

HOLOGIC®



ThinPrep® Integrated Imager

Operator's Manual



ThinPrep[®] Integrated Imager Operator's Manual

HOLOGIC[®]



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The ThinPrep® Integrated Imager is a PC-based automated imaging and review system for use with ThinPrep cervical cytology sample slides. The ThinPrep Integrated Imager is intended to help a cytotechnologist or pathologist highlight areas of a slide for further manual review. The Product is not a replacement for manual review. Determination of slide adequacy and patient diagnosis is at the sole discretion of the cytotechnologists and pathologists trained by Hologic to evaluate ThinPrep-prepared slides. If and only if it is finally determined by a court of competent jurisdiction that the Product sold to Customer hereunder was defective in design or contained a manufacturing defect and that such defect was solely responsible for an error in diagnosis that caused harm to a patient, Hologic shall indemnify Customer for the compensatory damages paid by Customer to discharge the personal injury judgment with respect to Product.

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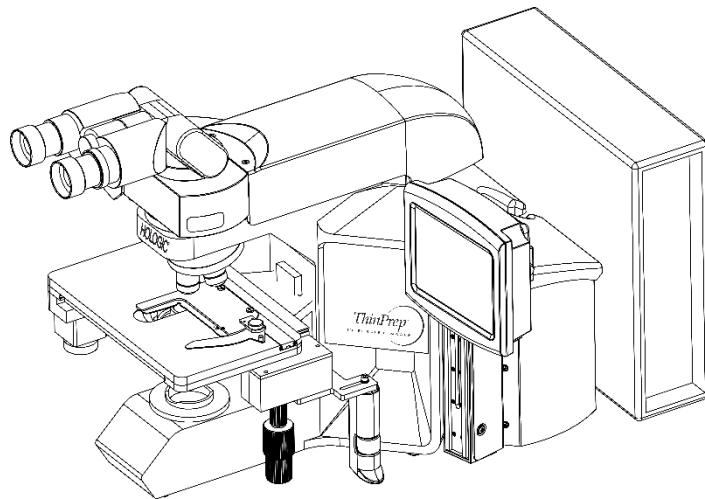


Instructions For Use

Instructions For Use



Operation Summary and Clinical Information



The ThinPrep[®] Integrated Imager



A. INTENDED USE

The Hologic ThinPrep® Integrated Imager is a device that uses computer imaging technology to assist in primary 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 cytologic criteria as defined by the Bethesda System: Terminology for Reporting Results of Cervical Cytology¹.

B. SUMMARY AND EXPLANATION OF THE SYSTEM

The ThinPrep Integrated Imager is an automated imaging and review system for use with ThinPrep Pap Test slides. It combines imaging technology to identify microscopic fields of diagnostic interest with automated stage movement of a microscope in order to locate these fields. In routine use, the ThinPrep Integrated Imager selects 22 fields of view for a cytotechnologist (CT) to review. Following review of these fields, the cytotechnologist will either complete the diagnosis if no abnormalities are identified or review the entire slide if any abnormalities are identified. The ThinPrep Integrated Imager also allows the physical marking of locations of interest for the cytopathologist.

C. PRINCIPLES OF OPERATION

The ThinPrep Integrated Imager is a combined system which uses computerized image analysis and automated microscope location to assist a cytotechnologist or pathologist to identify areas of a slide that are of most interest. Slides used with this system must first be prepared on the ThinPrep® 2000 System or ThinPrep® 5000 processors, and stained with ThinPrep® Stain. The ThinPrep Integrated Imager can be used as a conventional microscope when not used for ThinPrep® imaging.

The ThinPrep Integrated Imager images the entire cell spot of the slide in approximately 90 seconds. The system acquires and processes image data from the slides to identify diagnostically relevant cells or cell groups based on an imaging algorithm that considers cellular features and nuclear darkness. During slide imaging, the alphanumeric slide accession identifier is recorded and the *x* and *y* coordinates of 22 fields of interest are stored in the system.

After image processing, the device acts as an automated microscope, presenting the 22 fields containing the cells of interest to the cytotechnologist for review. The cytotechnologist uses the review control or touch screen to step through each of the fields of interest (Autolocate). Additionally, the review scope provides a method for automated marking of objects for further review. If the cytotechnologist identifies any of these fields as containing abnormal objects, that field may be marked electronically. The Integrated Imager will guide the cytotechnologist to conduct a review of the entire cell spot for any slide that has had fields electronically marked (Autoscan).

The cytotechnologist determines specimen adequacy and the presence of infections during the review of the 22 fields of view presented by the ThinPrep Integrated Imager. Either of two methods can be used to determine specimen adequacy. The first method is to count cells and determine the average number of cells in the 22 fields of view presented by the Imager. The second method is to count and determine the average number of cells in 10 fields of view across the diameter of the cell spot. Either method will enable the cytotechnologist to determine if the minimum cells, as recommended by Bethesda System criteria, are present on the slide. At the conclusion of the slide review, electronically marked objects are manually marked on the slide by the cytotechnologist. Slide information is stored in the computer database including the *x* and *y* coordinates representing the electronically marked locations, and the status of the slide is designated as “complete”.

The cytotechnologist can review the slides immediately after each slide is imaged (sequential modality) or, as an alternative workflow for labs, slides can be imaged in succession, and coordinates stored in the computer database for later cytotechnologist or pathologist review (batched modality).

D. LIMITATIONS

- Only personnel who have been appropriately trained should operate the ThinPrep Integrated Imager.
- All slides that undergo primary automated screening with the Integrated Imager require manual rescreening of the selected fields of view by a cytotechnologist or pathologist.
- The ThinPrep Integrated Imager is only indicated for use with the ThinPrep Pap Test.
- The ThinPrep Integrated Imager is only indicated for the ThinPrep Pap Test slides prepared with the ThinPrep[®] 2000 System and the ThinPrep[®] 5000 processor. The Integrated Imager has not been evaluated for use with ThinPrep Pap test slides prepared using the ThinPrep Genesis processor.
- ThinPrep[®] slides with fiducial marks must be used.
- Slides must be stained using the ThinPrep Stain according to the applicable ThinPrep Integrated Imager slide staining protocol.
- Slides should be clean and free of debris before being placed on the system.
- The slide coverslip should be dry and located correctly.
- Slides that are broken or poorly coverslipped should not be used.
- Slides used with the ThinPrep Integrated Imager must contain properly formatted accession number identification information as described in the operator's manual.
- Slides once successfully imaged on the Integrated Imager cannot be imaged again.
- The performance of the ThinPrep Integrated Imager using slides prepared from reprocessed sample vials has not been evaluated; therefore it is recommended that these slides be manually reviewed.

E. WARNINGS

- The Integrated Imager generates, uses, and can radiate radio frequency energy and may cause interference to radio communications.
- A Hologic authorized service representative must install the ThinPrep Integrated Imager.

F. PRECAUTIONS

- Caution should be used when loading and unloading glass slides on the ThinPrep Integrated Imager to prevent slide breakage and/or injury.
- The Integrated Imager should be placed on a flat, sturdy surface away from any vibrating machinery to assure proper operation.

G. PERFORMANCE CHARACTERISTICS

The ThinPrep Integrated Imager is technologically similar to the ThinPrep Imaging System. The performance characteristics of the ThinPrep Integrated Imager were compared to the ThinPrep Imaging System in a multi-center clinical study. The ThinPrep[®] Imaging System was compared to Manual

Review in a separate multi-center clinical study. Both clinical studies are described in the following sections.

G.1 ThinPrep Imaging System Compared to Manual Review

A multi-center, two-armed clinical study was performed over an eleven (11) month period at four (4) cytology laboratory sites within the United States². The objective of the study entitled “Multi-Center Trial Evaluating the Primary Screening Capability of the ThinPrep[®] Imaging System” was to show that routine screening of ThinPrep Pap Test slides using the ThinPrep Imaging System is equivalent to a manual review of ThinPrep slides for all categories used for cytologic diagnosis (specimen adequacy and descriptive diagnosis) as defined by the Bethesda System criteria¹.

The two-arm study approach allowed for a comparison of the cytologic interpretation (descriptive diagnosis and specimen adequacy) from a single ThinPrep-prepared slide, screened first using standard laboratory cervical cytology practices (*Manual Review*) and then after a 48-day time lag were screened with the assistance of the ThinPrep Imaging System (*Imager Review*). A subset of slides from the study were reviewed and adjudicated by a panel of three (3) independent cytopathologists to determine a consensus diagnosis. The consensus diagnosis was used as a “gold standard” for truth to evaluate the results of the study.

G.1.1 Laboratory and Patient Characteristics

Of the 10,359 subjects in the study, 9,550 met the requirements for inclusion in the descriptive diagnosis analysis. During the study, 7.1% (732/10,359) slides could not be read on the Imager and required a manual review during the *Imager Review* arm. Excessive number of air bubbles on the slides was the leading contributor. Additional factors included focus problems, slide density, slide identification read failures, slides detected out of position, multiple slides seated within a cassette slot and slides that had already been imaged. The cytology laboratories participating in the study were comprised of four centers. All sites selected had extensive experience in the processing and evaluation of gynecologic ThinPrep slides, and were trained in the use of the ThinPrep Imaging System. The study population represented diverse geographic regions and subject populations of women who would undergo cervical screening with the ThinPrep Imaging System in normal clinical use. These sites included both women being routinely screened (screening population) and patients with a recent previous cervical abnormality (referral population). The characteristics of the study sites are summarized in Table 1.

Table 1. Site Characteristics

Site	1	2	3	4
Screening (Low Risk) Population	88%	82%	90%	94%
Referral (High Risk) Population	12%	18%	10%	6%
HSIL+ prevalence	1.1%	0.7%	0.4%	0.6%
ThinPrep Pap Tests Per Year	120,000	70,200	280,000	105,000
Number of Cytotechnologists	14	9	32	11
Number of Cytotechnologists in Study	2	2	2	2
Number of Cytopathologists	6	5	6	14
Number of Cytopathologists in Study	1	2	1	2

G.1.2 Descriptive Diagnosis Sensitivity and Specificity Estimates

A panel of three independent cytopathologists adjudicated slides from all discordant (one-grade or higher cytologic difference) descriptive diagnosis cases (639), all concordant positive cases (355) and a random 5% subset of the 8550 negative concordant cases (428). The cytopathologists on the adjudication panel were board-certified, all of whom had a subspecialty certification in cytopathology. Their experience levels in cytopathology ranged from 6 to 12 years. Two of the adjudicators were from university practices and one adjudicator was from a private medical center. The volumes for the adjudicators' institutions ranged from 12,000 to 30,000 ThinPrep Pap Tests annually.

A consensus diagnosis was defined as agreement by at least 2 of 3 cytopathologists. All slides sent to the panel of cytopathologists were not identified by site nor ordered in any fashion. When a consensus diagnosis could not be obtained by at least 2 of 3 cytopathologists, the full panel of cytopathologists reviewed each case simultaneously using a multi-headed microscope to determine a consensus diagnosis.

The adjudicated results were used as a “gold standard” to define the following major “true” descriptive diagnosis classifications of the Bethesda System: Negative, ASCUS, AGUS, LSIL, HSIL, Squamous Cell Carcinoma (SQ CA) and Glandular Cell Carcinoma (GL CA). Estimates of sensitivity and specificity together with 95% confidence intervals were calculated for the *Manual Review* and *Imager Review* arms of the study. The differences in sensitivity and specificity between the two arms, together with their 95% confidence intervals were also calculated. Among the random 5% subset of 8,550 cases (428 slides) that were found to be negative by both arms and adjudicated, there were 425 “true” negative and 3 “true” ASCUS slides. A multiple imputation technique was used to adjust the numbers of true positives and true negatives for the 8,550 negative concordant cases based on the 5% of cases that were adjudicated².

Table 2 summarizes the descriptive diagnosis sensitivity and specificity estimates with 95% confidence intervals for all sites combined for “true” ASCUS+, LSIL+ and HSIL+.

Table 2. Manual Review Versus Imager Review, Descriptive Diagnosis Summary

Threshold	Sensitivity			Specificity		
	Manual (95% CI)	Imager (95% CI)	Difference (95% CI)	Manual (95% CI)	Imager (95% CI)	Difference (95% CI)
ASCUS+	75.6% (72.2% to 78.8%)	82.0% (78.8% to 84.8%)	+6.4% (2.6% to 10.0%)	97.6% (97.2% to 97.9%)	97.8% (97.4% to 98.1%)	+0.2% (-0.2% to 0.6%)
LSIL+	79.7% (75.3% to 83.7%)	79.2% (74.7% to 83.2%)	-0.5% (-5.0% to 4.0%)	99.0% (98.8% to 99.2%)	99.1% (98.9% to 99.3%)	+0.09% (-0.1% to 0.3%)
HSIL+	74.1% (66.0% to 81.2%)	79.9% (72.2% to 86.2%)	+5.8% (-1.1% to 12.6%)	99.4% (99.2% to 99.6%)	99.6% (99.5% to 99.7%)	+0.2% (0.06% to 0.4%)
UNSAT	29.3% (18.1% to 42.7%)	13.8% (6.1% to 25.4%)	-15.5% (-25.9% to 5.0%)	99.5% (99.3% to 99.6%)	99.8% (99.7% to 99.9%)	+0.3% (0.2% to 0.4%)

The results presented in Table 2 show that for ASCUS+, the increase in sensitivity of the *Imager Review* over the *Manual Review* was statistically significant with the lower limit of the 95% confidence interval being 2.6% for all sites combined. The observed difference between sensitivities for ASCUS+ varied among the sites from -2.8% with a 95% confidence interval of (-10.6%; 5.0%) to +14.4% with a 95% confidence interval of (8.2%; 20.5%). The difference in specificity results between the *Imager Review* and the *Manual Review* was not statistically significant with a 95% confidence interval of -0.2% to +0.6%. The observed differences between specificities varied among the sites from -0.3% to +0.4%.

The results presented in Table 2 show that the difference between sensitivities of the *Imager Review* and *Manual Review* arms for LSIL+ for all sites combined was not statistically significant with a 95% confidence interval of -5.0% to +4.0%. The observed difference between sensitivities for LSIL+ varied among the sites from -6.3% with a 95% confidence interval of (-14.7%; 2.1%) to +8.1% with a 95% confidence interval of (-4.0%; 20.1%). The difference in specificity results between the *Imager Review* and the *Manual Review* was not statistically significant with a 95% confidence interval of -0.1% to +0.3%. The observed differences between specificities varied among the sites from -0.4% to +0.6%.

The results presented in Table 2 show that the difference between sensitivities of the *Imager Review* and *Manual Review* arms for HSIL+ for all sites combined was not statistically significant with a 95% confidence interval of -1.1% to +12.6%. The observed difference between sensitivities for HSIL+ varied among the sites from -2.5% with a 95% confidence interval of (-15.4%; 10.4%) to +13.6% with a 95% confidence interval of (-0.7%; 28.0%). The increase in specificity of the *Imager Review* over the *Manual Review* was statistically significant with a 95% confidence interval of +0.06% to +0.4%. The observed differences between specificities varied among the sites from -0.1% to +0.7%.

Table 3 shows the unadjudicated marginal frequencies data for benign cellular changes for all sites combined.

Table 3. Unadjudicated Marginal Frequencies – Summary of Descriptive Diagnosis for Benign Cellular Changes – All Sites Combined

	Manual Review		Imager Review	
Number of Patients:	9550		9550	
Descriptive Diagnosis	N	%	N	%
Benign Cellular Changes:	405	4.2	293	3.1
Infection:				
Trichomonas Vaginalis	8	0.1	8	0.1
Fungal organisms consistent with Candida spp.	47	0.5	31	0.3
Predominance of coccobacilli	71	0.7	60	0.6
Bacteria consistent with Actinomyces spp.	1	0.0	1	0.0
Cellular Changes associated with Herpes virus	1	0.0	1	0.0
Other Infection	1	0.0	0	0.0
Reactive Cellular Changes Associated with:				
Inflammation	218	2.3	156	1.6
Atrophic with inflammation (atrophic vaginitis)	68	0.7	46	0.5
Radiation	0	0.0	0	0.0
Intrauterine contraceptive device (IUD)	0	0.0	0	0.0
Other Reactive Cellular Change	34	0.4	14	0.1

Note: Some patients had more than one diagnostic subcategory.

The *Manual Review* showed a higher rate of Benign Cellular Changes (405) than the *Imager Review* cases (293).

Please refer to the ThinPrep® Imaging System Operation Summary and Clinical Information (MAN-03938-001) for detailed information about the performance of ThinPrep Imaging System.

G.2 ThinPrep Integrated Imager Compared to the ThinPrep Imaging System

A multi-center, two-armed clinical study was performed at three (3) sites within the United States. The objective of the study entitled “Multi-Center Evaluation of the ThinPrep® Integrated Imager” was to show that routine screening of ThinPrep Pap Test slides prepared on the ThinPrep® 2000 System and the ThinPrep® 5000 processor using the ThinPrep Integrated Imager is similar to the review of ThinPrep slides using the ThinPrep Imaging System for all categories used for cytologic diagnosis (specimen adequacy and descriptive diagnosis) as defined by the Bethesda System criteria¹.

The two-arm study approach allowed for a comparison of the cytologic interpretation (descriptive diagnosis and specimen adequacy) from a single ThinPrep-prepared slide (of known diagnosis), screened first using the Integrated Imager and then after two-week lag were screened with the assistance of the ThinPrep Imaging System. The adjudicated diagnosis at enrollment was used as a “gold standard” for truth to evaluate the results of the study.

Slides utilized in this study were processed on the ThinPrep® 2000 System and the ThinPrep® 5000 processor. Study slides were produced, reviewed manually and adjudicated during the execution of a previous study².

All slides were reviewed independently for both study arms. The slides were randomized prior to slide review in each study arm. Cytological diagnoses and specimen adequacy were determined in accordance with the Bethesda System criteria for both arms of the study.

G.2.1 Laboratory and Patient Characteristics

The cytology laboratories participating in the study were comprised of three (3) centers. All sites selected had extensive experience in the processing and evaluation of gynecologic ThinPrep slides, and were trained in the use of the ThinPrep Integrated Imager.

Number of patients (planned and analyzed)

2520 slides (840 each site) were enrolled in this study. Six (6) out of 2520 (0.2%) slides were excluded from review and analysis as they were broken and unreadable.

Basic demographic information was collected for each slide enrolled at each site to aid the cytotechnologist in making a diagnosis for the resulting slides. A summary of this demographic information is presented in Table 4 for all sites.

Table 4. Site Demographics

Site Number	Age (yrs) Median	# Hysterectomy (% of enrolled)	# Postmenopausal (% of enrolled)
1	36 yrs	11 (2.6%)	30 (7.1%)
2	33 yrs	15 (3.6%)	25 (6.0%)
3	37 yrs	25 (6.0%)	51 (12.1%)
Overall	35 yrs	51 (4.0%)	106 (8.4%)

Each slide was reviewed independently three (3) times at each site, by three (3) separate pairs of cytotechnologists and pathologists using normal laboratory and clinical procedures. This produced a total of 7542 diagnostic results. None of these results were excluded from analysis.

Main Eligibility Criteria

Inclusion Criteria

Study slides (two slides per case, one slide was prepared on the ThinPrep 2000 System and another slide was prepared on the ThinPrep 5000 processor) were produced, reviewed manually and adjudicated during the execution of a previous study². The ThinPrep Pap Test slides from three sites included the following:

- NILM: 1260 slides from 630 cases
- ASC-US: 300 slides from 150 cases
- LSIL: 300 slides from 150 cases
- ASC-H: 300 slides from 150 cases
- AGUS: 30 slides from 15 cases
- HSIL: 300 slides from 150 cases
- Cancers: 30 slides from 15 cases

Exclusion Criteria

Slide broken or rendered unreadable for the purposes of this study.

Criteria for Evaluation

The primary objective of this study was to estimate the sensitivity, specificity, and likelihood ratios when diagnosing slides imaged and reviewed on the Integrated Imager (sequential

modality) and to compare with the ThinPrep Imaging System (TIS). The reference standard for the slides in this study was pathologist adjudication consensus diagnosis from a previous study².

G.2.2 Descriptive Diagnosis Sensitivity and Specificity Estimates

Abbreviations for Diagnostic Thresholds:

Category Partitions

Threshold	Negative	Positive
ASCUS+	NILM	ASCUS, LSIL, ASC-H, AGUS, HSIL, Cancer
LSIL+	NILM, ASCUS	LSIL, ASC-H, AGUS, HSIL, Cancer
ASC-H+	NILM, ASCUS, LSIL	ASC-H, AGUS, HSIL, Cancer
HSIL+	NILM, ASCUS, LSIL, ASC-H, AGUS	HSIL, Cancer

The study results are presented in Table 5. In all abnormal categories, the sensitivity for the Integrated Imager was higher than the ThinPrep Imaging System across all thresholds listed in Table 5. There was a slight decrease in specificity for the Integrated Imager as compared to the ThinPrep Imaging System.

Table 5. ThinPrep Imaging System (TIS) Versus Integrated Imager, Descriptive Diagnosis Summary (All Slides)

Threshold	Sensitivity			Specificity		
	TIS (95% CI)	Integrated Imager (95% CI)	Difference (95% CI)	TIS (95% CI)	Integrated Imager (95% CI)	Difference (95% CI)
ASCUS+	86.0% (84.7% to 87.3%)	89.8% (88.6% to 90.9%)	3.8% (2.6% to 5.0%)	89.8% (88.9% to 90.6%)	87.9% (86.9% to 88.8%)	-1.9% (-2.8% to -1.0%)
LSIL+	77.8% (76.0% to 79.6%)	83.7% (82.0% to 85.2%)	5.8% (4.1% to 7.5%)	92.5% (91.7% to 93.2%)	90.6% (89.8% to 91.4%)	-1.9% (-2.6% to -1.2%)
ASC-H+	73.3% (70.4% to 75.9%)	80.7% (78.1% to 83.0%)	7.4% (4.7% to 10.1%)	92.7% (92.0% to 93.3%)	91.1% (90.4% to 91.8%)	-1.6% (-2.1% to -1.0%)
HSIL+	59.6% (55.9% to 63.3%)	67.5% (63.9% to 70.9%)	7.9% (4.5% to 11.2%)	95.1% (94.6% to 95.6%)	94.0% (93.4% to 94.6%)	-1.1% (-1.6% to -0.6%)
UNSAT	78.9% (71.6% to 84.7%)	77.6% (70.2% to 83.5%)	-1.4% (-7.3% to 4.5%)	98.4% (98.1% to 98.6%)	98.4% (98.1% to 98.7%)	0.1% (-0.2% to 0.3%)

In addition, the data is presented below stratified by the type of processor used (ThinPrep 2000 System and ThinPrep 5000 processor). In all abnormal cases, the sensitivity for the Integrated Imager was higher than the ThinPrep Imaging System across all thresholds. There was a slight decrease in specificity for the Integrated Imager as compared to the ThinPrep Imaging System.

**Table 6. ThinPrep Imaging System (TIS) Versus Integrated Imager (I2),
Descriptive Diagnosis Summary (ThinPrep 2000 System-processed Slides Only)**

Threshold	Sensitivity			Specificity		
	TIS [# of reads] (95% CI)	I2 [# of reads] (95% CI)	Difference [# of reads] (95% CI)	TIS [# of reads] (95% CI)	I2 [# of reads] (95% CI)	Difference [# of reads] (95% CI)
ASCUS+	85.7% [1209/1411] (83.8% to 87.4%)	90.0% [1270/1411] (88.3% to 1.5%)	4.3% [61/1411] (2.6% to 6.1%)	90.3% [2006/2222] (89.0% to 91.4%)	88.9% [1975/2222] (87.5% to 90.1%)	-1.4% [-31/2222] (-2.7% to -0.1%)
LSIL+	77.6% [820/1057] (75.0% to 80.0%)	84.3% [891/1057] (82.0% to 86.4%)	6.7% [71/1057] (4.3% to 9.1%)	92.7% [2388/2576] (91.6% to 93.6%)	91.3% [2353/2576] (90.2% to 92.4%)	-1.4% [-35/2576] (-2.3% to -0.4%)
ASC-H+	73.1% [370/506] (69.1% to 76.8%)	81.8% [414/506] (78.2% to 84.9%)	8.7% [44/506] (4.9% to 12.5%)	92.8% [2903/3127] (91.9% to 93.7%)	91.1% [2849/3127] (90.1% to 92.1%)	-1.7% [-54/3127] (-2.5% to -1.0%)
HSIL+	59.0% [214/363] (53.8% to 63.9%)	70.2% [255/363] (65.4% to 74.7%)	11.3% [41/363] (6.4% to 16.1%)	95.4% [3118/3270] (94.6% to 96.0%)	94.2% [3081/3270] (93.4% to 95.0%)	-1.1% [-37/3270] (-1.8% to -0.5%)
UNSAT	83.3% [65/78] (73.5% to 90.0%)	82.1% [64/78] (72.1% to 89.0%)	-1.3% [1/78] (-8.9% to 6.2%)	98.6% [3647/3699] (98.2% to 98.9%)	98.6% [3649/3699] (98.2% to 99.0%)	0.1% [2/3699] (-0.3% to 0.4%)

**Table 7. ThinPrep Imaging System (TIS) Versus Integrated Imager (I2),
Descriptive Diagnosis Summary (ThinPrep 5000 Processor-processed Slides Only)**

Threshold	Sensitivity			Specificity		
	TIS [# of reads] (95% CI)	I2 [# of reads] (95% CI)	Difference [# of reads] (95% CI)	TIS [# of reads] (95% CI)	I2 [# of reads] (95% CI)	Difference [# of reads] (95% CI)
ASCUS+	86.4% [1190/1377] (84.5% to 88.1%)	89.6% [1234/1377] (87.9% to 91.1%)	3.2% [44/1377] (1.6% to 4.8%)	89.3% [1989/2228] (87.9% to 90.5%)	86.8% [1935/2228] (85.4% to 88.2%)	-2.4% [-54/2228] (-3.8% to -1.1%)
LSIL+	78.1% [796/1019] (75.5% to 80.5%)	83.0% [846/1019] (80.6% to 85.2%)	4.9% [50/1019] (2.5% to 7.3%)	92.2% [2385/2586] (91.1% to 93.2%)	89.9% [2324/2586] (88.6% to 91.0%)	-2.4% [-61/2586] (-3.4% to -1.4%)
ASC-H+	73.4% [354/482] (69.3% to 77.2%)	79.5% [383/482] (75.6% to 82.8%)	6.0% [29/482] (2.2% to 9.8%)	92.5% [2888/3123] (91.5% to 93.3%)	91.1% [2845/3123] (90.0% to 92.0%)	-1.4% [-43/3123] (-2.2% to -0.6%)
HSIL+	60.4% [194/321] (55.0% to 65.6%)	64.5% [207/321] (59.1% to 69.5%)	4.0% [13/321] (-0.6% to 8.6%)	94.9% [3116/3284] (94.1% to 95.6%)	93.8% [3082/3284] (93.0% to 94.6%)	-1.0% [-34/3284] (-1.7% to -0.3%)
UNSAT	73.9% [51/69] (62.5% to 82.8%)	72.5% [50/69] (61.0% to 81.6%)	-1.4% [1/69] (-11.3% to 8.4%)	98.2% [3628/3696] (97.7% to 98.5%)	98.2% [3630/3696] (97.7% to 98.6%)	0.1% [2/3696] (-0.3% to 0.4%)

Tables 8 through 14 show the performance of TIS review and Integrated Imager review compared to adjudicated diagnosis made by the adjudication panel (truth, from previous study) for the following major descriptive diagnosis classifications of the Bethesda System: NILM, ASCUS, LSIL, ASC-H, AGUS, HSIL and Cancer.

**Table 8. “True Negative” (NILM) Contingency Table (for All Sites Combined)
Overall Adjudicated NILM
TIS vs. I2**

		TIS							
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	Cancer
I2	UNSAT	75	29	2	0	1	1	0	0
	NILM	25	3735	147	5	13	7	3	0
	ASCUS	5	187	123	11	16	1	1	0
	LSIL	0	21	22	14	2	0	2	0
	ASC-H	1	29	20	1	23	1	4	0
	AGUS	1	15	3	0	0	5	0	0
	HSIL	0	8	4	0	10	0	10	0
	Cancer	0	0	2	0	0	1	0	4

**Table 9. “True ASCUS” Contingency Table (for All Sites Combined)
Overall Adjudicated ASCUS
TIS vs. I2**

		TIS							
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	Cancer
I2	UNSAT	2	0	1	0	2	0	0	0
	NILM	1	143	36	7	4	5	2	1
	ASCUS	0	76	113	23	15	0	3	0
	LSIL	1	11	33	45	5	0	2	0
	ASC-H	0	16	18	5	37	1	19	0
	AGUS	1	0	0	0	1	2	0	0
	HSIL	0	5	6	5	19	0	53	0
	Cancer	0	0	0	1	0	0	0	0

**Table 10. “True LSIL” Contingency Table (for All Sites Combined)
Overall Adjudicated LSIL
TIS vs. I2**

		TIS							
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	Cancer
I2	UNSAT	1	0	0	0	0	0	0	0
	NILM	0	13	11	8	0	0	1	0
	ASCUS	0	18	107	49	4	0	1	0
	LSIL	0	19	86	516	10	0	17	0
	ASC-H	0	3	12	13	16	1	16	9
	AGUS	0	0	0	0	0	0	0	0
	HSIL	0	1	3	40	11	2	107	0
	Cancer	0	0	0	2	0	0	0	1

**Table 11. “True ASC-H” Contingency Table (for All Sites Combined)
Overall Adjudicated ASC-H
TIS vs. I2**

		TIS							
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	Cancer
I2	UNSAT	0	0	0	0	1	0	0	0
	NILM	0	5	4	0	2	1	1	0
	ASCUS	0	9	16	1	13	0	4	0
	LSIL	0	1	3	2	7	0	1	0
	ASC-H	0	4	14	1	31	1	9	0
	AGUS	0	1	1	0	0	0	0	0
	HSIL	0	4	4	2	17	0	31	1
	Cancer	0	0	1	0	0	0	0	2

**Table 12. “True AGUS” Contingency Table (for All Sites Combined)
Overall Adjudicated AGUS
TIS vs. I2**

		TIS							
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	Cancer
I2	UNSAT	1	0	0	0	0	0	0	0
	NILM	1	30	2	0	1	3	0	0
	ASCUS	0	2	0	0	1	0	1	0
	LSIL	0	0	0	0	0	0	0	0
	ASC-H	0	1	0	0	4	1	2	0
	AGUS	2	10	3	0	1	12	1	1
	HSIL	1	2	2	0	4	3	9	0
	Cancer	2	2	1	0	0	1	1	9

**Table 13. “True HSIL” Contingency Table (for All Sites Combined)
Overall Adjudicated HSIL
TIS vs. I2**

		TIS							
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	Cancer
I2	UNSAT	0	0	0	0	0	0	0	0
	NILM	0	4	0	0	0	0	0	0
	ASCUS	0	3	12	1	7	0	2	1
	LSIL	0	2	7	28	7	0	5	0
	ASC-H	0	0	16	13	58	1	23	2
	AGUS	0	1	3	0	1	1	3	0
	HSIL	0	3	12	26	44	6	243	5
	Cancer	0	0	0	1	0	1	16	12

**Table 14. “True Cancer” Contingency Table (for All Sites Combined)
Overall Adjudicated Cancer
TIS vs. I2**

		TIS							
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL	Cancer
I2	UNSAT	0	0	0	0	0	0	0	0
	NILM	0	0	0	0	0	0	0	0
	ASCUS	0	0	0	0	1	0	0	0
	LSIL	0	0	1	0	0	0	0	0
	ASC-H	0	0	1	1	2	0	0	0
	AGUS	0	0	0	1	0	6	0	8
	HSIL	0	0	0	0	1	0	19	1
	Cancer	0	0	0	0	0	4	5	63

Table 15 shows the descriptive diagnosis marginal frequencies for benign cellular changes for all sites combined. Each slide was read three times, first by a cytotechnologist and then by a pathologist.

**Table 15. Unadjudicated Marginal Frequencies –
Summary of Descriptive Diagnosis for Benign Cellular Changes –
All Sites Combined**

Number of Reads	TIS Review		I2 Review	
	7542		7542	
Descriptive Diagnosis	N	%	N	%
Benign Cellular Changes	402	5.3%	420	5.6%
Organisms:				
Trichomonas vaginalis	20	0.3%	28	0.4%
Fungal organisms consistent with Candida spp.	122	1.6%	128	1.7%
Shift in Flora s/o bacterial vaginosis	183	2.4%	208	2.8%
Bacteria consistent with Actinomyces spp.	2	0.0%	3	0.0%
Cellular changes consistent with Herpes virus	2	0.0%	1	0.0%
Other infection	0	0.0%	0	0.0%
Other Non-Neoplastic Findings				0.0%
Reactive cellular changes assoc. w/ inflammation	34	0.5%	16	0.2%
Atrophy	33	0.4%	26	0.3%
Reactive cellular changes assoc. w/ radiation	0	0.0%	0	0.0%
Reactive cellular changes assoc. w/ IUD	0	0.0%	1	0.0%
Glandular cells status post hysterectomy	0	0.0%	0	0.0%
Endometrial cells in a woman ≥ 45 yrs of age	6	0.1%	9	0.1%

The Integrated Imager showed a slightly higher rate of Benign Cellular Changes (420 out of 7542, or 5.6%) than TIS Review (402 out of 7542, or 5.3%), however this was not statistically significant.

Conclusion

The sensitivity and specificity of Integrated Imager for review of ThinPrep 2000 slides and ThinPrep 5000 slides are similar to the sensitivity and specificity of the ThinPrep Imaging System.

G2.3 Analytical performance of Integrated Imager

Within-instrument Reproducibility

Analytical performance was evaluated by reviewing the content of the 22 fields of view (FOVs) presented by the Integrated Imager. Evaluations were carried out by cytotechnologists. No pathologist reviewed the FOV. Full slide reviews were not carried out for this evaluation.

Within-instrument reproducibility results were collected by three (3) cytotechnologists who performed review of slides three (3) times on the same instrument with a washout period of a minimum of 14 days.

The 260 slides used in this study were previously prepared from ThinPrep specimens and had an adjudicated cytology diagnosis.

The highest ranked diagnosis from review of 22 FOVs and number of abnormal FOVs were recorded for each of three runs for both TIS review and I2 review.

In Table 16, the within-instrument results are summarized for each diagnostic category of slides (according to adjudicated truth results). For each grouping, the following metrics are reported:

- % Abnormal
The proportion of slides for which any abnormal FOVs were observed.
(For NILM or UNSAT slides, the % Normal column is used to record the proportion that are not abnormal).
- % Category+
The proportion of slides for which at least one FOV was observed with content of the slide's true category or higher.
- % N/A
The proportion of slides in that category that are excluded from analysis (slide not able to be imaged by imager or missing data)
- Abnormal FOV, % zero
The proportion of slides for which zero abnormal FOV were observed.
- Abnormal FOV, Median
The median number of abnormal FOV observed (out of 22 total).

Table 16. Summarized Results of Within-instrument Study

Dx	Imager	% Abnormal	% Category+	% Normal	% N/A	Abnormal FOV	
						% zero	Median
NILM	TIS			69.6%	11.0%	70.4%	0
	I2			78.1%	4.3%	78.4%	0
ASCUS	TIS	75.9%	75.9%		13.3%	25.0%	6
	I2	71.9%	71.9%		5.0%	28.1%	7
LSIL	TIS	97.3%	93.2%		3.3%	2.8%	14
	I2	96.0%	94.0%		0.7%	4.0%	15
ASC-H	TIS	93.3%	86.7%		0.0%	6.7%	11.5
	I2	100%	83.3%		0.0%	0.0%	14
AGUS	TIS	63.0%	51.9%		6.7%	35.7%	2
	I2	55.6%	48.1%		10.0%	44.4%	2
HSIL	TIS	98.0%	77.3%		0.0%	2.0%	20
	I2	97.3%	71.3%		0.7%	2.7%	20
CANCER	TIS	100%	46.7%		0.0%	0.0%	22
	I2	100%	53.3%		0.0%	0.0%	22
UNSAT	TIS			72.2%	40.0%	72.2%	0
	I2			85.7%	36.7%	94.7%	0

Between-instrument Reproducibility

Between-instrument reproducibility results were derived from the clinical study. In the clinical study, three (3) cytotechnologist/pathologist pairs reviewed slides on different instruments.

In Table 17, the between-instrument results are summarized for each diagnostic category of slides (according to adjudicated truth results). For each grouping, the following metrics are reported:

- % Abnormal
The proportion of slides for which any abnormal diagnosis was recorded.
(For NILM or UNSAT slides, the % Normal column is used to record the proportion that are not abnormal).
- % Category+
The proportion of slides for which the site diagnosis was equal to or higher than the slide’s adjudicated category.

Table 17. Summarized Results of Between-instrument Study

Dx	Imager	% Abnormal	% Category+	% Normal
NILM	TIS	--	--	90.0%
	I2	--	--	88.1%
ASCUS	TIS	64.4%	64.4%	--
	I2	71.7%	71.7%	--
LSIL	TIS	95.0%	75.0%	--
	I2	96.9%	80.6%	--
ASC-H	TIS	87.7%	62.6%	--
	I2	92.8%	63.6%	--
AGUS	TIS	53.8%	37.6%	--
	I2	67.5%	57.3%	--
HSIL	TIS	97.7%	54.7%	--
	I2	99.3%	64.7%	--
CANCER	TIS	100%	63.2%	--
	I2	100%	63.2%	--
UNSAT	TIS	--	--	95.2%
	I2	--	--	93.2%

G2.4 Cytotechnologist Screening Rates During Clinical Study

During the study, nine (9) cytotechnologists (CTs) recorded the number of hours they worked each day and the number of slides screened for both the TIS and I2 reviews. The experience levels of the cytologists ranged from 4 to 30 years. During the study, the cytotechnologist’s screening times for both TIS Review and I2 Review included automated screening of the 22 fields of view, full slide review if the automated screening was not applicable, and automated screening of the 22 fields of view followed by full slide review when abnormal cells were identified during automated screening. The number of hours each cytotechnologist screened slides per day varied due to logistical issues and scheduling. Only the sequential modality of I2 Review was evaluated during clinical study.

These data are summarized in Table 18 below.

Note: These numbers represent total number of slides and does not consider the review type; Field of view (FOV) only, Full Manual Review (FMR), or FOV+FMR. These rates are lower than would be routinely observed in clinical practice as the number of abnormal cases in this clinical study was much higher than typically observed in normal clinical practice (50% versus 10–20%).

Table 18. CT Screening Rates

	TIS Average Slides/Hour	I2 Average Slides/Hour
Site 1		
CT 1	9.8	9.9
CT 2	10.4	9.7
CT 3	11.1	8.1
Site 2		
CT 1	6.2	6.1
CT 2	9.0	6.4
CT 3	9.1	6.5
Site 3		
CT 1	9.2	6.6
CT 2	9.9	6.8
CT 3	10.1	6.5
Combined Median	9.8	6.6
	100%	67%

In this study, the number of equivalent slides reviewed could not be determined as the review type was not tracked.

CTs using the Integrated Imager scanned and reviewed 67% of the slides that CTs reviewed when using TIS.

Note: The time recorded for the TIS-reviewed slides does not account for the scanning time. The scanning time adds approximately 90 seconds per slide when using the Integrated Imager Sequential Modality.

G2.5 Cytotechnologist Timing Study (Batched and Sequential Modalities)

An additional study “Cytotechnologist Screening Time Study ThinPrep® Integrated Imager” was performed to characterize the screening volumes for cytotechnologists (CTs) when assistive imaging is implemented as part of the slide review process. These data were collected using the Integrated Imager in two ways:

1. Each slide was imaged and then reviewed by a CT using the Integrated Imager. This is referred to as *Sequential Modality* in this study (i.e., imaging and slide review is performed consecutively, by the CT).
2. All slides were imaged as a batch using the Integrated Imager and then the CT reviewed slides as a batch. This is referred to as *Batched Modality* in this study. In batched modality, imaging of slides is performed in advance, separate from the slide review.

Three (3) CTs participated in this study. The CTs reviewed slides over three (3) days (screening slides for an 8-hour day) for each arm of the study. Slides were imaged and reviewed independently by each of the three CTs.

All slides were prepared from ThinPrep® specimens of known cytology diagnoses, on a ThinPrep processor, and stained with ThinPrep Stain. Sets of 400 randomized slides per CT, each with approximately 10% abnormal diagnosis were provided in order to fully occupy a CT for three (3) full days of screening. The CTs were blinded to the diagnoses.

A minimum one-week “washout period” occurred between study arms for each CT.

Table 19 shows the total breakdown of the types of reviews performed in the CT Timing Study.

Table 19. Total Slides Reviewed by Review Type / CT
 (% Autoscan = #FOV+FMR / Total # Slides Reviewed over 3 Days)

	Sequential Review				Batched Review			
	CT #1	CT #2	CT #3	Overall	CT #1	CT #2	CT #3	Overall
Total # slides reviewed	255	285	300	840	365	340	353	1058
# FOV only	212	179	239	630	308	226	265	799
# FOV+FMR	42	100	37	179	51	109	75	235
# FMR Only	1	6	4	11	6	5	13	24
% Autoscan Referral	16%	35%	19%	24%	14%	32%	21%	22%

The results are shown in **Table 20**. The median number of slides screened per day when the Integrated Imager in Sequential Modality was used for screening and reviewing of slides was **92** slides. CTs using the Integrated Imager in Batched Modality reviewed 86% of the maximum number of slides that CTs could have reviewed when using TIS.

Table 20. Cytotechnologist Daily Slide Review Rates

	CT	# Slides Reviewed				Overall Daily Median
		Day 1	Day 2	Day 3	Daily Median	
Sequential Modality	CT #1	87	80	88	87	92 (67%*)
	CT #2	90	100	95	95	
	CT #3	92	108	100	100	
Batched Modality	CT #1	119	123	123	123	119 (86%*)
	CT #2	124	106	110	110	
	CT #3	119	120	114	119	

* Percentage with regards to TIS being 100%.

The agreement of the CT diagnosis was compared to the adjudicated results and are shown in Table 21. High rates of agreement in diagnosis with the adjudicated slide results supports the clinical utility of this study.

**Table 21. PPA and NPA Results by Cytotechnologist Based on Adjudicated Results.
(Positive Results Mean ASC-US+)**

	Sequential Modality		Batched Modality	
	PPA	NPA	PPA	NPA
CT #1	100%	97%	97%	96%
CT #2	100%	76%	100%	79%
CT #3	91%	94%	100%	90%
Overall	97%	89%	99%	89%

Workload is defined by CLIA as a maximum limit of 100 slides in no less than an 8-hour workday. This refers to a full manual review of 100 slides.

When using automated Imaging systems, users may need to review only a portion of the slide in order to make a diagnosis of NILM, thereby decreasing the time needed for CT review. Conversely, in cases where abnormality is present, the partial slide review is followed by a full manual review, leading to a longer CT review time. In both cases, different values are used to account for the difference in review times in order to arrive at slide workload estimates. (See Tables 22 and 23.)

When using the Sequential Modality, the Integrated Imager scans the slide in approximately 90 seconds. This time should be considered when determining the value used for workload calculations.

When using the Batched Modality, the scanning time is not considered in the review time, and as such, more slides can be reviewed in an 8-hour day.

In order to help laboratories determine the workload, based on the number of slides reviewed with FOV only and FOV+FMR, for their cytotechnologists when using the Integrated Imager, laboratories should use the following method in **Table 22 and Table 24 for Sequential Modality and Table 23 and Table 25 for Batched Modality** when calculating workload:

Tables 24 and 25 are intended to help individual cytotechnologists keep an on-going tally of the FOV only and FOV+FMR slides screened during each workday.

**Table 22. Values for Calculating Workload,
Integrated Imager, Sequential Modality**

FMR = 1 slide
FOV = 0.85 slide
FMR + FOV = 1.85 slides
Upper Limit = 100 slides

When using Sequential Modality, use the following equation for determining workload:

$$[(\# \text{ slides FMR}) (1) + (\# \text{ slides FOV}) (0.85) + (\# \text{ slides FOV+FMR}) (1.85)] = 100 \text{ slides}$$

**Table 23. Values for Calculating Workload,
Integrated Imager, Batched Modality**

<p>FMR = 1 slide FOV = 0.65 slide FMR + FOV = 1.65 slides Upper Limit = 100 slides</p>

When using Batched Modality, use the following equation for determining workload:

$$[(\# \text{ slides FMR}) (1) + (\# \text{ slides FOV}) (0.65) + (\# \text{ slides FOV+FMR}) (1.65)] = 100 \text{ slides}$$

Note: The ThinPrep® Integrated Imager workload limit in an 8-hour workday includes all activities needed to process the cases, not exclusively time spent using the microscope:

- Screening 22 Fields of View
 - Full manual slide review using the Autoscan feature
 - Review clinical history
 - Record results and triage appropriately
- Slides where only 22 Fields of View (FOV) are used for diagnosis should be considered as less than a full slide.
 - When using the *Sequential Modality*, a slide should be considered as 0.85 of a slide.
 - When the *Batched Modality* is used, a slide should be considered 0.65 of a slide.
 - Slides where full manual review (FMR) is performed using either manual stage indexing, or with the Autoscan feature should be considered as one (1) slide (as mandated by CLIA '88 for manual screening).
 - Slides where **both** FOV review and an FMR are conducted should be considered as :
 - 1.85 slides when using Sequential Modality,
 - 1.65 slides when using Batched Modality.
 - If less than an 8-hour workday is practiced, the following formula must be applied to determine the maximum number of slides to be reviewed during that workday:

$$\left(\frac{\text{Number of hours examining slides}}{8} \right) \times 100$$

- **Note:** ALL laboratories should have a clear standard operation procedure for documentation of their method of workload counting and for establishing workload limits.
- It is the responsibility of the Technical Supervisor to evaluate and set workload limits for individual cytotechnologists based on laboratory clinical performance.

- **Note:** The manual workload limit does not supersede the CLIA requirement of 100 slides in a 24-hour period in no less than an 8-hour day. When conducting manual review, refer to the CLIA requirements for calculating workload limits. Manual review includes the following types of slides:
 - Slides reviewed on the ThinPrep Imaging System using the Autoscan feature
 - Slides reviewed without the ThinPrep Imaging System
 - Non-gynecologic slides.
 - According to CLIA '88, these workload limits should be reassessed every six months.

Table 24. Screening Work Completion Look up Table – Integrated Imager, Sequential Modality

		FOV+FMR																																																						
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
FOV	0	0	2	4	6	7	9	11	13	15	17	19	20	22	24	26	28	30	31	33	35	37	39	41	43	44	46	48	50	52	54	56	57	59	61	63	65	67	68	70	72	74	76	78	80	81	83	85	87	89	91	93	94	96	98	100
	1	1	3	5	6	8	10	12	14	16	18	19	21	23	25	27	29	30	32	34	36	38	40	42	43	45	47	49	51	53	55	56	58	60	62	64	66	67	69	71	73	75	77	79	80	82	84	86	88	90	92	93	95	97	99	
	2	2	4	5	7	9	11	13	15	17	18	20	22	24	26	28	29	31	33	35	37	39	41	42	44	46	48	50	52	54	55	57	59	61	63	65	66	68	70	72	74	76	78	79	81	83	85	87	89	91	92	94	96	98	100	
	3	3	4	6	8	10	12	14	16	17	19	21	23	25	27	28	30	32	34	36	38	40	41	43	45	47	49	51	53	54	56	58	60	62	64	65	67	69	71	73	75	77	78	80	82	84	86	88	90	91	93	95	97	99		
	4	3	5	7	9	11	13	15	16	18	20	22	24	26	27	29	31	33	35	37	39	40	42	44	46	48	50	52	53	55	57	59	61	63	64	66	68	70	72	74	76	77	79	81	83	85	87	89	90	92	94	96	98	100		
	5	4	6	8	10	12	14	15	17	19	21	23	25	26	28	30	32	34	36	38	39	41	43	45	47	49	51	52	54	56	58	60	62	63	65	67	69	71	73	75	76	78	80	82	84	86	88	89	91	93	95	97	99			
	6	5	7	9	11	13	14	16	18	20	22	24	25	27	29	31	33	35	37	38	40	42	44	46	48	50	51	53	55	57	59	61	62	64	66	68	70	72	74	75	77	79	81	83	85	87	88	90	92	94	96	98	99			
	7	6	8	10	12	13	15	17	19	21	23	24	26	28	30	32	34	36	37	39	41	43	45	47	49	50	52	54	56	58	60	61	63	65	67	69	71	73	74	76	78	80	82	84	86	87	89	91	93	95	97	98				
	8	7	9	11	12	14	16	18	20	22	23	25	27	29	31	33	35	36	38	40	42	44	46	48	49	51	53	55	57	59	60	62	64	66	68	70	72	73	75	77	79	81	83	85	86	88	90	92	94	96	97	99				
	9	8	10	11	13	15	17	19	21	22	24	26	28	30	32	34	35	37	39	41	43	45	47	48	50	52	54	56	58	59	61	63	65	67	69	71	72	74	76	78	80	82	84	85	87	89	91	93	95	96	98					
	10	9	10	12	14	16	18	20	21	23	25	27	29	31	33	34	36	38	40	42	44	46	47	49	51	53	55	57	58	60	62	64	66	68	70	71	73	75	77	79	81	83	84	86	88	90	92	94	95	97	99					
	11	9	11	13	15	17	19	20	22	24	26	28	30	32	33	35	37	39	41	43	45	46	48	50	52	54	56	57	59	61	63	65	67	69	70	72	74	76	78	80	82	83	85	87	89	91	93	94	96	98	100					
	12	10	12	14	16	18	19	21	23	25	27	29	31	32	34	36	38	40	42	44	45	47	49	51	53	55	56	58	60	62	64	66	68	69	71	73	75	77	79	81	82	84	86	88	90	92	93	95	97	99						
	13	11	13	15	17	18	20	22	24	26	28	30	31	33	35	37	39	41	43	44	46	48	50	52	54	55	57	59	61	63	65	67	68	70	72	74	76	78	80	81	83	85	87	89	91	92	94	96	98	100						
	14	12	14	16	17	19	21	23	25	27	29	30	32	34	36	38	40	42	43	45	47	49	51	53	54	56	58	60	62	64	66	67	69	71	73	75	77	79	80	82	84	86	88	90	91	93	95	97	99							
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H. Clinical Investigation Conclusions

- When ThinPrep Integrated Imager is compared to ThinPrep Imaging System, reviewers achieved higher sensitivity in all abnormal categories. There was some decrease in specificity.
 - For ASCUS+ slides, the increase of sensitivity was 3.8% with 95% confidence interval of 2.6% to 5.0% and a decrease of specificity was -1.9% with 95% confidence interval of -2.8% to -1.0%.
 - For LSIL+ slides, the increase in sensitivity was 5.8% with 95% confidence interval of 4.1% to 7.5% and a decrease of specificity was -1.9% with a 95% confidence interval of -2.6 to -1.2%
 - For HSIL+ the increase in sensitivity was 7.9% with a 95% confidence interval of 4.5% to 11.2% and a decrease in specificity of -1.1% with a 95% confidence interval of -1.6% to -0.6%.
- Considering the technological similarity of the ThinPrep Imaging System and the comparative clinical study results, it is concluded that the ThinPrep Integrated Imager is similar to the ThinPrep Imaging System and may be used as replacement for manual review of ThinPrep® Pap Test slides prepared on the ThinPrep 2000 System and the ThinPrep 5000 processor 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.
- The screening volume for the CTs when using the Integrated Imager for the imaging and review of slides is within the Clinical Laboratory Improvement Amendments (CLIA) guidelines for total number of slides that can be screened in one day.
- In order to increase the number of slides that can be reviewed by a cytotechnologist in one day, slides can be imaged in advance (in batched modality) and then reviewed by the CT in a batch.
- The number of slides that a cytotechnologist can scan and review in one day is less on the Integrated Imager than the ThinPrep Imaging System.
 - 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 to ensure proper use and selection of appropriate workload limits.
 - For these clinical sites and these study populations, the data from the clinical trial demonstrate that the use of the ThinPrep Integrated Imager to assist in primary cervical cancer screening of ThinPrep® Pap Test slides for the presence of atypical cells, cervical neoplasia, including its precursor lesions, and carcinoma as well as all other cytological criteria as defined by the Bethesda System, is safe and effective for the detection of cervical abnormalities.

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2. Hologic, Inc. ThinPrep® Imaging System Operation Summary and Clinical Information. Part number MAN-03938-001.



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Chapter One

Introduction

SECTION A

OVERVIEW

The ThinPrep® Integrated Imager is an automated cytology review microscope with ThinPrep slide imaging functionality. It is specifically designed to image and review ThinPrep Pap Test microscope slides on-demand. It also has the ability to act as a conventional microscope when not used in conjunction with ThinPrep imaging.

The Integrated Imager consists of:

The **Microscope** - a customized microscope with imaging camera, slide ID reader, automated stage, hand controls and adjustable touch screen user interface.

Controller, which controls the electromechanical and imaging subsystems.

Computer with touch screen display that hosts the system application and database.



Figure 1-1 Integrated Imager

1 INTRODUCTION

SECTION B

THE THINPREP IMAGING AND REVIEW PROCESS

Imaging

A prepared ThinPrep® Pap Test microscope slide is loaded onto the stage of the device. A slide identification camera reads the slide label ID and compares it against slide IDs already in the computer database.

- If the slide ID is new, the slide is imaged.
- If the slide ID is already in the database, the software prompts for the slide to be reviewed.
- If the slide has already been reviewed, it may be reviewed again.

To ensure that the focus and light requirements for imaging are correct and will not be interrupted during the scan, the system disables any manual stage, focus and illumination controls. The instrument uses an LED light source to illuminate the optical path to image. The entire cell spot is imaged in approximately 90 seconds. The system identifies objects of interest on the slide based on integrated optical density. The coordinates of 22 of those objects are recorded and, with the slide ID, are stored in the system database. (See Figure 1-3.)

Review

The device next behaves as an automated microscope, presenting the 22 fields of interest to the CT (cytotechnologist) and providing additional slide review when suspect cells are found. This is termed 'Auto Locate.' Manual control of the stage, focus and illumination is returned for the CT's use. The instrument uses a white LED light source for illumination for slide review. The CT interacts with the review controls both via substage hand controls and by the touch screen.

Each field of view is presented to the CT at 10X magnification. The nosepiece also has 4X and 40X objectives, which the CT can switch manually. Before the next field of view can be presented, the Integrated Imager senses if the 10X objective is engaged in the light path. If not, the system prompts the CT to return the magnification to 10X. All 22 fields of view will be presented to the CT at 10X magnification.

Note: The object of interest is typically placed in the center of the field of view, however the CT must screen the entire field of each of the 22 fields of view presented.

During slide review, the CT has the option to electronically mark an area for subsequent review and/or physical marking. One or more electronic marks enforces a review of the entire cell spot. This is termed 'Auto Scan.'

During Auto Scan review, the CT may add or delete electronic marks. Physical marking of these areas on the slide coverslip with a pen is done manually by the CT.

The CT has the option to control the position of the stage manually, which provides complete freedom to move any portion of the cell spot into the field of view for examination.

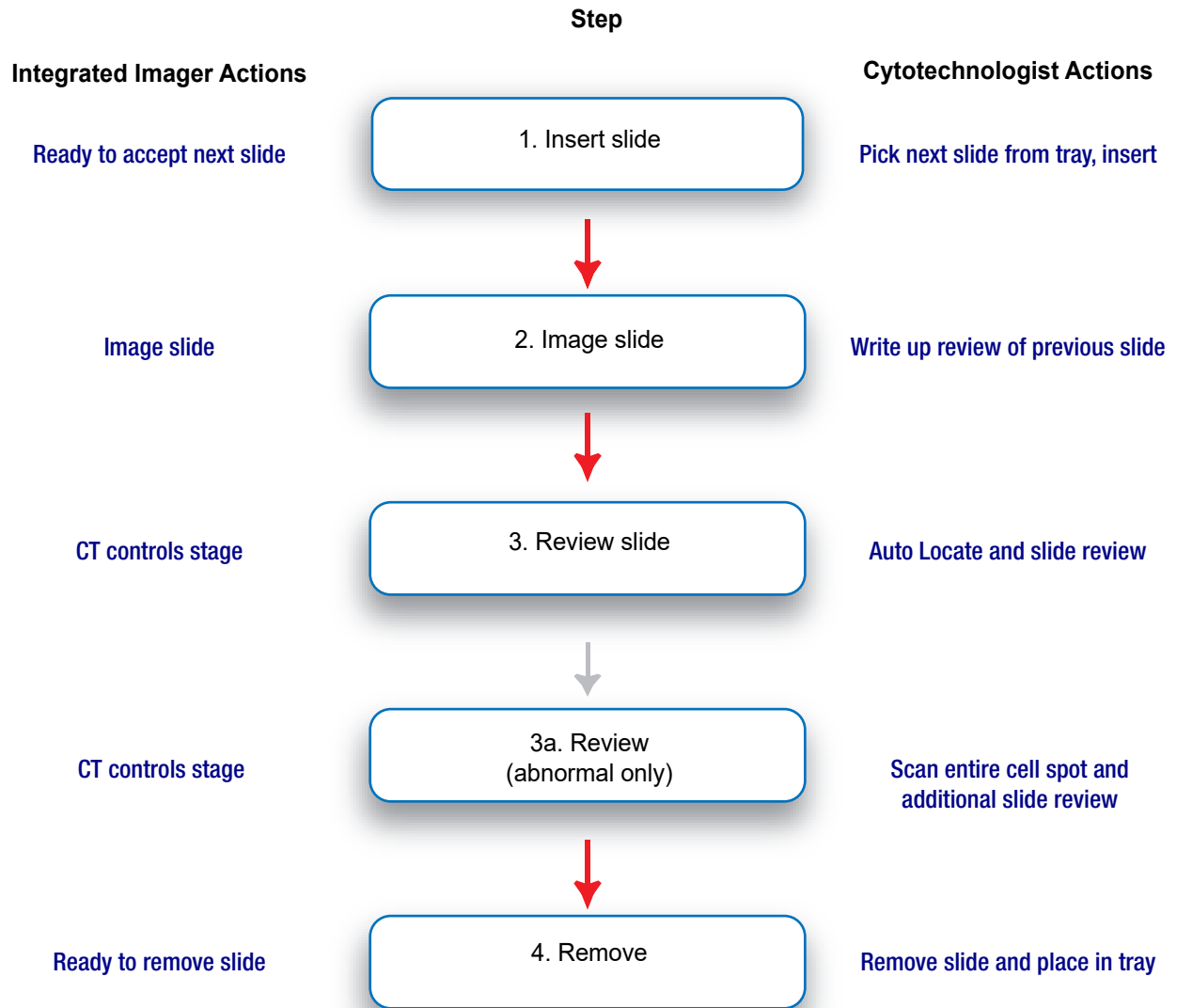
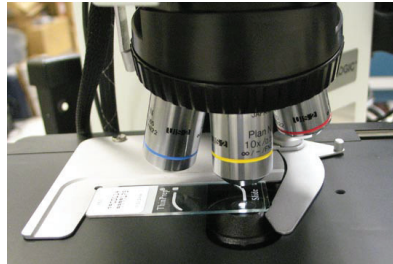


Figure 1-2 Integrated Imager Workflow

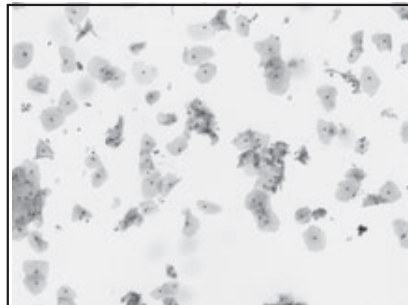
1 INTRODUCTION

A prepared ThinPrep® Pap Test slide is loaded onto the Integrated Imager stage.



- The slide ID is scanned.
- If an ID is new to the database the slide will be imaged.
 - An ID already in the database prompts the user to review the slide.

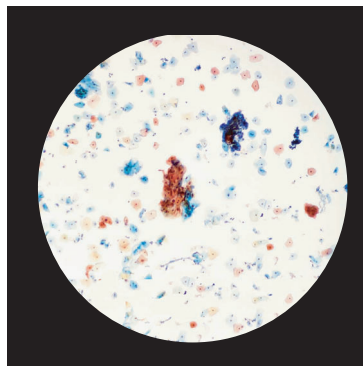
The cell spot is imaged.



The slide imaging system scans the entire cell spot. The system identifies objects of interest found on the slide.

The coordinates of 22 objects of interest with the highest integrated optical density will be stored in the computer's database.

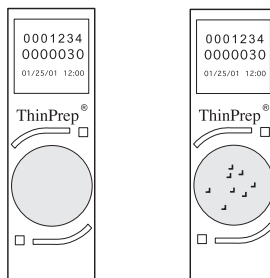
Slide review by the cytotechnologist.



During Auto Locate the system presents the 22 selected fields of view in geographic order to the cytotechnologist.

Suspect cells may be electronically marked by the CT and a review of the entire cell spot is enforced. The slide is manually marked by the CT. At completion, the slide data is updated with the location of electronic marked areas as well as information on the review session.

Normal slide



Abnormal slides are reviewed by a cytopathologist for interpretation and diagnosis.

Figure 1-3 ThinPrep Imaging Process

**SECTION
C****SPECIMEN PREPARATION**

Specimens for the ThinPrep® Pap Test cytology slide are collected by a clinician, then immersed and rinsed in a PreservCyt® Solution sample vial. The sample is then capped, labeled, and sent to a laboratory equipped with a ThinPrep Processor. After being processed, the slides are stained with ThinPrep Stain and coverslipped with one of the following:

- glass coverslips, #1 thickness, 24 mm wide, 40–50 mm long
- Sakura Tissue-Tek® SCA™ coverslipped film, 45 mm long, not covering any portion of the frosted area (Sakura part number 4770)
- Klinipath KP-Tape, 45 mm long, not covering any portion of the frosted area (Klinipath part number 3020)

Please refer to the operator's manuals of these instruments for more information regarding preparation and processing of ThinPrep slides.

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.

- ThinPrep microscope slides with fiducial marks are being used. The fiducial marks should not be scratched or marred.
- 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 and the label do not extend beyond the surface of the slide.
- The slide is labeled in one of the formats supported by the ThinPrep Integrated Imager.

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 Integrated Imager in a timely manner, according to normal laboratory practices. Imaging performance has not been assessed beyond 4 months.

Specimen sample - the use of lubricants (e.g., KY Jelly) should be minimized prior to specimen collection. Lubricants can adhere to the filter membrane and may cause poor cell transfer to the slide.

Stain - 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.

Specimen Handling

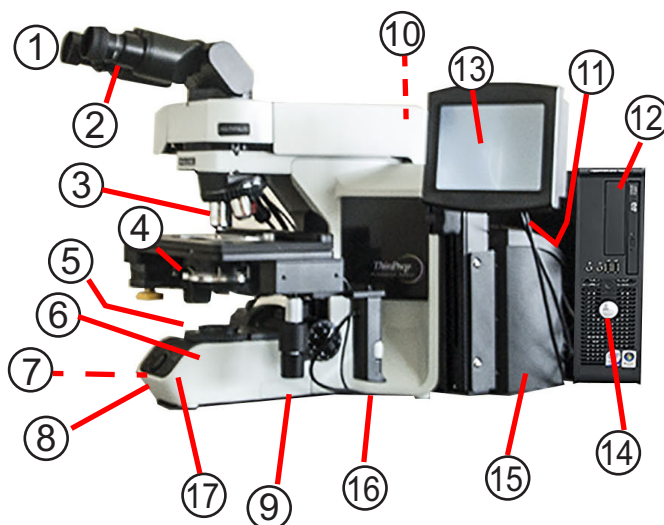
The ThinPrep slides are stored, transported and handled the same as conventional cytology slides. Please refer to your laboratory guidelines for specimen handling.

1 INTRODUCTION

SECTION D

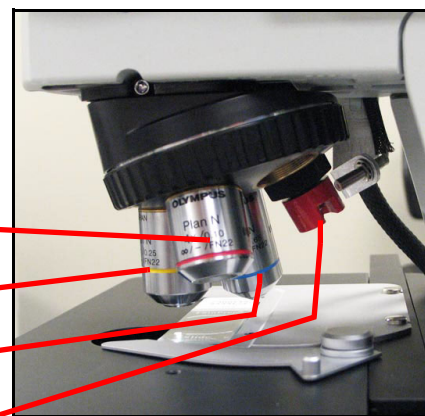
INTEGRATED IMAGER TECHNICAL SPECIFICATIONS

Overview of Components



- | | | |
|---|--|--|
| <ol style="list-style-type: none"> 1. Eyepieces 2. Binocular tube 3. Revolving nosepiece (4X, 10X, 40X, plus position sensor) 4. Motorized stage 5. Condenser (under stage) 6. Collector 7. Coarse/fine focus knob (on left side of microscope) 8. Light intensity adjustment knob 9. X,Y axis stage control knobs (stage control) 10. Microscope power switch (on back left of microscope with black side panel) | <ol style="list-style-type: none"> 11. Allen screwdriver (near the controller on the back of the microscope with the black side panel) 12. Computer 13. Touch screen interface 14. Computer power switch 15. Controller 16. Review control | <ol style="list-style-type: none"> 17. Note: The “SET” button is not used. The “LIM” button is also not used and will illuminate, with no effect, if pushed. |
|---|--|--|

- | | |
|-------------------------------|---|
| 4X objective (red stripe) | → |
| 10X objective (yellow stripe) | → |
| 40X objective (blue stripe) | → |
| 10X objective position sensor | → |



Revolving nosepiece

Figure 1-4 Integrated Imager Components

Dimensions

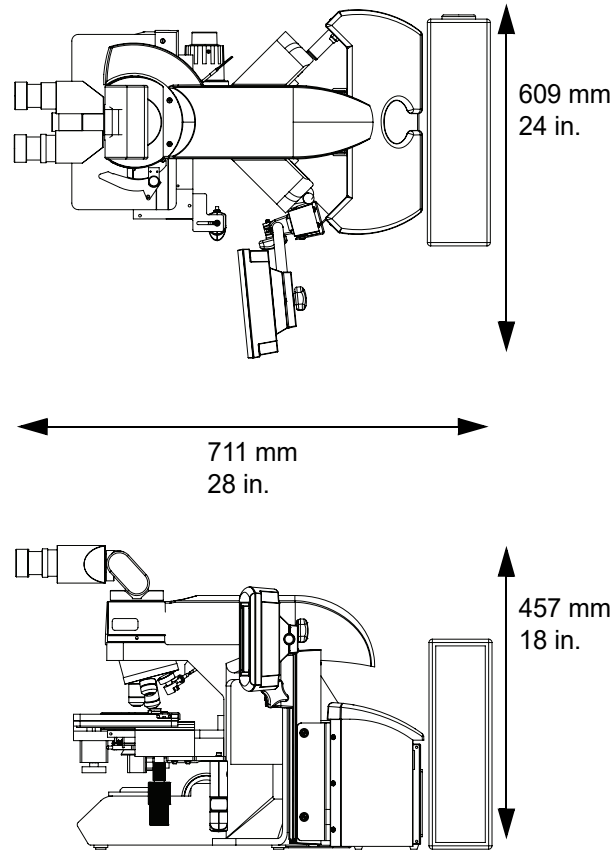


Figure 1-5 Integrated Imager Dimensions

ThinPrep® Microscope Slide for Use with the Imaging System

The ThinPrep microscope slide is used by the ThinPrep Processor in preparing the patient slide. The slide utilizes fiducial marks, or fixed reference points, which are permanently printed features on the slide that are used to register the slide position on the stage. A coordinate system is based on the fiducial marks, for locating objects of interest on the cell spot.

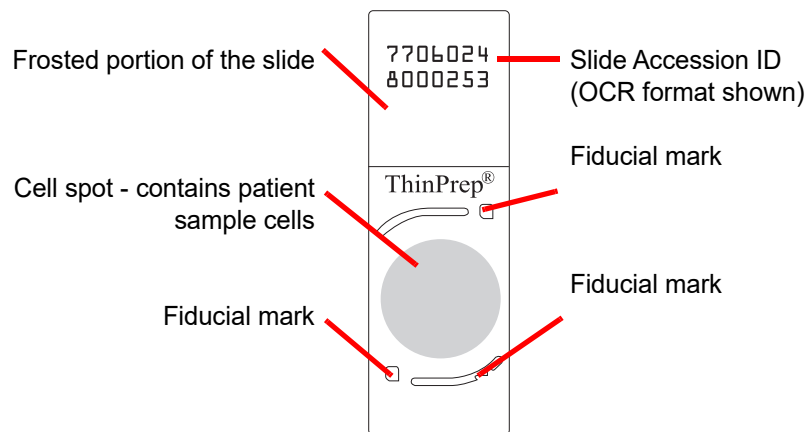


Figure 1-6 ThinPrep Microscope Slide

Weight

The Integrated Imager system - including the microscope, controller, computer and all cabling weighs approximately 32 kg (70 lbs.).

Environmental

Operating temperature range

16°C to 32°C (60°F to 90°F)

Non-operating temperature range

-29°C to 50°C (-20°F to 122°F)

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 Integrated Imager is for indoor use only in an office or a clean laboratory environment.

Altitude

0 meters (sea level) to 2000 meters

Atmospheric pressure

1100 millibar to 500 millibar

Sound levels

Maximum A-weighted sound pressure level at the operator's position and at a bystander's position is 66.2 dBA.

Power**Voltage**

100-120V~/220-240V~ single phase, 50-60 Hz

Power

Less than 150 Watts (512 Btu/hour) for the microscope and controller, not including the computer

Power cables

Maximum length must be less than 3 m (9.8 ft.).

Fusing

Two 3.15A, 250 VAC, time delay, low break capacity (instrument)

Note: Fuses are not user-accessible and are not intended to be changed by users. Contact Technical Support if the instrument does not operate. Do not remove any covers on the components.

Connections to external circuits

The external connections on the PC are PELV (Protected Extra Low Voltage) as defined by IEC 61140. Outputs of other devices connected to the PC should also be PELV or SELV (Safety Extra Low Voltage). Only devices approved for safety by an appropriate agency should be connected to the PC.

Note: The computer manufacturer provides documentation for the PC. Refer to that for technical specifications. Do not discard.

Safety, EMI and EMC Standards

The Integrated Imager 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 model/rating label, located on the rear of the controller, to see the safety certification markings. This equipment meets the IEC 61010-2-101 particular safety requirements for IVD equipment.

This equipment meets the emission and immunity requirements of IEC 61326-2-6. This equipment has been tested and found to comply to CISPR 11 Class A emission limits.

In a domestic environment it may cause radio interference, in which case, measures to mitigate the interference may be necessary. The electromagnetic environment should be evaluated prior to operation of the equipment. Do not use this device in close proximity to sources of strong

1 INTRODUCTION

electromagnetic radiation (e.g., unshielded 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 as a Class I LED product.

SECTION E

INTERNAL QUALITY CONTROL

Power On Self Test (POST)

At the time the Integrated Imager is powered on, the system goes through a self-diagnostic test. All 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 7, Service Information).

Post Scan Functional Checks

At the completion of slide imaging and slide review, the instrument will do functional checks to ensure integrity of the data gathered during imaging or review. 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 7, Service Information).

SECTION
F

INTEGRATED IMAGER HAZARDS

The Integrated 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.

Do not operate the Integrated Imager with the dust cover on it.

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
	In vitro diagnostic medical device	Indicates a medical device that is intended to be 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
	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
	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
	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
	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
	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

Symbol	Title	Description	Standard information
	Fuse	To identify fuse boxes or their location.	IEC 60417 Graphical symbols for use on equipment, symbol 5016

And this instrument uses the following markings:



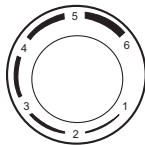
Waste Electrical and Electronic Equipment
Do not dispose in municipal waste
 Contact Hologic for disposal of the instrument



On (Power switch on the microscope)



Off (Power switch on the microscope)



Lamp intensity adjustment



Standby power (computer)



USB port icon (computer)



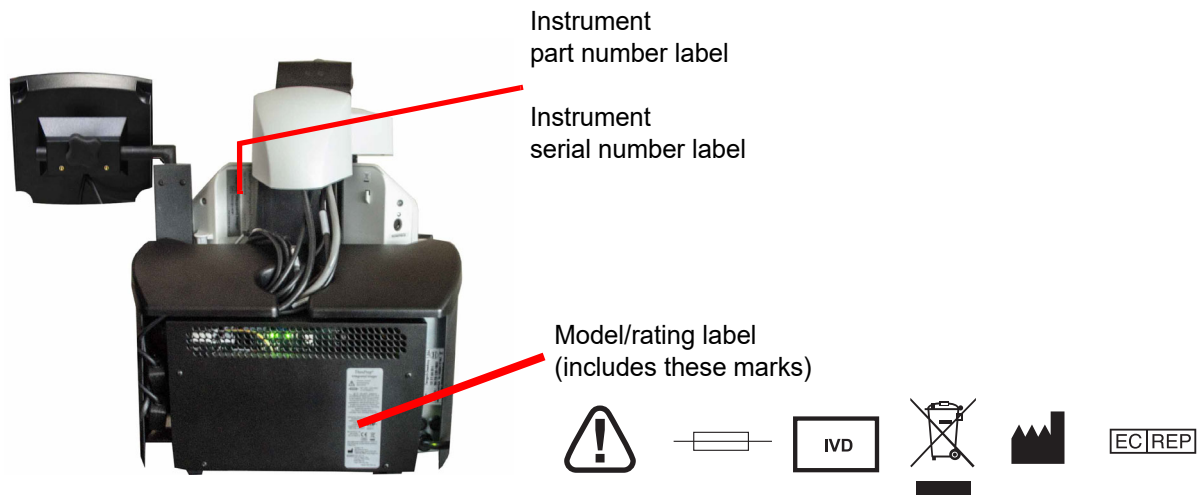
Ethernet port icon (computer)



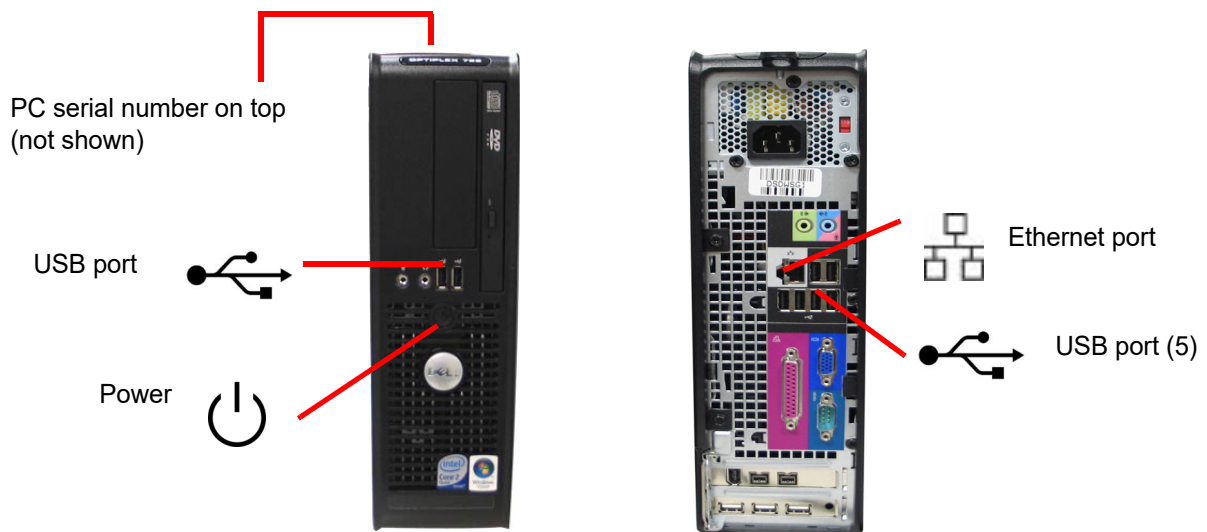
Monitor display (computer)

1 INTRODUCTION

Location of Labels



Rear of Instrument (PC removed for clarity.)



Front and Rear of Computer

(Note: The number and exact location of ports may be different, depending on the PC model you have.)

Figure 1-7 Location of Labels

Warnings Used in this Manual

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

WARNING: Moving Parts. The instrument contains moving parts. Keep hands, loose clothing, jewelry, etc., clear.

WARNING: Grounded Outlet. To ensure safe operation of the instruments, use a three-wire grounded outlet.

WARNING: Glass. The instrument uses microscope slides, which have sharp edges. In addition, the slides may be broken in their storage packaging or on the instrument. Use caution when handling glass slides and when cleaning the instrument.



DISPOSAL

Disposal of consumables

Disposal of instrument fuses. No special instructions, used fuses may be disposed of in your laboratory refuse.

Broken glass. Dispose of in a sharps container.

Disposal of the device

Please contact Hologic Service (refer to Chapter 7, Service Information).

Do not dispose in municipal waste.



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1-508-263-2900
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1 INTRODUCTION

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Chapter Two

Installation

WARNING: Service Installation Only

SECTION A

GENERAL

The ThinPrep[®] Integrated Imager must be installed by Hologic service personnel. When installation is complete, Hologic personnel train the operator(s), using the operator's manual as the training guide.

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. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible. (Refer to Chapter 7, Service Information.)

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

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

Note: The computer manufacturer provides documentation for the PC. Refer to that for technical specifications. Do not discard.

SECTION C

PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

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

The Integrated Imager will require two outlets to power the instrument. Make sure there is adequate electrical supply within 2 meters of the instrument. It must be plugged into a three-prong grounded outlet. Disconnection from the power supply source is by removal of the power cord.

Note: Do not position the instrument so that it is difficult to disconnect the power cords.

2 INSTALLATION

Location

The Integrated Imager 'foot print' is approximately 76.2 cm x 61 cm, and <76.2 cm high (30 in. x 24 in., and < 30 in. high). Make sure there is adequate desk space for placing slide flats or containers. (See Figure 2-1.) The instrument is approximately 32 kg (70 pounds). Be sure the table or bench can support the weight.

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

The Integrated Imager is sensitive to vibrations. It should be placed on a flat, sturdy surface away from any vibrating equipment.

If your system is configured with the computer located separately from the microscope, be sure it is in a dust-free area, with reasonable access to the power switch.

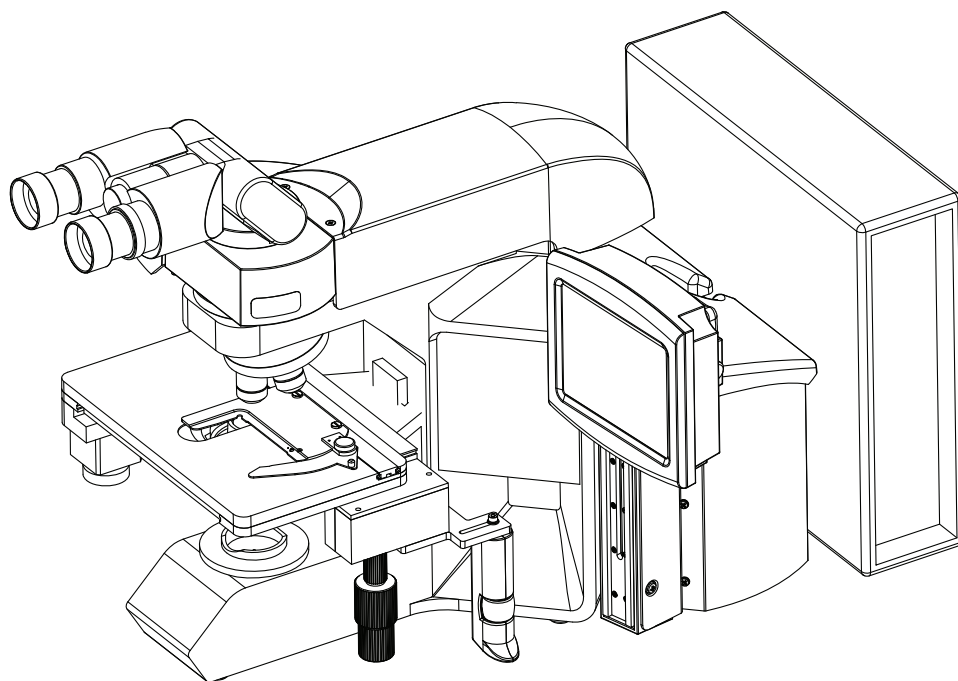


Figure 2-1 A Typical Integrated Imager Configuration

SECTION D

MOVING THE INTEGRATED IMAGER

The Integrated Imager is a precision instrument and should be handled with care. If the system must be moved, the controller and computer PC must be disconnected from one another, moved separately and reconnected at the new location.

The microscope and controller are mechanically and electronically connected and should NOT be separated. The cabling between the controller and the computer may be disconnected and reconnected, see Figure 2-2.

Before disconnecting any of the components, be sure to observe how they are originally connected. See Figure 2-2.

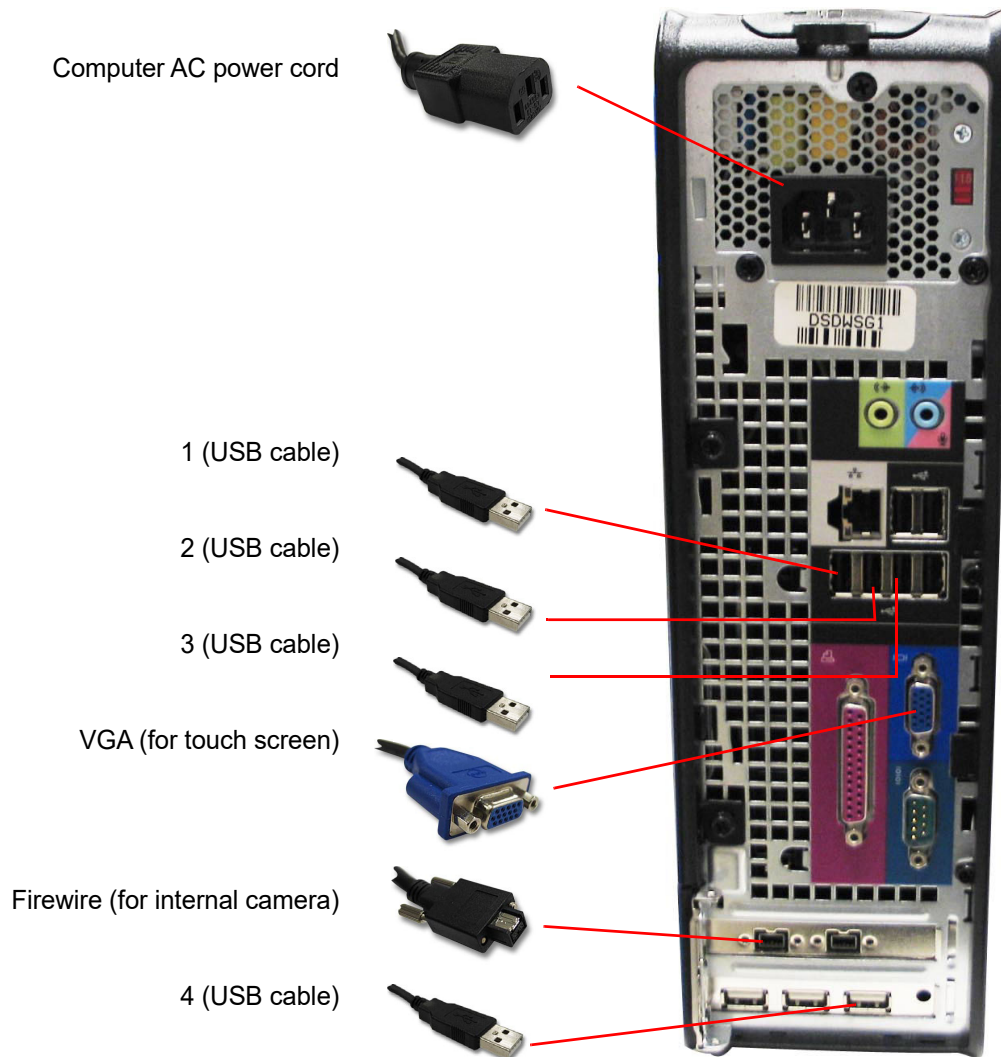


Figure 2-2 Integrated Imager Interconnections

Note: The computer may be set up to face either side, or with the use of the extension cable set, it can be placed further away from the microscope and controller. Your final configuration may look slightly different than Figure 2-2. The cable connections to the computer ports remain the same.

2 INSTALLATION

The microscope should be grasped and lifted by the frame housing. Grasp the frame behind the nosepiece turret as shown in Figure 2-3.

CAUTION: The instrument weighs 70 lbs. (32 kg) and should be moved by at least two people.

CAUTION: Lifting the instrument by the motorized stage or top cover will cause damage to the microscope and may render it inoperable.



Figure 2-3 Moving the Integrated Imager

SECTION E

CONNECTING INTEGRATED IMAGER COMPONENTS

The Integrated Imager components must be fully assembled before turning on the power and using the instrument. Hologic service personnel will assemble the instrument:

- Controller
- Computer
- Microscope
- Assemble spacers, trinocular head (optional telescoping head or riser)
- Eyepieces
- Objectives
- User interface touch screen and mounting rail

Controller, which controls the electromechanical and imaging subsystems.

Computer that hosts the system application and database.

The **Microscope** - a customized microscope with imaging camera, slide ID camera, automated stage, stage controls and touch screen interface.

The **trinocular head** - a tilting binocular observation tube and a fixed, straight tube for the imaging camera. The light path and camera focus have been optimized by placement of spacers in the assembly of the optical components. Do not add or remove spacers or risers.

If an optional **telescoping head** is being used, be sure to use the specific riser that Hologic supplies. One ocular has a diopter adjustment ring to provide common focus capability.

If the optional riser is being used, do not use it in conjunction with the telescoping head. Use one or the other, but not both.

CAUTION: Only use Hologic-supplied eyepieces and objective lenses. DO NOT substitute eyepieces or objectives.

Eyepieces - 10X magnification with a field size of 22 mm.

Objectives - 4X, 10X and 40X objectives are mounted on the revolving nosepiece at production. They are specifically compatible with the supplied eyepieces and the camera for the imaging system. They should not be substituted with any other objectives.

The other object in the nosepiece is the magnetic 10X position sensor. It must not be removed.

An optional 20X objective is available. (Refer to Chapter 8, Ordering Information.) It can be installed by the operator. If the 20X objective is installed, the objectives should be positioned as shown in Figure 2-4.

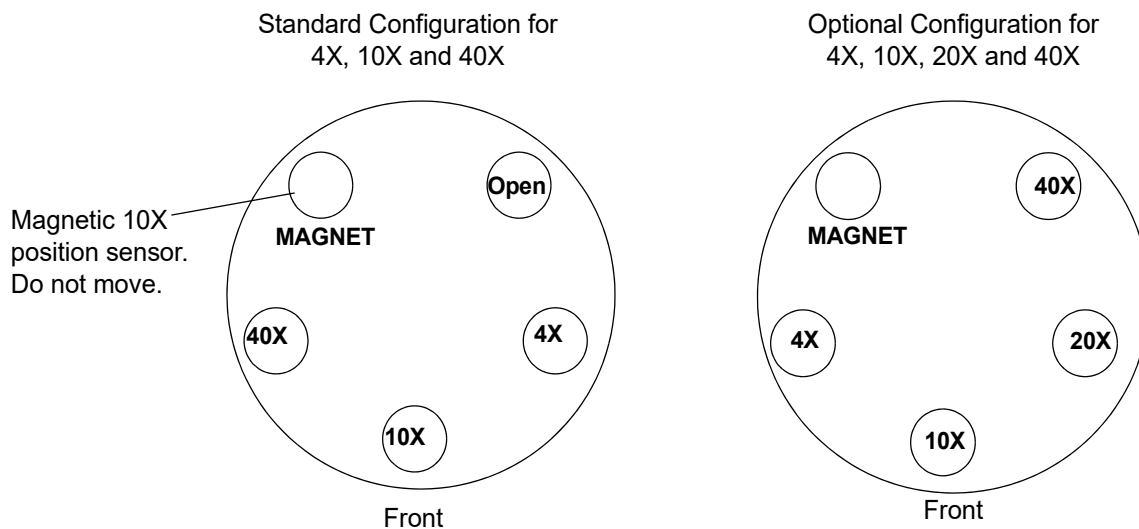


Figure 2-4 Positions of Objectives in the Nosepiece

User interface **touch screen** and mounting rail - the touch screen height can be adjusted by moving the screen up or down along the mounting rail. The tilt and rotational angle of the screen may be adjusted by loosening the adjustment knobs, changing the tilt and rotation, and then tightening each knob.

CAUTION: Do not use filters on the collector or in the objectives.

2 INSTALLATION

Filters - To ensure that the imaging camera images the cell spot at the correct gray scale for which the imaging is intended, do *not place filters* in the illumination path on the collector or in the objectives. Adjusting the X,Y Axis Stage Control Knob Tension and Height

The X- and Y-axis stage control knob tension and height may be adjusted to suit the operator's preference. See Figure 2-5.

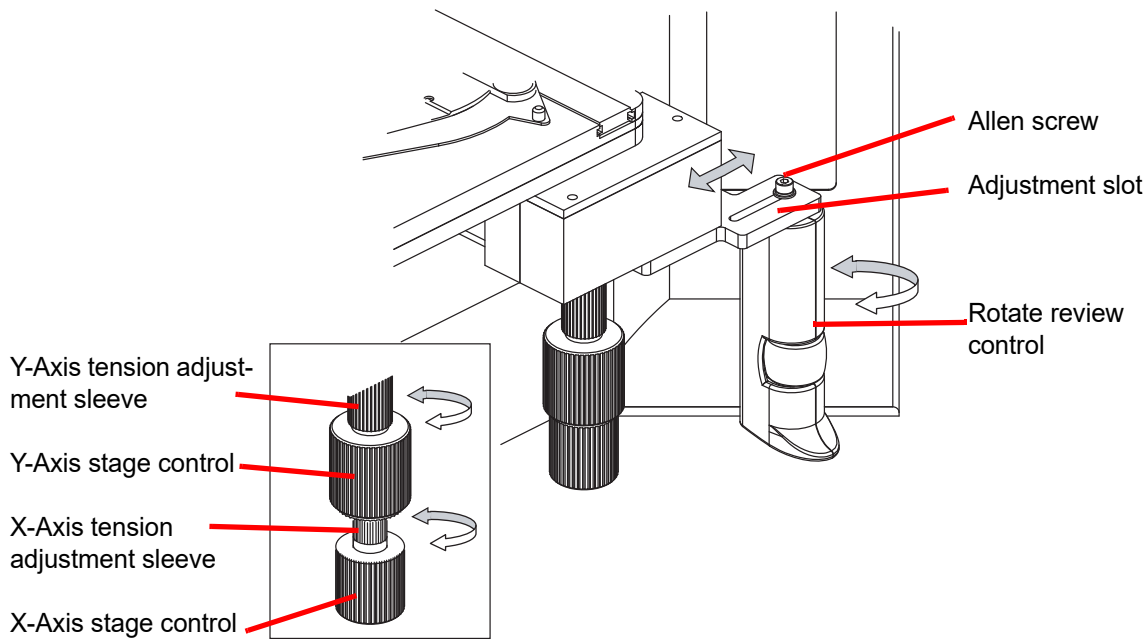


Figure 2-5 Adjust Substage Controls

The Y-axis is adjusted by accessing the adjustment sleeve above the knob. To adjust the X-axis, pull the X- and Y-axis stage control knobs apart to reveal the adjustment sleeve of the X-axis stage control. To loosen the tension, turn the adjustment sleeves counterclockwise. For a tighter tension, turn the sleeve clockwise for either control.

To adjust the height, the X- and Y-axis stage control knobs may be slid downward or upward on the vertical axis of the assembly shaft.

Leave a small gap between the X- and Y-axis stage control knobs, to ensure there is no interference in the movement of either knob.

Adjust the Review Control Position

The Review Control may be positioned closer or further from the stage controls via an adjustment slot. See Figure 2-5.

Using the Allen screwdriver that comes with the Integrated Imager (see Figure 1-4), loosen but do not remove the Allen screw that holds the review control to the mounting bracket.

Slide the review control along the slot to where it feels most comfortable for your hand position.

The review control may also be rotationally adjusted, if desired. When finished, tighten the Allen screw with the screwdriver.

**SECTION
F****POWER ON THE INTEGRATED IMAGER****WARNING:** Grounded Outlet

Do not power on or operate if equipment has been damaged.

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

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

It is important to apply power to the Integrated Imager system in the correct order.

1. First power on the microscope.
2. Then power on the computer.

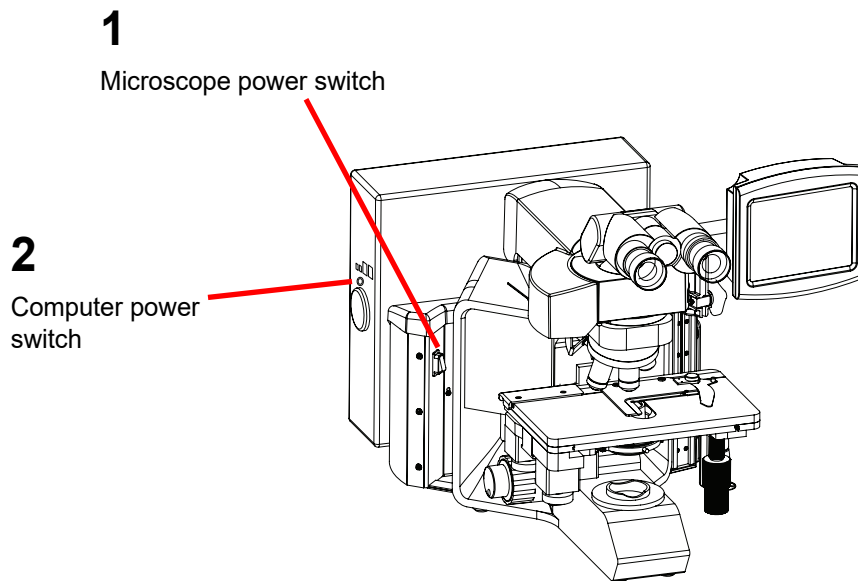


Figure 2-6 Power Switches

The power switch for the Integrated Imager is located on the back left of the microscope. Press the switch to the on position.

Then press the power button on the computer. Allow the instrument to initialize. While the instrument boots up and does self checks, a splash screen is displayed, Figure 2-7. Status messages

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during boot up are displayed on the lower left of the screen (For example, doing self test, auto backup in process, etc.) The system software version is displayed on the lower right of the screen.

WARNING: Moving Parts



Figure 2-7 Integrated Imager Startup Screen

The instrument is ready for use when the application main screen is displayed (Figure 2-8).



Figure 2-8 Application Main Screen

**SECTION
G****SYSTEM SETTINGS**

Refer to User Interface chapter, “System Settings” on page 3.8.

**SECTION
H****USER PREFERENCES**

Refer to User Interface chapter, “USER PREFERENCES” on page 3.32.

**SECTION
I****STORAGE AND HANDLING - POST INSTALLATION**

The Integrated Imager may be stored in the location where it was installed. When it is not in use, the power should be turned off. Cover the instrument with the provided microscope dust cover.

**SECTION
J****SYSTEM SHUTDOWN**

Normal Shutdown

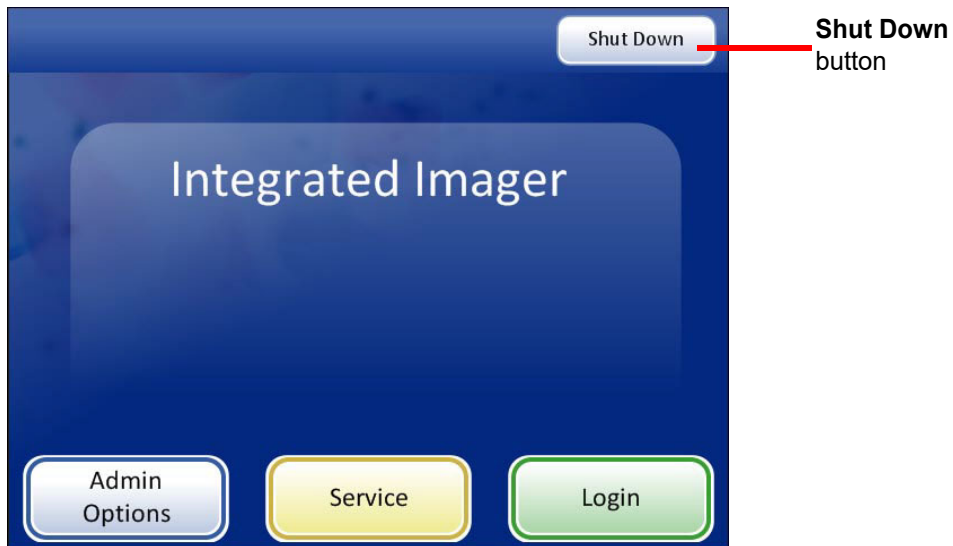


Figure 2-9 Shutdown

It is important to shut down the system in the correct order. To shut down the Integrated Imager:

1. Log out if you haven't already.
2. From the startup screen, press the **Shut Down** button in the upper right corner.

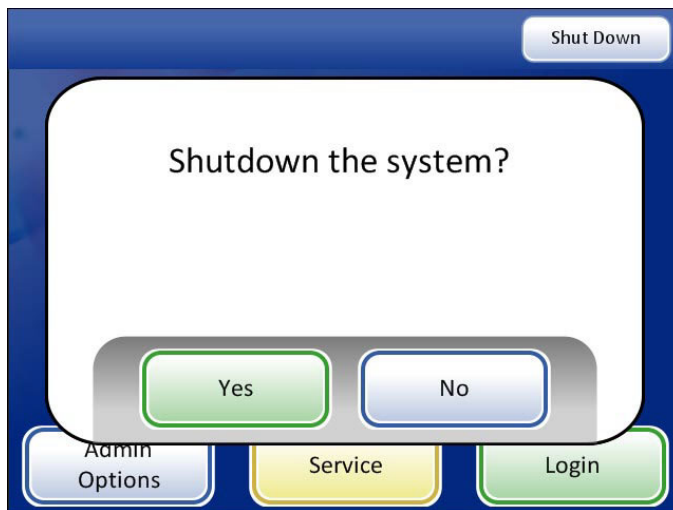


Figure 2-10 Confirm Shutdown

3. A confirmation prompt is displayed. (See Figure 2-10.)
Press the **No** button to cancel shutdown and return to the main screen.

4. Press the **Yes** button to shut down the system. This will shut down the application and turn off the computer.
5. Turn off the power switch on the instrument. (See Figure 2-6.)

Extended Shutdown

If the instrument is to be shut down for an extended amount of time or be taken out of service, shut down as described in Normal Shutdown. Remove any slides that may be on the stage. Completely remove power by unplugging the controller power cord and the computer cord from the power outlet. Cover the instrument with the provided dust cover.



2 INSTALLATION

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Chapter Three

User Interface

SECTION A OVERVIEW

The ThinPrep® Integrated Imager images prepared ThinPrep Pap Test cervical cytology microscope slides. The slides are reviewed by a cytotechnologist. The instrument may also be used as a conventional microscope, for viewing slides not associated with the ThinPrep imaging process.

The Integrated Imager enables the user to administer certain functions, such as user preferences, system settings and database backup. The user interacts with the instrument via a touch screen graphic interface.

Refer to Figure 3-1 for an overview of the workflow options.

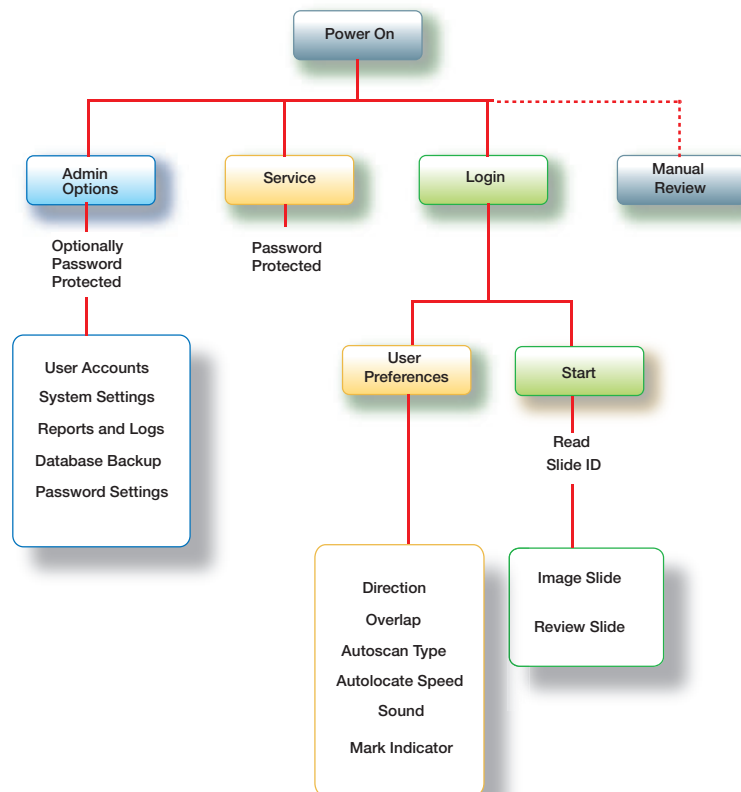


Figure 3-1 Overview of Integrated Imager Menu

3 USER INTERFACE

This chapter introduces the user interface modules of the Integrated Imager and describes the usage of each. It is recommended that users acquaint themselves with the material in this chapter before operating the instrument.

The content found in this chapter:

STARTUP	3.3
ADMINISTRATIVE OPTIONS.....	3.4
•User Accounts.....	3.4
•System Settings.....	3.8
Date	
Time	
Lab Name	
Instrument Name	
Label Format	
Language	
•Reports and Logs	3.17
•Database Backup	3.24
•Password Settings	3.26
LOGIN	3.30
MAIN MENU	3.31
USER PREFERENCES	3.32
•Scan Direction.....	3.32
•Scan Overlap.....	3.33
•Scan Type.....	3.33
•Speed	3.38
•Sound	3.40
•Mark Indicator	3.41
SAVE TO USB	3.42
START.....	3.45

SECTION
B

STARTUP



Figure 3-2 Startup Display

When the Integrated Imager is powered on and ready for use, the screen display will appear as it does in Figure 3-2.

The options available from this interface are:

- **Admin Options** - System settings and user accounts are maintained from this module. An optional password setting can be applied to access this area. Refer to “ADMINISTRATIVE OPTIONS” on page 3.4.
- **Service** - This is a password-protected module for use by Hologic service personnel only.
- **Login** - Enter a user ID to access the system for ThinPrep Imaging and Slide Review functions. Refer to “LOGIN” on page 3.30.
- **Shut Down** - This is how to turn off the Integrated Imager. Refer to “SYSTEM SHUTDOWN” on page 2.9.
- **Manual Slide Review** - Without logging in, the user may look at slides as on a conventional microscope. The stage is maneuvered by the stage control knobs. No data is retrieved or transmitted to the database.

Note: The Integrated Imager must be powered on to manually review slides. The light source, stage and X, Y axis stage control knobs are powered by the system controller.

3

USER INTERFACE

SECTION C

ADMINISTRATIVE OPTIONS

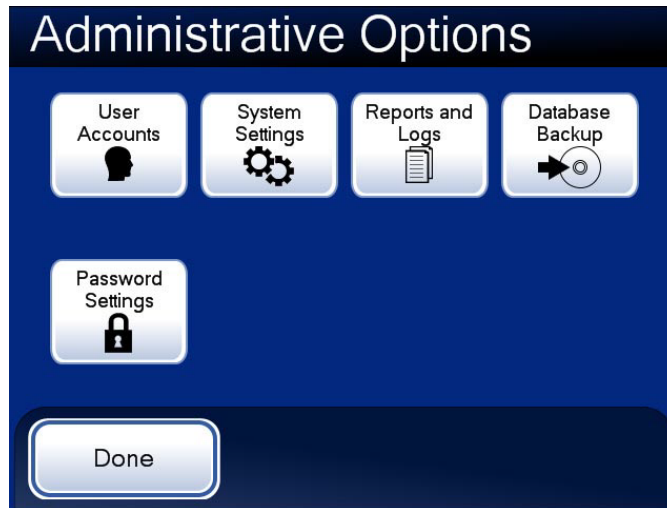


Figure 3-3 Administrative Options Screen

The Administrative Options screen allows set up and customizing of the Integrated Imager. From this menu the Operator may:

- Administer User Accounts
- Apply or change System Settings
- View system logs or save them to a USB key
- Backup the system database to a CD ROM or USB key
- Apply or remove password access to the administrative options interface.

User Accounts



Figure 3-4 User Accounts Button

The User Accounts interface is used to create and retire User IDs. A User ID is required when a person presses the **Log In** button to initiate a session with the Integrated Imager.

Information associated with a User ID becomes part of the slide data record when a slide is imaged and when a slide is reviewed, using the Integrated Imager.

Note: To maintain the integrity of the slide data records, User IDs are not to be reissued. Only unique IDs may be assigned.

When the User Accounts screen is displayed, a list of all accounts that have been created is displayed: the user’s name and the login ID number. (Refer to Figure 3-5.)



Figure 3-5 User Accounts Display

Add account

To add a new User Account, press the **Add Account** button. A keypad display appears (Figure 3-6). Enter a unique three-digit number and touch the **Continue** button. If the desired ID number is already assigned, an “invalid ID” message will appear and a new ID number must be entered.

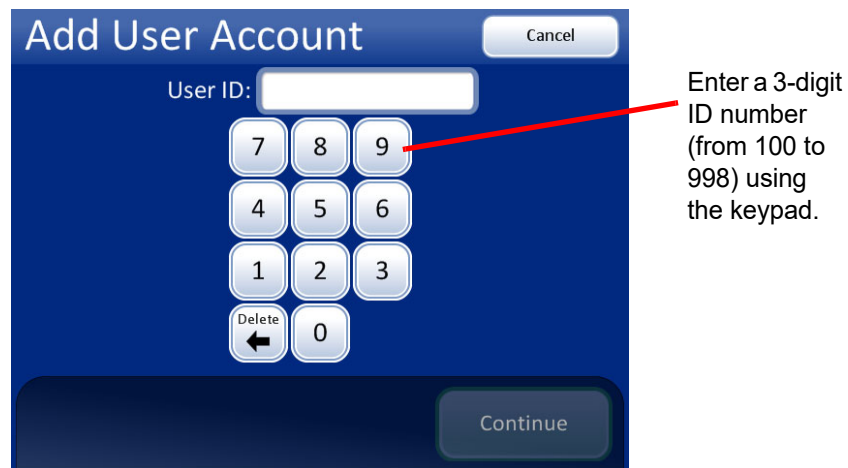


Figure 3-6 Add User Account Screen

3 USER INTERFACE

If the ID number is not assigned, the next display is a keyboard for entering the name of the User Account. See Figure 3-7.

Note: User ID numbers must be between the range of 100 to 998. Numbers beginning with a zero will cause errors.

Note: User ID 999 is reserved for Hologic service personnel. Do not use this ID.



Figure 3-7 Enter User Name Screen

Press the letter buttons to enter a first name. 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 **Delete** button to remove entered letters.

Press the **Continue** button to continue to enter the last name using the same method. Press the **Done** button when finished to return to the User Accounts main screen. The new account will be listed. See Figure 3-8.

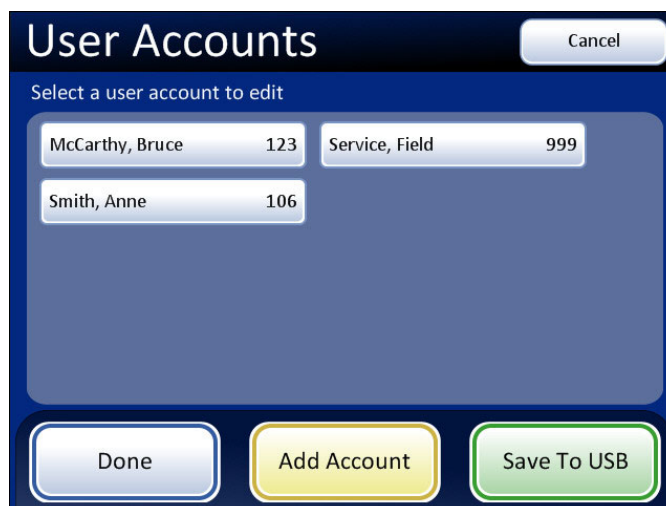


Figure 3-8 User Accounts Display

Edit/retire an account

To view or edit the status of a user account, at the User Accounts display, touch the field for that account.

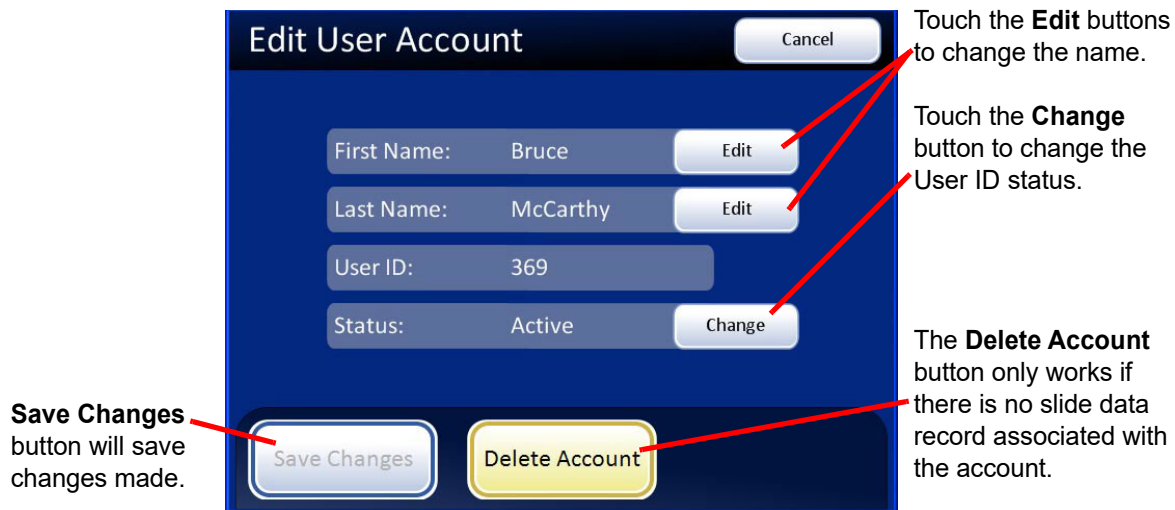


Figure 3-9 Edit User Account Screen

To edit the first or last name, press the **Edit** field on that name. The on-screen keyboard will appear. Make the desired changes and press the **Done** button.

To retire a User ID, touch the **Change** field on the Status line. The status will change to Retired.

Note: The three-digit User ID cannot be changed once it is created. It can only be retired. A User Account cannot be edited or deleted once a slide data record is associated with it (by imaging or reviewing one or more slides).

System Settings



Figure 3-10 System Settings Button

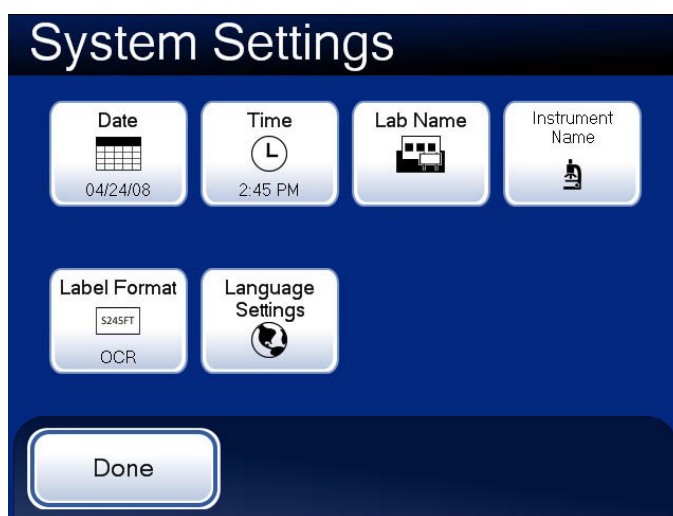
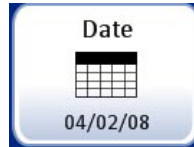


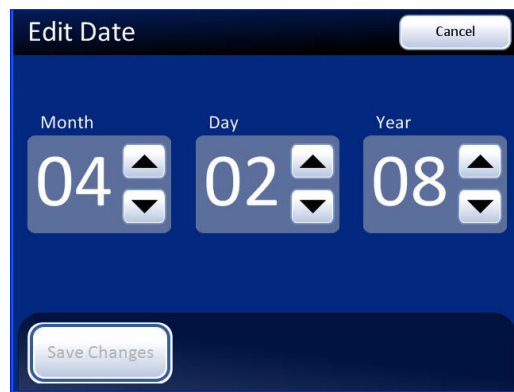
Figure 3-11 System Settings Screen

The System Settings interface allows you to set or update Integrated Imager settings. The following parameters can be set:

- Date
- Time
- Lab Name
- Instrument Name
- Label Format
- Language

Set date**Figure 3-12 Set Date Button**

To change the date (month, day, year) touch the up/down button for that field until the desired value is displayed. Press the **Save Changes** button to return to the System Settings screen. See Figure 3-13.

**Figure 3-13 Edit Date Screen**

Note: Depending on which language has been selected, the order of month and day on the display may change to reflect customary usage.

Set time



Figure 3-14 Time Button

To change the time (hour, minute, meridian), touch the up/down button for that field until the desired value is displayed. For the meridian, press the AM or PM button, as appropriate. Press the **Save Changes** button to save and return to the System Settings screen. See Figure 3-15.

Note: Depending on which language has been selected, the clock on the display may change from 12 hour to 24 hour, to reflect customary usage.

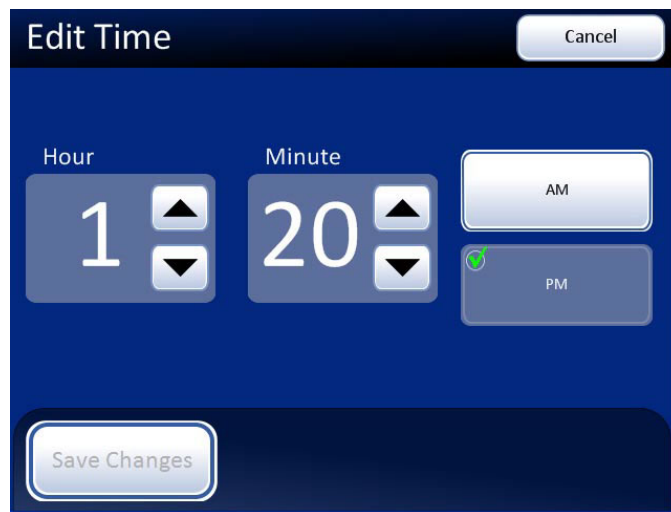


Figure 3-15 Edit Time Screen

Lab name

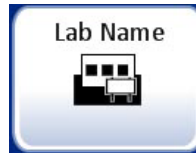


Figure 3-16 Lab Name Button

To enter or edit a name for the facility at which the Integrated Imager is located, press the **Lab Name** button. Press the letter buttons to enter a name, up to 20 characters long. See Figure 3-17. 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 **Delete** button to remove entered letters.

Press the **Switch Keys** button to display a keypad screen to enter numbers. Switch between keyboard and keypad as often as desired before saving changes.



Keyboard Display

- Shift** for a capital letter
- Delete** to remove entries
- Switch Keys** to display keypad
- Cancel** to return to System Settings screen. Reverts to previous entry (if any)
- Continue** to save the entry and return to System Settings screen



Keypad Display

- Type in numbers
- Delete** to remove entries
- Switch Keys** to display keyboard
- Cancel** to return to System Settings screen. Reverts to previous entry (if any)
- Continue** to save the entry and return to System Settings screen

Figure 3-17 Edit Lab Name Keyboard and Keypad Screens

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USER INTERFACE



Figure 3-18 Enter Lab Name Example

Press the **Continue** button to save and return to the System Settings screen.

Note: If a lab name is used, the name will appear on every report that is generated by the Integrated Imager (usage history, system errors). It is not necessary to enable a lab name.

Instrument name



Figure 3-19 Instrument Name Button

To enter or edit a name for the Integrated Imager, press the **Instrument Name** button. Press the letter buttons to enter a name, up to 20 characters long. See Figure 3-20. 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 **Delete** button to remove entered letters.

Press the **Switch Keys** button to display a keypad screen to enter numbers. Switch between keyboard and keypad as often as desired before saving changes.

Press the **Continue** button to save and return to the System Settings screen.



Figure 3-20 Edit Instrument Name Screen

Label format



The Label Format button shows the current setting. (1-D barcode in this example).

Figure 3-21 Label Format Button

The camera that scans the slide label accession ID recognizes 1-dimensional or 2-dimensional barcode format (1-D or 2-D) or OCR (optical character recognition) format. It cannot use more than one format at the same time. Select the format for scanning labels and press the **Save Changes** button when done. See Figure 3-22.

Select **OCR** label format. The format is always 14 characters long (not adjustable).

Select **1D Barcode** label format.

For the 1D barcode label format, select the 1D barcode type(s) used in your facility

Select **2D Barcode** label format.

See Table 3.1, "Slide Restrictions Based on Barcode Symbology Used," on page 15 for more information.

Figure 3-22 Edit Label Format Screens

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 (which cannot be altered by the operator) at the end. The font must be 12 point OCR-A. Numbers only, no alpha characters.

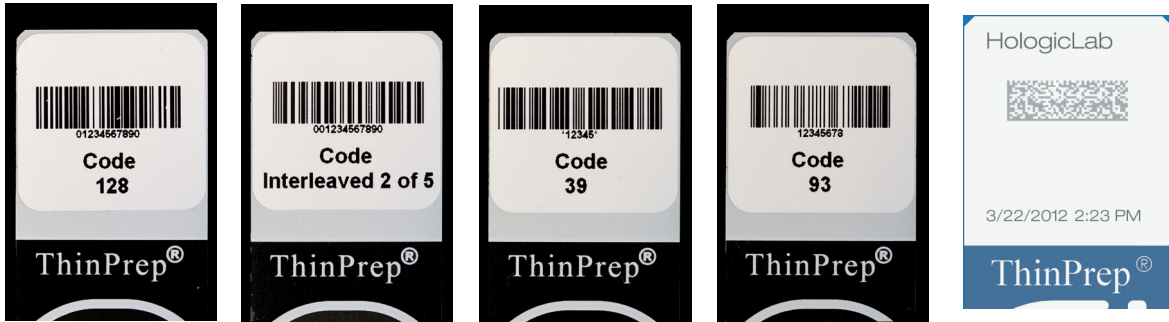
Note: For OCR format, '9999' as the last 4 digits before the CRC are reserved for field service use. Slide IDs with those reserved numbers are removed from the patient database during a service visit, so do not use that sequence.

Slide barcode labels may be 1- or 2-dimensional. 1-D barcodes must meet ANSI X3.182 specifications with a quality of grade B or better. See the table below for any restrictions. Slide labels may be printed and applied or directly printed or etched onto the slide. (See Figure 3-23.) In any case, make sure the contrast is sufficient for the scanner to read the label.

Table 3.1 Slide Restrictions Based on Barcode Symbology Used

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

3 USER INTERFACE



1-Dimensional barcode examples

2-D barcode example

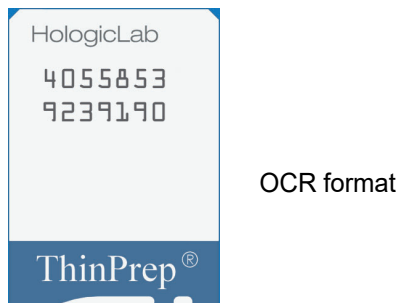


Figure 3-23 Examples of Barcodes on a ThinPrep Slide

Language



Figure 3-24 Language Settings Button

Press the **Language Settings** button to change the language that is displayed on the user interface and on the reports.

Press the button for the desired user interface language and press **Done** to apply it. (English is selected in this display.)



Cancel button, to quit the language screen and return to the Settings display. No changes apply.

Figure 3-25 Select Language Screen

Press the button for the desired language, and press the **Done** button to immediately apply the setting.

Reports and Logs



Figure 3-26 Reports and Logs Button

The Reports and Logs interface presents system information in three forms:

- System Errors - a log of all of the 200 most recent system errors, from oldest to most recent. After 200 errors have been logged, the newest are added and the oldest are purged.
- Usage History - Lists the number of slides imaged and reviewed on the Integrated Imager
- Slide search - a specific slide ID or range of IDs and the associated slide data can be found in the database using this search.

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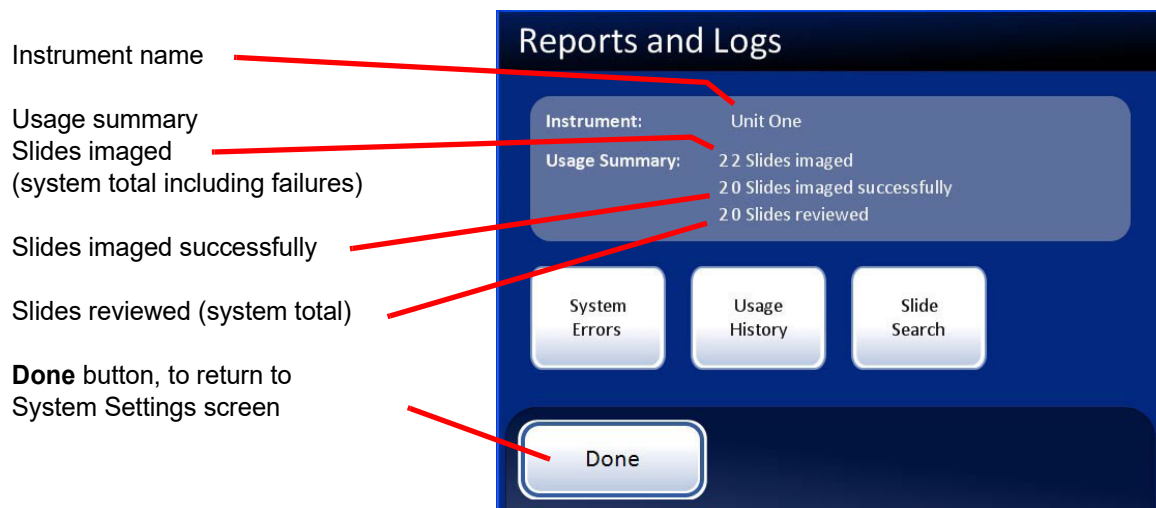


Figure 3-27 Reports and Logs Screen

System errors

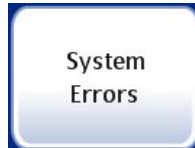


Figure 3-28 System Errors Report Button

The System Errors report displays all of the error conditions encountered during slide imaging and review (200 are stored at one time). See Figure 3-29. The events are listed from most recent to oldest. Use the up/down arrows to scroll through the list using the touch screen. To download this report, place a USB key in the appropriate port of the computer and press the **Save to USB** button.



Figure 3-29 System Events Report Screen

Usage history



Figure 3-30 Usage History Report Button

The Usage History report provides a Summary or a Detailed report of all activity on the Integrated Imager within a specific time period.

Press the **Usage History** button. First you will select if the usage history report is for a one-week time period or for a one-day time period. See Figure 3-31.

3

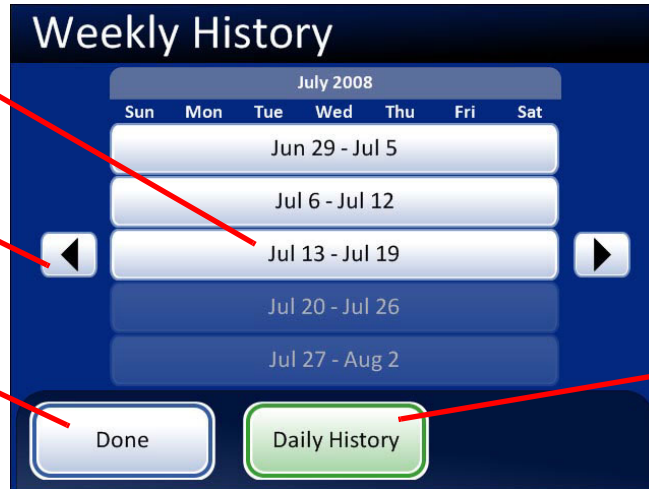
USER INTERFACE

Weekly History Screen

Select which week to view by touching on any week.

Use the scroll arrow to change to a different month.

Press **Done** to view the report.



Daily History button, to switch to Daily History screen

Daily History Screen

Select which day to view by touching the date.

Use the scroll arrow to change to a different month.

Press **Done** to view the report.



Weekly History button, to switch to Weekly History screen

Figure 3-31 Weekly/Daily History Selection Screens

Press the **Done** button on the History screen to generate the report, displayed on the following page. The default view is the Usage Summary screen. It can be changed to the Usage Details screen.



Figure 3-32 Usage Summary Screen (A Weekly History is Shown)

The Usage Summary screen lists a total of all slides imaged in that week (or day) and how many of those slides were imaged successfully.

Note: Slides not imaged successfully may have failed due to a biological quality which prevented successful imaging, or a fiducial mark error or a system error. Cancellation by the operator during imaging is not included in the total.

The Review Summary lists:

- All users logged on to the Integrated Imager that week (or day)
- How many slides in total were reviewed
- How many slides were Auto Locate only in the “FOV Only” column (fields of view presented by the Integrated Imager)
- How many slides were a full slide review in the “Full Review” column (Auto Locate plus Auto Scan of the entire cell spot)

This summary may be saved to a USB key by pressing the **Save to USB** button.

A detailed list of the slides reviewed is displayed by pressing the **View Details** button. Refer to the following section.

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USER INTERFACE



Figure 3-33 Usage Detail Screen (A Weekly History is Shown)

The Usage Details displays all slide review activity for that week (or day). For every slide, it lists:

- The slide ID number
- Date and time the slide was imaged
- The status of the image (OK or Fail)
- The user ID (who was logged into the Integrated Imager)
- Date and time the review took place (the time being the completion time)
- Full review of the slide conducted ()

This summary may be saved to a USB key by pressing the **Save to USB** button.

Slide search



Figure 3-34 Slide Search Report Button

A specific slide number or range of slide numbers can be searched for in the database. After pressing the **Slide Search** button, a keypad will display. See Figure 3-35.



Figure 3-35 Enter Slide ID to Begin Search

To search for a specific slide, enter the slide ID using the keypad buttons. Switch between keypad and keyboard, if the ID contains alpha and numeric characters. Press the **Continue** button when ready to perform the search.

To search for a range of slides, enter the first digits of the slide ID that they have in common. For example, enter "01234" and then press the **Done** button.

The database retrieves the slide ID or range of IDs and lists them as shown below, Figure 3-36.



Figure 3-36 Slide Search Report Screen

The slide IDs are listed with any available data for that ID:

3 USER INTERFACE

- The slide ID number
- Date and time the slide was imaged
- The status of the image (“OK” for successful; “Fail” for unsuccessful)
- The user ID (who was logged onto the Integrated Imager)
- Full review of the slide conducted - yes or no

This summary may be saved to a USB key by pressing the **Save to USB** button.

Database Backup

The Integrated Imager automatically makes a scheduled backup of the database every night at 2:00 am. If the instrument is turned off, then a backup of the database is made the next time it is turned on, if 2:00 am has passed. The automatic backup is stored internally in the system.

If desired, the operator can make a backup of the database onto a CD ROM or USB key.



Figure 3-37 Database Backup Button

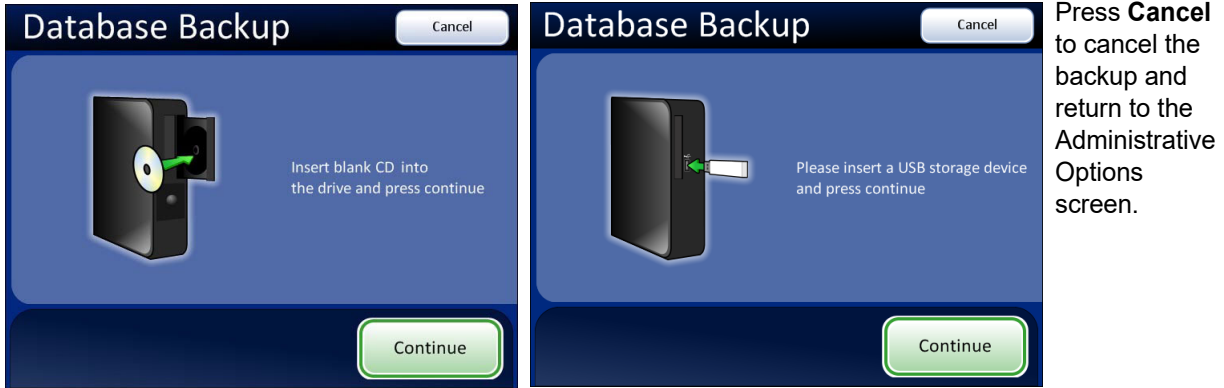
From the Administrative Options screen, touch the **Database Backup** button to display the backup screen.



Select the media type, **CD** or **USB**.

Press **Cancel** to cancel the backup and return to the Administrative Options screen.

Figure 3-38 Database Backup, Select Backup Type



Press **Cancel** to cancel the backup and return to the Administrative Options screen.

After loading a blank CD or a USB storage device into the drive, press **Continue**.

Figure 3-39 Database Backup Screen

To open the CD drive, press the release button on the drive door. (See Figure 3-40.)

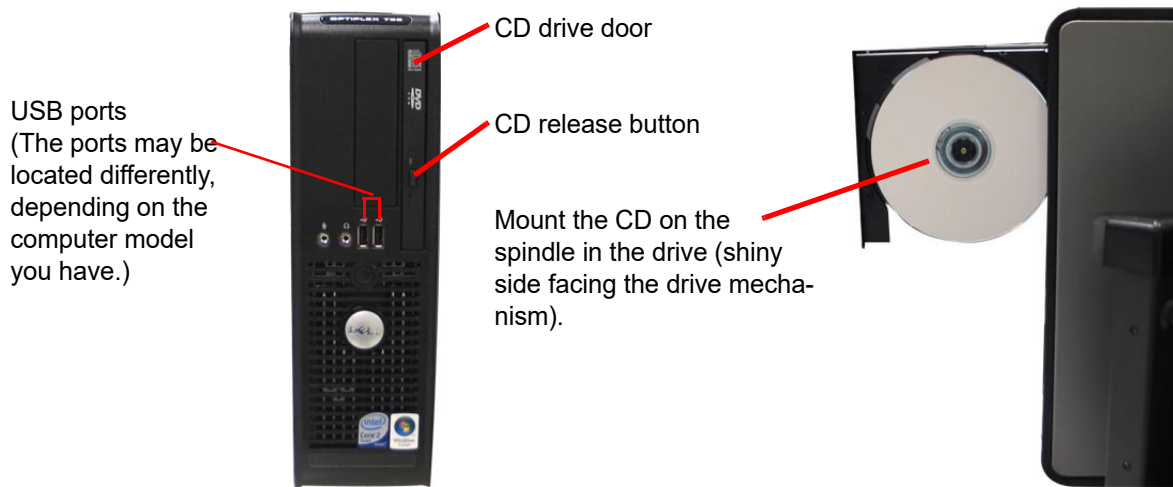


Figure 3-40 USB and CD: Open CD Drive - Insert Disc

As prompted, insert a blank disk into the CD drive and close the door, or insert a USB storage device into a USB port. The Integrated Imager will back up to the first USB storage device detected by the Integrated Imager. It is recommended to have only one USB device connected to the Integrated Imager at a time.

Note: The CD drive of this computer only writes to a CD ROM (do not use a DVD disc, the system will not recognize it).

Note: The CD ROM must be blank, or the system will reject it. You cannot accumulate backups onto a single disk. The USB storage device, however, does not need to be blank. The USB storage device only needs adequate space to store the database backup.

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Press the **Continue** button. The system checks the media, writes the data and displays a backup completed message when finished. See Figure 3-41.

The Integrated Imager can use another USB storage device to save reports. Refer to “SAVE TO USB” on page 3.42.

Refer to the Chapter 6, Troubleshooting, if any other messages display during backup.

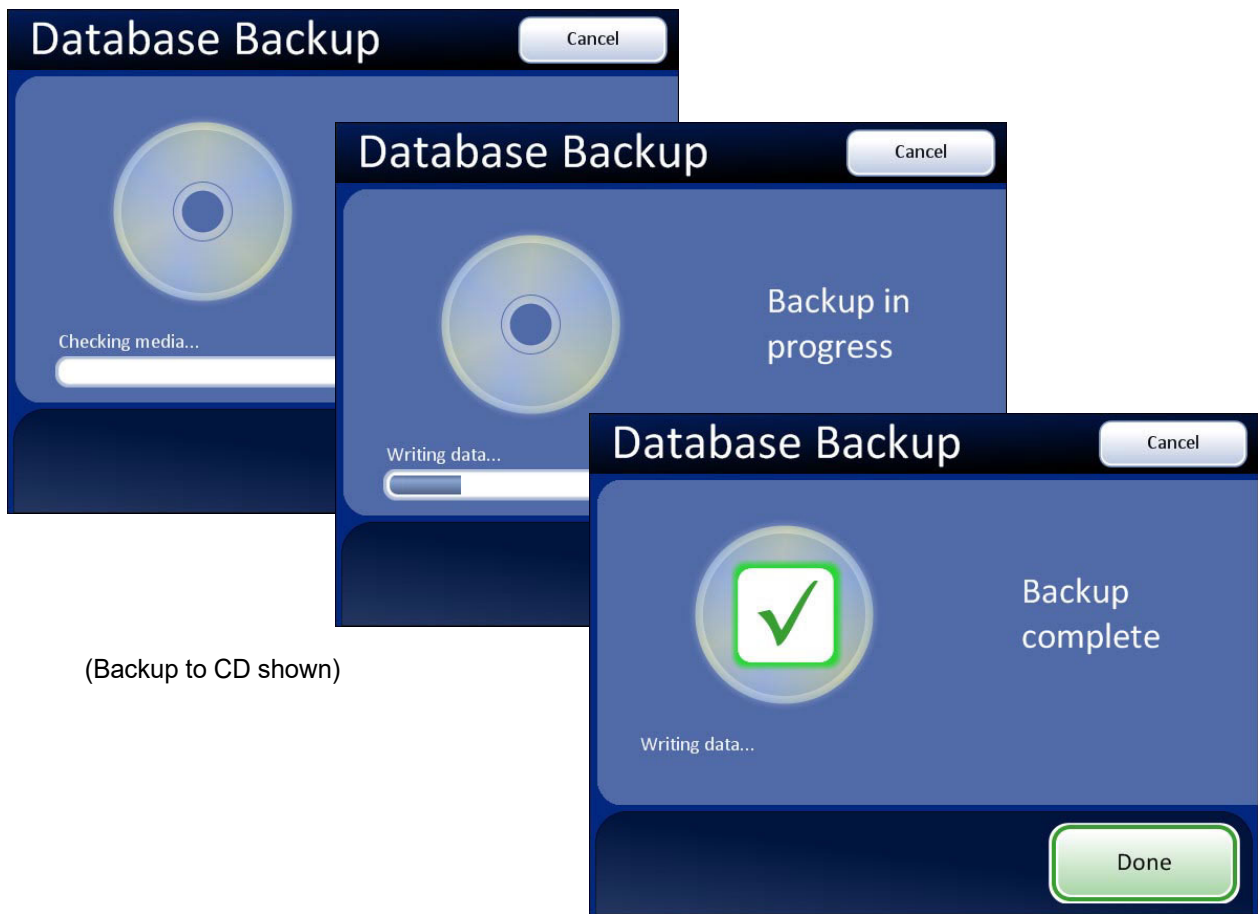


Figure 3-41 Database Backup

Password Settings



Figure 3-42 Password Settings Button

An administrative password may be set to limit access to the Administrative Options screen. Only by entering the correct password can the screen be displayed and used.

Press the **Password Settings** button to display the Password screen (Figure 3-43).



Figure 3-43 Password Settings Screen

To Set a Password



Figure 3-44 Password Settings Keyboard

Press the **Enabled** button. The keyboard screen will appear and prompt for a password to be entered. The word may be up to 20 alpha characters long and it is case-sensitive.

Press the **Continue** button and the display returns to the Password Settings screen. The password is visible in the password field.

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Figure 3-45 Password Enabled

Once Admin Options screen is exited, the system displays a keyboard and prompts for a password to access that screen. See Figure 3-46.

If the password is lost or forgotten, contact Hologic Technical Support (Chapter 7, Service Information).



Figure 3-46 Password Required

Change a Password

Enter the Admin Options screen by entering the required password. Press the **Password Setting** button to view the password screen. (See Figure 3-45.)

Press the **Change** button and type the new word using the keyboard that appears. Press the **Done** button to set the new password and return to the System Settings screen.

Remove a Password

To remove a password, access the Admin Options screen using the current password. At the Password Settings screen, press the **Disabled** button. Then press the **Done** button to accept the change.



Figure 3-47 Disable the Password

Note: The password is removed. If an admin password is used later, the password has to be set up again, as described in “To Set a Password” on page 3.27.

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SECTION D LOGIN



Figure 3-48 Login Screen

To access the Imaging and Slide Review functions of the Integrated Imager, a three-digit operator ID must be entered.

Press the digits on the display keypad, and touch **Continue** when done.

Use the **Delete** key to clear mistakes. To cancel login and return to the startup screen, press the **Cancel** button.

As soon as the number is entered, the system database checks that it is a valid operator ID. Any user preferences that have been saved with that ID will be active.

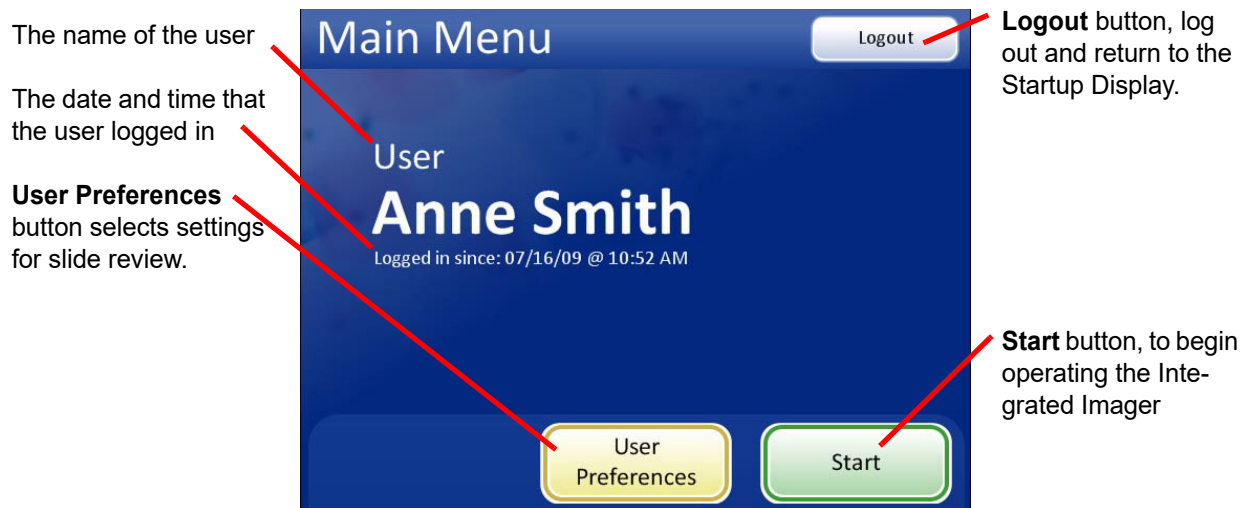
The message "Invalid User ID" might occur if the three-digit number was entered incorrectly, if there is no user ID with that number, or if that number has been retired.

See "Add account" on page 3.5 for creating a user ID.

See "User Preferences" on page 3.32 for selecting user preferences.

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E

MAIN MENU, (Logged In)

**Figure 3-49 Main Menu Screen**

Successful login will display the main screen. The name of the user who logged in is shown on the screen. Just below the name is the date and time that login started. While a user is logged in, the system will revert to the main screen after completing any services (slide imaging & review, setting preferences). The options available from this interface are:

- **User Preferences** - this module allows the cytotechnologist to adjust some of the parameters for automated slide review, such as scan direction, overlap, type, speed and sound alerts. Refer to "USER PREFERENCES" on page 3.32.
- **Start** - to begin using the Integrated Imager to image and review a slide, press the **Start** button. Refer to Chapter 4, Operation.
- **Logout** - to end the session with the Integrated Imager, press the **Logout** button. The system will return to the Startup screen. The instrument may be powered off or a user may log in to begin a new session.

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USER INTERFACE

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USER PREFERENCES

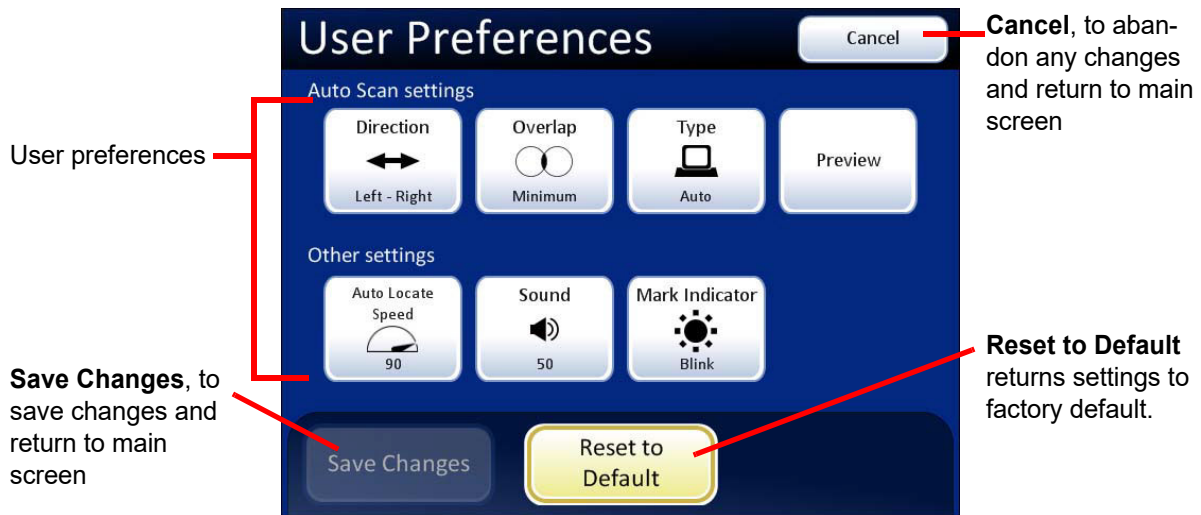


Figure 3-50 User Preferences Screen

The User Preferences allow the cytotechnologist to customize preferences for Slide Review. These are settings for direction of scan, overlap, Auto Scan and maximum speed for Auto Locate, plus audible beep volume and mark indicator. Once settings have been adjusted, they will remain from session to session until they are changed again. The preferences are associated with each user ID. If there are multiple users of an Integrated Imager, the preferences associated with the ID the will be uploaded at Login.

Auto Scan Settings

Direction



Figure 3-51 Select Stage Movement Direction

The direction of the stage movement during Auto Scan may be selected. Press the **Direction** button to toggle between the choices of Direction Up-Down or Direction Left-Right. (Figure 3-51.) To view the selection through the eyepieces, ensure the 10X objective is in position, load a slide in the slide holder for reference, and press the **Preview** button.

From the User Preferences screen, press **Save Changes** to retain your preference now, or continue to set your next preference.

Overlap



Figure 3-52 Select Auto Scan Overlap

Auto Scan overlap may be selected. This sets how much the fields of view overlap from field to field or row to row during Auto Scan of the cell spot. (Default is minimum.)

Press the **Overlap** button repeatedly to change between the choices of minimum, medium or maximum overlap. (Figure 3-52.) To view the selection through the eyepieces, ensure the 10X objective is in position, load a slide in the slide holder for reference, and press the **Preview** button.

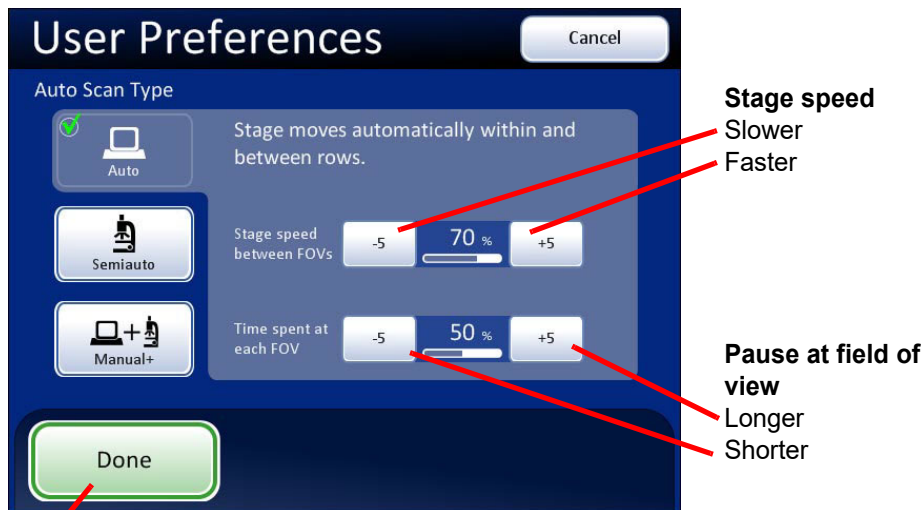
From the User Preferences screen, press **Save Changes** to retain your preference now, or continue to set your next preference.

Type

The Auto Scan function presents the entire cell spot in a defined path at 10X magnification. Three types of scan motion are selectable:

- Automatic Start/Stop
- Semiautomatic Start/Stop
- Manual +

Auto Scan - Automatic Start/Stop



Done. Save setting adjustments and return to User Preferences screen.

Figure 3-53 Select Auto Start/Stop Scan

Scan motion is initiated by the Integrated Imager and consists of a series of discrete, overlapping fields of view, including a pause at each view.

The movement of the stage speed from field of view (FOV) to field of view may be adjusted faster or slower by repeatedly pressing the **-5** or **+5** buttons to slow or increase the speed. (Figure 3-53.)

The length of pause at the field of view may be adjusted to be shorter or longer by repeatedly pressing the **-5** or **+5** buttons to define the pause. (Figure 3-53.)

To preview the setting, press the **Done** button and then press the **Preview** button on the User Preferences screen.

To view the selection through the eyepieces, load a slide in the slide holder for reference, ensure the 10X objective is in position, and press the **Preview** button. Observe the stage movement.

To pause the scan, scroll the review control forward or press the **Pause** button on the touch screen. Scroll forward again to resume scanning. Also, changing the magnification will cause the scan to pause. To resume the scan, scroll the review control forward again or press the **Resume** button on the touch screen.

During scan pause, the X, Y axis stage controls are available to move the view about the cell spot. Upon resuming, the area of review will return to the part of the cell spot where you left off and continue to present the rest of the cell spot. The display on the touch screen is shown below.

Press the **Cancel Scan** button on the touch screen to stop the preview.

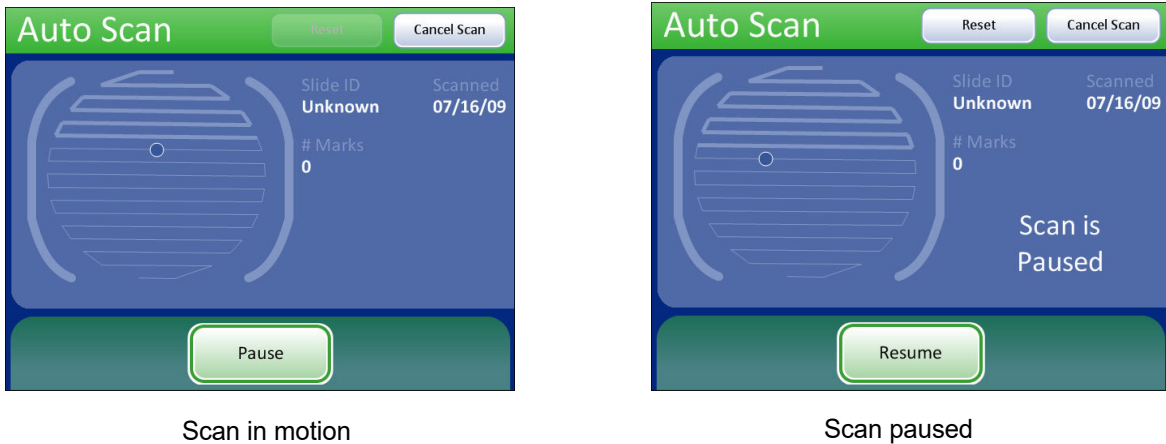
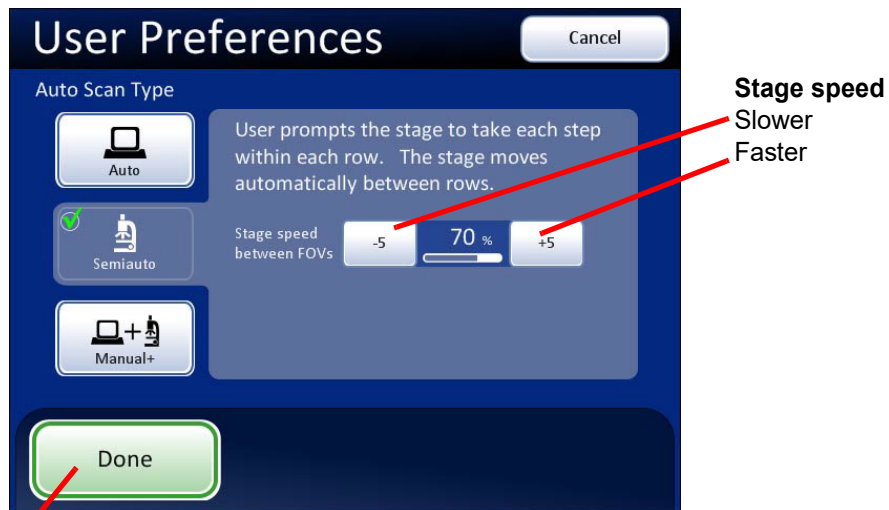


Figure 3-54 Automatic Scan Mode Preview

Continue to adjust and preview the stage speed and length of pause for viewing until they are satisfactory. Press the **Done** button to save the settings and return to the User Preferences screen.

From the User Preferences screen, press **Save Changes** to retain your preference now, or continue to set your next preference.

Auto Scan - Semiautomatic Start/Stop



Done. Save setting adjustments and return to User Preferences screen.

Figure 3-55 Select Semiautomatic Start/Stop Scan

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Using the **Next** function on the hand control, the user initiates the scan motion, which is a series of discrete, overlapping fields of view. The Auto Scan stops at each field of view and remains there until the user presses the **Next** function again.

Note: The **Next** and **Previous** functions are also available as buttons on the touch screen.

The movement of the stage speed from field of view (FOV) to field of view may be adjusted faster or slower by repeatedly pressing the **-5** or **+5** buttons to slow or increase the speed. (Figure 3-55.)

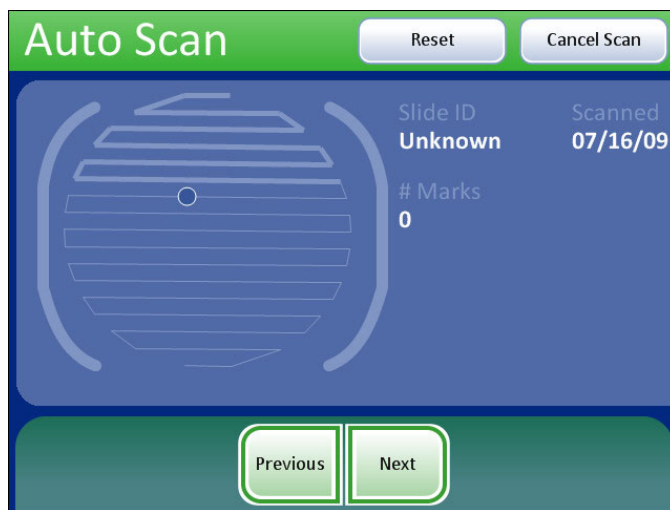
To preview the setting, press the **Done** button, and then press the **Preview** button on the User Preferences screen.

To view the selection through the eyepieces, load a slide in the slide holder for reference, and press the **Preview** button. Observe how the stage advances each time the review control is scrolled forward (Next) or backward (Previous).

In between stage movements, the X- and Y-axis stage controls are available to move about the cell spot. Upon resuming, the field of view will return to the part of the cell spot where you left off, and the scan will resume along the row.

Press the **Cancel Scan** button on the touch screen to stop the preview.

The display on the touch screen is shown below.



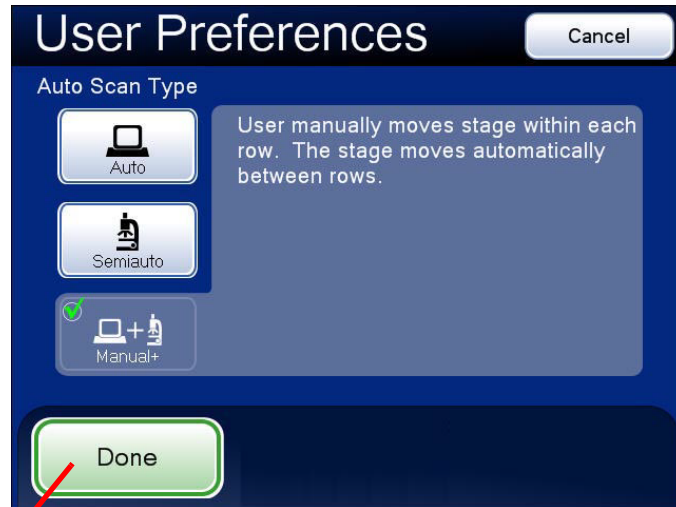
Scan is always paused. It only advances when the **Next** or **Previous** function is activated via review control or touch screen.

Figure 3-56 Semiautomatic Scan Mode Preview

Continue to adjust and preview the stage speed until it is satisfactory. Press the **Done** button to save the settings and return to the User Preferences screen.

From the User Preferences screen, press **Save Changes** to retain your preference now, or continue to set your next preference.

Auto Scan - Manual +



The user manually moves along the row using the stage control knob and pauses as desired. No speed settings are necessary.

Done. Save setting adjustments and return to User Preferences screen.

Figure 3-57 Select Manual + Auto Scan

The user provides the scan motion by using the X- or Y-axis stage control knob (depending on which Scan Direction has been selected) to traverse the row. The other knob is disabled. At the end of the row, the stage automatically moves to the next row.

To preview the setting, press the **Done** button, and then press the **Preview** button on the User Preferences screen.

To view the selection through the eyepieces, load a slide in the slide holder for reference, and press the **Preview** button. Observe movement of the stage as the X- (or Y-) axis stage control knob is moved.

Pause the scan in one of three ways:

- Scroll the review control forward
- Change the magnification
- Touch the **Pause** button on the touch screen

Both axis stage control knobs will be activated and the user can move about the cell spot.

Note: The Auto Scan must be resumed from pause in order to complete the scan.

To resume Auto Scan:

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- Scroll the review control forward
- Or touch the **Resume** button on the touch screen

Press the **Cancel Scan** button on the touch screen to stop the preview.

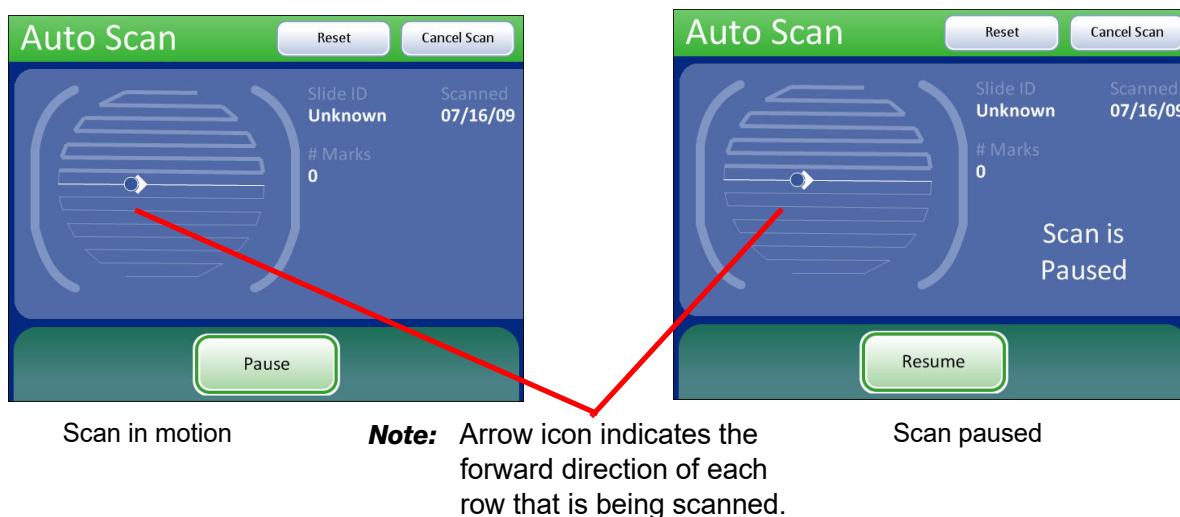


Figure 3-58 Manual + Scan Mode Preview

Press the **Done** button to save the setting and return to the User Preferences screen.

From the User Preferences screen, press **Save Changes** to retain your preference now, or continue to set your next preference.

Auto Locate Speed



The Auto Locate Speed setting adjusts how quickly the stage moves from field to field during presentation of the 22 fields of view. The stage moves to each field of view and stops until the user advances using the **Next** function.

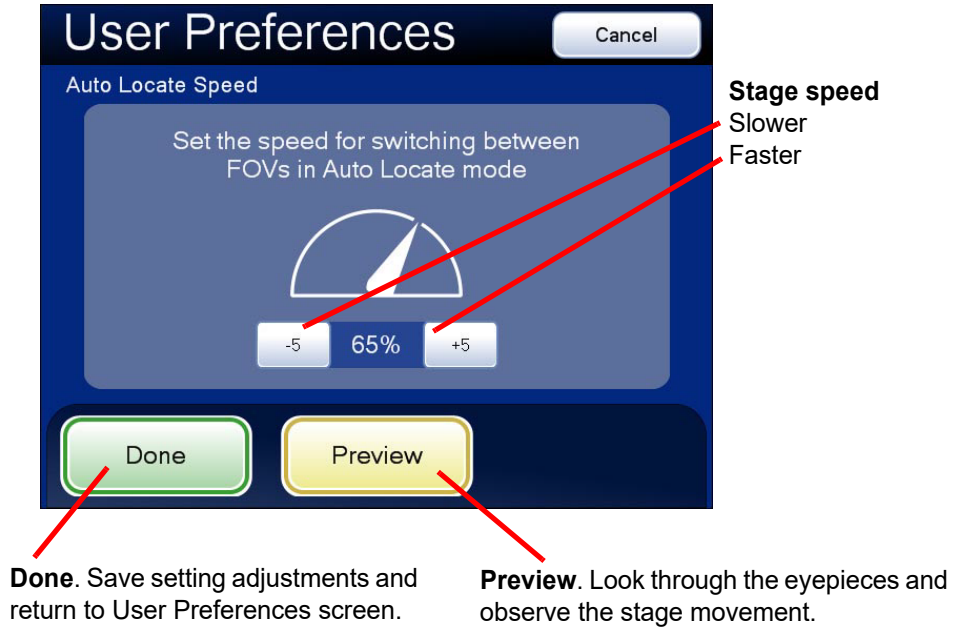


Figure 3-59 Adjust Auto Locate Speed

The movement of the stage speed from field of view (FOV) to field of view may be adjusted faster or slower by repeatedly pressing the -5 or +5 buttons to slow or increase the speed. (Figure 3-59.)

To view the selection through the eyepieces, load a slide in the slide holder for reference, and press the **Preview** button. Observe the speed at which the stage advances. The preview displayed on the touch screen is shown below.



Figure 3-60 Auto Locate Speed Preview Screen

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To stop the preview, press the **Cancel** button on the touch screen.

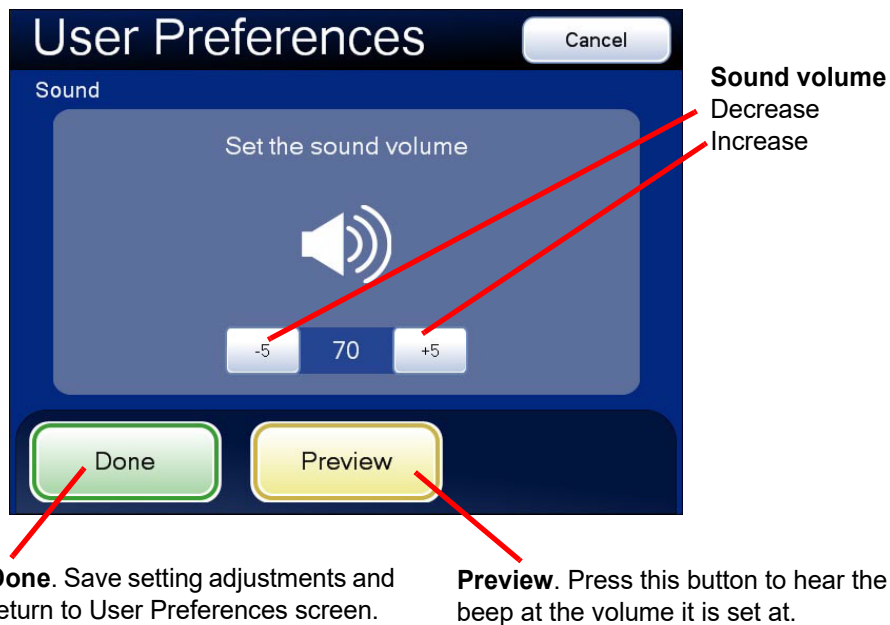
Continue to adjust and preview the stage speed until it is satisfactory. Press the **Done** button to save the settings and return to the User Preferences screen.

From the User Preferences screen, press **Save Changes** to retain your preference now, or continue to set your next preference.

Sound



The volume of the audible beep may be increased or decreased.



Done. Save setting adjustments and return to User Preferences screen.

Preview. Press this button to hear the beep at the volume it is set at.

Figure 3-61 Adjust Sound Screen

Press the **Preview** button to hear the beep.

The volume of the beep may be adjusted quieter or louder by repeatedly pressing the **-5** or **+5** buttons to decrease or increase the volume. (Figure 3-61.) Test it by pressing the **Preview** button to hear the beep. To disable the audible beep, adjust it to its lowest setting.

Continue to adjust and preview the beep volume until it is satisfactory. Press the **Done** button to save the setting and return to the User Preferences screen.

From the User Preferences screen, press **Save Changes** to retain your preference now, or continue to set your next preference.

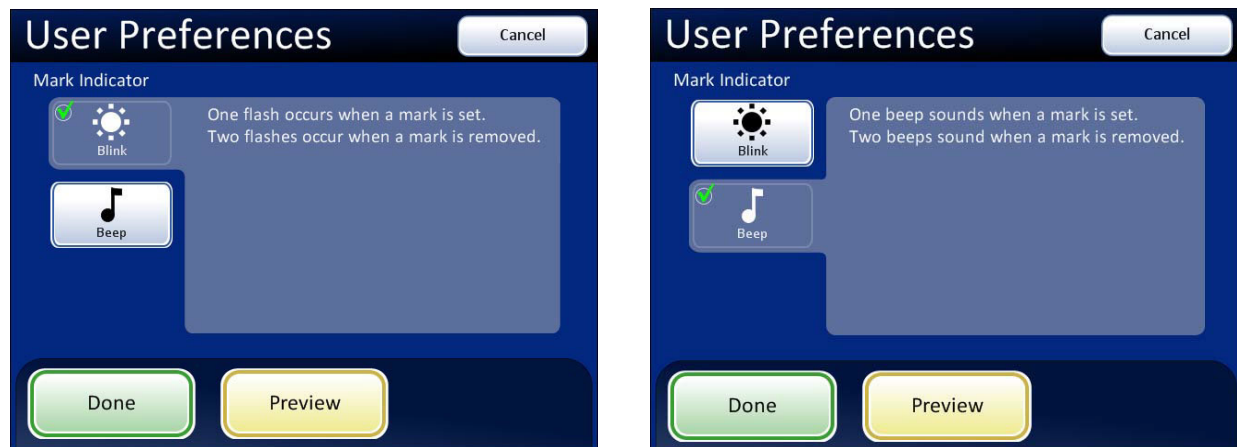
Note: If you prefer not to hear a beep, set the volume to its lowest limit.

Mark Indicator



Figure 3-62 Mark Indicator Button

When an electronic mark is made via the review control or the touch screen, it is indicated by the instrument either as a blink (seen through the binoculars as the light source turning off then on) or as a beep (heard as an audible alert). Use this setting to select which indicator is enabled.



Mark Indicator - blink selected

Mark Indicator - beep selected

Figure 3-63 Select Blink or Beep Mark Indicator

When the review control or touch screen is pressed to make a mark, the indicator will blink or beep once. If it is pressed again to unmark the area, the indicator blinks or beeps twice, to differentiate.

Note: The volume of the beep is the same as the sound volume setting in the user preferences.

Therefore, if an audible beep is desired to indicate end of Auto Locate and end of Auto Scan, it will also be heard for mark/unmark.

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If the audible beep is turned too low to hear, then it will not be heard for Auto Locate, Auto Scan and mark/unmark.

Reset to Default



Figure 3-64 Reset to Default Button

User preferences may be reset to the factory defaults by pressing the **Reset to Default** button. System defaults are:

- Direction - left/right
- Overlap - minimum
- Auto Scan type - Auto Start/Stop
- Auto Locate speed - 90% (of stage movement capability)
- Stage speed between fields of view - 50%
- Time spent at each field of view - 50%
- Sound - 50% of beep volume
- Mark Indicator - blink

SECTION G

SAVE TO USB

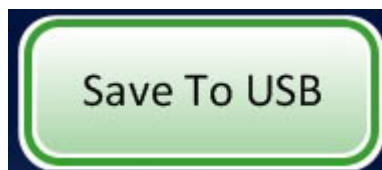


Figure 3-65 Save to USB Button

Any of the modules that report some kind of database query offer a **Save to USB** function, in order to download the report to a USB key, if desired. These are:

- User Accounts
- System Events
- Usage Summary
- Slide Search

The Integrated Imager has two USB ports available for use. Either may be used. (See Figure 3-66.)

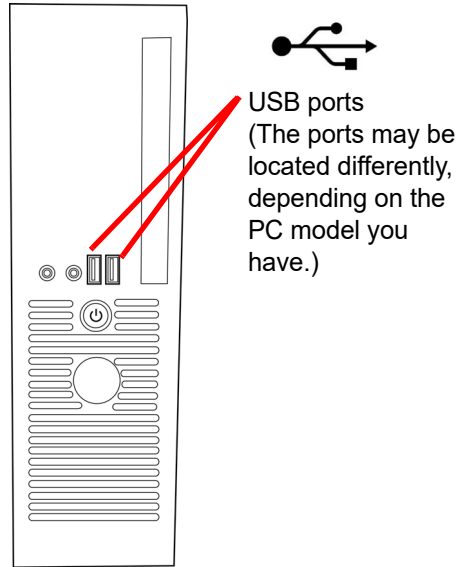


Figure 3-66 USB Drive Ports

Insert a USB key into either of the ports on the computer. From the touch screen, press the **Save to USB** button. A message indicates that the report was saved.

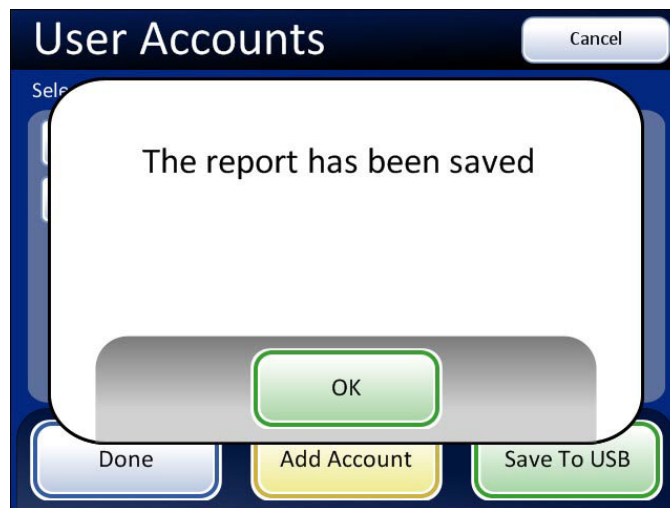


Figure 3-67 Report Has Been Saved Message

The USB key can then be removed and taken to any computer.

The system creates a folder titled “IIReports” on the USB device. Each report is written to this folder. Reports are automatically named by the convention of “Report type - Instrument Name - Year Month Day Hour Minute Second. XML.” This is illustrated below. A style sheet file IIReports.xml” is also written to the USB key. This is needed to view the reports on a browser.

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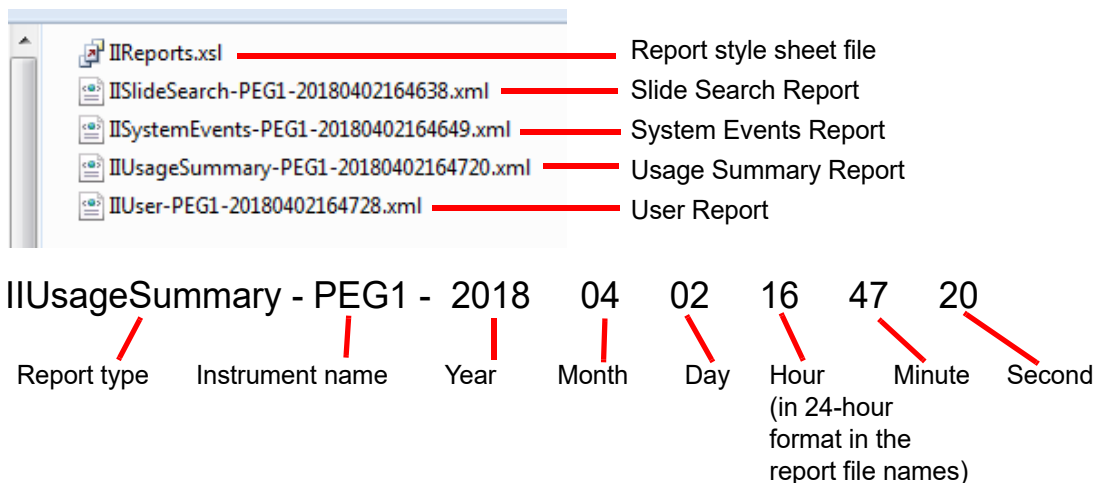


Figure 3-68 Reports Saved to USB Key

Reports may be downloaded to the USB device any time the instrument is idle. Because the report names have a date/time stamp, they will be added to the same folder and not overwrite previous reports of the same type.

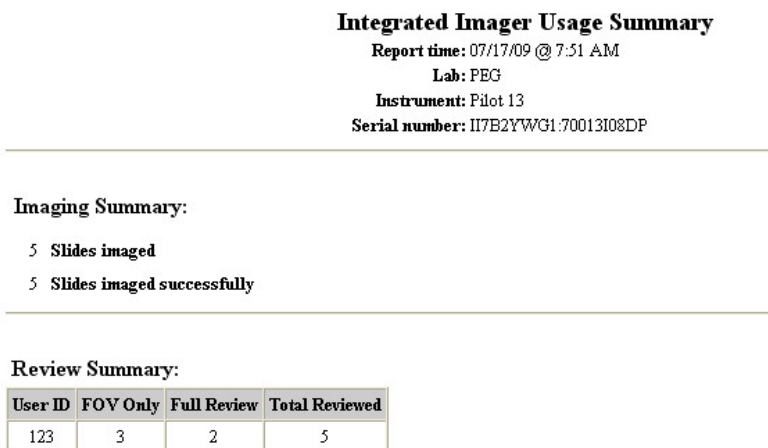


Figure 3-69 Example of a Usage Summary Report

The Integrated Imager can use a USB storage device to save the database backup. Refer to “Database Backup” on page 3.24.

SECTION
H**START (Begin using the Integrated Imager)**

Press the **Start** button to begin imaging and review of a slide.

Refer to Chapter 4, Operation for instructions on operating the Integrated Imager.

The logo for Section 3, 'User Interface', features a large blue number '3' centered within a circular arc. The arc is multi-colored, transitioning from yellow at the top to orange, then red, and finally purple at the bottom. To the right of the circle, the words 'USER INTERFACE' are written in a blue, serif, all-caps font.

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Chapter Four

Operation

SECTION A

OVERVIEW

The ThinPrep[®] Integrated Imager images prepared ThinPrep Pap Test cervical cytology microscope slides. The slides are reviewed by a cytotechnologist. The instrument may also be used as a conventional microscope, for viewing slides not associated with the ThinPrep imaging process.

Slide Preparation

Proper slide preparation is critical to successful imaging of the ThinPrep Pap Test microscope slide. Prior to being imaged on the Integrated Imager, the slide must be:

- Processed on a ThinPrep[®] 2000 System or a ThinPrep[®] 5000 Processor using microscope slides for use with the Integrated Imager (has fiducial marks)
- Stained, using ThinPrep Stain
- Coverslipped (allowed to dry thoroughly)
- Labeled in a format for use with the Integrated Imager

For the processes listed above, please consult the appropriate user documentation that came with the equipment.

Imaging

The Integrated Imager will automatically image a slide after scanning a valid slide accession ID that is not already in the database.

CAUTION: Do not handle the instrument during imaging.

Proper lighting and focus of the slide is critical to successful imaging. The system disables manual stage, focus and illumination controls. The operator should not interact with the Integrated Imager during the approximately 90 seconds it takes to image a slide.

Slide Review

Auto Review

In this manual, Auto Review refers to a slide review in which the Integrated Imager:

- scans the slide ID number from the slide

4 OPERATION

- communicates with the database for appropriate slide data record
- makes use of the Auto Locate function (where the 22 fields of view identified by the imaging process are presented to the cytotechnologist, CT)
- makes use of the Auto Scan function, as required or desired
- writes slide data record to the database at conclusion of slide review

(Refer to Figure 4-1 for a graphical representation of the typical slide review process.)

Subsequent Review

A slide that has undergone Auto Review may be reviewed again, making use of the Auto Locate, review and Auto Scan functions. Further electronic marks may be added (to a maximum of 30 marks on a slide), but no previous marks may be removed. The slide data record will be revised in the database at the conclusion of the review.

Note: Slides previously screened either via auto review or manually may always be examined again manually.

Manual Review

Manual Review refers to a slide review in which:

- patient slide data is not retrieved from or communicated to the database
- a review of the entire cell spot is conducted by the CT, manually operating the illumination, focus, magnification and stage movement
- there is no update of the slide data record in the database

Slide Data Record

The slide data record is the accumulation of all imaging and review events the slide encounters. The Usage Summary and Slide Search reports are generated from data that is in the slide data record. A slide data record is generated when a valid slide ID is accepted into the Integrated Imager's database. Items that are associated with the slide data record include:

- Date/time stamp when Imaging began and ended (even if imaging was unsuccessful)
- Serial number of the Integrated Imager that imaged the slide
- Fiducial mark coordinates
- Field of view coordinates
- Date/time stamp when slide review began and ended (including subsequent reviews)
- Serial number of the Integrated Imager that reviewed the slide
- Operator ID for each review of the slide (including subsequent reviews)
- Status whether Auto Scan was completed for each review
- Electronic mark coordinates

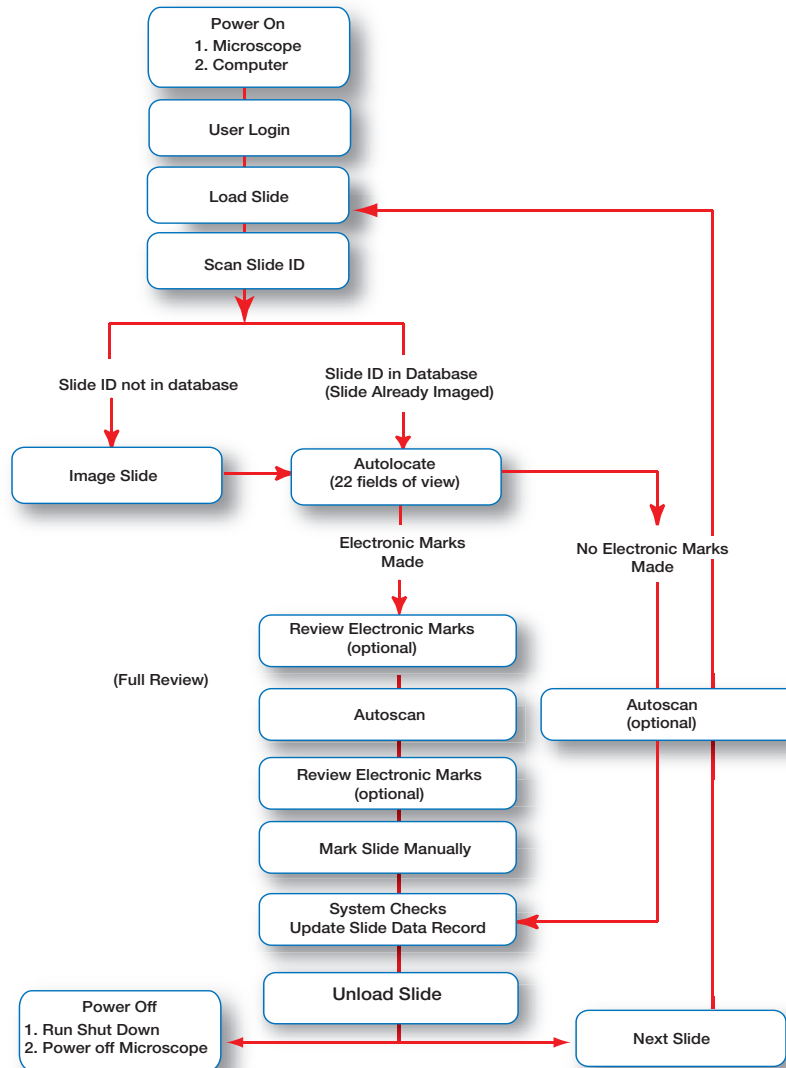


Figure 4-1 Typical Slide Review Process

**SECTION
B**

MATERIALS REQUIRED PRIOR TO OPERATION

Prepared ThinPrep® Pap Test microscope slides

Integrated Imager

Marking pen for slide marking

4 OPERATION

Important Operational Notes:

- A slide can only be imaged once on an Integrated Imager.
- The mounting medium must be thoroughly dry.
- The label must be appropriate for the ThinPrep® Integrated Imager (refer to page 3.14).
- Always keep the instrument in proper Koehler alignment (refer to page 5.2).
- Do not use filters on the collector or in the objectives - this will interfere with correctly imaging the slide.
- During slide imaging keep motion or vibration near the instrument at a minimum.
- A slide must be reviewed on the same Integrated Imager that was used to image it.
- Marking the slide - the slides are manually marked by the CT. Follow your laboratory's guidelines for marking slides. It is recommended that at least Auto Locate is completed prior to making any physical marks.
- When using Auto Locate, the CT must always examine the entire field of view.

SECTION C

USING THE TOUCH SCREEN AND REVIEW CONTROLS

Touch Screen

The touch screen can be adjusted higher or lower from the desktop by sliding it up or down along its mounting rail. The screen will stay at the height it is left at. The range is between 5 to 12 inches above the desktop.

The touch screen horizontal or vertical tilt may be adjusted to fit user preferences. See Figure 4-2. Turn the adjustment knob to loosen and adjust the tilt, then tighten the knob when the screen is in the desired position.

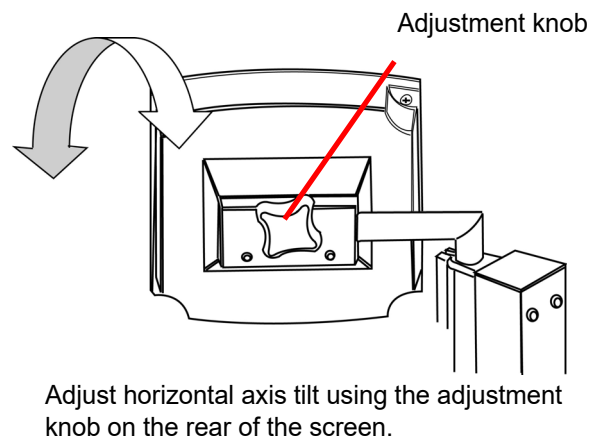
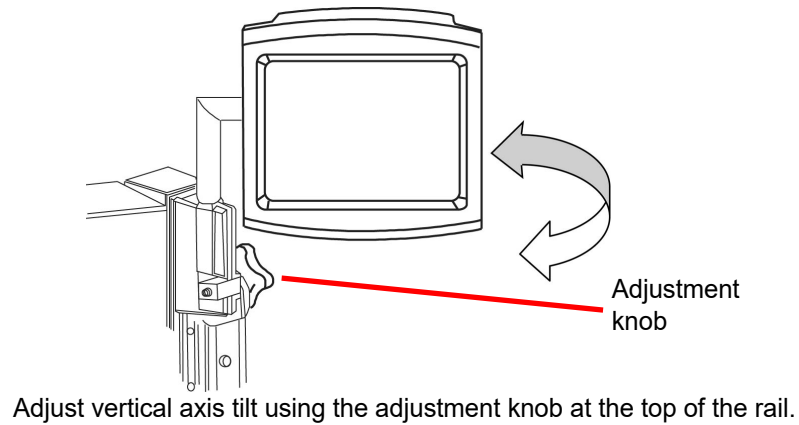


Figure 4-2 Touch Screen Horizontal and Vertical Axes Adjustment

Review Control

The review control has a scroll wheel that acts like the scroll wheel found on a computer mouse. It enables the operator to execute the main review functions (Next, Previous, Mark) without having to take their eyes away from the binoculars.

4 OPERATION

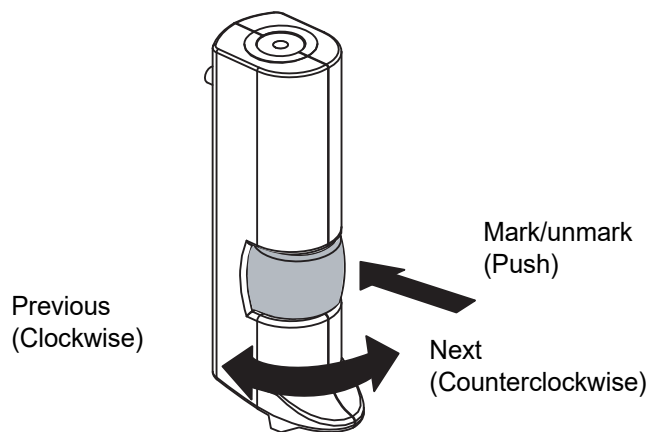


Figure 4-3 The Review Control

The review functions are:

- | | |
|-----------------|--|
| Next | used to advance through functions
used to pause/resume stage motion during Auto Scan
used to adjust user preference settings |
| Previous | used to return to fields of view during review
used to adjust user preference settings |
| Mark | used to electronically mark or unmark areas for review or dotting |

SECTION
D

SLIDE IMAGING

To begin imaging a slide, log in to the system with a valid user ID. Press the **Start** button.



Press the **Start** button.

Figure 4-4 Log in and Start

The message on the screen prompts for a slide to be loaded onto the stage.



Figure 4-5 Load Slide Screen

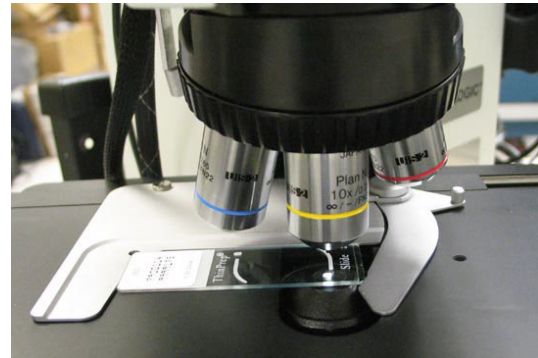
Load a slide into the slide holder on the stage. (See Figure 4-6.) With your right thumb against the slide clip button, open the slide clip. With your left hand, load the slide onto the stage with the label

4 OPERATION

on the left. Release the button, allowing the slide clip to secure the slide against the holder for the best registration. No further adjustment of the slide or clip is necessary.



Use the button to open the slide clip. Load slide.
Release the slide clip.



A loaded slide

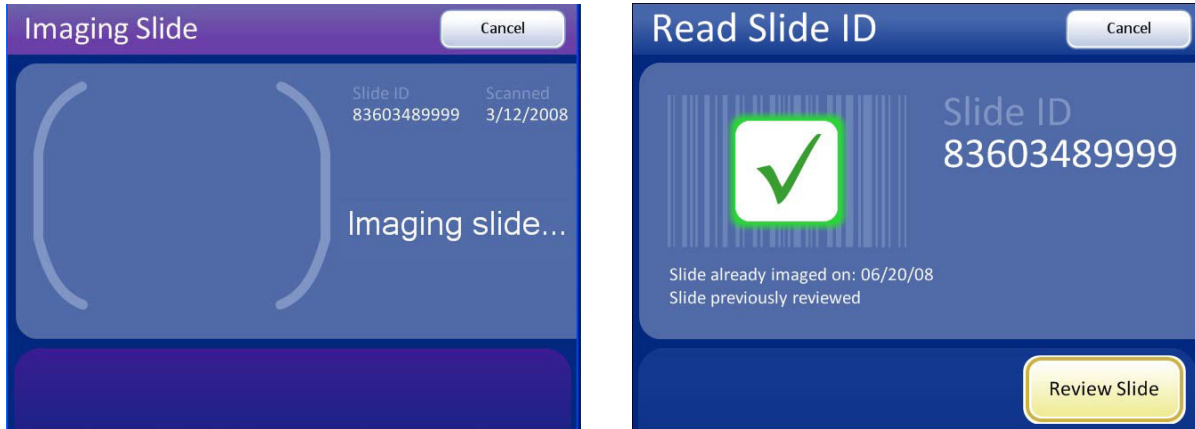
Figure 4-6 Load Slide

Press the **Continue** button when ready. The system scans the slide ID and compares it with the database. If the slide ID is in the acceptable format and is not in the database, the system immediately begins to image the slide. (Figure 4-7.)



Figure 4-7 Reading Slide ID

If the slide ID is already in the database, a message will state so. Review is available as an option or the slide review may be cancelled. See Figure 4-8.



If the slide ID is successfully read and not in the database, the Integrated Imager immediately begins imaging the slide. Press the **Cancel** button to cancel the process and return to the Load Slide screen.

If the slide ID is successfully read, but is already in the database, the options are to review the slide or cancel. See “SLIDE REVIEW” on page 4.11. Refer to Chapter 6, Troubleshooting if any other message is displayed.

Figure 4-8 Read Slide ID Results

Note: A slide may have been imaged and already reviewed, or a slide may have been imaged and not been reviewed. In either case, the options are to review the slide or cancel.

Do not look through the binoculars while the system is imaging a slide. The light blinks rapidly while imaging takes place. Do not bump the instrument while imaging a slide.

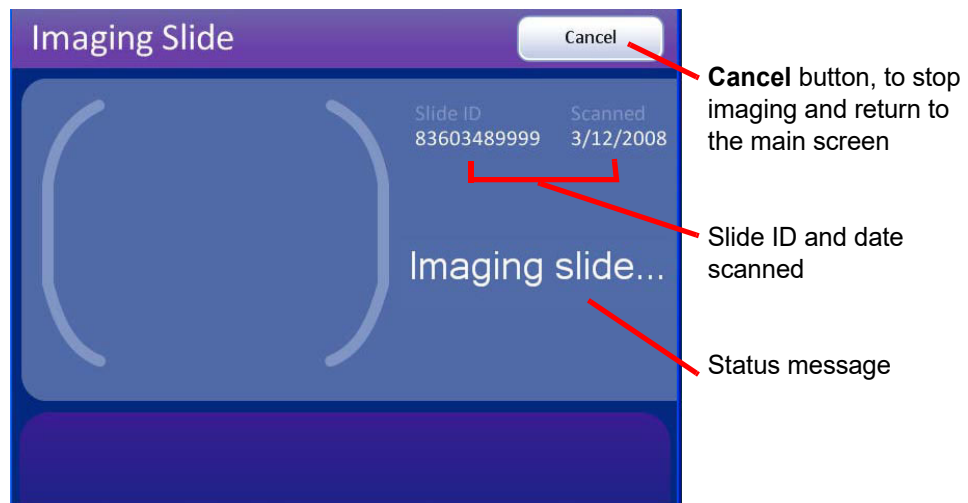
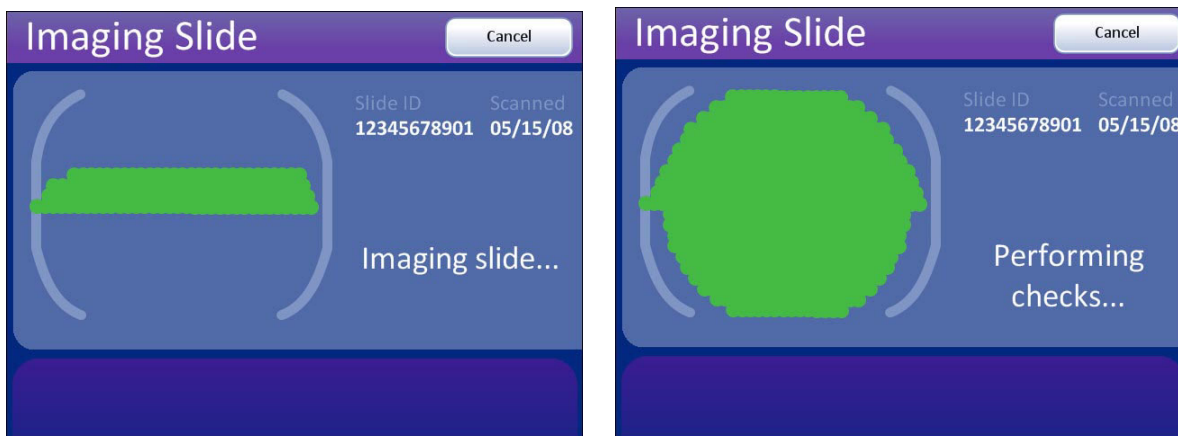


Figure 4-9 Imaging Slide Screen

4 OPERATION

The Integrated Imager images the cell spot.

Note: To ensure that the focus and illumination requirements for imaging are met, the system disables manual control of the X, Y axis stage control knobs, focus knobs and light adjustment. Manual control is returned to the operator after the imaging process is complete.



During imaging a green progress bar represents how much of the cell spot has been imaged.

When the cell spot has been imaged, the Integrated Imager performs functional checks prior to completion.

Figure 4-10 Imaging Slide in Process

Do not remove the slide from the stage during imaging. To cancel imaging, press the **Cancel** button.



Figure 4-11 Imaging Complete

The Imaging Complete message is displayed upon successful completion of imaging the cell spot. Refer to Chapter 6, Troubleshooting for any other message that may display. Touch the **Review Slide** button to continue.

The software transitions immediately to slide review, beginning with the Auto Locate sequence. Using this sequential modality, the slide is reviewed directly after the slide is imaged.

If there is reason not to continue immediately with review of the slide, press the Cancel button to end the session and return to the main screen. The slide may be removed from the stage. The slide can be reviewed later. The slide data record will reflect that the imaging was complete but no slide review took place. Using this batched modality, any number of slides can be reviewed after they have all been imaged.

If the slide is to be reviewed, refer to the next section.

**SECTION
E****SLIDE REVIEW**

Note: During slide review, the CT may proceed through all of the fields of view in Auto Locate without looking away from the microscope. The review control scroll wheel has the same control functions that are displayed as touch buttons on the user interface. The user interface is only a graphic representation of the review process. Touch screen input is only required at the transition from Auto Locate to Auto Scan, as described in this section.

Auto Locate

The Auto Locate feature presents the 22 fields of interest that have been identified by the Integrated Imager. The fields are presented in geographic order as they are located on the slide, not by any significance in ranking. The CT must scan the entire field of view for each of the 22 fields that are presented.

CAUTION: Scan the entire field of view.

Every field is presented at 10X magnification. At each location the operator may:

- focus as necessary
- manually switch to a different objective
- move about the cell spot using the stage control knobs
- return to the previous location by pressing **Previous** using the review control or the touch screen
- add and remove electronic marks by pressing **Mark** using the review control or the touch screen

To advance to the next location, the 10X objective must be in the engaged position. Press **Next** using the review control or the touch screen.

4 OPERATION

Note: The speed that the stage moves from location to location when **Next** or **Previous** is used is a user-adjustable preference. Refer to “Auto Locate Speed” on page 3.38.

22 fields of interest are graphically represented.

As each location is visited, the dot changes from green to blue:

Previous button, to go back one field of view

Next button, to proceed to next field of view

Mark button, to electronically mark an area of interest

Note: The **Next**, **Previous**, and **Mark** functions are also available on the review control.

Auto Locate in progress; electronic marks display as a yellow dot with an x.

Cancel button, to end slide review and return to the Load Slide screen

The slide ID and the date of imaging

Number of electronic marks made

Current area - which field of view is presented

Number of electronic marks made

Current area - which field of view is presented

Do not remove the slide from the stage during Auto Locate. To end slide review before finishing, press the **Cancel** button.

Figure 4-12 Auto Locate Screen

Mark Indicator

The mark indicator is set up in User Preferences as either a blink in the field of view or an audible beep (page 3.40).

When the review control or touch screen is pressed to make a mark, the indicator will blink or beep once. If it is pressed again to unmark the area, the indicator blinks or beeps twice, to differentiate.

Note: The same beep that indicates mark/unmark is the beep for the audible alarm. The beep volume is adjusted via user preference (page 3.41). Blink and beep cannot occur together.

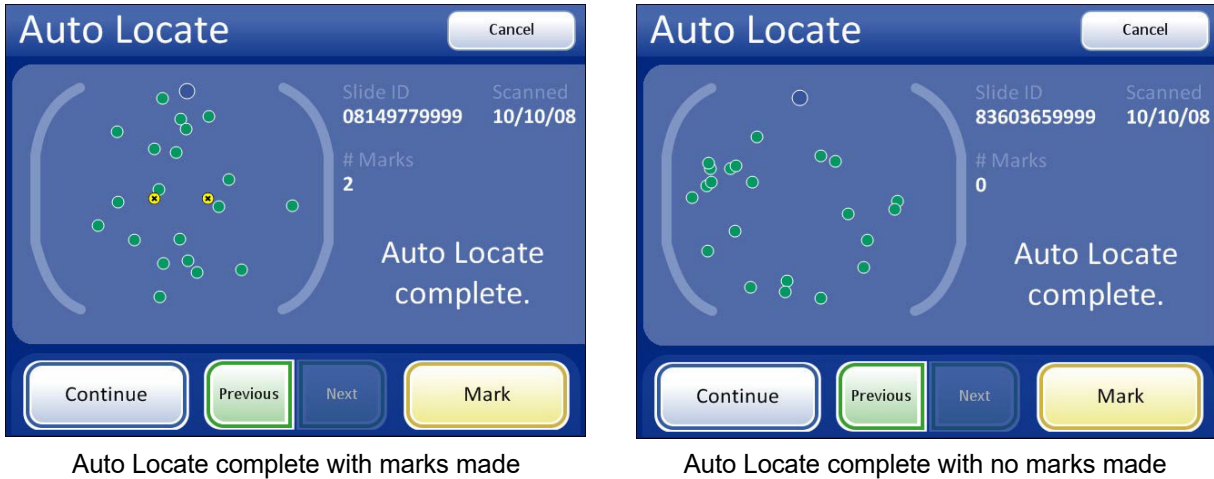


Figure 4-13 Auto Locate Complete

When all 22 fields have been viewed, an audible beep will sound. The display indicates the Auto Locate function is complete. The system is in a paused state. You may go to previous locations and continue to mark and unmark. See Figure 4-13.

Note: If a check for specimen adequacy or endocervical component is indicated, do it now before leaving Auto Locate. See the next section.

Specimen Adequacy

After presenting the 22 fields of interest in the Auto Locate mode, the stage positions the cell spot at the 6:00 position (on the stage) and stops. (On the user interface, the path through the fields of view is removed.) See Figure 4-14.

4 OPERATION



Figure 4-14 Stage in Position for Specimen Adequacy Check

The system does not determine specimen adequacy; use your standard lab protocol. To estimate the cellularity of the preparation in scanty cellular specimens, a specimen adequacy check can be performed. In accordance with Bethesda criteria¹, a minimum of 10 fields should be counted along a diameter of the cell spot that includes the center. Dependent upon the microscope objective used, use the chart below and count the average number of cells in each field.

Use the stage control knobs to traverse the cell spot.

PREP DIAM (mm)	AREA (mm ²)	FN 22 Eyepiece/ 10X Objective		FN 22 Eyepiece/ 40X Objective	
		Total Number of Fields	Number of Cells per Field for 5,000 Total	Total Number of Fields	Number of Cells per Field for 5,000 Total
20	314.2	82.6	60.5	1322	3.8

Once Auto Locate is complete, the operator may press the **Continue** button to proceed to:

- Auto Scan if any marks were made or further review is desired
- review electronic marks
- complete the review if no marks were made and no further review is desired (see page 4.18)
- press the **Cancel** button to cancel the review (No slide review data will be written to the database.)

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 4-15 Auto Locate Complete - Continue

Review Marks

If electronic marks were made during review of the 22 fields of interest, they can be reviewed prior to proceeding with Auto Scan. This is an optional step. Press the **Review Marks** button on the touch screen. The stage will present the marks in the order they were made. Use **Next** and **Previous** on the review control or the touch screen to move among the locations. Marks may be added or deleted at this time.



Figure 4-16 Review Marks Screen

4 OPERATION

Auto Scan

CAUTION: Auto Scan must be completed if any electronic marks have been made.

If electronic marks were made during review of the 22 fields of interest, a review of the entire cell spot is required. If no marks were made, a scan of the entire cell spot is available but not required.

The Auto Scan feature presents the entire cell spot in a defined path at 10X objective. During Auto Scan the operator may:

- focus as necessary
- pause and resume stage motion
- manually switch to a different objective
- move about the cell spot using the stage control knobs
- advance to the next location by using the **Next** button function on the review control or the button on the touch screen
- return to the previous location by using the **Previous** function on the review control or the button on the touch screen (in Automatic or Semiautomatic mode)
- add and remove electronic marks by using the **Mark** function on the review control or the button on the touch screen

Note: Preferences for scan mode must be set up ahead of time, in the user preference menu (i.e., scan type, speed, overlap, etc.). Refer to “User Preferences” on page 3.32.

To begin, at the Auto Locate Complete screen, press the **Continue** button.

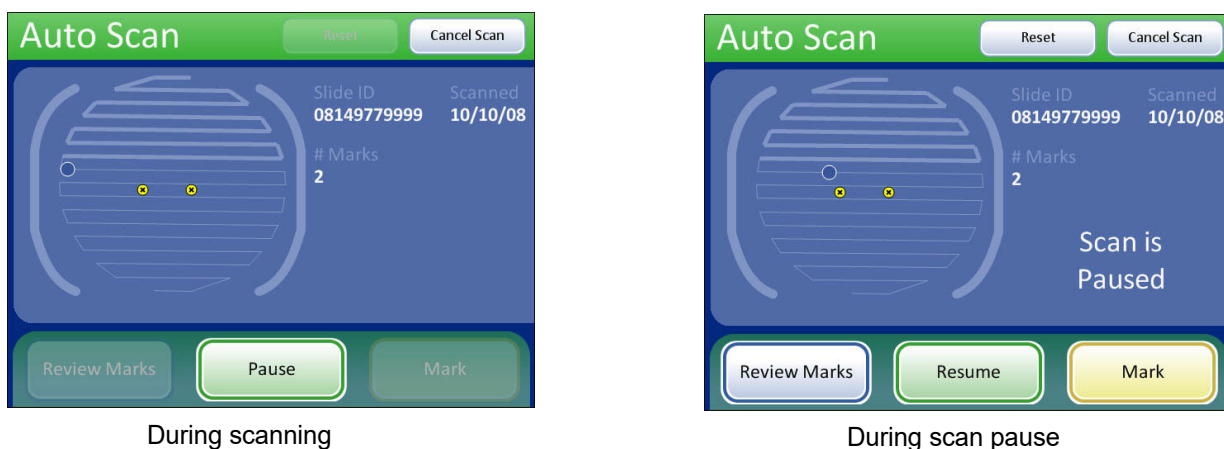


Figure 4-17 Auto Scan Screen (Automatic scan type shown)

Depending on the type of scan mode that is chosen, the stage motion is user-initiated or self-driven. Use the scroll wheel on the review control or buttons on the touch screen to pause and resume stage motion as desired. For all modes, changing the objective will pause the scan. The scan cannot continue until the 10X objective is in position. Electronic marks may be added, removed or left as is.

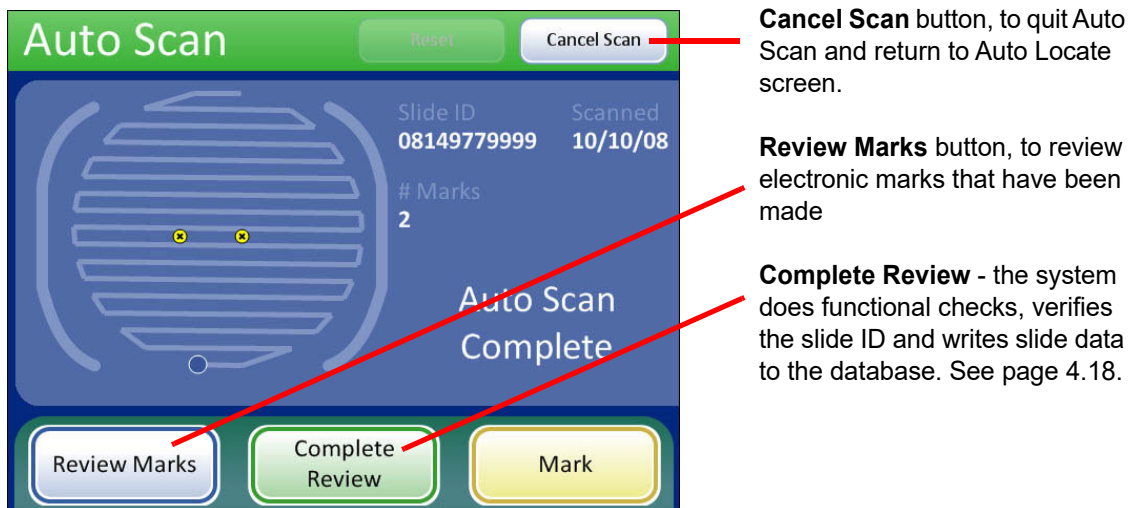
- **Automatic Start/Stop:** the stage moves and pauses automatically. To enforce a pause to view an object longer or to manually maneuver about the cell spot, scroll the review control forward to pause, and forward again to resume. To make an electronic mark, pause the scan, and press the review control.
- **Semiautomatic Start/Stop:** the stage only moves to the next field of view by operator prompt. Move the scroll wheel forward for each movement of the stage. Scroll the review control back to move to a previous view. Press the review control to make an electronic mark.
- **Manual + :** The operator moves along the length of each row by using the stage control knob. You are constrained to that row until the end has been reached, and then the instrument automatically moves over to the next row. To manually maneuver to an object during Auto Scan, scroll the review control forward to pause Auto Scan. Scroll the review control forward again, to resume Auto Scan. To make an electronic mark, pause the scan, and press the review control.

Note: The **Pause**, **Resume** and **Mark** functions are also available as buttons on the touch screen.

When the entire cell spot has been scanned, an audible beep will sound. To finish the review, touch the **Complete Review** button on the touch screen. See Figure 4-18.

Note: Do not remove the slide from the stage during Auto Scan. To end Auto Scan before finishing, press the **Cancel Scan** button.

The user interface returns to the Auto Locate Complete screen.



Cancel Scan button, to quit Auto Scan and return to Auto Locate screen.

Review Marks button, to review electronic marks that have been made

Complete Review - the system does functional checks, verifies the slide ID and writes slide data to the database. See page 4.18.

Figure 4-18 Auto Scan Complete

The operator may:

- press **Review Marks** to see the electronically marked locations again
- manually mark the slide

4 OPERATION

Note: To facilitate marking the slide with the marking pen, press the **Review Marks** button and mark as each location is presented to you.

- press **Complete Review** to save the slide review data to the database and return to the Load Slide screen
- press **Cancel** to end slide review and return to the main screen. The slide data record will not be updated with any data from the review session.

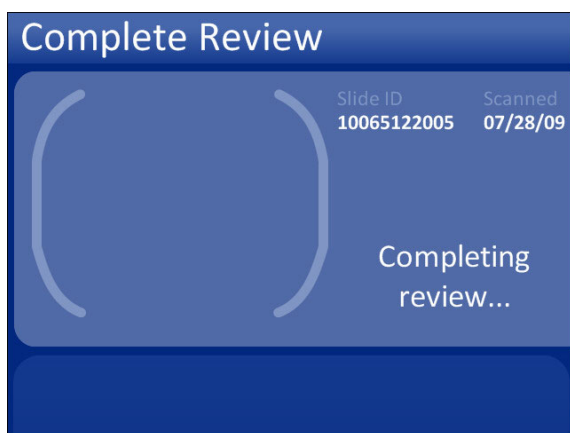
Complete the Review

If review of the slide is complete, press the **Complete Review** button.

Note: If no electronic marks were made during Auto Locate, the review may be completed after viewing the 22 fields of interest.

If electronic marks were made during Auto Locate, the review must be completed after performing Auto Scan.

The instrument will check the fiducial marks and scan the slide ID. The slide review data is written to the database. The stage is moved to the load/unload slide position, and the display transitions to the Load Slide screen. See Figure 4-19. The slide can be removed from the stage.



The instrument does functional checks.



The display prompts to load the next slide.

Figure 4-19 Completing Slide Review

If another slide is ready to be reviewed, load it onto the stage and press the **Continue** button.

If the slide has not been imaged, the Integrated Imager will automatically image it. (Refer to “Imaging” on page 4.1.)

If the slide has been imaged already, the **Review Slide** button is displayed. (See Figure 4.8.)

Subsequent Review

A slide that has already been imaged and reviewed may be reviewed again. When the slide ID is scanned, the slide data record is retrieved from the database. See Figure 4-20.

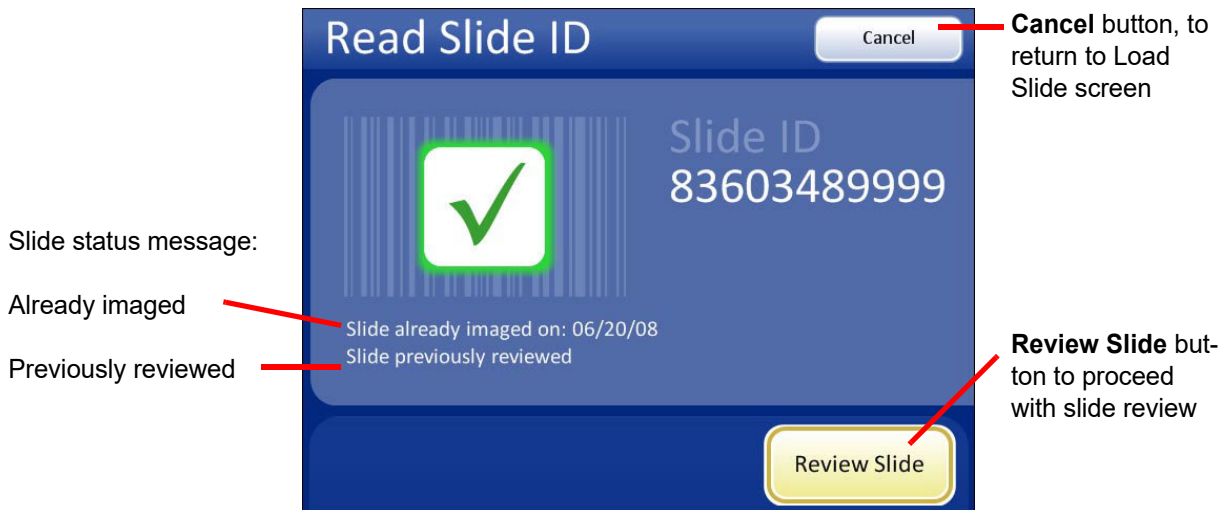


Figure 4-20 Slide Previously Reviewed

Press the **Review Slide** button to continue with review of the slide. The review goes in the same order as an initial review: Auto Locate and then Auto Scan with a chance to review marks. Auto Scan and Auto Locate are optional during a subsequent review.

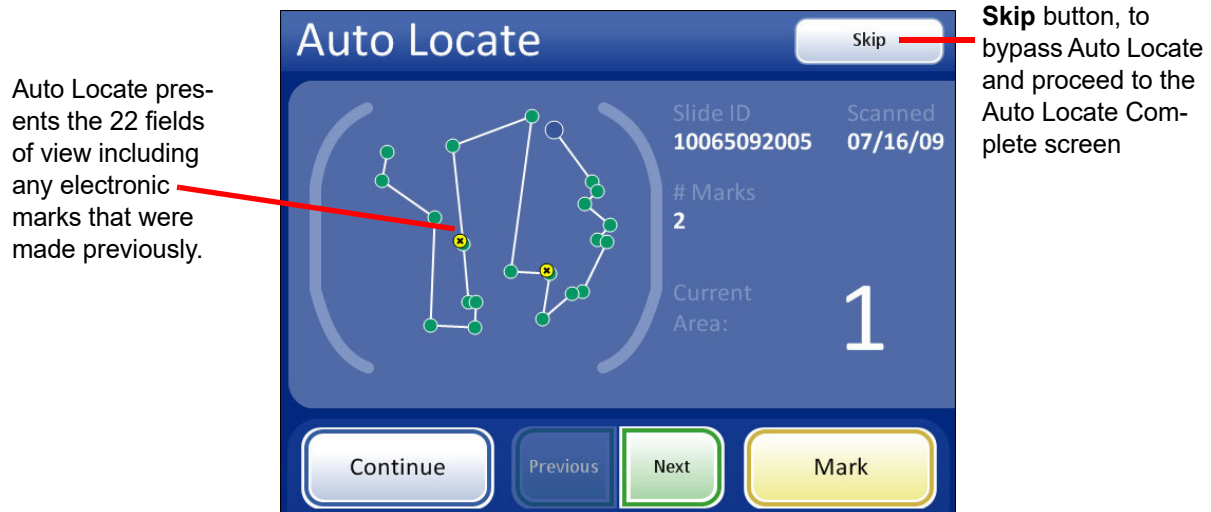


Figure 4-21 Auto Locate During Subsequent Review

4 OPERATION

Auto Locate presents the same 22 fields of interest that have been identified by the Integrated Imager. (The coordinates are stored as part of the slide data record.) If electronic marks have been made during previous review(s), they are indicated as highlighted areas on the graphic interface.

More electronic marks may be added, up to a total of 30 on a slide. No previous electronic marks can be eliminated.

The operator may review marks, perform an Auto Scan, complete review, or skip to the Auto Locate Complete screen.

To leave Auto Locate before all 22 fields of view have been viewed, press the **Skip** button. This will transition to the Auto Locate Complete screen (Figure 4-22).

At completion of a subsequent Auto Locate the operator may:

- Auto Scan if any marks were made or further review is desired
- review electronic marks
- complete the review if no marks were made and no further review is desired
- press the **Cancel** button to cancel the review (No slide review data will be written to the database.)

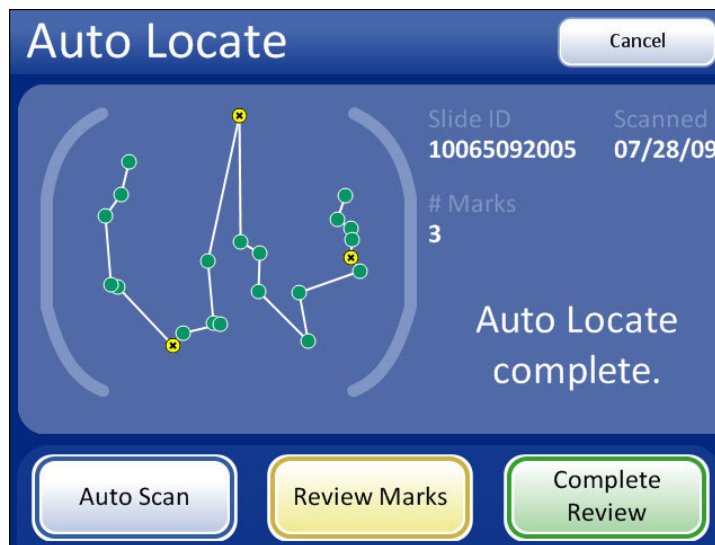


Figure 4-22 Auto Locate Complete - Subsequent Review

During Auto Scan of a subsequent review, the operator may review marks, pause and resume scanning, electronically mark and unmark new locations. (Electronic marks from previous reviews cannot be deleted.) The **Cancel Scan** button will cancel the scan and transition to the Auto Locate Complete screen. See Figure 4-23.

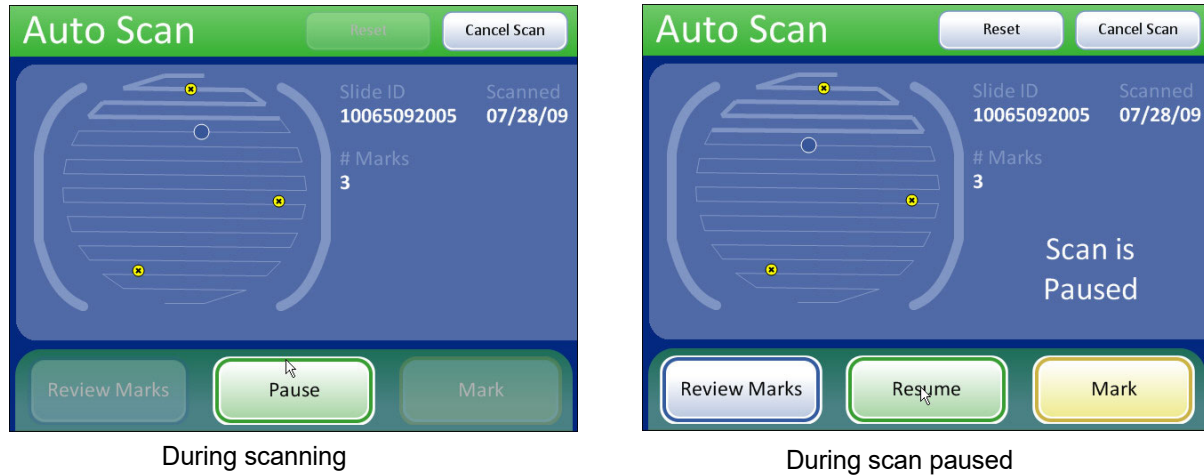


Figure 4-23 Auto Scan - Subsequent Review

The slide data record will be updated to reflect:

- The time/date stamp that is written to the database at the time the slide is reviewed
- The user ID of the operator who conducted the review
- Coordinates of any electronic marks that were added during the review

SECTION
F

REVIEW OF SLIDES NOT FOR USE WITH THINPREP IMAGING

If the Integrated Imager is used to look at non-Imager slides, the power must be on in order for the controller to power the illumination, stage and X,Y axis stage controls.

The stage motion, focus, magnification and illumination are all manually adjusted by the user. Follow your lab protocols for handling and screening of slides not for use with the Integrated Imager.



4 OPERATION

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Chapter Five

Maintenance

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

SECTION A

GENERAL CLEANING

CAUTION: Do not use strong solvents on painted or plastic surfaces.

When not using the microscope, keep it covered with the provided dust cover.

Wipe down the exterior housing of the microscope monthly or as needed with a lint-free wipe dampened with water.

Clean the eyepieces and lenses as necessary with lens paper.

Using a cotton or foam-tipped swab, clean the slide holder, the slide registration edges and the top surface of the stage with xylene or a suitable solvent that will remove mounting medium. (Do not drip the cleaning agent on painted surfaces or plastic.) Remove any glass dust from these areas.

The top surface of the slide holder has perforations that are used to perform functional checks when the Integrated Imager images slides. It is critical that these remain free of dust or debris. See Figure 5-1. Use a can of condensed air to blow away any matter that might settle into or block these holes.

Additionally, use condensed air to blow dust off of the collector lens and the top surface of the condenser lens.

Note: For systems with the white plastic ring that covers the condenser lens, be sure not to lose the ring. Either remove it before air dusting, or hold it down with a finger while cleaning.

5

MAINTENANCE



Figure 5-1 Functional Check Features To Be Kept Clean

Note: Do not detach or remove any covers or panels on the microscope, controller or computer.

SECTION B

KOEHLER ALIGNMENT

Keeping the Integrated Imager in good Koehler alignment will help optimize the proper illumination and contrast for imaging slides. It aids CT slide review by reducing extraneous light.

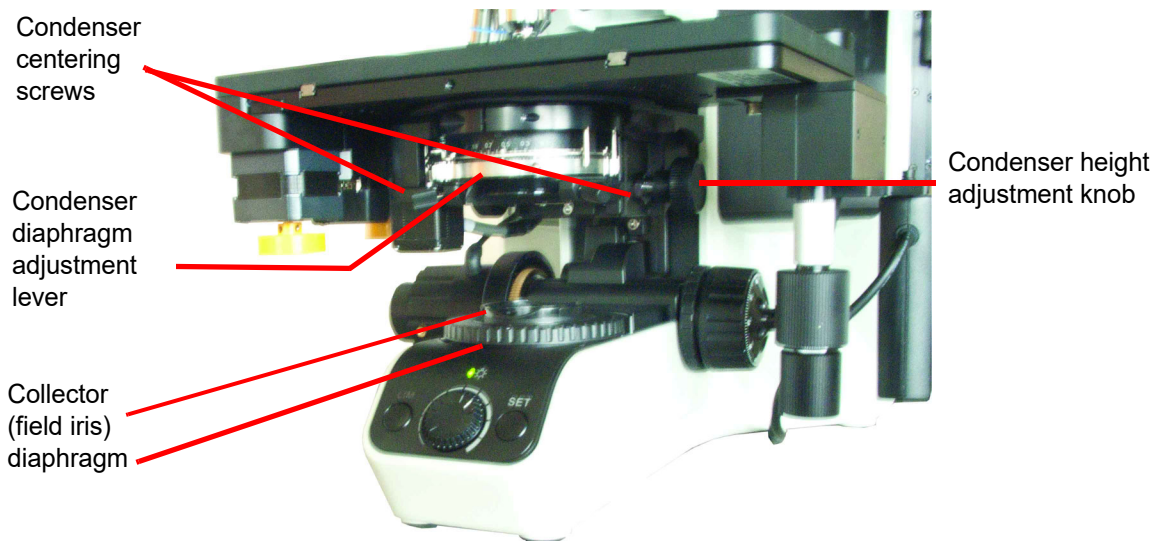


Figure 5-2 Koehler Alignment

1. Load a slide with stained cells into the slide holder (with the slide label on the left).
2. Focus on the cells using the 10X objective and observing through the fixed focus ocular on the right.
3. Reduce the collector (field iris) to its smallest aperture diameter by rotating the diaphragm collar.

4. Focus (sharpen the contrast of the edges of the aperture) by adjusting the condenser height up or down using the condenser height adjustment knob.
5. Open the collector (field iris) aperture until it is slightly smaller than the field of view.
6. Rotate the two condenser centering thumbscrews to center the aperture.
7. Open the collector aperture until it just disappears from view.
8. Adjust the condenser aperture to achieve desired contrast by moving the condenser diaphragm adjustment lever left or right to close or open the aperture.

The logo for section 5 consists of a large, stylized number '5' in a dark blue serif font. The '5' is partially enclosed by a circular arc that transitions from yellow at the top to orange and then to a reddish-pink at the bottom. To the right of this graphic, the word 'MAINTENANCE' is written in a dark blue, all-caps, sans-serif font.

5 MAINTENANCE

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Chapter Six

Troubleshooting

An error condition that is encountered during operation of the Integrated Imager may be recoverable or non-recoverable. A message is presented to the operator via the touch screen user interface. Non-recoverable errors require the system to be restarted.

SECTION A

AUTOMATED DATABASE BACKUP FAILED

The Integrated Imager automatically makes a scheduled backup of the database every night at 2:00 am. If the instrument is turned off, then a backup of the database is made the next time it is turned on, if 2:00 am has passed.

If the automatic database backup failed, a message is displayed (Figure 6-1.)

CAUTION: Contact your field service representative.

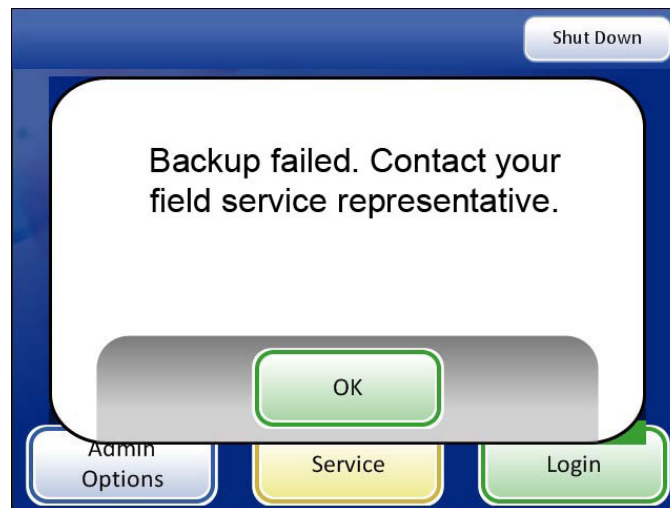


Figure 6-1 Backup Failed Message

As directed, contact your field service representative. (See Chapter 7, Service Information, for contacting Technical Support.)

6 TROUBLESHOOTING

Once the **OK** button has been pressed, slide imaging and review may be performed. However, if the problem is not resolved by the next backup time, the system will lock and will require technical service intervention.

SECTION B

USER-INITIATED DATABASE BACKUP FAILED

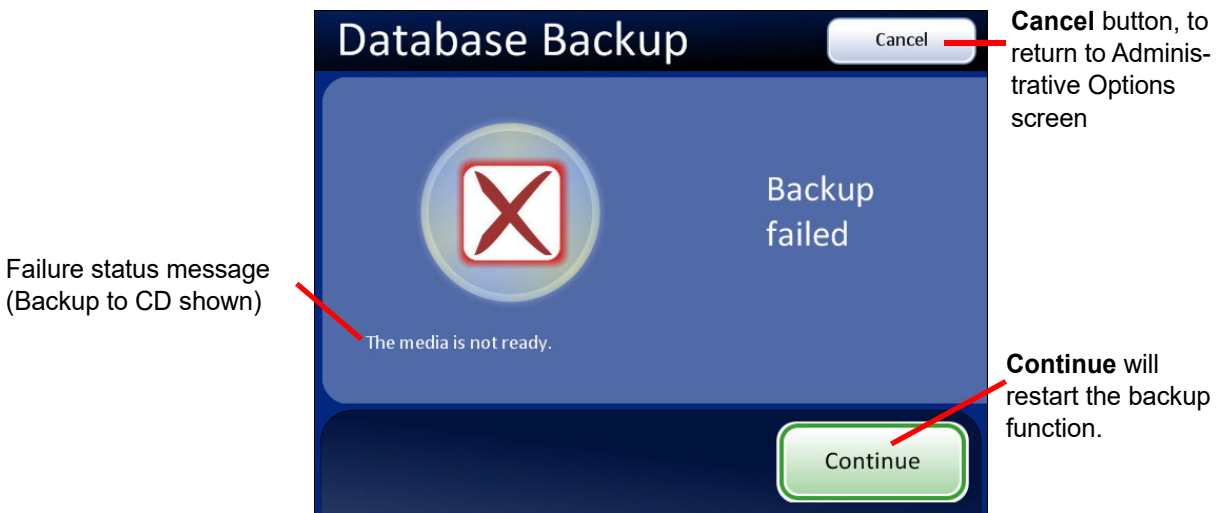


Figure 6-2 Database Backup Failed Screen

Failure Status Message	Possible Cause/Action
Could not initialize the CD writer	Problem with the computer. Contact Hologic Technical Support.
Database error occurred during backup	Problem with the computer. Contact Hologic Technical Support.
Failed to write data to the media	Check that the disk is CD ROM and not DVD. Confirm it is blank and seated correctly in the drive. Otherwise contact Hologic Technical Support.
Load a writable CD into the drive	The CD drive is empty or the system does not recognize the disk.
The media is locked	The CD drawer or the USB key is in use. Wait for the computer to unlock it.
The media is not blank	Only a blank CD may be used.
The media is not ready	The CD drive or USB port is empty or the system does not recognize the disk. The USB key does not have enough memory. Use a USB key with adequate free space.

Failure Status Message	Possible Cause/Action
The media is not writable	The CD or USB key must not be Read Only. Use writable media.
Unexpected backup error	Problem with the computer. Contact Hologic Technical Support.

SECTION
C

INVALID SLIDE ID

When a slide is placed on the stage and **Start** is pressed, the Integrated Imager reads the slide ID via the ID reader. A slide ID that is read but considered invalid will not be imaged or reviewed. Reasons for an invalid ID are:

- Not the correct number of digits in the slide ID number
OCR format labels require 14 digits in a 7-over-7 row format (refer to “Label format” on page 3.14).
Barcode format labels require specific characters and length, depending on the type of barcode (refer to Table 3.1, “Slide Restrictions Based on Barcode Symbology Used,” on page 15).
- The label is damaged, illegible or missing.
- OCR format label may have a missing or bad CRC (last three digits of the 14-digit format).

Press the **OK** button to clear the message from the display. Check the label format.

SECTION
D

FAILED TO READ SLIDE ID

When a slide is placed on the stage and **Start** is pressed, the Integrated Imager reads the slide ID via the ID reader. A slide ID may not be read if:

- The label format conflicts with the format selected under System Settings. (Refer to “Label format” on page 3.14.) For example, barcode format may be selected, but an OCR label is on the slide.
- The label format is not compatible with the system.
- The label is damaged, illegible or missing.
- Mechanical failure of the slide ID reader device

After attempting to scan the slide ID and failing, a message is displayed:

6 TROUBLESHOOTING

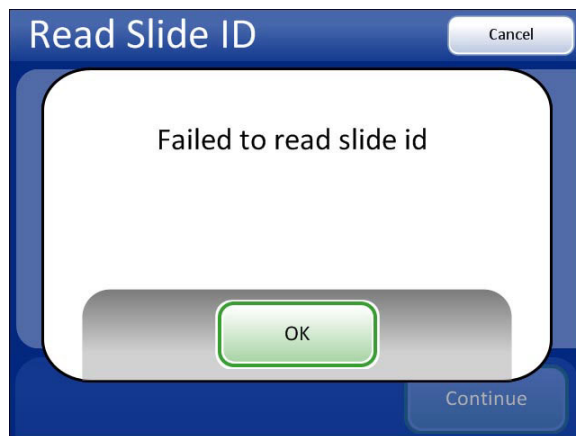


Figure 6-3 Failed to Read Slide ID

Press the **OK** button. The system will present a keypad for manual entry of a valid slide ID.

Using the keypad, enter the entire slide ID. Use the **Switch Keys** button to use a keyboard if the slide ID contains alpha characters. Press the **Continue** button when done. See Figure 6-4.

Use the keypad to enter the Slide ID.



Figure 6-4 Manually Enter the Slide ID

Note: The slide ID must be in a valid format for use on the Integrated Imager. Refer to “Label format” on page 3.14.

If the slide ID is new to the database, the system will begin imaging the slide. If the slide ID is already in the database, the Read Slide ID screen is displayed with a “slide already imaged” message. (See Figure 4-8.)

Continue to review the slide as usual. At the end of slide review, when the system would normally scan the ID to confirm identity of the slide, a message prompts the user to confirm the slide ID.

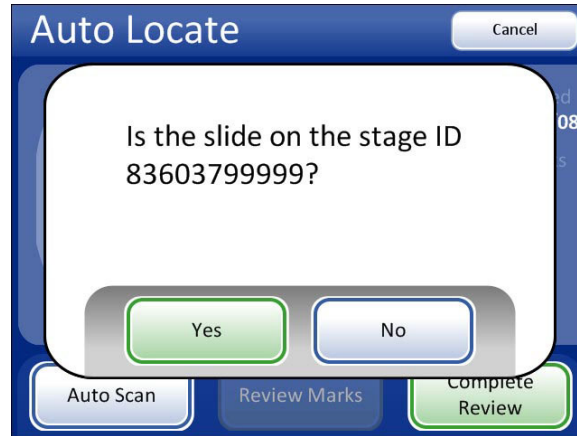


Figure 6-5 Confirm Slide ID

Press **Yes** if the slide ID is correct. The slide review completes, and the Load Slide screen appears.

Press **No** if the ID is not correct. The slide review data will not be written to the database. The slide ID must be reconciled with your records.

Contact Technical Support if this error persists.

**SECTION
E**

SLIDE ID MISMATCH WHILE COMPLETING THE REVIEW

At the end of a slide review, the system scans the slide ID and compares it with the ID that it read at the beginning of the review. If the slide ID does not match, or it cannot read the slide ID, the review data is not saved to the database, and this error message is displayed. This may be caused by:

- Removal of the slide from the stage during review
- Malfunction of the slide ID reader

6

TROUBLESHOOTING

SECTION F

ERROR HANDLING

Note: Proper slide preparation is critical to the success of imaging by the Integrated Imager. If your laboratory does any of the ThinPrep® slide preparation processes, please consult the appropriate user documentation that came with the equipment.

Recoverable Errors

Recoverable errors are system errors that the Integrated Imager can recover from with user intervention. Usually they are errors that occur during the slide imaging process. They may be due to:

- slide preparation (slide quality)
 - fingerprints or dust on slide
 - slide label missing, damaged or illegible
 - mounting medium has bubbles or it is retracted under the coverslip
 - cell stain is too dark or too light
 - coverslip is the wrong size or thickness
- slide placement on the stage
 - slide is not registered tightly against slide holder edges
 - slide is oriented the wrong way
 - slide is tilted or uneven
 - slide moves due to unclean stage
- slide biology
 - specimen is too dense
 - specimen is too scant
 - specimen has badly shaped artifacts
- instrument or operator error
 - stage adjustment is not correct
 - 10X objective is not in place
 - obstruction of the light path
 - obstruction of the slide ID reader
 - slide ID mismatch at conclusion of imaging
 - instrument malfunction
- calibration error

When such an error condition is detected, the instrument will stop operation and display a message on the user interface. A system error is recorded in the System Error Log. Slide-related errors are listed in the History Usage Report. The slide will not have been imaged.

You may attempt to image the slide again. If the second attempt produces the same error, the slide will need to be manually screened.

Non-recoverable Errors

Non-recoverable errors are system errors that prevent the Integrated Imager from operating properly. The system will stop operation and log the error to the database. The system will need to be restarted to recover. Some of these errors or repeated errors will require field service assistance. Figure 6-6 is an example of an error message.



Figure 6-6 Non-recoverable Error Example

If the system must be restarted to recover from an error condition, acknowledge the error message by pressing the **OK** button. The user interface transitions to a restricted version of the main screen, with only the **Restart**, **Shut Down** and **Service** buttons enabled. See Figure 6-7.

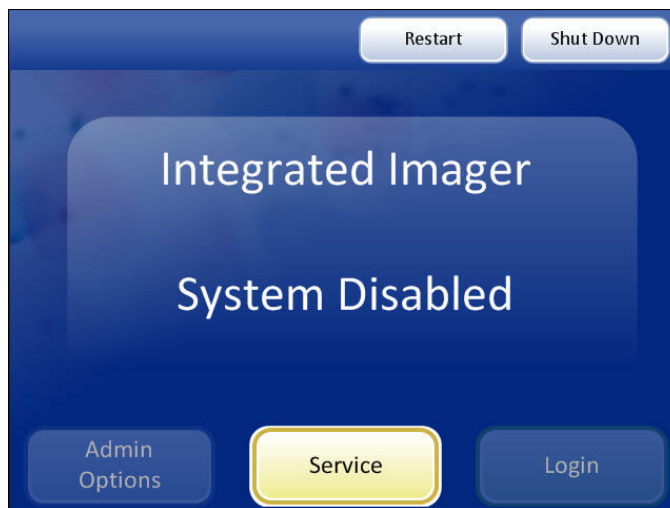


Figure 6-7 System Disabled Screen

To restart the Integrated Imager, press the **Restart** button. The application quits and restarts. (The computer stays powered on.) The splash screen will display while the system goes through the power on self test. The system is ready for use when the main screen displays and the **Admin Options** and **Login** buttons are active again.

If an error persists, or if the instrument cannot successfully reboot, contact Technical Support.

If you wish to turn the instrument off, rather than restart, press the **Shut Down** button and allow the system to quit the application and shut down the computer. Do not interfere with the instrument while this happens. After the computer has shut down, turn off the power switch on the microscope. The error should be cleared when the system next boots up. If it persists or the instrument cannot successfully boot up, contact Technical Support.

The **Service** button is available for Hologic service personnel to access the service mode, if a field service call is necessary.

Table 6.1 Integrated Imager Error Codes

Error Number	Display Message	Error Type	Action
4600	Time out waiting for Frame Processor completion	Recoverable	Press OK . Check slide morphology (too dense). Attempt to reimage slide.
6200	Slide cannot be imaged	Recoverable	Press OK . Check slide quality. Attempt to reimage slide.
6201	Slide cannot be imaged	Recoverable	Press OK . Check slide quality. Attempt to reimage slide.

Table 6.1 Integrated Imager Error Codes

Error Number	Display Message	Error Type	Action
6354	Image processing algorithm failure	Non-recoverable	Press OK . Shut down Imager and restart.
6357	Invalid image frame object reference	Non-recoverable	Press OK . Shut down Imager and restart.
6371	Frame processor startup error	Non-recoverable	Press OK . Shut down Imager and restart.
6615	Slide cannot be imaged	Recoverable	Press OK . Check slide morphology (artifacts). Attempt to reimage slide.
6617	Slide cannot be imaged	Recoverable	Press OK . Check slide quality (bubbles). Attempt to reimage slide.
6621	Slide cannot be imaged	Recoverable	Press OK . Check slide morphology (scant). Attempt to reimage slide.
6623	Slide cannot be imaged	Recoverable	Press OK . Check slide morphology (overabundance of cells). Attempt to reimage slide.
6628	Slide cannot be imaged	Recoverable	Press OK . Check slide morphology (too dense). Attempt to reimage slide.
6630	Slide cannot be imaged	Recoverable	Press OK . Check slide morphology. Check stain quality. Attempt to reimage slide.
6907	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6910	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6911	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6913	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6914	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6930	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6933	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6936	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6951	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
6960	Processing of Verification Images failed	Non-recoverable	Press OK . Shut down Imager and restart.
8010	Database connection fail	Non-recoverable	Press OK . Restart or shut down Imager and restart.

Table 6.1 Integrated Imager Error Codes

Error Number	Display Message	Error Type	Action
11200	The Imager cannot continue until the 10X objective is in place	Operator	Change to 10X objective. Press OK button and continue.
11300	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
11301	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
11302	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
11303	Calibration Error	Recoverable	Press OK . Attempt to reimage slide.
11304	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11305	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11306	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11307	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11308	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11309	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11310	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11311	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11312	Slide cannot be processed	Recoverable	Press OK . Attempt to reimage slide.
11400	Slide ID mismatch when completing review	Recoverable	Press OK . See if the slide moved during review. Check for obstruction to the slide ID reader.
11401	Slide is too dark to be processed	Recoverable	Press OK . Check for obstruction in the light path. Check Koehler alignment. Attempt to reimage slide.
11402	Slide cannot be processed	Recoverable	Press OK . Check slide cleanliness and quality. Attempt to reimage slide.
11403	Slide cannot be processed	Recoverable	Press OK . Check slide cleanliness and quality. Attempt to reimage slide.
11500	Image camera device error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
11501	Label reader device error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
11502	Controller device error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
11503	Stage device error	Non-recoverable	Press OK . Restart or shut down instrument and restart.

Table 6.1 Integrated Imager Error Codes

Error Number	Display Message	Error Type	Action
11504	Image camera device error	Recoverable	Press OK and continue on with a manual review, or press Cancel and attempt to reimage the slide.
11600	Image camera connection error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
11601	Label reader connection error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
11602	Controller connection error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
11603	Stage connection error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
12100	Auto Scan thread startup error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
12200	Database error	Non-recoverable	Press OK . Restart or shut down instrument and restart.
12201	Invalid database argument	Non-recoverable	Press OK . Restart or shut down instrument and restart.
12202	Invalid database operation	Non-recoverable	Press OK . Restart or shut down instrument and restart.
12203	Database null reference	Non-recoverable	Press OK . Restart or shut down instrument and restart.
12500	Slide record has invalid data	Recoverable	Press OK . Slide can only be manually reviewed.
12501	Slide record has invalid data	Recoverable	Press OK . Slide can only be manually reviewed.

The logo for section 6 consists of a large blue number '6' centered within a circular arc. The arc is multi-colored, transitioning from yellow at the top to orange, then red, and finally purple at the bottom.

6 TROUBLESHOOTING

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Chapter Seven

Service Information

Corporate Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

Business Hours

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

Customer Service

Product orders, which include standing orders, are placed through Customer Service by phone during business hours at 1-800-442-9892 Option 5 or 508-263-2900.

Orders can also be faxed to the attention of Customer Service at 508-229-2795.

Warranty

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

Technical Support

For questions about ThinPrep® Integrated Imager issues and related application issues, representatives from Technical Support are available by phone 7:00 a.m. to 7:00 p.m. EST Monday through Friday at 1-800-442-9892 Option 6 or 508-263-2900.

Service contracts can also be ordered through Technical Support.

Protocol for Returned Goods

For returns on warranty-covered ThinPrep Integrated Imager accessory and consumable items, contact Technical Support.



SERVICE INFORMATION

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Chapter Eight

Ordering Information

Mailing Address

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

Remittance Address

Hologic, Inc.
PO Box 3009
Boston, MA 02241-3009 USA

Business Hours

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

Customer Service

Product orders, which include standing orders, are placed through Customer Service by phone during business hours at 1-800-442-9892 Option 5 or 508-263-2900.

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Protocol for Returned Goods

For returns on warranty-covered ThinPrep® Integrated Imager accessory and consumable items, contact Technical Support.



Table 8.1 Reordering Supply Items for the Integrated Imager

Item	Description	Quantity	Part Number
Extension cable set	10-ft. extension cable for PC connection	ea.	53033-001
Eyepiece, 10X, 24 mm	Replacement eyepiece (should be used in pairs)	ea.	51815-001
Objective, 4X	Replacement 4X objective	ea.	52462-001
Objective, 10X	Replacement 10X objective	ea.	52463-001
Objective, 40X	Replacement 40X objective	ea.	51200-001
Dust cover	Microscope dust cover	ea.	06210-001
Integrated Imager Operator's Manual	Additional operator's manual	ea.	MAN-08733-001

Table 8.2 Optional Accessories

Item	Description	Part Number
Telescoping head*	Telescoping binocular tube	52029-001
Riser	Hologic riser (10mm)	ASY-03268
Riser**	Olympus (30mm)	OEM-00585
Objective, 20X	Optional objective	ASY-03287

* If the telescoping head is installed, it must be configured with **ONE** Hologic riser.
The telescoping head must not be used with the Olympus riser.

** The standard tilting binocular head is limited to accommodating only **ONE** Olympus riser.



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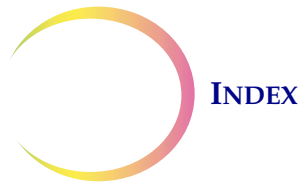
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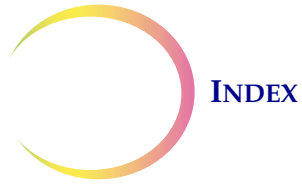
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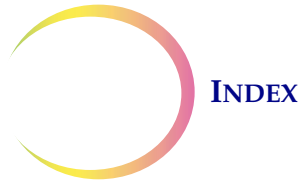
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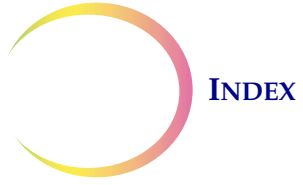
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Autoscan modes - used when performing a full slide review

Automatic start/stop



The stage moves automatically in discrete, overlapping fields of view. The degree of overlap from row to row and the speed of stage movement are user-adjustable. The user may pause and resume stage motion.



Semiautomatic start/stop



The user prompts the stage to advance to the next field of view. The degree of overlap from row to row and the speed of stage movement are user-adjustable.



Manual+



The user manually moves the stage within each row using the stage control knob. The degree of overlap from row to row is user-adjustable. The stage moves automatically between rows. No speed setting is necessary.



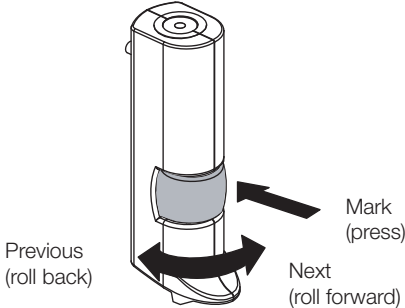
Refer to the ThinPrep® Integrated Imager operator's manual for full operating instructions, including any warnings, contraindications and safety information.

ThinPrep® Integrated Imager Quick Reference Guide

Integrated Imager Components



Review Controls

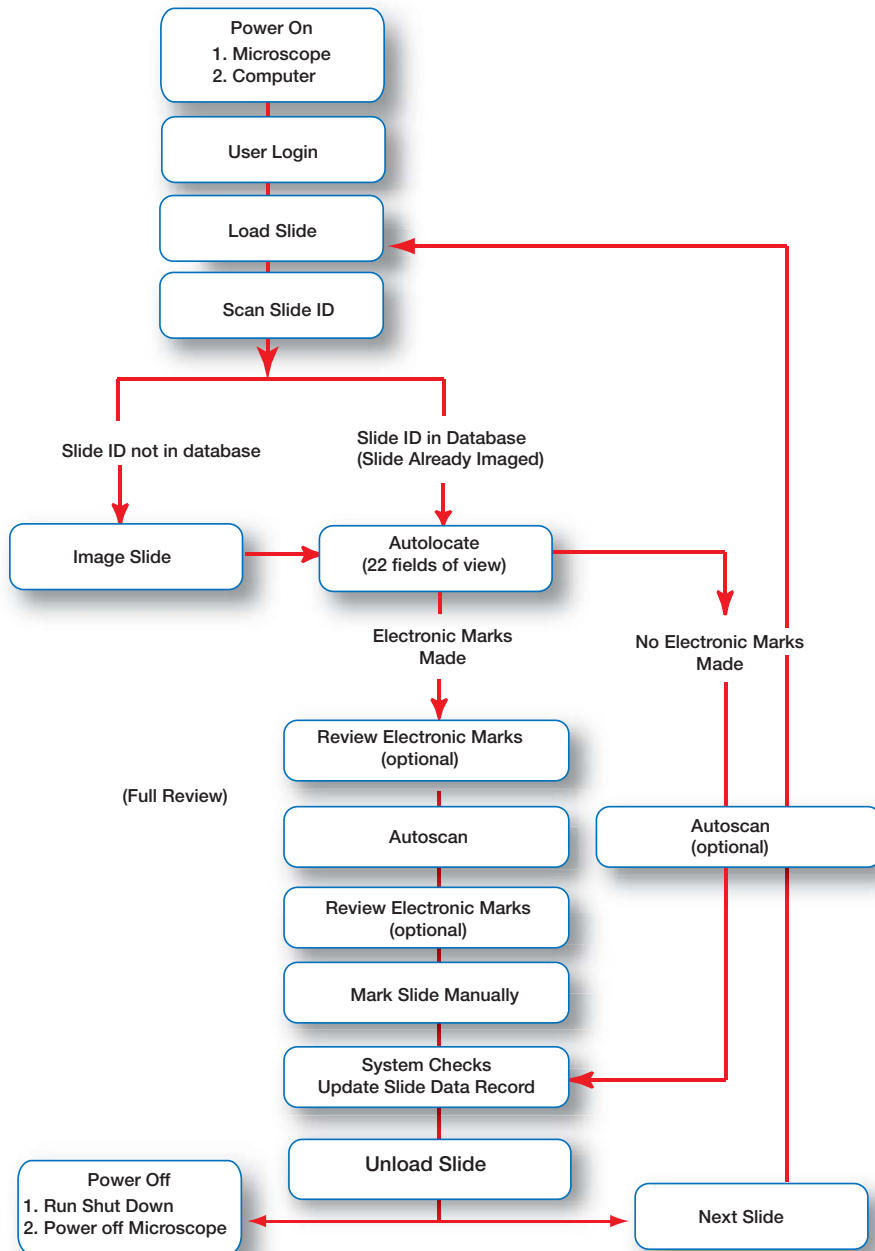


Review Control with Scroll Wheel

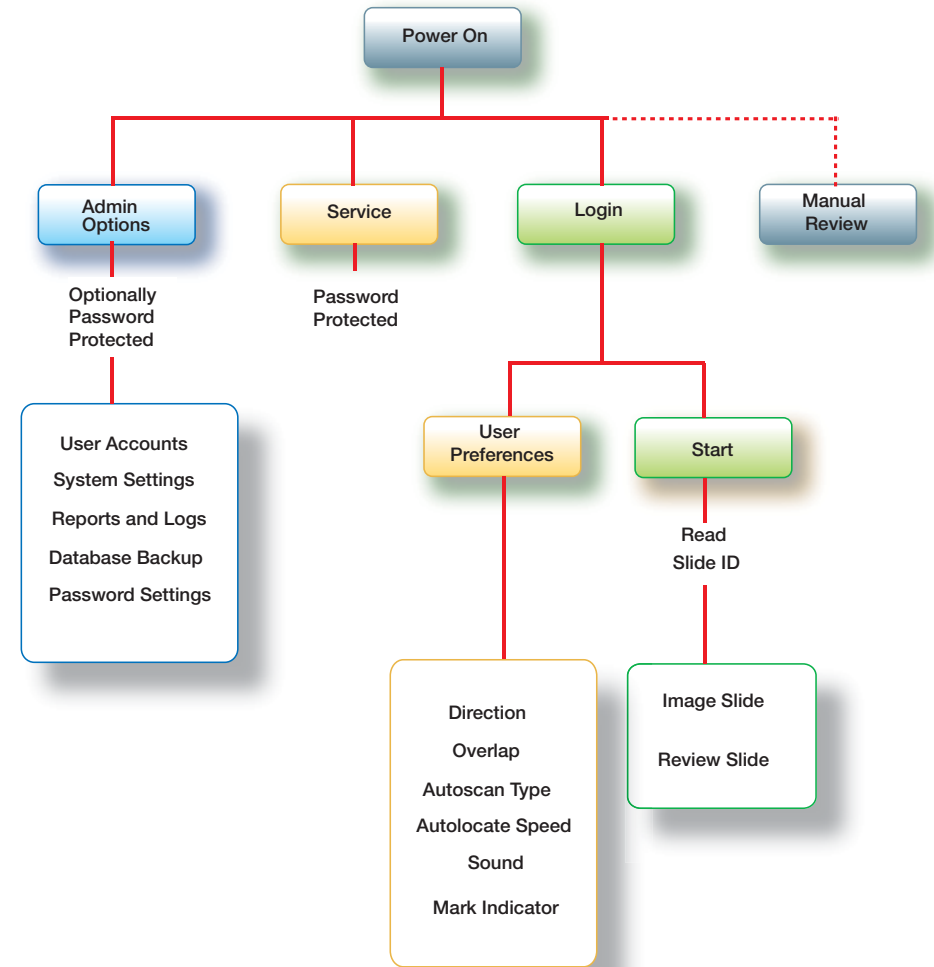


Touch Screen (example)

Typical Slide Review Process



Software Menu Overview



ThinPrep® **Hologic®** **Integrated Imager** | **Operator's Manual**



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MAN-08733-001 Rev. 001