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Essential Information for the Aerospray Hematology® Slide Stainer/Cytocentrifuge (Model 7150) its Accessories and Supplies.

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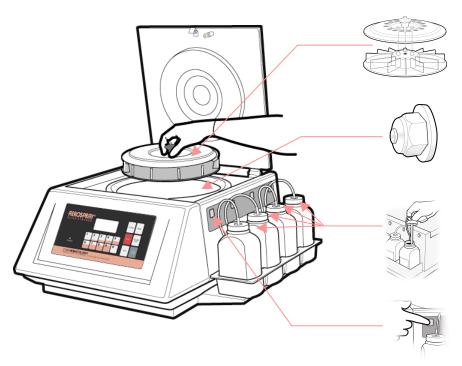
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#### 1 Introduction

This document contains the information required by the In Vitro Diagnostic Directive (98/79/EC) Annex I (Essential Requirements), Part B, Section 8 (Information supplied by the manufacturer) for the Aerospray® Hematology Slide Stainer/Cytocentrifuge (Model 7150), its accessories and supplies. In particular, it describes any symbols used on labels and on the instrument, hazards associated with the stain reagents used, the intended purpose of the device, lot numbers and expiration dates, and instructions for the use and maintenance of the device.

Some sub-requirements of Section 8 are not applicable to this product, but the applicable requirements are referenced herein. This document is available in the official language of each EC member state where the product is sold that requires information in its own language. Additional helpful information may be found in Wescor User's Manuals, Service Manuals, Technical Bulletins, or other information supplied by Wescor or its Authorized Distributors for specific countries. Some supplementary materials are in the English language only. Many of these materials may be found on Wescor's web site: <a href="https://www.wescor.com">www.wescor.com</a>. A Document Packet is included with each Aerospray<sup>®</sup> Hematology Slide Stainer/Cytocentrifuge, which includes MSDS sheets, a Declaration of Conformity, Nozzle Cleaning Instructions, an Installation Checklist, and a User's Manual (8.1).

## Aerospray® Hematology Slide Stainer/Cytocentrifuge Front and Side



#### Slide Staining Carousel

The carousel holds 1 to 12 slides. It mounts on the drive hub, rotating at approximately 20 rpm for staining, 600 rpm for stain evaporation, and approximately 950 rpm for drying.

#### **Reagent Spray Nozzles**

The spray nozzles are the key to good staining. There are two spray nozzles. The A, B, and C reagents spray out of the the front nozzle (ABC nozzle). Reagent D sprays out of the back nozzle (D nozzle).

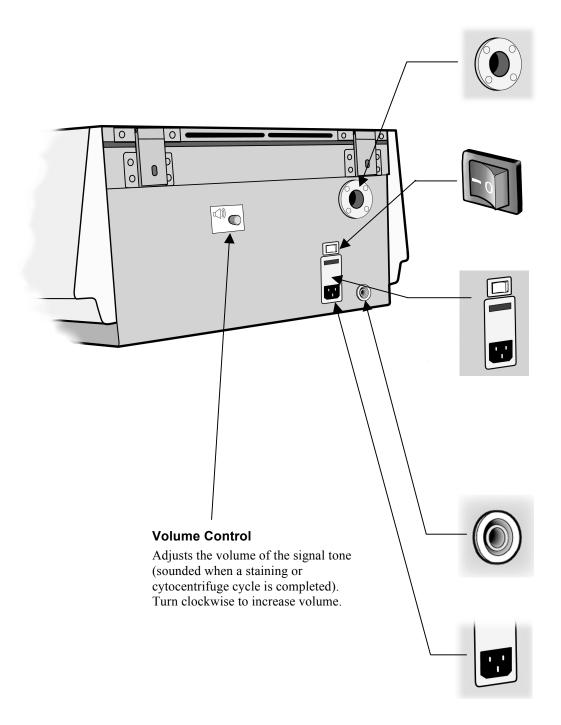
#### **Reagent Bottle Dip Tubes**

Four reagent dip tubes, A through D, connect the reagents to the internal pumps and spray nozzles.

## **Manual Priming Buttons**

These buttons (located above each reagent bottle) operate the corresponding pumps for priming.

## Aerospray® Hematology Slide Stainer/Cytocentrifuge Back Panel



#### **Exhaust Vent**

During operation, air is drawn through openings at the rear of the instrument lid and expelled through the exhaust vent.

#### **Power Switch**

The main power switch turns the stainer on and off. When the instrument is connected to the proper power source and the power switch is on, the front panel power indicator is lit.

#### **Fuse Door**

To get to the main fuses, turn the power off, disconnect the power cord and use a small screwdriver to open the fuse door. Before replacing the fuses for any reason, please follow normal safety precautions. For continued protection against fire hazard, use fuses only with the correct type and rating. All fuses in this equipment are type T.

#### **Drain Port**

Provides connection for ¼ inch inside diameter drain tube. This port must be connected to a drain or vented waste container.

#### **Power Entry Module**

Provides connection for a standard IEC 320 type power cord (provided).

# 2 Symbols Used (8.2)

# Symbols used on instruments and reagents

$\sim$	Alternating Current (AC)
EC REP	Authorized Representative in the European Community
LOT	Batch Code
8	Biological Hazards (Biological Risks)
REF	Catalog Number (Model Number)
<u> </u>	Caution, Consult Accompanying Documents (Attention, see instructions for use)
C€	CE
i	Consult Instructions For Use
3	Do Not Reuse
	Do not use if package damaged
	Fragile, Handle with Care
<del></del>	Fuse
<b>E</b>	General Symbol for Recovery, Recyclable
IVD	In vitro Diagnostic Device (In vitro Diagnostic Medical Device)
类	Keep away from sunlight (Keep away from heat)
	Manufacturer
	"New Waste"

ı	"On" (Power)
0	"Off" (Power)
510	RoHS Pollution Control
SN	Serial Number
	Temperature Limitation – indicates high and low limits (normal room temperatures are specified for all Wescor Reagents).
$\subseteq$	Use By
	Volume Control
<u>^</u>	General Warning, Caution, Risk of Danger
	Warning, Biological Hazard
	Corrosive
*	Environment Hazard
	Flammable
×	Harmful / Irritant
	Oxidant
	Toxic

## 3 Hazards (8.3)

## a. Risk and Safety Phrases

Reagent SS-071A – Reagent A Buffer (pH 6.8), and the following reagents; SS-072A – Reagent A Buffer (pH 7.2), SS-171A – Reagent A Buffer (pH 6.8) Concentrate 30 mL, SS-171A500 – Reagent A Buffer (pH 6.8) Concentrate 500 mL, SS-172A – Reagent A Buffer (pH 7.2) Concentrate 30 mL, and SS-172A500 – Reagent A Buffer (pH 7.2) Concentrate 500 mL when diluted as directed are not associated with any Risk and Safety Phrases. They are not associated with any EU Symbols of Danger.

R Phrases:	None
S Phrases:	None

Reagents SS-071B – Reagent B Thiazin Stain, 500 mL bottle, and SS-171B2 – Reagent B Thiazin Stain Concentrate, 195 mL, when diluted as directed are associated with the following Risk and Safety Phrases. The associated EU Symbol of Danger is T.

R 10:	Flammable
R 23/24/25:	Toxic by inhalation, in contact with skin and if swallowed
R 39/23/24/25:	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
S 36/37:	Wear suitable protective clothing and gloves
S 45:	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

Reagents SS-071C – Reagent C Eosin Stain, 500 mL bottle and SS-171C2 Reagent – C Eosin Stain Concentrate, 220 mL, when diluted as directed are associated with the following Risk and Safety Phrases. The associated EU Symbols of Danger is T.

R 10:	Flammable
R 23/24/25:	Toxic by inhalation, in contact with skin and if swallowed
R 39/23/24/25:	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if
	swallowed
S 36/37:	Wear suitable protective clothing and gloves
S 45:	In case of accident or if you feel unwell seek medical advice immediately (show the label where
	possible)

SS-MeOH Aerospray Reagent-Grade Methanol is associated with the following Risk and Safety Phrases. European Symbols of Danger are: F and T.

R 11:	Highly Flammable
R 23/24/25:	Toxic by inhalation, in contact with skin and if swallowed
R 39/23/24/25:	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if
	swallowed
S 7:	Keep container tightly closed
S 16:	Keep away from sources of ignition – No smoking
S 36/37:	Wear suitable protective clothing and gloves
S 45:	In case of accident or if you feel unwell, seek medical advice immediately (show label where possible)

Reagents SS-048 – Aerofix Fixative, 500 mL, and SS-148 – Aerofix Additive for methanol reagent after dilution as directed, are associated with the following Risk and Safety Phrases. The associated EU Symbols of Danger are F and T.

R 11:	Highly Flammable
R 23/24/25:	Toxic by inhalation, in contact with skin and if swallowed
R 39/23/24/25:	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
S 7:	Keep container tightly closed
S 16:	Keep away from sources of ignition – No smoking
S 36/37:	Wear suitable protective clothing and gloves

Reagents SS-171A / SS-171A500 – Reagent A Buffer (pH 6.8) Concentrates, and SS-172A / SS-172A500 – Reagent A Buffer (pH 7.2) Concentrates are associated with the following Risk and Safety Phrases. The associated EU Symbol of Danger is Xn.

R 20/21/22:	Harmful by inhalation, in contact with skin and if swallowed
R 68/20/21/22:	Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed
R 36/37/38:	Irritating to eyes, respiratory system and skin
R 40:	Limited evidence of a carcinogenic effect
R 43:	May cause sensitization by skin contact
S 26:	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S 36/37:	Wear suitable protective clothing and gloves
S 45:	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
S 51:	Use only in well-ventilated areas

Reagent SS-171B2 – Reagent B Thiazin Stain Concentrate and Reagent SS-171C2 – Reagent C Eosin Stain Concentrate are associated with the following Risk and Safety Phrases. It is not associated with any EU Symbols of Danger.

R 10:	Flammable
S Phrases:	None

Reagents SS-148 – Aerofix Additive for Methanol is associated with the following Risk and Safety Phrases. The associated EU Symbol of Danger is Xn.

R 22:	Harmful if swallowed
S phrases:	None

SS-029 Aerospray Nozzle Cleaning Solution and SS-029C when diluted as instructed are associated with the following Risk and Safety Phrases. European Symbols of Danger are: F and T.

R 11:	Highly Flammable
R 23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R 39/23/24/25:	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
S 7:	Keep container tightly closed
S 16:	Keep away from sources of ignition – No smoking
S 36/37:	Wear suitable protective clothing and gloves
S 45:	In case of accident or if you feel unwell, seek medial advice immediately (show label where possible)

SS-029C Aerospray Nozzle Cleaning Solution Concentrate is associated with the following Risk and Safety Phrases. European Symbol of Danger is: None.

R:	None
S:	None

SS-230 Aerospray Stain Residue Solvent is associated with the following Risk and Safety Phrases. European Symbols of Danger are: None.

R:	None
S	None

SS-133 Decontamination Solution Concentrate is associated with the following Risk and Safety Phrases. European Symbols of Danger is C.

R 34	Causes burns
R 22	Harmful if swallowed
R 67	Vapors may cause drowsiness and dizziness
S 24/25	Avoid contact with skin and eyes

S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S 36/37/39	Wear suitable protective clothing, gloves and eye/face protection
S 45	In case of accident or if you feel unwell seek medical advice immediately (show the label where
	possible)

# 4 Intended Purpose (8.5)

The Aerospray® Hematology Slide Stainer/Cytocentrifuge (Model 7150) is intended for use by medical professionals to stain specimens that may include blood and other body fluids, as a step of standard laboratory practice in diagnosing disease in humans. Addition of the Cytopro rotor allows preparation of slides by cytocentrifugation before staining.

# 5 Identification / Lot / Expiration Dates (8.6)

The device and all accessories and supplies are clearly identified. Labels on reagents include lot number and expiration date information as shown in section 6.

# 6 Details from Labels (8.7a and 8.4a)

## a. Manufacturer Name and Address (8.7a and 8.4a)

Wescor, Inc 370 West 1700 South Logan, UT 84321-8212 USA

Phone: (+1) 435-752-6011 Fax: (+1) 435-752-4127 Email: <u>service@wescor.com</u> www.wescor.com

## b. Authorized Representative Name and Address (8.7a and 8.4a)

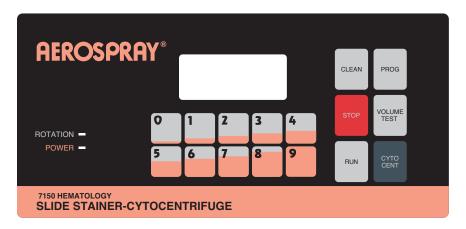
Medical Technology Promedt Consulting
Altenhofstraβe 80
66386 St. Ingbert
Germany
Tel. +49 6894 581020

Fax: +49 6894 581021 Email: <u>info@mt-procons.com</u>

#### c. Identification of the Device, Accessory, or Supply Item (8.7a and 8.4b)

The model number and name is on the front panel of the instrument. Accessories and supplies are labeled with names and product numbers.

# Aerospray® Hematology Slide Stainer/Cytocentrifuge Faceplate (Label)



## A list of **Accessories** follows:

of Accessories follows.	
Slide Carousel (12 Slide Capacity)	AC-028
Nozzle Tool	AC-034
Nozzle Hex Wrench	AC-035
5.0 Liter Space-Saver Container with Cap (for Concentrate Reagents)	AC-038
Spigot for Space-Saver Container	AC-039
Cover Slip Holder (for 22 mm Square Cover Slips)	AC-040
Drain Tube (1.8 meter, 6 feet length)	AC-041
500 mL Bottle with Cap	AC-043
Cover Slip Holder (For 22 mm x 50 mm Cover Slips)	AC-051
Nozzle Orifice Cleaning Wire	AC-059
Cytopro Cytocentrifuge Rotor	AC-060
Reagent Pump Priming Tool	AC-069
5.0 Liter Bottle Assembly for Buffer (Reagent A)	AC-072
Nozzle Maintenance Kit	AC-077
Aerospray / Cytopro Safety Shield	AC-110

## A list of **Supplies** follows:

SS-071A
SS-072A
SS-071B
SS-071C
SS-MeOH
SS-048
SS-171A
SS-172A
SS-171A500
SS-172A500
SS-171B2
SS-171C2
SS-148
SS-029C
SS-029CG
SS-100
SS-222
SS-230
M2189
PRINT-0077
57-0001

## d. In Vitro Diagnostic Use (8.7a and 8.4g)

The symbol on the label recognizes the diagnostic use described above (Intended purpose).

## e. Storage and Handling Conditions (8.7a and 8.4h)

Reagents are marked with a storage temperature range of 15° to 30°C degrees. Do not freeze reagents or store in direct sunlight. Temperatures slightly outside these specified limits for a short duration will not harm the reagents.

If the Aerospray stainer will be idle for more than a week, the following procedure prevents nozzle plugging problems when ready to use the instrument again. Do this for each reagent line.

- Carefully loosen the ring-cap from the reagent bottle.
- Lift the dip tube out of the bottle and wipe off any remaining reagent from the tube.
- Install a cap on the reagent bottle and set aside.
- Place the dip tube in a bottle of methanol or ethanol.
- Flush at least 250 mL of methanol or ethanol through the line and spray nozzle. Leave methanol or ethanol in the line.
- Leave flushing fluids in the reagent lines during storage. Do not run reagent lines dry.
- One at a time, remove and disassemble each spray nozzle. After removing o-ring, place metal nozzle parts in a 50 mL centrifuge tube (provided in the Aerospray Maintenance Kit) filled with methanol, ethanol, or prepared SS-029C.
- Mark the tube to identify the correct reagent line. Use the provided cleaning kit tube stand to store the tubes. Place each tube holding nozzle parts in the position corresponding with the reagent line that the nozzle is removed from. Be sure the nozzles are returned to their original position in the stainer.
- Flush the instrument drain tube with water to prevent build-up of paper fibers, precipitates, or other materials.

CAUTION! Do not subject stainer to freezing temperatures while aqueous fluids remain in any reagent lines. Serious damage can result.

# f. Operating Instruction (8.7a and 8.4j)

## i. Initial Setup

- Install the drain tube
- Plug in the power cord and switch the power on
- Install all reagent bottles
- Prime all reagent lines
- Run the CLEAN cycle twice to purge the reagent nozzles of precipitates and debris. (See Clean Cycle 6.f.ix.)

**NOTE:** Dirty nozzles cause most staining problems. Check spray pattern and clean nozzles as necessary.

## ii. Selecting a Program

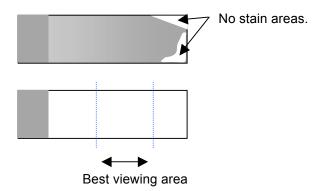
Press **PROG** to open the program menu. Press **4** to select the Stain Mode menu. Press the number (1-4) of the desired staining mode.

- 1. **Rapid Stain** The concentrated stain is evaporated centrifugally to remove the alcohol and rapidly stain the slide with a film of concentrated stain. Cycle times range from 3.2 to 6.7 minutes.
- 2. **Wright-Giemsa** The Wright-Giemsa mode employs a single application of concentrated stain primarily to stabilize the basophil granules and other water-soluble components. Staining is accomplished with a dilute stain (stain plus rinse buffer) over a somewhat longer staining period. Cycle times range from 5.4 to 9.2 minutes.
- 3. **May-Grunwald Giemsa** The May-Grunwald Giemsa stain uses both the concentrated stain and the dilute staining steps to produce a longer and more extensive stain. Cycle times range from 6.8 to 10.6 minutes.
- 4. **Custom Stain** The Custom Stain can be used as a preset stain mode with 9 intensity selections. Cycle times range from 6.3 to 9.7 minutes. Custom Stain mode is fully programmable to cover a wide range of staining preferences.

The Custom Mode allows the altering each of the 11 steps in the Run sequence, including different T/E ratios and spin time adjustments in the concentrated and dilute stain steps.

#### iii. Smear Placement

The portion of the slide closest to the nozzle is covered by the carousel post and the reagent spray misses the top corner of the slide. Also, the conical expansion of the reagent spray misses the top corner of the slide. Specimens placed in these areas will not be stained. Staining is maximum directly underneath the air inlet in the carousel lid and lessens as the air expands across the slide. Place smears on the slides within the best viewing area as shown below.



#### iv. Load Carousel

Press the center button to remove the carousel lid. Load the 12-slide carousel with labeled end of the slide facing the inside rim of the carousel. Smears must face clockwise

The stainer can be programmed to save reagent when staining partial loads. To use this feature, place slides in the marked slots on the carousel and enter the number of slides on the keypad. Put the first slide in position 1, the second in position 2, and so on. If there is an odd number of slides, place a blank slide in the next position for balance. If there are empty slots in the carousel, place a blank blocking slide in the first empty slot clockwise from a specimen slide and another blank blocking slide directly across the carousel.

### v. Programming Number of Slides

If staining a partial load, enter the number of slides into the stainer by using the numbered keypads. Slide selection defaults to Full Carousel at the end of the run or after pressing STOP.

This instrument treats anything over a partial load as a full carousel. To stain more than a partial load there is no need to program the number of slides. A partial load on the 12-slide carousel is anything from 1 to 6 slides.

#### vi. Selecting Stain Intensity

Change the stain intensity as needed using the numbered keypads. The stainer permits setting reagent intensity on a scale of 1 to 9 for each stain mode, with 9 being the darkest intensity.

When powering the stainer for the first time, or whenever power is interrupted, the last setting used is shown on the display.

To change the stain intensity, press PROG to enter the stain intensity menu. Press 1 to change the intensity. Press the number (1-9) that corresponds to the desired intensity. The stain intensity selected remains current in the staining mode until it is changed.

#### vii. Slide Fixation

Before staining, all specimens must be fixed. The Aerospray staining system provides alternatives for slide fixation. The instrument automatically fixes slides with Reagent D at the beginning of the stain cycle if the alcohol fixation function is ON. If hand-fixing slides, instrument fixation can be turned off to conserve reagents and time.

**NOTE:** Settings 1-3 deliver 3 seconds of spray of alcohol with 30, 60 and 90 second pauses. Settings 4-6 deliver 6 seconds of spray with the same pauses. Settings 7-9 deliver 9 seconds of spray with the same pauses.

To activate or deactivate the alcohol fixation function, press PROG. Press 2 to access the alcohol fixation menu. Press 1-9 on the keypad to select alcohol fixation, or press 0 to turn alcohol fixation off. Once a selection is made,

the main display returns with the selection indicated. To remove the changes, press PROG, then press 2. From that menu, press CLEAN. This clears the run display and returns the stainer to the default value.

### viii. Thiazin/Eosin (T/E) Ratio and Other Adjustments

Press PROG to enter the Main Programming Menu. Press 3 to enter the Adjust Stain display. Follow the cursor to enter the desired selection (0-9) on each setting. Pressing the CLEAN keypad in this screen restores the factory default settings. Press STOP to exit.

#### 1. Thiazin/Eosin Ratio

Since the eosin and thiazin stains are separate reagents, their ratio can be adjusted in the instrument. Higher numbers yield higher thiazin and bluer slides. Lower numbers yield lower eosin and redder slides.

#### 2. Spin Time Adjustment

The spin time adjustment controls the duration of slide centrifugation after stain application. Evaporating the methanol content of the stain dramatically accelerates staining. This drying step concentrates the dye in the staining film as well, an important parameter in accelerating staining results. The granulation of monocytes and neutrophilic leukocytes is particularly sensitive to the spin time. As the selection number is increased, staining intensity also increases.

#### 3. Rinse Adjustment

A selection of 1-9 (0 = OFF) final rinse applications are available. The rinse is important in developing eosinophilic staining and developing the final color balance of the slide. The mid-rinse is adjustable only in the custom stain mode.

**NOTE:** A plus sign on the display next to the intensity setting indicates that the settings have been adjusted.

## ix. Running a Staining Cycle

After programming the settings and number of slides, run a staining cycle by pressing RUN to start the cycle. During the staining cycle, the display shows the current stain setting and reagent currently being applied. When reagent is spraying an icon shows on the display. At the bottom of the display, a progressing bar graph portrays remaining time (approximate) in the cycle.

If the alcohol fixation is on, Reagent D (fixative) is applied first to fix the cells to the glass slide. Reagents C, B and A are blended and applied to the slides as programmed. The carousel accelerates to high speed to spin off excess rinse and to dry the slides. During the high-speed spin Reagent D is sprayed through the stain nozzle to clean the lines and wash debris from the slides. The backs of the slides are cleaned by a spray from the D nozzle in a reverse high-speed spin. When the cycle is complete the signal tone sounds.

### x. CLEAN Cycle

CAUTION! Remove all specimen slides before using the CLEAN cycle, otherwise specimens will be ruined.

At the end of each shift, or whenever the stainer will be idle for more than four hours, use the CLEAN cycle to maintain nozzle performance. Place an empty carousel in the stainer and close the lid. Press CLEAN. Two cleaning options are available; (1) SYSTEM CLEAN – for routine cleaning, and (2) CAROUSEL CLEAN – for cleaning the carousel more thoroughly. After running the CLEAN cycle, spray nozzle faces with methanol, ethanol, or SS-230. Use a nozzle brush to clean the nozzle orifices when patterns are less than optimal.

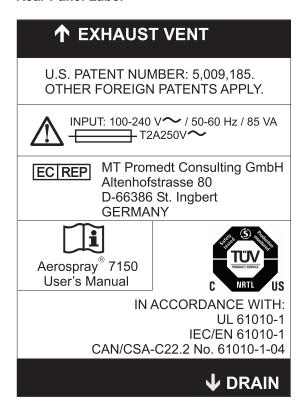
## xi. Emergency Stop

The STOP button interrupts any cycle immediately. Pressing STOP during a CLEAN cycle establishes a warning routine that cannot be escaped until a CLEAN cycle is repeated.

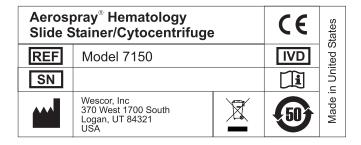
## g. Appropriate Warnings and Precautions (8.7a and 8.4j)

The device, its accessories and supplies are labeled with appropriate warnings.

#### **Rear Panel Label**



#### **Model / Serial Number Label**



#### **Side Panel Membrane Switch**



## h. Composition of Critical Chemicals in Reagent Products (8.7b)

SS-071A Reagent A Buffer (pH 6.8)

SS-072A Reagent A Buffer (pH 7.2)

SS-171A Reagent A Buffer (pH 6.8) after dilution

SS-171A500 Reagent A Buffer (pH 6.8) after dilution

SS-172A Reagent A Buffer (pH 7.2) after dilution

SS-172A500 Reagent A Buffer (pH 7.2) after dilution

- <1% Imidazole
- <1% Maleic Acid
- <1% Triton X-100
- <1% Potassium Hydroxide
- <0.1% Preservative
- > 99% Deionized Water

SS-071B Reagent B Thiazin Stain, 500 mL

SS-171B2 Reagent B Thiazin Stain after dilution

50-65% Methyl Alcohol

35-40% Deionized Water

- <5% Ethanol
- <1% Triton X-100
- <1% Imidazole Hydrochloride
- <1% Azure B
- <1% Methylene Blue

SS-071C Reagent C Eosin Stain, 500 mL

SS-171C2 Reagent C Eosin after dilution

50-65% Methyl Alcohol

35-50% Deionized Water

- <5% Ethanol
- <1% Triton X-100
- <1% Eosin Y
- <1% Potassium Maleate

SS-048 Aerofix Fixative High Humidity, 500 mL

SS-148 Aerofix Additive for methanol, after dilution

- >95% Methyl Alcohol
- <4% Ethylene Glycol
- <2% Polyvinylpyrrolidone (PVP)
- <1% Azure B

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SS-148 Aerofix Additive for methanol

55-70% Ethylene Glycol

30-45% Polyvinylpyrrolidone (PVP)

<1% Azure B

SS-171A Reagent A Buffer (pH 6.8) Concentrate, 30 mL

SS-171A500 Reagent A Buffer (pH 6.8) Concentrate, 500 mL

#### SS-172A Reagent A Buffer (pH 7.2) Concentrate, 30 mL

#### SS-172A500 Reagent A Buffer (pH 7.2) Concentrate, 500 mL

- < 25% Potassium Maleate
- < 10% Imidazole
- < 1% Triton X-100
- < 1% Maleic Acid
- < 1% Potassium Hydroxide
- <12% Formaldehyde
- < 5% Methanol
- > 55% Deionized Water

## SS-171B2 Reagent B Thiazin Stain Concentrate, 200 mL

- <24% Ethanol
- < 2% Triton X-100
- < 2% Imidazole Hydrochloride
- < 1% Azure B
- < 1% Methylene Blue
- > 76% Deionized water

#### SS-171C2 Reagent C Eosin Stain Concentrate, 220 mL

- <24% Ethanol
- < 5% Potassium Hydrogen Maleate
- < 2% Triton X-100
- < 1% Eosin Y
- > 76% Deionized water

#### SS-148, Aerofix Fixative Concentrate High Humidity

55-70% Ethylene Glycol

30-45% Polyvinylpyrrolidone (PVP)

<1% Azure B

## SS-MeOH Reagent-Grade Methanol contains:

≥99.5% Methyl Alcohol, Reagent Grade, Anhydrous

#### SS-029 Nozzle Cleaning Solution contains:

40-50% Methyl Alcohol

1-5% Oxalic Acid

#### SS-029C, SS-029CG Nozzle Cleaning Solution Concentrate:

95-99% Deionized Water

1-5% Oxalic Acid

## SS-230 Aerospray Stain Residue Solvent contains:

70-85% Dimethyl sulfoxide

## 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

## i. Storage Conditions and Shelf Life (8.7c)

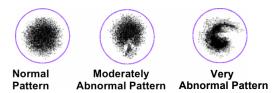
Reagents should be stored at room temperature away from direct light. Expiration dates are shown on each reagent label with the international symbol  $\square$ .

## j. Performance of Device (8.7d)

This is not a measurement instrument; however, running a spray pattern, and volume test can check instrument performance. Run this test if any abnormal results are observed after completing a staining cycle:

### i. Spray Pattern Test

- a. Remove the carousel from the instrument.
- b. Press VOLUME TEST.
- c. Press 1 for Pattern Test.
- d. Hold a sheet of white paper in front of the carousel hub.
- e. Press the prime button that corresponds with the reagent line to be tested. The display shows the selected Pattern Test and which reagent line is being tested. The instrument sprays a short burst of the corresponding reagent.
- The spray pattern must be round and uniform. If the spray pattern is abnormal, a clogged nozzle may be the reason. Resolution to this problem is usually achieved by doing one or more of the following:



- 1. Wipe the nozzle orifice with methanol or ethanol, then run a CLEAN cycle.
- 2. Briskly push the bristles of the nozzle cleaning brush into the nozzle orifice. Repeat several times to allow bristles to remove debris blocking the orifice.
- 3. Disassemble and clean the nozzle.
- g. Press STOP to exit Pattern Test.
- h. If the spray pattern is normal but staining results are abnormal, perform a Slide Pattern Test.

**NOTE:** Reagents A, B, and C spray from the stain nozzle (ABC).

#### ii. Slide Pattern Test

- a. Place a 26 mm x 76 mm (1" X 3") piece of paper in slots 1 and 2 of the carousel with a blocking slide in the slot before the paper slides. Replace the carousel lid. Load the carousel into the instrument and close the lid.
- b. Press VOLUME TEST.
- c. Press 1.
- d. Press the manual prime button for the reagent line to be tested. This sprays the paper "slide" and reveals the pattern of stain application to the slide.
- e. Remove the paper slides.
- f. Repeat steps a to e for each reagent line.
- g. Press STOP to exit the Pattern Test.
- h. The pattern on the slide should be uniform without any continuous lines or streaks. If continuous lines or streaks on the paper slides are observed, disassemble and clean the defective nozzle.

NOTE: Reagents A, B, and C spray from the stain nozzle (ABC).

## iii. Spray Volume Test

- a. To test the volume of stain being delivered, press VOLUME TEST.
- b. Press 2 to select Volume Test.
- c. Hold a small container such as the 14 mL centrifuge tube included with the Aerospray Maintenance Kit to capture the spray from the desired nozzle.
- d. Press the corresponding prime button. The pump for that position runs for 20 seconds.

- e. Place the centrifuge tube with the collected reagent in the tub stand of the maintenance kit. Place the tube in the position that corresponds to the reagent line being tested. Use the information found in Interpreting Results to determine the results of the Spray Volume test.
- f. To exit Volume Test press STOP.

### iv. Interpreting Results

When factory new, the B and C reagents should deliver 9.5 to 12.0 mL over the 20 second spray sequence. The A and D reagents should deliver between 9 and 11 mL. Older nozzles may exhibit higher volumes. The instrument usually stains properly with reagent deliveries above and below these levels. Volume relationships between nozzles are at least as important as the actual volumes collected and your investigation should center on whether the nozzles are delivering close to the same levels.

#### **Low Volume**

Reagent precipitate or foreign matter inside the nozzle typically causes low volume from a spray nozzle. If the CLEAN cycle does not help, the best solution is to manually disassemble and clean the spray nozzle.

#### **Excessive Volume**

If collecting excessive volume, make sure the nozzle is assembled correctly (see Reassembly in Section 6o). If this fails to correct the problem, contact an authorized representative or Wescor for assistance.

## k. Special Equipment Required (8.7e)

See the list of Accessories in Section 6c for the maintenance tools and supplies provided with each stainer.

## I. Type of Specimen to be Used (8.7f)

The equipment is used to stain hematology specimens (blood smears, bone marrows, and other bodily fluids) that are applied to microscope slides.

# m. Procedure for Use (8.7g)

Refer to Operating Instructions in section 6f.

## n. Internal Quality Control (8.7k)

Refer to Spray Pattern Test, Slide Pattern Test and Interpreting Results in Section 6j.

## o. Performance Verification, Maintenance, and Safe Waste Disposal (8.7n)

#### i. Performance Verification

To verify performance see Spray Pattern test, Spray Volume test and Interpreting Results in Section 6j.

#### ii. Maintenance

After each run the lines are flushed with buffer and Reagent D, which removes the stain and prevents fouling while the instrument is idle. This greatly reduces the need for maintenance; however, we recommend the following measures to keep the instrument in top running condition. Use the following Preventive Maintenance (PM) chart to document maintenance.

WARNING! Always wear eye and hand protection when performing preventive maintenance on this instrument.

**NOTE:** To protect staining quality, the instrument requires the lines to be filled with Reagent D. If a prime keypad has been pressed prior to staining or if a staining cycle is interrupted a SYSTEM (or CAROUSEL) CLEAN is

required. If you press RUN with any reagent other than Reagent D in the lines, a warning display and signal will be given until SYSTEM CLEAN is run.

**NOTE:** As you begin a new month, the "Volume after Monthly Cleaning" becomes the "Previous Month's Ending Volume" and should be transferred to that category on the PM chart.

#### DAILY:

At end of each shift or if instrument will be idle for more than 4 hours:

- 1. Run a CAROUSEL CLEAN cycle followed by a SYSTEM CLEAN cycle.
- 2. Use a spray bottle filled with methanol, ethanol or SS-230 to spray the front of each nozzle, and clean each nozzle orifice with nozzle brush.
- 3. Spray the stainer bowl and exterior case using methanol or ethanol. Wipe clean with a paper towel.
- 4. Initial completion of daily procedure on preventive maintenance (PM) chart.
- 5. When ready to use the instrument again, run a SPRAY PATTERN test to verify nozzle performance before staining. Should any pattern appear abnormal, repeat step 2 to clean nozzle orifice.

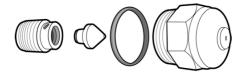
#### WEEKLY:

- Perform SPRAY VOLUME test as described in Section 6.j. Record the volume collected from each nozzle on PM chart.
- 2. If volume trends lower or spray pattern is abnormal, disassemble and clean affected nozzle(s). *Do not mix or interchange nozzles or nozzle parts. Always return nozzles to same location in stainer.* Repeat SPRAY PATTERN and SPRAY VOLUME tests on cleaned nozzle(s).
- 3. Pour 50 mL of SS-230 into the bowl drain. Wipe down the nozzles, carousel tray and carousel lid using methanol or ethanol in a squirt bottle or SS-230 and a paper towel.
- 4. Slowly pour 200-300 mL of water 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.
- 5. Initial completion of weekly PM.

#### MONTHLY:

1. Disassemble and clean all nozzles as described in the following section (Section 6.p). *Do not mix or interchange nozzles or nozzle parts.* 

#### **D Nozzle Components**



#### **ABC Nozzle Components**



- 2. Reinstall nozzles. Always return nozzles to the same location in stainer.
- 3. Perform SPRAY PATTERN and SPRAY VOLUME tests. Record results from end of month SPRAY VOLUME test on preventive maintenance chart. *NOTE: When entering a new month, the Volume After Monthly Cleaning number becomes Previous Months Ending Volume number.*
- 4. Disinfect reusable bottles with a 1/10 dilution of bleach. Rinse thoroughly with deionized water.
- 5. Initial completion of monthly PM.
- 6. Supervisor checks and initials.

#### **ANNUALLY or AS NEEDED:**

- 1. Check internal and exterior tubing and fittings for cracks, leaks, or any type of deterioration. Replace as needed.
- 2. Place Reagent B and C dip tubes into 500 mL of methanol/bleach solution (3 parts household bleach to 7 parts methanol).
  - a. Press VOLUME TEST, then press **3** for the Line Flush. The display prompts you to REMOVE THE STAIN SPRAY NOZZLE.
  - b. Press RUN to activate the automated line cleaning procedure. The procedure includes multiple purges over approximately 60 minutes. Extracted text

#### WARNING! DO NOT LEAVE BLEACH SOLUTION IN LINE LONGER THAN 3 HOURS.

- c. Once the alarm sounds, replace the ABC nozzle. Rinse the B and C dip tube thoroughly in DI water and run 30 mL (60 seconds) in the lines to avoid contaminating the reagent with bleach. Replace the dip tubes in their respective reagent bottles. Press RUN to reprime the lines. When complete, the display returns to the last run screen used.
- d. Check internal and exterior tubing and fittings for cracks, leaks, and any type of deterioration. Replace as needed.

**NOTE:** Press STOP to exit the Line Flush. Press RUN and then STOP to advance to the next step.

# **Preventive Maintenance Chart**

Aerospray® Hematology Slide Stainer/Cytocentrifuge, Model 7150 Month / Year:

Daily				Weekly						Monthly							
Clean Cycle and Wiping					Nozzle Performance					Clean Reagent Nozzles and Instrument							
Day	AM	PM	Night	*Daily Control Slides	Week	Reagent	Spray Pattern (✔ if okay)	**Expected Spray Volume	Measured Spray Volume	New Spray Volume (if nozzle was cleaned)	Drain Line Flush (see back page weekly step 4)	Initial	Reagent	Previous Months Ending Volume	Volume After Monthly Cleaning	Disinfect DI Water Bottle	Initial
1						Α		9-11 mL	mL	mL							
2					1 4	В		9.5-12.0 mL	mL	mL			٨				
3						С		9.5-12.0 mL	mL	mL			Α				
4						D		9-11 mL	mL	mL							
5						Α		9-11 mL	mL	mL							
6					2	В		9.5-12.0 mL	mL	mL			В			Not Applicable	
7						С		9.5-12.0 mL	mL	mL			Ь				
8						D		9-11 mL	mL	mL							
9						Α		9-11 mL	mL	mL						Not Applicable	
10					3	В		9.5-12.0 mL	mL	mL							
11					J	С		9.5-12.0 mL	mL	mL							
12						D		9-11 mL	mL	mL							
13						Α		9-11 mL	mL	mL							
14					4	В		9.5-12.0 mL	mL	mL			ח			Not	
15					~	С		9.5-12.0 mL	mL	mL					Applicable		
16						D		9-11 mL	mL	mL							
17								Annually	or as need	ed							
18					Clean B	and C lines v	vith MeOH-E	Bleach mixture	Date								
19					Check in	nternal and ex	terior tubing	g and fittings	Date				Superv	isor Appr	oval		
20																	
21					Preventive Maintenance Chart procedures are located on reverse side.												
22					Instru	Instructions for the Spray Pattern Test, Spray Volume Test, and cleaning the nozzles are contained in the User's Manual.											
23					The frequencies set forth on this chart for maintenance are only estimates. Field conditions and usage affect the need for maintenance.												
24					Do preventive maintenance at the level necessary to keep nozzle performance within specification and slides staining correctly.												
25					Warning: Always wear eye and hand protection when performing preventive maintenance on the Aerospray Slide Stainer.												
26					This Preventive Maintenance Chart may be reproduced in its entirety by Aerospray users.												

\*\*Volume relationships between nozzles are as important as the actual volumes collected. Investigation should center on whether the nozzles are delivering close to the same volumes.

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29 30 31

#### Reagent Lot Record Preventive Maintenance Procedure Corrective Action Log **DAILY:** At end of each shift or if instrument will be idle for more Reagent Reagent Reagent Reagent Day than four hours: Ā B Č D 1. Run the Carousel Clean followed by a System Clean cycle at the end of each shift or as required to keep the stainer clean. The carousel can also be cleaned manually as needed. 2 2. Once each day or as needed, use a squirt bottle filled with SS-230. methanol or ethanol to spray the stainer interior. With a 3 clean paper towel, wipe the nozzle faces and interior surfaces. 4 Use a fine bristled brush as necessary to clean the nozzle 5 Spray the exterior case using methanol or ethanol. Wipe all 6 surfaces clean with a paper towel. 4. Initial completion of daily procedure on preventive maintenance (PM) chart. 5. When you are ready to use the instrument again, you may want 8 to run a SPRAY PATTERN test to verify nozzle performance 9 prior to staining. Should any pattern appear abnormal repeat step 2 to clean nozzle orifice. (Run control slides if desired). 10 WEEKLY: 1. Perform the Spray Pattern and Spray Volume tests. Record the 11 volume collected from each Reagent on the PM chart. 12 2. If volume trends lower, or if the spray pattern is abnormal, clean the nozzle orifice with a fine-bristled brush or disassemble and 13 clean the affected nozzle(s). 14 3. Pour 50 mL of SS-230 into the bowl drain. Wipe down the nozzles, carousel tray and carousel lid using methanol or 15 ethanol in a squirt bottle or SS-230 and a paper towel. 4. Slowly pour 200-300 mL of water into instrument drain to 16 prevent build up of paper fibers, precipitates, etc. Verify drain is 17 flowing properly and not allowing fluid to back up in bowl or flow out of air vent on case back. 18 5. Initial completion of weekly PM. MONTHLY: 19 1. Disassemble and clean both nozzles. **Do not** mix or interchange 20 nozzles or nozzle parts. 2. Reinstall nozzles. Always return nozzles to the same location in 21 stainer. 22 3. Perform SPRAY PATTERN and SPRAY VOLUME tests. Record results of end of month SPRAY VOLUME test on preventive 23 maintenance chart. NOTE: As you enter a new month the Volume After Monthly 24 Cleaning number becomes Previous Months Ending Volume 25 4. Disinfect reusable rinse (Reagent A) bottles with a 1/10 dilution 26 of household bleach. Allow to stand in bottle for 10 minutes. Rinse thoroughly with deionized water. 27 5. Initial completion of monthly PM. 28 6. Supervisor checks and initials. ANNUALLY: 29 1. Clean the B & C reagent lines with a mixture of 3 parts 30 household bleach and 7 parts methanol. This procedure may be used whenever volume test shows declining values with a clean 31 nozzle. 2. Check internal and exterior tubing and fittings for cracks, leaks. Corrective Action Log Instructions or any type of deterioration. Replace as needed. Instructions for Reagent Lot Record The Corrective Action Log is optional. Document each Each time you replace a reagent bottle, record lot number from the new bottle problem occurrence with (1) the date. (2) a brief in the box that corresponds to the reagent changed and current months

numeric date.

description of the nature of problem, and (3) any

corrective action taken to resolve or correct problem.

## p. Troubleshooting

## i. Abnormal Staining Results

#### 1. Smear Loss

If smear loss occurs;

- a. Check Reagent D spray pattern and volume. Clean nozzle if necessary. If any volumes are high, contact your Wescor dealer.
- b. The problem is likely poor slide quality and will probably resolve with new slides.
- c. Dipping the slides into methanol as they are being loaded into the Aerospray carousel often solves the problem.

#### 2. Uneven Staining

- a. Check spray patterns and volumes.
- b. Clean nozzles.
- 3. Some Slides stain well, others do not
  - a. Check slide placement in the carousel and number of slides programmed.
  - b. Check carousel magnets.

#### 4. Color Shift

- a. Clean nozzle. Check volumes. If volumes have changed, contact you Wescor Dealer. If possible, adjust the T/E ratio until repairs are made.
- 5. B and C volumes are low with clean nozzle
  - a. Run line flush.
- 6. Frequent internal nozzle plugging
  - a. Run line flush.
- 7. Refractile artifacts in Red Cells
  - a. Use Aerofix SS-048 or add SS-148 to the fixation alcohol.
- 8. Weak Staining
  - a. Check pattern and delivery
  - b. Clean nozzles.
  - c. Adjust settings.

### ii. Instrument Malfunctions

#### 1. Drive Problems

The microprocessor monitors the rotation of the carousel during a staining cycle. The motor control adjusts the carousel to approximately 20 rpm for reagent application. If the rotation varies widely from that called for by the operating system, the display shows ERROR DRIVE PROBLEM:

A likely cause is improper carousel installation. Other problems such as malfunction of the drive motor or electronic components require servicing of internal components.

## 2. Wrong Rotor Message

A wrong rotor message displays when a staining cycle is attempted with a cytocentrifuge rotor in the stainer, or when a cytocentrifuge run is attempted with a staining carousel in the stainer.

## 3. Electronic Failure

If you suspect an electronic problem with this instrument, the following will help you identify the specific nature of the problem.

An electric failure would appear as an obvious malfunction such as a scrambled or totally inoperative display panel, or improper response to the keypad.

Like all microprocessor-controlled instruments, transient voltages coming through the power lines may cause the stainer to "lose its place."

- a. If this occurs, switch OFF the main power for 10-20 seconds to reset the instrument.
- b. If this works temporarily, but the problem recurs, install a computer-type surge protector to isolate the instrument from power line transients.
- c. If possible, connect the stainer to a power circuit not shared by centrifuges, refrigerators, air conditioner, or other motorized equipment.

If you suspect a more obscure electronic problem, monitor the stainer through a complete operating cycle to determine if the operating sequence is correct. Do this by running the stainer while watching the display and listening to the pumps.

Observe the operating sequence display to verify that each event occurs according to the operating sequence.

Following is a typical timing sequence for the 7150. All times are approximate and are merely to establish the sequence of events. Actual cycle times may vary.

#### **RUN SEQUENCE (AT INTENSITY 5)**

#### APPROXIMATE TIME (IN SECONDS)

Staining Mode:	Rapid	Wright-Giemsa	MG Giemsa	Custom
Fixation	43	42	42	41
Concentrated Stain	149	57	138	163
Mid Rinse	0	30	32	30
Dilute Stain	0	225	223	234
Final Rinse	30	44	45	46
Drying	64	70	70	69
Total (In Minutes)	4.9	7.8	9.2	8.2
	Reag	ent Consumption (mL)		
Fixative	6.6	6.6	6.6	6.6
Eosin Stain	4.0	4.2	4.3	5.0
Thiazin	4.0	4.2	7.6	6.8
Buffer	9.3	30.0	30.0	30.0

#### iii. Reagent Delivery

If you suspect a problem with reagent delivery, diagnose the problem by assessing the performance of each spray nozzle.

Press the prime buttons and observe each nozzle for uniform dispersion, pattern shape, and direction of spray. Test spray pattern and spray volume to determine which nozzle is not functioning properly. Use the instructions under Disassembly and Cleaning to clean any nozzle that does not appear to function normally.

#### Disassembly and Cleaning

The automatic clean cycle eliminates the evaporative accumulation of reagent solute in the nozzle system. Foreign material may, however, get into the system and eventually plug the nozzle. If this happens, manually disassemble and clean the spray nozzle as follows:

- 1. Slide the nozzle tool over the spray nozzle and turn counter-clockwise to loosen and remove.
- 2. While taking the nozzle apart, become familiar with the nozzle, its parts and assembly.

**NOTE:** The following procedure requires using the Nozzle Maintenance Kit. Use the kit to prevent mixing nozzles or nozzle parts. When removing Aerospray nozzle(s), be sure to return all nozzles to their original positions after cleaning. This helps ensure consistent staining performance.

- 3. Hold the spray nozzle with the nozzle tool and insert the 5/32 nozzle hex wrench into the compression screw. Turn counter-clockwise to loosen and remove. DO NOT DROP COMPRESSION SCREW OR SWIRL CONE.
- 4. Remove the o-ring.

**NOTE:** Excessive force used to loosen and remove the compression screw can damage the plastic nozzle tool. If the compression screw cannot be readily loosened, soak the nozzle in methanol, ethanol, or prepared SS-029C to remove residue. If the problem continues, use light penetrating oil and a 5/8-inch wrench to loosen the nozzle.

#### CAUTION! Do not use hardened metal instruments to clean or scrape nozzle components.

- 5. Place disassembled metal nozzle parts in one of the provided 50 mL centrifuge tubes.
- 6. Fill tube to 25 mL mark with methanol, ethanol, or SS-230.
- 7. Cap tube, agitate, and then soak parts until clean.

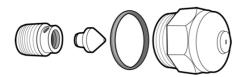
# WARNING! Always wear protective clothing and eye protection when using the SS-230. Dispose of used cleaning solution in the correct manner.

- 8. Agitate again, and pour off the solution.
- 9. Use the provided cleaning wire (AC-059) to clean the nozzle orifice.
- 10. Remove any material in the swirl cone grooves by sliding the edge of a piece of paper through each groove.
- 11. Inspect nozzle parts to ensure they are completely clean. Repeat soaking if necessary.

**NOTE**: To prevent mixing nozzle parts, use the tube stand inside the Nozzle Maintenance Kit. Place tube containing nozzle parts in the punched hole that corresponds with the reagent line that the nozzle came from.

- 12. Rinse parts in the tube with deionized water. Continue rinsing until cleaning solution is completely removed from parts and tube.
- 13. Rinse parts in the tube with methanol, ethanol, or SS-230, and then remove parts from tube.
- 14. Reassemble nozzles and return nozzles to their original locations in the stainer.

## **D Nozzle Components**



## **ABC Nozzle Components**



## Reassembly:

- 1. Use a swab to apply a small amount of silicone lubricant (SS-103, included with the instrument) to the threads of the compression screw to prevent binding.
- 2. Insert the swirl cone into the compression screw. Hold this assembly and nozzle housing in a vertical position. HOLD THIS POSITION UNTIL THE NOZZLE REASSEMBLY IS COMPLETED.
- 3. Insert the long end of the hex wrench into the screw up to the stop. Turn the compression screw into the nozzle housing. Tighten firmly with the nozzle tool and hex wrench. If assembled correctly, the compression screw should screw into the nozzle housing approximately ½ inch.
- 4. Replace the O-ring.
- 5. Install the spray nozzle by turning it in a clockwise direction. Be sure to return each nozzle to its original position. Use the nozzle tool and tighten to a snug fit. **DO NOT OVERTIGHTEN**. Prime the nozzle and check spray pattern and spray volume before staining.

#### iv. Safe Waste Disposal

Disposal of fluids may be governed by local regulations, consult material safety data sheets.

## q. Setup and Pre-use Procedures (8.70)

## i. Installing Drain Tube

Place the slide stainer on a level counter surface near a sink or suitable drain or waste container. Attach the drain tube to the drain port on the back lower right of the unit. Route the tube to a drain or vented waste container. Make certain the tube remains below the drain port. Run the tube continuously downward to the drain or waste container so that liquid cannot be trapped in the line. Keep the tube as short as possible, no longer than 1.8 meters.

NOTE: Do not submerge the end of the drain tube in liquid (this interferes with draining).

## ii. Connecting Power

- 1. The power switch is located on the back panel in the power entry module.
- 2. Make certain the switch is **OFF** (O).
- 3. Plug the female end of the power cord into the power entry module (90 to 264 Volts AC).

**NOTE:** We recommend utilization of a power line surge protector to isolate the instrument from spikes and surges.

- 4. Plug the male end of the power cord into a grounded power outlet.
- 5. Turn the power switch **ON** (I). The power indicator on the front panel should now be on. The display initially shows the software version.

**NOTE:** Leave the power on except when the instrument is serviced or moved.

### iii. Install all reagent bottles

Place the reagent bottles front to back in the following order:

- (A) Rinse
- (B) Thiazin Stain
- (C) Eosin Stain
- (D) Methanol, Ethanol, or Aerofix

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

CAUTION! To avoid severe damage, never use reagents containing organic solvents in this instrument unless they are supplied by Wescor or specified in official Wescor formulation instructions.

Remove the cap from each bottle. Remove the central portion of the seal.

Insert the dip tubes into the reagent bottles and screw on the ring caps.

#### iv. Aerospray Nozzle Maintenance Kit

The Aerospray Nozzle Maintenance Kit (AC-075) is provided to help maintain optimum performance from the reagent delivery system. The kit contains tools and equipment to clean the nozzles, check reagent delivery and to prime the instrument.

#### v. Prime all reagent lines

For peak stainer performance, thoroughly purge and prime each reagent delivery line using the following instructions. This procedure uses approximately 250 mL of reagent per line. Extra reagent is included with the new instrument for this purpose.

Remove each spray nozzle with the provided nozzle tool by turning it counterclockwise. Note the location of each nozzle (so you can return it to the original location).

Place a carousel in the stainer to prevent stain from entering the motor shaft. Briefly press each prime button. Stain should appear within 10 seconds. If no stain appears within 10 seconds there may be an air lock in the line. Immediately stop priming. Use Reagent Pump Priming Tool (AC-069), part of Nozzle Maintenance Kit, to remove the air lock.

If stain begins to appear within 10 seconds (or once an air lock is resolved), prime all reagent lines. This can be done manually or by using Prime Lines or Volume Test functions. When properly primed, a steady stream of reagent (no sputtering or breaks) flows from each nozzle receptacle while pressing the corresponding prime button.

#### WARNING! Never operate a dry pump longer than 10 seconds.

#### Simultaneously Priming All Lines

Press VOLUME TEST. Press 4 on the keypad to prime all the reagent lines. The pumps run for 60 seconds. After priming reagent lines, replace the nozzles. Return each nozzle to its original location for consistent staining performance.

#### **Priming Individual Lines**

Prime manually for 60 seconds or press VOLUME TEST. Press 3 on the Keypad. Press the desired prime button. The pump for that position runs for 20 seconds. Repeat twice more to achieve 60 seconds of flow.

After priming all reagent lines, replace the nozzles. Return each nozzle to its original location for consistent staining performance.

With the nozzles installed, repeat the priming sequence above. Use a carousel in the instrument. A fine cone of spray should come from each nozzle. Run the Spray Volume and Spray Pattern tests. After verifying nozzle performance, run the CLEAN cycle.

## vi. Run the CLEAN cycle

The CLEAN cycle uses Reagent D to purge the reagent nozzles of precipitates and debris. Reagent D remains in the lines until a stain cycle starts. At that time, the Reagent D is purged out of the line and replaced with Reagents A, B or C. The steps described below are for initial setup (see following Note), routine cleaning of the instrument, or to keep the nozzles clean while the instrument is idle. We recommend frequent use (at least once per shift) of the CLEAN cycle to ensure reliable nozzle performance.

**NOTE:** Run the following CLEAN cycle routine twice during initial setup, to help remove any air bubbles from the reagent lines and ready the instrument for slide staining.

- Place an empty carousel in the instrument and close the lid.
- Push CLEAN. Select SYSTEM CLEAN. This sprays Reagent D through the nozzles and onto the carousel.
- Wipe nozzle orifices to remove all residual liquid.
- At this point, the instrument "stands by" with Reagent D remaining in the nozzles. The instrument can be left in this standby mode for extended periods to prevent clogging while the stainer is idle.

# CAUTION! Do not place any carousel loaded with specimens in the instrument during a CLEAN Cycle.

**NOTE:** Pressing STOP during the CLEAN cycle causes a warning to be displayed until a complete CLEAN cycle is completed.

## r. Process for Cleaning, Decontamination (8.7q)

Under normal clinical use the Aerospray® Hematology Slide Stainer/Cytocentrifuge poses very little risk of biological infection to laboratory workers. The stainer is essentially an environmental surface, which should be kept clean. Only low-level disinfection is required.

Biological contamination occurs only when specimens slough off the slides during staining. These tend to be removed by the continual flow of reagents through the instrument. In addition, the reagents used in the staining and cleaning process

are suitable for low to intermediate level disinfection. The stainer is self-cleaning under normal use, but cannot be considered decontaminated. The stainer exterior can also be contaminated by touching with contaminated gloves and requires routine surface cleaning.

For additional decontamination, the following procedures provide low to intermediate disinfection. If the stainer is contaminated by unusually hazardous or disinfection resistant organisms, further treatment with appropriate procedures may be necessary. If sending the stainer to Wescor for service or repair, contact Wescor for current decontamination and shipping instructions.

- 1. Mask the lid latch and locking pin holes with waterproof tape to protect the stainer Interior.
- 2. Place the stainer in a biological safety hood or well-ventilated area. Use prudent safety precautions including hand and eye protection.

CAUTION! Do not flood the stainer bowl by overloading the drain. Never allow fluid to rise above the base of the drive hub. Do not spray fluids near openings in the stainer housing that lets fluid into the instrument interior. This can cause severe damage.

- 3. Spray inner bowl and inner lid with disinfectant detergent such as a 10% bleach solution or Wescor's Decontamination Solution (SS-133).
- 4. Repeat spray treatment every 2 or 3 minutes. Leave solution on surfaces for approximately 10 minutes. Do not allow cleaning solutions to dry on the stainer surfaces.
- 5. Rinse inner bowl and lid thoroughly with tap water.
- 6. With the stainer lid closed, apply decontamination solution to a cloth. Wipe the exterior surfaces of the stainer. Do not flood the display panel with excessive moisture. Any moisture that seeps through could damage the internal electronics. Repeat wipe down every 2 or 3 minutes for about 10 minutes total.
- 7. Remove decontamination solution by thoroughly wiping surfaces with a cloth soaked in tap water.
- 8. Immerse or generously spray the carousel and lid with disinfectant detergent. Allow to sit for 20 to 30 minutes. **Do not autoclave the carousel or lid**.
- 9. Thoroughly rinse the carousel and lid with tap water.

NOTE: These decontamination procedures are for routine use only. If shipping the stainer to Wescor for repair or service, contact Wescor 's Service department for a current copy of the decontamination and shipping instructions before preparing and shipping the stainer. Shipping stainers without decontaminating them according to these instructions is dangerous to service personnel and results in a significant decontamination charge.

# s. Environmental Specifications and Precautions (8.7r)

Device conforms to EMS directive 89/336/EC. Using this instrument in a manner not specified by Wescor may impair the safety protection designed into the equipment and may lead to injury.

## t. Disposal of Device (8.7s)

The device is subject to the WEEE Directive 2002/96/EC and cannot be disposed of in a normal landfill. Instead, the equipment must be disposed of either by routing to an authorized local facility approved for handling hazardous materials, or returning the equipment to Wescor, Inc.

**END**