Welch Allyn®

REF 9515-218-51-ENG Rev A1

Connex® Cardio

12-LEAD ELECTROCARDIOGRAPH SYSTEM

USER MANUAL

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

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

For patent information, please visit www.welchallyn.com/patents.

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1. GENERAL STATEMENTS

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2. NOTICES

Manufacturer's Responsibility

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

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

Responsibility of the Customer

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

Equipment Identification

Mortara Instrument, LLC 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. Software equipment is accompanied by an identification card; carefully store this card as the information is needed for activation, upgrade and customer service.

Copyright and Trademark Notices

Other Important Information

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

Mortara Instrument, LLC makes no warranty of any kind with regard to this material including, but not limited to, implied warranties of merchantability and fitness for a particular purpose. Mortara Instrument, LLC assumes no responsibility for any errors or omissions that may appear in this document. Mortara Instrument, LLC makes no commitment to update or to keep current the information contained in this document.

3. WARRANTY INFORMATION

Your Mortara Warranty

MORTARA INSTRUMENT, LLC (hereafter referred to as "Mortara") warrants that components within Mortara products (hereafter referred to as "Product/s") will be free from defects in workmanship and materials for the number of years specified on documentation accompanying the product, or previously agreed to by the purchaser and Mortara, or if not otherwise noted, for a period of thirteen (13) months from the date of shipment.

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

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

a) Freight damage;

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

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

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

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

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

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

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

4. 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. Consult the actual screen in the host language for specific wording.*

Warnings

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. Device 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.

3. 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 service for additional training options.

4. To maintain designed operator and patient safety, peripheral equipment and accessories used that can come in direct patient contact must be in compliance with UL 60601-1, IEC 60601-1, and IEC 60601-2-25. Only use parts and accessories supplied with the device and available through Mortara Instrument

5. 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.

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

7. Do not attempt to clean the 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.

8. The device is part of an integral personal computer-based diagnostic system. The user must adhere to all warnings in order to ensure safe and reliable performance.

9. If operated on AC (~) power, the personal computer must be connected with its original power cable to an electrical installation that complies with applicable regulations for environments where patients are treated.

10. The personal computer used and any peripheral devices connected to it must be approved to the appropriate safety standard for nonmedical information technology equipment per IEC 60950, or its national variants. The

personal computer and any peripheral devices connected to it, being non-medical electrical equipment, must be situated outside the patient environment per IEC 60601-1–1. To ensure the safety of the patient it must not be possible for the operator to touch the patient and the computer at the same time. In general, at least 1.5 meters (5') of open area must surround the patient to achieve this.

11. If the personal computer is situated within the patient environment, ensure that its level of safety is that of medical electrical equipment per IEC 60601-1. This may be accomplished by powering the computer and any other equipment connected to it through an isolation transformer or by operating on battery power.

12. If the personal computer is situated within the patient environment, to maintain designed operator and patient safety when a LAN network connection is being used, the network cable must be connected to the device through an Ethernet isolator module that complies with IEC 60601-1-1 (available from Mortara Instrument).

13. 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.

14. 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.

15. 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. Do not mix electrodes made of dissimilar metals.

16. 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.

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

18. Possible malfunction risks may be present when installing third-party software. Mortara Instrument. cannot verify the compatibility of all possible hardware/software combinations.

19. 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.

20. 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.

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

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

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

24. Test Connex Cardio functions after each Microsoft critical and security update with a simulator prior to patient use.

25. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.

26. 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.

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

28. 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.

FCC Compliance Statement for the WAM

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

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

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

These devices comply with Part 15 of the FCC rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and

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

Cautions

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

3. Windows compatibility, updates and anti-virus policy: The Connex Cardio™ software has been fully tested with Windows 7 (32-bit and 64-bit) Professional Service Pack 1, and Windows 10 Pro (64-bit) operating systems. The Connex Cardio software has also been tested with Windows Server 2008 R2 (32-bit and 64-bit) Service Pack 1 and Windows Server 2012 R2(32-bit and 64-bit). Although it is unlikely that Windows updates and security patches affect Connex Cardio functionality, Mortara recommends turning automatic Windows update off, and periodically running it manually. A functional test should be executed after update, which includes acquiring a recording, editing and printing a report, as well as importing an order and exporting results, if activated. Compatibility of Connex Cardio with corporate anti-virus software packages has been evaluated. Mortara recommends excluding the Connex Cardio 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.

4. No other non-recommended PC application software should be running while the Connex Cardio application is being used.

5. It is recommended that all resting ECG 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.

6. To prevent delivery of malware into the system Mortara recommends that institution operating procedures are written to prevent malware to be transmitted into the system from removable media.

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

8. 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.

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

10. 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.

11. Be careful to insert the correct lead wire into the connector block with the appropriate input connector by matching the lead wire labels to the WAM or AM12 lead labels.

12. Test information should be backed up to prevent loss of critical data as a result of a malware attack or system failure.

Notes

1. Local Administrator permissions are required for software installation, and application configuration. Local User privileges are required for application users. Roaming and temporary accounts are not supported.

2. 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.

3. 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.

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. 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.

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

8. A thick baseline presentation on the display while using the AM12 may be due to a calibration error. Review the LED indicator on the AM12 to ensure the unit is connected, or disconnect and reconnect to the PC USB port to re-calibrate.

9. The WAM will automatically start flashing LEDs if the batteries have been discharged below 1.0 volts.

10. During normal WAM/AM12 operation, the green LED will display continuously.

11. 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.

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

13. The WAM will automatically turn off when the electrocardiograph is powered down.

14. The WAM will automatically turn off after being disconnected from the patient. This will happen regardless of Connex Cardio battery/AC power state.

15. A thick baseline presentation on the display while using the WAM may be due to the WAM being turned off, having no battery, not being paired correctly, operating out of range, or due to a calibration error. Review the LED indicator and auditory advisory on the WAM to ensure the unit is turned on, has proper battery level, is paired correctly, and is within recommended proximity of the electrocardiograph, or power cycle the WAM to re-calibrate.

16. As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
    - Type CF, defibrillation-proof applied parts.

17. If not specifically indicated otherwise, personal computer equipment used with the device can be regarded as:
    - Class I (if the computer has a three-prong power inlet) or class II (if it has a two-prong inlet)
    - Ordinary equipment.
    - Equipment not suitable for use in the presence of a flammable anesthetic mixture.
    - Continuous operation.

18. To prevent possible damage to the device during transport and storage (while in original packaging) the following environmental conditions must be adhered to:

    Ambient temperature: -20° C to 60° C (-4° F to 149° F)
    Relative humidity: 10% to 95%, non-condensing

19. Allow the device and any computer equipment used to stabilize within its intended operating environment for a minimum of two hours prior to use. Refer to the computer equipment user manual for allowable environmental conditions. The allowable environmental conditions for the AM12 and WAM acquisition modules are as follows:

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

20. The WAM is UL classified:

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

5. EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

	Defibrillation protection in patient cable
	Defibrillator-proof type CF applied part
	General Warning
	Consult instructions for use
PC 	USB connection to PC
	Do not dispose as unsorted municipal waste. Per European Union Directive 2002/96, requires separate handling for waste disposal according to national requirements

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

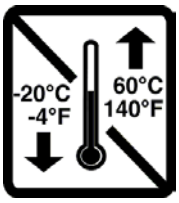
Package Symbol Delineation

This side up

Fragile

Keep Dry

Keep Away from Heat



Acceptable Temperature Range

6. 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, alcohol, 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 and Disinfecting

1. Disconnect the power source. 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 exterior surfaces of the device, patient acquisition module, cables, and lead wires, wipe exterior using:

   Clorox Healthcare® Bleach Germicidal Wipes (use according to instructions on product label), *or*

   a soft, lint-free cloth with 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

***WARNING**: Prevent liquid from penetrating the device and 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. Do not sterilize the device or ECG lead wires with Ethylene Oxide (EtO) gas.*

***WARNING**: Use of unspecified cleaning/disinfecting agents or failure to follow recommended procedures could result in increased risk of harm to users, patients and bystanders, or damage to the device.*

7. ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

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

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See 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 Mortara Instrument may result in increased emissions or decreased immunity of the equipment.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

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

Emissions Test	Compliance	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment.
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.

<table>
<tr><th>Emissions Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment: Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to
80 MHz</td><td>3 Vrms
150 kHz to
80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$

$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz

$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to
2.5 GHz</td><td>3 V/m
80 MHz to
2.5 GHz</td></tr>
</table>

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.*

8. INTRODUCTION

Manual Purpose

This manual is intended to provide the user with information about the Connex Cardio resting electrocardiograph's display screen, menu structure, icons, and navigation tools pertaining in the following sections:

- Using Connex Cardio
- Preparing the Patient
- Using MWL/Patients
- Record an ECG
- Context menus
- Exam Search
- System Settings

***NOTE**: This manual contains screen images that are for illustration, and might be different in the actual product. Consult the actual screen in the host language for specific wording.*

Audience

This manual is written for clinical professionals with a working knowledge of medical procedures and terminology as required for monitoring cardiac patients.

Intended Use

The Connex Cardio Electrocardiograph is a multi-channel electrocardiograph product used for acquiring, analyzing, displaying and printing resting ECG's. The Connex Cardio is a 12-channel diagnostic electrocardiograph intended for recording and printing ECG's of adult and pediatric patients. The acquired ECG will be displayed for quality check purpose, analyzed using the Mortara VERITAS resting interpretation, optionally printed, stored and/or transmitted to a ECG Management System or Hospital Information System. The device is not intended to be used as a vital signs physiological monitor.

It is a system comprised of a Mortara ECG amplifier (Wireless Acquisition Module [WAM] or AM12 Acquisition Module) and an off-the-shelf personal computer with Mortara software application that allows clinicians to collect ECGs on patients during routine visits. The patient populations for which the device will be used may be healthy or diseased of any age. ECG's are taken with the patient in the supine position. The Connex Cardio is intended to be used by a licensed health care practitioner in a hospital, medical clinic and offices of any size, including Clinical Research Organizations.

Indications for Use

The Connex Cardio electrocardiograph is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display, transmit and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.
- The device is not designed for out of hospital transport.
- The device is not designed for use in highly invasive environments, such as an operating theatre.

System Description

Connex Cardio is a multi-lead, diagnostic, computer-based resting electrocardiograph capable of acquiring, viewing, transmitting, printing, and storing ECG data.

Connex Cardio models ordered with the VERITAS™ resting ECG interpretation algorithm option are capable of specific age and gender interpretation criteria. The VERITAS algorithm provides an over-reading physician with a silent second opinion through diagnostic statements displayed on the ECG report. For additional information on the VERITAS algorithm, please refer to the *Physician's Guide to VERITAS with Adult and Pediatric Resting ECG Interpretation* (see Accessories).

Connex Cardio can be configured with bidirectional connectivity and DICOM® protocol support.

The Connex Cardio application is integrated with a patient and exam management system that handles the scheduling of exams, database storage and maintenance, exam and patient search, printing, communication with external systems and dispatches the modality dependent acquisition and review functions. Connex Cardio can be configured for data distribution. When so configured, the database resides on a server supporting a number of networked client workstations.

The Connex Cardio Review software offers authorized users with the ability to schedule new exams when not linked to an external scheduling system, view reports, enter conclusions, and generate printed or electronic reports for completed exams.

The Connex Cardio server, workstations, and review stations can be set up as Citrix® Application Servers for remote access from client computers with Citrix XenApp™ installed.

The Connex Cardio supports print formats that include:

- Standard or Cabrera,
- 3+1,
- 3+3,
- 12,
- 6+6 channel in automatic mode;
- Single channel on one page (60 min of acquired ECG for rhythm strip (Full Disclosure) printing.

The Connex Cardio packing list includes:

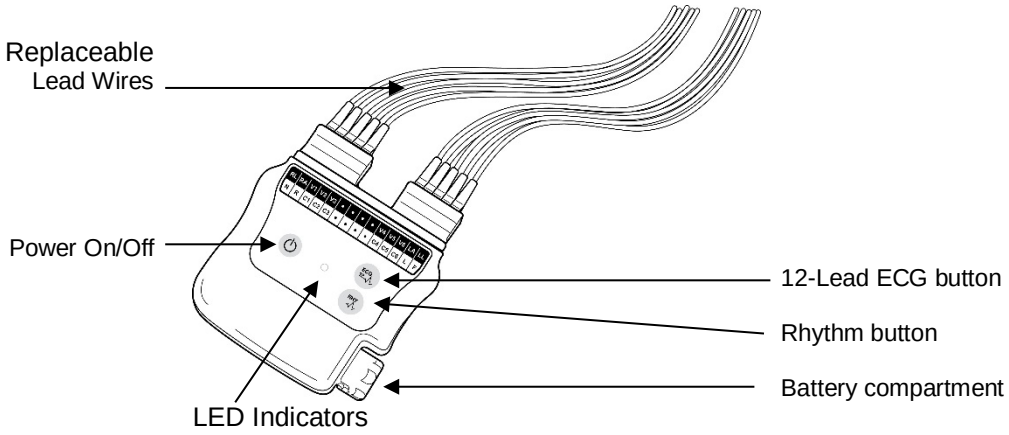
- Acquisition module with lead wire set and accessory starter kit
- Software loaded on the USB
- Physician's Guide to VERITAS and User Manual PDFs on the USB

Acquisition Module Types

Two types of ECG acquisition modules are used with the software, the Connex Cardio Wireless Acquisition Module (WAM) and the Connex Cardio AM12 acquisition Module.

WAM with Lead Wires

Figure 1 WAM with Lead Wires



The WAM incorporates frequency-hopping technology in the 2500 MHz frequency range with 40,000 Hz ECG acquisition and is operated by two buttons located on the front of the device when used with Connex Cardio:

1. Power On/Off
2. Acquiring a 12-lead ECG

NOTE: *Rhythm button is non-functional for use with Connex Cardio.*

The WAM uses one AA alkaline, 1.5V battery for approximately 8-hours of continuous operation.

WARNING: *Use of other cells may present a risk of fire or explosion.*

USB Transceiver Key (UTK)

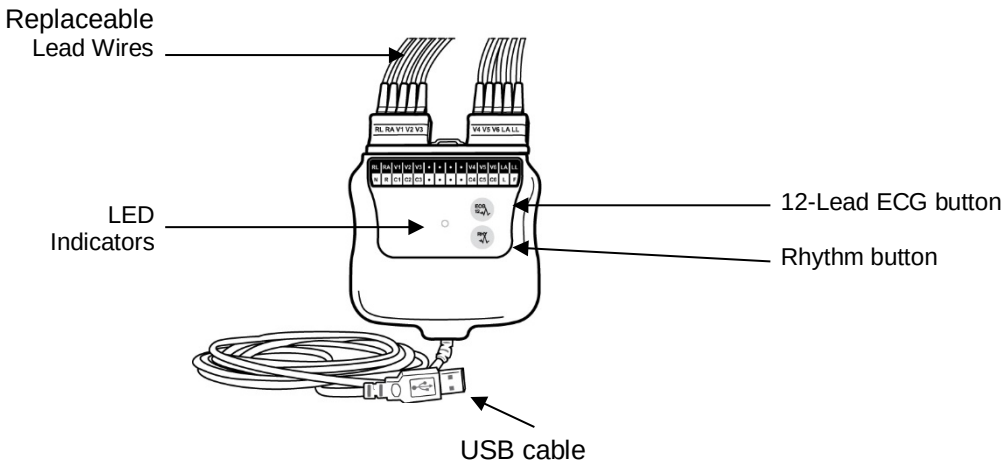
The UTK connected to the Connex Cardio USB port receives ECG signals from the paired WAM for presentation of the electrocardiogram. The UTK connected to USB cable (6400-015) from the PC port is positioned in an unobstructed location.

WAM LED Indicators

LED	+ Audio	MODE
GREEN off YELLOW off	Intermittent beeping	WAM is on but not paired to an electrocardiograph, is out of range of the paired electrocardiograph.
YELLOW solid or flashing GREEN off		One or more leads are not connected properly.
GREEN solid YELLOW off		No lead fail condition is detected; battery is OK.
GREEN solid YELLOW off	Intermittent beeping	WAM is collecting a 10-second ECG.
Blinking LED (yellow or green depending on lead fault status)		WAM has detected a low battery condition. Replace the battery within 15 minutes.
GREEN off YELLOW off	1 second audio on, then device turns off.	WAM has detected a very low battery status and powered off.

AM12 with Lead Wires

Figure 2 AM12 with Lead Wires



The AM12 is available for a traditional wired connection with direct USB connection and 40,000 Hz ECG acquisition. The 12-Lead ECG button can be used to acquire a 12-lead ECG at the patient's side.

NOTE: *Rhythm button is non-functional for use with Connex Cardio.*
NOTE: *Rhythm button is non-functional for use with Connex Cardio.*

Lead Fail

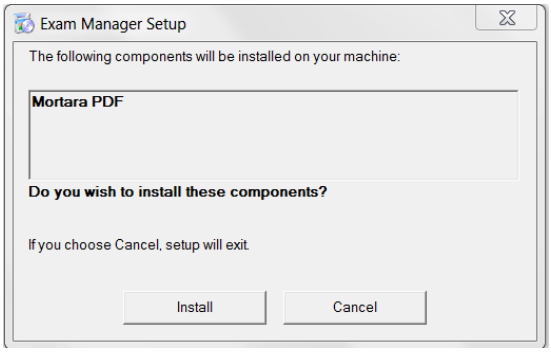
Lead fail can be observed either by indication in Connex Cardio or on the acquisition modules. In the software, lead failure is represented as a square wave being presented on the lead that has failed. On the acquisition modules lead fail is indicated using LEDs located on the front of the WAM and AM12. A yellow LED (solid or flashing) indicates a lead fail condition is present. A solid green LED indicates proper lead connection. On the WAM, a solid green LED also indicates adequate battery voltage for ECG acquisition.

Connex Cardio Software Installation Process

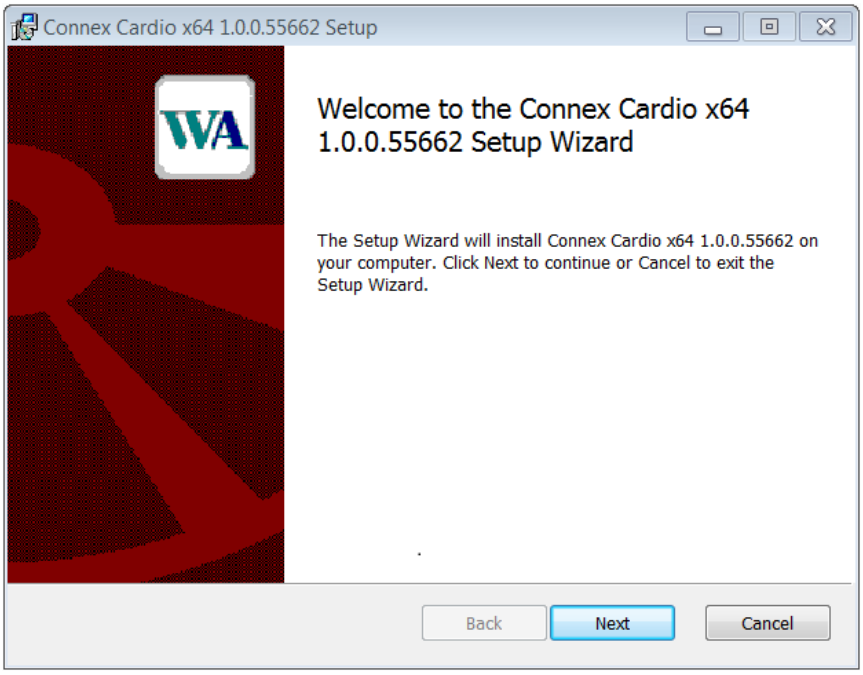
Important Notes:

- Prior to beginning the installation, verify the computer, server, or workstation is within documented compatible specifications.
- The user logged into the computer, server, or workstation, must have administrative rights to make changes to that system. Failure to have the proper credentials will lead to a failure of the installation.
- Some installation pathways include the reboot of the system on which the software is installed. Best practice is to reboot the system immediately when prompted, therefore it is important to schedule the installation timing accordingly.
- The type of output should be known prior to starting the installation. For a PDF output, ensure the export folder has already been created prior to starting the installation.
- If installing Connex Cardio as a distributed system (central database with multiple clients connected), the Server (database) portion of the install must be done before the installation of the clients.
- If performing an installation in the simple configuration, ELI Link 5.0 is automatically installed. If Connex Cardio is installed in the advanced setup to connect to a centralized ELI Link, it is important to note that edited measurements and interpretations only export when connecting to ELI Link 5.0 and greater. When a version lower than 5.0 is used, it is advisable to perform reviewing, editing, and signing in the PACS or ECG Management system instead of in Connex Cardio.

1. Navigate to the location where the software to be installed is located
2. Double click on the application file **Setup.exe**, indicated by the following icon: 
3. If prompted by a User Account Control window, allow the program to make changes to the computer by clicking **Yes**. Note: User must have Administrator access to complete the installation.
4. The following Exam setup prompt window appears informing Mortara PDF as a component to be installed on the user's machine. Click **Install**.

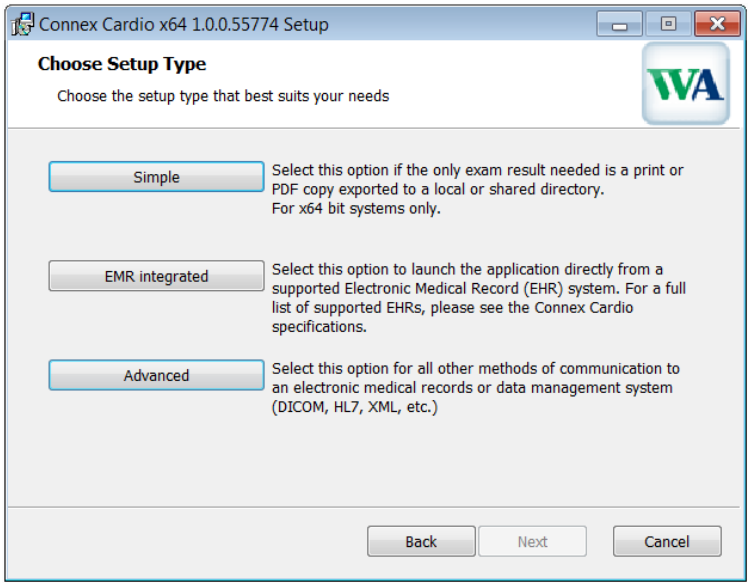


5. The following Connex Cardio v1.X.X Setup window will appear, click **Next** to continue.



Setup Type:

The Choose Setup Type window details the setup types that can be selected:



There are three available choices for the installation process:

Simple: This option is to be selected if the user wants the exam result to be obtained in a PDF format only. The choice Simple details the configuration of the system to export the PDF exam reports to a directory by automatically installing and configuring both Connex Cardio and ELI Link. Do not use this option if installing multiple Connex Cardio systems that are to be connected to a common ELI Link.

EHR Integrated: This option is to be selected when the user has a supported EHR (Electronic Health Record) system that can integrate with Connex Cardio. The choice EHR Integrated installs the necessary components and configures the system to launch from a supported EHR system. The choices of EHR's in the list include: AllScripts, eClinical, Epic, and default.

Advanced: This option is to be selected for any other type of installation or integration with a 3rd party system, including HL7, DICOM, XML, or PDF. The choice Advanced does not automatically install or configure ELI Link – this needs to be done separately. Note: if DICOM connectivity is desired, each Connex Cardio system needs to be licensed for DICOM.

The detailed configuration of the above three Setup Types is as follows:

Selecting the Simple option

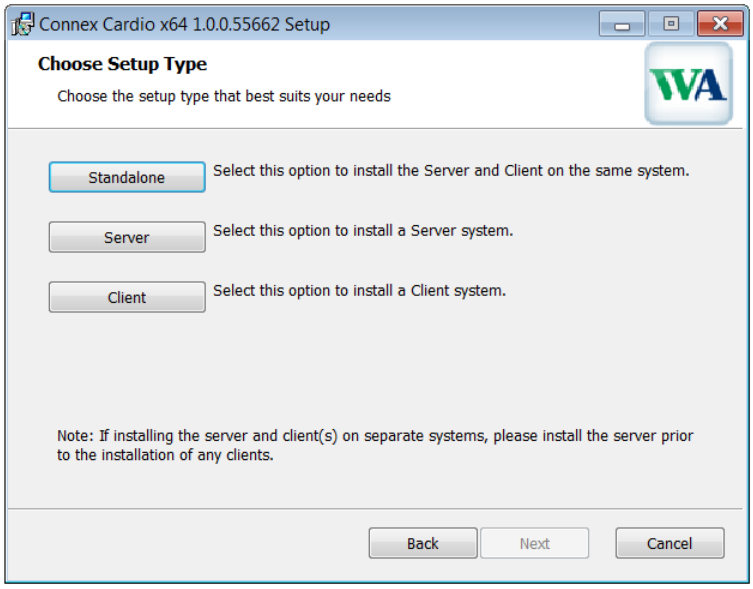
Simple – Click on the Simple choice and a window with the following three installation options will be displayed:

Standalone: Choose this option to install a single Connex Cardio application with the Database Server functionality included on a single computer.

Server: Choose this option to configure the system to have Database Server functionality and be networked to separate Client systems that will run the modality.

Client: Choose this option to install the Connex Cardio application on a computer that will be networked to the Database Server functionality on a different computer.

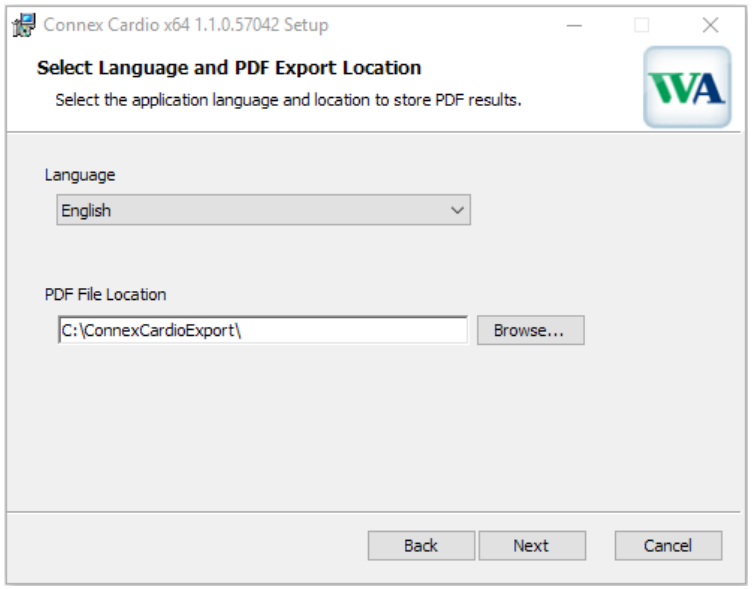
> ***Note**: If installing a Client system, install the Server system that the Client will be connected to first.*



Selecting the Standalone option

The following window containing the language dropdown options (English by default) and the information for the path to place the PDF file on the C:\ drive will be displayed. If the user wants to setup a different location, click the Browse button and set the desired location for the PDF file.

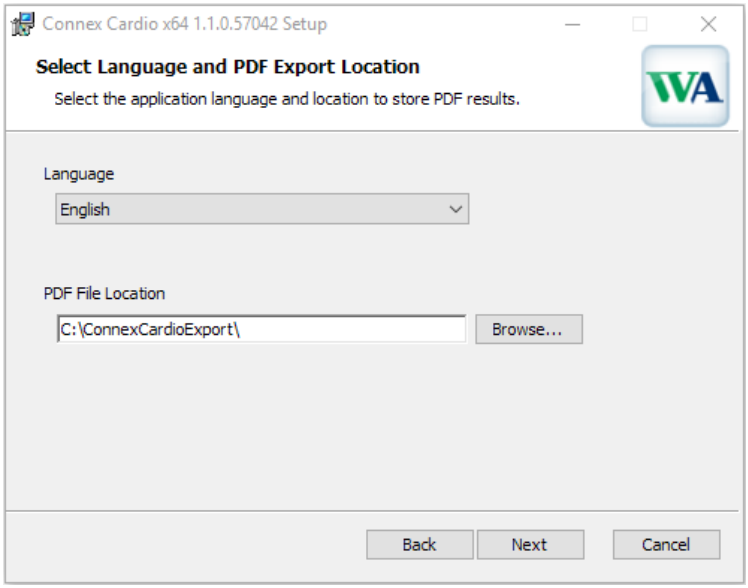
Upon selecting the desired language and location, click **Next** and the user will be navigated to the final installation window.



Selecting the Server option

The following window containing the language dropdown options (English by default) and the information for the path to place the PDF file on the C:\ drive will be displayed. If the user wants to setup a different location, click the Browse button and set the desired location for the PDF file. ELI Link automatically installs on the server, and Connex Cardio Server is automatically configured to communicate with the installed instance of ELI Link.

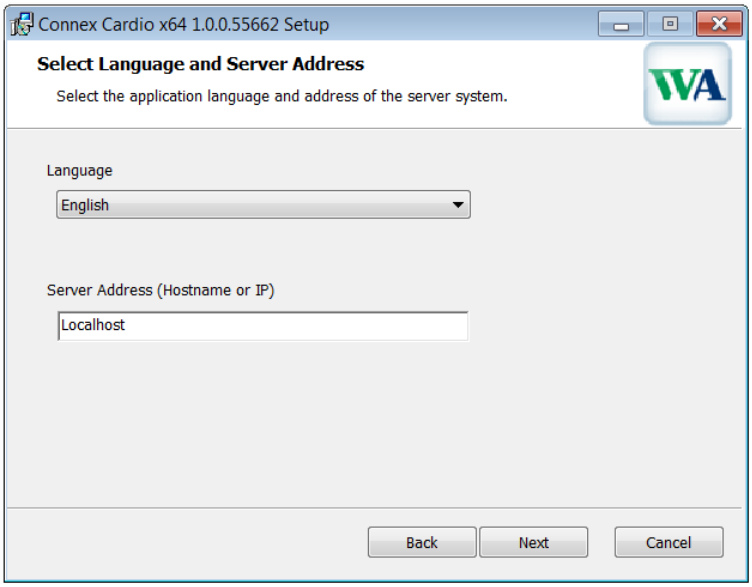
Upon selecting the desired language and location, click **Next** and the user will be navigated to the final installation window.



Selecting the Client option

The following window containing the language dropdown options (English by default) and the information for the Server Address will be displayed.

Upon selecting the desired language and server location, click **Next** and the user will be navigated to the final installation window.



If you select the EHR Integrated option

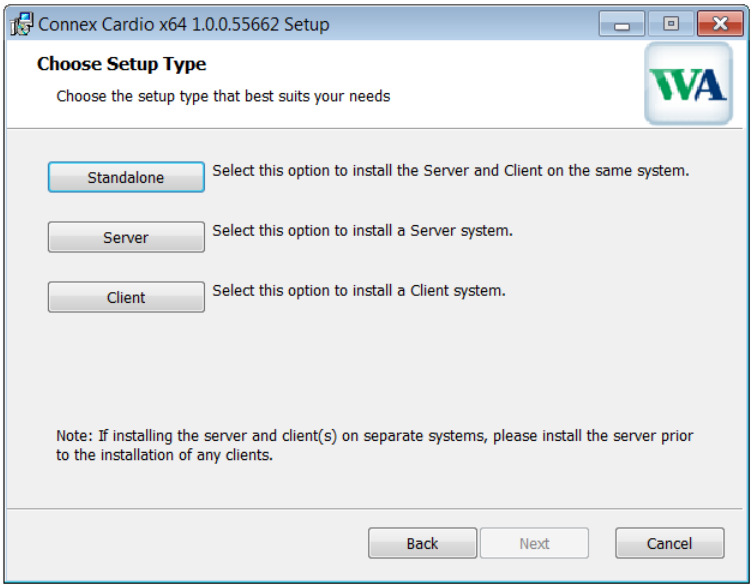
EHR Integrated – Click on the EHR Integrated choice and a window with the following three installation options will be displayed:

Standalone: Choose this option if the user wants to load a single Connex Cardio application with the Database Server functionality included on a single computer.

Server: Choose this option if the user wants to configure this system to have Database Server functionality and be networked to separate Client systems that will run the modality.

Client: Choose this option if you are loading the Connex Cardio application on a computer that will be networked to the Database Server functionality on a different computer.

Note: If installing a Client system, install the Server system that the Client will be connected to first.

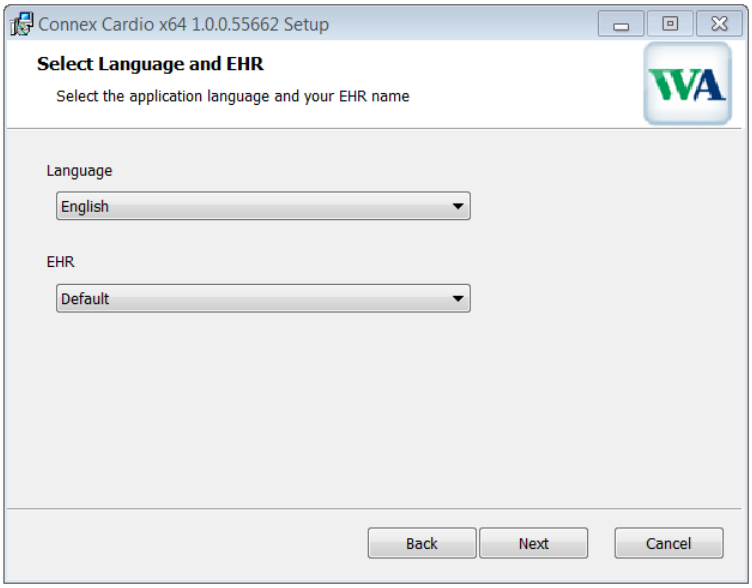


If you select the Standalone option

The following window containing the language dropdown options (English by default) and the EHR dropdown information will be displayed.

The available options of EHRs in the drop-down menu include Allscripts, eClinicalWorks, Epic, and Default

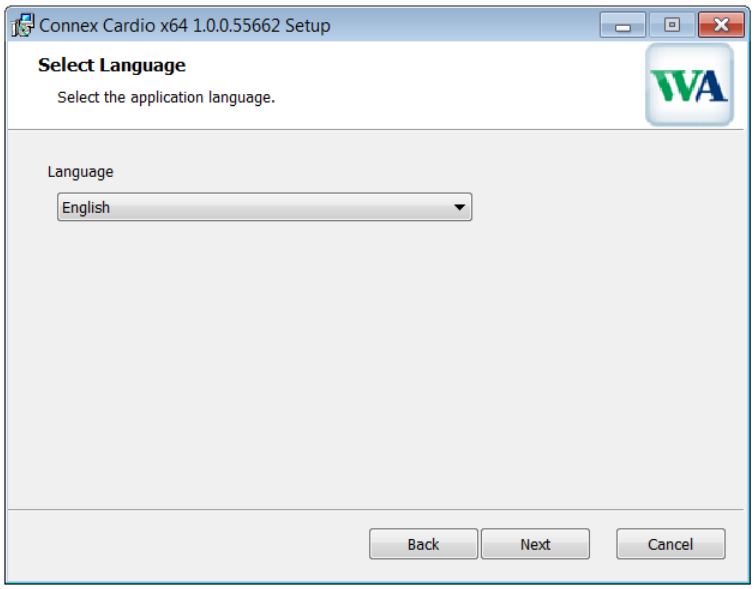
Upon selecting the desired language and supported EHR, click **Next** and the user will be navigated to the final installation window.



If you select the Server option

The following window containing the language dropdown options (English by default) will be displayed.

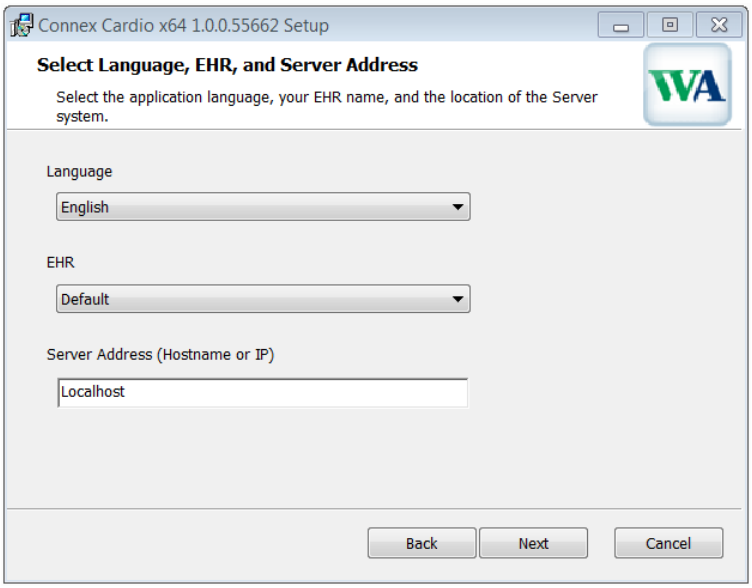
Upon selecting the desired language, click **Next** and the user will be navigated to the final installation window.



If you select the Client option

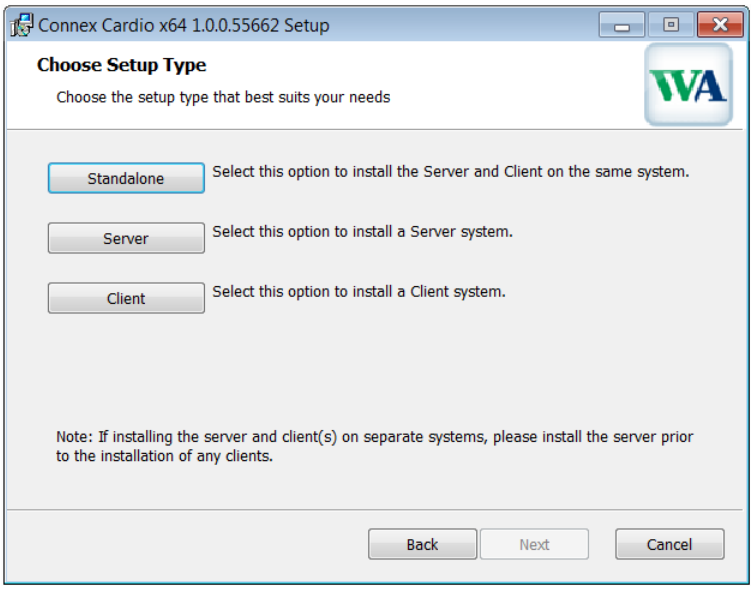
The following Select Language, EHR and Server Address window containing the language dropdown options (English by default), EHR dropdown options and the field for Server Address (Localhost by default) will be displayed.

Upon selecting the desired language, supported EHR and server address, click **Next** and the user will be navigated to the final installation window.



If you select the Advanced option

Advanced – Click on the Advanced choice and a window with the following three installation options will be displayed:



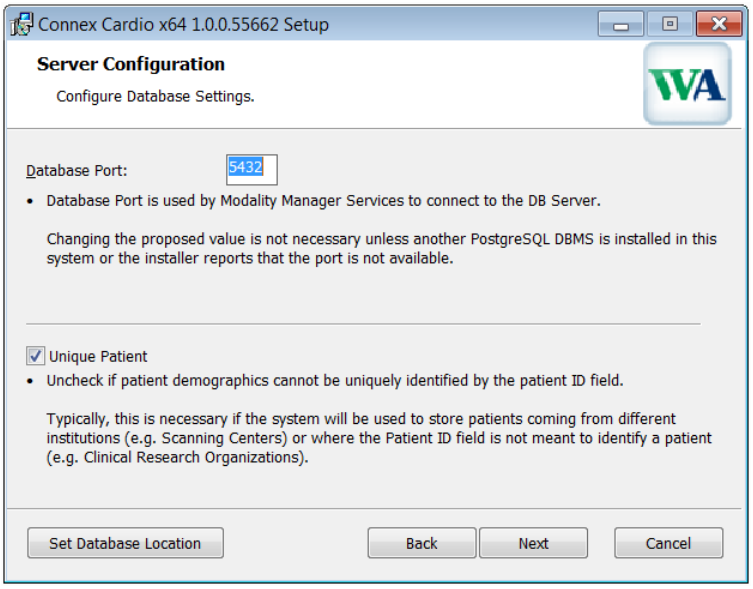
Standalone: Choose this option if the user wants to load a single Connex Cardio application with the Database Server functionality included on a single computer.

Server: Choose this option if the user wants to configure this system to have Database Server functionality and be networked to separate Client systems that will run the modality.

Client: Choose this option if you are loading the Connex Cardio application on a computer that will be networked to the Database Server functionality on a different computer.

Note: If installing a Client system, install the Server system that the Client will be connected to first.

If you select the Standalone option



The following Server Configuration window will be displayed containing the default Database Port number (5432) and an option to enable or disable the Unique Patient option.

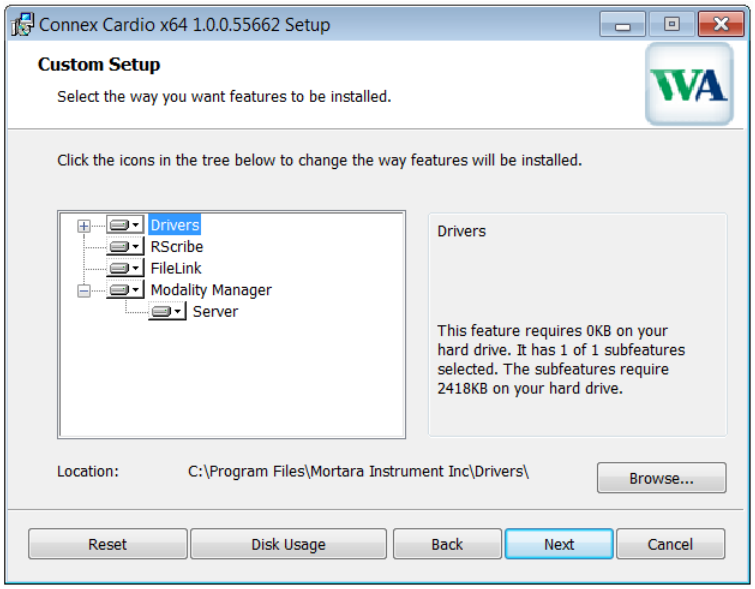
Database Port: It is recommended that the User uses the default port number for the installation. If the port is already in use the installation tool will alert the user that the port is already taken and that a new port number will need to be entered to continue with the installation.

Unique Patient: This option defaults to an enabled (checked) condition to configure the system to utilize the Patient ID field as a unique identifier for patient demographic information. This is the most commonly used system configuration.

The Unique Patient option box can be UNCHECKED to NOT use the Patient ID field as a unique identifier for patient demographics. Choose to uncheck the Unique Patient ID when patients can be entered from different institutions (such as scanning centers) that use different ID schemes. Choose to uncheck the Unique Patient when the Patient ID field is not used to identify a patient, such as with clinical research studies.

Set Database Location: Selection of this button allows the User to Browse to a location for the Connex Cardio application and database other than the local default (C:\) directory. This is beneficial when it is necessary to define the application and database locations on a different data drive.

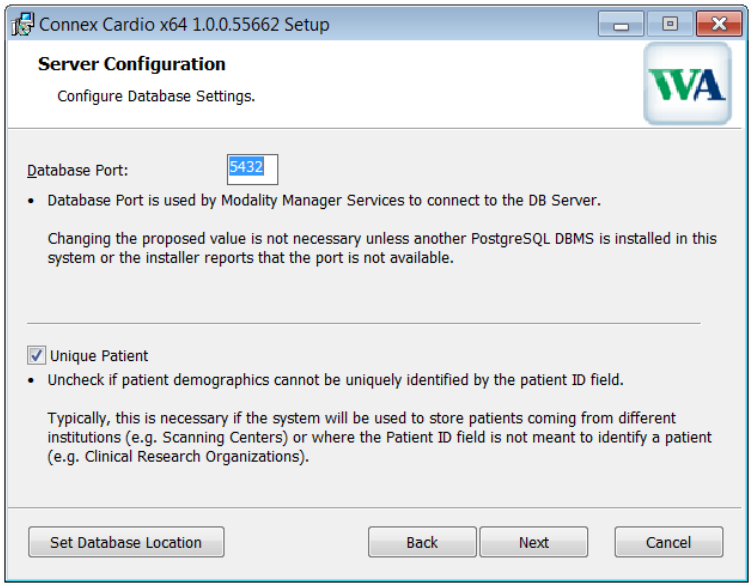
- This selection allows a preview of Disk Usage to ensure requirements are met.
- The Reset selection will return all changes to default settings.
- Select Next to return to the Server Configuration window to continue the installation steps.
- Select Cancel to exit the installation process.



Back at the Server Configuration window, click **Next** and the user will be navigated to the final installation window.

If you select the Server option

The following Server Configuration window will be displayed containing the default Database Port number (5432) and an option to enable or disable the Unique Patient option.

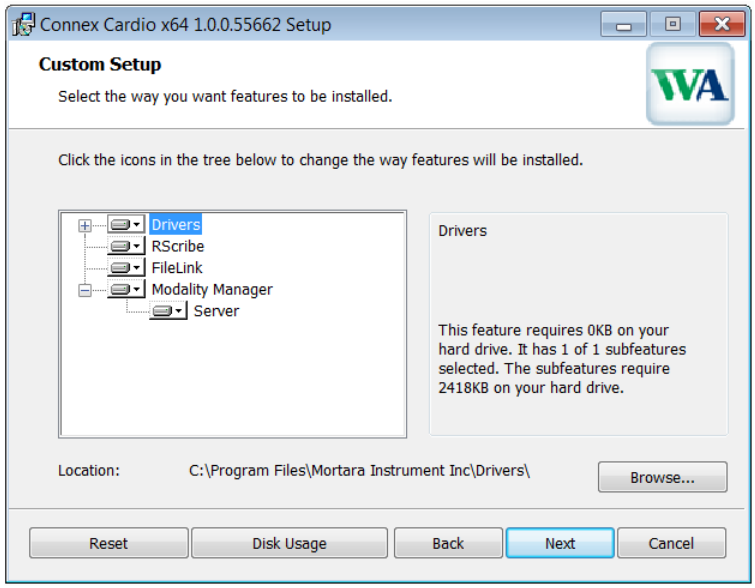


Database Port: It is recommended that the User uses the default port number for the installation. If the port is already in use the installation tool will alert the user that the port is already taken and that a new port number will need to be entered to continue with the installation.

Unique Patient: This option defaults to an enabled (checked) condition to configure the system to utilize the Patient ID field as a unique identifier for patient demographic information. This is the most commonly used system configuration.

The Unique Patient option box can be UNCHECKED to NOT use the Patient ID field as a unique identifier for patient demographics. Choose to uncheck the Unique Patient ID when patients can be entered from different institutions (such as scanning centers) that use different ID schemes. Choose to uncheck the Unique Patient when the Patient ID field is not used to identify a patient, such as with clinical research studies.

Set Database Location: Selection of this button allows the user to browse to a location for the Connex Cardio application and database other than the local default (C:\) directory. This is beneficial when it is necessary to define the application and database locations on a different data drive.



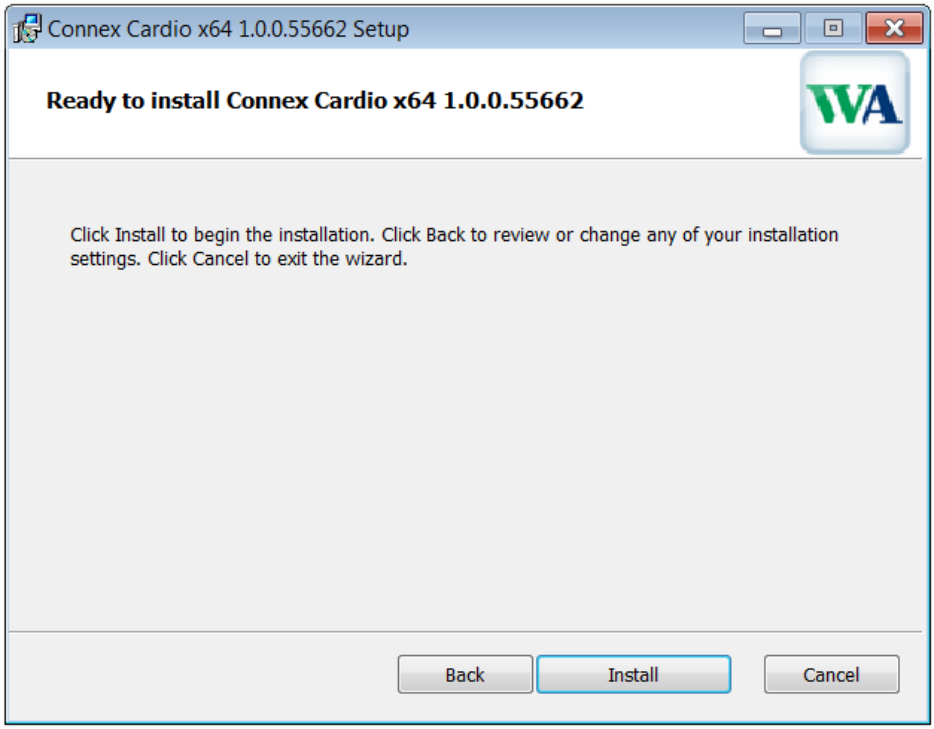
- This selection allows a preview of Disk Usage to ensure requirements are met.
- The Reset selection will return all changes to default settings.
- Select Next to return to the Server Configuration window to continue the installation steps.
- Select Cancel to exit the installation process.

Back at the Server Configuration window, click **Next** and the user will be navigated to the final installation window.

If you select the Client option

The user will be navigated to the final installation window.

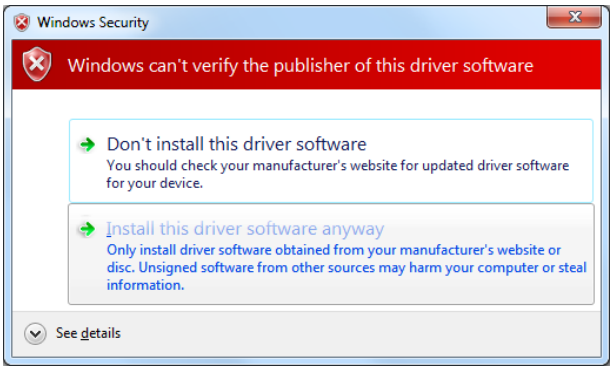
Final Installation Window:



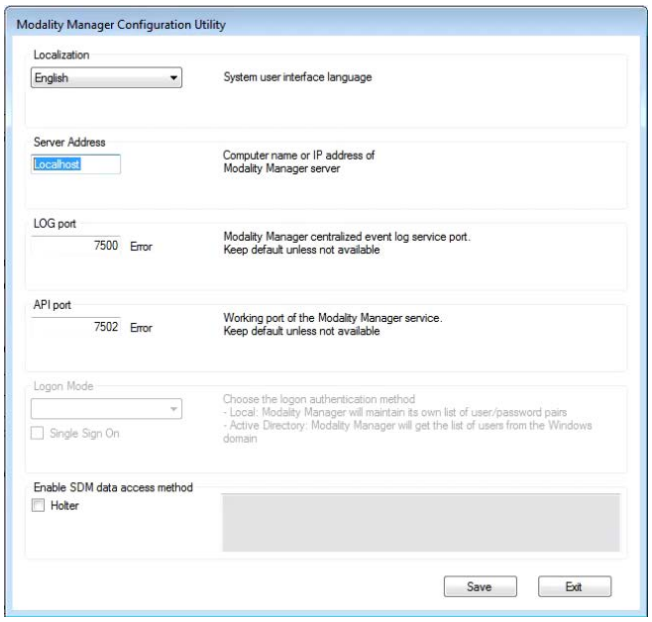
1. Click Install to load the software files to the defined location.

   During the software installation, you may be prompted to install device driver software. This is needed for the AM12 or WAM UTK drivers.

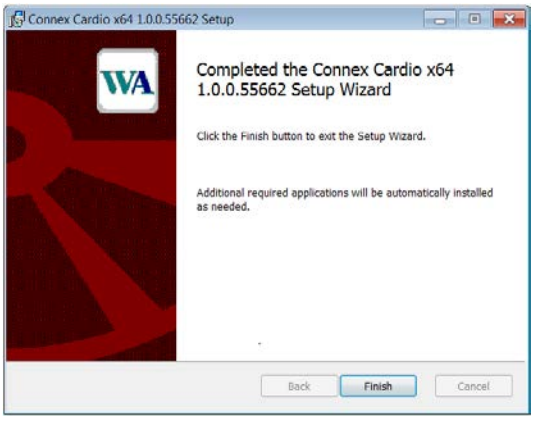
2. Select **Install this driver software anyway**.



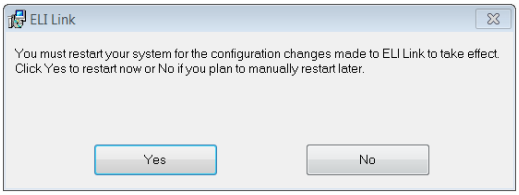
If you selected the Advanced configuration, at this point the Modality Manager Configuration window will appear. If this is a Client install you must enter the location where you installed the Server under Server Address. This can either be the computer name or the IP address of where you installed the Server. If this is the Server install, you will not be able to edit this field as it is the location of the computer the program is currently installed on.



3. Click **Finish** to complete the installation process of Connex Cardio and exit the window.



If the Simple configuration was selected, at this point Microsoft SQL Server and ELI Link will install automatically on the system. If prompted for permissions, allow the installation of both programs. When ELI Link finishes installing a window will appear informing that for the installation to be successful a system restart is required. Click Yes to restart the system now or No to manually restart the system later. The system should be restarted before using Connex Cardio to ensure full functionality.



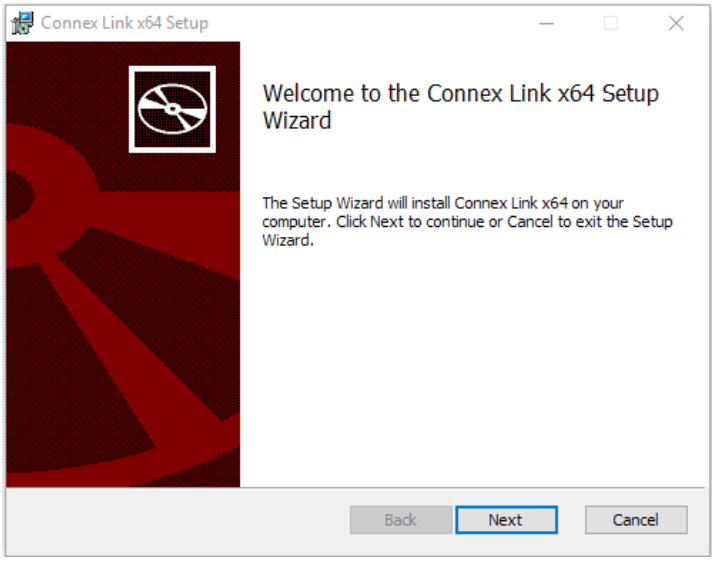
EHR integrated installations

After installing the EHR integrated version of Connex Cardio, steps must be taken by the supported EHR to allow Connex Cardio to be launched. The EHR representative should know that to complete the integration they should follow the same steps that are taken to integrate with Welch Allyn's CardioPerfect. Please note, that the component in the EHR to launch Connex Cardio is the same as CardioPerfect and may even be named CardioPerfect.

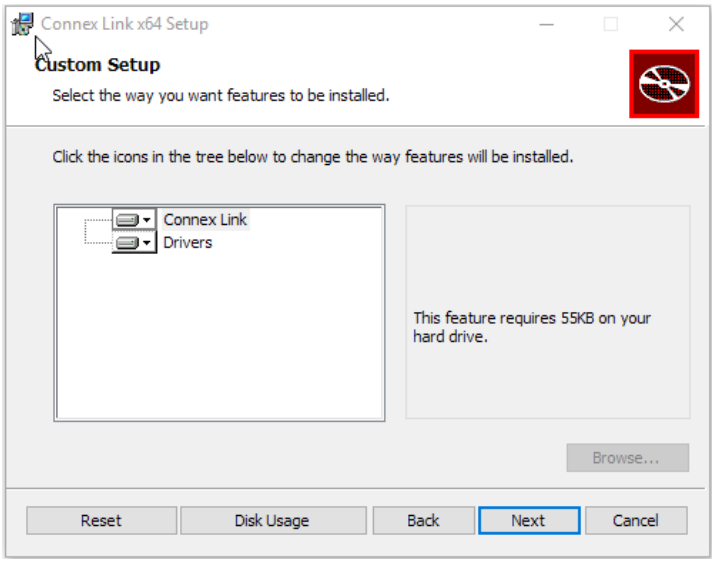
Thin Client Installations

If Connex Cardio is being installed on a client that will run Citrix XenApp or Windows Remote Desktop, Connex Link must be installed. The file can be found on the installation media in a folder titled “Connex Link”. **It must be installed on every client machine that will acquire ECGs.** Connex Link can be installed before or after the client software is installed.

1. Starting the installer will launch this window. Select **Next** if you are ready to proceed with installation.

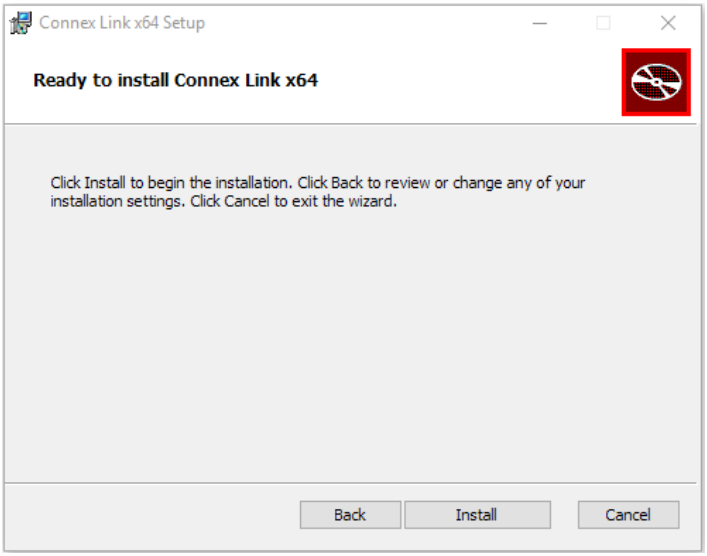


2. The Custom Setup window allows you to customize the installation. Select **Next** unless you know your system requires extra customization.

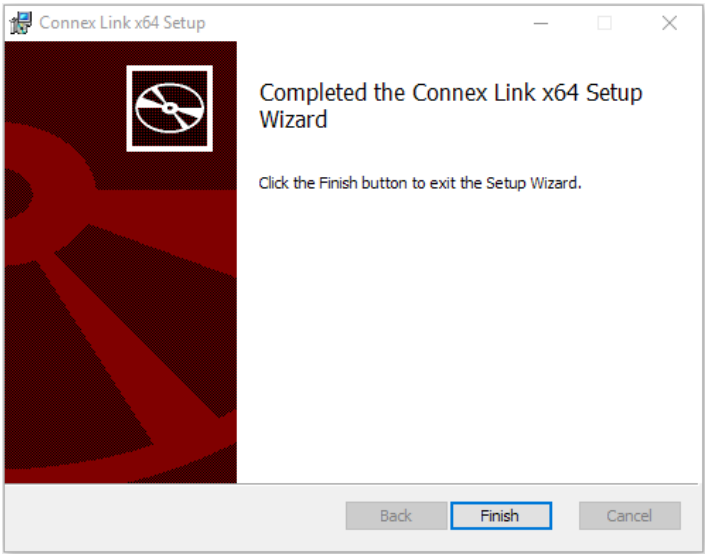


Selecting Disk Usage shows the system drives to ensure storage requirements are met.
The Reset selection will return all changes to default settings.
Select Next to continue to the final installation window.
Select Cancel to exit the installation process.

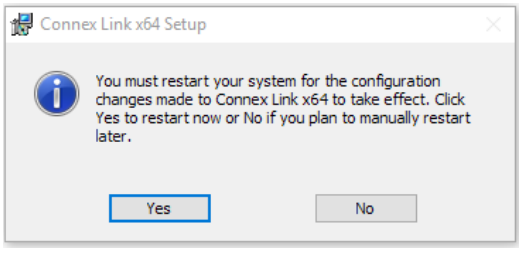
3. Click **Install** and the wizard will load the software files.



4. Click **Finish** to complete the installation process of Connex Link and exit the window.



5. When Connex Link finishes installing a window will appear informing that for the installation to be successful a system restart is required. Click Yes to restart the system now or No to manually restart the system later. The system must be restarted before using Connex Cardio to ensure full functionality.



DICOM Feature Activation

Activation is required to enable DICOM functionality.

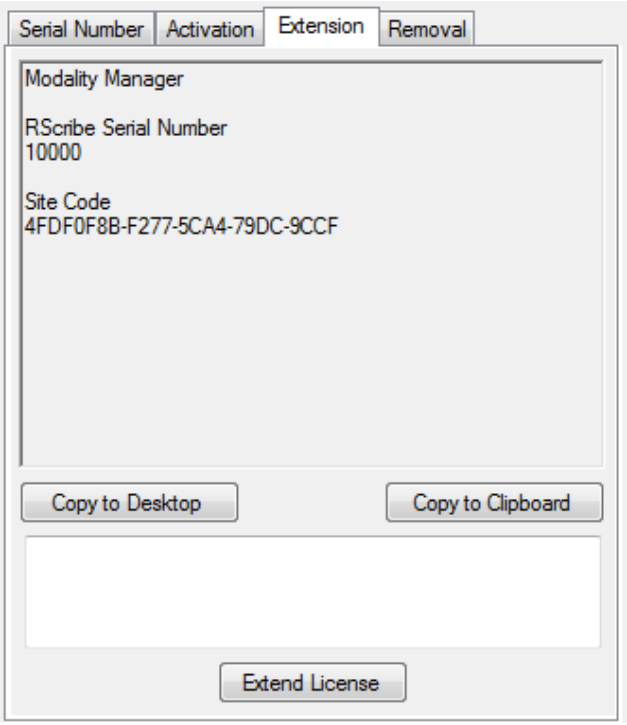
To prepare for activation, run the Modality Manager Activation Tool accessed from the following menus:

- Start menu
- All Programs
- Mortara Modality Manager
- Modality Manager Activation Tool (click **Yes** when prompted to allow changes to the computer)

To enter your serial number, select the Serial Number tab and enter the serial number that appears on the product registration card that was shipped with the product. Since the software can be installed on multiple systems, it is acceptable to use the same serial number for multiple installations. If you no longer have your product registration card and do not know your serial number, please contact Technical Support for assistance.

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

Technical Support will return an activation code that can be typed or copied and pasted into the white space above the "Extend License" button. Select the Extend License button to activate the DICOM feature. Contact Technical Support personnel for further information.



Connex Cardio Login and Main Display

Use the 

icon on the desktop to start the Connex Cardio application.

If not set up with "single sign on", Connex Cardio will require user credentials on startup. Enter your Connex Cardio Username and Password and then select **OK** to open the application main menu.

Note: The default Username and Password are "admin" (password is case-sensitive).

Upon successful login, the Connex Cardio application screen will appear displaying the user name and software version in the bottom left corner.

The icons in the center of the screen indicate workflow tasks in presumed order left to right. Click the icon representing workflow task you wish to perform.

Hover the mouse over an icon to display its function.

Connex Cardio Program Icons and Descriptions

Icon and Hover Text	Description
	Desktop shortcut icon to launch the Resting ECG application.
 MWL/Patients	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.
 STAT ECG	Use to bypass Exam Data Entry and proceed directly to real-time ECG for immediate acquisition
 Start a Resting Exam	Use to enter exam data and begin real-time ECG acquisition
 Exam Search	Use to search for exams in the database using filters.
 User Preferences	Use to configure user preferences for the Worklist and to change the password.
 System Configuration	For administrative users to configure system settings such as creating/modifying users, changing the Connex Cardio default acquisition criteria, defining archive directories, and so on.
 Exit	Use to close the Connex Cardio application and return to the desktop.
	Use to minimize or exit the application and return to the desktop.

User Roles and Permissions

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

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

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

Refer to *User Role* assignment table with details.

Connex Cardio Standalone/Client Specifications

Feature	Specification*
Input Channels	Simultaneous acquisition of all 12 leads
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Waveform Display	Compatible with 1024 x 768, 1366 x 768, 1280 x 800, 1680 x 1050, 1920 x 1080, 1920 x 1200, and 2736 x 1824 resolutions
Compatible Operating Systems	Microsoft® Windows® 7 Professional 32 bit or 64 bit and Microsoft® Windows® 10 Pro 64-bit operating systems**
Processor	Performance equivalent or better than an Intel® Core™ i3
RAM	Minimum 4 GB
Hard Drive Capacity	Minimum 250 GB (If client: minimum 160 GB)
Storage Capacity	Unlimited with external archive
Archive	Network or external USB disks (standalone installation)
USB ports	Requires at least two USB 2.0 ports (WAM/AM12 modules, external USB drive)
Input devices	Standard keyboard and 2-button scroll mouse
Software Installation	USB
Network	100 Mbps connection or better required for use with server
Printing Device	HP M501dn Windows printer with HPUPD PCL 5 driver† or equivalent
On-Screen Tools	Time and amplitude calipers; 40 Hz and 150 Hz noise filters; various lead layouts and grid
Digital Sampling Rate	40,000 s/sec/channel used for pacemaker spike detection; 1,000 s/sec/channel used for recording and analysis
Gain Setting	2.5, 5, 10, 20 mm/mV
Report Formats	Standard or Cabrera; 3+1, 3+3, 6, 6+6, or 12 channel
Rhythm Print Format	Single lead of up to 60 minutes of data
Frequency Response	0.05 – 300 Hz
Filters	High-performance baseline filter; AC interference filter 50/60 Hz; low-pass filters 40 Hz, 150 Hz, 300 Hz
Power Requirements	Dependent on computer, 100 – 240 VAC at 50/60 Hz

** Specifications subject to change without notice.*
***Installations that include ELI Link 5.0 and later require 64-bit systems (Simple – Standalone; Simple – Server).*
† *For optimal printing the PCL 5 driver is recommended to be used where possible. This driver is included on the installation media.*
Note that PDF printers are not supported.

Connex Cardio Minimum Server Specifications

Feature	Server Minimum Specifications*
Processor	Performance equivalent to an Intel Xeon class; Quad-core with hyperthreading
Graphics	1024 x 768
RAM	Minimum 4 GB
Operating System	Microsoft® Windows® 2008 Server R2 (64-bit) Microsoft® Windows® 2012 R2 (64-bit) *If installing ELI Link with Connex Cardio, system requires 64-bit OS to operate both. (Simple Installer will automatically load ELI Link and Connex Cardio together.)
System Disk	100 GB for OS and product installation (RAID recommended for data redundancy)
Data Disks	550 GB hard drive space available HD controller with 128 MB read/write cache (RAID recommended for data redundancy)
Archive	Network or external USB drive
Software Installation	USB
Network	100 Mbps connection or better
Input Devices	Standard keyboard and mouse

**Specifications subject to change without notice.*

Requirements for Connex Cardio deployed via Citrix® XenApp®

	Requirements*
Client Machines that will run Citrix XenApp	Microsoft® Windows® 7 Professional (64-bit and 32-bit) Microsoft® Windows® 10 Professional (64-bit)
	Citrix Receiver
	Internet Browser – any that is supported by Citrix
Citrix Desktop Delivery Controller	Citrix XenApp version 7.13
	Any operating system supported by Citrix
Citrix App Servers	Microsoft® Windows® 2008 Server R2 (64-bit) Microsoft® Windows® 2012 R2 (64-bit)
	Citrix Virtual Delivery Agent 7.13
	Connex Cardio Client software
Required for ECG acquisition	Installation of Connex Link – found on installation media

NOTE: *A system running in a virtual environment may experience a streaming lag between input and output of the system.*

**Requirements subject to change without notice.*

Requirements for Connex Cardio deployed via Windows Remote Desktop Protocol

	Requirements*
Client Machines that will run Windows RDP	Microsoft® Windows® 7 Professional (64-bit and 32-bit) Microsoft® Windows® 10 Professional (64-bit)
RDP Servers	Microsoft® Windows® 2008 Server R2 (64-bit) Microsoft® Windows® 2012 R2 (64-bit)
	Connex Cardio Client software
Required for ECG acquisition	Installation of Connex Link – found on installation media

NOTE: *A system running in a virtual environment may experience a streaming lag between input and output of the system.*

**Requirements subject to change without notice.*

WAM Specifications

Feature	Specification*
Instrument Type	12-lead wireless acquisition module for resting ECG
Input Channels	12-lead signal acquisition and transmission
ECG Leads Transmitted	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
WAM Transmission Protocol	Bidirectional and frequency hopping; beacon and response method links a single acquisition module to a single electrocardiograph
Frequency Range	2400.96 MHz to 2482.56 MHz
WAM and Receiver Distance	Approximately 10 feet (3 meters)
Lead Set	RA, LA, RL, LL, V1, V2, V3, V4, V5, and V6 (R, L, N, F, C1, C2, C3, C4, C5, and C6) with detachable lead wires
Sampling Rate	40,000 samples/second/channel acquisition; 1,000 samples/second/channel transmitted for analysis
Resolution	1.875 microvolt LSB
User Interface	Two-button operation: ON/OFF and 12-lead ECG acquisition; Rhythm button is non-functional
Defibrillator Protection	Complies with AAMI standards and IEC 60601-2-25
Special Functions	LED indication of power status, operating mode, lead fail, and remaining battery charge
Device Classification	Type CF, battery operated
Weight	6.7 oz. (190 g) with battery
Dimensions	4.45 x 4.25 x 1.1” (11.3 x 10.8 x 2.79 cm)
Battery	1 AA alkaline battery typically powers WAM for acquisition of 250 resting ECGs

** Specifications subject to change without notice.*

WAM and AM12 Accessories

Part Number	Description
9293-046-07	COMBINER WAM LEADS 10 POS GRAY
9293-046-60	LEAD SET WAM 10 WIRE BANANA AHA GRAY
9293-046-61	LEAD SET WAM 10 WIRE BANANA IEC GRAY
9293-046-62	RPLCE LD SET WAM/AM12 LIMBS BANA AHA GRY
9293-046-63	RPLCE LD SET WAM/AM12 LIMBS BANA IEC GRY
9293-046-64	RPLCE LD SET WAM/AM12 V1-V3 BANA AHA GRY
9293-046-65	RPLCE LD SET WAM/AM12 C1-C3 BANA IEC GRY
9293-046-66	RPLCE LD SET WAM/AM12 V4-V6 BANA AHA GRY
9293-046-67	RPLCE LD SET WAM/AM12 C4-C6 BANA IEC GRY
9293-047-60	LEAD SET WAM 10 WIRE CLIPS AHA GRAY
9293-047-61	LEAD SET WAM 10 WIRE CLIPS IEC GRAY
9293-047-62	RPLCE LD SET WAM/AM12 LIMBS CLIP AHA GRY
9293-047-63	RPLCE LD SET WAM/AM12 LIMBS CLIP IEC GRY
9293-047-64	RPLCE LD SET WAM/AM12 V1-V3 CLIP AHA GRY
9293-047-65	RPLCE LD SET WAM/AM12 C1-C3 CLIP IEC GRY
9293-047-66	RPLCE LD SET WAM/AM12 V4-V6 CLIP AHA GRY
9293-047-67	RPLCE LD SET WAM/AM12 C4-C6 CLIP IEC GRY

Electrodes

Part Number	Description
9300-032-50	ECG MONITORING ELECTRODES CASE 300
9300-033-51	ELECTRODE RESTING TAB BOX/500
9300-033-52	ELECTRODE RESTING TAB CASE/5000
042729	CardioSens / Ultra II Electrodes

Acquisition Modules

Part Number	Description
9293-048-65	CONNEX CARDIO WIRED PATIENT CABLE (AM12)
30012-019-76	CONNEX CARDIO WIRELESS ACQUISITION MODULE (WAM)
30012-021-60	UTK (Wireless receiver / transceiver)

Manuals

Part Number	Description
9515-001-51-CD	PHYSICIAN'S GUIDE ADULT & PEDIATRIC UM
9515-218-50-CD	CONNEX CARDIO USER MANUAL PDFS
9515-218-50-ENG	CONNEX CARDIO USER MANUAL ENGLISH
9515-166-50-CD	ELI LINK USER MANUALS

Contact your dealer or go to **www.mortara.com** for more information.

Connex Cardio Network Operation in a Distributed Configuration

The Connex Cardio network capabilities leverage a common database across multiple networked Connex Cardio workstations where exams will be conducted and acquired exams can be reviewed and edited.

A distributed configuration is comprised of a dedicated server and a number of networked client Connex Cardio workstations and Connex Cardio Review Stations sharing the same database.

A distributed configuration supports efficient operation for a busy department to:

- Create logins for all users at a single location who can log into any networked station.
- Define system settings at a single location for all networked workstations and review stations.
- Manually schedule exam orders, when no orders interface exists, that are available to all Connex Cardio workstations regardless of the lab location.
- Access and update Patient Information, exam data, and final reports from multiple locations.
- Start exams utilizing scheduled orders received from the institution information system with a single DICOM or HL7 interface to the shared database. Refer to the ELI Link Administrator manual for network interface configuration instructions.
- Selectively search the database to review any completed exam. This includes the ability to edit, sign, print, and export the final report from multiple Connex Cardio workstations and review stations on your network, dependent on the user permissions.
- Manage the stored data for all exams with ability to view audit trails, create groups, configure workflow, troubleshoot issues, and archive/restore/delete exams at a single location according to user permissions.

Microsoft Updates

Mortara recommends that all Connex Cardio 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. The following guidelines apply for Microsoft updates:

- Customer is responsible for applying Microsoft updates.
- Configure Microsoft updates to be manually applied.
    - Turn automatic Windows update off and run it periodically as a manual action.
- Do not install Microsoft updates during active use of the product.
- Run a functional test after any update which includes conducting a test exam as well as importing an order and exporting results (if activated) before running patient exams.

Each Connex Cardio product release is tested against the cumulative Microsoft updates at the time of product release. There are no known Microsoft update conflicts with the Connex Cardio application. Please contact Technical support if conflicts are identified.

Anti-Virus Software

Mortara recommends the use of anti-virus (AV) software on computers hosting the Connex Cardio application. The following guidelines apply in the use of AV software:

- Customer is responsible for installation and maintenance of AV software.
- AV software updates (software and definition files) should not be applied during active use of the Connex Cardio application.
    - AV patch updates and system scans should be scheduled for time periods when the system is not actively in use or should be performed manually.
- AV software must be configured to exclude files/folders as defined in *Cautions* in User Safety Information and below:
    - Mortara recommends excluding the Connex Cardio database folder (normally *C:\ProgramData\MiPgSqlData*) from the folders to be scanned.

If a technical support issue is reported, you may be asked to remove the virus scanning software to allow investigation of the issue.

Encrypt Protected Health Information (PHI) Stored in Connex Cardio

The Connex Cardio database may be configured for Windows Encrypted File System (EFS) for protection of patient data security. EFS encrypts individual files with a key stored with the Windows user account. Only the Windows user that encrypts or creates new files in an EFS-enabled folder can decrypt the files. Additional users can be granted access to individual files by the original account that encrypted the files.

> ***NOTE:*** *The Connex Cardio system database must be unencrypted prior to performance of any software upgrades.*

Contact technical support if your facility requires this security feature.

9. USING CONNEX CARDIO

A typical workflow on Connex Cardio consists of the following actions:

Schedule an exam

An exam is scheduled for a patient; exam data such as referring physician and requested date and time are entered. If the patient does not exist in the database, patient demographic data is entered. Orders may be managed through the Connex Cardio Modality Worklist (MWL) feature, or through an external scheduling system interface.

Start a resting exam

The patient is ready to begin a resting exam when he or she is connected to the Connex Cardio system via the data acquisition module. An exam may fulfill an order or be an ad-hoc exam. For an ad-hoc exam, a patient must be selected from the database or a new patient must be created by entering demographic information before starting the exam. When an ECG is taken, 10 seconds of the ECG waveform is selected and presented to the operator. The operator may then edit, print, review, sign or save the ECG and future processing and analysis. The operator may also delete the acquired ECG and acquire a new one.

Acquiring a STAT ECG exam

The STAT ECG icon can be selected when there is an immediate need to acquire an ECG without prior demographic data entry. The patient is connected to the Connex Cardio system via the data acquisition module, data is collected and a 10 second ECGs is acquired. Patient demographics may be entered during ECG collection or after ECG acquisition, before saving. Patient Information can also be accessed after the ECG is saved. These saved exams can be found through exam search and the patient information can be updated in the MWL/Patient window. By default the exams are saved with the last name STAT ECG.

Reviewing and signing an exam and printing a report

In order to edit an exam and electronically sign it, you must have the necessary permission to do so. The program will automatically start the Review mode after exiting the acquisition session with the ECG that was collected. Previously acquired ECGs are saved and can be found through exam search in order to review or sign after acquisition.

Real-time Display

Real-time ECG may be displayed in one of two full-screen views. The standard (12x1) full-screen view displays 10 or more seconds of continuous waveform data for each of the 12 leads. The split-screen (6x2) view displays 5 or more seconds of continuous waveform data for each of the 12 leads. The six (6) limb leads appear on the left and the six (6) precordial leads appear on the right side of the screen.

To change the default display format for the real-time ECG view, see the *Settings* section in this manual.

> ***NOTE**: The amount of data displayed may vary and depends on display speed and display size.*

Recording an ECG

Connex Cardio can acquire an ECG in real time or retrospectively from the full disclosure history, or can be configured to collect multiple ECGs in a timed sequence.

Prepare the patient for best conductivity between the skin surface and the electrode. Place the electrodes on the patient according to lead placement guidelines. Ensure that the proper lead wire is firmly and correctly attached to each electrode.

Select a patient to associate the exam with by choosing an existing order from the MWL tab, search for a patient from the Patients tab, or manually enter patient demographics to create a new patient.

The real-time ECG display can be exited with selection of the Done  button to return to the Start a Resting Exam display at any time. The user is prompted to select Yes or No when an ECG has not been acquired.

To acquire a real-time ECG:

- Select the ECG button on the display to capture Best 10  or Last 10  12-lead ECG data.
    - BEST 10 captures the best quality, 10-second ECG accumulated within the full disclosure
    - LAST 10 captures the most recently acquired 10-second ECG
- Or, select the **ECG** button  on the Connex Cardio WAM™ or the Connex Cardio AM12™ that will capture either the BEST or LAST 10-seconds of acquired ECG dependent on Connex Cardio configurations.

Preview Acquisition Screen

The ECG preview screen appears with the ECG report information.

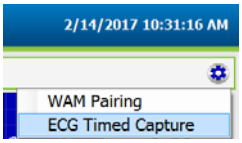
- Select the **Save**  button to save the ECG as acquired, exit, and return to the Start a Resting Exam display.
- Select the **Delete**  button to discard the ECG and return to the real-time ECG display to capture a new ECG.
- Select the **Review**  button to save the ECG as reviewed, exit, and return to the Start a Resting Exam display. The user is prompted to enter the reviewer's name prior to exit.
- Select the **Sign**  button to save the ECG as signed, exit, and return to the Start a Resting Exam display. The user is prompted to enter the signer's name prior to exit. When Legal Signature has been defined in the workflow configuration settings, the signer is prompted to enter the user name and password.
- Select the **Print ECG**  button to print the displayed ECG according to the Resting ECG settings.

Timed ECG Capture

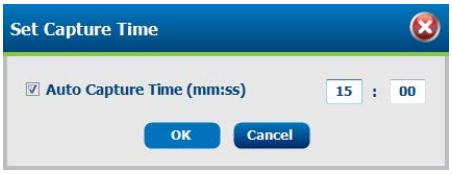
Connex Cardio can automatically acquire ECGs at preset time intervals for future review and processing on the full disclosure screen. Automatic acquisition may be as frequent as every 20 seconds or once per a 60-minute period (dependent on the amount of full disclosure time set by the administrator).

To acquire timed ECGs:

- Prep the patient and place the electrodes in the correct locations (ensuring lead wires are securely attached).
- Select **ECG Timed Capture** from the settings icon in the upper right corner of the real-time ECG display.



- Enable **Auto Capture Time** by checkbox.
- Enter the frequency in the **Set Capture Time (mm:ss)** window
  - 20 seconds up to 59-minutes and 59-seconds.
- Select **OK** to begin automatic ECG collection or **Cancel** to exit the window.
  - Message appears prompting a manual ECG capture



- Capture the first ECG to begin the timed ECG capture. The time remaining to the next capture and the number of ECGs captured is displayed in the lower right corner of the display.

ECGs are automatically captured according to the Full Disclosure duration defined by the administrator. ECG capture automatically ends when the duration has been reached. ECGs can also be selected manually at any frequency within the full disclosure window.

Automatic ECG capture can be manually ended with selection of the done button.

Captured ECGs are saved and can be reviewed and edited using the Exam Search feature.

ECG Capture from the Full Disclosure Data Window

The full disclosure data window is located at the bottom of the ECG display screen. ECG data is displayed using a single lead or three leads according to the settings.

To acquire a retrospective ECG:

- Use a left mouse click anywhere in the full disclosure ECG to highlight 10-seconds of data. Once clicked, the Page Up, Page Down, Select, and Print Full Disclosure buttons become active allowing navigation and ECG selection.
- Position the 10-second box of highlighted ECG anywhere in the full disclosure ECG using left mouse clicks and the Page Up/Down buttons.
- Select the ECG button to the right of the full disclosure to capture the highlighted 10-second 12-lead ECG.

Note: an ECG may only be captured from the Full Disclosure when the patient is connected – the Full Disclosure data is not saved with the resting ECG after the exam has been completed and patient disconnected.

ECG Collection Using the Acquisition Module

ECG acquisition can be performed at the WAM or AM12 acquisition modules. Refer to the AM12 short-form instruction card when using the AM12.

> ***NOTE**: The WAM must be synchronized to the UTK before Connex Cardio operation. The Universal Transmitter/receiver Key (UTK) is a bidirectional device that links the PC's USB port to the WAM.*

Select the **ECG** button  on the WAM™ or the AM12™ to capture the last 10-seconds of acquired ECG.

Connecting the Acquisition Module

The AM12 connects to a USB port on the PC for signal acquisition. The Connex Cardio will automatically detect the AM12 once it's connected to the USB port.

The WAM communicates via the UTK (Universal Transmitter/receiver Key) connected to an active USB port on the PC. The WAM is synchronized with the UTK making them a matched pair. Using the same UTK and WAM that were last paired maintains their synchronization.

Pairing WAM with Connex Cardio

Start the Connex Cardio application. Navigate to the real-time display and:

- Select the settings icon  in the upper right corner of the real-time display
- Select **WAM Pairing**
- Place the WAM (powered off) in close proximity to the UTK receiver connected to an Connex Cardio USB port.
- Select **Start** and then **Yes**
- Power the WAM on**.**
- A successfully paired message will display.
- Select **DONE**.

> ***NOTE**: The wireless acquisition module (WAM) must be paired to a specific Connex Cardio prior to signal acquisition.*
>
> ***NOTE**: If both AM12 and the UTK are connected simultaneously, Connex Cardio will default to the AM12 over the UTK with WAM for acquisition.*
>
> ***NOTE**: Disconnecting the UTK and connecting the AM12 will automatically cause the Connex Cardio to switch to the AM12. It is not necessary to pair the same WAM with the same UTK to use it again.*

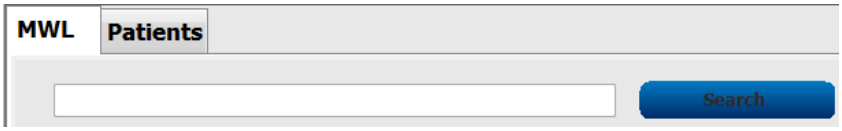
10. MWL/PATIENTS

The MWL/Patients icon  allows you to schedule exams and enter patient demographics information. Select this icon to open a window for scheduling resting ECG exams and to view the existing schedule.

When Connex Cardio is linked to an external scheduling system, this information arrives from institution entered orders.

When the icon is selected, a split window appears with two selectable tabs (MWL and Patients) on the left and Patient or Order Information fields on the right, dependent on the selected tab.

A Search field and button are present below the tab selections.



MWL

Text that is entered in the search field will be used to search through the Modality Worklist (MWL) to display orders that start with matching text in the Last Name, First Name, or Patient ID. A blank search field will list all orders.

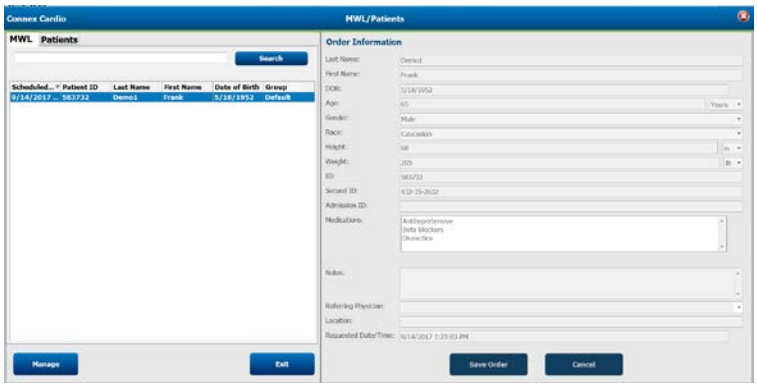
MWL columns include Scheduled Date/Time, Patient ID, Last Name, First Name, Date of Birth, and Group. The list can be sorted by a click on the column headers. A second click on the same header will reverse the column order.

> ***NOTE:*** *Selection of an unavailable order (e.g. in use at another workstation, deleted, or canceled) will result in a refresh of the listed orders.*

Edit Order

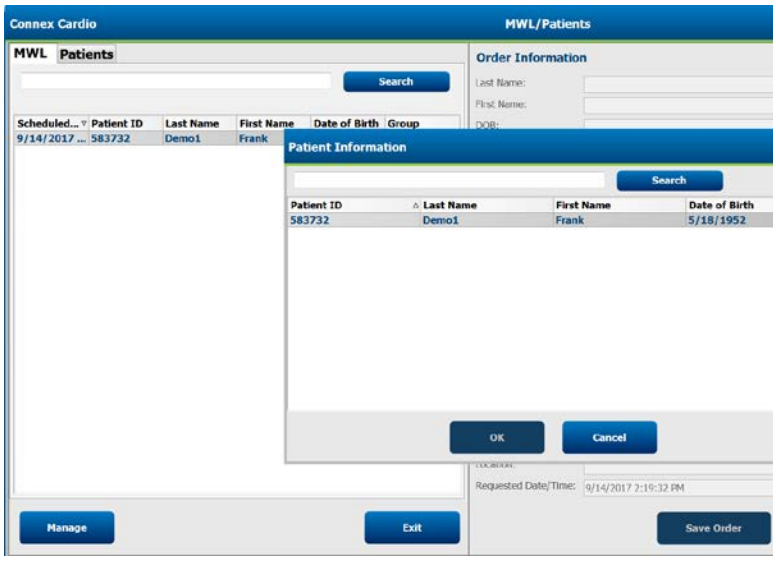
Selection of an entry in the list will display the Order Information as read-only. Select the **Manage** button and click on the item Edit Order to modify the order. Select the **Save Order** button to save changes or **Cancel** to cancel all changes.

NOTE: *This function is not available when an orders interface is enabled.*



New Order

A **New Order** button allows a Patient ID or name search of patient information in the database allowing addition of a new order in the MWL list. A blank search field will list all patients in the database.

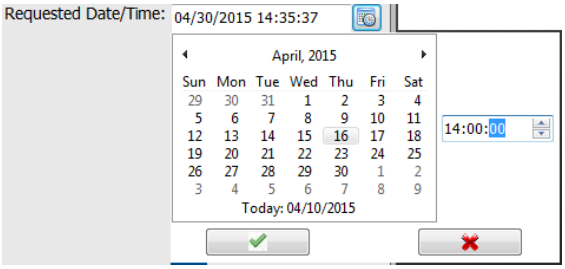


When the patient does not exist in the database, **Cancel** the Patient Information search and select the **Patients** tab to enter a new patient. Instructions are on the following page.

The patient information populates the Order Information at the right of the display. Additional order information can be entered and the order saved. The **Cancel** button will close the order without saving.

When entering an order, use the **Group** drop-down list to assign the order to a specific group that has been configured in the system settings. This is not necessary when there is no more than one Group.

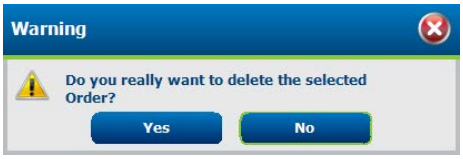
Select the calendar icon in the bottom right corner of the **Order Information** section to open a calendar for selection of the scheduled order date and time. Date and time may also be entered by typing in the **Requested Date/Time** field.



Delete an Existing Order

Select an existing patient order by highlighting the line and then select **Manage** and then **Delete Order**.

A warning message prompting delete confirmation will appear. Select **Yes** to delete the order or **No** to cancel and return to the MWL listing.



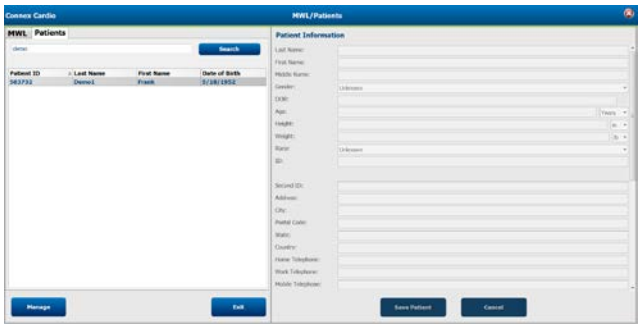
Exit MWL/Patients

Select the **Exit** button when finished to return to the main menu.

Patients

Text that is entered in the search field will be used to search through the patient demographics in the database to display any patients that start with matching text in the Last Name, First Name, or Patient ID.

Patients' columns include Patient ID, Last Name, First Name, and Date of Birth. The list can be sorted by selecting the column headers. A second selection on the same header will reverse the column order.



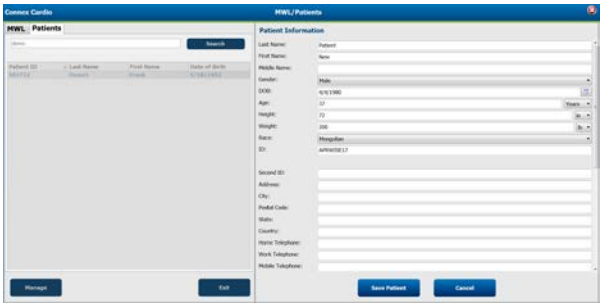
Edit Patient

Selection of an entry in the list will display the Patient Information as read-only. Select the **Manage** button and then **Edit** to enable and modify the patient demographics fields.

Select the **Save Patient** button when finished to save changes or the **Cancel** button to return to read-only demographics without saving changes.

New Patient

Selecting the **Manage** button and then **New Patient** clears any selected patient information allowing addition of a new patient in the list. The new patient information can be entered in the demographic fields and the **Save Patient** button selected to save it to the database. The **Cancel** button will close the patient information without saving.

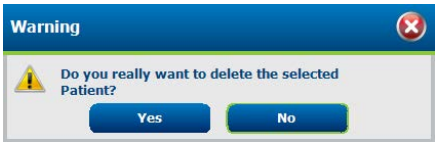


Delete Patient

Select the **Manage** button and then **Delete** to remove patient demographics from the database.

> ***NOTE:*** *The Delete button is disabled when the patient demographics are associated with an existing order or exam. All orders and exams for that patient must first be deleted before the patient demographics can be deleted.*

A warning message prompting delete confirmation will appear. Select **Yes** to delete the patient demographics or **No** to cancel and return to the Patients listing.



Exit MWL/Patient

Select the **Exit** button when finished to return to the main menu.

11. RECORD AN ECG

Patient Preparation

Before attaching the electrodes, assure the patient fully understands the procedure and what to expect.

- Privacy is very important in assuring the patient is relaxed.
- Reassure the patient that the procedure is painless and that the electrodes on their skin are all that they will feel.
- Make sure the patient is lying down and is comfortable. If the table is narrow, tuck the patient's hands under his/her buttocks to ensure their muscles are relaxed.
- Once all the electrodes are attached, ask the patient to lie still and to not talk. Explain this will assist you in acquiring a good ECG.

Preparing Patient Skin

Thorough skin preparation is very important. There is natural resistance on the skin surface from various sources such as hair, oil, and dry, dead skin. Skin preparation is intended to reduce resistance and maximize the quality of the ECG signal.

To prepare the skin:

- Clip hair from electrode sites if necessary.
- Wash area with warm, soapy water or alcohol if dirty or oily.
- Dry skin vigorously with a pad such as 2 x 2 or 4 x 4 gauze to remove residue from cleaning, dead skin cells and oil, and to increase capillary blood flow.

***NOTE**: With elderly or frail patients take care to not abrade the skin causing discomfort or bruising.*

Patient Hookup

Correct electrode placement is essential for acquiring a diagnostically valid ECG.

A low resistance highly conductive pathway from the skin surface to the electrocardiograph provides superior noise-free waveforms. Good quality silver-silver chloride (Ag/AgCl) electrodes within their expiration date should be used whenever taking an ECG.

***TIP**: Electrodes should be stored in an air-tight container. Electrodes will dry out if not stored properly causing reduced adhesion and conductivity, leading to poor trace quality.*

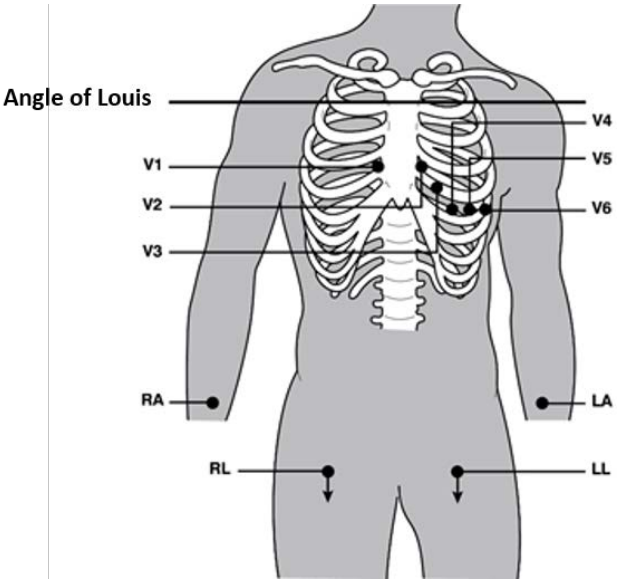
To Attach the Electrodes

1. Expose the arms and legs of the patient to attach the limb leads.
2. Place the electrodes on flat, fleshy parts of the arms and legs.
3. If a limb site is not available, place the electrodes on a perfused area of the stump.
4. Attach the electrodes to the skin. A good test for firm electrode contact is to slightly tug on the electrode to check adhesion. If the electrode moves freely, it needs to be changed. If the electrode does not move easily, a good connection has been obtained.

For accurate V-lead placement, it is important to locate the 4th intercostal space Because patients vary with respect to body shape, it is difficult to palpate the 1st intercostal space with accuracy. Thus, locate the 2nd intercostal space by first palpating the little bony prominence called the **Angle of Louis**, where the body of the sternum joins the manubrium. This rise in the sternum identifies where the second rib is attached, and the space just below it is the 2nd intercostal space. Palpate and count down on the chest until you locate the 4th intercostal space.

Patient Hookup Summary Table

AAMI Lead	IEC Lead	Electrode Position
V1 Red	C1 Red	On the 4th intercostal space at the right sternal border.
V2 Yellow	C2 Yellow	On the 4th intercostal space at the left sternal border.
V3 Green	C3 Green	Midway between V2/C2 and V4/C4 electrodes.
V4 Blue	C4 Brown	On the 5th intercostal space at the left midclavicular line.
V5 Orange	C5 Black	Midway between V4/C4 and V6/C6 electrodes.
V6 Violet	C6 Violet	On the left midaxillary line, horizontal with V4/C4 electrode.
LA Black RA White	L Yellow R Red	On the deltoid, forearm, or wrist.
LL Red RL Green	F Green N Black	On the thigh or ankle.



Patient Demographic Entry

Patient demographic information can be entered before, during or after acquisition. The entered patient ID fields will remain populated until you acquire the ECG; however, if you turn off the device before exiting the patient information will be cleared.

In addition to the default patient ID format, Connex Cardio also supports custom ID formats for each group through use of ELI Link. Refer to the ELI Link Administrator Manual, Part number 9515-166-50-ENG, for instructions on Custom ID.

STAT ECG

To begin STAT ECG acquisition without patient demographic entry, select the STAT ECG icon  from the main display to directly start continuous ECG display. Skip to ECG, Acquisition, and Storage on the following pages. Patient demographics may be entered during ECG collection or after ending ECG acquisition by retrieval of the STAT ECG from the database.

Start a Resting Exam

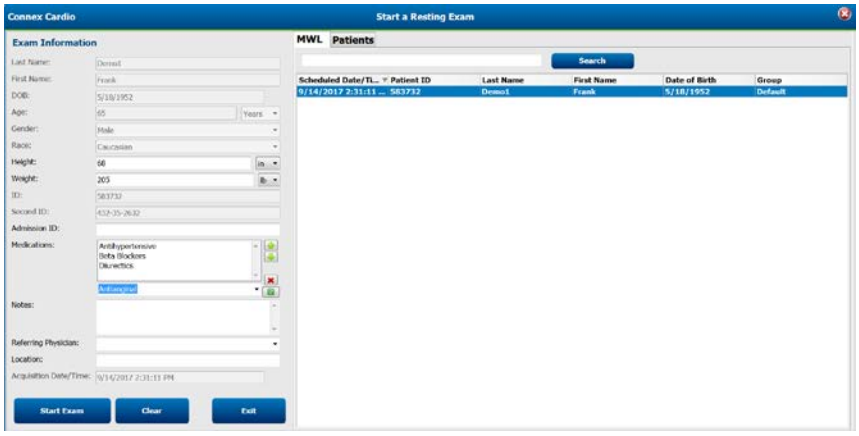
Select the Start a Resting Exam icon to open the MWL/Patients window.

- When scheduled orders exist, the MWL tab is automatically selected.
- When no scheduled orders exist, the Patients tab is automatically selected.

Scheduled Order(s)

1. When there is an existing order for the patient, highlight the patient in the MWL list.

   The Exam Information section on the left side of the display is populated by the previously entered patient demographics.

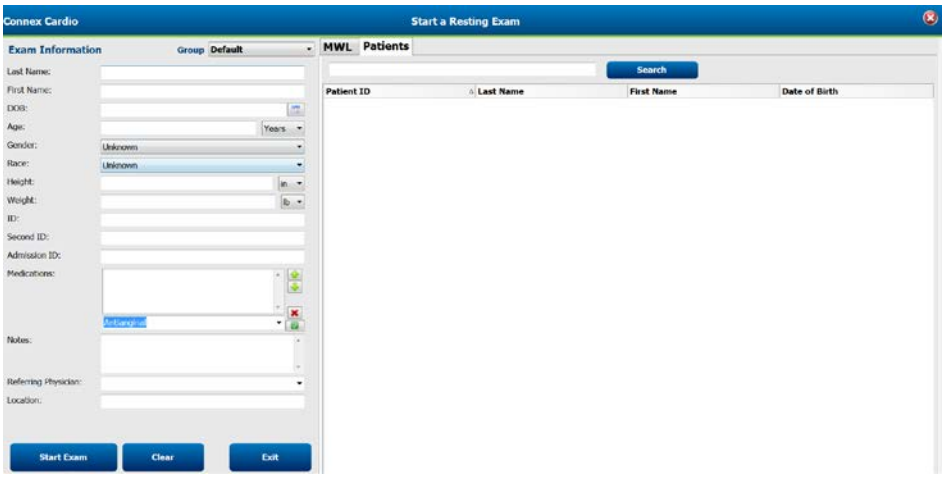


2. Enter any desired exam information on the left panel and select **Start Exam**.

   NOTE: *Selection of an unavailable order (e.g. in use at another workstation, deleted, or canceled) will result in a refresh of the listed orders.*

No Scheduled Order(s)

When no scheduled orders exist, the Patient tab is automatically selected.



1. Search for existing patients in the database by entering a name or ID number, and then select the **Search** button.

2. When the patient information is not found, enter any desired patient and exam information on the left panel.

   ***NOTE**: If the entered ID number already exists in the database, a warning will appear informing you to click OK to continue or Cancel to correct the entered demographics.*

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

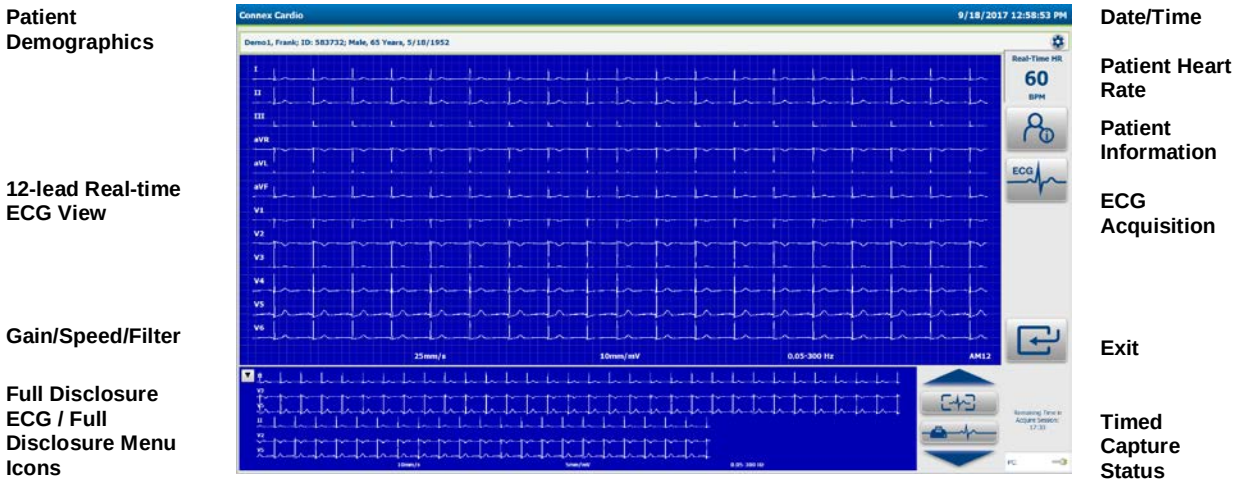
   Connex Cardio will remember list items such as Indications, Medications, Procedure Type, and Referring Physician as they are entered. The added items will be available for future selection. Enter text or choose items from the drop-down menu and then click on the green checkmark to enter. Use the red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

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

ECG Acquisition, Printing, and Storage

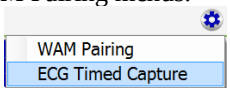
Once the patient is connected and the Start Exam button is selected from the Exam Information window, Connex Cardio continuously captures and displays ECG data. The patient should be in a supine position and encouraged to relax to ensure that the ECG is free from artifact (noise) due to patient activity.

Display Overview



Menu Selections

- Click on the settings button in the upper-right area of the display to open the ECG Timed Capture and WAM Pairing menus.



  - Select **ECG Timed Capture** to automatically acquire ECGs at preset time intervals.
    - Refer to previous section for instructions
  - Select **WAM Pairing** to pair the WAM acquisition module.
    - Refer to previous section for instructions

- Click the show/hide Full Disclosure ECG section in the lower-left area of the display as desired.

Date/Time

Current date/time according to the computer regional settings is displayed in the upper right-hand corner of the display.

Real-Time Heart Rate

When a patient is connected to the Connex Cardio, his/her heart rate is displayed in real time. The HR is the average ventricular rate measured over the patient's last five beats.

> ***NOTE:*** *If a lead fail occurs or swapped leads are suspected, a red message is visible next to the HR, indicating the leads off or possibly misplaced, for both limb lead and chest lead fault conditions.*

Timed Capture Status

Values in the lower-right area of the ECG display indicate the time remaining until the next timed ECG capture and the total number of 10-second 12-lead ECGs that are currently captured and saved.

Full Disclosure ECG

Single lead ECG or three (3) lead ECG (configurable) is accumulated and displayed along the bottom area of the display. Twelve (12) leads of ECG are accumulated and stored for up to 60 minutes of full disclosure, which can be reviewed or printed as a single lead or as acquired ECG.

ECG Display Menu Icons

Icon	Description
	Patient Demographics allows editing of existing and entry of new demographics.
	ECG button permits the capture of an ECG at any time the patient is connected.
	10 appears in the place of ECG when Best 10 capture mode is configured; selects the Best 10 seconds of the full disclosure as the captured ECG.
	Done ends and exits the ECG acquisition session.

Full Disclosure Menu Icons

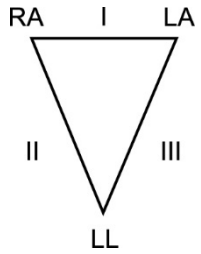
Click within the full disclosure ECG to enable the menu icons for selection.

Icon	Description
	Page Up advances the cursor back one page. Page size is determined by the format, speed, and computer screen size.
	Select allows for the selection of the data in the cursor to be analyzed.
	Prints a single lead rhythm page of the Full Disclosure.
	Page Down advances the cursor forward one page. Page size is determined by the format, speed, and computer screen size.

Acquire ECGs

Examine the display for artifact or baseline drift. Re-prep and replace electrodes if necessary to obtain satisfactory waveforms. (See *Patient Preparation*.)

Please refer to the following troubleshooting guide based on Einthoven's Triangle:



Artifact	Check Electrode
Lead II and III artifact	Poor LL electrode or left leg tremor
Lead I and II artifact	Poor RA electrode or right arm tremor
Lead I and III artifact	Poor LA electrode or left arm tremor
V Leads	Re-prep site & replace electrode

If a lead fault occurs, square waves appear on the display for that lead and the lead(s) that are faulty will display in the upper left corner of the screen one at a time. After the leads are reattached correctly at least 10 seconds must be acquired before an ECG can be captured.

The program monitors the ECG waveform for unusual configurations that could be caused by misplaced (swapped) electrode positions. If the program detects a high probability of electrode swap, it will display a message like "RA or LA misplaced?" in the same message area as used for lead fault. Check the electrode connections for any misplacement.

> ***NOTE:*** *Although the majority of lead wire swaps are correctly detected, some real ECG configurations may give rise to an inappropriate "misplaced" message, and some real swaps may not be detected due to patient specific ECG morphologies. The automatic detection helps to prevent lead wire swaps but do not rely completely on the automatic detection.*

Manual ECG Capture

Use the Capture ECG  icon to capture the last 10 seconds of the real time ECG. The captured ECG will appear on the screen in a format similar to a printout. An average beat can also be viewed if enabled.

The print ECG icon  can be used to print the unconfirmed report; if set in the configuration, the ECG will print automatically.

ECG acquisition can also be captured by pressing the ECG button  on the WAM or AM12 acquisition module.

Best 10 Seconds Selection

When the BEST 10  icon is selected, Connex Cardio automatically selects the best quality10 seconds of acquired ECG available from within the full disclosure ECG buffer.

ECG acquisition can also be captured by pressing the ECG button  on the WAM or AM12 acquisition module when Best 10 capture has been set up. However, this action will always capture the last 10-seconds of acquired ECG.

Capturing ECGs from Full Disclosure

Click anywhere in the full disclosure display at the bottom of the screen to capture an ECG retrospectively from the buffer. A green rectangle will appear highlighting the selected 10-seconds of ECG data. You can navigate through the window with the mouse, or use the page up/down buttons to the right. Use the ECG icon  to capture the 12-lead ECG. The complete full disclosure data can be printed as a single lead by using the Print Full Disclosure  icon. Waveform data reviewed on the screen can be selected and printed as a single lead of up to 60 minutes of data, depending on the amount of ECG data that has been acquired.

> ***NOTE:*** *ECG size and gain will automatically adjust to allow all data to fit on one page.*
> ***NOTE:*** *The full disclosure data cannot be accessed once the acquisition session has ended.*

Timed ECG Recording

Connex Cardio automatically acquires ECGs at preset time intervals for future review and processing on the full disclosure screen. Automatic acquisition is based on the amount of full disclosure time set by the administrator. It may be set as frequent as every 20 seconds or as infrequently as once per a 60-minute period.

The ECGs captured for the current patient are presented as white rectangles in the full disclosure window. As the waveform data on the screen refreshes, additional ECGs can be acquired as necessary. Previously acquired data will be retained in the buffer until the full disclosure buffer has been filled.

See the description of the Menu Item "ECG Timed Capture" in previous section for instructions how to initiate and set up timed capture of ECGs. To begin, manually capture an ECG to start timed collection.

> ***NOTE****: When the full disclosure buffer duration set by the administrator is reached, Connex Cardio automatically ends ECG capture and will display the last captured ECG.*

Captured ECG Display and Icons

Once captured, the ECG is displayed with global measurements and the VERITAS automatic interpretation. Icon button selections are located at the right of the captured ECG and actions are described below.

Icon	Description
	**ID** allows editing of existing and entry of new patient information.
	**Sign** the displayed ECG. Icon is only available for those logged in with signing authority.
	Mark the displayed ECG with a **Review**ed status. Icon is only available for those logged in with permission to Edit and Review exams. User is prompted to enter the Reviewer's name and select OK. Start a Resting Exam is then displayed.
	**Save** the ECG. ECG is saved with an "Acquired" status. Start a Resting Exam is then displayed.
	**Delete** the ECG. User is prompted to select Yes or No and is then returned to the real-time ECG display.
	**Print ECG** will send the displayed ECG to the default printer.

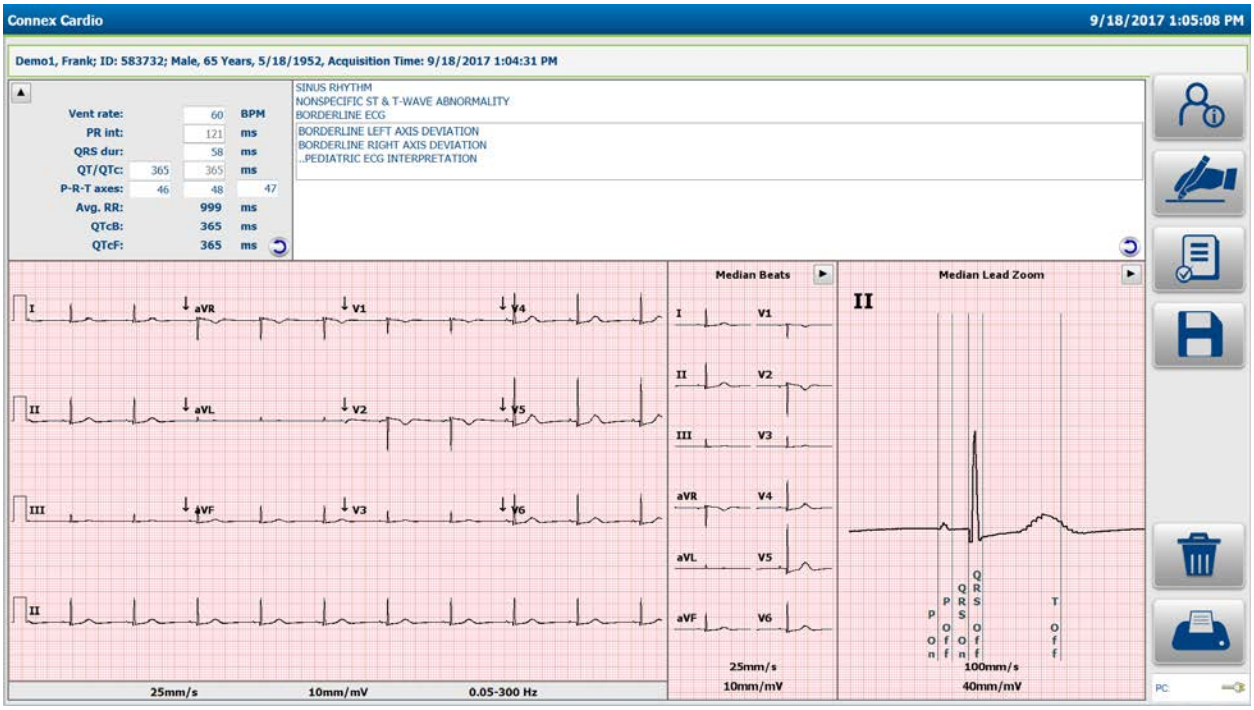
Median Beats and Median Lead Zoom panels can be shown or hidden by toggling the small arrow buttons in the upper-right corners.

The global measurement and interpretation panels can be shown or hidden by toggling the small arrow button in the upper-left corner.

Measurement parameters can be changed with a double-click in the Median Lead Zoom area and by dragging the cursors to the desired positions. Global measurements are updated upon selection of the OK button. Cancel will undo any changes and revert back to the original locations and global values.

For users with editing permission, the interpretation area can be edited by a single-click in the text area. When the user begins to type characters, a scrollable pick-list with commonly used statements that begin with, or contain the characters typed appears allowing quick selection of the desired statement.

An undo icon in the bottom-right corner of the interpretation or measurements area can be selected to revert back to the original interpretation or measurements respectively when selected before saving the ECG.



***NOTE**: If no patient age is entered prior to acquiring an ECG, the interpretation algorithm assumes a 40-year old male. The statement "INTERPRETATION BASED ON A DEFAULT AGE OF 40 YEARS" will be added to the Interpretation text.*

***NOTE**: If a patient age of zero (0) is used the interpretation algorithm will assume a 6-month old infant. The statement "INTERPRETATION BASED ON A DEFAULT AGE OF 6 MONTHS" will be added to the interpretation text.*

***NOTE**: Where global measurement values are not available (i.e., rate, interval, axis), text such as '- -'or '*' or similar will display/print for the unavailable value.*

Printing

If Auto-Print is enabled in the configuration, an ECG is printed following ECG capture, both for manual or timed capture.

For manual printing, select the Print ECG  button icon. The view on the display is what will print out.

To change the speed, gain, filter, or print format (regardless of the plot format configuration setting) of the acquired ECG, use a right mouse click over the acquired ECG (see below).

The complete full disclosure data can be printed as a single lead by selecting the Print Full Disclosure  icon. Waveform data reviewed on the screen can be selected and printed as a single lead of up to 60 minutes of data, depending on the amount of ECG data that has been acquired.

Storage

When an ECG is acquired the data is temporarily stored until a user decides to either delete the exam or save it permanently to the database. If timed capture is enabled, ECGs are automatically saved to the database upon acquisition. When multiple timed ECGs are captured, they can be edited using the exam search functions.

Change Settings

Many settings can be changed by clicking the right mouse button on areas of the display. The context menus may be different depending on the area selected. Some specific context menus are available for display speed, gain, filter settings and lead layout in the area of the window where that parameter is displayed. The context menu is also specific to the display area (e.g. the full disclosure window or the captured ECG window), but where appropriate, the settings may apply to all windows; for example, if you change the gain through the menu in the full disclosure window, the gain in the real time window is also changed.

Refer to the next section of this manual for a detailed description of the context menus allowing change.

12. CONTEXT MENUS

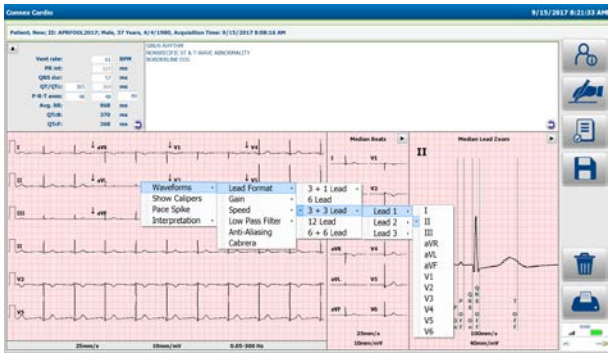
Context Menu Settings

Many settings can be changed by clicking with the right mouse button on areas of the display. A so-called "context menu" will be displayed as seen in the examples below. The context menus may be different depending on the area selected. Some specific context menus are available for display speed, gain, filter settings and lead layout in the area of the window where that parameter is displayed. The context menu is also specific to the display area (e.g. the full disclosure window or the captured ECG window), but where appropriate, the settings may apply to all windows; for example, if you change the gain through the menu in the full disclosure window, the gain in the real time window is also changed. Some context menus activate specific tools, like measurement calipers.

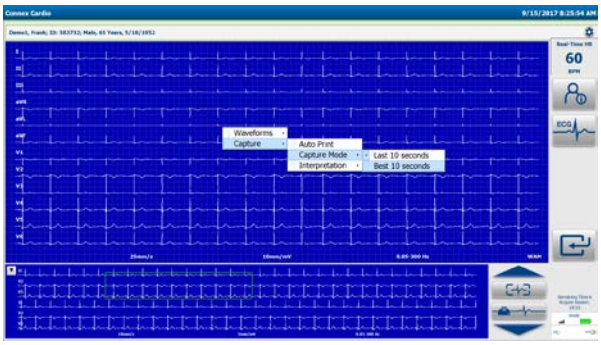
> ***NOTE**: Changes are maintained ONLY for the current sessions. Settings will revert back to the default settings with the next exam. Refer to the System Settings section in this manual to change the default settings.*

> ***NOTE**: Some of the described menus may not be present if they were locked by the administrator in the Connex Cardio configuration settings.*

Context Menus in Captured ECG



Context Menus in Real-time ECG



Change Lead Format

- Right mouse click while the cursor is over the captured ECG waveform
- Select **Waveforms**
- Select **Lead Format**
- Select from: 3+1, 6, 3+3, 12, or 6+6

> ***NOTE:** In the real time display only 6+6 and 12 lead formats are available. It is recommended to choose a format that allows at least 10 seconds of real time ECG on the screen during acquisition.*

3 + 1 Lead Format – Select Lead

- Right mouse click while the cursor is over the captured ECG waveform
- Select **Waveforms**
- Select **Lead Format**
- Select: **3+1**
- Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

3 + 3 Lead Format – Select Leads

- Right mouse click while the cursor is over the captured ECG waveform
- Select **Waveforms**
- Select **Lead Format**
- Select: **3+3**
- Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

NOTE: *3+3 lead format requires a lead selection for each of the three leads presented.*

Full Disclosure Change Lead Format

To change lead format in the full disclosure display:

- Right mouse click while the cursor is over the ECG waveform in the Full Disclosure window
- Select **Waveforms**
- Select **Lead Format**
- Select from: single lead by 3, single lead by 6, or 3 lead

NOTE: *Single lead by 3 displays three lines of ECG data in the full disclosure buffer. Single lead by 6 displays six lines of ECG data in the full disclosure buffer. Three lead displays two groups of three leads in the full disclosure buffer. The amount of data displayed is dependent on the size of the display and the ECG sweep speed selected.*

Full Disclosure Single-lead Format – Change Lead

To change the full disclosure lead to a single-lead format:

- Right mouse click while the cursor is over the ECG waveform in the Full Disclosure window
- Select **Waveforms**
- Select **Single Lead Format**
- Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

Full Disclosure Three-lead Format – Change Leads

To change the full disclosure lead to a 3-lead format:

- Right mouse click while the cursor is over the ECG waveform in the Full Disclosure window
- Select **Three Lead Format**
- Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

NOTE: *Three-lead format requires a lead selection for each of the three leads presented.*

Full Disclosure Change Print Lead

To change the full disclosure print lead:

- Right mouse click while the cursor is over the ECG waveform in the Full Disclosure window
- Select **Print Lead**
- Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6

Change the ECG Presentation Gain

- Right mouse click while the cursor is over the real-time or captured ECG waveform
- Select **Waveforms**
- Select **Gain**
- Select from: 2.5 mm/mV, 5 mm/mV, 10mm/mV, or 20 mm/mV
- Gain displays and prints at the bottom of the ECG

NOTE: *A shortcut to this menu is available when you right-click on the current gain display of the window. Different gains are available in the median and full disclosure windows.*

Change the ECG Presentation Speed

- Right mouse click while the cursor is over the real-time or captured ECG waveform

- Select **Waveforms**
- Select **Speed**
- Select from: 5 mm/s, 10 mm/s, 25mm/s, or 50 mm/s (real-time only)
- Select from: 25mm/s or 50mm/s in the captured ECG waveform
- Gain displays and prints at the bottom of the ECG

***NOTE**: A shortcut to this menu is available when you right-click on the current speed display of the window. Different speeds are available in the median and full disclosure windows.*

Change ECG Low Pass Filter

- Right mouse click while the cursor is over the real-time or captured ECG waveform
- Select **Waveforms**
- Select **Low Pass Filter**
- Select from: 0.05 – 40 Hz, 0.05 – 150 Hz, or 0.05 – 300 Hz

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

***NOTE**: A filter setting lower than 150 Hz will reduce the visibility of fast transients in the ECG like pacemaker spikes or fast notches. For pediatric ECGs a 300 Hz setting is recommended. Filter settings apply only to displayed and printed data. Data is stored in unfiltered format.*

***NOTE**: The High Pass filter (or base line filter), indicated by the number "0.05" cannot be changed. Connex Cardio automatically implements a high performance base line filter that does not distort the ECG waveform. High Pass filters that do distort the ECG waveform are not available.*

Apply Anti-Aliasing to the ECG Display

- Right mouse click while the cursor is over the real-time or captured ECG waveform
- Select **Waveforms**
- Select **Anti-Aliasing**

***NOTE**: Anti aliasing reduces slightly the "staircase" effect due to individual pixels in digital monitors, but may put a strain on low performance computers.*

Change AC Filter on the Real-time ECG

- Right mouse click while the cursor is over the real time ECG waveform
- Select **Waveforms**
- Select **AC Filter**
- Select from: None, 50 Hz, or 60 Hz

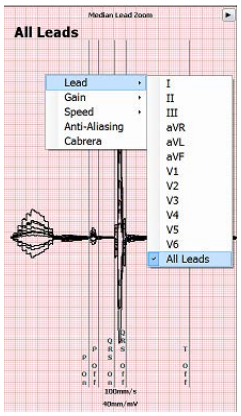
***NOTE**: Connex Cardio removes 60 Hz or 50 Hz interference. The setting you select depends on the line frequency in your country. For example, use the 60 Hz setting in the U.S. If the setting is correct but you still see mains interference, check the electrode connections, mains interference sources like transformers or motors close to the patient, and the connection to the safety ground of the computer. Try operating from battery power if needed.*

Change ECG Presentation To or From Cabrera Format

- Right mouse click while the cursor is on the ECG waveform.
- Select Waveforms
- Select or unselect

Change Median Zoomed Lead in ECG Review Mode

- Right mouse click while the cursor is over the Median Lead Zoom ECG
- Select **Lead**
- Select from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, or All leads (all 12 leads superimposed)



Switch Between Best Ten and Last 10 Seconds Capture in Real-Time ECG Mode

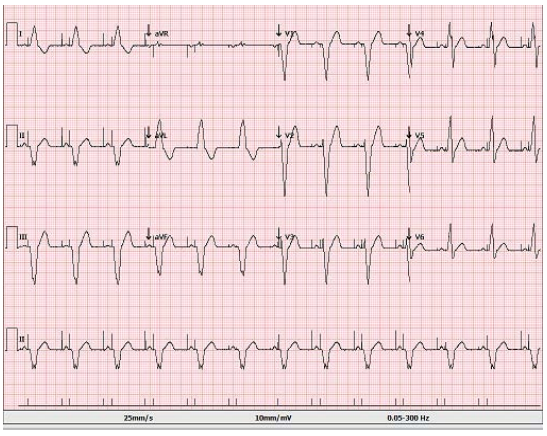
- Right mouse click while the cursor is over the real-time ECG waveform
- Select **Capture**
- Select **Capture Mode**
- Select from: Best 10 or Last 10

NOTE: *Defines whether or not the Connex Cardio will automatically capture the 10 seconds ECG with the lowest noise level from the full disclosure buffer, or the last 10 seconds of data when the ECG button is selected.*

Print Pace Spike Channel

- Right mouse click while the cursor is over the acquired ECG waveform
- Select **Pace Spike** on or off

NOTE: *When Pacer Spike is selected small tick marks will appear at the bottom of the ECG printout where each pacemaker spike was detected by Connex Cardio.*



Display and Print Average RR Interval

- Right mouse click while the cursor is over the acquired ECG waveform
- Select **Interpretation**
- Select **Avg RR** on or off

Display and Print QTcB (Bazett)

- Right mouse click while the cursor is over the acquired ECG waveform
- Select **Interpretation**
- Select **QTcB** on or off

Display and Print QTcF (Fridericia)

- Right mouse click while the cursor is over the acquired ECG waveform
- Select **Interpretation**
- Select **QTcF** on or off

NOTE: *Mortara VERITAS calculates by default the QTc with a linear correction method for average RR-interval similar to the Framingham method. In addition it is possible to display and print the QTc corrected with the Bazett or Fridericia correction methods.*

Print Automatic Interpretation Text

- Right mouse click while the cursor is over the acquired ECG waveform
- Select **Interpretation**
- Select **Print Interpretation** on or off

Display and Print Automatic Interpretation Reasons Text

- Right mouse click while the cursor is over the real time ECG waveform
- Select **Capture**
- Select **Interpretation**
- Select **Reasons Text** on or off

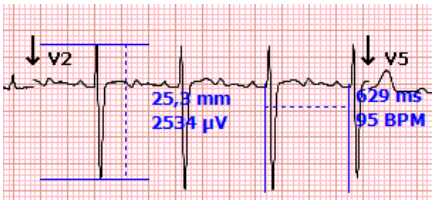
NOTE**:** *Reasons statements indicate why a particular interpretive statement was printed. Reasons statements print enclosed in [square brackets] within the interpretive text if the interpretation option is turned on. Turning the reasons statement function on or off does not affect the measurements performed or the interpretive statements selected by the analysis program.*

For Example, Anteroseptal Infarct [40+ ms Q WAVE IN V1-V4] where "Anteroseptal Infarct" is the interpretive statement, and "40+ ms Q WAVE IN V1-V4" is the reason statement or explanation as to why the interpretive statement was printed.

Display Calipers for on-screen measurement

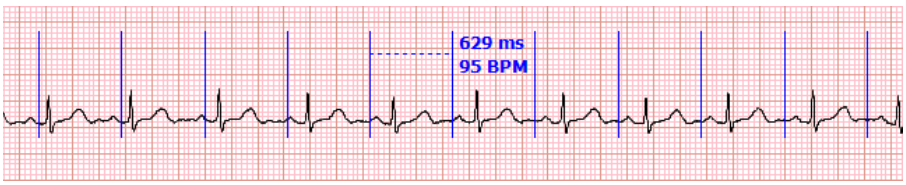
- Right mouse click while the cursor is over the acquired ECG waveform
- Select **Show Calipers** on or off

A caliper tool is available in the context menus when you right click anywhere in the main ECG window, and select Calipers. Calipers for amplitude and interval measurements will appear on the waveform.



Hover with the mouse over the caliper area. When you are close to the dotted line, the mouse cursor will change to a cross and you can now drag the caliper to desired position without changing the distance. When you are close to the solid line, the mouse cursor will change to a double arrow, and you can drag the single line to the desired position.

When you right click when the arrows or cross is present on the interval calipers, you can select **March Out** to repeat the interval caliper over the duration of the recording. You can use any of the vertical solid line to expand or shrink the calipers, and the horizontal dotted line to drag the whole series to a different position.



13. EXAM SEARCH

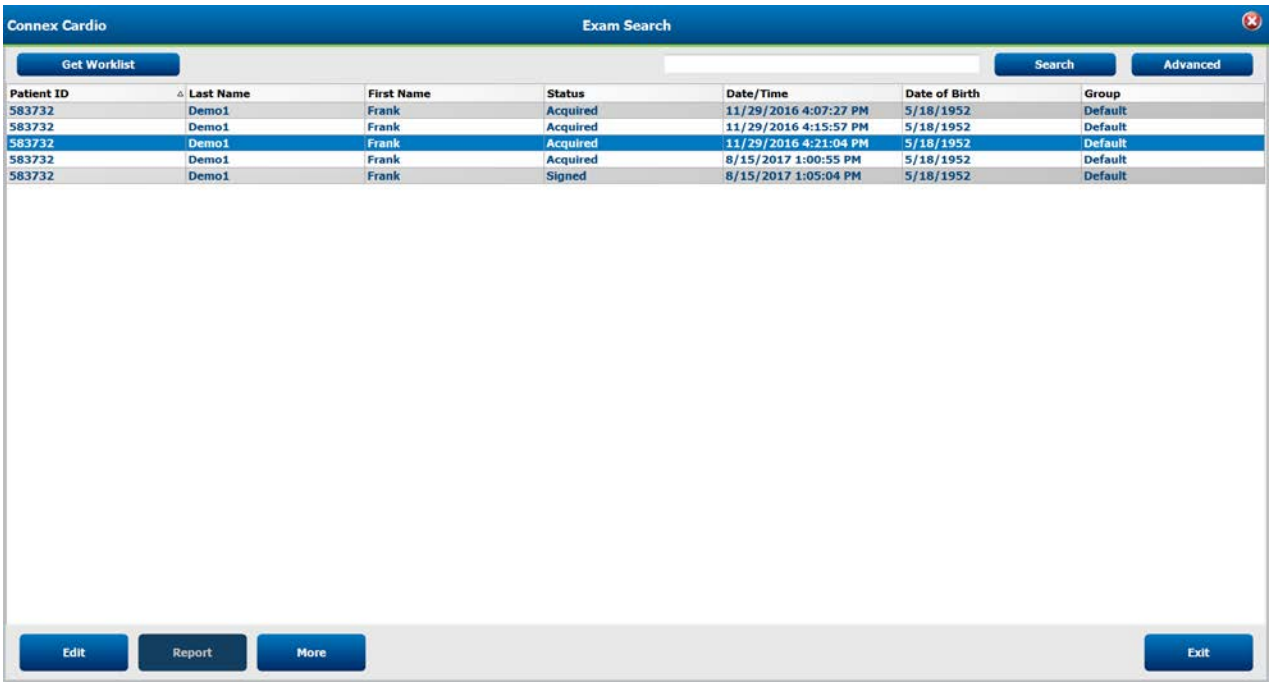
Selecting ECG Reports to Review

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

The **Get Worklist** button will filter the list of exams according to the User Preferences for the logged in user.

A search field is available for entry of a patient name or ID number. When you enter one or more alphanumeric characters, all exams that start with those characters are displayed in a list when the **Search** button is clicked. Listed exams can be sorted by clicking any of the column headers.

When a complete last name, first name, or patient ID is entered in the search field and the **Search** button is clicked, all matching exams will appear in the list.

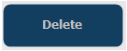


Highlight an exam in the list and then click the

- **Edit** button to open the exam for review and editing, or
- **Report** button to open the final report for review and printing, or
- **More** button to display more advanced selections explained below.

- **Copy Offline** button that allows an existing exam to be copied to an external drive using a browser for review at another Connex Cardio system.
- **Open Offline** button that allows an Connex Cardio system user to open an exam from another system by browsing to the location of the copied exam.

- **Transmit** button allows the exam results to be sent to the ELI Link destination defined in the system configuration settings. This selection is only enabled when the selected exam(s) has the associated export status enabled in the Workflow Config settings.
- **Reconcile** button is used to match an order to an exam that was performed before the order was available, or to correct information after the exam has been completed with incorrect patient demographics.
- **Archive** button is used to move the exam from the database to an external drive for long-term storage purposes.
- **Delete** button is used to permanently remove an exam or an order from the system database. The exam is not recoverable after performing this action.

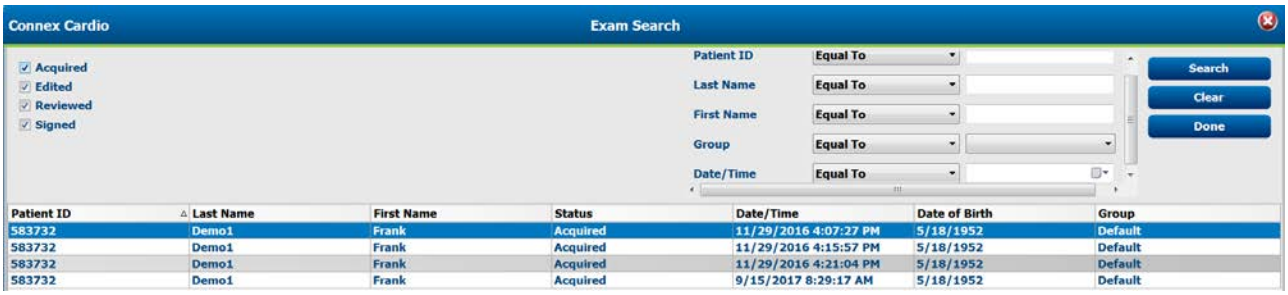
  Button actions are dependent on user permissions. Unavailable buttons will appear grayed. 

Advanced Search

For more sophisticated exam list filtering, click on the **Advanced** button. The identifier selections are relational to the selected filter and are dependent on your system configuration.

The exam state(s) are selected by checkbox as identifiers. Click the **Search** button after your filter and identifiers are selected. Click the **Clear** button to cancel and remove your entries from the search fields.

When finished, click the **Done** button to exit the advanced search selections and return to the main Exam Search window.



Exam State Identifiers

- Acquired
  - Checked if equal to
- Edited
  - Checked if equal to
- Reviewed
  - Checked if equal to
- Signed
  - Checked if equal to

Exam Criteria Identifiers

- Patient ID
  - Equal To
  - Start With
- Last Name
  - Equal To
  - Start With
- First Name
  - Equal To
  - Start With
- Group
  - Equal To
  - Blank (All)
  - Any defined Group this user can access
- Date/Time
  - Equal To
  - Prior To
  - Later Than

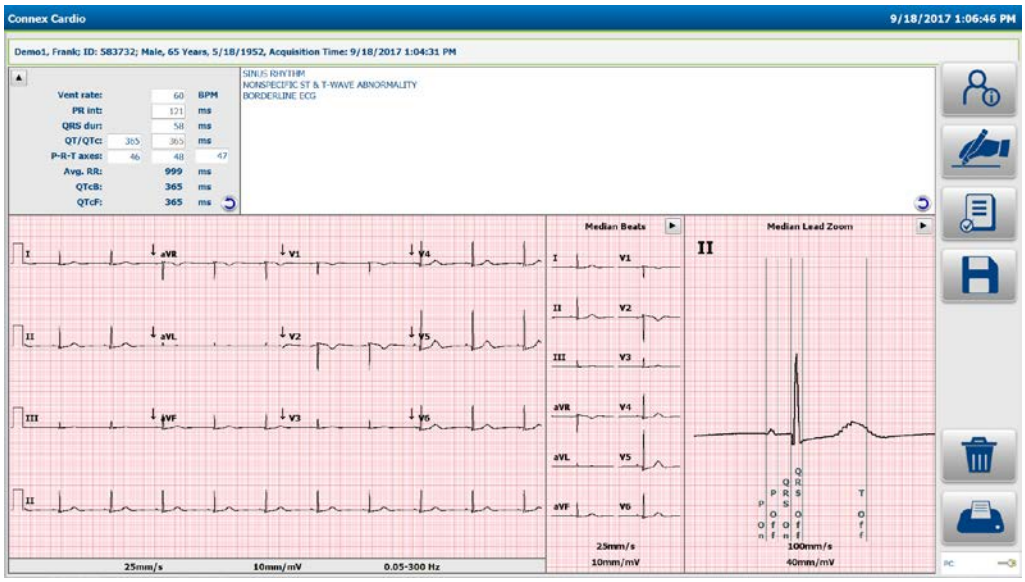
Edit a Resting ECG Report

When a report is selected from the Exam Search list by a user with review and signing permissions, it is presented on the screen similar to the one shown below. The Sign and Review button icons are not present for those without appropriate permissions.

Presence of the Save and Review button icons is dependent on how the administrator has configured workflow in system settings.

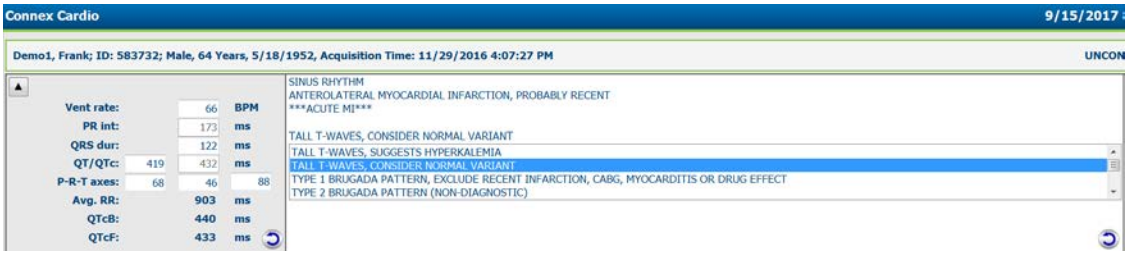
The Patient Information window can be opened and edited with selection of the **ID** icon button.

If the user agrees with the interpretation statements, the ECG can be saved, marked as reviewed, or signed. After selection of any of these icon buttons, the user is returned to the Exam Review list.



Editing Interpretation

Interpretation statements may be deleted, modified, and new statements added. When adding statements, Connex Cardio will predict the full statement as characters are typed and will present statements in a pick-list in order of use frequency. A single-click in the text area allows editing for users with appropriate permissions.



Editing Actions	Description
Down arrow	Moves focus to the statement pick-list
Enter (in statement pick-list)	Adds highlighted statement to the interpretation
Ctrl+L	Deletes the statement text leaving a blank line
Ctrl +L Ctrl+L	Deletes the statement without leaving a blank line

Esc	Closes the statement pick-list

An undo icon in the bottom-right corner of the interpretation area can be selected to revert back to the interpretation before any editing changes were made, and when selected before saving the ECG.

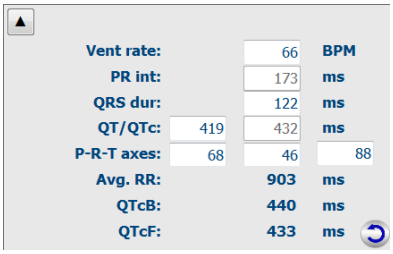
***NOTE**: Each interpretation field line allows up to approximately 65 characters. Additional characters will wrap to the next line.*

***NOTE:** The interpretation area supports up to 11 lines of text. Additional lines are allowed but may overwrite the ECG waveform.*

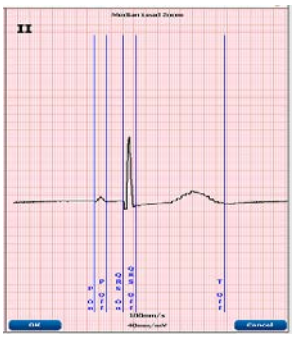
Editing Measurements

There are two ways to edit the global measurement values:

1. Measurement Value Editing
   - Left-click in the value measurement field and enter the desired value.
   - The undo icon in the bottom-right corner of the interpretation area can be selected to revert back to the measurement values before any editing changes were made, and when selected before saving the ECG.

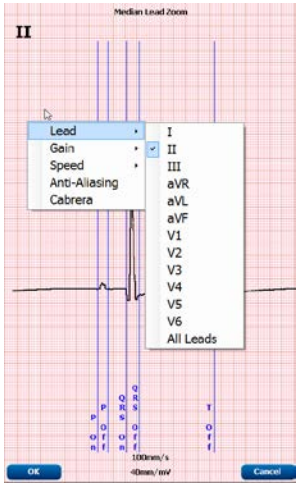


2. Editing Interval measurements using the Median Beat Calipers
   - This method can be used for the PR-interval, QRS duration, and QT duration editing
   - Double-click in the Median Lead Zoom window. Measurement calipers are now active in this window.
   - Drag the calipers to the desired position. Involved and related interval measurements will be automatically recalculated.
   - Select **Cancel** to leave the editing process without saving.
   - Select **OK** to complete the editing process



To change the lead or presentation of the Median Beat displayed in the Median Lead Zoom area:

- Double-click in the Median Lead Zoom window.
- Right-click within the Median Lead Zoom window.
- Change the lead displayed be selecting from the Lead menu
- Modify the Gain or Speed by selecting from the respective menus



***NOTE**: Interval measurements can also be edited using the interval caliper tool. See next page for details.*

Settings

Many settings can be changed using context menus. Right click the mouse on any part of the ECG tracing for the following settings:

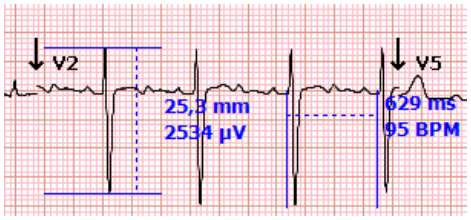
- Change the waveform presentation
- Print pacemaker spikes
- Print interpretation

See the *Context Menus* section in this manual for a complete description of the context menus.

Measurement caliper tool

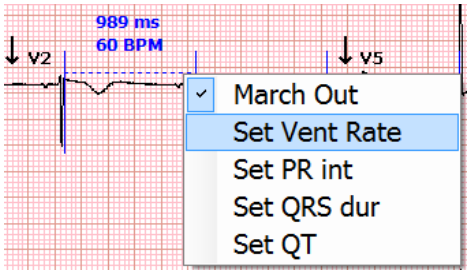
A caliper tool is available in the context menus when you right click anywhere in the main ECG window, and select **Show Calipers**.

Calipers for amplitude and duration measurements will appear on the waveform.

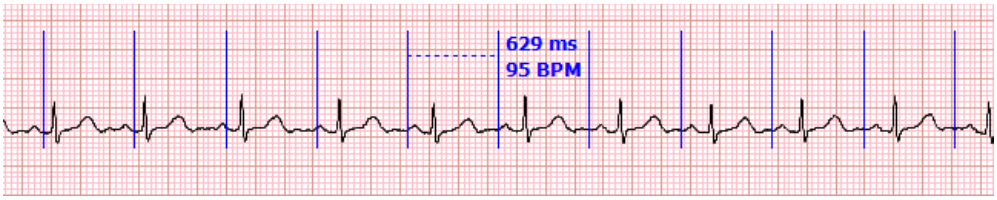


Hover with the mouse over the caliper area. When you are close to the dotted line, the mouse cursor will change to a cross and you can now click and drag the caliper to a desired position without changing the distance.

When you are close to the vertical line, the mouse cursor will change to a double arrow, and you can then drag the vertical line to a desired position.



When you right click when the arrows or cross is present on the interval calipers, a special context menu appears that allows you to use the displayed caliper value to modify the ECG interval measurements. You can also select **March Out** to repeat the interval caliper over the duration of the recording. You can use any of the vertical solid lines to expand or shrink the marching calipers, and the horizontal dotted line to drag the whole series to a different position.



Editing Patient Information

Use the ID button icon at the right to edit select patient and exam demographic information

Printing the Report

Use the Print ECG button icon to the right to print the ECG in the currently displayed format on the default Windows printer.

Note: The state of the exam is not updated when printed immediately upon acquisition, so the previous state of the ECG (e.g. Unconfirmed report) will be printed on the resting ECG.

Complete the Editing process

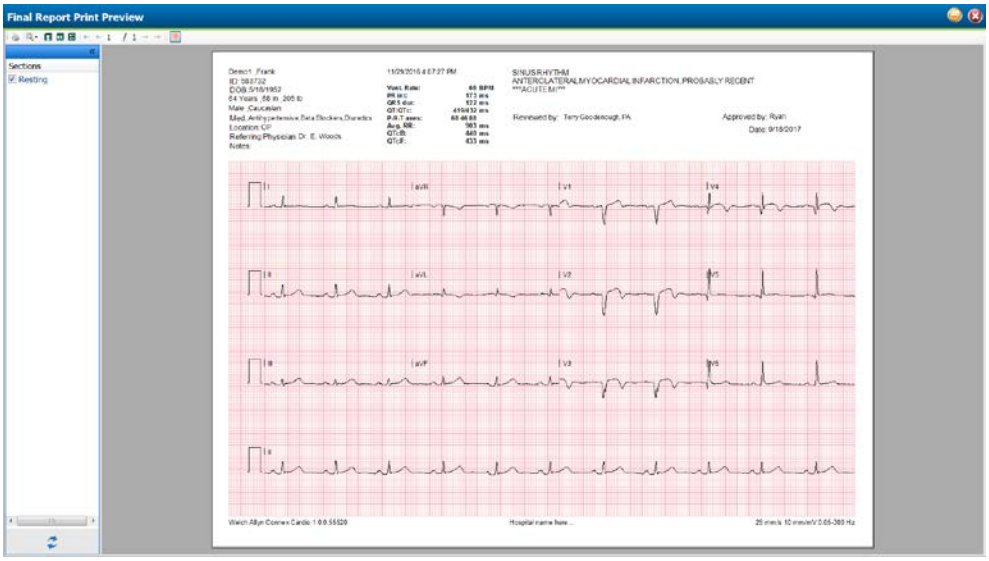
- Select **Save** to complete the editing process and return to the Exam Review list.
  - ECG is saved with an acquired status if not previously marked as reviewed or signed.
- Select **Review** to mark the ECG status as Reviewed and return to the Exam Review list.
  - User is prompted to enter the reviewer's name.
- Select **Sign** to mark the ECG status as Signed and return to the Exam Review list.
  - User is prompted to enter signer's name or signing authority depending on system configuration.

Report Print Preview

To open a preview of the ECG report that has been reviewed or signed, select the **Report** 

button icon in Exam Search. A preview is generated and the first report page is displayed.

Icon Tool Bar



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

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

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

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

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

Sections

Use the checkboxes at the left of the display to choose sections for inclusion or exclusion in the final report. Select the arrows in the bottom left corner of the display to refresh the displayed report after a change is made. The "Resting" section will print the predefined 12-lead ECG report with demographic information, measurements, interpretation and signature block.

The "Rhythm" section prints a 12-lead rhythm strip with summarized patient information and no measurements and interpretation. This section is enabled in the configuration settings by the administrator and may not be present.

Exit the Print Preview

Click on the red **X** to close the report preview and return to the previous display.

14. SYSTEM SETTINGS

Use the System Configuration icon on the main screen to enter the system configuration menus

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

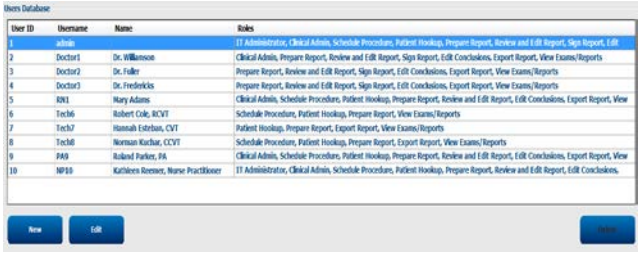
A list of administrative task buttons is presented to:

- Manage user accounts
- Manage personnel lists
- Manage Groups
- Manage archived exams
- View audit trail logs
- Export service logs for troubleshooting purposes
- Configure system-wide modality settings
- Configure ELI Link for DICOM connectivity, XML, and PDF file exchange
- Configure workflow
- Unlock exams
- Configure patient demographics fields

Manage User Accounts and Personnel

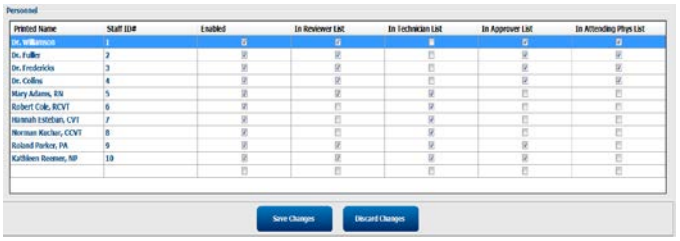
User's Database

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



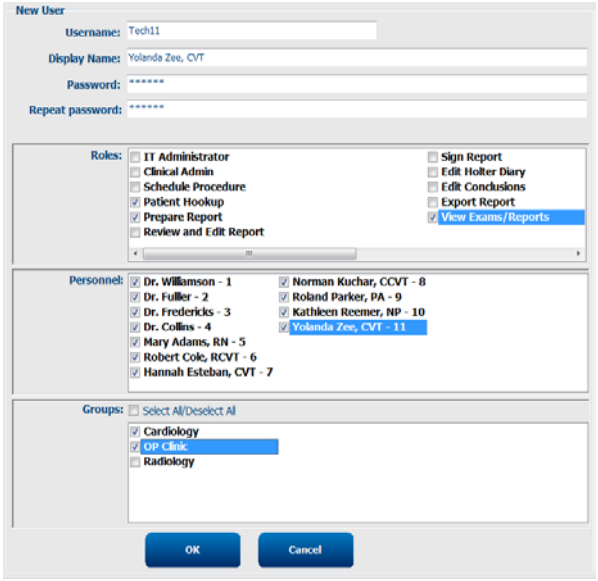
Personnel

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



New User

Selection of the **New** button within the Users Database window will open the New User dialog, similar to the window to the right.



> ***Tip:*** *It is recommended to complete the Personnel list before adding Users so they can be selected as New Users are added.*

The name entered in the Display Name field will appear on the Connex Cardio display when that user logs in.

The login password is entered and repeated.

Roles for this user, Personnel that will populate drop-down lists for this user, and Groups that this user will have access to are checked.

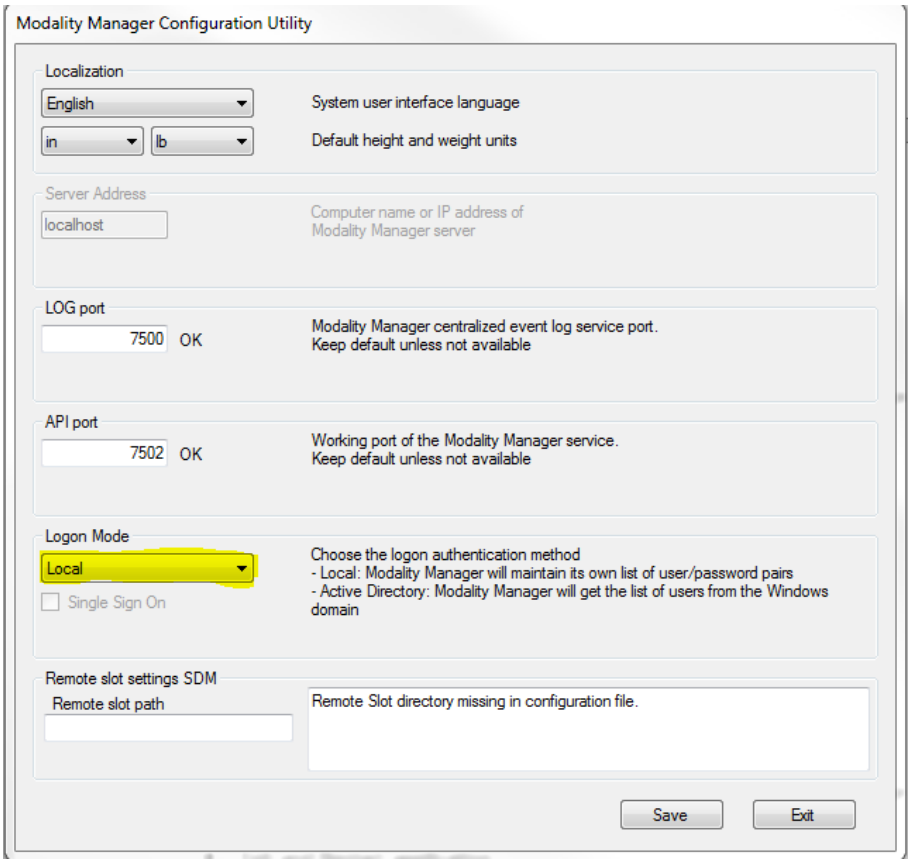
> ***Tip:*** *Refer to User Role Assignment Table.*

New User through Active Directory

Connex Cardio has the ability to integrate with Active Directory for authentication of users. Activation of Active Directory must be completed by an IT administrator.

To activate Active Directory:

1. Close out of the Connex Cardio application
2. From the start menu browse to All Programs/Mortara Modality Manager/Modality Manager Configuration Utility
3. When prompted that services will stop click OK
4. In the Logon Mode drop down, select “Active Directory”
5. To enable single Sign-On, check the box below. This is only available when Active Directory is enabled.
6. Click Save, then Exit



7. Log in with the local administrator username and password
8. Click on the gears Icon to enter system configurations, then click on the Users Database button
9. To add a new Active Directory user, click "New"
10. Select the user by using the drop-down list, or typing in the search bar and click search. A list of users and their role is provided by Project Management and added to the onsite form.
11. Select the appropriate roles, personnel, and groups the user should be part of.
12. Click OK and repeat for all users.

Manage/Create Groups

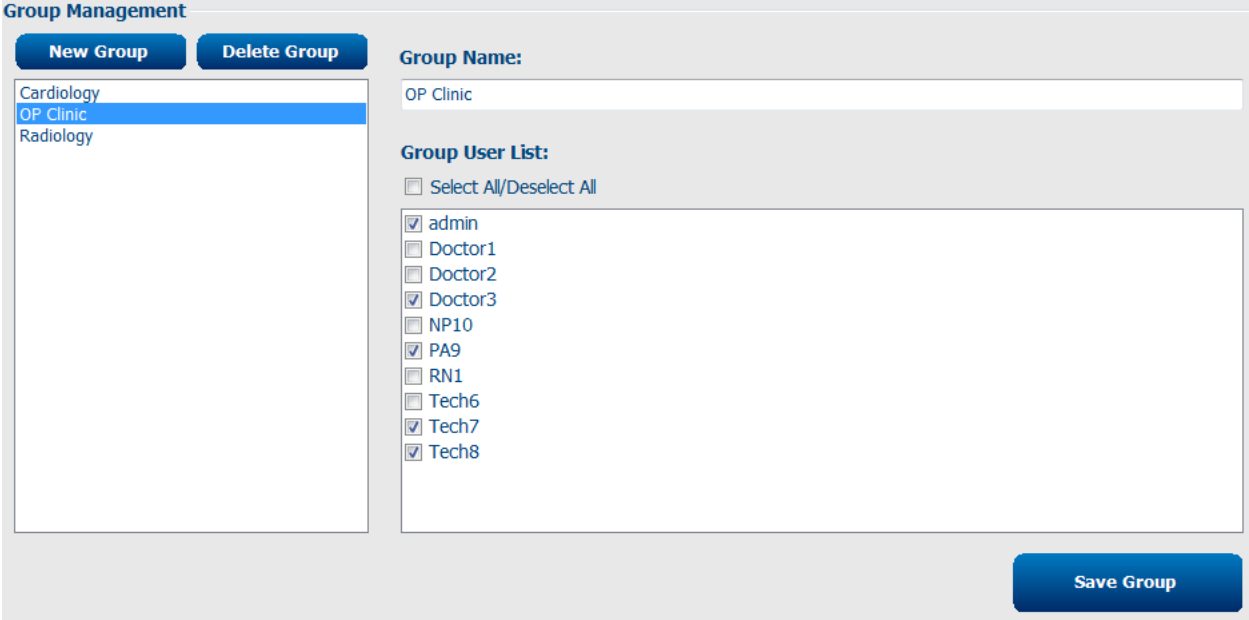
Groups allow the IT administrator to group exams according to user access, reporting preferences (modality settings) and file exchange preferences. Any user can be assigned to multiple groups. A group definition can be copied and saved with a new name to create a second group, copying all settings and preferences of the existing group.

- Select the **Groups** button to make changes. Any created group can be copied, renamed and modified.
- To create a new group, highlight the group you would like to copy, select **New Group**, and enter the new **Group Name**. A new group will be created with the settings of the highlighted group.
- Select the users under the **Group User List** that may have access to the highlighted group. The Select All and Deselect All selection can be used to enable or disable all users.

If you want to rename a group without creating a new one, highlight the group, and enter a Group Name

- Select **Save Group** to save your changes.

The Default group (first in the list) can only be renamed. An unlimited number of new groups can be created and modified.



Connex Cardio Modality Settings, CFD Configuration, and ELI Link configurations can be uniquely defined for each individual group.

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

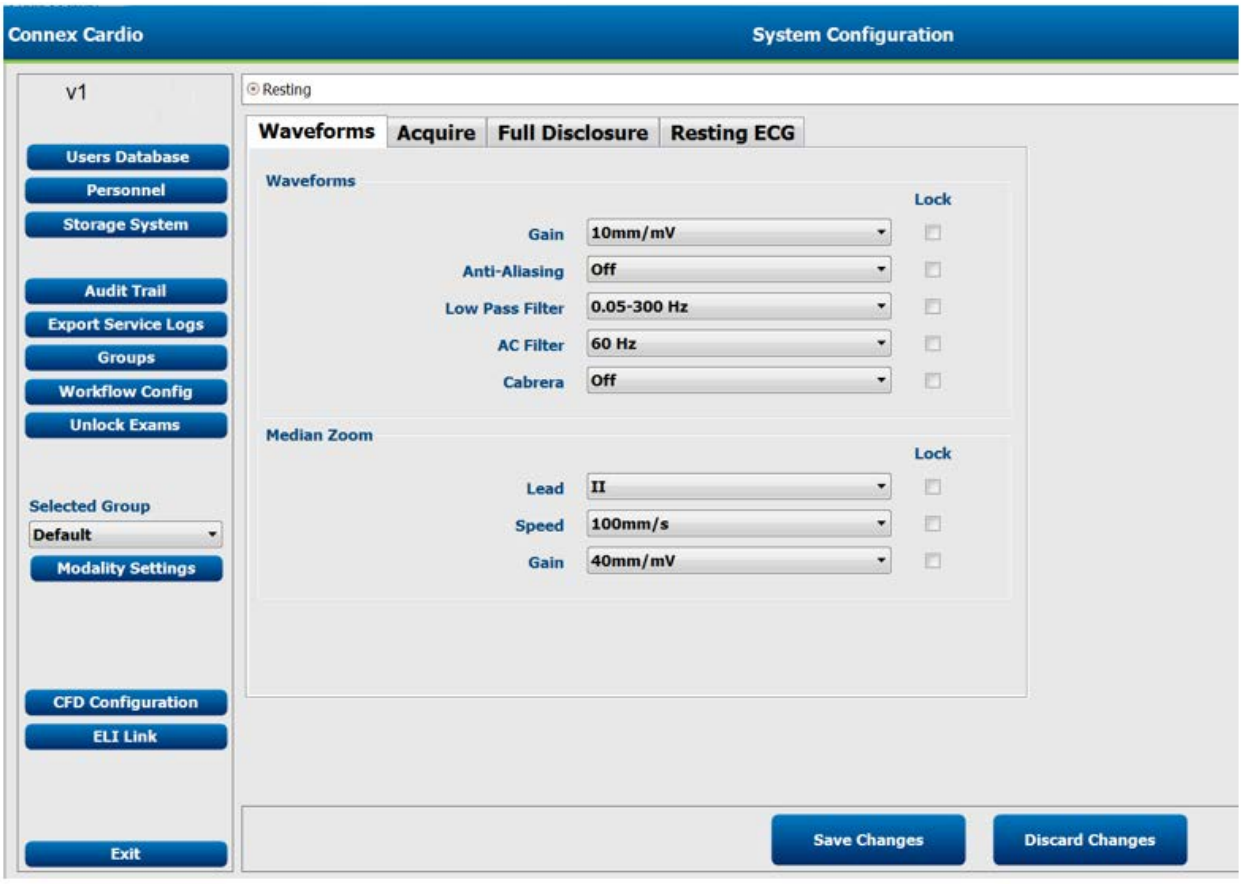
Modality Settings

Modality Settings define all Connex Cardio modality specific default values that do not change on a daily or patient-to-patient basis. Most of these settings can be modified within the Connex Cardio modality for a single exam, but most of these default conditions will rarely need to change. The Modality settings may be "Locked" by the administrator, meaning that the setting will not be available from within the modality. Use the "Lock" checkbox to the right of each setting to exclude it from the settings available from within the modality.

Modality settings and file exchange settings are Group dependent. Ensure that the desired group is selected from the drop-down list before proceeding.

Select the tab you wish to modify and click on **Save Changes** to apply or **Discard Changes** to cancel changes before exiting.

Waveforms Tab



Waveforms

Gain

- To change default ECG gain:
  - Position the left mouse key over the **Gain**
  - Select **Gain**
  - Select from: 2.5 mm/mV, 5 mm/mV, 10mm/mV, or 20 mm/mV
  - Gain displays and prints at the bottom of the ECG

Anti-aliasing

- To apply anti-aliasing to ECG view:
  - Select **Anti-aliasing**
  - Choices: On, Off

NOTE: *Anti aliasing reduces slightly the "staircase" effect due to individual pixels in digital monitors, but may put a strain on low performance computers.*

Low Pass Filter

- To change default ECG low pass filter:
  - Select **Low Pass Filter**
  - Select from: 0.05 – 40 Hz, 0.05 – 150 Hz, or 0.05 – 300 Hz

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

***NOTE*:** *A filter setting lower than 150 Hz will reduce the visibility of fast transients in the ECG like pacemaker spikes or fast notches. For pediatric ECGs a 300 Hz setting is recommended. Filter settings apply only to displayed and printed data. Data is stored in unfiltered format.*

***NOTE*:** *The High Pass filter (or base line filter), indicated by the number "0.05" cannot be changed. Connex Cardio automatically implements a high-performance base line filter that does not distort the ECG waveform. High Pass filters that do distort the ECG waveform are not available.*

AC Filter

- To change default ECG AC filter:
  - Select **AC Filter**
  - Select from: None, 50 Hz, or 60 Hz

***NOTE*:** *Connex Cardio removes 60 Hz or 50 Hz interference. The setting you select depends on the line frequency in your country. For example, use the 60 Hz setting in the U.S. If the setting is correct but you still see mains interference, check the electrode connections, mains interference sources like transformers or motors close to the patient, and the connection to the safety ground of the computer. Try operating from battery power if needed.*

Cabrera

- To change default ECG to Cabrera:
  - Left mouse click on the **Cabrera** icon
  - Choices: On, Off

***NOTE*:** *Using the lock indicator to the right of this selection can be enabled to hide this choice from the technician, permitting only unlocked choices.*

Median Zoom

Lead

- To change default median ECG lead format display:
  - Select **Lead**
  - Choices: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6. All leads (all 12 leads superimposed)

Speed

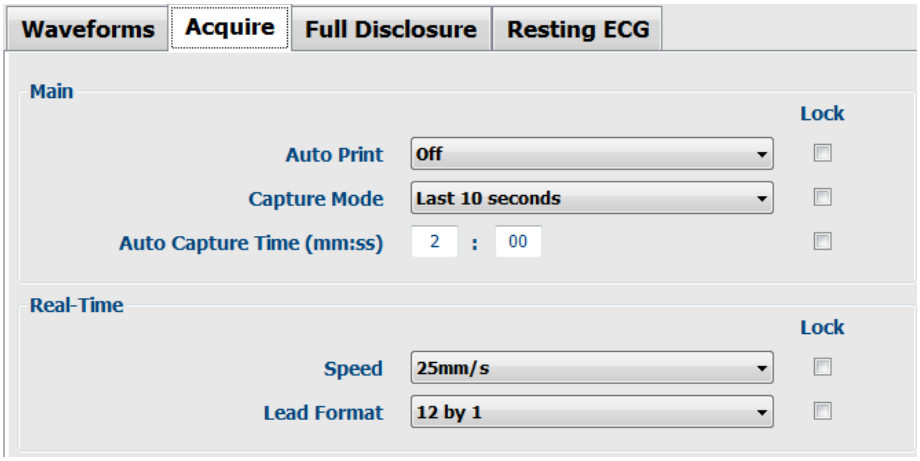
- To change default speed on the display:
  - Select **Speed**
  - Choices: 100 mm/s, 200 mm/s

Gain

- To change default ECG gain:
  - Select **Gain**
  - Choices: 10, 20, 40, 80 mm/Mv

Acquire Tab

This Tab is for the default settings of the real time acquisition function of Connex Cardio.



Main

Auto Print

- Select **Auto Print**
- Choices: On, Off

NOTE: *Defines whether or not Connex Cardio will automatically print an unconfirmed ECG after a timed or manual capture. Manual printout is always possible.*

Capture Mode

- Select **Capture Mode**
- Choices: Best 10 seconds, Last 10 seconds

NOTE: *Defines whether or not the Connex Cardio will automatically capture the 10-second ECG with the lowest noise level from the full disclosure buffer, or the last 10 seconds of data when the ECG button is selected.*

Auto Capture Time (mm:ss)

- Set from: a minimum of 20 seconds up to 59-minutes and 59-seconds.

NOTE: *Defines the time intervals in which the ECG will automatically be acquired once "Timed ECG Capture" is selected.*

Real Time

Speed

- Select **Speed**
- Choices: 5, 10, 25, 50 mm/sec

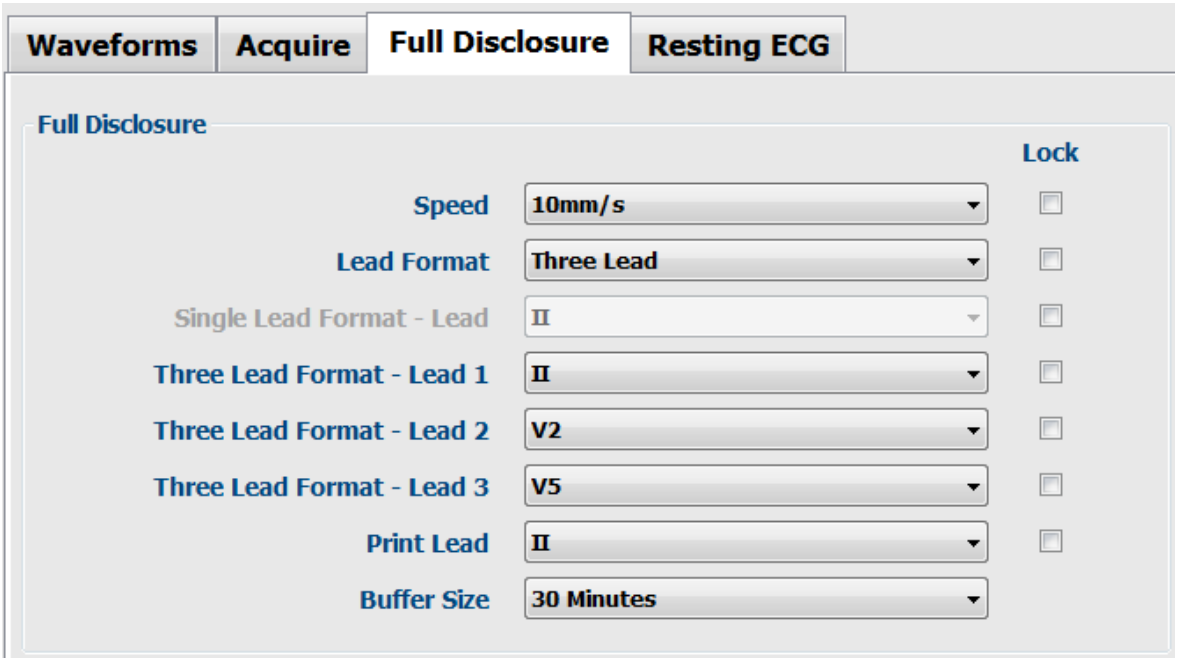
Lead Format

- Select **Lead**
- Choices: 12 by 1, 6 by 2

NOTE: *In the real time display only 6+6 and 12 lead formats are available. It is recommended to choose a format that allows at least 10 seconds of real time ECG on the screen during acquisition.*

Full Disclosure Tab

This Tab is for the default settings of the full disclosure buffer at the bottom of the acquisition screen.



Speed

- Select **Speed**
- Choices: 5, 10, 25, 50 mm/s

Lead Format

- Select **Lead Format**
- Choices: single lead by 3, single lead by 6, or 3 lead

NOTE: *Single lead by 3 displays three lines of ECG data in the full disclosure buffer. Single lead by 6 displays six lines of ECG data in the full disclosure buffer. Three lead displays two groups of three leads in the full disclosure buffer. The amount of data displayed is dependent on the size of the display and the ECG sweep speed selected.*

Single Lead Format - Lead

- Select **Single Lead Format**
- Choices: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

Three Lead Format - Lead 1, 2 or 3

- Select **Three Lead Format**
- Choices: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

NOTE: *The three-lead format requires a lead selection for each of the three leads presented.*

Print Lead

- Select **Print Lead**
- Choices: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

NOTE: *Use Print Lead to select the lead printed on full disclosure printouts.*

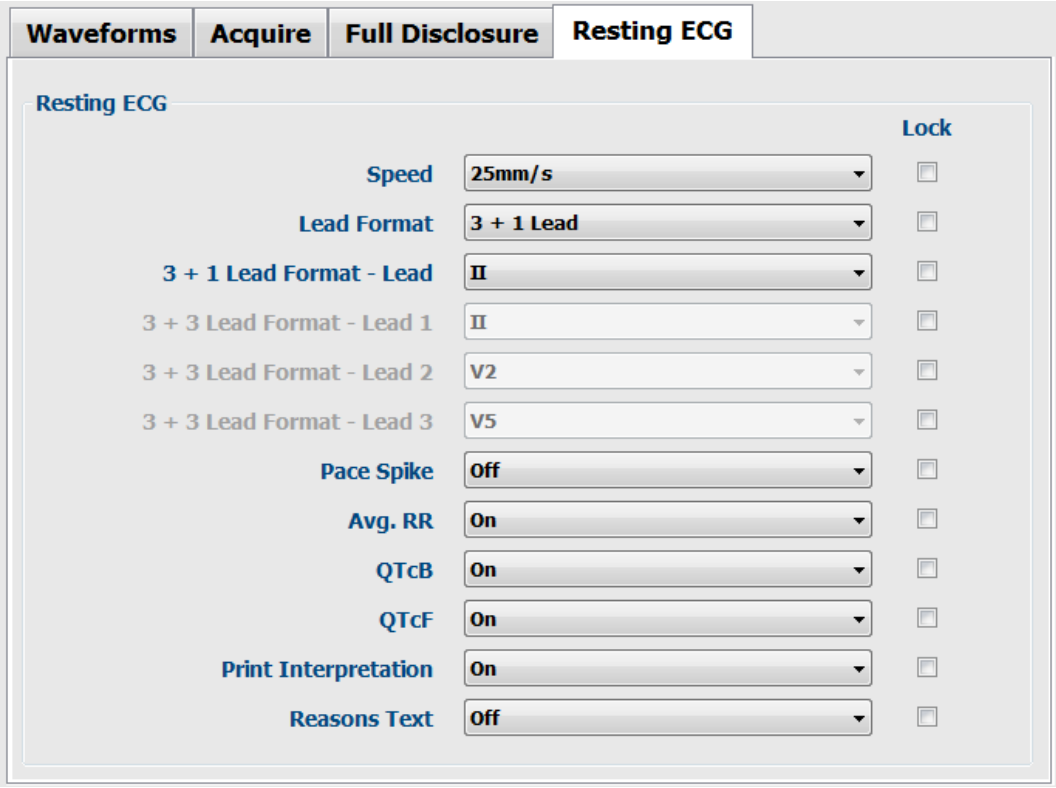
Buffer Size

- Select **Buffer Size**
- Choices: 5, 10, 20, 30, 45, 60 minutes

NOTE: *Use the Buffer Size to select the total amount of acquisition time permitted in the full disclosure memory. A warning message will display when the selected time limit has been reached, and acquisition terminated.*

Resting ECG Tab

This Tab is for the default settings of the captured ECG waveform and printouts.



Speed

- Select **Speed**
- Choices: 25, 50 mm/sec

Lead Format

- Select **Lead Format**
- Choices: 3+1, 6, 3+3, 12, 6+6

3 + 1 Lead Format - Lead

- Select **3+1 Lead Format**
- Choices: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

3 + 3 Lead Format - Lead

- Select **3+3 Lead Format**
- Choices: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

NOTE: *3+3 lead format requires a lead selection for each of the three leads presented.*

Pace Spike

- Select **Pace Spike**
- Choices: On, Off

NOTE: *When Pace Spike is on, pacemaker spikes will be visible on the waveform display and at the bottom of the page on captured ECG printouts.*

Average RR

- Select **Avg. RR**
- Choices: On, Off

NOTE: *Use this option to display an averaged RR value on the report.*

QTcB (Bazett)

- Select **QTcB**
- Choices: On, Off

QTcF (Fridericia)

- Select **QTcF**
- Choices: On, Off

NOTE: *Mortara VERITAS calculates by default the QTc with a linear correction method for average RR-interval similar to the Framingham method. In addition it is possible to display and print the QTc corrected with the Bazett or Fridericia correction methods.*

Print Interpretation

- Select **Print Interpretation**
- Choices: On, Off

Reasons Text

- Select **Reasons Text**
- Choices: On, Off

***NOTE*:** *Reasons statements indicate why a particular interpretive statement was printed. Reasons statements print enclosed in [square brackets] within the interpretive text if the interpretation option is turned on. Turning the reasons statement function on or off does not affect the measurements performed or the interpretive statements selected by the analysis program.*

For Example:

Anteroseptal Infarct [40+ ms Q WAVE IN V1-V4] where "Anteroseptal Infarct" is the interpretive statement and "40+ ms Q WAVE IN V1-V4" is the reason statement or explanation as to why the interpretive statement was included.

CFD Configuration

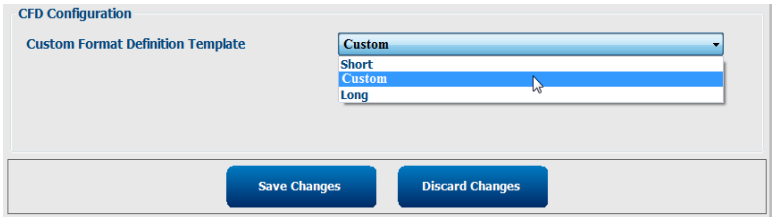
A long, custom, or short format for displayed items and report contents can be uniquely defined per Group. Select the **CFD Configuration** button to display the Custom Format Definition Template drop-down list. Choose the Long, Custom, or Short template for the selected group and then click the **Save Changes** button, or the **Discard Changes** button to cancel any changes.

The **Long** format contains all available demographics.

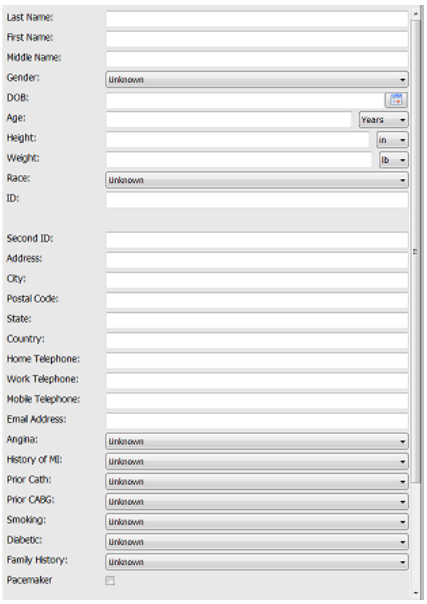
The **Custom** format has been created through use of the ELI Link tool. Refer to the ELI Link administrator manual, part number *9515-166-50-ENG*, for information regarding Custom IDs.

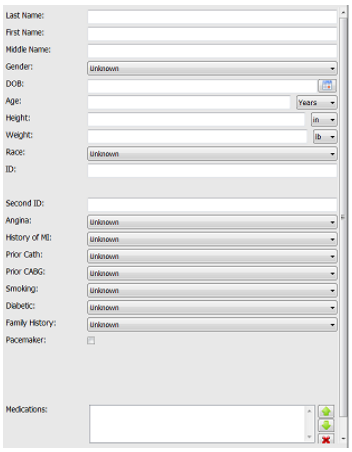
Note: Custom IDs are only available when connected to ELI Link and when an order is used to populate patient demographics. If no order, the Short format is defaulted.

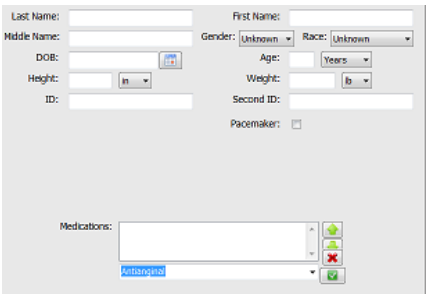
The **Short** format excludes the patient history and contact information in the report summary.



Long CFD	Custom CFD	Short CFD



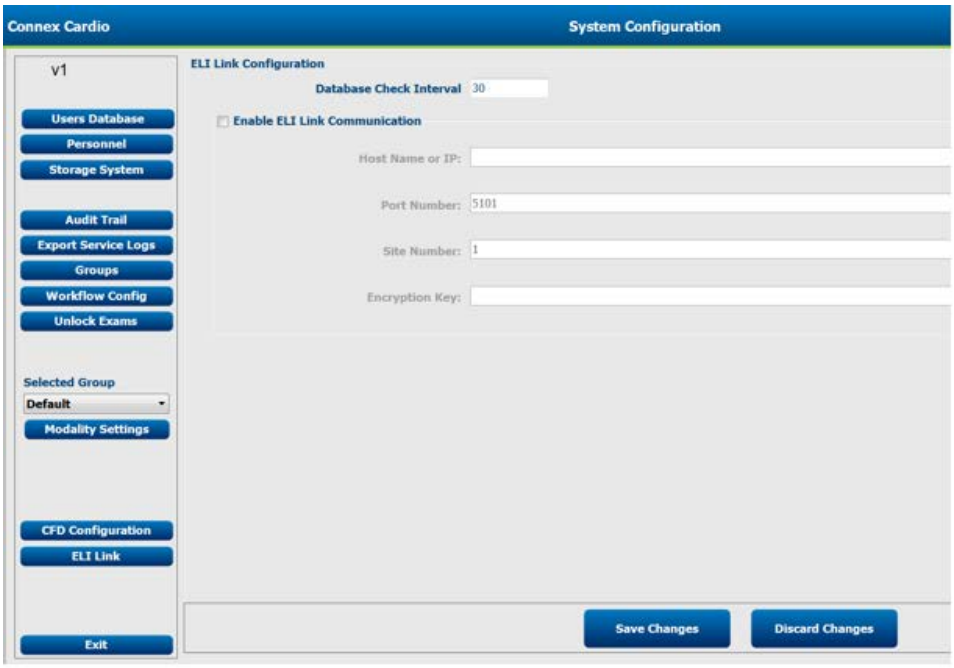




ELI Link Configuration

Connex Cardio supports the ability to exchange information with DICOM systems, import orders from XML files, and export PDF and XML results to an external system via ELI Link. Available connectivity options are dependent on the Connex Cardio system activated features. Refer to the *ELI Link Administrator Manual*, part number *9515-166-50-ENG*, for information regarding installation and configuration of the ELI Link gateway service.

When using ELI Link connectivity, check the box to enable communication and enter appropriate information into the available fields.



The following table describes the available ELI Link configuration settings:

Item	Description
Host Name or IP	Entry field for the network name or IP address of the networked ELI Link service
Port Number	Entry field for the TCP port number for network communication with the ELI Link service
Site Number	Entry of a number will uniquely identify the Connex Cardio that is communicating with the ELI Link service
Encryption Key	Entry field for use of a secret string shared between the ELI Link service and the Connex Cardio

Enter your desired settings and then click the **Save Changes** button, or the **Discard Changes** button to cancel any changes.

Note: If orders are used with Connex Cardio in XML format and setup through ELI Link, XML order refresh must be checked in ELI Link or orders will not appear in the worklist in Connex Cardio.

Unlock Exams

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

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

Manage Archive Storage

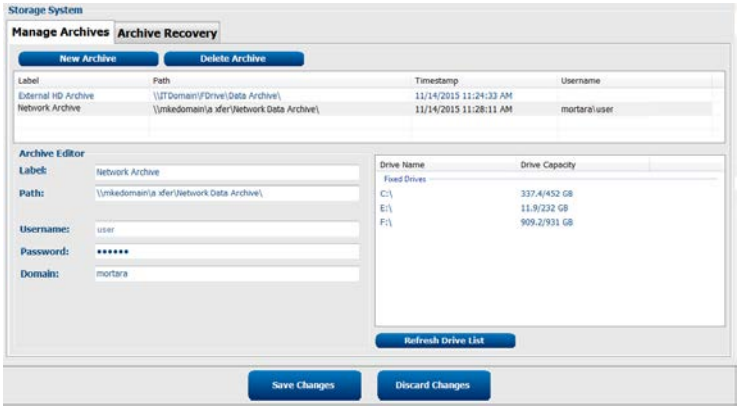
The Connex Cardio administrative user will manage storage system disks through selection of **Storage System**.

Add Archive Location

Select **New Archive** button to define a path to the archive directory destination.

- Any external disk (e.g. NAS, USB, etc.) accessible from the Connex Cardio central database is a candidate for becoming an archive volume.
- The archive path should be defined as a UNC path such as \\ServerName\ShareName\Directory\
- A Username, Password and Domain may be entered as needed to add the new storage disk to the Archive drive listing.

Select **Save Changes** button to create the archive location or **Discard Changes** button to exit this window without saving changes.



The **Refresh Drive List** button is available to update the list of available drives.

An archive path may also be deleted by highlighting the desired label and selecting the **Delete Archive** button. When selected, a prompt asking if you are sure you want to delete the selected archive is presented. Select **Yes** or **No**. All archived ECGs will remain at the destination until they are manually deleted.

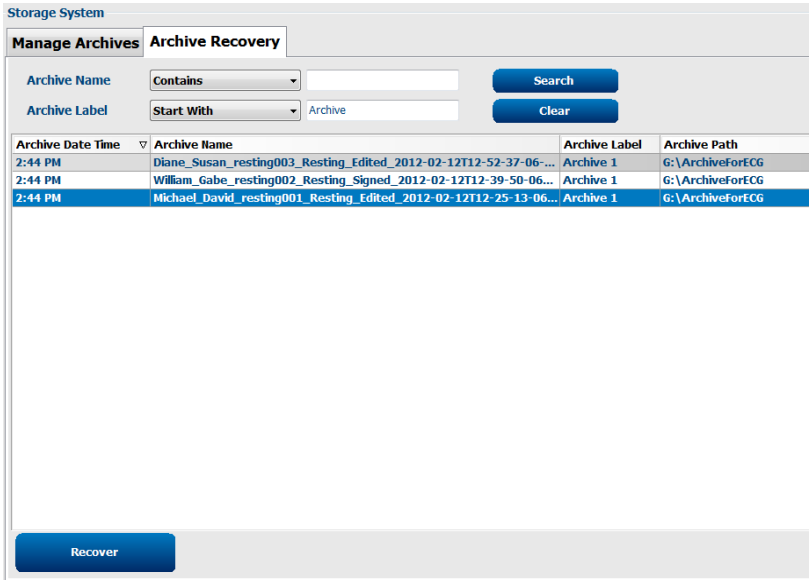
Recover Archived Exams

Administrative users can restore exams from the archive location to the Connex Cardio database through selection of **Archive Recovery** tab. Once selected, a window will open allowing a search of the Archive Name or the Archive Label.

To search by Archive Name, a letter or number combination may be entered to show exams that contain the characters. To search by Archive Label, the first letter of the label can be entered with the Start With description, or the entire Archive Label can be entered with the Equal To description. Select the **Search** button when ready. The **Clear** button can be selected to clear all search fields. Column headers can be selected to sort listed exams by that item.

To restore exams, highlight the desired exam(s) in the list and click on **Recover**.

Multiple exams can be restored by highlighting them followed by a single **Recover** button click.

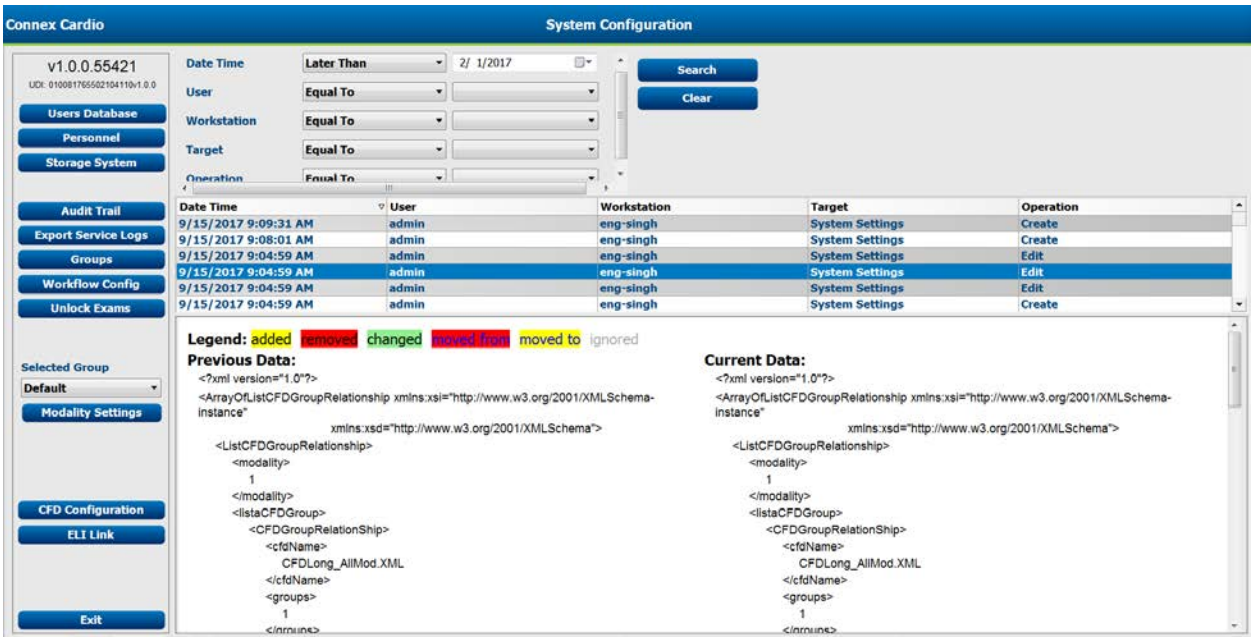


Audit Trail Logs

The Connex Cardio administrative user will select **Audit Trail** to view the audit trail history. Selections for filter criteria are 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 trail information.

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

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

Configure Workflow

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

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

2. ACQUIRED
   The resting ECG exam is completed at the Connex Cardio system and is ready for editing.

3. EDITED
   The resting ECG exam has been analyzed and saved with changes, ready for review by a physician. Interpretation may be edited at this state.

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

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

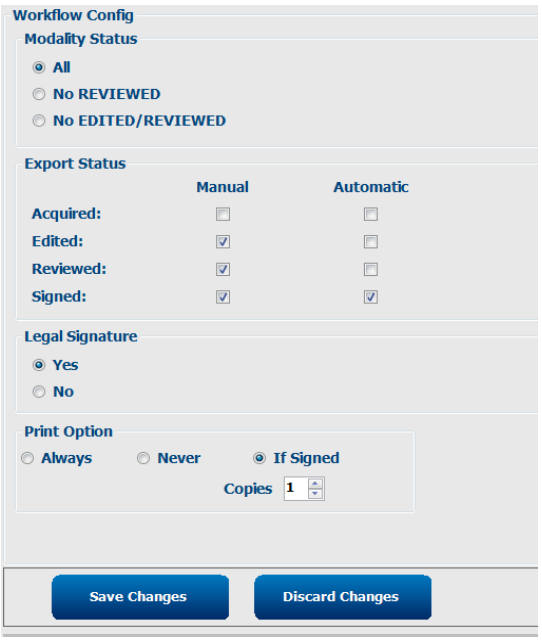
Workflow Config

A Legal Signature can be enabled by selecting **Yes** or disabled by selecting **No**. When legal signature is set to Yes, the user is prompted to enter their login password and ID.

Administrative users can configure the workflow to include all, or exclude some states through selection of **Modality Status** radio buttons.

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

Checkboxes under Export Status allow choices for Manual or Automatic export of the results when the state moves to Acquired, Edited, Reviewed or Signed. Any combination may be selected.



A default **Print Option** with the number of automatic **Copies** from 1 to 9 can be defined to

- **Always** print automatically when moving to the next state
- **Never** print automatically
- Automatically print only **If Signed**

No Legal Signature

When updating the exam to the signed state, the signature area will show the approver's name with a label of **Approved by:** in the final report.

About the Legal Signature

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

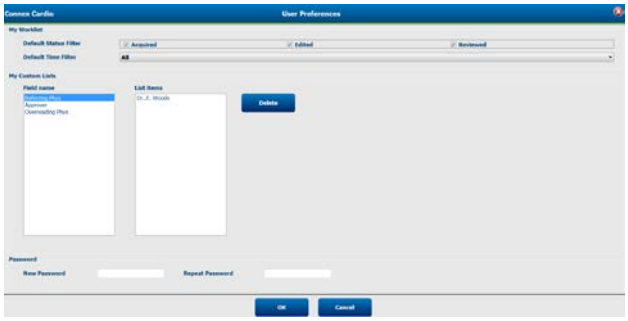
When the signing physician has been set up as an Attending Physician under Personnel, the printed name will appear in the Connex Cardio final report on the signature line following the **Electronically Signed by:** field label.

User Preferences

Select the User Preferences icon on the home screen to open the window. Set selections define the default criteria for the Get Worklist in the Search feature when the particular user is logged into Connex Cardio.

Set selections can be changed when the user selects the Advanced search selections.

The user can also change the password in this window when the system is not set up with a single sign-on.



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

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

1. Acquired
2. Edited
3. Reviewed

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

1. All
2. Today
3. Last week

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

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

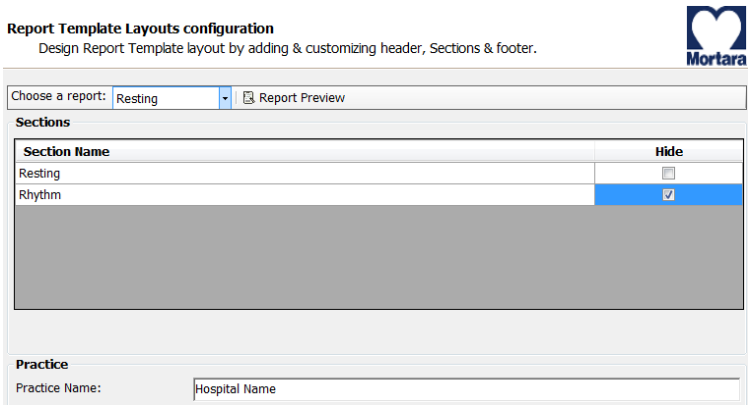
When finished, select **OK** to save changes or **Cancel** to exit the window without saving changes.

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

Report Configuration Tool

Connex Cardio final reports can be configured with the practice name prior to using the system. The practice name is printed at the bottom of each ECG report. In addition, the system can be set up to add or omit a 10 s 12-lead rhythm strip to each ECG report.

The Report Configuration Tool is a separate program. Click on the Start menu from the Connex Cardio workstation desktop. Choose "All Programs", "Mortara Modality Manager" followed by "Report Configuration Tool". This will open a dialog window prompting a Group choice from a drop-down list. Each group that has been defined will have its own report configuration. Select the group.



Choose the **Resting** report from the top left. Enter the practice name at the bottom white space. Select the **Hide** checkbox if you do not want to print a rhythm strip with each ECG. You can use **Report Preview** to see a preview of what will appear on each report.

> ***NOTE*: A*s an individual ECG report is reviewed, rhythm strips can be manually added if "Hide" has been selected by default.***

Select **Next** and **Finish** to save the configuration for the selected group. Select another group to configure or **Exit** to leave the report configuration tool.

User Role Assignment Table

	IT Admin	Clinical Admin	Schedule Procedure	Patient Hookup	Prepare Report
Main Screen					
Schedule / Orders	No	Yes	Yes	No	No
Start a Resting Exam	No	No	No	Yes	No
Exam Search	No	Yes	No	No	Yes
User Preferences	Yes - No Status Filter	Yes - No Status Filter	Yes - No Status Filter	Yes - Filter Acquired only	Yes - Filter Acquired and Edited only
System Configuration	Yes - No Modality Settings, CFD or Report Settings	Yes - Audit Trail, Service Logs, Report Settings, Modality Settings and CFD	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only
Exam Search					
Edit	No	No	No	No	Yes - Acquired and Edited Exams only
Report	No	No	No	No	No
Copy Offline	No	Yes	No	No	No
Open Offline	No	No	No	No	Yes
Export	No	No	No	No	No
Reconcile	No	Yes (Signed only)	No	No	No
Archive	No	Yes	No	No	No
Delete	No	Yes	No	No	No
Editing Permissions					
Summary Tables	No	No	No	No	Yes
Conclusions Section	No	No	No	No	Diagnosis, Reason For End and Technician
Patient Data	No	No	No	Patient and Contact Fields - only after Acquisition	Admission ID, Indications, Referring Physician, Procedure type, Location, Notes, and Technician
Page Review	No	No	No	No	Yes - View/Add/Edit Events and Print
Update Exam State	No	No	No	Acquired only	Edited only

	Review and Edit Report	Sign Report	Edit Conclusions	Export Report	View Exams/Reports
Main Screen					
Schedule / Orders	No	No	No	No	No
Start a Resting Exam	No	No	No	No	No
Exam Search	Yes	Yes	Yes	Yes	Yes
User Preferences	Yes	Yes	Yes - Filter Acquired and Edited only	Yes - No Status Filter	Yes - No Status Filter
System Configuration	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only	Yes - Service Logs only
Exam Search					
Edit	Yes - Acquired, Edited, Reviewed Exams only	Yes	Yes - Acquired and Edited Exams only	No	Yes
Report	No	No	No	No	Yes - Reviewed and Signed Exams only
Copy Offline	No	No	No	No	No
Open Offline	Yes	Yes	Yes	No	Yes
Export	No	No	No	Yes - Reviewed and Signed Exams only	No
Reconcile	Yes (Not Signed)	Yes (Not Signed)	No	No	No
Archive	No	No	No	No	No
Delete	No	No	No	No	No
Editing Permissions					
Summary Tables	No	No	No	No	No
Conclusions Section	Symptoms and Conclusions	Symptoms and Conclusions	Symptoms and Conclusions	No	No
Patient Data	No	No	No	No	No
Page Review	Yes - View and Print only	View and Print only	Yes - View and Print only	No	Yes - View and Print only
Update Exam State	Reviewed only	Signed only	Edited only	No	No - Screen is not shown

15. Software Upgrade

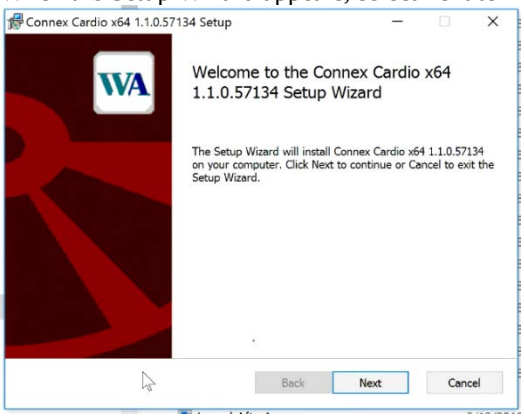
When upgrades of Connex Cardio software versions become available, the following process may be followed:

Prior to the upgrade:

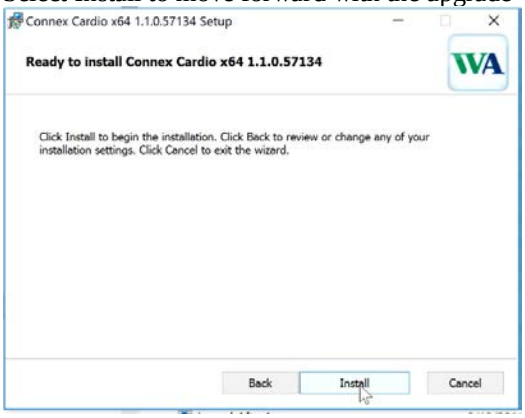
- Always review specifications for the specific version being installed prior to upgrading the software.
- For networked installations, upgrade the software on the server prior to upgrading software on the clients.
- Upgrades should be scheduled while Connex Cardio is not in use. The software on the server must not be modified during ECG acquisition on any of the clients
- The user logged in and performing the upgrade must have administrator privileges

Software Upgrade Steps

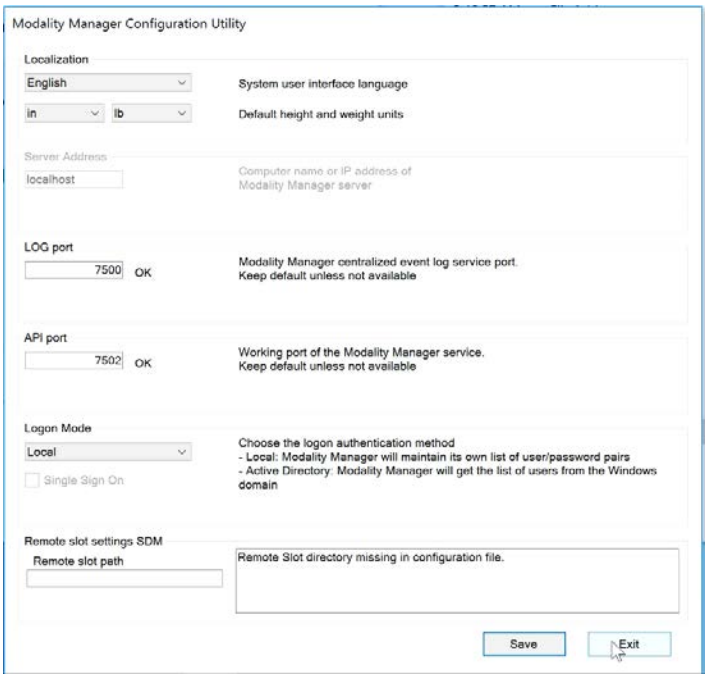
1. Browse to the location where the Connex Cardio software is located
2. Double-click on the Setup.exe file
3. If prompted, allow the program to make changes to the computer, select yes
4. When the Setup Wizard appears, select next to move forward



5. Select Install to move forward with the upgrade



6. When the Modality Manager Configuration Tool appears, select Exit



7. Select Finish to complete the upgrade.

16. Troubleshooting

Software Installation

Symptom	Resolution
Software did not install.	Ensure that the user logged in at the time of installation has administrative privileges. To check if a user has administrative privileges, right click on the setup.exe file and ensure “Run as Administrator” is available. Contact Technical Support for assistance
User prompted for database credentials during Simple installation	Contact Technical Support for assistance

Accessing Connex Cardio

Symptom	Resolution
Login fails.	Ensure the correct username and password are used. Contact administrator of Connex Cardio to ensure the username being used is registered in the Users Database section of the System Configuration. If using Active Directory, contact IT administrator for assistance with credentials. Contact Technical Support for assistance
Server not available message appears.	Select Cancel to exit the application and try to login again. If system is setup in a networked configuration, check with the administrator that the Connex Cardio server is up and running. Contact IT Administrator to perform the following function: Under Windows Services, ensure the CorScribeGateServer is running. If stopped, start service, and set restart to Automatic if set to manual. Contact Technical Support for assistance.
Schedule, Exam Search, User Preferences, and Settings icon are grayed out	System is in offline mode. Follow steps above.
Connex Cardio was installed as EHR integrated, but is not launching from my EHR.	The interface between Connex Cardio and the EHR must be enabled by the EHR. Contact your IT administrator or EHR to ensure the interface is enabled. Contact Technical Support for assistance

ECG Acquisition

Symptom	Resolution
AM12 is connected to the PC, but no waveforms appear.	Physically inspect the USB port to ensure that it is not damaged. Ensure the AM12 is completed seated in the USB port. Check the system for compatible software and hardware. From the main screen, select the System Configuration icon. ON the top left side of the window that appears, note the software version. If the version is 1.1.0 or later, it must be used with AM12 with a listed reference number as 9293-048-64. Contact Technical Support for assistance
WAM is connected, but no waveforms appear.	Ensure the USB receiver is completed seated in the computer USB port. Complete the process to pair the WAM to the USB receiver. Instructions listed under “Pairing the WAM to Connex Cardio.” Check the system for compatible software and hardware. From the main screen, select the System Configuration icon. ON the top left side of the window that appears, note the software version. If the version is 1.1.0 or later, it must be used with WAM with a listed reference number as 30012-019-76 and the UTK listed with a PN of 30012-021-60.
Connex Cardio is set to Best 10 but Last 10 ECG is captured.	The ECG button on the AM12 or WAM is always set to capture the Last 10 seconds regardless of settings.

ECG Troubleshooting Chart

Symptom	Resolution
Artifact in Lead I and Lead II	Check the RA electrode, re-prep if necessary, and ensure patient is relaxed and muscles are not tense.
Artifact in Lead II and Lead III	Check the LL electrode, re-prep if necessary, and ensure patient is relaxed and muscles are not tense.
Artifact in Lead I and Lead III	Check the LA electrode, re-prep if necessary, and ensure patient is relaxed and muscles are not tense.
High frequency noise in all leads	Adjust low pass filter setting; check proximity to power cables; check that the proper AC filter setting is selected (50 Hz or 60 Hz). Remove all portable electronic devices from the vicinity of the patient and the acquisition module. Check to see if the patient has an implanted muscle stimulator. Ensure patient is relaxed and muscles are not tense.

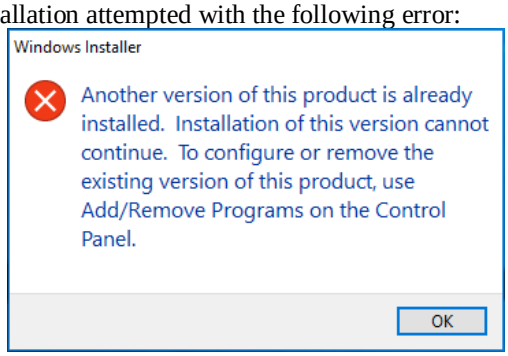
	 **WARNING**: When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met.
Excess artifact	Pull the clips off the end of all lead wires (if applicable), visually inspect the connector for corrosion. Inspect the metal portion that comes in contact with the electrode for corrosion. Clean or replace as needed. Inspect the lead wires for cracks or breakages. Ensure each lead wire is completely seated in the acquisition module. If available: Attach a simulator and view the waveforms on screen for artifact. If artifact is present, try another acquisition module. If artifact is still present, contact Technical Support. If no artifact while connected to the simulator, turn off the simulator and gently bend all wires. If artifact is seen, replace applicable lead wire.
No tracings on screen or gaps in the tracings. Screen shows Leads Off	If using the AM12, the cable between the module and the computer may be damaged or broken. Contact Technical Support for assistance. If using the WAM, ensure that the PC where the USB receiver is connected is in range by checking WAM signal strength on screen. Inspect the battery cap for signs of damage and to ensure it is completely connected. Press the power button on the WAM to turn on. Ensure the battery is placed in the proper direction in the WAM, or replace. Inspect the battery compartment for signs of corrosion.

Data Export

Symptom	Resolution
Exam export not found.	Exams are set to automatically export upon completion of the configured steps. Under the Workflow Config settings of the System Configuration, check the boxes that are checked under the Manual and Automatic columns. Ensure the appropriate box is checked that matches the step after which the user expects the exam to be exported.

	In the Users Database under System Configurations, ensure that the user logged in has the proper role selected to export exams. Contact IT administrator to ensure the interfaces are setup and connected. Contact Mortara Technical Support for assistance
Duplicate exams are exported.	Exams are set to automatically export upon completion of configured steps. Under the Workflow Config settings of the System Configuration, check the boxes that are checked under the Manual and Automatic columns. Ensure the appropriate box is checked that matches the step after which the user expects the exam to be exported. If multiple boxes are checked, the exam will export each time the step is completed. Ensure that only the steps after which the exam should be exported are checked automatically.

Software Upgrade

Symptom	Resolution
Installation attempted with the following error: 	Browse to the Control Panel to Add/Remove programs. Find and highlight Connex Cardio and uninstall. Browse to the new version of software and attempt to install again.