Mortara

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HScribe

HOLTER ANALYSIS SYSTEM

SERVICE MANUAL

CE 0459

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

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

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

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

- To maintain operator and patient safety, peripheral equipment and accessories used that can come in direct patient contact must be in compliance with IEC 60601-1 and associated safety standards.

- To maintain operator and patient safety, only use parts and accessories supplied with the device and available through Mortara Instrument, Inc.

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

- Before attempting to use the device for clinical applications, the operator must read and understand the contents of the user manual and any documents accompanying the device. Contact Mortara service for additional training options.

- Do not operate the device if it has been damaged. Have damaged equipment repaired by qualified personnel. Contact Mortara service for assistance.

⚠ **Caution(s)**

- Loading or operating commercially available software might affect the performance of the device.

- Do not attempt to clean the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning. Wipe the exterior surface of the device with alcohol-free sterilizing disinfectant avoiding aggressive detergents; 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.

- Recordings that are saved to the local or server database on the hard drive will cause the device to fill over a period of time. These recordings must be removed from the database by deleting or archiving prior to causing the device to cease to operate. Periodic checks of the device's capacity are recommended; a safe minimum capacity capacity is 10 Gb. See Section 7 "Exam Search" for ways to select recordings for deletion or archiving.

- System environment: It is the user's responsibility to use, transport, and store the device in conditions that are compatible with the components of the system (PC, printer, display, etc.).

- Separate instructions for storage, use and disposal are included with the computer, display and printer. Read and follow these, and keep them available for consultation.

- Windows compatibility, updates and anti-virus policy: The HScribe software has been fully tested with Windows 7 Service Pack 1. Although it is unlikely that Windows updates and security patches affect HScribe 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 HScribe with major corporate anti-virus software packages has been verified. Mortara recommends excluding the HScribe 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.

Note(s)

- Poor patient preparation prior to electrode attachment may affect the recording and could interfere with the operation of the device.

- An ambulatory 12-lead ECG obtained with torso-located limb electrodes is not equivalent to a conventional diagnostic ECG.

- When necessary, dispose of the device, its components and accessories and/or packing materials in accordance with local regulations.

EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

Atention, consult accompanying documents

Indicates compliance to applicable European Union directives

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

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INTRODUCTION

Manual Purpose

This manual is intended to provide the user with information about service related activities associated with the HScribe™ Holter analysis system and the following functions:

- Device Specifications
- Troubleshooting
- Conformance Testing
- System Utilities
- System Backup and Restoration

Audience

This manual is written for service technicians who are expected to have a working knowledge of electrical and mechanical repair techniques, computer skills, and terminology as required for servicing medical devices.

Indications for Use

The HScribe system is indicated for use in a clinical setting, by qualified medical professionals only, for patients requiring ambulatory (Holter) monitoring of 24-48 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. The analysis software package includes, among others, detection and reporting features appropriate to the indications below:

- Evaluation of adult patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmia

- Evaluation of adult patients for ST segment changes

- Evaluation of adult patients with pacemakers

- Reporting of time domain heart rate variability

- Evaluation of infant patients, including those weighing less than 22 pounds or 10 kilograms, limited to QRS detection and heart rate reporting only

System Description

HScribe is a high-speed, PC-based Holter scanner. Used in conjunction with Mortara Instrument's H3+™ and H12+™ digital Holter recorders, the HScribe provides full-disclosure data for arrhythmia analysis, and incorporates Mortara Instrument's exclusive VERITAS™ ECG algorithms for superior beat detection and ST segment analysis on all recorded leads to acquired recorded ECG data. ECG data from an H3+ or a compact flash (CF) memory card is downloaded for analysis to the HScribe. After acquisition the recorder or CF memory card is erased and prepared for the next recording session using the HScribe application software.

The HScribe system is available as a single workstation system with a centralized exam database that can support networked HScribe Review and HScribe Download workstations; or in a distributed configuration where the database resides on server hardware supporting a number of networked HScribe workstations.

The HScribe review station offers equivalent review, editing and reporting capabilities to the HScribe excluding data acquisition. Holter ECG recordings are acquired at the HScribe or a networked download station.

The HScribe download station allows either recorder or CF memory card data acquisition and erasure, entry of patient information, automatic scanning, and archive to external or network drive. It does not review ECG data. Recordings must be reviewed at any networked HScribe or review station where the final report is also generated.

The Surveyor™ Central system (software versions 3.00 and later) receives 12-lead ECG data from a Mortara digital transmitter. Full-disclosure patient monitoring data can be imported into the HScribe for Holter analysis through the use of the HScribe Surveyor Import application.

H3+ and H12+ Holter recordings can be acquired from a web server when they have been uploaded from a remote location with the HScribe Web Upload option.

Report formats include scan criteria, tabular and narrative report summaries, rhythm profiles, 24-hour or 48-hour trends of all arrhythmias, QT/QTc and ST segment values, template pages, automatic and operator-selected strips with one, two, three, or twelve-lead ECG, and full disclosure of selected channels. HScribe supports a paperless workflow with user verification and an option for electronic signature.

Multiple recordings with analyses are stored in the HScribe database in a central location. Users with the appropriate permissions can import a new recording or review existing analyses.

User access to HScribe is defined by the system administrator allowing the ability to modify patient demographics, report conclusions, diary events and Holter ECG data editing. HScribe access is controlled by each user's role (e.g. IT administrator, Clinical Administrator, Physician Reviewer, Holter analyst, etc.) and associated permissions.

Long-term storage of full-disclosure patient recordings is accomplished by the archive feature. Archived Holter recordings can be restored to the HScribe database for further analysis, review, report export, and printing.

An audit trail allowing administrative personnel to query details for user actions and operations is maintained by HScribe.

The HScribe system layouts and contents are customizable for both display and final reporting. Contact Mortara Customer Service for more information.

Interacting with Windows Environment

HScribe is based on a Microsoft® Windows® operating system and runs on an industry-standard platform. Conforming to Windows' intuitive "graphical user interface," the HScribe uses the mouse to point, click, and drag what is displayed on the monitor. Keyboard entries, called shortcut keys, can also be used in conjunction with the mouse.

Login and Main Display

If not set up with a single sign on, HScribe will require user credentials on startup. The default factory username and password is **admin** (password is case sensitive).


Upon successful login, the HScribe application screen will appear displaying the user name and software version in the bottom left corner. Click on any of the icons representing workflow to perform a specific task.

Hover over an icon to display the icon's function. Icons not permissible to the user are grayed and not available.

Program Icons

Icon/Function	Description
HScribe 5	Desktop shortcut icon to launch the Holter modality application.
Schedule/Orders	Use to schedule an exam and/or review the exam schedule. *This icon is only available when HScribe is not linked to an external scheduling system.*
Prepare Recorder/Card	Use for compact flash (CF) card or recorder erasure and preparation for the next exam.
Import Recordings	Use to display connected devices (CF card, recorder, web upload, and Surveyor data folders) allowing association of patient demographic data and acquisition.
Worklist	Use to display exams with a preset filter showing only Acquired, Edited, or Reviewed status according to user preference and permissions. Checkboxes allow for further filtering.
Exam Search	Use to search for Holter exams in the database using filters.
Patient Search	Use to search for patients in the database using filters and to edit patient demographics.
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 HScribe default scan criteria, defining archive directories, and so on.
Exit	Use to close the HScribe application and return to the desktop.
	Use to minimize or exit the application and return to the desktop.

User Roles and Permissions

HScribe 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, Holter Hookup 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.

Roles	Permission Assignment
IT Administrator	Manage user permissions; manage personnel lists; export settings; Web upload and Surveyor data folders; archive settings; workflow configuration; storage system configuration; unlock exams; view audit trail reports; export service logs.
Clinical Administrator	Manage database exams (delete, archive, and restore); export settings; copy exams offline to share with Mortara personnel or other sites; view audit trail reports; modify modality settings (scan criteria defaults and other Holter specific settings); reconciliate; export service logs; create and modify groups.
Schedule Procedure	Create new patient orders; associate an order with an existing patient; modify demographics of an existing patient; export service logs. *Scheduling and order entry is only available when HScribe is not linked to an external scheduling system.*
Patient Hookup	Start and import new recordings using the Import Recordings icon. Includes the ability to prepare recorder/card and create a new patient; associate an order or recording with an existing patient; create and modify diary events; export service logs.
Edit Holter Diary	Create and modify diary events; export service logs. Must be assigned in conjunction with another role (e.g. Review Report).
View Exams/Reports	Review exams and final reports only. Includes the ability to search exams, view and print reports; export service logs.
Prepare Report	Review and edit exams to move them to the edited state. Includes ability to search exams and view and print reports; export service logs.
Review Report	Review and edit exams to move them to the reviewed state. Includes ability to search exams and view and print reports; modify and create conclusions; export service logs.
Edit Conclusions	Create and modify conclusions. Includes ability to review exams and final reports only; search exams and view and print reports; export service logs.
Sign Report	Ability to move exams to a signed state. Includes ability to review exams and final reports; search exams and view and print reports; export service logs.
Export Report	Ability to export a PDF, XML and/or waveform strips when features are enabled. Must be assigned in conjunction with another role (e.g. Review, View, or Conclusions).

Feature Activation

An activation code is required to operate full HScribe software functions such as acquisition, network access, storage, archiving, and export. Without activation, the system will function for a period of fourteen days only. Contact Mortara Technical Support personnel for information.

Specifications

Feature	Workstation Minimum Specifications*
Processor	Performance equivalent to an Intel Core i3
Graphics	1280 x 1024 (1920 x 1080 recommended)
RAM	4 GB
Operating System	Microsoft Windows 7 Professional 32-bit or 64-bit (required)
Storage Capacity	160 GB
Archive	Network or external USB drive
Input Devices	USB Standard keyboard and 2-button scroll mouse
DVD Drive	CD-ROM
Network	100 Mbps connection or better
Printing Device	HP PCL5-compatible printer series (recommended)
USB Ports	2 free USB 2.0 ports

* Specifications subject to change without notice.

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 (required)
System Disk	100 GB for OS and product installation (RAID recommended for data redundancy)
Data Disks	550 GB hard drive space available HD controller with 128 MB read/write cache (RAID recommended for data redundancy)
Archive	Network or external USB drive
Software Installation	CD-ROM
Network	100 Mbps connection or better
Input Devices	Standard keyboard and mouse

* Specifications subject to change without notice.

SYSTEM AND USER CONFIGURATION

Administrative Tasks

The IT and Clinical Administrator user will select the **System Configuration** icon to enter the HScribe 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
- Configure Web Upload file location for import
- Configure Surveyor Data file location for import

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

Manage User Accounts

User's Database

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

Personnel

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

Manage/Create Groups

Groups allow the administrator to group exams according to reporting preferences (modality settings) and file exchange preferences. A single default group exists that can be copied and saved with a new name to create a second group. Select **Groups** to make a change. Any created group can be copied, renamed and modified. The Default group can be renamed. An unlimited number of groups can be created and modified.

HScribe Modality Settings, File Exchange paths, Web Upload directory paths, and Surveyor Data import paths can be uniquely defined for each individual group.

Groups, with exception of the Default group, can be deleted resulting in deletion of all exams that exist within the deleted group.

Modality Settings

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

ECG Strips

ECG strip annotations available for selection when adding a strip to the final report can be added, removed, and moved up or down in the list.

One, two, three, or 12 leads can be selected as a default for auto-strips settings selection for the final report. Periodic strips can be set every HH:MM:SS as well as a set offset for the first strip. ECG strips with lead failure can be excluded by checking the **Skip Lead Fail** checkbox.

Scan Criteria

Scan Criteria default settings are defined under this tab. Factory settings can be modified as desired and saved for all recordings imported after saving. Current recordings will retain the set Scan Criteria at the time of import.

Supraventricular (SVPB) prematurity percent, pause, ST elevation and depression, tachycardia and bradycardia thresholds are defined in this window. Determination to consider a pause using all beats, or only normal-to-normal beats is selected with a radio button. Beat types to be used for heart rate and Heart Rate Variability calculations are selected in this window. Atrial Fibrillation automatic detection is enabled/disabled in this window. Pacemaker Analysis is not available for selection as a default, although it is shown in this window.

Diary

Diary annotations available for selection when editing diary entries can be added, removed, and moved up or down in the list.

Event Labels

Event labels available for selection when identifying an ECG event in the recording can be added, removed, and moved up or down in the list. A maximum of three event labels selected from the Event Labels listing can be identified as default in this window.

QTc

The default formula choice for QTc Linear, Bazett, or Fridericia is chosen in this window with a radio button.

Three user-selectable choices for RR intervals to be used for QTc calculation are selectable by radio button. Choices are RRprior (previous RR interval in milliseconds), RR16 (sum of the previous 16 RR intervals), and RRc (weighted average of the past 256 RR intervals).

File Exchange

HScribe 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-ENG) for external system integration details.

Standard Export

Systems configured with standard export options will always export XML V5 Holter Statistics and a PDF copy of the final report to the defined destination.

RX Export

Systems configured with RX export options will always export XML V5 RX Holter Statistics and can optionally export Holter ECG strips with waveform in Mortara XML format, Holter ECG strips with waveform in FDA XML format, UNIPRO32 12-lead ECG strips and a PDF copy of the final report to the defined destination.

PDF File Name

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

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

DICOM Settings

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

Web Upload/Surveyor Folders (WU/Serv)

HScribe supports the ability to import Web Upload server recordings and Surveyor Central system monitoring data dependent on the system activated features. The Web upload and Surveyor import paths are defined within this selection.

The Windows user running HScribe must have read/write access to the directories. Select the Path field and select **Browse** to navigate to the appropriate directory, or enter the path manually. Click **Add** to include the path for the selected group.

Web upload and Surveyor data paths can be removed by highlighting the path and selecting **Delete**.

Web upload and Surveyor paths can be authenticated using **Validate**. When the path is not valid a red exclamation mark is displayed next to the path field.

Unlock Exams

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

Add Archive Location

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

Restore Archived Exams

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

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

Audit Trail Logs

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

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

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

Service Logs

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

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

Configure Workflow

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

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

2. IN PROGRESS
   The Holter recorder or CF card has been prepared and is in process of recording patient data at the acquisition device.

3. ACQUIRED
   The recording device has completed data collection and the recording has been imported at the HScribe system and is ready for scanning.

4. EDITED
   The Holter recording has been analyzed with or without changes to the computer analysis and is ready for review by a physician. Conclusions may be entered at this state.

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

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

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

Workflow Config

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

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

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

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About the Legal Signature

The legal signature requires the user credentials prior to updating a Holter 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 Holter final report on the signature line following the "Electronically Signed By:" field label.

User Preferences

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

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

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

1. Acquired
2. Edited
3. Reviewed

There are three choices for a default time filter.

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

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

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

Report Configuration Tool

HScribe final reports should be configured with the practice name, address, and phone number prior to using the system. The practice logo and default sections for final report inclusion are also customizable within this tool.

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

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

Configuring the Final Report

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

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

2. **Add** or **Remove** a logo image for the HScribe final report header. The **Stretch** checkbox causes the logo to fit into the header area appropriately.

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

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

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

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UNIT DISASSEMBLY

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.

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UNIT DISASSEMBLY

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

- 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.
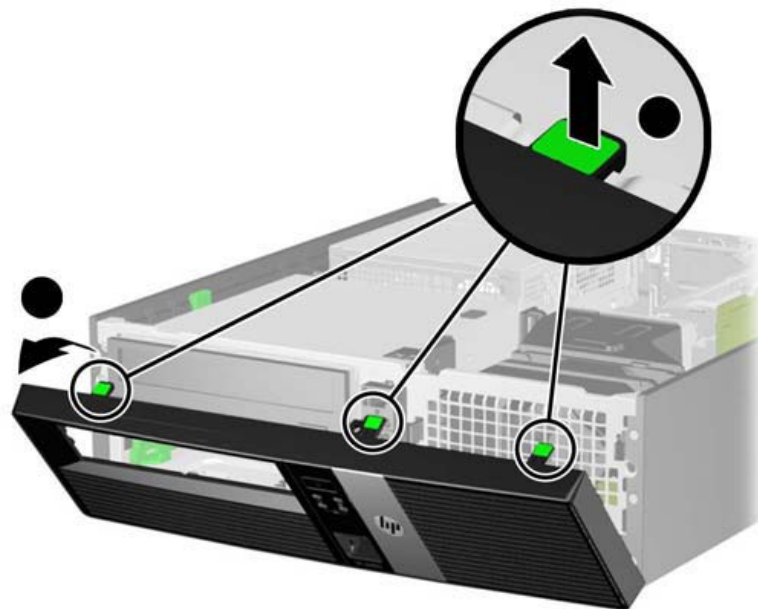3. Rotate the panel up and lift it away from the chassis.

To install the computer cover, reverse the removal procedure.

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UNIT DISASSEMBLY

Front Bezel

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)**.

Removing the Front Bezel (shown with optical drive installed)

To install the new front bezel, reverse the removal procedure.
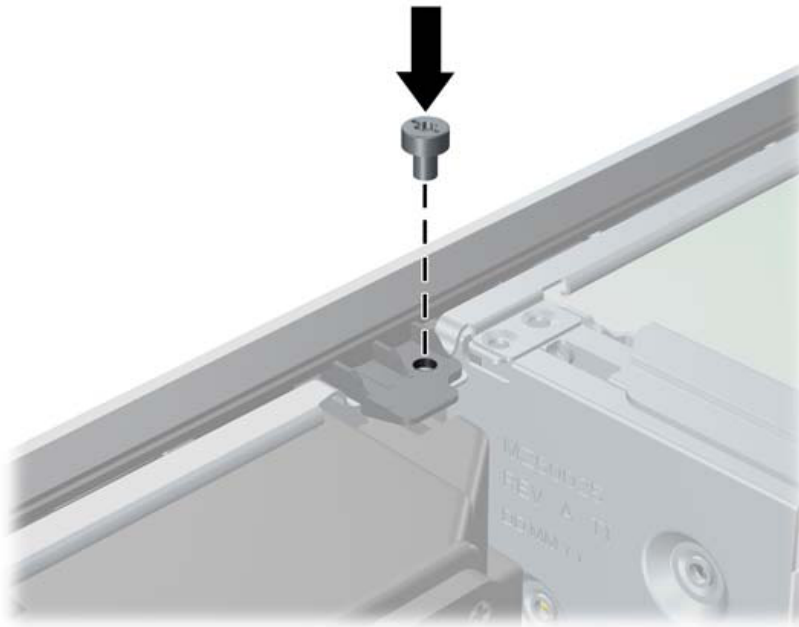
Front Bezel Security

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.

UNIT DISASSEMBLY

Retrieving the Front Bezel Security Screw
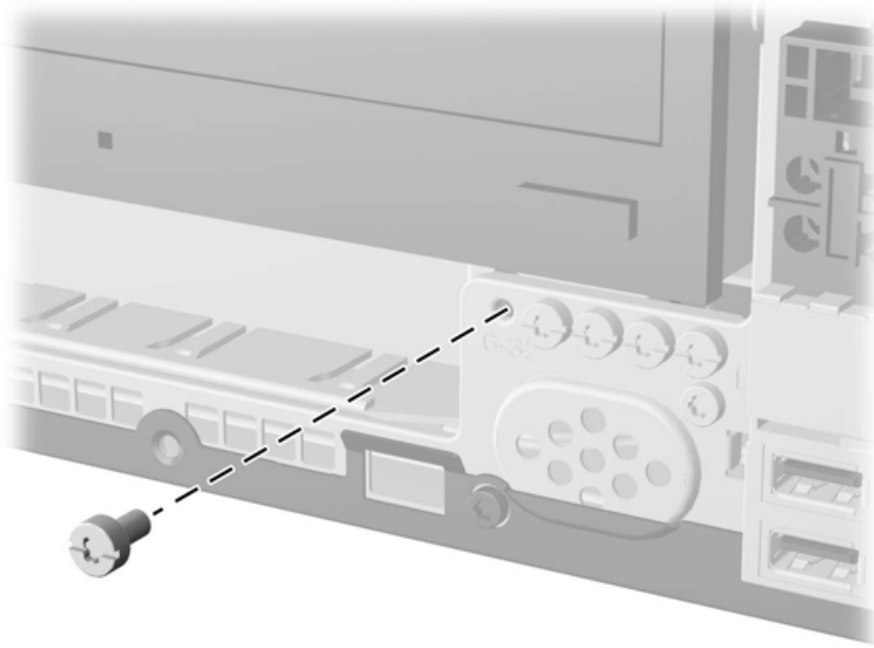
5. Replace the front bezel.
6. Install the security screw next to the middle front bezel release tab to secure the front bezel in place.

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

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UNIT DISASSEMBLY

HScribe 5 - Item Identification Table	
Mortara Item #	**Description**
25019-006-50	CABLE ASSEMBLY USB H3+
6400-012	CABLE USB TYPE A-TO-B FULL SPD (Printer)
9900-014	MONITOR 24" LCD 1920x1200 WIDE DVI + VGA
9903-013	DRIVE COMPACT FLASH EXTERNAL
9903-030	MOUSE 2-BUTTON w/SCROLL WHEEL USB
9906-037	CPU LONG LIFE w/WINDOWS 7 (
9907-016	PRINTER HP LASERJET USB + NETWORK
SERV PART 184-01	LONG LIFE PC POWER SUPPLY

UNIT DISASSEMBLY

TROUBLESHOOTING

Computer Faults

Dual colored power LED on front of computer to indicate either normal or fault condition
Diagnostic LED Explanation Table:

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

Printer Information/Settings

Driver: HP Universal Printing PCL5 (V5.4)

Recommended Raster Graphics Printer Setting:

To change the printer settings, click on <start>, then <Devices and Printers>
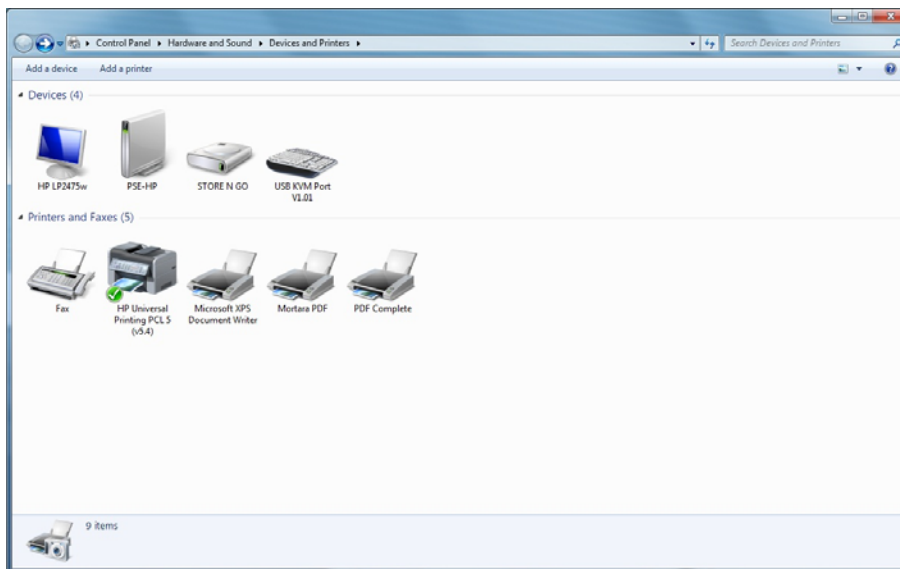
Right click on the appropriate printer. Select <Printer Properties>

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TROUBLESHOOTING

Click the Preferences button.
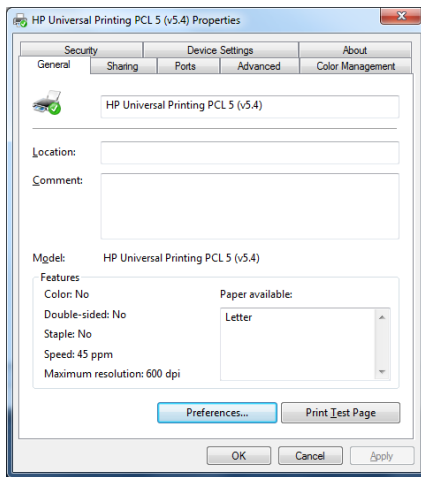
From the Advanced Tab, set Graphics Mode to: Send Graphics as Raster

TROUBLESHOOTING
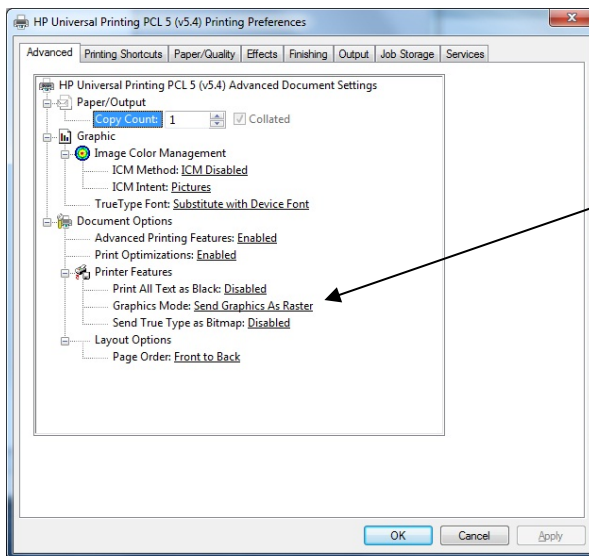
HScribe Application

Upon completion of installing software, Program Icons (grayed out) not able to access function.

You must click on the system configuration Icon ![icon] and setup User preferences (To configure user preferences to setup permissions to these functions).

Reference operator's manual for more details.

Unable to detect flashcard media

Check to ensure flashcard has volume label of: **Mortara_H12**

- From Windows explorer, right click on drive that has the CF card installed.

- Go to properties and check volume label

- Close Windows explorer.

Unable to detect H3+ recorder

- Ensure that the AAA battery is removed prior to USB download cable connection

- Is recorder listed in the Recording List in Hscribe?

- Is USB displayed on the H3+ display when connected to PC?
    - Check to ensure proper connection is made at the PC and at the recorder.
    - Check for damaged connector on cable and recorder.

- Is recorder listed in Windows explorer? It should be displayed as Mortara_H3.

- Close Windows explorer. (Contact Technical support)

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TROUBLESHOOTING

Windows "Scan and Fix" Message Appearing when CF card/Recorder connected
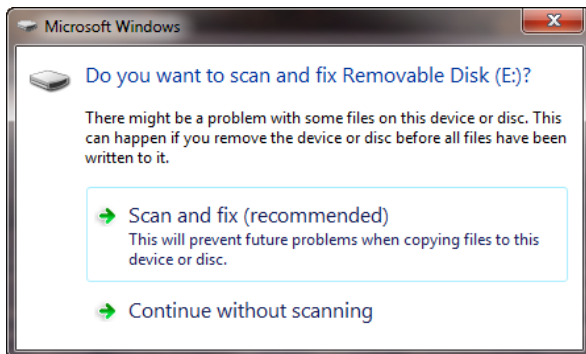
If the message above appears when inserting a CF card of H3+ recorder each time, and the system administrator would like to disable this message, the following steps can be performed.

Note – Disabling this feature will apply to all newly connected hardware devices and the decision to disable the feature should be considered in the context of the facility IT security policy.
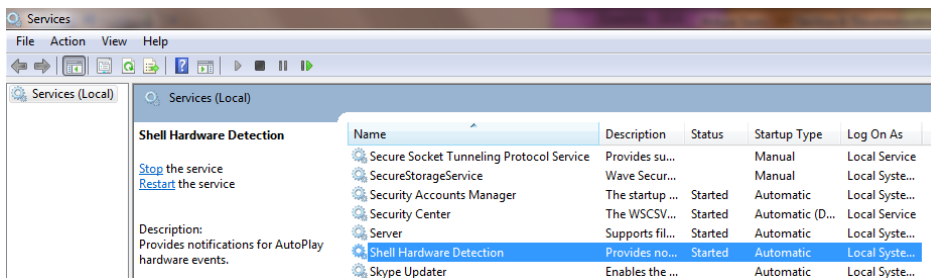
From the Services menu, select "Shell Hardware Detection". When the window below appears, change the "Startup Type" from Automatic to Disabled.

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TROUBLESHOOTING
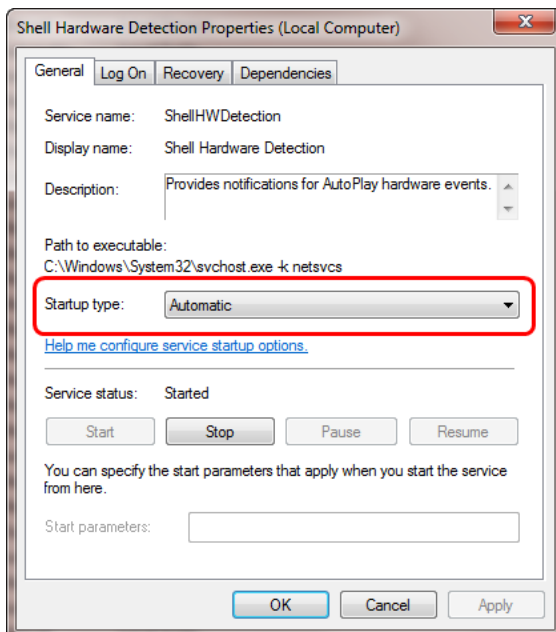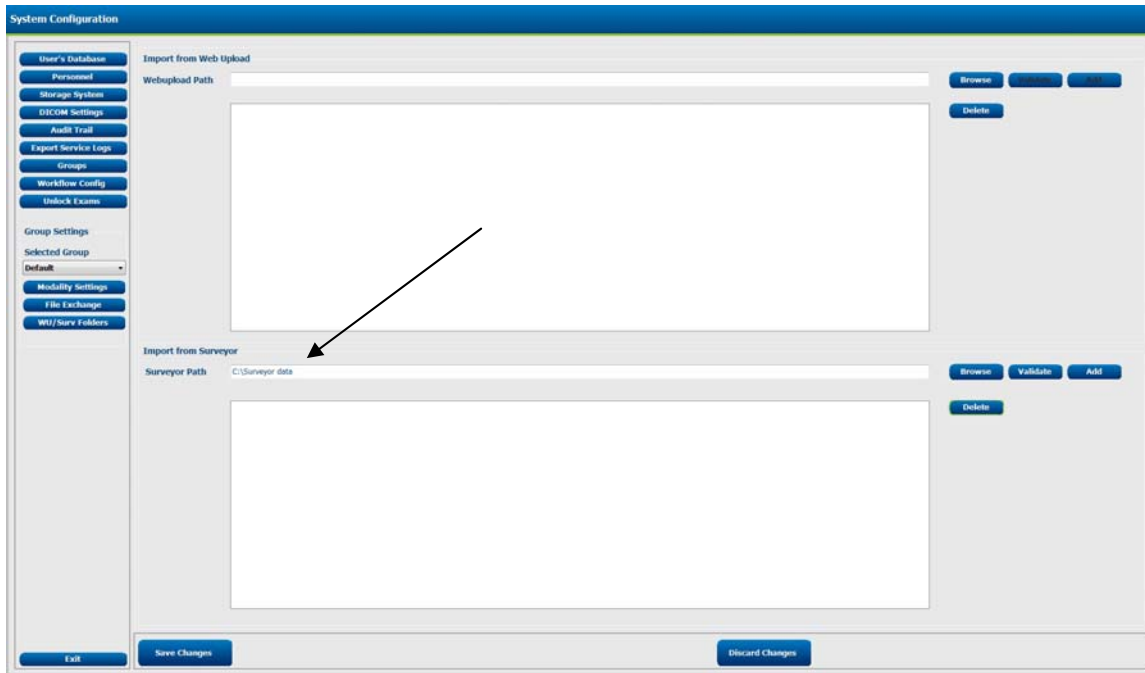
Unable to acquire Data from Surveyor Import

Click on system settings

Click on WU/Surv Folders and set the path to the location set in Surveyor Import. (E.g. C:\Surveyor data)

Verify data appears in recording list to import data

TROUBLESHOOTING

Unable to access MWL:

Open system configuration

Proceed to the MWL settings tab and ensure the information is correct.

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CONFORMANCE TESTING

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. System must be configured prior to tests. Testing results can be documented on the test data record provided at the end of this section of the manual.

Required Equipment:

- H3+ recorder or H12+ CF card with previously recorded data
- Legacy recordings <Where applicable>

Launch HScribe application and Login

HScribe will require user credentials on startup. The default factory username and password is **admin** (password is case sensitive).

Schedule Order <Where applicable>

The Schedule/Orders icon is only available when the modality is not linked to an external scheduling system. Click on the icon to open a window allowing you to schedule Holter exams and view the existing schedule (Refer to operator's manual for details).

Import H3+ and/or H12+ Compact Flash Card Recordings

Import H3+ Recording

Insert the USB interface cable connector into the recorder's input connector. A tone sounds indicating that the HScribe has detected the recorder. The recorder LCD will show "USB" indicating a powered connection.
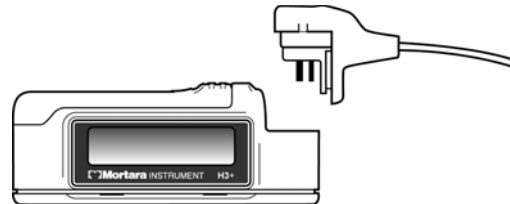
- Click on Import recording ICON

- Select recording from the recording list

- Click on Acquire recorder/card.

- Upon completion the Profile page will appear

CONFORMANCE TESTING

Import H12+ Compact Flash (CF) Card Recordings

Insert flashcard with data into the HScribe CF card reader.

- Click on Import recording ICON

- Select recording from the recording list

- Click on Acquire recorder/card. Upon completion the Profile page will appear

Review and Edit Recording

- Upon completion of the Holter data import and processing, or when a previously acquired recording is opened, the Profile screen is displayed.

- Press CTRL S to view Profile and ECG screen

- Verify the recorded data is present for the appropriate time period of the recording

- Select various strips and save to prepare a final report

Print final Report

- To open a preview of the final report, select **Print Report…** from the Exam pull-down menu or use the shortcut keys Ctrl + P. A preview is generated and the first report page is displayed.

- View each page of report for accuracy and print final report

CONFORMANCE TESTING

Export Data <Where applicable>

- Click on exam search ICON

- **Export** to send the exam data to the defined destination.

- Export is only available when the export feature is enabled.

- Export button is only enabled when the exam status is <u>Signed.</u>

- Verify exported files are in specified location as configured in File Exchange configuration

- Open and view PDF files

Import Legacy Recordings <Where applicable>

- Click on **Import Legacy** and browse to the directory where the legacy recordings are stored. Legacy recordings must be in folder named Usr on hard drive with names of PATxx for Legacy recordings .Once selected, all recordings at that location are shown in the Recording List.

- Click on **New Patient** under the Search Patient tab.The Exam Data Entry window opens displaying the existing demographics attached to the recording.

- Click **Confirm** after demographic information is complete and the Recording Information screen showing the recording and the recorder information is displayed.

- Upon completion, Click on exit and the Profile page will be displayed.

- Press CTRL S to view Profile and ECG screen

- Select various strips and save for final report. Print report.

CONFORMANCE TESTING

HScribe 5 Test Data Record

Software Serial #: _____

Software Version: _____

PASS / FAIL   HScribe application login

PASS / FAIL/NA   Schedule order

PASS / FAIL   Import data from Holter recorder

PASS / FAIL   Edit and review data

PASS / FAIL / NA   Print data

PASS / FAIL / NA   Export data

PASS / FAIL / NA   Import legacy recording

Performed by: _____ Date: _____/_____/_____

System Utilities

System Utilities

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

C:\Program Files (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

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System Utilities

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.

System Utilities

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.

System Utilities
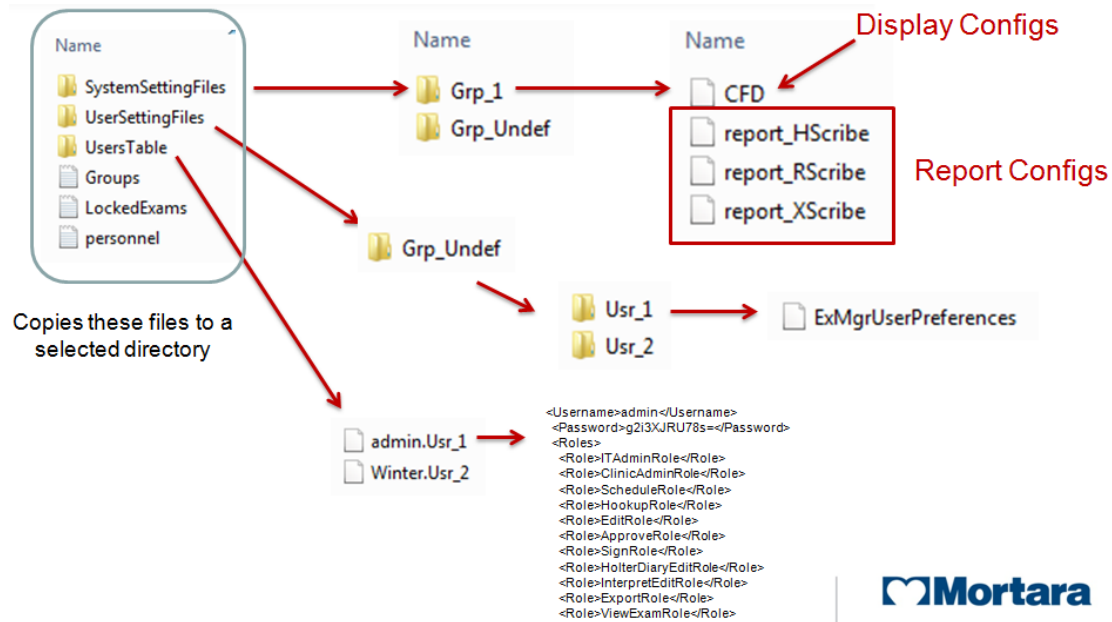
ActivationTool.exe

This utility will display the current software license status, serial number information, and all enabled options.
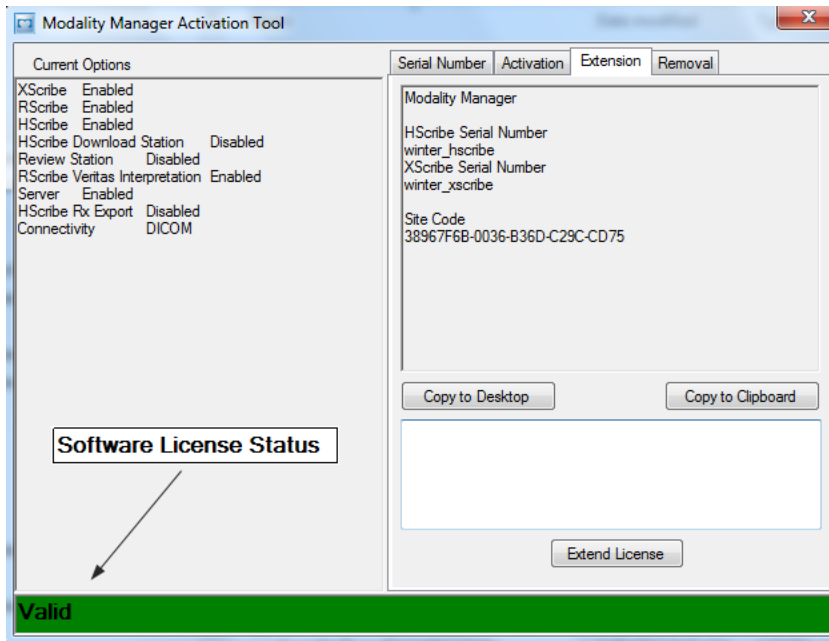
The serial number information is necessary when contacting a Mortara Service Center for technical assistance.

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.

System Utilities

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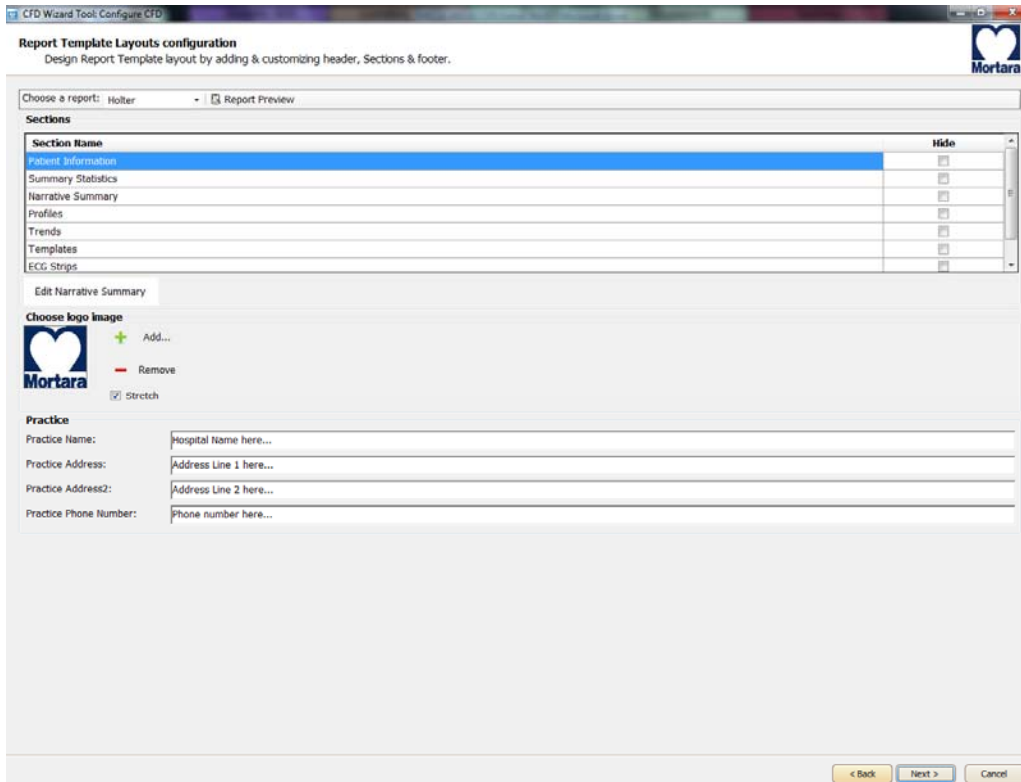
Customization of the Scribe 5 display appearance and reports are also available. Please contact your regional Mortara Service Center for assistance with this level of customization.

System Utilities

System Backup and Restoration

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 <u>must</u> 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**

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

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

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

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

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

  - o

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System Backup and Restoration

- o *Information regarding modifications to the backup file are located within the Backup.bat file itself.*
- o *Please contact Mortara Instrument Technical Support Group if you require assistance with modifying the backup file.*
- o *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.

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System Backup and Restoration

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

- Place the backup file into the appropriate folder:

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

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

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

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

  C:\Program Files\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.

System Backup and Restoration

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.*

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