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Sorvall Automated Cell Washer Preventative Maintenance - Royal Oak Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide policies and procedures for the preventative maintenance (PM) that is required for the Sorvall Automated Cell Washer.

II. PRINCIPLE:

A. Antihuman globulin (AHG) is inactivated readily by unbound immunoglobulin. The red blood cells (RBCs) to which AHG will be added must be washed free of all proteins and suspended in a protein-free medium. A properly functioning cell washer must add large volumes of saline to each tube, resuspend the cells, centrifuge them adequately to avoid excessive RBC loss, and decant the saline to leave a dry cell button. The preventative maintenance described in this document will help ensure that the cell washer is functioning properly.

III. INTRODUCTION:

A. The *Sorvall Cellwasher 2 Operating Instructions* indicate that routine maintenance procedures should be performed on a regular basis, with the specific time interval determined by the user and based on instrument usage. The instructions also indicate that the following preventative maintenance checks and cleaning procedures be performed regularly:

1. Inspection
2. Cleaning
3. Decontamination

4. Adjustment of the saline flow volume, periodically and after replacing the saline supply

B. This facility has two automatic cell washers and routinely uses two different sizes of test tubes. Each cell washer will be used with specific sized test tubes. The Sorvall cell washer is tagged with a *Sorvall Cell Washer Tag* which indicates the appropriate test tube size. The saline flow volume of the Sorvall cell washer must be adjusted periodically and after replacing the saline supply as described in the *Procedure* section of this document.

Cell Washer	For Use with the Following Sized Test Tubes
WBHC # 069814	12 x 75 mm test tubes

IV. DEFINITIONS:

A. **Monthly**: Within the first two weeks of each calendar month.

B. **Quarterly**: Within the calendar months of January, April, July, and October.

C. **Yearly**: Within a twelve month period. For example, the tubing must be replaced within 12 months from the time that the tubing was most recently replaced.

D. **Beaumont Health Biomedical**: Performs repairs and some maintenance of equipment for Beaumont Health.

V. POLICIES:

A. Unsatisfactory Preventative Maintenance

1. If any part of preventative maintenance reveals that any part of the Cell Washer 2 is not functioning properly (e.g., unsatisfactory inspection, or the saline flow volume cannot be correctly adjusted), then:
    a. Do not use the cell washer.
    b. Tag the cell washer with an Equipment Out of Service form.
    c. Notify the Medical Technologist (MT) Lead assigned to Quality Control.
    d. The MT Lead shall arrange for repair from Biomedical or from Sorvall (now Kendro Laboratory Products at 800-522-7746).
    e. Document and submit a variance.
2. There are no user-serviceable items inside the cell washer. Due to the hazards involved, repair shall only be made by the manufacturer or other qualified personnel.

B. Required Preventative Maintenance Schedule

1. Spills are to be wiped from the interior and exterior as they occur using a damp cloth and mild detergent.
2. The saline fill volume of each rotor is checked each day of use as described in Transfusion Medicine policy, *Sorvall Automated Cell Washer Operation* and is documented on the *Sorvall Cell Washer Saline Fill Volume Check Log*.

3. Monthly saline flow volume check, to be performed after replacing the saline supply and monthly, as described in the *Procedure* section of this document. If the saline supply needs replacing in the first two weeks of the month, then the check that is performed after the saline supply is replaced may also count as the monthly check. This task is documented on the *Sorvall Cell Washer Saline Flow Volume Check Log*.
4. The following tasks are documented on the *Sorvall Automated Cell Washer Preventative Maintenance Log*.
    a. Monthly inspection.
    b. Monthly cleaning.
    c. Quarterly cleaning.
    d. Quarterly decontamination.
    e. The tubing shall be replaced yearly, or as needed; e.g., if it is damaged or leaking. The technologist will follow the installation instructions provided with the Tubing Replacement Kit (Catalog No. 12977). Beaumont Health Biomedical may also replace the tubing.

C. Saline Supply

1. When opening a new saline cube record the open date, the expiration date (1 month from the open date), and the technologist's initials on a *Blood Bank Saline Supply* sticker and affix this sticker to the saline cube. The saline flow volume check must be performed after replacing the saline supply and monthly, as described in the *Procedure* section of this document.

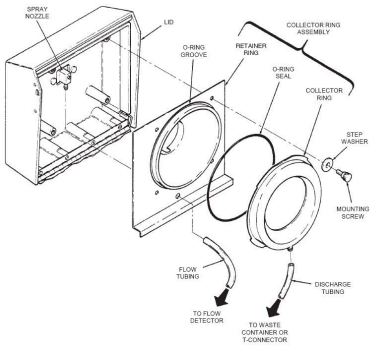
D. Preventative Maintenance Performed by Beaumont Health Biomedical

1. Refer to the Beaumont Health Biomedical Centrifuge General Inspection reports.

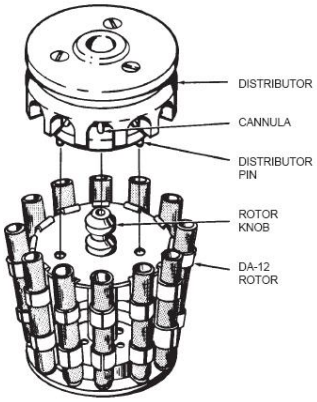
VI. PROCEDURE:

A. Monthly Inspection of the Sorvall Automated Cell Washer

1. Inspect the vents on the bottom of the cell washer to be sure that they are not blocked; remove any obstructions.
2. Check all sealing surfaces, tubing, liners, and the collecting ring assembly for cleanliness and good condition.



3. Inspect the distributor, rotor, and stainless steel rotating bowl:



   a. Remove the distributor from the top of the rotor; check for cracks and make sure cannulas are not bent, damaged or clogged. Flush water through the head to check for clogs. If the water does not flow freely through the cannulas they may be clogged (perhaps with broken glass); refer to the *Unsatisfactory Preventative Maintenance* section of this document. From underneath, make sure the metal clip that holds the distributor to the rotor is not cracked or broken.

   b. Remove the rotor from the rotating bowl assembly. Make sure that the rotor does not wobble on its base. Make sure that the pivot pin at the top of each tube holder is not loose. Also, check the gaps in the tube holder bands – gaps may widen over time due to centrifugal force, and the rotor should not be used if the gaps become greater than 2 mm. Do not compress the tube holder bands to close the gaps; bands are precisely shaped to support tubes during centrifugation, and tube support will be compromised if the bands are deformed in this manner.

   c. Remove the stainless steel rotating bowl assembly and inspect for signs of corrosion or cracks.

4. Document the applicable columns of the *Sorvall Automated Cell Washer Preventative Maintenance Log*, to indicate whether the inspections is satisfactory or unsatisfactory (S / U).

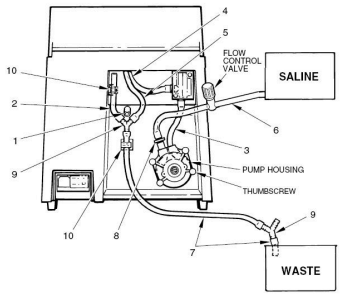
B. Monthly Cleaning of the Automated Cell Washer

1. Clean the cabinet with a damp cloth and mild detergent.
2. Remove the rotor, distributor, and rotating bowl and wash them with warm water and mild detergent.

3. Document the applicable columns of the *Sorvall Automated Cell Washer Preventative Maintenance Log*, to indicate that monthly cleaning was performed (√).

C. Quarterly Cleaning of the Automated Cell Washer

1. Remove the collecting ring assembly and tubing for routine cleaning as follows:
    a. From the back of the instrument, open the adjustable tubing clamp that secures the Y-Connector in place and remove the discharge tubing from the Y-Connector.



Item	Description
1*	Overflow Tubing (from overflow tray), 150 mm (6 inch)
2	Vent Tubing, 150 mm (6 inch)
3	Pump Tubing, 255 mm (10 inch), frosted
4	Flow Tubing (to nozzle), 305 mm (12 inch)
5	Discharge Tubing (from collector ring), 200 mm (8 inch)
6	Supply Tubing, 610 mm (24 inch),
7	Drain Tubing 1220 mm (48 inch),
8	Pump Connector
9	Y-Connector
10	Adjustable Tubing Clamp

    b. Remove the four mounting screws and step washers securing the collecting ring assembly to the lid.
    c. Pull the collecting ring assembly away from the lid, and pull the discharge tubing up through the wet guard (molded black liner).
    d. Disconnect the flow tubing from the spray nozzle in the lid and pull it through the hole in the retainer ring. If it proves difficult to remove the flow tubing (e.g., if a clamp has been placed on the flow tubing) then it is acceptable to omit this step and to omit washing the flow tubing (step f) as long as the quarterly decontamination procedure is performed.
    e. Separate the collector ring assembly by pulling the collector ring and O-ring off.
    f. Remove the discharge tubing and flow tubing; wash with warm water and mild detergent, and reinstall.
    g. Wash the retainer ring, O-ring seal, and collector ring with warm water and mild detergent.
    h. To reassemble, replace the clean O-ring and collector ring on the clean retaining ring; work the O-ring seal around the large opening of the retainer ring until it is fully seated in the groove. Then, place the collector ring so that it rests concentrically over the O-ring seal and press firmly into place. Make sure the nozzle for the discharge tubing on the collector ring aligns with the groove in the wet guard when the

collecting ring assembly is reinstalled in the lid.

i. Reinstall the collecting ring assembly by reversing steps a through d. When replacing the four mounting screws, make sure the flat side of each step washer faces the screw head.

j. Document the applicable columns of the *Sorvall Automated Cell Washer Preventative Maintenance Log*, to indicate that quarterly cleaning was performed (√).

D. Quarterly Decontamination of the Automated Cell Washer

1. Prepare a 3-10% solution of household liquid chlorine bleach.
2. Soak a wash rag or sponge with the bleach solution and gently wipe the bowl assembly, the wet guard, and the inner portion of the Cellwasher 2, making sure all encrusted material is gone. Do this step twice.
3. Disconnect the supply tubing from the saline supply and set the tubing to draw from the bleach solution.
4. Pump the bleach solution through the Cellwasher 2 for four cycles.
5. Set the tubing to draw from clean water and follow the bleach solution with 4 to 12 water washes, so that no bleach remains.
6. Reconnect the tubing to the saline supply and follow the water washes with four cycles of saline.
7. Place 12 tubes in the rotor and place 1 drop of any cell suspension (2 – 4%) in each tube. Wash the cells, stopping the cell washer after the tubes fill for the last wash.
8. Perform a pH and hemolysis check as follows:
    a. Take a sample of the last wash to the STAT lab to determine the pH.
    b. Observe the last wash for hemolysis.
9. Proceed as follows:
    a. If the pH is within the normal range (7.0 – 7.2) and hemolysis is not observed , proceed to step 10.
    b. If the pH check is not within the normal range or if hemolysis is observed then repeat steps 6 through 9 until the pH is normal and hemolysis is no longer observed.
    c. If the pH is still not within the normal range after several additional saline cycles, verify that the pH of the saline supply itself is within the normal range.
10. Document the applicable columns of the *Sorvall Automated Cell Washer Preventative Maintenance Log* with the pH and the hemolysis check results.
    a. Document the hemolysis check as satisfactory if hemolysis is not observed and as unsatisfactory if hemolysis is observed (S / U).
11. Open the lid, turn the main power switch OFF, and unplug the power cord. Wipe all parts (including parts inside the lid and chamber, the cabinet, the control panel, and the front surface

of the main power switch) with a 70% ethanol solution and allow to dry (do not flood the switch or power cord connector areas).

E. Saline Flow Volume Check

1. Prime the system as follows:
    a. Open the lid.
    b. Press the AUTO button / then the 2 button.
    c. Holding a graduated cylinder under the saline dispenser in the lid, press the PRIME button. Saline will be dispensed into the graduated cylinder.
2. Observe the actual volume of saline that was dispensed and document it on the *Sorvall Cell Washer: Saline Flow Volume Check Log*.
3. Determine the “correct” saline flow volume and document this volume on the *Sorvall Cell Washer: Saline Flow Volume Check Log*.

Cell Washer	"Correct" Saline Flow Volume for Current Adjustment (Approximates the post-adjustment saline flow volume from the previous adjustment)
WBHC# 069814	Approximately 65 mL

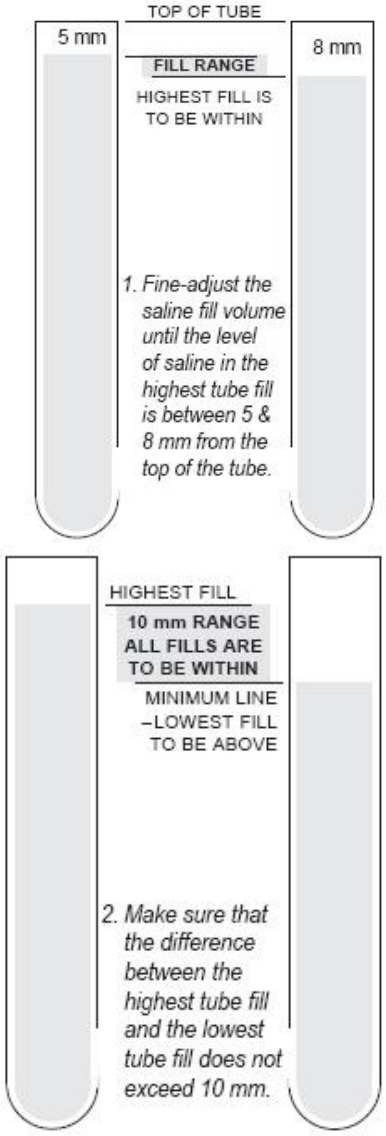
    a. Note: The “correct” volume will be approximately the volume indicated in the table above. However, the “correct” saline flow volume will continue to change over time due to tube lot tolerances and normal changes to system flow. Therefore, the “correct” saline flow volume should be adjusted on the current date to approximate the post-adjustment saline flow volume from the previous adjustment. Refer to the *Sorvall Cell Washer Saline Flow Volume Check Log* for the post-adjustment volume from the previous adjustment.
4. Compare the actual dispensed saline volume to the “correct” saline flow volume.
5. Proceed as follows:
    a. If the volume dispensed into the graduated cylinder is “correct”, then proceed to step 6.
    b. If the volume dispensed into the graduated cylinder is “incorrect,” then adjust the flow control valve.
        i. Turn the valve counterclockwise to increase the flow.
        ii. Turn the valve clockwise to decrease the flow.
6. Repeat steps 1 - 5, above, until the volume of saline dispensed into the graduated cylinder is “correct” (approximately).
7. Place 12 tubes in the rotor. Be sure to use the correct sized tubes for the cell washer.

Cell Washer	Test Tubes
WBHC# 069814	12 x 75 mm

8. Close the lid, press START, and then press CHECK. After filling is complete, the lid light will

come on.

9. Press the LID button, open the lid, and observe the saline level in each tube.
10. Determine whether the volume dispensed into the tubes is acceptable. As illustrated below, the saline volume is acceptable if:
    a. The level of saline in the fullest tube is between 5 and 8 mm (0.2 and 0.3 inch) from the top of the tube, AND
    b. The difference between the fullest and the least full tube is not more than 10 mm (0.4 inch).



11. Proceed as follows:
    a. Document whether the volume dispensed into the tubes is satisfactory or unsatisfactory (S/U) on the *Sorvall Cell Washer Saline Flow Volume Check Log*.
    b. If the volume dispensed into the tubes is acceptable, no further actions are

indicated.

c. If the volume dispensed into the tubes is unacceptable, refer to the *Sorvall Cellwasher 2 Operating Instructions / Troubleshooting / Problem B (Improper saline fill of tubes)*. Note that the following additional actions may resolve the unacceptable volume:
    i. Verify that the correct sized tubes were filled for the particular cell washer.
    ii. Clean the distributor or cannulas, which may have been clogged.
    iii. Document any additional actions taken.

d. If applicable, refer to the policy *Unsatisfactory Preventative Maintenance*.

12. Repeat steps 1 and 2, above. Document the post-adjustment volume of saline dispensed into the graduated cylinder.

VII. REFERENCES:

1. Sorvall Cellwasher 2 Operating Instructions, issued January 2005.
2. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.

Attachments

Blood Bank Saline Supply

Sorvall Automated Cell Washer Preventative Maintenance Log

Sorvall Cell Washer Saline Flow Volume Check Log

Sorvall Cell Washer Tag

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	5/26/2023
	Kristina Davis: Staff Physician	5/26/2023
Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist Lead	4/28/2023
	Kelly Sartor: Mgr, Division Laboratory	4/28/2023

Brooke Klapatch: Medical Technologist Lead	4/28/2023