



University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 06-20-2019	Number: EQ-0009.01
	Revision Effective Date:	
TITLE: Ortho Vision® - Maintenance		

PURPOSE:

To outline the procedure for routine scheduled maintenance of the Ortho Vision® according to the manufacturer recommendations and the University of Washington Medical Center (UWMC) standards

PRINCIPLE & CLINICAL SIGNIFICANCE:

N/A

POLICIES:

- **The system must be in *Maintenance Mode* to perform Maintenance Tasks.** When in Maintenance Mode, the Maintenance screen is available and the Maintenance Tasks and Action Buttons on the screen are active. When the system is not in Maintenance Mode, only the status of Maintenance Tasks can be viewed.
- Maintenance Wizards provide step by step instructions to assist you in the completion of Maintenance Tasks. To display a Maintenance Wizard, select a Maintenance Task and touch <Execute>. The Maintenance Wizard provides by step by step instruction and pictures for execution and completion of all Maintenance Tasks. In addition, this procedure provides the steps in a written format as an additional resource.
- If maintenance is not completed on time, the results are flagged and an error message is displayed on the screen.
- Maintenance are performed at the frequency recommended by the manufacturer and listed on the following **Maintenance Schedule**. In addition to the frequency below, Daily Maintenance may be required to decontaminate probes when carryover is suspected during testing.
- When [Weekly](#) and [Daily Maintenance](#) are performed back to back, the manufacturer recommends performing Weekly Maintenance first. Otherwise, if Weekly Maintenance fails, the system will prompt the user to start Daily Maintenance all over again
- Backing up of quality control, maintenance and patient testing data is performed as part of the monthly maintenance. Data is backup to the USB flash drive dedicated to the instrument.
- A **Maintenance History Report** should be printed and retained after completion of a maintenance task. When more than one maintenance tasks (daily, weekly, or monthly) are completed at the same time, only one *Maintenance History Report* needs to be printed. All maintenance tasked completed on the same day will be included on the *Maintenance History Repor*.

Maintenance Schedule:

Frequency	Maintenance Task	Time
Daily	Probe Decontamination	15 minutes
Weekly	Liquid System Decontamination and Pump Test	30 minutes
Monthly	<ul style="list-style-type: none"> Instrument Cleaning Image Area Cleaning Data Backup 	60 minutes
Annual	<ul style="list-style-type: none"> Liquid container replacement Liquid waste container replacement Pipette tubing replacement System air filter replacement Dilutor valve replacement Syringe and tubing replacement System tubing replacement 	NA- Performed by Ortho Technician

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
<ul style="list-style-type: none"> DI Water 70% isopropyl alcohol 0.1N Sodium Hydroxide (NaOH) 	<ul style="list-style-type: none"> Kimwipes or other lint free cloth Paper towels Cotton swabs Soft nylon-bristled brush Warm, soapy water Empty 16 x 100 mm sample tube Tongue depressors Cotton applicator sticks 	Ortho Vision®

SPECIMEN REQUIREMENTS:

N/A

QUALITY CONTROL:

N/A

INSTRUCTIONS:**TABLE of CONTENTS**[Daily – Probe Decontamination](#)[Weekly – Liquid System Decontamination and Pump Test](#)[Monthly – Instrument Cleaning](#)[Monthly - Image Area Cleaning](#)[Monthly - Data Backup](#)[Yearly](#)[Appendix 1: Data Backup Using the Maintenance Menu](#)

Daily – Probe Decontamination

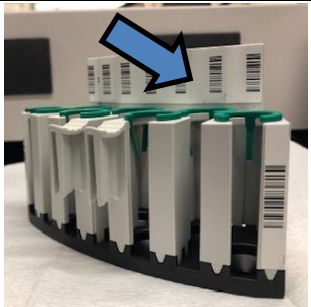
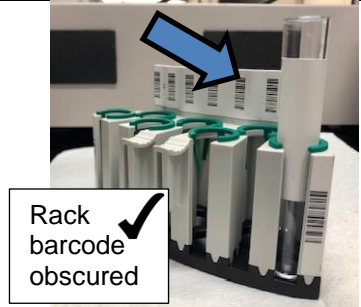
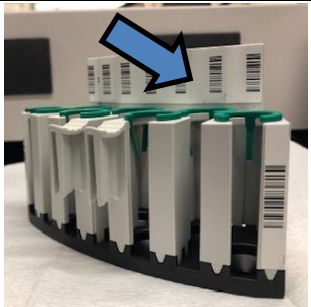
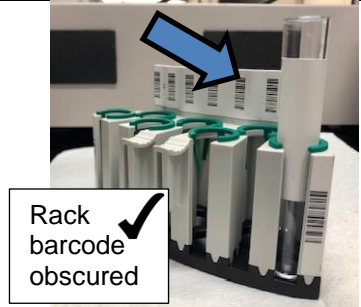
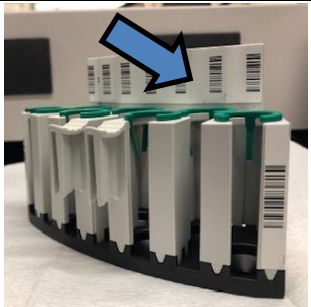
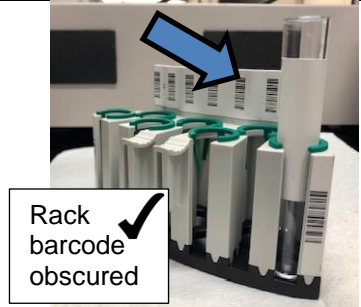
STEP	ACTION
1	<p>Verify that the instrument is on Maintenance Mode:</p> <ul style="list-style-type: none"> • Touch <Stop Processing> • Touch <Stop Processing> again • Touch <Maintenance> menu button • Touch <Enter Maintenance Mode> • Touch <Daily> • Touch <Daily Probe Maintenance> • Touch <Execute> <p>NOTE: The interactive screen will guide the user through the process</p>
2	<p>Open Load Station Door when prompted and touch <OK></p> <p>NOTE: It will take about a minute before prompted</p>
3	<p>Add 5 mL of 0.1N NaOH to a 10 mL vial with a supported barcode and place into position 3 of a Diluent Rack</p> <p>NOTE: A DIN barcode sticker from any blood component is acceptable</p>
4	<p>Place a new 5 mL vial of 7% BSA into position 2</p> <p>NOTE: Use a new vial of BSA each time and do not combine vials</p>
5	<p>Load the Diluent Rack and touch <OK></p>
6	<p>Close Load Station Door and touch <OK></p> <p>NOTE: Probe decontamination will start and run for about 5 minutes</p>
7	<p>Open the Maintenance Door when prompted and touch <OK></p>
8	<p>Clean the probe using Kimwipes moistened with 70% isopropyl alcohol and touch <OK></p> <p>IMPORTANT: Wipe the probe in downward motion two to three times without wiping up</p>
9	<p>Close Maintenance Door and touch <OK></p> <p>NOTE: The system will automatically complete decontamination</p>
10	<p>Open Load Station Door when prompted and touch <OK></p>
11	<p>Remove Diluent Rack and touch <OK></p>
12	<p>Close Load Station Door and touch <OK></p> <p>NOTE: The system will indicate when maintenance is complete.</p>
13	<p>Print a <i>Maintenance History Report</i></p> <ul style="list-style-type: none"> • Touch <Show Maintenance History Report> • Touch <Presets> • Touch <Today> • Touch <OK> • Touch <Print>

STEP	ACTION	
14	If result is	Then
	Done	File in the appropriate location
	Not done	Troubleshoot the failure and repeat Daily Maintenance NOTE: Patient and donor testing should not be performed if maintenance is not completed successfully per Maintenance Schedule
15	Touch <Resume Processing> to resume testing when maintenance is finished	
16	Complete entry on the Ortho Vision Maintenance Form to indicate Daily Maintenance is complete	

Weekly – Liquid System Decontamination and Pump Test

STEP	ACTION	
1	Verify that the instrument is on Maintenance Mode: <ul style="list-style-type: none"> • Touch <Stop Processing> • Touch <Stop Processing> again • Touch <Maintenance> menu button • Touch <Enter Maintenance Mode> • Touch <Weekly> • Touch <Weekly Liquid System Decontamination and Pump Test> • Touch <Execute> NOTE: The interactive screen will guide the user through the process.	
2	Open Liquid Access Door and pull Bottle Release for the Liquid Waste Bottle and touch <OK>	
3	Remove Liquid Waste Bottle (grey) from the system by pulling up and out simultaneously to avoid waste touching the cap and touch <OK>	
4	Remove the Bottle Cap and dispose of the liquid waste in a dirty sink	
5	Install Bottle Cap and slide the Liquid Waste Bottle into the system manually or using the Bottle Insertion Tool, until it snaps into place and touch <OK>	
6	Pull the Bottle Release for the Liquid Container (white) and remove Liquid Container from the system and touch <OK>	
7	Remove the Bottle Caps from both the white and blue sections of the Liquid Container and dispose of the residual liquid in a dirty sink	
8	Fill the bottles per the following table and then touch <OK>	
	Fill	With
	Smaller bottle (blue)	400 mL of 70% isopropyl alcohol
	Larger bottle (white)	600 mL of 70% isopropyl alcohol
9	Install bottle caps, and gently tilt side to side and touch <OK>	
10	Slide the Liquid Container bottle back into the system manually or with the Bottle Insertion Tool, until it snaps into place	

STEP	ACTION						
11	Close the door and touch <OK> NOTE: The system will automatically perform decontamination						
12	Open Liquid Access Door, and pull the Bottle Release and remove the Liquid Container from the system and touch <OK>						
13	Remove the two bottle caps, and discard the liquid in the alcohol hazardous waste container						
14	Fill the bottles per the following table and then touch <OK>						
	<table border="1"> <thead> <tr> <th>Fill</th> <th>With approximately</th> </tr> </thead> <tbody> <tr> <td>Smaller bottle (blue)</td> <td>500 mL deionized water</td> </tr> <tr> <td>Larger bottle (white)</td> <td>3000 mL of deionized water</td> </tr> </tbody> </table>	Fill	With approximately	Smaller bottle (blue)	500 mL deionized water	Larger bottle (white)	3000 mL of deionized water
	Fill	With approximately					
Smaller bottle (blue)	500 mL deionized water						
Larger bottle (white)	3000 mL of deionized water						
15	Install bottle caps, and gently tilt side to side and touch <OK>						
16	Remove bottle caps, and discard liquids in the dirty sink and touch <OK>						
17	Fill the bottles per the following table and then touch <OK>						
	<table border="1"> <thead> <tr> <th>Fill</th> <th>With approximately</th> </tr> </thead> <tbody> <tr> <td>Smaller bottle (blue)</td> <td>900 mL deionized water</td> </tr> <tr> <td>Larger bottle (white)</td> <td>4700 mL of saline</td> </tr> </tbody> </table>	Fill	With approximately	Smaller bottle (blue)	900 mL deionized water	Larger bottle (white)	4700 mL of saline
	Fill	With approximately					
Smaller bottle (blue)	900 mL deionized water						
Larger bottle (white)	4700 mL of saline						
18	Install Bottle Caps and touch <OK>						
19	Slide the Liquid Container bottle back into the system manually or with the Bottle Insertion Tool, until it snaps into place and touch <OK>						
20	Wait while alcohol is rinsed from the system						
21	Open Liquids Door when prompted, pull Bottle Release, and remove the Liquid Waste Bottle from the system and touch <OK>						
22	Remove the Bottle Cap and touch <OK>						
23	Dispose of the liquid waste into a dirty sink and touch <OK>						
24	Fill Liquid Waste Bottle at least half-full with tap water and touch <OK>						
25	Install bottle cap, gently tilt side to side to rinse, remove bottle cap and discard liquid into a dirty sink						
26	Install Bottle Cap and slide the Liquid Waste Bottle into the system manually or using the Bottle Insertion Tool, until it snaps into place and touch <OK>						
27	Close the door and touch <OK>						
28	Wait while the Fast Wash Delivery Rate Test runs						
29	Open Load Station Door when prompted and touch <OK>						
30	Place an empty 16 x 100 sample tube into position 1 of a green S16B SAMPLE Rack						

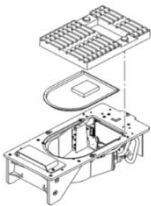

STEP	ACTION					
31	Place a blank label sticker on the section of the tube where Position 1 barcode on the rack is visible through the tube so the barcode is covered and cannot be read by the barcode scanner	<table border="1"> <thead> <tr> <th data-bbox="665 279 1047 342">Barcode to be obscured</th> <th data-bbox="1047 279 1429 342">Barcode obscured by label on loaded tube</th> </tr> </thead> <tbody> <tr> <td data-bbox="665 342 1047 646">  </td> <td data-bbox="1047 342 1429 646">  </td> </tr> </tbody> </table>	Barcode to be obscured	Barcode obscured by label on loaded tube		
Barcode to be obscured	Barcode obscured by label on loaded tube					
						
32	Load the Sample Rack					
33	Close the door and touch <OK>					
34	Wait while the Pump Test runs					
35	Open Load Station Door when prompted, touch <OK>					
36	Remove and empty the sample tube, and place sample tube back into Sample Rack at position 1 and touch <OK>					
37	Close Load Station Door and touch <OK>. Testing will continue automatically.					
38	Open Load Station Door when prompted and touch <OK>					
39	Remove Sample Rack and the sample tube and touch <OK>					
40	Close Load Station Door and touch <OK> NOTE: The system will indicate when maintenance is complete.					
41	Print a <i>Maintenance History Report</i> <ul style="list-style-type: none"> • Touch <Show Maintenance History Report> • Touch <Presets> • Touch <Today> • Touch <OK> • Touch <Print> 					
42	If test is	Then				
	Done	File in the appropriate location				
Fails	Contact Ortho Customer Technical Support NOTE: Patient and donor testing should not be performed if maintenance is not completed successfully per Maintenance Schedule					
43	Touch <Resume Processing> to resume testing when maintenance is finished					
44	Complete entry on the <i>Ortho Vision Maintenance Form</i> to indicate Weekly Maintenance is complete					

Monthly – Instrument Cleaning

STEP	ACTION
1	Verify that the instrument is on Maintenance Mode: <ul style="list-style-type: none"> • Touch <Stop Processing> • Touch <Stop Processing> again • Touch <Maintenance> menu button • Touch <Enter Maintenance Mode> • Touch <Monthly> • Touch <Instrument Cleaning> • Touch <Execute> <p>NOTE: The interactive screen will guide the user through the process</p>
2	Open the Load Station Door and touch <OK>
3	Remove all racks and trays from the Agitated (inner) and Non-agitated (outer) rotors and touch <OK>
4	Avoiding the barcode of the outer cover piece, use a Kimwipe or lint-free cloth moistened with 70% isopropyl alcohol to clean all positions and surfaces of the Agitated(inner) and Non-Agitated (outer) Rotors and touch <OK> <p>IMPORTANT: If barcode is damaged the whole rotor area has to be replaced</p>
5	Close the Load Station Door and touch <OK>
6	Open the Maintenance Door and touch <OK>
7	Remove both centrifuge covers and touch <OK>
8	Clean all surfaces of both centrifuges including the covers with Kimwipe moistened with 70% isopropyl alcohol
9	Remove and clean Centrifuge Cards Holders with a tongue depressor covered with a Kimwipe or lint-free cloth moistened with 70% isopropyl alcohol and touch <OK>
10	Install both centrifuge covers and touch <OK>
11	Clean all surfaces of the Incubator and Probe Adjustment Position located between the Incubator and the Load Station with a Kimwipe moistened with 70% isopropyl alcohol and touch <OK> <p>IMPORTANT: Move the probe arm to the right if needed to clean the incubator and move back into position over the card waste area when cleaning is complete – If the arm is not returned to the card waste position, normal operation may be disrupted and the instrument damaged</p>
12	Close Maintenance Door and touch <OK>
13	Open Load Station Door and touch <OK>
14	Load an empty NAA (N02B) Reagent Rack and touch <OK>

STEP	ACTION
15	Touch <OK> after the Load Station moves to the reagent rack load position
16	Load an empty 10 mL Reagent Rack (labeled R10b), and close the Load Station Door and touch <OK>
17	Touch <OK> when “The test completed successfully on SRDR:1.” message appears
18	Open the Load Station Door and touch <OK>
19	Unload empty NAA reagent rack and touch <OK> NOTE: The Load Station will move to the reagent rack load position Touch <OK>
20	Unload the empty reagent rack, and close the Load Station Door and touch <OK> NOTE: The test is complete
21	Go to next section <i>Monthly – Image Area Clean</i>
22	Complete entry on the Ortho Vision Maintenance Form to indicate Monthly-Instrument Cleaning is complete

Monthly – Image Area Cleaning

STEP	ACTION								
1	Verify that the instrument is on Maintenance Mode: <ul style="list-style-type: none"> Touch <Stop Processing> Touch <Stop Processing> again Touch <Maintenance> menu button Touch <Enter Maintenance Mode> Touch <Monthly> Touch <Imaging System Cleaning> Touch <Execute> NOTE: The interactive screen will guide the user through the process.								
2	Open the Maintenance Door and touch <OK>								
3	<ul style="list-style-type: none"> Loosen the thumb screws and remove the Punch Tray and cover and touch <OK> Gently wipe the cover and all inner surfaces, including the holder and diffuser plate and avoid touching the following: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 40%; padding: 2px;">Vision Part</th> <th style="padding: 2px;">Location</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Camera</td> <td style="padding: 2px;">Rounded end</td> </tr> <tr> <td style="padding: 2px;">Calibrator stickers</td> <td style="padding: 2px;">Flat end</td> </tr> </tbody> </table>	Vision Part	Location	Camera	Rounded end	Calibrator stickers	Flat end		
Vision Part	Location								
Camera	Rounded end								
Calibrator stickers	Flat end								
4	Install the cover and punch tray and touch <OK>								
5	Tighten the thumb screws to hold the punch tray firmly in place, but not too tight to prevent future removal and touch <OK>								

TITLE: Ortho Vision® - Maintenance	Number: EQ-000901
---	------------------------------

STEP	ACTION
6	Close the maintenance door. Touch <OK>
7	Touch <OK> after “Image System Health Check will start now” displays
8	Complete entry on the Ortho Vision Maintenance Form to indicate Monthly-Image Area Cleaning is complete
9	Go to next section: Monthly - Data Backup

Monthly – Data Backup

STEP	ACTION						
1	Ensure USB device is inserted into the USB port on the instrument						
2	Touch <Backup>: a table will display all current backups NOTE: See Appendix 1 for backup instructions if software menu is inaccessible						
3	Touch <Execute>						
4	Touch <OK> when “Backup is ready to start” displays						
5	Touch <Start Backup> and the status will change to “Backup in progress” NOTE: Touch <Stop Processing> twice if the ‘Start Backup’ button is not active. NOTE: Backup may be aborted any time prior to completion by touching <Abort Backup>						
6	Touch <Backup Complete> when the status is “Backup Complete.”						
7	Print a <i>Maintenance History Report</i> <ul style="list-style-type: none"> • Touch <Show Maintenance History Report> • Touch <Presets> • Touch <Today> • Touch <OK> • Touch <Print> 						
8	<table border="1"> <thead> <tr> <th>If test is</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Done</td> <td>File in the appropriate location</td> </tr> <tr> <td>Fails</td> <td>Contact Ortho Customer Technical Support NOTE: Patient and donor testing should not be performed if maintenance is not completed successfully per Maintenance Schedule</td> </tr> </tbody> </table>	If test is	Then	Done	File in the appropriate location	Fails	Contact Ortho Customer Technical Support NOTE: Patient and donor testing should not be performed if maintenance is not completed successfully per Maintenance Schedule
	If test is	Then					
Done	File in the appropriate location						
Fails	Contact Ortho Customer Technical Support NOTE: Patient and donor testing should not be performed if maintenance is not completed successfully per Maintenance Schedule						
9	Touch <Resume Processing> to resume testing when maintenance is finished						
10	Complete entry on the Ortho Vision Maintenance Form to indicate Monthly-Data Backup is complete						

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES:

NA

CALIBRATION:

NA

PROCEDURE NOTES AND LIMITATIONS:

- When performing maintenance or troubleshooting there are several areas in the system where the operator may be exposed to components that move suddenly. Use caution when working on and around the following system components:
 - Centrifuge
 - Gripper arm
 - Incubator
 - Load station
 - Pipette arm
 - Dual purpose drawer
- Always exercise appropriate caution when operating the system and correcting any condition
- Ensure that each instruction has been read and performed before touching the <OK> button from the interactive screen.
- System processes are often prevented when some maintenance tasks are due. Rows in the table appear in different colors, which indicate when the task is due and when a system is blocked. Green indicates that user action is required. Orange indicates that there is a warning or error that requires user action, however, processing continues. Red indicates that there is an error, requiring immediate user action.

REFERENCES:

- ORTHO VISION® Analyzer Key Operator Training Instructor Guide Version 01-05-15
- ORTHO VISION® Analyzer ID-MTS® Gel Cards Reference Guide
- ORTHO VISION® and/or ORTHO VISION® Max Analyzer Self Service Customer Procedure Guides, Pub. No. J56102, Version 04-26-2016
- ORTHO VISION® Analyzer Periodic Maintenance Video
- ORTHO VISION® Analyzer Reference Guide, Pub. No. J40050ENNA, Version 07-20-2015

RELATED DOCUMENTS:

Form Ortho Vision Maintenance

APPENDIX:**Appendix 1: Data Backup Using the Maintenance Menu**

STEP	ACTION
1	Touch <Maintenance>.
2	Touch <All>, then <Backup>.
3	Touch <Execute>.
4	Follow the prompts in the Backup wizard.

TITLE: Ortho Vision® - Maintenance

**Number:
EQ-000901**

UWMC SOP Approval:

**UWMC CLIA
Medical Director**

Mark H. Wener, MD

Date

**Transfusion
Service Manager**

Nina Sen

Date

**Compliance
Analyst**

Christine Clark

Date

**Transfusion
Service
Medical Director**

Monica B. Pagano, MD

Date

UWMC Biennial Review:

Date

Date