TRAINING UPDATE

Lab Location:	SGMC and WOMC	**Date Implemented:**	7/9/21
Department:	Blood Bank	**Due Date:**	7/23/21

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Galileo Echo/Echo Lumena Routine Maintenance

Description of change(s):

We recently upgraded the software in the Echo/Lumenas. The following changes are required, effective immediately.

1. Decontamination is now performed with 0.25% bleach. We will no longer use RelyOn.

   To prepare the bleach mixture, mix 60 mL of Clorox Germicidal bleach to 1940 mL of Deionized water. Note: This bleach mixture changes if we use a different bleach. Instructions are in the SOP.

2. We need to change the wash priming strips as part of monthly maintenance.
   a. Remove the current wash priming strips when you open the shroud to wipe the probe block and manifold.
   b. After initialization, have the instrument install new wash priming strips through the maintenance menu.

SGAH.BB110 Galileo Echo / Echo Lumena Routine Maintenance

Copy of version 5.0 (approved and current)

Last Approval or Periodic Review Completed 7/7/2021

Next Periodic Review Needed On or Before 7/7/2023

Effective Date 7/7/2021

Controlled Copy of a Manual ID 18926

Location SGMC & WOMC BB vol 9

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	7/7/2021	5.0	Nicolas Cacciabeve	
Approval	BB approval	7/1/2021	5.0	Stephanie Codina	
Approval	QA approval	7/1/2021	5.0	Leslie Barrett	
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Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
5.0	Approved and Current	Major revision	6/30/2021	7/7/2021	Indefinite
4.0	Retired	First version in Document Control	8/15/2019	12/19/2018	7/7/2021

Linked Documents

- AG.F123 Galileo Echo Maintenance Record
- AG.F124 Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record

Non-Technical SOP

Title	**Galileo Echo / Echo Lumena Routine Maintenance**	
Prepared by	Stephanie Codina	Date: 6/9/2011
Owner	Stephanie Codina	Date: 6/9/2011

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

TABLE OF CONTENTS

1. PURPOSE

To provide instructions for daily, weekly, and monthly maintenance of the Echo.

2. SCOPE

This procedure applies to all routine maintenance activities performed on the Echo.

3. RESPONSIBILITY

All blood bank staff members must perform maintenance as required and as described in this procedure.

4. DEFINITIONS

A. Daily: Day of use
B. Weekly: 7 ± 1 day
C. Monthly: 30 ± 7 days
D. PBS = Phosphate buffered saline; saline with pHix solution added to maintain a pH between 6.5 and 7.5 for testing.

5. EQUIPMENT

Echo tool kit: provided by Immucor
Ohaus Scout Pro Balance (Electronic Balance)
Calculator

6. SUPPLIES

Alcohol pads
Phosphate-buffered saline (PBS)
Funnel
Shuttle waste container
Capture strips
Absorbent wiping material
Cleaning solution
De-ionized water
Commercial grade sodium hypochlorite (bleach)
CMT plate strips

7. PROCEDURE

Daily Maintenance

Step	Action
1	All maintenance tasks are recorded on the Echo Maintenance Log.
2	Refill the PBS Supply Container. A. Lift the fluidics module lid to access the PBS supply container and secure in place by manually locking the left-hand side support bracket. B. Remove the cap from the PBS supply container. C. Using the funnel, add PBS to the PBS supply container. D. Remove the funnel and securely replace the cap back onto the PBS supply container. E. Return the fluidics module lid to the horizontal position by manually unlocking the left-hand side support bracket and allowing the lid to gently return to the horizontal position. F. The instrument will not run if the PBS level is too low.

Step	Action
3	Empty the Waste Container. A. Attach the waste shuttle container to the waste container to drain the waste container. B. After the waste fluid has drained, detach the waste shuttle container. C. Discard the waste down the sink. D. The instrument will not run if the waste container gets too full.
4	Initialize the instrument. A. Press the "Initialization" button on the tool bar. B. When prompted by the software, place two empty strip trays in the top two positions of the strip loading bay. C. Press the "OK" button to continue. D. When prompted by the software, remove the top two strip trays from the strip loading bay. E. Press the "OK" button and the instrument will automatically complete the initialization. F. The instrument will perform its instrument checks. The instrument will not run specimens until all checks have passed.
5	Clean the instrument. Wipe down the external casings, shroud, and external surfaces with alcohol.
6	Check the Probe Alignment. A. Click on the "Tools" dropdown list and select "Maintenance." B. Click on the "Check Probe Alignment" task. C. Press the "Start" button to begin the task. D. The instrument will prompt, "Is the probe aligned with the alignment hole?" E. Inspect the probe alignment and respond to the software dialog by pressing either the "yes" or "no" button. a. The probe alignment is acceptable when the probe tip is within the probe target area of the probe wash tower. Click the "Yes" button. b. The probe alignment is unacceptable when the probe tip is not within the probe target area of the probe wash tower. i. Press the "No" button. ii. Perform a "Probe Calibration."

Step	Action
7	Check the Probe Vertical Position. A. Click on the "Tools" dropdown list and select "Maintenance." B. Click on the "Check Probe Vertical Position" task. C. Press the "Start" button to begin the task. D. You must visually observe the probe during this task. a. In case of failure, the same error message is generated if it is seated either too high or too low. b. The probe will crash if is seated too low. c. If this task fails, the problem must be corrected before proceeding to repeat the task and perform any assays. E. The instrument will prompt, "The probe vertical position check passed" if the maintenance task is successful. F. Press the "OK" button.
8	Perform a Washer Residual Volume Test (visual). A. Click on the "Tools" dropdown list and select "Maintenance." B. Click on the "Washer Residual Volume Test" task from the drop-down list. C. Place two (2) Capture strips into a strip holder and then insert the holder into position 1 of a strip tray or use the strips that are maintained in the "Maintenance" strip holder. Note: The directions on the Echo screen are for the monthly washer residual volume test. **There is no need to weigh the balance strips daily.** D. Load the strip tray into strip tray position 1 of the strip tray loading bay. E. Press the "Start" button on the "Run" tab to start the task. F. Immediately remove the two (2) strips from the strip tray and the holder when the test is complete and visually estimate the volume of residual saline for all wells of both strips. a. The test is acceptable when the level of residual volume for every well presents as a thin meniscus of fluid inside the bottom of the well. b. The test is unacceptable when the volume for every well does not present as a thin meniscus of fluid inside the bottom of the well. i. Do not perform patient testing using the instrument until the Washer Residual Volume Test is acceptable. ii. Contact Immucor Technical support if the Washer Residual Volume Test fails.

Step	Action
9	Record the incubator temperatures. A. Point the mouse to "Incubators" on the instrument map. B. Record temperatures for the following: a. Incubator 1 Sensor 1 b. Incubator 1 Sensor 2 c. Incubator 2 d. Incubator 3 C. The acceptable range is 38.1 – 38.9ºC. Do not use the instrument if the incubators are out of acceptable range.
10	Perform reagent quality control per the procedure, "Galileo Echo / Echo Lumena Daily Reagent Quality Control."

Weekly Maintenance

Step	Action
1	Shut Down the Instrument and Computer. A. Shutdown the computer via the "Shut down" sub-menu item under the "File" item of the "Pull-down menu." B. Power down the Echo by turning off the power supply unit. C. Power up the Echo by turning on the power supply unit. D. Press the power switch on the front panel of the PC. E. Allow enough time for the computer to start up and the Echo program to load.
2	Archive Results and Delete from the database. A. Archive Results a. Press the "File Management" button on the "Tool Bar." This is the icon that looks like a CD. b. In the "Results" tab, click on the "select all" button to back up all result data. c. Verify that the "Copy files" action item **is** checked. d. Verify that the "Delete files" action item **is not** checked. e. Select the "Events Log" tab, and then click on the "select all" button to back up all event log data. f. Select the "Configuration files" tab, and then click on the "select all" button to choose all configuration files for archive. g. Click on the "Archive" button. h. Select "Yes" to begin the archive procedure. i. A series of progression bars and details of what is occurring will appear on the screen during the archive process. A message will appear when the archive is complete.

Step	Action
2 cont.	B. Verify the backup information. a. Redirect the computer to the network drive that houses the data. i. Click on the "Tools" dropdown menu and select "General Options." ii. Click on the "Results" tab. iii. Select the network folder from the dropdown list. 1. SGMC \\10.57.151.31\dfs\Apps\sgmc 2. WOMC \\10.57.151.31\dfs\Apps\womc iv. If needed, the information for this network account is as follows: 1. Username: MyAHC\immucor 2. Password: PlantersPeanutMan v. Click the "Close" button. b. The "Results" area on the left-hand side of the screen will change to "Archived Results" when the information on the network drive is read. c. Randomly open 3 patient specimens and confirm the results in the LIS to confirm the results were copied to network drive correctly. d. Redirect the disc back to the hard drive. i. Click on the "Tools" dropdown menu and select "General Options." ii. Click on the "Results" tab. iii. Select the "C:" drive from the dropdown list. iv. Select "G3" from the dropdown list. v. Select "Results" from the dropdown list. vi. Click "OK." vii. Click the "Close" button. e. The "Archived Results" box on the left-hand side of the screen will change to "Results." C. Delete the archived data from the database. a. Press the "File Management" button on the "Tool Bar." This is the icon that looks like a CD. b. In the "Results" tab, click on the "select all" button to delete all of the result data. c. Verify that the "Copy files" action item **is not** checked. d. Verify that the "Delete files" action item **is** checked. e. Select the "Events Log" tab and click on the "select none" box. Ensure none of the boxes are checked. f. Select the "Configuration files" tab and click on the "select none" box. **Ensure none of the boxes are checked.**

Step	Action
2 cont.	g. Click on the "Archive" button. h. Select "Yes" to begin the archive (delete) procedure. i. The prompt, "All selected files have been archived successfully" will appear. Click on the "OK" button.
3	Change the Capture strips used for the washer residual volume test. Any Capture strip may be used, but the Capture-R, Ready Screen (3) strips are preferred.
4	Open new WB corQC specimens. Discard the used specimens. One set of reagent QC generally lasts 1 week.
5	Open a new bottle of DAT positive control cells. Ensure a stirball is added prior to placing the cells on the Echo.

Monthly Maintenance

Step	Action
1	Perform instrument decontamination. Note: An alert message is displayed on the bottom of the screen signifying that the buffer container is low during the Decontaminate Instrument, Flush Instrument, and Purge Instrument functions. This alert message does not negatively impact these maintenance tasks. A. Decontaminate the instrument. a. Prepare 2L of a 0.25% sodium hypochlorite (NaCIO) Solution using deionized water. Note: We normally purchase Clorox Concentrated Germicidal Bleach which is 8.25%. In this case, use 1940 mL of DI water and 60 mL of concentrated bleach. For other concentrations, please refer to the below instructions: i. Verify the concentration of the NaCIO (bleach) using the certificate of analysis (CoA) for the lot used. ii. Determine the volume of NaCIO required based on the concentration on the CoA, using the formula $V = 500 \div C$ Where: V = the volume of undiluted bleach C = the concentration of bleach indicated on the CoA as a percent

Step	Action
1 cont.	

Volumes required for typical bleach concentrations			
Concentration of Bleach	Volume of Dionized H_2O	Volume of undiluted bleach	Final Volume of 0.25% bleach
8.27%	1940 mL	60 mL	2L
12.0%	1958 mL	42 mL	
14.0%	1965 mL	35 mL	

iii. Fill a container with the desired volume of distilled water.
iv. Measure the desired volume of concentrated bleach.
v. Pour the bleach into the distilled water, cover the container, and gently mix.

b. Wet some gauze with the diluted bleach in preparation for cleaning the probe block in step 2 of this procedure.
c. Empty the PBS out of a PBS supply bottle into the sink. New PBS will be placed in the bottle following decontamination.
d. Add the diluted bleach to the empty PBS supply bottle.
e. Swirl the fluid inside the PBS supply container so that it comes into contact with all internal surfaces including the inside of the handle.
f. Connect the PBS supply bottle to the Echo.
g. Make sure the tubing inside of the PBS supply bottle is fully extended to the bottom of the bottle and not hooked on the inside shelf.
h. Empty the waste container.
i. Click on the "Tools" dropdown menu and select the "Maintenance" tab.
j. Select the "Decontaminate instrument" task from the drop-down list.
k. Press the "Start" button of the "Run" tab to begin the procedure.
l. Allow the diluted bleach solution to soak for ten (10) minutes in the instrument after the procedure is complete.

B. Flush the instrument.

a. Empty the remaining bleach solution out of the PBS supply bottle and replace it with at least 1 liter of de-ionized water.
b. Swirl the fluid inside the PBS supply container so that it comes into contact with all internal surfaces including the inside of the handle.
c. Discard the de-ionized water and repeat.
d. Place approximately 1L of deionized water in the PBS supply bottle and connect the PBS supply bottle to the Echo.
e. Make sure that the tubing inside of the PBS supply bottle is fully extended to the bottom of the bottle and not hooked on the inside shelf.
f. Empty the waste container.
g. Select the "Flush instrument" maintenance task from the drop-down list on the "Run" tab of the "Maintenance" window.
h. Press the "Start" button of the "Run" tab to begin the procedure.

Step	Action
1 cont.	C. Purge the instrument. a. Empty the remaining de-ionized water out of the PBS supply bottle. b. Connect the **empty** PBS supply bottle to the Echo. c. Empty the waste container. d. Select the "Purge instrument" maintenance task from the drop-down list on the "Run" tab of the "Maintenance" window. e. Press the "Start" button of the "Run" tab to begin the procedure. D. Prime the instrument. a. Fill the PBS supply bottle with PBS. b. Make sure that the tubing inside of the PBS supply bottle is fully extended to the bottom of the bottle and not hooked on the inside shelf. c. Empty the waste container. d. Select the "Prime instrument" maintenance task from the drop-down list on the "Run" tab of the "Maintenance" window. e. Press the "Start" button of the "Run" tab to begin the procedure.
2	Power down the instrument and the computer. A. Shutdown the computer via the "Shut down" sub-menu item under the "File" item of the "Pull-down menu." B. Power down the Echo by turning off the power supply unit.
3	Remove the shroud (instrument cover).
4	Wipe down the probe splash guard and clean instrument interior. A. Clean any crystallized PBS off the probe splash guard using gauze soaked with diluted bleach (prepared in step 1). a. Take care not to bend the probe during this step. b. Allow the diluted bleach to remain on the probe block for 10 minutes. B. Wipe the probe block with gauze soaked in deionized water to remove residual bleach solution. C. Clean the inside of the instrument by wiping with gauze soaked diluted bleach or 70% isopropyl alcohol.
5	Clean the manifold. A. Release the flathead screw in the center of the front of the manifold. B. Pull out the manifold. Remove the tubing by disconnecting the luer locks on the end of the manifold. Be careful to leave the connectors inside the wash manifold and make sure they are tight. C. Do NOT remove the bumpers from the body of the manifold. This can result in loss of some associated washers which will result in manifold leakage.

Step	Action
5 cont.	D. Inspect the manifold. a. If necessary, use the stylus to clean out all of the metal aspirating and cleaning probes. The styluses are stored in a clear plastic cylinder and gripped by a clip located in the inside upper back right corner of the main instrument. b. You can also soak the manifold in warm tap water for 20 minutes. After soaking, flush the manifold with warm tap water through the luer connection (using a syringe). E. Following inspection and cleaning if necessary, reconnect the manifold to its tubing. F. Slide the manifold back into the groove and secure the flathead screw.
6	Remove the wash priming strips from the instrument.
7	Replace the shroud.
8	Power up the instrument and computer. A. Power up the Echo by turning on the power supply unit. B. Press the power switch on the front panel of the PC. C. Allow enough time for the computer to start up and the Echo program to load.
9	Replace the wash priming strips A. Click on the "Tools" dropdown list and select "Maintenance." B. Select "Install priming strip holder" from the list. C. Place a strip holder with two (2) CMT Plate Strips onto the left position (position 1) of a strip tray. D. Insert the strip tray into the top position of the strip loading bay. E. Press the "Start" button on the "Run" tab to start the task. F. Press the "OK" button on the information dialog to complete the task.
10	Complete the Washer Basic Test. A. Select the "Tools" dropdown menu and select "Maintenance." B. Select "Washer basic test" from the list. C. Press the "Start" button on the "Run" tab to start the task.
11	Perform the Washer Residual Volume Test A. Record the following on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." a. Serial number of the electronic balance. b. Tech initials or identification. c. Date of performance. d. Instrument serial number.

Step	Action
11 cont.	B. Perform quality control on the scale and document the results on the QC form. C. Select the "Tools" dropdown menu and select "Maintenance" from the list. D. Select "Washer residual volume test." E. Weigh two (2) capture strips and record the weight on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." The two strips are weighed **together** when performing the Washer Residual Volume Test. F. Place the two (2) strips into a strip holder and then place the holder in position 1 of a strip tray. G. Load the strip tray into strip tray position 1 of the strip tray loading bay. H. Press the "Start" button on the "Run" tab to start the task. I. Reweigh the two (2) strips when the test is complete and record the weight on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." J. Using a calculator, subtract the weight obtained in step C (pre-weight) from the weight obtained in step G (post-weight) and record the value on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." K. Interpret the acceptability of the resulting value based on the acceptable range and record this conclusion on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." a. Acceptable = 0.06 – 0.16 grams b. Unacceptable = <0.06 grams or >0.16 grams. DO NOT use the instrument until an unacceptable Washer Residual Volume Test has been resolved.
12	Perform the Washer Dispense Accuracy Test. A. Record the following on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." a. Serial number of the electronic balance. b. Tech initials or identification. c. Date of performance. d. Instrument serial number. B. Select the "Tools" dropdown menu and select "Maintenance" from the list. C. Select the "Washer dispense accuracy test" from the drop-down list. D. Weigh two (2) Capture strips and record the weight on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." The two strips are weighed **individually** when performing the Washer Dispense Accuracy Test. E. Place the two (2) strips into the strip holder and then place the holder in position 1 of a strip tray. F. Load the strip tray into strip tray position 1 of the strip tray loading bay.

Step	Action
12 cont.	G. Press the "Start" button on the "Run" tab to start the task. H. Reweigh the two (2) strips when the test is complete and record the weight on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." I. Using a calculator, subtract the weight obtained in step C (pre-weight) from the weight obtained in step G (post-weight) and record that value on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." J. Interpret the acceptability of the resulting value based on the acceptable range and record this conclusion on the "Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record." a. Acceptable = 1.92 – 2.08 grams b. Unacceptable = <1.92 grams or >2.08 grams. DO NOT use the instrument until an unacceptable Washer Dispense Accuracy Test has been resolved.

8. RELATED DOCUMENTS

SOP: Galileo Echo / Echo Lumena Daily Reagent Quality Control
SOP: Galileo Echo /Echo Lumena As Needed Maintenance
Form: Echo Maintenance Log (AG.F123)
Form: Washer Residual Volume Test and Washer Dispense Accuracy Test Maintenance Record (AG.F124)

9. REFERENCES

Immucor, Inc. (2018). Galileo Echo Operator Manual. ECO-001-201. Norcross, GA.

10. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	1.19.2012	Section 4: Updated pH of PBS	SCodina	NCacciabeve
001	2.17.2013	Section 7: Add replacing DAT-positive control cells to weekly maintenance. Add clean inside of instrument, clean manifold, and perform washer basic test to monthly maintenance. Added that strips are weighed together for washer residual volume test and individually for washer dispense accuracy test.	SCodina	NCacciabeve
002	11.29.16	Header: Add WAH Section 8: Move forms from section 11 Footer: Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	LBarrett	NCacciabeve

Version	Date	Reason for Revision	Revised By	Approved By
3	11/29/2018	Section 7: Updated instructions for backing up instrument to a network drive instead of a disc. Section 9: Updated references. Section 11: Added Appendix A.	SCodina	NCacciabeve
4	6/29/2021	Section 7: Changed decontamination procedure from Relyon to bleach per Immucor upgrade. Added step to replace priming strips monthly. Updated backup path.	SCodina	NCacciabeve

11. ADDENDA AND APPENDICES

Appendix A: Accessing backup data that was saved to a CD

Appendix A

Accessing backup data that was saved to a CD

Prior to December 2018, Echo archives were saved on discs. Access data saved to discs using the following procedure.

A. Select the disc that contains the desired information. Discs are labeled with the serial number of the Echo and the inclusive dates of the backup information.
B. Insert the CD-R, DVD+R, or DVD-R disk into the PC drive. Allow the PC to recognize the disc before beginning the archive procedure (wait approximately 60 seconds or until the light on the disc drive turns off).
C. Redirect the disc to the D: drive.
    a. Click on the "Tools" dropdown menu and select "General Options."
    b. Click on the "Results" tab.
    c. Select the "D:" drive from the dropdown list.
    d. Click the "Close" button.
    e. The "Results" area on the left-hand side of the screen will change to "Archived Results" when the disc is read.
D. Obtain the desired information.
E. Redirect the disc back to the hard drive.
    a. Click on the "Tools" dropdown menu and select "General Options."
    b. Click on the "Results" tab.
    c. Select the "C:" drive from the dropdown list.
    d. Select "G3" from the dropdown list.
    e. Select "Results" from the dropdown list.
    f. Click "OK."
    g. Click the "Close" button.
    h. The "Archived Results" box on the left-hand side of the screen will change to "Results."

Adventist HealthCare

- ☐ Shady Grove Medical Center
- ☐ White Oak Medical Center

Echo Maintenance Log

Echo S/N: _____

Month/Year: _____

DAILY MAINTENANCE REQUIREMENT	Date																													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1.Refill PBS supply bottle																															
2.Empty waste container																															
3.Initialize instrument																															
4.Clean instrument																															
5.Check probe alignment																															
6.Check probe vertical position																															
7a. Incubator 1, Sensor 1 (38.1 – 38.9C)																															
7b. Incubator 1, Sensor 2 (38.1 – 38.9C)																															
7c. Incubator 2 (38.1 – 38.9C)																															
7d. Incubator 3 (38.1 – 38.9C)																															
8.Washer residual volume test (visual)																															
9.Reagent QC																															

WEEKLY MAINTENANCE REQUIREMENT	WEEK 1		WEEK 2		WEEK 3		WEEK 4		WEEK 5	
	Operator	Date	Operator	Date	Operator	Date	Operator	Date	Operator	Date
Shutdown instrument and computer										
Archive results (at least weekly) and delete from database										
Change the strips used for the Washer residual volume test										
Start new corQC tubes										
Lot Number and Expiration of CorQC	Lot	Exp	Lot	Exp	Lot	Exp	Lot	Exp	Lot	Exp

MONTHLY MAINTENANCE REQUIREMENT	Operator	Date
1.Decontamination (Decontaminate/Flush/Purge/Prime)		
2. Wipe down probe splash guard with recommended cleaning solution		
3. Replace the Wash Priming Strips		
4. Washer residual volume test		
5. Washer dispense accuracy test		