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Area	Laboratory-Blood Bank
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Helmer UltraCW™ Automatic Cell Washing System 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 Helmer UltraCW™ Automatic Cell Washing System.

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 Helmer UltraCW™ Automatic Cell Washing System Operation Manual indicates 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

IV. DEFINITIONS:

A. **Weekly**: Every week, within 7 ± 2 days of the previously performed weekly task.

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

C. **Semi-Annual**: Twice a year, within the months of January and July.

D. **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.

E. **Biomedical**: Performs repairs and some maintenance of equipment for the hospitals.

V. POLICIES:

A. Unsatisfactory Preventative Maintenance

1. If any part of preventative maintenance reveals that any part of the Helmer UltraCW™ is not functioning properly, 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 Helmer Scientific.
    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 should be wiped from the interior and exterior as they occur using a damp cloth and mild detergent.
2. The saline fill volume and daily maintenance checks are performed each day of use as described in the Procedure section of this document and is documented on the *Helmer UltraCW™ Daily Maintenance* form.
3. The system will be flushed and the rotor fill ports inspected and cleaned weekly as described in the Procedure section of this document and is documented on the *Helmer UltraCW™ Weekly Maintenance* form.
4. The following tasks are documented on the *Helmer UltraCW™ Preventative Maintenance* form:
    a. Monthly flow volume check.
    b. Monthly inspection and cleaning.
    c. Semi-annual rotor speed calibration.
    d. Yearly parts replacement.

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 Biomedical

1. Refer to the Biomedical Centrifuge General Inspection reports.

VI. EQUIPMENT:

A. Bypass tool (provided by Helmer)

B. Flat-head screwdriver

C. Graduated cylinder (100 mL)

D. Laser tachometer

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

VII. SUPPLIES:

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

B. Distilled water

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

VIII. PROCEDURE:

A. Saline Fill Volume and Daily Maintenance Checks

The saline fill volume of each rotor is checked each day of use. This check will be documented on the *Helmer UltraCW™ Daily Maintenance* form.

1. After the START WASH button was pressed to begin the run, press the CHECK button. At the end of the fill step, the cell washer will stop, give an audible alert, and allow the lid to be opened.
2. Examine the level of saline in each tube.
3. Determine whether the saline fill volume is acceptable. The approximate volume per 10 x 75 mm test tube is 3.2 mL, which fills the tube up to the middle of the opening in the test tube holder. The volume dispensed into the tubes is acceptable if the volume is within ± 0.5 cm of this point.

a. If the saline fill volume check is acceptable, close the lid and press START WASH to continue the run and document as “S” (satisfactory).

b. If the saline fill volume check is unacceptable, the following apply:

i. Check for kinks in the tubing and repeat the volume check.

ii. If the volume is still unacceptable, then temporarily discontinue use of the automatic cell washer; manually wash the test cells 3 – 4 times, using large volumes of saline and decanting completely after each wash.

iii. Preventative maintenance of the cell washer is required; the saline flow volume must be adjusted as described *Procedure* section of this document.

iv. Place an *Equipment out of Service* form on the cell washer until the saline flow volume has been correctly adjusted.

v. Submit a variance.

vi. Once the saline flow volume has been correctly adjusted, document the acceptable saline fill volume check.

4. Each day of use, the tubing and drain will be inspected for damage or obstructions. These checks will be documented on the *Helmer UltraCW™ Daily Maintenance* form.

a. Inspect the tubing and the drain for any possible obstructions. Clear any obstructions if necessary.

b. Inspect the tubing connections to verify all tubing is securely attached. If necessary, secure any loose tubing.

c. If any of the tubing is damaged and needs replacing, refer to the *Yearly Parts Replacement* section of this document.

5. 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 *Helmer UltraCW™ Daily Maintenance* form.

a. 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.

b. Use a dry cloth to wipe the entire inside of the lid, including the drainage system and painted surfaces.

B. Weekly Inspection and Cleaning

The cell washer will be flushed weekly to clean and disinfect the device, as well as remove blockages due to

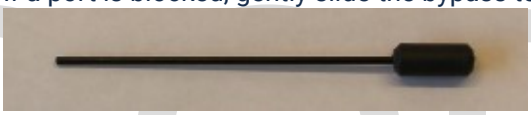
salt crystallization.

1. Load the rotor with tubes, leaving every other position on the rotor empty.
2. Install the rotor and close the lid. Ensure the Lid Ready LED is illuminated.
3. Connect the supply tube to the container of 10% bleach solution.
    a. The total volume of the bleach solution should be approximately 500 mL.
4. Use the up and down arrow buttons (▲ and ▼) to select the CLEAN program.
5. Press the START WASH button to start the program.
6. When the cleaning sequence is complete, OPEN LID is displayed and the Lid Ready LED will be illuminated. Open the lid. The display will now read Clean proc.DONE.
7. Connect the supply tubing to the container of approximately 1 L of distilled water.
8. Hold a graduated cylinder under the dispensing nozzle on the underside of the lid.

9. Press and hold the SALINE button for about 3 seconds.
    a. The Saline LED will illuminate and REFILL process is displayed on the screen.
    b. 60 mL of residual bleach solution and distilled water is dispensed from the nozzle into the graduated cylinder.
    c. When this process is complete, the Saline LED will no longer be illuminated. REFILL proc.DONE will briefly display, followed by Program 1.
10. Dispose of the purged liquid down a standard sink drain.
    a. Dispose the liquid in a dirty sink, not a clean sink used for hand washing.
11. Repeat steps 4-5 to flush the system with distilled water.
12. Connect the supply tubing to the container of saline solution.
13. Repeat step 9 to purge any remaining distilled water from the system.
14. Select Program 1, and press the START WASH button to run four cycles with saline.
15. Place 12 tubes in the rotor and place 1 drop of any cell suspension (2 – 4%) in each tube. Wash the cells using Program 1, stopping the cell washer after the tubes fill for the last wash.
16. 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.

17. Proceed as follows:
    a. If the pH is within the normal range (7.0 – 7.2) and hemolysis is not observed, proceed to step 18.
    b. If the pH check is not within the normal range or if hemolysis is observed then repeat steps 14 through 17 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.
18. If applicable, refer to the *Unsatisfactory Preventative Maintenance* section of this document.
19. Document the completion of the system flush, as well as the pH and hemolysis check results on the *Helmer UltraCW™ Weekly Maintenance* form.
20. The fill ports on the rotor are cleaned weekly to remove any debris that was not removed when the system was flushed. This will prevent debris from clogging the fill ports, preventing saline from entering the tubes.
    a. Soak the rotor in clean, warm water or run warm water directly into the top of the rotor for several minutes. Check that water is flowing freely out of all the fill ports.
    b. If a port is blocked, gently slide the bypass tool in and out several times to clean the port.



    c. Allow the rotor to dry completely before returning to the cell washer and closing the lid.
        i. If the rotor is required for use before it has dried, verify that all fresh water has been purged from the system and replaced by saline before processing.
    d. Document the cleaning of the fill ports on the *Helmer UltraCW™ Weekly Maintenance* form.

C. Monthly Flow Volume Check

The saline flow volume check will be performed monthly, anytime the saline supply is replaced mid-month, or anytime the daily saline fill volume is unacceptable. 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. **Note: During the first month of usage, this saline flow volume check will be performed weekly. After the first month of usage, it will be performed based off of the above criteria.**

1. Make sure the cell washer is set to Program 1. If necessary, use the up and down arrow buttons (▲ and ▼) to select Program 1.
2. Open the lid.
3. On the control panel, press and hold the SALINE button for about four seconds, until CALIBRATE XXX.X ml is displayed.
4. Hold the graduated cylinder under the nozzle in the lid of the cell washer.

5. On the control panel, press the CHECK button. The Saline LED will illuminate and the volume of saline being dispensed will display.
    a. For Program 1, the volume displayed should be 38.4 mL.
6. When the cell washer is done dispensing the programmed volume of saline, the Saline LED will turn off and the process is complete.
7. Observe the saline volume in the graduated cylinder. If the dispensed saline is within acceptable limits, the saline flow check is complete. If the dispensed saline is unacceptable, proceed to step 8.
    a. The acceptable volume of saline for Program 1 is 38.4 mL ± 5%, resulting in an acceptable range of 38.4 mL ± 1.92 mL (36.5 mL – 40.4 mL).
    b. If it appeared there was air or another obstruction in the saline supply tubing which led to an unacceptable saline volume, it is acceptable to repeat steps 4 - 7 once or twice to see if the saline volume dispensed is corrected. If the saline volume is still unacceptable, proceed to step 8.
8. For unacceptable saline flow volume results, determine the difference in volume of the displayed volume compared to the actual measured volume. Ask a MTII for assistance with the adjustment process if necessary.
    a. Equation: Displayed – Measured = Difference
9. Use the volume difference calculated in step 8 to determine the adjustment value. Round the adjustment value to the nearest whole number.
    a. Equation: Difference ÷ Measured x 200 = Adjustment Value
10. After the saline adjustment volume has been determined, change the value of the VOLUME ADJUST XX global parameter by the determined amount.
    a. Press and hold the parameter selection button (◄) for about eight seconds.
        i. The VOLUME ADJUST XX parameter is now displayed.
    b. Use the up and down arrow buttons (▲ and ▼) to change the adjusted volume until the desired value is displayed.
    c. Press the START WASH button to save the parameter setting.
11. Following the cell washer adjustment, repeat the saline flow volume to verify it is now acceptable. If necessary, repeat the adjustment process until it is within the acceptable range.

12. Documented the saline flow volume check and any adjustments on the *Helmer UltraCW™ Preventative Maintenance* form.

D. Monthly Inspection and Cleaning

The monthly inspection and cleaning consists of:

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 the *Helmer UltraCW™ Preventative Maintenance* form.

E. Semi-Annual Rotor Speed Calibration

Twice a year, the rotor speed must be verified that it is within tolerance. The cell washer has a sight window in the lid and an optical reference on the rotor.

1. Install the rotor.
2. 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.
3. Press the SPIN button. This will start the Spin (S) program.
4. 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.
5. Obtain the reading from the tachometer, and document it on the *Helmer UltraCW™ Preventative Maintenance* form.
6. Verify the tachometer reading is within the acceptable range of 3500 RPM ± 20 RPM.
    a. 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 Helmer UltraCW™ Service Manual.

F. Yearly Parts Replacement

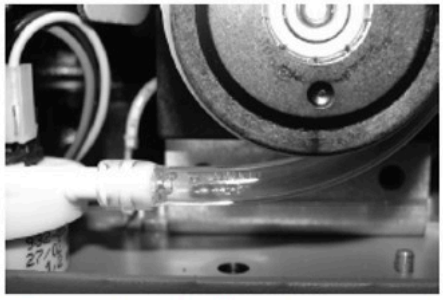
It is recommended by the *Helmer UltraCW™ Operation Manual* that certain parts of the cell washer are replaced yearly. Those parts include the supply and drain tubing, the pump tubing, and the tube holder inserts

used for the 10 x 75 mm test tubes.

1. Supply and Drain Tubing 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.
        i. 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.
    c. Discard the old tubing into the biohazard waste.
    d. Connect a new piece of tubing to the saline inlet fitting, and place the other end in the saline source.
    e. Connect a new piece of tubing to the drain outlet fitting, and place the other end in the drain.
    f. Perform a saline flow volume check 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.
    g. Document the supply and drain tubing replacement on the *Helmer UltraCW™ Preventative Maintenance* form.
2. Pump Tubing Replacement
    a. Power the cell washer off and disconnect the power cord.
    b. Disconnect the supply tubing from the saline supply.
    c. On the rear of the cell washer, open the access door.

Access door open with pump visible.

Pump tubing detail, routed from pump, through grommet, to lid.

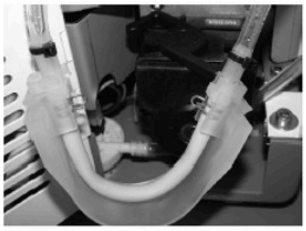


Pump tubing detail, tubing connected to flow meter.

    d. Remove the existing tubing assembly:
        i. On the top of the pump, turn the locking lever clockwise until the tubing holder loosens.
        ii. Free the tubing and tubing holder from around the pump.
        iii. Remove the tubing from the tubing holder.
        iv. Disconnect the ends of the tubing from the fittings.
        v. Pull the tubing through the grommet toward the pump, and remove it from the

pump area.

Pump with loosened tubing holder.



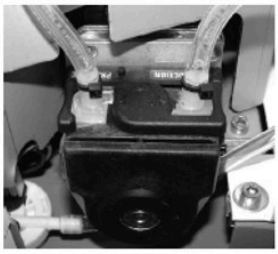
Tubing and holder freed from pump.

Tubing removed from holder.

e. Install the new tubing assembly:
    i. Orient the tubing assembly so the middle section of tubing is aligned with the tubing holder. Press the tubing into the holder.
    ii. Wrap the tubing holder around the pump so the middle section of tubing is against the pump.
    iii. While squeezing the tubing holder around the pump, turn the locking lever counter-clockwise until it locks into position.
    iv. Thread the tubing out through the grommet, then connect it to the fitting on the back of the lid.
    v. Connect the right side of the tubing to the fitting on the flow meter.

Middle section of pump tubing oriented in tubing holder.

Tubing holder wrapped around pump and held captive in position.



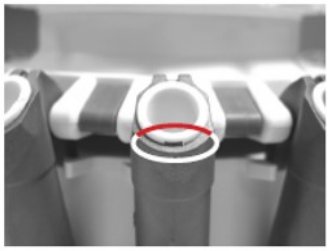
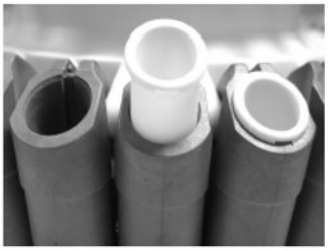
Holder locked in position around pump. Right side of tubing connected to flow meter fitting.

    vi. The pump tubing assembly is required to replace the pump tubing. The pump tubing assembly may be ordered from Helmer Technical Service.

f. Connect the supply tubing to the saline supply.
g. Plug in the cell washer and power the cell washer on.
h. Perform a saline flow volume check to verify the new tubing is installed correctly, and the correct volume of saline is being dispensed. During this step, check for leaks around the connections to the fittings.
i. Document the pump tubing replacement on the *Helmer UltraCW™ Preventative Maintenance* form.

3. Tube Holder Insert Replacement
    a. Place the rotor on a solid surface.

b. While holding the tube holder with one hand, insert a flat-head screwdriver into the slot and slightly twist the screwdriver to raise the top of the insert.
c. Grasp the top of the insert and pull it straight out.
d. Align the key on the new tube holder insert with the groove in the tube holder.
e. Press the insert into the tube holder all the way down, as shown below.
f. Document the tube holder insert replacement on the *Helmer UltraCW™ Preventative Maintenance* form.

Left: Slot in tube insert (circled). Right: Rotor with tube inserts (no insert, partially installed, fully installed).

IX. NOTES:

A. Yearly tubing replacements may be performed by a technologist following this policy or Helmer UltraCW™ Service Manual, or may be performed by Biomedical.
B. It is recommended in the Helmer UltraCW™ Service Manual that the rotor is replaced every four years.
C. It is recommended in the Helmer UltraCW™ 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. Helmer UltraCW™ Automatic Cell Washing System Operation Manual, June 2014.
3. Helmer UltraCW™ Automatic Cell Washing System Service Manual, June 2014.

Attachments

GraduatedCylinder2.jpg

Helmer UltraCW Daily Maintenance

Helmer UltraCW Preventative Maintenance

Helmer UltraCW Weekly Maintenance

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	6/9/2023
	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