Error – Can't Proceed	The Front-End device is not correctly connected.	Disconnect the USB cable from the PC. Reconnect the USB cable to the PC. The system emits a confirmation beep.
	The Front-End device drivers are not correctly installed.	Contact Mortara Service.
	Incorrect Power Savings settings.	Restart the PC. Should rebooting the system fix the problem, it is likely that system has incorrect Power Saving settings. Try the following: 1) Close the XScribe application. 2) Select "Start", "Settings", then "Control Panel". 3) Double click on "Power Management" icon. 4) If displayed, set "Stand-by" setting to "Never". 5) Click OK and close all open Windows. 6) Reboot system.

Troubleshooting Chart (Continued)

Screen Message or Issue	Possible Cause	Solution
No Exams are Currently Selected	An attempt to access a final report but no patient is selected from the Search Exam list.	Click on the patient name to select and access the file.
A warning sign appears on the screen next to ST measurements.	The measurement points (J-point, Isoelectric point, or J+ XX msec) have been modified by the user during or after the stress test.	Warning sign indicates that a manual change occurred and that the results are now based on new user determinations.
RA/LA//LL/V1/V2/V3/V4/V5/V6 or C1/C2/C3/C4/C5/C6 FAIL	One or more leads are in fail.	Connect or replace the electrodes to turn off the warning message.
X12+ signal shows artifact even when tested with a simulator.	Signal onscreen shows artifact even when tested with a simulator.	Check that no medical equipment is operating at the same frequency in proximity of the system. Run the RF Scan tool (spectrum analyzer) to locate the optimal channel setting for transmission. Make sure to set the same channel on the X12+ and XScribe.
No signal onscreen	With the patient connected (or with a simulator) no waveforms are displayed, but only the squared waveform/lead fail indicator appears (wireless option).

NOTE: if neither the signal nor the squared waveform is present, ESC or Abort and start a new exam from the main menu. | Check that XScribe and the digital transmitter work on the same channel. Refer to the transmitter user manual to check and change channel. Refer to Settings in this manual to set the receiving channel for XScribe. |
| No signal from X12+ Transmitter | X12+ is not selected as Front End.

M12RF-USB cable is unplugged.

Drivers for M12RF-USB not loaded. | Select X12+ as front end in the Observation screen.

Place USB plug into any rear USB slot.

Load drivers for M12-USB from XScribe software CD. |
| No signal from the M12A patient cable connection | M12A is not selected as Front End.

USB cable plugged into wrong USB slot.

Drivers for M12-USB patient module not loaded. | Select M12 as front end in the Observation screen.

Assure M12-USB Green light is on, if not plug USB cable into the USB adapter on the upper left-hand side.

Load drivers for M12-USB from XScribe software CD. |

Troubleshooting Chart (Continued)

Screen Message or Issue	Possible Cause	Solution
No signal from the WAM patient connection	WAM is not selected as Front End or paired with XScribe	Select WAM as front end and PAIR WAM in the Observation screen
	UTK module is not connected.	Plug UTK module into the USB port.
	WAM is not powered on or battery is not inserted.	Power WAM on and assure LCD is lit; replace battery.
	Drivers for WAM UTK not loaded.	Load drivers for WAM UTK from XScribe software CD.
	AM12 connection is causing a conflict.	Disconnect the AM12 patient cable.
No signal from the AM12 patient cable connection	AM12 not selected as Front End.	Select AM12 as front end in the Observation screen.
	Drivers for AM12 patient cable not loaded.	Load drivers for AM12 from XScribe software CD.
	WAM UTK connection is causing a conflict.	Disconnect the UTK.
No Network or LAN communication	RJ45 plug connected to the wrong RJ45 slot.	Disconnect the RJ45 plug from the back of the PC and connect it to the other RJ45 slot.
No or unreliable TTL or Analog output signals	Bad connection or cable	Check connection between M12USB device and Tango or Echo device
	Use of lead with noise, low amplitude QRS or high amplitude T-waves	Select a more appropriate lead for the TTL and analogue output with the "Softkey" button

System Information Log

The following system information log is provided for your convenience. You will need this information if the system needs servicing. Update the log when you add options or your system has been serviced.

> *NOTE: It is strongly recommended that you make a copy of this log and file it after you enter the information.*

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 record of when your system was placed in service.

Manufacturer:

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

Telephone Numbers:

Domestic: 800-231-7437
European: +39-051-298-7811

Sales Department: 800-231-7437
Service Department: 888-MORTARA

Product Information:

Name of Unit/Product: XScribe

Date of Purchase: _____/_____/_____

Purchased Unit From: _____

_____

_____

_____

Serial Number _____

Software Version: _____

For questions or service information when calling into Mortara Technical Support, have the system serial number and the reference number available. The serial number and part number (REF) are printed on the Software License Certificate (9517-001-01-ENG) delivered with the system software.

PROTOCOLS

The following protocols are delivered with every XScribe:
- Bruce
- Modified Bruce
- Naughton
- Balke
- Ellestad
- USAF/SAM 2.0
- USAF/SAM 3.3
- High Ramp
- Medium Ramp
- Low Ramp
- Pharmacological
- Astrand (Ergometer)
- Cycle (Ergometer)

These sample protocols produce the following operations and conditions:

- An automatic blood pressure acquisition towards the end of each stage.
- An automatic ECG report at the end of each stage.
- In the Recovery phase, an automatic blood pressure measurement every 2 minutes starting at 1 minute, 40 seconds and an ECG report every 2 minutes starting at 1 minute until the end of the Recovery phase.

   NOTE: Protocols are subject to physician preference and may be modified as deemed appropriate.

Bruce Protocol

The sample Bruce protocol produces the following operations and conditions:

- A stage change occurs every 3 minutes with an increase in treadmill speed and grade.
- An automatic blood pressure measurement is initiated one minute before the end of each stage.
- A 12-lead ECG report is automatically printed at the end of each stage. ECG acquisition begins 12 seconds prior to the end of a stage.
- In the Recovery phase, the treadmill slows to 0.5 mph and the following reports are automatically printed:
    - Peak Exercise ECG report prints immediately.
    - Recovery ECG prints in one minute.
    - Recovery ECG prints every two minutes until the end of the Recovery phase.
- Blood pressure measurement is set to every 2 minutes until the end of the Recovery phase.

PROTOCOL: BRUCE By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	1.0	0.0	----	----
1	3:00	1.7	10.0	End	End
2	3:00	2.5	12.0	End	End
3	3:00	3.4	14.0	End	End
4	3:00	4.2	16.0	End	End
5	3:00	5.0	18.0	End	End
6	3:00	5.5	20.0	End	End
7	3:00	6.0	22.0	End	End
Recovery (one stage)	3:00 (infinite)	1.5	0.0	Every	Every

PROTOCOL: MODIFIED BRUCE By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	0.5	0.0		
1	3:00	1.7	0.0	End	Begin
2	3:00	1.7	5.0	End	Begin
3	3:00	1.7	10.0	End	Begin
4	3:00	2.5	12.0	End	Begin
5	3:00	3.4	14.0	End	Begin
6	3:00	4.2	16.0	End	Begin
7	3:00	5.0	18.0	End	Begin
8	3:00	5.5	20.0	End	Begin
9	3:00	6.0	22.0	End	Begin
Recovery (one stage)	3:00 (infinite)	1.0	0.0	Every	Every

PROTOCOL: NAUGHTON By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	0.5	0.0	----	----
1	2:00	1.0	0.0	End	Off
2	2:00	2.0	2.0	End	End
3	2:00	2.0	3.5	End	Off
4	2:00	2.0	7.0	End	End
5	2:00	2.0	10.5	End	Off
6	2:00	2.0	14.0	End	End
7	2:00	2.0	17.5	End	Off
Recovery (one stage)	3:00 (infinite)	1.0	0.0	Every	Every

PROTOCOL: BALKE By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	1.0	0.0	----	----
1	1:00	3.3	1.0	End	Off
2	1:00	3.3	2.0	End	Off
3	1:00	3.3	3.0	End	End
4	1:00	3.3	4.0	End	Off
5	1:00	3.3	5.0	End	Off
6	1:00	3.3	6.0	End	End
7	1:00	3.3	7.0	End	Off
8	1:00	3.3	8.0	End	Off
9	1:00	3.3	9.0	End	End
10	1:00	3.3	10.0	End	Off
11	1:00	3.3	11.0	End	Off
12	1:00	3.3	12.0	End	End
13	1:00	3.3	13.0	End	Off
14	1:00	3.3	14.0	End	Off
15	1:00	3.3	15.0	End	End
16	1:00	3.3	16.0	End	Off
17	1:00	3.3	18.0	End	Off
18	1:00	3.3	20.0	End	End
19	1:00	3.3	21.0	End	Off
20	1:00	3.3	22.0	End	Off
21	1:00	3.3	23.0	End	End
22	1:00	3.3	24.0	End	Off
Recovery (one stage)	3:00 (infinite)	1.0	0.0	Every	Every

PROTOCOL: ELLESTAD By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	1.0	0.0	----	----
1	3:00	1.7	10.0	End	End
2	3:00	3.0	10.0	End	End
3	3:00	4.0	10.0	End	End
4	3:00	5.0	10.0	End	End
5	3:00	6.0	15.0	End	End
6	3:00	7.0	15.0	End	End
7	3:00	8.0	15.0	End	End
Recovery (one stage)	3:00 (infinite)	1.5	0.0	Every	Every

PROTOCOL: USAF/SAM 2.0 By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	0.5	0.0	----	----
1	3:00	2.0	0.0	End	Off
2	3:00	2.0	5.0	End	End
3	3:00	2.0	10.0	End	Off
4	3:00	2.0	15.0	End	End
5	3:00	2.0	20.0	End	Off
6	3:00	2.0	25.0	End	End
Recovery (one stage)	3:00 (infinite)	1.0	0.0	Every	Every

PROTOCOL: USAF/SAM 3.3 By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	1.2	0.0	----	----
1	3:00	3.3	0.0	End	Off
2	3:00	3.3	5.0	End	End
3	3:00	3.3	10.0	End	Off
4	3:00	3.3	15.0	End	End
5	3:00	3.3	20.0	End	Off
6	3:00	3.3	25.0	End	End
Recovery (one stage)	3:00 (infinite)	1.2	0.0	Every	Every

PROTOCOL: HIGH RAMP By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	1.0	0.0	----	----
1	0:30	1.6	5.0	End	End
2	0:30	1.7	10.0	End	End
3	0:30	1.7	10.0	End	End
4	0:30	2.0	10.0	End	End
5	1:00	2.2	11.0	End	End
6	0:30	2.4	11.5	End	End
7	0:30	2.5	12.0	End	End
8	0:30	2.6	12.5	End	End
9	0:30	2.8	13.0	End	End
10	1:00	3.0	13,5	End	End
11	0:30	3.2	14.0	End	End
12	0:30	3.4	14.0	End	End
13	0:30	3.5	14.5	End	End
14	0:30	3.6	15.0	End	End
15	1:00	3.7	15.5	End	End
16	0:40	4.0	16.0	End	End
17	0:40	4.2	16.0	End	End
18	0:40	4.4	16.5	End	End
19	0:40	4.6	17.0	End	End
20	0:40	4.8	17.5	End	End
21	0:40	5.0	18.0	End	End
22	0:40	5.2	19.0	End	End
23	0:40	5.5	20.0	End	End
24	0:40	5.8	21.0	End	End
25	0:40	6.0	22.0	End	End
Recovery (one stage)	3:00 (infinite)	1.0	0.0	Every	Every

PROTOCOL: MEDIUM RAMP By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	1.0	0.0	----	----
1	0:30	1.5	3.0	End	End
2	0:30	1.6	4.0	End	End
3	0:30	1.7	5.0	End	End
4	0:30	1.7	6.0	End	End
5	1:00	1.8	7.0	End	End
6	0:30	1.9	8.0	End	End
7	0:30	2.0	8.5	End	End
8	0:30	2.1	9.0	End	End
9	0:30	2.2	9.5	End	End
10	1:00	2.3	10.0	End	End
11	0:30	2.4	11.0	End	End
12	0:30	2.5	11.5	End	End
13	0:30	2.6	12.0	End	End
14	0:30	2.7	12.5	End	End
15	1:00	2.8	13.0	End	End
16	0:40	3.0	13.5	End	End
17	0:40	3.2	14.0	End	End
18	0:40	3.4	14.5	End	End
19	0:40	3.6	15.0	End	End
20	0:40	3.8	15.5	End	End
21	0:40	4.0	16.0	End	End
22	0:40	4.2	17.0	End	End
23	0:40	4.5	18.0	End	End
24	0:40	4.8	19.0	End	End
25	0:40	5.2	20.0	End	End
Recovery (one stage)	3:00 (infinite)	1.0	0.0	Off	Off

PROTOCOL: LOW RAMP By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP
Pre-Exercise	----	1.0	0.0	----	----
1	0:30	1.0	0.0	End	End
2	0:30	1.1	1.0	End	End
3	0:30	1.2	1.0	End	End
4	0:30	1.3	2.0	End	End
5	1:00	1.4	3.0	End	End
6	0:30	1.5	4.0	End	End
7	0:30	1.6	4.0	End	End
8	0:30	1.7	5.0	End	End
9	0:30	1.8	6.0	End	End
10	1:00	1.9	7.0	End	End
11	0:30	2.0	8.0	End	End
12	0:30	2.1	8.5	End	End
13	0:30	2.2	9.0	End	End
14	0:30	2.3	9.5	End	End
15	1:00	2.4	10.0	End	End
16	0:30	2.5	10.5	End	End
17	0:30	2.6	11.0	End	End
18	1:00	2.7	12.0	End	End
19	0:30	2.8	13.0	End	End
20	0:30	2.9	14.0	End	End
21	1:00	3.0	15.0	End	End
22	0:30	3.1	16.0	End	End
23	0:30	3.2	17.0	End	End
24	1:00	3.4	18.0	End	End
25	1:00	3.6	19.0	End	End
Recovery (one stage)	3:00 (infinite)	1.5	0.0	Every	Every

PROTOCOL: PHARMACOLOGICAL By Stage

STAGE NUMBER	LENGTH	SPEED	GRADE	PRINT	BP	DOSE
Pre-Exercise	----	0.0	0.0	End	End	Off
1	3:00	0.0	0.0	End	End	Every (2:30)
2	3:00	0.0	0.0	End	End	Every (2:30)
3	3:00	0.0	0.0	End	End	Every (2:30)
4	3:00	0.0	0.0	End	End	Every (2:30)
5	3:00	0.0	0.0	End	End	Every (2:30)
6	3:00	0.0	0.0	End	End	Every (2:30)
7	3:00	0.0	0.0	End	End	Every (2:30)
Recovery (one stage)	3:00 (infinite)	0.0	0.0	Every	Every	Off

PROTOCOL: ASTRAND (ERGOMETER) By Stage

STAGE NUMBER	LENGTH	WATTS	Print	BP
Pre-Exercise	----	50	----	----
1	6:00	50	End	End
2	6:00	100	End	End
3	6:00	150	End	End
4	6:00	200	End	End
5	6:00	250	End	End
6	6:00	300	End	End
Recovery (one stage)	3:00 (infinite)	50	Every	Every

PROTOCOL: CYCLE (ERGOMETER) By Stage

STAGE NUMBER	LENGTH	WATTS	Print	BP
Pre-Exercise	----	10	----	----
1	3:00	25	Begin	End
2	3:00	50	Begin	End
3	3:00	75	Begin	End
4	3:00	100	Begin	End
5	3:00	125	Begin	End
6	3:00	150	Begin	End
7	3:00	175	Begin	End
8	3:00	200	Begin	End
9	3:00	225	Begin	End
10	3:00	250	Begin	End
Recovery (one stage)	3:00 (infinite)	25	Every	Every

TTL/ANALOG OUTPUT

XScribe supports the capability of interfacing to a cardiac ultrasound (Echo) imaging system. This feature is accomplished with an optional TTL (transistor, transistor, logic) or analog output.
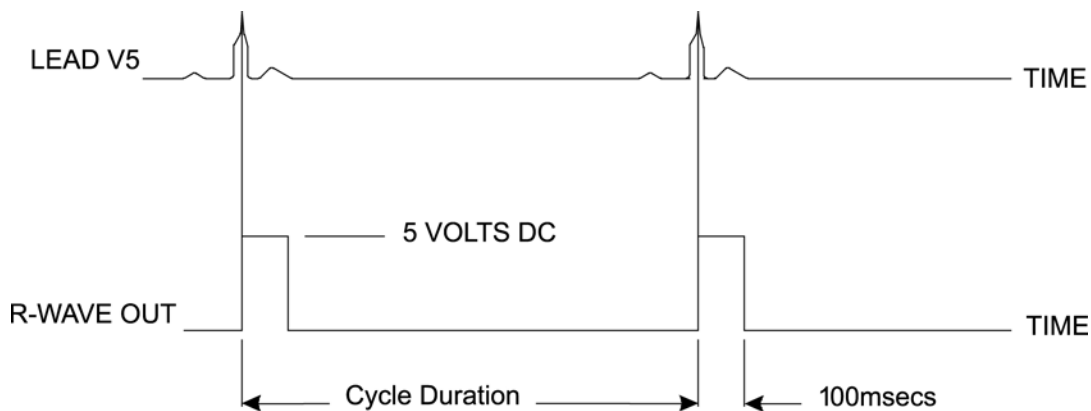
⚠ **WARNING:** *Equipment connected via the TTL or analog cable must be IEC 60601-1 compliant.*

TTL Output

The signal complies with the TTL standards and can be derived from any of the 12 leads. The Echo captures images of ventricular systole and diastole based on R-wave gating.

**Sample Representation of R-wave Pulse Output**

Analog Output

The analog option includes a cable that must be plugged into the analog output jack on the back of the M12-USB device.

Sample Representation of R-wave Pulse Output

> **NOTE:** *The interface cable to the Echo device or other equipment requiring an ECG trigger should be supplied by the manufacturer of the equipment requesting the signal, or the facility Biomedical Department. This is a standard RCA to device interface cable.*

M12RF Analog and TTL Interface Ports
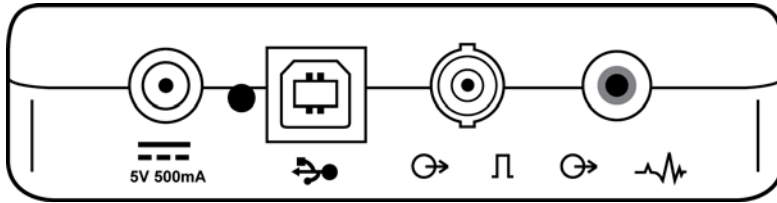
The TTL option requires a BNC male connector on one end with the other end having the connector required by the Echo or device you are interfacing to.

The analog option requires an RCA male connector on one end with the other end having the connector required by the Echo device you are interfacing to.

TREADMILL/ERGOMETER HOOKUP

XScribe to Treadmill Hookup Instructions

1. Connect one end of the XScribe-to-treadmill interface cable to the top 9-pin serial COM1 port on the back of CPU, and the other end to the 9-pin serial port on the treadmill.

2. Connect the treadmill power cord to a dedicated circuit as recommended by the treadmill manufacturer.

3. Turn the treadmill power switch **ON**.

4. Turn the XScribe **ON**.

NOTE: Do not connect the treadmill to the patient isolation transformer. It is important that the treadmill has its **OWN SOURCE OF UNSHARED POWER** *to avoid an interruption to the power supply to the XScribe. The treadmill should have its own circuit and fuse/breaker in a local power distribution box.*

NOTE: Hookup may vary depending on treadmill model version.

XScribe to Ergometer Hookup Instructions

1. Connect one end of the XScribe-to-ergometer interface cable to the top 9-pin serial COM 1 port on the back of CPU, and the other end to the 9-pin serial port on the ergometer.

2. Connect the ergometer power cord to a dedicated circuit as recommended by the ergometer manufacturer.

3. Turn the ergometer power switch **ON**.

4. Turn the XScribe **ON**.

NOTE: Do not connect the ergometer to the patient isolation transformer. It is important that the ergometer has its **OWN SOURCE OF UNSHARED POWER** *to avoid an interruption to the power supply to the XScribe. The ergometer should have its own circuit and fuse/breaker in a local power distribution box.*

NOTE: Hookup may vary, depending on ergometer model version.

NOTE: When using the Ergoline ergometer with NIBP, you must select the 900S from the equipment selection in the Settings menu.

Treadmill Remote Keypad

Increase Speed: Increases speed by 0.1 mph.

Decrease Speed: Decreases speed by 0.1 mph.

Increase Elevation: Increases elevation by 1%.

Decrease Elevation: Decreases elevation by 1%.

12 Lead ECG: Acquires a 12-lead ECG at any time during Pre-exercise, Exercise, Recovery, or Post recovery.
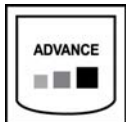
Rhythm Strip: Acquires a rhythm strip of the 6 user-definable leads as defined in Settings. Depress a second time to change to leads I, II, III, aVR, aVL, and aVF. Depress a third time to change to leads V1, V2, V3, V4, V5, and V6. Depress a fourth time to revert back to original 6 leads.

Stop Rhythm Strip: Stops rhythm strip from printing.

Phase Advance: Advances phase.

Advance Stage: Advances stage.

Acquire NIBP: Send a signal to the NIBP device to acquire a NIBP.

Start Treadmill: Starts treadmill belt at the speed set in the Pre-exercise phase.

Stop Treadmill: Stops treadmill.

Z200+ THERMAL PRINTER AND SUPPLIES

Z200+ Thermal Printer

The Z200+ thermal printer uses an eight-dot-per-millimeter (dpm) print head to print ECG tracings and report data. Multiple print formats, and standard (8.5" x 11") or A4 thermal paper sizes are supported.
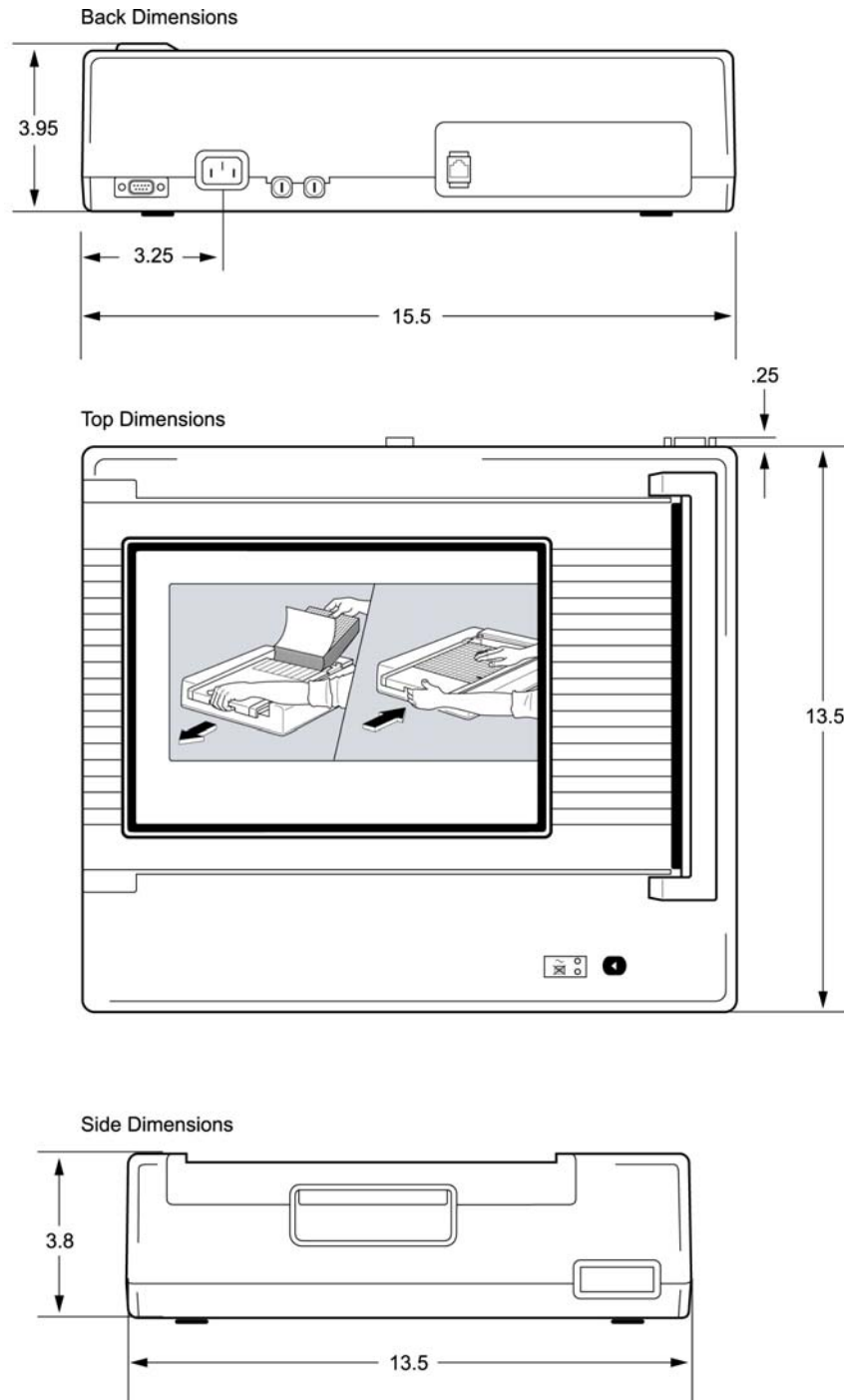
The Z200+ thermal printer includes:
- Hospital-grade power cord for connection to the isolation transformer.
- Crossover network cable for connection to the PC.

Figure E-1
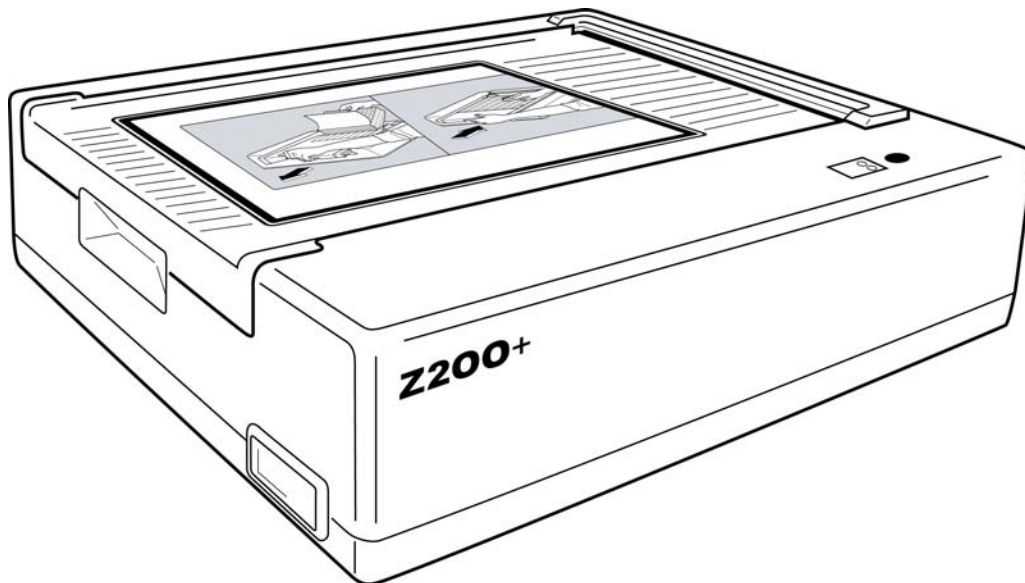
Z200+ Thermal Printer Dimensions

Figure E-2

Back Dimensions

Top Dimensions

Side Dimensions

Z200+ Thermal Printer Specifications

Feature	Specification*
Instrument Type	Thermal printer
Paper Type	8 ½" x 11" or A4, cued, perforated, Z-fold with full grid
Recording Technique	Computer controlled, thermal dot array, 8 dots/mm
Writer Speeds	5, 10, 25, or 50 mm/sec, computer controlled
External Ports and Data Interfaces	Networking capability to allow high-speed data transfer for printing External RJ-45 connector
Chassis Leakage Current	Meets or exceeds requirements of ANSI/AAMI EC11
Power	100-240 VAC at 50/60 Hz
Weight	9 lbs. or 4.09 kg
Dimensions H x W x D	4" x 16" x 13" (10 cm x 41 cm x 33 cm)
Fuses	T-Type 1 Amp, 250 V
Special Functions	LAN communication that provides continuous printing

***** *Specifications subject to change without notice*

Input and Output Descriptions

Feature	Description
AC Power	The Z200+ thermal printer operates on 120/240 VAC at 50/60 Hz. Power is supplied as soon as the AC power cord is connected to an AC power outlet.
Power-On Indicator	This indicator will illuminate in green when AC power is applied.
Form Feed/Reset Button	The form-feed pushbutton is a momentary contact switch that advances the paper until an infrared, reflective sensor detects a "cue mark" on the printing side of the paper. This button will reset the thermal printer when it is depressed for a period of seven seconds.
Hard-Copy Printout	The Z200+ thermal printer uses 8 1/2" x 11" sheets of Z-folded, thermal-sensitive paper with cue marks. Printing speeds are 10, 25, and 50 mm/second. Dot density is eight dots per millimeter or 203.2 dpi.
Paper Out/Writer Error Indicator	This indicator will illuminate in green when writer-error conditions are detected. Errors include not detecting a cue mark at the expected time (due to a paper jam or drive system failure) and detecting a cue mark longer than expected. The writer error will remain illuminated until the form-feed button is depressed.

Setting Up the Z200+ Thermal Printer

1. Connect the AC power cord to the AC connector on the printer and to an AC power outlet.

2. Connect one end of the crossover network cable to the network connector on the Z200+ thermal printer and the other end to the network (LAN) connector on the back of the XScribe 5 PC.

Figure E-3

A	Serial connector. Not used.	**C**	AC fuses
B	AC connector (for power cord)	**D**	Integrated network (LAN) connector
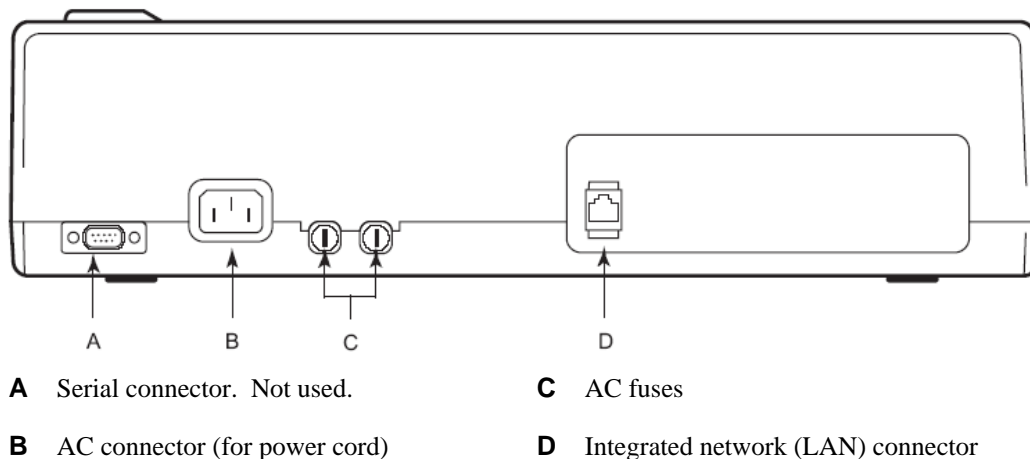
The Z200+ thermal printer operates on line power and is controlled by a LAN connection to the XScribe.

To configure the LAN connection for the Printer

1. On the XScribe PC, log in as Administrator.

2. Click **Start > Settings > Control Panel**.

3. Double click **Network Connections**.

4. Double click the appropriate **Local Area Network** icon. The Local Area Connection Properties dialog box will appear.

5. In the items list, select **Internet Protocol (TCPIP)**, and click **Properties**. The Properties dialog box will appear.

   Network settings are:
   IP Address: 192.168.10.100
   Subnet Mask: 255.255.255.0
   Default Gateway: 192.168.10.1

6. Click OK in each dialog box to save the entries and exit.

Maintaining the Z200+ Thermal Printer

If the hospital or institution fails to implement a satisfactory cleaning and inspection schedule for this equipment, it may result in equipment failure and health hazards.

> *NOTE: Only qualified service personnel should repair or replace Z200+ thermal printer parts.*

Inspect the equipment for the following conditions on a regular basis:

- Examine power cable and the network cable for obvious damage (i.e., torn insulation, broken connectors, etc.). Replace cables as necessary.

- All cords and connectors are securely seated in their corresponding connections.

- Examine the equipment for missing screws, cracks, or broken areas that might allow unintended access to internal electronics areas.

Cleaning the Z200+ Thermal Printer

> *NOTE: If using a laser printer, refer to the printer user manual for maintenance and cleaning instructions.*

To clean the printer:

1. Disconnect the power source.

2. Clean the exterior surface of the unit with a damp cloth using a solution of mild dishwashing detergent diluted in water.

3. After washing, thoroughly dry off the unit with a clean, soft cloth or paper towel.

To clean the print head:

NOTE: Do not let soap or water come into contact with the writer, plugs, jacks, or vents.

1. Open writer door.

2. Lightly rub print head with an alcohol pad.

3. Wipe with a clean cloth to remove alcohol residue.

4. Allow print head to air dry.

5. Clean the platen by using adhesive tape. Apply the tape and pull it off. Rotate roller and repeat until entire roller is clean.

6. Clean cue sensor photo detector.

Testing Printer Operation

After cleaning and inspecting the Z200+ thermal printer, confirm the printer is working properly.

To test printer operation:

1. Using an ECG simulator with the XScribe, acquire and print ECGs of known amplitude.

A successfully printed ECG report has the following characteristics:

1. Printing should be dark and even across the page.

2. There should be no evidence of print head dot failure (i.e., breaks in printing forming horizontal streaks).

3. Paper motion should be smooth and consistent during printing.

4. Waveforms should appear normal, with proper amplitude, and without distortion or excessive noise.

5. Paper should stop with perforations near the tear bar (indicating proper cue sensor operation).

Post-Service Testing

Following any service to the Z200+ thermal printer or when non-compliant operation is suspected, Mortara Instrument recommends the following procedures:
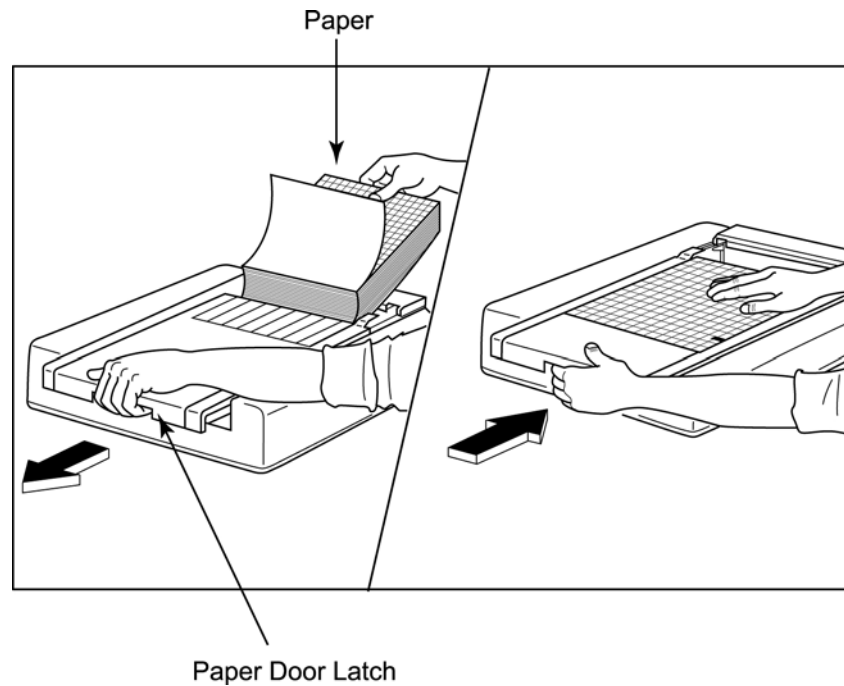
- Confirm proper operation as described in *Testing Printer Operation.*
- Perform testing to ensure continued electrical safety of the device
  (use IEC 60601-1 or ANSI/AAMI ES1 methods and limits).
  - Earth leakage current.

NOTE: There is no exposed metal and no patient connection to this unit.

Loading the Thermal Printer Paper

Figure E-4

1. Remove the outer packaging from the paper stack.

2. Facing the front of the unit, use the release latch on the left side and slide the paper tray cover to the left.

3. Place the pack of thermal paper into the paper tray such that the grid side of the paper is up when it is pulled over the paper tray cover. The paper cue mark (a small black rectangle) should be in the lower left corner.

4. Manually advance one page of paper beyond the closure point of the writer. Make sure the paper lies on the black roller evenly within the channel of the paper door.

5. Slide writer cover to the right until the cover latches in a locked position. You will hear a sharp click when the door is properly latched.

6. Push the form-feed button to align the cue mark and prepare the paper for printing.

A4 Paper Spacer Insertion

If your Z200+ thermal writer was ordered with A4 paper, the paper-tray spacer needs to be inserted in the paper tray. A paper-tray spacer will not be provided if the device was purchased with standard paper.
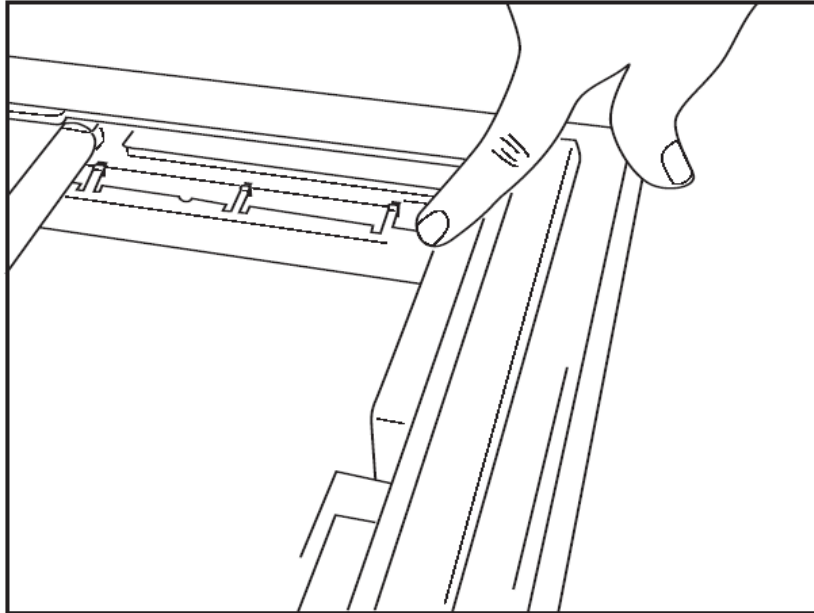
To insert the paper-tray spacer:

Figure E-5
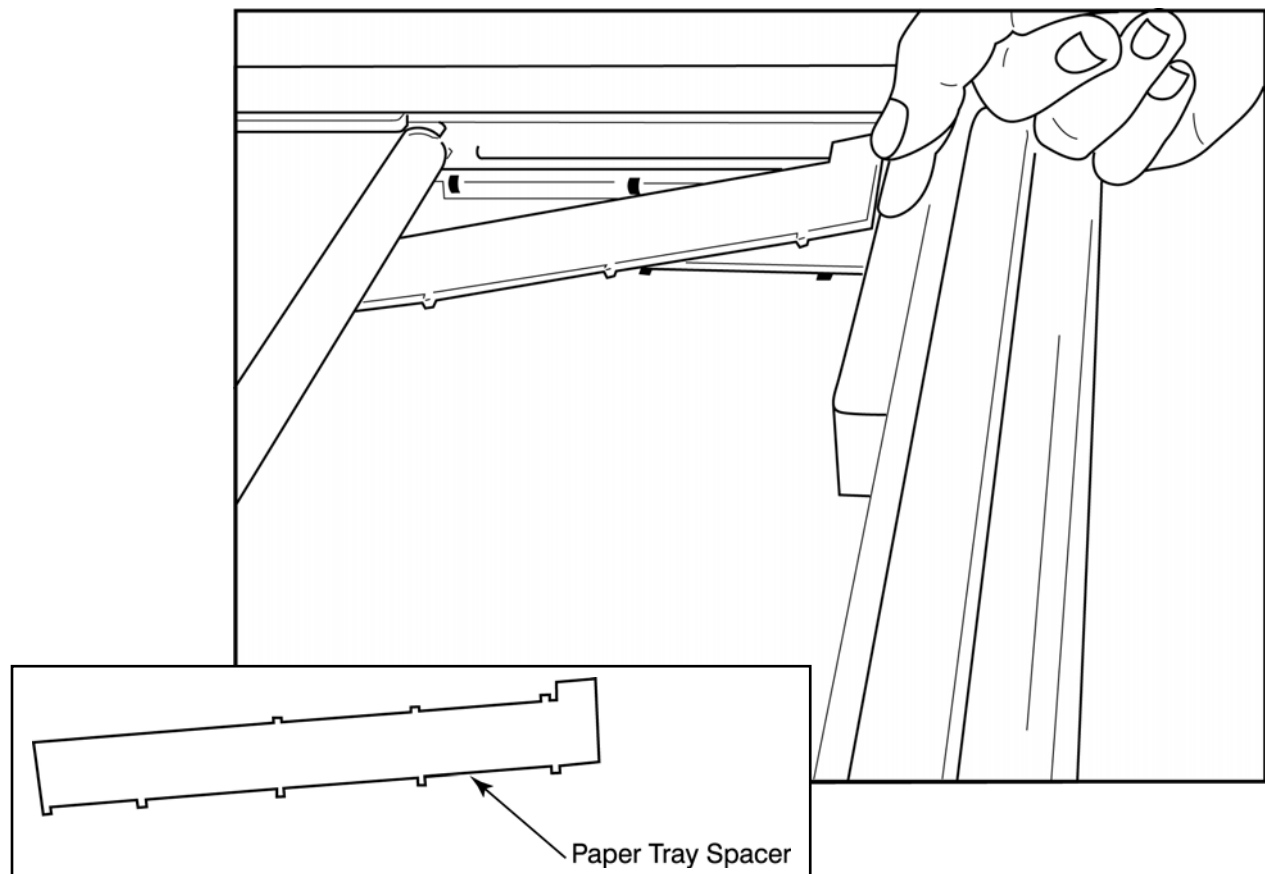
Paper Tray Spacer

1. Slide paper-tray spacer towards rear wall of writer tray. Align the bottom four plastic arms with the four openings in the base of the writer tray. Similarly, align the top 3 plastic arms with the three openings on the rear wall of the writer tray.

Figure E-6

2.   The paper-tray spacer should be parallel to the rear wall of the writer tray as pictured above.
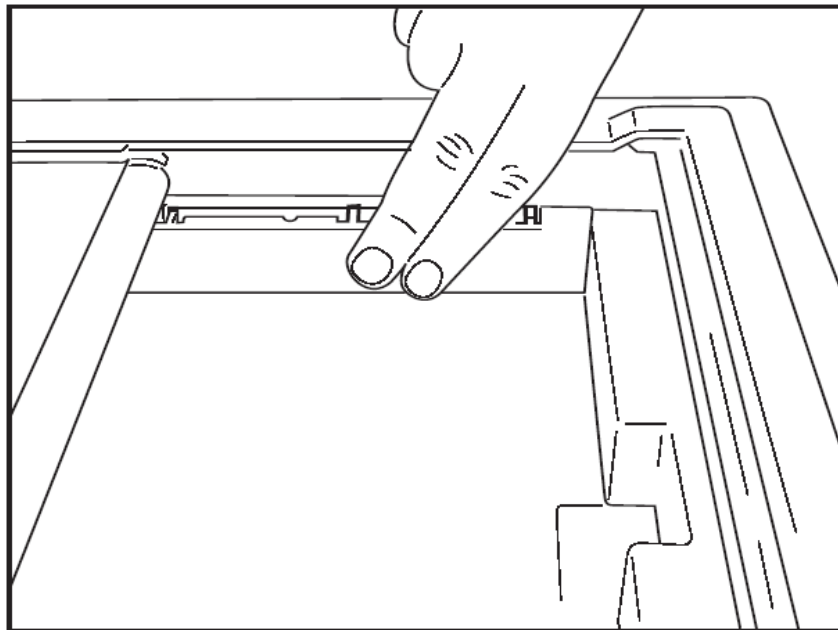
3.   Gently press paper-tray spacer in place.

> *NOTE: If you wish to remove the paper-tray spacer, gently press on the top three plastic arms to remove.*

Troubleshooting Chart

| Issue	Solution
No Printing	Check to see that the LAN Connection properties on the system computer are defined correctly. Ensure that a crossover network cable is used and check connections. Check AC power cord connections and confirm that the Power-On indicator is illuminated. Check to see that paper has been loaded. Check to see that no error indicator lights are illuminated. If the error indicator is on, depress the black form-feed button for approximately 10 seconds to reset the printer. If the problem persists, contact technical service. Check to see that the proper Mortara paper is being used.
Distorted printing	Check with Mortara Service to ensure that the correct firmware version is installed on the Z200+ printer.
Uneven printing	Possible causes of uneven printing could be the print head itself, the platen, poor or damaged paper, or the mechanical alignment of the print head. Have a technician check the platen for uneven wear and check that the print head shoulder screws are secure before replacing the print head. The shoulder screws which secure the print head should be properly centered in their holes, allowing the print head slight vertical movement.
Printing too light or too dark	Change the Waveform Print radio button to Normal or Bold in the System Configuration Modality Settings under the Miscellaneous tab. Contact Mortara Instrument Technical Service Department for assistance if this does not resolve the problem
Gaps in Printing	Have a technician check the power head cable and the signal cable for shorts, opens, or damaged connectors. These cables plug in between the circuit board and the thermal print head. If the cables are all right, then the problem could be either the print head or the circuit board, or defective paper.
Defective Paper	Thermal paper which is old or which was improperly stored can cause light or uneven printing. Exposure to heat or chemical vapors can damage the paper. Test your Z200+ thermal writer using a fresh pack of properly stored paper.
No Motor Drive	The problem of no motor drive could be caused by insufficient paper tension, a faulty writer assembly, or a faulty circuit board.

SUNTECH TANGO+ AND TANGO M2 INTERFACE

SunTech Tango+ Blood Pressure (BP) Monitor and XScribe Connections

To setup Tango+ with the XScribe system, follow the directions below.
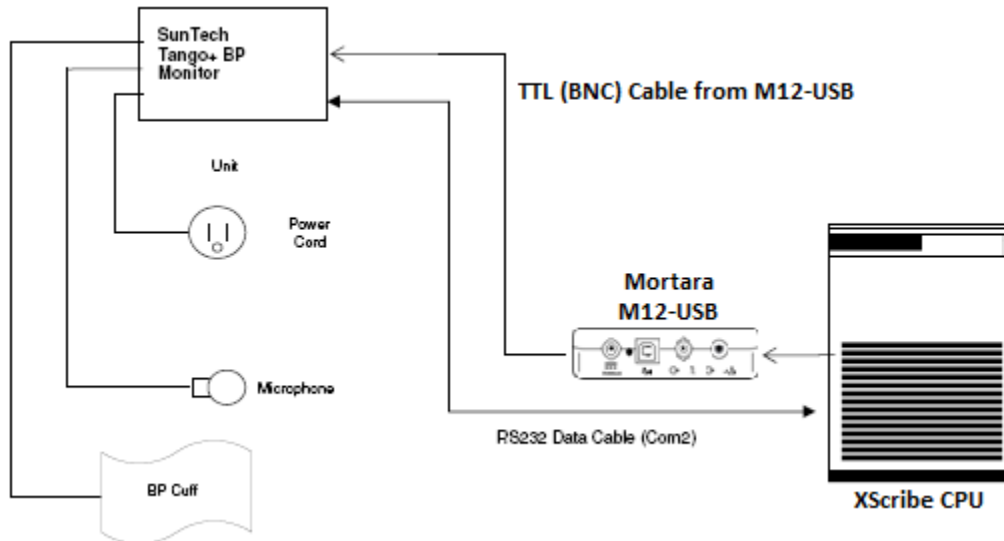
1. Connect the RS-232 cable (SunTech Part Number 91-0013-00) to the 9-pin connector on the rear panel of the Tango+, and the other end to the COM 2 port on the back of the XScribe CPU.

2. Connect the ECG Trigger Cable (SunTech Part Number 91-0011-00) to the BNC external ECG connection on the rear panel of the Tango+, and the other end to the TTL output connection on the Mortara M12-USB.
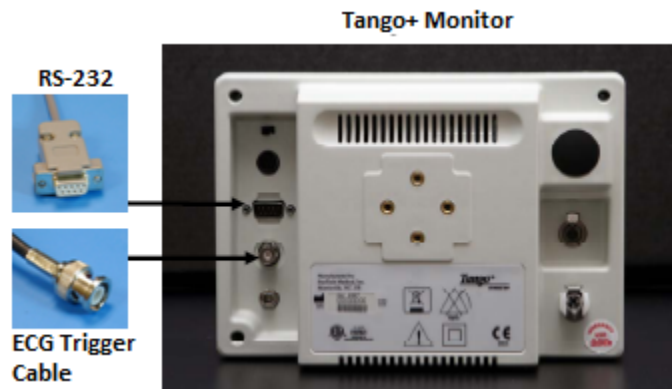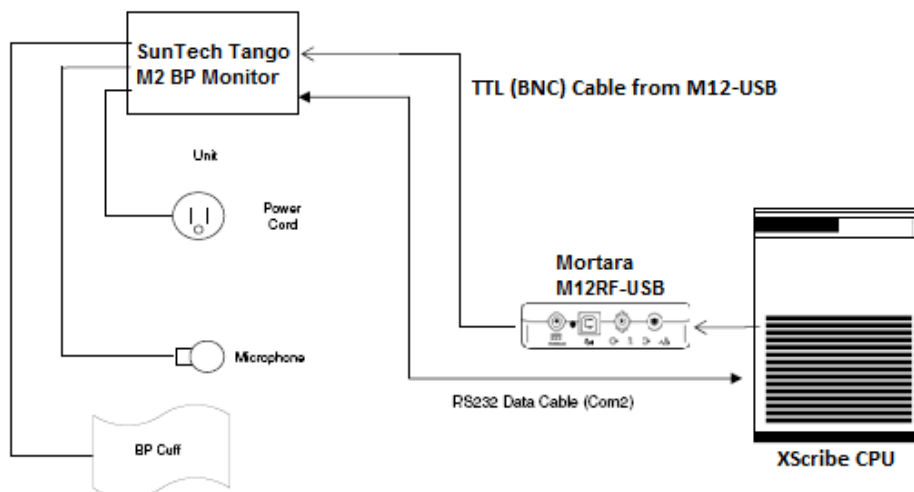

Tango+ BP Monitor Setup

1. When the operating screen is displayed, press the **SELECT** button twice to display the **MAIN MENU**.

2. Use the **UP**/**DOWN** arrows to highlight **MONITOR SET UP** and press the **SELECT** button.

3. Use the **UP/DOWN** arrows to highlight **STRESS SYSTEM** and press the **SELECT** button.

4. Use the **UP/DOWN** arrows to scroll through the list until **X-Scribe II** is highlighted and press the **SELECT** button to confirm.

5. Use the **UP/DOWN** arrows to select **EXIT** twice to return to the operating screen.

SunTech Tango M2 Blood Pressure (BP) Monitor and XScribe Connections

To setup Tango M2 with the XScribe system, follow the directions below.

1. Connect the RS-232 cable (SunTech Part Number 91-0013-00) to the 9-pin connector on the rear panel of the Tango M2, and the other end to the COM 2 port on the back of the XScribe CPU.

2. Connect the ECG Trigger Cable (SunTech Part Number 91-0011-00) to the BNC external ECG connection on the rear panel of the Tango M2, and the other end to the TTL output connection on the Mortara M12RF-USB.

   NOTE: If this port is already in use, a BNC Splitter may be needed (SunTech Part Number 64-0080-00).

Tango M2 Blood Pressure (BP) Monitor Setup

    a.   When the operating screen is displayed, press the **SELECT** button once to display the **MAIN MENU**.

    b.   Use the **UP**/**DOWN** arrows to highlight **MONITOR SET UP** and press the **SELECT** button.

    c.   Use the **UP/DOWN** arrows to highlight **STRESS SYSTEM** and press the **SELECT** button.

    d.   Use the **UP/DOWN** arrows to scroll through the list until **X-Scribe** is highlighted and press the **SELECT** button to confirm.

    e.   Use the **UP/DOWN** arrows to select **EXIT** twice to return to the operating screen.

XScribe System Setup

    1.   While the Observation Phase is displayed, select the **Local Conf** [F2] button to display Local Settings pop up menu.

    2.   From the BP Equipment drop-down list, select **SunTech BP** and then click **OK**.

The selected setting is remembered for all future stress tests. However, this selection can be changed on a per-exam basis. The Softkey [F6] pop up window also allows a change from automatic to manual BP when necessary during an exam.

The XScribe blood pressure entry control for Exercise and Recovery phases will now automatically initiate and acquire BP readings and optional SpO2 values from the SunTech Tango BP Monitor.

Refer to the SunTech Tango+ or Tango M2 Stress BP User's Guide included with the BP Monitor for information about indications for use, warnings and contraindications, BP monitor operation, patient preparation, maintenance, and troubleshooting information. This information is also available at the SunTech Medical website: www.suntechmed.com.