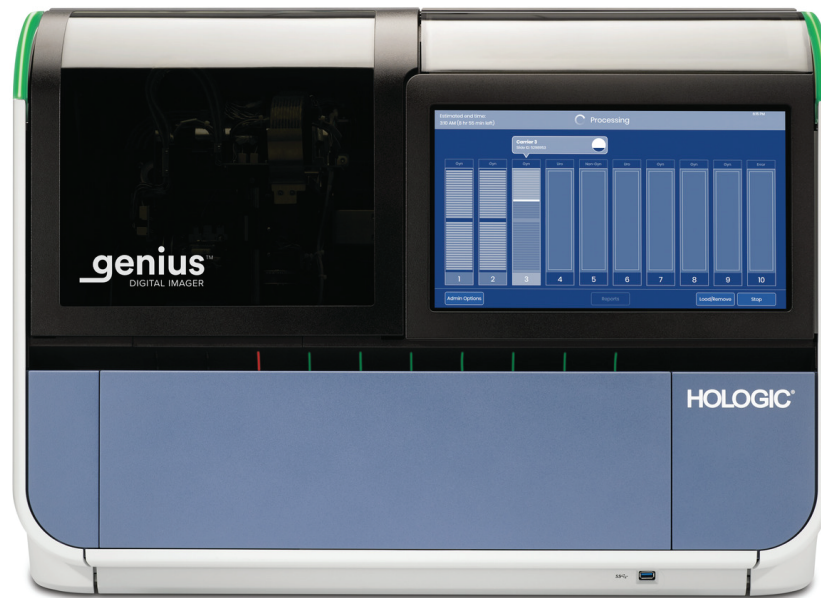# HOLOGIC®

Genius™ Digital Imager

Operator's Manual

genius™
DIGITAL IMAGER

Genius™
Digital Imager
Operator's Manual

HOLOGIC®

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For Use With Version 1.x.y Software   MAN-08022-001

The Genius™ Digital Diagnostics System is a PC-based and 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.

Document Number: AW-22962-001 Rev. 001

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IVD

HOLOGIC®

Genius™ Digital Diagnostics System

Instructions for Use

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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

OOI	TIS								Total
	UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	CANCER	
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	PPA	97%	(89%, 99%)
Rates	NPA	11%	(5%, 26%)
Detection	TIS	64%	(54%, 72%)
Rates	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	**PPA**	89%	(57%, 98%)
Rates	**NPA**	99%	(97%, 100%)
Detection	**TIS**	3.5%	(1.9%, 6.5%)
Rates	**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	PPA	77%	(57%, 90%)
Rates	NPA	99%	(96%, 100%)
Detection	TIS	8.6%	(5.7%, 12.6%)
Rates	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	**PPA**	85%	(69%, 93%)
Rates	**NPA**	91%	(86%, 94%)
Detection	**TIS**	12.8%	(9.3%, 17.5%)
Rates	**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.
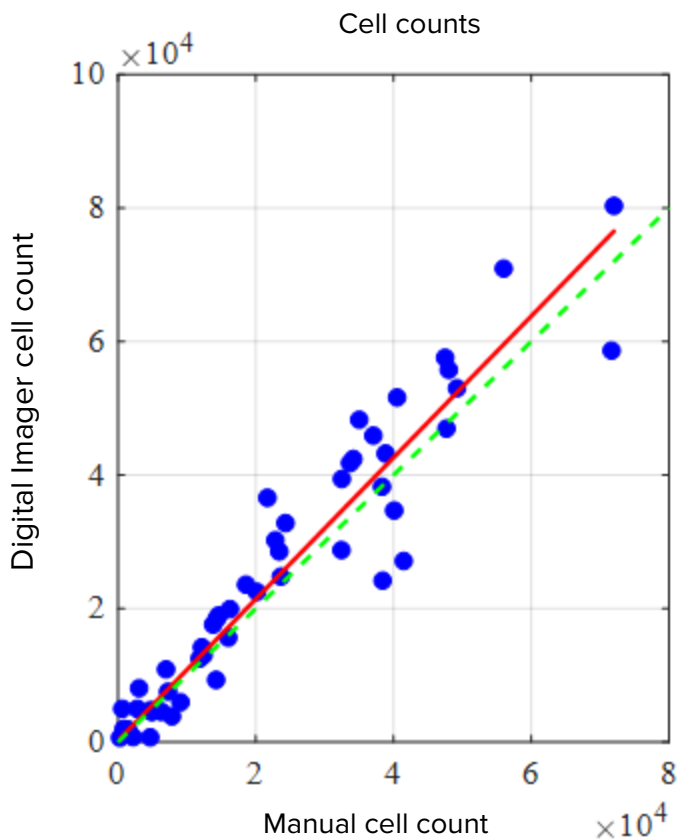
CELL COUNT STUDY

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:

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

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Genius™ Digital Imager Operator's Manual

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C h a p t e r   O n e

Introduction

OVERVIEW AND FUNCTION OF THE GENIUS™ DIGITAL IMAGER

The Digital Imager is one component of the Genius™ Digital Diagnostics System. The Digital Imager is a system for imaging ThinPrep® cytology sample slides. Slides that have been processed on a ThinPrep processor are then stained and coverslipped. The slides are loaded into slide carriers and placed into the Digital Imager. The slides are processed one slide at a time by the Digital Imager, which reads the slide accession ID number and images the cell spot of the slide. The Digital Imager computer contains the processors used to image and to transmit data. The case data and images are sent to the Genius™ Image Management Server (IMS) for storage. The Image Management Server maintains the database and the images, and the Image Management Server communicates with the Genius™ Review Station.

Genius Digital Diagnostics System is a version of ThinPrep® Imaging System.

The user interface for the Digital Imager is a menu-driven, graphical display touch screen, used by the operator for operating the equipment. The Digital Imager comprises:

- **Digital Imager processor**: images the slides. (See Figure 1-1.)
- **Digital Imager computer**: captures the images and controls the electromechanical components of the system.
- **Image Management Server**: stores the slide ID and pertinent image data. The Digital Imager requires a connection to the Image Management Server.

Note: Throughout this manual, unless a component is specifically called out, the term "Digital Imager" refers to the combined system of the Digital Imager processor and Digital Imager computer.

Note: Throughout this manual, illustrations of the Digital Imager computer, the Review Station computer and the Image Management Server are representative. The appearance of the actual equipment may differ from the illustrations.
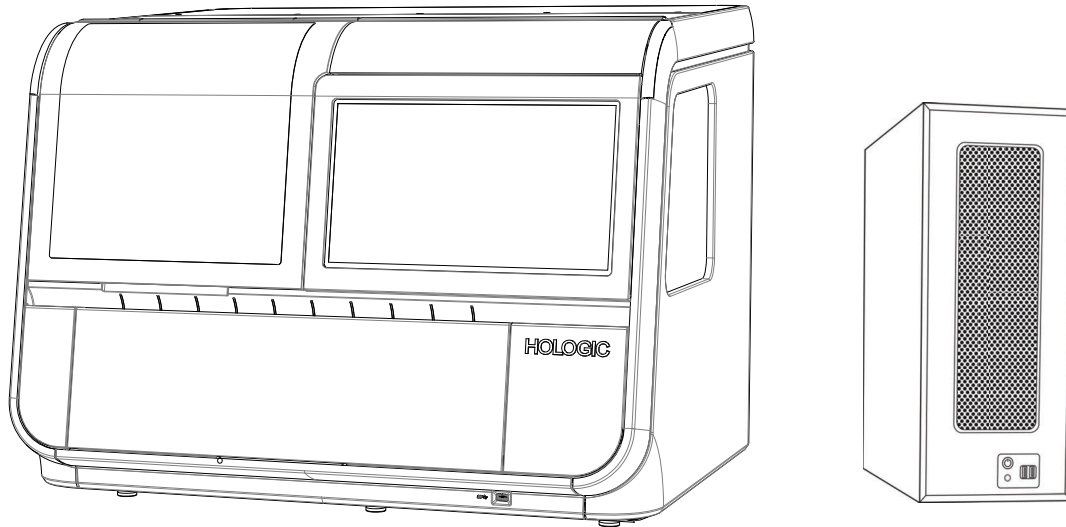
1 | INTRODUCTION

**Figure 1-1   The Genius Digital Imager Processor
and Digital Imager Computer**

Indication for Use

The Digital Imager 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.

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

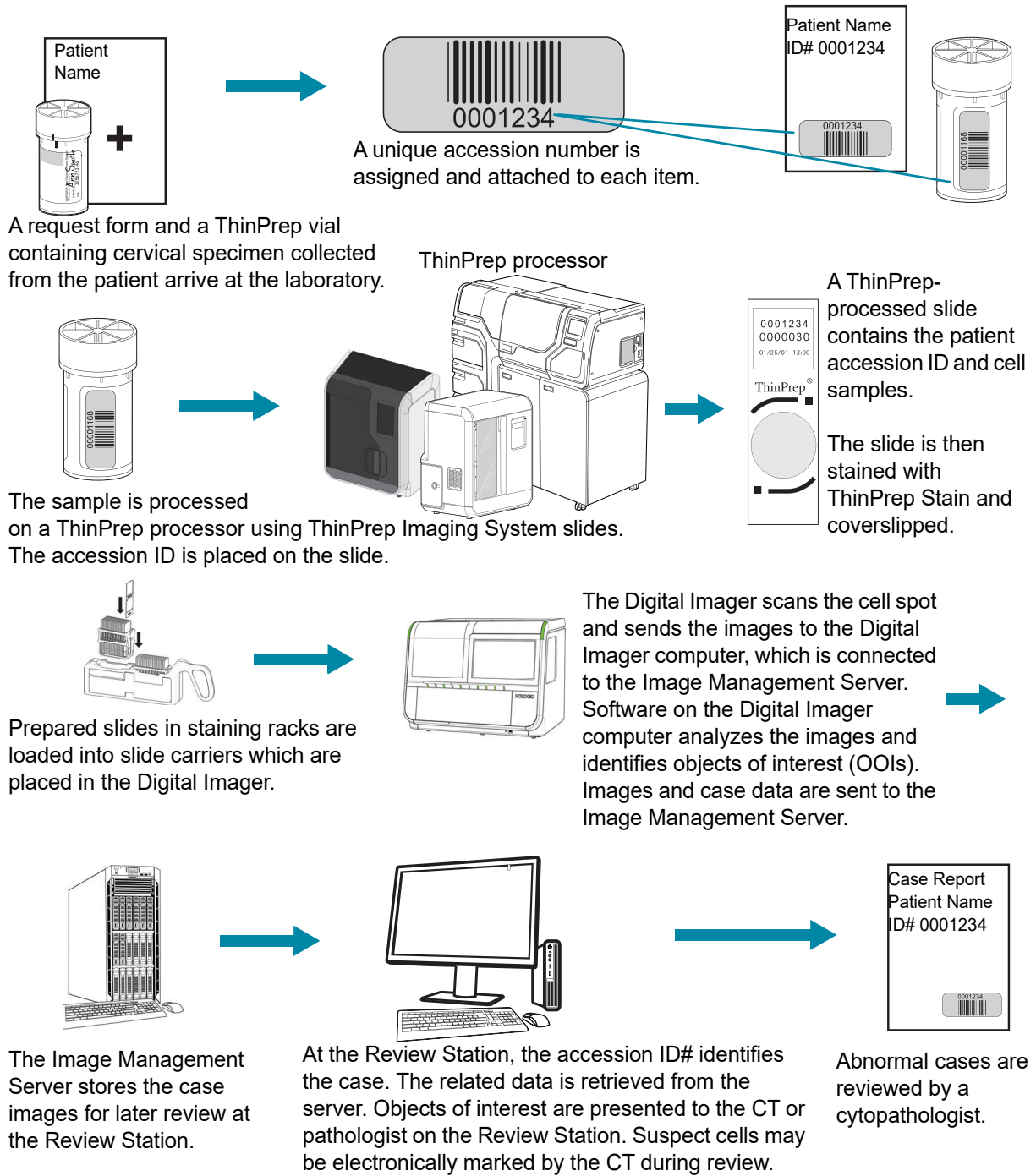## Genius Digital Diagnostics System: Laboratory Flow for Cervical Cancer Screening

Patient Name

A request form and a ThinPrep vial containing cervical specimen collected from the patient arrive at the laboratory.

0001234

A unique accession number is assigned and attached to each item.

Patient Name
ID# 0001234

The sample is processed on a ThinPrep processor using ThinPrep Imaging System slides. The accession ID is placed on the slide.

ThinPrep processor

0001234
0000030
01/25/01 12:00

ThinPrep®

A ThinPrep-processed slide contains the patient accession ID and cell samples.

The slide is then stained with ThinPrep Stain and coverslipped.

Prepared slides in staining racks are loaded into slide carriers which are placed in the Digital Imager.

The Digital Imager scans the cell spot and sends the images to the Digital Imager computer, which is connected to the Image Management Server. Software on the Digital Imager computer analyzes the images and identifies objects of interest (OOIs). Images and case data are sent to the Image Management Server.

The Image Management Server stores the case images for later review at the Review Station.

At the Review Station, the accession ID# identifies the case. The related data is retrieved from the server. Objects of interest are presented to the CT or pathologist on the Review Station. Suspect cells may be electronically marked by the CT during review.

Case Report
Patient Name
ID# 0001234

Abnormal cases are reviewed by a cytopathologist.

Figure 1-2   Lab Flow for ThinPrep® Pap Test Cases

Genius Digital Diagnostics System: Laboratory Flow, Non-Gyn and UroCyte Specimens

0001234

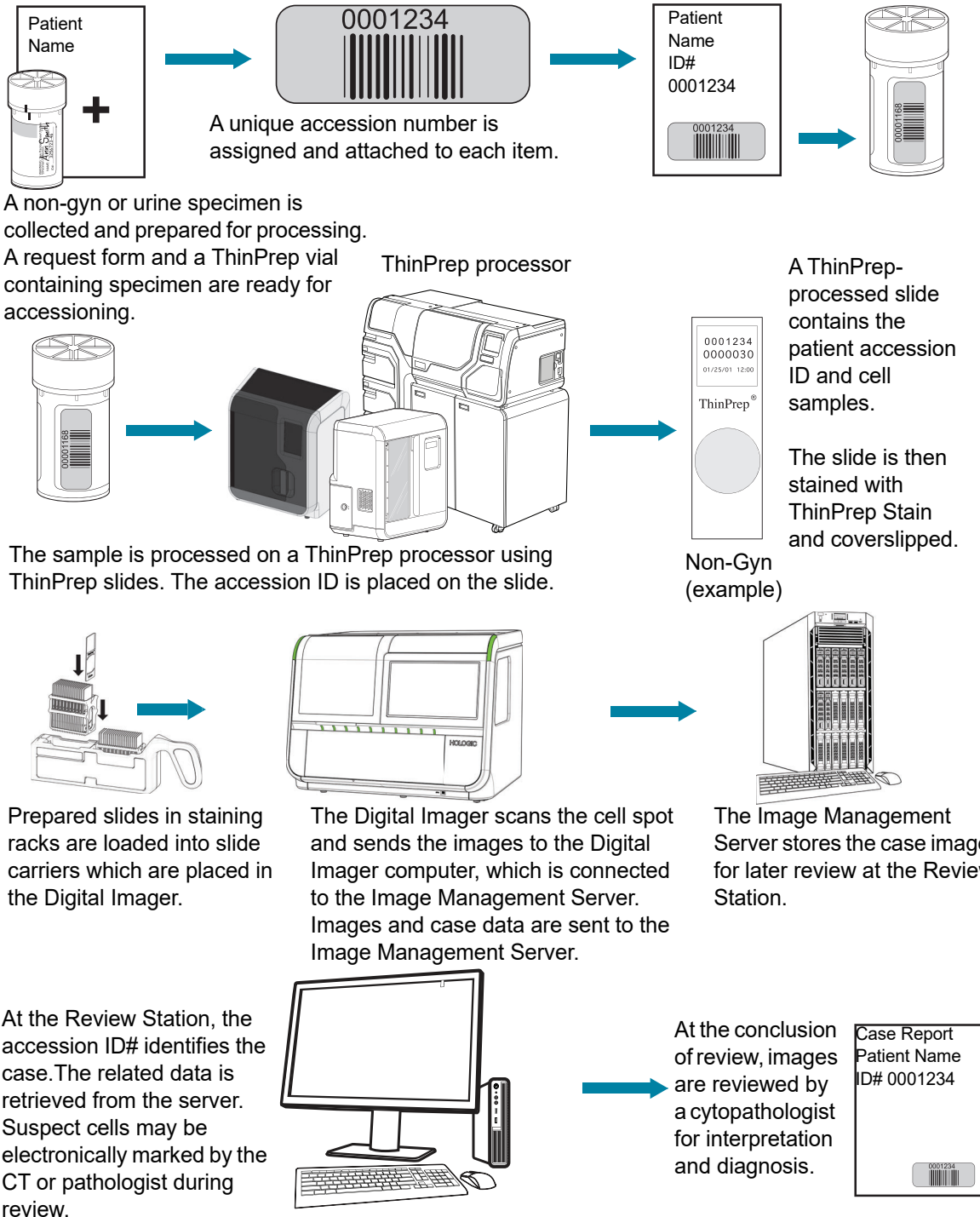A unique accession number is assigned and attached to each item.

Patient Name
ID#
0001234

0001234

A non-gyn or urine specimen is collected and prepared for processing. A request form and a ThinPrep vial containing specimen are ready for accessioning.

ThinPrep processor

A ThinPrep-processed slide contains the patient accession ID and cell samples.

The sample is processed on a ThinPrep processor using ThinPrep slides. The accession ID is placed on the slide.

0001234
0000030
01/25/01 12:00

ThinPrep®

Non-Gyn (example)

The slide is then stained with ThinPrep Stain and coverslipped.

Prepared slides in staining racks are loaded into slide carriers which are placed in the Digital Imager.

The Digital Imager scans the cell spot and sends the images to the Digital Imager computer, which is connected to the Image Management Server. Images and case data are sent to the Image Management Server.

The Image Management Server stores the case images for later review at the Review Station.

At the Review Station, the accession ID# identifies the case. The related data is retrieved from the server. Suspect cells may be electronically marked by the CT or pathologist during review.

At the conclusion of review, images are reviewed by a cytopathologist for interpretation and diagnosis.

Case Report
Patient Name
ID# 0001234

0001234

Figure 1-3   Lab Flow for Non-Gyn and UroCyte Cases

THE GENIUS DIGITAL DIAGNOSTICS SYSTEM PROCESS FOR CERVICAL CANCER SCREENING

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 system identifies objects of interest found on the slide. The objects classified as most clinically relevant are presented 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 slide 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.
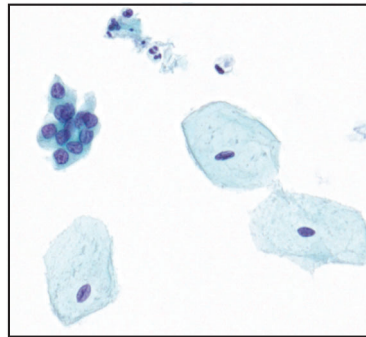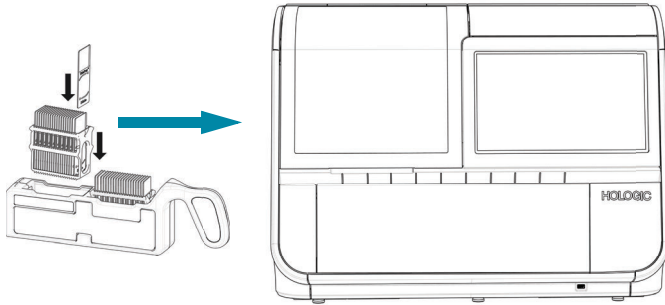
Digital Diagnostics Process, Gyn Samples
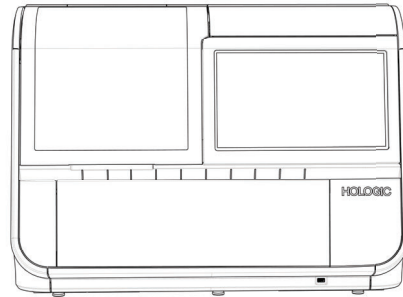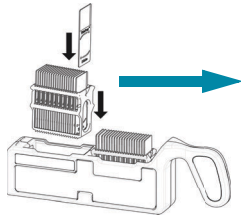
Prepared ThinPrep slides are loaded into a slide carrier, which is loaded into the Digital Imager.

The cell spot is imaged

The Digital Imager scans the entire cell spot. The algorithm identifies objects of interest found on the slide.

Case data and images, including objects of interest, are stored on the Image Management Server.

Case review by the cytotechnologist or pathologist

During review, the Review Station presents a gallery of images with the objects of interest to the reviewer.

Cells and other objects of interest may be electronically marked by the reviewer. The case is marked as reviewed.

At completion, the case data is updated with any marked areas as well as information on the review session.

The case is available to subsequent reviewers at the Review Station.

Figure 1-4   Genius Digital Diagnostics System Process, Gyn Samples

<div style="float:left">SECTION
C</div>

THE GENIUS DIGITAL DIAGNOSTICS SYSTEM PROCESS FOR NON-GYN AND UROCYTE SPECIMENS

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 a whole slide image.

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 slide ID.

The cytotechnologist (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 a whole slide image. 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 whole slide image for that ID, and the CT or pathologist is presented with the whole slide image for review.

The CT or pathologist has the option to electronically mark objects of interest and include the marks 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 cell spot into the field of view for examination.

Genius Digital Diagnostics System Process, Non-Gyn or UroCyte Sample

Prepared ThinPrep slides are loaded into a slide carrier, which is loaded into the Digital Imager.
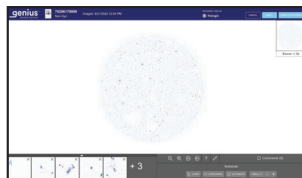
The cell spot is imaged.
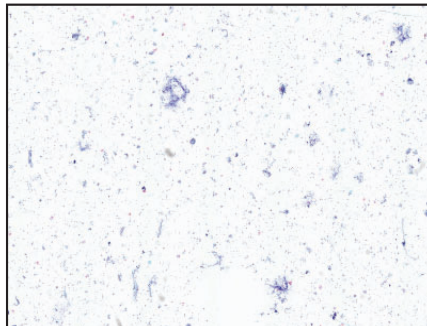
The Digital Imager scans the entire cell spot.

Case data and images are stored on the Image Management Server.

During review, the Review Station presents a whole slide image to the reviewer.

Case review by the cytotechnologist or pathologist

Cells and other objects of interest may be electronically marked by the reviewer. The case is marked as reviewed.

At completion, the case data is updated with any marked areas as well as information on the review session.

The case is available to subsequent reviewers at the Review Station.

Figure 1-5   Imaging Process, Non-Gyn or UroCyte Sample

SECTION D

SPECIMEN PREPARATION AND PROCESSING

Gyn Samples

Specimens for the ThinPrep® Pap test are collected by a clinician, then immersed and rinsed in a PreservCyt® Solution sample vial. The vial is then capped, labeled, and sent to a laboratory equipped with a ThinPrep® processor. After being processed, the ThinPrep® Imaging System microscope slides are stained with ThinPrep® Stain and coverslipped.

Specimen integrity

PreservCyt Solution *with* cytologic sample intended for ThinPrep Pap testing must be stored between 15°C (59°F) and 30°C (86°F) and tested within 6 weeks of collection.

Slides processed by a ThinPrep processor should be stained within 5 days.

Stained slides should be imaged by the Imager in a timely manner, according to normal laboratory practices. Imaging performance has not been assessed beyond 4 months.

Interfering substances

Specimen sample - the use of lubricants and other interfering substances should be minimized prior to specimen collection. Lubricants can adhere to the filter membrane and may cause poor cell transfer to the slide.

Please refer to the operator's manuals of the ThinPrep processors for more information regarding preparation and processing of ThinPrep slides. Please refer to the ThinPrep Stain User's Manual for information regarding use of the stain and recommendations for coverslipping. Coverslips must be completely dry before using slides on the Digital Imager.

Non-Gyn Samples and UroCyte Samples

Non-gynecological specimens for the ThinPrep® non-gynecological (Non-Gyn) slide are collected and, depending on the sample type, further prepared. Prior to processing on a ThinPrep processor, the specimen is immersed in a PreservCyt® Solution sample vial. The vial is then capped, labeled, and run on a ThinPrep processor. After being processed, the slides are stained and coverslipped.

Urine specimens for the ThinPrep Non-Gyn slide or the ThinPrep® UroCyte slide are collected and, depending on the sample type, further prepared. Prior to processing on a ThinPrep processor, the specimen is immersed in a PreservCyt® Solution sample vial or a ThinPrep UroCyte PreservCyt sample vial. The vial is then capped, labeled, and sent to a laboratory equipped with a ThinPrep processor. After being processed, the slides are stained and coverslipped.

Specimen integrity

PreservCyt Solution *with* non-gynecologic samples intended for cytology must be stored between 4°C (39°F) and 37°C (98°F) and tested within 3 weeks of collection, or sooner depending on the sample type.

Please refer to the operator's manuals of the ThinPrep processors for more information regarding preparation and processing of ThinPrep slides. Coverslips must be completely dry before using slides on the Digital Imager.

Special Precautions

There are conditions that might result in a slide not being successfully imaged. Some conditions may be prevented or corrected by following these guidelines.

- The coverslip media is dry. (Wet media could cause equipment malfunction.)
- The slides are clean (no fingerprints, dust, debris, bubbles). Handle the slides by the edges.
- The coverslip does not extend beyond the surface of the slide.
- The label is applied smoothly, without overhang. (Lifted edges may stick during handling, causing broken slides or instrument malfunction.)
- The slide is appropriately labeled for use with the Digital Imager. Refer to "Slide Labeling" on page 4.7.
- Stain - for staining Gyn slides, do not substitute solutions for the ThinPrep Stain solutions. Follow the stain protocols exactly as they are written. Refer to the ThinPrep Stain User's Manual.
- ThinPrep microscope slides appropriate for the sample type must be used. On ThinPrep Imaging System microscope slides, the fiducial marks should not be scratched or marred.

Specimen handling

Please refer to your laboratory guidelines for specimen handling.

<div>SECTION</div>
<div>E</div>

PRINCIPLES OF OPERATION

The Genius Digital Imager consists of a slide handling system, a slide carrier deck, scanning and imaging modules, and electronics and cabling. Sensors on the slide handling arm detect the location of microscope slides loaded into the instrument by the operator.

The Digital Imager is controlled by the Digital Imager computer. The Digital Imager computer also performs image compression and analysis, and it provides the communication to and from the Image Management Server.

Each slide imaging sequence is optimized for the biological characteristics of the various cytological specimens.

For Gyn samples, the Digital Imager computer uses the Genius™ Cervical AI to assist in primary cervical cancer screening of ThinPrep® Pap tests. Samples are prepared on ThinPrep Imaging System microscope slides and imaged on the Genius Digital Diagnostics System 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: Definitions, Criteria, and Explanatory Notes*[1].

DIGITAL IMAGER TECHNICAL SPECIFICATIONS

Overview of Components

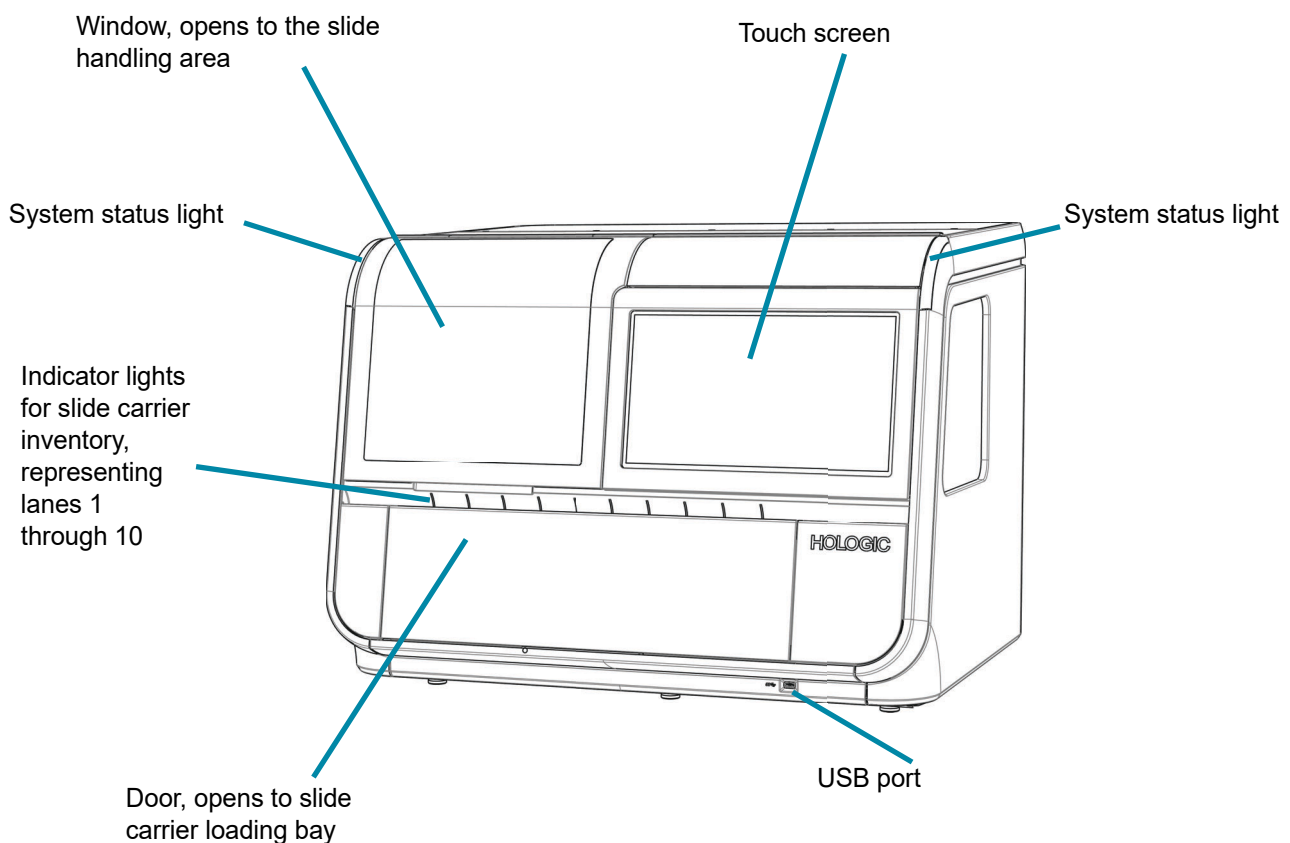See Figure 1-6 through Figure 1-15 for information regarding components and specifications.

Window, opens to the slide handling area

Touch screen

System status light

System status light

Indicator lights for slide carrier inventory, representing lanes 1 through 10

HOLOGIC

USB port

Door, opens to slide carrier loading bay

Figure 1-6   Front View, Digital Imager

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

Serial number

Model/rating labels

Audio cable connection to the Digital Imager computer

On/Off switch

Fuse holder

Power cord connection

USB port for service personnel use

Ethernet connections (2) to the Digital Imager computer

USB cable connection to the Digital Imager computer

VGA cable connections to the Digital Imager computer

Fiber ethernet connection to the Digital Imager computer
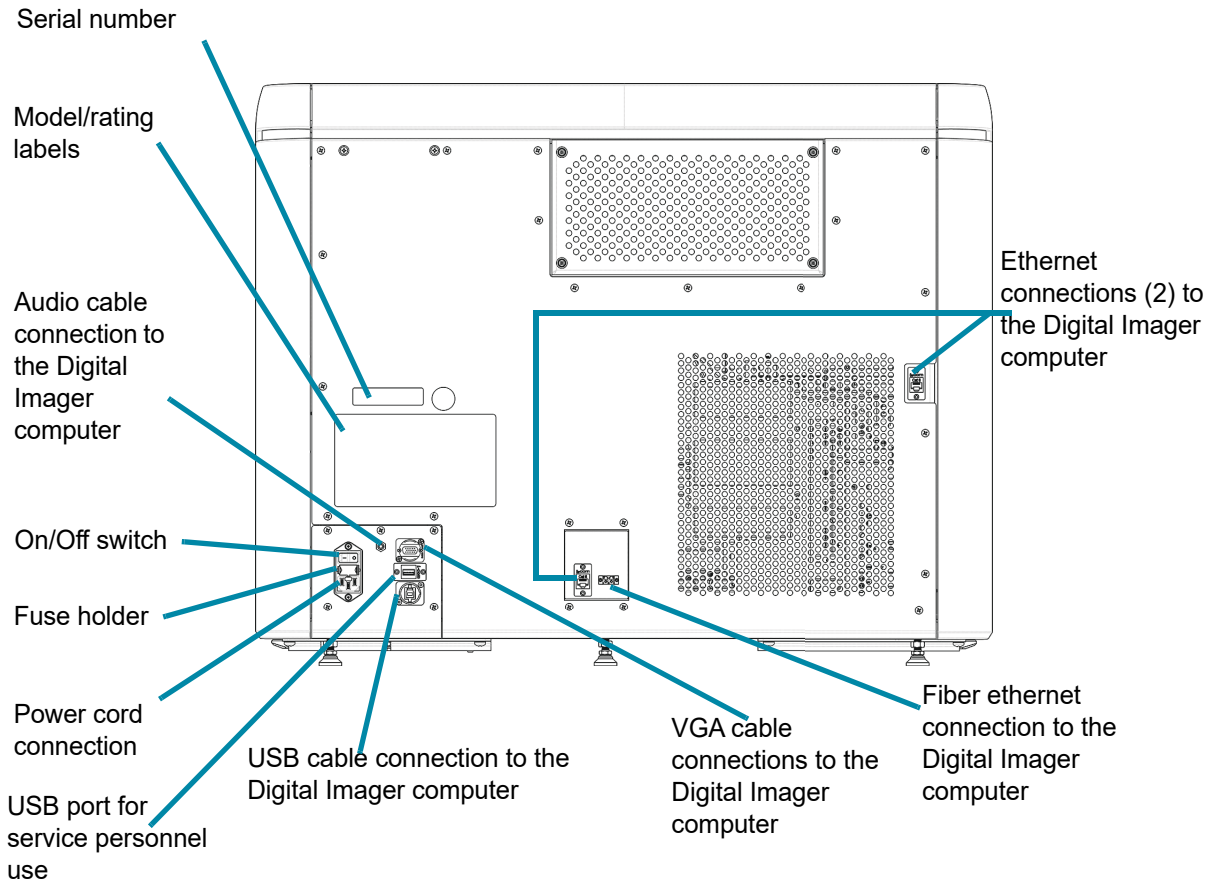
Figure 1-7   Rear View, Digital Imager

Audio cable connection to the Digital Imager

Serial number, on top

Fiber ethernet connection to the Digital Imager

Ethernet connection to the Digital Imager

VGA cable connections to the Digital Imager

Ethernet connection to the Digital Imager

Scanner control connection to the Digital Imager

Power button and indicator light

On/Off switch

Power cord connection

Cable connection to the Image Management Server

Front View

Rear View

Figure 1-8   Digital Imager Computer

ThinPrep microscope slides with patient sample, stained, coverslipped and completely dry

Slide staining rack. Either Sakura part number 4768 (Hologic part number 51873-001) or Leica 14 0474 33463.

Slide carrier

Slide carriers, loaded by the operator
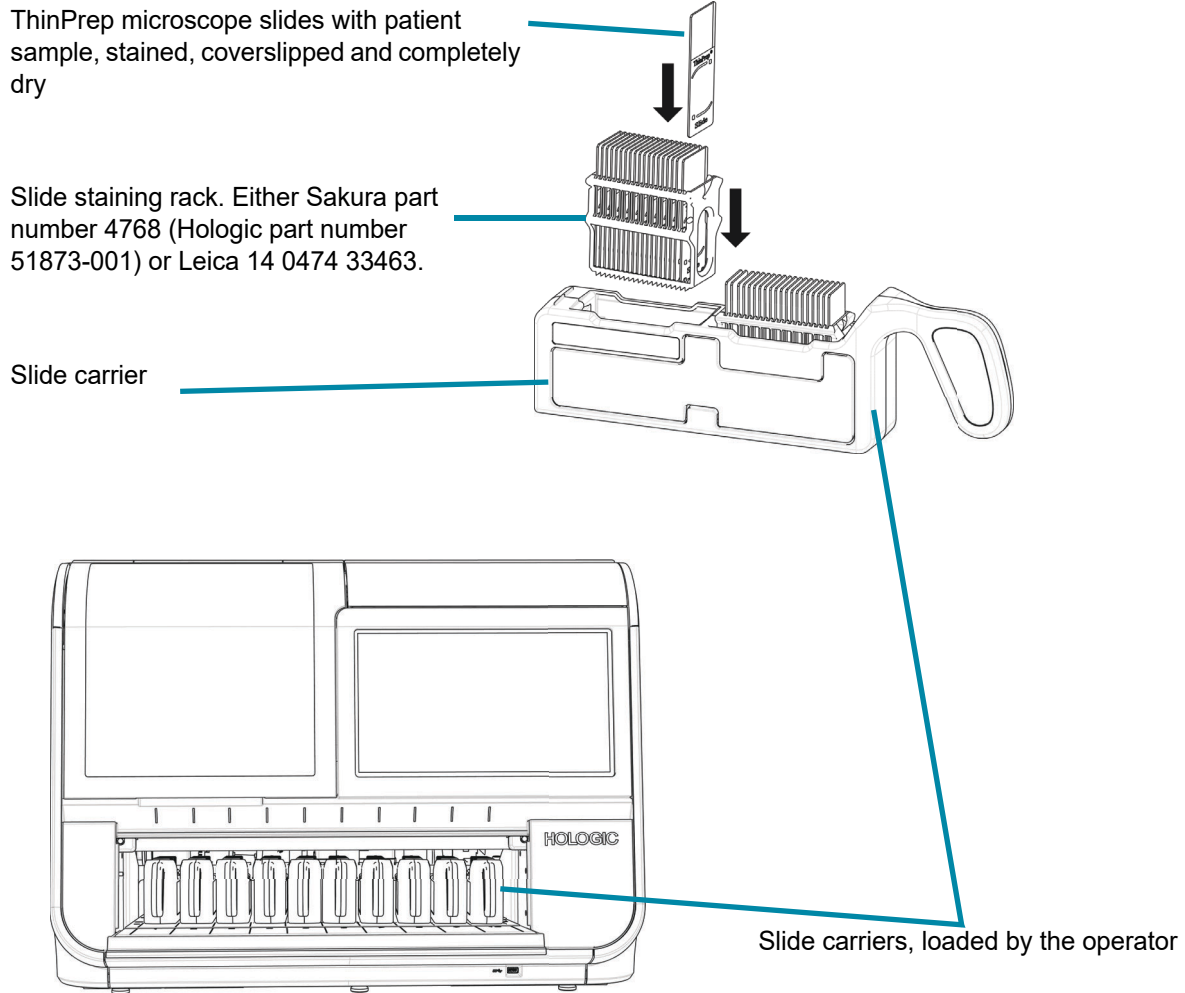
Figure 1-9   Slide Carriers in the Digital Imager (Digital Imager Door Open)
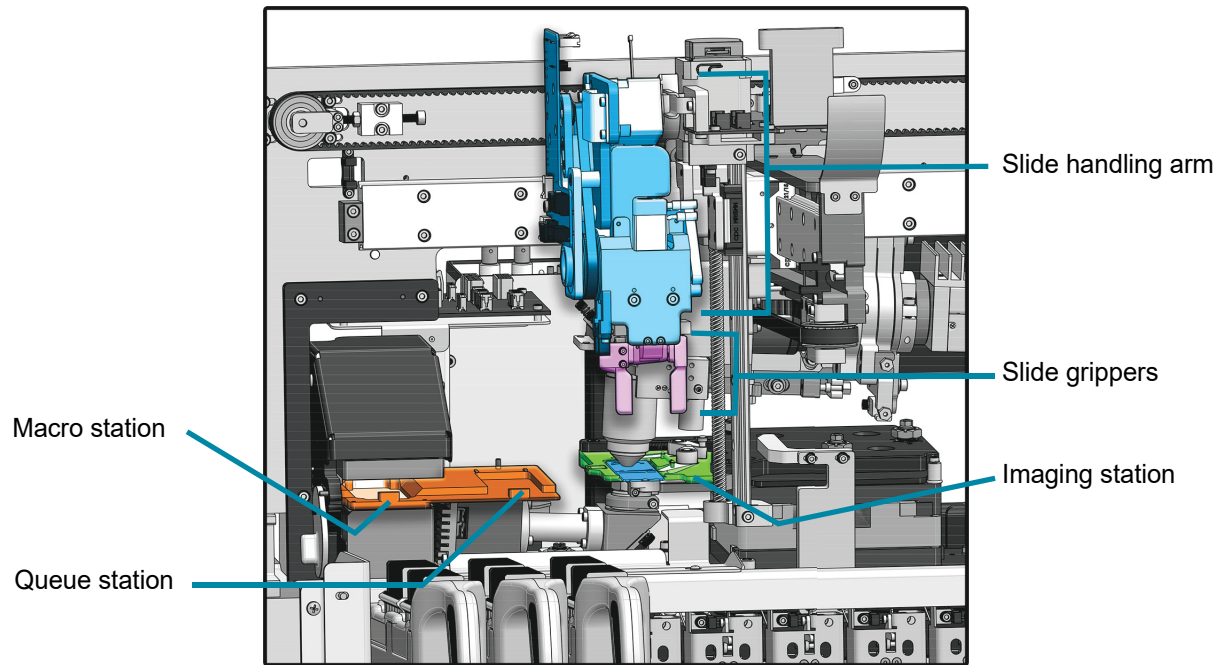
Interior of the Digital Imager - covers removed to show detail

Figure 1-10   Slide Handling in the Digital Imager

Slide handling arm

Slide grippers

Imaging station

Macro station

Queue station

Slide accession ID (OCR format shown)

Slide accession ID (1-D format shown)

Slide accession ID (2-D format shown)

Frosted region of each slide

7706024
8000253

ThinPrep®

01234567890

ThinPrep®

ThinPrep®

Fiducial mark

UroCyte™

Cell spot - contains patient cells

ThinPrep Imaging System microscope slide, for Gyn specimens

ThinPrep Non-Gyn microscope slide

ThinPrep UroCyte microscope slide

Figure 1-11   Slides Used in the System

Digital Imager Dimensions

25.5"
(65 cm)

31.5"
(80 cm)

28"
(71.1 cm)

Approximate weight: 242 lbs. (110 kg)
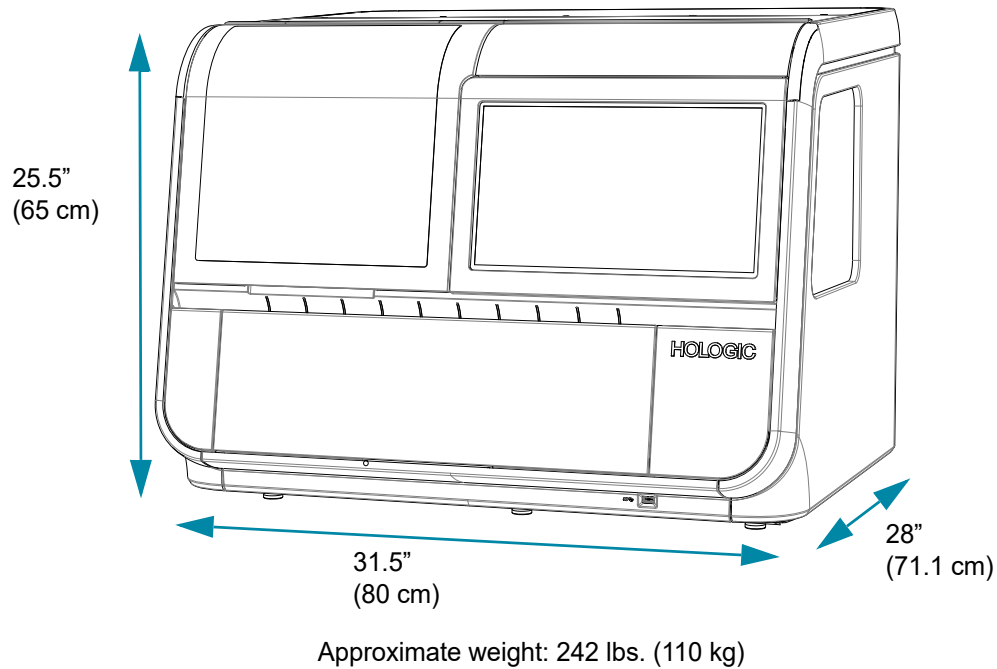
Figure 1-12   Digital Imager Dimensions

Recommended clearances: 3″ (76.2 mm) on all sides. Make sure there is sufficient clearance to disconnect the power cord. The depth of the Digital Imager with the door open is 34″ (86.4 cm). The height with the window open is 28″ (71.1 cm).

Slide Carrier Dimensions

3" (76.2 mm)

5.5" (139.7 mm)

10" (254 mm)

Empty slide carrier

8.9" (226 mm)

1.8" (46 mm)
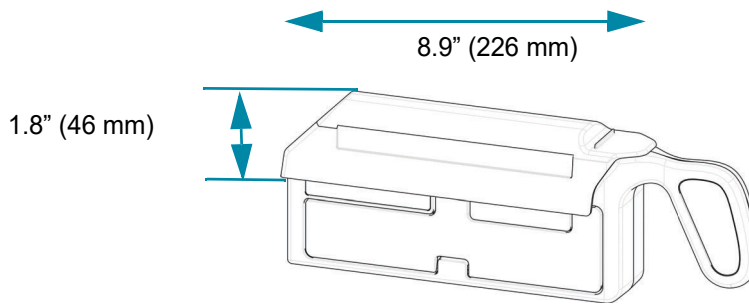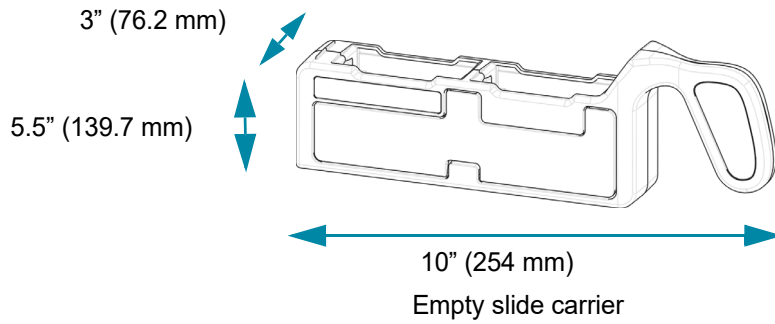
Optional slide carrier cover on slide carrier

Figure 1-13   Slide Carrier Dimensions

Digital Imager Computer Dimensions
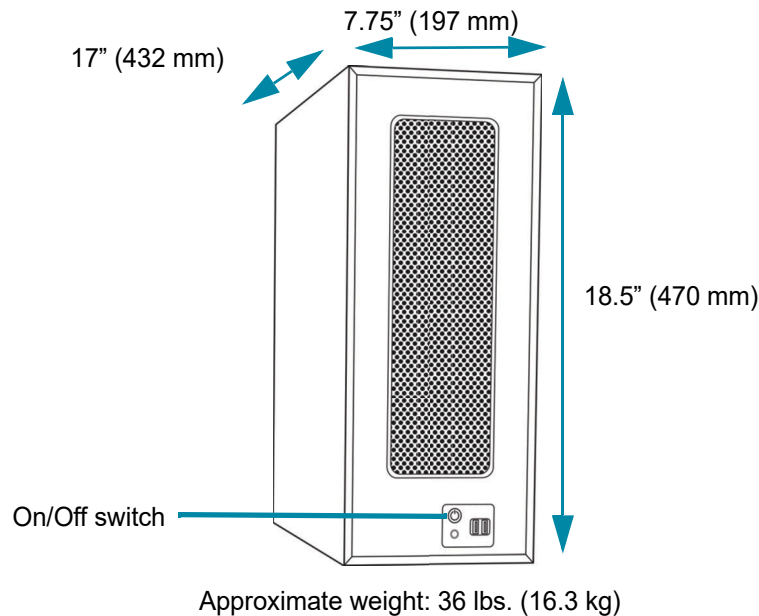
Figure 1-14   Digital Imager Computer Dimensions

Refer to the documents which come with the equipment for technical specifications.

Other Components

The other components that complete the Genius Digital Diagnostics System network will be unpacked and installed by Hologic personnel. Please refer to the instructions supplied with the other components or specifications, operation, safety and maintenance.

Note: If a component within the Genius Digital Diagnostics System network requires maintenance, contact Hologic Technical Support or your local distributor.

Environmental

Operating temperature range
    16°C to 32°C

Non-operating temperature range
    -28°C to 50°C

Operating humidity range
    20 to 80% relative humidity, non-condensing

Non-operating humidity range
    15% to 95% relative humidity, non-condensing

Pollution degree: II, in accordance with IEC 61010-1.

Category II, the Genius Digital Diagnostics System is for indoor use only in an office or a clean laboratory environment.

Sound levels

This equipment does not create sound levels above 80 dBA.

Power

Voltage

100–240 Volts Alternating Current, no selection required

Mains supply voltage not to exceed ± 10% of the nominal voltage

Frequency

50 to 60 Hz

Power

Digital Imager	5A maximum
Digital Imager Computer	Refer to the documents that come with the equipment.

Heat generated

Digital Imager	Approximately 1600 BTU/HR (470 W)
Digital Imager Computer	Refer to the documents that come with the equipment.

Fusing

Digital Imager	Two 5 x 20 mm, 10A time delay glass fuses
Digital Imager Computer	Refer to the documents that come with the equipment.

Dimensions and Weight (Approximate)

Digital Imager: 25.5″ (65 cm) H x 31.5″ (80 cm) W x 28″ (71 cm) D, 242 lbs. (110 kg) uncrated

Digital Imager Computer: 18.5″ (470 mm) H x 7.75″ (197 mm) W x 17″ (432 mm) D, 36 lbs. (16.3 kg) uncrated

Genius Digital Diagnostics System Standards

The Genius Digital Diagnostics System has been tested and certified by a U.S. Nationally Recognized Testing Laboratory (NRTL) to comply with current Safety, Electro-Magnetic Interference (EMI) and Electro-Magnetic Compatibility (EMC) standards. Refer to the product label, located on the rear of the instrument, to see the safety certification markings.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper operation.

This product is *in vitro* diagnostic (IVD) medical equipment.

This product contains a device classified per EN 60825-1: 2014, Edition 3 as a Class 1 Laser Product.

1 | INTRODUCTION

This equipment meets the emission and immunity requirements of IEC 61326-2-6 and IEC 60601-1-2. This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operation of the equipment.

Electromagnetic Environment Information

The following tables provide information on the electromagnetic environment that the Digital Imager is capable of operating safely. Use of this equipment in an environment that exceeds these limits may cause the device to stop working properly.

Table 1. Guidance and manufacturer's declaration–electromagnetic emissions

Guidance and manufacturer's declaration–electromagnetic emissions		
The Digital Imager is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Imager should assure that it is used in such an environment.		
Emmisisons test	**Compliance**	**Electromagnetic environment guidance**
Radiated and conducted emissions CISPR 11 FCC 47 CFR 15 CSA/CAN	Group 1,Class A	Operation of the Digital Imager is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
Harmonic emissions IEC 61000-3-2	Class A	The Digital Imager is suitable for use in all commerical or hospital environments.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2. Guidance and manufacturer's declaration—electromagnetic immunity

Guidance and manufacturer's declaration—electromagnetic immunity			
The Digital Imager is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Imager should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV,±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Facilities should have electrostatic discharge mitigation measures, including the humidity level.
Electrical fast transient/burst IEC 61000-4-4	±0.5 kV, ±1 kV, ±2 kV for power supply lines Duration≥1 min 100 kHz repetition frequency 5 kHz repetition frequency	±2 kV for power supply lines at 100kHz ±1 kV for power supply lines at 5kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle at 0° 40% U_T; 6 cycles at 0° 70 % U_T; 30 cycles at 0° 0 % U_T; 300 cycles at 0°	0 % U_T; 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0 % U_T; 1 cycle at 0° 40% U_T; 6 cycles at 0° 70 % U_T; 30 cycles at 0° 0 % U_T; 300 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Digital Imager requires continued operation during power mains interruptions, it is recommended that the Digital Imager be powered from an uninterruptible power supply.
Power frequency magnetic field IEC 61000-4-8	30 A/m @ 60 Hz	30 A/m	Power frequency magnetic fields should be at levels typical for commercial or hospital environments.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3. Guidance and manufacturer's declaration—electromagnetic immunity

Guidance and manufacturer's declaration—electromagnetic immunity			
The Digital Imager is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Imager should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6	3 Vrms, 0.15 MHz–80 MHz, 80 % AM at 1 kHz 6 Vrms, in ISM band between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 Vrms, 6 Vrms	Conducted electrical fields should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m, 80 MHz–2.7 GHz, 80 % AM at 1 kHz	3 V/m	Radiated electrical fields should be that of a typical commercial or hospital environment
Radiated electric immunity to proximity fields from RF wireless communications equipment IEC 60601-1-2	Test levels as defined in Table 9 of IEC 60601-1-2	up to 28 V/m	Immunity to proximity fields from RF wireless communications equipment

SECTION
G

INTERNAL QUALITY CONTROL

Power On Self Test (POST)

At the time the Digital Imager is powered on (refer to "Applying Power to the Equipment" on page 4.3), the system goes through a self-diagnostic test. All the electrical, mechanical and software/communication systems are tested to confirm each performs properly. The operator is alerted to any malfunction via a message on the user interface. If the system does not function or there are persistent errors, contact Hologic Technical Support. Refer to Chapter 8, Service Information.

DIGITAL IMAGER HAZARDS

The Digital Imager 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.
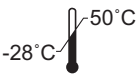
Warnings, Cautions And Notes

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.
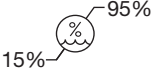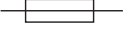
Symbols Used on the Instrument

The following symbols are used on this instrument:

⚠	Attention, refer to accompanying documents.
⚡	Warning, risk of electric shock (internal use only, not accessible to operators).
📖	Consult instructions for use. Indicates the need for the user to consult the instructions for use.
-28˚C / 50˚C	Temperature limit. Indicates the temperature limit to which the medical device can safely be exposed.

95% 15%	Humidity limitation. Indicates the range of humidity to which the medical device can safely be exposed.
(symbol)	Protective Conductor Terminal (internal use only, not accessible to operators).
I	Power Switch On
O	Power Switch Off
(symbol)	Fuse
(symbol)	Waste Electrical and Electronic Equipment. Contact Hologic for disposal of the instrument.
SN	Serial number
(symbol)	Date of manufacture
(symbol)	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue number

SS←	USB 3 port
IVD	*In Vitro* diagnostic medical device
(50)	China RoHs usable life
USA CANADA	For instruments used in the USA and Canada, compliance information.

Location of Labels Used on the Instrument

Serial number

Serial number

Model/rating

Digital Imager computer, rear
Grounded outlet

Digital Imager, rear
Grounded outlet
External connections
Fusing
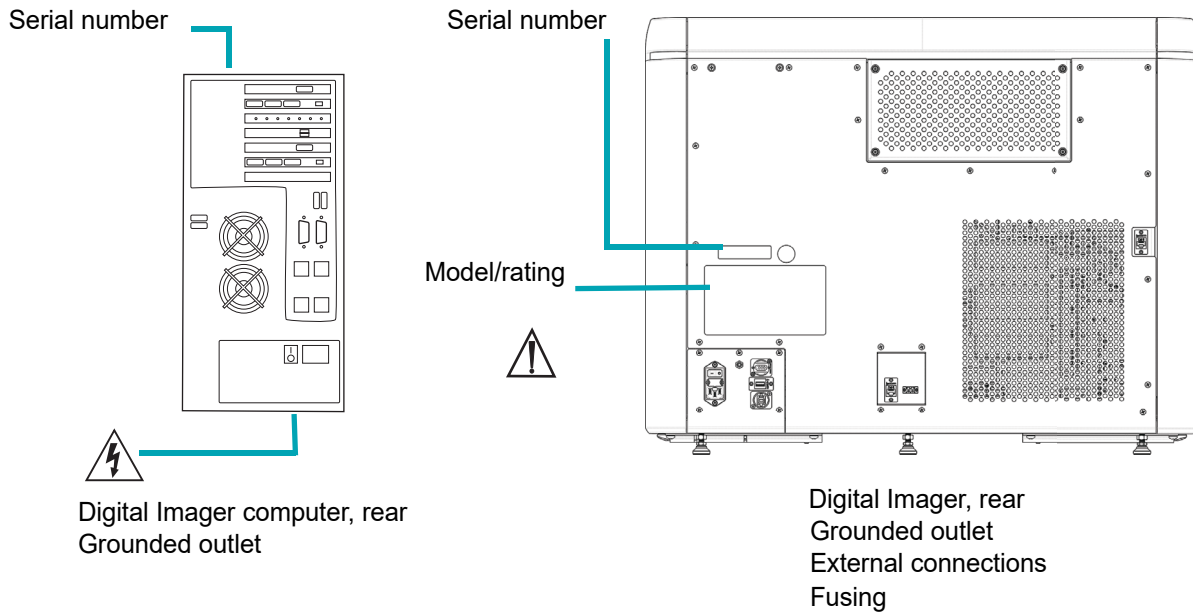
Figure 1-15   Label Locations

1 |

Warnings Used in this Manual:

WARNING

Service Installation Only

This instrument is to be installed by trained Hologic personnel only.

WARNING

No modification to the system is allowed by the user during the service life of the instrument.

WARNING

Instrument Fusing

For continued protection against fire, replace only with fuses of the specified type and current rating. Fuses are to be replaced by trained Hologic personnel only.

WARNING

Only use cables and support equipment specified by Hologic with the Digital Imager. Do not connect items that have not been specified as compatible with the Digital Imager to the Digital Imager.

WARNING

Use of accessories, transducers and cables other than those specified or provided by Hologic could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING

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.

WARNING

Moving Parts

The instrument contains moving parts. Keep hands, loose clothing, jewelry, etc., clear.

WARNING

Grounded Outlet

To ensure safe operation of the instruments use a three-wire grounded outlet.

WARNING

Glass

The instrument 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.

SECTION I

DISPOSAL

Disposal of the Device

Do not dispose in municipal waste.

Please contact Hologic Technical Support.

Hologic will provide for the collection and proper reclamation of electrical devices we provide to our customers. Hologic strives to reuse Hologic devices, subassemblies, and components whenever possible. When reuse is not appropriate, Hologic will ensure the waste material is properly disposed of.

EC REP

Hologic, Inc.   Hologic BV
250 Campus Drive   Da Vincilaan 5
Marlborough, MA 01752 USA   1930 Zaventem
Tel: 1-800-442-9892   Belgium
         1-508-263-2900
Fax: 1-508-229-2795
Web: www.hologic.com

1 | INTRODUCTION

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C h a p t e r   T w o

Digital Imager Installation

WARNING: Service Installation Only

SECTION A   GENERAL

The Digital Imager and Digital Imager computer must be installed by Hologic service personnel. The complete Genius Digital Diagnostics System must be installed by Hologic service personnel. When installation is complete, the service personnel trains the operator(s), using the operator's manual as the training guide.

In the event the equipment must be moved after installation, please contact Hologic Technical Support. Refer to Chapter 8, Service Information.

SECTION B   ACTION UPON DELIVERY

Remove and read the *Operating Instructions Prior to Installation* sheet attached to the packing carton.

Inspect the packing cartons for damage. Inspect the shock sensor on the packing carton for the Digital Imager for damage. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible. Refer to Chapter 8, Service Information.

Leave the equipment in the packing cartons for Hologic service installation.

Store the equipment in a suitable environment until installation (cool, dry, vibration-free area).

PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

A pre-installation site assessment is performed by Hologic service personnel. Be sure to have prepared any and all site configuration requirements as instructed by the service personnel.

Location And Configuration

CAUTION: Route all connectors carefully to avoid pinching the cables. To avoid tripping over or disconnecting cabling, do not place cabling near foot traffic.

Note: To install the entire Genius Digital Diagnostics System, Hologic service personnel will require assistance from the lab's IT staff to properly configure the system.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Local Network Configuration

The cables connecting components of the Genius Digital Diagnostics System must be the cables supplied by Hologic. The cables cannot be substituted with other cabling. The Digital Imager and Digital Imager computer must be located in the same area, so that interconnection cables easily reach each component (within 2 meters [6.6 feet] of each other). See Figure 2-1. The Digital Imager system and the Image Management Server may be located further apart, as determined in the site assessment with your laboratory and Hologic service personnel.

Switch

Digital Imager

Image Management Server

Monitor

Keyboard

Mouse

Table, desk or lab bench

(One or more Digital Imagers depending on site configuration)

Review Station

Mouse

Keyboard

Table, desk or lab bench

(One or more Review Stations depending on site configuration)
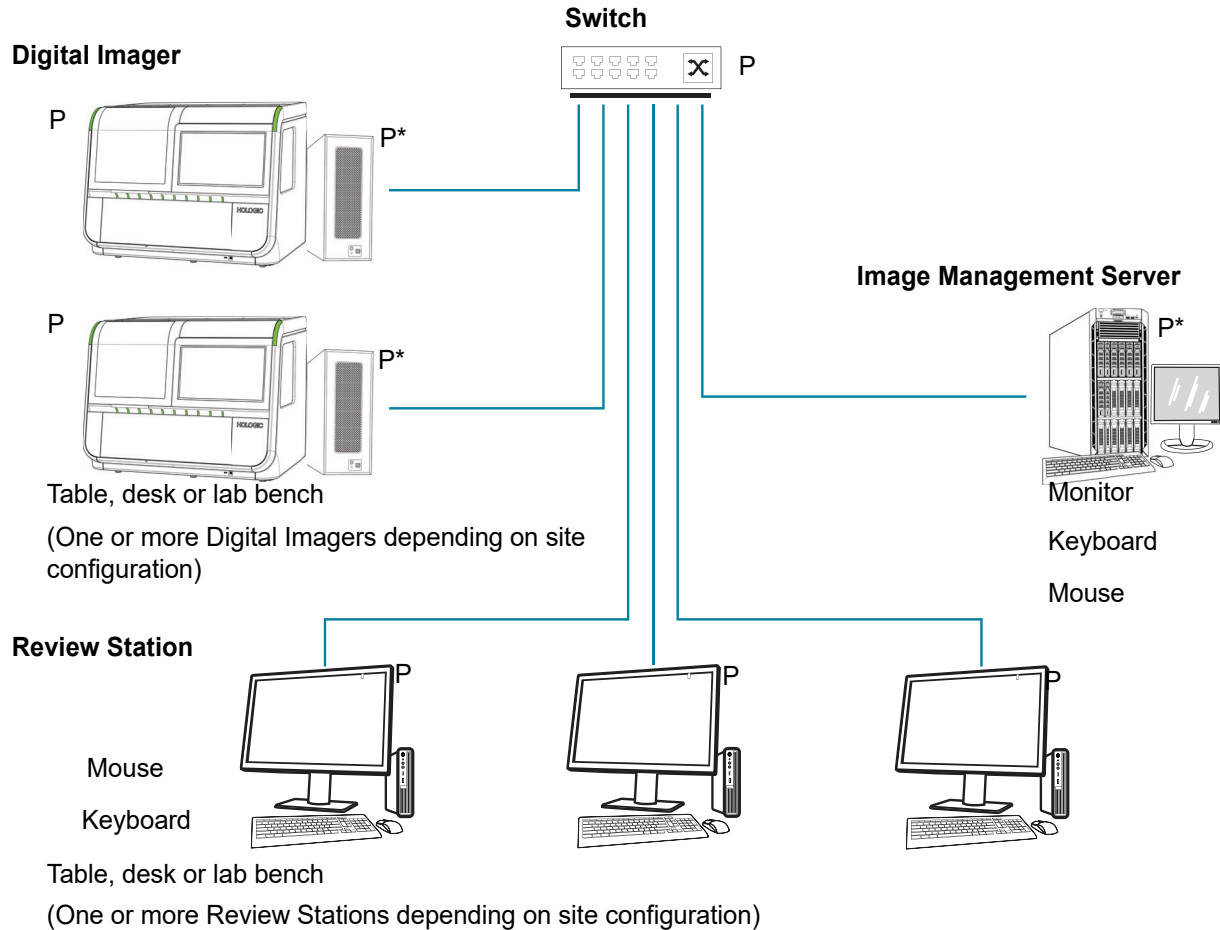
P = Power cord, requires an outlet

*May go on the floor, provided there is no dust accumulation on or around it.

Figure 2-1   Local Network Interconnection Schematic (Example)

CAUTION: Route all connectors carefully to avoid pinching the cables. To avoid tripping over or disconnecting cabling, do not place cabling near foot traffic.

WARNING: Grounded Outlet

Component configuration

The components may be arranged on the benchtop as desired, providing the connection cables can reach easily. The Digital Imager computer may be placed on the floor near the work area, provided it has adequate air circulation to prevent dust accumulation and it is safely removed from foot traffic or other interference. It should be accessible for routine maintenance.

2 | DIGITAL IMAGER INSTALLATION

A pre-installation site assessment by Hologic service personnel will identify all additional requirements. Be sure to have prepared the site as instructed by the service personnel prior to scheduling the system installation.

SECTION
D

STORAGE AND HANDLING - POST INSTALLATION

Environmental Considerations

- The Digital Imager is sensitive to sudden thermal or humidity changes. Do not locate it next to windows, heaters, air conditioners, HVAC vents or doors that are frequently opened and shut.

- During operation, the Digital Imager is sensitive to vibrations. It should be placed on a sturdy flat surface away from centrifuges, vortexors or any equipment that may cause vibrations. Keep away from other environmental activity, such as constant foot traffic, proximity to elevators or doors that are frequently open and shut.

Chapter Three

User Interface

This chapter provides detailed information on the user interface screens and how to use them to operate, troubleshoot and maintain the Digital Imager.

The content found in this chapter:

3

USER INTERFACE

MAIN SCREEN , DIGITAL IMAGER IDLE, READY TO PROCESS

When the Genius Digital Imager is powered on and ready for use, the main screen will be displayed.

Ten positions for slide carriers
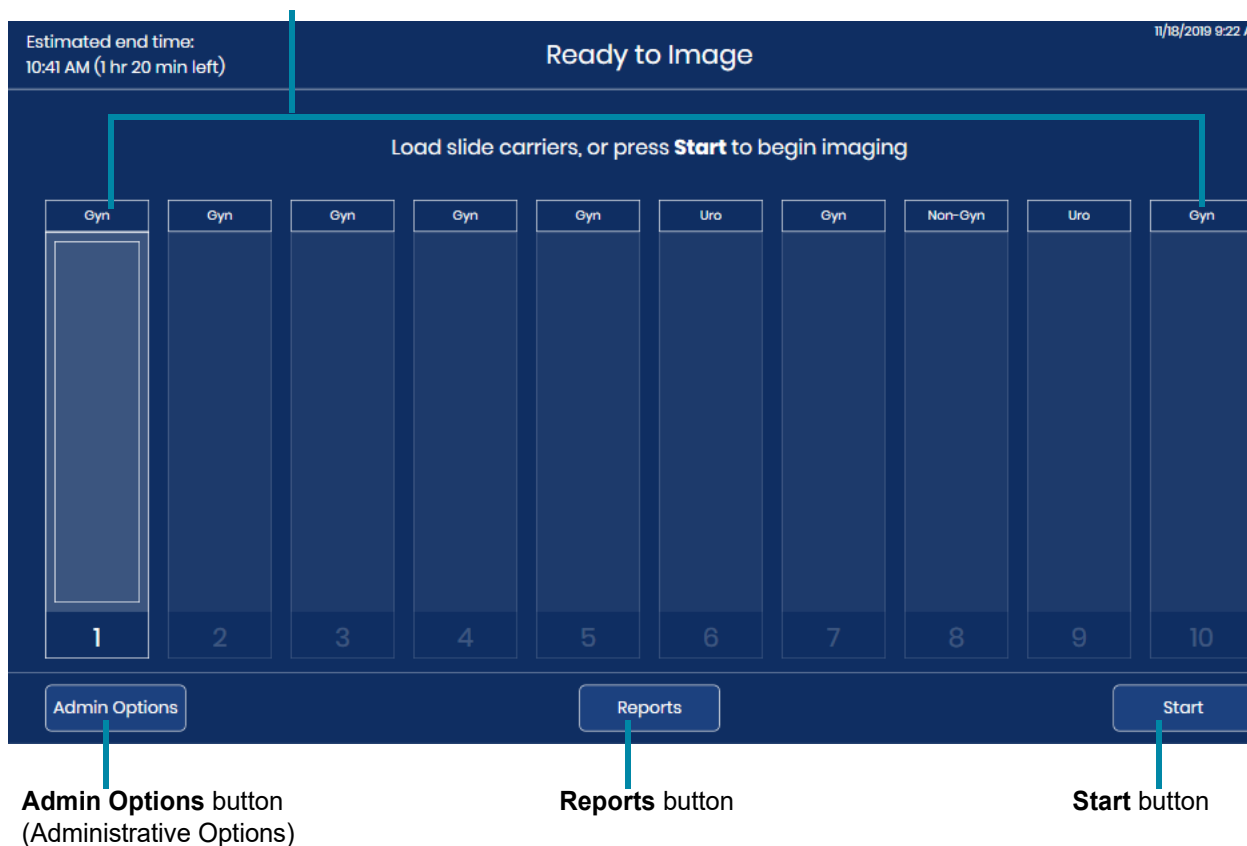Touch to change the specimen type for a slide carrier position.

Figure 3-1   Main Screen, Ready to Image

The **Admin Options** button opens the Administrative Options screen. Refer to "Administrative Options" on page 3.14.

The **Reports** button opens the Reports screen. Refer to "Reports" on page 3.39.

The **Start** button starts processing slides. Refer to "Slide Processing" on page 4.14. At least one slide carrier must be loaded into the Digital Imager for the **Start** button to be available.

STATUS INDICATORS

Lights

LED lights indicate the overall system status, the slide carrier whose slides are being processed, and the positions where slide carriers can be loaded or reloaded into the Digital Imager.

System status lights

Red slide carrier
indicator light

Slide carrier indicator
lights, marking
positions 1-10

Green slide carrier indicator lights
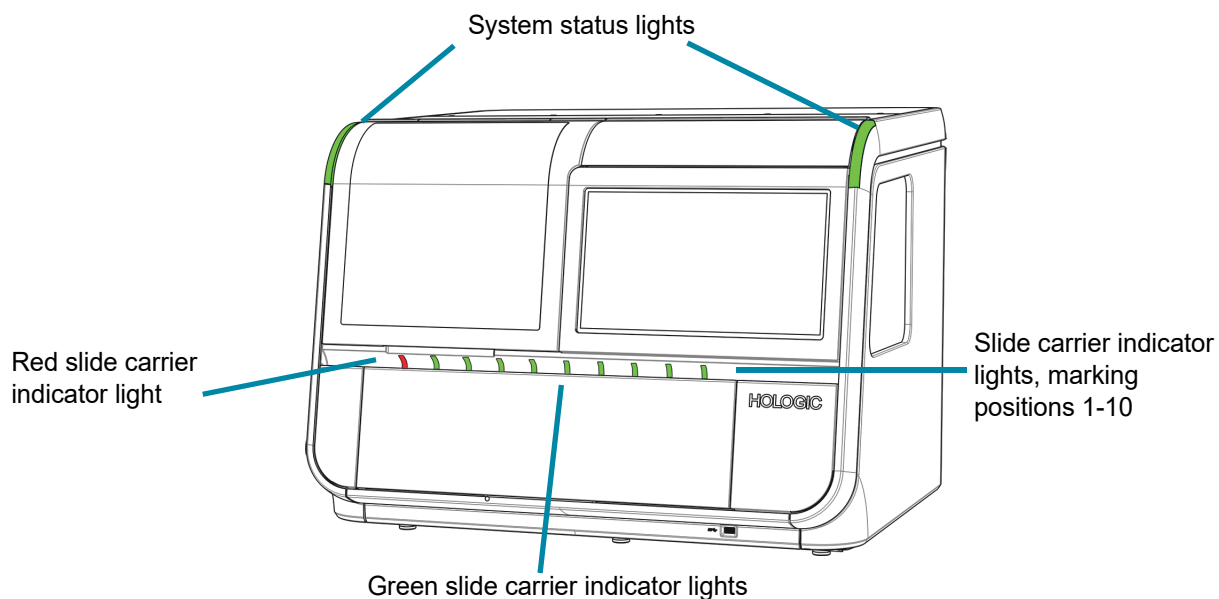
Figure 3-2   Indicator Lights

Exterior LED lights		
System status light	Green	The Digital Imager is on, and the Digital Imager is operational.
	Red	The Digital Imager is on, and the Digital Imager has an error.
	Not illuminated	The Digital Imager is not turned on, or it does not have power.

Exterior LED lights		
Slide carrier indicator light	Green	A slide carrier can be loaded or removed in this position. Slides from this slide carrier are not actively in process on the Digital Imager. In this position: • There may be a slide carrier with slides that have not yet been processed • There may be a slide carrier without any slides in it • There may be a slide carrier with slides whose imaging is complete, or There may not be a slide carrier loaded into the Digital Imager.
	Red	Do not remove the slide carrier in a position marked by a red light. Slides from the slide carrier in this position are in use by the Digital Imager.

Slide Carrier Inventory

The touch screen display indicates where slide carriers are loaded, and where slides are loaded into the staining racks in those slide carriers. During processing, the appearance of the touch screen display changes as imaging progresses through each of the slides in each of the slide carriers.
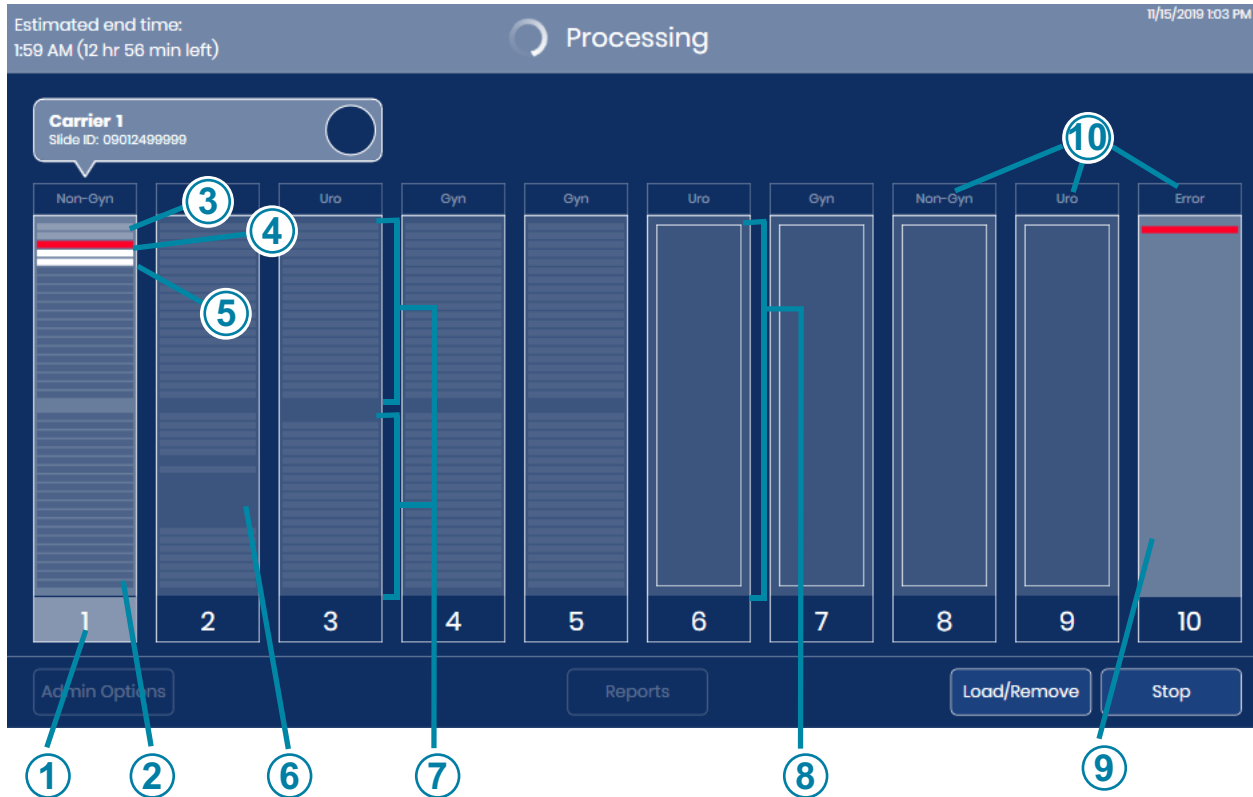
Figure 3-3   Screen Display Indicates Slide Carrier Position

Key to Figure 3-3	
①	Highlighted number Slides from this carrier are in use by the Digital Imager.
②	Dark grey stripes, carrier in use Slides in staining rack slots in the slide carrier The Digital Imager conducted an inventory and detected slides in the slots that appear as stripes.
③	Light grey stripes, carrier in use Processed slides The Digital Imager imaged the slides in these slots of the staining rack in the slide carrier and returned the slides to the slide carrier.

Key to Figure 3-3	
④	Red stripe Slide event The Digital Imager attempted to image the slide in this slot of the staining rack, and a slide imaging event occurred. The Digital Imager returned the slide to the staining rack in the slide carrier. ***Note:*** When position 10 is designated as an error carrier, a slide with a slide event is returned to the error carrier. The empty slot in the staining rack of the starting carrier and the slot holding the slide in the error carrier appear red.
⑤	White stripe Slide(s) removed from slide carrier The Digital Imager has removed the slide in this slot of the staining rack and has not returned the slide to the staining rack in the slide carrier.
⑥	Dark area amid thin stripes Empty slots in a staining rack in a slide carrier loaded into the Digital Imager
⑦	Grey stripes, carrier not in use Slides in staining rack slots in the slide carrier The Digital Imager conducted an inventory and detected slides in the slots that appear as stripes.
⑧	"Empty" box The Digital Imager detected that a slide carrier is loaded in this position, but the Digital Imager has not yet conducted an inventory of the slides in that slide carrier.
⑨	Error carrier Position 10 can be designated as an error carrier. A slide with a slide event is moved to the error carrier when position 10 is used as an error carrier.
⑩	Sample type Refer to "Select Sample Type for a Slide Carrier" on page 3.13.

During Processing

During processing, the Digital Imager touch screen displays information about the progress of the batch. Detailed information about each slide is also available.

Figure 3-4   Screen Display During Processing

Key to Figure 3-4	
①	Slides in carrier 1 are being processed. To open the detailed display of this slide carrier's slides, touch anywhere in the illustration of carrier 1 on the touch screen.
②	During processing, the position of the carrier currently in progress appears above the illustration of the carrier. The slide ID for the slide whose image data is currently being transmitted is also displayed. Refer to "Slide data transmission status" on page 3.10.

Key to Figure 3-4	
③	Estimated end time During slide processing, the Digital Imager estimates the end time for imaging all of the slides in all of the slide carriers. At the beginning of slide processing, the estimated end time is based on the number of slide carriers loaded into the instrument. As processing progresses, the instrument conducts an inventory of each slide carrier. The number of slides in each slide carrier is then factored into the estimated end time. When the inventory is complete, the estimated end time is more accurate than when the slide inventory is in progress.
④	System status The system status appears at the top of the display area. The status changes from "Ready to Image" to "Processing" after the operator touches the **Start** button. When processing is complete, the status changes to "Processing Complete". If processing is paused, if communication to the Image Management Server is disrupted, or if a system error occurs, the status bar at the top of the display area changes.
⑤	Current date and time. The date and time on the Digital Imager are set by the Image Management Server.

Slide data transmission status

The circle icon depicts the progress of data transfer from the Digital Imager to the Image Management Server.

Carrier 1
Slide ID: 09012499999

The Digital Imager has read the slide ID at the macro station and is starting to send data for this slide to the Image Management Server.

The Digital Imager is sending data for this slide to the Image Management Server.

The Digital Imager finished sending data for this slide to the Image Management Server.
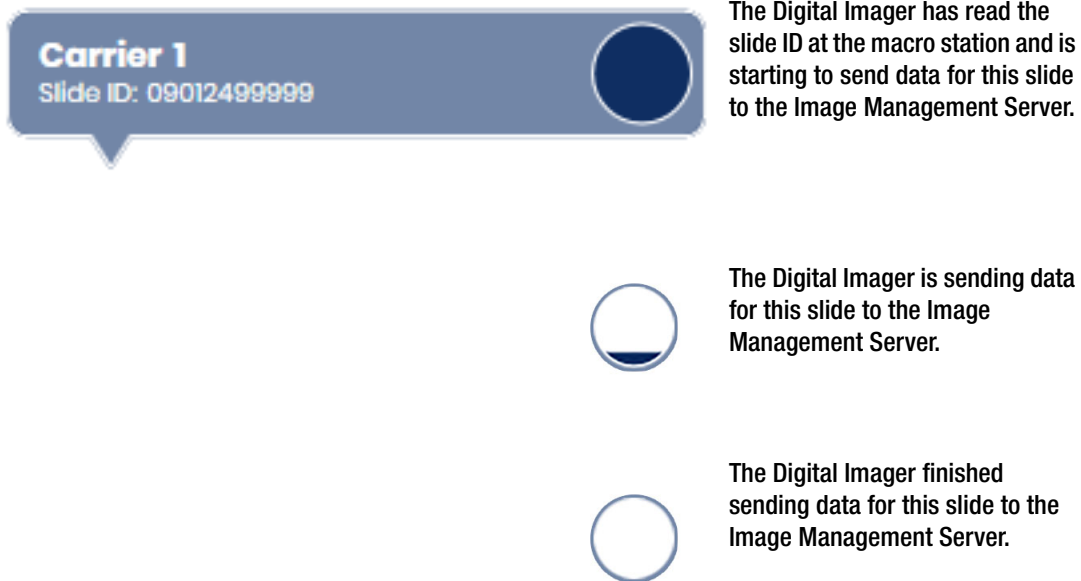
Figure 3-5   Slide Data Transmission Status

Slide carrier details

Touch the rectangle representing the slide carrier on the touch screen during processing to show details about the slides in that carrier.
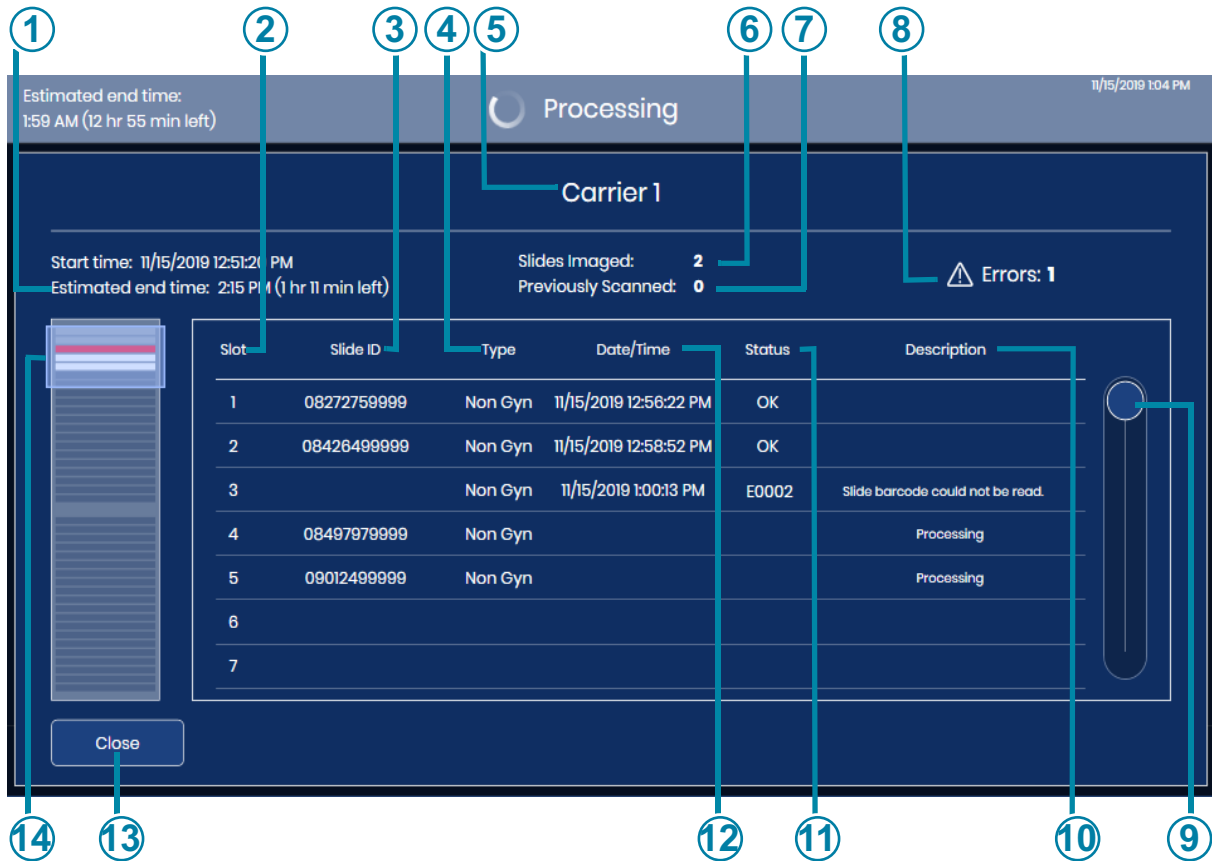
Figure 3-6   Slide Carrier Details Screen (Carrier 1, Example)

Key to Figure 3-6	
①	The date and time that processing started for all of the slide carriers loaded in the instrument and the estimated time that all of the slide carriers loaded in the instrument will finish processing
②	The slot number in the staining rack of the slide carrier
③	The slide ID read by the Digital Imager

Key to Figure 3-6	
④	The sample type, selected by the operator for the slide carrier
⑤	The position number for the slide carrier whose details are displayed
⑥	The total number of slides from the current carrier that have been successfully imaged.
⑦	The total number of slides from the current carrier that have been previously scanned by the Genius Digital Diagnostics System. A slide ID already successfully imaged cannot be imaged again.
⑧	Total number of errors for the slides already processed from this slide carrier
⑨	Touch and slide the circle to move through the list
⑩	Description of imaging status For slides with an error, the status column lists the error code, and a brief description is shown. For slides in progress, the description is "Processing". When processing finishes successfully, the date/time and the status are shown.
⑪	Imaging status For slides with the status of "OK", imaging is complete and was successful. For slides with an error, the status column lists the error code.
⑫	The date/time the slide was imaged
⑬	**Close** button Touch the **Close** button to return to the processing screen

The slide carrier details screen shows information for each of the slide IDs in that slide carrier. The information in the slide carrier details screen populates as processing progresses one slide at a time.

The details are available on the touch screen while slide processing is in progress. At the end of slide processing and before slide carriers are reloaded, details from the previous run are available by touching a slide carrier's graphic on the main screen.

After a slide carrier has been removed or reloaded in a slide carrier position, the information that was in the slide carrier details screen is available as the Imaging Report on the Digital Imager.

SAMPLE TYPE OPTIONS

Select Sample Type for a Slide Carrier

Prior to processing slides, the sample type for each lane in the slide carrier can be changed. To change the sample type, touch the name of the process at the top of each slide carrier graphic on the touch screen to open the options: gynecologic samples (Gyn), non-gynecologic samples (Non-Gyn), UroCyte® samples (UroCyte).

Position 10, and only position 10, can be designated as an error slide carrier.

For imaging gynecologic slides.
Use ThinPrep Imaging System microscope slides.

For imaging non-gynecologic slides.
Use ThinPrep non-gynecological microscope slides.

For imaging slides of urine specimens.
Use ThinPrep UroCyte microscope slides.
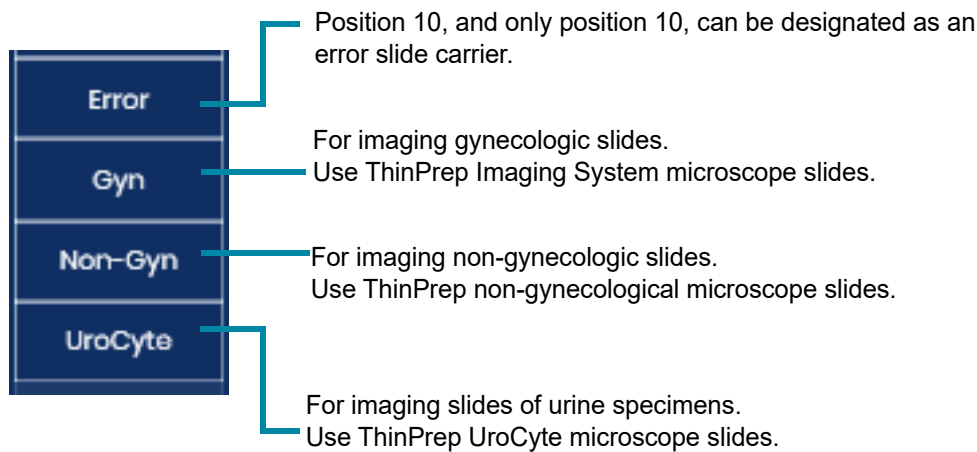
Figure 3-7   Sample Type Selection

The selection for sample type remains until the user changes it again or until the instrument is restarted.

CAUTION: To run Non-Gyn or UroCyte samples, after the Digital Imager is restarted, the operator must designate a slide carrier position as Non-Gyn or UroCyte again. When the Digital Imager is re-started, all of the slide carriers are set to the default sample type of Gyn.

3

USER INTERFACE

ADMINISTRATIVE OPTIONS

The system has options for configuring certain features of the Digital Imager.
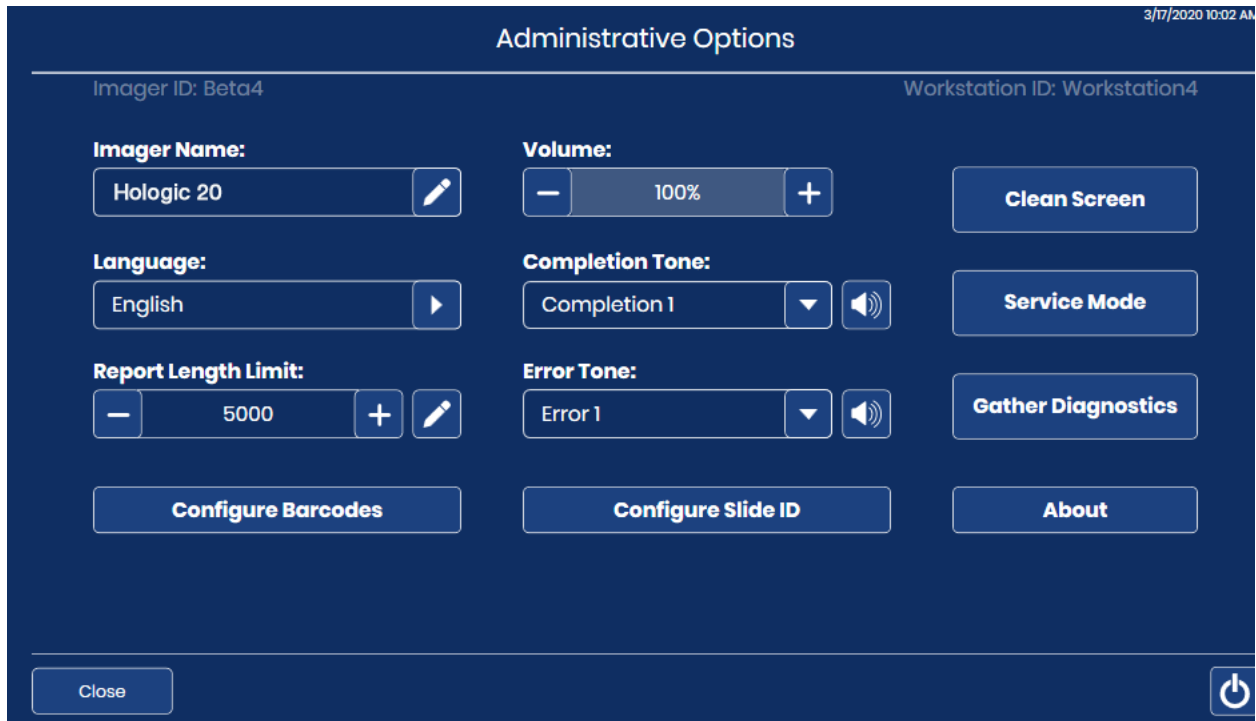
Figure 3-8   Administrative Options Screen

The serial number for the Digital Imager (Imager ID) and the serial number for the Digital Imager computer (Workstation ID) appear near the top of the Administrative Options screen. The current settings for the Administrative Options are displayed. Use the buttons on the Administrative Options screen to change an option.

Imager Name

The screen shows the current setting.

Figure 3-9   Imager Name Button

To enter or edit a name for the Digital Imager press the **Imager Name** button.

Touch the edit button to open the keyboard on the touch screen.

Press the letter buttons to enter a name, up to 20 characters long. See Figure 3-10. To create a capital letter, press the **Shift** button and then press the letter. With the next letter, the system reverts to lowercase.

Use the **Space** button for a space and the **Backspace** [×] button to remove entered letters.

Press the **!@#** button to display a screen to enter special characters. Press the **ABC** button to return to the alphabet keys. While in the alphabet keys, the up arrow switches to all capital letters (ALL CAPS) and the down arrow returns to lowercase letters.

Press the **Apply** button to save and return to the Administrative Options screen.

Press the **Close** button return to the Administrative Options screen.
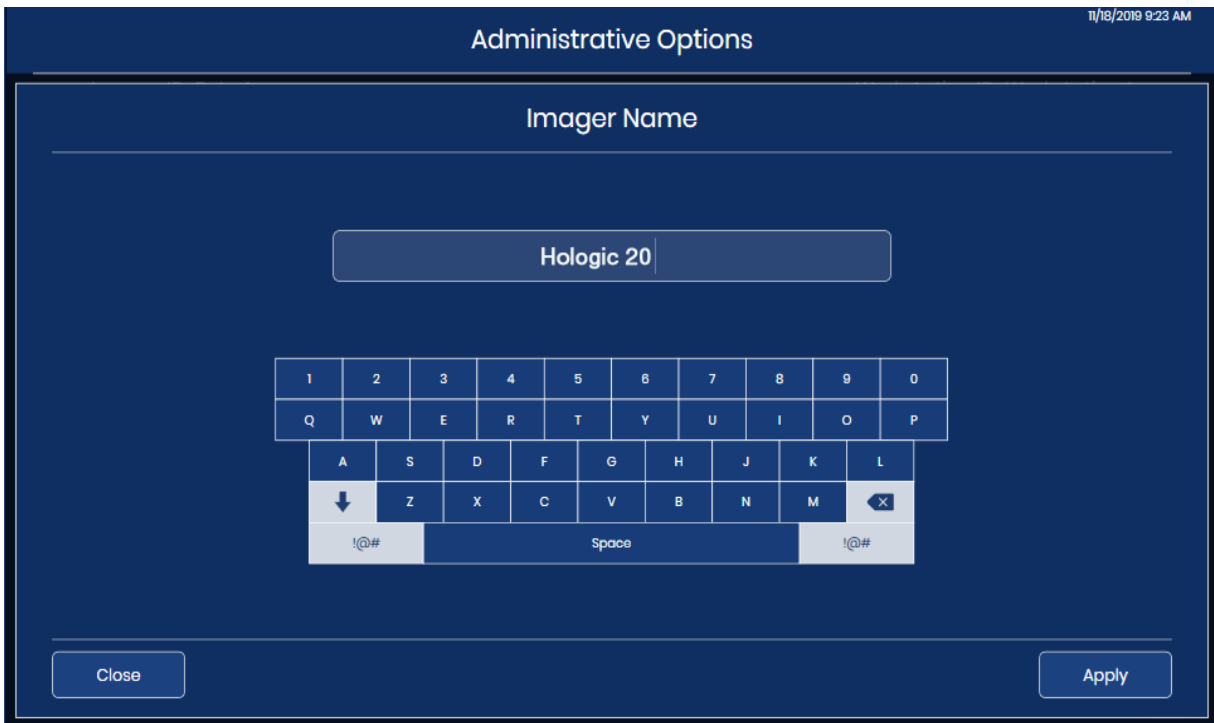
Figure 3-10   Edit Imager Name Screen

Language

The screen shows the current setting.

Figure 3-11   Language Button

Press the **Language** button to select the language that is displayed on the user interface and in the reports.
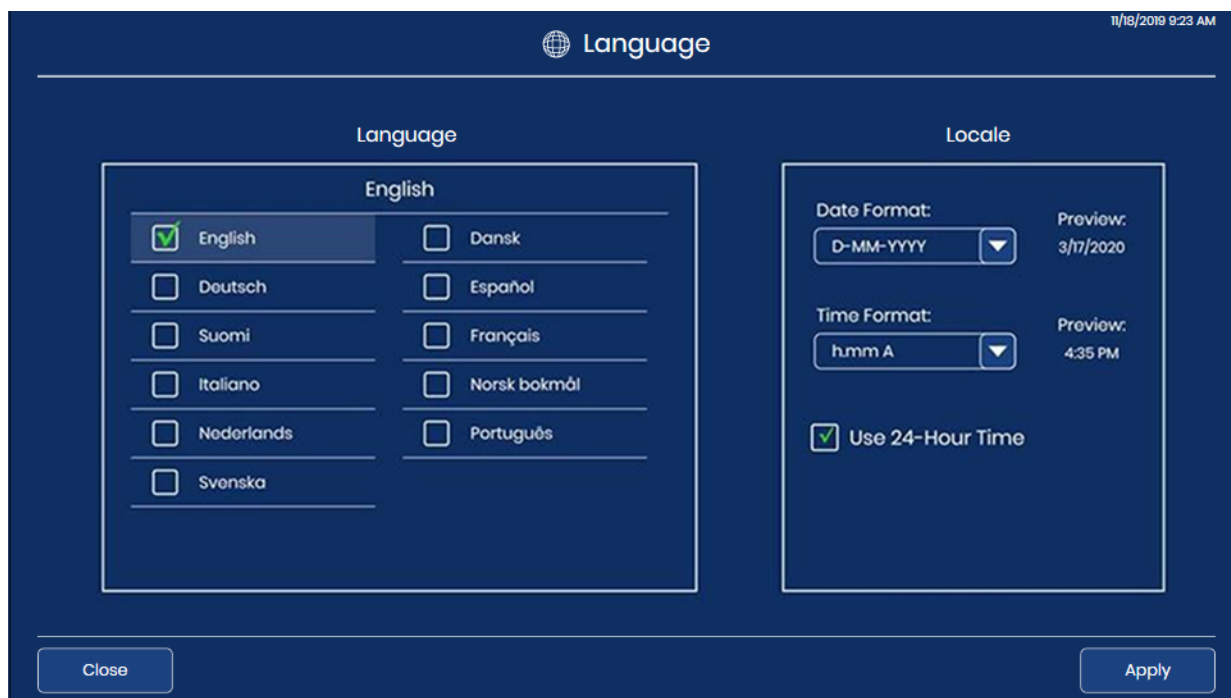
Figure 3-12 Select Language Screen

The current selection displays at the top of the screen. Touch the name of the language to select it.

The green check mark marks the selection.

Select the date format. To change the date format used on the touch screen display and in reports, touch the arrow to the right of the current date format to see the available options. Touch a date format to select it. The preview of the date format shows today's date in the selected format.

Select the time format. To change the time format used on the touch screen display and in reports, touch the arrow to the right of the current time format to see the available options. Touch a time format to select it. The preview of the time format shows the current time in the selected format.

Note: In the 12-hour time formats, the "A" or "P" in the time format screen indicates a.m. or p.m.

To express the date in 24-hour format, move the slider to the right. To use a 12-hour format, move the slider to the left

Press the **Apply** button to save and return to the Administrative Options screen.

Press the **Close** button return to the Administrative Options screen.

Report Length Limit

Report Length Limit:
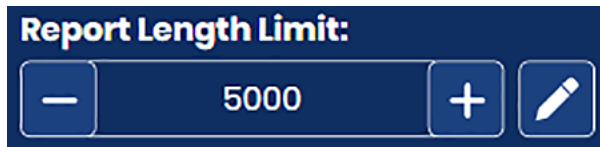
—   5000   +   ✎   The screen shows the current setting.

Figure 3-13   Report Length Limit

The report length limit is the maximum number of lines of data that are retrieved from the database for a report, from 500 to 5000. (If there is less data than the number chosen, all the available data will report.) The default setting is a limit of 500 results.

When a report is run, if the number of entries is greater than the report length limit, the report displays only a portion of the results, and a message displays on the touch screen. There are two ways to set the limit:

1. Touch the edit button ✎ to open the keyboard on the touch screen.
2. Type the number
3. Press the **Apply** button to save and return to the Administrative Options screen.
    or

4. Use the plus sign ＋ to increase the limit or the minus sign — to lower the limit.

Note: To generate reports that do not exceed the report length limit, consider setting more narrow reporting criteria, such as a shorter date range.

Set Volume
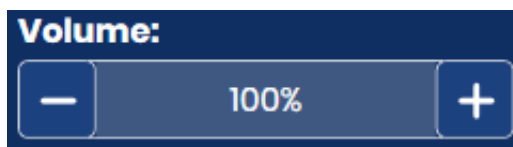
Volume:

—   100%   +   The screen shows the current setting.

Figure 3-14   Sound Volume

Audible alert tones can be set for the completion of slide processing and for an error condition. The volume of the audible alert tones may be increased or decreased using the **Volume** setting.

Use the plus sign ＋ to increase the volume or the minus sign — to lower the volume.

A tone plays at the volume level when the plus or minus signs are touched. The sound volume can be adjusted from 0% to 100%.

With the volume set to 0%, the instrument will not emit a tone, as if the sound is turned off.

Completion Tone

 The screen shows the current setting.

Completion Tone:
Completion 1

Figure 3-15   Completion Tone

The completion tone is an audible alarm that sounds briefly when slide processing is complete. Four sounds are offered.

To play the current tone, touch the speaker icon .

To change the completion tone, touch the down arrow to open the list.

Touch one of the four entries to select it.

Note: The volume of the tone is adjusted by the Volume setting. Refer to "Set Volume" on page 3.17.

Having differentiated tones makes it easier to know if the instrument has completed processing. In a setting that might have multiple machines, the different tones can help identify them.

Error Tone

 The screen shows the current setting.

Error Tone:
Error 1

Figure 3-16   Error Tone

The error tone is an audible alarm that sounds during an error condition. Four sounds are offered.

To play the current tone, touch the speaker icon .

To change the error tone, touch the down arrow to open the list.
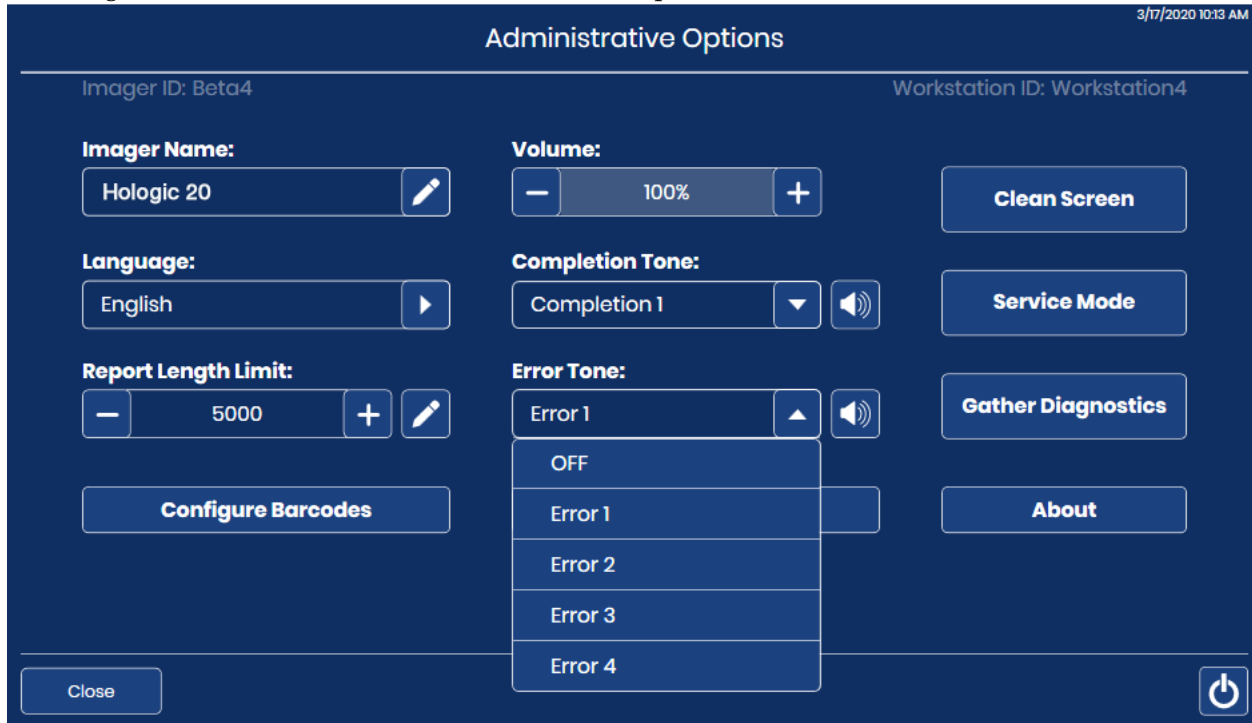
Figure 3-17   Select Error Tone (Optional)

Touch one of the four entries to select it.

Note: The volume of the tone is adjusted by the Volume setting. Refer to "Set Volume" on page 3.17.

Having differentiated tones makes it easier to know if the instrument has completed a batch. In a setting that might have multiple machines, the different tones can help identify them.

When an error condition occurs, the error tone will sound and then repeat every few seconds. The error message window will have a **Silence Alarm** button that can be pressed to turn the alarm off. (Figure 3-18.)
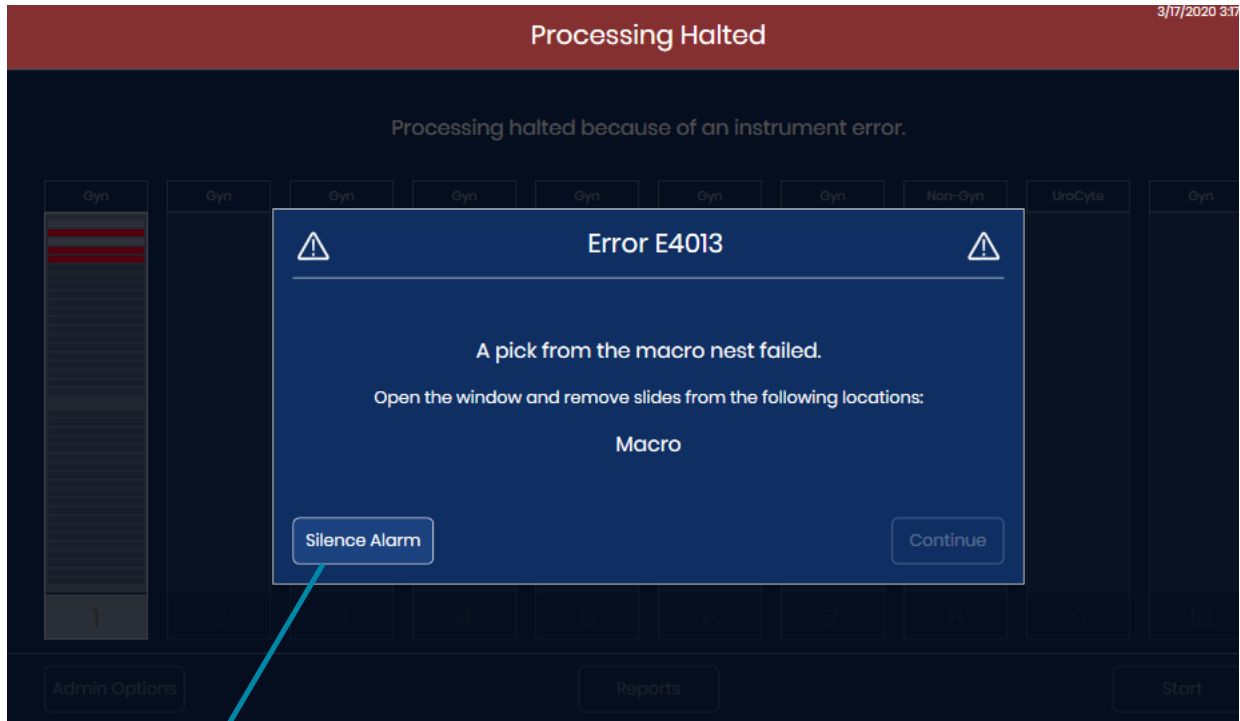
Press the **Silence Alarm** button to turn off the alarm but keep the error message on the touch screen display

Figure 3-18   Silence Alarm Button

Clean Screen

This is described in Chapter 5, Digital Imager Maintenance.

Service Mode

Figure 3-19   Service Mode Button

A **Service Mode** button is available for Hologic service personnel usage, and it is password-protected.

Gather Diagnostics

Figure 3-20   Gather Diagnostics Button

Gather Diagnostics is a function intended for instrument troubleshooting by Hologic Technical Support. It gathers and zips the error history logs and other instrument operating information. The zip file contents are password-protected.

1. Touch the Gather Diagnostics button from the Administrative Options screen to start.
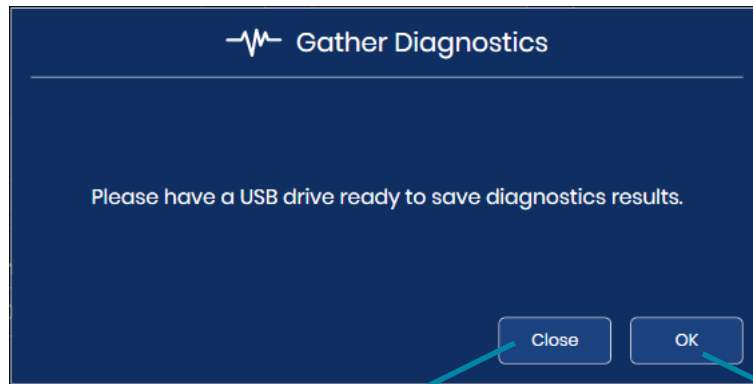
To close the Gather Diagnostics screen without gathering the information, touch the **Close** button.

Touch **OK** to continue the Gather Diagnostics steps.

Figure 3-21   Gather Diagnostics: Insert a USB Drive

2. Put a USB device into the USB port on the front of th instrument. See Figure 1-6. If there is a USB device in one of the other ports on the instrument, the instrument will prompt to select one of them. The system gathers the files and zips them, placing the zip folder on a USB drive the user has placed in the USB port.
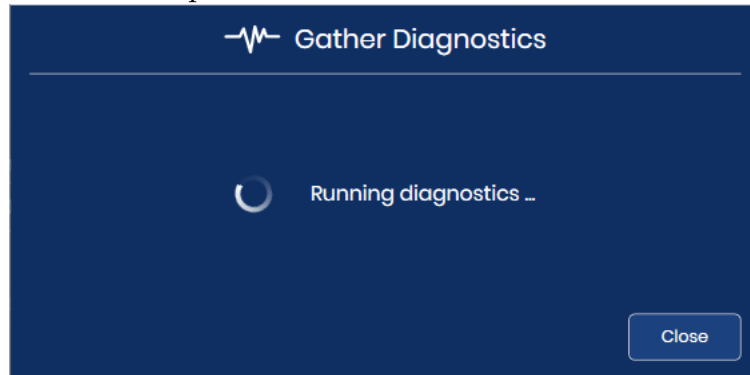
Figure 3-22   Gather Diagnostics: Running Diagnostics

3. The touch screen display confirms a successful file transfer. The instrument information will be gathered into a folder on the USB device titled **ImagerDiagnostics.zip**. The files in the folder are password-protected. The zip file can be emailed to Hologic Technical Support for diagnostic troubleshooting.
Or, if the instrument cannot not successfully gather, zip and transfer the files, an error message displays.

Figure 3-23   Gather Diagnostics: File Saved on USB Drive

4. Touch **Close** to return to the Administrative Options screen.

Configure Barcodes

Figure 3-24   Configure Barcodes

The Configure Barcodes settings are questions about how slides are labeled in your laboratory.

The Digital Imager can be set up to read slide IDs as 1-D barcodes, 2-D barcodes, or OCR format. If slide labels have more than one barcode on them, the Configure Barcode settings on the Digital Imager direct the Digital Imager to the barcode that represents the slide ID.

The slide ID must be in one of six 1-D barcode symbologies supported (Code 128, Interleaved 2 of 5, Code 39, Code 93, Codabar or EAN-13/JAN) or in one of the two 2-D barcode symbologies supported (DataMatrix or QR Code). A 7-over-7 OCR slide label format may be used.

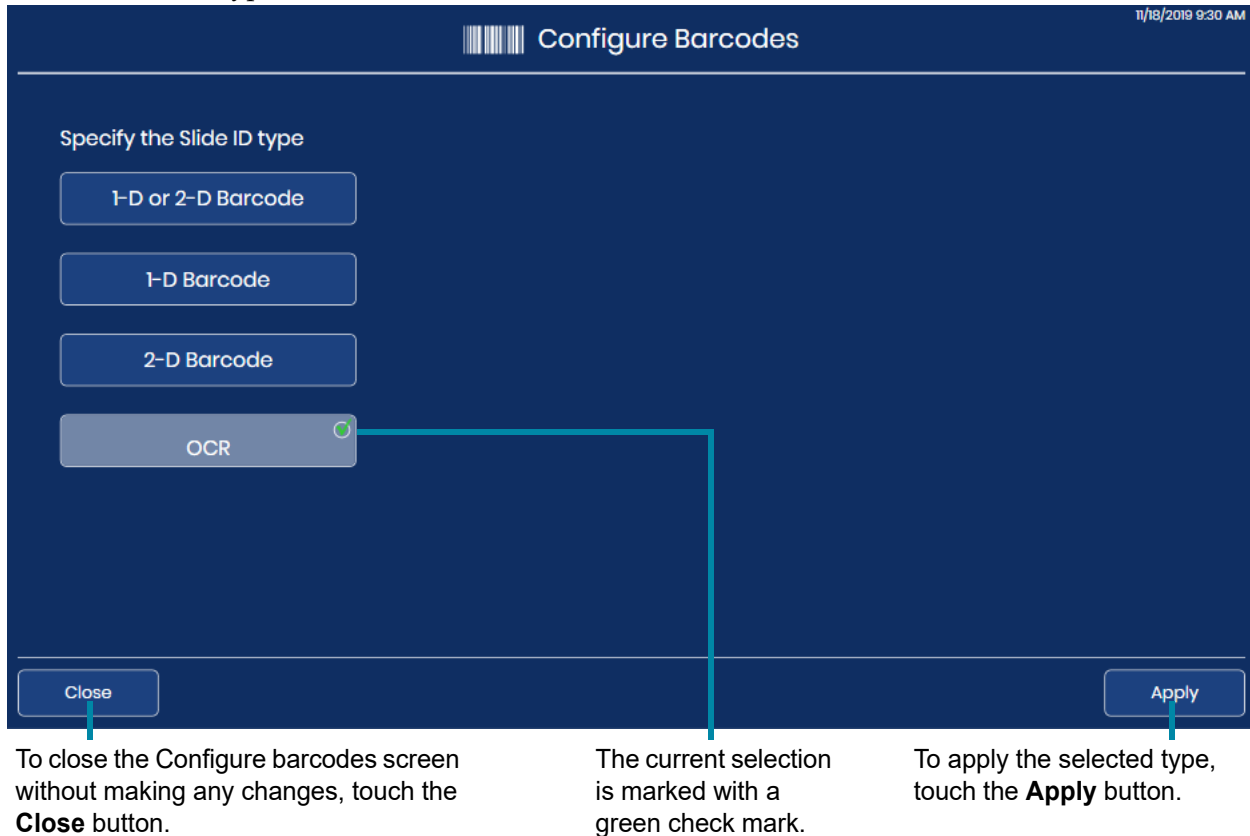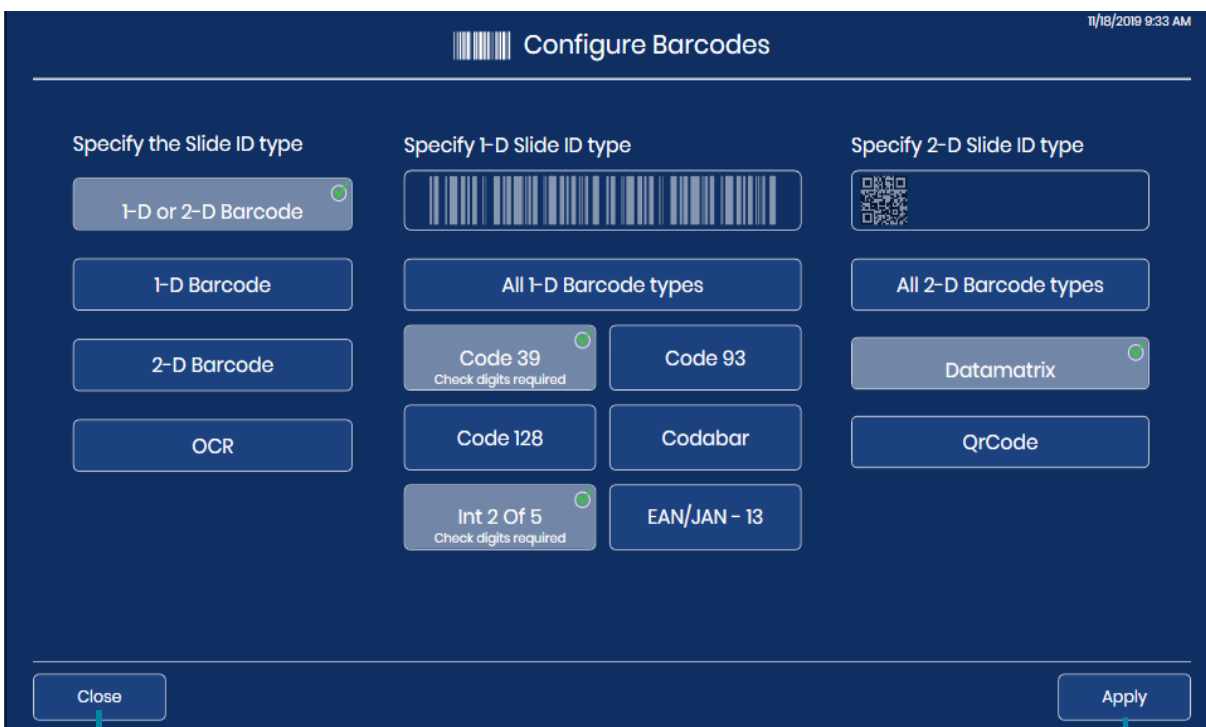1.   Touch the ID type to select it: 1-D Barcode, 2-D Barcode, or OCR

To close the Configure barcodes screen without making any changes, touch the **Close** button.

The current selection is marked with a green check mark.

To apply the selected type, touch the **Apply** button.

Figure 3-25   Configure Barcodes: Specify the Slide ID Type

Note: For best performance, select only the barcode type(s) that are used for slide IDs in your laboratory, and do not select barcode types that are not used in your lab.

2.   Touch **Apply** to save the selection and close this screen. Or, touch **Close** to close the screen without changing the current selection.

3. For 1-D barcodes and 2-D barcodes, specify the 1-D slide ID type(s) and/or the 2-D slide ID type(s). Touch the name of the barcode type to select it.
Since the OCR type is always 7-over-7, there are no options to select for OCR.

To close the Configure barcodes screen and discard any changes, touch the **Close** button.

To apply the selected type, touch the **Apply** button.

Figure 3-26 Configure Barcodes: Specify the 1-D Barcode or 2-D Barcode Types

Note: For best performance, select only the barcode type(s) that are used for slide IDs in your laboratory, and do not select barcode types that are not used in your lab.

4. Touch **Apply** to save the selection and close this screen. Or, touch **Close** to close the screen without changing the current selection.
For Code 39 and for Interleaved 2 of 5, there is one more setting to set. For other barcode types, the touch screen display returns to the slide ID type selection screen.

5. For Interleaved 2 of 5 and for Code 39, specify whether your laboratory uses a check digit in the barcode. Touch "Yes" or "No"
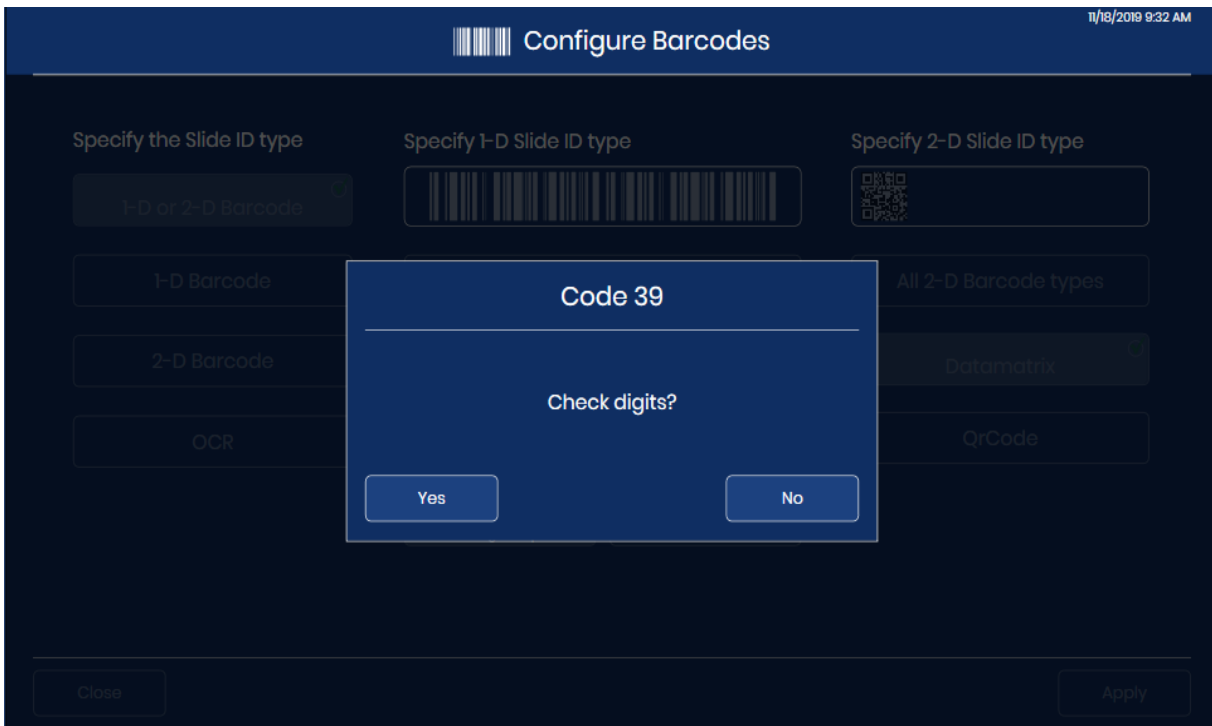

Figure 3-27   Configure Barcodes: Choose Check Digit Use for Interleaved 2 of 5 and for Code 39

6. For Code 39 or Interleaved 2 of 5 barcodes, the touch screen display returns to the Slide ID type selection screen. Either "Check digits not required" or "Check digits required" appears under the **Code 39** button or the **Interleaved 2 of 5** button.
   To change the check digit setting touch Code 39 or Interleaved 2 of 5 again.
7. For Code 39 or Interleaved 2 of 5 barcodes, touch **Apply** to save the selection and close this screen. Or, touch **Close** to close the screen without changing the current selection.

Configure Slide ID

Figure 3-28   Configure Slide ID Button

The Configure Slide ID feature allows the slide ID or accession ID number used by the Genius Digital Diagnostics System to be the same as, or only a portion of, the slide ID on the slide label itself. The

accession number used by the Genius Digital Diagnostics System is derived from the slide ID printed on the slide label itself.

For Gyn slides, the options in the Configure Slide ID feature are to use the entire printed slide ID or to use a portion of the printed slide ID.

For Non-Gyn slides where one sample may have more than one slide, the Configure Slide ID feature allows the system to use the entire printed slide ID, to use a portion of the printed slide ID, and to group the accession IDs for several slides for one case together.

For UroCyte slides, the options in the Configure Slide ID feature are to use the entire printed slide ID or to use a portion of the printed slide ID.

Figure 3-29   Configure Slide ID Summary Screen

In the Configure Slide ID settings, the Digital Imager software compares the configuration to your lab's slide ID barcode configuration set on the Digital Imager. If an impossible combination is entered, such as a length that is too long to be a valid slide ID, the green data entry box on the touch screen turns red and the configuration cannot be applied. A Configure Slide ID setting can only be applied when the box around the data entry field is green.

Figure 3-30 Configure Slide ID Edit Setting: Green for Valid Entry

Configuring Slide ID settings is optional. If nothing is set up in the Configure Slide ID screens, the Genius Digital Diagnostics System will use the entire slide ID printed on the slide label.

Configure slide ID - Gyn slides

If Gyn slides arrive in your laboratory with characters in the slide ID that you want to exclude from the accession ID used by the Genius Digital Diagnostics System, the Digital Imager can be configured to exclude those characters. The data transferred to the Image Management Server, available at the Review Station, and displayed on the Digital Imager will use the slide ID or accession ID as it appears after the Configure Slide ID settings are applied to it.

Note: At the macro station on the Digital Imager, the Digital Imager takes an image of the slide label. A record of the entire slide ID on the slide label is available in the image taken at the macro station.

1. From the Administrative Options screen, touch **Configure Slide ID**. The current selection is described under the name of the sample type.
2. Under **Gyn** options, choose between "Entire scanned value" or "Select a segment."

   • **Entire scanned value:** the slide ID or accession ID number in the Digital Imaging System will be the same as the ID printed on the slide label. Skip to step 7.

   • **Select a segment:** the slide ID or accession ID number used by the Digital Imaging System will be derived from the ID printed on the slide label. Continue through the steps to specify what segment of the printed ID will be used by the Digital Imaging System.

Figure 3-31   Configure Slide ID: Select a Segment, Gyn Slides

3. Indicate where, in the slide ID printed on the slide label, the segment that is used by the Genius Digital Diagnostics System for the slide ID starts.
    Touch **Character** or **Position**:

    •   If the starting point is a certain character in the printed slide ID, such as a hyphen character, touch the **Character** button to enter that character.

    •   If the starting point is a certain position in the printed slide ID, such as the fifth character, touch the **Position** button to enter the position.

    •   If the first character of the segment to use in the slide ID for the Genius Digital Diagnostics System is the first character of the printed slide ID, leave the "Position" field blank.

4. Use the keyboard on the touch screen to indicate which character or position starts the segment. Use the backspace button to backspace if needed. For example, touch the hyphen to indicate that the segment begins after the hyphen character, or touch the 5 to indicate that the segment starts after the fifth character.

Note: The start of the segment is treated like a boundary, and this character is not included in the Genius Digital Diagnostics System slide ID. The accession ID will start after the character entered.

Note: If the "Start at" character is blank, the ID excludes the first character. To include the first character of the slide ID printed on the slide label, select **Position** and leave the box empty.

5. Indicate where, in the printed slide ID, the segment that is used on the Genius Digital Diagnostics System slide ID ends.
   Touch **Length** or **Character**:

   - If the ending point is always the same number of characters from the starting point of the segment, such as 8 characters, use the **Length** field.

   - If the ending point is always a certain character, such as the hyphen, use the **Character** setting.

   - If the end of the segment to use in the slide ID for the Genius Digital Diagnostics System is the end of the printed slide ID, leave the "Length" field blank.

6. Use the keyboard on the touch screen to indicate the length or ending character for the segment. For example, touch the 8 to indicate that the segment ends 8 characters after it starts, or touch the hyphen to indicate that the segment ends at the hyphen.

Note: The end point of a segment is treated like a boundary, and this character is not included in the Genius Digital Diagnostics System slide ID. The accession ID will end before the character entered.

7. Press the **Apply** button to save and return to the Configure Slide ID summary screen. To return to the Configure Slide ID summary screen without applying the settings, touch the **Close** button.

Configure a slide ID segment as an Administrative Option for your lab.

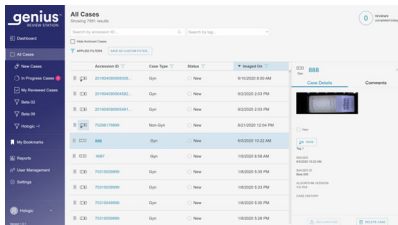Example: Set a segment that starts at the character "C" and ends at the hyphen character.

Image slides labeled with slide IDs:

Examples:
01ABC888-CYT
02987-C4567-LAB
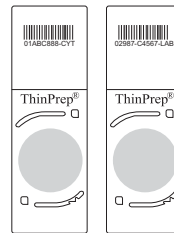
The slide IDs appear on the Review Station with the Configure Slide ID settings applied.

The slide IDs appear on the Digital Imager with the Configure Slide ID settings applied.

Example: The images for the slides are available to review on the Review Station as accession IDs "888" and "4567".

Example: The slide IDs are reported as "888" and "4567" on the Digital Imager.

Figure 3-32   Configure Slide ID Settings, Gyn (Example)

Configure slide ID - Non-Gyn slides

If Non-Gyn slides arrive in your laboratory with characters in the slide ID that are not used in your facility, the Digital Imager can be configured to exclude those characters. The data transferred to the

Image Management Server, available at the Review Station, and displayed on the Digital Imager will use the slide ID as it appears after the Configure Slide ID settings are applied to it.

The Digital Imager can also be configured to group the slide IDs together for multiple slides for the same Non-Gyn vial. The slides appear as a group when their data is viewed from the Review Station.

Note: At the macro station on the Digital Imager, the Digital Imager takes an image of the slide label. A record of the entire slide ID on the slide label is available in the image taken at the macro station.

When a case has more than one slide, ensure that all the slides for the case are available for review at the same time. For all of the slides in a grouped case to appear in a group on the Review Station, data for every one of the slides in the case must be on the Image Management Server.

Each slide in a group is available for review by itself. Each slide appears in reports by itself.

1. From the Administrative Options screen, touch **Configure Slide ID**. The current selection is described under the name of the sample type.
2. Under **Non-Gyn** options, choose "Same as Gyn," "Entire scanned value" or "Select a segment."

   - **Same as Gyn:** the configuration for Non-Gyn slide IDs will be the same as your laboratory's settings for Gyn slide IDs. Skip to step 12.

   - **Entire scanned value:** the ID used by the Digital Imaging System will be the same as the ID printed on the slide label. Skip to step 12.

   - **Select a segment:** the ID used by the Digital Imaging System will be derived from the ID printed on the slide label.

     For Non-Gyn slides, a lab has the option to configure a portion of the slide ID as a Primary ID and another portion of the slide ID as a secondary ID. Continue through the steps to specify what segment of the printed ID will be used by the Digital Imaging System as the Primary ID and as the Secondary ID.

     The Primary ID is the portion of the Genius Digital Diagnostics System slide ID that is used for all of the slides in the patient case. The Primary ID is the portion of the slide ID that slides in the group have in common.

     The Secondary ID is the portion of the Genius Digital Diagnostics System slide ID that differs for each of the slides in the patient case.

Figure 3-33   Configure Slide ID for Non-Gyn Slides with Primary ID and Secondary ID

3. For the Primary ID, indicate where, in the slide ID printed on the slide label, the segment that is used in the Genius Digital Diagnostics System slide ID starts.
   Touch **Character** or **Position**:

   - If the starting point is a certain character in the printed slide ID, such as a hyphen character, touch the **Character** button to enter that character.

   - If the starting point is a certain position in the printed slide ID, such as the fifth character, touch the **Position** button to enter the position.

   - If the first character of the segment to use in the slide ID for the Genius Digital Diagnostics System is the first character of the printed slide ID, leave the "Position" field blank.

4. For the Primary ID, use the keyboard on the touch screen to indicate which character or position starts the segment. Use the backspace button to backspace if needed. For example, touch the hyphen to indicate that the segment begins after the hyphen character, or touch the 5 to indicate that the segment starts after the fifth character.

Note: The start of the segment is treated like a boundary, and this character is not included in the Genius Digital Diagnostics System slide ID. The accession ID will start after the character entered.

5. For the Primary ID, indicate where, in the printed slide ID, the segment that is used in the Genius Digital Diagnostics System slide ID ends. Touch **Length** or **Character**:

- If the ending point is always the same number of characters from the starting point of the segment, such as 8 characters, use the **Length** field.

- If the ending point is always a certain character, such as the hyphen, use the **Character** setting

- If the end of the segment to use in the slide ID for the Genius Digital Diagnostics System is the end of the printed slide ID, leave the "Length" field blank.

6. For the Primary ID, use the keyboard on the touch screen to indicate the length or ending character for the segment. For example, touch the 8 to indicate that the segment ends 8 characters after it starts, or touch the hyphen to indicate that the segment ends at the hyphen.

Note: The end point of a segment is treated like a boundary, and this character is not included in the Genius Digital Diagnostics System slide ID. The accession ID will end before the character entered.

7. To configure a Secondary ID, touch the **Enable** button.
   If your laboratory does not need to group multiple slides from a single Non-Gyn case together, do not select **Enable**. Skip to step 12.

8. For the Secondary ID, indicate where, in the slide ID printed on the slide label, the unique segment in the slide ID for a slide that is part of a multiple-slide Non-Gyn case starts.
   Touch **Character** or **Position**:

   - If the starting point is a certain character in the printed slide ID, such as a hyphen character, touch the **Character** button to select it.

   - If the starting point is a certain position in the printed slide ID, such as the fifth character, touch the **Position** button to select it.

   - If the first character of the unique segment is the first character of the printed slide ID, leave the "Position" field blank.

9. For the Secondary ID, use the keyboard on the touch screen to indicate which character or position starts the segment. For example, touch the hyphen to indicate that the segment begins after the hyphen character, or touch the 5 to indicate that the segment starts after the fifth character.

Note: The start of the segment is treated like a boundary, and this character is not included in the Secondary ID. The accession ID will start after the character entered.

10. For the Secondary ID, indicate where, in the printed slide ID, the unique segment in the slide ID for a slide that is part of a multiple-slide Non-Gyn case ends.
    Touch **Length** or **Character**:

    - If the ending point is always the same number of characters from the starting point of the segment, such as 8 characters, use the **Length** field.

    - If the ending point is always a certain character, such as the hyphen, use the **Character** setting.If the end of the unique segment is the end of the printed slide ID, leave the "Length" field blank.

11. For the Secondary ID, use the keyboard on the touch screen to indicate the length or ending character for the segment. For example, touch the 8 to indicate that the segment ends 8 characters after it starts, or touch the hyphen to indicate that the segment ends at the hyphen.

Note: The end point of a segment is treated like a boundary, and this character is not included in the Secondary ID. The accession ID will end before the character entered.

12. Press the **Apply** button to save and return to the Configure Slide ID summary screen. To return to the Configure Slide ID summary screen without applying the settings, touch the **Close** button.

Example:
Digital Imager configured with:
Primary ID: Position 1 to - (hyphen)
Secondary ID: Start after - (hyphen) to End

Example slide IDs for Non-Gyn
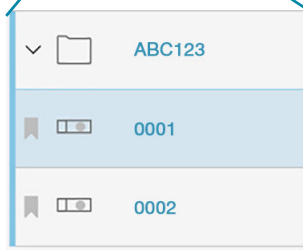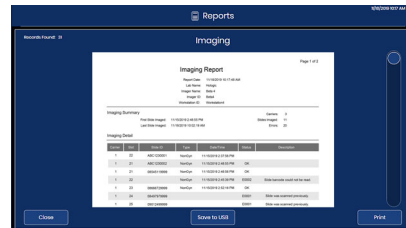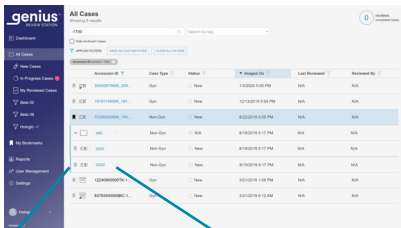multiple slides per vial:
ABC-0001
ABC-0002
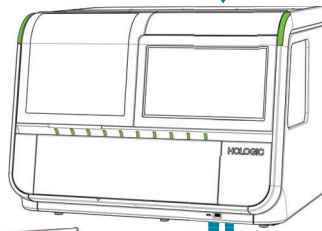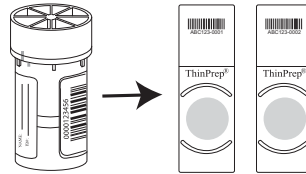
Image the slides on the Digital Imager.

At the Review Station, images for each slide with the same Primary ID are grouped together.

Example:
The Case List on the Review Station has a folder called "ABC". Images for slides with accession IDs "0001" and "0002" are within the folder.

Each slide is tracked on the Digital Imager.
Example:
The slide IDs are reported as "ABC-0001" "ABC-0002" on the Digital Imager.

Figure 3-34 Configure Slide ID Settings, Non-Gyn Sample with Multiple Slides per Vial (Example)

Configure Slide ID - UroCyte slides

If UroCyte slides arrive in your laboratory with characters in the slide ID that are not used in your facility, the Digital Imager can be configured to exclude those characters. The data transferred to the Image Management Server, available at the Review Station, and displayed on the Digital Imager will use the slide ID as it appears after the Configure Slide ID settings are applied to it.

Note: At the macro station on the Digital Imager, the Digital Imager takes an image of the slide label. A record of the entire slide ID on the slide label is available in the image taken at the macro station.

1. From the Administrative Options screen, touch **Configure Slide ID**. The current selection is described under the name of the sample type.
2. Under **UroCyte** options, choose "Same as Gyn," "Entire scanned value" or "Select a segment."

    • **Same as Gyn:** the configuration for UroCyte slide IDs will be the same as your laboratory's settings for Gyn slide IDs. Skip to step 7.

    • **Entire scanned value:** the ID used by the Digital Imaging System will be the same as the ID printed on the slide label. Skip to step 7.

    • **Select a segment:** the ID used by the Digital Imaging System will be derived from the ID printed on the slide label. Continue through the steps to specify what segment of the printed ID will be used by the Digital Imaging System.
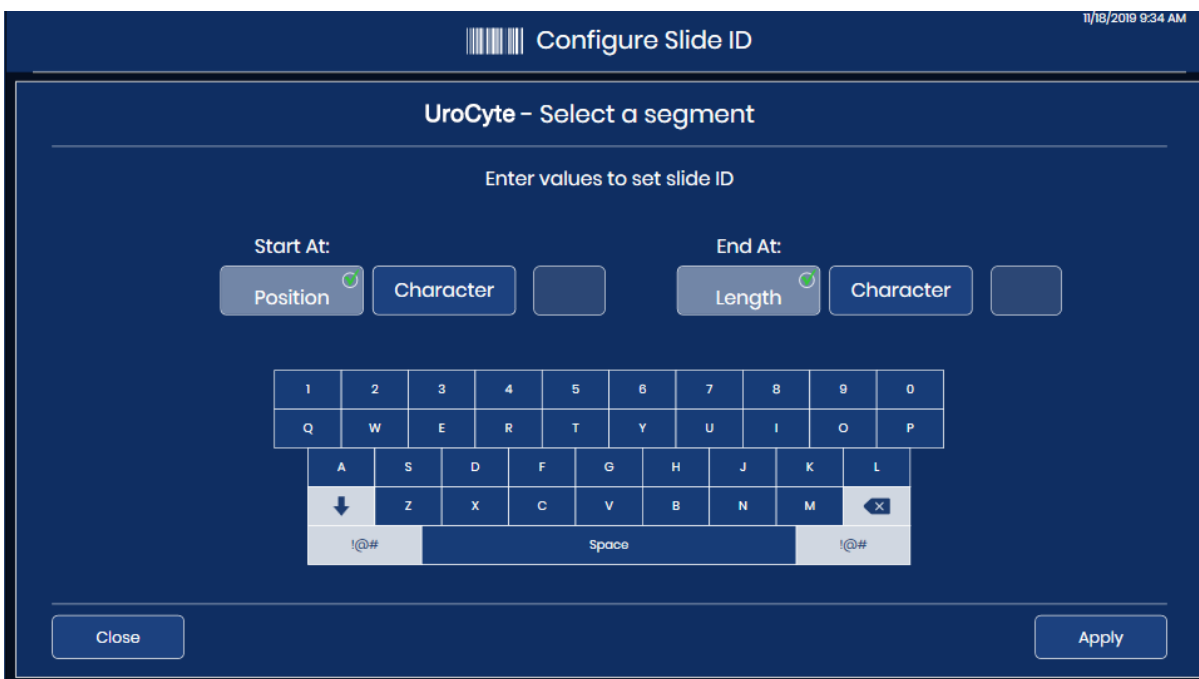

Figure 3-35   Configure Slide ID: Select a Segment, UroCyte Slides

3. Indicate where, in the slide ID printed on the slide label, the segment that is used by the Genius Digital Diagnostics System for the slide ID starts.
Touch **Character** or **Position**:

- If the starting point is a certain character in the printed slide ID, such as a hyphen character, touch the **Character** button to enter that character.

- If the starting point is a certain position in the printed slide ID, such as the fifth character, touch the **Position** button to enter the position.

- If the first character of the segment to use in the slide ID for the Genius Digital Diagnostics System is the first character of the printed slide ID, leave the "Position" field blank.

4. Use the keyboard on the touch screen to indicate which character or position starts the segment. Use the backspace button to backspace if needed. For example, touch the hyphen to indicate that the segment begins after the hyphen character, or touch the 5 to indicate that the segment starts after the fifth character.

Note: The start of the segment is treated like a boundary, and this character is not included in the Genius Digital Diagnostics System slide ID. The accession ID will start after the character entered.

5. Indicate where, in the printed slide ID, the segment that is used on the Genius Digital Diagnostics System slide ID ends.
Touch **Length** or **Character**:

- If the ending point is always the same number of characters from the starting point of the segment, such as 8 characters, use the **Length** field.

- If the ending point is always a certain character, such as the hyphen, use the **Character** setting.

- If the end of the segment to use in the slide ID for the Genius Digital Diagnostics System is the end of the printed slide ID, leave the "Length" field blank.

6. Use the keyboard on the touch screen to indicate the length or ending character for the segment. For example, touch the 8 to indicate that the segment ends 8 characters after it starts, or touch the hyphen to indicate that the segment ends at the hyphen.

Note: The end point of a segment is treated like a boundary, and this character is not included in the Genius Digital Diagnostics System slide ID. The accession ID will end before the character entered.

7. Press the **Apply** button to save and return to the Configure Slide ID summary screen. To return to the Configure Slide ID summary screen without applying the settings, touch the **Close** button.

About button

Figure 3-36   About Button

Touch the **About** button to view the Digital Imager software version.

The touch screen displays the total number of slides imaged by the Digital Imager. The touch screen displays the Success Count, which is the total number of slides imaged without error.

The screen also shows the Imager name, the serial number for the Digital Imager (Imager ID) and the serial number for the Digital Imager computer (Workstation ID).
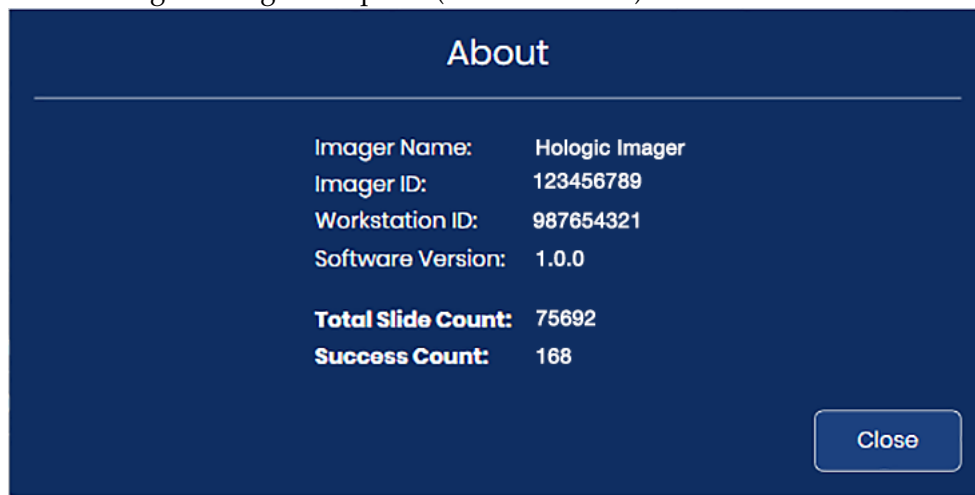
Figure 3-37   About the Digital Imager

Power button

The power button on the touch screen is on the Administrative Options screen. For complete instructions refer to "Shutting down the Digital Imager" on page 4.35.
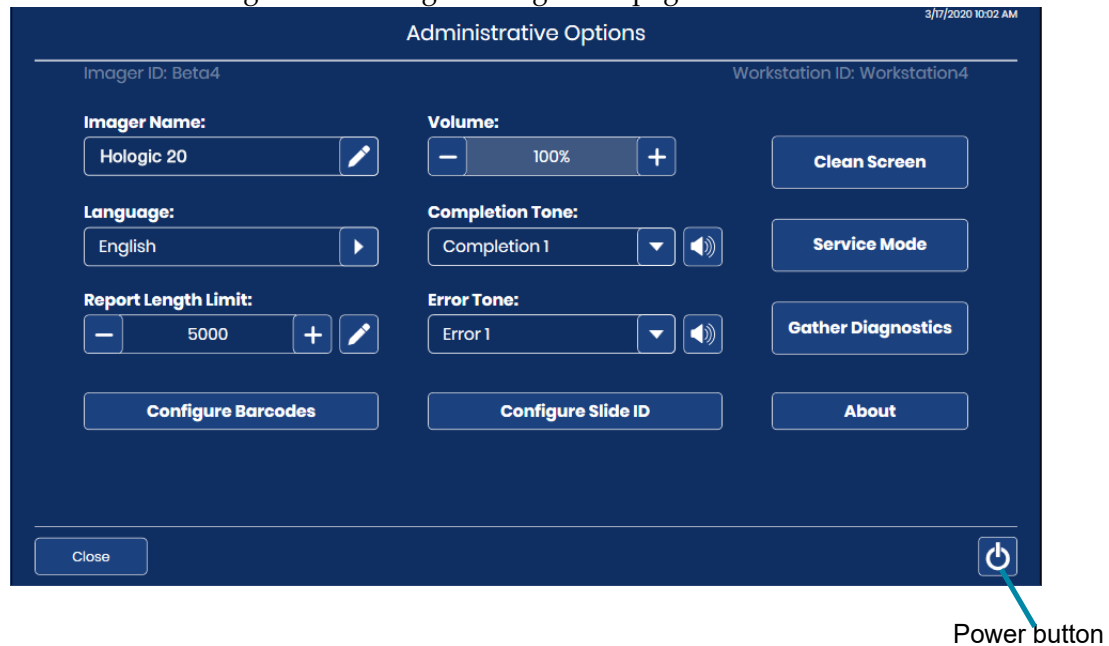

Figure 3-38   Power Button

SECTION
E
REPORTS

The Reports screen allows the operator to generate reports of activity on the Genius Digital Diagnostics System. Each kind of report requires the user to enter some criteria, such as a date range or slide ID. Each report is displayed on the touch screen and can be saved onto a USB. Reports can be run while the Digital Imager is idle. During processing, data for any slide carrier in the batch can be viewed on screen, but the Digital Imager cannot generate reports. Refer to "Slide carrier details" on page 3.11.

Touch the **Reports** button from the main screen to display the Reports screen.
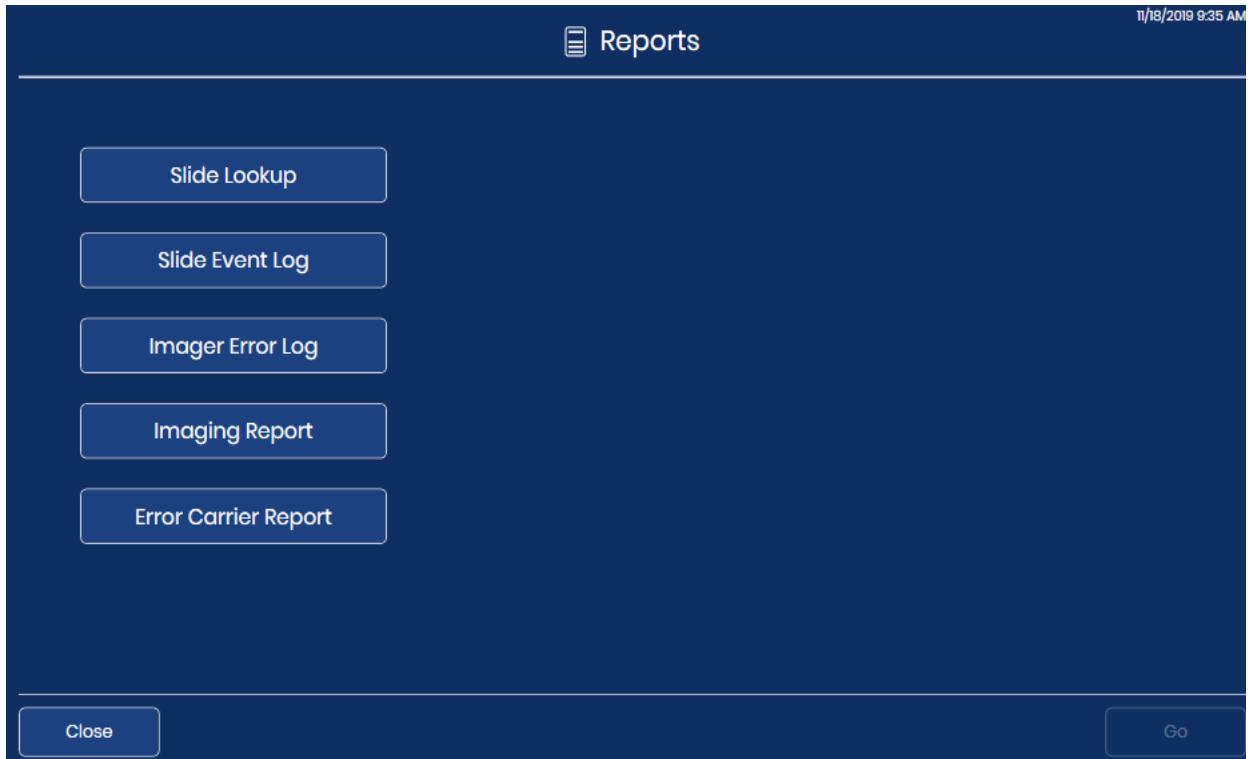
Figure 3-39   Reports Screen

Touch the name of a report to run the report.

Slide Lookup

Use the Slide Lookup report to determine if a particular slide was already processed. The Slide Lookup Report queries data from all the Digital Imagers connected to the same Image Management Server.
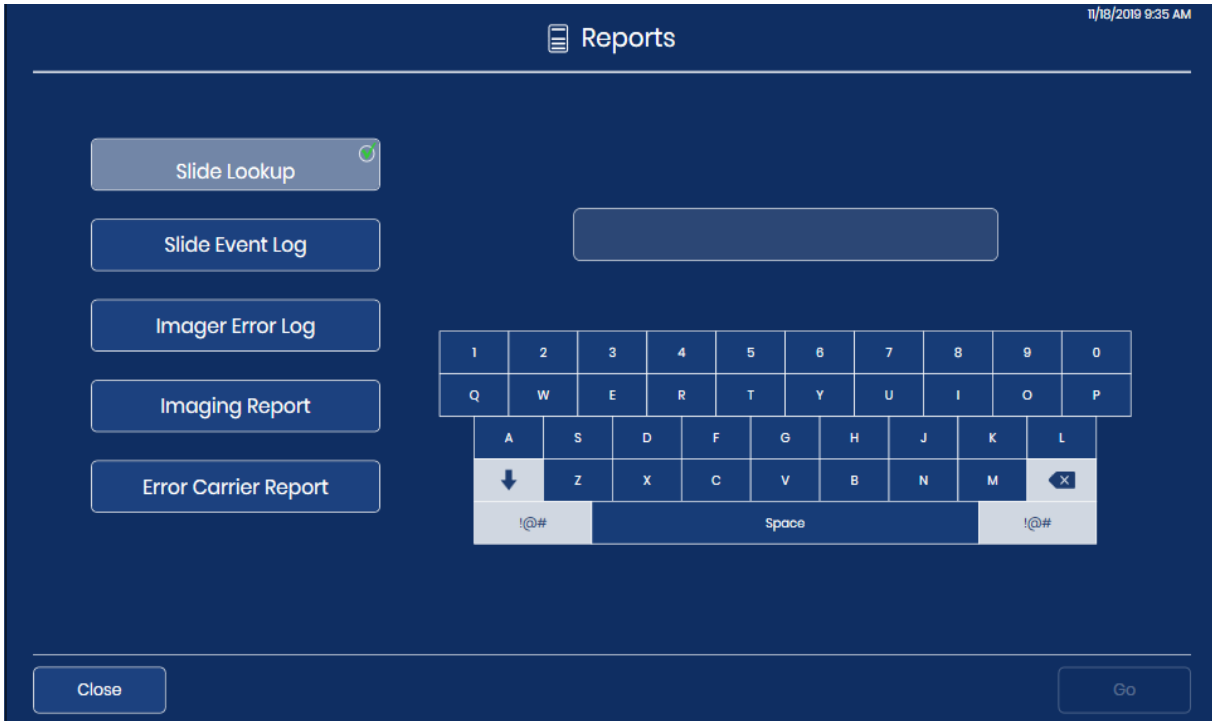

Figure 3-40   Slide Lookup: Type the Slide ID with the Keyboard

1. Touch the **Slide Lookup** button to select it. A keyboard appears on the touch screen.
2. Type the slide ID for a slide to search for it. To search for a group of slides that contain the same characters, type in the characters.

    -   Use the **Space** button for a space and the **Backspace** button to remove entered letters.
    -   Press the **!@#** button to display a screen to enter special characters. Press the **ABC** button to return to the alphabet keys. While in the alphabet keys, the up arrow switches to all capital letters (ALL CAPS) and the down arrow returns to lowercase letters.

3. Touch the **Go** button to search.

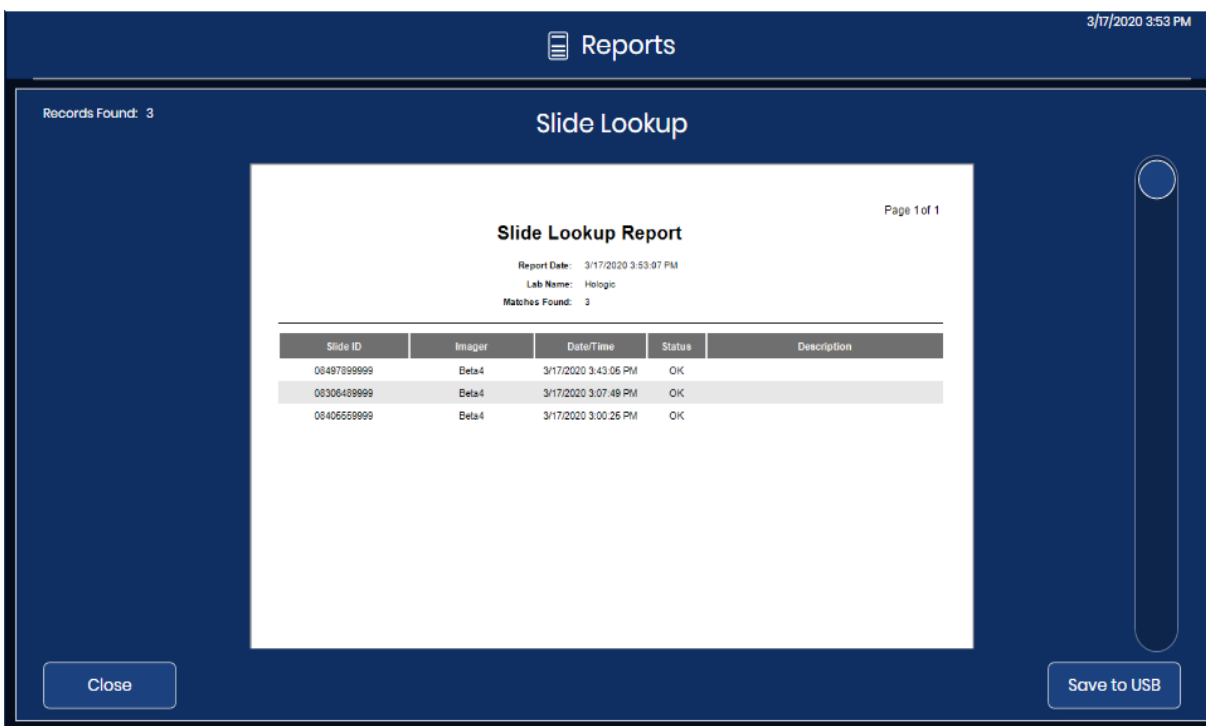4.   The search results are displayed on the touch screen.

Figure 3-41   Slide Lookup Report

The heading of the report lists the date that the report was run, the lab name, and the number of slides that match the search criteria. The number of slides that match the search criteria is also displayed in the upper left of the touch screen. The report remains on the screen until the **Close** button is pressed.

The results are displayed in alphabetical or numeric order by slide ID. Each slide entry shows the slide ID, the name of the Digital Imager that processed the slide, the time and date the slide was processed, the status, and, if there was an error, a description of the error.

For reports with multiple pages, touch the circle on the right side of the touch screen to scroll through the results.

To save the report to a USB drive, touch the **Save to USB** button.

To leave the report and return to the main screen, touch the **Close** button.

If a slide with the slide ID has not been processed on any Digital Imager in your laboratory, the search yields 0 results and presents an empty report.

Slide Event Log

The Slide Event Log displays all slide event occurrences from this Digital Imager. These are the same slide events that are displayed while slide processing is in progress, in a report format.

1.   Touch the **Slide Event Log** button to select it. Buttons to set the date range appear.

2. Select the time period.

   • To generate a log of all the slide events ever generated by the Digital Imager, select **All dates**. If the report yields more results than allowed by the report length limit, a message will display at the top of the report. Refer to "Report Length Limit" on page 3.17.

   • To generate a log of all the slide events for a particular time period, use the buttons to set a start date and an end date for the data in the report.

   A. Touch the **Set start date** button. A calendar for the current month appears. Use the arrows to the left and right of the name of the month to change the month for the starting date. Touch a date on the calendar to select the day which will be the start date for the report.

   B. Touch the **Set end date** button. A calendar for the current month appears. Use the arrows to the left and right of the name of the month to change the month for the ending date. Touch a date on the calendar to select the day which will be the end date for the report. If a start date is set without an end date, the report will run from the start date to the current day (today).
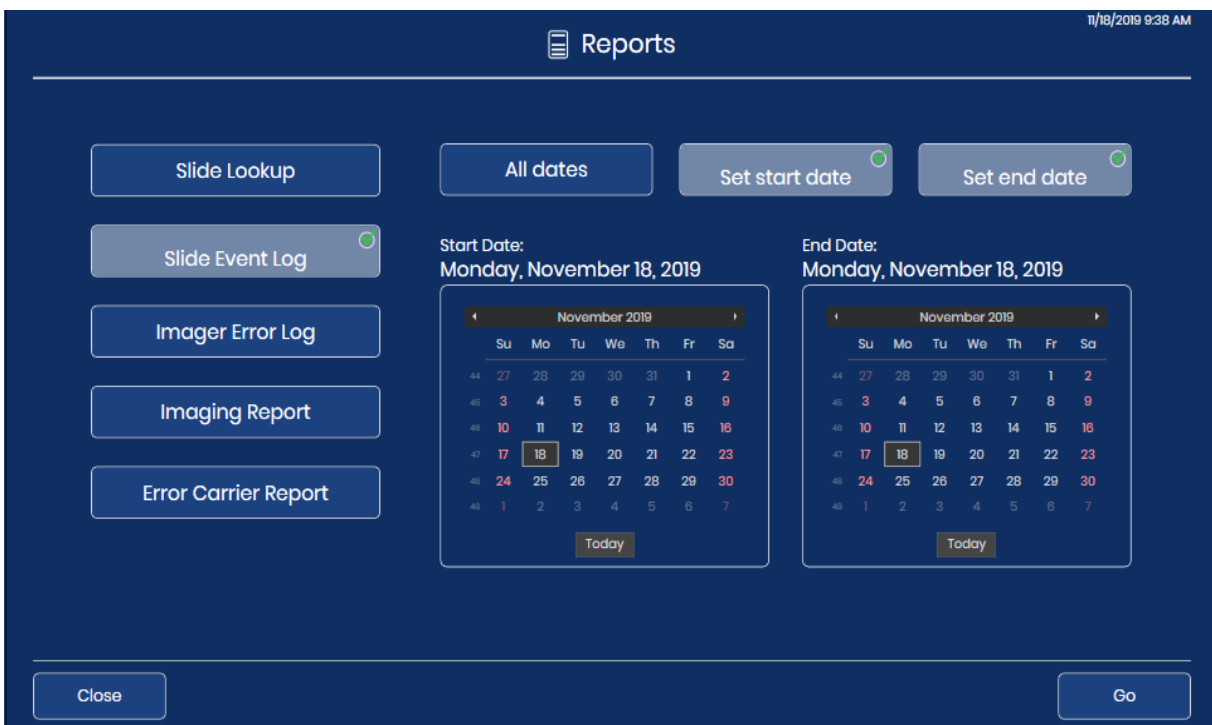
3. Touch the **Go** button to search.

Figure 3-42   Slide Event Log: Set the Date Range, Touch Go

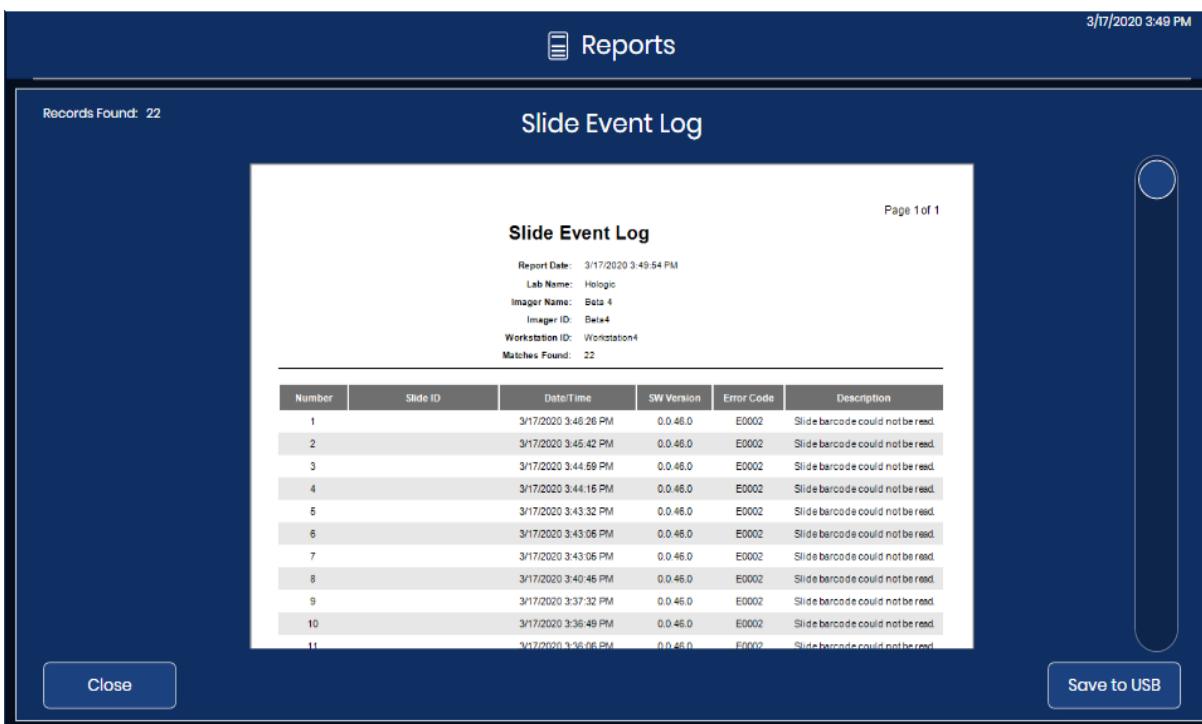4. The results are displayed on the touch screen.

Figure 3-43   Slide Event Log

The heading of the report lists the date that the report was run, the lab name, the Digital Imager name, the Imager ID (Digital Imager serial number), the Workstation ID (Digital Computer serial number), and the number of slide events that match the search criteria. The number of slide events that match the search criteria is also displayed in the upper left of the touch screen.

The errors are displayed with the most recent event as number 1 and older events following. Each event entry shows the slide ID, a time and date stamp, the version of software running on the Digital Imager at the time, and a brief error code/description.

The report will display as many lines of data as selected in the report limit setting (500 to 5000), refer to "Report Length Limit" on page 3.17.

For reports with multiple pages, touch the circle on the right side of the touch screen to scroll through the results.

To save the report to a USB drive, touch the **Save to USB** button.

To leave the report and return to the main screen, touch the **Close** button.

If no slide events occurred on the Digital Imager for the date range, the report generates 0 results and presents an empty report.

Imager Error Log

This report displays errors encountered by the Digital Imager.

1. Touch the **Imager Error Log** button to select it. Buttons to set the date range appear.
2. Select the time period.

    •   To generate a log of all the Imager errors ever generated by the Digital Imager, select **All dates**. If the report yields more results than allowed by the report length limit, a message will display at the top of the report. Refer to "Report Length Limit" on page 3.17.

    •   To generate a log of all the Imager errors for a particular time period, use the buttons to set a start date and an end date for the data in the report.

    A. Touch the **Set start date** button. A calendar for the current month appears. Use the arrows to the left and right of the name of the month to change the month for the starting date. Touch a date on the calendar to select the day which will be the start date for the report.

    B. Touch the **Set end date** button. A calendar for the current month appears. Use the arrows to the left and right of the name of the month to change the month for the ending date. Touch a date on the calendar to select the day which will be the end date for the report.

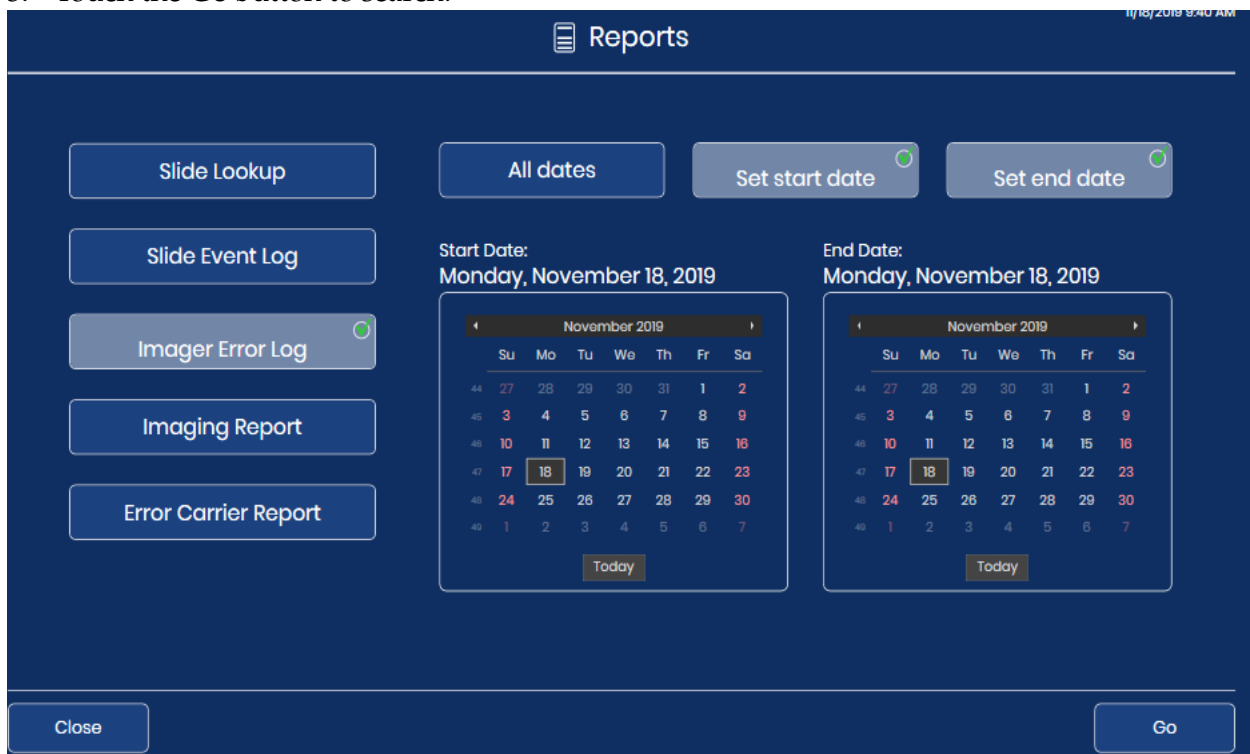3. Touch the **Go** button to search.

Figure 3-44   Imager Error Log: Set the Date Range, Touch Go

4. The results are displayed on the touch screen.

Figure 3-45   Imager Error Log

The heading of the report lists the date that the report was run, the lab name, the Digital Imager name, the Imager ID (Digital Imager serial number), the Workstation ID (Digital Computer serial number), and the number of slide events that match the search criteria. The number of errors that match the search criteria is also displayed in the upper left of the touch screen.

The errors are displayed with the most recent event as number 1 and older events following. Each entry shows the error code, the time and date that the error occurred, the version of software running on the Digital Imager at the time, and a brief description of the error.

The report will display as many lines of data as selected in the report limit setting (500 to 5000), refer to "Report Length Limit" on page 3.17.

For reports with multiple pages, touch the circle on the right side of the touch screen to scroll through the results.

To save the report to a USB drive, touch the **Save to USB** button.

To leave the report and return to the main screen, touch the **Close** button.

If no Imager errors occurred on the Digital Imager for the date range, the report generates 0 results and presents an empty report.

Imaging Report

The Imaging Report lists the results from processed slide carriers. The Imaging Report describes each slide in each slide carrier. The Imaging Report considers the position that the slide carrier was in and the date that the slide carrier was processed. The report can be run for slide carriers run in the past 24 hours, 48 hours, or from a custom date range.

If your lab does not use position 10 as an error carrier, the Imaging Report offers a convenient method for identifying which slide carrier holds a slide that had a slide event.

If your lab does use position 10 as an error carrier, the Error Carrier Report can be used for identifying a slide that had a slide event.

The Imaging Report is also useful for seeing the total number of slides run during a time period, for the slide carriers and time period selected for the report.

Slides run in the past 24 hours

1. Touch the **Imaging Report** button to select it. The default setting, which is for slide carriers run in the past 24 hours, appears. Use 24 hours or select another option.

Figure 3-46   Imaging Report: Slide Carriers from the Past 24 Hours

2. A list of slide carriers appears on the screen. Touch the check box to select the slide carrier(s) to include in the report.

Note: When more than one slide carrier has been run in the same position during the time period selected for the report, the start and end time will be different for the first run and any

subsequent run. For example, two carriers could have been run in Position 5 in the past 24 hours. Use the date and time stamp to distinguish them.

3. Touch **Next** to generate the report.
4. The results are displayed on the touch screen. Refer to "Imaging Report" on page 3.50.

Advanced settings for an Imaging Report

1. Touch the **Imaging Report** button to select it.
2. Touch the down-arrow next to the "24 hrs" selection in the upper left.
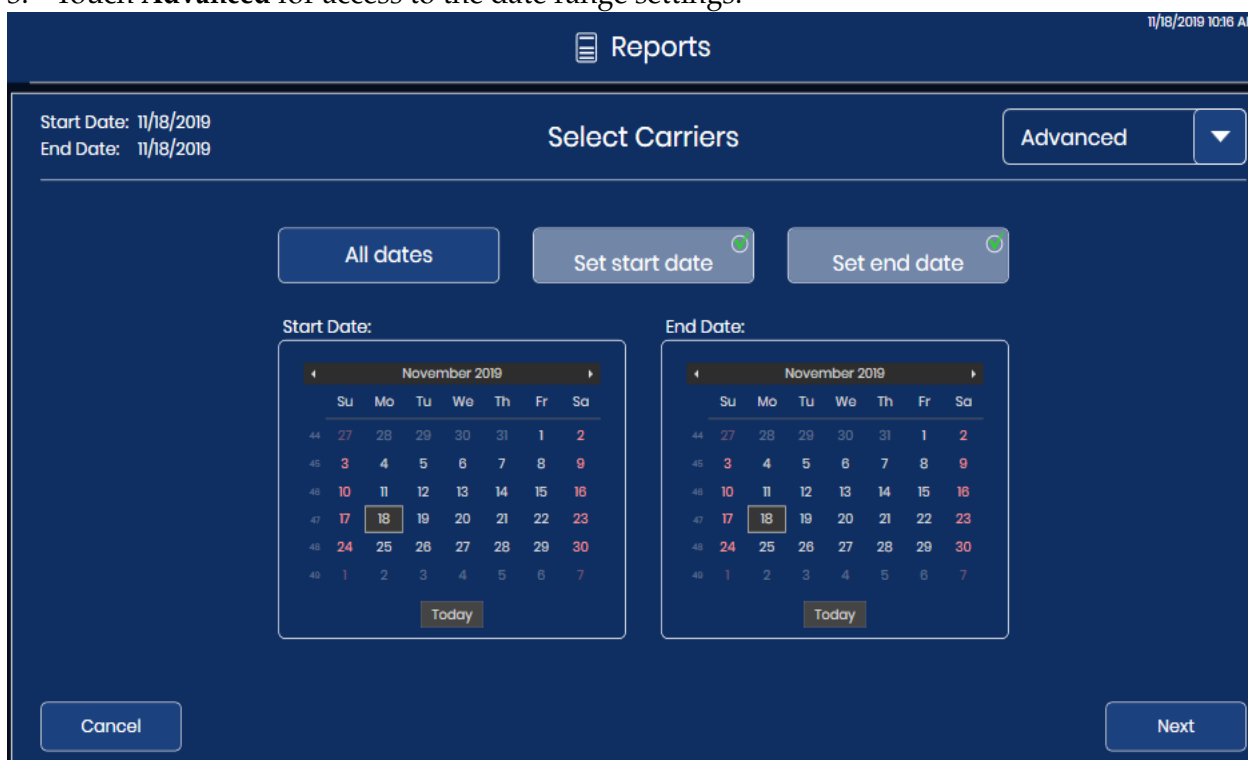3. Touch **Advanced** for access to the date range settings.

Figure 3-47   Imaging Report: Advanced Option, Set the Date Range

4. Select the time period.

- To generate a report for every slide carrier ever processed on the Digital Imager, select **All dates**. If the report yields more results than allowed by the report length limit, a message will display at the top of the report. Refer to "Report Length Limit" on page 3.17.

- To generate a log of all the slide carriers processed during a particular time period, use the buttons to set a start date and an end date for the data in the report.

A. Touch the **Set start date** button. A calendar for the current month appears. Use the arrows to the left and right of the name of the month to change the month for the starting date. Touch a date on the calendar to select the day which will be the start date for the report.

B. Touch the **Set end date** button. A calendar for the current month appears. Use the arrows to the left and right of the name of the month to change the month for the ending date. Touch a date on the calendar to select the day which will be the end date for the report. If a start date is set without and end date, the report will run from the start date to the current day (today).

5. Touch **Next** to generate a list of slide carriers run during that time period. The list appears in chronological order with the most recent carrier at the top of the list.

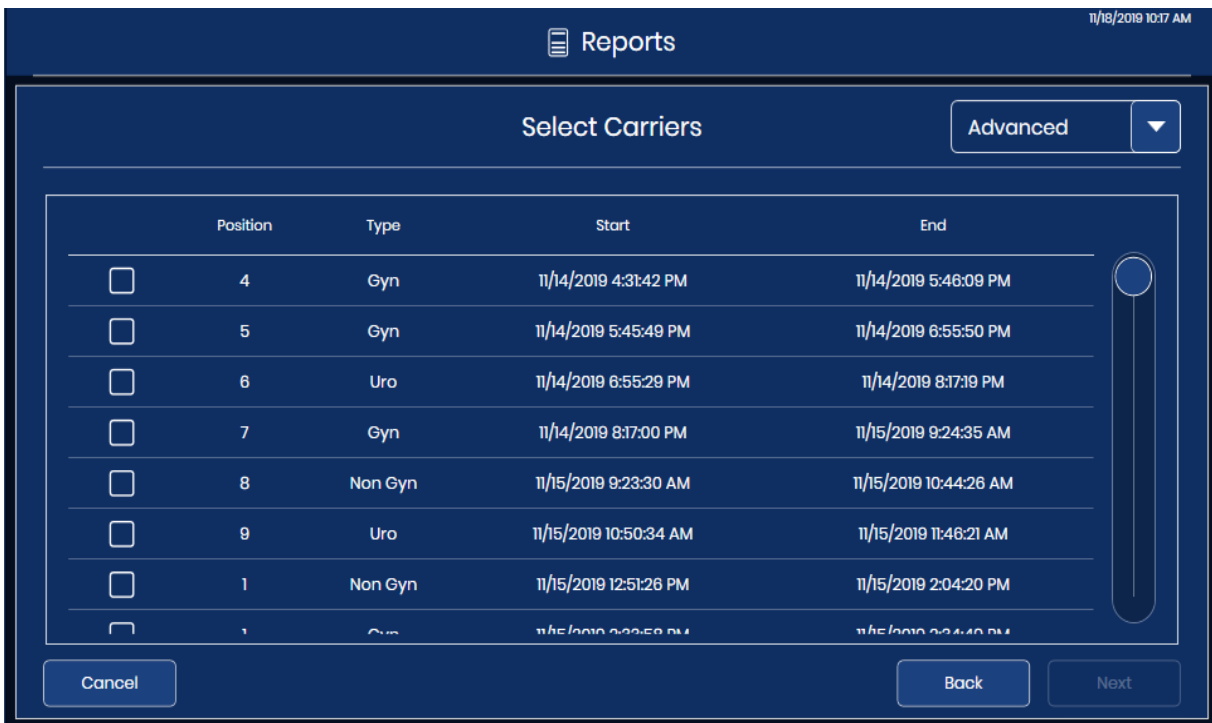6. Touch the check box to select the slide carrier(s) to include in the report.

Figure 3-48   Imaging Report: Select from the List of Slide Carriers

7. Touch **Next** to generate the report.
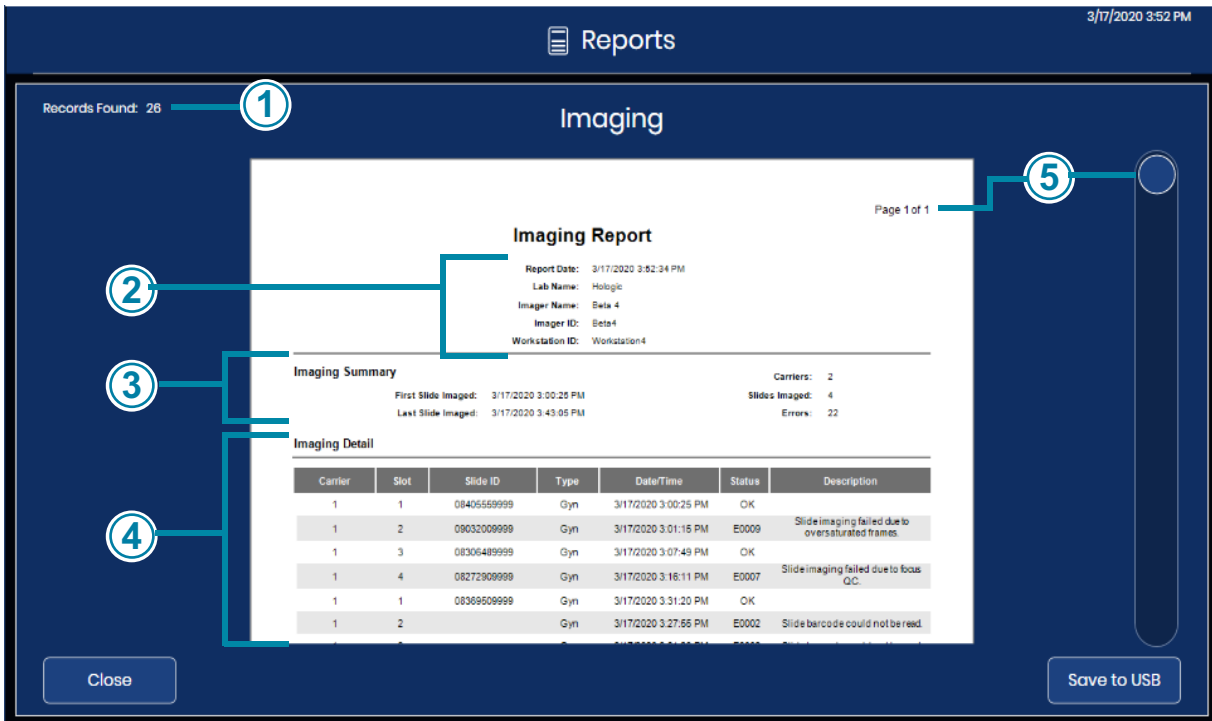
8. The results are displayed on the touch screen.

Figure 3-49   Imaging Report

Key to Figure 3-49	
①	The number of records found is the total number of slides run, with and without errors, for the slide carriers and time period selected for the report.
②	The heading of the report lists the date that the report was run, the lab name, the Digital Imager name, the Imager ID (Digital Imager serial number), and the Workstation ID (Digital Computer serial number).

Key to Figure 3-49	
③	An Imaging Summary section lists: First slide imaged: the date and time for the first slide imaged in the carriers selected for the report Last slide imaged: the date and time for the last slide imaged in the carriers selected Carriers: the quantity of slide carriers selected for the report Slides imaged: the quantity of slides imaged successfully in the group of slides in the slide carriers selected for the report Errors: the quantity of slides with slide events, in the group of slides in the slide carriers selected for the report. The number of slides that are described in the report is also displayed in the upper left of the touch screen. The number of records found is the sum of the slides imaged and the slides with errors.
④	The entries in the Imaging Detail section of the report are organized by slide carrier and then by slot number in the staining rack. The entries start with the slide carrier in the position with the lowest number (e.g., slide carrier in position 1) and continue to the slide carrier in the position with the highest number (e.g., slide carrier in position 10). Within each slide carrier, the entries start with the slot in the staining rack with the lowest number (e.g., slot 1) and continue to the slot with the highest number (e.g., slot 40). For each slide in each carrier, the report includes the slide ID, the sample type, a date and time stamp, and the status. For slides that were successfully imaged, the status is "OK". For slides where an error occurred, the status is the error code and the "Description" field describes the slide event. The report will display as many lines of data as selected in the report limit setting (500 to 5000), refer to "Report Length Limit" on page 3.17.
⑤	For reports with multiple pages, touch the circle on the right side of the touch screen to scroll through the results

To save the report to a USB drive, touch the **Save to USB** button.

To leave the report and return to the main screen, touch the **Close** button.

If no slides were processed on the Digital Imager in the time period for the report, the report generates 0 results and presents an empty report.
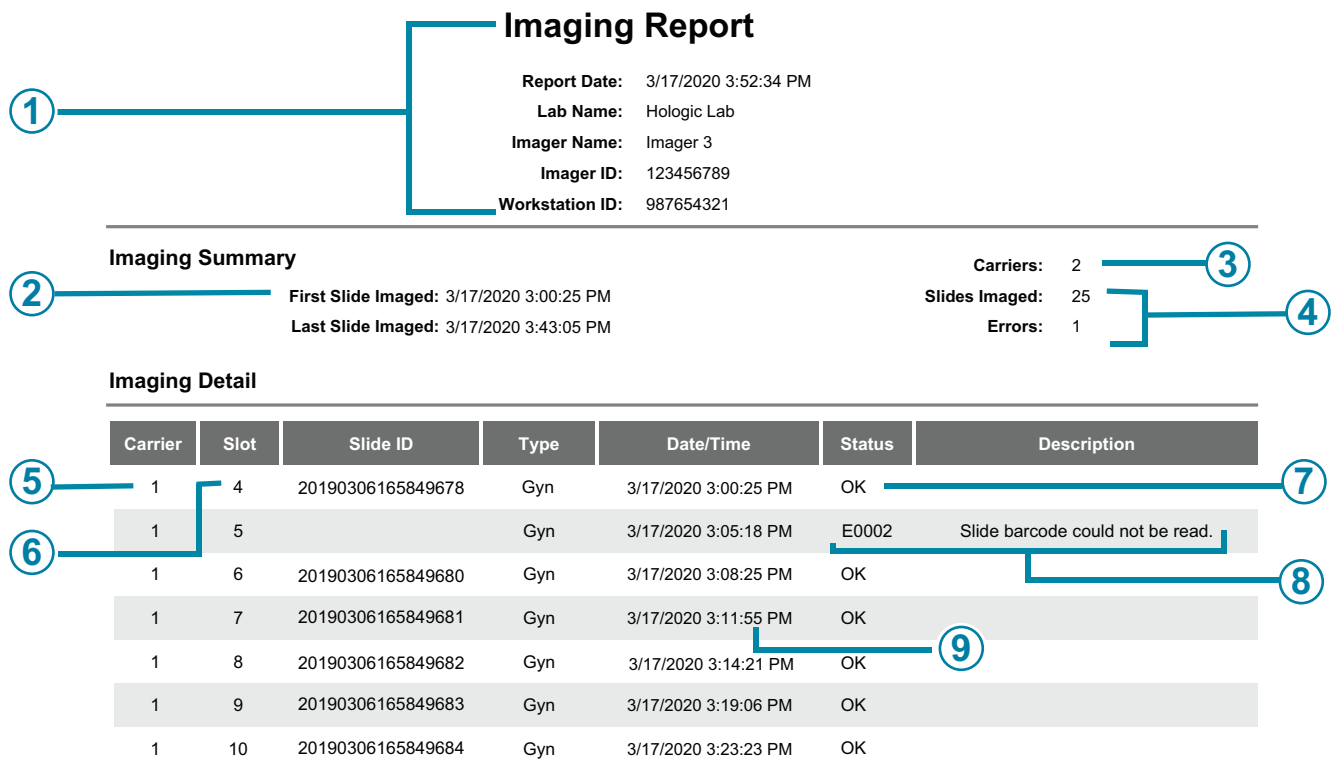
Imaging Report

Report Date:	3/17/2020 3:52:34 PM
Lab Name:	Hologic Lab
Imager Name:	Imager 3
Imager ID:	123456789
Workstation ID:	987654321

① ──

Imaging Summary

First Slide Imaged: 3/17/2020 3:00:25 PM   **② ──**

Last Slide Imaged: 3/17/2020 3:43:05 PM

Carriers: 2   **── ③**

Slides Imaged: 25   **── ④**

Errors: 1

Imaging Detail

Carrier	Slot	Slide ID	Type	Date/Time	Status	Description
1	4	20190306165849678	Gyn	3/17/2020 3:00:25 PM	OK	
1	5		Gyn	3/17/2020 3:05:18 PM	E0002	Slide barcode could not be read.
1	6	20190306165849680	Gyn	3/17/2020 3:08:25 PM	OK	
1	7	20190306165849681	Gyn	3/17/2020 3:11:55 PM	OK	
1	8	20190306165849682	Gyn	3/17/2020 3:14:21 PM	OK	
1	9	20190306165849683	Gyn	3/17/2020 3:19:06 PM	OK	
1	10	20190306165849684	Gyn	3/17/2020 3:23:23 PM	OK	

Figure 3-50   Imaging Report (Example)

	Key to Figure 3-50
①	The information in the heading is generated by the report. The Digital Imager is identified by its serial number and Imager name (if a name is used).
②	The report uses the date range that the operator specified; the last 24 hours, 48 hours, or an advanced date range.
③	The report shows the quantity of slide carriers that the operator specified for the report. Two slide carriers are included in this example.
④	For all of the slides in all of the slide carriers selected for the report's date range, the quantity of slides imaged successfully and the quantity of slides with slide events appears in the Imaging Summary section. In this example, the two slide carriers carried a total of 26 slides.

Key to Figure 3-50	
⑤	Carrier: in this example, the slide carrier in position 1 was selected by the operator for inclusion in the report.
⑥	Slot: in this example, the first slide (lowest slot number) in the slide carrier in position 1 was in slot 4.
⑦	Example of a successfully imaged slide
⑧	Example of a slide with a slide event
⑨	The date/time the slide was imaged

Error Carrier Report

If the slide carrier in position 10 has been used as an error carrier, an Error Carrier Report describes the slides deposited into the error carrier. If your lab uses position 10 as an error carrier, the Error Carrier Report offers a convenient method for identifying why a slide had a slide event, which helps determine how the slide can be imaged again.

Consider running the Error Carrier Report at the end of processing each time position 10 is used as an error carrier.

1. Touch the **Error Carrier Report** button to select it. Buttons to set the date range appear.
2. Select the time period. If a start date is set without and end date, the report will run from the start date to the current day (today).
3. Touch **Next** to generate a list of error carriers for that time period.

4. Touch the check box to select the slide carrier(s) to include in the report
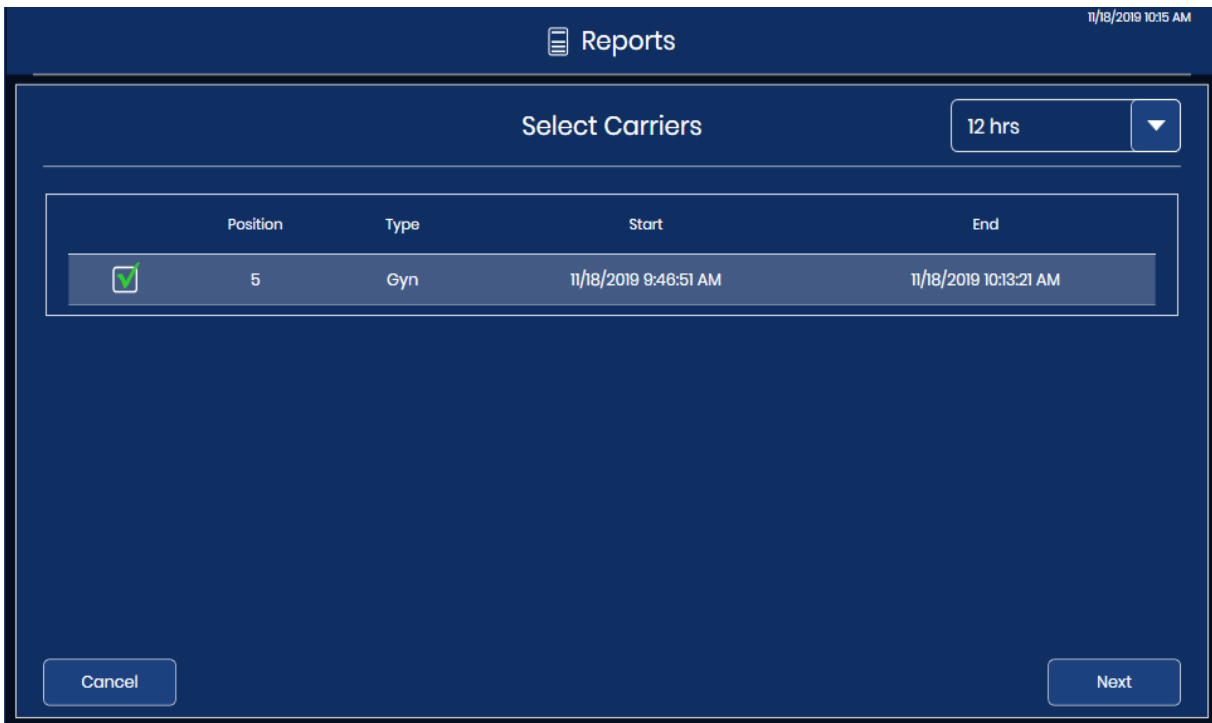

Figure 3-51   Error Carrier Report: Select Error Carrier from the List

5. Touch **Next** to generate the report.

6. The results are displayed on the touch screen.

Figure 3-52   Error Carrier Report

The heading of the report lists the date that the report was run, the lab name, the Digital Imager name, the Imager ID (Digital Imager serial number), and the Workstation ID (Digital Computer serial number). The number of slides in the report is also displayed in the upper left of the touch screen.

The entries in the Error Carrier Report are organized by slot number in the staining rack. The entries start with the slot in the staining rack with the lowest number (e.g., slot 1) and continue to the slot with the highest number (e.g., slot 40).

For each slide in each carrier, the report includes the slot number, slide ID (if read), the sample type, a date and time stamp, the error code and a description of the error.

The report will display as many lines of data as selected in the report limit setting (500 to 5000), refer to "Report Length Limit" on page 3.17.

For reports with multiple pages, touch the circle on the right side of the touch screen to scroll through the results.

To save the report to a USB drive, touch the **Save to USB** button.

To leave the report and return to the main screen, touch the **Close** button.

If no error carrier was designated or if no slides had slide events in the time period for the report, the report generates 0 results and presents an empty report.

3   USER INTERFACE

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C h a p t e r   F o u r

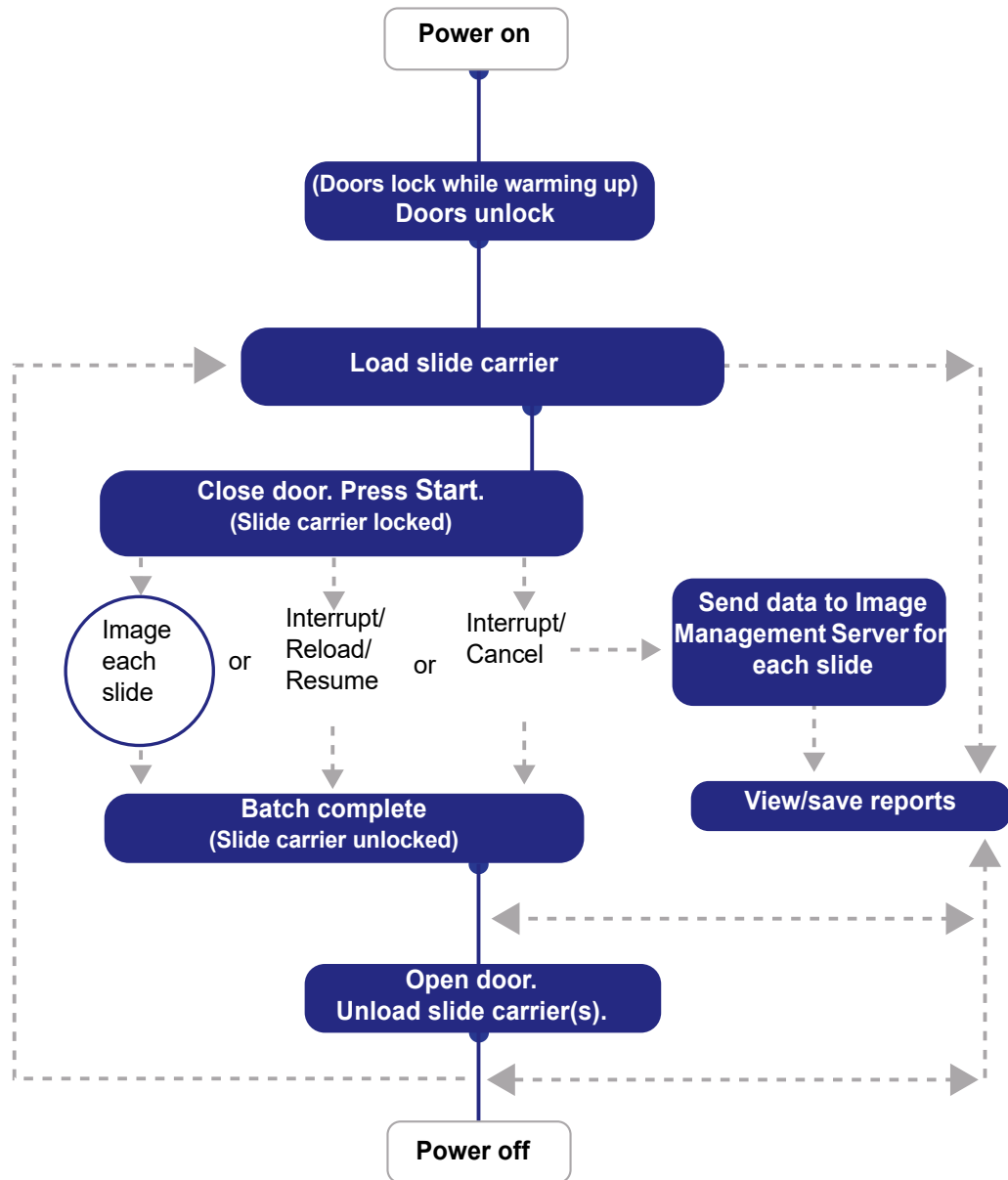# Operation of the Digital Imager

CHAPTER OVERVIEW

Proper operation of the Genius Digital Diagnostics System requires the Digital Imager, the Image Management Server and the Review Station to be connected, and it requires a connection between the Image Management Server and a laboratory archiving system. The instructions in this operator's manual describe the operation of the Digital Imager portion of the overall system. Refer to the Review Station operator's manual and the Image Management Server's operator's manual for more information about those components.

Normal operation of the Genius Digital Imager consists of powering on the Digital Imager computer and the Digital Imager, loading prepared slides in slide carriers and starting the slide processing function. At the conclusion of slide processing, slide carriers are removed from the Digital Imager. During slide processing, the status of each slide and an indication of which slide(s) may require further operator attention is available on the user interface. This information is also reported as a Slide Event Log. The report may be viewed on the user interface, and the report may be saved as a text file to a USB key.

At any time during slide processing, the operator may interrupt and resume processing or interrupt and cancel processing.

If necessary, the equipment may be shut down, following a prescribed sequence. Refer to "Shutting down the Digital Imager" on page 4.35.

See Figure 4-1 for a diagram of a typical slide imaging process.

```
                    ┌──────────────┐
                    │   Power on   │
                    └──────────────┘
                           │
            ┌──────────────────────────────────┐
            │  (Doors lock while warming up)    │
            │         Doors unlock              │
            └──────────────────────────────────┘
                           │
            ┌──────────────────────────────────┐
  ─────────▶│        Load slide carrier         │─────────▶
            └──────────────────────────────────┘
                           │
        ┌──────────────────────────────────────┐
        │   Close door. Press Start.            │
        │      (Slide carrier locked)           │
        └──────────────────────────────────────┘
           │            │              │
     ╭──────────╮  Interrupt/    Interrupt/    ┌──────────────────────┐
     │  Image   │  Reload/       Cancel   ────▶│ Send data to Image   │
     │  each    │  Resume                      │ Management Server for │
     │  slide   │   or           or           │    each slide         │
     ╰──────────╯                              └──────────────────────┘
           │            │              │                  │
        ┌──────────────────────────────┐       ┌──────────────────────┐
        │      Batch complete          │       │   View/save reports  │
        │   (Slide carrier unlocked)   │       └──────────────────────┘
        └──────────────────────────────┘
                      │
        ┌──────────────────────────────┐
        │        Open door.            │
        │   Unload slide carrier(s).   │
        └──────────────────────────────┘
                      │
               ┌──────────────┐
               │   Power off  │
               └──────────────┘
```

Figure 4-1   Typical Slide Imaging Process

APPLYING POWER TO THE EQUIPMENT

WARNING: Grounded Outlet. Instrument Fusing. Do not power on or operate if equipment has been damaged.

Apply power to the server, the Digital Imager and the Digital Imager computer according to the following procedure.

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

Application of power to the equipment must be performed in the sequence described in order to establish proper communication between the Digital Imager, the Digital Imager computer and the Image Management Server.

Make sure the door and window of the Digital Imager are fully shut.

Note: The Digital Imager computer needs a connection to the Image Management Server before the Digital Imager and Digital Imager computer can work properly.

Note: The Digital Imager should be turned on before turning on the Digital Imager computer. Turning on power to the Digital Imager initiates a 7-minute warm-up cycle.

1. If the window or the door is open, the touch screen displays a message to close the window and door. Close the window and door to continue.
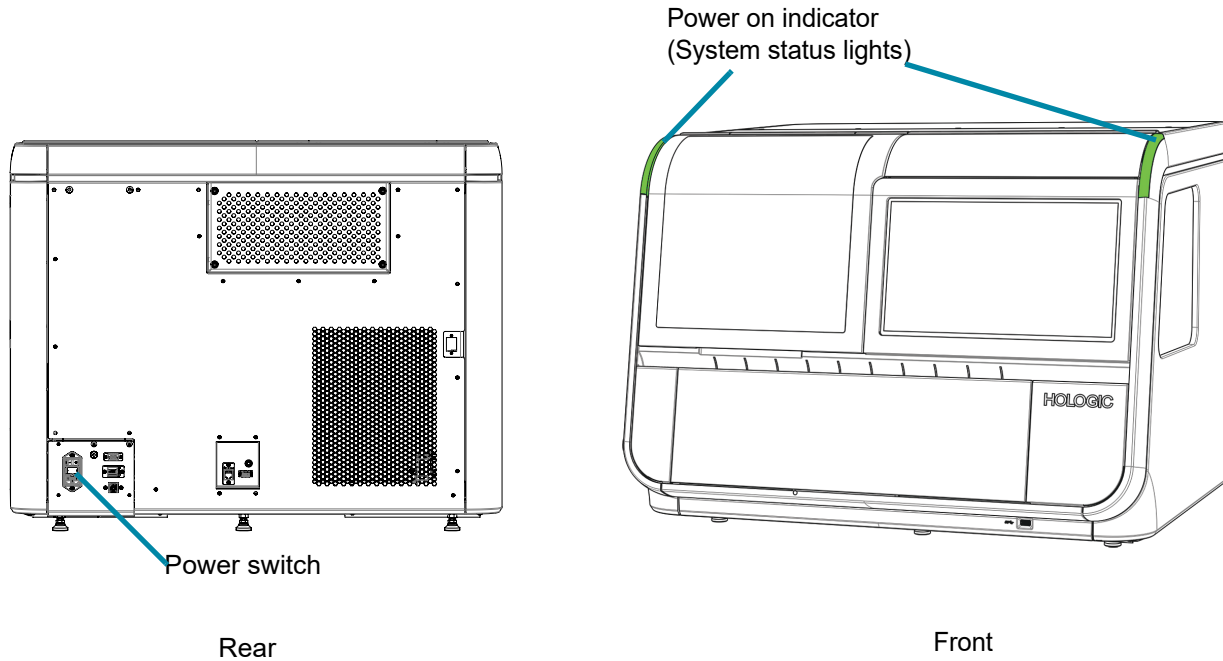
Figure 4-2   Digital Imager Power Switch

2.   Press the rocker switch on the rear of the Digital Imager to ON (**l**). (See Figure 4-2.)
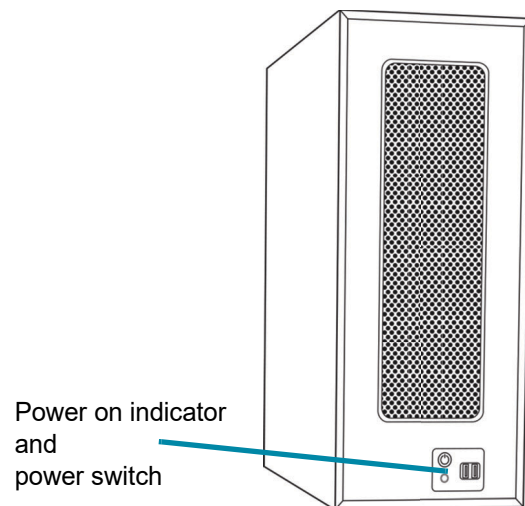
Figure 4-3   Power On the Digital Imager Computer

3.   At the Digital Imager computer, turn on the power. (See Figure 4-3.)

4. The touch screen displays the status as the system checks various subsystems while the system boots. The touch screen displays the progress of the Power On Self-Test with a bar and the percentage. The slide handling mechanisms move through the slide handling path.
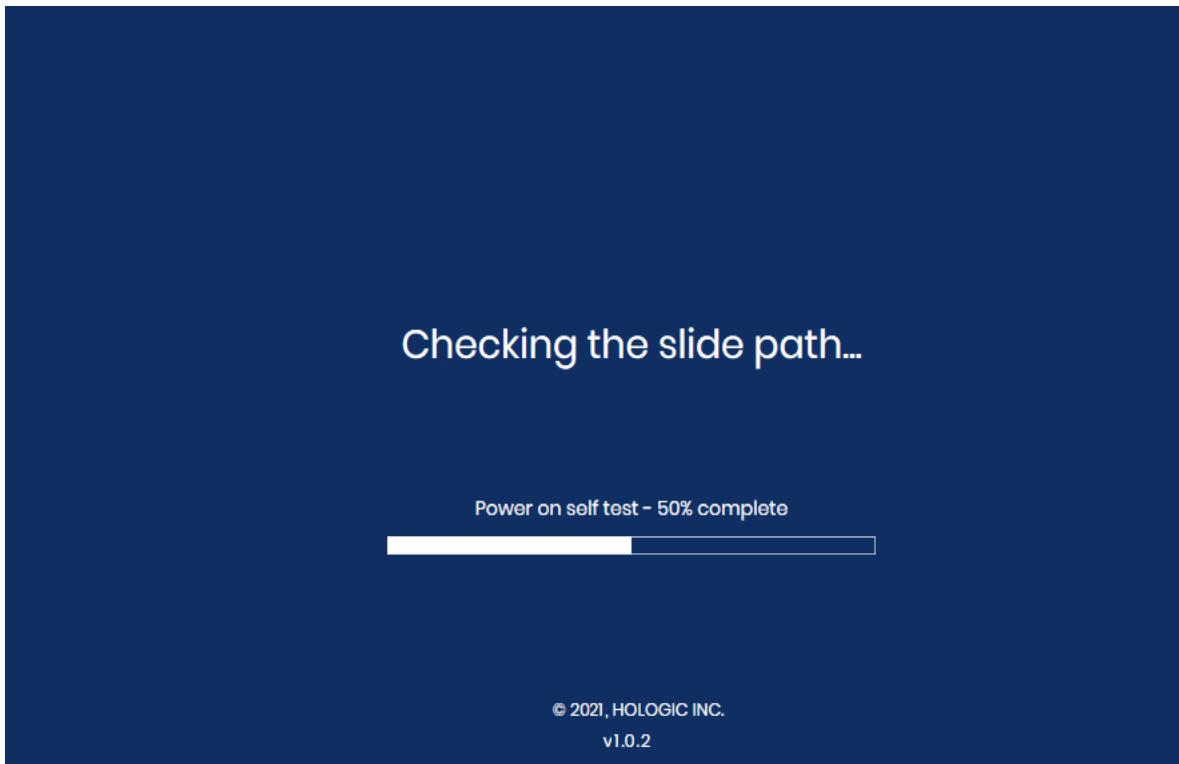
Figure 4-4   Warm-up in Progress

If a slide is detected in the instrument during the Power on Self-Test, follow the instructions on the touch screen to remove the slide and close the window.

- If a slide can be moved to a slide carrier, the touch screen displays instructions to place an empty slide carrier in position 1 (Bay 1) so that the instrument can return the slide to a slide carrier.

- If there is a slide in the instrument that cannot be moved to a slide carrier, follow the instructions on the touch screen to retrieve the slide by opening the slide gripper.

Note: When the warm-up cycle ends, the message disappears and the doors unlock.

The **Ready to Image** screen appears when the Digital Imager is ready for use. See Figure 3-1.

To power the Digital Imager off, refer to "Shutting down the Digital Imager" on page 4.35. The Digital Imager and Digital Imager computer should be shut off in the sequence described there.

MATERIALS REQUIRED PRIOR TO OPERATION

Digital Imager

Digital Imager computer

Connection to the Image
Management Server

Slide carrier with
staining rack(s)

ThinPrep
microscope slides
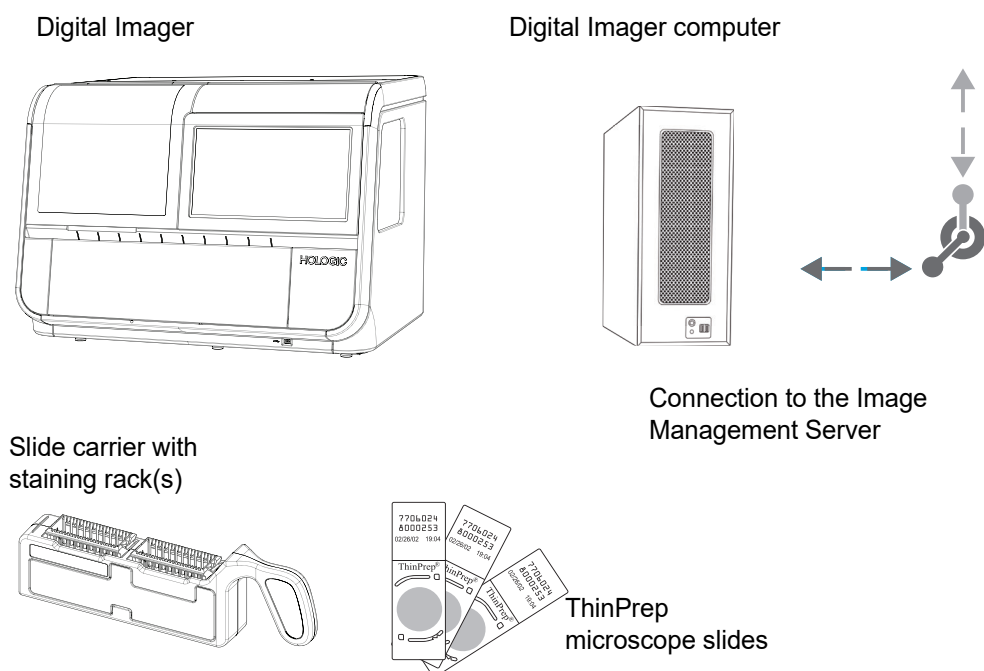
Figure 4-5   Items Required for Slide Image Processing

Slide carriers are provided at installation. Refer to Ordering Information for ordering more.

The **Digital Imager** has two components, a Digital Imager processor and a Digital Imager computer. The Digital Imager processor holds the slide carrier(s). The operator ensures that the Digital Imager processor is powered on, the slide carriers are loaded properly, and the doors are securely closed prior to slide processing. The user interface is the touch screen on the Digital Imager. The Digital Imager processor images each slide and sends the data to the Digital Imager computer. The Digital Imager computer contains the imaging processor and controls the electromechanical functions of the instrument. For Gyn sample types, the Digital Imager computer also analyzes the imaged slide data. For all sample types, the Digital Imager computer sends the data to be stored on the **Image Management Server**.

The **Image Management Server** stores the slide-related data and controls communication of all system services to the other devices in the Genius Digital Diagnostics System. It is the master controller when more than one Digital Imager is connected to the server.

SLIDE LABELING

The camera that scans the slide label accession ID recognizes barcodes (1-dimensional or 2-dimensional) or OCR (optical character recognition) format. It cannot read both at the same time. As part of the initial set-up of the Digital Imager or when your laboratory changes slide label types, select the label format via the user interface. Refer to "Configure Barcodes" on page 3.22.

Note: For Digital Imagers configured to read 1-dimensional (1-D) and 2-dimensional (2-D) slide labels, slide carriers can have mixed barcode label formats as long as the slide labels match the configuration on the instrument. A Digital Imager configured to read OCR slide labels cannot read barcoded slide labels.

The OCR format must be 14 digits long in two rows, 7 digits over 7 digits, with the patient ID being 11 digits and a 3-digit CRC at the end. The font must be 12-point OCR-A. Numbers only, no alpha characters. (See Figure 4-6.) On some ThinPrep processors, this format is named "OCR Imager."

Slide barcode labels may be 1- or 2-dimensional; see the table below for any restrictions required. Slide labels may be printed and applied or directly printed or etched onto the slide. (See Figure 4-6.) In any case, make sure the contrast is sufficient for the scanner to read the label.

Table 4.1 Slide Restrictions Based on Barcode Symbology Used

| 1-D Code 128	All printable ASCII 128 characters are supported. The barcode width varies with content. Minimum of 5 characters is required and maximum of 8 alphas or 14 digits will fit on a slide. Mixing will shorten the max length.
1-D Interleaved 2 of 5	Only digits are supported. 5,7,9, or 11 characters +1 (optional) check digit is the format.
1-D Code 39	Supported characters are A–Z, 0–9, - + . $ / % 'space' Minimum of 5 characters is required and maximum of 6 characters will fit on a slide. (A single character check digit is optional.)
1-D Code 93	All printable ASCII 128 characters are supported. A minimum of 5 characters is required and a maximum of 8 characters will fit on a slide.
2-D datamatrix	All printable ASCII 128 characters are supported. A maximum of 16 characters is supported.

1-Dimensional barcode examples

2-D barcode example
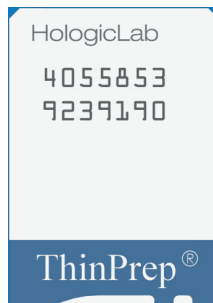
OCR format

Figure 4-6   Examples of How Barcodes Fit onto a ThinPrep Slide

LOADING SLIDE CARRIERS

WARNING: Glass. Sharp Edges.

All of the slides in the same slide carrier must be the same type of slides (all Gyn slides, all Non-Gyn slides or all UroCyte slides). Refer to "Select Sample Type for a Slide Carrier" on page 3.13 for information on designating slide types.

When the Gyn sequence is used, only stained, coverslipped ThinPrep® Imaging System microscope slides may be used. Refer to the ThinPrep Stain User's Manual for recommendations for coverslipping media.

For Non-Gyn slides, only stained, coverslipped ThinPrep® non-gynecological microscope slides may be used.

For UroCyte slides, only stained, coverslipped ThinPrep® UroCyte® microscope slides may be used.

CAUTION: The slides must have been processed on a ThinPrep processor.

See Figure 4-7. On ThinPrep Imaging System microscope slides, the fiducial marks are permanently printed features on the slide used to register the slide position on the imaging stage.
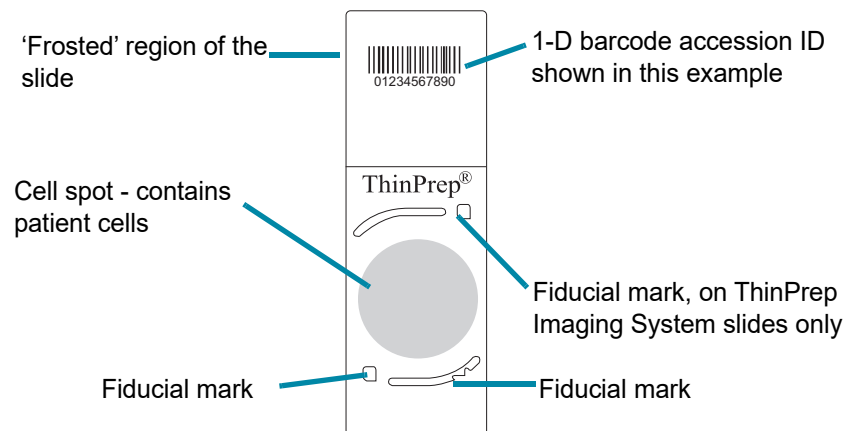
**Figure 4-7   ThinPrep Microscope Slide for Use with the Digital Imager
(ThinPrep Imaging System Microscope Slide for Gyn Sample Shown)**

CAUTION: To prevent unnecessary slide events during batch processing, slides must be placed properly into the slide carrier.

Visually inspect slides before loading them into the slide carrier.

Carefully load the microscope slides into a slide staining rack, one slide per slot. Orient the slide so that the label side is up and facing the "up side" wording embossed in the staining rack.

The slide carrier has two openings. Each opening holds one rack of microscope slides. Gently lower the slides in the slide staining rack into the slide carrier.

If the staining rack is facing the wrong way in the slide carrier, the slides will not sit flat, the paddle on the side of the slide carrier will bump out, and red tabs will show. If the staining rack is facing the wrong way in the slide carrier, the slide carrier cannot be loaded into the Digital Imager.

A slide carrier can be used with one or two staining racks in it. A slide carrier can run on the Digital Imager with 1-40 slides in it. The Digital Imager starts with the slide furthest from the slide carrier handle.

CORRECT SLIDE POSITION:
Slide labels face away from the slide carrier handle.
Empty slots are OK.
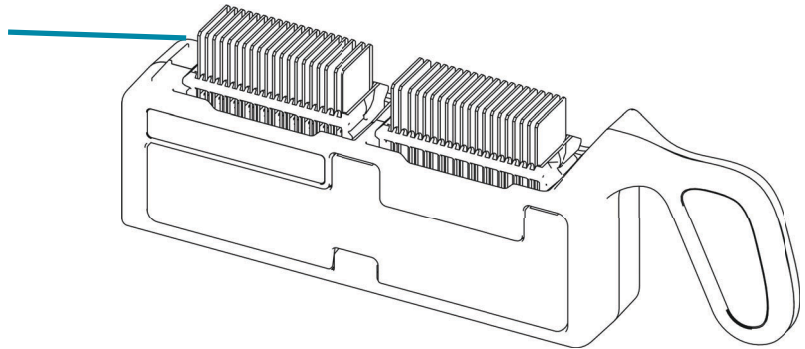
INCORRECT SLIDE LOADING:
Staining rack in backward - red tabs visible.
Slide in backward or upside down
Multiple slides in one slot
Slide crooked or askew between slots
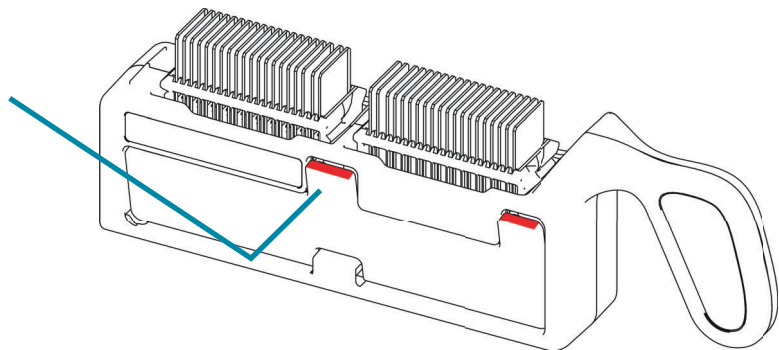
Figure 4-8   Loading Slides into the Slide Carrier

When loading slides, confirm that:

- ThinPrep® microscope slides with fiducial marks are used for Gyn samples. The fiducial marks should not be scratched or marred.

CAUTION: Mounting media must be completely dry before loading slides into the Imaging Station.

- The coverslip media is dry (wet media could cause equipment malfunction). This is especially important for slides using glass coverslips.

- The slides are clean (no fingerprints, dust, debris, bubbles). Handle the slides by the edges. Chipped or damaged slides might not be imaged.

- The coverslip does not extend beyond the surface of the slide.

- The label is applied smoothly, without overhang. (Lifted edges may stick during handling, causing broken slides or instrument malfunction.)

- The slide is appropriately labeled for use with the Digital Imager. Refer to "Slide Labeling" on page 4.7.

- Slide IDs in OCR format cannot be mixed with slide IDs in any barcode format in the same slide carrier.

The Digital Imager must be set up to match the format of the slide labels in the slide carrier. Refer to "Configure Barcodes" on page 3.22 for more information. Once the configuration is set, the setting persists.

Each slide carrier holds up to 40 slides. It is not necessary for the slides to be in any particular order; slots may be skipped.

LOAD SLIDE CARRIER INTO THE DIGITAL IMAGER

1. Open the door to access the slide carrier deck. The lanes or positions on the slide carrier deck are marked 1-10, with position 1 furthest on the left.
2. Verify or select the slide type for a lane. The positions on the slide carrier deck are represented on the touch screen display.

    *   To change a slide type designation for the slide carrier, touch the name of the slide type above position on the touch screen. Touch the name of the desired slide type (Gyn, Non-Gyn or UroCyte) to select it. Position 10 can also be designated as an error slide carrier (Gyn, Non-Gyn, UroCyte or Error).
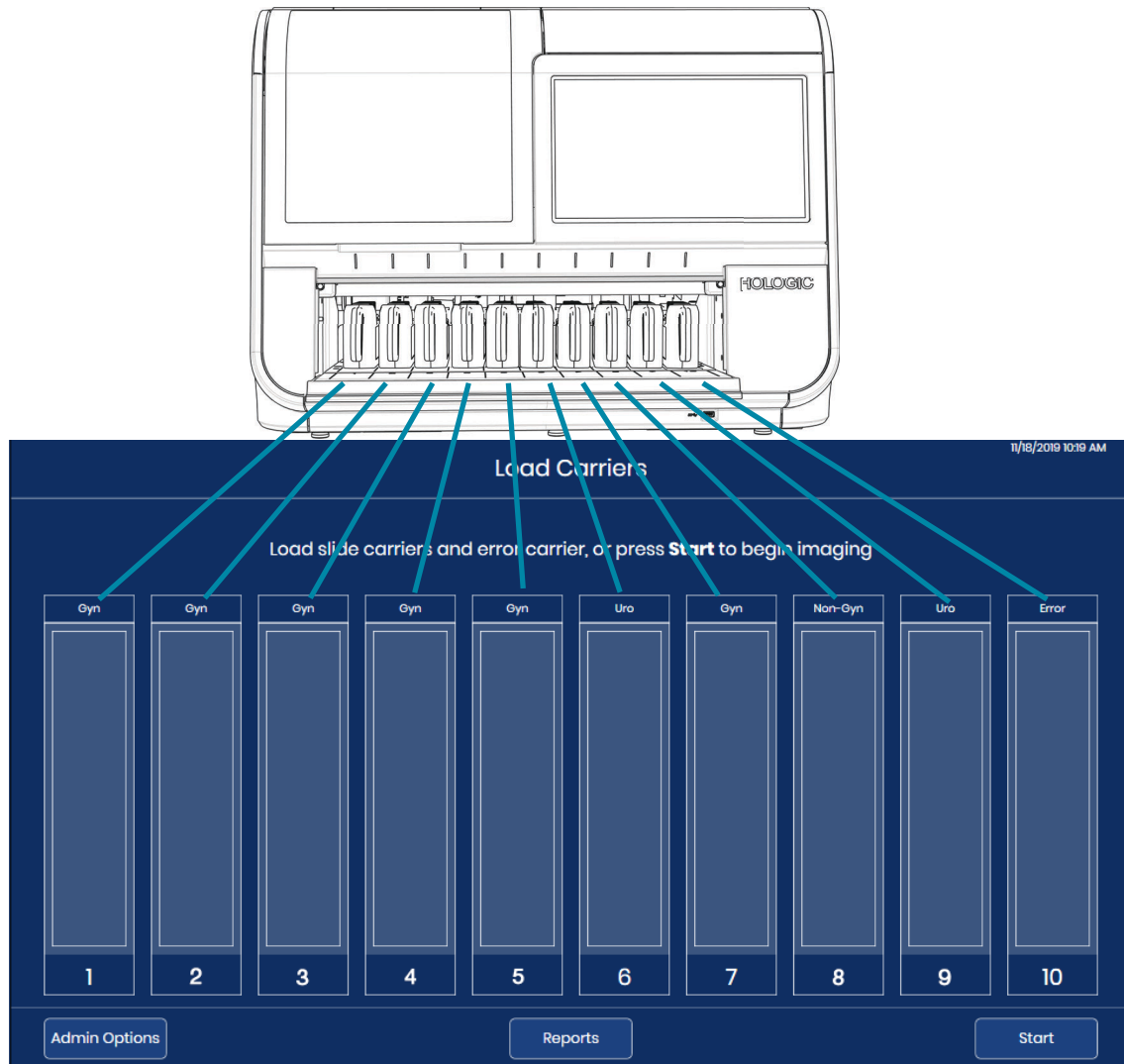
Figure 4-9   Slide Carrier Deck Corresponds to Touch Screen Display

3. Holding a loaded slide carrier by its handle, place the slide carrier on an empty position on the open door. The light above an inactive slide carrier position is green.

4. Push the slide carrier forward. The groove in the bottom of the slide carrier fits onto the rail in the slide carrier bay. The slide carrier is properly seated when it clicks into the latch and touches the sensor at the far side of the instrument. When the slide carrier is in place, the illustration of the position on the touch screen display changes to a lighter color blue. The light above an inactive slide carrier position is green.
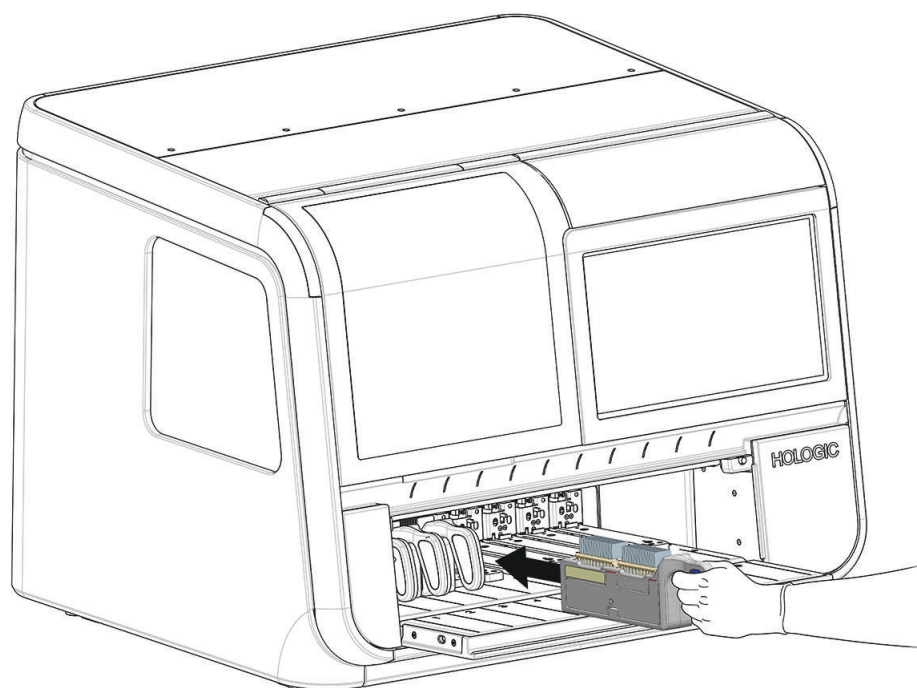
Figure 4-10   Push Loaded Slide Carrier into an Empty Position

Slides can be imaged with 1-10 slide carriers loaded in the Digital Imager. The Digital Imager starts processing with the slide carrier furthest to the left and continues past any open positions. The Digital Imager holds up to 10 slide carriers. It is not necessary for the slide carriers to be in any particular order; lanes may be skipped.

Slide carriers cannot be loaded or unloaded from the Digital Imager while slides from that slide carrier are in process. The slide carrier is locked in place and the light above the position on the slide deck is red until the imaging processes are complete for slides from that slide carrier.

Processing can be paused by the operator to load slide carriers into an empty position, a position where slide processing is complete or a position where an urgent group of slides can be loaded. Refer to "Stat Slide Processing" on page 4.31.

5. Continue to load slide carriers into available lanes on the slide carrier deck.

Note: There are ten slide carrier lanes. Load as many slide carriers as necessary. Each slide carrier can hold 40 slides for a total batch size of 400 slides. At least one slide carrier containing at least one slide must be present to begin slide imaging.

Note: If position 10 is designated as an error carrier, load an empty slide carrier into position 10 before starting slide processing.

6. Fully close the door.

SECTION G

SLIDE PROCESSING

1. Press **Start** on the touch screen to begin processing. The door and the window must be shut, and a minimum of one slide carrier must be loaded before the **Start** button is available.
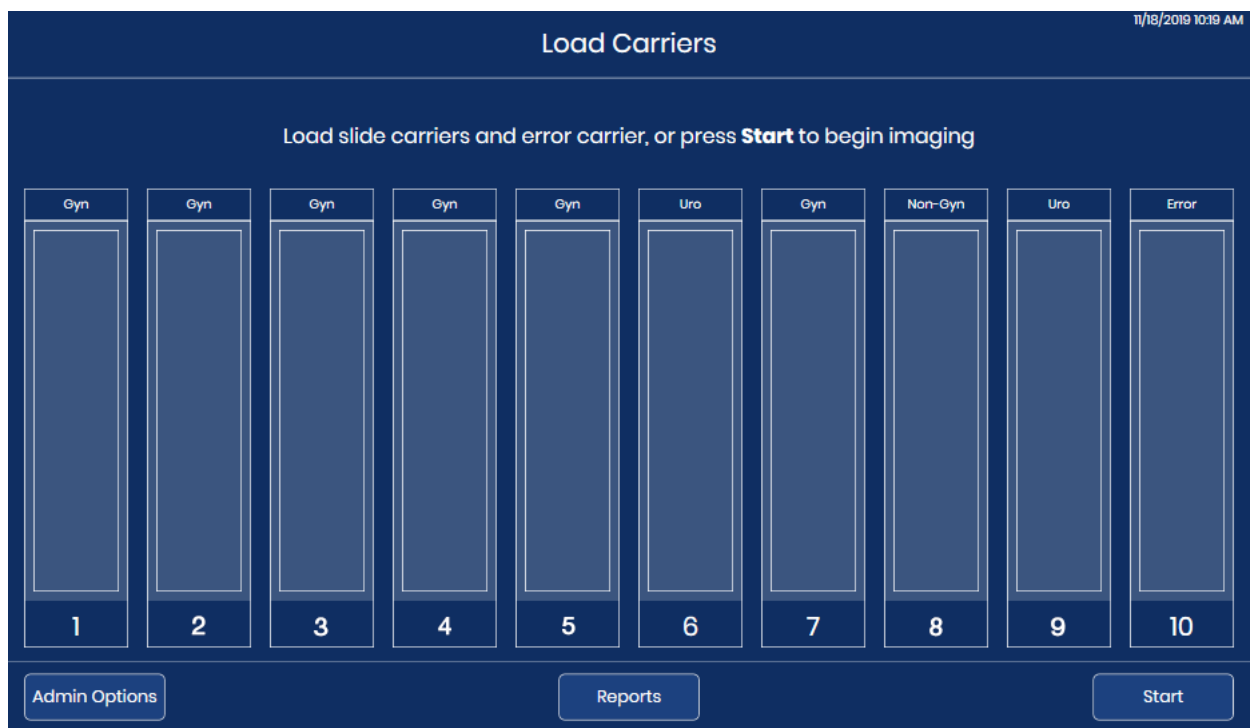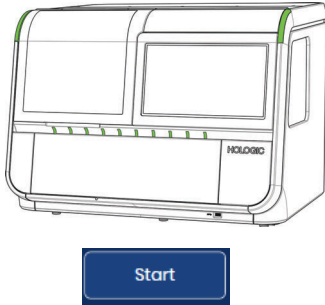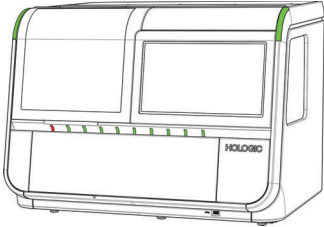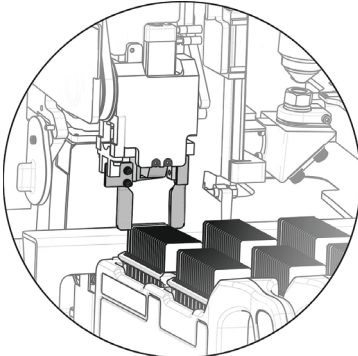
Figure 4-11   Begin Slide Imaging: Load Slide Carriers, or Press Start

2. The Digital Imager proceeds through the sequence of events listed here.

Table 4.2 Sequence of Events in Imaging Slides

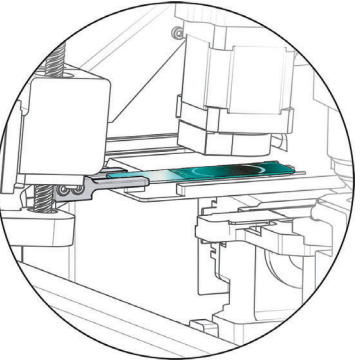|	
	Start button is pressed.
	The door locks and remains locked until slide processing finishes or is paused by the operator. Check for the presence of slides in one slide carrier. The slide carrier indicator light for that slide carrier turns red. The software estimates the time to process all of the slides loaded into the first carrier.
	Remove one slide from one slide carrier. Slide processing starts with the first occupied slide carrier on the left (the lower number positions) and continues toward the right (the higher number positions). Within each slide carrier, slide processing starts with the slide in the occupied slot furthest from the handle of the slide carrier.

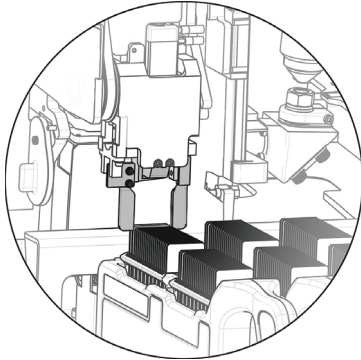## Table 4.2 Sequence of Events in Imaging Slides
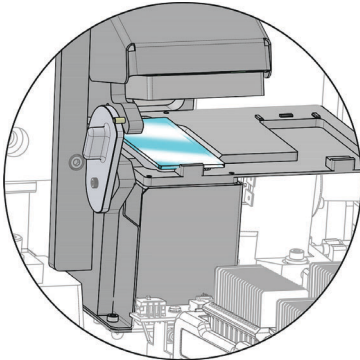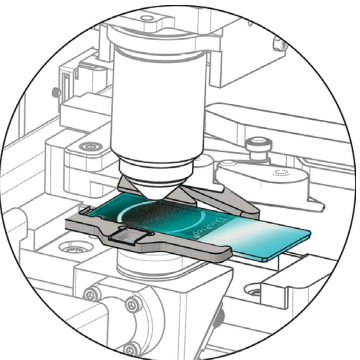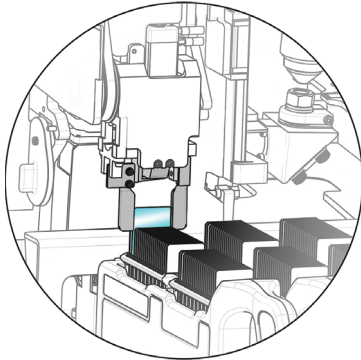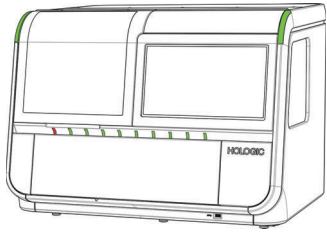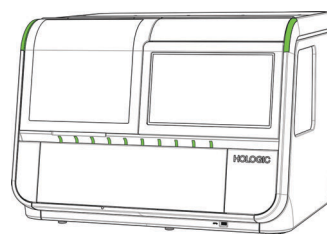
	Move the slide to the macro station. Scan the slide with the macro scanner to capture the slide ID on the slide label. Use the Configure slide ID - Gyn slides settings to record the accession ID based on the slide ID on the slide label. Check that the slide has not already been imaged.
	Move the slide to the imaging stage. Scan the slide in high resolution. While one slide is on the imaging stage, remove the next slide from the slide carrier and move it to the macro station. Move the slide handling arm to the next occupied slide carrier and conduct an inventory to determine where slides are loaded into the slide carrier.
	Send the accession ID, the slide images and related data (date, time, digital imager name, etc.) to the Image Management Server. The Image Management Server stores this data so that the data can be accessed from the Review Station. To free up the slide handling arm to advance the next slide, temporarily place the slide on the queue station.

Table 4.2 Sequence of Events in Imaging Slides

	Return the slide to its slide carrier. Note: Typically, the slide is returned to the starting carrier. In cases where the operator has designated position 10 as an error carrier, a slide with a slide event is returned to the error carrier in position 10.
	Remove the next available slide from the slide carrier. The process repeats until each slide in the slide carrier is processed.
	When all of the slides in a slide carrier have been processed, the light above the slide carrier position changes from red to green. The process repeats until all slide carriers are processed.
	The Digital Imager continues until each slide in each slide carrier loaded in the instrument has been processed.

3. When the green light indicates that all of the slides in a slide carrier have been processed, the slide carrier may be removed from the Digital Imager.

During Slide Processing

As slides are processed, the touch screen display changes to represent how much progress has been made. For more information on touch screen display status indicators, refer to "Status Indicators" on page 3.4.   Figure 4-12 shows how the touch screen display depicts progress through the loaded slide carriers.
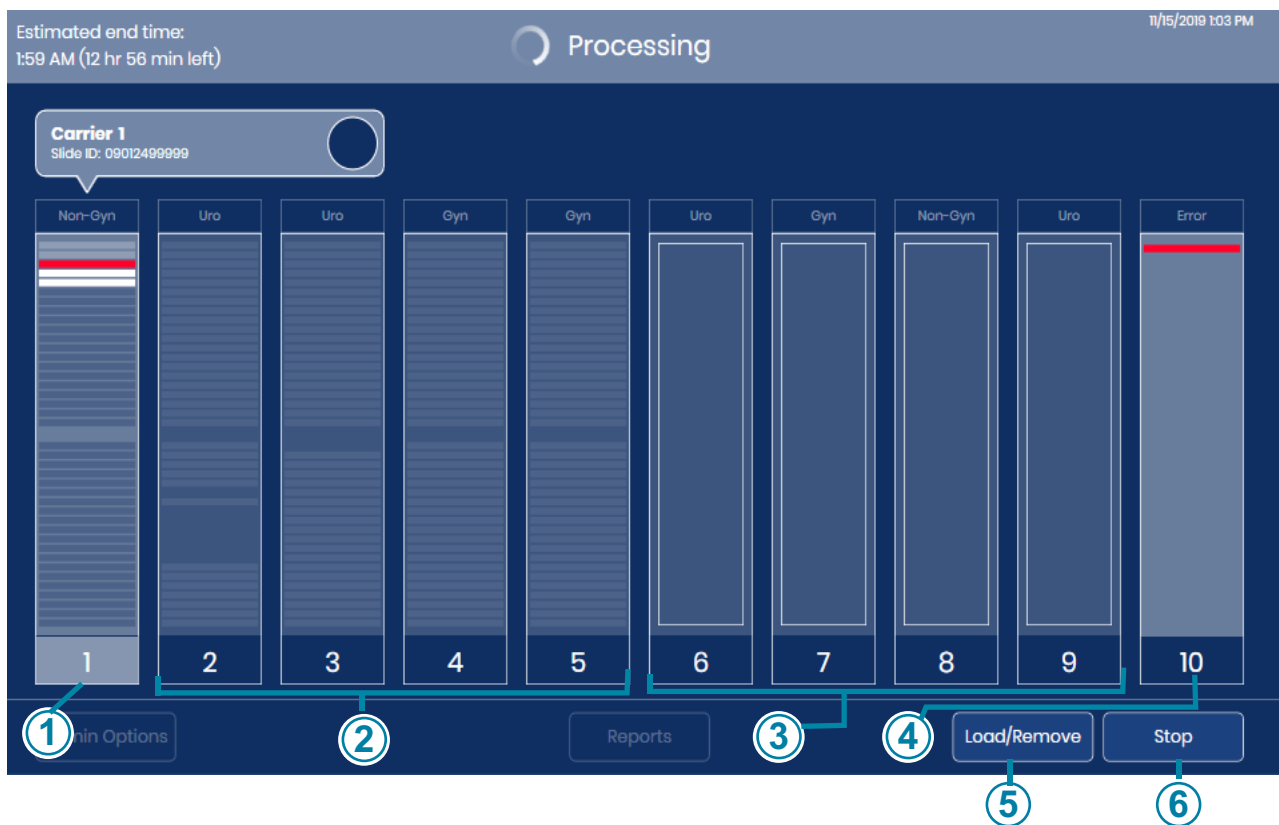

Figure 4-12   Slide Carrier Imaging Status (Example)

Key to Figure 4-12	
①	In this example, slides in slide carrier 1 are being processed. To open the detailed display of this slide carrier's slides, touch anywhere in the illustration of carrier 1 on the touch screen.

Key to Figure 4-12	
②	Slide carriers are loaded in positions 2-5 in this example. While imaging slides from the slide carrier in position 1, the Digital Imager conducted an inventory for the presence or absence of slides in slide carriers in positions 2, 3, 4, and 5. When all the slides in the first slide carrier are processed, the Digital Imager will start to process slides in the next slide carrier, which is in position 2 in this example.
③	The Digital Imager has detected that slide carriers are loaded in positions 6, 7, 8 and 9 in this example. The Digital Imager will conduct an inventory for the presence or absence of slides in those slide carriers.
④	Position 10 has been designated by the operator as an error carrier. In this example, one slide, which started in the slide carrier in Position 1, has been returned to the error carrier in position 10.
⑤	The **Load/Remove** button is available when the Digital Imager is processing slides.
⑥	The **Start** button is replaced with a **Stop** button when the Digital Imager is processing slides.

The Digital Imager sends data to the Image Management Server for each slide. The circle in the box above the slide carrier on the touch screen display indicates the progress of the data transfer. Refer to "Slide data transmission status" on page 3.10 for more information.

While slide processing is in progress, touch the rectangle representing the slide carrier on the touch screen to show details about the slides in that carrier as shown in Figure 3-6.

Periodic check

Periodically during the course of normal operation, the Digital Imager conducts a check of its various systems and subsystems. If the door is open, the Digital Imager will prompt the operator to close the door. The door will lock. A message appears on the touch screen display.

There is no action for the operator to take. Once the check is complete, the Digital Imager resumes what it was doing before it stopped to check.
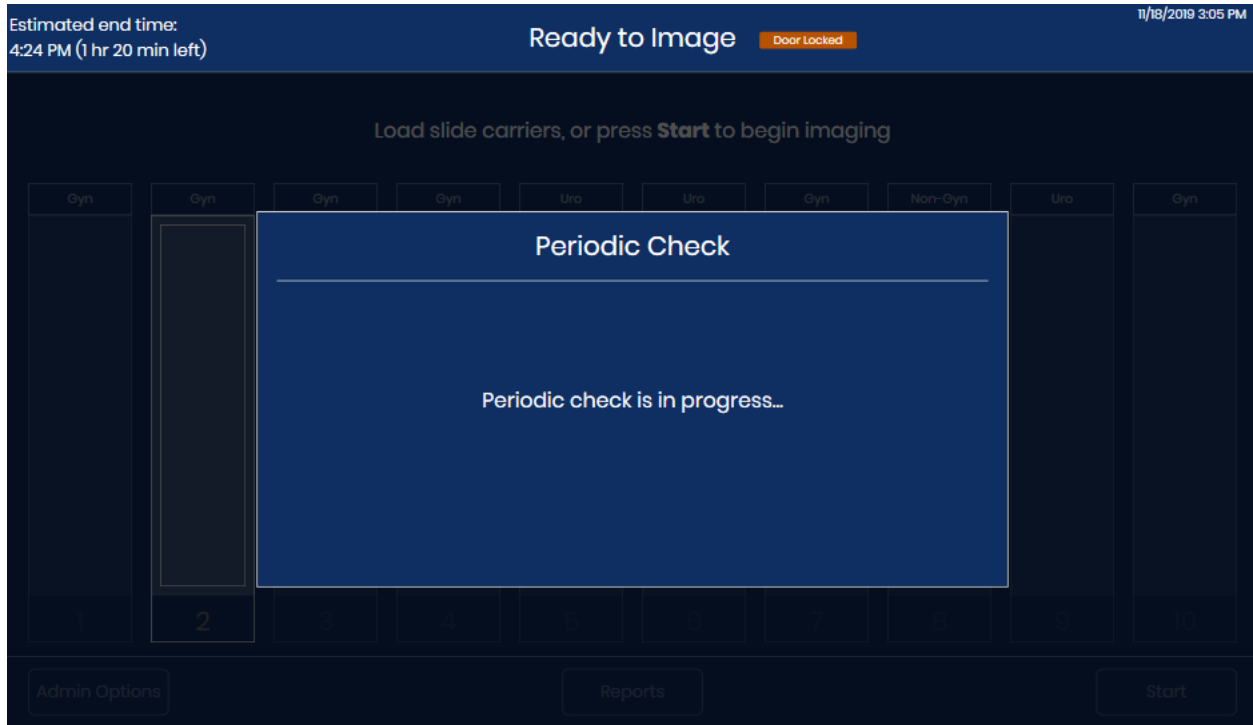

Figure 4-13   Periodic Check

Processing complete

When all of the slides in all of the carriers are processed, the touch screen displays the number of slides processed and the number of slide events during processing.
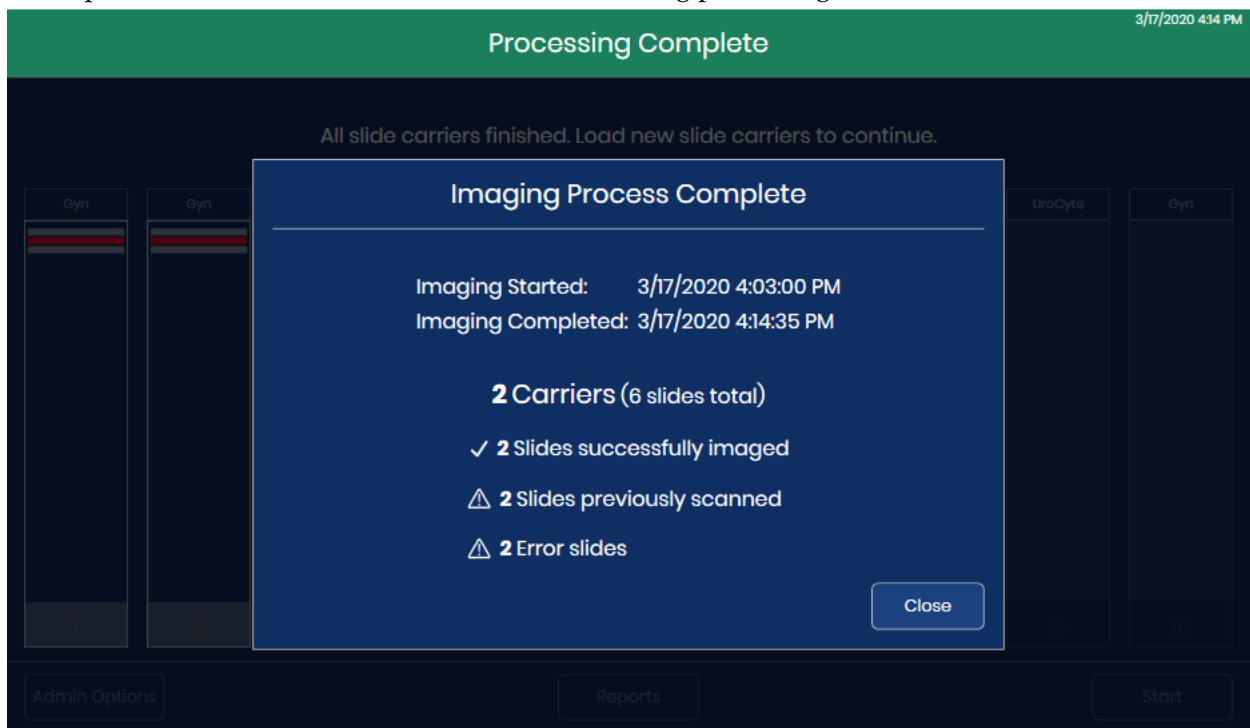

Figure 4-14   Processing Complete

Touch the **Close** button to return the main screen with "Processing Complete" displayed. When the Digital Imager is idle (not processing slides), reports can be generated. Refer to "Reports" on page 3.39.

Slide event during processing

As the Digital Imager processes slides, the depiction of a slide carrier on the touch screen display changes to represent progress. A red stripe indicates a slide event.

While slide processing is in progress, touch the rectangle representing a slide carrier on the touch screen to show details about the slides in that carrier.
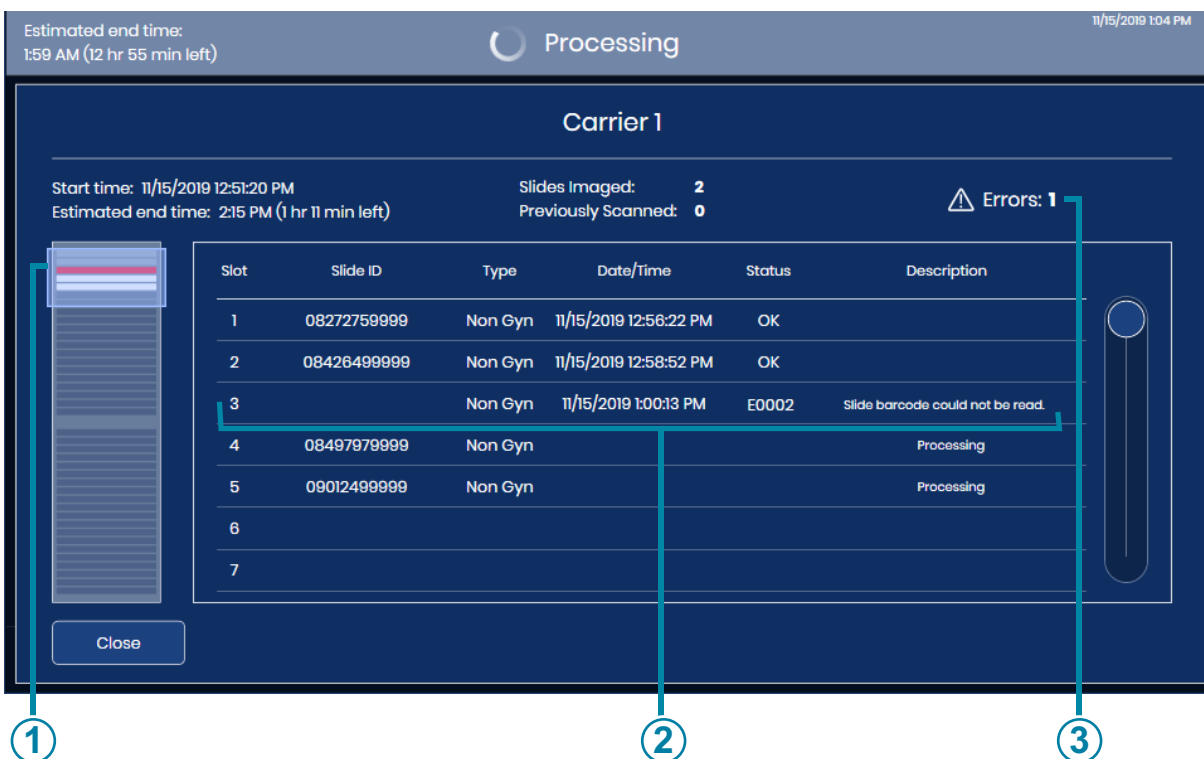

Figure 4-15   Slide Event During Processing

Key to Figure 4-15	
①	The red stripe represents a slide with an error.
②	The screen lists the slot number in the staining rack, the slide ID, the sample type, the date and time, and a description of the error.
③	This is the running total of slides with errors incurred for the slides in this slide carrier.

If a slide caused an event during processing, use the description of the error to determine if there is any corrective action that would allow the slide to be successfully processed in another carrier. This may include:

• Slide incorrectly loaded into the slide carrier

- Slide was not completely dry when loaded into the slide carrier
- Mounting media was on the frosted portion of the slide
- Slide contains bubbles
- Slide coverslip protrudes over the edge & causes interference
- Slide is dirty (dust, fingerprints)
- Slide label not legible for scanning of the accession ID
- Slide label is legible, but the Digital Imager is configured to read a different barcode type or OCR format
- Slide has already been imaged (accession ID already in the server database)

    Note: With an error of "Slide was scanned previously" always check the slide ID against the patient record, to confirm that it is not a duplicate accession ID.

- Other slide related errors (but not necessarily user correctable) may include:
- Sample too dense
- Sample is sparse
- Other biological artifacts
- Occlusions or holes in the cell spot
- The slide is not a ThinPrep microscope slide

Note: If a slide is not successfully processed by the Digital Imager, its images cannot be reviewed at the Review Station. A slide may be rerun on the Digital Imager.

UNLOAD SLIDE CARRIER FROM THE DIGITAL IMAGER

1. When the instrument is idle (not processing slides), open the door to access the slide carrier deck. The lanes or positions on the slide carrier deck are marked 1-10, with position 1 furthest on the left.
2. A slide carrier in a position marked by a green light can be removed from the Digital Imager. Grasp the handle of the slide carrier and carefully pull the loaded slide carrier back towards you.
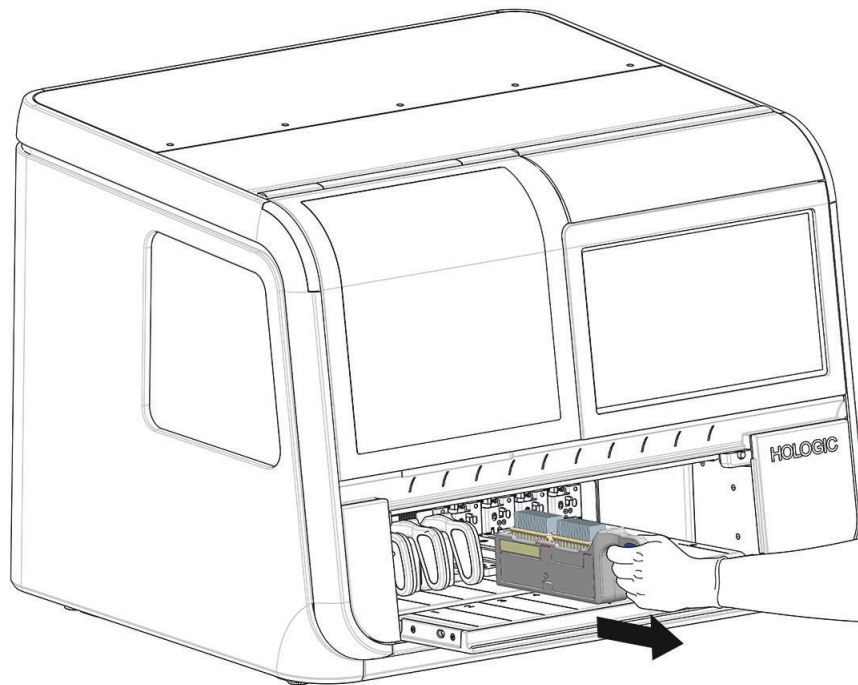

Figure 4-16   Remove Slide Carrier from Digital Imager

3. When the groove on the bottom of the slide carrier is no longer engaged with the rail in the slide carrier bay, move the slide carrier to your storage location.

CAUTION: Handle slides carefully. Slides will fall out of the slide carrier if the slide carrier is turned upside-down.

<div style="background:teal">SECTION
I</div>

USING AN ERROR SLIDE CARRIER

The Digital Imager can be set up to return slides that have slide events to one of two places:

- Return the slide to the same slide carrier that it started in.
- Return the slide carrier to an error slide carrier in position 10.

To designate position 10 as an error slide carrier, touch the name of the slide type above position 10 and select **Error**. Only position 10 has the option to be designated as an error slide carrier. When position 10 is designated as an error carrier, the selection will remain on the Digital Imager until it is changed again. If desired, the operator can change the setting any time the instrument is idle.

To use an error slide carrier, load an empty slide carrier with one or two empty staining racks in it before starting slide processing.

When the error slide carrier is used, any slide that has a slide event error in the entire slide run of slides will be returned to the error carrier rather than the slide carrier that it started from. In the slide carrier that the slide started from, there will be an empty slot for any slide that is returned to the error slide carrier. The Slide Event Log and the Imaging Report each describe the error and the starting carrier position for the slide. An error carrier report describes the error and the returned position within the error carrier for the slide.

A slide carrier with two staining racks in it has a capacity of 40 slides. When the error carrier senses that there are only 10 empty slots remaining, a "low on space" message appears on the touch screen display and the error carrier is shown in yellow.

Touch the **Load/Remove** button to stop processing so that the door will unlock. Replace the full error carrier with an empty error carrier. Refer to "Loading Slide Carriers" on page 4.9.

The Digital Imager will stop processing if the error carrier reaches capacity.

Replace the full error carrier with an empty error carrier. Consider using an error carrier where an operator is available to replace a full error carrier if needed.

Description of the Slides in the Error Slide Carrier

To see descriptions of the slide event for each of the slides in the error carrier, touch the graphic representing the error carrier. The touch screen display shows the slot number, slide ID, type, date and time, status, and description.
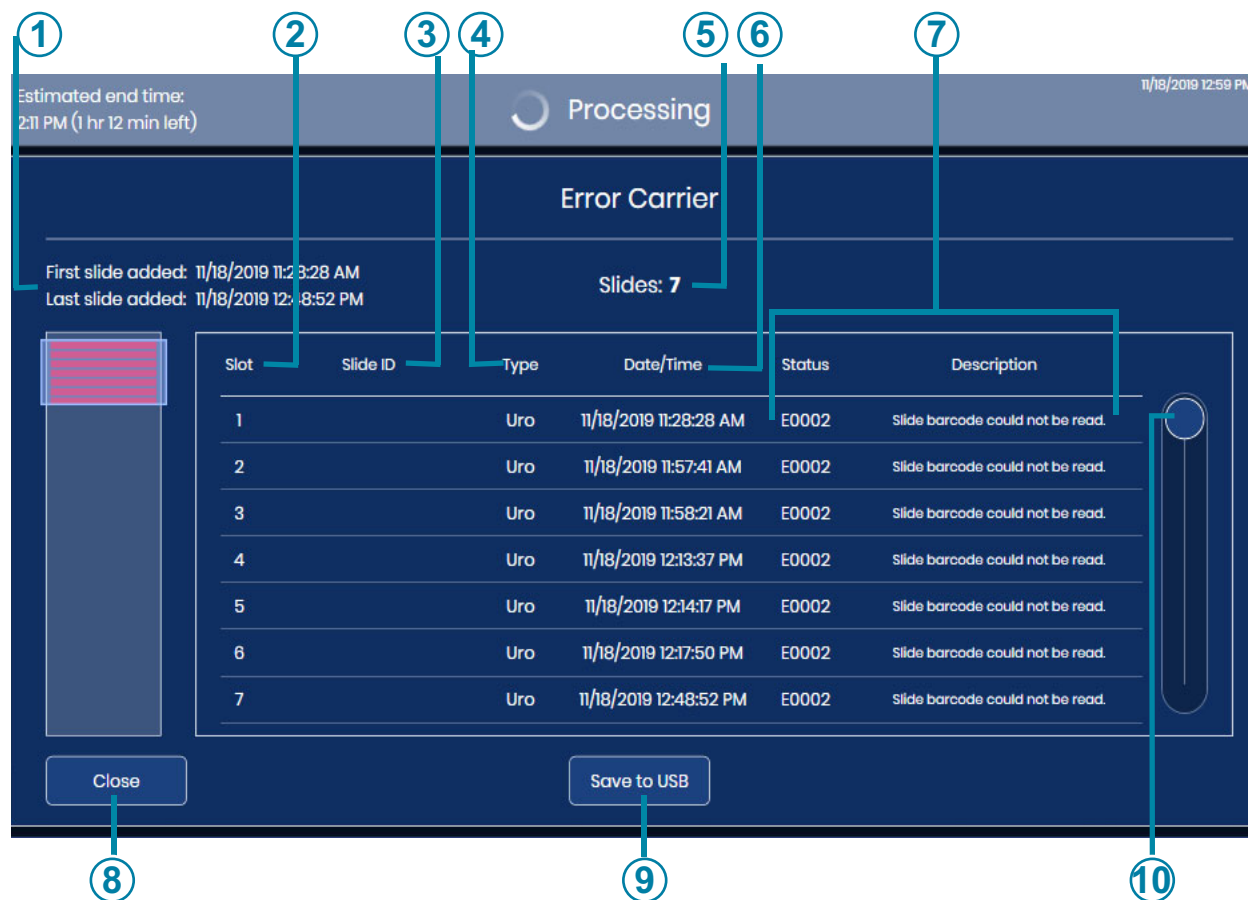

Figure 4-17   Details for Slides in the Error Carrier

Key to Figure 4-17	
①	Time period that this error carrier has been in use
②	Slot in the staining rack in the error carrier

Key to Figure 4-17	
③	The slide ID is shown (for slides with a successful barcode scan)
④	Sample type: Gyn, UroCyte, or Non-Gyn
⑤	The quantity of slides in the error carrier
⑥	Date and time that the error occurred
⑦	Error code and its description
⑧	Touch **Close** to return to the main processing screen
⑨	Save the data as xml file to a USB drive
⑩	Touch and slide the circle to scroll through the list

When position 10 is used as an error carrier, each slide in the error carrier is described in several places. The on-screen description of the error carrier and the Error Carrier Report describe the error carrier to which a slide is returned. The Slide Event Log and the Imaging Report describe the slide and its slide event based on where the slide started. For more information on reports, refer to "Reports" on page 3.39.

SECTION J PAUSE AND RESUME A BATCH

Interrupt Slide Processing

Slide processing may be interrupted and resumed or interrupted and canceled via the user interface. Slide processing might be interrupted for reasons below:

CAUTION: The Digital Imager is designed to make sure all of the slides from a slide carrier are returned to a slide carrier before the instrument stops processing. All of the slides in a slide carrier must be returned to a slide carrier before the slide carrier can be removed.

- To run a Stat slide
- To remove completed slide carriers and load new slide carriers to have the Digital Imager continuously processing slides
- To shut the system down prior to a known power outage event
- To shut the system down in order to do maintenance or repair
- To address observable slide loading errors

1. To load or remove one or more slide carriers while the Digital Imager is processing slides, touch **Load/Remove** on the touch screen.

Note: Take care to remove the correct slide carrier when processing is paused. When a slide carrier is removed and a new slide carrier is loaded in that same position, the Digital Imager assumes that the slides in that slide carrier need to be processed. If processing is paused and a carrier with processed slides is removed by mistake and replaced with the same carrier, then the Digital Imager will attempt to process the slides in that carrier again. The Digital Imager will take the time to report that those slides have been scanned previously.
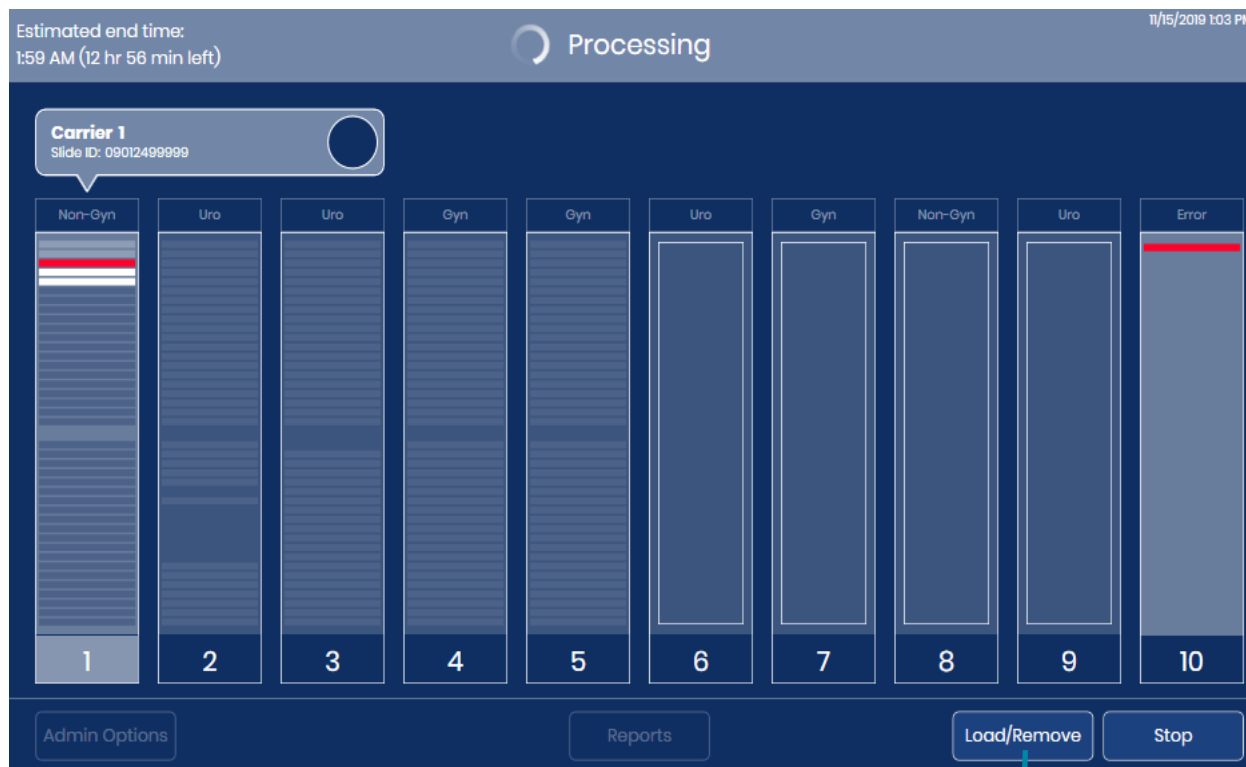
Load/Remove button

Figure 4-18   Slide Processing: Load/Remove Button

2. The Digital Imager finishes processing the slide or slides removed from a slide carrier within 60 seconds. The touch screen shows a **Processing Paused** status. The active slide carrier, marked by a red light above the door, cannot be removed or replaced.
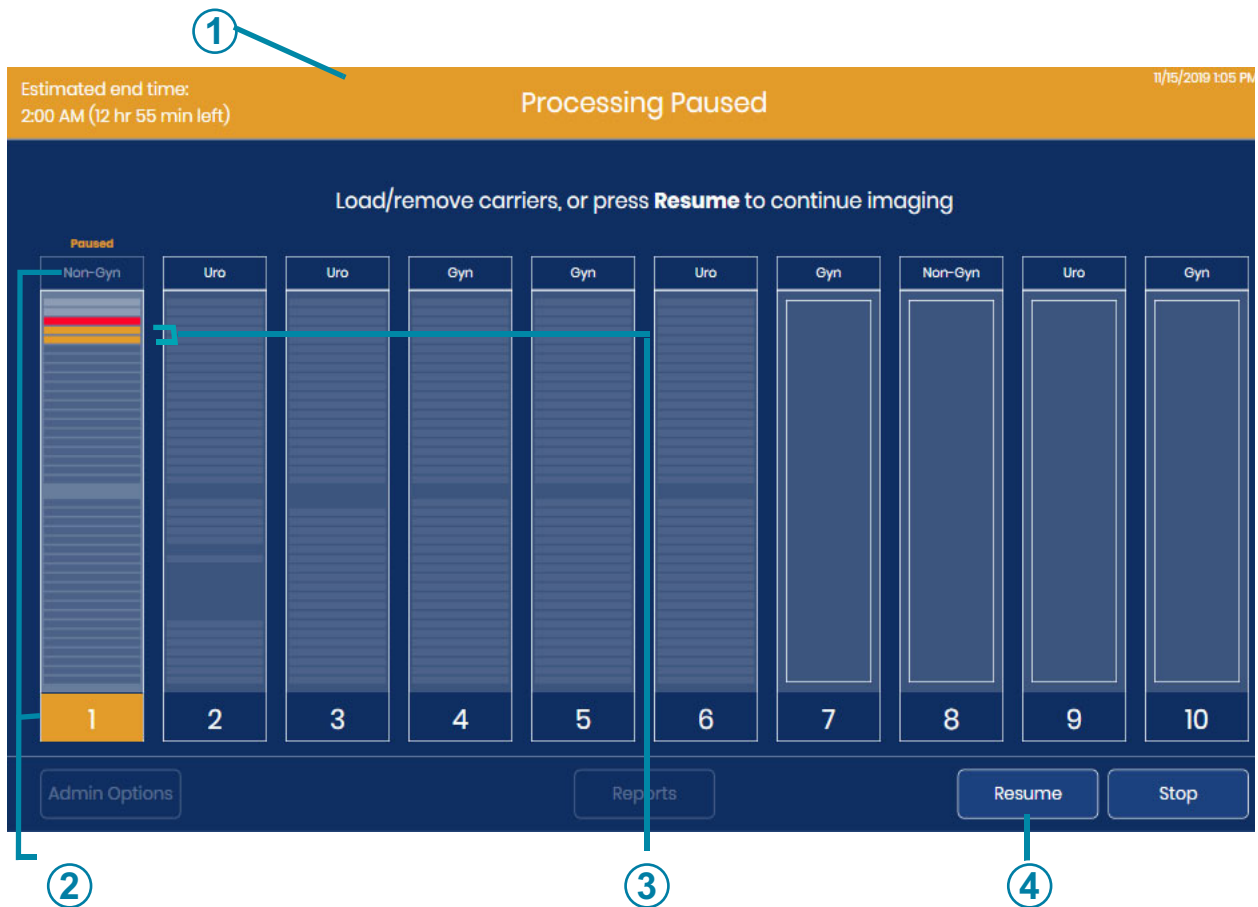

Figure 4-19   Slide Processing Paused

Key to Figure 4-19	
①	Orange heading indicates that processing is paused
②	Orange color indicates that processing is paused. In this example, slides from slide carrier 1 were in progress when processing paused.
③	In this example, two slides were removed from the carrier when processing paused.

Key to Figure 4-19	
④	**Resume** button

3. Open the door.
4. Remove any slide carrier from a position with a green light, and/or load a slide carrier with slides into a position with a green light.
    A. Completed slide carriers may be removed and replaced with unprocessed slide carriers or slide carrier positions may be left empty.

Note: The error slide carrier may also be removed and replaced with an empty slide carrier, with empty staining racks. The error carrier must not have any slides in it when the error carrier is swapped while the processing on the Digital Imager is the paused.

    B. If uncompleted slide carriers are removed, they must be reimaged at another time to be considered complete.
    C. If the system is to be shut down, remove the slide carriers. Run unprocessed slide carriers at another time.
5. Close the door.
6. To shut down the system, press the **Stop** button while the instrument is paused. Refer to "Shutting down the Digital Imager" on page 4.35 for more instructions.
7. Press **Resume** to resume processing. The system begins processing at the next unprocessed slide, which may be in the slide carrier that was active when the **Load/Remove** button was pushed. The Digital Imager conducts an inventory of any slide carrier that was loaded or replaced in the instrument. Processing continues with the next unprocessed slide carrier it comes to when operation is resumed, starting with the slide carrier in the lowest-numbered, occupied position (the position furthest to the left).

Cancel processing after pausing slide processing
1. If the system is to be shut down, remove the slide carriers. If a slide carrier is partially processed and is a mix of processed and unprocessed slides, consider separating the processed slides from the unprocessed slides so that the unprocessed slides can run at another time.
2. To shut down the system, press the **Stop** button while the instrument is paused. Refer to "Shutting down the Digital Imager" on page 4.35 for more instructions.

Stat Slide Processing

A batch may be interrupted to run a single slide carrier of Stat slides. The operator may resume or terminate the batch after running the stat slides, similar to pausing and resuming to load other slide carriers. The stat slide or slides are placed in a slide carrier at any position marked with a green light. One to 40 slides can be run.

1. While the Digital Imager is processing slides, touch **Load/Remove** on the touch screen.

2.   The Digital Imager finishes processing the slide or slides removed from a slide carrier. The touch screen shows a **Processing Paused** status. The active slide carrier, marked by a red light above the door, cannot be removed or replaced

3.   Open the door.

4.   Load the slide carrier containing the stat slides into an available position. If all of the slide carrier positions are full, unload a carrier from a position marked with a green light so that there is room for the stat slide carrier. If position 10 is designated as an error carrier, consider putting the stat slide carrier in another position to keep position 10 for an error carrier.

5.   Press the **Mark as STAT** button.
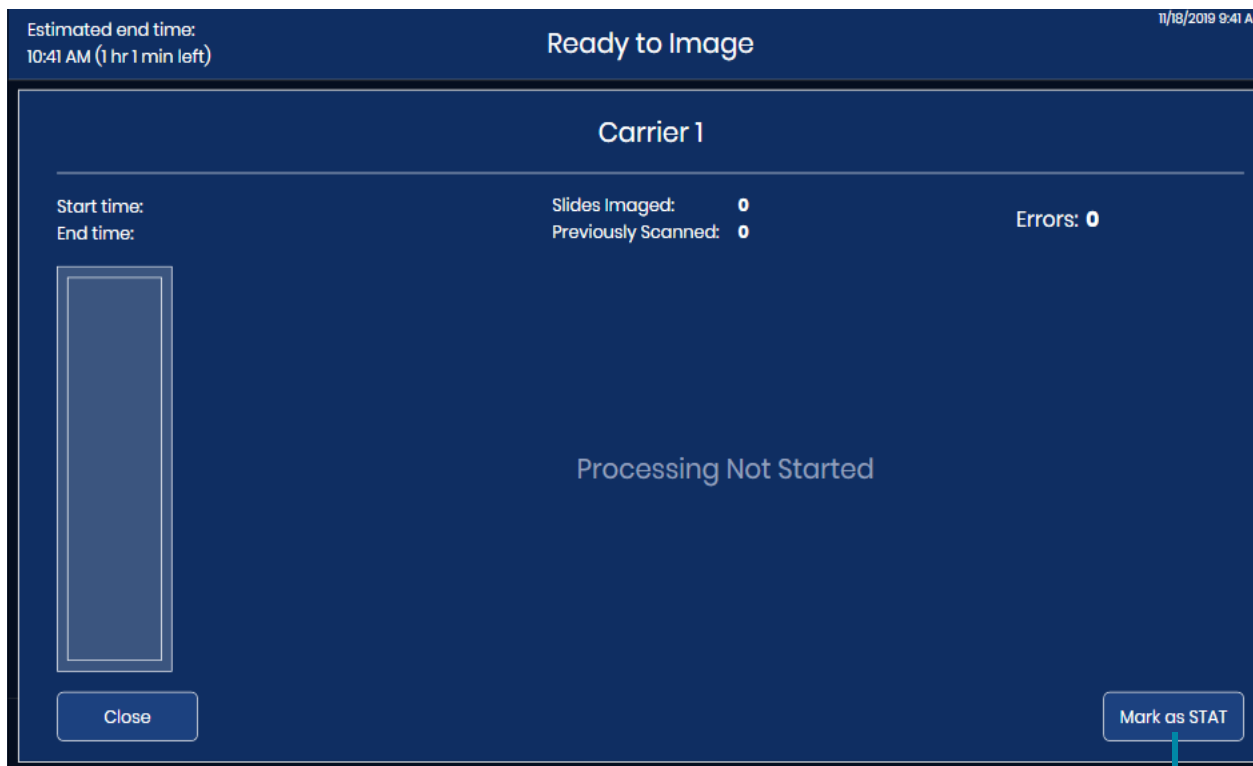
Mark as STAT button

Figure 4-20   Run Stat Carrier: Mark Slide Carrier as STAT

A message, "Marked as STAT - will be processed next," appears on the touch screen. The button in the lower right changes to a **Remove STAT** button.
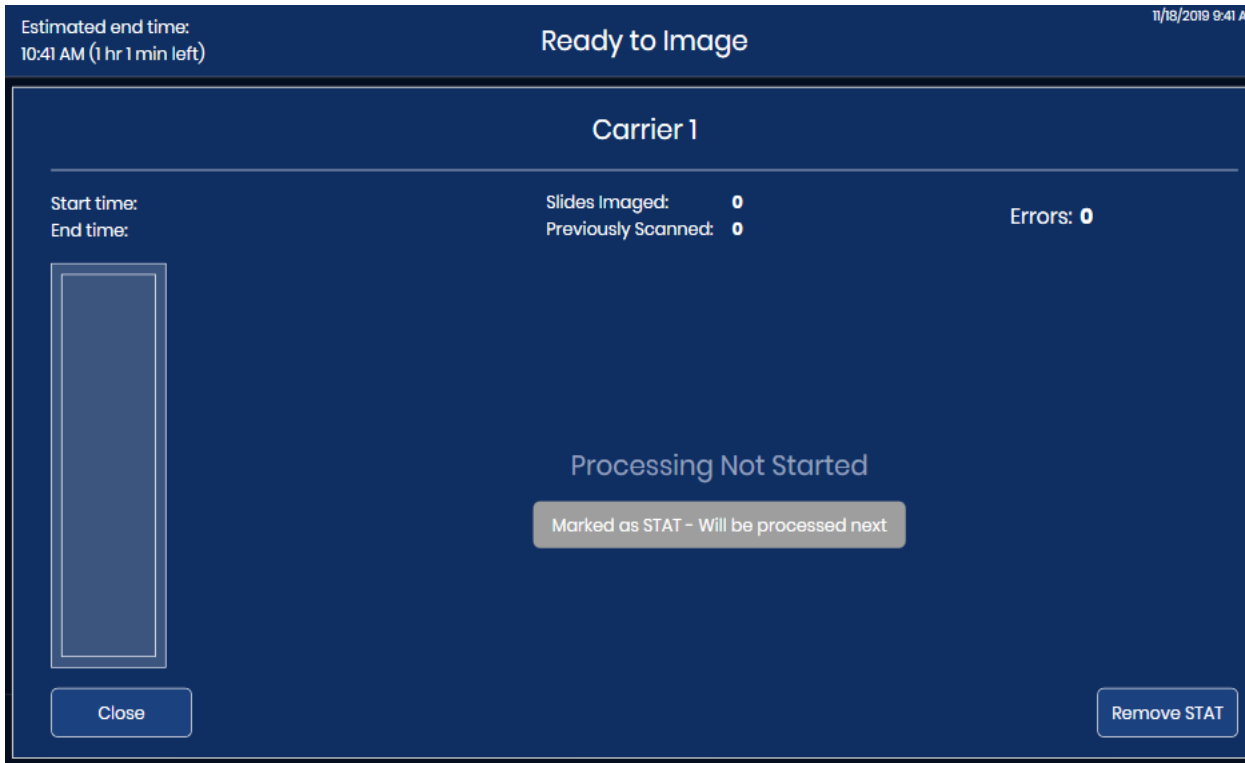
Close button returns to the **Ready to Image** screen

Remove STAT button

Figure 4-21   Stat Interruption Confirmation Message

6. Touch **Close** to exit this screen and proceed with the stat slide(s).
    Or, touch **Remove STAT** to continue processing slides from the slide carrier with unprocessed slides in lowest numbered position towards the slide carrier with the highest numbered position (from left to right).

7. The system processes slide(s) in the stat slide carrier.

    > *Note:* If slides were removed from a slide carrier when processing was paused, for example if a slide is on one of the instrument's stages, the Digital Imager will return those slides to a slide carrier before processing the slides in the stat slide carrier.
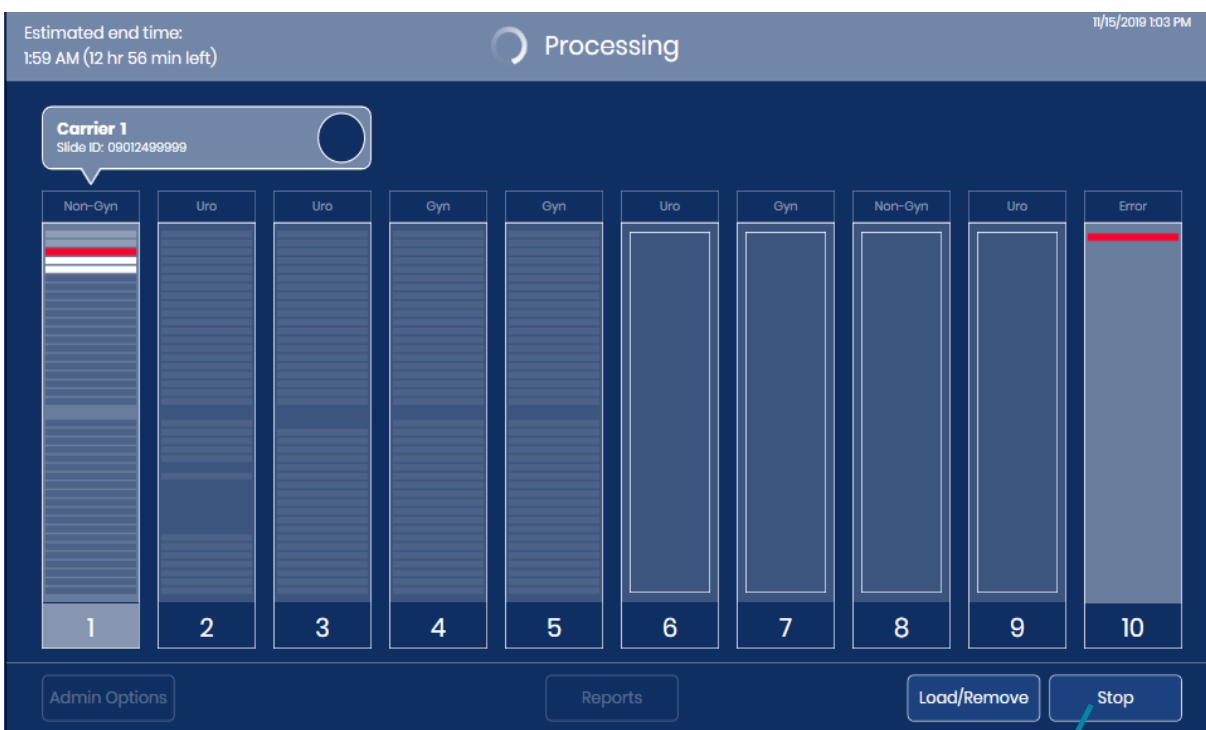
    The progress of the slide(s) in the stat slide carrier cassette displays on the touch screen.

8. When the slide(s) in the stat slide carrier are complete, the processing resumes on the slides from the slide carrier with the lowest numbered position. Use the **Load/Replace** button to remove the stat slide carrier, or wait to remove the stat slide carrier until processing of all the slide carriers completes.

CANCEL PROCESSING

Use the **Stop** button to cancel processing. The **Stop** button is available while the Digital Imager is processing slides. And, the **Stop** button is also available when processing has been interrupted with the **Pause** button.

Figure 4-22   Stop Button

The instrument will finish the current step for any slides in progress and return those slides to a slide carrier.

Select "Yes" on the confirmation screen to continue with shutdown.

The touch screen display returns to the "Ready to image" main screen.

SHUTTING DOWN THE DIGITAL IMAGER

WARNING: Never turn off power to the equipment without shutting down the system via the user interface!

The Digital Imager is intended to be left on. In the event that the Digital Imager needs to be powered down, follow these instructions.

Normal Shutdown

Digital Imager computer
1. Stop any slide processing, or wait until the Digital Imager is idle.
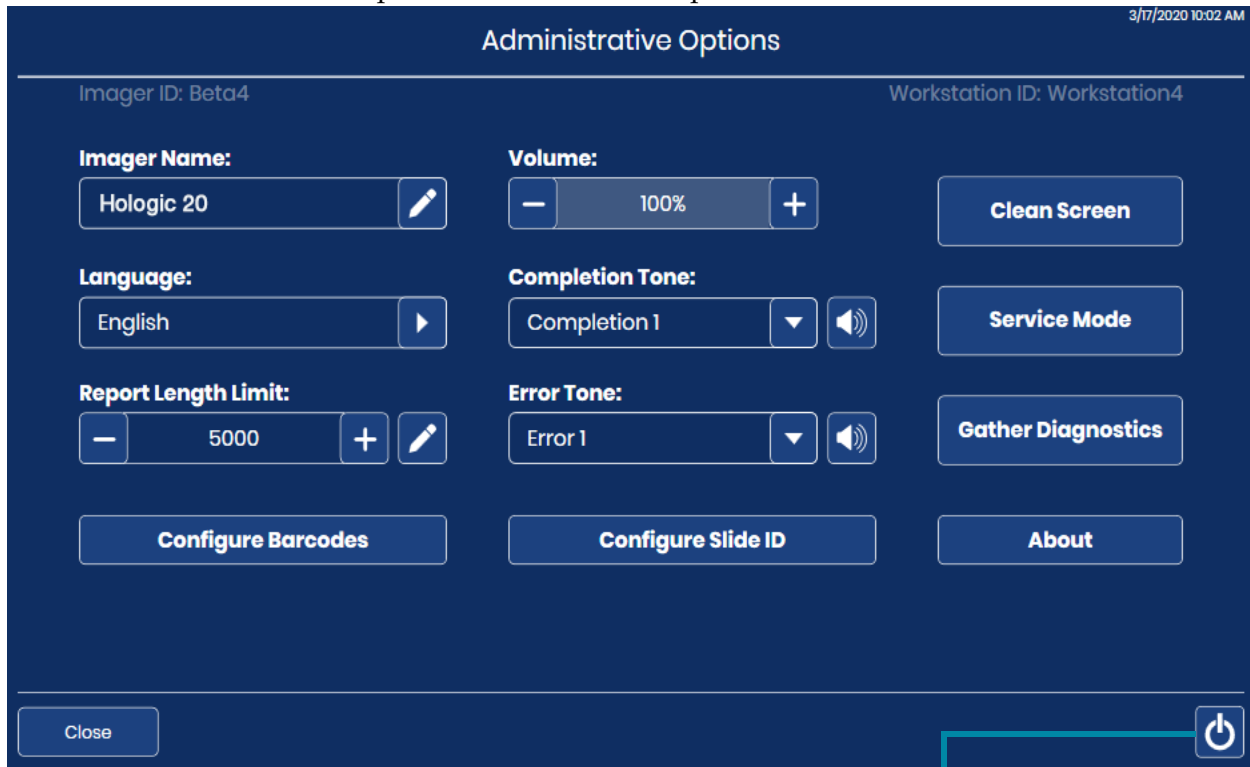2. On the main screen, touch **Admin Options**.
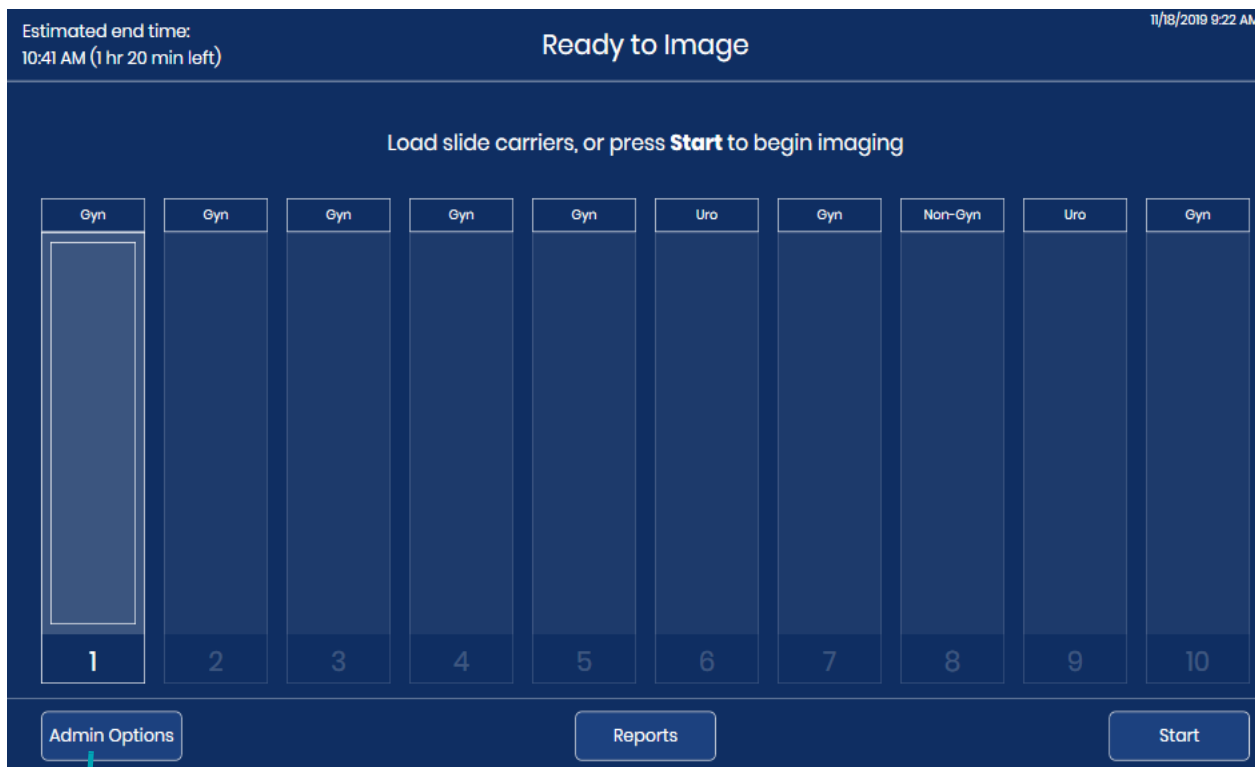
Admin Options button

Figure 4-23   Touch Admin Options from Main Screen

3. On the Administrative Options screen, touch the power button.

Power button to turn off the Digital Imager computer

Figure 4-24   Power Button on the Touch Screen

4. Select "Yes" on the confirmation screen to continue with shutdown. (See Figure 4-25).
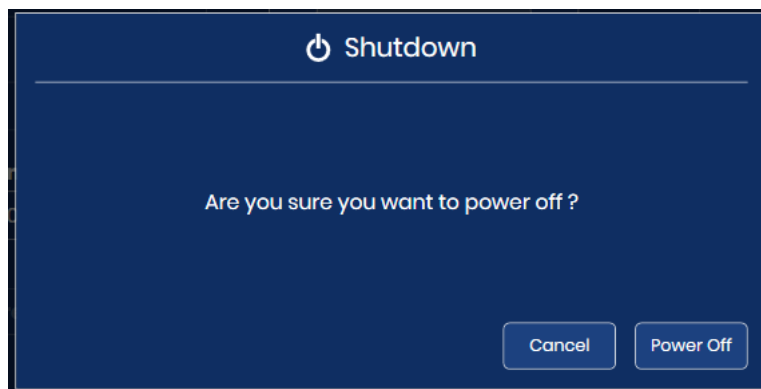

Figure 4-25   Confirm Shutdown

5. The Digital Imager computer powers down. The touch screen on the Digital Imager processor and the status indicator lights turn off.

Digital Imager

1. To completely remove power from the Digital Imager, after the Digital Imager computer is shut down, press the rocker switch on the back of the Digital Imager. See Figure 1-7.

Shutdown Due to Power Outage

If a power outage condition occurs, when power is restored, follow the normal instructions for turning on the instrument. Refer to "Applying Power to the Equipment" on page 4.3.

Taking the Instrument Out of Service (Extended Shutdown)

In the event the equipment must be moved after installation, contact Hologic Technical Support. Refer to Chapter 8, Service Information.

If the Digital Imager is to be shut down for an extended time, follow the shutdown instructions on "Shutting down the Digital Imager" on page 4.35.

Remove any slide carriers from the Digital Imager and safely store any patient slides.

Close the door.

Unplug the power cord to the Digital Imager.

SECTION
M   REBOOTING THE SYSTEM

If the Digital Imager is being rebooted for any reason:

1. Shut down components as described in "Shutting down the Digital Imager" on page 4.35.
2. Allow 15 seconds to pass before powering on the Digital Imager and the Digital Imager computer.

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Chapter Five

Digital Imager Maintenance

The system must be maintained regularly in order to ensure reliable performance. Perform maintenance on the system as described in this section. The system requires supplemental preventive maintenance annually by Hologic service personnel.

|	
Weekly, or more frequently	Clean the Queue Station and Slide Grippers
	Clean the Slide Carrier Deck
	Clean Slide Carriers
As needed	Clean the Verification Chip
	Clean the Touch Screen
	Clean the Exterior of the Imager

SECTION A

WEEKLY

The weekly maintenance tasks can be performed more frequently, depending on instrument usage in your laboratory.

Clean the Queue Station and Slide Grippers

1. Wait until the instrument is idle (not processing slides). Open the window.
2. Wipe any glass dust and debris from the queue station and the slide grippers in the Digital Imager with a lint-free wipe, dampened with deionized water.
3. Then, wipe the queue station and the slide grippers with a lint-free wipe, moistened with 70% alcohol. Allow the queue station and slide grippers to dry before using the processor.

WARNING: Sharp edges

The slide gripper fingers have sharp edges. Use caution when cleaning the slide gripper fingers.
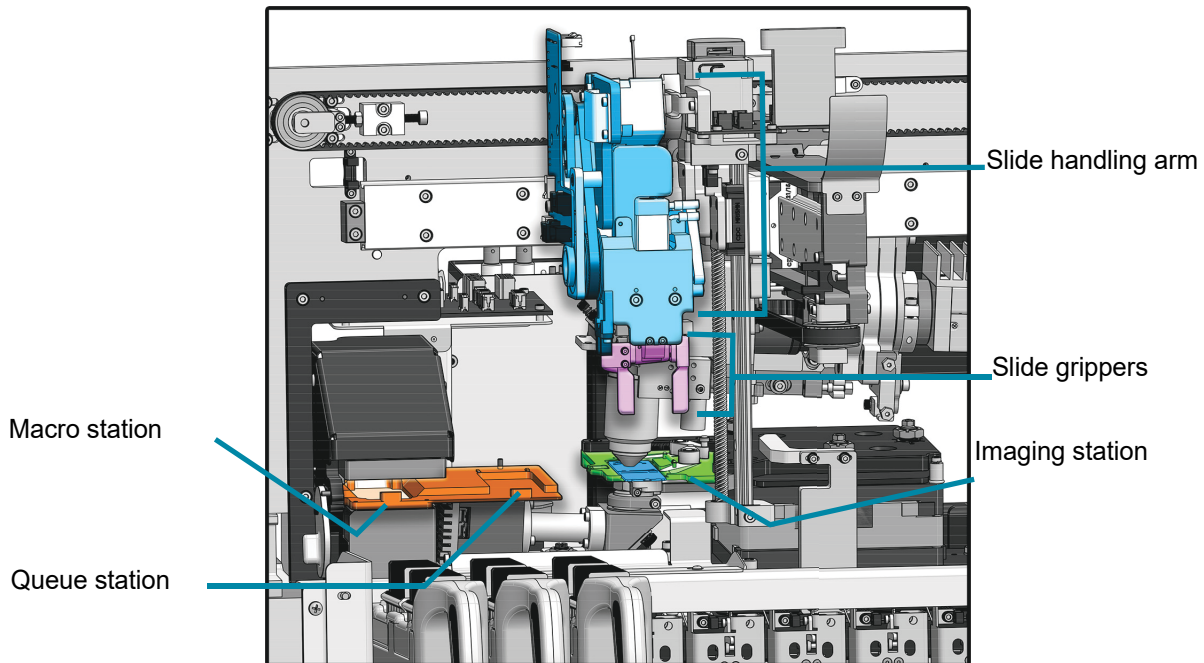
Interior of the Digital Imager - covers removed to show detail

Figure 5-1   Macro Station, Queue Station, Imaging Station and Slide Gripper

WARNING: Glass

The instrument 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 cleaning the instrument.

Clean the Slide Carrier Deck

On a weekly basis, clean around the bottom of the processing area, using 70% alcohol and lint-free wipes. Wear gloves while cleaning.
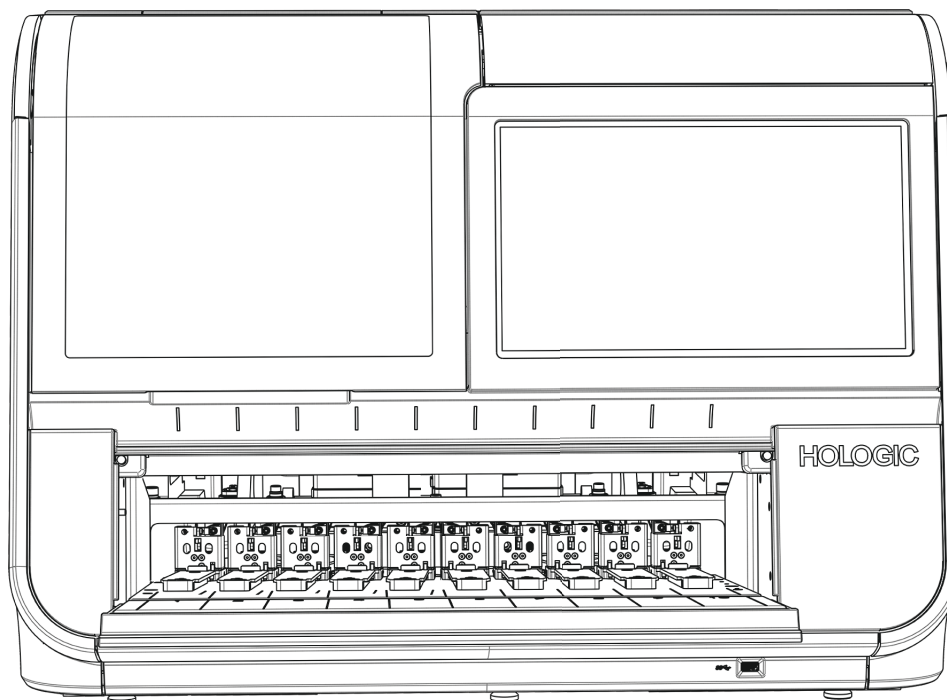
Remove all slide carriers from the Digital Imager.

Figure 5-2   Remove Slide Carriers to Wipe Slide Carrier Deck

Wipe any glass dust and debris from the slide carrier deck, the rails that hold the slide carriers, and the interior of the door. See Figure 1-9.

Do not spray the interior of the Digital Imager with water or any cleanser.

CAUTION: To avoid damaging the sensors at the back fo the loading area, do not touch the mechanism and sensors at the back of the loading area.

Clean Slide Carriers

Clean an empty slide carrier, without any slides or staining racks in it, with soap and water.

The optional cover for a slide carrier can also be cleaned with soap and water.

Allow the slide carrier and cover to dry completely before using them.

Clean the slide carriers when they are not loaded into the Digital Imager.

AS NEEDED

Clean the Verification Chip

The imaging stage is delicate. It must be in the same position and free of scratches for proper performance of the Digital Imager. The verification chip or "V-chip" is a small piece of slide glass permanently attached to the imaging stage.

Over time, dust builds up on the imaging stage, and the verification chip needs to be cleaned with a manual air blower or a combined lens blower/cleaning brush designed for cleaning lenses.
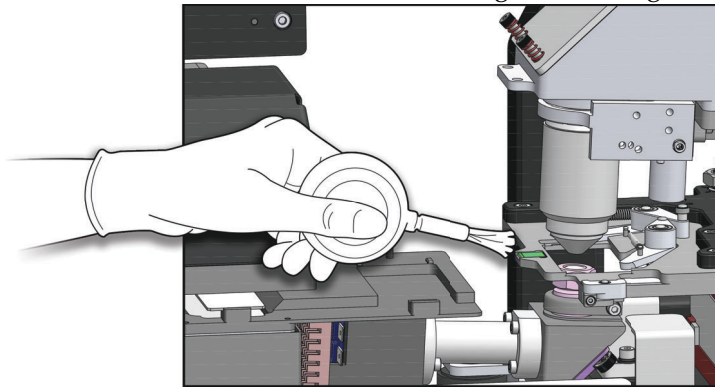

Figure 5-3   Clean the Verification Chip

1. With the Digital Imager idle, open the window. Wear clean, nitrile gloves and avoid touching the stage surfaces.
2. Squeeze the bulb of the air blower with compressor or the combined lens blower/brush, to gently blow the dust from the verification chip.
3. Close the window.

CAUTION: Do not use propellant, like canned air, because the components around the verification chip could be damaged. Do not wipe the verification chip because it or the components near it could be scratched by debris.

Clean the Touch Screen

Clean the user interface touch screen with a lint-free cloth lightly dampened with 70% alcohol.

1. From the main screen, select **Admin Options**. Then, select **Clean Screen**.

Figure 5-4   Clean Screen Button

2. On the confirmation screen, touch **OK** to lock the touch screen so that the touch screen can be cleaned. To cancel and return to the Administrative Options screen, touch **Cancel**.
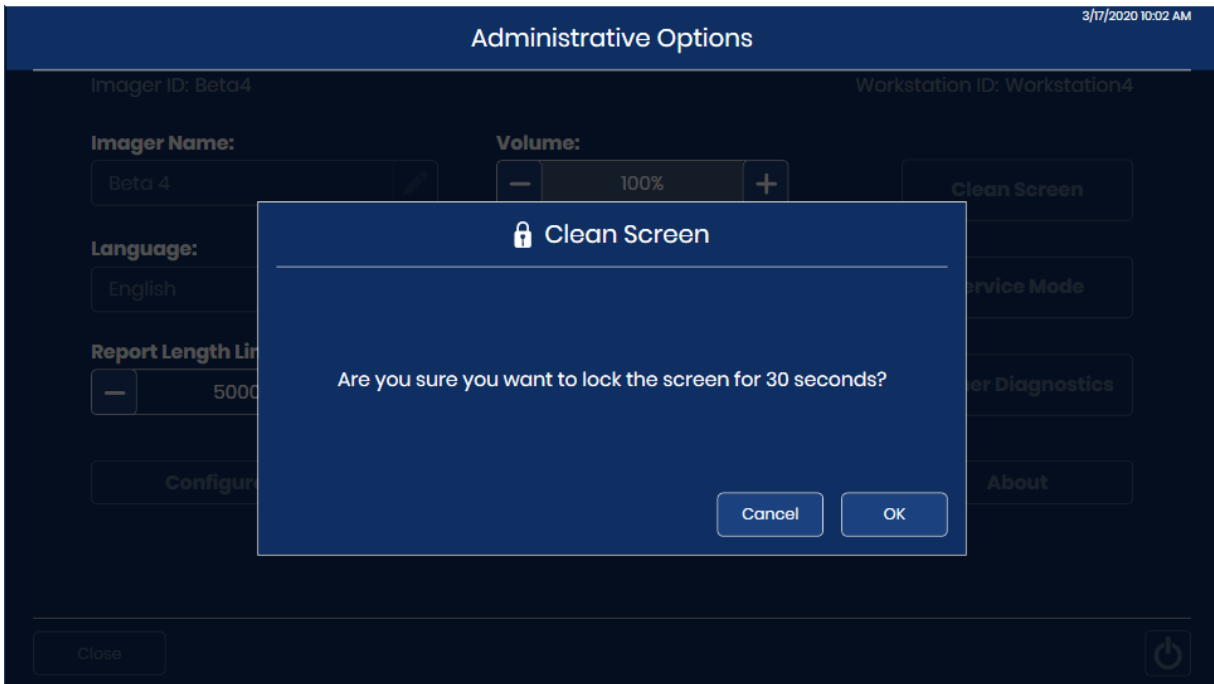

Figure 5-5   Confirm That the Touch Screen Will Be Disabled for Cleaning

3. The system disables the touch screen for 30 seconds so that the touch screen may be cleaned without inadvertently activating buttons or having to power off the Digital Imager.
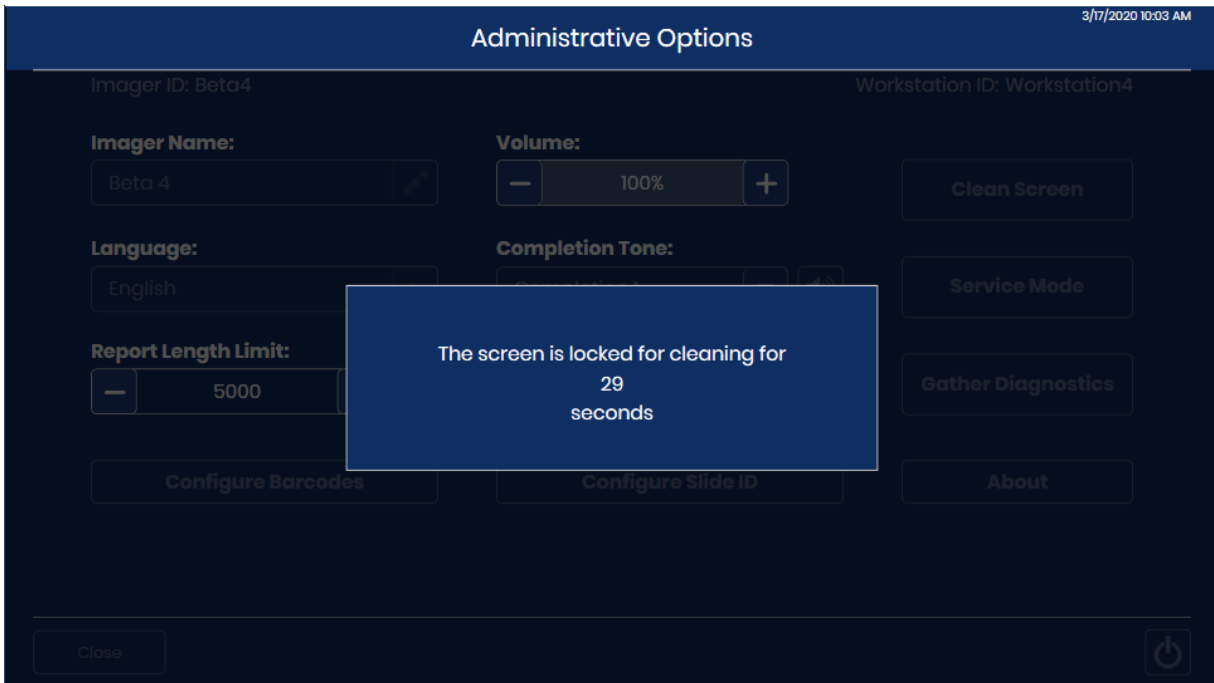
Figure 5-6   Clean Screen Counts Down 30 Seconds

Caution: Do not put the door or the touch screen on the Digital Imager in contact with strong solvents such as xylene, which may damage the surface of the door or the touch screen.

Clean the Exterior of the Imager

To clean the window, it is best to use a commercially available glass cleaner. Open the window and clean the inside surface with a lint-free wipe. Close the window and clean the outside surface of the Digital Imager with a lint-free wipe.

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MOVING THE IMAGER

If it becomes necessary to change the location of your Digital Imager and Digital Imager computer, contact Hologic Technical Support or your local Hologic distributor. A service visit is required.

Unit Shipped to New Location:

If the Digital Imager is to be shipped to a new location, please contact Hologic Technical Support or your local Hologic distributor. Refer to Chapter 8, Service Information.

Genius Digital Imager

Routine Maintenance for the month of: _____

Date	Weekly			As Needed		
	Clean Queue Station and Slide Grippers page 5.1	Clean Slide Carrier Deck page 5.2	Clean Slide Carriers page 5.3	Clean the Verification Chip page 5.4	Clean Touch Screen page 5.4	Clean Exterior of Digital Imager page 5.6
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C h a p t e r   S i x

Troubleshooting

NO CONNECTION TO THE IMAGE MANAGEMENT SERVER

The Digital Imager must have an active connection to the Image Management Server in order to image slides or display data describing slides.

If communication between the Digital Imager and Image Management Server is disrupted, the banner across the top of the touch screen display turns red. Slides cannot be imaged until after the connection with the Image Management Server is restored.
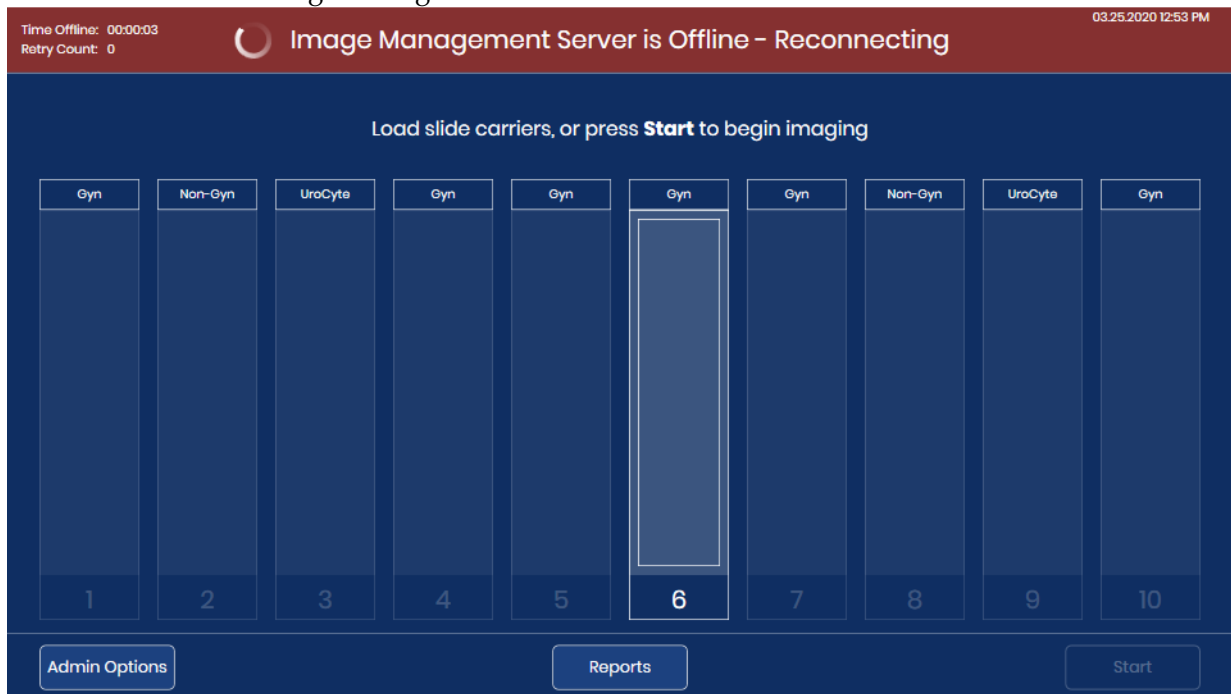

Figure 6-1   No connection between Image Management Server and Digital Imager

Check that the cable to the Image Management Server is properly connected to the Digital Imager computer. Check that the Image Management Server is up and running. This may require assistance from your facility's network administrator.

SLIDE EVENTS

The Digital Imager errors sort into two groups: Slide Events and Imager Errors.

During processing, slide events are logged in a file and depicted on the user interface with a red stripe in the status of a slide carrier. To see the details of a slide event while the Digital Imager is still processing a slide carrier, touch the rectangle representing the slide carrier as shown in Figure 3-6. To generate a Slide Event Log, refer to "Slide Event Log" on page 3.42.

When an error carrier is used, Slide Events are also listed in the Error Carrier Report. Refer to "Error Carrier Report" on page 3.53.

Slide events indicate some condition of the slide that makes the imaging process not possible (with the exception of the slide already imaged). When processing is completed or stopped, inspect the specific slides listed in the slide event log to see if the slide problem can be corrected and the slide imaged in another run.

Note: If a slide is not successfully processed by the Digital Imager, its images cannot be reviewed at the Review Station.

The following is a list of Slide Events. The slide is not imaged when there is a slide event.

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action
E0001	**Slide was scanned previously**	The slide has been imaged.	The slide may undergo review at the Review Station.
		Duplicate slide accession ID.	Use the Slide Lookup query (page 3.41). Confirm if the ID is unique. If there is a duplicate, reconcile both patient records; re-label one and reprocess the slide.

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action
E0002	Slide barcode could not be read	Wrong kind of slide or slide label.	Confirm that a ThinPrep microscope slide is being used. Check that the Digital Imager is configured to read the barcode format or OCR format used in your lab. Refer to "Configure Barcodes" on page 3.22.
		Wrong accession ID format. Slide ID misprint.	Check the condition of the label and that the ID is in a format that the Digital Imager can read. Refer to "Slide Labeling" on page 4.7.
		Slide not loaded in slide carrier correctly.	Load the slide into the slide carrier with the label face up and away from the slide carrier handle.
		Possible malfunction at the macro station.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0007	Slide imaging failed due to focus QC	Slide label extending beyond the right-hand side of the slide label area, causing the slide to not sit properly in the imaging stage	Check that the slide label is applied properly, without overhang.
		Possible instrument slide scanning issue	Attempt to process the slide again. If the error persists, contact Technical Support.
E0009	Slide imaging failed due to oversaturated frames	Possible issue with imaging frequency or illumination during imaging.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0010	Slide imaging failed due to an imaging stage disturbance	The stage moved or was disturbed during imaging.	During operation, the Digital Imager is sensitive to vibrations. It should be placed on a sturdy flat surface away from centrifuges, vortexors or any equipment that may cause vibrations. Keep away from other environmental activity, such as constant foot traffic, proximity to elevators or doors that are frequently open and shut.
E0013	Barcode contains invalid characters	The barcode for the slide ID has characters that are not accepted by the Digital Imager for that barcode type.	Label the slide with the correct ID format. Refer to Table 4.1 on page 4.7.

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action
E0014	**Failed to grip at macro. Slide manually removed by operator**	The slide gripper failed to properly grip a slide, or the slide was manually removed by the operator.	If the slide was manually removed by the operator, process the slide again. Check that the slide is properly coverslipped and labeled. Refer to "Slide Labeling" on page 4.7. If the error persists, contact Technical Support.
E0015	**Failed to parse barcode**	The ID printed on the slide label cannot be used by the Genius Digital Diagnostics System. The ID printed on the slide label is correct and the settings for Configure Slide ID are wrong.	The Configure Slide ID settings on the Digital Imager are too long or too short for the slide. Change the Configure Slide ID settings. Refer to "Configure Slide ID" on page 3.25.
		The settings for Configure Slide ID are correct and the ID printed on the slide label is wrong (too long, too short, does not use a specified character).	Check that the ID printed on the slide label is in the correct format for your lab. Label the slide with the correct ID format.
E0016	**Slide imaging failed due to cell focus error**	Sample collection or slide preparation issue causing the cell spot to be blank or very faint.	Make sure the proper specimen collection procedures and slide preparation procedures are followed. Refer to the instructions in the ThinPrep processor operator's manual.
		An issue with the Digital Imager has the slide in a position that is difficult to image.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0004, E0005, E0006, E0008, E0011, E0012, E0017, E0018	Slide processing events	---	Attempt to process the slide again. If the error persists, contact Technical Support.

SECTION C — IMAGER ERRORS

There are three types of Digital Imager errors: system self-recoverable errors, user-correctable errors and unrecoverable errors.

All Digital Imager errors are logged to a file, which may be accessed via the user interface. Refer to "Imager Error Log" on page 3.45.

System Self-recoverable Errors

These automatically recoverable errors are Digital Imager errors that do not require user or service personnel intervention. When the Digital Imager encounters such an error condition during processing, it has a sequence of steps to perform to recover from the condition.

When the Digital Imager recovers, the Digital Imager returns to processing slides, continuing from where it stopped prior to the error. A notification box displays the error number and brief description. Touch the **Close** button to acknowledge and close the notification box. (See Figure 6-2.)

If the audible alarm is enabled, the alarm will sound until either the **Silence Alarm** button or the **Close** button is touched. The system status lights flash in red.
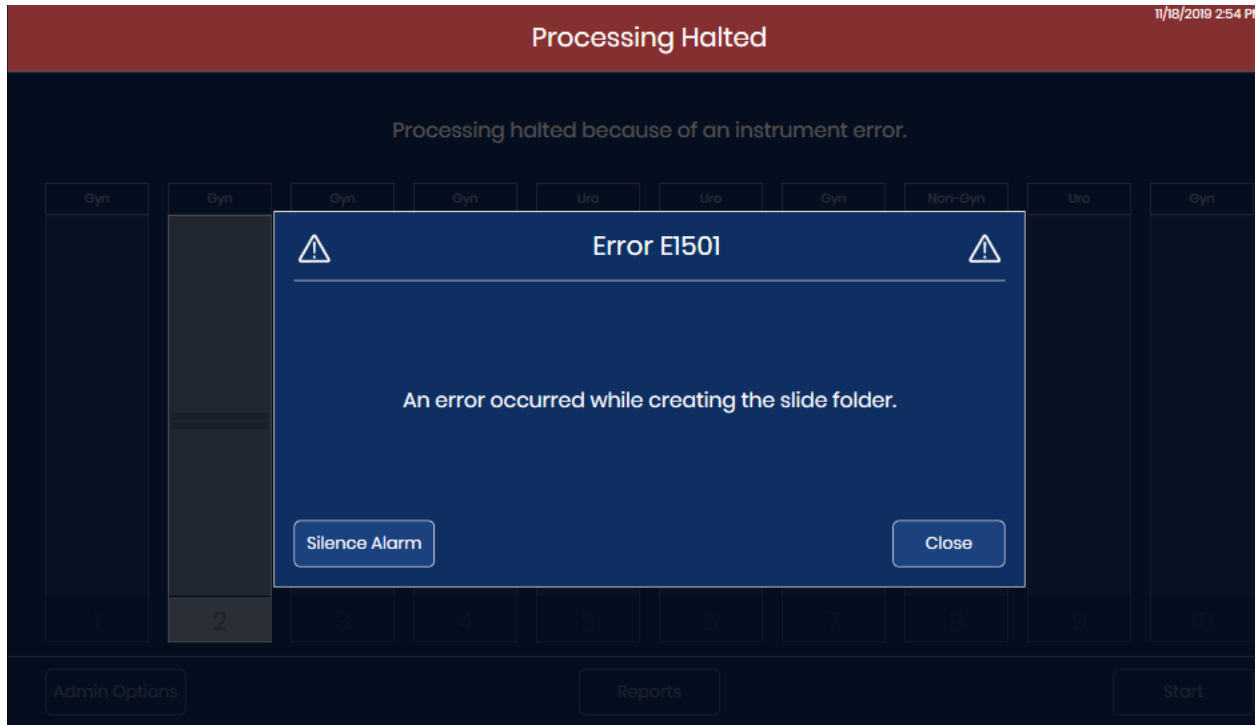

Figure 6-2   User Notification: Recoverable Error

User-correctable Errors

For user-correctable errors, the Digital Imager needs assistance from the user to recover from the error. When the Digital Imager encounters a user-correctable error condition during processing, it

has a sequence of steps to perform to recover from the condition. One or more steps requires an action from the operator, typically assisting in moving a slide.
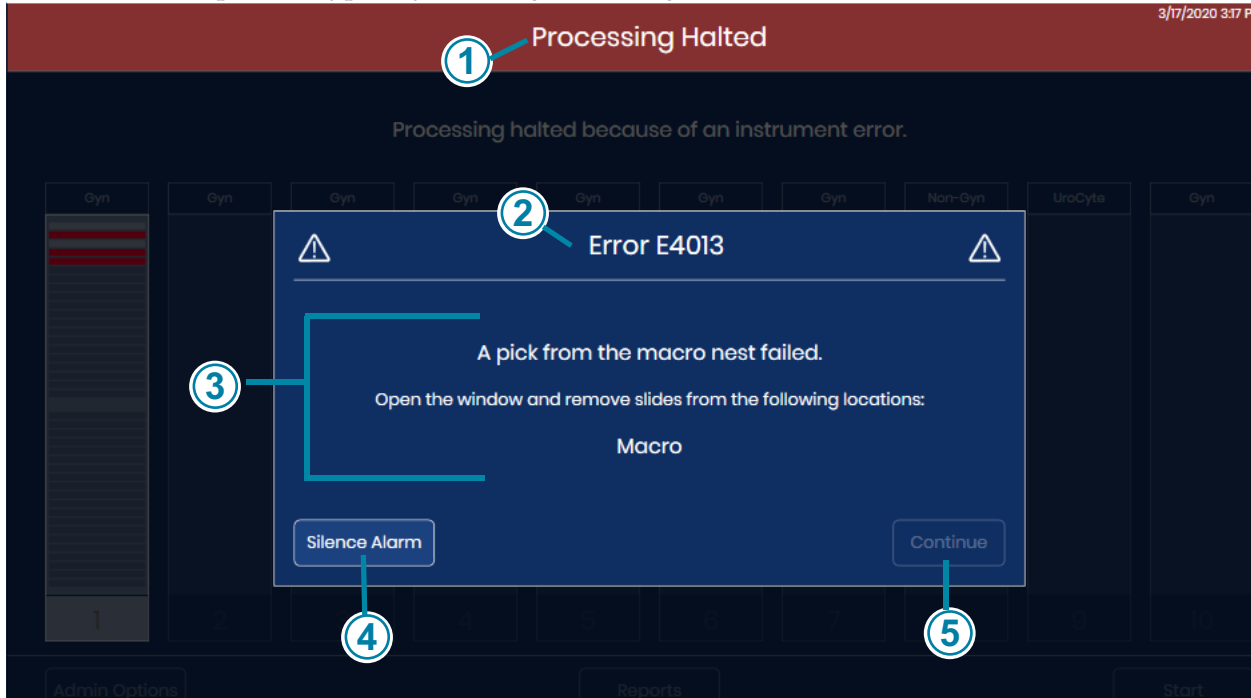
Figure 6-3   User-correctable Error (Example)

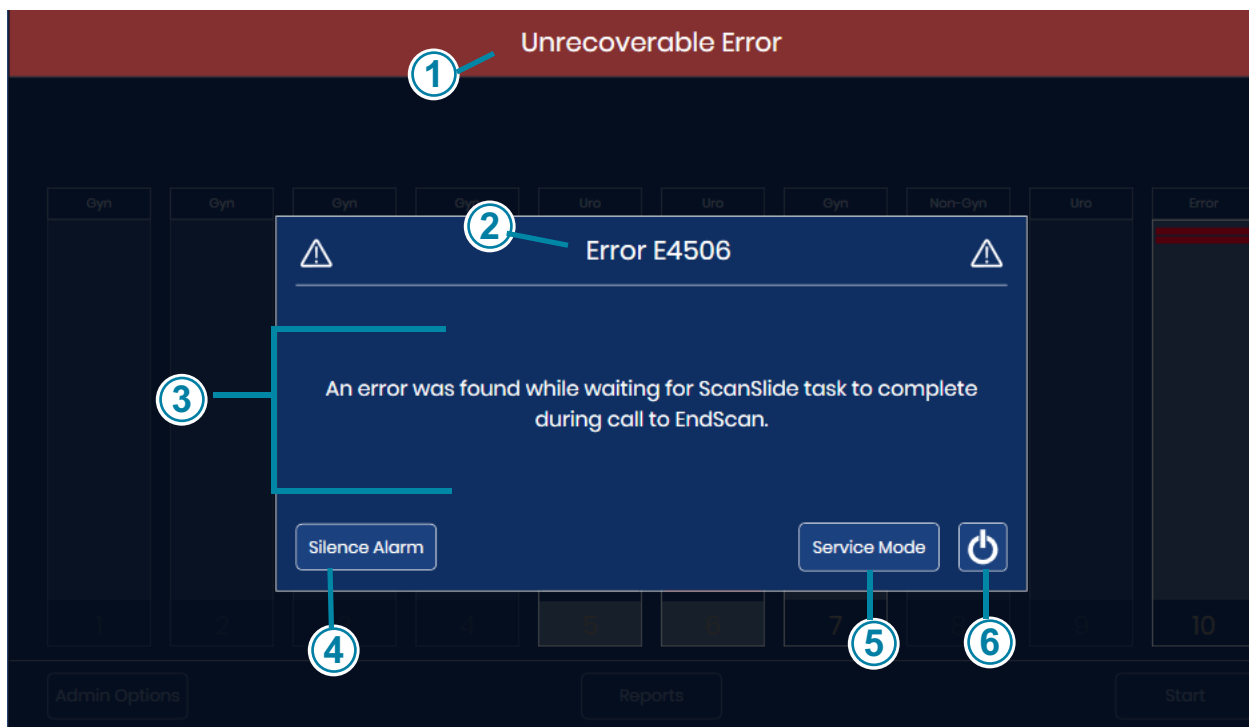| Key to Figure 6-3	
①	The touch screen display says that processing is halted in a red banner at the top.
②	The error code is displayed.
③	In addition to a description of the error, the error message provides instructions for the operator.
④	If the audible alarm is enabled, the alarm will sound until either the **Silence Alarm** button or the **Close** button is touched. The system status lights flash in red.
⑤	For user-correctable errors, the **Close** button is available after the operator assists in the error recovery. In this example the **Close** button will be available after the operator opens the window and removes the slide from the macro nest.

When the Digital Imager recovers, the Digital Imager returns to processing slides, continuing from where it stopped prior to the error.

Unrecoverable Errors

For unrecoverable errors, the Digital Imager must be restarted to attempt recovery. In some cases, the Imager may require a Hologic service visit.

When an unrecoverable error condition is encountered, slide processing is interrupted. The recovery requires a shutdown and restart of the Digital Imager.

If the audible alarm is enabled, the alarm will sound until either the **Silence Alarm** button or the **Close** button is touched. The system status lights flash in red.

Figure 6-4   Unrecoverable Imager Error, Restart Required

The window displays the error number, a brief description of the error and a power button.

Key to Figure 6-3	
①	The touch screen display says it has an unrecoverable error in a red banner at the top.
②	The error code is displayed.

Key to Figure 6-3	
③	A description of the error is displayed.
④	If the audible alarm is enabled, the alarm will sound until either the **Silence Alarm** button or the instrument is powered down. The system status lights flash in red.
⑤	With non-recoverable errors, a **Service Mode** button is available on the error notification. The service mode is for Hologic service personnel and is password-protected.
⑥	With non-recoverable errors, the power button is available on the error notification. To attempt error recovery with a restart or to shut down the instrument, press the power button.

1. If the alarm is playing and you wish to silence the alarm, press the **Silence Alarm** button.

Note: To avoid the "slide already processed" slide event once the Digital Imager restarts, remove slide carriers whose slides have been imaged from the Digital Imager before shutting down the Digital Imager. When the Digital Imager shuts down, it loses track of where in the batch it stopped. When it restarts, the Digital Imager conducts a new inventory of the slide carriers, and it will attempt to process the slide in the lowest numbered slot of the slide carrier in the lowest position (e.g., slot 1 of the slide carrier in position 1) regardless of whether that slide was processed.

2. Touch the **power** button on the touch screen to shut down the Digital Imager application and to power down the Digital Imager computer.
3. Press the rocker switch on the back of the Digital Imager to turn off the Digital Imager completely.
4. Open the window and remove any slides resting on the macro stage, queue stage or imaging stage. Remove any slide that is noticeable out of place. Do not attempt to remove a slide from the Digital Imager slide gripper.
5. Close the window.

Note: If the error occurred with the empty slide gripper near a slide carrier containing slides, remove the slide carrier from that position. When the Digital Imager starts, it will move the slide gripper in a way that the empty slide gripper might collide with a slide in that slide carrier.

6. Wait 15 seconds.
7. Press the rocker switch on the back of the Digital Imager to turn on the Digital Imager.
8. Upon restart, the Digital Imager attempts all of the usual Power On Self Test (POST) checks.
   A. In some cases, the restart is sufficient to clear the error. When the main screen displays, load slide carriers as needed and touch **Start** to process slides.

B. In other cases, during POST, the Digital Imager will detect one or two slides in a position where user action is necessary to clear the error. Follow the instructions on the touch screen display.

If the Digital Imager detects a slide that it can move to a slide carrier, but no slide carrier is loaded, the touch screen displays instructions to load an empty slide carrier into the Digital Imager.
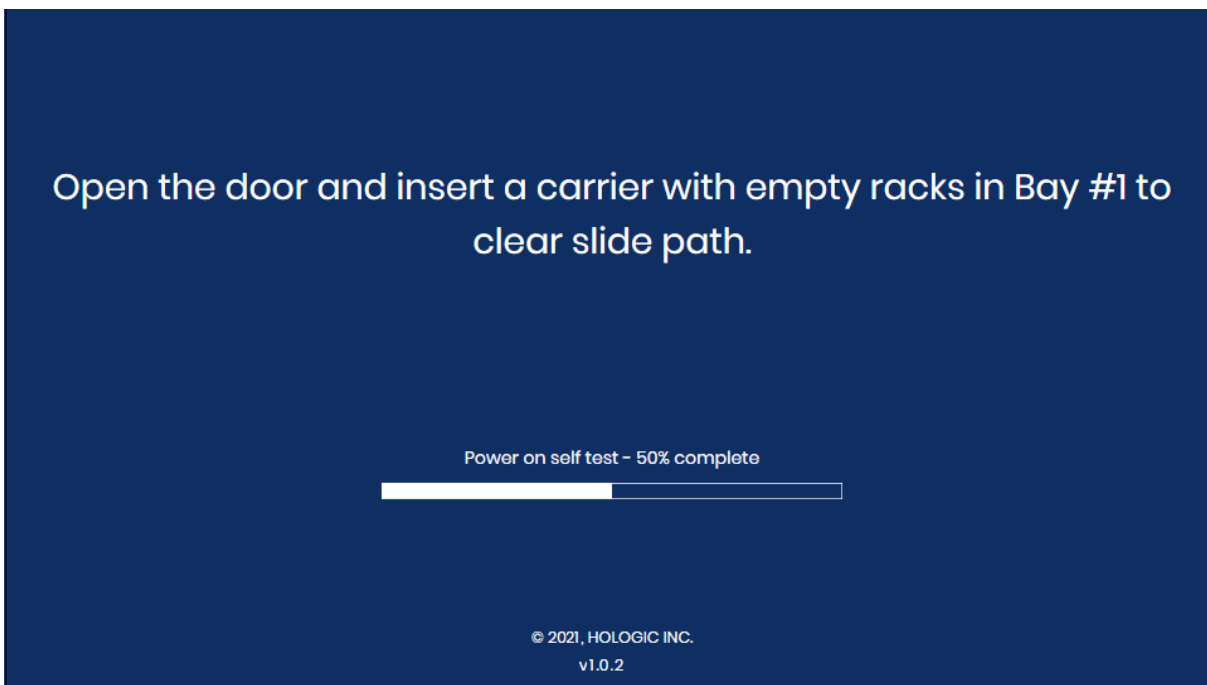

Figure 6-5   User-assisted Error Recovery: Load an Empty Slide Carrier

Load an empty slide carrier in position 1 and close the door.

After the Digital Imager returns the slide(s) to the slide carrier, remove the slide carrier as prompted on the touch screen display.

When the main screen displays, load slide carriers as needed and touch **Start** to process slides.

If the Digital Imager detects a slide that it cannot move to a slide carrier, the touch screen displays instructions to open the window.
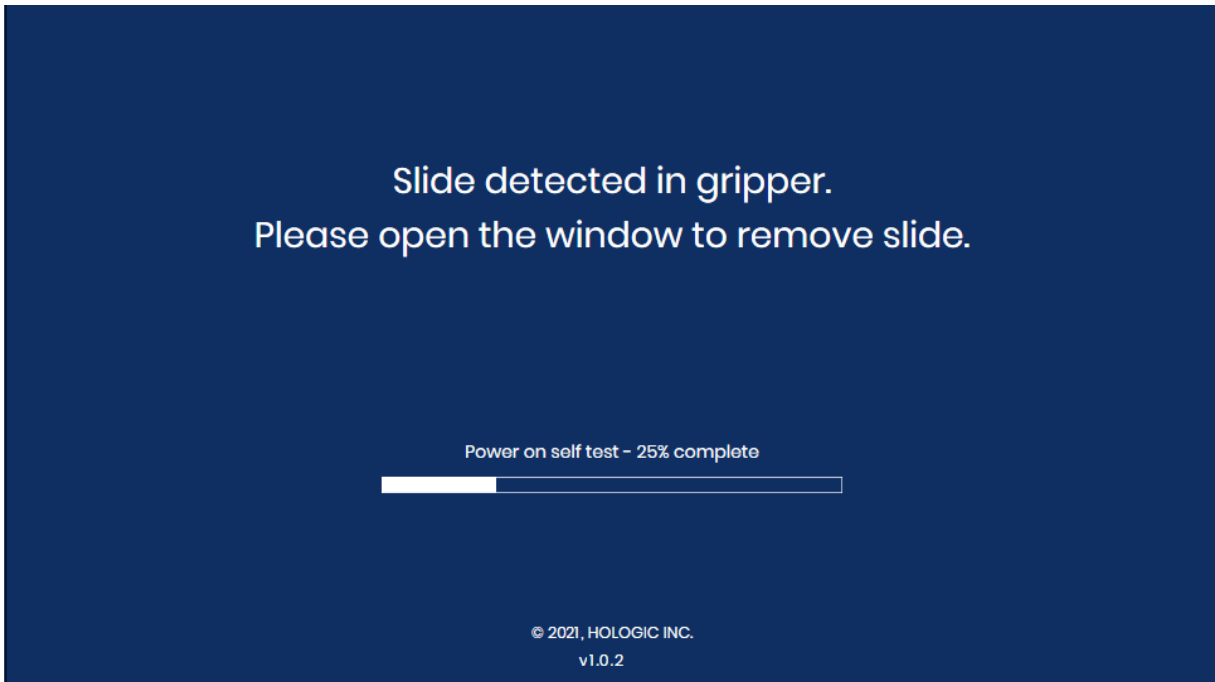

Figure 6-6 User-assisted Error Recovery: Open Window to Remove Slide

- Open the window.
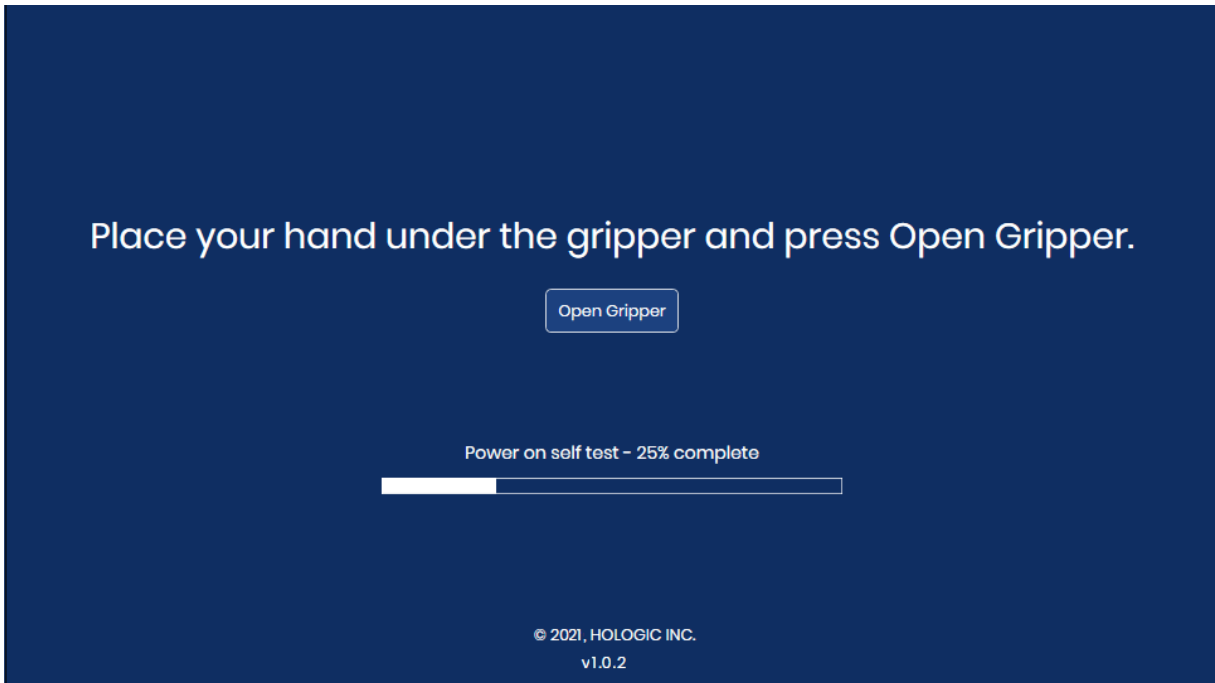- Position a gloved hand below the slide gripper.

Figure 6-7   Ready to Press Open Gripper

- With one hand ready to receive the slide, touch the **Open Gripper** button. The slide gripper opens to release the slide.
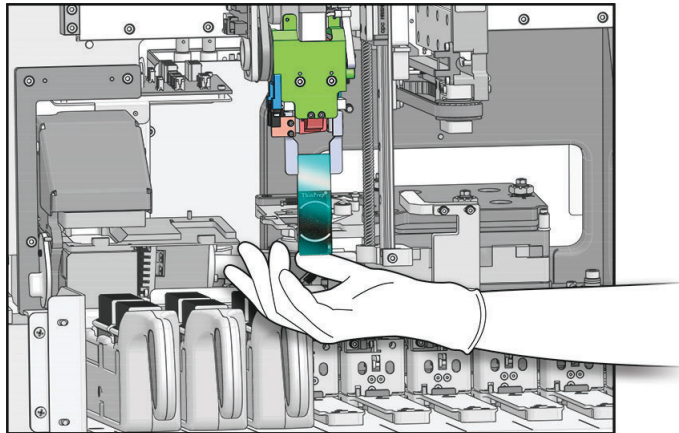

Interior of the Digital Imager - covers removed to show detail

Figure 6-8   Ready to Press Open Gripper

- Retain the slide. The slide has not been imaged successfully by the Digital Imager.

- Close the window. When the main screen displays, load slide carriers as needed and touch **Start** to process slides.

C. And, in other cases, the restart will not clear the error. Contact Hologic Technical Support or your local distributor for assistance. A service visit may be required.

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TROUBLESHOOTING

SECTION D

SLIDE PREPARATION AND QUALITY

Careful preparation of the microscope slides can prevent many types of slide events or system errors. When a slide event or system error occurs, inspect the slide that generated the event.

Correct Slide

When the Gyn sequence is used, only stained, coverslipped ThinPrep® Imaging System microscope slides may be used. The ThinPrep Imaging System microscope slides have fiducial marks. (See Figure 6-9.) Refer to the ThinPrep Stain User's Manual for recommendations for coverslipping media.

For Non-Gyn slides, only stained, coverslipped ThinPrep® non-gynecological microscope slides may be used.

For UroCyte slides, only stained, coverslipped ThinPrep® UroCyte® microscope slides may be used.

CAUTION: The slides must have been processed on a ThinPrep processor.

Make sure the slide is not damaged, fiducial marks are present and unmarred, the slide is not scratched or chipped, the frosted area is unblemished.

Clean any dirt or stain using isopropyl alcohol and a lint free wipe. Be sure to clean the edges of the slide.
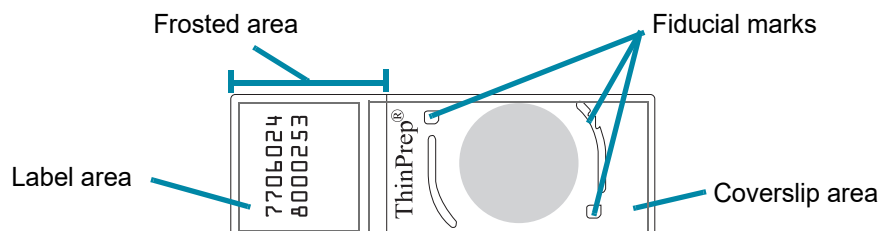

Figure 6-9   ThinPrep Imaging System Microscope Slide for Gyn samples

Dry Mounting Media

The mounting media must be dry before loading slides into the cassettes and imaging them. Wet or tacky mounting media could cause equipment malfunction.

Mounting media should not overhang the edge of the slide. Clean the edges of the slide with xylene and a lint free wipe.

There should not be any bubbles present over the fiducial marks or the cell spot.

Coverslip Material and Placement

Refer to the ThinPrep Stain User's Manual for recommended coverslipping and mounting media.

The coverslip must be placed so that it does not overhang any part of the slide.

Ensure that the coverslip is present and undamaged.

Note: If Sakura Tissue-Tek SCA coverslipping film is used, slides must be cleared with xylene.

Slide Label Format and Placement

The slide label must have the correct accession ID format for the Digital Imager to successfully scan and read the ID. Refer to "Slide Labeling" on page 4.7.

The slide label must be positioned correctly on the slide so that the ID reader can locate it.

The slide label must be clean, undamaged and not overhanging the edge of the slide.

SECTION
E   IMAGER ERROR CODES

Table 6.2 Digital Imager Error Codes

Event code	Event description	Possible cause	Corrective action
E0500 through E0512, E0515	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E0514	**An error was detected while running periodic check.**	Imager conducted a self-check that did not pass.	Power cycle the system. If the error persists, contact Technical Support.
E0516	**The error carrier is full.**	Error carrier contains 40 slides.	Replace the full slide carrier in position 10 with an empty slide carrier.
E0518	**Illumination uniformity across the image is not within specification.**	Illumination is misaligned with the objective, or the V-Chip is damaged, dirty or out of position.	Clean the verification chip. Refer to "Clean the Verification Chip" on page 5.4. If the error persists, contact Technical Support.
E1000, E1001, E1002, E1004, E1005, E1006	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.

Table 6.2 Digital Imager Error Codes

E1003	**The door or window was found open during start unexpectedly.**	Door or window lock failed; user opened door or window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1007	**The door or window was found open during resume unexpectedly.**	Door or window lock failed; user opened door or window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1008 through E1012, E1014 through E1017	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E1013	**The door or window was found open during periodic check unexpectedly.**	Door or window lock failed; user opened door or window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1018	**Unexpected door opening.**	Lock failed to prevent user from opening the door.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1019	**Unexpected window opening.**	Lock failed to prevent user from opening the window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1500 through E1504	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E2000	**An error occurred while starting the process image task.**	The camera fails to produce frames; the stage fails to move.	Power cycle the system. If the error persists, contact Technical Support.
E2001	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E2002	**An error occurred during processing a swath.**	An ImageProcessor component threw an exception.	Power cycle the system. If the error persists, contact Technical Support.
E2003	**An error occurred while waiting for the ending swath.**	Camera failed to produce frames. FocalMerger timed out while merging.	Power cycle the system. If the error persists, contact Technical Support.
E2004	**An error occurred while ending a swath.**	An image processing component threw an exception. Image compression failure.	Power cycle the system. If the error persists, contact Technical Support.

Table 6.2 Digital Imager Error Codes

E2005	**An error occurred while waiting for the image processing task to complete.**	An image processing component threw an exception.	Power cycle the system. If the error persists, contact Technical Support.
E2006 through E4000	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4001	**A slide was found in the gripper at startup.**	The instrument was powered off with a slide in the gripper.	Power cycle the system. After the re-start, follow instrument prompts to remove the slide from the slide gripper. If the error persists, contact Technical Support.
E4003	**The slide handler failed to home.**	Motor move error caused by mechanical obstruction.	Power cycle the system. If the error persists, contact Technical Support. When the instrument is powered down, remove any obstruction.
E4004	**A move to a carrier location failed.**	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4005	**A move to the thumbnail location failed.**	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4006	**A move to the macro location failed.**	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4007	**A move to the queue location failed.**	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4008	**A move to the imaging stage location failed.**	Mechanical interference with one or more axes	Power cycle the system. If the error persists, contact Technical Support.
E4009	**A move to the safe location failed.**	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4010	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4011	**A multiple-axis concurrent motor move failed.**	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4012	**A pick from a carrier failed.**	The slide was not present in the slot or was incorrectly inserted in the slot.	The system will move to the next slide to pick.

Table 6.2 Digital Imager Error Codes

E4013	A pick from the macro nest failed.	The slide on the macro was dropped, or incorrectly placed.	A recovery dialog is displayed.
E4014	A pick from the queue failed.	The slide on the queue was dropped or incorrectly placed	A recovery dialog is displayed.
E4015	A pick from the imaging stage failed.	The slide on the imaging stage was not in the expected location, or the stage was not in the loading position.	Power cycle the system. If the error persists, contact Technical Support.
E4016	Placing a slide in a carrier failed.	The value for the place location in the carrier was incorrectly calculated.	Power cycle the system. If the error persists, contact Technical Support.
E4017	Placing a slide in the macro nest failed.	One or more axis movements failed, or the gripper failed to open.	Power cycle the system. If the error persists, contact Technical Support.
E4018	Placing a slide in the queue failed.	One or more axis movements failed, or the gripper failed to open.	Power cycle the system. If the error persists, contact Technical Support.
E4019	Placing a slide in the imaging stage failed.	One or more axis movements failed, or the gripper failed to open.	Power cycle the system. If the error persists, contact Technical Support.
E4020	The inventory carrier operation failed.	One or more motor axis movements failed, or the inventory sensor read failed.	Power cycle the system. If the error persists, contact Technical Support.
E4022 through E4513	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4514	An error occurred during auto-calibration.	Incorrectly configured V-Chip positions.	Power cycle the system. If the error persists, contact Technical Support.
E4515	Particle defect found during auto-calibration.	Particles on the V-Chip or lens. Incorrectly configured V-Chip position.	Clean the verification chip. Refer to "Clean the Verification Chip" on page 5.4. If the error persists, contact Technical Support.
E4516 through 4518	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.

Table 6.2 Digital Imager Error Codes

E5000	The low-level hardware failed to initialize.	CAN bus communication failure. Hardware failure.	Check that the system has a power connection. Power cycle the system. If the error persists, contact Technical Support.
E5002	The gripper failed to home.	The gripper motor move operation failed.	Power cycle the system. If the error persists, contact Technical Support.
E5003	The gripper failed to open.	The gripper motor move operation failed.	Power cycle the system. If the error persists, contact Technical Support.
E5001, E5004 through E6001	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E6002	Failed to connect to post scan service.	Post Scanning Service is disconnected.	Power cycle the system. If the error persists, contact Technical Support.
E6003 through E6006	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E6007	Server error	Network disruptions, Server Side Error	Contact your laboratory's system administrator to power cycle the Image Management Server. Power cycle both the Digital Imager system and the Image Management Server. If the error persists, contact Technical Support.
E6500	The workflow proxy cannot connect to the workflow server.	Workflow server is down, IIS in Workflow is not running, or Imager Service in Workflow is not running.	Contact your laboratory's system administrator to power cycle the Image Management Server. Power cycle both the Digital Imager system and the Image Management Server. If the error persists, contact Technical Support.

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TROUBLESHOOTING

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C h a p t e r   S e v e n

Definitions and Abbreviations

Cell Spot

The area within the pre-printed arcs on a ThinPrep® microscope slide that contains the patient sample cells.

Fiducial Marks

Permanently printed features on the ThinPrep Imaging System microscope slides, used as a reference axis to establish the position of Objects Of Interest for Gyn samples processed on the Digital Imager. The fiducial marks are also used to register the slide position on the imaging stage at the beginning and end of slide imaging.

Gallery

On the Review Station, for slides that have been analyzed by Genius Cervical AI the gallery is the group of objects of interest, separated into square tiles, displayed in the left-hand side of the Review Station display.

Image Management Server

The Image Management Server is the computer server that controls communication between the Genius Digital Diagnostics System components. The server also stores the slide images and slide data record.

OCR

Optical Character Recognition. The Digital Imager contains a scanner with Optical Character Recognition. Refer to "Configure Barcodes" on page 3.22

OOI

Object of Interest. A cell or cluster on a slide preparation that most likely contains clinically relevant information for diagnostic purposes. For cervical cancer screening of Gyn samples, OOIs are identified and selected by the Genius Cervical AI algorithm.

Power Cycle

Turning the Imaging System off and then on again, usually to clear an error condition. Refer to "Shutting down the Digital Imager" on page 4.35 before turning off power to any of the components.

Slide Carrier

The container that holds staining racks with slides for processing. Each slide carrier may hold up to 40 slides. The slide carriers are designed to hold slides securely in the Digital Imager during slide processing. There are positions for 10 slide carriers to be loaded into the Digital Imager. An optional slide carrier cover is available to protect slides in the slide carrier when the slide carrier is not loaded in the Digital Imager.

Slide Data Record

The case data record. The data associated with a specific accession ID/slide. The data is stored on the server database. It is generated at the time a slide ID is successfully scanned in the Digital Imager prior to imaging. The data record is updated when the slide has been imaged and image analysis completed. The data record is updated again when the case is reviewed at the Review Station.

Slide Event

Slide events are errors that occur during slide processing. During processing, on the touch screen display, a red stripe in the carrier graphic represents a slide event, whose description can be viewed by opening the slide details screen. After processing, slide events are listed in the slide events log, the Imaging Report and, if your lab uses an error carrier, in the error carrier report.

ThinPrep® Imaging System Microscope Slide

A specific brand of glass microscope slide, used with the ThinPrep processors. The slide has features on it that enable automated registration of the slide with the Digital Imager.

1-D barcode

One-dimensional or linear barcode. The Digital Imager contains a scanner that can be configured to read slide IDs in a certain 1-D barcode formats. Refer to "Configure Barcodes" on page 3.22 for the available types.

2-D barcode

Two-dimensional barcode. The Digital Imager contains a scanner that can be configured to read slide IDs in a certain 2-D barcode formats. Refer to "Configure Barcodes" on page 3.22 for the available types.

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C h a p t e r   E i g h t

Service Information

Corporate Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

Customer Service

Product orders, which include standing orders, are placed through Customer Service by phone during business hours. Contact your local Hologic representative.

Warranty

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

Technical Support

For technical support, contact your local Hologic Technical Solutions office or your local distributor.

For questions about Digital Imager issues and related application issues, representatives from Technical Support are available in Europe and the UK by phone 8.00 to 18.00 CET Monday through Friday, at TScytology@hologic.com and via the toll-free numbers listed here:

Finland	0800 114829
Sweden	020 797943
Ireland	1 800 554 144
United Kingdom	0800 0323318
France	0800 913659
Luxemburg	8002 7708
Spain	900 994197
Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	0800 8002 9892

8 | SERVICE INFORMATION

Protocol for Returned Goods

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

Chapter Nine

Ordering Information

Mailing Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

Remittance Address

Hologic, Inc.

PO Box 3009

Boston, MA 02241-3009 USA

Customer Service

Product orders, which include standing orders, are placed through Customer Service by phone during business hours. Contact your local Hologic representative.

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.

Reordering Supplies for the Digital Imager

From Hologic

Item	Description	Quantity	Part Number
Slide carriers, 10-pack	Additional slide carriers	10 slide carriers	ASY-14299
Slide carrier covers, 10-pack	Optional cover for storing slides in a slide carrier	10 covers	ASY-14300
Slide staining rack, Sakura 4768	Additional slide staining racks	10 racks	51873-001
Air blower	Air blower for cleaning the v-chip	ea.	MME-04132
Air blower/brush	Combination air blower/brush for cleaning the v-chip	ea.	MME-04131
Operator's Manual	Additional operator's manual	ea.	MAN-08022-001

From other suppliers

Supplier	Description	Part Number
Leica	Slide staining rack, Sakura type	14 0474 33463

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Label Specifications for Use with the ThinPrep® Imaging System

The following information provides specifications for slide labels
used with the ThinPrep Imaging System.

Slide Accession IDs

Cyclical Redundancy Check (CRC)

Of the 14 numeric characters of the Accession ID, the last three numerals are the CRC. These are automatically generated when the label software creates the series of Accession IDs. The Imaging System uses these numerals to confirm that it read the ID correctly. (Refer to Figure 1.)

Reserved Numbers

A range of numbers has been reserved for use by Hologic personnel. Do not use slide IDs within this reserved range at risk of losing patient data during a service visit.

Any slide ID with the four digits before the CRC as '9999' is a reserved number. These will be removed from your patient database at the time of a service call. (Refer to Figure 1.)

Starting with an even-numbered accession ID and incrementing the IDs by two (2) is one way to avoid conflict with the reserved numbers.
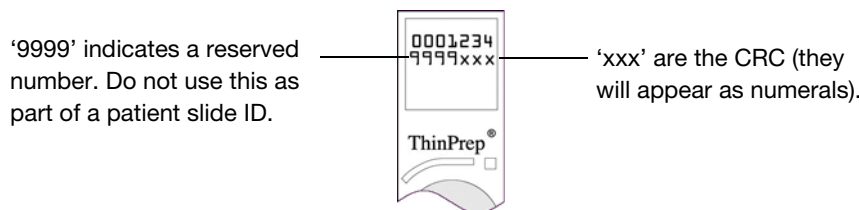
'9999' indicates a reserved number. Do not use this as part of a patient slide ID.

'xxx' are the CRC (they will appear as numerals).

Figure 1 Accession ID

Required Format

Xylene-resistant 52-lb. label stock on backing roll or sheet, with clear laminate and rubber-based adhesive on back.

Black characters on white stock.

Label Contents: up to an 11-digit number.

Print quality to meet ANSI X3. 182 requirements.

The required format is a row of seven numerals over seven numerals (no alpha characters). The first seven numerals are placed on the top row of the label and the second seven numerals are placed on the bottom row.

The font must be 12-point OCR-A. The dimensions of the placement of the characters are shown in Figure 2. Please note that a 'no text' zone of exactly one (1) character dimension (1.6 mm or .063") should surround the print area.

Label Specifications for Use with the ThinPrep® Imaging System
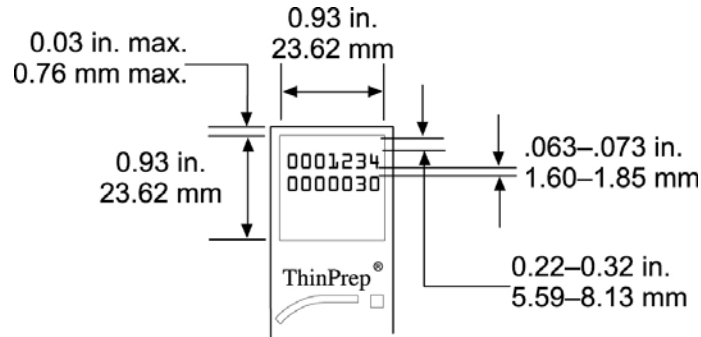
Dimensions

Figure 2 Dimensions of the Slide Label

Vial Barcode Labels (for the ThinPrep 3000 Processor)

Figure 3 Vial Barcode Label (ThinPrep 3000)

Because the ThinPrep 3000 Processor prints the Accession ID directly onto the patient slide, slide labels are not required. However, the CRC and reserved number conditions described previously should be followed.

Cyclical Redundancy Check (CRC)

This is required for vial barcodes which will be used to prepare slides for use with the ThinPrep Imaging System. The ThinPrep 3000 system setup configuration must be in Imaging System Mode Printing. The system software will automatically append the CRC numerals to the Accession ID when the vial barcode is scanned. The patient slide will be printed in the correct format.

Reserved Numbers

Accession ID numbers with '9999' in the position just before the CRC are reserved for Hologic personnel and will be removed from the patient database at the time of a service visit.

Starting with an even-numbered accession ID and incrementing the IDs by two (2) is one way to avoid conflict with the reserved numbers.

Refer to the ThinPrep 3000 Processor Operator's Manual for specifications for printing vial barcode labels (Ordering Information, Consumable Accessory Items).

Genius™ Digital Imager

Operator's Manual

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