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	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	Next Review: 11/18/2024
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: Muhammad Idrees (Physician) (11/18/2022)		

Procedure: Cell Washer – UltraCW Helmer, Use & Maintenance

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I. PURPOSE

To detail procedures for use and maintenance of Helmer Cell Washers used in the Blood Bank, UltraCW and UltraCW II.

II. SCOPE

This SOP addresses aspects of UltraCW and Ultra CW 2 Helmer saline delivery in cell washer equipment which impacts antiglobulin testing and thus integrity of patient, donor, and reagent quality control testing systems. This procedure applies to all IUH AHC Blood Banks.

The Ultra CW and Ultra CW 2 is available at the IUH AHC Blood Banks.

III. STATEMENTS/REQUIREMENTS

A. Tachometer (RPM), and timer readings are performed by Biomedical Engineering on a Bi-Annual schedule maintained by Biomedical Engineering.

B. Cell washer may be used for washing or for saline spin time.

C. To prevent imbalance, make sure tubes are evenly loaded in rotor.

D. Using 10mm x 75mm tubes, make sure the white tube inserts are installed. The instrument may be used without the inserts but works best with the white inserts.

E. To prevent running out of saline, ensure that the saline cube is not empty, and the supply tubing is not kinked or restricted.

F. Any time tube breakage occurs:

1. Do not continue to use the cell washer.
2. All glass should be removed promptly.
3. Special attention is required to clearing drain line blockage by the glass.

4. Complete disassembly and cleaning must be performed before resuming use of the cell washer.

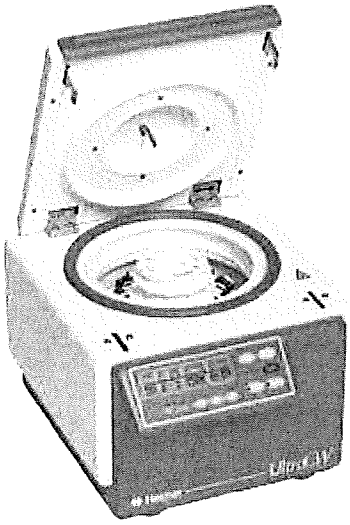
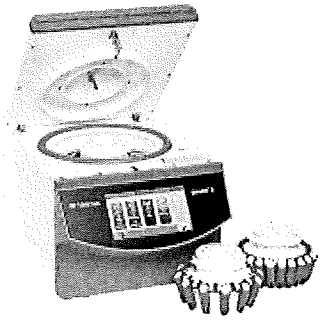
G. Lid of the Cell Washer should remain open when not in use.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies'

AHC: Academic Health Center

V. EQUIPMENT/RESOURCES

Cell Washer model	Ultra Cell Washer (CW)  Ultra Cell Washer II 
Saline delivery:	100 mL graduated cylinder
Cleaning/ decontamination:	• Soft cloth/towel • Disinfecting wipes • Gloves

Supplies:	1) 0.9% Saline, blood bank saline 2) 2 containers: **a) Bleach 10% Solution** Prepare the 10% Bleach solution Add 1 part commercial Sodium hypochlorite (NaCl) (5%) to 9 parts tap water) in a labeled container. **b) De Ionized Water.** B. Test tubes (10 X 75 mm (or dropper bottle)] with test tube rack C. Pipettes (plastic dispenser)

VI. PROCEDURE

A. USE of Cell Washer

1. Ultra CW

a. **Starting wash process: (Automatic: Three washes will be completed)**

i. Press and release ▲or▼ until the Program Number 1 (One) appears.

ii. Install and load rotor, then close and latch Lid.

iii. Press START WASH to start Program 1.

b. **To Interrupt a wash process:**

i. To PAUSE program, press CHECK.

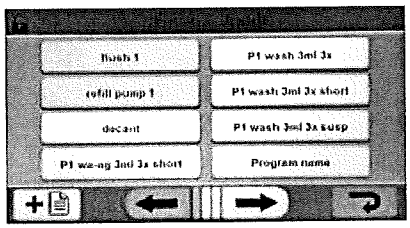
ii. To RESUME program, make sure Program Number 1, is selected, then press START WASH.

iii. To STOP the program, PRESS and HOLD STOP until the Stop lamp lights.

2. Ultra CW II

a. From the Start screen, select the Menu button.

b. Select the desired program.



Program menu screen (showing examples of custom programs)

Table 1. Pre-Installed User Programs

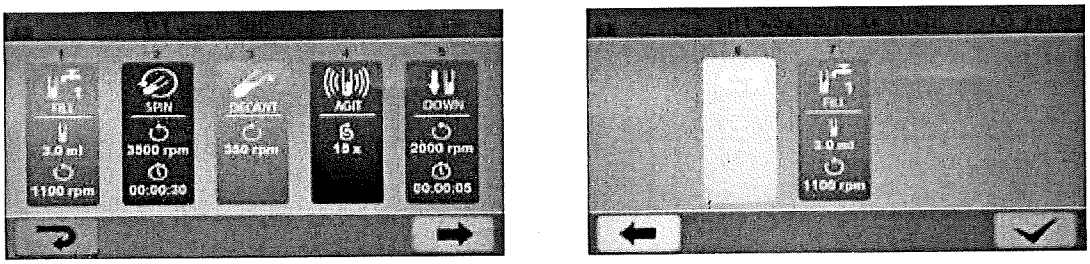
Process	Program				
	10x75 45sec wash	12x75 45sec wash	10x75 35sec wash	12x75 35sec wash	20sec spin 3500
Fill	3.5ml, 1100rpm	4.3ml, 1100rpm	3.5ml, 1100rpm	4.3ml, 1100rpm	
Spin	45 seconds, 3500rpm	45 seconds, 3500rpm	35 seconds, 3500rpm	35 seconds, 3500rpm	20 seconds, 3500rpm
Decant	460rpm	460rpm	460rpm	460rpm	
Agitate	15x	15x	15x	15x	
Loop	3x	3x	3x	3x	
Fill	3.5ml, 1100rpm	4.3ml, 1100rpm	3.5ml, 1100rpm	4.3ml, 1100rpm	
Spin	45 seconds, 3500rpm	45 seconds, 3500rpm	35 seconds, 3500rpm	35 seconds, 3500rpm	
Decant	460rpm	460rpm	460rpm	460rpm	
Check					
Agitate	15x	15x	15x	15x	
Spin	15 second, 3500rpm	15 second, 3500rpm	15 second, 3500rpm	15 second, 3500rpm	

c. The program screen is displayed.

d. Use the green and yellow directional arrows to scroll through and review each process.

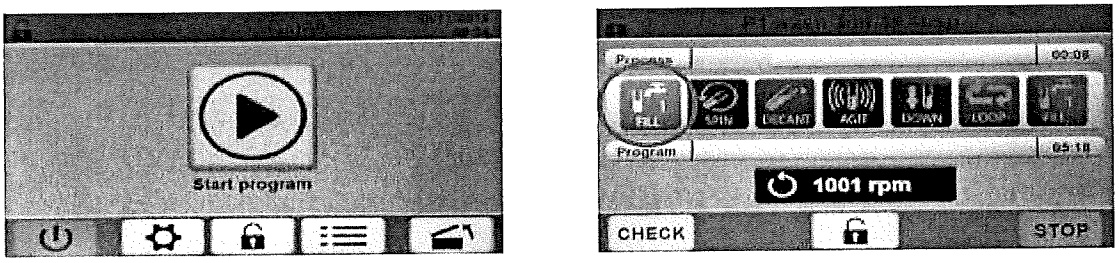
e. Verify setting are accurate prior to running the program.

f. Select the green checkmark to load the program.



Program screens

g. The Start screen appears with the loaded program name at the top of the screen.



Start screen *Process screen*

h. Select "Start Program".

i. The Process screen appears with the process being executed highlighted.

j. The "Program successful" dialog box appears once the program is complete.

B. Daily Cleaning and Maintenance for Ultra CW and Ultra CW II.

1. Document on the Daily QC Reagent form for each blood bank:

a. BBQC- F003 Daily Reagent QC: RHBB

b. BBQC-F004 Daily Reagent QC: University and Methodist

2. Wipe/Clean Interior:
    a. Remove rotor.
    b. Remove upper drainage ring, which is labeled **"this side up"**, by pulling it upward until it clears the gasket.
    c. Using damp towel wipe down entire inside of centrifuge.
        i. Wipe bowl removing all debris.
        ii. Using a dry towel wipe entire inside of lid, including drainage system and painted surfaces.
        iii. Some disassembly may be required.
    d. Reinstall upper drainage ring, which is labeled **"this side up"**, by reseating drainage ring.
    e. Reinstall rotor.
    f. Close lid and clean any saline residue from top.
2. Empty waste container.
3. Check the saline cube in use.
    a. Verify the saline is in-date. Saline on the cell washer has a 30-day expiration.
    b. Verify the saline cube has adequate volume for the day.
4. Inspect Cell Washer Tubing
    a. Clear any obstructions, if necessary.
    b. Inspect tubing connections and secure, if necessary.
5. Complete Deionized Water (DI) Flush – Perform daily or if the unit has been idle for more than 4 hours.
6. Refer to BBQC-JA 015 Helmer UltraCW and UltraCW II – Flushing and Clean Maintenance.

C. Weekly Maintenance for Ultra CW and Ultra CW II

1. Clean and Flushing of Cell Washer. Follow Job Aid BBQC-JA 015 Helmer UltraCW and UltraCW II – Flushing and Clean Maintenance
2. Clean Ports: **CAUTION:** Cleaning fill ports using methods other than what is described here could damage the fill ports and alter the results, which may void the warranty.
    a. Rinse rotor in clean warm tap water, directing flow into the top of the rotor for several minutes and make sure water is flowing freely out of all fill ports.
    b. Return rotor to centrifuge and run through one wash cycle with no test tubes to rinse out tap water with saline.
    c. When a port is blocked, gently slide a **straightened paperclip** into the fill port from the outside toward the center of the rotor. Gently slide the bypass tool in and out several times to clean the port.
    d. Do one of the following:

i. If the rotor will not be used immediately, ensure that it is dry before returning it to the cell washer, closing the lid and running One wash cycle before processing specimens.

ii. If the rotor will be used immediately, ensure that all fresh water has been purged from the system and replaced by saline by running One wash cycle before processing specimens.

D. Monthly Maintenance for Ultra Cell Washer and Ultra Cell Washer II

1. Document monthly maintenance on the Form: BBQC-F019 UltraCW Periodic QC.

2. Volume check is completed as part of the monthly maintenance or steps may be used to prime the instrument after changing the saline cube.

a. Ultra CW Volume Check

i. Select the program (Program 1) using ▲ or ▼ that contains desired saline volume.

ii. Open the lid.

iii. Remove rotor and set aside.

iv. On the control panel, press and hold the **SALINE** button for about FOUR SECONDS until **CALIBRATE 38.4 mL** appears on screen.

v. Cell washer is now in calibration mode.

vi. Hold 100 mL Graduated cylinder under fill nozzle, on lid.

vii. On control panel, press **CHECK** button. The Saline (Green) lamp lights. Volume of saline solution that was displayed is dispensed from nozzle into Graduated Cylinder.

viii. When the process is complete, the Saline lamp clears.

ix. Obtain volume from Graduated Cylinder.

x. Use this value to adjust the volume when required.

xi. To stop the flow of saline during dispensing.

xii. On control panel, press STOP button. Saline stops flowing.

xiii. Document the volume Check Saline fill volume on Form: BBQC-F019 UltraCW Periodic QC.

1. Normal Value: Standard fill 38.4+/- 5% (1.92 mL)
2. Range 36.5-40.3mL.

xiv. Reinstall rotor.

xv. The cell washer is ready for use.

b. UltraCW II Volume Check

i. From the Start screen, touch the login button.

ii. Enter a Service User password and select the green checkmark to confirm.

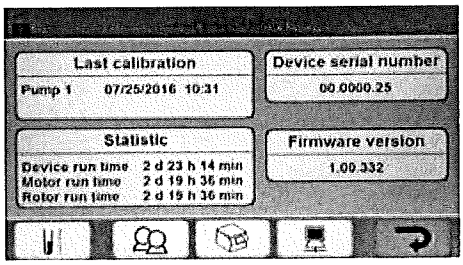
Password = 40606

iii. Select the settings button.

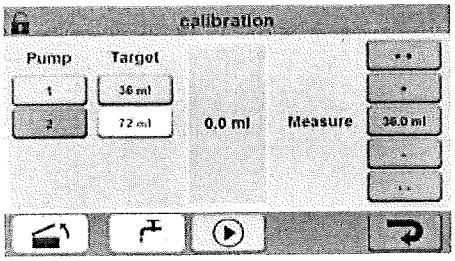
iv. On the System Settings screen, select the tools button to open the Service Menu.

v. On the Service Menu screen, select the ruler icon to open the Calibration screen.

vi. Touch the target calibration volume, 36mL.



Service Menu screen



Calibration screen

vii. Hold a clean, dry graduated cylinder below the spout on the lid and press the start button.

viii. Wait until liquid has stopped flowing from spout.

ix. Measure the liquid collected in the graduated cylinder.

x. Document the volume Check Saline fill volume on Form: BBQC-F019 UltraCW Periodic QC.

1. Normal Value: Standard fill

xi. Use the "+", "++", "-", and "--" on the right side of the screen to adjust the number as needed.

xii. Select the green checkmark to finish calibration.

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

2. Inspect rotor for wear, corrosion, and damage.

a. Replace the rotor if these conditions exist, or after the rotor has been in use for **4 years.**

3. Inspect tube holders for wear and damage.

a. Replace tube holders if they are worn or damaged, or after they have been in use for **2 years.**

4. Clean the exterior using soft cloth or disinfecting wipe.

E. Performed by Bio-Medical Engineering Tachometer (Bi-Annually and Annually)

1. Ultra CW

Task	Frequency				
	Daily	Weekly	Monthly	Semi-Annually	Annually
Inspect the tubing and drain and clear obstructions if necessary.	✓				
Inspect the tubing connections and secure them if necessary.	✓				
Clean and dry the interior after normal usage to prevent corrosion and contamination.	✓				
Flush the system.		✓			
Clean the fill ports on the rotor.		✓			
Check the saline volume setting and calibrate it if necessary. Frequency varies by length of service.		✓ (1)	✓ (2)		
Check the rotor speed and calibrate it if necessary.				✓	
Inspect the rotor for wear, corrosion, and damage. Replace the rotor if these conditions exist.			✓		
Inspect the tube holders for wear and damage. Replace tube holders if they are worn or damaged, or after they have been in use for two years.			✓		
Clean the exterior.			✓		
Replace the supply and drain tubing.					✓
Replace the pump tubing.					✓
Replace the tube holder inserts for 10 mm x 75 mm tubes.					✓

(1) During first month of usage.
(2) After first month of usage.

NOTE
- Cell washers shipped before 04 October 2012: Replace the rotor every five years.
- Cell washers shipped 04 October 2012 and later: Replace the rotor every four years.

2. Ultra CW II

Task	Frequency				
	Daily	Weekly	Monthly	Annually	4 years
Inspect tubing and drain and clear obstructions if necessary.	✓				
Inspect tubing connections and secure if necessary.	✓				
Clean and dry interior after normal usage to prevent corrosion and contamination.	✓[1]				
Flush system with distilled water.	✓[1]				
Flush system with cleaning solution.		✓			
Clean fill ports on the rotor.		✓			
Check the saline volume setting and calibrate it if necessary. Frequency varies by length of service.			✓		
Check rotor speed and ensure within tolerance.				✓	
Inspect rotor for wear, corrosion, and damage. Replace rotor if these conditions exist.			✓		
Replace rotor					✓
Inspect tube holders for wear and damage. Replace tube holders if worn or damaged, or after they have been in use for two years.			✓		
Clean exterior.			✓		
Replace supply and drain tubing.				✓	
Replace tube holder inserts for 10 mm x 75 mm tubes.				✓	

(1) Perform daily or if unit has been idle for 4 hours or more.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition.
AABB Standards, current edition.
Helmer, Operation Manual, UltraCW™ Automatic Cell Washing System, Version B, 360084 1/K.
Quality System, AABB/IU Health.

IX. FORMS/APPENDICES

Forms

Form: BBQC-F019 UltraCW Periodic QC

BBQC- F003 Daily Reagent QC: RHBB

BBQC-F004 Daily Reagent QC: University and Methodist

Form: UltraCW Helmer - Quick Reference Guide

Bleach 10% and Deionized Water Bottle Labels

Bleach 10% Solution

De Ionized Water (Label)

Job Aid

BBQC-JA 015 Helmer UltraCW and UltraCW II – Flushing and Clean Maintenance

X. APPROVAL BODY

None

PROCEDURE #:

BBQC – 005

Indiana University Health

Indianapolis, IN 46202

Form #: BBQC – F 019.01
Manual: Quality Control
Original Effective: 07/24/2013

Standard Operating Procedure Manual (SOP) – Transfusion Medicine

UltraCW Periodic QC

YEAR:_____ **SN:**_____ **Location:** _____

	Monthly Volume Check *Ultra CW 36.5-40.3mL* *Ultra Cell Washer II 36mL*	**Insp. Rotor** ✓	**Insp. White tube holders** ✓	**Clean Exterior** ✓	**Tech Initials**	**Sup Review** **Initials and Date**
January						
February						
March						
April						
May						
June						
July						
August						
September						
October						
November						
December						

Ok/Acceptable = ✓, **Not Acceptable = X**

If any Maintenance Tasks not acceptable, then notify BB Leadership for next steps for resolution.

Annually: completed by Trimedx
Replace Supply & Drain tubing
Replace Pump tubing
Replace Damaged White tube Inserts

Suggested Periodic – completed by Trimedx
Replace rotor (Every 4 Years)
Replace WHITE tube holders (Every 2 years)

Annual Sup Review/Date: _____

Indiana University Health

Indianapolis, IN 46202

Helmer UltraCW and Ultra CW II – Flushing and Clean Maintenance

Preparation "WASH Solution bottles":

1. Using Pre labeled BLEACH 10% Solution bottle: (stored – EMPTY), Dilute 1 volume household bleach / 9 volumes of Tap water.
2. Volume for use with only one cell washer:
   - Add 50 mL of Bleach to 50 ml Line on bottle.
   - Add Tap water to 500 mL line on same bottle.
3. Gently mix, swirling to mix bleach and Water.
4. Apply small BLEACH 10% Solution label with Fill DATE / EXP DATE(24 hours) and TECH Initials to bottle.(BBQC-F 022, Label: Bleach 10% Solution).
5. Alternately, one may prepare the 10% Bleach as described above when needed, pour out the unused 10% Bleach when task completed and store empty.

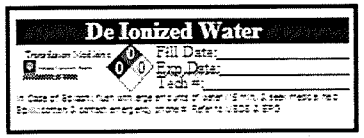
Using Pre Labeled De Ionized Water bottle: (stored – EMPTY)

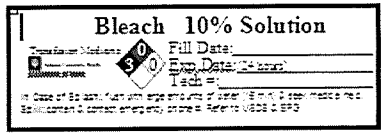
1. Fill to top of label with De Ionized Water.
2. Apply small De Ionized Water label with Fill DATE / EXP DATE(24 hours) / TECH Initials. (BBQC-F 023, Label: De Ionized Water)
3. Alternately, one may prepare the DeIonized water bottle when needed, pour out unused water when task completed and store empty.

Ultra CW Flushing and Clean System:

1. **CLEAN the Ultra CW with Bleach**
   - a. Load rotor with 6 - 10x75 tubes, leaving every other position empty.
   - b. Install rotor in cell washer, close lid, close latch and ensure
   - c. Lid Ready lamp is lit.
   - d. **MOVE** supply tubing from Normal saline carboy and place in Bleach 10% Solution bottle.
   - *e.* **Return to display mode** *If message screen displays completion message, open lid to clear message and return to display mode.*
   - f. Select **"Clean Program"**
   - g. On Control Panel press and release either parameter value button (▲or▼) until desired program appears: **CLEAN PROGRAM**: Program 1-5 #; Spin Program; Clean Program).
   - h. Press **START WASH** button. Cleaning sequence starts.
   - i. When cleaning sequence is complete, OPEN LID appears on message screen and Lid Ready GREEN lamp lights.
   - j. **Open lid**. Lid Ready lamp clears and **Clean proc. DONE** appears on the message screen.
   - k. Remove supply tubing from Bleach Bottle and place in Deionized Water bottle.

2. **Flushing Ultra CW with DI Water**
   - a. With the supply tubing in the DI Water bottle, hold 100 mL Graduated cylinder in front of fill nozzle.
   - b. On control panel, PRESS and HOLD **SALINE** button for about three(3) seconds until Saline lamp lights and **REFILL process** appears on message screen. RESULT: Approximately 60 ml of liquid is dispensed from nozzle into graduated cylinder.
   - c. When process is complete, Saline lamp clears and **REFILL proc.DONE** briefly appears on message screen, followed by display mode for Program 1.
   - d. Dispose of the Graduated Cylinder- purged De Ionized Water. Close the Lid.
   - e. Select **"Clean Program" (De Ionized Water)**. On Control Panel press & release either parameter value button (▲or▼) until desired program appears: **CLEAN PROGRAM**: Program 1-5 #; Spin Program; Clean Program)
   - f. Press **START WASH** button. Cleaning sequence starts.
   - g. When cleaning sequence is complete, OPEN LID appears on message screen and Lid Ready GREEN lamp lights.
   - h. **Open lid.** Lid Ready lamp clears and **Clean proc. DONE** appears on message screen.
   - i. **MOVE** supply tubing from De Ionized Water and place in Saline Carboy.
   - j. Hold 100 mL Graduated cylinder in front of fill nozzle.
   - k. On control panel, PRESS and HOLD **SALINE** button for about three(3) seconds until Saline lamp lights and REFILL process appears on message screen. RESULT: Approximately 60 ml of liquid is dispensed from nozzle into graduated cylinder.
   - l. When process is complete, Saline lamp clears and **REFILL proc.DONE** briefly appears on message screen, followed by display mode for Program 1.
   - m. Dispose of Graduated Cylinder purged Saline.
   - n. Remove the test tubes.
   - o. Close lid.
   - p. While in Program 1 using (▲or▼), Select **START WASH**.
   - q. This concludes FLUSHING SYSTEM.
   - r. Leave centrifuge lid open, to signify UltraCW is available for use.





Helmer UltraCW and Ultra CW II – Flushing and Clean Maintenance

Ultra CW II Flushing and Clean System:

3. **CLEAN the Ultra CW with Bleach**
   a. Load rotor with 6 - 10x75 tubes, leaving every other position empty.
   b. Install rotor in cell washer and CLOSE LID.
   c. **MOVE** supply tubing from Normal saline carboy and placie in Bleach 10% Solution bottle.
   d. Enter menu by touching the Control Panel screen on the Ultra CW II.
   e. Select **"FLUSH 1"** on the Control Panel and toggle through the program.
   f. Press **START** button. Cleaning sequence starts.
   g. When cleaning sequence is complete, OPEN LID
   h. Set a timer and let the bleach solution remain in the instrument for 5 minutes.
   i. After incubation, move the supply tubing to **De Ionized Water** bottle by removing supply tubing from BLEACH 10% Solution bottle and placing in De Ionized Water bottle.

4. **Flushing Ultra CWII with DI Water**
   a. CLOSE LID
   b. Enter menu by touching the Control Panel screen on the Ultra CW II.
   c. Select **"FLUSH 1"** on the Control Panel and toggle through the program.
   d. Press **START** button. Flush sequence starts
   e. When Flushing sequence is complete, OPEN LID
   f. **MOVE** supply tubing from DI Water and place in Saline Carboy.
   g. **CLOSE LID**
   h. Select **"FLUSH 1"** on the Control Panel and toggle through the program.
   i. Press **START** button. Flush sequence starts
   j. When Flushing sequence is complete.
   k. From the Control Panel Menu, select **"Refill Pump 1."** and toggle through the program.
   l. Press **START** button. Flush sequence starts
   m. When Flushing sequence is complete, OPEN LID.
   n. This concludes FLUSHING SYSTEM.
   o. Discard the test tubes in the rotor.
   p. Leave centrifuge lid open, to signify UltraCWII is available for use.