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Quality Control and Preventative Maintenance of Helmer UltraCWII Cell Washing System

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will identify and provide policy and instructions for the preventative maintenance (PM) that is required for the Helmer UltraCW®II Automatic Cell Washing System.

II. INTRODUCTION

A. The Helmer UltraCW®II Automatic Cell Washing System Operation and Service Manuals 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

III. CLINICAL SIGNIFICANCE:

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.

IV. SCOPE:

A. The Helmer UltraCW®II Automatic Cell Washing System will only be used with 12 x 75 mm test tubes.

V. POLICIES:

A. The saline fill volume is checked each day of use as described in the Procedure VIII.A *Saline Fill Volume* and is documented on *Cell Washer Daily Maintenance Log.*

B. The saline supply will be confirmed as adequate each of day of use as described in the Procedure VIII.B Saline Supply and is documented on the *Cell Washer Daily Maintenance Log.*

C. The tubing and drain will be inspected each day of use for damage or obstructions. These checks will be documented on *Cell Washer Daily Maintenance Log.*

D. Each day of use, the system will be flushed with distilled water and documented on the the *Cell Washer Daily Maintenance Log*

E. Each day of use, the interior of the cell washer will be cleaned and dried to prevent corrosion and contamination. The cleaning will be documented on the *Cell Washer Daily Maintenance Log.*

F. The system will be flushed and the rotor fill ports inspected and cleaned weekly as described in the Procedure VIII.F and is documented on *Cell Washer Weekly Maintenance Log*

G. Saline flow volume check,will be performed monthly and after saline supply change as directed in the Procedure VIII.G and is documented on the *Cell Washer Daily Maintenance Log*

H. Monthly inspection and cleaning, as described in the Procedure VIII.H and is documented on the *Cell Washer Preventative Maintenance Log.*

I. Cell Washers are calibrated upon receipt, after major adjustments or repairs, and yearly as described in the Procedure, VIII.I *Functional Calibration* to ensure proper washing and packing of the red cell button.

J. Semi-annual rotor speed calibration checks will be performed by Biomedical Engineering and documented in the Biomedical Equipment logs and/or on the *Cell Washer Preventative Maintenance Log.*

K. Yearly supply and drain tubing replacement, will be performed as described in the Procedure VIII.K *Supply & Drain Tube Replacement and documented on the Cell Washer Preventative Maintenance Log.*

L. If any part of the preventative maintenance reveals that the system is not functionally properly or deemed unsatisfactory then the equipment will be:

    1. Removed for service and not returned for use with patient samples until issues are resolved.

    2. Tag the cell washer with the "Equipment of Service" form.

3. Beaumont Health Biomedical Department will be contacted to arrange for equipment repair
4. Blood Bank Lead Technologist and/or Supervisor will be made aware of the issue.
5. The Equipment failure will be documented on an internal variance.

VI. EQUIPMENT:

A. Bypass tool (provided by Helmer)

B. Flat-head screwdriver

C. Graduated cylinder (100 mL)

D. Pump tubing assembly (ordered from Helmer Technical Service)

VII. SUPPLIES:

A. 12 x 75 mm test tubes

B. Blood Bank Saline

C. Disposable pipettes

D. Plastic specimen rack

E. Distilled Water

F. 10% bleach solution (1:9 ratio of household bleach to water, or 1 part commercial sodium hypochlorite to 9 parts water)

G. Non-abrasive liquid cleaner (with a pH between 5 to 8)

VIII. PROCEDURE:

A. Saline Fill Volume

1. Open the cell washer lid, and load the entire rotor with 12 x 75 mm test tubes. Close the Lid.

2. From the Start screen, select the Menu button .
3. Select the *daily maintenance* program. The program screen is displayed.

4. Select the green check mark to load the program. The Start screen appears with the loaded program name at the top of the screen.
5. Select *Start Program*. The lid will open once the fill process has completed.

6. Examine the level of saline in each tube.
7. Determine whether the saline fill volume is acceptable. The approximate volume per test tube is 4.7mL, which fills the tube up to the middle of the opening of the test tube holder. The volume dispensed into the tube is acceptable if the volume is within ± 0.5 cm of this point.
8. If the saline fill volume check is acceptable, close the lid and verify that the cycle automatically continues the run. Document the saline fill volume check column on *Cell Washer Daily Maintenance Log* as "S" (satisfactory).
9. If the saline fill volume check is unacceptable, the following apply:
    1. Check that all tubes are completely seated in tube holder.
    2. Check for kinks in the tubing and repeat the volume check.
    3. If the volume is still unacceptable, then temporarily discontinue use of the automatic cell washer; place Equipment out of Service tag on the cell washer until the saline flow volume has been correctly adjusted.
    4. Complete an internal variance.
    5. Perform the saline flow volume adjustment as described in procedure VIII.G.
    6. Once the saline flow volume has been correctly adjusted, document the acceptable saline fill volume check on *Cell Washer Daily Maintenance Log*.
10. At the end of the run, the Program successful dialog box appears once the sample is complete. Open the lid and discard the test tubes.

B. Saline Supply Check and Replacement

1. Each day of use verify that the saline supply is sufficient and is with in expiration date.
2. If necessary replace the saline cube.
    a. 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 the saline cube.
    b. Insert the small end of the adapter into the open end of the saline supply tubing.
    c. Connect the large end of the adapter to the connector on the saline supply container.
    d. Perform the saline flow volume check as described in the Procedure G, *Saline Volume Flow Check*.
3. Document the inspection of the saline supply with a √ on the *Cell Washer Daily Maintenance Log*.

C. Tubing and Drain Inspection

1. At the end of the run, once the the Lid Ready LED illuminated, lift on the lid handle to open the cell washer lid.
2. Inspect the tubing and the drain for any possible obstructions.

a. Clear any obstructions if necessary.

b. Document the inspection as satisfactory with a √ in the appropriate column on the *Cell Washer Daily Maintenance Log.*

3. Inspect the tubing connections to verify all tubing is securely attached.

   a. If necessary, secure any loose tubing.

   b. If any of the tubing is damaged and needs replacing, refer to Procedure VIII.K *Supply and Drain Tube Replacement.*

4. Document the inspection as satisfactory with a √ in the appropriate column on the *Cell Washer Daily Maintenance Log.*

D. Daily Distilled Water Flush

1. Load the rotor with tubes, leaving every other position on the rotor empty.
2. Prepare a container of deionized or distilled water (approximately 1 L).
3. Disconnect the Saline-tube, solution 1, from the saline solution container and place it into the container with deionized or distilled water.
4. Select and run the "flush 1" program.
5. Remove the Saline-tube from the deionized or distilled water container and place it in the saline solution container.
6. Select and run the "flush 1" program.
7. Document completion of this maintenance with a √ in the appropriate column on the *Cell Washer Daily Maintenance Log.*

E. Daily Cleaning

1. Use a damp cloth to wipe down the bowl of the cell washer, removing any debris that may be present. It is not necessary to remove the bowl or clean under the bowl.
2. Use a dry cloth to wipe the entire inside of the lid, including the drainage system and painted surfaces.
3. Remove and clean the splash guard.

   1. Remove the splash guard cap by pulling upward.

   2. Remove the splash guard by folding back the grey rubber seal to expose the edge of the splash guard

   3. Gently lift the splash guard working a section at a time until the splash guard is clear from the gasket

   4. Wipe the splash guard and cap with damp cloth to remove any debris that may be present.

5. Wipe with a dry cloth

4. Reinstall Splash Guard

    1. Place the splash guard in the bowl so the drain hole in the guard is directly above the drain in the bowl.

    2. Working one section at a time around the bow, fold back the gasket and press the splash guard downward so the edge of the guard rests on the lip of the bowl. The edge of the splash guard should slightly overlap the lip of the bowl.

    3. With the labeled side up, place the splash guard cap into the bowl on top of the splash guard.

5. Document completion of this maintenance with a √ in the appropriate column on the *Cell Washer Daily Maintenance Log.*

F. Weekly Fill Port Maintenance

1. Soak the rotor in clean, warm water or run warm water directly into the top of the rotor for several minutes. Ensure water is flowing freely out of all the fill ports.

2. If a port is blocked, gently slide the lid release tool into the fill port from the outside toward the center of the rotor. Gently slide the lid release tool in and out several times to clean the port.

3. If the rotor will not be used immediately, ensure it is dry before returning it to the cell washer and closing the lid or if the rotor will be used immediately, ensure all fresh water has been purged from the system and replaced by saline solution before running a program.

G. Weekly Cleaning

1. Load the rotor with tubes, leaving every other position on the rotor empty.

2. Install the rotor and close the lid.

3. Prepare a container with 400 ml of 0.5% sodium hypochlorite (bleach) cleaning solution (1:9 ratio of bleach to water).

4. Prepare a container of deionized or distilled water (approximately 1 L).

5. Disconnect the Saline-tube, solution 1, from the saline solution container and place it into the container with the bleach cleaning solution.

6. Select and run the "flush 1" program and wait 5 minutes.

7. Take the Saline-tube from the container and place it in the container with deionized or distilled water.

8. Select and run the "flush 1" program.

9. Open the lid and dry the centrifuging area.

10. Remove the Saline-tube from the deionized or distilled water container and place it in the saline solution container.

11. Select and run the "flush 1" program.
12. Remove the Saline-tube from the saline solution container and place it in the container with deionized or distilled water.
13. Select and run the "flush 1" program.
14. Connect the supply tubing to the container of saline solution.
15. Select Program 1, and press the START WASH button to run four cycles with saline.
16. Place 12 tubes in the rotor and place 1 drop of any cell suspension (2 – 4%) in each tube.
17. Wash the cells using Program 1, stopping the cell washer after the tubes fill for the last wash.
18. Perform a hemolysis check as follows:
19. Observe the last wash for hemolysis.
20. Cell button should be present with no trace of hemolysis in supernatant.
21. If there is evidence of hemolysis, repeat steps 15-18. If still unresolved, ,submit a variance and place Equipment out of Service on the cell washer and notify blood bank management.
22. Document the completion of the system flush as well as the results of the hemolysis check on the *Cell Washer Weekly Maintenance Log.*

H. Saline Volume Flow Check

A. From the Start Screen, touch the login button  .

B. Enter the service user password, 46060 and select the green check mark to confirm.

C. Select the settings button  .

D. In the System Setting screen, select the tools button  .

E. On the Service Menu screen, select the ruler icon  .

F. Select the 36.0 mL target volume.

G. Hold a clean, dry graduated cylinder below the spout on the lid and press the start button. Wait until liquid has stopped flowing from spout.

H. Measure the liquid collected in the graduated cylinder.

I. The acceptable volume of saline for this validation is 36.0 mL ± 1.0 mL, resulting in an acceptable range of 35.0 mL – 37.0 mL.
Use the "+", "++", "-" and "-.-" on the left side of the screen to adjust the number to match the measured volume in Step 8.

J. Select the green check mark  to finish the calibration.

K. Use the red arrow to return to the home screen.

I. Monthly Inspection and Cleaning

1. Inspect the rotor for wear, corrosion, and damage. If any of these conditions exist, the rotor needs to be replaced.
2. Inspect the tube holders for wear and damage. If any of the tube holders appear worn or damaged, they need to be replaced. The tube holders should be replaced at least once every two years. To remove a tube holder:
    a. Remove the rotor from the cell washer.
    b. Turn the rotor upside down.
    c. Move the rotor lock so that it clears the clip.
    d. While holding the tube holder to be removed in the vertical position, firmly press the tube holder down until the clip snaps free from the ring.
3. Clean the exterior of the cell washer using a soft cotton cloth and a non-abrasive liquid cleaner. Dry the exterior with a dry cloth.
4. Document the above inspections and cleaning on *Cell Washer Preventative Maintenance Log*.

J. Functional Calibration

A. Document the cell washer ID (Asset Tag), the date, and initials of the technologist who is calibrating the cell washer on the Cell Washer Calibration Worksheet.

B. To each of twelve (12) test tubes the following reagents:
    1. 2 drops LISS
    2. 2 drops serum
    3. 1 drop Coombs Check Cells

C. Place the tubes in the cell washer and start the wash cycle.

D. After addition of saline in the second cycle, stop the cell washer.
    1. Observe for the following:

2. There should be an equal volume of saline in all tubes
3. Tubes should be approximately 80% full
4. Confirm that the red cell button has been thoroughly resuspended. (Cells should not stream down the sides of the tube.
5. Record your observations on the Cell Washer Calibration Worksheet.

E. Continue the cell washing cycle until just after the addition of saline in the third cycle.

F. After the addition of saline in the third cycle, stop the cell washer.

G. Observe for the following:

1. There should be an equal volume of saline in all tubes
2. Tubes should be approximately 80% full
3. Confirm that the red cell button has been thoroughly resuspended. (Cells should not stream down the sides of the tube.
4. Record your observations on the Cell Washer Calibration Worksheet.

H. Continue the cell washing cycle until the completion of the third cycle.

I. After the third wash and decant cycle, stop the cell washer.

J. Observe for the following:

1. Confirm that the saline has been completed decanted from all tubes and that the button in each is dry.
2. Confirm that the size of the cell button is the same in all tubes.
3. Read and record the reactions. All tubes should show the same degree of agglutination.
4. Record your observations on the Cell Washer Calibration Worksheet.

K. Add 2 drops of AHG to each of the tubes.

L. Centrifuge using the spin cycle.

M. Observe each tube for the following:

N. Confirm the size of the cell button is the same in each tube.

O. Read and record the reactions. All tubes should show the same degree of agglutination.

P. Record the observations on the Cell Washer Calibration Worksheet.

Q. Determine if the calibration check is satisfactory or unsatisfactory by referring to the interpretation section below and record whether 3 cell wash cycle is sufficient.

R. If the calibration check fails, the instrument must be taken out of service in accordance with policy Appropriate Actions to take if the Calibration Check is Unsatisfactory

K. Semi Annual Rotor Speed Calibration

Twice a year, the rotor speed must be verified to ensure it is within tolerance. This maintenance is typically done by the Beaumont Health Biomedical Department.

A. Install the rotor.

B. Program the Spin (S) program with a spin speed of 3500 RPM and spin time that is long enough for the speed to be measured.

C. Press the SPIN button. This will start the Spin (S) program.

D. While the rotor is spinning and 3500 is displayed on the message screen, point the tachometer's laser beam through the sight window in the lid. As the rotor spins, the laser momentarily reflects off the optical reference on the rotor.

E. Obtain the reading from the tachometer, and document it on the Cell Washer *Preventative Maintenance Log.*

F. Verify the tachometer reading is within the acceptable range of 3500 RPM ± 20 RPM.

1. If the tachometer reading is outside of this range, it is considered unacceptable and must be corrected. Refer to the Troubleshooting section (chapter 9) of the Cell Washer Service.

L. Supply and Tube Drain Tube Replacement

A. Power the cell washer off.

B. Carefully disconnect the ends of the supply and drain tubing from the fittings on the back of the cell washer.

C. The tubing will likely have residual saline in it. Disconnect the tubing slowly and as upright as possible to limit saline spilling out of the tubing.

D. Discard the old tubing into the biohazard waste.

E. Connect a new piece of tubing to the saline inlet fitting, and place the other end in the saline source.

F. Connect a new piece of tubing to the drain outlet fitting, and place the other end in the drain.

G. Perform a saline flow volume check as described in the Procedure VII.G. to remove any air from the saline supply tubing, and to verify the correct volume of saline is being dispensed. If necessary, repeat the saline flow volume check more than once to remove all the air from the tubing.

H. Document the supply and drain tubing replacement on *Cell Washer Preventative Maintenance Log.*

IX. NOTES:

A. This facility has two different models of Helmer cell washer. Each cell washer must be used in accordance with manufacturer instructions.

B. Yearly supply and drain tubing replacements may be performed by a technologist following this procedure or Cell Washer Service Manual, or may be performed by Beaumont Health Biomedical.

C. It is recommended in the Cell Washer Service Manual that the rotor is replaced every four years.

D. It is recommended in the Cell Washer Service Manual that the rotor tube holders are replaced every two years.

X. REFERENCES:

1. AABB Standards for Blood Banks and Transfusion Services, Current edition.
2. College of American Pathologists, Transfusion Medicine Checklist, current edition.
3. Helmer UltraCW®II Automatic Cell Washing System Operation Manual rev.D August 20, 2018.
4. Helmer UltraCW®II Automatic Cell Washing System Service Manual, rev B, August 20, 2018.

Attachments

Cell Washer Daily Maintenance Log

Cell Washer Preventative Maintenance Log

Cell Washer Weekly Maintenance Log

Approval Signatures

Step Description	Approver	Date

Beaumont HEALTH

Beaumont Laboratory
Dearborn, MI

Cell Washer Daily Maintenance Log

Month / Year:_____ Cell Washer Model: _____Asset Tag #:_____

Day	Tech	Saline Fill Volume Check (S or U)	*Saline Supply Exp. Date Checked, and Saline Flow Volume Check is on Schedule (√)	Tubing and Drain Inspected and Clear of Obstructions (√)	Tubing Connections Inspected and Secured (√)	Daily H2O Flush (√)	Bowl Wiped with Damp Cloth (√)	Lid and Drainage System Wiped with Dry Cloth (√)
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*The saline flow volume check is documented on *Cell Washer Preventative Maintenance*

QC Review / Date:_____

Refer to Quality Control & Preventative Maintenance of *Helmer UltraCW™ and Quality Control & Preventative Maintenance of UltraCW®II Automatic Cell Washing Systems.*

Beaumont HEALTH

Beaumont Laboratory

Dearborn, MI

Cell Washer Weekly Maintenance

Month / Year: _____ Cell Washer Asset Tag # _____

Date	Tech	System Flushed with 10% bleach and distilled water using the CLEAN Program (√)	Four Wash Cycles Performed with Saline (√)	Hemolysis Check (S/U)	Rotor Fill Ports Inspected and Cleaned (√)

- Performed every week, within 7 ± 2 days of the previously performed weekly task

QC Review / Date: _____