Sutter Health
Sutter Roseville Medical Center

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Applicability:	*Sutter Roseville Medical Center*

Performing Echo QC and Maintenance (Daily, Weekly, Monthly)

PURPOSE

To provide instructions on how to create phosphate buffered saline (PBS), run quality control (QC), and perform daily, weekly, and monthly Echo maintenance.

POLICY

- The Echo's PBS container may be filled via transfer container/bottle at any time by lifting the fluidics module lid to gain access to the container.
  - Do not detach probes to waste or PBS containers from the Echo while running.
- The manufacturer's schedule for preventative maintenance will be followed, unless variation is recommended or necessary. Variations will be documented, including reason for variation. The Transfusion Services Supervisor will be consulted, if indicated.
- Daily, weekly, and monthly maintenance will be performed according to assignment schedule.
- Daily maintenance includes priming, probe alignment, probe vertical position check, and washer residual volume test.
- Weekly maintenance includes Echo and computer shut down, archiving results, and deleting results from Echo's database.
  - For instruction on shutting down and starting up the Echo and computer, ensure all patient specimens, reagents, and supplies are removed from the Echo and see steps 1-4 of *Weekly Maintenance* SOP below.
- Monthly maintenance includes decontamination, wiping down the probe block, cleaning the wash manifold, washer residual volume test, and washer dispense accuracy test.
- Monthly maintenance must be performed prior to relocation of the Echo. It is not necessary to perform this maintenance after the Echo has been relocated and prior to beginning use. Major relocation of the Echo is only done by Immucor technical support.
- Flushing, purging, and priming the Echo can be run as stand-alone maintenance tasks when required.
- Maintenance and rack used for QC will be documented on the *Echo Maintenance Record*.

EQUIPMENT/SUPPLIES

Phosphate Buffered Saline (PBS)	Quality Control (QC)	Daily	Weekly	Monthly
• Unbuffered saline • pHix (Phosphate Buffer Concentrate) • 7.0 pH reference standard (control) • pH indicator paper with a range of 6.9-7.2 • Transfer container/ bottle • Test tubes • Pipettes • TS Buffered Saline Log	• WBcorQC	• PBS • 2 capture strips • Strip trays • Strip holder • Alcohol pads	• CD-R, DVD+R or DVD-R disc	• Deionized (DI) or distilled water • Warm tap water • 8.25% bleach • PBS • 2 CMT strips • 4 RS3 strips (expired okay) • Strip trays • Absorbent wiping material • Kimwipes or lens paper • Alcohol pads • Syringe • Electronic balance and calculator

PROCEDURE

Phosphate Buffered Saline (PBS)

- If standard 20L unbuffered saline cubes are unavailable and have been replaced by 10L unbuffered saline cubes, perform procedure with only 100mL from a 200mL bottle of pHix. Document initials and date opened on outside of pHix buffer.

Step	Action
1.	Add an entire 200mL bottle of pHix to a 20L cube of unbuffered saline.
2.	Mix cube by making at least one complete rotation across counter.
3.	Attach included spigot to cube and dispense sufficient amount of PBS into a disposable test tube to perform pH testing.
4.	Dispense sufficient amount of pH 7.0 control into a separate disposable test tube.
5.	To perform pH testing, dip the pH test strip into the solution (PBS or pH 7.0 control), in the direction of the arrow, for roughly 3 seconds, so that all color zones are immersed.

6.	Follow the instructions found on the pH indicator paper container to determine pH acceptability. Compare the PBS and pH control strips to the result chart on the pH indicator paper container to determine the pH of the PBS and the pH control strips. Acceptable pH must be 6.9-7.2. **If:** / **Then:** pH control does not read 6.9-7.2 → • Repeat using new aliquot of pH control and new test strip. PBS result does not read 6.9-7.2 → • Remix PBS and repeat using new aliquot and new test strip. • Add additional pHix until pH is within acceptable range. • If unable to obtain appropriate range, discard PBS cube and repeat procedure with a new unbuffered saline cube.
7.	Complete all fields on the *Transfusion Services Buffered Saline Log*, including pH results garnered from step 6.
8.	Note initials, date pHix added, and revised expiration date on the PBS cube. • Revised expiration is ***30 days*** from date pHix was added.

Running Quality Control (QC)

- QC will be performed and must pass criteria prior to Echo being placed into service after repairs, at least once every 24 hours when patient testing is being performed, and as needed upon opening a new lot/ shipment of reagents or strips.
  - WBcorQC levels 1-3 will be run daily on both Echos for *Group*, *Screen*, and *Weak D* assays.
  - QC for antigen typing shall be performed on Echo 2 as needed on each day of testing.
- QC is packaged with two sets in each clamshell. Each set will be used for 7 days.
  - If needed, QC may be used for an additional 7 days as long as QC failure does not occur.
- Once QC run is initiated, it must be processed successfully before additional samples may be processed or results released for the assays being QC'd.
- If any QC results are unacceptable for an assay, the entire run will be invalidated and require repeat. The Echo has expected QC results preprogrammed and will invalidate anything that does not pass QC.

Step	Action
1.	Allow WBcorQC and reagents to equilibrate to room temperature for at least 20 minutes.
2.	Mix WBcorQC thoroughly but inverting 5-10 times and rolling between hands for 20 seconds, then centrifuge for 7 minutes at 3500 RPM.
3.	Remove sample caps and place centrifuged WBcorQC samples into sample rack with barcode showing, then load into the sample bay of the Echo.
4.	Select the **Run Test Wizard**.
5.	Select the assay to be QC'd from the **Select tests** window, then select **Next**.
6.	Select the sample(s) to be tested from the **Select samples** screen, then select **Next**.
7.	If not loaded already, load any reagents or supplies listed on the **Supplies** screen, then select **Next**.
8.	Select **Begin Tests.**

9.	Upon successful completion of QC run, print results and file in designated location. Note rack QC'd and initials of person performing QC on the *Echo Maintenance Record*. • If QC results are unacceptable, perform the following troubleshooting steps. If still unacceptable after performing all steps, perform testing on alternate Echo (or manually if unable to obtain valid QC on either Echo) until appropriate reactions are obtained: • Repeat testing with same reagent. • Repeat testing with fresh bottle of same lot number (liquid reagent). • Repeat testing with fresh pouch of same lot number (strip). • Repeat testing using different shipment date (same lot number) or different lot number (if available). • If unable to resolve issue, contact Immucor technical support.

Daily Maintenance

Place a check mark next to each item on the *Echo Maintenance Record* as each item is completed. To be performed prior to running standard daily QC run.

Step	Action
1.	Refill the PBS supply container.
2.	Confirm that the waste container is draining properly. Adjustment of the waste container drainage tubing may be required.
3.	Prime the instrument. Select **Tools** followed by **Maintenance**. Select the **Prime instrument** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window, then select **Start**.
4.	Initialize the instrument. Press the initialization button on the tool bar or go to **File** and select **Initialize**. Note: During initialization watch the monitor for error codes/alerts as these will not remain on the screen. • Place 2 empty strip trays in the top 2 positions of the strip loading bay when prompted by the instrument. Select **OK** to continue. • Remove the top 2 strip trays from the strip loading bay when prompted by the instrument. • Select **OK** to allow initialization to be completed.
5.	Check the probe alignment. Select **Tools** and then **Maintenance**. • Select the **Check probe alignment** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window, then select **Start**. • Observe the position of the probe and respond to the software question, *Is the probe aligned with the alignment hole?*, by selecting **Yes** or **No**.
6.	Check the probe vertical position. Select the **Check probe vertical position** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window, then select **Start**. • Respond to the software dialogue, *The probe vertical position check passed,* by selecting **OK**.

7.	Perform the washer residual volume test (visual). Select the **Washer residual volume test** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window. • Place 2 capture strips into a strip holder, and then insert the strip holder into position 1 of a strip tray. • Load the strip tray into position 1 of the strip loading bay and select **Start**. • Immediately remove the 2 test strips from the strip holder and tray when the test is complete. • Visually estimate the volume of the residual PBS for all wells in both strips. A uniform small amount of PBS should be present for each well. Note: If unable to see volume, place a fresh paper towel on the counter and slam the test strip down on top of it.
8.	Wipe down the external instrument casings, shroud and external surfaces with alcohol pads. Clean the computer monitor and keyboard as needed.
9.	Refer to *Running Quality Control (QC)* section of the SOP to perform daily QC. Document the reagent rack and tech initials on the *Echo Maintenance Record*.

Interpretation

Test	Result
Check probe alignment	**Acceptable**: Probe tip is within probe target area of probe wash tower. **Unacceptable**: Probe tip is not within probe target area of probe wash tower. • Gently rotate the probe to align it correctly and repeat the task. • Make a dated comment documenting corrective action on the *Echo Maintenance Record*.
Check probe vertical position	**Acceptable**: Probe vertical position passed. **Unacceptable**: Error message indicating that probe is seated too low or high is displayed. • Re-seat the probe correctly and repeat the task. • Make a dated comment documenting corrective action on the *Echo Maintenance Record*.
Washer residual volume test (visual)	**Acceptable**: Thin meniscus of fluid is present in the bottom of each well. **Unacceptable**: Thin meniscus of fluid is absent from bottom of 1 or more wells. • Investigate the wash manifold and repeat the task. • Make a dated comment documenting corrective action on the *Echo Maintenance Record*.

Weekly Maintenance

Perform this maintenance every 7 days (no less than 6 days or greater than 8 days). Archiving procedure should not be attempted if the Echo is processing samples or running any maintenance task.

Step	Action
1.	Shut down the computer by selecting **File**, then select **Shut down**.
2.	Power down the Echo by turning off the power supply unit.
3.	Power up the Echo by turning on the power supply unit.
4.	Press the power switch on the front panel of the PC. Allow enough time for the computer to start up and the Echo program to load.
5.	Insert a blank CD-R, DVD+R or DVD-R disc into the PC drive. Wait approximately 60 seconds after insertion of the disc before accessing the file management menu in order for the PC to recognize the disc before beginning the archive procedure.
6.	Select **File Management** (CD icon) on the tool bar or go to **File**, then select **File management.**
7.	In the **Results** tab, select the month(s) of data you wish to archive by placing a check beside them. Multiple months may be selected depending on the date at which weekly maintenance is performed.
8.	Verify that the **Copy files** action item is checked. Verify that the **Delete files** action item is not checked.
9.	Select the **Event logs** tab and select the current month(s) of event logs you wish to archive. Note: Include the abort files during selection. More than one month may need to be selected depending on the date at which weekly maintenance is performed.
10.	Select the **Configuration files** tab and select all the configuration files. Select **Archive** and then **Yes** to begin the archive procedure. As the archive procedure is in process, a series of progression bars and details of what is occurring will appear on the screen. The archiving may take several minutes to complete depending on the amount of information on the hard drive.
11.	After archiving is complete, select **OK** on the information dialog and the disc will be ejected.
12.	Before deletion of the files, verify that the contents of the disc can be viewed. View archived results by reinserting the disc. Select **Tools**, then **General options**, then **Results**, click on browse (...), then **CD Drive (D:) Immucor**, then **OK**, and **Close**. The heading on the results panel should now say *Archived results* and convert to read the results that were just archived on the disc. If they do not appear, the copy to the disc was not successful and must be repeated. If they do appear, then the copy was successful and you can continue to the deleting process.
13.	Return to the results file before removing disc. Select **Tools**, then **General options**, then **Results**, click on browse (…), double click on **C Drive**, double click **G3**, then select **Results**, then **OK**, and **Close**. The heading on the results panel should now say *Results* and show both archived and un-archived results in the results panel. Once the contents of the disc have been verified, delete the archived result files.
14.	Select the **File management** (CD icon) on the tool bar or go to **File** and then select **File management**.

15.	In the **Results** tab, select the month(s) of data you have archived and select the files to be deleted by placing a check beside them.
16.	Select **Delete files** action item and verify that the **Copy files** action item is not checked.
17.	Select the **Event logs** tab and click on the **Select none** button to deselect all of the event log files. Note: Immucor recommends that only the results, and not the event logs be selected for deletion.
18.	Select the **Configuration files** tab and click on the **Select none** to deselect all of the configuration files.
19.	Select **Archive**, then **Yes** to begin the archive procedure. Select **OK** when you see the screen verifying that all selected files have been deleted successfully.
20.	Remove archive disc and label with the instrument serial number and dates of archived data. Store disc in archive box.
21.	Document tech initials and date on the *Echo Maintenance Record*.

Monthly Maintenance

Perform this maintenance monthly, at least every 31 days. Monthly maintenance will take about 1 to 1½ hours to complete.

- Decontamination must always be followed by flush, purge and prime.
- Wiping down the probe block should be completed after the decontamination procedure.
- An alert message is displayed on the bottom of the screen signifying that the buffer container is low during decontamination, flushing, and purging. This alert message does not negatively impact these three maintenance tasks.
- Prior to beginning maintenance tasks, confirm that the waste container is draining properly.
- If performing weekly maintenance prior to monthly maintenance, initialization of the instrument will be required.
- QC must be performed following completion of the monthly maintenance. Refer to *Running Quality Control (QC)* section of the SOP to perform QC.

Decontamination

Step	Action
1.	Prepare 1L of 0.25% bleach by mixing 970mL of DI water with 30mL of 8.25% bleach.
2.	Pour off a small amount of bleach into a container and put aside to use when cleaning the probe block.
3.	Empty the PBS out of the PBS supply container and pour the remaining bleach into the PBS supply container.
4.	Swirl the bleach inside the PBS supply container so that it comes into contact with all internal surfaces.
5.	Connect the PBS supply container to the instrument. Note: Make sure that the tubing inside of the PBS supply container is fully extended to the bottom of the container and not hooked on the inside shelf.

6.	Select **Tools** and then **Maintenance**. Select the **Decontaminate instrument** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window, then select **Start**.
7.	Allow the bleach to soak for 10 minutes in the instrument after the procedure is complete.

Flush

Step	Action
1.	Empty the remaining bleach out of the PBS supply container.
2.	**Thoroughly** rinse all internal surfaces of the PBS supply container with DI water ensuring that all surfaces have been rinsed. Discard DI rinse water.
3.	Refill PBS supply container with at least 1L of fresh DI or distilled water.
4.	Connect the PBS supply container to the instrument. Note: Make sure that the tubing inside of the PBS supply container is fully extended to the bottom of the container and not hooked on the inside shelf.
5.	Select **Flush instrument** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window, then select **Start**.

Purge

Step	Action
1.	Empty the remaining DI or distilled water out of the PBS supply container.
2.	Connect the empty PBS supply container to the instrument. Note: Make sure that the tubing inside of the PBS supply container is fully extended to the bottom of the container and not hooked on the inside shelf.
3.	Select **Purge instrument** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window, then select **Start**.

Prime

Step	Action
1.	**Thoroughly** rinse all internal surfaces of the PBS supply container with PBS ensuring that all surfaces have been rinsed. Discard PBS rinse.
2.	Add 1L of fresh PBS to the PBS supply container.
3.	Connect the PBS supply container to the instrument. Note: Make sure that the tubing inside of the PBS supply container is fully extended to the bottom of the container and not hooked on the inside shelf.
4.	Select **Prime instrument** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window, then select **Start**.
5.	Repeat step 4. Instrument should be primed a total of 2 times.

6.	Initialize the instrument. Press the initialization button on the tool bar or go to **File** and select **Initialize**. Note: During initialization watch the monitor for error codes/alerts as these will not remain on the screen. • Place 2 empty strip trays in the top 2 positions of the strip loading bay when prompted by the instrument. Select **OK** to continue. • Remove the top 2 strip trays from the strip loading bay when prompted by the instrument. • Select **OK** to allow initialization to be completed. If fluidics error is encountered, prime instrument 2 times and repeat initialization.
7.	Document tech initials and date on the *Echo Maintenance Record*.

Clean Wash Manifold

This should be performed after the decontamination procedure has been completed.

Step	Action
1.	Power down the Echo and computer. • Select **File** and then **Shut down**. • Power down the Echo by turning off the power supply unit.
2.	Remove the cover from the instrument.
3.	Loosen and remove the screw in the center of the front of the manifold with a flathead screw driver.
4.	Disconnect the luer locks on the end of the manifold and remove the tubing. Note: Be sure to leave the connectors inside the wash manifold and make sure that they are tight. Do not remove the bumpers from the body of the manifold.
5.	Use the stylus (located in the clear plastic cylinder gripped by a clip located in the upper back right corner of the inside of the main instrument) to clean out the metal aspirating and dispensing probes.
6.	Soak the manifold in warm tap water for 15-20 minutes.
7.	Perform the following housekeeping items: • Remove the CMT strips from the storage tupperware container and clean the container with an alcohol pad. Allow to air dry before returning the CMT strips to the container. • Remove priming strip holder and discard the 2 CMT priming strips. Replace with a new pair of CMT strips. Set the strip holder containing the new priming strips aside for re-installation (step 4 *Wiping Down Probe Block* procedure). • Check wash overflow trough for spills. Wipe with warm water to clean as required. • Clean the strip holder transport arms with alcohol pad. • Wipe mirrors and bar code readers gently with damp Kimwipe or lens paper as needed, if dust is present. • Clean splashes or dust bunnies in lower cabinet with damp Kimwipe or lens paper as needed. • Do NOT use canned air on the instrument.
8.	After soaking, flush the manifold with warm tap water by pushing it through the luer using a syringe.

9.	Slide the manifold back into the groove and secure it with the flathead screwdriver.
10.	Reconnect the male and female tube endings matching them to their respective luer lock.
11.	Document tech initials and date on the *Echo Maintenance Record*.

Wiping Down Probe Block

Step	Action
1.	Check for leaks from bottom of probe by looking upwards from the bottom of the grey shield to the base of the probe and checking for salt accumulation.

If:	Then:
Absent	Wipe the probe splash guard using absorbent wiping material and the bleach solution set aside in step 2 of the *Decontamination* procedure. • Wipe the probe splash guard with DI water. • Use Kimwipe to wipe off excess liquid from the probe splash guard.
Present	• Use screwdriver to remove 2 screws attaching probe splash guard to probe block. • Slide probe splash guard down probe and set it aside. • Wipe down probe and base of block with DI water to remove salt residue. • Wipe the probe splash guard using absorbent wiping material and the bleach solution set aside in step 2 of the *Decontamination* procedure. ◦ Wipe the probe splash guard with DI water. ◦ Use Kimwipe to wipe off excess liquid from the probe splash guard. • Slide shield up probe and reinsert screws.

2.	Replace the cover and power up the Echo and computer. • Power up the Echo by turning on the power supply unit. • Press the power switch on the front panel of the PC. Allow enough time for the computer to start up and the Echo program to load.
3.	Initialize the instrument. Press the initialization button on the tool bar or go to **File** and then select **Initialize**. Note: The washer fill test will fail for all wells and the camera bottom chamber test will fail as a result of the missing wash priming strips. • Place 2 empty strip trays in the top 2 positions of the strip loading bay when prompted by the instrument. Select **OK** to continue. • Remove the top 2 strip trays from the strip loading bay when prompted by the instrument. • Select **OK** to allow initialization to be completed.
4.	Select **Tools** and then **Maintenance**. Select the **Install priming strip holder** maintenance task from the drop-down list on the **Run** tab of the **Maintenance** window and then select **Start**. An information dialog box with additional instructions is displayed. • Place the strip holder with the 2 CMT priming strips (from step 7 *Clean Wash Manifold* procedure) into position 1 of a strip tray. • Load the strip tray into position 1 of the strip loading bay and then select **Start**.

5.	Initialize the instrument. Press the initialization button on the tool bar or go to **File** and select **Initialize**. Accept the prompt regarding initialization already being performed. If fluidics error is encountered, prime instrument and repeat initialization.
6.	Select **Tools** and then **Maintenance**. Select **Washer basic test** from the drop-down list on the **Run** tab of the **Maintenance** window.

If:	Then:
Washer basic test passed	Proceed to *Washer Residual Volume Test* and *Washer Dispense Accuracy Test*
Washer basic test fails	• Prime instrument and repeat. • If unresolved, call Immucor technical support.

7.	Document tech initials and date on the *Echo Maintenance Record*.

Washer Residual Volume Test

This test should be performed in tandem with the *Washer Dispense Accuracy Test.*

Note: Residual volumes that exceed acceptable range may result in false negative antibody screen and ABID reactions.

Step	Action
1.	Document the instrument serial number, tech initials, date, and serial number of the electronic balance on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.
2.	Select **Tools** and then **Maintenance**. Select **Washer residual volume test** from the drop-down list on the **Run** tab of the **Maintenance** window.
3.	Weigh 2 RS3 Capture strips and record the weight on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.
4.	Place the 2 strips into a strip holder and place the holder in position 1 of a strip tray.
5.	Load the strip tray into position 1 of the strip loading bay and select **Start**.
6.	Reweigh the 2 strips when the test is complete and record the weight on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.
7.	Using a calculator, subtract the weight obtained in step *B* from the weight obtained in step *C* and record that value on the *Washer Residual Volume Test & Dispense Accuracy Test Maintenance Record*.

8.	Interpret the acceptability of the resulting value based on the acceptable range and record this conclusion on the *Washer Residual Volume Test & Dispense Accuracy Test Maintenance Record*.

If:	Then:
Weight is within 0.06g and 0.16g	Task has been successfully completed.
Weight is not within 0.06g and 0.16g	• Instrument is not acceptable for use until problem is resolved. • Failures may be due to problems with washer manifold or washer tubing. • Contact technical support as needed to resolve problem.

9.	Document tech initials and date on the *Echo Maintenance Record*.

Washer Dispense Accuracy Test

This test should be performed in tandem with the *Washer Residual Volume Test.*

Step	Action
1.	Document tech initials, date, and serial number of the electronic balance on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.
2.	Select **Tools** and then **Maintenance**. Select **Washer dispense accuracy test** from the drop-down list on the **Run** tab of the **Maintenance** window.
3.	Weigh 2 RS3 Capture strips individually and record the weight on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.
4.	Place the 2 strips into a strip holder and place the holder in position 1 of a strip tray.
5.	Load the strip tray into position 1 of the strip tray loading bay and select **Start**.
6.	Reweigh the 2 strips individually when the test is complete and record the weight on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.
7.	Using a calculator, subtract the weight obtained in step B from the weight obtained in step C and record that value on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.

8.	Interpret the acceptability of the resulting value based on the acceptable range and record this conclusion on the *Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record*.

If:	Then:
Weight is within 1.92g and 2.08g for each strip	Task has been successfully completed
Weight is not within 1.92g and 2.08g	• Instrument is not acceptable for use until problem is resolved • Failures may be due to problems with washer manifold or washer tubing. • Contact technical support as needed to resolve problem.

9.	Document tech initials and date on the *Echo Maintenance Record*.

REFERENCE

Immucor, Inc. *Echo Operator Manual*. ECO-001-204. Norcross, GA

All revision dates:

Attachments

Echo Maintenance Record.pdf
Probe Accuracy Test Maintenance Record.pdf
Transfusion Services Buffered Saline Log.pdf
Washer Residual Volume Test & Washer Dispense Accuracy Test Maintenance Record.pdf