HOLOGIC®

Genius™ Digital Imager

Operator's Manual

MAN-12119-001 Rev. 001

Genius™ Digital Imager

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For Use With Version 1.2.x Software

MAN-12119-001

Caution: Federal law restricts this device to sale by or on the order of a physician, or any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device and are trained and experienced in the use of the Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm.

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

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

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

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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℞ only

IVD

Genius Digital
Diagnostics System

Genius Digital
Diagnostics System

Genius™ Digital Diagnostics System with the Genius™ Cervical AI Algorithm

Instructions for Use

℞ only

IVD

INTENDED USE

The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm includes the Genius™ Digital Imager, Genius™ Image Management Server (IMS), the Genius™ Review Station, and the Genius™ Cervical AI algorithm. The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm is intended for the creation and viewing of digital images of scanned ThinPrep® Pap Test glass slides. Objects of interest selected by the Genius™ Cervical AI algorithm from the scanned digital image are presented in a gallery format, next to the image of the whole cell spot on the Genius™ Review Station, for review and interpretation. The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm is intended to aid in cervical cancer screening 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 as defined by The Bethesda System for Reporting Cervical Cytology[1].

After digital review with the Genius™ Cervical AI algorithm, if there is uncertainty in the diagnosis, then direct examination of the glass slide by light microscopy should be performed. Digital images from the Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm should be interpreted by qualified cytologists and pathologists in conjunction with the patient's screening history, other risk factors, and professional guidelines which guide patient management.

SUMMARY AND EXPLANATION OF THE SYSTEM

The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm uses Pap test slides prepared from gynecologic (cervical/vaginal) samples obtained from women for screening, diagnosis and management.

Slides that have been prepared for screening using the ThinPrep® 2000 system, the ThinPrep® 5000 processor, or the ThinPrep® Genesis™ processor and stained with ThinPrep® stain (Papanicolaou stain) are loaded into slide carriers which are placed into the Digital Imager. The operator uses a touch screen on the Digital Imager to interact with the instrument via a graphic, menu-driven interface.

A slide ID reader scans the slide's accession ID and locates the scan area. Then, the Digital Imager scans a designated area of the microscope slide, creating an in-focus, whole slide image.

For ThinPrep® Pap test patient sample slides, the Genius™ Cervical AI algorithm identifies objects of interest found on a digital image of the slide. The objects classified as most clinically relevant are presented to a cytologist (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 with the Genius™ Cervical AI algorithm. 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 and comments in the case review. The reviewer, in addition to reviewing the gallery images, has the option to move to any portion of the cell spot for examination.

LIMITATIONS

- Performance characteristics of the Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm are based on using Genius Cervical AI tools, including the entire gallery, to assist in diagnosing a case and should be used accordingly. The performance of the Genius Digital Diagnostics System with the Genius™ Cervical AI algorithm using only a digital review of the entire cell spot has not been evaluated.
- There is no priority or ranking in the order with which the objects of interest are displayed in the gallery and therefore, the user must review all objects in the gallery.
- After review of the entire gallery of images provided by the Genius Cervical AI algorithm, if there is uncertainty in diagnosis, then direct examination of the glass slide by light microscopy should be performed.
- Only personnel who have been trained in the use of the Genius Digital Imager, Review Station and Genius Cervical AI algorithm should operate the system.
- ThinPrep Imaging System microscope slides with fiducial marks must be used.
- The Genius Digital Diagnostics System with the Genius™ Cervical AI algorithm is indicated for use only with the slides prepared using a ThinPrep 2000 system, ThinPrep 5000 processor or ThinPrep Genesis processor and stained with ThinPrep stain. The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is not indicated for the ThinPrep Pap test slides prepared with any other cytology processor including the ThinPrep® 3000 processor.
- The laboratory Technical Supervisor should establish individual workload limits for personnel using the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. Please also see section on “Cytologist Workload Determination”.
- Gynecological slides must be stained using the ThinPrep stain (Papanicolaou 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 should be imaged by the Genius Digital Imager in a timely manner, according to normal laboratory practices.
- 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 with the Genius™ Cervical AI algorithm 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 with the Genius™ Cervical AI algorithm. They are required for proper performance of the system and cannot be substituted.

WARNINGS

- For *In Vitro* Diagnostic Use
- The Genius™ Digital Imager generates, uses, and can radiate radio frequency energy and may cause interference to radio communications.
- The Genius™ Digital Imager uses glass microscope slides, which may 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.
- Performance may vary from site to site as a result of differences in patient populations and reading practices. As a result, each laboratory using this device should employ quality assurance and control systems per CLIA regulation 42 CFR 493.1257 to ensure proper use and selection of appropriate workload limits.
- Users should employ appropriate cybersecurity measures when the device is used for remote review.
- Service Installation Only. The system must be installed by trained Hologic personnel only.
- For professional use 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.

TRAINING AND QUALITY CONTROL

- Evaluation of cases should be performed only by cytologists and pathologists who have been trained, by Hologic or organizations designated by Hologic, to evaluate digital images of scanned ThinPrep® Pap Test glass slides using Genius Cervical AI.
- For Cytologists who begin clinical use of the device, labs should consider additional training policies and procedures, as needed, such as re-review of a lab-determined number of cases.
- If a product malfunction occurs, which caused, or could lead to an adverse event, the device user should consider filing a Medical Device Report (MDR) to US FDA using MedWatch Form 3500 (https://www.fda.gov/media/76299/download) for voluntary reporting.

PERFORMANCE CHARACTERISTICS

GENIUS™ DIGITAL DIAGNOSTICS SYSTEM WITH THE GENIUS™ CERVICAL AI ALGORITHM COMPARED TO GLASS SLIDE MANUAL REVIEW

A multi-center Genius Cervical AI Clinical Study was performed within the United States. The objective of the study was to show that routine screening of ThinPrep Pap test slides using the Genius Digital Diagnostics System with the Genius Cervical AI algorithm was comparable to the approved method of screening using glass slides with a light microscope.

The study included 1994 slides and four (4) clinical sites (laboratories). Slides were prepared from residual material after the clinical sites signed out the case, from women who were screened for cervical cancer using the ThinPrep Pap test. Samples that were enrolled were processed on the ThinPrep® 2000 system, the ThinPrep® 5000 processor, or the ThinPrep® Genesis™ processor. At each of four (4) clinical sites, three (3) independent teams consisting of one (1) cytologist (CT) and one (1) pathologist at each site (CT/Pathologist teams) reviewed all cases at their site. All cases at the corresponding site were reviewed independently by the three teams at that particular site and, therefore, the number of reviews at the site were 3 x the number of slides at the site. Site CT/Pathologist teams screened cases in 3 review phases as follows: manual review of glass slides with a light microscope without the assistance of the ThinPrep Imaging System (TIS) (Manual review), review of glass slides with the ThinPrep Imaging System (TIS review), and review of digital images with the Genius Digital Diagnostics System with the Genius Cervical AI algorithm (Genius Cervical AI review), in that order. Cases with an ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer or unsatisfactory for evaluation (UNSAT) result by the CT were also reviewed by the pathologist. A minimum 14-day washout period occurred between each review phase. The cases were

randomized prior to each review phase. Cytological diagnoses and specimen adequacy were determined in accordance with the Bethesda System criteria.

An adjudicated diagnosis was used as a “gold standard” (“reference” or “ground truth”). Cases were screened by an adjudication panel, composed of three (3) adjudication CT/Pathologist teams, consisting of one (1) CT and one (1) pathologist each (adjudication CT/Pathologist teams). Slides were reviewed independently by the three teams. All cases, regardless of result, were reviewed by CTs and pathologists. For each case, results from each adjudication CT/Pathologist team were used to obtain a consensus result, defined as the result for which there was majority agreement (by at least two of the three adjudication CT/Pathologist teams). If a consensus result was not obtained initially, these cases underwent review by the three adjudication pathologists simultaneously using a multi-headed microscope (multi-head review). The reference result was based on either the consensus result (if met initially) or the multi-head review result (if consensus was not obtained initially). Cytological diagnoses and specimen adequacy were determined in accordance with the Bethesda System criteria: NILM, ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer and UNSAT.

Laboratory and Patient Characteristics

The cytology laboratories participating in the study were comprised of four (4) sites. All sites selected had extensive experience in the processing and evaluation of gynecologic ThinPrep Pap test slides and were trained in the use of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

There were 1995 slides that were eligible for the study. Of these, 1994 slides were included in the study and one (1) was excluded from the study because the slide failed the quality audit due to a scratched coverslip, an exclusion criterion. The total number of reviews was 5,982 (3 x 1994 slides). Thirty-four (34) cases (102 reviews) had adjudication results of UNSAT and the remaining 1960 cases (5,880 reviews) were Satisfactory (SAT) for evaluation and had reference adjudication diagnoses. Table 1 provides characteristics of the participating clinical sites. Table 2 describes the patient populations with SAT slides, at each of the study sites.

Table 1. Site Characteristics

Site	1	2	3	4
ThinPrep Pap Tests Per Year	48,000	239,750	329,500	4,500
Number of Cytologists in Study	3	3	3	3
Number of Pathologists in Study	3	3	3	3

Table 2. Site Demographics

Site Number	Total number	Median Age (yrs)	# Hysterectomy (% of enrolled)	# Postmenopausal (% of enrolled)
1	488	33.0	18 (3.7)	37 (7.6)
2	494	36.0	6 (1.2)	24 (4.9)
3	490	35.0	22 (4.5)	43 (8.8)
4	488	37.0	6 (1.2)	41 (8.4)
Overall	1960	35.0	52 (2.6)	141 (7.4)

Eligibility Criteria

Cases were eligible to be included in the study if they met the following criteria: ThinPrep slides of known diagnoses generated from residual cytological specimens (within 6 weeks from date of collection) in the approximate number from the following enrollment diagnostic categories:

- NILM: 1060 cases
- ASCUS: 225 cases
- AGC: 20 cases
- LSIL: 225 cases
- ASC–H: 225 cases
- HSIL: 225 cases
- Cancers: 20 cases (squamous and/or adenocarcinoma)
- UNSAT 20 cases

Cases were excluded from the study if any of the following criteria applies:

- Any slides deemed not adequate, (if slide is broken, dilute, or is otherwise unreadable).

Objective of the Clinical Study

The primary objectives of this study included comparing the sensitivity and specificity when diagnosing cases imaged and reviewed on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm with the sensitivity and specificity of Manual review and also with TIS review. An adjudicated diagnosis was used as a “gold standard” (“reference” or “ground truth”). The comparison of sensitivities and specificities was performed at the following thresholds (described in Table 3 below): ASCUS+, LSIL+, ASC-H+, HSIL+, Cancer.

Table 3. Category Partitions

Threshold	Negative	Positive
ASCUS+	NILM	ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer
LSIL+	NILM, ASCUS, AGC	LSIL, ASC-H, HSIL, Cancer
ASC-H+	NILM, ASCUS, AGC, LSIL	ASC-H, HSIL, Cancer
HSIL+	NILM, ASCUS, AGC, LSIL, ASC-H	HSIL, Cancer
Cancer	NILM, ASCUS, AGC, LSIL, ASC-H, HSIL	Cancer
Abbreviations for Diagnostic Thresholds: NILM: negative for intraepithelial lesion or malignancy; ASCUS: atypical squamous cells of undetermined significance; AGC: atypical glandular cells; LSIL: low grade squamous intraepithelial lesion; ASC-H: atypical squamous cells – cannot exclude HSIL; HSIL: High grade squamous intraepithelial lesion		

Sensitivity and specificity of each review type (Genius Cervical AI review, Manual review and TIS review) were calculated on all cases with a satisfactory reference result at the ASCUS+, LSIL+, ASC-H+, HSIL+ and Cancer diagnostic thresholds. Of these cases, UNSAT Genius Cervical AI, Manual, or TIS review results were considered positive at each diagnostic threshold.

Sensitivity was separately calculated on all cases with an UNSAT reference result, where sensitivity was defined as the proportion of Genius Cervical AI, Manual, or TIS review results of UNSAT or ASCUS+. Specificity was also calculated, where specificity was defined as the proportion of satisfactory Genius Cervical AI, Manual, or TIS review results on all cases with a satisfactory reference result.

Differences in sensitivities and differences in specificities were calculated along with two-sided 95% confidence intervals (95% CI).

A) GENIUS CERVICAL AI REVIEW COMPARED WITH MANUAL REVIEW

A.1 Performance of Genius Cervical AI Review and Manual Review

Table 4.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Compared to Adjudicated Diagnosis

	Sensitivity %			Specificity %		
Diagnostic Threshold	**Genius (95% CI)**	**Manual (95% CI)**	**Difference (Genius – Manual) (95% CI)**	**Genius (95% CI)**	**Manual (95% CI)**	**Difference (Genius – Manual) (95% CI)**
ASCUS+	91.7 [1950/2127] (90.1, 93.3)	90.1 [1917/2127] (88.7, 91.8)	1.6 [33/2127] (-0.1, 3.2)	91.0 [3414/3753] (89.7, 92.1)	92.2 [3461/3753] (91.1, 93.2)	-1.3 [-47/3753] (-2.3, -0.2)
LSIL+	89.1 [1467/1647] (87.2, 91.0)	84.7 [1395/1647] (82.3, 86.8)	4.4 [72/1647] (2.1, 6.7)	91.7 [3883/4233] (90.5, 92.9)	94.1 [3984/4233] (93.1, 95.0)	-2.4 [-101/4233] (-3.5, -1.4)
ASC-H+	87.8 [938/1068] (84.8, 90.2)	79.6 [850/1068] (76.3, 82.5)	8.2 [88/1068] (4.8, 11.6)	94.2 [4531/4812] (93.2, 95.1)	97.0 [4669/4812] (96.4, 97.7)	-2.9 [-138/4812] (-3.8, -1.9)
HSIL+	81.5 [699/858] (78.5, 84.4)	74.0 [635/858] (70.1, 77.5)	7.5 [64/858] (4.0, 11.4)	94.8 [4763/5022] (94.0, 95.6)	97.2 [4882/5022] (96.6, 97.8)	-2.4 [-119/5022] (-3.0, -1.7)

The sensitivity of the Genius Cervical AI was statistically significantly higher for LSIL+, ASC-H+ and HSIL+. Increase in sensitivity was 4.4%, 8.2% and 7.5% for LSIL+, ASC-H+ and HSIL+, respectively. There were statistically significant decreases in specificity for ASCUS+, LSIL+, ASC-H+, and HSIL+ diagnostic thresholds. The decrease in specificity was 1.3%, 2.4%, 2.9% and 2.4% for ASCUS+, LSIL+, ASC-H+, and HSIL+, respectively.

A.2 Genius Cervical AI Review vs. Manual Review Stratified by Site

ASCUS+

Sensitivity is a percent of "reference" ASCUS+ cases classified in Genius Cervical AI reviews or in Manual reviews as ASCUS+ or UNSAT, and specificity is a percent of "reference" NILM cases classified in either review as NILM.

Table 5.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at ASCUS+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius	Manual	Difference	Genius	Manual	Difference
Site 1	488	93.4 [538/576] (90.0, 96.1)	87.8 [506/576] (83.9, 91.3)	5.6 [32/576] (1.7, 8.7)	91.7 [814/888] (88.6, 94.1)	95.6 [849/888] (93.6, 97.3)	-3.9 [-35/888] (-6.3, -1.7)
Site 2	494	87.7 [479/546] (83.6, 90.9)	93.2 [509/546] (90.0, 95.8)	-5.5 [-30/546] (-9.0, -2.0)	93.3 [873/936] (91.2, 95.2)	90.9 [851/936] (88.4, 93.5)	2.4 [22/936] (0.3, 4.7)
Site 3	490	92.2 [506/549] (88.9, 95.0)	88.7 [487/549] (85.4, 92.0)	3.5 [19/549] (0.4, 6.1)	92.6 [853/921] (90.1, 94.9)	92.0 [847/921] (89.9, 93.8)	0.7 [6/921] (-1.9, 2.8)
Site 4	488	93.6 [427/456] (90.8, 96.1)	91.0 [415/456] (87.3, 94.7)	2.6 [12/546] (-0.6, 5.8)	86.7 [874/1008] (83.9, 89.4)	90.7 [914/1008] (88.1, 93.0)	-4.0 [-40/1008] (-6.2, -1.6)
Total	1960	91.7 [1950/2127] (90.1, 93.3)	90.1 [1917/2127] (88.7, 91.8)	1.6 [33/2127] (-0.1, 3.2)	91.0 [3414/3753] (89.7, 92.1)	92.2 [3461/3753] (91.1, 93.2)	-1.3 [-47/3753] (-2.3, -0.2)

LSIL+

Sensitivity is a percent of "reference" LSIL+ cases classified in Genius Cervical AI reviews or in Manual reviews as LSIL+ or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC) cases classified in either review as NILM or ASCUS or AGC.

Table 6.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at LSIL+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius	Manual	Difference	Genius	Manual	Difference
Site 1	488	88.5 [401/453] (84.2, 92.2)	83.7 [379/453] (78.9, 87.8)	4.9 [22/453] (0.5, 9.5)	91.0 [920/1011] (88.2, 93.8)	94.3 [953/1011] (92.3, 96.4)	-3.3 [-33/1011] (-5.6, -1.1)
Site 2	494	85.9 [348/405] (81.0, 89.8)	93.1 [377/405] (89.7, 96.2)	-7.2 [-29/405] (-11.1, -3.3)	92.9 [1000/1077] (90.8, 94.8)	92.3 [994/1077] (89.8, 94.5)	0.6 [6/1077] (-1.5, 2.7)
Site 3	490	89.7 [390/435] (86.2, 93.0)	72.6 [316/435] (66.9, 77.6)	17.0 [74/435] (12.2, 22.3)	92.4 [956/1035] (89.9, 94.5)	97.1 [1005/1035] (95.9, 98.3)	-4.7 [-49/1035] (-7.1, -2.9)
Site 4	488	92.7 [328/354] (89.5, 95.1)	91.2 [323/354] (87.2, 94.6)	1.4 [5/354] (-2.7, 5.9)	90.7 [1007/1110] (88.4, 92.9)	93.0 [1032/1110] (90.8, 94.9)	-2.3 [-25/1110] (-4.1, 0.1)
Total	1960	89.1 [1467/1647] (87.2, 91.0)	84.7 [1395/1647] (82.3, 86.8)	4.4 [72/1647] (2.1, 6.7)	91.7 [3883/4233] (90.5, 92.9)	94.1 [3984/4233] (93.1, 95.0)	-2.4 [-101/4233] (-3.5, -1.4)

ASC-H+

Sensitivity is a percent of "reference" ASC-H+ cases classified in Genius reviews or in Manual reviews as ASC-H+ or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC or LSIL) cases classified in either review as NILM or ASCUS or AGC or LSIL.

Table 7.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at ASC-H+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius	Manual	Difference	Genius	Manual	Difference
Site 1	488	85.7 [257/300] (80.0, 90.4)	80.0 [240/300] (74.1, 85.3)	5.7 [17/300] (0.0, 11.8)	92.4 [1075/1164] (89.7, 94.6)	96.1 [1119/1164] (94.5, 97.7)	-3.8 [-44/1164] (-5.6, -2.0)
Site 2	494	83.3 [230/276] (77.3, 88.7)	90.9 [251/276] (86.1, 95.4)	-7.6 [-21/276] (-13.4, -2.7)	96.5 [1164/1206] (94.9, 97.9)	96.0 [1158/1206] (94.5, 97.5)	0.5 [6/1206] (-1.0, 2.1)
Site 3	490	92.3 [241/261] (87.8, 95.9)	69.7 [182/261] (62.6, 77.2)	22.6 [59/261] (15.6, 28.9)	94.5 [1143/1209] (92.5, 96.4)	98.5 [1191/1209] (97.7, 99.2)	-4.0 [-48/1209] (-5.7, -2.3)
Site 4	488	90.9 [210/231] (87.0, 94.4)	76.6 [177/231] (68.8, 84.0)	14.3 [33/231] (6.3, 22.8)	93.2 [1149/1233] (91.2, 95.1)	97.4 [1201/1233] (96.3, 98.5)	-4.2 [-52/1233] (-6.2, -2.4)
Total	1960	87.8 [938/1068] (84.8, 90.2)	79.6 [850/1068] (76.3, 82.5)	8.2 [88/1068] (4.8, 11.6)	94.2 [4531/4812] (93.2, 95.1)	97.0 [4669/4812] (96.4, 97.7)	-2.9 [-138/4812] (-3.8, -1.9)

HSIL+

Sensitivity is a percent of "reference" HSIL+ cases classified in Genius reviews or in Manual reviews as HSIL+ or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC or LSIL or ASC-H) cases classified in either review as NILM or ASCUS or AGC or LSIL or ASC-H.

Table 8.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at HSIL+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius	Manual	Difference	Genius	Manual	Difference
Site 1	488	79.4 [193/243] (72.4, 86.3)	74.5 [181/243] (68.4, 81.0)	4.9 [12/243] (-2.4, 12.3)	93.5 [1142/1221] (91.1, 95.4)	95.7 [1169/1221] (94.0, 97.2)	-2.2 [-27/1221] (-3.9, -0.9)
Site 2	494	77.5 [179/231] (70.3, 84.6)	87.4 [202/231] (80.3, 93.3)	-10.0 [-23/231] (-17.0, -4.1)	96.8 [1211/1251] (95.5, 97.9)	96.8 [1211/1251] (95.4, 98.0)	0.0 [0/1251] (-1.1, 1.0)
Site 3	490	83.8 [171/204] (77.8, 89.5)	54.4 [111/204] (45.7, 62.9)	29.4 [60/204] (22.4, 37.5)	95.6 [1210/1266] (94.0, 97.0)	99.4 [1259/1266] (98.9, 99.8)	-3.9 [-49/1266] (-5.3, -2.5)
Site 4	488	86.7 [156/180] (82.1, 91.3)	78.3 [141/180] (70.7, 86.8)	8.3 [15/180] (0.0, 15.7)	93.5 [1200/1284] (91.8, 95.1)	96.8 [1243/1284] (95.5, 98.0)	-3.3 [-43/1284] (-4.9, -1.7)
Total	1960	81.5 [699/858] (78.5, 84.4)	74.0 [635/858] (70.1, 77.5)	7.5 [64/858] (4.0, 11.4)	94.8 [4763/5022] (94.0, 95.6)	97.2 [4882/5022] (96.6, 97.8)	-2.4 [-119/5022] (-3.0, -1.7)

Cancer

Sensitivity is a percent of "reference" Cancer cases classified in Genius Cervical AI reviews or in Manual reviews as Cancer or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC or LSIL or ASC-H or HSIL) cases classified in either review as NILM or ASCUS or AGC or LSIL or ASC-H or HSIL.

Table 9.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at Cancer

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius	Manual	Difference	Genius	Manual	Difference
Site 1	488	66.7 [14/21] (25.0, 100.0)	76.2 [16/21] (50.0, 100.0)	-9.5 [-2/21] (-33.3, 11.1)	98.3 [1418/1443] (97.0, 99.2)	98.6 [1423/1443] (97.7, 99.3)	-0.3 [-5/1443] (-1.1, 0.3)
Site 2	494	66.7 [14/21] (20.8, 100.0)	85.7 [18/21] (63.0, 100.0)	-19.0 [-4/21] (-44.4, 0.0)	98.6 [1440/1461] (97.8, 99.3)	97.7 [1428/1461] (96.5, 98.8)	0.8 [12/1461] (0.1, 1.6)
Site 3	490	60.6 [20/33] (33.3, 84.6)	39.4 [13/33] (16.7, 66.7)	21.2 [7/33] (3.7, 40.0)	98.9 [1421/1437] (98.2, 99.5)	99.4 [1429/1437] (98.8, 99.9)	-0.6 [-8/1437] (-1.3, 0.1)
Site 4	488	76.2 [16/21] (44.4, 100.0)	81.0 [17/21] (55.6, 100.0)	-4.8 [-1/21] (-22.2, 13.3)	98.4 [1420/1443] (97.6, 99.1)	98.4 [1420/1443] (97.6, 99.2)	0.0 [0/1443] (-0.8, 0.8)
Total	1960	66.7 [64/96] (51.7, 80.6)	66.7 [64/96] (54.3, 79.0)	0.0 [0/96] (-9.8, 11.1)	98.5 [5699/5784] (98.0, 98.9)	98.5 [5700/5784] (98.1, 98.9)	-0.0 [-1/5784] (-0.4, 0.4)

UNSAT

Sensitivity is a percent of "reference" UNSAT cases classified in Genius reviews or in Manual reviews as UNSAT or ASCUS+, and specificity is a percent of "reference" Satisfactory (SAT) slides classified in either review as SAT.

Table 10.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at UNSAT

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius	Manual	Difference	Genius	Manual	Difference
Site 1	503	86.7 [39/45] (71.1, 100)	51.1 [23/45] (26.7, 73.3)	35.6 [16/45] (11.1, 57.8)	99.6 [1458/1464] (98.9, 100)	99.9 [1463/1464] (99.8, 100)	-0.3 [-5/1464] (-1.0, 0.1)
Site 2	500	77.8 [14/18] (55.6, 94.4)	77.8 [14/18] (55.6, 100)	0.0 [0/18] (-16.7, 16.7)	99.6 [1476/1482] (99.1, 100)	99.7 [1478/1482] (99.3, 100)	-0.1 [-2/1482] (-0.5, 0.1)
Site 3	495	80.0 [12/15] (40.0, 100)	53.3 [8/15] (26.7, 66.7)	26.7 [-4/15] (13.3, 33.3)	99.7 [1465/1470] (99.2, 100)	99.9 [1468/1470] (99.7, 100)	-0.2 [-3/1470] (-0.6, 0.1)
Site 4	496	70.8 [17/24] (37.5, 95.8)	75.0 [18/24] (50.0, 95.8)	-4.2 [-1/24] (-29.2, 25.0)	100 [1464/1464] (100, 100)	99.3 [1454/1464] (98.8, 99.8)	0.7 [10/1464] (0.2, 1.2)
Total	1994	80.4 [82/102] (67.6, 91.2)	61.8 [63/102] (50.0, 72.5)	18.6 [19/102] (5.9, 31.4)	99.7 [5863/5880] (99.5, 99.9)	99.7 [5863/5880] (99.5, 99.9)	0.0 [0/5880] (-0.2, 0.2)

A.3: Tables of performance of each Bethesda Category

Table 11 through Table 18 summarize results from Genius Cervical AI review and Manual review for each of the major descriptive diagnosis classifications of the Bethesda System as determined by the adjudication diagnosis: NILM, ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer, and the diagnostic category UNSAT.

Table 11. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of NILM

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	3	10	1	0	0	0	0	0	14
	NILM	10	3250	113	12	8	19	2	0	3414
	ASCUS	0	122	43	0	7	4	1	0	177
	AGC	1	19	1	0	0	2	2	0	25
	LSIL	0	16	22	0	4	0	0	0	42
	ASC-H	1	30	10	0	1	5	1	1	49
	HSIL	1	10	6	0	3	2	5	0	27
	Cancer	0	4	0	1	0	0	0	0	5
	Total	16	3461	196	13	23	32	11	1	3753

Among the 3753 reviews determined by the adjudication panel to be NILM, 3414 (91.0%) reviews in the Genius Cervical AI Review and 3461 (92.2%) reviews in the Manual Review were diagnosed as NILM, and 81 (2.2%) reviews in the Genius Cervical AI Review and 44 (1.2%) reviews in the Manual Review were diagnosed as ASC-H+, including 5 (0.13%) reviews in Genius Cervical AI Review and 1 (0.03%) review in the Manual Review that were diagnosed as Cancer.

Table 12. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of ASCUS

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	0	2	1	0	0	0	0	0	3
	NILM	0	49	40	0	16	6	2	0	113
	ASCUS	0	35	70	1	32	1	3	0	142
	AGC	0	0	0	0	0	0	0	0	0
	LSIL	0	20	51	0	48	2	0	0	121
	ASC-H	0	11	15	0	10	8	3	0	47
	HSIL	0	1	8	0	11	3	6	0	29
	Cancer	0	0	2	0	0	1	0	1	4
	Total	0	118	187	1	117	21	14	1	459

Among the 459 reviews determined by the adjudication panel to be ASCUS, 142 (30.9%) reviews in the Genius Cervical AI Review and 187 (40.7%) reviews in the Manual Review were diagnosed as ASCUS, and 113 (24.6%) reviews in the Genius Cervical AI Review and 118 (25.7%) reviews in the Manual Review were diagnosed as NILM.

Table 13. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of AGC

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	5	0	0	0	1	0	1	7
	ASCUS	0	0	0	0	0	0	0	0	0
	AGC	0	1	0	1	0	0	0	3	5
	LSIL	0	0	0	0	0	0	0	0	0
	ASC-H	0	1	0	0	0	0	0	0	1
	HSIL	0	0	0	0	0	0	0	0	0
	Cancer	0	0	0	0	0	0	1	7	8
	Total	0	7	0	1	0	1	1	11	21

Among the 21 reviews determined by the adjudication panel to be AGC, 5 (23.8%) reviews in the Genius Cervical AI Review and 1 (4.8%) review in the Manual Review were diagnosed as AGC, and 7 (33.3%) reviews in the Genius Cervical AI Review and 7 (33.3%) reviews in the Manual Review were diagnosed as NILM.

Table 14. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of LSIL

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	2	6	0	2	0	1	0	11
	ASCUS	0	10	17	0	35	1	1	0	64
	AGC	0	0	0	0	0	0	0	0	0
	LSIL	0	18	35	0	351	2	4	0	410
	ASC-H	0	0	8	0	16	1	1	0	26
	HSIL	0	1	3	0	39	7	15	1	66
	Cancer	0	0	1	0	1	0	0	0	2
	Total	0	31	70	0	444	11	22	1	579

Among the 579 reviews determined by the adjudication panel to be LSIL, 410 (70.8%) reviews in the Genius Cervical AI Review and 444 (76.7%) reviews in the Manual Review were diagnosed as LSIL, and 11 (1.9%) reviews in the Genius Cervical AI Review and 31 (5.4%) reviews in the Manual Review were diagnosed as NILM.

Table 15. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of ASC-H

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	9	0	0	0	5	5	0	19
	ASCUS	0	4	4	1	2	4	5	0	20
	AGC	0	1	1	0	0	1	0	0	3
	LSIL	0	0	0	0	3	1	2	0	6
	ASC-H	0	6	14	0	8	23	10	0	61
	HSIL	0	10	20	0	10	21	33	1	95
	Cancer	0	0	0	0	0	0	1	5	6
	Total	0	30	39	1	23	55	56	6	210

Among the 210 reviews determined by the adjudication panel to be ASC-H, 61 (29.0%) reviews in the Genius Cervical AI Review and 55 (26.2%) reviews in the Manual Review were diagnosed as ASC-H, and 19 (9.0%) reviews in the Genius Cervical AI Review and 30 (14.3%) reviews in the Manual Review were diagnosed as NILM.

Table 16. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of HSIL

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	1	1	1	0	5	11	4	23
	ASCUS	0	0	3	0	0	7	9	0	19
	AGC	0	1	1	0	0	2	6	1	11
	LSIL	0	0	0	0	12	0	7	0	19
	ASC-H	0	3	9	1	8	18	34	2	75
	HSIL	1	18	21	8	23	62	418	21	572
	Cancer	0	0	1	1	1	1	20	19	43
	Total	1	23	36	11	44	95	505	47	762

Among the 762 reviews determined by the adjudication panel to be HSIL, 572 (75.1%) reviews in the Genius Cervical AI Review and 505 (66.3%) reviews in the Manual Review were diagnosed as HSIL, and 23 (3.0%) reviews in the Genius Cervical AI Review and 23 (3.0%) reviews in the Manual Review were diagnosed as NILM.

Table 17. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of Cancer

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	1	0	0	0	0	1	2	4
	ASCUS	0	0	0	0	0	0	1	0	1
	AGC	0	0	1	1	0	0	0	3	5
	LSIL	0	0	0	0	0	0	0	0	0
	ASC-H	0	0	0	0	0	1	0	1	2
	HSIL	0	0	1	1	0	1	13	4	20
	Cancer	0	0	1	5	0	1	3	54	64
	Total	0	1	3	7	0	3	18	64	96

Among the 96 reviews determined by the adjudication panel to be Cancer, 64 (66.7%) reviews in the Genius Cervical AI Review and 64 (66.7%) reviews in the Manual Review were diagnosed as Cancer, and 4 (4.2%) reviews in the Genius Cervical AI Review and 1 (1.0%) review in the Manual Review were diagnosed as NILM.

Table 18. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Results of UNSAT

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	**UNSAT**	50	22	0	0	0	0	0	0	72
	NILM	6	14	0	0	0	0	0	0	20
	ASCUS	2	1	0	0	0	0	0	0	3
	AGC	0	1	1	0	0	0	0	0	2
	LSIL	0	0	0	0	0	0	0	0	0
	ASC-H	1	0	1	1	0	1	0	0	4
	HSIL	0	0	0	0	0	0	0	0	0
	Cancer	0	1	0	0	0	0	0	0	1
	Total	59	39	2	1	0	1	0	0	102

Among the 102 reviews determined by the adjudication panel to be UNSAT, 72 (70.6%) reviews in the Genius Cervical AI Review and 59 (57.8%) reviews in the Manual Review were diagnosed as UNSAT, and 20 (19.6%) reviews in the Genius Cervical AI Review and 39 (38.2%) reviews in the Manual Review were diagnosed as NILM.

For slides diagnosed as UNSAT by adjudication, the Genius Digital Diagnostics System with the Genius Cervical AI algorithm correctly identified 18.6% more slides than Manual as UNSAT or ASCUS+.

In summary, comparison of the performances of Genius Digital Diagnostic System with the Genius Cervical AI algorithm and Manual reviews with regard to false NILM results is presented in Table 19 below.

Table 19. Summary of False NILM results for Genius Cervical AI Review and Manual Review

Review Type	Reference results by Adjudication						
% False NILM	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Overall**
Genius	24.6% (113/459)	33.3% (7/21)	1.9% (11/579)	9.0% (19/210)	3.0% (23/762)	4.2% (4/96)	8.3% (177/2127)
Manual	25.7% (118/459)	33.3% (7/21)	5.4% (31/579)	14.3% (30/210)	3.0% (23/762)	1.0% (1/96)	9.9% (210/2127)
Genius–Manual	-1.1% (-5/459)	0.0% (0/21)	-3.5% (-20/579)	-5.2% (-11/210)	0.0% (0/762)	3.1% (3/96)	-1.6% (-33/2127)

Comparison of the performances of Genius Digital Diagnostic System with the Genius Cervical AI algorithm and Manual reviews with regard to false LSIL+ for the cases with NILM reference results by adjudication is presented in Table 20 below.

Table 20. Summary of False positive results for Genius Cervical AI Review and Manual Review

Percent of LSIL, ASC-H, HSIL and Cancer for cases with NILM reference results by Adjudication					
Review Type	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius	1.12% (42/3753)	1.31% (49/3753)	0.72% (27/3753)	0.13% (5/3753)	3.28% (123/3753)
Manual	0.61% (23/3753)	0.85% (32/3753)	0.29% (11/3753)	0.03% (1/3753)	1.79% (67/3753)
Genius–Manual	0.51% (19/3753)	0.45% (17/3753)	0.43% (16/3753)	0.11% (4/3753)	1.49% (56/3753)

B. GENIUS CERVICAL AI REVIEW COMPARED WITH TIS REVIEW

Performance of Genius Cervical AI Review and TIS Review

The study also compared the performance of ThinPrep slides reviewed on the Genius Digital Diagnostic System with the Genius Cervical AI algorithm with ThinPrep slides reviewed on the ThinPrep Imaging System (TIS). The results for the Genius Cervical AI review versus TIS review are presented in Table 21.

Table 21. Sensitivity and Specificity of Genius Cervical AI Review and TIS Review Compared to Adjudicated Diagnosis

	Sensitivity %			Specificity %		
Diagnostic Threshold	**Genius (95% CI)**	**TIS (95% CI)**	**Difference (Genius – TIS) (95% CI)**	**Genius (95% CI)**	**TIS (95% CI)**	**Difference (Genius – TIS) (95% CI)**
ASCUS+	91.7 [1950/2127] (90.1, 93.3)	91.6 [1948/2127] (90.0, 93.0)	0.1 [2/2127] (-1.6, 1.5)	91.0 [3414/3753] (89.7, 92.1)	92.6 [3474/3753] (91.5, 93.6)	-1.6 [-60/3753] (-2.8, -0.6)
LSIL+	89.1 [1467/1647] (87.2, 91.0)	87.7 [1444/1647] (85.6, 89.8)	1.4 [23/1647] (-0.6, 3.6)	91.7 [3883/4233] (90.5, 92.9)	93.3 [3950/4233] (92.2, 94.4)	-1.6 [-67/4233] (-2.6, -0.5)
ASC-H+	87.8 [938/1068] (84.8, 90.2)	84.3 [900/1068] (80.9, 87.0)	3.6 [38/1068] (0.6, 6.6)	94.2 [4531/4812] (93.2, 95.1)	96.4 [4639/4812] (95.6, 97.2)	-2.2 [-108/4812] (-3.1, -1.3)
HSIL+	81.5 [699/858] (78.5, 84.4)	77.9 [668/858] (74.0, 81.5)	3.6 [31/858] (0.0, 7.4)	94.8 [4763/5022] (94.0, 95.6)	96.6 [4850/5022] (95.9, 97.3)	-1.7 [-87/5022] (-2.4, -1.0)

The observed sensitivity of the Genius Cervical AI was greater than TIS at the ASCUS+, LSIL+, ASC-H+, and HSIL+ thresholds. The increase in sensitivity was 3.6% for both ASC-H+ and HSIL+ and statistically significant. There were statistically significant decreases in specificity for the ASCUS+, LSIL+, ASC-H+, and HSIL+ diagnostic thresholds. The decrease in specificity was 1.6%, 1.6%, 2.2% and 1.7% for ASCUS+, LSIL+, ASC-H+, and HSIL+, respectively.

C. DESCRIPTIVE DIAGNOSIS FOR BENIGN CELLULAR CHANGES

Table 22 shows the descriptive diagnosis marginal frequencies for benign cellular changes and other non-neoplastic findings for all sites combined. Each case was read by each of 3 site CT/Pathologist teams. Each case was read first by a cytologist; non-NILM slides (as determined by the cytologist) were read by a pathologist from the same site CT/Pathologist team.

Table 22. Unadjudicated Marginal Frequencies – Summary of Descriptive Diagnosis for Benign Cellular Changes

	Manual Review		**TIS Review**		**Genius Review**	
Number of Reviews	5880		5880		5880	
Descriptive Diagnosis	**N**	**%**	**N**	**%**	**N**	**%**
Benign Cellular Changes	**721**	**12.3**	**686**	**11.7**	**1035**	**17.6**
Organisms:						
Trichomonas vaginalis	71	1.2	70	1.2	103	1.8
Fungal organisms consistent with *Candida* spp.	261	4.4	222	3.8	312	5.3
Shift in flora s/o bacterial vaginosis	371	6.3	373	6.3	562	9.6
Bacteria consistent with *Actinomyces* spp.	16	0.3	19	0.3	54	0.9
Cellular changes consistent with Herpes virus	2	0	2	0	3	0.1
Other infection	0	0	0	0	1	0
Other Non-Neoplastic Findings	**440**	**7.5**	**346**	**5.9**	**513**	**8.7**
Reactive cellular changes associated with inflammation	227	3.9	160	2.7	279	4.7
Atrophy	191	3.2	168	2.9	198	3.4
Reactive cellular changes associated with radiation	1	0	0	0	0	0
Reactive cellular changes associated with IUD	0	0	1	0	0	0
Glandular cells status post hysterectomy	0	0	0	0	2	0
Endometrial cells in a woman ≥45 yrs of age	21	0.4	17	0.3	34	0.6

Presence of Endocervical Component	**4387**	**74.6**	**4239**	**72.1**	**4602**	**78.3**

A higher percentage of infectious organisms/vaginal infections (17.6% [1035/5880] vs 12.3% [721/5880]) and non-neoplastic findings (8.7% [513/5880] vs 7.5% [440/5880]) was observed using Genius Cervical AI review compared to Manual review, respectively. A higher percentage of infectious organisms/vaginal infections (17.6% [1035/5880] vs 11.7% [686/5880]) and non-neoplastic findings (8.7% [513/5880] vs 5.9% [346/5880]) was also observed using Genius Cervical AI review compared to TIS review, respectively.

ANALYTICAL PERFORMANCE OF THE GENIUS DIGITAL DIAGNOSTICS SYSTEM WITH THE GENIUS CERVICAL AI ALGORITHM

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.

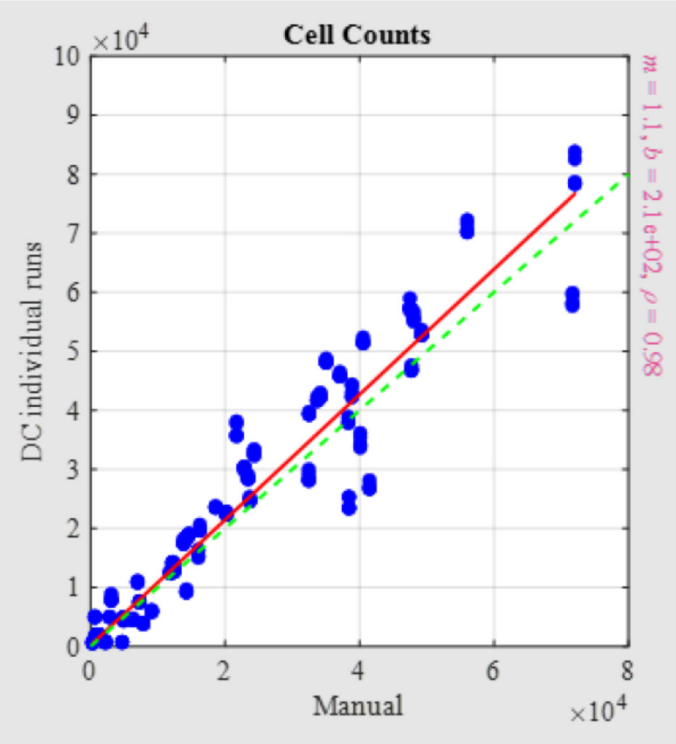
ThinPrep Pap test patient sample slides were prepared on a ThinPrep 5000 processor, stained and coverslipped. The same slides were imaged on three Genius Digital Imagers three separate times. To obtain the manual cell count for the slides in the study, a CT viewed the whole slide image presented on the 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 important threshold of 5000 cells, were enrolled in the study. The slides covered a range of cellularity typical of a clinical environment.

Using this study data, the within-imager precision %CV was 0.6% and between-imager %CV was 2.7%.

Figure 1 compares the cell counts between the Genius Cervical AI algorithm and a manual cell count method for each specimen.

Figure 1. Scatter Plot of Digital Result versus Manual Result



The appropriate linear regression analysis was performed, and slope was 1.06 with 95% CI: (1.01; 1.11) and the intercept of 213 with 95% CI: (28; 398). The relative systematic difference between digital review and manual review counts at 5,000 cells was 10% with 95% CI: (4%; 17%).

The results of the Cell Count Study were acceptable.

OBJECTS OF INTEREST (OOI) REPRODUCIBILITY STUDY

A study was conducted to demonstrate that the Genius Cervical AI algorithm accurately and reproducibly selects Objects of Interest (OOI), at one site. An OOI is a cell or cluster of cells on a glass slide scanned by the Genius Diagnostics System with the Genius Cervical AI algorithm that most likely contains clinically relevant information for diagnostic purposes. The study compared OOIs selected by the Genius Cervical AI algorithm to the reference diagnosis by adjudication for the slide. The study evaluated the performance of the Genius Cervical AI algorithm to present images suitable for diagnosing abnormal cervical cases. The study also measured reproducibility of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

In the study, 37 ThinPrep Pap test slides were enrolled, selected from slides used in the clinical study for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, covering the full range of abnormal diagnostic categories as defined in *The Bethesda System for Reporting Cervical Cytology*. These slides were made on the ThinPrep 2000 system, ThinPrep 5000 processor, and ThinPrep Genesis processor. The slides were imaged three times on three different Genius Digital Imagers.

Three CTs independently reviewed the nine runs of each case on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, blinded as to the reference diagnosis for the case. In each review on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, the CT recorded what the CT observed in every tile in the gallery for the case on the Review Station.

The accuracy and reproducibility of the algorithm were measured by comparison to the adjudicated reference diagnoses determined during the clinical study.

OOI Study Results

Table 23. OOI Summary by Reference Category (all CTs)

Reference Dx	# Slides	# of Evalua-tions	Proportion Abnormal OOIs	Median # Abnormal OOIs	Range of Number Abnormal OOIs (Min; Max)	Proportion Category+ OOIs	Median # Category+ OOIs	Range of Number Cat+ OOIs (Min; Max)
UNSAT	2	54	31%	0	0 ; 5			
NILM	5	135	16%	0	0 ; 4			
ASCUS	5	135	100%	6	2 ; 17	100%	6	2 ; 17
LSIL	5	135	100%	10	3 ; 23	96%	5	0 ; 23
ASC-H	5	135	100%	13	4 ; 22	100%	11	3 ; 19
AGC	5	135	100%	12	3 ; 24	100%	12	3 ; 24
HSIL	5	135	100%	18	12 ; 25	100%	9	2 ; 21
CANCER	5	135	100%	14	5 ; 20	92%	6	0 ; 14
All Abnormal	30	810	100%	13	3 ; 25	98%	8	0 ; 24

OOI Summary by Reference Category Table Key:

- # of evaluations = (total valid runs) * (# of CTs for the given diagnosis subset of slides)
- Proportion abnormal = the fraction of evaluations for which at least one abnormal OOI was observed
- Median # abnormal = the median number of abnormal OOIs in the evaluations
- Proportion category+ = the fraction of evaluations for which at least one OOI that is equal or greater than the reference diagnosis observed.

Reference Dx	"Category+" OOI labels
ASCUS	ASCUS, LSIL, ASC-H, AGC, HSIL, Cancer
LSIL	LSIL, ASC-H, HSIL, Cancer
ASC-H	ASC-H, HSIL, Cancer
HSIL	HSIL, Cancer
Cancer	Cancer

- Median # category+ = the median number of OOIs that are category+ in the evaluations

Note that, for the reference cancer slide reviews, while 100% had OOIs marked by the CTs as ASCUS+, 92% had OOIs marked as cancer.

Agreement Rates by Threshold

Table 24 below shows the positive agreement rate of the OOIs at various abnormal thresholds. For example, there were 20 LSIL+ slides (combined LSIL, ASC-H, HSIL, and CANCER), evaluated by 3 CTs over 9 imaging runs for a total of 540 evaluations. Of those, 530 had LSIL OOIs or higher for an agreement rate of 530/540 = 98%.

Table 24. Agreement rates by Reference Threshold

Threshold	# of Evaluations	Agreement Rate
ASCUS+	810	100%
LSIL+	540	98%
ASC-H+	405	99%
HSIL+	270	99%
CANCER	135	92%

OOI Reproducibility

Table 25 below shows the between-instrument and within-instrument agreement rates for the presence of Category+ OOIs.

Table 25. OOI Reproducibility

	# of Pairs	% Agreement
Between-instrument	999	96%
Within-instrument	999	99%

TECHNICAL PERFORMANCE CHARACTERISTICS

Multiple studies were conducted to evaluate the performance of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

Study Name	Study Description	Results
Slide Feeder	Evaluate the configuration of the slide feeder mechanism, user interaction with the slide feeder, including hardware, software, feedback mechanisms, and Failure Mode and Effects Analysis (FMEA).	Performance met the defined criteria
Light Source	Verify the intensity and spectral variation of the LED light source at various time intervals.	Performance met the defined criteria
Imaging Optics	Test magnification, relative irradiance, optical distortions, and chromatics aberrations.	Performance met the defined criteria
Mechanical Scanner Movement	Test positioning accuracy and repeatability for the X-Y and Z stages.	Performance met the defined criteria
Digital Imaging Sensor	Measure and evaluate linearity, spatial uniformity, dark current, noise, opto-electronic conversion function, and electron conversion factor of the sensor.	Performance met the defined criteria
Image Processing Software	Test image processing for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.	Performance met the defined criteria
Image Composition	Test specifications on the scanning method.	Performance met the defined criteria

Image File Format	Test compression method, compression ratio, file format, and file organization.	Performance met the defined criteria
Image Review Manipulation Software	Test continuous panning, continuous zooming, and digital bookmarks.	Performance met the defined criteria
Computer Environment	Test computer hardware, operating system, memory, hard disk, graphics card, graphics card driver, color management settings, color profile, display interface and network specification.	Performance met the defined criteria
Display	Test to verify the performance of the display including color-calibration tools and quality-control.	Performance met the defined criteria
Structural Similarity Index Measurement (SSIM)	Assessment of the SSIM that combines measurements of luminance, contrast, and structure at the pixel level across multiple runs, instruments, and calibration cycles.	Performance met the defined criteria
Color Reproducibility	Test to quantify the accuracy and precision of the color transformation from the slide to the display monitor.	Performance met the defined criteria
Spatial Resolution	Test to evaluate the spatial resolution, including the composite optical performance of all components in the image acquisition phase.	Performance met the defined criteria
Focus Test	Test to demonstrate the focus quality of the whole slide images produced by the Genius Digital Imager.	Performance met the defined criteria
Whole Slide Tissue Coverage	Test to demonstrate that the entire specimen on the clinical slide is detected by the device.	Performance met the defined criteria
Stitching Error	Test to assess the quality and accuracy of stitching image swaths in the Genius Digital Imager.	Performance met the defined criteria
Turnaround Time	Test to evaluate the average time required to execute zooming and panning operations, and to refresh the display in response to user input.	Performance met the defined criteria

User Interface	Human Factors Engineering or Usability Engineering testing regarding user interactions with the Genius Digital Imager and Genius Review Station.	Performance met the defined criteria

CYTOLOGIST SCREENING TIME STUDY

As part of the Genius Cervical AI Clinical Study, Hologic collected cytologist screening time data and calculated accuracy.

The study data includes the case review times for a total of 12 cytologists, screening a total of 1994 digital cytology cases in a clinical setting, although the review periods varied as cytologists were not fully dedicated to the clinical study. The study measured the diagnostic performance results of each CT compared to adjudicated diagnoses.

The results are summarized below in Table 26 which shows the median case review time for the 12 CTs compared to the sensitivity and specificity results at the ASCUS + threshold, as compared to adjudicated results.

Table 26. CT Review Times and ASCUS+ Sensitivity / Specificity

Site ID	Number of Cases	% ASCUS+	CT	Median Case Review Time (sec)	Range of Case Review Time (sec) (5^{th} ; 95^{th} percentile)	ASCUS+ Sensitivity	ASCUS+ Specificity
1	488	39.3 (192/488)	1	104	41 ; 644	90.7%	90.4%
			2	116	48 ; 479	81.3%	96.8%
			3	103	48 ; 416	91.2%	92.6%
2	494	36.8 (182/494)	1	94	49 ; 348	85.5%	95.5%
			2	148	82 ; 363	98.0%	72.6%
			3	105	66 ; 249	97.4%	92.0%
3	490	37.3 (183/490)	1	46	25 ; 120	92.3%	93.8%
			2	93	44 ; 263	96.2%	87.9%
			3	99	46 ; 284	88.0%	96.1%
4	488	31.1 (152/488)	1	136	72 ; 290	92.7%	91.6%
			2	73	42 ; 259	93.8%	91.9%
			3	57	31 ; 232	93.8%	91.6%

Figures 2 and 3 show scatterplots for the sensitivity and specificity results, respectively, as well as the resulting regression coefficients.

Figure 2. Sensitivity vs. Median Review Time

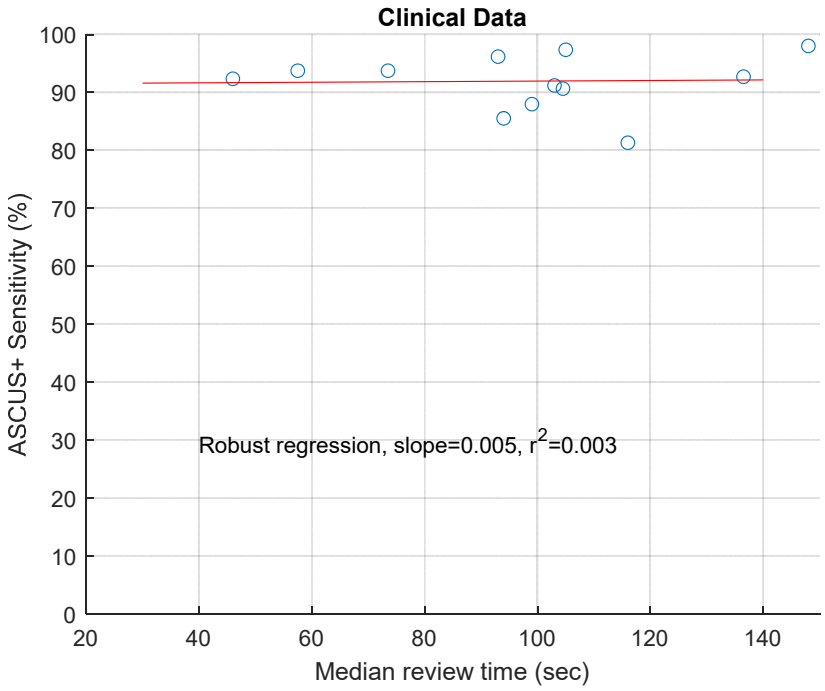
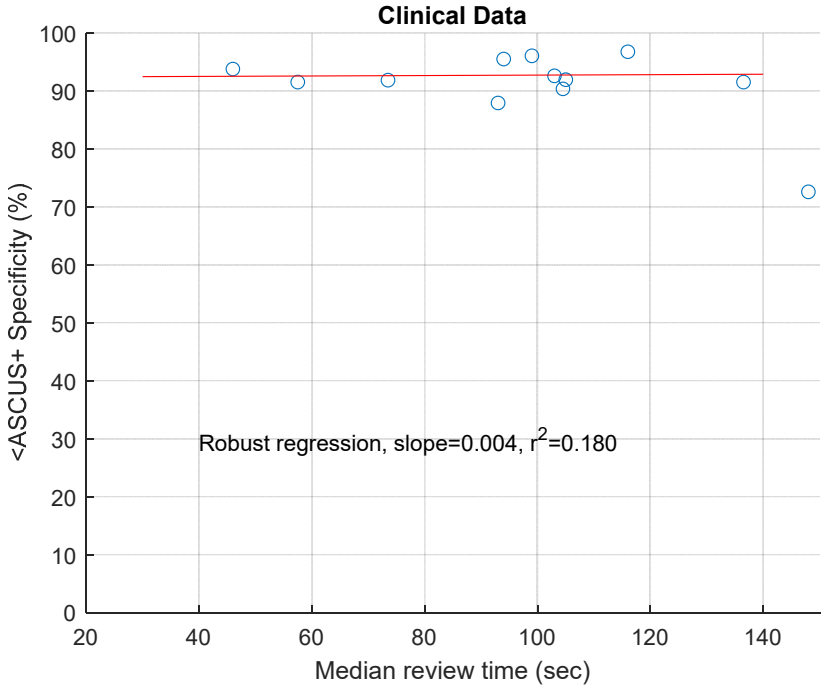


Figure 3. Specificity vs. Median Review Time



Regression analysis based on performance of 12 CTs showed that correlation coefficients for both the sensitivity and specificity analyses are low (0.003 and 0.180, respectively), indicating minimal dependence between performance and review time.

The data based on performance of 12 CTs in this study did not find that the CT case review time impacted the diagnostic performance at the ASCUS+ threshold.

CYTOLOGIST WORKLOAD DETERMINATION

Workload is defined by CLIA as a maximum of 100 slides in no less than an 8-hour workday. This refers to a full manual review (FMR) of 100 slides on a microscope. All cases diagnosed from the Genius Digital Diagnostics System with the Genius Cervical AI algorithm count as 0.5 or ½ CLIA slide equivalent. In the Genius Cervical AI clinical study, CTs accurately diagnosed cases using digital images presented by the system more efficiently than with a full manual review of a case.

Use the below method to calculate workload, which cannot exceed the CLIA maximum limit of 100 slides (or 100 CLIA slide equivalents) in no less than an 8-hour workday:

- All Genius Cervical AI (GCAI) case reviews count as 0.5 slide (½ CLIA slide equivalent)
- All full manual reviews of the glass slide count as 1 slide (1 CLIA slide equivalent)
- A full manual review of the glass slide in addition to a GCAI review counts as 1.5 slides (1.5 CLIA slide equivalents)

0.5*GCAI + 1.5*(GCAI + FMR)+ 1*FMR ≤ 100 CLIA slide equivalents

Example 1 - workload for reviewing ThinPrep Pap tests with the Genius Digital Diagnostic System with the Genius Cervical AI algorithm:

200 Genius Cervical AI Case Reviews = 100 CLIA slide equivalents
(200 * 0.5 = 100)

Total number of CLIA slide equivalents screened: 100

Example 2 - workload for reviewing ThinPrep Pap tests with the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, when some cases were reviewed both digitally and on glass:

180 Genius Cervical AI Case Reviews = 90 CLIA slide equivalents [180 * 0.5 = 90]

6 Genius Cervical AI Case Reviews + FMR = 9 CLIA slide equivalents [(6 * 0.5)+(6 * 1) = 9]

Total number of CLIA slide equivalents screened: 99 (90 + 9)

Notes:

- ALL laboratories should have a clear standard operating procedure for documentation of workload counting and for establishing workload limits.
- It is the responsibility of the Technical Supervisor to evaluate and set workload limits for individual cytologists based on laboratory clinical performance.
- According to CLIA '88, these workload limits should be reassessed every six months.

CYBERSECURITY

Medical device security is a shared responsibility between stakeholders, including healthcare facilities, patients, providers, and manufacturers of medical devices.

The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is designed for security using a layered architecture approach to cybersecurity. Risks have been reduced as far as possible, and Hologic continually evaluates security patches, software updates including off-the-shelf (OTS), and the effectiveness of controls in the layered security architecture. Hologic applies critical security updates immediately after validation and applies non-critical security patches during regular scheduled maintenance periods.

Refer to and follow the Security instructions in the Genius Digital Imager Operator's Manual, the Genius Review Station Operator's Manual and the Genius IMS User's Manual.

CONCLUSIONS

The data from the studies conducted on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm demonstrate that the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, is safe and effective 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 criteria as defined *by The Bethesda System for Reporting Cervical Cytology*[1].

- In the Genius Cervical AI Clinical Study, for all sites combined for ASCUS+, there was an observed improvement in sensitivity of the Genius Digital Diagnostics System with Genius Cervical AI review method over the Manual Review method. This increase of 1.6% was not statistically significant, with a 95% confidence interval of -0.1% to 3.2%.

- For LSIL+, ASC-H+ and HSIL+, the improvement in sensitivity of the Genius Digital Diagnostics System with Genius Cervical AI method over the Manual Review method was statistically significant and was as follows-

    - For LSIL+: 4.4% with a confidence interval of 2.1% to 6.7%
    - For ASC-H+: 8.2% with a confidence interval of 4.8% to 11.6%
    - For HSIL+: 7.5% with a confidence interval of 4.0% to 11.4%. With regard to false negative (less than HSIL) rate for HSIL+, the 7.5% increase in HSIL + sensitivity means a decrease in Manual false negative rate of 26.0% to 18.5% false negative rate by the Genius Digital Diagnostics System with the Genius Cervical AI algorithm resulted in 28.8% reduction in the number false negative reviews (28.8% = (26.0%-18.5%)/26.0%).
- For Cancer, the observed sensitivities of the Genius Digital Diagnostics System with Genius Cervical AI method and Manual Review method were the same, with a confidence interval of -9.8% to 11.1%.

The data from the studies conducted on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm showed that screening time is reduced without affecting diagnostic performance when compared to the manual review. The workload limit for the Genius Digital Diagnostic System with the Genius Cervical AI algorithm was established at 200 case reviews in no less than an 8-hour workday, if there were no cases reviewed with FMR and is not to exceed 100 CLIA equivalent slides in no less than an 8-hour workday.

Specimen adequacy as described in Bethesda 2014 can be determined using Genius Digital Diagnostics System with the Genius Cervical AI algorithm. Unsatisfactory rates between manual and Genius Cervical AI-assisted review were similar in the clinical study. Estimated cell count was found to be comparable between manual and Genius Cervical AI-assisted review as well. Additionally, endocervical component was similar using Genius Cervical AI-assisted review compared to manual review.

For the clinical sites and the study populations tested, the data from the clinical study demonstrates that the use of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm to assist during primary screening of ThinPrep Pap test slides for all cytologic interpretations, as defined by the Bethesda System, is safe and effective for the detection of cervical abnormalities.

MATERIALS REQUIRED

MATERIALS PROVIDED

- Genius Digital Imager
    - Digital Imager (PRD-05815)
    - Digital Imager computer (CMP-01687)
    - Slide carriers (ASY-14299)
- Genius Review Station
    - Monitor (CMP-01669)
    - 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. Refer to Genius Review Station Operator's Manual for the minimum specifications for the computer. In some configurations of the system, a laboratory may supply the server hardware and network switch. Refer to Genius IMS user's manual for the minimum specifications for the server and network switch.

- Complete instructions for operating the components in the system are also required and provided by Hologic. Depending on the software version installed, the operating instructions are:
    - Genius Digital Imager Operator's Manual:
      MAN-08469-001 (software version 1.1.x) or MAN-12119-001 (software version 1.2.x)
    - Genius Review Station Operator's Manual:
      MAN-08467-001 (software version 1.1.x) or MAN-12121-001 (software version 1.2.x)
    - Genius Image Management Server Dashboard User's Manual:
      MAN-08468-001 (software version 1.1.x) or MAN-12120-001 (software version 1.2.x)

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 with the Genius Cervical AI algorithm, contact Hologic:

Telephone: 1-844-465-6442

Fax: 1-508-229-2795

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

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1. Introduction

Chapter One

Introduction

SECTION A

OVERVIEW AND FUNCTION OF THE GENIUS™ DIGITAL IMAGER

The Digital Imager is one component of the Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm. 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.

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 accession 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.

Note: In this operator's manual, a shortened form of the system name is sometimes used for clarity. "Genius Digital Diagnostics System" and "Genius Digital Diagnostics System with the Genius™ Cervical AI algorithm" refer to the same thing.

1 INTRODUCTION

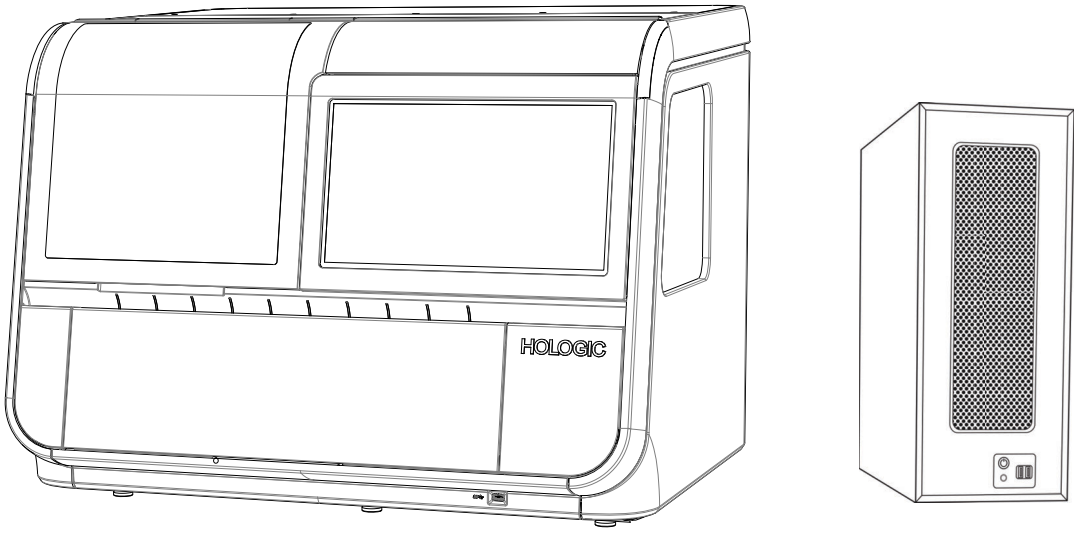


Figure 1-1 The Genius Digital Imager Processor and Digital Imager Computer

Indication for Use

The Digital Imager is one component of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm includes the Genius™ Digital Imager, Genius™ Image Management Server (IMS), the Genius™ Review Station, and the Genius™ Cervical AI algorithm. The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm is intended for the creation and viewing of digital images of scanned ThinPrep® Pap Test glass slides. Objects of interest selected by the Genius™ Cervical AI algorithm from the scanned digital image are presented in a gallery format, next to the image of the whole cell spot on the Genius™ Review Station, for review and interpretation. The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm is intended to aid in cervical cancer screening 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 as defined by *The Bethesda System for Reporting Cervical Cytology*[1].

After digital review with the Genius™ Cervical AI algorithm, if there is uncertainty in the diagnosis, then direct examination of the glass slide by light microscopy should be performed. Digital images from the Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm should be interpreted by qualified cytologists and pathologists in conjunction with the patient's screening history, other risk factors, and professional guidelines which guide patient management.

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

1 INTRODUCTION

Genius Digital Diagnostics System with the Genius Cervical AI Algorithm: Laboratory Flow for Cervical Cancer Screening

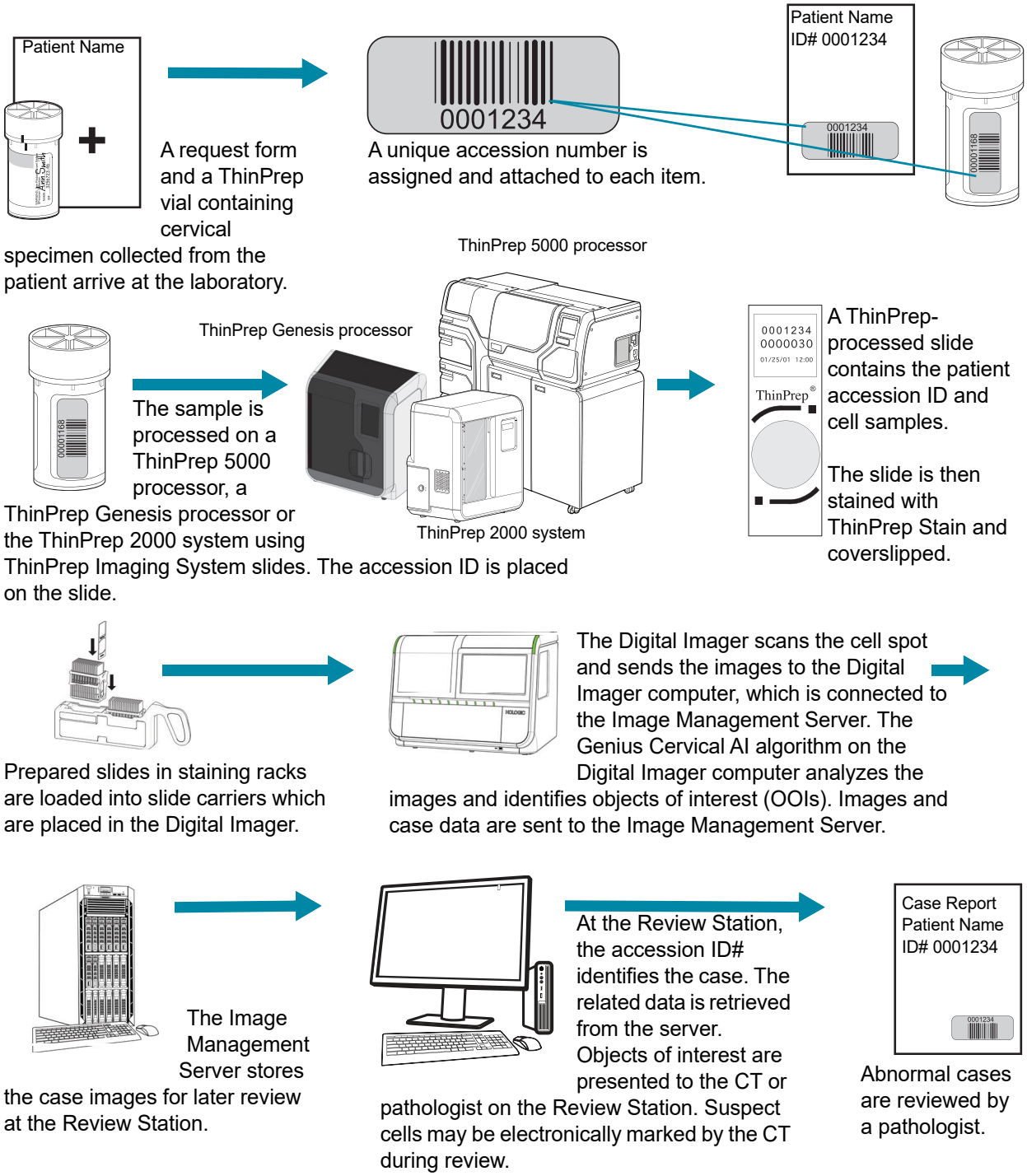


Figure 1-2 Lab Flow for ThinPrep® Pap Test Cases

SECTION B

THE GENIUS DIGITAL DIAGNOSTICS SYSTEM PROCESS FOR CERVICAL CANCER SCREENING

The Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm uses Pap test slides prepared from gynecologic (cervical/vaginal) samples obtained from women for screening, diagnosis and management.

Slides that have been prepared for screening using the ThinPrep® 2000 system, the ThinPrep® 5000 processor, or the ThinPrep® Genesis™ processor and stained with ThinPrep® stain (Papanicolaou stain) are loaded into slide carriers which are placed into the Digital Imager. The operator uses a touch screen on the Digital Imager to interact with the instrument via a graphic, menu-driven interface.

A slide ID reader scans the slide's accession ID and locates the scan area. Then, the Digital Imager scans a designated area of the microscope slide, creating an in-focus, whole slide image.

For ThinPrep® Pap test patient sample slides, the Genius Cervical AI algorithm identifies objects of interest found on a digital image of the slide. The objects classified as most clinically relevant are presented to a cytologist (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.

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

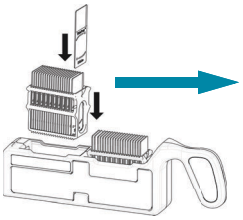
The Image Management Server acts as the central data manager for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. As slides are imaged by the Digital Imager and reviewed at the Review Station, the server stores, retrieves and transmits information based on the case ID.

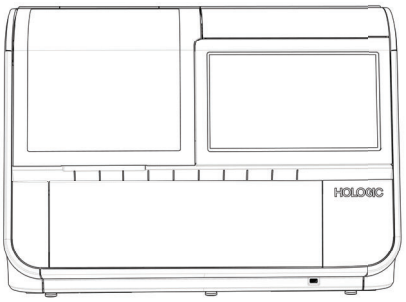
The CT or pathologist reviews cases at the Review Station. The Review Station is a dedicated computer running a Review Station software application, with a monitor suitable for diagnostic review of objects of interest and/or whole slide images. The Review Station is connected to a keyboard and mouse. 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 and comments in the case review. The reviewer, in addition to reviewing the gallery images, has the option to move to any portion of the cell spot for examination.

1 INTRODUCTION

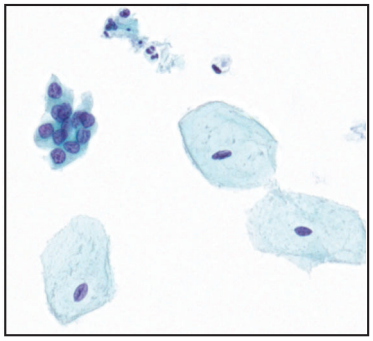
System Process: Genius Digital Diagnostics System with the Genius Cervical AI Algorithm





Prepared ThinPrep slides are loaded into a slide carrier, which is loaded into the Digital Imager.

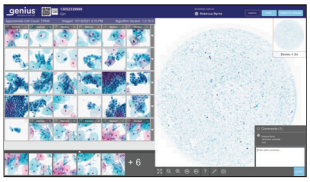
The cell spot is imaged



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

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

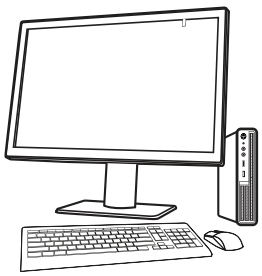
Case review by the cytologist or pathologist



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 1-3 System Process:
Genius Digital Diagnostics System with the Genius Cervical AI Algorithm

SECTION C

SPECIMEN PREPARATION AND PROCESSING

ThinPrep Pap Test 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 Digital Imager in a timely manner, according to normal laboratory practices.

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.

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 Imaging System microscope slides must be used. The fiducial marks should not be scratched or marred.

Specimen handling

Please refer to your laboratory guidelines for specimen handling.

SECTION D

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.

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

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 with the Genius™ Cervical AI algorithm 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, as defined by *The Bethesda System for Reporting Cervical Cytology: Definitions, Criteria, and Explanatory Notes*[1].

SECTION E

DIGITAL IMAGER TECHNICAL SPECIFICATIONS

Overview of Components

See Figure 1-4 through Figure 1-13 for information regarding components and specifications.

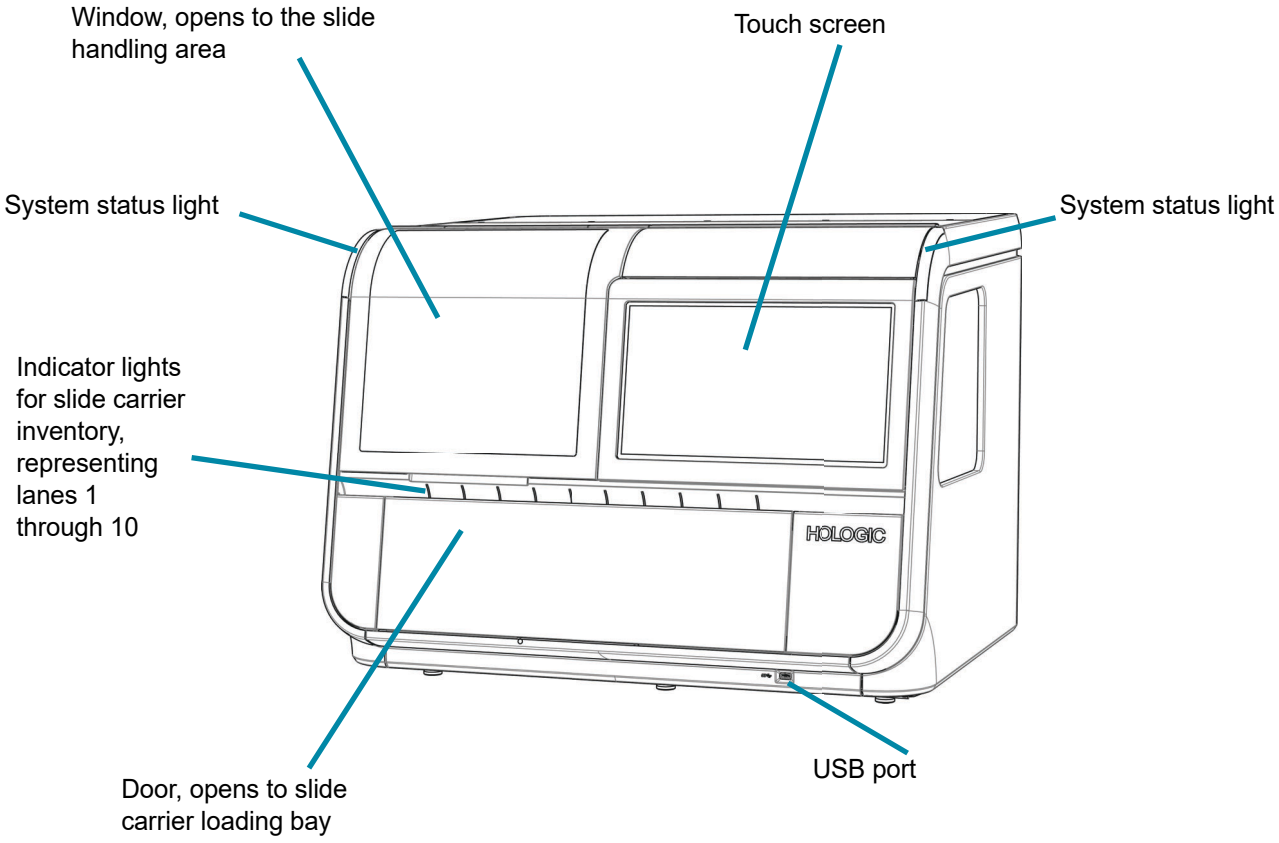


Figure 1-4 Front View, Digital Imager

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

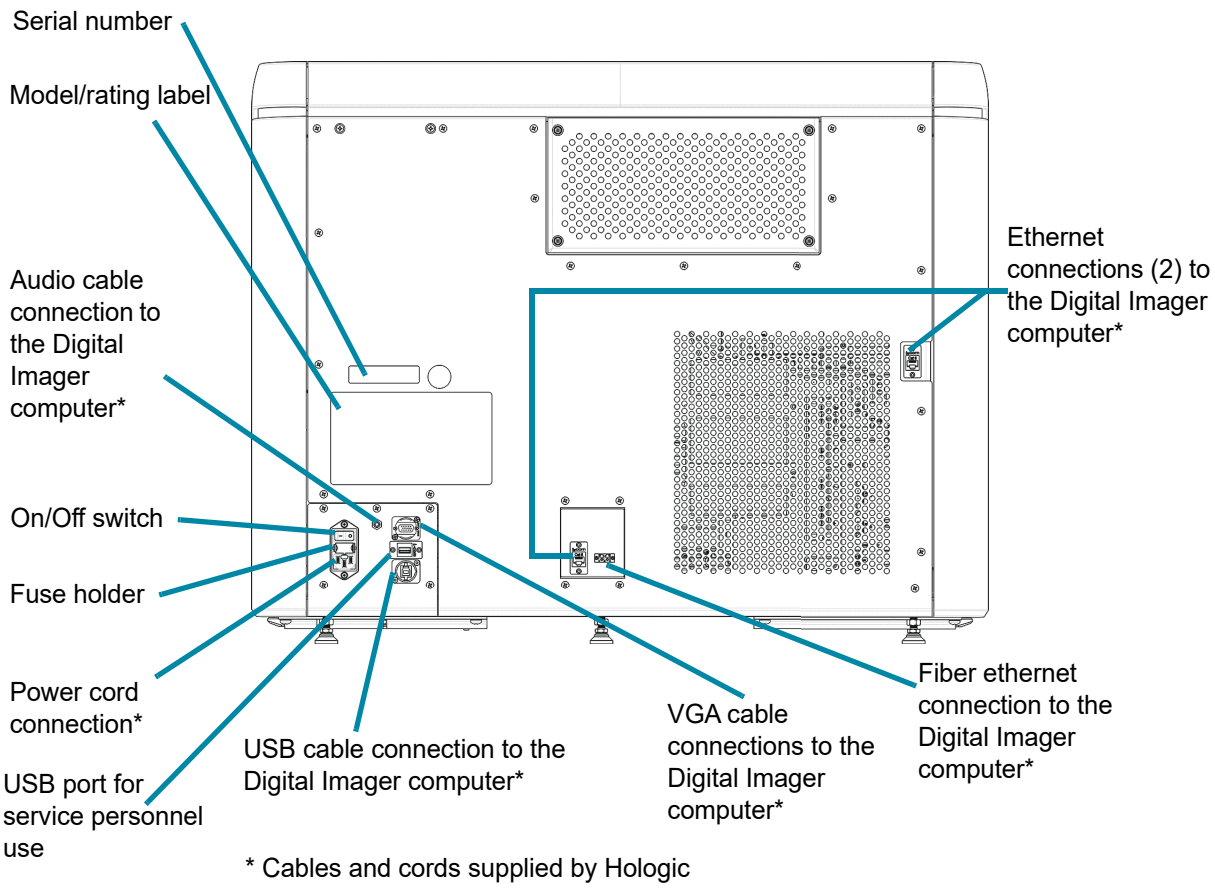
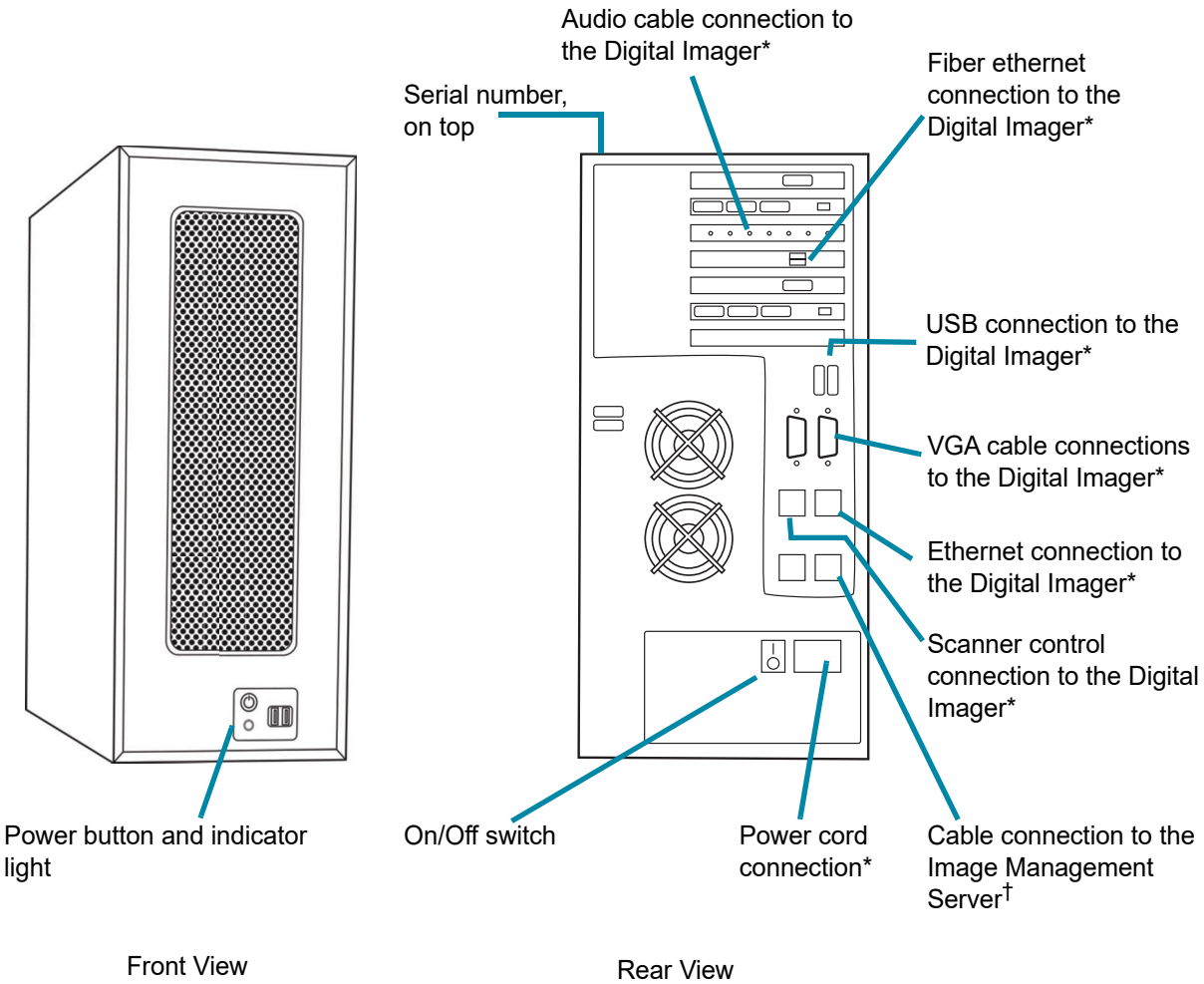


Figure 1-5 Rear View, Digital Imager



*Cables and cords supplied by Hologic

†The connection from the Digital Imager computer to the Image Management Server must have a network speed of 1Gbps or faster.

Figure 1-6 Digital Imager Computer

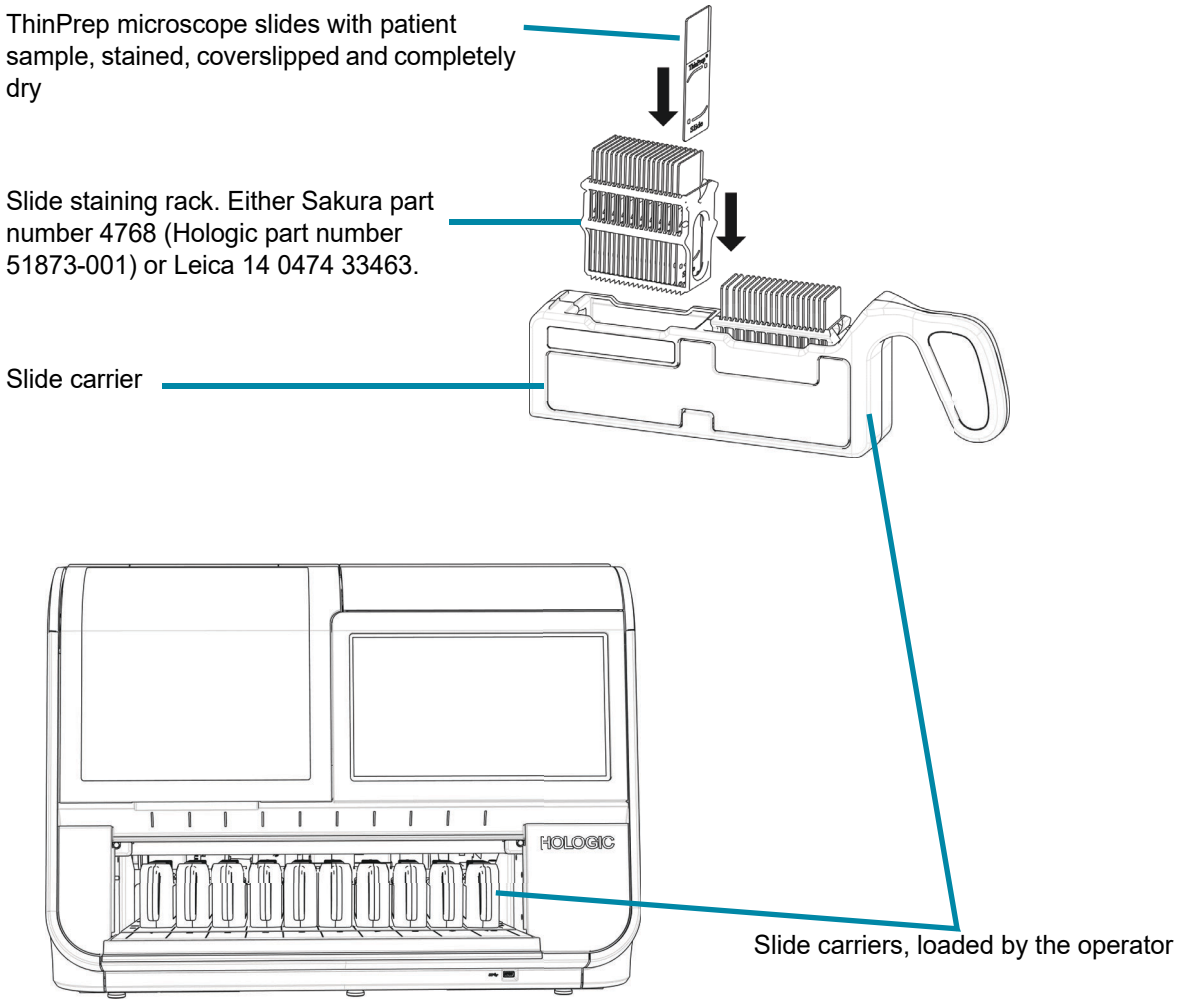
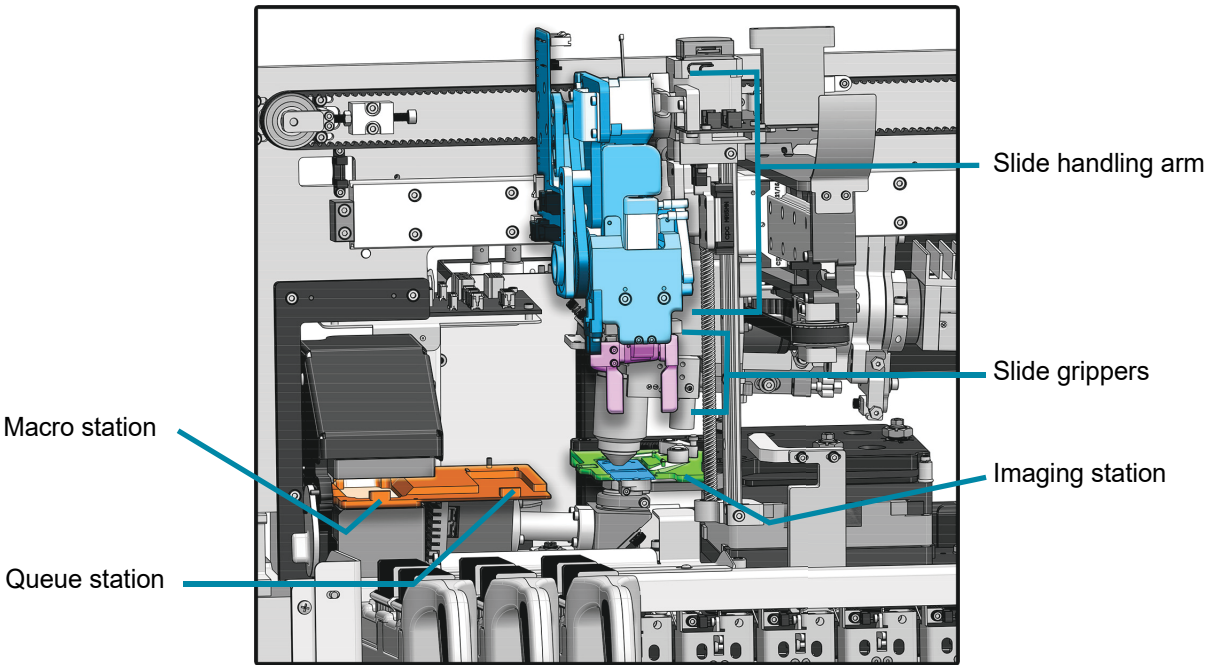


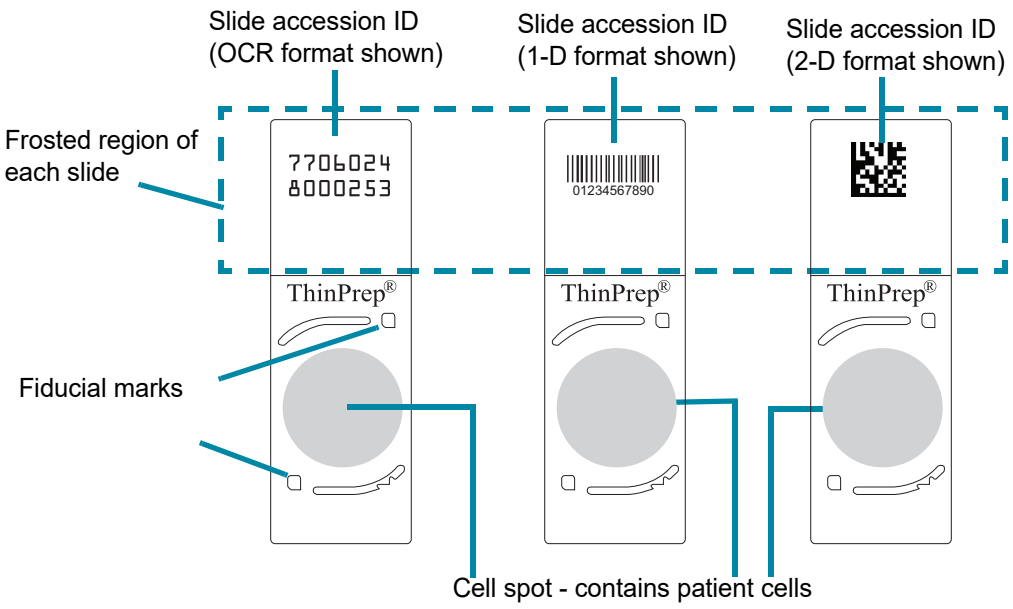
Figure 1-7 Slide Carriers in the Digital Imager (Digital Imager Door Open)



Interior of the Digital Imager - covers removed to show detail

Figure 1-8 Slide Handling in the Digital Imager

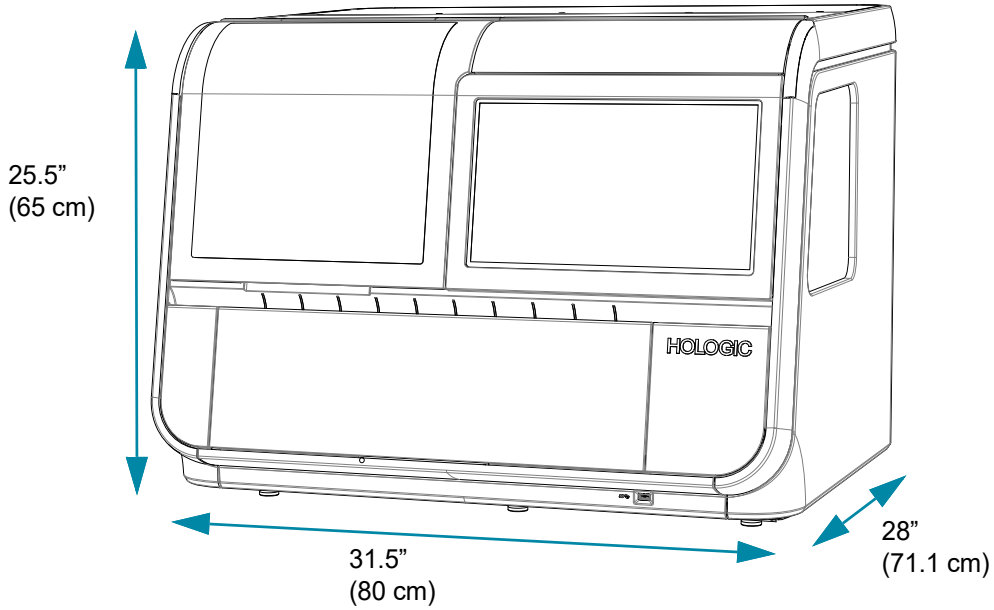
1 INTRODUCTION



ThinPrep Imaging System microscope slide, for Gyn specimens

Figure 1-9 Slides Used in the System

Digital Imager Dimensions

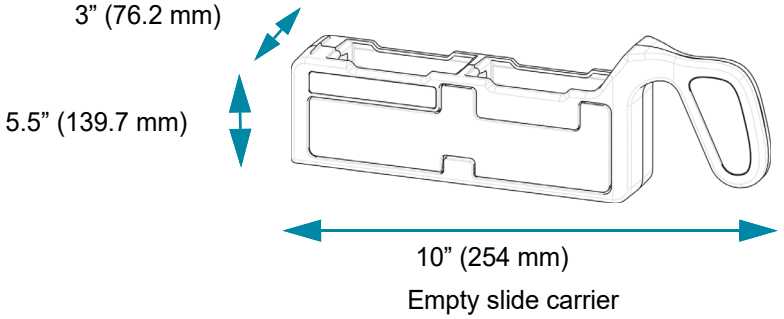


Approximate weight: 242 lbs. (110 kg)

Figure 1-10 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



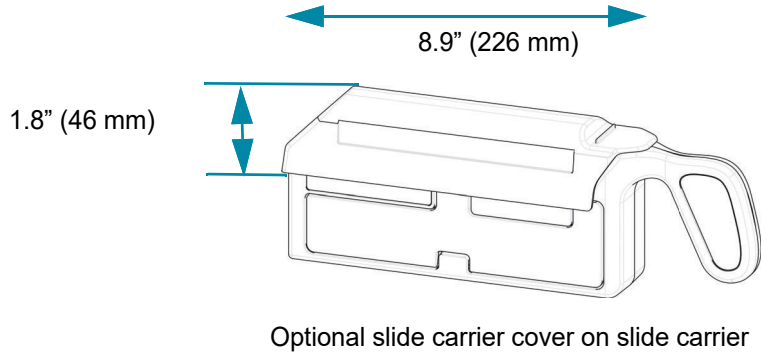


Figure 1-11 Slide Carrier Dimensions

Digital Imager Computer Dimensions

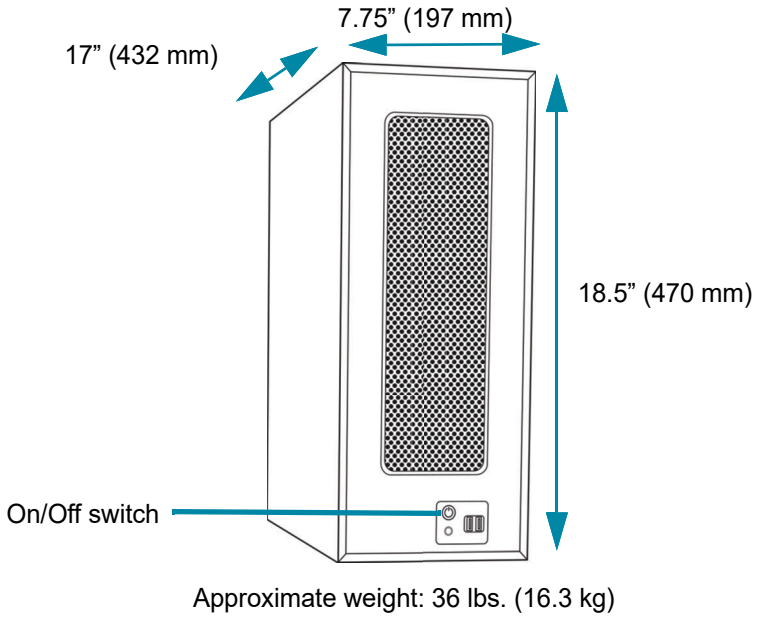


Figure 1-12 Digital Imager Computer Dimensions

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.

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.		
Emissions 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 commercial 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 F

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.

1 INTRODUCTION

SECTION G

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

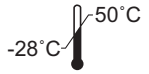
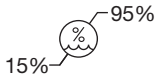
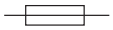
The terms **WARNING**, **CAUTION** and ***Note*** have specific meanings in this manual.

- 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:

Symbol	Title	Description	Standard information
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.4
	Caution, risk of electric shock (internal use only, not accessible to operators).	To identify equipment that has risk of electric shock	IEC 60417 Graphical symbols for use on equipment, symbol 5042
 hologic.com/ifu	Consult the instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3

Symbol	Title	Description	Standard information
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.8
	Protective earth; protective ground (internal use only, not accessible to operators).	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode	IEC 60417 Graphical symbols for use on equipment, symbol 5019
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Fuse (Not user-accessible)	To identify fuse boxes or their location	IEC 60417 Graphical symbols for use on equipment, symbol 5016
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.7
	Authorized Representative in the European Community	Indicates the Authorized Representative in the European Community	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.2
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1

1 INTRODUCTION

Symbol	Title	Description	Standard information
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.3
	Country of manufacture	To identify the country of manufacture of products	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.7.10
	Importer	Indicates the entity importing the *medical device* into the locale	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.8
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	On (Power switch)	Indicates that the control places the equipment in a fully powered state.	IEC 60417-1 Graphical symbols for use on equipment, symbol 5007
	Off (Power switch)	Indicates that using the control will disconnect power to the device.	IEC 60417-1 Graphical symbols for use on equipment, symbol 5008
	On/Off, Standby mode	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption.	IEC 60417—Graphical symbols for use on equipment -- Reference number 5009

Symbol	Title	Description	Standard information
SS	USB 3 port (computer)	To identify a port or plug meeting the generic requirements of the Universal Serial Bus (USB). To indicate that the device is plugged into a USB port or is compatible with a USB port.	IEC 60417 —Graphical symbols for use on equipment -- Reference number 3650

Location of Labels Used on the Instrument

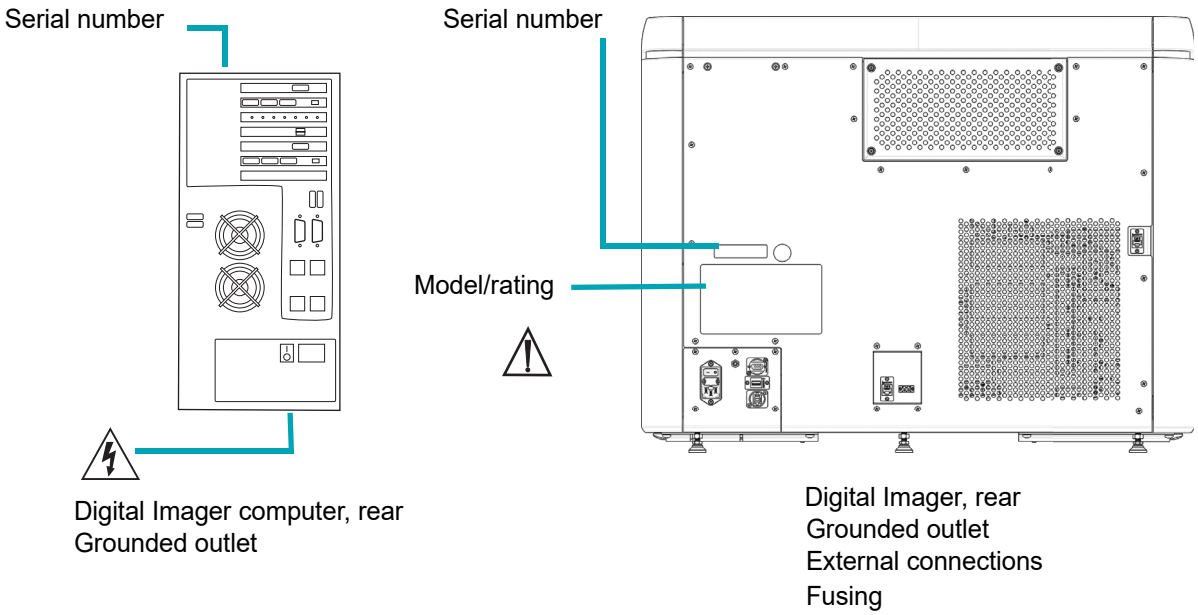


Figure 1-13 Label Locations

Warnings Used in this Manual:

WARNING

For professional use only.

1 INTRODUCTION

WARNING

Service Installation Only

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

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 service personnel trained by Hologic.

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 Genius Digital Imager uses glass 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.

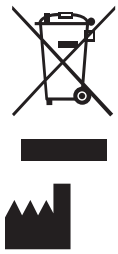
SECTION H DISPOSAL

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.



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1 INTRODUCTION

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2. Installation

Chapter Two

Digital Imager Installation

WARNING: Service Installation Only

SECTION A GENERAL

The Digital Imager and Digital Imager computer must be installed by service personnel trained by Hologic. The complete Genius Digital Diagnostics System must be installed by service personnel trained by Hologic. 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 installation by service personnel trained by Hologic.

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

2 DIGITAL IMAGER INSTALLATION

SECTION C

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, service personnel trained by Hologic 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 Genius Digital Imager and the Genius Digital Imager computer 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 service personnel trained by Hologic.

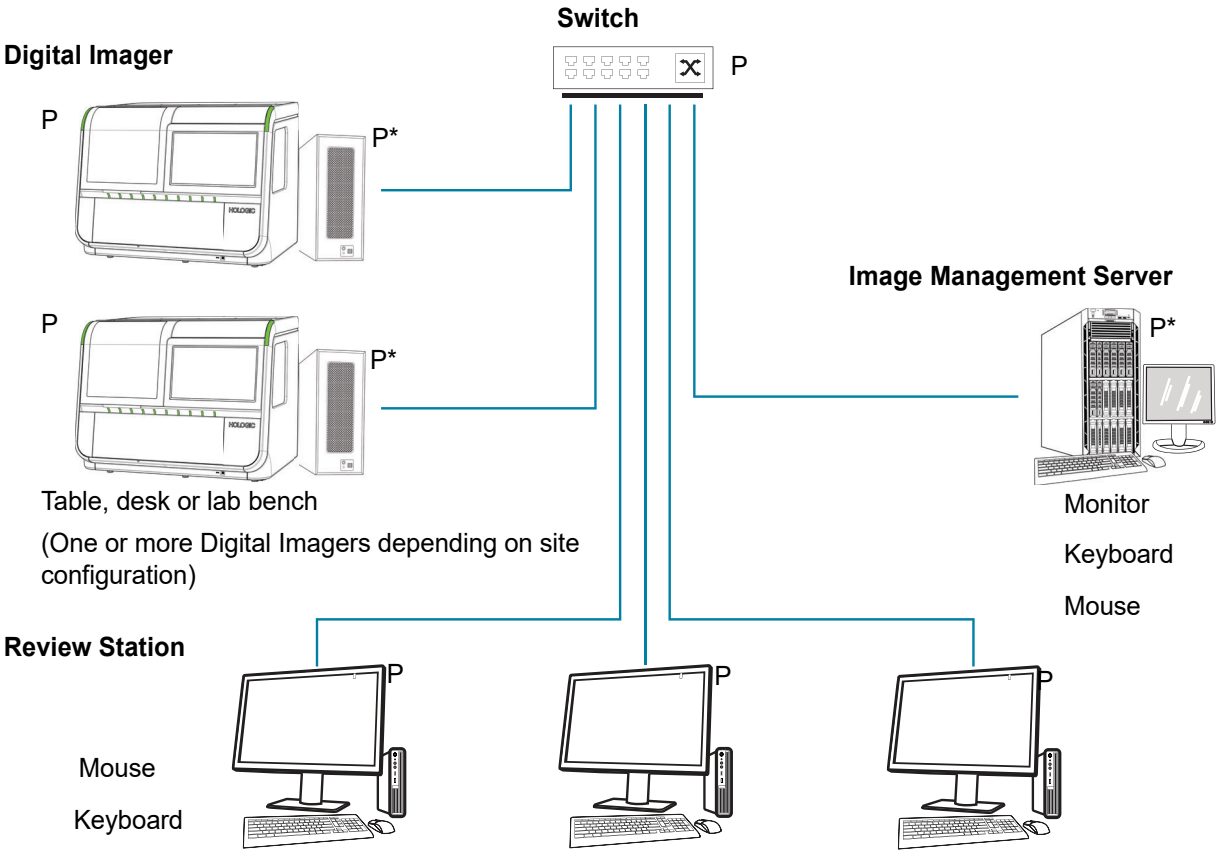

Figure 2-1 Local Network Interconnection Schematic, example

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

Security

Hologic recommends that each laboratory works directly with your existing information systems and security staff to determine the most appropriate actions to take based on the information technology (IT) infrastructure at your site.

Limit access to trusted users

The Genius Digital Imager employs Windows® security and access controls. The Digital Imager does not require a user logon to access the user-level interface. This interface is accessible to anyone who has physical access to the system. There are minimal cybersecurity risks to the system but someone with physical access to the user-level interface could cause unintentional or intentional harm. This harm is limited to causing a non-functional system which could delay slide imaging in the lab. Hologic recommends that the Digital Imager should be located in an area that is only accessible to trusted users as the customer sees fit. In the event of a non-functioning system, contact Hologic Technical Support as detailed in Chapter 8, Service Information.

Cybersecurity and data protection

To support data integrity, confidentiality and security, the Genius Digital Imager processor and computer prevent the installation and execution of unauthorized software and disallows unauthorized changes to the system software. To complement these protective measures, take the following actions to ensure the system is protected and secure:

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

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

Cybersecurity updates

Hologic continually evaluates software updates, security patches, and the effectiveness of the implemented security safeguards to determine if updates are needed to mitigate emerging threats.

Hologic will provide validated software updates and patches throughout the lifecycle of the medical device to assure its continued safety and effectiveness.

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.

2 DIGITAL IMAGER INSTALLATION

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3. User Interface

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

SECTION A

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.

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 3.43.

The **Start** button starts processing slides. Refer to "Slide Processing" on page 4.15. At least one slide carrier must be loaded into the Digital Imager for the **Start** button to be available.

SECTION B

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.

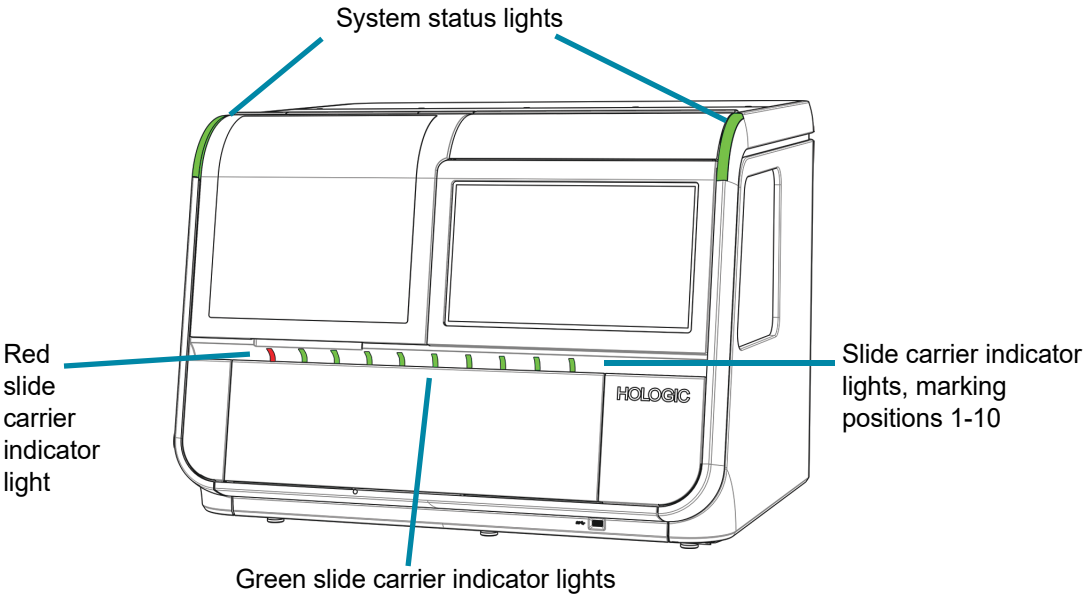


Figure 3-2 Indicator Lights

Exterior LED lights		
System status light	Green	The Digital Imager is on, and the Digital Imager is operational.
	Flashing amber	The Digital Imager is on, and the Digital Imager requires user intervention to continue. After the user intervenes, the Digital Imager continues the action that was interrupted.
	Flashing red	The Digital Imager is on, and the Digital Imager has a system error. • If the system error is recoverable with user intervention, after the error is resolved, the user will be able to start slide processing. • If the system error is unrecoverable, the user will need to restart the Digital Imager and a service visit may be required. The lights also flash red if the Digital Imager is on and there is an issue with the communication with the Image Management Server.

Exterior LED lights		
	Not illuminated	The Digital Imager is not turned on, or it does not have power.
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.

3 User Interface

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.

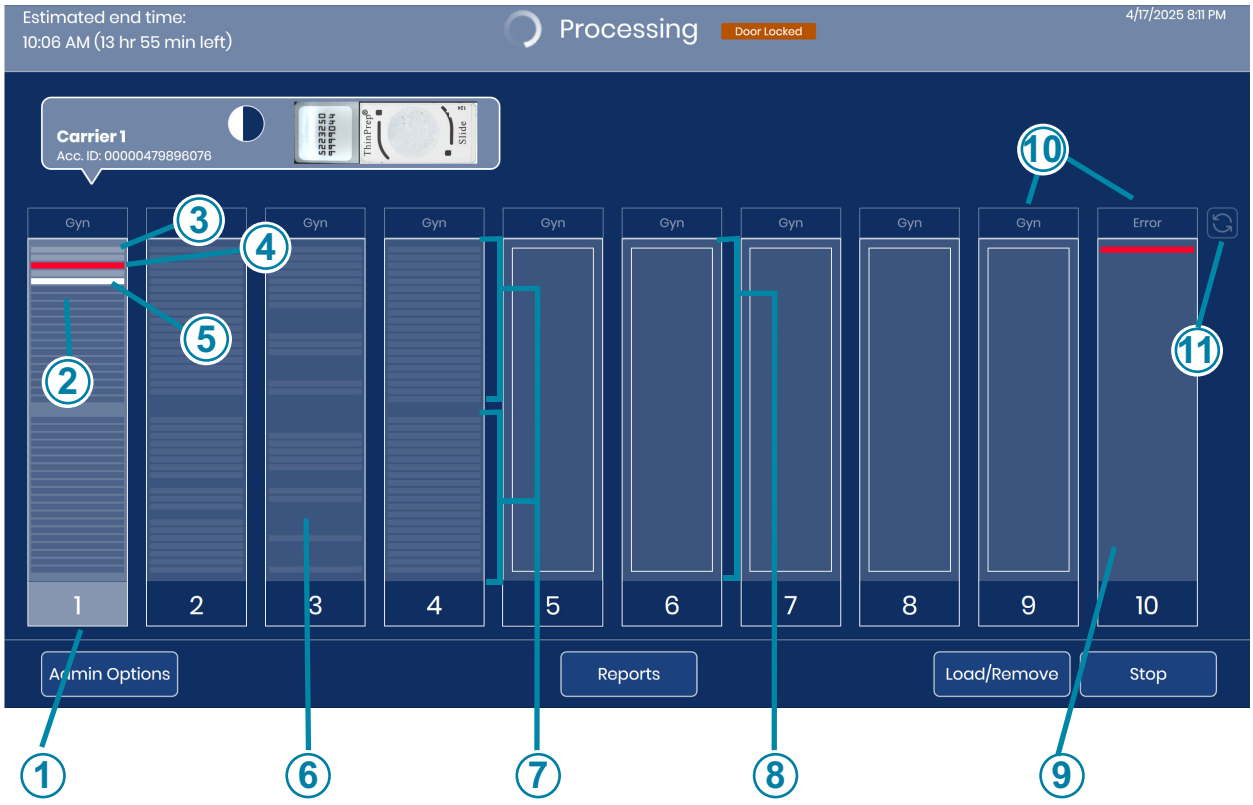


Figure 3-3 Screen Display Indicates Slide Carrier Position

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 or has not finished transferring data for that slide to the Genius Image Management Server. ***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	Case type Refer to “Select Case Type for Slide Carrier, Position 10” on page 3.13.
⑪	A button is available to refresh the names of the case types. When the Gyn case type is the only available case type, pressing the button has no effect.

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.

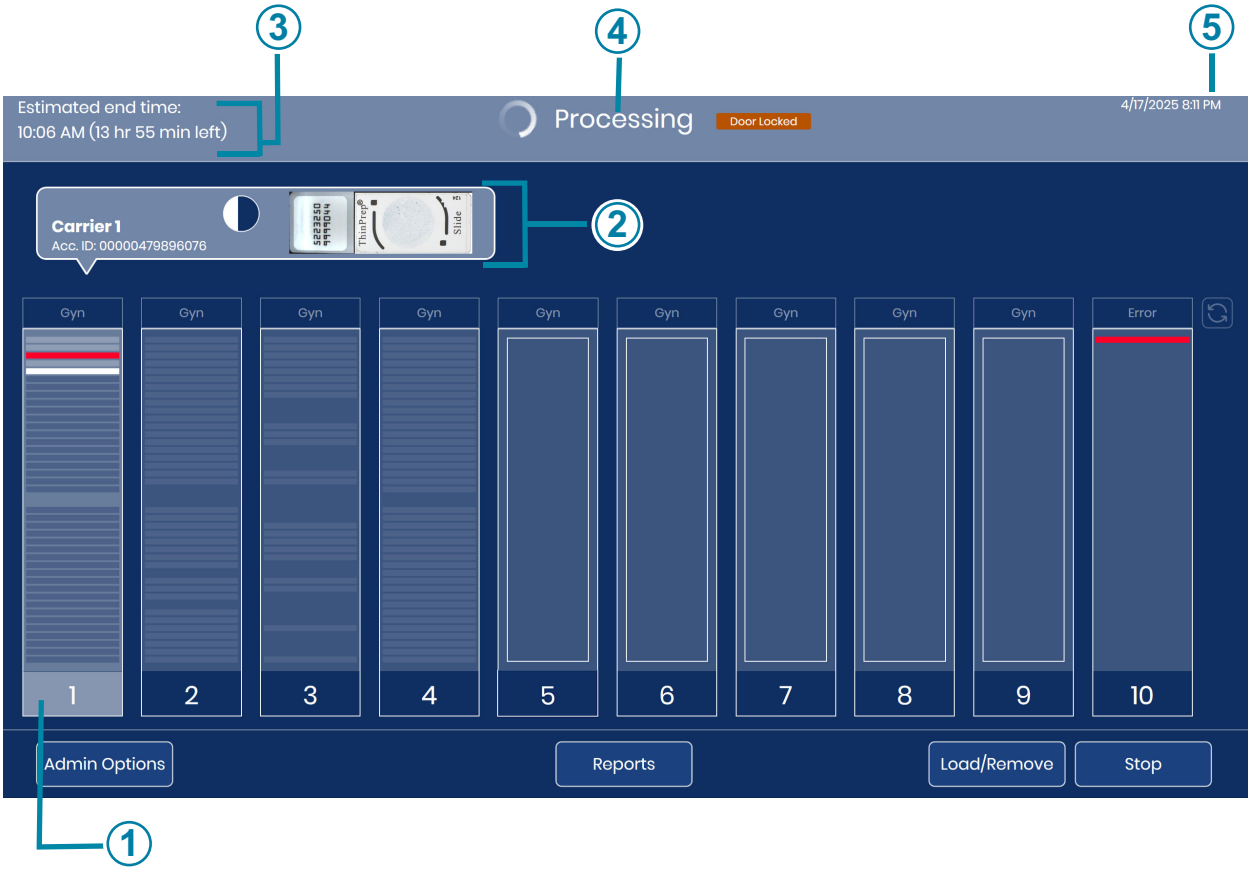


Figure 3-4 Screen Display During Processing

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 accession 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

An icon depicts the progress of the scanner within the Digital Imager. The light grey stripe indicates the completion of the data transfer from the Digital Imager to the Image Management Server.

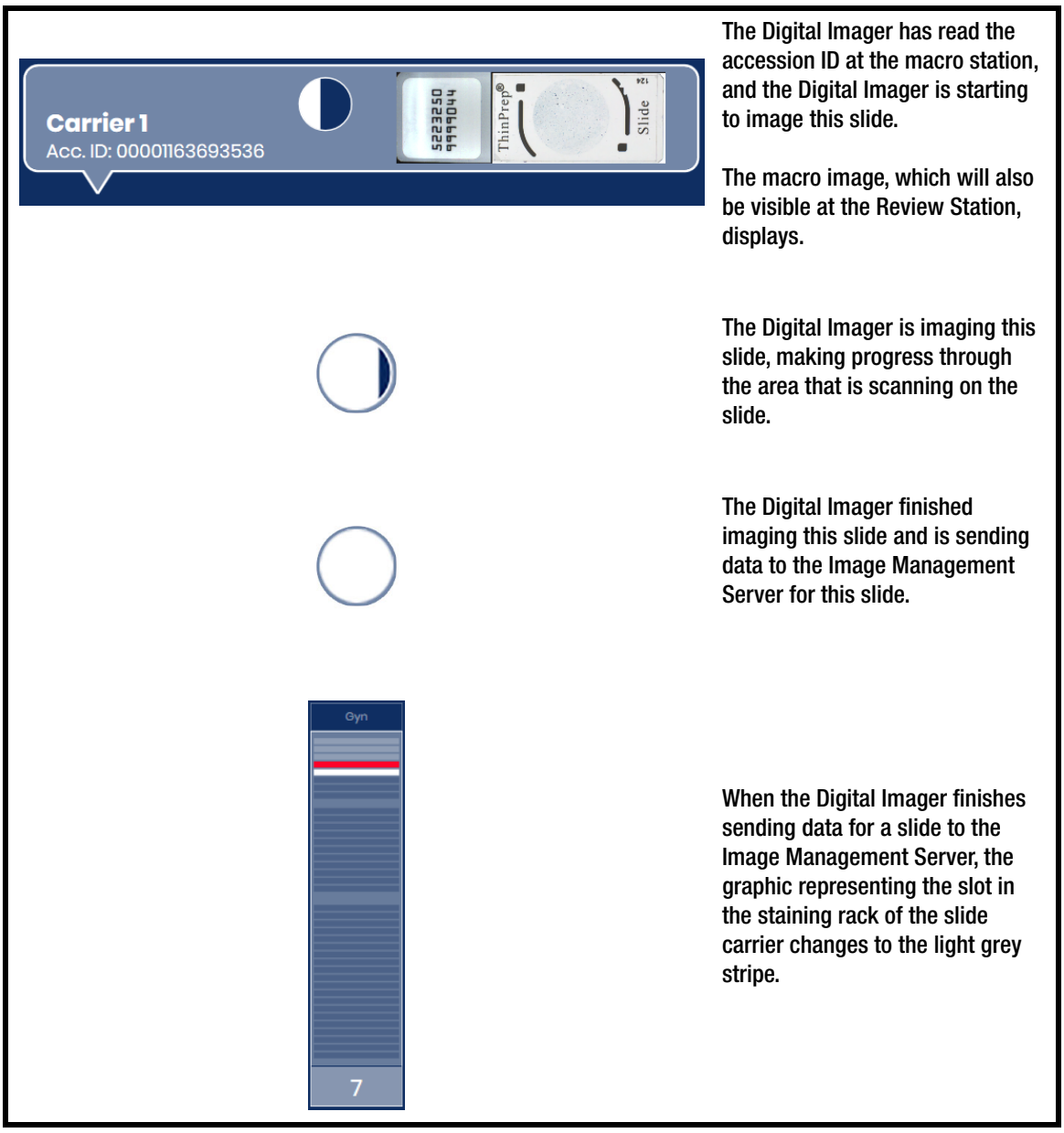


Figure 3-5 Slide Data Transmission Status

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.

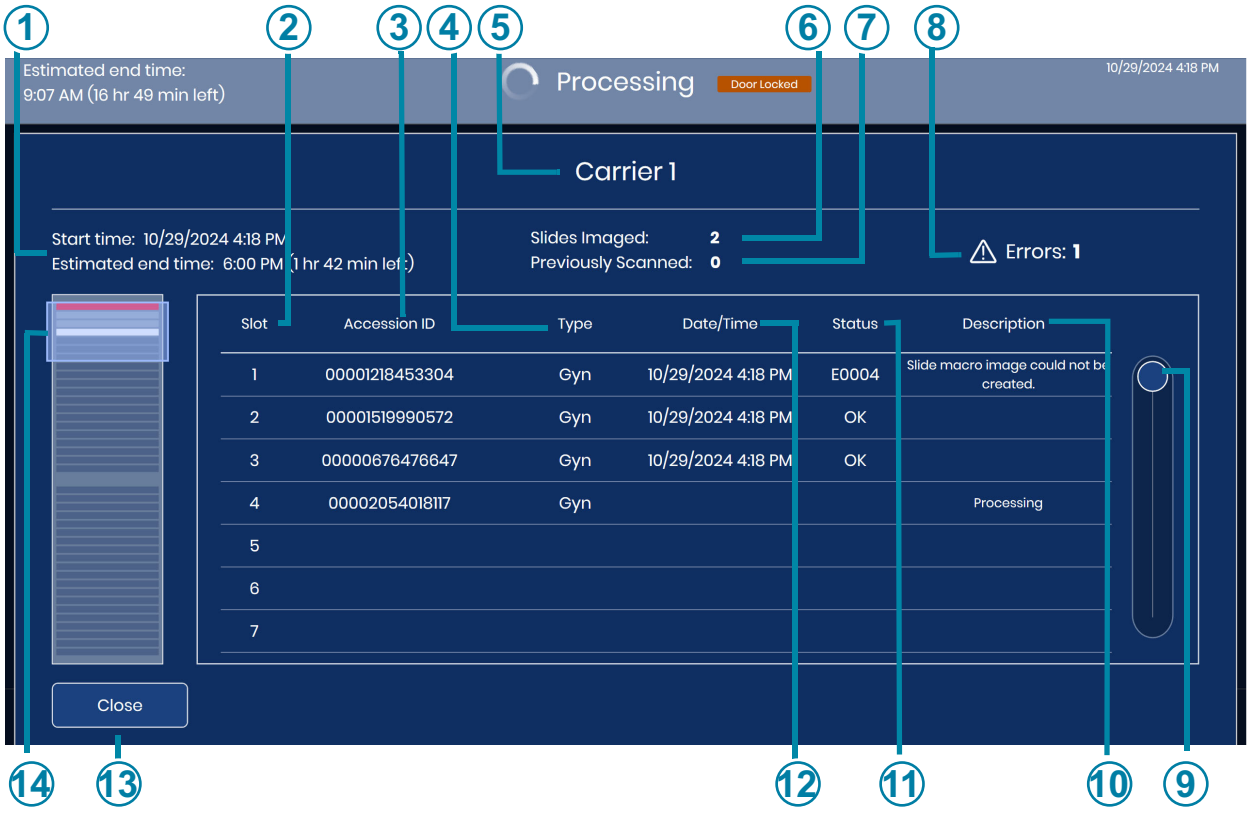


Figure 3-6 Slide Carrier Details Screen (Carrier 1, example)

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 accession ID read by the Digital Imager ***Note:*** If the accession ID is too long to display the full ID on this screen, the display ends with points of ellipsis (...) in the accession ID field.
4	The case type for the slide carrier (Gyn)

Key to Figure 3-6	
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. In general, an accession ID already successfully imaged cannot be imaged again. There are actions an operator can take to delete the case from the system. Refer to the Genius Review Station Operator's Manual for instructions for deleting a case. The Digital Imager can be configured to add the date and time to accession IDs for custom case types. Refer to "Acession ID Settings: Advanced Settings" on page 3.33.
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.
⑭	The box represents the progress of processing slides through the carrier.

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.

SECTION C

CASE TYPE OPTIONS

Select Case Type for Slide Carrier, Position 10

The slide carrier in position 10 of the Digital Imager can be designated to hold Gyn slides for processing, or it can be designated as an error slide carrier. Refer to "Using an Error Slide Carrier" on page 4.26. Position 10, and only position 10, can be designated as an error slide carrier, and the designation must be made prior to processing slides. To change the case type designation, touch the name of the case type above position 10 on the touch screen. Touch a name to select it: gynecologic cases (Gyn) or Error.

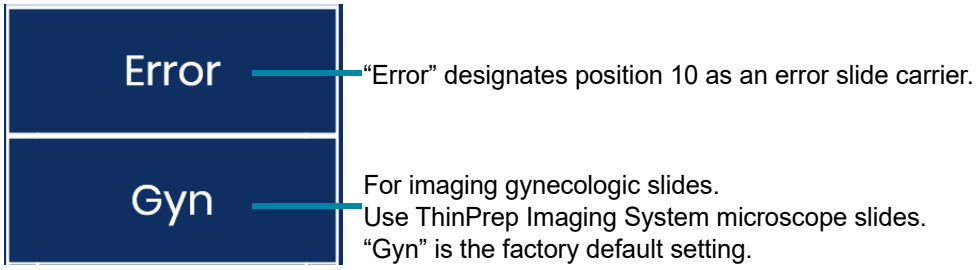


Figure 3-7 Sample Type Selection

The selection for case remains until the user changes it again.

SECTION D ADMINISTRATIVE OPTIONS

The system has options for configuring certain features of the Digital Imager.

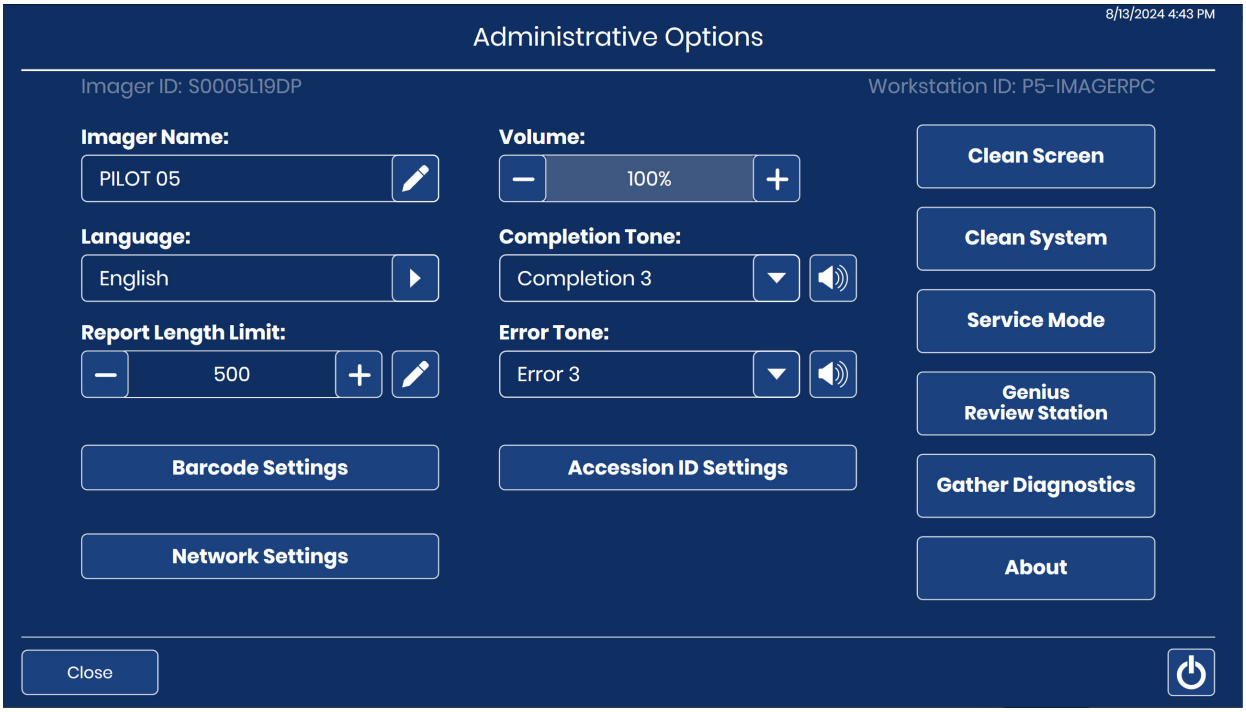


Figure 3-8 Administrative Options Screen

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.

Note: The Digital Imager must be in the idle state to change some of the Administrative Options settings: Barcode Settings, Accession ID Settings, Network Settings, Clean System, and Service Mode.

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.

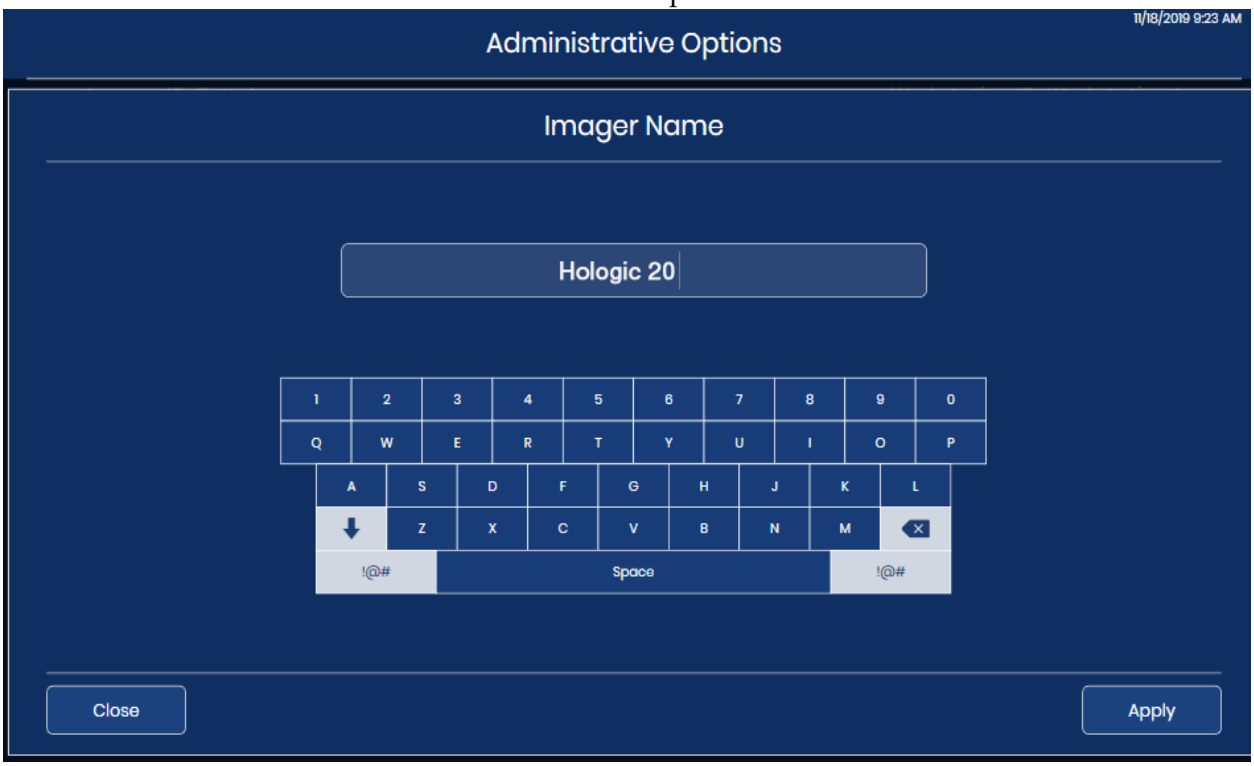


Figure 3-10 Edit Imager Name Screen

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.

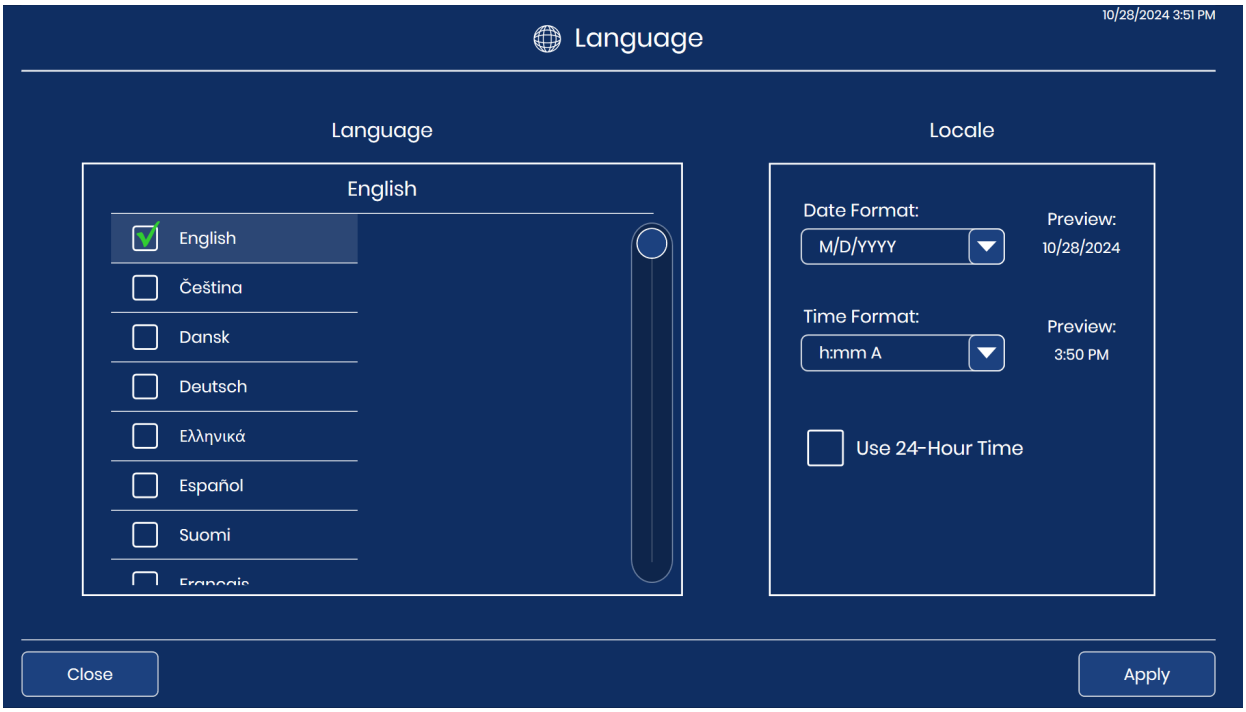


Figure 3-12 Select Language Screen

The current selection displays at the top of the screen. Touch the name of the language to select it.Use the scroll bar to scroll through the list of languages. 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, touch the box to select it. To use a 12-hour format, leave the check box empty, or touch the box to deselect it.

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

The screen shows the current setting.

Figure 3-13 Report Length Limit

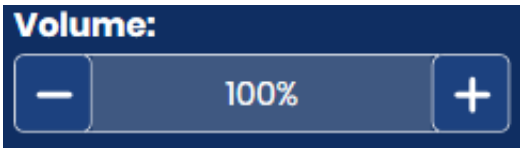
The report length limit is the maximum number of lines of data that are retrieved from the database for a report, from 500 to 5000. (If there is less data than the number chosen, all the available data will report.) The default setting is a limit of 500 results.

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



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.

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 3.18.

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.

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.

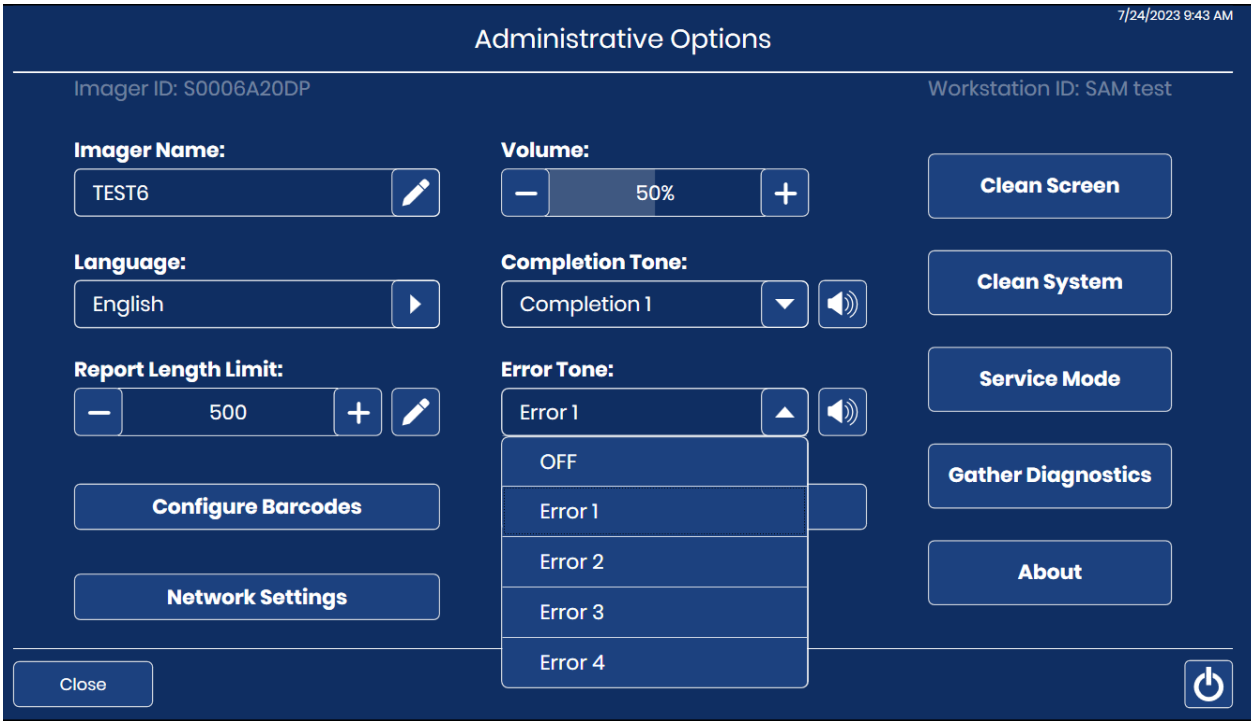


Figure 3-17 Select Error Tone (Optional)

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 3.18.

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.)

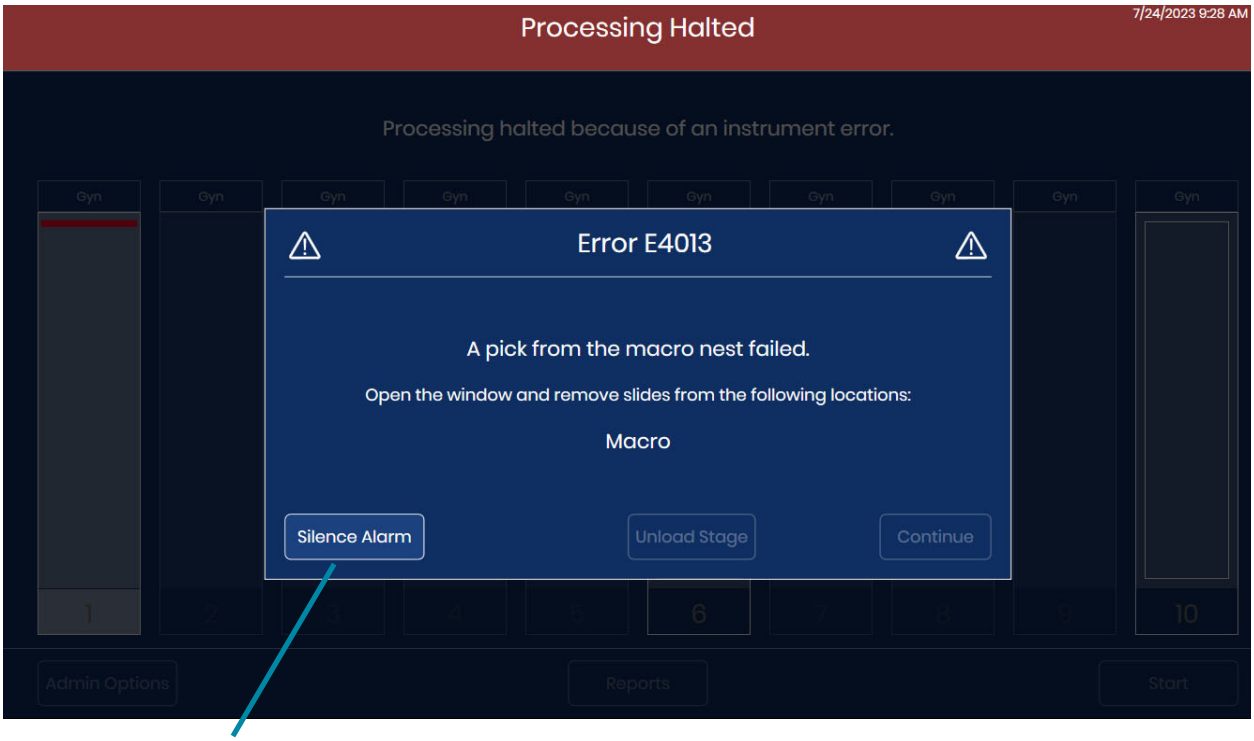


Figure 3-18 Silence Alarm Button

Clean System

This is used during maintenance to allow the operator access to the slide handling path in the instrument's interior. This is described in Chapter 5, Digital Imager Maintenance.

Clean Screen

This is described in Chapter 5, Digital Imager Maintenance.

Log in to the Genius Review Station from the Genius Digital Imager

Figure 3-19 Genius Review Station Button

3 User Interface

The operator of the Genius Digital Imager has the option to log in to the Genius Review Station from the Genius Digital Imager. This is optional. Logging in to the Genius Review Station from the Genius Digital Imager may be a convenient technique for activities such as deleting a new case that needs to be re-scanned.

In order to log in, the operator of the Genius Digital Imager must already be set up with a valid user account on the Review Station. A user has the same privileges as if they were logged in at the Review Station, with the exception of reviewing cases. A user can view case images, but they cannot save the review in progress or complete a review.

The URL for the Review Station must be configured before the Digital Imager operator can connect. Refer to “Network Settings” on page 3.26.

To log in to the Genius Review Station from the Genius Digital Imager, touch the **Genius Review Station** button.

When the Review Station application launches, log in with your Review Station username and password.

Navigate through the Review Station features using the Digital Imager touch screen. To type with a keyboard, first touch the keyboard icon in the lower right. To close the keyboard, touch the keyboard icon again.

To log out of the Review Station and close the Review Station window on the Digital Imager, touch the **Close Review Station** button.

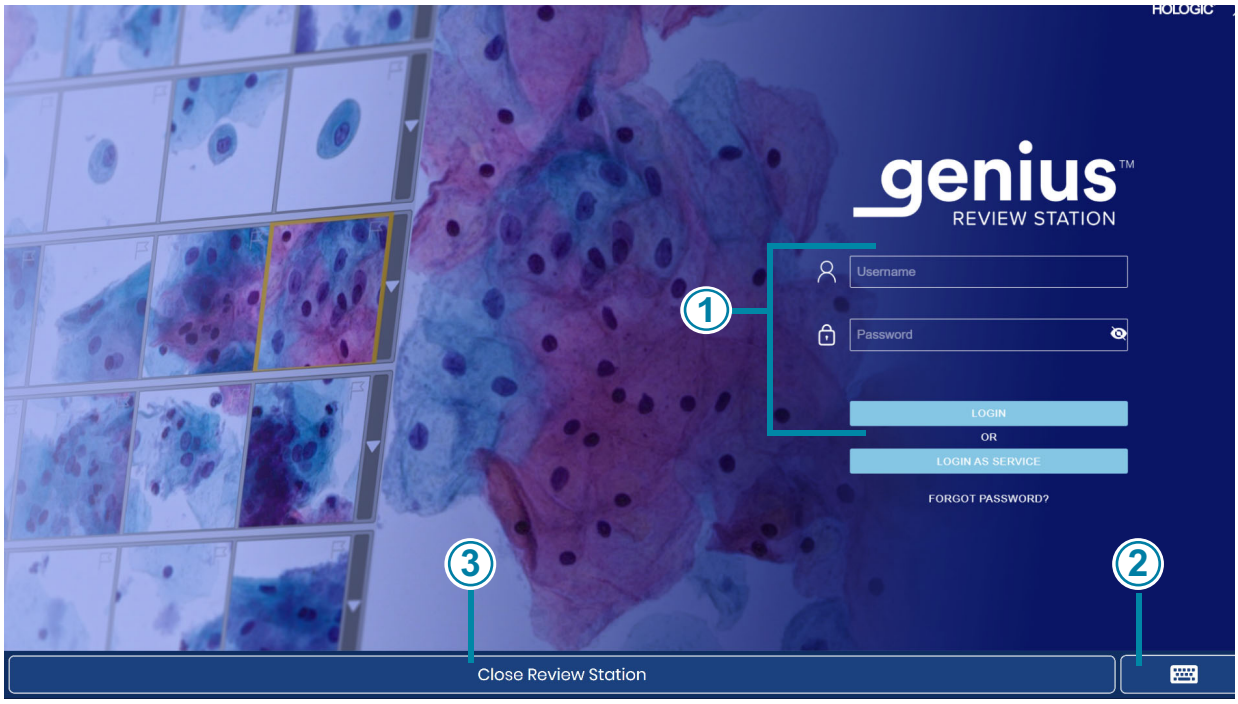


Figure 3-20 Access a Genius Review Station from a Genius Digital Imager

Key to Figure 3-20	
1	Log in to the Review Station using your Review Station credentials.
2	To type, touch the keyboard button to open an on-screen keyboard.
3	Touch **Close Review Station** to log out of the Review Station.

Service Mode

Figure 3-21 Service Mode Button

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

Gather Diagnostics

Figure 3-22 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.

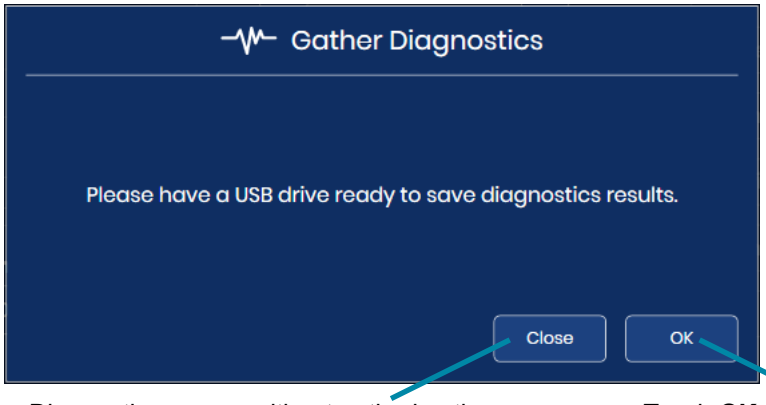


Figure 3-23 Gather Diagnostics: Insert a USB Drive

2. Put a USB device into the USB port on the front of the instrument. See Figure 1-4. 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.

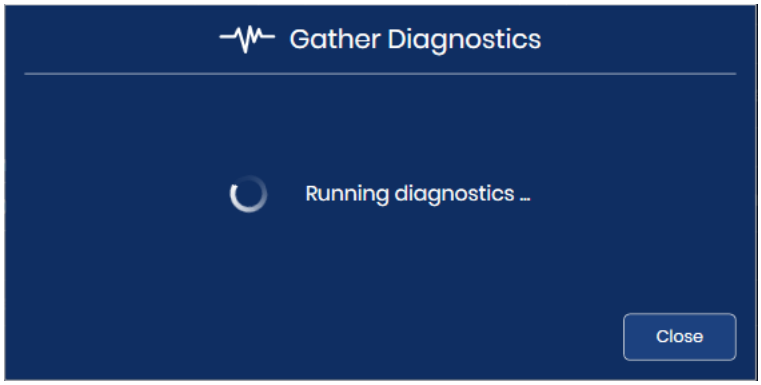


Figure 3-24 Gather Diagnostics: Running Diagnostics

3. The touch screen display confirms a successful file transfer. The instrument information will be gathered into a file on the USB device. The file name starts with "**DCDiagnostics**" and includes the Digital Imager's serial number, the date and the time. 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 3-25 Gather Diagnostics: File Saved on USB Drive

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

Network Settings

Figure 3-26 Network Settings

The Network Settings show information about the Genius Image Management Server connected to this Digital Imager in the Genius Digital Diagnostics System. The Network Settings provide an option to change the connection if more than one Image Management Server is configured and available in your lab, and if your lab opts to connect to the Genius Review Station application from the Digital Imager.

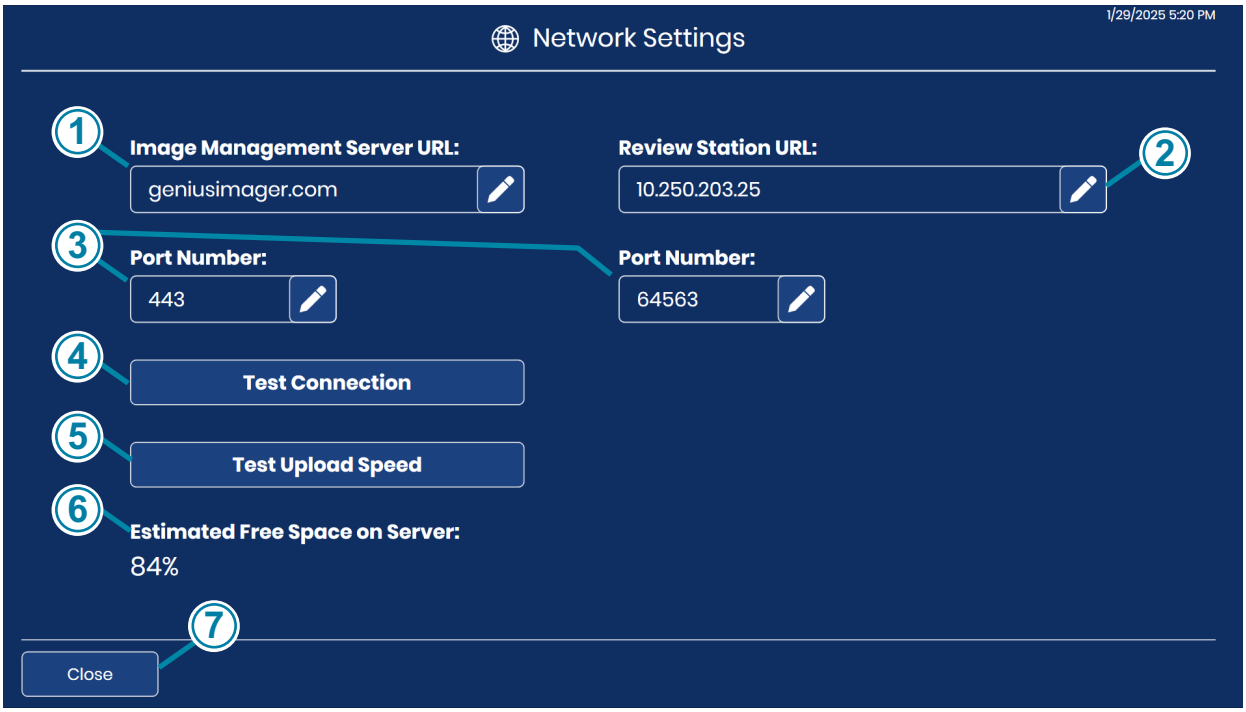


Figure 3-27 Network Settings Screen

Key to Figure 3-27	
①	**Image Management Server URL** The host name or IP address for the Image Management Server currently connected is displayed. To change the server, touch the edit button  . Type in the host name or IP address of another Genius Image Management Server configured in your lab's Genius Digital Diagnostics System. Do not enter the protocol prefix. The https protocol will be applied automatically when the connection is established. For example, if the host name were "hologic.com", enter "hologic.com" rather than "https://hologic.com". Hologic recommends that configuration and verification of the network address and port number are performed by service personnel trained by Hologic.
②	**Review Station URL** This is the URL or IP address for the Genius Review Station application running on the same Genius Image Management Server that is connected to the Genius Digital Imager. The screen displays the URL or IP address of the current connection. To change to a different URL or IP address, touch the edit button  . Type in the URL or IP address of the Genius Review Station application running on the same Genius Image Management Server as the Digital Imager. Do not enter the protocol prefix. The https protocol will be applied automatically when the connection is established. For example, if the host name were "hologic.com", enter "hologic.com" rather than "https://hologic.com". Hologic recommends that configuration and verification of the address and port number are performed by service personnel trained by Hologic.
③	**Port Number** The network port number used currently to connect the Digital Imager and the Image Management Server is displayed on the left of the screen. The network port number used currently to connect the Digital Imager and the Review Station is displayed on the right of the screen. To change the port setting, touch the edit button  and type in the new port number. Hologic recommends that configuration of the port number is performed by service personnel trained by Hologic.

Key to Figure 3-27	
④	**Test Connection** Touch the **Test Connection** button to test if the Digital Imager can successfully communicate with the Image Management Server. If the test fails, a message displays. The Digital Imager must have a connection to the Image Management Server in order to process slides.
⑤	**Test Upload Speed** Touch the **Test Upload Speed** button to get a measurement of the speed at which data is uploaded from the Digital Imager computer to the Image Management Server. Results are displayed below the button in Mbps. The upload speed may be helpful in some instances of troubleshooting.
⑥	**Estimated Free Space on Server** This is the approximate free space that the Image Management Server has available for storing images and data generated by the Digital Imager, shown as a percentage. The exclamation point displays when the free space is at or below 10% (or the Image Management Server's storage capacity is 90% full). When the Digital Imager cannot check the amount of free space on the Image Management Server (typically due to a connection issue), the question mark depicts the **Unknown** status. The Image Management Server must have sufficient storage capacity to store the images and data from the Digital Imager. The number of slides imaged, the overall storage capacity of the Image Management Server, and the frequency of archiving and slide management are all factors which influence the period of time each laboratory will have sufficient free space on the server.
⑦	**Close** button Touch the **Close** button to return to the Administrative Options screen.

Barcode Settings

Figure 3-28 Barcode Settings

The Barcodes Settings are for information about how slides are labeled in your laboratory.

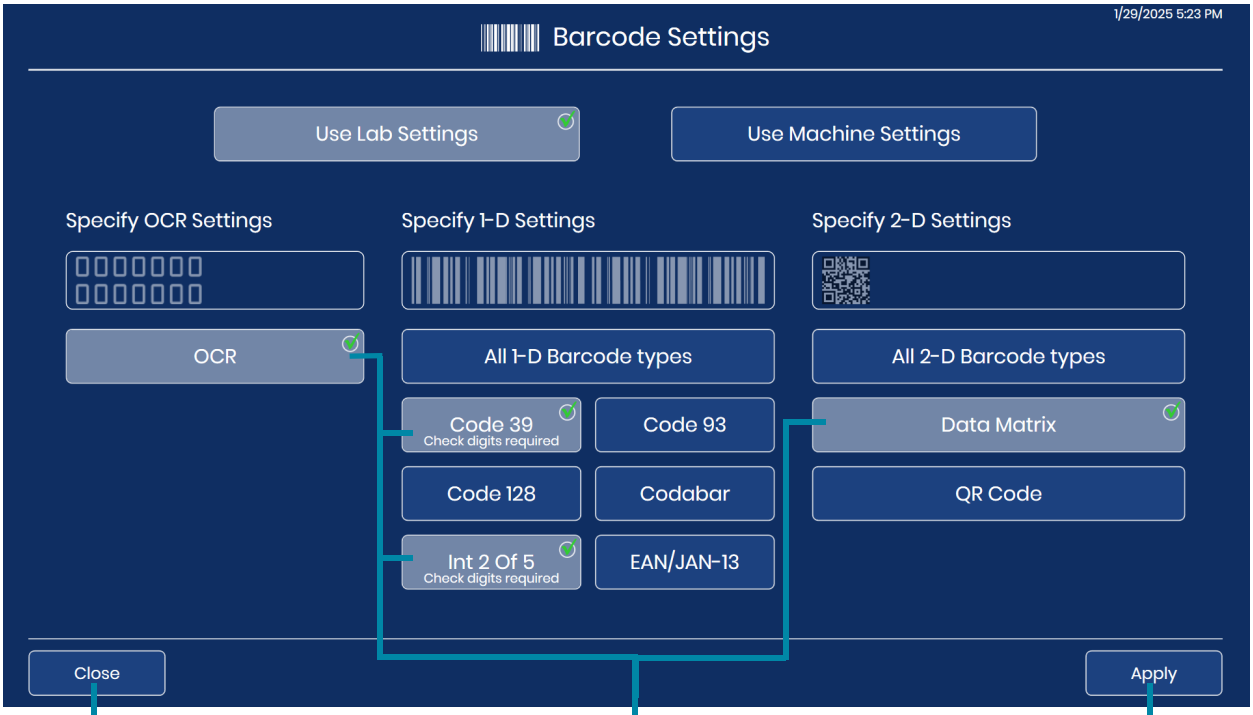
The Digital Imager can be set up to read slide IDs as 1-D barcodes, 2-D barcodes, or OCR format. If slide labels have more than one barcode on them, the **Barcode Settings** on the Digital Imager direct the Digital Imager to the barcode that represents the slide ID.

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 (Data Matrix or QR Code). A 7-over-7 OCR slide label format may be used.

Each Digital Imager connected to the same Genius Image Management Server can be set to have its own barcode settings. Or, each Digital Imager can be set to use settings that apply to other Digital Imagers connected to the same Genius Image Management Server.

1. Decide if the Digital Imager will use the same barcode settings as other Digital Imagers connected to the same Genius Image Management Server. The default setting is to use the lab settings.
   - If the Digital Imager will use the same barcode settings as other Digital Imagers, select the **Use Lab Settings** button. The screen display shows the current lab settings for barcodes. If an operator makes changes to the barcode settings, the same barcode settings change for all other Digital Imagers that are also set to use lab settings. The changes take effect on a Digital Imager after any in-progress processing finishes.
   - If the Digital Imager will use barcode settings that only apply to this Digital Imager, select the **Use Machine Settings** button. The screen display shows the settings for barcodes on this Digital Imager. If an operator makes changes to the barcode settings, the changes apply to the one Digital Imager that they are operating.

2. To change the barcode settings for the lab or for one machine, touch the ID type to select it.



To close the Barcode Settings screen without making any changes, touch the **Close** button.

The current selections are marked with a green check mark.

To apply the selected type, touch the **Apply** button. In this example, the changes apply to this one Digital Imager because **Use Machine Settings** is selected.

Figure 3-29 Barcode Settings: Specify the Barcode Type for the Slide ID

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. The default setting selects OCR, all 1-D barcode types and all 2-D barcode types.

3. For 1-D barcodes and 2-D barcodes, specify the type of 1-D or 2-D barcodes used on your labels. 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.

4. For Code 39 and for Interleaved 2 of 5, there is one more setting to set. For Interleaved 2 of 5 and for Code 39, specify whether your laboratory uses a check digit in the barcode. Touch "Yes" or "No".

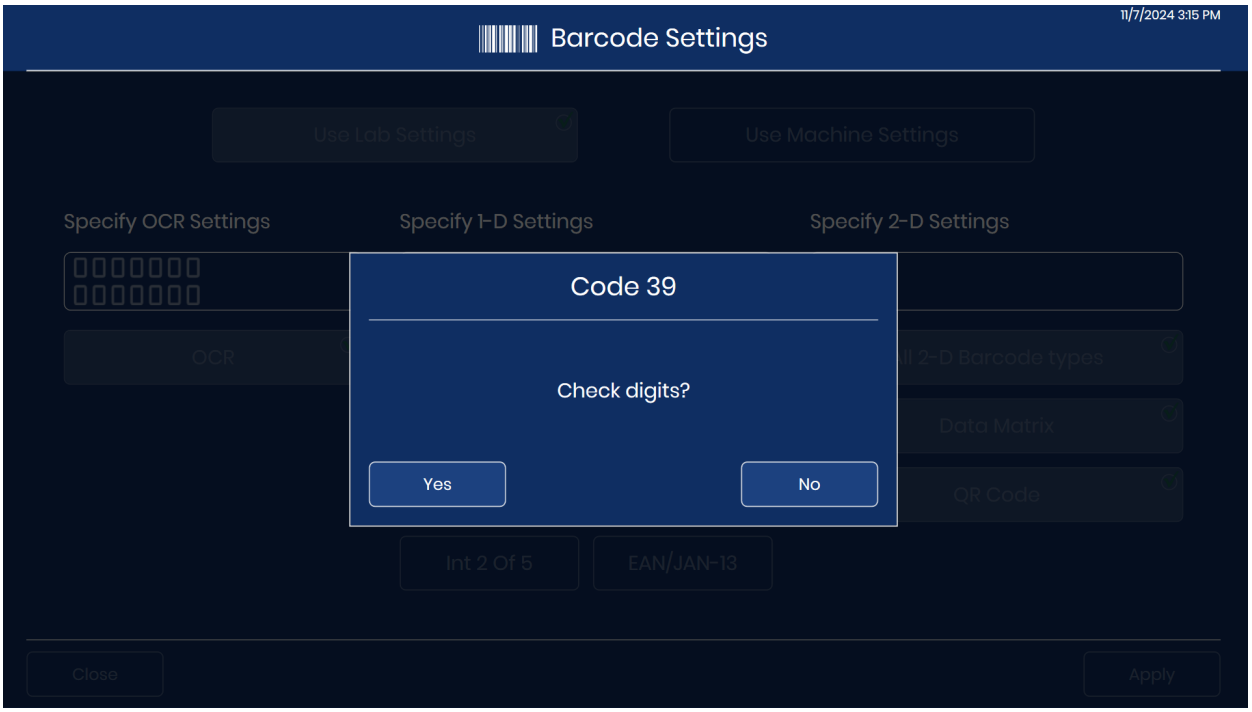


Figure 3-30 Barcode Settings: Choose Check Digit Use for Interleaved 2 of 5 and for Code 39

Note: To change the check digit setting touch Code 39 or Interleaved 2 of 5 again.

5. For OCR or any barcode type, touch the **Apply** button to save the selection. Or, touch the **Close** button to close the screen without changing the current selection.
6. When the confirmation screen displays, touch **Yes** to save the new settings and start to use them the next time slides are imaged. Or, touch **No** to return to the Barcode Settings page.
   - If the **Use Lab Settings** was selected in step 1, these barcode settings will apply to all the Digital Imagers connected to the same Genius Image Management Server that are also set to **Use Lab Settings**. When any in-progress processing finishes at each Digital Imager, the new barcode settings take effect at that Digital Imager.
   - If the **Use Machine Settings** was selected in step 1, these barcode settings are now in effect for this one Digital Imager.

Note: If you make a mistake and inadvertently Use Lab Settings when you intend to Use Machine Settings, the settings apply to other Digital Imagers in your lab. This could be the source of some Slide Events. The solution is to redo the Lab Settings and then redo the Machine Settings.

Note: If you make a mistake and inadvertently Use Machine Settings when you intend to Use Lab Settings, redo the Lab Settings to apply the barcode setting to other Digital Imagers in your lab.

Accession ID Settings

Figure 3-31 Accession ID Settings Button

The Accession ID Settings feature allows the accession ID 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 cases, the options in the Accession ID Settings are:

- to use the entire printed slide ID,
- to use a portion of the printed slide ID, and/or
- to add a time stamp to the ID printed on the slide label,
- to replace characters used in the printed slide label that are not supported by the Genius Digital Imager,
- to assign an accession ID of the date and time for slides whose labels cannot be read

Each Digital Imager connected to the same Genius Image Management Server can be set to have its own Accession ID settings. Or, each Digital Imager can be set to use settings that apply to other Digital Imagers connected to the same Genius Image Management Server.

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

The **Accession ID Settings** button is on the Administrative Options screen.

If 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 or to substitute those characters.

The Genius Digital Diagnostics System requires a unique Accession ID for each slide. If slides arrive in your laboratory with several slides for the same case labeled with the same slide ID, the Digital Imager can be configured to add a time stamp to the Accession ID to make the ID used by the Genius Digital Diagnostics System unique.

And, if a slide is loaded into the Digital Imager with a label that cannot be scanned, the Digital Imager can be configured to automatically assign an Accession ID to the case, based on the imaging time.

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 Accession 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.

Note: The slide data set used by the Genius Digital Diagnostics System includes both the printed slide label (the barcode value) and accession ID used by the Genius Digital Diagnostics System. This may be helpful in laboratories that integrate an interface between Genius Event Bridge Messaging and the laboratory's LIS system.

Note: Due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a ThinPrep Pap test slide with the Genius Cervical AI algorithm may not produce a gallery of Objects of Interest (OOIs) identical to the original gallery. Refer to the Instructions for Use for the performance characteristics of the Genius Digital Diagnostics System.

Maintain the chain of custody for all samples to ensure the integrity and reliability of test results. Ensure compliance with all applicable quality control procedures, regulations, and policies.

Acession ID Settings: Advanced Settings

There are three optional Advanced Settings for Accession IDs.

Add the date and time: The Digital Imager software includes an option to add the date and time to the end of accession IDs. With this option, the accession ID used by the Genius Digital Diagnostics System will end with the date and time that the slide is imaged. The format for the date and time for the accession ID starts with the year, then the month, the day, and then the time as a 2-digit hour, 2-digit minute and 2-digit second, _YYYYMMDD_HHMMSS. The added date is separated from the rest of the accession ID by an underscore character, _ and the time is separated from the date with an underscore character, _.

The default setting is to not add the date/time to accession IDs.

Replace Invalid Characters: The Digital Imager software includes an option to replace certain characters used in the printed slide label (the barcode value) in accession IDs. With this option, each of the characters used in the slide label, but not supported in Windows file paths, will be replaced in the accession ID used by the Genius Digital Diagnostics System with a user-specified replacement character. The replacement character is chosen by the laboratory. The invalid characters that will be replaced are listed in Table 3.1.

Table 3.1 Characters Considered Invalid in Accession IDs in the Genius Digital Diagnostics System

Character	Description
*	Asterisk
\	Back-slash

Table 3.1 Characters Considered Invalid in Accession IDs in the Genius Digital Diagnostics System

Character	Description
/	Forward-slash
:	Colon
<	Less than
>	Greater than
?	Question mark
“	Quotation mark
|	Bar

For example, if a Digital Imager is set up to use a replacement character of “-” (hyphen), and a slide with a barcode value printed on the slide label of 1\2/3:4<5>6?7”8|9 is scanned, then the accession ID that the Genius Digital Diagnostics System uses is: 1-2-3-4-5-6-7-8-9.

The default setting is to not replace invalid characters in accession IDs. The default setting generates a slide event if there is an invalid character in an accession ID.

Generate ID for unreadable slides: The Digital Imager software includes an option to generate an Accession ID for slides where the accession ID on the label cannot be read. The generated Accession ID is based on the date and time that the slide is scanned. With this option, the accession ID used by the Genius Digital Diagnostics System is the year, then the month, the day, and then the time as a 2-digit hour, 2-digit minute and 2-digit second, YYYYMMDD_HHMMSS. The time is separated from the date with an underscore character, _.

The default setting is to not generate an accession ID. The default setting generates a slide event if the ID on the slide label cannot be read.

The default setting also generates a slide event if the ID on the slide label is legible but does not use a barcode format selected as a Barcode Setting on the Digital Imager. Refer to “Barcode Settings” on page 3.28 for more information.

If the **Generate ID for Unreadable Slides** option is used in a lab, and a slide is scanned with a legible label, but that label has a format not specified in the Barcode Settings for the Digital Imager, then the slide label ID will not be read and a date-based Accession ID will be generated.

Accession ID Settings: Slides for the Gyn Case Type

1. From the Administrative Options screen, touch **Accession ID Settings**. The current settings are shown.

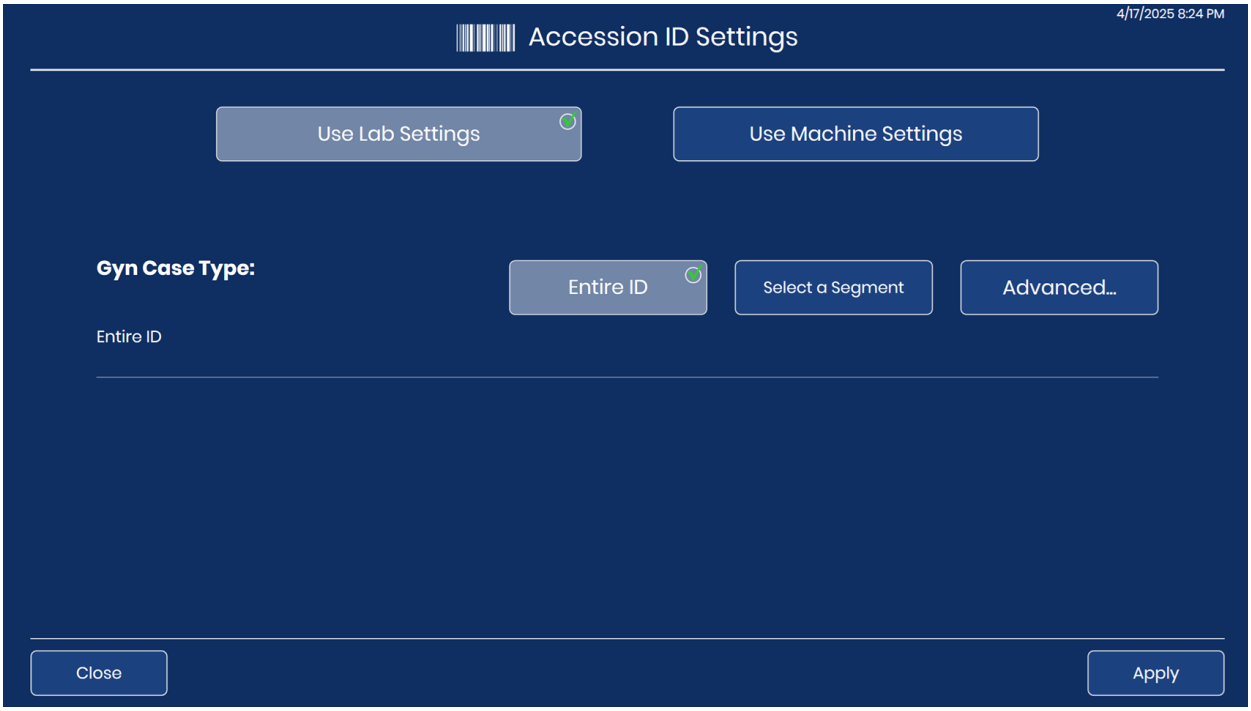


Figure 3-32 Accession ID Settings, Summary Screen

2. Decide if the Digital Imager will use the same Accession ID settings as other Digital Imagers connected to the same Genius Image Management Server. The default setting is to use the lab settings.
   - If the Digital Imager will use the same Accession ID settings as other Digital Imagers, select the **Use Lab Settings** button. The screen display shows the current lab settings for accession IDs. If an operator makes changes to the Accession ID settings, the same Accession ID settings change for all other Digital Imagers that are also set to use lab settings. The changes take effect on a Digital Imager after any in-progress processing finishes.
   - If the Digital Imager will use Accession ID settings that only apply to this Digital Imager, select the **Use Machine Settings** button. The screen display shows the settings for accession IDs on this Digital Imager. If an operator makes changes to the Accession ID settings, the changes apply to the one Digital Imager that they are operating.
3. For the Gyn Case Type, choose "Entire ID" or "Select a segment" and/or "Advanced..."
   - **Entire ID:** the accession ID number in the Genius Digital Diagnostics System will be the same as the ID printed on the slide label. Skip to step 9.
   - **Select a segment:** the accession ID number used by the Genius Digital Diagnostics 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 Genius Digital Diagnostics System.

- **Advanced...**: The Genius Digital Diagnostics System adds the date and time that the slide was imaged to the accession ID, converts invalid characters in the slide label ID to a valid character, and/or generates a date-based accession ID for a case whose slide label ID cannot be read. Follow step 10.

  Note: The advanced settings can be used in combination with the Entire ID setting or the Select a segment settings.

4. Indicate where, in the slide ID printed on the slide label, the segment that is used by the Genius Digital Diagnostics System for the accession 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 accession ID is the first character of the printed slide ID, leave the "Position" field blank.
5. 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 accession ID. The accession ID will start after the character entered.

   Note: If the "Start at" character is blank, the accession 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.
6. Indicate where, in the printed slide ID, the segment that is used on the Genius Digital Diagnostics System accession 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 accession ID for the Genius Digital Diagnostics System is the end of the printed slide ID, leave the "Length" field blank.
7. 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 accession ID. The accession ID will end before the character entered.

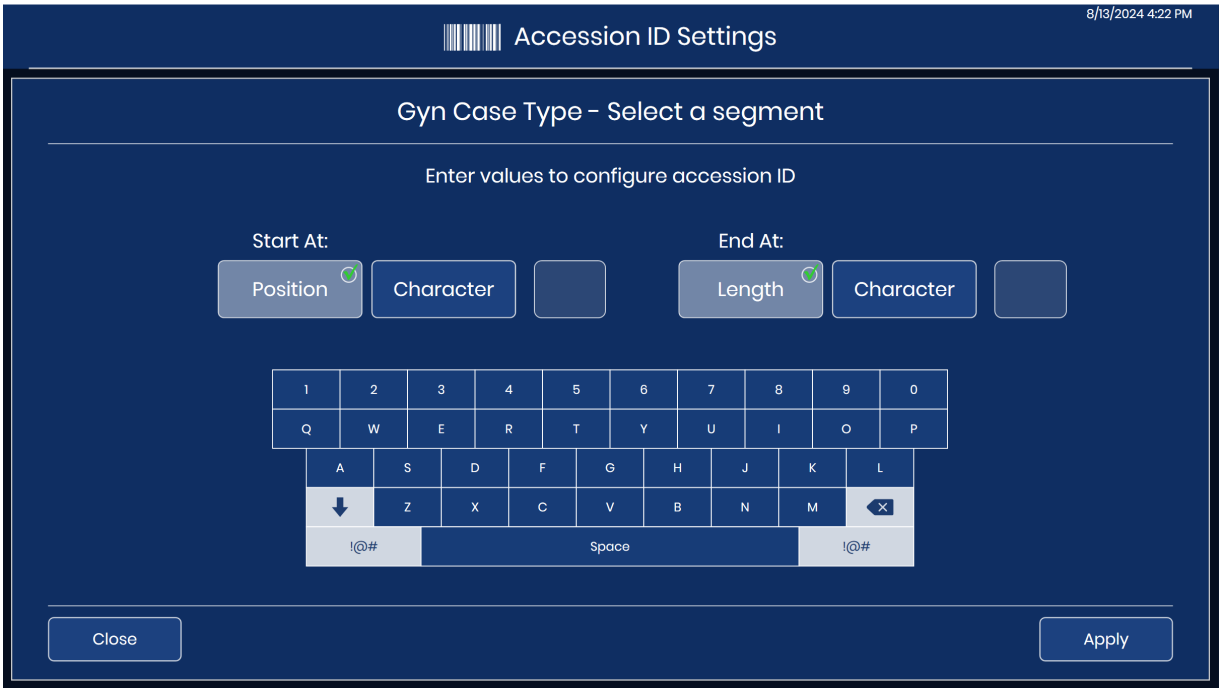


Figure 3-33 Accession ID Settings: Select a Segment, Gyn Cases

In the Accession ID Settings, the Digital Imager software compares the configuration to the slide ID barcode settings 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 data entry box on the touch screen is outlined in red and the configuration cannot be applied. An Accession ID setting can only be applied when a valid combination is entered (no red around the box).

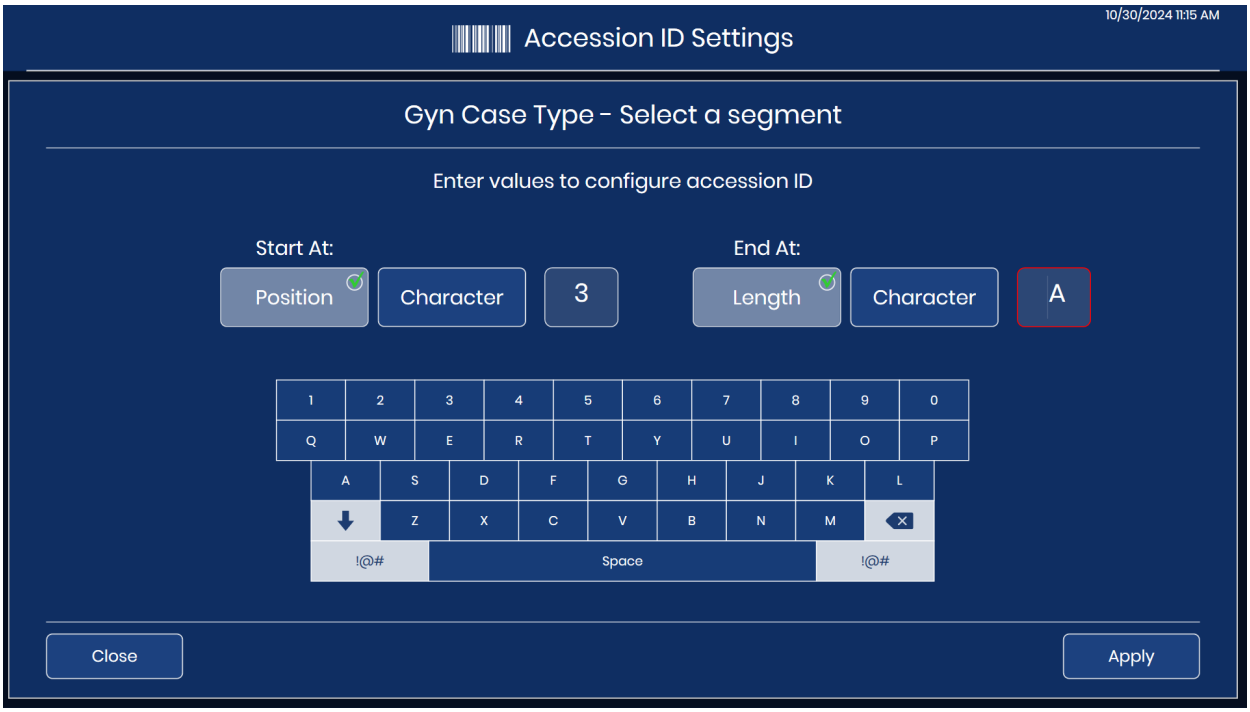


Figure 3-34 Accession ID Settings: Red for Invalid Entry

8. Touch the **OK** button to save the selection. Or, touch the **Cancel** button to close the screen without changing the current selection.
9. On the Accession ID Settings summary screen, touch the **Apply** button to save the selection. Or, touch the **Close** button to close the screen without changing the current selection.
10. To set up the Digital Imager to use an Advanced Setting for accession IDs, select **Advanced...**
    A. Select **Yes** to select one or more of the Advanced Settings.

B. Then press the **OK** button to save and return to the Accession ID Settings summary screen.

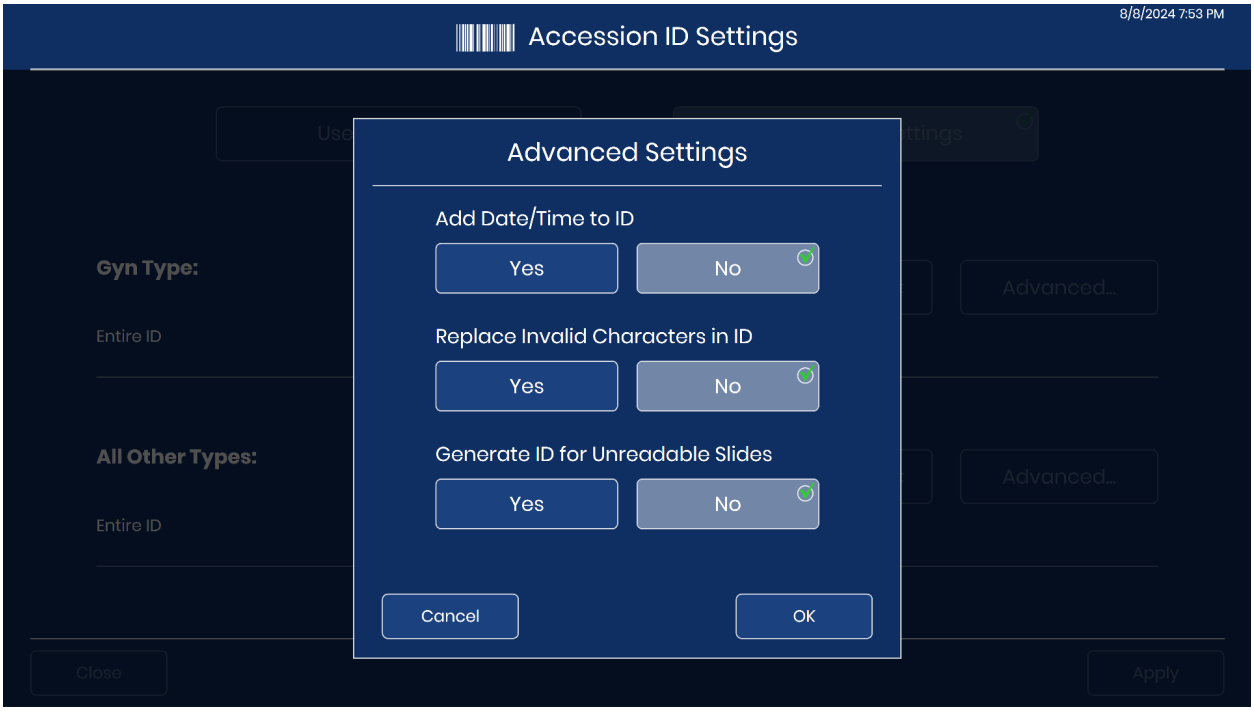


Figure 3-35 Advanced Settings for Accession IDs, Default Settings Shown

C. For the character replacement option, use the keyboard on the touch screen to type the character which will appear in the accession ID used by the Genius Digital Diagnostics System. This character replaces any invalid character in an accession ID for slides with the

Gyn case type. Touch the **Apply** button to save the selection. Or, touch the **Close** button to close the screen without changing the current selection.

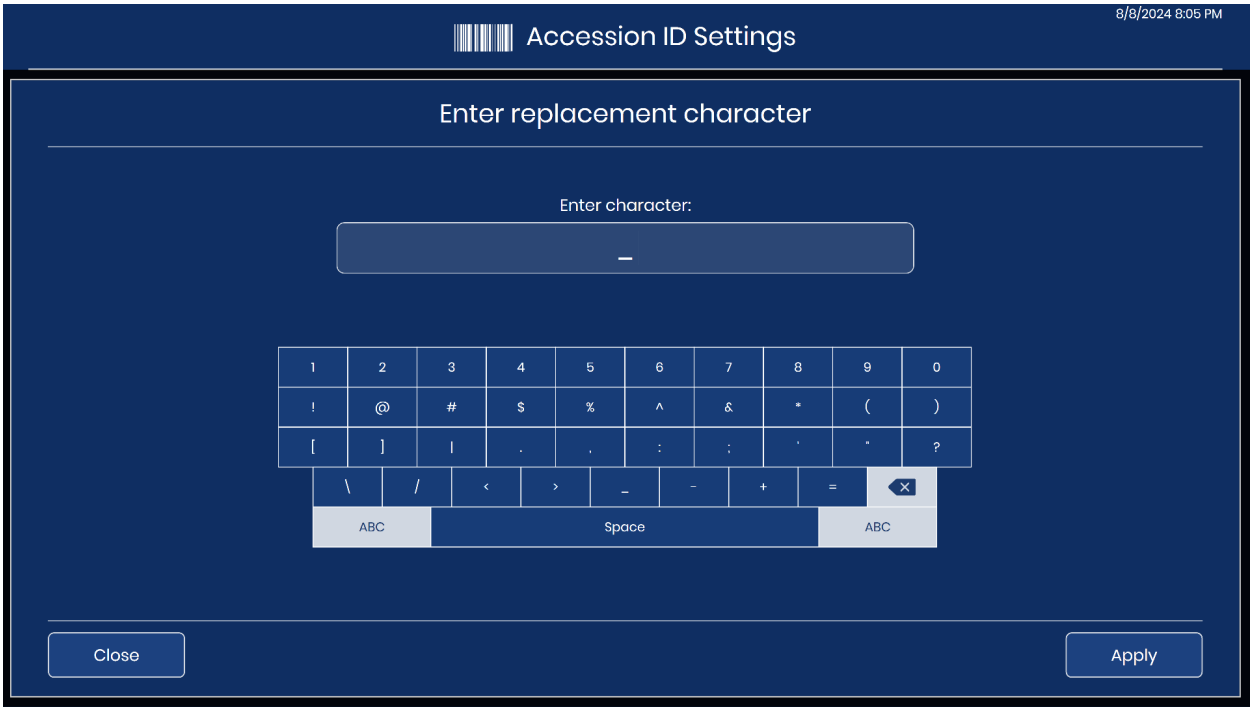


Figure 3-36 Enter the Character that Replaces Invalid Characters in an Accession ID, example

D. To return to the Accession ID Settings summary screen without applying the Advanced Settings, touch the **Cancel** button.

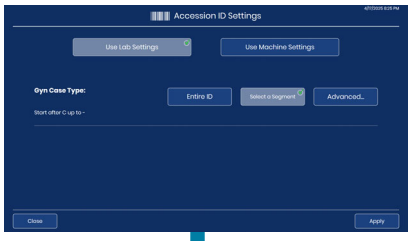
11. When the confirmation screen displays, touch **Yes** to save the new settings and start to use them the next time slides are imaged. Or, touch **No** to return to the Accession ID Settings summary page.
    - If the **Use Lab Settings** was selected in step 1, these Accession ID settings are now in effect for all of the Digital Imagers connected to the same Genius Image Management Server that are also set to **Use Lab Settings**. When any in-progress processing finishes at each Digital Imager, the new Accession ID settings take effect at that Digital Imager.
    - If the **Use Machine Settings** was selected in step 1, these Accession ID settings are now in effect for this one Digital Imager.

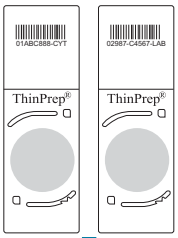
Configure a slide ID segment as an Administrative Option for your lab.

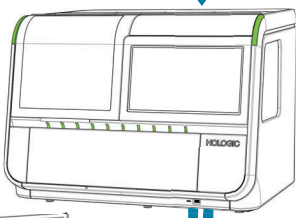
Example: Set a segment that starts at the character “C” and ends at the hyphen character.

Image slides labeled with slide IDs:

Examples:
01ABC12345-CYT
02987-C12346-LAB

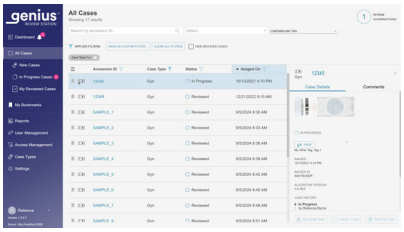


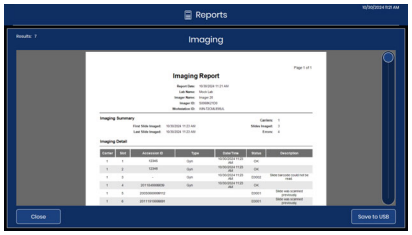




The accession IDs appear on the Review Station with the Accession ID settings applied.

The accession IDs appear on the Digital Imager with the Accession ID settings applied.





Example: The images for the slides are available to review on the Review Station as accession IDs “12345” and “12346”.

Example: The accession IDs are reported as “12345” and “12346” on the Digital Imager.

Figure 3-37 Accession ID Settings, Gyn, example

About button

Figure 3-38 About Button

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

The **About** 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), the serial number for the Digital Imager computer (Workstation ID), the serial number for the scanning components, the software version, and the date of the most recent color-calibration performed by service personnel trained by Hologic.

The **Regulatory Info...** button opens a screen with a product label that only has significance in Europe. To see the label, touch the **Regulatory Info...** button. To close the view of the label, touch the **Close** button. There is currently one label. If more than one label were available, the **Back** and **Next** buttons would scroll through all of the labels.

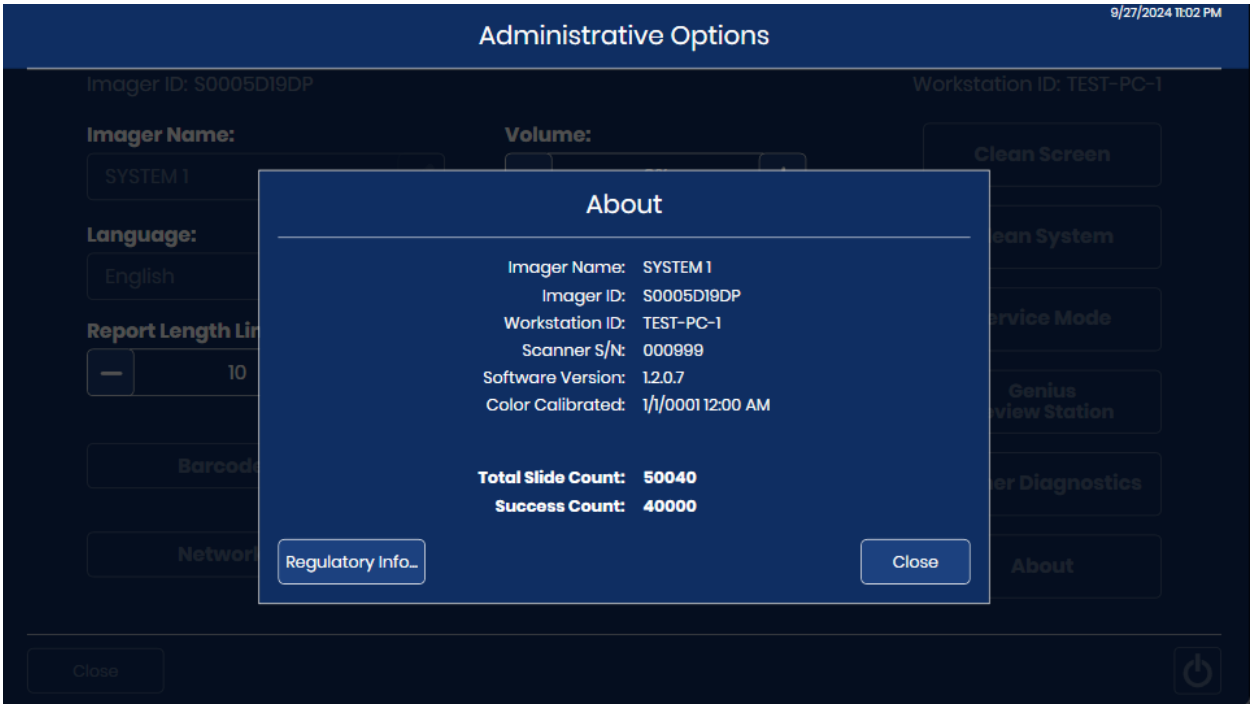


Figure 3-39 About the Digital Imager

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 4.36.

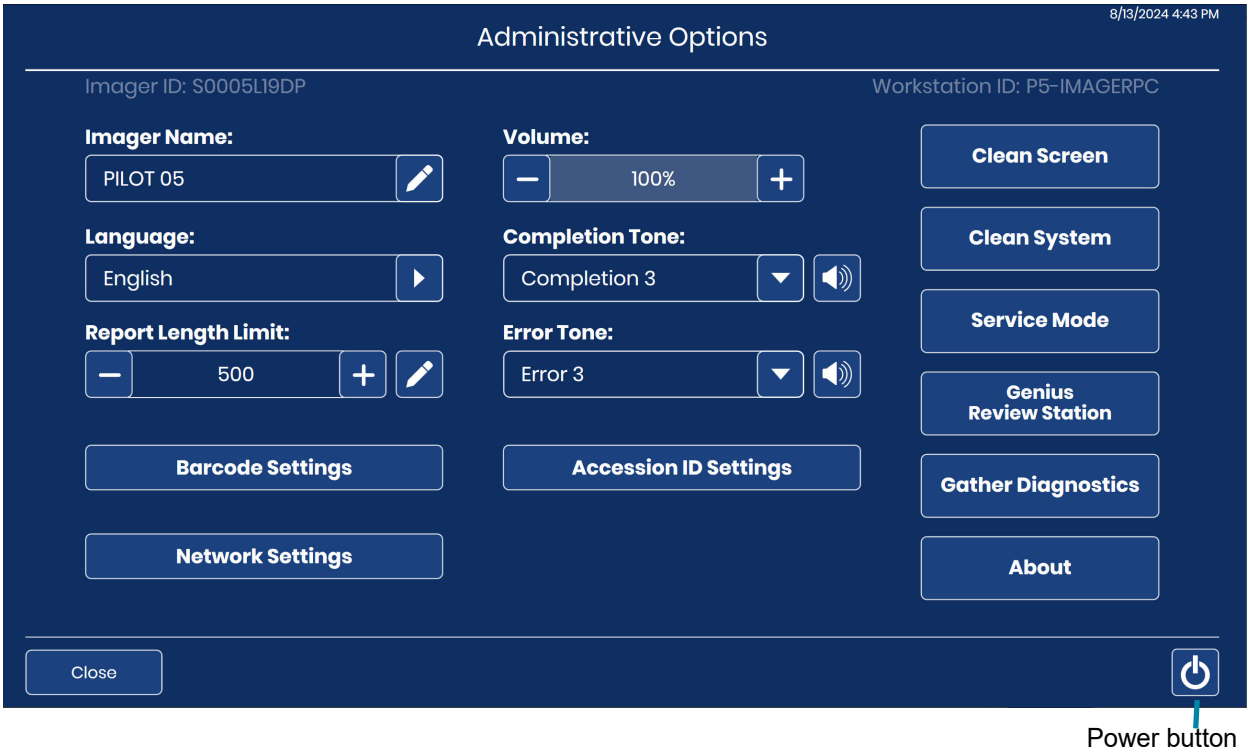


Figure 3-40 Power Button

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 accession ID. Each report is displayed on the touch screen and can be saved onto a USB. Reports can be run at any time. During processing, data for any slide carrier in the batch can be viewed on screen, but the Digital Imager cannot generate reports that include data for a slide carrier until that slide carrier has finished processing. Refer to “Slide carrier details” on page 3.11.

Touch the **Reports** button from the main screen to display the Reports screen.

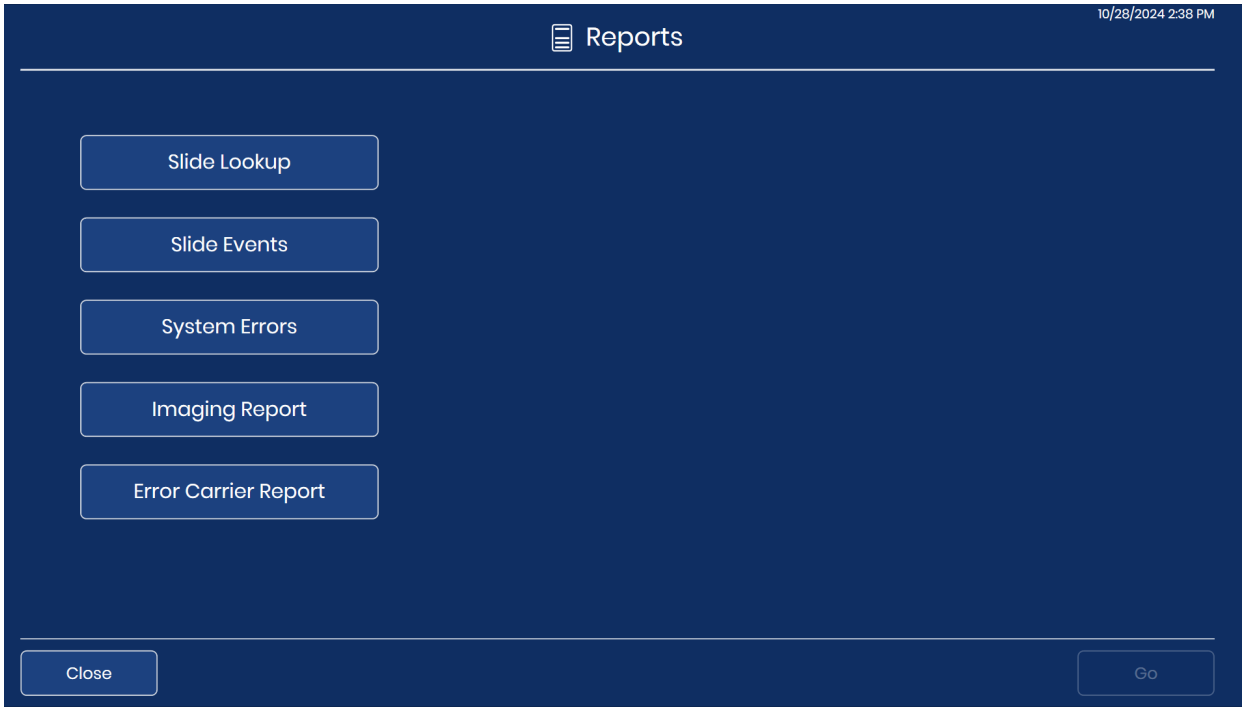


Figure 3-41 Reports Screen

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.

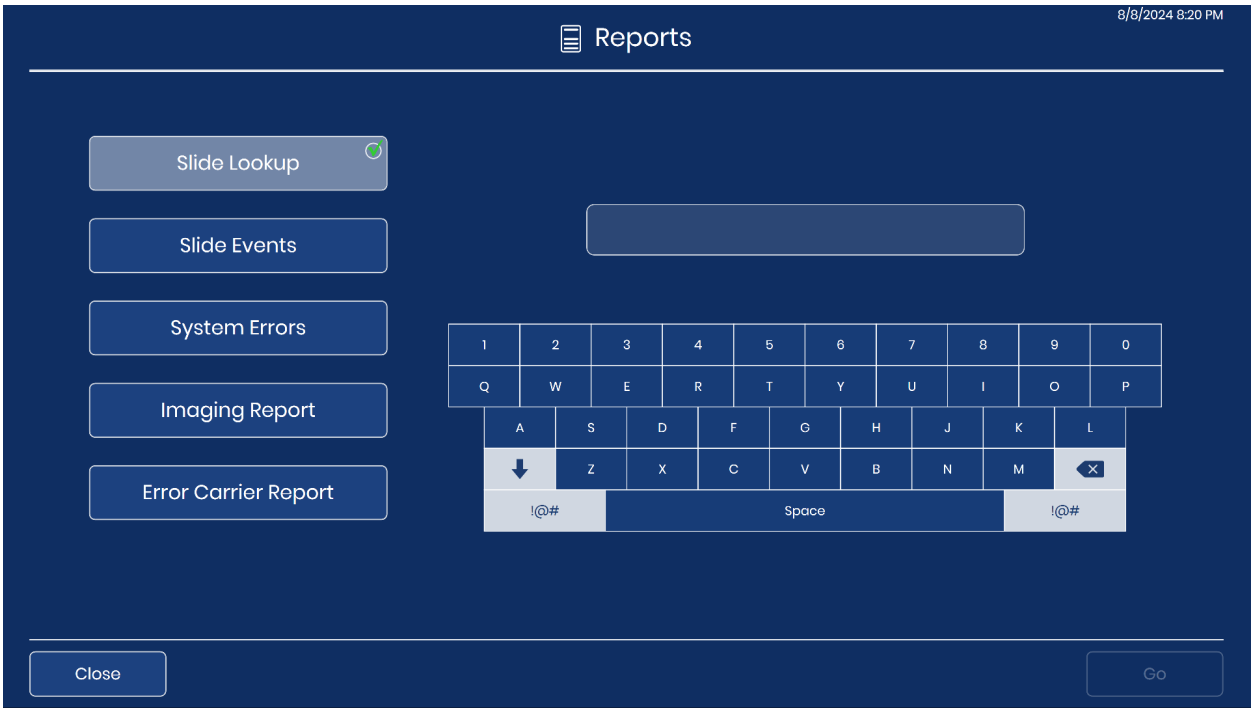


Figure 3-42 Slide Lookup: Type the Slide ID with the Keyboard

1. Touch the **Slide Lookup** button to select it. A keyboard appears on the touch screen.
2. Type the accession 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.

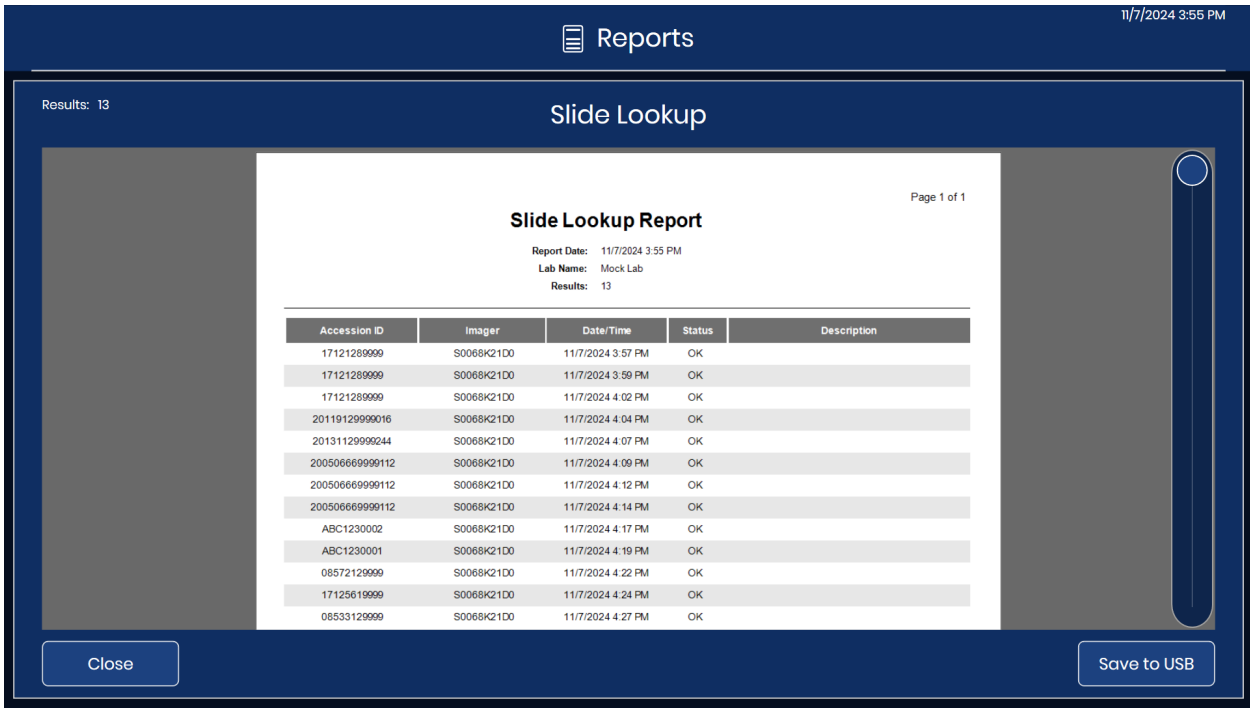


Figure 3-43 Slide Lookup Report, example

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 accession ID. Each slide entry shows the accession 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 accession ID has not been processed on any Digital Imager in your laboratory, the search yields 0 results and presents an empty report.

Slide Events

The Slide Events Report 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 Events** button to select it. Buttons to set the date range appear.

2. Select the time period.
   - To generate a report 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 3.18.
   - To generate a report 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.

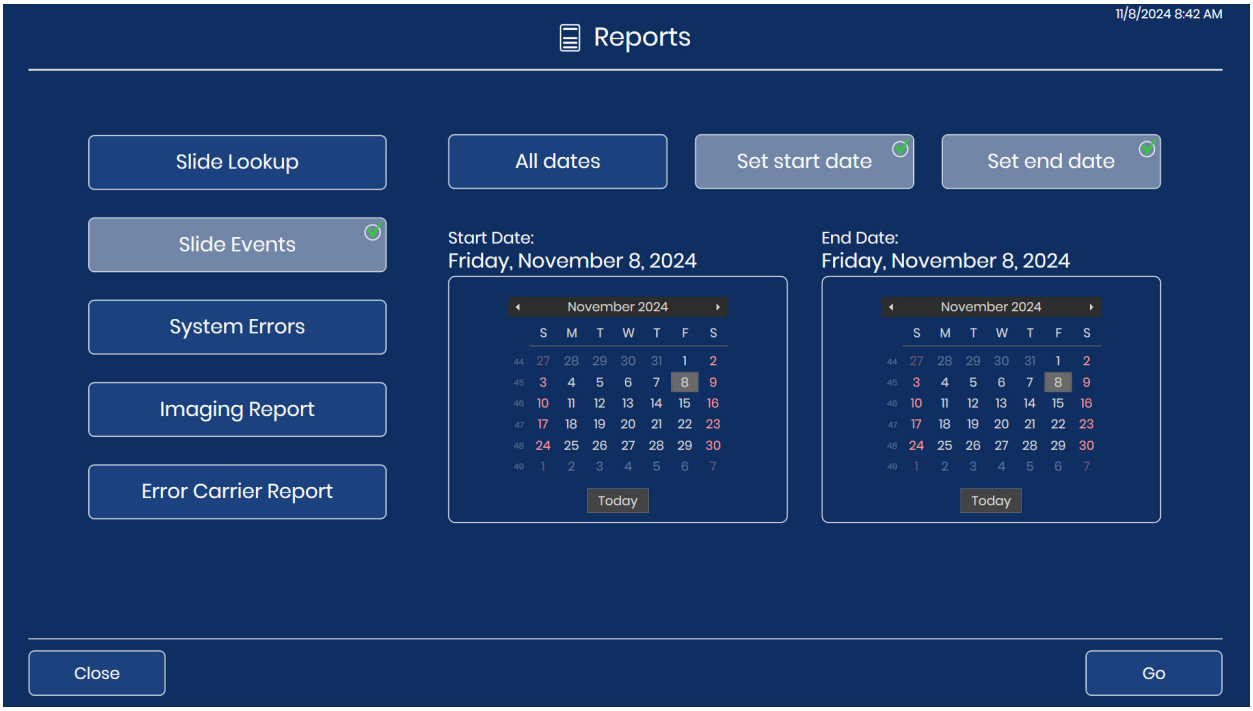


Figure 3-44 Slide Events Report: Set the Date Range, Touch Go

4. The results are displayed on the touch screen.

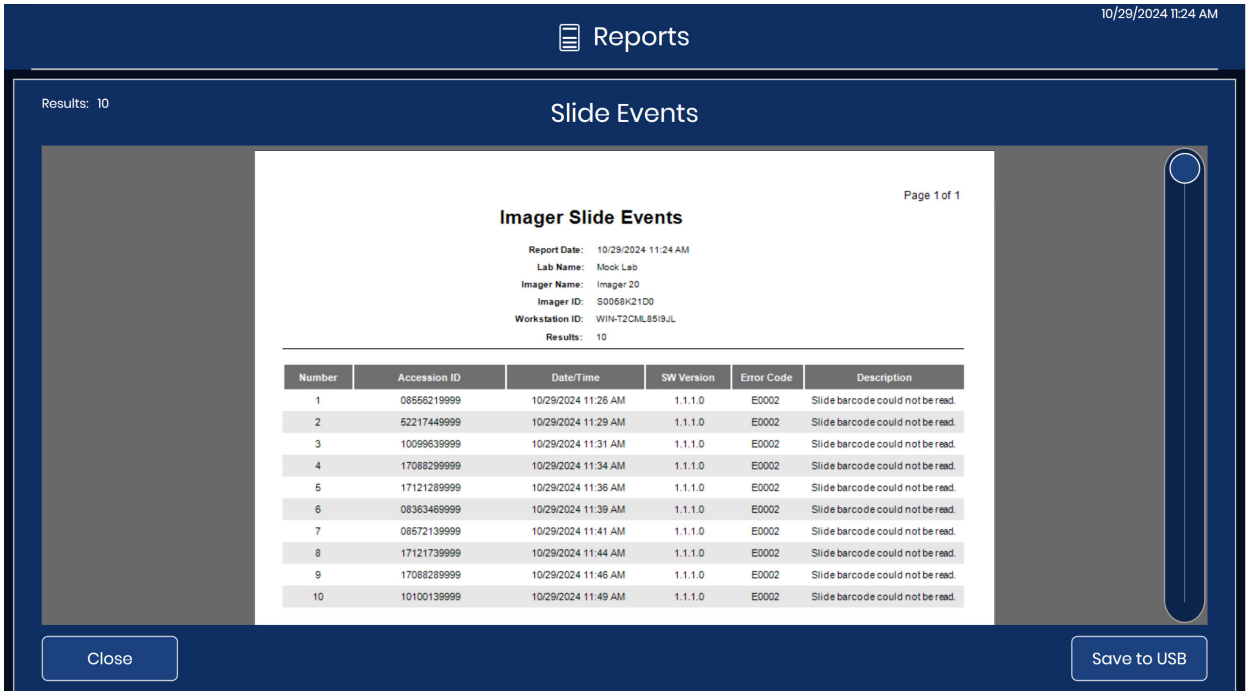


Figure 3-45 Slide Events Report, example

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 Imager 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 accession 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 3.18.

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 System Errors

This report displays errors encountered by the Digital Imager.

1. Touch the **Imager System Errors** button to select it. Buttons to set the date range appear.
2. Select the time period.
   - To generate a report of all the Imager system 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 3.18.
   - To generate a report of all the Imager system 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.

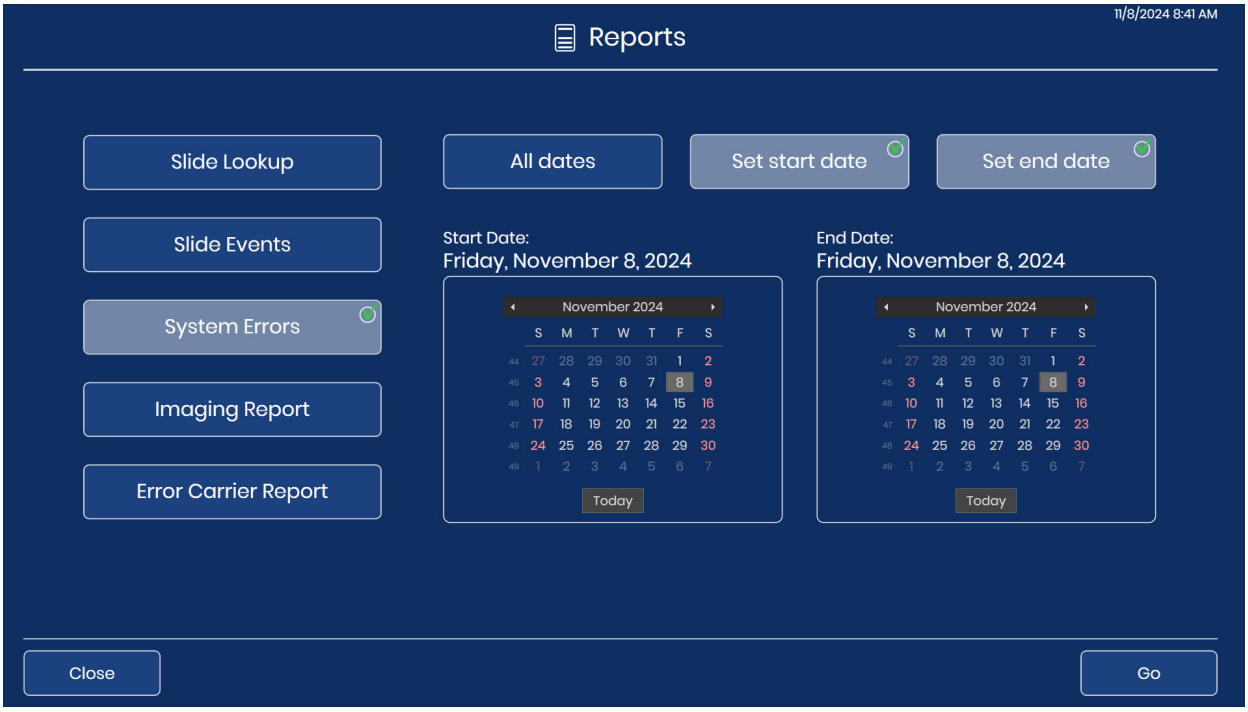


Figure 3-46 Imager System Errors: Set the Date Range, Touch Go

4. The results are displayed on the touch screen.

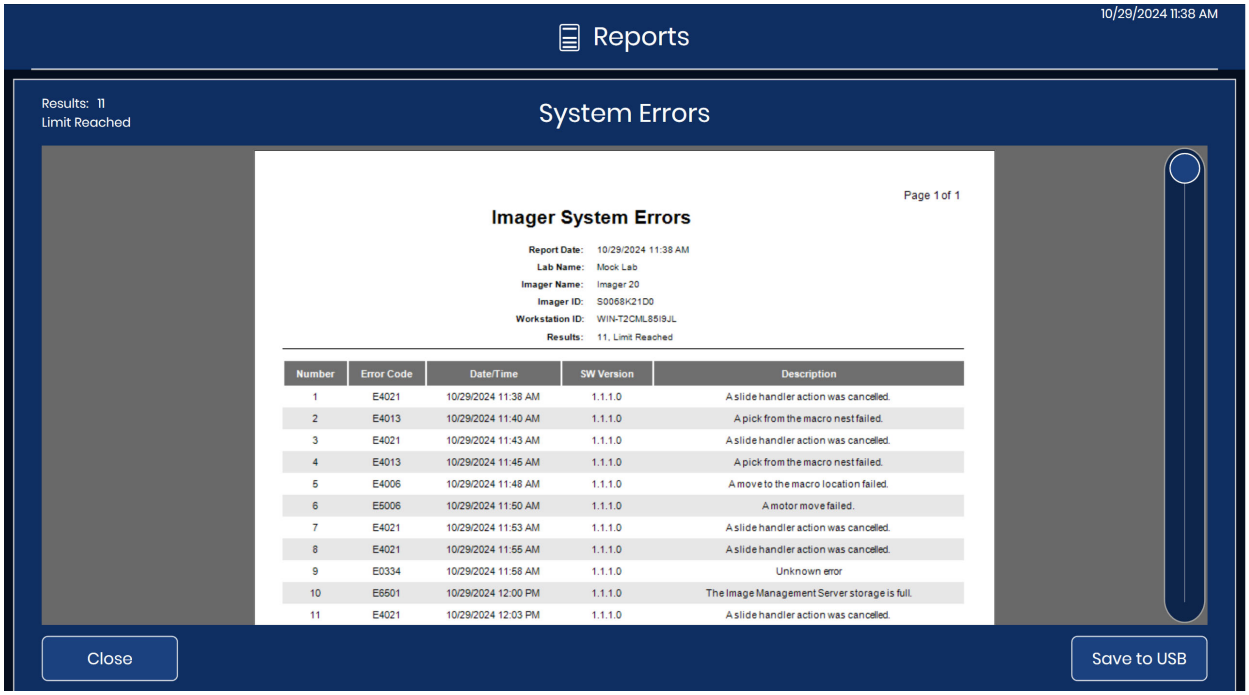


Figure 3-47 Report of Imager System Errors, example

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 Imager 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 3.18.

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 system 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.

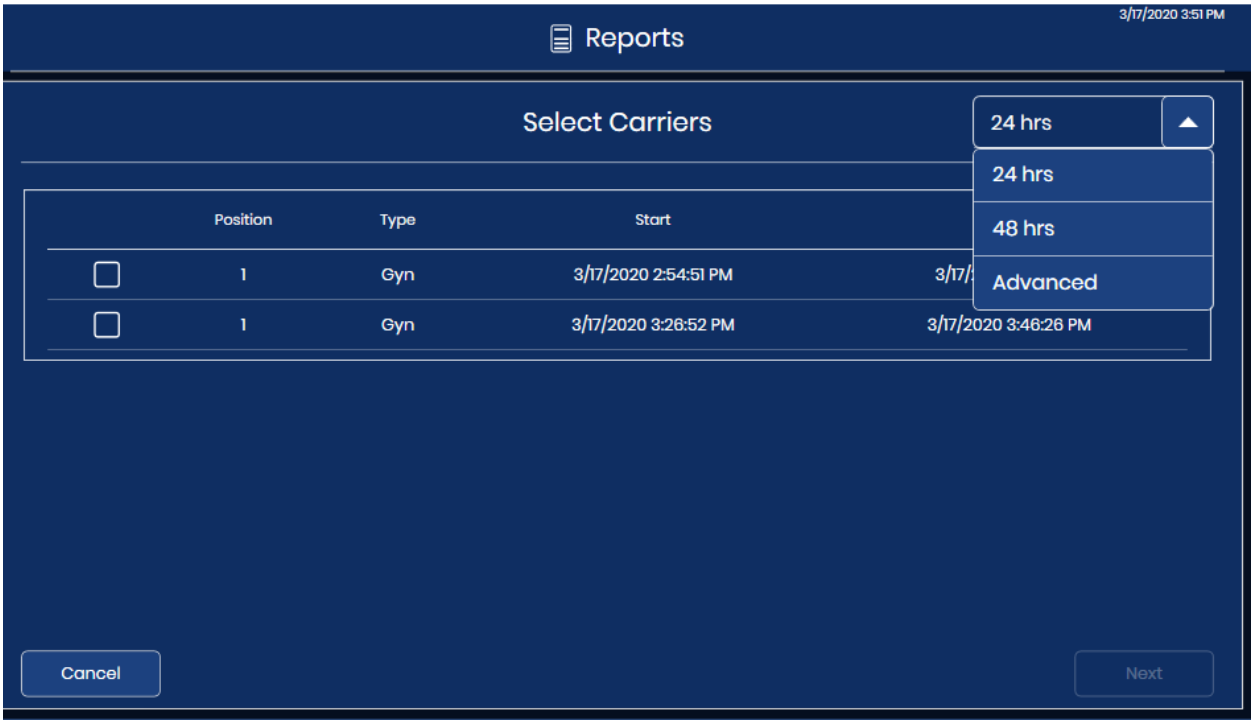


Figure 3-48 Imaging Report: Slide Carriers from the Past 24 Hours

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 3.54.

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.

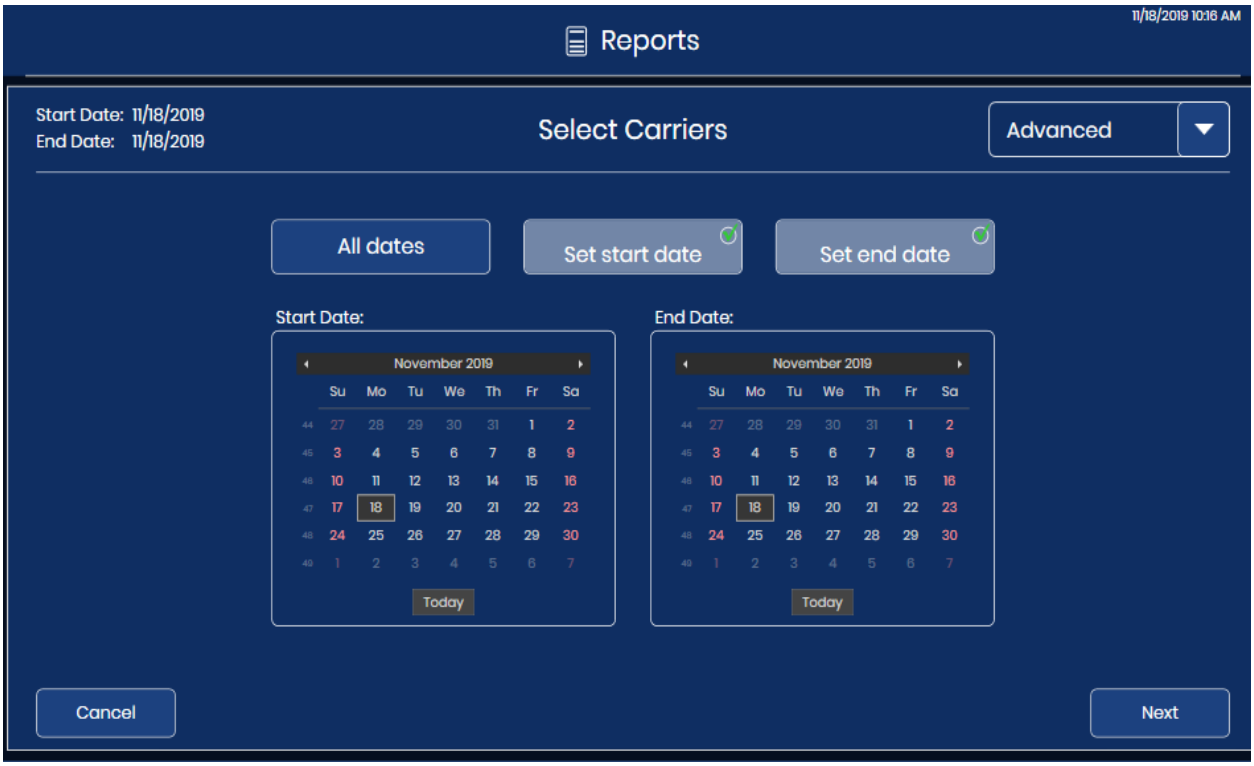


Figure 3-49 Imaging Report: Advanced Option, Set the Date Range

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 3.18.
   - To generate a report 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.

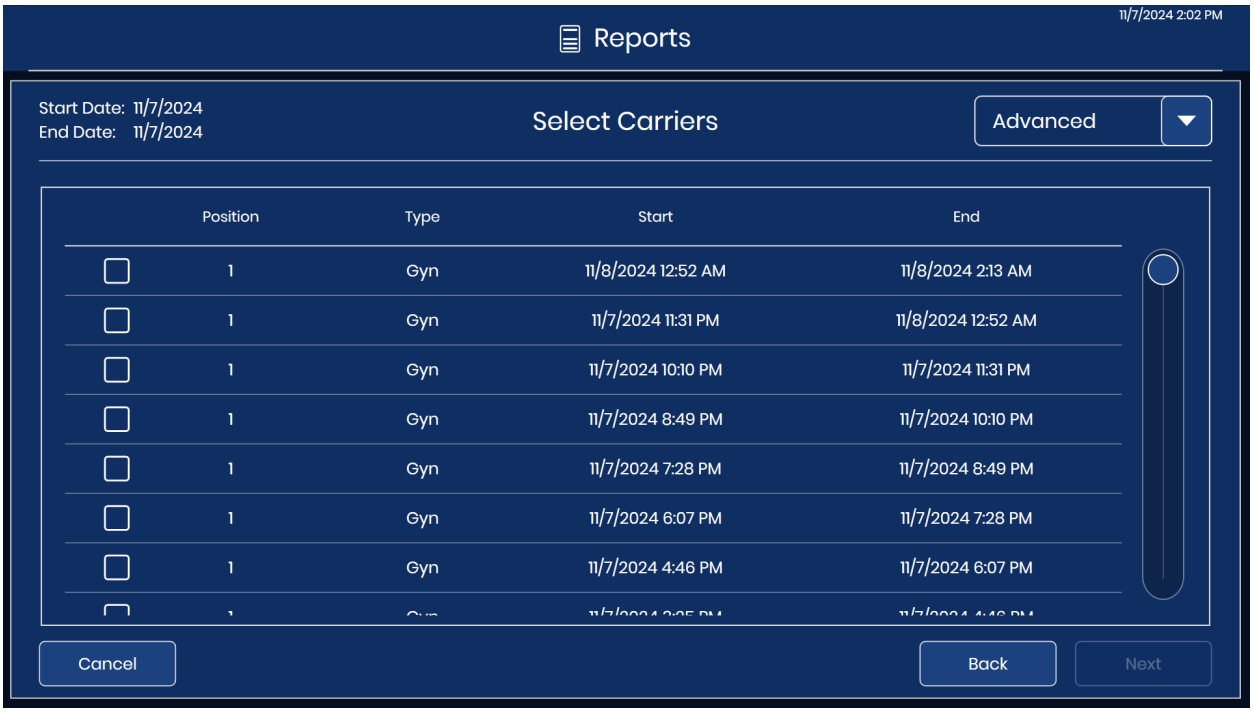


Figure 3-50 Imaging Report: Select from the List of Slide Carriers

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

8. The results are displayed on the touch screen.

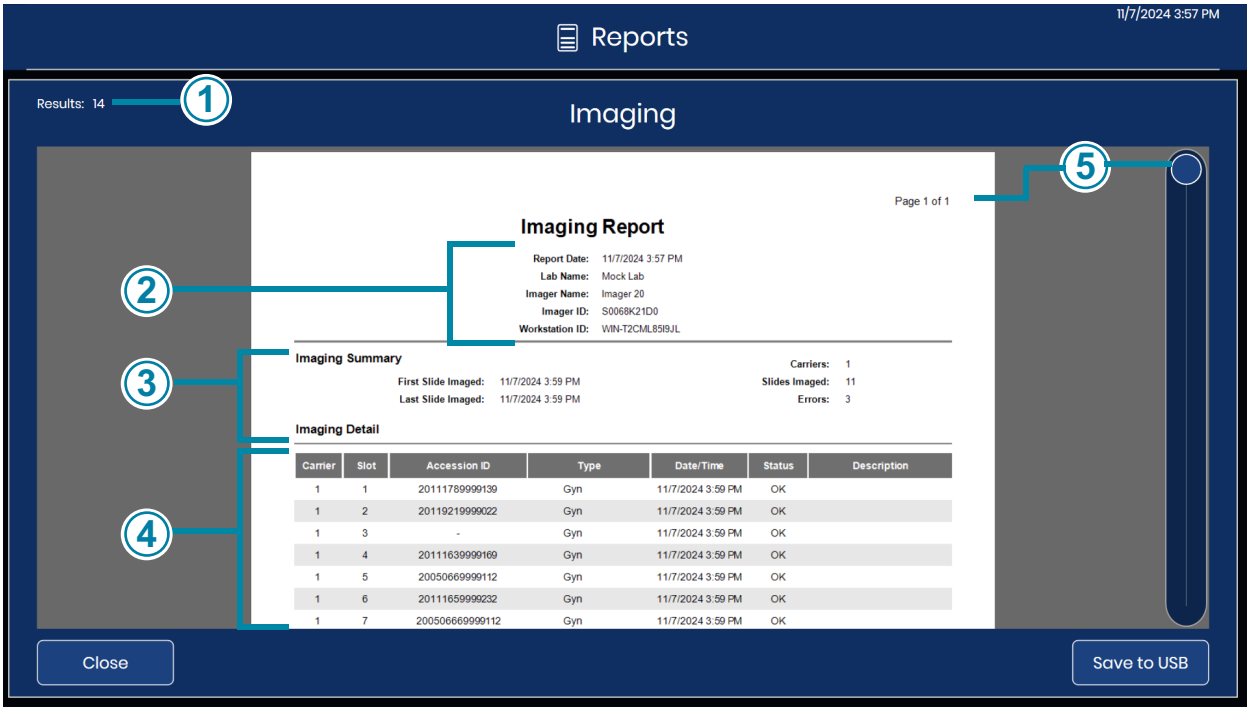


Figure 3-51 Imaging Report

Key to Figure 3-51	
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 Imager computer serial number).

Key to Figure 3-51	
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 accession ID, the case type (Gyn), 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 3.18.
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.

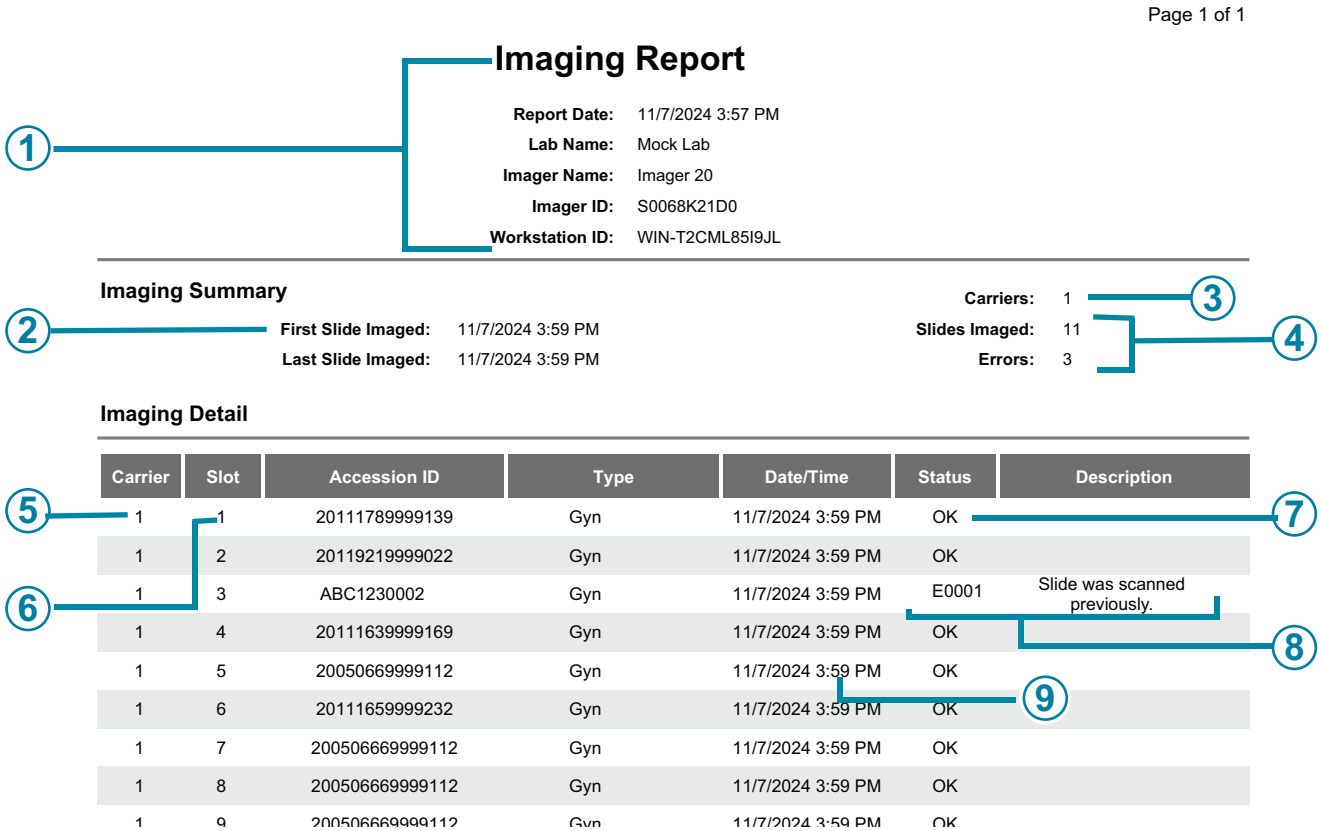


Figure 3-52 Imaging Report, example

Key to Figure 3-52	
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. One slide carrier is 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, one slide carrier carried a total of 14 slides.

Key to Figure 3-52	
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 1.
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.

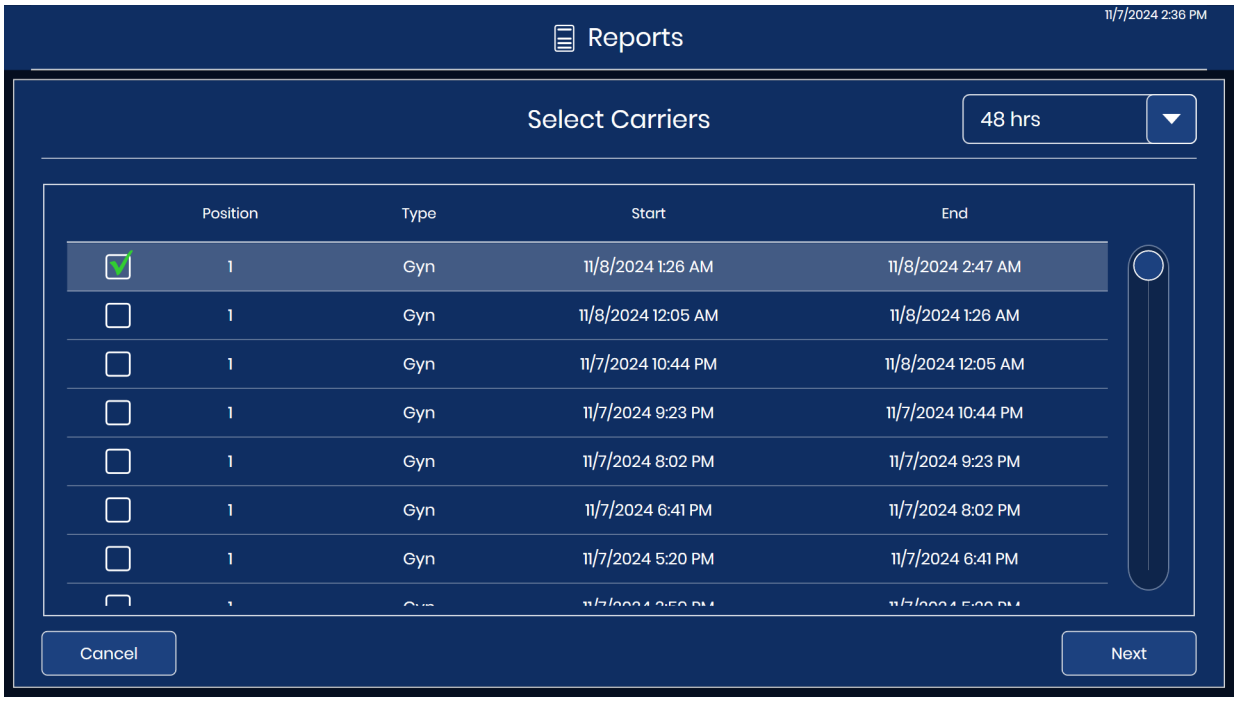


Figure 3-53 Error Carrier Report: Select Error Carrier from the List

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

6. The results are displayed on the touch screen.

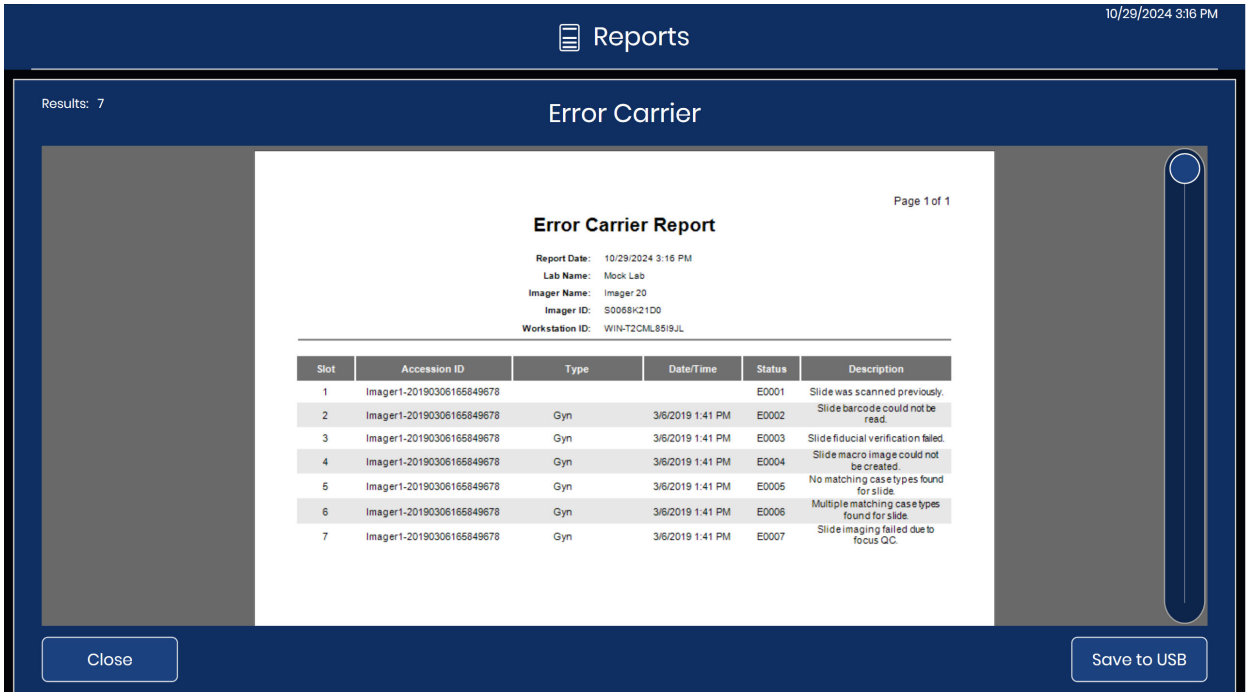


Figure 3-54 Error Carrier Report

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 Imager 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, accession ID (if read), the case type (Gyn), 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 3.18.

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.

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4. Operation

Chapter Four

Operation of the Digital Imager

SECTION A

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 Hologic recommends 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 Events Report. 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 4.36.

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

4 Operation of the Digital Imager

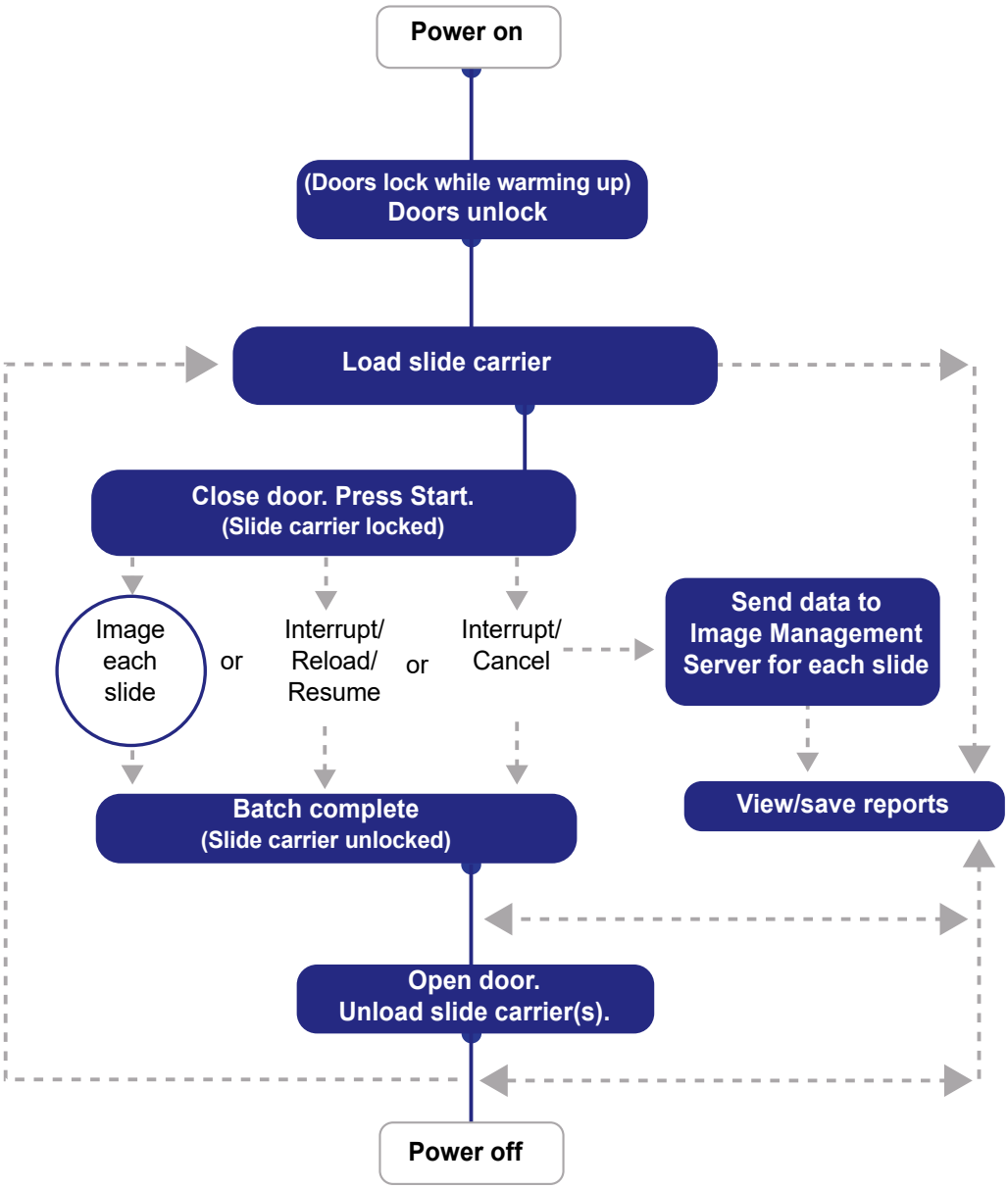


Figure 4-1 Typical Slide Imaging Process

SECTION B

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 with the Genius Image Management Server running. The warm-up cycle is longer if the Digital Imager has not completed a self-check in the past 24 hours. In that case, the warm-up cycle may take 12 minutes.

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.

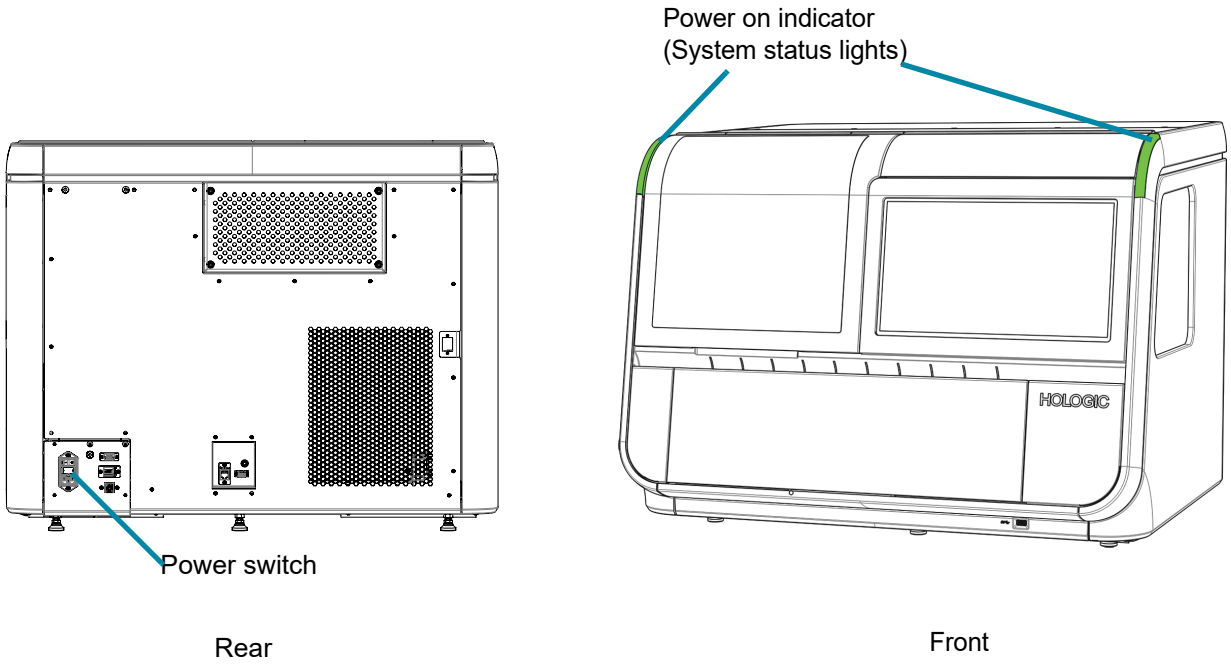


Figure 4-2 Digital Imager Power Switch

2. Press the rocker switch on the rear of the Digital Imager to ON (**I**). (See Figure 4-2.)

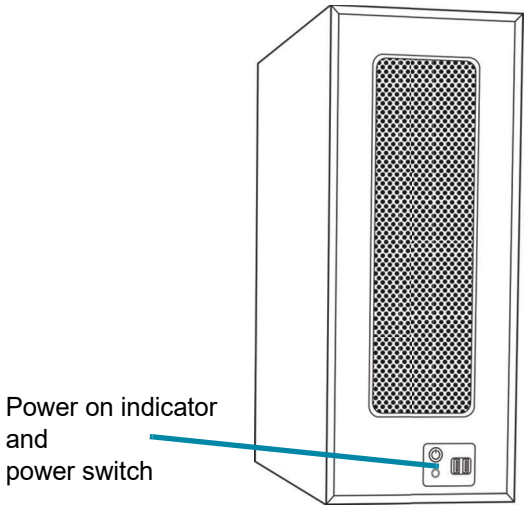


Figure 4-3 Power On the Digital Imager Computer

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.

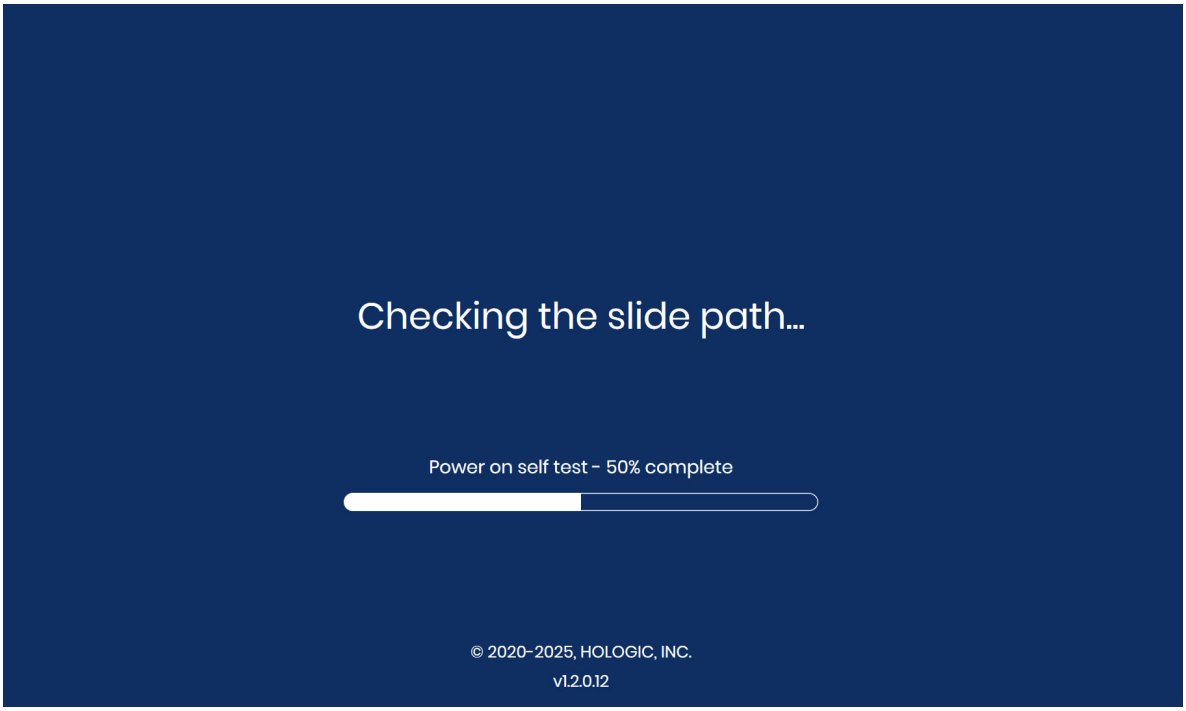


Figure 4-4 Warm-up in Progress

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.
- And, if debris is detected at the macro station, follow the instructions on the touch screen to remove the debris.

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 4.36. The Digital Imager and Digital Imager computer should be shut off in the sequence described there.

SECTION C

MATERIALS REQUIRED PRIOR TO OPERATION

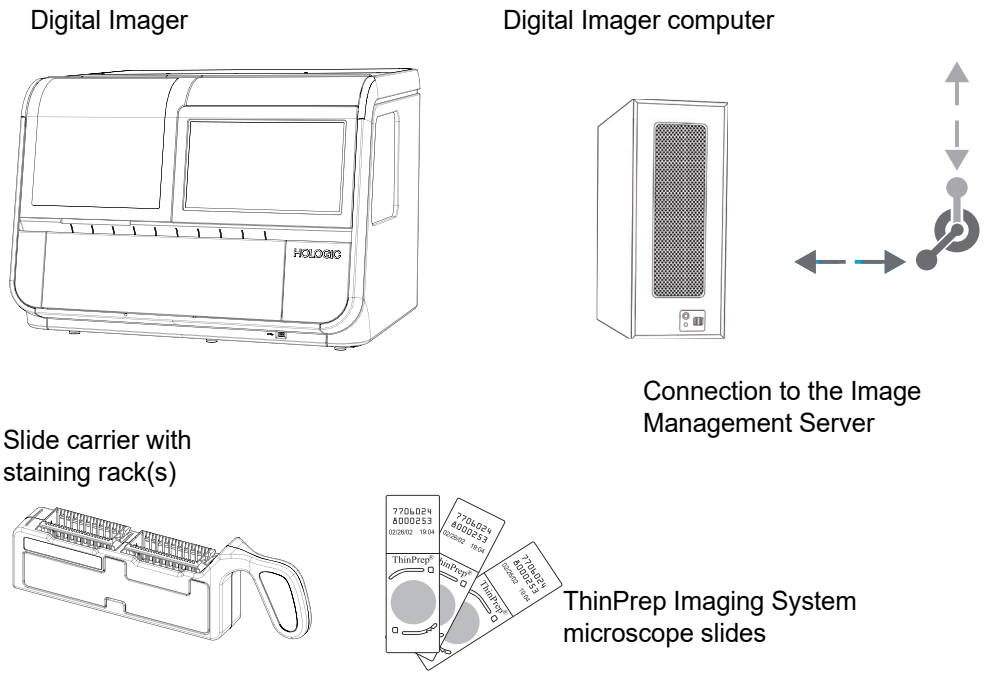


Figure 4-5 Items Required for Slide Image Processing

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. The Digital Imager computer also analyzes the imaged slide data. 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.

SECTION D

SLIDE LABELING

The camera that scans the slide label accession ID recognizes barcodes (1-dimensional or 2-dimensional) or OCR (optical character recognition) format. 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 "Barcode Settings" on page 3.28.

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 CRC (Cyclical Redundancy Check) is automatically generated when the label software creates the series of Accession IDs. The Genius Digital Imager uses these numerals to confirm that it read the ID correctly. The font must be 12-point OCR-A. Numbers only, no alpha characters. (See Figure 4-8.) Please note that a 'no text' zone of exactly one (1) character dimension (1.6 mm or .063") should surround the print area. On some ThinPrep processors, this format is named "OCR Imager."

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 4-6.)

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

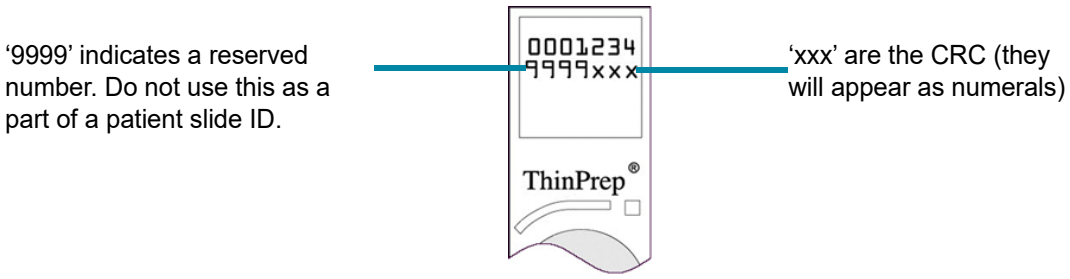


Figure 4-6 Accession ID in OCR format

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 4-8.) In any case, make sure the contrast is sufficient for the scanner to read the label.

Slide labels must be 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.

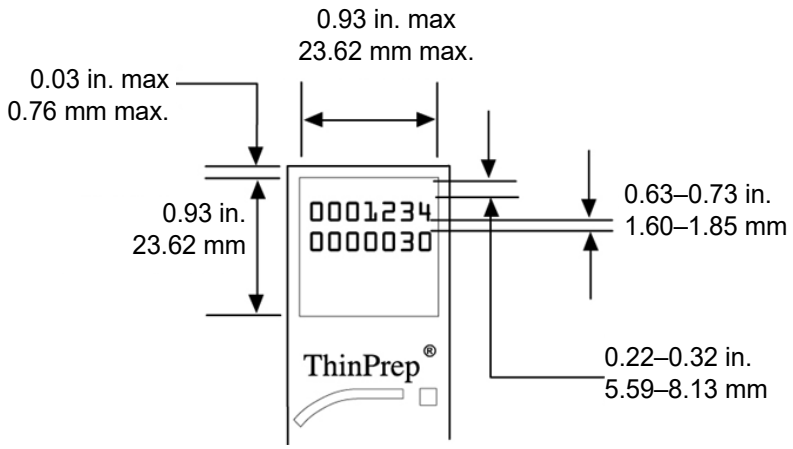


Figure 4-7 Dimensions of the Slide Label

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 93	Supported characters are A–Z, 0–9, - + . $ / % 'space'* A minimum of 5 characters is required and a maximum of 8 characters will fit on a slide.
1-D Code 39	Supported characters are A–Z, 0–9, - + . $ / % 'space'* A 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 Codabar	Supported characters are 0–9, : / + . - * $* ABCD are used as start and stop characters.
1-D EAN/JAN-13	Supported characters are 0–9. The code must be 13 digits.
2-D QR	All printable ASCII 128 characters are supported.*
2-D Data Matrix	All printable ASCII 128 characters are supported.*
*Barcodes for slide IDs cannot typically use characters prohibited in Windows file names (\, /, :, <, >, *, ?, ", and |).	

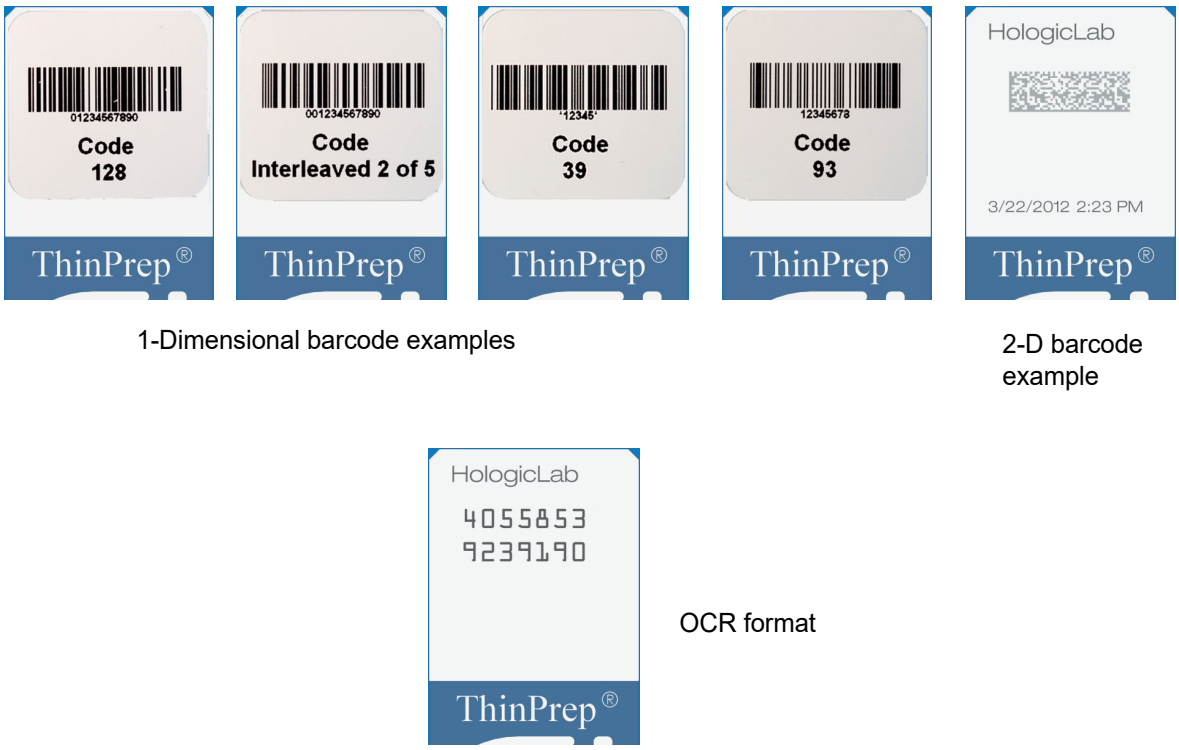


Figure 4-8 Examples of How Barcodes Fit onto a ThinPrep Slide

SECTION E

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). Refer to "Select Case Type for Slide Carrier, Position 10" on page 3.13 for information on designating slide types.

Only stained, coverslipped ThinPrep® Imaging System microscope slides may be used. The Digital Imager will generate a slide event and it will not image the slide if the slide is not a ThinPrep Imaging System microscope slide. Refer to the ThinPrep Stain User's Manual for recommendations for coverslipping media.

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

See Figure 4-9. 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.

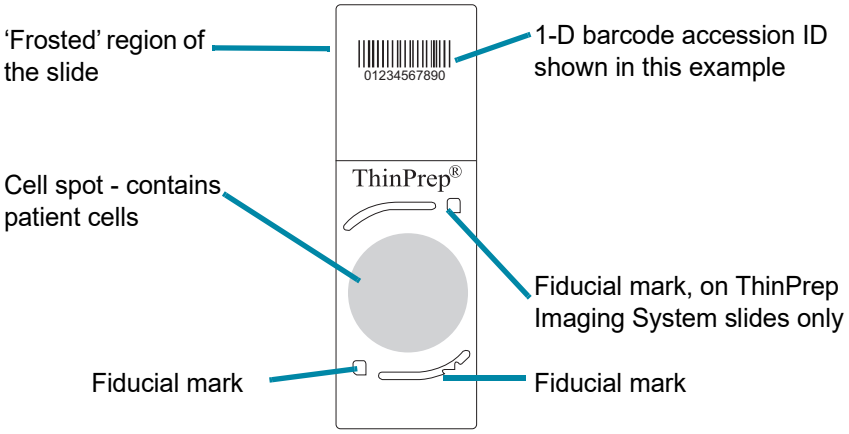


Figure 4-9 ThinPrep Imaging System Microscope Slide for Use with the Digital Imager

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. If slides are already loaded this way in a slide staining rack, this step may not be necessary.

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.

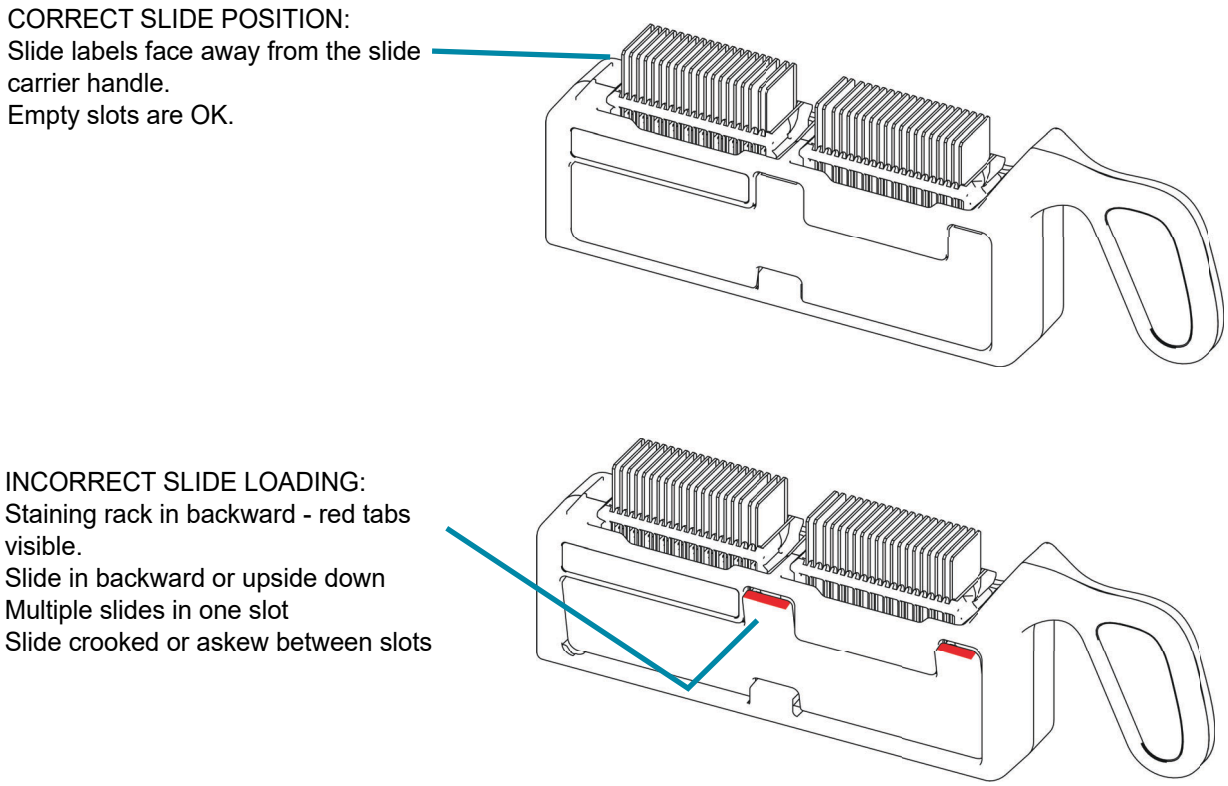


Figure 4-10 Loading Slides into the Slide Carrier

When loading slides, confirm that:

- ThinPrep® Imaging System 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 "Barcode Settings" on page 3.28 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.

SECTION F 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.
   - Position 10 can be designated as an error slide carrier. To change a case type designation, touch the name of the case type above position 10 on the touch screen. Touch a name to select it: gynecologic samples (Gyn) or Error.

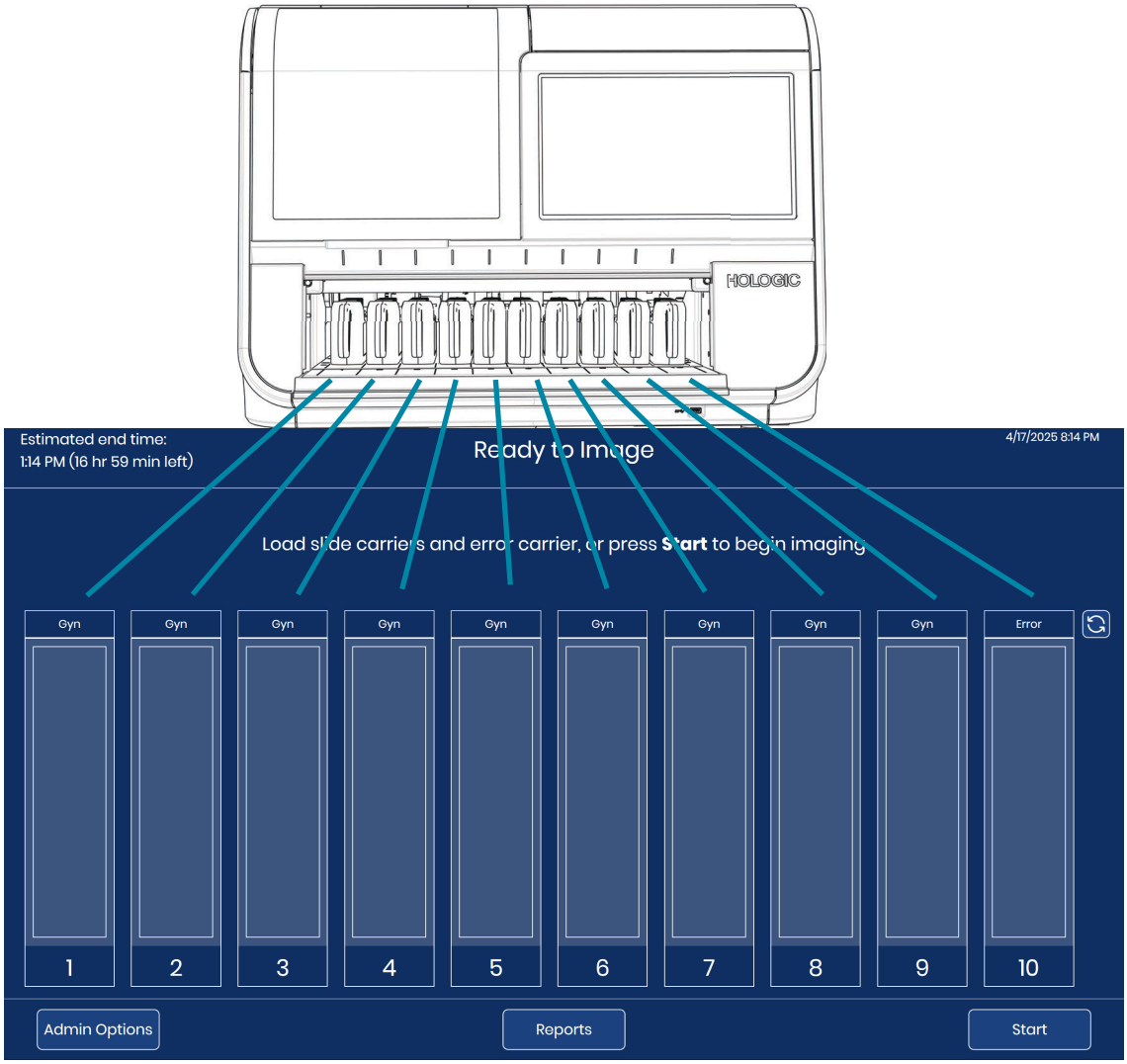


Figure 4-11 Slide Carrier Deck Corresponds to Touch Screen Display

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.

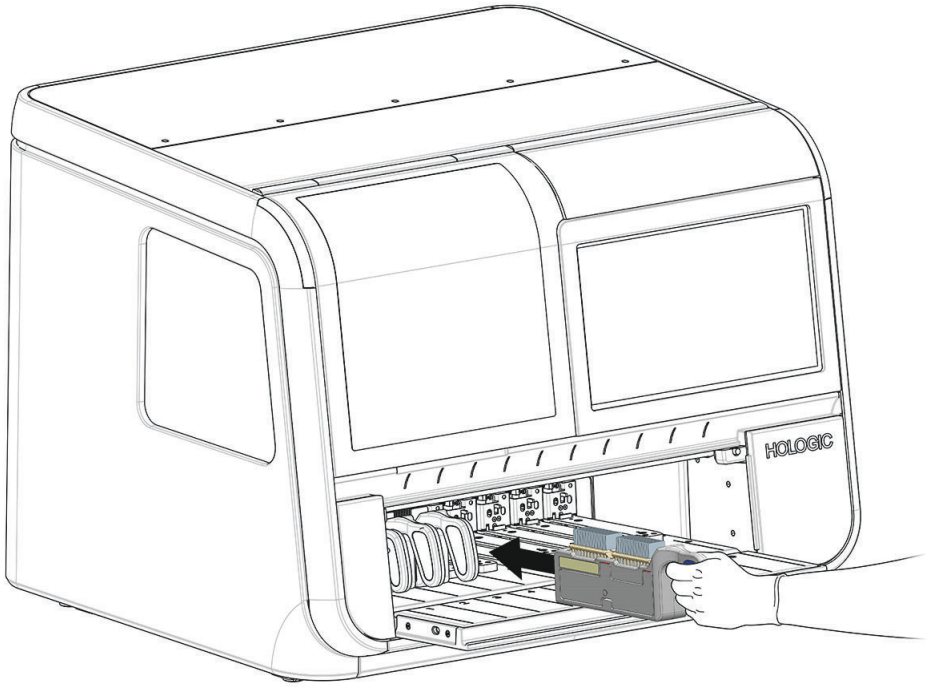


Figure 4-12 Push Loaded Slide Carrier into an Empty Position

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 4.32.

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 a slide carrier with empty staining racks 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.

Note: If position 10 is designated as an error carrier, a slide carrier with empty staining racks in position 10 must also be loaded before the **Start** button is available.

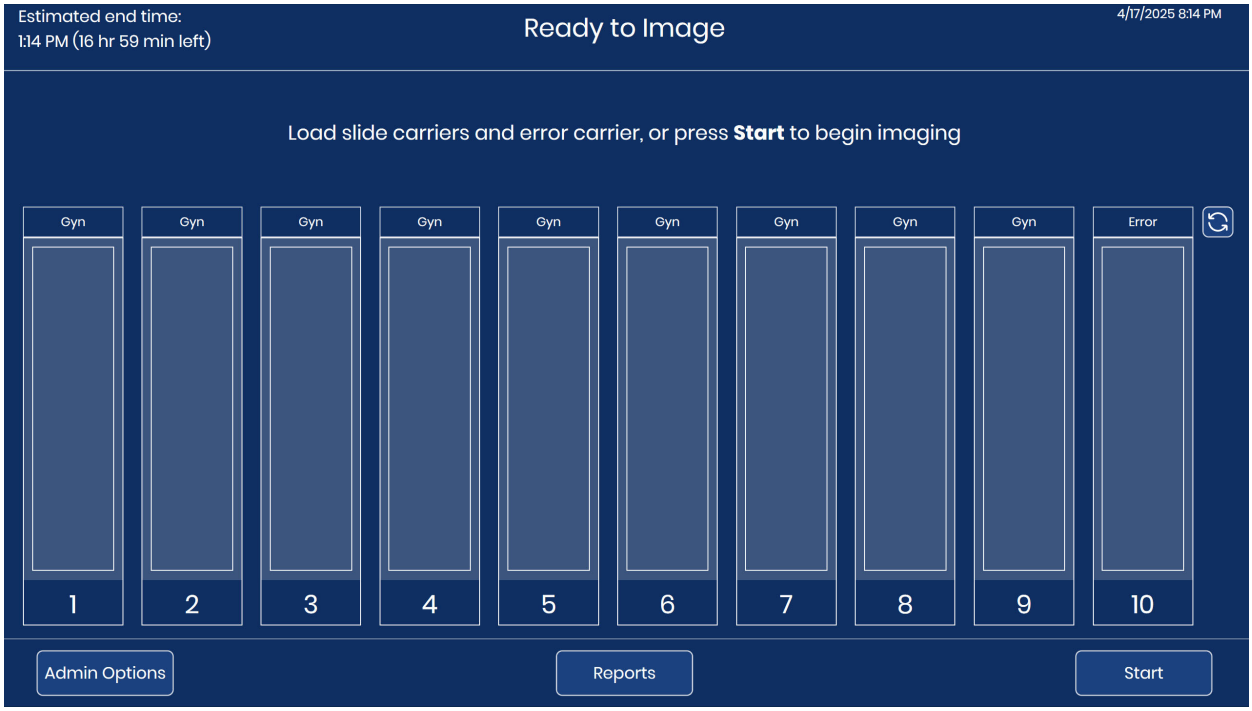


Figure 4-13 Begin Slide Imaging: Load Slide Carriers, or Press Start

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

Table 4.2 Sequence of Events in Imaging Slides

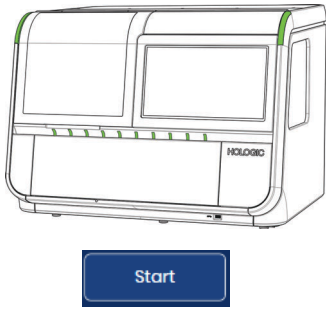
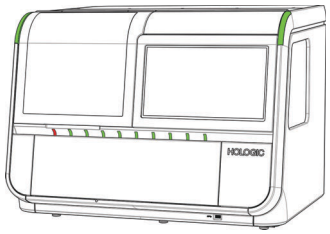
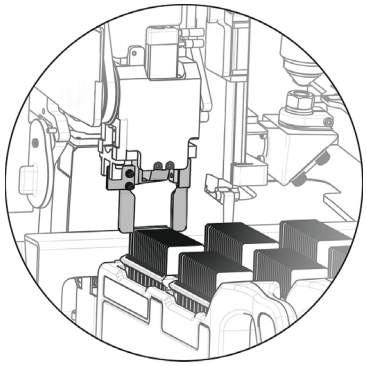
	**Start** button is pressed.
	The door locks and remains locked until slide processing finishes or is paused by the operator. Check for the presence of slides in one slide carrier. The slide carrier indicator light for that slide carrier turns red. Check that the macro station is free from debris and ready to receive a slide. 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

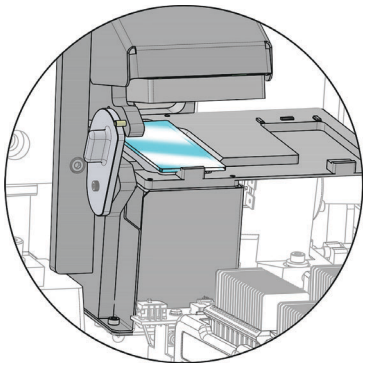
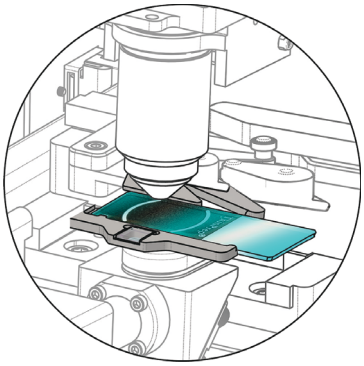
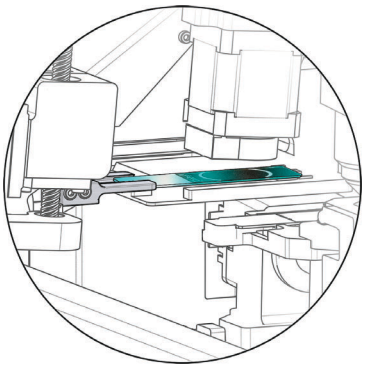
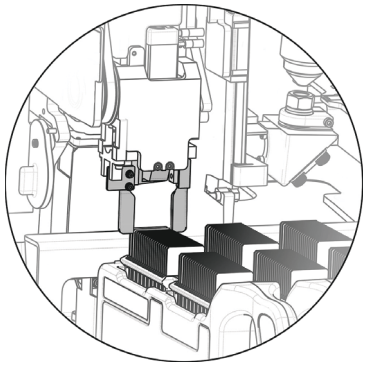
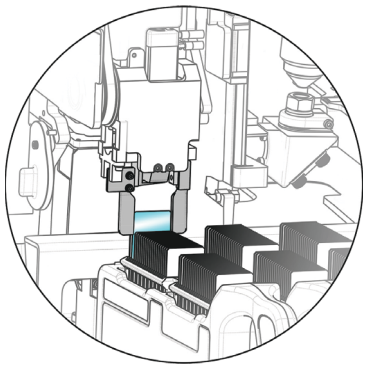
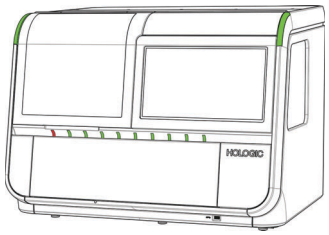
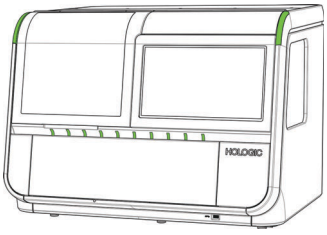
	Move the slide to the macro station. Scan the slide with the macro scanner to capture the slide ID on the slide label. Use the Accession ID Settings to record the accession ID based on the slide ID on the slide label. Check that the slide has not already been imaged.
	Move the slide to the imaging stage. Scan the slide in high resolution. While one slide is on the imaging stage, check that the macro station is free from debris and ready to receive a slide. 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 4-14 shows how the touch screen display depicts progress through the loaded slide carriers.

Figure 4-14 Slide Carrier Imaging Status, example

Key to Figure 4-14	
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.
2	Slide carriers are loaded in positions 2-4 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, and 4. 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.

Key to Figure 4-14	
③	The Digital Imager has detected that slide carriers are loaded in positions 5, 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 icon 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. A routine, periodic check is scheduled for 2 a.m. to minimize disruption, but a periodic check may also happen when the Digital Imager recovers from an error. 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.

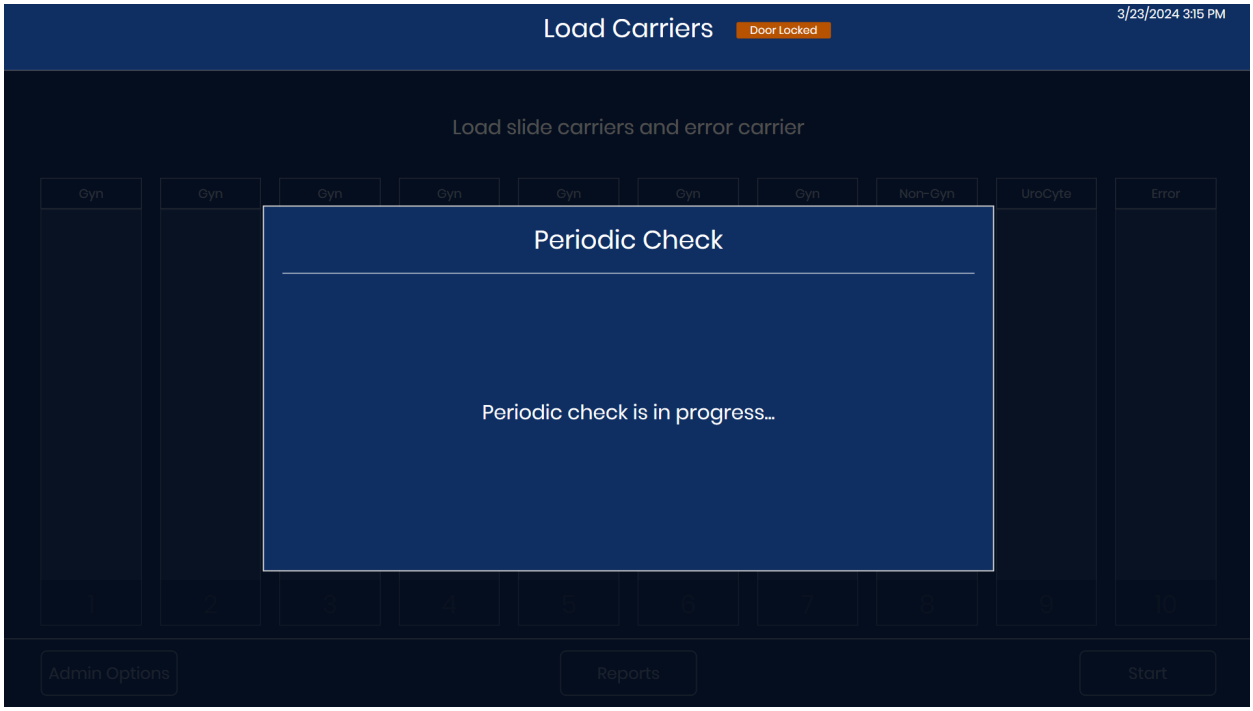


Figure 4-15 Periodic Check

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.

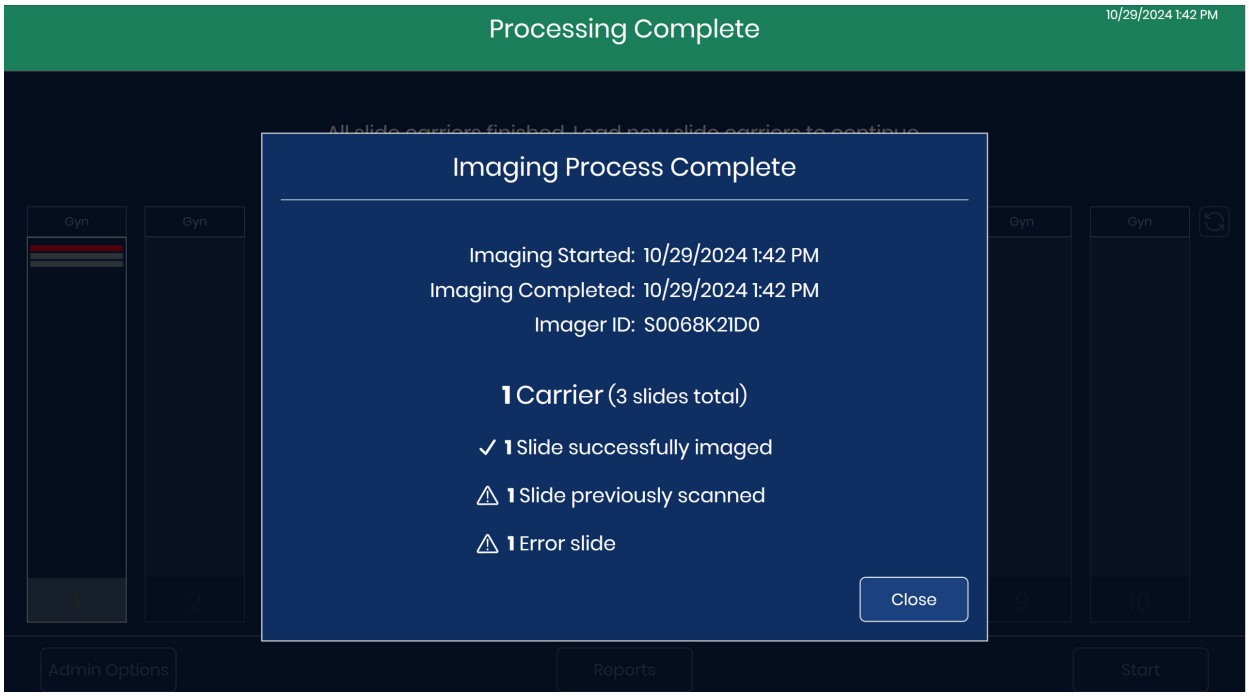


Figure 4-16 Processing Complete

Touch the **Close** button to return to the main screen with "Processing Complete" displayed.

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.

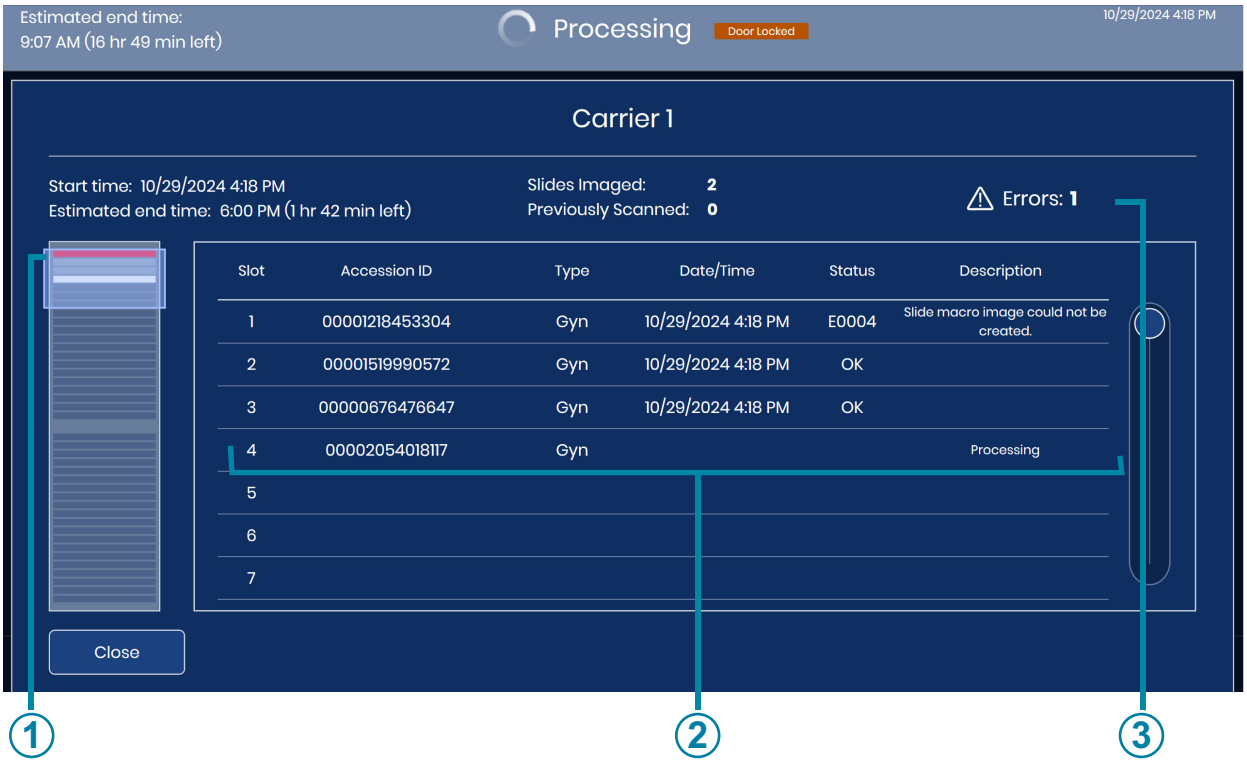


Figure 4-17 Slide Event During Processing

Key to Figure 4-17	
1	The red stripe represents a slide with an error.
2	The screen lists the slot number in the staining rack, the accession ID, the case type (Gyn), 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 label 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 label includes characters that are not allowed for the barcode type
- 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
  - Macroartifacts or holes in the cell spot
  - The slide is not a ThinPrep Imaging System 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.

SECTION H

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.

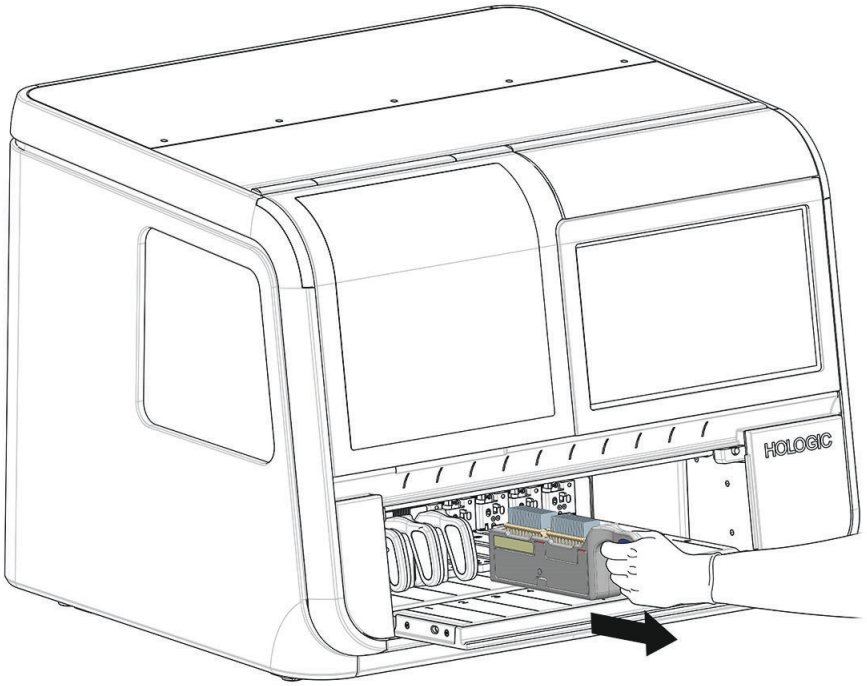


Figure 4-18 Remove Slide Carrier from Digital Imager

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.

SECTION I

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 Events Report 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 4.10.

The Digital Imager stops processing and the system status lights flash amber 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's accession ID, case type (Gyn), date and time, status, and description.

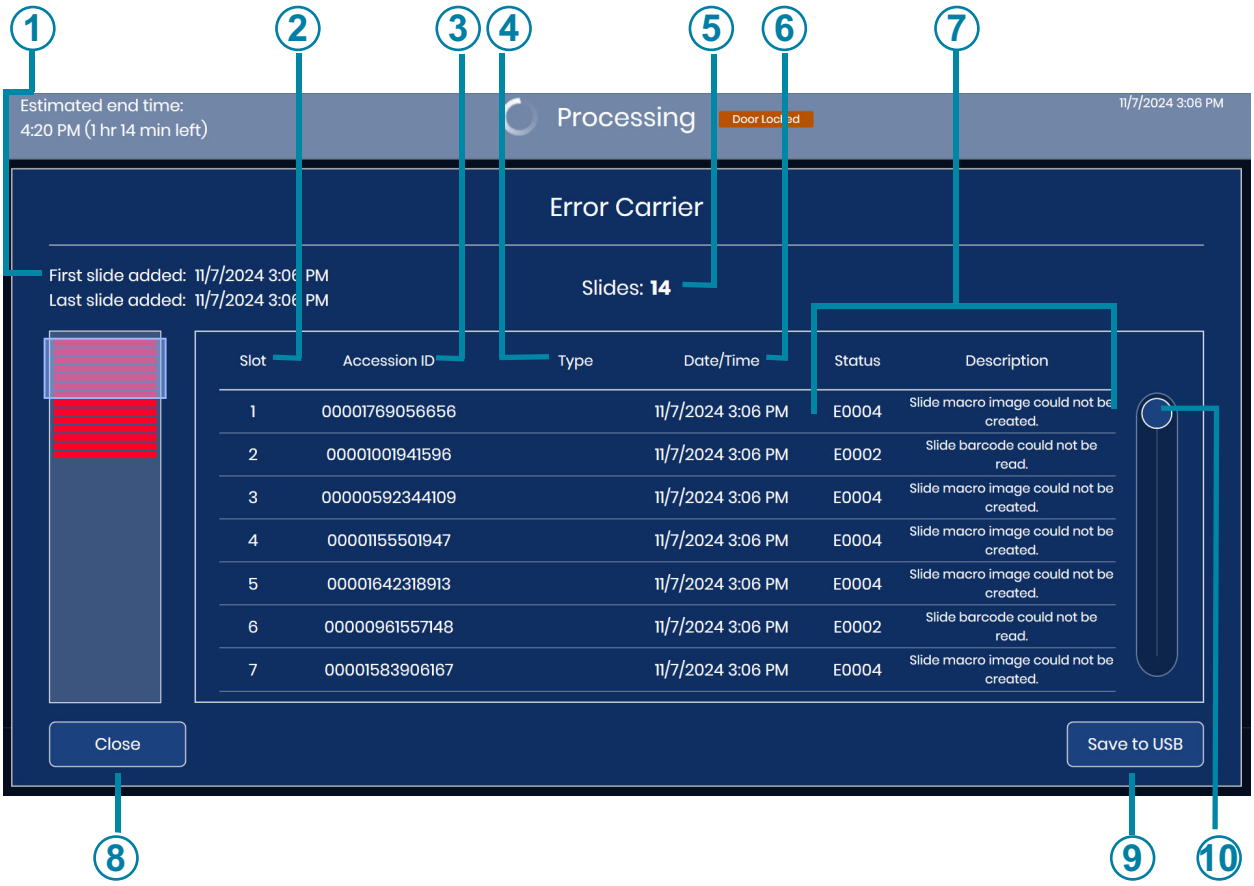


Figure 4-19 Details for Slides in the Error Carrier

Key to Figure 4-19	
1	Time period that this error carrier has been in use
2	Slot in the staining rack in the error carrier

Key to Figure 4-19	
③	The accession ID is shown (for slides with a successful barcode scan)
④	Case type: 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 Events Report 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 3.43.

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.

4 Operation of the Digital Imager

Figure 4-20 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.

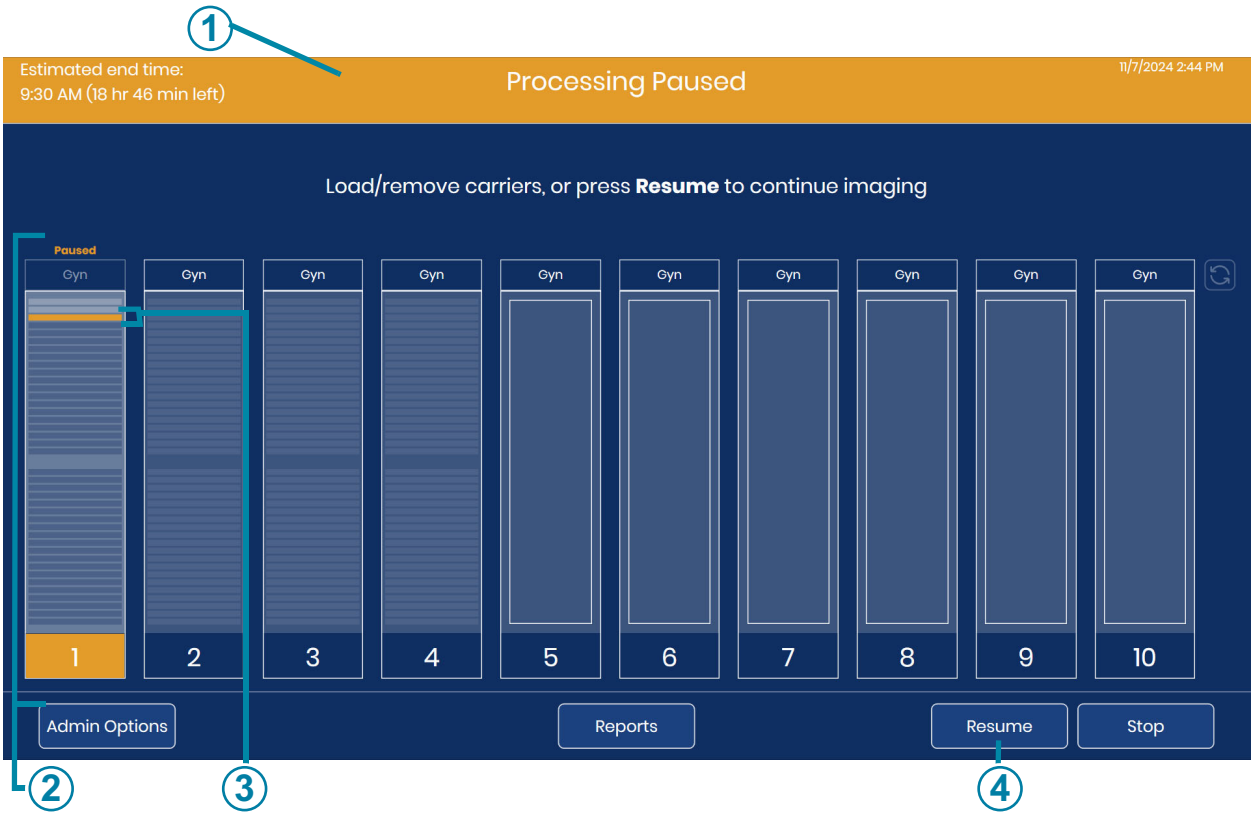


Figure 4-21 Slide Processing Paused

Key to Figure 4-21	
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, the Digital Imager had one slide out of the carrier when processing paused.

Key to Figure 4-21	
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 4.36 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 4.36 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. Touch the rectangle representing the slide carrier on the touch screen to select the carrier with Stat slides in it.
6. Press the **Mark as STAT** button.

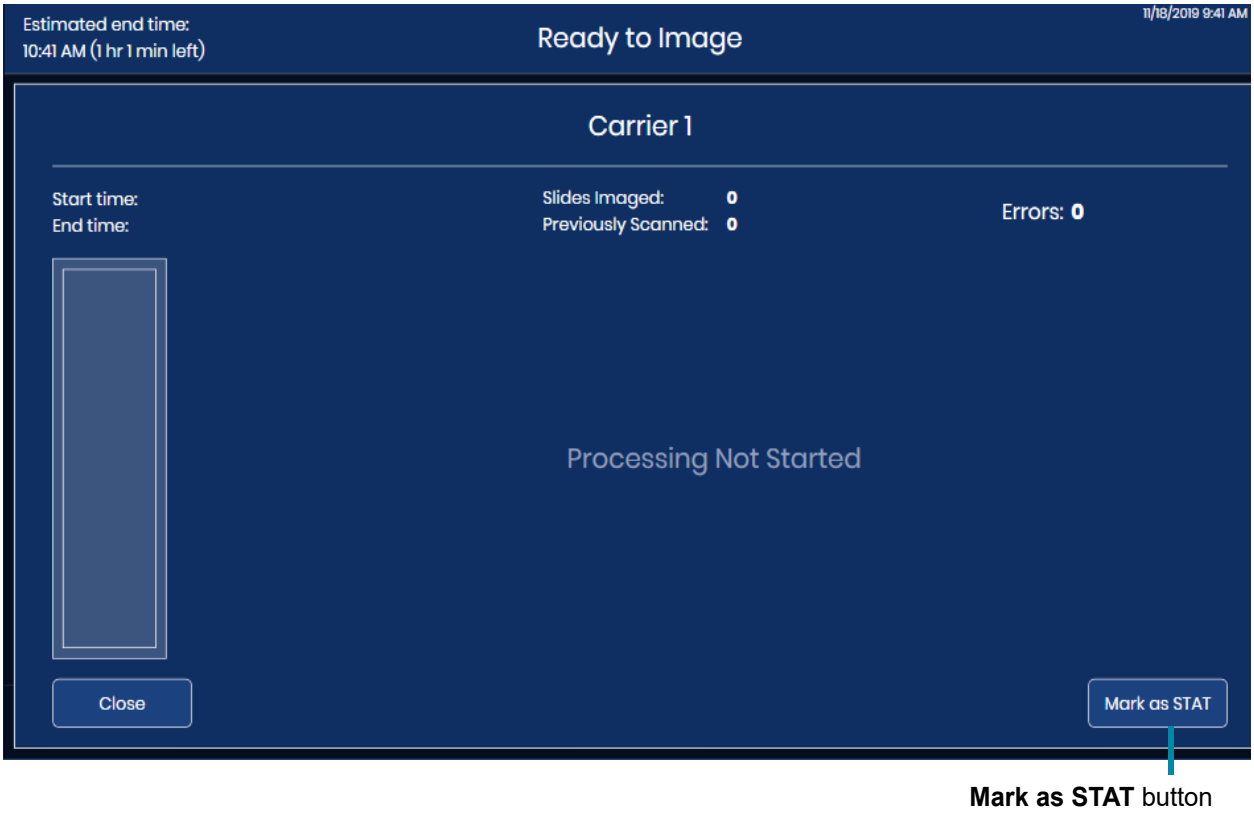


Figure 4-22 Run Stat Carrier: Mark Slide Carrier as STAT

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.

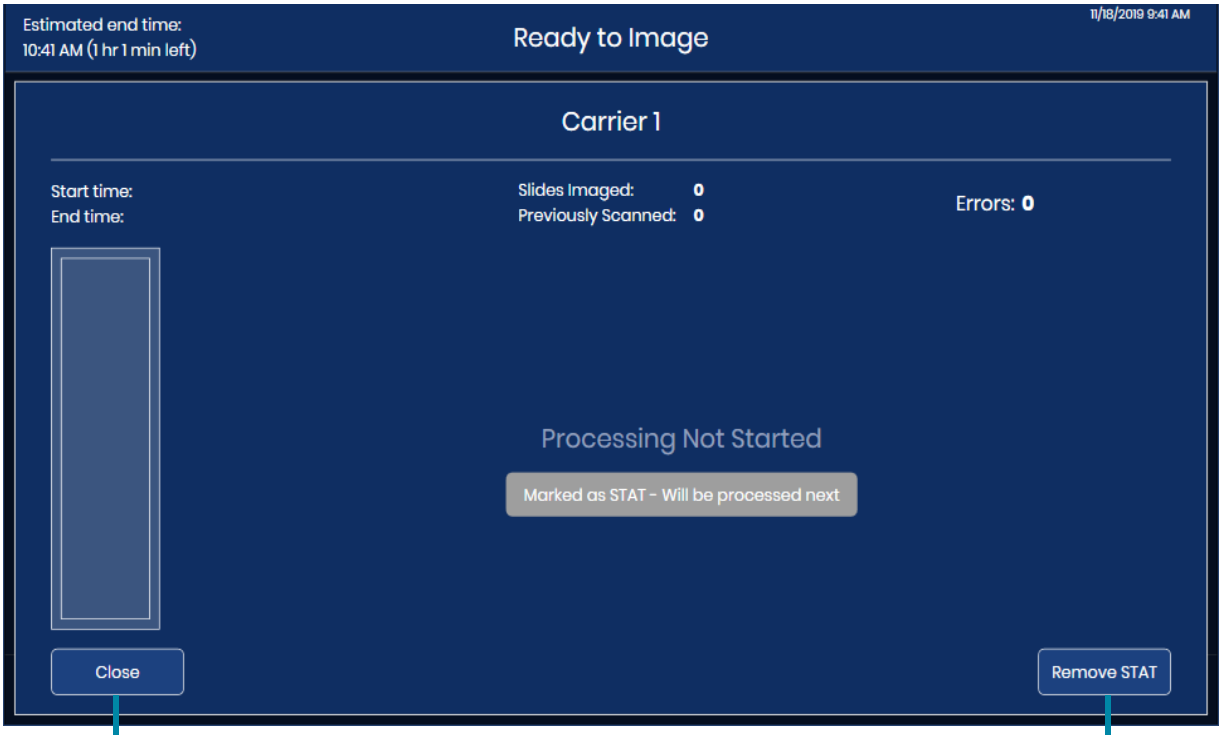


Figure 4-23 Stat Interruption Confirmation Message

7. 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).
8. Touch **Resume** and 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.
9. 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.

SECTION K

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 **Load/Remove** button.

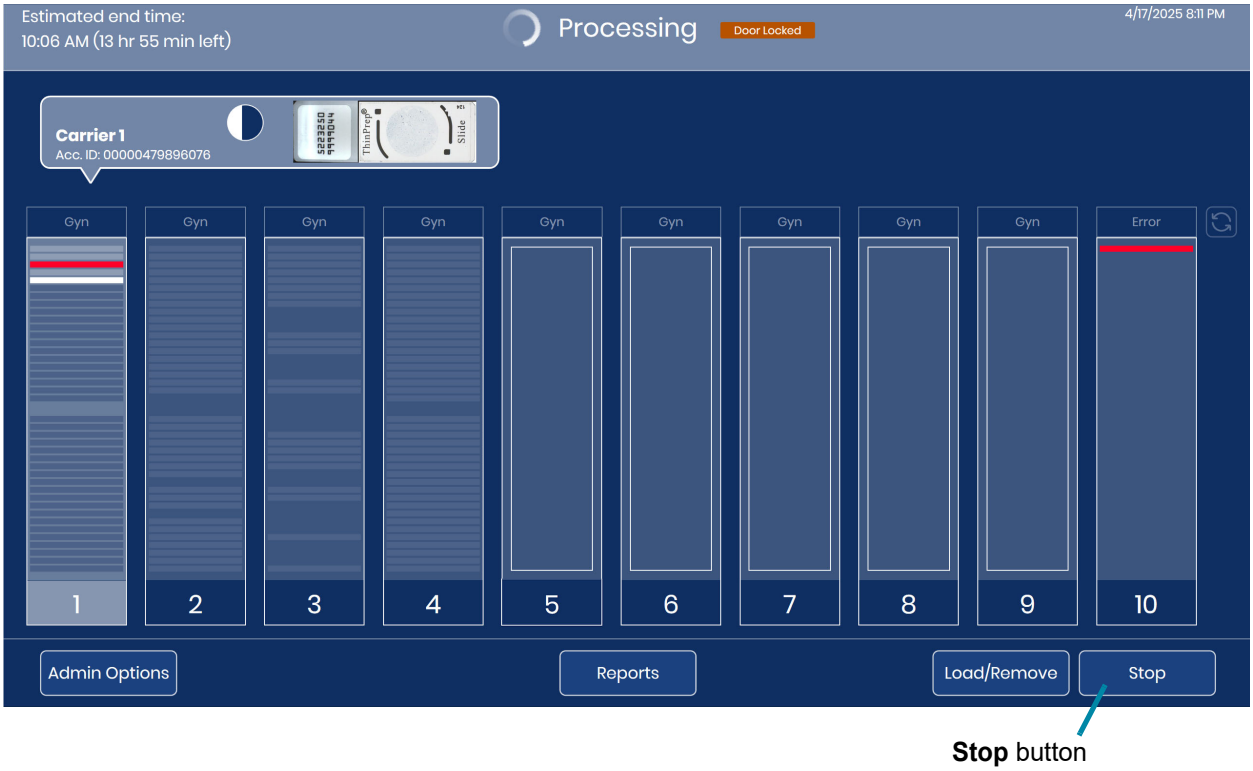


Figure 4-24 Stop Button

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.

SECTION L

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**.

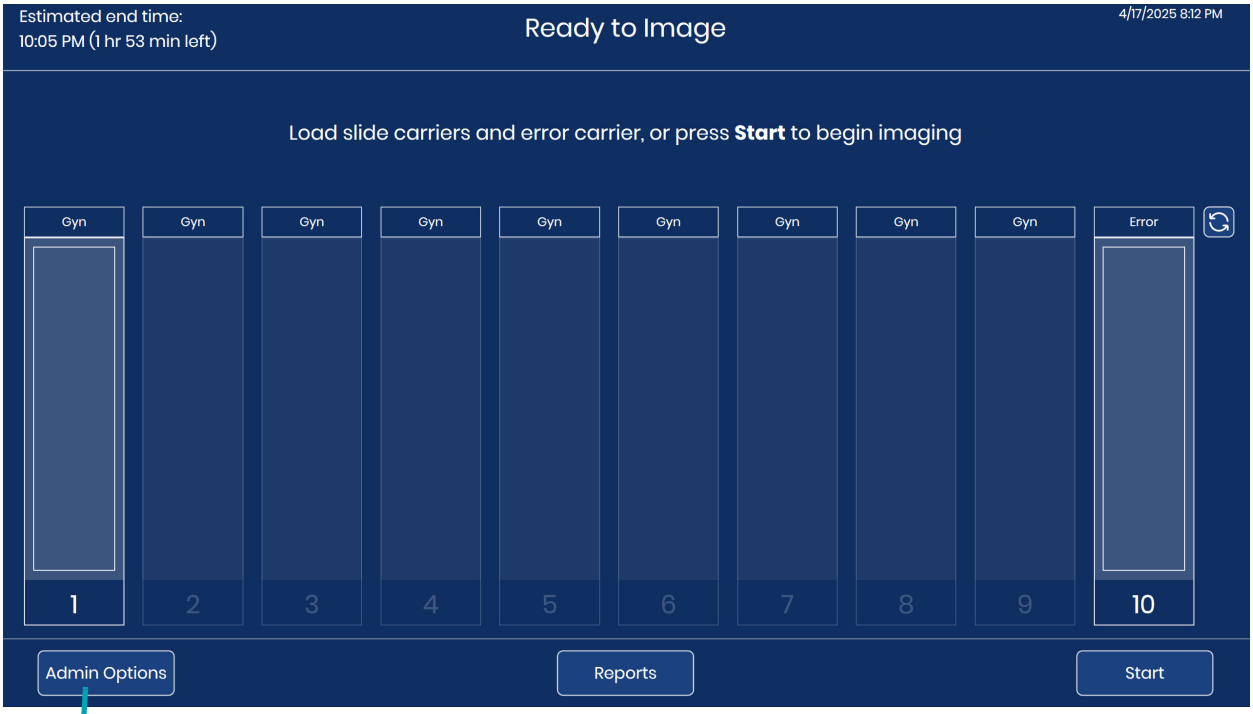


Figure 4-25 Touch Admin Options from Main Screen

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

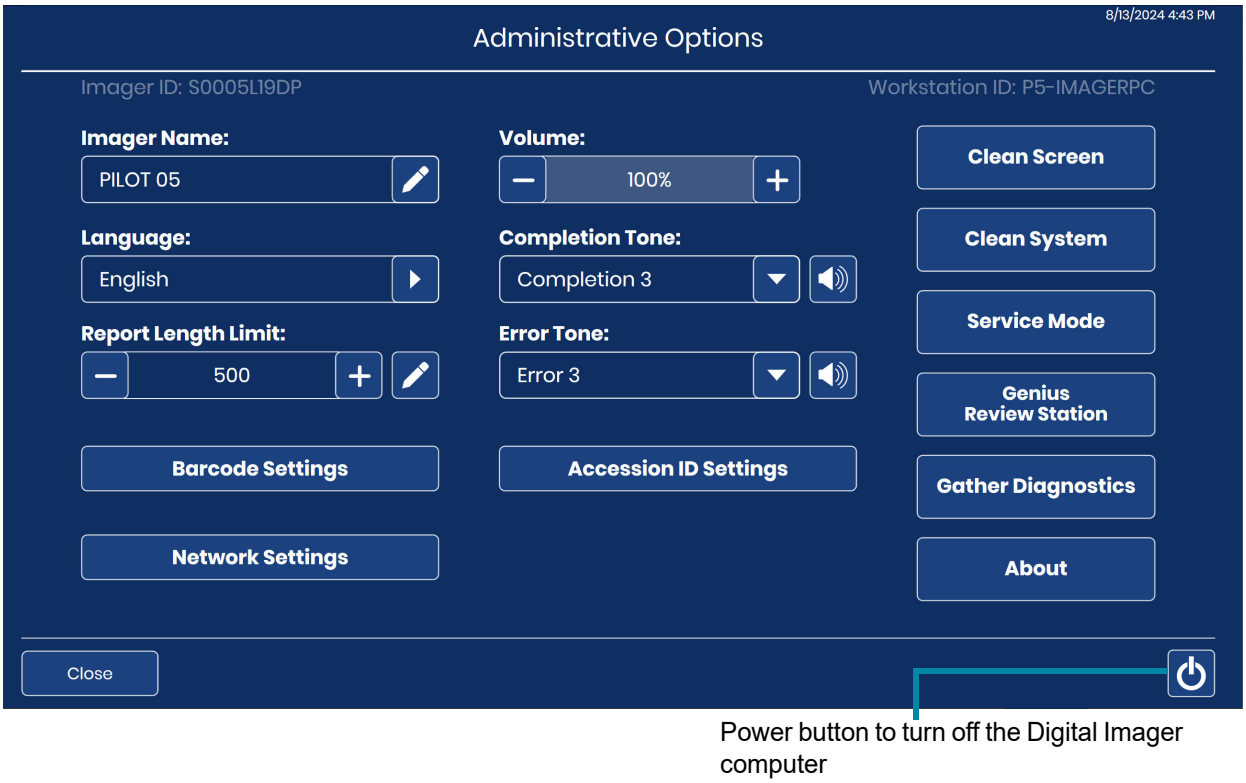


Figure 4-26 Power Button on the Touch Screen

4. Select **Power Off** on the confirmation screen to continue with shutdown. (See Figure 4-27).

Figure 4-27 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 1-5.

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 4.36.

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 4.36.
2. Allow 15 seconds to pass before powering on the Digital Imager and the Digital Imager computer. Refer to "Applying Power to the Equipment" on page 4.3.

5. Maintenance

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 service personnel trained by Hologic.

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

5 Digital Imager Maintenance

Clean System

When a component on the interior of the Digital Imager needs to be cleaned, use the **Clean System** mode. The Clean System mode de-energizes the slide handling arm, allowing the operator to gently move the arm for better access to the interior of the instrument.

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

Figure 5-1 Clean System Button

2. On the confirmation screen, touch **OK** to disable the motors so that portions of the Digital Imager can be accessed by the operator. To cancel and return to the Administrative Options screen, touch **Cancel**.

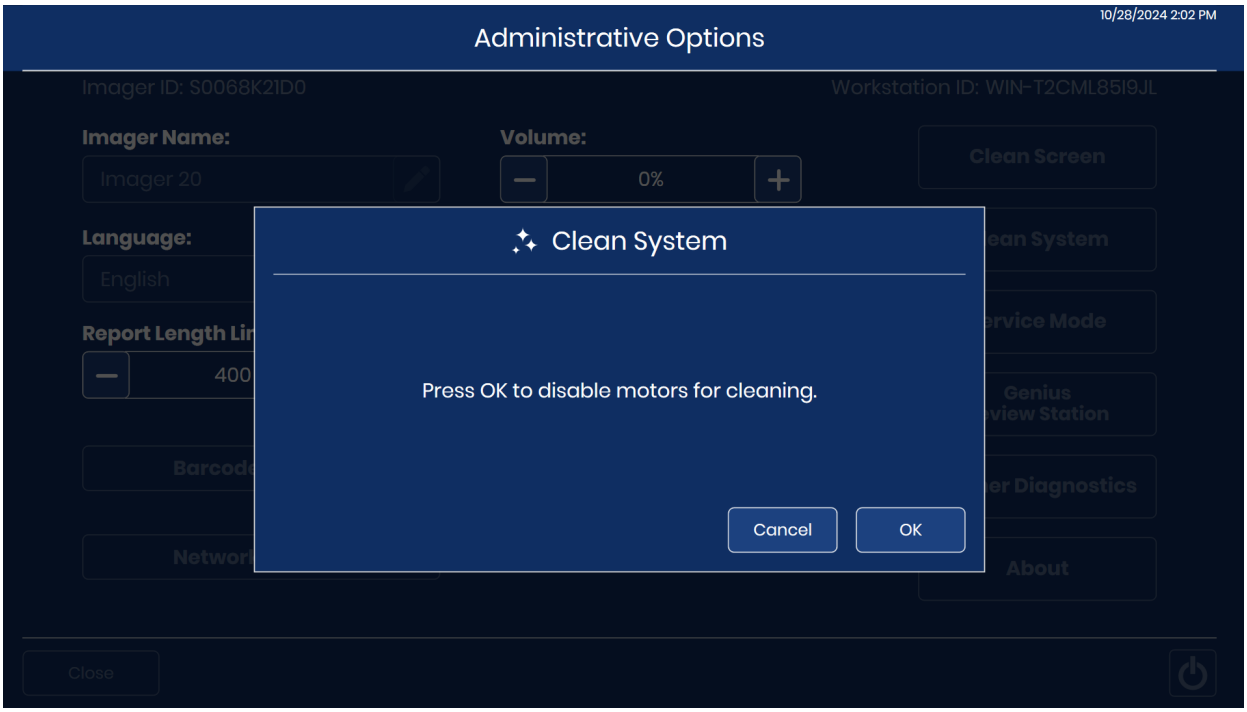
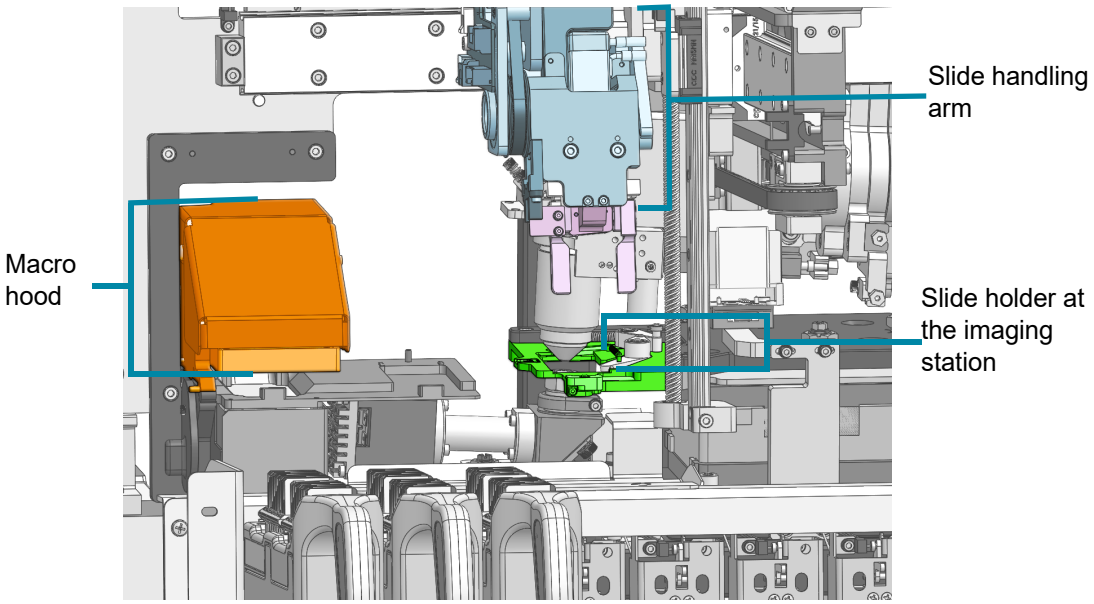


Figure 5-2 Clean System Mode to Disable Motors

3. Open the window and/or the door to access the interior of the Imager. In **Clean System** mode, the slide handling arm and the macro hood can be moved.
   - To move the slide handling arm, gently push, pull, or rotate the slide handling arm. The slide handling arm will move left, right, forward, backward, up or down.
   - To move the macro hood, gently lift it up.

Caution: In the interior of the Digital Imager, only touch the components described in these maintenance instructions. Other, delicate components must be in the correct position and undamaged for proper performance of the Digital Imager.



Interior of the Digital Imager - covers removed to show detail

Figure 5-3 Clean System: Macro Hood, Slide Handling Arm and Slide Holder at the Imaging Station are Movable

4. When cleaning is complete, close the door and window. Both the door and window must be closed before the **OK** button is available on the touch screen. Touch **OK** to reset the Digital Imager and return to the Administrative Options screen.

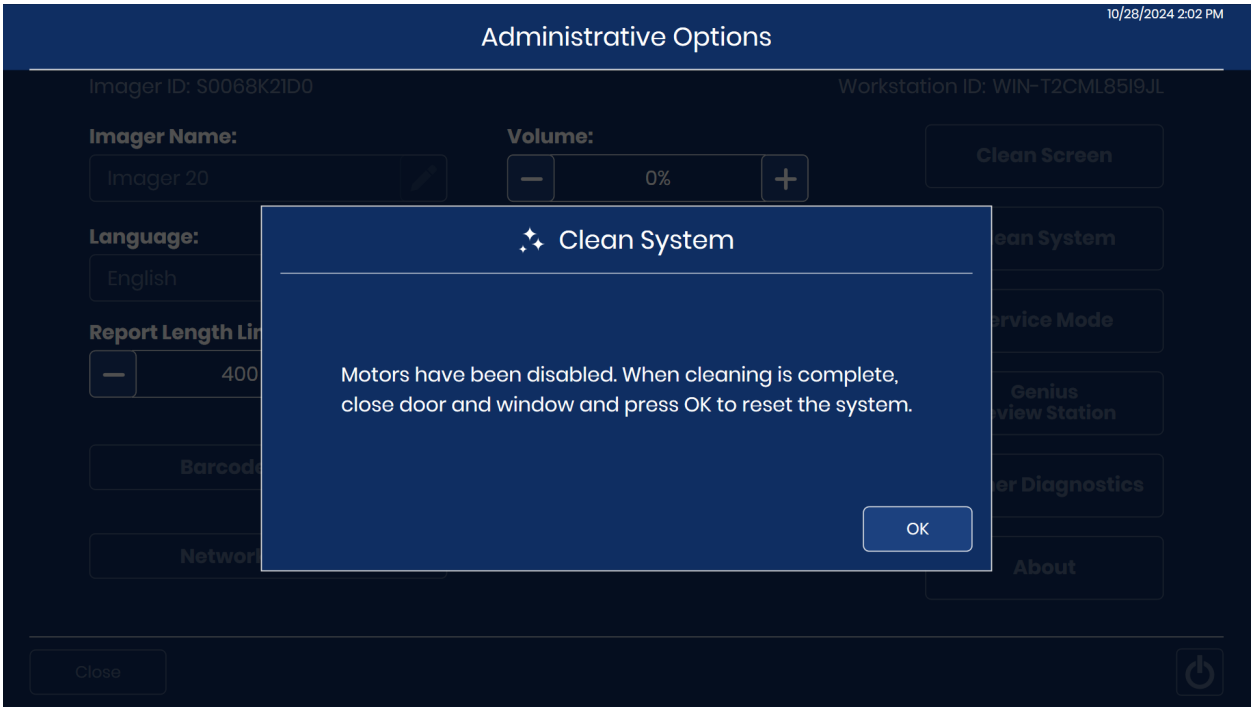


Figure 5-4 Reset System When Cleaning is Complete

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). Set the Digital Imager in Clean System mode. (Refer to “Clean System” on page 5.2.) Open the window.
2. Move the slide handling arm so that the slide grippers are easy to reach. 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.

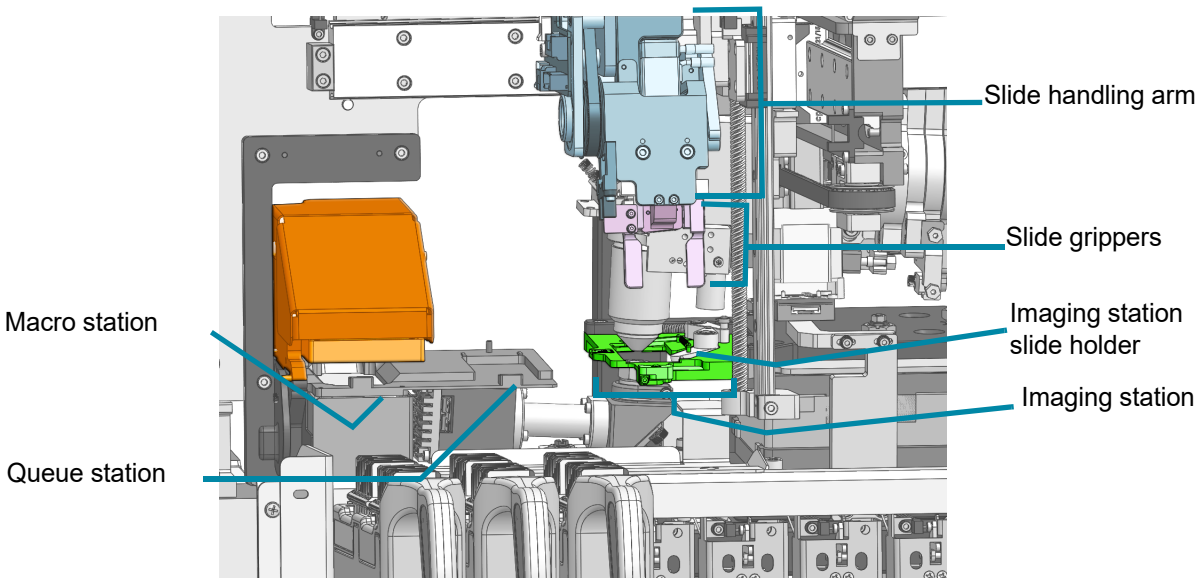


Figure 5-5 Macro Station, Queue Station, Imaging Station and Slide Gripper

WARNING: Glass
The Genius Digital Imager uses glass 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 Macro Station

Over time, dust builds up on the macro station. When the Digital Imager removes a slide from the slide carrier, the Digital Imager checks for debris at the macro station. If debris is detected, the Digital Imager will interrupt processing and prompt the user to clean the macro station. Use a manual air blower or a combined lens blower/cleaning brush, designed for cleaning lenses, to gently remove dust from the macro station.

1. Wait until the instrument is idle (not processing slides). Set the Digital Imager in Clean System mode. (Refer to "Clean System" on page 5.2.) Open the window. Wear clean, nitrile gloves and avoid touching the stage surfaces.
2. Move the slide handling arm so that the macro station is easy to reach. Do not press on the macro station. Gently, wipe any glass dust and debris from the macro station with a with a lint-free wipe, dampened with deionized water. Refer to Figure 5-5.
3. Squeeze the bulb of the air blower with compressor or the combined lens blower/brush, to gently blow the dust from the macro station.
4. Close the window.

CAUTION: Do not use propellant, such as canned air, because the components around the macro station could be damaged.

WARNING: Glass
The Genius Digital Imager uses glass 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.

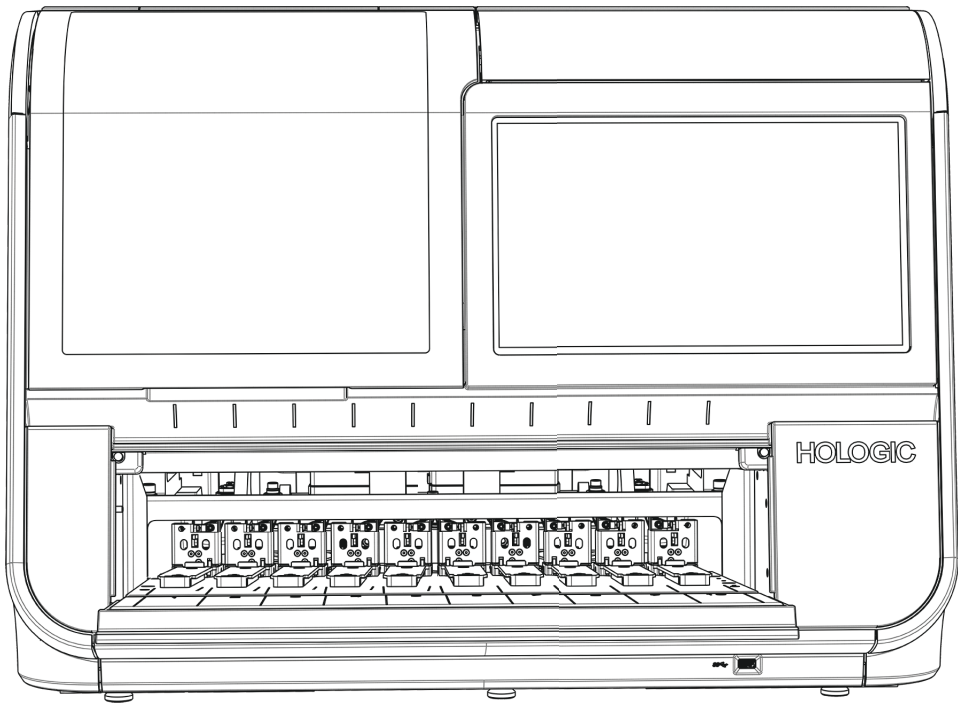


Figure 5-6 Remove Slide Carriers to Wipe Slide Carrier Deck

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 1-7.

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

CAUTION: To avoid damaging the sensors at the back of 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.

SECTION B

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. A lab imaging a high volume of slides may need to clean the verification chip daily.

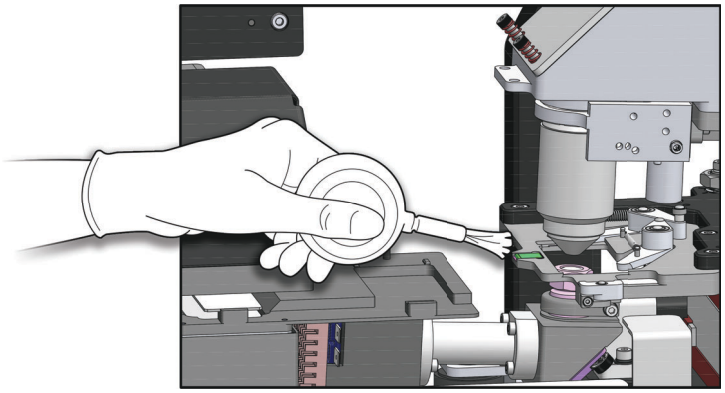


Figure 5-7 Clean the Verification Chip

1. Wait until the instrument is idle (not processing slides). Set the Digital Imager in Clean System mode. (Refer to "Clean System" on page 5.2.) Open the window. Wear clean, nitrile gloves and avoid touching the stage surfaces.
2. Move the slide handling arm so that the imaging station is easy to reach. 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, such as 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.

WARNING: Glass
The Genius Digital Imager uses glass 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 Imaging Station Slide Holder

The imaging stage is delicate. It must be in the same position and free of scratches for proper performance of the Digital Imager. The imaging station slide holder is the "C"-shaped gripper near the imaging stage. The imaging station slide holder has a slide holder arm and a slide holder head.

Over time, dust builds up on the imaging station and may accumulate in the imaging station slide holder. Clean the imaging station slide holder with a manual air blower or a combined lens blower/cleaning brush designed for cleaning lenses.

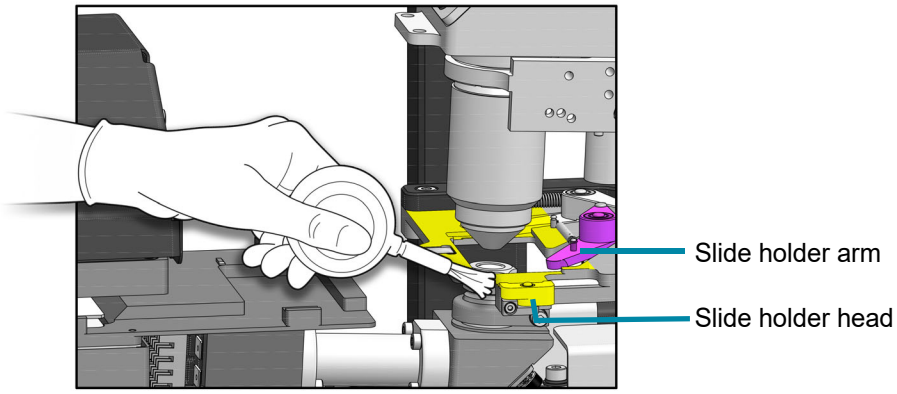


Figure 5-8 Clean the Imaging Station Slide Holder

1. With the Digital Imager idle, open the window. Wait until the instrument is idle (not processing slides). Set the Digital Imager in Clean System mode. (Refer to "Clean System" on page 5.2.) Open the window. Wear clean, nitrile gloves and avoid touching the stage surfaces.
2. Move the slide handling arm so that the imaging station is easy to reach. Squeeze the bulb of the air blower with compressor or the combined lens blower/brush, to gently blow the dust from the imaging station slide holder.
3. Close the window.

CAUTION: Do not use propellant, such as canned air, because the components around the imaging stage could be damaged. Do not wipe the imaging station slide holder because it, or the components near it, could be scratched by debris.

WARNING: Glass
The Genius Digital Imager uses glass 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 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 5-9 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**.

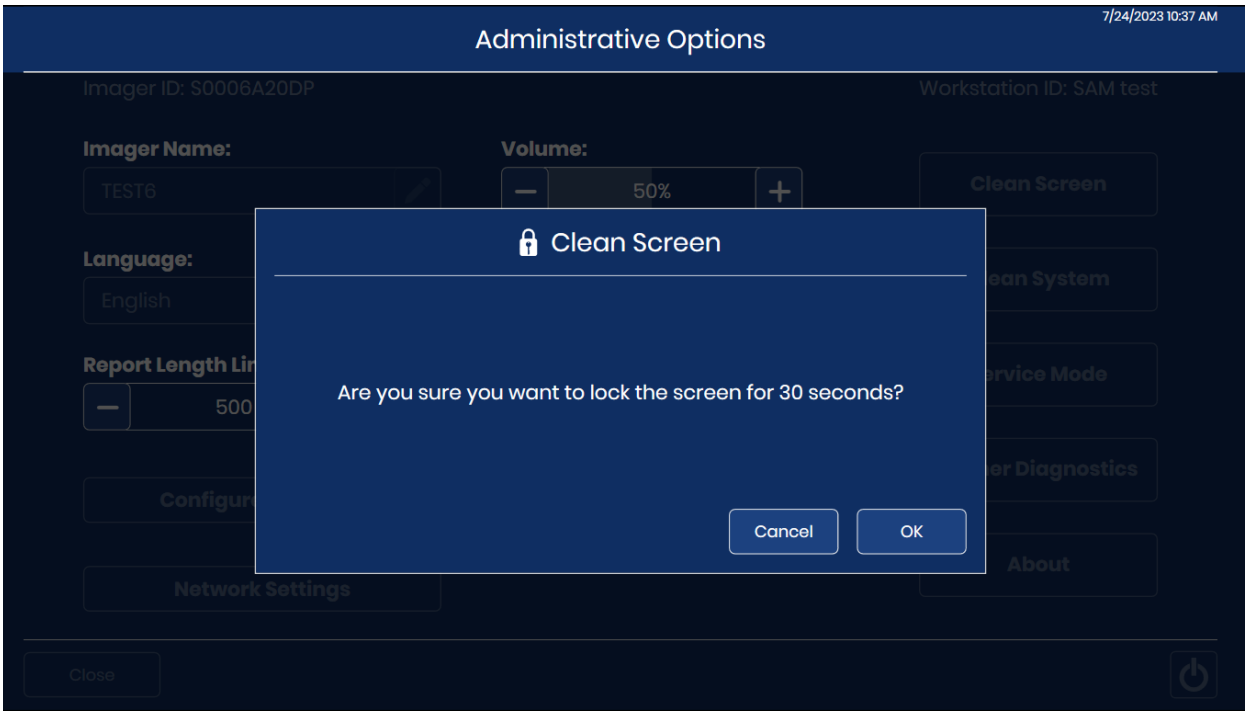


Figure 5-10 Confirm that the Touch Screen Will Be Disabled for Cleaning

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.

5 Digital Imager Maintenance

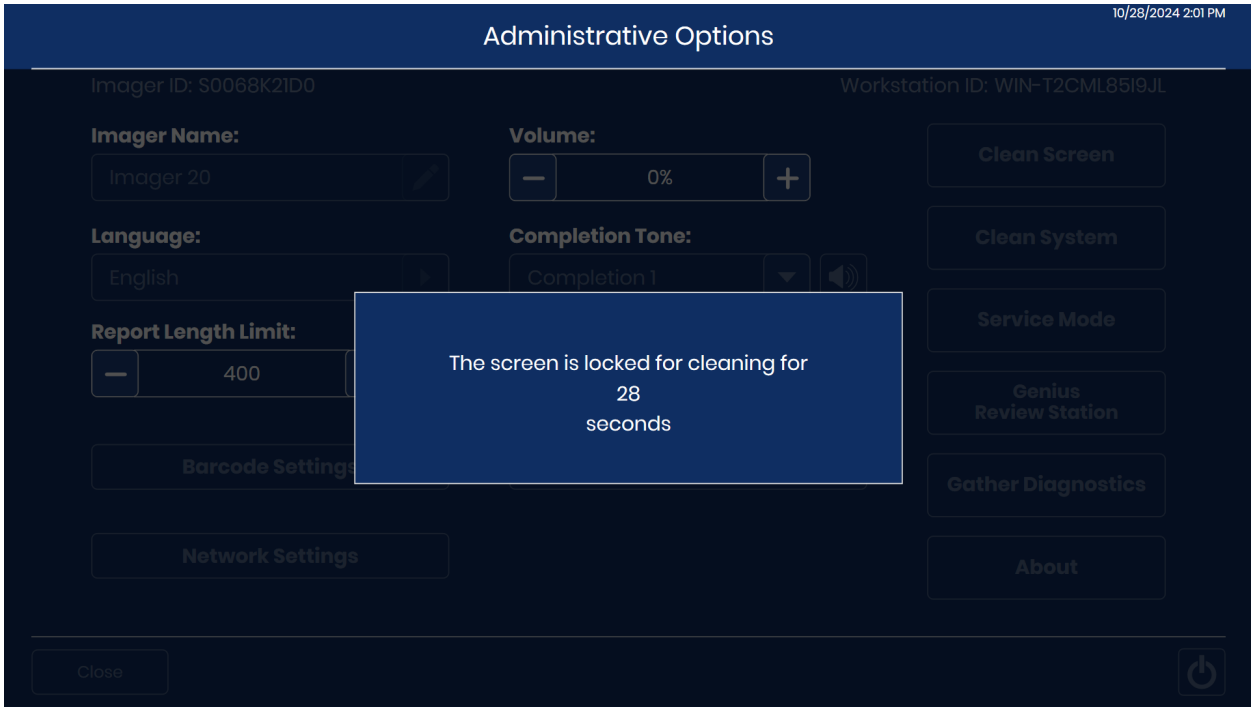


Figure 5-11 Clean Screen Counts Down 30 Seconds

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.

SECTION C

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:_____

	Weekly				As Needed			
Date	Clean Queue Station and Slide Grippers page 5.4	Clean Macro Station page 5.5	Clean Slide Carrier Deck page 5.6	Clean Slide Carriers page 5.6	Clean the Verification Chip page 5.7	Clean Slide Holder page 5.8	Clean Touch Screen page 5.9	Clean Exterior of Digital Imager page 5.10
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6. Troubleshooting

Chapter Six

Troubleshooting

SECTION A

THE IMAGE MANAGEMENT SERVER IS UNAVAILABLE

The Digital Imager must have an active connection to the Image Management Server in order to image slides or display slide data. The Image Management Server must have sufficient storage capacity available in order for the Digital Imager to transmit data to the Image Management Server.

Image Management Server is Unavailable - Offline

If communication between the Digital Imager and Image Management Server is disrupted, the banner across the top of the touch screen displays turns red. The system status lights flash in red. Slides cannot be imaged until after the connection with the Image Management Server is restored.

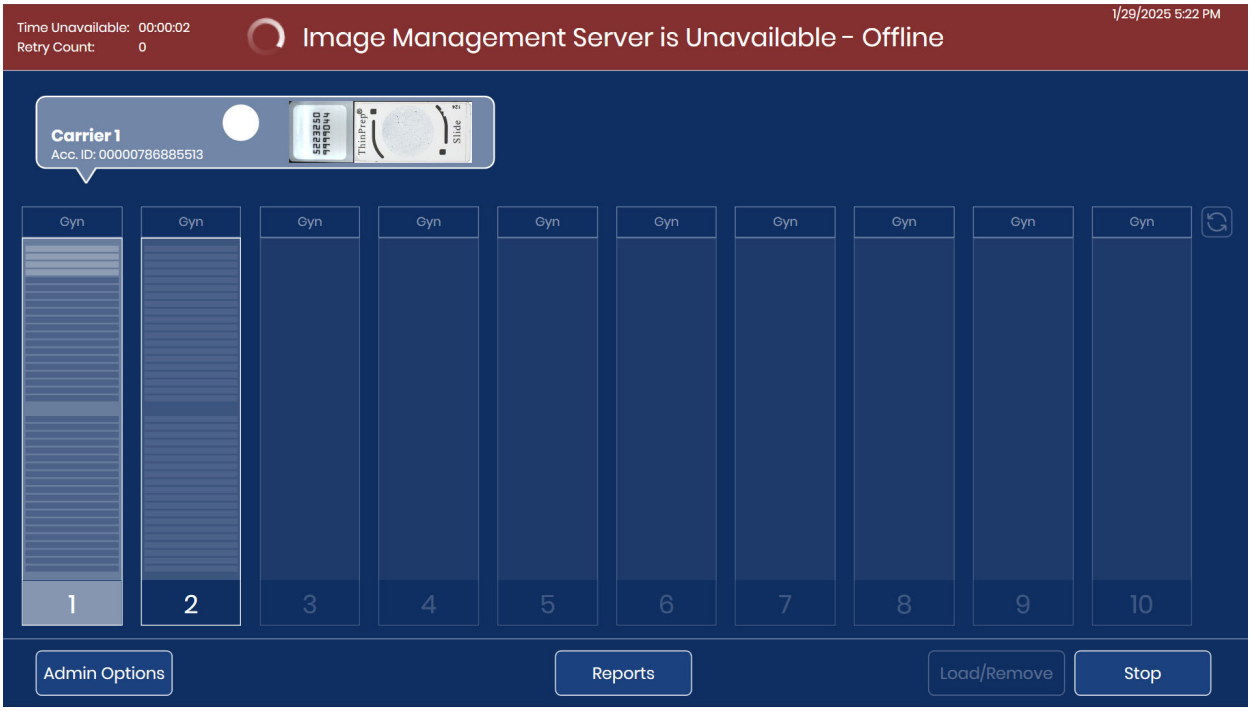


Figure 6-1 No Connection Between Image Management Server and Digital Imager

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. Check that network settings for the Image Management Server are correct. This may require assistance from your facility's network administrator.

Image Management Server is Unavailable - Storage Full

Communication between the Digital Imager and Image Management Server detects the amount of storage capacity available on the Image Management Server. If the Image Management Server approaches full storage capacity, the banner across the top of the Digital Imager touch screen turns red. The system status lights flash in red. Slides cannot be imaged until storage capacity is available on the Image Management Server.

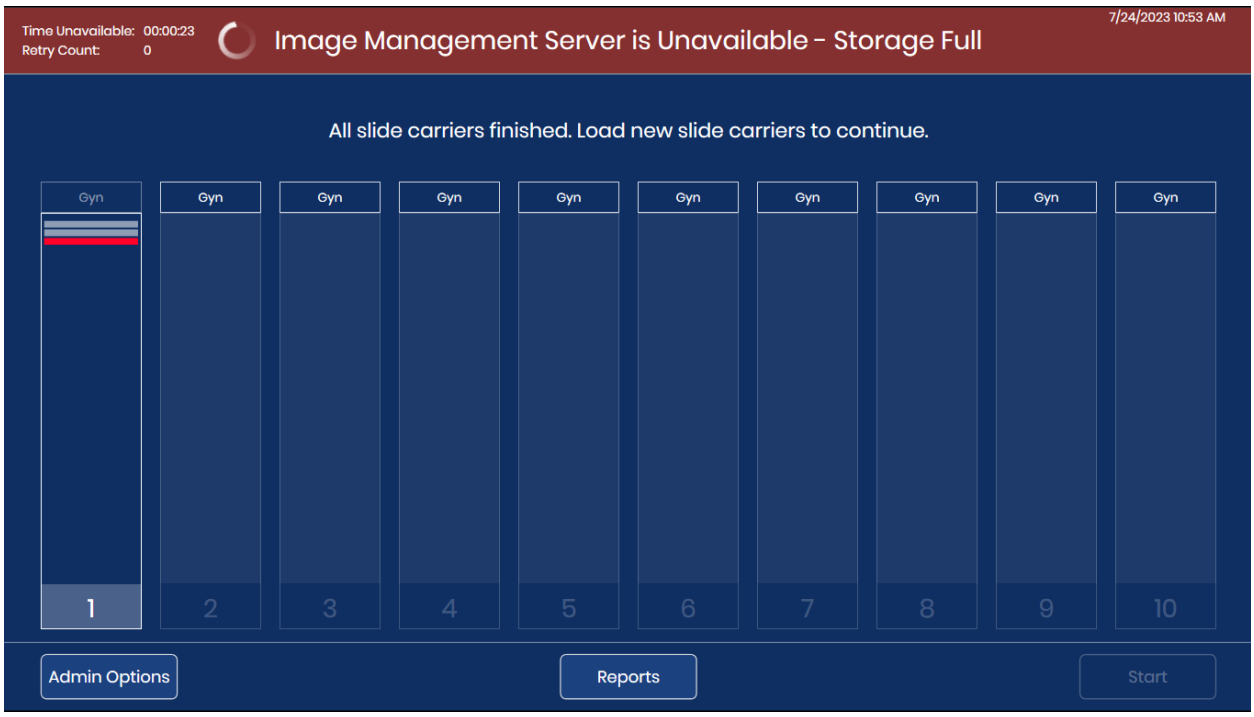


Figure 6-2 Insufficient Storage Available on the Image Management Server

An operator at the Digital Imager can monitor the storage capacity of the Image Management Server Refer to "Network Settings" on page 3.26. A lab manager at a Genius Review Station can change the settings for archiving or slide management, to free up storage capacity on the Image Management Server. Refer to the Genius Review Station Operator's Manual for more information.

Note: For labs using the slide management feature, the slide management feature starts deleting slides at 3 a.m. The start time cannot be changed by an administrator or a lab manager at the Review Station. To avoid a full server, archiving and slide management settings should be set up at installation and adjusted when there is a change in the volume of slides processed in

your lab. Consider slide volume before the Genius Image Management Server storage approaches full capacity.

After sufficient storage capacity is available on the Image Management Server, the Digital Imager system indicator lights illuminate in green, and slides can be imaged.

SECTION B

SLIDE EVENTS

The Digital Imager errors sort into two groups: Slide Events and Imager System Errors. Refer to "Imager Errors" on page 6.7 for information about Imager System 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 Events Report, refer to "Slide Events" on page 3.46.

When an error carrier is used, Slide Events are also listed in the Error Carrier Report. Refer to "Error Carrier Report" on page 3.57.

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 events report 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 3.45). 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.	Check that the Digital Imager is configured to read the barcode format or OCR format used in your lab. Refer to "Barcode Settings" on page 3.28.
		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.
E0003	**Slide fiducial verification failed**	The slide is missing one or more of the ThinPrep Imaging System microscope slide's fiducial marks.	ThinPrep Imaging System microscope slides are required for ThinPrep Pap tests analyzed by the Genius Cervical AI algorithm. Check that the slide is a ThinPrep Imaging System microscope slide.
E0007	**Slide imaging failed due to focus QC**	Slide label extending beyond 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. Correct the label and attempt to image the slide again.
		The slide or coverslip may be scratched.	Check if the slide or coverslip is scratched. Attempt to image the slide again.
		There may be debris on the slide or on the imaging stage.	Check for debris. Remove any debris from the slide. If there is debris on the imaging stage, clean the imaging station slide holder. Refer to "Clean the Imaging Station Slide Holder" on page 5.8.
		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.

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action
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. Attempt to process the slide again. If the error persists, contact Technical Support.
E0012	**Image analysis failed**	The software attempted image analysis, and the analysis failed.	Attempt to process the slide again. If the error persists, contact Technical Support.
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 4.8.
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 Accession ID Settings are wrong.	The Accession ID Settings on the Digital Imager are too long or too short for the slide. Change the Accession ID Settings. Refer to “Accession ID Settings” on page 3.32.
		The Accession ID Settings 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.

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action
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, E0008, E0017 through 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 System errors: system self-recoverable errors, user-correctable errors and unrecoverable errors. Refer to “Slide Events” on page 6.3 for information about conditions of the slide that make the imaging process not possible.

All Digital Imager errors are logged to a file, which may be accessed via the user interface. Refer to “Imager System Errors” on page 3.49.

System Self-recoverable Errors

These automatically recoverable errors are Digital Imager errors that do not require user or service personnel intervention to recover from the error. 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 user can resume processing slides, continuing from where the Digital Imager 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 6-3.)

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.

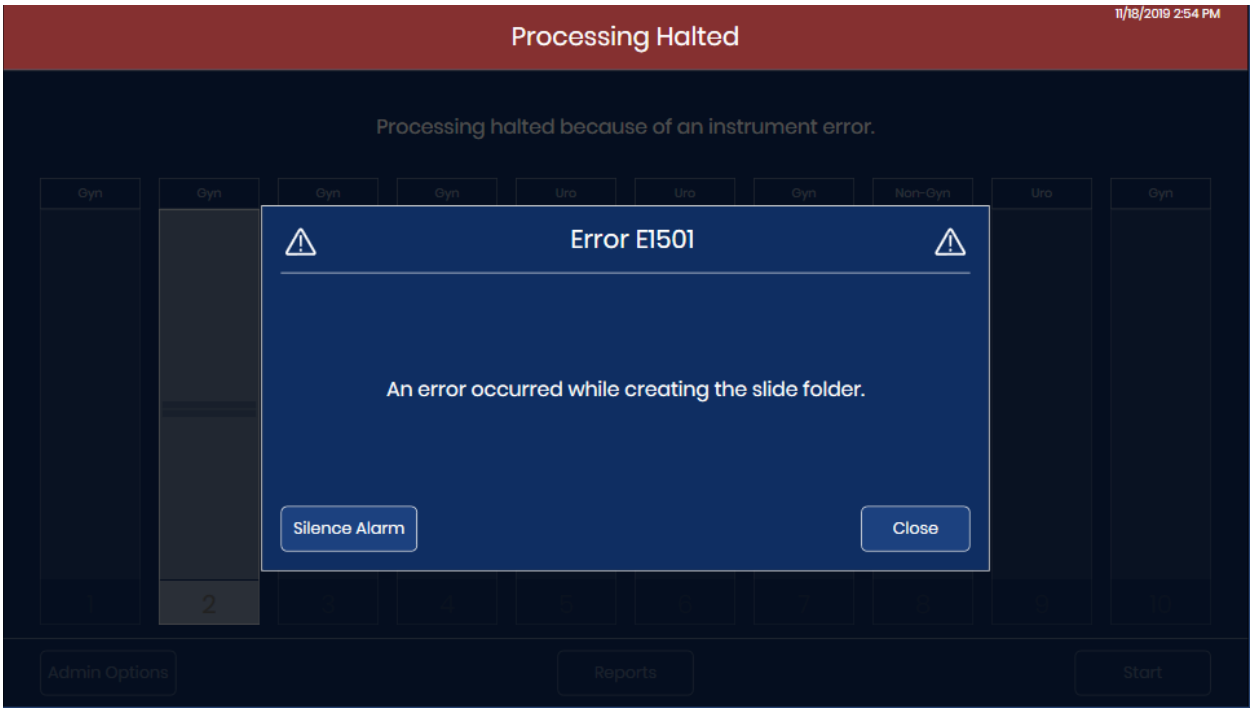


Figure 6-3 User Notification: Recoverable Error, example

6 TROUBLESHOOTING

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.

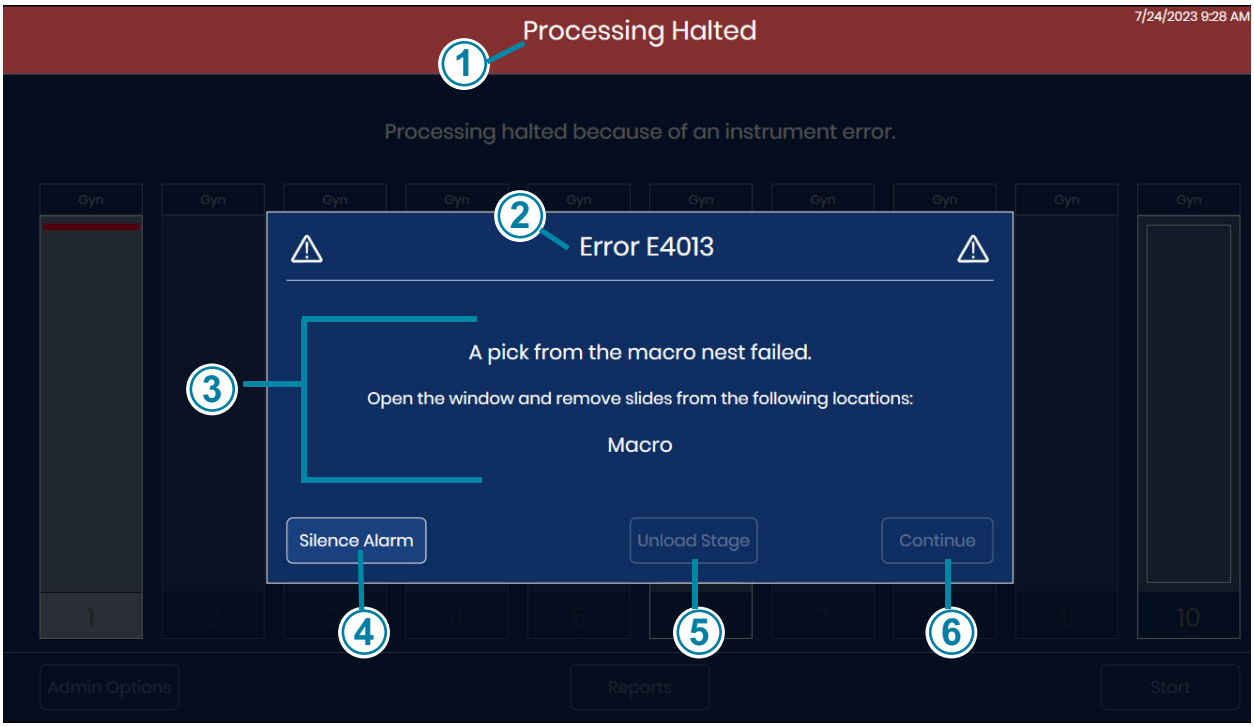


Figure 6-4 User-correctable Error, example

Key to Figure 6-4	
1	The touch screen display says that processing is halted in a red banner at the top.
2	The error code is displayed. See Figure 6-12 and Table 6.2 for additional information on error codes.
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 amber.

Key to Figure 6-4	
⑤	**Unload Stage** To resolve certain errors, the Digital Imager may prompt the operator to remove a slide from the imaging station slide holder. For errors where the **Unload Stage** button is available, touch the **Unload Stage** button. The Digital Imager releases the grip on the slide in the imaging station slide holder. Open the window and remove the slide. Close the window, and touch the **Close** button on the touch screen.
⑥	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 user can resume processing slides, continuing from where the Digital Imager stopped prior to the error.

Unrecoverable Errors

For unrecoverable errors, the Digital Imager must be reset to attempt recovery. For some errors, the operator may be able to follow instructions on the touch screen display to remove a slide and let the instrument run through its POST test. For other errors, the Digital Imager must be restarted. In some cases, the Imager may require a Hologic service visit.

When an unrecoverable error condition is encountered, slide processing is interrupted.

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.

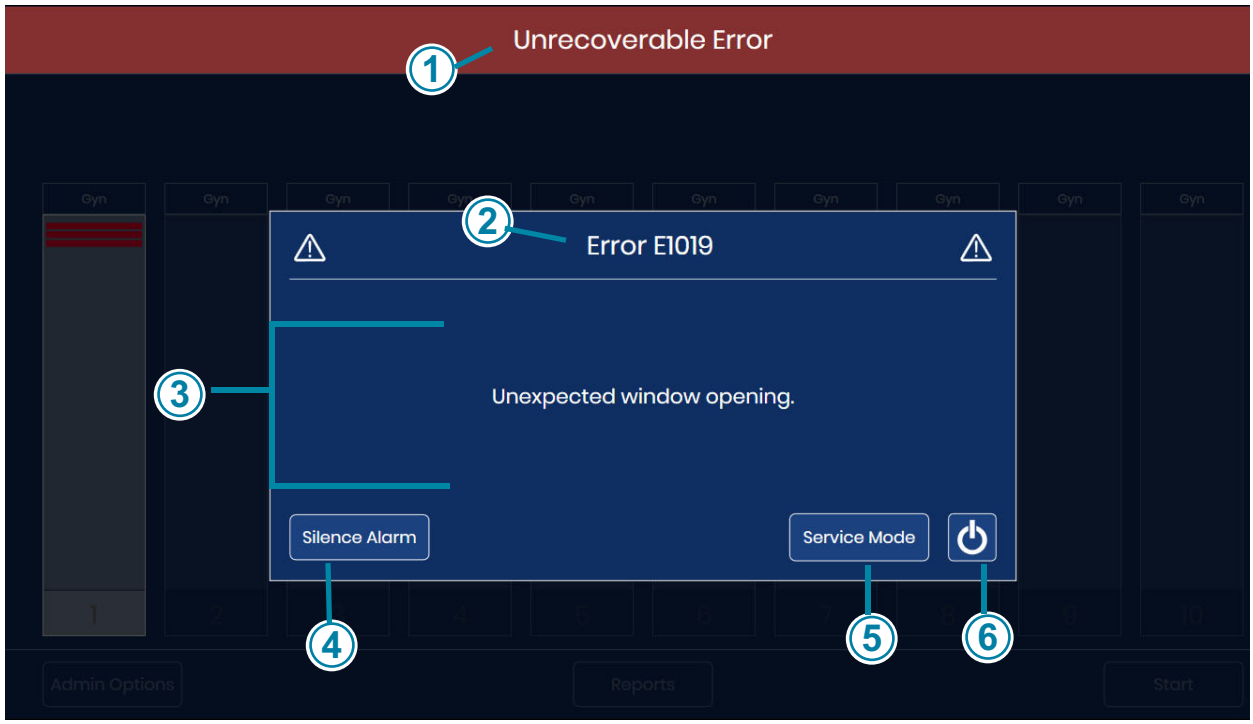


Figure 6-5 Unrecoverable Imager Error, Restart Required, example

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

Key to Figure 6-5	
1	The touch screen display says it has an unrecoverable error in a red banner at the top.
2	The error code is displayed. See Figure 6-12 and Table 6.2 for additional information on error codes.
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 unrecoverable errors, a **Service Mode** button is available on the error notification. The service mode is for service personnel trained by Hologic and is password-protected.

Key to Figure 6-5	
⑥	With unrecoverable 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 until prompted by instructions on the screen display.
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.

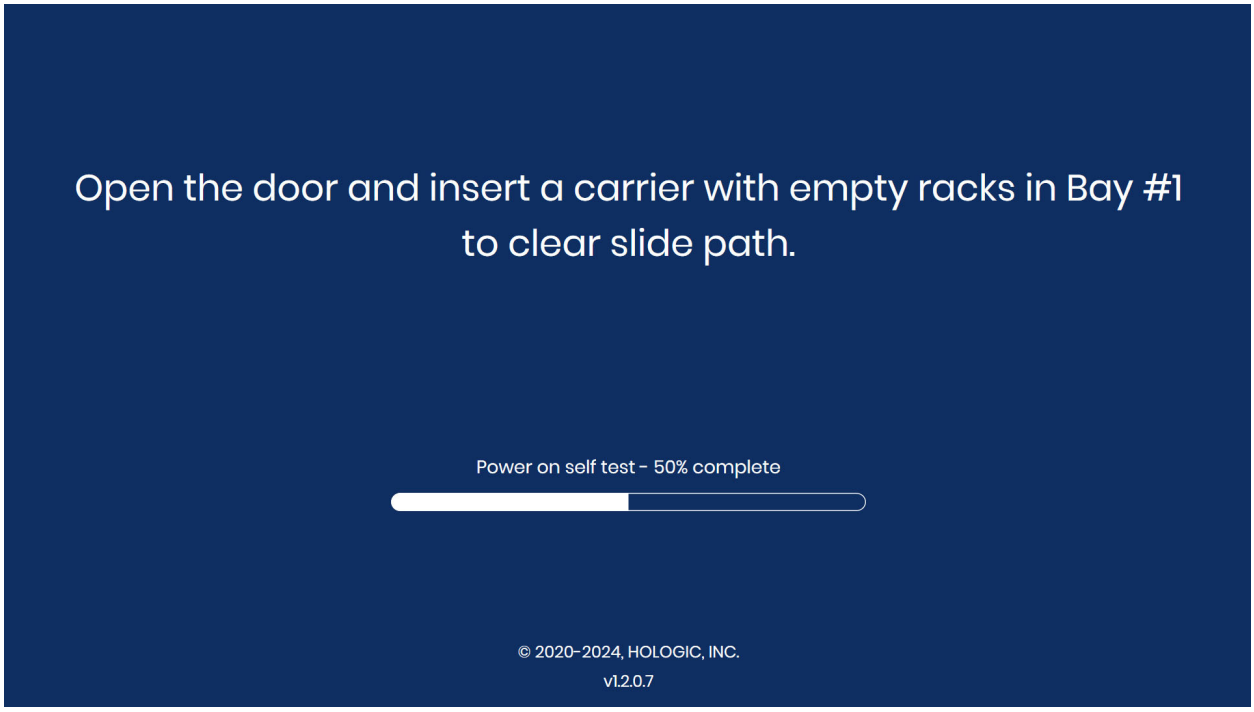


Figure 6-6 User-assisted Error Recovery: Load an Empty Slide Carrier

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.

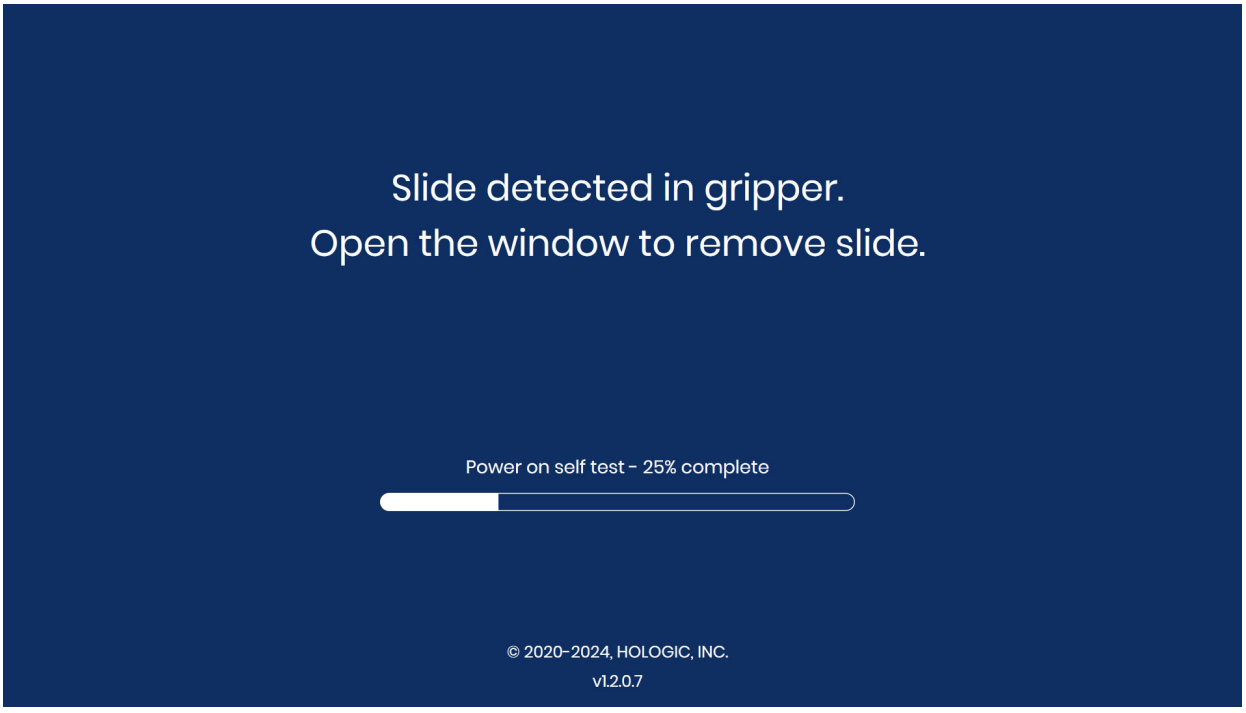


Figure 6-7 User-assisted Error Recovery: Open Window to Remove Slide

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

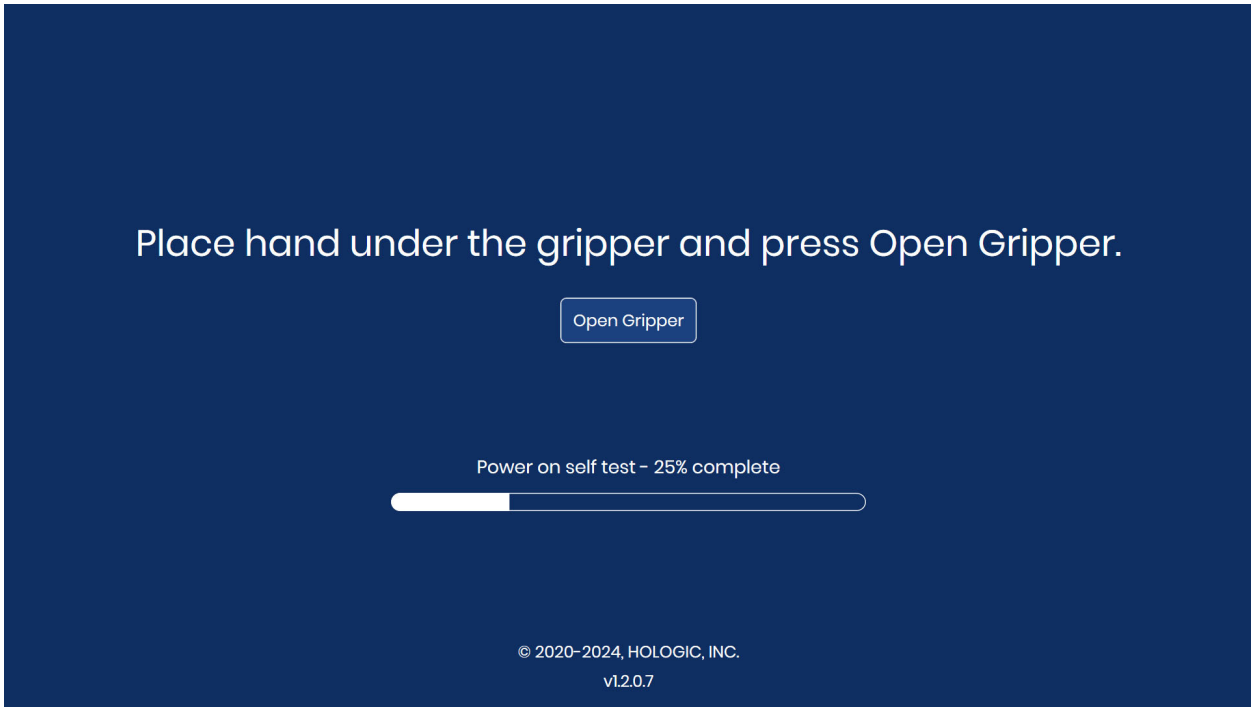
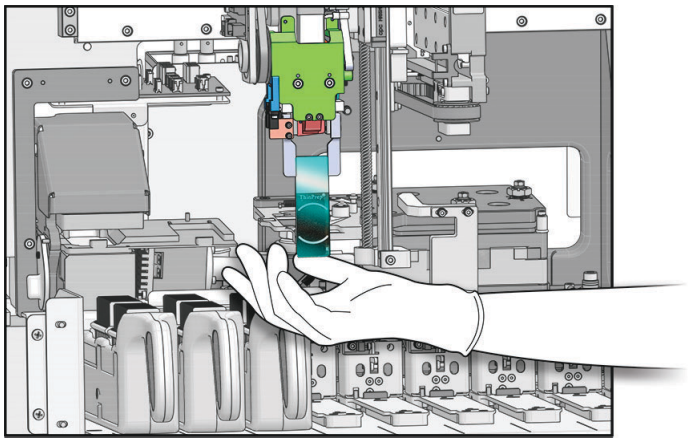


Figure 6-8 Ready to Press Open Gripper

- 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 6-9 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.

  If the Digital Imager detects debris on the macro station, or an obstruction such as a slide from a previous error condition, the touch screen displays instructions to clean the macro station.

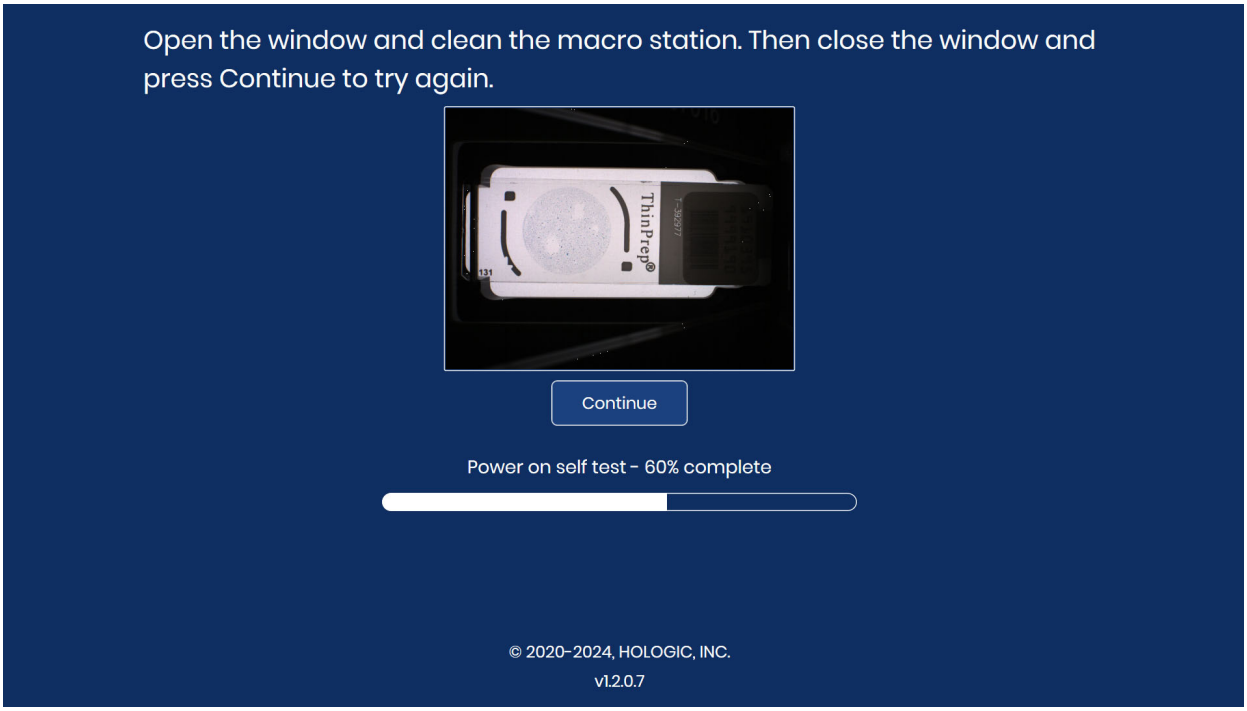


Figure 6-10 Remove Debris from the Macro Station

- Open the window. Clean the macro station. Refer to "Clean the Macro Station" on page 5.5. There is no need to put the Digital Imager in "Clean System" mode because the slide handling arm will already be in a good position for accessing the macro station.
- The image shown in the error message is intended to help show the position on the macro station of the debris or other obstruction.
- When the cleaning is finished, close the window and the door (if open). Touch the **Continue** button to continue the POST test.

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.

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

Only stained, coverslipped ThinPrep® Imaging System microscope slides may be used. The ThinPrep Imaging System microscope slides have fiducial marks. (See Figure 6-11.) Refer to the ThinPrep Stain User's Manual for recommendations for coverslipping media.

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.

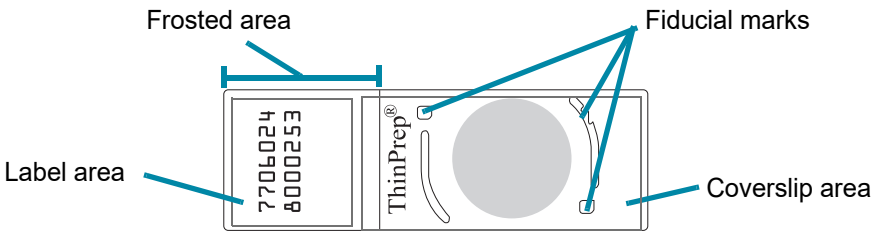


Figure 6-11 ThinPrep Imaging System Microscope Slide

Dry Mounting Media

The mounting media must be dry before loading slides into a slide carrier 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

Depending on the cause of the error, the Digital Imager event codes listed below may display with or without a suffix. For errors that generate the two-part error code, the first four digits represent the event code and the subsequent characters represent the status of the particular electromechanical device at the time the fault occurred.

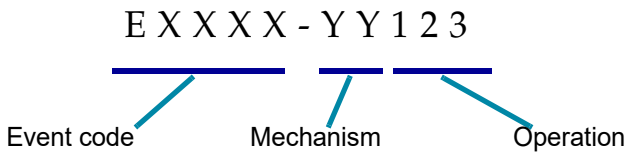


Figure 6-12 Two-part Error Code

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.

Table 6.2 Digital Imager Error Codes

E0517	**Error during light calibration.**	Unable to focus on the v-chip.	Clean the verification chip. Refer to "Clean the Verification Chip" on page 5.7. If the error persists, contact Technical Support.
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.
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.
E1200-E1203, E1206	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E1204, E1205	**Debris found in the macro slide path.**	A slide has been left on the macro station or the macro station is dirty.	Clean the macro station. Refer to "Clean the Macro Station" on page 5.5. If the cleaning does not resolve the issue the first time, the Digital Imager instructs the operator to clean the macro station a second time. If the second cleaning does not resolve the issue, power cycle the system. If the error persists, contact Technical Support.

Table 6.2 Digital Imager Error Codes

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.
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.
E2007 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. When the instrument is powered down, remove any obstruction. If the error persists, contact Technical Support.
E4004	**A move to a carrier location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed.
E4005	**A move to the thumbnail location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed.

Table 6.2 Digital Imager Error Codes

E4006	**A move to the macro location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed.
E4007	**A move to the queue location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed.
E4008	**A move to the imaging stage location failed.**	Mechanical interference with one or more axes	A recovery dialog is displayed.
E4009	**A move to the safe location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed.
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	**The slide handler was not able to pick a slide from the carrier.**	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.
E4013	**The slide handler was not able to pick a slide from the macro stage.**	The slide on the macro was dropped, or incorrectly placed.	A recovery dialog is displayed.
E4014	**The slide handler was not able to pick a slide from the queue station.**	The slide on the queue was dropped or incorrectly placed	A recovery dialog is displayed.
E4015	**The slide handler was not able to pick a slide from the imaging stage.**	The slide on the imaging stage was not in the expected location, or the stage was not in the loading position.	A recovery dialog is displayed.
E4016	**Placing a slide in a carrier failed.**	The value for the place location in the carrier was incorrectly calculated.	A recovery dialog is displayed.
E4017	**Placing a slide in the macro nest failed.**	One or more axis movements failed, or the gripper failed to open.	A recovery dialog is displayed.
E4018	**Placing a slide in the queue failed.**	One or more axis movements failed, or the gripper failed to open.	A recovery dialog is displayed.

Table 6.2 Digital Imager Error Codes

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.	A recovery dialog is displayed.
E4021 through E4513	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4514, E4520, E4521, E4522	**An error occurred during auto-calibration.**	Incorrectly configured V-Chip positions.	Power cycle the system. If the error persists, contact Technical Support.
E4515, E4523	**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 5.7. 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.
E4519	**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 5.7. If the error persists, contact Technical Support.
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, E5005, E5007 through E6001	**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

E5006	**A motor move failed to complete successfully.**	Mechanical error with a motor.	A recovery dialog is displayed.
E6002	**Failed to connect to post scan service.**	Post Scanning Service is disconnected.	Power cycle the system. If the error persists, contact Technical Support.
E6005, E6006	**Imager error**	Error with one of the system components.	Power cycle the system. 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.
E6501	**The Image Management Server storage is full.**	The Image Management Server repository storage disk has insufficient space to upload slide data sets.	The Image Management Server must have sufficient storage capacity available in order for the Digital Imager to transmit data to it. Slide management and archiving criteria are set by a manager at the Genius Review Station. Ensure that slide management and archiving methods are in place and operational.

7. Definitions and Abbreviations

7. Definitions and Abbreviations

Chapter Seven

Definitions and Abbreviations

Case Type

A named configuration that represents a set of options related to the imaging, processing and viewing of cases on the Genius Digital Diagnostics System.

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 “Barcode Settings” on page 3.28.

7 Definitions and Abbreviations

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 4.36 before turning off power to any of the components.

Scan Profile

A set of instructions that the Genius Digital Imager uses to scan and process a slide. Depending on the options available to your lab, a scan profile may include scan pattern, image analysis and/or other techniques and operations.

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 report, 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. In order for the Genius Cervical AI algorithm to analyze a case, the case must be on a ThinPrep Imaging System Slide.

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 “Barcode Settings” on page 3.28 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 “Barcode Settings” on page 3.28 for the available types.

7 DEFINITIONS AND ABBREVIATIONS

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8. Service Information

Chapter Eight

Service Information

Mailing Address

Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA

Remittance Address

Hologic, Inc., P.O. Box 3009, Boston, MA 02241-3009 USA

Business Hours

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

Customer Service

To order products, and place or amend standing orders, call Customer Service at 1-844-465-6442 or 1-508-263-2900 during business hours or fax your order to the attention of Customer Service at 1-508-229-2795.

To order service contracts call Technical Support at 1-844-465-6442 or 1-508-263-2900 during business hours.

Technical Support

Technical service representatives are available to answer questions about your Genius™ Digital Imager at 1-844-465-6442 or 1-508-263-2900 from 7:00 a.m. to 7:00 p.m. Eastern Time Monday through Friday excluding company holidays.

Hologic technical service representatives are also available to address questions and concerns regarding cybersecurity.

Cytology application representatives are available to address application issues related to the Genius™ Digital Diagnostics System at 1-844-465-6442 or 1-508-263-2900 from 8:30 a.m. to 5:30 p.m. Eastern Time Monday through Friday excluding company holidays.

Returns

For returns related to warranty issues, please contact Technical Support at 1-844-465-6442 or 1-508-263-2900 and for questions regarding any other type of return, please contact Customer Service.

8 SERVICE INFORMATION

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9. Ordering Information

Chapter Nine

Ordering Information

Mailing Address

Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA

Remittance Address

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To order service contracts call Technical Support at 1-844-465-6442 or 1-508-263-2900 during business hours.

Terms

Net 30 days.

Shipping

All prices are F.O.B. Marlborough, Massachusetts, USA. All in-stock items are shipped on the next business day after the order is placed via UPS ground delivery. Second day and overnight delivery are available upon request.

Technical Support

Technical service representatives are available to answer questions about your Genius™ Digital Imager at 1-844-465-6442 or 1-508-263-2900 from 7:00 a.m. to 7:00 p.m. Eastern Time Monday through Friday excluding company holidays.

Cytology application representatives are available to address application issues related to the Genius™ Digital Diagnostics System at 1-844-465-6442 or 1-508-263-2900 from 8:30 a.m. to 5:30 p.m. Eastern Time Monday through Friday excluding company holidays.

9 Ordering Information

Returns

For returns, please call Customer Service at 1-844-465-6442 or 1-508-263-2900 to obtain a Return Goods Authorization number. Hologic will not accept any returned items without this number.

For returns related to warranty issues, please contact Technical Support at 1-844-465-6442 or 1-508-263-2900 and for questions regarding any other type of return, please contact Customer Service.

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-12119-001

From other suppliers

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

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Patent Information
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