

Genius™

Image Management Server

Dashboard

User's Manual

Genius™ Image Management Server Dashboard User's Manual

HOLOGIC®



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The Genius™ Digital Diagnostics System is a PC-based automated imaging and review system for use with ThinPrep cervical cytology sample slides. The Genius Digital Diagnostics System is intended to help a cytologist or pathologist highlight objects on a slide for further professional review. The Product is not a replacement for professional review. Determination of slide adequacy and patient diagnosis is at the sole discretion of the cytologists and pathologists trained by Hologic to evaluate ThinPrep-prepared slides.

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Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. Use of the Genius™ Image Management Server not in accordance with these instructions may void the warranty.

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7-2025

Revision History

Revision	Date	Description
AW-32545-001 Rev. 001	7-2025	Initial release without the IVD intended use statement. Add description of remote access with SecureLink software. Add information for 20-mm circle, 10-mm circle, Sample Detect and Whole Slide Imaging scan profiles. Administrative changes.

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Table of Contents

Chapter One

Introduction

Overview	1.1
The Genius Digital Diagnostics System	1.3
Image Management Server Technical Specifications.....	1.7
Internal Quality Control	1.9
Genius Image Management Server Hazards.....	1.11
Disposal.....	1.15

Chapter Two

Installation

General	2.1
Action upon Delivery.....	2.1
Preparation prior to Installation.....	2.2
Moving the Image Management Server.....	2.11
Connecting Image Management Server Components	2.11
Power on the Server	2.11
Storage and Handling - Post Installation	2.13
System Shutdown.....	2.13

Chapter Three

Image Management Server Dashboard

Overview	3.1
System	3.2
Archiver and Retriever	3.8
Review Station	3.14
Network	3.15

Time Server	3.16
Imager Service.....	3.17
ThinPrep DB	3.18
Settings	3.22

Chapter Four

Maintenance.....	4.1
-------------------------	------------

Chapter Five

Troubleshooting	5.1
Red Status Indicator on System Dashboard	5.1

Chapter Six

Service Information	6.1
----------------------------------	------------

Chapter Seven

Ordering Information	7.1
-----------------------------------	------------

Index

Chapter One

Introduction

SECTION**A****OVERVIEW**

The Genius™ Image Management Server (IMS) is one component of the Genius™ Digital Diagnostics System. The Image Management Server is a Windows-based server computer connected via wired Ethernet. The Image Management Server stores the image data set, maintains the image metadata database, and hosts web services for external Genius™ Review Stations. The Image Management Server has the capability to manage communication with an external archive. The Image Management Server provides a finite amount of storage and is intended as a cache to hold image files. The server capacity and lab data volumes will determine the time duration that the cache can support.

The Image Management Server is connected to a network switch, which connects the Genius™ Digital Imager to the Image Management Server, and connects the Review Station to the Image Management Server.

The Image Management Server stores the slide data set (imaging and review information) in a SQL database and stores the image files as a repository on disk. The Image Management Server facilitates the display of the images in the Genius Digital Diagnostics System for cytologists for review and QC reviews, as well as pathologists review as needed.



Figure 1-1 Genius Image Management Server

Note: The hardware shown in this operator's manual may differ from the appearance of the hardware used at your site.

It is the customer's responsibility to comply with all applicable record retention procedures. It is also the customer's responsibility to establish and implement policies and practices for maintaining storage capacity on the Genius Image Management Server. The Genius Image Management Server acts as a short-term cache for the slide data sets. The Genius Image Management Server can be configured to transfer slide data sets to a laboratory's archive storage system, and the Genius Image Management Server can be configured to delete older slide data sets. The system monitors the available storage capacity of the Genius Image Management Server. Users can view the Image Management Server storage capacity from the IMS dashboard, the Review Station and the Digital Imager.

Intended Use/Intended Purpose

Refer to the Instructions for Use for your configuration of the Genius Digital Diagnostics System for information on the intended purpose of the system. The Image Management Server is one component of the Genius Digital Diagnostics System.

**SECTION
B****THE GENIUS DIGITAL DIAGNOSTICS SYSTEM**

Slides that have been prepared for screening are loaded into slide carriers which are placed into the Digital Imager. The operator uses a touch screen on the Digital Imager to interact with the instrument via a graphic, menu-driven interface.

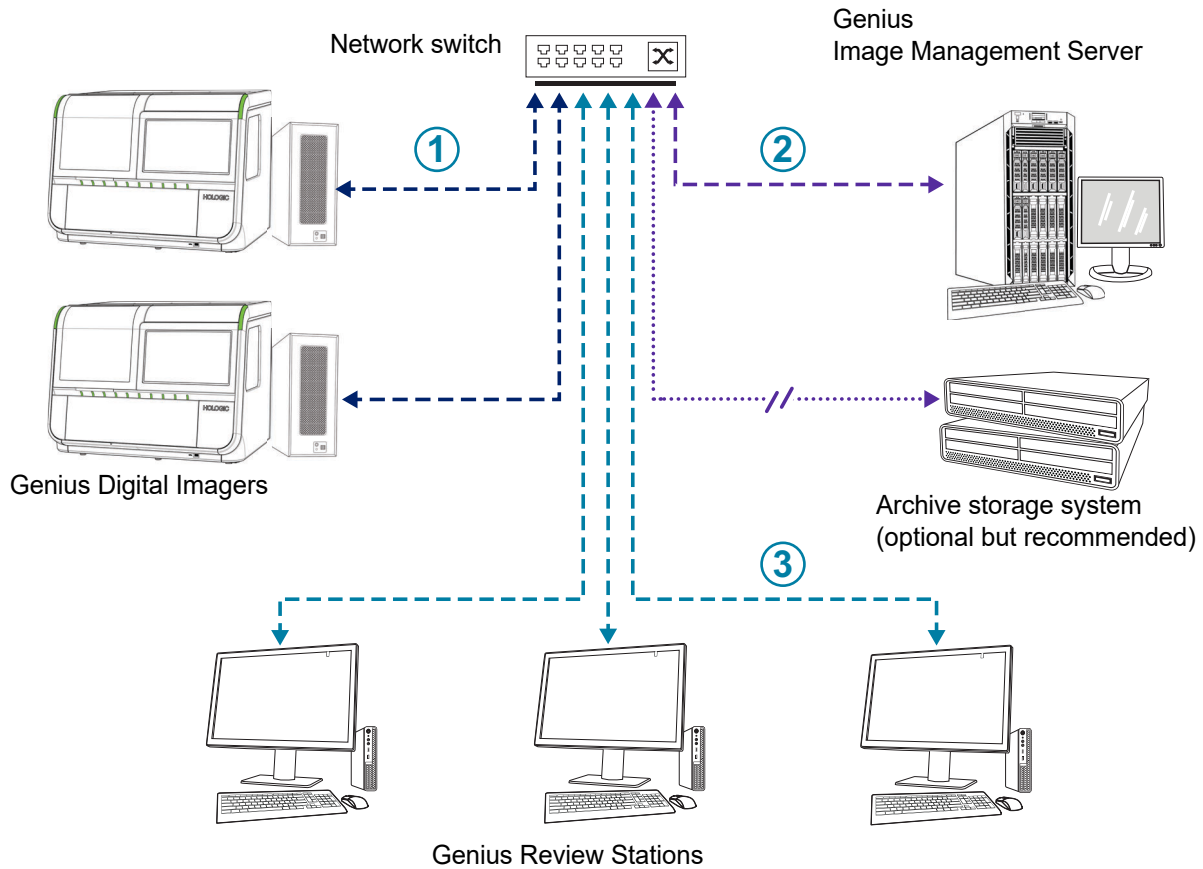
A slide ID reader scans the slide's accession ID and locates the scan area. Then the Digital Imager scans a designated area of the microscope slide, creating a whole slide image. The slide image data, the accession ID and its associated data record are transmitted to the Image Management Server, and the slide is returned to its slide carrier.

The Image Management Server acts as the central data manager for the Genius Digital Diagnostics System. As slides are imaged by the Digital Imager and reviewed at the Review Station, the server stores, retrieves and transmits information based on the accession ID.

The cytologist (CT) or pathologist reviews cases at the Review Station. The Review Station is a computer running a Review Station software application, with a monitor suitable for diagnostic review of whole slide images. When a valid case accession ID has been identified at the Review Station, the server sends the whole slide image for that ID, and the CT or pathologist is presented with the whole slide image for review. If your product configuration includes an image analysis algorithm, the algorithm analyzes the images before the images display at the Review Station. When any image is being reviewed, the CT or pathologist has the option to electronically annotate the image, mark objects of interest, and include the annotations and comments in the case review. The reviewer always has the option to move and zoom through a view of the whole slide image, which provides complete freedom to move any portion of the specimen on the slide into the field of view for examination.

1

INTRODUCTION



Note: Throughout this manual, illustrations of the Image Management Server, an archive storage system and other components are representative. The appearance of the actual equipment may differ from the illustrations.

Figure 1-2 Genius Digital Diagnostics System Network

Key to Figure 1-2

①

Connection between a Genius Digital Imager and the network switch
The recommended network speed between the Genius Digital Imager and Genius Image Management Server is 1 Gbps or faster.

Key to Figure 1-2

②	<p>Connection between the network switch and a Hologic-provided Genius Image Management Server</p> <p>The minimum speed required for this connection is the aggregate of the speeds required for all of the Genius Digital Imagers and Genius Review Stations connected to the same Genius Image Management Server.</p> <p>For example, the connection for a Genius Image Management Server in an installation of six Genius Digital Imagers (6 x 1 Gbps=6 Gbps, minimum) and twenty Genius Review Stations (20 x 200 Mbps = 4 Gbps, minimum) would need to a speed of 10 Gbps or higher.</p>
③	<p>Connection between a Genius Review Station and the network switch</p> <p>The recommended network speed between the Genius Review Station and Genius Image Management Server is 200 Mbps or faster.</p>

Required Materials

- Genius Digital Imager
- Genius Review Station
- Network switch – available from Hologic, or provided by customer
- Server – available from Hologic, or provided by customer
- Computer monitor, keyboard, and mouse – available from Hologic, or provided by customer

Recommended but not provided

- Archive storage system

A network connection between the Image Management Server and the other components of the Genius Digital Diagnostics System is required.

Because the Genius Image Management Server handles all of the communication between the system components, the Genius Image Management Server connection requires a minimum of cat 6 cabling.

For the cabling requirements for the connections to the Genius Review Station and the Genius Digital Imager, consider the cable length. A minimum of cat 5e cabling is required, with distances not exceeding these maximum distances:

- Cat 5e Up to 1 Gbps speed, maximum distance of 100 meters
- Cat 6 Up to 10 Gbps speed, maximum distance of 55 meters
- Cat 6a Up to 10 Gbps speed, maximum distance of 100 meters

Additionally, another network connection to the site's archive storage system is required.

A user must have System Administrator rights in Windows to access the Image Management Server dashboard. And, to change any archive settings, a user must have the proper credentials to access both the archive storage system and the Image Management Server.

1

INTRODUCTION

If Hologic has not supplied the server, a user must have access to the server. Field Service personnel trained by Hologic will install the Genius Image Management Server software on the server.

A laboratory must have a secure lab firewall and strong network security before the Image Management Server can be installed.

SECTION
C

IMAGE MANAGEMENT SERVER TECHNICAL SPECIFICATIONS

Overview of Components

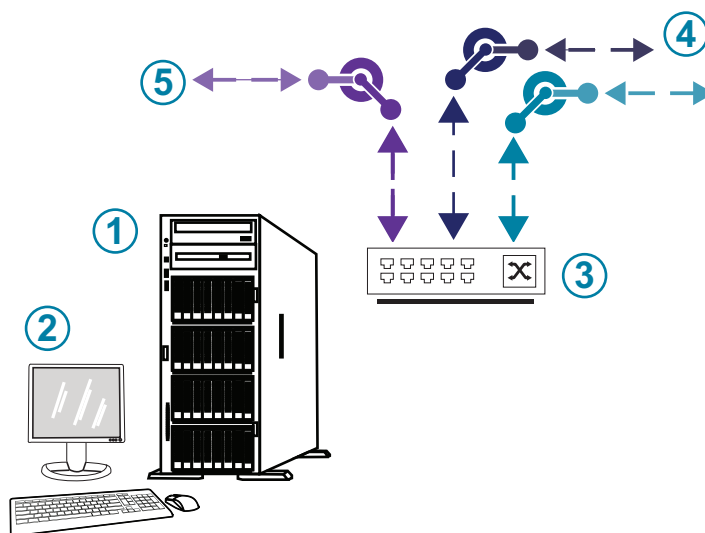


Figure 1-3 Image Management Server Components

Key to Figure 1-3	
①	Server The hardware shown may differ from the appearance of the hardware used at your site.
②	Monitor, keyboard, and mouse (for customers using a Hologic-supplied server)
③	Network switch
④	Connections to the Digital Imager and Review Station
⑤	Connection to the archive storage system

Image Management Server Specifications

The Genius Image Management Server software supplied by Hologic is required.

The hardware can be supplied by Hologic or supplied by your facility, provided it meets the required minimum specifications. The hardware configuration will vary, depending on the quantity and type of slides imaged in your facility. The minimum specifications for the hardware are:

Server Hardware:

- Dual Intel Xeon Silver 4214 2.2 GHz processor
- 64GB memory
- 240GB SSD for OS (boot)
- Raid 10 Array configuration
- 30 Terabytes configured storage capacity
- 2 10 GE ports
- 3 USB 2.0 (or faster) ports (not applicable to a virtual machine environment)
- Video graphics display interface of type VGA, HDMI, or display port (not applicable to a virtual machine environment)
- Dual, hot-plug, redundant power supply (1+1), 750 W or greater

Operating System:

- A minimum of 64-Bit Windows Server is required. Windows Server 2016 is recommended.

Note: To properly display the dashboard, the minimum recommended display resolution for the monitor is 1366 by 768 ppi.

Operating temperature range

Refer to the documentation provided with the server and computer.

Non-operating temperature range

Refer to the documentation provided with the server and computer.

Operating humidity range

Refer to the documentation provided with the server and computer.

Non-operating humidity range

Refer to the documentation provided with the server and computer.

Pollution Degree

Refer to the documentation provided with the server and computer.

Altitude

Refer to the documentation provided with the server and computer.

Atmospheric pressure

Refer to the documentation provided with the server and computer.

Sound levels

Refer to the documentation provided with the server and computer.

Power

Refer to the documentation provided with the server and computer.

Fuses

Refer to the documentation provided with the server and computer for power specifications. Fuses are not user-accessible and are not intended to be changed by users. Contact Technical Support if the instrument does not operate.

Safety, EMI and EMC Standards

Refer to the documentation provided with the server and computer for safety, EMI and EMC standard information.

**SECTION
D****INTERNAL QUALITY CONTROL**

The Image Management Server hosts the Review Station application, hosts applications and services, and provides data storage for the Review Station and Digital Imager.

The Genius Digital Diagnostics System uses secure communications protocols to protect the integrity of the slide data set (digital slide images and case data record) transferred between the Digital Imager, the Review Station, and the Image Management Server. The use of the customer's Windows domain ensures secure communications between the IMS and the customer's archive repository (NAS). In addition, The Genius Digital Diagnostics System uses a Secure Hash Algorithm (SHA)-256 to verify the integrity of data being returned to the system. A hash manifest containing SHA-256

checksum information is generated for each file in a slide image data set. The hash manifest is stored in the Genius IMS database. The Genius Image Management Server software verifies the hash each time that slide image data set is retrieved from the customer's archive.

The Genius Digital Diagnostics System continuously checks for a proper connection between the Image Management Server and its clients: the Review Station and Digital Imager. If the connection to the server is broken, a message is shown on the Review Station or Digital Imager.

The Image Management Server continuously monitors the storage capacity available for storing new data from the Digital Imager. If the Image Management Server approaches full capacity, a message is shown on the Digital Imager.

The Review Station cannot be used until connection with the Image Management Server is reestablished.

The Digital Imager cannot image slides or generate reports until connection with the Image Management Server is reestablished. The Digital Imager cannot image slides until sufficient storage capacity is available on the Image Management Server.

**SECTION
E****GENIUS IMAGE MANAGEMENT SERVER HAZARDS**

The Image Management Server is intended to be operated in the manner specified in this manual. Be sure to review and understand the information listed below in order to avoid harm to operators and/or damage to the instrument.

If this equipment is used in a manner not specified by the manufacturer, then the protection provided by the equipment may be impaired.

The installation and configuration of the Image Management Server must not be altered after installation by qualified Field Service personnel trained by Hologic and your facility's IT staff. Proper installation and configuration are required for proper performance of the system and cannot be substituted.

If any serious incident occurs related to this device or any components used with this device, report it to Hologic Technical Support and the competent authority local to the user and/or patient.











Warnings, Cautions and Notes

The terms **WARNING**, **CAUTION** and **Note** have specific meanings in this manual.

- A **WARNING** advises against certain actions or situations that could result in personal injury or death.
- A **CAUTION** advises against actions or situations that could damage equipment, produce inaccurate data or invalidate a procedure, although personal injury is unlikely.
- A **Note** provides useful information within the context of the instructions being provided.

Symbols Used on the Instrument

Refer to the documentation provided with the server for a description of any symbols used on the hardware. The following symbols may appear on the labels supplied by Hologic.

 hologic.com/ifu	Consult the instructions for use
	Serial number
	Manufacturer
	Authorized representative in the European Community
	Catalogue number
	Date of manufacture
	<i>In vitro</i> diagnostic medical device
	On (Power switch)
	Off (Power switch)
	On/Off, Standby mode










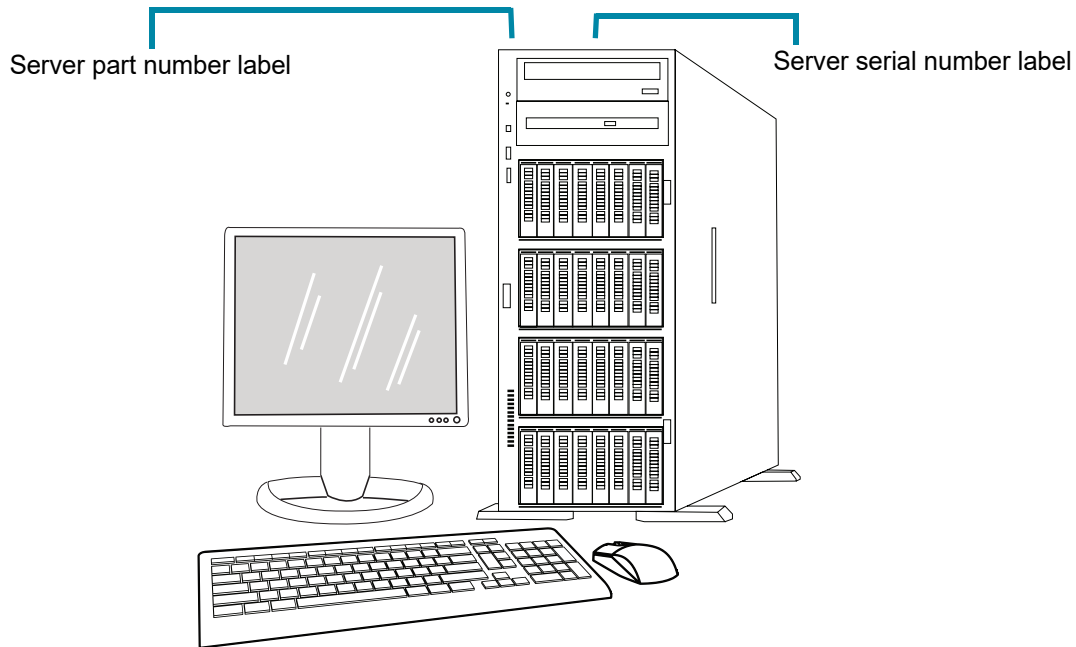
	USB port icon (computer)
	Made in USA
	Information is applicable only in the USA and Canada
	Information is applicable only in the USA
	Ethernet port icon (computer)
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician, or any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device and are trained and experienced in the use of the product.
	Country of manufacture
	Unique Device Identifier
	Importer

Figure 1-4 Symbols used on the server

Location of Labels

Refer to the documentation provided with the server and computer for additional information on the location of labels on the hardware. Labels on the hardware supplied by Hologic are shown in Figure 1-5:



Note: The appearance of the server in this illustration may differ from the server installed at your site, depending on the model of Hologic-supplied hardware you have.

Note: If the server hardware is not supplied by Hologic, the serial number may be in a different location and the server part number label will not be present.

Figure 1-5 Location of Labels on the Server

Warnings

WARNING: Service Installation Only. This instrument is to be installed by Field Service personnel trained by Hologic only.

WARNING: Grounded Outlet. To ensure safe operation of the instruments, use a three-wire grounded outlet. Refer to the documentation provided with the server.

Limitations

The server must meet the specifications in this manual. The Image Management Server is designed specifically for the Genius Digital Diagnostics System. The Image Management Server must be

running the Hologic-supplied software for proper performance of the system and the software cannot be substituted.

**SECTION
F****DISPOSAL****Disposal of the device**

Please contact Hologic Service. (Refer to Chapter 6, Service Information.)

Do not dispose in municipal waste.



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1

INTRODUCTION

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Chapter Two

Installation

WARNING: Service Installation Only

SECTION A

GENERAL

The Genius Image Management Server must be installed and configured by qualified Field Service personnel trained by Hologic.

The duration of the installation is dependent on the complexity of integration with the laboratory information technology (IT) infrastructure and connected systems. When installation and configuration are complete, Field Service personnel trained by Hologic trains the laboratory's information system staff, using the user's manual as the training guide.

In addition to the Hologic-installed components, a laboratory must provide a method for maintaining storage capacity on the Image Management Server, to allow the Genius Digital Diagnostics System to continue to image slides. A laboratory must establish their own policies and practices for maintaining storage capacity on the Image Management Server. The Genius Digital Diagnostics System can be configured to permanently delete older slide data set records, and the Genius Digital Diagnostics System can be configured to transfer slide data set records to a laboratory's archive storage system. The laboratory is responsible for the installation and configuration of the archive storage system. Field Service personnel trained by Hologic collaborate with a laboratory's IT staff to connect the Image Management Server to the archive storage system.

The Image Management Server dashboard should only be used by personnel who have been trained by Hologic or by organizations or individuals designated by Hologic.

SECTION B

ACTION UPON DELIVERY

For installations with hardware supplied by Hologic, inspect the packing cartons for damage. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible. (Refer to Chapter 6, Service Information.)

Leave the server in the packing cartons for installation by Field Service personnel trained by Hologic. Store the server in a suitable environment until installation (cool, dry area).

Note: The server manufacturer and the computer manufacturer provide documentation for those components. Refer to that for technical specifications. Do not discard.

**SECTION
C****PREPARATION PRIOR TO INSTALLATION****Pre-Installation Site Assessment**

A pre-installation site assessment is performed by qualified Field Service personnel trained by Hologic. The site assessment requires networking considerations with your laboratory's IT (Information Technologies) personnel. Be sure to have prepared any and all site configuration requirements as instructed by the qualified Field Service personnel trained by Hologic.

The site must have a secure firewall and strong network security for devices connected to the Image Management Server and Review Station computer.

Physical location requirements for the server

- The Image Management Server supplied by Hologic is a Windows-based tower server. The dimensions of the hardware vary with the model of server for your facility. The Image Management Server must be easily accessible from all sides to accommodate proper servicing.
- The Image Management Server must be staged in a location suitable for IT infrastructure components. The Image Management Server is networked with the Genius Digital Imager and the Genius Review Station.
- As a general best practice, an uninterruptible, conditioned power supply as well as environmental conditioning, are recommended with proper regard for physical dimensions, power requirements and BTU output. The power requirements and environmental conditioning vary with the model of server for your facility.

Network requirements for the server

- The recommended network speed between the Genius Digital Imager and the Genius Image Management Server is a minimum of 1 Gbps.
- The recommended network speed between the Genius Review Station and Genius Image Management Server is 200 Mbps or faster. However, if this speed is not attainable, a minimum network speed of at least 100 Mbps is recommended for optimal speed in loading images and case data.
- Connectivity can be accomplished utilizing facility infrastructure or direct connection through the 10-Gbps network switch following applicable standards for 10 Gbps Ethernet.
- Each facility must provide a static IP address for the customer network interface.

- The Image Management Server runs web services on port 443.

Note: If utilizing remote Review Stations firewall access must be configured accordingly.

Physical requirements for the network switch

- The network switch should be staged in a location suitable for IT infrastructure components, such as a rack in a network closet or suitable countertop with appropriate power and environmental controls.
- If placed on a countertop, the rubber-footpads provided with the network switch must be installed to prevent movement and improve airflow.
- Network switch must be easily accessible on all sides to accommodate proper servicing.

Network requirements for the network switch

- The network switch is a Layer 2 type switch.
- The network switch has a minimum of twelve RJ-45 Ethernet ports with 10 Gbps.

Security

Medical device security is a shared responsibility between stakeholders, including healthcare facilities, patients, providers, and manufacturers of medical devices. Hologic recommends that each laboratory works directly with your existing information systems and security staff to determine the most appropriate actions to take based on the information technology (IT) infrastructure at your site.

Limit access and back-up off-system

As part of normal operation, data is saved to the Genius IMS in the following directories:

- **Hologic Main Application Folder**

C:\Program Files\Hologic

Hologic application files for IMS dashboard, Archiver, etc., as well as SQL Server MDF/LDF database files

- **Default Database Backup Folder**

D:\Hologic\DC\Database

Default location for creating nightly database backups. This is a user-definable folder location.

- **Image Repository Folder**

D:\SlideData

Location of main image repository. As this is a user-definable location, it may be different on an installed system.

Limit direct access to these directories, and follow your site's best practices for backing up this data (off-system).

Cybersecurity and Data Protection

Use the information in this section as well as your site's best practices for cybersecurity and data protection.

- The computer USB ports should only be used in accordance with the instructions provided with the system. Always ensure the external USB flash drive or portable storage medium is virus-free and not used on public or home computers.
- If the instrument is connected to a network, Hologic requires a firewall be placed between the system and the network to protect against malicious network threats.
- Ensure all external storage devices are kept in a secure location and only available to authorized personnel.

If your laboratory uses images and slide data generated by the Genius Digital Diagnostics System outside the Genius Digital Diagnostics System, then your laboratory is responsible for maintaining the integrity of the data in those other applications. The slide data set generated by the Genius Digital Diagnostics System includes a hash manifest with SHA-256 checksum information. The Secure Hash Algorithm (SHA) can also be utilized by the laboratory's archiving system to check data integrity as the laboratory moves files throughout their long-term storage solution.

Overall, please keep in mind that all employees are responsible for the integrity, confidentiality, and availability of the data being processed, transmitted, and stored on the system. Failure to follow these recommendations could increase the risk of exposure to a virus, spyware, Trojan or other hostile code intrusion. If any of these are suspected, please contact Hologic Technical Support as soon as possible.

Windows Domain and Active Directory

The IMS supports the use of Active Directory as a mechanism for Windows authentication. Domain membership is permitted; however, care must be taken to ensure domain policies do not adversely affect system functionality or performance.

The IIS application pool runs under a single administrative account for all Hologic web services. As an IIS service-account, the password does not expire.

The Genius IMS database is SQL Server® 2022. Applications use Windows authentication for SQL access.

Genius Review Station users are independent and not integrated with Active Directory. Review Station usernames and passwords are stored in the IMS SQL database. Review Station user passwords are encrypted in the SQL database.

Third party software packages

Genius IMS software may come preinstalled on the Genius IMS server hardware provided by Hologic or hardware provided by the customer.

Installation of third-party software beyond antivirus software is not officially supported by Hologic and may adversely affect system performance. Intrusion detection and/or system management software may be installed at customer's discretion.

Antivirus

The use of antivirus software is recommended on the IMS. Installation instructions provided with the antivirus software product should be used for installation and configuration.

Exclude the following parent directories and subdirectories from antivirus scanning. Failure to exclude these directories may result in degraded system performance:

- **Hologic Main Application Folder**

C:\Program Files\Hologic

Hologic application files for IMS dashboard, Archiver, etc., as well as SQL Server MDF/LDF database files

- **Hologic Web Services Folder**

C:\inetpub\wwwroot\Hologic

Application files for all three Hologic web services (.ImagerService, .ReviewStation, and .SlideRetriever subdirectories)

For installations that use Genius Event Bridge, the application files for the Hologic Genius Event Bridge web service (.GeniusEventBridge subdirectory) are also in this folder.

- **Default Database Backup Folder**

D:\Hologic\DC\Database

Default location for creating nightly database backups. This is a user-definable folder location.

- **Image Repository Folder**

D:\SlideData

Location of main image repository. As this is a user-definable location, it may be different on an installed system.

Hologic recommends the use of antivirus software on the computer that will run the IMS Server. Hologic has tested the following antivirus software on the computer that will run the IMS Server:

- Microsoft Defender Version 1.417.647.0
- ESET - 11.0.12012.0
- MalwareBytes - 4.6.9.314

Antivirus software other than those listed has not been tested. The impact of antivirus software other than those listed has not been established.

Intrusion detection

Real-time intrusion detection monitoring software is not recommended to be run when the IMS is active as it may affect performance of the application. Intrusion detection could be run in an offline manner on the system when the IMS application is idle.

Encryption

Software-encryption may adversely affect system performance. If encryption is desired, hardware-based disk encryption is recommended. Installation instructions provided with the encryption product should be used for installation and configuration. It is recommended to consult Hologic Technical Support to better understand the implications of such encryption on performance.

Operating system patching

The IMS software runs on Microsoft Windows Server 2016, Microsoft Windows Server 2019, and Microsoft Windows Server 2022 (various editions). Customers may implement Windows updates as desired. Customers should schedule updates that do not conflict with clinical operations or predefined scheduled tasks. It is recommended to have a rollback strategy when applying patches.

IMS tasks are set to run in the Windows Task Scheduler. Source files for these tasks reside in the Hologic Main Application Folder. Refer to “Hologic Main Application Folder” on page 2.3.

- “Hologic IMS Archiver” – Nightly image archiving function
- “Hologic IMS Database Backup” – Powershell to execute database backup script.

Cybersecurity assessment

A cybersecurity assessment of the Genius IMS running Windows Server 2016 was performed. The results are presented in Table 2.1. The same assessment has been run with Windows Server 2019 and Windows Server 2022.

Table 2.1 Cybersecurity Assessment, IMS Running Windows Server 2016, Windows Server 2019 or Windows Server 2022

Number	Severity	Vulnerability Description	Affected (ports)
1	Severe	SMB signing disabled - This system does not allow SMB signing. SMB signing allows the recipient of SMB packets to confirm their authenticity and helps prevent man in the middle attacks against SMB. SMB signing can be configured in one of three ways: disabled entirely (least secure), enabled, and required (most secure).	446
2	Severe	SMB signing not required - This system enables, but does not require SMB signing. SMB signing allows the recipient of SMB packets to confirm their authenticity and helps prevent man in the middle attacks against SMB. SMB signing can be configured in one of three ways: disabled entirely (least secure), enabled, and required (most secure).	446
3	Severe	SMB: Service supports deprecated SMBv1 protocol - The SMB1 protocol has been deprecated since 2014 and is considered obsolete and insecure.	446
4	Severe	SMBv2 signing not required - This system enables, but does not require SMB signing. SMB signing allows the recipient of SMB packets to confirm their authenticity and helps prevent man in the middle attacks against SMB. SMB 2.x signing can be configured in one of two ways: not required (least secure) and required (most secure)	446
5	Moderate	DNS Traffic Amplification - A Domain Name Server (DNS) amplification attack is a popular form of distributed denial of service (DDoS) that relies on the use of publicly accessible open DNS servers to overwhelm a victim system with DNS response traffic.	53

Number	Severity	Vulnerability Description	Affected (ports)
6	Moderate	TCP timestamp response - The remote host responded with a TCP timestamp. The TCP timestamp response can be used to approximate the remote host's uptime, potentially aiding in further attacks. Additionally, some operating systems can be fingerprinted based on the behavior of their TCP timestamps	N/A
7	Moderate	The remote service accepts connections encrypted using TLS 1.0. TLS 1.0 has a number of cryptographic design flaws. Modern implementations of TLS 1.0 mitigate these problems, but newer versions of TLS like 1.2 and 1.3 are designed against these flaws and should be used whenever possible.	N/A

To address potential vulnerabilities, Hologic recommends:

- Keep SMB signing disabled. (SMB signing is disabled by default on Windows Server® 2016, Windows Server® 2019, and Windows Server® 2022.)
- Disable SMB1 by using Windows® Powershell® Administrator commands.
- Use a series of standard information systems' security practices, such as Source IP verification for network devices, disabling recursion on applicable name servers or limiting recursion to authorized clients, and implementing rate limiting on DNS Server as needed.

Note: TCP timestamp responses are a common function inherent to the TCP protocol itself. Disabling this feature can cause TCP communication to malfunction. McAfee® and other security organizations consider this a low vulnerability and recommend keeping this feature enabled.

- Enable support for TLS 1.2 and 1.3 and disable support for TLS 1.0

Remote Access

Hologic offers an optional, remote support system, SecureLink® software, for the Genius Digital Diagnostics System. SecureLink software allows authorized Hologic support personnel to view computers running Hologic software, installed in your laboratory, in real time and to transfer files remotely over secure servers, after the operator grants access to Technical Support personnel to initiate communication. The Technical Support personnel must be trained by Hologic. The lab can disable access at any time from a Genius Review Station.

Access through the SecureLink remote diagnostics support platform facilitates efficient diagnosis and resolution of issues that may arise during operation of the Genius Digital Diagnostics System. The remote support session allows authorized service personnel trained by Hologic to securely access the system to provide system service, view the desktop GUI, or provide guidance to a local instrument operator. In addition, the system allows for remote file transfer of files needed to troubleshoot an instrument error.

From the Review Station, an administrator can initiate a remote session to allow Field Service personnel trained by Hologic to access the Genius Image Management Server. From the kiosk application at the Review Station, any user can initiate a remote session to allow Field Service personnel trained by Hologic to access the Genius Review Station computer.

The use of remote access troubleshooting is optional.

- If a laboratory does not want to allow Field Service personnel trained by Hologic remote access to the Genius Image Management Server, the SecureLink software is not installed on the Genius Image Management Server for that lab.
- If a laboratory does not want to allow Field Service personnel trained by Hologic remote access to Genius Review Station computers, the SecureLink software is not installed on the Genius Review Station computers for that lab.

The SecureLink software for remote access must be installed by Field Service personnel trained by Hologic at a customer site before it can be used. The installation and configuration can be part of the site visit to install or upgrade the Genius Digital Diagnostics System. A site visit is required to install the SecureLink software.

The Genius Review Station Operator's Manual describes the procedure for enabling a session for authorized support personnel trained by Hologic to access your Genius Digital Diagnostics System remotely, if SecureLink software has been installed.

Technology Description

The SecureLink remote support platform is an optional service that can be installed once customer approval has been received by Field Service personnel trained by Hologic. Upon approval, the SecureLink GateKeeper will be installed as a Windows Service on the IMS server. When the service is not running, a remote support connection is not available.

The installation package used by the Field Service personnel trained by Hologic will modify the Windows Firewall Outbound Rule Set on the firewall installed on the Image Management Server. This modification allows a connection to be established from the GateKeeper to Hologic's SecureLink Application Server appropriate for your region. As a final step, the customer firewall must allow outbound connections using the outside interface IP of the Cisco ASA as the source IP.

The SecureLink GateKeeper service establishes a secure, end-to-end outbound connection from the GateKeeper host system to the Hologic-maintained SecureLink Application Server using SSHv2. The GateKeeper is locked from modification and only allows connection to the Hologic-maintained SecureLink Application Server.

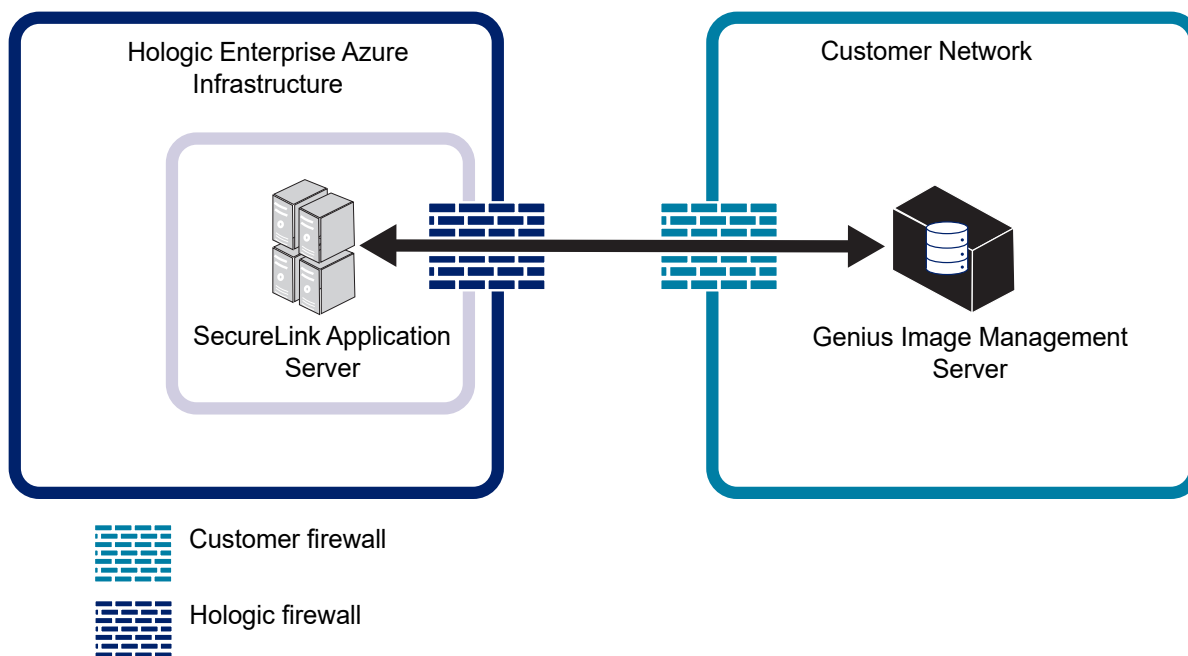


Figure 2-1 Network Diagram for SecureLink Remote Access

Refer to Table 2.2 on page 10. It is the customer's responsibility to select the appropriate IP address from the Table 2.2.

The SecureLink service is set to start automatically with Windows by default when SecureLink is initially installed. However, as part of the installation of the Genius Digital Diagnostics System software, the SecureLink GateKeeper service is automatically disabled. For Field Service personnel trained by Hologic to access a customer's system, a customer must enable the remote connection as described in the operator's manual for the Genius Review Station.

Note: Hologic does not currently support the use of a customer's existing SecureLink GateKeeper or SecureLink Nexus infrastructure.

Authentication into the SecureLink Application Server for Hologic service personnel is managed through Hologic Active Directory, and authenticated using Okta[®] with multi-factor authentication, ensuring only authorized personnel trained by Hologic have system access. Details of each remote support session (including a record of the employee ID) are archived indefinitely for audit purposes. The remote support connection activity can be made available upon request to Hologic Technical Support.

Each SecureLink GateKeeper instance is uniquely identified by a registration code that is entered during installation by Field Service personnel trained by Hologic, allowing for granular control of GateKeeper systems that are authorized to connect to the SecureLink Application Server.

The SecureLink GateKeeper is capable of automatically updating itself to a new version to ensure vulnerabilities are addressed and allow product enhancements to be delivered without requiring a site visit by Field Service personnel trained by Hologic. Once a connection has been established to the SecureLink Application Server, a version check will be performed. If a higher version is found, the GateKeeper will download the necessary components for the upgrade, perform the upgrade, and restart the service.

The SecureLink Application Server resides in Hologic's Enterprise Azure Infrastructure and is isolated onto its own network segment. The server instance Operating System is hardened to reduce attack vectors by disabling and removing unnecessary services and tools. All SecureLink session connections utilize the SSHv2 protocol for data transport with AES-256 for bulk encryption, and RSA (2048-bit key length) for key exchange. Every key is uniquely generated per session and mutual authentication is enforced to mitigate Man-In-The-Middle attacks.

Configuration Information

It may be necessary to configure the customer's enterprise firewall to allow the Genius Digital Diagnostics System to utilize SecureLink depending on the current Outbound Rule Set. No Inbound rules need to be added for a remote support connection to be established. The following connections must be allowed to enable a successful remote connection.

Table 2.2 Connectivity Guidance

Application	URL	IP Address*	Protocol and Port	Connection Type
SecureLink EU	connect-de.hologicsecurecare.com**	20.79.74.76	TCP 22	Outbound
SecureLink Australia and Asia Pacific	connect-au.hologicsecurecare.com	20.211.18.95	TCP 22	Outbound
<p>* The IP addresses have been provided however, Hologic recommends utilizing the URL in any firewall configuration to support additional server deployments in the future as well as disaster recovery.</p> <p>** The connect-de.hologicsecurecare.com server is physically located in Germany to support GDPR compliance for EU customers.</p>				

**SECTION
D****MOVING THE IMAGE MANAGEMENT SERVER**

If it becomes necessary to change the location of your Image Management Server, contact Hologic Technical Support or your local Hologic representative. Collaboration between your IT staff and Hologic is required, and a service visit may be necessary.

Unit Shipped to New Location

If the Image Management Server is to be shipped to a new location, please contact Hologic Technical Support or your local Hologic representative. Refer to Chapter 8, Service Information.

**SECTION
E****CONNECTING IMAGE MANAGEMENT SERVER COMPONENTS**

If it becomes necessary to change the archive storage system connected to your Image Management Server, contact Hologic Technical Support or your local Hologic representative. A service visit is required.

The Genius Digital Diagnostics System components must be fully assembled before turning on the power and using the instrument. Field Service personnel trained by Hologic will install and configure the system components.

A network connection (see Figure 1-5) connects the Review Station to a networking device, enabling communication to the Genius Image Management Server.

Note: It is the responsibility of the customer to purchase and install the necessary quantities and lengths of Ethernet cable required for networking the Review Station to the system. Installation configuration should be planned prior to instrument installation.

**SECTION
F****POWER ON THE SERVER**

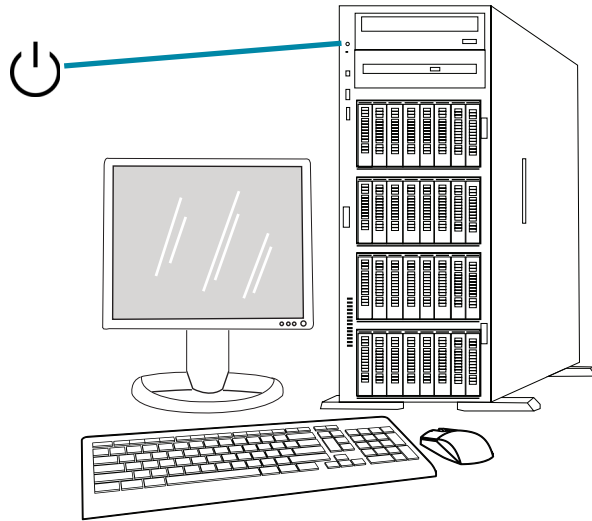
WARNING: Grounded Outlet

To ensure safe operation of the instrument use a three-wire grounded outlet. Typically, the server is always powered on, left running.

2

INSTALLATION

Note: All power cords must be plugged into a grounded outlet. Disconnection from the power supply source is by removal of the power cord.



Note: The appearance of the server in this illustration may differ from the server installed at your site, and the position of the power button may differ.

Figure 2-2 Power Switch

Launch the application

The Image Management Server dashboard application can be left running. If the dashboard application is closed, to launch the application, click on the desktop shortcut.

SECTION
G

STORAGE AND HANDLING - POST INSTALLATION

The Image Management Server must be stored in the location where it was installed. Typically, the server is left running. Follow your laboratory's policy for handling computer equipment.

SECTION
H

SYSTEM SHUTDOWN

Normal and Extended Shutdown

Typically, the Image Management Server is left running.

Because the Image Management Server hosts services and applications necessary to the operation of the Digital Imager and the Review Station, shutting down the Image Management Server shuts down the operation of the Genius Digital Diagnostics System. Notify the staff using the Digital Imagers and Review Stations before shutting down the server.

Caution: If the Image Management Server needs to be shut down, ensure that the Digital Imagers and Review Stations are idle, to avoid disruptions.

In the event that the server must be shut down:

1. Close the application.
2. Shut down Windows.
3. Press the power button on the server (The location of the button varies with the model of server.)
4. Completely remove power by unplugging the monitor power cord and the computer cord from the power outlet.

2

INSTALLATION

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Chapter Three

Image Management Server Dashboard

SECTION A

OVERVIEW

The user interfaces with the Genius Image Management Server through the Image Management Server dashboard. The dashboard presents a quick confirmation or error notification for the services and applications necessary to store and retrieve data for the Digital Imager and the Review Station.

It is recommended that the IT support staff for a laboratory acquaint themselves with the material in this chapter using the Image Management Server dashboard.

This chapter describes each of the dashboard's tabs:

System	3.2
Archiver and Retriever	3.8
Review Station	3.14
Network	3.15
Time Server	3.16
Imager Service	3.17
ThinPrep DB	3.18
Settings	3.22

SECTION
B

SYSTEM

The System dashboard shows an overview of the entire Image Management Server services, applications and connections.

Status Indicators

The System dashboard displays a summary of each of the other tabs in the dashboard. Each of the services and applications on the left of the System dashboard are described in more detail further in this chapter.

A green circle indicates that the services and applications are running. In normal operating conditions, all circles are green.

A red circle indicates that a service or application is not running. Hover over the status to see more information.

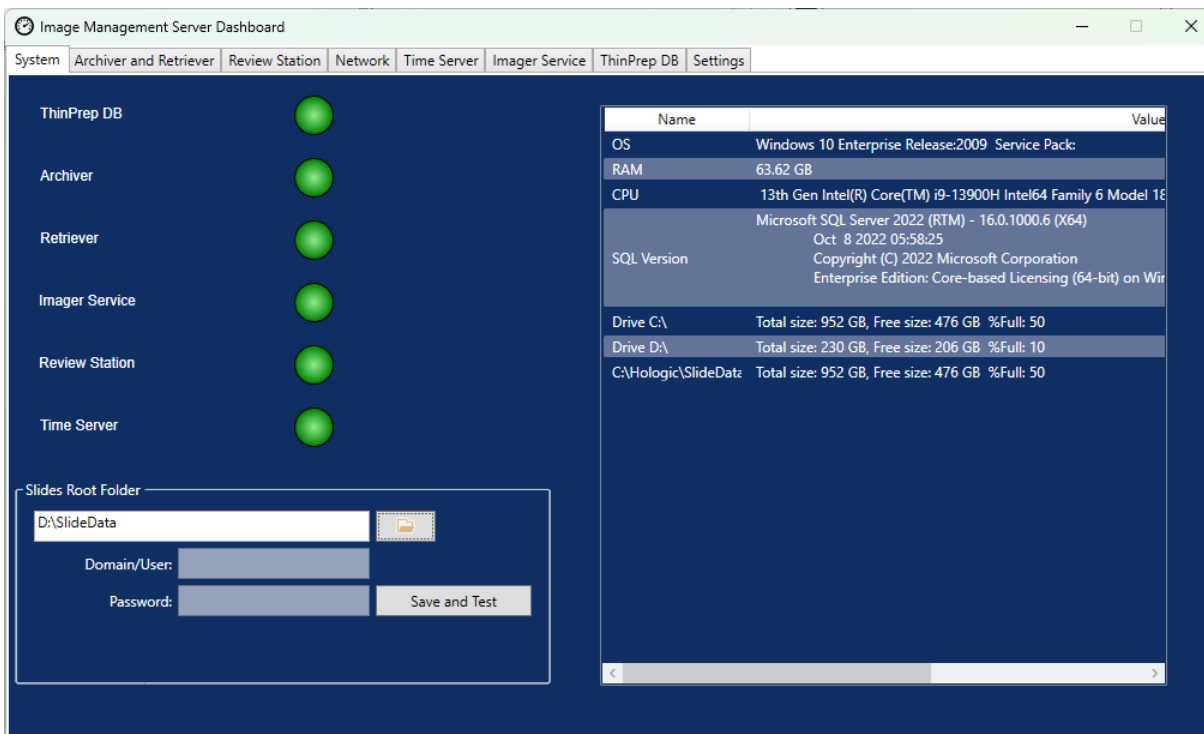


Figure 3-1 System dashboard

Slides Root Folder

The Slides Root Folder is the storage location for the images sent by the Digital Imager and reviewed at the Review Station. The Slides Root Folder is set up during the system installation. Only qualified Field Service personnel trained by Hologic should change the domain name or IP address for the Slides Root Folder.

When the amount of data saved to the Slides Root Folder approaches the limit of its storage capacity, and a notification message appear. The notification appears when 10% of the storage capacity remains. Refer to “Unable to Archive or Approaching Full Capacity” on page 5.3.

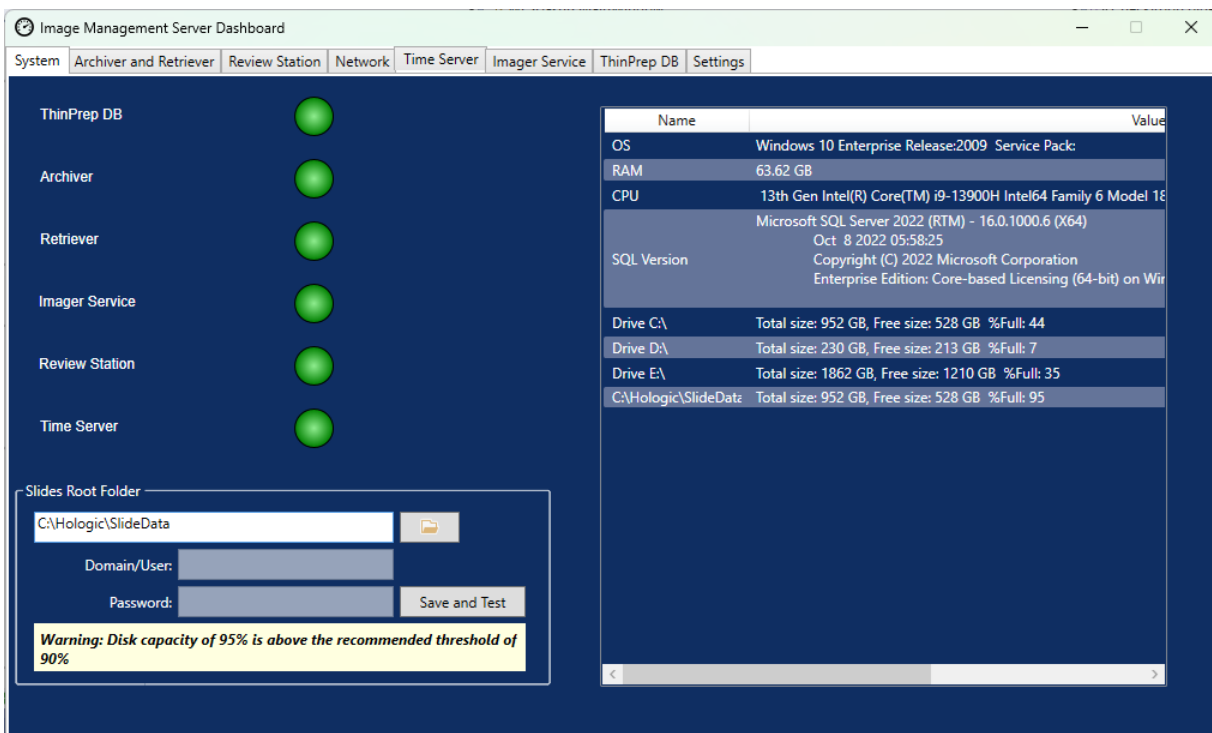


Figure 3-2 Slides Root Folder Approaching Full Storage Capacity

Adequate storage capacity is necessary to continue to image slides at the Digital Imager. The amount of storage capacity varies with Imager usage.

Data clean-up

It is the customer's responsibility to perform a regular data clean-up to create free space on the Genius Image Management Server, to enable the continued addition of new images and case data.

The Genius Digital Diagnostics System features listed below support your data clean-up:

- Use an archive storage solution and routinely archive cases. Refer to “Archiver and Retriever” on page 3.8 and to the Genius Review Station Operator's Manual for instructions.

- Delete unnecessary slide data sets. Refer to “Slide Management” on page 3.4 and to the Genius Review Station Operator’s Manual for instructions.
- Deactivate user accounts when the user leaves the organization. Refer to the Genius Review Station Operator’s Manual for instructions.
- Delete unused tags. Refer to the Genius Review Station Operator’s Manual for instructions.

The Slides Root Folder is only changed by qualified Field Service personnel trained by Hologic. Hologic Technical Support may ask for the Slides Root Folder file path to assist with support.

Slide Management

The Genius Digital Diagnostics System can be set up to permanently and routinely delete slide images and case data records (slide data sets) from the Genius Digital Diagnostics System. The files are deleted from the Genius Image Management Server. The Genius Digital Diagnostics System can be set up to never delete files from the system. The criteria for slide management are set up at the Review Station.

Follow all applicable record retention policies established by your IT department, health institution, or other groups when considering the slide management settings. The Genius Digital Diagnostics System does not require files to be deleted; the system does require sufficient storage space on the server.

Caution: Deleted image files, including the gallery of OOLs, marks, comments and annotations, cannot be recovered once deleted. There is no way to retrieve the deleted data.

Caution: Deleted image files are not transferred to a lab’s long-term storage or archiving system.

When enabled by the lab manager at the Review Station, the Slide Management tasks run nightly in the background on the Genius Image Management Server and require no user interaction. Slide Management is a task within the Windows Task Scheduler on the Genius Image Management Server.

The system monitors the available local disk space, and, if slide management is set to delete slides, the system deletes the oldest image files to free up storage capacity to store the newly scanned image files.

In the settings for Slide Management at the Review Station, a manager chooses if cases that have been tagged or bookmarked by a Review Station user will be included in the delete operation, or if tagged or bookmarked cases will be retained on the system.

- If the free storage capacity (disk space) in the image repository is lower than the threshold set by the lab manager, Slide Management will exit and perform no action.
- If the free disk space in the image repository meets or exceeds the threshold set by the lab manager, Slide Management will delete the oldest slides (slide image files from the repository and corresponding internal database records) until the storage capacity threshold is met. Slide Management operates on blocks of 1,000 slide data sets at a time and not individual image files. This may result in freeing up slightly more storage capacity than the threshold percentage.

Note: While Slide Management runs nightly, it may not need to delete image files every night. Deletion volume depends on the volume of new slides scanned in the Genius Digital Diagnostics System since the last run of Slide Management and a laboratory's long-term storage archiving schedule.

If the Slide Management utility on the Image Management Server fails to delete any of the eligible images from the slides root folder, the Review Station users with a manager role or an administrator role receive an alert at the Review Station. The alert instructs the user to contact the site network administrator.

If the slides root folder approaches the slide management threshold and some of the eligible images are successfully deleted each night, no alert is sent to the manager or administrator at the Review Station.

Storage capacity considerations

Hologic recommends considering the archiving criteria and the local repository size (image cache) of the Genius Image Management Server in your lab when setting the storage capacity threshold for Slide Management to run.

For example, if the slide management is set to delete slide data sets when 90% of the Genius Image Management Server storage capacity is full, then the number of slides whose data is stored on the Image Management Server will reach a steady state when the lab has consumed over 90% of repository storage. At the 90% threshold, the system deletes the oldest slide data sets to maintain sufficient free space. As more slides are imaged, the oldest slide data sets (digital slide images and case data) will be deleted.

The number of slide data sets at this steady state can be estimated based on the storage size of the repository on the Genius Image Management Server. The file size per slide data set varies with the different scan profiles available on the system. The table below provides an example of server capacity and number of slides:

IMS Storage Capacity	Estimated Number of Slides Stored Locally, for Different Scan Profiles			
	Gyn*	20-mm circle*	10-mm circle**	Whole Slide Image***
72 TB	48,000	48,000	144,000	16,000
<p>72 TB is 90% of the capacity of an 80-TB server.</p> <p>The actual size of the slide image files is variable based on multiple factors, including cellularity and sample type. The size of the slide image files for slides scanned with the Sample Detect file is variable, typically between 1.5 GB and 4.5 GB.</p> <p>*Calculation based on an estimate of 1.5 GB file size per case.</p> <p>**Calculation based on an estimate of 0.5 GB file size per case.</p> <p>***Calculation based on an estimate of 4.5 GB file size per case.</p>				

A server with 72 TB of storage can store approximately 48,000 of the most recently imaged ThinPrep Pap test slides (and related internal database records) in the local repository. The time duration that this spans is directly proportional to the lab's scanning volume. The greater the volume, the shorter the duration of slides kept in the cache. The table below illustrates approximate durations for a 72-TB server to reach 90% storage capacity:

Weekly Lab Slide Volume (slides)	Estimated Duration of Local Repository Cache, for Different Scan Profiles			
	Gyn*	20-mm circle*	10-mm circle**	Whole Slide Image***
500	96 weeks	96 weeks	288 weeks	32 weeks
1,000	48 weeks	48 weeks	144 weeks	16 weeks
2,000	24 weeks	24 weeks	72 weeks	8.0 weeks
3,000	16 weeks	16 weeks	48 weeks	5.3 weeks
4,000	12 weeks	12 weeks	36 weeks	4.0 weeks
5,000	9.6 weeks	9.6 weeks	28 weeks	3.2 weeks
<p>The actual size of the slide image files is variable based on multiple factors, including cellularity and sample type. The size of the slide image files for slides scanned with the Sample Detect file is variable, typically between 1.5 GB and 4.5 GB.</p> <p>*Calculation based on an estimate of 1.5 GB file size per case.</p> <p>**Calculation based on an estimate of 0.5 GB file size per case.</p> <p>***Calculation based on an estimate of 4.5 GB file size per case.</p>				

A manager or administrator at the Review Station can adjust the Slide Management Settings and the Archive Settings to adjust to a change in lab slide volume. Refer to the Review Station Operator's Manual for details.

Re-imaging slides

Case data records are internal database entries of each slide's imaging and review activity. Case data records and images (slide data sets) are deleted by the slide management feature. The deletion of the database entry allows the slide to be scanned again in the future if required.

After a case is deleted from the Genius Image Management Server, it is possible to re-image a slide to produce another digital image of the slide. Due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a ThinPrep Pap test slide may not produce a gallery of Objects of Interest (OOIs) identical to the original gallery. Refer to the Instructions for Use for the performance characteristics of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

And, due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a slide may not produce an identical image. Refer to the Instructions for Use for the performance characteristics of the Genius Digital Diagnostics System.

Hologic recommends that customers enable a solution for long-term storage and archiving of digital image files. It is a customer's responsibility to determine the storage and archival strategy, which could be affected by rules or requirements affecting retention of such information. Rules or requirements vary from jurisdiction to jurisdiction. Accordingly, Hologic recommends that customers consult with their regulatory and/or legal counsel prior to deciding to delete the digital image files from the local repository on the Genius Image Management Server.

Impact of deleting slides

In addition to not storing a long-term archive of the image files with the Slide Management feature, there are other impacts to the Genius Digital Diagnostics System to be aware of.

- The deleted images no longer appear in the Genius Review Station Case List and are not viewable.
- Any comments or marks associated with a case are also deleted.
- The CT workload reports (CT Workload Summary, CT Workload History and CT Reviews) and the Slide Data reports will only be accurate for the duration of the cached slides (before the case data record is deleted). Reports for date ranges older than the cache will not have the data for the reviews associated with each user. If this reporting is important to your lab, it is recommended that reports be run on a cadence well within the duration of the cache to ensure accurate reports. The report results can be saved or printed.
- Genius Review Station widgets for Slides Imaged and Reviews Completed will only be accurate for the duration of the cached slides.

Notes: System Usage History, Slide Events, and Slide Error reports retain all the data from the Digital Imagers and are not impacted by deleting slides with the Slide Management utility.

Reports that are run on the Genius Digital Imager are not affected by the Slide Management file deletion activity.

List of Network Hardware

The System dashboard displays information about the network hardware, installed and configured at the time of the system installation. The storage capacity and free space on each network drive is shown along with the percentage of used storage capacity (%Full).

SECTION
C

ARCHIVER AND RETRIEVER

The Archiver and Retriever dashboard shows information about the archiver service and the retriever service hosted on the Image Management Server.

In the Genius Digital Diagnostics System, slide data sets (images and case data records) are stored on the Image Management Server from the time a slide is imaged until the time a case is archived or deleted. Each day, the Image Management Server checks for cases whose images are eligible to be archived. The criteria for archiving cases is set up at the Review Station. When a case is archived, its slide images are moved from the Image Management Server to a laboratory's archive storage system.

Note: Case data records continue to reside on the Image Management Server after the images for the case are archived. To view images from an archived case, a reviewer at a Review Station must retrieve the images from the archive first, as described in the operator's manual for the Review Station.

Information relating to the Archiver status appears on the left of the screen. Information relating to the Retriever status appears on the right side of the screen.

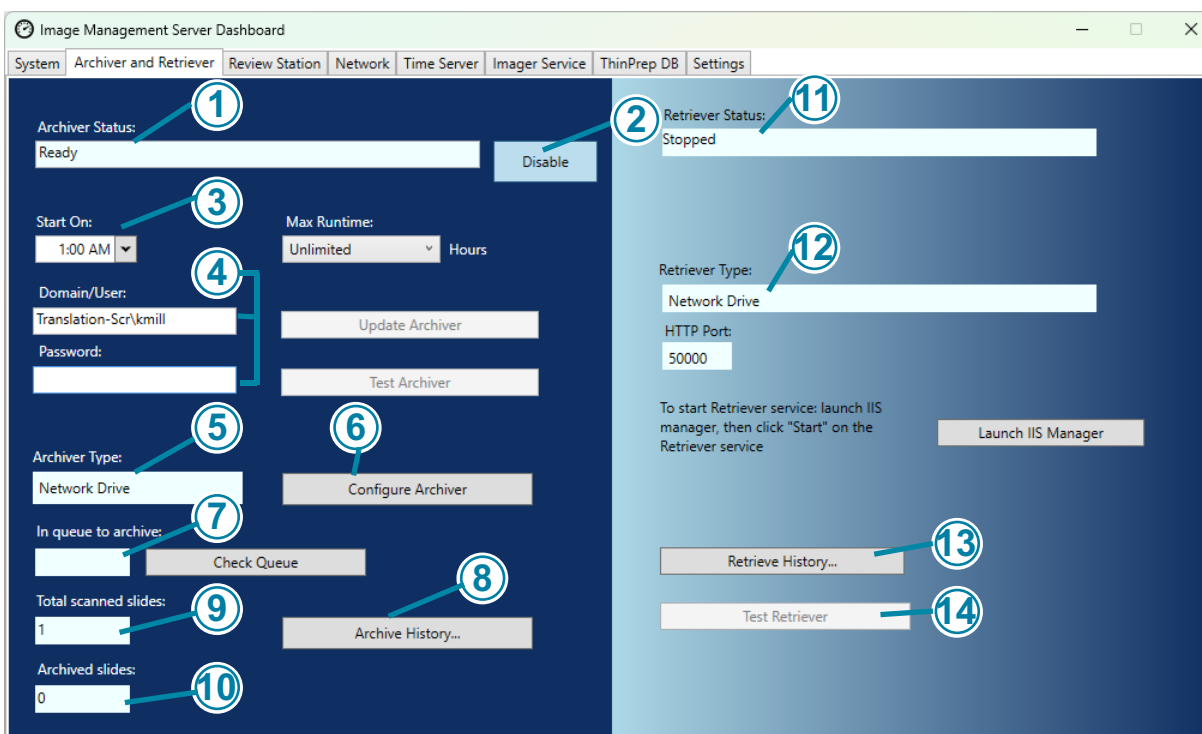


Figure 3-3 Archiver and Retriever dashboard

Key to Figure 3-3

①	Archiver Status Refer to “Archiver Status” on page 3.10.
②	Enable/Disable Archiver Refer to “Enable or Disable existing archiver” on page 3.10.
③	Current time settings for the daily archive Refer to “Current time settings for the daily archive” on page 3.10.
④	Username and password to apply and test changes to the time settings for the daily archive Refer to “Change start or duration of daily archive” on page 3.11.
⑤	Archiver The Archiver information on the dashboard describes the archived storage device configured with this Image Management Server. The archiver is configured by qualified Field Service personnel trained by Hologic.
⑥	Configure For use by Field Service personnel trained by Hologic. The archiver is configured by qualified Field Service personnel trained by Hologic.
⑦	Archive queue To display the quantity of slides that are eligible to be archived at the current point in time, click the Check queue button. The number in the In queue to archive field updates each time the Check queue button is clicked.
⑧	Archive History button Refer to “Archive History” on page 3.12.
⑨	Total scanned slides This is the quantity of slides whose data has been saved to the server, from all of the Digital Imagers connected to the server, since installation of the Genius Digital Diagnostics System.
⑩	Total archived slides This is the quantity of slides whose images have been archived from the server, since installation of the Genius Digital Diagnostics System.
⑪	Retriever status Refer to “Retriever Status” on page 3.13.

Key to Figure 3-3	
12	<p>Retriever and http port</p> <p>The Retriever information on the dashboard describes the archive storage system device configured with this Image Management Server. When configured correctly, the retriever is the same device as the archiver.</p> <p>The http port in the retriever section of the dashboard displays the name of the port through which the retriever transfers data from the archive storage system to the Image Management Server. The archiver and retriever are configured by qualified Field Service personnel trained by Hologic.</p>
13	<p>Retrieve History</p> <p>Refer to “Retrieve history” on page 3.13.</p>
14	<p>Test Retriever</p> <p>The Test Retriever is used by qualified Field Service personnel trained by Hologic. after an archiver is set up. The test confirms that the current settings are properly set up for retrieving slides from the archive storage system.</p>

Archiver Status

Under normal operating conditions, when the **Archiver Status** is **Ready**, there are no actions required to archive data from the Image Management Server.

Enable or Disable existing archiver

In order to archive data, the archiver service must be configured, installed and enabled.

- If there is a need to disable the archiver configured for and connected to the Image Management Server, the setting can be changed to Disable.
- To enable a disabled archiver, change the setting to Enable.

Configure archiver

The Archiver and Retriever dashboard has a **Configure** field, to be used only by qualified Field Service personnel trained by Hologic. The field has the network storage location for the archiver.

Current time settings for the daily archive

The **Start On** field on the dashboard is the time that the daily archive starts.

The **Max runtime** on the dashboard is the duration that the daily archive will run. An unlimited max runtime will continue archiving until all of the eligible cases are archived. The max runtime can be set to a specific number of hours.

For example, if the Start On time is 2 a.m. and the Max runtime is 4 hours, the Image Management Server will stop archiving eligible images at 6 a.m. each day. If the Start On time is 2 a.m. and the Max runtime is unlimited, the Image Management Server will run until all of the eligible images are archived.

Change start or duration of daily archive

After the initial system set-up, there may be no need to change any archive setting. However, a user with System Administrator rights on the server can change the start time and the runtime for the archiving service. In the event that the start time or runtime needs to change:

1. To change the starting time for the daily archive, click the down-arrow next to the current Start On time and select a new time.
2. To change the duration of the daily archive, click the down-arrow next to the Max Runtime and select a new time.
3. Enter your username. The user must have System Admin rights.
4. Enter your password.
5. Click the **Update Archiver** button. This applies the changed settings.
6. Click the **Test Archiver** button. This tests that communication between the archive storage system and the server is not disrupted by the changed settings.
7. Click **OK** when the “Archiver task updated successfully” message appears on the screen.

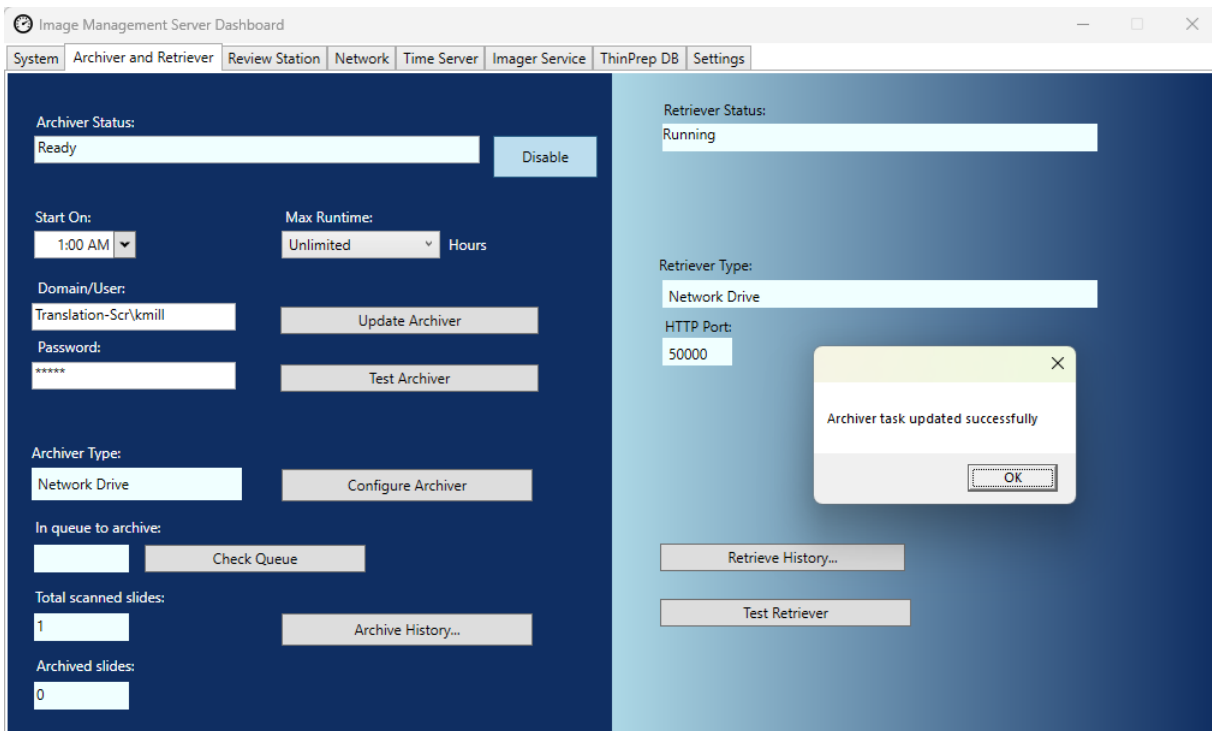


Figure 3-4 Archiver task updated successfully

Caution: If the archiver is not successfully updated and tested, images will not be archived from the server to the archive storage system. Daily archive is intended to keep sufficient server space available for imaging slides on the Digital Imager.

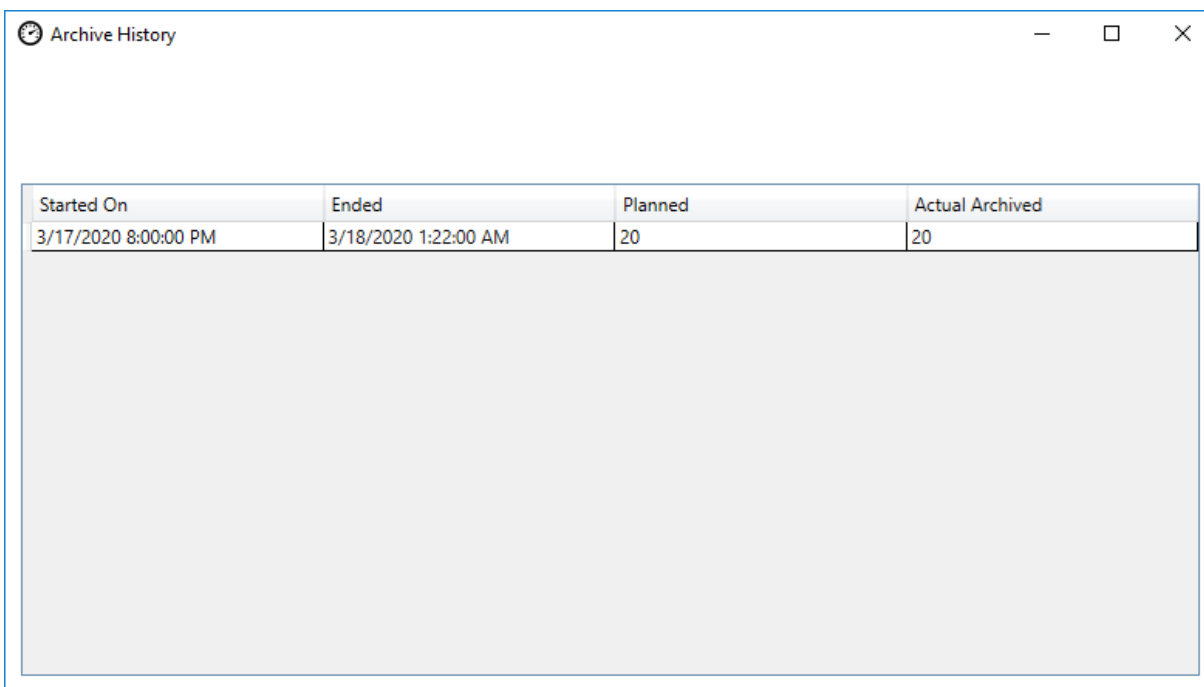
Archive History

The **Archive History** button on the dashboard generates a list of daily archive activity. When the quantity of cases listed in the **Planned** column equals the quantity of cases in the **Actual Archived** column, the server successfully transferred all of the images eligible for archive for that date from the Slides Root Folder to the archive storage system.

If the quantity of cases planned for the daily archive is lower than the quantity actually archived, something prevented all of the cases from transferring to the archive storage system. The difference could be caused by a max runtime that is too short, or it could be one of the indicators of a failure to archive. Refer to “Unable to Archive or Approaching Full Capacity” on page 5.3.

If all of the cases that are eligible for archive on a given day are not successfully archived because the max runtime is too short, the archive service attempts to archive the cases again the next day. The Archive History shows past activity. To see the queue of cases eligible for archive at the current time, click the **Check Queue** button, and the number of cases appears in the box for **In queue to archive**.

Note: If the volume of slides imaged or reviewed at your lab increases significantly, the Archive History list can be helpful in considering if the current archive criteria at your lab should change so that cases are archived more frequently.



Started On	Ended	Planned	Actual Archived
3/17/2020 8:00:00 PM	3/18/2020 1:22:00 AM	20	20

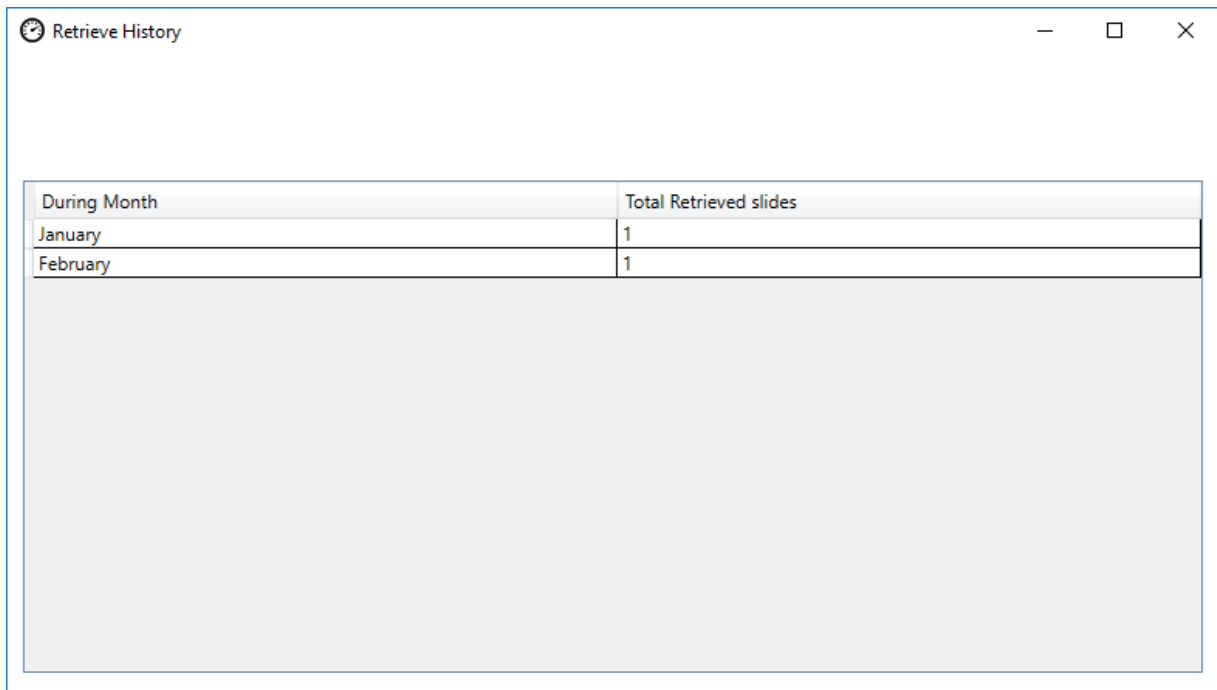
Figure 3-5 Archive History, example

Retriever Status

Under normal operating conditions, when the **Retriever Status** is **Ready**, there are no actions required to archive data from the Image Management Server.

Retrieve history

The **Retrieve History** button generates a list of the quantity of slides whose images were retrieved from the archive storage system each month.



During Month	Total Retrieved slides
January	1
February	1

Figure 3-6 Retrieve History, example

3

IMAGE MANAGEMENT SERVER DASHBOARD

SECTION D

REVIEW STATION

The Review Station dashboard displays the current status of the service that allows any Review Station on the network to launch and run the Review Station application. The status must be “Running” to use a Review Station in the Genius Digital Diagnostics System network.

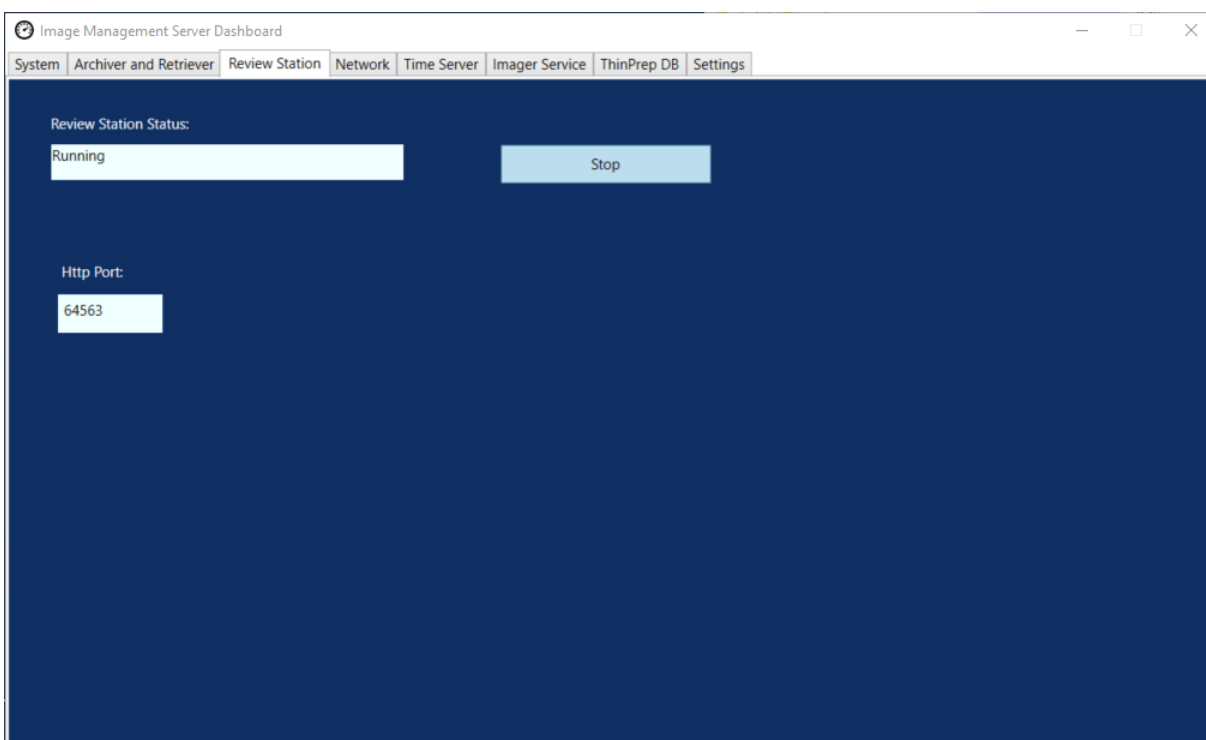


Figure 3-7 Review Station dashboard

The Http port is the name of the port through which the Image Management Server runs the Review Station service. The communication between the Review Station and the Image Management Server is set up by Field Service personnel trained by Hologic as part of system installation.

The Review Station dashboard has a **Start/Stop** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION
E

NETWORK

The Network dashboard displays the current network connections for the Image Management Server.

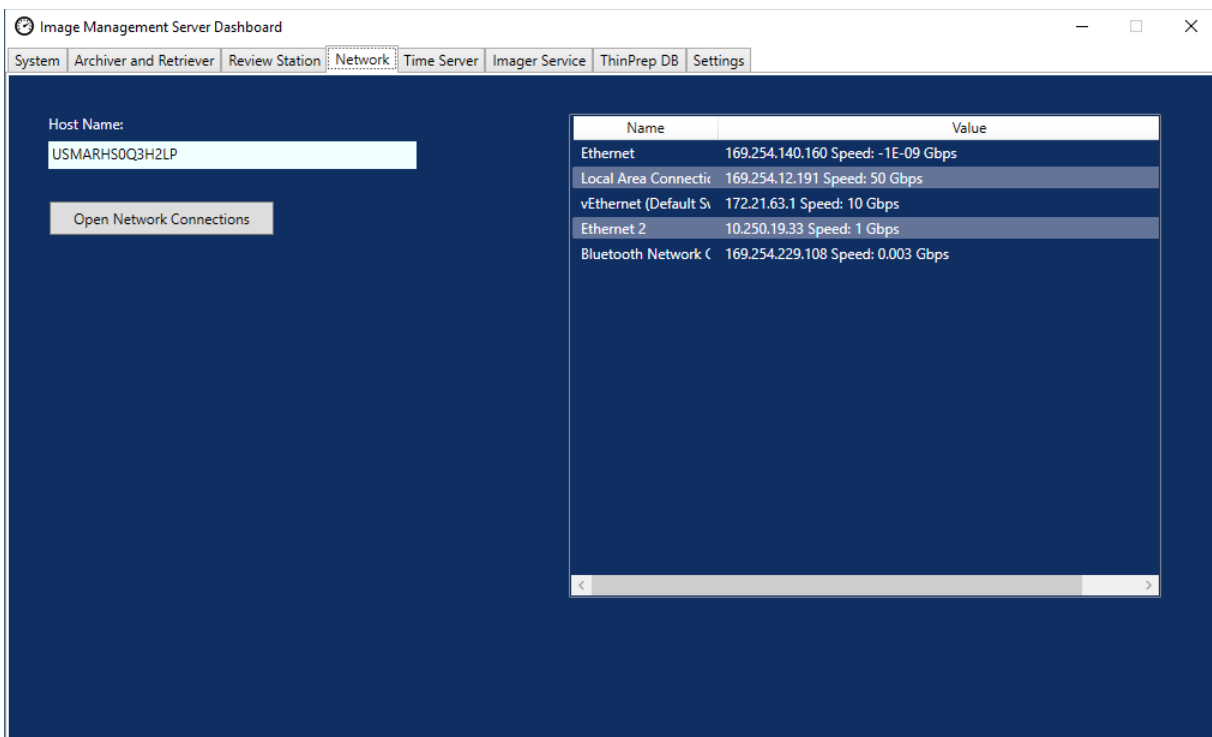


Figure 3-8 Network dashboard

The dashboard displays the name of the network on which the Image Management Server runs, along with the current network connections. The network information may be helpful in troubleshooting connection issues with Hologic Technical Support.

The Network dashboard has an **Open Network Connections** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION
F

TIME SERVER

The Time Server dashboard displays the current status of the Windows time server. The time server on the Image Management Server governs the time set not only on the server, but also on the Digital Imagers and Review Stations in the network. The time server status must be “Running” in order for the Genius Digital Diagnostic System to operate.

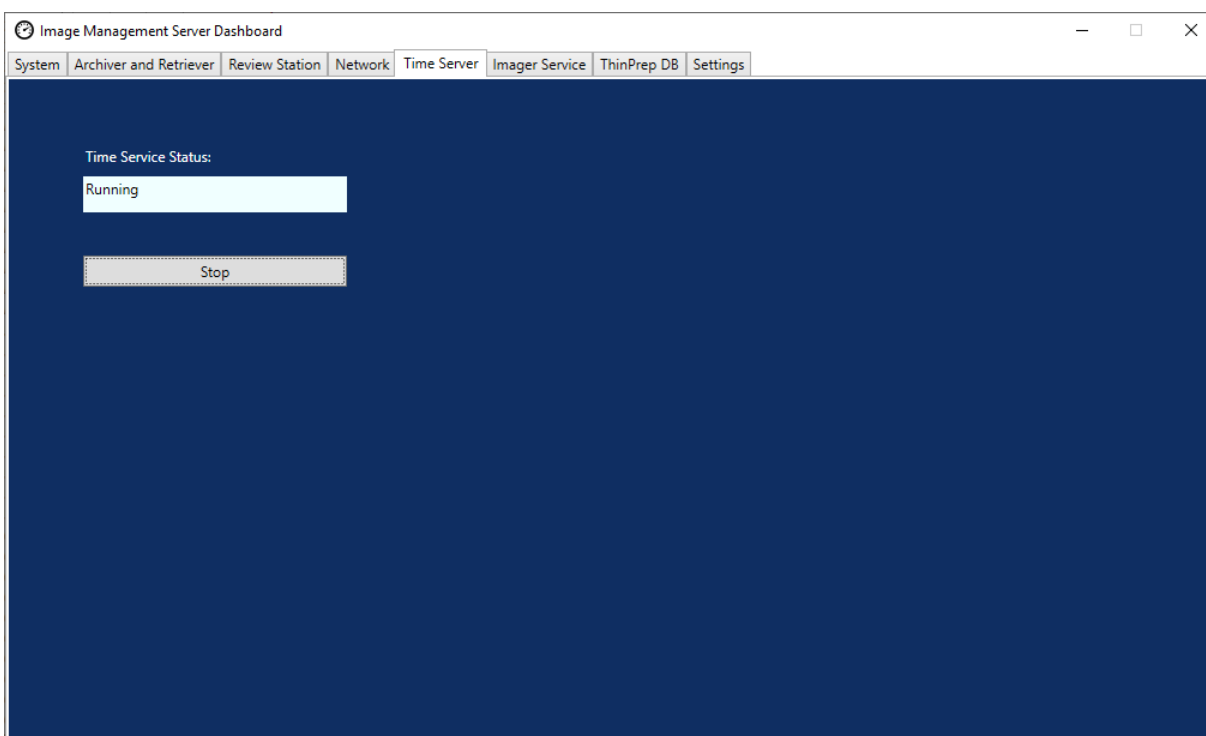


Figure 3-9 Time Server dashboard

The Time Server dashboard has a **Start/Stop** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION
G

IMAGER SERVICE

The Imager Service dashboard displays the current status of the service that allows any Digital Imager on the network to image slides and run reports. The status must be “Running” for normal operation of a Digital Imager in the Genius Digital Diagnostics System network.

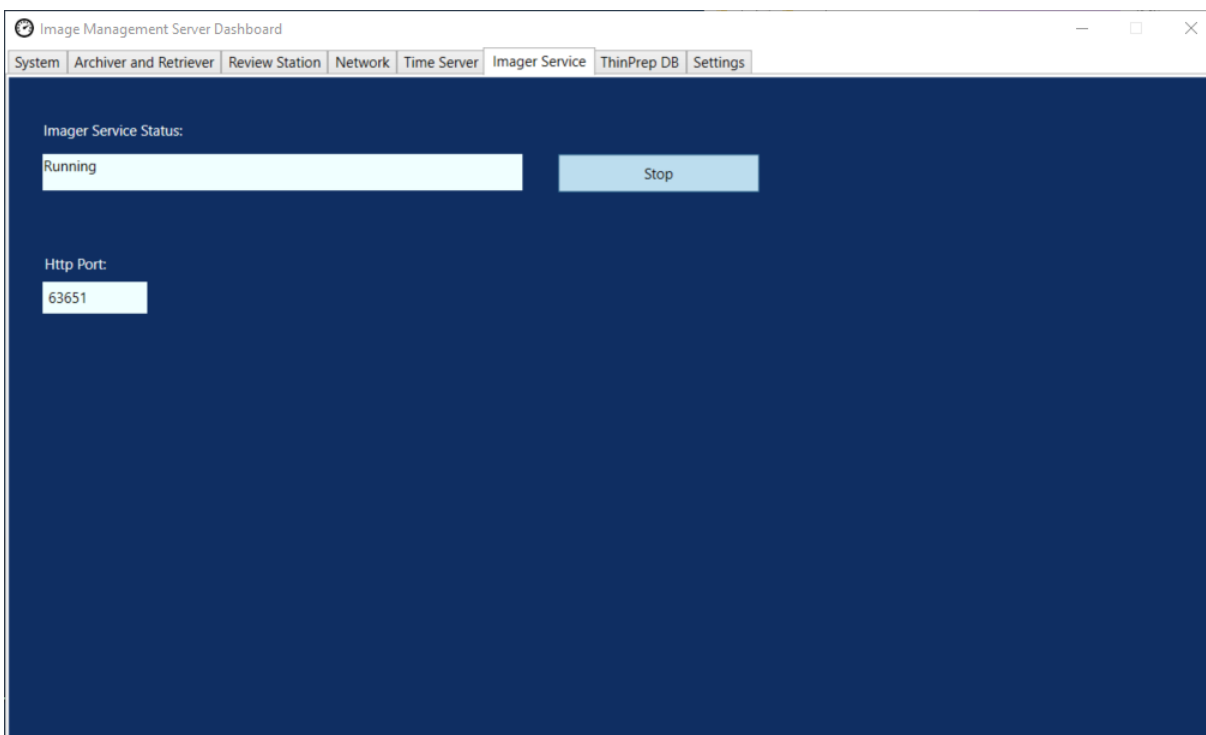


Figure 3-10 Imager Service dashboard

The Http port is the name of the port through which the Image Management Server runs the Imager service. The communication between the Digital Imager and the Image Management Server is set up by Field Service personnel trained by Hologic as part of system installation.

The Imager Service dashboard has a **Start/Stop** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION
H

THINPREP DB

The ThinPrep DB dashboard displays information about the database containing slide image data. The slide image data stored on the Image Management Server includes the accession ID, the date and time the slide was imaged, and the date and time a case was reviewed, as well as other data. The accession ID is stored both as the barcode value scanned from the slide label and the ID used by the Genius Digital Diagnostics System. The slide image data is available on the Image Management Server even after a slide's images have been archived. This allows reports run from the Digital Imager or from the Review Station to include information about all slides, if the person running the report so chooses.

Note: Deleting slides removes data from the Image Management Server. Refer to “Impact of deleting slides” on page 3.7.

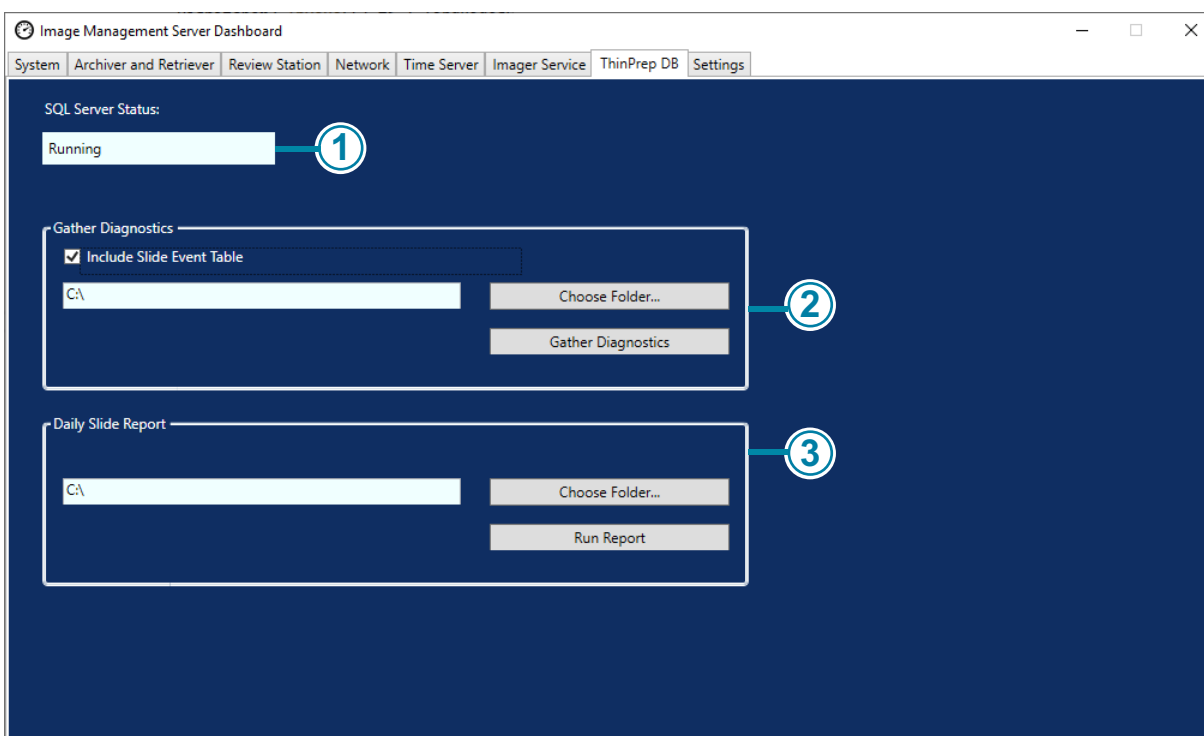


Figure 3-11 ThinPrep DB dashboard

Key to Figure 3-11	
①	SQL Server Status Displays the current status of the SQL server. The status must be “running” in order for the Genius Digital Diagnostics System to function.
②	Gather Diagnostics Refer to “Gather diagnostics” on page 3.19.
③	Daily Slide Report Refer to “Daily slide report” on page 3.20.

Gather diagnostics

Use the **Gather Diagnostics** feature to create a zip file of system data for troubleshooting. The system data in the Gather Diagnostics file is intended for instrument troubleshooting by Hologic Technical Support. It gathers and zips the error history log and other instrument operating information.

1. To gather that data, click the **Choose Folder...** button to navigate to the folder to which the zip file will be written, or type in a file path.
By default, the box is checked for **Include Slide Event Data**. The slide accession IDs are included in the slide event data. To exclude slide event data, click to un-check the box.
Note: To save the Gather Diagnostics file to a thumb drive, put a thumb drive into a USB port on the server and choose that drive in the Choose Folder option.
2. Click the **Gather Diagnostics** button to gather the data. The Image Management Server creates a "IMSDiagnostics" zip file whose file name contains the host name of the computer as well. If a file with the same name already exists in the same location, an error message displays, giving the option to overwrite the existing file.

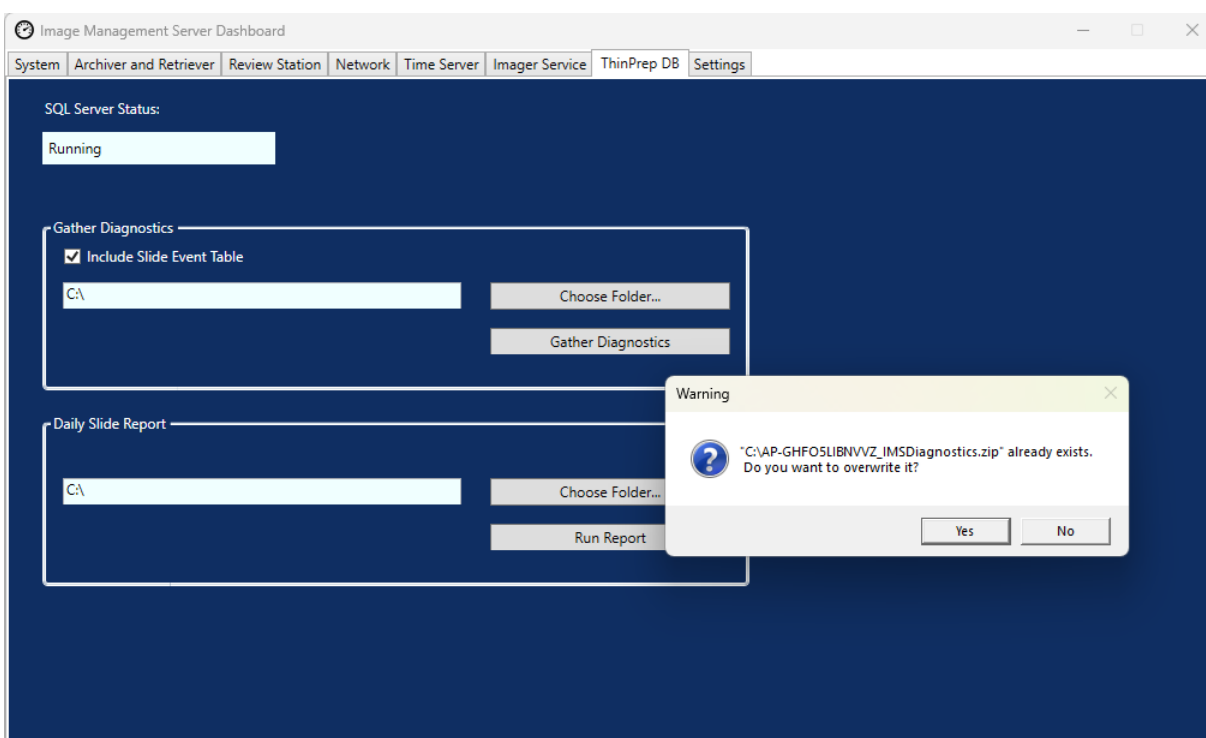


Figure 3-12 Gather Diagnostics, overwrite existing file?

3. To overwrite the existing file, select **Yes**, or select **No** and navigate to a different path using the **Choose Folder...** button.
4. Follow the instructions provided by Hologic Technical Support. Typically, the Gather Diagnostics file is small enough to send to Hologic Technical Support by e-mail.

Daily slide report

The Daily Slide Report is a .csv file showing the quantity of slides imaged each day for each sample type.

To generate a Daily Slide Report:

1. Click the **Choose Folder...** button to navigate to the folder to which the .csv file will be written, or type in a file path.

Note: To save the Daily Slide Report file to a thumb drive, put a thumb drive into a USB port on the server and choose that drive in the Choose Folder option.

2. Click the **Run Report** button to generate the report. The .csv file is named "TotalSlidesByType.csv" and lists the date, the sample type for the slide, and the number of slides.

Date	SlideTypeName	NumOfSlides
7/8/2020 0:00	Gyn	280
7/8/2020 0:00	NonGyn	80
7/8/2020 0:00	Uro	40
7/13/2020 0:00	Gyn	400
7/14/2020 0:00	Gyn	400
7/15/2020 0:00	Gyn	400

Figure 3-13 Daily Slide Report, example

3

IMAGE MANAGEMENT SERVER DASHBOARD

SECTION I

SETTINGS

After the Image Management Server is installed by Field Service personnel trained by Hologic, there may be no need to change the language displayed on the dashboard. The Settings dashboard provides the option to change the language setting to a user with System Administrator rights on the server.

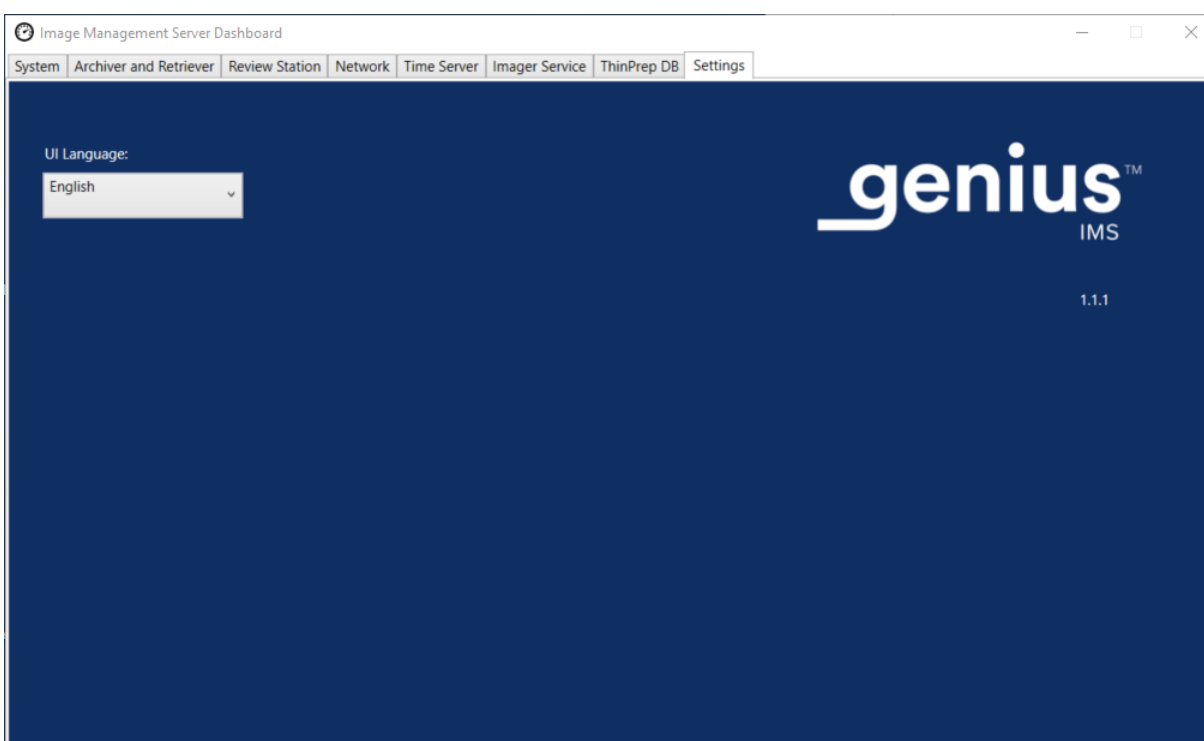


Figure 3-14 Settings dashboard

To change the language, use the down-arrow to select one of the available options.

Chapter Four

Maintenance

SECTION A

GENERAL MAINTENANCE

Hologic does not require preventive maintenance for the Genius Image Management Server. Refer to the documentation provided by the server manufacturer.

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Chapter Five

Troubleshooting

SECTION A

RED STATUS INDICATOR ON SYSTEM DASHBOARD

The Image Management Server System dashboard shows all green status indicators when all of the services and applications are running properly.

A red status indicator indicates that a service or application is not at the “running” or “ready” status. Hover over the status to see more information. On the corresponding tab, the same information displays.

Because the Image Management Server runs on a network at your site, troubleshooting some issues may require collaboration between your laboratory’s network IT staff and Field Service personnel trained by Hologic. The troubleshooting steps described in this manual are intended to resolve issues that arise from the Hologic-controlled components in the network. Additional troubleshooting by a laboratory’s network IT staff may be necessary. For example, if a laboratory’s network IT staff pings the archive storage system from the server, and the ping fails, then a laboratory’s network IT staff will need to troubleshoot the issue. Similarly, if something changes on the laboratory’s network, a laboratory’s network IT staff will need to help troubleshoot issues related to the changes.

Hologic Technical Support is usually required to resolve a “red status” and a service visit by Field Service personnel trained by Hologic may be required. Hologic Technical support will typically request information available on the dashboard to assist with troubleshooting.

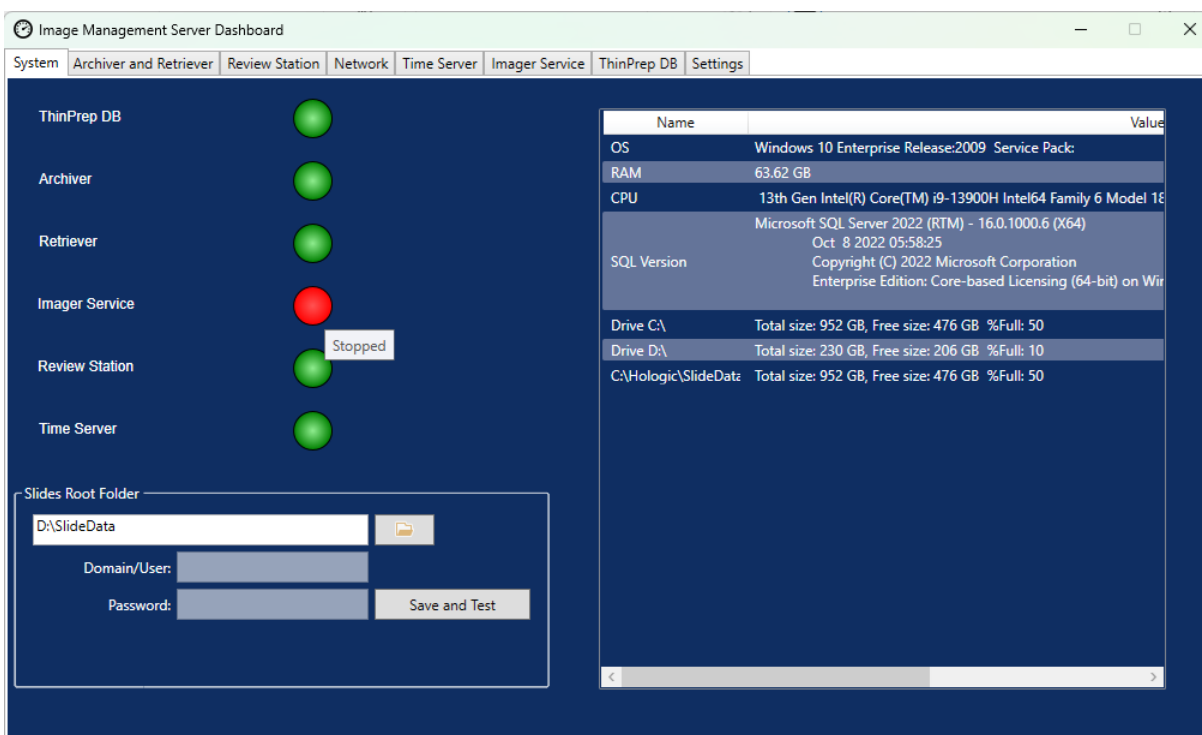


Figure 5-1 Hover mouse for more information, Imager service has stopped in this example

Unable to Archive or Approaching Full Capacity

When the storage capacity in the Slides Root Folder on the server approaches 90% full (10% free), the Image Management Server displays a red status indicator, with a warning message near the folder path information.

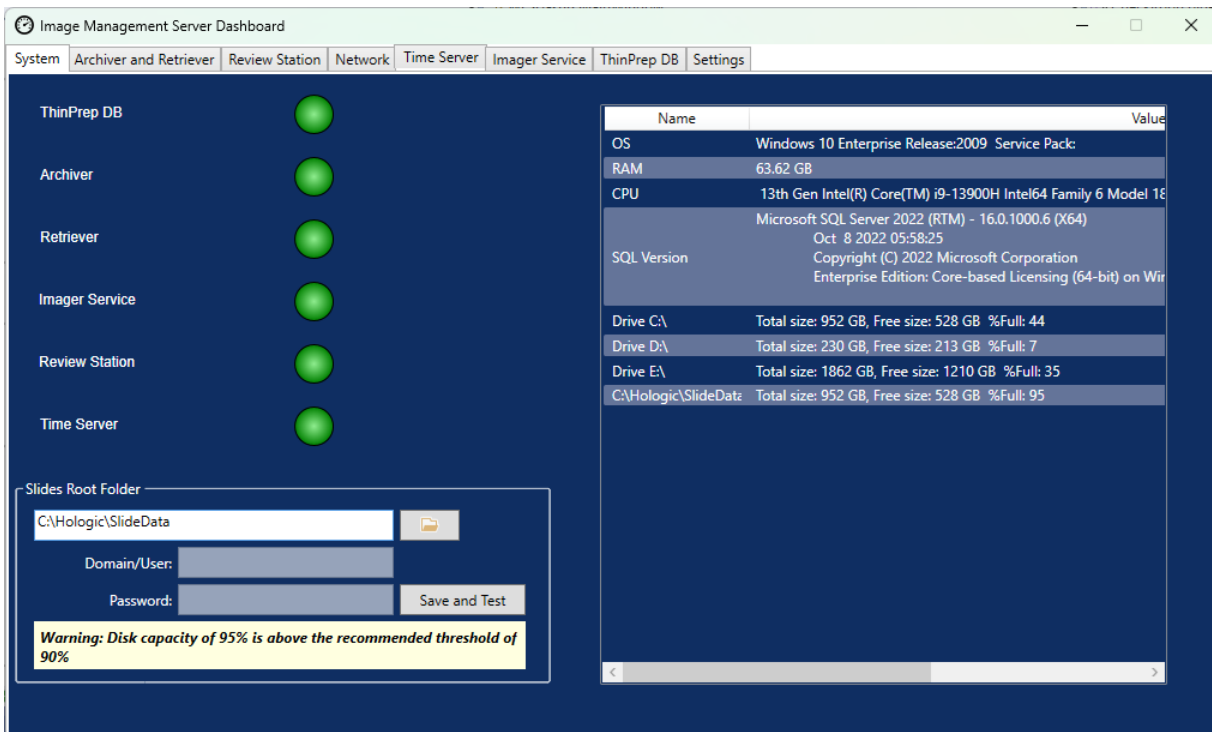


Figure 5-2 Slides Root Folder approaching capacity

Approaching capacity in the slides root folder may indicate that the Image Management Server is unable to transfer images from the slides root folder to the archive storage system. The slides root folder's storage capacity will fill up if the archive storage system is not properly installed and configured before slides are imaged.

If the Image Management Server fails to transfer any of the eligible images from the slides root folder to the archive storage system, the Review Station users with a manager role receive an alert at the Review Station. The alert instructs the manager to contact the site network administrator.

If the slides root folder approaches capacity and some of the eligible images are successfully archived each night, the Review Station users with a manager role do not receive an alert.

The issue may be in the Image Management Server's side of the transfer, or the issue may be in the archive storage system's side of the transfer. Hologic Technical Support can help troubleshoot, and IT network help at your site may be required, for example, if the laboratory's connection to the laboratory's archive storage system is down.

Hologic Technical Support may ask you to check the archive queue, test the archiver, or access Archive History to assist with troubleshooting. Refer to "Archive History" on page 3.12.

If the slides root folder is approaching full and the **Test Archiver** test is successful, the communication between the Image Management Server and the archive storage system is intact.

Communication may have been interrupted temporarily, at the moment the daily archive attempted to start. After a successful test of the archive, verify that the disruption was temporary and not a recurrent issue by checking the archive queue and Archive History the next day, after the scheduled daily archive.

Archiver Test Failed

To change any archive settings and to effectively troubleshoot archive issues, a user must have the proper credentials to access both the archive storage system and the Image Management Server. If a user has System Administrator rights in Windows for the Image Management Server and does not have the proper access to the archive storage system, the test of the archiver will fail. Follow your facility's policy for passwords and network security.

If a user attempts to test the archiver with a wrong or expired username and/or password for either the server or the archive storage system, the test will fail, without revealing any other cause of the failure to archive images.

If the test is not successful, there is an issue with the Image Management Server's communication with the archive storage system. If the **Test Archiver** fails, the Image Management Server will not be able to do the daily transfer of slide image files from the server to the archive storage system. Without the ability to archive, storage space on the server will fill up. The volume of slides imaged, the settings for archive criteria, and the server storage capacity influence how quickly storage space on the server is filled.

If the **Test Archiver** fails, contact Hologic Technical Support.

Username or password is incorrect

To change the start or duration of the daily archive, a user with System Administrator rights in Windows enters a username and password.

If the username or password is incorrect, the Image Management Server displays an error message.

If you have System Administrator rights, attempt the password and user name again.

If you do not have System Administrator rights, contact your site IT support.

Other Messages

There are several activities that should be performed by Field Service personnel trained by Hologic, such as setting up or changing an archive storage location or the storage location for the Slides Root Folder. For some of these activities, dialog boxes will pop up on the Genius IMS dashboard to alert the Field Service personnel of the success or failure of the activity.

Chapter Six

Service Information

Corporate Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

Business Hours

Hologic's business hours are 8:30 a.m. to 5:30 p.m. EST Monday through Friday, excluding holidays.

Europe, UK, Middle East

Technical Solutions Cytology can be reached:

Mon-Fri : 08.00 – 18.00 CET

TScytology@hologic.com

And via the toll-free numbers below:

Finland	0800 114829
Sweden	020 797943
Ireland	1 800 554 144
United Kingdom	0800 0323318
France	0800 913659
Luxembourg	8002 7708
Spain	900 994197
Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	00 800 800 29892

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Chapter Seven

Ordering Information

Europe, UK, Middle East

Technical Solutions Cytology can be reached:

Mon-Fri : 08.00 – 18.00 CET

TScytology@hologic.com

And via the toll-free numbers below:

Finland	0800 114829
Sweden	020 797943
Ireland	1 800 554 144
United Kingdom	0800 0323318
France	0800 913659
Luxembourg	8002 7708
Spain	900 994197
Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	00 800 800 29892

Warranty

A copy of Hologic's limited warranty and other terms and conditions of sale may be obtained by contacting Customer Service at the numbers listed above.

Protocol for Returned Goods

For returns on warranty-covered Genius Digital Diagnostics System items, contact Technical Support.

Table 7.1 Orderable Items, Image Management Server Dashboard

Item	Description	Quantity	Part Number
Image Management Server Dashboard User's Manual	Additional user's manual	ea.	MAN-11754-001

Index

A

- Antivirus 2.4
- Archive history 3.12
- Archive, troubleshooting 5.3
- Archiver
 - change start or duration 3.11
 - current settings 3.10
- Archiver Status 3.10
- Archiver Test Failed 5.4

C

- component overview 1.7
- Cybersecurity 2.3

D

- Daily slide report 3.20
- Dashboard
 - archiver and retriever 3.8
 - imager 3.17
 - network 3.15
 - Review Station 3.14
 - settings 3.22
 - system 3.2
 - ThinPrep DB 3.19
 - time server 3.16
- Dashboard, launch 2.12
- Data clean-up 3.3
- Delete slide data sets 3.4
- Digital Imager 1.4, 3.17

G

- Gather diagnostics 3.20
- Genius Digital Diagnostics System 1.4

H

- hazards 1.11
- humidity range 1.8

I

- Image Management Server Specifications 1.8
- Indication for use 1.2
- Installation 2.1
- Intended purpose 1.2
- Intended use 1.2

L

- labels, location on instrument 1.14
- Launch the application 2.12

M

- Manage
 - delete slide images and case data records 3.4

N

- Network
 - requirements 2.2
- normal shutdown 2.13

O

Operating System 1.8
ordering information 7.1

R

Required Materials 1.5
Retrieve history 3.13
Review Station 1.4, 3.14

S

safety standards 1.9
Security 2.3
Server Hardware 1.8
Shipped to new location 2.11
shutdown 2.13
slide image data 3.19
Slide Management 3.4
Slides Root Folder 3.3
Slides Root Folder, approaching capacity 5.3
Specifications 1.8
 network 2.2
Status Indicators 3.2
System Network 1.4

T

Technical Solutions Cytology 6.1
temperature range 1.8
ThinPrep database 3.19
Troubleshooting 5.1

INDEX

W

Warnings 1.11

HOLLOGIC[®] Genius[™] Image Management Server Dashboard User's Manual



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Patent Information
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