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1.0 Purpose

This document provides instructions for performing preventative maintenance on the Ortho Vision analyzer. Maintenance tasks are to be performed as described below according to the given frequency.

Maintenance tasks are guided by the analyzer software and are accessible by using the Maintenance button on the touch screen monitor. The Maintenance screen allows you to view and maintain a schedule of Maintenance Tasks that must be performed to keep the system operating at an optimal level. The Maintenance screen is used to monitor and execute required Maintenance Tasks. Action buttons are selected along the bottom of the Maintenance screen to execute procedures with Maintenance Wizards or create a Maintenance Report.

All maintenance tasks must be completed successfully. If maintenance is not completed on time, then the results are flagged, and an error message is displayed on the screen.


2.0 Scope

	CLS trained and deemed competent on performing Ortho Vision Maintenance tasks.
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3.0 Materials

Safety Precautions

a.	Use of PPE and current biological hazard safety practices will be followed as defined in the laboratory safety manual.
b.	Treat all waste materials used in the cleaning process as contaminated. Follow laboratory procedures to dispose of these materials.
c.	Handle all equipment with care. Mechanical parts may have sharp edges, pinch points, and corners that potentially could cause injury.
d.	Liquid may drip from disconnected tubing. If necessary, use an absorbent material to absorb the drops of liquid.

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Supplies


	<ul style="list-style-type: none"> • Clean, lint-free cloth (Kim wipes) • Paper towel • Cotton swabs • Tongue depressor sticks • Deionized (DI) water • Saline • 70% isopropyl alcohol • 1M NaOH • 7% BSA
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4.0 Quality Control

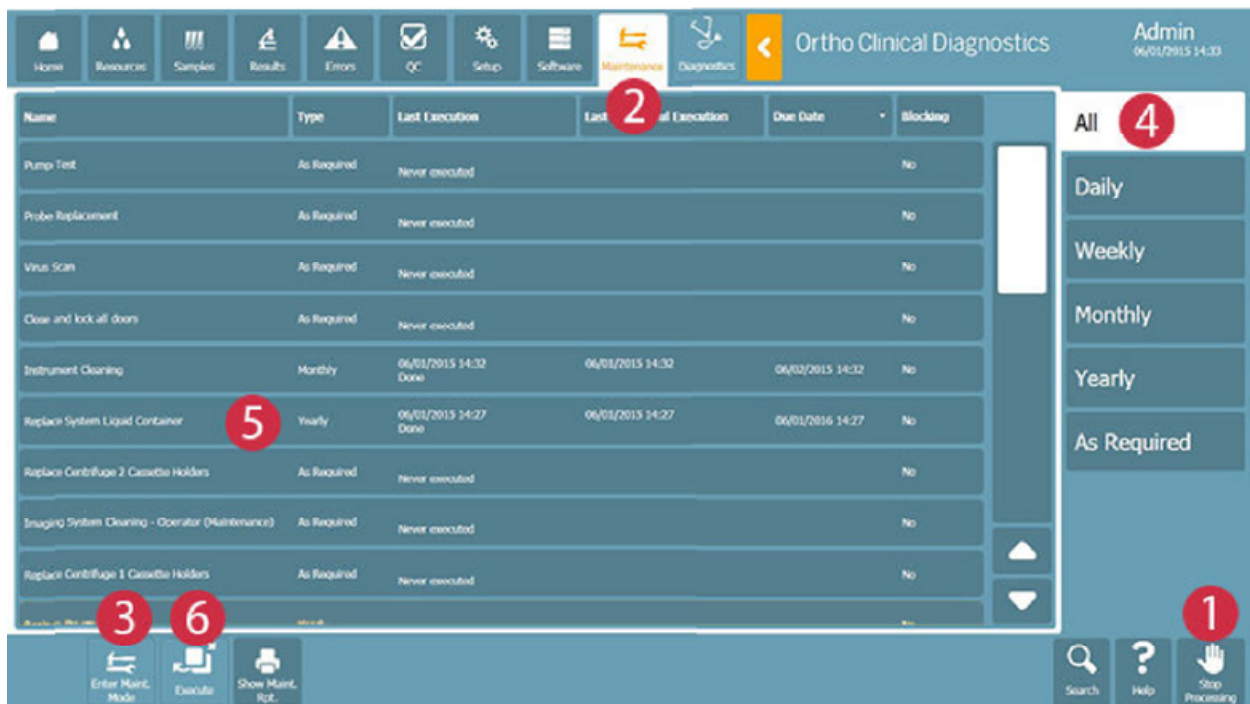
a.	Daily QC will be performed immediately after all scheduled maintenance.
b.	All maintenance tasks must be successfully completed in order to perform Daily QC.

5.0 Procedure

Step	Action
1.	<p>Maintenance Mode</p> <p>Maintenance Mode is an Instrument State that is safe for System Maintenance Tasks to be executed. The system must be in Maintenance Mode in order for System Maintenance Tasks to be performed. The Instrument State displayed in the top-center of the screen indicates when the system is in Maintenance Mode.</p> <p>When in Maintenance Mode, the Maintenance screen is available. The Maintenance Tasks and Action Buttons on the screen are active. System doors are monitored so that the appropriate inventory and initialization processes can be performed once Maintenance Tasks have been completed.</p> <p>To exit Maintenance Mode and return the system to the Operational state, touch another Menu.</p> <p>NOTE: If the system is not in Maintenance Mode, only the status of Maintenance Tasks can be viewed on the Maintenance screen. The system must be in Maintenance Mode to enable the Execute action button.</p>


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- 2. Enter Maintenance Mode and Execute Maintenance Task**
1. Touch the **Stop Processing** button. The system will ask if you want Urgent Stop or Stop Processing. Touch **Stop Processing**.
 2. Touch the Maintenance menu button.
 3. Touch **Enter Maintenance Mode**.
 4. Select the desired maintenance frequency.
 5. Select the desired maintenance task.
 6. Touch the **Execute** action button.




Name	Type	Last Execution	Last Execution	Due Date	Blocking
Pump Test	As Required	Never executed			No
Probe Replacement	As Required	Never executed			No
Virus Scan	As Required	Never executed			No
Close and lock all doors	As Required	Never executed			No
Instrument Cleaning	Monthly	06/01/2015 14:32 Done	06/01/2015 14:32	06/02/2015 14:32	No
Replace System Liquid Container	Yearly	06/01/2015 14:27 Done	06/01/2015 14:27	06/01/2016 14:27	No
Replace Centrifuge 2 Cassette Holders	As Required	Never executed			No
Imaging System Cleaning - Operator (Maintenance)	As Required	Never executed			No
Replace Centrifuge 1 Cassette Holders	As Required	Never executed			No


- 3. Maintenance Wizards**
- Maintenance Wizards provide step by step guided instructions to assist you in the completion of Maintenance Tasks. To display a Maintenance Wizard, select a Maintenance Task and touch Execute.
- NOTE:** Touch the Help button to display Maintenance screen help and access system documentation. The Search and Stop Processing buttons are inactive when a Maintenance Wizard is in use.
- The Maintenance Wizard displays steps and images for each Maintenance Task. **For a Maintenance Task to be successfully executed, each step must be completed.** If the Maintenance Wizard is closed before all the steps are completed, you must start the task over again.
- Use the Action Buttons located in the black bar, below the images, to advance through the Maintenance Wizard steps.

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4.	<p>Document Completion of Maintenance Upon completion of any maintenance task, verify that the task was successful and document your initials and date on the appropriate VISION Maintenance and QC Log.</p>
5.	<p>Sequence of Maintenance Tasks Perform Monthly maintenance first, followed by Weekly maintenance and lastly Daily maintenance. Performing these maintenance tasks out of sequence will result in failed maintenance. If a holiday falls on the day of Weekly or Monthly maintenance, the said task will be performed a day earlier. The week after the holiday, Weekly maintenance will be performed twice so that Weekly maintenance will return to regular schedule thereafter.</p> <p>NOTE: Check the VISION Maintenance and QC Log to determine which maintenance tasks are due prior to starting maintenance.</p>

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6.	<p>Daily Maintenance</p> <p>The Daily Maintenance Task includes (perform in the following sequence):</p> <ol style="list-style-type: none"> i. Empty Card Waste & Clean ii. Empty Liquid Waste iii. Refill Saline & DI H2O iv. Daily Probe Maintenance v. Change Diluent 2 and Diluent 2+ daily vi. Discard and Change RBC Reagents (every 5 days and on day of expiration) <p>Daily Probe Decontamination Daily Probe Decontamination should require no more than 15 minutes to complete. Make sure that the system is in Maintenance Mode before any System Maintenance Task is executed.</p> <p>IMPORTANT: This procedure is accessed using system maintenance. Complete each step as prompted using the system software.</p> <p>NOTE: Detailed pictures of each step can be found in the Maintenance Wizard or the Ortho Vision ID-MTS Gel Cards Self-Service Customer Procedures Guide.</p> <ol style="list-style-type: none"> 1. When prompted, open the LOAD STATION DOOR. 2. Add 5 mL of 0.1M NaOH to a 10 mL vial with a supported barcode. Place the vial into position 3 of a DILUENT RACK. 3. Place a new 5 mL vial of 7% BSA into position 2. Load the DILUENT RACK. <p>IMPORTANT: Use a new vial of BSA each time. Do not combine open vials.</p> <ol style="list-style-type: none"> 4. Close the LOAD STATION DOOR. 5. When prompted, open the MAINTENANCE DOOR. 6. Clean the PROBE with a lint free cloth moistened with 70% isopropyl alcohol. <ul style="list-style-type: none"> • Caution: Be careful not to bend the PROBE. 7. Remove any partial cards from the RT Incubator. Close the MAINTENANCE DOOR. <ul style="list-style-type: none"> • The system will automatically complete the probe decontamination. 8. When prompted, open the LOAD STATION DOOR. 9. Remove the DILUENT RACK. 10. Close the LOAD STATION DOOR. 11. Dispose the NaOH into the “Dirty” sink with tap water running. <ul style="list-style-type: none"> • The system will indicate when the procedure is complete.
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7. Weekly Maintenance

The Weekly Maintenance Task includes (perform in the following sequence):

- i. Weekly Liquid System Decontamination and Pump Test
- ii. Change ALBA Q Check and new DAT POS & DAT NEG controls prior to QC (include change to new lot# once a month)

Weekly Liquid System Decontamination and Pump Test

This task should require no more than 30 minutes to complete. Make sure that the system is in Maintenance Mode before any System Maintenance Tasks are executed.

IMPORTANT: This procedure is accessed using system maintenance. Complete each step as prompted using the system software.

While the system is in normal operation, the LOAD STATION DOOR and MAINTENANCE DOOR are interlocked to prevent exposure to any dangerous movements. However, when loading and unloading supplies and 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 caution when operating the system and correcting any conditions.


Note: Detailed pictures of each step can be found in the Maintenance Wizard or the Ortho Vision ID-MTS Gel Cards Self-Service Customer Procedures Guide.

Prepare system for decontamination

1. When prompted, open the Liquids Door and pull BOTTLE RELEASE for the LIQUID WASTE BOTTLE.
2. Remove the LIQUID WASTE BOTTLE from the system.
3. Remove the BOTTLE CAP.
4. Dispose of the liquid waste into sink with tap water running.
5. Install the BOTTLE CAP and slide the LIQUID WASTE BOTTLE into the system either manually or with the Bottle Insertion Tool, until it snaps into place.
6. Pull the BOTTLE RELEASE for the LIQUID CONTAINER.
7. Remove the LIQUID CONTAINER from the system.
8. Remove the 2 BOTTLE CAPS one after the other.
9. Dispose of the residual liquids.

NOTE: For laboratories with smaller sinks, it may be necessary to empty each BOTTLE individually.

10. Fill the smaller BOTTLE (blue) with approximately 400 ml of 1M NaOH and the larger BOTTLE (white) with approximately 600 ml of 1M NaOH.
11. Install the BOTTLE CAPS and gently tilt side to side.
12. Push the BOTTLE back into the system either manually or with the Bottle Insertion Tool, until it snaps into place. Close the DOOR.

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- **The system will perform the decontamination.**

Liquid Bottles empty, rinse, refill and replace

1. When prompted, open the Liquids Door and pull the BOTTLE RELEASE for the LIQUID CONTAINER.
2. Remove the LIQUID CONTAINER from the system.
3. Remove the 2 BOTTLE CAPS.
4. Dispose of the liquids into the “Dirty” sink with tap water running.
5. Fill the smaller BOTTLE (blue) with approximately 500 ml of deionized water and the larger BOTTLE (white) with approximately 3000 ml of deionized water.
6. Install the BOTTLE CAPS and gently tilt side to side to rinse.
7. Remove the BOTTLE CAPS and dispose of the liquids into sink.

NOTE: For laboratories with smaller sinks, it may be necessary to empty each BOTTLE individually.

8. Fill the smaller BOTTLE (blue) with approximately 900 ml deionized water and the larger BOTTLE (white) with approximately 4700 ml of Saline. Install the BOTTLE CAPS.
9. Push the BOTTLE back into the system either manually or with the Bottle Insertion Tool, until it snaps into place. Close the DOOR.


Liquid Waste Bottle empty, rinse and replace.

1. When prompted, open the Liquids Door and pull the BOTTLE RELEASE for the LIQUID WASTE BOTTLE.
2. Remove the LIQUID WASTE BOTTLE from the system
3. Remove the BOTTLE CAP.
4. Dispose of the liquids into the “Dirty” sink with tap water running.
5. Fill the LIQUID WASTE BOTTLE at least half full with tap water.
6. Install the BOTTLE CAP and gently tilt side to side to rinse.
7. Remove the BOTTLE CAP and dispose of the liquid into sink.
8. Install the BOTTLE CAP and push the LIQUID WASTE BOTTLE into the system either manually or with the Bottle Insertion Tool, until it snaps into place.
9. Close the DOOR.


Pump Test

1. When prompted, open the LOAD STATION DOOR.
 2. Place an empty 16 x 100 sample tube (that is affixed with a blank white label lengthwise) into position 1 of a green SAMPLE RACK. Load the SAMPLE RACK.
 3. Close the LOAD STATION DOOR.
 4. The test will begin automatically.
 5. When prompted, open the LOAD STATION DOOR.
 6. Remove and empty the sample tube. Place the empty sample tube back into the SAMPLE RACK at position 1.
 7. Close the LOAD STATION DOOR.
- The test will continue automatically.**
8. When prompted, open the LOAD STATION DOOR.
 9. Remove the SAMPLE RACK and sample tube.
 10. Close the LOAD STATION DOOR.
 11. The test is complete.

NOTE: Acceptable result: The wash pump dispenses liquids at ≥ 2 ml per second.
If the test fails, contact Customer Technical Support.

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<p>8.</p>	<p>Monthly Maintenance Monthly Maintenance Tasks should require no more than 60 minutes to complete.</p> <p>The Monthly Maintenance Task includes (perform in the following sequence):</p> <ul style="list-style-type: none"> i. Instrument Cleaning ii. Image System Cleaning iii. Data Backup <p>Instrument Cleaning Make sure that the system is in Maintenance Mode before any System Maintenance Tasks are executed.</p> <p>IMPORTANT: This procedure is accessed using system maintenance. Complete each step as prompted using the system software.</p> <p>NOTE: Detailed pictures of each step can be found in the Maintenance Wizard or the Ortho Vision ID-MTS Gel Cards Self-Service Customer Procedures Guide.</p> <ol style="list-style-type: none"> 1. When prompted, open the Load Station Door. 2. Remove all Racks and Trays from the Agitated (inner) and Non-agitated (outer) Rotors. 3. Clean all positions of the Agitated (inner) and Non-agitated (outer) Rotors. 4. When prompted, open the Maintenance Door. 5. Remove both Centrifuge Covers. 6. Clean all surfaces of both Centrifuges. Clean Centrifuge Cards Holders. 7. Install both of the Centrifuge Covers. 8. Clean all surfaces of the Incubator. 9. Close the Maintenance Door. 10. When prompted, open the Load Station Door. 11. Load an empty NAA Reagent Rack (labeled N02B). <ol style="list-style-type: none"> a. The Load Station will move to the reagent rack load position. 12. Load an empty 10 mL Reagent Rack (labeled R10b) and close the Load Station Door. <ol style="list-style-type: none"> a. "The test completed successfully" message will appear. 13. When prompted, open the Load Station Door. 14. Unload the empty Reagent Rack. 15. The Load Station will move to the reagent rack load position. 16. Unload the empty Reagent Rack and close the Load Station Door. 17. The test is complete.
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9. Monthly Image System Cleaning

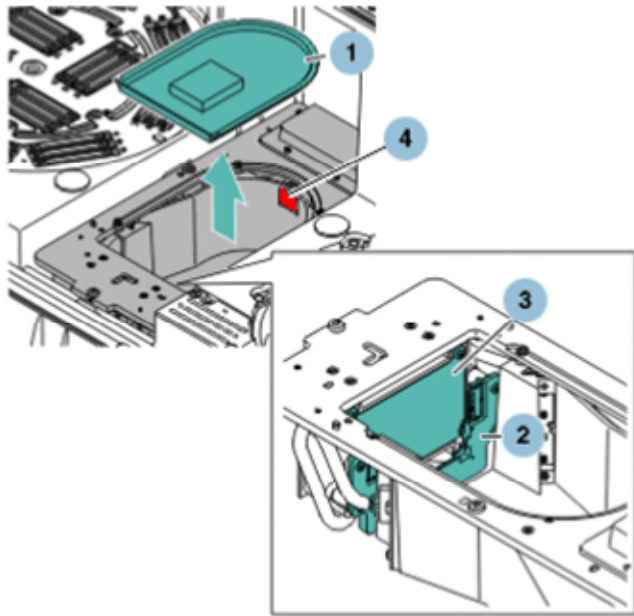
Make sure that the system is in Maintenance Mode before any System Maintenance Tasks are executed.

IMPORTANT: This procedure is accessed using system maintenance. Complete each step as prompted using the system software.

1. This task requires a clean, dry, lint-free cloth.
2. Open the MAINTENANCE DOOR.
3. Loosen the thumb screws  and remove the PUNCH TRAY



4. Remove the COVER. 



Caution: Do not touch or clean the lens

The lens is serviced by OCD Personnel.

5. Clean by gently wiping the COVER and all inner surfaces of the IMAGING SYSTEM


including the CARD HOLDER

and the DIFFUSER PLATE.


6. Install the COVER.

7. Install the PUNCH TRAY and tighten the thumb screws.

8. Close the MAINTENANCE DOOR and wait for the system to initialize.

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10.	<p>Data Back-Up Make sure that the system is in Maintenance Mode before any System Maintenance Tasks are executed.</p> <p>IMPORTANT: This procedure is accessed using system maintenance. Complete each step as prompted using the system software.</p> <p>Configure Settings and Create a Back Up Folder (Initial System Set-up)</p> <ol style="list-style-type: none"> 1. If processing is underway, touch the Stop Processing button and then touch Stop Processing again. 2. Touch the Setup menu button. 3. Touch System. 4. Touch the Modify Backup action button. 5. Select a Backup Media Type: <ul style="list-style-type: none"> • Removable Media 6. Create and name a folder on your USB drive. Use the following folder name: Backup3189. NOTE: This step must be performed every time for a new USB drive. 7. Insert USB into 1/5 Vision ports. 8. Touch Data Sources and select a Data Source: <ul style="list-style-type: none"> • Database and Column Images 9. Touch Automatic Images Synchronization and select Active. Selecting Active will shrink the images. 10. Touch Save. <p>Monthly Back Up of Data Monthly system backup of data records will be saved to a 256GB USB thumb drive to prevent data loss.</p> <p>Initiate Backup Task from the Monthly Maintenance Screen</p> <ol style="list-style-type: none"> 1. Touch Maintenance. 2. Touch Monthly. 3. Touch Backup. 4. Touch Execute. 5. Follow the on-screen prompts. NOTE: Do not remove the USB drive from the Vision. <p>Initiate Backup Task from the Software Menu Tab (for supervisor)</p> <ol style="list-style-type: none"> 1. Touch Software. 2. Touch Backup. 3. Review settings for: <ol style="list-style-type: none"> a. Data Sources b. Backup Media Type c. Media Path d. Available disk space e. Backup description — the system provides a default description consisting of a timestamp for the backup. You can accept the default backup description, or you can enter your own. f. Status 4. Touch Start Backup. “Backup is Progress” message will appear on-screen. NOTE: Once backup has started, it could be aborted at any time prior to completion by touching the Abort Backup button.
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	<p>5. When the backup is complete, the message “Maintenance Backup successfully completed” will display on screen. NOTE: Do not remove the USB drive from the Vision.</p>
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6.0 Documents and Records

6.1	Record maintenance tasks on the Ortho VISION Maintenance and QC Logs.
6.2	Completed maintenance logs will be retained for 5 years.

7.0 Related Documents

7.1	ORTHO Vision [®] Analyzer Quick Reference Guide, current revision.
7.2	ORTHO Vision [®] Analyzer ID-MTS [®] Gel Cards Reference Guide, current revision.
7.3	ORTHO Vision [®] Analyzer ID-MTS [®] Gel Cards Self-Service Customer Procedures Guide, current revision.