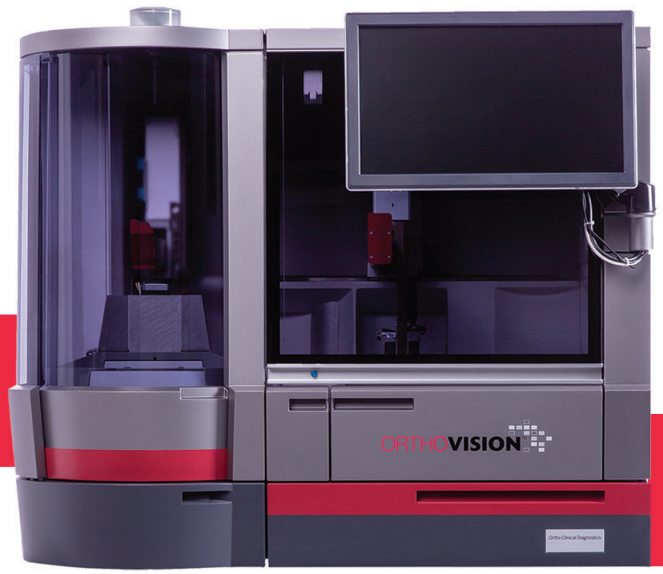
Analyzer
ORTHOVISION®

ORTHO BioVue® Cassettes

Reference Guide



TRANSFUSION MEDICINE

J55655ENX

Ortho Clinical Diagnostics

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IMPORTANT

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Revision History: Reference Guide

Title	Location	Description
Introduction	• On the System: Trademarks and Third Party Disclosures (page 1-1) • On the USB: Chapter 1, Introduction: Trademarks	Incorporated the Technical Bulletin [J67237EN - VISION Operating System Upgrade]. Updated the antivirus name as "Trend to Cylance Protect" and Manufacturer from "Trend to Blackberry".
Safeguards and Precautions	• On the System: Summary of System Performance Characteristics and Specifications (page 1-15) • On the USB: Chapter 2, Safeguards and Precautions: General Precautions	As per the IVDR updates added "Presence of Chemicals of Concern within the System. This system may contain small quantities of chemicals within its components that are classified as carcinogenic, mutagenic, or reproductive toxins, endocrine disruptors, or skin sensitizers, or cause an allergic reaction. However, if the Universal Precautions are followed as instructed below, the risk of exposure to these substances is remote. Under normal operating conditions, as described in this guide, exposure to these components/chemicals is not expected." and added Impoter Symbol at the backpage.
Startup and Shutdown	• On the System: System Startup (page 4-1) • On the USB: Chapter 4, Startup and Shutdown: System Startup	Added New content for "Sleep mode" Pipa43
Startup and Shutdown	• On the System: System Shutdown (page 4-3) • On the USB: Chapter 4, Startup and Shutdown: System Shutdown	Incorporated the Technical Bulletin [J67237EN - VISION Operating System Upgrade]. IMPORTANT: When the monitor displays a message that it is safe to shut down, then you can completely shut down the master computer. If you power off the system while the master computer is still running, then you will have the risk of losing data or corrupting the operating system.
Samples	• On the System: Positive Sample Identification (page 9-21) • On the USB: Chapter 9, Samples: “Positive Sample Identification”	Added "Caution: With Software versions 5.12.8 and below, when multiple samples with the same sample ID are placed on board, the system would display an "Apsw81— Sample ID is Not Unique" error, but the system may have processed orders on one sample while blocking subsequent samples. With Software version 5.13.0 and above, the system correctly blocks all in-process orders for that sample ID, in addition to displaying the "Apsw81— Sample ID is Not Unique" error. Added "Note: User should follow their Laboratory Standard Operating Procedures and the common blood bank safety practices to ensure that the samples are properly labeled prior to loading on the system.

(Continued)

Title	Location	Description
Results	• On the System: Results (page 10-4) • On the USB: Chapter 10, Results: Results	Incorporated the Technical Bulletin [J68339EN - Auto-archiving of orders] Touch the Results button to access and view active orders. Orders are removed from the Results list when they are archived according to your settings. For example, if auto-archiving is enabled and set to 24 hours, an accepted order will disappear from the Results list 24 hours after the order was created. If an order is archived manually, it will disappear from the Results list immediately after being archived.
Results	• On the System: Flags (page 10-23) • On the USB: Chapter 10, Results: Flag and Codes	Added Liquid level detection does not occur when performing a UDP test with total dispensed volume (reagent with sample) different than 50 µl, 90 µl, and 100 µl. Wrong liquid level checks are not performed by the software if total dispensed volume (reagent with sample) specified by a UDP is different than 50 µl, 90 µl, and 100 µl.
Setup	• On the System: General (page 14-7) • On the USB: Chapter 14, Setup: General	Incorporated the Technical Bulletin [J68339EN - Auto-archiving of orders] Auto Archive Completed Orders after [h] If Auto Archive Completed Orders is enabled, define the time (in hours) between the creation of an order and when the order is archived. Note: Orders are completed when all tests are processed and results are uploaded to the LIS.
Introduction	• On the System: Limitations (page 1-3) • On the USB: Chapter 1, Introduction: “Limitations”	Added the bullet point “When running panel tests, users should be aware that the lowest numbered cell selected will run in column 1 of the Cassette, and the remaining cells selected for that sample will run sequentially in the remaining columns.” in Testing section. Changed the word “undefined” to “one or more tests are not completed” in 6th bullet point of “Cassettes” section. Added the bullet point “Ensure your sample preparation centrifuge is calibrated to achieve an 80-90% packed cell concentration. This will allow you to achieve a cell suspension of 3-4% and 0.8%, based on the test requirement.” in Samples section. Changed the word “next” to “subsequent” in 5th bullet point of Samples section. Changed the text “Performance of the daily and weekly routine maintenance tasks” to “Performance of the daily maintenance task” in 5th bullet, 2nd sub point of Samples section.

(Continued)

Title	Location	Description
Introduction	• On the System: Summary of System Performance Characteristics and Specifications (page 1-15) • On the USB: Chapter 1, Introduction: “Summary of System Performance Characteristics and Specifications”	Removed the “Metering Dead Volume - The metering dead volume for reagents and plasma samples is 8 µL” and added “Metering Dead volume of Serum, Cells_08 (reagent), Cells_35 (reagent), and Reagent with Dispense Count” table in System Performance Specifications section.
Introduction	• On the System: Available Tests (page 1-20) • On the USB: Chapter 1, Introduction: “Available Tests”	Added the IMPORTANT statement “When using the ABD/Reverse Cassette (product code 6986736) it is mandatory that the ORTHO BioVue® System Rh/K Cassette (product code 707250/707280) be run in parallel. Results from the same sample run in the control column of the Rh/K Cassette will be used as the control for the sample run in the ABD/Reverse Cassette and determine the validity of the test results.” in Available Tests section. Added the Notes “The BioVue® Rh/K II Cassette used for the Rh/K II-14 test has the same intended use as the BioVue® Rh/K Cassette used for the Rh/K-77 test, therefore both serve as qualitative tests for the recognition of the C (RH2), E (RH3), c (RH4), e (RH5) and K (K1) antigens on human red blood cells for in vitro diagnostic use. The BioVue® Rh/K II Cassette includes antibodies of the same specificity but derived from different clones compared to the BioVue® Rh/K Cassette to comply with German regulations and therefore should be used in compliance with local regulatory requirements and lab practices.”, “The BioVue® ABD/Reverse Cassette is identified as 46: ABD/Reverse Cassette in the profile configuration screen. The test 46: ABD/Reverse Cassette will automatically include the 77: Rh/K Cassette and its associated tests. The selection of 46: ABD/Reverse Cassette will list either “ABD/Rev-46 + Rh/K-77 and/or UPR ABD/Rev-46 + sim 2”. The users can select the tests they want to include in the profile.” and “The ABD/Rev-46 + Rh/K-77 and UPR ABD/Rev-46 + Sim 2 tests utilize the new ORTHO BioVue® ABD/Reverse Cassette. The UPR ABD/Rev-46 + Sim 2 test may not be available for all regions and may not be visible during test profile configuration.” in Available Tests section. Added test names and short names “ABD/Rev-46 + Rh/K-77 – Not Applicable”, “UPR ABD/Rev-46 + sim 2 – Not Applicable” and “Rh/K II-14 – Rh/K II-14” in Available Tests section.

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Title	Location	Description
Safeguards and Precautions	• On the System: General Precautions (page 2-2) • On the USB: Chapter 2, Safeguards and Precautions: “Laser Safety Precautions”	As per Technical Bulletin (Laser Standard Update J65460) Removed the Year “2007” from the statement “The system is equipped with a Class 1 laser per IEC 60825-1: 2007” in Laser Safety Precautions section.
Safeguards and Precautions	• On the System: System Cleaning (page 2-7) • On the USB: Chapter 2, Safeguards and Precautions: “System Cleaning”	Changed the 2nd Caution “Be sure to only use 70% isopropyl alcohol when cleaning the IMAGING SYSTEM” to “Be sure to only use a clean, dry, lint-free cloth when cleaning the IMAGING SYSTEM” in Solutions to Use section.
System Components	• On the System: PIPETTE and Liquid System (page 3-12) • On the USB: Chapter 3, System Components: “PIPETTE and LIQUID SYSTEM”	Changed “Replace Liquid Waste Container” to “Inspect Liquid Waste Container” in yearly maintenance list, in PIPETTE and LIQUID SYSTEM Maintenance Tasks section.
Startup and Shutdown	• On the System: System Shutdown (page 4-3) • On the USB: Chapter 4, Startup and Shutdown: “System Shutdown”	Added the IMPORTANT statement “The master computer is completely shut down when the monitor screen is black and the LED is blinking. If you power off the system while the master computer is still running, you risk losing data, or corrupting the operating system” after the statement “The system is safe ....” in Normal Shutdown section.
User Interface	• On the System: The Dashboard (page 5-4) • On the USB: Chapter 5, User Interface: “The Dashboard”	Added the statement “Touch anywhere on the Dark Blue portion of the quadrant to display the function screen information.” in the 'The Dashboard' section. Removed the statement “Touch anywhere on the dark blue portion of the quadrant to display the Resources screen.” from the 'Resources' section. Removed the statement “Touch anywhere on the dark blue portion of the quadrant to display the Samples screen.” from the 'Samples' section. Removed the statement “Touch anywhere on the dark blue portion of the quadrant to display the Results screen.” from the 'Results' section. Changed the 3rd bullet point from “The number of samples that are in test processes” to “The number of samples that are assigned to tests that are currently processing” in Samples section. Changed the 1st bullet point from “The number of test results that require review” to “The number of orders with results that require review” in Results section.

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Title	Location	Description
Resources	• On the System: Cassettes (page 7-11) • On the USB: Chapter 7, Resources: “ Cassettes”	Changed and modified the IMPORTANT statement “Make sure resources are not expired. Check the expiration date on the label. When expired resources are detected by the system, an error is posted and the resource is moved to the MANUAL REVIEW RACK to be discarded. To load a sleeve with more than one lot, leave an empty slot between lots.” into two separate IMPORTANT statements “Make sure Cassettes are not expired. Check the expiration date on the label. When expired Cassettes are detected by the system, an error is posted and the Cassette is moved to the MANUAL REVIEW RACK to be discarded.” and “To load a sleeve with more than one lot, leave an empty space in the sleeve between lots.” in Cassettes section. Changed the IMPORTANT statement from “The system assumes resources in groups separated by an empty slot are all the same type of test. Do not mix resources within a group” to “To load Cassettes of different types in the same sleeve, leave an empty space between each Cassette type.” in Cassettes section.
Resources	• On the System: Supported Cassettes (page 7-12) • On the USB: Chapter 7, Resources: “Supported Cassettes”	Added two new Cassettes “BioVue® Rh/K II Cassette” and “BioVue® ABD/Reverse Cassette”.
Resource Categories	• On the System: Materials Required But Not Supplied (page 8-2) • On the USB: Chapter 8, Resource Categories: “Materials Required But Not Supplied”	Added the text “and some ORTHO™ Sera tests” in the second Note.
Samples	• On the System: Create Order (page 9-6) • On the USB: Chapter 9, Samples: “Create Order”	Added the Note “When running panel tests, the lowest numbered cell selected will run in column 1 of the Cassette, the remaining cells selected for that Sample will follow sequentially in the remaining columns.” in Assigned Profiles sub section.
Samples	• On the System: Load/Unload Samples (page 9-13) • On the USB: Chapter 9, Samples: “ Load/Unload Samples”	Changed the 3rd bullet point “Centrifuged whole blood and packed cells have been prepared” to “Whole Blood and packed cells samples are centrifuged.” in Load Samples section.

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Title	Location	Description
Samples	• On the System: Sample Specifications (page 9-14) • On the USB: Chapter 9, Samples: “Sample Specifications”	Changed the word “next” to “subsequent”, “microtubes” to “columns” and added the statements “The number of columns affected is dependent on the magnitude of the high titer sample”, “to review column results for all plasma and/or cells dispenses that occurred after the high titer sample and” in Antibody Titers section.
Samples	• On the System: Serial Dilution and Red Cell Suspension (page 9-18) • On the USB: Chapter 9, Samples: “ Serial Dilution and Red Cell Suspension”	Added “The user needs to select the start and end for a dilution level (example 1:8) where the options are from 1:1 to 1:1024. The start selection will be defaulted to 1:1 and the end selection will be defaulted to 1:1024. The user must select an end dilution that is equal to or greater than the starting point. If a dilution starting of greater than 1:1 is selected the system will still use dilution wells to dilute each step. A control will always be run with the test.” after the second sentence in the Serial Dilution section.
Samples	• On the System: Minimum Sample Fill Volume Recommendations (page 9-28) • On the USB: Chapter 9, Samples: “Minimum Sample Fill Volume Recommendations”	Removed the text “at a target volume of 50 µL” from the sentence “The guidelines represent the minimum quantity of centrifuged ……” in Minimum Sample Fill Volume Recommendations section. Added two new sections “Sample Containers” and “Micro-Collection Containers” in Minimum sample fill volume Recommendations.
Samples	• On the System: Create an Order (page 9-32) • On the USB: Chapter 9, Samples: “Create an Order”	Added the Note “When running panel tests, the lowest numbered cell selected will run in column 1 of the Cassette, the remaining cells selected for that Sample will follow sequentially in the remaining columns.” in step 7.
Setup	• On the System: Testing (page 14-11) • On the USB: Chapter 14, Setup: “ Testing”	Added bullet point “Require Manual Review of UDP” in Automatic Result Acceptance Rules sub section of Test Settings section.

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Title	Location	Description
Setup	• On the System: Profiles (page 14-13) • On the USB: Chapter 14, Setup: “ Profiles”	Removed the sentence “Yes: The profile must be successfully QC tested with the method based QC strategy. An order with the profile will only run if a QC tested reagent and lot set exists.” in QC Mode Description profiles section. Added sentences “MBC: The profile must be successfully QC tested with the method based (MBC) QC strategy.” , “BRC: The profile must be successfully QC tested with the blood bank reagent (BRC) based QC strategy.” in QC Mode Description profiles section. Modified the sentence “No QC: The profile does not require method based QC testing. The normal allocation strategies can be applied for the orders of the profile” as bullet point in QC Mode Description profiles section. Added Information item and Description “Profile QC Interval [h] - The QC Interval defined for the profile. Options: Global QC Interval or the number of hours (if different than the Global QC Interval).” in profiles section.
Setup	• On the System: Set Up an IH Profile (page 14-30) • On the USB: Chapter 14, Setup: “Set Up an IH Profile”	Added the Note “The selection of each test automatically includes the set of Cassettes types, by default. You cannot deselect the default Cassette type.” in step 10. Added the point and Note “For MBC QC Management Mode, select QC Interval Length for Profile [h] to enter a profile specific QC Interval. If no value is entered, the default interval will be the Global QC Interval.” , and “Note: The option “QC Interval Length for Profile [h]” is only available if the setting “Allow Override of Global QC Interval Length Per Profile” is enabled.” in step 11.
Maintenance	• On the System: Yearly and As Required Maintenance (page 16-6) • On the USB: Chapter 16, Maintenance: “Yearly and As Required Maintenance”	Changed the bullet point “Replace Liquid Waste Container” to “Inspect Liquid Waste Container” in Yearly Maintenance section.

Refer to the Library for Revision Histories of previous versions.

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Chapter 1 Introduction

Introduction Overview

This chapter provides an introduction to the ORTHO VISION® Analyzer and summarizes some of the main features and specifications of the system.
Use this chapter to review the Intended Use, system requirements, performance characteristics, available tests, and additional information to help you get started using your system.

This chapter reviews the topics listed below:

Manufacturer's Contact Information

Ortho-Clinical Diagnostics

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United Kingdom

Ortho provides hardware and software technical support for the ORTHO VISION® Analyzer. For field service or technical support, contact Ortho Care™ Technical Solutions Center (Ortho Care) provided by your local Ortho company or distributor.

Intended Use

ORTHO VISION® Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing the Ortho BioVue® System cassette technology. ORTHO VISION® Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cassettes and digital image processing. ORTHO VISION® Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).

Trademarks and Third Party Disclosures

Trademarks

- MICROTAINER® is a registered trademark of Becton, Dickinson and Company.

- Eppendorf® is a registered trademark of Eppendorf AG.
- MiniCollect® is a registered trademark of Greiner Bio-One GmbH.
- Safe-T-Fill® is a registered trademark of RAM Scientific, Inc..
- Microvette® is a registered trademark of Sarstedt.
- CapiJect® is a registered trademark of Terumo Medical Corporation.
- Alba Q-Chek® is a registered trademark of Alba Bioscience, Inc..

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- Blood Bank Reagent Control (BRC)® kit
- ORTHO CONFIDENCE™ WB Simulated Whole Blood Quality Control Kit
- ORTHO VISION® Analyzer
- ORTHO® BLISS (BioVue Low Ionic Strength Solution)
- RESOLVE®
- SURGISCREEN®
- EASYNAV™ Software

Third Party Software Disclosures

Name	Manufacturer
Barcode 128 fonts 1.1	Grandzebu
DTK Barcode Reader	http://www.dtksoft.com/
Intel Gigabit Network drivers	Intel Corporation
Internet Explorer 9	Microsoft
Lexmark Universal print driver	Lexmark
Axeda	PTC
Realtek Audio Driver	Realtek Semiconductor
UltraVNC	Questra/FOSS GPL v2
Windows 10 IoT Enterprise x64	Microsoft
Tecan WinUSB Driver	Tecan Schweiz AG
Cylance Protect	BlackBerry

Limitations

Testing

- The ORTHO VISION® Analyzer is designed to process immunohematology tests only, and does not support other types of tests commonly performed in clinical laboratories.
- When running panel tests, users should be aware that the lowest numbered cell selected will run in column 1 of the Cassette, and the remaining cells selected for that sample will run sequentially in the remaining columns.
- The system does not support evaporation caps on 5 mL Bloodbank Reagent Control (BRC) vials.
- Ortho will not be responsible for any consequential or incidental damages resulting from the sale of, use of, or improper operation of this equipment.
- A Sample ID can only be reused for different blood samples once it has been archived. If an archived Sample ID is reused, patient demographic information must be entered through the LIS to distinguish between Sample IDs. Sample IDs should not be reused if the associated patient demographics cannot be entered through an LIS.
- Cassettes cannot be loaded through the LOAD AREA of the DUAL PURPOSE DRAWER.
- Ortho recommends that you restart the system if you experience excessive rates of slow system responses.
- When naming profiles or tests, avoid using non-alphanumeric characters such as “&”, “+”, etc.
- Ortho does not recommend running multiple serial dilutions at the same time against the same sample. Running multiple serial dilutions may affect the reaction strengths.
- Attempts to manually upload large files, such as uncompressed images from several days of processing, may be unsuccessful. Ortho recommends that uploads are limited to no more than two days of uncompressed image files at one time.
- Partially completed orders will be automatically cancelled if not completed within 24 hours.
- Routine orders that have already started will continue to process when a STAT sample is added; this can potentially affect the completion time.
- An order cannot be modified once test processes begin for any test assigned to the order.
- A result can no longer be edited once a result has been accepted with the Accept Result button.
- Any results data or changes to system configurations that occurred since the last successful backup event will be lost with the recovery.
- The backup media used (folder location, USB) must be a minimum of 32 GB.
- Data older than six months is automatically removed from the system database. If a backup containing data older than 6 months is restored to the system, the data older than 6 months will be automatically removed from the restored database. The backup database remains intact.
- The system is not designed to automatically report hemolysis as a final result; however, a ‘CI’ microtube result will be reported for a microtube that cannot be appropriately graded as result of contrast interference (CI), often caused by hemolysis.
    - The user, upon manual review of the result, can enter a comment of hemolysis, if hemolysis is observed.
- Antigen typing tests with mixed field will be resulted as mixed field ‘MF’, requiring users to determine the appropriate grading based on patient history and clinical information.
- When the user initiates stop processing in the middle of an operation: an Urgent Stop will stop all operations in process, while Stop Processing will continue processing all orders started, but will not start any new orders.

- RhD antigen testing in ORTHO BioVue®Cassettes containing Anti-D is performed by direct agglutination; therefore, very weak expressions of D may not be detected and may require the use of a validated antiglobulin test for detection.
- When a sample is collected from a recently transfused patient, the potential exists for the transfused red cells to concentrate after centrifugation at the bottom of the sample tube below their autologous cells. The probe aspirates from the bottom of the tube where the transfused cells generally concentrate which may lead to an unexpected result.

DANGER: After making any Load/Unload request, only make changes in the LOAD STATION position for which access was requested on the APPLICATION SOFTWARE screen. The system does not inventory load station positions that were not selected through the APPLICATION SOFTWARE screen.

- The system does not inventory samples that were not selected through the APPLICATION SOFTWARE screen.
- The analyzer does not rescan sample barcode of the two sample tube positions briefly exposed to the user in the left adjacent sample rack during sample rotor access.

Conditions

- System operation outside of the validated laboratory settings, listed below, has not been established.
  - The system was validated in the power supply range of 100–240 V AC at 50 & 60 Hz.
  - The system was validated under the following environmental conditions:
    - Temperature: 18 - 30°C (64.4 - 86.0°F)
    - Relative Humidity: 15 to 85% (non-condensing)
    - Altitude: 0 m (0 ft) to +2438 m (+8000 ft)
- Under ambient conditions of high temperature and humidity, condensation from system coolers may collect on table surfaces. Contact Ortho Care to request installation of an additional drainage line.
- The full functionality of the system and software is based on user configurable options.
  - It is the administrative user's responsibility to configure and validate these options in compliance with the regulations governing your facility.

Cassettes

- The system is designed to use ORTHO BioVue® Cassettes manufactured by Ortho Clinical Diagnostics only.
- Cassettes containing bubbles in the beads should not be used.
- After a system shutdown, do not remove cassettes from the INCUBATOR, CENTRIFUGE, or the GRIPPER for reuse on the system. The system will perform the appropriate cleanup operations and will automatically discard the cassettes.
- Do not remove cassettes from the WASTE DRAWER for reuse on the system.
- The Cassette WASTE DRAWER is assumed to be empty when the system is started. The capacity of the WASTE DRAWER is not physically measured; available capacity is determined by cassette count.
- When running a profile requiring a discrepancy check between two tests, the system places the first cassette in the review rack pending the results of the second cassette. If the user then selects the graphic of the first cassette, the system displays a status of "one or more tests are not completed" because results of the discrepancy check are incomplete.
- The SUPPLY DRAWER is not intended for long-term storage of cassettes. Unused cassettes should be removed and returned to storage upon completion of the days testing.

- The SUPPLY DRAWER is temperature monitored, but not under active temperature control.
- When there is a SUPPLY DRAWER error, such as expired contents, the system may indicate that the same error applies to the contents of the DUAL PURPOSE DRAWER or the WASTE DRAWER. Resolving the error in the SUPPLY DRAWER will resolve the error for the DUAL PURPOSE DRAWER or the WASTE DRAWER.

Samples

- Do not use samples that are hemolyzed, lipemic or icteric as these conditions may lead to discrepant or Indeterminate (IND) interpretations or to no result due to an error.
- Do not use clotted or incompletely anti-coagulated samples as they may interfere with instrument pipetting.
- Fibrin or particulate matter can interfere with reaction interpretations.
- Ensure your sample preparation centrifuge is calibrated to achieve an 80-90% packed cell concentration. This will allow you to achieve a cell suspension of 3-4% and 0.8%, based on the test requirement.
- A sample with a very high-titered antibody (>1:1024) when tested for antibody screening may intermittently cause carry-over in the subsequent pipetted sample.
  - Carry-over was not observed in samples with antibody titers of 1:512 or 1:1024 under normal operating conditions.
  - Performance of the daily maintenance task, outlined in the ORTHO VISION® Analyzer Reference Guide will act to decrease the potential for carry-over when a sample containing a high-titered antibody is encountered.
- The LOAD STATION is not intended for long-term sample storage: samples should be removed from the LOAD STATION if not tested within 4 hours.

Reagents

- System performance with non-Ortho reagents and diluents that have not been approved for system use is unknown. Ortho does not assume responsibility for the results obtained with non-Ortho reagents and diluents. ORTHO Sera™ products, ORTHO BioVue® Cassettes, and Ortho Reagent Red Blood Cells and Diluents are the only products approved for use on the system.
- The system does not provide a means for control or tracking of reagent preparation steps required before reagents are placed on the instrument.
- On analyzer stability of Reagent Red Blood Cells without the use of evaporation caps has not been validated.
- Ortho Reagent Red Blood Cells BioVue® Screen, Resolve® (Panels A, B, C) and 0.8% Resolve® (A, B, C) are not intended to be stored on the system and should be removed from the system, sealed with original closure cap, and stored at 2 to 8° C when not in use.
- Do not store Reagent Red Blood Cells that require agitation on-board the system if the system is going to be powered off or in maintenance mode, otherwise they will be designated as unusable.
- Test routines will not begin unless a sufficient quantity of reagents with the same lot number are loaded on the system.
- The system tracks the storage duration of cassettes, reagents, and diluents while on-board and powered on. The user is responsible for monitoring if removed from the system.
- Reagent Red Blood Cells can be affected by evaporation, particularly in extreme laboratory conditions of low humidity and high temperature. Evaporation may lead to a “Too Many Cells (TMC)” error.
- The system is not intended for reagent or diluent long-term storage.

Startup, QC, and Maintenance

- If users exit the Daily, Weekly, Monthly, or As Needed Maintenance procedures via the Cancel button, tasks already performed will be marked as Failed and must be repeated.
- Testing will not start until the system, and each subsystem, has been initialized and in the ready state (for example, INCUBATOR at control temperature).
- The individual microtube results for QC must be reviewed prior to accepting the QC results.
- When lot tracking is off, it is possible for a reagent that has not undergone QC to be substituted for a reagent that has passed QC if the substitution occurs within the user specified QC interval. It is the responsibility of the user to manage QC lot changes when lot tracking is off.

Barcodes

- Sample barcodes must include checkdigit and checksums which must be enabled on the system configuration set up for positive identification to be guaranteed.
- Although the software reads sample, reagent, diluent and cassette barcode symbologies, it does not verify barcode quality.
- Positive identification of samples, reagents and cassettes is guaranteed only when barcode labels are automatically read by the instrument or by a manual barcode reader.
- The instrument has been validated to read barcodes with quality grades A-C that are not damaged, dirty or have multiple barcode labels on a sample tube.
- Sample barcodes are intended to be mounted vertically, therefore should be mounted vertically and facing out from the rotor to be read.
- The flag characters in an ISBT 128 barcode are not used for sample identification.
  - Each ISBT 128 Donation Identification Number must have a unique 13-digit number.

Getting Started

This section provides an introduction to the ORTHO VISION® Analyzer and additional information about the resources available to you.

Safety and Precautions

Review warnings and precautions to be taken before operating the system.

IMPORTANT: The system is intended for users who are qualified laboratory personnel with knowledge of immunohematology, under professional supervision and suitably trained to operate the equipment.

IMPORTANT: Use only Ortho BioVue® Cassettes with this system.

For more information, see Safeguards and Precautions Overview (page 2-1).

Self-Service

Self-Service Procedures are procedures that a user can perform themselves without the need for a service call.

WARNING: Proper training is required before a user can execute self-service procedures.

ORTHO VISION® Analyzer Functions

The primary functions of the system are:

- Liquid pipetting
- Reagent handling

- Incubation
- Centrifugation
- Reaction grading and interpretation by digital image processing
- Data management

System Components

The ORTHO VISION® Analyzer is made up of multiple system components that work together to complete test processes:

- UPS (optional)
- Application Data (AD)
- Printer (optional)
- FRAME
- HOUSING
- POWER SUPPLY
- MASTER COMPUTER
- APPLICATION SOFTWARE
- Load Station
- Waste Drawer
- Supply Drawer
- Dual Purpose Drawer
- GRIPPER
- Incubator
- Pipette Arm
- Probe
- Liquid System
- Centrifuge
- CASSETTE IMAGING SYSTEM

For more information, see System Components Overview (page 3-1).

Software Functions

The primary functions of the ORTHO VISION® Analyzer Software are:

- Identify samples, reagents, diluents, and Cassettes
- Control operations of the system:
  - Identify materials (Cassettes, reagents, diluents, and system liquids) required to process tests and warn operators if insufficient quantities are detected
  - Verify positions of barcoded samples and reagents on the sample and reagent racks
  - Execute tests
  - Monitor hardware functions such as incubator temperatures, centrifugation speed and other critical operations
  - Track partially used Cassettes for reuse prioritization
  - Identify and bring forward Cassettes that require manual review
  - Manage incubation time of Cassettes, as needed

  - Manage centrifugation
- Interpret test results
- Grade test results
- Store data of test results in short-term and long-term archives
- Download test requests from, and upload test results to the LIS
- Track operator and system actions
- Inform operators of maintenance and quality control schedules and requirements

For more information, see User Interface Overview (page 5-1).

What You Need to Process Tests

- Order – Orders can either be downloaded via the Laboratory Information System (LIS) or created manually on the Samples screen.

  For more information, see Create Order (page 9-6).
- Sample and appropriate Sample Rack

  For more information, see Sample Specifications (page 9-14).
- Required reagents and appropriate Reagent Rack

  For more information, see Reagents (page 8-2).
- Required Cassette

  For more information, see Supported Cassettes (page 7-12).
- Required diluents and Dilution Tray
- Evaporation caps – Evaporation caps are optional if reagents are not stored on-board the system.

  For more information, see On Analyzer Stability of Ortho Reagent Red Blood Cells (page 7-5)

Documentation

The documentation listed below is available to you on-board the system:

- ORTHO VISION® Analyzer Reference Guide
- ORTHO VISION® Analyzer Customer Procedures
- ORTHO VISION® Analyzer Help

For more information, see Available Documentation (page 6-3).

The documentation listed below is provided separate from the system, or can be requested from Ortho-Clinical Diagnostics, Inc.:

- ORTHO VISION® Analyzer Maintenance and Troubleshooting Guide
- ORTHO VISION® Analyzer Networking Guide
- ORTHO VISION® Analyzer LIS Guide

Documentation Notations

Notations call attention to important details. All notations should be read and understood to make sure you are prepared to properly operate the system.

Note: To emphasize or clarify information or instructions.

IMPORTANT: To emphasize information or instructions that are essential to read and follow.

Caution: To prevent damage to the equipment.

WARNING: To prevent actions that can cause personal injury.

DANGER: TO INFORM THE USER THAT A SAFETY RISK EXISTS.

Targets, Keys, and Buttons

As you move through the Library documentation you may see boxes around words, or different text used within a screen. Refer to the table below for the different styles used to recognize targets, keys, system prompts, or buttons encountered while operating the system.

Screen Convention	Example
Names of buttons on the screen appear with a blue background color.	Touch Close
Names of system components appear in upper-case.	PIPETTE
Glossary terms within the text appear underlined in blue.	Load Station
Links appear underlined in blue.	Library Overview (page 6-1)
Screen names are shown in a different typeface	Samples screen

Installation and Site Specifications

Although trained service personnel install the ORTHO VISION® Analyzer at the laboratory site, the site must be prepared according to site specifications.
This section describes general requirements for installation of theORTHO VISION® Analyzer at the site, including physical and environmental requirements.
For more information, see the topics listed below:

- Safety Requirements (page 1-9)
- Power Requirements (page 1-10)
- Physical Dimensions (page 1-12)
- Environmental Specifications (page 1-11)
- Site Requirements (page 1-14)

Safety Requirements

This system meets the international standards for safety for *in vitro* diagnostic electrical equipment. These standards are listed below:

- IEC 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use, Part 1: General requirements
- JIS C 1010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
- IEC 61010-2-010: Particular requirements for laboratory equipment for the heating of materials
- IEC 61010-2-020: Particular requirements for laboratory centrifuges
- IEC 61010-2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- IEC 61010-2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EMC Requirements

- IEC 61326-1 Electrical Equipment for Measurement, Control and Laboratory Use-EMC Requirements
- IEC 61326-2-6 Particular requirements - In vitro diagnostic (IVD) medical equipment
- JIS C 1806 -1 (equivalent to IEC 61326 using Japanese Voltage Requirement)
- IEC 61000-3-2: Limits - Limits for harmonic current emissions
- IEC 61000-3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems

For more information, see Safeguards and Precautions Overview (page 2-1) .

Power Requirements

The system requires one dedicated (3-wired single phase; line-neutral and single circuit) AC power line for connection to facility power.

Input Voltage	100 – 240 V AC	50/60 Hz	1000 VA
Circuit Type	Dedicated with isolated ground		
Receptacle Type	US and Canada – NEMA 5–15 Continental EU – CEE 7 (Shucko) Other regions – contact Ortho-Clinical Diagnostics, Inc. for specific information		
Power Cord	The POWER CORDS are region specific and will be provided by Ortho. **IMPORTANT:** Use ONLY the power cord provided with your instrument. The unit requires the use of a certified Class 1 grounded power cord and appliance coupling to provide for a connection to the protective earth conductor terminal on the instrument. The protective terminal is internally located in the instrument, indicated with the IEC60417-5017 symbol, accessible only by Ortho field service personnel.		
Overvoltage Category	Category II		
Pollution Degree	Degree 2		
Customer Replaceable Fuses	For continued protection against electrical hazard, use fuses of the same type and rating: FUSE, 16A SLOW-BLOW HIGH LOAD SPT CERAMIC.		
MAINS Supply Voltage Fluctuations	Up to ±10% of the nominal voltage		

AC Power Quality

The system is designed to perform with reasonable disturbances and voltage tolerance to the AC power. The quality and reliability of the power source is often dependent on the geographic location of the site. Some sites, where power quality is exceptionally poor, may require special power conditioning equipment to ensure that the tolerances are maintained within acceptable limits. Some models of Uninterruptible Power Supplies (UPS) are recommended as optional equipment.

Uninterruptible Power Supply

Caution: Ortho Clinical Diagnostics highly recommends the use of an Uninterruptable Power Supply (UPS). Operating the system without a UPS could lead to loss of tests in case of power loss and is not recommended.

Contact your sales representative for more information.

e-Connectivity®

A secure connection is established between the system and Ortho for remote support and data transfer.

For more information, see Interfaces (page 14-18).

Network Connection

The following are required for e-Connectivity® network connection:

IMPORTANT: An auxiliary means of establishing a connection must not be used for the network connection. For example, a dialup PPP connection to establish connectivity to the broadband connection must not be used.

Note: Category 5e or better cabling should be utilized for the network connection.

Note: A Category 5e cable with a male RJ45 connector is provided with the equipment. This cable is connected to the network port provided.

Note: Ortho is not responsible for any other equipment necessary to support the network connection.

- Continuous broadband connection or direct connection to the customer LAN with access to the Internet at a speed greater than or equal to 128 kbps.
- Support local area network port speeds of automatic, 10/100 Mbps with half and full duplex, and 1 Gb full duplex and automatic detection of duplex.
- Dynamic or Static IP Address, Subnet Mask and Default Gateway IP Address assigned by the Information Technology (IT) department and provided to Ortho Care.
- Female RJ45 connector on the network port within 20 feet of the center of the system.

Broadband Internet

A broadband Internet connection is required for e-Connectivity®, Ortho Chat and web site access.

Environmental Specifications

The environmental limits for normal operation of the system are defined and shown below.

- Operating Temperature: 18 - 30° C (64.4 - 86.0° F)
- Site Relative Humidity: 15 - 85% RH (non-condensing)
- Maximum Altitude: 2438.0 m (8000ft.)
- Heat Output: 3412 BTU/hr

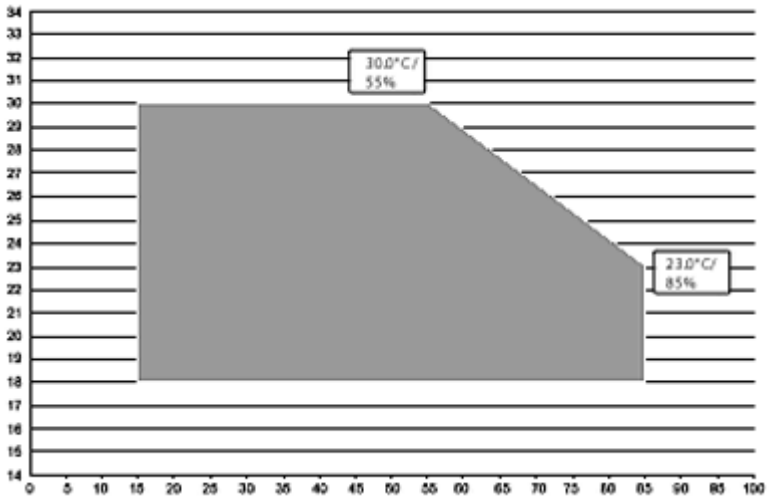
The environmental limits for normal operation of the system are defined and shown below.

- Operating Temperature: 18 - 30° C (64.4 - 86.0° F)
- Site Relative Humidity: 15 - 85% RH (non-condensing)
- Maximum Altitude: 2438.0 m (8000ft.)
- Heat Output: 3412 BTU/hr

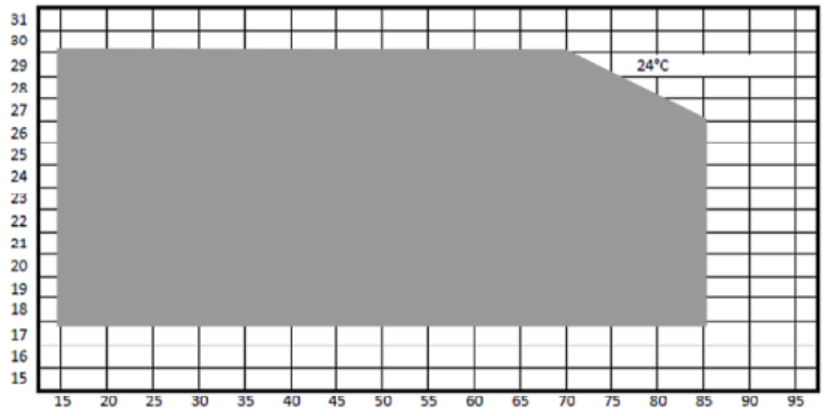
Note: An external ventilation system is not required.

Temperature-Humidity Range

If your system has an INCUBATOR without a COVER



If your system has an INCUBATOR with a COVER



Reagents

When performing tests with the ORTHO Sera™ specifically, Anti-Le[a] (REF 6904557), the external environmental temperature for automated testing is a maximum of 23° C. Weaker than expected positive test results may occur, if the ranges are not followed. For more information, see On Analyzer Stability of Ortho Reagent Red Blood Cells.

Non-Operational Environmental Conditions

The packaged system has been tested to withstand normal shipping and storage conditions without degradation. No special provisions are required for storage and transport.

Physical Dimensions

The following sections provide general component dimensions and a site image that illustrates setup and space requirements.

Dimensions

The table below provides the physical dimensions of the ORTHO VISION® Analyzer.

Width	107.4 cm (42.3 in.)
Depth	77 cm (30.31 in.)
Height	88.9 cm (35 in.)

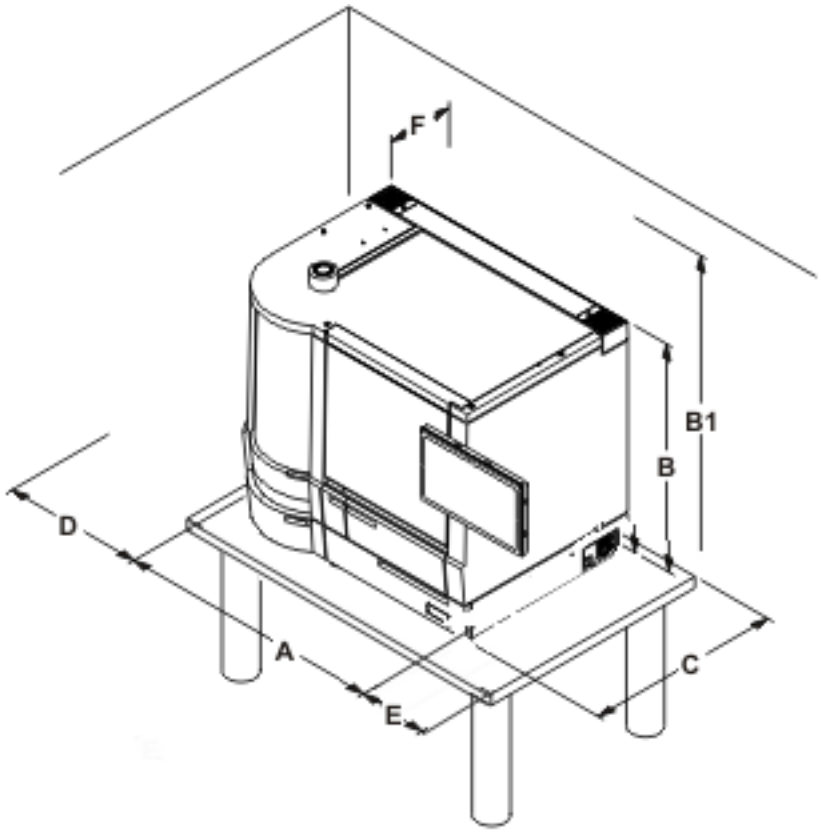
Weights

UPS*	22.7 kg (50.0 lbs)
Printer*	14.1 kg (31.1 lbs)
Liquid Waste Bottle (full)	5.4 kg (11.9 lbs)
Liquid Container (full)	5.6 kg (12.3 lbs)
ORTHO VISION® Analyzer	190 kg (419 lbs)

*Accessories available through Ortho.

Site Image

The site image below provides the physical dimensions of the system in operation and the space requirements of the location.



Reference	Dimension
A. Width	107.4 cm (42.3 in.)
B. Height	88.9 cm (35 in.)
B1. Height (with Maintenance Door open)	137 cm (54 in.)
C. Depth	77 cm (30.31 in.)
D. Room needed between the wall and the system, for access to the Load Station.	80 - 120 cm (31 - 47 in.)
E. Space for Monitor movement	15 cm (6 in.)
F. Space required for Ortho Care to access the system	System cannot touch wall

Entrance to Room

The entrance to the room where the system is to be located, should be a minimum of 75 cm (29.52 in.) wide.

Site Requirements

Telephone Access	A telephone should be available within the area that the system is located. This is recommended to allow users access to the system when working with Ortho-Clinical Diagnostics, Inc. service personnel via phone.
Storage	Storage space is needed for consumable supplies.
Location	• The system should be located on a work bench or table in an area that allows the drawer to be opened. • The printer and UPS can be located under the system on the bottom shelf of the table. The printer will require a standard wall outlet. A customer added UPS requires a dedicated power outlet. • The ORTHO VISION® Analyzermust not be within 185 cm (6 ft.) of any equipment that produces excess vibrations, such as centrifuges or cell washers.
Ambient Light	The system should not be located in an area of direct sunlight.

Summary of System Performance Characteristics and Specifications

The system performance specifications define the range of performance levels of the ORTHO VISION® Analyzer intended to support the available test menu. The actual performance parameters (such as incubation temperature, incubation duration, nominal metered values, etc.) are based on the Ortho BioVue® Cassette Instructions for Use, and are defined and fixed in software. Performance parameters, therefore, respect the method protocols defined in the Ortho BioVue® Cassette Instructions for Use, and are not selectable by the operator.
The tables below summarize system performance characteristics, capacities, and computer and interface specifications. Consult the Instructions for Use for individual test performance characteristics.

Sample and Test Performance Characteristics

Characteristic	Description
Technology	Column Agglutination Technology; with the use of Cassettes
Test Menu	• ABO and Rh Typing • Rh/K Phenotype • Antibody Screen • Antibody Identification • Crossmatch • Direct Antiglobulin • Antigen Testing • QC Testing • Serial Dilutions for Titration Studies For more information, see Available Tests (page 1-20).
Supported Sample Types	• Centrifuged whole blood (anticoagulated) • Plasma and Serum • Packed red blood cells • 3-5% Red cell suspension (Pre-diluted Patient/Donor) • 0.8% Red cell suspension (Pre-diluted Patient/Donor)
Sample Containers	Sample Racks accommodate Patient Sample Tubes. Racks and tubes are available in multiple sizes. For more information, see Load Station Supplies (page 9-23).

(Continued)

Sample Tube Sizes	• 16 x 100 mm (10 mL)
	• 16 x 75 mm (7 mL)
	• 12-13 x 100 mm
	• 12-13 x 75 mm
	• 10.25 x 75 mm
	• 10.25 x 64 mm (2.5 mL)
	• 10.25 x 47 mm (5 mL)
	• 2.0 mL and 1.5 mL Micro-collection Container 11 x 41 mm (Eppendorf® or equivalent)
	• 15 x 92 mm (Sarstedt S-Monovette 7.5 mL)
	• 13 x 90 mm (Sarstedt S-Monovette 4.9 mL)
	• 13 x 75 mm (Sarstedt S-Monovette 2.7 mL)
	• 8 x 66 mm (Sarstedt S-Monovette® 1.2 mL K3E)
	• 11 x 66 mm (Sarstedt Monovette® 2.7 mL K3E)
	• 13 x 65 mm (Sarstedt Monovette® 3.4 mL K3E)
	• 13 x 65 mm (Sarstedt Monovette® 2.6 mL K3E)
	• 11 x 92 mm (Sarstedt Monovette® 4.5 mL K3E)
	• Pediatric Containers:
	  • Eppendorf® (1.5 mL or equivalent diameter, length and cap) Micro-centrifuge Tube
	  • Terumo CapiJect® Capillary Blood Collection Tubes
	  • Greiner MiniCollect® Capillary Blood Collection Tube (0.5 mL and 1.0 mL)
	  • RAM Scientific Safe-T-Fill® Capillary Blood Collection Tube (200 µL and 300 µL, without optional tube extender)
	  • Sarstedt Microvette® (200 µL and 500 µL, with cylindrical inner vessel)
	  • TEKLAB (2 mL)
	  • Becton-Dickinson (B-D) Microtainer® (with or without optional extender)
	  • Becton-Dickinson (B-D) Microtainer® MAP Microtube for Automated Process
	  • 10.8 x 41 mm (Sarstedt Micro Tube 1.3 mL K3E)
	  • 10.8 x 45 mm (Sarstedt Micro Tube 1.3 mL screw cap K3E)

Sample and Test Processing Plumbing	Continuous, random, STAT access and batch (STAT samples can be processed with STAT priority processing at any time). Self-contained, on-board liquid waste management eliminates the need for off-board plumbing. An optional drain kit for waste management is also available.

System Performance Specifications

Characteristic	Description

(Continued)

Centrifuge Performance Specifications

- Process Step 1:
  - Speed: 783.3 – 803.3 rpm
  - G-force: 50 – 60 G
- Process Step 2:
  - Speed: 1499.9 – 1519.9 rpm
  - G-force: 194 – 204 G

Incubator Performance Specifications

Cassettes are incubated at 35°C – 39°C for at least 10 minutes (based on the specific test protocols).

The room temperature Incubator is maintained at 21°C – 27°C.

PIPETTE Performance Specifications

Volume	Accuracy (ACC%)	Precision (CV%)
Serum/ Plasma: 40 µL	+/– 5%	<5%
Diluted RBC: 10 µL (4% dilution)	+/– 10%	<10%
Diluted RBC: 50 µL (0.8% dilution)	+/– 10%	<5%
RBC Reagent: 10 µL (4% dilution)	+15% / –10%	<10%
RBC Reagent: 50 µL (0.8% dilution)	+15% / –10%	<5%
Bliss Reagent: 50 µL	+/– 10%	<5%
Bromelin Reagent: 40 µL	+/– 10%	<5%
ORTHO™ Sera Reagent: 40 µL	+/– 5%	<5%

PIPETTE Volume Verification Criteria

Volume	Acceptance Criteria (ACC% and CV%)
40 µL	≤5%
50 µL	≤5%

Wash Pump Performance Specifications

The Wash Pump dispenses liquids at ≥2 mL per second.

Metering dead volume	**Dispense Count**	**Serum (µL)**	**Cells_08 (reagent) (µL)**	**Cells_35 (reagent) (µL)**	**Reagent (µL)**
	1	50	14	3	14
	2	50	14	3	14
	3	50	15	3	15
	4	56	20	4	20
	5	70	25	5	25
	6	84	30	6	30
	7	98	35	7	35
	8	112	40	8	40
	9	126	45	9	45
	10	140	50	10	50
	11	154	55	11	55
	12	168	60	12	60
Load Station Temperature	The agitated inner rotor is maintained at 18°C – 25°C.				

System Capacities

Characteristic	Description
Load Station Capacity	OUTER ROTARY RING (non-agitated area): • 6 Interchangeable Sample Racks • 6 Interchangeable Dilution Trays • 1 DILUENT RACK INNER ROTARY RING (agitated area): • 3 RBC Reagent Racks
Reagent Red Blood Cell Supply	Any combination of 3 racks can be used to accommodate Reagent Red Blood Cell (RRBC) testing needs. The 10 mL rack can accommodate reverse grouping and antibody detection (screen) RRBC. The 3 mL rack can accommodate antibody identification RRBC. For more information about supported reagents, see Reagents (page 8-2).
Diluent Supply	The system capacity for diluent supply is listed below: • 1 50 mL position for ORTHO® BLISS • 1 60 mL position for Red Cell Diluent • 5 10 mL positions for Red Cell Diluents For more information about supported reagents, see Reagents (page 8-2).
Supply Drawer Capacity	140 Cassettes

(Continued)

Sample Capacity	Up to 42 samples can be loaded, 7 on each Sample Rack.
Waste Capacity	The system contains one Waste Tray and one Liquid Waste Bottle. • Waste Tray Capacity – 100 Cassettes • Liquid Waste Bottle Capacity – 5.2 L For more information, see Containers (page 8-1) .
Centrifuge Capacity	20 Cassettes (10 Cassettes per Centrifuge)
Incubator Capacity	Heated Incubation – 12 Cassettes Room Temperature Incubation – 16 Cassettes **Note:** The Incubator has 24 total positions, but only 16 are available for use.

eConnectivity®

Characteristic	Description
Interactive System Management	Provides real-time, secure, two-way interactive connection between your system and Ortho-Clinical Diagnostics, Inc..
Automatic Two-Way Data Exchange	Automatically send and retrieve data with Ortho Care. Data regarding multiple aspects of system performance can be automatically transferred to Ortho Care for real-time analysis. Includes automatic download of system software updates.
Remote Connectivity	Provides the ability to connect your system to Ortho-Clinical Diagnostics, Inc. in a way that enables remote diagnostics. Remote connectivity includes the ability for Ortho Care to perform remote control operation of the system, as well as, monitor and review system configuration, data, and performance information.

System Computer and Interface Specifications

Characteristic	Description
Operator Interface	**Monitor**– Ergonomically designed, flat screen monitor, with touch interface, that provides for flexible positioning for customized operator interaction. **Keyboard** – The on-screen keyboard is the primary keyboard interface. **Application Data (AD)** – Software that contains test protocol definitions. The AD can be delivered directly to the system with eConnectivity® or uploaded to the system from a media device. **IMPORTANT:** Ensure that the correct AD is loaded for your system. Japan requires a unique AD.
Computer Specifications	RAM – 8 GB CPU – minimum of 2.1GHz Hard Drive – 1 TB
Interface Specifications	Bidirectional protocols for a Laboratory Information System (LIS). For more information, see Interfaces (page 14-18).

(Continued)

Remote Review Station	An optional computer that is dedicated to the ORTHO VISION® Analyzer, located outside the laboratory, on the laboratory's network where authorized people can review results. **Note:** Ortho does not provide the Remote Review Station.
Universal Sample Barcode Reader	Reads, with auto-discrimination capability, the standard barcode symbologies listed below. • 2 of 5 (Interleaved) • Code 3 of 9 (Code 39) • NW7 (Codabar) • Code 128 (A, B and C subtypes) • ISBT 128 Only these standard symbologies are approved for use on patient sample containers. **DANGER:** The system cannot verify the quality of the barcode used. For more information, see Barcode Labels (page 9-19).
Reagent Barcode Readers	Reads internal proprietary labels to identify consumables, reagents, diluents, and Cassettes. Code 128 is supported.
Communication Ports	The system provides the I/O ports listed below: • 1 DB-9 serial port (RS-232 port for LIS support) • 1 RJ45 LAN port supports port speeds of automatic, 10/100 Mbps with half and full duplex, and 1 Gb full duplex and automatic detection of duplex. • Line out jacks for audio cable V 2.0/ V 1.1 USB ports are located on the right side panel and are available for the functions listed below: • Printer • Mass Storage Device • Keyboard • Mouse • Handheld Barcode Scanner

Printer Specifications

Characteristic	Description
Standard laser printer for the system. Printers are ordered in accordance with regional specifications.	Serves as an output device for system reports. Results, quality control, and a variety of other reports can be created and printed for distribution outside the laboratory.

Available Tests

The tables below list the tests that can be processed on the system.

IMPORTANT: When using the ABD/Reverse Cassette (product code 6986736) it is mandatory that the ORTHO BioVue® System Rh/K Cassette (product code 707250/707280) be run in parallel. Results from the same sample run in the control column of the Rh/K Cassette will be used as the control for the sample run in the ABD/Reverse Cassette and determine the validity of the test results.

Note: The availability of these tests in certain markets is subject to regulatory clearance or approval.

Note: The Reference Guide lists ORTHO™ Sera Reagent Anti-D (IAT) as “Anti-DWK.” This is the same reagent.

Note: Not all classes of products are listed below. Outside the United States, when using a product that isn't listed, please refer to the User Defined Protocols (UDP) & User Defined Reagents (UDR) Guide.

Note: The BioVue® Rh/K II Cassette used for the Rh/K II-14 test has the same intended use as the BioVue® Rh/K Cassette used for the Rh/K-77 test, therefore both serve as qualitative tests for the recognition of the C (RH2), E (RH3), c (RH4), e (RH5) and K (K1) antigens on human red blood cells for in vitro diagnostic use. The BioVue® Rh/K II Cassette includes antibodies of the same specificity but derived from different clones compared to the BioVue® Rh/K Cassette to comply with German regulations and therefore should be used in compliance with local regulatory requirements and lab practices.

Note: The BioVue® ABD/Reverse Cassette is identified as 46: ABD/Reverse Cassette in the profile configuration screen. The test 46: ABD/Reverse Cassette will automatically include the 77: Rh/K Cassette and its associated tests. The selection of 46: ABD/Reverse Cassette will list either “ABD/Rev-46 + Rh/K-77 and/or UPR ABD/Rev-46 + sim 2”. The users can select the tests they want to include in the profile.

Note: The ABD/Rev-46 + Rh/K-77 and UPR ABD/Rev-46 + Sim 2 tests utilize the new ORTHO BioVue® ABD/Reverse Cassette. The UPR ABD/Rev-46 + Sim 2 test may not be available for all regions and may not be visible during test profile configuration.

ABO & Rh Grouping, Phenotype, DAT Program

Test Name	Short Name
ABO(FWD)/Rh-00	NA01-00
ABO(FWD)-ABODD-48	NA01-48
ABO(FWD)-ADDK-40	NA04-40
ABO(FWD)-D/CDE-44	NA04-44
ABO(FWD)-00	NA11-00
ABO(FWD)-44	NA12-44
ABD Conf-10	NA15-10
ABD Conf New Susp-10	NA15-10_NS
Rh-hr-11	NR01-11
Rh/K-77	NR02-77
ABD/Rev-46 + Rh/K-77	Not Applicable

(Continued)

UPR ABD/Rev-46 + Sim 2	Not Applicable
Rh/K II-14	Rh/K II-14
Kell-90	NR02-90
Kell+Control-95	NR02-95
4 ABO(RVS)-A1,A2,B	NA05-66
4 ABO(RVS)-A1,A2,B,O	NA08-66
4 ABO(RVS)-A1,B	NA10-66
4 ABO(RVS)-A1,B,O	NA16-66
08 ABO(RVS)-A1,A2,B	NA22-66
UPR ABO-Sim 2 (3)	EA22-66
08 ABO(RVS)-A1,A2,B,O	NA23-66
UPR ABO-Sim 3 (4)	EA23-66
08 ABO(RVS)-A1,B	NA24-66
UPR ABO-Sim 4 (2)	EA24-66
08 ABO(RVS)-A1,B,O	NA25-66
UPR ABO-Sim 5 (3-O)	EA25-66
4 ABO(FWD/RVS)/Rh-00	NA03-00
08 ABO(FWD/RVS)/Rh-00	NA12-00
4 ABO(FWD)-44 + (RVS)-A1,A2,B	NA05-4466
4 ABO(FWD)-D/CDE-44 + (RVS)-A1,A2,B	NA06-4466
4 ABO(FWD)-ABODD-48 + (RVS)-A1,A2,B	NA07-4866

(Continued)

4 ABO(FWD)-ADDK-40 + (RVS)-A1,A2,B	NA08-4066
4 ABO(FWD)-44 + (RVS)-A1,A2,B,O	NA09-4466
4 ABO(FWD)-D/CDE-44 + (RVS)-A1,A2,B,O	NA10-4466
4 ABO(FWD)-ABODD-48 + (RVS)-A1,A2,B,O	NA11-4866
4 ABO(FWD)-ADDK-40 + (RVS)-A1,A2,B,O	NA12-4066
4 ABO(FWD)-44 + (RVS)-A1,B	NA13-4466
4 ABO(FWD)-D/CDE-44 + (RVS)-A1,B	NA14-4466
4 ABO(FWD)-ABODD-48 + (RVS)-A1,B	NA15-4866
4 ABO(FWD)-ADDK-40 + (RVS)-A1,B	NA16-4066
4 ABO(FWD)-44 + (RVS)-A1,B,O	NA17-4466
4 ABO(FWD)-D/CDE-44 + (RVS)-A1,B,O	NA18-4466
4 ABO(FWD)-ABODD-48 + (RVS)-A1,B,O	NA19-4866
4 ABO(FWD)-ADDK-40 + (RVS)-A1,B,O	NA20-4066
08 ABO(FWD)-44 + (RVS)-A1,A2,B	NA25-4466
08 ABO(FWD)-D/CDE-44 + (RVS)-A1,A2,B	NA26-4466
08 ABO(FWD)-ABODD-48 + (RVS)-A1,A2,B	NA27-4866

(Continued)

08 ABO(FWD)-ADDK-40 + (RVS)-A1,A2,B	NA28-4066
08 ABO(FWD)-44 + (RVS)-A1,A2,B,O	NA29-4466
08 ABO(FWD)-D/CDE-44 + (RVS)-A1,A2,B,O	NA30-4466
UPR ABO/D-44 + Sim 4	EA30-4466
08 ABO(FWD)-ABODD-48 + (RVS)-A1,A2,B,O	NA31-4866
UPR ABO/DD-48 + Sim 4	EA31-4866
08 ABO(FWD)-ADDK-40 + (RVS)-A1,A2,B,O	NA32-4066
08 ABO(FWD)-44 + (RVS)-A1,B	NA33-4466
08 ABO(FWD)-D/CDE-44 + (RVS)-A1,B	NA34-4466
UPR ABO/D-44 + Sim 2	EA34-4466
08 ABO(FWD)-ABODD-48 + (RVS)-A1,B	NA35-4866
UPR ABO/DD-48 + Sim 2	EA35-4866
08 ABO(FWD)-ADDK-40 + (RVS)-A1,B	NA36-4066
08 ABO(FWD)-44 + (RVS)-A1,B,O	NA37-4466
08 ABO(FWD)-D/CDE-44 + (RVS)-A1,B,O	NA38-4466
UPR ABO/D-44 + Sim 3-O	EA38-4466
08 ABO(FWD)-ABODD-48 + (RVS)-A1,B,O	NA39-4866
UPR ABO/DD-48 + Sim 3-O	EA39-4866

(Continued)

08 ABO(FWD)-ADDK-40 + (RVS)-A1,B,O	NA40-4066
4 ABO(RVS)-6 cell	NA02-66
08 ABO(RVS)-6 cell	NA21-66
4 ABO(FWD)-44 + (RVS)-6 cell	NA01-4466
4 ABO(FWD)-D/CDE-44 + (RVS)-6 cell	NA02-4466
4 ABO(FWD)-ABODD-48 + (RVS)-6 cell	NA03-4866
4 ABO(FWD)-ADDK-40 + (RVS)-6 cell	NA04-4066
08 ABO(FWD)-44 + (RVS)-6 cell	NA21-4466
DAT Poly	ND01-22
DAT IgG, C3b,C3d	ND01-30
DAT IgG	ND02-33
Newborn	NC01-20

Antibody Screening and Crossmatch

Test Name	Short Name
08 AbScr Sel Poly	NS19-22
08 AbScr Sel IgG	NS19-33
08 AbScr Surg Poly	NS20-22
UPR 8 DEP_Nat 3 Poly	ES20-22
08 AbScr Surg IgG	NS20-33
08 AbScr BVSF Unt Poly	NS24-22
08 AbScr BVSF Unt IgG	NS24-33
08 ABSCR4 Poly	NS27-22
08 ABSCR4 IgG	NS27-33

(Continued)

08 AbScr Sel+Auto Poly	NU15-22
08 AbScr Sel+Auto IgG	NU15-33
08 AbScr Surg+Auto Poly	NU16-22
UPR 8 DEP_Nat 3 + Auto Poly	EU16-22
08 AbScr Surg+Auto IgG	NU16-33
08 AbScr BVSF Unt+Auto Poly	NU22-22
08 AbScr BVSF Unt+Auto IgG	NU22-33
4 AbScr Sel Poly	NS01-22
4 AbScr Surg Poly	NS02-22
4 AbScr Sel IgG	NS03-33
4 AbScr Surg IgG	NS04-33
4 AbScr Surg+Dia Poly	NS06-22
4 AbScr Surg+Dia IgG	NS07-33
4 AbScr Sel+Dia Poly	NS08-22
4 AbScr Sel+Dia IgG	NS08-33
4 AbScr Dia Poly	NS09-22
4 AbScr Dia IgG	NS09-33
4 AbScr BVSF Unt Poly	NS11-22
4 AbScr BVSF Unt IgG	NS11-33
4 AbScr BVSF Unt+Dia Poly	NS13-22
4 AbScr BVSF Unt+Dia IgG	NS13-33
4 ABSCR4 Poly	NS26-22
4 ABSCR4 IgG	NS26-33

(Continued)

4 AbScr Sel+Auto Poly	NU02-22
4 AbScr Surg+Auto Poly	NU03-22
4 AbScr Sel+Auto IgG	NU04-33
4 AbScr Surg+Auto IgG	NU05-33
4 AbScr Surg+Dia+Auto Poly	NU06-22
4 AbScr Surg+Dia+Auto IgG	NU07-33
4 AbScr Sel+Dia+Auto Poly	NU08-22
4 AbScr Sel+Dia+Auto IgG	NU08-33
4 AbScr Dia+Auto Poly	NU09-22
4 AbScr Dia+Auto IgG	NU09-33
4 AbScr BVSF Unt+Dia+Auto Poly	NU12-22
4 AbScr BVSF Unt+Dia+Auto IgG	NU12-33
4 AbScr BVSF Unt+Auto Poly	NU14-22
4 AbScr BVSF Unt+Auto IgG	NU14-33
4 BVSF Trt Neut	NS02-88
08 BVSF Trt Neut	NS26-88
08 BVSF Poly/Neut	NS24-55
UPR 8 DEP_Mixte	ES24-55
4 BVSF Poly/Neut	NS06-55
Bro 2ｾﾙｽｸﾘｰﾝ	NS21-88
Bro 3ｾﾙｽｸﾘｰﾝ	NS22-88
Bro Dia Neut	NS23-88
Bro 2ｾﾙｽｸﾘｰﾝ+Dia	NS24-88

(Continued)

Bro 3ｾﾙｽｸﾘｰﾝ+Dia	NS25-88
Bro 2ｾﾙｽｸﾘｰﾝ PLN	NS21-55
Bro 3ｾﾙｽｸﾘｰﾝ PLN	NS22-55
Bro 2ｾﾙ+Dia PLN	NS23-55
Bro 2ｾﾙ+自己 PLN	NU20-55
Bro Dia+自己	NU18-88
Bro 2ｾﾙｽｸﾘｰﾝ+自己	NU20-88
Bro 3ｾﾙｽｸﾘｰﾝ+自己	NU21-88
Bro 2ｾﾙ+Dia+自己	NU22-88
Bro 3ｾﾙ+Dia+自己	NU23-88
08 Auto Poly	NU17-22
08 Auto IgG	NU17-33
4 Auto Poly	NU10-22
4 Auto IgG	NU10-33
4 Auto IgG, C3b,C3d	NU10-30
Bro 自己対照	NU19-88
4 Min XM Poly	NX01-22_Min
4 Min XM IgG	NX03-33_Min
4 Maj XM Poly	NX01-22
4 Maj XM IgG	NX03-33
Bro ｸﾛｽ(主)	NX07-88
08 Maj XM Poly	NX06-22
08 Maj XM IgG	NX06-33
08 Min XM Poly	NX06-22_Min
08 Min XM IgG	NX06-33_Min
4 IS XM Rvs	NX05-66
08 IS XM Rvs	NX06-66

Antibody Identification

Test Name	Short Name
08 Panel A Poly	NI05-22
08 Panel A IgG	NI05-33

(Continued)

08 Panel B Poly	NI06-22
08 Panel B IgG	NI06-33
08 Panel C Unt Poly	NI07-22
UPR 8 ID_Nat 11 Poly	EI07-22
08 Panel C Unt IgG	NI07-33
08 Panel A+Auto Poly	NI12-22
08 Panel A+Auto IgG	NI12-33
08 Panel B+Auto Poly	NI13-22
08 Panel B+Auto IgG	NI13-33
08 Panel C Unt+Auto Poly	NI14-22
UPR 8 ID_Nat 11 + Auto Poly	EI14-22
08 Panel C Unt+Auto IgG	NI14-33
4 Panel A Poly	NI02-22
4 Panel A IgG	NI02-33
4 Panel B Poly	NI03-22
4 Panel B IgG	NI03-33
4 Panel C Unt Poly	NI04-22
4 Panel C Unt IgG	NI04-33
4 Panel A+Auto Poly	NI09-22
4 Panel A+Auto IgG	NI09-33
4 Panel B+Auto Poly	NI10-22
4 Panel B+Auto IgG	NI10-33
4 Panel C Unt+Auto Poly	NI11-22
4 Panel C Unt+Auto IgG	NI11-33

(Continued)

4 Panel C Trt Neut	NI13-88
08 Panel C Trt Neut	NI14-88
UPR 8 ID_Enz 11 Neut	EI14-88
08 Panel A IS Neut	NI05-88
08 Panel B IS Neut	NI06-88
08 Panel C Unt IS Neut	NI07-88
08 Panel A+Auto IS Neut	NI19-88
08 Panel B+Auto IS Neut	NI20-88
08 Panel C Unt+Auto IS Neut	NI21-88
4 Panel A IS Neut	NI02-88
4 Panel B IS Neut	NI03-88
4 Panel C Unt IS Neut	NI04-88
4 Panel A+Auto IS Neut	NI16-88
4 Panel B+Auto IS Neut	NI17-88
4 Panel C Unt+Auto IS Neut	NI18-88
4 Panel A+Brom Neut	NI09-88
4 Panel B+Brom Neut	NI10-88
4 Panel C Unt+Brom Neut	NI11-88
4 Panel A+Brom+Auto Neut	NI23-88
4 Panel B+Brom+Auto Neut	NI24-88
4 Panel C Unt+Brom+Auto Neut	NI25-88

Quality Control Tests

Test Name	Short Name
BRC ABD Surg	QA01-10
BRC Newborn Neg	QA01-20
BRC ABD Sel	QA02-10
BRC Newborn Surg	QA02-20
BRC 00 Neg	QA03-00
BRC Newborn Sel	QA03-20
BRC 00 Surg Pos	QA04-00
BRC ABD Fic	QA04-10
BRC 00 Sel Pos	QA05-00
BRC 10 WkD	QA05-10
BRC Newborn Fic	QA05-20
BRC 20 WkD	QA06-20
BRC ADK Neg	QA06-40
BRC ABO-Rh Neg	QA06-44
BRC 00 Fic Pos	QA07-00
BRC 20 B of A+B	QA07-20
BRC ADK Surg	QA07-40
BRC ABO-Rh Surg	QA07-44
BRC 00 WkD	QA08-00
BRC ADK Sel	QA08-40
BRC ABO-Rh Sel	QA08-44
BRC Rvs 2 cell	QA09-66
BRC ADK Fic	QA10-40
BRC ABO-Rh Fic	QA10-44
BRC Rvs 3 cell	QA10-66
BRC ABO-Rh E	QA11-44
BRC Rvs 4 Neg	QA11-66
BRC ABO-Rh C	QA12-44
BRC Rvs 4 Pos	QA12-66
BRC 40 WkD	QA13-40

(Continued)

BRC 44 WkD	QA13-44
BRC Rvs 6 Neg	QA13-66
BRC Rvs 6 Pos	QA14-66
BRC Rvs A1,B,O	QA15-66
BRC C3d Poly	QD01-22
BRC C3d DAT	QD01-30
BRC C3d Poly/Neut	QD01-55
BRC Rh-hr Surg Neg	QR03-11
BRC Rh/K Pos	QR03-77
BRC Rh-hr Surg Pos	QR04-11
BRC Rh/K Surg Neg	QR04-77
BRC Rh-hr Sel Neg	QR05-11
BRC Rh/K Sel Neg	QR05-77
BRC Rh-hr Sel Pos	QR06-11
BRC Rh/K Fic Neg	QR07-77
BRC Rh-hr Fic Neg	QR09-11
BRC Rh-hr Fic Pos	QR10-11
BRC 11 WkD	QR11-11
BRC IAT Surg	QS01-30
BRC IAT Sel	QS02-30
BRC 3 Poly Ltd	QS03-22
BRC IAT Fic	QS04-30
BRC 2 Poly	QS05-22
BRC 3 IgG Ltd	QS05-33
BRC 88 Fic	QS06-88
BRC BVSF Poly Ltd	QS07-22
BRC 2 IgG	QS07-33
BRC BVSF IgG Ltd	QS09-33
BRC 55 Fic Neg	QS11-55

(Continued)

BRC 55 Fic Pos	QS12-55
BRC 0.8% 3 Poly Ltd	QS13-22
BRC 0.8% 3 IgG Ltd	QS13-33
BRC 0.8% 2 Poly	QS14-22
BRC 0.8% 2 IgG	QS14-33
BRC 55 Bro 2cell Pos	QS15-55
BRC 88 Bro 2 cell	QS15-88
BRC 55 Bro 2cell Neg	QS16-55
BRC 88 Bro 3 cell	QS16-88
BRC 55 Bro 3cell Pos	QS17-55
BRC 55 Bro 3cell Neg	QS18-55

Antisera Tests

Note: The system does not consider mixed fields (“MF”) for ORTHO™ Sera tests. An actual mixed field reaction is reported as “Positive.

Note: The Reference Guide lists ORTHO™ Sera Reagent Anti-D (IAT) as “Anti-DWK.” This is the same reagent.

Test Name	Short Name
08 RAS Fya IgG	NI47-33
08 RAS Fyb IgG	NI48-33
08 RAS Jka Rvs	NI49-66
08 RAS Jkb Rvs	NI50-66
08 RAS MNS3 IgG	NI51-33
08 RAS MNS4 IgG	NI52-33
08 RAS K 2nd Rvs	NI58-66
08 RAS Weak D IgG	NI57-33
08 RAS M Neut	NI53-88
08 RAS Lea Rvs	NI55-66
08 RAS Leb Rvs	NI56-66
08 RAS P1 Rvs	NI59-66

(Continued)

08 RAS DVI Rvs	NI60-66
4 RAS Fya IgG	NI67-33
4 RAS Fyb IgG	NI68-33
4 RAS Jka Rvs	NI69-66
4 RAS Jkb Rvs	NI70-66
4 RAS MNS3 IgG	NI71-33
4 RAS MNS4 IgG	NI72-33
4 RAS K 2nd Rvs	NI78-66
4 RAS Weak D IgG	NI77-33
4 RAS M Neut	NI73-88
4 RAS Lea Rvs	NI75-66
4 RAS Leb Rvs	NI76-66
4 RAS P1 Rvs	NI79-66
4 RAS DVI Rvs	NI80-66
08 RAS Fya IgG + Control	NI81-33
08 RAS Fyb IgG + Control	NI82-33
08 RAS Jka Rvs + Control	NI83-66
08 RAS Jkb Rvs + Control	NI84-66
08 RAS MNS3 IgG + Control	NI85-33
08 RAS MNS4 IgG + Control	NI86-33
08 RAS K 2nd Rvs + Control	NI87-66
08 RAS Weak D IgG + Control	NI88-33
08 RAS M Neut + Control	NI89-88
08 RAS Lea Rvs + Control	NI90-66
08 RAS Leb Rvs + Control	NI91-66
08 RAS P1 Rvs + Control	NI92-66

(Continued)

08 RAS DVI Rvs + Control	NI93-66
4 RAS Fya IgG + Control	NI94-33
4 RAS Fyb IgG + Control	NI95-33
4 RAS Jka Rvs + Control	NI96-66
4 RAS Jkb Rvs + Control	NI97-66
4 RAS MNS3 IgG + Control	NI98-33
4 RAS MNS4 IgG + Control	NI99-33
4 RAS K 2nd Rvs + Control	NI100-66
4 RAS Weak D IgG + Control	NI101-33
4 RAS M Neut + Control	N102-88
4 RAS Lea Rvs + Control	NI103-66
4 RAS Leb Rvs + Control	NI104-66
4 RAS P1 Rvs + Control	NI105-66
4 RAS DVI Rvs + Control	NI106-66
08 RAS Fya/Fyb IgG + Control	NI107-33
08 RAS Jka/Jkb Rvs + Control	NI108-66
08 RAS MNS3/MNS4 IgG + Control	NI109-33
08 RAS Lea/Leb Rvs + Control	NI110-66
08 RAS K 2nd/DVI Rvs + Control	NI111-66
4 RAS Fya/Fyb IgG + Control	NI112-33

(Continued)

4 RAS Jka/Jkb Rvs + Control	NI113-66
4 RAS MNS3/MNS4 IgG + Control	NI114-33
4 RAS K 2nd/DVI Rvs + Control	NI115-66
4 RAS Lea/Leb Rvs + Control	NI116-66
8 RAS Anti-k (cellano) Neut	NI117-88
4 RAS Anti-k (cellano) Neut	NI118-88

Dilution Series

Test Name	Short Name
DS BV Rvs 08 RT RRBC	DS_80001
DS BV Rvs 4 RT RRBC	DS_80003
DS BV IAT IgG 08 37 RRBC	DS_80005
DS BV IAT IgG 4 37 RRBC	DS_80007
DS BV IAT Poly 08 37 RRBC	DS_80009
DS BV IAT Poly 4 37 RRBC	DS_80011
DS BV Neut 08 37 RRBC	DS_80021
DS BV Neut 4 37 RRBC	DS_80022
DS BV EFS Rvs 08 RT RRBC	DS_80101
DS BV EFS IAT IgG 08 37 RRBC	DS_80105
DS BV EFS IAT Poly 08 37 RRBC	DS_80109
DS BV EFS Neut 08 37 RRBC	DS_80121

Chapter 2 Safeguards and Precautions

Safeguards and Precautions Overview

This chapter describes the general safeguards and precautions to observe when operating the ORTHO VISION® Analyzer. Observe these safety precautions to avoid possible harm to personnel or damage to the instrument, and to help avoid incorrect test results and/or interpretations.
Refer to the Instructions For Use for each product used with the system for important information, including proper handling and storage temperature.

IMPORTANT: The documentation must be consulted in all cases where the  symbol is used, in order to determine the nature of the potential hazard and any actions which must be taken.

This chapter reviews the topics listed below:

Proper Equipment Use

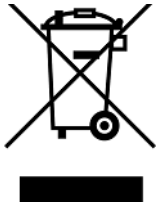
Use of this equipment in a manner not specified by the manufacturer may cause possible harm to personnel and the instrument. The ORTHO VISION® Analyzer should be installed and serviced only by Ortho authorized personnel.
Proper training is required in order to execute procedures identified as Self-Service. For more information, see Available Documentation (page 6-3).

WARNING: The system processes potentially biohazardous materials. Observe Universal Precautions following the applicable regulatory agencies safety guidelines at all times when dealing with blood or body fluid and contaminated equipment. Operate the system in compliance with your laboratory procedures for handling biohazardous materials, and in accordance with the procedures defined by the appropriate national biohazard safety guidelines or regulations. Equipment operators should wear personal protective equipment and follow applicable regulatory agencies safety guidelines.

The ultimate responsibility for the integrity and identity of blood samples lies with trained personnel. Results obtained by the ORTHO VISION® Analyzer must be clinically interpreted and validated by qualified personnel. Ortho disclaims any liability for any erroneous results which may stem from using ORTHO VISION® Analyzer for purposes other than those outlined in this guide.
Ortho has validated the use of its proprietary reagents on the ORTHO VISION® Analyzer. Ortho does not assume responsibility for results obtained with non-Ortho approved reagents. It is the responsibility of the user to validate non-Ortho approved reagents.
The list of Ortho-approved reagents is provided in the Reagents (page 8-2) section.
The system is intended for indoor use only.
The system does not require any special services (for example, air or cooling liquid).

Labeling of Electrical and Electronic Equipment

In compliance with the European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), this device must not be disposed of as unsorted municipal waste. Instead, this device must be collected separately in accordance with local recycling regulations. Presence of the symbol below indicates that compliance must be adhered to for this device.



Moving the Equipment

Never lift and move a fully installed ORTHO VISION® Analyzer to another location. Contact Ortho Care if you need to move the system to another location.

The packaged system has been tested to withstand normal shipping and storage conditions without degradation. No special provisions are required for storage and transport.

Environmental Conditions

The system is designed to run within a specified range of environmental conditions. For example, altitude, temperature, or humidity can affect system performance. Use environmental monitoring to make sure the system is within its specified range.

For more information, see Environmental Specifications (page 1-11).

General Precautions

These precautions should be considered while the system is in operation.
The system is intended for users who are qualified laboratory personnel with knowledge of immunohematology, under professional supervision and suitably trained to operate the equipment. Only users who have been given the necessary access rights can complete maintenance tasks.

Biohazardous Materials

Handle all blood, and materials that may be in contact with blood, as if capable of transmitting infectious agents. All areas of the system must be considered potentially biohazardous and handled with the appropriate care as per your laboratory procedures for handling biohazardous materials, and in accordance with the procedures defined by the appropriate national biohazard safety guidelines or regulations. Observe Universal Precautions following the applicable regulatory agencies safety guidelines at all times when dealing with blood or body fluid and contaminated equipment.

Presence of Chemicals of Concern within the System

This system may contain small quantities of chemicals within its components that are classified as carcinogenic, mutagenic, or reproductive toxins, endocrine disruptors, or skin sensitizers, or cause an allergic reaction.

However, if the Universal Precautions are followed as instructed below, the risk of exposure to these substances is remote.

Under normal operating conditions, as described in this guide, exposure to these components/chemicals is not expected.

Cassette Handling

The system is designed to use Ortho BioVue® Cassettes.

When preparing and loading Cassettes, follow the precautions listed below:

- Ensure that the Cassettes have been inspected and defective Cassettes with bubbles or dried columns have been removed from the sleeve prior to loading, as per the Instructions for Use.
- Ensure that the foil seal on the Cassette is in place and aligned.
- Do not use Cassettes that appear damaged (i.e., break in foil seal or break, crack or bubble in the column), or exhibit drying (i.e., liquid level is at or below the top of the glass beads), or exhibit discoloration (due to bacterial contamination which can cause false reactions).
- Some Cassette components may be considered as hazardous or potentially infectious waste. Dispose of all materials according to applicable guidelines and regulations.
- Freezing of a Cassette or evaporation of the liquid, due to heat, may interfere with the free passage of unagglutinated red blood cells through the glass bead column.
- Place partially used cassettes with unused columns in the Load Area within the Dual Purpose Drawer. Do not place partially used cassettes with unused columns in the Supply Drawer.

Caution: Resources require certain handling conditions.

- The Supply Drawer is monitored at a temperature between 18°C-33°C. If the system detects resources outside of the temperature range, results are either flagged or not reported.
- Do not use the Supply Drawer to store resources.
- Add enough cassettes for daily use.

IMPORTANT: Excessive reuse of sleeves in the Supply Drawer may cause Grip01, Grip07, and Grip08 errors. Inspect the sleeves for damage and make sure the Cassettes are not tilted.

IMPORTANT: Refer to the Instructions for Use for additional information related to the visual inspection and storage of each Cassette.

IMPORTANT: A Cassette in process should only be removed from the system under error conditions and direction from the software.

Reagent and Diluent Handling

Freshly opened Ortho Reagent Red Blood Cells have been validated for continuous use on-board the system when using the ORTHO VISION® Evaporation Cap. Review the table below for the validated time periods that Ortho Reagent Red Blood Cells can be kept on the system.

Ortho Reagent Red Blood Cell Product	Time that freshly opened Ortho Reagent Red Blood Cells can be kept on the analyzer when using the ORTHO VISION® Evaporation Cap
0.8% Selectogen® 0.8% Surgiscreen® 0.8% BioVue® Screen: Untreated and Ficin Treated	5 Days (120 Hours) Performance after five days of continuous use on-board the system has not been validated.

Ortho Reagent Red Blood Cell Product	Time that freshly opened Ortho Reagent Red Blood Cells can be kept on the analyzer when using the ORTHO VISION® Evaporation Cap
0.8% Affirmagen® 0.8% Affirmagen® 3 0.8% Affirmagen® 4	2 Days (48 Hours) Performance after two days of continuous use on-board the system has not been validated.

(Continued)

3% Affirmagen®	3 Days (72 Hours) Performance after three days of continuous use on-board the system has not been validated.
3% Affirmagen® 4	
3% Selectogen®	
3% Surgiscreen®	
4% BioVue® Screen J	

Ortho Reagent Red Blood Cell Product	Handling
BioVue® Screen	Ortho Reagent Red Blood Cells should be capped and stored at 2 to 8°C when not in use.
Resolve® Panel A	
Resolve® Panel B	
Resolve® Panel C	
0.8% Resolve® Panel A	
0.8% Resolve® Panel B	
0.8% Resolve® Panel C	

IMPORTANT: The system is not intended for reagent or diluent storage. The customer is responsible for monitoring the length of time reagents and diluents have been on the system.

Reagent Red Blood Cells must be at room temperature when they are loaded on the system.

IMPORTANT: If there is suspicion of testing performed with reagent red cells that were not completely resuspended, discard the entire set of the reagent red cells and repeat testing with a new set of reagent red cells.

IMPORTANT: Do not store Reagent Red Blood Cells that require agitation on-board the system if the system is going to be powered off or in maintenance mode. If Reagent Red Blood Cells that require agitation are left on-board the system after the system has been powered off or has been in maintenance mode, the Reagent Red Blood Cells are marked unusable. For Daily maintenance and Weekly maintenance tasks only, it is not required to remove Reagent Red Blood Cells from the system, since the system continues to agitate the Reagent Red Blood Cells during maintenance mode.

For more information, see On Analyzer Stability of Ortho Reagent Red Blood Cells (page 7-5).

Centrifuge

Use only Ortho BioVue® Cassettes.

Inspect all HOLDERS before use: Do not use if the HOLDER is cracked. Replace any cracked HOLDERS.

All HOLDERS are color coded. All HOLDERS in the CENTRIFUGE must be black. Do not use ORTHO™ Workstation HOLDERS in the CENTRIFUGE.

Only HOLDERS supplied by Ortho-Clinical Diagnostics, Inc. can be used in the CENTRIFUGE.

HOLDERS can be used in any position within the CENTRIFUGE. They are not assigned to a specific position.

Samples

Use of hemolyzed, lipemic or icteric samples may lead to unexpected results, including discrepant or indeterminate (IND) interpretations or no result determined (NRD) due to an error.

All sample dilutions must be prepared using the correct diluents outlined in the Instructions For Use to the corresponding ORTHO BioVue® Cassette used for testing.

For more information, see Sample Specifications (page 9-14).

Ensure your sample preparation centrifuge is calibrated to achieve an 80-90% packed cell concentration. This will allow you to achieve a cell suspension of 3-4% and 0.8%, based on the test requirement.

When a sample is collected from a recently transfused patient, the potential exists for the transfused red cells to concentrate after centrifugation at the bottom of the sample tube below their autologous cells. The probe aspirates from the bottom of the tube where the transfused cells generally concentrate which may lead to an unexpected result.

Note: Refer to Instructions for Use for more information about proper sample preparation.

Laser Safety Precautions

The system is equipped with a Class 1 laser per IEC 60825-1.

WARNING: The system uses a laser to scan barcodes. To prevent injury, do not look into the laser at any time. Do not attempt to service the barcode scanning device.

For more information, see System Labels (page 2-8).

Product Disposal

Customers within the European Union should dispose of labeled products (including associated cables, cords, and accessories) at the end of life by returning them to a collection system or treatment and recycling facilities. Follow your local decontamination procedures before returning electrical and electronic equipment. Contact local waste management authorities for additional information on the disposal of electrical and electronic equipment.

For customers outside the European Union, no special disposal is required unless specified otherwise by local or national regulations.

IMPORTANT: The system should be decontaminated any time it is removed for repair or disposal. Follow your local decontamination procedures. Observe Universal Precautions following the applicable regulatory agencies safety guidelines at all times when dealing with blood or body fluid and contaminated equipment.

Contact Ortho Care when the system needs to be removed.

Load/Unload Precautions

DANGER: After making any Load/Unload request, only make changes in the LOAD STATION position for which access was requested on the APPLICATION SOFTWARE screen. The system does not inventory load station positions that were not selected through the APPLICATION SOFTWARE screen.

Moving Parts

WARNING: To prevent damage to the equipment, or injury to the operator access to all Doors, Drawers, or Covers must be requested through the software.

While the system is in normal operation, the Load Station Door and Maintenance Door are interlocked to prevent exposure to any dangerous movements. 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 conditions.

Interference From Radio Frequencies

This system has been tested for Radio Frequency Immunity compliance to the requirements of EN 61000-4-3 to a signal strength of 3V/m. Cellular phones, two-way pagers, and other radio frequency transmitting devices when used in close proximity to the system exceed this signal strength and can cause some test results to be suppressed with an error reported instead.

Cellular phones, two-way pagers, and other RF transmitting devices should not be used within 1 m (3.28 ft) of the system.

Electromagnetic Compatibility (EMC)

It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or operator. It is the operator's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the instrument will perform as intended.

This IVD equipment complies with the emissions and immunity requirements described in IEC 61326-2-6 for IVD equipment. This equipment has been designed and tested to CISPR 11 Class A as part of the above requirement. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operation of the instrument. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

Safety Standards

This system meets the international standards for safety for in vitro diagnostic electrical equipment.

For more information, see Safety Requirements (page 1-9).

Electrical Safety Precautions

The precautions listed below should be considered while the system is in operation.

- Service must be performed by qualified service personnel.
- Do not remove the service or cover panels as serious injury or electrical shock may result.
- Do not position the system so that it is difficult to operate the main power switch or remove the power cord.
- No tool should be used to remove pieces or to access inaccessible parts without the user first disconnecting the instrument from the main power supply.
- In order to totally disconnect the instrument from the AC electrical power Mains power supply, the instrument must be unplugged (the ON/OFF switch is insufficient).
- The instrument must be connected to an earth-grounded outlet with an Ortho supplied power cord.
- Do not use the power cord if the grounding plug is damaged.
- Although the instrument is completely isolated and grounded, it is important that all operators realize the danger of using liquids near an AC electrical power Mains power supply. In the case of a large liquid spill, the instrument should be immediately disconnected

from the AC electrical Mains power supply and cleaned. It must not be reconnected until an Ortho field service engineer has inspected it.

- The instrument does not create sound pressure levels above 70 dBA. No additional hearing protection is required.
- The System should be adequately grounded to prevent the effects of static charges generated. Static problems can also be reduced by ensuring that the relative humidity of the room is maintained above 30 percent. Special anti-static floor pads can be purchased and positioned where the operator is required to make contact with the instrument.
- For continued protection against electrical hazard, use fuses of the same type and rating: FUSE, 16A or 12.5A SLOW-BLOW HIGH LOAD SPT CERAMIC. Refer to the labeling on the system for the proper fuse type.

For safety precautions associated with a customer added UPS, refer to the UPS operator's manual provided with the UPS.

System Cleaning

This section contains general information on how to clean the system. Refer to Maintenance Schedule (page 16-4) for maintenance procedures and frequency. Refer to the individual customer procedures for instructions on how to clean a specific area of the system.

Precautions

Assume that all used equipment is contaminated with potentially infectious biological material. In the United States, OSHA, CDC, and NIH recommend Univeral Precautions described in the Bloodborne Pathogen Standard 29CFR1910.1030 when handling, cleaning and packing the equipment.

- Wear gloves, closed shoes, closed lab coats, and safety glasses throughout the cleaning process (and packing, if the system is being shipped or relocated).
- Handle all equipment with care. Mechanical parts may have edges, pinch points, and corners that could potentially cause injury.
- Treat materials used in the cleaning process as contaminated. Follow the site procedures for your laboratory to dispose of these materials.
- Disconnecting tubing may result in liquid drips; soak up any liquid drips with an absorbent material.

Outside the United States, follow WHO (World Health Organization) and your country's regulations for handling and cleaning bloodborne pathogens.

Solutions to Use

Note: For the LIQUID SYSTEM Decontamination only, the solutions listed below can be used:

- 70% isopropyl alcohol
- 70% ethanol
- 0.1M NaOH

Use only a mild detergent or a 70% isopropyl alcohol solution when cleaning system components or surfaces. To prevent corrosion of system parts and possible erroneous results, do not use any other cleaning solutions or solvents on the system unless specifically directed in a maintenance wizard or procedure.

Caution: Be sure to use 70% isopropyl alcohol and not more-concentrated solutions. Do not use bleach for cleaning.

Caution: Be sure to only use a clean, dry, lint-free cloth when cleaning the IMAGING SYSTEM.

Caution: Be sure to only use deionized water followed by 70% isopropyl alcohol when cleaning the MONITOR.

Caution: Before using any cleaning or decontamination methods except for those recommended by the manufacturer, you should check with the manufacturer that the proposed method will not damage the equipment.

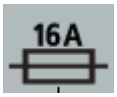
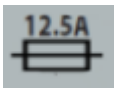
Caution: Do not expose the Liquid System and Liquid Waste Bottle Caps to soap, hand cream, or moisturizer. Exposure to these contaminants may lead to cap venting failures. Replace any contaminated caps with a new cap.

System Labels

The ORTHO VISION® Analyzer is labeled with safety and service labels that indicate areas on the system important for operators and service personnel to be aware of. Safety labels indicate areas on the system where operators should be aware of biohazards, high voltage, hot surfaces or places where operators could pinch or injure their hands in normal operation modes.
The table below describes the symbols and labels you will see on the system:

Label	Description
	General Warning (Direct or indirect danger to personal safety or system): • Laser light – Do not stare into beam
	Caution, Hot Surface
	Biohazard
	Laser Radiation: Do not stare into beam: Class 1 laser product
	Class 1 laser product
	High Voltage

(Continued)

	Load Station finger hazard when the cover is turning
	Prohibit the use of cellular phones and two-way radios at least one meter from the system.
	For *In Vitro* Diagnostic Use
	Primary Protective Main Power Ground
	Fuse Label
	Fuse Label
	Catalog Number or Product Code
	Manufacturer's Serial Number
	Date of Manufacture
	Manufacturer
	In compliance with European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), the device must not be disposed of as unsorted municipal waste. Separate disposal collection is required at the end of the product's life cycle. (Applies to customers within the European Union only.)
	The Chinese Regulation, Management Methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products (“China RoHS”), requires an electrical or electronic product to be labelled with the Environmentally Friendly Use Period symbol if it contains restricted substances above specified levels. The Environmentally Friendly Use Period refers to the period in years (Y) during which the hazardous substances contained in the electronic and electrical product will not leak or mutate suddenly under normal operation conditions and will not result in serious environmental pollution or cause serious bodily injury to the user or damage to their assets during normal use by the user of the electronic and electrical products.

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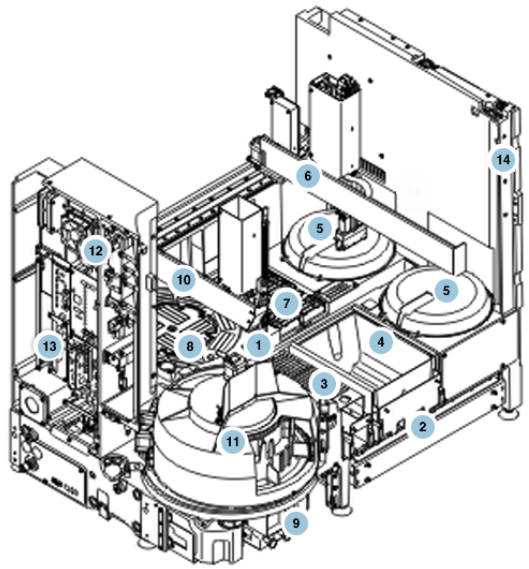
Chapter 3 System Components

System Components Overview



1	DECK
2	Supply Drawer
3	Dual Purpose Drawer
4	Waste Drawer
5	Centrifuge
6	GRIPPER
7	Imaging System
8	Incubator
9	Liquid System
10	PIPETTE
11	Load Station
12	MASTER COMPUTER
13	POWER SUPPLY
14	HOUSING

ORTHO VISION® Analyzer contains multiple system components that help the system process patient samples and generate results. The MASTER COMPUTER is a dedicated computer that stores data, provides application software through a graphical user interface, and controls user interface services (monitor, keyboard, Handheld Barcode Scanner, printer). For your safety and the safety of the system, access to all system components must be requested through the application software. The application software also allows you to manage all samples, system resources, and test results.

All samples, reagents, diluents, and Dilution Trays are loaded into the Load Station. Each time the Load Station is accessed, a barcode reader scans each sample or resource to identify type and position only in the Load Station sections that were accessed through the APPLICATION SOFTWARE screen. The system tracks how long each sample or resource is on the system, and keeps red blood cells in suspension through agitation.

WARNING: If a sample or reagent is moved to another location in the Load Station , the time it is on the system is restarted. Monitor the length of time samples and reagents are on the system.

All Cassettes are loaded into the room temperature Supply Drawer. The system monitors the Supply Drawer and can detect when new Cassettes are added to the system. Prior to use, all Cassettes are moved by the GRIPPER to the Imaging System for identification and quality review.

Once a Cassette is ready for use, the GRIPPER places the Cassette into the heated or room temperature Incubator, depending on the test order, where only the columns of the Cassette required for the test are punched. If required, the PIPETTE prepares red cell suspensions or plasma/serum dilutions by aspirating sample and diluent and mixing both in a Dilution Tray in the Load Station. While the Cassette is in the Incubator, the PIPETTE aspirates and dispenses sample fluid, reagents, and any required red cell suspensions or plasma/serum dilutions from the Load Station into the Cassette. When fluids are pipetted into the column, an airgap is created between the reactant dispensed in the reaction chamber and the reagent present in the column. The Liquid System provides any saline required for test processing as well as deionized water required for system cleaning, washes the PIPETTE, and stores any liquid waste.

Cassettes remain in the Incubator and are further processed as defined by the software. After incubation is complete, the GRIPPER moves the Cassette to a Centrifuge to continue processing according to test protocol.

Once centrifugation is complete, the GRIPPER moves the Cassette to the Imaging System where multiple front and rear images of the agglutination reactions are captured. The Imaging System analyzes the images to produce test results. The Cassette images and test results are displayed through the user interface (Results). The GRIPPER moves used Cassettes to either the Waste Drawer or the Dual Purpose Drawer. Cassettes moved to the Dual Purpose Drawer require further analysis to determine a result. Partially used Cassettes with unused columns are moved to the room temperature Incubator.

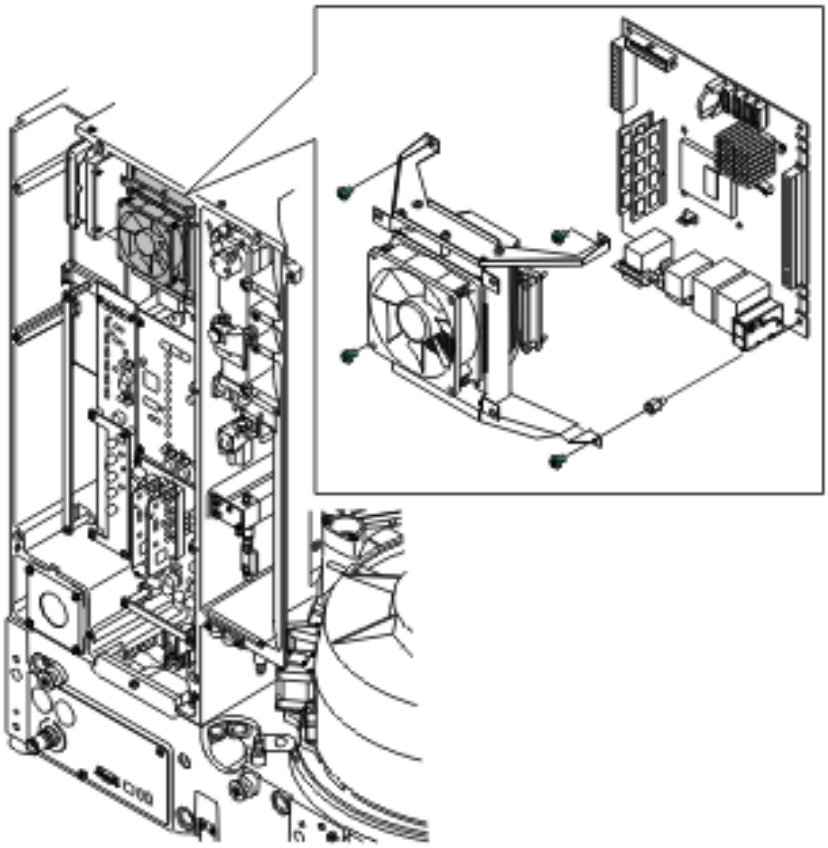
All system components are contained within the DECK; the visible area exposed for cleaning above the FRAME. Any covers, doors, or panels are contained within the HOUSING; the outside of the system. The system is powered by one power cord connected to the POWER SUPPLY.

- MASTER COMPUTER and POWER SUPPLY (page 3-3)
- Load Station (page 3-5)
- Supply Drawer and Dual Purpose Drawer (page 3-6)
- GRIPPER (page 3-9)
- PIPETTE and Liquid System (page 3-12)
- Incubator (page 3-10)
- Centrifuge (page 3-11)
- Imaging System (page 3-8)
- FRAME and HOUSING (page 3-14)

Refer to Summary of System Performance Characteristics and Specifications (page 1-15) for system component capacities.

MASTER COMPUTER and POWER SUPPLY

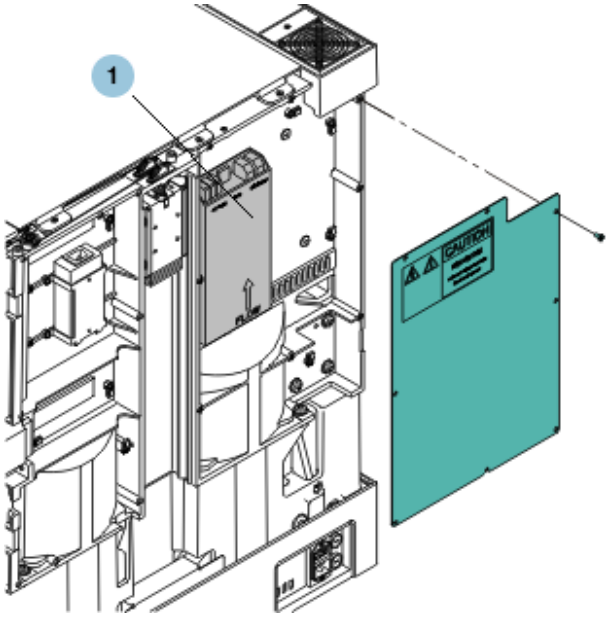
MASTER COMPUTER



The MASTER COMPUTER is a dedicated computer that stores data, provides application software through a graphical user interface, and controls user interface services (monitor, keyboard, Handheld Barcode Scanner, printer). The MASTER COMPUTER is located on the left side of the system.

For your safety and the safety of the system, access to all system components must be requested through the application software. The application software also allows you to manage all samples, system resources, and test results. You can access and use the application software via the 19in monitor provided on the front of the system.

POWER SUPPLY



1	POWER SUPPLY

The system is powered by one power cord connected to the POWER SUPPLY. The POWER SUPPLY is located on the right side of the system.

Caution: Ortho Clinical Diagnostics highly recommends the use of an Uninterruptable Power Supply (UPS). Operating the system without a UPS could lead to loss of tests in case of power loss and is not recommended.

For more information, see Power Requirements (page 1-10).

MASTER COMPUTER and POWER SUPPLY Maintenance Tasks

The default Maintenance Tasks scheduled for this system component are listed below:

Daily	There are no Maintenance Tasks scheduled for this time interval.
Weekly	There are no Maintenance Tasks scheduled for this time interval.
Monthly	There are no Maintenance Tasks scheduled for this time interval.
Yearly	There are no Maintenance Tasks scheduled for this time interval.
As Required	• Virus Scan • Maintenance Backup • Prepare System for Downtime

Load Station

The LOAD STATION has an agitated (inner) ROTOR, for reagents, and a non-agitated (outer) ROTOR, for samples, ORTHO™ Sera Reagents, and diluents. The inner rotor is agitated and temperature controlled and the outer ROTOR includes a lower and upper location. Samples, reagents, diluents, and Dilution Trays are loaded into the temperature controlled Load Station. Each time the Load Station is accessed, a barcode reader scans the area that was accessed to identify type and position. The system tracks how long each sample or resource is on the system, and keeps red blood cells in suspension through agitation. The remaining volume of liquid in vials on the Load Station is checked by the PIPETTE .

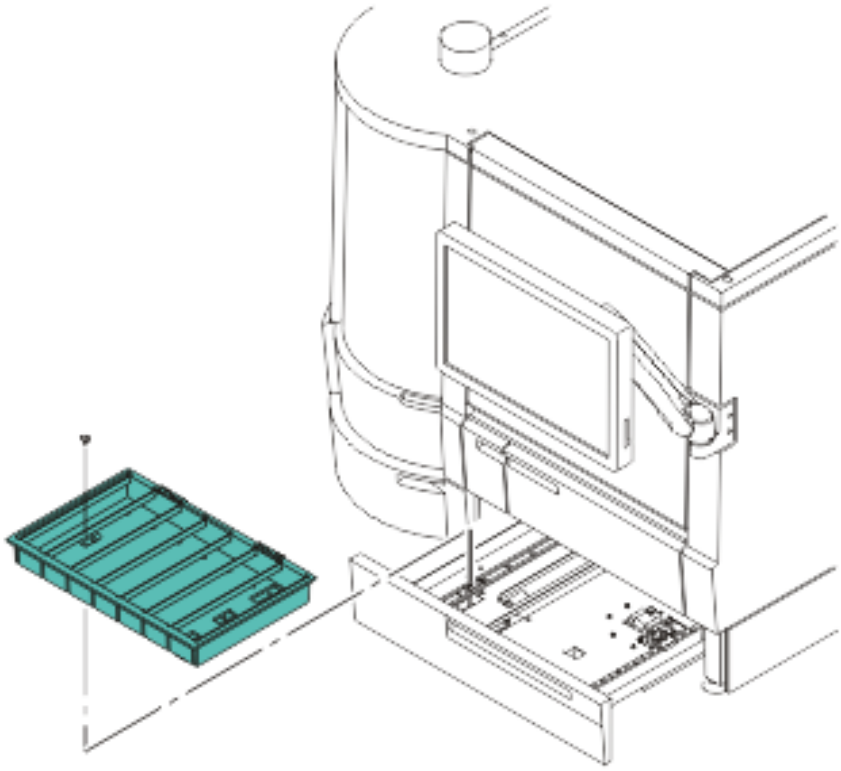
Maintenance Activities

The default Maintenance Tasks scheduled for this system component are listed below:

Daily	There are no Maintenance Tasks scheduled for this time interval.
Weekly	There are no Maintenance Tasks scheduled for this time interval.
Monthly	Instrument Cleaning
Yearly	There are no Maintenance Tasks scheduled for this time interval.
As Required	Configure Handheld Barcode Scanner

Supply Drawer, Dual Purpose Drawer, and Waste Drawer

Supply Drawer



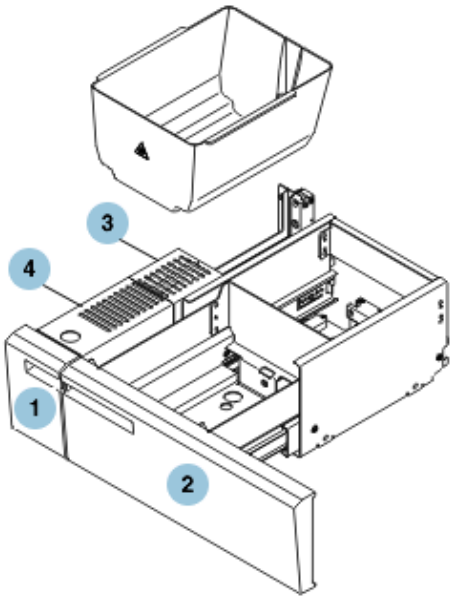
All Cassettes are loaded into the room temperature Supply Drawer. The system monitors the Supply Drawer and can detect when new Cassettes are added to the system. Before Cassettes can be used, they are moved by the GRIPPER to the Imaging System for identification and quality review.

IMPORTANT: Excessive reuse of sleeves in the Supply Drawer may cause Grip01, Grip07, and Grip08 errors. Inspect the sleeves for damage and make sure the Cassettes are not tilted.

Caution: Resources require certain handling conditions.

- The Supply Drawer is monitored at a temperature between 18°C-33°C. If the system detects resources outside of the temperature range, results are either flagged or not reported.
- Do not use the Supply Drawer to store resources.
- Add enough cassettes for daily use.

Dual Purpose Drawer and Waste Drawer



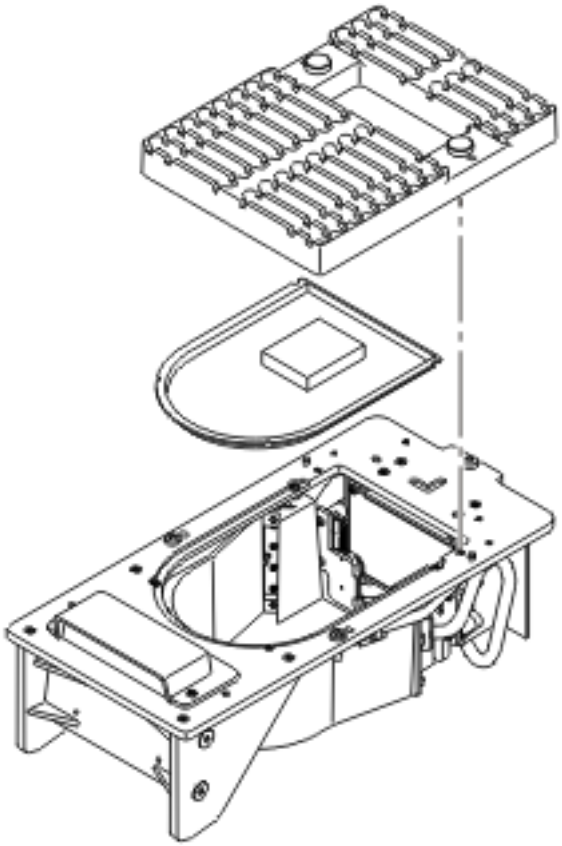
1	Dual Purpose Drawer
2	Waste Drawer
3	Load Area
4	Manual Review Rack

The Dual Purpose Drawer contains both the Manual Review Rack and the Load Area. Cassettes are moved to the Manual Review Rack when further analysis is required to determine a result. The Manual Review Rack can be removed from the Dual Purpose Drawer. Use the Load Area to load a low-volume Cassette. The system may also place partially used Cassettes, with unused columns in the Load Area when the room temperature Incubator is full. The Load Area cannot be removed from the Dual Purpose Drawer.
The Waste Drawer is located to the right of the Dual Purpose Drawer. Cassettes are moved to the Waste Drawer once test processes are complete and all columns have been used.

Supply Drawer, Dual Purpose Drawer, and Waste Drawer Maintenance Tasks

There are no default Maintenance Tasks scheduled for this system component.

Imaging System



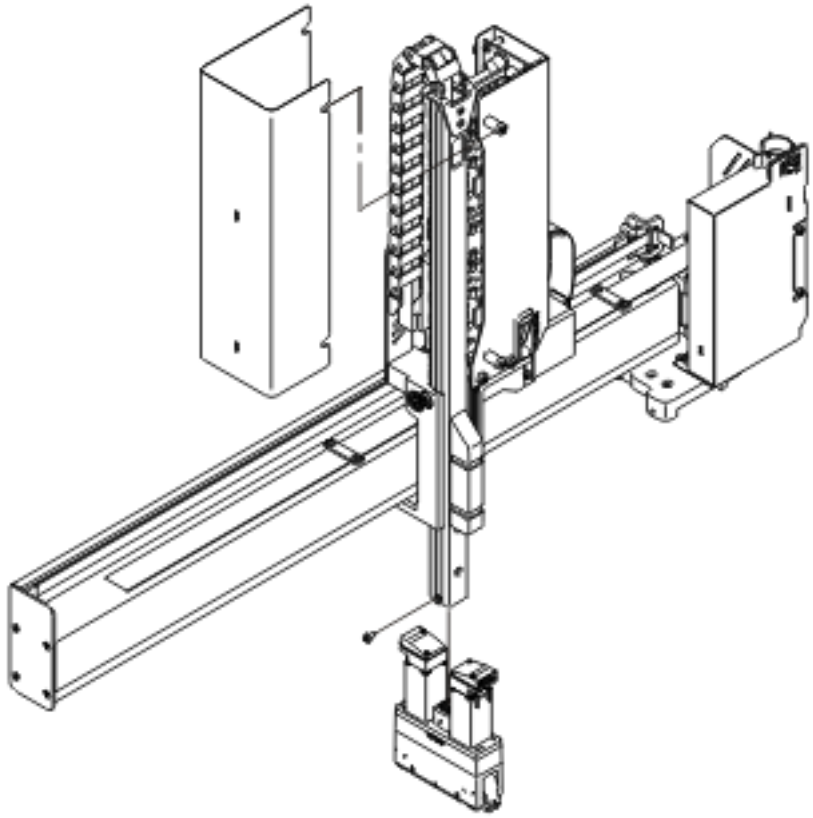
The Imaging System captures multiple images of the agglutination reactions and then analyzes the images to produce test results. The Cassette images and test results are displayed through the user interface (Results).
The Imaging System also performs positive identification and a quality check of all Cassettes before they can be used for test processing.

Maintenance Tasks

The default Maintenance Tasks scheduled for this system component are listed below:

Daily	There are no Maintenance Tasks scheduled for this time interval.
Weekly	There are no Maintenance Tasks scheduled for this time interval.
Monthly	There are no Maintenance Tasks scheduled for this time interval.
Yearly	Imaging System Cleaning – Operator
As Required	There are no Maintenance Tasks scheduled for this time interval.

GRIPPER

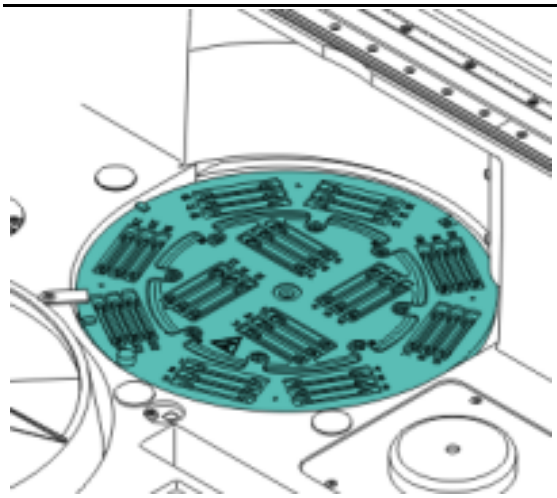


The GRIPPER uses a PUNCH TOOL to open the foil seal on the column of Cassettes and moves them around the system.
Prior to use, Cassettes are moved by the GRIPPER to the Imaging System for identification and quality review.
Once a Cassette has passed identification and quality review, the GRIPPER places the Cassette into the heated or room temperature Incubator where the Cassette is punched.
After pipetting is complete and incubation is over, the GRIPPER moves the Cassette to a Centrifuge to continue processing according to test protocol.
Once centrifugation is complete, the GRIPPER moves the Cassette to the CASSETTE IMAGING SYSTEM where multiple images of the agglutination reactions are captured of both the front and rear of the Cassette.The GRIPPER moves used Cassettes to either the Waste Drawer or the Dual Purpose Drawer.

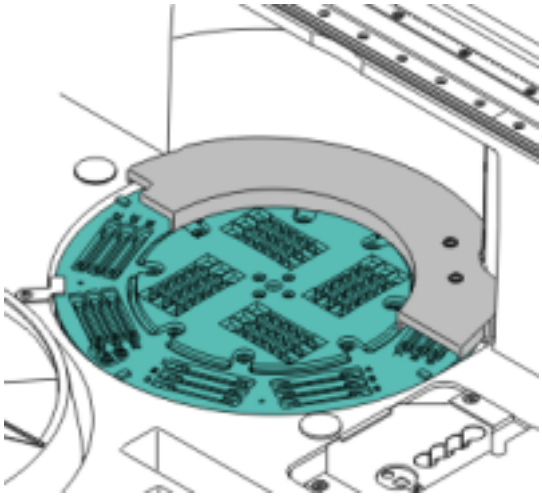
Maintenance Tasks

There are no default Maintenance Tasks scheduled for this system component.

Incubator



Incubator , without INCUBATOR COVER



Incubator, with INCUBATOR COVER

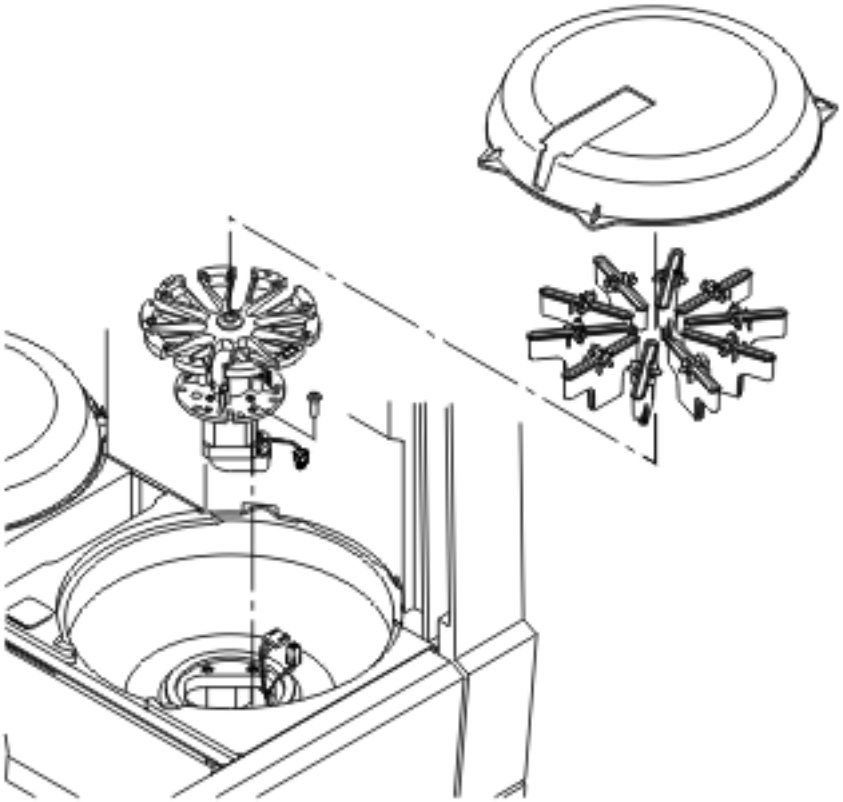
The GRIPPER places the Cassette into the heated or room temperature Incubator where the Cassette is punched. While in the Incubator, the PIPETTE aspirates and dispenses sample fluid, and reagents into the Cassette.
Cassettes remain in the Incubator and are further processed as defined by the software.

Maintenance Tasks

The default Maintenance Tasks scheduled for this system component are listed below:

Daily	There are no Maintenance Tasks scheduled for this time interval.
Weekly	There are no Maintenance Tasks scheduled for this time interval.
Monthly	Instrument Cleaning
Yearly	There are no Maintenance Tasks scheduled for this time interval.
As Required	There are no Maintenance Tasks scheduled for this time interval.

Centrifuge



After incubation is complete, the GRIPPER moves the Cassette to a Centrifuge to continue processing according to test protocol.

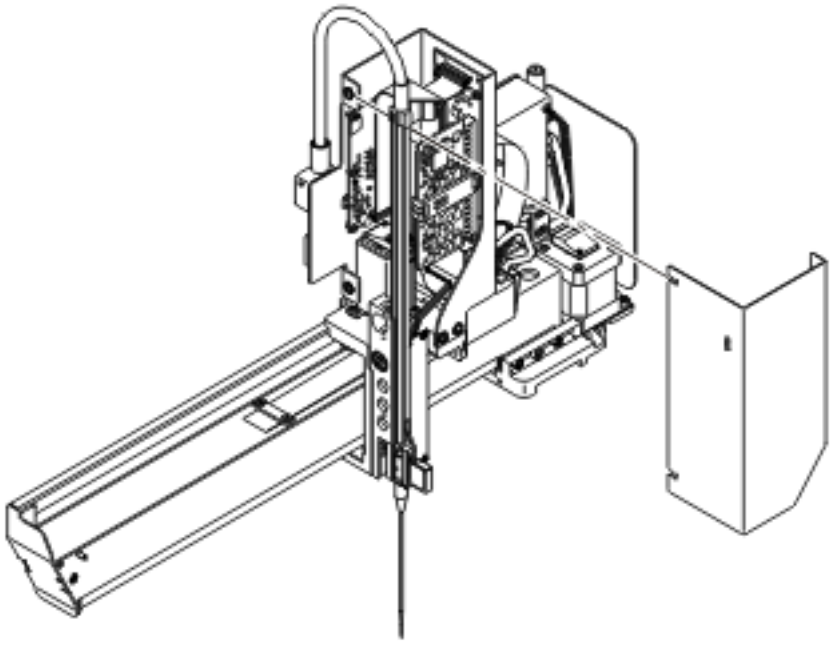
Maintenance Tasks

The default Maintenance Tasks scheduled for this system component are listed below:

Daily	There are no Maintenance Tasks scheduled for this time interval.
Weekly	There are no Maintenance Tasks scheduled for this time interval.
Monthly	Instrument Cleaning
Yearly	There are no Maintenance Tasks scheduled for this time interval.
As Required	• Replace Centrifuge 1 HOLDERS • Replace Centrifuge 2 HOLDERS

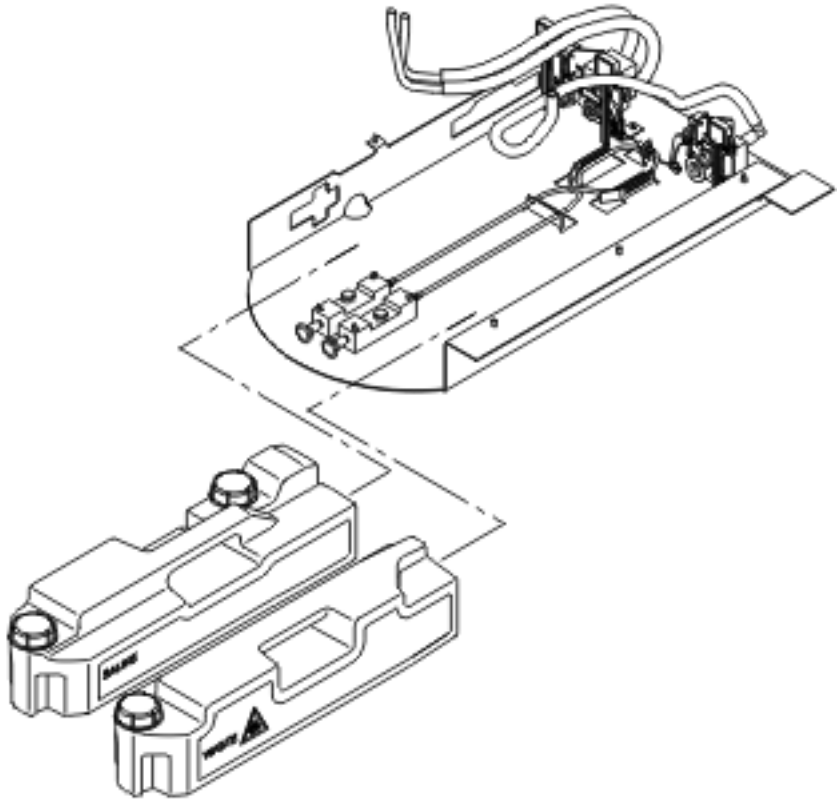
PIPETTE and Liquid System

PIPETTE



The PIPETTE aspirates and dispenses sample fluid, reagents, and diluents from the Load Station, prepares red cell suspensions and plasma/serum dilutions in Dilution Trays in the Load Station, and dispenses the required sample fluids, reagents, red blood cell suspensions, or plasma/serum dilutions into the appropriate columns in the Cassette while in the Incubator.

Liquid System



The Liquid System provides any saline or deionized water used for test processing or system cleaning, washes the PIPETTE, and stores any liquid waste.

PIPETTE and Liquid System Maintenance Tasks

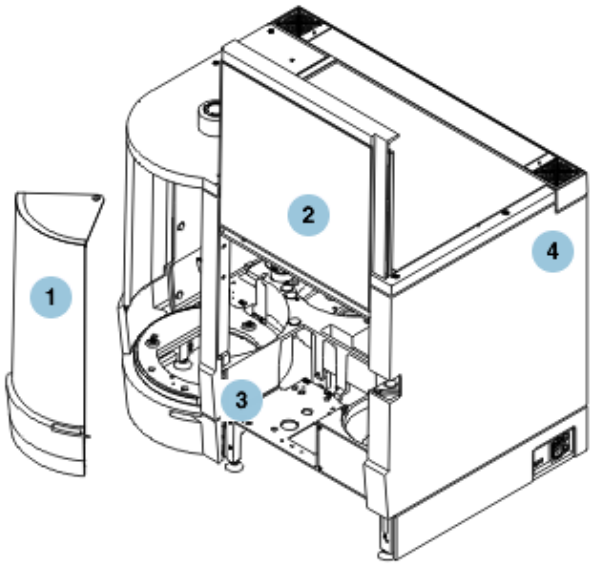
The default Maintenance Tasks scheduled for this system component are listed below:

Daily	Daily Probe Maintenance
Weekly	• Weekly Liquid System Decontamination and Pump Test
Monthly	There are no Maintenance Tasks scheduled for this time interval.
Yearly	• Replace System Liquid Container • Inspect Liquid Waste Container • Replace Pipetting Tubing • Replace Diluter Valve and Syringe • Replace System Tubing

(Continued)

As Required	• Fill Liquid System – Saline • Empty Liquid System • Probe Replacement • Pipetting Volume Test • Liquid System Decontamination • Pump Test • Pipette Probe Adjustment

FRAME and HOUSING



1	Load Station Door
2	Maintenance Door
3	DECK
4	HOUSING

All system components are contained within the DECK; the visible area exposed for cleaning above the FRAME. Any covers, doors, or panels are contained within the HOUSING; the outside of the system.

Maintenance Tasks

The default Maintenance Tasks scheduled for this system component are listed below:

Daily	There are no Maintenance Tasks scheduled for this time interval.
Weekly	There are no Maintenance Tasks scheduled for this time interval.
Monthly	Instrument Cleaning
Yearly	Replace Instrument Fan Filter
As Required	Unlock/Open and Close/Lock all Doors

Chapter 4 Startup and Shutdown

Startup and Shutdown Overview

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. 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.

Review this chapter upon initial startup and in the event that a shutdown and startup is required.

This chapter reviews the topics listed below:

System Setup

This information should be reviewed before the system is started for the first time, or after the system has been shutdown for an extended period of time.

Note: Qualified Ortho Clinical Diagnostics Service Personnel perform initial system setup in your location.

Before the system is started, be sure to check the items below:

- Ensure that all system doors are closed.
- Ensure that the system is plugged into a grounded receptacle.
- Check that the power and data connections are properly connected.
- Ensure that the Waste Tray is empty.
- Ensure that system liquid containers are filled.

IMPORTANT: Samples and agitated reagents should not be on the Load Station at startup. 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.

System Startup

Startup begins when the system is powered on. It is complete when the Dashboard is displayed and you can login.
For more information, see Login (page 5-2).
Power-on the system with the power switch located on the right side of the analyzer.
For more information, see Power-on (page 4-4) .
Once powered on, the system completes a series of initialization processes, which include:

- Hardware Initialization
- Component Inventory
- Consumable Inventory

Hardware Initialization

Initialization is the systems opportunity to check that components are both functioning properly and ready for operation. At initialization, the System ID is validated, each system component (for example the Centrifuge and Incubator) are confirmed to be ready for test processing, door locks are checked and environmental control begins for the DECK, Centrifuge, and Incubator.

Component Inventory

The system runs a series of inventory checks on system components listed in the table below:

Component	Description
Liquid System	Confirms the capacitive liquid level of the Probe.
Imaging System	Confirms that there are no items present in the Imaging System.
Waste Drawer	Confirms that the Waste Tray is present in the Waste Drawer. **IMPORTANT:** The system assumes that the Waste Tray is empty at startup and does not inventory the waste levels. Ensure that the Waste Tray is empty when the system is powered on.
Incubator	All Cassettes that remain in the Incubator, are rejected to the Dual Purpose Drawer. **Note:** This includes any used, unused, and partially used Cassettes .
PUNCH TOOL	Ensures that the PUNCH TOOL is present in the designated area. The PUNCH TOOL is moved to the Waste Drawer for identification and then replaced to it's designated area.
Centrifuge	All Cassettes that remain in the Centrifuge, are rejected to the Dual Purpose Drawer. **Note:** This includes any used, unused, and partially used Cassettes .

Consumable Inventory

At start up, the system completes the consumable inventory. The system scans all positions and consumables present on the Sample Rack, Reagent Rack, and the Supply Drawer to assess what consumables are loaded and where they are located on the system. The Consumable inventory also determines the available volume of reagents.

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.

Sleep Mode

The system normally performs a saline flush every 2 hours while the system is not in use to keep the liquids moving and prevent crystallization. Sleep mode automatically conserves saline by stopping the flushes after an extended period and filling the system with deionized water.

When does the sleep mode occur

Sleep mode starts automatically when at least three saline flushes have occured (approximately 6 hours since the last active use of the instrument).

What happens if there is insufficient Dionized Water to enter Sleep mode

If when entering Sleep mode the instrument detects a shortage of deionized water, the deionized water container is marked as “empty” and shows 0 L on the User Interface. The instrument then executes a saline flush and remains in operational mode, continuing with a saline flush every 2 hours if the instrument is not in active use.

How to identify if the instrument is in Sleep mode

In Sleep mode the annunciator light will remain green. On the user interface, the Errors tab will be yellow, and “APSW02 – Instrument in Sleep mode” will appear in the errors list.

How to exit Sleep mode

Any operator action related to samples, reagents, consumables, or tests will cause the instrument to automatically exit Sleep mode. No special operator procedure is required.

Is Sleep mode configurable

No, the instrument cannot be configured to avoid Sleep mode nor to alter the time required before entering Sleep mode.

What are the benefits of Sleep mode

Sleep mode reduces saline usage when the instrument is idle for longer periods like overnight or over a weekend.

System Shutdown

Normal Shutdown

IMPORTANT: When the monitor displays a message that it is safe to shut down, then you can completely shut down the master computer. If you power off the system while the master computer is still running, then you will have the risk of losing data or corrupting the operating system.

Touch Home > Shut Down to initiate a normal system shutdown.

Once a shutdown is initiated, the system completes a system cleanup to prepare for shutdown:

- Orders that are in process are completed.

  Note: The system will not begin to process orders that have not yet been started after a shutdown is initiated.

- The Centrifuge is cleared.

  - Partially used Cassettes are moved to the Dual Purpose Drawer.

  Note: If the Dual Purpose Drawer is full, the Cassettes are left in the Centrifuge to be cleaned out at system startup.

- The PIPETTE is flushed with deionized water.
- The application software shuts down and enters a state that is safe for power off.

The system is safe for power off when these processes have completed.

IMPORTANT: The master computer is completely shut down when the monitor screen is black and the LED is blinking. If you power off the system while the master computer is still running, you risk losing data, or corrupting the operating system.

For more information, see Shut Down the System (page 4-4).

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 anytime. A user does not need to be logged in; therefore, the user who performed the emergency shutdown may not be recorded.

For more information, see Stop Processing Action Button (page 5-12).

Startup and Shutdown Procedures

The following procedures are referred to in Startup and Shutdown:

Power-on

The Power-on switch is located on the right side of the analyzer. Turn it on and wait for the system to initialize. Make sure power cable is plugged in.

Shut Down the System

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to perform an orderly shutdown of the system. This procedure is accessed from the Home screen.

1. Touch the Home menu button.
2. Touch the Shut Down action button.

   A confirmation screen is displayed.
3. Touch Yes to confirm the shutdown procedure. Shutdown processing begins. When shutdown is complete, you can power off the system using the power switch on the right side of the instrument.

The system shuts down.

Chapter 5 User Interface

User Interface Overview

This section discusses navigation, features, and the functionality of the EASYNAV™ Software of the user interface. The user interface for the master computer consists of a flat panel monitor with an integrated touch screen. Use the touch screen to access software screens and navigate through system functions.

This chapter reviews the topics listed below:

Action Buttons

The action buttons described below are located along the bottom of the Home screen.

Action Button	Description
 Log Out	Allows you to log out of the system. For more information, see Login (page 5-2).
 Show Health Check Report	Displays the Health Check Report; which includes the acceptable ranges, current values and status of system components.
 Shut Down	Allows you to shutdown the system. For more information, see System Shutdown (page 4-3).

System Access

System access is controlled by the access levels configured for each user group that is created on the system. Each user of the ORTHO VISION® Analyzer is provided a unique user name and assigned to a user group. Users with administrative access levels can define tailored access privileges for the user groups on the Setup-Users screen.

Note: You may not have access to this screen, based on the access level that has been assigned to you.

The user interface screens and system functions that access levels can be defined for are listed below.

- **Diagnostic User Group**– Select the type of user group
- **Maintenance Execution** – Set access for executing Maintenance tasks
- **Maintenance Setup** – Set access to the Setup-Maintenance screen. Users can be given access to view and/or modify this screen.
- **Remote Login**– Set access to use the Remote Result Review feature, where users can initiate remote sessions.
- **Results** – Set access to the functions that can be performed by the user in the Results menu screens. Options are listed below:
    - Accept/ Reject
    - Add comment
    - Edit results
    - Edit column gradings
- **Menus** – Set access to menu screens. Users can be permitted or denied access to each menu screen listed below:
    - Maintenance
    - Results
    - Errors
    - Software
    - QC
    - Resources
    - Setup
    - Samples

When a user who is assigned to a user group where access to a menu screen has been disabled, the Menu Button that corresponds to that menu screen is unavailable.
When a user is assigned to a user group where a system function is disabled, that area of the interface is unavailable to that user. For example, the Accept Result button appears inactive if you are assigned to a user group where Accept/ Reject is disabled.
For more information, see User Interface Navigation (page 5-12).

Login

Use the Home screen to login to the system. The Home screen is the first screen that displays once the system is started. The Home screen is displayed anytime a user is not logged in. Before a user can login to the system they are assigned a unique user name and a 6 character password. This password must be changed after the first time you login. All characters available on the keyboard can be used in the creation of both the user name and password. To login, touch anywhere on the Home screen. The Home-Login screen displays. Enter your user name and password.

IMPORTANT: Multiple failed login attempts could lead to a lockout dependent on Password Security setting, see Modify PWD Security (page 14-17).

For more information, see User Login (page 5-18).

WARNING: To prevent personal injury and damage to the equipment, only trained service personnel are allowed to access restricted service software screens and documentation. Never access service software screens or documentation without the permission of Ortho Clinical Diagnostics.

Once logged in, the user name is displayed on the user interface and the system activities you perform (i.e., samples loaded, orders created, and reports generated) are logged by the system as completed under your user name.
After a specified amount of idle time, you will be logged out of the system automatically. This time period can be configured on the Setup-System-Modify Auto Log Off screen. The maximum time period allowed is 60 minutes.

Log Out

Touch Home > Log Out to log out of the system. Once a user has logged out, the Home screen displays again and all buttons, except for the Stop Processing button become inactive. Scheduled and started tests continue to process, but a user must be logged into the system to interact with user interface screens.

For more information, see User Logout (page 5-18).

Home

The Home screen is the first screen displayed when the system is started. Use the Home screen to login, logout, view the Health Check Report, and to shutdown the system.
For more information, see User Login (page 5-18), User Logout (page 5-18), and System Shutdown (page 4-3).
The Home screen provides an overview of system processes with the Dashboard, which displays current status information for Resources, Samples, Results, and STAT samples.
For more information, see The Dashboard (page 5-4).

Instrument Health Check Report

The Instrument Health Check Report details the environmental conditions for the system. To display the Instrument Health Check Report, touch Show Health Check Report. The report displays the current conditions from 8 sensors located throughout the system:

Sensor Name	Description
ElectronicBox	Monitors the temperature at the POWER SUPPLY area of the system
CCLA	Monitors the temperature of the Supply Drawer
CHAS	Monitors the humidity inside the system
CHAS	Monitors the temperature inside the system
SOL.CINC.AmbientIncubator	Monitors the temperature of the Room Temperature Incubator
SOL.CINC.WarmIncubator	Monitors the temperature of the Heated Incubator
SRDR1	Monitors the relative humidity in the Load Station
SRDR1	Monitors the temperature in the Load Station

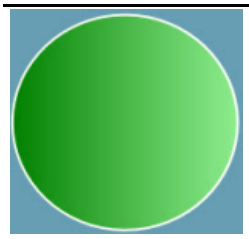
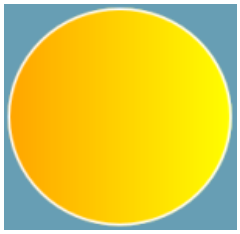
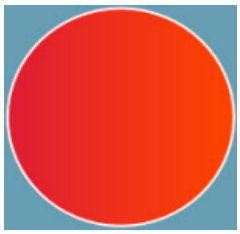
The information, listed below, is reported for each sensor:

- Sensor Type
- Current Value
- Warning Range
- Critical Range
- Status

The report can be saved and printed.

The Dashboard

Touch Home to display the Dashboard. The Dashboard provides a status of system processes. The screen is divided into 4 quadrants that display current system information for Resources, Samples, Results, and STAT samples.
The Resources, Samples, and Results quadrants display a large status indicator that changes color to indicate when user action is required.

	Green – Indicates that user action is not required. Samples and Resources are adequate for scheduled testing, manual review is not required, and there are no current warnings or errors.
	Orange – Indicates that there is a warning or error that requires user action, but processing continues. A sample may need to be assigned to an order, a resource may be low, or manual review may be required for a result.
	Red – Indicates that there is an error and user action is required now. Processing may have stopped. A sample may have an error, a resource may be depleted, or manual review result may be expired.

Touch anywhere on the Dark Blue portion of the quadrant to display the function screen information.

Resources

The text to the right of the status indicator displays the current status of resources. If a resource requires user action, the type of resource that needs attention is displayed.

Resources may include reagents, diluents, system liquids, or Cassettes.

The text in the lower portion of the quadrant displays:

- The number of resources that require refill
- The number of empty positions on the Reagent Racks

Samples

The text to the right of the status indicator displays the current status of samples. If warnings or errors are present, the number of samples affected is displayed.

The text in the lower portion of the quadrant displays:

- The number of samples with an error
- The number of missing samples (samples that are not loaded but an order is pending)
- The number of samples that are assigned to tests that are currently processing
- The number of empty sample positions and the number of samples that can be removed; either because all orders for the sample have been processed, all tests for the sample have been pipetted, or because there is no order for the sample.

  Note: Because a sample can be removed from the system as soon as all pipetting is complete, the same sample may be counted on the dashboard as both a running sample and a removable sample.

  Note: If a reflex test is triggered for a sample, but the sample has already been removed from the system, the sample will need to be reloaded.

Results

The text to the right of the status indicator displays the current status of results. If manual review is required, the number of results that require review is displayed.

The text in the lower portion of the quadrant displays:

- The number of orders with results that require review
- The number of orders that are complete

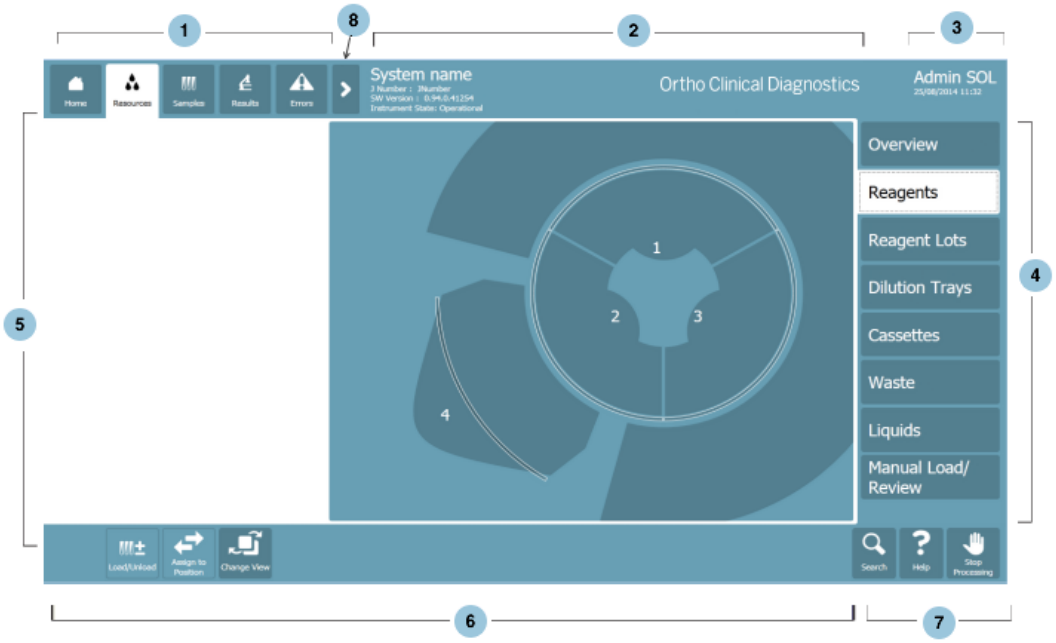
STAT Samples

The STAT Samples quadrant displays information about samples in process with a STAT priority:

- Sample ID
- Patient name
- Assigned Tests
- Estimated time of completion and the time until completion

Screen Layout

Refer to the table below for more information about the areas of the user interface.



1. Menus	Displays the different menu screens. For more information, see Menu (page 5-7).
2. System Name and Logo Display	Displays the System Name, the J Serial Number, the installed software version, and the Instrument State. For more information, see System Name and Logo Display (page 5-8). **Note:** The System Name and Logo Display is hidden when all tabs are expanded.
3. Indicator	Displays the current date and time and the user name currently logged into the system.
4. Tools	Buttons located vertically along the right-side of some menu screens. Use Tools to navigate through screens within the selected menu. For more information, see Tools (page 5-9).
5. Menu Screen	Displays the content of the selected Menu and Tools. Use the Menu buttons to change between menu screens.
6. Action Buttons	Executes actions within the current menu screen. These buttons change according to the menu screen displayed. For more information, see Action Buttons (page 5-9).
7. Assistance Buttons	The Search, Help, and Stop Processing Action Buttons that are displayed on all screens. For more information, see Assistance Buttons (page 5-10).
8. Expand Button	Touch the Expand button to display all of the available Menus. To return to the default view, touch the Expand button again.

Menu

Menu buttons are located horizontally along the top of the user interface and are used to display the different menu screens. The buttons are divided into high-traffic and low-traffic menus.

High-traffic menus include the areas of the software used to process tests: Home 1, Resources 2, Samples 3, Results 4, and Errors 5.

Use the Expand button (located next to the Errors menu) to display the low-traffic menu buttons.

Low-traffic menus include the areas of the software used to configure and maintain your system: QC 6, Setup 7, Software 8, Maintenance 9, and Diagnostics 10.

Each Menu is described in the table below:

Menu	Description
 Home	Displays the Home screen, where you can view the status of system processes on the Dashboard. For more information, see Home (page 5-3) and The Dashboard (page 5-4).
 Resources	Displays the Resources screen, used to manage resource; such as reagents, Cassettes, and diluents. For more information, seeOverview (page 7-3).
 Samples	Displays the Samples screen, used to view, manage and create orders for samples loaded to and registered on the system. For more information, see Samples Overview (page 9-1).
 Results	Displays the Results screen, used to view, accept, and monitor test results as they are completed. For more information, see Results Overview (page 10-1).
 Errors	Displays the Errors screen. Use the Errors screen to view and manage errors that may occur. For more information, see Errors Overview (page 12-1).

(Continued)

 QC	Displays the QC screen. Use the QC screen to manage QC tasks. For more information, see QC Overview (page 13-1).
 Setup	Displays the Setup screen. Use the Setup screen to manage all configurable options for your system. Configurable items include system access, user management, test setups, results, and much more. For more information, see Setup Overview (page 14-1).
 Software	Displays the Software screen. Use the Software screen to manage software updates, system backups and Internet connections. For more information, seeSoftware Overview (page 15-1).
 Maintenance	Displays the Maintenance screen. Use the Maintenance screen to view and perform required periodic maintenance procedures. For more information, see Maintenance Overview (page 16-1).
 Diagnostics	Displays the Diagnostics screen. The Diagnostics screen is not available to customers without a password.

System Name and Logo Display

Identifiable information about your system is displayed at the top center area of all screens; in the System Name and Logo Display, when low-traffic menus are not expanded.
Items that appear here are:

- **System Name** – A unique name given to your system at initial setup
- **J Serial Number** – A unique system identification number that is entered at manufacture and/or at system installation
- **Software Version** – The current software version that is loaded on your system
- **The Ortho Clinical Diagnostics logo**
- **Instrument State** – The current functional state of your system

  Instrument States include:

  - Diagnostics Mode – A user with diagnostic access rights has logged in
  - Await Shutdown Request – An urgent stop has been requested and the system is preparing for the user to shutdown the system
  - Not Starting New Orders – Stop Processing > Stop Processing has been touched; the system is not starting any new orders
  - Initializing – The system is preparing for operation
  - Maintenance Mode – Maintenance Mode has been requested; the system is prepared for maintenance tasks
  - Operational – The system is ready for test processing

- Performing Device Inventory – The system is scanning system resources
- Ready for Maintenance Mode – Stop Processing has been touched from the Maintenance screen; the system is waiting for Maintenance Mode
- Shutdown Cleanup – A shutdown has been initiated; the system is cleaning up resources
- Shutdown Order Execution – The system has stopped processing orders due to a shutdown request
- Shutdown Processing – The system is processing for a shutdown
- Shutting Down – The system is shutting down
- Stop Order Processing – A Stop Processing request has been initiated; the system is preparing to stop test processes
- Stop Process Execution – The system is executing the Stop Processing request

Tools

Tools are labeled buttons that appear along the right side of the Resources, Setup, and Software screens. Tools are used to filter and navigate through topics available in each menu. When you select a Tool, a new menu screen is displayed.
For example, the Resources tab displays 8 Tools:

- Overview
- Reagents
- Reagent Lots
- Dilution Trays
- Cassettes
- Waste
- Liquids
- Manual Load/Review

If you select the Reagents Tool, then the Resources-Reagents screen displays information about reagents only.

Action Buttons

Action buttons are located in a horizontal bar at the bottom of each screen. Use these buttons to prompt an action on the data or contents of the current screen.
For example, the Show Details action button is displayed on several screens. Use the Show Details button to display more information about selected content.

Assistance Buttons

Assistance buttons are the 3 action buttons that remain visible at the bottom right corner of all screens.

- Search
- Help
- Stop Processing

For more information, see Assistance Buttons (page 5-10).

Assistance Buttons

Assistance buttons include the Search, Help, and Stop Processing buttons located in the bottom right corner of user interface screens.

Action Button	Description
 Search	Opens the Search screen that allows you to search for information in the system databases. For more information, see Search (page 5-10).
 Help	Displays the help screen that contains screen information for the current screen. For more information, see Help (page 5-12).
 Stop Processing	Offers two choices to stop processing: • Stop New Processing — All tests currently in process will be completed. Pending tests will not begin. • Urgent Stop — All tests in process will stop immediately. These tests will be Failed and any results will be lost. Pending tests will not begin. For more information, see Stop Processing Action Button (page 5-12).

All 3 Assistance Buttons remain active on most screens of the user interface, with the exception of a few types of screens:

- When a Help screen is open all 3 buttons are unavailable.
- Only the Help button is active when a wizard is in use. For example, if you are in a Load/Unload screen; the Search and Stop Processing buttons are unavailable.

Search

Use the Search feature to search the system database and on-board publications for stored information. Touch the Search button, located at the bottom right corner of all screens, to display the Search screen.

Note: The Search button remains active unless a wizard or modal dialogue window is displayed.

The Search screen displays an entry field and keyboard to enter search terms. Once the search is executed, the keyboard on the Search screen is replaced with a list of search results. Touch a search result to display details for the object.
To narrow your search parameters to a specified area of information, you can select one or more of the buttons displayed at the top of the Search screen.

- Resources
- Samples
- Errors
- Maintenance
- Setup
- Help

Select All to search through all menus. Select Clear All to deselect all selected menus.

To search for results, select the Results button. You can narrow your search based on the status of the tests:

- Auto Accepted - Returns results for tests that were accepted automatically
- Manually Accepted - Returns results for tests that were accepted manually
- Canceled - Returns results for tests that have been canceled

IMPORTANT: The Auto Accepted, Manually Accepted, and Canceled buttons filter the search to find results based on the individual test. The orders that those tests are a part of are also returned. For example, if you complete a blank search with the Results and Canceled buttons selected; the search returns all orders that include a test that is canceled. This may include orders that are canceled, aborted, completed, and in process.

Search for results with the inputs listed below:

- Sample ID
- Patient ID
- Patient Name
- Reagent Type
- Reagent Lot
- Cassette Type
- Cassette Lot, profile
- Software Version
- Date and Time
- Profile Name
- Donor ID
- Cassette ID
- AD Version

Search a Date Range

Touch the Date Range button to enter a specified date range to search. On the Date Range screen you can either enter a date range by selecting a start and end date, or choose from the presets listed below:

- Last 24 hours
- Today (from 00:00 to current time)
- Yesterday (24 hour period of the prior day)
- This week (Monday 00:00 to current time and day)
- Last week
- This month
- Last month

Once you have made your date selections, touch apply to return to the Search screen.

Search with the HANDHELD BARCODE SCANNER

A Cassette or sample barcode can be scanned with the HANDHELD BARCODE SCANNER to perform a search. You can scan a Cassette or Sample ID from any screen, as long as the input field is not selected or active, and the system automatically searches the database for all objects associated with that Cassette or Sample ID. The results include any archived tests. Select a result to view the details.

Help

The Help button is one of the Assistance Buttons that displays at the bottom right corner of all screens. The Help button has 2 functions:

- To display a Help screen
- To display the Library

Help Screens

Touch the Help button, from any screen, to display a Help screen with information specific to that screen. Use Help screens for descriptions of screen items and links to related information.

For more information, see Available Documentation (page 6-3).

The Library

Touch Help > Help Home to display the Library. Use the Library to view the on-board documentation for your system.

For more information, see Library Overview (page 6-1).

Stop Processing Action Button

The Stop Processing button is a system button that provides the opportunity to cancel test system processes quickly. Use the Stop Processing button in two ways:

- To stop new processing
- To perform an urgent stop of all processing

The Stop Processing button is the only button that will remain active when there is not a user logged in. If the Stop Processing action is completed without a user logged in, the system will not have a record of who performed the stop.

Note:

The Stop Processing button is inactive when a wizard or help screen is displayed.

Stop New Processing

To stop the system from starting any new test orders, touch Stop Processing > Stop Processing. All orders that have tests already in progress will be completed, while those orders that have not yet been started are held back. Use the stop new processing feature when system maintenance is performed, changes are required on the Setup screen, or whenever it is necessary to prevent the start of orders.

To resume processing, touch Resume Processing.

Urgent Stop

To perform an Urgent Stop of all test process; touch Stop Processing > Perform Urgent Stop. The system stops all test processes and prepares for shutdown. Touch Home > Shut Down to complete the system shutdown.

IMPORTANT: When the Urgent Stop option is selected, tests are not completed and system does not perform normal system shutdown cleanup procedures.

User Interface Navigation

Navigate through screens and complete actions with buttons displayed on user interface screens. Each type of button has a different function in the software:

- **Menus** – Displays menu screens. Menus are located along the top of the user interface.

For more information, see Menu (page 5-7).

- **Tools** – Sort and display new information. Tool buttons are located along the right side of Resources, Setup, and Software screens.

  For more information, see Tools (page 5-9).

- **Action Buttons** – Initiates actions to be performed. Action buttons are located along the bottom of the user interface.

  For more information, see Action Buttons (page 5-9).

Move Between Menu Screens

To access a menu screen, touch the Menu Button located along the top of the user interface. Select a new Menu Button to move between menu screens.

The menu screen that was last displayed persists when a new Menu is selected; so that when you move from one Menu to another, the last menu screen displayed under the Menu will display again. For example, if the Resources-Reagents menu screen is displayed under the Resources Menu and you move to the Samples Menu; the Resources-Reagents screen will display again the next time the Resources Menu is selected.

Button Behavior

Button	Result
 Back	Returns you to the previous screen.
 Save	Saves the entries or changes made on this screen.
 Cancel	Closes the screen and does not save entered data.
 Close	Closes the present screen and returns you to the previous screen.
 Next	Opens the next screen.

Button Conventions

Buttons on user interface screens appear in different colors at different times to indicate availability or selection.

Button conventions are described below:

Button State	Example	Description
Active		Button appears with a dark-blue background and white font. The button is available. You can touch the button and access that area of the interface.
Inactive		Button appears with a light-blue background (matches interface background) and white font. The button is not available. The area of the interface or function, accessed by the button is either not available at the time, you do not have the required access configurations, or the feature is not available in your region.
Selected		Button appears with a white background and black font. The button is currently selected.

The background color of Menu Buttons and Tools change to red or orange when a related area of the user interface displays an error or warning.

- Orange – Warning or error is present that has not blocked test processes
- Red – Warning or error is present that has blocked test processes

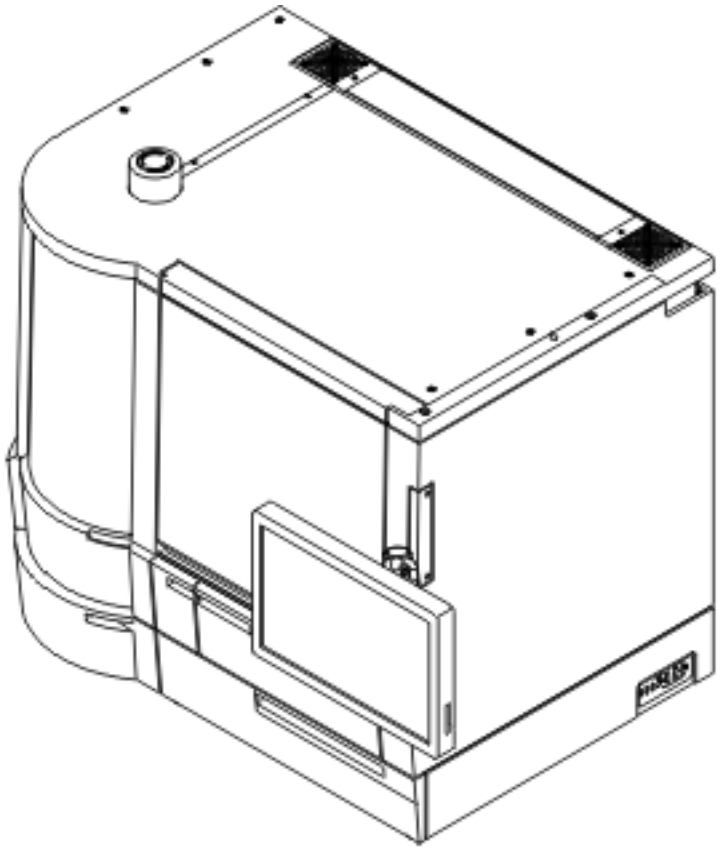
Delivered Files

Ortho Clinical Diagnostics can remotely deliver updates to your system electronically through e-Connectivity®. These files may include:

- **Application Software** – A software update that contains test rules
- **Application Data (AD)** – An update to test protocol definitions
- **System Publications** – An update to the on-board documentation (includes Self-Service Customer procedures Guide, the Reference Guide, and Instructions for Use)
- **Antivirus** – An update to the antivirus and firmware software installed on the MASTER COMPUTER
- **Operating System** – An update to the operating system of the MASTER COMPUTER

Updates are managed in the Software menu. When an update or delivery is available, the Software menu button changes to yellow to notify you. Touch Software. The update or updates available are outlined in yellow on the Software-Installation as well.
For more information, see Software Overview (page 15-1).

SIGNAL LIGHT



The SIGNAL LIGHT, located on top of the ORTHO VISION® Analyzer, notifies users of system status or alerts from across the laboratory.
When enabled, the SIGNAL LIGHT remains lit as long as the system is powered on. The SIGNAL LIGHT changes color when there is a change in system status to alert users. There are three colors that indicate the status of the system. These colors correspond with Status Indicators as they are used on the user interface.

Color	Description
Green	No alert. Assigned processes are complete and the system is idle or the system is currently processing.
Yellow	User intervention will soon be required.
Red	Test processing has stopped. Immediate attention from a user is required to resume.

For example, if the level of a required reagent reaches the threshold level that is set for notification, the Resources menu button turns red to notify users that an action is required in this area. When this happens, the SIGNAL LIGHT also turns red.
In addition to the light, there is an audio alarm that will sound when there is a change in system status.
The SIGNAL LIGHT and audio alarm can be configured on the Setup-System screen.
For more information, see System (page 14-16).

Status Indicators

Status Indicators are a combination of colors and graphics displayed on user interface screens that indicate the current state for the positions or locations of resources and samples. Status Indicators are used on Diagram View screens in the Resources and Samples tabs.

Status Indicators for RACKS, Samples, Reagents, and the Supply Drawer

The table below describes the Status Indicators that are displayed for Sample Racks, sample positions, Reagent Racks, reagent positions, the Supply Drawer, and Cassettes.

State	Image	Color		Description
Not Present	No icon for this status		Teal	There is no Sample Rack,Cassette sleeve, or Reagent Rack at the current position.
Not Present	No icon for this status		Dark Teal	There is no sample, Cassette, or reagent at the current position.
Ready			Green	The system location and/or position is ready for use.
Allocated			Blue	A sample or resource at the location is related to an order that is processing.
Scanning			Purple	The position or system location is currently being scanned by the system. While scanning is in process, it is unclear if the position or system location is ready or how the volume has been determined.
Running			Dark Blue	All pipetting has completed for the sample or all samples loaded in the Sample Rack and the item is ready to be removed from the system.

(Continued)

Warning		Orange	Indicates that there is a warning.
Error		Red	Indicates that there is an error with a severity level of either Problem or Critical.

Status Indicators for DILUTION WELLS

The table below describes the Status Indicators that are displayed for DILUTION WELLS in a Dilution Tray.

State	Color		Description
Used		Dark Teal	The dilution well has been used.
Unused		Green	The dilution well has not been used.
Allocated		Blue	The dilution well is allocated for processing.
Scanning		Purple	The dilution well is currently being scanned by the system. While scanning is in process, it is unclear if the position is used or unused.
Warning		Orange	Indicates that the dilution well has a warning.
Error		Red	Indicates that the dilution well has an error with a severity level of either Problem or Critical.

User Interfaces

The following procedures are referred to in Software:

Adjust the Monitor (page 5-18)

User Login (page 5-18)

User Logout (page 5-18)

Adjust the Monitor

For information on adjusting the monitor, please refer to the manufacturer's instructions.

User Login

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

A valid user name and password are required for this procedure.

Use this procedure to login to the system. If another user is currently logged in, log that user out by touching the Log Out button on the Home screen.

This procedure is located on the Home screen.

1 Touch anywhere on the Home screen to display the User Login screen.

2 Enter your user name and password in the corresponding fields.

Note: These entries are case sensitive.

3 Touch Enter.

The Home screen is displayed with the current logged in user.

TouchHelp for more information.

User Logout

Use this procedure to log out of the software as the current user. This procedure is located on the Home screen.

1 Touch the Home menu button.

2 Touch the Log Out action button.

No further actions are possible until a new user logs in.

Chapter 6 Library

Library Overview

Touch Help > Help Home to enter the Library. The Library provides you with information about your system at the touch of a button. The Library explains how to perform specific tasks on the system. It describes the various system components, maintenance procedures, and troubleshooting actions. The Library helps you to understand the software that controls the system and enables you to interact with it. It also provides you with important information about the tests the system can process and the materials required to perform those tests.

This chapter reviews the topics listed below:

Audience

Ortho Clinical Diagnostics provides Help for clinical laboratory personnel that are responsible for operation of the system, Ortho Laboratory Specialists, Ortho trained service personnel, and other support groups who maintain and troubleshoot the system. The system has different access levels for general users; laboratory personnel will not typically have access to certain service related system features and documentation.

For more information, see System Access (page 5-2).

Library Features

Library screens use features to help you navigate through system publications. For example, some Library features are the Change View button and rows that are expandable.

For more information, see Library Features (page 6-2).

Library Configurations

These screens do not have configurable options.

Library Action Buttons

The action buttons described below are located along the bottom of Library screens.

Action Button	Description
 Help Home	Displays the Library.
 Ortho Web	Redirects to the Ortho website (http://www.orthoclinical.com), which will display in the menu screen. For more information, see Ortho-Clinical Diagnostics, Inc. Communication (page 6-5).

(Continued)

 Ortho Chat	Enables direct messaging with Ortho Care personnel. For more information, see Ortho-Clinical Diagnostics, Inc. Communication (page 6-5) .
 Close	Closes the Library and displays the most recently viewed system software screen.
 Back	Returns you to the previous Library screen.
 Forward	Returns you to the Library screen where the Back button was touched.
 Print	Prints the current Library screen.

Library Features

Library screens use features to help you navigate through the system documentation provided.

Change View	Switches the display among up to 3 view options: • Diagram View – System image • List View – List of system components • Frequency View – Maintenance procedures organized by interval to be completed For more information, see Available Documentation (page 6-3).
Expandable Rows	Touch rows of information displayed on Library screens to expand a list of options directly below the row.

Return to the Library Overview (page 6-1).

Library Access

You can access the Library by selecting either the Help or Help Home links.

Help Links	Touch the Help button in the lower right corner of any system screen. The system displays the Help screen for the current screen. The Help information may contain links to related Library procedures, or links to related information in the Reference Guide.

(Continued)

The Help Home button	Touch Help > Help Home . If this is the first time you've accessed the Library, the Library welcome screen will display. If you have already used the Library, the Library home page will display.

Navigation

Similar to other areas of the user interface, you can select a tool from the right side of the screen to navigate through the Library. The tools displayed on Library screens are identified and described in the table below.

Tool	Description
System Operation	Displays procedures used for regular operation of the system.
Maintenance	Displays procedures for completion of required periodic maintenance tasks; daily, weekly, monthly, and yearly.
Self-Service	Displays Self-Service procedures.
Reference Guide	Provides the entire contents of the ORTHO VISION® Reference Guide, organized by chapter.
FAQ	Displays Frequently Asked Questions about the system.
Troubleshooting	Displays troubleshooting topics for the system.
About Help	Displays information about software versions.

For more information, see Available Documentation (page 6-3).

Available Documentation

The documentation available to you in the Library is described below.

Procedures

These procedures are step-by-step instructions that help you perform an action on the system. For example, there are procedures that explain how to load samples or how to perform maintenance activities. Many procedures include illustrations that show you how to do the task. Often, there are links to other related procedures that you need to perform as part of a major activity.

Procedures in the Library are categorized into 3 categories:

System Operation	Procedures that are used to keep the system in operation, or are frequently used. For example, you can find procedures on how to load or unload samples and reagent and how to create an order.
Maintenance	Procedures for system maintenance that reflect the default Daily, Weekly, Monthly and Yearly periodic maintenance tasks listed on system Maintenance screens.
Self-Service	Self-Service procedures are procedures for as needed service to the system that a customer can complete without the need to make a service call. For example, you can find a Probe replacement procedure under this category. **WARNING:** Proper training is required before a user can execute self-service procedures. For more information, see Getting Started (page 1-6).

Procedures are provided in multiple views: diagram view, list view and frequency view. The Diagram View is the default view and will display the first time the screen is visited. Touch the Change View button to toggle between views.

Diagram View	An image of theORTHO VISION® Analyzer displays, with a list of the different components of the system to the left. Touch either the desired component on the system diagram or the name of the component from the list to display the procedures available for the selected system component.
List View	In the list view procedures are organized by system component. A list of system components displays. Touch a component to expand the procedures available under that component.
Frequency View	The frequency view is an additional view available for the Maintenance procedures. Procedures are organized based on the recommended interval of how often they are to be completed: Daily, Weekly, Monthly, or Yearly. Touch the interval to expand the procedures available below the row.

Help

Help screens assist in understanding the various software screens used to interact with the system. When you touch the Help button, (located in the bottom right corner of any screen), the system displays a Help screen with information specific to the current screen.

The Help screen may describe the following:

- the access level required for certain functions on the screen to be enabled
- the purpose of the system screen
- links to tell you more about a specific topic
- links to procedures for the specific topic
- screen information descriptions of the fields or other data on the screen
- instructions to help you use the screen
- action or filter buttons listed on the system screen

The topics listed below will appear at the top of the Help screen.

What Help Do You Need?	Links to Reference Guide material to tell you more about a specific topic
Quick Links	Includes direct links to specific areas of the Library: • System Operation – Displays the Help-Help Home-System Operation screen. • Maintenance – Displays the Help-Help Home-Maintenance screen. • Self-Service – Displays the Help-Help Home-Self-Service screen. • Reference Guide – Displays the Help-Help Home-Reference Guide screen. These same links will appear on all Help screens.

Reference Guide

The Reference Guide summarizes the concepts and procedures that you might encounter while using the system. It explains how the system works including safeguards and precautions, system components, functional theory and other operational topics.

For your convenience, this Reference Guide is designed to correspond with the user interface on the system. It is organized by the menus displayed along the top of the user interface: Home through Maintenance.

Touch Reference Guide to display a list of the chapters in the Reference Guide. Touch a chapter to display the expanded options to focus your search for specific information:

- Overview – displays the Overview page for the selected chapter
- Features – view the software features that are used in the area of the software that corresponds with the selected chapter
- Topics – displays the topics that are discussed in the selected chapter
- Tasks – displays the procedures that are included in the selected chapter

For example if you want to know how to load a sample, touch Reference Guide to display the Reference Guide chapters. Select Samples and then touch Tasks, from the expanded menu, and find the Load Samples procedure in the list provided.

Ortho provides the Reference Guide in printed form for use away from your system. The printed guide contains the same content as the Reference Guide provided on-board your system.

Note: If you need to replace your printed Reference Guide, please contact your Ortho Account Manager, or Ortho Laboratory Specialist.

FAQ

Touch FAQ to display a list of frequently asked questions about the system. The list is organized by category (procedures, maintenance, operation etc.). Touch a question to expand the answer below it.

Troubleshooting

Touch Troubleshooting to display a list of common troubleshooting topics quickly. For example, topics in this section include Fill Requirements, System Components, and System Startup and Shutdown.

About Help

Touch About Help to display information about other properties of your system, when they apply.

- The current Library version number
- The latest software release notes
- Current and previous Library revision histories
- AD History chart

Glossary

The Glossary provides definitions of terms used throughout the Library. Access the Glossary from the Reference Guide menu, touch Glossary. The system opens the Glossary. You can scroll through the list displayed for a term.

Ortho-Clinical Diagnostics, Inc. Communication

Communicate directly with Ortho-Clinical Diagnostics, Inc. (Ortho) Customer Ortho Care and view the Ortho website from the Library screen.

Note:

e-Connectivity® is required for the Ortho Chat feature to be operational.

For more information, seeInterfaces (page 14-18).

Ortho Chat

Touch Help > Ortho Chat to access the Ortho Chat screen. The Ortho Chat feature allows you to communicate directly with Ortho Care for inquiries, and service information.

Ortho Web

The Ortho Web feature provides access to the Ortho Website (http://www.orthoclinical.com) directly from your system. Touch Help > Ortho Web to display the Ortho website.

Use the Ortho website to review product information, customer toolkits, technical documentation, training and education information, as well as find information about support services.

The Ortho website is displayed in the menu screen. To return to the Library, touch Back.

Chapter 7 Resources

Resources Overview

Touch the Resources button to access the Resources screen. Use the Resources screen to monitor, discard, and replenish resources as needed. Select a button along the side of the Resources screen to display information about each resource.

This chapter reviews the topics listed below:

Resources Features

Resources features are used to give additional details about resource topics. For more information, see Resources Features (page 7-3).

Resources Configurations

These screens do not have configurable options.

Resources Action Buttons

The action buttons described below are located along the bottom of Resources screens:

Action Button	Description
 Assign to Position	Displays the Assign to Position wizard. **Note:** The Assign to Position button is active when a reagent position is selected.
 Change View	Switches the display between a diagram view and a table view.

(Continued)

Show Details

Displays additional information for the selected item.

Note: The Show Details button is active when a table row is selected.

To ORTHO Sera

Switches the diagram view display from the reagents rotor to the samples rotor, where ORTHO Sera™ Reagents are loaded.

Empty Liquid

Starts a wizard which guides you through the process of emptying the liquids container.

Empty Cassettes

Starts a wizard which guides you through the process of emptying the Cassettes container.

Load/Unload

Starts a wizard which guides you through the process of loading/unloading reagents.

Note: This button is active when a reagent position or reagent rack position is selected.

Pause Auto Refresh

Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refreshbutton to resume the automatic update.

Refill

Starts a wizard which guides you through the process of refilling the Deionized Water and Saline.

Register Ortho Lot

Starts a wizard which guides you the process of adding an Ortho Lot.

Register User Defined

Starts a wizard which guides you the process of adding a User Defined Lot.

Show Inventory Rpt.

Displays the Inventory report.

(Continued)

 Show Lot Switch Log	Displays the Lot Switch Log.
 Show Usage Statistics	Displays the Usage Statistics report.

Also see Assistance Buttons (page 5-10) , these buttons are available on each screen.

Resources Features

Resources screens have several features that are used to view details, or sort information about system resources.

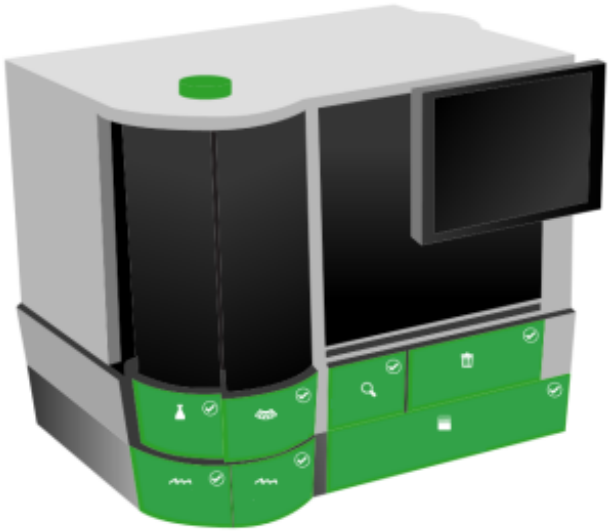
This chapter reviews the topics listed below:

Feature	Description
Change View (page 7-16)	Switches the display between a diagram view and a table view.
Status Indicators (page 5-16)	Explains the current status using text, colors, or icons.
Sort Option	Arranges table information in ascending or descending order when you select a column heading.
Show Details	Displays additional information for the selected item.

Return to Resources Overview (page 7-1)

Overview

The Resources Overview screen allows you to view a picture of the system in the Diagram View or a list in the Table View. In the Diagram View, notice an icon on each accessible area of the system. The buttons along the side of the screen display the same information about the system. Touch an icon or a button along the side of the screen to access an area of the system. The Diagram View is seen here:
Diagram View



The action buttons along the bottom of the screen are defined below:

Information Item	Description
Change View	Switches the display between a diagram view and a table view.
Show Inventory Rpt.	Displays information about the quantity of consumables on-board the system.
Show Lot Switch Log	Displays information about the product name, Lot ID, and first use.
Show Usage Statistics	Displays information about used/unused consumables. Number of orders failed/finished. Number of tests started/reportable/finished/failed. Number of test results started/indeterminate/finished/failed

For a list of action buttons in this chapter see Resources Overview (page 7-1).

Reagents

The Reagents screen allows you to review current inventory information for the Reagents loaded on the system. Touch Resources > Reagents to access this screen. Use this function to evaluate inventory and manage Reagent Lots (page 7-9). You can also load and unload Reagents as necessary. To access the Load/Unload button, touch Show Details while in the Table View of the Resources screen. Information is displayed in the Diagram View. The appearance and data displayed varies based on the barcode. The action buttons described below are located along the bottom of the Reagents screen:

- Load/Unload: Allows you to place or remove Reagents on or off the system.

  Note: When the Load/Unload button is touched, a timer appears along the bottom of the screen. The timer displays how much time is left until the door closes.

  Note: Load/Unload Reagents only from Load Station sections that were accessed through the APPLICATION SOFTWARE screen.

  DANGER: All Reagent Red Blood Cells must be fully resuspended prior to being loaded onto the system.

- Change View: switches the display between a Diagram View and a Table View.

- Assign to Position: allows you to select a position to load reagents. Use the Assign to Position button to identify reagents based on position. The reagent barcode can be scanned with the Handheld Barcode Scanner or entered manually, if the reagent does not have a barcode label, or the label cannot be read.
- **To ORTHO Sera**:

  Switches the diagram view display from the reagents rotor to the samples rotor, where ORTHO Sera™ Reagents are loaded.
- Pause Auto Refresh: Pauses the automatic update of the table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refresh button to resume the automatic update.

See Resources Overview (page 7-1) for a list of all action buttons in this chapter.

ORTHO™ Sera Reagents

ORTHOSera™ Reagents are loaded in Sample Racks on the sample rotor. From the Diagram View, touch the **To ORTHO Sera** action button to display the sample rotor and view the ORTHOSera™ Reagents loaded on the system. Only the rack positions that are available for reagents, or those that reagents are currently loaded to, are available when the sample rotor is viewed from the Resources-Reagents screen. Racks that have samples loaded are grayed out and indicated with a lock icon. Touch the To Normal action button to return to the Diagram View of the reagent rotor.

Note: You can also use the Zoom icon, located on the graphic to between the sample and reagent rotors. For more information, seeChange View (page 7-16).

Selected Reagent Rack

The table below is an example of the information displayed in the Diagram View after you select a Reagent Rack:

Information Item	Description
Status	See Status Indicators (page 5-16)
Location	The position of the selected resource.
Capacity	The amount the Reagent Rack can hold.
Barcode	The barcode of the selected resource or Reagent Rack.
Loaded by	The name of the user who loaded the resource.
Loaded when	Date and time of the last loading event of the selected resource.
Time since loaded	Elapsed time since the last loading event of the selected resource.

On Analyzer Stability of Ortho Reagent Red Blood Cells

This topic describes how to handle reagents. The cells must be gently inverted to mix, mixing is considered complete when the reagent red cells are completely suspended in the diluent. Place reagent red cells in an appropriate Reagent Rack. If any bubbles are on the top of the meniscus, they must dissipate before loading on the system.

IMPORTANT: Avoid agitation which could cause bubbles in the fluids. Remove any bubbles from the surface of the fluids prior to processing. Be careful to maintain the concentration and integrity of the fluids.

Freshly opened Ortho Reagent Red Blood Cells have been validated for continuous use on-board the system when using the ORTHO VISION® Evaporation Cap. Review the table below for the validated time periods that Ortho Reagent Red Blood Cells can be kept on the system.

(Continued)

Ortho Reagent Red Blood Cell Product	Time that freshly opened Ortho Reagent Red Blood Cells can be kept on the analyzer when using the ORTHO VISION® Evaporation Cap
0.8% Selectogen® 0.8% Surgiscreen® 0.8% BioVue® Screen: Untreated and Ficin Treated	5 Days (120 Hours) Performance after five days of continuous use on-board the system has not been validated.

Ortho Reagent Red Blood Cell Product	Time that freshly opened Ortho Reagent Red Blood Cells can be kept on the analyzer when using the ORTHO VISION® Evaporation Cap
0.8% Affirmagen® 0.8% Affirmagen® 3 0.8% Affirmagen® 4	2 Days (48 Hours) Performance after two days of continuous use on-board the system has not been validated.
3% Affirmagen® 3% Affirmagen® 4 3% Selectogen® 3% Surgiscreen® 4% BioVue® Screen J	3 Days (72 Hours) Performance after three days of continuous use on-board the system has not been validated.

Ortho Reagent Red Blood Cell Product	Handling
BioVue® Screen Resolve® Panel A Resolve® Panel B Resolve® Panel C 0.8% Resolve® Panel A 0.8% Resolve® Panel B 0.8% Resolve® Panel C	Ortho Reagent Red Blood Cells should be capped and stored at 2 to 8°C when not in use.

IMPORTANT: The system is not intended for reagent or diluent storage. The customer is responsible for monitoring the length of time reagents and diluents have been on the system.

Reagent Red Blood Cells must be at room temperature when they are loaded on the system.

IMPORTANT: If there is suspicion of testing performed with reagent red cells that were not completely resuspended, discard the entire set of the reagent red cells and repeat testing with a new set of reagent red cells.

IMPORTANT: Do not store Reagent Red Blood Cells that require agitation on-board the system if the system is going to be powered off or in maintenance mode. If Reagent Red Blood Cells that require agitation are left on-board the system after the system has been powered off or has been in maintenance mode, the Reagent Red Blood Cells are marked unusable. For Daily maintenance and Weekly maintenance tasks only, it is not required to remove Reagent Red Blood Cells from the system, since the system continues to agitate the Reagent Red Blood Cells during maintenance mode.

IMPORTANT: Make sure to load agitated or non-agitated reagents in their proper locations - Agitated (inner Rotor), non-agitated (outer Rotor). Refer to the Instructions for Use for information about a specific reagent.

DANGER: All Reagent Red Blood Cells must be fully resuspended prior to being loaded onto the system.

IMPORTANT: Open Ortho Reagent Red Blood Cells can be affected by evaporation, particularly in laboratory conditions of low humidity and high temperature. In extreme laboratory conditions, such as 15% relative humidity and a temperature of 30° C, excessive evaporation of Ortho Reagent Red Blood Cells reagent may be observed and result in analyzer error.

Evaporation Caps

Evaporation caps are disposable caps the user places on the Reagent Red Blood Cell vial. Evaporation caps fit 10 mL and 3 mL vials. The cap is intended to allow access to the metering probe and prevent evaporation of liquid from the Reagent Red Blood Cell vial. Evaporation caps are single use and are only used on Reagent Red Blood Cells.

On Analyzer Stability of ORTHOSera™ Reagents

The table below identifies the validated maximum cumulative hours that ORTHO Sera™ Reagents can be kept on the analyzer. When not on the analyzer the ORTHO Sera™ Reagents should be stored at 2-8 °C in a refrigerator. Also included are the On Analyzer Stability study conditions including the Number of Non-Consecutive Test Days and Total Test Duration.

Caution: Instances have been observed when using ORTHO Sera™ Anti-Le^{b} with the Buffered Gel Card on the ORTHO VISION® Analyzer where small agglutinates may be present above the cell button resulting in a false positive result when graded by the ORTHO VISION® Analyzer.

Caution: Instances have been observed when using ORTHO Sera™ Anti-P1 with the Anti-IgG Gel Card on the ORTHO VISION® Analyzer where small agglutinates may be present above the cell button resulting in an IND or false positive result when graded by the ORTHO VISION® Analyzer.

IMPORTANT: It is the customer's responsibility to ensure that the maximum continuous hours are not exceeded. The system does not track how long the ORTHO Sera™ Reagents are on the analyzer. Ortho cannot guarantee stability for reagents kept on the analyzer beyond the continuous use periods listed in the table. Follow your local operating procedures to determine suitability when used beyond the stated periods.

ORTHOSera™ Reagent	Maximum Continuous Hours On Analyzer

(Continued)

Anti-Fy[b]	18
Anti-Le[a]	
Anti-Le[b]	
Anti-P1	
Anti-M	
Anti-K	
Anti-Fy[a]	21
Anti-Jk[a]	
Anti-Jk[b]	
Anti-S	
Anti-s	
Anti-D (IAT)	
Anti-D (DVI)	

Note: The ORTHO Sera™ Reagents were used for 3 hours on the Analyzer each day of testing.

ORTHOSera™ Environmental Conditions

The analyzer is intended to be used in environmental conditions as high as 30° C. The ORTHO Sera™ products include the known cold reacting antibodies; Anti-Le[a], Anti-Le[b], Anti-P1, which may display reduced sensitivity, specifically, weaker than expected positive test results, when used on the analyzer in environments at or near their maximum thermal amplitude.

Specific studies were conducted to determine the maximum environmental temperatures for optimal performance with these specificities. The table below shows the maximum environmental temperature for the analyzer where assay reactivity was not reduced. When performing tests with the ORTHO Sera™ specificities listed below, Ortho recommends controlling, to the extent possible, the external environmental temperature to the ranges specified. In so doing, weaker than expected positive test results may be avoided.

Note: See Load Station Supplies (page 9-23) for more information on the appropriate rack to use with the ORTHO Sera™ Reagents.

ORTHOSera™ Name/ Reference Number	Maximum External Environmental Temperature when using 0.8% red cells (°C)	Maximum External Environmental Temperature when using 3-5% red cells (°C)
ORTHOSera™ Anti-Le[a] REF 6904497	23°C	23°C
ORTHOSera™ Anti-Le[b] REF 6904498	25°C	25°C
ORTHOSera™ Anti-P1 REF 6904496	24°C	24°C

Reagent Lots

Touch Resources > Reagent Lots to access this screen. Use this screen to register lots and view information about reagent kits. The information listed below is an example of the information located on this screen:

Information Item	Description
Lot Id	The Lot ID of the reagent.
Expiration date	The Lot's expiration date.
Consumables loaded	Reagents loaded at this time.
QC	If this is a sample based quality control, a list of the quality control passed profiles is displayed.
Reagent Kit	The name of the reagent kit or reagent family associated with the lot.
User defined	An indicator marks the associated reagent kit as user defined.

The Register Ortho Lot and Register User Defined action buttons are located along the bottom of the screen. See Resources Overview (page 7-1) for a list of action buttons in this chapter.

Register an Ortho Lot

The Register Ortho Lot button allows you to register an Ortho Lot. Use this feature to select from predefined tests on the system.

Register a User Defined Lot

This feature may not be available in your region.

The Register User Defined button allows you to expand the test menu beyond those tests currently available from Ortho Clinical Diagnostics.

Dilution Trays

The Dilution Trays screen allows you to view information about the availability and position of dilution wells. Touch Resources Dilution Trays to access this screen. The first time the Dilution Trays screen is accessed, the default selection is shown:
Dilution Trays

DANGER: Dilution Trays must be used only once. Never load a partially used Dilution Tray. Discard the Tray in compliance with your laboratory procedures for handling biohazardous materials.

The default selection displays information about the first tray, loading, usage, and consumption statistic. The information below is an example of what is displayed in the Diagram View once a tray is selected:

- Dilution tray- tray position
- Status- see Status Indicators (page 5-16)
- Location- rotor, tray, and position
- Barcode- barcode of the corresponding resource or tray
- Serial ID- serial number of one tray, included in the barcode information

The Load/Unload, Change View, and Pause Auto Refresh buttons are located along the bottom of the screen. See Resources Overview (page 7-1) for a list of action buttons in this chapter.

Load/Unload

DANGER: After making any Load/Unload request, only make changes in the LOAD STATION position for which access was requested on the APPLICATION SOFTWARE screen. The system does not inventory load station positions that were not selected through the APPLICATION SOFTWARE screen.

Select a tray to load or unload dilution wells. Information about the selected tray and dilution is displayed. Dilution wells are outlined in a color associated with the indicators listed below:

Well Position State	Color	Description
Used	Gray/Blue	Well has been used
Unused	Green	Well has not been used
Allocated	Blue	The well is allocated for processing
Scanning	Purple	It is unsure if the position is free or occupied
Warning	Yellow	Dilution well has a warning
Error	Red	Dilution well has an error

On Analyzer Stability of Diluents

The system is not intended for diluent storage. The system uses the diluents listed below:

- Buffered Saline
- 0.8% Red Cell Diluent
- ORTHO® BLISS

Cassettes

The Cassettes screen displays information about the Cassette carton position state and associated information (location and lot expiration dates). Use this screen to view the Cassette type as well as errors and warnings. Touch Resources > Cassettes to access this screen.

IMPORTANT: Make sure Cassettes are not expired. Check the expiration date on the label. When expired Cassettes are detected by the system, an error is posted and the Cassette is moved to the Manual Review Rack to be discarded.

IMPORTANT: To load a sleeve with more than one lot, leave an empty space in the sleeve between lots.

IMPORTANT: To load Cassettes of different types in the same sleeve, leave an empty space between each Cassette type.

Caution: Resources require certain handling conditions.

- The Supply Drawer is monitored at a temperature between 18°C-33°C. If the system detects resources outside of the temperature range, results are either flagged or not reported.
- Do not use the Supply Drawer to store resources.
- Add enough cassettes for daily use.

IMPORTANT: Excessive reuse of sleeves in the Supply Drawer may cause Grip01, Grip07, and Grip08 errors. Inspect the sleeves for damage and make sure the Cassettes are not tilted.

Caution: Before loading cassettes to the system, make sure the cassettes do not contain any liquid on the foil. Cassettes with liquid on the foil may cause contamination with the Gripper or Punch Tool. Discard cassettes with liquid on the foil.

Make sure the foil is sealed properly over all microtubes.

IMPORTANT: Do not manually punch the foil. The system will automatically punch the foil over the correct microtubes before running the test.

Place partially used cassettes with unused columns in the Load Area within the Dual Purpose Drawer. Do not place partially used cassettes with unused columns in the Supply Drawer.

IMPORTANT: Inspect all resources for potential quality problems prior to loading into the Supply Drawer or the Load Area of the Dual Purpose Drawer. For example, do not load resources that appear dried out.

Cassette Groups

Each Cassette carton contains Cassette groups. The carton displays the name of the Cassette in the group. Every Cassette position is numbered even if the position is empty. The table below is an example of information available when a Cassette group is selected:

Information Item	Description
Status	Location and warnings
Barcode	The barcode of the corresponding resource

(Continued)

Loading section	The name of the user who loaded the resource
Next action	Refill or change
Quantity available	Total number of Cassettes in the current Cassette group minus the number of allocated Cassettes
Lot number	Resource Lot ID Manufacturing Date Lot expiration Date QC Validity date
Consumption Statistic	The number of Cassette required for all test and pending orders

Partially Used / Processed Cassettes

Type	Definition
Partially Used	A partially used Cassette is a Cassette that contains some punched columns that have been fully processed, and some columns that have not been punched and are available for use
Partially Processed	A partially processed Cassette is a Cassette with punched columns where some fluids have been dispensed but the Cassette has not been centrifuged

Upon receiving an error free result, the Cassette is placed in the room temperature Incubator. Cassettes can remain in the room temperature Incubator, and be used for additional test processing, for up to 4 hours. If a partially used Cassette is not used within 4 hours, or there is no available space in the room temperature Incubator; the Cassette is placed in the Manual Review Rack. If the Manual Review Rack is full, the Cassette is discarded to the Waste Drawer.

Partially used Cassettes are tracked in software inventory. Partially used Cassettes are only displayed in the Table View and cannot be viewed in the Diagram View.

Note: Unallocated, partially used Cassettes remaining in the Incubator are not displayed in the user interface.

IMPORTANT: To prevent the reuse of partially used cassettes, do not manually reintroduce partially used Cassettes to the ORTHO VISION System.

Supported Cassettes

Caution: Ortho does not assume responsibility for results obtained with non-Ortho Cassettes. Use caution when handling Cassettes and sleeves. The Cassettes are sealed with foil which may have sharp edges. Keep hands and clothing clear while closing the Supply Drawer to avoid pinching fingers in the door.

The system is designed to use Cassettes and approved Ortho reagents. The system supports the Cassettes listed below:

- BioVue® ABO-Rh/Reverse Cassette
- BioVue® ABD Confirmation Cassette
- BioVue® Rh-hr

- BioVue® AHG Polyspecific Cassette
- BioVue® DAT/IDAT Cassette
- BioVue® AHG Anti-IgG Cassette
- BioVue® ABO-Rh Cassette
- BioVue® ADK Cassette
- BioVue® AHG Polyspecific/Neutral Cassette
- BioVue® Reverse Diluent Cassette
- BioVue® Rh/K Cassette
- BioVue® Rh/K II Cassette
- BioVue® ABD/Reverse Cassette
- BioVue® Neutral Cassette
- BioVue® Kell Cassette
- BioVue® ABO-DD Cassette
- BioVue® Newborn Cassette

Waste

The Waste screen displays the current status of theWaste Drawer and the Liquid Waste Bottle. Touch Resources > Waste to access this screen.
The Diagram View displays graphics of the Cassette waste and the liquid waste. The information below is displayed:

Information Item	Description
Total Capacity	The total available capacity of the container.
Free Capacity Estimate	The estimated available fill level of the container. **Note:** The Free Capacity Estimate includes calculated allocations based on the tests that are programmed on the system.

Available waste space is displayed in green. As the waste containers are filled, the used space displays in orange.
Notice the Empty Cassettes, Empty Liquid, and Change View buttons along the bottom of the screen. Touch Empty Cassettesor Empty Liquid to access the system and empty the Waste Drawer or the Liquid Waste Bottle.

Empty Waste

Touch the Empty Liquid button to empty the Liquid Waste Bottle. Every time the Liquid Waste Bottle is emptied, the saline and deionized water containers must also be completely refilled.

Each time the following sequence of events occurs, the onscreen confirmation dialogue becomes activated:

- A LIQUID ACCESS DOOR is opened
- A bottle is removed from the system
- At least 8 seconds of time elapses
- The bottle is replaced

The confirmation dialogue asks you to confirm that both the saline and deionized water containers have been completely filled and the Liquid Waste Bottle has been emptied. Select Yes to confirm. When Yes is selected, the system automatically resets the fill levels for both the

saline and deionized water containers and the Liquid Waste Bottle. If you select No, the refill levels are not reset.

IMPORTANT: Verify that the Waste Tray is fully seated in the Waste Drawer. Processing cannot start until the Waste Tray is fully seated in the Waste Drawer.

Biohazards

Handle all blood, and materials that may be in contact with blood, as if capable of transmitting infectious agents. All areas of the system must be considered potentially biohazardous and handled with the appropriate care as per your laboratory procedures for handling biohazardous materials, and in accordance with the procedures defined by the appropriate national biohazard safety guidelines or regulations. Observe Universal Precautions following the applicable regulatory agencies safety guidelines at all times when dealing with blood or body fluid and contaminated equipment.

Liquids

The Liquids screen allows you to monitor the availability of deionized water and saline on the system. Touch Resources > Liquids to access this screen. The system stores up to 1 liter of deionized water and up to 4.7 liters of saline in separate containers. The fill capacity displays on the screen below each container.

Information Item	Description
Total Capacity	The total available capacity of the container.
Current Capacity Estimate	The estimated fill level of the container. **Note:** The Current Capacity Estimate includes calculated allocations based on the tests that are programmed on the system.

As liquids are used, the remaining liquid level is displayed in green for both containers. The empty level displays in orange. Notice the Refill and Change View buttons along the bottom of the screen.
Touch the Change View button to display the Table View. The Table View displays information about the last time the liquid was refilled and remaining liquid level until the next required refill. An example of the Table View is below:

Information Item	Description
Resource name	Deionized water or saline solution
Quantity available	Calculated fill level
Quantity needed	Liquid volume required by the tests of all pending orders
Location	Location of the corresponding resource
Lot number	Does not apply for Liquids
QC valid for	Does not apply for Liquids
Time since load	Elapsed time since last loading event of the corresponding resource
Next action	No action/refill/change
Type	Type of resource

Refill Liquids

The Refill button is used to refill the liquids. When this button is pressed, a timer is displayed indicating the amount of time left to load/unload liquids. Every time the saline and deionized water containers are refilled, the Liquid Waste Bottle must also be emptied.

Each time the following sequence of events occurs, the onscreen confirmation dialogue becomes activated:

- A LIQUID ACCESS DOOR is opened
- A bottle is removed from the system
- At least 8 seconds of time elapses
- The bottle is replaced

The confirmation dialogue asks you to confirm that both the saline and deionized water containers have been completely filled and the Liquid Waste Bottle has been emptied. Select Yes to confirm. When Yes is selected, the system automatically resets the fill levels for both the saline and deionized water containers and the Liquid Waste Bottle. If you select No, the refill levels are not reset.

IMPORTANT: Only fill with liquids at room temperature.

IMPORTANT: Do not mix the liquids; avoid agitation which could cause bubbles in the liquids.

Manual Load/Review

The Manual Load/Review screen allows you to view the status of tests on the system that require manual review. Touch the Resources > Manual Load/Review button to access this screen.
A test requires manual review when one or more of the following applies:

- The global option for manual review is enabled
- The option for manual review of an order is enabled
- At least one of the selected options for automatic result acceptance is not fulfilled
- The pattern of interpreted assays does not match with any of the predefined test results
- The result is flagged for review
- Test results of the same test analysis within an order are discrepant

Notice the Load/Unload and Change View buttons along the bottom of the screen.
Use the Load/Unload button to open the Dual Purpose Drawer and access the Cassettes on the system.

Note: The system may occasionally take longer to open the Dual Purpose Drawer than is indicated in the “Time remaining” field on the screen. This can happen when a test is underway that requires two Cassettes. The system places the first Cassette in the manual review area of the Dual Purpose Drawer while the second Cassette is still in the Incubator or Centrifuge. The system will not allow access to the Dual Purpose Drawer until it has determined whether the second Cassette also requires review.

Use the Change View button to open the Dual Purpose Drawermove between the Table View or Diagram View.

Pause Auto Refresh

Screens containing information about Resources and Results refresh frequently. The Pause Auto Refresh button pauses the automatic update of the Table View and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refresh button to resume the automatic update.

Change View

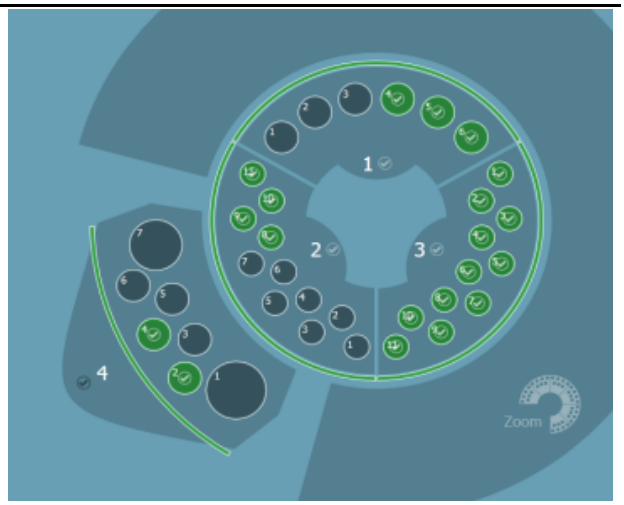
The system displays information in two ways, a Diagram View and a Table View. The Diagram View is the default view for each screen. The Diagram View displays a picture of the selected resource. The Table View displays an interactive data table for the selected resource. Touch the Change View button to display the Table View of the selected resource.

Diagram View

The Diagram View is the default view for each screen. The Diagram View displays an interactive graphic of the selected resource. Each resource area is highlighted in a color based on the status of the resource.

Resources > Reagents

The Reagents Diagram View screen displays a Zoom button that allows you to switch between the reagent rotor and the sample rotor. Touch Zoom on the graphic to view the ORTHO™ Sera Reagents on the sample rotor.



Note: When the sample rotor is viewed from the Resources-Reagents screen; any location on the rotor that is occupied with a SAMPLE RACK is indicated with a lock icon. These locations are not available for use with ORTHO™ Sera Reagents and can only be accessed from the Samples screen

Resources > Cassettes

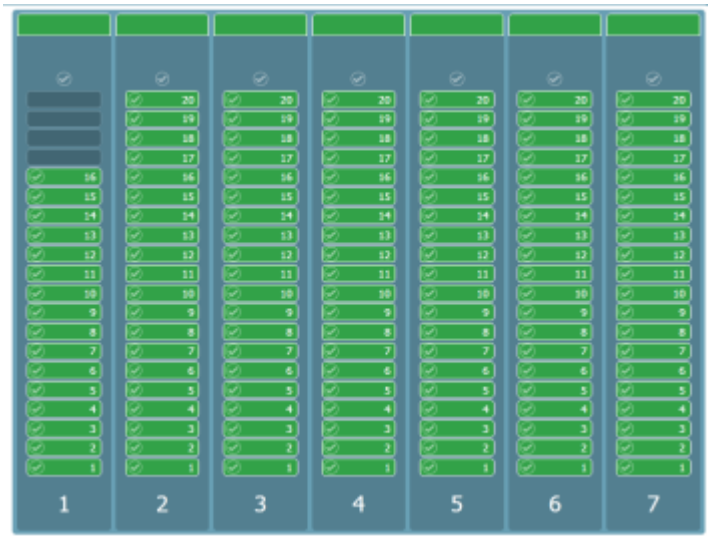


Table View

The table view displays an interactive data table for the selected resource. The table below is an example of information displayed in Cassettes . Each row in this table will give you information about available Cassettes, location, and lot number.

Resources	Quantity Available	Quantity Needed	Location	Lot Number
Rh-hr (11)	20 Cas.	0 Cas.	Supply Drawer Sleeve 2, Positions 1–20	1
AHG Polyspecific (22)	20 Cas.	0 Cas.	Supply Drawer Sleeve 3, Positions 1–20	1
DAT (30)	20 Cas.	0 Cas.	Supply Drawer Sleeve 4, Positions 1–20	1
Rh/K (77)	20 Cas.	0 Cas.	Supply Drawer Sleeve 5, Positions 1–20	1

Print

The Print option is available when you touch any of the report buttons located along the bottom of the Resources > Overview screen. Reports are available based on the topic selection.

Resources Procedures

The following procedures are referred to in Resources:

Manual Review (page 7-18)

Print the Inventory Report (page 7-18)

Manual Review

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to access the Manual Load/Reviewrack in the Dual Purpose Drawer. This procedure is accessed from the Resources screen.

1 Touch the Resources menu button.

2 Touch Manual Load/Review.

The Manual Load/Review screen is displayed.

3 Touch the Load/Unload action button.

A wizard is displayed, allowing you to open the Dual Purpose Drawer, unload cassettes, and close the drawer.

Touch Help for more information.

Print the Inventory Report

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

The Inventory Report shows information for the available resources on the system. This procedure is located in Resources overview diagram view.

1 Touch the Resources menu button.

2 Touch Overview.

3 Touch the Show Inventory Rpt. action button.

The Inventory Report is displayed.

4 Touch Print.

Touch Help for more information.

Chapter 8 Resource Categories

Resource Categories Overview

The system includes resources that require regular loading, unloading, replacement and maintenance. Resource categories are listed here:

Barcode Labels

Ortho reagents are barcoded to indicate reagent type, lot number, and expiration date. The reagent barcodes are scanned for positive reagent identification. Reagent expiration is verified prior to use, and once sample testing has been initiated with reagents that are in-date, the testing is considered valid.

Barcode Types:

The system supports the barcode type(s) listed below:

- Code 128 (A, B and C)
- CODABAR
- Code 39
- Interleaved 2 of 5
- ISBT 128

Containers

The system includes one of each of the containers listed below:

- Waste Tray
- Liquid Waste Bottle
- Liquid Container

Empty the waste containers as part of daily maintenance. The waste containers can be emptied at any time during the system operation.

DANGER: HANDLE WASTE AS BIOHAZARDOUS MATERIAL. DISPOSE OF WASTE ACCORDING TO ACCEPTED LABORATORY INSTRUCTIONS AND PROCEDURES.

Sample Containers

Sample containers are standard blood collection tubes. See Load Station Supplies (page 9-23) for information about sample containers.

Liquids

This system uses the wash liquids listed below:

- NaOH
- Buffered saline
- Deionized water

IMPORTANT: Only fill with liquids at room temperature.

IMPORTANT: Do not mix the liquids; avoid agitation which could cause bubbles in the liquids.

Materials Required But Not Supplied

The materials listed below are required for use with the system but are not supplied:

- 70% Isopropyl alcohol
- ORTHO™ 7% BSA (Bovine Serum Albumin) (5mL) (REF: 6844285)

  Note: ORTHO™ 7% BSA is required for the Daily Probe Maintenance task, to condition the probe after decontamination.
- Buffered saline
- Deionized or distilled water
- ORTHO VISION® Dilution Trays
- Mild detergent
- ORTHO VISION® Evaporation Caps
- ORTHO Red Cell Diluent
- ORTHO® BLISS
- 0.1 M NaOH

  Note: 0.1 M NaOH is required for the Daily Probe Maintenance task and some ORTHO™ Sera tests, to decontaminate the probe.
- Reagent Red Blood Cells
- ORTHO BioVue® Cassettes
- Quality Control Samples

70% isopropyl alcohol 70% ethanol 0.1M NaOH

Reagents

The system uses the reagents listed below:

- 0.8% AFFIRMAGEN® Reagent Red Blood Cells
- 0.8% AFFIRMAGEN® 3 Reagent Red Blood Cells
- 0.8% AFFIRMAGEN® 4 Reagent Red Blood Cells
- 0.8% BioVue® Screen Reagent Red Blood Cells
- 0.8% Red Cell Diluent
- 0.8% RESOLVE® Panel Reagent Red Blood Cells
- 0.8% RESOLVE® Panel A Reagent Red Blood Cells
- 0.8% RESOLVE® Panel B Reagent Red Blood Cells

- 0.8% RESOLVE® Panel C Reagent Red Blood Cells
- 0.8% SELECTOGEN® Reagent Red Blood Cells
- 0.8% SURGISCREEN® Reagent Red Blood Cells
- BioVue Screen J Reagent Red Blood Cells (3 mL)
- AFFIRMAGEN® Reagent Red Blood Cells (3 mL)
- AFFIRMAGEN® 4 Reagent Red Blood Cells (3 mL)
- Diego Reagent Red Blood Cells
- ORTHO BioVue® SCREEN
- ORTHO® BLISS
- ORTHO™ BROMELIN MT6
- SELECTOGEN® Reagent Red Blood Cells (3 mL)
- SURGISCREEN® Reagent Red Blood Cells (3 mL)
- RESOLVE® Panel A Reagent Red Blood Cells
- RESOLVE® Panel B Reagent Red Blood Cells
- RESOLVE® Panel C Reagent Red Blood Cells

Quality Control

- Blood Bank Reagent Control (BRC) kit
- AlbaQ-Chek J
- ORTHO CONFIDENCE™ WB

ORTHOSera™

- ORTHO™ Sera Anti-Fy^{a}
- ORTHO™ Sera Anti-Fy^{b}
- ORTHO™ Sera Anti-Jk^{a}
- ORTHO™ Sera Anti-Jk^{b}
- ORTHO™ Sera Anti-S
- ORTHO™ Sera Anti-s
- ORTHO™ Sera Anti-K
- ORTHO™ Sera Anti-D (IAT) (Anti-RH1)
- ORTHO™ Sera Anti-M
- ORTHO™ Sera Anti-Le^{a}
- ORTHO™ Sera Anti-Le^{b}
- ORTHO™ Sera Anti-P1
- ORTHO™ Sera Anti-D (DVI)

Not all products are available in all regions.

IMPORTANT: Outside the United States, when using a reagent not listed above, please refer to the User Defined Protocols (UDP) & User Defined Reagents (UDR) Guide.

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Chapter 9 Samples

Samples Overview

Touch the Samples button to display the Samples screen. The Samples screen allows you to review registered samples. Use the Samples screen to monitor, register, load and unload samples as needed. Select an action button along the bottom of the Samples screen to complete actions and view information about samples.
This chapter reviews the topics listed below:

Samples Features

Samples screens have several features that are used to view details about system samples. For example, some Samples features are the Change View button, sample status indicators, and the ability to sort sample data tables.

For more information, see Samples Features (page 9-3).

Samples Configurations

Control the appearance and functionality of Samples screens with Samples configurations. These items are configurable in the Setup Menu.

Note:

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

- General (page 14-7)
  - Patient Information Fields
  - ISBT Sample Barcode Display
  - Sample Barcode Interpretation
  - Sample ID Encryption
  - Order Archiving
- Testing (page 14-11)

- Profiles (page 14-13)

Samples Action Buttons

The action buttons described below are located along the bottom of Samples screens.

Action Button	Description
 Load/Unload	Displays the Samples-Load/Unload screen. Use this screen to open the Load Station Door in order to load and unload samples on the system. For more information, see Load/Unload Samples (page 9-13).
 Assign to Position	Displays the Samples-Assign to Position screen. Use this screen to select a position to assign a sample to. For more information, see Sample Registration (page 9-17).
 Change View	Switches the display between a diagram view and a table view.
 Create Order	Displays the Samples-Create Order screen. Use this screen to manually create an order. For more information, see Create an Order (page 9-32).
 Modify Order	Displays the Samples-Modify Order screen. Use this screen to select an order and make modifications to that order. **Note:** Orders can only be modified up until the first test process has started.
 Show Details	Displays additional information for the selected item.
 Batch Order	Displays the Samples-Batch Order. Use this screen to select multiple samples for an order. For more information, see Create a Batch Order (page 9-31).
 Cancel Order	Displays all orders on the Samples-Cancel Order screen. When an order is canceled, test processes are stopped. **Note:** If a test was completed before the order was canceled, those results are still reported.

(Continued)

 Pause Auto Refresh	Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refreshbutton to resume the automatic update.
 Add Donor Sample	Displays a field to enter Donor IDs when creating an order for cross-match tests.
 Cancel	Closes the screen and does not save entered data.
 Save and Start	Saves the entries or changes made on the screen and starts the order.

Samples Features

Samples screens have several features that are used to view details about system samples.

Change View	Switches the display between a diagram view and a table view. For more information, see Change View (page 7-16) .
Status Indicators (page 5-16)	Explains the current status using text, colors, or icons. For more information, see Status Indicators (page 5-16) .
Sort Option	Arranges table information in ascending or descending order when you select a column heading.
Show Details	Displays additional information for the selected item.
Pause Auto Refresh	Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refreshbutton to resume the automatic update.

Return to Samples Overview (page 9-1).

Samples Change View

The system can display sample information in two ways; a Diagram View and a Table View . The Diagram View is the default view for each screen, and displays an interactive graphic of the Sample Racks . The Table View displays an interactive data table of sample information. Touch the Change View button to display the Table View of the selected item. A selected sample position on the Diagram View automatically selects the row that corresponds with that sample on the Table View.

Diagram View

The Samples-Diagram View screen provides information about samples that have been assigned and loaded to the system, in a diagram that represents Sample Racks .

Note: Cancelled orders may not be displayed on the Diagram View of the Samples screen. Refer to the Table View of the Samples screen to review all orders including cancelled orders.

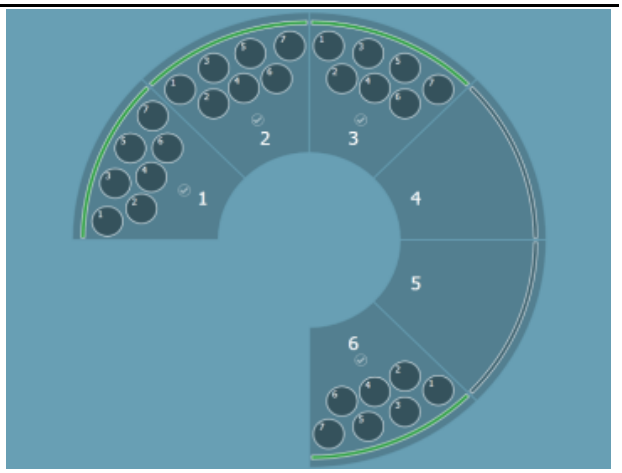
Samples screens use Status Indicators; a combination of symbols and colors that indicate the state and availability of samples, sample positions and Sample Racks.

For more information, see Status Indicators (page 5-16).

Note:

Racks 1, 2, 3 and 6 depict the Sample Rack positions.

Racks 4 and 5 depict what displays when there is no Sample Rack loaded on the system.



Note: ORTHO™ Sera Reagents loaded on Sample Racks (indicated with a lock symbol), are not accessible from the Samples screen. Load, unload, and view the ORTHO™ Sera Reagents from the Resources-Reagents screen. For more information, see Reagents (page 7-4).

Touch a sample position to view the additional details listed in the table below. Details display along the left side of the screen.

Sample Position Details

Sample ID	The barcode string of the selected sample
Status	The current state of the selected sample
Location	The Sample Rack and position the sample is assigned to
Sample Type	The liquid type of the selected sample For more information, see Sample Specifications (page 9-14).
Loading	Information about when the selected sample was loaded: • Loaded By – First and last name of the user who loaded the sample • Loaded When – Date and time the sample was loaded • Time Since Loaded – Elapsed time since the sample was loaded • Assign Mode – Indicates if the sample assigned to the position automatically or manually • Assigned When – Date and time when the sample was assigned • Estimated time to completion (pipetting) – Estimated time that pipetting from the selected sample will complete.
Usage	• Quantity Available – Available volume of sample liquid • Indication of Level – The method used for level detection

(Continued)

Most Recent Order	Order Information that displays when an order is assigned to the selected sample: • Patient ID • Priority • Profile Name • Number of Tubes • Saved for Manual Review • Manual Review Required • Processing Start Time • Cassette Selection • Reagent Selection • Diluent Selection

Touch a Sample Rack to view the detailed information listed in the table below. Details display along the left side of the screen.

Sample Rack Details	
Status	The current state of the selected Sample Rack
Location	Identifies the selected Sample Rack
Capacity	The number of sample positions and tube diameter
Barcode	Barcode string of the selected Sample Rack
Loading	Information about when the selected Sample Rack was loaded: • Loaded By – First and last name of the user who last loaded the Sample Rack • Loaded When – Date and time the Sample Rack was loaded • Time Since Loaded – Elapsed time since the Sample Rack was loaded • Estimated time to completion (pipetting) for the rack – Estimated time that pipetting from all samples on the Sample Rack will complete
Samples	Identifies the Sample ID and number of associated orders for each sample currently loaded on the Sample Rack

Table View

The Samples-Table View screen provides information for all samples registered to the system in a table format. Touch Samples > Change View to display the table. Each row of the table represents one sample, regardless of how many orders the sample may be associated with.

The information listed below is available for each sample, in the table.

Information Item	**Description**
Sample ID	The barcode string of the selected sample
Status	The current state of the selected sample
Priority	The priority of orders for the selected sample: STAT or Routine

(Continued)

Assigned Profile	Lists the profile(s) that are assigned to the selected sample
Load Time	The date and time when the selected sample was loaded
Location	The Sample Rack and position the selected sample is assigned to
Patient ID	The patient ID of the patient associated with the selected sample
Patient	The first and last name of the patient associated with the selected sample
Manual Review	Indicates the orders assigned to the selected sample that require manual review
Sample Role	Indicates whether the selected sample is used as first patient, second patient, or donor in assigned orders **Note:** Each line in the cell represents an individual order.

Show Details

Touch the Show Details button to display additional details about a selected sample.

For more information, see Show Details (page 9-11).

Create Order

Touch Samples > Create Order to display the Samples-Create Order screen. Use the Samples-Create Order screen to manually enter sample and test details to create an order. The Samples-Create Order screen displays information fields along the left side of the screen. Touch a field to activate it and display an editor along the right side of the screen. Use the fields on the right to input data and configure options for the order.
The table below describes the input fields.

Note: For a cross-match, multiple donors can be assigned to one recipient within a single order.

Note: To assign a single donor to multiple recipients for a cross-match, you must create multiple orders.

Note: Information for different patients can be associated with one Sample ID if the Patient Information is entered into the software manually. This can occur if the Patient Information feature has been turned on in the “Setup” area of the program and if the sample is scheduled for two different orders.

Input Field	Description
1st Sample ID	Enter or scan the Sample ID of the 1st Sample to be assigned to the order. The Sample ID must be entered twice when manually entered. **Note:** This field is pre-populated if the sample was selected when Create Order was touched.

(Continued)

1st Sample Liquid Type	Select the liquid type of the sample: • CENTBLOOD – Centrifuged whole blood (anticoagulated) • PACKED CELLS – Packed red blood cells • 0.8CELLS – 0.8% red cell suspension • 3CELLS – 3% red cell suspension • PLASMA – Plasma or Serum **Note:** CENTBLOOD is the default for 1st Sample Liquid Type **IMPORTANT:** All sample dilutions must be prepared using the correct diluents outlined in the Instructions For Use to the corresponding ORTHO BioVue® Cassette used for testing. **IMPORTANT:** The Sample Liquid Type selected for the Sample ID can only be changed once the results from all orders associated with that Sample ID have been archived.
1st Sample Location	A read-only field that displays the location of the 1st Sample, if loaded to the system.
2nd Sample ID	If a two sample order; enter or scan the Sample ID of the 2nd Sample to be assigned to the order. The Sample ID must be entered twice when manually entered. **IMPORTANT:** Do not assign a donor for a 2nd Sample. The 2nd Sample is only intended for a two tube assignment from the same patient.
2nd Sample Liquid Type	Select the liquid type of the 2nd Sample.
2nd Sample Location	A read-only field that displays the location of the 2nd Sample, if loaded to the system.
Assigned Profiles	Select the profile or profiles to be processed on the sample from the list that displays to the right. **Note:** When running panel tests, the lowest numbered cell selected will run in column 1 of the Cassette, the remaining cells selected for that Sample will follow sequentially in the remaining columns.
Add Donor Sample	**Note:** The Add Donor Sample button becomes active when a profile is assigned that requires a cross-match test. Touch the Add Donor Sample button to display Sample ID and Sample Type fields for the donor sample. Select the Sample ID Donor 1 field to display a list of the donor samples that are currently loaded on the system. You can select the Sample ID from the list displayed or touch Keyboard to scan the sample or manually enter the Sample ID. Touch the Add Donor Sample button again to add additional donors to the order. **IMPORTANT:** Make sure that a donor entry appears in the donor field, and not in the 2nd Sample field.
Priority	Select the priority of the order: • Routine – the default option • STAT

(Continued)

Manual Rev. required	Select whether a manual review of the Cassette is required: • Yes • No – the default option

(Continued)

Patient Information

IMPORTANT: Ortho Clinical Diagnostics does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the Sample ID. Ortho occasionally requests files from your system that may contain Sample IDs, if used as a sample identifier, to assist in troubleshooting or performing routine maintenance of the system. Avoid the use of patient-identifying information as part of the Sample ID, or configure the system to enable Sample ID Encryption.

Enter or edit the demographic information about the patient

Note: Patient Information can be configured on the Setup screen. These fields may appear differently dependent of how your system is configured. For more information, see General (page 14-7).

Patient Information can be associated with orders using the Patient Information feature in Setup

Note: If any of the following fields are set to “Yes” on the Setup > General >Create Order screen, the designated information can be entered manually on the Samples >Create Order screen.

- Patient ID
- Gender
- First Name
- Last Name
- Mother's Birth Name
- Patient's Birth Name
- Middle Initial
- Birthdate
- Medical Record
- Address
- National ID
- Other ID

Note: If all fields for Patient Information are set to “No” on the Setup > General > Patient Information screen, no Patient Information can be entered manually on the Samples > Create Order screen. In this case, the Sample ID cannot have any Patient Information associated with it. “No” is the default setting for all Patient Information fields.

When creating an order for a Sample ID and Patient Information is allowed to be entered on the Samples > Create Order screen, the operator can manually enter Patient Information for the Sample ID. If a second order is created for the same Sample ID, the software allows the operator to enter the same or different Patient Information. The operator could enter a completely different Patient Name, for example, and then the Sample ID would have two patients assigned to it.

Refer to example below to create two different orders with same Sample ID.

Touch Setup > General > Patient Information, to display options.

Patient Information allowed to be entered manually includes:

- Name
- First Name

(Continued)

For Order 1: Touch Samples > Create Order for Sample ID 12345

Field Name	Value
1st Sample ID	12345
Assigned Profiles	Type
Last Name	Jones
First Name	Richard

- After each entry, the value is shown next to the field name on the left side of the screen.
- The order begins when the operator touches the Save and Start button.

For Order 2: Touch Samples > Create Order for Sample ID 12345

Field Name	Value
1st Sample ID	12345
Assigned Profiles	Screen3
Last Name	Jones
First Name	Richard

- After each entry, the value is shown next to the field name on the left side of the screen.
- The order begins when the operator touches the Save and Start button.

Note: If the operator does not recognize that the name Jones was spelled J-O-N-A-S for the second order and does not correct the error before touching the Save and Start button, the Sample ID 12345 now has two patient names associated with it.

Search Results by Patient Information:

Results are displayed for only the patient name that is entered into the Search screen. No other names that may be assigned to the same Sample ID are displayed. For example, If the operator enters Richard Jones into the Search Results screen, results for Sample ID 12345, Profile Type are displayed.

Search Results by Sample ID:

All results for the Sample ID that is entered into the Search screen are displayed. This search displays all information for the Sample ID including all Patient Names assigned to the Sample ID. For example, If the operator enters Sample ID 12345 into the Search Results screen, results for Sample ID 12345 for both Profile Type (Richard Jones) and Profile Screen3 (Richard Jonas) are displayed.

IMPORTANT: Enter Patient Information very carefully into the Samples > Create Order screen. Always examine the information displayed on the left side of the screen to make sure it is accurate. Correct any errors and review the information again. Then touch the Save and Start button to begin the order.

Serial Dilution Setup	**Note:** This field only displays when a profile that requires dilution is selected above. Setup the serial dilution by completing a series of steps: select the dilution series to setup, select the diluent to be used, select the reagent red cells to be used. **IMPORTANT:** Ortho does not recommend running multiple serial dilutions at the same time against the same sample. Running multiple serial dilutions may affect the reaction strengths. For more information, see Serial Dilution and Red Cell Suspension (page 9-18).
Enabling of Assays	**Note:** This field only displays if a profile that requires panel cells is selected above. First, select a test under Test Specification; then, deselect the Assays of the selected test that you do not want to be processed on the sample.

Validation Information

Touch Save and Start to save and start your order. The system performs a validation check of the input data and all onboard consumables to determine the order details are valid and there are enough resources onboard the system to complete all order processes.

If the order is validated, the Samples screen displays and the order is created.

If the order is not validated, the information listed below is displayed about the invalid order:

- Profile Name – name of the profile associated with the invalid order
- Tests – a list of all tests associated with the invalid order
- Information – a description for why the order is invalid and therefor cannot begin processing

Invalid orders will not start processing. You can edit the order information from this screen by touching an input field to the left. The same input screen appears. Make your changes and touch Save and Start again. The system performs another validation check.

Show Details

View details about a sample with the Show Details button. Select a sample on the Samples-Table View screen and touch Show Details to display additional information.
The Samples-Show Details screen displays the information items described in the table below.

Information Item	Description
Sample ID	The barcode string of the selected sample
Status	The current state of the selected sample
Location	The Sample Rack and position the sample is assigned to
Sample Type	The liquid type of the selected sample

(Continued)

Loading	Information about when the selected sample was loaded: • Loaded By – First and last name of the user who loaded the sample • Loaded When – Date and time the sample was loaded • Time Since Loaded – Elapsed time since the sample was loaded • Assign Mode – Indicates if the sample assigned to the position automatically or manually • Assigned When – Date and time when the sample was assigned • Estimated time to completion (pipetting) – Estimated time that pipetting from the selected sample will complete.
Usage	• Quantity Available – Available volume of sample liquid • Indication of Level – The method used for level detection
Order	Information about orders that the sample is assigned to: • Order ID • Priority • Creation Date • Auto Cancel Date/Time • Profile Name • Registration Mode • Number of Tubes • 1st Sample • 2nd Sample • Donor Samples • Reflex • Saved for Manual Review • Manual Review Required • Processing Start Time • Selected Cells • Cassette Lots • Reagent Lots • Cassette Selection • Reagent Selection • Diluent Selection

(Continued)

Patient Demographics	Displays the information below about the patient: • Patient ID • Gender • Patient Name • Mother's Birth Name • Patient's Birth Name • Middle Initial • Date of Birth • Medical Record • Address • National ID • Other ID For more information, see Patient Data (page 9-17).
Attending Physician	Displays the information below, about the physician: • ID • Last Name • First Name • Middle Initial

Load/Unload Samples

Load and unload samples with a wizard that displays on the Samples-Load/Unload screen. Touch Load/Unload to display the wizard. Use the wizard to unlock the Load Station Door and guide you through the steps to load or unload samples.
Once the wizard is opened; a progress bar is displayed at the bottom of the screen that indicates the time that remains before the Load Station Door is unlocked. When the time elapses, the Load Station Door is unlocked and you can access the Load Station to load or unload your samples.
Make sure all samples, diluents and reagents have been properly loaded into either the agitated (inner) Rotor or non-agitated (outer) Rotor. Reagent Red Blood Cells must be loaded in the agitated (inner) Rotor. Store all reagents and diluents off-board the system according to their IFUs.

Load Samples

Before you load samples ensure that:

- Tubes contain at least the minimum volume of sample (based on maximum height of the packed red cell volume and tube size) and are free of bubbles or foam.

  For more information, see Load Station Supplies (page 9-23).
- Barcode labels are affixed correctly and firmly to the sample tubes.

  For more information, see Sample Barcode Label Use (page 9-21).
- Whole Blood and packed cells samples are centrifuged.
- Pre-diluted samples are fully suspended.
- Caps/stoppers are removed from samples, reagents and diluents.
- Reagents are mixed, free of bubbles or foam, in-date, and in sufficient quantity for run.

- If quality control is configured for the test to be performed and is expired, or near expiration; add the quality control samples appropriate for the test. For more information, see QC Overview (page 13-1).

IMPORTANT: Avoid agitation which could cause bubbles in the fluids. Remove any bubbles from the surface of the fluids prior to processing. Be careful to maintain the concentration and integrity of the fluids.

For more information, see Sample Specifications (page 9-14).

Unload Samples

To remove samples, touch Load/Unload from the Samples screen. A sample can be removed from the Load Station once pipetting has completed for all tests assigned to the sample. Samples and SAMPLE RACKS that are ready to be removed from the system display on the Diagram View of the Samples screen in dark blue.

For more information, see Status Indicators (page 5-16).

Note: The estimated time until pipetting is complete is displayed on the Diagram View of the Samples screen and the Samples-Show Details screen.

Load/Unload Samples Simultaneously

If you want to load or unload samples to another Sample Rack, select the Sample Rack from the Diagram View on the screen: the Load Station rotates to the selected location.

Note: The Consumable Inventory is completed after each time the Load Station is accessed to determine what samples were loaded or unloaded. The Inventory applies only to the Load Station sections that were accessed through the APPLICATION SOFTWARE screen.

Diagram View vs. Table View

The Load/Unload button functions differently when touched on the Diagram View screen or the Table View screen.

You can both load and unload samples from the Diagram View screen. Just touch the sample position or Sample Rack and touch Load/Unload.

Samples can only be unloaded from the Table View. To unload a sample, touch the row that corresponds with the sample to be unloaded and touch Load/Unload. The wizard will display, and the Load Station Door will open to the location of the selected sample.

Sample Specifications

Supported Sample Types

The system supports the use of 5 fluid types for samples.

- Centrifuged Whole Blood (anticoagulated)
- Plasma and Serum
- Packed Red Blood Cells
- 3% Red Cell Suspension
- 0.8% Red Cell Suspension

Sample Tube Materials

The containers listed below are allowed:

- Glass tubes
- Plastic tubes

Sample Tube Size

- Automatic diameter adapter (minimum = 9 mm; maximum = 16 mm)
- Maximum tube height = 100 mm
- Minimum tube height = 47 mm

Sample Racks are available in multiple sizes to accommodate the tubes supported by the system.

For more information, see Load Station Supplies (page 9-23).

Sample Preparation

IMPORTANT: Avoid agitation which could cause bubbles in the fluids. Remove any bubbles from the surface of the fluids prior to processing. Be careful to maintain the concentration and integrity of the fluids.

Both single and double tube samples may be loaded for the same test.

Samples should be brought to room temperature before use. If using one tube per sample, the centrifuged anticoagulated whole blood should have RBCs at the bottom of the tube and plasma as the supernatant. If using two tubes per sample, the centrifuged anticoagulated whole blood can be separated into two tubes; the first tube may contain packed RBCs, and the second tube may contain plasma. If non-anticoagulated whole blood is used, only the serum may be used. Single tubes containing serum and a red cell clot may not be used.

DANGER: Make sure to select the proper sample type before proceeding. Selecting an incorrect sample type may cause incorrect results.

Samples collected with anticoagulant must be centrifuged to provide a top layer of plasma, free of clots and fibrin, and a lower layer of packed red cells.

Coagulated samples must be centrifuged to provide a top layer of serum, free of clots and fibrin. The serum must be transferred to a separate tube prior to processing on the system. The clotted red cell layer is unusable for testing.

IMPORTANT: Tubes containing both serum and a red cell clot may not be used on the system. Transfer serum to an appropriate aliquot tube for serum only testing.

IMPORTANT: Plasma separators are not supported.

Refer to the table below for the testing supported for each available sample type.

Sample Type	Liquid Type (on-screen selection)	Supported Testing
Whole Blood - Anticoagulated - Centrifuged	CENTBLOOD	Antibody, Antigen, Crossmatch (RBC and plasma)
Donor segments (centrifuged)	PACKEDCELLS	Antigen, Crossmatch (RBC only)
Plasma only	PLASMA	Antibody, Crossmatch (plasma only)
Serum only	PLASMA	Antibody, Crossmatch (serum only)
3% Red Cell Suspension	3CELLS	Antigen, Crossmatch (RBC only)

(Continued)

0.8% Red Cell Suspension	0.8CELLS	Antigen, Crossmatch (RBC only)

DANGER: A 0.8% or 3-5% pre-diluted cell suspension is a suspension prepared by the user, not by the system. When programming a sample as pre-diluted, select the appropriate sample type: 0.8CELLS or 3CELLS. It is important to remove any bubbles on the surface of the suspension. The system maintains a uniform suspension by aspirating and dispensing in the sample tube, and bubbles may cause the system to aspirate air which can result in foam. A minimum fill height of 12mm is recommended for pre-diluted cell suspensions to ensure proper mixing.

Reducing Fibrin Errors

To reduce the frequency of FIB errors, the samples should be centrifuged at a Relative Centrifugal Force (RCF) of 2338 for 10 minutes. Alternate RCF and time parameters may be used to achieve similar results. Each laboratory needs to verify their own sample preparation protocols, taking into account the sample tube manufacturers' recommendations and population they support.

For more information, see Codes (page 10-17).

RCF (Relative Centrifugal Force) = $(N/1000)^2 * R * G$

G = Gravitational Constant = 1.118

R = Radius of centrifuge in mm; measuring from the center of the rotor to the bottom of the test tube

N = Revolutions/ minute (RPMs)

Antibody Titers

Testing of the ORTHO VISION® Analyzer indicated that a sample with a high-titered antibody (>1:1024) when tested may intermittently cause carryover in the subsequent sample test columns. The number of columns affected is dependent on the magnitude of the high titer sample. Testing also indicated that carryover was not observed in samples with antibody titers of 1:512 or 1:1024. If a high titer antibody sample (>1:1024) is suspected of being processed it is recommended to review column results for all plasma and/or cells dispenses that occurred after the high titer sample and to perform the Daily Probe Maintenance procedure.

On-board Residence

IMPORTANT: Do not store samples on-board the system if the system is going to be powered off. Samples can remain on-board the system for up to 4 hours.

Once a sample barcode is scanned for the first time, the system begins to time how long it has been on-board the system. If a sample is detected on-board the system at start up, the sample is marked as unusable.

The load time and on-board residence time is displayed on the Samples screen. For more information, see Samples Change View (page 9-3).

Sample Inventory

Samples on-board the system are tracked with Sample Inventory. The system scans sample barcodes at start up, shutdown and whenever there is user access to the Load Station, to inventory samples. After user access, each sample is scanned to determine if samples were removed or added only in the Load Station sections that were accessed through the APPLICATION SOFTWARE screen.

Sample Registration

Samples can be registered in one of two ways:

- Automatically, through the Laboratory Information System (LIS)
- Manually, by physical position

Manual Sample Registration

Manual registration of a sample may be required when:

- The system is not connected to a Laboratory Information System (LIS)
- The barcode label on the sample tube is not able to be scanned by the system
- The sample does not have a barcode label

Note: Refer to Sample Barcode Label Use (page 9-21) and your laboratory SOPs for more information about acceptable sample labeling standards.

Assign to Position

Use the Assign to Position feature to identify a sample based on it's location on the system. You can use the Handheld Barcode Scanner or enter the Sample ID manually, if the sample does not have a barcode label, or it cannot be scanned. Access this feature from the Samples screen. Touch Assign to Position to display the Samples-Assign to Position screen.

The Samples-Assign to Position screen displays a wizard. Use the wizard to gain access to the Load Station. Once the Load Station Door is unlocked, select a Sample Rack and position on the user interface and load the sample. The sample is then identified by the system and automatically linked with the orders that correspond with it's Sample ID.

DANGER: Mismatched samples, reagents, or diluents may result in incorrect results. Remove the appropriate Rack from the Load Station. Enter the sample ID, reagent ID, or diluent ID in the appropriate fields on the screen, as needed. Verify all sample, reagent, or diluent positions are correct through the software screen diagram before starting sample processing.

For more information, see (Library).

Double-blind Entry

Double-blind entry is required when a Sample ID must be entered manually. If the barcode can be read by the Handheld Barcode Scanner, then the item needs to be scanned once and the system automatically validates the entry. If the barcode cannot be read by the Handheld Barcode Scanner, then the barcode must be entered manually. Use the on-screen keyboard to enter the Sample ID twice. The barcode is then validated by the system.

DANGER: To prevent incorrect assignment for samples, reagents, or diluents without barcodes do not unload or load more than one sample, reagent, or diluent at a time.

Patient Data

Demographic information about the patient is displayed when the sample details are viewed from theSamples or Results screens. The data is either delivered by the Laboratory Information System (LIS) or entered manually by a user when an order is created.
The patient data items that are displayed on these screens can be configured on the Setup-General-Modify Patient Data screen; so not all of the items below may be visible on your system, dependent on how your laboratory has configured these options.
For more information, see General (page 14-7).

Patient ID	The unique identifier for the patient.

(Continued)

Gender	Gender of the patient.
Name	The first name of the patient.
Surname	The last name of the patient.
Mother's Birth Name	The birth name of the patient's mother.
Patient's Birth Name	The birth name of the patient.
Middle Initial	The first letter of the patient's middle name.
Date of Birth	The patient's birth date.
Medical Record	The medical record of the patient.
Address	The address of the patient.
National ID	The National ID of the patient.
Other ID	Additional identification.

Edit Patient Data

Patient data can be edited when an order is created or modified. Touch Modify Order or Create Order on the Samples screen. Patient data displays to the left of the screen. Select the item that you want to edit to display a keyboard and an input field on the right of the screen to enter your changes.

Note: When the patient information fields are selected, the fields are pre-populated with the most recent patient demographic information saved on the system.

For more information, see Create an Order (page 9-32).

Profiles

In the software, analyses are set up and labeled as profiles. Both single or multiple tests can be added to one profile. For example, you might set up a test profile that provides analysis results for ABO, Rh, and antibody screening. In this profile, you would indicate the appropriate tests you want the system to process on the sample.
Profiles can be created, modified, and deleted on the Setup-Testing screen. The items listed below are defined when a profile is created.

- Profile name
- Tests to be included in the profile
- Reflex test rules

Note:

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

For more information, see Profiles (page 14-13).

Serial Dilution and Red Cell Suspension

The system supports both serial dilutions and red cell suspensions.

Serial Dilution

Serial dilutions are required for some samples before testing. Serial dilutions from 1:1 to 1:1024 are supported. The user needs to select the start and end for a dilution level (example 1:8) where the options are from 1:1 to 1:1024. The start selection will be defaulted to 1:1 and the end selection will be defaulted to 1:1024. The user must select an end dilution that is equal to or greater than the starting point. If a dilution starting of greater than 1:1 is selected the system will still use dilution wells to dilute each step. A control will always be run with the test. Serial Dilutions are prepared by the system with diluents that are stored in the Load Station. Serial dilutions are performed with Blood Bank Saline.

Serial dilutions are completed in disposable Dilution Trays. Each dilution series uses twelve wells of the Dilution Tray: eleven wells are used for the dilutions of 1 to 1024, and the twelfth well is used for a saline control.

IMPORTANT: A positive reaction in the saline control of a serial dilution test may indicate carryover has occurred and that a high titer antibody (> 1:1024) is present in the sample. All associated results from this test are invalid. For more information, see Sample Specifications (page 9-14).

When a serial dilution is required for a test that has been selected, the field displays on the Samples-Create Order screen. You can select the dilution series test to use, the diluent, and the Reagent Red Blood Cells to be used in the serial dilution.

For more information, see Create Order (page 9-6).

Red Cell Suspension

Red Cell suspensions are created automatically when required, without intervention from the user. The diluents used are:

- Blood Bank Saline
- ORTHO® Red Cell Diluent
- ORTHO® BLISS

Barcode Labels

Barcode labels automate identification of a sample and its corresponding order. The sample identification number is printed in barcode form on a label that is affixed to the original sample container or other specimen container. The barcode label represents the sample identification number in both barcode symbology and human-readable characters. The barcode appears with its bars perpendicular to the label length.
When using barcode labels, it is not necessary to assign the sample to a position on the Samples screen. Place the barcoded sample container in any position on any rack with the label facing out. A scanner reads and decodes the barcode, then transmits the Sample ID to the system. The system searches its database to find the corresponding order, or if the system is configured for Host Query, it will request the order from the Laboratory Information System (LIS).
You can place human-readable information or graphics on the label in any orientation, as long as it does not interfere with the barcode, the barcode quiet zone, or the human-readable interpretation of the barcode.

PSID Barcode Labels

Positive Sample Identification (PSID) identifies a sample and its corresponding sample program through an alphanumeric identification number. This identification number is printed in barcode form on a label affixed to the primary sample container. Ortho Clinical Diagnostics supports but does not provide PSID Barcode labels.

For more information, see Positive Sample Identification (page 9-21).

Barcode Types

Refer to the following table for supported barcode types. The table identifies the character length of the Sample ID and type of characters used for each barcode.

IMPORTANT: Only Barcodes with quality grades A-C should be used on-board the system. Strong symbologies are highly recommended; for example Code 128. These symbologies are considered weak on-board the system: NW7 (Codabar), 2 of 5 (Interleaved), 3 of 9 (Code 39). Verify that barcode labels are not damaged, dirty or that the tube contains multiple barcode labels.

Barcode Type	Sample ID Length	Alphanumeric/Numeric
Code 3 of 9 (Code 39)	4 to 15	Alphanumeric
NW7 (Codabar)	4 to 15	10 numeric and 6 additional characters
2 of 5 (Interleaved)	4 to 14	Numeric
Code 128 (A, B, and C subtypes)	4 to 15	Alphanumeric (A and B subtypes) Numeric (C subtype)
ISBT 128	16	Alphanumeric

Code 39 (also called Code 3 of 9) is an alphanumeric barcode symbology consisting of 43 data characters.

Codabar symbology uses characters 0 to 9, A to D, and 6 additional characters (/ . : + - $). It also designates four different start and stop characters. The system does not differentiate the various start/stop combinations.

Interleaved 2 of 5 uses numeric barcode symbology only. The characters interleave together to represent data characters in the odd positions, and spaces represent data characters in the even positions. The total number of characters you place on the label must be even, since the characters are interleaved in pairs. If you encode an odd number of characters, add a leading zero to change to an even number of characters.

Note: The system performs a length check of the characters for Interleaved 2 of 5 barcodes.

Code 128 (A and B) uses 103 encodable characters, including the full 128 ASCII character set. This code contains an encodable character set, four non-data function characters, four code-set selection function characters, three start characters, and one stop character. The check digit is encoded into this character set.

Code 128 C uses numeric barcode symbology only and requires an even number of characters.

ISBT 128 barcode symbology uses a specific format for labels that contain the Donation Identification Number. ISBT 128 barcodes uses a 16 character format: **Pappppyynnnnnnff.**

- P is the primary data identifier (“=”)
- apppp designates the country/collection facility
- yy designates the year in which the donation was made
- nnnnnn is the serial number associated with the donation
- ff represent special flag characters

Enable or disable the display of the “=” in ISBT 128 barcodes on the Setup screen.

For more information, see General (page 14-7).

How to Place the Barcode Label on the Sample Container

For more information, see Sample Barcode Label Use (page 9-21).

Positive Sample Identification

Positive Sample Identification (PSID) uses barcode labels on the sample container to automate the process of identifying samples. When using PSID, you do not have to assign rack positions in Samples. The PSID scanner reads and decodes the barcode, then transmits the Sample ID number to the system. Sample processes continue normally.
For maximum efficiency:

- Print the barcode labels that contain the Sample ID number while printing the draw list during sample collection
- Download sample information such as the Sample ID number and test request from the LIS to the system using the bidirectional interface.
- Make sure the pre-printed barcode labels containing matching Sample ID numbers (or labels generated by your laboratory printer) are on the sample containers.

Caution: Do not move samples from one position to another in the rack until sample processing is completed.

Caution: With Software versions 5.12.8 and below, when multiple samples with the same sample ID are placed on board, the system would display an "Apsw81— Sample ID is Not Unique" error, but the system may have processed orders on one sample while blocking subsequent samples. With Software version 5.13.0 and above, the system correctly blocks all in-process orders for that sample ID, in addition to displaying the "Apsw81— Sample ID is Not Unique" error.

Note: User should follow their Laboratory Standard Operating Procedures and the common blood bank safety practices to ensure that the samples are properly labeled prior to loading on the system.

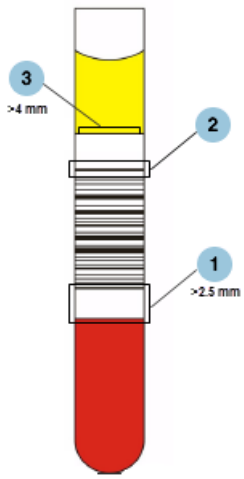
Sample Barcode Label Use

Barcode Accommodation

To ensure correct reading of sample tube barcodes, observe the label and position requirements below:

- Barcode labels must have a “quiet” (white) zone 1 that is 10 times the size of the smallest element (or line) 2 of the barcode but a minimum of 2.5 mm on each side.
- The width 3 of the label must be at least 4 mm.
- The label must be placed on the upper-half of the sample tube

Note: Readability of sample barcodes is dependent upon the print quality and label position of the sample barcode label.



IMPORTANT: Barcode labels should be placed on sample containers vertically. When placed on the system, the containers should be placed in a vertical orientation with the barcode label faced outward.

IMPORTANT: Only Barcodes with quality grades A-C should be used on-board the system. Strong symbologies are highly recommended; for example Code 128. These symbologies are considered weak on-board the system: NW7 (Codabar), 2 of 5 (Interleaved), 3 of 9 (Code 39). Verify that barcode labels are not damaged, dirty or that the tube contains multiple barcode labels.

IMPORTANT: To improve system reading, or if the system is unable to read a sample barcode; place the sample barcode label higher on the sample container and ensure the label is vertical (not tilted) with the sample container. If frequent no tube found errors are observed, position the sample barcode label on the sample container such that the sample barcode label, when placed in the SAMPLE RACK, obscures the no tube label on the SAMPLE RACK.

Refer to the table below for additional specifications.

Container Size	Maximum Symbol Length
16 mm diameter	2.125 inches
13 mm diameter	2.125 inches
10.25 mm diameter	2.125 inches
Pediatric Containers	For pediatric containers, the symbol length must not exceed the actual cylindrical container length. The barcode must be entirely visible through the adaptor window, as appropriate. Pediatric Sample Racks can accommodate barcode labels for pediatric containers. For more information, see Load Station Supplies (page 9-23).

STAT Samples

STAT indicates that a sample is assigned a test that has a higher priority to be processed than other samples that have been indicated as routine, or normal priority. The software will prioritze tests with a STAT priority to be processed before routine samples.

Note: Routine orders that have already started will continue to process when a STAT sample is added. The time to completion may be affected. Monitor STAT and routine sample time to completion on the Dashboard.

The priority of a test is indicated when an order is created on the Samples-Create Order screen. This option must be selected by the user, as the default setting is to run the sample as a routine priority. A STAT sample can also be received from the Laboratory Information System (LIS).
A STAT sample can be added at anytime when the sample is registered manually. You can reprioritize a sample from STAT to routine or from routine to STATon the Samples-Modify Order screen.

Note: Once any test assigned to an order starts processing, that order cannot be modified.

Test Processing Order

Testing order is not necessarily based on tube position on the Sample Rack. The system selects to process in an order that maximizes workflow. This means that samples in Sample Rack 5 may process prior to Sample Rack 2 based on the tests requested and the availability of the consumables required for those tests.

View test process status on the Results screen. For more information, see Results (page 10-4)

Sample Recovery

In the event of an error that causes a test to be canceled the system automatically restarts processing on the single test level. For example:

- 6 columns of a Cassette are processing 6 different tests. An error occurs that causes processing to stop for only one of those tests. The system continues processing the 5 columns, that are associated with separate tests and unaffected, to completion and the results for those 5 columns are reported. The test that was canceled will restart on a new Cassette, when the issue is resolved.
- If a single test is spread across 2 Cassettes and an error occurs that causes one column of the test to be canceled, all of the columns for the canceled test are also canceled, even if processing on a separate Cassette. If one of the 2 Cassettes contains columns in process associated with a different test; those columns will continue to process to completion and only the results of the unaffected columns are reported. The canceled test will restart on a new Cassette, when the issue is resolved.

Load Station Supplies

Load Station supplies consist of containers, racks, and other supplies that are used in the preparation and handling of patient samples and reagents.

Sample Containers

The tubes, listed below, are supported by the system.

- 16 x 100 mm (10 mL)
- 16 x 75 mm (7 mL)
- 12-13 x 100 mm
- 12-13 x 75 mm
- 10.25 x 75 mm
- 10.25 x 64 mm (2.5 mL)
- 10.25 x 47 mm (5 mL)
- 2.0 mL and 1.5 mL Micro-collection Container 11 x 41 mm (Eppendorf® or equivalent)
- 15 x 92 mm (Sarstedt S-Monovette 7.5 mL)
- 13 x 90 mm (Sarstedt S-Monovette 4.9 mL)
- 13 x 75 mm (Sarstedt S-Monovette 2.7 mL)
- 8 x 66 mm (Sarstedt S-Monovette® 1.2 mL K3E)
- 11 x 66 mm (Sarstedt Monovette® 2.7 mL K3E)
- 13 x 65 mm (Sarstedt Monovette® 3.4 mL K3E)
- 13 x 65 mm (Sarstedt Monovette® 2.6 mL K3E)
- 11 x 92 mm (Sarstedt Monovette® 4.5 mL K3E)
- Pediatric Containers:
  - Eppendorf® (1.5 mL or equivalent diameter, length and cap) Micro-centrifuge Tube
  - Terumo CapiJect® Capillary Blood Collection Tubes
  - Greiner MiniCollect® Capillary Blood Collection Tube (0.5 mL and 1.0 mL)
  - RAM Scientific Safe-T-Fill® Capillary Blood Collection Tube (200 µL and 300 µL, without optional tube extender)

- Sarstedt Microvette® (200 µL and 500 µL, with cylindrical inner vessel)
- TEKLAB (2 mL)
- Becton-Dickinson (B-D) Microtainer® (with or without optional extender)
- Becton-Dickinson (B-D) Microtainer® MAP Microtube for Automated Process
- 10.8 x 41 mm (Sarstedt Micro Tube 1.3 mL K3E)
- 10.8 x 45 mm (Sarstedt Micro Tube 1.3 mL screw cap K3E)

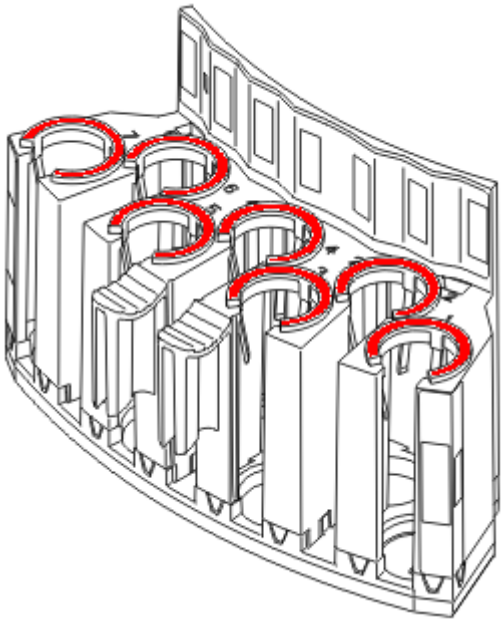
IMPORTANT: For fill requirements, refer to the Minimum Sample Fill Volume Recommendations (page 9-28)

Patient Sample Racks

Sample Racks are used for both routine and STAT samples. Sample Racks are rounded and fit onto the Load Station Rotor. Sample Racks contain 7 numbered positions for sample containers. Each Sample Rack contains a barcode label for identification.

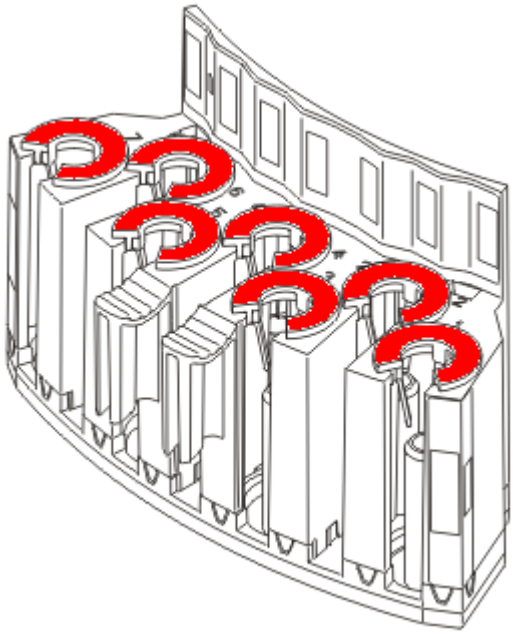
Sample Racks are supplied in multiple sizes to accommodate the different Sample Containers available. Each size of Sample Rack is color-coded.

The system accommodates the Sample Racks listed in the table below:



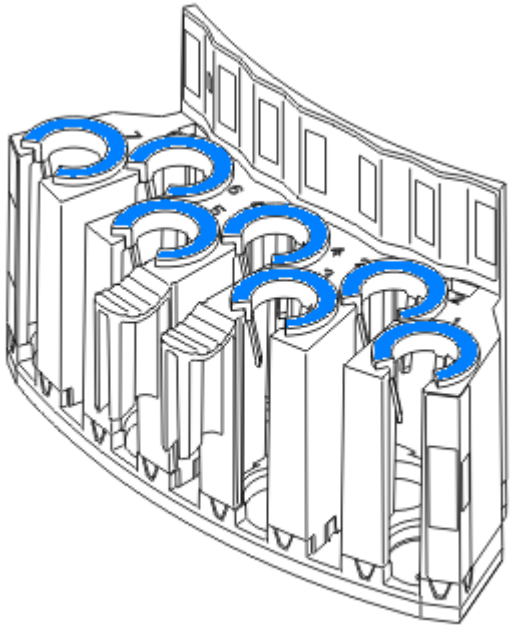
10 mm diameter Sample Rack (red, labeled S10B)

(Continued)



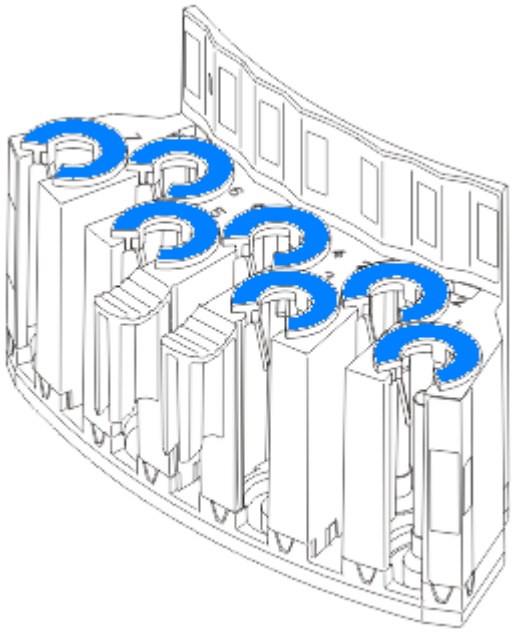
10 mm diameter Sample Rack, with extenders (red. labeled S43B).

Note: Use the 10.25 x 47 sample tubes with the 10 mm diameter Sample Rack, with extenders.



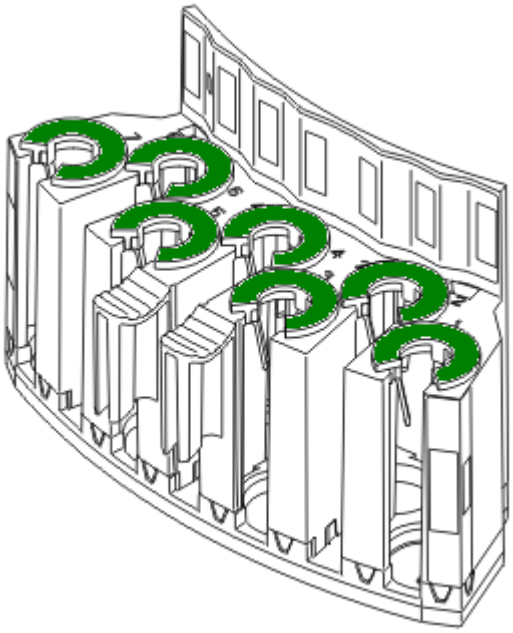
13 mm diameterSample Rack (blue, labeled S13B)

(Continued)



13 mm diameterSample Rack, with extenders (blue, labeled S41B)

Note: Use Becton-Dickinson (B-D) MICROTAINER sample tubes with the 13 mm diameter Sample Rack, with extenders.



16 mm diameter Sample Rack (green. labeled S16B)

Pediatric Sample Racks

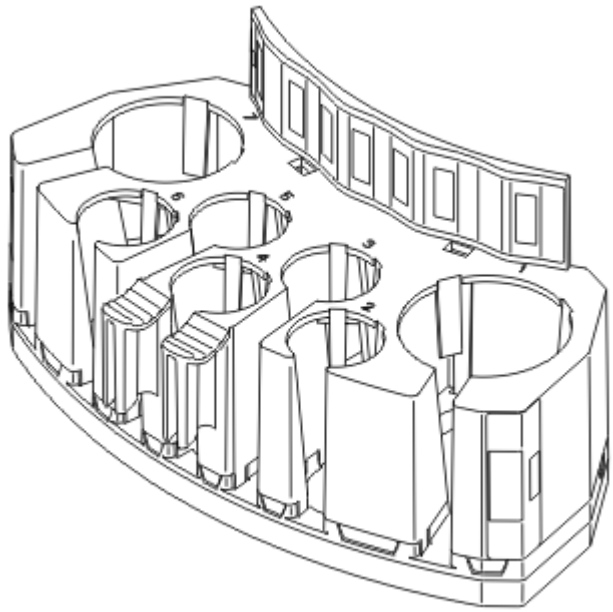
Pediatric Sample Racks are available in multiple sizes and colors to accommodate pediatric tubes.

Contact your sales representative for more information.

Reagent Racks and DILUENT RACKS

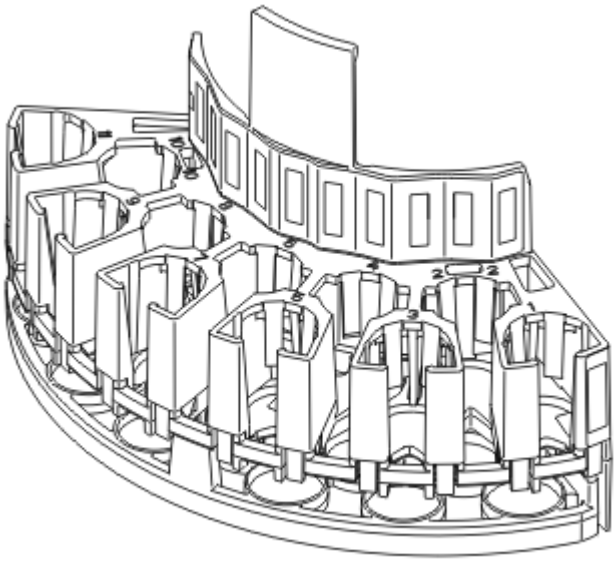
Reagent Racks and DILUENT RACKS are used to load reagent and diluent vials on the system. The racks are rounded in shape and fit onto the Load Station Rotor. There are 2

Reagent Racks and 1 DILUENT RACK available to accommodate the different reagents and diluents used in testing.



DILUENT RACK

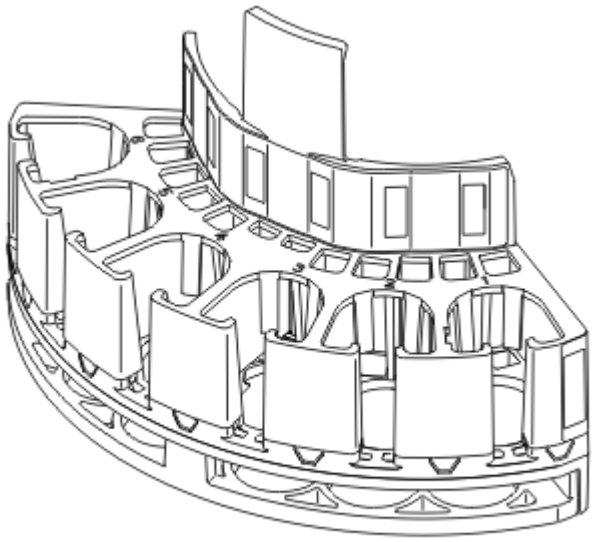
The DILUENT RACK supports one 50 mL vial, one 60 mL vial and five 10 mL vials.



3 mL Reagent Red Cell Rack

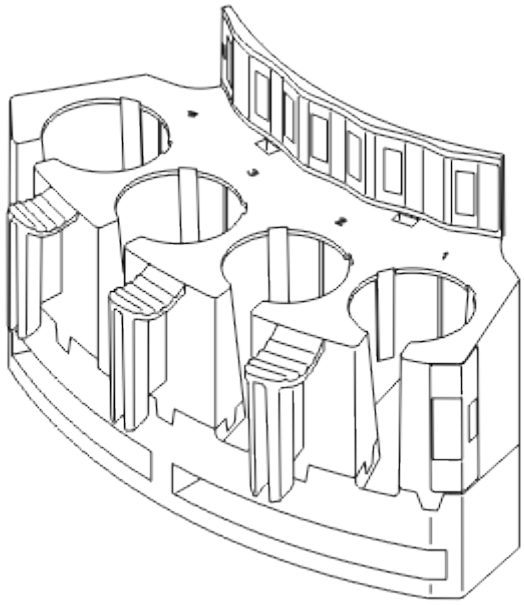
The 3 mL Reagent Red Cell Rack has a capacity for eleven 3 mL vials and caps. Caps are stored directly below the corresponding vial.

(Continued)



10 mL Reagent Red Cell Rack

The 10 mL Reagent Red Cell Rack has a capacity for six 10 mL vials and caps. Caps are stored directly below the corresponding vial.



ORTHOSera™ Reagent Rack

The ORTHO Sera™ Reagent Rack (REF: 6904838) has a capacity for four 5 mL vials and caps. Caps are stored directly below the corresponding vial. ORTHOSera™ Reagent Racks are loaded to the sample rotor.

Minimum Sample Fill Volume Recommendations

Minimum sample fill volumes are dependent upon a number factors including sample type (whole blood and hematocrit level, plasma/serum only, packed red blood cells only, diluted red blood cells only), container size and geometry, the combination of tests executed, and the number of retests anticipated. The minimum sample fill volume must be able to accommodate the minimum fluid component volumes required for the intended testing (plasma/serum and packed red blood cells). This includes excess volumes required by the pipette system for reliable aspiration and dispense, some number of retesting to resolve instrument flags, and sufficient fill heights given the specific sample container for reliable fluid level detection.
The information below provides guidelines for minimum sample fill volume for the various sample containers that can be used on the ORTHO VISION® Analyzer. The guidelines represent the minimum quantity of centrifuged anticoagulated whole blood that is required to support at least one plasma dispense and/or one packed red cell dilution based on a 50%

hematocrit. For tests that require packed red cells, a single 15µL aspirate is diluted and can support up to 12 dispenses to test columns. To accommodate retesting, additional sample quantities are required, with estimates by test type provided below.
A minimum fill height is required by the system to ensure reliable sample aspirations and dispenses. If the minimum height is detected during test processing, the analyzer will post a Pipa30 error (i.e. the system detected a fluid level in the sample container that is too low or too high after retry) and sample processing is suspended until the required sample volume is provided.

Sample Containers

For tests that require plasma and more than one column, additional sample volume is required. The following table provides an estimate of the additional volume of either anticoagulated whole blood or serum/plasma required for a given number of tests at a given test volume. Please refer to the respective ORTHO BioVue® Cassette Instructions For Use to determine the volume used for a given test.

Vision Sample Rack	Sample Container	Minimum Fill Height[1]	Typical Volume Required for 10 mm[2]	Sample Types
S16B	16 x 100 mm 16 x 75 mm	10 mm	1100 µL	Centrifuged Anticoagulated Whole Blood
S13B	12-13 x 100 mm 12-13 x 75 mm	10 mm	670 µL	Packed Reagent Red Blood Cells Plasma
S10B	10.25 x 75 mm 10.25 x 64 mm 10.25 x 47 mm	10 mm	500 µL	Serum

[1]This is the quantity of centrifuged anticoagulated whole blood required to support at least one plasma dispense and/or one packed red cell dilution based on a 50% hematocrit.

[2]Due to dimensional variation between sample tube manufacturers it is recommended to verify that the minimum height is maintained for the volume provided.

For tests that require plasma and more than one column, additional sample volume will be required. The table below provides an estimate of the additional volume of either anticoagulated whole blood or serum/plasma required for a given number of tests at a given test volume. Please refer to the respective ORTHO BioVue® Cassette Instructions For Use to determine the volume used for a given test.

Required Volume Anticoagulated Whole Blood (µL)		**Required Volume Plasma/ Serum (µL)**	
Number of Tests	**Volume per Test**	**Number of Tests**	**Volume per Test**
	40		**40**
1	82	**1**	41
2	225	**2**	112
3	327	**3**	164
4	429	**4**	215
5	531	**5**	266

(Continued)

6	634	**6**	317
7	736	**7**	368
8	838	**8**	419
9	940	**9**	470
10	1042	**10**	521
11	1145	**11**	572
12	1247	**12**	623

Micro-Collection Containers

Vision Sample Rack	Container Manufacturer	Manufacturer Part No.	Extender Required	Nominal Fill (µL)	Recommended Minimum Volume (µL)[1]
S21	TEKLAB	H3130	No	2000	1000
S22	Sarstedt	20.1341.100 20.1343.100 20.1345.100	No	500	325
S23	Sarstedt	72.730*	No	500	500
S24	RAM	07 7053 07 7251	Yes	300	300
S26	BD Microtainer	365973 365971 365957*	Yes	500	300
S27	Greiner	450480 450478 450447	Yes	500	450
		450479	Yes	800	720
		450474 450477 450413 450409	Yes	1000	900
S28	Sarstedt	20.1292.100	No	200	200
S29	Terumo	T-MLH T-MQK	Yes	500	320
S30	Sarstedt	72.703*	No	1500	360
S31	Sarstedt	72.694*	No	2000	500

S32	BD Microtainer	365963 365975 365974 365965	No	500	400
S33	Sarstedt	72.733*	Yes	500	320
S34	Eppendorf	0030 120.094*	Yes	2000	600
S35	Sarstedt	72.693*	No	2000	500
S36	Sarstedt	72.692*	Yes	1500	400
S38	Eppendorf	0030 120.086 (Eur)* 022363204 (US)*	Yes	1500	400

[1]This is the quantity of centrifuged anitcoagulated whole blood required to support at least one plasma dispense and/or one packed red cell dilution.

*These tubes do not contain anticoagulant. They are acceptable to use as aliquot tubes for serum, plasma or centrifuged anti-coagulated whole blood.

Samples Procedures

The following procedures are referred to in Samples:

Create a Batch Order (page 9-31)

Create an Order (page 9-32)

Create a Batch Order

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to assign profiles to a group of samples. This procedure is located in theSamples screen.

Samples should be brought to room temperature before use. If using one tube per sample, the centrifuged anticoagulated whole blood should have RBCs at the bottom of the tube and plasma as the supernatant. If using two tubes per sample, the centrifuged anticoagulated whole blood can be separated into two tubes; the first tube may contain packed RBCs, and the second tube may contain plasma. If non-anticoagulated whole blood is used, only the serum may be used. Single tubes containing serum and a red cell clot may not be used.

DANGER: Make sure to select the proper sample type before proceeding. Selecting an incorrect sample type may cause incorrect results.

1 Load the samples for the order:

- Touch the Samples menu button.
- Select a rack on the diagram and touch the Load/Unload action button.

The wizard lets you open the Load Station Door, load the samples, and close the Load Station Door. The system then scans the contents of the sample racks and updates the information on the Samples screen.

2 Touch the Batch Order action button.

A list of settings is displayed on the left. Sample IDs for samples currently loaded on the system are displayed on the right.

3 Select Sample IDs for the batch order. Select all and Deselect all buttons are available.

4 Touch Samples Liquid Type, and select a liquid type for the samples in the batch:

- CENTBLOOD
- PACKED CELLS
- 0.8CELLS
- 3CELLS
- PLASMA

5 Touch Assigned Profiles, and select one or more profiles.

After selecting a profile, you can touch Save and Startto accept the remaining defaults and begin processing the order.

6 Touch Priority if you wish to change Routine to STAT.

7 Touch Manual Rev. required if you wish to change No to Yes.

You can change any setting by selecting it on the left and making your changes.

8 Touch Save and Start.

The system will process your batch order.

Touch Help for more information.

Create an Order

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to assign profiles to samples for processing. This procedure is located in the Samples screen.

Samples should be brought to room temperature before use. If using one tube per sample, the centrifuged anticoagulated whole blood should have RBCs at the bottom of the tube and plasma as the supernatant. If using two tubes per sample, the centrifuged anticoagulated whole blood can be separated into two tubes; the first tube may contain packed RBCs, and the second tube may contain plasma. If non-anticoagulated whole blood is used, only the serum may be used. Single tubes containing serum and a red cell clot may not be used.

DANGER: Make sure to select the proper sample type before proceeding. Selecting an incorrect sample type may cause incorrect results.

1 Load the samples for the order:

- Touch the Samples menu button.
- Select a rack on the diagram and touch the Load/Unload action button.

The wizard lets you open the Load Station Door, load the samples, and close the Load Station Door. The system then scans the contents of the sample racks and updates the information on the Samples screen.

2 Select the sample for the order and touch the Create Order action button.

Order settings are displayed for the Sample ID you selected.

3 Review the 1st Sample ID. This should be the Sample ID you selected.

4 Touch 1st Sample Liquid Type, and select the liquid type. The choices are:

- CENTBLOOD

- PACKED CELLS
- 0.8CELLS
- 3CELLS
- PLASMA

5 Review the Sample Location: the rack number and position.

6 If necessary, touch 2nd Sample ID and repeat steps 3 and 4 for the second sample.

7 Touch Assigned Profiles and select one or more from the profiles displayed.

After selecting a profile, you can touch Save and Start to accept the remaining defaults and begin processing the order.

Note:

When running panel tests, the lowest numbered cell selected will run in column 1 of the Cassette, the remaining cells selected for that Sample will follow sequentially in the remaining columns.

8 Touch Priority if you wish to change Routine to STAT.

9 Touch Manual Rev. required if you wish to change No to Yes.

You can change any option by selecting it and making your change.

10 Touch Save and Start.

The system will process your order.

Note: You can create an order for a sample not yet loaded on the instrument by touching the Create Order action button and then manually entering the Sample ID.

Touch Help for more information.

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Chapter 10 Results

Results Overview

The Results screen allows you to view current active orders on the system. You can also print reports, view details, and cancel orders using the buttons located along the bottom of the screen. Touch the Results button to access this screen.

This chapter reviews the topics listed below:

Results Features

Results features are used to give additional information about Results topics. For more information, see Results Features (page 10-3).

Results Configurations

Configure Results settings in Setup. Touch Setup > Results to view configurable screens.

Results Action Buttons

The action buttons described below are located along the bottom of Results screens:

Action Button	Description
 Add Comment	Allows you to add comments to results. **Note:** This button is available from the details view.
 Accept Result	Accepts the selected test. **Note:** After a result is accepted, the Accept Result button is disabled and the result can no longer be edited.
 Archive Order	Archives a canceled or reviewed order.

(Continued)

Cancel Order

Cancels an order in process or an order that has not been started.

Change to Back

Changes the view of the image from the back to the front. The button text will adapt based on which side is displayed.

Change Color

Changes the color of the column of images from gray scale to color. The button text adapts based on what is displayed.

Edit Grades

Starts a wizard which guides you through the process of editing the column grade.

Note: The Edit Grades button is active if all test analysis results are available and the test has not been accepted.

Edit Results

Starts a wizard which guides you through the process of editing the final interpretation.

Enable Multiselect

Enables the selection of multiple table rows and changes the text of the button to Disable Multiselect. Touch Disable Multiselect to disable the selection of multiple table rows. When multiselect is disabled, only one table row can be selected at a time.

Filter Disabled

Allows you to filter the results displayed on the Results screen. When enabled, the button text changes to Filter Enabled and the color changes to indicate that the results displayed are currently filtered.

Pause Auto Refresh

Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refreshbutton to resume the automatic update.

Reject Result

Rejects the selected test.

Note: This will disable the Reject Result button. The rejected test analysis can still be edited or accepted.

Send to LIS

Sends all accepted results of the related profile to LIS.

Note: The Send to LIS button is only active if the result is accepted.

(Continued)

 Show Details	Displays additional information for the selected item. **Note:** The Show Details button is active when a table row is selected.
 Show Assay Statistics	Displays the Assay Statistics Report.
 Show Intelli Report	Displays the IntelliReport.
 Show Lab Report	Displays the Lab Report.
 Show Order Report	Displays the Order Report.

Results Features

Results screens have several features that are used to view details about Results, or sort information. The table below contains a description of available features:

Feature	Description
Change View (page 7-16)	Switches the display between a diagram view and a table view.
Status Indicators (page 5-16)	Explains the current status using text, colors, or icons.
Sort Option	Arranges table information in ascending or descending order when you select a column heading.
Show Details (page 10-7)	Displays additional information for the selected item.
Change Color	Toggles between color and black & white.
Zoom (page 10-7)	Displays an image on a larger scale.
Change to front	Toggles between the front and back view of the result.
Enable Multiselect	Enables the selection of multiple table rows and changes the text of the button to Disable Multiselect. Touch Disable Multiselect to disable the selection of multiple table rows. When multiselect is disabled, only one table row can be selected at a time.

(Continued)

Pause Auto Refresh	Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refreshbutton to resume the automatic update.

Results

Touch the Results button to access and view active orders. Orders are removed from the Results list when they are archived according to your settings. For example, if auto-archiving is enabled and set to 24 hours, an accepted order will disappear from the Results list 24 hours after the order was created. If an order is archived manually, it will disappear from the Results list immediately after being archived.
Orders are grouped by patient Sample IDs and priority. All sample orders are grouped with a selectable row composition. The Sample ID columns show the 1st and 2nd patient samples of the corresponding order. Sort by the Sample ID column to sort by the 1st Sample ID. This table provides a description of the information available on the Results screen:

Information Item	Description
Sample ID	Shows the first and second patient samples of the corresponding order
Patient	Name of the patient
Profile Name	Name of the profile of the corresponding order
Status	Status of the corresponding order
Priority	Priority of the corresponding order
Results	Tests still processing: estimated time until the corresponding test result is available, progress bar to visualize this time. Available tests: actual result is displayed
Order Type	Indicates normal IH order or a QC order
Patient ID	ID of the patient

See Results Overview (page 10-1) for a list of action buttons in this chapter. The action buttons listed here are located along the bottom of the Results screen:

- Filter Disabled
- Enable Multiselect (page 10-3)
- Show Details (page 10-7)
- Pause Auto Refresh (page 10-3)
- Show Order Report (page 10-8)
- Show Lab Report (page 10-8)
- Archive Order (page 10-6)
- Cancel Order (page 10-7)
- Show Assay Statistics (page 10-8)

Filter Results

Use the Filter Disabled button to filter the results that display on the results screen. Touch Filter Disabled and then select one or more of the filter options:

- Pending

- Processing
- Canceled
- Aborted
- Review Required (Completed)
- Accepted
- Rejected

Touch back to return to the Results screen. Only the results applicable to the options you selected are displayed. The Filter Disabled button is changed to Filter Enabled and the color is changed to indicate that results are filtered and not all results are currently displayed.

To remove the filters, touch Filter Enabled and deselect all filter options. Touch back to return to the Results screen and display all current results.

Navigation Between Tests

Navigate between tests to view multiple results. Touch Results > Show Details to access this option.
If more than two Cassettes are available for the selected test, the view will show information for two consecutive Cassettes only.
Touch the arrow to the left of the image to view information about additional tests. If the image displays n-1, there is additional information to view. If the image displays n+1, all test information is displayed. This rule will also apply when you touch the arrow to the right of the image.

Manual Review

Use the manual review option to resolve indeterminate Results, when a test has been flagged for manual review, or if the system has been configured to require manual review for specific test. Touch Results > Show Details to access this option. Manual review options are configured in Setup > Testing. During manual review, you can edit the column grade results and select any of the possible test results from the corresponding analysis type as the interpreted test result. If the test has been manually reviewed, the information below is displayed:

Information Item	Description
Reviewer Login Name	The login name of the last user who edited a test result of this order or a column grade of a Cassette of this order.
Review Date/Time	Date and time when a user last edited a test result of this order or a column grade of a Cassette for this order.
User Connection Mode	Local, if the reviewer was a local user. Remote, if the reviewer used the 'Remote Review' capability.
Elapsed Time between Completion and Review	Time elapsed between order completion and time stamp of last edit of a test result of the order or a column grade of a Cassette of the order.

IMPORTANT: At least one Review Rack must be present on the system for processing to occur.

Add Comment

Touch Results > Show Details > Add Comment to enter details about results. Information is displayed in the Comments section in the order of most recent entry. For a list of action buttons in this chapter, see Results Overview (page 10-1).

Results Options

An action must be taken after results are reviewed. The available action buttons are located along the bottom of the Results-Show Details screen and are detailed below. For a list of all action buttons in this chapter, see Results Overview (page 10-1).

For more information about result interpretation refer to the BioVue® Visual Reference Guide. For more information about editing results see Reference Guide task Edit Results.

Archive Order

When a cancelled or completed order is selected, you can archive the results by touching the Archive Order button. Touch Setup > General for order archiving options. Once order archiving is enabled, all accepted and rejected orders are archived. If an order is not executed within 24 hours, the order is automatically archived.

Edit Grades

The Edit Grades button is enabled if all test analysis are available and the test has not been accepted. In addition, if you have modified the overall result, the microtube cannot be used for interpretation. For each edited grade result, the original result and the edited result are displayed. After every edited grade, the test analysis results are recalculated automatically. You can add comments about the edited results or edited grade. You can also accept or reject the edited results.

To edit grades, Cassette barcodes can either be scanned or selected from a list displayed on the screen dependent on the configurations selected on the Setup-General screen. Additionally, after the current user edits the grade another user can accept the edit while the current user is still logged in if the current user does not have privileges to accept the edit. For more information, see General (page 14-7).

Note: The Cassette must be available in the Manual Review Rack when grades are edited.

Note: QC test grades can be edited, by qualified personnel. Editing QC grades may result in the QC Status changing from failed to pass. Refer to your laboratory Standard Operating Procedures when editing QC grades.

Note: The customer is responsible for edited grades.

Edit Results

The Edit Results button allows you to edit test result interpretations. You must enter your password to Edit Results. This button is enabled if all test analysis results are available and the tests have not been accepted. The edited test results are flagged with an asterisk. The flags are displayed in a list for the selected test. The available result options are retrieved from the AD for the selected test. Flagged test results require manual review. Edited result interpretations require acceptance by a different user. After the current user edits the results another user can accept the edit while the current user is still logged in if the current user does not have privileges to accept the edit. Touch Results > Show Details > Edit Results to access this item.

Note: The Cassette does not need to be available when test analysis are edited (for example, the Cassette may have already been rejected to the Waste Drawer).

Reject Result

The Reject Result button is located along the bottom of the Results screen. Touch the Reject Result button to reject the analysis result of the selected test. A Reject icon displays to the right of the selected test. After this action, the Reject Result button is disabled, but the rejected test analysis results can still be edited or accepted.

Accept Result

The Accept Result button is located along the bottom of the Results screen. Touch the Accept Result to accept the analysis result of the selected test. An Accept icon is displayed to the right of the selected test. After this action, the Accept Result button is disabled and the result cannot be edited.

Send to LIS

Manually accepted or rejected results must be manually sent to the LIS. Touch the Send to LIS button to do this. No data is sent for tests that are not accepted at the time this action is taken. When a test has been sent to the LIS, a Sent to LIS icon is shown in the tests list to the right of the corresponding test. This button is disabled when result transmission to the LIS is disabled.

Show Details

The Show Details button provides additional information about Results. Touch Results, select a result and touch Show Details. When the Results view is opened from the results list, the Cassette images are displayed in gray from the front side. The column grading results are shown as 0, 0.5+,1+, 2+, 3+, 4+ or as the abbreviation of a reported error. If a column grade result is equal to or below the defined threshold, the cassette is placed in the Manual Review Rack. The associated column image and details have a border with a warning color to indicate that manual review is required. Results that are greater than the defined threshold are automatically accepted (when Automatic Result Acceptance Rules are enabled), and the cassette is not placed in the Manual Review Rack. Column grades that have been edited are indicated with an asterisk * on the Results screen and the Order Report.
The Show Details view is divided into two areas: Left Side (tests), Right Side (details about selected tests).
The action buttons listed here are located along the bottom of the Results > Show Details screen:

- Show Details
- Show Intelli Report
- Show Order Report
- Send to LIS
- Edit Grades
- Edit Results
- Reject Result
- Accept Result

See Results Options (page 10-6) for more information.
For a list of action buttons in this chapter, see Results Overview (page 10-1).

Cancel Order

The Cancel Order button is active when an executing order is associated to the selected sample. You must select the order you would like to cancel. When this button is touched, a dialog opens and shows all executing orders in which the selected sample participates. Exit the dialog without canceling if you would not like to cancel the order.

Zoom

Use the Zoom option to display an image on a larger scale. Select a column image to open a details view with an enlarged image of the selected column. The column images are shown in gray using the available space. Access this feature from Results > Show Details. The Zoom view contains the information below:

- Type
- Column Number
- Original Result
- Edited Result
- Threshold

Results Reports

The system displays results on the reports listed below:

- Assay Statistics Report
- Intelli Report
- Lab Report
- Order Report

Assay Statistics Report

The Assay Statistics Report displays detailed information about the number and type of tests. The information below is displayed:

- Reported date/time range
- Number of samples: executed/accepted/reported results
- ABScr results: POS/NEG/No match
- A/B/D and Reverse Group: reportable/accepted
- ABO results: POS/NEG/No match
- Rh results: No match/NEG/POS
- Anti-A,B and Anti-D: Executed/Accepted/Reported
- Anti-AB: NEG/POS/ No match

Intelli Report

The Intelli Report displays detailed information about individual tests. Touch Results, select a result and touch Show Details > Show Intelli Report to access this information. An example of the Intelli report is seen below:

Item	Description
Error codes	A list of error codes is displayed.
Order	Order number
Test ID	Name of test
Creator	Location the test originated
QC Management Mode	Yes/no
QC Expires	Disabled/enabled
Time of QC	If enabled, the time QC was performed

(Continued)

Patient Sample	Location
	Liquid Type
	Loading Operator ID
	Time scanned
Cassette Lot	Column used
	Shelf expiration
	Loading operator ID
	Location
Reagent Lot ID	Shelf Expiration
	Loading operator ID
	Location
Processing Steps	Cassette Added
	Start Time
	Completion Time
	Location
	Cassette environment
	Heated environment
Column Results	Displays the result and the information below for each column used:
	Column index
	Modifying operator
	Modification time
	Is remote reviewed
Analysis Result	Displays the analysis result and the information below for each result:
	Modifying operator ID
	Modification time
	Result acceptor
	Result accept time
	Result rejector
	Result reject time
	Is remote review
Patient Data	For more information, see Patient Data (page 9-17).

Lab Report

The Lab Report displays detailed information about all on-board samples with finished orders. The information listed below is displayed:

- Sample ID
- Patient
- Profile
- Results

- Status
- Accepted by
- Order created/date/time
- Order completed date/time
- Results Flags
- Comments

Order Report

The Order Report shows information about results for a patient order. The information below is displayed:

- Patient Data (page 9-17)
- Profile name
- Results Flags
- Sample fields
- Results
- Cassetteinformation
- Graphic view of wells

Note: Results that have been edited are indicated on the Order Report with an asterisk *.

Results Procedures

The following procedures are referred to in Results:

Accept Results

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Results requiring manual review must be accepted or rejected. Only accepted results can be sent to the LIS. This procedure is located in Results.

1 Touch the Results menu button, select a result. Review the result prior to accepting.

2 Select a result and touch the Show Details action button.

3 Touch the Accept Result action button.

When a result has been accepted, the will change to “Accepted” in the status a window on the Details screen.

Note: Accepted results cannot be edited.

Touch Help for more information.

Add or Edit Patient Data

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

You can add or edit patient information when you create an order. This procedure is located in Samples.

1 Touch the Samples menu button.

2 Touch the Create Order action button.

3 After specifying Sample ID, Sample Liquid Type, and Sample Location (if necessary), touch Assigned Profiles and select a profile for this order.

The parameters for this order appear on the left of the screen. Each parameter can be selected and edited, including the patient information fields that have been specified in Setup - General - Modify Patient Info.

4 Touch the patient information field you wish to edit, and enter the information using the keyboard displayed.

5 When you have completed your entries, touch Save and Start to run the order.

NOTE: The input field is pre-populated with the patient data received from the LIS.

Touch Help for more information.

Change Cassette View

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

You can view either side of tested cassettes. This procedure is located in Results.

1 Touch the Results menu button.

2 Select a result and touch the Show Details action button.

The Results — Details screen is displayed with an image of the cassette.

3 Touch the Change to Back action button.

The reverse side of the cassette is displayed, and the button becomes **Change to Front** .

Touch Help for more information.

Change Image to Color or Grayscale

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

You can view the cassette image in color or in grayscale. This procedure is located in Results.

1 Touch the Results menu button.

2 Select a result and touch the Show Details action button.

3 Touch the Change to Color button.

The color image is displayed and the button becomes Change to Grayscale.

Touch Help for more information.

Edit a Microtube Grade

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

The Edit Grades action button is enabled if all test analysis results are available and the test has not yet been accepted. This procedure is located in Results.

Note: QC test grades can be edited, by qualified personnel. Editing QC grades may result in the QC Status changing from failed to pass. Refer to your laboratory Standard Operating Procedures when editing QC grades.

Note: The customer is responsible for edited grades.

1 Touch the Results menu button.

2 Select a Sample ID and touch the Show Details action button.

3 Touch the Edit Grades action button.

A wizard opens.

4 Select the cassette with the grade you wish to edit.

- If scanning the barcode is required, scan the barcode for the cassette.
- If scanning the barcode is not required, and there is more than one cassette for this test, select the image of the cassette from those displayed.
- If scanning the barcode is not required, and there is only one cassette for this test, this step is omitted.

5 Touch the grade for the microtube you wish to edit.

Alternative grades are displayed.

6 Select the grade you want for that microtube.

The grade you selected now appears as the grade for that microtube. An asterisk indicates the edit.

7 Touch Next to add a comment describing the reason for the change.

This step may not be required.

8 Touch Next and enter your password and touch Confirm Password.

Touch Help for more information.

Edit Results

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Test results can be edited only when all results are available and the test has not been accepted. This procedure is located in Results.

For more information about result interpretation refer to the BioVue® Visual Reference Guide. For more information about editing results see Reference Guide task Edit Results.

1 Touch the Results menu button.

2 Select the results you wish to edit and touch the Show Details action button.

3 Touch the Edit Results action button.

A three-screen wizard opens.

4 Select the result you wish to edit, select a new result and touch Next.

5 Enter a comment describing your change and touch Next.

6 Enter your password and touch Confirm Password.

Your edit is reflected in the Results — Details screen, marked with an asterisk indicating a modified result.

Touch Help for more information.

Move Between Cassettes

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Move between cassettes to view multiple results. This procedure is located in Results.

1 Touch the Results menu button.

2 Select a result and touch the Show Details action button.

3 Touch the Next and Previous arrows to view multiple cassettes.

Touch Help for more information.

Print a Report

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

The Print button is available whenever a report is displayed and a printer is configured. “Show Report” buttons appear throughout the software.

1 Touch a Show Order Report button.

The report is displayed, and the Print button becomes available.

2 Touch the Print button.

A printed copy of the report is generated.

Touch Help for more information.

Reject Results

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Results that are not automatically accepted must be reviewed before they can be accepted or rejected. This procedure is located in Results.

1 Touch the Results menu button.

2 Touch a row to select a test.

3 Touch the Show Details action button. Review the results before rejecting the result.

4 Touch the Reject Result action button.

The “Rejected Result” icon appears next to this result on the Details screen. Rejected results can still be edited or accepted.

Touch Help for more information.

Search

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to search for Results information.

1 Touch the Results menu button.

2 Touch Search.

3 Enter the search term and touch Search. Some examples of search terms you can enter include: Patient ID, Sample ID, Profile name, etc.

The items matching your search are displayed.

4 Touch theResults link to access that information. Touch back.

5 Touch New Search icon to repeat the operation with new search term. You need to deselect your previous search.

6 Touch Close Action button to exit from Search function.

Touch Help for more information.

Send Results to the LIS

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Results must be accepted before you can send them to the LIS. This procedure is located in Results.

1 Touch the Results menu button.

2 Select a result and touch the Show Details action button.

3 Touch the Send to LIS action button.

4 Touch Help for more information.

Sort Results

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

This procedure is located in Results.

1 Touch the Results menu button.

2 Touch a column heading to sort the information in that column alpha-numerically. All other information is sorted accordingly. Touching a row the second time reverses the sort order.

Touch Help for more information.

Zoom the Image

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

You can view enlarged column images in the Results — Details screen.

1 Touch the Results menu button.

2 Select a result and touch the Show Details action button.

The Details screen is displayed with an image of the cassette.

3 Touch the column you wish to see enlarged.

An enlarged view of the column is displayed in color and in grayscale. This view also shows both the front and back sides of the column.

4 Touch Back to return to the Details view.

Touch Help for more information.

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Flags and Codes

Codes

Codes indicate conditions that require operator attention. For example, if a bubble is detected in a column during the post processing check, the result is not reported and the system assigns the code 'BUB' to the result to call attention to the bubble that was detected. The table below displays Result Values. Results Values are shown on the Results screen, printed on reports, and included on Log files. If a result code is frequent, contact Ortho Care. Always refer to the Instructions for Use and the Reference Guide for additional information.

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
0	NA	Negative	NA	Follow your laboratory Standard Operating Procedures.
0.5+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
1+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
2+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
3+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
4+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
U	Unknown	No result reported	The system received a result from the IMAGING SYSTEM that was not interpretable.	Rerun the test.

(Continued)

CNF	Column not found	If the correct location could not be ensured during the preprocessing check, the column will be marked as not usable; if the correct location could not be found during the post processing check the result is not reported.	The CASSETTE IMAGING SYSTEM could not ensure the column was in the correct location.	If the correct location could not be ensured during the preprocessing check, clean any debris from the surface of the Cassette and load the Cassette into the Supply Drawer to be reused. If the correct location could not be found during the post processing check, manually read the reaction.

(Continued)

WLL	Wrong liquid level	No result reported	The IMAGING SYSTEM could not confirm that the correct volume of liquid is in the reaction chamber. One of the liquid additions may be missing.	Inspect the reaction chamber to determine if the liquid level is correct or not. A false error may be caused by a faint meniscus. If the liquid level is correct, manually read the column and edit the column result. If the liquid level is not correct, inspect the sample and reagents. Remove bubbles or foam before loading tubes and vials onto the instrument. Review the error screen for liquid flow or liquid level errors that are time related and troubleshoot as necessary. Rerun the test. If the error persists, inspect the SYRINGE, DILUTOR VALVE, and TIP TUBING fittings for leaks. Perform the PIPETTE Volume Test to verify metering system integrity. Liquid level detection does not occur when performing a UDP test with total dispensed volume (reagent with sample) different than 50 µl, 90 µl, and 100 µl. Wrong liquid level checks are not performed by the software if total dispensed volume (reagent with sample) specified by a UDP is different than 50 µl, 90 µl, and 100 µl.

(Continued)

LTL	Light too low	No result reported	The light level between the columns is checked with every read; the adjacent light level read was too low. This may be caused when too many red blood cells were pipetted.	There may be debris on the Cassette, or there was not enough sample serum/plasma and patient red blood cells (RBCs) were aspirated instead of serum/plasma. If there were too many RBCs in the column, they can block light. If the result code is intermittent, there may be debris on the Cassette. Clean the debris from the surface of the Cassette and perform a manual read of the column. Check the sample container and if the serum/plasma has been depleted, rerun the test using a new sample.
LTH	Light too high	No result reported	The light level between the columns is checked with every read; the adjacent light level read was too high.	Inspect the Cassette for holes or reflective debris, and manually read the reaction. If the result code is frequent, you may need to clean or adjust the CASSETTE IMAGING SYSTEM.
CI	Contrast inference	No result reported	The liquid in the column above the media was dark and the IMAGING SYSTEM could not confidently interpret the reaction. This can be caused by Hemolysis, icterus, turbidity, or lipemia.	Rerun the test, or manually read the reaction.

(Continued)

NC	No cells	No result reported	The IMAGING SYSTEM found that there were no cells or almost no cells in the column.	You may have insufficient reagent or sample volume. Confirm there is reagent and sample available and rerun the test.
TFC	Too few cells	No result reported	The IMAGING SYSTEM determined that there were not sufficient cells in the column for a valid interpretation.	You may have insufficient volume of reagent or sample, or Reagent Red Blood Cells (RBCs) may not have been properly suspended. Check the reagent vials and replace the reagents if necessary. Rerun the test.
TMC	Too many cells	No result reported	The IMAGING SYSTEM determined that there were too many cells in the column for a valid interpretation.	Reagent Red Blood Cells (RBCs) may not have been properly suspended, RBCs may have evaporated, or there was not enough sample serum/plasma and patient red blood cells (RBCs) were aspirated instead of plasma. If you suspect the Reagent Red Blood Cells have been compromised due to improper suspension or evaporation (exceeded on-board stability), discard all vials from that set and replace with a new set. Resuspend the reagents and rerun the test. If you suspect the sample is the source of the TMC code, make sure there is adequate plasma volume and rerun the test. Re-centrifuge the sample if needed.

(Continued)

MF	Mixed field	No result reported	The distribution of the cells within the column indicates that there may be a dual population of cells.	Manually interpret the reaction; follow your laboratory Standard Operating Procedures for dual population reactions.
?	Indeterminate	No result reported	The strength of the reaction or the distribution of the cells within the reaction prevented the IMAGING SYSTEM from determining whether the reaction was positive or negative.	Rerun the test or manually interpret the reaction following your laboratory Standard Operating Procedures.
FIB	Fibrin	No result reported	The IMAGING SYSTEM saw an agglutinate distribution which may have been caused by fibrin in the sample.	• Manually review the Cassette. • Follow Standard Operating Procedures for manually reviewing, reporting results and retesting. • Inspect the sample for quality issues. Follow your Standard Operating Procedures for sample processing before testing. • Adjust the centrifugation speed and time to achieve the optimal cell/plasma separation. For more information, see Sample Specifications (page 9-14). • If the problem persists, call Ortho Care.

(Continued)

BUB	Bubble	If a bubble is found during the preprocessing check the column will be marked as not usable; if a bubble is found during the post processing check the result is not reported.	The IMAGING SYSTEM detected a bubble that was large enough to effect the reaction.	Rerun the test or manually interpret the reaction following your laboratory Standard Operating Procedures.
FOC	Focus error	If the focus targets are not correct in the preprocessing check, the Cassette will be marked as not usable; if the focus targets do not look correct during the post processing check the result is not reported.	The focus targets appear to be incorrect to the CASSETTE IMAGING SYSTEM.	Inspect the focus targets for debris and clean them if necessary.
PE	Position error	No result reported	The CASSETTE IMAGING SYSTEM has determined that the Cassette is not properly positioned.	If the result code is intermittent, rerun the test.
CVE	Column volume error	If the liquid volume is inadequate during the preprocessing check, the column will be marked as not usable.	The liquid volume above the media is inadequate or during the pre-processing quality check, the CASSETTE IMAGING SYSTEM detected that the foil above the column may have already been punched.	Evaporation of the column liquid may have occurred, or the system rejected the Cassette before it was used and automatically ran the test using another Cassette. Refer to the CassetteInstructions For Use to determine proper disposition of the Cassette.
CND	Cassette not detected	No result reported	The CASSETTE IMAGING SYSTEM has determined that the Cassette is not properly positioned, or missing.	If the result code is intermittent, rerun the test.

Flags

Results flag information identifies results that are above or below the reportable range. If the result has been flagged, the information listed below is shown:

- Accepted/Rejected
- Transferred to LIS
- Instrument simulated
- Result edited by user

In addition, the flags listed below require a manual review of the result:

- Result expired
- Errors from imaging system
- QC expired
- Lot expiration
- Sensor reading temperature dropping out of the notification range
- Sensor reading humidity dropping out of the notification range
- Maintenance expired/failed
- Edited results

LIS

The Ortho Vision® Analyzer implements an interface to a remote LIS connected through TCP/IP, RS232, or shared folders. Results of patient samples are always sent to the LIS (if LIS is defined in setup). For more information about messages, refer to the Laboratory Information System (LIS) Guide.

Chapter 11 Reports

Reports Overview

This chapter discusses how reports are accessed and where they are located on the system.

This chapter reviews the topics listed below:

Reports Configurations

Reports are configured in Setup. Touch Setup > General > Modify Rpt. Settings to configure report settings.

Batch

The system generates standard and configurable reports. Each report displays the lab name, logged in user, system, and J-Number. The table lists available reports and the screen they can be accessed. Available reports are listed here:

Note: The totals for failed tests shown on the Usage Statistic Report and the Assay Report include both failed test results and tests for which the Cassette failed the pre-processing quality check.

Report	Location	Action Button	Brief Description
Order Report	Results Reports (page 10-8)	Show Order Report	• Patient info • Sample ID • Order Info • Profile Name • Test • Results
MBC/QC Report	QC Report (page 13-5)	Show MBC Report	• Profile • QC Management Mode • QC Status • Job Status • QC Expiration

(Continued)

QC History Report	QC Report (page 13-5)	Show QC History Report	• Profile • Completion Time • QC Status • Test Name • QC Expiration
BRC/QC Report	QC Report (page 13-5)	Show BRC Report	• QC • Status • Job Status • QC Expiration
Lab Report	Results Reports (page 10-8)	Show Lab Report	• Sample ID • Patient Info • Profile • Result • Status • Accepted by
Instrument Health Check Report	Home (page 5-3)	Show Health Check Report	• Device Name • Sensor • Current Value • Warning Range • Critical Range • Status
Maintenance Report	Maintenance Report (page 16-7)	Show Maint. Rpt.	• Task • Type • Last Result • Last Execution • Next Execution • Operator
Error Review Report	Errors Overview (page 12-1)	Show Error Report	• Code • Error Title • Count
Usage Statistics Report	Overview (page 7-3)	Show Usage Statistics	• Consumable type • Test name • Lot • Quantity • Number microtubes used/unused • Number of orders started

(Continued)

Intelli Report	Results Reports (page 10-8)	Intelli Report	• Error codes • Order • Creator • Patient Sample • Reagent Lot ID • Processing Steps
Assay Statistics	Results Reports (page 10-8)	Show Assay Statistics	• Number samples • Executed • Accepted • Reported results
On-board Inventory Report	Overview (page 7-3)	Show Inventory Rpt.	• Consumable • Lot ID • Remaining Quantity • Position • Shelf Expiration • Loaded by
e-Connectivity	Interfaces (page 14-18)	Show e-Conn Log	• Date • Time • Activity • User
LIS Log	Interfaces (page 14-18)	Show LIS Log	• Report date/time range • Event Date/time • Sources (LIS, local host) • Message type (Broadcast, Host Query, Result transmission)
Lot Switch Log	Overview (page 7-3)	Show Lot Switch Log	• Product Name • Lot ID • First used

Review and Set Report Status

Review and set report options on the Setup > General > Modify Rpt. Settings screen. Selections can be made for the export format and directory for all available reports.

Export Report Data

You can select the format in which reports are exported in Report Settings. Touch Setup > General > Modify Rpt. Settings. The available formats are listed below:

- PDF
- CSV
- XML
- Text
- XLS

Chapter 12 Errors

Errors Overview

Touch the Errors button to display the Errors screen. The Errors screen allows you to review the status of Errors that have occurred on the system.

This chapter reviews the topics listed below:

Errors Features

Errors features are used to give additional information about Errors topics. This table contains a description of available features:

Information Item	Description
Show Details	Provides a description of the error.
Pause Auto Refresh	Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refreshbutton to resume the automatic update.
Enable Multiselect	Enables the selection of multiple table rows and changes the text of the button to Disable Multiselect. Touch Disable Multiselect to disable the selection of multiple table rows. When multiselect is disabled, only one table row can be selected at a time.

Errors Configuration

These screens do not have configurable options.

Errors Action Buttons

Action Button	Description
 Back	Returns you to the previous screen.
 Clear Error	Flags a resolved error to remove it from the list of errors. Errors that have not been resolved cannot be cleared.

(Continued)

 Enable Multiselect	Enables the selection of multiple table rows and changes the text of the button to Disable Multiselect. Touch Disable Multiselect to disable the selection of multiple table rows. When multiselect is disabled, only one table row can be selected at a time.
 Show Details	Displays additional information for the selected item.
 Pause Auto Refresh	Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refreshbutton to resume the automatic update.
 Resolve	Informs the system that an error has been manually resolved.
 Show Error Report	Allows you to print the error report.

Errors

When an error occurs, a new Error Signature instance with an Issue Code is created. The Issue Code identifies the error type and the recovery scenario as well as the error message text. Only pending errors are highlighted by a color. If an error is resolved, the background color of the corresponding row changes to normal and the row has a border colored with the original error color. See Status Indicators (page 5-16) for further details about how Errors are displayed. The system displays error codes with an acronym.

Note: If an error message is displayed but no audio alarm sounds, check that the audio cable is not damaged, and is properly connected to the MONITOR and MASTER COMPUTER.

The acronym identifies the location of the error. The acronyms listed here are used:

Acronym	Description
APSW	Application Software
CCLA	Supply Drawer
CCRW	Dual Purpose Drawer
CENT	(F) Front centrifuge (B) Back centrifuge
CHAS	Deck
CIMS	Imaging system
CINC	Incubator

(Continued)

GRIP	Gripper arm
PIPA	Pipette arm
SRDR	Load Station

An example of the Errors screen is seen here:

Date	Issue Code	Error State	Title	Error Message	User Name
12/02/2014	Ccwa11	pending	Waste full soon	Waste full in 5 minutes	No user
12/02/2014	Ccla05	pending	Cassette not identified	Could not read barcode on first cassette	No user
12/02/2014	Srdr03	pending	Cannot move rotor	The Load Station is blocked	No user

Touch a row to select an error. When an error is selected the buttons listed here are enabled:

- Errors Details (page 12-4)
- Resolve (page 12-3)
- Clear Error (page 12-4)

Comments

Use the Comments feature to enter additional information about Errors. The Edit Comment button is accessible from the details view of the Errors screen. The details view displays a full error description, comments, and the recommended recovery.
There is one comment field that all users can share and edit. Information about the last edit event is displayed at the end of the comment section in the details view. Comments are displayed in chronological order, with the most recent comment at the top. Comments cannot be changed or deleted. There may be a scrollbar, if the comment is too long to be displayed. The Back button displays the error list again.

Resolve

When an error is selected, the Resolve button is active. If an error is not automatically resolved by a recovery sequence, you must touch the Resolve button to address the error. Most errors are resolved automatically without your intervention. When an error cannot be resolved automatically it displays on the Errors screen to indicate to the user that action is required. When an error requires user intervention such as, removal of a Cassette dropped by the Gripper, you must touch the Resolve button to alert the system of the removal.
When the Resolve button is applied to an error, the system enters the normal operation mode. The error state of a pending error changes to Resolved. When an error is automatically or manually resolved, it has no influence on the overall error status or colors on the system or signal light.

Maintenance Errors

While executing maintenance the system may encounter an error. These errors do not display on the Errors screen. Follow the suggestions listed in the Errors Details on the Maintenance screen to resolve Maintenance Errors and continue completing maintenance.

Clear Error

Use the Clear Error button to flag an error as cleared. When an error is flagged as cleared, it is immediately removed from the list. Errors that have not been resolved cannot be cleared from the list.
When active, the Clear Error is located along the bottom of the screen.

Errors Details

Touch the Show Details button to display information about the selected Error. Touch a row to select an Error. The Errors-Show Details screen displays the title bar and the status of the error on the right side of the screen. You can determine if the error is pending or resolved. The left side displays the error description. There may be a scroll bar if the error description is too long to be fully displayed.

Errors Procedures

The following procedures are referred to in Errors:

Add a Comment to the Error — Details Screen

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Enter comments in an Error — Details screen to provide information to other users, and, if necessary, to Ortho. This information might include user actions that led to the error.

There are two basic procedures for adding comments to errors.

1. For **Instrument errors**, touch the Errors menu button.
2. Select an error and touch the Show Details action button.

   The Errors — Details screen is displayed for the selected error.
3. Touch the Edit Comment action button.
4. Enter a comment and touch Save.

   Your comment appears in the Comment field of the Errors — Details screen.
5. For **Sample** or **Resource** errors, touch the sample or resource in the diagram view.
6. Touch the error information panel on the left.

   The Errors — Details screen is displayed.
7. Touch the Edit Comment action button.
8. Enter a comment and touch Save.

   Your comment appears in the Comment field of the Errors — Details screen.

Touch Help for more information.

Clear an Error

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

After an error has been resolved it must be cleared. Use this procedure to clear a resolved error.

1 Touch the Errors menu button.

2 Select an error and touch the Show Details action button.

The Errors — Details screen is displayed.

3 Touch the Clear Error action button.

The error is cleared.

Note: The Clear Error action button will not be available if the error has not been resolved.

Touch Help for more information.

Resolve an Error

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Most errors are resolved automatically without user intervention. There are some errors, however, that require action by the user, such as removing a dropped cassette. After resolving the error, the user must indicate this by touching the Resolve button. This procedure is located in Errors.

1 Touch the Errors menu button.

2 Select an error and touch the Show Details action button.

The Errors — Details screen is displayed.

3 Take the necessary steps to resolve the error, and touch the Resolve action button.

The Error state changes to Resolved, and the Clear Error action button is enabled.

4 Touch the Clear Error action button to remove the error from the list and remove error status indicators for this error.

The error is removed from the Errorslist.

Touch Help for more information.

Show Error Details

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use the Show Details action button to view additional information about an Error. This procedure is located in Errors.

1 Touch the Errors menu button.

2 Select an error and touch the Show Details action button.

The Errors — Details screen is displayed for the selected error.

3 Touch the Back button to return to the Errors screen.

Touch Help for more information.

Sort Errors

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to sort the errors according to the column heading selected in the Errors screen.

1 Touch the Errors menu button.

2 Touch a column heading (Date, Error Code, Error State, Title, or Error Message).

The rows are displayed in alpha-numeric order according to the data in the column you selected. Touch the column heading again to reverse the order.

Touch Help for more information.

Chapter 13 Quality Control

QC Overview

The QC screen allows you to manage all quality control jobs and QC status information. Touch the QC button to access this screen.

This chapter reviews the topics listed below:

- QC Report (page 13-5)
- Run QC Job (page 13-6)
- QC Screen (page 13-3)

QC Features

BRC refers to Reagent control and only utilizes BRC kits. For more information see Reagents (page 8-2).

MBC refers to system control and utilizes whole blood QC kits or Reagent Red Blood Cells.

QC features are used to give additional details about QC topics. QC features are listed here:

- Details: displays additional information for the selected item.

QC Configurations

The system provides the ability to enable QC management for profiles. Two QC management methods are supported: Method Based Control, or MBC, and Blood Bank Reagent Control, or BRC. MBC refers to system control and utilizes whole blood QC kits or Reagent Red Blood Cells. BRC refers to reagent control and only utilizes BRC kits. MBC and BRC are configured with profiles on the Setup-Testing screen and is typically done in collaboration with Ortho Care during initial profile setup.

Both the MBC and BRC QC methods allow for the configuration options below:

- System enforced QC interval length, configured on the Setup-Testing-QC Settings screen.
- Start warning before the expiration of a QC interval length, configured on the Setup-Testing-QC Settings screen.
- Tracking of QC status based on reagent and cassette lot, configured on the Setup-Testing-Profiles screen when a profile is setup.

If MBC is enabled, the system tracks the time that has elapsed since the last successful QC was performed for the given profile. If the time since the last successful QC exceeds the set QC interval length and MBC QC Managed Profile Run Anyway is not enabled, the system will prevent processing of tests with that profile.

If BRC is enabled, the system tracks the time that has elapsed since the last successful QC was performed for the given profile. If the time since the last successful QC exceeds the set QC interval length and BRC QC Managed Profile Run Anyway is not enabled, the system will prevent processing of tests with that profile.

If Track QC-tested Lots is enabled, the system will also track the cassette and reagent lot combination used during processing of QC samples. If MBC QC Managed Profile Run Anyway or BRC QC Managed Profile Run Anyway is enabled, processing will continue even if the QC status is expired for the tested lots, but the results will be flagged. If MBC QC Managed Profile

Run Anyway or BRC QC Managed Profile Run Anyway is disabled, the system will prevent processing of tests until the loaded resource lot combination for that profile is valid for QC.

Refer to the table below:

Configuration		System Response
MBC QC Managed Profile Run Anyway = Disabled BRC QC Managed Profile Run Anyway = Disabled	Track QC-tested Lots = Enabled	BRC and MBC profiles with expired QC status will be prevented from running. System will track cassette and reagent lot numbers for profile QC status. System will prevent processing of tests if the loaded resource lots are not valid for QC.
MBC QC Managed Profile Run Anyway = Disabled BRC QC Managed Profile Run Anyway = Disabled	Track QC-tested Lots = Disabled	BRC and MBC profiles with expired QC status will be prevented from running. System will not track cassette and reagent lot numbers for profile QC status.
MBC QC Managed Profile Run Anyway = Enabled BRC QC Managed Profile Run Anyway = Enabled	Track QC-tested Lots = Enabled	BRC and MBC profiles with expired QC status will be allowed to run but results are flagged. System will track cassette and reagent lot numbers for profile QC status. System will prevent processing of tests if the loaded resource lots are not valid for QC.
MBC QC Managed Profile Run Anyway = Enabled BRC QC Managed Profile Run Anyway = Enabled	Track QC-tested Lots = Disabled	BRC and MBC profiles with expired QC status will be allowed to run but results are flagged. System will not track cassette and reagent lot numbers for profile QC status.

QC Action Buttons

Action Buttons	Description
 Show BRC Report	Displays BRC quality control information.
 Show QC History	Displays the QC history of the selected profile, for up to 7 days from the current date.

(Continued)

Displays MBC quality control information.

Show MBC Report

Starts a QC job.

Run QC Job

QC Screen

The QC main screen is the starting point for all quality control functions. Use this screen to review all controls established for the system.
The following tables display an example of the available information on this screen:

Information Item	Description
QC Type	Type of the QC Group For each test-Profile-Resource-Lot-combination one BRC group
Profile	Tests are run for QC
QC Management Mode	Not applicable for BRC profile
QC Status	Passed/Expired/Failed/Initial
Job Status	The progress of the least advanced order of all orders of all BRC profiles.
QC Expiration	When QC expires
Tested Cassette Lots	Cassette lot tested

Information Item	Description
QC Type	Type of the QC Group For each test-Profile-Resource-Lot-combination one MBC group
(MBC) Profile	Each QC Sample Set contains: • Indicator for one or two tube sample • Indicator for patient or QC sample • Barcode string or if available from the AD, then name of the QC sample and lot number • Sample Liquid Type of patient, Sample Liquid Type of RBC Reagent and cell name or QC kit name
QC Management Mode	QC Management Mode as configured for the profile in the corresponding setup screen
QC Status	Passed/Expired/Failed/Initial

(Continued)

Job Status	The progress of the least advanced order of all orders of all corresponding sample sets
QC Expiration	When QC expires
Tested Reagent Lots	Reagent lots, which are tested with the corresponding profile

Details

The Show Details button is located along the bottom of the screen. This button is enabled if a row in the Quality Control table is selected. The information listed below is displayed:

The information below is displayed for a BRC group:

- QC Status
- Job Status
- QC Expiration
- QC Interval Length
- Start Warning Before QC Interval Expiration
- BRC QC Managed Profile Run Anyway

The information below is displayed for an MBC group:

- Profile
- QC Management Mode
- QC Status
- Job Status
- QC Expiration
- Tested Cassette Lots
- Tested Reagent Lots
- QC Interval Length
- Start Warning Before QC Interval Expiration
- MBC QC Managed Profile Run Anyway

Details about the most recent MBC QC jobs per defined QC sample set are also displayed for the selected profile.

Show BRC Report

The Show BRC Report is located along the bottom of the screen. It displays the BRC report. The BRC report contains information about the overall BRC QC state. Information about the most recent completed BRC QC job per BRC Profile is also displayed.

Show MBC Report

The Show MBC Report button is located along the bottom of the screen. It displays information about the QC state and the most recent completed MBC QC Job per QC sample set.

Run QC Job

The Run QC Job button is located along the bottom of the screen. The information displayed by this button changes based on the selected row in the table view.

QC Report

The system generates a Blood Banking Reagent Control (BRC) report, a Method Based Control (MBC) report, and a Method Based Control (MBC) QC History report. Touch either button to access the appropriate report.

- Profile name
- QC management mode
- QC status
- Job status
- QC expiration
- Tested Cassette lots
- Warning interval
- Global QC flag

Additionally, the QC Report shows the most recently completed BRC and MBC QC job per QC sample set:

- QC sample set
- User logged in when job was created
- QC status
- QC expiration

For each QC job, the information listed below is shown:

- Test name
- Expected results
- Original results
- Modified results

QC History Report

The MBC QC history report displays QC information for a single profile for a user selectable date range. The following information is shown:

- Profile name

For each job, the following is displayed:

- Completion time
- QC sample set
- User logged in when job was created
- QC status
- QC expiration
- Tested Cassette lots
- Tested reagent lots

For each test, the following information is displayed:

- Test name
- Expected results
- Original results

- Modified results
- Modified by
- Comments

BRC QC Report

The system generates a BRC QC report which displays the overall BRC QC state:

- QC status
- Job status
- QC expiration
- QC interval length
- Warning interval
- Global QC flag

Additionally the report shows the most recent completed BRC QC job per BRC profile:

- Profile name
- User logged in when job was created
- QC status
- Tested Cassette lots
- Tested reagent lots

For each job, the information listed below is displayed:

- Test name
- Expected results
- Original results
- Modified results

Run QC Job

The Run QC Job button is located along the bottom of the QC screen. To start a QC job, select from the list of current QC profiles and touch the Run QC Job button. Once a profile is selected, the system will process the QC job.

Note: For MBC QC, a QC sample must be assigned to the QC profile.

Show QC History

The history view shows the complete QC-history of the selected profile. The information below is displayed:

- QC Sample Set
- Completion Time
- Created by
- QC Status
- Tested Cassette lots
- Tested Reagent lots

For each job, the following information is displayed (per test)

- Test name

- Expected results
- Original results
- Modified by
- Comments

QC Procedures

The following procedures are referred to in QC.

Access the BRC QC Report

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

There is a single BRC report which shows information for all BRC profiles. This procedure is located in QC.

1 Touch the QC menu button.

Select the BRC profile (A table of current profiles is displayed).

2 Touch the Show BRC Report action button.

The BRC report is displayed.

3 Touch Print to print the report, Save to save the report, or Cancel to close the report window.

Touch Help for more information.

Access an MBC QC Report

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

This procedure is located in QC.

1 Touch the QC menu button.

2 Select the MBC profile for the report you want, and touch the Show MBC Report action button.

The MBC report is displayed.

3 Touch Print to print the report, Save to save the report, or Cancel to close the report window.

Touch Help for more information.

Process a BRC Control

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

A BRC (blood bank reagent control) is a pre-packaged control used for reagents only.

Use this procedure to process a BRC control. This procedure is located in QC.

1 Touch the QC menu button.

A table of current profiles is displayed.

2 Select a BRC profile, and touch the Run QC Job action button.

The system processes the QC job you requested.

Touch Help for more information.

Process an MBC Control

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

MBC refers to system control and utilizes whole blood QC kits or Reagent Red Blood Cells.

Use this procedure to process an MBC control. This procedure is located in QC.

1 Touch the QC menu button.

2 Select the MBC QC sample set you wish to process, and touch the Run QC Job action button.

Configure the QC by selecting an item on the left and touching an option or entering information on the right.

Note: You can touch Save at any time to accept the defaults and begin processing.

3 Select QC Sample Info to see information about the QC sample sets configured for this profile.

4 Optional: If this profile uses an Ortho QC Sample, select Change Ortho QC Sample ID to use a different Sample ID.

5 Select Reagent Lots, and touch a reagent lot for each required reagent kit.

If there is more than one reagent lot loaded on the instrument, the default selection is the lot that was most recently registered.

6 Select Cassette Lots, and touch a cassette lot for each required cassette type.

If there is more than one required cassette lot loaded on the instrument, the default selection is the lot that was most recently registered.

7 Select Manual Rev. Required (Manual Review Required), and touch Yes or No.

8 Touch Save.

The system processes the QC job you requested.

Touch Help for more information.

Chapter 14 Setup

Setup Overview

The Setup screen allows you to set system defaults, customize settings, and perform system services. Touch the expand button, located at the top of the screen, to expand the menu and then touch the Setup button to access this screen. After the initial settings are saved, the Setup function should be utilized on an as-needed basis, since these features are not part of routine system operation. Select a button along the side of the screen to display information about available settings.

This chapter reviews the topics listed below:

Access Restrictions

Access to some of the Setup functions is restricted based on the level assigned to your user group, or because this feature is not available in your region. This restriction prevents changing of important operating parameters by unauthorized personnel. If your access level does not permit you to perform a procedure, you may view the settings only; you cannot change them.

Setup Action Buttons

The action buttons described below are located along the bottom of Setup screens:

Action Button	Description
 Add User defined	Allows you to create a user defined reagent kit.
 Change to User Groups	Changes to the user group table view.

(Continued)

Change Waste

Allows you to select the waste location: external/internal.

Create Group

Allows you to select user group settings.

Create BRC Profile

Allows you to select desired test for a BRC Profile.

Create IH Profile

Allows you to create a new test profile.

Create QC Sample

Allows you to create QC Samples.

Create Reflex Rules

Allows you to set up a reflex condition based on possible results of different analysis result specifications of all tests within the selected profile.

Create Test

Allows you to select from a list of tests to be included in a user defined test.

Create User

Allows you to select create a user and select settings.

Delete Selected

Deletes the selected item.

Edit Automatic Result

Allows you to enable/disable and change the settings for Automatic Result Settings.

(Continued)

Edit Manual Result

Allows you to enable/disable and change the settings for Manual Result Settings.

Edit Selected

Allows you to edit the selected item.

Enable/Disable User Def. Protocol

Allows you to enable/disable user defined test.

Export Encryption

Allows you to Export Encryption data.

Modify active directory

Allows you to modify the active directory.

Modify ASTM

Allows you to change the settings used to send and receive LIS files.

Modify Audio Alarms

Allows you to enable/disable the LED and audio alarms.

Modify Auto Log Off

Allows you to set the number of minutes of inactivity until the logged in user is automatically logged off.

Modify Backup

Allows you to change backup setting (backup medium, folder path, data sources).

Modify Con. Settings

Allows you to enable/disable and edit LIS connection settings.

(Continued)

Modify Con. Type

Allows you to change and set up the communication channel used by LIS to communicate with the other LIS host.

Modify e-Conn

Allows you to enable/disable and change e-Connectivity configurations.

Modify Display Format

Settings for date/time display format.

Modify Group

Allows you to edit the settings for the selected user group.

Modify ISBT Display

Settings for the ISBT display format.

Note: If set to Yes, ISBT code 128 sample barcodes do not show the additional “=” and the two flag characters at the end.

Modify Lab Info

Stores the laboratory information (name, address, etc.).

Modify Network

Allows you to change the IP address assignment.

Modify Order Archiving

Enables/disables automatic order archiving.

Modify PWD Security

Allows you to modify the password security.

Modify Patient Info

Modifies the information displayed in patient fields when orders are created.

(Continued)

 Modify Printer	Allows you to select a printer or indicate if a printer is not in use.
 Modify Remote Acc.	Allows you to enable/disable and change settings for Remote Access.
 Modify Rpt. Settings	Modifies the report export format and directory.
 Modify Regional Settings	Allows you to modify the language configurations on the system.
 Modify Resolvigen	Allows you to enable/disable and change Resolvigen settings.
 Modify Result Thresh.	Allows you to select values for the Result Positive Thresholds.
 Modify Result Settings	Modifies result expiration, enables/disables comments, enables/disables barcode scanning.
 Modify BC Inter.	Enable or disable the interpretation of QC sample barcodes.
 Modify Sample Key	Enables/disables Sample ID encryption key.
 Modify Selected	Allows you to modify the selected item.

(Continued)

 Modify Sys. Name	Allows you to modify the System Name and J Number.
 Modify Upload	Allows you to change the settings for the uploaded data and upload mode.
 Modify User	Modify information of previously created users.
 Modify user defined	Allows you to modify any selected user defined reagent kit. **Note:** This feature may not be available in your region.
 Modify Warning Level	Settings determine when a user is notified of an issue.
 Show Details	Displays additional information for the selected item. **Note:** The Show Details button is active when a table row is selected.
 Show QC Samples	Displays the QC Samples overview for the selected profile.
 Show Reflex Rules	Displays the Reflex Rules overview for the selected profile
 Show LIS Log	Displays the LIS Log.
 Show e-Conn Log	Displays the e-Connectivity Log.

General

Touch Setup > General to display an overview of available Setup options. Use this screen to modify or program initial settings as shown in this table:

Information Item	Description
Patient Information Fields	Patient ID, Last Name, First Name, Birthday, Gender, Medical Record, National ID, and other ID
Laboratory	Name, address, city and director
Warning Level	Remaining levels of resources and fill capacities on the system
Barcode Interpretation - Ortho QC	Enables QC Sample barcode interpretation. **Note:** Other patient or user-defined QC samples using the same barcode symbology as a Method Base Control cannot be loaded on the system. Doing so will result in “Barcode unreadable” or Apsw00 errors or incorrect barcode interpretation.
Results Positive Threshold	Configure the positive result threshold value. Positive result grades that are equal to or below the defined threshold require manual review. Result grades that are greater than the defined threshold are automatically accepted, when Automatic Result Acceptance Rules are enabled.
ISBT Sample Barcode Display Format	Yes/No
Date/Time Display Format	Configure the date and time display options shown in the table below.

Time Display Format	12h ((hh: mm tt) 24h (HH:mm)
Date Display Format	dd/MM/yyyy (default) yyyy/MM/dd MM/dd/yyyy
Time	Set the current system time. **IMPORTANT:** The system automatically restarts once a time change is saved. **IMPORTANT:** The time zone is not adjusted when the system time is manually changed.
Time Zone	Select the time zone the system operates in. **IMPORTANT:** A system restart is required for the time zone change to take effect.
Date	Set the current system date.

Results Settings	Override Default Time Limits: Y/N Enforce Result Comments: Y/N Enforce Barcode Scanning for Edit Grades: Y/N **Note:** Enforce Barcode Scanning for Edit Grades enables or disables the manual input of a barcode when grades are edited. When disabled, the barcode can be selected from a list displayed on the screen. When enabled, the barcode must be scanned with the Handheld Barcode Scanner. **Note:** Enforce Barcode Scanning for Edit Grades must be disabled in order to edit results with the Remote Results Review feature.
Reports Settings	Export Format Export Directory
Sample ID Encryption	Used to encrypt samples
Order Archiving	Configure options for archiving orders:

Auto Archive Completed Orders	Allows you to automatically archive all orders that have completed all test processes.
Auto Archive Completed Orders after [h]	If Auto Archive Completed Orders is enabled, define the time (in hours) between the creation of an order and when the order is archived. **Note:** Orders are completed when all tests are processed and results are uploaded to the LIS.
Auto Archive Not Running Orders	Allows you to automatically cancel and archive orders that have not completed and are not processing.
Auto Archive Not Running Orders after [h]	If Auto Archive Not Running Orders is enabled; define a time out period (in hours) for orders that were created but have stopped processing and have not completed in the specified time span. Orders that have timed out are automatically canceled and archived.

IMPORTANT: Ortho Clinical Diagnostics does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the Sample ID. Ortho occasionally requests files from your system that may contain Sample IDs, if used as a sample identifier, to assist in troubleshooting or performing routine maintenance of the system. Avoid the use of patient-identifying information as part of the Sample ID, or configure the system to enable Sample ID Encryption.

The Help and Stop Processing buttons are always available as process buttons. Notice the additional action buttons along the bottom of the screen. These buttons change based on the selected screen:

Information Item	Description
Modify Lab Info	Allows you to edit laboratory name, address, city, and director.

(Continued)

Modify Patient Info	Allows you to edit Patient ID, Last name, First name, Birth date, Gender, Medical record, National ID, Other ID.
Modify Sample Key	Allows you to set key encryption configuration.
Modify Warning Level	Allows you to define preventative alarm for reagents and all consumable.
Modify Display Format	Allows you to set the date and time display to either 24h or 12h.
Modify Rpt. Settings	Allows you to select the report export format (PDF, CSV, XML, text and XLS).
Modify Order Archiving	Allows you to enable/disable auto archiving.
Modify Result Settings	Allows you to select the information displayed in Results (global time limit, enforce Results comments, allow manual barcode input).
Modify BC Inter.	Allows you to enable/disable and modify the interpretation of QC Sample barcodes.
Modify ISBT Display	Allows you to enable/disable this function and modify the ISBT display format.
Modify Result Thresh	Allows you to change the thresholds.

See Setup Overview (page 14-1) for a complete list of action buttons in this chapter.

Modify Lab Info

Use the Modify Lab Info button to enter identifying laboratory information. Touch Setup > General > Modify Lab Info to access this function. Enter the information seen here:

- Name
- Address
- City
- Director

Users

The Users screen is used to verify and manage user groups. Touch Setup > Users to access this screen. An example of available information is seen here:

Information Item	Description
User Group	The User Group to which the user is associated.
Description	The category of the User Group.
Password Validity	Length of time until the password expires.
Number of Users	Number of users in a User Group.

WARNING: To prevent personal injury and damage to the equipment, only trained service personnel are allowed to access restricted service software screens and documentation. Never access service software screens or documentation without the permission of Ortho Clinical Diagnostics.

The Change to User Groups, Modify User, and the Create User action buttons are located along the bottom of the screen. For a complete list of action buttons in this chapter, see Setup Overview (page 14-1).

Change to User Groups

Touch the Change to User Groups button display the Table View. A list of all users, and the number of days until the user must change a password is displayed.

Modify User

Touch the Modify User button to display a pre-populated dialog with details about a selected user. The same screen displays when you touch the Create User button. Enter the information you would like to modify. You can modify all user information and reset the password with generating a new one. When a password is reset, the user must enter a new password at the first login.

Create User

Touch the Create User button to display the required information for a new user. An example of required information is seen here:

- Last name
- First name
- Login name
- User Group
- Active/Inactive

You must also select the Admin or User option. When you make a selection, it limits the access level of the user.

Delete Group

The Delete Group button is visible if a User Group is selected and the group is not associated with any other users. When the Delete Group button is touched, a confirmation dialog is shown with the text 'Do you want to delete the User Group?'. If you delete the User Group, you will not be able to use it again.

Create Group

Touch the Create Group button to add a User Group. The information listed below is required to create a group.

- Name of the User Group
- Description of the User Group
- Password validity
- Password history
- Diagnostic User Group
- Maintenance execution
- Maintenance setup
- Remote login

Generate Password

Generate a new password when a new user is added, or if you have forgotten your password. From Setup, touch Users > Create User-Password-Generate New Password, and enter the information listed below:

- Last name
- First name
- Login name
- User group
- Password
- State (status)

Testing

The Testing screen is used to display available test settings. Touch Setup > Testing to access this screen. Use this screen to configure:

- Profiles: Select one or more tests for the profile
- Test Settings: Global settings for Test Result Acceptance
- Reagent Kits: Register user defined Reagent Kits and link to an Ortho Reagent Kit

  Note:

  This feature may not be available in your region.
- User Defined Tests: Enable/disabled

  Note:

  This feature may not be available in your region.
- QC Settings: QC-Strategy and global default parameters

The Search, Help, and Urgent Stop buttons are located along the bottom of the screen and are always available as action buttons.

Profiles

Touch the Profiles row then the Show Details button to view the Profiles Overview page. To display all Profiles action buttons, you must touch the Stop Processing action button (if tests are in process).

These options are specific to certain screens and only display when available for use.

Touch the Show Details button to view additional information as seen here:

Name	Type	Test(s)	QC Management Mode	Lot Tracking	Reflex Rules	Created by
My Profile 1	IH	ABO(FWD)-44 + RVS 6 ABScr 2 Poly	Yes	Yes	No	Admin
My Profile 2	IH	VSP Neut ABScr 3 Poly Pap ABScr	Yes	No	Yes	Admin

(Continued)

ABO (FWD) + AbScr 2 Poly	IH	ABO (FWD) — 44 + RVS 6 ABScr 2 Poly	Yes	Yes	No	Admin

For more information, see Profiles (page 14-13).

Test Settings

To display the Test Settings Overview screen, touch Setup > Testing , select the Test Settings row and touch the Show Details button. The Tests Settings Overview displays the current Automatic Result Acceptance and Manual Acceptance settings.

Touch Edit Automatic Result and select “yes” or “no” to configure the settings described in the table below.

IMPORTANT: Only one option to enforce manual review can be enabled at a time (Enforce Manual Review or Enforce Manual Review for Cassettes with Error Grades). When both options to enforce manual review are disabled, the Automatic Result Acceptance rules will apply.

Information Item	Description
Enforce Manual Review	• Yes: Every test result has to be manually reviewed, independent of any flag. All Cassettes are moved to the Manual Review Rack. If the Manual Review Rack is full, Cassettes are placed in the Waste Drawer. • No: If Enforce Manual Review for Cassettes with Error Grades is also disabled, then manual review is not enforced and the Automatic Result Acceptance rules, as configured, apply.
Enforce Manual Review for Cassettes with Error Grades	• Yes: Every test result has to be manually reviewed, but only Cassettes with error grades or Cassettes that originate from a test where the result has been flagged are moved to the Manual Review Rack for review. Cassettes without error grades are moved to the room temperature Incubator, if partially used, or to the Waste Drawer, if all microtubes are punched; and the digital image can be viewed to complete manual review and edit grades. • No: If Enforce Manual Review is also disabled, then manual review is not enforced and the Automatic Result Acceptance rules, as configured, apply.
Automatic Result Acceptance Rules	**Note:** Automatic Acceptance Rules are ignored if Enforce Manual Review or Enforce Manual Review for Cassettes with Error Grades is enabled. • All Maintenance Tasks must be completed successfully • All column reactions must be without errors • Valid Test Result Interpretations (incl. non-discrepent columns) • Above/below positive reaction threshold **Note:** Manual Review is required for results that are equal to or below the defined threshold. Results that are greater than the defined threshold are automatically accepted. • Entire order must be completed • Require Manual Review of UDP

Touch Edit Manual Result and select “yes” or “no” to set whether a different user must accept results.

QC Settings

Touch Setup > Testing and select the QC Settings row to display the overview. When a new test profile is created, default settings are applied to the profile settings. If a QC strategy is set to NO, the QC strategy is not applied during the flagging of the results and when determining the status of the system.
It is possible to enable both QC strategies. If both strategies are enabled, and the BRC fails, it is not possible to run any profile for which there is no passed method-based QC.
The available QC Setting(s) are seen here:

- QC strategies- BRC based Quality Control, Method based Quality Control.
- Method based QC Management default settings-QC required for all Profiles, Track QC-tested Lots. QC interval length. Allow override of global QC interval length per profile. Start warning before QC interval expiration.

Modify QC Settings

Touch Setup > Testing and select the QC Settings row and touch the Modify button.
Configurable options are seen here:

- QC Interval Length
- Allow override of global QC interval length per profile
- Start warning before QC-interval expiration
- MBC QC Managed Profile Run Anyway
- BRC QC Managed Profile Run Anyway

Reagent Kits

Touch Setup > Testing and select the Reagents row to see an overview of all Reagent Kits.

Test Selection

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

From the Setup screen, touch Testing > Create BRC Profile or Create IH Profile. Select from the list of available tests. This list will vary based on the selected profile. See Profiles (page 14-13) for more information.
Enter the information listed here:

- Profile name
- Test selection
- QC-settings

Profiles

The Profiles screen is used to group tests into Profiles. Touch Testing > Profiles > Show Details to access this screen. If tests are in process, you must touch the stop processing button to gain access to these buttons.
The buttons listed below are located along the bottom of the screen:

- Show Details
- Edit Selected
- Delete Selected
- Create BRC Profile
- Create IH Profile

- Show Reflex Rules
- Show QC Samples

The Profiles Overview screen displays a table with the information listed below:

Information Item	Description
Name	The name of the profile
Type	Type of profile: Group of tests or BRC
Test (s)	Tests associated with the profile
QC Mode	• MBC: The profile must be successfully QC tested with the method based (MBC) QC strategy. • BRC: The profile must be successfully QC tested with the blood bank reagent (BRC) based QC strategy. • No QC: The profile does not require method based QC testing. The normal allocation strategies can be applied for the orders of the profile.
Lot Tracking	Lot tracking rules defined for the profile. Options: Yes/No
Reflex Rules	Reflex rules defined for the profile. Options: Yes/No
Created by	The name of the user who created the profile.
Profile QC Interval [h]	The QC Interval defined for the profile. Options: Global QC Interval or the number of hours (if different than the Global QC Interval).

Edit and Delete Profiles

Select a profile and touch the Delete Selected button to delete a profile. The Delete Selected button is only active when an order is not pending for the selected profile. When a profile is deleted it is flagged as deleted in the system database. The deleted profile can no longer be used for orders. A profile can only be deleted when all tests associated with the profile are archived.

Select a profile and touch the Edit Selected button to modify an existing profile. The Edit Selected button is only active when an order is not pending for the selected profile. When a profile is modified, the current profile is deleted and a new profile is created based on your changes. The deleted profile can no longer be used for orders. A profile can only be modified when tests are not currently processing, and all tests associated with the profile are archived.

IMPORTANT: Once a profile is modified or deleted, the profile data record remains within the database in order to guarantee data integrity for the orders associated with the profile. The data for the original profile is no longer accessible.

For more information, see Modify or Delete a Profile (page 14-25).

Create BRC Profile

Touch the Create BRC Profile to enter a new profile name using the keyboard. You will also see the information listed below next to the keyboard:

- Test Selection
- QC- Setting
- Override Global Setting
- QC Required
- Track QC-Tested Lots

- QC- Interval Length (h)

Touch the Show All action button to display all BRC-tests again.

Create IH Profile

Touch the Create IH Profile button to enter the name of the profile. You will need to use the keyboard to enter this information. For more information, seeTest Selection (page 14-13).

Show Reflex Rules

Touch the Show Reflex Rules button to display an overview of defined reflex rules for the selected profile. You will see information about:

- Conditions
- Target Profile
- Tests in Target Profile

Notice three buttons along the bottom of the screen. Touch the Delete Selected button to delete a reflex rule. Touch the Modify Selected button to modify an existing reflex rule. Touch the Create Reflex Rules button to set reflex conditions.

Show QC Samples

Touch the Show QC Samples to display an overview of QC Samples for the selected profile. When a QC Sample is created, the user must enter the information listed below:

- The QC Sample Type
- The Sample ID and the Sample Type of the first Patient Sample
- The Expected Results for all or a subset of the Test Analysis Specifications in the selected Profile.

Create QC Sample

Touch the Create QC Sample button to create a set of patient QC-Samples. You must enter the information listed here:

- QC-Sample-Kit or RBC Reagent
- Sample ID and Sample Liquid Type (first patient) - patient, QC or RBC Reagent
- Sample ID and Sample Liquid Type (optional-second patient)
- Lot information
- Expected Results for all or a subset of the test analysis specifications

Results

The Results screen is used to configure display options for Results. Touch Setup > Results to access this screen. This screen displays an item for each available setting.

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

An example of available settings is seen here:

Display Option Group	Display Option
No Match	?

(Continued)

Pos/Neg	Pos
Done	Done
Comp/Incomp	CMP/INCMP
Pass/Fail	Fail/Pass
Pheno	C+E+c+e-
ABO	A

The Modify button is located along the bottom of the screen. Touch the Modify button to change the display options for the selected results.

Note: Touch the Save button after making any changes. Any unsaved changes are lost when the screen is dismissed.

System

Touch Setup > System to access this screen. The System screen is used to view and modify the settings listed here:

- Audio Alarms
- Regional Settings
- Printer
- Backup
- System Name Configurations
- External Waste Configuration
- Network
- Auto Log Off
- Automatic Database Cleanup
- Sample Conservation
- Password Security

Touch the buttons along the bottom of the screen to edit the settings.

Modify Audio Alarms

Touch the Modify Audio Alarms button to enable or disable Audio Alarms and/or the LED alarm. A list of available alarms is displayed. Select Yes or No for the alarms you wish to enable/disable.

Modify Regional Settings

Touch the Modify Regional Settings button to set the system language for the numeric format translation, and the keyboard. For more information, seeRegional Settings (page 14-18).

Modify Printer

Touch the Modify Printer to configure the system printer. You can select from:

- None
- Local
- Print Server

Backup

The Backup screen is used to adjust the settings listed below:

- Backup media type
- Shared folder path - if security settings are not assigned to "Everyone" for the shared directory folder, a user name (including domain) and password can be used.
- Data sources
- Automatic image synchronization
- Encryption of the database backup

Modify Sys. Name

Touch the Modify Sys. Name button to view the system name and J number.

Change Waste

Touch the Change Waste button to select an internal or external (direct drain) liquid waste location.

- Use External Liquid Waste – Enables the use of a direct drain for liquid waste.

Contact Ortho Clinical Diagnostics for more information.

Modify Network

Touch the Modify Network button to select the network configuration of the computer. You can select from a static or dynamic IP address. If a static address is selected, you must enter the IP, subnet mask and the default gateway.

Modify Auto Log Off

Touch the Modify Auto Log Off button to enable/disable, and set the number of minutes until auto log off.

Modify Db. Cleanup

Touch the Modify Db. Cleanup button to enable or disable the Automatic Database Cleanup feature. Automatic Database Cleanup is enabled by default.

Modify Samp. Cons.

Touch the Modify Samp. Cons. button to enable or disable the Sample Conservation feature. When Sample Conservation is enabled, sample clots are disposed to the system waste. When Sample Conservation is disabled, sample clots are returned to the sample container.

Modify PWD Security

Touch the Modify PWD Security button to adjust the settings listed below:

- Minimum length (Value of 0 means disabled)
- Maximum Tries
- Lower and Upper Required
- Numeric Required
- Special Characters Required

Note: Feature is not available if Active Directory is enabled.

Regional Settings

Select the regional settings before using the system for the first time. Touch Modify Regional Settings > Setup to access this screen. You can set the language for Numeric Formats, Translations, and the Keyboard. The available languages are listed below:

- English
- Spanish
- French
- German
- Italian
- Portuguese
- Japanese
- Swedish
- Danish
- Chinese (Simplified)
- Polish
- Korean
- Norwegian
- Russian
- Turkish
- Greek
- Dutch
- Czech

After you select a language, it is applied to all screens except for the service screens. The language for the service screens is English.

Interfaces

The Interfaces screen allows you to configure the e-Connectivity backend server and activate e-Connectivity. Touch Setup > Interfaces to access configuration settings. From this screen you can configure the items below:

- LIS Settings
- LIS Connection
- e-Connectivity
- Remote Access
- Active Directory
- Resolvigen

Notice the action buttons along the bottom of the screen:

Information Item	Description
Modify ASTM	Edit ASTM format settings
Modify Upload	Edit the settings for the uploaded data and upload mode

(Continued)

Modify Con. Settings	Activate or deactivate the LIS interface
Modify Remote Acc.	Review password Disable/enable review mode Observe password Disable/enable observe mode
Modify active directory	Disable/enable active directory Configure domain Configure LDAP path
Modify e-Conn	Change e-Connectivity configurations
Modify Resolvigen	Enable/disable Resolvigen Determine export directories
Show LIS Log	Displays a report with the event date/time, source, and message
Show e-Conn Log	Displays an e-Conn report

For a complete list of action buttons in this chapter, see Setup Overview (page 14-1).
The options below should be modified on an as needed basis:

- The upload mode for Test Results
- A flag which tells the system to request Orders from the LIS host if there are Samples without an Order loaded.
- A flag that enables/disables the LIS interface to include Column Grading Results in addition to the Test Results.
- The connection settings
- A flag that enables/disables the LIS interface

LIS Settings

You must select LIS settings:

Information Item	Description
Record Termination Character	Termination Character (line break) of a Record which can be part of a LIS-message • CRLF (Windows) • CR (Linux) • LF (Mac)
Character Encoding	The encoding of the LIS messages: • UTF-8 which is the recommended setting • Shift- JIS (CP 932) • Windows CP 1252 • ISO 8859/1 (ISO Latin 1)
ASTM Mode	Configuration of the ASTM format used to send/receive messages

(Continued)

Maximum Message Length	The maximum length in Bytes of a single ASTM message
Strip trailing delimiters	Yes: trailing Pipe characters between null fields are not serialized. No, otherwise.
Use default ASTM Escape Sequences	Yes: the default ASTM escape sequences are used. No, otherwise.

Modify Upload

Touch Modify Upload to configure result upload and LIS query settings.

Information Item	Description
Result Upload	Select the method for result uploads: • Disabled • Manual • Automatic • Automatic Partial
Transmit Column Grade Results	Select Yes or No to configure if column grade results should be included for upload.
Send Host Query	Select Yes or No to configure if the system should send a query for missing sample orders. **IMPORTANT:** If the LIS interface is configured to allow host queries, a queue of duplicate queries may form during periods when the LIS is offline. These duplicate queries will be sent when the LIS is online again, possibly resulting in duplicate tests.
Number of retries to query for order	Define the maximum times the system should query for orders, per sample. This value can range from 1 to 11 retries.
Retry interval [s]	Define the elapsed time (in seconds) between retries that the system should query for orders, per sample. This value can range from 30 to 999 seconds.
Max. time to wait for host to respond [s]	Define the maximum time (in seconds) to wait for a response from a host query. This value can range from 10 and 300 seconds

LIS Connection

You must select theLIS connection mode. Touch the Modify Con. Type button to select the connection type:

Information Item	Description

(Continued)

Mode	Enabled/Disabled: • Modify TCP/IP • Modify RS232 • Edit shared folder **Note:** The upload and download folders can be a combined folder. **Note:** Shared folders can be folders on the system or external shared folders on a network.

File patterns for Shared folders are case sensitive; upper/lower letters are recognized as different characters. For example, the files lis022.upl and LIS022.upl are considered two different files. Make sure to enter the exact characters you want when defining the file pattern.

See Set Up theLIS Connection (page 14-28) for more information.
You can also change and configure the communication channel used by the LIS to communicate with the other LIS host.

e-Connectivity

e-Connectivity settings allow you to enable or disable e-Connectivity, configure the e-Connectivity backend server IP, and setup periodic logset uploads. The configurable options described in the table below are displayed:

Information Item	Description
Mode	Displays whether the connection to the backend server is enabled or disabled. If this is set to Disabled, the settings below are inactive.
Backend Server IP or URL	Displays the IP address or URL of the backend server.
Backend Server Port	Displays the port of the backend server.
Enterprise Tunnel Host	Displays the enterprise tunnel IP or URL. This should be modified only at the direction of Ortho Care.
Enterprise Tunnel Port	Displays the enterprise tunnel port. This should be modified only at the direction of Ortho Care.
Periodic Logset Upload Frequency [h]	Displays the upload frequency for periodic logsets. To enable and configure an automatic periodic upload of logfiles, enter a frequency in hours (maximum frequency is 48 hours). A frequency set to 0 means the auto upload feature is disabled, and logfiles will not be automatically uploaded. Only files that were created since the last successful upload are uploaded each time.

Note: The Backend Server IP can be entered as an IP address or URL.

IMPORTANT: The system cannot be shutdown while an upload is in progress.

Remote Access

When Remote Access is enabled, there are two available modes: Remote Observation and Remote Review. Remote Observation is used to allow Ortho personnel to monitor the system and to retrieve logs or files for error tracking. A password is required and randomly chosen. Remote Connections are only accepted while a user is logged in. The Remote Observer can only watch what the current operator is doing. The remote mouse and keyboard inputs are

disabled during this time. When the remote user closes the connection, this mode is automatically disabled.

Remote Review is used to allow Results review from a remote computer. The remote reviewer must log in with a special account, which limits the permissions and required functions to review test results. The required password is manually selected from a list and saved in the database. This password must be entered each time a VNC connection is established.

Resolvigen

The Resolvigen screen is used to:

- Turn the export in Resolvigen format on and off
- Configure a shared folder in which the data will be exported

IMPORTANT: Resolvigen can be used only with samples that have Patient IDs downloaded from the LIS.

Maintenance

The Maintenance screen allows you to view and maintain a schedule of all Maintenance tasks. Touch Setup > Maintenance to access this screen. The table below is an example of the information displayed:

Information Item	Description
Name	Name of the Maintenance task
Interval	The interval of the maintenance task execution. **Note:** The time interval between Maintenance Tasks can be decreased, but not increased. Modifying the interval of tasks that have a default interval of As Required will not flag results.
Notification Lead Time	The time span before a reminder/warning to complete theMaintenance task.
Blocking	Maintenance tasks with Blocking enabled will block system processes if the task is not executed successfully in time. **IMPORTANT:** All test results obtained while a Maintenance Task is past due will be flagged. **Note:** The default setting for Maintenance tasks is blocking.

DANGER: The system is designed to prevent incorrect result generation by not allowing processing of tests if maintenance tasks are expired. Ortho Clinical Diagnostics recommends you configure your system to enable Blocking; to prevent the system from processing if maintenance is expired.

Intervals

Maintenance tasks are categorized by how often they must be performed:

- Daily
- Weekly
- Monthly
- Yearly
- As Required

Touch the Modify button to update Intervals or Notification Lead Time.

User Defined Reports

Access the User Defined Reports screen to view and select report settings. Touch Setup > User Defined Reports to access this screen. A list of all available reports is displayed. The Modify button is located along the bottom of the screen.

Modify

Touch a row to select a report, then touch the Modify button to display available settings. You can select available content visibility options.

Setup Procedures

The following procedures are referred to in Setup:

Configure Reports

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to select a format and specify a directory for exported reports. This procedure is located in Setup.

1. If processing is underway, touch the Stop Processing button and the touch Stop Processing again.
2. Touch the Setup menu button.

3 Touch General.

4 Touch the Modify Rpt. Settings action button.

5 Select Export Format, and touch a format in the list.

6 Select Export Directory, and enter a path for the export directory (for example, C:\Vision\ReportExports).

7 Touch Save.

You return to the Setup — General screen. Touch Resume Processing.

Touch Help for more information.

Define a Quality Control Sample

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Define a control in the Setup — Testing screen.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Testing.

4 Touch the Profiles module.

5 Touch the Show Details action button.

The Profile Overview screen is displayed.

6 Touch the profile you want to QC.

7 Touch the Show QC Samples action button.

Note: The selected profile must have the QC Mode enabled for the Show QC Samples button to be available.

A table showing QC samples is displayed.

8 Touch the Create QC Sample action button.

9 Define the QC Sample:

- If this is a user-defined QC sample, specify Sample ID(s), sample liquid type(s), lot information, and the expected results.
- If this is an Ortho QC sample, enter an Ortho QC Sample ID.
- If this is a RBC Reagent, enter an Ortho reagent barcode and expected result.

10 Touch Save.

The QC Sample is now listed with any other defined QC Samples. Touch Close to return to the Profile Overview list. Touch Close again to return to the main Setup screen.

Touch Help for more information.

Delete a Quality Control Sample

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Delete a control in the Setup — Testing screen.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Testing.

4 Touch the Profiles module.

5 Touch the Show Details action button.

The Profile Overview screen is displayed.

6 Touch the profile containing the QC sample to be deleted.

7 Touch the Show QC Samples action button.

8 Select the QC sample to be deleted.

9 Select the Delete Selected action button.

The QC Sample you selected is deleted. Touch Back to go back to the Profile Overview list. Touch Back again to return to the main Setup screen.

Touch Help for more information.

Modify or Delete a Profile

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Prior to modifying or deleting a profile, make certain there is no sample linked to the profile on the Result screen. All linked profiles must be archived.

Use this procedure to remove an unused profile from your system.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Testing.

4 Select the Profiles module and touch the Show Details action button.

A table showing all current profiles is displayed.

5 Select the profile you wish to modify or delete.

6 Touch Delete Selected or Edit Selected action button.

a If Delete Selected: Confirm that you wish to delete the selected profile. The profile is no longer available for use.

b If Modify Selected make the required changes to the Profile and touch Save.

The profile is deleted and is no longer available for use.

Touch Back to return to the Setup — Testing screen.

Touch Help for more information.

Edit a Quality Control Sample

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Note: Settings for Ortho QC samples cannot be modified by the user.

This procedure is located in Setup.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Testing.

4 Touch the Profiles module.

5 Touch the Show Details action button.

The Profile Overview screen is displayed.

6 Select the profile that includes the QC sample you wish to edit, and touch Show QC Samples action button.

A table showing QC samples is displayed.

7 Select a QC sample and touch the Modify Selected action button.

The settings for the selected sample are displayed.

8 Make the modifications you wish to the sample.

9 Touch the Save button.

Your modifications are reflected in the QC sample. Touch Back to return to the Profile list. Touch Back again to return to the main Setup screen.

Touch Help for more information.

Configure Date and Time Display

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

This procedure is located in Setup.

1 Touch Stop Processing. Stop processing.

2 Touch the Setup menu button.

3 Touch General.

4 Touch the Modify Display Format action button.

5 Touch Time Display Format, and touch 24h or 12h.

6 Touch Date Display Format, and touch dd/mm/yyyy, yyyy/mm/dd, or mm/dd/yyyy.

7 If needed, set the time.

8 Changing the time will restart the instrument after you have saved the changes.

9 To set the time zone, touch Time Zone Display Format, and select the appropriate time zone from the list.

10 Touch Save.

You return to the Setup — General screen.

Touch Help for more information.

Set Up Audio and LED Alarms

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to enable or disable audio alarms and the signal light.

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 Audio Alarms action button.

5 Touch Audio Enable, then touch Enabled or Disabled.

6 Touch LED Enable, then touch Enabled or Disabled.

7 Touch Save.

The audio alarms and the signal light are now configured.

Touch Help for more information.

Set Up a BRC Profile

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

1. If processing is underway, touch the Stop Processing button and then touch Stop Processing again.
2. Touch the Setup menu button.
3. Touch Testing.
4. Touch Profiles on the list of modules.
5. Touch the Show Details action button.

   The Profile Overviewscreen is displayed.
6. Touch the Create BRC Profile action button.
7. Select Profile Name, and enter a name for the profile.
8. Select Available Tests, and select at least one test from the list displayed.
9. Touch Save.

Touch Help for more information.

Set Up eConnectivity

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to specify settings for eConnectivity. This procedure is located in Setup.

1. If processing is underway, touch theStop Processing button and then touch Stop Processing again.
2. Touch the Setup menu button.
3. Touch Interfaces .
4. Touch the Modify e-Conn action button.
   - For Mode, select Enabled or Disabled.
   - Touch Backend Server IP to enter an IP address or URL.
   - Touch Backend Server Port to enter a port number.
   - Touch Periodic Logset Upload Frequency [h] to enter the frequency, in hours, of logset uploads. A setting of zero means this option is disabled.
5. Touch Save.

Touch Help for more information.

Set Up theLIS

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to configure parameters for the Laboratory Information System (LIS). This procedure is in Setup.

Note: Any adjustment to the LIS should be made in consultation with your LIS vendor.

1. If processing is underway, touch the Stop Processing button and then touch Stop Processing again.
2. Touch the Setup menu button.
3. Touch Interfaces.
4. Touch the Modify ASTM action button.

   The current ASTM settings are displayed. Touch Save at any time to accept the displayed settings.
5. Select Record Termination Char, and touch CR, CLRF (Windows), or LF (Mac/Linux).
6. Select Character Encoding and touch UTF-8, a code (UTF-8 is recommended).
7. Select ASTM mode, and touch ASTM, Enhanced ASTM, or Vision ASTM.
8. Select Max. Message Length, and enter a byte limit.
9. Select Use Default ASTM Escape Sequences, and touch ASTM or Vision ASTM.
10. Select Strip Trailing Field Delimiters, and touch Yes or No.
11. Touch Save .
12. Touch the Modify Upload action button.
13. Select Result Upload, and touch Disabled, Manual, Automatic, or Automatic Partial.
14. Select Transmit Column Grading Results, and touch Yes or No.
15. Select Send Host Query, and touch Yes or No.
16. Touch Save .

Touch Help for more information.

Set Up theLIS Connection

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to configure the Laboratory Information System (LIS) connection.

Note: Any adjustment to the LIS should be made in consultation with your LIS vendor.

1. If processing is underway, touch the Stop Processing button and then touch Stop Processing again.
2. Touch the Setup menu button.
3. Touch Interfaces.
4. Touch the Modify Con. Settings action button.
5. Select Enabled to enable or disable the LIS connection.
6. Select Images Path, and enter a path for the images folder.
7. Touch Save.
8. Touch the Modify Con. Type action button.

   A wizard opens in which you select and then configure one of the following connection types.

   - Modify TCP/IP: Touch Next to configure Host and Port, then touch Apply.
   - Modify RS232: Touch Next to configure Com Port Name, Baud Rate, Start Bits, Data Bits, Stop Bits, then touch Apply.
   - Edit Shared Folders: Touch Next to configure Upload File Pattern, Upload Folder Path, Download File Pattern, Download Folder Path, Query File Pattern, and Traces Folder Path, then touch Apply.

Note: The upload and download folders can be a combined folder.

Note: Shared folders can be folders on the system or external shared folders on a network.

You return to the Setup — Interfaces screen.

Touch Help for more information.

Set Up or ModifyMaintenance

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Select Maintenance options when you set up or modify the system.

1. If processing is underway, touch the Stop Processing button and then touch Stop Processing again.
2. Touch the Setup menu button.
3. Touch Maintenance.
4. Make a selection from the list of Maintenance options and touch the Modify action button.
5. Enter the Interval, Notification Lead Time, and Blocking information.
6. Touch Save.

   Your settings are reflected in the Maintenance screen.

Touch Help for more information.

Set Up a Printer

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Set up the printer for normal system operation or when the printer location is changed.

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 Printer action button.
5. Select the printer type:
   a. None
   b. Local
   c. Print Server
6. If Local is selected, touch Local Printer and select a printer from those displayed.
7. If Print Server is selected, touch:
   a. Print Server IP and enter the IP address for the network printer

      Note: If you changed the IP address of the printer, or the printer cannot be located on the network, it may cause the software to become unresponsive for several minutes. Once the system successfully connects to the printer, the system should begin responding normally. If the printer cannot be located on the network, check the new IP address of the printer and try again.

   b. Printer Name and enter the name of the network printer.
8. Touch Save.

Touch Help for more information.

Set Up an IH Profile

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Testing.

4 Touch Profiles on the list of modules.

5 Touch the Show Details action button.

The Profile Overview screen is displayed.

6 Touch the Create IH Profile action button.

7 Select Profile Name, and enter a name for the profile.

8 Select Available Tests.

A list of available cassette types is displayed.

9 Select one or more cassette types.

A list of tests processed with the selected cassette types is displayed.

10 Select the tests you wish to be included in the profile. To deselect a test, touch it again. Touch Show Selected to display only the tests you have selected.

After you select one or more tests, you can touch Save to accept the remaining settings and return to the Profile Overview screen.

Note: The selection of each test automatically includes the set of Cassettes types, by default. You cannot deselect the default Cassette type.

11 Select QC Management Mode, and touch No QC, MBC, or BRC.

For MBC QC Management Mode, select Track QC-tested Lots, and touch Yes or No.

For MBC QC Management Mode, select QC Interval Length for Profile [h] to enter a profile specific QC Interval. If no value is entered, the default interval will be the Global QC Interval.

Note: The option “QC Interval Length for Profile [h]” is only available if the setting “Allow Override of Global QC Interval Length Per Profile” is enabled.

12 Touch Save.

Touch Help for more information.

Set Up QC

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to configure overall QC options. This procedure is in Setup.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Testing.

4 Select the QC Settings module and touch the Show Details action button.

5 Touch the Modify action button.

6 Enter a QC Interval Length. This is how long, in hours, a passed QC will be valid before it must be repeated.

7 Select Start Warning before QC-Interval expiration, and enter how long, in hours, the system will warn of a pending expiration.

8 Select MBC QC Managed Profile Run Anyway?, and touch Yes or No to indicate whether this profile must have passed MBC QC to be used in normal testing.

9 Select BRC QC Managed Profile Run Anyway?, and touch Yes or No to indicate whether this profile must have passed BRC QC to be used in normal testing.

10 Touch Save.

The settings you specified take effect. Touch Back to close the Setup screen.

Note: It is possible to enable both method-based quality control (MBC) and BRC-based quality control (blood bank reagent control). If both strategies are enabled, the following rule will apply: If BRC QC fails, it is not possible to run any profile that does not have a passed MBC QC.

Touch Help for more information.

Configure Remote Access

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to configure the system for remote access.

This feature may not be available in your region.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Interfaces.

4 Touch the Modify Remote Acc. action button.

5 For Remote Review Mode, select Enabled or Disabled.

6 If Remote Review is enabled, touch Generate Remote Review Password, and touch the Generate Password button.

Write down the generated password.

7 Touch Remote Observe Mode, and select Enabled or Disabled.

8 Touch Save.

The system is now configured for remote access.

Touch Help for more information.

Set Up a User

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to add a new user to the system. This procedure is in Setup.

1 If processing is underway, touch theStop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Users.

If the Change to Users action button is available, touch it to switch to Users.

4 Touch the Create User action button.

5 Select Last Name, and enter the user's last name.

6 Select First Name, and enter the user's first name.

7 Select Log-in name, and enter the log-in name for this user.

8 Select User Group, and touch the user group to which this user will belong.

9 Select Password, and touch Generate New Password.

The system generates a password for this user. The first time this user logs in with this password, the system will prompt the user to create a new password.

10 Select State, and touch Active or Inactive.

11 Select Locked, and touch Locked or Usable. Locked users cannot log in.

12 Touch Save.

The Users screen is displayed, with this user added.

Touch Help for more information.

Set Up a User Group

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to add a user group to the system. This procedure is in Setup.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Setup menu button.

3 Touch Users.

If the Change to User Groups action button is available, touch it to switch to User Groups.

4 Touch the Create Group action button.

5 Enter the user group name.

When a group name has been entered, you can touch Save to accept the remaining default values.

6 Select Description, and enter the description for this user group.

7 Select Password Validity, and enter the number of days passwords for this group will be valid.

8 Select Password History, and enter the number of unique passwords required for each user before a password may be repeated.

9 Select Diagnostic User Group, and touch the diagnostic level for this group:

- Labor
- Normal
- Instrument Assembly
- Field Service Engineer

10 Select Diagnostic Login, and touch Yes or No.

11 Select Maintenance Execution, and touch Yes or No.

12 Select Maintenance Setup, and touch Yes or No for Modify and View.

13 Select Remote Login, and touch Yes or No to enable or disable remote login for this group.

This feature may not be available in your region.

14 Select Results, and indicate privileges for this group by touching Yes or No for:

- Accept/Reject
- Add Comment
- Edit Results
- Edit Well Gradings (Column Grades)

15 Select Task Screen, and indicate privileges for this group by touching Yes or No for:

- Enable Errors
- Enable Maintenance
- Enable QC
- Enable Resource Management (Resources)
- Enable Results
- Enable Sample Management (Samples)
- Enable Setup
- Enable Software Management (Software)

16 Touch Save.

Touch Help for more information.

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Chapter 15 Software

Software Overview

The Software screen allows you to review the system software options. Use the Software screen to add, update, and monitor software related functions and tasks. Select a button along the side of the screen to display information about available options.

This chapter reviews the topics listed below:

Software Configurations

Configure Software setting in Setup. Touch Setup > Software to view configurable screens.

Software Action Buttons

The action buttons described below are located along the bottom ofSoftware screens:

Action Button	Description
 Add/Export Logset	Allows you to collect the most recent Logsets
 Delete Selected	Allows you to delete the selected Logset.
 Display Rel. Notes	Displays the release notes for the selected software update item. **Note:** If there are no release notes for a specific software update item, the button is not active.
 Export All	Allows you to export all Logsets.

(Continued)

 Export Selected	Allows you to export the selected Logsets.
 Install Software (from Download)	Starts a wizard for installing the selected software item.
 Install Software (from USB)	Starts a wizard for installing the selected software item from a USB.
 Recover From Backup	Starts the recovery process from the selected backup file.
 Refresh all	Updates the information displayed on the Status screen.

Installation

Touch Software > Installation to access this screen. Use the Installation screen to view information about:

- Software
- Current Version
- Last Update
- Description

An example of the screen is seen here:

Software	Current Version	Last Update	Description
Application Software	V0.7.10.2	17.02.2013, 08:12 PM msimmons	Version 0.7.11.1 is available to install
AD	V1.34	17.02.2013, 08:12 PM mbrink	Version 2.6 is available to install
System Publication	7.02	11.01.2013, 12:10 PM cclark	Publications are up to date
Antivirus	V3.5	17.02.2013, 09:11 PM nwest	Antivirus is up to date

(Continued)

Operation System	7.02	11.01.2013, 12:10 PM rgreen	Operating system is up to date

The action buttons listed here are located along the bottom of the screen:

- Display Rel. Notes
- Install Software (from Download)
- Install Software (from USB)

You must touch the Stop Processing button to enable the action buttons on this screen.

Display Rel. Notes

Use the Display Rel. Notes button after you have selected a Software update item. If there are no release notes for the selected Installation item, the button is not active.

Install Software (from Download)

Use the Install Software (from Download) button to install an update of the selected Installation item.

Install Software (from USB)

Use the Install Software (from USB) button when software is loaded from an external device. You are asked to select the installer package and given the option to Backup (page 15-5) the system.

Logsets

The Log Collector prepares and stores all available log files into sets and combines them as one single and easily exportable file. Touch Software > Logsets to access this screen. You can set the date range of the exported data from the present day and back to a maximum of one week. The information below is displayed:

Information Item	Description
File name	The name of the ZIP file
Date	Date and time the ZIP file has been created
Size	Size of the ZIP file

Note: The current Application Software and AD version are included with every log file.

There are four action buttons along the bottom of the screen:

- Add/Export Logset
- Export All
- Export Selected
- Delete Selected

You must touch the Stop Processing button to enable the action buttons on this screen. For a complete list of action button in this chapter, see Software Overview (page 15-1).

Add/Export Logset

Use the Add/Export Logset button to collect the most recent Logsets. The Add/Export Logset button collects all log information belonging to the selected logset. A list of newly created exportable zip files is displayed after you touch the button. You will also need to define the export interval and select an export target/location. The available Logsets are as follows:

- Common Logs
- Reduced Common Logs
- Windows Event Log
- Usage Statistics Report
- Cassette Images (Raw)
- Cassette Images (Compressed)

Export All

Use the Export All button to download all Logsets. You must define the export interval and select and export target/location. After selecting the log type, enter the interval date (up to 7 days). The system generates a file for you to select and save.

Export Selected

Use the Export Selected button to export individual Logsets. Touch the Export Selected button after you have selected the desired Logsets. You must define the export interval (up to 7 days) and select and export location (Backend Server or USB).

Delete Selected

Use theDelete Selected button to remove selected Logsets from the system.

Status

The Status overview screen is used to display a summary of Software information. Touch Software > Status to access this screen. An example of the information displayed is seen here:

Name	Status
Network connection	Internet access available.
e-Connectivity	Please refresh.
Remote Review Access	Please refresh.

This is an example of how LIS information is displayed:

Information Item	Description

(Continued)

LIS Connection	• Disabled • TCP/IP connecting • TCP/IP connected • RS232 disconnected • RS232 connecting • Shared Folders connecting • Shared Folders connected
LIS Message sent counter	Displays activity in send directory
LIS Message received counter	Displays activity in received directory
LIS Last Message received Timestamp	Date and time the last LIS message/file was received

The Refresh all action button is located along the bottom of the screen. Use this button to update the information that appears in the status log. You must touch the Stop Processing button to enable the action buttons on this screen. For a complete list of action buttons in this chapter, see Software Overview (page 15-1).

Backup

Touch Software > Backup to access this screen. Use the Backup screen to see an overview of backups by description and date. You can select a Backup to restore from the list displayed. Prior to recovery, the Backup is verified to prevent a corrupted restore. In the event of data loss, the application software must be manually reinstalled by Ortho Clinical Diagnostics' service personnel.
Notice the action buttons along the bottom of the screen:

- Recover From Backup
- Start Backup
- Export Encryption

IMPORTANT: Ortho Clinical Diagnostics highly recommends monthly system backups of data records onto an export device. More frequent backups reduce the possibility of data loss.

Recover From Backup

DANGER: Before restoring a database with the intention to process orders, remove and dispose of all DILUTION TRAYS. Partially used DILUTION TRAYS must not be reloaded onto the analyzer after a restore from backup.

Touch the Recover From Backup button to start the recovery process from the selected Backup file. After Backup, the system is restarted.

IMPORTANT: Any results data and changes to system settings that occurred since the last successful backup event will be lost with the recovery.

To abort the recovery process, touch the Cancel button. You must touch the Stop Processing button to enable the action buttons on this screen.

For more information, see Restore from Backup (page 15-8).

Start Backup

Touch the Start Backup button to start the backup process The system creates a backup based on your settings. The options listed below are displayed:

- Data Sources
- Backup Media Type
- Media Path
- Available disk space

IMPORTANT: The backup media used (folder location, USB) must be a minimum of 32 GB in size.

IMPORTANT: Users should use a single USB drive for data export. If multiple USB drives are used with the system, a different drive letter may be associated with the USB drive than that which was provided in the Setup screen. Data export may fail as a result.

Data Status

Touch Software > Data Status to access this screen. The Data Status screen is a read only screen. Use this screen to view automatic system maintenance jobs:

- Database Disk Space Monitoring- monitors the database disk usage
- Database Cleanup- indexes the database tables
- Database Backup- backup of the entire database

Software Procedures

The following procedures are referred to in Software :

Load Software (page 15-6)

Restore from Backup (page 15-8)

Add/ Export Logset (page 15-9)

Create a Backup (page 15-7)

Encryption Key Export (page 15-9)

Decryption Key Export (page 15-10)

Load Software Updates

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to load software updates as they become available. It is recommended that the Release Notes be read prior to installation. This procedure is located in Software.

1. If processing is underway, touch the Stop Processing button and then touch Stop Processing again.
2. Touch the Software menu button.
3. Touch Installation.

   A table is displayed showing information for the currently loaded software packages:

   - Application Software

- AD (Application Data)
- System publications (on-line documentation)
- Anti-virus software
- Operating system

4 Select the software you wish to update, and touch the Install Software (from Download) action button.

The installation wizard opens prompting you to read the software Release Notes, perform an optional backup, and then install the software. Respond to any additional prompts to complete the installation.

Note: To install a software update from a USB drive, touch the Install Software (from USB) action button. The installation wizard prompts you to select the file you wish to install, and then continues as above.

5 To resume processing, touch Resume Processing.

Touch Help for more information.

IMPORTANT: Ensure that the correct AD is loaded for your system. Japan requires a unique AD. Refer to the printed Release Notes to determine the correct AD version to be installed. Refer to the Software — Installation screen to confirm the AD installed on your system.

Create a Backup

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to specify backup settings and then create the backup. This procedure is located in Setup and Software.

IMPORTANT: Ortho Clinical Diagnostics highly recommends monthly system backups of data records onto an export device. More frequent backups reduce the possibility of data loss.

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:

- Removable Media
- Shared Folder

If Removable Media is selected, continue to step 6.

If Shared Folder is selected, skip to step 8.

6 Create and name a folder on your USB drive.

7 Touch Media Path and enter the folder name. Skip to step 9.

IMPORTANT: Do not enter the path to the folder. Enter only the folder name. For example, if your folder is named “temp”, enter only “temp” as the media path.

8 Touch Media Path and enter the location of the shared folder.

IMPORTANT: Enter the complete path to the folder. For example, if the folder is named “temp” and on your C: drive, enter “C:/temp” as the media path.

9 Touch Data Sources and select a Data Source:

- Complete - Contains the database, all images and the system configurations

- Database and Column Images - Contains the complete database, the system configurations, and downscaled images (no raw images)
- Raw Images Only - Only the raw images are backed up
- Database Only - Contains the complete database and the system configurations (no images)

10 If you selected a data source that includes images, touch Automatic Images Synchronization and select Active or Inactive.

11 Touch Save.

12 To create the backup media, touch the Software menu button.

13 Touch Backup.

A table displays all current backups.

14 Touch the Start Backup action button.

15 Review settings for:

- Data Sources
- Backup Media Type
- Media Path
- Available disk space
- 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.
- Status

16 Touch Start Backup to create a backup according to your settings. Touch Cancel to cancel the operation. Once the system starts creating the backup, you can touch Abort Backup to stop the process.

17 When the backup is complete, touch Backup Completed.

You return to the table of completed backups.

Restore from Backup

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Use this procedure to restore the system from a backup file. This procedure is located in Software.

DANGER: Before restoring a database with the intention to process orders, remove and dispose of all DILUTION TRAYS. Partially used DILUTION TRAYS must not be reloaded onto the analyzer after a restore from backup.

1 If processing is underway, touch the Stop Processing button and then touch Stop Processing again.

2 Touch the Software menu button.

3 Touch Backup.

A table showing all available backup files is displayed.

4 Touch a row to select a backup file, and touch the Recover From Backup action button.

The system begins the recovery process, and the screen displays “Recovering from Backup in progress.” When recovery is complete, the system performs a restart, and the screen displays “Restarting instrument.”

You also have the option to restore test parameters only by touching the TEST Setup only restore action button.

Touch Help for more information.

Add/Export Logset

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

Add/Export Logset allows the user to choose the data, the time interval, and the export destination. Once begun, the export cannot be canceled. A summary report is displayed after the export is finished.

Note: To export the logset to a USB drive, make sure the USB drive is inserted into the port before beginning the Add/Export function.

1. Touch Add/Export Logset from the Software Logset screen.
2. Choose the type of logset from these choices:
   - Common Logs: Log files from instrument.
   - Reduced Common Logs.
   - Windows Event Log.
   - Cassettes Images (Raw.)
   - Cassettes Images (Compressed.)
   - Usage Statistic Report.
3. Click Next.
4. Determine the export interval for the logset — from one day to 7 days.
5. Click Next. The program creates and saves the zip file for the logset.
6. Select the logset to export and click Next.
7. Select the export destination. Select Yes if you want to delete the selected files after export. Select No if you do not want to delete files after the export. Then click Apply. A report is displayed.

Touch Help for more information.

Encryption Key Export

IMPORTANT: This procedure cannot be executed until a backup has been performed and a removable media (minimum 32 GB) is plugged into the USB port. If either of these conditions are not met, the Export Encryption button will not be accessible.

IMPORTANT: Install 7-zip application prior to encryption.

1. Touch Software menu button.
2. Touch Backup (stop processing).
3. Select Export Encryption button.
4. Touch Resulting Data Entry screen and enter a filename for the key file.

   Note: A file extension is not required as it will be exported as a zip file.
5. Create a password (minimum 4 characters long).

   Note: The requirement in setting up a password for the encryption export key does not follow the same requirements indicated in the Password Security feature.
6. Note the filename and the password combination as it will be necessary while you decrypt the key.

Note: Decryption must be performed before the key can be installed back on to the system.

7 Touch the Save button on the data entry page. The file is written to the removable device's root directory.

Decryption Key Export

1 Plug-in the removable media which contains the encryption key.

2 Select the removable media. Double click the key zip file and extract the encryptionkey.dat file.

3 Enter the password (Refer to Step 5 in Encryption Key Export). Follow the prompt on the screen to decrypt the encryptionkey.dat file.

4 Install the file on the system in the folder C:\ProgramData\Tecan\SOL.

Chapter 16 Maintenance

Maintenance Overview

Touch Maintenance to display the Maintenance screen. 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. Use the Maintenance screen to monitor and execute required Maintenance Tasks. Select an action button 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 results are flagged and an error message is displayed on the screen.

This chapter reviews the topics listed below:

Maintenance Features

Maintenance screens have several features that are used to view details about the required Maintenance Tasks. For example, Maintenance Features include the ability to sort Maintenance tables and to change the Instrument State to Maintenance Mode.

For more information, see Maintenance Features (page 16-2).

Maintenance Configurations

Control the appearance and functionality of Maintenance screens with Maintenance configurations. These items are configurable in the Setup Menu.

- Maintenance (page 14-22)
  - Interval of the Maintenance procedure
  - Notification lead time
  - Enable/disable blocking

Maintenance Action Buttons

The action buttons described below, are displayed at the bottom of Maintenance screens.

Action Button	Description

(Continued)

 Enter Maint. Mode	Puts the system into a state that is safe for Maintenance Tasks to be performed. Touch Maintenance > Stop Processing > Stop Processing > Enter Maint. Mode to put the system into the Maintenance Mode state. For more information, see Maintenance Mode (page 16-4).
 Execute	Initiates a Maintenance Wizard to walk you through the steps of the selected Maintenance Task.
 Show Maint. Rpt.	Create and view Maintenance Reports. For more information, see Maintenance Report (page 16-7).

Maintenance Features

Maintenance screens have several features that are used to view details about required Maintenance Tasks.

Maintenance Mode	An Instrument State that is safe for Maintenance Tasks to be performed. For more information, see Maintenance Mode (page 16-4).
Sort Option	Arranges table information in ascending or descending order when you select a column heading.
Maintenance Wizards	Guided procedures that walk you through the step by step completion of Maintenance Tasks. For more information, see Maintenance Wizards (page 16-7).

Return to Maintenance Overview (page 16-1).

User Maintenance Screen

Touch Maintenance to display the Maintenance screen.

Access to this screen is determined by the individual user settings assigned on the SetupUsers screen. For access to this task, contact your system administrator.

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. For more information, seeMaintenance Mode (page 16-4).

The Maintenance screen displays all Maintenance Tasks for the system in a Table View. Select a Tool on the right-side of the screen to display only the Maintenance Tasks scheduled for that interval. The Tools displayed on the Maintenance screen are listed below.

- All
- Daily
- Weekly
- Monthly

- Yearly
- As Required

Use the Maintenance screen to view, maintain and execute the Maintenance Tasks that must be performed for the system.
Each row of the table displayed on the Maintenance screen corresponds to one Maintenance Task and provides information about that Maintenance Task. The information provided is described in the table below.

Information Item	Description
Name	The name of the Maintenance Task
Type	The interval the Maintenance Task is scheduled to be completed: • Daily • Weekly • Monthly • Yearly • As Required For more information, see Maintenance Schedule (page 16-4).
Last Execution	• The time the Maintenance Task was last completed • The user name of the user who completed the Maintenance Task • The outcome of the completed Maintenance Task
Last Successful Execution	• The time the Maintenance Task was last completed, successfully • The user name of the user who successfully completed the Maintenance Task
Due Date	The next time that the Maintenance Task is due
Blocking	Displays whether or not the uncompleted Maintenance Task will block system processes

Blocking

Some Maintenance Tasks may prevent system processes when the task is due. Rows in the table appear in different colors to indicate when a task is due and if system processes are blocked.

- Red – The Maintenance Task is due and system processes are blocked until the task has been successfully completed.
- Yellow – The Maintenance Task will soon be due, or is due but no system processes are blocked.

When a Maintenance Task is not due, the row appears in the standard dark-blue color.

Maintenance Tasks are set to block system processing by default. Blocking can be configured for each Maintenance Task on the Setup-Maintenance screen.

Note: The time interval between Maintenance Tasks can be decreased, but not increased. Modifying the interval of tasks that have a default interval of As Required will not flag results.

For more information, see Maintenance (page 14-22).

Note: If the frequency of a Maintenance Task is changed from As Required to a more frequent interval, the task will not block system processes.

DANGER: The system is designed to prevent incorrect result generation by not allowing processing of tests if maintenance tasks are expired. Ortho Clinical Diagnostics recommends you configure your system to enable Blocking; to prevent the system from processing if maintenance is expired.

IMPORTANT: All test results obtained while a Maintenance Task is past due will be flagged.

Maintenance Report

You can also create, view, and save a Maintenance Report that displays a recent history of when Maintenance Tasks are completed.

For more information, see Maintenance Report (page 16-7).

Maintenance Mode

Maintenance Mode is an Instrument State that is safe for Maintenance Tasks to be executed. The system must be in Maintenance Mode in order for Maintenance Tasks to be performed.

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.

Touch Maintenance > Stop Processing > Stop Processing > Enter Maint. Mode to put the system into Maintenance Mode. The Instrument State, displayed in the top-center of the screen indicates when the system is in Maintenance Mode.
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.
To exit Maintenance Mode and return the system to the Operational state, touch another Menu.

Note: In Maintenance Mode the system may occasionally appear to be unresponsive. While the system may appear unresponsive, the system is processing the screen touches. Users should refrain from repeating screen touches while in Maintenance Mode to ensure they do not make unintended screen selections, causing them to cancel and restart the maintenance action. To avoid the need to cancel and restart the maintenance action, wait for the expected response.

Maintenance Schedule

The system requires Maintenance Tasks to be completed periodically. Maintenance Tasks are procedures that you perform to keep the system operating properly. Each task should be completed at the recommended interval (daily, weekly, monthly, yearly, or as required). Ensure that you read all the precautions associated with system maintenance before any maintenance work is done. Only users who have been given the necessary access rights can complete Maintenance Tasks.
If questions arise about system maintenance through daily operation, refer to the maintenance procedures provided in the Library. If you still need assistance, contact Ortho Care.
Review each frequency below for a list of the default Maintenance Tasks that must be performed at each interval.

- Daily Maintenance (page 16-5)
- Weekly Maintenance (page 16-5)
- Monthly Maintenance (page 16-6)
- Yearly and As Required Maintenance (page 16-6)

Note: The listed Maintenance Tasks represent the manufacturer recommended schedule of maintenance and are the default tasks for each interval. If the schedule on your system is different, your laboratory may have modified the required intervals for completion.

Precautions

Assume that all used equipment is contaminated with potentially infectious biological material.

Note:

In the United States, use the “Universal Precautions” recommended by OSHA (Occupational Safety and Health Administration) Bloodborne Pathogen Standard 29CFR1910.1030 when handling, cleaning, and packing equipment.

In particular:

- Wear gloves, closed shoes, buttoned lab coats, and safety glasses when the system is cleaned and maintained.
- Treat all waste materials used in the cleaning process as contaminated. Follow the site procedures for your laboratory to dispose of these materials.
- Handle all equipment with care. Mechanical parts may have edges, pinch points, and corners that potentially could cause injury.
- Liquid may drip from disconnected tubing. If necessary, use an absorbent material to absorb the drops of liquid.

Outside the United States, follow WHO (World Health Organization) and your country's regulations for handling and cleaning bloodborne pathogens.

For more information, see General Precautions (page 2-2).

Special Requirements

The supplies and materials listed below are commonly required to perform various maintenance tasks:

- Clean, lint-free cloth
- Paper towel
- Cotton swabs
- Soft, nylon-bristle brush
- Distilled or deionized water
- 70% isopropyl alcohol
- NaOH
- Warm, soapy water

Daily Maintenance

Users with the required access rights should perform each Daily Maintenance Task listed on the Maintenance-Daily screen. Daily Maintenance Tasks should require no more than 15 minutes, in total, to complete.
Be sure that the system is in Maintenance Mode before any Maintenance Task are executed.
The Maintenance Task, listed below, is the default Daily Maintenance Task for the system:

- Daily Probe Maintenance

Return to Maintenance Schedule (page 16-4).

Weekly Maintenance

Users with the required access rights should perform each Weekly Maintenance Task listed on the Maintenance-Weekly screen. Weekly Maintenance Tasks should require no more than 30 minutes, in total, to complete.
Be sure that the system is in Maintenance Mode before any Maintenance Tasks are executed.
The Maintenance Task, listed below, is the default Weekly Maintenance Task for the system:

- Weekly Liquid System Decontamination and Pump Test

Return to Maintenance Schedule (page 16-4).

Monthly Maintenance

Users with the required access rights should perform each Monthly Maintenance Task listed on the Maintenance-Monthly screen. Monthly Maintenance Tasks should require no more than 60 minutes, in total, to complete.
Be sure that the system is in Maintenance Mode before any Maintenance Tasks are executed.
The Maintenance Task, listed below, is the default Monthly Maintenance Task for the system:

- Instrument Cleaning

Return to Maintenance Schedule (page 16-4).

Yearly and As Required Maintenance

Users with the required access rights should perform each Yearly and As Required Maintenance Task listed on the Maintenance-Yearly and Maintenance-As Required screens.
Be sure that the system is in Maintenance Mode before any Maintenance Tasks are executed.

Yearly Maintenance

Yearly Maintenance Tasks should require no more than 240 minutes, in total, to complete.

The Maintenance Tasks, listed below, are the default Yearly Maintenance Tasks for the system:

- Replace System Liquid Container
- Inspect Liquid Waste Container
- Replace Pipetting Tubing
- Replace Instrument Fan Filter
- Replace Diluter Valve and Syringe
- Replace System Tubing

As Required Maintenance

The Maintenance Tasks, listed below, are the default As Required Maintenance Tasks for the system:

- Replace Centrifuge 1 Cassette Holders
- Replace Centrifuge 2 Cassette Holders
- Imaging System Cleaning – Operator
- Pipetting Probe Adjustment
- Prepare System for Downtime
- Fill Liquid System – Saline
- Unlock/open and Close/Lock all Doors
- Empty Liquid System
- Virus Scan
- Probe Replacement
- Pipetting Volume Test
- Liquid System Decontamination
- Pump Test

- Configure Handheld Barcode Scanner
- Maintenance Backup

Return to Maintenance Schedule (page 16-4).

Maintenance Wizards

Maintenance Wizards are guided procedures that 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.

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 steps.

Action Button	Description
OK	Completes the step advances the wizard to the next step.
Cancel	Closes the wizard. The task is not completed. The task can be restarted from the first step.

Maintenance Report

The Maintenance Report shows the execution times of maintenance tasks over a specified time period. To create a Maintenance Report, touch Show Maint. Rpt.. The Maintenance-Show Maint. Rpt. screen displays. You will be prompted to select the date range you would like to create the report for. The Maintenance Report will display all instances of Maintenance Tasks that were executed during the date range selected or preset value selected.
The Maintenance Report displays a table of the Maintenance Tasks scheduled for your system. The information described below is displayed for each Maintenance Task:

Information Item	Description
Task	Displays the name of the Maintenance Task.
Type	Displays the frequency that the Maintenance Task is scheduled to be completed. • Daily Maintenance • Weekly Maintenance • Monthly Maintenance • Yearly Maintenance
Last Result	The result for the last completion of the Maintenance Task.
Last Execution	The date the Maintenance Task was last completed.
Next Execution	The date the Maintenance Task is next due to be completed.

(Continued)

Operator	The user name of the operator who completed the last execution of the Maintenance Task.

The information listed below is displayed at the top of the Maintenance Report:

- Lab Name
- Logged in User Name
- System Name
- System J Number
- Reported Date Range

The Maintenance Report can be saved and printed.

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