

AEROSPRAY[®]

TB

MODEL 7722

Applications Manual



SLIDE STAINER/CYTOCENTRIFUGE

AEROSPRAY® TB

SLIDE
STAINER/CYTOCENTRIFUGE

Model 7722

Applications Manual

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REF

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1.1 Aerospray TB Stainer Overview

Using this Manual

This manual provides instructions to install, operate, and maintain the Aerospray TB Stainer/Cytocentrifuge.

The manual is an important part of the product. Read it carefully and completely before setup and first use of the instrument.

If additional accident prevention and environmental protection requirements exist in the country of operation, this manual must be supplemented by appropriate instructions to ensure compliance.

Safety Regulations

This instrument has been built and tested in accordance with safety regulations for electrical control, regulating, and laboratory devices. In order to maintain this condition and ensure safe operation, the operator must observe all the instructions and warnings contained in this manual. For current information about applicable standards, please refer to the CE Declaration of Conformity included with the documents shipped with this device.

Understanding Warnings

This manual uses three warning levels to alert you to important information as shown in the following examples.



WARNING!

A Warning alerts to the possibility of personal injury, death, or other serious adverse reactions stemming from the use or misuse of this device or its components.



CAUTION:

A Caution alerts to possible problems with the device associated with its use or misuse. Such problems include device malfunction, failure, damage, damage to the sample, or damage to other property. Where applicable, a Caution may include precautions to be taken to avoid the hazard.

NOTE: A Note reinforces or supplies additional information about a topic.

Specific Warnings

Pay particular attention to the following safety precautions. If these safety precautions are ignored, injury or damage to the instrument may occur. Each individual precaution is important.



WARNING!

Place the stainer in an area with ventilation in accordance with local regulations.

SECTION 1

INTRODUCTION

1.1 Aerospray TB Stainer Overview



WARNING!

Reagents used in the Aerospray stainer contain moderately hazardous chemicals that require care in handling. Refer to the provided Safety Data Sheets (SDS). Always use appropriate safety measures including gloves and eye protection when handling reagents.



WARNING!

Always wear protective clothing and eye protection when using cleaning solutions (diluted SS-029C or SS-266) and stain residue solvent (SS-230). Dispose of used solution properly.



WARNING!

If power is lost while the stainer is running, the lid will remain locked until power is restored. Do not attempt to open the lid while power is off.



WARNING!

Electrical shock hazard: Do not open this instrument or attempt internal repairs. Refer servicing to qualified service personnel. Contact ELITechGroup Biomedical Systems service.



CAUTION:

This equipment has been designed and tested to CISPR 11 Class A and FCC Part 15 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. This equipment complies with the emission and immunity requirements described in the IEC 61326 series.



CAUTION:

To avoid serious instrument damage, never use reagents other than those supplied for this model stainer by ELITechGroup. Except for deionized or distilled water and approved alcohol, using reagents not supplied by ELITechGroup may void the warranty.



CAUTION:

Only spare parts supplied or specified by ELITechGroup should be used. Using non-approved parts may affect the performance and safety features of the instrument. If the equipment is used in a manner not specified by ELITechGroup the protection provided by the equipment may be impaired. If in doubt, contact your ELITechGroup representative.

Functional Description

The Aerospray TB stainer stains specimen smears on microscope slides to determine the presence of acid-fast bacilli (AFB) including *Mycobacterium tuberculosis* and other species which are part of the *Mycobacterium* genus. The TB stainer simulates traditional manual staining techniques and the stained slides are representative of traditional manual stains. The TB stainer is capable of either fluorescence or carbol fuchsin staining, depending on the reagents loaded on the instrument. For best results when using the Aerospray TB stainer, body fluid specimens should be digested and spread as thin as possible on the microscope slide prior to staining.

1.1 Aerospray TB Stainer Overview

Key Features

The key features of the Aerospray TB stainer are:

- Minimized reagent consumption
- Rapid staining
- Barcode scanner for tracking specimens and reagents
- Reagent and specimen traceability
- User traceability
- Administrator password
- Interactive touchscreen display
- Multiple languages
- High volume staining productivity (12 or 30 slides per stain cycle)
- Automatic clean cycle to purge each reagent spray nozzle (except D)
- Separate reservoir, delivery tube, pump, and spray nozzle for each reagent
- Stain sequence programmability
- Reagent and waste level monitoring
- Log files

The correct accessory must be used for each function. The Cytopro® Cytocentrifuge Rotor is available as an option offering additional features. See Section 8 for more information.

Intended Use

The Aerospray TB Slide Stainer/Cytocentrifuge (Model 7722) is a dual-purpose stainer intended for in vitro diagnostic use by medical professionals to stain microbiological specimens suspected of containing acid-fast organisms, a step in the standard laboratory practice of diagnosing disease. The use of Aerospray TB reagents is required for successful use of this instrument. Adding the optional Cytopro rotor allows preparation of slides by cytocentrifugation before staining.

SECTION 1 INTRODUCTION

1.1 Aerospray TB Stainer Overview

Table 1: General Specifications

Category	Characteristics
Slide Carousel Capacity	1 to 12 or 1 to 30, depending on carousel
Carousel Rotation Speed	From 10 to 1,000 rpm (pre-programmed). 100 rpm to 1,000 rpm \pm 5%_ 10 rpm to 99 rpm \pm 2 rpm.
Cytocentrifuge Rotor Speed	100 to 2000 rpm (\pm 5%), User programmable
Reagent Consumption	Refer to Approximate Reagent Consumption in Table A or B in Appendix D
Operating Time	Refer to Table A or B in Appendix D
Display	7 in. LCD WVGA (800 x 480 pixels) TFT
Touch Screen Controls	Menu driven icons
Drain Connection	Connector on rear panel accepts male connector attached 3/8" ID to vinyl drain tube. 1.8 meters (6 ft.) length supplied.
Ventilation	Air is exhausted from the stainer via a female ½ inch SAE pipe thread fitting to allow connection to ventilation systems.
Dimensions Width Height (lid closed) Depth Height (lid open)	57 cm (22 in.) 25 cm (10 in.) 54 cm (21 in.) 58 cm (23 in.)
Weight	17.5 kg (38.6 lb) unpacked 21.8 kg (48.1 lb) packed
Electrical Requirements	100 to 240 VAC @ 50 to 60 Hz
Power Consumption	200 VA
Overcurrent	Fuses (quantity-2) T2A250V
Ambient Temperature Operating Storage	15 to 30 °C (59 to 86 °F) -10 to 50 °C (14 to 122 °F)
Relative Humidity	\leq 80% non-condensing
Altitude	\leq 2000 m (\leq 6562 ft.)

SECTION 1 INTRODUCTION

1.1 Aerospray TB Stainer Overview

Table 1: General Specifications (continued)

Category	Characteristics
Pollution Degree	2
Heat Dissipation Maximum Average During Staining Average While Idle	150 watts (512 Btu/hour) 30 watts (102 Btu/hour) 12 watts (41 Btu/hour)
Maximum Sound Emission	Adjustable; maximum 60 dB (SPL) intensity @1m and <80 dB. (Typical-72 dB)

Table 2: Performance Specifications

Category	Characteristics
Reagent Spray Nozzles	Each reagent has a separate spray nozzle* to dispense the correct amount of reagent. *The D reagent sprays through two nozzles.
Reagents NOTE: Use only ELITechGroup reagents, with diluents as specified for ELITechGroup concentrated reagents. REF numbers for this stainer begin with one of the following: SS-061 or SS-161. See Appendix D for detailed information about reagents.	A - Decolorizer
	B - Counterstain
	C - Primary Stain (fluorescence or carbol fuchsin)
	D - Deionized or distilled water NOTE: Deionized or distilled water is not provided by ELITechGroup and must be obtained locally. Water should be filtered (0.2 micron inline filter) to remove bacteria and particulates.
	E – “Approved” ethanol, methanol, or reagent alcohol NOTE: Approved ethanol or methanol must be 99.5% pure. NOTE: Approved reagent alcohol must meet the following specifications: <ul style="list-style-type: none"> • Greater than 90% ethanol • Approximately 10% isopropyl alcohol or methanol • Less than 0.5% water • No ketones
Stain Settings	Up to 12 programs (stored)

SECTION 1

INTRODUCTION

1.1 Aerospray TB Stainer Overview

Table 3: Carousel and Rotor Information

Only the following slide staining carousels or cytocentrifuge rotor can be used in this instrument. Each should be used following the instructions in this manual or the Cytopro® Applications Manual (RP-517).











Rotor/Carousel	Maximum rpm	Maximum Capacity	Maximum Sample Volume
ELITechGroup 12-Slide Carousel (AC-188)	950 rpm (\pm 5%)	12 each, 26 mm x 76 mm (1 x 3 inch) microscope slides	N/A
ELITechGroup 30-slide Carousel (AC-189)	950 rpm (\pm 5%)	30 each, 26 mm x 76 mm (1 x 3 inch) microscope slides	N/A
Cytopro Cytocentrifuge Rotor (AC-160)	2000 rpm	8 each, standard chambers, plus slides	Up to 600 μ L*
		8 each, Cytopro Magnum chambers, plus slides	Up to 6 mL*
















*Do not overfill cytocentrifuge chambers. See Cytopro® Applications Manual or Methods Manual for detailed instructions and warnings.











SECTION 1 INTRODUCTION

1.1 Aerospray TB Stainer Overview

Table 4: Explanation of Symbols

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	SYMBOL MEANING
	IEC 60601- 1 Reference no. Table D1, Symbol 8 (IEC 60417-5032)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals
	ISO 15223-1: 2021 Reference no. 5.1.2	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community / European Union
	MU600_00_016e V3.0	Information Sheet Obligations Economic Operators CH	Swiss Authorized Representative	Indicates the authorized representative in Switzerland
	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. Synonyms for “batch code” are “lot number”, “lot code” and “batch number”.
	ISO 15223-1:2021 reference no. 5.4.1 (ISO 7010 – W009)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Warning; Biological hazard	Bio-contamination warning: Use care when operating upper cooling system and initiation needle.
	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Catalogue number Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified ISO 15223 Catalogue number ISO 7000 Catalog number
	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	EU 2017-746 Reference no. ANNEX V	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/ EEC and 2010/227/EU	CE marking	(43) ‘CE marking of conformity’ or ‘CE marking’ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonization legislation providing for its affixing
	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	ISO 15223-1:2021 Reference no. 5.4.2. (ISO 7000- 1051)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once”.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	SYMBOL MEANING
	ISO 15223-1: 2021 Reference no. 5.2.8. (ISO 7000-2606)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	ISO 15223-1: 2021 Reference no. 5.3.1. (ISO 7000-0621)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	IEC 60417-1 Reference no. ISO 7000-5016	Graphical symbols for use on equipment	Fuse	To identify fuse boxes or their location
	IEC-TR-60878 Reference no. ISO 7000-1135	Graphic symbols for use on electrical equipment in a medical practice	General symbol for recover/recyclable	To indicate that the marked item or its material is part of a recovery or recycling process
	ISO 15223-1:2021 Reference no. 5.5.1.	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	In Vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	ISO 15223-1: 2021 Reference no. 5.3.2. (ISO 7000-0624)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer
	DIRECTIVE 2012/19/EU (WEEE)	N/A	Collect separately	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required
	DIRECTIVE 2002/96/EC/WEEE	N/A	Waste stream disposal status	Do not dispose of electronic equipment in general waste stream.
	N/A	N/A	Open bottle stability	Indicates a reagent is stable after opening for the number of months specified
	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 15223-1: 2021 Reference no. 5.3.7. (ISO 7000-0632)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Use by date	Indicates the date after which the medical device is not to be used
	iso_grs_7010_W001	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	General warning sign	To signify a general warning
	GHS02	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	flammable	Medical device contains materials that are flammable. Appropriate caution should be taken

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	SYMBOL MEANING
	GHS03	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Oxidizing	Medical device contains materials that are oxidizing. Appropriate caution should be taken
	GHS05	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Corrosive	Medical device contains materials that are corrosive. Appropriate caution should be taken
	GHS06	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Toxic	Medical device contains materials that are toxic. Appropriate caution should be taken
	GHS07	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Harmful	Medical device contains materials that are harmful. Appropriate caution should be taken
	GHS08	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Health Hazard	Medical device contains materials that are a health hazard. Appropriate caution should be taken
	GHS09	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Environmental Hazard	Medical device contains materials that are an environmental hazard. Appropriate caution should be taken
	N/A	Administrative Measure on the Control of Pollution Caused by Electronic Information Products (China)	Environment Friendly Use Period	Indicates the period of time before any RoHS substances are likely to leak out causing harm to the environment.
	N/A	N/A	Do not use pumps	Indicates products are to be used for manual cleaning only. Do not pump the product through instrument.
	ISO 15223-1: 2021 Reference no. 5.3.8. (ISO 7000-2620)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Humidity limitation	Indicates the range of humidity t which the medical device can be safely exposed
	N/A	https://www.gov.uk/guidance/using-the-ukca-marking#when-to-use-the-ukca-marking	UKCA Mark	UK product marking that is required for medical devices being placed on the marketing in Great Britain.

SECTION 1 INTRODUCTION

1.2 Instrument Description

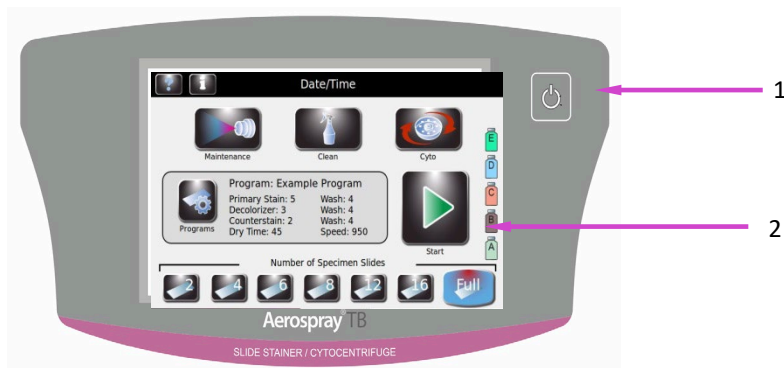
Figure 1: Front and Right Side Panels



- 1 – Optional 30-slide Carousel
- 2 – Front Panel with Touch Screen Display
- 3 – Bowl
- 4 – 12-slide Carousel
- 5 – Lid with Safety Lock
- 6 – Right Side Panel with Label Indicating Reagent Positions:
 - A – Decolorizer
 - B – Counterstain
 - C – Primary Stain
 - D – Deionized or Distilled Water
 - E – Approved Alcohol
- 7 – Reagent Tray

1.2 Instrument Description

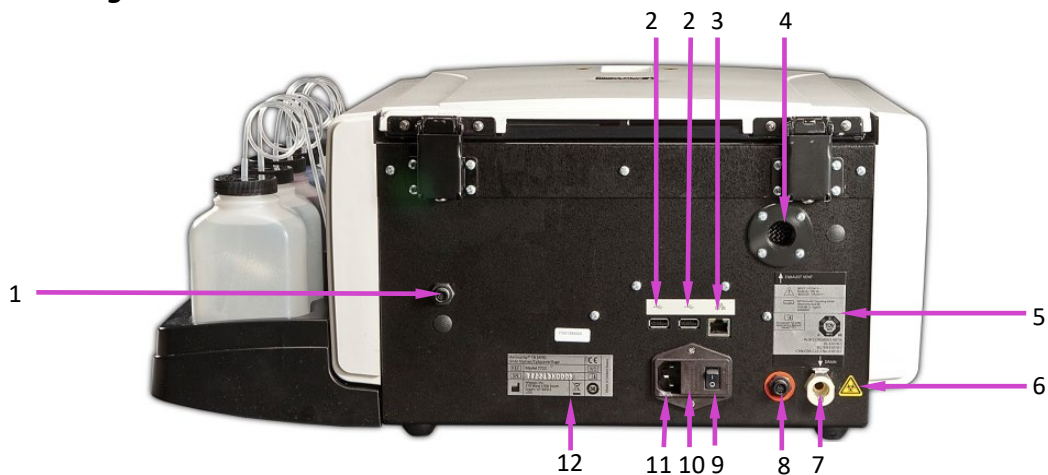
Figure 2: Front Panel and Touchscreen



- 1 – Standby/Ready Button
- 2 – Touchscreen

The front panel features an interactive touchscreen display. Refer to Touchscreen and User Interface (Section 1.3) for more information.

Figure 3: Rear Panel

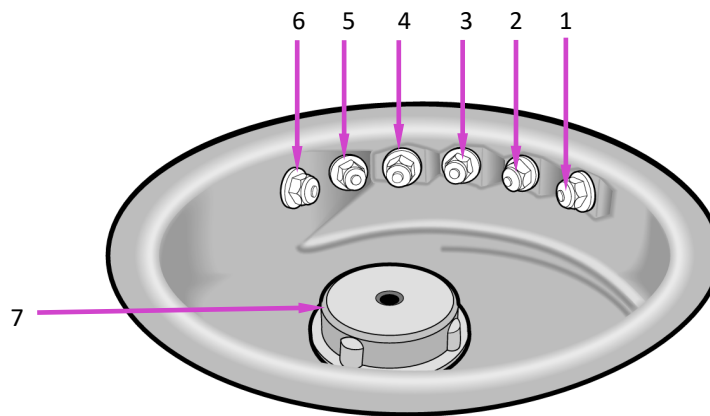


- 1 – Level Detect Connection for Reagent D (deionized or distilled water)
- 2 – USB Ports
- 3 – Network Ethernet Connection
- 4 – Exhaust Vent
- 5 – Rear Panel Label
- 6 – Biohazard Warning Label
- 7 – Drain Tube Connection
- 8 – Level Detection Connection for Waste Container
- 9 – Power Switch
- 10 – Fuse Door
- 11 – Power Cord Connection
- 12 – Model/Serial Number Label

SECTION 1 INTRODUCTION

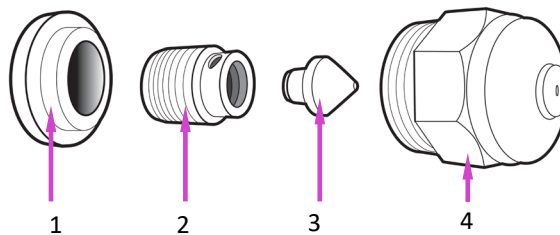
1.2 Instrument Description

Figure 4: Stainer Bowl Components



- 1 – Nozzle D_F (Deionized or Distilled Water, front)
- 2 – Nozzle A (Decolorizer)
- 3 – Nozzle B (Counterstain)
- 4 – Nozzle C (Primary Stain)
- 5 – Nozzle E (Approved Alcohol)
- 6 – Nozzle D_R (Deionized or Distilled Water, rear)
- 7 – Drive Hub

Figure 5: Nozzle Diagram



- 1 – Nozzle Insert
- 2 – Compression Screw
- 3 – Swirl Cone
- 4 – Nozzle Housing

SECTION 1 INTRODUCTION

1.2 Instrument Description


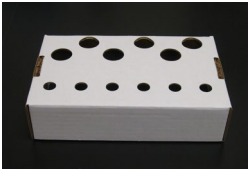
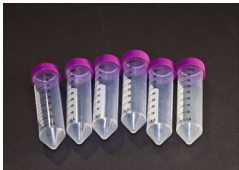
Table 5: Preventive Maintenance Kit

Component	Name	Description
	Manual Priming Tool	Primes air-locked pumps
	Silicon Grease	Lubricates the nozzle threads for easy assembly
	Nozzle Wire	Cleans nozzle housing orifices
	Nozzle Cleaning Strainer	Holds nozzle parts to prevent loss during cleaning
	Nozzle Tool	Unscrews nozzles from the stainer bowl
	Nozzle Wrench	Disassembles the nozzle
	Nozzle Brush	Cleans nozzles without removing them from the stainer

SECTION 1 INTRODUCTION

1.2 Instrument Description

Table 5: Preventive Maintenance Kit (continued)

Component	Name	Description
	Volume Test Collection Tubes (small tube)	Collects reagents while performing the Volume Test
	Nozzle Maintenance Tube Stand	Holds Nozzle Cleaning Tubes (large tube) and Volume Test Tubes (small tube)
	Nozzle Cleaning Tubes (large tube)	For soaking nozzles in the Nozzle Cleaning Solution

Barcode Reader

An optional barcode reader is available for use with the Aerospray TB Stainer/Cytocentrifuge (Model 7722).

Figure 6: Barcode Reader



Other Needed Items

The following parts are not available worldwide from ELITechGroup, but they can be obtained locally:

- Approved alcohol (methanol, ethanol, or reagent alcohol)
- Deionized or distilled water

Empty bottles are available from ELITechGroup.












CAUTION:

ELITechGroup does not provide approved alcohol. It should be purchased locally, observing the recommendations for safety and chemical risk on the Safety Data Sheet (SDS).

1.3 Touchscreen and User Interface

Users control all instrument functions from the interactive touchscreen display.

Table 6: Front Panel/Main Screen Function Keys

Button	Name	Description
	Standby/Ready	With instrument power ON: Blue = Ready Amber = Standby Pressing Standby runs a Clean cycle and places instrument in standby mode The Standby/Ready button also accesses the touchscreen calibration function (Section 7.4).
	Maintenance	Accesses features for verifying proper nozzle performance and places pumps in a testing sequence. Accesses the line priming, Pattern Test, Volume Test, and Line Flush functions
	Clean	Performs the Clean cycle
	Cyto	Enters the Cytocentrifuge mode
	System Information	Shows the system information, including serial number and software version. Allows access to the System Setup features. Refer to System Setup Menu, (Section 3.1)
	Help	Opens the Help file
	Programs	Allows users to select or edit stain programs
	Start/Load Slides	Begins a cycle in Stain or Cytocentrifuge mode. The Start button is inactive until a program is created. Refer to Creating a Stain Program in Section 3.1 With Slide Tracking enabled, opens the Scan and Load Slides menu, (Section 3.2)
	Number of Specimen Slides	Used to enter the number of specimen slides in the carousel. Users staining an odd number of specimen slides should enter the next higher specimen slide number icon

SECTION 1 INTRODUCTION

1.3 Touchscreen and User Interface

Table 6: Front Panel/Main Screen Function Keys (continued)


























Button	Name	Description
	Back	Returns to the previous menu
	Stop	Aborts any operation
	OK	Indicates completion of current task
	System Setup	Allows users to modify the software settings. See System Setup menu, (Section 3.1)

Table 7: System Setup Keys

Button	Name	Description
	Stain Programs	Allows users to create, edit, and delete stain programs
	Cyto Programs	Allows users to create, edit, and delete cytocentrifuge programs
	Reagents	Allows users to edit reagent information
	Users	Allows users to create and change user accounts
	QC/Maintenance Tracking	Enables slide tracking, preventive maintenance tracking, and reagent tracking
	Level Detect	Allows users to manage the automatic reagent level detection system
	Language	Allows users to change the display language
	System Log	Allows users to control logging functions
	Network Settings	Allows users to change network settings
	Beeper	Allows users to change audible alerts

1.3 Touchscreen and User Interface








Table 7: System Setup Keys (continued)

Button	Name	Description
	Set Date/Time	Allows users to set the date and time
	Restore Defaults	Restores programming to default settings
	Login	Enters Login sequence for authorized users
	Logout	Logs authorized users out. Users must log in again to use the stainer
	Save	Saves the entered or selected information.
	Add	Enters programming mode for creating staining and cytocentrifuge programs. Also allows the system administrator to authorize new users. Allows manual entry of slide or specimen information
	Delete/Erase/Remove	Deletes or erases the selected item
	Edit/Change User	Allows editing of an existing stain or cytocentrifuge program. Allows manual entry of slide or specimen information (stain or cytocentrifuge mode). Also allows system administrator to edit user information
	Zero	Zeros the Level Detect sensors
	Calibrate	Calibrates the Level Detect system
	Unselected	Shows an unselected option
	Selected	Shows a selected or enabled option

SECTION 1 INTRODUCTION

1.3 Touchscreen and User Interface

Table 8: Maintenance Function Keys

Button	Name	Description
	Prime A, B, C, D, E	Primes the selected line
	Prime ABCDE	Primes all lines simultaneously
	Pattern Test	Performs Slide Pattern or Hub Pattern Test to ensure nozzles are clear of debris and spraying properly
	Volume Test	Performs Volume Test to verify the selected nozzle volume is within the correct range
	Line Flush	Performs Line Flush function for B and/or C reagent lines
	60-Sec Prime	Runs the pumps for 60 seconds and primes the lines
	QC/PM	Shows the Preventive Maintenance and Quality Control logs (must be enabled from the System Setup menu)

SECTION 2

SETUP AND PREPARATION FOR OPERATION

2.1 Instrument Setup

Unpacking and Installing the Stainer

Follow this sequence if you are using this instrument for the first time. Details about these operations are given in the next three sections.

- Install the drain tube
- Plug in the power cord and switch the power on
- Install all reagent bottles
- Install the barcode reader (optional)
- Prime all reagent lines
- Perform the Clean cycle
- Zero the automated reagent level detect sensors
- Perform the Hub Pattern and Spray Volume tests



CAUTION:

Contact ELITechGroup before installing the instrument if you observe any damage to the packaging or equipment.

- 1 Unpack and inspect the instrument.
- 2 Check that the contents of the boxes match the packing lists for instrument and accessories.
- 3 Open the instrument lid and remove the cardboard tube that protects the instrument hub.

NOTE: Keep the box and packaging material to repack the instrument if you intend to ship it to the manufacturer for service.

- 4 Place the instrument on a flat surface, free from dust and vibration and away from direct sunlight.

NOTE: Position the instrument with the rear panel at least 30 cm (12 in.) from obstructions or hazardous materials.

SECTION 2

SETUP AND PREPARATION FOR OPERATION

2.1 Instrument Setup

Connecting the Drain Tube and Waste Container



- 1 Insert the waste tube connector into the rear panel receptacle until you hear a click.
- 2 Adjust the tube length to less than 1.8 m (72 in.).



CAUTION:

Keep the drain tube straight and as short as possible. The maximum length is 1.8 m (72 in.). The waste container must be positioned lower than the stainer.

NOTE: Ensure the waste tube has no loops or kinks, and is as straight and as short as possible. Cut off excess tubing as needed.

- 3 Connect the drain tube to the waste container.

If using a waste bottle with level detect (AC-182):

- 4 Connect the waste monitoring cable to the rear panel receptacle.
- 5 Connect the waste monitoring cable to the waste container lid.

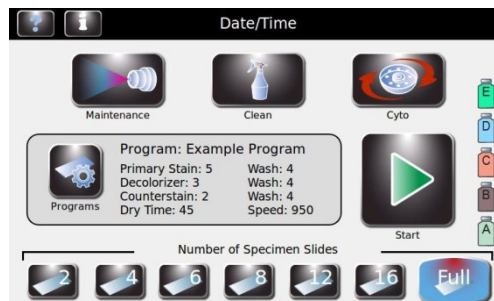


Connecting Power

- 1 Make sure the power switch is **OFF** (O).
- 2 Plug the power cord into the power connector on the rear panel of the instrument.

NOTE: Use a surge protector to isolate the instrument from spikes and surges.

- 3 Plug the power cord into a properly rated AC electrical outlet.
- 4 Turn the power switch **ON** (I). After a brief delay the Main menu will appear.



SECTION 2 SETUP AND PREPARATION FOR OPERATION

2.1 Instrument Setup

Installing Standard 500 mL Reagent Bottles



WARNING!

Reagents used in the instrument contain moderately hazardous chemicals that require care in handling. Always handle reagents using appropriate safety measures, including gloves and eye protection.



NOTE: Reagents should be stored according to the conditions specified on their label. After opening, reagents are stable for 90 days unless otherwise indicated by the symbol shown at left.

- 1 Place the reagent bottles front to back according to the particular staining option desired. Be sure reagents are in the correct position. **Switching between staining options may require instrument programming changes (Section 3), specific combinations of reagents (Appendix D), and cleaning certain reagent lines.**



CAUTION:

When switching between carbol fuchsin and fluorescence staining the user must perform a B-Line Flush (Section 6.5) before installing potassium permanganate.



CAUTION:

Users must adjust the stain programming, depending upon the type of staining (carbol fuchsin or fluorescence) desired, which reagents are being used and user preferences. Refer to Appendix D for complete information.



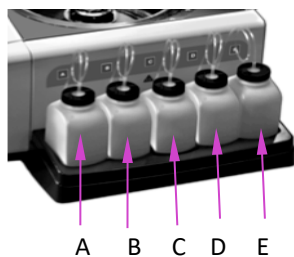
CAUTION:

The stainer cannot detect which reagents are loaded on the instrument. The user must take care to load the correct reagents in the correct positions, based upon the options given here and user preference.



WARNING!

Each new stainer ships with a pink label attached to the B reagent line. This label indicates that the B-line must be flushed with 100 mL of DI water before installing potassium permanganate.



- 2 Place each 500 mL reagent bottle in the correct position.

- (A) Decolorizer
- (B) Counterstain
- (C) Primary Stain
- (D) Deionized or Distilled Water
- (E) Approved Alcohol

SECTION 2

SETUP AND PREPARATION FOR OPERATION

2.1 Instrument Setup

NOTE: See Appendix A and Appendix D for complete identification of all reagents used in this stainer.



CAUTION:

To avoid severe damage, never use reagents containing organic solvents in this instrument, unless supplied by ELITechGroup, or specified in official ELITechGroup formulation instructions.

NOTE: Immediately remove spills in the reagent tray to preserve the accuracy of the reagent level detecting system.

3 For all reagents using the standard 500 mL bottles:

- Open a new bottle of reagent. Use empty 500 mL bottles for reagents D and E with user-supplied DI water and alcohol (see specifications in Table 2).
- Record the reagent letter on each cap and retain for future use (such as long-term storage).
- Insert the corresponding dip tube and bottle adapter into the reagent bottle and install the ring cap.

SECTION 2

SETUP AND PREPARATION FOR OPERATION

2.1 Instrument Setup

Installing the 5 Liter Reagent Bottle

NOTE: A 5 Liter (L) bottle for reagent D is available. If using the 5 L bottle, install it near the side or back of the instrument not in the instrument tray.

NOTE: If using the 5 L bottle, you must replace the standard dip tube with the longer dip tube that comes with the 5 L bottle.



- 1 Cut the existing dip tube just before the standard dip tube coil.
- 2 Connect the 5 L bottle dip tube to the cut end of the existing dip tube.
- 3 Insert the dip tube into the 5 L reagent bottle and install the ring cap.
- 4 Place the 5 L bottle in a vertical position at the same level as the instrument.
- 5 Install the reagent detection cable from the 5 L bottle cap to the connector on the back of the instrument.
- 6 Refer to Using Reagent Information Tracking in Section 3.1 for more information on tracking reagents manually or using a barcode reader.
- 7 Refer to Modifying Level Detect Functions in Section 3.1 to enable reagent monitoring.

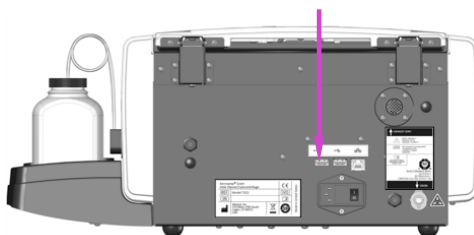
Installing the Barcode Reader

A barcode reader can be connected to the stainer for scanning reagent bottles and specimen slides that contain barcodes. This allows easy reagent and specimen information tracking. If a barcode reader is not installed, reagent and specimen information can be entered manually (Section 3.2).



Installing the Barcode Reader

- 1 Place the barcode reader and stand on a level surface near the stainer.
- 2 Plug the barcode reader into the *left* USB port on the rear panel of the stainer. See Section 3.2 for instructions on using the barcode reader.



SECTION 2

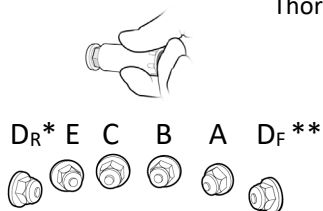
SETUP AND PREPARATION FOR OPERATION

2.2 Preparing the Stainer for Operation

Priming Procedures

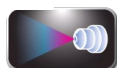
NOTE: The instrument is shipped with alcohol in the reagent lines. For proper performance, this alcohol must be replaced with the correct reagent for each reagent line prior to use.

Thoroughly purge and prime each reagent delivery line using the following instructions.



* D_R = D Rear

**D_F = D Front



- 1 Remove each spray nozzle with the provided nozzle tool by turning counterclockwise.
 - 2 Note the location of each nozzle so you can return it to the original position during reassembly.
 - 3 Place a carousel on the stainer hub to prevent stain from entering the motor shaft.
- CAUTION:**
Fluid from priming can flood and damage the motor if the drain tube is not properly installed.
- 4 Press **Maintenance** from the Main menu.
 - 5 Press the **A** prime button. Stain should appear within 10 seconds. When properly primed, a steady stream of reagent (no sputtering or breaks) flows from the nozzle receptacle.
 - If stain appears, proceed to the next step.
 - If stain does not appear within 10 seconds, perform the manual priming procedure in Section 6.3.



CAUTION:

Never operate a dry pump for more than 10 seconds. Operating a dry pump may cause damage to the instrument.

- 6 Repeat the previous steps for each nozzle (B, C, D, and E). When the D prime button is pressed, most of the reagent will come out of the D_R position. With nozzles installed, reagent should spray equally from D_R and D_F.

SECTION 2 SETUP AND PREPARATION FOR OPERATION

2.2 *Preparing the Stainer for Operation*

Priming Procedures (continued)



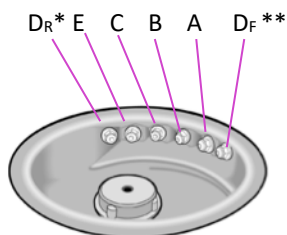
- 7 Press **60-Sec Prime** to prime each reagent line with at least 200 mL of reagent to remove all of the alcohol from the reagent lines and pumps.

- 8 Choose one of the following:



- For initial setup, press **ABCDE** to prime all lines simultaneously.
- To prime individual lines, press the appropriate individual prime button (A, B, C, D, E).

The pumps will run for 1 minute and prime the selected lines. Run at least 200 mL of reagent through each reagent line.



* D_R = D Rear

**D_F = D Front

- 9 Return the nozzles to their original positions and tighten clockwise with the nozzle tool.
- 10 With the nozzles installed, repeat Steps 5 and 6. A fine cone of spray should come from each nozzle.
- 11 After verifying nozzle performance, run the Clean cycle (see below).

SECTION 2

SETUP AND PREPARATION FOR OPERATION

2.2 Preparing the Stainer for Operation

The Clean Cycle

NOTE: The Clean cycle uses 20 mL of alcohol divided equally among nozzles C and E to clean the carousel and stainer bowl after staining. Water is sprayed from the D and B nozzles and Reagent A is sprayed from the A nozzle. Pressing Standby/Ready performs the same function.

- 1 Place an empty carousel in the instrument and close the lid.



CAUTION:

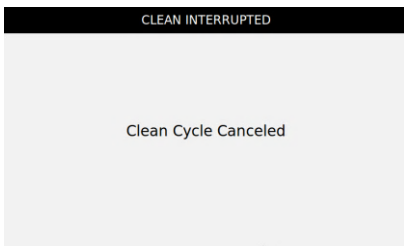
Never place any carousel loaded with specimens in the instrument for a Clean cycle (including placing the instrument in standby mode). Specimens will be damaged if they contact reagents sprayed from the nozzles when you press Clean or Standby.



- 2 Press **Clean**.



NOTE: Pressing Stop during the Clean cycle causes the Incomplete Clean message to be displayed. Press Clean to complete the interrupted cycle.



- 3 Open the lid and remove the carousel when the Clean cycle is complete.
- 4 Spray the interior of the bowl with 70 to 100% methanol or ethanol. Wipe the stainer bowl dry with paper towels.

NOTE: Perform the Storing the Instrument procedure (Section 5.2), if the instrument will remain idle for more than 1 week.

NOTE: At the end of a Clean cycle, cleaning reagents (alcohol or water) remain in the nozzles. These are primed out of the nozzles during the first steps of a stain cycle.

Performing Tests

You must perform the Pattern Test and Volume Test before using the instrument. See Section 6, Nozzle Maintenance and Performance.

SECTION 2 SETUP AND PREPARATION FOR OPERATION

2.2 Preparing the Stainer for Operation

Reagent Level Monitoring



Reagent Level Detect monitors reagent levels and alerts you when the reagent is running low, or when the waste container is full (when using the waste container with level detect). You can turn reagent and waste container monitoring ON or OFF from the Level Detect menu. The system default is ON for reagent monitoring and OFF for waste container monitoring.

NOTE: The instrument must be installed on a flat, level surface for accurate monitoring of the reagents.

Disable the Level Detect function for any line not using the standard 500 mL bottle, except Line D. Line D features a level detection option for the 5 L external bottle.



CAUTION:

This system is designed to warn you when the reagent level is getting low. The instrument will continue running through these warnings. The user must monitor and replenish the reagent before running a stain cycle.

Enabling/Disabling Reagent Level Detect



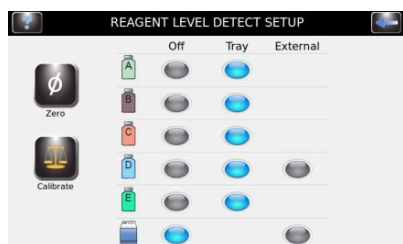
- 1 Press **Information** from the Main menu.



- 2 Press **System Setup**.



- 3 Press **Level Detect**. The display shows:



- 4 Press **Tray** to enable, or **OFF** to disable a reagent line. Functions are grey when unselected, blue when selected. Press **External** to enable the external level detect for the D reagent line (when using the 5 L bottle). Press **External** to enable level detect for the waste bottle.



- 5 When finished, press **Back** to exit to System Setup menu.

SECTION 2

SETUP AND PREPARATION FOR OPERATION

2.2 Preparing the Stainer for Operation

Zeroing the Reagent Level Sensors

The Level Detect function must be zeroed at initial setup, when the stainer is moved, or if the level detect is not reporting correctly. If zeroing does not correct the problem, recalibrate the Level Detect function (Section 7.3).



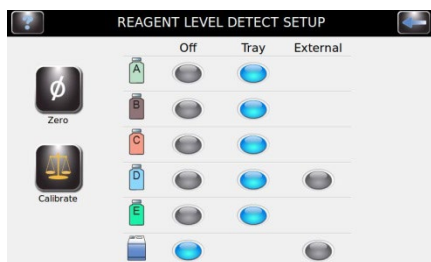
1 Press **Information**.



2 Press **System Setup**.



3 Press **Level Detect** to enter the Reagent Level Detect Setup menu:



NOTE: The stainer should be turned ON for at least 30 minutes before zeroing to stabilize level sensors. The instrument can be used during this time.



4 Press **Zero**. The display shows:



SECTION 2 SETUP AND PREPARATION FOR OPERATION

2.2 Preparing the Stainer for Operation



- 5 Remove all reagent bottles and press **Start**. The display shows:



NOTE: Vibrations or bumps to the instrument or lab bench can cause inaccuracies in zeroing or calibration.



- 6 After zeroing, press **OK**. Press the **Back** button to exit to the System Setup menu.



- 7 Return the reagent bottles to their correct positions in the tray.

NOTE: For accurate reagent level detection and calibration, dip tubes must follow their pre-formed coiled shapes.

SECTION 3

CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

Many software settings can be controlled from the System Setup menu, including:

- Creating, editing, and deleting stain programs
- Creating, editing, and deleting cytocentrifuge programs
- Tracking reagent information
- Managing user accounts
- Enabling tracking features for slides, preventive maintenance, and reagents
- Managing reagent and waste level sensing
- Changing the display language
- Viewing and exporting the system log
- Changing beeper settings
- Setting the date and time
- Restoring default settings

Accessing the System Setup Menu



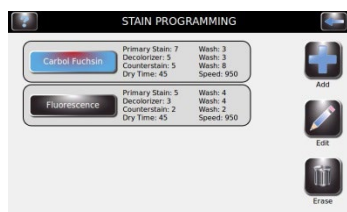
1 Press **System Information** from the Main menu.



2 Press **System Setup**.



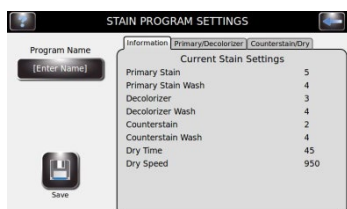
Creating a Stain Program



1 From System Setup, press **Stain Programs**.

2 Press **Add**.

3 Press **Enter Name**.



4 Enter a program name in the Program Name field.

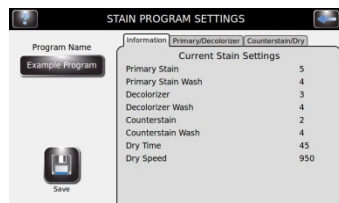
5 Adjust the settings (see Adjusting Stain Settings on the next page). Information concerning stain setting options is found in Appendix D.

6 Press **Save**.

SECTION 3 CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

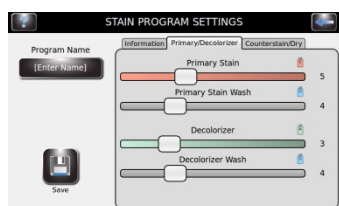
Editing a Stain Program or Adjusting Stain Settings



1 From System Setup, press **Stain Programs**.

2 Select the program to be modified.

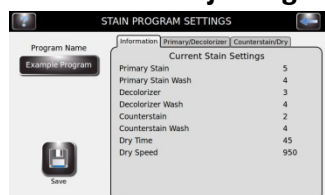
3 Select the **Primary/Counterstain** or **Counterstain/Dry** tab.



4 Modify the desired staining parameters using the sliding tabs.

5 Press **Save**.

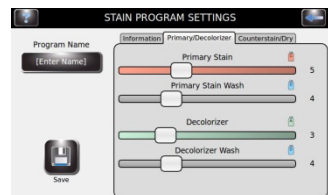
Adjusting Stain Settings



1 From Stain Settings menu, select the **Primary/Decolorizer** or **Counterstain/Dry** tab.

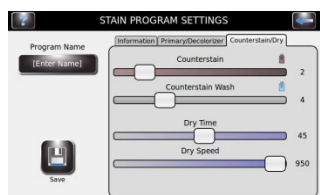
2 Select and adjust the desired stain parameter using the sliding tab.

3 Press **Save**.

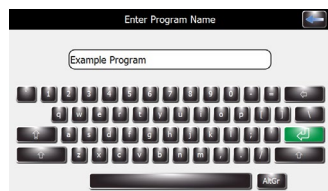


4 Refer to Performing a Stain Cycle in Section 4 to begin staining specimens.

NOTE: See additional information about editing or adjusting stain programs in Appendix D.



Changing the Program Name



1 From the Stain Program Settings menu, select **Program Name**.

2 Enter the program name.

3 Press **Enter**.

SECTION 3

CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

Administrator and User Accounts

You can create one Administrator account and multiple (up to 50) user accounts. The administrator controls access to the system by adding and editing user accounts. Users cannot edit System Settings unless permitted by the administrator.

Creating an Administrator Account

- 1 From System Setup, select **Users**.
- 2 Select **Lock System Setup Access**.
- 3 Enter a password for the Administrator account (at least 4 characters).
- 4 Re-enter the password to confirm.

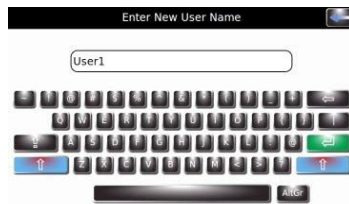
Creating User Accounts

- 1 Select **System Setup**.
- 2 Enter the Administrator password.
- 3 Press **Users**.
- 4 Select **Enable Global Login**.
- 5 Select **Add User**.
- 6 Enter a user name.
- 7 Press **Enter**.
- 8 Enter a numeric passcode (at least 4 numbers) for the user account.
- 9 Press **Enter**.
- 10 Re-enter the same passcode to confirm.
- 11 Press **Enter**.

Managing User Access

On the Manage Users screen, the Administrator has several options to manage user access to the instrument.

- Enable Global Login allows users to log in to the instrument. Users will log out manually or automatically (with user-selectable time options). See User Login/Logout below.



SECTION 3 CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

Managing User Access (continued)

- Enable Run Login requires the current user to enter a password to run a Stain or Cytocentrifuge cycle. Global Login must be enabled to use this option.
- User System Access enables complete control of the instrument, including changing the System Setup options. This option can be controlled on an individual user basis, if Global Login is enabled.

User Login/Logout

With System Access locked and Global Login enabled, users must log in to use the stainer:



- 1 Select **User ID** and select a time from the **Logout After Idle** drop-down menu.
- 2 Press **Login**.
- 3 Enter the correct passcode for the selected user and press **Enter**.
- 4 The stainer returns to the Main menu and is ready for programming and staining.
- 5 Once Login is complete, the stainer advances to the Main screen. A Logout button and the user name appears at the top right of the Main screen.

Using Reagent Information Tracking

You can enter reagent information to help track reagent usage and expiration. Reagent information includes reference number, expiration date, lot number, date and time the reagent was last installed.



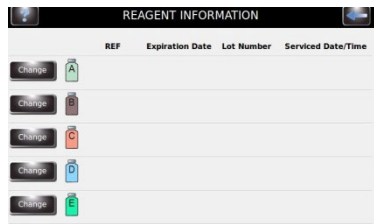
- 1 From System Setup, select **QC/Maintenance Tracking**.
- 2 Select **Enable Reagent Tracking** by choosing reagent A, B, C, D, or E. This enables reagent lot number and expiration date tracking.
- 3 Select **Back** to return to System Setup.
- 4 Select **Reagents**.

SECTION 3

CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

Using Reagent Information Tracking (continued)



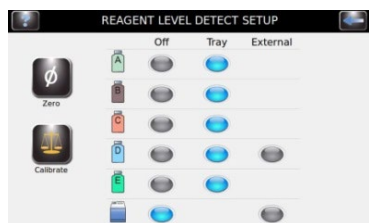
- 5 Select **Change** next to the appropriate reagent.
- 6 Scan the reagent bottle barcodes (Section 3.2) or manually enter the reagent information in the correct fields.
- 7 Select **Save** for each reagent. Repeat steps 5-7 for each reagent.

Modifying Level Detect Functions

The Level Detect function alerts you when the reagent is running low, or when the waste container is almost full. You can turn reagent and waste container monitoring ON and OFF from the System Setup screen. The system defaults to ON for reagent monitoring and to OFF for waste container monitoring. See Section 2.2 for complete instructions.



- 1 From System Setup, select **Level Detect**.



- 2 Select the reagent monitoring options to be modified.
 - To disable monitoring, select **OFF** next to the appropriate reagents.
 - To enable monitoring, select **Tray** next to the appropriate reagents.
 - Press **External** if you are using a 5 L bottle for reagent D.
 - To monitor the waste container, select **External**.

Changing User Language



- 1 From System Setup, press **Language**.
- 2 Select the software language from the list on the left.



- 3 Select **OK**.

Setting the Date and Time



- 1 From System Setup, press **Set Date/Time**.
- 2 Choose **12** for a 12-hour clock or **24** for a 24-hour clock.



- 3 Use the up and down arrows to modify the time and date.
- 4 Press **Save**.

SECTION 3 CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

System Log

The instrument records all login, logout, stain or cytocentrifuge cycles, setting changes, maintenance functions and specimen identification (if enabled).

Accessing Logs



- 1 From System Setup, press **System Log**.

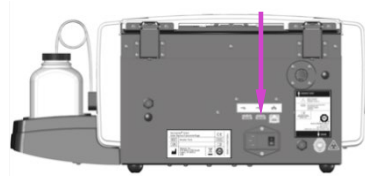
- 2 Use navigation arrows to scroll through the log.

Exporting Logs



- 1 From System Setup, Press **System Log**.

- 2 Plug a Flash Drive into the right USB port.



- 3 Press **Export**.

NOTE: The log files are exported to the Flash Drive for access to a CSV file in spreadsheet software programs.

SYSTEM LOG				
Date/Time	User	Type	Status	
2013-03-20 11:30:03		System	System Settings Accessed	
2013-03-20 09:12:30		Stain Cycle	Complete	
2013-03-20 09:11:57		Stain Cycle	Info	Slide 2/12
2013-03-20 09:11:50		Stain Cycle	Slides	(RM) 000000
2013-03-20 09:11:46		Stain Cycle	Levels	Reagent A Expired, Reagent B Expired, Reagent C Expired, Reagent E Expired
2013-03-20 09:11:36		Stain Cycle	Reagents	JA 9801-50-402A Exp 12-Dec-2012 Lot 123456789 12-Feb-2012 1443, B 9801-1
2013-03-20 09:11:36		Stain Cycle	Reagent	Prong Sample Program, Desc: B, Chl Med, ID Med, Fix Off
2013-03-19 10:00:00		System	System Settings Accessed	

Week 12, 2013

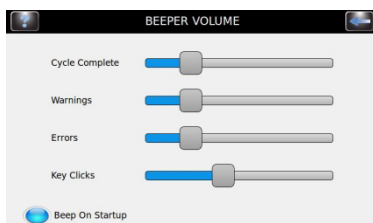
Export

Controlling Beeper Alerts



- 1 From System Setup, select **Beeper**.

- 2 Use the sliders to modify the beeper volume for Cycle Complete, Warnings, Errors, or Key Clicks.



- 3 Select **Beep On Startup** to turn the audible startup alert ON or OFF.

SECTION 3

CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

QC/Maintenance Tracking

Under system default settings, The following QC/Maintenance Tracking options are disabled:

- Enable Stain Slide Tracking
- Enable Cyto Slide Tracking
- Manual Entry
- Enable Preventive Maintenance Tracking
- Enable Reagent Tracking

Enable Stain Slide Tracking

1 From System Setup, Press **QC/Maintenance Tracking**.

2 Press **Enable Stain Slide Tracking**.

NOTE: Selecting *Enable Stain Slide Tracking* changes the Start button on the Main menu to “Load Slides.”

3 Press **Back** twice to return to the main screen. Verify that the Start Button on the main screen reads “Load Slides.”

4 Press **Load Slides**. The Scan and Load Slides menu appears.

5 Enter slide information.

- a. If using the barcode reader, scan the specimen slides that contain barcodes. See Scanning Slides with the Barcode Reader in Section 3.2 for complete instructions.
- b. If entering specimen information manually, see Recording Specimen and Reagent Information in Section 3.2.

6 See Section 4 for remaining steps for running a stain cycle.



SECTION 3 CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu



Enable Cyto Slide Tracking

Allows slide tracking in cytocentrifuge mode. See the Cytopro® Applications Manual for complete information.

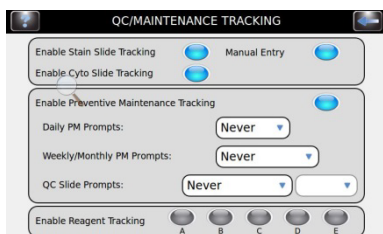
Enable Manual Entry

If selected, allows manual entry of slide information using the keypad (limited to 24 characters).

Enable Preventive Maintenance Tracking

To activate the tracking prompts for Preventive Maintenance Tracking, use the following steps:

- 1 From System Setup, select **QC/Maintenance Tracking**.



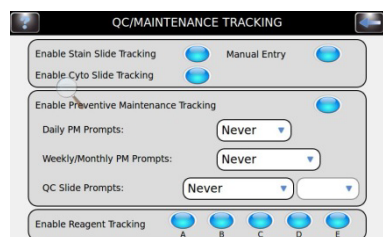
- 2 Select **Enable Preventive Maintenance Tracking**.

- 3 Enter the information for the Daily, Weekly, and QC Slide prompts in corresponding fields. See Using the Preventive Maintenance Log in Section 5.1.

Enable Reagent Tracking

To activate Reagent Tracking:

- 1 From System Setup, select **QC/Maintenance Tracking**.



- 2 Select **Enable Reagent Tracking**.

- 3 Select the reagent to be tracked (A, B, C, D, E).

SECTION 3

CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.1 System Setup Menu

Restoring Software Defaults

- 1 From System Setup, select **Restore Defaults**.



CAUTION:

Restoring the system defaults will remove all personal settings.

- Restoring *System* Settings will delete all user names and passwords as well as all stain and cytocentrifuge programs.
- Restoring *Stain* Settings will delete all stain programs and restore the default program.
- Restoring *Cytocentrifuge* Settings will delete all cytocentrifuge programs and restore the default program.

- 2 Select the settings you would like to restore to factory defaults: System Settings, Stain Settings, or Cytocentrifuge Settings.

- 3 Press **Restore**.



- 4 The display returns to the Main menu.

SECTION 3 CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.2 Recording Specimen and Reagent Information

Scanning Slides with the Barcode Reader



- 1 From System Setup select **QC/Maintenance Tracking**.



- 2 Select **Enable Stain Slide Tracking**.

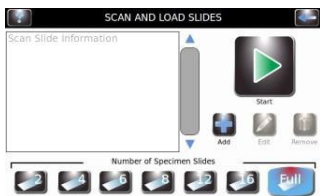
NOTE: Selecting *Enable Stain Slide Tracking* changes the *Start* button on the *Main* menu to “*Load Slides*.” See *Scanning Slides with the Barcode Reader* (Section 3.2).



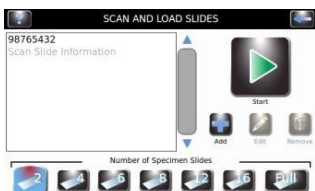
- 3 Press **Back** twice to return to the Main menu.



- 4 Press **Load Slides** on the Main menu. The Scan and Load Slides menu will appear.



- 5 Scan the barcode of each slide in the batch and load into the carousel according to instructions in Section 4.1.



- 6 Verify that each barcode appears on the Scan and Load Slides menu.



- 7 When you have completed preparations to stain, (Section 4) press **Start**.

SECTION 3

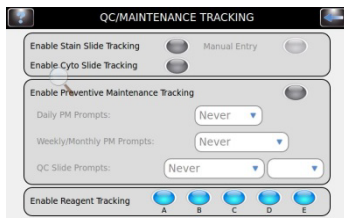
CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.2 Recording Specimen and Reagent Information

Scanning Reagent Bottles with the Barcode Reader



- 1 From System Setup select **QC/Maintenance Tracking**.

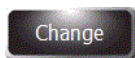
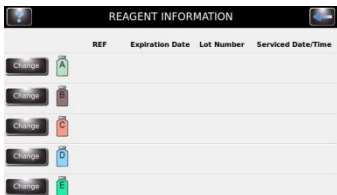


- 2 Select **Enable Reagent Tracking** for each desired reagent (A, B, C, D, E).

- 3 Press **Back** to return to the System Setup menu.



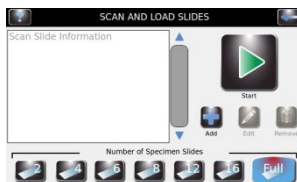
- 4 Press **Reagents** to access the Reagent Information screen.



- 5 Select the desired Reagent (A, B, C, D, E) and press **Change**.



- 6 Scan the barcode of each enabled reagent bottle.



- 7 Verify that the barcode appears on the Scan and Load Slides menu.

SECTION 3 CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

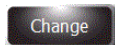
3.2 Recording Specimen and Reagent Information

Scanning Reagent Bottles with the Barcode Reader (continued)

- 8 Press **Save**.



- 9 Repeat steps 3-8 for each reagent bottle that is enabled in QC Maintenance Tracking.



NOTE: You can access Reagent Information by pressing the bottle icons on the right side of the Main menu. This takes you directly to Reagent Information menu, where you can scan or manually enter reagent information by pressing **Change**.

Manually Entering Specimen Information

With Stain Slide Tracking and Manual Entry enabled in the QC Maintenance menu:

- 1 Press **Load Slides** on the Main menu.



- 2 Press **Add** to access the keypad.



- 3 Enter slide information (maximum of 24 characters) and press **Enter**.



- 4 To change or delete the entry, select the entry on the display and press **Edit** or **Remove**.



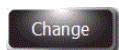
- 5 Load slides and run stain cycle as shown in Section 4.1.

Manually Entering Reagent Information

- 1 Press **Reagents** from the System Setup menu, or press the reagent status icon on the Main menu to access the Reagent Information menu.



- 2 Select the desired reagent and press **Change**.



- 3 Press the desired field (Reagent REF, Expiration Date, Lot Number, or Service Date/Time); enter the information on the keypad and Press **Enter**.



NOTE: Reagent REF number must be a valid ELITechGroup REF number for the selected reagent (A, B, and C reagents only). Incorrect entries will generate an error message.

- 4 When you have entered all the information press **Save**.



SECTION 3

CONTROLLING AND CUSTOMIZING STAINER FUNCTIONS

3.3 The Help Menu

The Help menu is a comprehensive onscreen help function that provides detailed information on the following subjects:

Basic Operation

- Loading the Carousel
- Correct Reagents and Locations
- Nozzle Volumes
- Nozzle Spray Pattern

Selecting a Stain Program

- Setting Up Stain Programs
- System Setup Help
- Setting Up Cyto Programs
- Setting Up Users
- Setting Up Level Monitoring System
- Setting Instrument Language
- Setting the Date and Time
- Instrument Logging
- Setting Up Network Settings
- Setting Instrument Beeps
- Calibrating Touch Screen
- Restoring Instrument Defaults

Maintenance Functions

- Pattern Tests
- Volume Tests
- Line Flush
- 60-Second Prime

Cleaning the Instrument

Cytocentrifuge Use

Setting Up Cyto Programs

Using Help



- 1 Press **Help** to access the help function.
- 2 Select the desired topic.
- 3 Use the direction arrows to navigate.
- 4 Press **Exit** to return to the Main menu.

SECTION 4 OPERATING THE STAINER

4.1 Operating Instructions

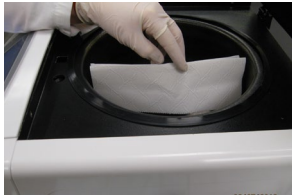
Suggested Staining Protocol

NOTE: Samples and slides should be prepared and fixed according to recommendations in Appendix E or equivalent.

- Hub Pattern Test (once per day).
- If slide tracking is enabled, scan or enter slide information.
- Load slides into the carousel. Use blocking slides if needed.
- Place loaded carousel into the stainer and close the lid.
- Check reagent and waste levels.
- If slide tracking is not enabled, enter the number of slides on the Main menu.
- Select or verify desired stain program.
- Perform a stain cycle.
- Unload the carousel.

Performing a Hub Pattern Test

Use the Hub Pattern Test to ensure the nozzles are clear of debris and spraying properly.



- 1 From the Maintenance menu, Select **Pattern Test**.
- 2 Hold a sheet of white paper towel near the drive hub, squarely facing the target nozzle.
- 3 Select the corresponding prime button.
- 4 Check the quality of the pattern. If the pattern is not correct, refer to Nozzle Maintenance and Performance (Section 6).



Figure 7: Correct Hub Pattern Test Result



Figure 8: Incorrect Hub Pattern Test Result



NOTE: If the Hub Pattern Test result is incorrect, clean the nozzle orifice with the nozzle brush provided in the Nozzle Maintenance Kit.

NOTE: If not staining immediately after Hub Pattern Test, it is recommended to run a clean cycle to prevent concentrated reagent from sitting in the lines for extended periods of time.

SECTION 4

OPERATING THE STAINER

4.1 Operating Instructions

Loading the Carousel



CAUTION:

Never load chipped or cracked slides into the carousel. Slides in poor condition may break during the staining cycle. If a slide breaks in the bowl, refer to Cleaning Broken Slides, Section 5.4.



CAUTION:

Keep small ferrous metal objects away from the lab bench. These objects can be attracted to the magnets on the bottom of the carousel and cause damage if spun free during instrument operation.

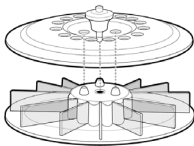


CAUTION:

Load slides in balanced pairs. If staining an odd number of slides, use a blank slide to balance the carousel.

NOTE: Load the carousel with similar specimens for a similar level of staining. There is no guarantee of staining performance when dissimilar specimens are used.

- 1 Remove the carousel from the bowl and place it on a solid, level surface.



- 2 Remove the carousel lid by pressing the button in the center of the knob and lifting the lid.



- 3 If Slide Tracking is enabled (Section 3.1), select **Load Slides**.
 - If using the barcode reader, scan each specimen slide barcode before loading it into the carousel.
 - If entering slide information manually, follow the instructions in Section 3.2.
- 4 Insert the slides into the carousel with the first slide in position 1.
 - Load slides in balanced pairs (directly opposite one another) to balance the carousel. If staining an odd number of slides, use a blank slide to balance the carousel.
 - If there are empty slots in the carousel, use blocking slides to prevent overspray (see below).

SECTION 4 OPERATING THE STAINER

4.1 Operating Instructions

Loading the Carousel (continued)

- If using a 12-slide carousel, load slides with the labels toward the *outer* rim of the carousel.
- If using a 30-slide carousel, load slides with the labels toward the *center* of the carousel.
- Always load slides with the specimen facing clockwise.
- Always place the first slide in position 1, the second in position 2, and so on.

NOTE: A warning will sound during the staining cycle if the carousel is unbalanced.

Figure 9: Loading a 12-Slide Carousel (Slide Labels Toward Outer Rim)

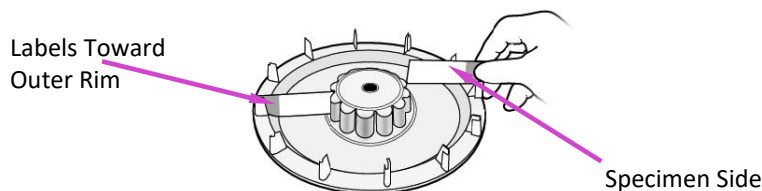


Figure 10: Loading a 30-Slide Carousel (Slide Labels Toward Center)

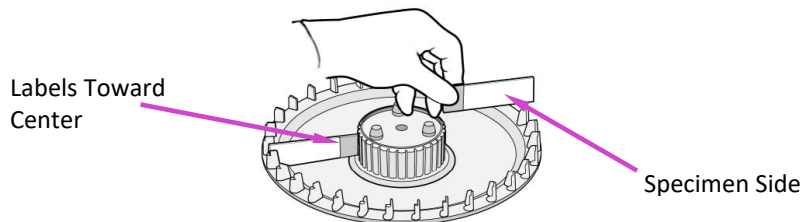
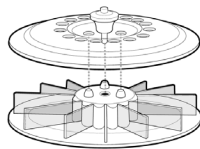


Figure 11: Reattaching the Carousel Lid



- 5 Replace the carousel lid by pressing the button and lowering the lid over the indexing posts.
- 6 Release the button and press the lid handle until it is firmly closed and locked.

SECTION 4

OPERATING THE STAINER

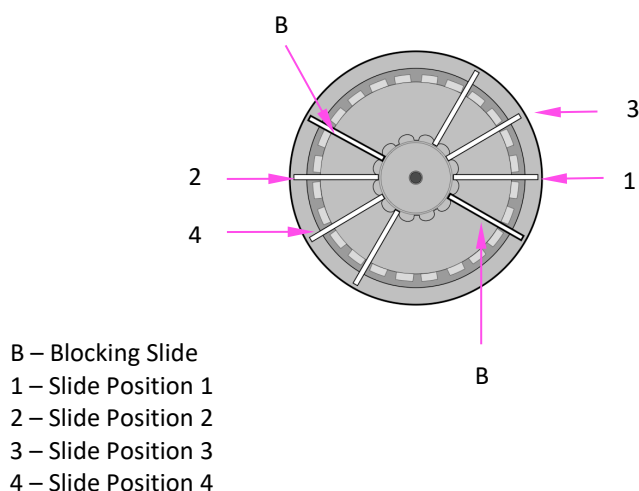
4.1 Operating Instructions

Using Blocking Slides

If the carousel is not full, blank slides should be used as blocking slides. Blocking slides prevent overspray of reagents onto the specimen slides. Overspray can cause slides to become over-decolorized.

- Place a blocking slide in front of position 1 and 2.

Figure 12: Using Blocking Slides

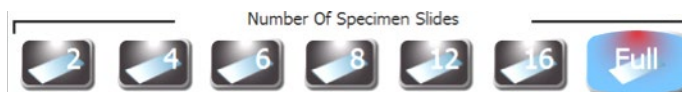


Performing a Stain Cycle

NOTE: Using this stainer requires specific sample pre-treatment and fixation steps (Appendix E). It also requires specific combinations of reagents to be loaded on the stainer (Appendix D) in combination with programming adjustments (Section 3).

- 1 Insert a carousel with specimen slides and close the instrument lid.
- 2 If you have not enabled Slide Tracking, select the number of slides to be stained. Slide selection defaults to full carousel at the end of the run, after pressing Stop, or selecting a number greater than the full carousel default.

NOTE: To stain an odd number of specimen slides, select the next higher number listed on the display. For example: to stain 3 slides, select 4. To stain 7 slides select 8, etc.



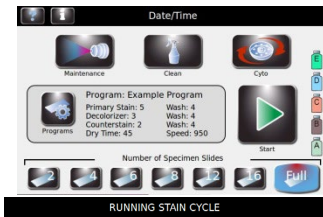
If you are using the optional barcode reader, the number of slides is programmed automatically. See Enable Stain Slide Tracking in Section 3.1.

NOTE: Do not count blocking slides as part of the total number of slides.

SECTION 4 OPERATING THE STAINER

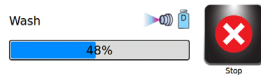
4.1 Operating Instructions

Performing a Stain Cycle (continued)



- 3 If you have created a stain program, and it appears on the display, proceed to Step 4. If the desired program does not appear on the display, select **Programs**. Then select the desired program and proceed to Step 4.
- 4 Select **Start**. The display shows the progress of the program, and a signal tone (if enabled) indicates the end of the cycle.

NOTE: Use the emergency Stop button when required, for example, if there is abnormal vibration or noise. This will abort the staining cycle.

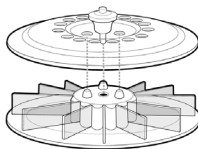


Unloading the Carousel

WARNING!

Treat slides in accordance with good laboratory practices and local regulations.

- 1 Remove the carousel from the bowl and place it on a solid, level surface.
- 2 Remove the carousel lid by pressing the button and lifting the lid.
- 3 Carefully remove each slide and read the results using a microscope.



SECTION 4

OPERATING THE STAINER

4.1 Operating Instructions

Monitoring Reagent and Waste Levels



If enabled, the stainer displays the approximate reagent and waste container levels and other information.



CAUTION:

You must monitor the reagent and waste container levels on the display (if enabled) and by direct inspection of the bottles. The monitor will show the approximate level of each reagent. This can be compared to the actual level in the bottles.

- Never allow a reagent to run dry. When the reagent level is near empty, replace the reagent bottle with a new one (see below).
- Never allow the waste container level to go above the maximum safety level.

Table 9: Reagent Level Detect Display Symbols (Reagent E shown)

	Reagent unselected in Level Detect
	Reagent Bottle Full
	Reagent Bottle 2/3 Full
	Reagent Bottle 1/3 Full
	Reagent Bottle Empty
	Measurement Error (such as unplugged external level detect)
	Reagent has exceeded expiration date (enabled from QC Maintenance menu)
	Waste bottle empty
	Waste bottle error
	Waste bottle full

SECTION 4 OPERATING THE STAINER

4.1 Operating Instructions



NOTE: You can access the Reagent Information menu by pressing the bottle icons on the right side of the Main menu. Press **Change** to scan or manually enter reagent information.

NOTE: Do not put residual reagent from a used bottle into a new bottle. This can lead to an accumulation of residue on the slides and may be a source of contamination.

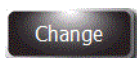


WARNING!

Reagents used in the instrument contain moderately hazardous chemicals that require care in handling. Always use appropriate safety measures, including gloves and eye protection, when handling reagents.

Replacing a Reagent Bottle

- 1 Remove the empty reagent bottle from the tray but do not disconnect the dip tube.
- 2 Open the Reagent Information menu by pressing the reagent bottle icon on the right side of the Main menu.
- 3 If you are using reagent tracking, scan the barcode, or manually enter the reagent REF, expiration date, and lot number in the Using Reagent Information Tracking menu (Section 3.1).
- 4 Open the new bottle and record the letter on the cap for future use such as long-term storage.
- 5 Place the new bottle in the tray.
- 6 Select the desired reagent and press **Change**.
- 7 Unscrew the cap and remove the dip tube from the empty bottle.
- 8 Insert the dip tube into the new reagent bottle and screw on the cap.



Emptying the Waste Container

The Reagent Level Detect function automatically monitors the waste level and indicates when the waste container should be emptied. It is still necessary to check waste levels visually to ensure the waste container does not overfill.



CAUTION:

Dispose of collected waste according to local statutes and safety requirements.



- 1 Unscrew the cap from the full waste container.
- 2 Discard the waste according to local regulations.
- 3 Reinstall the cap on the empty waste container.

-SECTION 5 PREVENTIVE MAINTENANCE AND SAFETY

5.1 Preventive Maintenance

The system provides a Preventive Maintenance Log for tracking the most recent maintenance activities. See Enable Preventive Maintenance Tracking in Section 3 and Using the Preventive Maintenance Log in this section.

Daily Maintenance/Quality Control (QC)

- 1 Check reagent levels and expiration dates.
- 2 Empty the waste container if necessary.
- 3 At the beginning of the day:
 - Perform a Hub Pattern test.
 - Run a QC slide if required by your laboratory.

NOTE: QC slides (REF: SS-249) can help you determine if the stainer is functioning as required for acid-fast staining in a laboratory environment.

NOTE: If staining will not be performed immediately run a clean cycle after Hub Pattern test.

- 4 If necessary, use the nozzle brush from the Maintenance Kit to clean the nozzle orifices. Press the individual bristles into the nozzle openings.
- 5 At the end of each shift or if the instrument is idle for more than four hours:
 - Place an empty carousel in the bowl and close the lid.
 - Press the **Standby/Ready** button on the front panel and wait until the end of the automatic cleaning process. Pressing the **Standby/Ready** button runs a System Clean. Operator can also press **Clean**.
 - Spray and wipe the bowl, interior lid, and nozzles with 70 to 100% alcohol (methanol or ethanol). Wipe clean with a paper towel.
 - Wipe down the exterior of the instrument with 70 to 100% alcohol.
 - If using Potassium Permanganate, wipe the orifice of nozzle with a paper towel dampened with SS-266.
 - For overnight storage, fill a #13 rubber sleeve stopper with SS-266 and slip it over the B line nozzle. When ready to use the instrument again, remove rubber sleeve from B nozzle.
- 6 Ensure the maintenance procedures listed on the Maintenance Log have been performed, and entered into the chart or log.



SECTION 5 PREVENTIVE MAINTENANCE AND SAFETY

5.1 Preventive Maintenance

Weekly Maintenance

- 1 Wipe the nozzle, carousel tray and lid using 70 to 100% alcohol (methanol or ethanol). Wipe with paper towel.
- 2 Slowly pour 200-300 mL of water, or SS-029C into instrument drain to prevent build-up of paper fibers, precipitates, etc. Verify drain is flowing properly and not allowing fluid to back up in bowl or flow out of air vent on case back.
- 3 Perform a Volume Test (Section 6.4).
- 4 Perform a Hub Pattern Test (Section 4.1)

NOTE: If staining will not be performed immediately run a clean cycle after Volume and Hub Pattern tests.

- 5 Manually clean the nozzles if necessary.
- 6 Ensure the maintenance procedures listed on the Maintenance Log have been performed and entered into the chart or log.

NOTE: Key to weekly maintenance is flushing the waste tube to assure proper drainage. Follow Step 2 carefully to assure proper drainage maintenance.

Monthly Maintenance

Hub Pattern	
Date Completed	Result
A.	
B.	
C.	
D.	
E.	

Nozzle Volume	
Date Completed	Result (mL)
A.	
B.	
C.	
D.	
E.	

Maintenance	
Task	Date Completed
Line Flush	
Disinfect Bottles	
Drain Check	
Waste Cleaning	

QC Slides	
Date Completed	Result

Record Maintenance

- 1 Disassemble and manually clean all nozzles. Refer to Nozzle Disassembly and Cleaning (Section 6.1). **DO NOT mix or interchange nozzles or nozzle parts.**
- 2 Disinfect the Reagent D bottle (Section 5.5).
- 3 If using potassium permanganate, flush the B-line monthly (Section 6.5).
- 4 Reinstall nozzles. **Always return nozzles to same location.**
- 5 Perform HUB SPRAY PATTERN and SPRAY VOLUME tests.
- 6 Disinfect reusable bottles with a 1/10 dilution of household bleach. Rinse thoroughly with deionized water.
- 7 If using Potassium Permanganate (SS-061BP, SS-061BP-EU, or diluted SS-161BP) as the counterstain for fluorescent stains, then run a monthly line flush on the B line as described (section 6.5).
- 8 Ensure the maintenance procedures on the Preventive Maintenance (PM) Log have been performed and entered into the PM chart or log.

SECTION 5 PREVENTIVE MAINTENANCE AND SAFETY

5.1 Preventive Maintenance

Annual Maintenance

- 1 Check internal and exterior tubing and fittings for cracks, leaks, or any type of deterioration. Replace as needed.
- 2 Run a line flush for both the B and C lines as described (section 6.5).

Using the Preventive Maintenance Log

With Preventive Maintenance Tracking enabled, the PM Log provides a convenient and structured means of recording important maintenance and QC functions. The system allows you to set up timely prompts that require response by the user. See Enable Preventive Maintenance Tracking (Section 3.1).



- 1 From the Maintenance menu, press **QC/PM** to open the PM Log.

- 2 Press **Record Maintenance**.

PM Task entry options:

QC SLIDE Staining (Drop Down Menu)

Not Completed

Acceptable

Unacceptable

Inconclusive

Disinfect Reusable Bottles

Completed (Select/Deselect)

Drain Check

Completed (Select/Deselect)

Manual Nozzle Cleaning

Completed (Select/Deselect)



- 3 Press **Save** to record entries.

SECTION 5 PREVENTIVE MAINTENANCE AND SAFETY

5.2 Storing the Instrument

If the instrument is inactive for more than one week, you may want to perform the long-term storage procedure. This will prevent nozzles and internal valves from clogging when the machine is reactivated.

Preparing for Long-Term Storage

- 1 With the carousel removed, remove and clean the nozzles. Be sure to store nozzle parts in tubes that correctly indicate their position.
- 2 Unscrew the cap and remove the dip tube from the reagent bottles.
- 3 Place the end of the dip tube in a bottle of approved alcohol.
- 4 Flush at least 250 mL of approved alcohol through the reagent line by priming all lines simultaneously. Leave the alcohol in the line.

NOTE: When using potassium permanganate: flush the B-line with 250 mL of water before flushing with alcohol.



CAUTION:

Leave alcohol in the reagent lines during storage. Allowing reagent lines to run dry can damage the instrument.



CAUTION:

Do not subject the instrument to freezing temperatures. Freezing of aqueous fluids in the lines may cause damage to the instrument.

- 5 Flush the bowl with water.
- 6 Return nozzles to their original positions

Preparing for Operation after Storage

Follow the Setup and Preparation for Operation instructions in Section 2.

SECTION 5

PREVENTIVE MAINTENANCE AND SAFETY

5.3 Replacing Fuses



WARNING!

To prevent the risk of fire, the main fuses should only be replaced with fuses of the same type and rating. Recurring fuse failure indicates serious internal problems, if this occurs, contact ELITechGroup.

- 1 Power **OFF** the instrument.
- 2 Disconnect the power cord from the power outlet and the rear panel of the instrument.
- 3 Open the fuse cover by inserting a screwdriver in the slot on the right side of the cover and gently prying the cover out.
- 4 Remove the fuse holders to inspect the fuses.
- 5 Replace the fuses if necessary.
- 6 Push the fuse holder in.
- 7 Close the fuse cover.
- 8 Reconnect the main power cord to the rear panel of the instrument and to the power outlet.
- 9 Power **ON** the instrument.

SECTION 5 PREVENTIVE MAINTENANCE AND SAFETY

5.4 Cleaning the Stainer and Carousels



WARNING!

All cleaning procedures should be performed in an area with ventilation in accordance with local regulations by authorized trained personnel wearing appropriate protection equipment.

- 1 Clean the outside of the instrument with 70 to 100% alcohol.
- 2 Clean the carousel and lid with 70 to 100% alcohol.

NOTE: Freshly prepared (< 24 hours old) 10% dilution of household bleach solution (5.25% sodium hypochlorite) can also be used. The 10% bleach solution helps clean the stained areas.

Cleaning Liquid Spills

Remove any liquid spilled on the instrument immediately to avoid damage to the equipment.



WARNING!

If potentially infectious liquid is spilled on the instrument, the instrument must be disinfected in accordance with all applicable local regulations. Refer to Decontaminating the Stainer and Carousels (below) for instructions.

Cleaning Broken Slides

You must take stringent precautions if a slide breaks inside the instrument during a staining cycle, especially if the instrument has been processing dangerous pathogens. Always use protective gloves, safety glasses, and forceps when removing broken glass from inside the instrument.

- Glass shards embedded in the walls of the bowl can cause serious cuts and pose a risk of infection.
- Always remove embedded shards with a scraper before attempting to remove loose glass.
- Use a vacuum or adhesive tape to pick up loose glass inside the stainer bowl.

SECTION 5

PREVENTIVE MAINTENANCE AND SAFETY

5.5 Decontaminating the Stainer and Carousels

All parts of the instrument that come into contact with biological specimens, patient specimens, positive control specimens, or hazardous material must be treated as potentially infectious.

Before the instrument is returned for service, all outer surfaces must be decontaminated. The operating authority must complete a disinfection declaration, otherwise the instrument may be rejected by the distributor or service center or quarantined by customs authorities.



WARNING!

Reagents used with the instrument contain moderately hazardous chemicals that require care in handling. Always use appropriate safety measures including gloves and eye protection, when handling reagents.



WARNING!

Authorized, trained personnel wearing appropriate protection equipment should perform the decontamination procedure in an area with ventilation in accordance with local regulations. It is very important to thoroughly decontaminate the instrument before removing it from the laboratory or before performing any technical service. This procedure may not be effective against prions.



WARNING!

Prior to decontaminating, disconnect the instrument from the main power supply to avoid any risk of fire and explosion.



WARNING!

The decontamination procedure and the disinfectants must comply with the local applicable regulations.

Solutions for Decontaminating the Instrument

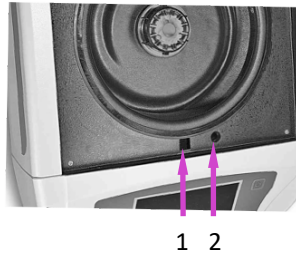
The outer surfaces of the instrument should be decontaminated using a decontaminating solution such as:

- 70% ethanol, methanol, or isopropanol
- Mild detergent
- 10% bleach solution (< 24 hours old)
- Decontamination Solution (REF: SS-133)

SECTION 5 PREVENTIVE MAINTENANCE AND SAFETY

5.5 Decontaminating the Stainer and Carousels

Figure 13: Lid Latch and Locking Pin Hole Locations



- 1 – Lid Latch Hole
2 – Locking Pin Hole

Decontaminating the Instrument

- 1 Prepare a suitable container for all disposables.
- 2 Cover the lid latch and locking-pin holes with waterproof tape to protect the interior (Figure 13).
- 3 Place the instrument in an area with ventilation in accordance with local regulations.
- 4 Spray the inner bowl and inner lid with a decontaminating solution such as REF: SS-133.
- 5 Repeat the spray treatment every 2 or 3 minutes for a total of 20 minutes. Do not allow cleaning solutions to dry on the instrument surfaces.
- 6 Rinse the inner bowl and lid thoroughly with water.
- 7 Spray and wipe the exterior surfaces with decontamination solution such as REF: SS-133.



CAUTION:

Do not flood the display panel with excessive moisture. Any moisture that seeps through could damage the internal electronics.

- 8 Repeat the spray treatment of exterior surfaces every 2 or 3 minutes for a total of 20 minutes. Do not allow cleaning/decontamination solutions to dry on the instrument surfaces.
- 9 Wipe surfaces thoroughly with a cloth soaked in water until you have removed all decontamination solution.
- 10 Immerse or generously spray the carousel and lid with decontaminating solution. Allow the solution to react for 20 minutes.
- 11 Thoroughly rinse the carousel and lid with deionized or distilled water.

SECTION 5

PREVENTIVE MAINTENANCE AND SAFETY

5.5 Decontaminating the Stainer and Carousels

Decontaminating the Reagent D Bottle

- 1 Fill the reagent D (deionized or distilled water) bottle with a fresh (< 24 hours old) 10% dilution of household bleach solution (5.25% sodium hypochlorite).
- 2 Allow the bleach solution to react in the bottle for 10 minutes.
- 3 Rinse the bottle thoroughly with tap water.
- 4 Rinse the bottle thoroughly with deionized or distilled water to remove all of the decontamination solution.

SECTION 5 PREVENTIVE MAINTENANCE AND SAFETY

5.6 Shipping or Disposing of the Stainer or Carousels

Shipping the Instrument



WARNING!

You must disinfect the carousel before returning it to ELITechGroup. The operating authority must complete a disinfection declaration, otherwise the distributor or service center may not accept the instrument; or customs authorities may hold it.



WARNING!

Shipping the rotor without decontaminating it according to these instructions is dangerous to service personnel. You will be charged additional fees for decontamination performed by ELITechGroup.



CAUTION:

Ship the instrument in a container comparable to its original packaging.

Disinfection Declaration

The operating authority must print and complete the disinfection declaration (obtained from ELITechGroup Customer Service).

Attach the declaration to the top of the instrument package before sending the package to ELITechGroup.

Disposing of the Instrument

This device should be completely decontaminated and disposed of as follows:



Under WEEE Directive 2012/96/EU, this equipment cannot be disposed of in a normal landfill. Instead, the equipment must be disposed of by:

- 1 Routing to an authorized local facility approved for handling hazardous materials.

OR

- 2 Returning the equipment to ELITechGroup or an authorized distributor.

SECTION 6

NOZZLE MAINTENANCE AND PERFORMANCE

6.1 Nozzle Disassembly and Cleaning

Nozzle maintenance requires the Nozzle Maintenance Kit and Cleaning Solution (diluted SS-029C or SS-266).



WARNING!

Do not run Stain Residue Solvent (SS-230) through stainer as serious damage could result. This solvent is for the cleaning of nozzles, carousels and bowls for Aerospray slide strainers. SS-230 should not be used for line flush.

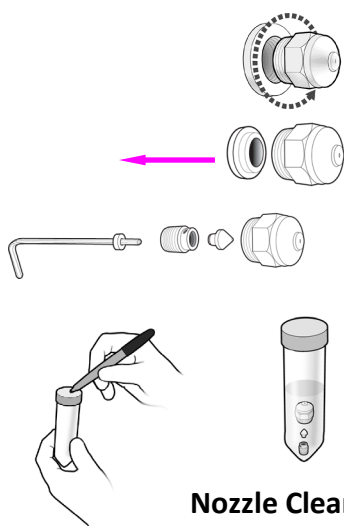


WARNING!

Always wear protective clothing and eye protection when using Cleaning Solution (diluted SS-029C or SS-266) or stain residue solvent (SS-230). Dispose of used solution properly.

Note: Do not mix or interchange nozzles or nozzle parts. Always return nozzles to same location in stainer.

Nozzle Disassembly



1 Remove the nozzle using the nozzle tool from the Nozzle Maintenance Kit.

2 Disassemble the nozzle. See Figure 5: Nozzle Diagram in Section 1.

NOTE: If the compression screw cannot be easily loosened, use light penetrating oil and a 5/8-in. wrench to loosen the nozzle.

3 Place the nozzle parts in a 50 mL conical tube that has been clearly marked with the correct nozzle position.

4 Repeat Steps 1 through 3 for each nozzle.

Nozzle Cleaning



1 Fill each 50 mL tube with 25 mL of prepared Cleaning Solution (SS-029C or SS-266) and cap the tube.

2 Gently invert the tube at least ten times to ensure all parts come in contact with the Nozzle Cleaning Solution.

3 Place the tube in the correctly marked position in the provided tube stand. Soak the parts as long as possible.

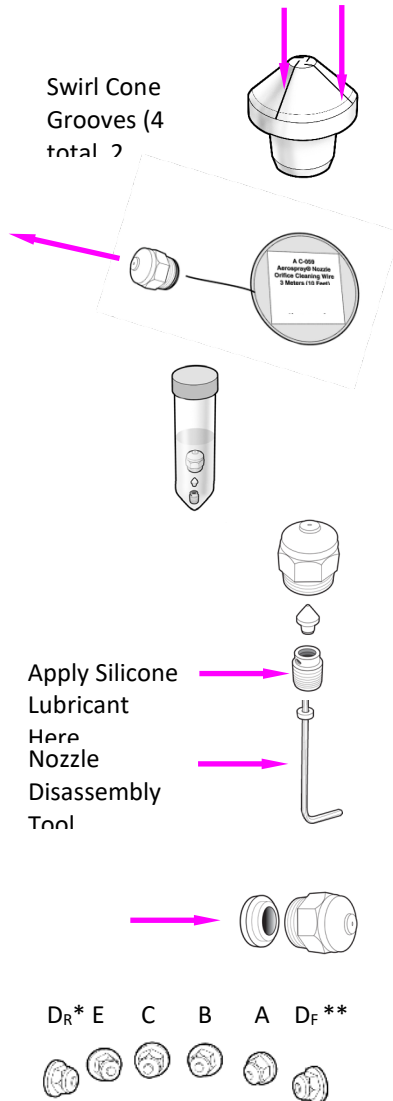
NOTE: Soak nozzle parts for at least 15 minutes. Parts can be soaked in Nozzle Cleaning Solution overnight.

4 Repeat steps 1 through 3 for each nozzle.

SECTION 6

NOZZLE MAINTENANCE AND PERFORMANCE

6.2 Nozzle Reassembly



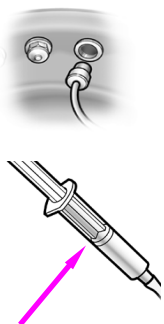
- 1 Hold your thumb or a strainer over the end of the tube to keep the nozzle parts in the tube. Pour out the liquid used to clean the nozzle parts.
 - 2 Inspect the nozzle parts. Remove any material in the swirl cone grooves by sliding a piece of paper along each of the 4 grooves.
 - 3 Thread the nozzle orifice cleaning wire (REF: AC-059) through the back of the disassembled nozzle housing.
 - 4 Place the nozzle parts back into the tube and rinse them with water.
 - 5 Rinse the parts again with alcohol.
 - 6 Apply a small amount of silicone lubricant (REF: SS-103) to the compression screw threads.
 - 7 Reassemble the nozzle by placing the compression screw on the nozzle disassembly tool, then inserting the swirl cone into the compression screw.
- NOTE:** Hold all the parts in a vertical position during reassembly.
- 8 Reinstall the nozzle housing over the swirl cone and compression screw.
 - 9 Reinstall the nozzle insert.
 - 10 Return the assembled nozzle to its original position in the instrument.
 - 11 Repeat Steps 1 through 10 for each nozzle.
 - 12 Perform a Hub Pattern Test (Section 4) and record results.
 - 13 Perform a Volume Test (Section 6.4) and record results.

NOTE: You must perform the Hub Pattern Test and Volume Test before operating the instrument. If the results are incorrect, manually prime the instrument. If not staining immediately after Hub Pattern Test, it is recommended to run a clean cycle to prevent concentrated reagent from sitting in the lines for extended periods of time.

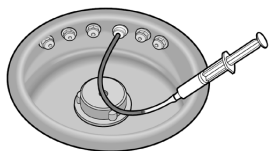
SECTION 6

NOZZLE MAINTENANCE AND PERFORMANCE

6.3 Manual Priming



- 1 Remove the carousel from the bowl.
- 2 Remove the nozzle connected to the reagent line to be manually primed.
- 3 Insert the priming tool nozzle adapter (included in the Nozzle Maintenance Kit) into the nozzle holder.
- 4 Turn the nozzle adapter clockwise to install the adapter into the holder.
- 5 Withdraw the priming tool plunger halfway to create a vacuum. Hold the plunger in position.
- 6 Press **Maintenance** from the Main menu.
- 7 Press **Volume Test**.
- 8 Press the desired prime button to start the reagent pump.
- 9 Run the reagent into the tube until the fluid is free of bubbles, then press **Stop**.



WARNING!

Do not pull the plunger completely out of the priming tool. Pulling the plunger out of the tool may result in splashing or spraying of reagents. Do not push the plunger in while it is connected to the nozzle holder.



- 10 Turn the nozzle adapter counterclockwise to remove it from the nozzle holder.
- 11 Discard the collected fluid into the stainer bowl.
- 12 Perform the 60 Second Prime function on the affected reagent line to remove any remaining air in the pump or reagent line.
- 13 Reinstall the nozzle.
- 14 Perform the Hub Pattern Test and record results.
- 15 Perform the Volume Test and record results.

NOTE: This requires at least 250 mL of reagent. Make sure there is enough reagent in the selected bottle before starting this function.

NOTE: If not staining immediately after Hub Pattern Test, it is recommended to run a clean cycle to prevent concentrated reagent from sitting in the lines for extended periods of time.

SECTION 6

NOZZLE MAINTENANCE AND PERFORMANCE

6.4 Performing the Volume Test

The Volume Test requires the Nozzle Maintenance Kit.

NOTE: The Volume Test must be performed weekly.



- 1 From the Maintenance menu, select **Volume Test**.
- 2 Hold a Volume Test tube (small tube) to cover the selected nozzle.
- 3 Press the corresponding reagent button to collect the reagent.
- 4 Remove and cap the tube.
- 5 Record the nozzle position on the tube.
- 6 Place the tube in the appropriate position in the tube stand.
- 7 Repeat Steps 2 through 7 for each nozzle.
- 8 Compare collected nozzle volumes with the following table.



Table 10: Volume Test Tolerances (Carbol Fuchsin Stains)

Nozzle/Reagent Line	Minimum	Maximum
A, B	8.5 mL	11.0 mL
C	8.5 mL	13.0 mL
D _F , D _R	8.0 mL	10.5 mL
E	9.0 mL	12.0 mL

Table 11: Volume Test Tolerances (Fluorescent Stains)

Nozzle/Reagent Line	Minimum	Maximum
A	9.0 mL	12.0 mL
B	8.5 mL	11.0 mL
C	8.5 mL	11.5 mL
D _F , D _R	8.0 mL	10.5 mL
E	9.0 mL	12.0 mL

NOTE: The stainer normally functions correctly if nozzle volumes are slightly higher or lower than the specified range. Spray volumes < 7.5 mL or > 14.0 mL indicate serious problems with the nozzles or reagent delivery lines.

- If the volume is within the tolerance range, go to Step 10.
- If the volume is outside the tolerance range:
 - a. Clear the nozzle orifice with the nozzle brush found in the maintenance kit.



SECTION 6

NOZZLE MAINTENANCE AND PERFORMANCE

6.4 Performing the Volume Test

- b. If necessary, remove the nozzle and perform the Nozzle Cleaning procedure (Section 6.1).
- c. If the problem persists, replace the nozzle.

NOTE: *If the problem persists after you have replaced the nozzle, contact ELITechGroup.*

NOTE: *If not staining immediately after Hub Pattern Test, it is recommended to run a clean cycle to prevent concentrated reagent from sitting in the lines for extended periods of time.*

- 9 Prepare the Maintenance Kit for future use:
 - Empty the contents of the tubes into the stainer bowl.
 - Rinse the tubes with water.
 - Put the tubes back into their original place in the Maintenance Kit or tube stand.
- 10 Select **Back** twice to return to the Main menu.

SECTION 6

NOZZLE MAINTENANCE AND PERFORMANCE

6.5 Using the Line Flush

This procedure may be performed when troubleshooting a staining issue. It is also required when switching from carbol fuchsin to fluorescence staining reagents. This procedure requires the Nozzle Maintenance kit. You can flush the B or C line separately or both lines at the same time. The B-line must be flushed at least once per month when using potassium permanganate.

NOTE: This procedure requires a minimum of 1 hour and at least 250 mL of cleaning solution (diluted SS-029C or SS-266).

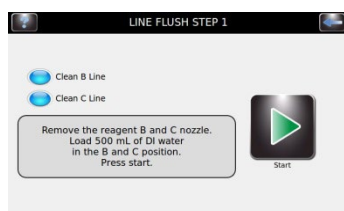
NOTE: A carousel must be in place during the procedure or the instrument will generate an error and abort the procedure.

- 1 Remove the B or C nozzle, or both, depending on the desired line flush.



- 2 From the Maintenance menu, press **Line Flush**.

- 3 Select the desired line or lines to be flushed.



- 4 Load 500 mL of deionized or distilled water into the each line you are flushing. **DO NOT RUN STAIN RESIDUE SOLVENT (SS-230) OR ALCOHOL THROUGH STAINER.**

- 5 Insert an empty carousel and close the lid.



- 6 Press **Start**. Follow the prompts on the display to complete the line flush. The instrument will pump approximately 400 mL of water through the line(s). A status bar will indicate progress.

- 7 When the flush is complete, remove the remaining water.

- 8 Load 200 mL of the prepared cleaning solution (diluted SS-029C or SS-266) into the line(s).

- 9 Press **Start**. The instrument will pump approximately 100 mL of the prepared cleaning solution through the line(s) and will then start a 1-hour countdown timer.

- 9 Wait for the timer to complete, or allow the instrument to remain idle up to a maximum of 12 hours.

SECTION 6

NOZZLE MAINTENANCE AND PERFORMANCE

6.5 Using the Line Flush

NOTE: You can still use the Cytocentrifuge mode during this time by selecting Cyto.

11 Load 500 mL of deionized or distilled water into the line(s).



12 Press **Start**. The instrument will pump approximately 400 mL of water through the line(s). A status bar will indicate progress.

13 When the flush is complete, remove the remaining water.

14 Load at least 300 mL of the correct reagent for that position into the line(s).



15 Press **Start**. The instrument will pump approximately 200 mL of the reagent(s) through the line(s).

16 Reinstall nozzle(s). Make sure you reinstall the correct nozzle for each line.



17 Press **Continue**. The stainer cleans and primes the lines and returns to the Main menu.

SECTION 6 NOZZLE MAINTENANCE AND PERFORMANCE

6.6 Performing the Slide Pattern Test

This test can differentiate poor staining results from sample preparation problems, or nozzle obstructions. Perform the Slide Pattern test when a Hub Pattern test produces a normal result, but staining is still inadequate.

- 1 Place a 1 x 3 inch (2.5 x 7.6 cm) piece of paper (available from ELITechGroup, REF: RP-500) in positions 1 and 2 of the carousel, with a blocking slide in front of positions 1 and 2.

- 2 Load the carousel into the stainer and close the lid.



- 3 From the Main menu, select **Maintenance**.

- 4 Press **Pattern Test**.

- 5 Press the corresponding prime button for the reagent line to be tested.



- 6 Remove the paper slides.

- 7 Repeat Steps 1 through 6 for each reagent line.

- 8 Examine the paper slides for each reagent. The pattern on the slide should be uniform, without any continuous lines or streaks.

Figure 14: Correct Slide Pattern Test Result

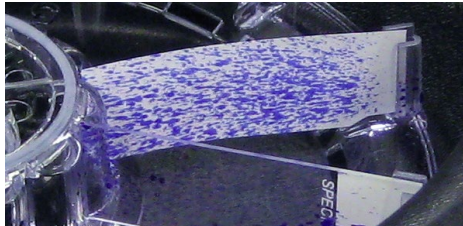
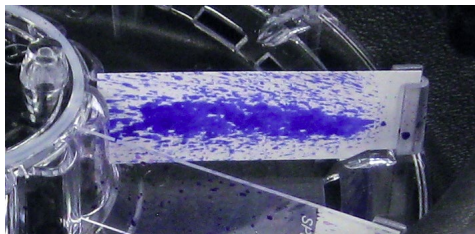


Figure 15: Incorrect Slide Pattern Test Result



- 9 If the result is incorrect, clear the nozzle blockage using the nozzle brush, or disassemble and clean the nozzle.

NOTE: If staining will not be performed immediately run a clean cycle after Volume and Hub Pattern tests.

SECTION 7

SOLVING PROBLEMS

7.1 Troubleshooting


This section helps you identify and solve routine problems with the stainer. More difficult problems may require technical service. Contact your ELITechGroup representative for assistance.



WARNING!

Due to the electrical shock hazard, do not open this instrument or attempt internal repairs. Refer servicing to qualified service personnel. Contact your dealer or ELITechGroup Service.

Table 12: General Troubleshooting and Diagnosis

Problem	Solution
There is no power to the stainer when the power switch is turned ON.	<p>Check the facility outlet and the power cord connection. Check the fuses. Refer to the Replacing Fuses procedure.</p> <p> CAUTION: Fuse failure may indicate a serious internal problem.</p>
Strange information shows on the display, and/or erratic stainer operation.	<p>Switch the stainer OFF, wait 10 to 20 seconds, then switch power ON again. If problem recurs, install a computer-type surge suppressor to protect the instrument from power line transients. If possible, connect the stainer to a power circuit that is not shared by centrifuges, refrigerators, air conditioners, or other motorized equipment.</p> <p>If the above steps do not solve the problem, consult the Aerospray Service Manual, or contact your dealer or ELITechGroup for assistance.</p>
A reagent line will not prime when power is ON and you have pressed the prime button.	Follow the procedures in Section 6.3 for priming reagent pumps.
A reagent line will not prime, even with the priming tool (Section 6.3).	Press the priming button and listen carefully for the sound of the pump. If you can hear the pump, try the priming tool again. If the problem is not solved or if you cannot hear the pump there may be an internal problem. Contact your dealer or ELITechGroup for assistance.
Stainer bowl fills with reagent after use.	A small puddle of stain around the drain inlet or the bottom of the bowl is normal. If the bowl is filling with a large quantity of stain, check the external drain tube for blockage. Make sure the drain tube is properly connected and running continuously down toward the lab drain or vented waste container, with no loops, rises, or obstructions. Make sure the end of the tube is not submerged. This can prevent proper drainage. The internal drain may need to be cleaned or replaced. See the Aerospray Service Manual, or contact your dealer or ELITechGroup Service.

SECTION 7 SOLVING PROBLEMS

7.1 Troubleshooting

Table 12: General Troubleshooting and Diagnosis (continued)

Problem	Solution
Stain is leaking onto the counter.	<p>Check all external reagent lines for visible signs of cracks or loose fittings.</p> <p>Make sure the drain outlet is not blocked.</p> <p>Make sure the drain tube is securely attached to the drain port and that the tubing is not cracked or deformed.</p> <p>Reagent leaks may indicate an internal problem (see Section 7.3). See the Aerospray Service Manual, or contact your dealer or ELITechGroup for further assistance.</p>
<p>Error messages on the screen.</p> <div data-bbox="472 982 639 1098" data-label="Image"> </div> <div data-bbox="444 1262 647 1377" data-label="Image"> </div> <div data-bbox="433 1520 659 1633" data-label="Image"> </div>	<p>If the display shows Lid Not Shut: Verify that the lid is fully closed and latched. If the Lid Not Shut indication remains, contact ELITechGroup for assistance.</p> <p>If the display shows Wrong Rotor after pressing Start: Make sure the slide carousel is properly loaded on the drive hub. In staining mode, the instrument detects whether the staining carousel is present before proceeding. In cytocentrifuge mode, the instrument will stop if it senses the staining carousel. After verifying the carousel is correctly loaded, press Start. If the display still shows Wrong Rotor, there may be an internal problem. Check for missing carousel magnets.</p> <p>The microprocessor monitors carousel rotation during a staining cycle. The display shows an error message if the rotation is not within the specified range.</p> <p>If the display shows Motor Drive Error: Check the stainer bowl for interference: Turn the hub or carousel by hand; it should turn freely.</p> <p>Drive motor or electronic component malfunctions require servicing of internal components. Contact your dealer or ELITechGroup for assistance.</p> <p>If the display shows Rotor Imbalance, make certain the Cytopro rotor is balanced, or the staining carousel is seated correctly on the hub.</p> <p>See Electronic Failure (below).</p>

SECTION 7

SOLVING PROBLEMS

7.1 Troubleshooting

Table 12: General Troubleshooting and Diagnosis (continued)

Problem	Solution
The stainer fails to spray reagent during a staining cycle and/or continues to run after the cycle should be complete.	<p>To allow programmed staining of partial loads, the stainer monitors the position of the carousel as it rotates in the bowl. In normal operation, stain is sprayed only in the correct position. This causes the actual cycle time to vary, depending on the position of the carousel at the beginning of the cycle. However, if the cycle continues for an abnormally long period, or if the bar graph and percentage complete icon do not change after 1 minute, it may indicate an electronic problem or an internal problem. To determine this, press Stop.</p> <p>If the cycle stops: this indicates a problem with the carousel position sensor. Consult the Aerospray Service Manual, or contact your dealer or ELITechGroup for assistance.</p> <p>If the cycle continues: this indicates an electronic problem (see below).</p>
Abnormal staining on entire surface of all slides.	<p>Check the reagent level on the display and/or in the reagent bottles.</p> <p>Make sure the external reagent dip tubes are securely attached to each bottle (Section 2.1).</p> <p>Open the lid and verify that each reagent pump is primed, by pressing the corresponding prime button. The nozzle should immediately spray a fine mist of reagent. There should be no sputtering or hissing sounds, which indicate air in the reagent lines.</p> <p>Watch the external tubes for air bubbles. Air bubbles indicate inadequate priming or possibly an air or reagent leak in the system. Air in any reagent line will cause poor staining. Refer to Section 7.3 for more information.</p> <p>Check nozzle performance using the Slide Pattern (Section 6.6) and Volume Tests (Section 6.4). If necessary, clean nozzle(s) using the procedures in Section 6.1.</p> <p>Verify that the vent hole in each reagent dip tube bottle adapter is free of obstructions (this small vent hole is found in the bottle adapter of each reagent line).</p>

SECTION 7 SOLVING PROBLEMS

7.1 Troubleshooting

Table 12: General Troubleshooting and Diagnosis (continued)

Problem	Solution
Abnormal staining on entire surface of all slides (continued).	<p>When staining a full carousel (7 or more slides for the 12-slide carousel or 17 or more for the 30-slide carousel), make certain you have not programmed the stainer for fewer slides.</p> <p>If staining a partial load, load the slides in the correct positions as indicated by the markings on the carousel (see Section 4.1).</p> <p>Depending on the carousel being used (12- or 30-slide), make sure slides are oriented correctly on the carousel (see Section 4.1).</p> <p>Review sample and slide preparation procedures in Appendix E.</p>
Abnormal staining on entire surface of some slides, while other slides from the same carousel appear normal.	<p>Make certain that all position magnets are still attached to the bottom of the carousel. Make certain you have not programmed the stainer for fewer slides than you have loaded.</p> <p>If you program the stainer for a partial load, load the slides in the correct positions as indicated by the markings on the carousel (see Section 4.1).</p> <p>Verify that each reagent pump is primed by opening the lid and pressing the corresponding prime button. The nozzle should immediately spray a fine mist of reagent. There should be no sputtering or hissing sounds to indicate the presence of air in the reagent lines (see Section 7.3).</p> <p>Review sample and slide preparation procedures in Appendix E.</p>
Streaks or bands of discoloration on one or more slides.	<p>Check the level of the Reagent A bottle. Check Reagent A spray volume according to Section 6.4.</p> <p>Check nozzle spray pattern according to the procedures in Section 6.6. This type of discoloration is usually caused by a piece of debris or reagent precipitate clogging the spray nozzle orifice.</p> <p>Clean any nozzle that exhibits a poor spray pattern.</p>

SECTION 7

SOLVING PROBLEMS

7.1 Troubleshooting

Table 12: General Troubleshooting and Diagnosis (continued)

Problem	Solution
Specimens are washing off slides.	<p>Try to make your smears as thin as possible for a given specimen, to minimize fixation problems.</p> <p>Always use clean, premium quality slides.</p> <p>Review sample fixation procedures in Appendix E.</p>
Electronic Failure	<p>An electronic failure would appear as an obvious malfunction such as a scrambled or totally inoperative display panel.</p> <p>Transient voltages coming through the power lines may cause the stainer to “lose its place.”</p> <p>If this occurs, switch the main power OFF for 10-20 seconds and then back ON to reset the instrument.</p> <p>If the problem recurs, install a computer-type surge protector to isolate the instrument.</p> <p>If possible, connect the stainer to a power circuit not shared by centrifuges, refrigerators, air conditioners, or other motorized equipment.</p> <p>For more obscure electronic problems, monitor the stainer through a complete staining cycle to determine if the operating sequence is correct. Do this by running the stainer while watching the display and listening to the pumps.</p> <p>Ensure that each event occurs according to the operating sequence, shown in Tables A and B in Appendix D.</p> <p>If the problem recurs, contact your dealer or ELITechGroup for assistance.</p>

7.2 Abnormal Staining Results

Smear Separation or Cell Loss

Possible causes for losing smears from the slide surface during a staining cycle:

- Improper fixation
- Reagent application force-poor nozzle spray
- Wet smears
- Thick smears
- Dirty slides
- Low inherent adhesion

Over-Decolorization

Over-decolorization occurs when acid fast bacteria (AFB) positives are incompletely stained or when the decolorizer removes the stain from the organisms to make them appear negative.

Possible causes include:

- Insufficient primary stain application
- Decolorizer setting too high
- Slides incorrectly placed in carousel
- Improper specimen preparation

Under-Decolorization

Insufficient decolorization of specimens will result in a partially acid fast positive appearance in the smear's AFB negative bacteria and background, due to incomplete removal of the primary stain. Possible causes for under-decolorization include:

- Inadequate decolorizer application
- Decolorizer setting too low
- Primary stain settings too high
- Thick smears
- Slides incorrectly placed in the carousel

Artifacts and Microbial Contaminates

Staining artifacts can be caused by precipitate buildup from transferring the residual stains to the fresh bottles when reloading reagents. Such artifacts may also indicate microbial contamination of the reagent lines and pumps.

If you suspect microbial contamination, use the following solution to disinfect the reagent lines and pumps.

Replace precipitated stain with fresh stains after flushing the lines with the disinfecting solution.

Disinfectant Solution:

15% freshly prepared dilution of household bleach (5.25% Sodium Hypochlorite).

SECTION 7

SOLVING PROBLEMS

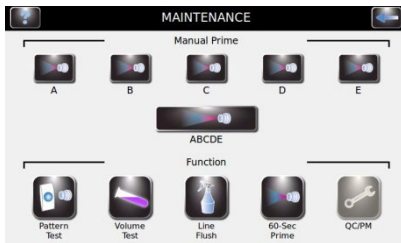
7.2 Abnormal Staining Results

Dilution:

150 mL household bleach

+ 850 mL deionized water

= 1000 mL



NOTE: Do not remove nozzles.

- 1 Pump 150 mL of prepared solution through each affected reagent line (B, C and D). Wait 20 minutes.

NOTE: It is unlikely for the A line to have precipitate build up or bacterial contamination due to the chemical makeup of Reagent A.



100 mL Disinfectant



150 mL Deionized Water

- 2 Pump another 100 mL of disinfectant solution through each affected reagent line and let sit for 20 minutes.

- 3 Flush each affected reagent line with 150 mL of deionized water.

- 4 Reprime the stainer with fresh reagents (Section 2.2) and clean nozzles according to instructions in Section 6.1.

- 5 Perform Volume Test according to instructions in Section 6.4 and record on PM Chart.



CAUTION:

To avoid damage to the instrument, do not leave disinfectant solution in the reagent lines longer than recommended. This procedure should only be performed on an “as needed” basis.

7.3 Instrument Malfunction

Air or Reagent Leaks

Repriming the instrument is usually unnecessary unless a reagent bottle runs completely dry.

An air leak is usually to blame if a smooth and continuous liquid spray fails to come from the nozzles. Carefully inspect all components in the external reagent delivery lines. Look for loose connections, cracks, or breaks that might allow air to be drawn in when the pump operates. Replace any defective part or assembly.

An internal leak may cause fluid to leak from the line when the pump is not running. If an abnormal liquid spray still occurs after all the external reagent delivery line components have been verified, the instrument may require service.

Reagent Delivery Lines



A reagent line leak between the pump outlet and the nozzle will cause fluid to leak into the interior of the stainer housing and ultimately onto the counter. If you observe this, the instrument will require service. Contact your dealer or ELITechGroup for assistance.



WARNING!

A break or malfunction in the reagent delivery system can potentially release up to 1000 mL of highly flammable anhydrous alcohol in and around the instrument. If this occurs, carefully shut off the power to the instrument and consult the SDS for information in handling alcohol spills. Do not use the instrument again until any leaks are repaired.



WARNING!

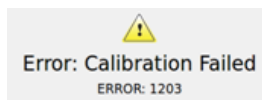
Electrical shock hazard—do not open this instrument or attempt internal repairs. Refer servicing to qualified service personnel. Contact your dealer or ELITechGroup Service.

SECTION 7

SOLVING PROBLEMS

7.3 Instrument Malfunction

Reagent Level Detect System Errors



Reagent A-E Not Calibrated

During the second part of calibration, if no bottles are detected, the display shows an error message.

Calibrate again, making sure that the correct reagent bottles are placed in the enabled tray positions.

LD (Level Detection) Unstable

If bottle movement is detected while calibrating/zeroing, the display shows an error message.

NOTE: While zeroing or calibrating, do not bump the instrument or lab bench. Ensure that no nearby equipment vibrations can be transmitted to the stainer.

7.3 Instrument Malfunction

Calibrating the Reagent Level Detect System

If the Reagent Level Detect System is reporting incorrectly and zeroing (Section 2.2) does not correct the problem, calibrate the system as follows:



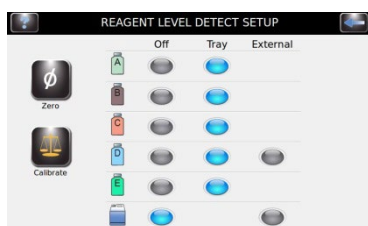
- 1 Press **System Information** from the Main menu.



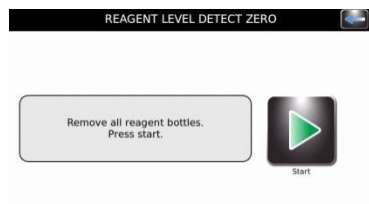
- 2 Press **System Setup**.



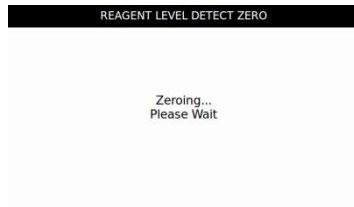
- 3 Press **Level Detect**.



- 4 Press **Calibrate**. Follow the display prompts.



- 5 Remove all reagent bottles and press **Start**. The display shows:



SECTION 7

SOLVING PROBLEMS

7.3 Instrument Malfunction

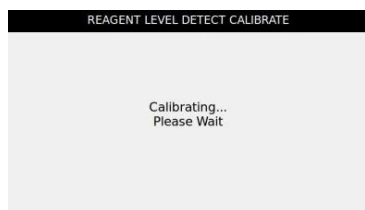
Calibrating the Reagent Level Detect System (continued)

NOTE: Any vibrations or bumps to the instrument or lab bench can cause inaccuracies in zeroing or calibration.

NOTE: Calibration requires full, unopened (caps and seals in place) 500 mL bottles of reagent, placed in the correct tray positions (due to different densities of each reagent type).



- 6 Place the correct reagent bottles in all **enabled** positions, and press **Start**. The display shows:



NOTE: The calibration function ignores any disabled reagent line.



- 7 Press **OK**. Press **Back** twice to return to the Main menu.
- 8 Return the reagent bottles to the tray as indicated in Section 2.1 to prepare for staining.

NOTE: For accurate reagent level detection and calibration, dip tubes must follow their pre-formed coiled shapes.

7.4 Calibrating the Touchscreen



- 1 Select and hold **Standby/Ready** for 5 seconds. A calibration screen with a target appears.
- 2 Select the center of the target with a finger, stylus, or similar tool. Another target will appear in a different location.
- 3 Continue to press the center of the targets until you have pressed all the targets (five total). After the fifth target is pressed, the instrument will save the touch screen calibration and return to the Main menu.

SECTION 7

SOLVING PROBLEMS

7.5 Customer Service

ELITechGroup's Service Department will help you resolve any questions about the operation or performance of your Aerospray Stainer/Cytocentrifuge.

Customers in the United States should contact us by telephone. Outside the U.S., our authorized dealers offer full local service and support.



ELITechGroup Inc.

370 West 1700 South
Logan, Utah 84321 USA

Telephone:

800 453 2725 (*United States & Canada*)
(+1) 435 752 6011 (*International calls*)

Fax:

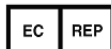
(+1) 435 752 4127

Email:

service_EBS@elitechgroup.com (*Service*)
sales_EBS@elitechgroup.com (*Sales*)

Web Page:

www.elitechgroup.com



European Authorized Representative:

Medical Technology Promedt Consulting
Ernst-Henkel-Straße 7
66386 St. Ingbert
Germany

Telephone: +49(0)68 94-58 10 20

Fax: +49(0)68 94-58 10 21

Email: info@mt-procons.com



Swiss Authorized Representative:

Decomplic AG
Freiburgstrasse 3
3010 Bern
Switzerland
Telephone: +41 32 365 33 33
Email: sar@decomplic.com

8.1 Cytopro® Cytocentrifuge Information

Functional Description

The Cytopro Cytocentrifuge rotor allows rapid sedimentation of specimen cells onto microscope slides for staining or other purposes. Up to eight disposable/reusable sample chamber assemblies with absorbent pads and glass microscope slides can be loaded into the Cytocentrifuge rotor.

Cytocentrifuge and staining functions are independent of one another.

The Cytopro rotor reduces cell loss during collection and prevents accidental damage to the collected specimen. The rotor is sealed to control aerosol release during cytocentrifugation.

Key Features

Adding the Cytopro Cytocentrifuge rotor transforms the stainer into a standard cytocentrifuge with:

- Single, Dual, and Cytopro Magnum chambers
- Reusable or disposable, chambers (single and dual)
- Holds Eight slides and chambers
- User-programmable memory locations for settings (speed, acceleration rate, and time)
- Easy switching between staining and cytocentrifuge modes
- Autoclavable rotor

NOTE: Pressing Cyto brings up the Cytocentrifuge mode. Pressing Back returns to stain mode.

WARNING!

The Cytopro rotor lid, rotor gaskets and related components are intended to be part of biosafety system as specified in international and national biosafety guidelines. They cannot be relied on as the only means of safeguarding workers and the environment when handling pathogenic microorganisms.

Intended Use

The Cytopro Cytocentrifuge rotor is an in vitro diagnostic medical device for professional use only. It is an accessory for fixing biological cell suspensions on glass microscope slides for cytological examination.

The Cytocentrifuge rotor can be used with the following cell suspensions:

- Bronchoalveolar liquid (BAL)
- Cerebrospinal fluid (CSF)
- Urine
- Synovial fluid
- Digested sputum
- Others

Complete information on the Cytopro Cytocentrifuge is available from ELITechGroup. Instructions for use are available in the Cytopro Rotor (AC-160) Series 2 User Manual (REF: RP-517).

APPENDIX A

Critical Reagent Components



The following information identifies the critical chemicals of each reagent used in this instrument.

Reagent(s)	Critical Components
SS-061A or SS-061A-EU Aerospray TB Reagent A Carbol Fuchsin Decolorizer; SS-161A Aerospray TB Reagent A Carbol Fuchsin Decolorizer Concentrate when diluted properly contains:	>90% Methyl Alcohol <2% Nitric Acid
SS-061AF or SS-061AF-EU Aerospray TB Reagent A Fluorescence Decolorizer; SS-161AF Aerospray TB Reagent A Fluorescence Decolorizer Concentrate when diluted properly contains:	<80% Isopropyl Alcohol <1% Nitric Acid
SS-061BMB or SS-061BMB-EU Aerospray TB Reagent B, Methylene Blue; SS-161 BMB Aerospray TB Reagent B Methylene Blue Concentrate when diluted properly contains:	<1% Methylene Blue <1% Benzalkonium Chloride <10% Ethanol
SS-061BBG or SS-061BBG-EU Aerospray TB Reagent B, Brilliant Green; SS-161 BBG Aerospray TB Reagent B Brilliant Green Concentrate when diluted properly contains:	<1% Brilliant Green <1% Benzalkonium Chloride <10% Ethanol
SS-061BP or SS-061-BP-EU Aerospray TB Reagent B with Potassium Permanganate; SS-161BP Aerospray TB Reagent B Potassium Permanganate Concentrate when diluted properly contains:	<1% Potassium Permanganate
SS-061BRT-EU Aerospray TB Reagent B Thiazin Red contains:	< 1% Thiazin Red
SS-061BCS-EU Aerospray TB Reagent B Carbol Solution contains:	< 1% Phenol
SS-061CEZ or SS-061CEZ-EU Aerospray TB Reagent C, Carbol Fuchsin contains:	< 24% Ethanol < 2% Basic Fuchsin < 6% Phenol
SS-061CA or SS-061CA-EU Aerospray TB Reagent C; Auramine contains:	<10% Ethanol <6% Phenol <1% Auramine
SS-061CAR or SS-061CAR-EU Aerospray TB Reagent C with Auramine and Rhodamine contains:	<10% Ethanol <6% Phenol <1% Auramine <1% Rhodamine

Critical Reagent Components

Reagent(s)	Critical Components
SS-061M or SS-061M-EU Aerospray TB Mycohold Cell Adhesive; SS-161M Aerospray TB Mycohold Cell Adhesive Concentrate when diluted properly contains:	<1% Sodium Azide
SS-161A Aerospray TB Reagent Carbol Fuchsin Decolorizer Concentrate contains:	<30% Nitric Acid
SS-161AF Aerospray TB Reagent Fluorescence Decolorizer Concentrate contains:	<10% Nitric Acid
SS-161BMB Aerospray TB Reagent Methylene Blue Concentrate contains:	<5% Methylene Blue <10% Methyl Alcohol
SS-161BBG Aerospray TB Reagent Brilliant Green Concentrate contains:	<24% Ethanol <5% Brilliant Green <2% Malic Acid <1% Benzalkonium chloride
SS-161BP Aerospray TB Reagent Potassium Permanganate Concentrate contains:	<10% Potassium Permanganate
SS-161M Aerospray TB Mycohold Cell Adhesive Concentrate contains:	<1% Sodium Azide
SS-MeOH Reagent-Grade Methanol contains:	≥99.5% Methyl Alcohol, Reagent Grade, Anhydrous
SS-266 or SS-266-EU PM Cleaning Solution contains:	<10% Ethanol 85-95% Deionized Water
SS-133 Decontamination Solution Concentrate contains:	<30% Germicidal Detergent >70% Deionized Water
SS-133 Decontamination Solution when diluted as directed contains:	<2% Germicidal Detergent >98% Deionized Water
SS-029 Nozzle Cleaning Solution contains:	40-50% Methyl Alcohol 1-5% Oxalic Acid
SS-029C, SS-029C-EU, SS-029CG Nozzle Cleaning Solution Concentrate:	95-99% Deionized Water 1-5% Oxalic Acid

APPENDIX B

Stain Information

Stain Description

The stains listed in this manual are for use with the Aerospray Hematology Pro Slide Stainer/Cytocentrifuge for use by medical professionals to stain specimens as a step of standard laboratory practice in diagnosing disease.

Stain Composition

Critical components of stains and cleaning solutions used with this instrument are listed in Appendix A.

Storage and Shelf Life

Stains and cleaning solutions are stable up to the expiration date indicated on the label. Stains and cleaning solutions should be stored 15 – 30 °C unless otherwise stated on the label. Once opened, stains are stable for 90 days on board the instrument.

Hazards and Precautions

The stains and cleaning solutions used with the Aerospray Hematology Stat Slide Stainer/Cytocentrifuge have been classified according to the following standards:

- Globally Harmonized System (GHS) United States Classification
- Regulation (EC) 1272/2008 Classification, Labelling and Packaging of Substances and Mixtures (CLP)

Information for each stain and cleaning solution regarding signal words, hazard classification, hazard pictograms, hazard and precautions statements can be found in the applicable Safety Data Sheet (SDS) for each stain or cleaning solution as well as the product labeling.

SDS for all stains and cleaning solutions can be requested from ELITechGroup technical service or can be obtained by accessing the following website:

<https://ebs.elitechgroup.com/SDS/>

APPENDIX C

Accessories and Supplies

Only replacement parts supplied by ELITechGroup should be used in this instrument. Use of non-approved parts may affect the performance and safety features of this product.

ACCESSORIES NUMBER	REFERENCE
Slide Carousel (12-Slide Capacity)	AC-188
Slide Carousel (30-Slide Capacity)	AC-189
Cytopro® Rotor	AC-160
STAINS AND CLEANING REAGENTS	
<i>Carbol Fuchsin Ready-To-Use Reagents</i>	
Aerospray® TB Reagent A, Carbol Fuchsin Decolorizer, 500mL	SS-061A* or SS-061A-EU
Aerospray® TB Reagent B, Methylene Blue, 500mL	SS-061BMB or SS-061BMB-EU
Aerospray® TB Reagent B, Brilliant Green, 500mL	SS-061BBG or SS-061BBG-EU
Aerospray® TB Reagent C, ELITe ZN, 500mL	SS-061CEZ* or SS-061CEZ-EU
<i>Fluorescence Ready-To-Use Reagents</i>	
Aerospray® TB Reagent A, Fluorescence Decolorizer, 500mL	SS-061AF* or SS-061AF-EU
Aerospray® TB Reagent B, Potassium Permanganate, 500mL	SS-061BP or SS-061BP-EU
Aerospray® TB Reagent B, Thiazin Red, 500 mL **	SS-061BRT-EU
Aerospray® TB Reagent B, Carbol Fuchsin, 500mL **	SS-061BCS-EU
Aerospray® TB Reagent C, Auramine O, 500mL	SS-061CA or SS-061CA-EU
Aerospray® TB Reagent C, Auramine/Rhodamine (mod), 500mL	SS-061CAR or SS-061CAR-EU
<i>Common Ready-To-Use Reagents</i>	
Aerospray® Reagent Grade Methanol, 500mL	SS-MEOH
Aerospray® TB, Mycohold™ Cell Adhesive, 500mL	SS-061M or SS-061M-EU
<i>Carbol Fuchsin Reagent Concentrates</i>	
Aerospray® TB Reagent A, Carbol Fuchsin Decolorizer Concentrate, 30mL	SS-161A
Aerospray® TB Reagent B, Methylene Blue Concentrate, 130 mL	SS-161BMB
Aerospray® TB Reagent B, Brilliant Green Concentrate, 130mL	SS-161BBG
<i>Fluorescence Reagent Concentrates</i>	
Aerospray® TB Reagent A, Fluorescence Decolorizer Concentrate, 30mL	SS-161AF
Aerospray® TB Reagent B, Potassium Permanganate Concentrate, 200mL	SS-161BP
<i>Common Concentrate Reagents</i>	
Aerospray® TB, Mycohold™ Cell Adhesive Concentrate, 100mL	SS-161M
<i>Cleaning Reagents</i>	
Aerospray® Nozzle Cleaning Solution, 355mL	SS-029
Aerospray® Nozzle Cleaning Solution Concentrate, 250mL	SS-029C or SS-029C-EU
Aerospray® PM Cleaning Solution, 500mL	SS-266 or SS-266-EU

*Special hazardous shipping and packaging fees apply. Contact ELITechGroup for details.

** These reagents are mixed 50:50 prior to use.

Reagents with the EU suffix are manufactured in Europe and are available in the European market.

APPENDIX C

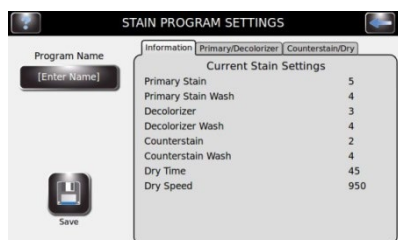
Accessories and Supplies

SUPPLIES NUMBER	REFERENCE
Nozzle Tool	
AC-034	
Nozzle Hex Wrench	AC-035
5 L Space-Saver Container w/cap (For Concentrate Reagents)	AC-038
Spigot for Space-Saver Container	AC-039
Drain Tube, 1.8 meter (6 foot) Length.....	AC-041
500 mL bottle with cap (pack of 5 bottles).....	AC-043-05
5 L Reagent Bottle Assembly (for Reagent D) (without level detect)	AC-072
Nozzle Orifice Cleaning Wire	AC-059
Reagent Pump Priming Tool	AC-069
Aerospray®/Cytopro® Safety Shield	AC-110
10 L Waste Container (without level detect).....	AC-170
1D Barcode Scanner	AC-181
10 L Waste Container (with level detect)	AC-182
5 L Bottle Assembly (with level detect)	AC-183
Nozzle Maintenance Kit.....	AC-184
2D Barcode Scanner	AC-185
O-Ring/Nozzle Thread Grease (3 grams)	SS-103
Aerospray® Nozzle Caps	SS-105
Decontamination Solution Concentrate.....	SS-133
Aerospray® Stain Residue Solvent.....	SS-230
Aerospray® PM Cleaning Solution	SS-266
5 L Reagent Bottle Pickup Tube	RP-171
Acid Fast Control Slides (pack of 50)	SS-249
Preventive Maintenance Chart, pad of 24 sheets	SS-267
Aerospray® TB (Model 7722) Applications Manual.....	RP-464
Cytopro® Cytocentrifuge Rotor (Model AC-160) Applications Manual	RP-517

Contact ELITechGroup for a complete list of replacement parts.

General Programming Information

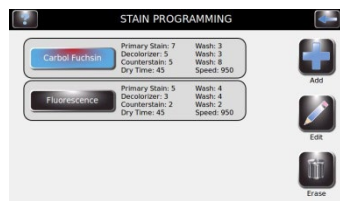
- The Aerospray TB stainer uses two acid-fast staining options: carbol fuchsin or fluorescence. Each option can be modified by the choice of reagents and program settings.
- The stainer comes with two default programs (one fluorescence and one carbol fuchsin) that have been designed to meet the needs of most users without adjustment.
- Users can create their own custom programs if the default programs do not meet their needs.
- Use the preset information as a starting point to build custom programs.
- Use the Stain Programs menu to add, edit, or erase programs, (see Section 3.1).
- The maximum number of programs stored in the instrument is 12.
- Users can rename default programs as desired.
- Users can erase any unused default program. For example, if only fluorescent stains are used, the user can erase the unneeded carbol fuchsin program.
- Use the Restore Defaults function (Section 3.1) to restore deleted preprogrammed routines.
- Use either the 12-place carousel or 30-place carousel. The stainer automatically adjusts programming for the carousel that is loaded in the stainer.
- Users should adjust the programming as necessary depending on which type of reagents are loaded onto the stainer and based on user preferences.



Reagent Options for Staining

The TB stainer is fully capable of using either fluorescence or carbol fuchsin stains depending on user preference. Successful staining depends on using the correct combination of ELITechGroup reagents that have been developed specifically for this instrument. Use caution in loading the correct reagents in the correct positions using the information referenced below. See Section 2.1 for reagent loading instructions.

Which Stain Group and Why?



Fluorescence Stains

Preferred for screening patient specimens.¹

Carbol Fuchsin Stains

Used to observe positive cultures and other specimens where the study of morphology is important.

¹ Vance Sassaman, Mary J. Public Health Practice Program Office Division of Laboratory Systems. Centers for Disease Control and Prevention. *Mycobacterium Tuberculosis: Assessing Your Laboratory*. Atlanta, Georgia 30333: Centers for Disease Control, 1995. Print.

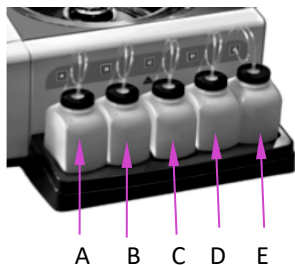
APPENDIX D

Programming Options



CAUTION:

The stainer is not capable of detecting which reagents are loaded on the instrument. The user must take care to load the correct reagents in the correct positions, based upon the options given here and according to user preference.



Reagent Options for Carbol Fuchsin Staining (by position)

(A) Reagent: A Carbol Fuchsin Decolorizer:

- Ready-to-use: SS-061A or SS-061A-EU
- Concentrate: SS-161A

(B) Reagent: Brilliant Green or Methylene Blue (depending on preference). See Section 1.1 Table 2 for more detailed information about reagents.

Methylene Blue:

- Ready-to-use: SS-061BMB or SS-061BMB-EU
- Concentrate: SS-161BMB

Brilliant Green:

- Ready-to-use: SS-061BBG or SS-061BBG-EU
- Concentrate: SS-161BBG

NOTE: Brilliant green and methylene blue are interchangeable according to customer preferences.

(C) Reagent: Primary Stain (ELITE ZN™):

- Ready-to-use: SS-061CEZ or SS-061CEZ-EU
- No concentrate available

(D) Reagent: Deionized or Distilled Water

(E) Reagent: Approved Alcohol:

- Methanol: SS-MEOH (Available in USA only)
- Ethanol
- Reagent alcohol

Reagent Options for Fluorescence Staining (by position)

(A) Reagent: Fluorescence Decolorizer Options:

- Ready-to-use: SS-061AF or SS-061AF-EU
- Concentrate: SS-161AF

(B) Reagent: Counter Stain (Potassium Permanganate or Thiazin Red depending upon preference)

APPENDIX D

Programming Options

Potassium Permanganate Stains:

- Ready to use: SS-061BP or SS-061BP-EU
- Concentrate: SS-161BP

Thiazin Red Stain:

- Ready to use: SS-061BRT-EU and SS-061BCS-EU (Reagents are mixed 50:50 before use. Mixture is stable for 2 days after mixing.)

NOTE: Thiazin Red is available in Europe as a replacement for Potassium Permanganate.

(C) Reagent: Primary Stain

Auramine O (stains organisms yellowish-green):

- Ready to use: SS-061CA or SS-061CA-EU
- No concentrate available

Auramine- Rhodamine (stains organisms yellowish-orange):

- Ready to use: SS-061CAR or SS-061CAR-EU
- No concentrate available

NOTE: Auramine O and Auramine Rhodamine are interchangeable according to customer preferences.

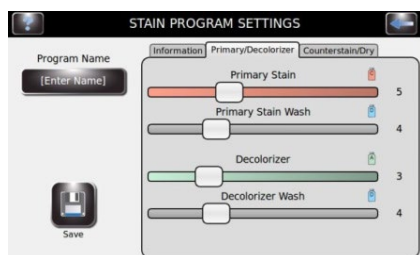
(D) Reagent: Deionized Water

(E) Reagent: Approved Alcohol:

- Methanol: SS-MEOH (available in USA only)
- Ethanol
- Reagent alcohol

Stain Program Options

The following is an explanation of the user-adjustable staining parameters and how staining can be affected by adjusting these parameters.



Primary Stain Setting

Increase the setting to increase the primary stain intensity.

Primary Wash Setting

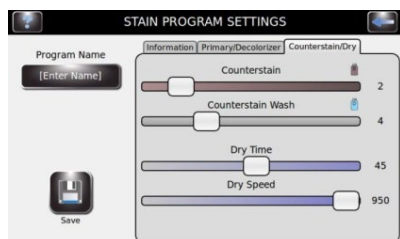
Increase setting to increase washing. A higher setting produces cleaner slides, but can also impact primary stain intensity.

Decolorizer Setting

Increase setting to increase decolorizer level, washes primary stain out of background material and non-Acid-Fast-Bacilli (AFB).

APPENDIX D

Programming Options



Decolorizer Wash Setting

Increase setting to increase washing, a higher setting cleans the slides better and helps even decolorization across the slide.

Counterstain Setting

Increase setting to increase intensity of the background staining counterstain.

Counterstain Wash Setting

Increase setting to increase washing, a higher setting cleans the slides better after counterstain step. This can impact counterstain intensity.

Dry Time Options

Adjust options, if specimen wash off is suspected. Spinning poorly fixed specimens for long periods and at high speeds can spin the stained specimen off of the slide. Users should find the lowest time and speed setting that produces slides that are dry at the end of the cycle. Some water droplets are acceptable on the slide after staining; they should be small enough that the slides are completely dry less than 1 minute after being removed from the stainer (about the length of time to take the slide to the microscope). Most users will use the default settings.

Table A: 12-Slide Carousel Timing:

KEY	Default Program for Carbol Fuchsin Stain
	Default Program for Fluorescent Stains
	Same setting for both Carbol Fuchsin Stain and Fluorescent Stains

Primary Stain Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Primary Stain, total number of applications per slide	0	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31
Primary Stain, total wait time (sec.)	0	12	24	36	48	60	72	84	96	108	120	132	144	156	168	180
Approximate reagent usage for a full carousel (mL)*	0	5	8	11	14	17	20	23	26	29	32	35	38	41	44	47

Primary Wash Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Primary Wash, total number of applications per slide	0	2	4	7	10	12	14	16	18	20	22	24	26	28	30	32
Approximate water (D-line) usage for a full carousel (mL)*	0	6	12	21	30	36	42	48	54	60	66	72	78	84	90	96

*Based upon flow rate of 0.5 mL per second

APPENDIX D

Programming Options

Decolorizer Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Decolorizer, total number of applications per slide	0	2	2	3	3	4	5	6	7	8	9	10	11	12
Decolorizer, total wait time (sec.)	0	0	6	6	12	18	24	30	36	42	48	54	60	66
Approximate reagent usage for a full carousel (mL)*	0	3	3	4.5	4.5	6	7.5	9	10.5	12	13.5	15	16.5	18

Decolorizer Wash Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Decolorizer Wash, total number of applications per slide	0	2	4	7	10	12	14	16	18	20	22	24	26	28	30	32
Approximate water (D-line) usage for a full carousel (mL)*	0	6	12	21	30	36	42	48	54	60	66	72	78	84	90	96

Counterstain Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Counterstain, total number of applications per slide	0	2	2	3	3	4	5	6	7	8	9	10	11	12	13	14
Counterstain, total wait time (sec.)	0	0	6	6	12	18	24	30	36	42	48	54	60	66	72	78
Approximate reagent usage for a full carousel (mL)*	0	4	4	5.5	5.5	7	8.5	10	11.5	13	14.5	16	17.5	19	20.5	22

Counterstain Wash Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Counterstain Wash, total number of applications per slide	0	2	4	7	10	12	14	16	18	20	22	24	26	28	30	32
Approximate water (D-line) usage for a full carousel (mL)*	0	10	15	24	33	39	45	51	57	63	69	75	81	87	93	99

Dry Time Options (seconds)	0	5	10	15	20	25	30	35	40	45	50	60	70	80	90	100	110	120
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Dry Speed Options (rpm)	200	250	300	350	400	450	500	550	600	650	700	750	800	850	900	950
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Table B: 30-Slide Carousel Timing:

KEY	Default Program for Carbol Fuchsin Stain
	Default Program for Fluorescent Stains
	Same setting for both Carbol Fuchsin Stain and Fluorescent Stains

Primary Stain Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Primary Stain, total number of applications per slide	0	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31
Primary Stain, total wait time (sec.)	0	6	12	18	24	30	36	42	48	54	60	66	72	78	84	90
Approximate reagent usage for a full carousel (mL)*	0	19	31	43	55	67	79	91	103	115	127	139	151	163	175	187

*Based upon a flow rate of 0.5 mL per second

APPENDIX D

Programming Options

Primary Wash Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Primary Wash, total number of applications per slide	0	2	4	7	10	12	14	16	18	20	22	24	26	28	30	32
Approximate water (D-line) usage for a full carousel (mL)*	0	12	24	42	60	72	84	96	108	120	132	144	156	163	175	187

Decolorizer Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Decolorizer, total number of applications per slide	0	2	2	3	3	4	5	6	7	8	9	10	11	12
Decolorizer, total wait time (sec.)	0	0	6	0	6	12	12	18	18	24	24	30	30	36
Approximate reagent usage for a full carousel (mL)*	0	6	6	9	9	12	15	18	21	24	27	30	33	36

Decolorizer Wash Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Decolorizer Wash, total number of applications per slide	0	2	4	7	10	12	14	16	18	20	22	24	26	28	30	32
Approximate water (D-line) usage for a full carousel (mL)*	0	12	24	42	60	72	84	96	108	120	132	144	156	163	175	187

Counterstain Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Counterstain, total number of applications per slide	0	2	2	3	3	4	5	6	7	8	9	10	11	12	13	14
Counterstain, total wait time (sec.)	0	0	6	0	6	12	12	18	18	24	24	30	30	36	36	42
Approximate reagent usage for a full carousel (mL)*	0	7	7	10	10	13	16	19	22	25	28	31	34	37	40	43

Counterstain Wash Setting	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Counterstain Wash, total number of applications per slide	0	2	4	7	10	12	14	16	18	20	22	24	26	28	30	32
Approximate water (D-line) usage for a full carousel (mL)*	0	14	26	44	62	74	86	98	110	122	134	146	158	170	182	194

Dry Time Options (sec.)	0	5	10	15	20	25	30	35	40	45	50	60	70	80	90	100	110	120
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Dry Speed Options (rpm)	200	250	300	350	400	450	500	550	600	650	700	750	800	850	900	950
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*Based upon a flow rate of 0.5 mL per second

Sample Preparation

For best results samples should be liquefied and decontaminated. The *N*-acetyl-L-cysteine-sodium Hydroxide Method has been reported to be an appropriate liquefying and decontamination method for sputum samples stained with the TB stainer. Use this technique or an equivalent² on specimens intended for staining in the Aerospray TB stainer.

The *N*-acetyl-L-cysteine-sodium Hydroxide Method is summarized as follows³:

Principle: Sodium hydroxide (NaOH), a decontaminating agent, also acts as an emulsifier. Because of its potential toxicity, NaOH should be used at the lowest concentration that effectively digests and decontaminates the specimen (2 to 4 % is typical, the exact percentage of NaOH should be determined by the lab). The addition of a mucolytic agent, *N*-acetyl-L-cysteine (NALC) reduces the concentration of NaOH required and also shortens the time required for decontamination, thus aiding the optimal recovery of acid-fast bacilli.

Method:

1 Reagent preparation:

- a. NALC-4% NaOH preparation: For each day's cultures, add up the total volume of specimens to be treated and prepare an equal volume of digestant-decontamination mixture, as follows:

- 1 N (4%) NaOH: 50 mL
- 0.1 M (2.94%) trisodium citrate 3H₂O: 50 mL
- NALC powder: 0.5 g

Use sterile deionized or distilled water for preparations of solutions to minimize chance of inadvertently adding acid-fast tap water contaminants to the specimens. Mix, sterilize, and store the NaOH and the citrate in sterile, screw-capped flasks for later use. This solution should be used within 25 hours after the NALC is added.

- b. 0.67 M phosphate buffer, pH 6.8 preparation: Made of the following solutions:

- Solution A (0.067 M disodium phosphate):
 1. Sodium monohydrogen phosphate (anhydrous): 9.47g
 2. Deionized or distilled water: 1000 mL
- Solution B (0.067 M mono potassium phosphate):
 1. Potassium dihydrophosphate: 9.07g
 2. Deionized or distilled water: 1000 mL

Add 50 mL of solution B to 50 mL of solution A and adjust pH to 6.8.

² Other acceptable methods of liquefying and decontaminating samples include: oxalic acid, chitin, and benzalkonium.

³ Forbes, Betty A., Sahm, Daniel F., and Weissfeld, Alice S, *Bailey & Scotts Diagnostic Microbiology*. 11th ed. St. Louis: Mosby, Inc., 2002. Print.

APPENDIX E

Sample/Slide Preparation

- 2 Work within a biological safety cabinet and wear protective clothing, gloves, and mask. Transfer a maximum of 10 mL of sputum, urine, or other fluid to be processed to a sterile, disposable plastic 50-mL conical centrifuge tube with a leak-proof and aerosol-free plastic screw cap. Tubes with easily visible volume indicator marks are best.
- 3 Add an equal volume of freshly prepared digestant to the tube, being very careful when pouring digestant, not to touch the lip of the specimen container, which might inadvertently transfer positive material to a negative specimen. Tighten the cap completely.
- 4 Vortex the specimen for approximately 15 seconds or for a maximum of 30 seconds, being certain to create a vortex in the liquid and not to merely agitate the material. Check for homogeneity by inverting the tube. If clumps remain, vortex the specimen intermittently while the rest of the specimens are being digested. An extra pinch of NALC crystals may be necessary to liquefy mucoid sputa.
- 5 Start a 15-minute timer when the first specimen is finished being vortexed. Continue digesting the other specimens, noting the amount of time that the entire run takes. The digestant should remain on the specimens for a maximum exposure of 20 minutes.
- 6 After 15 minutes of digestion, add enough phosphate buffer to reach within 1 cm of the top of the tube, screw the cap tightly closed and invert the tube to mix the solutions and stop the digestion process. Addition of this solution also reduces the specific gravity of the specimen, aiding sedimentation of the bacilli during centrifugation.
- 7 Centrifuge all tubes at 3600X g for 15 minutes, using aerosol-free sealed centrifuged cups.
- 8 Carefully pour off the supernatant into a splash-proof container. To ensure the specimen does not run down the outside of the tube after pouring, the lip of the tube may be wiped with an amaryl- or phenol-soaked gauze to absorb drips. Be careful not to touch the lip of any tube to another container. It is helpful to watch the sediment carefully as the supernatant is being decanted, because a very mucoid sediment may be loose and may pour out with the supernatant. If the sediment begins to slip, stop decanting and use a sterile capillary pipette to remove the supernatant without losing the sediment.
- 9 Resuspend the sediment in 1 to 2 mL phosphate butter, pH 6.8 buffer.
- 10 Inoculate the sediment to culture media and prepare slides.
- 11 Vortex concentrated sediment. Aspirate 0.1 to 0.2 mL into a Pasteur pipette and add 2 to 3 drops on the slide. Place the end of the pipette, or sterile applicator stick parallel to the slide and slowly spread the liquid uniformly to make a thin smear.

Sample Fixation



WARNING!

Survival of mycobacteria is possible even after fixation. Always handle all specimens with proper precautions.

- 1 After sample preparation, fix the smear at 80 °C for 15 minutes or for 2 hours at 65 to 70 °C on an electric hot plate. The Centers for Disease Control (CDC) recommends heat fixing for 2 hours at 60 to 70 °C⁴ in order to insure inactivation of the *Mycobacterium* organisms. Samples should not be flame fixed. The flame is too hot and can destroy the cell wall of the organisms; the flame also applies heat unevenly across the slide, leaving some areas of the slide un-fixed and organisms still active.
- 2 Other fixation methods can be used and verified by each lab. Some labs have reported good results when heating slides for 10 minutes at 60 to 70 °C, then soaking slides in methanol for 10 minutes, then heating slides again for 10 minutes at 60 to 70 °C. This method has not been tested for viability of organisms after fixation.
- 3 For thick specimens or for users that experience frequent sample loss during staining, ELITechGroup recommends using Mycohold™. Mycohold was developed by ELITechGroup to stabilize specimen stained in the Aerospray TB stainer. This proprietary protein solution (REF: SS-061M) is also available as a 10X concentrate (REF: SS-161M). Suggested directions for use are given below.

Using Mycohold Cell Adhesive

SS-061M Mycohold Solution

Procedure A

- 1 Place a drop of Mycohold onto a microscope slide with a drop of specimen.
- 2 Heat dried specimen at 60 to 70 °C for at least 15 minutes.
- 3 Process slides as usual.

Procedure B

- 1 Apply sample to slide and allow to dry.
- 2 Place one or two drops of Mycohold next to the specimen.
- 3 Spread the Mycohold across the specimen and allow to dry.
- 4 Heat slide at 65 to 70 °C for at least 15 minutes.

SS-161M Mycohold Concentrate Solution

Procedure A

- 1 Add 1 part SS-161M and 9 parts of 0.85% sodium chloride solution.
- 2 Use the diluted concentrate in place of SS-061M as described above.

⁴ Vance Sassaman, *Mycobacterium Tuberculosis: Assessing Your Laboratory*.

APPENDIX E

Sample/Slide Preparation

Using Mycohold Cell Adhesive (continued)

Procedure B

- 1 Add 1 part SS-161M and 9 parts of liquid specimen and mix well.
- 2 Apply the specimen containing the Mycohold to a microscope slide and allow to dry.
- 3 Heat dried specimen at 65 to 70 °C for at least 15 minutes.
- 4 Process the slides as usual.



WARNING!

Survival of mycobacteria is possible even after fixation. Always handle all specimens with proper precautions.

Staining Slides

- 1 After sample fixation the slides are ready for staining with the Aerospray TB stainer. Stain slides using either carbol fuchsin or fluorescence stains with the desired program. Control slides can be used to help determine the appropriate program for each laboratory.

NOTE: *The CDC recommends⁵ using fluorescence stains when screening suspected TB samples. They recommend staining with carbol fuchsin when confirming samples of TB and also when staining cultures.*

⁵ Vance Sassaman, *Mycobacterium Tuberculosis: Assessing Your Laboratory*.

APPENDIX F

Cleaning Solutions

ELITechGroup Inc. offers several cleaning solutions for the Aerospray Stainer/ Cytocentrifuge family. The following products are available to keep your Aerospray running safely and optimally.

SS-029 and SS-029C/SS-029C-EU Aerospray® Nozzle Cleaning Solution

Aerospray Nozzle Cleaning Solution (SS-029) and Aerospray Nozzle Cleaning Solution Concentrate (SS-029C/SS-029C-EU) when diluted as recommended should be used for cleaning the instrument. Specifically for:

- General cleaning
- Nozzle cleaning
- Instrument interior and exterior cleaning
- Carousel cleaning

The Aerospray Nozzle Cleaning Solution may be purged through the instrument pumps without causing damage to the instrument. Dilution instructions for the Aerospray Nozzle Cleaning Solution Concentrate (SS-029C/SS-029C-EU) can be found by referring the instructions in **DOC-00123**.

SS-133 Decontamination Solution Concentrate

Decontamination Solution Concentrate (SS-133) when diluted as recommended should be used for decontamination of the inner and outer surfaces before the instrument is returned to ELITechGroup Inc. for Service or when instrument will be prepared for long-term storage.

SS-222 Aerospray® Line Cleaner

Aerospray Line Cleaner (SS-222) may be used If needed or if recommended by ELITechGroup Inc. service personnel to clean out the stainer lines.

Aerospray Line Cleaner can be purged through pumps without causing damage to the instrument.

Contact ELITechGroup technical service for more information.

SS-230/SS-230-EU Aerospray® Stain Residue Solvent

The Aerospray Stain Residue Solvent (SS-230/SS-230-EU) is for exterior cleaning of the nozzles, carousels, and bowls of Aerospray Slide Stainers. The Aerospray Stain Residue Solvent can be used as a cosmetic cleaner for the outside of the instrument, sinks, floors, counter tops, etc.



WARNING!

Do not run Aerospray Stain Residue Solvent (SS-230/SS-230-EU) through stainer pumps as serious damage will result to the instrument. This solvent is for the exterior cleaning of nozzles, carousels and bowls for Aerospray slide stainers only.

Cleaning Carousels

1. Remove carousel from instrument.
2. Remove lid.
3. Pour a small amount of SS-230 Aerospray Stain Residue Solvent (~5-10 ml) on the carousel and the lid.
4. Lightly scrub the carousel with a paper towel or brush over all fouled areas. Rinse lid and carousel with water, methanol, and/or spray the top of the lid and run a carousel clean cycle.
5. Repeat as necessary.

APPENDIX F

Cleaning Solutions

All other Cleaning

1. Test the use of SS-230 Aerospray Stain Residue Solvent on a small non-conspicuous area of the surface to be cleaned to ensure compatibility.
2. Lightly scrub area to be cleaned with a paper towel.
3. Rinse the area cleaned with deionized water or methanol and wipe dry.

SS-266/SS-266-EU Aerospray® PM Cleaning Solution

Aerospray PM Cleaning Solution (SS-266/SS-266-EU) can be used for cleaning the instrument when performing preventive maintenance on the instrument. The Aerospray PM Cleaning Solution is recommended for nozzle cleaning especially for nozzles that have stubborn contamination.

The Aerospray PM Cleaning Solution may be purged through the instrument pumps without causing damage to the instrument.

See Section 5 of this manual for information on preventive maintenance procedures.

SS-MeOH Aerospray® Reagent Grade Methanol

Aerospray Reagent Grade Methanol (SS-MeOH) can be used for general exterior and internal cleaning of the instrument and pumps. Refer to the relevant sections in this manual for its applicable use.

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