Mortara

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RScribe

12-LEAD ELECTROCARDIOGRAPH SYSTEM

SERVICE MANUAL

CE 0459

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

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

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NOTICES

Manufacturer's Responsibility

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

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

Responsibility of the Customer

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

Equipment Identification

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

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WARRANTY INFORMATION

Your Mortara Warranty

MORTARA INSTRUMENT, INC. (hereinafter referred to as "Mortara") hereby warrants that Mortara products (hereinafter referred to as "Product/s") shall be free from defects in material and workmanship under normal use, service, and maintenance for the warranty period of such Product/s from Mortara or an authorized distributor or representative of Mortara. The warranty period is defined as twenty-four (24) months following the date of shipment from Mortara. Normal use, service, and maintenance means operation and maintenance in accordance with appropriate instructions and/or information guides. This warranty does not apply to damage to the 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.

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

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USER SAFETY INFORMATION

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

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

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

Warning(s)

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

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

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

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

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

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

- 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.

- 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.

- 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.

- 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.
- 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).
- ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation.
- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with device or patient cables. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
- This device was designed to use the electrodes specified in this manual. Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or other adverse reactions. Electrodes are intended for short-term use and should be removed from the patient promptly following testing. Do not mix electrodes made of dissimilar metals.
- To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.
- A possible explosion hazard exists. Do not use the device in the presence of flammable anesthetic mixture.
- Possible malfunction risks may be present when installing third-party software. Mortara Instrument, Inc. cannot verify the compatibility of all possible hardware/software combinations.
- The device has not been designed for use with high-frequency (HF) surgical equipment and does not provide a protective means against hazards to the patient.
- The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillation and ultrasound machines.
- When the software is installed on the XScribe™ Stress Exercise system, refer to the XScribe user manual for additional warnings.

Caution(s)

- 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.
- 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.

Note(s)

- Patient movements may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.
- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.
- If 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.
- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
  - Type CF, defibrillation-proof applied parts.

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

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

- Allow the device 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
Atmospheric pressure:	500 hPa to 1060 hPa

EQUPMENT SYMBOLS AND MARKINGS

Symbol Delineation

	Attention, consult accompanying documents
	Do not dispose as unsorted municipal waste. Per European Union Directive 2002/96, requires separate handling for waste disposal according to national requirements
	Indicates compliance to applicable European Union directives

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

GENERAL CARE

Precautions

- Turn off the device before inspecting or cleaning.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia based solutions, 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 Exterior Surfaces and Patient Cables

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

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

Cleaning the Device

Disconnect the power source. Clean the exterior surface of the device with a damp, soft, lint-free cloth using a solution of mild detergent diluted in water. After washing, thoroughly dry off the device with a clean, soft cloth or paper towel. Consult computer and peripheral equipment user manual for specific instructions and precautions.

Sterilization

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

Cautions

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

ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

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

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

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

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

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

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 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	

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

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

Emissions Test	Compliance	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 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.*

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

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

<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.

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

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

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

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

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

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

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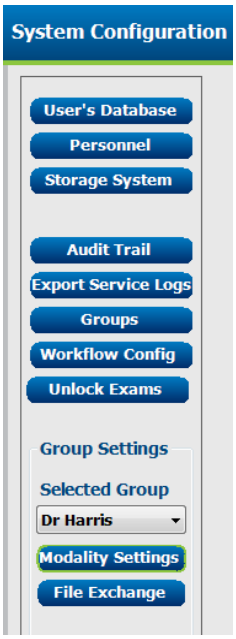
SYSTEM SETTINGS

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 RScribe administrative functions. All other users can enter this menu to access the Export Service Log task only.

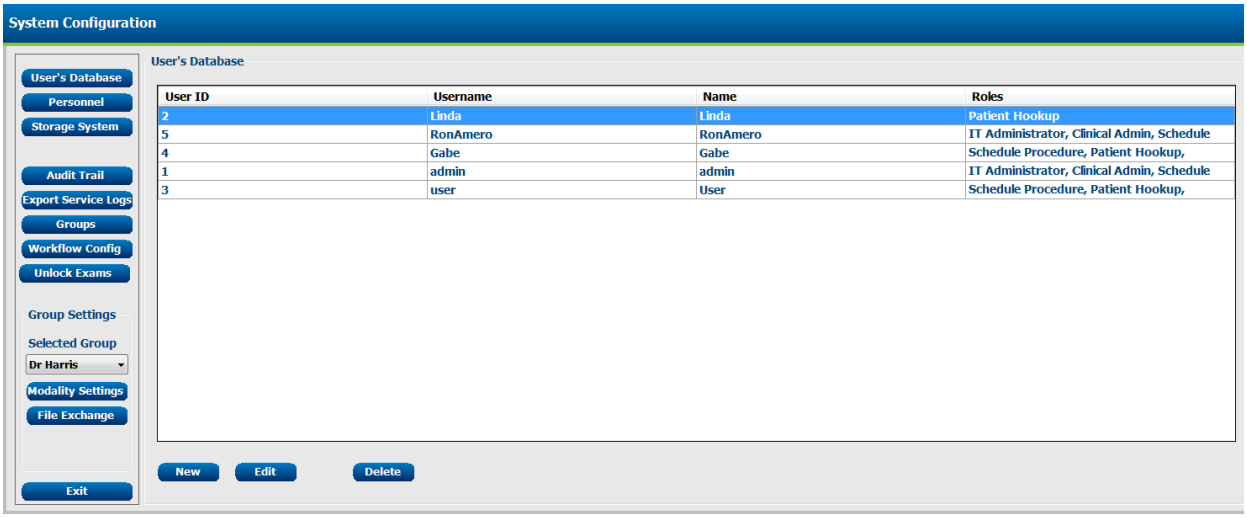


A list of administrative tasks is presented to:

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

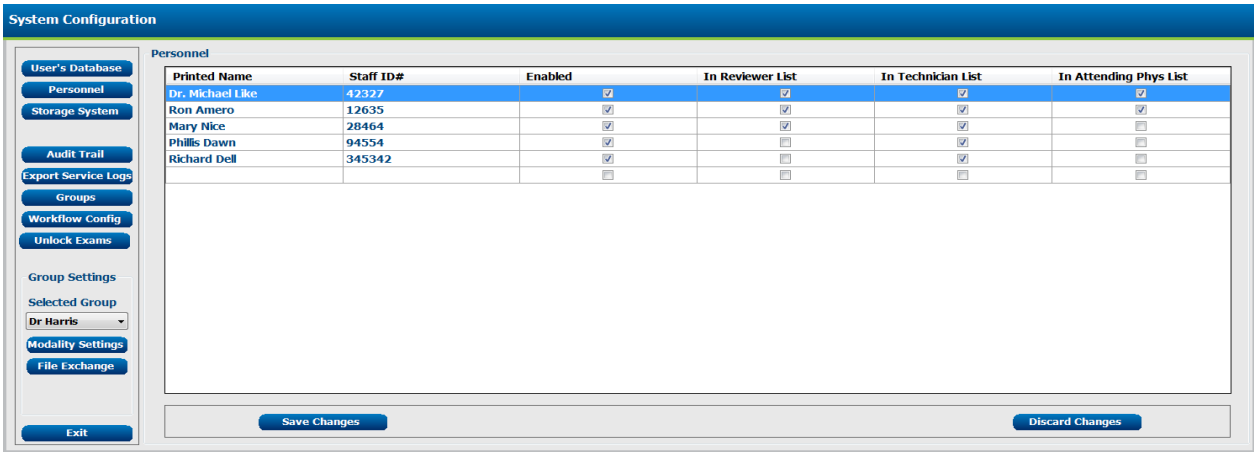
**** Task may not be available when operating with DICOM.***

User's Database



For every user, the IT Administrator can choose a user name, a password, assign roles and enter a displayed name to be used in reports. In addition he can assign "personnel" to the user from the list of available personnel. When "active directory" is used, no user account and password creation is needed, but users are selected from the list provided by the domain server.

Personnel



Personnel is selected to add personnel that will be available in the lists for Technicians, Reviewers and Attending Physicians. 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. Click on the printed name field of the empty line to add a new member. You may add a Staff ID to uniquely identify the person, and select in which list he or she will appear. Personnel cannot be deleted, but can be disabled.

Storage System

The RScribe administrative user can manage storage system disks through selection of Storage System.

Add Archive Location

The system will show a list of available disks that may be used for archiving. Select what you want to use for archiving. If the volume you select has not be used for archiving before, the system will ask you for a volume name.

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

Restore Archived Exams

Administrative users can restore exams from the archive location to the RScribe database through selection of Archive Recovery. Once selected, a window will open listing exam archive date and time, archive name, volume name, volume ID, and drive letter of the archive volume.

To restore exams highlight the desired exam(s) in the list and click on Recovery. Multiple exams can be restored by highlighting them and single clicking the Recovery button.

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

Archive recovery is only available if the archive volume is mounted.

Audit Trail

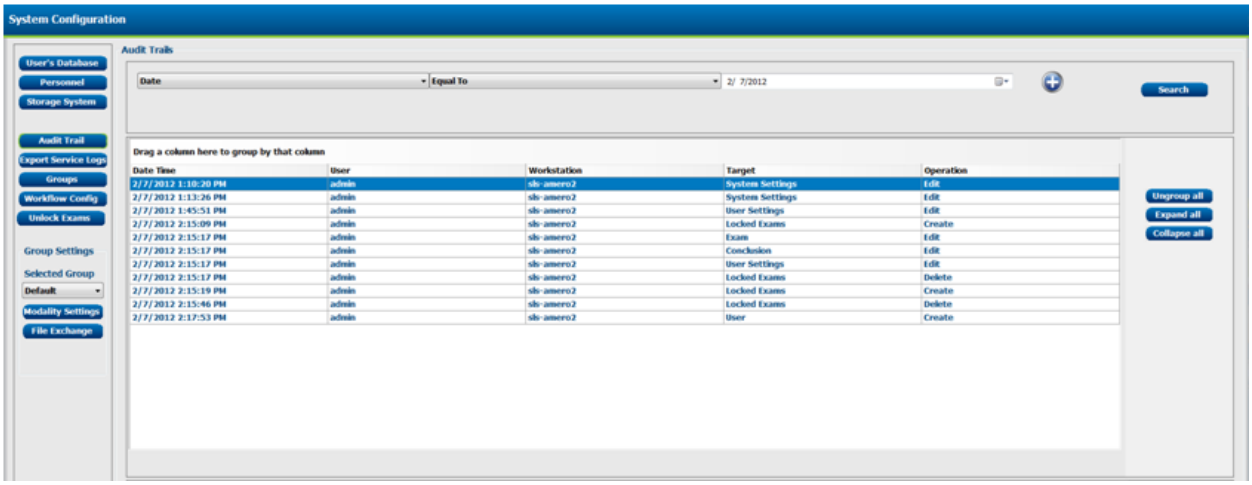
An Audit Trail is a series of computerized records that document user activities marked in the system. The Audit Trail is generated by a system that monitors activities. These systems are intended to create a level of security for recorded events. Individual user actions are tracked in an audit trail.

Audit trails can also be used to reconstruct computer events after a problem has occurred. The amount of damage that occurred with an incident can be assessed by reviewing audit trails of system activity to pinpoint how and when an incident occurred.

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

One or two filter criteria can be used to find audit trails. Selection of results will display the differences by comparing the XML statistics data before and after changes. A legend with colored highlighting will point to added, removed, changed, and moved information.

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



Service Logs

All RScribe users have access to Export Service Logs. Selection of the button creates a file on the desktop containing a copy of the systems logged events.

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

Manage/Create Groups

Groups allow the administrator to group exams according to reporting preferences, modality settings and files exchange preferences. A single **Default** group exists that can be copied and saved with a new name to create a second group. Any group can be copied, renamed and modified.

RScribe Modality Settings, Display and Report formats and File Exchange paths are uniquely defined for each individual group.

Groups, with exception of the Default group, can be deleted. Existing exams are not affected when a group is deleted.

Configure Workflow

Exam states, once executed, are designed to follow typical user workflow. There are four possibilities with meanings defined below each state:

ACQUIRED

Acquired indicates that the recording has been acquired and is waiting for the analyst to confirm or modify results.

EDITED

Edited indicates the analyst has examined the results and prepared the recording for review.

REVIEWED

Reviewed indicates that an authorized user (e.g. physician, fellow, clinician, etc.) has confirmed the results are correct.

SIGNED

Signed indicates that the exam results are correct and no further processing is necessary. The exam is signed by an authorized user. No further workflow processing is required. This state will trigger all automatic exports and remove the exam from worklists

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

Modality Status

Select All under Modality Status to enable all states; this setting is typically used in settings where an analyst first processes the recording, a fellow then reviews it and adds conclusions, and finally an attending physician signs the report.

Select No REVIEWED under Modality Status to move the state from EDITED to SIGNED; this is typically used when there is only one clinician that reviews the recording before it is confirmed and signed by the attending physician.

Select No EDITED/REVIEWED under Modality Status to move the state from ACQUIRED directly to SIGNED; this is typically used if the attending physician reviews and signs the recordings directly without any intermediary.

Legal Signature

The "Legal Signature" setting can be enabled by selecting Yes or disabled by selecting No.

The legal signature requires the specific input of user credentials prior to updating an 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 Legal Signature is active, the printed name of the authenticated user will appear in the report on the signature line following the "Electronically Signed By:" field label.

Unlock Exams

RScribe internally tracks transitioning exams preventing the same exam to be processed by two or more users at the same time. When a second user attempts to access an exam that is currently in use a notification message is displayed that the exam is not currently available. It may happen that an unexpected power failures will cause an exam to remain in a locked state.

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**.

Modality Settings

Modality Settings define all RScribe 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 RScribe 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; make sure to select the desired group 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

***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. RScribe 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**: RScribe 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**: Use the lock indicator to the right of the selections to eliminate the selection from the technician permitting only unlocked selections.*

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

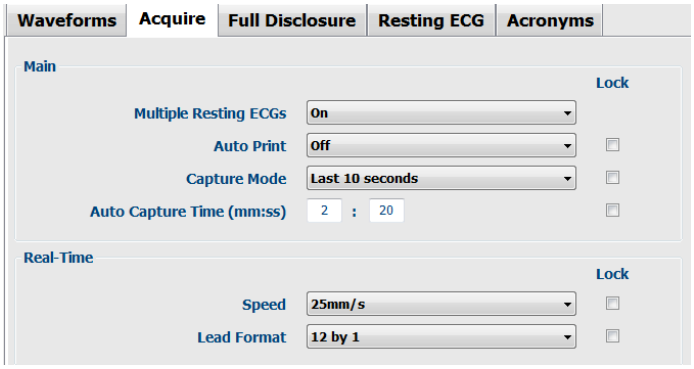
- To change default speed on the display:
  - Select **Speed**
  - Choices: 100 mm/s, 200 mm/s

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 RScribe.



Main

Multiple Resting ECGs

- Select **Multiple Resting ECGs**
- Choices: On, Off

NOTE: *Multiple Resting ECGs set to the ON position allows for multiple ECG acquisitions within the same session. When multiple ECGs are collected during a session, separate exams will be created automatically for each ECG in the systems database when exiting the session. If the field is set to Off, each time an ECG is collected within the session, it will replace the previous one.*

Auto Print

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

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

Capture Mode

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

NOTE: *Defines whether or not the RScribe 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.*

Auto Capture Time (mm:ss)

- Set from: a minimum of 20 seconds up through 59:59

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

Real Time

Speed

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

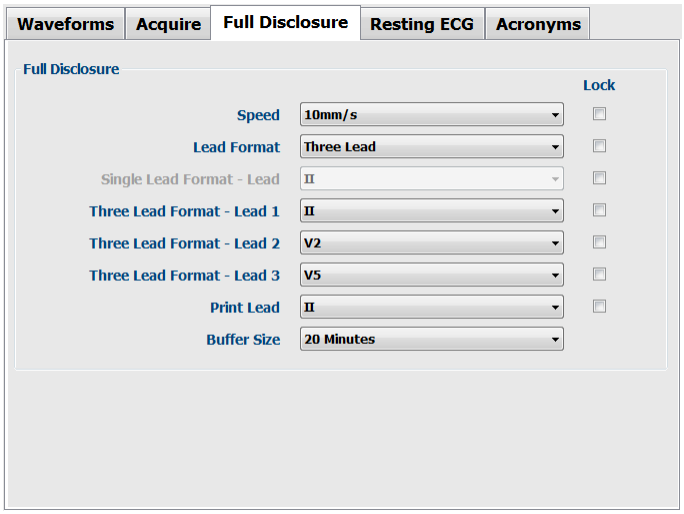
Lead Format

- 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.*

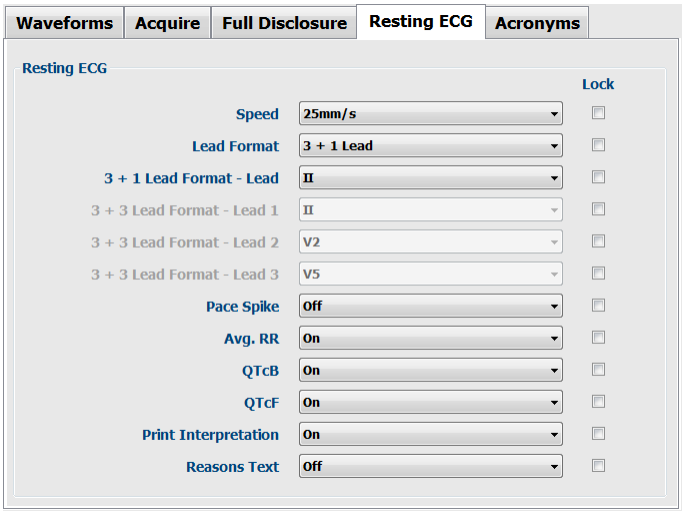
Buffer Size

- 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 selected small tick marks will indicate at the bottom of the ECG printout where a pacemaker spike was detected by RScribe. This is visible only on the printout, not on the computer display.*

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 printed.

File Exchange Configuration

Use this page to set up file exchange folders for communication with external systems.

Modality settings and file exchange settings are Group dependent; make sure to select the desired group before proceeding

RScribe supports the ability to import orders from XML files and export PDF and XML results to an external system dependent on the system activated features. Import/Export directories for the selected group are defined in the File Exchange window. An E-Scribe Site Number is also defined in this window when applicable. Refer to the Scribe Data Exchange Administrator Manual (P/N: 9515-185-51-XXX) for external system integration details.

PDF File Name

The final report PDF file name will have the following structure:

R^<FileType>_EXMGR^<Group>_<PatID>^<LName>^<FName>^<MName>_
<TestDateTime>_<ReportDateTime>.XML

DICOM Settings

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

Accessing the User Preferences Screen

Select the User Preferences icon  on the main screen to open the window. Set selections define the default criteria for the Worklist when the particular user is logged into RScribe. Default selections can be changed when the user enters the Worklist window. The user can also change the password in this window if the system is not set up to be used with Active Directory.

There are three possible choices for the Worklist Holter 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 Reviewed may not appear as selections.

Acquired
Edited
Reviewed

There are three choices for a default work list time filter.

All
Today
Last Week

My Custom Lists present Field Name selections where items that have been entered by the logged on user in the Exam Data Entry or Patient Demographics windows will appear under the List items to the right. Use **Delete** to remove unwanted list items such as misspelled names, names with duplicate meanings, or items that are no longer applicable. List items can only be removed in this window.

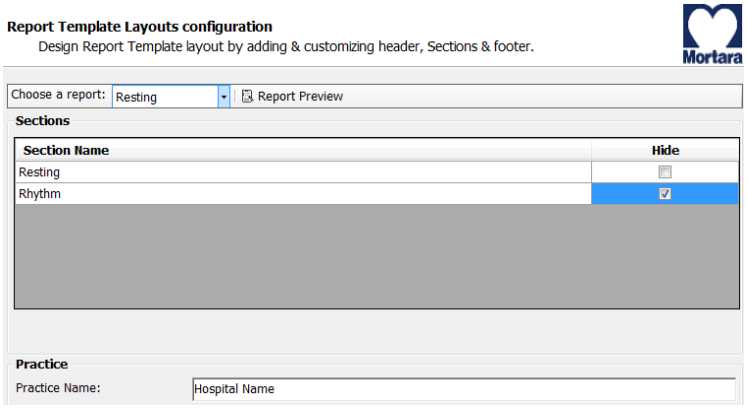
When finished, select **OK** to save changes or **Cancel** to exit the window without saving changes.

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

Report Configuration Tool

RScribe 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 RScribe workstation desktop. Choose "All Programs", "Mortara Instrument" 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.**

> ***NOTE*: *Rhythm strips can be added with selected ECGs also when the "Hide" is selected when you preview an individual ECG report.***

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.

(For Mortara Supplied Hardware Only)

Before you begin

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

Static electricity

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

- To avoid hand contact, transport products in static-safe containers such as tubes, bags, or boxes.
- Protect all electrostatic parts and assemblies with conductive or approved containers or packaging.
- Keep electrostatic-sensitive parts in their containers until they arrive at static-free stations.
- Place items on a grounded surface before removing them from their container.

- Always be properly grounded when touching a sensitive component or assembly.
- Avoid contact with pins, leads, or circuitry.
- Place reusable electrostatic-sensitive parts from assemblies in protective packaging or conductive foam.

Disassembly

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

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

Access panel removal

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

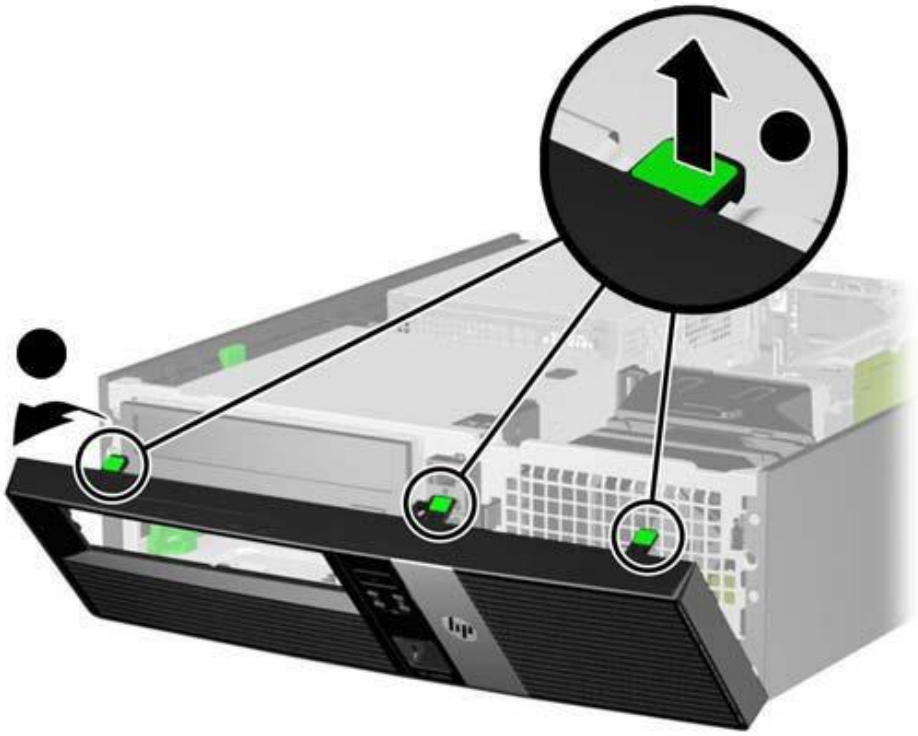
   CAUTION: Failure to comply with the *precautions* could result in damage to your product or loss of data.

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

To install the computer cover, reverse the removal procedure.

Front Bezel Removal

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



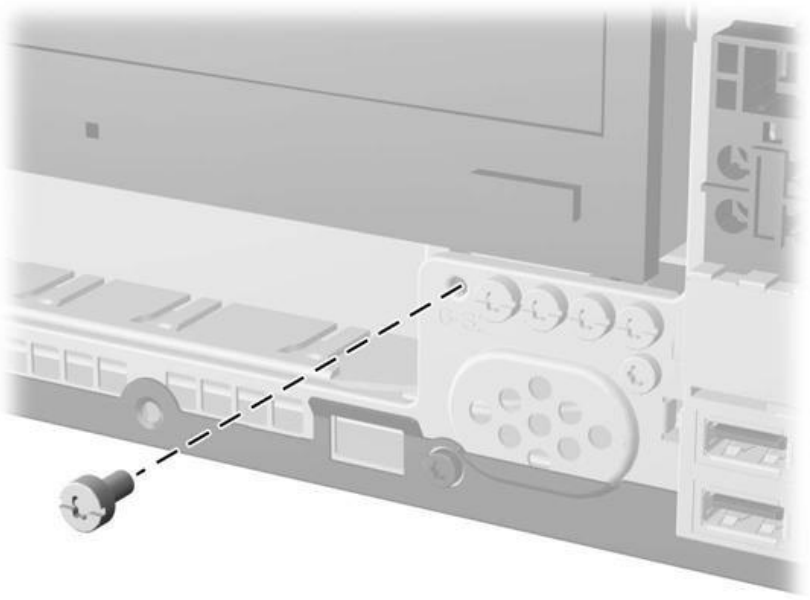
To install the new front bezel, reverse the removal procedure.

Front Bezel Security

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

To install the security screw:

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



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

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

Power Supply Replacement

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

1. Prepare the computer for disassembly
2. Remove the access panel
3. Disconnect the cabling from the power supply to the motherboard and other computer sub components
4. Remove the screws that fasten the power supply to the computer chassis

RScribe Item Description Listing		
Item #	**Part #**	**Description**
1	9906-037	Windows 7 Professional Computer
2	SERV PART 184-01	Computer Power Supply, 240W HP5800 (460889-001)
3	9900-014	MONITOR 24" LCD 1920x1200 WIDE DVI + VGA
4	SERV PART 184-02	PS2 Keyboard & Mouse
5	30012-019-xx	WAM Patient Cable
6	41000-032-xx	AM12 Patient Cable
7	30012-021-51	UTK Module
8	6400-015	USB Cable Extension – 6ft.

RScribe Item Identification Table		
Item #	**Part #**	**Picture**
1	9906-037	N/A
2	SERV PART 184-01	
3	9900-014	N/A
4	SERV PART 184-02	N/A
5	41000-031-XX With Lead Wires 30012-019-XX Without Lead Wires	
6	41000-032-XX With Lead Wires 9293-048-5X Without Lead Wires	
7	30012-021-51	
8	6400-015	

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 1366 x 768, 1280 x 800, 1680 x 1050, 1920 x 1080, or 1920 x 1200 Compatible with: Microsoft® Windows® 7 Professional 32 bit or 64 bit
Storage Capacity	100 GB SATA hard disk drive minimum Memory 2 Gb minimum USB ports 3 minimum
Archive	Network or external USB disks (standalone installation)
Input devices	Standard keyboard and 2-button scroll mouse
DVD drive	DVD-ROM, DVD-DRIVE
Network Support	Option to utilize industry-standard database server
Network Infrastructure	100 Mbps connection or better required for use with server
Printing Device	HP 2055DN or HP Enterprise M601 with HPUPD PCL 5 driver or equivalent
Optional Function	Mortara VERITAS resting ECG interpretation algorithm with age and gender specific criteria; connectivity with bidirectional communication
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; 1000 s/sec/channel used for recording and analysis
Gain Setting	2.5, 5, 10, 20
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	Depending on computer, 100 – 240 VAC at 50/60 Hz

*Specifications subject to change without notice.

DEVICE SPECIFICATIONS

Requirements for the server system in an advanced installation with separate secure server:

Feature	Server Minimum Specifications*
Processor	Performance equivalent to an Intel Xeon class; Quad-core with hyperthreading
Graphics	1024 x 768
RAM	4 GB
Operating System	Microsoft Windows 2008 server R2, 64-bit
System Disk	100 GB for OS and product installation (RAID recommended for data redundancy)
Data Disks	550 GB hard drive space available HD controller with 128 MB read/write cache RAID recommended for data redundancy
Archive	Network or external USB drive
Software Installation	CD-ROM
Network	100 Mbps connection or better
Input Devices	Standard keyboard and mouse

*Requirements for a multimodality server including Holter recordings.
*Specifications subject to change without notice.

PC Troubleshooting (Mortara supplied hardware)

Dual colored power LED on the front of the computer indicates either normal or fault condition. Refer to the Diagnostic LED Explanation Table below for fault descriptions.

Number of 1-second red LED blinks followed by a 2-second pause, then repeats:
2 – processor thermal protection activated
3 – processor not installed
4 – power supply failure
5 – memory error
6 – video error
7 – PCA failure (ROM detected failure prior to video)
8 – invalid ROM, bootblock recovery mode
9 – system not fetching code
10 – system hang while loading an option ROM

Installation Problems/Installation Logs

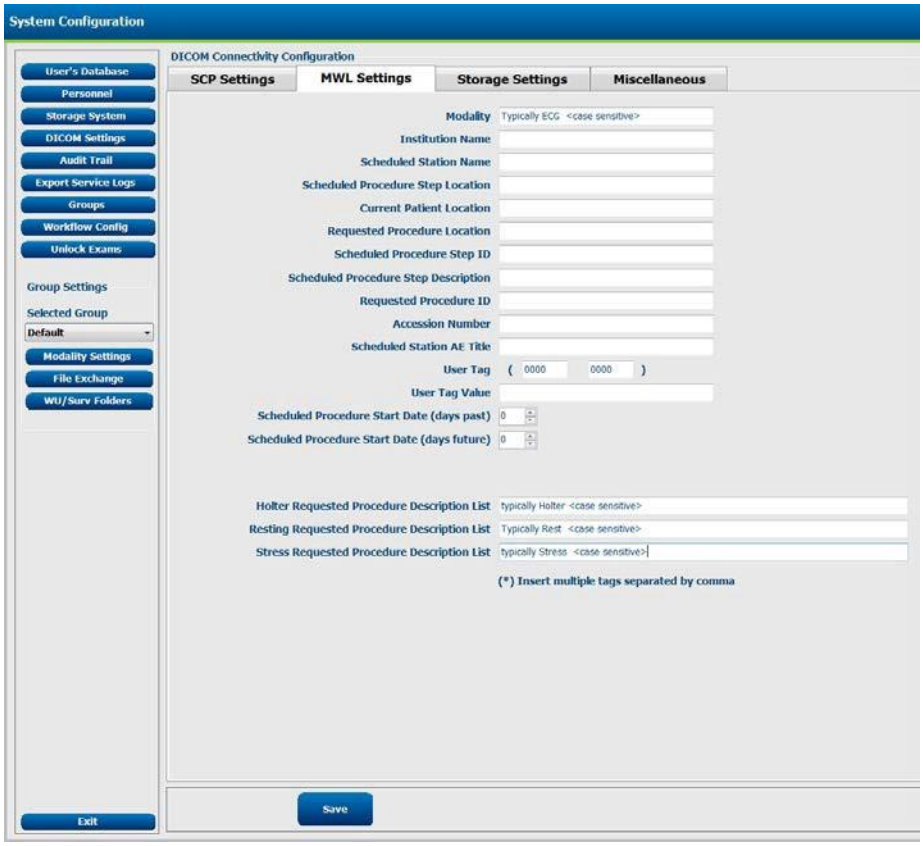
Log files associated with the installation of software are created and stored in a Temp folder on the system. The log files listed below can be copied and sent to a Mortara Service Center to assist with troubleshooting installation problems.

- MSIxxxxx (where x is variable and generated by the computer)
- CreateDB
- CSLoadUtility

To locate these files, launch Windows Explorer and enter %Temp% into the path bar to find the temporary directory where they will be stored. Once in the Temp directory, the files will need to be located by the Date Modified (this should be the date/time the installation occurred).

RScribe Troubleshooting

The items listed below are all accessed by going to System Configuration icon on the main screen of RScribe.



Upon completion of installing software, function icons on the main screen are grayed out (not able to access the function)

User preferences must be set up in the User's Database in order to access application functions and assign appropriate permissions. Personnel should also be added to the system via the "Personnel" button in order for them to appear in the appropriate dropdown lists.

Reference the RScribe User Manual for more details.

Unable to access MWL

- Press the DICOM Settings button in the left column and ensure the information is correct on all tabs.
- Press the File Exchange button for XML import.

Refer to the Scribe Data Exchange Administrator Manual (P/N: 9515-185-51-ENG) for external system integration details.

Service Logs

All RScribe users have access to Export Service Logs. Selection of the "Export Service Logs" button creates a file on the desktop containing a copy of the systems logged events. The created file named EMSysLog.xml.gz can be emailed to a Mortara service representative for troubleshooting purposes. (techsupport@mortara.com)

Audit Trail

Press the "Audit Trail" button in the left column to view the audit trail.

Specific audit trail information can be found by using the search tool on the top of the audit trail screen.

Copy exam files for sending to Mortara

The process listed below will allow the user to remove files from the system to be sent to Mortara for evaluation. This procedure will create a folder containing 5 to 10 files, all of the files must be sent to Mortara to ensure a proper investigation can be performed.

- Start the RScribe application
- Press Exam Search
- Find the exam by searching for it using the drop down menus at the top of the screen
- Highlight the exam by clicking on it once
- Click Copy Offline
- Select a location for the files
- Click OK
- Contact Mortara Technical Support for instructions on sending the files

RScribe will not start

On a single computer setup, if RScribe does not start with a message stating Server not found, go to Computer Management and Services and start CorScribeGateServer.

Not receiving data from AM12 or WAM

The AM12 or the UTK from the WAM may not be recognized by the system if they are plugged into the USB port on a docking station or a USB hub.

RScribe set to Best 10 but Last 10 ECG is taken

The ECG button on the M12 or WAM will always capture the last 10 seconds regardless of settings.

Conformance Testing

Conformance testing is to be performed by Authorized Mortara Service Representatives to verify the device is functioning correctly after repair operations have been performed. Testing results should be documented on the test data record at the end of this section of the manual.

Acquisition module preparation

Connect a patient simulator (set to a known heart rate and amplitude) to an AM12 or WAM patient interface. Connect the AM12 to a USB port on the PC, or pair the WAM to the UTK (USB Transceiver Key) connected to the PC.

Order Creation

- Schedule an exam by clicking on the **Schedule/Orders** icon, and selecting the **new** button for a new order.
- Click on the **new** button to create a new patient and enter demographic information using “TEST” as a first and last name, a patient ID # and a DOB. Click **confirm** when completed, then **Exit**.

Acquire, Print, and Edit ECG Data

- Click on the **Start a Resting Exam** icon and select the patient that you created the order for in the previous step, then click **Start Exam** and confirm the patient demographic information.
- ECG data should begin to be displayed. Allow about a minute of data to be collected then press the **Print Full Disclosure** button and then the **Print ECG** button.
- Verify the printouts are an accurate representation of the data collected.
- Click on the **ID** button and change the patient ID then click **Done**. Verify the ID change has been applied to the ECG on the screen.
- Click the **Done** button, then the **Done** button again.
- In the Finalize Exam Update window, change the **Next State** to **Reviewed** and enter “Test Physician_1” into the reviewed by field. Press **Update**, then **Close**.

Review / Edit recorded ECG Data

- Click on the **Worklist** icon and double click on the exam that you marked as reviewed in the previous step.
- Double click on Median Lead Zone. Verify that you can adjust the calipers and the measurement values adjust as the changes are made, then click **OK**.
- In the Finalize Exam Update window, change the **Next State** to **Signed** and enter “Test Physician_2” into the **Approved By** field. Press **Update**, then **Close**.

Retrieve Completed ECG Exam

- Click on the **Exam Search** icon.
- Locate and select the ECG you had Signed in the previous step by a double click.
- Review the ECG for accuracy including any edit operations that had been performed.

RScribe Test Data Record

Software Serial #: _____

- □ Schedule “Test” Order / Download DICOM Order (if applicable)
- □ Acquire ECG
- □ Print full disclosure / Resting ECG
- □ Patient Demographic Edit
- □ Review, Edit Measurements, Sign Acquired ECG
- □ Retrieve and review completed exam

Performed by:_____Date:_____/_____/_____

File Exchange

RScribe supports the ability to import orders from XML files and export PDF and XML results to an external system depending on the activated system features. Import/Export directories for the selected group are defined in the File Exchange window in System Configuration. An E-Scribe Site Number is also defined in this window when communicating with a Mortara EScribe system.

RScribe also supports DICOM communications. DICOM settings are entered through the System Configuration icon, then clicking on the DICOM Settings button.

Refer to the Scribe Data Exchange Administrator Manual (P/N: 9515-185-51-ENG) for external system integration details.

System Utilities

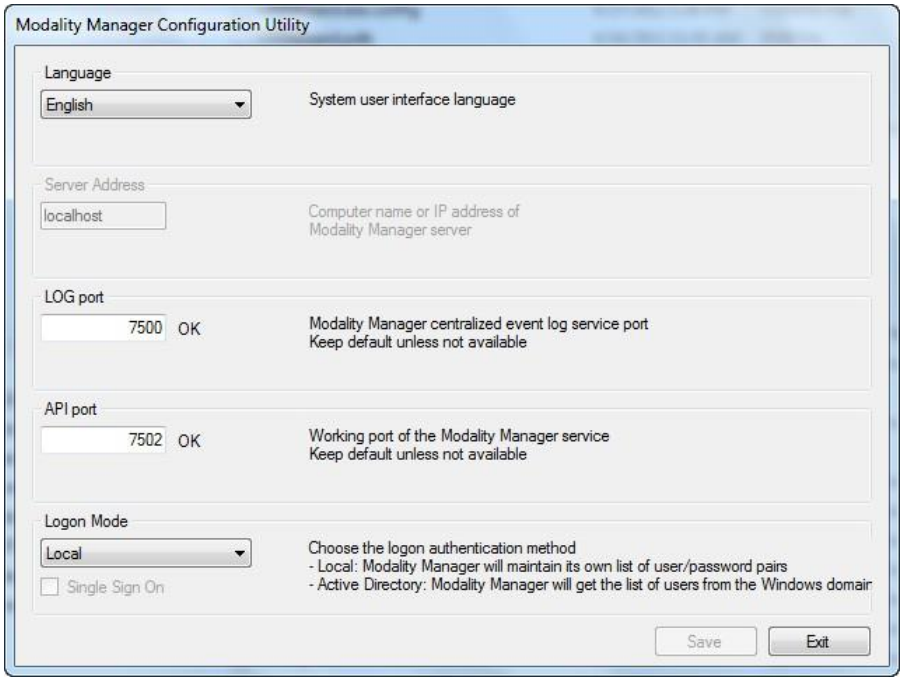
The following utilities are located at the path below to assist with system configuration and service functions as defined.

C:\Program Files (x86)\Mortara Instrument Inc\ModalityMgr

Configurator.exe	(language, networking, login)
FetchAllConfig.exe	(gathers all system configuration data)
ActivationTool.exe	(software license information)
CFDWizard.exe	(display and report configurator)

Configurator.exe

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



Refer to the following information regarding the configuration settings:

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

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

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

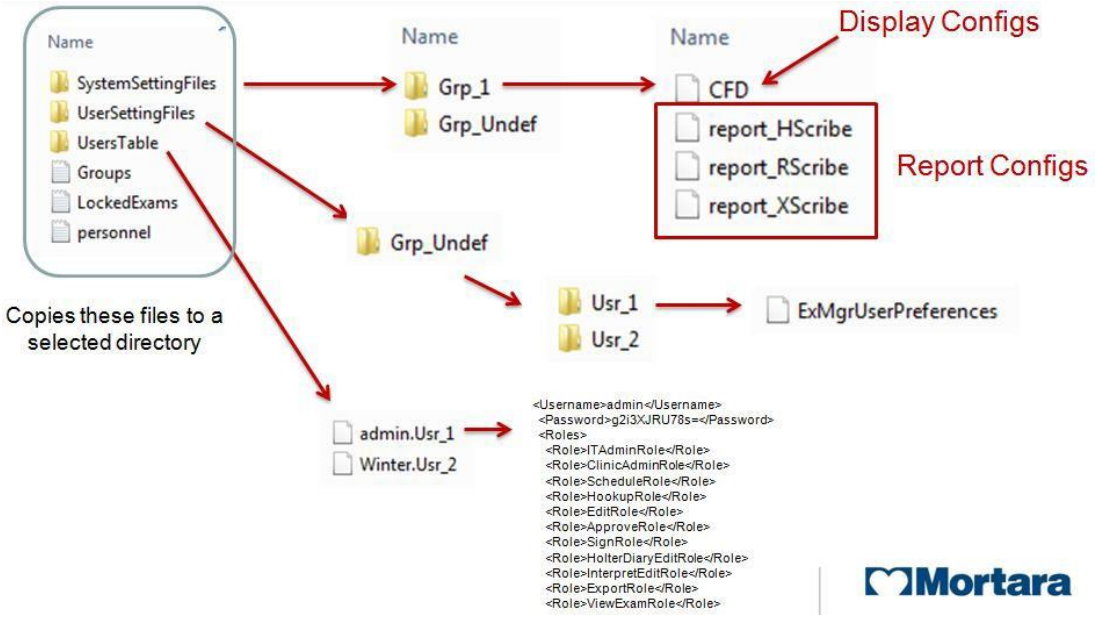
API Port: This setting is always available to select the port to be used for Modality Manager service.

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

If Active Directory is selected, the Modality Manager service will access the list of users from the Windows domain.

FetchAllConfig.exe

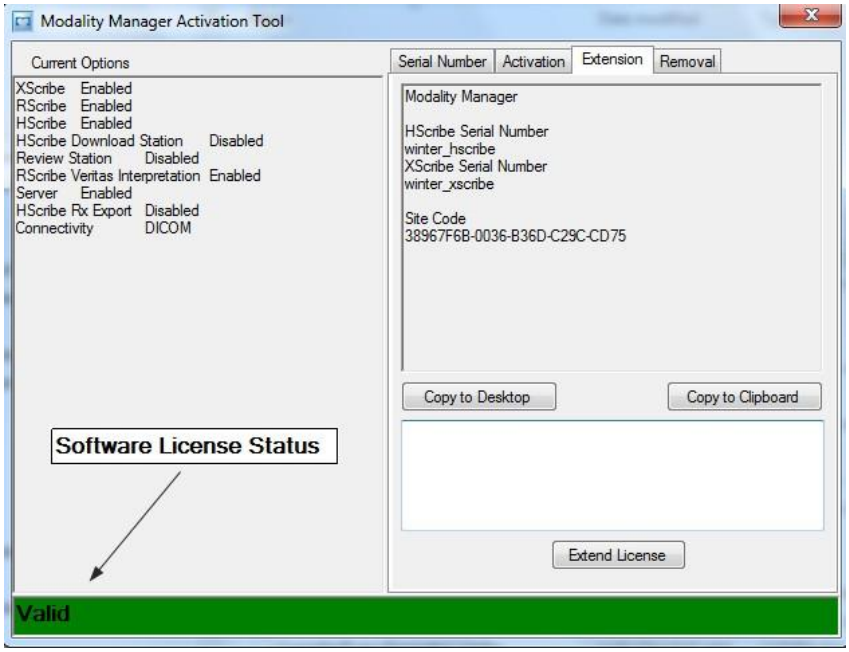
Copies all of the system configuration settings into the file structure displayed below to allow this information to be sent to a Mortara Service Center. The path can be entered by the user upon executing the utility.



ActivationTool.exe

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

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



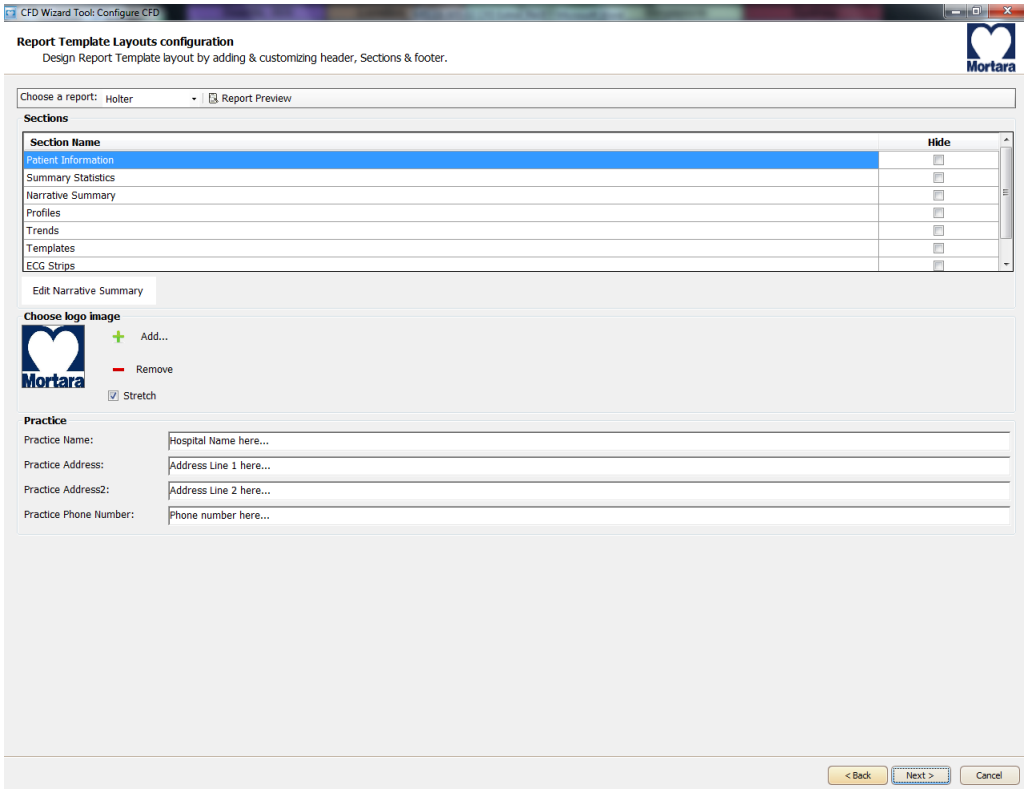
The Activation Utility is also used to perform a software Removal, which MUST be performed prior to uninstalling the Mortara software. The software Removal process will generate a Removal Code, which will need to be sent to Mortara to provide notification that the software license has been deactivated.

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

CFDWizard.exe

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

- Logo
- Facility Name
- Facility Address
- Phone Number
- Hide Items



Customization of the Scribe 5 display appearance and reports are also available. Please contact your regional Mortara Service Center for assistance with this level of customization.

System Backup

The Scribe 5 system installs a batch file that will back up all of the necessary data required to restore the system to operation in the case of a system failure. This file can be modified to direct the system to store the backup data to an alternate non-local location or designated storage system (recommended).

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

The backup file is located at the following path:

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

- Double click on Backup.bat

- A Command Prompt window will open and the backup process will begin, once the Command Prompt window closes the backup is complete.

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

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

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

Backup Notes:

 **Caution**

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

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

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

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

Everything else (users, DICOM settings, Modality settings etc…) is in the DB, hence it is backed up.

- *It is recommended that the backup be performed while the system applications are not in use (not receiving any data).*

- *The Backup.bat routine can be added as a scheduled process through the Task Scheduler*

- *If a local backup (factory default) is used It is recommended that after a backup has been performed that the file created from the backup be removed from the system and placed in a safe (non-local) location.*

- *The process is the same for a stand-alone system and a distributed system; when performing the backup on a distributed system the process must be performed on the PC or server that is running Modality Manager.*

- *The backup process can be customized by modifying the DefaultBackupSettings.bat file and renaming the modified file to CustomBackupSettings.bat*

    - *Information regarding modifications to the backup file are located within the Backup.bat file itself.*
    - *Please contact Mortara Instrument Technical Support Group if you require assistance with modifying the backup file.*
    - *Mortara technical support can assist with the modification of the backup file, however Mortara will not retain a copy of the file.*

- *On a distributed system the backup zip file may be parked in a sub folder:*

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

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

System Restoration *(restores to point of last performed backup)*

The following process should be followed to restore a Scribe 5 system.

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

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

- Place the backup file into the appropriate folder:

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

  On a distributed system the file may be located is a sub folder:
  C:\Users\<user>\AppData\Local\Temp\1

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

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

  C:\Program Files\Mortara Instrument Inc\Mortara PgSql\scripts>Restore.bat

- Double click on the Restore.bat file

- A Command Prompt window will open and the Restore process will begin

- The Restore program will ask whether or not CreateDB.BAT will need to be run before the restore is executed. If the system database does not need to be recreated, answer NO to this question. If the system database has been damaged, or is being recreated, answer YES to this question.

- Once the Command Prompt window closes the backup utility has completed restoring the following content:

    - *SQL Database information*
    - *Full Disclosure Data*
    - *User Configuration Settings*

- Verify that the appropriate data has been restored (system settings or system settings and exam data) and that the exams can be accessed.

Notes:

Caution

- *It is recommended that the restore be performed while the system applications are not in use (not receiving any data).*

- *The process is the same for a stand-alone system and a distributed system; when performing a Restore operation on a distributed system the process must be performed on the PC or server that is running Modality Manager.*