

HSCRIBE Technical System Requirements

Overview

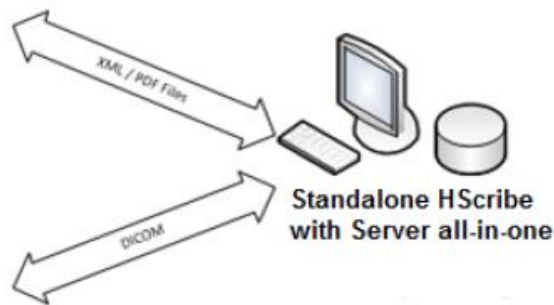
Purpose of this Document:

HSCRIBE is a high-speed, PC-based Holter product, that is used in conjunction with H3+™ and H12+™ digital Holter recorders. 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+, H12+, or a compact flash (CF) memory card is downloaded for analysis to the HSCRIBE. After acquisition and data upload, the recorder or CF memory card is erased and prepared for the next recording session using the HSCRIBE application software.

Configurations

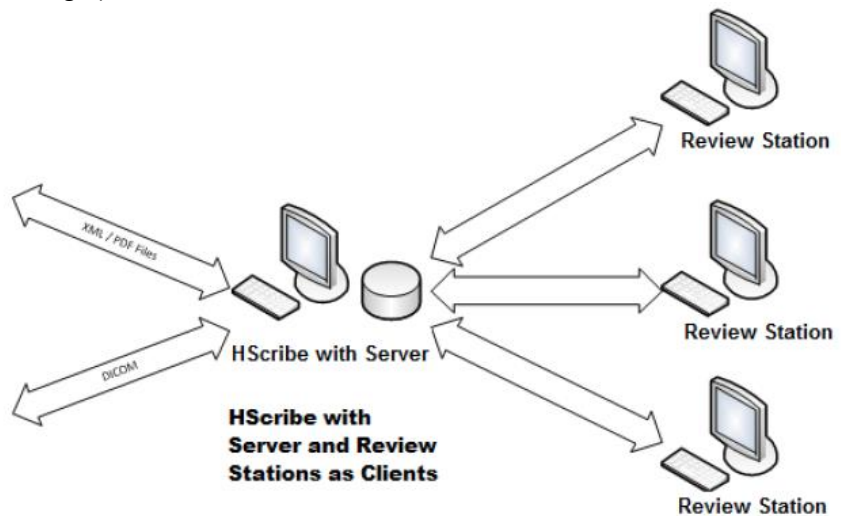
Standalone with Server

The simplest installation is a Standalone HSCRIBE with a local Server:



Standalone with Server and Review Stations

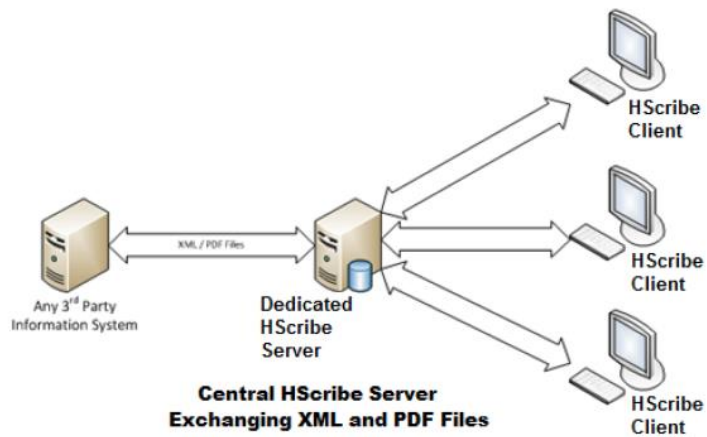
A small number of Review Stations can be networked to a HSCRIBE that hosts the central server (Modality Manager):



Note: It is highly recommended to move to a Dedicated HSCRIBE Server configuration (shown on next page) if more than 4 clients are intended to be connected.

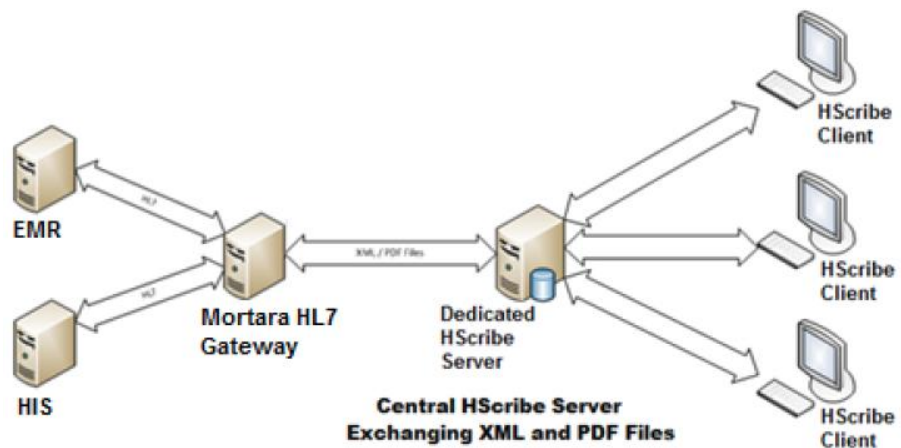
Client-Server with XML/PDF exchange

A central dedicated HScribe Server can be hosted on server hardware with any number of HScribe workstations as clients. Any 3rd-party information system can exchange XML and PDF files with the HScribe Server:



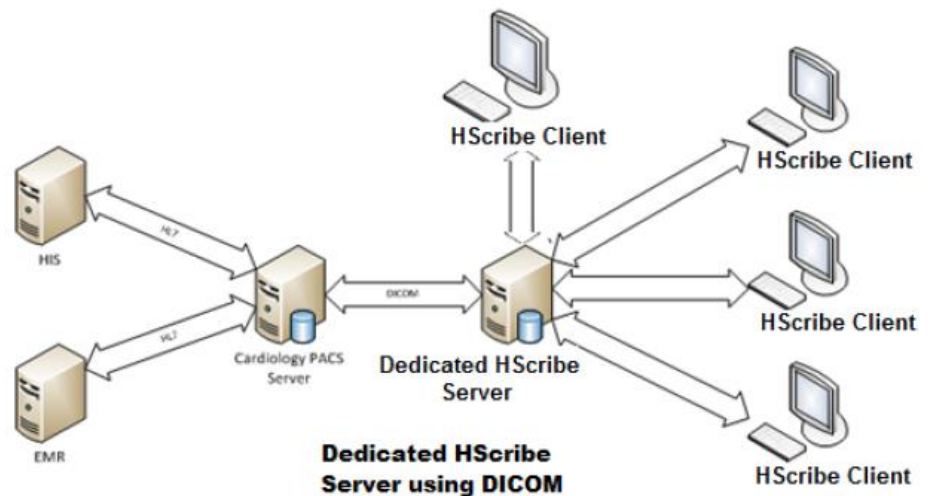
Client-Server with HL7 Gateway

A Mortara® HL7 Gateway can be added to the solution to enable exchange of HL7 messages between Health Information Systems (HIS) and Electronic Medical Record (EMR) systems and the central HScribe Server:



Client-Server with DICOM®

The central Modality Manager can exchange DICOM messages with a cardiology PACS system:



System Requirements

Workstation Minimum Specification

- **Processor:** Intel® Core i3-2120 3.30 GHz dual core CPU or better
- **OS:** Windows® 7 Pro (32 bit or 64 bit) or Windows® 10 Pro (64 bit)
- **Memory:** 8 GB
- **Graphics & Monitor:** 1920x1080 or 1920 x 1200 32-bit resolution
- **Hard Drive:** Minimum 160 GB free disk space
- **Archive:** Network or USB drive
- **Input Devices:** Standard keyboard and mouse
- **Software Installation:** CD or DVD ROM drive
- **Network:** IEEE 802.3 Wired LAN, 100 Mbps or faster
- *Additional LAN port if LAN option present*
- **USB Ports:** Minimum 3 USB 2.0 ports

Server Minimum Specification *(Server Installations Only)*

Specifications below are for a distributed system of up to 25 clients to 1 server.

- **Processor:** Performance equivalent to Intel® Xeon™ class, Quad-Core with hyper-threading
- **OS:** Windows® 2008 Server R2 SP1 or Windows® Server 2012 R2, 64-bit
- **Graphics:** 1024 x 768 resolution
- **Memory:** 4 GB
- **Software Installation:** CD or DVD ROM drive
- **Network:** IEEE 802.3 Wired LAN, 100 Mbps or faster
- **System Disk:** 100 GB for OS and product installation
(RAID recommended for data redundancy)
- **Data Disk:** 550 GB available, HD controller with 128 Mb read/write cache
(RAID recommended for data redundancy)

Specifications below are for a distributed system of up to 90 clients to 1 server.

- **Processor:** Performance equivalent to Intel® Xeon™ class, Quad-Core with hyper-threading
- **OS:** Windows® 2008 Server R2 or Windows® Server 2012 R2, 64-bit
- **Graphics:** 1024 x 768 resolution
- **Memory:** 16 GB
- **Software Installation:** CD or DVD ROM drive
- **Network:** IEEE 802.3 Wired LAN, 1 Gigabit
- **System Disk:** 100 GB for OS and product installation
(RAID recommended for data redundancy)
- **Data Disk:** 1 TB available, HD controller with 128 Mb read/write cache
(RAID recommended for data redundancy)

If running on a virtual machine, designated resources should be comparable to the recommended specifications for the HSCRIBE server as given above.

Citrix XenApp Review Station

Client

- **OS:** Windows 7 Professional 64-bit or Windows 10 Professional 64-bit
- **Internet Browser:**
 - Internet Explorer 11 and 10 (*HTTP connections only*)
 - Safari 7
 - Google Chrome 43 and 42
 - Mozilla Firefox 38 and 37

	<ul style="list-style-type: none"> ○ Any other Browser Supported by Citrix <p>Citrix Domain Controller Server</p> <ul style="list-style-type: none"> ▪ OS: any supported by Citrix ▪ Citrix XenApp Desktop Enterprise Edition 7.9 <p>Citrix Application Servers</p> <ul style="list-style-type: none"> ▪ OS: Windows 7 Professional 64-bit or Windows 10 Professional 64-bit ▪ Citrix Virtual Delivery Agent 7.9 ▪ Hscribe application v6.2.0 or higher
Antivirus Software	Compatibility with major corporate antivirus software packages has been verified and the use of antivirus (AV) software on computers hosting the Hscribe application is recommended. Welch Allyn 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, antivirus patch updates and system scans should be scheduled for time periods when the system is not actively in use or performed manually. AV software updates (software and definition files) should not be applied during active use of the Hscribe application.
User Authentication	Active Directory for User Authentication
Database	<ul style="list-style-type: none"> ▪ PostgreSQL v9.6
Product Services Installed	<ul style="list-style-type: none"> ▪ CorScribeDBsvc ▪ CorScribeAppServer ▪ CorScribeGateServer ▪ CorScribeLogServer
DB Admin Account	The CorScribeDBusr account cannot be altered in any way
Encryption	<p>The Hscribe database folders may be configured for Windows Encrypted File System (EFS) for protection of patient data security.</p> <p>NOTE: The Hscribe system database must be unencrypted prior to performance of any software upgrades.</p> <p>All H3+ recorders and H12+ Compact Flash cards must remain unencrypted for software to work properly (e.g. technologies such as BitLocker should not be used).</p>
DB Admin Account	The CorScribeDBusr account cannot be altered in any way
Backup/Restore	Backups performed manually to either a Network or external USB drive

System Capacity (per Server)

<i>Clients/Server</i>	Limit of 90 clients per Server (Note: dependent on Server Minimum Specifications above)
<i>Est. Size of Holter Exams</i>	Average: 300 MB for 24-hour exam
<i>Stored Exams in DB</i>	160 GB Drive – 520 exams 550 GB Drive – 1,800 exams 1 TB Drive – 3,300 exams <i>(assuming average 300 MB exams)</i>
<i># of Active Concurrent Users</i>	Up to 90 (Note: dependent on Server Minimum Specifications selected above)
<i># of Active Orders</i>	512

Connectivity Interfaces

<p>Orders</p>	<p>Supports external orders in the following formats:</p> <ul style="list-style-type: none"> ▪ XML <ul style="list-style-type: none"> ○ Mortara XML ○ Accepts orders via XML files saved by external system in a shared folder ▪ DICOM® Modality Worklist <ul style="list-style-type: none"> ○ Able to retrieve Holter test orders from a DICOM® Service Class Provider (SCP) by performing a DICOM® Modality Worklist query (<i>Query parameters are configurable per Group, see below</i>) ▪ HL7 (<i>by adding optional Mortara® HL7 Gateway</i>)
<p>DICOM® Modality Worklist query parameters</p>	<ul style="list-style-type: none"> ▪ Modality ▪ Institution Name ▪ Scheduled Station Name ▪ Scheduled Procedure Step Location ▪ Current Patient Location ▪ Requested Procedure Location ▪ Scheduled Procedure Step Description ▪ Scheduled Station AE Title ▪ number of days before and after “today ▪ Requested Procedure Description
<p>Export Formats</p>	<p>Supports exporting data in the following formats:</p> <ul style="list-style-type: none"> ▪ PDF ▪ XML ▪ DICOM® encapsulated PDF ▪ HL7 (<i>by adding optional Mortara®HL7 Gateway</i>)

Associated Software

<ul style="list-style-type: none"> ▪ Mortara® HL7 Gateway ▪ The Surveyor™ Central system (v3.00 and later) can receive 12-lead ECG data from a telemetry device. Full-disclosure patient monitoring data can be imported into HSCRIBE for Holter analysis using the HSCRIBE Surveyor Import application. ▪ Mortara Web Upload
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Remote Service Support

<p>Software</p>	<ul style="list-style-type: none"> ▪ Teamviewer v8.0 ▪ WebEx ▪ SecureLink ▪ Remote Desktop ▪ VPN
<p>Support Account</p>	<p>A service account should be set up by the IT department that has domain administrator privileges for troubleshooting.</p>

Hardware Interfaces

- Printers**
 - HP® LaserJet Printers with PCL5 driver (*recommended*)

Physical Characteristics

Operating Environment	Operating Temperature: +10 to +35 deg. C (+50 to +95 deg. F) Storage Temperature: -40 to +65 deg. C (-40 to +149 deg. F) Operating Humidity: 8% to 80%, non-condensing Storage Humidity: 8% to 80%, non-condensing Altitude (Pressure): 3,000 meters
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Supporting Documentation

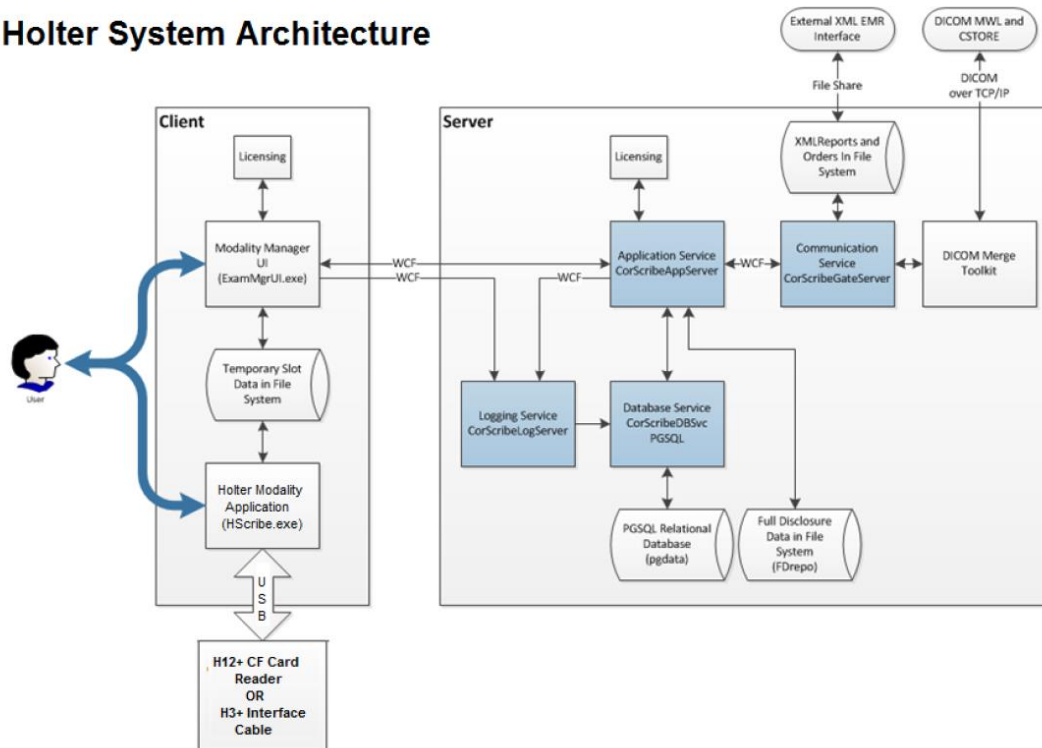
Manuals	IFU: 9515-213-71-xxx Physician's Guide: 9515-213-70-xxx MDS2: 9710-213-xx-ENG H3+ IFU: 9515-165-50-xxx H12+ IFU: 9515-160-50-xxx
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*xxx represents language specific extension (e.g. XXX = ENG, is the English manual)

** xx represents a number that increments for each version release

Architecture Diagram

Holter System Architecture



Digital Holter Recorders

H3+ - Digital Holter Recorder



Input Channels	Simultaneous acquisition of 3 channels
Leads Acquired	Modified I, II, III, aVR, aVL, aVF, and V
Input Impedance Input Dynamic Electrode Offset Tolerance Frequency Response	Meets or exceeds the requirements of IEC 60601-2-47
Digital Sampling Rate	180 s/sec/channel used for standard recording and storage
Special Functions	Pacemaker detection ECG display during hookup
A/D Conversion	12 bits
Data Storage and Capacity	Internal, non-volatile memory 48-hours 7-days (Not approved for US)
Device Classification	Type CF defibrillator-proof applied parts internally powered
Weight	1 oz. (28 g) without battery
Dimensions	2.5 x 1.0 x 0.75 inches (64 x 25 x 19 mm)
Battery	(1) AAA alkaline required

H12+ - 12-lead Digital Holter Recorder



Input Channels	Input Channels Simultaneous acquisition of all leads
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
Input Impedance Input Dynamic Range Electrode Offset Tolerance Frequency Response	Meets or exceeds the requirements of ANSI/AAMI EC38
Digital Sampling Rate	Digital Sampling Rate 10,000 s/sec/channel used for pacemaker spike detection 180 s/sec/channel used for standard recording and storage
HF Digital Sampling Rate	HF Digital Sampling Rate 1,000 s/sec/channel used for high-fidelity data storage
Special Functions	<ul style="list-style-type: none"> ▪ Pacemaker detection ▪ ECG display ▪ Lead quality check
A/D Conversion	20 bits
Storage	Compact flash memory card
Device Classification	Type CF Internally powered
Weight	4 oz. (125 g) without battery
Dimensions	2.5 x 3.5 x 0.98 inches (64 x 91 x 25 mm)
Batteries	(1) AA alkaline required for 24-hour recording (1) AA lithium required for 48-hour and for high-fidelity recordings