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Essential Information for the Aerospray® Gram Slide Stainer/Cytocentrifuge (Model 7320), its Accessories and Supplies

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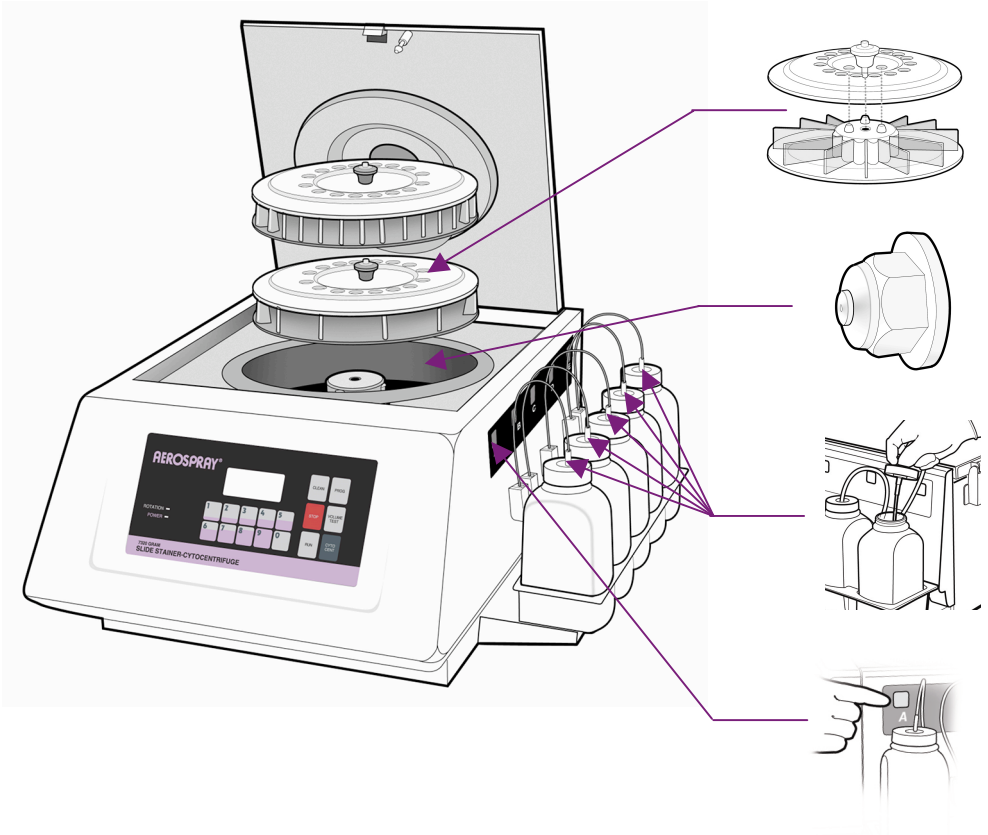
1 Introduction

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® Gram Slide Stainer/Cytocentrifuge (Model 7320), 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 material is in the English language only. Many of these materials may be found on Wescor's web site: www.wescor.com. A Document Packet is included with each Aerospray® Gram Slide Stainer/Cytocentrifuge, which includes MSDS sheets, a Declaration of Conformity, Nozzle Cleaning Instructions, an Installation Checklist, and a User's Manual **(8.1)**.

The cytocentrifugation function is available with the addition of the Cytopro® rotor, and is described in a separate Essential Information document and manual.

Aerospray® Gram Slide Stainer/Cytocentrifuge Front and Side



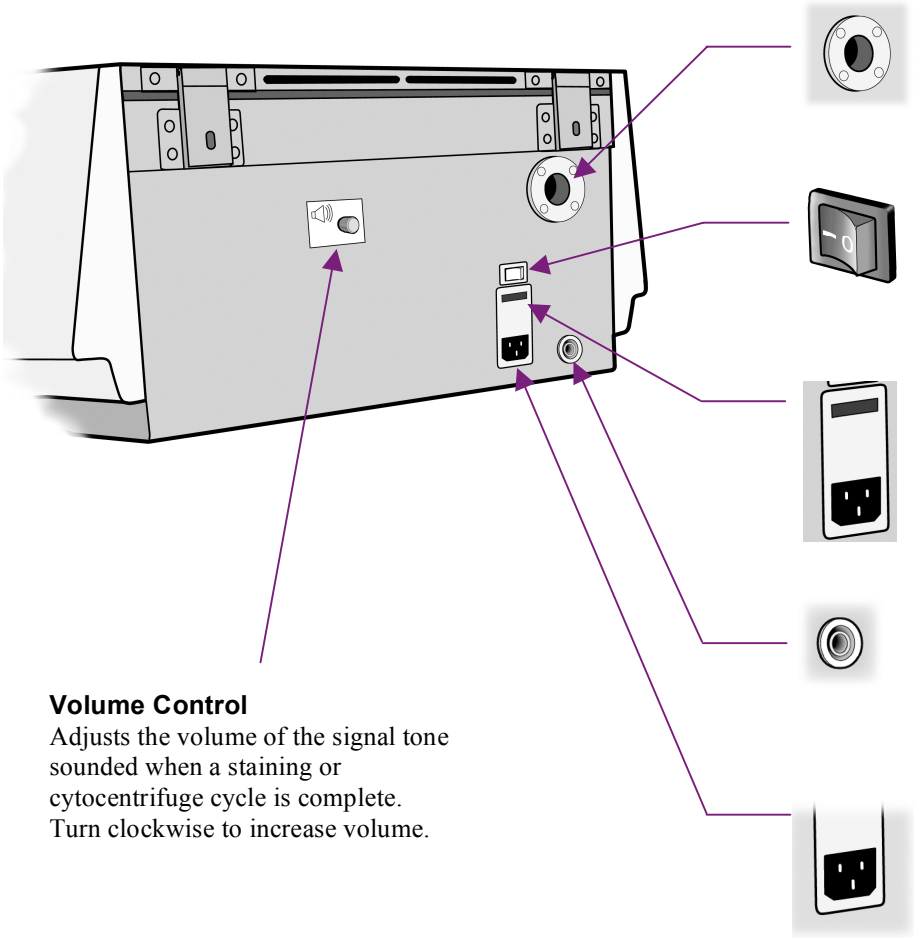
Slide Staining Carousels
Hold 1 to 12, or 1 to 30 slides. The carousel mounts on the drive hub, rotating at approximately 20 rpm for staining and approximately 950 rpm for drying.

Reagent Spray Nozzle
Each reagent has a separate spray nozzle(s) to dispense the correct amount of reagent.

Reagent Bottle Dip Tubes
Five reagent dip tubes, A through E, connect the reagents to the internal pumps and spray nozzles.

Manual Priming Buttons
These buttons operate the corresponding pumps for priming.

Aerospray® Gram Slide Stainer/Cytocentrifuge Rear Panel



Volume Control
Adjusts the volume of the signal tone sounded when a staining or cytocentrifuge cycle is complete. Turn clockwise to increase volume.

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 (I) and Off (O). When the instrument is connected to the proper power source and the power switch is on, the front panel power indicator is lit.

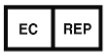
Fuse Door
To get to the main fuses, turn the power off, disconnect the power cord and use a small screwdriver to open the fuse door. Follow normal safety precautions.

Drain Port
Provides connection for 5/16 inch inside diameter drain tube (AC-041). 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:

	Alternating Current (AC)
	Authorized Representative in the European Community
	Batch Code
	Biological Hazards (Biological Risks)
	Catalog Number (Model Number)
	Caution, Consult Accompanying Documents (Attention, see instructions for use)
	CE
	Consult Instructions For Use
	Do Not Reuse
	Do not use if package damaged
	Fragile, Handle with Care
	Fuse
	General Symbol for Recovery, Recyclable
	*In vitro* Diagnostic Device (*In vitro* Diagnostic Medical Device)
	Keep away from sunlight (Keep away from heat)
	Manufacturer
	“New Waste”

I	“On” (Power)
O	“Off” (Power)
	RoHS Pollution Control
	Serial Number
	Temperature Limitation – indicates high and low limits (normal room temperatures are specified for all Wescor Reagents).
	Use By
	Volume Control
	General Warning, Caution, Risk of Danger
	Warning, Biological Hazard
	Corrosive
	Environment Hazard
	Flammable
	Harmful / Irritant
	Oxidant
	Toxic
	Product to be used for manual cleaning only. Do pump product through instrument.

3 Hazards (8.3)

a. Risk and Safety Phrases

Reagents SS-041AA Gram Reagent A Decolorizer with Acetone and Safranine and SS-141A Gram Reagent A Safranin Concentrate when diluted with isopropanol and acetone as directed are associated with the following Risk and Safety Phrases. European Symbols of Danger are: F and Xi.

R 11:	Highly flammable
R 36:	Irritating to eyes
R 67:	Vapors may cause drowsiness or dizziness
S 7:	Keep container tightly closed
S 16:	Keep away from sources of ignition – No smoking
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

SS-041AAF Gram Reagent A Decolorizer with Acetone and Fuchsin and SS-141AF Gram Reagent A Fuchsin Concentrate when diluted with isopropanol and acetone as directed are associated with the following Risk and Safety Phrases. European Symbols of Danger are: F and T.

R 11:	Highly flammable
R 36:	Irritating to eyes
R 67:	Vapors may cause drowsiness or dizziness
R45:	May cause cancer
S 7:	Keep container tightly closed
S 16:	Keep away from sources of ignition – No smoking
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
S45:	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
S53:	Avoid exposure - obtain special instructions before use

Reagents SS-041A Gram Reagent A Decolorizer with Safranin and SS-141A Gram Reagent A Safranin Concentrate when diluted with isopropanol and methanol as directed are associated with the following Risk and Safety Phrases. European Symbols of danger are: F and T.

R 11:	Highly Flammable
R 36:	Irritating to eyes
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)

SS-041AF Gram Reagent A Decolorizer with Fuchsin and SS-141AF Gram Reagent A Fuchsin Concentrate when diluted with isopropanol and methanol as directed are associated with the following Risk and Safety Phrases. European Symbols of danger are: F and T.

R 11:	Highly Flammable
R 36:	Irritating to eyes
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
R45	May cause cancer
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)
S53:	Avoid exposure - obtain special instructions before use

Reagents SS-041B Gram Reagent B Iodine, and SS-141B Gram Iodine Concentrate when diluted as directed are associated with the following Risk and Safety Phrases. European Symbols of Danger are: None.

R:	None
S	None

Reagents SS-041C Gram Reagent C Crystal Violet, and SS-141C Gram Crystal Violet Concentrate when diluted as directed are associated with the following Risk and Safety Phrases. European Symbols of Danger are: T.

R:45	May cause cancer
S 36/37:	Wear suitable protective clothing and gloves
S45	In case of accident or if you feel unwell, seek medical advice immediately (show label where possible)
S53:	Avoid exposure - obtain special instructions before use

Reagents SS-141B Gram Iodine Concentrate is associated with the following Risk and Safety Phrases. European Symbols of Danger are: None.

R:	None
S	None

Reagents SS-141A Gram Reagent A Safranine Concentrate is associated with the following Risk and Safety Phrases. European Symbol of Danger is: Xi.

R 36	Irritating to eyes
S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

Reagents SS-141AF Gram Reagent A Fuchsin Concentrate is associated with the following Risk and Safety Phrases. European Symbol of Danger is: T.

R 45:	May cause cancer
S 45	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
S 53	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

Reagents SS-141C Gram Reagent C Crystal Violet Concentrate is associated with the following Risk and Safety Phrases. European Symbols of Danger are: T and N.

R 45:	May cause cancer
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 43:	May cause sensitization by skin contact
R51:	Toxic to aquatic organisms
R53:	May cause long-term adverse effects in the aquatic environment
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 53:	Avoid exposure - obtain special instructions before use
S 45:	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

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 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)

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)

SS-103 O-ring/Nozzle Thread Grease is associated with the following Risk and Safety Phrases. European Symbols of Danger are: None.

R:	None
S:	None

4 Intended Purpose (8.5)

The Aerospray® Gram Slide Stainer/Cytocentrifuge is intended for use by medical professionals to stain specimens that typically include microbes, for identification of Gram Positive or Gram Negative Characteristics, 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 and User's Manuals (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: service@wescor.com
www.wescor.com

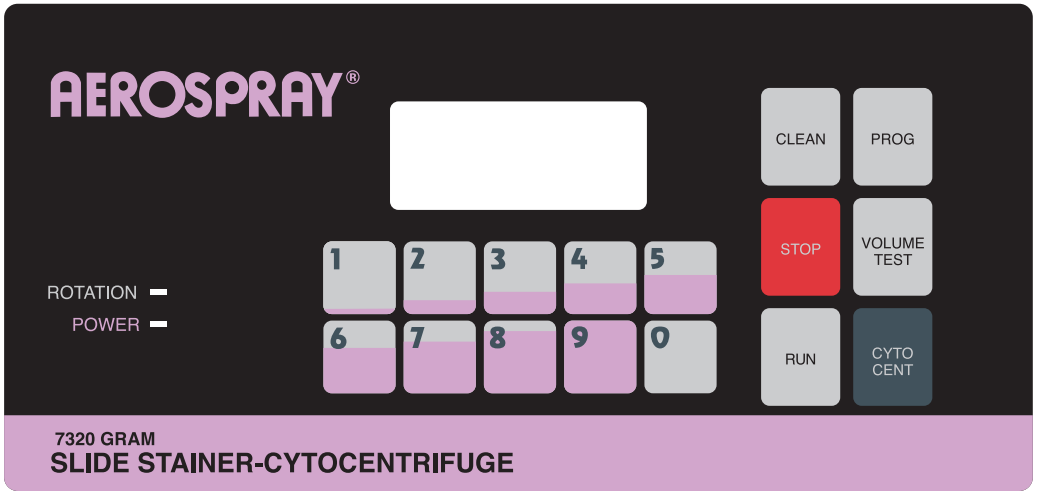
b. Authorized Representative Name and Address (8.7a and 8.4a)

Medical Technology Promedt Consulting
Altenhofstraβe 80
66386 St. Ingbert
Germany
Tel. +49 6894 581020
Fax: +49 6894 581021
Email: info@mt-procons.com

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® Gram Slide Stainer/Cytocentrifuge Faceplate (Label Print-0003)



A list of **Accessories** follows:

Slide Carousel (12 Slide Capacity)	AC-028
Slide Carousel (30 Slide Capacity)	AC-057
Nozzle Tool	AC-034
Nozzle Hex Wrench	AC-035
5.0 Liter Space-Saver Container with Cap	AC-038
Spigot for Space-Saver Container	AC-039
Drain Tube (1.8 meter length)	AC-041
500 mL Bottle with Cap	AC-043
Nozzle Orifice Cleaning Wire	AC-059
Cytopro Cytocentrifuge Rotor	AC-160
Reagent Pump Priming Tool	AC-069
5.0 Liter Bottle Assembly for water reagent (SS-H_2O)	AC-072
Nozzle Maintenance Kit	AC-075
Nozzle Cleaning Brush	AC-169
Aerospray/Cytopro Safety Shield	AC-110
User's Manual	M2259

A list of **Supplies** follows:

Decolorizer with Safranin, 500 mL bottle	SS-041A
Decolorizer with Acetone and Safranin Reagent, 500 mL bottle	SS-041AA
Decolorizer with Fuchsin Reagent, 500 mL bottle	SS-041AF
Decolorizer with Acetone and Fuchsin, 500 mL bottle	SS-041AAF
Iodine Reagent, 500 mL bottle	SS-041B
Crystal Violet Reagent, 500 mL bottle	SS-041C
Methanol Reagent, 500 mL bottle (Use in Reagent E position)	SS-MeOH
Decolorizer with Safranin Reagent Concentrate, 210 mL bottle	SS-141A
Decolorizer with Fuchsin Reagent Concentrate, 135 mL bottle	SS-141AF
Iodine Reagent Concentrate, 500 mL bottle	SS-141B
Crystal Violet Reagent Concentrate, 135 mL bottle	SS-141C
Nozzle Cleaning Solution, 355 mL	SS-029
Nozzle Cleaning Solution, 250 mL Concentrate	SS-029C
Nozzle Cleaning Solution, 1.89 liter Concentrate	SS-029CG
Aerospray Stain Residue Solvent, 500 mL	SS-230
Preventive Maintenance Chart, pad of 24 sheets	SS-125
O-Ring/Nozzle Thread Grease, 3 grams	SS-103
Decontamination Solution Concentrate, 15 mL	SS-133

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

The IVD 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 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 8.4i)

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. Select Alcohol Fixation

To activate or deactivate the alcohol fixation function, press PROG to open the program menu. Press 2 to select the alcohol fixation menu. Select 0 for Off, 1 for Normal or 2 to turn alcohol fixation to High. The display indicates the status of the alcohol fixation. Deactivate the alcohol fixation function if hand fixing slides.

iii. Selecting Decolorizer Cycle

Change the decolorizer intensity as needed by pressing the PROG keypad and the desired numbered keypad. The stainer allows selecting decolorizer applications on a scale of 1 to 9, 1 being light for thin smears, and 9 being heavy decolorization suitable for thick specimen smears.

To change the decolorizer settings, press PROG. Press 1 for the decolorizer option. Press the numbered keypad that corresponds with the desired cycle. The setting selected remains current until changed or power is interrupted.

iv. Stain Adjustments

After finding the decolorizer setting that works for the desired application, adjust the amount of crystal violet (Reagent C) and iodine (Reagent B). Both reagents have 3 settings. The default setting for crystal violet and iodine is Medium, which works well for most specimens.

To adjust the amount of crystal violet and/or iodine applied to the slides, press PROG to open the program menu. Press 3 to select the Adjust Stain Menu. Select either 1 for crystal violet, or 2 for iodine. Select 1, 2 or 3 for Low, Medium or High amounts of stain. Stain adjustments are saved even if the decolorizer settings are changed.

v. Load Carousel

Press the center button to remove the carousel lid. Load the 12-slide carousel with labeled end of the slide facing the outer rim of the carousel. Load the 30-slide carousel with labeled end of the slide facing the carousel hub. Smears in either carousel must face clockwise

The stainer can be programmed to save reagent when staining partial loads in either the 12-slide or the 30-slide carousel. To use this feature, place slides in the marked slots on the 12-slide or 30-slide 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.

vi. Load Instrument

Replace the carousel lid by pressing the release button while lowering the lid over the indexing posts. Release the button and press the lid handle lightly until it clicks into place. Place the carousel into the stainer and close the stainer lid.

vii. Program 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. A partial load on the 30-slide carousel is anything from 1-16 slides.

viii. Running a Staining Cycle

After programming the decolorizer setting, fixation, stain adjustments and number of slides, run a staining cycle by pressing RUN to start the cycle. During the cycle, the display shows the current decolorizer setting and reagent currently being applied. At the bottom of the display, an increasing bar graph and percentage-complete symbol indicate the approximate time remaining in the cycle. When the cycle is complete the signal tone sounds.

ix. Clean Cycle

CAUTION! Remove all specimen slides before using the clean or reprime cycles, 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. Leave the stainer with “Press Clean to Reprime” on the display while it is idle. When ready to stain slides, make sure there is a carousel in the stainer and press CLEAN to reprime the stainer. After running the CLEAN cycle, spray nozzle faces with methanol, ethanol, or prepared Nozzle Cleaning Solution (SS-029C). Use a nozzle brush to clean the nozzle orifices when patterns are less than optimal.

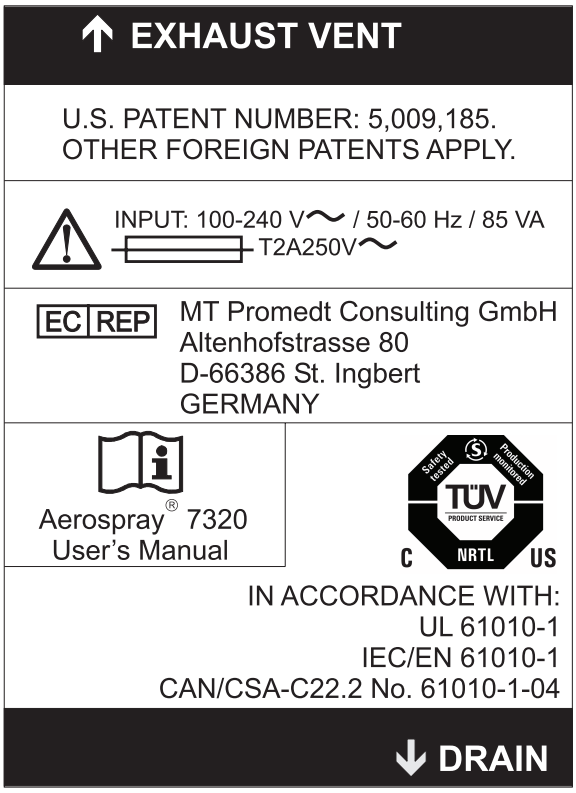
x. Emergency Stop

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

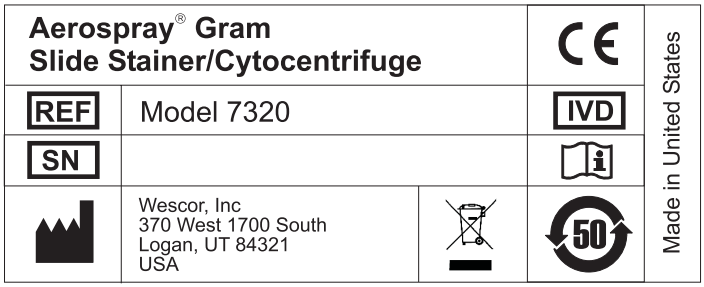
g. Appropriate Warnings and Precautions (8.7a and 8.4j)

Following are warning labels for the device and its reagents.

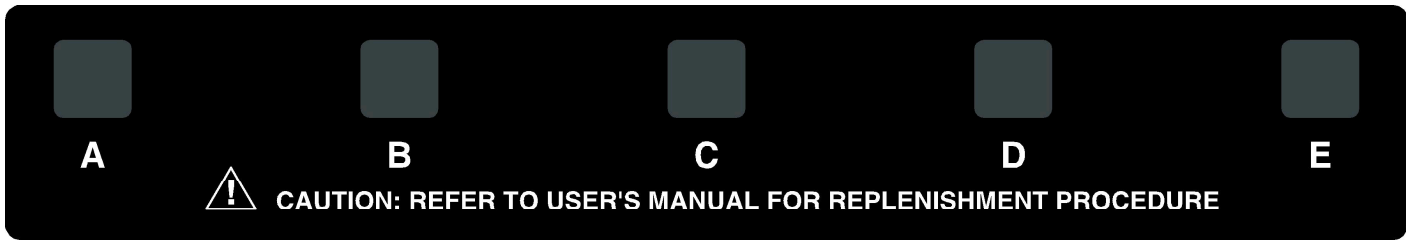
Rear Panel Label



Model / Serial Number Label



Side Panel Membrane Switch Label



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

SS-041A Gram Reagent A Decolorizer with Safranine contains:
- 55-65% Isopropyl Alcohol
- 35-45% Methyl Alcohol
- <1% Safranine

SS-041AF Gram Reagent A Decolorizer with Fuchsin contains:
- 55-65% Isopropyl Alcohol
- 35-45% Methyl Alcohol
- 0.1-0.2% Basic Fuchsin

SS-141A Gram Reagent A Safranine Concentrate when diluted with isopropanol/methanol as directed contains:
- 55-65% Isopropyl Alcohol
- 35-45% Methyl Alcohol
- <1% Safranine

SS-141AF Gram Reagent A Fuchsin Concentrate when diluted with isopropanol/methanol as directed contains:
- 55-65% Isopropyl Alcohol
- 35-45% Methyl Alcohol
- 0.1-0.2% Basic Fuchsin

SS-041AA Gram Reagent A Decolorizer with Acetone and Safranine contains:
- 70% to 80% Isopropyl Alcohol
- 20% to 30% Acetone
- <1% Safranine

SS-041AAF Gram Reagent A Decolorizer with Acetone and Fuchsin contains:
- 70% to 80% Isopropyl Alcohol
- 20% to 30% Acetone
- 0.1-0.2% Basic Fuchsin

SS-141A Gram Reagent A Safranine Concentrate when diluted with isopropanol/acetone as directed contains:
- 70% to 80% Isopropyl Alcohol
- 20% to 30% Acetone
- <1% Safranine

SS-141A Gram Reagent A Safranine Concentrate contains:
- 25-30% Deionized Water
- 5-10% Safranine

SS-141AF Gram Reagent A Fuchsin Concentrate when diluted with isopropanol/acetone as directed contains:
- 70% to 80% Isopropyl Alcohol
- 20% to 30% Acetone
- 0.1-0.2% Basic Fuchsin

SS-141AF Gram Reagent A Fuchsin Concentrate contains:
- 25-30% Deionized Water
- 2-4% Basic Fuchsin

SS-041B Gram Reagent B Iodine contains:
- 92-98% Deionized water
- <1% Iodine
- <1% Potassium Iodide

SS-141B Gram Iodine Concentrate when diluted as directed contains:
- 92-98% Deionized water
- <1% Iodine
- <1% Potassium Iodide

SS-141B Gram Iodine Concentrate contains:

60-70% Deionized Water
5-10% Potassium Iodide
2.5-5% Iodine

SS-041C Gram Reagent C, Crystal Violet contains:
95-99% Deionized water
0.1-0.2% Crystal Violet

SS-141C Gram Crystal Violet Concentrate when diluted as directed contains:
95-99% Deionized water
0.1-0.2% Crystal Violet

SS-141C Gram Reagent C Crystal Violet Concentrate contains:
45-55% Deionized Water
<5% Crystal Violet

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)

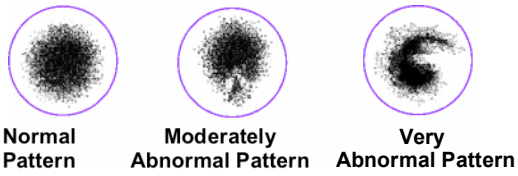
Reagents should be stored at room temperature away from direct light. Expiration dates are shown on each reagent label with the international symbol ⌛ .

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.
f. 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.

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.

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, C, D, and E nozzles should deliver 9.0 to 11.0 mL over the 20 second spray sequence. The A nozzle should deliver between 10 and 12 mL. Older nozzles may exhibit higher volumes. The instrument 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 these nozzle groups are delivering close to the same levels.

When operating correctly, nozzles B, C, and D (front) should deliver approximately the same volume of stain. The D (rear) nozzle volume may be slightly higher or lower. Reagent A will almost always be higher. Reagent E can be higher or lower than the other nozzles (except Reagent A).

Low Volume

Low volume from a spray nozzle is typically caused by reagent precipitate or foreign matter inside the 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.

l. Type of Specimen to be Used (8.7f)

The Aerospray Gram Slide Stainer/Cytocentrifuge stains specimens applied to microscope slides. Nine decolorizer settings allow compensation for slide specimen variation. The chart below suggests recommended settings for various specimens. All specimens should be as thin as possible. If prepared as thin smears, most specimens stain satisfactorily on settings 3 or 4.

NOTE: These are suggested settings only. Each laboratory should establish its own protocol for gram staining.

DECOLORIZER SETTING	THICKNESS	SUGGESTED SPECIMEN
1 -	Very Thin Smears	Weak reagent(s), instrument problem, old culture(s)
2 -		
3 -	Thin Smears	CSF, urine, peritoneal, vag, wounds, bronchial washes, etc.
4 -	Thin and Medium Smears	Vaginal, sputum, bronchial washes, CSF, urine, wounds etc.
5 -		
6 -	Medium and Thick Smears	Sputum, bronchial washes, wounds, blood cultures, etc.
7 -	Thick Smears	Sputum, bronchial washes, tissues, blood cultures, etc.
8 -		
9 -	Very Thick Smears	Very thick smears, stools, blood cultures, etc.

Over-decolorization and Weak Control Cultures

It is well known that weakly gram positive cultures, such as Bacillus sp. and Streptococcus sp. can be easily over-decolorized, especially when cultures are old or stressed. When decolorizing such cultures by hand, de-colorization can be limited to just a few seconds as the process can be "judged" by eye. Such cultures tend to be over-decolorized in the Aerospray unless the decolorizer application is limited by running at setting 1 or 2. A strongly positive culture such as 18-

hour Staphylococcus should remain mostly positive even at decolorizer setting 9. In addition, samples at the extreme edges of the slide may under-decolorize, or even over-decolorize, depending on the state of the nozzle spray pattern. **For the best results, use the center half of the slide for specimen loading.**

Fouled nozzles usually cause over-decolorization of normal specimens in the Aerospray. If over-decolorization problems persist (even though nozzle performance is within specifications and the iodine and other reagents are not expired), contact an authorized representative for assistance.

m. Procedure for Use (8.7g)

Refer to Operating Instructions in Section 6f.

n. Internal Quality Control (8.7k)

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

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

i. Performance Verification

To verify performances see the Spray Pattern Test, Spray Volume Test and Interpreting Results in Section 6.j.

ii. Maintenance

The Aerospray stainer requires little maintenance. To help document the maintenance, use the following procedures and Preventive Maintenance chart:

DAILY:

At end of each shift or if instrument will be idle for more than 8 hours:

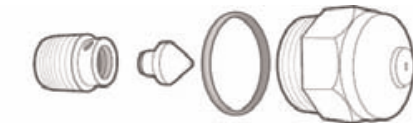
1. Run a CLEAN cycle. Leave instrument in CLEAN TO REPRIME.
2. Use a spray bottle filled with methanol or ethanol, spray the front of each nozzle, and clean each nozzle orifice with nozzle brush.
3. Spray the stainer bowl and exterior case using methanol or ethanol. Wipe clean with a paper towel.
4.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

WEEKLY:

1. 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. Wipe down nozzles, carousel tray, and carousel lid using methanol or ethanol spray bottle or prepared SS-029C Nozzle Cleaning Solution with 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.*



2. Remove Pick-up Tube from Reagent B (Iodine) bottle. Then:
   A. Flush 500 mL DI water through the line.
   B. Flush 100 mL prepared SS-029C through the line. Block flow at nozzle holder with a gloved finger for a few seconds during flushing. Stop flushing just before 100 mL is gone. Soak in line (1 hour to overnight as practical).
   C. Flush prepared SS-029C out of line with 500 mL of DI water.
   D. Reinstall Reagent B (Iodine) and flush 100 mL through the line to remove DI water.
3. Reinstall nozzles. *Always return nozzles to the same location in stainer.*
4. 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.*
5. Disinfect reusable bottles with a 1/10 dilution of bleach. Rinse thoroughly with deionized water.
6. Initial completion of monthly PM.
7. Supervisor check and initial.

ANNUALLY:

1. Check internal and exterior tubing and fittings for cracks, leaks, or any type of deterioration. Replace as needed.

Preventive Maintenance Chart

Month / Year: _____

Aerospray® Gram Slide Stainer/Cytocentrifuge, Model 7320

Daily — Clean Cycle and Wiping

Day	AM	PM	Night	*Daily Control Slides
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

Weekly — Nozzle Performance

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
1	A		10-12 mL	mL	mL		
	B		9.0-11.0 mL	mL	mL		
	C		9.0-11.0 mL	mL	mL		
	D Front		9.0-11.0 mL	mL	mL		
	D Back		9.0-11.0 mL	mL	mL		
	E		9.0-11.0 mL	mL	mL		
2	A		10-12 mL	mL	mL		
	B		9.0-11.0 mL	mL	mL		
	C		9.0-11.0 mL	mL	mL		
	D Front		9.0-11.0 mL	mL	mL		
	D Back		9.0-11.0 mL	mL	mL		
	E		9.0-11.0 mL	mL	mL		
3	A		10-12 mL	mL	mL		
	B		9.0-11.0 mL	mL	mL		
	C		9.0-11.0 mL	mL	mL		
	D Front		9.0-11.0 mL	mL	mL		
	D Back		9.0-11.0 mL	mL	mL		
	E		9.0-11.0 mL	mL	mL		
4	A		10-12 mL	mL	mL		
	B		9.0-11.0 mL	mL	mL		
	C		9.0-11.0 mL	mL	mL		
	D Front		9.0-11.0 mL	mL	mL		
	D Back		9.0-11.0 mL	mL	mL		
	E		9.0-11.0 mL	mL	mL		

Monthly — Clean Reagent Nozzles and Instrument

Reagent	Previous Months Ending Volume	Volume After Monthly Cleaning	Disinfect DI Water Bottle (✔ when cleaned)	Initial
A			Not Applicable	
B			Not Applicable	
C			Not Applicable	
D Front				
D Back				
E			Not Applicable	

Annually or as needed

Check internal and exterior tubing and fittings

Date		Initial	

Supervisor Approval

Preventative Maintenance Chart procedures are located on reverse side.

The frequency set forth on this chart for daily, weekly, and monthly maintenance is considered maximum. Field experience suggests the more the Aerospray Slide Stainer is used the less frequently it requires preventive maintenance. Do preventive maintenance at the level necessary to keep nozzle performance within specification and slides staining correctly.

Warning: Always wear eye and hand protection when performing preventive maintenance on the Aerospray Slide Stainer.

This Preventive Maintenance Chart may be reproduced in its entirety by Aerospray users.

*optional

**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.

WESCOR, INC 370 West 1700 South Logan, Utah 84321 USA (435) 752-6011 (800) 453-2725 Fax (435) 752-4127 email wescor@wescor.com

Preventive Maintenance Procedure

DAILY: At end of each shift or if instrument will be idle for more than 8 hours:

1. Run a CLEAN cycle. Leave instrument in CLEAN TO REPRIME mode.
2. Use a spray bottle filled with methanol or ethanol and 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 you are ready to use the instrument again, press CLEAN to reprime reagent lines. Run a SPRAY PATTERN test to verify nozzle performance prior to staining. Should any pattern appear abnormal repeat step 2 to clean nozzle orifice.

WEEKLY:

1. Perform SPRAY VOLUME test. Record 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. Wipe down nozzles, carousel tray, and carousel lid using methanol or ethanol spray bottle or prepared SS-029C Nozzle Cleaning Solution with 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, ***Do not*** *mix or interchange nozzles or nozzle parts.*
2. Remove Pick-up Tube from Reagent B (Iodine) bottle. Then:
   A. Flush 500 mL DI water through the line.
   B. Flush 100 mL prepared SS-029C through the line. Block flow at nozzle holder with a gloved finger for a few seconds during flushing. Stop flushing just before 100 mL is gone. Soak in line (1 hour to overnight as practical).
   C. Flush prepared SS-029C out of line with 500 mL of DI water.
   D. Reinstall Reagent B (Iodine) and flush 100 mL through the line to remove DI water.
3. Reinstall nozzles. *Always return nozzles to the same location in stainer.*
4. Perform SPRAY PATTERN and SPRAY VOLUME tests. Record results from end of month SPRAY VOLUME test on preventive maintenance chart. *NOTE: As you enter a new month the Volume After Monthly Cleaning number becomes Previous Months Ending Volume number.*
5. Disinfect reusable bottles with a 1/10 dilution of bleach. Rinse thoroughly with deionized water.
6. Initial completion of monthly PM.
7. Supervisor check and initial.

ANNUALLY:

1. Check internal and exterior tubing and fittings for cracks, leaks, or any type of deterioration. Replace as needed.

Reagent Lot Record

Day	Reagent A	Reagent B	Reagent C	Reagent D	Reagent E
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

Instructions for Reagent Lot Record

Each time you replace a reagent bottle, record lot number from the new bottle in the box that corresponds to the reagent changed and current months numeric date.

Corrective Action Log

Corrective Action Log Instructions

The Corrective Action Log is optional. Document each problem occurrence with (1) the date, (2) a brief description of the nature of problem, and (3) any corrective action taken to resolve or correct problem.

p. Troubleshooting

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 prepared SS-029C.
7. Cap tube, agitate, and then soak parts until clean.

WARNING! Always wear protective clothing and eye protection when using the SS-029C. 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 prepared SS-029C, then remove parts from tube.
14. Reassemble nozzles and return nozzles to their original locations in the stainer.

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 ¼ 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**.
6. Prime the nozzle and check spray pattern and spray volume before staining.

i. Safe Waste Disposal

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

q. Setup and Pre-use Procedures (8.7o)

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 (85 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) Decolorizer with Counterstain
(B) Iodine
(C) Crystal Violet
(D) Deionized Water
(E) Anhydrous Methanol or Ethanol (≤ 0.5% water)

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 2 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 is a two-stage process that uses methanol or ethanol to purge the reagent nozzles of precipitates and debris, then reprimes reagents into the nozzles. Each stage of the cycle requires user input to continue the

process. This allows delaying the second stage indefinitely. 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. This sprays methanol or ethanol (Reagent E) through the nozzles and onto the carousel. When the cycle is completed the display reads: PRESS CLEAN TO REPRIME.
- Wipe nozzle orifices to remove all residual liquid.
- At this point, the instrument "stands by" with methanol or ethanol remaining in the nozzles until pressing CLEAN again. The instrument can be left in this standby mode for extended periods to prevent clogging while the stainer is idle.
- If not staining slides immediately, leave the instrument in standby mode until ready to stain. This is particularly important if the instrument will be idle for more than 4 hours. Later, when ready to stain slides, make sure there is a carousel in the instrument, then:
- Press CLEAN again. This reprimes reagent into the nozzles, making the instrument ready for staining.

CAUTION! Do not place any carousel loaded with specimens in the instrument while CLEAN TO REPRIME appears on the display. Specimens will be damaged if they contact excess reagents sprayed from the nozzles when you press CLEAN.

NOTE: Pressing STOP during the clean or reprime cycles causes a warning to be displayed until a complete Clean and Reprime cycle is completed.

r. Process for Cleaning, Decontamination (8.7q)

Under normal clinical use the Aerospray® Gram 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 EMC 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

