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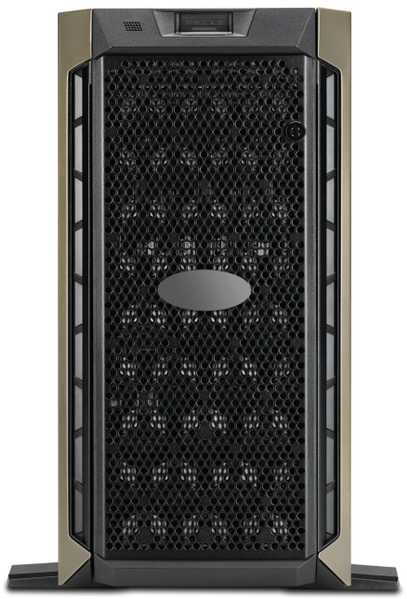

Genius™ Image Management Server Dashboard

genius™ IMS

Operator's Manual

Genius™
Image Management Server
Dashboard User's Manual

HOLOGIC®

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For Use With Version 1.x.y Software

MAN-08020-001

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 cytotechnologist 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 cytotechnologists and pathologists trained by Hologic to evaluate ThinPrep-prepared slides.

Although this guide has been prepared with every precaution to ensure accuracy, Hologic assumes no liability for any errors or omissions, nor for any damages resulting from the application or use of this information.

This product may be covered by one or more U.S. patents identified at hologic.com/patentinformation

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.

Document Number: AW-22965-001 Rev. 001

3-2021

CE

IVD

Genius Digital
Diagnostics System

HOLOGIC®

Genius™ Digital Diagnostics System

Instructions for Use

CE

IVD

INTENDED USE

The Genius™ Digital Diagnostics System, when used with the Genius™ Cervical AI algorithm, is indicated for assisting in cervical cancer screening of ThinPrep® Pap test slides, for the presence of atypical cells, cervical neoplasia, including its precursor lesions (Low Grade Squamous Intraepithelial Lesions, High Grade Squamous Intraepithelial Lesions), and carcinoma, as well as all other cytological categories, including adenocarcinoma, as defined *by The Bethesda System for Reporting Cervical Cytology*[1].

The Genius Digital Diagnostics System can also be used with ThinPrep® non-gynecological microscope slides and ThinPrep® UroCyte® microscope slides to provide a digital image of the whole cell spot for screening.

The Genius Digital Diagnostics System includes the Genius™ Digital Imager, the Genius™ Image Management Server (IMS), and the Genius™ Review Station. The system is for the creation and viewing of digital images of scanned ThinPrep glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this system.

For professional use.

SUMMARY AND EXPLANATION OF THE 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 position of the cell spot. Then the Digital Imager scans the entire ThinPrep cell spot, creating an in-focus, whole slide image.

For ThinPrep® Pap test patient sample slides, the Genius Cervical AI algorithm identifies objects of interest found on the slide. The objects classified as most clinically relevant are presented in a gallery to a cytotechnologist (CT) or pathologist for review in a gallery of images. The slide image data, the slide 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 case ID.

The CT or pathologist reviews cases at the Review Station. The Review Station is a dedicated computer running a Review Station software application, with a monitor suitable for diagnostic review of objects of interest and/or whole slide images. The Review Station is connected to a keyboard and mouse. When a valid case accession ID has been identified at the Review Station, the server sends the images for that ID. The CT or pathologist is presented with a gallery of images of objects of interest for that slide.

When any image is being reviewed, the CT or pathologist has the option to electronically mark objects of interest and include the marks in the slide 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 cell spot into the field of view for examination.

LIMITATIONS

- Only personnel who have been appropriately trained should operate the Genius Digital Imager or Review Station.
- The Genius Cervical AI algorithm is only indicated for use with the ThinPrep Pap test.
- The laboratory Technical Supervisor should establish individual workload limits for personnel using the Genius Digital Diagnostics System.
- ThinPrep microscope slides appropriate for the sample type must be used.
- Slides must be stained using the ThinPrep Stain according to the applicable ThinPrep® Imaging System slide staining protocol.
- Slides should be clean and free of debris before being placed on the system.
- The slide coverslip should be dry and located correctly.
- Slides that are broken or poorly coverslipped should not be used.
- Slides used with the Genius Digital Imager must contain properly formatted accession number identification information as described in the operator's manual.
- The performance of the Genius Digital Diagnostics System using slides prepared from reprocessed sample vials has not been evaluated.
- The monitor and graphics card for the Review Station are those supplied by Hologic specifically for the Genius Digital Diagnostics System. They are required for proper performance of the system and cannot be substituted.

WARNINGS

- For *In Vitro* Diagnostic Use
- The Digital Imager generates, uses, and can radiate radio frequency energy and may cause interference to radio communications.
- Glass. The Digital Imager uses microscope slides, which have sharp edges. In addition, the slides may be broken in their storage packaging or on the instrument. Use caution when handling glass slides and when cleaning the instrument.
- Service Installation Only. The system must be installed by trained Hologic personnel only.

PRECAUTIONS

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the

Digital Imager, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- Care should be taken to assure that slides are correctly oriented in the Digital Imager slide carrier to prevent rejection by the system.
- The Digital Imager should be placed on a flat, sturdy surface away from any vibrating machinery to assure proper operation.

PERFORMANCE CHARACTERISTICS

OBJECTS OF INTEREST (OOI) STUDY

A laboratory study was conducted to demonstrate that the Genius Cervical AI algorithm accurately selects OOIs. An OOI is a cell or cluster of cells on a slide preparation that most likely contains clinically relevant information for diagnostic purposes. The study compared OOIs selected by the GeniusCervical AI algorithm to the same samples imaged and reviewed by CTs using the ThinPrep Imaging System (TIS-assisted review). The study evaluated the performance of the Genius Cervical AI algorithm to present images suitable for diagnosing abnormal cervical cases, for detecting the presence of common infectious organisms in a case, and for detecting the presence of endocervical component (ECC) in a normal case. The study also measured reproducibility of the Genius Digital Diagnostics System.

In the study, 260 ThinPrep slides were enrolled, made from individual residual ThinPrep Pap test specimens, covering the full range of abnormal diagnostic categories as defined in *The Bethesda System for Reporting Cervical Cytology*. The slides were imaged once on the ThinPrep Imaging System, and the same slides were imaged three times on three different Genius Digital Imagers.

Slides were reviewed by CTs using the ThinPrep Imaging System (TIS-assisted review), and, after a washout period, the same CT reviewed the nine runs of that same case on the Genius Digital Diagnostics System. In each review on the Genius Digital Diagnostics System, the CT recorded what the CT observed in every tile in the gallery for the case on the Review Station. The CT reviews were conducted per standard laboratory procedure, recording the diagnostic result, the presences or absence of endocervical component (ECC) and the presence of any infectious organisms, such as trichomonas, candida, coccobacillus, for the TIS-assisted review.

The accuracy and reproducibility of the algorithm were measured by comparison to the TIS-assisted diagnoses. The average and standard deviation across runs leading to the same diagnosis or higher was the metric used.

OOI Study: Specimen Enrollment

Table 1 shows the nominal enrollment diagnoses (base on donor lab results) for the slides in the study. In this study there was no independent truth standard, so the study did not measure

absolute accuracy; the study compared TIS-assisted review with the OOIs on the Genius Digital Diagnostics System.

Table 1. Slides Enrolled in the OOI Study

Category	# of slides
NILM	99
ASCUS	6
LSIL	60
ASC-H	8
AGUS	10
HSIL	60
CANCER	16

Study Results: Cervical Cytology Diagnostic Categories

The highest OOI category for any case across the nine runs of the case on the Genius Digital Diagnostics System was compared to the diagnostic category for the same slide in the TIS-assisted review. Table 2 shows the relationship between the Genius Digital Diagnostic System results and the TIS-assisted results.

Table 2. TIS-assisted Results vs. Genius Digital Diagnostic System OOIs

		TIS								
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	CANCER	Total
OOI	NILM	2	83	4	0	0	2	0	0	91
	ASCUS	0	10	6	3	1	0	0	0	20
	LSIL	0	0	5	27	0	0	1	0	33
	ASC-H	0	1	5	11	2	0	7	0	26
	AGUS	0	2	0	0	0	5	1	1	9
	HSIL	0	0	2	2	2	1	49	5	61
	CANCER	0	0	0	0	1	1	6	9	17
		2	96	22	43	6	9	64	15	

The study showed an average of 6.8 OOIs in tiles per case on the Genius Digital Diagnostic System matched the TIS-assisted diagnosis. The standard deviation was 1.3. These results demonstrate that the Genius Digital Diagnostic System accurately selects OOIs of most interest for diagnosis. And, the results are repeatable across multiple instruments and multiple runs.

Study Results: ECC Detection on Normal Cases

Endocervical component (ECC) presence is noted during slide review to confirm adequate cellular sampling. ECC consists of either endocervical or squamous metaplastic cells. Because the Genius Digital Diagnostics cervical cancer algorithm prioritizes the presentation of abnormal cells when they are present, ECC detection was assessed in this study on the subset of slides deemed normal (NILM) by TIS-assisted review.

Table 3 shows the relationship of ECC presence on TIS-assisted versus OOI gallery review. In each case, the "+" or "-" corresponds to ECC present or absent, respectively. The count of slides in each category is shown in the table.

Table 3. ECC Detection on Normal Cases:
Agreement between TIS-assisted Review and OOI Study Results

ECC		TIS	
		-	+
OOI	-	4	2
	+	31	59
Agreement Rates	**PPA**	97%	(89%, 99%)
	NPA	11%	(5%, 26%)
Detection Rates	**TIS**	64%	(54%, 72%)
	OOI	94%	(89%, 99%)
	(Diff)	-30%	(-40%, -20%)

The positive and negative percent agreement (PPA and NPA) were calculated with reference to the TIS-assisted result. In addition, the detection rates and difference have also been provided. Confidence intervals for the proportions are calculated using the Newcombe score method and account for correlation between the matched pairs.

The ECC detection rate for OOI review was 94%, compared to 64% for TIS-assisted review. There were 31 NILM slides for which ECC was marked as present in the OOI gallery but not noted in TIS-assisted review. Upon further inspection of those cases, the ECC consisted of rare squamous metaplastic cells, which were not noted during the TIS-assisted review.

Infectious Organism Detection

The presence of infectious organisms is noted as part of slide review to help in the clinical assessment of the case. In this study, slides were enrolled that included three classes of organism: Trichomonas, Candida, and Coccobacilli. The tables below compare the detection of each organism on TIS-assisted review and review of OOIs in the gallery of a Genius Digital Diagnostic Review Station. For each table, the positive and negative agreement rates with reference to the TIS-assisted result are provided. The overall detection rate for each organism and the difference in detection rates (TIS – OOI) are also included.

Table 4. Trichomonas Detection:
Agreement between TIS-assisted Review and OOI Study Results

TRICH		**TIS**	
		-	**+**
OOI	**-**	246	1
	+	2	8
Agreement Rates	**PPA**	89%	(57%, 98%)
	NPA	99%	(97%, 100%)
Detection Rates	**TIS**	3.5%	(1.9%, 6.5%)
	OOI	3.9%	(2.1%, 7.0%)
	(Diff)	-0.4%	(-2.5%, 1.6%)

The detection rate for Trichomonas for the Genius Digital Diagnostics System was 3.9%, compared to 3.5% for TIS-assisted review.

Table 5. Candida Detection:
Agreement between TIS-assisted Review and OOI Study Results

CAND		TIS	
		-	+
OOI	-	232	5
	+	3	17
Agreement Rates	**PPA**	77%	(57%, 90%)
	NPA	99%	(96%, 100%)
Detection Rates	**TIS**	8.6%	(5.7%, 12.6%)
	OOI	7.8%	(5.1%, 11.7%)
	(Diff)	0.8%	(-1.8%, 3.4%)

The detection rate for Candida for the Genius Digital Diagnostics System was 7.8%, compared to 8.6% for TIS-assisted review.

Table 6. Coccobacilli Detection:
Agreement between TIS-assisted Review and OOI Study Results

COCCO		TIS	
		-	+
OOI	-	203	5
	+	21	28
Agreement Rates	**PPA**	85%	(69%, 93%)
	NPA	91%	(86%, 94%)
Detection Rates	**TIS**	12.8%	(9.3%, 17.5%)
	OOI	19.1%	(14.7%, 24.3%)
	(Diff)	-6.2%	(-10.3%, -2.3%)

The detection rate for Coccobacilli for the Genius Digital Diagnostics System was 19.1%, compared to 12.8% for TIS-assisted review. Further inspection of these cases indicated that bacteria were indeed present in moderate quantities on some cells. In this study, the CTs were required to mark the type of each OOI presented, so Coccobacilli would be noted if any normal cells with bacteria overlaid were presented in the gallery. During a TIS-assisted review, and in clinical practice, bacterial infection is typically noted only when it is considered of possible clinical significance (so-called “clue” cells or a large number of infected cells). The difference in detection rates in the study is due to this difference in counting methodology and would not necessarily be reflected in clinical practice.

Overall, the presentation of infectious organisms by the algorithm is equivalent or higher than with TIS-assisted review.

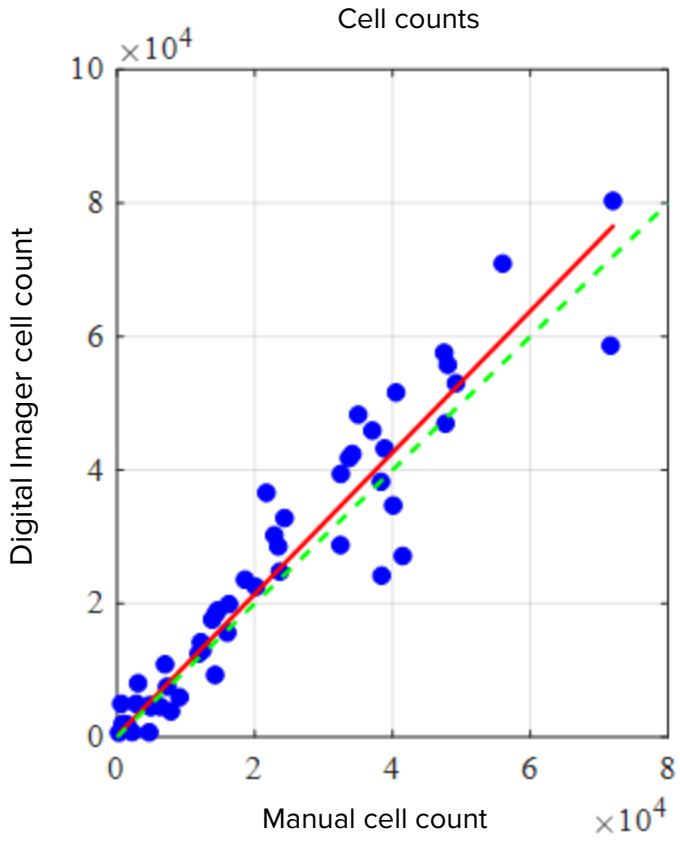
CELL COUNT STUDY

A study was conducted to evaluate the performance of the cell count metric produced by the Genius Cervical AI algorithm compared to a manual cell count.

ThinPrep Pap test patient sample slides were prepared on a ThinPrep processor, stained and coverslipped. The same slides were imaged on three Genius Digital Imagers three separate times. To obtain the manual cell count for the slides in the study, a CT viewed the whole slide image presented on the Genius Review Station, counted the cells presented in a portion of the cell spot image, and estimated the total number of cells based on the portion, similar to the normal process for counting cells on slides viewed on a microscope. The cell counts derived on each Digital Imager by the algorithm in the Genius Digital Diagnostics system were compared to the manual cell count estimate.

A total of 50 specimens, including at least 8 slides with counts near the clinically critical threshold of 5000 cells, were enrolled in the study. The slides covered a range of cellularity typical of a clinical environment. Figure 1 compares the cell counts between the Genius Cervical AI algorithm and a manual cell count method for each specimen.

Figure 1: Deming Regression
Cell Count: Digital Imager vs. Manual



The study calculated the average cell count generated by the Genius Cervical AI algorithm for each case across the three runs on each of the three Digital Imagers in the study. The intra-instrument %CV in the study was 0.6%. The inter-instrument %CV in the study was 2.7%.

The study also estimated the systematic bias of the cell count generated by the Genius Cervical AI algorithm as compared to the manual count, at a count of 5000 cells, the clinical threshold for diagnosis. In the Bethesda System[1], specimens with fewer than 5000 cells are considered unsatisfactory for screening. The count bias in the study was 528, with a 95% CI of -323 to 1379.

The results of the study demonstrate that the cell counts generated by the Genius Cervical AI algorithm are comparable to a manual cell count performed by a cytotechnologist.

CONCLUSIONS

- 89.3% of abnormal slides have OOIs matching or exceeding the TIS-assisted review result.
- On average, there are 6.8 OOIs that match or exceed the TIS-assisted result for abnormal slides.
- The standard deviation of number of matching OOIs is 1.3, for abnormal slides.
- Endocervical component (ECC) is detected in the OOI gallery at an equal or higher rate than in TIS-assisted reviews.
- Trichomonas is detected in the OOI gallery at an equal or higher rate than in TIS-assisted reviews.
- Candida is detected in the OOI gallery at an equal or higher rate than in TIS-assisted reviews.
- Coccobacilli are detected in the OOI gallery at an equal or higher rate than in TIS-assisted reviews.
- The Genius Digital Diagnostics System provides cell counts adequate for determining if specimen adequacy is sufficient for evaluating patient cases.

The data from the studies conducted on the Genius Digital Diagnostics System demonstrate that the Genius Digital Diagnostics System, when used with the Genius Cervical AI algorithm, is effective for assisting in cervical cancer screening of ThinPrep® Pap test slides, imaged on the Genius Digital Imager for the presence of atypical cells, cervical neoplasia, including its precursor lesions (Low Grade Squamous Intraepithelial Lesions, High Grade Squamous Intraepithelial Lesions), and carcinoma as well as all other cytological criteria, including adenocarcinoma, as defined *by The Bethesda System for Reporting Cervical Cytology*[1].

MATERIALS REQUIRED

MATERIALS PROVIDED

- Genius Digital Imager
    - Digital Imager
    - Digital Imager computer
    - Slide carriers
- Genius Review Station
    - Monitor
    - Review Station computer*
- Genius Image Management Server
    - Server*
    - Network switch

*In some configurations of the system, the laboratory may supply the Review Station computer into which Hologic installs a Hologic-supplied graphics card. In some configurations of the system, a laboratory may supply the server hardware.

MATERIALS REQUIRED BUT NOT PROVIDED

- Slide staining racks
- Monitor, keyboard, mouse for the Image Management Server
- Keyboard and mouse for each Review Station

STORAGE

- Refer to the Technical Specifications included in the Digital Imager operator's manual.
- Additional storage requirements may apply. Refer to the documentation provided with the server, monitors and computers.

BIBLIOGRAPHY

1. Nayar R, Wilbur DC. (eds), *The Bethesda System for Reporting Cervical Cytology: Definitions, Criteria, and Explanatory Notes.* 3rd ed. Cham, Switzerland: Springer: 2015

TECHNICAL SERVICE AND PRODUCT INFORMATION

For technical service and assistance related to use of the Genius Digital Diagnostics System, contact Hologic:

Telephone: 1-800-442-9892

Fax: 1-508-229-2795

For international or toll-free blocked calls, please contact 1-508-263-2900.

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1. Introduction

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, manages communication with an external archive and hosts web services for external Genius™ Review Stations. Depending on the Image Management Server specifications and data volumes the Image Management Server can act as either a short or long-term cache.

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 (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 cytotechnologists for primary review and QC reviews, as well as pathologists review as needed.

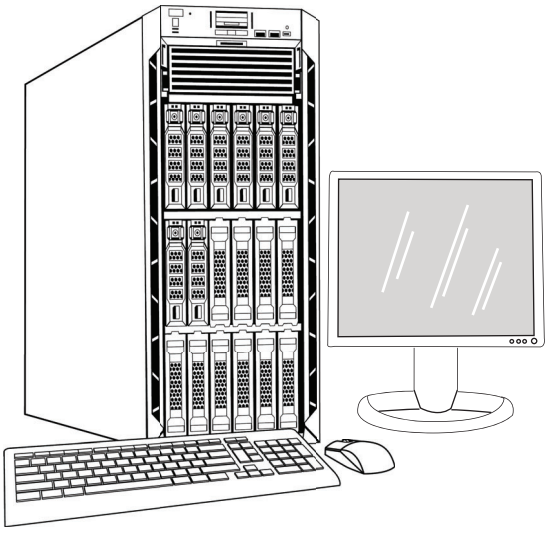


Figure 1-1 Genius Image Management Server

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

1 INTRODUCTION

Indication for Use

The Image Management Server is one component of the Genius Digital Diagnostics System.

The Genius Digital Diagnostics System, when used with the Genius™ Cervical AI algorithm, is indicated for assisting in cervical cancer screening of ThinPrep® Pap test slides for the presence of atypical cells, cervical neoplasia, including its precursor lesions (Low Grade Squamous Intraepithelial Lesions, High Grade Squamous Intraepithelial Lesions), and carcinoma, as well as all other cytological categories, including adenocarcinoma, as defined by *The Bethesda System for Reporting Cervical Cytology*[1].

The Genius Digital Diagnostics System can also be used with ThinPrep® non-gynecological microscope slides and ThinPrep® UroCyte® microscope slides to provide a digital image of the whole cell spot for screening.

The Genius Digital Diagnostics System includes the Genius Digital Imager, the Genius Image Management Server, and the Genius Review Station. The system is for the creation and viewing of digital images of scanned ThinPrep glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this system.

For professional use.

SECTION B THE GENIUS DIGITAL DIAGNOSTICS SYSTEM

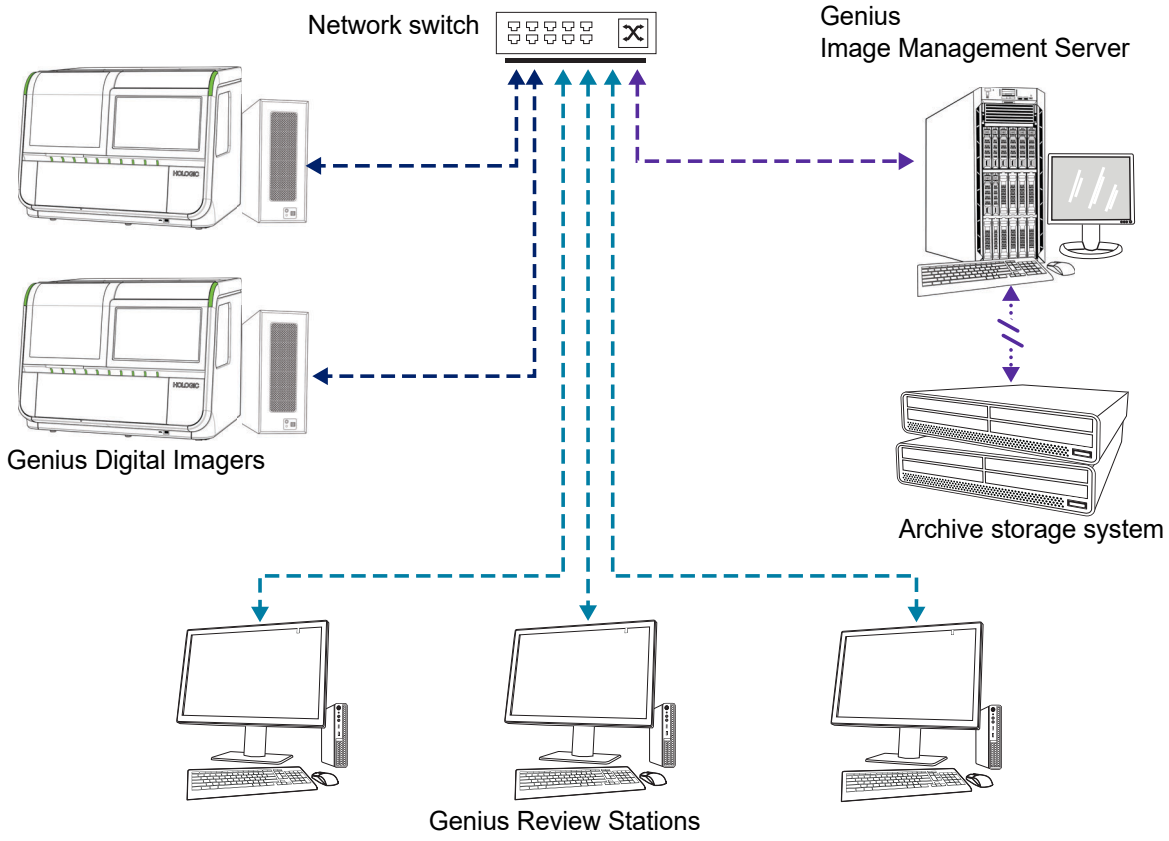
Slides that have been prepared for screening are loaded into slide carriers which are placed into the Digital Imager. The operator uses a touch screen on the Digital Imager to interact with the instrument via a graphic, menu-driven interface.

A slide ID reader scans the slide's accession ID and locates the position of the cell spot. Then the Digital Imager scans the entire ThinPrep cell spot, creating images of the slides. The slide image data, the slide 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 case ID.

1. Nayar R, Wilbur DC. (eds), *The Bethesda System for Reporting Cervical Cytology: Definitions, Criteria, and Explanatory Notes.* 3rd ed. Cham, Switzerland: Springer: 2015

The CT or pathologist reviews cases at the Review Station. The Review Station is a dedicated computer running a Review Station software application, with a monitor suitable for diagnostic review of images. When a valid case accession ID has been identified at the Review Station, the server sends the images for that ID. The CT or pathologist is presented with images at the Review Station. When any image is being reviewed, the CT or pathologist has the option to electronically mark objects of interest and include the marks in the slide 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 cell spot into the field of view for examination.



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

1 INTRODUCTION

Required Materials

- Genius Digital Imager
- Genius Review Station
- Network switch
- Server – available from Hologic, or provided by customer

Required but not provided

- Computer monitor, keyboard, and mouse
- Archive storage system

A network connection between the Image Management Server and the other components of the Genius Digital Diagnostics System is required, using a minimum of cat 6 cabling. 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.

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

SECTION D

IMAGE MANAGEMENT SERVER TECHNICAL SPECIFICATIONS

Overview of Components

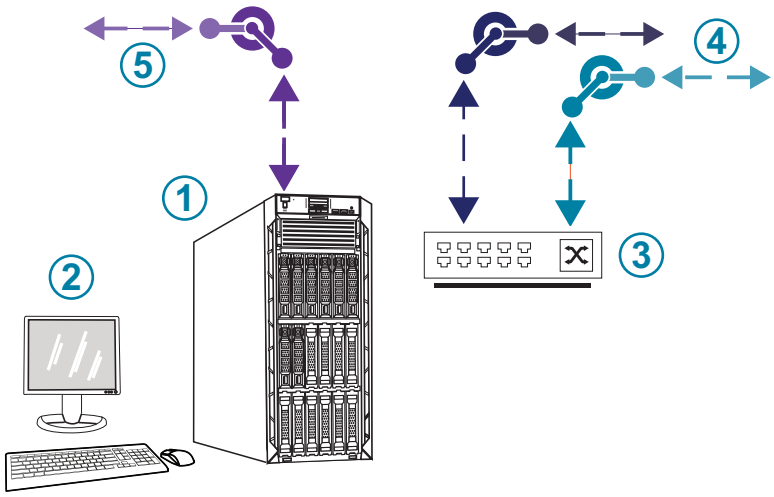


Figure 1-3 Image Management Server Components

Key to Figure 1-3	
1	Server
2	Monitor, keyboard, and mouse
3	Network switch
4	Connections to the Digital Imager and Review Station
5	Connection to the archive storage system

1 Introduction

Image Management Server Specifications

Depending on the configuration in your laboratory, the Image Management Server hardware may be supplied by Hologic. 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:

- 16.5M Cache, 2.20 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
- Video graphics display interface of type VGA, HDMI, or display port
- Dual, hot-plug, redundant power supply (1+1), 750 W or greater

Operating System:

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

Note: To properly display the dashboard, the minimum recommended display resolution for the monitor connected to server 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 E 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 Image Management Server continuously checks for a proper connection with Review Station and Digital Imager. If the connection to the server is broken, a message is shown on the Review Station or Digital Imager, and on the Image Management Server dashboard.

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.

1 INTRODUCTION

SECTION F

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 Hologic service personnel and your facility's IT staff. Proper installation and configuration are required for proper performance of the system and cannot be substituted.

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 and computer for a description of any symbols used on the hardware. The following symbols may appear on the labels supplied by Hologic.

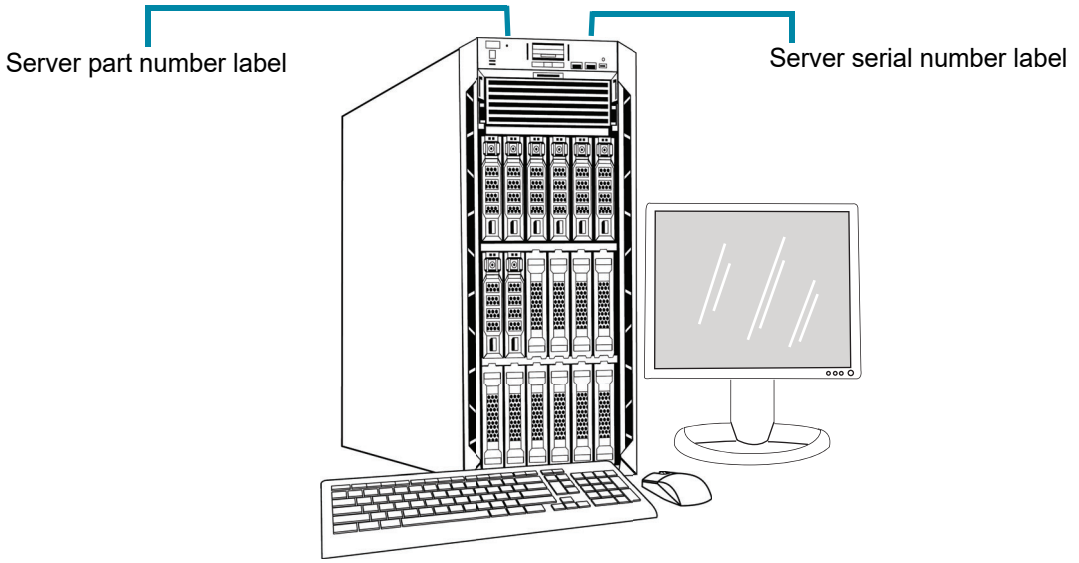
	Consult the instructions for use
	Serial number
	Manufacturer
	Authorized representative in the European Community
	Catalogue number
	Date of manufacture
	*In vitro* diagnostic medical device
	On (Power switch)
	Off (Power switch)
	On/Off, Standby mode

	USB port icon (computer)
	Ethernet port icon (computer)

Figure 1-4 Symbols used on the server and computer

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 an 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 trained Hologic personnel 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 G DISPOSAL

Disposal of the device

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

Do not dispose in municipal waste.

EC REP

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
1-508-263-2900
Fax: 1-508-229-2795
Web: www.hologic.com

Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

1 INTRODUCTION

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2. Installation

Chapter Two

Installation

WARNING: Service Installation Only

SECTION A GENERAL

The Genius Image Management Server must be installed and configured by qualified Hologic service personnel.

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, Hologic personnel 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 an archive storage system. The laboratory is responsible for the installation and configuration of the archive storage system. An archive storage system is mandatory. Hologic service personnel 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

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 Hologic service installation.

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.

2 INSTALLATION

SECTION C

PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

A pre-installation site assessment is performed by qualified Hologic service personnel. 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 Hologic service personnel.

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 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.
- 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 Image Management Server requires a minimum of 10 Gbps unimpeded network connectivity to the Digital Imager computer.
- The Image Management Server requires a minimum of 1 Gbps unimpeded network connectivity to the Review Station, in an on-premises configuration.
- Connectivity can be accomplished utilizing facility infrastructure or direct connection through the Hologic-provided 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 64563.

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

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 distributor. 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 distributor. 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 distributor. A service visit is required.

The Genius Digital Diagnostics System components must be fully assembled before turning on the power and using the instrument. Hologic service personnel 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.

2 INSTALLATION

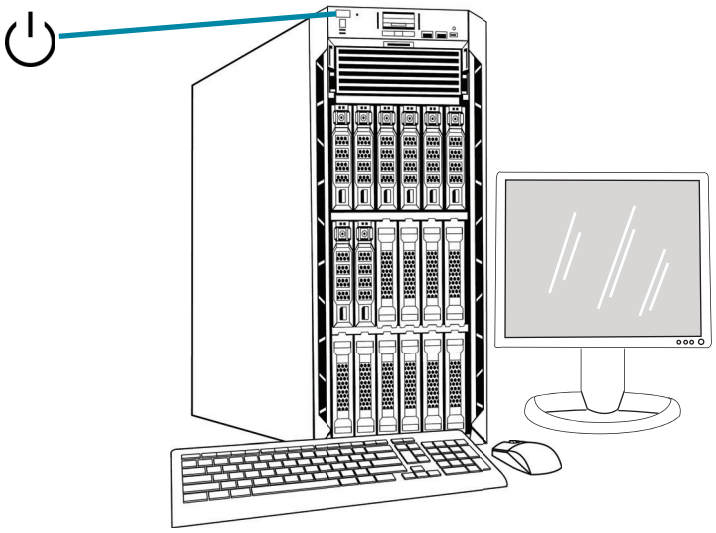
SECTION F

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.

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 2-1 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, shut down the Digital Imager first. If the Digital Imager is transmitting data to the Image Management Server when the Image Management Server is being shut down, the data will be lost, unable to be restored.

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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3 .Image Management
Server Dashboard

3 .Image Management
Server Dashboard

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:

3 IMAGE MANAGEMENT SERVER DASHBOARD

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.

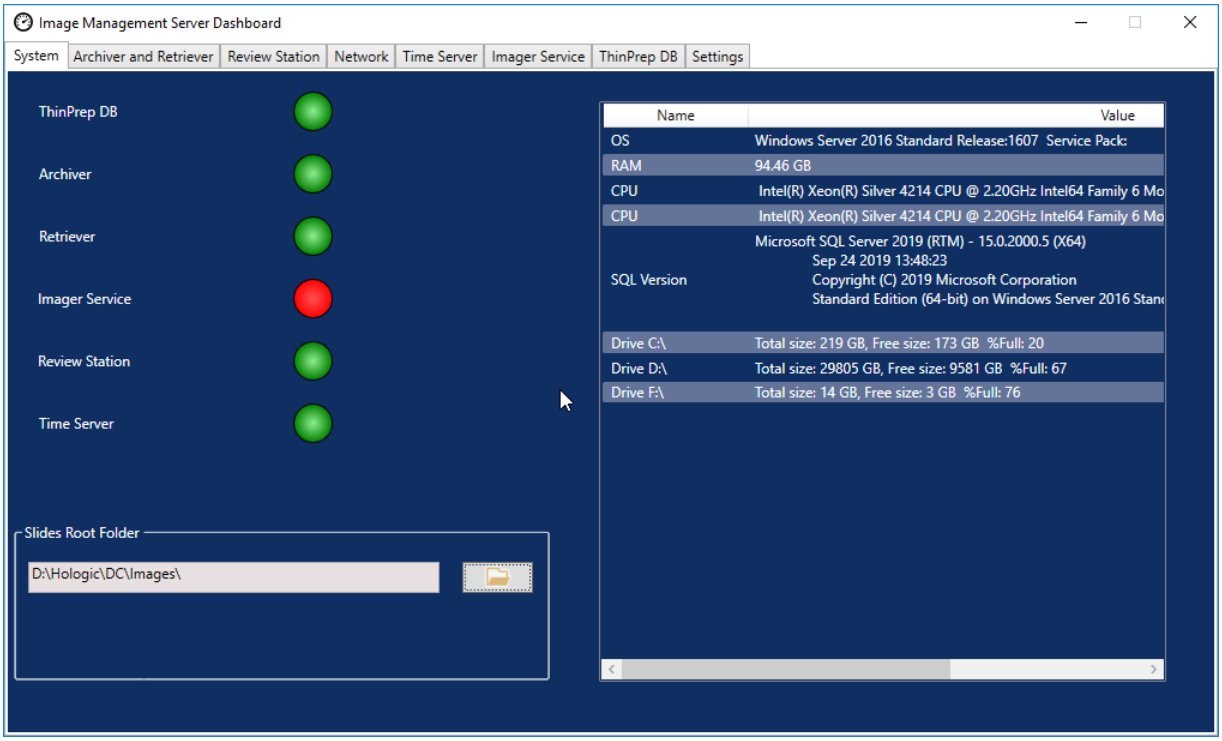
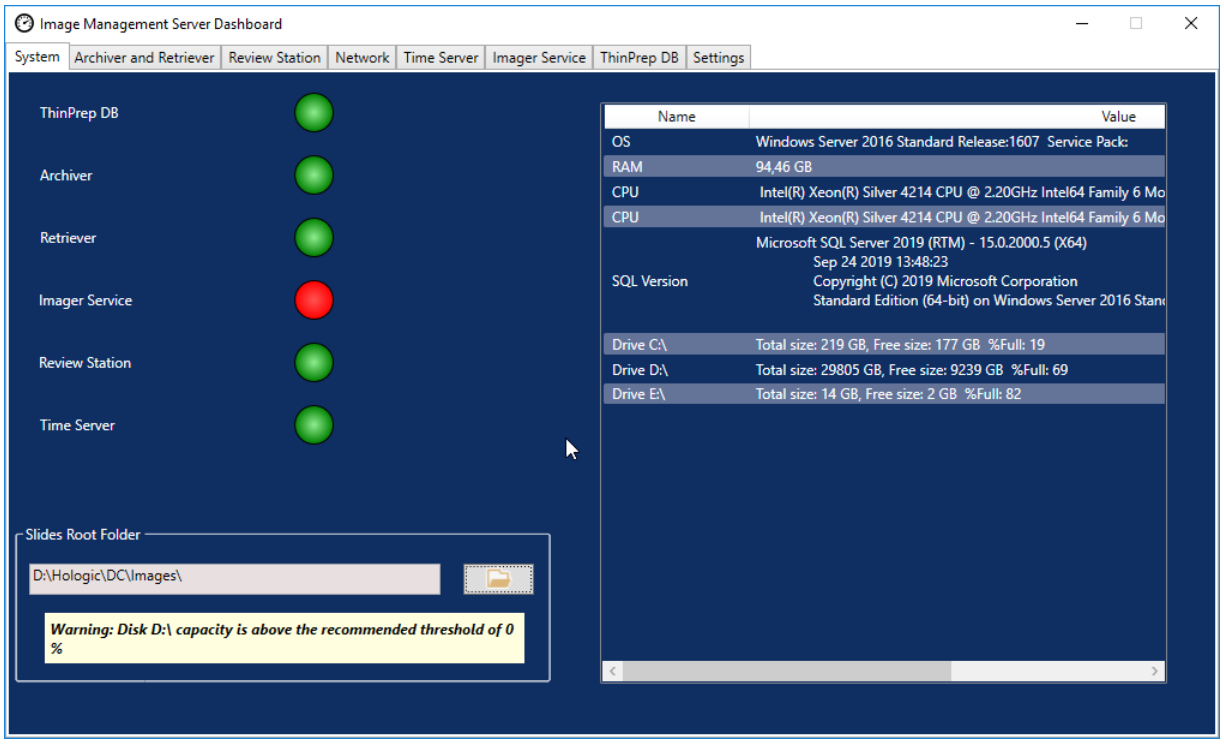


Figure 3-1 System dashboard

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.

When the amount of data saved to the Slides Root Folder approaches the limit of its storage capacity, a red status indicator 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.



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

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

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).

3 IMAGE MANAGEMENT SERVER DASHBOARD

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, 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. 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.

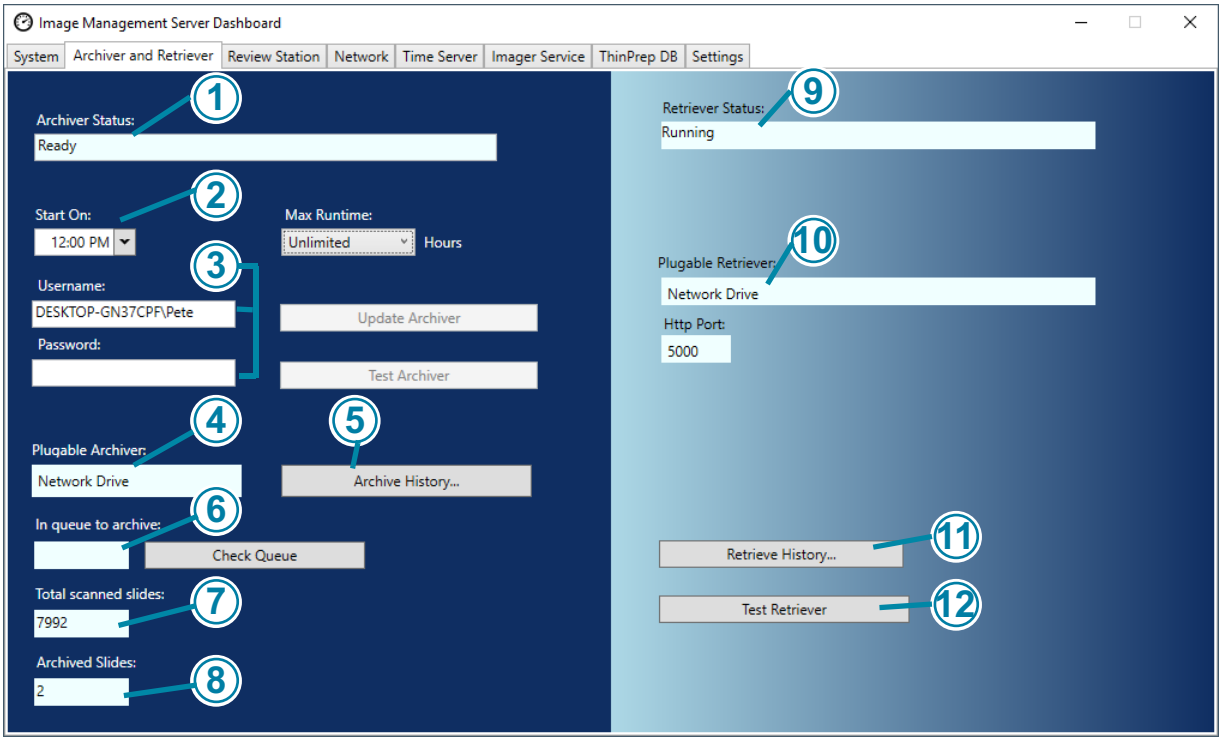


Figure 3-2 Archiver and Retriever dashboard

	Key to Figure 3-2
①	Archiver Status Refer to “Archiver Status” on page 3.6.
②	Current time settings for the daily archive Refer to “Current time settings for the daily archive” on page 3.6.
③	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 3.6.
④	Plugable Archiver The Plugable Archiver information on the dashboard describes the archived storage device configured with this Image Management Server. The plugable archiver is installed and configured by qualified Hologic service personnel.
⑤	Archive History button Refer to “Archive History” on page 3.7.
⑥	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.
⑦	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.
⑧	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.
⑨	Retriever status Refer to “Retriever Status” on page 3.8.

	Key to Figure 3-2
⑩	Plugable retriever and http port The **Plugable Retriever** information on the dashboard describes the archive storage system device configured with this Image Management Server. When configured correctly, the plugable retriever is the same device as the plugable archiver. 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 installed and configured by qualified Hologic service personnel.
⑪	Retrieve History Refer to “Retrieve history” on page 3.9.
⑫	Test Retriever The Test Retriever is used by qualified Hologic service personnel to confirm that the current settings are properly set up for retrieving slides from the archive storage system.

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.

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.

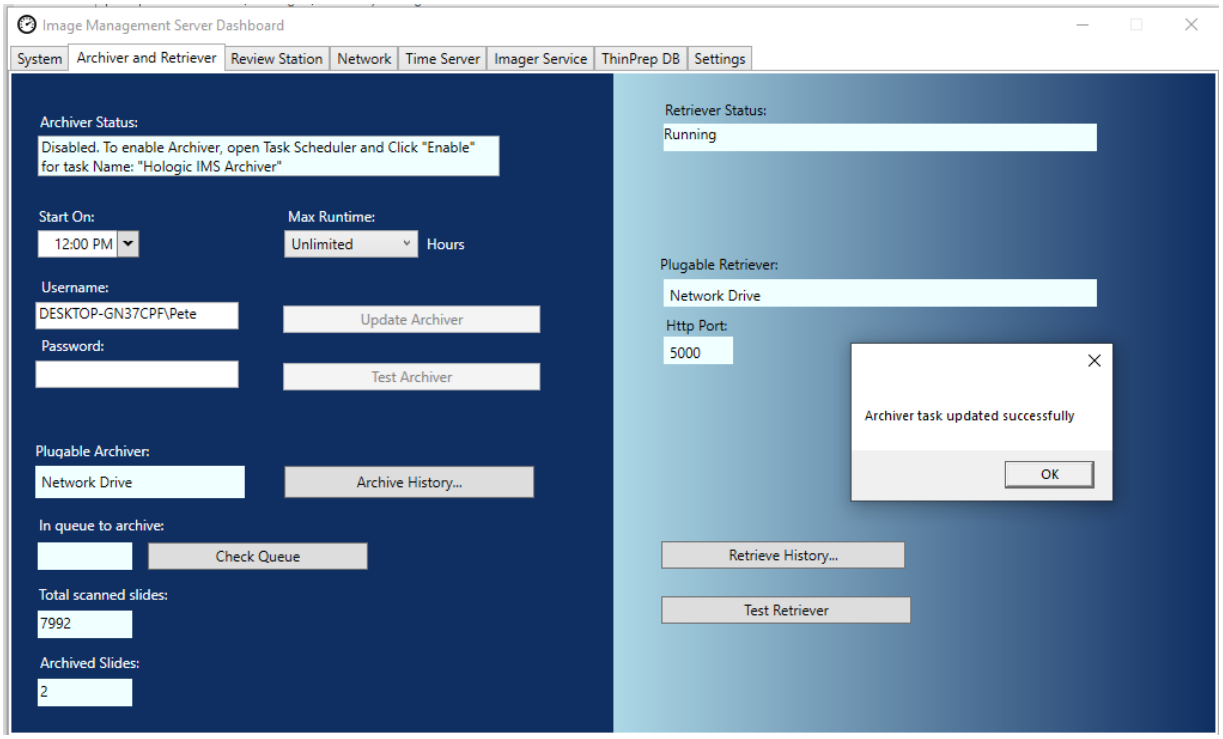


Figure 3-3 Archiver task updated successfully

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.

3 IMAGE MANAGEMENT SERVER DASHBOARD

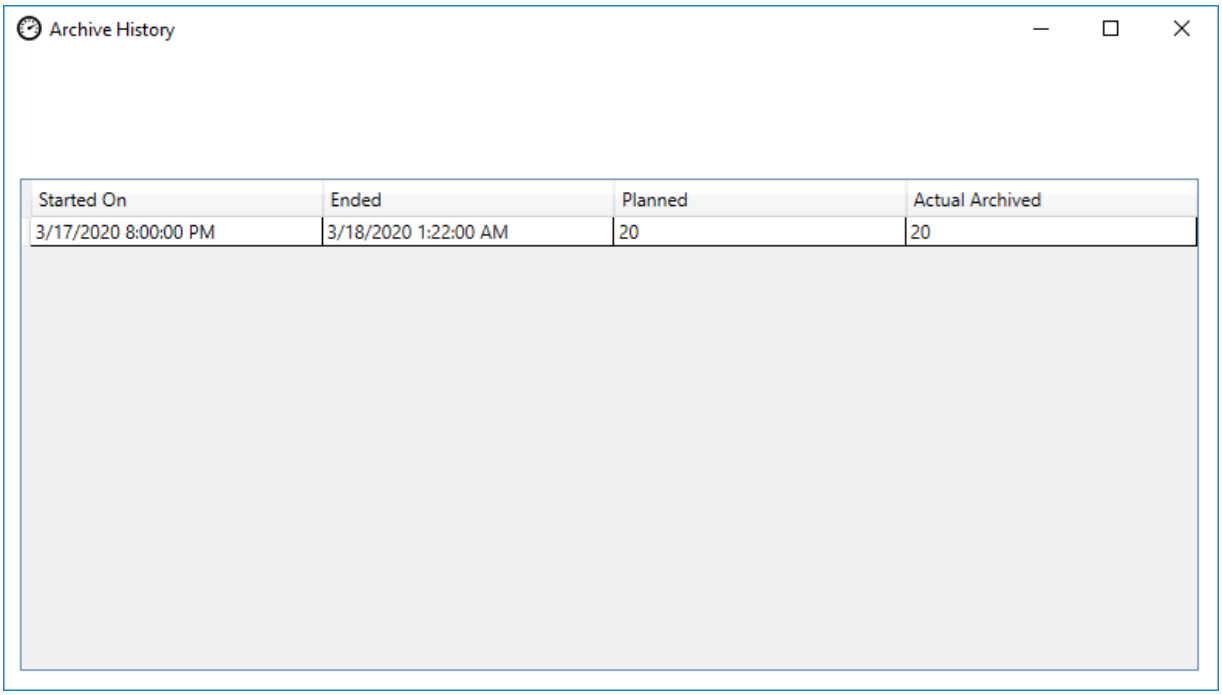


Figure 3-4 Archive History, example

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.

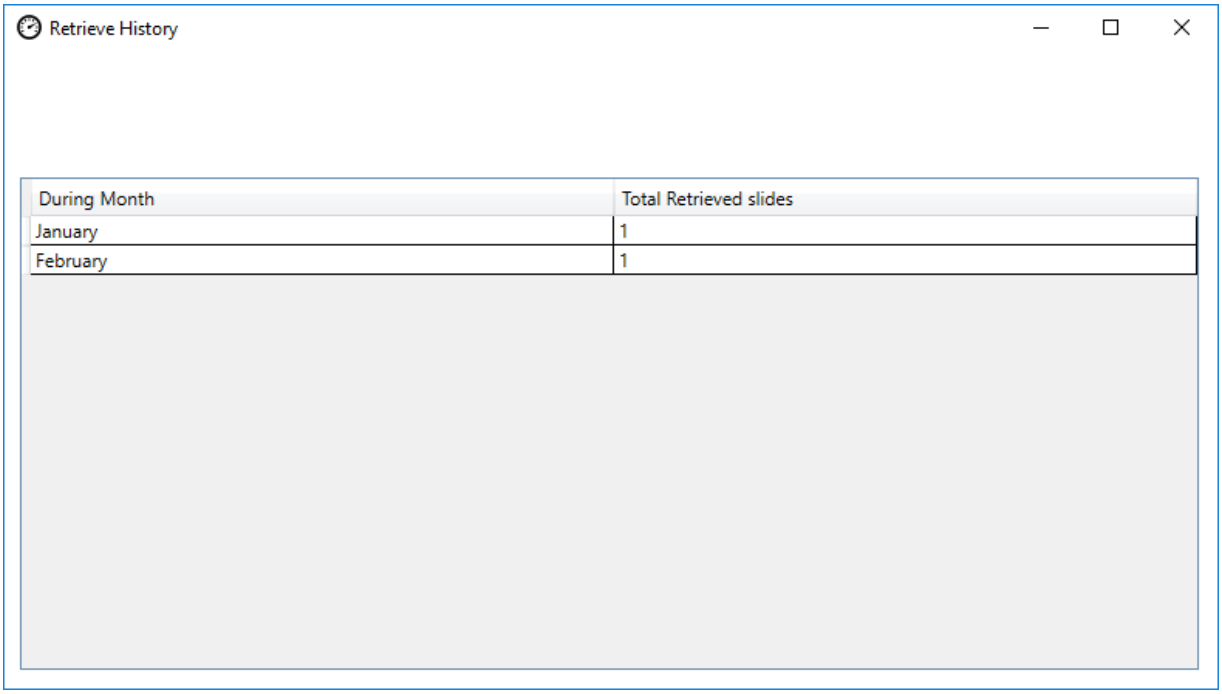


Figure 3-5 Retrieve History, example

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.

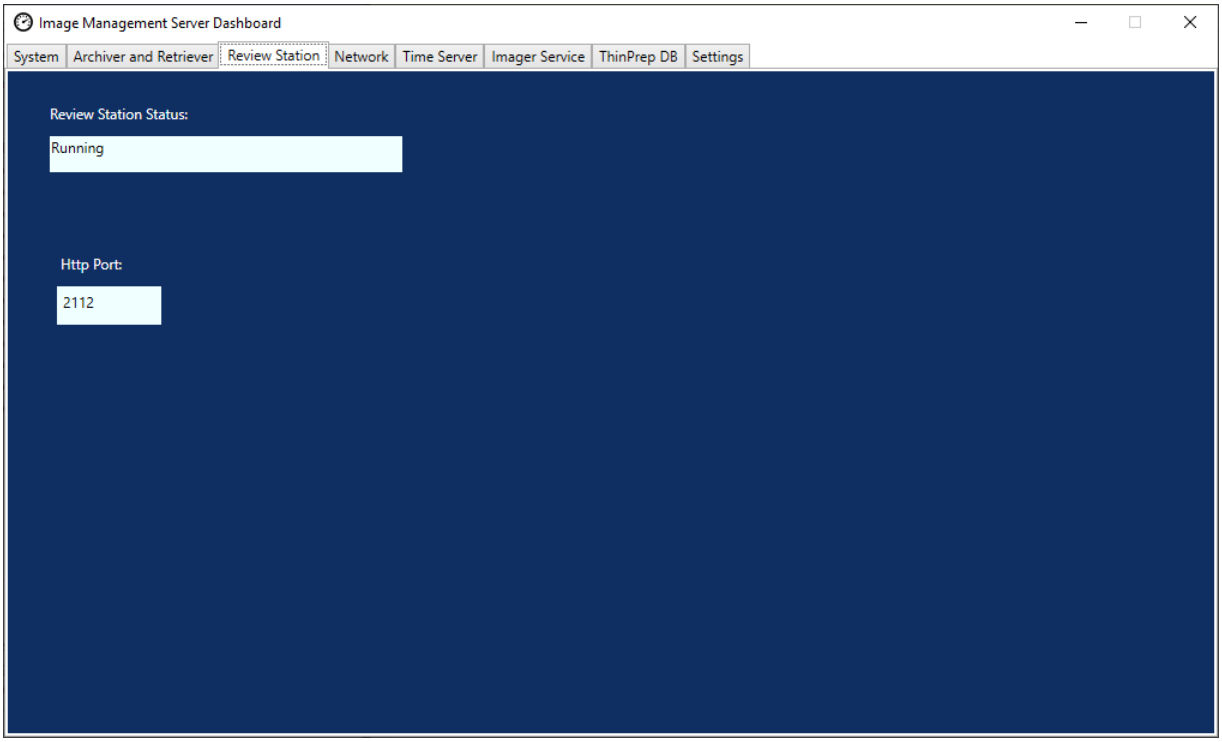


Figure 3-6 Review Station dashboard

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 Hologic service personnel as part of system installation.

SECTION E

NETWORK

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

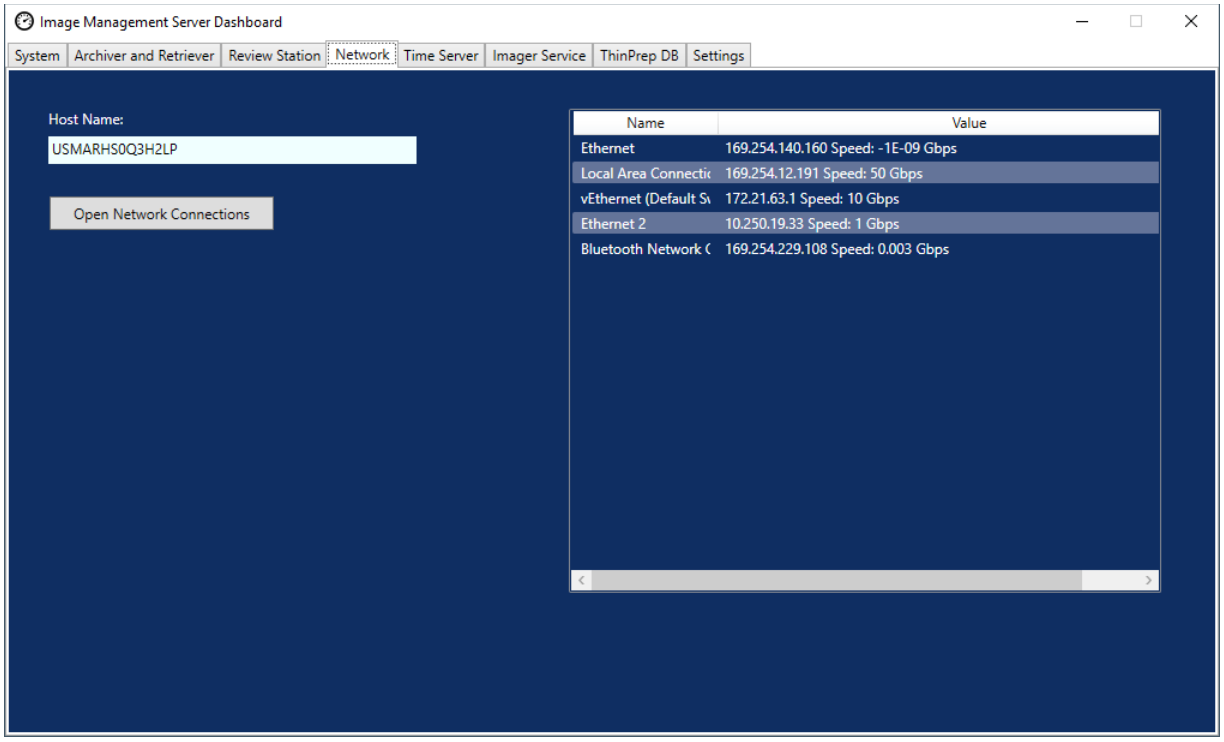


Figure 3-7 Network dashboard

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 Hologic service personnel.

3 IMAGE MANAGEMENT SERVER DASHBOARD

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.

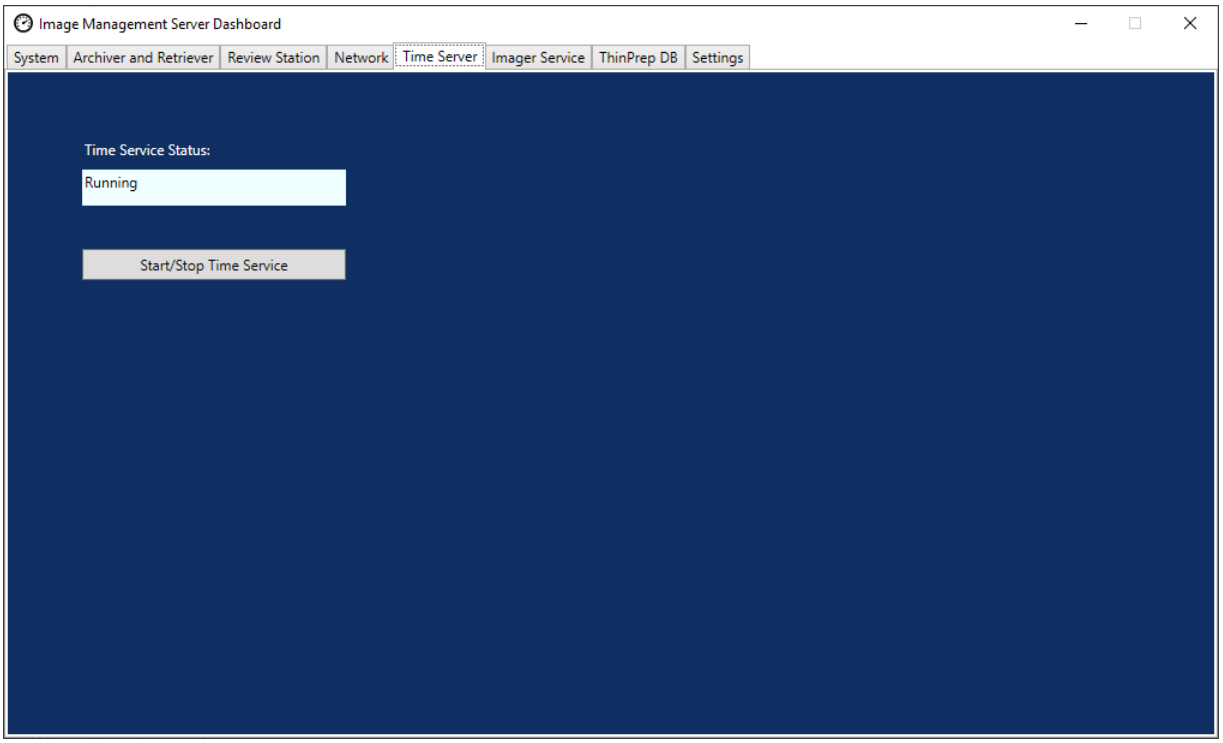


Figure 3-8 Time Server dashboard

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

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.

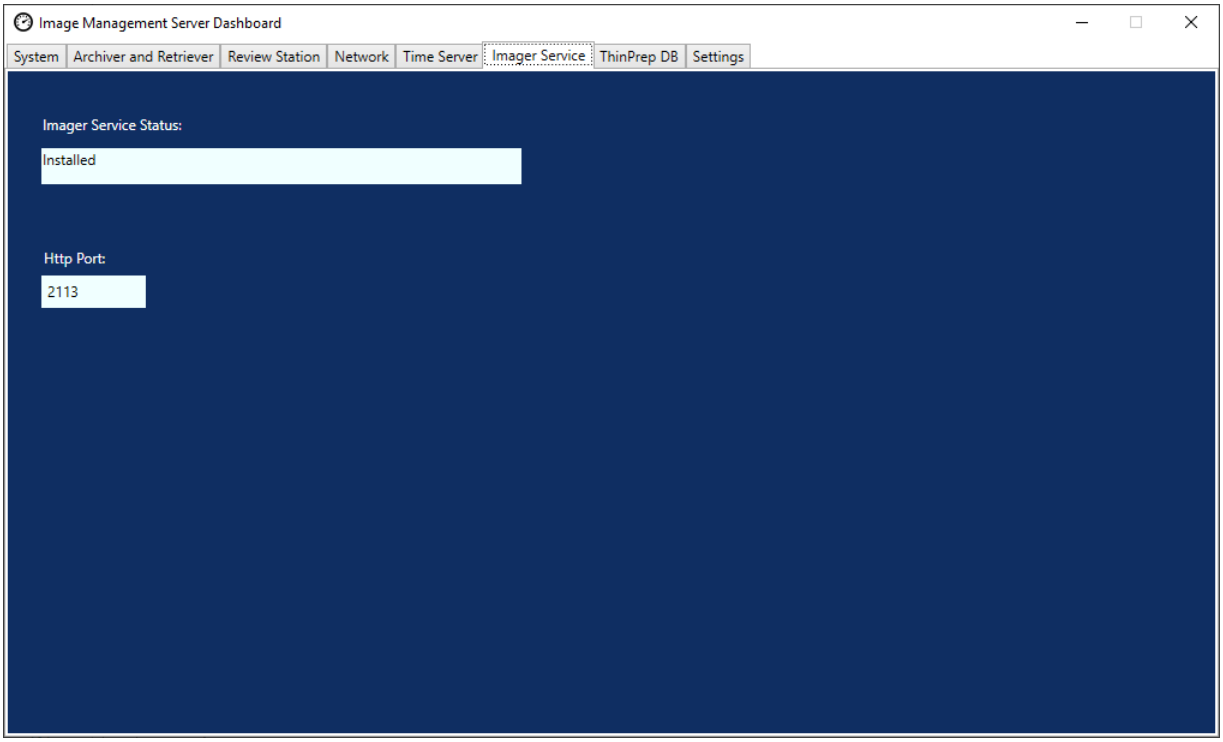


Figure 3-9 Imager Service dashboard

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 Hologic service personnel as part of system installation.

3 IMAGE MANAGEMENT SERVER DASHBOARD

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 slide image data is always 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.

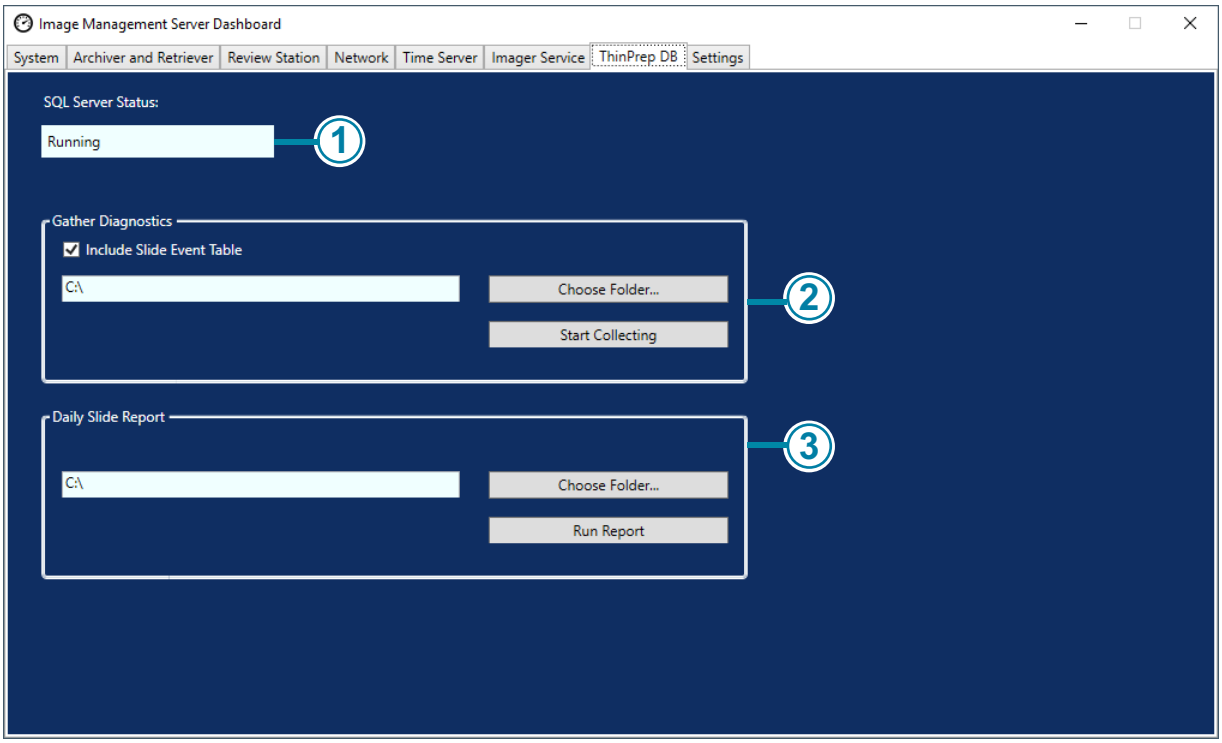


Figure 3-10 ThinPrep DB dashboard

	Key to Figure 3-10
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.

	Key to Figure 3-10
②	Gather Diagnostics Refer to “Gather diagnostics” on page 3.15.
③	Daily Slide Report Refer to “Daily slide report” on page 3.16.

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 Start Collection to gather the data. The Image Management Server creates a file called "WFSDiag.zip". 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.

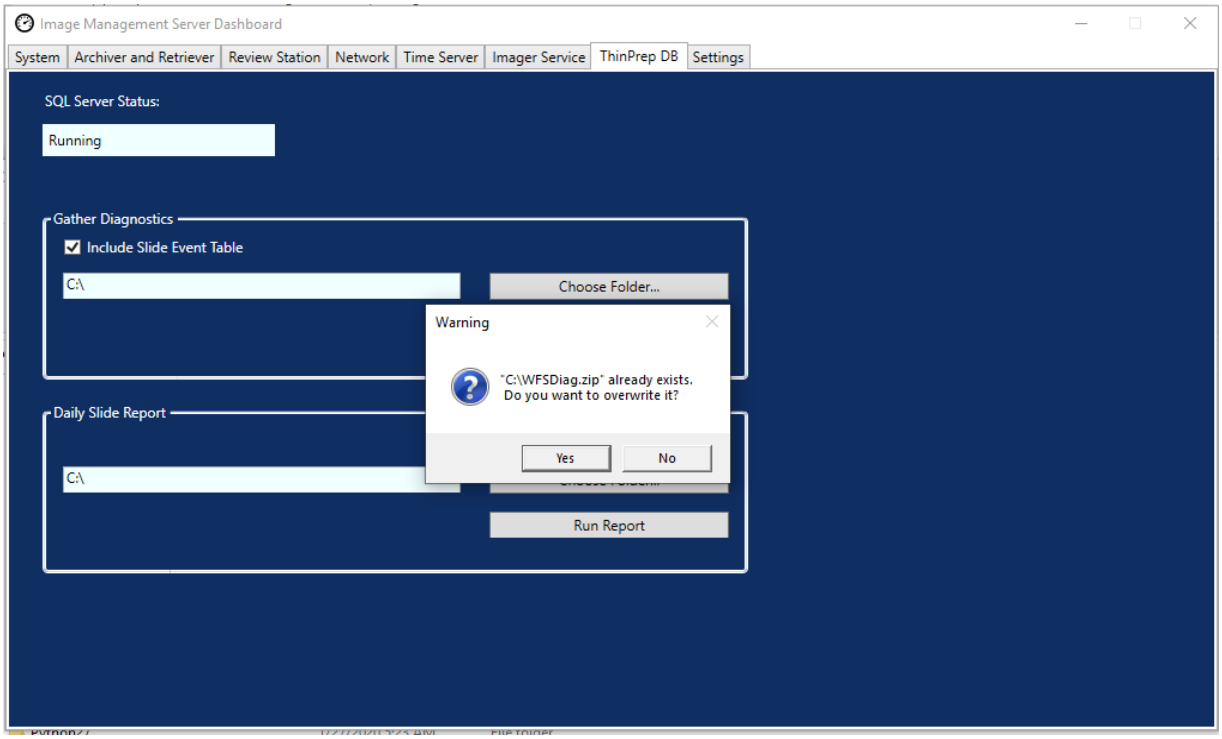


Figure 3-11 Gather Diagnostics, overwrite existing file?

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 3-12 Daily Slide Report, example

3 IMAGE MANAGEMENT SERVER DASHBOARD

SECTION I

SETTINGS

After the Image Management Server is installed by Hologic service personnel, 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.

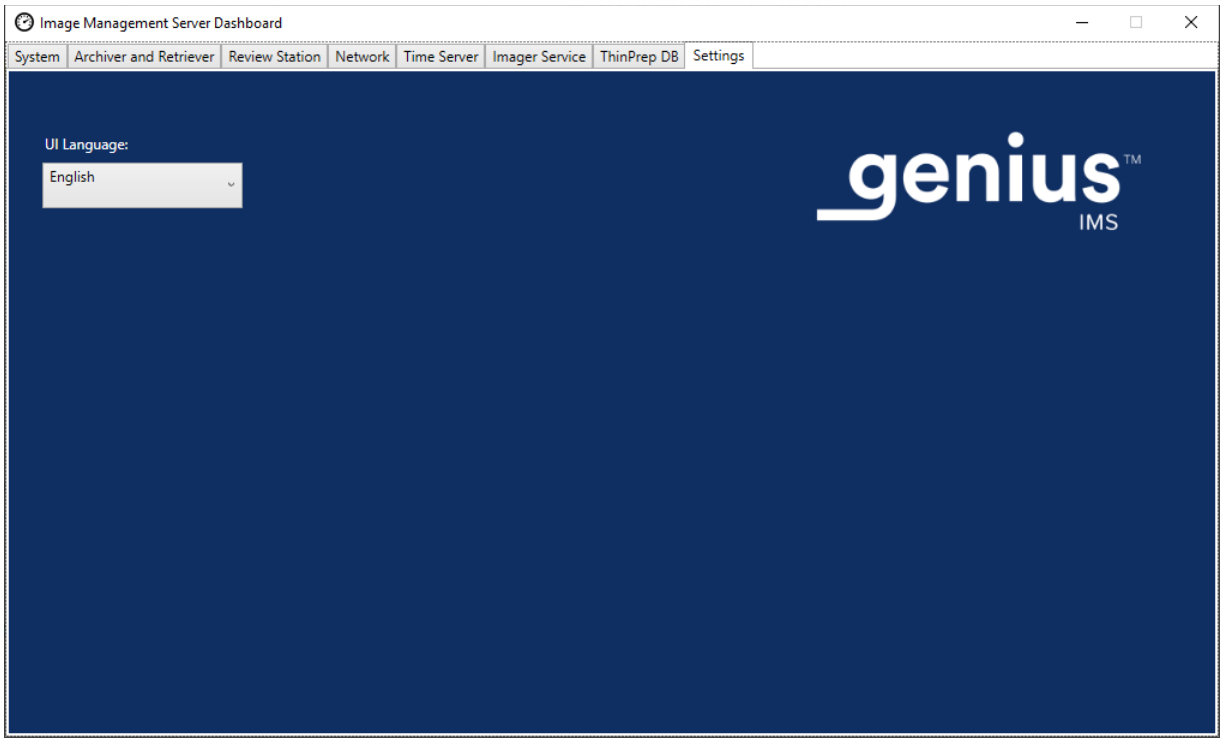


Figure 3-13 Settings dashboard

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

4. Maintenance

Chapter Four

Maintenance

SECTION A GENERAL MAINTENANCE

Refer to the documentation provided by the server manufacturer.

4 MAINTENANCE

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5. Troubleshooting

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 Hologic service personnel. 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.

5 TROUBLESHOOTING

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

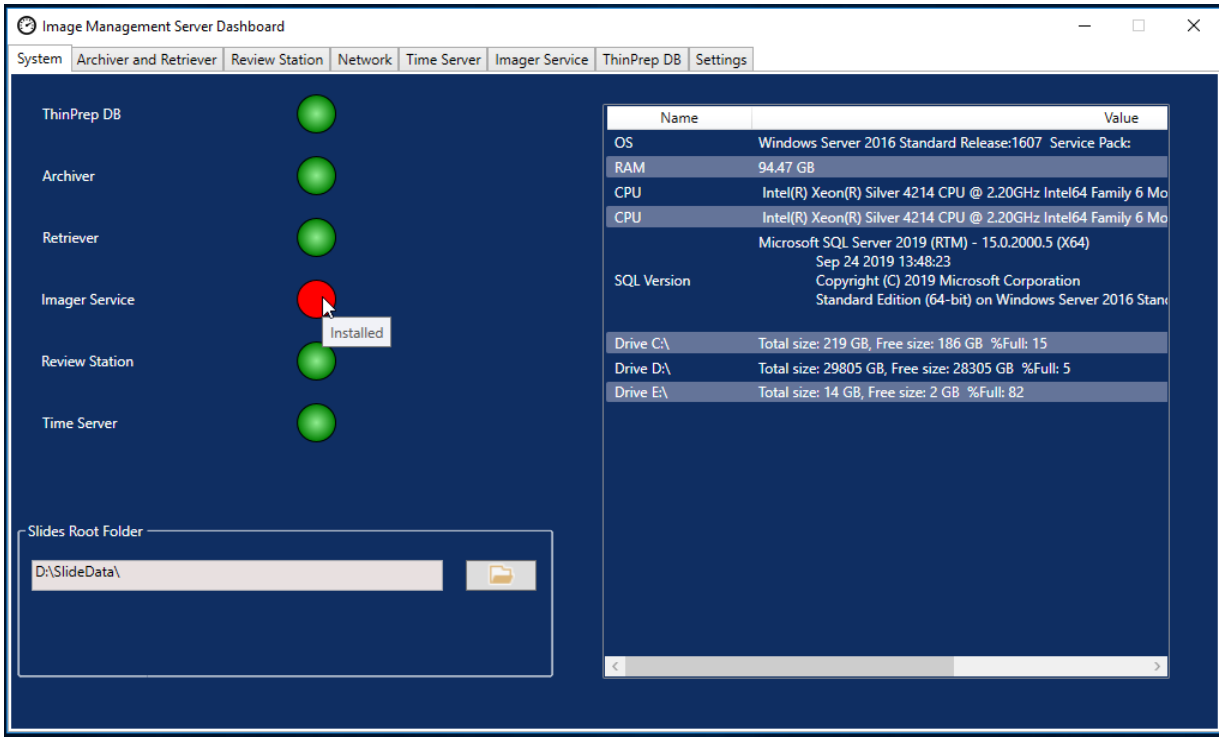

Figure 5-1 Hover mouse for more information, Imager service installed but not running in this example

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.

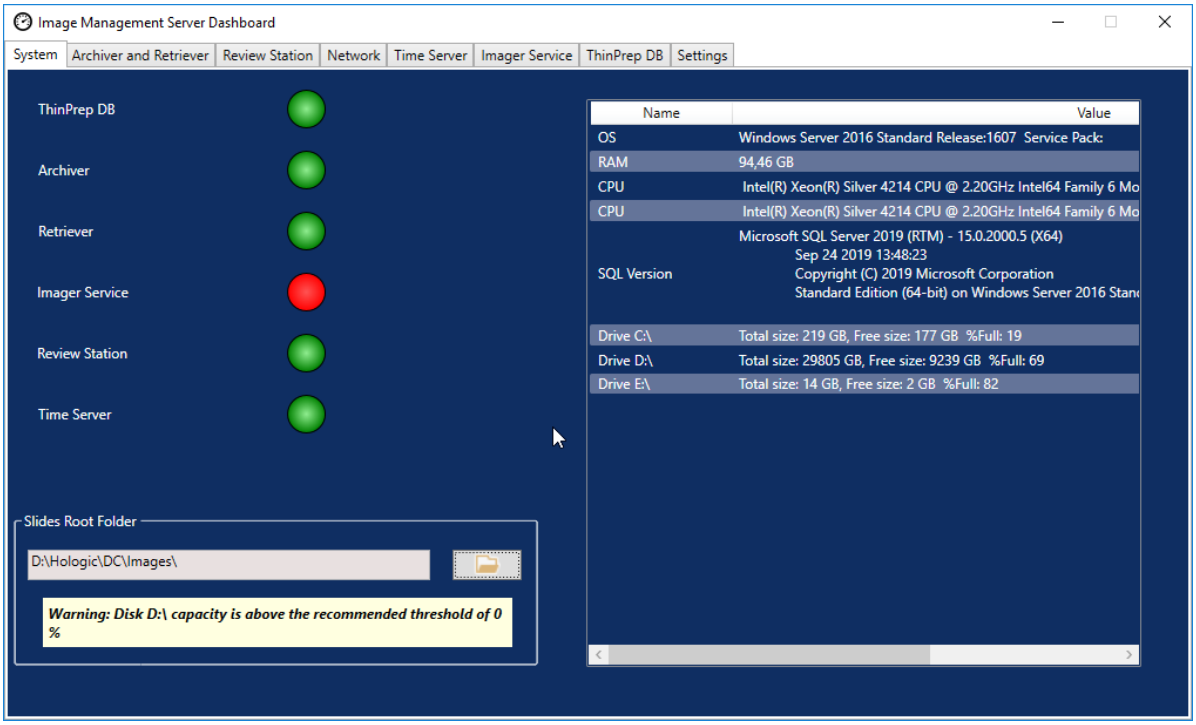

Figure 5-2 Slides Root Folder approaching capacity

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 3.7.

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.

6. Service Information

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	00800 8002 9892

6 SERVICE INFORMATION

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7. Ordering Information

7. Ordering Information

Chapter Seven

Ordering Information

Europe, UK, Middle East

Technical Solutions Cytology can be reached:

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TScytology@hologic.com

And via the toll-free numbers below:

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Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	00800 8002 9892

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.

7 Ordering Information

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-08020-001

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HOLOGIC®

Genius™ Image Management Server Dashboard

Operator's Manual

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