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| **SOP Number:** | CH030 | **Effective Date** |  |
| **Department & Section:** | Hematology | **Revision Date(s):** |  |
| **Author:** | K. Miller MT (ASCP)  K. Clark MT(ASCP) | **Version:** | 1 |

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| Applicable Standards | | | |  | Version History | | | |
| Standard | | Organization | |  | Version | Effective Date | | Retired Date |
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| Related Documents | | | |  |  |  | |  |
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| Review History (Up to the Last 15 Occurrences) | | | | | | | | |
| Date | Version | | Revision Type | | | | Review By/Initials & Date | |
|  | 1 | | New Policy/Procedure | | | | System Laboratory Medical Director, Joe A. Lewis, M.D., F.C.A.P. | |
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| Distribution |
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**Maintenance Procedures:** each facility/site will design a routine preventive maintenance schedule to accommodate the testing needs/volumes of the facility. Documentation of these procedures will happen according to each facility requirements.

**Daily Preparation and Maintenance:**

1. **Emptying the Waste Container**

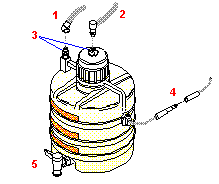
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| WARNING !  Local laws and regulations protect the environment and encourage resource conservation by regulating the disposal of hazardous wastes. Because some of the wastes generated by the analyzer may be classified as hazardous waste, you must be familiar with the applicable hazardous waste handling and disposal laws and regulations in your area. |

All analyzer waste is stored in an 11-liter waste container. When the fluid level in the container reaches the “Maximum Level” line (approximately 8 liters), an error message appears on the monitor and an audible alarm is sounded. The system will not aspirate any more samples until the waste container is emptied.

For information on how to empty the waste container, follow the type of waste-control system that is on your analyzer:

Manual, stand-alone container: Manual Waste Removal (refer to below diagram)

1. Make sure that the analyzer is not sampling.
2. Cancel all the auto cycles, Auto Wash, Auto Rinse, Auto Standby and Auto Startup.
3. Disconnect the waste line (1) and the vacuum line (2). To do this, press the buttons (3) on the quick-release connectors as you pull the lines straight up.
4. Disconnect the level switch sensor (4).
5. Replace the full container with an empty one and connect the waste and vacuum lines, and level sensor to the new container.



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| CAUTION !  Do not open the waste container cap! If the cap is loosened or not replaced correctly, sufficient operating vacuum cannot be reached. |

1. Empty the full container by opening the spigot (5) into a drain that is capable of accommodating a flow rate of approximately five liters per minute. Total drainage time will be about two and a half minutes.
2. When the waste container is empty, close the spigot and store the container for future use.

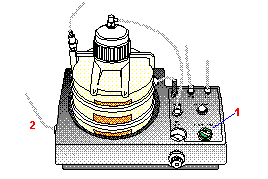
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| IMPORTANT !  Make sure that the spigot is closed securely; otherwise, sufficient operating vacuum may not be reached. |

1. Reset any auto cycles that you canceled in step 2.

Automatic waste removal

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| IMPORTANT!  In order to empty the automatic waste removal system, the analyzer must be on and must not be in Standby mode. |

1. Make sure that the analyzer is not sampling.
2. Cancel all the auto cycles, Auto Wash, Auto Rinse, Auto Standby, and Auto Startup.
3. On the waste removal assembly tray, turn the mode selector knob (1) from NORMAL to EMPTY. (Refer to below diagram.)
4. The waste in the container should start to empty. It will take between two and five minutes to completely empty the container. When you see air bubbles in the discharge line (2), the container is empty.
5. Once the container is empty, turn the mode selector knob (1) back to the NORMAL setting.
6. Reset any auto cycles that you canceled in step 2.



1. **CHECKING AND EMPTYING THE OVERFLOW BOTTLE**

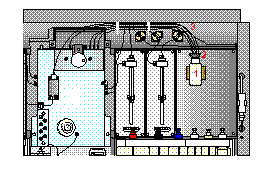
Visually check the fluid level in the small, overflow bottle (1) located to the right of the RBC sample and sheath pumps. If it has any liquid in it, empty the bottle, then clean the vent lines and chambers.

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| IMPORTANT !  If liquid consistently accumulates in the overflow bottle, call your Siemens service representative. |

**To empty the overflow bottle**

**Biohazard warning**

1. Snap the bottle (1) out of the clip, then remove the bottle cap (2). You can allow the lines (3) with the cap to hang loosely. (Refer to below diagram.)
2. Empty the contents of the bottle in accordance with proper laboratory practices and environmental regulations.
3. Replace the cap, then snap the bottle in place.
4. Make sure that the tubes have not slipped through the cap. The ends of the tubes should be at least 1.5 inches from the bottom of the bottle. Adjust if necessary.



**Checking the Reagents**

1. Use the Startup tab or the Reagent Log tab to check the supply of all reagents except ADVIA™ 2120i DEFOAMER.

Visually check the supply of ADVIA 2120i DEFOAMER.

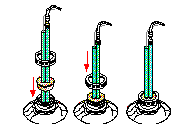
1. If you need to replace reagents, use the Reagent Log tab.

**Replacing the Sheath/Rinse**

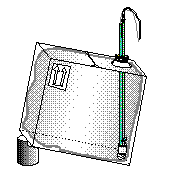
1. Run a precision control or a whole-blood control and print the CBC /DIFF /retic results**.**
2. Before opening the container, gently mix the SHEATH/RINSE CUBITAINERâ on the floor or counter several times. Do not remix a reagent after it is installed. Do not combine any remaining reagent with the new reagent.
3. Set the new bottle next to the empty one and remove the cap from the new bottle.
4. Remove the straw assembly from the empty CUBITAINER.

**NOTE**: A new CUBITAINER filter is packagedwith every container of SHEATH / RINSE.

1. Replace the CUBITAINER filter at the end of the straw and immediately insert the assembly into the new bottle. Do not put the straw assembly onto the floor or counter where dirt can get onto the straw or the float switch. (Refer to below diagram.)
2. Push the plastic stopper into the bottle until the extended edge of the stopper is against the bottle opening, then tighten the white screw cap over the bottle and stopper.



NOTE: If necessary, adjust the plastic stopper on the straw assembly so that when the stopper is pushed into the bottle opening, the filter at the end of the assembly touches the corner of the bottle. (Refer to below diagram.)



1. Using the hand-held barcode reader, scan the barcode on the CUBITAINER.
2. On the System Logs menu, click the Reagent Log tab. Click the Reagent Installation button.
3. Click Import Barcode, then click OK. When the Reagent Log box appears, click Yes to prime the reagent lines.
4. Alternately, enter the information by typing in the data.

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| **IMPORTANT !**  If the new reagents are a different lot number, the gains may need to be adjusted and the channels recalibrated. |

11. Run a precision control or a whole-blood control. Compare the CBC / DIFF results with the results in step 1.

**Parameters affected when changing Sheath/Rinse**

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| **Channel** | **Parameters to be evaluated** | **Adjust gains for following parameters before calibrating** |
| Baso | %Baso, MNx, Mny, WBCB | MNx, MNy |
| RBC/PLT | MCV, HCT, RBC | None |
| Retic | %Retic, RTC-RBC, MCVg, CHCMg | None |

1. If the variations in results are acceptable, resume running patient samples.
2. If the variations in results are not acceptable, the affected channels must be either recalibrated or the gains must be reset.

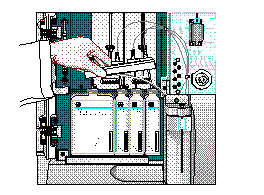
12. Discard the empty CUBITAINER.

1. **Replacing Reagent, Wash and Defoamer**

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| **IMPORTANT!**  The contents of the EZ KLEEN bottle is enough for 20 washes. The alarm criteria default value should be reset the first time you install EZ KLEEN.  To reset the values, on the Customize menu, select the System Setup tab. Click the Reagent Conditions button on the left. Type 2 in the EZ KLEEN Alarm Criteria field, then click Save. You only have to enter this value once. This will be the alarm condition until you choose to change it. The Stop Criteria default value is already set to 1. |

To replace the reagents, EZ KLEEN, and the DEFOAMER

1. Run a precision control or a whole blood control and print the CBC plus WBC DIFF results or the retic results if you are replacing the retic reagent. (Refer to below diagram.)
2. Remove the straw/filter assembly or individual straw from the bottles to be replaced. To avoid contamination, be careful that droplets do not splatter from the end of the straws.
3. To keep the straws out of the way while you are replacing the bottles, fasten the straw/filter assembly to the clip on the side of the aspirate assembly.
4. Remove the empty TIMEPAC™ or bottle from the analyzer and discard it in an environmentally safe manner.
5. Gently invert each new container several times. Do not remix a reagent after it is installed. Do not combine any remaining reagent with the new reagent.
6. Place the bottles on the analyzer and carefully replace the straw or straw assembly. Make sure that each straw enters the correct bottle.



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| **IMPORTANT!**  To avoid evaporation and possible clumping of the DEFOAMER, make sure that the straw/filter assembly is securely in place at all times. |

1. With the hand-held barcode reader, scan the barcodes on each of the new bottles to be replaced, except the DEFOAMER as noted below.
2. Click Import Barcode, then click OK.
3. When prompted, click Yes to prime lines for the new reagents. Enter the number of prime cycles, then click OK.
4. If bubbles remain in the reagent lines, prime the lines again by using the Reagent Inventory window.
5. Alternately, enter the information by typing in the data.

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| IMPORTANT  If the new reagents are a different lot number, the gains may need to be adjusted and the channels recalibrated. |

1. Run a precision control or a whole blood control and compare the CBC plus WBC DIFF results (or retic results) with the ones in step 1.

**Parameters affected when changing reagents**

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| **Reagents** | **Parameters to be evaluated** | **Adjust gains for following parameters before calibrating** |
| Baso | %Baso, MNx, Mny, WBCB | MNx, MNy |
| HGB | HGB, MCH, MCHC | None |
| PEROX 1, PEROX 2, PEROX 3 | WBCP, MPXI, NEUTx, and NEUTy | NEUTx and NEUTy |
| RBC/PLT | MCV, HCT, RBC | None |
| Retic  (only if autoRETIC replaced) | %Retic, RTC-RBC, MCVg, CHCMg | None |

1. If the variations in results are acceptable, resume running patient samples.
2. If the variations in results are not acceptable, the affected channels must be either recalibrated or the gains must be reset.
3. **Obtaining background counts**

Run a background count cycle to obtain a BASO WBC background count, a platelet background count, and an HGB Trans daily.

1. On the Routine Operations menu, click Startup
2. Click Refresh
3. The background results are color coded

**◼Green Within range**

**◼Red Out of range**

If any result is out of range, click Refresh on the Startup tab to run another background count cycle. If any result is still unacceptable, perform a system wash. Background counts are performed as scheduled by each facility and after a reagent change. The reagent log will list the dates and times of these checks. Also note background count was performed and acceptable on the Patient Control log sheet.

**As needed maintenance**

**Clean the Centering Collar:** this removes residues and salt build up around the sample aspirate area.

1. Turn off analyzer
2. Remove the centering collar from either the autosampler or manual closed-tube sampler.
3. Place the centering collar in a beaker filled with 25% solution of household bleach and water and let soak for 5 minutes.
4. Using a cotton swab, scrub off any remaining residue, then rinse with water,
5. Use a stylet or a piece of thin wire to clean the nipples and the center bore on the auto-sampler centering collar or manual closed-tube centering collar.
6. Attach a piece of 0.030 inch tubing to a syringe, then flush each port on the autosampler collar or the waste port on the manual close-tube sample collar with water.

**Important:** To prevent autosampler centering collar lock ups, apply Parker Super O-lube to the barrel part **(!)** of the centering collar.   
 Do not get lubricant near the needle port or the needle base. **(2)**

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1. Reconnect all the tubes, except the sample line on the autosampler, to the centering collar.
2. Remove the needle cover and carefully replace the collar over the needle.

On the autosampler centering collar, be sure to turn the spring-loaded knob back to its original position.

1. On the autosampler, reposition the autosampler aspirator assembly. Make sure that it drops firmly in place over the guide pins, then reconnect the sample line to the base of the centering collar.
2. Snap the manual- sampler centering collar into place.
3. Close the analyzer cover.
4. Turn on the analyzer power
5. Check saline background counts and run a whole blood primer to verify system performance.

**Cleaning the Shear Valve:** The shear valve is made up of two ceramic disks. The rear disk is stationary. The front disk rotates to “shear” or divide the sample into the proper aliquots for analysis.

**To take the shear valve face apart:**

1. Analyzer mode should be off
2. Place paper towels directly under the shear valve to prevent fluid from dripping down into the analyzer.
3. Remove the knurled nut **(1)** counterclockwise then remove the compression spring **(2)**



1. To remove the rotor **(3),** hold the shear valve with one hand and with the other hand rotate the rotor until it can be pulled forward and off the shaft.



1. To remove the front shear face **(4),** gently rotate the front face until it is loosened, then pull forward and remove.



To avoid damaging the seal that secures the shear valve to the acrylic layer of the UFC, do not use excessive force to remove the shear valve face.

DO NOT use sharp object, such as screwdriver, to separate the shear faces. If you have difficulty removing the rotor or the front shear face, hold paper towels under the shear valve and squirt the valve with a stream of warm water. If the rotor is off, squirt some water into the two holes in the front of the shear face. Allow to soak for a few minutes, then remove the rotor and/or shear face.

**To clean the shear valve faces:**

1. Place the front shear face in a beaker with household bleach.
2. To rinse the rear shear face, use a wash bottle filled with water.

Use paper towels to catch dripping water.

Do not wipe the shear faces with paper towels. They may leave fibers on the shear face that can clog the precision grooves

**To put the shear valves back together:**

****You may assemble the shear valve while the faces are still wet. Never use paper towels, gauze, or cotton swabs on the shear faces. These may leave fibers on the surface that can clog the precision groves.

1. Shake off any excess water, then install the front face on the shaft by aligning the black line on the front face with the black line and the **A** on the back face. The smaller loops should be at the 9 and 11 o’clock position and the large loop should be at the 5 o’clock position.



1. Install the rotor by inserting the drive pin **(2)** into the hole **(1)** on the right side of the front face.
2. Replace the spring **(3)** and the knurled nut **(4)**.
3. Hand tighten the nut.

**Checkout the shear valve:** Check the analyzer performance by:

1. Checking saline background counts.
2. Running a whole blood primer.
3. Running controls

If controls do not recover, calibrate the affected channel.

**Flowcell Wash:** This function flushes a clogged flowcell.

* To wash the perox flowcell, use EZ KLEEN.
* To wash the RBC/baso/retic flowcell, use a 25% solution of household bleach and deionized water.

**Procedure:**

1. In the Utilities tab select Hydraulics function.
2. Select the flowcell you desire to wash.

* Perox Flowcell
* RBC/Baso/Retic Flowcell

1. Hold a tube/beaker of either EZ KLEEN (perox flowcellO or 25% bleach solution (RBC/baso/retic flowcell) under the open-tube sample probe.
2. Hit the START butoon on the software screen
3. Remove container when the washblock starts to move down (approximately 80 seconds).
4. Hold a tube of EZ KLEEN (perox flowcell) or bleach (RBC

/baso/retic flowcell) under the open-tube sampler probe.

**IMPORTANT**

**Do not push the aspirate plate**.

1. Click Start to begin the flowcell wash. Continue to hold the tube under the probe until you hear a beep and the wash block starts to move down (approximately 80 seconds).

**To clean the aspiration pathways in the UFC**

1. At the utilities menu, select the Exerciser tab.
2. Select the Syringe Pumps button on the left.
3. If the arrow image of the valve under selector Valve does not point to Open, select the image until the arrow does point to open.
4. Select the Valves button on the left.
5. Select V72 to close.
6. Select V1,V47, and V74 to open.
7. Hold a beaker of household bleach under the open-tube sample probe until 5.0 mL is aspirated.
8. Repeat step 4 using 5 mL of water.
9. Close valve 74 and select V72 to open.
10. Repeat steps 4 and 5.
11. Select V73 to open.
12. Repeat steps 4 and 5.
13. Exit the Exerciser by selecting the Analyzer Status tab. The analyzer will do a hydraulics reset and perform background count.