Welch Allyn® XScribe™6 CARDIAC STRESS TESTING SYSTEM SERVICE MANUAL





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1. NOTICES

Manufacturer's Responsibility

Welch Allyn, 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 Welch Allyn, 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

Welch Allyn, 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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Other Important Information

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Notice to EU Users and/or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2. WARRANTY INFORMATION

Your Welch Allyn Warranty

WELCH ALLYN, INC. (hereafter referred to as "Welch Allyn") warrants that components within Welch Allyn 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 Welch Allyn, 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 Welch Allyn;
- 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 Welch Allyn;
- f) Other events outside of Welch Allyn's reasonable control or not arising under normal operating conditions.

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

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

3. 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.

NOTE: This manual may contain screen shots and pictures. Any screen shots and pictures 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.



WARNING(S)

- 1. 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.
- 2. The various manufacturers of accessories provide separate user manuals and/or instructions (e.g., display, blood pressure monitor, laser printer, patient cables, and 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 Welch Allyn.
- 3. Device (cardiac stress 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.
- 4. 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 Welch Allyn service for additional training options.
- 5. To ensure that electrical safety is maintained during operation from AC (~) power, the device must be plugged into a hospital-grade outlet.
- 6. 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.
- 7. 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 Welch Allyn, Inc.
- 8. 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, and leakage currents should be measured to confirm no electric shock hazard exists.

- 9. To avoid potential for electric shock, ensure that approved equipment and accessories are connected to the appropriate ports and that no incompatible equipment has been connected.
- 10. 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.
- 11. 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.
- 12. Conductive parts of the SunTech® Tango® blood pressure monitor's optional pulse oximeter (SpO₂ sensor used to monitor oxygen saturation) and associated connections of Type BF applied parts should not come into contact with other conductive parts, including earth ground. The pulse oximeter is not defibrillator protected. Refer to the SunTech Tango user instructions for further details.
- 13. To avoid risk of improper electrical isolation the Tango SpO₂ sensor must only be connected to the proper SpO₂ extension patient cable or port on the SunTech Tango blood pressure monitor.
- 14. 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.
- 15. 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.
- 16. Position the system in a location where the isolation transformer medical grade power cord plug can be quickly disconnected from the power source should it become necessary to isolate the cardiac stress system from the supply mains.
- 17. 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.
- 18. 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.
- 19. 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.
- 20. A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.
- 21. 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.
- 22. 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.
- 23. 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.

- 24. Test XScribe functions after each Microsoft critical and security update. Instructions for testing the system functions are located in the XScribe System Installation Manual, part number 9515-205-60-ENG.
- 25. To maintain designed operator and patient safety, the XScribe Front End, and conductive portions of connected cables must be positioned such that they are inaccessible during normal operation.
- 26. An additional Multiple Plug Socket Outlet (MPSO) or extension cord shall not be connected to the system.
- 27. Do not connect any items which are not specified as part of the system.
- 28. 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.
- 29. ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation. Electrode materials and ingredients are specified on the packaging or are available from the vendor upon request.
- 30. 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.
- 31. 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.
- 32. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.
- 33. To prevent emission of substances that may damage the environment, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials that are past the shelf life in accordance with local regulations.
- 34. When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- 35. Proper functioning backup items such as a spare patient cable, display monitor, and other equipment are recommended on hand to prevent delayed treatment due to an inoperable device.
- 36. To maintain a safe working environment, the cardiac stress cart including devices and equipment should not exceed 200 kg.

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
 - This device must accept any interference received, including interference that may cause undesired operation.



Cautions

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

- 1. 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.
- 2. Microsoft 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 and Windows Server 2012 R2. Although it is unlikely that Windows updates and security patches affect XScribe functionality, Welch Allyn 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. Welch Allyn 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.
- 3. No other non-recommended PC application software should be running while the XScribe application is being used.
- It is recommended that all cardiac stress workstations and review stations be periodically updated with Microsoft critical and security updates to protect from malware attacks and to fix critical Microsoft software issues.
- 5. To prevent delivery of malware into the system Welch Allyn recommends that institution operating procedures are written to prevent malware to be transmitted into the system from removable media.
- 6. 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 *Exam Search* in the User Manual for ways to select exams for deletion or archiving.
- 7. 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.
- 8. To avoid risk of unintentionally booting into a USB device, ensure that the Boot Order in BIOS is set with the SATA hard drive listed first in the boot order. Refer to computer manufacturer's instruction for entering BIOS on startup and configuring Boot Order.
- 9. The WAM will only work with receiving devices that are equipped with the appropriate option.

- 10. 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.
- 11. The following equipment may cause interference with the WAM RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.
- 12. When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- 13. 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.
- 14. Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the WAM.

Note(s)

- 1. 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.
- 2. 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.
- 3. Once the Pre-Exercise phase is started, full disclosure data storage begins and will continue for up to 120-minutes. It is recommended to Abort the exam and Begin again if waiting in this phase for up to 60-minutes. This prevents unnecessary data storage, however previously stored full disclosure, ECG events, and BP values are not saved when the exam is aborted.
- 4. Patient movements may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.
- 5. Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- 6. The Beat Consistency Filter (BCF) that produces averaged 12-lead ECG printout introduces an additional two-second delay to the real-time ECG data when enabled.
- 7. 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.
- 8. If the treadmill COM port was originally set to a USB port that was not used, a TREADMILL FAIL message will appear when the Trackmaster (No Sensing) selection is made in the Local Settings menu. When the COM port is set to Treadmill COM Port 1 or 2, which are serial ports, there will be no TREADMILL FAIL message.
- 9. 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.
- 10. 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 with exception of the optional pulse oximeter that is not defibrillation-proof
- 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.

11. 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: -40° C to 65° C (-40° F to 149° F)
 Relative humidity: 8% to 80%, non-condensing

12. 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 XScribe Front End and Trigger Module are as follows:

Ambient temperature: 10° C to 35° C (50° F to 95° F)
 Relative humidity: 8% to 80%, non-condensing

- 13. 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.
- 14. A square wave on the display and rhythm printout could be due to the lead wires not being connected to the patient.
- 15. The WAM must be paired to the XScribe system before operation.
- 16. 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.
- 17. The WAM will automatically turn off (LEDs off) if the battery has been severely discharged.
- 18. The WAM will automatically power off after the exam has ended.
- 19. The WAM Rhythm Print and 12-Lead ECG buttons are non-functional.
- 20. The WAM is UL classified:



WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH IEC 60601-1, CAN/CSA C22.2 No. 60601.1, IEC 60601-2-25

4. EQUIPMENT SYMBOLS AND MARKINGS

Device Symbol Delineation

















ECG A



ECG B







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

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

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

Protective earth symbol

Fuse symbol

Defibrillator-proof type CF applied part

Equipment mass including safe working load

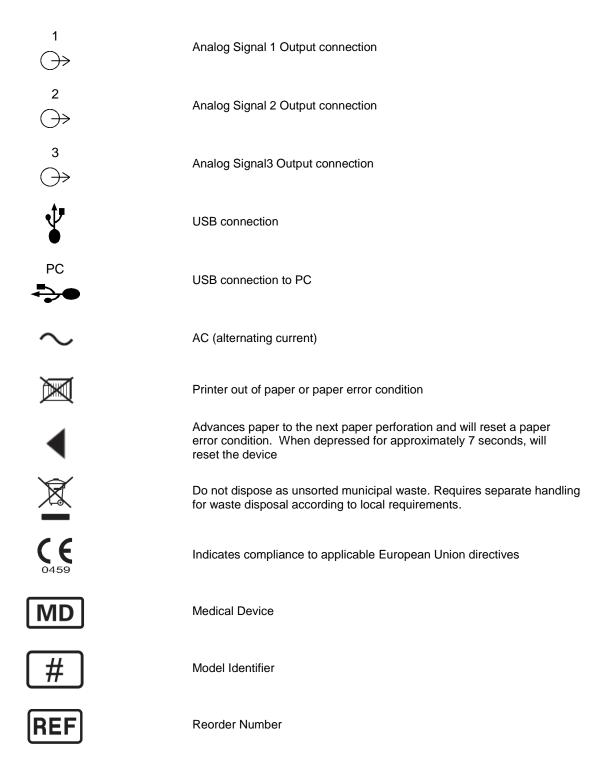
Input

ECG A input connection

ECG B input connection

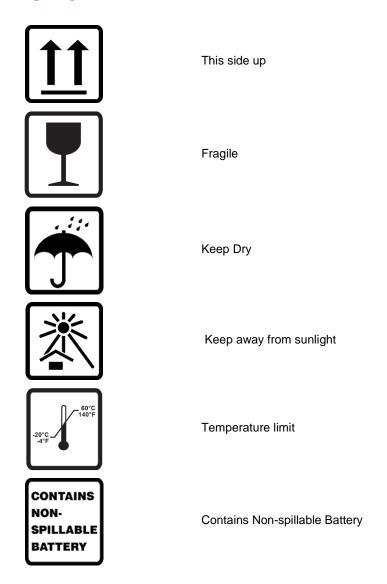
Output

TTL Signal Output connection



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

Package Symbol Delineation



5. 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 stress belt can be surface cleaned with a damp cloth or a disinfectant wipe or spray. The stress belt may also be machine or hand washed with detergent and air dried. Do not machine dry the stress belt. Cosmetic changes may occur during washing. Inspect stress belts 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.

Disposal

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

6. ELECTROMAGNETIC COMPATABILITY (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 EMC table for recommended separation distances between the radio equipment and the device.

The use of accessories, transducers and cables other than those specified by Welch Allyn 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
Harmonic Emissions IEC 61000-3-2	Complies	domestic purposes.
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	$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$
Radiated RF	3 V/m	3 V/m	$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b .
			Interference may occur in the vicinity of equipment marked with the following symbol:

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.

7. INTRODUCTION

Manual Purpose

The purpose of this manual is to supply information to service personnel so they can maintain the XScribe System, information for peripheral devices should be found in manuals supplied with equipment or by contacting original manufacturer. This manual is intended to function primarily as a guide to preventative and corrective maintenance and electrical repairs considered field repairable.

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.

Periodic Safety Inspections

Follow the recommended maintenance schedule. Inspect the power cord and transmission cables periodically for fraying or other damage and replace as needed. Broken or frayed wires may cause interference or loss of signal. Pay particular attention to points where wires enter connectors.

Proper Power Cord

The power cords from all the peripheral equipment should be plugged into the Isolation Transformer. This product requires a three-wire, (18 gauge, SJT-grade) power cord, which is supplied with a three-terminal, polarized plug (hospital grade) for connection to the power source and protective ground. Use of the Isolation Transformer supplied, is required. An interruption of the grounding connection could cause an electrical shock hazard.

Proper Fuse

Applies to Isolation Transformer only. Use only the fuse specified for the equipment (identical in type, voltage, and current rating). Substituting a different fuse type could cause a fire hazard. Always make sure fuses have been installed before operating the equipment.

Do Not Operate in Explosive Atmospheres

Do not operate the XScribe in the presence of flammable gasses or anesthetics, this environment could cause an explosion. Refer to Operator's Manual Safety Information: Warning(s) and Caution(s).

Use Only Safe Methods of Interconnection

To prevent electrical shock from the product when it is connected to other electrical equipment, proper grounding is essential. Refer to Operator's Manual Safety Information: Warning(s) Peripheral equipment.

Do Not Mount Product Above Patient

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

Recommended Accessories

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

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 Welch Allyn's VERITASTM 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 system includes a demonstration mode that provides a way to demonstrate system features and train clinicians on operation without the need for live physiological data. Refer to Using the System instructions in this manual for details.

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 configured with cardiac stress application software
- 24" wide-screen color monitor
- Z200+ thermal array writer
- XScribe front end (AM12) for signal processing
- Trigger Module for analog/TTL signal output
- Isolation transformer
- System cart
- 10-lead ECG patient cable with or without replaceable lead wires
- Stress belt to support the patient cable
- Local area network (LAN) support

Optional items include:

- High-speed laser printer
- Treadmill
- Ergometer
- Programmable remote keypad
- Integrated non-invasive blood pressure monitoring with or without SpO₂

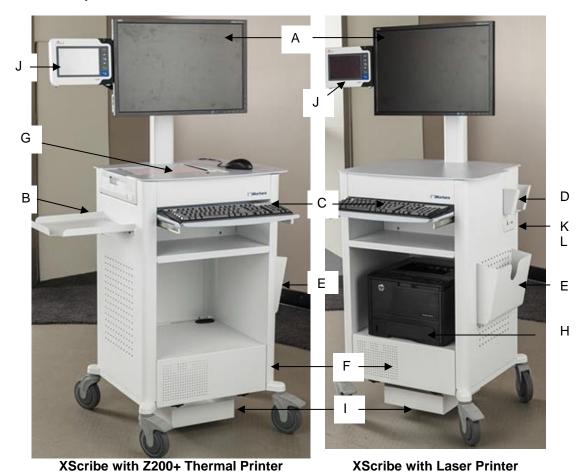
Miscellaneous System Information

- 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 Welch Allyn'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 standard.

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

XScribe System

Figure 1 XScribe System*



A. 24" Display

B. Paper catch tray

C. Keyboard

J. SunTech Tango M2 (optional)

D. Patient Cable Support

E. Storage bin

F. CPU compartment

K. Trigger Module

- **G.** Z200+ thermal printer
- **H.** Laser printer
- I. Isolation Transformer shelf
- L. XScribe Front End (AM12)

^{*}Subject to change without notice

XScribe ECG Acquisition Devices and Accessories

AM12 For XScribe patient cable connection ACQ MOD (AM12) W/O LEAD WIRES (9293-048-54)	
Wireless Acquisition Module (WAM) For wireless patient cable connection. WAM is only compatible with UTK item number 30012-021-51 and is not compatible with the earlier version of the UTK.	(*************************************
Universal Transceiver Key (UTK) 30012-021-51 Compatible ONLY with WAM.	COMortana ACTRUMENT RES BORT 2-24-1-5 RES BORT 2-2
Wireless Acquisition Module (WAM 2) For wireless patient cable connection. WAM 2 is ONLY compatible with the UTK item number 30012-021-52 and is not backwards compatible with any earlier version of the UTK. Please note the "2" on the lower left portion of the label.	
Universal Transceiver Key (UTK) 30012-021-52 Compatible ONLY with WAM 2 above. Please note the "2" on the left side of the serial number label.	MODEL: UTK REF: LOT: FCC ID: HURUTK2500 IC: 37588-UTK2500 Milwaukee, WI U.S.A. A. C. C.
Trigger Module Front ECG A connector for AM12Q connection and one analog signal connector	
Trigger Module Back Analog signal connector 2, analog signal connector 3, TTL output connector, ECG B connector and USB PC connector.	
Stress Pouch and Belt for the 10 lead wire patient cable	

IMPORTANT – Compatibility of WAM and UTK items must be according to the information listed below.

WAM - 30012-019-54	Use ONLY With	UTK - 30012-021-51
WAM (2) 30012-019-56	Use ONLY With	UTK (2) – 30012-021-52

Supported Treadmills, Ergometers, and Automatic Blood Pressure Devices

Refer to the product User Manual for information regarding compatibility with these types of devices.

XScribe Icon Descriptions

Icon and Hover Text	Description
XScribe	XScribe desktop shortcut icon to launch the Stress modality application.
M T W T F S S 1 2 3 4 6 7 8 9 10 1 13 14 15 16 20 21 22 23 27 28 29 30 Schedule/Orders	Opens a window with two selectable tabs. A MWL (Modality Work List) tab allows exam scheduling (when no orders interface exists) and schedule review. A Patients tab allows addition of new patient information and editing of existing patient information.
	Opens a window presenting scheduled exams under the MWL tab and patient demographics under the Patients tab.
Start a Stress Test	The observation screen with the stress hookup display is opened when the Start Exam button is selected.
Exam Search	Opens a window allowing users to search for Stress exams or patients in the database using filters.
User Preferences	Opens a window for configuring the user preferences for the Worklist, List Customization, 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.

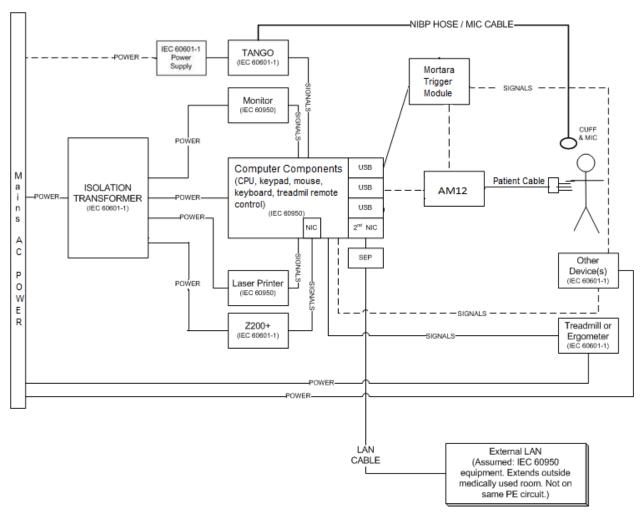
XScribe Specifications

Feature	Workstation Minimum Specification*		
Computer Model	HP rp5800, HP rp5810, Dell XE3		
Processor	Intel Core i3 (minimum)		
Graphics	1920 x 1080 or 1920 x 1200		
RAM	4 GB (minimum)		
Operating System	Microsoft Windows 7 Professional 32-bit or 64-bit, Windows 10 64-bit		
Hard Drive Capacity	500 GB (minimum)		
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	AM12 with Patient Cable connector Trigger Module for analog and TTL signal output to external devices		
Printing Devices	HP M401n Laser printer (recommended) Z200+ Thermal Printer (Version 1 requires additional network port / Version 2 requires additional USB port)		
USB Ports	2 free USB 2.0 ports		
Serial Ports 2 serial ports for serial interfaced equipment.			
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 or 2012 server R2, 64-bit		
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		
Archive Software Installation	Network or external USB drive CD-ROM		

^{*} Specifications subject to change without notice.

XScribe Interconnect Diagram

Figure 2 XScribe Interconnect Diagram





WARNING: To prevent electrical shock to the patient, the computer, monitor, and printer must receive power from the Certified Separating Device (Isolation Transformer).

NOTE: The Certified Separating Device (Isolation Transformer) will power up to four devices. When more than four devices require power, the Tango BP Monitor must be powered by another available AC power outlet. The SunTech Tango unit does not require connection to the isolation transformer, as it is a medical device that includes its own isolated power supply. The Tango may be powered by the isolation transformer as a convenience.

XScribe Front End and Patient Cable Connection

The XScribe AM12 is connected to the XScribe Trigger Module that digitizes and filters the patient's ECG signals.



XScribe Front End and Trigger Module Connection

The Trigger Module optionally provides analog and TTL signal output for connection to external devices such as an echocardiograph system. The Trigger Module is required when the SunTech Tango BP Monitor will be connected to the cardiac stress system.

Trigger Module Front



XScribe Front End is connected to the ECG A USB connector on the module front. One analog output connection is also on the front.

Trigger Module Back



The module back provides two analog output connectors and one TTL output connection.

The ECG B connector is unused with XScribe.

The Trigger Module is typically installed flush on the right or left side of the stress cart, dependent on the position of the XScribe Front End location.

As an option, the Trigger Module may be mounted to the Quinton TM55/TM65 treadmill. This configuration will utilize the Trigger Module Rail Clamp kit (PN 9911-022-50).

Medical Isolation Transformer

The isolation transformer is a separating device that prevents system components from developing excessive leakage current. It is plugged into a dedicated circuit.

Figure 3 Medical Isolation Transformer



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: 1404-004 TRANSFORMER ISOLATION 1000VA MED GLOBAL

Input 115VAC 50/60 Hz 2x10AT Fused / 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 switch) is set to the proper line voltage. All units shipped from Welch Allyn are set to 115V. To change voltage to 230V, move the voltage selector switch located to the right of the power switch.

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.

Treadmill

The treadmill models currently used with the XScribe Stress test system are the Quinton TM55, Quinton TM65, Trackmaster TMX425, and Trackmaster TMX428.



Please refer to the treadmill owner's manual that came with the treadmill for maintenance information.

NOTE: The treadmill MUST be connected to a dedicated mains outlet.



WARNING: To prevent electrical shock to the patient, the computer, monitor, and printer must receivepower from the Certified Separating Device (Isolation Transformer).

Maintenance Procedure

Welch Allyn recommends device maintenance is performed on an annual basis.

Equipment needed:

- Treadmill PM KIT (For Full Vision treadmills)
- Clean, lint-free cloth
- Cleaning solvent (isopropyl alcohol, 70% pure)
- DRY, low pressure, compressed air (30 psi)
- Masking tape
- Rubber Rejuvenator/Platen Cleaner
- Screwdriver Philips #2
- Safety Analyzer

Treadmill Preventive Maintenance

Refer to the service manual for the treadmill model utilized with the XScribe system for preventive maintenance information.

8. PREVENTIVE MAINTENANCE & CLEANING

Preventive Maintenance Schedule

MAINTENANCE TYPE	PERIOD	NOTES
Visual Inspection	Daily	Refer to inspection criteria listed in the Visual Inspection section.
Device Cleaning	As Needed	Refer to the device cleaning instructions below.
Battery Door Replacement	36 Months	Replacement period varies based on frequency of use; refer to visual inspection criteria for areas of concern.

Visual 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 Instructions

Keyboard/Mouse Cleaning

Turn the keyboard upside down. Gently tap the back of the keyboard and press the keys to release any debris from in between the keys.

If you have a can of compressed air then use it to blow any debris from around and under the keys, if not then use the hose of a vacuum cleaner to remove it.

If the keys appear to need cleaning, use a cotton swab with isopropyl alcohol on it to clean the sides of the keys as needed.

After cleaning the sides of the keys take your lint free cloth and dampen it with isopropyl alcohol (don't put the liquid directly on the keyboard), give the surface of the keyboard a good wipe over using the cloth to trace the contours of the keys. Use the damp cloth to gently wipe the mouse to remove any hand oils or debris that may be present.

Care and Handling of the Optional Antimicrobial Keyboard and Mouse

The antimicrobial keyboard and mouse are Silver SealTM protected and contain an antimicrobial agent that inhibits the growth of microbial bacteria, mold, mildew and fungi on the product's surface. A USB Seal CapTM is included that allows the product to be 100% waterproof and dishwasher safe.

These products are dishwasher safe for easy cleaning and may be disinfected with bleach.



Remove and open the system PC from the transport cart. Using an ESD rated vacuum or compressed air, remove any accumulated dust and debris from the PC. Take particular care to cleaning around cooling fans and inside media access slots (refer to cooling fan inspection below). Clean the cart area that the PC and peripheral equipment reside in, to prevent dust and debris accumulation from occurring. Close the system and reinstall the PC into the transport cart once completed.

Inspection of PC cooling fans

Inspect CPU fan, and power supply fan. If they are running too slowly or are making any unusual noises during operation, they should be replaced. For improperly operating PC power supply fans, Welch Allyn recommends replacing the entire power supply unit.

Monitor Cleaning

WARNING: To avoid risk of electric shock and damage to the monitor, do not disassemble the monitor cabinet. The unit is not user-serviceable. User maintenance is restricted to the following cleaning instructions.

Unplug the monitor from the power outlet before cleaning.

- To clean your monitor screen, lightly dampen a soft, clean cloth with water or mild detergent. If possible, use a special screen cleaning tissue or solution suitable for the anti-static coating.
- To clean the monitor cabinet, use a cloth lightly dampened with mild detergent. Make sure that water cannot drip into the case of the monitor.

Wipe off stubborn stains from the cabinet or screen with a cloth lightly dampened in isopropyl alcohol. Do not use benzene, thinner, ammonia, or abrasive cleaners.

Care and Handling of the Optional ELO Touch Monitor

- 1. Disconnect the AC power cable before cleaning
- 2. Use a clean cloth lightly dampened with mild detergent to clean the display unit cabinet. Do not get liquids on or inside the unit. It is important that the unit remains dry.
- 3. Clean the touch screen with window or glass cleaner applied to a clean cloth or sponge. Never apply cleaner directly to the touch screen. Do not use alcohol (methyl, ethyl, or isopropyl), thinner, benzene, or other abrasive cleaners.

XScribe Cart Cleaning

Use a damp, clean cloth to wipe off external surfaces with isopropyl alcohol. Do not use solvents, or cleaning solutions that may damage the surface of the instrument. Avoid contact with open vents, plugs, and jacks.

A 10% bleach solution is recommended for contaminated areas.

Cable Management

Arrange all of the cables per the Installation Instructions provided in the XScribe user manual (Welch Allyn Item # 9515-209-50-ENG).

Thermal Writer Cleaning

Use a damp, clean cloth to wipe off external surfaces. Open the writer door and use masking tape to clean the platen of the thermal writer. The platen should then be further cleaned with a Rubber Rejuvenator/Platen Cleaner to ensure it does not deteriorate over time. The thermal print head can be cleaned using a clean lint free cloth and isopropyl alcohol; simply wipe the print head surface that makes contact with the paper to remove any debris or residue that may have built up during operation.

Refer to the Z200+ Service Manual, 9516-163-70-ENG for additional cleaning or service related questions. Reference Service Manual 80025240 for the Z200+ v2 with USB connection.

System Checks

Archive Management

With customer's assistance, create additional Archive folders on the root directory or on the network (if option installed). Refer to the XScribe User Manual (9515-209-50-ENG) for complete instructions. Archive all the patient exams from the root Archive to the newly created Archive locations.

Hard Drive Space

Check the capacity of the system hard drive to ensure there is sufficient space for system operation. If the system drive is nearing capacity (approaching 90%), this issue should be discussed with the facility to create additional space for proper operation. If the drive was near capacity and unnecessary files were removed, a defragmentation may be performed to ensure optimal performance of the drive.

NOTE: The defragmentation process may take several hours and is only required in extreme cases.

PC Diagnostics

Disconnect all wires from the installed PC with the exception of mains power, monitor, keyboard and mouse. Run the PC diagnostics and address any failures during testing. Repair the PC using Welch Allyn authorized parts only.

Conformance Testing

Z200+ Writer Test

Using the Z200Plus Monitor software, print off a test page. The Z200PlusMonitor software can be loaded onto the XScribe system or ran from USB stick. Double click Z200PlusMonitor icon to launch the application. Press Connect and then press Print Test Page. Verify on the print out page that there are no missing pixels or light printing. Now press Disconnect and close the application.

Functional Testing

Patient Cable(s)

Place the XScribe system into the pre-exercise mode. Verify patient cable connector pins are not bent by disconnecting the patient leads from the AM12 and inspecting the contacts, then reinsert the cable into the AM12 for testing. Connect the patient leads to an ECG simulator and wiggle patient cable to verify lead wires looking at the ECG presented on screen for continuous proper waveform shape and amplitude. There should be no spikes, flatlines or interruptions of the waveform.

- Click on the **Start Stress Test** icon and select the **Search Patient** button. Click **New Patient** and enter test patient demographics.
- Click **Confirm** and verify the test starts. ECG data should begin to be displayed. Verify **Bruce** is the selected protocol from the top left hand drop down menu.
- Click the **Begin** button and allow about a minute of data to be collected. Then press the **Start Exe** button and verify treadmill turns on and begins to move.
- Allow the system to run through the full Bruce protocol. Verify treadmill is rising and that the speed increases throughout test. Verify printouts are coming from Z200+ writer or Laser Printer (if the option is installed).
- Once the test enters the Recovery phase, verify the treadmill slows down and returns to 0% grade. Press the ECG F11 button and verify a printout comes from the Z200+ writer or Laser Printer (if the option is installed).
- Press the **END F1** button and verify the test goes in to the Report Manager screen. Real Time ECG data should still be displayed at the bottom of screen. Press the **ECG** button and verify a printout comes from the Z200+ writer or Laser Printer (if the option is installed).
- Press the **EXIT** button and verify system exits the Report Manager screen.
- Verify the test results were stored properly in the appropriate location, and that any configured data export options were performed.

Data Export (if option installed)

• Verify XScribe is able to Export pdf's, xml. tif, DICOM, etc to the network. Verify XScribe is able to download a worklist from the network.

Safety Testing

The following safety tests should be performed in accordance with IEC 60601 or IEC 62353 standards and all local regulatory requirements:

- Earth Leakage (performed on medical isolation transformer)
- Enclosure Leakage (performed on medical isolation transformer)

The following safety tests are required only for systems utilizing a wired patient interface:

- Patient Leakage
- Patient Leakage Type-F
- Patient Auxiliary Current

XScribe Preventive Maintenance Report

Xξ	XScribe Serial #:				
Tr	Treadmill Serial #:				
	Treadmill Inspection / Maintenance				
	Treadmill Functional Testing				
	Visual Inspection/Cleaning Inspect/Clean system PC, monitor, keyboard and mouse Inspect/Clean any adhesive residue or scuff marks from transport cart Organize/fasten interconnect cables on cart				
	□ Thermal Writer Cleaning (if option installed) □ Platen Cleaning □ Thermal Printhead Cleaning				
	System Checks Archive management Sufficient hard drive space PC Diagnostics				
	Conformance Testing Perform lead check on system transmitter(s) and patient cable(s) Print writer test page and inspect for proper operation/darkness Perform a full stress test with a patient simulator Verify treadmill turns on as per protocol settings Verify writer prints as per protocol settings Verify data export functionality (if option installed)				
	Safety Testing Earth Leakage Transformer Enclosure Leakage (The following tests are performed for wired patient inputs only)				
	 Patient Leakage Patient Leakage Type-F Patient Auxiliary Current 				
ıd F	1 Bv· Date· /	/			

XScribe - Conformance Test Data Record

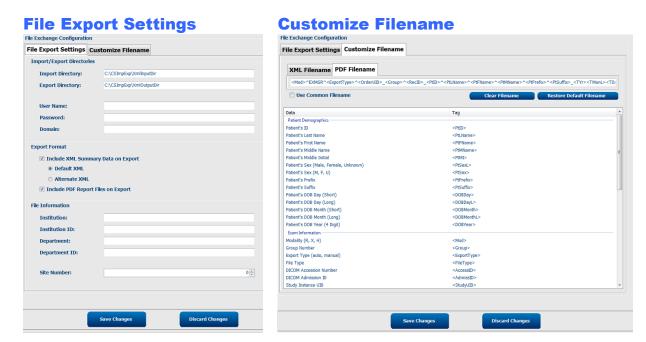
XS	XScribe Serial #:				
Tre	Treadmill Serial #:				
□ System Checks					
		Archive management Sufficient Hard drive space PC Diagnostics			
	Function	al Testing			
		Print writer test page and inspect for proper operation/darkness Perform lead check on system front end and patient cable(s) Perform a full stress test with a patient simulator Verify treadmill turns on as per protocol settings Verify writer prints as per protocol settings Verify test results were properly stored Verify data export functionality (if option installed)			
	Safety Te	esting			
		Earth Leakage Transformer Enclosure Leakage			
		(The following tests are performed for wired patient inputs only)			
		Patient Leakage Patient Leakage Type-F Patient Auxiliary Current			
		(Refer to appropriate Treadmill Service Manual for additional details)			
	Treadmill	I Inspection / Maintenance Running Belt Cleaning & Inspection Running Belt Tension Check / Adjustment Drive Belt Tension Check / Adjustment Elevation Screw Lubrication, (Full Vision Mill) Control Cable Fastened/Routed Appropriately			
	Treadmill	I Functional Testing Test Plug Operation, (Full Vision Mill) XScribe Control Test Emergency Stop Button Check			
- J D), ₄ ,	D-1-	,	,	

9. SPECIAL FUNCTIONS

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 Configuration window under the File Export Settings tab. The Site Number field is not applicable to XScribe. The file name configuration for XML and PDF results is customized under the Customize Filename tab. Refer to the 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.



CFD Configuration

A long, medium, or short format for displayed items and report contents can be uniquely defined per Group. Select the **CFD Configuration** button to display the Custom Format Definition Name drop-down list. Choose Long, Intermediate, or Short name for the selected group and then click the **Save** button, or the **Cancel** button to discard your changes.

The **Long** format contains all demographics.

The **Intermediate** format excludes the patient's contact information.

The **Short** format excludes the patient's history, contact information, and the diagnosis section in the report summary.

Stress Custom Format Definition Name	Short Intermediate Long
	Save

DICOM and MWL 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 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.

Manager 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

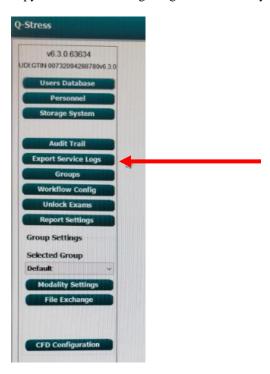
The XScribe administrative user will select Audit Trail to view the audit trail history. A selection of filter criteria is available to sort the listing by date, user, workstation, operation, or target (e.g. User, Patient, Exam, Conclusion, Locked Exams, User and System Settings). One or more filter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

Service Logs

All Q-Stress users have access to Export Service Logs from the main settings menu on the left side of the display. Selection of the **Export Service Logs** button creates a Win-7 zipped file that can be sent to the desktop containing a copy of the Exam Manager log data from the system database.



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

Additional log files may have also been generated by the system and stored at the path show below. Check this location and copy all files present for review by qualified Hillrom technical resources to assist with the troubleshooting process.

C:\ProgramData\Mortara Instrument X-Scribe\Logs\

Service Logs (v6.3.1 and newer)

Enhanced logging features were added to the software in v6.3.1, which are stored at the location shown below.

C:\ProgramData\Mortara Instrument X-Scribe\Logs\

The enhanced log files are generated by the modality software application, intended to be used by qualified technical resources to assist with diagnosing system related problems that may be of an intermittent nature or occur infrequently. To obtain the log files as part of a technical investigation, navigate to the path defined above and copy all of the files at that location with a file extension of ".el". These files should then be delivered to Hillrom technical support for review by qualified technical resources to assist with determining the cause of the reported problem.

Log files with a .el extension are text based and can be opened/read with a text-based application (such as Notepad). The top portion of the log file content does contain general information about the system the logs came from (see bullet points below), which is also useful for verifying various aspects about the system being investigated.

- Stress application software version
- User login ID
- OS Version
- Network IP information
- Computer Information
 - o Memory (size, free space)
 - o Hard disk (size, free space)
 - System up time (duration)
 - Processor
 - Display mode
 - o Video card
 - Printer driver

Example of General Log File Content:

Application:

- 1.1 Start Date : Thu, 25 Jun 2020 15:50:53 +0200
- 1.2 Name/Description: XScribeII.exe (Exercise ECG Application)
- 1.3 Version Number: 6.3.1
- 1.4 Parameters : /exam current /Language en /QSTRESS /RestInterp /DEMO_RAW /DEMO_RATE 2
- 1.5 Compilation Date: Thu, 25 Jun 2020 09:52:07 +0200
- 1.6 Up Time : 7 second(s)
- 1.7 Elevated : 0 1.8 Integrity : Medium 1.9 Allocated : 0
- 1.10 RAM : 192012288 (183,12 Mb); Max: 192413696 (183,50 Mb) 1.11 Private : 183558144 (175,05 Mb); Max: 186478592 (177,84 Mb)
- 1.12 Virtual : 624324608 (595,40 Mb)

User:

3.1 ID : admin

3.2 Name : Windows User

3.3 Email : example@example.com

3.4 Company:

3.5 Privileges: SeShutdownPrivilege - OFF

SeChangeNotifyPrivilege - ON (default)

SeUndockPrivilege - OFF SeIncreaseWorkingSetPrivilege - OFF SeTimeZonePrivilege - OFF

3.6 Admin : 0

Computer:

5.1 Name : DESKTOP-2BB10B2 5.2 Total Memory : 8588738560 (8,00 Gb) 5.3 Free Memory : 5458333696 (5,08 Gb) 5.4 Total Disk : 84992229376 (79,16 Gb) 5.5 Free Disk : 48958713856 (45,60 Gb)

5.6 System Up Time: 3 day(s), 17 hour(s), 58 minute(s), 25 second(s) 5.7 Processor: Intel(R) Core(TM) i7-8750H CPU @ 2.20GHz

5.8 Display Mode : 1920 x 1104, 32 bit

5.9 Display DPI : 96

5.10 Video Card : VMware SVGA 3D (driver 8.16.1.24 - RAM 1073741824) 5.11 Printer : Microsoft Software Printer Driver (driver 10.0.18362.387)

5.12 Virtual Machine: Hypervisor

Operating System:

6.1 Type : Microsoft Windows 10 (64 bit)

6.2 Build # : 1909 (10.0.18363.592)

6.3 Update : October 2019 Update [19H2] #592

6.4 Non-Unicode Language: English (0409)

6.5 Charset/ACP : 0/1252 6.6 Install Language : English (0409) 6.7 UI Language : Italian (0410) 6.8 Edition : Enterprise

6.9 UAC : 1

Network:

7.1 IP Address: fe80::6505:b889:3908:589b%11 - 192.168.189.150 - fe80::ccde:20ad:b236:65e7%9 - 169.254.101.231

 7.2 Submask
 : /64
 - 255.255.255.000 - /64
 - 255.255.000.000

 7.3 Gateway
 :
 - 192.168.189.002 - 000.000.000.000

 7.4 DNS 1
 :
 - 192.168.189.002 - fec0:0:0:ffff::1% 1
 - 000.000.000.000

 7.5 DNS 2
 :
 - 000.000.000.000 - fec0:0:0:ffff::2% 1
 - 000.000.000.000

7.6 DHCP : ON - ON

7.7 Description: Ethernet0 - [UNPLGGD] Bluetooth Network Connection

10. DISASSEMBLY AND REPAIR

For Welch Allyn Supplied Hardware Only

Before You Begin

- 1. Put on your electrostatic discharge (ESD) wrist strap to avoid damaging any circuitry.
- 2. Remove all devices (such as diskettes and CD-ROMs) from the computer.
- 3. Power off the computer and any peripheral devices that are connected to it.
- 4. Disconnect the power cord from the electrical outlet and then from the computer. When the computer is plugged into an AC power source, there is always voltage applied to the system board. You must disconnect the power cord from the power source before opening the computer to prevent system board or component damage.
- 5. Disconnect all peripheral device cables from the computer.

Static Electricity

Static electricity can damage electrical components. Before removing or replacing a component, touch a grounded metal object to discharge static electricity. Also observe the following precautions to prevent damage to electric components and accessories:

- To avoid hand contact, transport products in static-safe containers such as tubes, bags, or boxes.
- Protect all electrostatic parts and assemblies with conductive or approved containers or packaging.
- Keep electrostatic-sensitive parts in their containers until they arrive at static-free stations.
- Place items on a grounded surface before removing them from their container.
- Always be properly grounded when touching a sensitive component or assembly.
- Avoid contact with pins, leads, or circuitry.
- Place reusable electrostatic-sensitive parts from assemblies in protective packaging or conductive foam.

Disassembly



WARNING: Be sure the AC power cord is disconnected prior to performing servicing.

- During disassembly, label each cable as you remove it, noting its position and routing. This will make the
 replacement of the cables much easier, and will ensure that the cables are rerouted properly to protect the
 cables.
- Keep all screws with the units removed. The screws used in the computer are of different thread sizes and lengths; using the wrong screw in a component could damage the unit.

Model: HP RP5810 (item 20)

Access Panel Removal

1. Review the safety considerations before performing the steps listed below by clicking on the following:



CAUTION: Failure to comply with the *precautions* could result in damage to your product or loss of data.

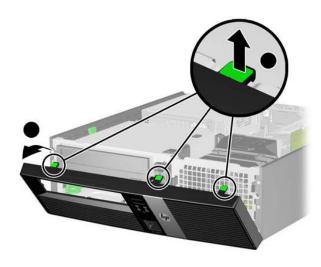
- 2. Pull up and hold the access panel release latch.
- 3. Rotate the panel up and lift it away from the chassis.



To install the computer cover, reverse the removal procedure.

Front Bezel Removal

- 1. Prepare the computer for disassembly
- 2. Remove the access panel
- 3. Lift up the three tabs on the side of the bezel (1), then rotate the bezel off the chassis (2).



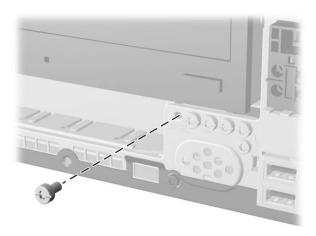
To install the new front bezel, reverse the removal procedure.

Front Bezel Security

The front bezel can be locked in place by installing a security screw provided by HP.

To install the security screw:

- 1. Prepare the computer for disassembly
- 2. Remove the access panel
- 3. Remove the front bezel
- 4. Remove one of the five silver 6-32 standard screws located on the front of the chassis behind the bezel.



- 5. Replace the front bezel.
- 6. Install the security screw next to the middle front bezel release tab to secure the front bezel in place.

To remove the front bezel security screw, reverse the installation procedures.

Power Supply Replacement (item 21)

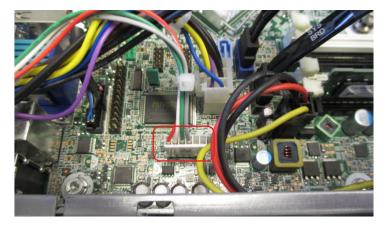


WARNING: Be sure the AC power cord is disconnected prior to performing servicing.

- Prepare the computer for disassembly
- Remove the access panel
- 1) Lift power supply back end as shown below right.



2) Remove 6 pin keyed power connector, P2, from PWRCMD connector as shown below.

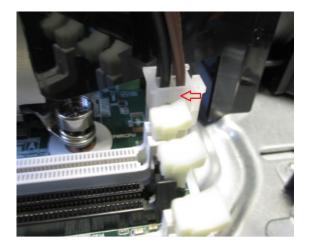


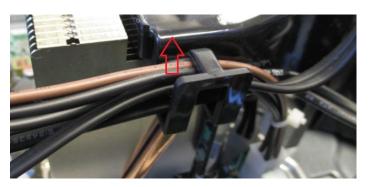
3) Remove the 6 pin lock tab power connector, P1, from the PWR connector.





4) Remove the 4 pin lock tab connector, P3, from the PWRCPU connector and remove the wires from the cable holder on the fan duct connected to the CPU heat sink.





5) Slide the base of the power supply towards the inside of the computer.



6) Lift the power supply up out of the power supply guides.



Hard Drive Replacement (item 22)

To replace the hard drive:

- Prepare the computer for disassembly
- Remove the access panel
- 1) Lift both the power supply and DVD drive up.



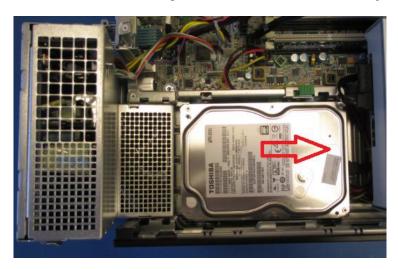
2) Remove both the SATA cable and power connector from the back of the hard drive.



3) Push down release tab on side of hard drive guides to release the tab lock on the hard drive.



4) Slide the hard drive toward the inside of the computer and lift the hard drive out of the guides.



5) Remove the side screws from the old hard drive and put the screws onto the replacement hard drive.



6) Take note of the keyed connectors on the SATA cable and the power connector when installing the cables into the new hard drive.



RAM Stick Replacement (Item 23)

To replace the RAM

- Prepare the computer for disassembly
- Remove the access panel
- 1) Push down side tabs on RAM slot.



2) Take note on notch on RAM stick when installing replacement RAM.



3) Install the replacement RAM into the notched RAM slot and push down on the sides of the RAM to lock into place.



Model: DELL XE3 (Items 25-30)

Prior to working on computer:

- 1. Turn off the computer.
- 2. Disconnect all network cables from the computer.
- 3. Disconnect the AC power cord from the computer.
- 4. Disconnect all connected devices from the computer (mouse, keyboard, etc.)
- 5. Press and hold the power button for 5 seconds with the computer unplugged to ground (discharge) the system board.

Access Panel Removal / Installation

- 1. Slide the release latch on the back side of the computer until it makes a click sound to unlock the side cover.
- 2. Slide and lift the side cover from the computer.

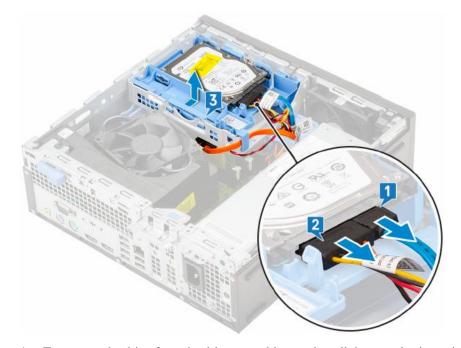


3. Reinstall in reverse order.

Hard Drive Replacement (item 32)

To replace the hard drive:

- Prepare the computer for disassembly
- Remove the access panel
 - 1. Disconnect the data cable from the hard drive as shown.
 - 2. Disconnect the power cable from the hard drive as shown.
 - 3. Push the release tab and lift the hard drive assembly from the system.



4. To remove the drive from the drive assembly, gently pull the two plastic retaining tabs outward to allow the drive to be slid out of the drive assembly.

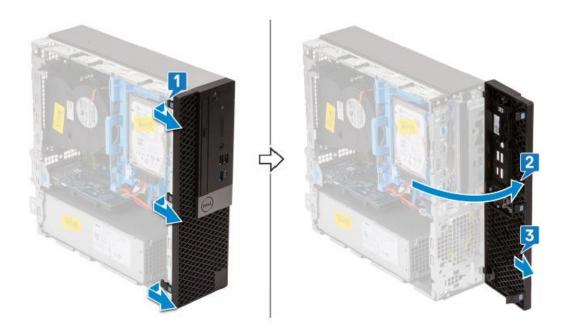


5. Reinstall in reverse order.

Removing/Installing Front Bezel

To replace the Front Bezel:

- Prepare the computer for disassembly
- Remove the access panel
- Gently lift the 3 retaining tabs shown below and rotate the panel to release the retaining hooks from their slots.

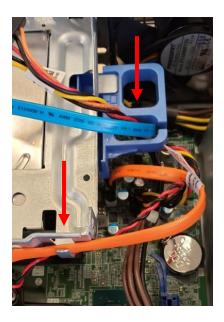


• Install in reverse order.

Removing/Installing the Hard Drive/DVD Chassis

To remove the hard drive chassis:

- Prepare the computer for disassembly
- Remove the access panel
- Remove the front bezel
 - 1. Disconnect the hard drive data and power cables.
 - 2. Slide the hard drive data and power cables out of the blue hard drive chassis latch (which doubles as a cable retainer), as shown below left.
 - 3. Slide the DVD power and data cables out of the metal retention clip on the chassis assembly, as shown below left.





- 4. Once the cables are removed from the retainers, slide the chassis latch and lift the chassis assembly upwards, until it can be lifted off of the two hooks located on the side of the computer, as shown above right.
- 5. Remove the DVD data and power cables from the DVD drive, which is mounted to the bottom of the chassis assembly.
- 6. Reinstall in reverse order.

Removing/Installing the DVD-ROM Drive

- Remove the Hard Drive/DVD Chassis per instructions on previous page.
 - 1. Using the DVD drive retaining clip connected to the back side of the DVD drive, gently squeeze the retainer as shown below, then slide it forward to extract the DVD drive from the chassis assembly.

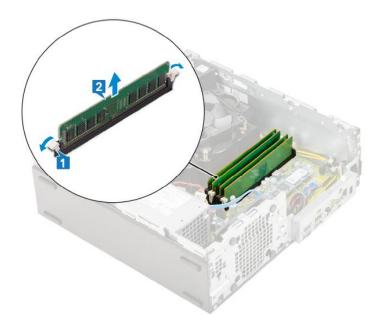


2. Reinstall in reverse order.

RAM Replacement (Item 33)

To replace the RAM:

- Prepare the computer for disassembly
- Remove the access panel
- Remove the Hard Drive/DVDD Chassis as defined in previous section.
 - 1. Press down and outwardly on the two RAM retention tabs simultaneously to lift the module from the connector.
 - 2. Remove the RAM module.



- 3. Install new RAM module by aligning the notch in the module with the tab on the RAM module connector.
- 4. Insert the module into the connector and press the module downward until the retention tabs click into the locking position.

Power Supply Replacement (item 31)

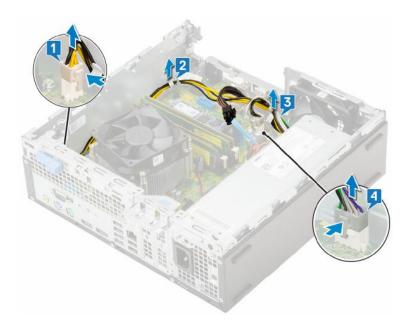


WARNING: Be sure the AC power cord is disconnected prior to performing servicing.

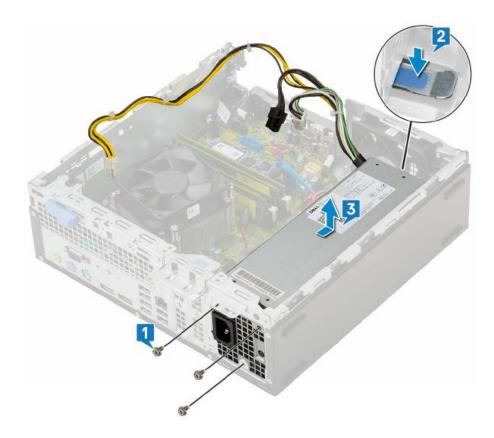
- Prepare the computer for disassembly
- Remove the access panel
- Remove the front bezel
- Remove the hard drive/DVD chassis
 - 1. Remove the heat sink duct by pulling outwardly on the 2 release tabs simultaneously
 - 2. Lift the plastic duct away from the heat sink assembly.



- 3. Disconnect the CPU power cable from the motherboard (step 1 shown below).
- 4. Un-route the power cables from the retention clips on the chassis (1 near CPU power cable, and steps 2,3 shown below).
- 5. Disconnect the system power cable from the motherboard (step 4 shown below).



- 6. Remove the 3 screws that secure the power supply to the PC as shown below.
- 7. Press the light-blue release tab at the rear of the power supply near the chassis bottom.
- 8. Slide the power supply into the computer chassis slightly, then lift upward to remove.



9. Reinstall in reverse order.

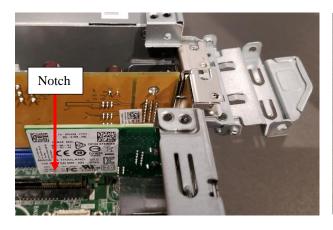
Network Interface Card (NIC) Replacement (Item 34)

To replace the NIC:

- Prepare the computer for disassembly
- Remove the access panel
 - 1. Remove the heat sink duct by pulling outwardly on the 2 release tabs simultaneously
 - 2. Lift the plastic duct away from the heat sink assembly.



- 3. Lift upwardly on the light-blue labeled metal retention tab and swing it 180 degrees to allow for removal of expansion cards.
- 4. Lift the NIC straight up to disengage it from the motherboard connector.





- To install a new NIC, align the notch in the NIC printed circuit board with the tab in the motherboard connector and press straight downward to insert.
- Close the metal retention tab until it snaps tightly into place.

m #	Part #	Description	
1	1404-004	TRANSFORMER ISOLATION 1000VA MED GLOBAL	
2	30012-024-50	TRIGGER MODULE ASSEMBLY	
3	3181-002	POWER CORD INTN'L CEE7/7+IEC320-C13	
4	3181-003	POWER CORD BRIDGE 2m IEC320-C13+C14	
_ 	3181-008	POWER CORD US/CAN HOSPITAL 5-15P+320-C13	
6	3181-012-01	POWER CORD AUSTRALIA AS3112+IEC320-C13	
7	3181-015-01	POWER CORD UK BS1363+IEC320-C13	
8	3181-016-01	POWER CORD BRAZIL NBR14136+IEC320-C13	
9			
	34000-025-1003	Z200+ THERMAL WRITER A/A4 COOL GRAY	
10	34000-025-1004	Z200+ V2 THERMAL WRITER COOL GRAY	
11	6400-008	CABLE ETHERNET RJ-45M TO RJ-45M STR-THRU	
12	6400-010	CABLE ETHERNET CAT5e RJ-45 M SHLD 2FT	
13	6400-012	CABLE USB TYPE A-TO-B FULL SPD	
14	6400-018	CABLE CROSSOVER CAT5E RJ-45 M SHLD 5FT	
15	8342-007-02	SPACER A4 PAPER ELI 200+ BLACK	
16	9293-048-54	ACQ MOD (AM12) W/O LEAD WIRES	
17	9900-014	MONITOR 24" LCD 1920x1200 WIDE DVI + VGA	
18 9900-015 MONITOR 24" TOUCH ELO WHITE			
19	9906-037	CPU LONG LIFE w/WINDOWS 7	
20	9906-043-01	CPU LONG LIFE W/WINDOWS 10 64BIT	
21 9906-043-11 POWER SUPPLY 240W HP5810		POWER SUPPLY 240W HP5810	
22	9906-043-21	HARD DRIVE RP5810 500GB	
23	9906-043-31	RAM DDR3 1600MHZ 4GB DIMM	
		COM PORT EXPANSION CARD DUAL RP5810	
25	749566	DELL CPU WINDOWS 10 64 BIT	
		DELL CPU WINDOWS 10 64 BIT - ITALIAN	
27	749568	DELL CPU WINDOWS 10 64 BIT - GERMAN	
28	749569	DELL CPU WINDOWS 10 64 BIT - DUTCH	
29	749570	DELL CPU WINDOWS 10 64 BIT - FRENCH	
30	749571	DELL CPU WINDOWS 10 64 BIT - UK	
31	749572	DELL CPU WINDOWS 10 64 BIT POWER SUPPLY	
32	749573	DELL CPU WINDOWS 10 64 BIT HARD DRIVE	
33	749574	DELL CPU WINDOWS 10 64 BIT RAM	
34	749575	DELL CPU WINDOWS 10 64 BIT NIC	
35			
36			
37	749579	DELL CPU WINDOWS 10 64 BIT KEYBOARD & MOUSE KIT	
38	749580	DELL CPU WINDOWS 10 64 BIT KEYBOARD - IT	
39	749581	DELL CPU WINDOWS 10 64 BIT KEYBOARD - DE	
40	749582	DELL CPU WINDOWS 10 64 BIT KEYBOARD - NL	
41	749583	DELL CPU WINDOWS 10 64 BIT KEYBOARD - FR	
42	749584	DELL CPU WINDOWS 10 64 BIT KEYBOARD - UK	
43	9907-016	PRINTER HP LASERJET USB + NETWORK	

DISASSEMBLY AND REPAIR

44	9911-023-11	STRESS CART BASE
45	9911-023-21	STRESS CART CUTOUT DESKTOP KIT
46	9911-023-22	STRESS CART SOLID DESKTOP KIT
47	9960-052	ISOLATOR ETHERNET LOW LEAKAGE RJ45/RJ45
48	9970-011-50	REMOTE KEYPAD ASSEMBLY
49	9970-012	KEYBOARD TOUCHPAD WHITE LED BACKLIT USB
50	SERV PART 184-01	LONG LIFE PC POWER SUPPLY
51	30012-019-54	WIRELESS ACQUISITION MODULE (WAM) w/o LEAD WIRES
52	30012-019-56	WIRELESS ACQUISITION MODULE (WAM2) w/o LEAD WIRES
53	30012-021-51	UTK MODULE (receiver for WAM)
54	30012-021-52	UTK MODULE (receiver for WAM2)

11. 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.	Correct faulty lead(s) identified in upper right corner of the screen. Replace patient cable or replaceable
		lead wires.
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.	Turn system OFF. Check mouse port
	Transposed keyboard/mouse cable.	connections.
Treadmill does not respond to the ON command from Q-Stress	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 Q-Stress cable connectors. 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 Q-Stress.
	Treadmill settings are incorrect.	Set Exercise Equipment 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 print head cleaning instructions in the "Thermal Writer Cleaning" Section of this manual.
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.

Screen Message or Issue	Possible Cause	Solution
	The Front-End device drivers are not correctly installed.	Contact Welch Allyn 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 Q-Stress 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.
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 symbol 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 symbol 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.
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 Q-Stress 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 Q-Stress.
No signal from the M12A patient cable connection	M12A is not selected as Front End.	Select M12 as front end in the Observation screen.
	USB cable plugged into wrong USB slot.	Assure M12-USB Green light is on, if not plug USB cable into the USB adapter on the upper left-hand side.
	Drivers for M12-USB patient module not loaded.	Load drivers for M12-USB from Q- Stress software CD.
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

Screen Message or Issue	Possible Cause	Solution
Server not available	CorScribeDBSvc becomes unresponsive which in turn stops the CorScribeAppServer from running	Manually restart the CorScribeDBSvc through the Windows Services Application If the above solution does not work, try the following steps: 1) Launch Task Manager and select the Details tab 2) Select the "End Task" on ALL postgres.exe processes (the number of postgres processes may vary) 3) Launch Windows Explorer and navigate to the following path: "C:\ProgramData\MiPgSqlData\pgd ata" 4) Delete the postmaster.pid file 5) Launch the Windows Services Application and restart the CorScribe services Application.
XScribe Modality Crashed. Up to 10 seconds of data may be lost. Do you want to use the data recovered?	XScribe application unexpectedly exits to Windows desktop.	If using v6.3.1 or newer, the exam data is saved every 10 seconds during the exam and can be used if desired, although the exam cannot be continued from that point in the protocol. For versions prior to v6.3.1, the data may be lost and not retrievable. Additional logging capability was also added in v6.3.1 which can be reviewed to investigate the root cause of the crash.

PC Diagnostics

Model: DELL XE3

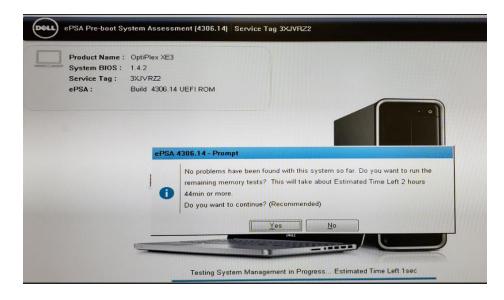
POST TESTING: The computer POST (Power On Self Test) ensures that it meets the basic computer requirements and the hardware is working appropriately before the boot process begins. If the computer passes the POST, the computer continues to start in a normal mode.

However, if the computer fails the POST, the computer emits a series of LED codes during the start-up. The system LED is integrated on the Power button. The following table shows different light patterns and what they indicate.

Number of LED flashes	Problem description
2 amber, 1 Amber	Motherboard failure
2 Amber, 2 Amber	Motherboard, PSU or PSU Cabling failure
2 Amber, 3 Amber	Motherboard, memory or CPU failure
2 Amber, 4 Amber	CMOS battery failure

DIAGNOSTIC TESTING: To enter the diagnostic testing menu, press the **F12 Key** when the PC is booting up and is at the DELL splash screen.

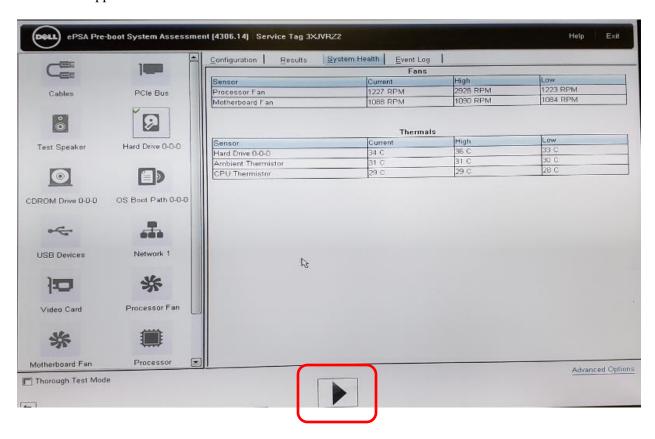
- Once the main menu appears, select the "Diagnostics" option to start the automated diagnostic testing process.
- If the diagnostic testing passes, a window will appear indicating "no problems found". It may also ask if exhaustive memory testing is desired, select **no** unless there is reason to suspect there may be problems with the PC memory.



• A "success" message should be displayed if all tests pass successfully.

Individual Diagnostic Tests: Individual diagnostic tests can be performed by selecting the desired test from the diagnostic test menu.

To enter the individual test menu, launch the automatic diagnostic testing as defined on the previous page, then press the ESC key on the keyboard. Once the auto testing process stops, and the mouse cursor reappears, select the ARROW in the bottom right hand corner of the display. The individual test menu should now appear.



- Select the test or tests desired, then click on the "play" button to begin testing.
- Testing can be stopped by pressing the ESC key.

Failures: If a diagnostic failure occurs, refer to the Item Description Listing to determine if the item identified as suspect is a serviceable part. If so, replace the part and retest the PC.

If the failure is not a serviceable part, the PC will need to be replaced.

Diagnostic Error Messages (Dell XE3):

Error Message	Error Description
AUXILIARY DEVICE FAILURE	The touchpad or external mouse may be faulty. For an external mouse, check the cable connection. Enable the Pointing Device option in the System Setup program.
BAD COMMAND OR FILE NAME	Ensure that you have spelled the command correctly, put spaces in the proper place, and used the correct path name.
CACHE DISABLED DUE TO FAILURE	The primary cache internal to the microprocessor has failed.
CD DRIVE CONTROLLER FAILURE	The optical drive does not respond to commands from the computer.
DATA ERROR	The hard drive cannot read the data.
DECREASING AVAILABLE MEMORY	One or more memory modules may be faulty or improperly seated. Reinstall the memory modules or, if necessary, replace them.
DISK C: FAILED INITIALIZATION	The hard drive failed initialization. Run the hard drive tests in Dell Diagnostics.
DRIVE NOT READY	The operation requires a hard drive in the bay before it can continue. Install a hard drive in the hard drive bay.
ERROR READING PCMCIA CARD	The computer cannot identify the ExpressCard. Reinsert the card or try another card.
EXTENDED MEMORY SIZE HAS CHANGED	The amount of memory recorded in non-volatile memory (NVRAM) does not match the memory module installed in the computer. Restart the computer. If the error appears again.
THE FILE BEING COPIED IS TOO LARGE FOR THE DESTINATION DRIVE	The file that you are trying to copy is too large to fit on the disk, or the disk is full. Try copying the file to a different disk or use a larger capacity disk.
A FILENAME CANNOT CONTAIN ANY OF THE FOLLOWING CHARACTERS: \/:*?"<> -	Do not use these characters in filenames.
GATE A20 FAILURE	A memory module may be loose. Reinstall the memory module or, if necessary, replace it.
GENERAL FAILURE	The operating system is unable to carry out the command. The message is usually followed by specific information. For example, Printer out of paper. Take the appropriate action.
HARD-DISK DRIVE CONFIGURATION ERROR	The computer cannot identify the drive type. Shut down the computer, remove the hard drive, and boot the computer from an optical drive. Then, shut down the computer, reinstall the hard drive, and restart the computer. Run the Hard Disk Drive tests in Dell Diagnostics.
HARD-DISK DRIVE CONTROLLER FAILURE 0	The hard drive does not respond to commands from the computer. Shut down the computer, remove the hard drive, and boot the computer from an optical drive. Then, shut down

	the computer, reinstall the hard drive, and restart the computer. If the problem persists, try another drive. Run the
HARD-DISK DRIVE FAILURE	Hard Disk Drive tests in Dell Diagnostics. The hard drive does not respond to commands from the computer. Shut down the computer, remove the hard drive, and boot the computer from an optical drive. Then, shut down the computer, reinstall the hard drive, and restart the computer. If the problem persists, try another drive. Run the Hard Disk Drive tests in Dell Diagnostics.
HARD-DISK DRIVE READ FAILURE	The hard drive may be defective. Shut down the computer, remove the hard drive, and boot the computer from an optical. Then, shut down the computer, reinstall the hard drive, and restart the computer. If the problem persists, try another drive. Run the Hard Disk Drive tests in Dell Diagnostics.
INSERT BOOTABLE MEDIA	The operating system is trying to boot to non-bootable media, such as an optical drive. Insert bootable media.
INVALID CONFIGURATION INFORMATION-PLEASE RUN SYSTEM SETUP PROGRAM	The system configuration information does not match the hardware configuration. The message is most likely to occur after a memory module is installed. Correct the appropriate options in the system setup program.
KEYBOARD CLOCK LINE FAILURE	For external keyboards, check the cable connection. Run the Keyboard Controller test in Dell Diagnostics.
KEYBOARD CONTROLLER FAILURE	For external keyboards, check the cable connection. Restart the computer, and avoid touching the keyboard or the mouse during the boot routine. Run the Keyboard Controller test in Dell Diagnostics.
KEYBOARD DATA LINE FAILURE	For external keyboards, check the cable connection. Run the Keyboard Controller test in Dell Diagnostics.
KEYBOARD STUCK KEY FAILURE	For external keyboards or keypads, check the cable connection. Restart the computer, and avoid touching the keyboard or keys during the boot routine. Run the Stuck Key test in Dell Diagnostics.
LICENSED CONTENT IS NOT ACCESSIBLE IN MEDIADIRECT	Dell MediaDirect cannot verify the Digital Rights Management (DRM) restrictions on the file, so the file cannot be played.
MEMORY ADDRESS LINE FAILURE AT ADDRESS, READ VALUE EXPECTING VALUE	A memory module may be faulty or improperly seated. Reinstall the memory module or, if necessary, replace it.
MEMORY ALLOCATION ERROR	The software you are attempting to run is conflicting with the operating system, another program, or a utility. Shut down the computer, wait for 30 seconds, and then restart it. Run the program again. If the error message still appears, see the software documentation.
MEMORY DOUBLE WORD LOGIC FAILURE AT ADDRESS, READ VALUE EXPECTING VALUE	A memory module may be faulty or improperly seated. Reinstall the memory module or, if necessary, replace it.
MEMORY ODD/EVEN LOGIC FAILURE AT ADDRESS, READ VALUE EXPECTING VALUE	A memory module may be faulty or improperly seated. Reinstall the memory module or, if necessary, replace it.
MEMORY WRITE/READ FAILURE AT ADDRESS, READ VALUE EXPECTING VALUE	A memory module may be faulty or improperly seated. Reinstall the memory module or, if necessary, replace it.
NO BOOT DEVICE AVAILABLE	The computer cannot find the hard drive. If the hard drive is your boot device, ensure that the drive is installed, properly seated, and partitioned as a boot device.
NO BOOT SECTOR ON HARD DRIVE	The operating system may be corrupted.
NO TIMER TICK INTERRUPT	A chip on the system board may be malfunctioning. Run the System Set tests in Dell Diagnostics.

NOT ENOUGH MEMORY OR RESOURCES. EXIT SOME PROGRAMS AND TRY AGAIN	You have too many programs open. Close all windows and open the program that you want to use.
OPERATING SYSTEM NOT FOUND	Reinstall the operating system. If the problem persists, Contact Dell.
OPTIONAL ROM BAD CHECKSUM	The optional ROM has failed.
SECTOR NOT FOUND	The operating system cannot locate a sector on the hard drive. You may have a defective sector or corrupted File Allocation Table (FAT) on the hard drive. Run the Windows error-checking utility to check the file structure on the hard drive. See Windows Help and Support for instructions (click Start > Help and Support). If a large number of sectors are defective, back up the data (if possible), and then format the hard drive.
SEEK ERROR	The operating system cannot find a specific track on the hard drive.
SHUTDOWN FAILURE	A chip on the system board may be malfunctioning. Run the System Set tests in Dell Diagnostics. If the message reappears.
TIME-OF-DAY CLOCK LOST POWER	System configuration settings are corrupted. Connect your computer to an electrical outlet to charge the battery. If the problem persists, try to restore the data by entering the System Setup program, then immediately exit the program. If the message reappears.
TIME-OF-DAY CLOCK STOPPED	The reserve battery that supports the system configuration settings may require recharging. Connect your computer to an electrical outlet to charge the battery. If the problem persists.
TIME-OF-DAY NOT SET-PLEASE RUN THE SYSTEM SETUP PROGRAM	The time or date stored in the system setup program does not match the system clock. Correct the settings for the Date and Time options.
TIMER CHIP COUNTER 2 FAILED	A chip on the system board may be malfunctioning. Run the System Set tests in Dell Diagnostics.
UNEXPECTED INTERRUPT IN PROTECTED MODE	The keyboard controller may be malfunctioning, or a memory module may be loose. Run the System Memory tests and the Keyboard Controller test in Dell Diagnostics.
X:\ IS NOT ACCESSIBLE. THE DEVICE IS NOT READY	Insert a disk into the drive and try again.

System Error Messages (Dell XE3):

System Error Message	Description
Alert! Previous attempts at booting this system have failed at checkpoint [nnnn]. For help in resolving this problem, please note this checkpoint and contact Dell Technical Support	The computer failed to complete the boot routine three consecutive times for the same error.
CMOS checksum error	RTC is reset, BIOS Setup default has been loaded.
CPU fan failure	CPU fan has failed.
System fan failure	System fan has failed.
Hard-disk drive failure	Possible hard disk drive failure during POST.
Keyboard failure	Keyboard failure or loose cable. If reseating the cable does not solve the problem, replace the keyboard.
No boot device available	No bootable partition on hard disk drive, the hard disk drive cable is loose, or no bootable device exists. If the hard drive is your boot device, ensure that the cables are connected and that the drive is installed properly and partitioned as a boot device. Enter system setup and ensure that the boot sequence information is correct.
No timer tick interrupt	A chip on the system board might be malfunctioning or motherboard failure.
NOTICE - Hard Drive SELF MONITORING SYSTEM has reported that a parameter has exceeded its normal operating range. Dell recommends that you back up your data regularly. A parameter out of range may or may not indicate a potential hard drive problem	S.M.A.R.T error, possible hard disk drive failure.

12. SYSTEM UTILITIES

System Utilities

The following utilities are located at the path below to assist with system configuration and service functions as defined.

C:\Program Files\Welch Allyn Inc\ModalityMgr

Configurator.exe (language, networking, login)

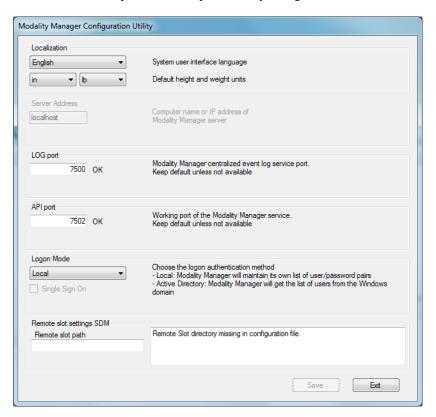
FetchAllConfig.exe (gathers all system configuration data)

ActivationTool.exe (software license information)

CFDWizard.exe (display and report configurator)

Configurator.exe

The Modality Manager Configuration Utility is stored as a unique EXE file (Configurator.exe) that can be accessed after the installation process is completed if any changes are needed to the Modality Configuration settings.



Refer to the following information regarding the configuration settings:

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

Server Address: The Server Address will read "localhost" if the local PC is hosting the Modality Manager database. If Modality Manager is not local, this box should contain the IP Address or Computer Name of the PC or server hosting Modality Manager.

Log Port: This setting is always available to select the port to be used for the event log service.

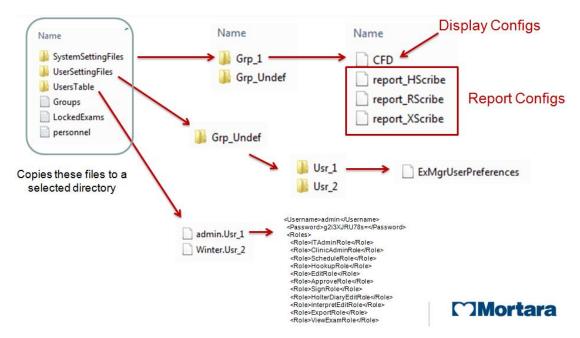
API Port: This setting is always available to select the port to be used for Modality Manager service.

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.

FetchAllConfig.exe

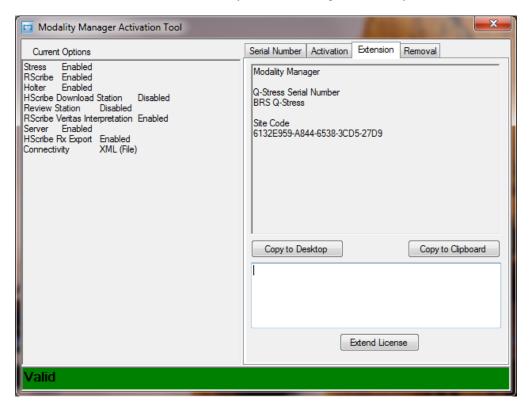
Copies all of the system configuration settings into the file structure displayed below to allow this information to be sent to a Welch Allyn Service Center. The path can be entered by the user upon executing the utility.



ActivationTool.exe

This utility will display the current software license status, serial number information, and all enabled options.

The serial number information is necessary when contacting a Welch Allyn Service Center for technical assistance.



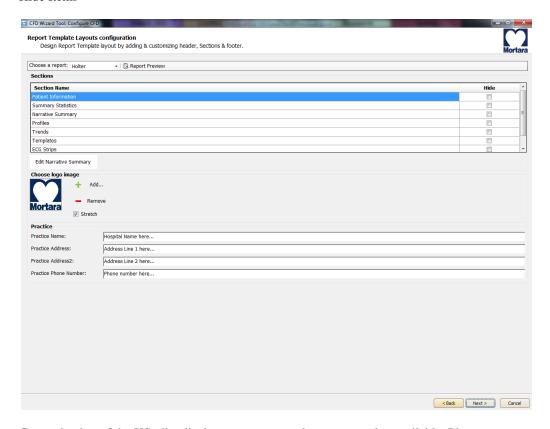
The Activation Utility is also used to perform a software Removal, which MUST be performed <u>prior</u> to uninstalling the Welch Allyn software. The software Removal process will generate a Removal Code, which will need to be sent to Welch Allyn to provide notification that the software license has been deactivated.

Once the software Removal has been reported to Welch Allyn, the software may be loaded on another computer and activated through the normal activation process.

CFDWizard.exe

The CFD (Custom Format and Display) Wizard can be used to change the following items:

Logo Facility Name Facility Address Phone Number Hide Items



Customization of the XScribe display appearance and reports are also available. Please contact your regional Welch Allyn Service Center for assistance with this level of customization.

13. BACKUP AND RESTORE FUNCTIONS

System Backup

The XScribe software installs a batch file that will back up all of the necessary data required to restore the system to operation in the case of a system failure. This file can be modified to direct the system to store the backup data to an alternate non-local location or designated storage system (recommended).

User must be logged into the operating system as a user with administrative permissions.

The backup file is located at the following path:

C:\Program Files\Welch Allyn Inc\Mortara PgSql\scripts>Backup.bat

- Double click on Backup.bat
- A Command Prompt window will open and the backup process will begin, once the Command Prompt window closes the backup is complete.

Executing the system backup copies the following information into a file called **CorScribeFullBackup.7z** located on the TEMP folder of the logged in user.

- SOL Database information
- Full Disclosure Data
- User Configuration Settings

This may be a hidden file based on the current system settings.



CAUTION:

Configuration settings made via the Modality Manager Configuration tool and the SW Activation utility are not stored in the DB, and are <u>not</u> included in the system backup.

The following items will need to be properly configured with the use of the tools/utilities after the restoration process:

- Language setting (in the server)
- The ports where the MM server and Log server can be found
- The authentication method (local vs. AD vs. AD+SSO)
- Serial number
- License/features

In case of restoring from a total failure (unrecoverable system, reinstall of the OS etc...), the user will have to go through the activation process again, hence an Activation Code will have to be regenerated (the old Activation Code cannot be used) and – during the process – S/N should be restored.

Users, DICOM settings, Modality settings etc, are stored in the DB, hence it is backed up.

- It is recommended that the backup be performed while the system applications are not in use (not receiving any data).
- The Backup.bat routine can be added as a scheduled process through the Task Scheduler.
- If a local backup (factory default) is used It is recommended that after a backup has been performed that the file created from the backup be removed from the system and placed in a safe (non-local) location.
- The process is the same for a stand-alone system and a distributed system; when performing the backup on a distributed system the process must be performed on the PC or server that is running Modality Manager.
- The backup process can be customized by modifying the DefaultBackupSettings.bat file and renaming the modified file to CustomBackupSettings.bat
 - o Information regarding modifications to the backup file is located within the Backup.bat file itself.
 - Please contact Welch Allyn Technical Support Group if you require assistance with modifying the backup file.
 - Welch Allyn technical support can assist with the modification of the backup file, however Welch Allyn will not retain a copy of the file.
- On a distributed system the backup zip file may be parked in a sub folder:

C:\Users\<User>\AppData\Local\Temp\1

This may be a hidden file based on the current system settings.

System Restoration (restores to point of last performed backup)



CAUTION:

- It is recommended that the restore be performed while the system applications are not in use (not receiving any data).
- The process is the same for a stand-alone system and a distributed system; when performing a Restore
 operation on a distributed system the process must be performed on the PC or server that is running
 Modality Manager.

The following process should be followed to restore a Scribe 6 system.

- 1) Prepare/Repair PC
- 2) Load OS (if applicable)
- 3) Install Product Software
- 4) Place file **CorScribeFullBackup.7z** in the correct restore location
- 5) Run Restore batch file

User <u>must</u> be logged into the operating system as a user with administrative permissions.

• Place the backup file into the appropriate folder:

C:\Users\<Administrator Name>\AppData\Local\Temp

On a distributed system the file may be located is a sub folder:

C:\Users\<user>\AppData\Local\Temp\1

This may be a hidden file based on the current system settings.

• Navigate to the following path to locate the Restore.bat file

$C:\ \ Program\ Files\ \ Welch\ Allyn\ Inc\ \ Mortara\ PgSql\ scripts\ > Restore. bat$

- Double click on the Restore.bat file
- A Command Prompt window will open and the Restore process will begin
- The Restore program will ask whether or not CreateDB.BAT will need to be run before the restore is executed. If the system database does not need to be recreated, answer NO to this question. If the system database has been damaged, or is being recreated, answer YES to this question.
- Once the Command Prompt window closes the backup utility has completed restoring the following content:
 - SQL Database information
 - Full Disclosure Data
 - User Configuration Settings
- Verify that the appropriate data has been restored (system settings or system settings and exam data) and that the exams can be accessed.