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# 1.0 Purpose

Qualified Ortho Clinical Diagnostics service personnel will perform initial system startup and setup. After initial startup and setup, you do not need to shut the system down; the system is intended to remain in operation 24 hours a day. When not in use, the system continues to control the environmental conditions of stored liquids and reagents for a specified time. Environmental conditions are not controlled when the system is shutdown.

**IMPORTANT:** The system should be restarted if you experience excessive rates of slow system responses.

### 2.0 Scope

CLS who have been trained and deemed competent for routine testing and trouble-shooting the Vision analyzer.

#### 3.0 Procedure

Steps	Action
1.	System Startup
	<ul> <li>Power On: <ol> <li>Before powering on the analyzer, <ol> <li>Fill up the system liquid containers will saline and DI water.</li> <li>Empty liquid waste and card waste tray.</li> <li>Remove samples and reagents from the Load Station. <ol> <li>If any samples are found on board, they will be marked as expired.</li> <li>If any liquid reagents are found in the agitated supply, they will be marked as requiring agitation.</li> <li>Close all the doors.</li> </ol> </li> <li>Confirm the system is connected to a power outlet. The system should be plugged into the UPS, which should be plugged into a proper power supply and turned on.</li> <li>Press the ON switch located on the lower right side of the analyzer.</li> <li>Once powered on, the system completes a series of initialization processes, which include: <ol> <li>Hardware Initialization</li> <li>Component Inventory</li> <li>Consumable Inventory</li> </ol> </li> <li>Startup is complete when the Dashboard is displayed, and you can login.</li> </ol></li></ol></li></ul>

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	IMPORTANT: Any samples found on board the system at startup will be marked as expired. Any liquid reagents in the agitated supply at startup will be marked as requiring agitation.
	<b>NOTE:</b> On startup, there is short time period for login with maintenance permissions (by use of a <b>Diagnostic</b> button on the screen available to Field Service or Key Operator as directed by Service).
	<ul> <li>i. Note that the system does not initialize after the Service Log in, leaving the system in a maintenance state.</li> <li>ii. If the operator does not touch the Diagnostics button, the software continues the startup process. Only touch the Diagnostics button if directed by an Ortho Service Engineer.</li> </ul>
2.	Normal Startup A normal system startup leaves the system in Operational state. The system will perform device and consumables inventories. The system will post an error for the Incubator (37° C) ring until the temperature is reached.
3.	Startup after an Urgent Shutdown If starting up after an urgent shutdown, any orders in the work list/database with status Running will be flagged as aborted. The system will discard any cards found onboard and perform an inventory.
4.	Shutdown Procedures
	Shut Down the System: Use this procedure to perform a graceful shutdown of the system. This procedure is accessed from the Home screen.
	<ol> <li>Remove samples and reagents from the Load Station.</li> <li>Empty card waste</li> <li>Touch the Home menu button.</li> <li>Touch the Shut Down action button.</li> </ol>
	<ul> <li>A confirmation screen is displayed.</li> <li>5. Touch Yes to confirm the shutdown procedure. Shutdown process begins. Before turning off the power, confirm that the green light under the monitor is blinking.</li> <li>6. Power off the Ortho Vision® Analyzer with the power switch, located on the right side of the analyzer.</li> </ul>
	The system shuts down.

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## 5. Emergency Shutdown

**IMPORTANT:** An emergency shutdown should only be performed if normal shutdown procedures are not available

To perform an emergency shutdown, touch the Stop Processing button from any screen and choose the **Perform Urgent Stop** option. The system must then be restarted.

**IMPORTANT:** All test processes are stopped immediately once an urgent stop is requested. These tests will be failed and any results are lost. Pending tests will not begin.

• **NOTE:** An emergency shutdown can be performed at any time. A user does not need to be logged in; therefore, the user who performed the emergency shutdown may not be recorded.

### 4.0 Documentation and Records

4.1	1.	Record analyzer issue using the Instrument Problem Log. Record the incident leading to the instrument shutdown and all actions taken to return the instrument to normal operation.
	2.	Submit completed log for supervisory review.

### 5.0 Related Documents

5.1	Ortho Vision Routine Testing SOP.
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#### 6.0 References

6.1	ORTHO Vision® Analyzer Quick Reference Guide, current revision.
6.2	ORTHO Vision® Analyzer ID-MTS® Gel Cards Reference Guide, current revision.
6.3	ORTHO Vision® Analyzer ID-MTS® Gel Cards Self-Service Customer Procedures Guide, current revision.