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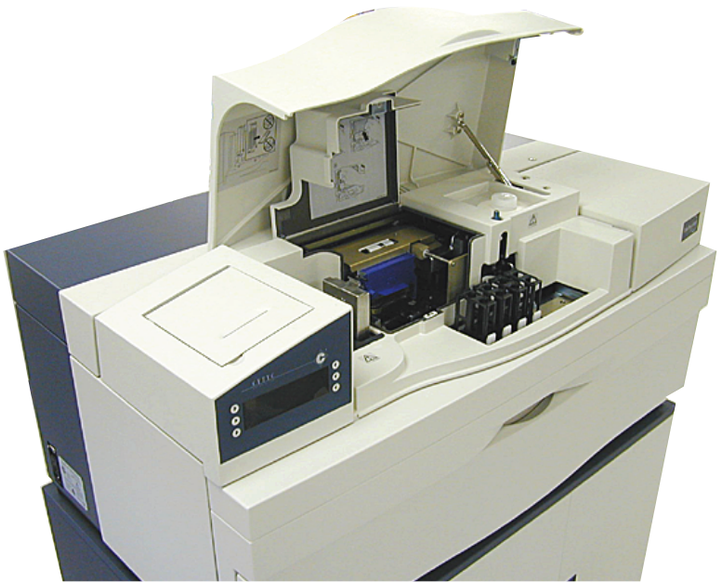

ThinPrep® 3000 Processor

Operator's Manual

ThinPrep® 3000 PROCESSOR

ThinPrep® 3000 Processor Operator's Manual

HOLOGIC®

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For Use With Version 1.x.y Software

MAN-02586-001

Caution: Federal law restricts this device to sale by or on the order of a physician, or any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device and are trained and experienced in the use of the ThinPrep® 3000 processor.

Preparation of microscope slides using the ThinPrep 3000 processor should be performed only by personnel who have been trained by Hologic or by organizations or individuals designated by Hologic.

Evaluation of microscope slides produced with the ThinPrep 3000 processor should be performed only by cytotechnologists and pathologists who have been trained to evaluate ThinPrep-prepared slides by Hologic or by organizations or individuals designated by Hologic.

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

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

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

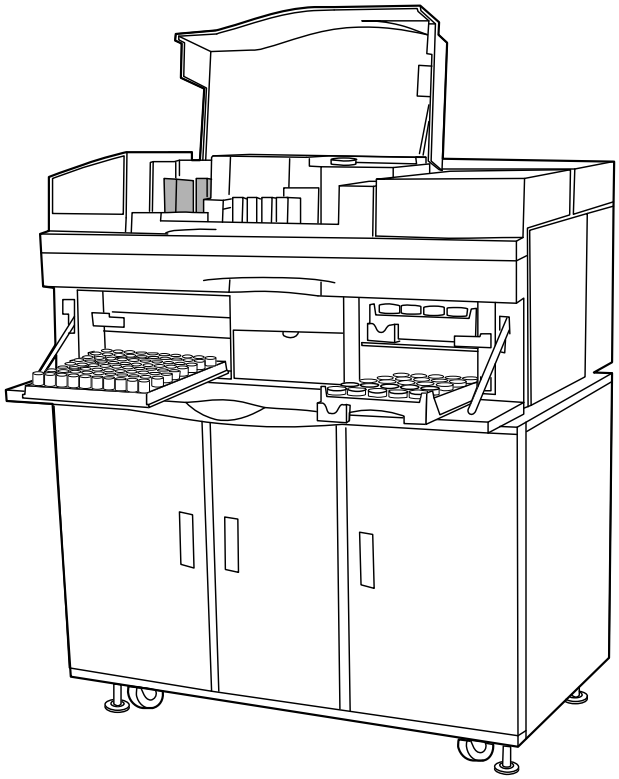
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protections against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy; and if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

For Use with Model: ThinPrep® 3000
Document Number: AW-07494-001 Rev. 006

The ThinPrep®
Processor

The ThinPrep®
Processor

ThinPrep® 3000 Processor



Instructions for Use

INTENDED USE

The ThinPrep® 3000 Processor (TP-3000) is a device that produces cytologic preparations on glass microscope slides from gynecologic (cervical) samples, and is intended for use in cervical cytologic examinations of material collected for the ThinPrep Pap Test. TP-3000 prepared microscope slides are examined by trained cytotechnologists and pathologists 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 for Reporting Cervical/Vaginal Cytologic Diagnoses*[1] (Bethesda System).

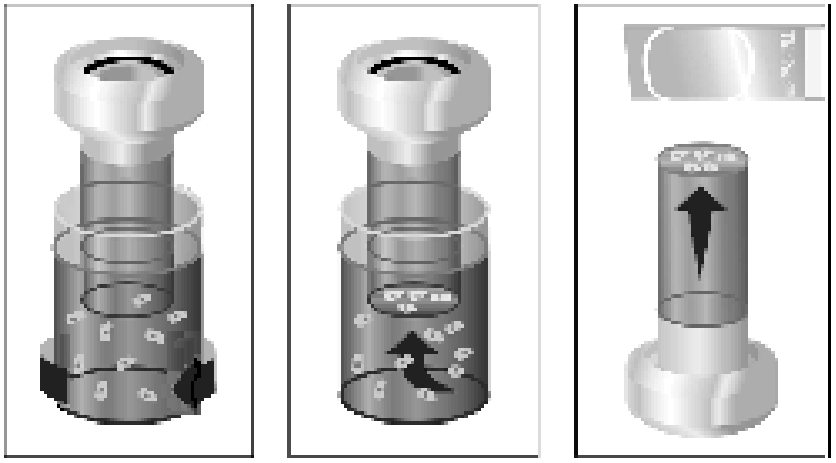
SUMMARY AND EXPLANATION OF THE SYSTEM

The ThinPrep process begins with the patient's gynecologic sample being collected by the clinician, which is then immersed and rinsed in a PreservCyt® Solution sample vial. The PreservCyt sample vial is then capped, labeled, and sent to a laboratory equipped with a TP-3000.

At the laboratory, the PreservCyt sample vial is bar-coded along with the test request form to establish a sample chain of custody and is placed into a TP-3000. A gentle dispersion step mixes the cell sample by currents in the fluid that are strong enough to separate debris and disperse mucus, but gentle enough to have no adverse effect on cell appearance.

The cells are then captured on a Gynecological ThinPrep Pap Test Filter that is specifically designed to collect cells. The TP-3000 constantly monitors the rate of flow through the ThinPrep Pap Test Filter during the collection process in order to prevent the cellular presentation from being too scant or too dense. The TP-3000 will label the glass slide with the sample identification number read from the bar-code on the sample vial. A thin layer of cells is then transferred to a glass slide in a 20 mm-diameter circle. The slide is completed when its cells are fixed in place by a fixative solution (CellFyx™ Solution) that is applied automatically by the processor.

The ThinPrep Pap Test Slide Preparation Process



1. Dispersion **2. Cell Collection** **3. Cell Transfer**

(1) Dispersion
The cell sample is mixed by currents created in the preservation fluid that are strong enough to separate debris and disperse mucus, but gentle enough to have no adverse effect on cell appearance.

(2) Cell Collection
A gentle vacuum is applied to the ThinPrep Pap Test Filter to collect cells.

(3) Cell Transfer
The ThinPrep Pap Test Filter is gently pressed against the ThinPrep Microscope Slide. Positive pressure applied to the inside of the filter assists in transferring the cells from the filter membrane to the surface of the slide.

As with conventional Pap smears, slides prepared with the TP-3000 are examined in the context of the patient's clinical history and information provided by other diagnostic procedures such as colposcopy, biopsy, and human papillomavirus (HPV) testing, to determine patient management.

The PreservCyt® Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the Cervista® HPV HR Test, the Cervista® HPV 16/18 Test, the Roche cobas® HPV Test and the Digene Hybrid Capture™ System HPV DNA. Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the Hologic APTIMA COMBO 2® CT/NG Assays, the Hologic APTIMA® Trichomonas vaginalis Assay, and the BD ProbeTec™ CT Q^{x} Amplified DNA Assay. Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is also an alternative collection and transport medium for gynecologic specimens tested with the Roche Diagnostics COBAS AMPLICOR™ CT/NG assay. Refer to Hologic's labeling (Document #MAN-02063-001) for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens and to the Roche Diagnostics COBAS AMPLICOR CT/NG package insert for instructions for use of that system.

LIMITATIONS

- Gynecologic samples collected for the TP-3000 should be collected using a broom-type or endocervical brush/plastic spatula combination collection devices. Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.
- Preparation of slides on the TP-3000 should be performed only by personnel who have been trained by Hologic or by organizations or individuals designated by Hologic.
- The staining procedure using the CellFyx® Fixative Solution has been demonstrated for Papanicolaou stain only.
- Evaluation of slides prepared on the TP-3000 should be performed only by cytotechnologists and pathologists who have been trained to evaluate ThinPrep Pap Test slides by Hologic or by organizations or individuals designated by Hologic.
- Supplies used for TP-3000 gynecologic slide preparations are those designed by Hologic specifically for use on the instrument. These supplies include PreservCyt® Solution vials for use with the ThinPrep Pap Test, ThinPrep Pap Test Filters, ThinPrep Microscope Slides, and CellFyx Fixative Solution. For proper performance of the system these supplies cannot be substituted. After use, supplies should be disposed of in accordance with local, state, and federal regulations.
- All supplies, with the exception of CellFyx Fixative Solution, are single-use disposable items and cannot be reused.
- The performance of HPV DNA and CT/NG testing on reprocessed sample vials has not been evaluated.

CONTRAINDICATIONS

- *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing using the Roche Diagnostics COBAS AMPLICOR and Gen-Probe APTIMA COMBO 2® CT/NG assays should not be performed on a sample that has already been processed using the ThinPrep 3000 processor.

WARNINGS

- For In Vitro Diagnostic Use.
- Danger. PreservCyt Solution contains methanol. Toxic if swallowed. Toxic if inhaled. Causes organ damage. Keep away from heat, sparks, open flames and hot surfaces. Other solutions must not be substituted for PreservCyt Solution. PreservCyt Solution should be stored and disposed of in accordance with local, state, and federal regulations.

PRECAUTIONS

- A TP-3000 generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the Operator's Manual, may cause interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case, the user will be required to correct the interference at his/her own expense.
- 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.
- PreservCyt Solution *with* cytologic sample intended for CT/NG testing using the Roche Diagnostics COBAS AMPLICOR CT/NG test must be stored between 4°C (39°F) and 25°C (77°F) and tested within 6 weeks of collection.
- Excessively bloody samples may result in a higher unsatisfactory[1] rate.

- PreservCyt Solution was challenged with a variety of microbial and viral organisms. The following table presents the starting concentrations of viable organisms, and the number of viable organisms found after 15 minutes in the PreservCyt solution. The log reduction of viable organisms is also presented. As with all laboratory procedures, universal precautions should be followed.

Organism	Initial Concentration	Log Reduction after 15 min.
Candida albicans	5.5×10^5 CFU/mL	>4.7
Aspergillus niger*	4.8×10^5 CFU/mL	2.7
Escherichia coli	2.8×10^5 CFU/mL	>4.4
Staphylococcus aureus	2.3×10^5 CFU/mL	>4.4
Pseudomonas aeruginosa	2.5×10^5 CFU/mL	>4.4
Mycobacterium tuberculosis**	9.4×10^5 CFU/mL	4.9
Rabbitpox virus	6.0×10^6 PFU/mL	5.5***
HIV-1	$1.0 \times 10^{7.5}$ $TCID_{50}$/mL	7.0***

* After 1 hour >4.7 log reduction
** After 1 hour >5.7 log reduction
*** Data is for 5 minutes

PERFORMANCE CHARACTERISTICS: REPORT OF CLINICAL STUDIES

A prospective multi-center clinical study was conducted at three sites to evaluate the performance of the TP-3000 in direct comparison to the ThinPrep® 2000 Processor (TP-2000). The objective of this clinical study was to demonstrate that gynecologic specimens prepared using both instruments were equivalent when used for the detection of atypical cells and cervical cancer or its precursor lesions in a variety of patient populations. In addition, an assessment of specimen adequacy was performed.

The initial clinical study protocol was a single-masked, direct-to-vial, matched-pair study, for which the order of preparation for each instrument was randomized. At the laboratory, the PreservCyt sample vial was placed into both a TP-3000 and a TP-2000 and two slides were prepared (one per instrument) from the patient's sample. All slides were examined and diagnosed independently. The same cytotechnologist and pathologist (if referred) reviewed each matched-paired slide set. To minimize slide recognition bias there was a minimum one-day lag between the cytotechnologist and pathologist review of all slides from a matched-pair set. Reporting forms containing patient history as well as a checklist of all possible categories of the Bethesda System were used to record the results of the screening. A panel of three independent pathologists adjudicated all discordant cases (a one-grade or higher cytologic difference) in a masked fashion to determine a consensus diagnosis.

LABORATORY AND PATIENT CHARACTERISTICS

The cytology laboratories participating in the study were comprised of one referral center (designated as S1), one screening/referral center (designated as S2) and one screening center (designated as S3).

The screening center in the study served patient populations (screening populations) with rates of abnormality (Low-grade Squamous Intraepithelial Lesion [LSIL] and more severe lesions) similar to the United States average of less than 5%.[3] The referral center in the study served a high risk referral patient population (referral populations) characterized by high rates (>10%) of cervical abnormality. The screening/referral center's abnormality rate was a combination of the two previously mentioned rates. Table 1 describes the laboratories and the patient populations.

Table 1: Site Characteristics

	Laboratory Characteristics			Clinical Study Demographics			
Site	**Type of Patient Population**	**Laboratory Volume - Smears per Year**	**Cases**	**Patient Age Range**	**Post Menopausal %**	**Previous Abnormal Pap Smear %**	**Con-current Infection %**
S1	Referral	44,709	1188	18-85	11.8	51.8	35.2
S2	Screening/Referral	62,195	1141	18-77	6.0	21.8	15.1
S3	Screening	90,639	1198	18-82	12.5	22.7	10.2

Cases with patient's age less than 18 years or patients with a hysterectomy were excluded from this analysis.

CLINICAL STUDY RESULTS

The diagnostic classes of the Bethesda System are used to present the comparison between the TP-3000 and TP-2000 findings from all of the clinical trial sites.

Three independent pathologists served as an adjudication panel for the three clinical sites. The panel reviewed all discordant cases (a one-grade or higher cytologic difference) for descriptive diagnosis and specimen adequacy. Since a true reference cannot be determined in such studies and therefore true sensitivity cannot be calculated, the use of an independent adjudicated review provides an alternative to histologic confirmation by biopsy or human papillomavirus (HPV) testing as a means for determining the reference diagnosis. Consensus was determined when a minimum of 2 out of 3 independent pathologists rendered an equivalent diagnosis. If a majority vote could not be obtained, a consensus was achieved during a review by all three pathologists at a multi-headed scope.

Table 2 shows the unadjudicated descriptive diagnosis results from all sites for the TP-3000 and TP-2000. Of the 3,527 total patients enrolled in the study, 3,224 were included in the descriptive diagnosis analysis after all data integrity sorting was applied.

Few cases of cervical cancer were represented in the clinical study, as is typical in the United States patient population.[4]

Table 2: Unadjudicated 7 x 7 Classification Table, All Categories

		TP-3000							
		NEG	**ASCUS**	**AGUS**	**LSIL**	**HSIL**	**SQ CA**	**GL CA**	**TOTAL**
TP-2000	**NEG**	**2570**	104	6	26	3	0	0	2709
	ASCUS	119	**90**	0	23	6	0	0	238
	AGUS	4	1	**0**	0	0	0	0	5
	LSIL	17	29	1	**132**	10	0	0	189
	HSIL	0	10	0	17	**54**	0	0	81
	SQ CA	0	0	0	0	0	**2**	0	2
	GL CA	0	0	0	0	0	0	**0**	0
	TOTAL	2710	234	7	198	73	2	0	**3224**

Abbreviations for Diagnoses*: **NEG** = Normal or negative, **ASCUS** = Atypical Squamous Cells of Undetermined Significance, **AGUS** = Atypical Glandular Cells of Undetermined Significance, **LSIL** = Low-grade Squamous Intraepithelial Lesion, **HSIL** = High-grade Squamous Intraepithelial Lesion, **SQ CA** = Squamous Cell Carcinoma, **GL CA** = Glandular Cell Adenocarcinoma*

Tables 3 - 9 show the adjudicated descriptive diagnosis results from all sites for the TP-3000 and TP-2000.

Table 3: Adjudicated 7 x 7 Diagnostic Classification Table, All Categories (Includes adjudicated cases only)

		TP-3000							
		NEG	**ASCUS**	**AGUS**	**LSIL**	**HSIL**	**SQ CA**	**GL CA**	**TOTAL**
TP-2000	**NEG**	**258**	25	0	5	1	0	0	289
	ASCUS	29	**11**	0	11	0	0	0	51
	AGUS	0	0	**0**	0	0	0	0	0
	LSIL	6	9	0	**10**	2	0	0	27
	HSIL	1	2	0	3	**3**	0	0	9
	SQ CA	0	0	0	0	0	**0**	0	0
	GL CA	0	0	0	0	0	0	**0**	0
	TOTAL	294	47	0	29	6	0	0	**376**

Abbreviations for Diagnoses*: **NEG** = Normal or negative, **ASCUS** = Atypical Squamous Cells of Undetermined Significance, **AGUS** = Atypical Glandular Cells of Undetermined Significance, **LSIL** = Low-grade Squamous Intraepithelial Lesion, **HSIL** = High-grade Squamous Intraepithelial Lesion, **SQ CA** = Squamous Cell Carcinoma, **GL CA** = Glandular Cell Adenocarcinoma*

The diagnostic data analysis from all sites is summarized in Table 4 for adjudicated cytologic results of LSIL+.

Table 4: Adjudicated Two-Category Diagnostic Classification Table, LSIL and More Severe Lesions (Includes adjudicated cases only)

		TP-3000		
		NEG/ASCUS/ AGUS	**LSIL+**	**TOTAL**
TP-2000	**NEG/ASCUS/AGUS**	**323**	**17**	**340**
	LSIL+	**18**	**18**	**36**
	TOTAL	**341**	**35**	**376**

The diagnostic data analysis from each site is summarized in Table 5 for adjudicated cytologic results of LSIL+. When the p-value is significant ($p < 0.05$), the method favored is indicated in the tables.

Table 5: Adjudicated Results by Site, LSIL and More Severe Lesions (Includes adjudicated cases only)

Site	Cases	TP-3000 LSIL+	TP-2000 LSIL+	p-Value	Method Favored
S1	240	13	15	0.791	Neither
S2	65	16	16	1.000	Neither
S3	71	6	5	1.000	Neither

For LSIL and more severe lesions, the adjudicated diagnostic comparison was statistically equivalent at all sites.

The diagnostic data analysis from all sites is summarized in Table 6 for adjudicated cytologic results of HSIL+.

Table 6: Adjudicated Two-Category Diagnostic Classification Table, HSIL and More Severe Lesions (Includes adjudicated cases only)

		TP-3000		
		NEG/ASCUS/ AGUS/LSIL	**HSIL+**	**TOTAL**
TP-2000	**NEG/ASCUS/ AGUS/LSIL**	**364**	**3**	**367**
	HSIL+	**6**	**3**	**9**
	TOTAL	**370**	**6**	**376**

The diagnostic data analysis from each site is summarized in Table 7 for adjudicated cytologic results of HSIL+. When the p-value is significant ($p < 0.05$), the method favored is indicated in the tables.

Table 7: Adjudicated Results by Site, HSIL and More Severe Lesions (Includes adjudicated cases only)

Site	Cases	TP-3000 HSIL+	TP-2000 HSIL+	p-Value	Method Favored
S1	240	1	1	1.000	Neither
S2	65	3	5	0.625	Neither
S3	71	2	3	1.000	Neither

For HSIL and more severe lesions, the adjudicated diagnostic comparison was statistically equivalent at all sites.

Table 8 below shows the summary of the Bethesda System categories of the unadjudicated descriptive diagnosis data for all sites.

Table 8: Unadjudicated Summary of Descriptive Diagnosis

Descriptive Diagnosis	TP-2000		TP-3000	
Number of Patients: 3224	N	%	N	%
Benign Cellular Changes:	**903**	**28.0**	**848**	**23.6**
Infection:				
Trichomonas Vaginalis	69	2.1	67	2.1
Candida spp.	208	6.5	193	6.0
Coccobacilli	346	10.7	347	10.8
Actinomyces spp.	0	0.0	1	0.0
Herpes	2	0.1	2	0.1
Other	7	0.2	2	0.1
Reactive Cellular Changes Associated with:				
Inflammation	313	9.7	292	9.1
Atrophic Vaginitis	16	0.5	16	0.5
Radiation	1	0.0	0	0.0
IUD	0	0.0	0	0.0
Other	89	2.8	72	2.2
Epithelial Cell Abnormalities:	**526**	**16.3**	**525**	**16.3**
Squamous Cell:				
ASCUS (combined)	239	7.4	236	7.3
Favor reactive	82	2.5	73	2.3
Favor neoplastic	81	2.5	69	2.1
Undetermined	76	2.4	94	2.9
LSIL	189	5.9	198	6.1
HSIL	81	2.5	73	2.3
Carcinoma	2	0.1	2	0.1
Glandular Cell:				
Benign Endometrial cells in Postmenopausal Women	11	0.3	11	0.3
AGUS (combined)	6	0.2	8	0.3
Favor reactive	2	0.1	2	0.1
Favor neoplastic	0	0.0	1	0.0
Undetermined	4	0.1	5	0.2

Note: Some patients had more than one descriptive diagnosis subcategory.

ASCUS=Atypical Squamous Cells of Undetermined Significance
AGUS=Atypical Glandular Cells of Undetermined Significance

Table 9 shows the summary of the Bethesda System categories of the adjudicated descriptive diagnosis data for all sites.

Table 9: Adjudicated Summary of Descriptive Diagnosis (Includes adjudicated cases only)

Descriptive Diagnosis	TP-2000		TP-3000	
Number of Patients: 376	N	%	N	%
Benign Cellular Changes:	**163**	**43.4**	**174**	**46.3**
Infection:				
Trichomonas Vaginalis	8	2.1	11	2.9
Candida spp.	35	9.3	30	8.0
Coccobacilli	62	16.5	72	19.1
Actinomyces spp.	0	0.0	0	0.0
Herpes	0	0.0	0	0.0
Other	2	0.5	0	0.0
Reactive Cellular Changes Associated with:				
Inflammation	89	23.7	96	25.5
Atrophic	1	0.3	0	0.0
Vaginitis	0	0.0	0	0.0
	0	0.0	1	0.3
Radiation	4	1.1	0	0.0
IUD				
Other				
Epithelial Cell Abnormalities:	**88**	**23.4**	**82**	**21.8**
Squamous Cell:				
ASCUS (combined)	87	23.2	78	20.7
Favor reactive	9	2.4	7	1.9
Favor neoplastic	33	8.8	31	8.2
Undetermined	45	12.0	40	10.6
LSIL	27	7.2	29	7.7
HSIL	9	2.4	6	1.6
Carcinoma	0	0.0	0	0.0
Glandular Cell:				
Benign Endometrial cells in Postmenopausal Women	1	0.3	0	0.0
AGUS (combined)	0	0.0	0	0.0
Favor reactive	0	0.0	0	0.0
Favor neoplastic	0	0.0	0	0.0
Undetermined	0	0.0	0	0.0

Note: Some patients had more than one descriptive diagnosis subcategory.

ASCUS=Atypical Squamous Cells of Undetermined Significance
AGUS=Atypical Glandular Cells of Undetermined Significance

The Bethesda System delineates specimen adequacy in three categories: satisfactory, satisfactory but limited by (SBLB) and unsatisfactory. Of the 3,527 total patients enrolled in the study, 3,489 were included in the specimen adequacy analysis after all data integrity sorting was applied.

Tables 10 and 11 show the summary of the Bethesda System categories of the unadjudicated and adjudicated specimen adequacy data for all sites.

Table 10: Unadjudicated Summary of Specimen Adequacy Results

Specimen Adequacy Number of Patients: 3489	TP-2000		TP-3000	
	N	%	N	%
Satisfactory	**2985**	**85.6**	**2951**	**84.6**
Satisfactory for Evaluation but Limited by:	**385**	**11.0**	**398**	**11.4**
Air-Drying Artifact	0	0.0	1	0.0
Thick Smear	1	0.0	2	0.1
Endocervical Component Absent	244	7.0	237	6.8
Scant Squamous Epithelial Component	125	3.6	122	3.5
Obscuring Blood	22	0.6	29	0.8
Obscuring Inflammation	15	0.4	24	0.7
No Clinical History	0	0.0	2	0.1
Cytolysis	1	0.0	4	0.1
Other	0	0.0	2	0.1
Unsatisfactory for Evaluation:	**119**	**3.4**	**140**	**4.0**
Air-Drying Artifact	0	0.0	0	0.0
Thick Smear	0	0.0	0	0.0
Endocervical Component Absent	2	0.1	3	0.1
Scant Squamous Epithelial Component	109	3.1	126	3.6
Obscuring Blood	20	0.6	36	1.0
Obscuring Inflammation	3	0.1	5	0.1
No Clinical History	0	0.0	0	0.0
Cytolysis	0	0.0	0	0.0
Other	0	0.0	1	0.0

Note: Some patients had more than one subcategory.

Table 11: Adjudicated Summary of Specimen Adequacy Results (Includes adjudicated cases only)

Specimen Adequacy *Number of Patients: 57*	TP-2000		TP-3000	
	N	%	N	%
Satisfactory	**12**	**21.1**	**9**	**15.8**
Satisfactory for Evaluation but Limited by:	**24**	**42.1**	**18**	**31.6**
Air-Drying Artifact	0	0.0	0	0.0
Thick Smear	0	0.0	0	0.0
Endocervical Component Absent	6	10.5	4	7.0
Scant Squamous Epithelial Component	24	42.1	18	31.6
Obscuring Blood	0	0.0	1	1.8
Obscuring Inflammation	1	1.8	3	5.3
No Clinical History	0	0.0	0	0.0
Cytolysis	0	0.0	0	0.0
Other	0	0.0	0	0.0
Unsatisfactory for Evaluation:	**21**	**36.8**	**30**	**52.6**
Air-Drying Artifact	0	0.0	0	0.0
Thick Smear	0	0.0	0	0.0
Endocervical Component Absent	13	22.8	9	15.8
Scant Squamous Epithelial Component	21	36.8	30	52.6
Obscuring Blood	0	0.0	10	17.5
Obscuring Inflammation	1	1.8	3	5.3
No Clinical History	0	0.0	0	0.0
Cytolysis	0	0.0	0	0.0
Other	0	0.0	0	0.0

Note: Some patients had more than one subcategory.

Table 12 shows the adjudicated specimen adequacy results, respectively, from all sites for the TP-3000 and TP-2000.

Table 12: Adjudicated Two-Category Diagnostic Classification Table, Specimen Adequacy Results (Includes adjudicated cases only)

		TP-3000		
		SBLB/SAT	**UNSAT**	**TOTAL**
TP-2000	**SBLB/SAT**	**23**	**13**	**36**
	UNSAT	**4**	**17**	**21**
	TOTAL	**27**	**30**	**57**

The adjudicated specimen adequacy results from each site are presented in Table 13 as SAT/SBLB versus UNSAT.

Table 13: Adjudicated Specimen Adequacy Results by Site *(*Includes adjudicated cases only)

		SAT/SBLB		UNSAT*	
Site	**Cases**	**TP-3000 Cases**	**TP-2000 Cases**	**TP-3000 Cases**	**TP-2000 Cases**
S1	50	24	33	26	17
S2	1	0	0	1	1
S3	6	3	3	3	3
All Sites	57	27	36	30	21

Note: Excessively bloody samples may result in a higher unsatisfactory rate.

The TP-3000 provides similar results to the TP-2000 System in a variety of patient populations. The TP-3000 may be used as a replacement for the TP-2000 System in the preparation of cervical cytology samples on glass microscope slides used in the detection of atypical cells, cervical cancer, or its precursor lesions, as well as all other cytologic categories as defined by The Bethesda System.

TECHNICAL SERVICE AND PRODUCT INFORMATION

For technical service and assistance related to use of the ThinPrep® 3000 Processor, contact Hologic:

Telephone: 1-800-442-9892
Fax: 1-508-229-2795

For international or toll-free blocked calls, please contact 1-508-263-2900.
Email: info@hologic.com

REQUIRED MATERIALS

The TP-3000 consists of the following components:

- The ThinPrep® 3000 Processor (Model TP-3000)
- ThinPrep 3000 Processor Operator's Manual
- Power Cord
- Program Memory Card
- Staining Rack Adapters
- Accessory Kit

MATERIALS REQUIRED BUT NOT PROVIDED

- Slide staining system
- Coverslips and mounting media
- 20 ml PreservCyt® Solution vials
- ThinPrep Pap Test Filters
- CellFyx™ Fixative Solution
- ThinPrep Microscope Slides

STORAGE

- Store PreservCyt Solution between 15°C (59°F) and 30°C (86°F). Do not use beyond the expiration date printed on the container.
- Store PreservCyt Solution *with* cytologic sample intended for ThinPrep Pap testing between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.
- Store PreservCyt Solution *with* cytologic sample intended for CT/NG using the Roche Diagnostics COBAS AMPLICOR CT/NG test testing between 4°C (39°F) and 25°C (77°F) for up to 6 weeks.
- Store CellFyx Solution between 15°C and 30°C. Do not use beyond the expiration date printed on the container.
- CellFyx Solution preserves cells on slides up to 5 days at 15°C to 30°C prior to staining.

BIBLIOGRAPHY

1. Kurman RJ, Solomon D. *The Bethesda System for Reporting Cervical/Vaginal Cytologic Diseases*, Springer-Verlag, New York 1994.
2. United States Pharmacopeia (U.S.P.), Preservative Antimicrobial Effectiveness Test, U.S.P. XXII (51).
3. Jones HW. Impact of The Bethesda System, *Cancer* 77 pp. 1914-1918, 1995.
4. American Cancer Society. Cancer Facts and Figures, 1995.

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AW-07101-001 Rev. 006

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1. Introduction

1. Introduction

Chapter One

Introduction

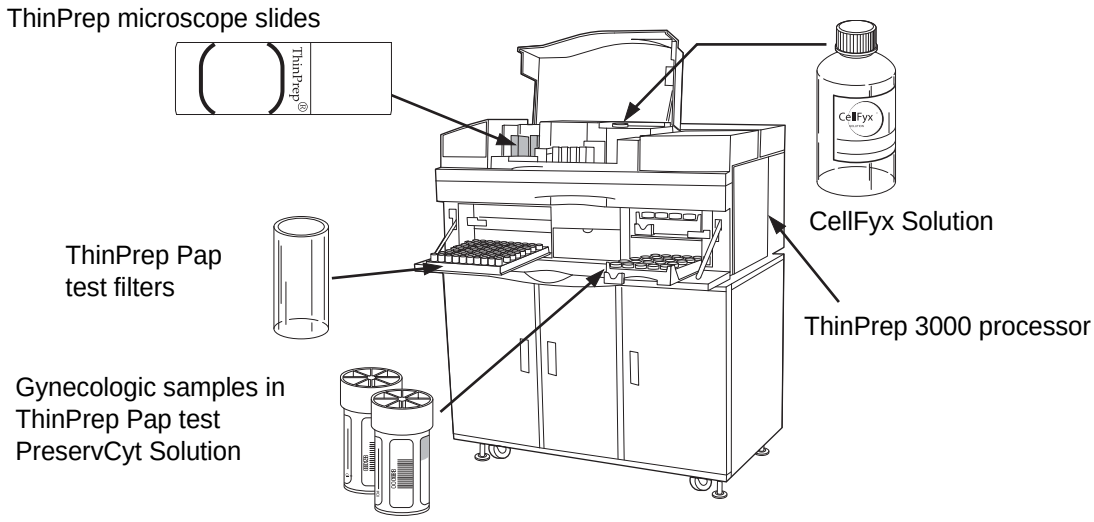
CONTENTS

SECTION A OVERVIEW AND FUNCTION OF THE THINPREP® 3000 PROCESSOR

The ThinPrep 3000 processor (refer to Figure 1-1) automates key steps in the batch processing of fluid-based gynecologic specimens for use with the ThinPrep® Pap test. The samples are collected, processed, transferred and fixed onto microscope slides in preparation for staining, cover slipping and screening. Key system components include The ThinPrep 3000 processor, sample vials of PreservCyt® Solution for use with the ThinPrep Pap test, ThinPrep Pap test filters for gynecologic use, CellFyx™ Solution, and ThinPrep microscope slides.

1 INTRODUCTION

Figure 1-1 The ThinPrep 3000 Processor



The ThinPrep® Pap Test

The ThinPrep Pap test is a fluid-based method for the collection and preparation of gynecologic samples.

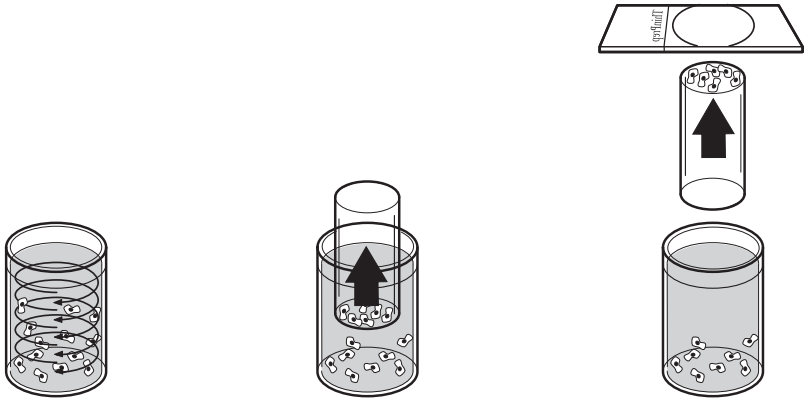
The ThinPrep Pap test begins at the physician's office where, using a broom-type collection device or endocervical brush/plastic spatula, cervical cells are collected from the patient. Rather than smearing the patient's sample directly onto a microscope slide, the collection device is immediately immersed and rinsed in a vial of PreservCyt Solution for use with the ThinPrep Pap test.

The sample vial is then capped and tightened. Patient information is recorded onto the vial of solution containing the sample and forwarded to a laboratory equipped to process the ThinPrep Pap test.

At the laboratory, matching barcoded labels are applied to the sample vial and accompanying test request form. The sample vial is then placed in a sample vial tray and loaded into the ThinPrep 3000 processor.

(Refer to Figure 1-2.) During the slide preparation process, a gentle dispersion step breaks up blood, mucus and non-diagnostic debris and thoroughly mixes the cell sample. The cells are then collected onto a ThinPrep Pap test filter. A thin layer of cells is then transferred to a ThinPrep microscope slide. The ThinPrep 3000 processor then applies CellFyx Fixative Solution to the slide, after which the slide is delivered to a staining rack.

Figure 1-2 The ThinPrep Sample Preparation Process



Dispersion

The sample vial is rotated, dispersing debris and mucus while thoroughly mixing the cell sample.

Cell Collection

A gentle vacuum is created in the ThinPrep Pap test filter, which collects cells on the exterior surface of the membrane.

Cell Transfer

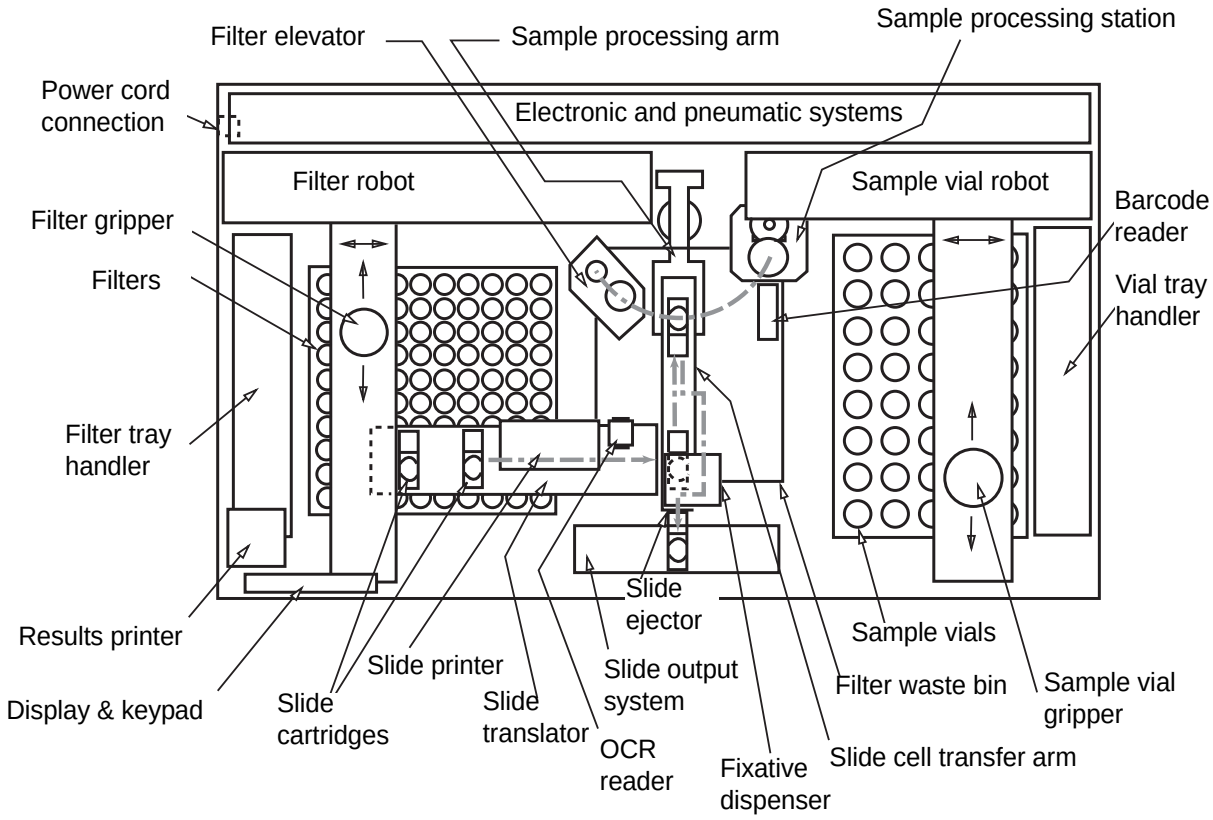
The ThinPrep Pap test filter is inverted and the collected cells are gently and evenly transferred onto the ThinPrep microscope slide in a defined area.

SECTION B

OVERVIEW OF INSTRUMENT SYSTEMS

Figure 1-3 Overview of Instrument Systems

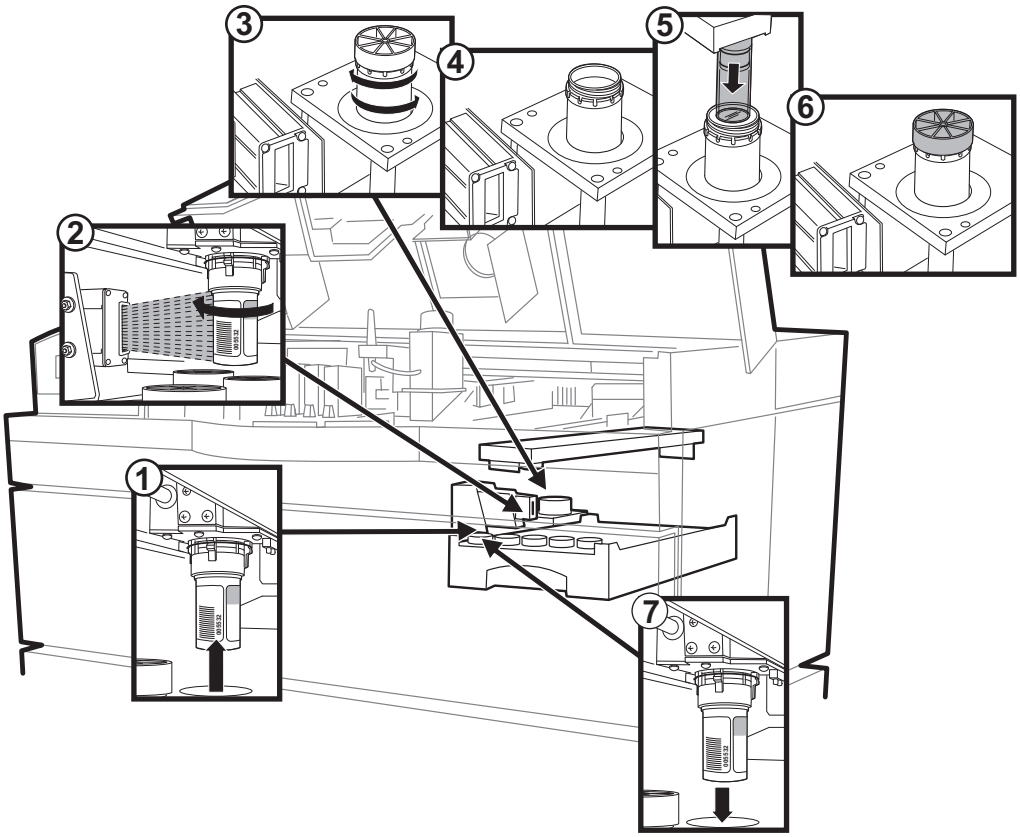
(TOP VIEW)



THINPREP 3000 PROCESSOR
(FRONT OF INSTRUMENT)

Vial Handling System

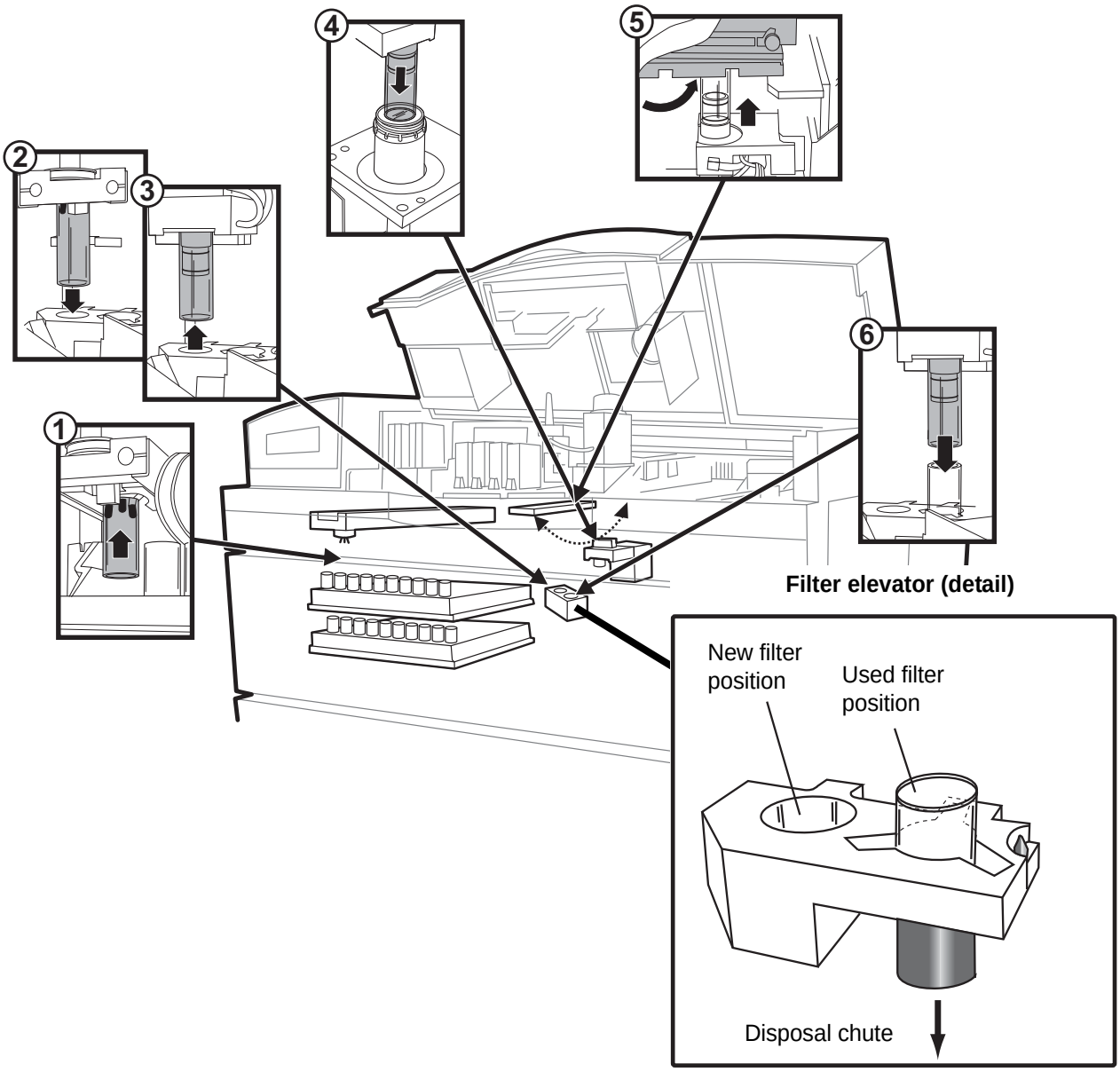
Figure 1-4 Vial Handling System



1. The sample vial is picked from the tray.
2. The barcode is scanned and read.
3. The sample vial is delivered to the sample processing station and the sample is dispersed by spinning the vial.
4. The vial is uncapped.
5. The filter is introduced for cell collection.
6. The vial is recapped.
7. The sample vial is returned to the sample tray.

Filter Handling System

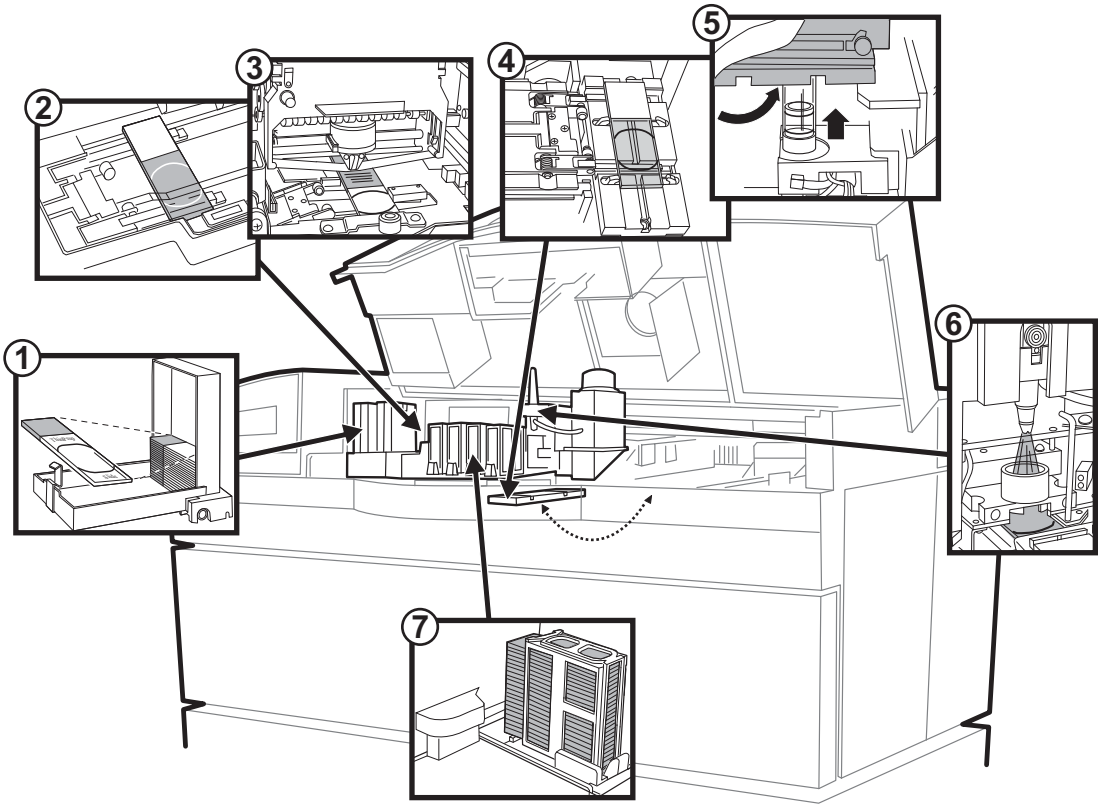
Figure 1-5 Filter Handling System



1. A ThinPrep Pap test filter is picked from the tray.
2. The filter is delivered to the filter elevator.
3. The sample processing arm retrieves the filter.
4. The filter is brought to the sample processing station and placed in the vial for sample collection.
5. The sample processing arm rotates and precisely meets with the slide cell transfer arm, bearing a slide. Cell transfer occurs.
6. The used filter is returned to the filter elevator for disposal.

Slide Handling System

Figure 1-6 Slide Handling System



1. Slide cartridge(s) loaded with slides are placed in the instrument.
2. The slide translator picks a slide from the cartridge and carries it to the slide printer.
3. The barcode number scanned from the sample vial is printed onto the slide, along with the time, date and facility name (optional).
4. The slide translator hands the slide off to the slide cell transfer arm.
5. The slide cell transfer arm pivots to convey the slide to meet the ThinPrep Pap test filter for cell transfer.
6. The slide cell transfer arm delivers the slide to the fixative dispenser, where fixative is applied.
7. The prepared slide is placed into a staining rack.

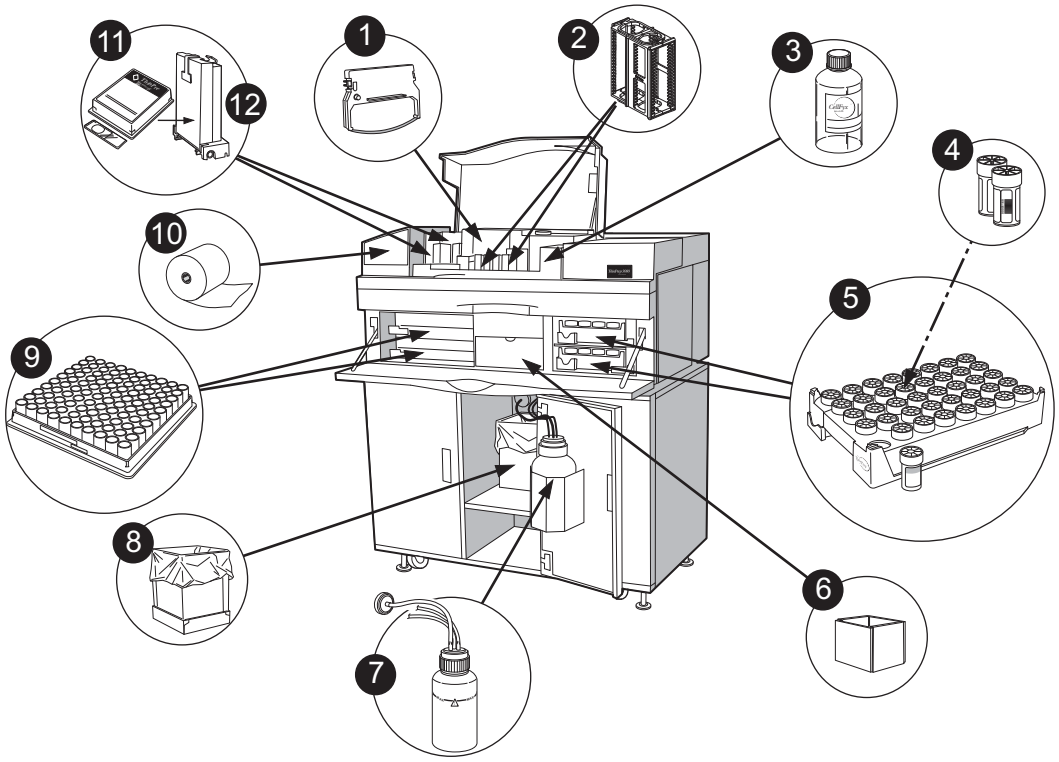
SECTION C

MATERIAL REQUIREMENTS

Components of the ThinPrep 3000 Processor

1. Slide printer ribbon
2. Staining racks
3. CellFyx Solution
4. Sample vials (with barcode)
5. Sample vial trays
6. Slide waste bin
7. Waste bottle assembly
8. Filter waste box
9. ThinPrep Pap test filter trays
10. Results printer paper
11. ThinPrep microscope slides
12. Slide cartridges

Figure 1-7 Material Requirements



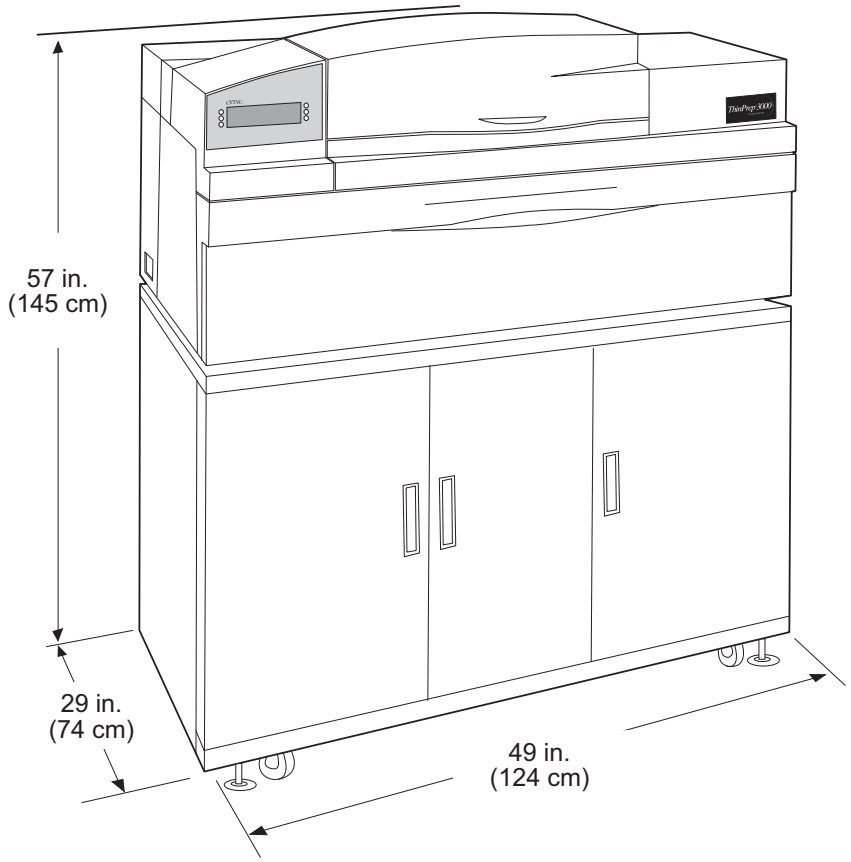
SECTION D

THINPREP 3000 PROCESSOR TECHNICAL SPECIFICATIONS

ThinPrep 3000 Processor Dimensions

Note: All measurements in this manual are rounded to the nearest whole number.

Figure 1-8 Dimensions

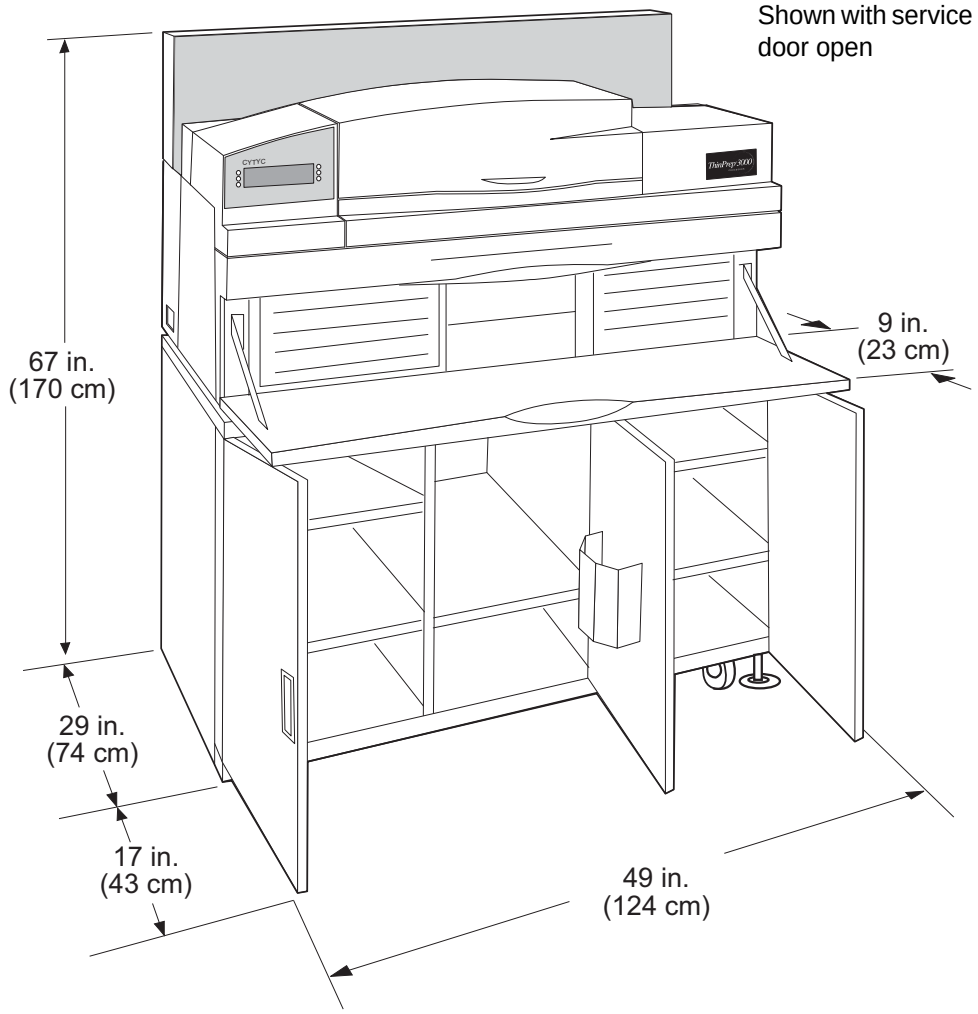


Approximate weight: 700 lb/318 kg.

ThinPrep 3000 Processor Clearances

A minimum installation clearance of 1 foot (30.5 cm) at the rear, top, and sides of the instrument is required for ventilation. (Shown with service cover open.)

Figure 1-9 Clearances



Environmental

Operating[1] Temperature Range:

60–90°F/16–32°C

Non-Operating[2] Temperature Range:

-20–122°F/ -29–50°C

Operating Humidity Range:

20–90% RH, non-condensing

Non-Operating Humidity Range:

15–95% RH, non-condensing

Pollution Degree:

II, in accordance with IEC 664.
The ThinPrep 3000 processor is for indoor use only in an office or a clean laboratory environment.

Power

Voltage:

100–240~ (Volts Alternating Current, no selection required)
Mains supply voltage not to exceed ± 10% of the nominal voltage

Frequency:

47–63Hz

Current:

4A maximum; 500W maximum

Heat Generated:

Approximately 1100BTU/HR

WARNING: Instrument Fusing

Fusing: (⏛)

External – 2 X T6.3AL 250V 5 x 20mm; 6.3A time delay low break capacity
Internal – 1 X 15A 250V 3AB; 15A fast blow high break capacity fuse internal to system power supply (non-operator accessible)

1. Operating: The ThinPrep 3000 processor is plugged in and turned on.
2. Non-Operating: The ThinPrep 3000 processor may be plugged in, but is not turned on.

Safety, EMI and EMC Standards

The ThinPrep 3000 processor has been tested and certified by a U.S. nationally recognized testing laboratory (NRTL) to comply with Safety, Electro-Magnetic Interference (EMI) and Electro-Magnetic Compatibility (EMC) standards.

SECTION E INTERNAL QUALITY CONTROL

Power On Self Test (POST)

At the time the ThinPrep 3000 processor is powered on (refer to page 2.4) the system goes through a self-diagnostic test. Electrical, mechanical and software systems are tested to confirm each performs properly. The operator is alerted to any malfunction via a message on the user interface. If the instrument does not function or there are persistent errors, contact Hologic Technical Support.

SECTION F THINPREP 3000 PROCESSOR HAZARDS

The ThinPrep 3000 processor is intended to be operated in the manner specified in this manual. Be sure to review and understand the information listed below in order to avoid harm to operators and/or damage to the instrument.

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

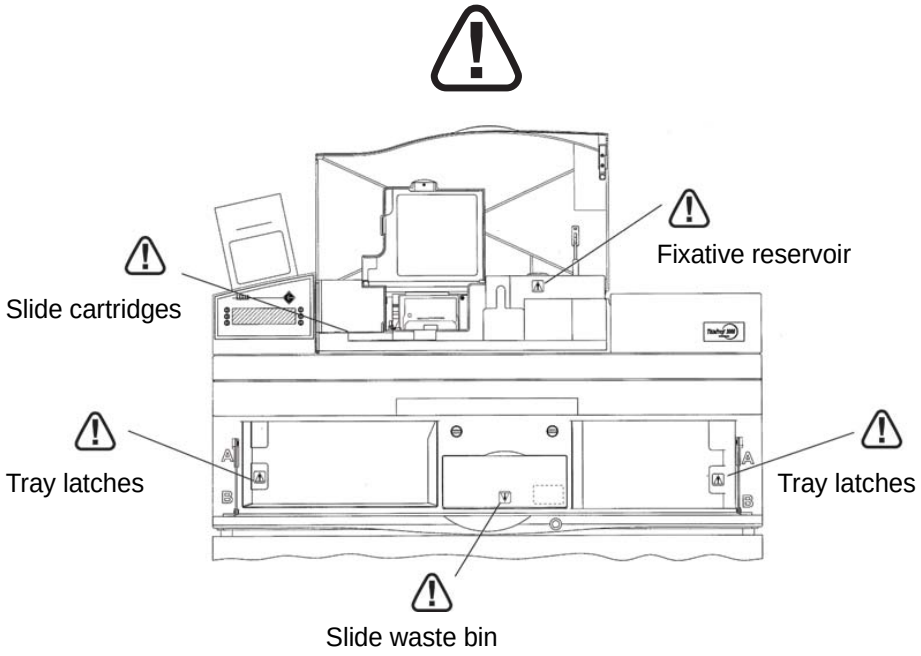
Warnings, Cautions and Notes

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

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

Warning Symbol Used on the Instrument

The ThinPrep 3000 processor has the exclamation mark within a triangle symbol placed on it specifically to warn the operator to refer to the operator's manual. (Refer to the illustration below.) Be sure to review and understand the warnings listed below in order to avoid damage to the instrument and any harm to operators. One or more of the warnings may be pertinent to the area marked.



Warnings Used in this Manual

WARNING

Service Installation Only

This instrument is to be installed and/or moved by trained Hologic personnel only.

CAUTION

There is a miniature barcode laser scanner embedded inside this product for identifying samples. There is no intended access to this laser source for operators. Use of controls, adjustments or procedures other than those specified in this manual may result in hazardous radiation exposure.

WARNING

Instrument Fusing

For continued protection against fire, replace only with fuses of the specified type and current rating. Refer to "Instrument Maintenance" on page 6.1 for instructions on replacing user accessible fuses.

WARNING

Flammable Liquid and Vapor

Flammable liquid and vapor. Keep away from heat, sparks, open flames and hot surfaces.

WARNING

Strong oxidizers, such as bleach, are incompatible with PreservCyt Solution and therefore should not be used to clean the waste bottle.

WARNING

Toxic Mixture

Refer to Safety Data Sheets (SDS) at www.hologicsds.com for safe handling instructions. Wear personal protective laboratory gear.

WARNING

Moving Parts

The instrument contains many internal moving parts. Keep hands, loose clothing, jewelry, etc., clear. Do not operate with the doors open.

WARNING

Power Connection

To ensure safe operation, the instrument must be connected to a three-wire grounded receptacle.

WARNING

Sharp Edges/Hot Surfaces

The instrument contains sharp edges and hot surfaces. Use extreme caution when handling items near these areas. Allow hot surfaces to cool before handling.

WARNING

Glass, Sharp Edges

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

WARNING

Protective Clothing

Wear protective clothing in accordance to universal precautions[1] when operating the instrument.

1. US Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 2nd Edition, May 1988. pp 109-111.

WARNING

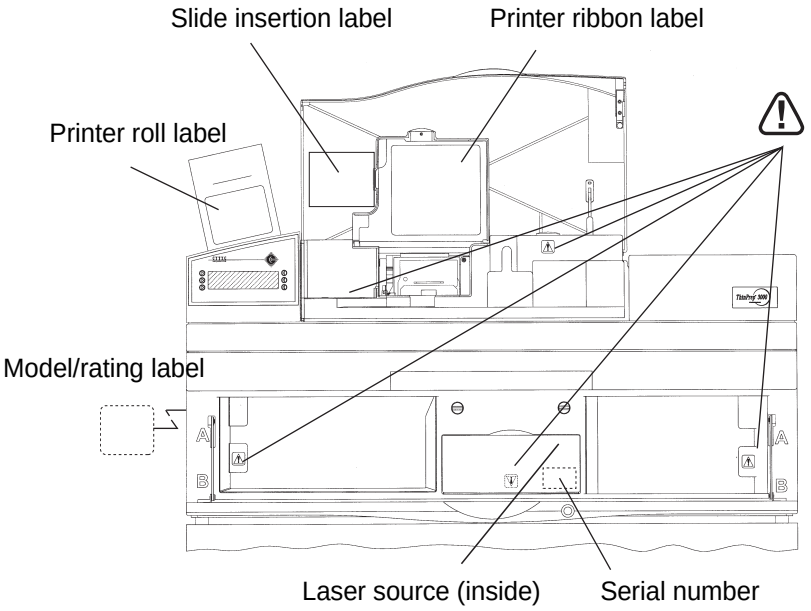
Waste Removal

Use caution when emptying the waste bottle. Refer to "Emptying the Waste Bottle" on page 6.28 for instructions on removing and emptying the waste bottle.

WARNING

Do not process a cerebral spinal fluid (CSF) specimen or other sample type that is suspected of possessing prion infectivity (PrPsc) derived from a person with a TSE, such as Creutzfeldt-Jakob disease, on a ThinPrep processor. A TSE-contaminated processor cannot be effectively decontaminated and therefore must be properly disposed of in order to avoid potential harm to users of the processor or service personnel.

Location of Instrument Labels



The **model/rating** label for the instrument is located on the left side of the machine.

The **serial number** label is located inside the flip-down center door.

A label illustrating how to insert a batch **printer roll** is located on the inside of the cover over the batch printer.

A label illustrating how to orient and insert the **slide cartridges** is located inside the top cover.

A label illustrating how to remove and replace the **slide printer ribbon** is located inside the top hatch.

Attention - labels are located at different parts of the instrument. Refer to the explanation and list of warnings on the previous pages.

SECTION G

DISPOSAL

Disposal of Consumables

- **Used filters.** Dispose of as regular waste.
- **Swabs and towels for instrument cleaning.** Dispose of as regular waste.
- **Waste bottle contents.** Dispose of all solvents as hazardous waste. Follow local, state, provincial and federal or country guidelines. As with all laboratory practices, universal precautions should be followed.
- **PreservCyt Solution.** Follow local, state, provincial and federal or country guidelines. Dispose of all solvents as hazardous waste.
- **CellFyx Solution.** Follow local, state, provincial and federal or country guidelines. Dispose of all solvents as hazardous waste.
- **Versa-Clean Solution.** Follow local, state, provincial and federal or country guidelines. Dispose of all solvents as hazardous waste.
- **Pinch valve tubing.** Dispose of as regular waste.
- **Broken glass.** Dispose of in a Sharps container.
- **Super Lube.** Dispose of as regular waste.

Disposal of the Instrument

Do not dispose in municipal waste.

Contact Hologic for information regarding proper disposal.

HOLOGIC, INC.
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752 USA
TEL: 1-800-442-9892
1-508-263-2900
FAX: 1-508-229-2795
WEB: WWW.HOLOGIC.COM

1 INTRODUCTION

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2. ThinPrep 3000
Installation

Chapter Two

ThinPrep 3000 Installation

CONTENTS

SECTION A GENERAL

The ThinPrep® 3000 Processor must be installed by Hologic service personnel. When installation is complete, the service personnel trains the operator(s), using the operator's manual as the training guide. In the event the instrument must be moved after installation, please contact Hologic Technical Support.

CAUTION: Vibrating machinery, such as centrifuges, should not be installed near the instrument.

SECTION B ACTION UPON DELIVERY

Inspect the packing carton(s) for damage. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible.

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

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

2 THINPREP 3000 INSTALLATION

Shipping Container Checklist

You will receive the following items when the ThinPrep® 3000 processor is delivered for installation. (These items may vary according to your order.)

- ***ThinPrep 3000 processor*** ***1***
- ***ThinPrep 3000 Processor Operator's Manual*** ***1***
- ***Power cord*** ***1***
- ***Program Memory Card*** ***1***
- ***Staining rack adapters*** ***4***
- ***Installation Kit, including:*** ***1***

Filter waste box	1
Fixative shield mount	1
Pinch valve tubing	4 pieces
Pneumatic test vial (in protective case)	1
Sample vial trays (*4 per package*)	2 packages
Slide cartridges	2
Staining racks (*4 per package*)	2 packages
Slide waste bin	2
Transport cover for the waste bottle	1
Aerosol spray bottle	1 bottle

(*Consumable Items*):

Filter waste box liner	5
Slide printer ribbon	2
Results printer paper (*5 rolls per box*)	1 box
ThinPrep 3000 Maintenance Kit	1 kit
Versa-Clean™ Solution	1 bottle

SECTION C

PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

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

Location and Configuration

Locate the ThinPrep 3000 processor near a three-wire grounded power outlet that is free of voltage fluctuations and power surges. Vibrating equipment, such as vortexors or centrifuges should not be installed near the instrument.

Refer to Figure 1-9, Clearances, for space needed for installation.

SECTION D

STORAGE AND HANDLING - POST INSTALLATION

Be sure to clean and maintain the ThinPrep 3000 processor as instructed in this manual. Refer to “Instrument Maintenance” on page 6.1.

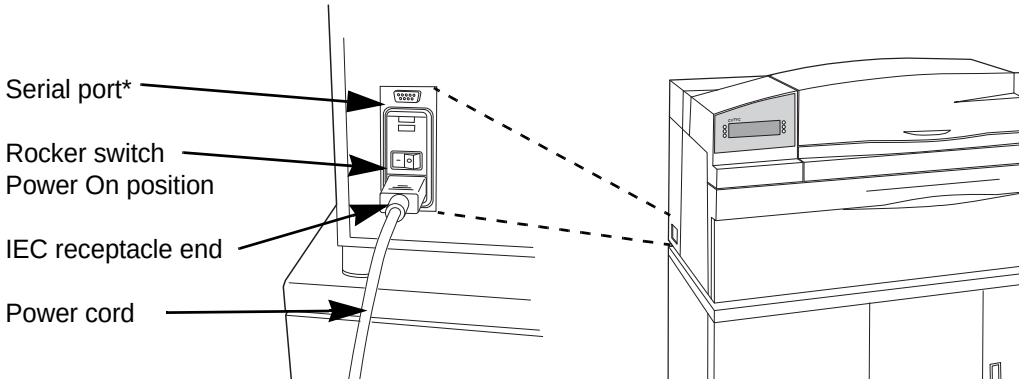
If the instrument is to be moved after installation, please contact Hologic Technical Support.

SECTION E CONNECT POWER

Plug the IEC receptacle end of the power cord (provided with the processor) into the socket, located beneath the power switch (Figure 2-1). Plug the other end of the power cord into the wall outlet. To ensure safe operation of the instrument, use a three-wire grounded outlet.

Figure 2-1 Connect Power to the Instrument

WARNING: Grounded Outlet

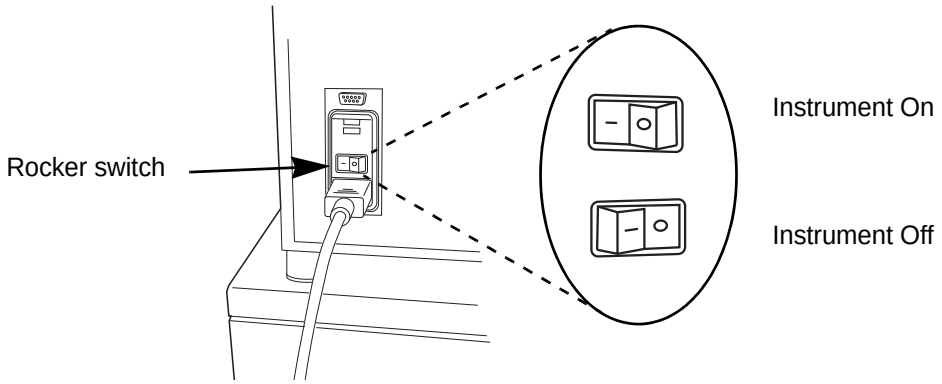


*Serial port: For use by Hologic personnel only.

SECTION F HOW TO TURN THE PROCESSOR ON/OFF

Turn the Processor On

To turn the ThinPrep 3000 processor on, press the rocker switch, located by the power cord, as shown below.



Turn the Processor Off

To turn the instrument off, press the rocker switch to the opposite position. To completely remove power from the instrument, unplug the power cord from the wall outlet.

Note: The ThinPrep 3000 processor is intended to remain on.

Extended Shutdown (Taking the Instrument Out of Service)

If the instrument is to be shut down for an extended time, turn it off as instructed above.

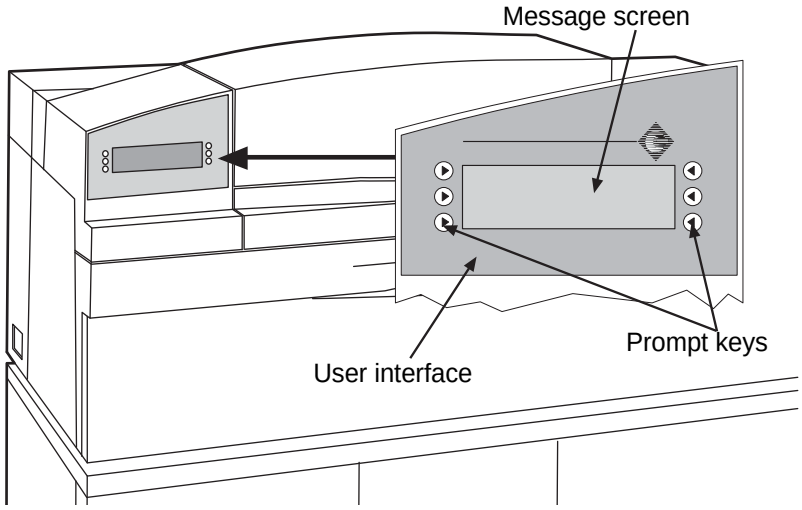
Remove and safely store any patient slides and sample vials that may be on-board the instrument.

Empty the waste bottle, the slide waste bin and the filter waste box (refer to Instrument Maintenance for each of these items).

Close all of the doors and unplug the power cord from the wall socket.

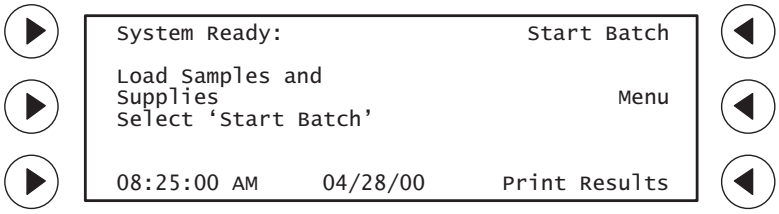
SECTION G

SYSTEM STARTUP



Upon startup, the instrument conducts an initial self test for several minutes. During this time, **Self Test in Progress** and a progress bar are displayed on the message screen:

At the conclusion of the self test, the main menu screen is displayed:



- Select **Start Batch** to begin processing samples.
- Select **Menu** to access the Utility menu: Status, Maintenance, Setup and Test menus.
- Select **Print Results** to print the batch report from the previous batch of samples processed.

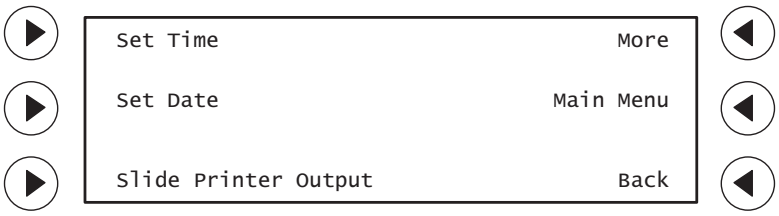
SECTION H

SETTING THE TIME AND DATE

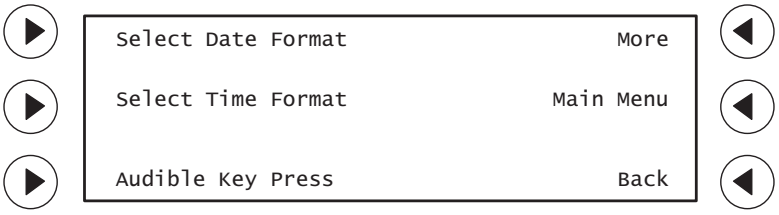
Setting the Time

In this procedure, first select the desired time format, then set the time.

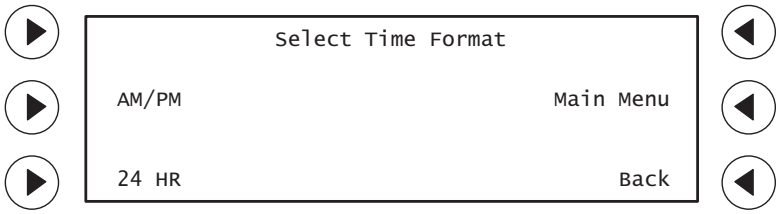
1. In the main menu screen, select **Menu**.
2. Select **Setup**.
3. Select **More** (option at the upper right of the display).



4. Press **Select Time Format**.

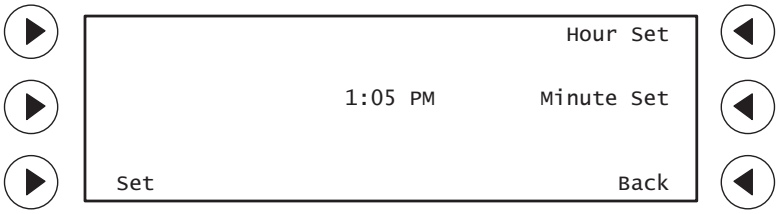


5. Select a time format: **AM/PM** or **24 HR**.



Note: Time format is for the user interface display only. All reporting (slide printing and batch reports) will automatically have 24-hour formats on them.

6. Press **Back** to return to the Set Time display screen. Select **Set Time**.

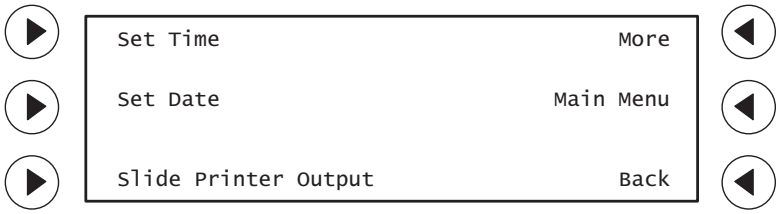


7. To set the hour, press the **Hour Set** prompt key until the correct hour appears.
8. To set minutes, press the **Minute Set** prompt key until the correct minutes appears.
9. Select **Set** to save.

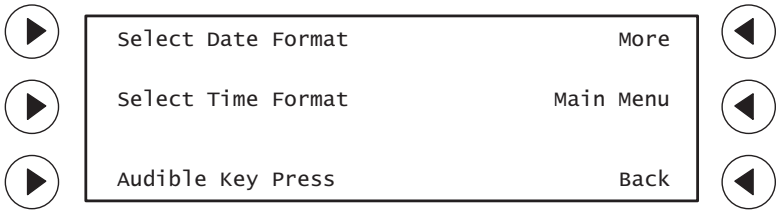
Note: Selecting **Back** at any time prior to selecting **Set** will delete all new entries and return to the previous screen.

Setting the Date

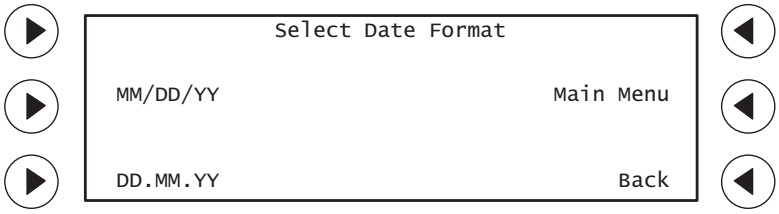
1. In the main menu screen, select **Menu**.
2. Select **Setup**.
3. Select **More** (option at the upper right of the display).



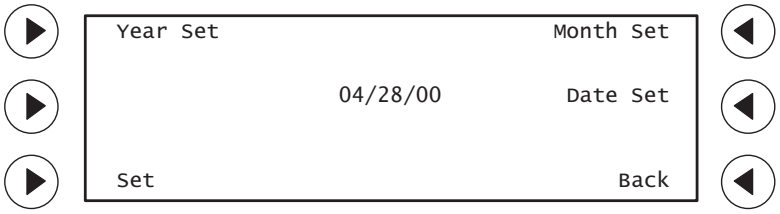
4. Press **Select Date Format**.



5. Select a date format: **MM/DD/YY** or **DD.MM.YY**.



6. Press **Back** to return to the Set Date display screen. Select **Set Date.**



7. To set the year, press the **Year Set** prompt key until the correct year appears.
8. To set the month, press the **Month Set** prompt key until the correct month appears.
9. To set the day, press the **Date Set** prompt key until the correct day appears.
10. Select **Set** to save.

Note: Selecting **Back** at any time prior to selecting **Set** will delete all new entries and return to the previous screen.

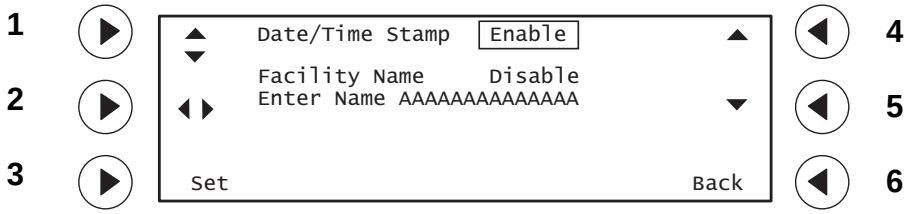
SECTION I

SETTING THE SLIDE PRINTER OUTPUT

The sample barcode number automatically prints on each slide. To record the date, time, and your facility's name on the ThinPrep microscope slide, you must enter this information using this setup utility.

1. In the main menu screen, select **Menu**.
2. Select **Setup**.
3. Select **Slide Printer Output**.

Note: Selecting **Back** at any time prior to selecting **Set** will delete all new entries and return to the previous screen



4. To activate the date/time feature, press prompt key #1 until the highlighted box appears next to **Date/Time Stamp**.
5. Press prompt key #4 or #5 until **Enable** appears. (Selecting **Disable** deactivates the date/time feature.)
6. To activate the facility's name, press prompt key #1 until the highlighted box appears next to **Facility Name**.
7. Press prompt key #4 or #5 until **Enable** appears.
8. To input your facility's name, press prompt key "1" until the highlighted box appears next to **Enter Name**.
9. Use prompt keys #4 (steps from A to Z) and #5 (steps from Z to A) to move one letter at a time through the alphabet.
10. After selecting a letter, press prompt key #2 to move to the next letter space.

Note: The field for the facility name is 14 characters' long, all capital letters.

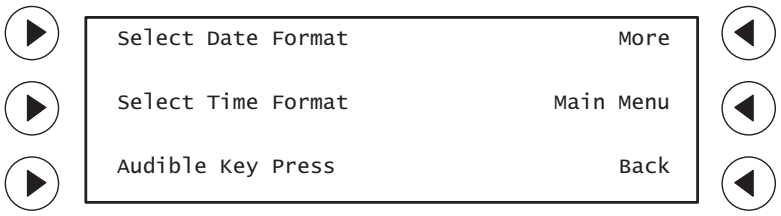
11. Select **Set** to save.

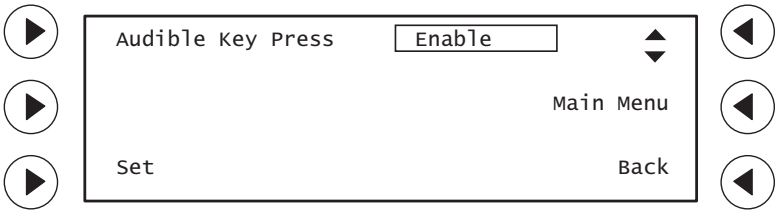
SECTION J

SETTING THE AUDIBLE KEY PRESS

This is an option that sounds a 'beep' every time a key on the user interface panel is pressed.

1. In the main menu screen, select **Menu**.
2. In the next display, select **Setup**.
3. In the **Setup** menu, select **More**. Select **Audible Key Press**.





4. The ▲▼ key will toggle between the Enable and Disable choices for this function.
   - To produce an audible beep with each key press, highlight **Enable** and then press **Set**.
   - To turn off the audible beep (if it has already been set on), highlight **Disable** and press **Set**.

2 THINPREP 3000 INSTALLATION

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3. PreservCyt and CellFyx Solutions

3. PreservCyt and CellFyx Solutions

Chapter Three

PreservCyt® and CellFyx™ Solutions

CONTENTS

SECTION A

INTRODUCTION

The following sections describe the function and specifications of Hologic cytologic preservative fluid, PreservCyt Solution and fixative fluid, CellFyx Solution.

SECTION B

PRESERVCYT® SOLUTION

PreservCyt Solution is a methanol-based, buffered solution designed to preserve cells during transport and slide preparation on the ThinPrep® 3000 processor.

PreservCyt Solution is optimized for the ThinPrep processor slide preparation process and cannot be substituted with any other reagents.

Packaging

Please refer to the **Ordering Information** in this manual for part numbers and detailed information regarding the ordering of solutions and supplies for the ThinPrep 3000 processor.

Vials (20 mL) of PreservCyt Solution are contained in each ThinPrep Pap Test Kit.

Composition

PreservCyt Solution contains buffered methanol. It contains no reactive ingredients. It contains no active ingredients.

WARNING:

Toxic

Flammable

WARNING: Danger. PreservCyt Solution contains methanol. Toxic if swallowed. Toxic if inhaled. Causes damage to organs. Cannot be made non-poisonous. Keep away from heat, sparks, open flames and hot surfaces. Other solutions cannot be substituted for PreservCyt Solution.

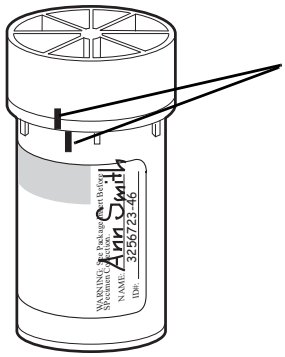
Storage Requirements

- Store PreservCyt Solution between 15°C (59°F) and 30°C (86°F). Do not use beyond the expiration date printed on the container.
- Store PreservCyt Solution *with* cytologic sample intended for ThinPrep Pap testing between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.
- Store PreservCyt Solution *with* cytologic sample intended for CT/NG testing using the Roche Diagnostics COBAS AMPLICOR CT/NG test between 4°C (39°F) and 25°C (77°F) for up to 6 weeks.

Transportation

When transporting a PreservCyt Solution vial containing cells, make sure the vial is tightly sealed. To prevent leakage, align the mark on the cap with the mark on the vial as shown in the figure below.

Figure 3-1 PreservCyt Solution Vial



The shipping category for PreservCyt Solution is

"flammable liquids, n.o.s. (methanol)" (USA only)
"flammable liquids, toxic, n.o.s. (methanol)" (outside the USA)

The shipping category for PreservCyt Solution containing cells is "diagnostic sample."

Please refer to the Shipping Requirements and Recommendations guide at the end of this chapter.

Stability

Do not use PreservCyt Solution after the expiration date on the container label. Expired vials should be discarded using appropriate laboratory procedures. Also, refer to storage requirements above for cell preservation limits.

Handling/Disposal

Handle all chemical-containing materials carefully in accordance with safe laboratory practices. When required by reagent composition, additional precautions are marked on the reagent containers or in the instructions for use.

Dispose of PreservCyt Solution according to the guidelines for disposing of hazardous waste. PreservCyt Solution contains methanol.

PreservCyt Solution was challenged with a variety of microbial and viral organisms. The following table presents the starting concentrations of viable organisms and the number of viable organisms found after 15 minutes in the PreservCyt Solution. The log reduction for viable organisms is also presented. As with all laboratory procedures, universal precautions should be followed.

Organism	Initial Concentration	Log Reduction after 15 min.
Candida albicans	5.5×10^5 CFU/mL	>4.7
Aspergillus niger*	4.8×10^5 CFU/mL	2.7
Escherichia coli	2.8×10^5 CFU/mL	>4.4
Staphylococcus aureus	2.3×10^5 CFU/mL	>4.4
Pseudomonas aeruginosa	2.5×10^5 CFU/mL	>4.4
Mycobacterium tuberculosis**	9.4×10^5 CFU/mL	4.9
Rabbitpox virus	6.0×10^6 PFU/mL	5.5***
HIV-1	$1.0 \times 10^{7.5}$ $TCID_{50}$/mL	7.0***

* After 1 hour >4.7 log reduction
** After 1 hour >5.7 log reduction
*** Data is for 5 minutes

Interfering Substances

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.

SECTION C

CELLFYX™ SOLUTION

CellFyx Solution is a methanol-based, fixative solution designed to preserve morphologic features of cells for up to 5 days at room temperature. CellFyx Solution is optimized for the ThinPrep 3000 processor slide preparation process and cannot be substituted with any other reagents.

Packaging

Please refer to the **Ordering Information** in this manual for part numbers and detailed information regarding the ordering of solutions and supplies for the ThinPrep 3000 processor.

Composition

CellFyx Solution contains methanol. It contains no reactive ingredients.

WARNING: Danger. CellFyx Solution contains methanol. Toxic if swallowed. Toxic if inhaled. Causes damage to organs. Cannot be made non-poisonous. Keep away from heat, sparks, open flames and hot surfaces. Other solutions cannot be substituted for CellFyx Solution.

Storage Requirements

- The storage condition for CellFyx Solution is up to two years from date of manufacture at 15°C to 30°C.
- Slides fixed with CellFyx are preserved for 5 days at room temperature.

Stability

Do not use CellFyx Solution after the expiration date on the container label. Expired bottles should be discarded using appropriate laboratory procedures.

Handling/Disposal

Handle all chemical-containing materials carefully in accordance with safe laboratory practices. When required by reagent composition, additional precautions are marked on the reagent containers.

Dispose of CellFyx Solution according to the guidelines for disposing of hazardous waste. CellFyx Solution contains methanol.

3 PRESERVCYT® AND CELLFYX™ SOLUTIONS

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ThinPrep® Solutions[1] Storage Guide[2]

The National Fire Protection Association (NFPA) is the expert authority that local fire departments and fire safety code enforcement authorities look to for fire safety standards and codes. Their codes are developed through a consensus standards development process approved by the American National Standards Institute. The NFPA codes are used as guidelines by most fire code enforcement agencies. Since these codes are guidelines, your local Authority Having Jurisdiction (AHJ) for fire code enforcement may make the final determination. The summary chart below is based upon guidelines for facilities protected by standard sprinkler systems. [3]

The ThinPrep products NFPA ratings are listed in a table below this chart.

Use this chart to help you determine your maximum storage limits for flammable and combustible liquids.

Maximum Quantities of Flammable and Combustible Liquids in Laboratory Units Outside of Inside Liquid Storage Areas[4]

Lab Unit Fire Hazard Class	Flammable & Combustible Liquid Class	NFPA Code	Quantities in Use						Quantities in Use and Storage					
			Max per 100ft² (9.2m²) of Lab Unit[5]			Max Quantity per Lab Unit			Max per 100ft² (9.2m²) of Lab Unit[5]			Max Quantity per Lab Unit		
			Gallons	Liters	Vials[8]	Gallons	Liters	Vials[8]	Gallons	Liters	Vials[8]	Gallons	Liters	Vials[8]
A (High)	I	45-2015	10	38	1900	480	1820	91,000	20	76	3800	480	1820	91,000
	I, II, IIIA	45-2015	20	76	3800	800	3028	151,400	40	150	7500	1600	6060	303,000
B[6] (Moderate)	I	45-2015	5	19	950	300	1136	56,800	10	38	1900	480	1820	91,000
	I, II, IIIA	45-2015	10	38	1900	400	1515	75,750	20	76	3800	800	3028	151,400
C[7] (Low)	I	45-2015	2	7.5	375	150	570	28,500	4	15	750	300	1136	56,800
	I, II, IIIA	45-2015	4	15	750	200	757	37,8520	8	30	1500	400	1515	75,750
D[7] (Minimal)	I	45-2015	1	4	200	75	284	14,200	2	7.5	375	150	570	28,500
	I, II, IIIA	45-2015	1	4	200	75	284	14,200	2	7.5	375	150	570	28,500

Maximum Quantities of PreservCyt Solution (Class IC) That Can Be Stored per Fire Area[9] Outside a Safety Flammable Cabinet

Location	NFPA Code	Gallons	Liters	Vials[8]
General Warehouse[10][12][13]	30-2015	120	460	23,000
Liquid Warehouse[3,11]	30-2015	Unlimited	Unlimited	Unlimited
Office, to include Exam Rooms	30-2015	10	38	1900

Allowable Quantities of PreservCyt Solution That Can Be Stored in a Liquid Storage Room

Location	NFPA Code	Gallons	Liters	Vials[8]
Maximum allowable storage per ft² in an inside storage room that is smaller than 150ft² in size.	30-2015	5	19	950
Maximum allowable storage per ft² in an inside storage room that is larger than 150ft² and less than 500ft² in size.	30-2015	10	38	1900

(1) Solution classifications: PreservCyt – Class IC; CytoLyt – Class II; CellFyx – Class IB

(2) This information is Hologic's summary of the various regulations. To view the codes in their entirety, please refer to NFPA 30 and NFPA 45.

(3) A Liquid Warehouse shall have a sprinkler system that complies with the appropriate system indicated in NFPA 30.

(4) An Inside Liquid Storage Area is a storage room totally enclosed within a building and having no exterior walls.

(5) A Laboratory Unit is the area surrounded by firewalls per NFPA 30 *Flammable and Combustible Liquids Code*.

(6) Reduce quantities by 50% for B laboratory units located above the 3rd floor.

(7) Reduce quantities by 25% for C and D laboratory units located on the 4th-6th floors of a building and reduce quantities by 50% for C and D laboratory units above the 6th floor

(8) 20ml PreservCyt vials.

(9) A Fire Area is the area of a building separated from the remainder of the building by construction having a fire resistance of at least 1-hour and having all communicating openings properly protected by an assembly having a fire resistance rating of at least 1-hour per NFPA 30 *Flammable and Combustible Liquids Code.*

(10) Allowable quantities in a warehouse can be increased with a sprinkler system rated higher than standard systems.

(11) A Liquid Warehouse is a separate, detached building or attached building used for warehousing-type operations for liquids.

(12) Quantities are permitted to be increased 100% where stored in approved flammable liquids storage cabinets.

(13) Quantities are permitted to be increased 100% in buildings equipped throughout with an automatic sprinkler system installed in accordance tiwh NFPA13, Standard for the Installation of Sprinkler Systems.

This table lists the NFPA ratings for all the ThinPrep products.

ThinPrep Product	Health Hazard	Flammability Hazard	Instability Hazard	Specific Hazard
ThinPrep PreservCyt Solution	2	3	0	N/A
ThinPrep CytoLyt Solution	2	2	0	N/A
ThinPrep CellFyx Solution	2	3	0	N/A
ThinPrep Rinse Solution	0	0	0	N/A
ThinPrep Bluing Solution	0	0	0	N/A
ThinPrep Rinse II Solution	2	3	0	N/A
ThinPrep Bluing II Solution	0	0	0	N/A
ThinPrep Stain EA Solution	2	3	0	N/A
ThinPrep Stain Orange G Solution	2	3	0	N/A
ThinPrep Nuclear Stain	2	0	0	N/A

ThinPrep® Solutions Shipping Requirements *

Scope:

These requirements include shipping:

- Biological specimens (patient specimens) in ThinPrep® solutions
- Biological specimens in solutions other than ThinPrep® solutions
- Biological specimens not in solutions
- ThinPrep® PreservCyt™ Solution without biological specimens
- ThinPrep® CytoLyt™ Solution without biological specimens

Note: Shippers of Hazardous Materials or Dangerous Goods must be trained according to the various Hazardous Materials/Dangerous Good regulations

A. Shipping Requirements when shipping patient samples in ThinPrep PreservCyt Solution only – Ambient Temperature:

1. Patient samples / biological substances (pathogens) contained ThinPrep PreservCyt Solution are neutralized or inactivated by the solution and as such no longer pose a health risk. (For further information regarding this, refer to the ThinPrep 2000 or ThinPrep 5000 Operators' Manual).
2. Materials that have been neutralized or inactivated are exempt from the Category B Class 6, Division 6.2 requirements.
3. Solutions that contain neutralized or inactivated pathogens, and meet the criteria of one or more of the other hazards risks, must be shipped according to the shipping requirements for that hazard risk(s).
4. ThinPrep PreservCyt Solution is a Flammable liquid when shipped domestic or international Therefore, follow the instructions in Section C below, Shipping ThinPrep® PreservCyt™ Solution Only (such as from a laboratory to a physician).

B Shipping Biological Specimens in Solutions (other than ThinPrep PreservCyt Solution) or Without Solutions

Notes:

When biological specimens are shipped in a solution of a quantity of 30 ml or less and are packed in accordance with these guidelines, no further requirements in the Hazardous Materials (Dangerous Goods) Regulations need be met. However, training is recommended." [1]

Definitions:

- Biological Substance, Category B: Materials containing or suspected to contain infectious substances that do not meet Category A criteria. IATA Dangerous Goods regulations were revised with an effective date of January 1, 2015. Note: The term "diagnostic specimen" has been replaced with "biological substance, Category B"
- Exempt specimens: Specimens that with the minimal likelihood that pathogens are present (fixed tissue, etc.)

* These instructions are Hologic's interpretation of the various regulations as of the effective date. However, Hologic will not be responsible for any non-conformance to the actual regulations.

Shipping Requirements Category B or Exempt [1] – Ambient Temperature:

1. Packaging must consist of three components
    a. a primary receptacle, leak proof
    b. secondary packaging, leak proof
    c. a rigid outer packaging

NOTES:

- FedEx will not accept clinical samples or diagnostic specimens packaged in FedEx envelopes, FedEx tubes, FedEx Paks, or FedEx Boxes, Styrofoam boxes, plastic bags, or paper envelopes.
- FedEx will accept clinical samples in FedEx Clinical Paks, FedEx Medium Clinical Boxes or FedEx Large Clinical Boxes.[2]

2. The primary receptacle cannot contain more that 1L of a liquid substance (500 ml if using FedEx).

3. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

4. Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material (cotton balls, cellulose wadding, absorbent packets, paper towels) must be in sufficient quantity to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or the outer packaging.

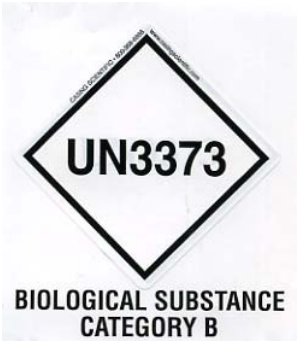
5. The outer packaging must not contain more than 4L or 4kg of material. This quantity excludes ice, dry ice, or liquid nitrogen when used to keep specimens cold.

6. An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

7. The packaging must successfully pass a 4 ft. drop test (Section 6.6.1 IATA regulations).

8. The UN3373 mark must be displayed on the external surface of the outer packaging (one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm FedEx minimum is 7”x 4”x 2”) on a background of a contrasting color and must be clearly visible and legible. The mark must be in the form of a diamond with each side having a length of at least 50 mm. Lettering must be at least 6mm high.

9. The proper shipping name “Biological Substance, Category B” in letters at least 6mm high must be marked on the outer package adjacent to the diamond shaped UN3373 mark.



10. If using FedEx, the FedEx USA Airbill, Section 6, Special Handling must be completed with dangerous goods/dry ice information:

    Does this shipment contain dangerous goods?

    ☑ *YES- Shipper's Declaration not required*

11. The outer container of all diagnostic/clinical specimen packages must display the following:

    a. Sender's name and address
    b. Recipient's name and address
    c. The words "Biological Substance, Category B"
    d. The UN 3373 label

Shipping Requirements Category B or Exempt [1] – Frozen or Refrigerated Specimens:

NOTE: FedEx defers to IATA regulations for the shipping of refrigerated or frozen diagnostic specimens.[2]

Follow all packaging directions for Category B or Exempt – Ambient Temperature plus:

1. Place ice or dry ice outside of the secondary packaging. Interior supports must be provided to secure the secondary packaging in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack must be leak proof. If dry ice is used, the packaging must be designed and constructed to permit the release of CO^2 gas to prevent a buildup of pressure that could rupture the packaging.

2. Always affix the Class 9, UN 1845 dry ice label as well as the UN 3373, Biological Substance, Category B label to these shipments

3. If using FedEx, the FedEx USA Airbill, Section 6, Special Handling must be completed with dangerous goods/dry ice information:
   Does this shipment contain dangerous goods?

   ☑ *YES- Shipper's Declaration not required*

   ☑ *Enter kg of dry ice used (if applicable)*

4. The outer container of all diagnostic/clinical specimen packages must display the following:

   a. Sender's name and address
   b. Recipient's name and address
   c. The words "Biological Substance, Category B"
   d. The UN 3373 label
   e. Class 9 label, including UN 1845, and net weight if packaged with dry ice

C Shipping ThinPrep® PreservCyt™ Solution Only (such as from a laboratory to a physician)

Domestic Ground Shipments - Limited Quantities:

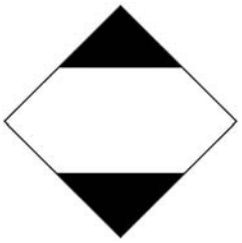
Notes:

ThinPrep® PreservCyt™ Solution is classified as a Class 3 Flammable liquid, assigned to Packing Group III (PG III).

49 CFR 173.150 (Limited Quantities) allows ThinPrep® PreservCyt™ Solution in vials to be shipped in Limited Quantities when shipped via ground transportation in a sturdy box. The total volume in a package cannot exceed 5 liters or weigh more than 30 kg (66 lbs). Limited Quantities are exempt from labeling requirements.

Limited Quantity domestic ground shipping recommendations:

1. ThinPrep® PreservCyt™ Solution must be shipped in the vials.
2. Place the vials in a good quality cardboard box, such as the ThinPrep® box that holds 250 vials. Pack vials in a manner (adding protective packing material as necessary) as to limit movement of individual vials.
3. Mark the package as “Flammable liquids, n.o.s., (Methanol Solution), 3, UN1993, Ltd. Qty.” add orientation arrows on the ends, and the Limited Quantity label:



4. Print “UN1993, Flammable liquids, n.o.s., (Methanol Solution), 3, PG III, Ltd. Qty.” on the Shipping papers.

Domestic Ground Shipments - Other than Limited Quantities:

When shipping packages in excess of “Limited Quantity” amounts:

1. Do not include “Ltd Qty” in the wording on the package or on the Shipping papers as indicated in c and d above.
2. Affix a Class 3 “Flammable Liquid” hazard label to the outer package in close proximity of the wording described in “C” above. See the example of the label on the last page of these recommendations.
3. Mark the package as “Flammable liquids, n.o.s., (Methanol Solution), 3, UN1993, Net Qty.”

Domestic Air Shipments:

In addition to 1 and 2 above in Domestic Ground Shipments – Other than Limited Quantities, the following are recommendations for domestic air shipments:

3. Maximum allowable package sizes are:
    i. Sixty (60) liters (3000-vials) for passenger aircraft, and
    ii. Two hundred twenty (220) liters (11,000-vials) for cargo aircraft.

4. Single packages containing more than sixty (60) liters (3000-vials) of total product must be clearly marked “FOR CARGO AIRCRAFT ONLY”.
5. The vials must be shipped in United Nations (UN) certified 4G packaging for any quantity in an aircraft. (e.g., ThinPrep® PreservCyt™ Solution 250-vial box or equivalent.)
6. A Class 3 “Flammable Liquid” label must be affixed to the outer package near the words “Flammable liquids, n.o.s., (Methanol Solution)”.

All Domestic Shipments:

The following are recommendations for all domestic ground and air shipments:

1. If the ThinPrep® PreservCyt™ Solution is shipped in a package also containing non-hazardous material, the hazardous material must be listed first, or be printed in a contrasting color (or highlighted) to differentiate it from the non-hazardous material.
2. The total volume of ThinPrep® PreservCyt™ Solution and the number of vials must appear on the shipping papers.

International Ground Shipments - Limited Quantities:

When shipping internationally, ThinPrep® PreservCyt™ Solution is classified with a primary hazard of Class 3 (Flammable Liquid), and with a secondary hazard of Class 6.1 (Toxic). It is assigned to PG III.

The reference used for the international ground recommendations is the *ADR - European Agreement Concerning the International Carriage of Dangerous Good by Road* (United Nations). A “Limited Quantity” is defined as a package containing a maximum net quantity of 5-liters and not weighing more than 20 kg (40 lbs). The recommendations for international ground shipments are as follows:

1. ThinPrep® PreservCyt™ Solution must be shipped in the vials.
2. Place the vials in a good quality cardboard box, such as the Cytyc box that holds 250 vials. Pack vials in a manner (adding protective packing material as necessary) as to limit movement of individual vials.
3. Mark the package with “UN1992, Flammable liquids, toxic, n.o.s., (Methanol Solution), 3, 6.1, PGIII Ltd. Qty” orientation arrows on the ends and the Limited Quantity label that has a “Y” on it.

4. The shipping papers should include all the information indicated in “3” above.

International Ground Shipments – Other then Limited Quantities:

1. Do not include “Ltd Qty” in the wording on the package or on the Shipping papers as indicated in c and d above.

2. Affix both a Class 3 “Flammable Liquid” label and a secondary Class 6.1 “Toxic” label to the package adjacent to the markings. (Copies of the labels can be found on the last page of this document.)

Class 6.1 “Toxic” secondary hazard label.

3. Mark the package with “UN1992, Flammable liquids, toxic, n.o.s., (Methanol Solution), 3, 6.1, PG III, Net Qty”.

International Air Shipments:

The references used for the International Air recommendations are: In addition to a and b above in International Ground Shipments, the following are the recommendations for international air shipments:

1. Maximum allowable package sizes are:
    i. Sixty (60) liters (3000-vials) for passenger aircraft, and
    ii. Two hundred twenty (220) liters (11,000-vials) for cargo aircraft.
2. Packages containing more than sixty (60) liters of product must be clearly marked “FOR CARGO AIRCRAFT ONLY”
3. The vials must be shipped in United Nations (UN) certified 4G packaging for any quantity in an aircraft. (e.g., ThinPrep® PreservCyt™ Solution 250-vial box or equivalent.) Pack vials in a manner (adding protective packing material as necessary) as to limit movement of individual vials.
4. Limited Quantity exemption can only be used if the package has a maximum net quantity of 2-liters.
5. Packaging manufacturer’s specifications markings are not required when shipping Limited Quantity.
6. Mark the package with “UN1992, Flammable liquids, toxic, n.o.s., (Methanol Solution), 3, 6.1, PGIII, Net. Qty”.
7. When a “Cargo Aircraft Only” marking is required, it must be affixed on the same package surface and near the hazard labels.
8. The shipper is responsible for the completion of a “Shipper’s Declaration for Dangerous Goods” form.

D. <u>Shipping ThinPrep® CytoLyt™ Solution Only (such as from a laboratory to a physician)</u>

Domestic Ground Shipments:

ThinPrep® CytoLyt™ Solution has a flash point of 109° F. For domestic ground transportation only, a flammable liquid with a flashpoint at or above 100° F that does not meet the definition of any other hazard class may be reclassed as a combustible liquid. As such, ThinPrep® CytoLyt™ Solution, shipped via ground, is exempt from the requirements of the DOT Hazardous Materials Regulations.

Domestic Air Shipments:

When shipping ThinPrep® CytoLyt™ Solution via air, follow the Domestic Air Shipments recommendations for Shipping ThinPrep® PreservCyt™ Solution Only that can be found in Section C of this document.

International Ground and Air shipments:

When shipping ThinPrep® CytoLyt™ Solution via ground or air, follow the International Ground or Air Shipments recommendations for Shipping ThinPrep® PreservCyt™ Solution Only guidelines that can be found in Section C of this document.

E. Shipping ThinPrep® CytoLyt™ Solution With Patient Sample (such as from a physician to a laboratory)

Domestic Shipments:

ThinPrep® CytoLyt™ Solution containing a patient sample is classified as a Biological Substance, Category B. Follow the recommendations in Section B of this document.

International Shipments:

ThinPrep® CytoLyt™ Solution containing a patient sample is classified as a Biological Substance, Category B. Follow the recommendations in Section B of this document.

References:

- 49 CFR 100 to 185, *Transportation*
- *Dangerous Goods Regulations*, 56th Edition, 2015, International Air Transportation Association (IATA)
- International Civil Aviation Organization's (ICAO) *Technical Instructions for the Safe Transport of Dangerous Goods by Air*

Foot Notes:

1. See Packing Instruction 650 in the IATA *Dangerous Goods Regulations*
2. FedEx Document 33539PL: "Packaging Clinical Samples" and "Packaging UN 3373 Shipments"

4. Sample Collection
and Preparation

Chapter Four

Gynecologic Sample Collection and Preparation

CONTENTS

SECTION A INTRODUCTION

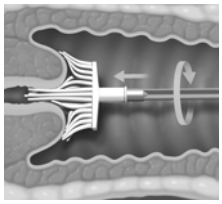
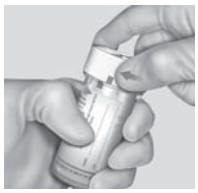
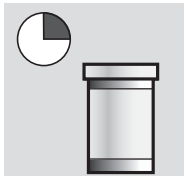
The ThinPrep® 3000 processor prepares microscope slides from ThinPrep Pap test gynecologic samples. The collected specimen includes cell samples from the ectocervix and the endocervix.

SECTION B

SPECIMEN COLLECTION

Collect Gynecologic Sample Using the Broom-Like Device

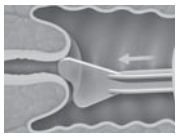
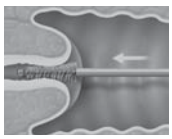
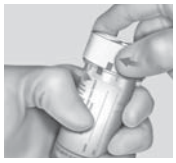
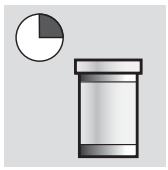
Physician/clinician instructions for collecting gynecologic samples.

	1. **Obtain** an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.
	2. **Rinse** the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.
	3. **Tighten** the cap so that the torque line on the cap meets or passes the torque line on the vial.
	4. **Record** the patient's name and ID number on the vial. **Record** the patient information and medical history on the cytology request form.
	***Note:*** If the sample is to be processed immediately, allow the sample to stand in the PreservCyt Solution vial for at least 15 minutes before processing. If the sample is to be sent elsewhere for processing, continue with the next step.
	5. **Place** the vial and requisition in a specimen bag for transport to the laboratory.

Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.

Collect Gynecologic Sample, Using the Endocervical Brush/Spatula Device

Physician/clinician instructions for collecting gynecologic samples.

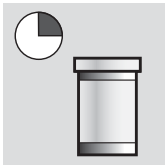
	1. **Obtain** an adequate sampling from the ectocervix using a *plastic* spatula.
	2. **Rinse** the spatula as quickly as possible into the PreservCyt Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
	3. **Obtain** an adequate sampling from the endocervix using an endocervical brush device. Insert brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate ¼ or ½ turn in one direction. DO NOT OVER-ROTATE.
	4. **Rinse** the brush as quickly as possible in the PreservCyt Solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl vigorously to further release material. Discard the brush.
	5. **Tighten** the cap so that the torque line on the cap meets or passes the torque line on the vial.
	6. **Record** the patient's name and ID number on the vial. **Record** the patient information and medical history on the cytology requisition form.
	***Note:*** If the sample is to be processed immediately, allow the sample to stand in the PreservCyt Solution vial for at least 15 minutes before processing. If the sample is to be sent elsewhere for processing, continue with the next step.
	7. **Place** the vial and requisition in a specimen bag for transport to the laboratory.

Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.

4 GYNECOLOGIC SAMPLE COLLECTION AND PREPARATION

SECTION C SPECIAL PRECAUTIONS

PreservCyt® Solution



After sample transfer to the PreservCyt Solution vial, the sample should stand for at least 15 minutes before processing.

For more information on PreservCyt Solution, refer to Chapter 3, "PreservCyt® and CellFyx™ Solutions".

Interfering Substances

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.

Handling/Disposal

Handle all chemical-containing materials carefully in accordance with safe laboratory practices. When required by reagent composition, additional precautions are marked on the reagent containers or the instructions for use.

Dispose of PreservCyt Solution according to the guidelines for disposing of hazardous waste. PreservCyt Solution contains methanol.

SECTION D SPECIMEN PROCESSING

Materials Required

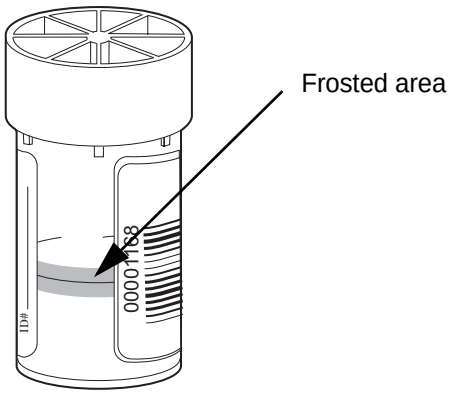
Refer to Materials Required in "MATERIAL REQUIREMENTS" on page 1.8 and "ITEMS REQUIRED TO BEGIN BATCH PROCESSING" on page 5.5 for a list and explanation of materials required.

Specimen Preparation

- The gynecologic sample should be deposited in the PreservCyt Solution immediately upon collection.

- The PreservCyt sample vial fluid level should be within the frosted area of the sample vial.

Figure 4-1 PreservCyt Sample Vial Fluid Level



Specimen Stability

- Store PreservCyt Solution *with* cytologic sample intended for ThinPrep Pap testing between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.

Run on ThinPrep 3000 Processor

Process samples on the ThinPrep 3000 processor. Refer to "Instrument Operation" on page 5.1.

SECTION E

SAMPLE PROCESSING TROUBLESHOOTING

REPROCESSING A THINPREP PAP TEST SAMPLE VIAL FOLLOWING AN UNSATISFACTORY RESULT

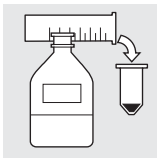
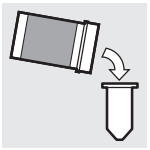
Note: This section specifically addresses reprocessing ThinPrep Pap test samples following an "unsatisfactory for evaluation" result. The 'reprocessing' of samples described in this section should not be confused with the reprocessing related to specimen sample errors outlined in Chapter 7 of this manual. Reprocessing as described in Chapter 7 refers to the re-running of a specimen.

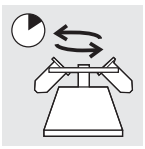
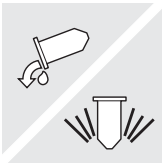
Laboratory personnel may reprocess ThinPrep Pap test specimens where slides have been interpreted as inadequate ("Unsatisfactory for Evaluation") for diagnosis following cytotechnologist screening. The instructions below must be followed in order to properly reprocess these specimens.

Note: Reprocessing a ThinPrep Pap test specimen may only be performed once.

Note: Good laboratory practices should be followed to avoid introducing contaminants into the PreservCyt Solution sample vial.

Reprocessing Protocol

	1	Prepare a wash solution of sufficient volume to add 30 mL to every ThinPrep Pap test specimen being reprocessed. The wash solution is made by mixing 9 parts CytoLyt Solution with 1 part glacial acetic acid.
	2	Prior to performing this step, assure there is sufficient volume in the ThinPrep Pap test specimen to result in a pellet, following centrifugation. Pour the contents of the ThinPrep Pap test specimen into a centrifuge tube appropriately labeled to maintain chain of custody. Retain the vial.
	3	Pellet the contents of the centrifuge tube by centrifugation at 1200 x *g* for 5 minutes. ***Note:*** Once centrifugation is complete, the cell pellet should be clearly visible but the cells may not be tightly packed together (the pellet may appear fluffy).

	4	a. Carefully pour off the supernatant from the centrifuge tube to avoid loss of cells. Dispose of according to local regulations. b. Vortex the centrifuge tube briefly. c. Pour 30 mL of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely. d. Invert the centrifuge tube by hand several times to mix.
	5	Pellet the cells again by centrifugation—1200 x *g* for 5 minutes.
	6	a. Carefully pour off the supernatant from the centrifuge tube to avoid loss of cells. Dispose of according to local regulations. b. Vortex the centrifuge tube briefly.
	7	a. Using the volume markings on the centrifuge tube, pour the necessary quantity of unused (i.e., containing no patient specimens) PreservCyt Solution to the cells and fill to a final volume of 20 mL. Secure the cap tightly. b. Invert the centrifuge tube several times to mix and transfer the sample back into the retained specimen vial.
	8	Process the specimen using a ThinPrep 3000 processor according to the procedure for running gynecologic specimens. Evaluate the resultant slide according to *The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnosis*. If after reprocessing, negative results from specimen do not fit with the clinical impression, a new specimen may be necessary.

4 GYNECOLOGIC SAMPLE COLLECTION AND PREPARATION

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5. Instrument Operation

Chapter Five

Instrument Operation

CONTENTS

SECTION A CHAPTER OVERVIEW

Routine instrument operation consists of loading supplies, starting the batch process and unloading the prepared slides and processed sample vials when the batch is complete. A batch report (or 'results printout') is automatically generated at the completion of each batch. Any samples that may require further operator attention are flagged on the batch report, along with a description of the type of process or sample error. The action of pausing or canceling a batch is available at any time during processing.

SECTION B

OPTIONAL INSTRUCTIONS FOR ANCILLARY TESTING

Testing for certain sexually transmitted diseases (STD) and for Human Papilloma Virus (HPV) in conjunction with cytology may be enabled by the removal of an aliquot of up to 4 mL (Aliquot Removal) from the PreservCyt sample vial before preparing the ThinPrep Pap test slide.

Laboratory personnel must follow the specific instructions in this section to appropriately remove the desired aliquot volume and prepare the PreservCyt sample vial for the ThinPrep Pap test. Adherence to these instructions must be maintained to ensure there is no adverse effect on the ThinPrep Pap test result.

Because cytology/HPV testing and STD testing address different clinical questions, Aliquot Removal may not be suitable for all clinical situations. Physicians and other persons responsible for ordering clinical tests should be familiar with the following:

- There is no evidence of degradation of cytology results by Aliquot Removal, however, this cannot be ruled out for all specimens. As with any subsampling step in anatomic pathology, chance misallocation of diagnostic cells may occur if they are very rare. If negative results from the specimen do not fit with the clinical impression, a new specimen may be necessary.
- Aliquot Removal from low-cellularity specimens may leave insufficient material in the PreservCyt sample vial for preparation of a satisfactory ThinPrep Pap test slide.
- Aliquot Removal may leave insufficient material In the PreservCyt sample vial for performance of ancillary testing (e.g., reflexive HPV testing) using the residual specimen following preparation of a ThinPrep Pap test slide.
- Co-collection of separate samples for the ThinPrep Pap test and STD testing may be considered in lieu of Aliquot Removal.
- When opting for concurrent cytologic and STD testing, providers should consider risk and clinical history (e.g., disease prevalence, patient age, sexual history or pregnancy) as well as specimen suitability (e.g., exudates or bleeding) that can impact diagnostic reliability.

Sexually Transmitted Diseases Treatment Guidelines 2002 (Centers for Disease Control and Prevention, MMWR 2002: 51(No. RR-6)) provides clinical guidance for the management and treatment of individual patients, including use of Pap testing.

It is contraindicated to perform *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing, using the Roche Diagnostics COBAS AMPLICOR CT/NG test, if the sample has already been processed using the ThinPrep 3000 processor.

Removing an Aliquot (of up to 4 mL) from the PreservCyt Sample Vial prior to Performing the ThinPrep Pap Test

Note: Only one aliquot may be removed from the PreservCyt sample vial prior to performing the ThinPrep Pap test, regardless of the volume of the aliquot (maximum aliquot volume = 4 mL).

Note: Good laboratory practices should be followed to avoid introducing contaminants into either the PreservCyt sample vial or the aliquot. It is recommended to use powder-free gloves and an individually wrapped, disposable pipetting device with an aerosol barrier tip that is sized appropriately for the volume being withdrawn and dispensed. You should not use serological pipettes. In order to minimize the potential for cross-contamination, aliquot removal should be performed in an appropriate location outside an area where amplification is performed.

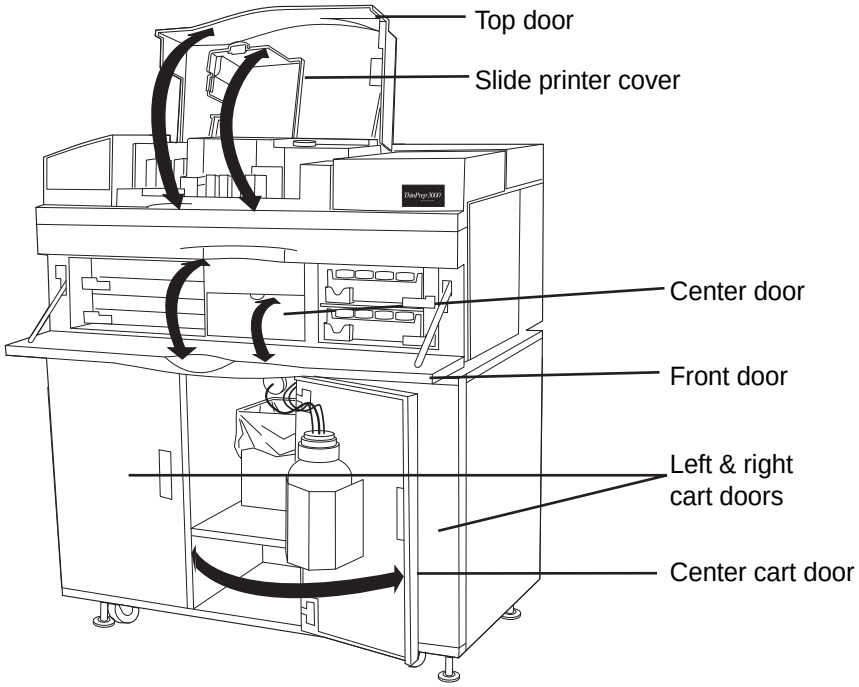
1. Vortex the vial at high speed for 8 to 12 seconds.

CAUTION: The desired aliquot must be removed immediately after vortexing the vial to ensure homogeneity of the sample.

2. Carefully remove the vial cap.
3. Using a pipetting device, withdraw an aliquot of up to 4 mL from the vial. Take care to avoid contaminating gloves with solution. If gloves should become contaminated, replace with a clean pair before proceeding to the next specimen.
4. Dispense the aliquot into a suitably sized and labeled polypropylene tube and close tightly to prevent leakage/evaporation.
5. Store the aliquot under conditions appropriate for ancillary test(s). Refer to manufacturer or laboratory instructions for performing ancillary test(s) on the aliquot.
6. Dispose of the pipetting device in accordance with local, state, and federal regulations.
7. Using a new pipetting device, withdraw a quantity of unused PreservCyt Solution from its container that is equal in volume to that of the aliquot removed from the vial in step 3.
8. Transfer the volume of unused PreservCyt Solution to the vial from which the aliquot was removed in step 3.
9. Secure the vial cap. (The line on the cap and line on the vial should meet or slightly overlap.)
10. Dispose of the pipetting device in accordance with local, state, and federal regulations.
11. Refer to the remaining steps in this chapter to complete the ThinPrep Pap test.

SECTION C

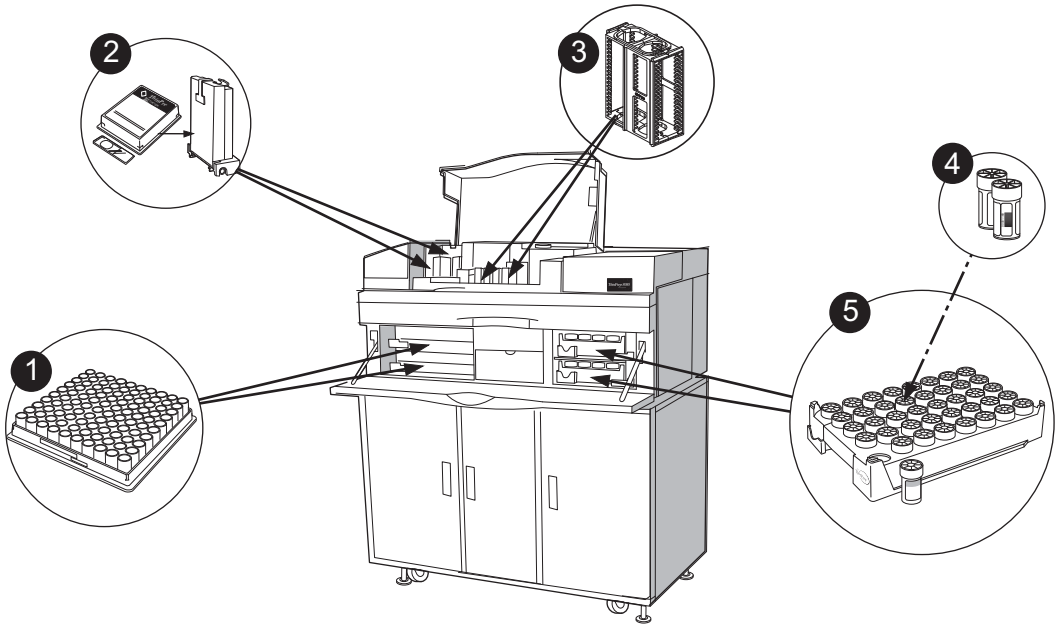
INSTRUMENT DOORS



- **Top door** provides access to the slide cartridges, slide printer cover, staining racks, fixative dispense area and the CellFyx™ Solution reservoir. This door locks with the front door during batch processing or when the processor is moving mechanisms.
- **Slide printer cover** provides access to the slide printer ribbon and the slide printer assembly.
- **Center door** flips down to access the slide waste bin and for replacement of the pinch valve tubing. The instrument serial number is located here.
- **Front door** provides access to the filter trays and area, the center door and the sample vial trays and area. This door locks with the top door during batch processing or when the processor is moving mechanisms.
- **Left and right cart doors** provide access to storage for accessories and consumables.

SECTION D

ITEMS REQUIRED TO BEGIN BATCH PROCESSING



To begin batch processing, it is necessary to have the following items ready for use:

1. Trays of Gyn ThinPrep® Pap test filters
2. ThinPrep microscope slides and slide cartridges
3. Staining racks
4. Barcoded ThinPrep Pap test sample vials
5. Sample vial trays

Gyn ThinPrep Pap Test Filters

Gyn ThinPrep® Pap test filters are disposable, clear plastic cylinders used in the collection and transfer of cells from gynecologic specimens onto ThinPrep microscope slides.

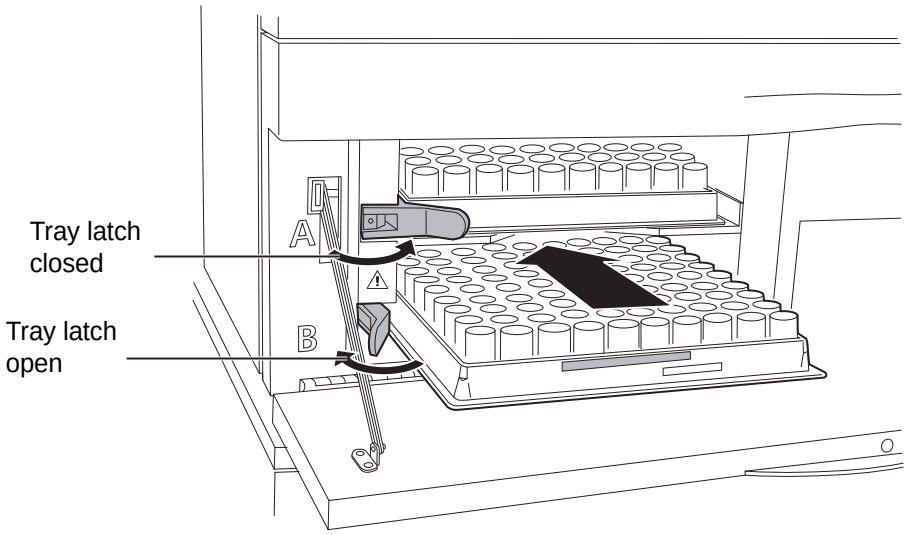
The filters come in trays of 100. Two trays can be loaded into the instrument. (A minimum of one is required.)

Loading the Gyn ThinPrep Pap test filters

CAUTION: Only replace filter trays if they are empty. Partially loaded trays should remain in place.

1. Open the tray latches as shown below.
2. Remove any empty filter trays, if present.
3. Remove and discard the clear plastic cover from the new tray(s) of filters.
4. Insert the new tray(s) of filters. Slide the tray all the way to the back of the shelf until it hits the stops at the rear.
5. Secure the trays by closing their respective latches.

Note: Do not handle the filters directly unless necessary. Only touch the outer surface. Do not touch the membrane on the bottom.



Note: The top tray is designated tray A and the bottom tray is tray B. Raised letters on the instrument cover near the latches help identify each tray.

ThinPrep Microscope Slides and Slide Cartridges

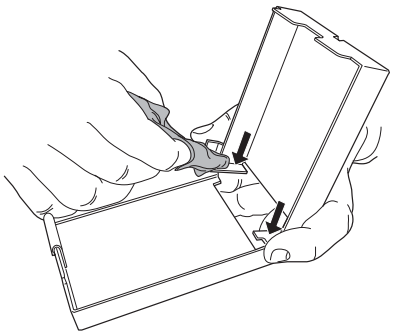
ThinPrep microscope slides are specially designed glass slides for use with the ThinPrep processor. Only ThinPrep slides are to be used.

WARNING: Sharp Edges. Glass

Two metal slide cartridges are used to insert the ThinPrep microscope slides into the processor. Each slide cartridge holds approximately 100 slides, or one package of ThinPrep microscope slides.

Clean the slide cartridge prior to loading slides

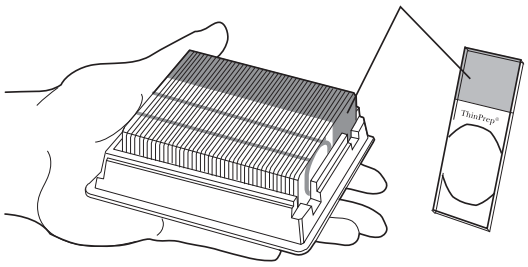
Before loading a cartridge with microscope slides wipe the inside of the cartridge with a lint-free cloth to remove glass dust. Clean the bottom surface where the slides sit, to ensure proper slide picking. (Refer to "CLEANING THE SLIDE PATH" on page 6.17.)



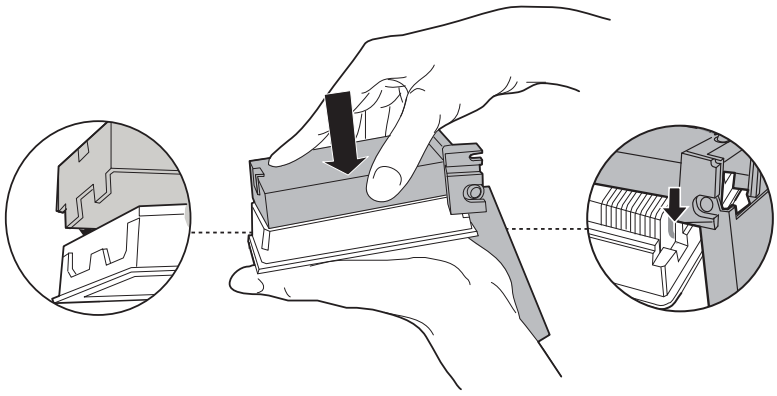
Loading the ThinPrep microscope slides into the slide cartridge

Note: **The slides must be oriented correctly to work with the automated functions of the ThinPrep 3000 processor.** The microscope slide package and the slide cartridge are keyed to ensure accurate loading of slides. A visual check of the slides after being loaded into the cartridge is recommended.

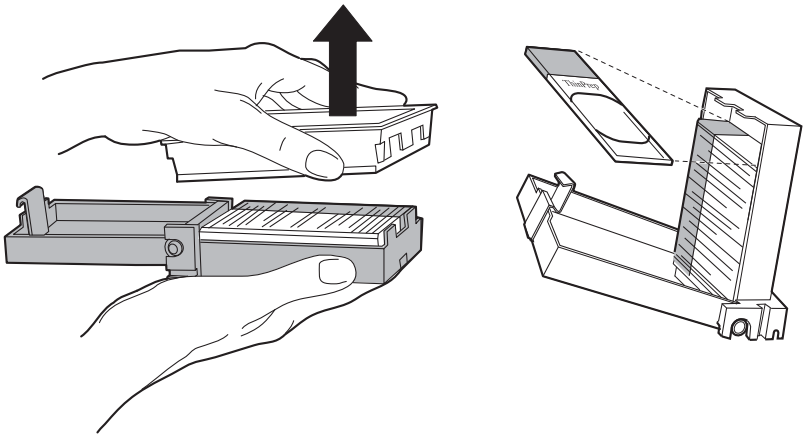
1. Remove the cover of the slide package.
2. Fold back the cellophane wrapper.
3. Hold the package of slides horizontally in your hand as shown.



4. Place an open slide cartridge over the slide package so that its metal grooves fall into the cutout slots.



5. Holding them together, gently flip the slide cartridge and slide package over.
6. After the slides are transferred into the slide cartridge, remove and discard the wrapper and plastic package.

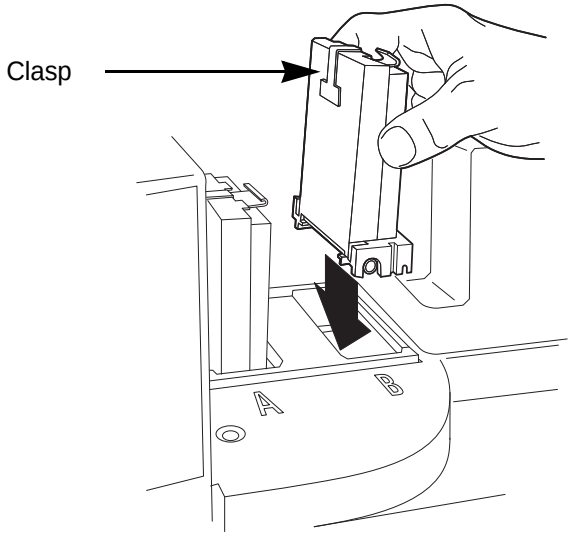


7. Tilt the cartridge up slightly and make sure the slides are aligned squarely, evenly and are sitting flat on the bottom of the cartridge. Confirm correct orientation of the slides. Gently close the slide cartridge door over the slides. The latch will click when the cartridge is completely closed.

Loading the slide cartridges into the processor

CAUTION: Only reload slide cartridges when prompted by the instrument. Do not manually load a partially filled cartridge.

With the slide cartridge clasp up and facing as shown, slide it into slot "A" or "B".



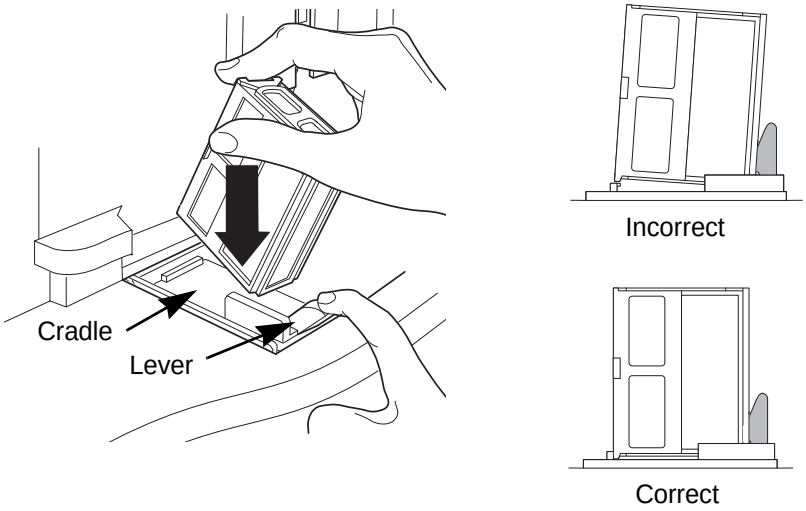
Staining Racks

Staining racks are plastic frames that hold the processed ThinPrep microscope slides. The slides remain in the staining racks until batch processing ends.

The processor can hold up to four staining racks. Each rack has a capacity of 20 processed ThinPrep slides.

Loading the empty staining racks

1. Pull the lever back with one hand.
2. With the other hand, insert the staining rack in the direction of arrow as shown below, releasing the lever to secure it. Make sure it sits flat on the cradle.

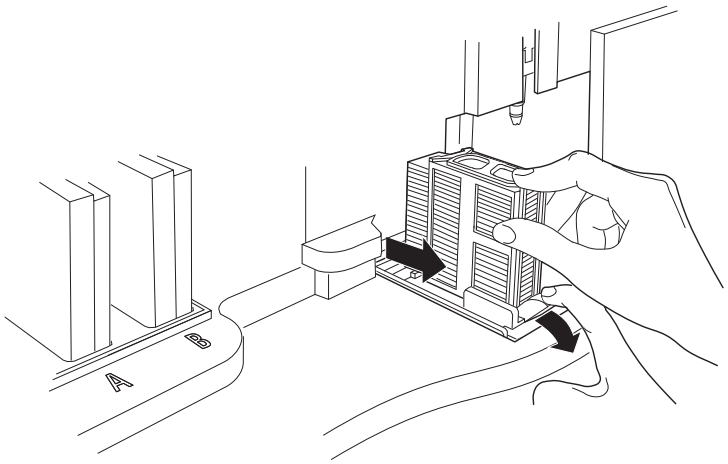


3. Place an empty staining rack into each of the four cradles.

Removing the staining racks

1. Positioning the thumb and index finger of one hand, grasp the rack as shown below.

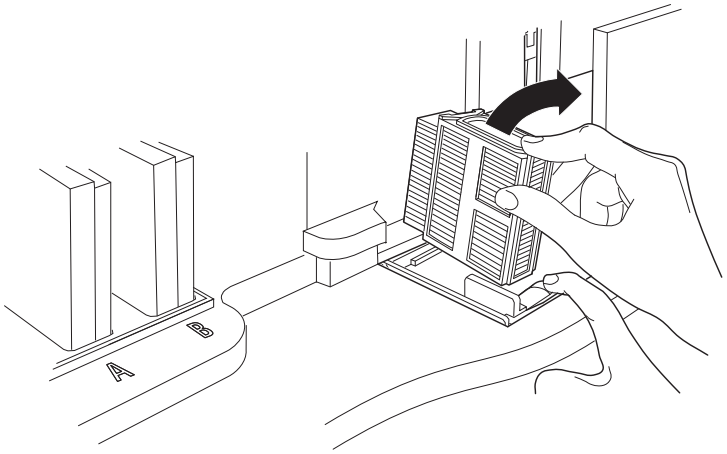
CAUTION: Avoid touching the slides with your fingers when removing the staining racks.



2. With the other hand, pull the lever down.

CAUTION: Slides are not securely held in the staining rack. Use caution when removing the racks.

3. Gently slide the rack toward the lever.



4. Tilt the staining rack as shown above.
5. Carefully lift out the staining rack. Avoid dislodging any processed slides.

Barcoded Sample Vials

WARNING: Toxic Mixture
Flammable Liquid and Vapor

The PreservCyt® Solution sample vials for use with the ThinPrep Pap test contain the collected cervical cell samples in a preservative solution. During processing, the ThinPrep 3000 processor collects the cells from the vials.

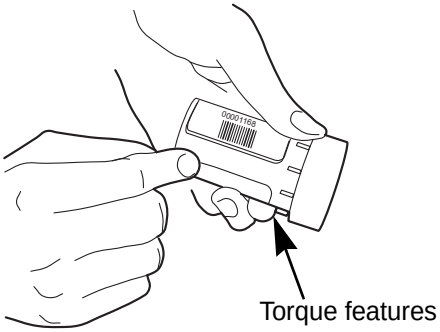
Vial preparation

See the Sample Vial Label Application Guide in the Appendix for recommended barcode label application.

Place the barcode labels **vertically** on the ThinPrep Pap test label, using the edge for alignment, as shown below. During application, avoid placing the barcode label over patient information, multiple labels, or on the torque features. Sticking labels on incorrectly can cause a failure to read the barcode or a failure of the instrument removing the vial from the tray.

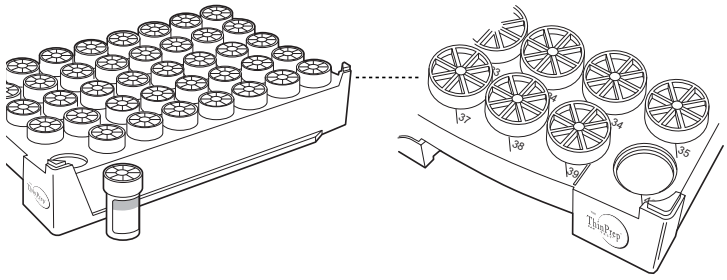
The uncovered strip of the sample vial allows you to see the frosted band which indicates the maximum/minimum acceptable fluid fill range for a sample. Make sure the fluid level is within this range. Refer to Chapter 7, "Troubleshooting", if the level is too high or too low.

Additionally, check to make sure there is no foreign matter in the vial. Refer to Chapter 7, "Troubleshooting", if an object is in the sample vial.



Inserting vials into the sample vial trays

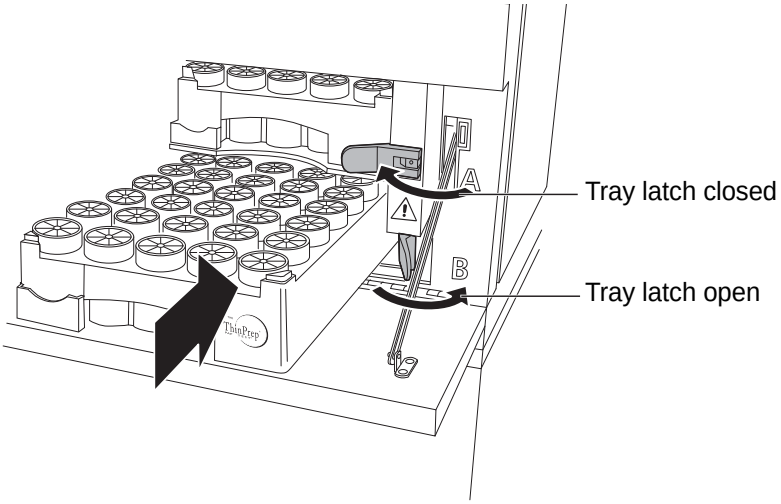
Place sample vials into the numbered holes of the sample vial tray (the tray does not have to be full to run a batch; the vials can be in any order). The ThinPrep 3000 processor can process up to 80 samples, (two full sample vial trays) per batch.



Loading the sample vial trays

1. Open the tray latches as shown below.

WARNING: Sharp Edges & Hot Surfaces.
Moving Parts



2. Remove any previously processed sample vial trays, if present.
3. Load the sample vial trays into the empty slots so that the ThinPrep Pap test logo on the tray is facing outward. (The trays only fit in one way.) Be sure to slide each tray fully into the instrument until it hits the stops at the rear.
4. Secure the trays by closing their respective latches.

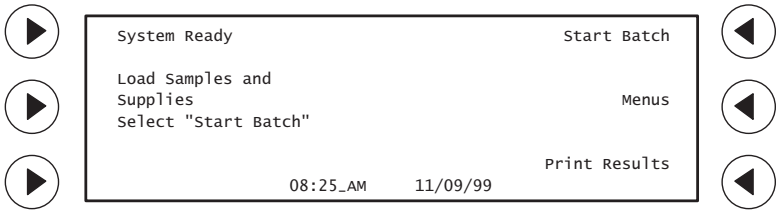
Refer to "READING THE BATCH REPORT" on page 5.20 for batch report information.

Note: The top tray is designated tray A and the bottom tray is tray B. Raised letters on the instrument cover near the latches help identify each tray. A results report for each tray, A and B, prints out at the conclusion of the batch. It is important to correlate the report with the correct tray.

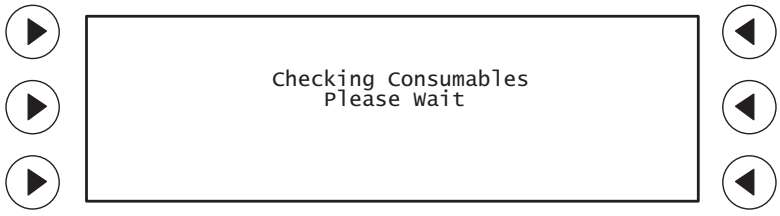
SECTION E

BEGIN BATCH PROCESSING

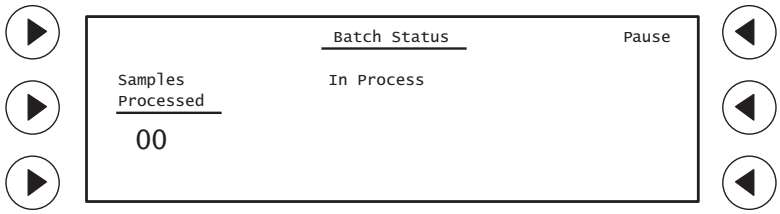
1. Confirm that the main menu, shown below, is displayed. If this menu is not displayed, follow the prompts[1] to return to the main menu.



2. In the main menu, follow the screen prompt to load samples and supplies. In order to begin processing, the following items must be properly loaded:
   - Sample vial tray(s) containing barcoded sample vials
   - Filter tray(s) of ThinPrep Pap test filters
   - Slide cartridge(s) containing ThinPrep microscope slides
   - Empty staining racks
3. Close both the front and top door of the instrument. Processing will not begin if they are not completely shut.
4. Press **Start Batch** to begin batch processing.
5. The instrument performs a check of supplies needed to process a batch.



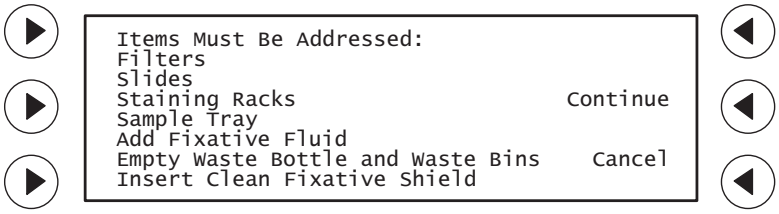
6. Processing begins when the following screen is displayed:



1. Prompt: Text that appears on the display next to the prompt keys.

If the instrument does not detect materials necessary to process a batch, the "Items Must Be Addressed" message screen appears.

Items Must Be Addressed



Listed on the screen are the specific materials to be addressed before beginning a batch. Only the items that need attention will be listed. You may see a display with some or all of the items shown above.

No batch will be processed until these items are addressed.

1. Press **Cancel** to cancel the batch entirely.
2. Press **Continue** to attend to the required items. Wait for the doors to unlock.

Requirements for any items appearing on this display are listed below:

Refer to "ITEMS REQUIRED TO BEGIN BATCH PROCESSING" on page 5.5 for instructions on loading items.

Filters

The processor does not detect at least one tray of Gyn ThinPrep Pap test filters.

- A minimum of one tray of filters must be loaded before batch processing can begin. Empty filter trays must be removed.

Slides

The processor does not detect at least one slide cartridge containing slides.

- A minimum of one slide cartridge containing slides must be inserted before batch processing can begin.
- If slide cartridges are present, check that *both* contain slides and that *neither* has a slide jam, which would prevent slide picking.

Staining racks

The processor does not detect any empty staining racks.

- At least one empty staining rack must be loaded before processing can begin.
- Be sure to remove any staining racks with slides from previous batches.
- If this message occurs during a batch, remove any staining racks containing processed slides and replace them with empty ones ***before*** pressing **Continue**.

Sample trays

The processor does not detect at least one tray of sample vials.

- A minimum of one sample tray must be loaded before batch processing can begin.

CAUTION: Never add fixative unless prompted by the instrument. Only add one bottle to the fixative reservoir. Do not overfill.

Refer to "REPLENISHING CELLFYX SOLUTION" on page 6.32, for filling the fixative reservoir.

Fixative

The fixative reservoir is low on CellFyx Solution.

- The fixative reservoir must be filled with ***one*** bottle of CellFyx Solution before processing can begin.

Fixative cap

The processor does not detect the cap on top of the fixative reservoir.

- The cap must be tightly screwed onto the top of the fixative reservoir before processing can begin.

Empty waste bottle and waste bins

The level of waste fluid within the waste bottle is above the maximum level. Make sure the slide waste bin is present and loaded correctly.

- The waste bottle must be emptied before processing can begin.
- Empty the filter waste box, and slide waste bin at this time.
- The slide waste bin must be properly loaded before processing can begin.

Insert clean fixative shield

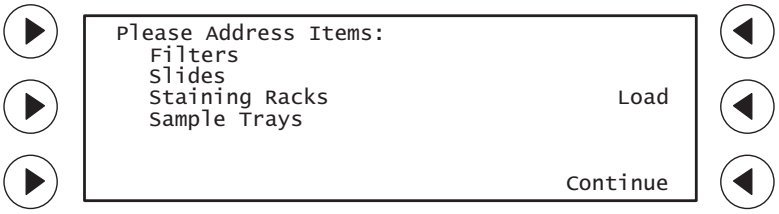
At the time the instrument prompts for CellFyx Solution replenishment, it will also display a message to insert a clean fixative shield. This is important in preventing unwanted fixative buildup.

Refer to "REPLACING THE FIXATIVE SHIELD" on page 6.23.

After addressing items and closing all doors on the instrument, press **Continue**.

If materials cannot be loaded at this time, press **Cancel** to end batch processing and return to the main menu.

Please Address Items



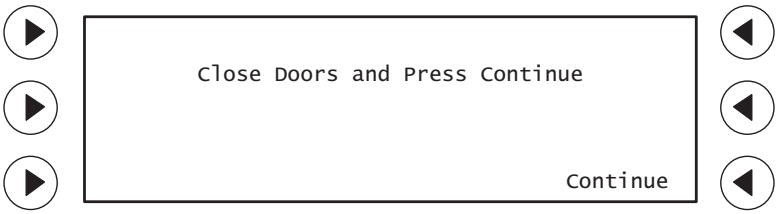
This message notifies you that these items are low in supply. Although the processor can start batch processing, the full batch of sample vials may not be completed. The following items may appear on this screen:

Filters
Slides
Staining Racks
Sample Trays

- Select **Load** to address the listed item(s). If supplies are loaded, the "Checking Consumables Please Wait" screen is displayed.
- Select **Continue** to bypass loading item(s) at this time, beginning batch processing.

Note: If the user does not respond to this message within five minutes, the batch will start by itself.

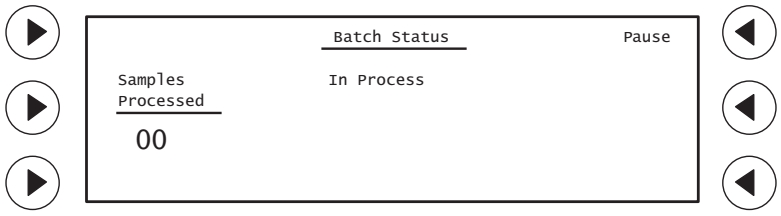
Close Doors and Press Continue



This message notifies you that an instrument door is open.

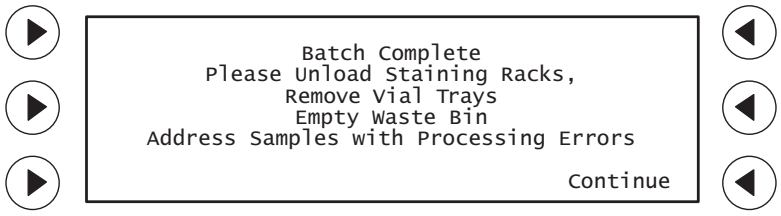
- Confirm that both the front door and top door are closed.
- After closing any open doors, select **Continue** to begin batch processing.

Processing begins when the following screen is displayed:



SECTION F COMPLETING A BATCH

1. At the completion of batch processing, "Batch Complete, Unload Staining Racks & Remove Vial Trays" is displayed on the message screen. If a sample error occurred, a bottom line reads "Address Samples with Processing Errors". A batch report will print from the results printer.



Note: The instrument will beep once per minute to indicate the batch is complete. If an error occurred, it will beep three times per minute. The beeps cease when the operator presses **Continue**. The display transitions to the System Ready screen.

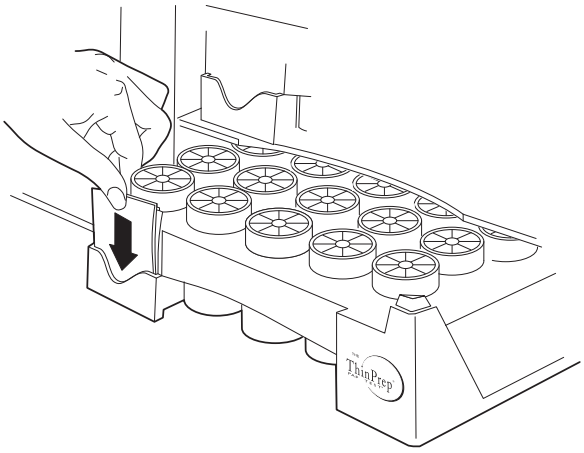
2. Carefully unload the staining racks containing processed slides from the instrument as described in "Removing the staining racks" on page 5.11.
3. Tear off the printed batch report by pulling it toward you, against the edge of the paper opening.
4. Separate tray "A" (top) batch report from tray "B" (bottom) batch report. Match them with the correct sample tray. (The tray slots are marked A and B on the instrument near the tray latches.)

Refer to "READING THE BATCH REPORT" on page 5.20 for batch report information.

5. Review the batch report for sample vials not processed. They will be marked with an asterisk and listed in the Reprocessing Required field. Refer to "SYSTEM FAULT ERRORS Reprocessing Required" on page 7.30, for follow-up action if sample vials were not processed.

6. Fold and insert the appropriate batch report into its corresponding sample vial tray for identification.

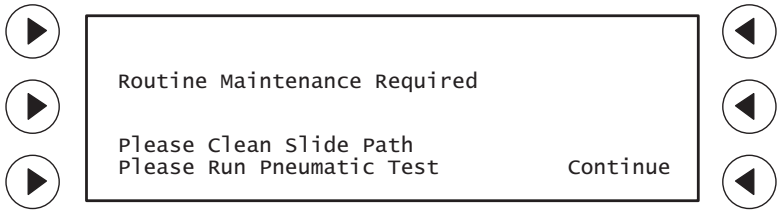
Note: Place the report so that the time and date can be seen. This will aid in locating a sample if necessary.



7. Remove the processed sample vial trays.
8. Remove the sample vials not processed from the tray(s). Address the issue, if possible. Refer to Chapter 7. Include these sample vials in another batch for reprocessing.

Routine Maintenance Required

Every 800 slides (10 full batches) the instrument will prompt for Operator Maintenance:



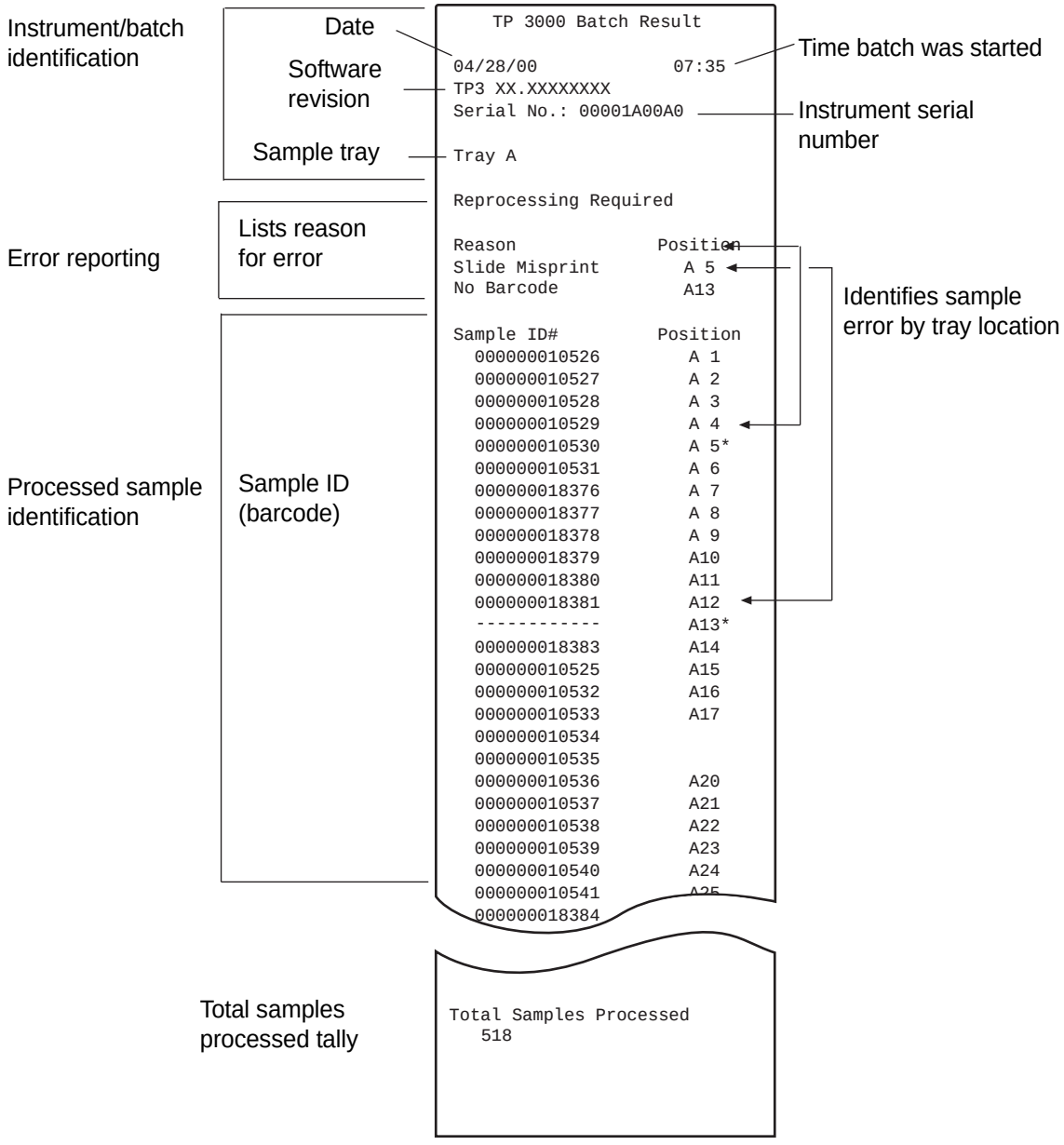
CAUTION: It is important to perform these maintenance tasks at this time, to ensure proper instrument operation.

Press **Continue**. Refer to "PNEUMATIC SYSTEM TESTING" on page 6.13, and "CLEANING THE SLIDE PATH" on page 6.17 for instructions.

SECTION G

READING THE BATCH REPORT

A sample batch report is shown. The samples needing operator attention are marked with an asterisk.



Reading the Batch Report

A batch report is automatically printed out at the conclusion of processing samples.

Note: Results are printed when the instrument can no longer process any more samples. This condition may be caused by:

- all samples processed - batch complete
- batch canceled by the operator
- two consecutive sample errors
- a mechanism failure.

The reason for termination of a batch will be printed on the batch report as the error reported for the last sample processed.

Instrument/batch identification

The top of the report lists instrument specific data: the date and time the batch was started (the time will print in 24-hour format, even if you have configured your display to show a.m. and p.m.), the version of software running on the ThinPrep 3000 processor and the instrument serial number.

Refer to Chapter 7, "Troubleshooting", for detailed sample status, error description and resolution.

Error reporting

This area reports any samples that may be problematic or did not result in a slide being prepared. Samples that require reprocessing are listed by their tray position with a reason why the instrument did not prepare a slide for that sample.

Sample identification

The next area lists the samples encountered by the instrument during processing. They are listed by their sample ID (barcode) number in the left column and the exact tray position of the vial in the right column. Those marked with an asterisk indicate an error was detected while processing that sample.

If sample processing was interrupted and unable to resume, only the *processed* vials will appear on the report. If there are more sample vials in your batch than are reported on the results printout, they must be removed and placed into a tray for another batch.

Printing Results

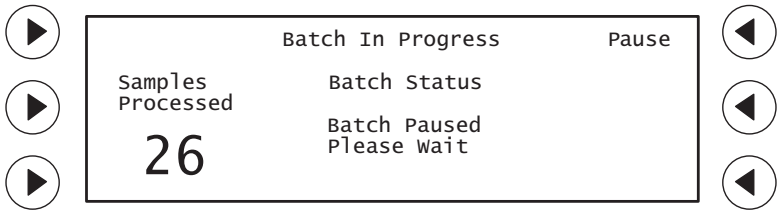
Only the last batch that was processed is kept in instrument memory. If you need more than one copy of a report, or a report did not generate (i.e., due to paper-out condition), it can be printed. From the main menu display, press **Print Results**.

SECTION H

PAUSING A BATCH IN PROCESS

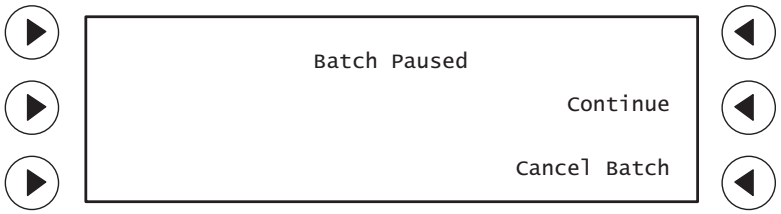
Processing of a batch may be halted and resumed using the "Pause" function. (For example, an operator may wish to remove completed staining racks for staining while the instrument finishes processing the batch.)

1. Select **Pause**.



2. "Batch Paused, Please Wait" is displayed under Batch Status as the processor interrupts batch processing.

   "Batch Paused" is displayed once the batch is paused. The doors of the instrument may be opened at this time.



Note: The system may take up to 3 minutes before "Batch Paused" is displayed. This allows the samples in process to finish before the system is made available for access.

CAUTION: Do not remove or replace the sample vial tray(s) or the batch will be canceled.

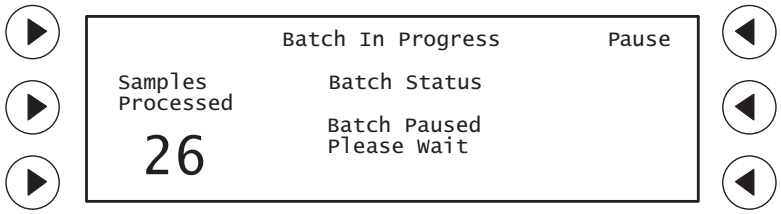
3. To resume batch processing, select **Continue**.

SECTION I

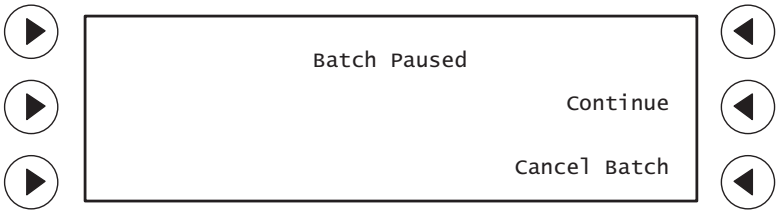
CANCELING A BATCH IN PROCESS

A batch that has begun processing may be canceled by using the "Pause" function. (For example, an operator may wish to start a small batch over again if a large number of samples is delivered to the lab, or to process rush samples.)

1. From the Batch In Progress display, select **Pause**.

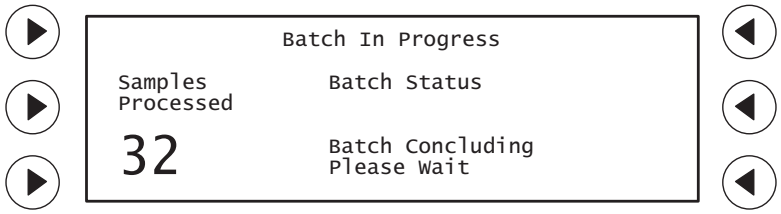


The "Batch Paused" screen is displayed after the processor has interrupted batch processing.

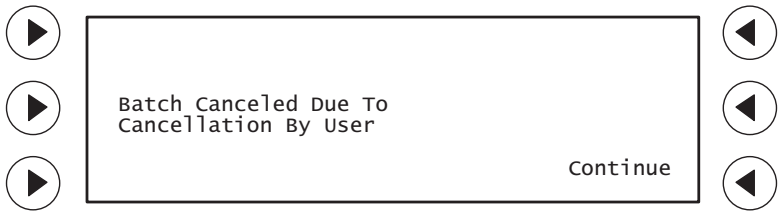


Note: The system may take up to 3 minutes before "Batch Paused" is displayed. This allows the samples in process to finish before the system is made available for access.

2. To cancel the batch, select **Cancel Batch**. The instrument checks the status of consumables and prints the batch report.



3. The following message is displayed when the batch is canceled:



4. Carefully unload the staining racks from the processor.
5. Tear off the printed batch report by pulling it toward you, against the edge of the paper opening.
6. Separate “A” (top) batch report from “B” (bottom) batch report.
7. Review the batch report for sample vials not processed.
8. Fold and insert the appropriate batch report into its sample vial tray for identification.
9. Remove sample vial tray(s).
10. Remove the sample vials not processed from the tray(s). Include these sample vials in another batch for reprocessing.

6. Maintenance

Chapter Six

Instrument Maintenance

CONTENTS

6 INSTRUMENT MAINTENANCE

SECTION A RECOMMENDED MAINTENANCE SCHEDULE

Regular maintenance of the ThinPrep® 3000 processor will greatly reduce the risk of sample handling or mechanism errors. A brief outline of recommended maintenance is listed below. The same procedures in chart form are on the next two pages, which may be removed and copied as needed.

Daily Maintenance

- Fixative spray preventative maintenance
- Empty the slide waste bin
- Check filter waste box
- Lubricate the sample processing arm O-rings

Monthly Maintenance

- General cleaning

Twice-Yearly Maintenance

- Pinch valve tubing replacement

Instrument-Prompted Maintenance

Refer to the Ordering Information in this manual for ordering supplies.

- Pneumatic system testing
- Cleaning the slide path
- Replacing the fixative shield
- Empty waste bottle, filter waste box and slide waste bin
- Replenishing CellFyx Solution
- Replacing the slide printer ribbon

As-Needed Maintenance

- Results printer paper replenishment: replenish when the red line appears along the edge of the paper roll.
- Fuse replacement: replace blown fuses.

ThinPrep® 3000 Processor Recommended Maintenance Schedule

Month: _____ Year: _____ Instrument # _____

Daily Maintenance	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
Fixative spray page 6.5																															
Empty slide waste bin page 6.9																															
Check filter waste box page 6.31																															
Lubricate the sample processing arm o-rings page 6.10																															

Instrument-prompted Maintenance	(Initial and Date)
Pneumatic system test page 6.13	
Clean slide path page 6.17	
Empty waste bottle, slide waste bin, filter waste box page 6.28, page 6.9, page 6.31	
CellFyx Solution replenishment. Insert clean fixative shield. page 6.32	
Slide printer ribbon page 6.34	

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ThinPrep® 3000 Processor Recommended Maintenance Schedule

Year: _____ Instrument # _____

Monthly Maintenance	(Initial and Date) J	F	M	A	M	J	J	A	S	O	N	D
General Cleaning page 6.24												

Twice-yearly Maintenance	(Initial and Date)
Pinch valve tubing replacement page 6.26	

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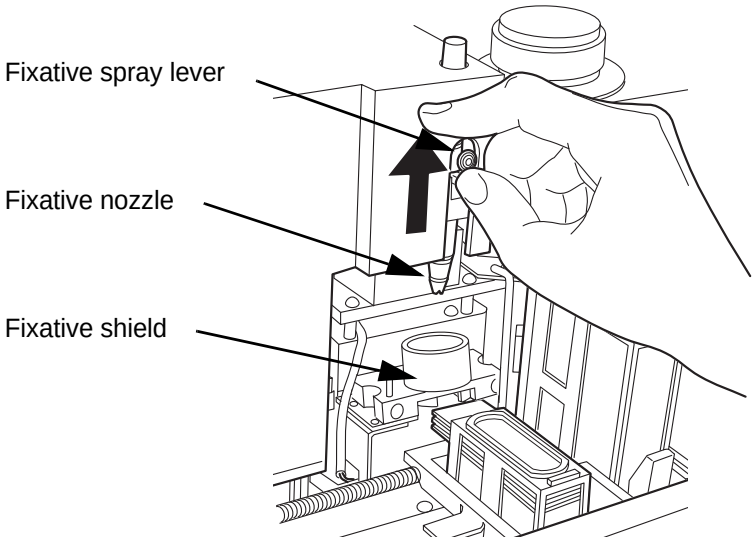
SECTION B

FIXATIVE SYSTEM PREVENTATIVE MAINTENANCE

CellFyx Solution fixes the prepared slides inside the instrument. The fixative properties of being very tacky as well as quick-drying can cause the slender air brush dispenser to clog easily. Long idle periods (when fixative is not being sprayed) may cause a clog to form. Before beginning a batch, the instrument tests that the fixative dispense path is clear. If a clog is detected, the display will change to the following screen.

1. Lift the fixative dispenser lever three or four times, as shown below.

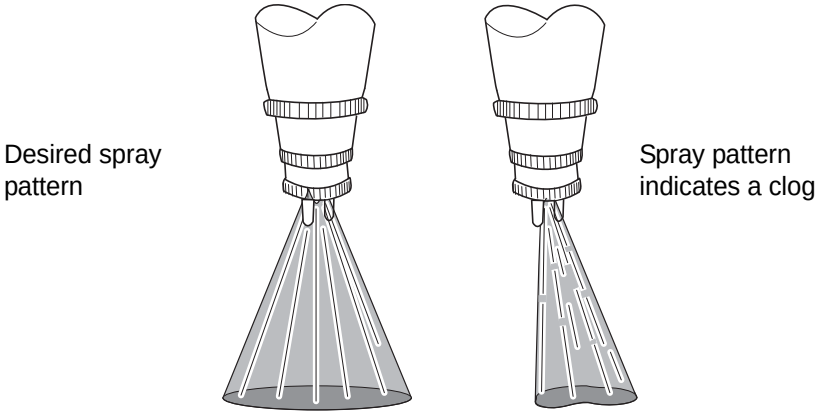


2. Observing the tip of the nozzle, select **Spray**. The fixative spray from the nozzle should appear in a fine, evenly distributed fan of mist as shown in the following illustration.

Note: Laying a tissue across the top of the fixative shield will capture the spray and indicate the spray pattern.

3. If that does not clear the device, hold the spray lever up and select **Prime**. A small drop of fixative solution will form at the nozzle tip. Let it sit about 30–60 seconds, to dissolve the blockage. Lift and release the lever a few times.

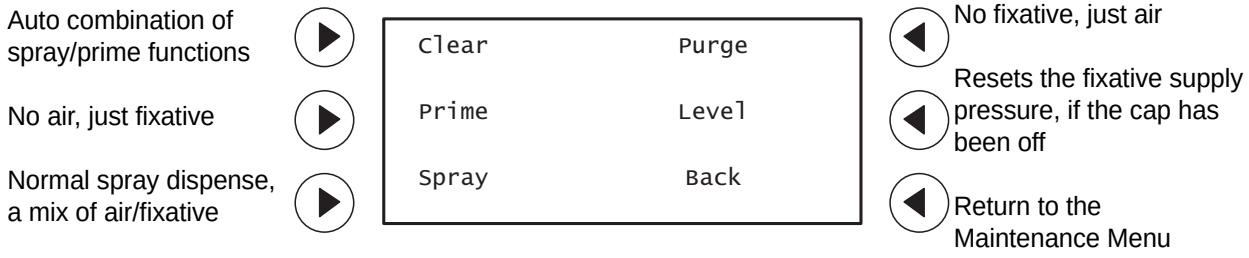
4. Observing the tip of the nozzle, press the **Spray** key.
   - If a fine, evenly distributed fan of fixative is sprayed, the solution is running freely through the system.
   - If there is no spray visible or the spray is uneven, repeat steps 3 and 4 several times.



Further Maintenance (If Needed)

Clearing clogs via the user interface

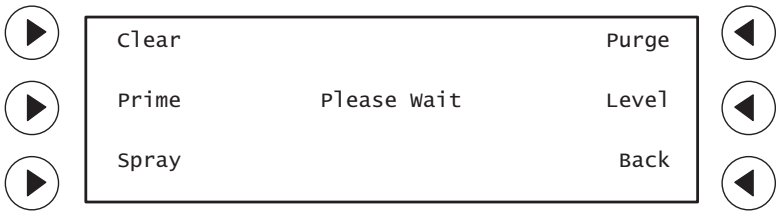
Fixative System menu:



If performing the preventative maintenance cycle does not result in the fixative nozzle spraying freely, the following steps will help dissolve fixative clogs.

1. Lift the dispense lever on the nozzle three or four times and select **Clear**. (This performs a series of spray & prime functions.) The fixative spray from the nozzle should appear in a fine, evenly distributed fan of mist as illustrated above.
2. If the fixative solution does not spray, or does not appear evenly distributed, repeat step 1 two or three more times.

Note: The fixative pressure tanks need a few seconds to recharge before the fixative can spray again. When a key is pressed, a "Please Wait" message will display until the system is ready.



3. If a clog remains, hold the spray lever up and press the **Prime** button until a drop of fixative can be seen at the spray nozzle. Stop pressing **Prime** and hold the lever up for 30 to 60 seconds.

CAUTION: The spray nozzle that delivers fixative solution to the slides is very delicate. DO NOT attempt to disassemble it. If recommended maintenance does not dissolve a clog, contact Hologic Technical Support.

4. Toggle the spray lever up and down a few times and press **Spray**. Observe for the desired spray pattern.
5. When the fixative sprays freely, return to the main menu to continue instrument operation.

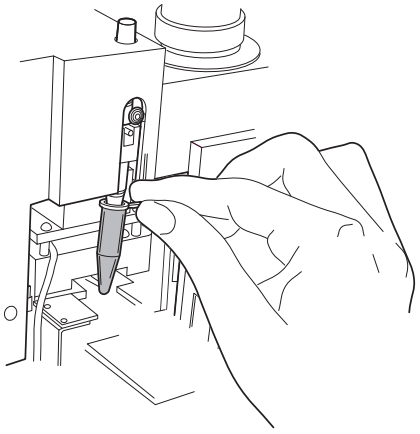
If this fails to resolve the problem, continue with the following procedure.

Dissolving Clogs with warm water

If an airbrush cannot be unclogged via the user interface the following steps may be performed.

1. Fill a microcentrifuge tube or any other small container with warm water.
2. Place the tube under the airbrush and lift the tube so the nozzle is submerged in the water, as shown below.

Note: A small amount of water will be displaced out of the tube or container. Do not allow water to spill into the instrument.



3. Allow the nozzle to soak in the warm water for approximately 60 seconds. Toggle the spray lever up and down several times. This will help dissolve the fixative that is clogging the nozzle.

4. Remove the container from the nozzle. Prime and spray as outlined previously, until the proper spray pattern is achieved.
5. Repeat steps 3 and 4 as needed. A longer soak time of 5–10 minutes and holding the spray lever up will help.
6. When the fixative sprays freely, return to the main menu to continue instrument operation.

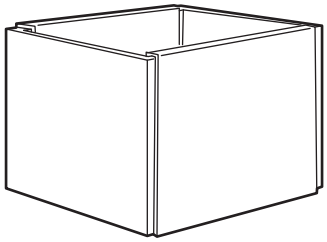
If the clog persists, contact Technical Support.

SECTION C

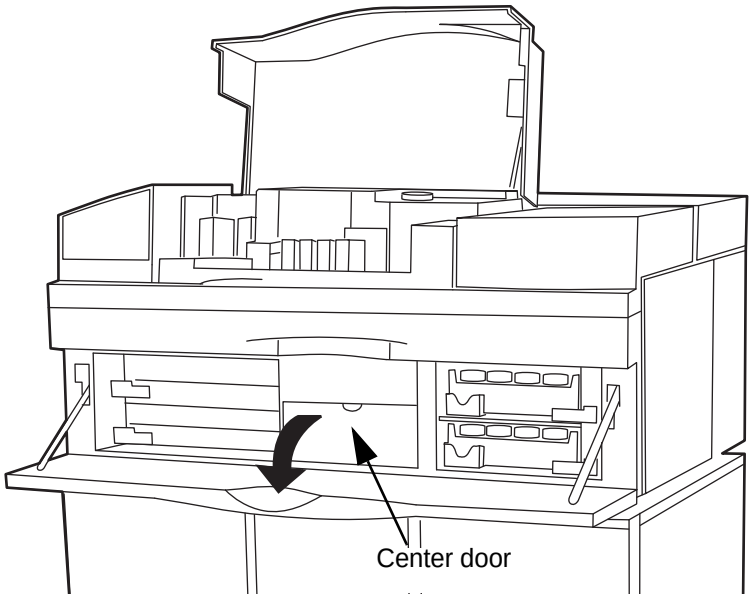
EMPTYING THE SLIDE WASTE BIN

The slide waste bin collects unusable slides. Empty it daily. Additionally, the message screen prompts you to empty the slide waste bin at the conclusion of each batch and when the waste bottle needs to be emptied.

WARNING: Sharp Edges
Glass

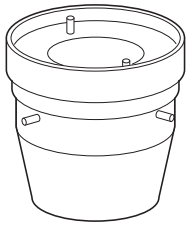


1. Open the front door on the ThinPrep 3000 processor.
2. Open the center door.
3. Remove the slide waste bin.
4. Dispose of the glass waste according to your laboratory's guidelines.
5. Return the slide waste bin to its original location.



SECTION D

LUBRICATING THE SAMPLE PROCESSING ARM O-RINGS



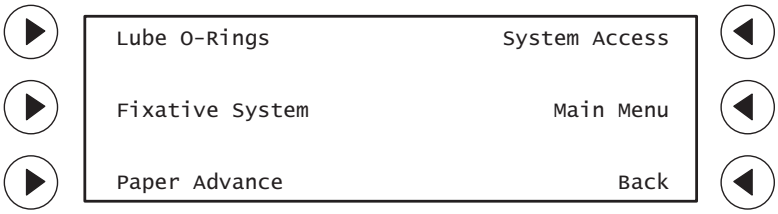
Once a day, or at the start of each shift, lubricate the sample processing arm (filter seal) O-rings. This maintenance lubricates the O-rings for ease of filter loading and disposal. Filter load failure errors and filter handling errors may occur if the sample processing arm O-rings are dry.

Refer to the Ordering Information in this manual for ordering silicone lubricant.

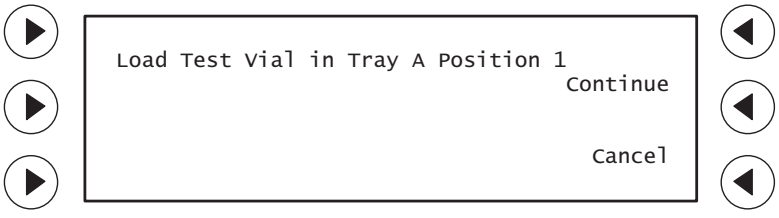
The pneumatic test vial is used for this maintenance; lubricant is required. The procedure takes about two minutes.

1. From the main menu, select **Menu**.
2. Select **Maintenance**.

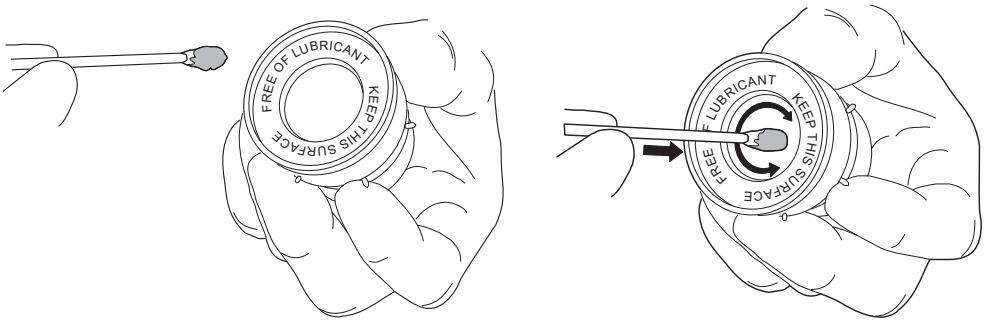
3. Select **Lube O-Rings**.



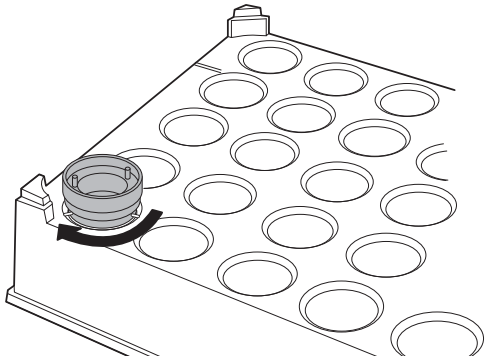
The following screen will be displayed.



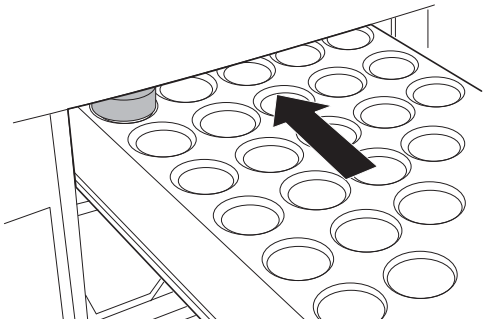
4. Wet the end of a swab with lubricant (Super Lube) and spread a light layer all around the **inside** surface of the pneumatic test vial.



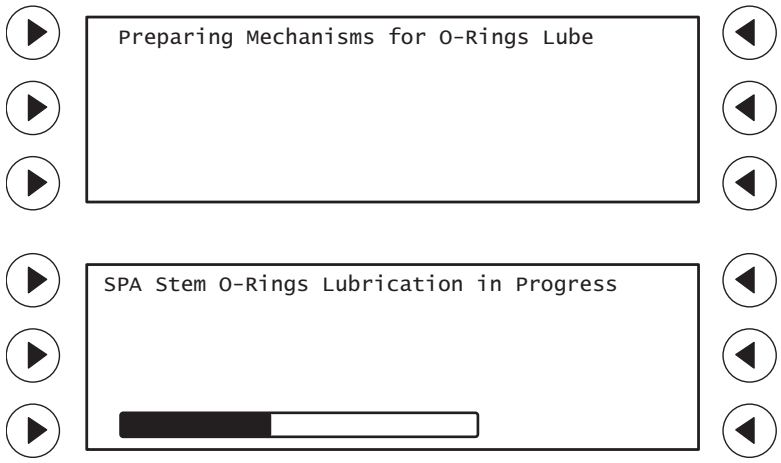
5. Load the pneumatic test vial into tray position **A1**, which is the first slot of the upper sample vial tray.



6. Rotate the test vial clockwise until the locator pins catch against the molded stops of the tray.

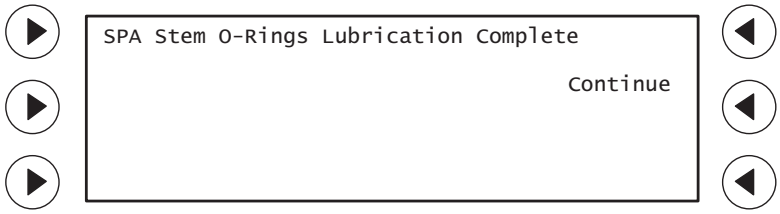


7. Load the tray into the instrument, close the tray latch and close all doors.
8. Press **Continue**. The doors will lock.
   The following sequence of screens will be displayed.



"SPA O-Rings Lubrication In Progress" appears on the message screen throughout the duration of the procedure.

9. The message screen displays completion of the lubrication.



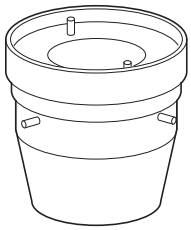
Press **Continue**. The doors will unlock.

CAUTION: The pneumatic test vial should always be stored in its protective box when not in use. Handle the vial with care.

10. Unload the sample tray. Remove the pneumatic test vial. With a lint-free cloth, wipe off any lubricant in and on the test vial. Return the test vial to its storage box.

SECTION E

PNEUMATIC SYSTEM TESTING

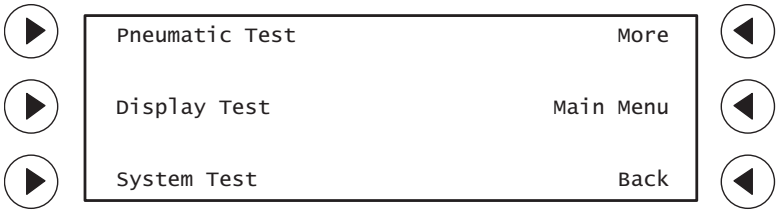


The pneumatic system must be tested to verify proper operation. The message "Please Run Pneumatic Test" will display when this is required. It is important to run the test when prompted. The test will take approximately 9 minutes to complete. Lubricant is required for this maintenance procedure.

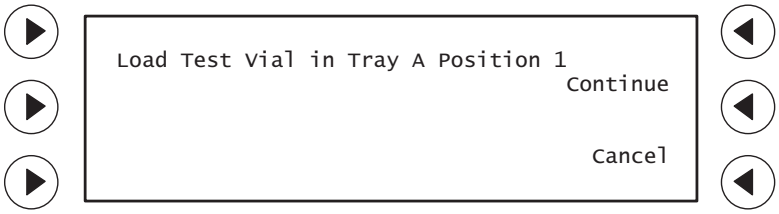
1. From the main menu, select **Menu**.
2. Select **Test**.

Refer to the Ordering Information in this manual for ordering silicone lubricant.

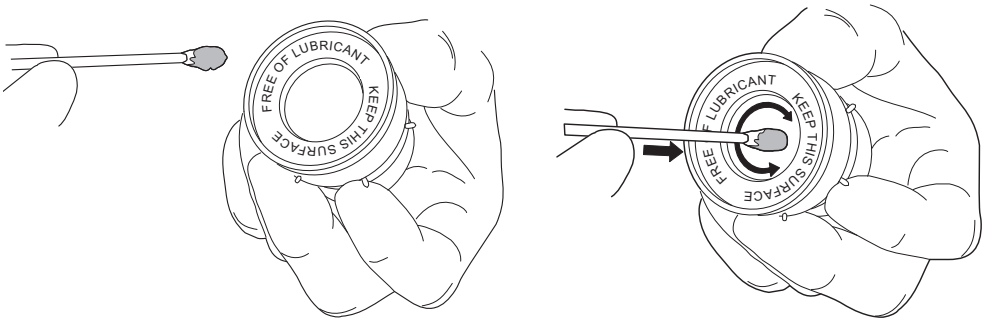
3. Select **Pneumatic Test**.



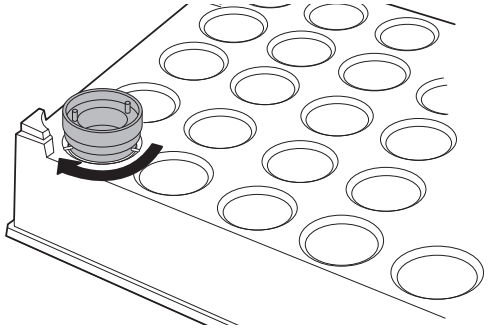
The following screen will be displayed.



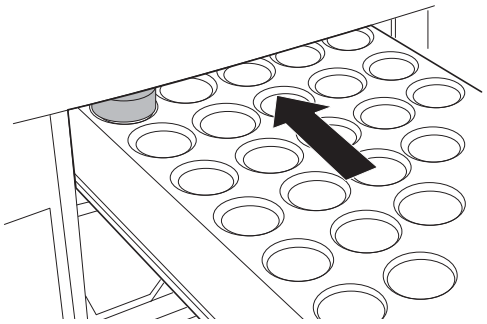
4. Wet the end of a swab with lubricant and spread a light layer all around the **inside** surface of the pneumatic test vial.



5. Load the pneumatic test vial into tray position **A1**, which is the first slot of the upper sample vial tray.



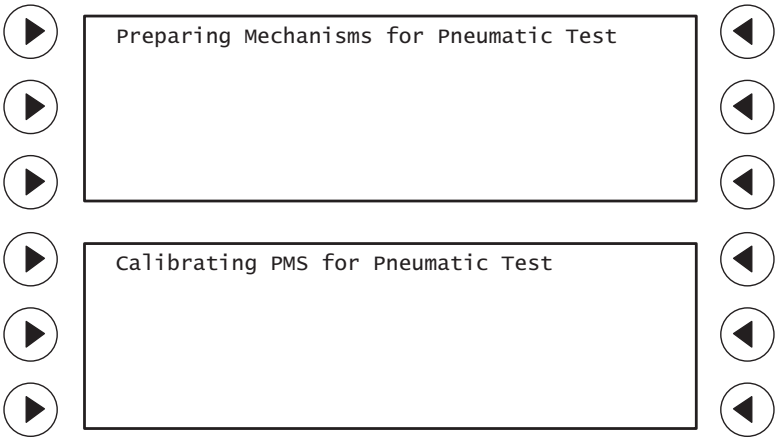
6. Rotate the test vial clockwise until the locator pins catch against the molded stops of the tray.



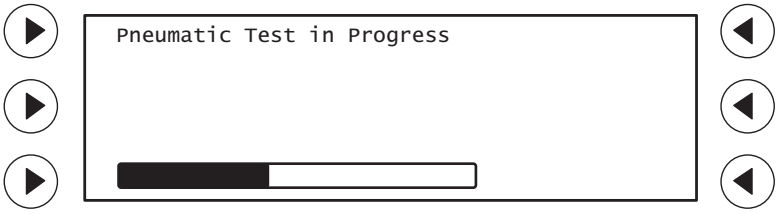
7. Load the tray into the instrument, close the tray latch and close all doors.
8. Press **Continue**.

   The results printer will print the start of a report for this procedure. The time, date and serial number of the instrument will be printed, with the message “Pneumatic Test Started”.

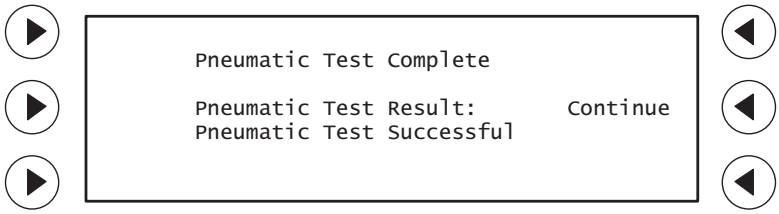
The following sequence of screens will be displayed.



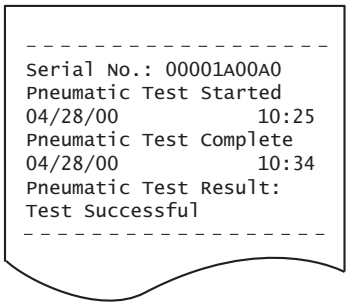
"Pneumatic Test In Progress" appears on the message screen throughout the duration of the system testing.



9. The message screen displays the test results.



The pneumatic system test report completes printing, as shown below.

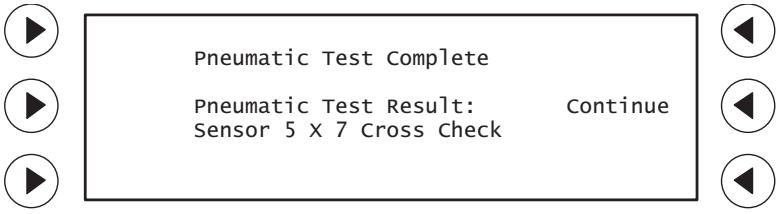


10. If the instrument passes pneumatic system testing, select **Continue**. The main menu screen will display.

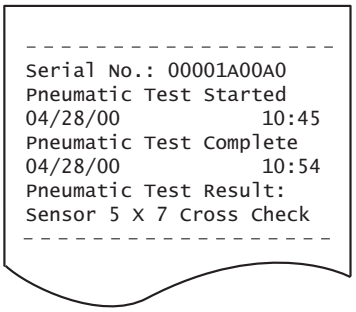
CAUTION: The pneumatic test vial should always be stored in its protective box when not in use. Handle the vial with care.

11. Unload the sample tray. Remove the pneumatic test vial. With a lint-free cloth, wipe off any lubricant in and on the test vial. Return the test vial to its storage box.

    If the instrument fails pneumatic system testing, the test that failed will be listed under Pneumatic Test Results. (There are 21 system tests; the message may be different from that shown below.)



    The printed test report will show the same message.



12. Press **Continue** to return to the main menu.
13. Repeat the pneumatic system test one more time.

CAUTION: Do not process samples on the instrument after failing pneumatic system testing. Contact Hologic Technical Support.

14. If the pneumatic test fails again, contact Hologic Technical Support before resuming instrument operation.

SECTION F

CLEANING THE SLIDE PATH

CAUTION: Proper instrument operation depends on routinely cleaning the slide path, as prompted.

Frequent cleaning of the mechanisms which handle the slides will greatly reduce the risk of sample errors or slide handling problems. The message "Please Clean Slide Path" will display when this is required. It is important to perform this maintenance when prompted.

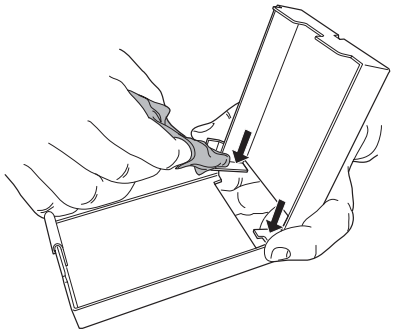
Note: Only de-ionized or distilled water should be used to moisten swabs or lint-free cloth for cleaning the instrument.

Microscope Slide Areas

Interior of Slide Cartridge

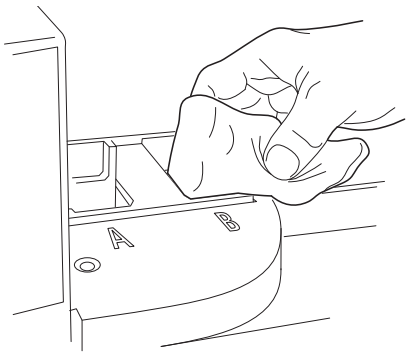
Each time a cartridge is loaded with microscope slides, wipe the inside of the cartridge with a lint-free cloth to remove glass dust. Clean the bottom surface where the slides sit, to help ensure proper slide picking.

WARNING: Sharp Edges
Glass



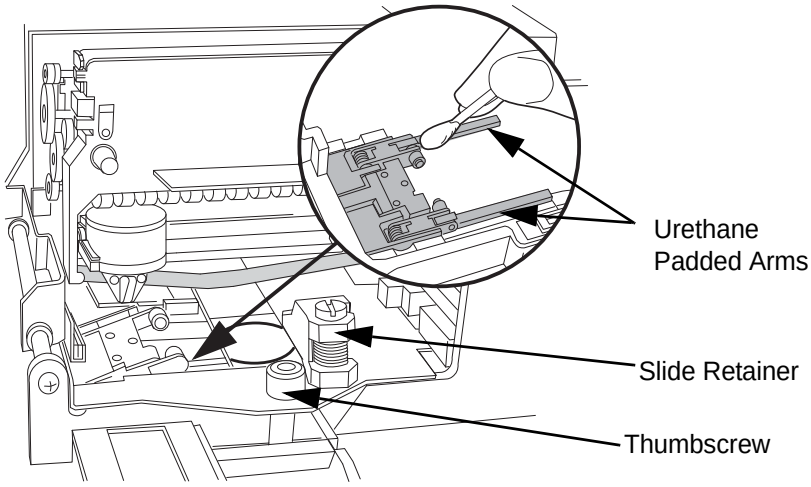
Inside of Slide Cartridge Well

Remove the slide cartridges and pull the black bezel off by pulling it upward. With a damp, lint-free cloth, wipe the surfaces to remove dust and any slide debris.

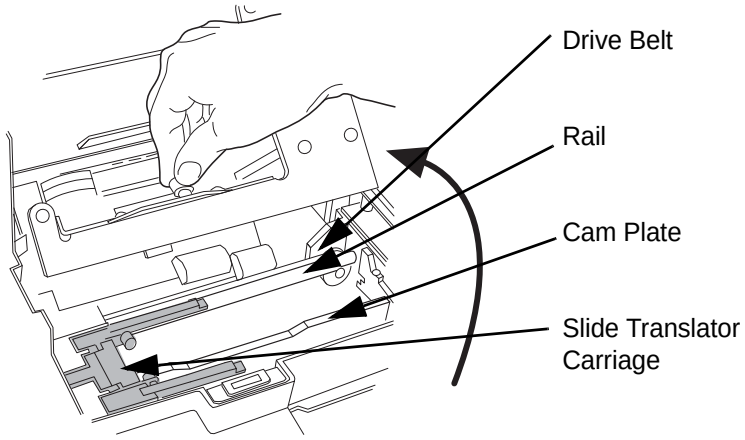


Slide Printer Area

Open the lid covering the slide printer. If a slide is there, remove it. Using a water dampened swab, clean the black urethane pads on the arms of the slide pick mechanism. Also, clean any glass dust from the metal surface surrounding the urethane pads. Clean under the print head, around the slide retainer and around the thumbscrew.



The thumbscrew at the front releases the assembly from the chassis on one side. Swing the module up to clean underneath. With a dry cloth or swab, brush any glass dust off of the slide translator carriage and the rails it rides on. Clean off the black cam plate. If the carriage is in the way, move it left or right by pulling the top section of the drive belt.



Note: If the arms of the slide translator carriage are raised, gently press them down while lowering the printer assembly back down.

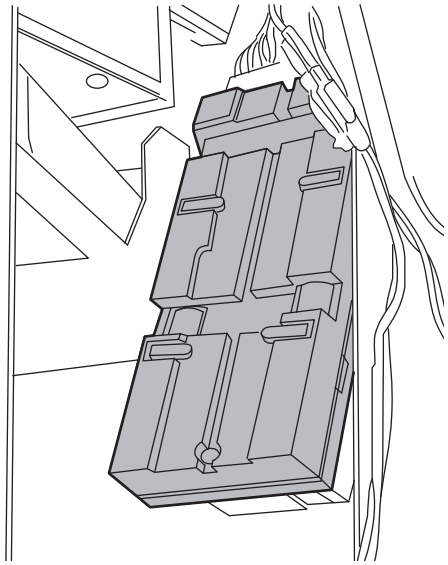
Note: Retighten the thumbscrew when done.

Note: Replace the bezel around the slide cartridge well.

Slide Cell Transfer Arm and Slide Clamps

CAUTION: Frequent cleaning of the slide cell transfer arm to remove fixative build up will reduce the risk of mis-seated or stuck slides.

The slide cell transfer arm is located centrally in the instrument (refer to Slide Handling System illustration on page 1.7). Use the ThinPrep 3000 Maintenance Kit to clean the slide cell transfer arm and slide ejector path. Directions are below. The first time you use the kit, the cleaning solution must be mixed.



Prepare the Versa-Clean™ Solution.

1. Fill the plastic aerosol spray bottle with 100 mL of plain water and add 3.33 mL of Versa-Clean Solution.
2. Close and shake the bottle to mix. Pump the overcap/piston assembly up and down 7 - 10 strokes to pressurize the bottle.

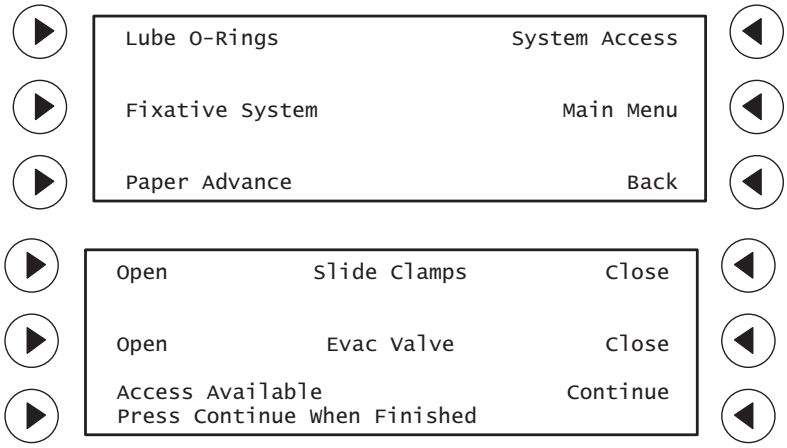
Note: Do not substitute other cleaning solutions for Versa-Clean Solution.

Clean the Slide Cell Transfer Arm

1. Remove the staining racks and fixative shield. Remove the lower filter and sample vial trays.

Refer to page page 6.23 for information on how to remove and replace the fixative shield.

2. Put an ordinary paper towel under the slide cell transfer arm to catch the cleaning solution that drips off of the mechanism.
3. From the Maintenance menu, select **System Access**.



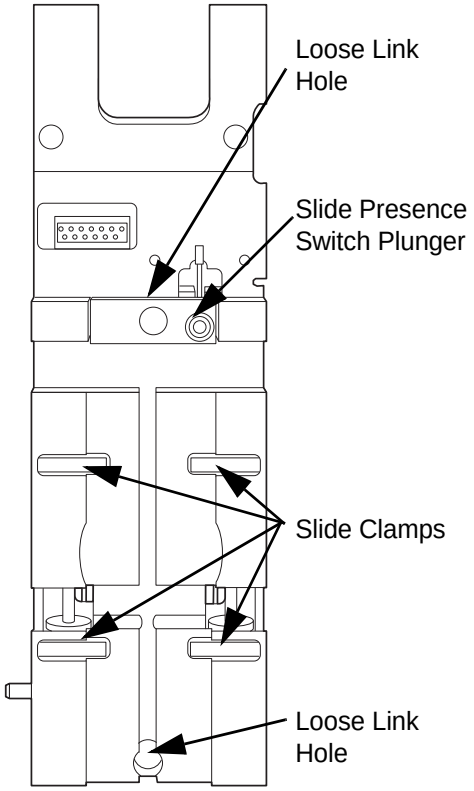
4. Select **Open** [Slide Clamps] to disengage the slide clamps. You will hear them click open.

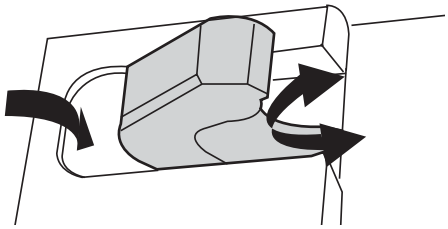
Note: To prevent overheating the solenoids, do not leave the slide clamps open for more than 15 minutes.

5. Spray the cleaner on the silver surface of the arm, spraying from top to bottom. Let it sit for 30 seconds to dissolve the fixative residue.

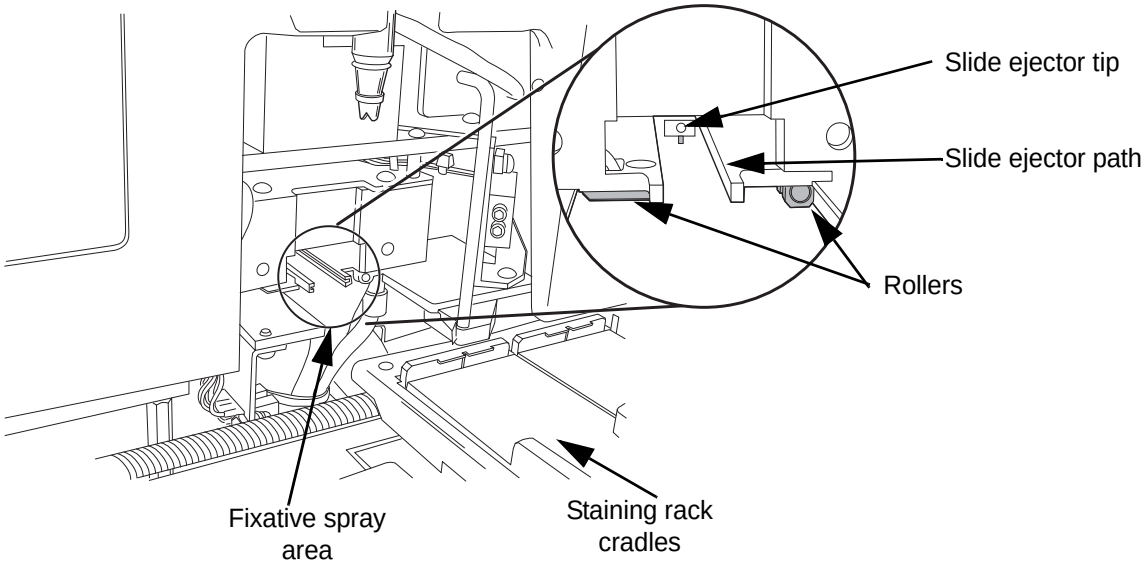
The slide clamps are fragile. Only use foam tipped swabs to clean and dry them. DO NOT USE FORCE! Thoroughly swab the slide presence switch plunger and opening.

6. Wipe the solution off the arm using lint-free wipes. Wipe from the top to the bottom, moving gently around the slide clamps.
7. Using foam tipped swabs, wipe out the grooves in the slide holder part of the arm, around the joints and underside of the slide clamps, the loose link holes and the slide presence switch.
8. Close the slide clamps. Do a final wipe down of the arm using the alcohol pad. Also use that to wipe the slide ejector path, rollers and the tip of the slide ejector.
9. Open the clamps once more. Wipe them with the alcohol pad, then thoroughly dry around and under them with foam tipped swabs. Close the clamps.
10. The alcohol will evaporate completely within one minute of cleaning the surface.
11. Remove any towels or cleaning supplies from the instrument.





An open slide clamp. Clean all surfaces and surrounding area.

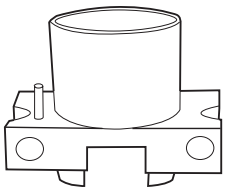


Fixative spray area

Using a swab or lint-free cloth moistened with water, clean around the fixative spray area as shown above. The staining rack cradles should be cleaned of spray and any glass dust. Replace the fixative shield when finished.

SECTION G

REPLACING THE FIXATIVE SHIELD



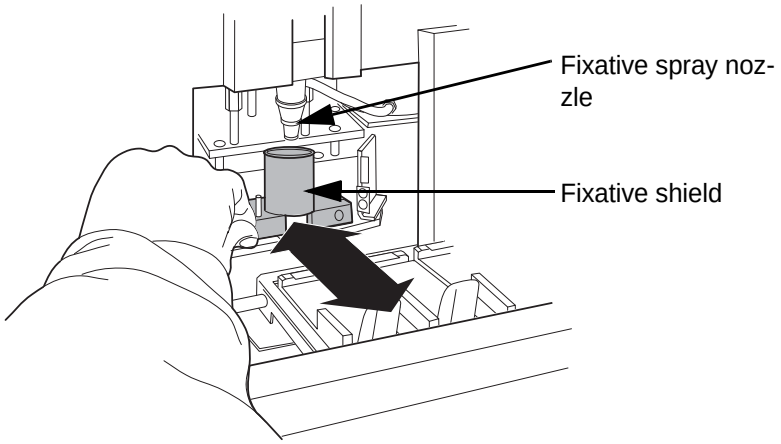
The fixative shield collects excess CellFyx Solution from the fixative spray nozzle during its distribution onto the slide. Each time the fixative is replenished with a bottle of CellFyx Solution, dispose of the old fixative shield and replace it with a new one.

Remove the Fixative Shield

WARNING: Toxic Mixture
Highly Flammable Liquid and Vapor

1. The fixative shield assembly is removed by sliding it straight out from below the spray nozzle. The plastic base of the assembly has a notch at either side, useful for gripping with your fingers to pull the block out.

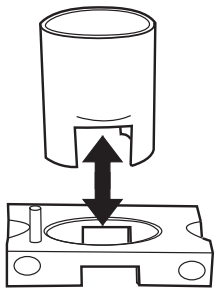
Each CellFyx Solution package contains six 115-mL bottles of CellFyx and six fixative shields.



2. Observe how the shield fits snugly against its plastic mounting block. Then separate the cylindrical fixative shield from the plastic base.

Insert the fixative shield

1. Insert the replacement fixative shield into the cutout area of the plastic base. Push it in until it is seated firmly against the base. The pin on the left side indicates the top surface of the plastic base.
2. Slide the fixative shield assembly back into position as shown above. The positioning pins on the back side of the block can be felt to snap into place when the assembly is correctly pushed against the wall of the fixative area.



SECTION H

GENERAL CLEANING

Exterior

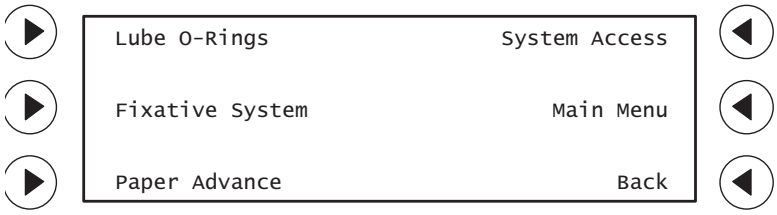
CAUTION: Do not use strong solvents such as acetone or xylene, as they may damage the paint or plastic surfaces.

We suggest you wipe down the exterior of the ThinPrep 3000 processor monthly or as needed with a lint-free wipe dampened with water. Clean the inside front door and under the top door and slide printer cover.

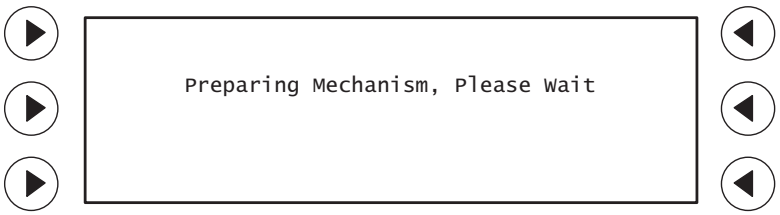
System Access

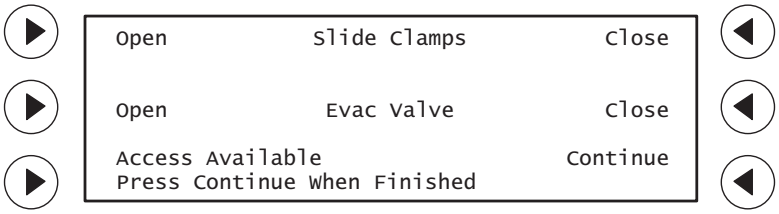
To gain the most room for cleaning, maintaining or accessing the interior of the instrument, a System Access function is available via the Maintenance menu. This moves the upper filter and sample vial trays to their topmost position and parks them on the robotic arms, allowing maximum access.

1. From the main menu, select **Menu**.
2. Select **Maintenance**.



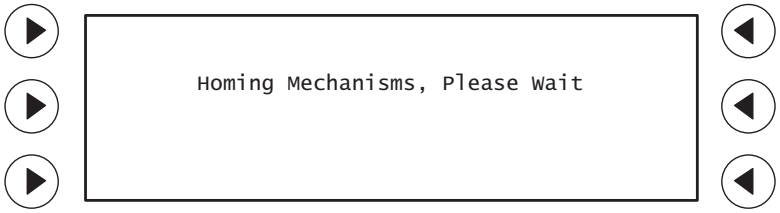
3. Select **System Access**. The following screens will display.



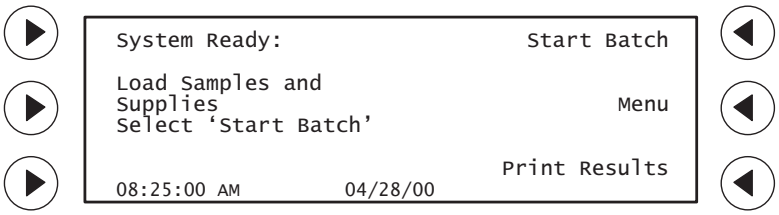


4. When the screen above displays, the doors will unlock. The instrument may be accessed. When finished, close the doors and press **Continue**.

   The following screen will display.



The instrument returns all trays and mechanisms to their ready position. When complete, the main menu screen appears.



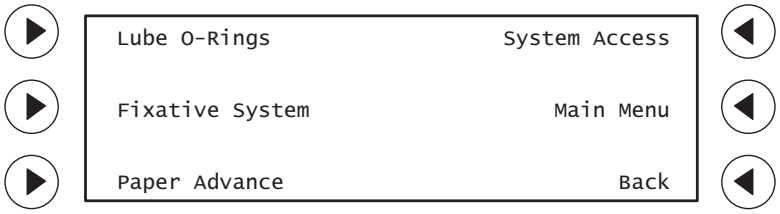
SECTION I

PINCH VALVE TUBING REPLACEMENT

The pinch valve tubing is the tubing connection between the pneumatic system and the waste system. For optimal performance, the pinch valve tubing should be replaced every six months.

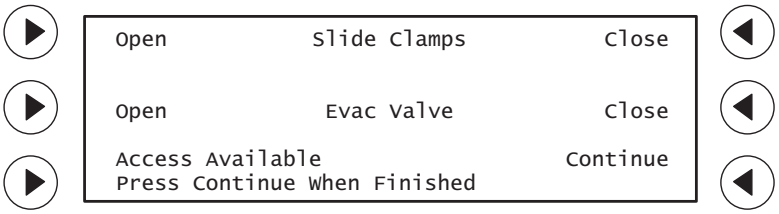
1. From the Maintenance menu, select **System Access**.

Refer to the Ordering Information in this manual for replacement tubing.



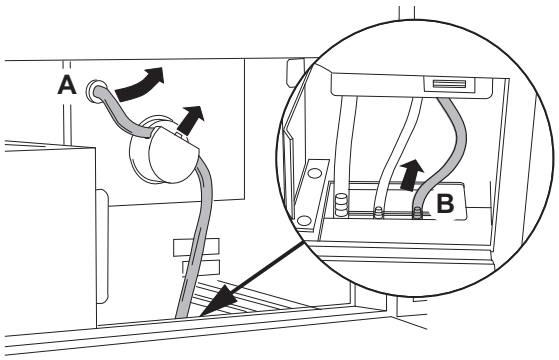
The doors will lock while the processor moves trays and mechanisms out of the way for access to the instrument. The doors will unlock and the following screen is displayed:

CAUTION: Only use Hologic-supplied tubing for replacement.



Press **Open** [Evac Valve] to open the pinch valve.

2. Open the front door and then open the center door. The pinch valve tubing is located to the right of the Slide Waste Bin.
3. Detach tubing from points A and B, as shown.



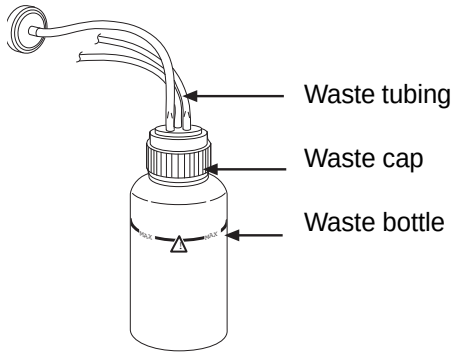
4. Hold the tubing on each side of the pinch valve and slide it in an upward motion, as shown below.

5. Discard the old tubing.
6. Slide the new tubing back down into the pinch valve opening. Make sure it is completely seated in the valve, with no kinks.
7. Connect the replacement tubing to points A and B.
8. Press the **Close** [Evac Valve] key on the display to close the pinch valve.
9. Close the center door and close the front door to the instrument.
10. Select **Continue** on the displayed menu.
11. The instrument doors will lock and the mechanisms will be returned to idle mode state. The **System Ready** screen will display and the doors will unlock.
12. To test the new tubing installation, process a new, unused PreservCyt® Solution sample vial.

SECTION J

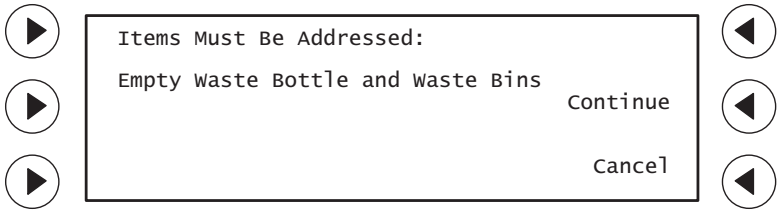
WASTE SYSTEM MAINTENANCE

Waste resulting from sample processing is routed to and stored in the waste bottle.



Emptying the Waste Bottle

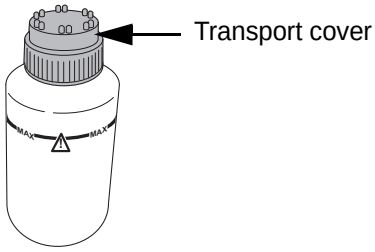
The message screen will notify you when to empty the waste bottle. The batch will not begin until the waste bottle has been emptied.



1. Open the middle door on the processor cabinet.
2. To remove the waste cap, rotate the waste cap with one hand while holding the waste bottle in place with the other hand. (Not much pressure is needed to unscrew the cap; do not exert too much force on the door hinge as you remove the waste cap.)
   - If the waste tubing becomes dislodged from the waste cap during this process, reconnect the tubing before continuing.

WARNING: Hazardous Waste
Toxic Mixture
Flammable Liquid and Vapor

3. Place the transport cover onto the waste bottle for transporting.
4. Remove the waste bottle from the instrument.
5. Dispose of the liquid waste from the waste bottle according to your laboratory guidelines. Dispose of all solvents as hazardous waste. Follow local, state, provincial and federal or county guidelines. As with all laboratory procedures, universal precautions should be followed.



CAUTION: The waste bottle must never contain bleach when it is connected to the processor.

- PreservCyt Solution was challenged with a variety of microbial and viral organisms. The following table presents the starting concentrations of viable organisms and the number of viable organisms found after 15 minutes in the PreservCyt Solution. The log reduction for viable organisms is also presented. As with all laboratory procedures, universal precautions should be followed.

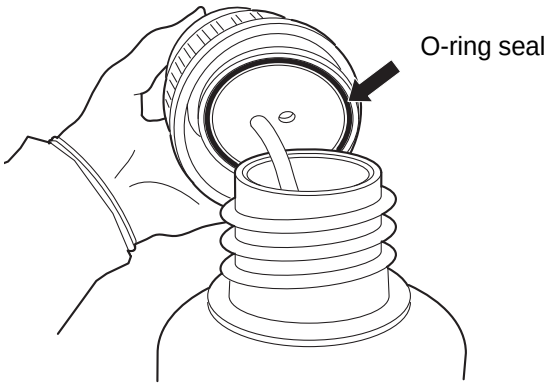
Organism	Initial Concentration	Log Reduction after 15 min.
Candida albicans	5.5×10^5 CFU/mL	>4.7
Aspergillus niger*	4.8×10^5 CFU/mL	2.7
Escherichia coli	2.8×10^5 CFU/mL	>4.4
Staphylococcus aureus	2.3×10^5 CFU/mL	>4.4
Pseudomonas aeruginosa	2.5×10^5 CFU/mL	>4.4
Mycobacterium tuberculosis**	9.4×10^5 CFU/mL	4.9
Rabbitpox virus	6.0×10^6 PFU/mL	5.5***
HIV-1	$1.0 \times 10^{7.5}$ $TCID_{50}$/mL	7.0***

* After 1 hour >4.7 log reduction
** After 1 hour >5.7 log reduction
*** Data is for 5 minutes

Refer to the Ordering Information in this manual for ordering silicone lubricant.

6. Before reattachment, inspect the O-ring seal on the inside of the waste cap for debris.

- If debris is present, clean the seal with water using a lint-free wipe.
- Apply a thin layer of lubricant to the O-ring.

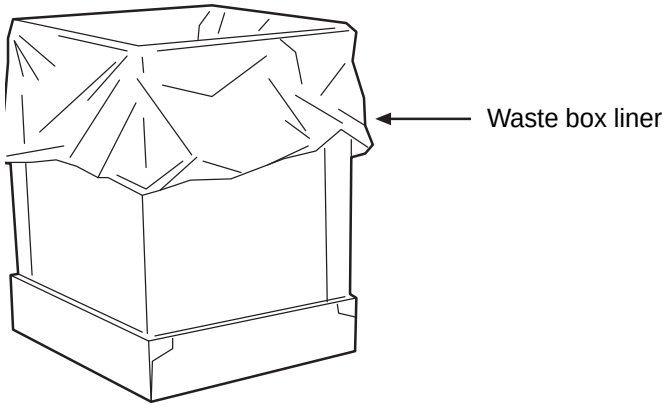


7. Return the waste bottle back to its original location and retighten the waste cap onto the bottle.
   - Verify that the waste cap is firmly tightened and confirm that the waste tubing is not pinched or twisted.
   - Once the waste bottle is connected to the instrument, the process is complete.
8. Select **Continue** to return to the main menu.

SECTION K

EMPTYING THE FILTER WASTE BOX

The filter waste box collects ThinPrep Pap test filters after use. The message screen will prompt you to empty the filter waste box at the time the waste bottle is to be emptied.



1. Open the center door on the ThinPrep 3000 processor cabinet.
2. Carefully pull the filter waste box out of the cabinet. Look for loose filters that might have missed the waste box and remove them as well.

Refer to the Ordering Information in this manual for ordering liners.

3. Remove the waste box liner.
4. Tie the waste box liner to prevent filters from falling out of the bag.
5. Dispose of the used filters and liner according to your laboratory's guidelines.
6. Insert a new waste box liner into the filter waste box.
7. Return the filter waste box to its original location.

SECTION L

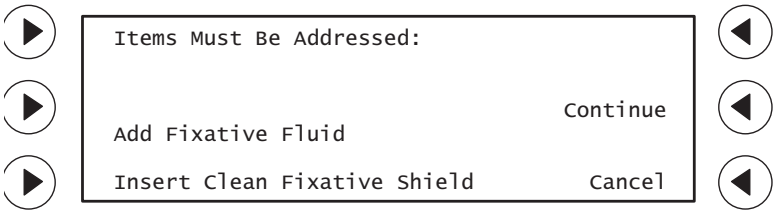
REPLENISHING CELLFYX SOLUTION

CellFyx Solution is a methanol-based fixative that is designed to preserve the morphologic features of the cell nucleus and cytoplasm. It is formulated for use with the ThinPrep 3000 processor.

WARNING: Toxic Mixture
Highly Flammable Liquid and Vapor

Do not use any other fixative solution with the instrument.

The message screen will notify you when to replenish fixative.



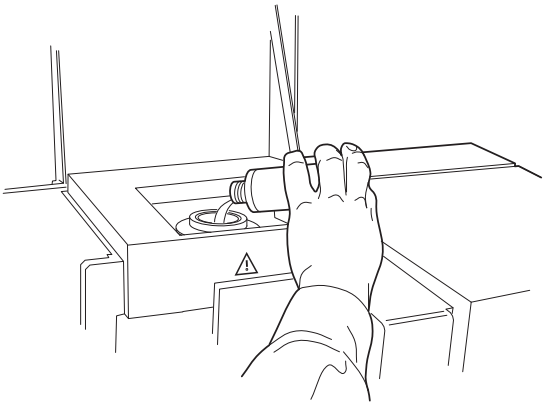
To fill the fixative reservoir, press **Continue**. The doors will unlock if they are currently locked.

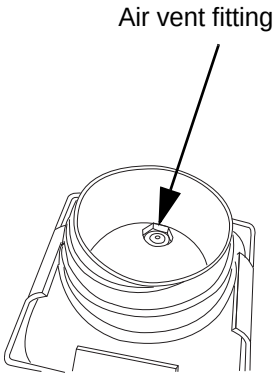
Pressing **Cancel** will cancel the current message, but a batch will not start until the reservoir has been replenished.

Filling the Fixative Reservoir

1. Open the top door on the instrument and locate the fixative reservoir.
2. Unscrew and remove the cap on top of the fixative reservoir.
3. Pour **one** bottle of CellFyx Solution (115 mL) into the fixative reservoir. Replace and tighten the cap on top of the fixative reservoir.

CAUTION: Only add one bottle to the fixative reservoir when prompted by the instrument. Do not overfill. The instrument will be damaged if the fixative level reaches or goes above the air vent fitting on the inside of the fixative reservoir.





Note: If the solution drips or spills, take care to wipe it off the surface of the instrument at that time. Do not let CellFyx Solution remain on the machine.

Insert Clean Fixative Shield

Remove the fixative shield and dispose of it. Replace it with a new fixative shield. Refer to "REPLACING THE FIXATIVE SHIELD" on page 6.23 for instructions on removing and replacing the fixative shield.

Repressurize the Fixative Reservoir

1. From the Maintenance menu, select **Fixative**.

If, during fixative maintenance, the Level button is pressed and the fixative reservoir is low, a message, "Add Fixative Fluid" appears on the display.

2. From the Fixative maintenance menu, select **Level**.

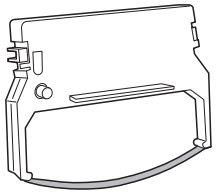
3. The pressure in the fixative reservoir resets, allowing the instrument to detect the fixative level.

   The level function only takes a minute to complete. A "Please Wait" message appears while the instrument performs Level.
4. When the level function has finished, press **Spray**. A "Fixative Clogged" message will appear. Continue to press **Spray** until the message no longer appears. A couple of times is sufficient.
5. Press the **Back** key to return to the main menu.

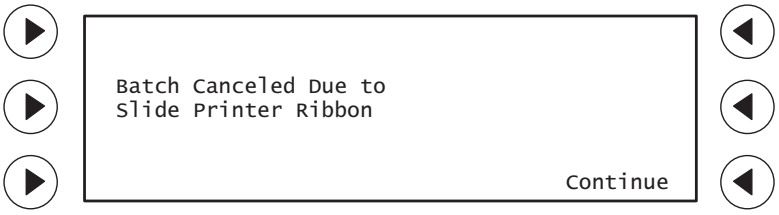
Note: Any time the cap to the fixative reservoir is removed and replaced, the find level function should be run, to ensure correct instrument operation.

SECTION M

REPLACING THE SLIDE PRINTER RIBBON



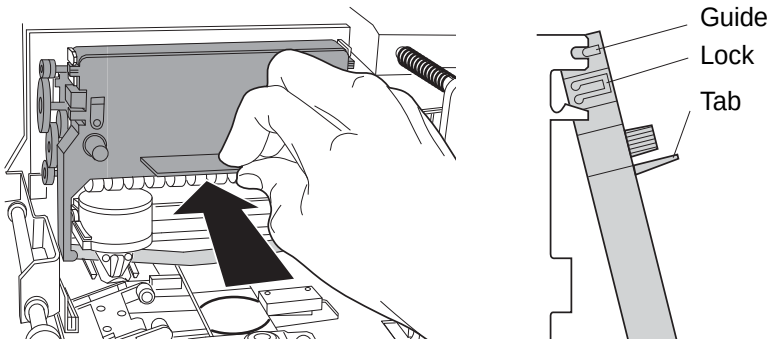
The slide printer ribbon is used to print the sample ID number and laboratory information directly onto the slides prior to sample processing. The message screen will notify you when to replace the slide printer ribbon cartridge.



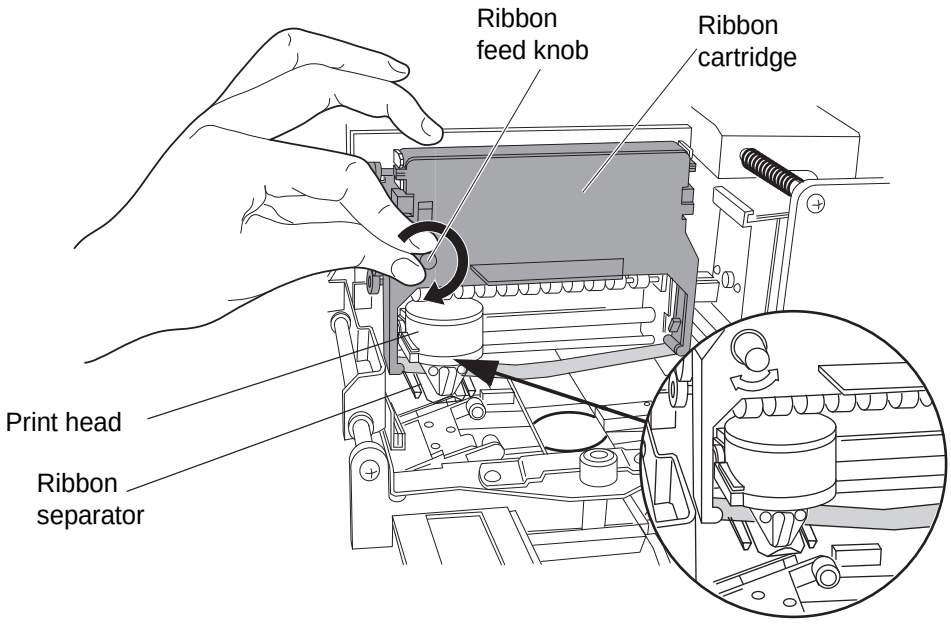
Note: Slides that are printed too lightly for the OCR camera to read are discarded. The instrument will print a second slide. If the second OCR read fails, the sample is not processed. A "Slide Misprint" error is recorded on the batch report. If you notice an increase in slides discarded, but no "Slide Misprint" messages on the batch report, the printer ribbon may be wearing out and causing a mix of normal and too-lightly printed slides. Try replacing the slide printer ribbon.

1. Open the top door on the instrument.
2. Open the slide printer cover and locate the ribbon cartridge. Note the routing of the printer ribbon under the print head.
3. Remove the old cartridge by holding the tab and carefully pulling it out.
4. Remove the new printer ribbon cartridge from its package.
5. Turn the ribbon feed knob on the new cartridge in the direction of the arrow to remove slack.

6. Insert the cartridge with the tab in the center facing outward, as shown.



- When inserting the cartridge, the printing ribbon should be routed slightly below the print head and above the ribbon separator, as shown below.



7. Turn the ribbon feed knob in the direction of the arrow to tighten the ribbon (clockwise). Confirm that the printing ribbon is not routed below the ribbon separator.

SECTION N

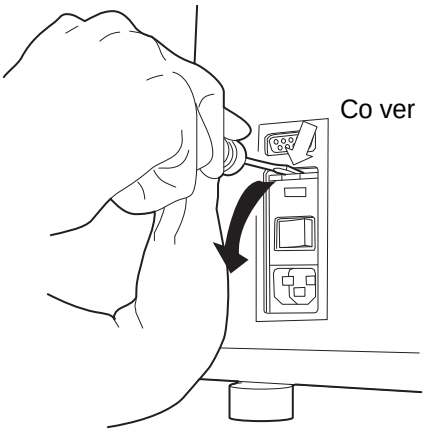
REPLACING THE USER-ACCESSIBLE FUSES

There are two user-accessible fuses located in the instrument. If the instrument fails to operate, replace these fuses as outlined below:

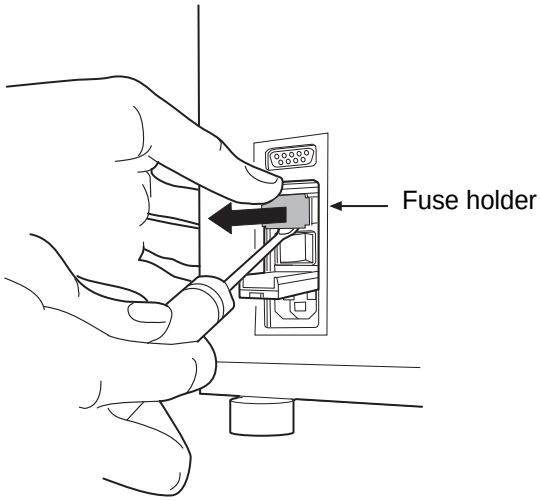
1. Turn off the instrument.
2. **Remove the power cord from the wall outlet.**
3. Remove the power cord from the receptacle on the instrument.

WARNING: Instrument Fusing

4. Using a small slotted screwdriver, carefully pry open the cover of the power entry module as shown below.



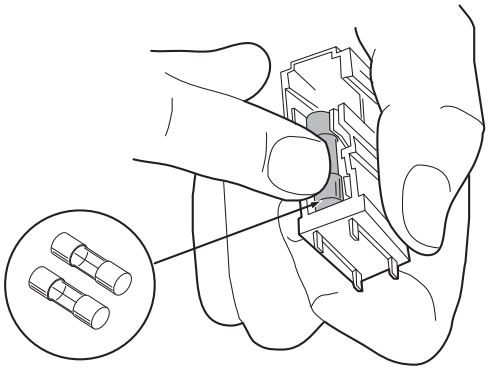
5. Gently pull down the cover. It is hinged at the bottom end.
6. Insert the screwdriver under the fuse holder to pull it out.



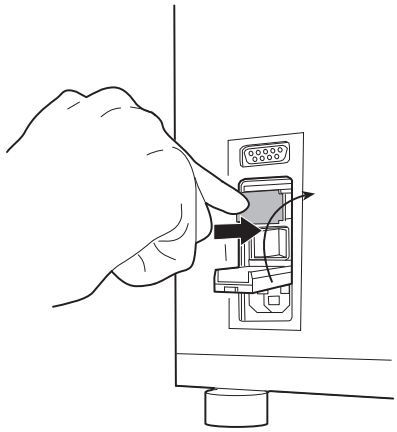
7. Remove the existing fuses and discard them.

Refer to the Ordering Information in this manual for ordering fuses.

8. Insert two new 250V T6.3AL 5x20 mm fuses into the fuse holder as shown.

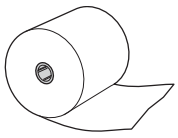


9. Insert the fuse holder back into the power entry module. The module can only be installed in one orientation.
10. Close the access cover.



11. Plug the power cord into the socket on the instrument.
12. Reattach the power cord to the wall outlet.
13. Turn on the instrument.
14. If the instrument still fails to operate, contact Technical Support.

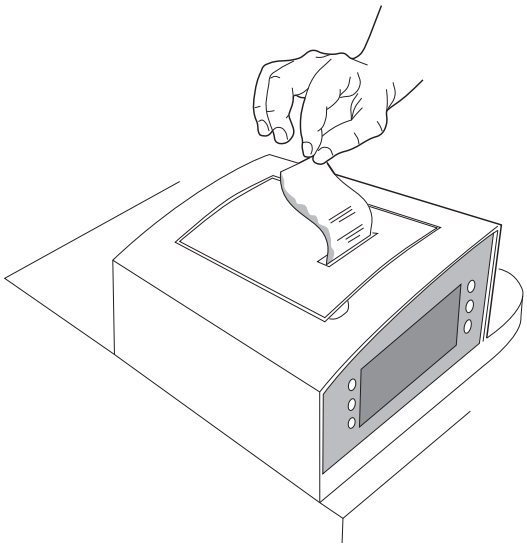
SECTION O REPLACING THE RESULTS PRINTER PAPER



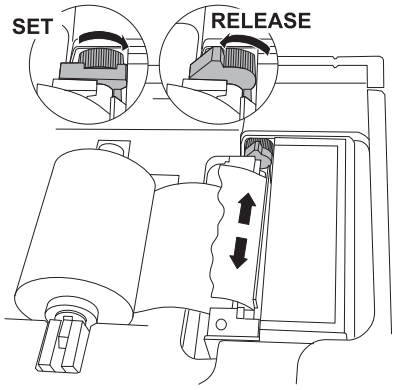
The results printer paper roll needs to be replaced when a red or black line appears along the edge of the batch report.

The printer paper is a thermal sensitive paper onto which the batch results are printed. The rolls should be kept in a cool, dark place. Each roll is sealed in a light resistant plastic wrapper to protect it until use. Do not open the package prior to installing the paper.

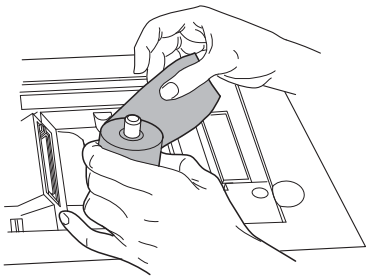
Refer to the Ordering Information in this manual for ordering printer paper.



1. Open the lid above the user interface panel.
2. If there is still paper left on the roll, press the left side of the green release lever down. Pull the end of the paper out from under the platen. Return the lever to the set position.



3. Lift up the metal roll holder. It is hinged on the left side.
4. Remove the used paper roll from the metal roll holder and discard. A translucent plastic washer at the left side of the roller keeps the roll of paper from skewing as it is used up. Do not discard this plastic piece.



5. Slide the new thermal paper roll onto the metal roll holder.

Note: The paper has a thermal sensitive side, on which the results are printed. If the batch report is not printing properly, check to see if the paper is loaded correctly. The orientation of the roll should be as shown, with the feeding edge being pulled from the bottom of the roll.

6. Lower the metal roll holder down.

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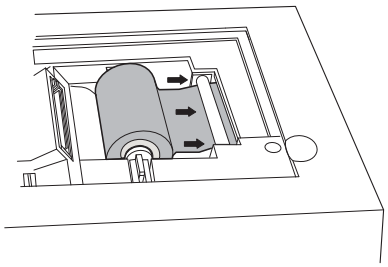
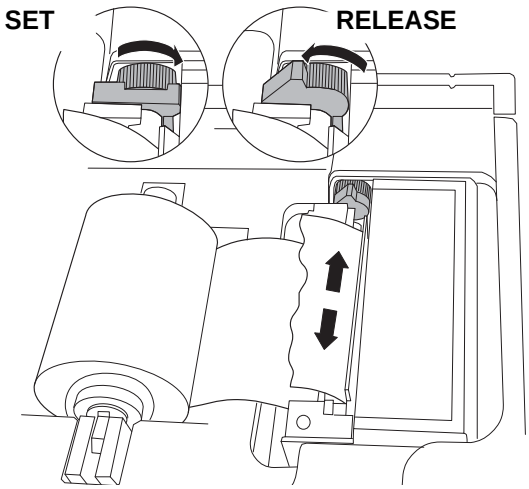
7. Insert the paper through the metal slot located directly in front of the metal roll holder as shown below. The paper should unroll from the bottom. The printer will auto advance a small amount of paper, when it senses the leading edge beneath the platen.

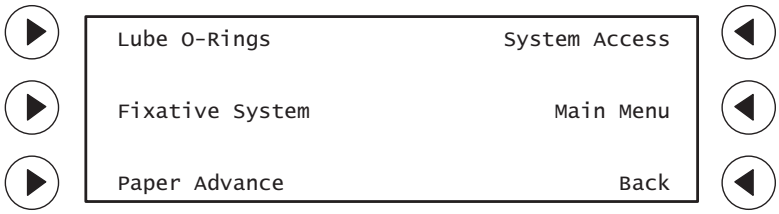


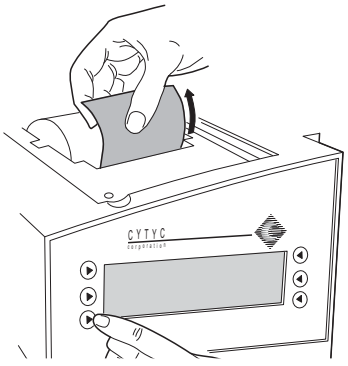
8. If the paper feeds crookedly through the roller, press the left side of the green paper release lever down, and straighten the paper in its path. Return the lever to set position to hold the paper in place.

Note: The lever must be in the **SET** position for the results printer to work.



9. Select **Menu** from the main menu.
10. Select **Maintenance**.
11. Press and hold **Paper Advance** to advance the paper three to four inches. Lead it through the opening of the cover.





12. Gently lower the lid back into place.
13. Select **Back** to return to the main menu. To test the legibility of the printer, press **Print Results** to print a copy of the last batch report.

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7. Troubleshooting

7. Troubleshooting

Chapter Seven

Troubleshooting

CONTENTS

SECTION A

CHAPTER OVERVIEW

Instrument troubleshooting falls into two categories: *Sample Errors* and *System Fault Errors*. This chapter addresses common error messages and corrective operator actions associated with each.

Note: Regular instrument maintenance, as described in Chapter 6, will reduce many instances of sample and system error.

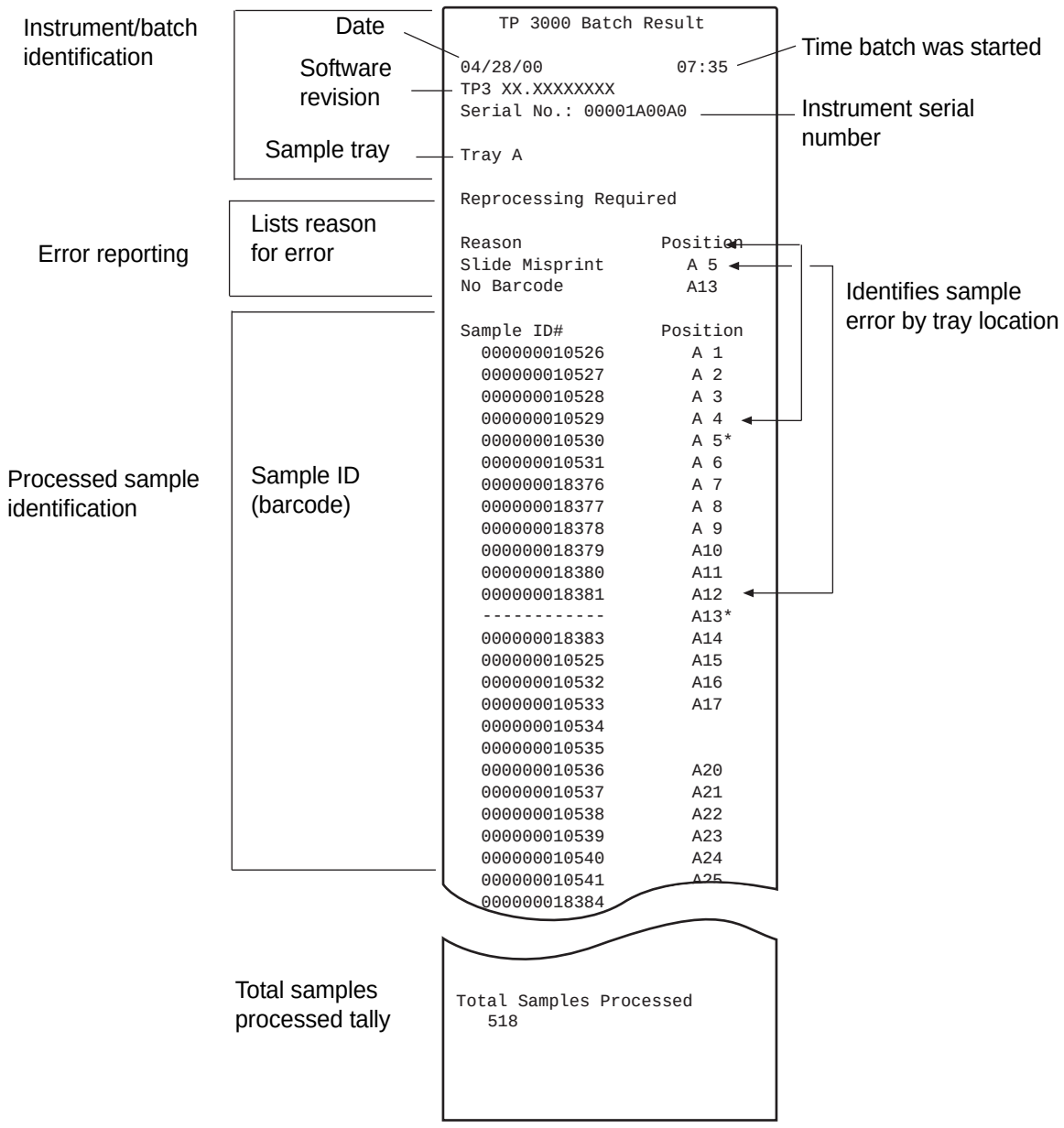
SECTION B

SAMPLE ERRORS

At the conclusion of batch processing sample errors are reported on the batch report. Sample errors occur when a sample vial is being processed. They are "sample specific" and usually only affect the sample vial being processed.

Sample errors are listed at the beginning of a batch report and can appear under two different headings: **Special Sample Status** or **Reprocessing Required**. The reason for the error and the vial position are listed. Additionally, the vial position is marked with an asterisk on the processed samples listing. **Reprocessing Required** vials require operator attention to address the type of error that occurred; all must be inserted into another batch for processing (a slide will not have been made).

Figure 7-1 Batch Report Example with Special Sample Status and Reprocessing Required



Sample Is Dilute *Special Sample Status*

This error message indicates the entire sample was utilized in preparing the slide. This is usually caused by a low concentration of cells in the sample. This message usually indicates a problem with the sample that was collected, rather than an issue with the instrument and its mechanisms. A slide is made from the sample vial.

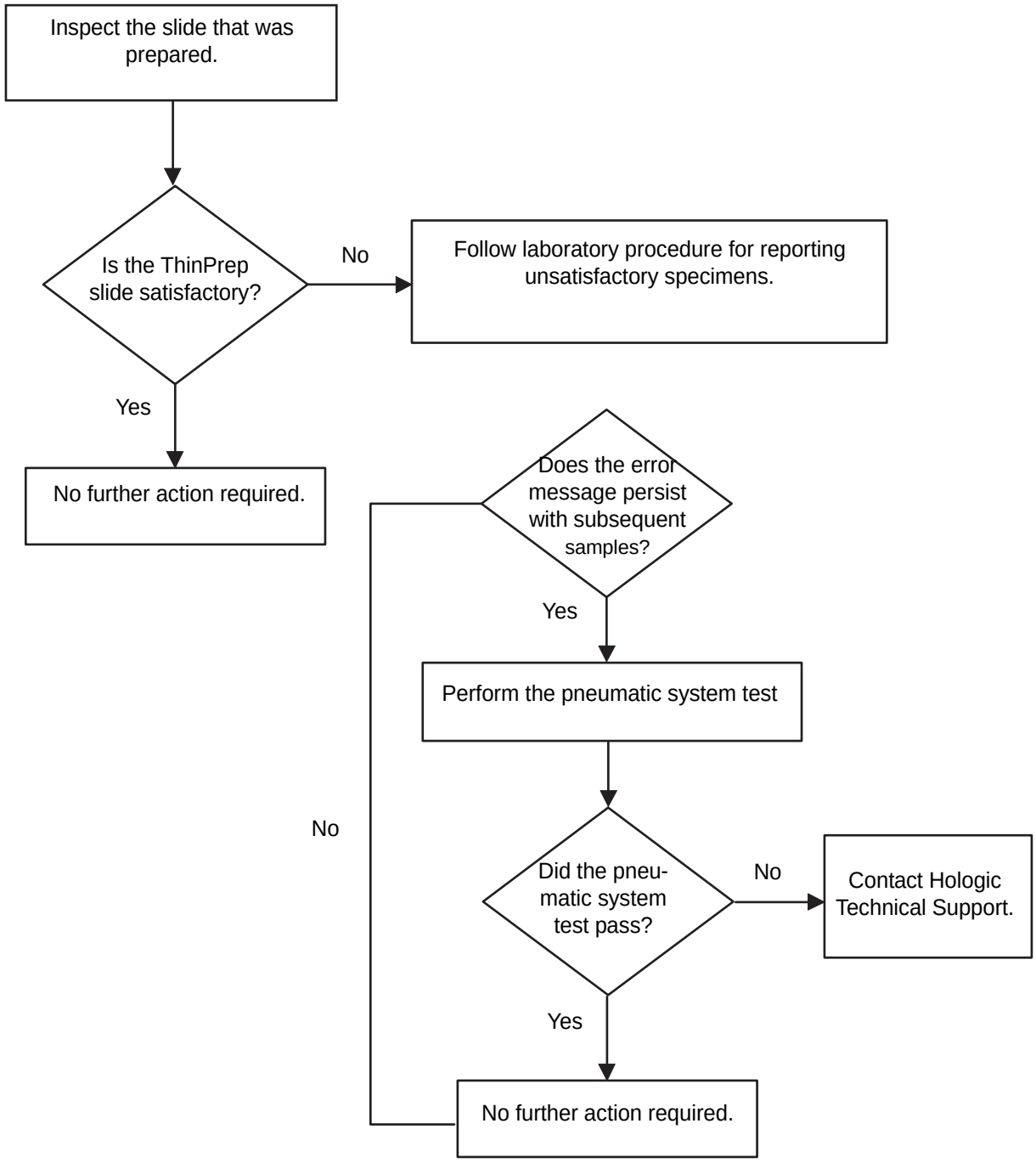
Possible Cause

- Low concentration of cells in the vial
- Pneumatic system failure

Corrective Action

1. If the slide is satisfactory for screening purposes, no further action is required.
2. If the slide is inadequate, follow laboratory procedure for reporting unsatisfactory specimens.
3. If the error persists on subsequent samples, perform pneumatic system testing. Refer to "PNEUMATIC SYSTEM TESTING" on page 6.13.

Sample Is Dilute *Special Sample Status*



Cap Tighten Failure *Reprocessing Required*

The sample vial cap cannot be tightened by the vial gripper. The sample is not processed. If three consecutive Cap Tighten Failure errors occur within a batch, the batch is terminated.

Any combination of three consecutive instances of Cap Tighten Failure error *and* Vial Cap Too Tight error (refer to page 7.26) will terminate the batch.

Possible Cause

- The plastic outer packaging of the vial was not removed.
- Vial labeling covers torque features.
- The vial cap is damaged.
- A mechanism fault

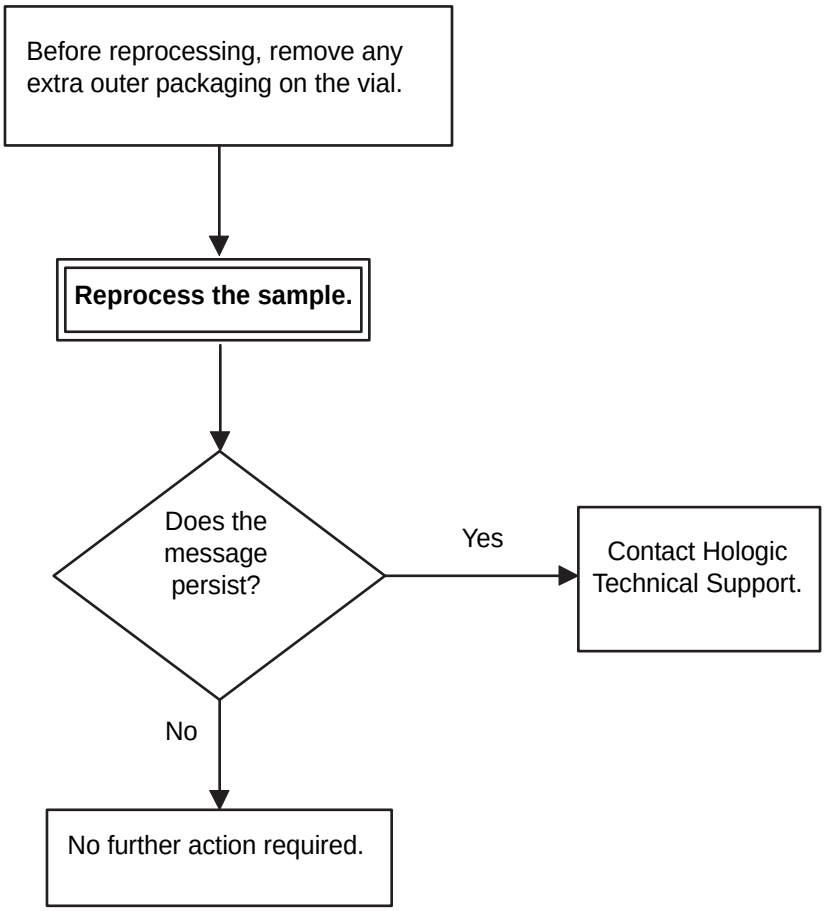
Corrective Action

1. The batch report indicates the position of the vial under the Reprocessing Required listing as Cap Tighten Failure.
2. Examine the vial cap and remove plastic outer packaging, if it is present. Examine the cap for defect or damage.
3. Reprocess the sample vial.
4. If the error persists with subsequent batches, contact Hologic Technical Support.

Preventative Action

When loading sample vial trays, ensure that all vials are unwrapped of their outer packaging and do not exhibit any obvious damage.

Cap Tighten Failure *Reprocessing Required*



Duplicate Barcode *Reprocessing Required*

The instrument has detected two sample vials in the batch with the same sample identification number (barcode). The sample with the duplicate identification number will not be processed. No slide is made from the vial bearing the duplicate barcode.

Possible Causes

- Duplicate barcode labels were inadvertently applied to different sample vials in the same batch.

Corrective Action

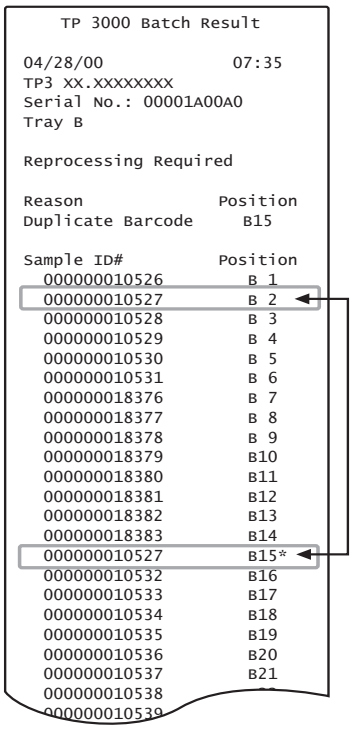
1. The batch report indicates the position of the sample vial under Reprocessing Required listing as Duplicate Barcode. Compare the barcode number of the flagged sample vial to the barcode numbers of the other sample vials processed.

Note: It is important that both vials with the identical sample ID be removed from the sample tray and marked with their tray position. The slide processed from the first incidence of this number is then associated with the first sample vial. (The instrument always processes samples vials in ascending order from position A1 to B40. The first occurrence of the identical sample ID number will always be at an earlier tray position and a slide will have been made.) The patient information must be checked and reconciled for both vials.

2. The second sample needs to be reprocessed, as no slide was made. Following the reconciliation of the patient information with the correct vials, apply a new barcode label to the second vial and insert it into a new batch to be processed.

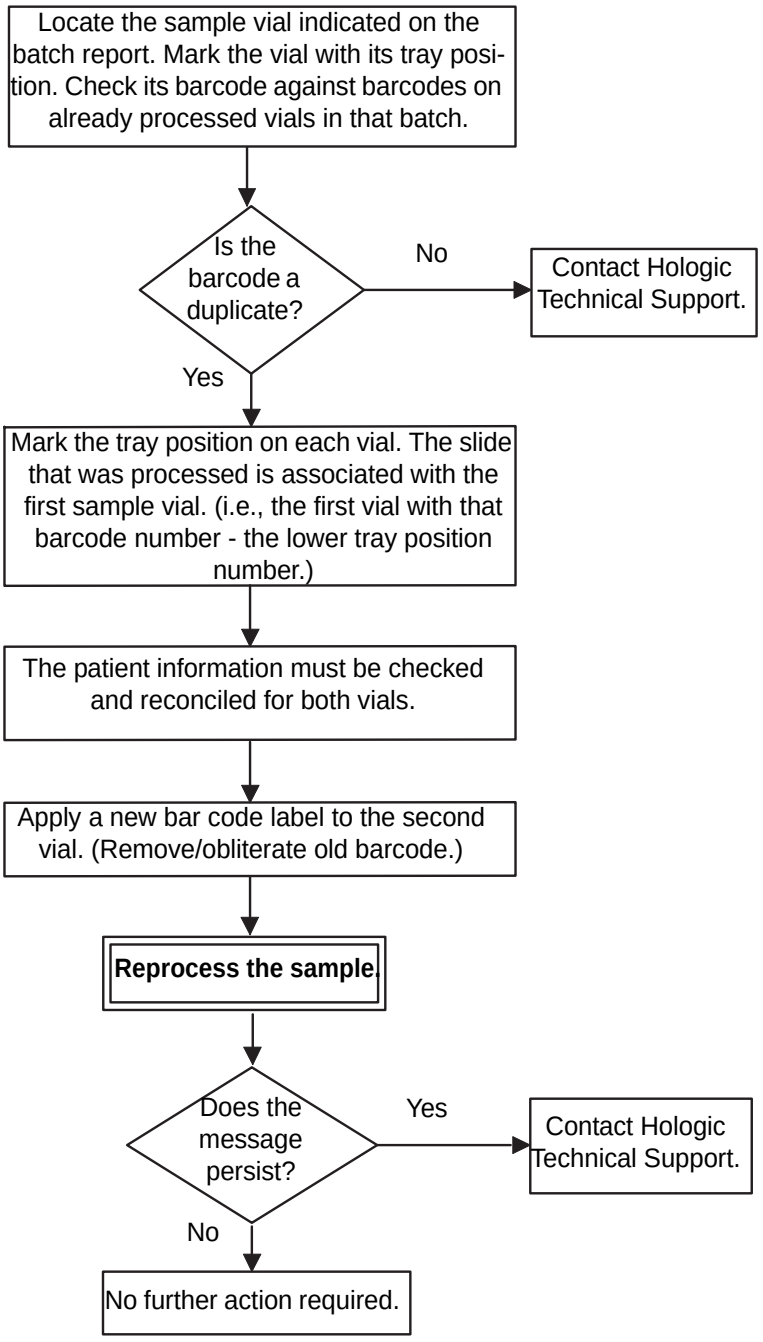
Note: Do not stack labels. Attempt to remove the old barcode label. If it cannot be removed, completely obliterate the barcode with a permanent marker or pen. Place the new barcode label elsewhere on the vial.

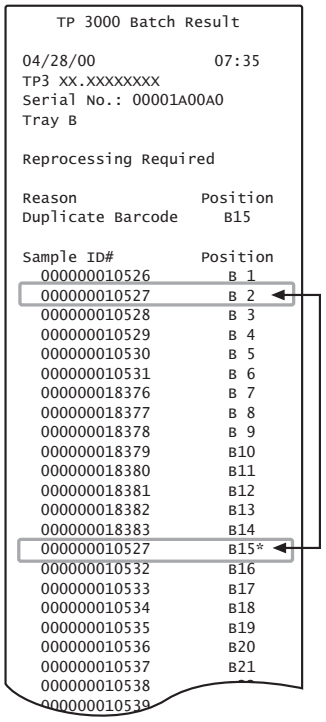
3. If this error persists with subsequent batches, contact Hologic Technical Support.



```
     TP 3000 Batch Result

04/28/00              07:35
TP3 XX.XXXXXXXX
Serial No.: 00001A00A0
Tray B

Reprocessing Required

Reason              Position
Duplicate Barcode      B15

Sample ID#          Position
  000000010526          B 1
  000000010527          B 2
  000000010528          B 3
  000000010529          B 4
  000000010530          B 5
  000000010531          B 6
  000000018376          B 7
  000000018377          B 8
  000000018378          B 9
  000000018379          B10
  000000018380          B11
  000000018381          B12
  000000018382          B13
  000000018383          B14
  000000010527          B15*
  000000010532          B16
  000000010533          B17
  000000010534          B18
  000000010535          B19
  000000010536          B20
  000000010537          B21
  000000010538
  000000010539
```

Duplicate Barcode *Reprocessing Required*





Filter Load Failure *Reprocessing Required*

A filter was not properly pressed on to the sample processing arm from the filter elevator. That filter is disposed of and a new filter is picked and presented. Three attempts are made on the same vial before the Filter Load Failure error occurs. The batch is canceled. The sample was not processed and a slide was not made.

Possible Cause

- The O-rings on the sample processing arm are not sufficiently lubricated.
- A mechanism fault has occurred.

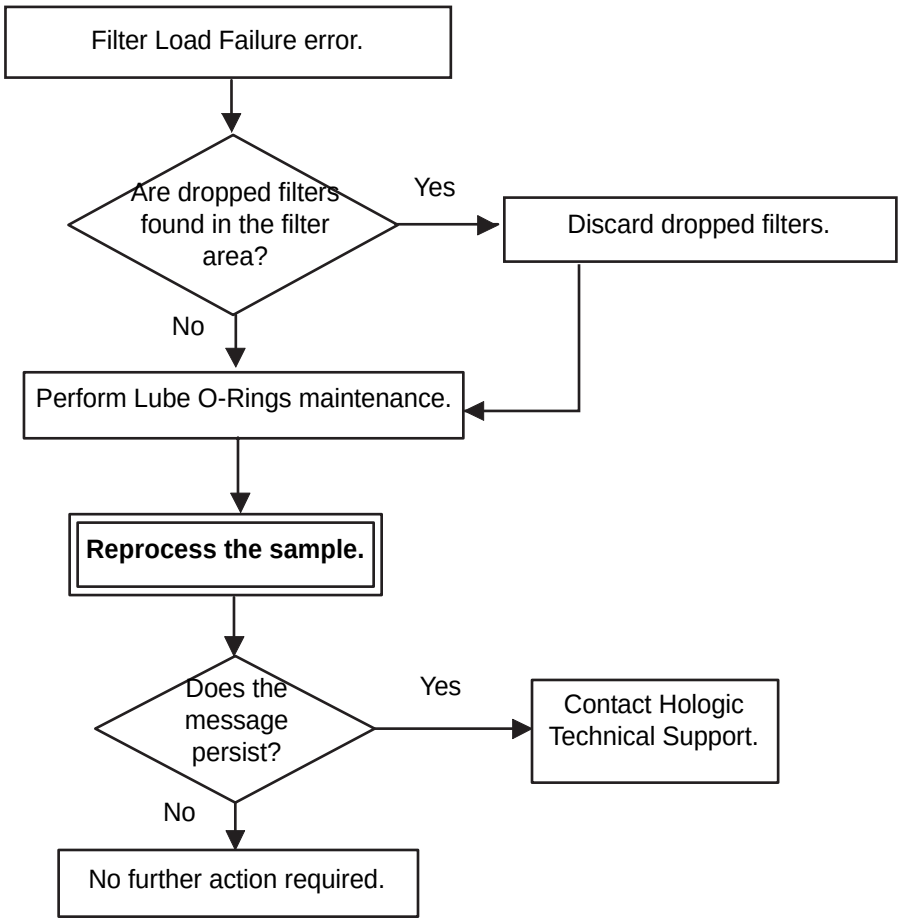
Corrective Action

1. The batch report indicates the position of the vial under the Reprocessing Required listing as Filter Load Failure.
2. Look to see if there is a dropped filter or other cause for interference in the filter area.
3. Perform the Lube O-Rings maintenance, taking care to lubricate the inner surface of the pneumatic test vial prior to testing. Refer to "LUBRICATING THE SAMPLE PROCESSING ARM O-RINGS" on page 6.10.
4. Reprocess the sample.
5. If the message persists with subsequent processing, contact Hologic Technical Support.

Preventative Action

Perform the Lube O-Rings maintenance daily or at the start of each shift. Perform the pneumatic test when prompted.

Filter Load Failure *Reprocessing Required*



Fixative Clog *Reprocessing Required*

A fixative clog developed, causing the batch to terminate. The sample must be reprocessed; no slide was made.

Possible Cause

- The instrument has been idle for an hour or more, enabling the fixative solution to form a clog in the spray nozzle.
- The fixative spray nozzle was not fully cleared by the previous maintenance.
- Pneumatic system failure

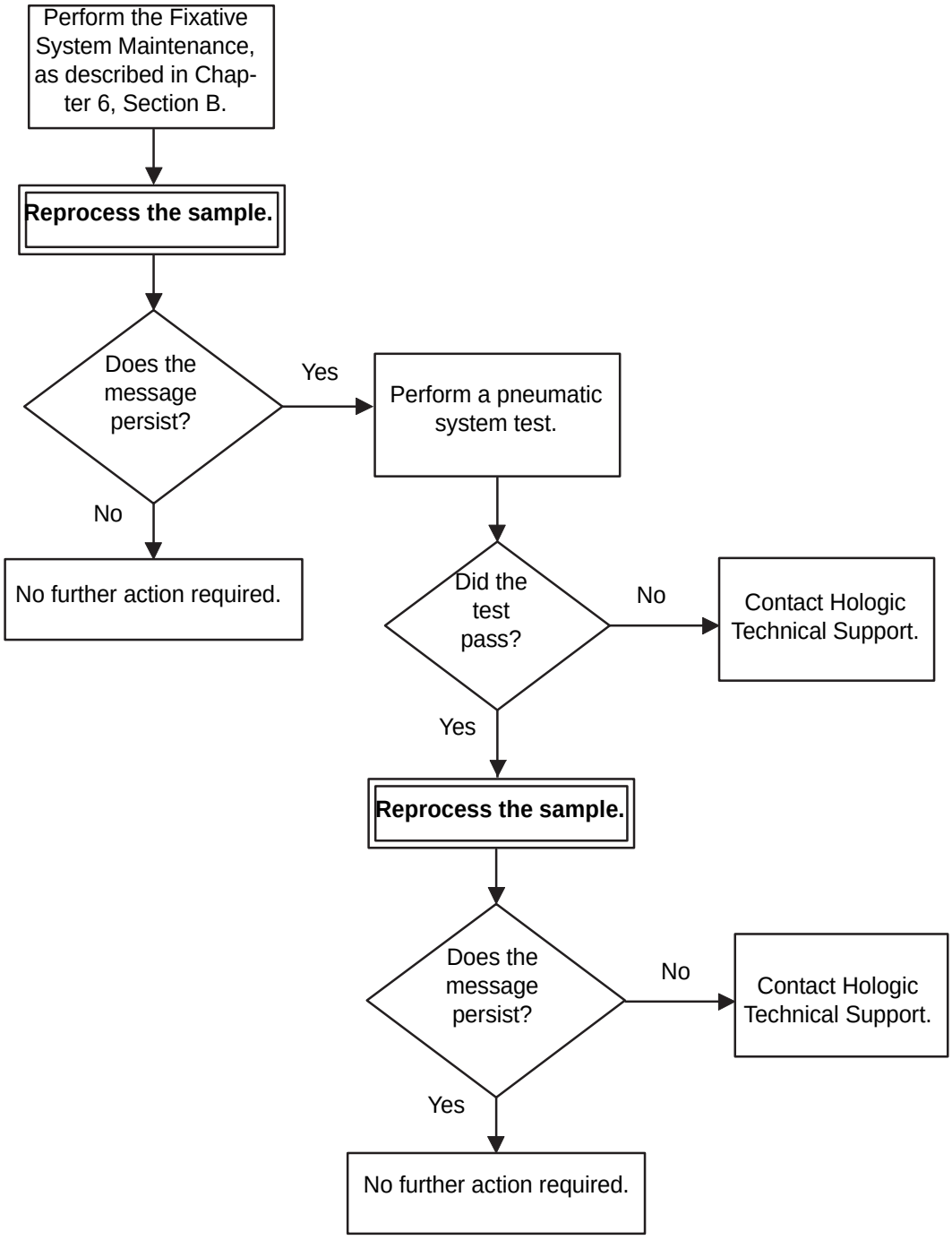
Corrective Action

1. Perform the fixative system preventative maintenance, as described in "FIXATIVE SYSTEM PREVENTATIVE MAINTENANCE" on page 6.5.
2. When the spray is flowing freely, reprocess the sample.
3. If the fixative maintenance display appears, even if the fixative seems to be flowing freely, perform a pneumatic system test.
4. If the pneumatic test passes, reprocess the sample.

Preventative Action

Always perform the fixative maintenance when prompted by the instrument.

Fixative Clog *Reprocessing Required*



Insufficient Vial Fluid *Reprocessing Required*

The vial does not contain enough sample fluid to properly process the sample. The sample was not processed and a slide was not made.

Possible Cause

- Previous testing with the sample vial may have reduced the volume of sample fluid in the vial below the minimum required.
- A displaced or missing cap liner may have caused fluid to leak out of the sample vial.
- A pneumatic system failure has occurred.

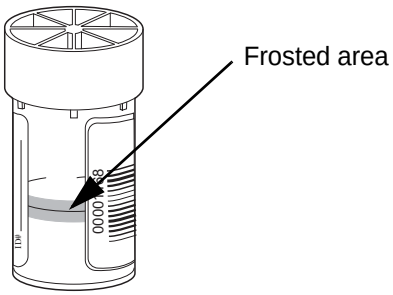
WARNING: Toxic Mixture
Flammable Liquid and Vapor

Corrective Action

1. The batch report indicates the position of the vial under the Reprocessing Required listing as Insufficient Vial Fluid. Check the fluid level in the vial.
2. Add additional PreservCyt Solution to the vial if fluid level is below the frosted area indicated on the vial. Do not fill beyond the frosted area.
3. Reprocess the sample vial.
4. If error recurs with the sample vial, perform the pneumatic system test. Refer to "PNEUMATIC SYSTEM TESTING" on page 6.13.

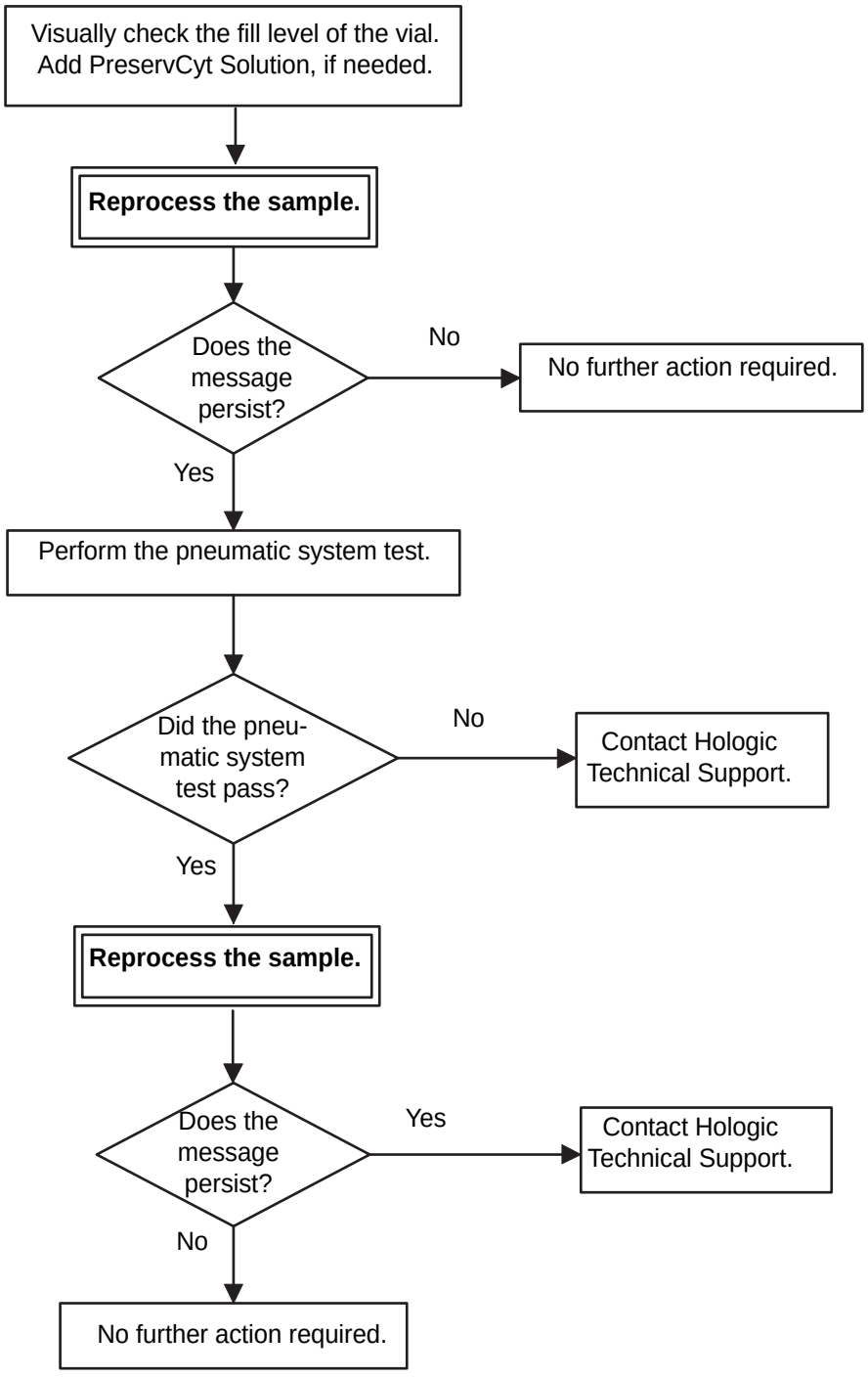
Preventative Action

Prior to sample processing, ensure that the sample fluid level is within the frosted area of the sample vial.



Insufficient Vial Fluid *Reprocessing Required*

WARNING: Toxic Mixture
Flammable Liquid and Vapor



No Barcode *Reprocessing Required*

The barcode scanner cannot scan the barcode information on the sample vial. The sample is not processed. If two consecutive No Barcode errors occur within a batch, the batch is terminated.

Possible Cause

- The barcode label is missing.
- The barcode label is not applied to the vial properly.
- The barcode label may be damaged.
- Wrong type of barcode was applied.

Corrective Action

1. The Batch Report indicates the position of the sample vial under the Reprocessing Required listing as No Barcode. Confirm that a barcode label is correctly applied to the sample vial.
2. If the barcode label is missing, place a label onto the vial as outlined in "Barcoded Sample Vials" on page 5.12. Be sure to review the patient information, it must agree with the sample ID. Reprocess the sample vial.
3. If a barcode label is present, check the condition of the label. A smudged, wrinkled or torn barcode label may not be scanned. Replace the label if this is the case. (Be sure to update the patient information with a matching label, as well.) Reprocess the sample vial.

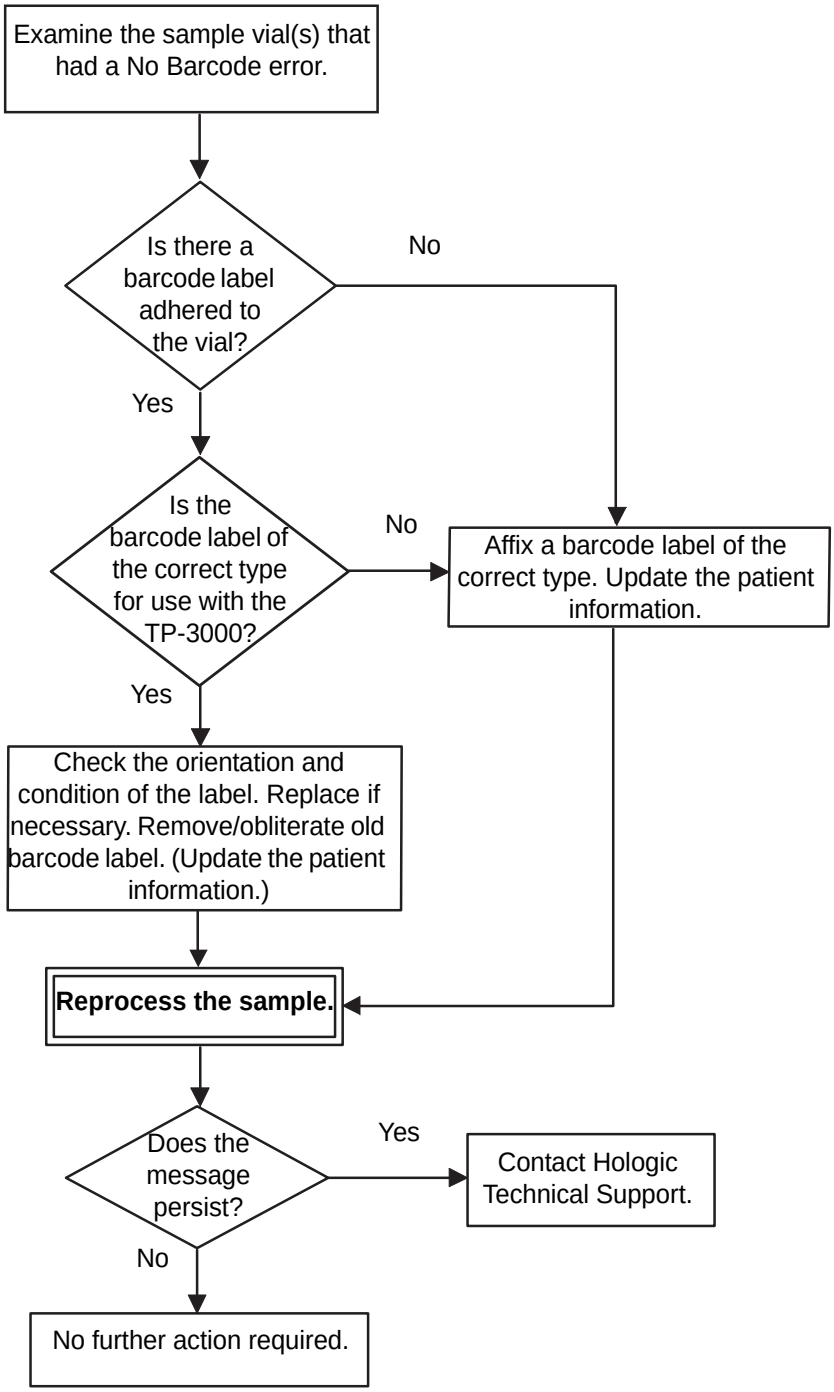
Note: Do not stack labels. Attempt to remove the old barcode label. If it cannot be removed, completely obliterate the barcode with a permanent marker or pen. Place the new barcode label elsewhere on the vial.

4. Confirm that a bar code label for use with the ThinPrep 3000 processor is applied to the sample vial. Apply a correct type of bar code label and update the patient information with a matching label.
5. If the barcode label is not missing or damaged, attempt to reprocess the sample vial as is.
6. If the No Barcode error persists with subsequent batches, contact Hologic Technical Support.

Preventative Action

Before the vial is placed into the sample vial tray, confirm that a barcode label is properly positioned on the vial. Follow the recommended label application protocol in "Barcoded Sample Vials" on page 5.12.

No Barcode *Reprocessing Required*



Out of Consumables *Reprocessing Required*

Required consumable item(s) are not in place to process sample vials, consequently the sample vial cannot be processed.

If the instrument detects that there are not enough consumable items to complete processing a sample, the "Items Must Be Addressed" message screen appears, listing the consumables required for further processing.

You may follow the screen prompts and load supplies into the instrument or you may press **Cancel** to end the batch. The batch terminates and the last sample in process will not have a slide made. It is listed on the batch report as Out of Consumables.

Possible Cause

- Instrument is out of ThinPrep Pap test filters.
- Instrument is out of slides, or cannot detect slide cartridges.
- Staining racks are full.

Corrective Action

1. Check and load items as prompted by the message screen.

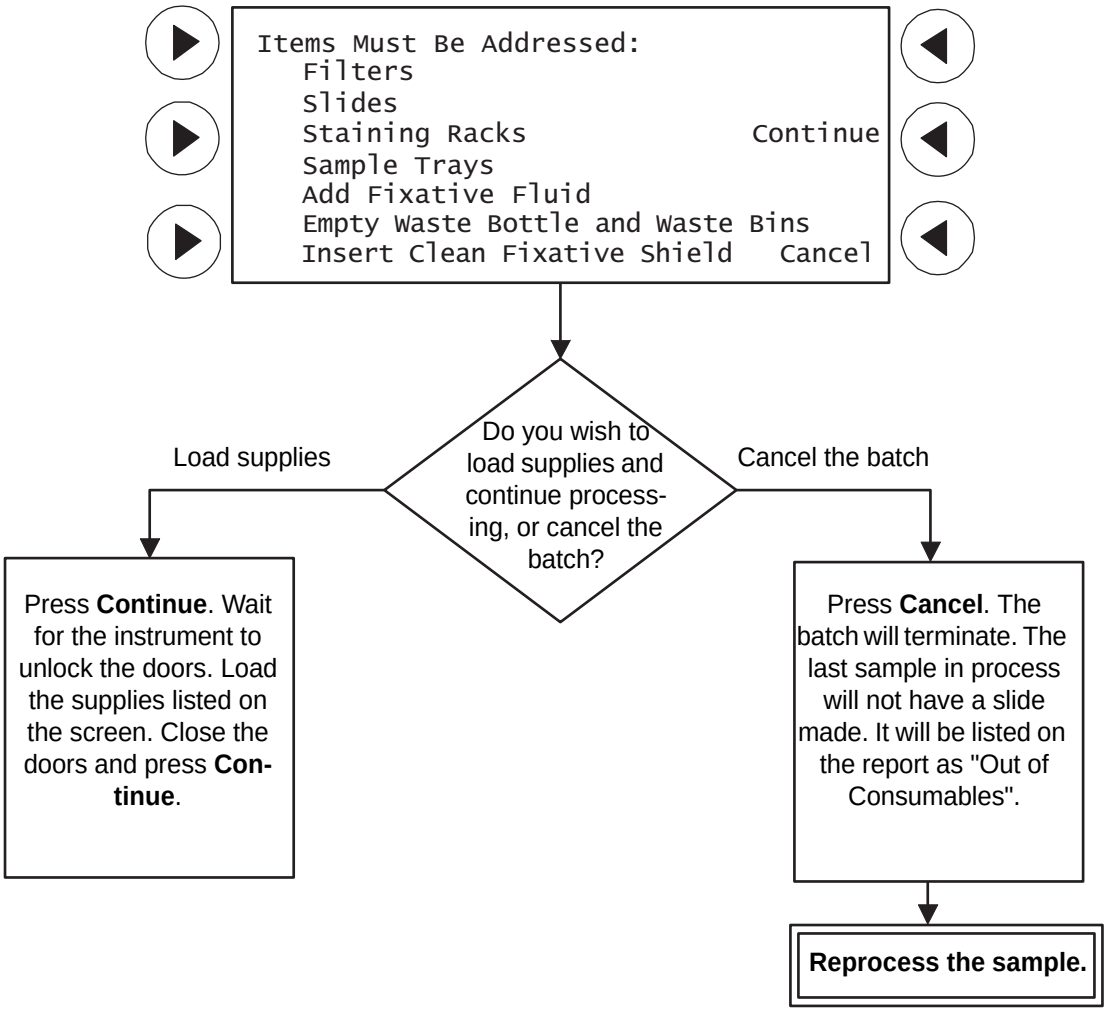
Preventative Action

Items appear on the message screen after **Start Batch** is selected. Follow the message screen prompts to load necessary items.

Out of Consumables *Reprocessing Required*

The batch halts processing and the message screen shown below appears.

Note: Only items needing attention will be listed. The display may show some or all of the items listed below.



Pneumatic Failure *Reprocessing Required*

A pneumatic error was detected while a sample was being processed. The sample was not processed and a slide was not made.

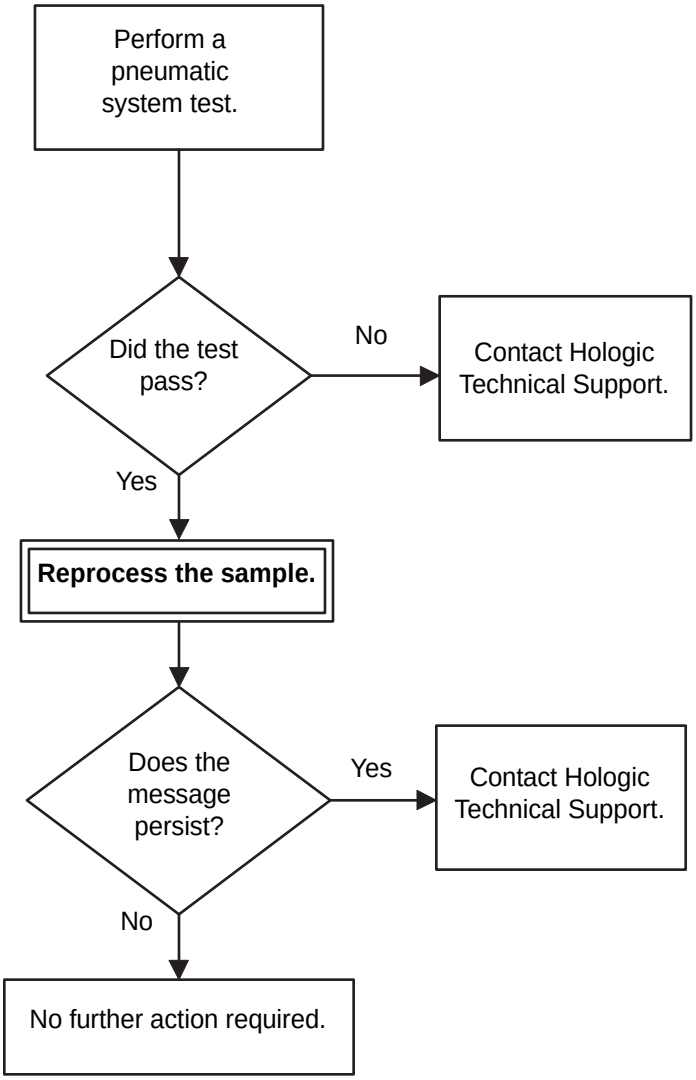
Possible Cause

- The ThinPrep Pap test filter is damaged.
- Pneumatic pressure is out of range.
- Failure of instrument mechanisms.

Corrective Action

1. Perform a pneumatic system test. Refer to "PNEUMATIC SYSTEM TESTING" on page 6.13.
2. If the test passes, reprocess the sample.
3. If the pneumatic test fails, or if the message persists with subsequent processing, contact Hologic Technical Support.

Pneumatic Failure *Reprocessing Required*



Slide Misprint *Reprocessing Required*

The slide ID reader was not able to confirm that the patient identification number from the barcode label was properly printed onto the microscope slide. The sample is not processed. If two consecutive misprint errors occur within a batch, the batch is terminated.

Possible Cause

- The printer ribbon needs replacing.
- The slide printer did not correctly or legibly print the barcode number onto the frosted end of the microscope slide.
- The printer ribbon cartridge was installed improperly.
- The microscope slide(s) may have a defect on the frosted area, such as a chip, void or dark spot.
- The microscope slides are not loaded correctly into the Slide Cartridge.
- The thumbscrew on the slide printer chassis is not secured.
- There is a problem with the slide print mechanism or slide ID reader.

Corrective Action

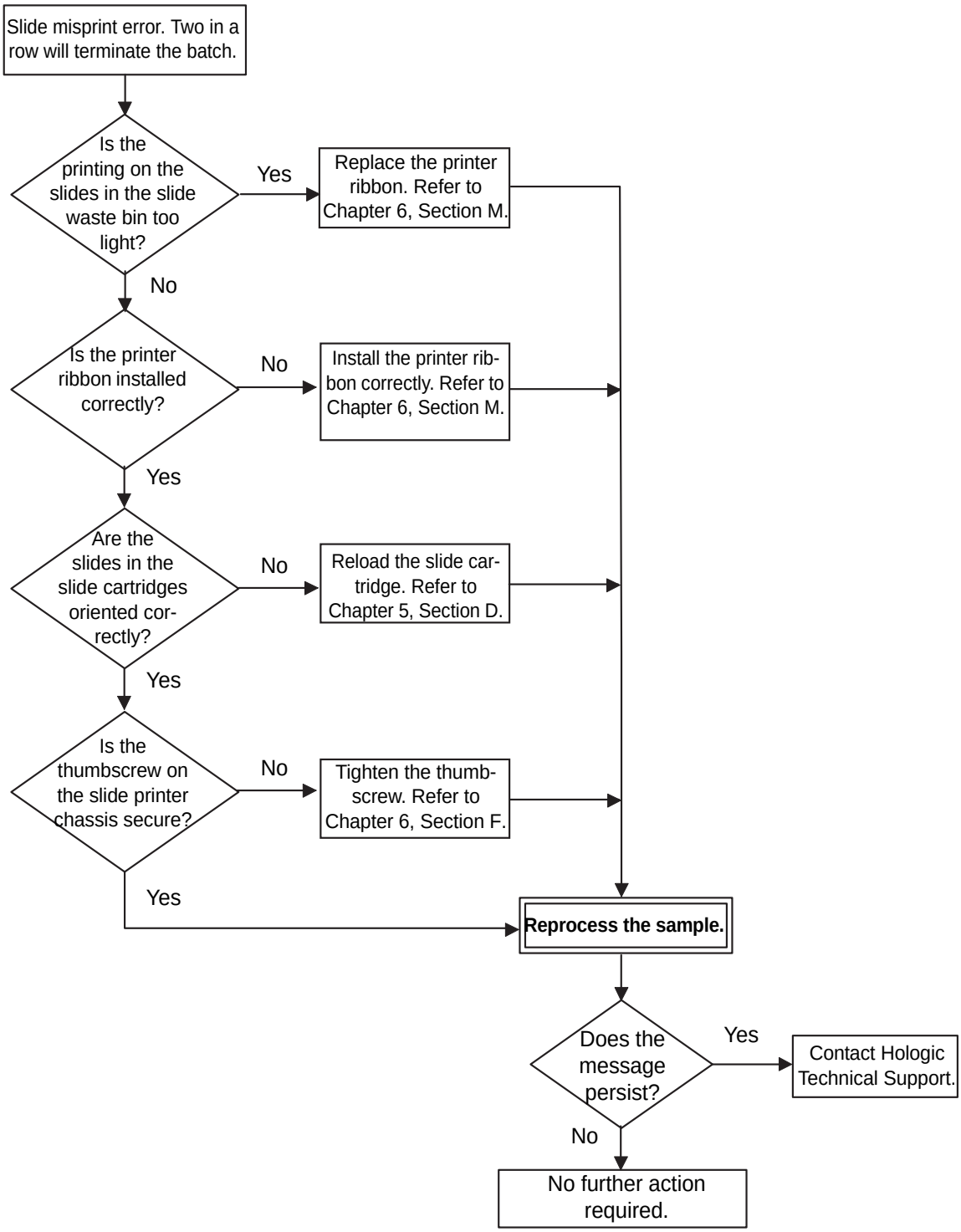
WARNING: Sharp Edges
Glass

1. The Batch report indicates the position of the vial under the Reprocessing Required listing as Slide Misprint. Inspect the slide(s) in the slide waste bin. If the printed text is too light, the ribbon should be changed. See "REPLACING THE SLIDE PRINTER RIBBON" on page 6.34. Reprocess the sample vial.
2. If the slide(s) in the waste bin appear to be marred or defective, check the slide cartridges to determine if other slides are defective. If so, replenish the cartridge with new slides. While the cartridge is open, confirm that the slides are oriented correctly. Refer to "ThinPrep Microscope Slides and Slide Cartridges" on page 5.7.
3. Improper installation of the printer ribbon cartridge can deposit ink on the slide surface and cause a "Slide Misprint" error message. Refer to "REPLACING THE SLIDE PRINTER RIBBON" on page 6.34 for installing a printer ribbon cartridge.
4. Confirm that the thumbscrew on the slide printer chassis is tightened. Refer to "CLEANING THE SLIDE PATH" on page 6.17, cleaning the slide path.
5. Reprocess the sample vial.
6. If the error persists with subsequent batches, contact Hologic Technical Support.

Preventative Action

Inspect the quality of the printed text on the slides from time to time. Change the printer ribbon cartridge when the text becomes too light.

Slide Misprint *Reprocessing Required*



Too Much Vial Fluid *Reprocessing Required*

The vial has too much sample fluid to properly process a sample. The sample was not processed and a slide was not made.

Possible Cause

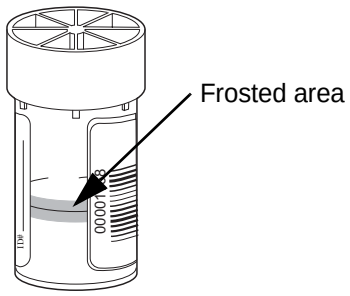
- There is too much fluid in the sample vial for the instrument to process a ThinPrep slide.
- Mechanism or pneumatic system fault.

Corrective Action

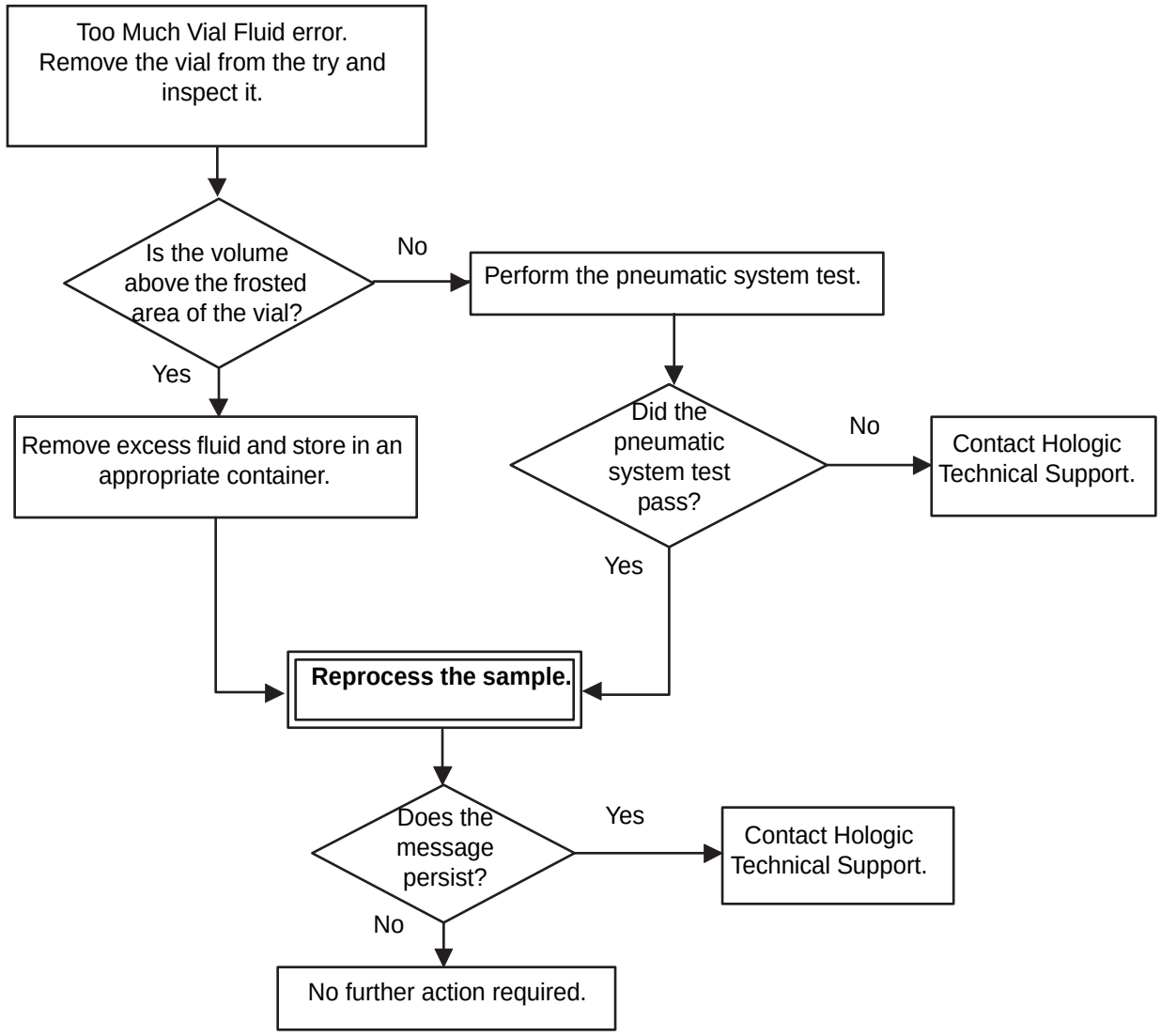
1. The Batch Report indicates the position of the vial under the Reprocessing Required listing as Too Much Vial Fluid. Check the sample.
   - If the fluid level is above the frosted area of the vial remove excess fluid (save it in an appropriate container) and reprocess.
2. Perform the pneumatic system test. Refer to "PNEUMATIC SYSTEM TESTING" on page 6.13. If the test passes, reprocess the sample.
3. If the pneumatic test fails, or if the message persists with subsequent processing, contact Hologic Technical Support.

Preventative Action

If PreservCyt Solution is added to a sample vial, ensure that the fluid does not exceed the maximum level, which is indicated by the frosted area of the vial.



Too Much Vial Fluid *Reprocessing Required*



Vial Cap Too Tight *Reprocessing Required*

The instrument cannot remove the cap from the sample vial. The sample vial was not processed and a slide was not made.

Possible Cause

- The cap is screwed onto the vial too tightly.
- A mechanism fault inhibits the removal of the sample vial cap.

Corrective Action

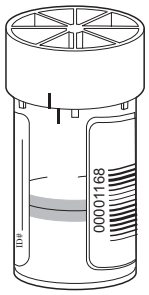
1. The batch report indicates the position of the vial under the Reprocessing Required listing as Vial Cap Too Tight.
2. Before reprocessing, loosen the cap. Tighten again and align the mark on the cap with the line on the vial.
3. Reprocess the sample vial.
4. If the error persists with subsequent batches, contact Hologic Technical Support.

Preventative Action

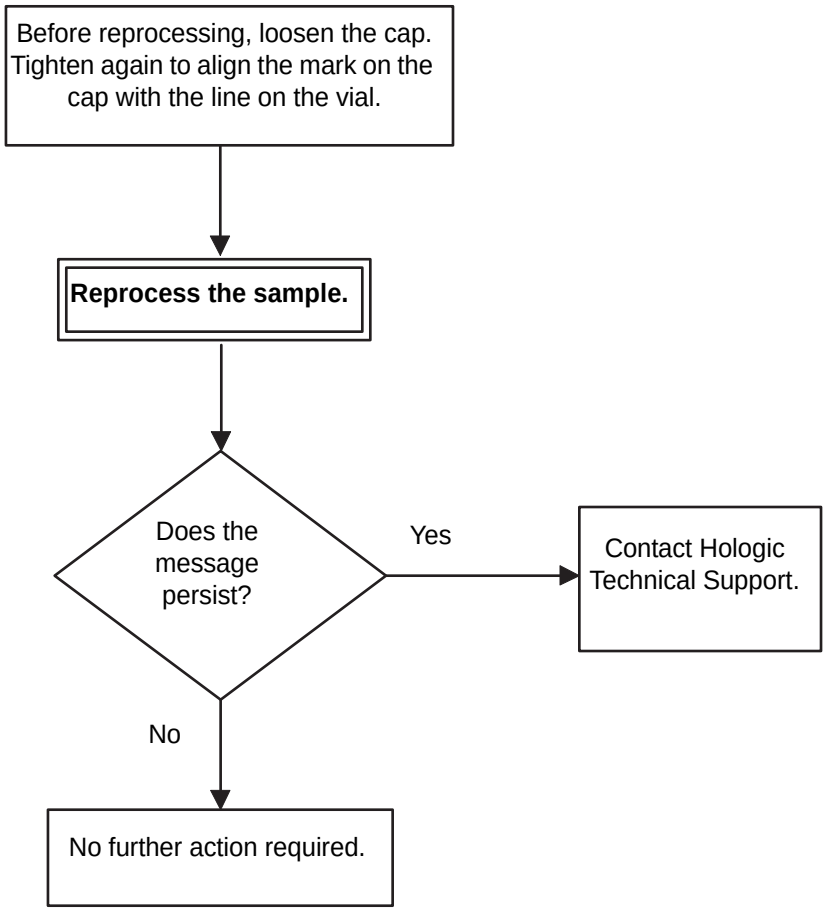
Avoid overtightening the cap onto the sample vial.

Provide the ThinPrep Pap Test Quick Reference Guide sampling instruction sheet to the physician or clinic.

Line on cap and line on vial should meet or slightly overlap. If the cap on the vial does not have a line, ensure the cap is tightened securely.



Vial Cap Too Tight *Reprocessing Required*



Waste System Failure *Reprocessing Required*

The waste evacuation system is not functioning properly. The liquid waste cannot be removed during sample processing. The sample cannot be processed. A slide was not made.

Possible Cause

- The waste bottle is full.
- Damaged or kinked pinch valve tubing
- Tubing connected incorrectly
- Pneumatic system failure
- Damaged ThinPrep Pap test filter

Corrective Action

1. Check the waste bottle fluid level. Empty the waste bottle if fluid is above the maximum level line.
2. Check the pinch valve tubing connection. Reconnect the tubing if it is disconnected, or connected to the wrong fitting. (Refer to "PINCH VALVE TUBING REPLACEMENT" on page 6.26.) Replace tubing if it is damaged.
3. Contact Hologic Technical Support if the error persists.

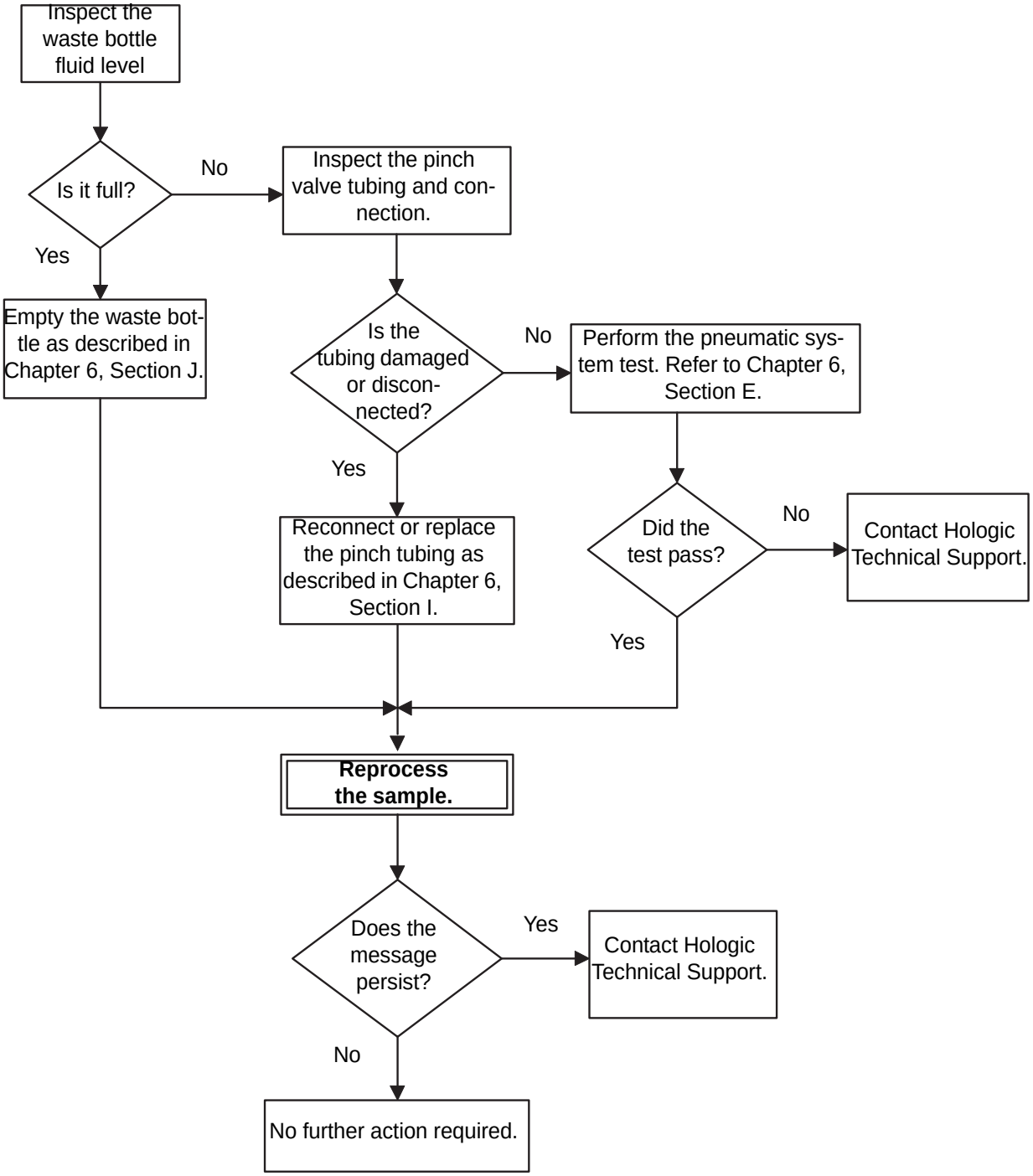
Preventative Action

Empty the waste bottle when prompted to do so by the instrument. Refer to "WASTE SYSTEM MAINTENANCE" on page 6.28.

Replace the pinch valve tubing as recommended in "PINCH VALVE TUBING REPLACEMENT" on page 6.26.

Perform the pneumatic system testing on a weekly basis as outlined in "PNEUMATIC SYSTEM TESTING" on page 6.13.

Waste System Failure *Reprocessing Required*

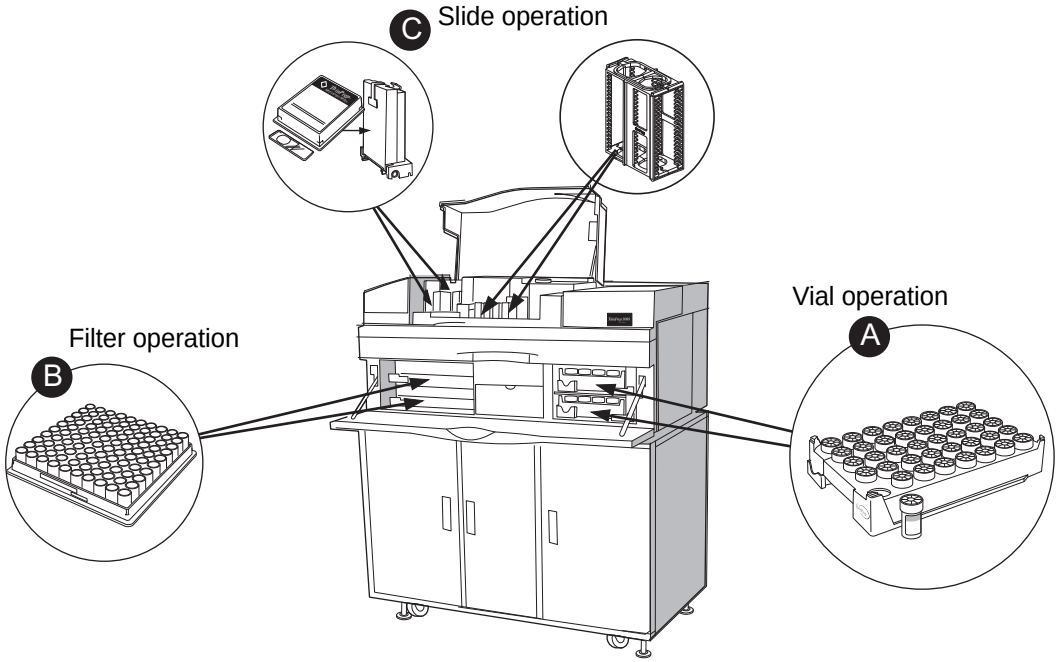


SECTION C

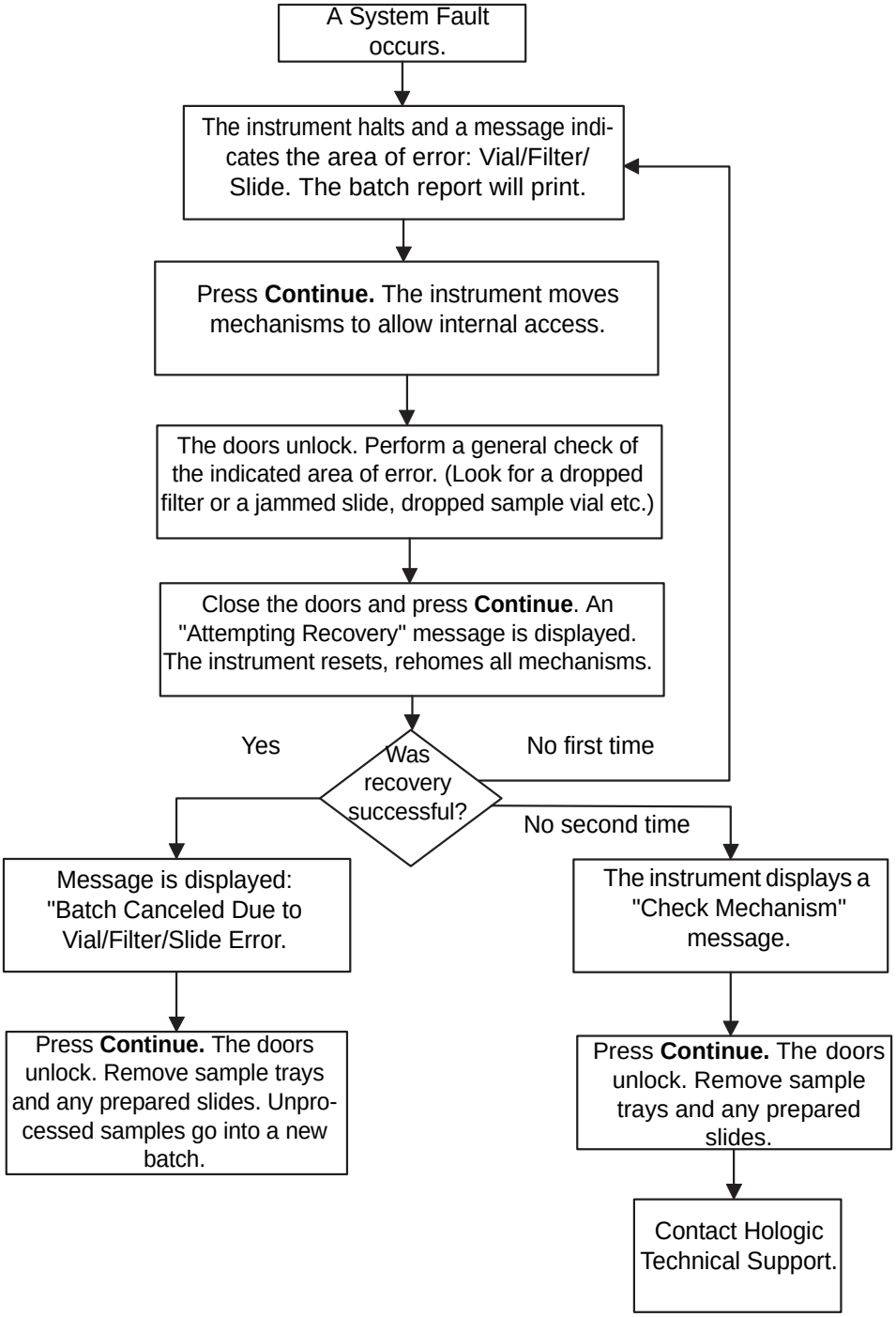
SYSTEM FAULT ERRORS — Reprocessing Required

System fault errors indicate a mechanical malfunction has occurred within the instrument while handling a consumable item, during sample processing, or during system self test. The sample is not processed if the fault occurs during batch processing. The instrument also stops processing the remainder of the batch.

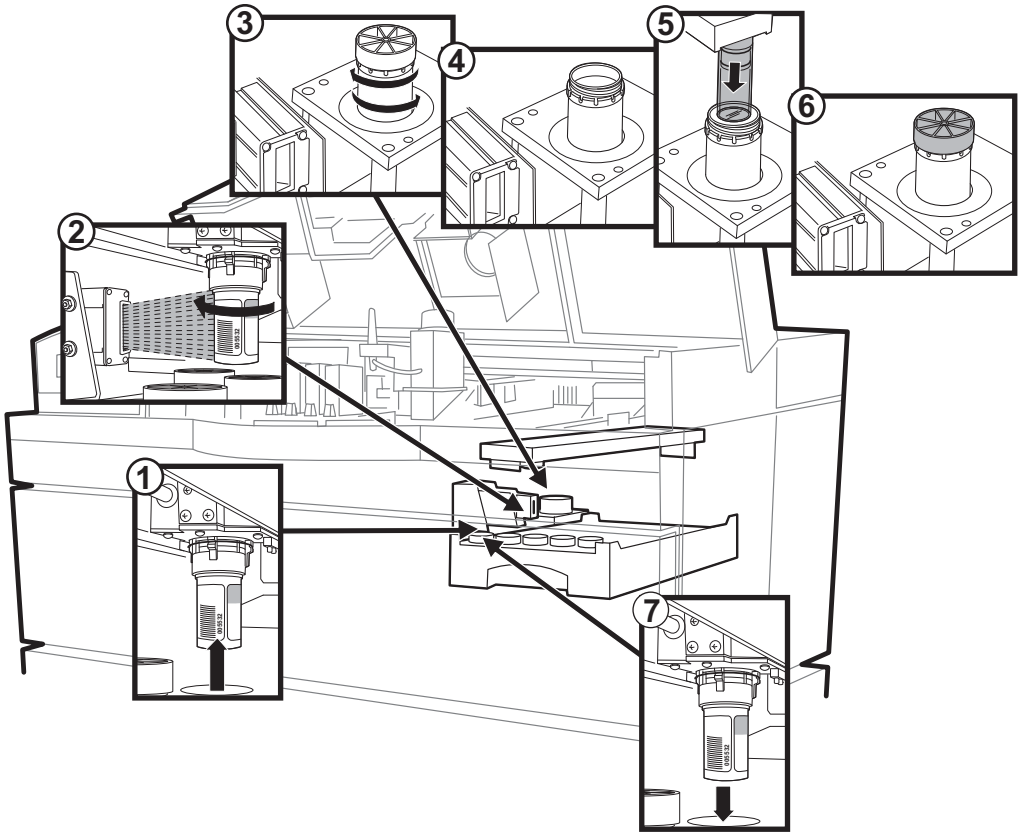
A message will appear on the display, indicating the area of the error: vial operation, filter operation or slide operation. Many of these conditions may be cleared by the operator and are described on the following pages.



System Fault Recovery Overview



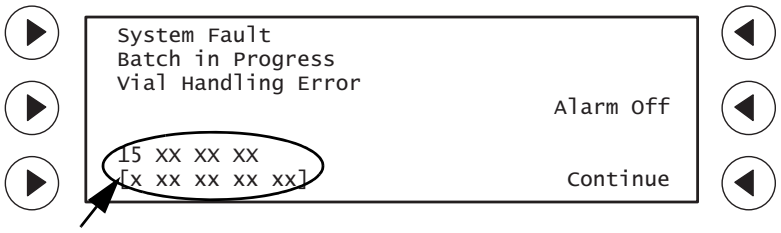
Vial Handling Operation



1. The sample vial is picked from the tray.
2. The barcode is scanned and read.
3. The sample vial is delivered to the sample processing station and the sample is dispersed by spinning the vial.
4. The vial is uncapped.
5. The filter is introduced for cell collection.
6. The vial is recapped.
7. The sample vial is returned to the sample tray.

Vial handling system fault

A system fault involving sample vial processing or transport will terminate processing and the following screen will be displayed:



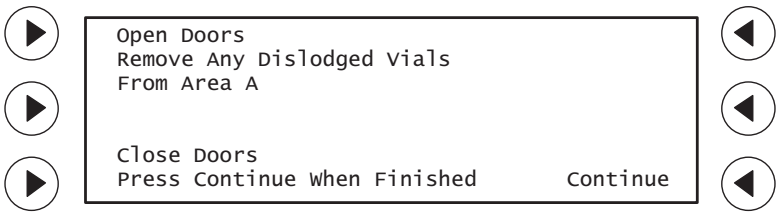
Error/sample status codes (record for Hologic Technical Support)

Possible Cause

- Labels applied improperly to the sample vial
- A foreign object is in the sample vial.
- Barcode scanning problem or error
- Damaged sample vial
- Mechanism fault

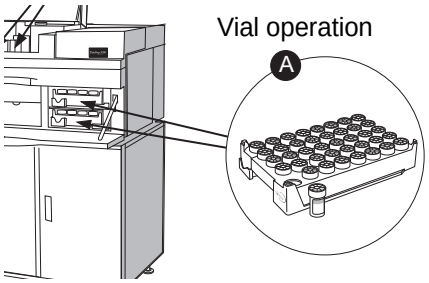
Corrective Action

1. (If desired, the audible beep can be stopped by pressing **Alarm Off**.) Press **Continue**. The following screen displays:



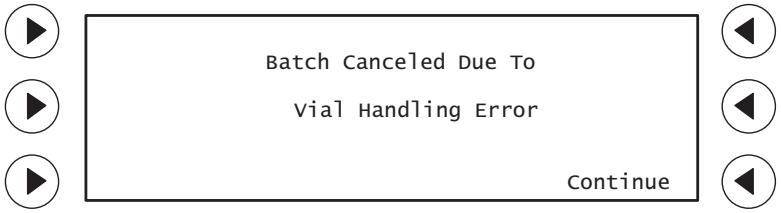
WARNING: Sharp Edges & Hot Surfaces

2. Open the front door when it unlocks.
3. Remove the sample vial trays and look in the vial bay (Area A) to see if there is a dropped sample vial or a vial stuck in the sample processing station. Retrieve the vial and cap for reprocessing.

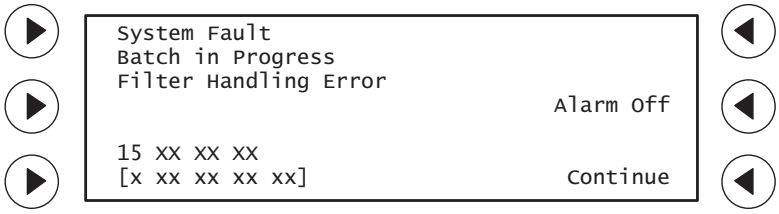


Refer to "Barcoded Sample Vials" on page 5.12 for sample vial label application guidelines.

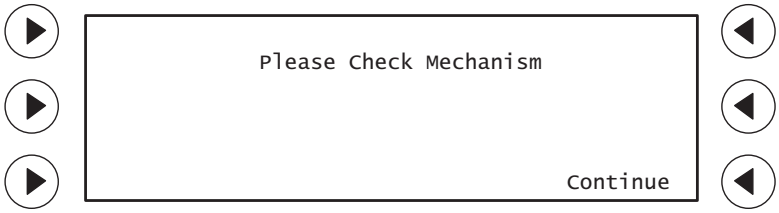
4. Check the condition of the sample vial(s) which caused the system fault. (The sample(s) will be flagged with an asterisk on the batch report, and described as a system fault error.)
   - Check that the label(s) is applied properly and does not impede movement of the vial into and out of the vial tray.
   - See if the barcode label is damaged, or defective, which might cause a scanner error.
   - Confirm that the vial does not include any foreign matter (such as a piece of the collection device, a piece of cap liner, a piece of label, etc.). Remove the object (with tweezers, for example) and reprocess the sample.
   - Inspect the vial for damage. If the cap is defective, discard it and replace it with a new cap from an unused PreservCyt vial. Reprocess the sample.
5. Replace the sample trays, close the door(s) and press **Continue**. The instrument will attempt recovery.
6. If your actions cleared the problem, the following screen appears:



7. Press **Continue**. The instrument will return to the System Ready screen. Remove staining racks and sample trays. Place unprocessed samples into a new batch.
8. If the instrument diagnoses that there is still an error state, the System Fault screen will display.



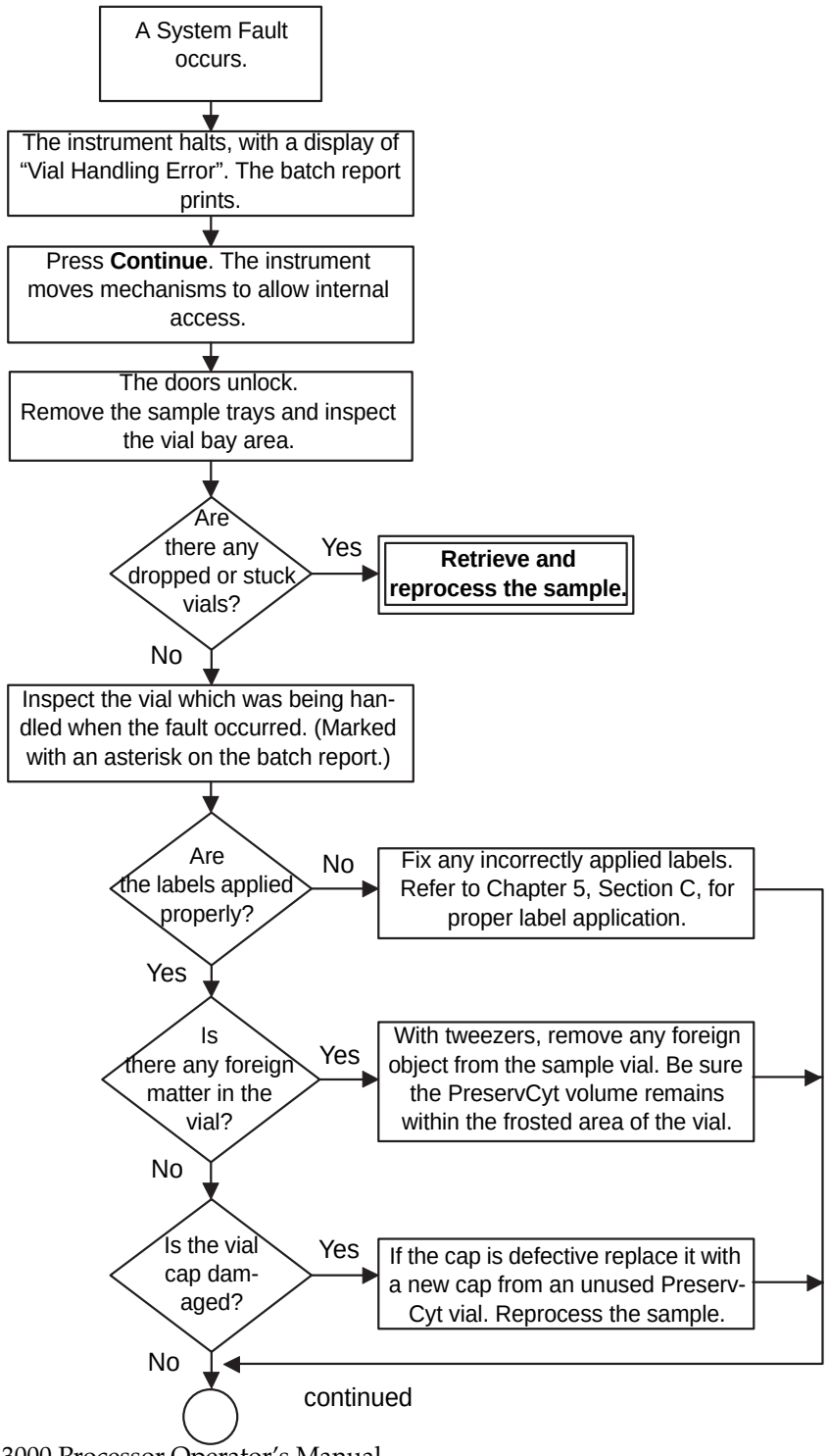
Repeat steps 1 through 7, above, to try to clear any obvious mechanical jams or interference. If the system does not recover, the following screen is displayed:



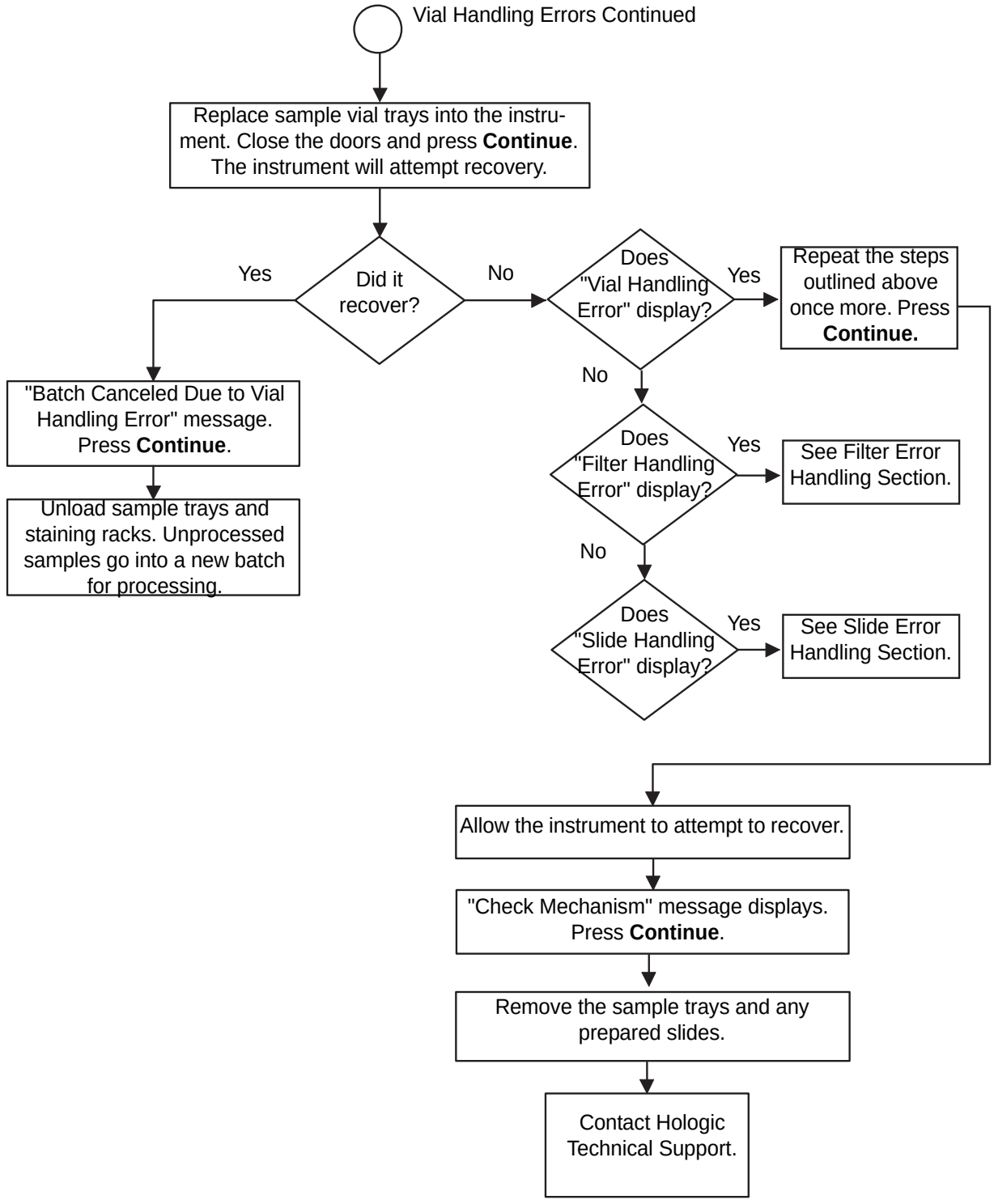
Any mechanical faults should be addressed by Hologic Technical Support. If errors recur, or do not appear as described here, contact Hologic Technical Support.

Vial Handling System Fault Recovery

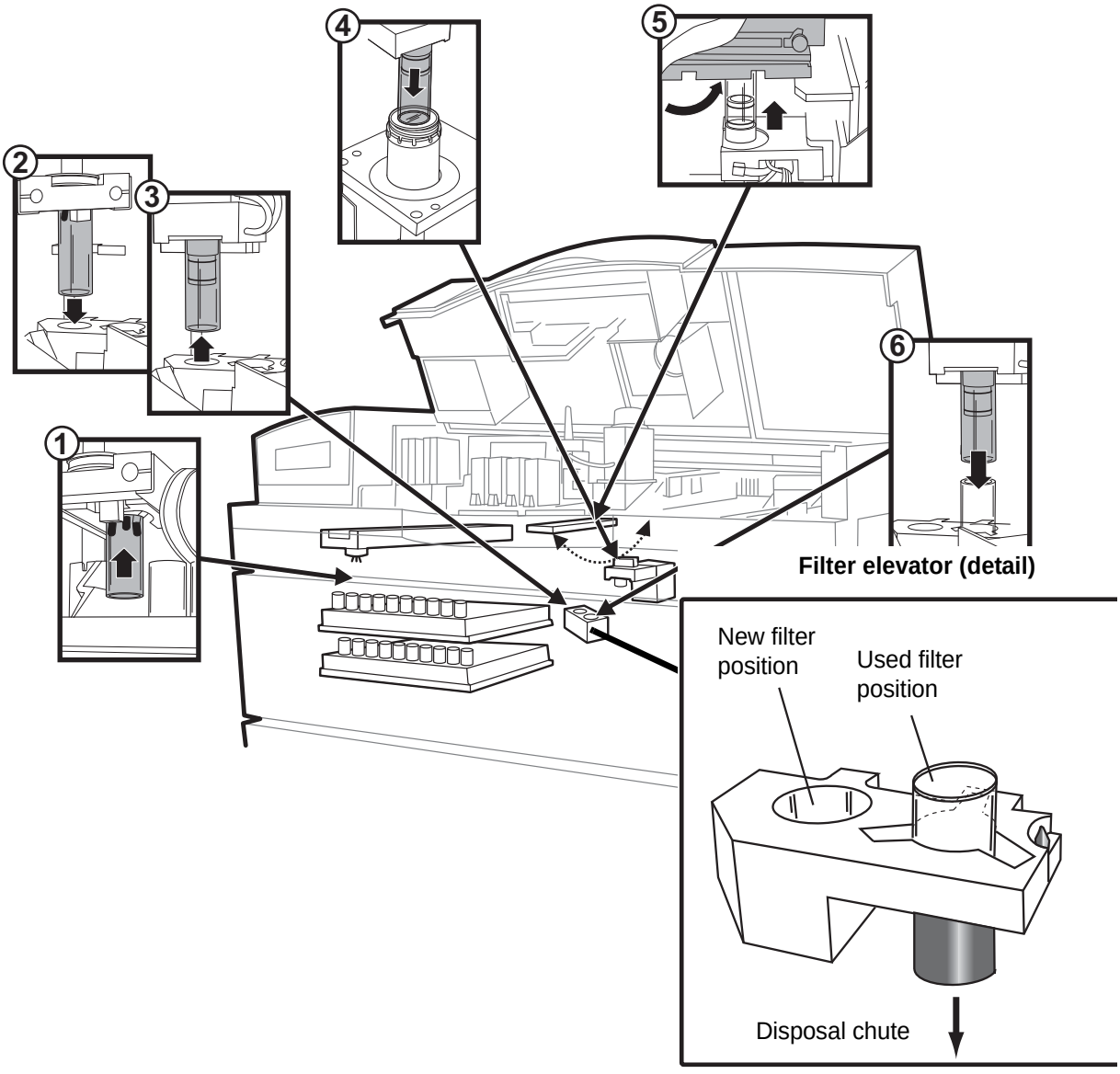
WARNING: Sharp Edges
Hot Surfaces



Vial Handling System Fault Recovery (continued)



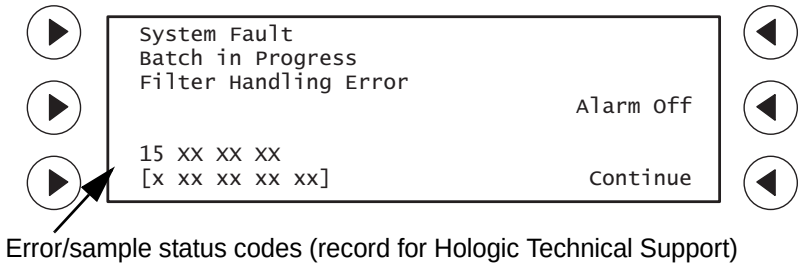
Filter Handling Operations



1. A ThinPrep Pap test filter is picked from the tray.
2. The filter is delivered to the filter elevator.
3. The sample processing arm retrieves the filter.
4. The filter is brought to the sample processing station and introduced to the prepared sample.
5. The sample processing arm rotates and precisely meets with the slide cell transfer arm, bearing a slide. Cell transfer occurs.
6. The used filter is returned to the filter elevator for disposal.

Filter handling system fault

If the instrument detects an error due to a filter operation malfunction, processing will halt and the following screen will be displayed:

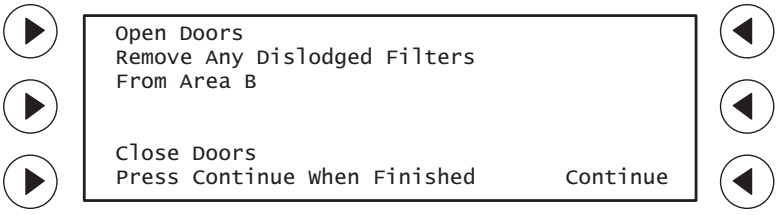


Possible Cause

- Error finding, transporting or disposing of filter
- Filter dropped
- A non-gynecological filter was detected. (Error code 16 13 42 30)
- Filter stuck on processing arm
- Filter stuck in filter tray
- Mechanism fault

Operator Corrective Action

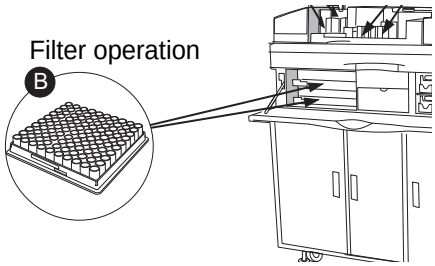
1. If desired, the audible beep can be stopped by pressing **Alarm Off**. Press **Continue**. The following screen is displayed.



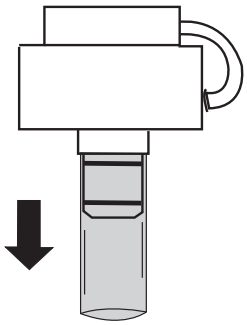
2. Open the front door when it unlocks.

WARNING: Sharp Edges
Hot Surfaces

3. Remove the filter trays and look in the filter bay (Area B) to see if there are any filters lying in or near the filter tray area. Discard any misplaced filters.



Look at the sample processing arm, to see if a filter is stuck or was not pushed all the way on. Remove it.

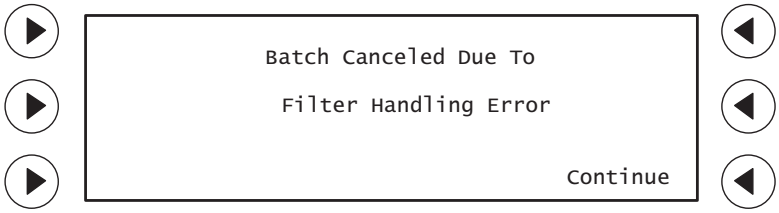


Look to see if a filter is stuck in the **new** filter position of the filter elevator. Remove it. (See illustration to the right on page 7.38.)

If the error code is specifically 16 13 42 30, a non-gynecological filter was detected in the system. Remove the filter from the **new** filter position of the filter elevator and verify that Gyn ThinPrep Pap test filters (clear) are loaded in the system.

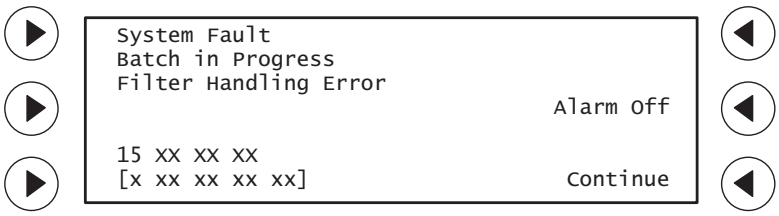
Make sure the filter waste box is reasonably empty and that the used filters have room to drop in when they are disposed of.

4. Replace the filter trays, close the door(s) and press **Continue**. The instrument will attempt recovery.
5. If your actions cleared the problem, the following screen appears:

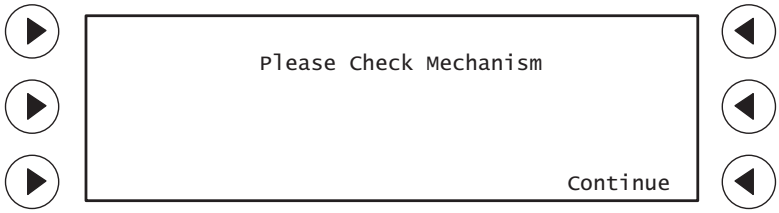


6. Press **Continue**. The instrument will return to the System Ready screen. Remove slides and sample trays. Place unprocessed samples into a new batch.

7. If the instrument diagnoses that there is still an error state, the System Fault screen will display.



Repeat steps 1 through 6, above, to try to clear any obvious mechanical jams or mishandled filters. If the system does not recover, the following screen is displayed:

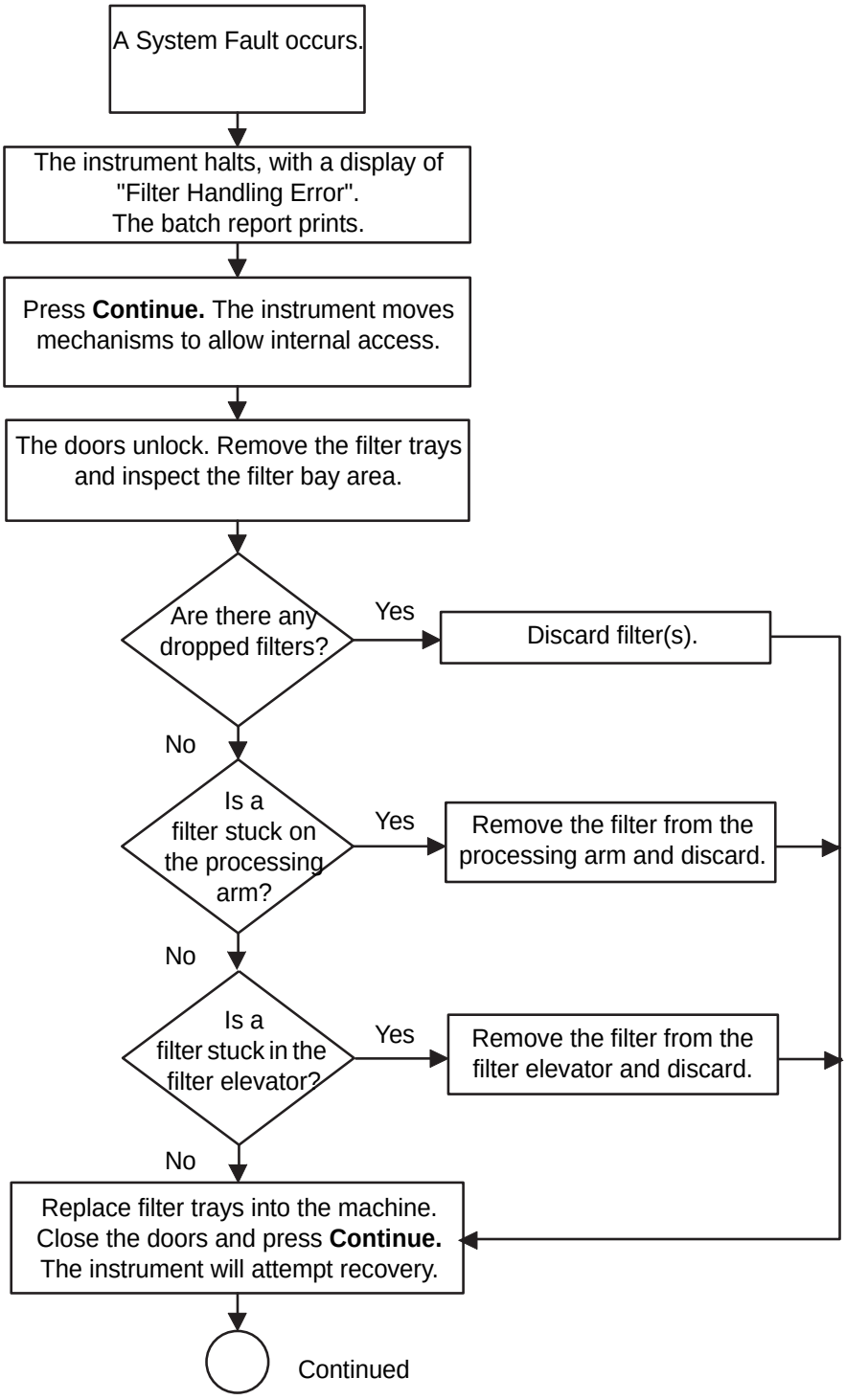


8. Press **Continue**. The main menu will display. Remove sample trays and staining racks.

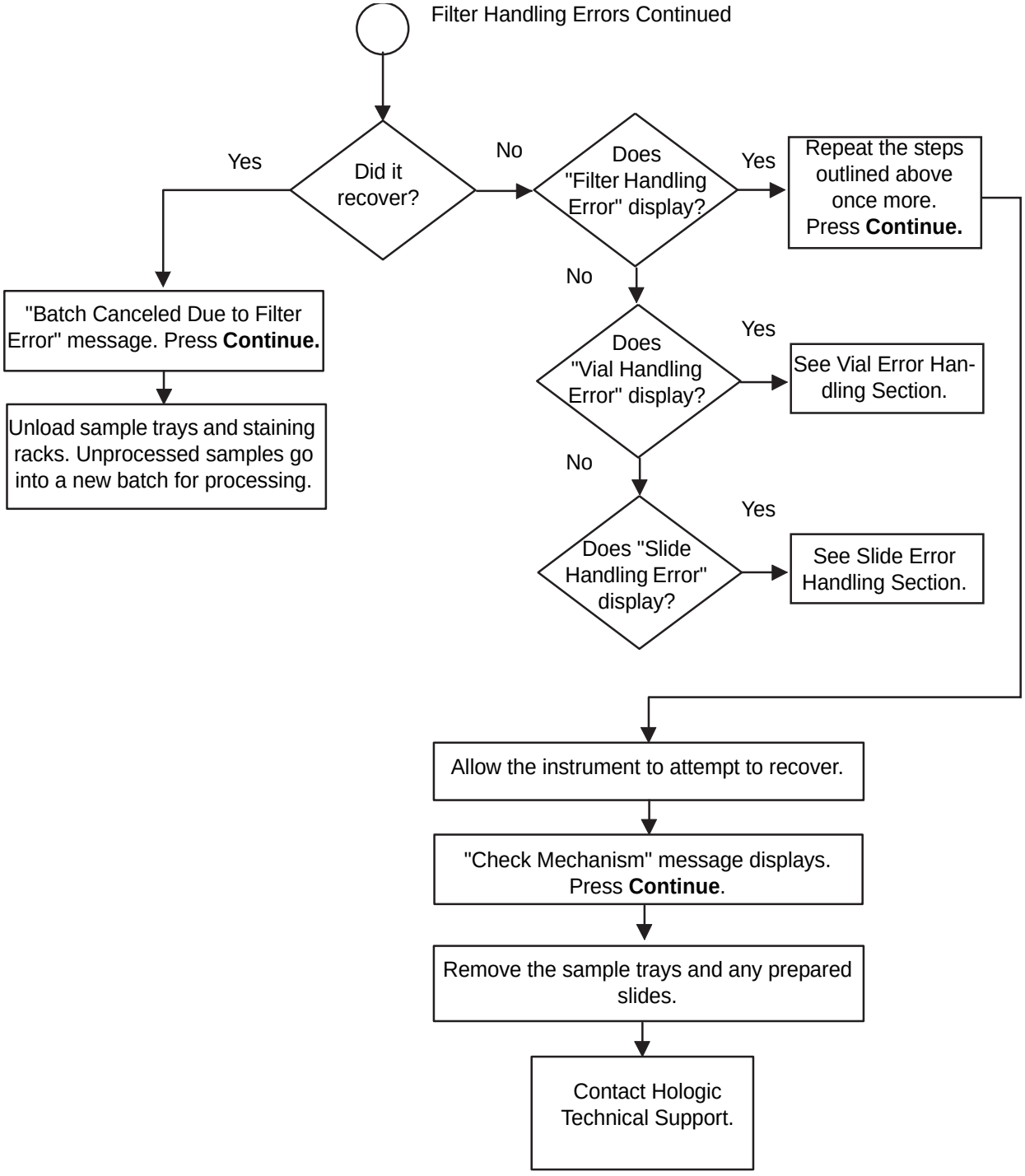
   Any mechanical faults should be addressed by Hologic Technical Support. If errors recur, or do not appear as described here, contact Hologic Technical Support.

Filter Handling System Fault Recovery

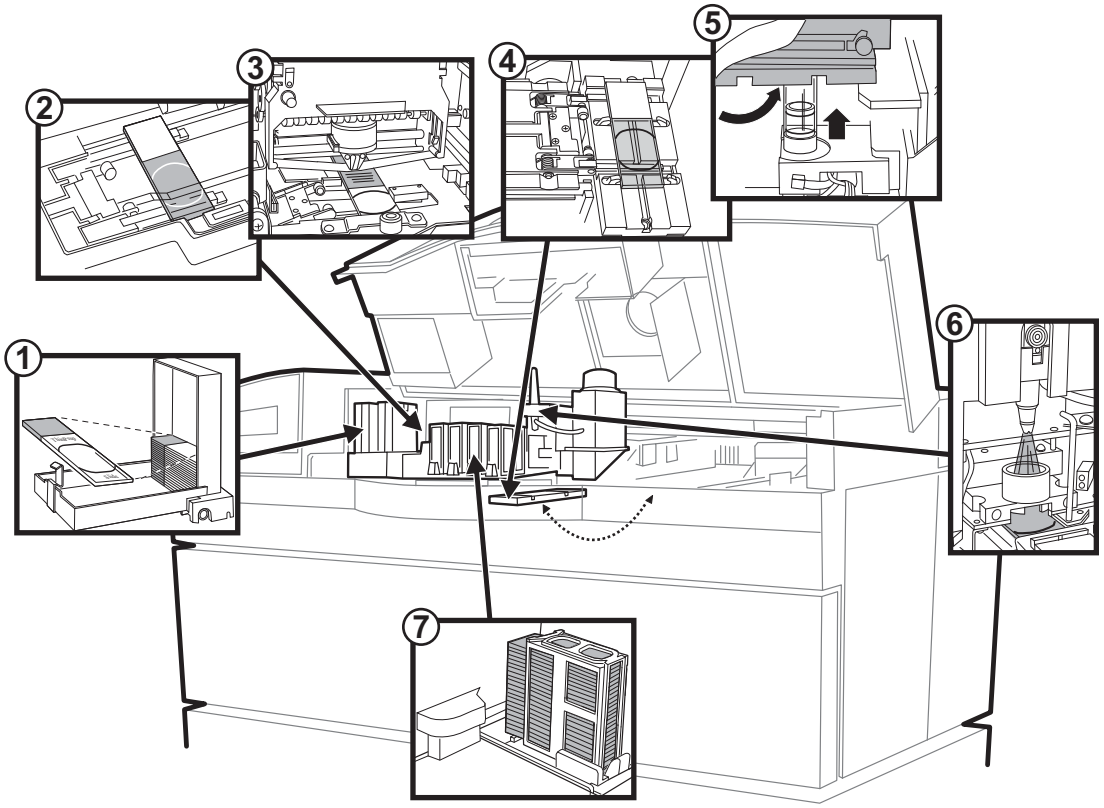
WARNING: Sharp Edges
Hot Surfaces



Filter Handling System Fault Recovery (continued)



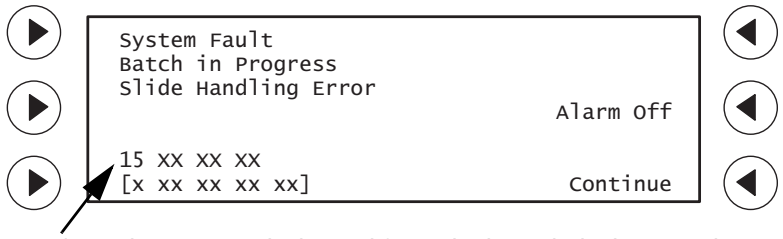
Slide Handling Operations



1. Slide cartridge(s) loaded with slides, are placed in the instrument.
2. The slide translator picks a slide from the cartridge and carries it to the slide printer.
3. The barcode number scanned from the sample vial is printed onto the slide, along with the time, date and facility name (optional).
4. The slide translator hands the slide off to the slide cell transfer arm.
5. The slide cell transfer arm pivots to convey the slide to meet the ThinPrep Pap test filter for cell transfer.
6. The slide cell transfer arm delivers the slide to the fixative dispenser, where fixative is applied.
7. The prepared slide is placed into a staining rack.

Slide handling system fault

A system fault involving microscope slide transport or processing will halt the batch and the following screen will be displayed:

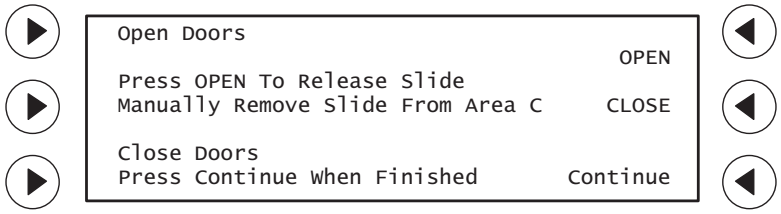


Possible Cause:

- Slide(s) jammed when picked from slide cartridge.
- Slide misprint or caught in printer area
- Slide fails to be released from slide transport arm.
- Slide holder mechanism not clean enough (error code 16 17 67 xx or 16 17 68 xx)
- Slide not properly ejected into the staining rack
- Mechanism fault

Corrective Action:

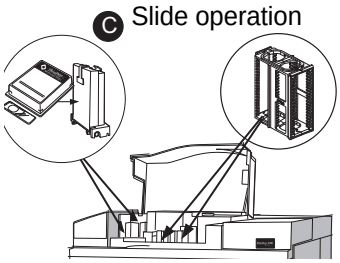
1. If desired, the audible beep can be stopped by pressing **Alarm Off**. Press **Continue**. The following screen displays:



2. Open the front door and top door when they are unlocked.

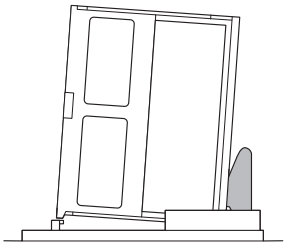
WARNING: Glass
Sharp Edges

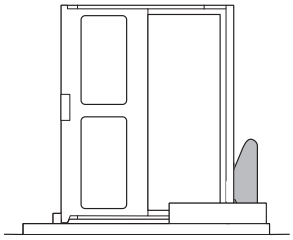
3. Look in the slide handling area (Area C) for stuck or broken slides.



a. Check the **staining racks** to see if a slide was not ejected properly. (As example, the slide bumped the rack and was not ejected, or the staining rack was not aligned correctly.)

If this is the case, manually remove the slide.


Incorrect installation


Correct installation

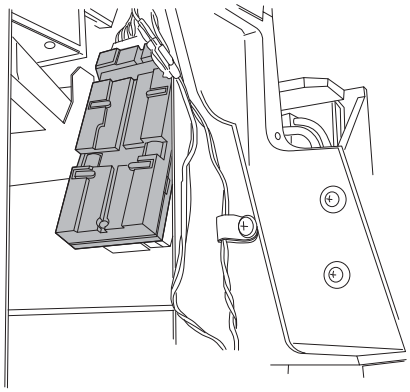
The staining rack should be seated flat on its bottom surface.

b. Check the **Slide Cell Transfer Arm** to see if a slide was not released from the slide clamps or is stuck due to fixative buildup. To get a clearer view of this apparatus, you may remove the staining racks, fixative shield, the filter trays and/or the sample vial trays.

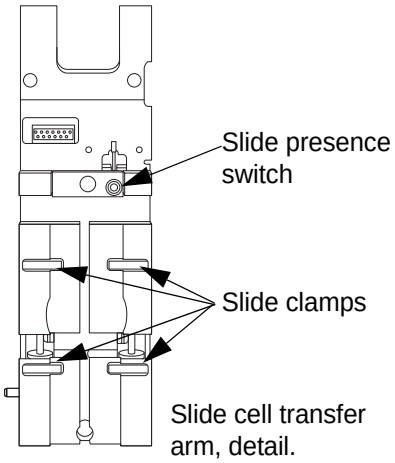
Press the OPEN prompt on the user interface to open the slide clamps of the slide cell transfer arm.

If a slide is present, manually remove it.

Press the CLOSE prompt on the user interface to close the slide clamps.



The slide cell transfer arm, viewed from the vial bay with the sample trays removed.



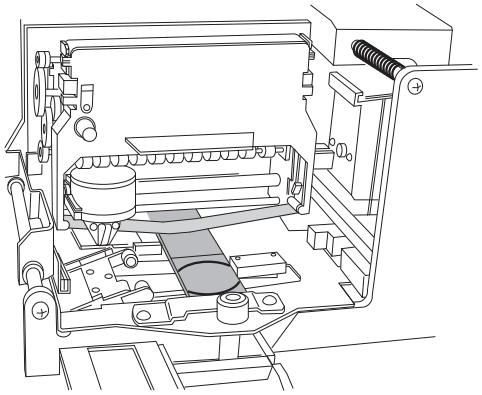
Slide cell transfer arm, detail.

If the numeric error code is specifically **16 17 67 xx** or **16 17 68 xx**, the slide cell transfer arm must be thoroughly cleaned, especially the slide presence switch and the slide clamps. Refer to "CLEANING THE SLIDE PATH" on page 6.17.

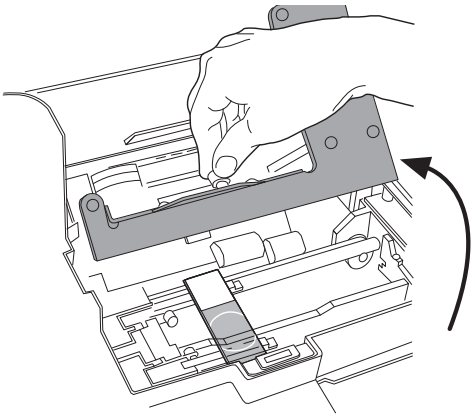
Note: The slide path must be cleaned regularly, as prompted.

c. Open the slide printer lid covering the slide printer area. Visually inspect the area to see if a slide has collided with the printer or fallen off the track (it may be above or below the print platform). Loosen the thumbscrew and lift the slide printer assembly to look for a slide underneath. Manually remove any slide located here.

Retighten the thumbscrew when done.



Slide printer area

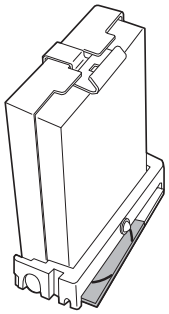


Slide printer assembly module

d. Lift out the slide cartridges and see if a slide jammed while exiting the cartridge. Manually remove the slide and check that the remaining slides are positioned correctly in the cartridge.

Refer to "ThinPrep Microscope Slides and Slide Cartridges" on page 5.7 for a description of the correct slide/cartridge loading procedure.

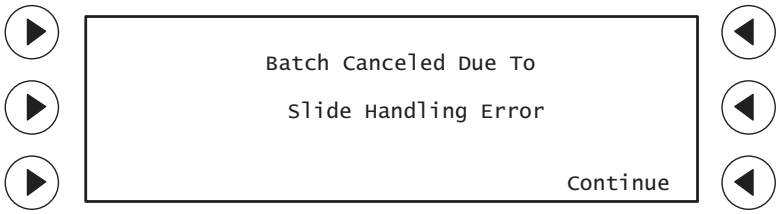
Keep the slide cartridges free of glass chips or slide dust for optimal operation.



e. See if the fixative spray nozzle is working freely. Ordinarily a fixative clog or low CellFyx Solution level will prompt a message specifically for that. Sometimes a clog will require further attention to fully dissolve it. Refer to "FIXATIVE SYSTEM PREVENTATIVE MAINTENANCE" on page 6.5 for detailed steps on reversing clogs. If the nozzle will not spray freely in a few attempts, contact Hologic Technical Support.

4. Close the door(s) and press **Close** to shut the slide clamps. Press **Continue**. The instrument will attempt recovery.

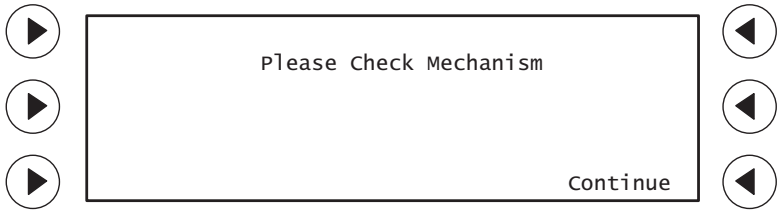
   If your actions cleared the problem, the following screen will be displayed:



5. Press **Continue**. The instrument will return to the System Ready screen. Remove slides and sample trays. Place unprocessed samples into a new batch.

   If the instrument diagnoses that there is still an error state, the System Fault screen will display.

   Repeat steps 1 through 5, above, to try to clear any obvious mechanical jams or interference. If the system does not recover, the following screen is displayed:

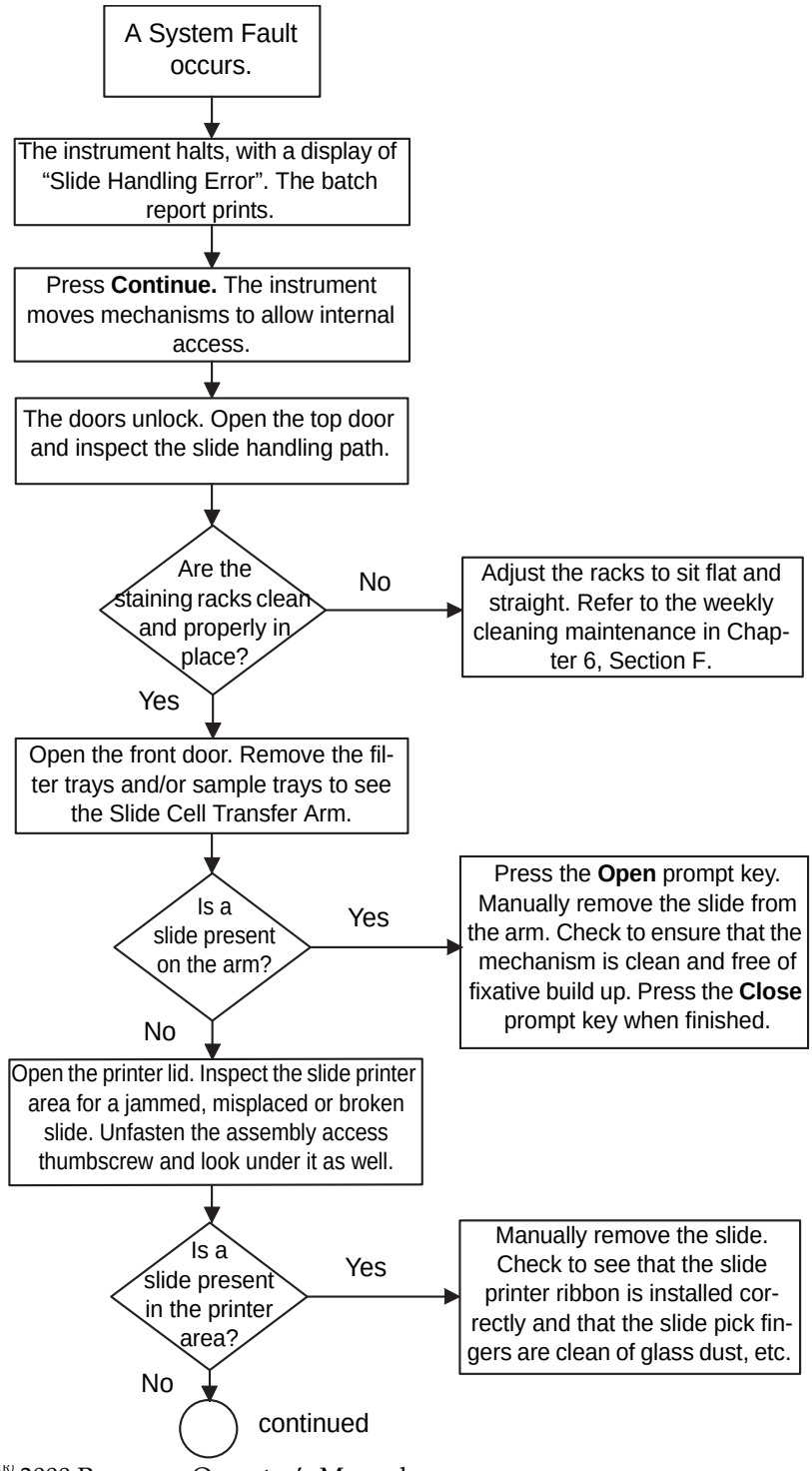


6. Press **Continue**. The main menu will display. Remove sample trays and staining racks.

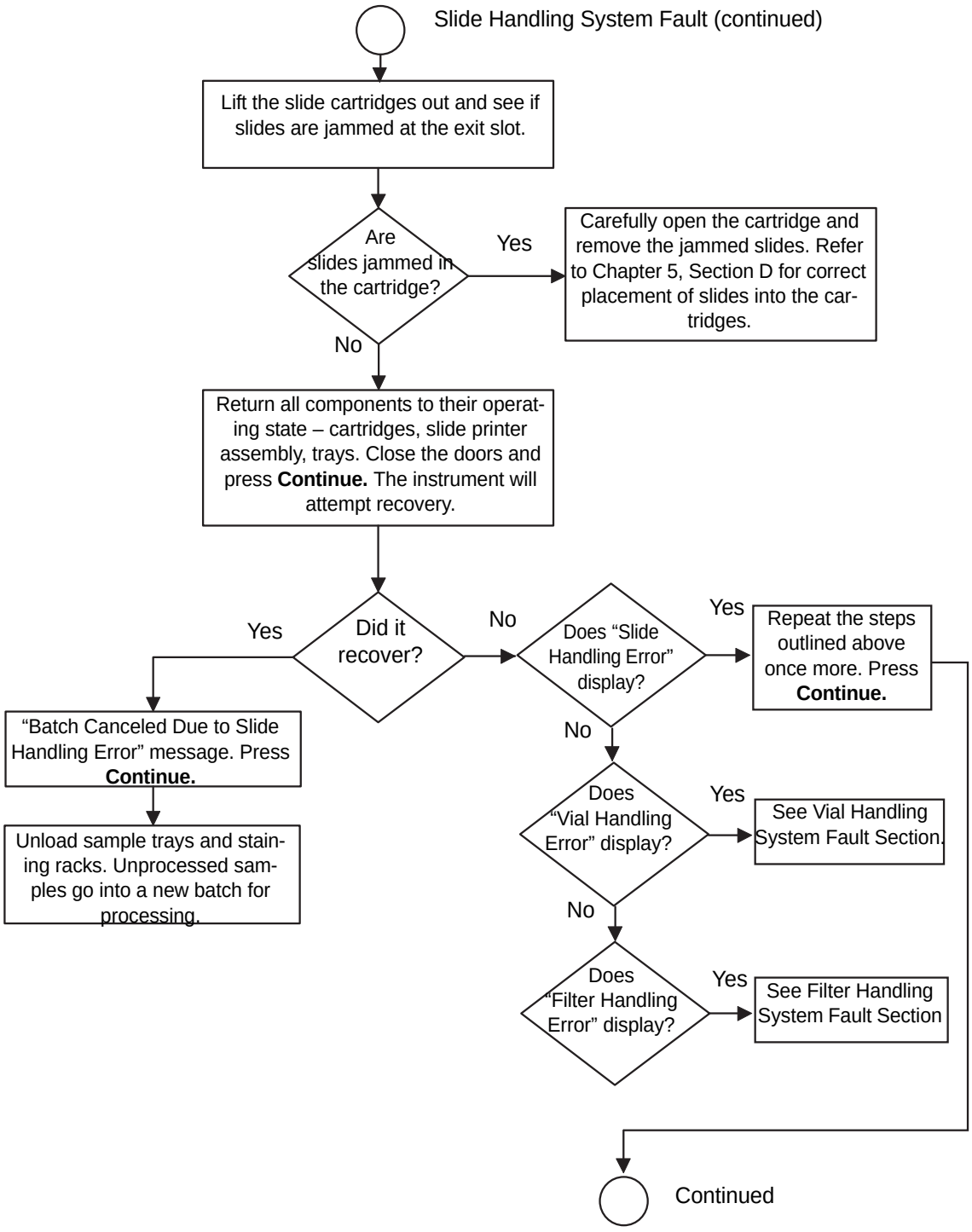
Any mechanical failures should be addressed by Hologic Technical Support. If errors recur, or do not appear as described here, contact Hologic Technical Support.

Slide Handling System Fault Recovery

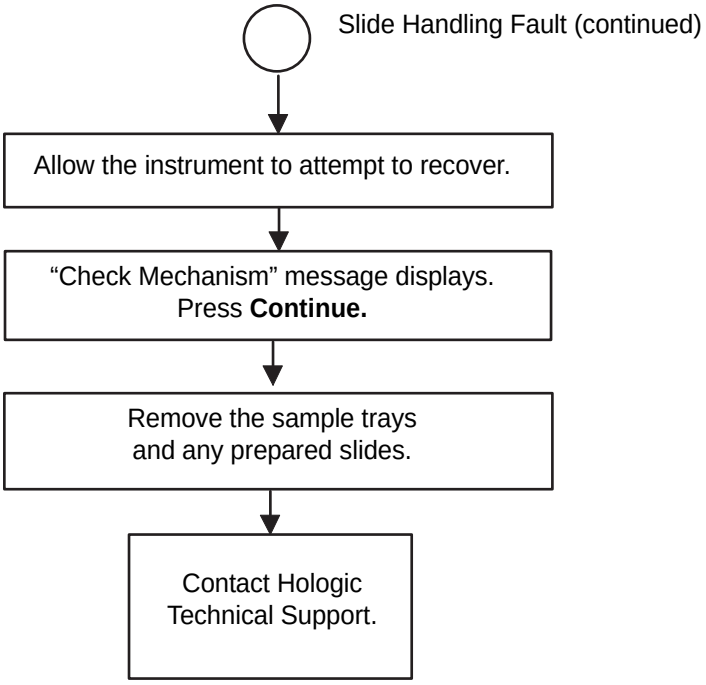
WARNING: Glass
Sharp Edges



Slide Handling System Fault Recovery (continued)



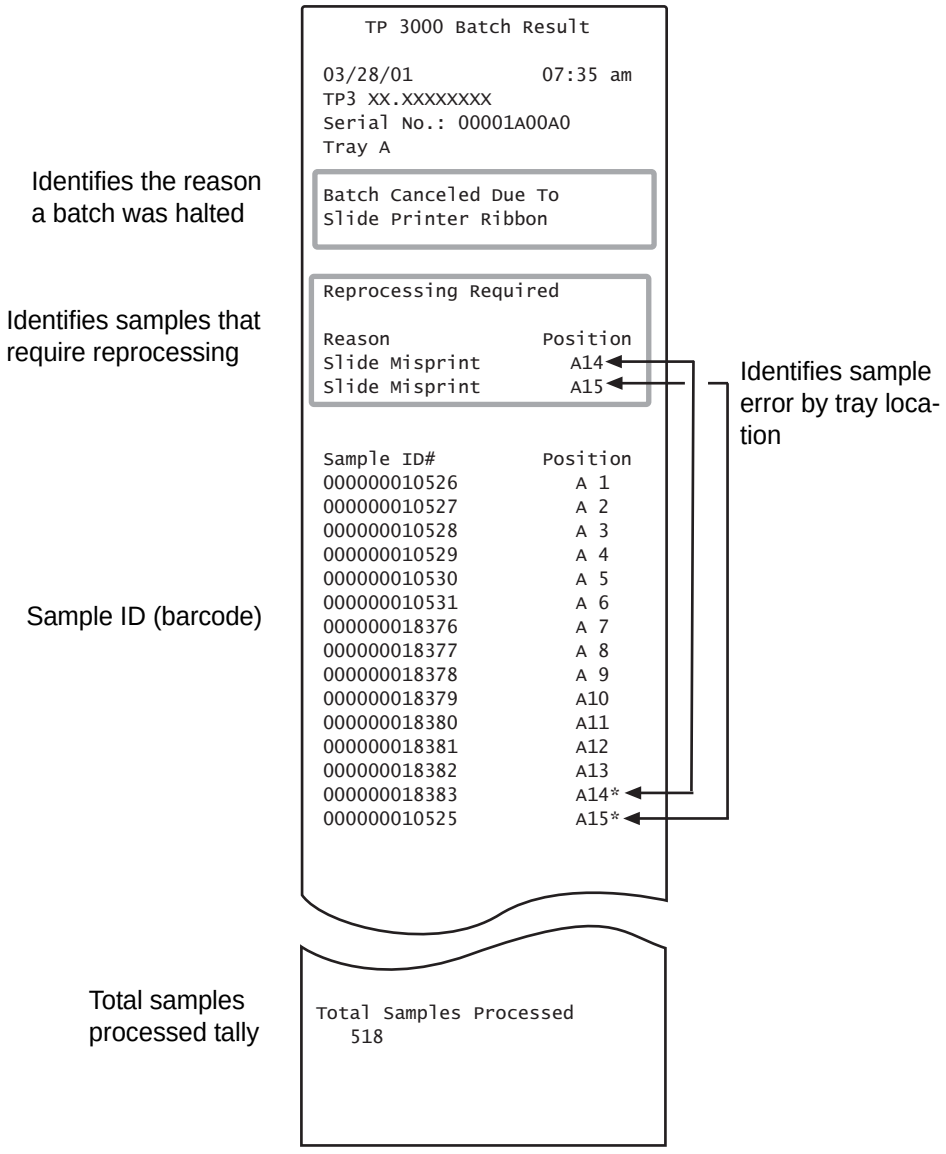
Slide Handling System Fault Recovery (continued)



SECTION D

'BATCH CANCELED DUE TO' REPORTING

For batches that concluded because of an interruption during processing, the batch report will indicate a reason for the halt. Batches may be canceled by the operator, by sample error or a system fault.



Batch Canceled Due To:

Barcode scan failure

The instrument was unable to successfully scan two consecutive sample vial barcodes. See "**No Barcode** Reprocessing Required" on page 7.16.

Cancellation by user

- An operator intentionally canceled a batch by pressing **Pause** and then pressing **Cancel Batch**.
- An operator may have unintentionally canceled a batch by pressing **Pause** and then removing one or both sample trays.

Cap tighten failure

The system was unable to tighten the vial cap while the vial is in the tray. Three consecutive errors will cancel the batch. See "**Cap Tighten Failure** Reprocessing Required" on page 7.6. Any three consecutive instances of Cap Tighten Failure *and* Vial Cap Too Tight in combination will cancel the batch.

Failure to scan tray ID

(This is only if you are using Tray ID Barcode Scan mode.)

- The instrument failed to properly scan the sample vial tray barcode.
- A sample vial tray did not have a barcode on it.

Filter load failure

A filter was not properly pressed onto the sample processing arm. See "**Filter Load Failure** Reprocessing Required" on page 7.10.

Fixative clogged

The fixative dispense system was unable to spray or unable to determine fluid level. See "**Fixative Clog** Reprocessing Required" on page 7.12.

Insufficient consumables

The supply of a consumable item was used up before the batch was complete. See "**Out of Consumables** Reprocessing Required" on page 7.18.

Sample processing error

An error occurred during sample processing.

- See "**Pneumatic Failure** Reprocessing Required" on page 7.20.
- See "**Waste System Failure** Reprocessing Required" on page 7.28.

Slide printer ribbon

Two or more consecutive slide misprints may have occurred. See "**Slide Misprint** Reprocessing Required" on page 7.22.

Vial fluid level error

Three or more consecutive vial fluid level errors will cancel the batch.

- Sample vials did not have enough fluid volume. See "**Insufficient Vial Fluid** Reprocessing Required" on page 7.14.
- Sample vials had too much fluid volume. See "**Too Much Vial Fluid** Reprocessing Required" on page 7.24.

7 TROUBLESHOOTING

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8. Staining and Coverslipping

8. Staining and Coverslipping

Chapter Eight

Staining and Coverslipping

CONTENTS

SECTION A INTRODUCTION

Hologic has established a recommended set of guidelines for staining and coverslipping slides prepared on the ThinPrep® 3000 processor.

ThinPrep microscope slides are prepared and fixed inside the ThinPrep 3000 processor. They are ready for staining when they are delivered to the staining racks.

SECTION B

RECOMMENDED STAINING GUIDELINES

Staining times are different for ThinPrep-prepared slides in comparison to conventional preparations and should be adjusted accordingly.

- Use graded concentrations of alcohol (50% or 70%) to lower the potential for osmotic shock or possible cell shedding during staining.
- The use of mild bluing solutions and dilute acid baths will optimize nuclear staining and minimize possible cell shedding. Hologic recommends the use of a dilute Lithium Carbonate solution, or Ammonium Hydroxide solution as the bluing solution.
- Avoid the use of strong salt solutions, like *Scotts Tap Water Substitute*.
- Bath solution heights should completely cover the slides to reduce the chance of cell shedding during staining.
- For optimal results, slides should be agitated for at least 10 dips in each bath.

Below are the maximum concentrations to be used for the following solutions during the staining process:

Hydrochloric acid (HCl)	0.025%
Lithium Carbonate (bluing) baths	10 mg per 1 liter[1]
Acetic acid	0.1%
Ammonium Hydroxide	0.1%

1. Refer to Bales, CE. and Durfee, GR. Cytologic Techniques in Koss, L, ed. Diagnostic Cytology and its Histopathologic Basis. 3rd Edition. Philadelphia: JB Lippincott. Vol. II: pp 1187-1260 for details.

Recommended Staining Protocol for the ThinPrep® 3000 System

Step	Solution	Time
1	Distilled H_2O (dH_2O)*	10 minutes with agitation
2	Richard-Allan Hematoxylin I	45 seconds with agitation
3	Distilled H_2O (dH_2O)	15 seconds with agitation
4	Distilled H_2O (dH_2O)	15 seconds with agitation
5	Clarifier (.025% glacial acetic acid)	30 seconds with agitation
6	Distilled H_2O (dH_2O)	30 seconds with agitation
7	Bluing Reagent (10 mg LiCarb/1 L)	30 seconds with agitation
8	Distilled H_2O	30 seconds with agitation
9	50% Reagent Alcohol	30 seconds with agitation
10	95% Reagent Alcohol	30 seconds with agitation
11	Richard-Allan Cytology Stain	1 minute with agitation
12	95% Reagent Alcohol	60 seconds with agitation
13	95% Reagent Alcohol	90 seconds with agitation
14	100% Reagent Alcohol	30 seconds with agitation
15	100% Reagent Alcohol	30 seconds with agitation
16	100% Reagent Alcohol	30 seconds with agitation
17	Xylene	1 minute with agitation
18	Xylene	1 minute with agitation
19	Xylene	3 minutes with agitation

* Place slides directly from the ThinPrep 3000 processor into distilled water to remove the CellFyx™ Solution.

Note: Hologic does not use commercially prepared clarifier or bluing reagent.

SECTION C

COVERSLIPPING RECOMMENDATIONS

Each laboratory should evaluate their choice of mounting media to ensure compatibility with ThinPrep slides. However, Permount® mounting media has been evaluated by Hologic and is recommended for use with ThinPrep-processor-prepared slides. Surgipath Clearium® is also acceptable mounting media for use with ThinPrep-processor-prepared slides. Hologic also recommends that 24 mm x 30 mm or 24 mm x 40 mm glass coverslips be used. Plastic coverslip material used with automated coverslipping instrumentation is also acceptable.

SECTION D

COMMON ARTIFACTS

Halo Artifact

In some cases of dense specimens, only the outer edge of cellular material may transfer to the ThinPrep slide forming a thin 'halo' or ring of cellular material on the slide. Evaluate the slide for adequacy and diagnostic category according to established laboratory guidelines.

Compression Artifact

Some samples may display what appears to be 'air-dry' artifact on the perimeter of the cell spot. This artifact is not air-drying but rather it is due to the compression of cells between the edge of the ThinPrep Pap test filter and the glass slide.

Staining Artifact

Some samples may display a staining artifact which mimics air-drying in appearance. This artifact appears as a red or orange central staining primarily in cell clusters or groups. This artifact is due to incomplete rinsing of the counterstains. Fresh alcohol baths or an additional rinse step after the cytoplasmic stains is required to reduce this artifact.

Edge of the Cylinder Artifact

Some samples may display a narrow rim of cellular material just beyond the circumference of the cell spot. This artifact is a result of cells from the outer edge of the wet filter cylinder being transferred to the glass slide. This may be more evident on highly cellular samples because there will be more cells to be transferred in the liquid.

Wrinkle Artifact

Wrinkles appear as elongated areas of low cellular density.

8 STAINING AND COVERSLIPPING

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9. The ThinPrep Pap
Test Training Program

9. The ThinPrep Pap
Test Training Program

Chapter Nine

ThinPrep Pap Test Training Program

Objective

The ThinPrep Pap Test Training Program was developed by Hologic to assist laboratories in the conversion process from the conventional Pap smear to the ThinPrep Pap Test. Hologic offers information, support and training for the conversion process, including communicating the change to the clinician, cytopreparatory training, ThinPrep Pap Test morphology training and guidelines to assist with training the entire cytology staff in the laboratory.

Design

Morphology Training is designed to communicate the differences between the conventional Pap smear and the ThinPrep Pap Test. The participants use a series of slide modules to familiarize themselves with a spectrum of normal and abnormal cytological entities on ThinPrep Pap Test samples.

This program is based on a cumulative learning process. Interpreting the morphologic criteria of ThinPrep Pap Test samples requires review and application of cytology skills and knowledge. A systematic approach allows for frequent assessment of an individual's understanding of the ThinPrep characteristics. The training program incorporates both pre- and post-tests in order to assess learning progress.

The training begins with the ThinPrep morphology lecture, which is designed to familiarize the participants with the microscopic presentation of cervical samples prepared using the ThinPrep System. The format summarizes the morphologic features common to specific diagnostic entities described in *The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses*[1].

Following the introductory session, a module of known ThinPrep Pap Test cases are reviewed by all participants. This module presents a wide variety of diseases and disease states and provides the participant a base reference for the full range of diagnostic categories to be encountered. Review of "look-alike" cases is also included. Through the use of the ThinPrep Gyn Morphology Atlas, which highlights common diagnostic entities and their differential diagnoses, participants will begin to recognize key look-alike entities on ThinPrep slides and the criteria that can be used in their proper classification.

A series of modules of unknown ThinPrep Pap Test cases is used to assess the ThinPrep screening and interpretive skills of each participant. Participants are required to screen and diagnose each set of cases and record their results on the provided answer sheet. Once complete, the cases and correct responses are reviewed individually by each participant.

9 THINPREP PAP TEST TRAINING PROGRAM

A final set of unknown ThinPrep Pap Test slides is provided. This final set of slides is modeled after current CLIA guidelines and will be scored by Hologic-designated personnel. Successful completion of these slides is necessary to receive a certificate of completion.

CLIA Proficiency Test Program standards are used as guidelines in establishing pass/fail scoring criteria. Individuals receiving a 90% or better on the Final Assessment are qualified to screen/interpret ThinPrep Pap Test cases, and to begin training additional cytotechnologists and pathologists in their laboratory under the supervision of the laboratory Technical Supervisor, if needed. Participants of the training program receiving less than 90% on the Final Assessment would require remedial training in their individual laboratories. This training involves the screening/diagnosing of an additional ThinPrep Pap Test slide module provided by Hologic and requires a score of 90% or better to complete Hologic's ThinPrep Pap Test Training Program.

Cytology Staff Training

Hologic supports cytology staff training by providing information and resources, such as slides, answer sheets, and online educational material, for use by the lab in training additional staff. The laboratory Technical Supervisor is ultimately responsible for ensuring adequate training for individuals prior to screening and interpreting ThinPrep Pap Test cases.

Bibliography

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

10. User Interface Screens

10. User Interface Screens

Chapter Ten

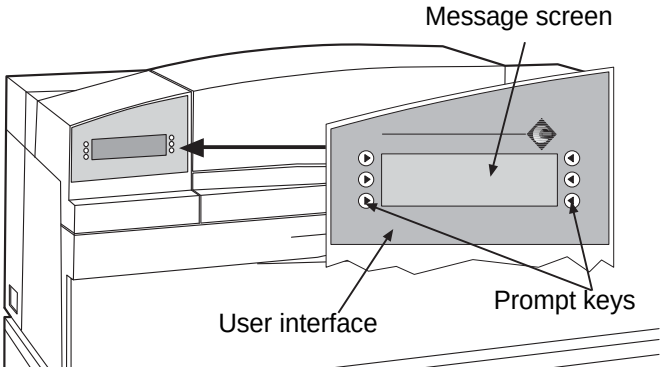
User Interface Screens

CONTENTS

SECTION A

OVERVIEW OF THE USER INTERFACE SCREENS

Operation of the ThinPrep® 3000 processor is via menu options selected by pressing the prompt keys. The 42-character by 8-line message screen shows instrument information including setup, operation, status, maintenance functions, tests and error messages. Most operator interaction is via the menu command trees listed on the following pages.

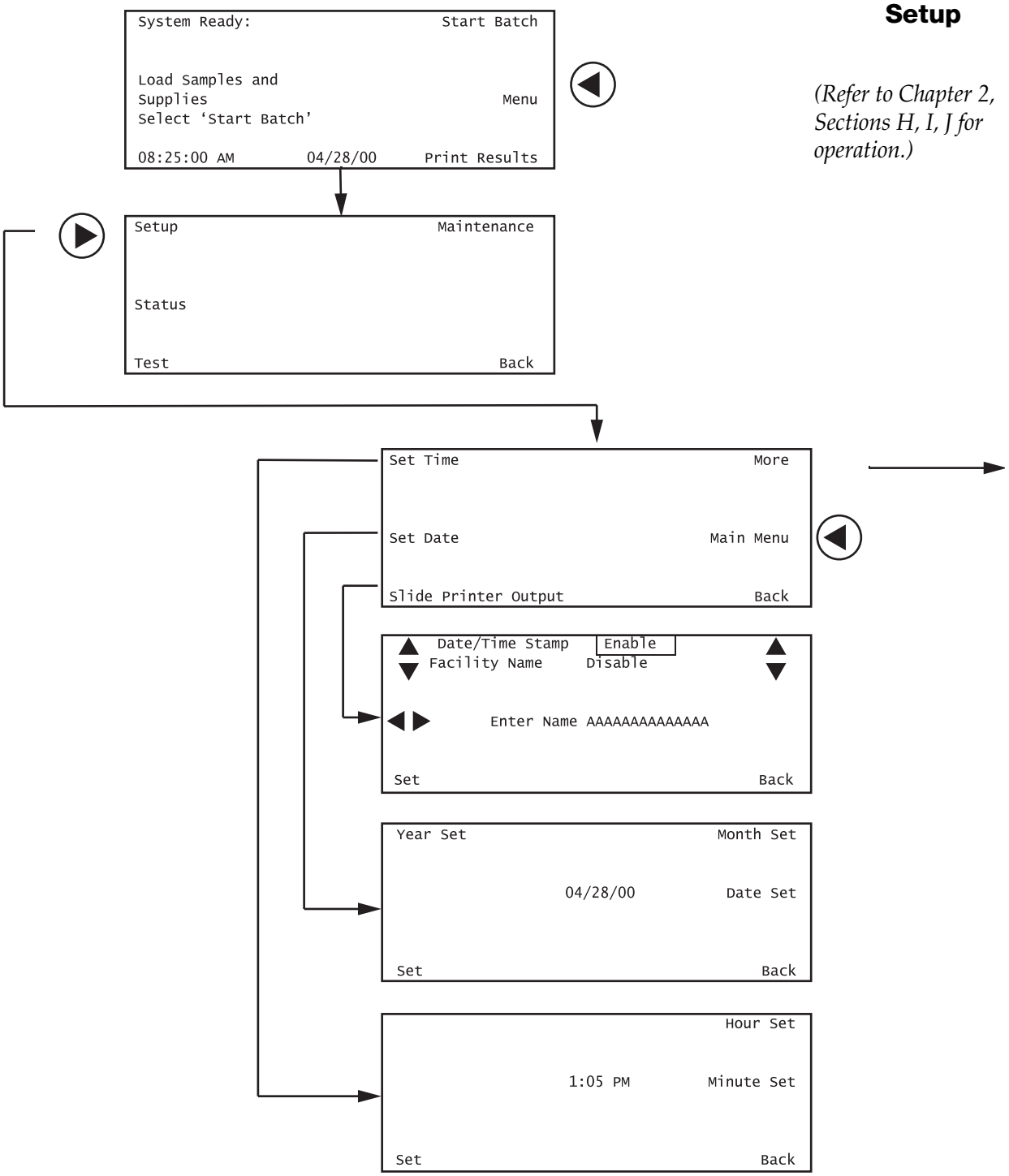


SECTION B

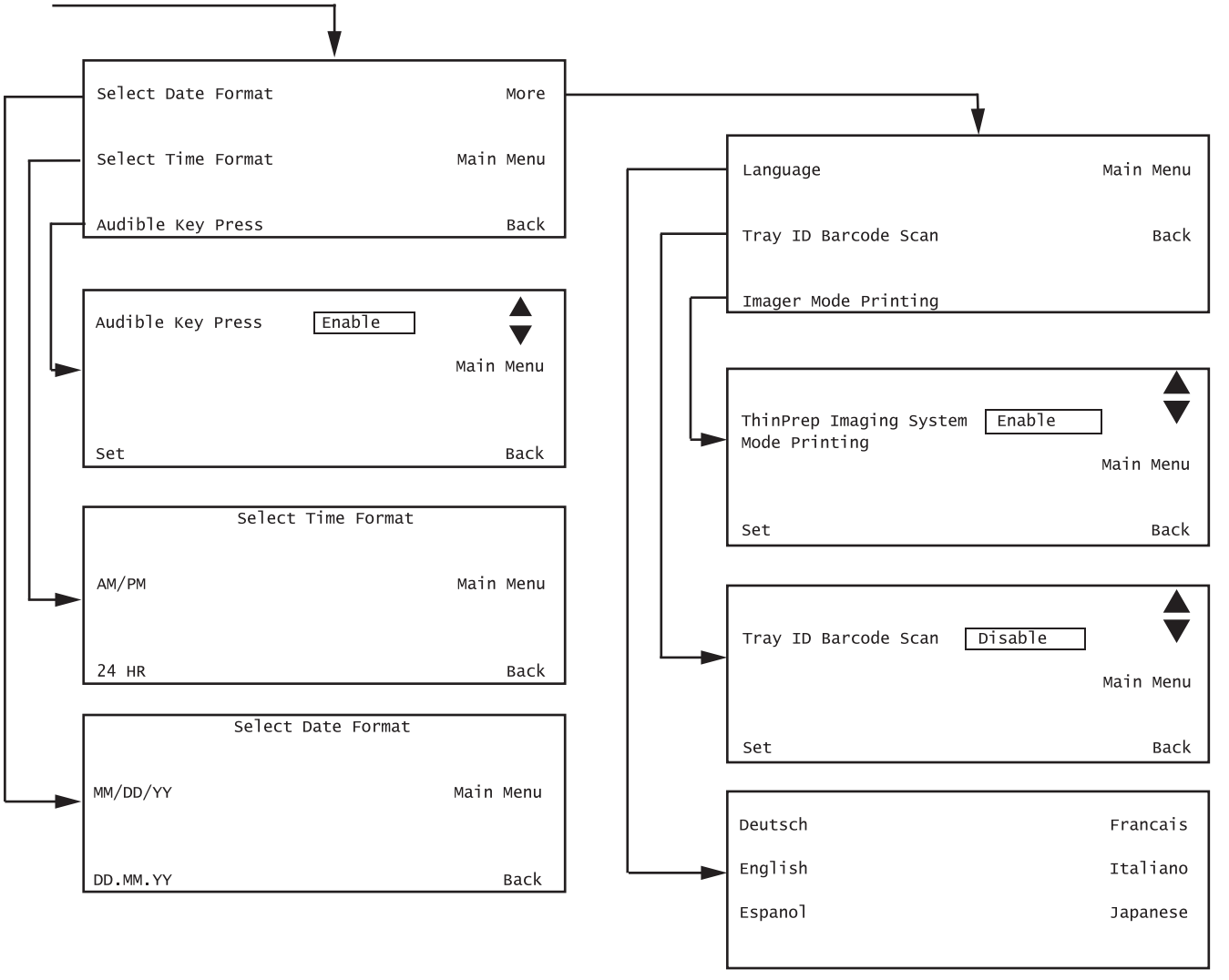
MENU TREES

Main/ Menu/ Setup

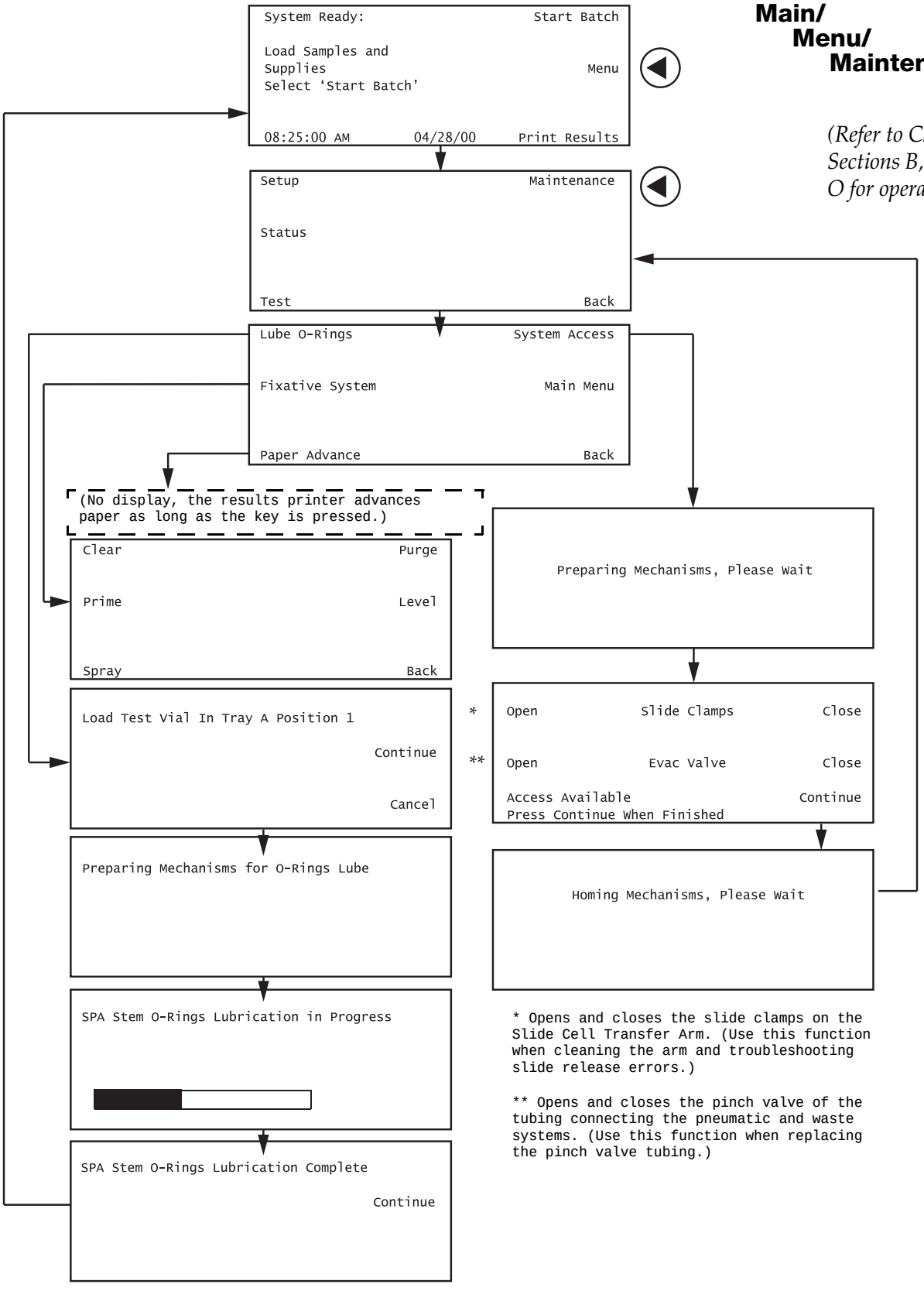
(Refer to Chapter 2, Sections H, I, J for operation.)



(Continued from previous page)



(Only English is available at this time)



Main/ Menu/ Maintenance

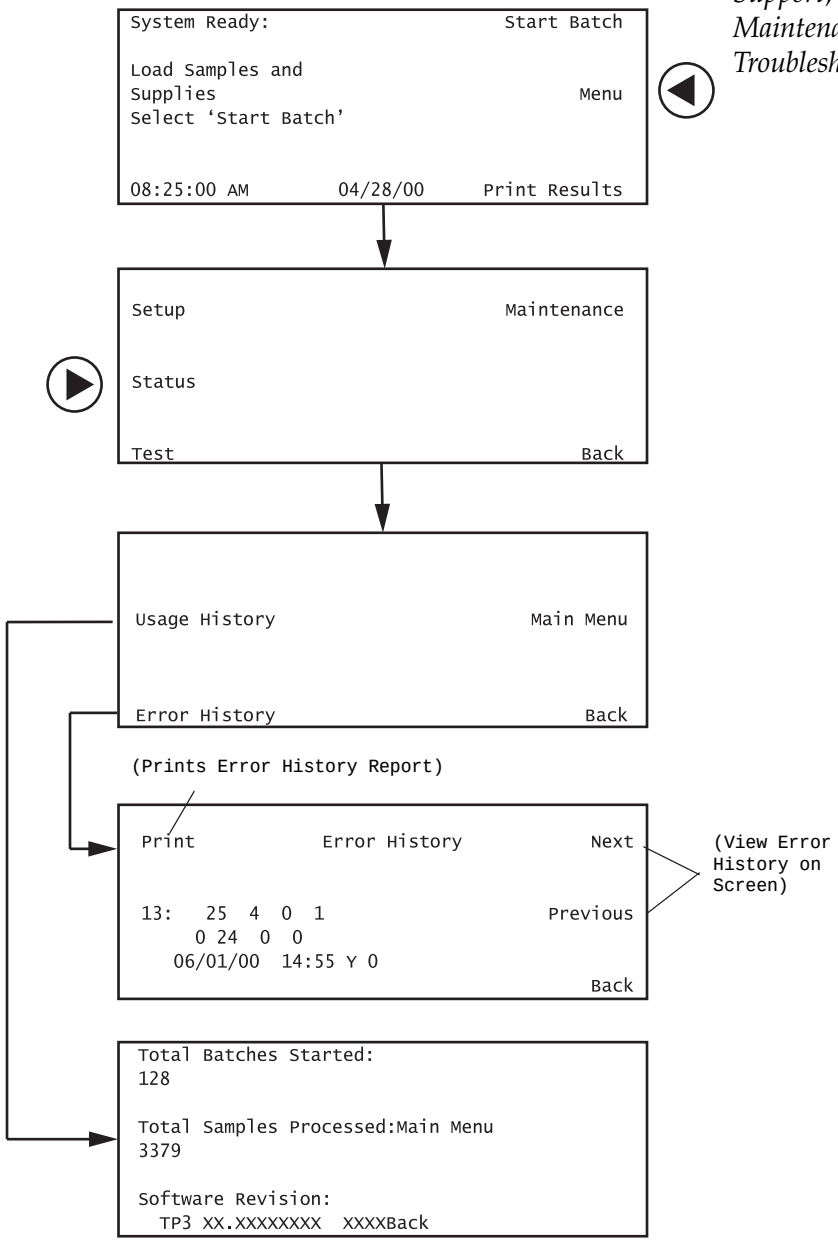
(Refer to Chapter 6, Sections B, D, F, H, I, O for operation.)

* Opens and closes the slide clamps on the Slide Cell Transfer Arm. (Use this function when cleaning the arm and troubleshooting slide release errors.)

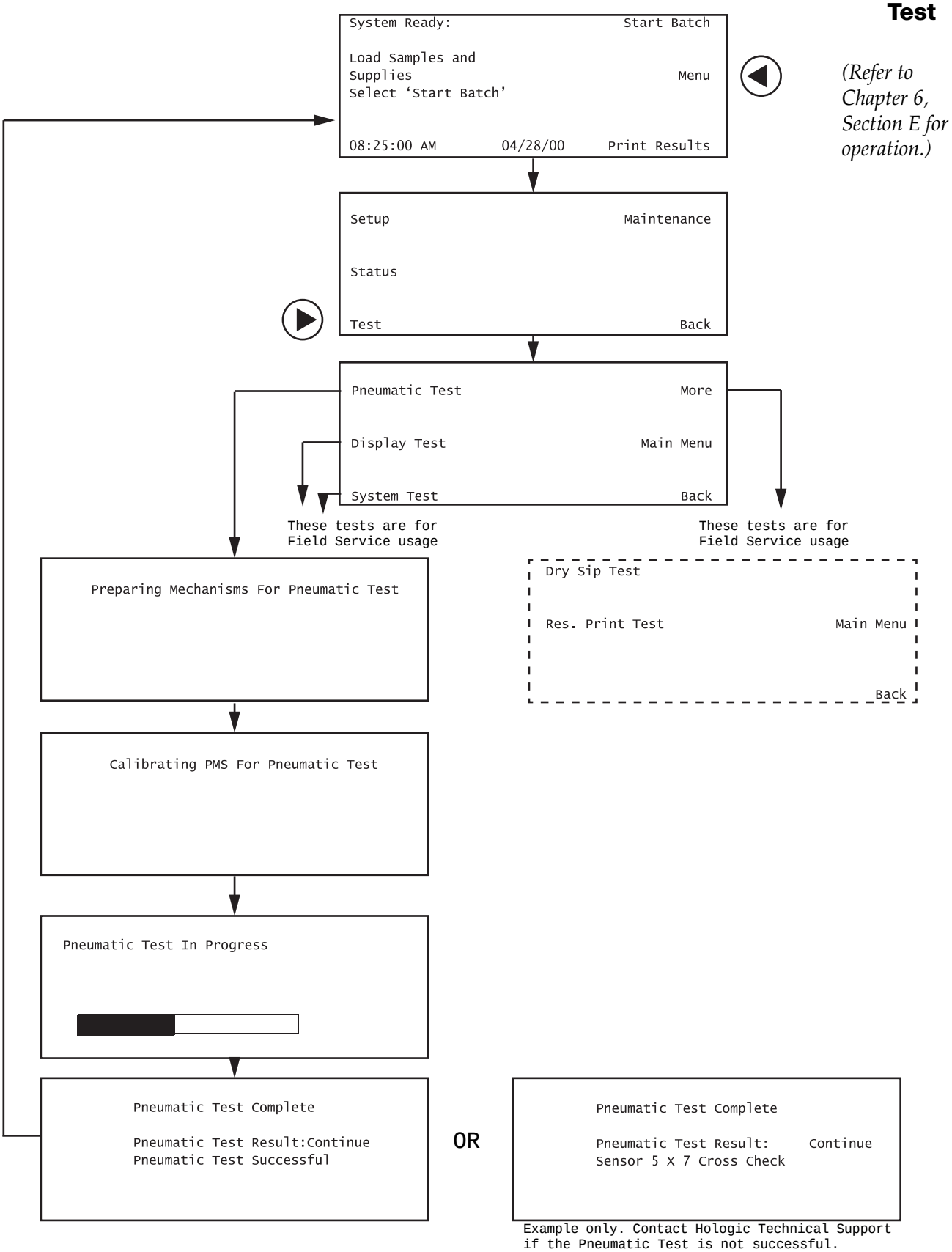
** Opens and closes the pinch valve of the tubing connecting the pneumatic and waste systems. (Use this function when replacing the pinch valve tubing.)

Main/ Menu/ Status

(Useful for Technical Support, Instrument Maintenance, and Troubleshooting)



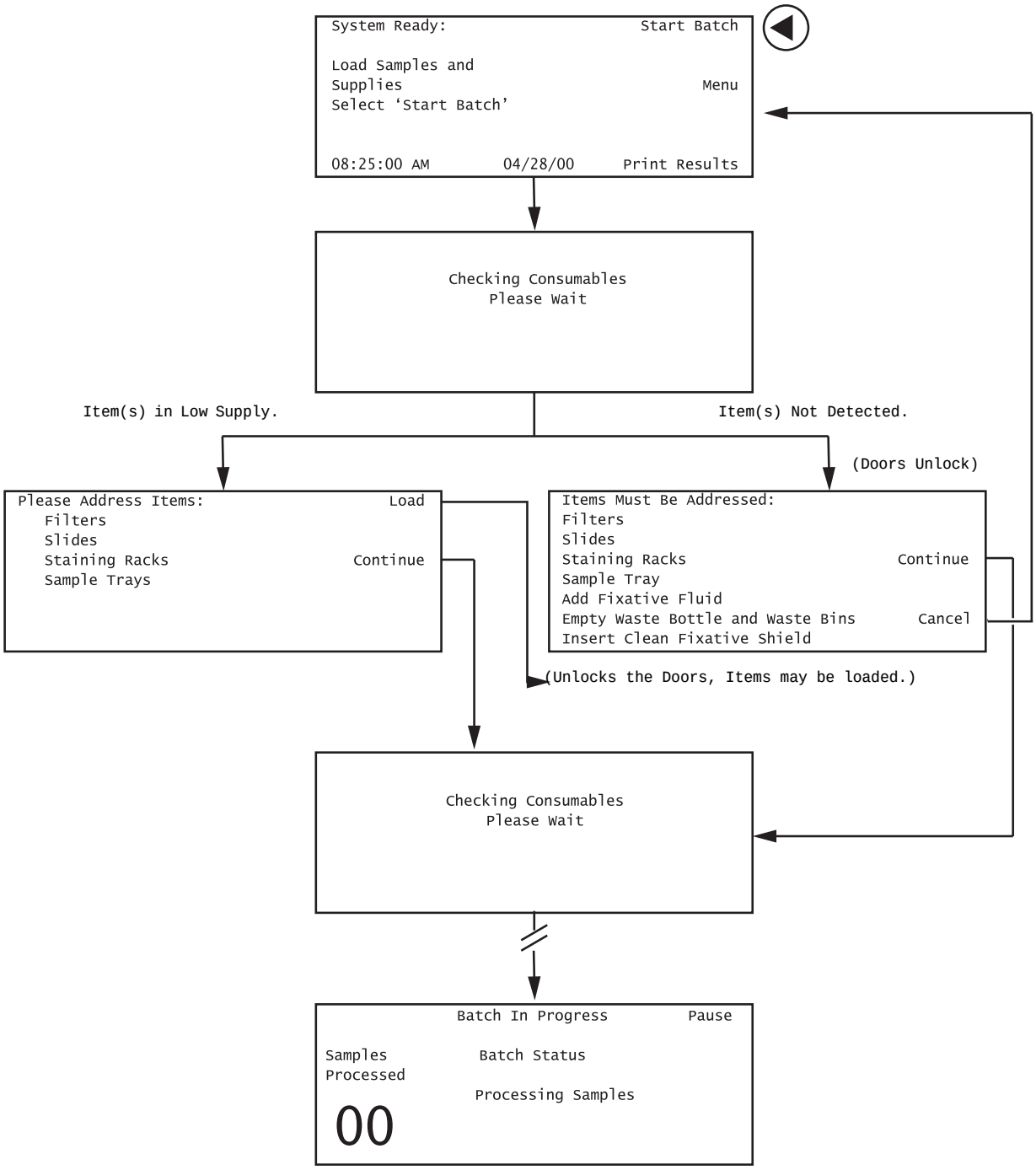
(Refer to Chapter 6, Section E for operation.)



Example only. Contact Hologic Technical Support if the Pneumatic Test is not successful.

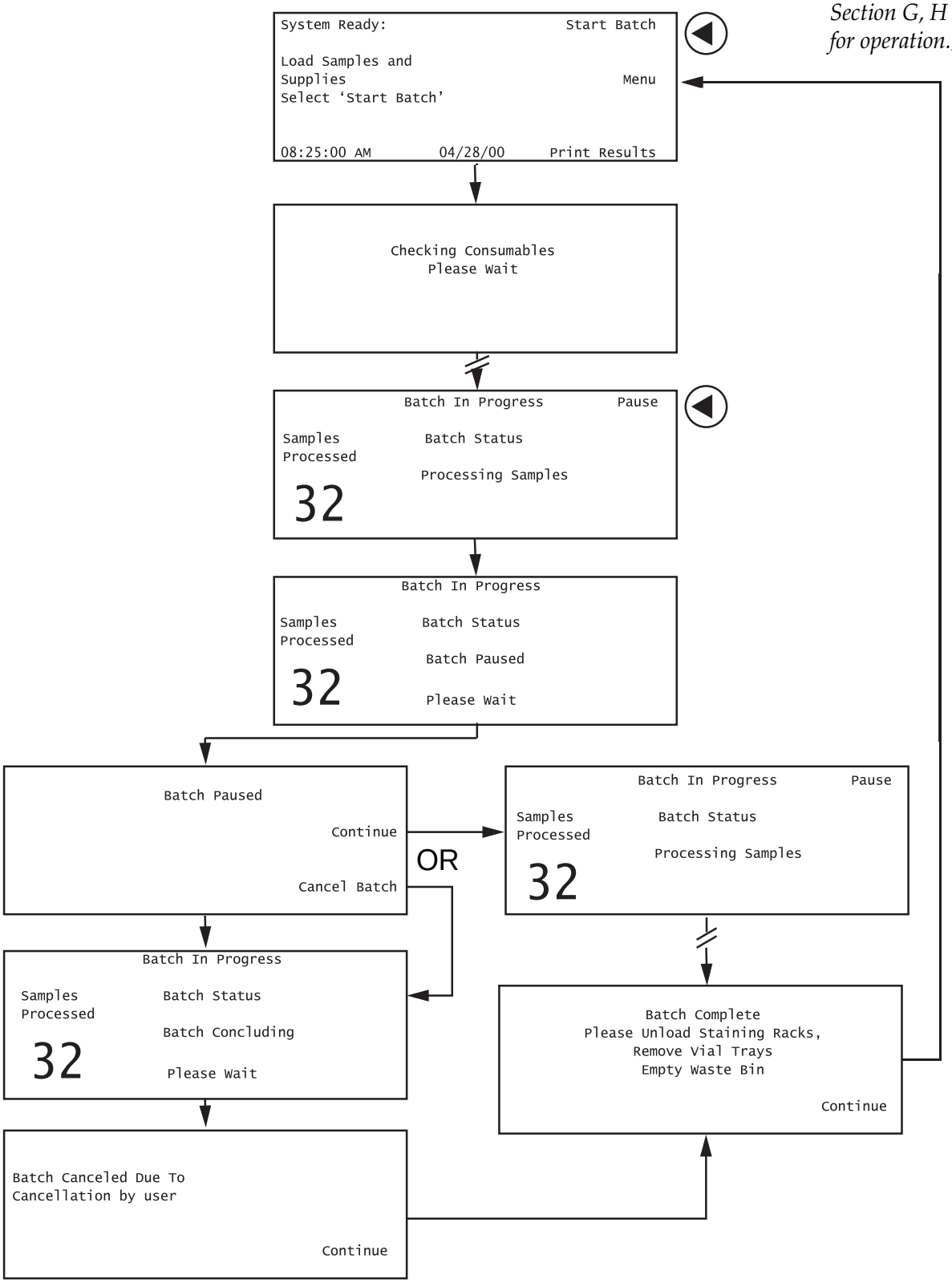
Start Batch/ Address Items

(Refer to Chapter 5, Section D for operation.)



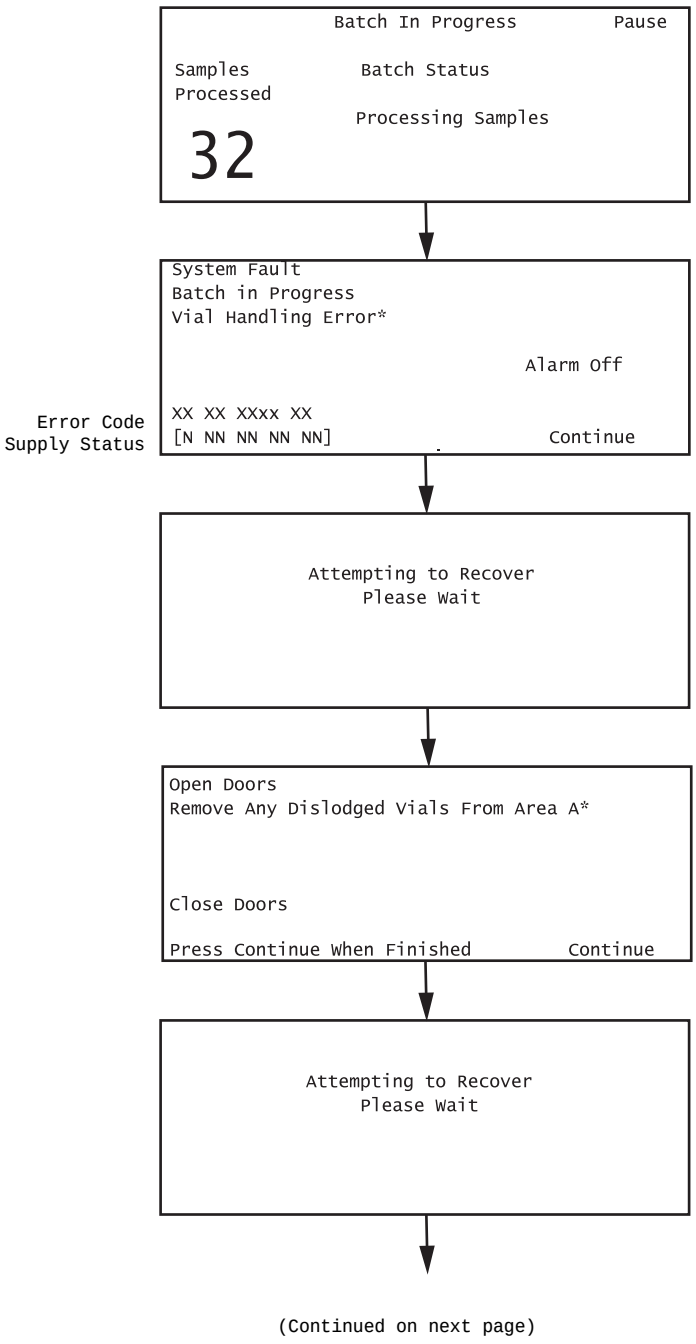
Start Batch/ Pause Cancel

(Refer to Chapter 5, Section G, H for operation.)



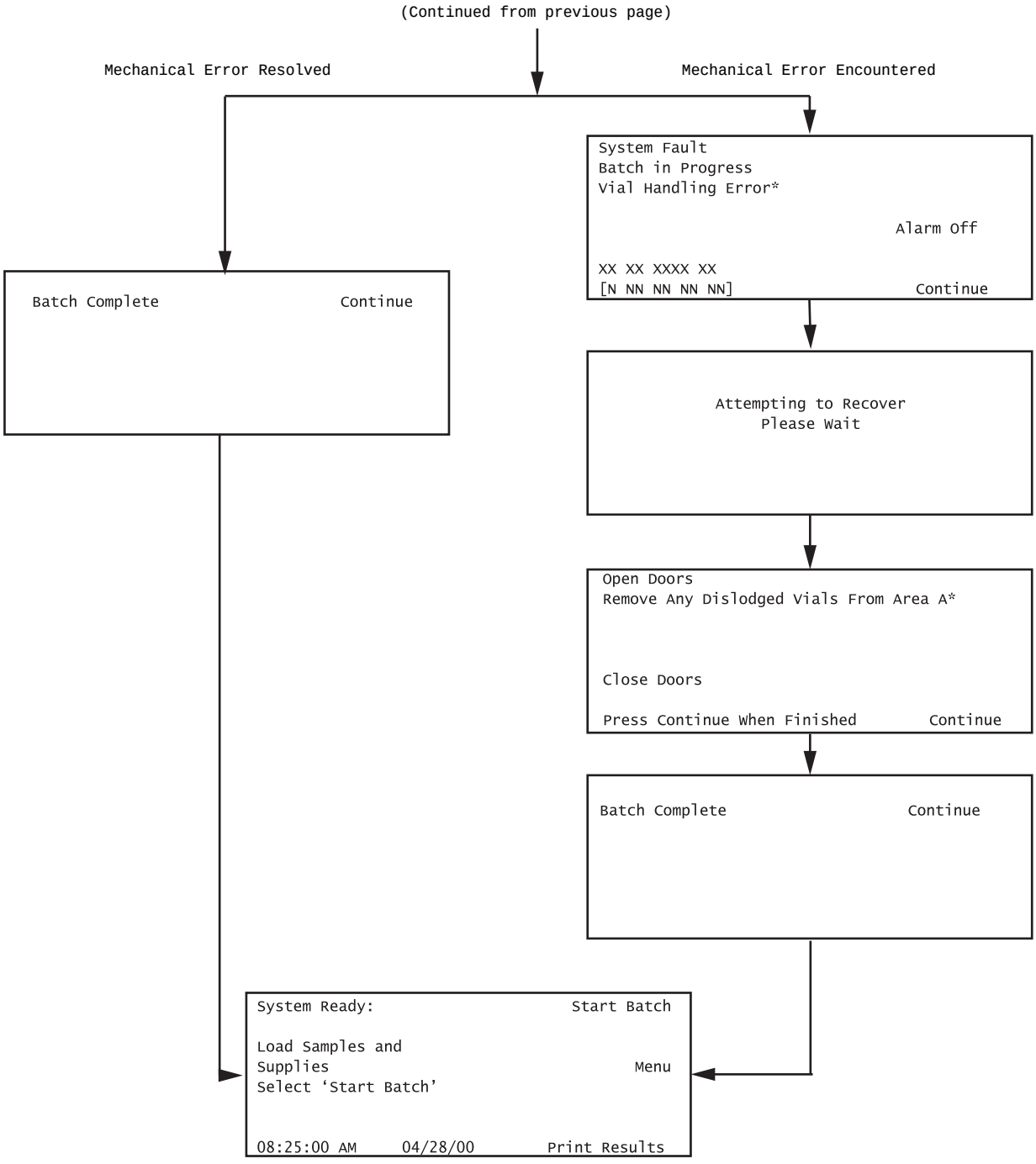
System Fault

(Refer to Chapter 7, Section C for Operation.)



(Continued on next page)

System Fault



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Service Information

Service Information

Service 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.

Orders can also be faxed to the attention of Customer Service at 1-800-409-7591.

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® processor 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 (USA and Canada).

For Technical Support outside USA and Canada:

Asia	+852 3526 0718	Netherlands	0800 022 6782
Australia	+61 2 9888 8000	Norway	800 155 64
Austria	0800 291 919	Portugal	800 841 034
Belgium	0800 773 78	Spain	900 994 197
Denmark	8088 1378	South Africa	0800 980 731
Finland	0800 114 829	Sweden	020 797 943
France	0800 913 659	Switzerland	0800 298 921
Germany	0800 183 0227	UK	0800 032 3318
Ireland (Rep)	1 800 554 144	Rest of the world	0041.21.633.39.26
Italy	800 786 308	Intl Fax number	0041.21.633.39.10

Service contracts can also be ordered through Technical Support.

Protocol for Returned Goods

For returns on warranty-covered ThinPrep 3000 processor accessory and consumable items, contact Technical Support.

For returns on warranty-covered ThinPrep Pap test consumable items, contact Customer Service to obtain a Return Goods Authorization (RGA) Number. Hologic will not accept any returned warranty-covered consumable items without this number.

The transportation of PreservCyt® Solution and CellFyx™ Fixative Solution is regulated by the DOT and will not be guaranteed by air freight companies for second-day or overnight delivery.

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Supplies for the ThinPrep® 3000 Processor

Item	Description	Quantity	Part Number
Filter Waste Box	Replacement filter waste box	1	50815-001
Fixative Shield Mount	Additional fixative shield mount	1	03178-001
Pinch Valve Tubing	Replacement pinch valve tubing kit (4 tubes)	1 kit	74030-001
Pneumatic Test Vial	Additional pneumatic test vial	1	02956-001
Sample Vial Tray, 4-pack	Additional sample vial trays	1 pkg	70264-001
Slide Cartridge	Additional slide cartridge	1	70348-001
Staining Rack, 4-pack	Additional staining racks	1 pkg	70265-001
Staining Rack Adapters	Attachment accessory: Leica Sakura Shandon	 1 1 1	 02975-001 02994-001 02976-001
Slide Waste Bin	Additional slide waste bin	1	50814-001
Waste Bottle and Harness Assembly	Replacement waste bottle and harness assembly	1	70213-001
Waste Bottle Transport Cover	Additional waste bottle transport cover	1	50247-001
ThinPrep 3000 Processor Operator's Manual	Additional operator's manual (for use in U.S.)	1	MAN-02586-001
Aerosol Spray Bottle	Spray bottle for Versa-Clean Solution	1 bottle	51432-001

Consumable Items for the ThinPrep 3000 Processor

Item	Description	Quantity	Part Number
CellFyx Solution	CellFyx Solution bottles, boxed (115 mL each) and 6 fixative shield replacements	6 bottles, 6 fixative shields	70207-001
Filter Waste Box Liner	Plastic bag insert for filter waste box	* See below for ordering specifications	
Fuse	5x20 mm, 6.3 Amp time delay glass, low break capacity replacement fuse	2	50077-021
Silicone Lubricant	Silicone lubricant, 2-oz. tube	1 tube	51298-001
Sample Identification Barcode Labels	Self-adhesive barcode labels	** See next page for ordering specifications	
Slide Printer Ribbon	Replacement printing ribbon for slide printer	1	MME-02836
Thermal Paper Roll	Replacement thermal paper for batch reporting	Box of 5	50516-001
ThinPrep 3000 Maintenance Kit	Pads, swabs, wipes for cleaning the slide cell transfer arm.	1 kit	70670-001
Versa-Clean™ Solution	Cleaning solution concentrate	1 Bottle	51431-001

*** Filter waste box liner, replacement bags:**

Order standard 14″ x 14″ x 26″ (36 cm x 36 cm x 66 cm) gusseted poly waste bags from your local lab supplier, based on your internal laboratory guidelines.

**** Barcode requirements:**

The barcode standard used is Code 128, subset C, with .013 "x" dimension. (Narrow bar width.)

1. Black bars on blue-white face stock with rubber based adhesive on back.

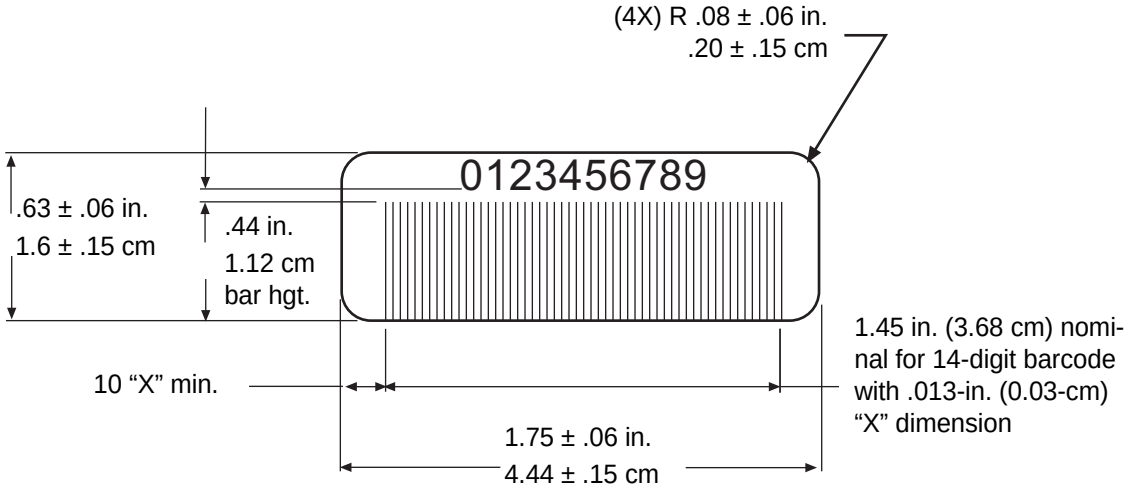
Refer to the Barcode Label Specifications for the ThinPrep 3000 Processor sheet in the Appendix for a copy of this information suitable for photocopy/facsimile use.

2. Label contents: a minimum of 5 and a maximum of 11 printed digits starting with a number defined by the laboratory, with each successive label incrementing by 1.

Note: Up to 2 leading or trailing alpha characters may be used. The instrument will not print letters to the microscope slide. Only the numeric accession number will be printed.

3. Printed as both a barcode and a 0.10-in.- (0.25-cm-) high human-readable number centered length wise on the label within 0.125 in (0.317 cm).
4. Print quality must meet requirements outlined in ANSI X3. 182.

Label dimensions:



Vendors:

Label Arts, Inc. (will take international orders)
P.O. Box 727
Kemp, TX 75143
Tel. in US: 1-800-634-99431-903-498-6041
Fax 1-903-498-8169

The barcode standard selected for use with the ThinPrep 3000 processor is one that is commonly used in many laboratories.

Consumable Items for the ThinPrep Pap Test

Item	Description	Quantity	Part Number
ThinPrep Pap Test Kit	*Materials for both the laboratory and the physician's office* Vials of PreservCyt Solution for use with the ThinPrep Pap test ThinPrep Pap test filters ThinPrep microscope slides Collection devices: Broom-like collection devices or Cytobrush and plastic spatula	500 Tests 500 500 500 500 500	 70096-001 70096-003
ThinPrep Pap Test Kit (for use with the ThinPrep Imaging System)	*Materials for both the laboratory and the physician's office* Vials of PreservCyt Solution for use with the ThinPrep Pap test ThinPrep Pap test filters ThinPrep Imaging System microscope slides Collection devices: Broom-like collection devices or Cytobrush and plastic spatula	500 Tests 500 500 500 500 500	 70662-001 70662-003
ThinPrep Pap Test Physician Office Kit	*Materials for the physician's office* Vials of PreservCyt Solution for use with the ThinPrep Pap test Collection devices: Broom-like collection device or Cytobrush and plastic spatula	 500 500 500	 70136-001 70136-002
ThinPrep Pap Test Laboratory Kit	*Materials for the laboratory* ThinPrep Pap test filters ThinPrep microscope slides	 500 500	70137-001
ThinPrep Pap Test Laboratory Kit (for use with the ThinPrep Imaging System)	*Materials for the laboratory* ThinPrep Pap test filters ThinPrep Imaging System microscope slides	 500 500	70664-001
Broom-like Collection Kit	Broom-like collection devices	500	70101-001
Cytobrush/Plastic Spatula	Cytobrush and plastic spatula collection devices	500	70124-001

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Safety Data Sheets

Safety Data Sheets

Safety Data Sheets

PreservCyt® Solution

CellFyx™ Solution

Fisher® brand Versa-Clean™

The Safety Data Sheets (SDS) for each solution may be requested from Hologic Technical Support at 1-800-442-9892 Option 6 (USA and Canada), or found on-line at www.hologicsds.com.

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Appendix

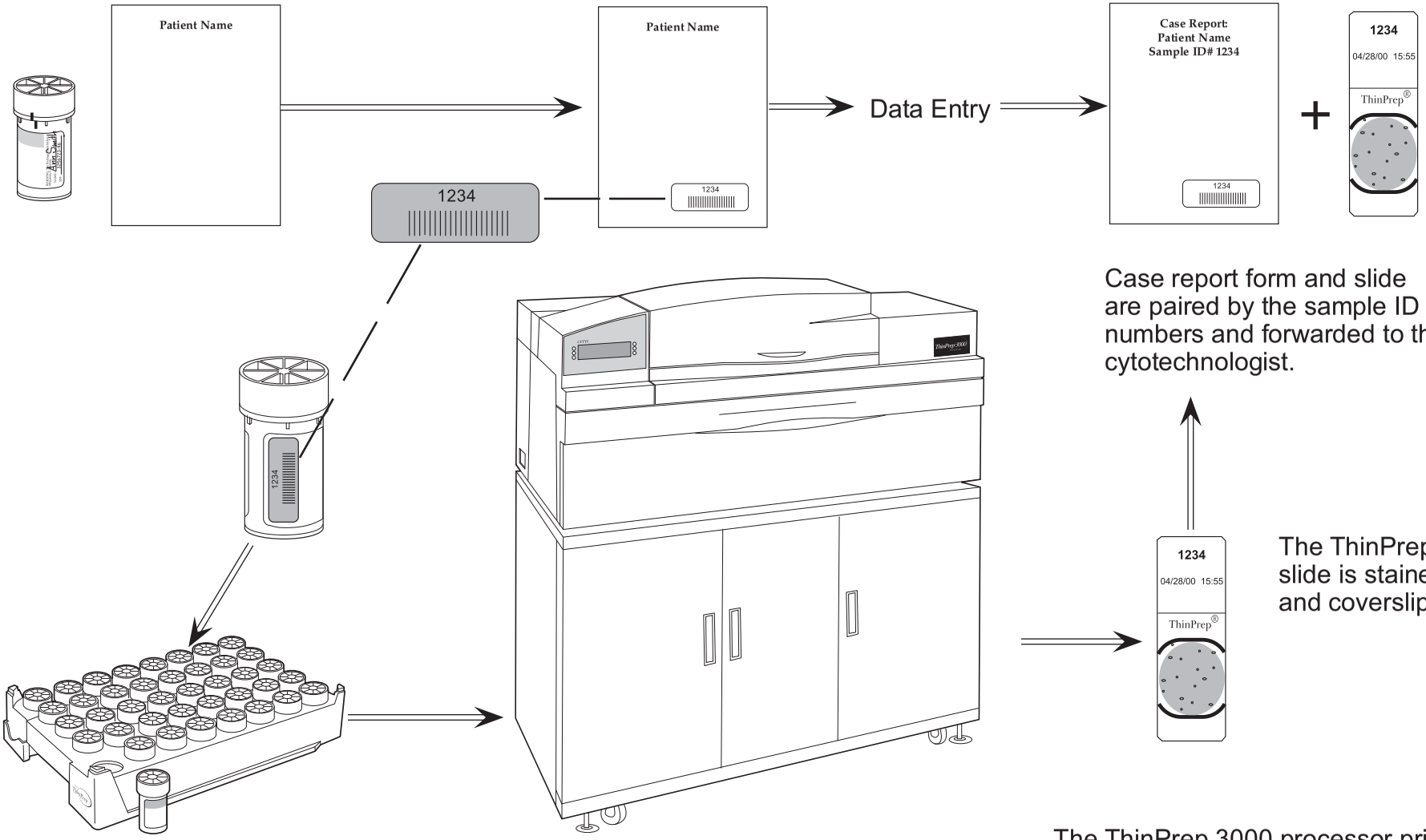
Appendix

ThinPrep 3000 Processor: Laboratory Flow

The ThinPrep® 3000 Processor: Laboratory Flow

The ThinPrep® Pap test sample vial and test request form arrive at the laboratory.

Matching barcoded labels containing unique ID numbers are placed on the sample vial and the test request form.



Case report form and slide are paired by the sample ID numbers and forwarded to the cytotechnologist.

The ThinPrep slide is stained and coverslipped.

The sample vials are loaded into the sample vial trays for processing.

The sample vial trays are loaded into the ThinPrep 3000 processor.

The ThinPrep 3000 processor prints the sample ID number that is read from the sample vial barcode label onto the slide, then processes the sample.

Barcode Label Specifications for the ThinPrep 3000 Processor

Bar Code Label Specifications
For the ThinPrep® 3000 Processor

A unique feature of the ThinPrep® 3000 processor is the ability to maintain chain of custody from the patient sample vial to the ThinPrep microscope slide. Chain of custody is achieved by the ThinPrep 3000 processor printing a numeric identifier on a ThinPrep microscope slide, which corresponds to the barcode on the sample vial. The numeric identifier is printed on the slide prior to processing. Note: If an alpha prefix or suffix is used in the sample ID number, the ThinPrep 3000 processor will not transfer letters, only numbers, to the microscope slide.

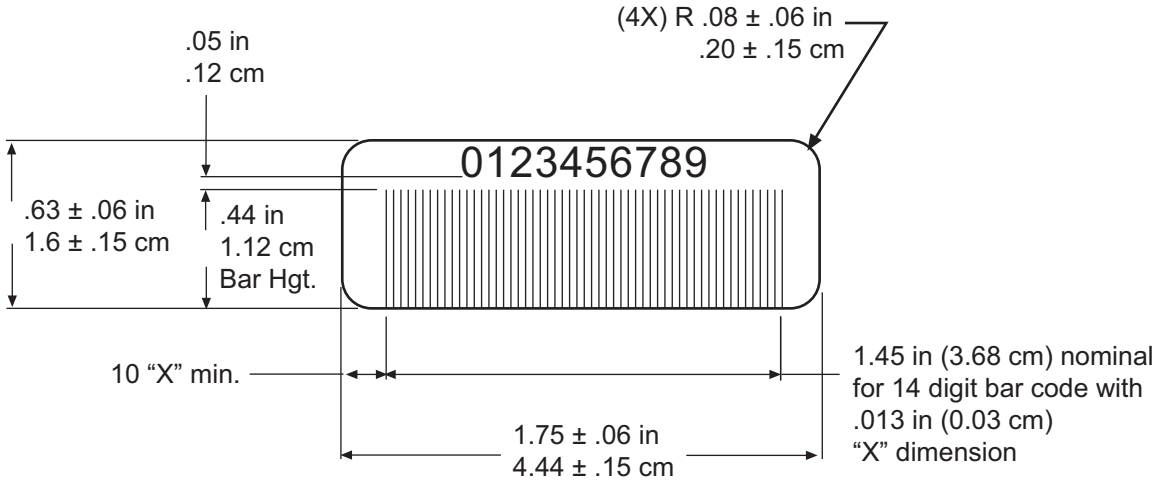
Many laboratories currently utilize barcode labels for specimen tracking. The barcode standard selected for use with the ThinPrep 3000 processor is one that is commonly used in many laboratories. The following information provides specifications for the barcode labels used with the ThinPrep 3000 processor.

Barcode Requirements

The barcode standard used is Code 128, Subset C, with .013 "X" dimension (narrow bar width).

1.) Black bars on blue-white face stock with rubber based adhesive on back.
2.) Label Contents: Up to 11-digit number, with a minimum of 5 digits.
3.) Printed as both a bar code and a 0.10-in.- (0.25-cm-) high human-readable number centered lengthwise on the label within 0.125 in. (0.317 cm).
4.) Print quality must meet requirements outlined in ANSI X3. 182.

Label Dimensions



Sample Vial Label Application Guide

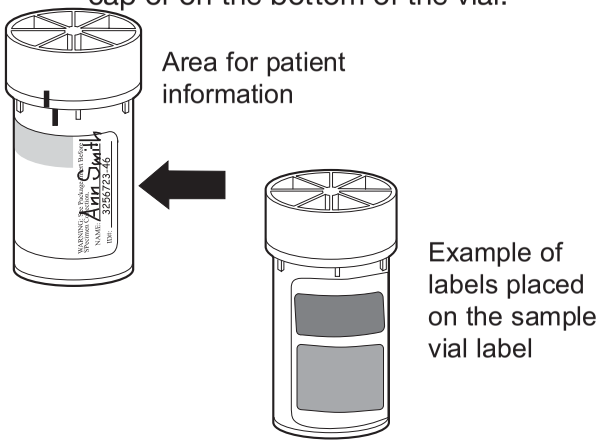
Sample Vial Label Application Guide
for use with the ThinPrep® 3000 Processor

Recommended Physician Protocol

The PreservCyt® Solution label has an area provided for recording patient information. For hand-written entries, use permanent markers or inks that will not easily rub off or blur.

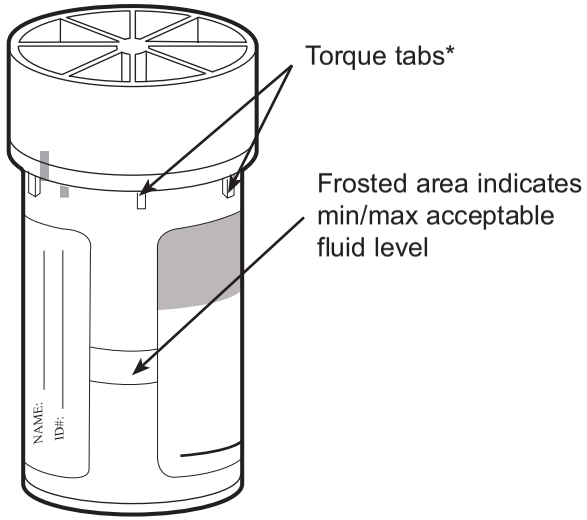
If your office or clinic prepares patient information via adhesive label, place the label over the PreservCyt Solution vial label. Additional labels may be applied, however take care not to overlap multiple labels.

- Apply labels smoothly and evenly, all edges should be flat and contacting the surface of the vial.
- Avoid overlapping or stacking labels on top of each other.
- When possible, limit the number of labels placed onto the vial.
- Do not place labels on top of the vial cap or on the bottom of the vial.



Proper application of labels onto the sample vial can avert some error conditions during slide processing.

The following protocols recommend the best placement of labels on the PreservCyt Solution vial for use with the ThinPrep Pap Test.



*The torque features on the vial enables the processor to grip, uncap and recap the vial. Leave the tabs and cap free of any obstruction.

Recommended Laboratory Protocol

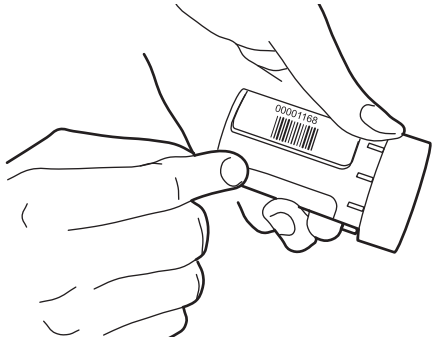
Place sample identification barcode labels lengthwise on the PreservCyt Solution vial. Use the edge of the sample vial label as a guide for applying the labels.

If additional labels were placed onto the sample vial by the physician prior to arriving at the laboratory, adhere the barcode label directly onto the sample vial lengthwise.

Avoid overlapping labels. Make certain no more than two labels are stacked together.

To reduce the possibility of instrument vial handling error,

- Make sure the barcode label is undamaged and readable.
- When applying the label to the vial, smooth all edges down. (Lifted edges may stick or tear during handling.)
- Apply the label vertically on the sample vial.
- Do not place any labels on the cap or the bottom of the vial.

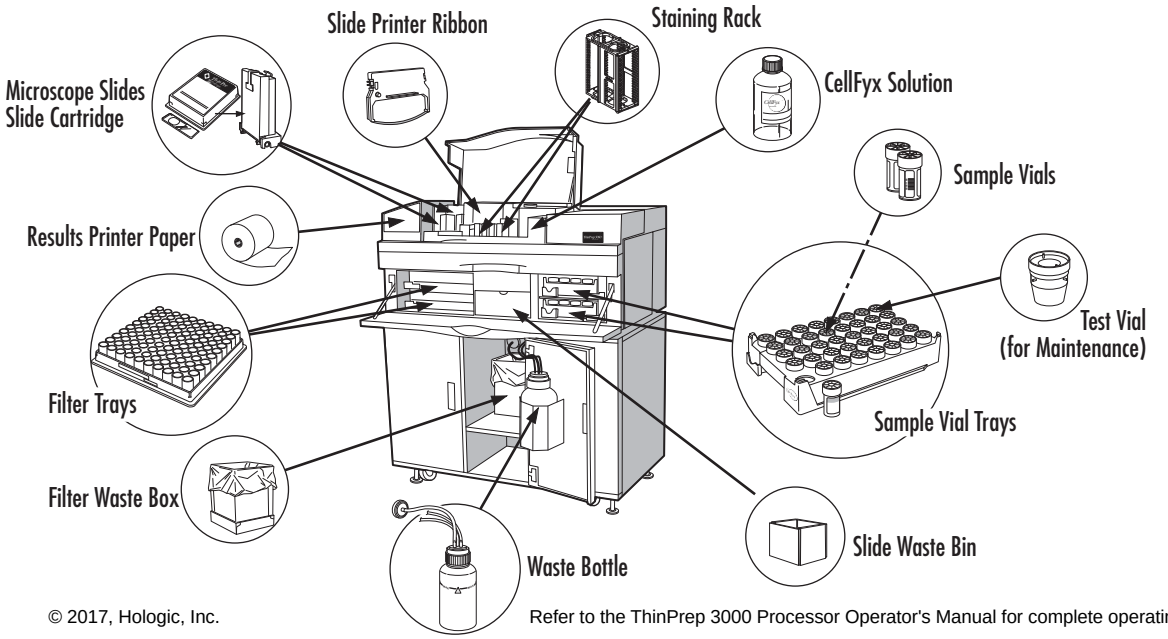


The ThinPrep® 3000 Processor Quick Reference Guide

Routine Operation

1. Apply Sample ID bar code to sample vials. Place vials in trays for processing.
2. Power on the ThinPrep 3000 Processor, if not already on.

   Wait for System Ready main menu screen.
3. Perform Lube O-Rings maintenance (only needed at the start of a shift).
4. Check/load supplies:
   - Filter trays (if a partial tray is present, do not remove it)
   - Slide cartridges
   - Empty staining racks
   - Sample vial trays
5. Perform Fixative Spray Preventative Maintenance if the instrument has been idle for more than an hour. See Daily Maintenance Section.
6. Close all doors.
7. Press **Start Batch**.
   - If the instrument detects missing or depleted supplies, read the message on the display and load or replenish those items. Close all doors and press **Continue** to begin processing.
   - If the instrument prompts for maintenance, read the message on the display and replace or empty the item(s) listed. Close all doors and press **Continue** to begin processing.
8. When the **Batch Complete** screen appears at the end of processing, open the instrument doors. Carefully remove staining racks and sample vial tray(s). Tear off the batch report and match report(s) to trays A and B. Identify any samples requiring reprocessing or further attention.



Daily Maintenance

Lubricate O-Rings

Lubricate the inner surface of the pneumatic test vial. Load it into tray position A1 of an empty sample vial tray. From the Maintenance menu, select **Lube O-Rings**.

Fixative Spray Preventative Maintenance

When the fixative menu screen appears, toggle the fixative dispense lever 3-4 times and press **Spray**. Repeat as needed.

Empty Slide Waste Bin

Remove the slide waste bin. If slides are present, check the print quality to see if the printer ribbon prints darkly enough. Dispose of any slides. Replace the slide waste bin.

Check Filter Waste Bin

Look in the filter waste bin to see if it needs to be emptied. Dispose of filters according to your laboratory guidelines.

Instrument-Prompted Maintenance

Pneumatic System Testing

Lubricate the inside surface of the pneumatic test vial. Load the test vial into tray position A1 of an empty sample vial tray. From the test menu, select **Pneumatic Test**.

Clean the Slide Path

Clean the slide translator, slide printer area, slide cell transfer arm, fixative spray area, staining rack area.

Empty Waste Bottle

Detach the waste bottle from the tubing connections, cap and remove. Dispose of liquid waste according to your laboratory guidelines. Lubricate the waste cap o-ring; reconnect the waste bottle.

Add Fixative Fluid / Insert Clean Fixative Shield

Fill the fixative reservoir with a bottle of CellFyx™ Solution.

Remove the plastic fixative shield and dispose of the removable cylinder. Replace it with a new one. From the Fixative Maintenance screen, press **Level** to recalibrate the fixative level.

Slide Printer Ribbon

Replace printer cartridge when prompted. Always be sure the ribbon is seated in the ribbon guide properly.

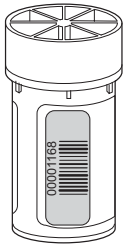
Refer to the ThinPrep 3000 Processor Operator's Manual for complete operating instructions.

Part No. AW-03369-001 Rev. 002

The ThinPrep® 3000 Processor Quick Reference Guide

TROUBLESHOOTING

Label Application



Proper application of labels onto the sample vial can avert some types of errors during slide processing. Some sample and system errors may actually be the result of a damaged or poorly placed adhesive label.

- Place the label vertically, *on* the PreservCyt® label. Do not cover patient information. If other labels are present, place the label where there is no overlap.
- When applying the label to the vial, smooth all edges down. (Lifted edges may stick or tear during handling.)
- Do not place any labels on the cap or the bottom of the vial.

Vial Operation (Area A)

⚠ **Sharp Edges/Hot Surfaces**

Removing the sample vial tray ends the batch being processed. Never remove sample vial trays unless the batch is complete, canceled or unable to complete due to a system fault.

A System Fault may be caused by:

- A dropped vial
- Labels applied improperly
- A foreign object in the sample vial
- Damage to the cap or vial
- Mechanical fault

If a system fault occurs, wait for the doors to unlock. Open the front door, remove the vial trays and inspect the bay for any dislodged vials or obvious obstruction. Let the instrument attempt to recover. If it does not, contact Hologic Technical Support.

Filter Operation (Area B)

⚠ **Sharp Edges/Hot Surfaces**

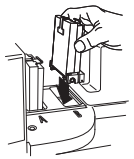
A system fault may be caused by:

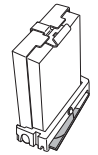
- A dropped filter
- A filter stuck on the processing arm or in the filter elevator
- Mechanical fault

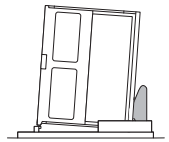
If a system fault occurs, wait for the doors to unlock. Open the front door, remove the filter trays and inspect the bay for any dislodged filters or obvious obstruction. Let the instrument attempt to recover. If it does not, contact Hologic Technical Support.

Slide Operation (Area C)

⚠ **Sharp Edges/Glass**





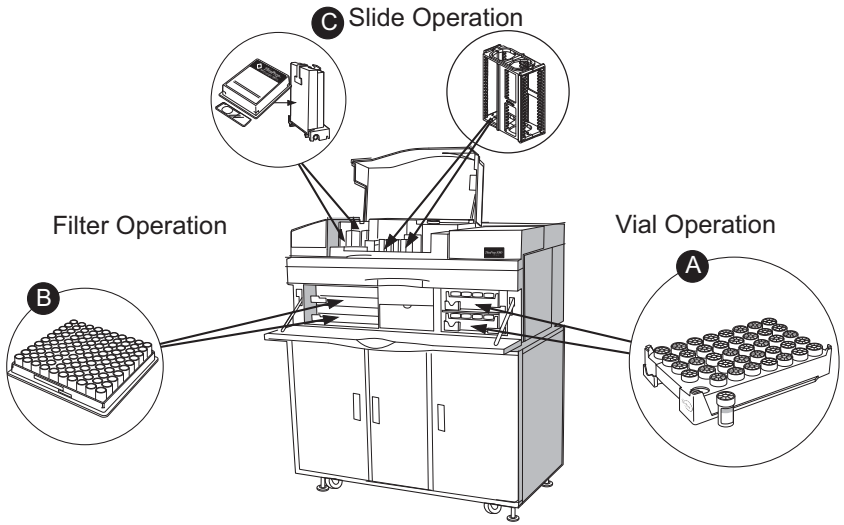


Load slides into the cartridge properly. Make sure the notched end of the cartridge matches the notched area on the box of slides before flipping the slides into the cartridge. Be sure the cartridge clicks shut entirely. The slide should issue from the cartridge frosted side up, the word "ThinPrep" reading left to right.

If slides jam when leaving the cartridge, remove cartridge from the cartridge well and make sure there is no glass dust or debris impeding the slide path.

If slides jam when being ejected into the staining rack, make sure the staining rack is properly seated flat in its cradle. Make sure the slide transfer arm and slide clamps are clean and free of fixative build up. (See Operator's Manual, Maintenance section.)

If a Slide Misprint error occurs, check the printer ribbon to see if it needs to be changed and that it is installed correctly. Check that the slides are loaded correctly in the cartridge and are not defective.



HOLOGIC®

ThinPrep® 3000 Processor

Operator's Manual

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