**Mortara** INSTRUMENT

# H-Scribe
# Service Manual

CE
0459

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

# Technical Support and Service

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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 (H-Scribe) is used in accordance with the instructions for use.

**Responsibility of the Customer**

The user of this product 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 serial and part numbers on the side, back or bottom of the device. Care should be taken so that these numbers are not defaced.

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Warning: The H-Scribe System offers network capabilities and more than one system can be installed on the same network to exchange patient data and Final Reports. Remote sites share drives, and there is no login or password required to run the H-Scribe software. A higher level of security, however, can be achieved through an existing local network with a security policy already in place. It is the responsibility of the local network administrator to connect an H-Scribe System to a network and to assign users' login names and passwords.

# Warranty Information

## *Your Mortara Warranty*

MORTARA INSTRUMENT, INC. (hereinafter referred to as "Mortara") hereby warrants that Mortara products (hereinafter referred to as "Products") shall be free from defects in material and workmanship under normal use, service and maintenance for the warranty period of such Product from Mortara or an authorized distributor or representative of Mortara. The warranty period is defined as twelve (12) 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 Products caused by any or all of the following circumstances or conditions:

a) Freight damage;

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

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

d) Accident, a disaster affecting the Products;

e) Alterations or modifications to the Products 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 PRODUCTS 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 Products (i) of all carrier charges with respect to any Products 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, by its acceptance and purchase thereof, acknowledges and agrees that Mortara is not liable for loss, harm or damage due directly or indirectly to an occurrence or consequence therefrom relating to the Products. 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 when sold.

EXCLUDED FROM THE LIMITED WARRANTY SET FORTH ABOVE ARE CONSUMABLE ITEMS SUCH AS PAPER, 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 equipment. |
| **Note** | Provides information to further assist in the use of the device. |

**Federal law restricts this device for sale to and use by or on the order of a physician.**

⚠ **Warning**

- Device (Holter 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.

- 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 UL 2601-1, IEC 601-1 and IEC 601-2-25.

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

- If 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 operator's manual and any documents accompanying the device.

⚠ **Caution**

- 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 an alcohol-free sterilizing disinfectant, avoiding aggressive detergents; then dry with a clean cloth.

- The internal battery is a lithium type and is maintenance free. If the battery appears to become defective, contact Mortara Instrument, Inc. Technical Support Group.

- A Final Report that includes the Summary, Profile, Trends and 5 pages of strips (including 3 pages of 12-lead strips and one 6-minute strip page) in PDF format is approximately 1,760 KB in size. Final reports that are saved to the local hard drive will cause the system to fill over a period of time. These files will need to be removed from the hard drive prior to causing the system to cease to operate. Periodic checks of the H-Scribe System capacity are recommended. Contact Mortara Instrument, Inc. Technical Support Group for assistance with removal of these files.

- System environment:

  | | |
  | --- | --- |
  | Operating temperature: | +10° to +35° C |
  | Storage temperature: | -40° to +65° C |
  | Relative humidity: | 8% to 80% |
  | Altitude: | -50 to 10,000 ft |

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

- The H12+ Digital Recorder High Fidelity data requires a special version of H-Scribe software to export the 1,000 samples per second waveforms.  If you have standard H-Scribe software on your analysis system, you will not benefit from the acquisition of this High Fidelity data.

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


# Equipment Symbols

## *Symbol Delineation*

Attention, consult accompanying documents

CE Mark

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

# Table of Contents

# 1 | General Information

## *Service Manual Purpose*

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

## *User Safety Information*

### *Periodic Safety Inspections*

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

### *Do Not Operate in Explosive Atmospheres*

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

### *Do Not Mount Product above Patient*

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

### *Recommended Accessories*

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

### *Sterilizing this Product*

Do not sterilize this product or any accessories unless specifically directed by the manufacturer. Sterilization and sterilization environments can seriously damage many components and accessories.

### *Liquid Spills*

Do not set beverages or other liquids on or near the H-Scribe, and/or optional equipment.

# 2　Maintenance and Cleaning

## *Introduction*

This section provides maintenance and cleaning instructions for the H-Scribe system.

## *Recommended Cleaning Supplies*

- Anti-static mat & wrist band, properly grounded

- Clean, lint-free cloth

- Cleaning solvent (isopropyl alcohol, 70% pure)

- DRY, low pressure, compressed air (30 psi)

- Electronic safe non-residue solvent

- Naphtha

- Non-metallic, soft-bristle brush

- Vacuum cleaner, Static Safe

## *List of Repair Materials*

- Screwdriver Philips #2

- T15 Torxdriver

*Note:　The equipment and solvent mentioned above are standard shop commodities that are available from commercial sources.*

## *Preventive Maintenance Schedule:*

| Maintenance to be Performed | Period | Notes |
|---|---|---|
| Clean and inspect system | 6 mo. | More frequent cleaning may be required in unusually dusty or dirty environments. |
| PC Performance check | 1 Yr. | Use of standard Windows utilities sufficient |

## PC Performance Check

⚠

### WARNING

*Additional third party software installed on any Mortara PC based system may affect the integrity of the system. Mortara is not responsible for issues resulting from the use or installation of additional software by non-Mortara personnel.*

- Check the hard disk space to verify the system is not nearing capacity; this could have an adverse affect on overall system performance (see below).

- Also check the **Programs** menu for any 3rd party software that may have been installed since the last maintenance check.
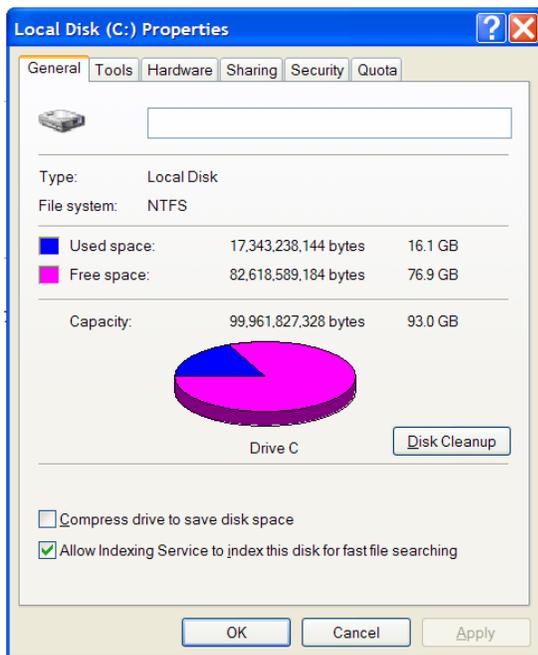
## *Cleaning and Inspecting Techniques*

This section contains instructions for periodic cleaning and inspection of the instrument as preventive maintenance measures



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### WARNING

*Ventilate work area thoroughly when using solvents. Observe manufacturers warnings on solvent containers with regard to personnel safety and emergency first aid. Be sure that first aid equipment is available before using chemicals. Observe shop safety and fire precautions. Ventilate all work areas where solvents are used. Store solvents and solvent-soaked rags in approved containers. Refer to manufacturers' instructions on containers for recommended fire-fighting procedures, and make sure that fire-fighting equipment is available.*

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### *Exterior Cleaning*



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### CAUTION

*Unplug from power outlet before cleaning.  Do not wipe over surfaces of nameplates or labels with abrasive cleaners or materials, as this will eventually wear away the nameplate information. Do not use solvents to clean plastic parts.*

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Use a damp, clean cloth to wipe off external surfaces and the line cord. Do not use solvents, or cleaning solutions that may damage the surface of the instrument. Alcohol or naphtha will not damage the unit's exterior. Avoid contact with open vents, plugs, and jacks. Naphtha removes sticker residue.

### *Interior Cleaning*

- Vacuum any dust or debris that may have collected in the PC housing, paying special attention to air ventilation passages and air cooling fans.

- Brush all surfaces and parts with a non-metallic, soft bristle brush.

- Wipe metal surfaces with soft, non-abrasive cloth dampened with isopropyl alcohol.

- Dry surfaces with clean cloth.

## Printed Circuit Board Cleaning

- The printed circuit board assemblies in the H-Scribe system contain static sensitive devices. Use special handling procedures to prevent damage due to ESD.

- Clean assembled parts with a vacuum cleaner or low pressure compressed air (30 psi). Take care when cleaning printed circuit boards that wires or component leads are not bent back and forth in such a manner as to weaken them and cause them to eventually break.

- Dry with low pressure compressed air.

## Monitor Cleaning

### WARNING

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

Unplug the monitor from the power outlet before cleaning.

- To clean your monitor screen, lightly dampen a soft, clean cloth with water or mild detergent. If possible, use a special screen cleaning tissue or solution suitable for the anti-static coating.

- To clean the monitor cabinet, use a cloth lightly dampened with mild detergent. Make sure that water can not drip into the case of the monitor.

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

## Compact Flash Card Reader Cleaning

### WARNING

*Safety glasses should be worn when using spray solvents to prevent the possibility of eye injuries.*

- Use "Electronic safe non-residue solvent" to carefully spray the connector pins to remove any residue, dust or debris that may have collected.

- Dry with low pressure compressed air.

## 3 │ **System Description**

### *System Description*

The H-Scribe System is a high-speed, PC-based Holter scanner.  Designed in conjunction with the H3+ Digital Holter recorder, the H12+ Digital Holter recorder and the X12+ ambulatory transmitter data received by the Surveyor Central patient monitoring system, the H-Scribe System provides three channels of full disclosure data for arrhythmia analysis and 12-Lead ST segment analysis depending on the recorder type used.  The H-Scribe System incorporates Mortara Instrument's exclusive VERITAS™ algorithm for superior beat detection and analysis. The H-Scribe System is offered in two versions.

- The H-Scribe Clinic Holter System is designed for institutions that need a centralized system for acquisition of H3+ 2-channel or 3-channel Holter data, review, editing, final report generation and archiving.  This is the central system on the network and allows acquisition of H3+ recorded Holter data, review, editing, final report generation and archiving.  This model allows the institution to take advantage of advanced scanning options, Final Report export, the network and multiple Patient List capabilities.

- The H-Scribe Enterprise Holter System is designed for large institutions and users that desire to take advantage of advanced acquisition options (Holter data uploaded to a web server and Surveyor Central 12-Lead telemetry patient monitoring data), the network and multiple Patient List capabilities.  This is the central system on the network and allows downloading of H3+ and/or H12+ recorded Holter data, review, editing, final report generation, final report export and archiving.

The H-Scribe Remote Download Station is designed for users that need a system for acquisition of Holter data and final report review.  This configuration does not allow review and editing of the Holter data and requires network connection to an H-Scribe Enterprise or Clinic system.  This configuration offers the ability to acquire recordings from both H3+ and H12+ recorders with the Enterprise System or H3+ with the Clinic System.  This model also supports multiple Patient List and network capability.

The H-Scribe Review Station is designed for users that need review, editing, final report generation and archiving capabilities.  This configuration does not allow acquisition of patient recordings and requires network connection to an Enterprise or Clinic system.

The H12+ Digital Holter Recorder records 12-lead ECG continuously for a 24-hour period using a 24-hour Compact Flash card.  The H12+ 48 Hour Digital Holter Recorder records 12-lead ECG continuously for up to 48 hours with the 48-Hour Compact Flash card.

The H3+ Digital Holter Recorder records two or three channels of continuous ECG data over a 24-hour or 48-hour period.  Stored ECG data is downloaded for analysis to the H-Scribe System with a USB interface cable after the H3+ patient cable has been disconnected from the recorder.  After the data is acquired at the H-Scribe System, the H3+ recorder memory is cleared and the recorder can be prepared for the next recording session using the H-Scribe application software.

The Surveyor Telemetry Central System at software version 3.00 and later receives 12-lead ECG data from the X12+ ambulatory transmitter.  The full disclosure monitoring data is imported into the H-Scribe system through the use of the H-Scribe Surveyor Import application.  Any Surveyor Central patient monitoring period up to 48 hours in duration can be chosen for Holter analysis.

24 and 48 hour Holter recordings can optionally be uploaded to an institution web server with the H-Scribe Web Option software component integrated into the web service from a remote client computer over the internet.  The H-Scribe system will then connect to and acquire the recordings from the web server for full Holter analysis.

Report formats include scan criteria, report summary, rhythm profile, 24-hour trends of all arrhythmias and ST segment changes, operator-selected strips in one, two, and three or twelve leads and full disclosure of three channels.

The user may customize the scanning criteria that are used to analyze a patient record.  Most changes, with a few exceptions, are instantly applied to the current analysis which eliminates the time spent on rescanning.  Scan criteria are saved on a per-patient basis and affect the current patient's analysis only, unless the user desires to modify the user preferences or scan criteria for future analyses.

Multiple recordings with analyses are stored on the hard drive of the H-Scribe System in patient slots. The user can select a patient slot to store a new recording or to review existing analyses.

Long term storage of full disclosure patient recordings is accomplished by archiving data to DVD-RW or CD-RW media as well as a local or network drive. Archived patient recordings can be restored to the H-Scribe system for further analysis, review, report export or printing at any time.



**H-Scribe System with CF Card Reader and Optional Cassette Reader**

## H-Scribe System Specifications

| CPU: | Pentium class tower |
|---|---|
| **Operating System:** | Windows |
| **Storage:** | Hard drive, DVD+/-RW or CD-RW disc, any arbitrary drive |
| **Input devices:** | H3+ USB interface cable, Compact Flash card reader; extended keyboard and 2-button mouse with wheel; 3.5" floppy disk drive, DVD+RW/CD-RW drive, Cassette reader (optional) |
| **Monitor:** | Color monitor |
| **Printing Device:** | High speed laser printer |
| **Operating Environment:** | Operating temperature: +10° to +35° C<br>Storage temperature: -40° to +65° C<br>Relative humidity: 8% to 80%<br>Altitude: -50 to 10,000 ft |
| **Power Requirements:** | 100 - 240 VAC at 50/60 Hz<br>800 watts maximum, 400 watts average |

# 4 Serviceable Items

## *System Identification*

Please provide the system serial# when contacting Mortara for servicing; the number will be located in the center of the serial # label pictured below.
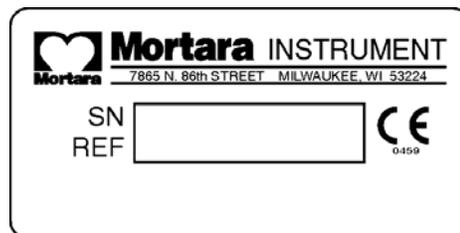


## *PC Interconnections*
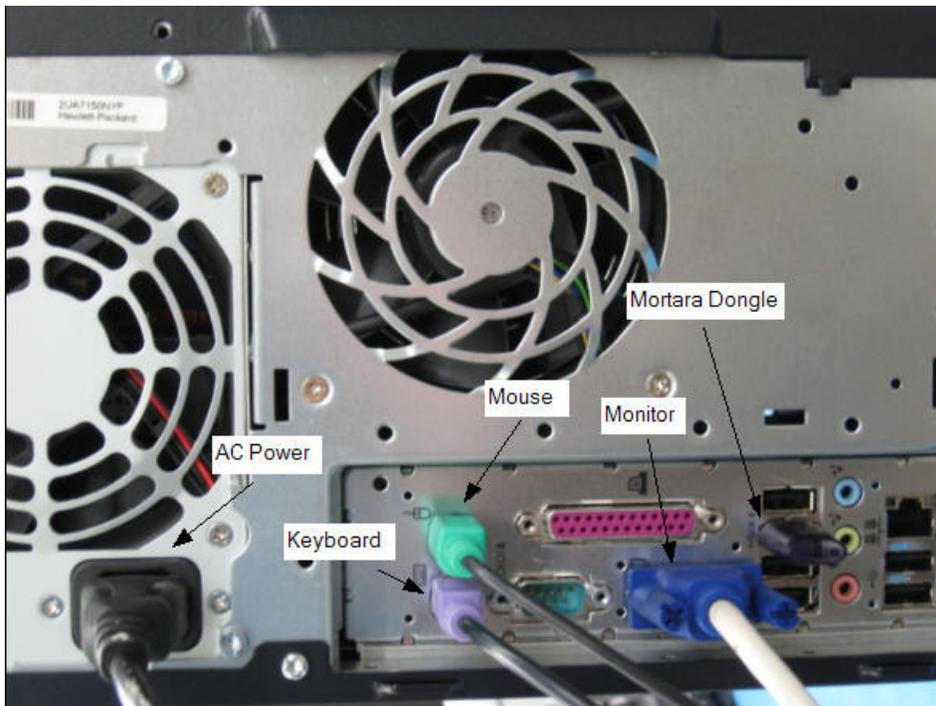
## PC Disassembly
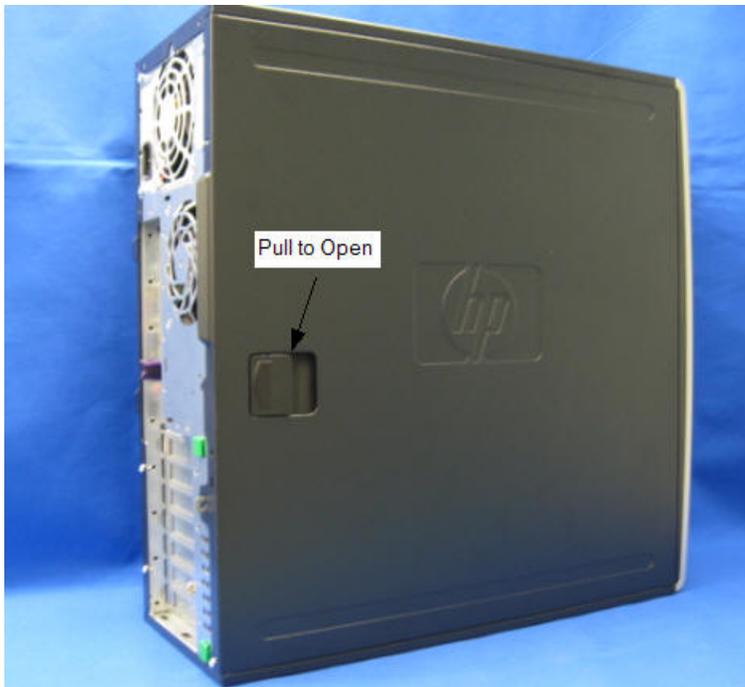


To open the PC cover, pull the cover latch.

## PC Components



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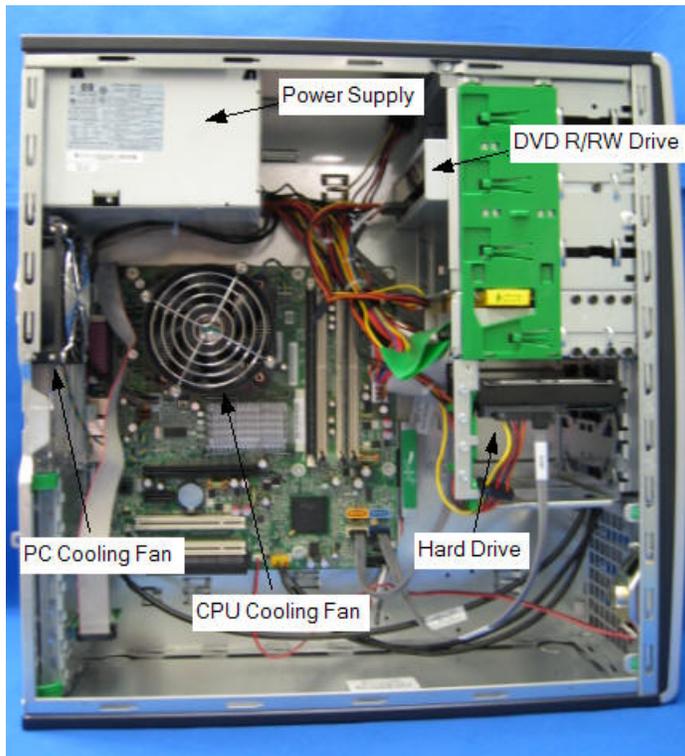
**WARNING**

*The cooling fans identified above should <u>always</u> be rotating when the PC in operating; if the fans are not rotating, or they appear to be running at less than optimal speed, the fans should either be cleaned or replaced prior to continued operation.*

---

The PC parts identified above (with the exception of the cooling fans) are considered "Field Replaceable" and can be purchased through Mortara, if desired (refer to the item listing for Mortara part numbers).



**DRIVE COMPACT FLASH EXTERNAL**

## *System Restoration*

⚠

> **WARNING**
>
> *The System Restoration process will overwrite <u>ALL</u> stored patient data, custom settings, and additional software or data that was loaded on the system. The PC will be restored to the exact state it was in, when delivered from Mortara Instrument.*

The System Restoration option should **<u>only</u>** be used on a system that is experiencing serious performance issues, or if the system is to be reassigned to a new facility or departmental area.

⚠

> **CAUTION**
>
> *Before performing system restoration, make sure you have properly identified the PC model number. The PC has an identification sticker indicating the model. If you have any questions regarding the identification, contact Mortara Service for assistance.*

**HP Model 7700 restoration process:**

- Turn the system on and then press the F11 key when instructed to do so. After some time, the PC Recovery Wizard will appear.

- Make sure the option "Recover the PC to a specific point in time" is selected and then click on Next.

- Under Description, click on "Initial Recovery Point" (or the most recent recovery point installed by the manufacturer) and then click on Next.

- In the Smart PC Recovery screen, select the option "Recover PC without preserving new and updated files" and then click on Next.

- Click on Yes to begin the Recovery Process. The drive will first be formatted; then the Recovery Point will be copied.

- Once the Recovery Process is complete, click on Restart. The system will then reboot. Log back into the system, and then click on Yes to restart the system. Log back into the system.

# Mortara Parts List

| ITEM NUMBER | ITEM DESCRIPTION |
| --- | --- |
| | |
| 25019-006-50 | CABLE ASSEMBLY USB H3+ |
| 9900-010 | MONITOR 19" LCD PANEL |
| 9903-013 | DRIVE COMPACT FLASH EXTERNAL |
| 9903-016 | MOUSE 2-BUTTON w/WHEEL PS/2 WHITE (PUTTY) |
| 9907-012 | PRINTER HP LASERJET |
| 9912-001 | CABLE LASER PRINTER TO CPU |
| 9930-033 | DVD+RW REWRITABLE 4.7Gb W/ JEWEL CASE |
| 9970-009 | KEYBOARD 104-KEY PS/2 WHITE |
| SERV PART 147-01 | H-SCRIBE DVD-ROM 16X/48X |
| SERV PART 147-02 | H-SCRIBE CASSETTE READER |
| SERV PART 147-03 | DVD R/RW DRIVE |
| | |
| **RECONDITIONED RECORDERS** | |
| SERV R50002-009-2000 | RECONDITIONED H12 DIGITAL RECORDER |
| SERV R50002-011-1000 | RECONDITIONED H12+ 24H DIGITAL RECORDER |
| SERV R50002-011-1001 | RECONDITIONED H12+ 48H DIGITAL RECORDER |
| | |
| **CF CARDS** | |
| 11018-001-50 | H12+ 24H FLASH CARD ASSEMBLY (current version) |
| 11018-001-52 | H12+ 48H FLASH CARD ASSEMBLY (current version) |
| 11018-002-50 | H12+ 512M FLASH CARD ASSEMBLY (current version) |
| **OLDER CF CARD VERSIONS** | |
| SERV CF 128-V3.13 | H12+ 128MB 24HR CF CARD VER 3.13 |
| SERV CF 48HR-V3.12 | H12+ 48H FLASH CARD ASSEMBLY VER 3.12 |
| SERV CF 48HR-V3.13 | H12+ 48H FLASH CARD ASSEMBLY VER 3.13 |
| SERV CF 512-V3.13 | H12+ 512MB FLASH CARD ASSEMBLY VER 3.13 |
| SERV CF 64-V3.12 | H12+ 24H FLASH CARD ASSEMBLY VER 3.12 |
| SERV CF 64-V3.13 | H12+ 24H FLASH CARD ASSEMBLY VER 3.13 |
| | |
| SERV R9960-039-51 | RECONDITIONED COMPACT FLASH CARD & ADAPTER ASSEMBLY (H12 RECORDER ONLY) |

# 5   **Troubleshooting**

## *PC Issues*

- System will not power up

  *Items to check prior to contacting Mortara Customer Service Center*
    - o   Check power connections
    - o   Is the PC fan turning?
    - o   Are there any LEDs (lights) on the front panel of the PC?
    - o   Does the display show anything at all?
    - o   Is Windows starting to load?
    - o   Does Windows finish loading and bring up the desktop?
    - o   Are there any error messages

- H-Scribe application will not run

    - o   Is software dongle installed?
    - o   Dongle Failure?
        - ▪   Replace the dongle

- Network Connectivity

    - o   Ping the remote workstation or networked device

- OS Errors or Bugs

    - o   Run Windows Update

## *Acquiring Data from CF Card*

- PC won't recognize card
    - Check windows explorer to verify system sees card.
    - Attempt to access card. If you are unable to access card it is likely a hardware problem with the flashcard. (contact Technical Support)

- Application can not acquire data from card
    - Verify flashcard has data files via Windows Explorer
    - Verify flashcard has correct Volume Label  **Mortara_H12**

- Error Messages
    - Incorrect recorder date



    - DATAF file is corrupt
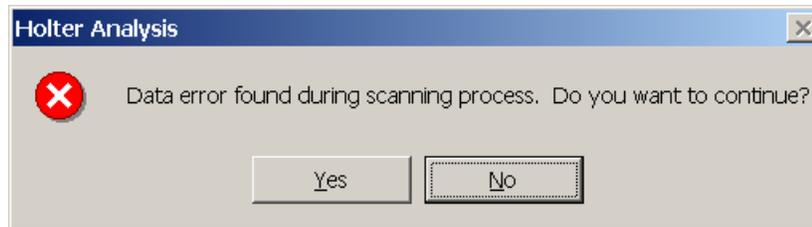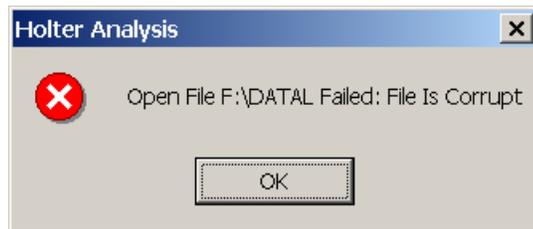
o DATAQ file is corrupt

**Holter Analysis** ✕

The entire recording has lead failure. Check your patient cable and its connectors.

OK

**Holter Analysis** ✕

This patient data appears to have no valid beats.

OK

o DATA0 file is corrupt

**Holter Analysis** ✕

The recording has zero samples

OK

o DATAT file is Corrupt

**Holter Analysis** ✕

Data error found during scanning process. Do you want to continue?

Yes    No