Pub. No. J23848EN
2009 November 10
Version 1.05

Training and Reference Guide

ORTHO AutoVue® *Innova*
ORTHO AutoVue® *Ultra*

Ortho Clinical Diagnostics
a Johnson & Johnson company

Table of Contents

1 Intended Use, Specifications, and Limitations

This chapter highlights important product, instrument and personal safety information for ORTHO AutoVue *Innova* and ORTHO AutoVue *Ultra* (ORTHO AutoVue *Innova/Ultra*).

Read this chapter, particularly the warnings and cautions, before using the systems.

Topics

Overview

If this equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. ORTHO AutoVue *Innova/Ultra* should be installed and serviced only by Ortho-Clinical Diagnostics authorized personnel.

Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. Use rubber gloves and eye/face splash protection at all times when operating the ORTHO AutoVue *Innova/Ultra* system. Use standard biohazard laboratory precautions when cleaning or decontaminating the instrument, handling samples, waste cassettes, dilution plates, and all system fluid connections and containers.

The ultimate responsibility for the integrity and identity of blood samples lies with trained personnel. Results obtained by the ORTHO AutoVue *Innova/Ultra* system must be clinically interpreted and validated by qualified personnel. Ortho-Clinical Diagnostics (OCD) disclaims any liability for any erroneous results which may stem from using ORTHO AutoVue *Innova/Ultra* for purposes other than those outlined in this guide.

Ortho-Clinical Diagnostics has validated the use of its proprietary reagents on the ORTHO AutoVue *Innova/Ultra* system. The list of OCD-approved reagents is provided in "Supported Cassettes, Reagents, Tests, and Test Results" on page B-1. OCD does not assume responsibility for results obtained with non-OCD reagents. It is the responsibility of the user to validate non-OCD reagents on this system.

Who Uses ORTHO AutoVue *Innova/Ultra*?

Typically, four types of laboratory specialists will use ORTHO AutoVue *Innova/Ultra*:

- Laboratory technicians who run tests using the instrument
- Biologists who conduct the biological validation and modification of results
- Laboratory administrators who setup the software and interface with the Laboratory Information System (LIS)
- OCD service personnel who execute quality controls, mechanical exercises and diagnostics, and resolve any problems with the instrument

How to Use this Guide

This guide is intended to be used:

- As a training guide for use during training sessions for operators.
- As a reference document that provides instructions for use. OCD recommends that operators use this guide while operating the instrument, using the software and the online help.

This guide includes:

- Diagrams that describe workflows for daily, weekly, monthly, and as required tasks.
- Procedures with detailed steps to carry out normal operation and error management.
- Software screen graphics that are representative of the software.

Note: The fields and buttons shown in the screen graphics may look or be positioned slightly differently on the ORTHO AutoVue *Innova/Ultra* system.

Graphic Symbols Used in this Guide and for Labeling

Table 1-1 Graphic Symbols

Symbol	What it means
	Biohazard
	Electrical Hazard
	Attention: See Instructions for Use (Direct or indirect danger to personal safety or instrument)
	Laser Hazard
	Do Not Reuse
	Lot Number
	Manufacturer's Serial Number
	Catalog Number or Product Code
	Manufacturer
	Authorized Representative
	Contains Sufficient for "n" Tests
	For *In Vitro* Diagnostic Use
	Store At or Below

Table 1-1 Graphic Symbols (continued)

Symbol	What it means
	Store At or Above
	Store Between
	Consult Instructions for Use
	Fragile, Handle with Care
	Keep Dry
	This End Up
	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.)
	Under normal use, this device will not require measures to mitigate environmental impact for fifty years. (Required by Chinese Environmental Regulations on Hazardous Substances - RoHS.)
	Procedure executed on instrument and/or software

Description of ORTHO AutoVue *Innova/Ultra*

Intended use

ORTHO AutoVue *Innova/Ultra* is designed to automate in vitro immunohematological testing of human blood utilizing ORTHO BioVue System (BioVue) cassette technology and digital image processing. ORTHO AutoVue *Innova/Ultra* can be used as a standalone instrument or interfaced with the customer's LIS.

ORTHO AutoVue *Innova/Ultra* automates test processing functions, including liquid pipetting, cassette handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements.

Tests supported by ORTHO AutoVue *Innova/Ultra*

ORTHO AutoVue *Innova/Ultra* has been qualified for use with ORTHO BioVue System cassettes, diluents, and ORTHO Reagent Red Blood Cells. Please refer to Appendix B: Supported Cassettes, Reagents, Tests, and Test Results.

Software versions

For software version information refer to Appendix C: Software Versions.

Common abbreviations used in ORTHO AutoVue *Innova/Ultra* documentation

Table 1-2 Abbreviations

Abbreviation	Explanation
3CELLS	3-5% cell suspension
ABScr	Antibody Screen
AC	Alternating Current
AHG	Anti-Human Globulin
ALT	Alternate key on the keyboard
ASCII	American Standard Code for Information Interchange
Auto	Autologous Control
BID	Bi-directional LIS Interface
°C	Degrees Celsius/Centigrade
Cass.	Cassette
CASUNCA	Cassette Storage for Uninterpretable (cannot interpret) Cassettes
Cent	Centrifuged
Cent WB	Centrifuged Whole Blood
COM 1, COM 2, etc.	Communication Serial Port
Conf. Sys	Configuration system
Confirm	Confirmation
Ctrl	Control
DAT	Direct Antiglobulin Test
DB	Database
DBMS	Database Management System
DEL	Delete key on the keyboard
DIST	Distilled
Dnr	Donor
DOS	Disk Operating System
EEC	European Economic Community
EMC	Electro Magnetic Compatibility
Enz	Enzyme
ESC	Escape key on the keyboard
Fic	Ficin
FTP	File Transfer Protocol
G	G force gravity
Hg	Mercury
H/I	Hemolysis or Icteric Reactions

Table 1-2 Abbreviations (continued)

Abbreviation	Explanation
I 2 of 5	Interleaved 2 of 5
IAT	Indirect Antiglobulin Test
IgG	Anti-IgG cassette
IPS	Image Processing System
IPX	Internetwork Packet Exchange (Novell)
IS or ImSp	Immediate spin: an immediate spin antibody detection test (ABScr or Crossmatch)
KERMIT	KI-10 Error-Free Reciprocal Micro Interconnect Over TTY Lines
LAN	Local Area Network
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LIS	Laboratory Information System
LPT 1, LPT 2, etc.	Computer Parallel Port
µL	Microliter
MF	Mixed-field or Fibrin
mil	1/1000th of a unit
Min	Minutes
mL	Milliliter
mm	Millimeter
MTP	dilution plate
Neut	Neutral cassette
OCD	Ortho-Clinical Diagnostics
Pap	Papain
PC	Personal Computer
Poly	Anti-IgG, -C3d; polyspecific cassette
Pt	Patient
QC	Quality Control
rbc	Red blood cell
RPM	Revolutions per minute
RTHA	Room Temperature Holding Area
RVW	Review
sec	Second(s)
Sel	Selectogen cells
STRV	Serological Time Restriction Violation
Surg	Surgiscreen cells
SVGA	Super Video Graphic Array

Table 1-2 Abbreviations (continued)

Abbreviation	Explanation
TCP/IP	Transmission Control Protocol/Internet Protocol
tm	Trademark
Trt	Treated
Unt	Untreated
UPC	Universal Product Code
UPS	Uninterruptible Power Supply
VGA	Video Graphic Array
W	Well
WB	Whole Blood
XM	Crossmatch

Instrument functions

The primary functions of the instrument are:

- Preparation of red cell suspensions
- Sample and reagent dispensing
- Incubation
- Centrifugation
- Automated reading and interpretation of results
- Inventory of reagents, consumables and other on-board resources

Use the ORTHO AutoVue *Innova/Ultra* software to operate the instrument. The software is installed on the personal computer that comes with your instrument.

Software functions

The functions of the ORTHO AutoVue *Innova/Ultra* software are to:

- Identify samples, reagents and cassettes
- Control ORTHO AutoVue *Innova/Ultra* operations; for example,
  - Identify materials (cassettes, reagents and system fluids) required to process tests and warn operators if insufficient quantities are detected
  - Verify positions of bar coded 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
  - Identify and bring forward cassettes requiring operator review
  - Manage incubation time of cassettes as needed
  - Manage the centrifuge
- Interpret test results (reaction grade)
- Store data of test results in short-term and long-term archives
- Download test requests from, and upload test results to, the LIS
- Export alarm messages to external monitor
- Track operator and system actions
- Inform operators of maintenance and quality control schedules and requirements

User interface security features

ORTHO AutoVue *Innova/Ultra* provides the following security features:

- Ability to define access privileges and passwords for individual operators
- Ability to inactivate operators
- Full access to system data files is limited to system administrators

Performance Criteria

Environmental Operating Parameters

- Operating/ambient temperature: 18-30°C
- Operating humidity: 20–95% humidity

The instrument must operate within the environmental conditions listed above. Operation of the instrument outside these limits is not supported.

Quality Control Limits

The following table details the allowable QC values and ranges by instrument module.

Table 1-3 Instrument Quality Control Limits

Module	Expected Value	Allowable Variance	Acceptable Low Value	Acceptable High Value
Pipette Position	Reference Pin	Not Applicable - Operator adjusts pipette to correct placement using reference pin when error ASPP030 is posted by the instrument through an automatic link to QC and to adjustment menu. If cannot adjust pin: 1) install a new pipette tip, and/or 2) call OCD service personnel.		
Pipette Volume Accuracy	10 µL	±5%	9.5 µL	10.5 µL
	40 µL	±5%	38 µL	42 µL
	50 µL	±5%	47.5 µL	52.5 µL
Pipette Volume Precision	10 µL	±7%	-7%	+7%
	40 µL	±6%	-6%	+6%
	50 µL	±3%	-3%	+3%
Centrifuge Speed[a]	55 g (673 rpm)	±3.6%	53 g (661 rpm)	57 g (685 rpm)
	199 g (1280 rpm)	±4.0%	191 g (1254 rpm)	207 g (1305 rpm)

[a] Requirements and the allowable variances are listed in terms of g-force. However, quality control on the centrifuge results in an rpm measurement. The calculation used to convert rpm to g-force is:

$g = rxv^2 \times 0.00001118$, where g ≡ g-force, r ≡ radial distance, measured in centimeters, from the center of the centrifuge to the inside bottom of the column of the cassette, at the bottom of the "V-shape", and v ≡ rpm (revolutions per minute) of the centrifuge. The radial distance on the ORTHO AutoVue *Innova/Ultra* is 10.869 cm.

Table 1-3 Instrument Quality Control Limits (continued)

Module	Expected Value	Allowable Variance	Acceptable Low Value	Acceptable High Value
Centrifuge Time	2 min	10 sec	1 min, 50 sec	2 min, 10 sec
	3 min	10 sec	2 min, 50 sec	3 min, 10 sec
AutoReader	Not Applicable - AutoReader QC automatically adjusts the Gain and Offset values to be within specifications. If AutoReader QC fails, call OCD service personnel. (See "AutoReader QC Procedure" on page 8-27.)			
RTHA Heat Block	≤ +5 °C from ambient	18 °C - 32 °C	18 °C	32 °C
RTHA Well Contents	≤ +2 °C from ambient	18 °C - 32 °C	18 °C	32 °C
37C Incubator Heat Block	39.5 °C	±1 °C	38.5 °C	40.5 °C
37C Incubator Well Contents	37 °C	±2 °C	35 °C	39 °C

System Specifications

Test Menu

- ABO/Rh
- Reverse grouping
- Rh phenotyping
- Patient/donor crossmatch
- Antibody screen
- Antibody identification
- Direct antiglobulin test
- Enzyme testing
- Special antigen typing
- QC testing

Sample Tube Capacity

- 42 sample tubes

Sample Tube Sizes

- 10 x 75 mm and 100 mm
- 13 x 75 mm and 100 mm
- 16 x 75 mm and 100 mm
- 10.25 x 47 mm (pediatric)
- Other special pediatric tubes

Sample Types

- Centrifuged whole blood
- Packed red cells
- 0.8% red cell suspension
- 3-5% red cell suspension
- Serum or plasma

Cassette Types

- ABO-Rh/Reverse
- ABD
- Rh-hr
- ABO-Rh/DAT
- AHG Polyspecific
- DAT
- AHG Anti-IgG
- ABO-Rh
- ADK
- AHG Polyspecific/Neutral (MIXTE)
- Reverse Diluent
- Rh/K
- Neutral
- Kell
- Kell/Control
- ABODD

Reagent Types

- SURGISCREEN® Reagent Red Blood Cells
- SELECTOGEN® Reagent Red Blood Cells
- AFFIRMAGEN® Reagent Red Blood Cells
- AFFIRMAGEN® 4 Reagent Red Blood Cells
- ORTHO BioVue SCREEN
- Diego Reagent Red Blood Cells
- ORTHO® BLISS
- Blood Bank Reagent Control (BRC) kit
- RESOLVE® Panel A Reagent Red Blood Cells
- RESOLVE® Panel B Reagent Red Blood Cells
- RESOLVE® Panel C Reagent Red Blood Cells
- 0.8% BioVue Screen 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% Red Cell Diluent
- 0.8% Diego Reagent Red Blood Cells
- 0.8% SURGISCREEN® Reagent Red Blood Cells
- 0.8% SELECTOGEN® Reagent Red Blood Cells
- 0.8% AFFIRMAGEN® Reagent Red Blood Cells
- AlbaQ-Chek® J Simulated Whole Blood Controls
- Ortho CQI 7® Control
- Ortho CQI 9® Control

Reagent Capacity

- Rotating Reagent Rotor with three different physical configurations available:
  - Type 01: contains 14 reagent positions: 12 positions for 3 mL vials and 2 positions for 5 mL or 10 mL vials.
  - Type 02: contains 14 reagent positions: 8 positions for 3 mL vials and 6 positions for 5 mL or 10 mL vials.
  - Type 03: contains 14 reagent positions for 5 mL or 10 mL vials
- Non-Agitating Reagent Area that contains:
  - 2 positions for 50 mL vials
  - 2 positions for 10 mL vials

Cassette Capacity

- 240 ORTHO BioVue System cassette capacity
- See Cassette Types above

Reagent, Sample, and Cassette Handling

The ORTHO AutoVue *Innova/Ultra* provides:

- Liquid-level detection and low-level detection of samples and reagents
- Sample clot detection and recovery
- Automatic agitation of reagent red blood cells
- Automated registration of cassettes and reagents into inventory
- Automated registration of samples when bi-directional connection to LIS
- Positive cassette, reagent, and sample ID using bar code reader
- The ability to reprocess partially used cassettes.

Dilution Plates

ORTHO AutoVue *Innova/Ultra* allows space for two dilution plates. Operators can load:

- 1 shallow well on the left or
- 1 shallow well always on the left + 1 deep-well plate on the right

Note: Dilution plates should be replaced daily.

Shallow-well dilution plates

- Shallow-well dilution plates are for 3-5% red cell suspension or dilution

Note: ORTHO AutoVue *Innova/Ultra* uses only approved replacement shallow-well dilution plates NUNC or Greiner with 96 wells that are flat-bottomed to ensure proper fluid dilution.

Deep-well dilution plates

- Deep-well dilution plates are for 0.8% red cell suspension or dilution
- The 0.8% crossmatch and autocontrol tests require a deep-well dilution plate installed on ORTHO AutoVue *Innova/Ultra*. The instrument will automatically prepare a 0.8% cell suspension from the patient or donor cell with the on-board Red Cell Diluent in the deep-well dilution plate.
- Use only a 96-well, 1 mL volume, round-bottom, polystyrene or polypropylene deep-well dilution plate. Specifications for these plates include 41 mm (depth) x 127 mm (length) x 85 mm (width) with 9 mm distance between the center of each well.
- The following plates are approved for use on the AutoVue *Innova/Ultra:*

  TREFF 96-well Polystyrene Plate (part no. 96.8564.9.01)

  Greiner 96-well Polypropylene Plate (part no. 780201).

Note: Validate any deep-well dilution plates manufactured by another company before using them.

PC

- Central Processing Unit (CPU)
  - See individual system for processor speed, RAM, and hard disk capacity
  - Serial and LAN interfaces to the hospital LIS
  - Universal DVD-Read/Write
  - Frame grabber
- Touch screen monitor
- Mouse
- Keyboard
- Hand-held bar code scanner

Note: The system should be rebooted daily.

Uninterruptible Power Supply (UPS)

- Ensure that the UPS used with the system is appropriate for the country of operation.

Printer

- Laser technology
- Prints 45 pages per minute
- Prints maximum of 225,000 pages per month

Instrument Size

- 75 cm (depth) x 92 cm (height) x 140 cm (width)

Instrument Weight

- 230 kg

⚠ Ensure the laboratory workbench where the ORTHO AutoVue *Innova/Ultra* system will be installed is safety rated to hold the full weight of the instrument. Consult the workbench manufacturer's specifications and ratings for the workbench equipment before installing ORTHO AutoVue *Innova/Ultra*.

Data Field Restrictions

Refer to the following table when entering data manually into the system. Use only the characters A through Z (capital letters) and the numbers 0 through 9. No other characters or spaces are permitted.

Table 1-4 Data Field Restrictions

Field	Maximum Number of Characters
Sample	20
Patient ID	20
First Name	30
Last Name	30
National ID	20
Other ID	20
Medical Record	20
Donation ID	20

Supported Bar Code Types

- Code 128C
- CODABAR
- Code 39
- Eurocode
- Interleaved 2 of 5 (I 2 of 5)
- ISBT 128
- UPC

Note: The software enables you to use all alphabetic characters in the barcode configurations.

Sample Bar Code Limits

ORTHO AutoVue *Innova/Ultra* requires the service personnel to indicate whether sample bar codes contain a check digit or not. The system cannot simultaneously handle sample bar codes of a given symbology with and without check digits.

Note: The sample and reagent racks contain code 39 bar code labels without check digits. Therefore, sample bar codes printed using Code 39 should not utilize a check digit.

Note: BioVue uses the Interleaved 2 of 5 symbology for cassette bar codes with a check digit. ORTHO AutoVue *Innova/Ultra* has been specially designed to support simultaneously the I 2 of 5 cassette bar code with a check digit and either:

- An I 2 of 5 sample bar code with a check digit

or

- An I 2 of 5 sample bar code without a check digit

Note: However, this special design is still limited. It cannot simultaneously support I 2 of 5 sample bar codes with and without a check digit: the hand-held bar code scanner must be configured differently depending upon the sample bar code contents.

The following table details additional limits on sample bar codes used on ORTHO AutoVue *Innova/Ultra*.

Table 1-5 Bar Code Limits

Parameter	Allowable Value and/or Range
Density	7.5 mil to 20 mil
Content	Depends upon bar code symbology and density
Quiet Zone	Minimum of 5 mm on all sides
Height	Maximum of 10 mm
Length of Bar Code without Quiet Zone	Maximum of 50 mm
Position on Container	Best Results: 5 mm from top rim of container

The Sample Racks contain a bar code behind the slots used for sample tubes. This bar code is used to indicate an empty Sample Rack position and is read as "$$" by the system scanner. To ensure proper instrument functionality, the following should be addressed:

1. The sample tube bar code label should be in front of the Sample Rack bar code label.
2. The sample tube bar code label should extend beyond the Sample Rack bar code label.
3. The sample tube label (with or without a bar code) should encircle the sample tube.

Instrument Supply Ratings

Voltage: 100-120VAC/200-240VAC

Frequency: 50/60Hz

Power: 520VA

Fuses: 2 * 5.0AT/250V (time lag)

ORTHO AutoVue *Innova/Ultra* requires AC power of the type specified above.

Properly trained personnel knowledgeable in electrical engineering safety must provide the external connections and power supply to the instrument.

Note: ORTHO AutoVue *Innova/Ultra* should be positioned so that the operator and service personnel can access the power cable and power supply.

Electrical Specifications

PC: 120VAC or 240VAC based upon position of switch on back of computer.

⚠ Always check switch setting before connecting computer to power supply.

PC Monitor: Autoswitching between 120VAC and 240VAC.

Uninterruptible Power Supply (UPS): Different units are available for 120VAC versus 240VAC power supply.

⚠ Ensure the UPS used with the system is correct for country of operation.

Printer: For information, refer to the manufacturer's information provided with the printer.

Instrument: Autoswitching between 120VAC and 240VAC.

Uninterruptible Power Supply (UPS)

The UPS will be provided by the local OCD company or distributor.

Hand-held Scanner

The hand-held scanner will be provided by the local company or distributor. For supported bar codes standards, refer to "Supported Bar Code Types" on page 1-20.

Serological Timing Restrictions

ORTHO AutoVue *Innova/Ultra* monitors all tests and imposes timing restrictions for tests performed in the Room Temperature Holding Area (RTHA) and 37C Incubator. Tests exceeding any of these limits result in a Serological Timing Restriction Violation (STRV) error, and are automatically aborted.

Table 1-6 Room Temperature Holding Area

Test	Cassettes	Open Well Awaiting First Fluid (min)	Well with First Fluid Awaiting Second Fluid (min)	Well with Second Fluid Awaiting Third Fluid (min)	Cassette Pipetting Complete Awaiting Removal from RTHA (min)	Cassette Removal from RTHA to Commencement of Centrifugation (min)	Completion of Centrifugation to Commencement of Reading Cassette (min)
ABO Forward and Rh	00 (wells 1-4), 10, 20, 40, 44	60	Not Applicable	Not Applicable	Not Applicable	30	30 (60' for #40 cassette)
ABO Reverse	00 (wells 5-6), 66	60	60	Not Applicable	Not Applicable	60	30
0.8% Affirmagen ABO Reverse	00 (wells 5-6), 66	60	60	Not Applicable	Not Applicable	60	20
Phenotype and Kell	11, 77	60	Not Applicable	Not Applicable	Not Applicable	30	30
DAT	22, 30[a], 33	60	Not Applicable	Not Applicable	Not Applicable	30	30
IS XM	66	60	60	Not Applicable	Not Applicable	60	30
0.8% IS XM	66	75	75	Not Applicable	Not Applicable	60	30
3% Minor XM	22, 33, 66	40	20	21	10-40	6	30
0.8% Minor XM	22, 33, 66	40	20	21	10-40	6	30
Minor XM Bromelin	88	40	20	21	10-40	6	30

a. This number is based upon data collected for similar cassettes (22, 33).

Table 1-7 37C Incubator

Test	Cassettes	Open Well Awaiting First Fluid (min)	Well with First Fluid Awaiting Second Fluid (min)	Well with Second Fluid Awaiting Third Fluid (min)	Cassette Pipetting Complete Awaiting Removal from 37C Incubator (min)[a]	Cassette Removal from 37C Incubator to Commencement of Centrifugation (min)	Completion of Centrifugation to Commencement of Reading Cassette (min)
ABScr w/ BLISS	22, 33, 55 (wells 1-3)	40	20	21	10-40	6	30
IAT	30[b]	40	20	21	10-40	6	30
Two Stage Enzyme ABScr	55 (wells 4-6)[b], 88[b]	40	21	Not Applicable	10-40	6	30
XM	22, 33	40	20	21	10-40	6	30
0.8% ABScr, 0.8% Autologous Control, 0.8% Maj XM	22	40	50	Not Applicable	15-60	10	20
	33	40	40	Not Applicable	15-40	10	20

a. The BioVue reagent and diluent instructions for use states a 10-30 minute incubation, and the software is designed to meet this restriction. However, data is on file at Ortho-Clinical Diagnostics, Inc. demonstrating that a 40 minute incubation has no impact upon test results.
b. The timing limits for this cassette are based upon results obtained with similar test.

Instrument and Software Limitations

- The instrument is designed to use BioVue system cassettes and approved Ortho-Clinical reagents.
- Refer to the instructions for use of each reagent and diluent used with ORTHO AutoVue *Innova/Ultra* for additional information regarding their use.
- OCD has validated the use of its proprietary reagents on the ORTHO AutoVue *Innova/Ultra* system. For a list of OCD-approved reagents refer to "OCD Reagent Kits" on page B-6. OCD does not assume responsibility for results obtained with non-OCD reagents. It is the responsibility of the operator to validate non-OCD reagents on this system.
- Barcodes for some reagents use only a single digit to indicate the expiration date. ORTHO AutoVue *Innova/Ultra* considers digits for the current year (e.g., 8 for 2008) and the three succeeding years (9, 0, 1) as valid and unexpired. It is therefore possible for items significantly past their expiration - six years or more - to be considered valid and unexpired. Users should confirm an item's expiration date in the Resources screen. For a list of OCD-approved reagents refer to "OCD Reagent Kits" on page B-6.
- ORTHO AutoVue *Innova/Ultra* has been designed to reduce the potential occurrence of technique-related problems, for example, carryover; however, these directions and limitations remain in effect when using ORTHO AutoVue *Innova/Ultra* to perform a BioVue test. For example, the BioVue system requires that cord blood samples be washed once in isotonic saline prior to use. This holds true for ORTHO AutoVue *Innova/Ultra* as well. The reagent instructions for use contain sample preparation and known limitations of the BioVue system.
- The full functionality of the instrument and software is based on operator-configurable options. It is the system administrator's responsibility to configure and validate these options in compliance with the regulations governing your facility.
- The instrument does not provide a means for control or tracking of reagent preparation steps required before reagents are placed on the instrument.
- Bar Code limitations:
  - Positive identification of samples, reagents, and cassettes is guaranteed only when bar code labels are automatically read by the instrument or by a hand-held bar code reader.

- Do not use samples that are grossly hemolyzed, lipemic, or icteric as these conditions may lead to discrepant interpretations using ORTHO AutoVue *Innova/Ultra*.
- Do not use clotted or incompletely anticoagulated samples as they may interfere with instrument pipetting.
- Fibrin or particulate matter can interfere with cassette reaction interpretations.
- Questionable or discrepant reactions must be validated by the operator.
- Use demographics when reusing a sample ID from different blood samples. If a sample ID is used more than once, without associating it to patient or donation demographics, reports on the sample ID (used for different blood) covering a span of time that includes the different tests with the same sample ID will show results (including those for different blood) on the same report implying it was for the same blood.
- The Cassette Drawer can only be opened using the command button in the software. It cannot be opened manually.
- Extreme care should be taken that sample ID and lot information that is entered manually with the keyboard is typed accurately.
- If the instrument switch is turned off while the ORTHO AutoVue *Innova/Ultra* software is running, Error 221 displays: “Serial communication lost! Application will be closed.” After the user touches “Ok,” the application closes. The user must then re-start the instrument and re-start the software.
- When entering information into alpha-numeric fields, do not include the pipe symbol (vertical bar). Using this character will cause problems associated with archiving.
- Cassette lot numbers consist of a three-letter product prefix (for example, IGC), followed by a three-digit lot number (for example, 353) followed by a letter (for example, A). In some cases, a single digit, representing a lot split, may follow the letter. The complete lot number would then be IGC353A or IGC353A1.

  An error condition occurs when splits from the same lot are mixed together on one system. If cassettes from lot IGC353A and IGC353A1 are loaded on ORTHO AutoVue *Innova/Ultra* and QC testing is performed on lot IGC353A, the system will treat lot IGC353A1 as if QC testing had been performed. The result is that lots which have not been QC tested will be treated as if they had been QC tested. Note, however, that the instrument correctly tracks these two lots separately as part of the testing record.
- While the system is pipetting, the Main Cover cannot be opened. The software does not display a message to indicate that the Main Cover cannot be opened during pipetting.

- The **Status** screen, **Drawer** tab accurately indicates the number of cassettes in the Cassette Sleeve. However, the display of the position of the cassettes in the sleeve may not match the actual Cassette Sleeve. For example, the Cassette Sleeve may contain cassettes in positions 1-10, but the software may display the cassettes in positions 10-20. This does not affect routine operations.

- If the operator is logged in under Setup mode, routine functions are not accessible. The "Scanning" message displays in the **Sample** screen and in the **Status** screen. The operator can ignore the "Scanning" message and continue working in Setup mode.

- When specifying a directory path for sound files in the **Setup** screen, **General** tab, the operator must touch the **Test** button before touching the **Ok** button in order for the software to accept the directory path for sound files.

- Error message 204 displays if the operator types an incorrect value in the **Auto Logout** field in the **Setup** screen, **Privileges** tab, **Login rules** section. The Auto Logout period is in the unit of minutes, but Error Message 204 indicates a unit of days. If the operator enters a value between 0-120 minutes, this error message will not display.

- The terms "interpretation" and "result" are used interchangeably in this manual.

- For daily maintenance operations, if maintenance is due in 4 hours, the software begins alerting the operator 4 hours and 20 minutes ahead of time instead of 4 hours ahead of time.

- The software might incorrectly display a “Well Not Found” error message instead of a “Light Too Low” error message. This could occur when the system does not find a well or when the AutoReader light is too faint to read the cassette and generate a cassette image.

- The software may incorrectly display an “Empty Well” error message instead of a “Too Few Cells” error message.

- The system cannot be shut down in the middle of an operation. If the operator touches the **Shutdown** button the software will not shut down until all operations are complete.

- In an emergency situation, immediately shut down the instrument using the power switch on the right side of the instrument.

- Test routines will not begin unless a sufficient quantity of reagents with the same lot number are loaded on the rack. Ensure that reagents of the same reagent type that are loaded on the rack have identical lot numbers.

- When diluent resources are unavailable to complete testing on a sample, the position of the sample displays a U symbol rather than an E symbol and the **Resources** button on the Dashboard blinks. Replenish diluent resources to resolve the error and continue the routine.

- If the test routine is not proceeding as expected, do the following:
  - Check to see if reagents on the instrument are expired. Replace reagents then open and close the Main Door to allow the system to detect reagents.
  - Check to see that all doors are closed. The system cannot perform a complete routine when a door is open. As soon as a door is opened to load or remove samples, centrifugation and cassette reading will continue, but the system will stop pipetting. Ensure all doors are closed and continue with the test routine.

- When a pipetting error occurs on a sample, because of a clot for example, in order to resolve the error, remove the clot and move the sample tube to another position so that the system can re-pipette the sample.

- When an empty sample tube error occurs, ensure that the tube contains adequate sample and move it to a new position on the sample rotor so the system can pipette the sample.

- If a donor sample is loaded for an existing crossmatch order after earlier donor results for the same order are available, tests for the donor sample may not be scheduled and may not take place. This results in an instrument error, CCIN002, indicating that tests for the donor will not be run.

- For crossmatches, the overall compatibility result and the detailed well result may be inconsistent if:
  - the crossmatch well result was positive (Incompatible), but a serological time restriction violation (STRV) occurred,

    and
  - results of rerunning the test were negative (Compatible).

  The overall results on both the display and the report will show it as Incompatible. Since results with STRV errors are not displayed or printed, the detailed results will show it as Compatible.

  Note that this limitation can result only in potential false Incompatible crossmatch results, not false Compatible crossmatch results. There will also be an apparent discrepancy in the above situation in the on-screen Test Detail results: the cassette image will show a Compatible result on the retested well, but the Donor Results shows Incompatible. This is also reflected in the Worklist and Profile Detail x/n count summaries.

- When first starting up the AutoVue, if the user enters a test request before the 37°C incubator has heated to the correct temperature, the test will not be scheduled and will not be performed. The user should reset the system scheduler by opening and closing the Main Door after the incubator has reached operating temperature.

- When the user displays the Review Sleeve Detail screen in the Status screen, Drawer tab, a “cassette save reason” displays. Currently, the software can display only two of the possible reason codes: reason 1 (Save by Thresholds, set by the user) and reason 3 (Not Saved). This will be corrected in a future update.

- Always select New Search when checking test order results through the Search screen.

- Previous testing of the ORTHO AutoVue *Innova/Ultra* system indicated that a sample with a very high-titered antibody (>1:1024) when tested for antibody screening may intermittently cause carry-over in the next pipetted sample. The remaining samples in the run were not affected. Testing also indicated no carry-over was observed in samples with antibody titers of 1:512 or 1:1024 using normal operating conditions. Performance of the daily and weekly routine maintenance procedures outlined in this Training and Reference Guide will act to decrease the potential for carry-over when a sample containing a high-titered antibody is encountered.

Warnings and Cautions

This section describes the general safety precautions to observe when operating ORTHO AutoVue *Innova/Ultra*. Observe these safety precautions to avoid possible harm to personnel and the instrument, and to help avoid false test interpretations.

Refer to reagent and diluent instructions for additional information regarding their use.

⚠ General precautions regarding use

- Operators must be trained as laboratory technicians, have a knowledge of immunohematology, possess basic computer skills, and be trained on ORTHO AutoVue *Innova/Ultra*.
- Use of the instrument in a different way than specified in this guide may damage the instrument and the operator-protective components of the instrument.
- If an error occurs in the ORTHO AutoVue *Innova/Ultra* hardware or software for which corrective action is not provided or assistance is needed, or if you have any doubts about the safety of the equipment, please contact OCD Technical Support International (TSI).
- Installation and servicing are to be performed by OCD-authorized personnel only. Only approved replacement parts must be used.
- For safe installation, operation, and maintenance of all equipment connected to the instrument and PC, follow the instructions of the original manufacturer's operating manuals, which are supplied with the system.
- To help ensure proper results, follow the procedures in this document exactly as described.

Electrical safety precautions

- Use caution when connecting or disconnecting the AC power source to the ORTHO AutoVue *Innova/Ultra* instrument or computer.
- Do not remove the service or cover panels as serious injury or electrical shock may result.
- No tool should be used to remove pieces or to access inaccessible parts without the operator first disconnecting the instrument from the main power supply.
- Any service must be performed by qualified service personnel.
- The instrument must be connected to an earth-grounded outlet.
- 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 printer must only be plugged into the AC electrical power Mains power supply. Plugging the printer into the UPS could damage the printer.
- For continued protection against electrical hazard, only voltages and fuses of the same type and rating as stated on the rear panel of the instrument must be used.
- 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 OCD field service engineer has inspected it.
- The ORTHO AutoVue *Innova/Ultra* system should be positioned in such a way to allow operators and OCD service personnel easy access to the main supply and power cords.
- The ORTHO AutoVue *Innova/Ultra* System complies with the following international standards:
  - EN 61326-1:1997 + A1:1998 “Electrical Equipment for Measurement, Control and Laboratory Use. EMC Requirements”
  - IEC 61010-2-101:2002 “Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.”
- All equipment connected to the instrument shall comply to: 73/23/EEC (Low Voltage Directive) and 89/336/EEC (EMC Directive) or appropriate national and international regulations concerning Equipment Safety and EMC requirements.

- For safety precautions associated with the UPS, refer to the operator's manual provided with the UPS by the UPS manufacturer.

Laser safety precautions

Do not attempt to service any scanning device. The patient and donation samples, reagents and cassettes use bar codes that are scanned by the hand-held bar code scanner and the sample/reagent rotor bar code scanner.

Potential exposure to the laser is possible. Do not look into the laser at any time when the instrument is on. Never look directly into an operating laser.

Precautions associated with using the ORTHO AutoVue *Innova/Ultra* software

- Only software that has been validated for use on the ORTHO AutoVue *Innova/Ultra* system and that has been installed by OCD-authorized personnel may be used on the computer provided with the instrument.
- In the unlikely event of an application software crash, call Customer Technical Services and describe the circumstances leading to the crash.
- The Windows® screensaver and other energy-saving devices must not be activated.
- The ORTHO AutoVue *Innova/Ultra* software automatically archives sample data and test results in order to optimize performance.
- Incorrect results can occur when incorrect bar code data are manually entered. The operator is responsible for ensuring that manually entered bar code data are correct.

  Note: ORTHO AutoVue *Innova/Ultra* requires double entry for all manually entered bar codes.

- Incorrect results can occur when non-barcoded reagent bottles/vials are incorrectly positioned in the reagent rack. The operator is responsible for ensuring that non-barcoded reagents are correctly positioned on the reagent rack. Positive identification is ensured for OCD reagents with bar code labels that are directly loaded onto the reagent rack.
- Incorrect results can occur when reagents are placed in the NAA rack and the instructions shown in Figure 6-6, on page 6-12 are not followed. The operator is responsible for ensuring that the reagent vials are placed on the NAA rack and bar-coded in the exact sequence as specified in Figure 6-6, on page 6-12.

- Obtaining results from the ORTHO AutoVue *Innova/Ultra* may be delayed if the operator performs a data backup or uses the DVD drive while the instrument is processing samples.
- Users should not change the time on the Windows operating system clock while the AutoVue is processing tests. Doing so may produce invalid test results.

⚠ Precautions associated with using the ORTHO AutoVue *Innova/Ultra* instrument

- Only ORTHO BioVue System cassettes may be used on the instrument.
- OCD has validated the use of its proprietary reagents on the ORTHO AutoVue *Innova/Ultra* system. For a list of OCD-approved reagents refer to "OCD Reagent Kits" on page B-6. OCD does not assume responsibility for results obtained with non-OCD reagents. It is the responsibility of the operator to validate non-OCD reagents on this system.
- Only original parts (for example tubings, filter, and lamps) from OCD may be used on the instrument.
- If the protective doors or safety latch are damaged, the instrument must be declared nonoperative and all necessary measures must be taken to prevent its use. The protective doors are considered "damaged" when any of the following apply:
  - The damage is visible
  - The closing mechanism operates incorrectly
- Incorrect results can occur when insufficient sample or reagent fluid is aspirated or the probe aspirates air above the sample (due to an air bubble on top of the fluid) causing early triggering of liquid level detection.
- The ORTHO AutoVue *Innova/Ultra* is not intended to be used for cassette, reagent, or diluent storage.
- If the ORTHO AutoVue *Innova/Ultra* has been idle for more than 2 hours, reagent red cells should be inspected for settling and resuspended, if required, prior to initiating a test routine.
- Hemolysis and concentration changes may occur in reagent red cells that are left on the instrument for more than eight hours at a time. Reagent red cells can be used on the ORTHO AutoVue *Innova/Ultra* for a maximum of 24 hours, in three eight-hour shifts with refrigeration overnight in between shifts, without significant impact to concentration or red cell integrity. If the instrument is not continually in use, OCD recommends the reagents be removed from the system and refrigerated. Prior to testing requiring these reagents, the reagent red cells should be re-suspended manually.

- Keep fingers, hands, arms, and clothing away from moving parts of instrument.
- In an emergency situation, immediately shut down the instrument using the power switch on the right side of the instrument.
- All instrument doors must be closed during testing. The system will be able to perform a complete routine only when all doors are closed. Only open the instrument's doors using the ORTHO AutoVue *Innova/Ultra* software. If the doors do not open in response to commands executed through the software, shut down the instrument and call OCD service personnel. Do not operate the instrument with a defective lock.
- When indexing a Sample Rack, ensure that your hands are clear of any moving parts of the instrument including the Sample Racks.
- Only use approved sample tubes. Do not interchange sample tubes and their respective labels.
- Do not leave the Main Cover open for an extended period of time. The reagent rotor will not spin which can result in settling of the reagent red cells. This can affect test results. Opening the cover will halt the rotation of the reagent rotor. If this motion is stopped for longer than 3-5 minutes, operator should remove reagents from the instrument and resuspend.
- Do not overfill reagent vials. Only use approved reagent vials.
- 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 cassette drawer to avoid pinching fingers in the door mechanism.
- ORTHO AutoVue *Innova/Ultra* is equipped with cooling fans. Do not put foreign objects into the fans, and keep the fan airflow area clear.
- Use replacement fuses as specified on the instrument label. Ensure all power to the instrument is shut off, and all power connections to the instrument (from the UPS) are disconnected before replacing the fuse. The fuse must only be replaced by properly trained personnel.
- Do not intermix the fluid connections, containers, and fluid contents. Use caution and discard the liquid waste according to the laboratory's procedures for handling liquid waste. After emptying the waste container ensure the connections are correct.
- When the Tip decontamination operation is cancelled, the Main Cover may unlock. Do not open the Main Cover until the operation is fully completed.

Biohazardous materials

- All areas of the instrument must be considered potentially biohazardous and handled with the appropriate care as per the laboratory's procedures.
- Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. Use rubber gloves and eye/face splash protection at all times when operating the ORTHO AutoVue *Innova/Ultra*. Use standard biohazard laboratory precautions when cleaning or decontaminating the instrument, handling samples, waste cassettes, dilution plates, and all system fluid connections and containers.
- Some instrument components may be difficult to access. Use extreme caution to avoid physical and biological injury.
- Use caution when handling sample racks containing samples to avoid spilling sample contents.
- When the Main Cover is open, use caution around the pipette probe as it is sharp and presents a biohazard.
- If the centrifuge becomes jammed with a cassette, turn off the instrument and remove the jammed cassette carefully. Any open cassettes in the centrifuge represent a biohazard.
- Use caution when handling a reagent rack loaded with reagents to avoid spilling contents.
- When replacing the dilution plates, a biohazard is present in the test wells. Use extreme caution when handling and discarding the plates.
- Use caution when emptying the waste container. Periodically inspect the waste container before long test runs to ensure that it does not overflow.
- Use caution when emptying the cassette waste container. Dispose of cassette waste properly (follow the guidelines of the laboratory for disposing biohazardous waste). Always make sure a bag (autoclavable) is present and loaded correctly (not loose) and the container is installed and ready for cassettes. Use two hands and remove the container carefully. The waste cassettes are a biohazard. Use extreme caution.
- Treat all instrument components to be discarded as biohazardous waste, and dispose of according to the laboratory's guidelines for handling biohazardous waste.
- When the instrument is no longer needed, treat the instrument and all components as biohazardous waste, and dispose of according to the laboratory's guidelines for handling biohazardous waste.

Cassette handling

When preparing and loading cassettes, ensure the following:

- The cassettes have been inspected and defective cassettes with bubbles or dried columns have been removed from the sleeve prior to loading (as per cassette reagent and diluent instructions for use).
- The cassette foil seal is in place and correctly aligned.
- Cassettes being processed should be removed from the ORTHO AutoVue *Innova/Ultra* only under error conditions and direction from the ORTHO AutoVue *Innova/Ultra* software.

Ensure regular cleaning and maintenance

- ORTHO AutoVue *Innova/Ultra* is a precision instrument and requires regular cleaning and maintenance to ensure accurate operation and positioning of its movable parts. Ensure that the maintenance procedures described in this guide and during the training sessions are followed according to the schedules recommended.

  Note: The schedule should be adapted and frequency of maintenance must be increased if system usage increases.

- Failure to perform the appropriate cleaning, maintenance, or quality control procedure at the necessary time can result in damaged parts, operating/reading inaccuracy and/or compromised sample results. (See the chapter “Maintenance Procedures” for details.)

Moving the Instrument

- Never lift and move a fully installed ORTHO AutoVue *Innova/Ultra* to another location. Contact your OCD technician.

Manufacturer's Contact Information and Technical Support

Manufacturer's Contact Information

Manufacturer's Name: Ortho-Clinical Diagnostics, Inc.

Manufacturer's Address: 1001 U.S. Highway 202
Raritan, New Jersey 08869 U.S.A

Product Names: ORTHO AutoVue *Innova*
ORTHO AutoVue *Ultra*

For future reference:
In the box below, please write the serial number as it appears on the instrument.

ORTHO AutoVue *Innova/Ultra* instrument serial number:

Technical Support

Contact technical support provided by your local OCD company or distributor.

Ordering Information

Contact the local OCD sales or service representative for ordering new systems or supplies for existing systems.

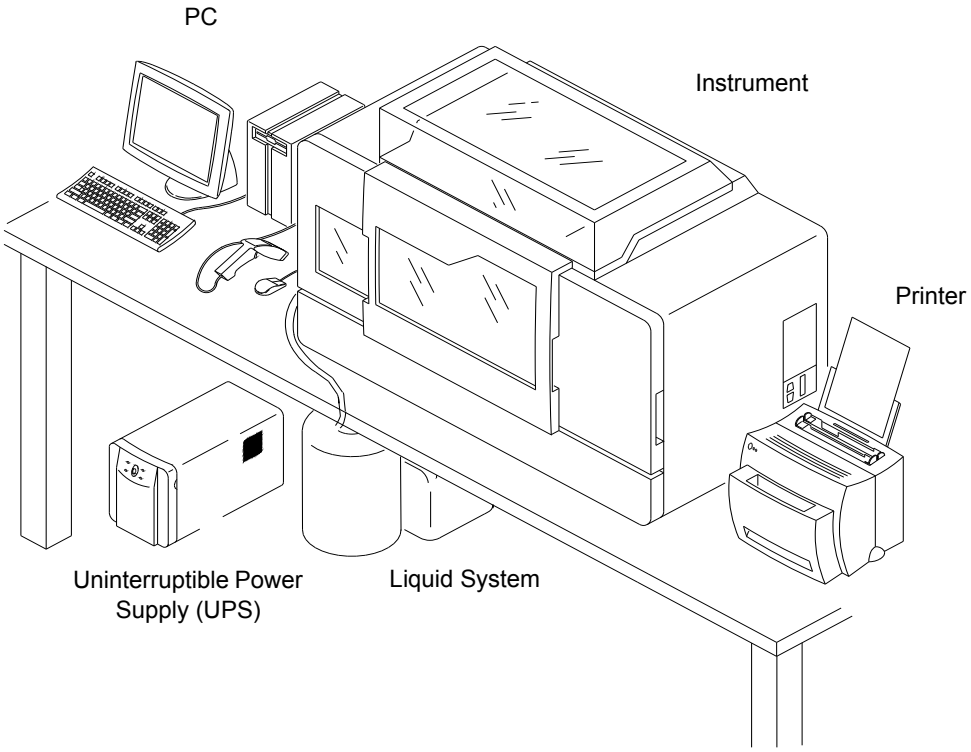
This page intentionally left blank.

2 Overview of the ORTHO AutoVue *Innova/Ultra* Instrument

Overview

ORTHO AutoVue *Innova/Ultra* is a fully automated test system for blood typing and compatibility testing using BioVue system cassettes. ORTHO AutoVue *Innova/Ultra* provides automated liquid pipetting, cassette handling, incubation, centrifugation, and reaction grading and interpretation. The ORTHO AutoVue *Innova/Ultra* system consists of the following primary components. See Figure 2-1 below.

Figure 2-1



Topics

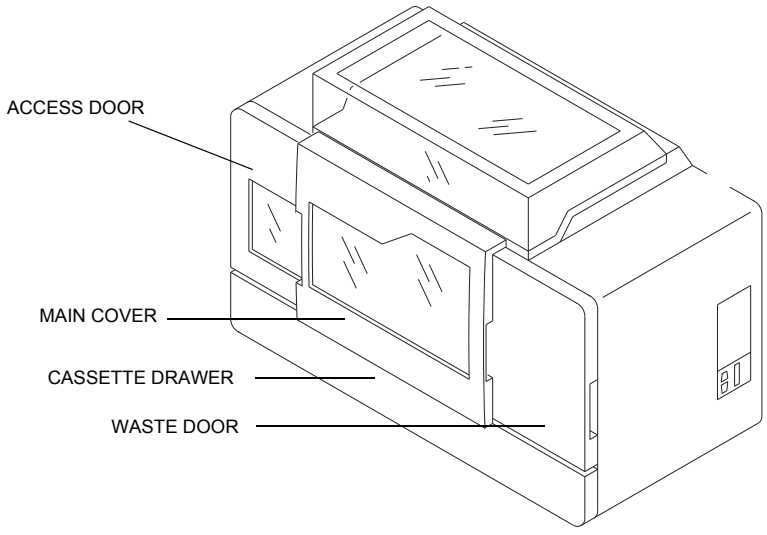
Section A: Accessing the Instrument

To access the inside of the instrument, use the four doors listed and described in Table 2-1 below.

Table 2-1 Accessing the Instrument

Instrument Door	Open this door
Access Door	To load samples on Sample Racks.
Main Cover	To load or remove Reagent Racks, replace dilution plates, and access cassettes requiring special handling.
Cassette Drawer	To load or remove Cassette Sleeves.
Waste Door	To remove, empty, or replace the waste container (for cassettes only).

Figure 2-2



Access Door

This door provides access to the Sample Rotor and Sample Racks. Use this door to:

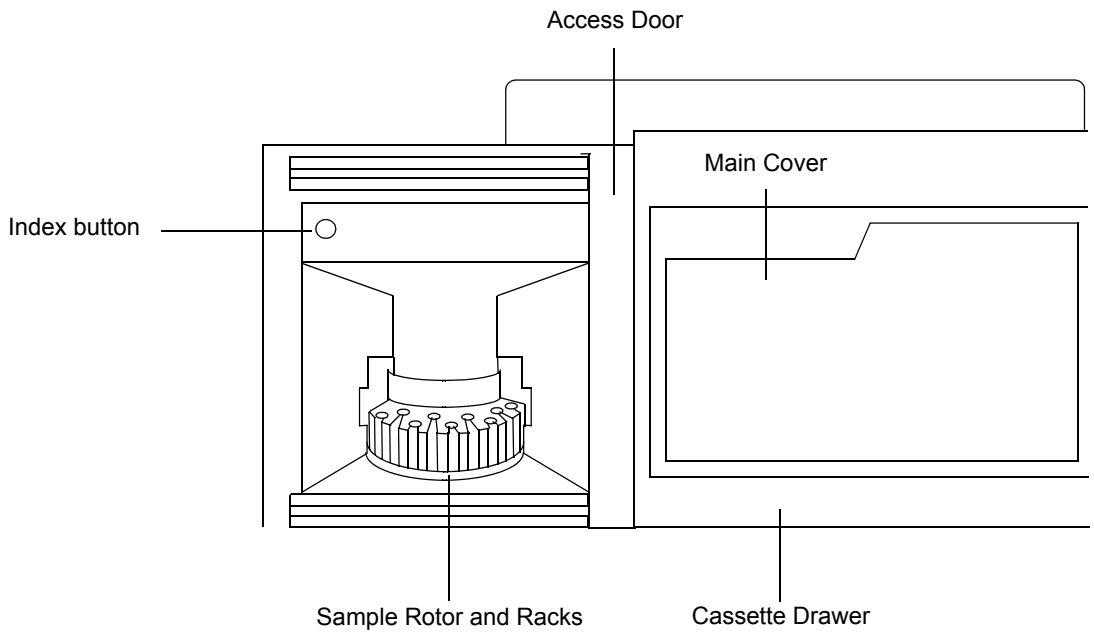
- Load/unload the Sample Rack on which the samples have been placed

  Note: The Sample Racks hold the sample tubes.

- Move the Sample Rotor to the next rack position using the Index button

The Access Door is equipped with an Index button. The Index button provides a manual method to move the Sample Rotor to the next Sample Rack position. Before indexing the Sample Rotor using the Index button, make sure that no body parts or clothing are near the rotating equipment. Keep hands and clothing away during the indexing. A potential pinch point exists between the rotor and the Access Door housing. Use caution when indexing.

Figure 2-3



Sample Rotor and Racks

- The Sample Rotor holds five Sample Racks:
  - 4 removable Sample Racks that hold up to 9 samples each
  - 1 fixed rack that holds up to 6 samples
- The STAT tubes can be placed anywhere on the Sample Racks
- There are 4 types of removable, color-coded Sample Racks:
  - Sample Rack ID 1, RED: used for 10 x 75 mm sample tubes
  - Sample Rack ID 2, BLUE: used for 13 x 75 mm sample tubes
  - Sample Rack ID 3, GREEN: used for 16 x 75 mm sample tubes
  - Sample Rack ID 2, RED: used for 10 x 47 mm sample tubes (pediatric)

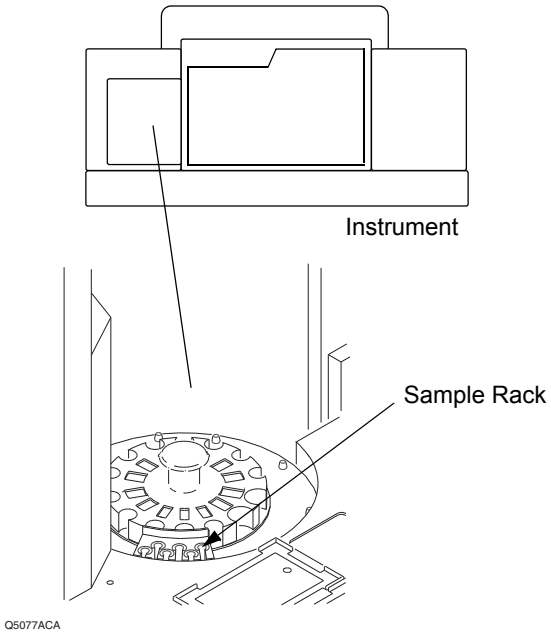
Note: The system's ability to accurately detect the sample volume is dependent upon the inner diameter of the sample tubes used and the maximum distance the pipette can travel in the downward direction for a specific Sample Rack. The type of Sample Rack used is critical.

Use caution when handling Sample Racks containing samples to avoid spilling sample contents.

Only use approved sample tubes. Do not interchange sample tubes and their respective labels.

Do not attempt to interchange color-coded sample clips between Sample Racks.

Figure 2-4



Main Cover

The Main Cover provides access to the primary section of the instrument housing the components shown in the following figure.

Note: Even if samples are visible from the Main Cover, samples and Sample Racks should only be removed from the Access Door.

The Main Cover remains closed for most of the test routine so the system can monitor the status of samples, reagents, and dilution plates. You can only open the Main Cover:

- Between pipetting and incubation
- Between incubation and spinning
- When arm is not moving

Figure 2-5

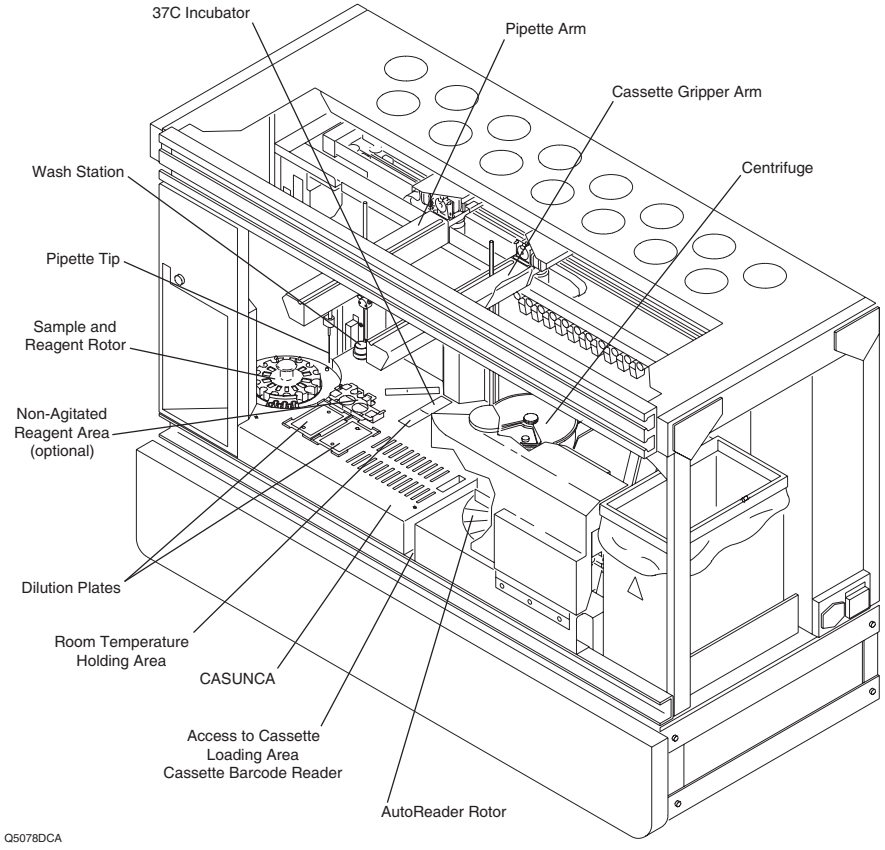


Table 2-2 Key Instrument Parts and Functions

Key Instrument Parts	Functions
Cassette Gripper Arm	Transfers cassettes from the: ▪ Cassette Loading Area (CLA) to the Heat Block and Room Temperature Holding Area (RHTA) ▪ Heat Block and RHTA to the Centrifuge ▪ Centrifuge to the AutoRotor ▪ AutoRotor to the Heat Block and RHTA or the CASUNCA or the Cassette Drawer
Automated Pipetting System including the pipette tip, pipette arm, and wash station	▪ Controls the preparation and transfer of samples from the sample tubes to the dilution plate, if required, and ultimately to the cassettes ▪ The Automated Pipetting System also aspirates and dispenses reagents and various system liquids ▪ The wash station is used in between pipetting of different samples or reagents to clean the tip and includes 2 wash positions: ▪ 1 deep well on the right to wash full length of the tip ▪ 1 shallow on the left well to wash the extremity of the tip Note: Following the wash operation, you will notice a small release of fluid into the wash station that was not evident in prior releases of the software. This is normal operation to clear the probe of all fluid. In the center of the wash station there is a hole connected via a tubing to the waste ▪ Pipette position is software monitored and error message is posted when not well positioned

Table 2-2 Key Instrument Parts and Functions (continued)

Key Instrument Parts	Functions
Automated Pipetting System including the pipette tip, pipette arm, and wash station (continued)	▪ Clot detection measurement utilizing the dip-in and dip-out signal of the pipette tip ▪ Pipette tip in addition to aspirate and dispense sample and reagent is also responsible for liquid level detection of the product that it aspirates via the insulation block (capacity change) ▪ Insulation block holds on its right top, a silver PIN responsible for the Z home position of the tip. This silver PIN is spring mounted to allow gentle touching of the stopping ring. ▪ Positioning of the tip is monitored via the Tip Alignment Pin or (Gold PIN). The Tip Alignment Pin is a spring loaded pin, which is used to periodically check the position of the pipette tip. A special machined "pin-cap" with a diameter of 1.0 mm is pressed on the standard pin to provide protection to the spring mechanism and prevent jamming in case of saline leakage. The Tip Alignment Pin is located on the right side of the wash station. ▪ Pipette tip does the Z and Y moves ▪ Pipette arm does the X moves
Diluter (syringe and valve)	▪ Is used to aspirate and dispense samples and reagents ▪ Syringe can be bypassed by the valve during flushing of tip in between aspiration/dispense of different samples or reagents

Table 2-2 Key Instrument Parts and Functions (continued)

Key Instrument Parts	Functions
Sample Rotor	▪ Holds sample tubes in 4 removable sample rack positions and 1 stationary rack position ▪ Positions samples for pipetting ▪ Advances to the next rack position when the Index button is pressed ▪ Samples added manually through the Access Door
Reagent Rotor	▪ Stores reagent vials in removable Reagent Racks ▪ Positions reagent vials for pipetting ▪ Maintains reagent red cells in suspension ▪ Rotates independently of the Sample Rotor ▪ Reagent Rotor and reagent vials are loaded manually through the Main Cover
Dilution plates	▪ Provides wells for preparing 3-5% and 0.8% red cell suspensions
37C Incubator	▪ The 37C heat block, which holds up to 24 cassettes, incubates each cassette. ▪ Quality control monitoring
Room Temperature Holding Area (RTHA)	▪ The RTHA, which holds up to 42 cassettes, is used for cassettes that do not require incubation ▪ One cassette, which is used for balance, is always in the RTHA. ▪ QC monitoring
Non-Agitated Reagent Area	▪ Holds 2-50 mL 0.8% Red Cell Diluent and 2-10 mL BLISS, 0.8% Red Cell Diluent or Bromelin reagents

Table 2-2 Key Instrument Parts and Functions (continued)

Key Instrument Parts	Functions

Punchers (not visible, behind back wall)	▪ Automatically open cassettes for dispensing sample and reagents
	▪ Multiple dedicated punches eliminate the risk of carryover and increase throughput
	  ▪ RTHA puncher
	  ▪ 37C incubator puncher
	▪ Different configurations for the puncher can be set up depending on the test and type of cassettes in use
	▪ Any configuration change needs the a decontamination of the puncher
	Note: If you try to change a puncher or delete a profile and there are results still associated with those settings, you won't be able to change/delete anything until the results have gone into the long-term archive.

Table 2-2 Key Instrument Parts and Functions (continued)

Key Instrument Parts	Functions
AutoReader	▪ AutoReader reads both sides of each BioVue system cassette using a camera and reports the grade reactions in each column of the cassette ▪ Reported results include +4, +3, 2+, 1+, 0.5+ and negative, IND (+-), mixed field, hemolysis, too few cells, and various other messages ▪ Results sent to PC so you can review, interpret, and accept result. ▪ QC monitoring with unique calibration cassette ▪ Bar Code reader for positive cassette ID AutoReader is composed of: ▪ AutoRotor which transfers cassette coming from centrifuge to pick up position for rotation gripper ▪ Rotation gripper which transfers cassette across Bar Code reader for positive cassette ID then in front of the camera for reading of one side, then rotates the cassette to be read on second side, then either transfers read cassette back to AutoRotor or to Lift depending on result read ▪ Lift which slides used cassettes to Waste Basket
Centrifuge	▪ The centrifuge can hold up to 24 cassettes. Centrifugation speed and time are automatically controlled and QC monitored. Cassettes for balance are automatically added.

Table 2-2 Key Instrument Parts and Functions (continued)

Key Instrument Parts	Functions
CASUNCA	▪ Stores the processed cassettes to be reviewed ▪ Stores the AutoReader QC calibration cassette ▪ Includes the cassette recovery station where the gripper places cassettes that cannot be used for testing
Calibration plate	▪ Provided by OCD to perform the QC Volume maintenance procedure

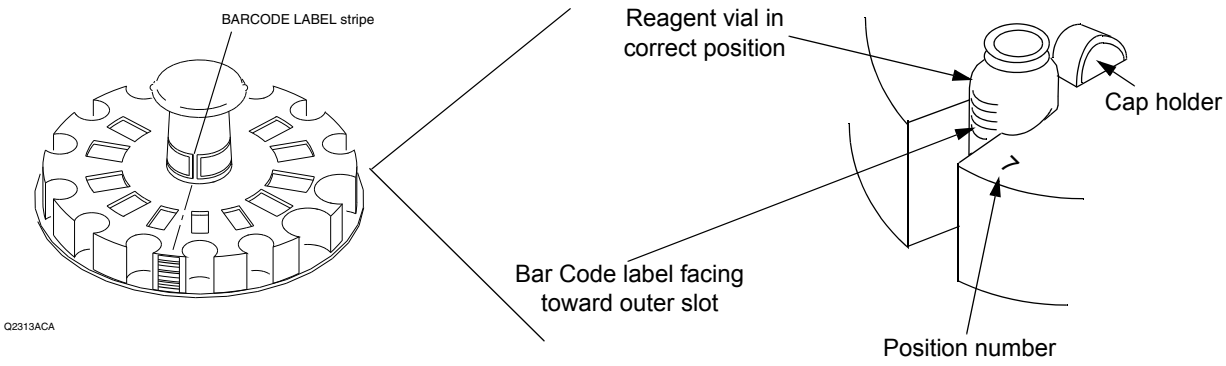
Following are further explanations of some components that require more detailed explanations.

Reagent Rotor

- The Reagent Rotor holds one rack and maintains reagent cell solution in suspension by intermittent left-right rotation.
- There are three physical types of racks available, Type 01, Type 02, and Type 03. Each reagent rack contains a bar code behind the slots used for reagent vials. This bar code indicates an empty slot and is read as "$$" by the system scanner.
  - Type 01 contains 14 reagent positions: 12 positions for 3 mL vials and 2 positions for 5 mL or 10 mL vials. A Type 01 reagent rack is identified by bar code 0101.
  - Type 02 contains 14 reagent positions: 8 positions for 3 mL vials and 6 positions for 5 mL or 10 mL vials. A Type 02 reagent rack is identified by bar code 0202.
  - Type 03 contains 14 reagent positions for 5 mL or 10 mL vials. A Type 03 reagent rack is identified by bar code 0303.
- The reagents have bar codes to indicate reagent type, lot number, expiration date. This provides positive reagent identification and helps ensure that quality control testing has been performed on new lots before testing begins.
- Reagent vials can be placed on any adapted position on the Reagent Rack as long the reagent is a barcoded reagent.

  If it is not the case, the non-barcoded reagent must be assigned on the rack prior to loading. Refer to "Registering and Loading Reagents and Dilution Plate(s)" on page 6-3.

Figure 2-6



Non Agitated Area

This area contains a removable reagent rack that holds large reagent vials that do not require agitation. The rack is identified with a bar code and each position in the rack is also identified with a bar code. The removable rack has positions for:

- Two 50 mL vials
- Two 10 mL vials

Dilution plates

When the Main Cover is closed, the system will automatically refill the first well of the dilution plate for red blood cell suspension every two hours to prevent the plate from drying and being reused. Do not leave the dilution plate on the instrument for more than 24 hours or when the system is turned off for an extended period of time.

Two kinds of dilution plates, shallow well and deep well, can be used.

Shallow-well dilution plates

- Shallow-well dilution plates are for 3-5% red cell suspension or dilution

Note: ORTHO AutoVue *Innova/Ultra* uses only approved replacement shallow-well dilution plates NUNC or Greiner with 96 wells that are flat-bottomed to ensure proper fluid dilution.

Deep-well dilution plates

- Deep-well dilution plates are for 0.8% red cell suspension or dilution
- The 0.8% crossmatch and autocontrol tests require a deep-well dilution plate installed on ORTHO AutoVue *Innova/Ultra*. The instrument will automatically prepare a 0.8% cell suspension from the patient or donor cell with the on-board Red Cell Diluent in a deep-well dilution plate.
- Use only a 96-well, 1 mL volume, round-bottom, polystyrene or polypropylene deep-well dilution plate. Specifications for these plates include 41 mm (depth) x 127 mm (length) x 85 mm (width) with 9 mm distance between the center of each well.

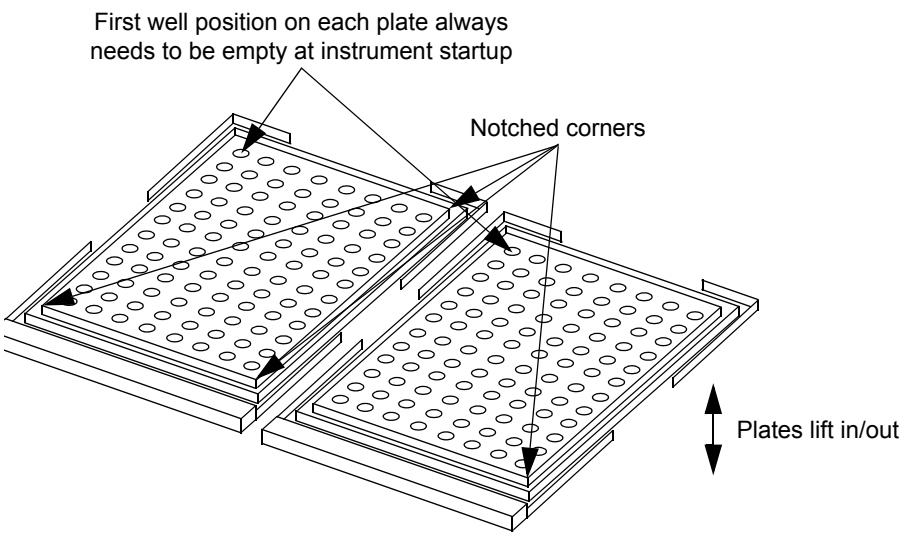
- The following plates are approved for use on the AutoVue *Innova/Ultra:*

  TREFF 96-well Polystyrene Plate (part no. 96.8564.9.01)

  Greiner 96-well Polypropylene Plate (part no. 780201).

Note: Validate any deep-well dilution plates manufactured by another company before using them.

Figure 2-7



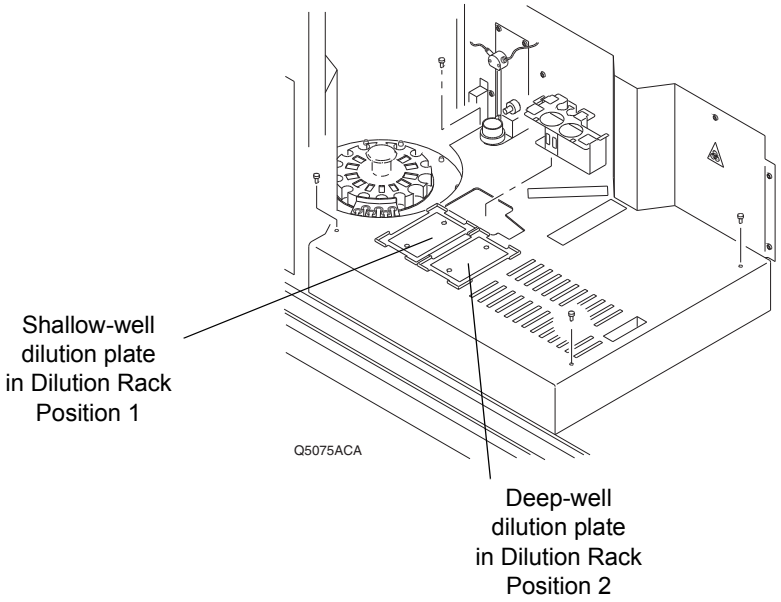
Installing dilution plates

We recommend the following configurations for your system:

- One shallow-well dilution plate in Dilution Rack Position 1 (left side) if preparing only 3-5% red cell suspensions
- One shallow-well in Dilution Rack Position 1 (left side) and one deep-well in Dilution Rack Position 2 (right side) if preparing 3-5% and 0.8% red cell suspensions

The shallow-well dilution plate should be installed in Dilution Rack Position 1 (left side), the space closest to the sample area of the instrument. See Figure 2-8, on page 2-16.

Figure 2-8



Note: The instrument will not initialize correctly if the dilution plates are in the wrong positions.

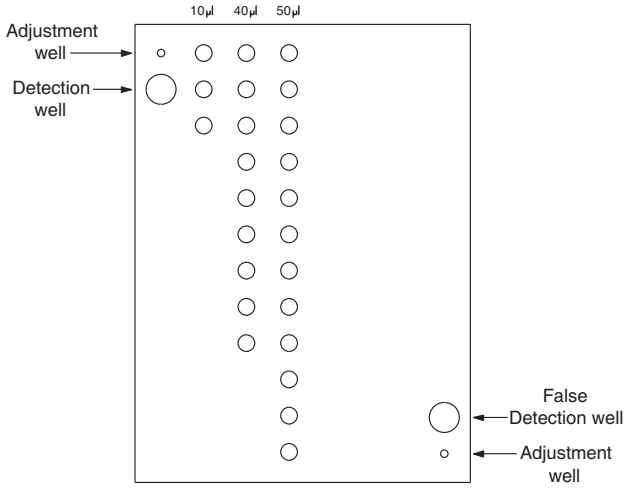
Note: If the shallow-well and deep-well dilution plates are placed in the wrong positions, the saline solution will spill over the shallow-well dilution plate. Reposition the plates. Make sure to clean up the spilled solution and the index well before attempting to continue with the processing.

Calibration plate

In order to complete the QC Volume procedure, the system must first check the X, Y, and Z positions of the pipette tip arm in relation to the adjustment well position on the calibration plate provided by OCD. See Figure 2-9, on page 2-17. The adjustment well position is used by the system to check the X, Y, and Z positions of the pipette tip arm. The other wells are used to perform the QC Volume procedure.

OCD configures instruments in your laboratory for use with a specific calibration plate. This calibration plate is to be used with multiple instruments. If a new calibration plate is required, contact OCD service personnel.

Figure 2-9



Cassette Drawer

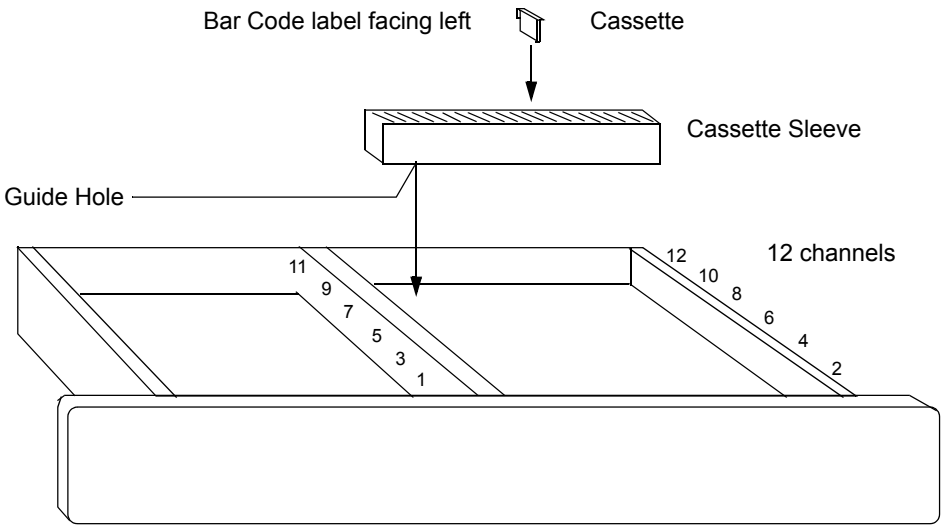
The Cassette Drawer provides access to:

- 12 channels for loading up to 12 Cassette Sleeves
- Each Cassette Sleeve that holds up to 20 cassettes
- Maximum capacity 240 cassettes
- Each channel may hold a different cassette type, but it is recommended to not mix different cassette types in the same sleeve, or to mix different lots of the same cassette type in the same sleeve.
- Positioning pin within channel ensures correct orientation of Cassette Sleeves within the channel
- Up to 4 channels may be designated as the Cassette Review area

Use the Cassette Drawer to:

- Load and unload Cassette Sleeves
- Store processed cassettes for which you want to review results

Figure 2-10



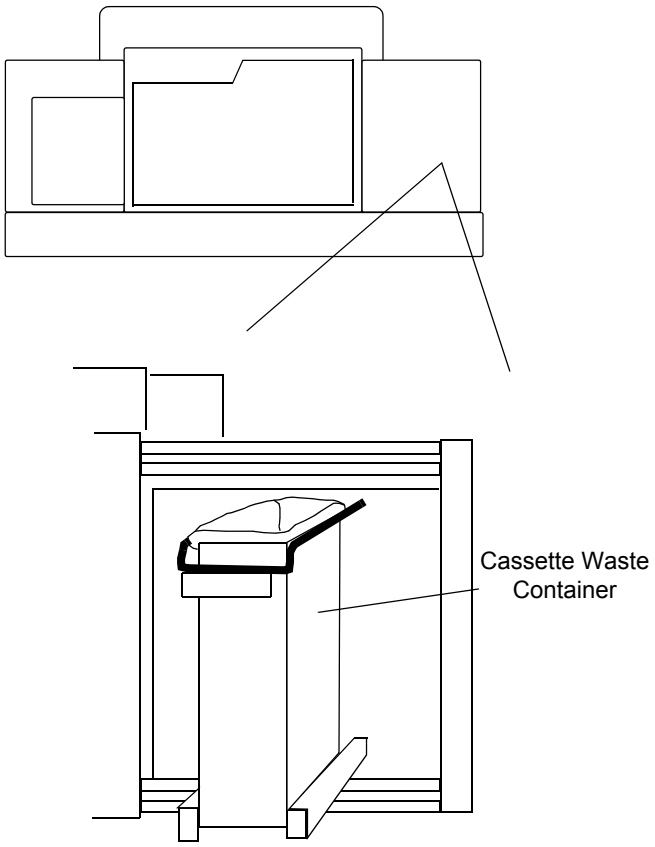
Waste Door

The Waste Door provides access to the cassette waste receptacle that slides out on a rail called lift.

ORTHO AutoVue *Innova/Ultra* discards used cassettes in the waste receptacle which can hold up to 250 discarded cassettes.

- When the number of discarded cassettes reaches 225, the system prompts the user to empty the trashcan. The system automatically resumes sample processing after the user opens the Waste Door, empties the trashcan, and then closes the Waste Door.
- If the system detects that the trashcan is physically full, the system will prompt the user to empty the trashcan and pause the current ongoing tests. If the trashcan is emptied by the user, the system will continue the tests. After the user opens and closes the trashcan door, if the system detects the trashcan is still physically full, a fatal instrument error will occur. All tests in progress will be aborted.
- See “Trash Container and Cassette Waste Lift Errors” on page 10-18

Figure 2-11
Instrument



For more information on how to manage the waste, refer to Chapter 8, “Daily Maintenance and QC Procedures” on page 8-7.

Fluid System

The fluid system manages the wash and dilution liquids during test processing. Tubing sets are placed in the 3 Polyethylene containers for aspiration of system liquids or draining of waste liquids:

- Waste Container 10 liter
- Saline Container 5 liter
- Distilled Water Container 5 liter

Do not intermix the fluid connections, containers, and fluid contents. Ensure that there are no leaks in the tubing and connections.

The liquid level of each container is software monitored via pressure detection, and a warning message is posted when empty or full:

- For saline and distilled water containers: low pressure generates a warning message indicating that system liquids are low
- For waste container: high pressure generates a warning message that the waste is full

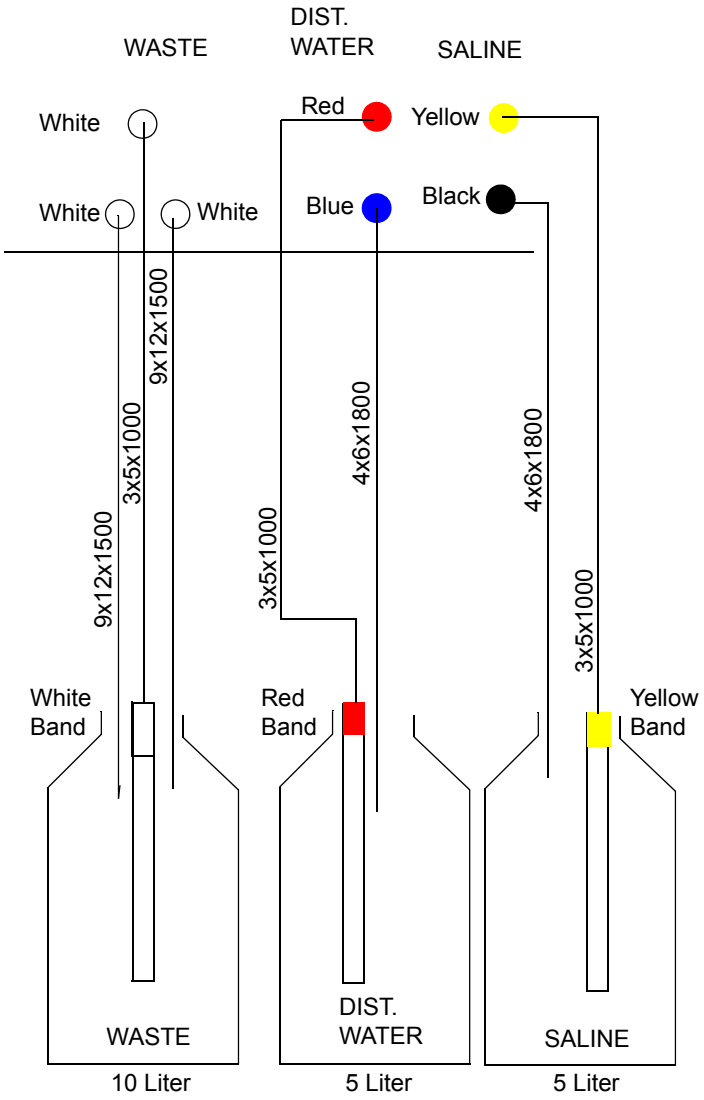
The liquids are aspirated by the action of a pump (FAWA or Fast Wash Pump). The type of liquid aspirated is controlled by the software via a valve that is in between the containers and the pump. Some examples:

- During routine testing, only saline is aspirated so valve is orientated to saline container
- During Shutdown, Saline is replaced by Distilled Water so valve changes its orientation to distilled water container
- During REBOOT, Distilled water is replaced by Saline.

Some more specifications:

- The FAWA delivers 300 mL/min at zero pressure

Figure 2-12



Fast Wash Pump

The fast wash pump delivers 300 mL/min at zero pressure.

Valve

The valve switches either the saline or the distilled water aspiration line to the intake of the Fast Wash Pump. It is a 3-port/2-way valve and the liquids are isolated from the solenoid control with a diaphragm.

Service access to the Liquid System is possible after removing the external left side cover.

Wash Station

The wash station combines the ability to wash at two different wash positions with different wash depths. This manages the cleaning of the pipette tip during test processing.

- Shallow Wash Depth: Wash station tube length 24 mm
- Deep Wash Depth: Wash station tube length 100 mm
- Waste Drain: The waste drain is connected to a tubing with an inner diameter of 9 mm.

Tip Alignment Pin

The Tip Alignment Pin is a spring loaded pin, which is used to periodically check the position of the pipette tip. A special machined “pin-cap” with a diameter of 1.0 mm is pressed on the standard pin to provide protection to the spring mechanism and prevent jamming in case of saline leakage. The Tip Alignment Pin is located on the right side of the wash station.

Section B: Personal Computer Parts and Functions

The PC consists of:

- Windows-based PC, keyboard, and mouse
- DVD with read/write capability
- Flat-panel monitor
- Hand-held bar code scanner
- Printer
- Uninterruptible Power Supply (UPS)

PC Components

The PC controls all aspects of the testing process including access to all components of the instrument. The PC is connected to a UPS to ensure data integrity, even in the event of a power loss.

Computer and Keyboard/Mouse

The PC runs on a Microsoft Windows operating system. The ORTHO AutoVue *Innova/Ultra* software runs as a desktop application and interfaces with proprietary XML databases.

The PC is equipped with a keyboard and a mouse to navigate the software and a bar code reader for quick input of cassette, reagent, and sample bar code information.

Flat-Panel Monitor

The flat-panel monitor is enabled with touch screen.

Refer to manufacturer's manual for instructions on adjusting the flat-panel monitor.

Hand-held Scanner

A timesaving hand-held scanner allows samples, reagent, and cassette labels to be scanned quickly. Information on the label is automatically entered into the software, eliminating manual keying of information.

For supported bar codes standards, refer to "Supported Bar Code Types" on page 1-20.

The hand-held scanner and system scanner use a laser to scan the patient and donation samples, reagents, and cassettes. Do not look into the laser scanner, defeat the protective shield, or attempt to service any scanning device.

Printer

A printer is provided. Refer to the manufacturer's guide included with the printer.

Uninterruptible Power Supply

The UPS protects both the computer and instrument against line power brownouts or power failure for up to 20 minutes. The 20-minute period provided by the UPS allows the operator to save results, complete processes underway, and conduct an orderly shutdown of the equipment.

The UPS provides short-term power to the system in the event of a power failure, and provides the power necessary to perform an orderly system shutdown without data loss.

The UPS connects to the AC power source, and the PC and instrument devices connect into the back outlets of the UPS. The UPS will be provided by the local OCD company or distributor.

The printer should not be attached to the UPS. Do not connect more equipment to the UPS than what is recommended. Connecting more equipment reduces the operating time to less than 20 minutes.

The UPS is provided by the local OCD company or distributor.

For information, refer to the manufacturer's guide included with the UPS.

This page intentionally left blank.

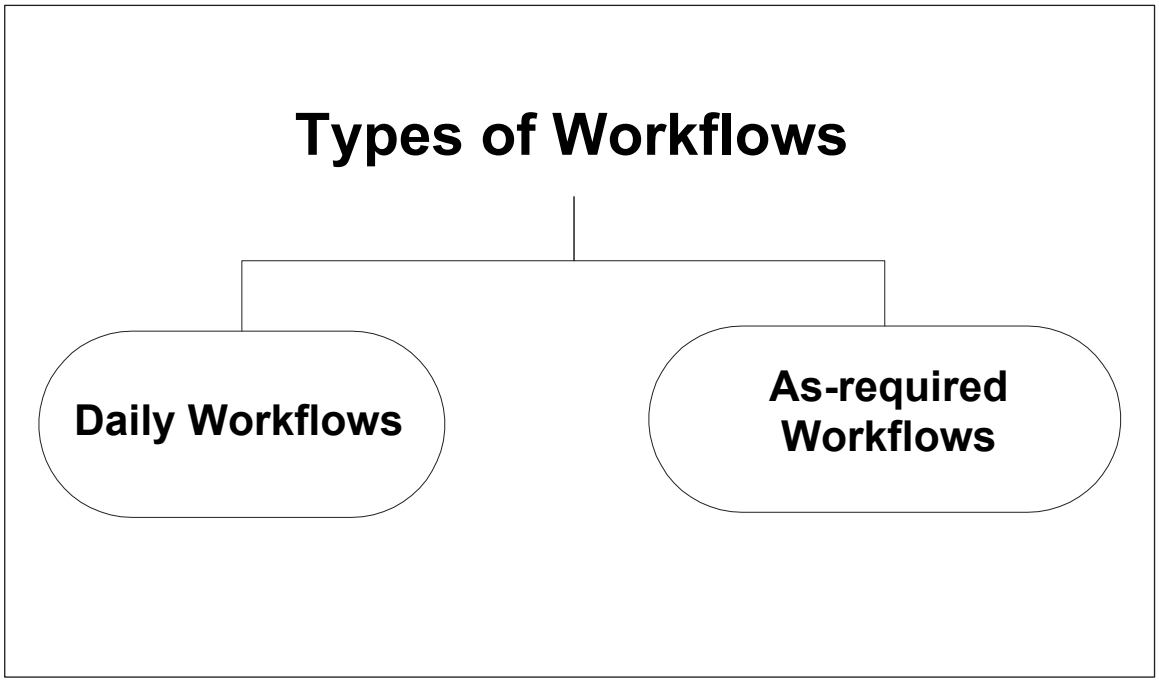
3 Using the ORTHO AutoVue *Innova/Ultra* Software to Execute Workflows

Topics

Section A: Types of Workflows

The ORTHO AutoVue *Innova/Ultra* software is designed to help you execute daily and as-required tasks in the lab.

Figure 3-1

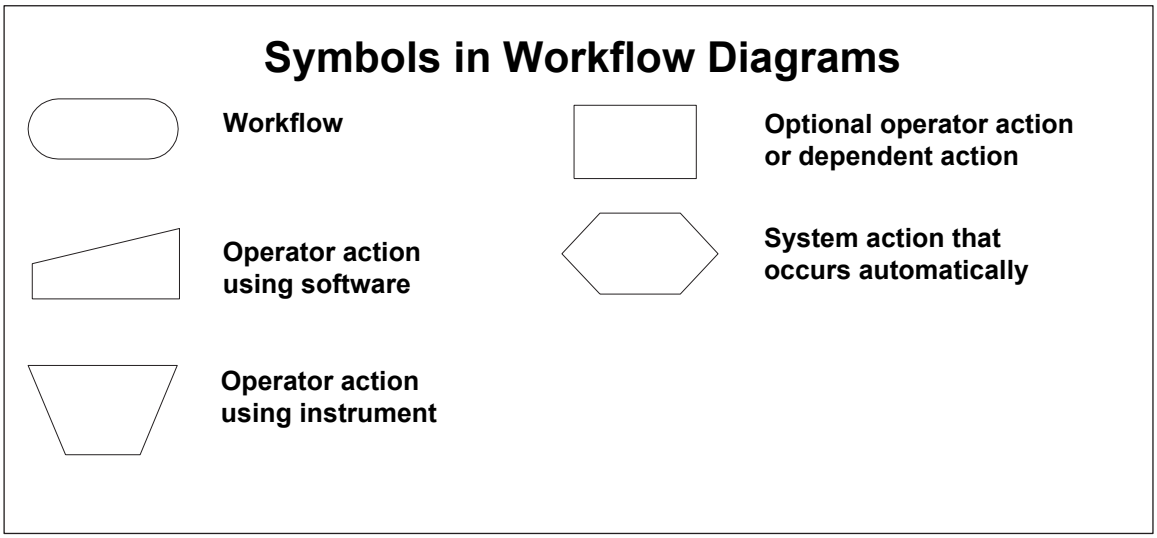


What is a workflow?

A workflow is a series of tasks you execute in order to complete an activity. For example, performing daily maintenance on an instrument is a workflow that consists of a series of tasks.

The following sections describe daily and as-required workflows that operators execute. The following symbols describe the tasks that are part of the workflows.

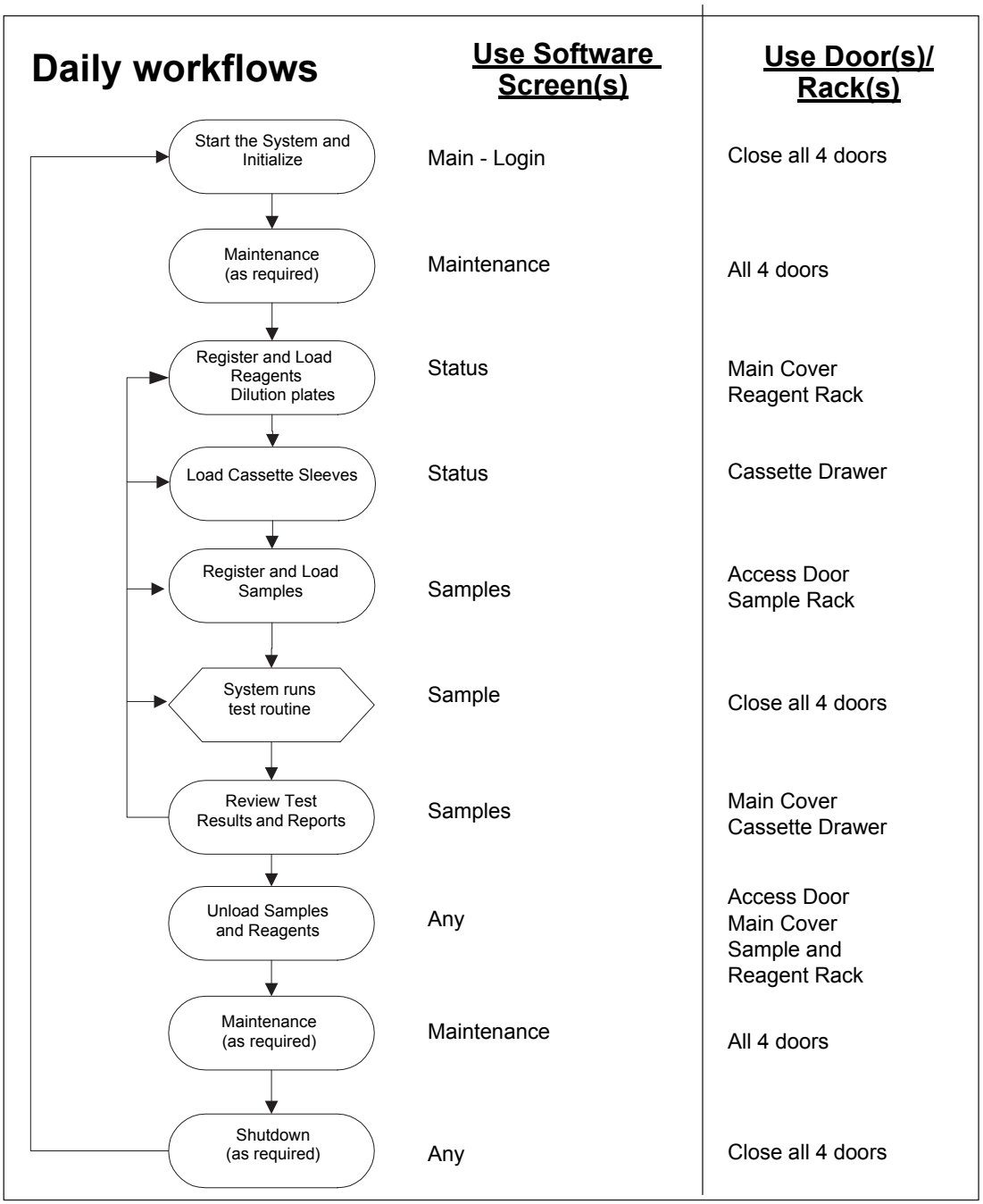
Figure 3-2


Symbols in Workflow Diagrams
Workflow
Optional operator action or dependent action
Operator action using software
System action that occurs automatically
Operator action using instrument

Section B: Daily Workflows Operators Execute

Figure 3-3 below outlines the daily workflows operators execute.

Figure 3-3

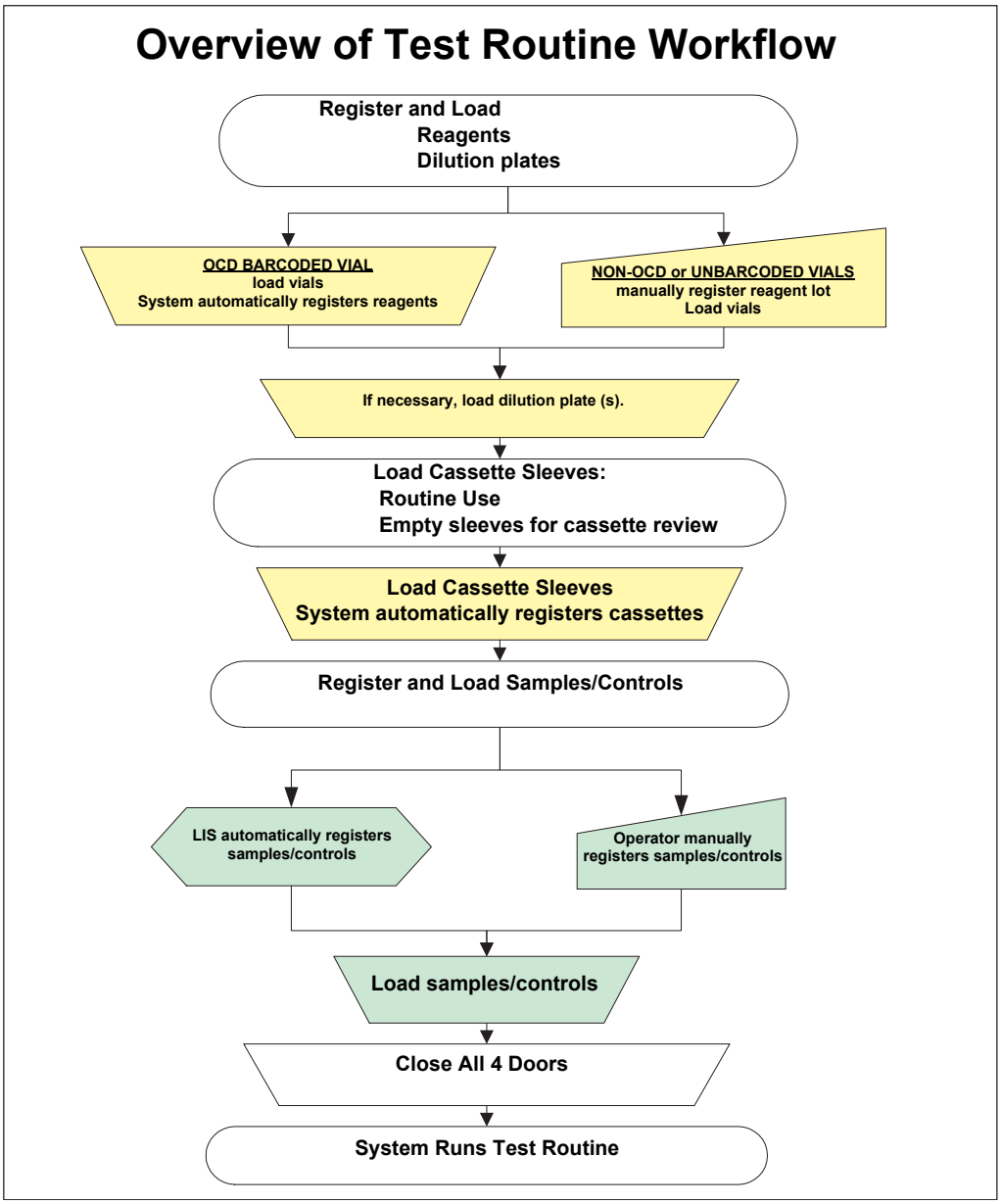


Overview of Test Routine Workflow

The following diagram describes the sub-workflows operators execute in order to run test routines on the ORTHO AutoVue *Innova/Ultra* system.

Notice that you register and load consumables first and then register and load samples.

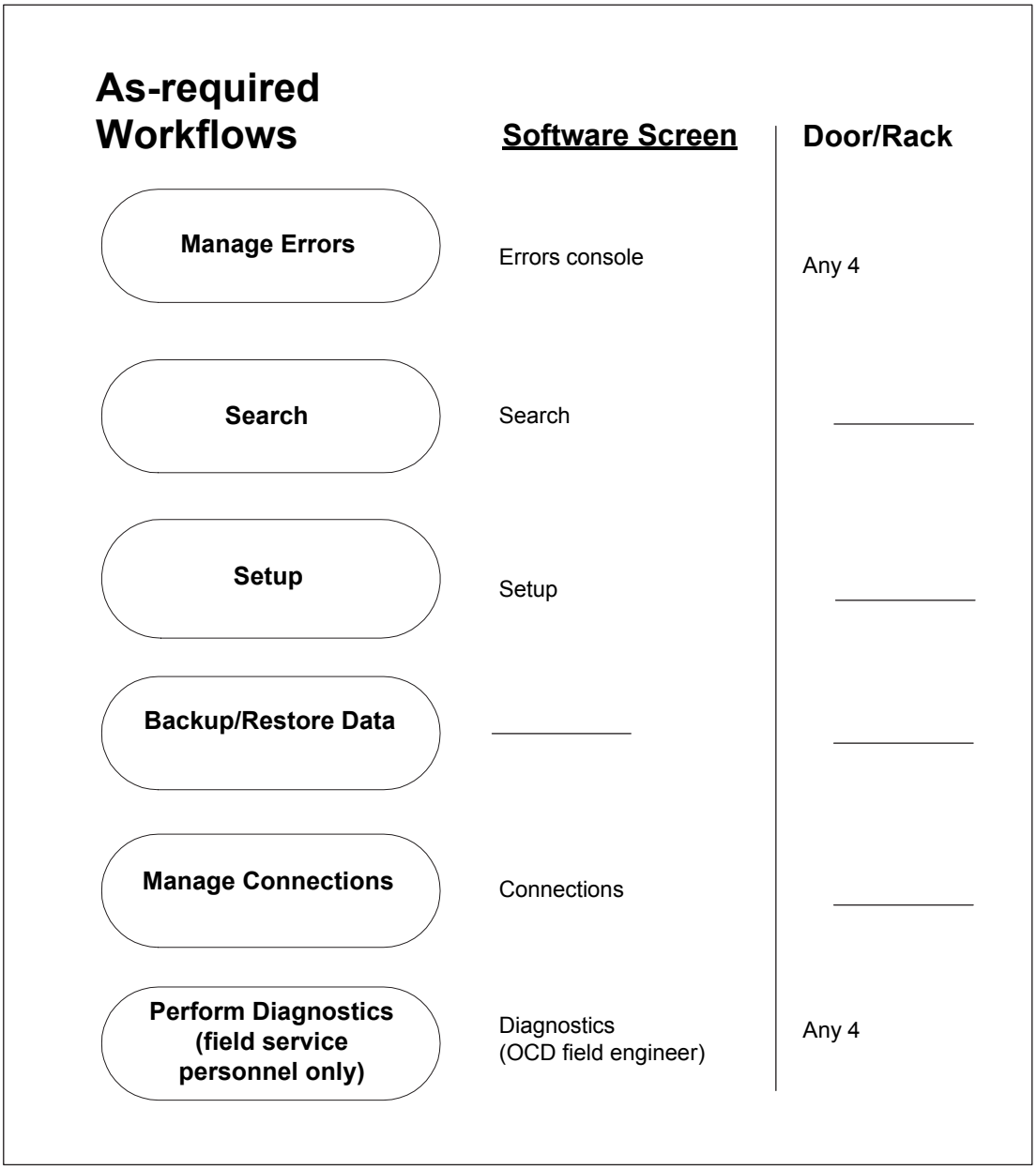
Figure 3-4



Section C: As-required Workflows Operators and Field Service Personnel Execute

The following diagram describes the as-required workflows that operators and field service personnel execute. For more information about the tasks you execute in software screens, refer to online help.

Figure 3-5



Section D: Software Screens

Main Navigation Screen

After logging in, the ORTHO AutoVue *Innova/Ultra* software displays and the instrument begins initializing. When initialization completes, the green **Continue** button displays.

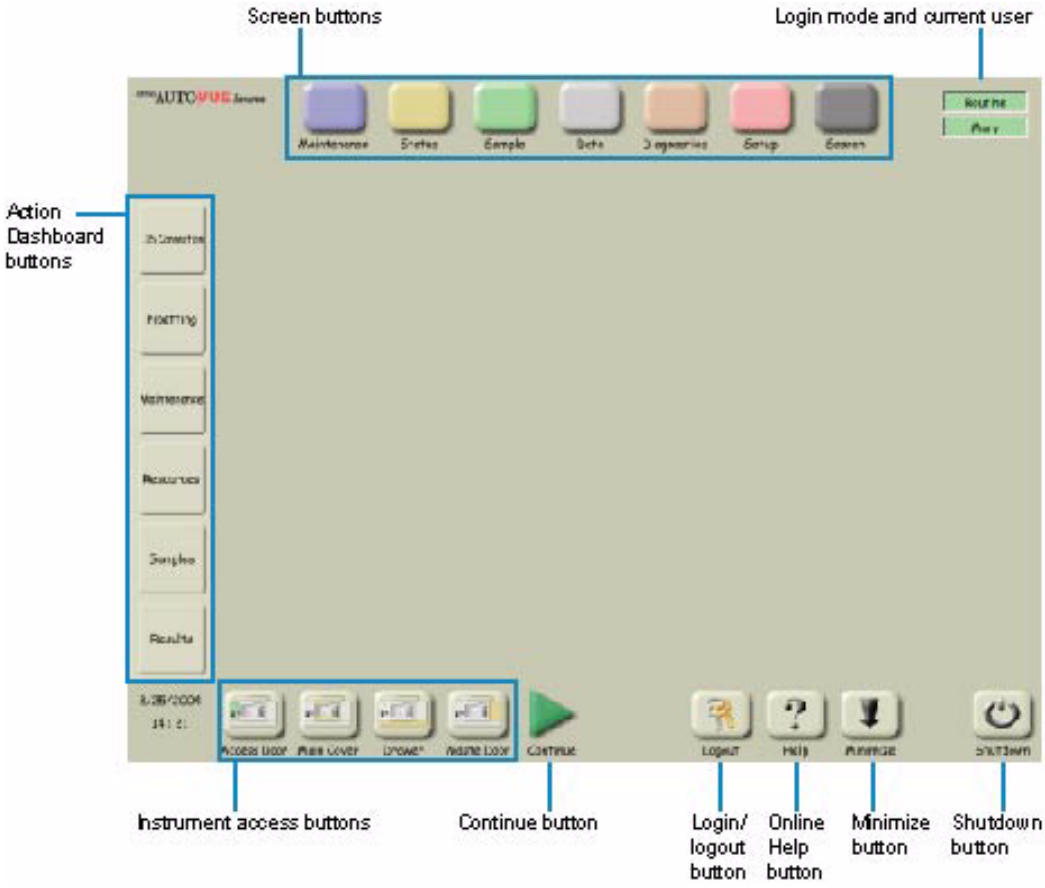
Do not touch the screen until the green **Continue** button displays.

Note: The Continue button displays for the first time when the system has completed initialization and any time you exit and re-enter routine mode. Touch the **Continue** button only when you are ready to continue with the routine.

Note: If the routine does not begin as expected, open and close the Access Door. The system will be able to perform a complete routine only when all doors are closed.

The main navigation screen displays information fields and navigation buttons.

Figure 3-6 Main Navigation Screen



Information Fields

Table 3-1

Button	Use
Login mode	Displays the current mode Modes include: ▪ Routine ▪ Setup ▪ Diagnostics (OCD service personnel only)
Current user	Displays the username of the user who is currently logged in

Navigation Buttons

Table 3-2

Buttons	Use
Maintenance **Status** **Sample** **Data** **Diagnostics** **Setup** **Search**	To display the selected software screen
Action Dashboard buttons: **LIS Connection** **Pipetting** **Maintenance** **Resources** **Samples** **Results**	To view error information
Access Door **Main Cover** **Drawer** **Waste Door**	To unlock the selected instrument door
Continue	To begin your routine. Displays after instrument completes initialization.
Login/logout	To log in or log out of the software
Help	To access the online help
Minimize	To minimize the software window. To maximize, touch the Maximize button
Shutdown	To shut down the software

Overview of the Software Screens

Table 3-3

Screen	Use
Maintenance	To execute daily, weekly, monthly, and as-required maintenance and QC operations
Status	To view the status of consumables
Sample	To view sample status, position errors, and samples not loaded. Also use this screen to manage test results and print reports.
Data	To view instrument errors, the LIS communication log, and the manual actions log
Diagnostics	Used by OCD service personnel only
Setup	To assign configuration options for the instrument and software
Search	To search for and display sample data

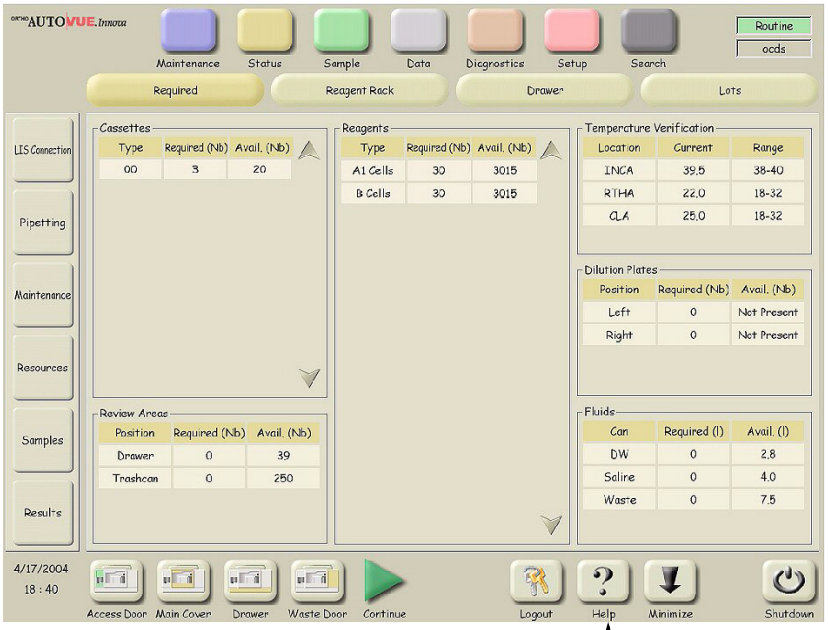
To view more detailed descriptions, refer to the online help.

Section E: Using ORTHO AutoVue *Innova/Ultra* Online Help

Online help gives you quick assistance while you are working in the laboratory by providing descriptions of graphical elements you will use in the software including:

- Buttons
- Fields
- Icons
- Other symbols

Figure 3-7



This page intentionally left blank.

4 Overview of the Testing Process

Topics

Theory and Structure of Analyses, Test Profiles, and Tests

Physicians request analyses for patients. Based on the requested analysis, the lab runs specific tests using the ORTHO AutoVue *Innova/Ultra* system. Multiple combinations of analyses may be requested.

Examples of Analyses Requested for Patients

For example, the physician may request the following analyses for a new patient: ABO, Rh, and antibody screening.

For another patient, perhaps only the crossmatch (XM) analyses is requested.

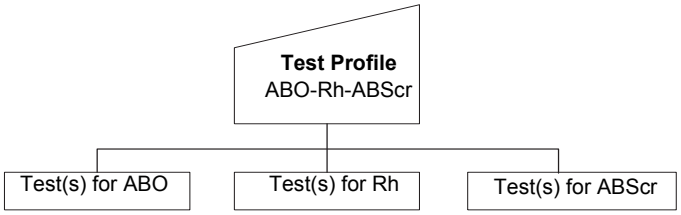
For a pregnant patient, the physician may request all of the above analyses and the Rh Phenotype and K1 (Kell) special antigen type.

Setting Up Tests Profiles in the Software

Single analyses or combinations of multiple analyses can be set up in the software.

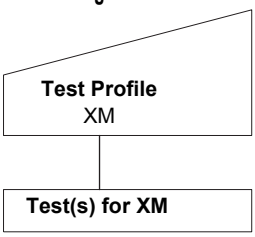
In the software, analyses are set up and labeled as test profiles. For example, you might set up a test profile that provides analysis results for ABO, Rh, and antibody screening. In this test profile, you would indicate the appropriate ABO, Rh, and ABScr tests you want the system to run on the sample. Within a test profile, you can include a single test or multiple tests.

Figure 4-1



Or, you might set up a test profile for the crossmatch (XM) analysis result and label it XM. In this test profile, you would indicate the single XM test you want the system to run on the sample.

Figure 4-2

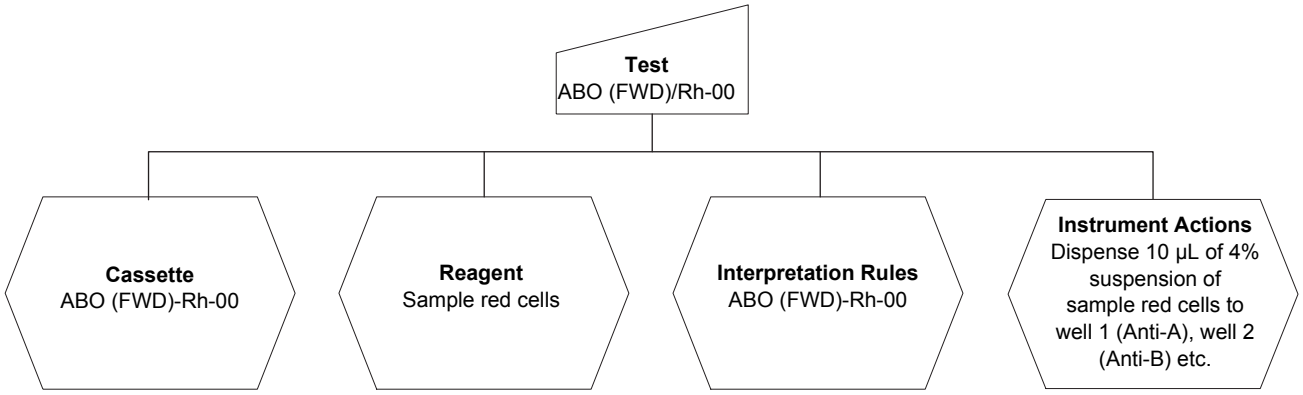


Test Descriptions in the Software

As described above, test profiles can contain single or multiple tests. For each single test performed, the software will determine the reagents required to run the test and the actions to be performed by the system.

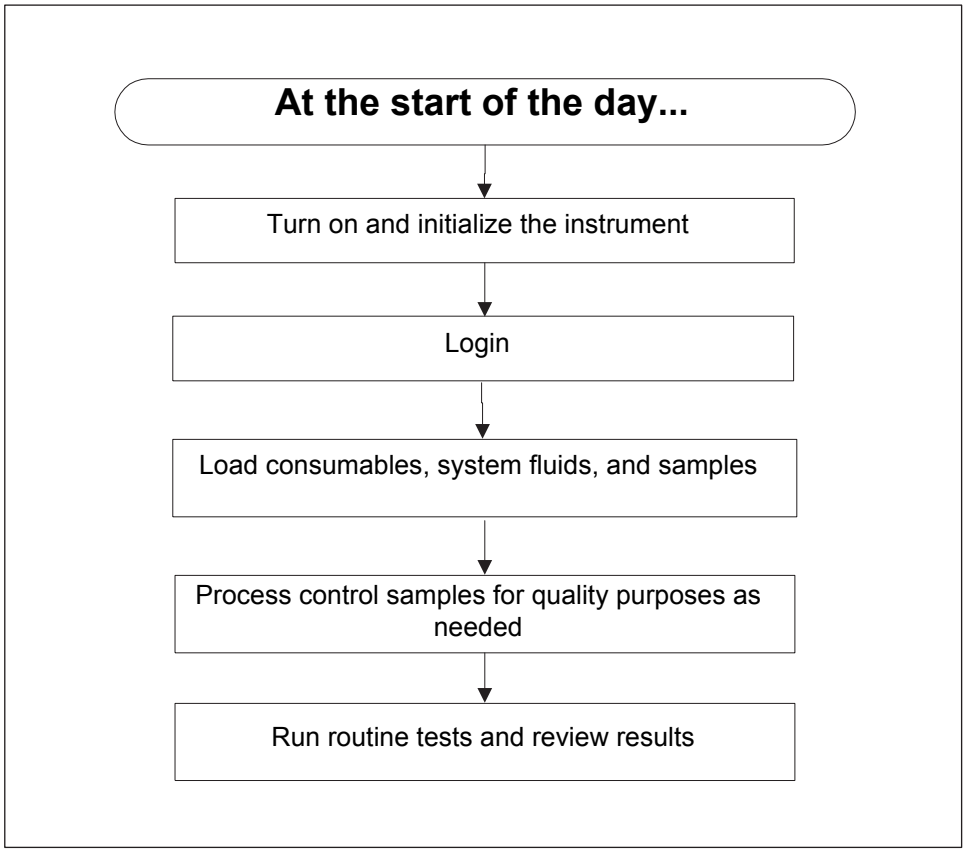
The diagram below shows the consumables, interpretation rules, and actions the system uses to run the ABO (FWD)/Rh test.

Figure 4-3



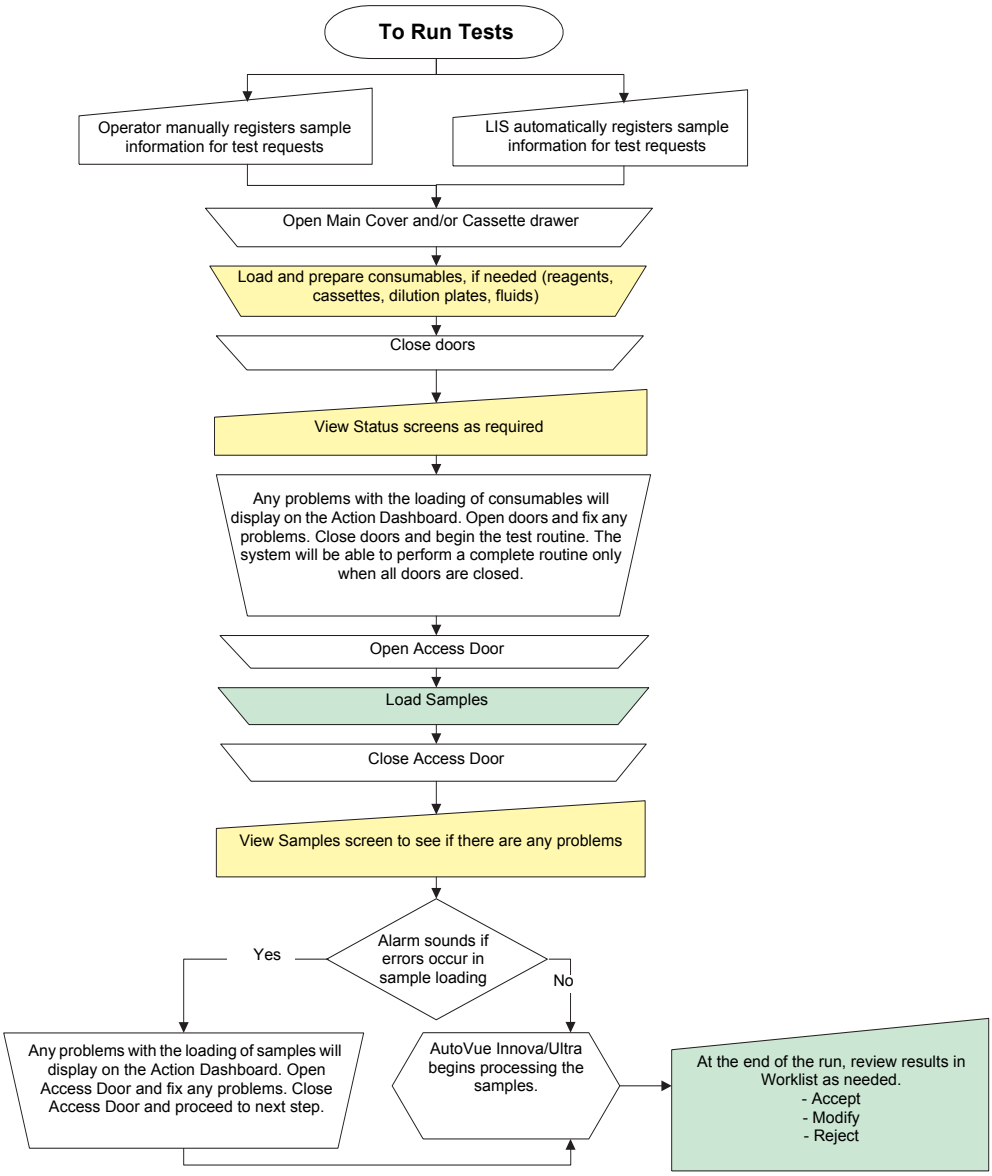
Tasks to Perform at the Start of the Day

Figure 4-4



Tasks Involved in Running Test Routines

Figure 4-5

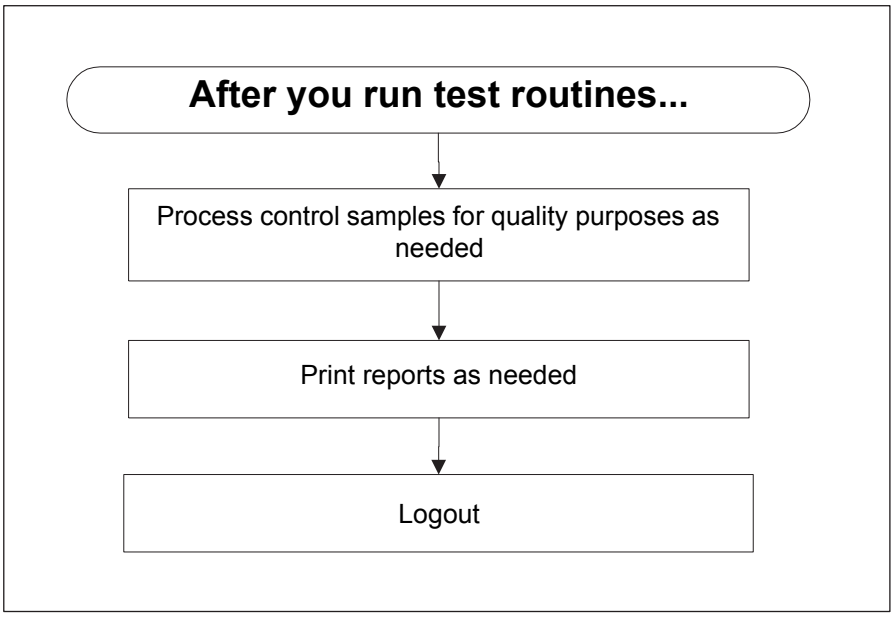


Note: A different workflow can be used if you have an LIS connection and the instrument is capable of querying the LIS. In this case:

1. Load samples
2. The system queries the LIS for sample information
3. Proceed to the workflow shown above

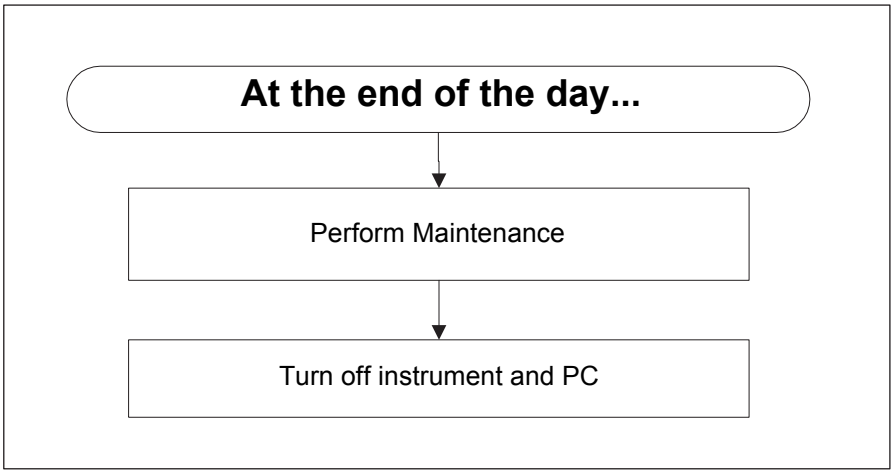
Tasks to Perform After Routine is Complete

Figure 4-6



Tasks to Perform at the End of the Day

Figure 4-7



This page intentionally left blank.

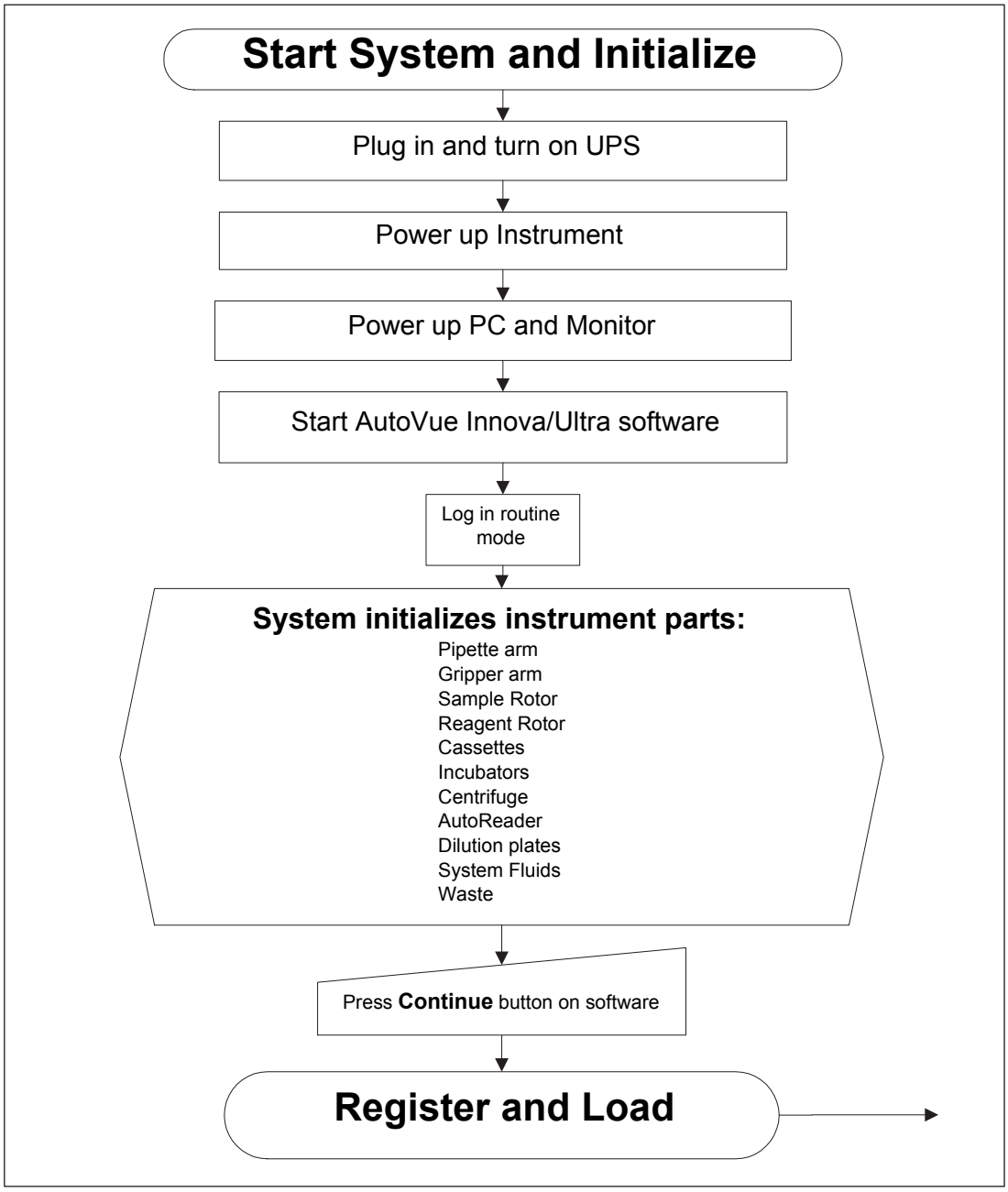
5 Starting Up and Shutting Down the System

This chapter describes how to start up and shut down the instrument.

Topics

Section A: Start System and Initialize Workflow

Figure 5-1



Checks to Perform Before Powering Up System

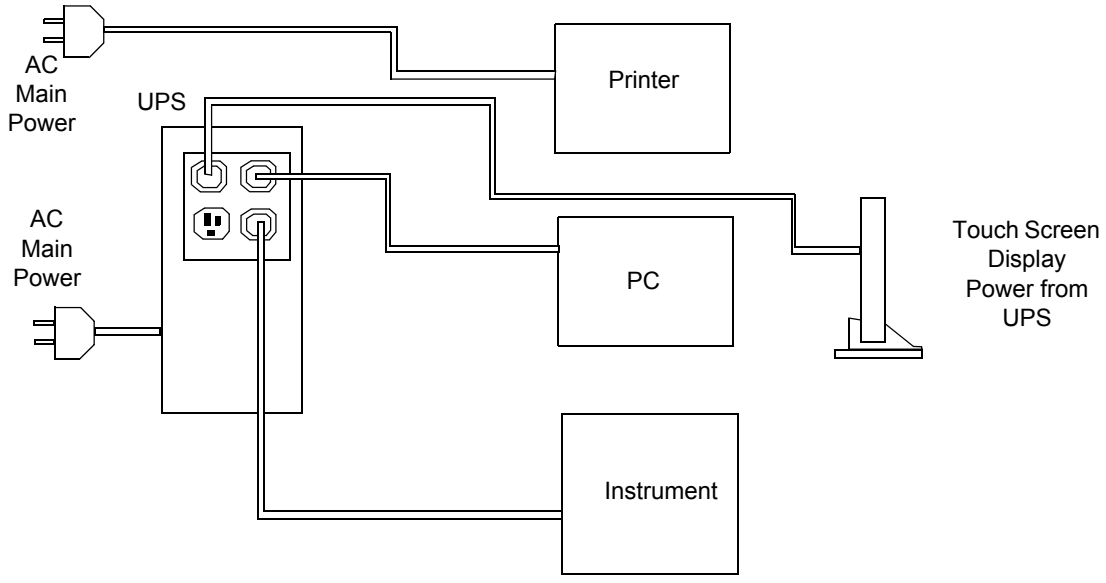
Perform the following steps in sequence to start the ORTHO AutoVue *Innova/ Ultra* when the instrument and PC are off.

1. Check the power connections.
2. Check the data connections.
3. Check fluid connections.
4. Check the UPS.

Check Power Connections

Check the power connections shown.

Figure 5-2 Power Connections



Check Data Connections

Check the PC and instrument connections shown. See the figure "PC and Instrument Connections" below for general information and the figure "PC Rear View Details" on page 5-5 for detailed information.

Figure 5-3 PC and Instrument Connections

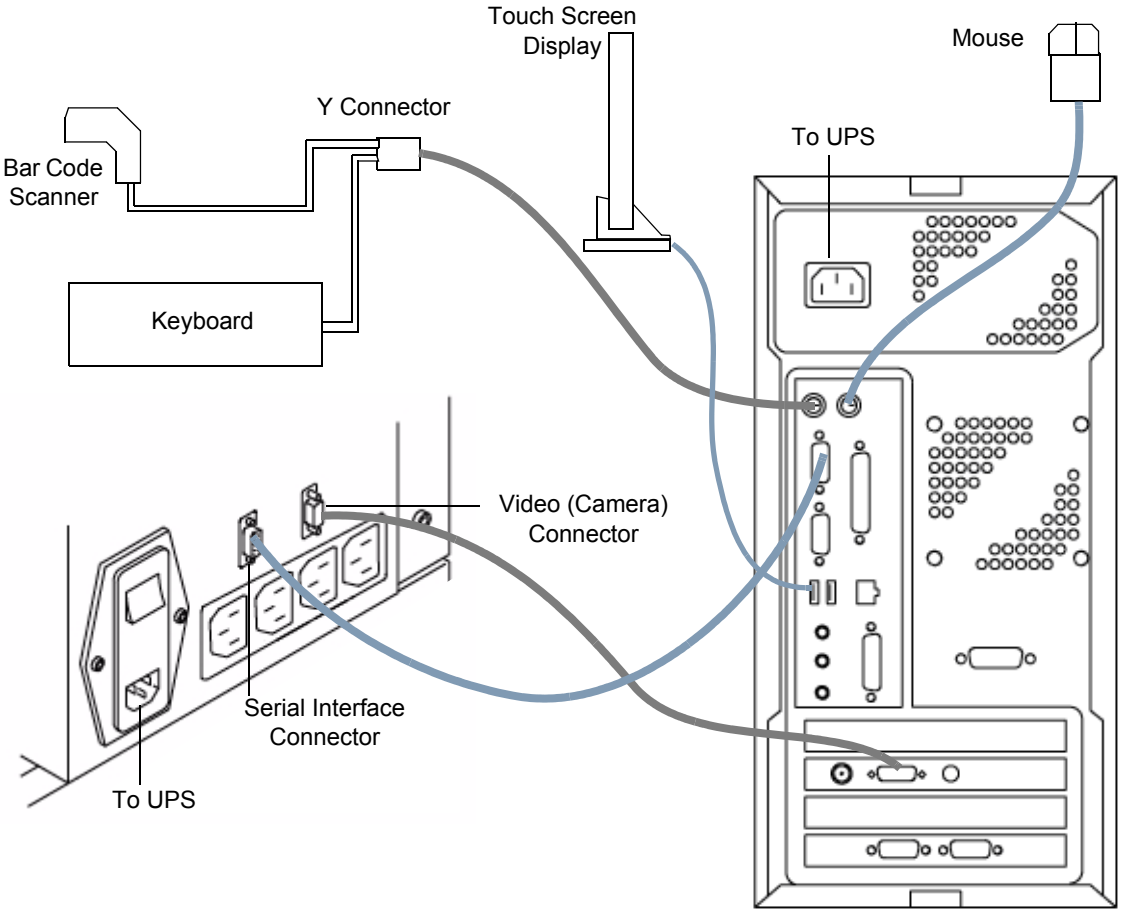
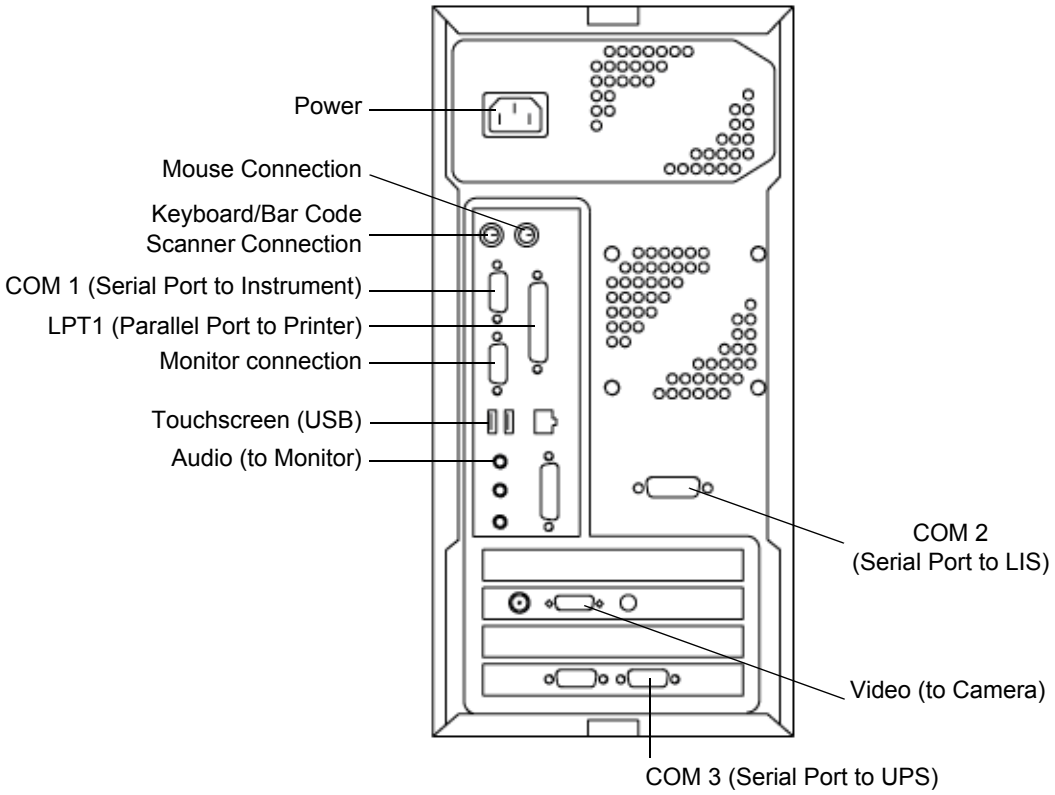


Figure 5-4 PC Rear View Details

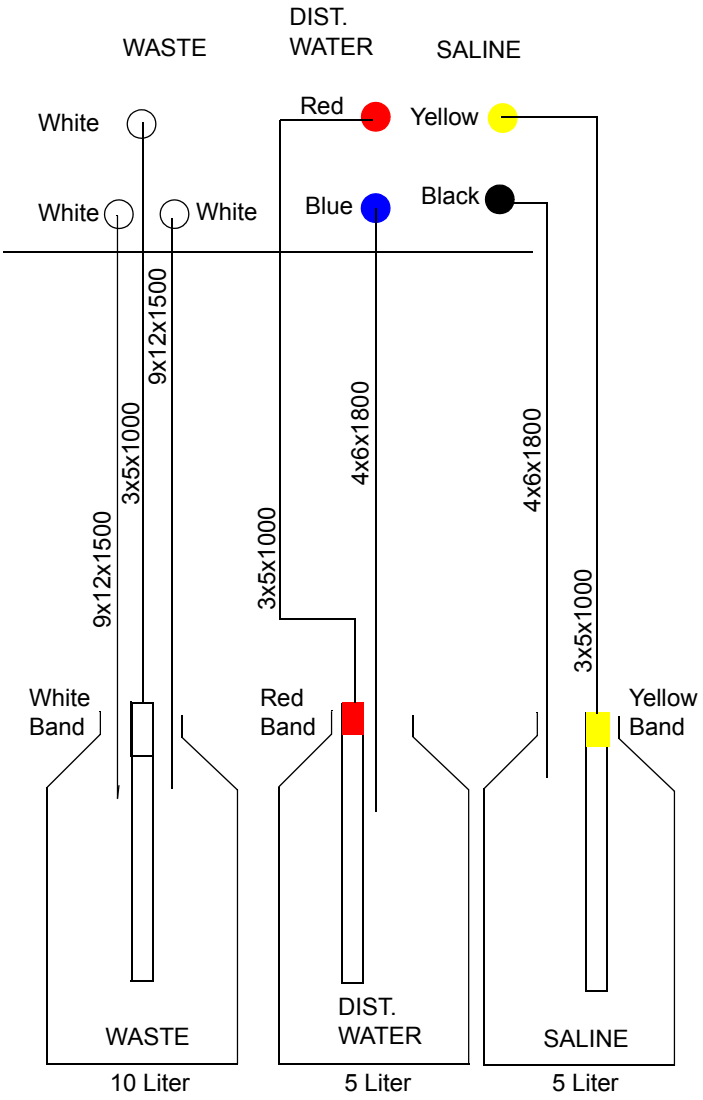


Check Fluid Connections

Check the fluid connections to the ORTHO AutoVue *Innova/Ultra*. Inspect the system for leaks by flushing the system. Correct any leaking connections before continuing.

For more information, refer to "Daily Maintenance and QC Procedures" on page 8-7.

Figure 5-5 Fluid Connection Panel



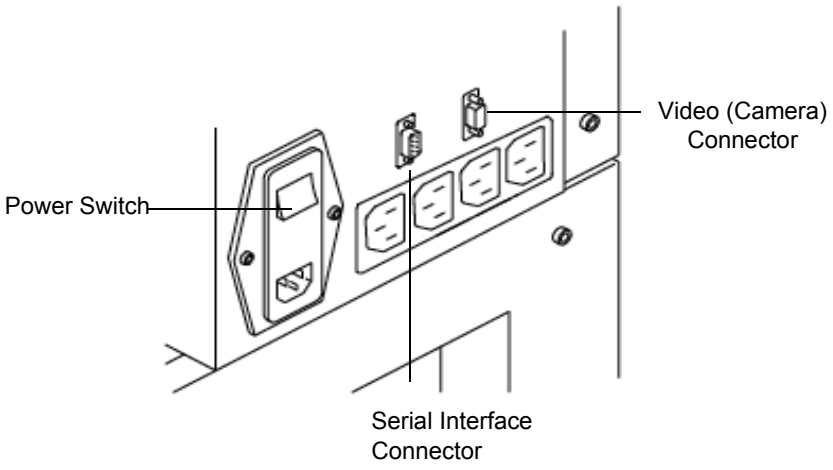
⚠ If fluid lines are disconnected, the system must be re-primed. Perform a series of five flushes with water and five flushes with saline to prime each line.

Verify that the UPS is Functioning

Consult the user manual provided by the UPS manufacturer for information on how to verify the UPS is functioning.

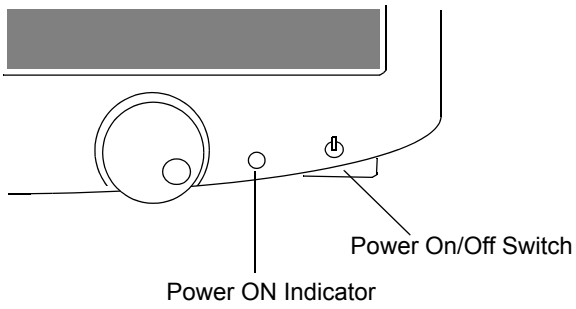
Power Up the Instrument

Figure 5-6 Instrument Power Switch



Turn on the PC and Monitor

Figure 5-7 Monitor Power Switch



Note: The figure above is an example which may not represent the customer's actual monitor.

Start the ORTHO AutoVue *Innova/Ultra* Software

- Log in to the software in three possible modes:
  - Routine (most operators)
  - Setup (to set up software)
  - Diagnostic (OCD service personnel only)
- Log out

System Initializes Instrument Parts

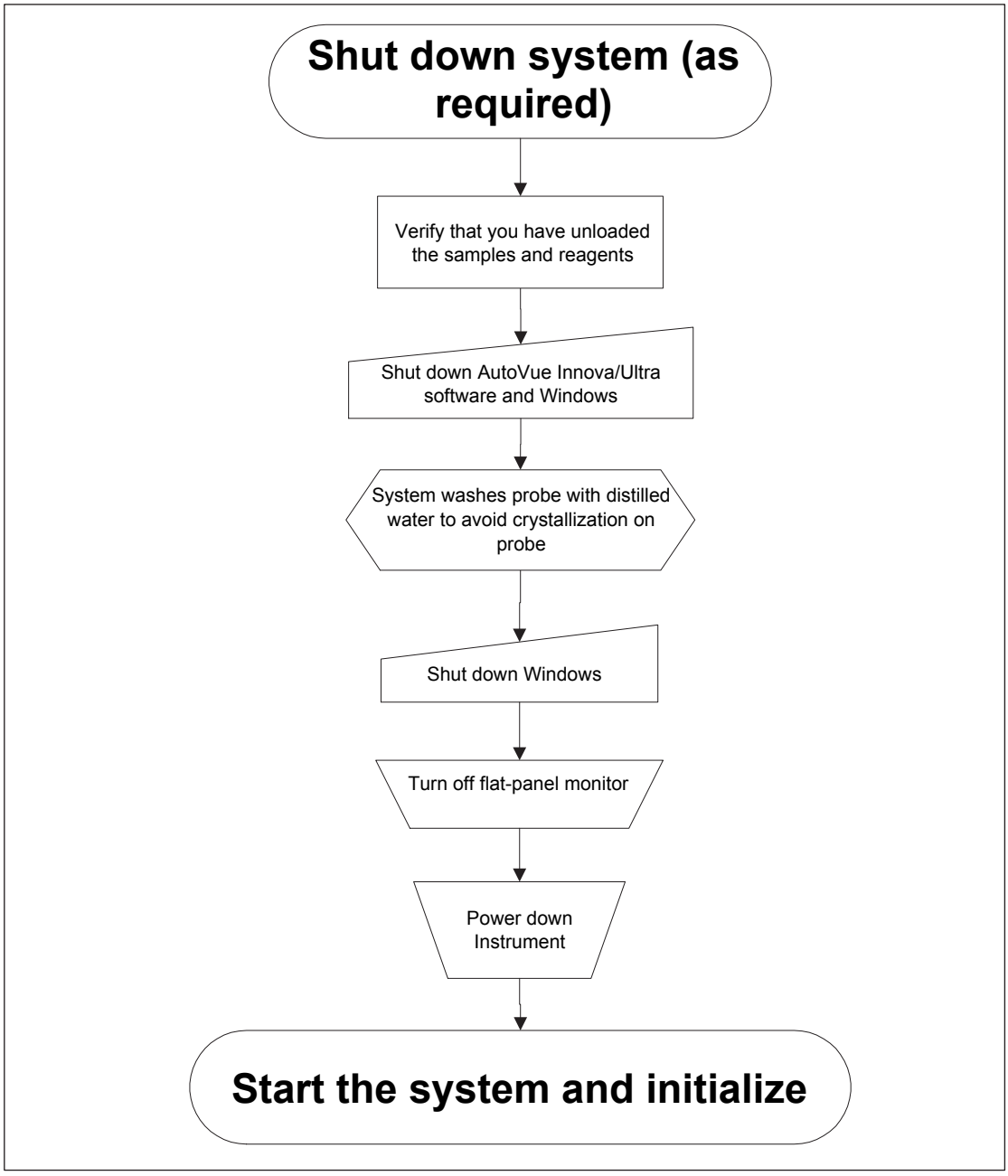
ORTHO AutoVue *Innova/Ultra* Initialization

Initialization is the system's opportunity to check that the instrument and the software are functioning correctly. Initialization has two phases:

- **Phase 1 – Mechanical Initialization:** Each instrument part (for example, the pipette arm and Sample Rotor) goes through a self-check. The self-check is attempted 3 time before the system posts an error.
- **Phase 2 – Software Initialization:** After mechanical initialization, the software displays the status of the instrument including:
  - Errors on parts
  - Consumables to load
  - Samples to load
  - Results ready to be reviewed
- Press the Continue button after the system initializes.

Section B: Shutdown Workflow

Figure 5-8



ORTHO AutoVue *Innova/Ultra* may be used 24 hours a day, but we recommend a daily system reboot. The system cannot be shut down in the middle of an operation. If you touch the Shutdown button in the software, the system will not shut down until all operations are complete. To immediately shut down the instrument, use the power switch on the right side of the instrument.

⚠ Ensure dilution plates are exchanged at appropriate points, even if the system is left on continuously. If the system is run 24 hours a day, reagent dating should be reviewed manually (visually) to ensure use of in-date reagents. Reassessment of dating is not performed by the system until the cover is opened and the **Continue** button is touched.

⚠ Avoid using the command ALT-F4 to close the software application or the instrument will have to be shutdown, re-started, and re-initialized.

6 Registering and Loading Consumables and Samples/ Controls

Overview

You can process samples, controls, or donation samples on the ORTHO AutoVue *Innova/Ultra*. In order to run a test routine, ORTHO AutoVue *Innova/Ultra* requires you to perform two procedures:

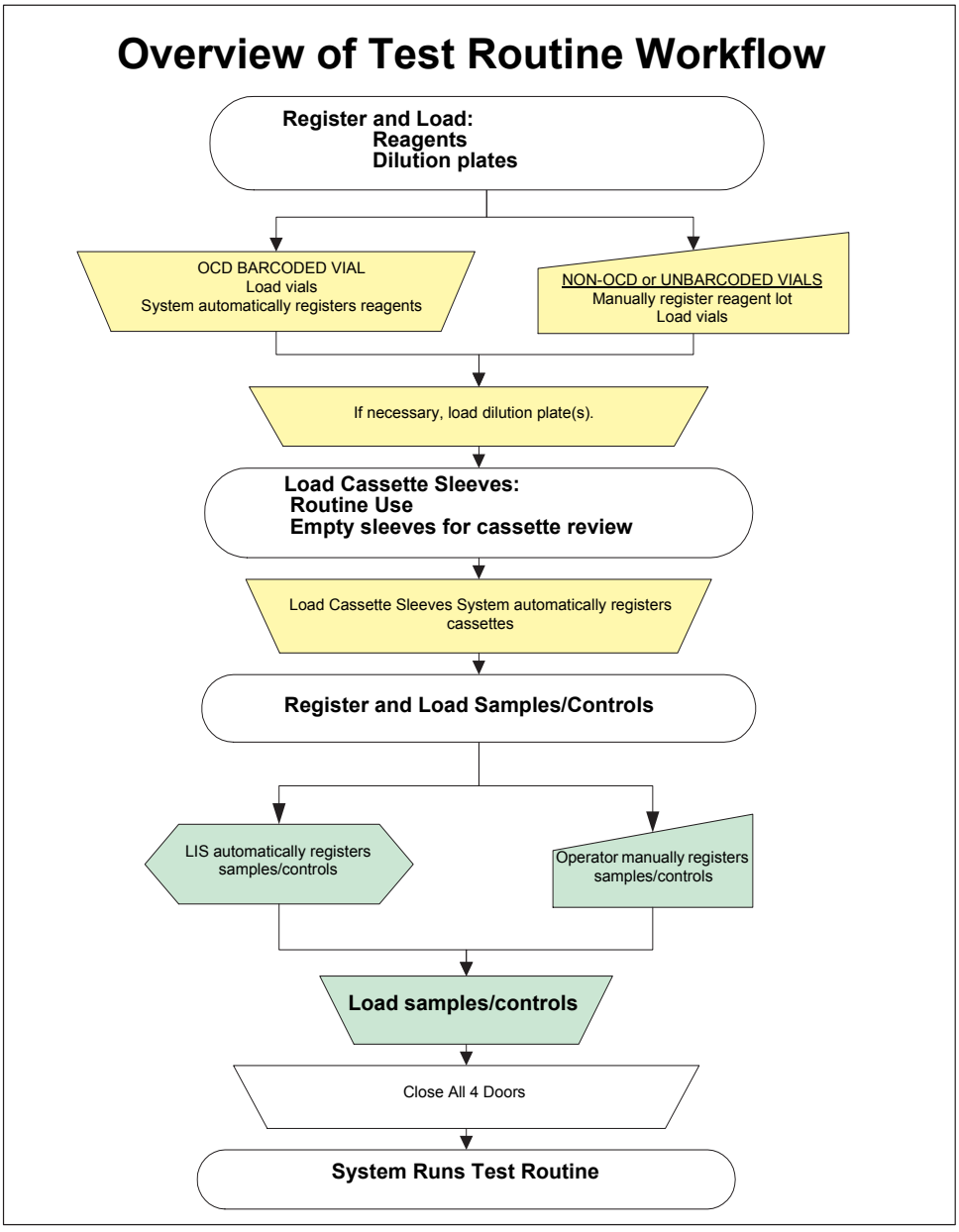
- Register consumables and sample information in the software
- Load consumables and sample tubes on the instrument

Topics

Section A: Overview of Register and Load Workflow

The following diagram depicts the workflow you follow to register and load samples and consumables.

Figure 6-1



Section B: Registering and Loading Reagents and Dilution Plate(s)

The workflow to register and load reagents and dilution plates is executed through the Main Door.

Register Reagent Lots Workflow

You can register reagent lots into ORTHO AutoVue *Innova/Ultra* in two ways:

- The system automatically registers OCD reagent lots with bar codes.

or

- You must manually register non-OCD reagent lots or those vials whose bar codes are not able to be scanned by the system.

System Automatically Registers OCD Reagent Lots with Bar Codes

You can place OCD reagents with bar codes directly on the Reagent Rack and load the rack onto the instrument. ORTHO AutoVue *Innova/Ultra* automatically scans the bar codes on these vials and registers lot IDs into the system.

Operator Manually Registers Reagent Lots

You will manually register the lot ID for a reagent vial when:

- The reagent is a non-OCD reagent

  Note: OCD has validated the use of its proprietary reagents on the ORTHO AutoVue *Innova/Ultra* system. For a list of OCD-approved reagents refer to "OCD Reagent Kits" on page B-6. OCD does not assume responsibility for results obtained with non-OCD reagents. It is the responsibility of the user to validate non-OCD reagents on this system.

- The reagent vial does not have a bar code or the bar code is not able to be scanned by the system

Reagent Bar Code Description

When you scan an OCD reagent vial, the following bar code information is recorded in the ORTHO AutoVue *Innova/Ultra* software depending on one of two data structures:

- **DDD-Y-ID-LLLL**
  - Julian day (Julian date + 600) consists of three digits (DDD).
  - Year consists of one digit for the last digit in the year. For example, 5 for 2005 and 6 for 2006.
  - ORTHO AutoVue *Innova/Ultra* Product ID.
  - Lot number which is always four digits in the bar code. If a lot number is three digits then AutoVue eye-readable automatically inserts a 0 in front of the three digits. For example, if the lot number is 765, then ORTHO AutoVue *Innova/Ultra* records the lot number as 0765.

- **DD-MM-Y-ID-LLL**
  - Day consists of two digits (DD).
  - Month consists of two digits (MM).
  - Year consists of one digit (Y).
  - Product identification consists of two digits (ID).
  - Lot number consists of three digits (LLL).

Figure 6-2

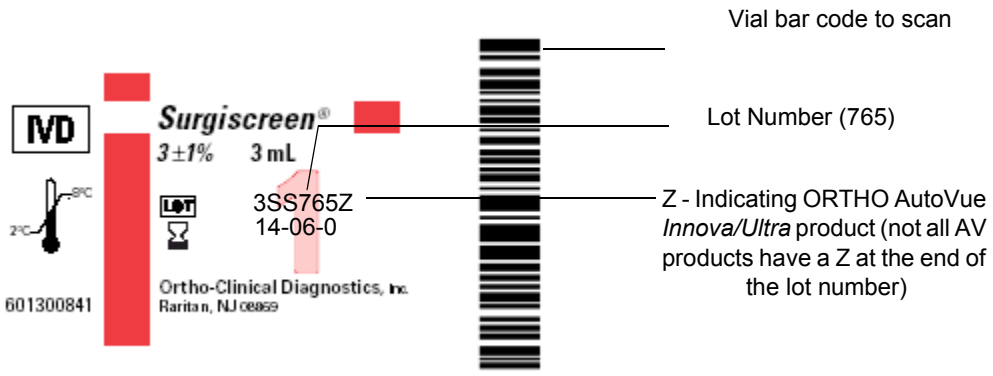
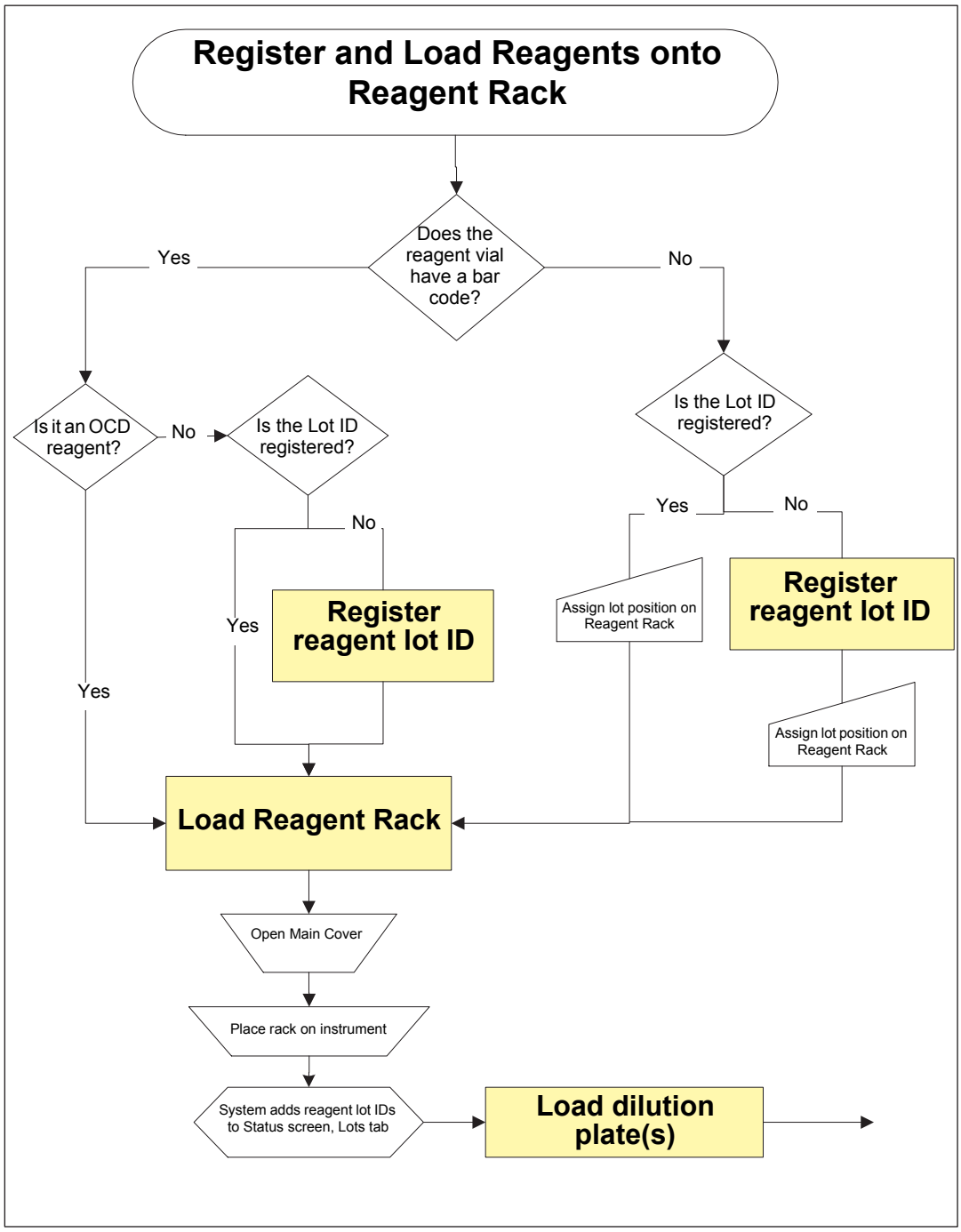


Figure 6-3


Register and Load Reagents onto Reagent Rack
Does the reagent vial have a bar code?
Yes
No
Is it an OCD reagent?
No
Is the Lot ID registered?
Yes
No
Register reagent lot ID
Yes
Is the Lot ID registered?
Yes
No
Assign lot position on Reagent Rack
Register reagent lot ID
Assign lot position on Reagent Rack
Load Reagent Rack
Open Main Cover
Place rack on instrument
System adds reagent lot IDs to Status screen, Lots tab
Load dilution plate(s)

Procedure to Manually Register Reagents

Enter the following information to register the reagent lot:

- Select an OCD kit for the reagent.
- Select a linked kit. A linked reagent kit is a non-OCD reagent that substitutes for a comparable OCD reagent kit.

  Note: Linked reagent kits must be previously established in the **Setup** screen, **Testing** tab.
- Create a new lot.
- Change the status from **Quarantine** to **Available**.

	To register a reagent lot ID
1	Touch the **Status** button and then touch the **Lots** tab.
2	Touch the OCD kit to which the non-OCD reagent or reagent without a bar code belongs or compares. For example, BLISS or Surgiscreen.
3	Touch **New Lot**. Result: The **Lot creation** dialog box displays.
4	Type a Lot ID and touch **Validate**. The Lot ID can be 1-20 characters in length.
5	Re-type the Lot ID to confirm input and touch **Validate** again.
6	Touch the **Next** button.
7	Type an expiry date or select one from the calendar and touch the **Next** button.
8	Type bar code(s) for the component reagents included in the reagent kit and touch **Validate**. The bar codes can be 1-20 characters in length.
9	Touch **End**. Result: The **Lot Creation Validation** dialog box displays with the information you entered.

To register a reagent lot ID (continued)

10 Touch **Ok** to save lot information.

or

Touch **Cancel** to exit without saving.

11 The new Lot ID displays in the **Available Lots** list on the **Lots** tab and the default status is **Quarantine**.

To change the status of the lot and make it available for use in testing, touch the Lot ID in the **Available Lots** list to display the **Lot detail** dialog box.

12 Touch the **Routine Status** field and select **Available**.

13 Touch **Ok** to save lot information.

or

Touch **Cancel** to exit without saving.

14 View the registered lot in the **Available Lots** list.

15 Optional: Assign a position for the reagent on the **Reagent Rack** tab.

- Open the Main Cover.
- Touch a position on the Reagent Rack graphic and then touch the **Assign** check box.

Note: Unbarcoded or unscannable vials must be assigned a position. OCD recommends not to manually assign positions for barcoded vials. Allow the system to automatically detect barcodes.

16 Load the reagent(s) on the Reagent Rack as described in "Load Reagents on Reagent Rack" on page 6-8.

Load Reagents on Reagent Rack

Reagent Rack Types

Reagents required for testing are placed in rotating Reagent Racks or a stationary rack in the Non-Agitated Area. Four physical types of racks labeled, Type 01, Type 02, and Type 03 are available.

- Type 01 contains 14 reagent positions: 12 for 3 mL vials and 2 for 5mL or 10 mL vials.
- Type 02 contains 14 reagent positions: 8 for 3 mL vials and 6 for 5mL or 10 mL vials.
- Type 03 contains 14 reagent positions for 10 mL vials.

Note: The Non-Agitated Reagent Rack is used for reagents that do not require mixing. The rack has 2 positions for 50 mL vials and 2 10 mL vials.

OCD reagents have bar codes to indicate reagent type, lot number, expiration date and a checksum. AutoVue scans these reagent bar codes for positive reagent identification, and ensures that quality control testing has been performed on new lots before actual testing, if this feature has been enabled. 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.

Warnings and Precautions About Reagents

Hemolysis and concentration changes may occur in reagent red cells that are left on the instrument for more than eight hours at a time. Reagent red cells can be used on ORTHO AutoVue *Innova/Ultra* for a maximum of 24 hours, in three eight-hour shifts with refrigeration overnight in between shifts, without significant impact to concentration or red cell integrity.

If the instrument is not continually in use, OCD recommends the reagents be removed from the system and refrigerated. Prior to testing requiring these reagents, the reagent red cells should be re-suspended manually.

Ensure that reagent vials have been configured for use on ORTHO AutoVue *Innova/Ultra* by your OCD field representative.

Load Reagent Vial(s)

.

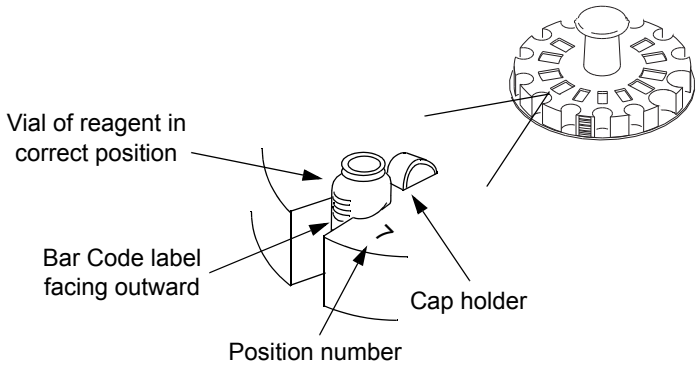
To load the Reagent Rack

1 Touch the **Main Cover** button to open the Main Cover.

2 Load the reagent vials onto the rack as shown in the following diagram. Unscrew the cap for each vial one at a time, and place in the cap holder. Tension clips hold the vials securely in place. Ensure that the bar code label for each reagent faces outward.

Note: If you assigned positions for non-OCD reagents or vials without bar codes, ensure that the correct reagent is placed in the correct reagent rack position. Placing the wrong reagent in the wrong position can negatively affect test results.

Figure 6-4



Note: Completely mix reagent red blood cells by gently inverting the bottle several times.

Note: Use caution when placing reagent vials into Reagent Rack. Tension clips can be bent during placement of vials. Bent clips can result in difficulties in vial placement.

Note: Test routines will not begin unless a sufficient quantity of reagents with the same lot number are loaded on the reagent rack. Ensure that reagents of the same reagent type that are loaded on the rack have identical lot numbers.

To load the Reagent Rack (continued)

⚠ Ensure that the cap for each vial is placed next to its corresponding vial. Do not mix up the vials and caps among different reagents. This could result in contamination of the reagents.

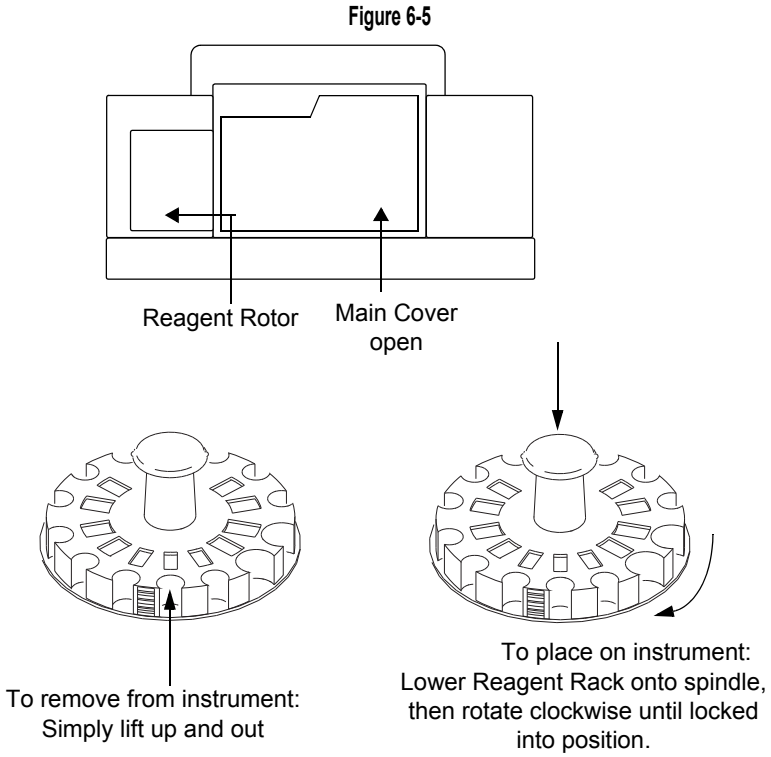
Cap each reagent vial before storing. Reagents should not be used on ORTHO AutoVue *Innova/Ultra* for more than eight continuous hours due to possible evaporation effects. When a reagent is not in use, store the reagent at 2-8°C.

3 When all reagent vials have been placed on the Reagent Rack, place the Reagent Rack on the Reagent Rotor. Rotate the Reagent Rack clockwise until it is locked into position. See Figure 6-5.

If an empty Reagent Rack is loaded onto the Reagent Rotor, the system generates an error message. For more information on error messages, refer to Appendix A: Error Messages.

Note: Take care not to bump the pipette tip with the Reagent Rack when loading.

Figure 6-5

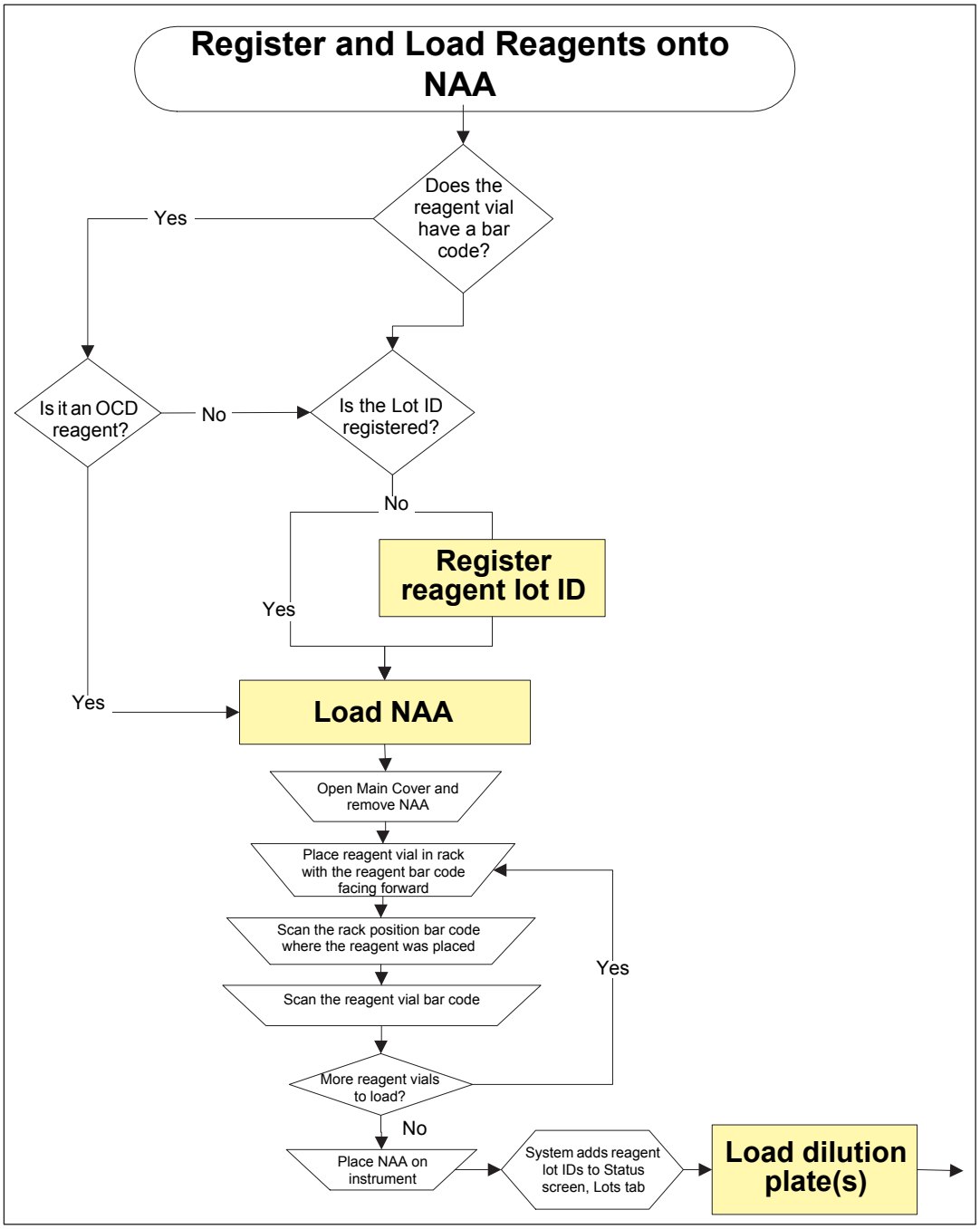


	To load the Reagent Rack (continued)
4	If the test routine requires dilution plate(s), then load dilution plates as described in the next section called "Load Dilution Plate(s)" on page 6-13.
5	Physically close the Main Cover.
6	Check Dashboard.

Load Reagents onto the Non-Agitating Area (NAA)

The workflow to load reagents on the NAA differs from the workflow to load reagents on the Reagent Rack.

Figure 6-6



Load Dilution Plate(s)

Acceptable Replacement Dilution Plates

Once a day place two clean, unused dilution plates into the instrument. Place a deep-well dilution plate on the right and a shallow-well dilution plate on the left. Dilution plates are divided into columns. ORTHO AutoVue *Innova/Ultra* checks which columns are filled by having the pipette check corner wells. For more information, refer to "Dilution plates" on page 2-14.

Note: A deep-well dilution plate is required only if a sample requiring a 0.8% patient or donor red blood cell dilution is registered.

Load Dilution Plate(s)

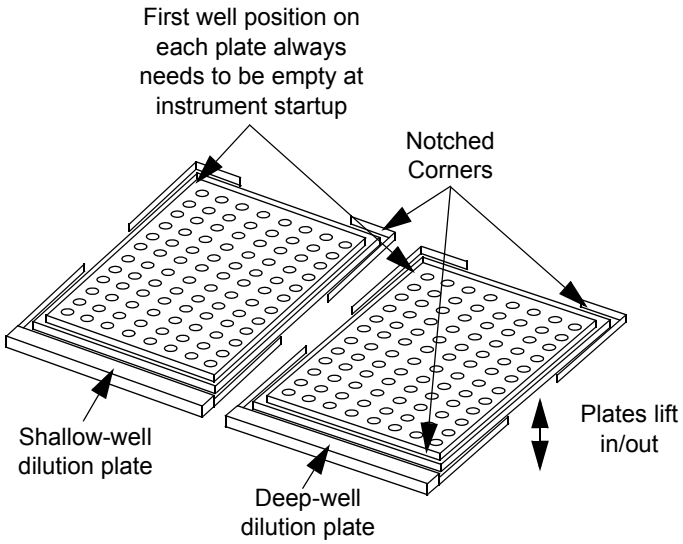
	To load dilution plate(s)
1	If necessary, touch the **Main Cover** button to open the Main Cover.

To load dilution plate(s) (continued)

2 Remove any existing dilution plates from the instrument and discard. The dilution plates are held in place by the notched corners.

When removing the dilution plates, follow your laboratory's standards for handling biohazardous materials. Use extreme caution when handling and discarding the plates.

Figure 6-7



3 Insert new dilution plates.

Note: It it critical that the dilution plates be placed securely in the allotted space. Verify that the plate is not resting on the edge of the notched corners.

4 Manually close the Main Cover.

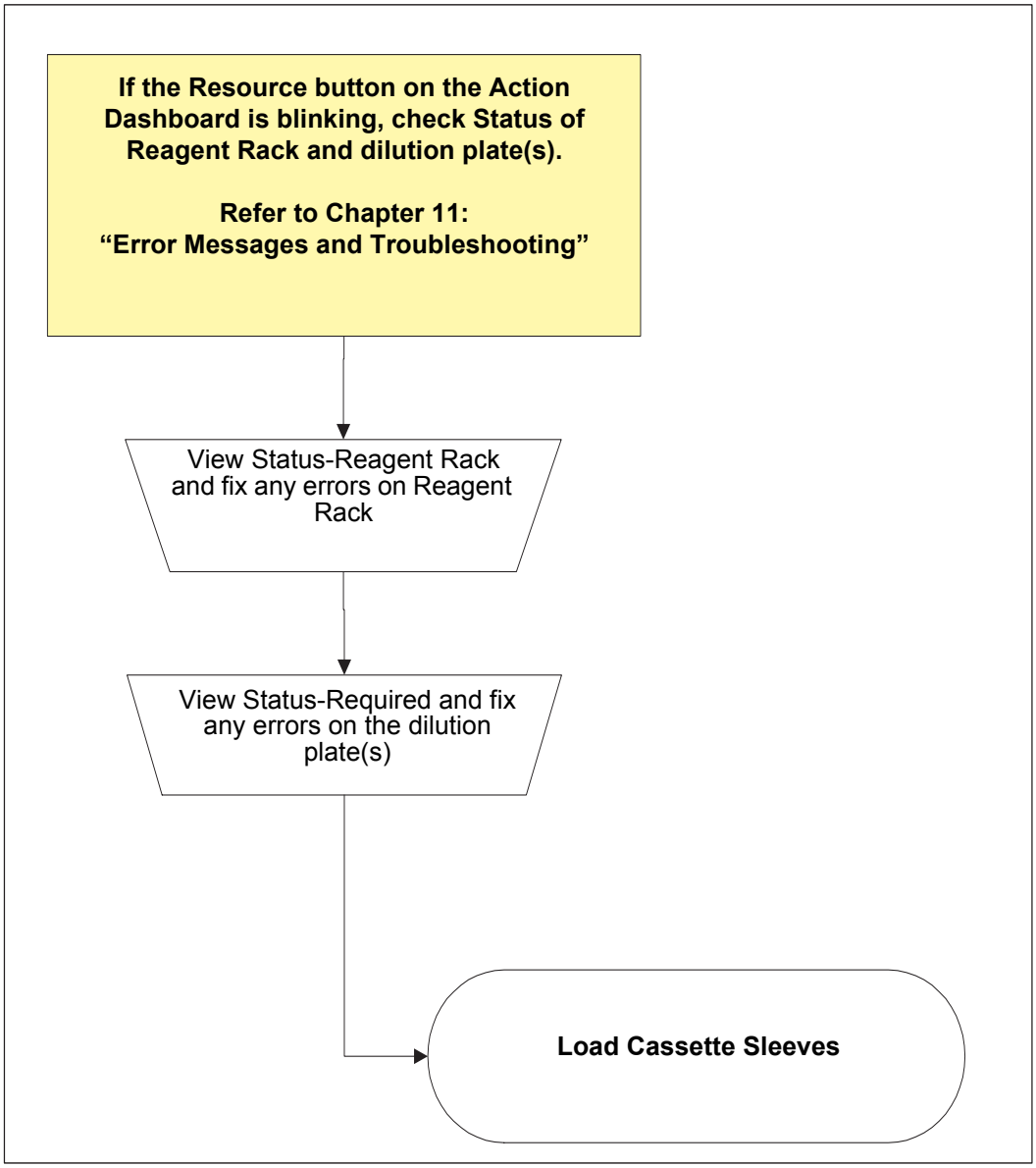
5 Check Action Dashboard for alerts.

Section C: Checking Status of Reagent Rack and Dilution Plate(s)

Check status of dilution plate(s)

- Use the **Required** tab and touch the **Dilution Plates** section to view the status of dilution plates.

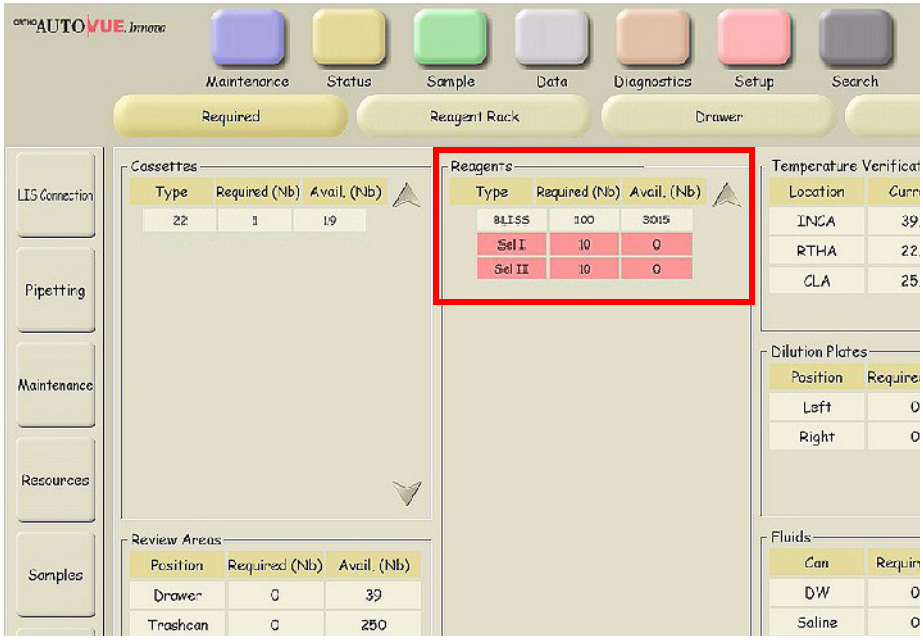
Figure 6-8



Check status of the reagents

- Use the **Status** screen **Required** tab and view the **Reagents** section. Any reagents required for testing that are not yet loaded onto ORTHO AutoVue *Innova/Ultra* are highlighted in red.

Figure 6-9

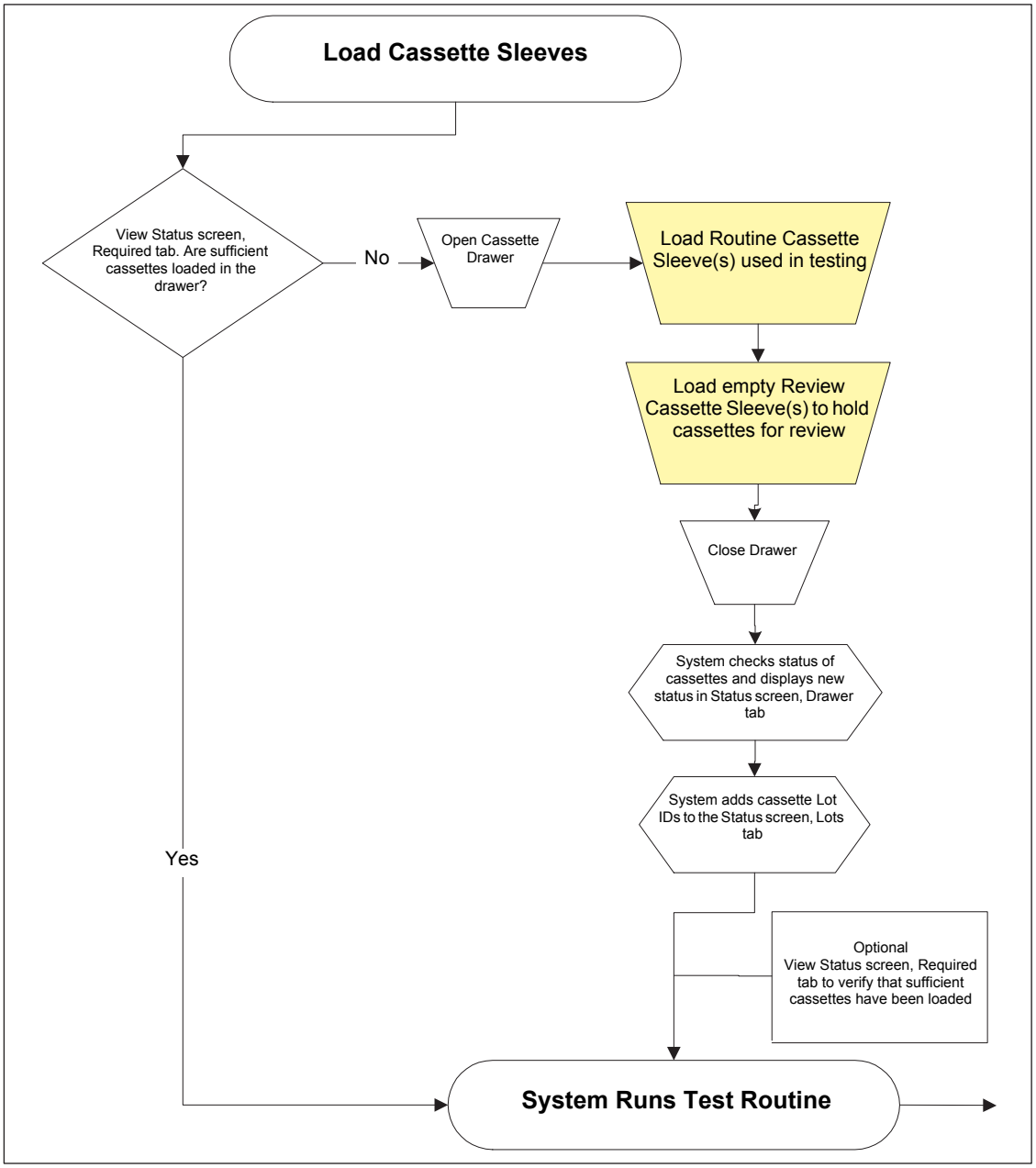


- Use the **Reagent Rack** tab to view a graphical representation of the Reagent Rack layout.

Section D: Loading Cassettes

During testing the operator loads routine Cassette Sleeves and/or replaces Review Cassette Sleeves. Routine Cassette Sleeves contain cassettes that are used for testing while Review Cassette Sleeves contain empty slots to hold cassettes for which the operator wants to manually review results.

Figure 6-10



Load Routine Cassette Sleeves

To load Cassette Sleeves into the drawer

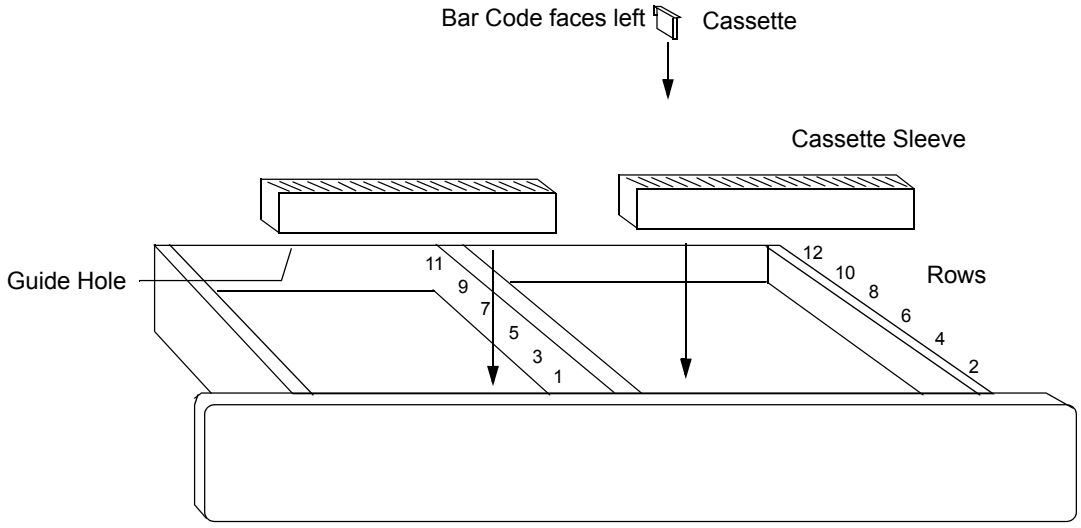
1 Touch the **Drawer** button to open the Cassette Drawer.

2 Place new Cassette Sleeves in the drawer. If you change the type of cassette present in a row (for example, removing a sleeve of one type and replacing it with another), ORTHO AutoVue *Innova/Ultra* will automatically recognize the new type of Cassette Sleeve. The system optimizes the use of cassettes in the Drawer. The cassette sleeve closest to expiration is used first, followed by the sleeve that has the fewest number of remaining cassettes.

Note: Sleeves in a row across from each other do not need to be the same type of cassette, for example, each sleeve position could hold a different cassette type.

Note: Cassette expiration is verified prior to use, and once sample testing has been initiated with cassettes that are in-date, the testing is considered valid.

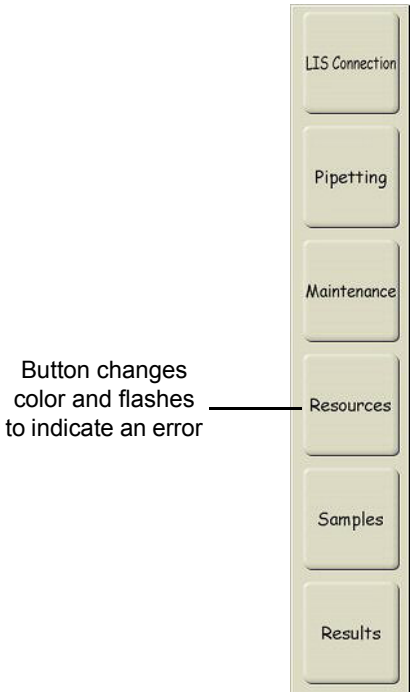
Figure 6-11



3 After loading cassettes, manually close the Cassette Drawer.

To load Cassette Sleeves into the drawer (continued)

4 Check Dashboard for issues or alerts.



Load or Replace Review Cassette Sleeve(s)

To replace a Review Cassette Sleeve that has been filled with cassettes to be reviewed, execute the following procedure:

	To replace Review Cassette Sleeve(s)
1	Print the current Review Cassette Sleeve description.
2	On the **Status** screen, **Drawer** tab touch the graphic of the Review Cassette Sleeve you want to replace. Result: A dialog box displays details about the Review Cassette Sleeve including the cassettes to be reviewed by position. The detail of the Review Cassette Sleeve displays the following information: ▪ Sleeve ID as shown on the Drawer screen ▪ Sleeve position ▪ Date & time ▪ Up to 20 cassettes on the Routine Cassette Sleeves ▪ 19 cassette positions and their status—as designated in the Setup (The 20th cassette is always a control cassette which can be expired or previously used) ▪ Cassette type
3	Touch **Print** to print these details about the Review Cassette Sleeve.
4	Touch the **Drawer** button to open the drawer.
5	Place a new empty box containing at least one control cassette in position 20 of the Cassette Sleeve. AutoVue only recognizes a Review Cassette Sleeve that has a control cassette in position 20 and generates an error if the control cassette is in any position other than 20. Note: The control cassette can be a used cassette as the bar code for it will not be identified by AutoVue. AutoVue only detects the control cassette's foil. Note: Once you remove a filled Review Cassette Sleeve from the Drawer, you cannot reload it. Replace it with an empty box containing only a control cassette.
6	Close the Cassette Drawer.
7	To view the updated layout of the Cassette Drawer, touch the **Status** button and then the **Drawer** tab.

Section E: Registering Samples

Sample information is:

- Automatically registered when the LIS sends test requests to AutoVue

  or

- Manually registered when you enter sample information by hand

Note: Do not use the following characters in sample registration information: **| \ ^ &**

Note: If a user is not logged in and the LIS auto-transfer feature is activated, test results uploaded to the LIS will be associated with the last user logged onto the system.

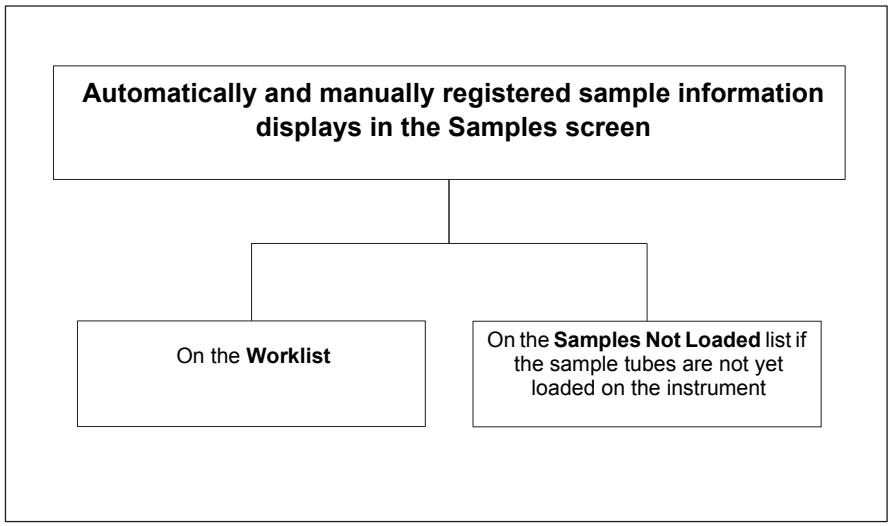
When to Register Sample Information Manually

You will register sample information manually when:

- AutoVue is used not connected to an LIS or used in an upload only mode
- The bar code on the sample tube is not able to be scanned by the system
- The sample does not have a bar code

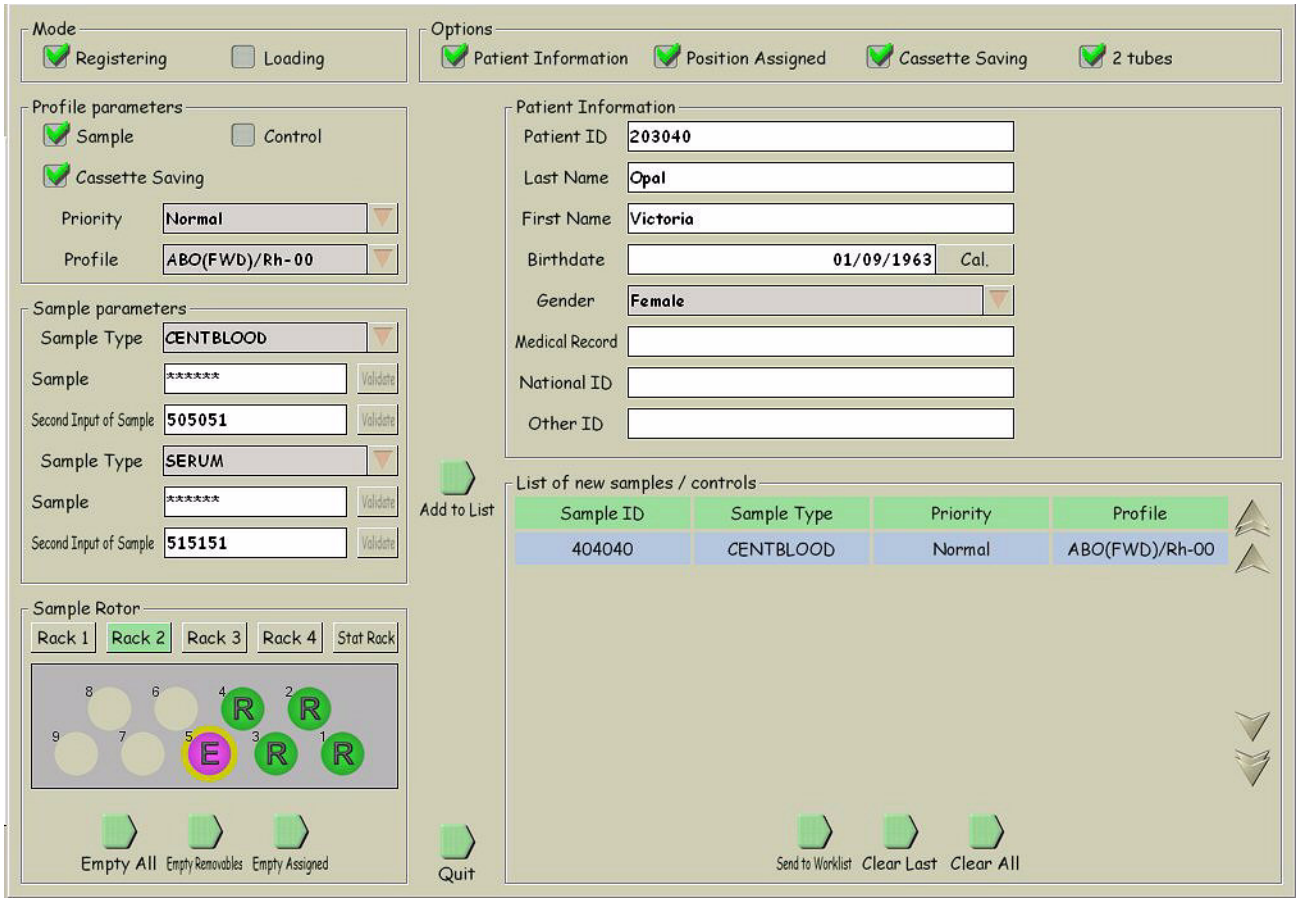
View Registered Samples

Figure 6-12



Buttons and Fields Used to Register and Load Samples/Controls

Figure 6-13 The Register/Load Samples or Controls Screen



Select a Mode

Table 6-1 Mode Options

Mode	Purpose
Registering check box	▪ Select to manually register samples that have not been registered by the LIS
Loading check box	▪ Select to load samples that have already been registered by the LIS ▪ To display this check box, open the Access Door. The **Loading** check box only displays when the Access Door is open.

Select Sample Parameters

Table 6-2 Sample Parameters

Name	Purpose
Sample check box	▪ Select to register a sample
Control check box	▪ Select to register a control
Priority list	▪ Select a priority for the sample/control you are registering
Profile list	▪ Select a profile for the sample/control you are registering

Enter Sample ID Information

Table 6-3 Sample ID Fields

Name	Purpose
Sample Type list	▪ Select a type for the sample/ control you are registering
Sample ID field	▪ Scan the bar code or type the Sample ID for the sample/ control you are registering
Second input of ID field	▪ Re-scan or re-type to confirm the Sample ID for the sample/control you are registering

Note: If you are registering sample parameters for a 2-tube sample, then you will enter the Sample Type and Sample ID for both sample tubes.

View the Samples on the Sample Rotor

Table 6-4 Sample Rotor Options

Name	Purpose
Rack 1, 2, 3, or 4 buttons	▪ Select a button to display the graphic view for that Sample Rack
Stat Rack button	▪ Select to display the graphic view of the Stat Rack Note: The STAT sample rack position numbers displayed in the software correspond with the position numbers on the instrument STAT Sample rack.

Note: The Access Door must be open to display the options in the Sample Rotor section.

Select Options

Table 6-5 Options

Name	Purpose
Patient Information check box	▪ Select to display fields to enter patient information Note: Your system administrator must configure the software to accept patient information. This can be done in the **Setup** screen, **General** tab.
Position Assigned check box	▪ Select to assign a position on the Sample Rack for sample tubes without a bar code or with a bar code that cannot be scanned
Cassette Saving check box	▪ Select to enable Cassette Saving option in the Profile Parameter section. Otherwise, the instrument sends the cassette directly to the waste basket, unless there have been review parameters pre-set.
"2-tubes" check box	▪ Select when you want to register two sample tubes with different Sample IDs that you want AutoVue to link together. Note: Unbarcoded tubes can be used for 2-tube samples as well as the donor associated with a crossmatch test. For unbarcoded 2-tube samples, register the samples and then load them using the **Position Assigned** check box on the **Register/ Load** and **Samples** or **Control** screen.

Enter Patient Information

Only Patient Information that is configured in the Setup screen, General tab displays on the Register/Load Samples screen.

Table 6-6 Patient Information Section

Name	Purpose
Patient ID field (20 char)	▪ Type the patient ID
Last Name field (30 char)	▪ Type the patient's last name
First Name field (30 char)	▪ Type the patient's first name
Birth date field (20 char)	▪ Type the patient's birth date
Gender list	▪ Select the patient's gender
Medical Record field (20 char)	▪ Type medical record information for the patient
National ID field (20 char)	▪ Type the patient's national ID
Other ID field (20 char)	▪ Type any other relevant ID for the patient

View the Sample Rotor List

Table 6-7 Sample Rotor list

Name	Purpose
Sample ID column	▪ Displays the Sample ID you registered for a sample/control
Sample Type column	▪ Displays the sample type you registered for a sample/control
Priority column	▪ Displays the priority (normal or STAT) you registered for a sample
Profile column	▪ Displays the profile you registered for a sample
Send to Worklist button	▪ Touch to send registered samples to the Worklist.
Clear Last button	▪ Touch to clear the most recently registered sample in the list
Clear All button	▪ Touch to clear all registered samples in the list

Workflow for Register and Load Samples/Controls

Note: A Control is a sample for which you specify the expected result because you want to compare the expected with the obtained result.

Figure 6-14

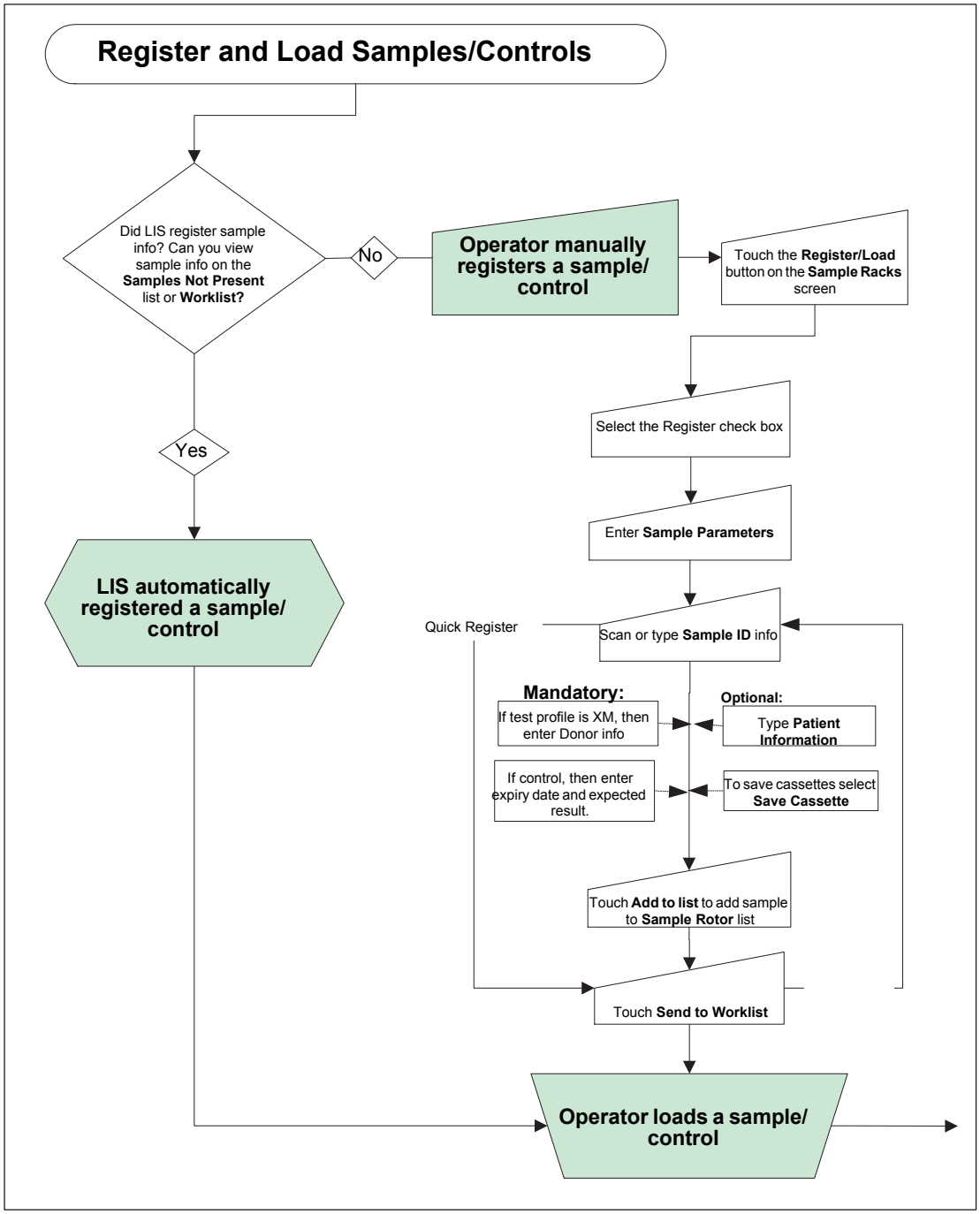
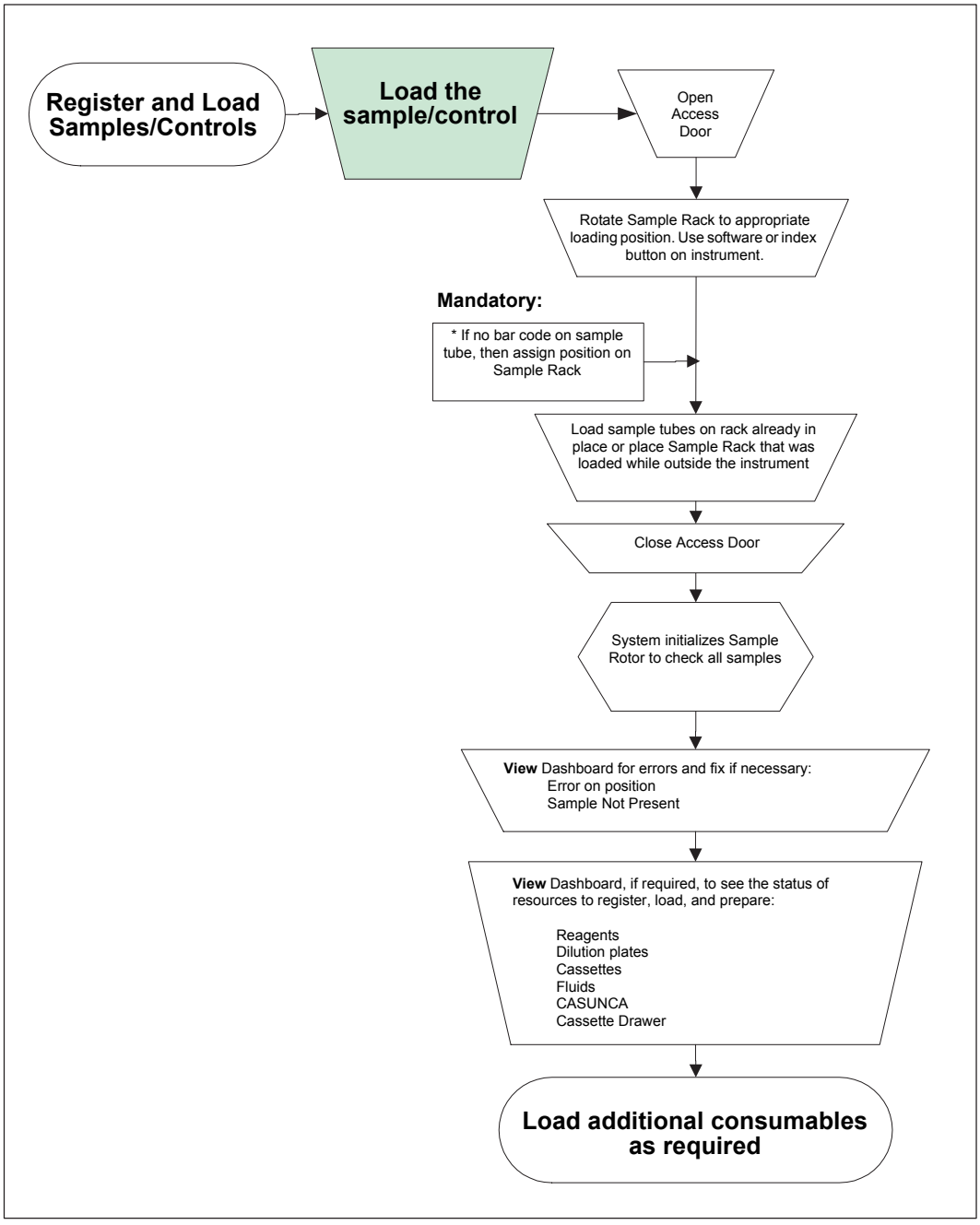


Figure 6-15


Register and Load Samples/Controls
Load the sample/control
Open Access Door
Rotate Sample Rack to appropriate loading position. Use software or index button on instrument.
Mandatory:
* If no bar code on sample tube, then assign position on Sample Rack
Load sample tubes on rack already in place or place Sample Rack that was loaded while outside the instrument
Close Access Door
System initializes Sample Rotor to check all samples
View Dashboard for errors and fix if necessary:
Error on position
Sample Not Present
View Dashboard, if required, to see the status of resources to register, load, and prepare:
Reagents
Dilution plates
Cassettes
Fluids
CASUNCA
Cassette Drawer
Load additional consumables as required

Manually Register a Sample/Control

	To manually register a sample/control
1	Is sample information displayed on the **Samples Not Loaded** list or **Worklist**: **YES:** The sample information is already registered. You are ready to load the sample. Go to "Load Samples/Controls" on page 6-42, and follow the steps to load the sample tubes. **NO:** Go to next step.
2	Touch the **Register/Load** button. Result: The Register/Load Sample screen displays. Select the **Registering** check box so you can register sample information manually.
3	Enter the following information in the **Sample parameters** section: ▪ Check **Sample** or **Control**. ▪ Select a priority level, **Normal** or **Stat**. ▪ Select a test profile from the list, for example ABO-D.
4	Decide if you want to do a quick entry using only Sample parameters and Sample ID, or if you want to do a full register entering information for any or all of the following: Patient information, Assign Position, Save Cassettes. **Quick register:** Proceed to next step. **Full register:** Go to step 7.

To manually register a sample/control (continued)

Quick Register

5 Scan the bar code to enter the Sample ID or type the Sample ID and touch **Validate**.

Note: If the sample ID was entered manually, repeat to verify the Sample ID.

Result: The system adds the Sample ID to the **Sample Rotor** list.

Repeat this step to add additional Sample IDs to the **Sample Rotor** list.

Note: You can select the Save Cassettes check box to save the cassette(s) for review.

6 To add results to the **Worklist**, touch **Send to Worklist** and load samples as described in "Load Samples/Controls" on page 6-42.

Note: Samples will not be processed unless they are sent to the Worklist.

To manually register a sample/control (continued)

Full Register

7 Scan the bar code to enter the Sample ID or type the Sample ID using the keyboard and touch **Validate**.

Note: If the Sample ID was entered manually, repeat to verify the Sample ID.

Since there is a possibility of error when manually registering Sample IDs by typing, ORTHO AutoVue *Innova/Ultra* requires that each Sample ID be entered twice for positive sample identification. The Sample ID typed the first time must match the Sample ID typed the second time. ORTHO AutoVue *Innova/Ultra* displays the characters typed in the field as asterisks (***).

8 *Optional*: To enter patient information:

- Check the **Register** check box
- Check the **Patient Information** check box

Result: **Patient information** fields display. Depending on parameters designated by your laboratory, any or all of the following fields display:

- Patient ID
- Last name
- First name
- Gender
- Birth date
- Medical record
- National ID
- Other ID

- Type patient information in the fields displayed.

Note: Although the Sample ID is used for tracking during sample processing, the main key for data management is either the patient ID or donation ID, both of which must be unique across all patients and donations (only when patient demographics are enabled). If no patient ID is entered, the system will automatically assign an ID based on the current date and time.

9 *Optional*: To assign a position for a sample tube on the Sample Rack, refer to "Assign a Position for a Sample on the Sample Rack" on page 6-44.

To manually register a sample/control (continued)

10 *Optional*: To save the cassette(s) for this sample to review the results:

- Select the **Cassette Saving** check box in the **Options** section of the screen.

Result: The **Cassette Saving** check box displays in the **Profile Parameters** section.

- Select the **Cassette Saving** check box in the Profile Parameters section.

11 *Optional*: If you selected a crossmatch test profile, then you will provide information about the donor.

- Touch **New Donor**.
- Select a sample type.
- Type the donor ID.
- Touch **Ok** to save information or touch **Cancel** to exit without saving.

Note: Although the Sample ID is used for tracking during sample processing, the main key for data management is either the patient ID or donation ID, both of which must be unique across all patients and donations (only when patient demographics are enabled). If no patient ID is entered, the system will automatically assign an ID based on the current date and time.

12 Touch **Add to List** to add the sample to the List of Registered Samples.

13 To register additional samples, go to step 1.

To send samples to the Worklist, touch **Send to Worklist**.

14 This concludes the steps to register samples. To load samples, see the "Load Samples/Controls" on page 6-42.

Registering and Loading AlbaQ-Chek® J, CQI 7 and CQI 9 Controls

AlbaQ-Chek® J is a simulated whole blood QC kit manufactured by Alba BioScience, and is available only in Japan. CQI 7/9 is a control kit containing whole blood samples and serum samples manufactured by EFS in France.

The ORTHO AutoVue *Innova/Ultra* will recognize barcodes from AlbaQ-Chek J, Ortho CQI 7 and Ortho CQI 9 controls. The user has the option to make auto-recognition of these barcodes active or inactive. See "To set miscellaneous results preferences" on page 11-26.

To register AlbaQ-Chek J, CQI 7 and CQI 9 controls

1. Touch the **Register/Load** button on the Samples screen.

   Result: The Register/Load Sample screen displays.

   In **Mode,** touch the **Registering** checkbox so you can register sample information manually.

2. In Profile parameters, touch the **Control** checkbox.

   Result: The Control Information dialog displays.

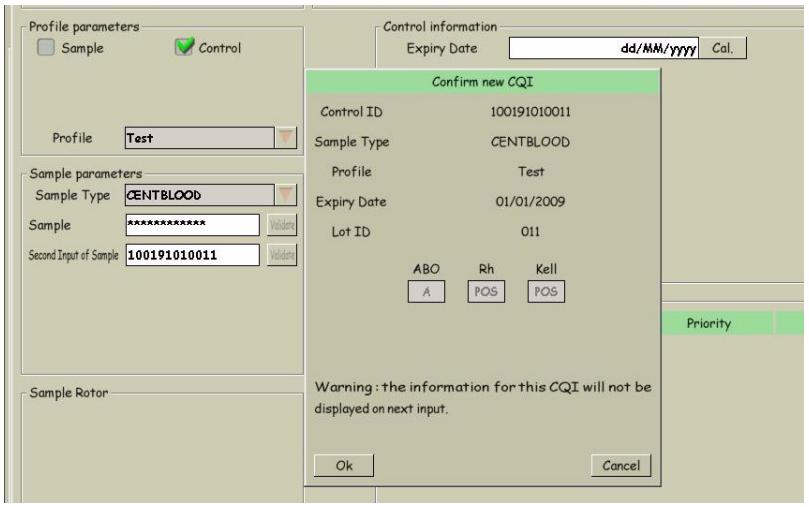
3. Scan the barcode to enter the control ID or type the control ID and touch **Validate**.

   Note: If the control ID was entered manually, repeat and touch Validate.

To register AlbaQ-Chek J, CQI 7 and CQI 9 controls (continued)

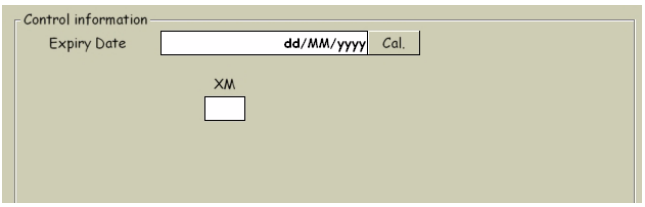
4 If Differentiate Patient/AlbaQ-Chek J or Differentiate Patient/CQI is set to **Yes** in the **Setup** screen, **Results** tab, **Miscellaneous** section, the system recognizes the ID, and the Confirm New AlbaQ-Chek J or Confirm New CQI window displays, showing the information specified in the barcode:

- Control ID
- Sample Type
- Profile
- Expiry Date
- Lot ID
- the expected test results.



To confirm the information, touch **Ok**.

If the Differentiate setting is **No**, the Confirm New AlbaQ-Chek J, or Confirm New CQI window does not display, and you must enter the expiration and expected test results in the Control information section.

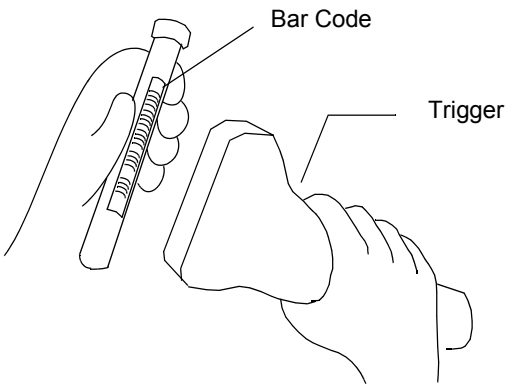


Register Samples Using the Hand-Held Scanner

For each sample tube, a unique bar code number is required. Multiple sample tubes cannot have the same bar code number. In most laboratories, samples have bar code labels that may be scanned using the bar code wand. This is the preferred method to help ensure positive sample identification.

Use the hand-held scanner to register samples with suitable bar code labels. The instrument will scan these labels again when you place them on the Sample Rack to confirm that the correct samples are loaded and available for testing. For more information about acceptable bar code types, refer to "Supported Bar Code Types" on page 1-20.

Figure 6-16



Register Samples by Keyboard Entry of Information

You can use the keyboard to enter information for samples when a bar code label cannot be scanned or there is no bar code label on the sample. You must assign a position on the Sample Rack for samples with bar code labels that cannot be scanned.

A laser is used by ORTHO AutoVue *Innova/Ultra* for reading bar codes. Potential exposure to the laser is possible. Do not look into the laser at any time when the instrument is on. Never look directly into an operating laser.

Note: Up to 20 characters may be entered for the Sample ID.

Register Samples Using Quick Register

Quick entry registration refers to entering sample information without patient or sample demographics that is required including:

Sample parameters

- Touch the **Sample** or **Control** check box, depending on the type of sample you are registering.
- Select a priority level, **Normal** or **Stat**.
- Select a test profile from the list, for example ABO-D.

Sample identification

- Scan the Sample ID

You can register the same sample bar code multiple times if you have a different test profile for each registration. The same sample with another test profile attached to it, displays on another line in the **Worklist**.

Register Samples Using Full Register

Full entry refers to registering sample information that is optional, but not required.

Enter Patient Information (optional)

Your laboratory may choose to make the entry of patient information required or optional. Depending on parameters designated by your laboratory in the **Setup** screen, **General** tab any or all of the following fields can require input:

- Patient ID
- Last name
- First name
- Gender
- Birth date
- Medical record
- National ID
- Other ID

Cassette Saving (optional)

You have the option to save cassettes to review analysis results for a specific sample. ORTHO AutoVue *Innova/Ultra* can send these cassettes to the Cassette Drawer or CASUNCA (depending on the location specified in the **Setup** screens) rather than discard them in the Waste Basket.

When you register a sample, you have the option to save the cassette(s) for that sample by selecting the **Save Cassettes** check box in the **Options** section of the Register/Load Samples screen.

Other ways to tell ORTHO AutoVue *Innova/Ultra* to save cassettes include:

- Setting Results Thresholds in the **Setup** screen, **Results** tab
- Programming the LIS to save cassettes
- ORTHO AutoVue *Innova/Ultra* will automatically save cassettes to be reviewed by the operator when the reaction was not successfully graded by the AutoReader.

Assign a Position for a Sample on the Sample Rack

See “Assign a Position for a Sample on the Sample Rack” on page 6-44.

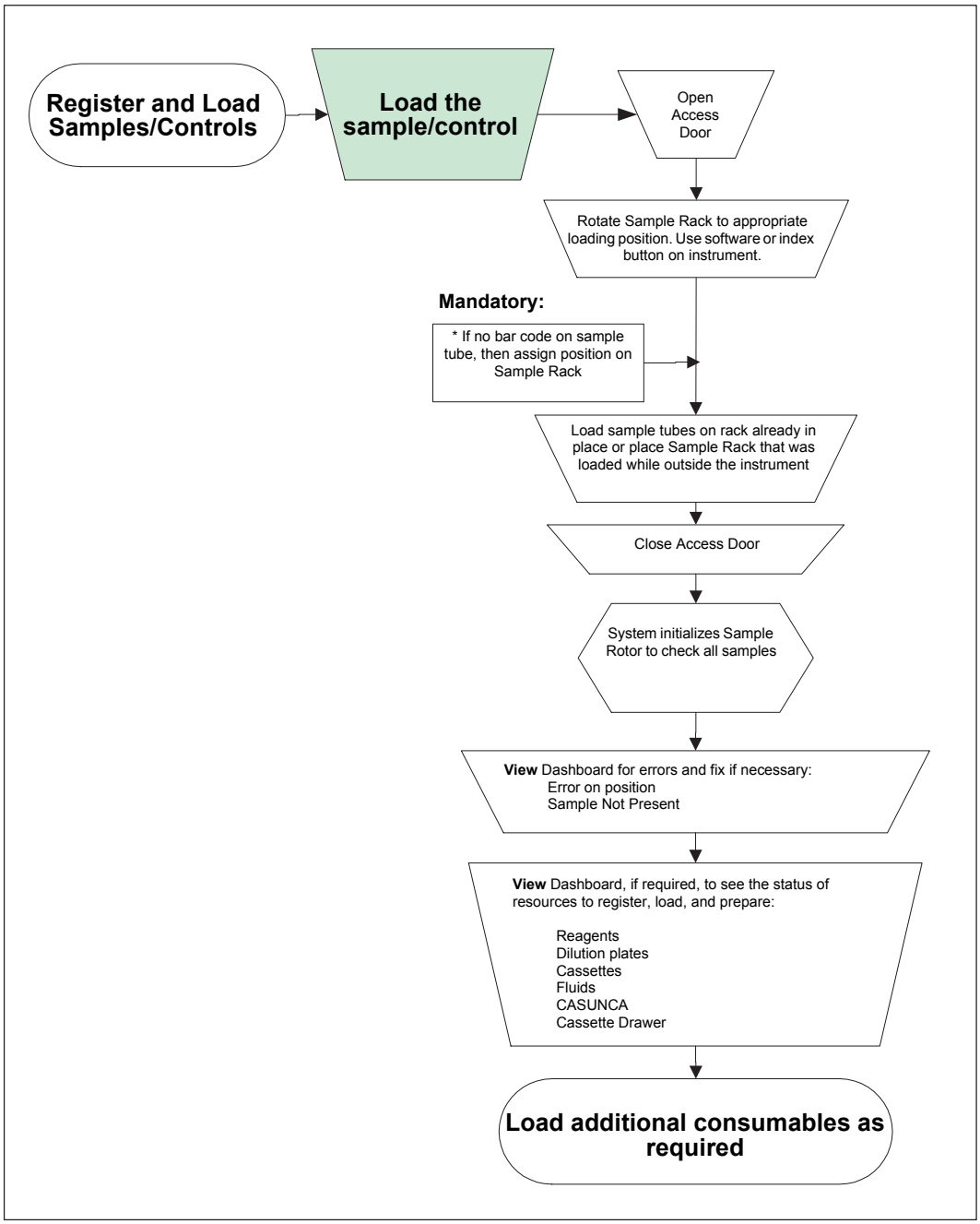
View Registered Sample Information

After sample information is registered either by the LIS or by hand, you can view it in the **Sample** screen.

Section F: Load Samples/Controls

You can load registered samples onto the instrument after they have been registered into ORTHO AutoVue *Innova/Ultra* either automatically by the LIS or manually by the operator. Following is a workflow describing the process for loading samples onto the instrument.

Figure 6-17



Load Bar Coded Samples/Controls

The Access Door must be open in order to load samples/controls.

Note: Ensure that each sample without a bar code label or a bar code label that is not able to be scanned by the system is assigned a position. Mixing up samples and positions can affect test results.

To load bar coded sample/control

1. Load samples into the appropriate size Sample Rack(s). For more information about Sample Rack types, refer "Sample Rotor and Racks" on page 2-5.

   Note: Emergency or STAT samples do not need to be loaded into the fixed rack.

2. Touch the **Access Door** button to open the Access Door.

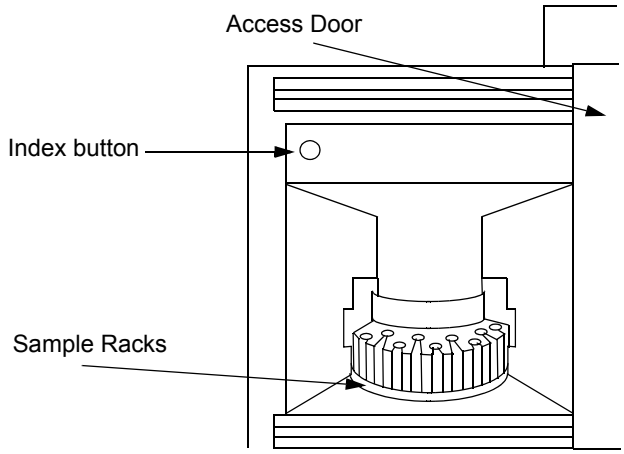
3. On the **Sample Racks** screen, touch the **Register/Load** button.

   Result: The Register/Load Samples screen displays.

4. Touch the **Loading** check box to load samples.

5. Use the Index button on the instrument to rotate the Sample Rotor or touch **Rack 1, Rack 2, Rack 3, Rack 4**, or **Rack STAT** to instruct the instrument to rotate to that rack.

Figure 6-18



⚠ Use caution when indexing the Sample Rack. Ensure that hands are clear of any moving parts before indexing the Sample Rack.

	To load bar coded sample/control (continued)
6	Load Sample Rack(s) onto Sample Rotor.
7	Manually close the Access Door. Result: The instrument scans the Sample Racks and displays the status of each sample on **Sample Racks** screen.

Assign a Position for a Sample on the Sample Rack

The Access Door must be open in order to assign a position for a sample tube.

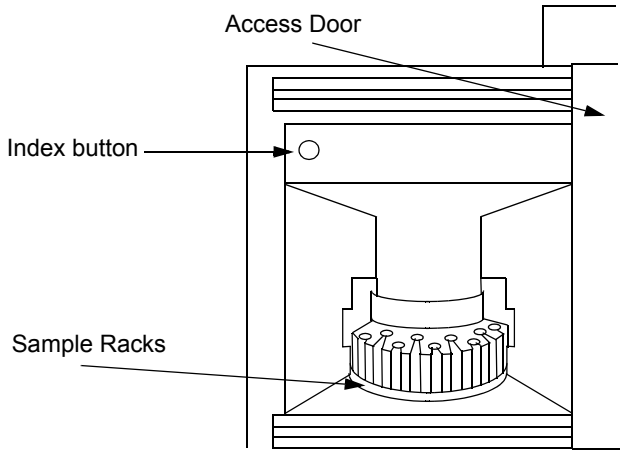
Note: Ensure that each sample without a bar code label or a bar code label that is not able to be scanned by the system is assigned a position. Mixing up samples and positions can affect test results.

	To designate an assigned position for an unlabeled or unscannable sample
1	Touch the **Access Door** button to open the Access Door.
2	On the **Sample Racks** screen, touch the **Register/Load** button. Result: The **Register and Load Samples** dialog box displays.
3	Touch the **Loading** check box and then touch the **Position Assigned** check box. Result: You can now assign a position on the Sample Rack.
4	Confirm that you have entered the sample parameters and Sample ID.

To designate an assigned position for an unlabeled or unscannable sample (continued)

5 Touch **Rack 1, Rack 2, Rack 3, Rack 4**, or **Rack STAT** to instruct the instrument to rotate to that rack. Or, you can use the Index button on the instrument.

Figure 6-19



⚠ Use caution when indexing the Sample Rack. Ensure that hands are clear of any moving parts before indexing the Sample Rack.

6 Touch a position on the screen of the rack to assign the sample to that position.

Result: The sample is now assigned a "U" (in Use) status on the Sample Rack.

7 Touch **Send to Worklist** to add the sample with an assigned position to the Worklist.

8 Repeat the process for any additional unlabeled or unscannable samples to be loaded on that Sample Rack. When complete, physically load the Sample Rack into the instrument.

9 Physically close the Access Door.

Result: The instrument scans the Sample Racks and displays the status of each sample on **Sample Racks** screen.

Supported Sample Types

ORTHO AutoVue *Innova/Ultra* supports several sample types. You can use:

- One-tube (for example, Cent WB)

  or

- Two-tube (for example, Cent WB *and* plasma/serum). In a two-tube sample type, each tube requires a unique Sample ID. In most laboratories, samples are labeled with unique bar code labels.

The correct sample type is necessary in order to perform an ORTHO AutoVue *Innova/Ultra* test. For example, for forward and reverse blood typing, a sample type that includes red blood cells and plasma is needed. Follow the appropriate BioVue cassette instructions for sample preparation.

⚠ Do not use flat-bottomed sample tubes. The pipette is set based on round-bottom tubes. If flat-bottomed tubes are used, the tube can break and/or the pipette tip can bend or break. This may cause a biohazard and instrument maintenance may be required.

Serum and Plasma

When serum or plasma is required, fatty (lipemic) deposits, fibrin and debris can cause testing errors. Make sure that samples are centrifuged according to the instructions found in the BioVue cassette package inserts. Serum and plasma samples are treated equivalently on ORTHO AutoVue *Innova/Ultra.* The abbreviation for both serum or plasma is PLASMA.

Table 6-8

Sample Type	Sample Type Abbreviation Displayed on Screen	
	RBC Source (First Tube)	Serum or Plasma Source (Second Tube)
3-5% rbc/serum or plasma D 3-5% rbc/serum or plasma	3CELLS	PLASMA
0.8% rbc/serum or plasma D 0.8% rbc/serum or plasma	0.8 Cells	PLASMA
Cent WB/serum or plasma D Cent WB/serum or plasma	CENTBLOOD	PLASMA
Packed rbc/serum or plasma D Packed rbc/serum or plasma	PACKEDCELLS	PLASMA

rbc – red blood cells; *Cent* – centrifuged; *WB* – whole blood

Red Blood Cells

A 3-5% rbc suspension is a suspension that has been prepared by the user, not by the instrument. A manually prepared 3-5% red blood cell suspension (patient or donation) has a minimum volume limit of 200 µL and a maximum volume limit of 1500 µL. This is to ensure that they system is capable of resuspending the manually prepared suspension prior to aspiration and dispense. The minimum volume required for a centrifuged whole blood sample is 300 µL. This volume was selected assuming a 45% hematocrit.

Expiration Times for Samples

A sample's expiration time is based upon the sample type and the amount of time it has been loaded on the ORTHO AutoVue *Innova/ Ultra*.

Table 6-9

Sample Component Type (Applies to Patient and Donation Samples)	Expiration Time (hours)
Centrifuged Whole Blood	8
Packed Cells	8
Serum/Plasma	8
Manually Prepared 3-5% red blood cell suspension	1
0.8% Cell suspensions	1

7 Monitoring Status and Managing Results

Overview

The operator manages test requests, results, and reports in the **Worklist** tab. From the **Worklist** tab, you can:

Table 7-1

Action	To
View status of processing	View test requests, routines in progress, results for completed tests, and errors.
Edit well gradings and test results	Edit well gradings and test results based on your laboratory's internal criteria and procedures. Note: Only test results which have not yet been accepted or rejected can be edited.
Accept test results	Accept results that you deem valid. After you have accepted results, they can be reported out and/or uploaded to the LIS. Note: You can set up the ORTHO AutoVue *Innova/Ultra* to automatically accept and upload test results to the LIS. Or, you can require the operator to manually accept and upload test results to the LIS. This option is configured in the **Setup** screen, **Results** tab. When this option is enabled, only results which require operator review must be uploaded manually to the LIS.
Reject test results	Reject results that you deem invalid. Your laboratory's internal criteria and procedures determine the results to reject. Note: You can set up the ORTHO AutoVue *Innova/Ultra* to automatically upload rejected results to the LIS to manage rejected results at the LIS level.

Table 7-1 (continued)

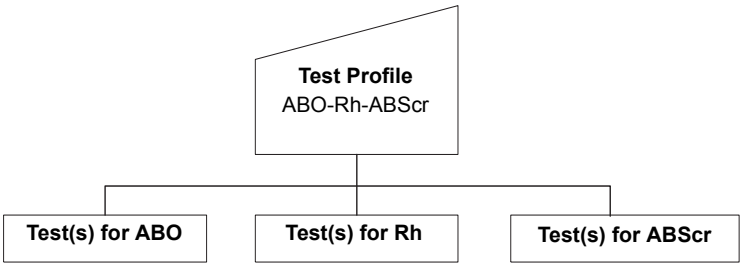
Action	To
Review Cassettes	Review cassettes that are questionable. When this feature is activated on the **Setup > Results** tab, cassettes in the review sleeve need to be manually reviewed and scanned into the system. The **Review cassettes** dialogue box will appear. The cassette ID needs to be entered manually or hand scanned. Once the cassette ID is accepted, the **Review cassette** screen will appear with the image of the cassette. From that screen you can accept or reject the cassette, move on to scanning the next cassette ID, or cancel out of the screen.
Review Order	Review orders whose test results have been modified. When this feature is activated on the **Setup > Results** tab, all orders that are successfully interpreted but have not yet been accepted can be reviewed and accepted or rejected. The **Review order** screen will appear with an image of the cassette. From this screen, you can accept results, modify results, move to the previous cassette, move to the next cassette, or cancel out of the screen.
Cancel a test profile	Cancel a test profile when you do not want to send results to the LIS. For example, you might cancel a profile if the sample tube breaks or is not labeled correctly. You can cancel profiles before processing, during processing, or after the system yields a test result.
Print reports	Print reports to review and share test data.

Topics

View Results for Profiles and Tests

You can view results for a sample ID by profile or by individual test. The difference between a profile and test is described in the diagram below and also described in greater detail in "Overview of the Testing Process" on page 4-1.

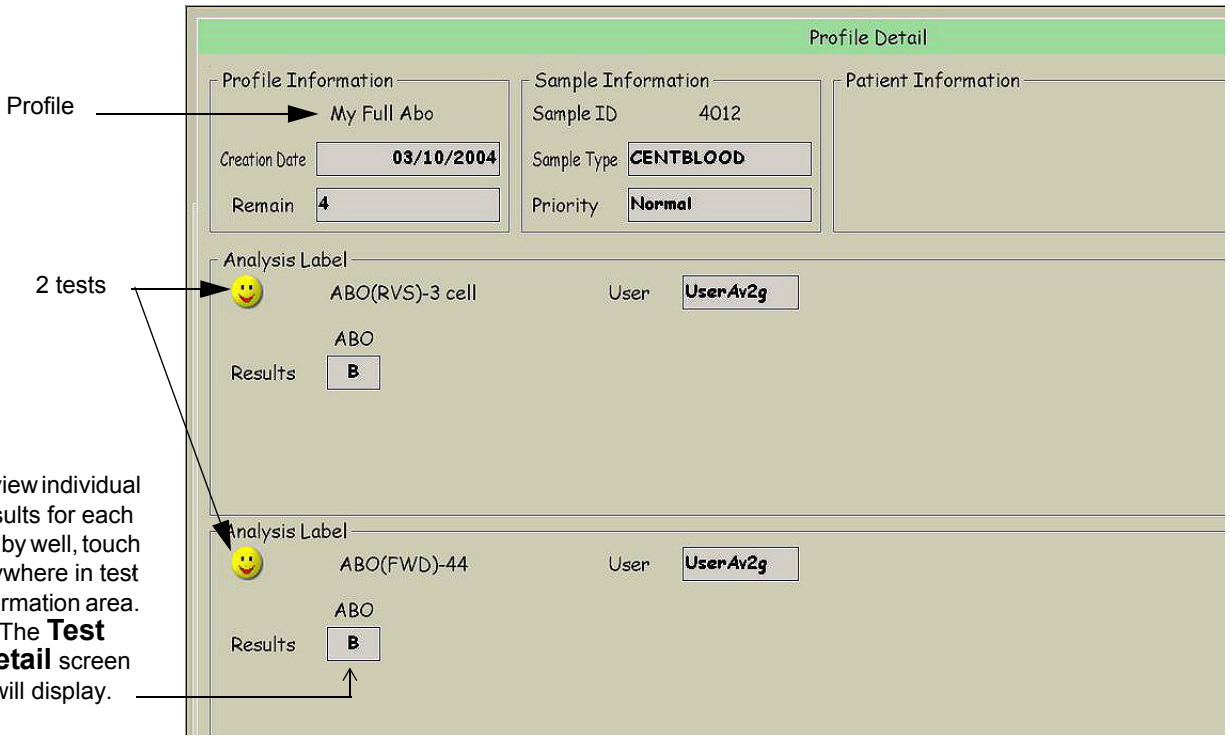
Figure 7-1



View Results for Profiles

For a single sample ID, you can view results for the profile in the **Profile Detail** screen.

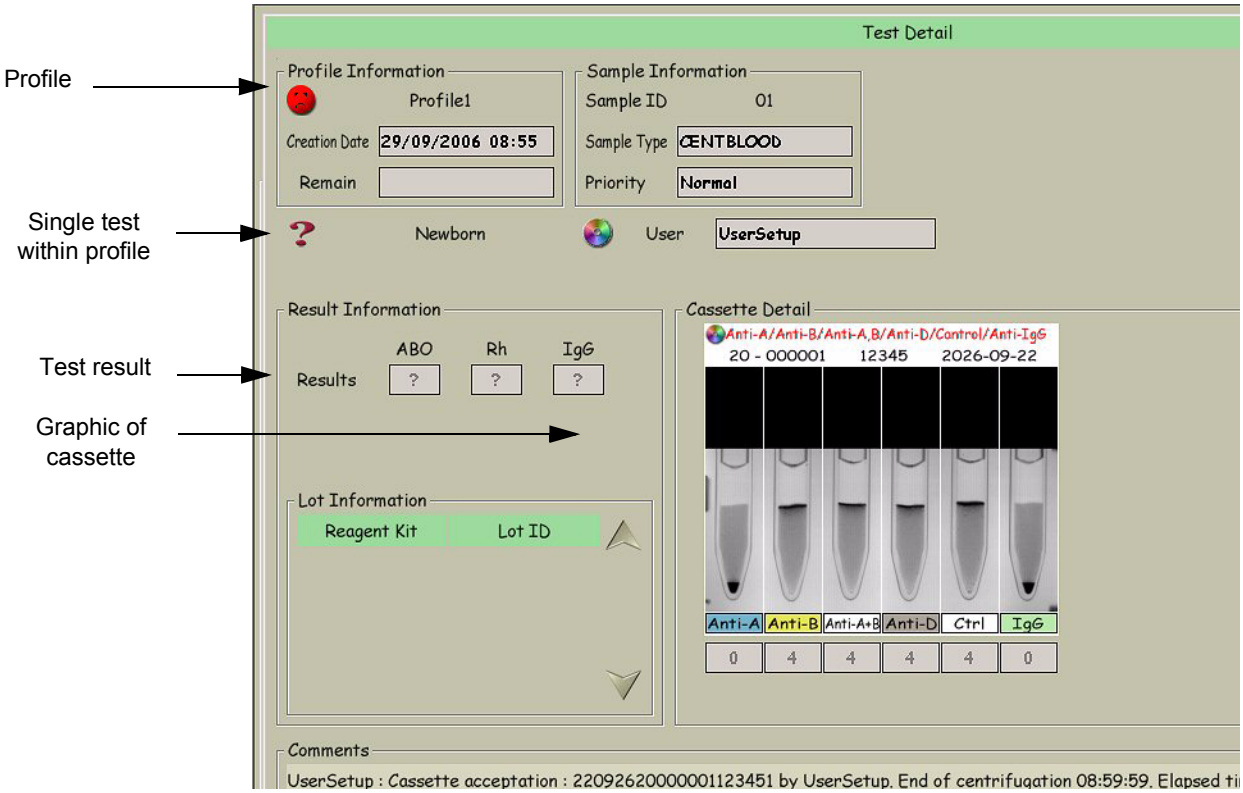
Figure 7-2



View Results for an Individual Test within a Profile

You can also view results for an individual test within the profile.

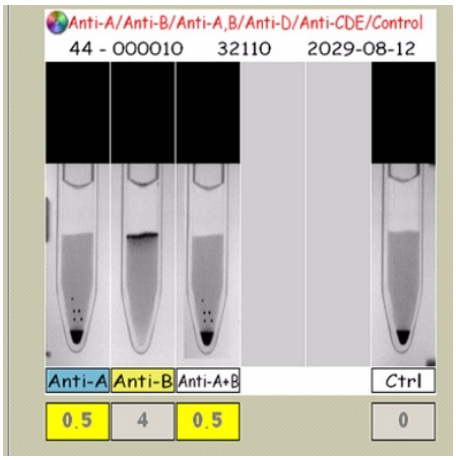
Figure 7-3



Note: When the format "C+c-E-e+" is used, the Rh Phenotype result in the **Test Details** and **Profile Details** screens partially displays. The operator must scroll to read the entire result.

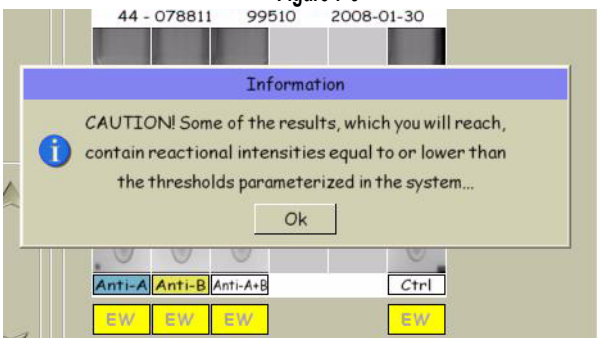
Note: When test results fall at or below the thresholds specified by the user in the Setup screen, Results tab, the results in question are highlighted in yellow:

Figure 7-4



If the user has enabled Review cassettes and/or Review orders, an information box displays:

Figure 7-5



Section A: The Worklist

The **Worklist** displays test request and test result information for samples. Each row in the **Worklist** contains:

- Test request information displayed in the following columns:
  - **Remain** – Remaining time for test request to complete
  - **Status** – Status of test request
  - **Sample ID –** Sample ID of test request
  - **Profile name** – Test profile requested for the sample
  - **Patient information** – Patient information for the sample depending on options enabled in the **Setup** screen.
  - **Review Cassettes** – Cassette information for cassettes with results that have not been interpreted yet.
  - **Review Orders** – Determines what to do with the interpreted results.
- Test result information including columns that display test results. For example if the test profile for the request included results for **ABO**, **Rh**, and **ABScr** then these columns display as shown in the diagram below.

Figure 7-6

Highlighted columns indicate operator action required

Two data display options can be selected using the **Worklist** and **Completed** check boxes.

View the Worklist

The Worklist is accessible from either the **Samples** or **Results** screens.

Select the **Worklist** check box to view the **Worklist** and samples for which:

- Test(s) have been requested
- Test routine(s) are in progress
- Test routine(s) have concluded and results have not yet been accepted, or rejected.

View the Completed list

Select the **Completed** check box to view the **Completed** list displaying only the samples for which:

- Testing is complete
- Results have been cancelled, edited, accepted, or rejected

The **Completed** list can also display the following information if automatic archiving and transfer of data to the LIS are not enabled in the Setup screen:

- Results are ready to be archived
- Results are ready to be transferred to the LIS

Filter Data

You can filter out data from the **Worklist** and **Completed** list to view smaller amounts of data at a time. For example, you might filter the **Worklist** to view only those sample IDs for which results have been modified.

	To filter data:
1	Touch the **Filter** button on the **Worklist** or **Completed** list.
2	Touch the category of data you want to view and then touch **Next**. For example, touch **Sample Type**. Result: The subcategories of the selected category display.
3	Touch the subcategory of data you want to view and then touch **End**. For example, touch **Control**. Result: The Worklist displays the filtered data. For this example, only control sample types will display; not patient sample types.
4	To display all data, touch the **Filter** button.
5	Touch **Filter**, then touch **No filter** and then touch **End**. Result: All data displays on the **Worklist**.

Sort Data

You can sort data that displays in the **Worklist** and **Completed** by individual column. For example, you might sort the **Worklist** by the **Profile Name** column to view all sample IDs with the same profile(s) grouped together.

To sort data:

1 Touch the column name on the **Worklist** or **Completed** list. For example, **Profile Name**.

Result: ORTHO AutoVue *Innova/Ultra* sorts data by the column name you touched and displays a symbol next to the column to indicate that the column has been sorted.

Touch the column once to switch between ascending and descending order.

2 To sort data by another column, touch another column name. For example, **Sample ID**.

Result: ORTHO AutoVue *Innova/Ultra* sorts data by the column name you touched and displays a symbol next to that column.

When the last line of results from a Search is truncated, touch the **Profile Name** column header to display the full line of text.

Edit Results

Once cassettes have been read, graded, and interpreted by AutoVue, you can edit individual well grading results and test results with appropriate access privileges. For example:

- To interpret an indeterminate reaction grading
- To resolve a discrepancy between results

⚠ Possible false readings may occur when test result modification is used incorrectly. The operator is responsible for editing results according to their laboratory's standards and practices.

A test result can only be edited if the initial result has not been accepted or rejected. Modifications to well grading results or overall test results must be accepted or rejected before they can be printed or uploaded to the LIS.

⚠ Editing the well grading results of a test may change the overall test results. The effect is determined by the change in value and test type. For example, changing a 0.5 reading to a 0 reading on a crossmatch test would affect the result: an incompatible result would become compatible. Changing the result from 0.5 to 1 would not: the result would remain incompatible.

⚠ To modify well results you must scan the barcode on the cassette using the handheld scanner. Failure to do this may result in erroneous test results being reported.

When performing antibody screening with polyspecific and enzyme testing, the software uploads the cumulative results from both tests to the LIS as described below:

Polyspecific/Enzyme Result	Cumulative Result Sent to LIS
Pos/Pos	Pos
Neg/Neg	Neg
Pos/Neg	Pos
Neg/Pos	Pos

Graded Result Values

Table 7-2

Grade	Definition	Software Abbreviation	Editable Well Result
0	"0" reaction	0	X
5	"(+)" reaction	0.5	X
10	"1+" reaction	1	X
20	"2+" reaction	2	X
30	"3+" reaction	3	X
40	"4+" reaction	4	X
-90	Well not found	WNF	
-95	Wrong liquid level	WLL	
-100	Light too low	LTL	
-101	Light too high	LTH	
-110	Hemolysis or Icteric reactions	HEM	
-111	Empty well	EW	
-112	Few cells	FC	
-113	Too many cells	TMC	
-114	Features out of range	OUT	
-115	Mixed field or Fibrin (forward grouping test)	MF	X
-116	Indeterminate reaction or unsuccessfully graded result	?	X
-117	Top-line or fibrin (reverse and screening test)	FIB	
-118	Bubble detected in the column	BUB	

Unsuccessfully graded results (indeterminate, MF, H/I, etc.) are automatically saved in the CASUNCA or Cassette Drawer depending on the location specified in the **Setup** screen. The cassette must be at hand to scan the bar code and modify results.

Unsuccessfully graded results are generated:

- When the Image Processing System cannot read the cassette
- If the system cannot interpret the results

Edit Test Results and Well Grading Results

You might edit a test profile's result if a discrepancy occurs when two different cassette types are used for ABO typing (ABO-Rh [44] for forward and Reverse Diluent [66] for reverse). The ABO-Rh cassette types as a Group O while the Reverse cassette types as a Group B. The results of each cassette are acceptable but when ORTHO AutoVue *Innova/Ultra* compares the results of both cassettes it indicates a discrepancy between the two cassettes.

Note: OCD recommends that the results should be modified based on your laboratory standards and after appropriate investigation of the discrepant results.

Another situation when the test profile result can be edited is when more than one antibody screening test (for example, ABScr 2-cell [IgG], ABScr 3-cell [Poly], Papain ABSCR, etc.) is included in a test profile.

To edit overall test results and/or well grading results

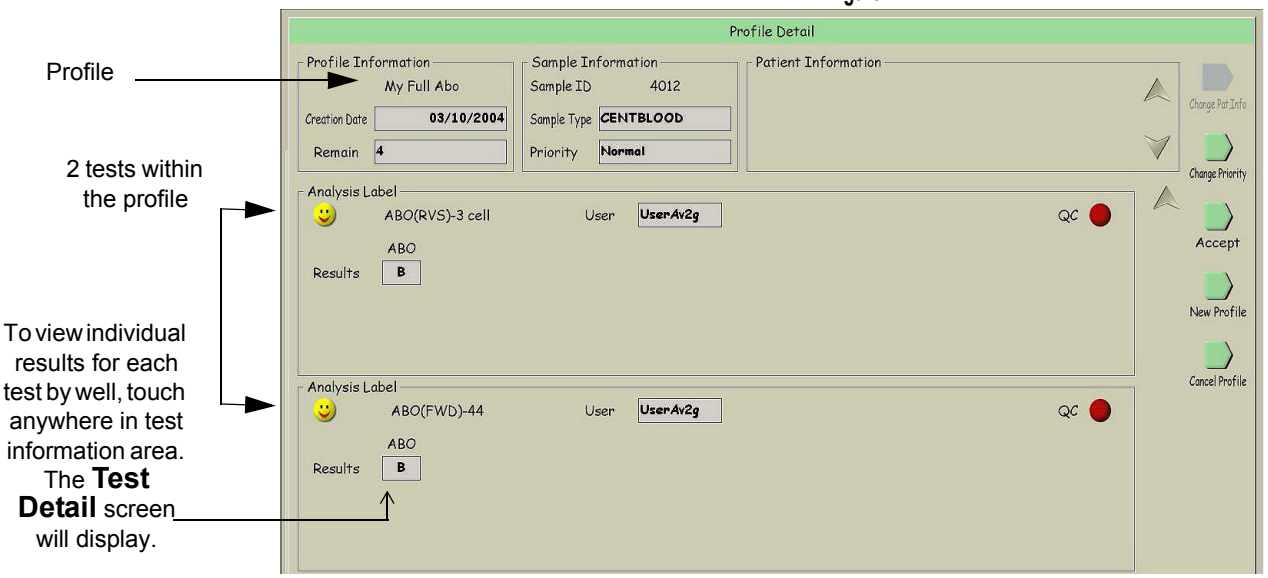
1 On the **Worklist** tab, select the **Worklist** check box.

To edit overall test results and/or well grading results (continued)

2 Touch a sample row anywhere left of the test results to display the **Profile Detail** screen. To display the **Test Detail** screen, touch a test result, or touch within the Test Information area on the Profile Detail screen.

Alternatively, you can touch **Review Orders** to sequence through all of the orders that have been successfully interpreted but have not yet been accepted. To view the **Profile Detail** screen for a specific order, touch **Modify**.

Figure 7-7



To edit overall test results and/or well grading results (continued)

On the **Profile Detail** dialog box, a number of buttons are available on the right side of the screen. In addition, you can also edit the following using these buttons:

- **Change Pat Info** – Edit patient information for the sample
- **Change Priority** – Change the priority of the sample

  Note: The priority of a sample can only be changed if the instrument has not yet started to test the sample.

- **Accept** – Accept the result

  Note: If you accept results in the **Profile Detail** screen, results for all tests within the profile are accepted. To accept or reject results for each individual test, use the **Test Detail** screen.

- **New Profile** – Order a new profile for the sample

  Note: If a donor requires a test, such as AB0-Rh, register and complete testing on the donor sample prior to registering and completing the cross match testing on the patient sample.

- **Cancel Profile** – Cancel the current profile for the sample so results are not used

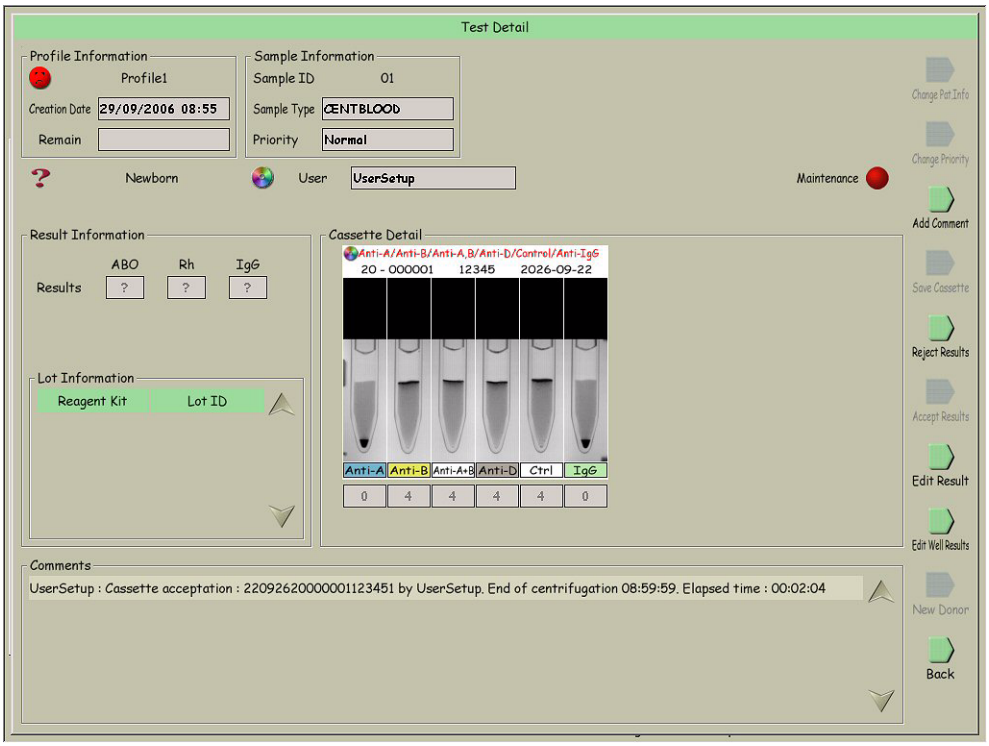
  Note: You can only cancel a profile in this screen. To reject results, use the **Test Detail** screen.

3 Touch a button and fill in required information or answer the question.

To edit overall test results and/or well grading results (continued)

4 To edit the results for individual tests, touch a test result in the **Results** section (for example XM, AB, or Rh) to display the **Test Detail** dialog box as shown below.

Figure 7-8



To edit overall test results and/or well grading results (continued)

On the **Test Detail** dialog box, a number of buttons are available on the right side of the screen. In addition to editing results on this screen, you can also do the following:

- **Change Pat Info** – Edit patient information for the sample
- **Change Priority** – Change the priority of the sample

  Note: The priority of a sample can only be changed if the instrument has not yet started to test the sample.
- **Save Cassette** – Save Cassette graphic in the long-term archive.

  Note: When you select **Save Cassette** in the **Test Detail** screen the cassette graphic is saved in the long-term archive. But, if you select **Save Cassette** in advance of the testing process in the Register/Load screen the cassette will be saved for review in the Cassette Drawer or the CASUNCA. Refer to "Cassette Saving (optional)" on page 6-39. If you save cassette after test processing only the data and graphic is saved, not the physical cassette.
- **Add Comment** – Add a comment

  Note: There is an option in Setup > Miscellaneous to require a comment before the system will accept edited results.
- **Reject Results** – Reject the result
- **Accept Results** – Accept the result
- **Edit Result** – Edit the test result

  Note: In the **Setup** screen, you can activate an option to be sure that the operator who accepts the result is NOT the same as the operator who edits the results.
- **Edit Well Results** – Edit the well grading results
- **New Donor** – Add a new donor (for crossmatch)

Note: If a donor requires a test, such as AB0-Rh, register and complete testing on the donor sample prior to registering and completing the cross match testing on the patient sample.

5 Touch a button and fill in required information or answer the question.

Continue with step 6 to edit overall test results or skip to step 8 to edit well grading results.

To edit overall test results and/or well grading results (continued)

For Overall Test Results:

6 To edit the test results, touch the **Edit Results** button.

7 Enter valid result values and then touch the **Validate** button.

Result: AutoVue updates result value(s).

Note: If "Require comments for editing results" is enabled, the user must make an entry in the Comments screen before the system will accept changes in the Edit Results window.

Edit well grading results:

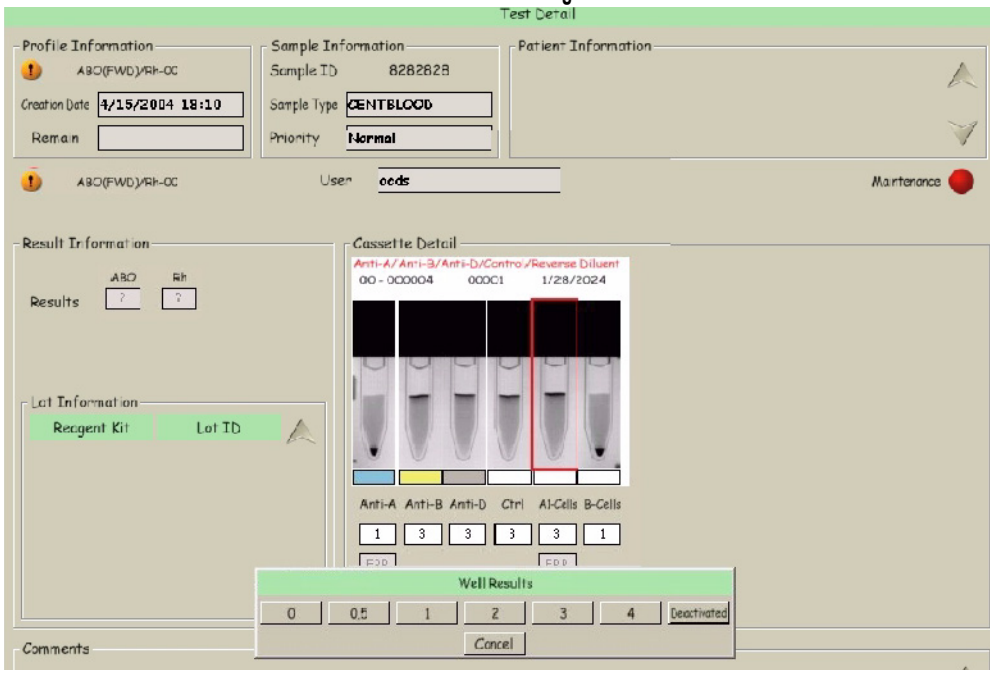
8 To edit results, touch the **Edit Well Results** button.

9 Scan the bar code of the cassette.

Note: Keyboard entry of the bar code is not permitted.

10 Select a well to edit the result for that well in the **Well Result** dialog box that displays.

Figure 7-9



To edit overall test results and/or well grading results (continued)

11 Touch **Validate** to confirm that you want the system to accept your edits to the results.

Note: If "Require comments for editing results" is enabled, the user must make an entry in the Comments screen before the system will accept changes in the Cassette Detail display.

12 Accept or reject the results by touching the **Accept** or **Reject** button.

Review Cassettes

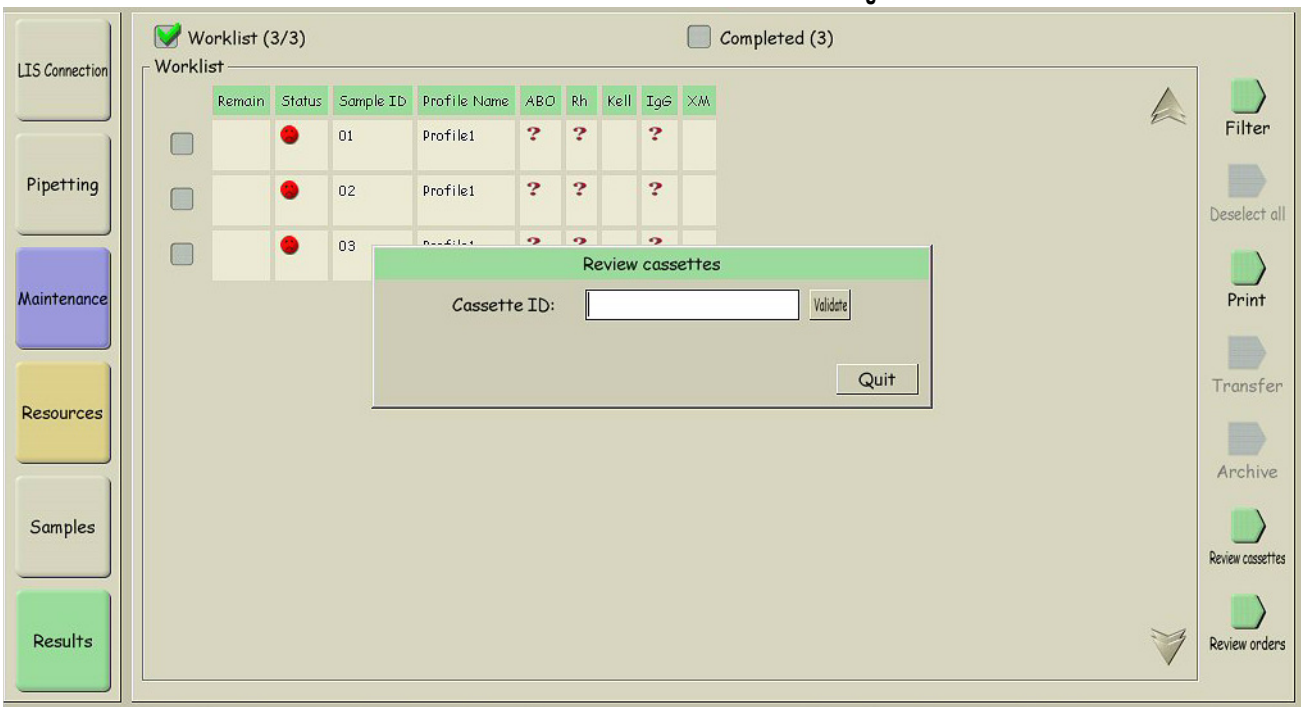
The Review Cassettes feature enables you to manually check cassettes that are questionable. You will not modify results in this view, but you can confirm that they were visually inspected.

To review cassettes

1. Remove any cassettes to be reviewed from the cassette drawer.
2. On the **Results > Worklist** tab, select the **Worklist** check box.
3. Touch the **Review Cassettes** button and the Review Cassettes dialog appears.

   Scan the cassette ID.

Figure 7-10



To review cassettes (continued)

4 Review the cassette details and choose one of the following options:

Accept – Accepts the data as presented.

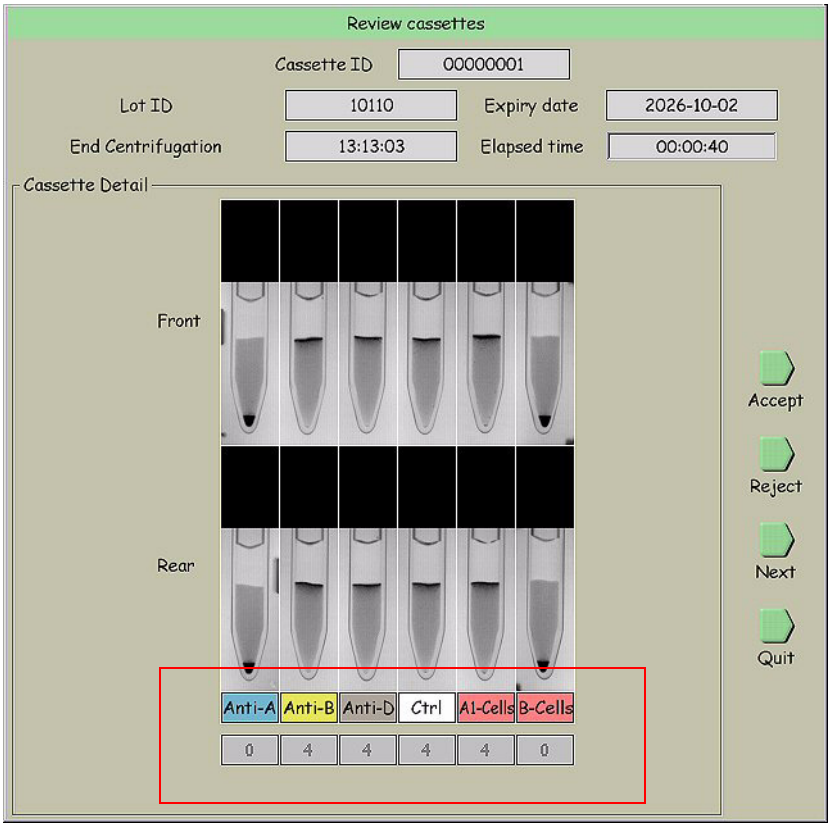
Reject – Rejects all of the cassettes in the series.

Next – Advances to the next cassette to be reviewed.

Quit – Closes out of the review cassettes activity.

Note: The cassette to be reviewed may look different than the image displayed on the screen.

Figure 7-11



Note: Cassettes must be reviewed within 20 minutes from the time the cassettes were read. A yellow caution (see Figure 7-11) appears after 17 minutes have elapsed and a red warning appears after 20 minutes. When the 20-minute time period is exceeded, you can continue to review cassettes but the tests should be re-run.

Section B: The Completed List

The **Completed** list displays test results that have already been accepted or rejected in the **Worklist** and are ready to be transferred to the LIS or printed out for laboratory records.

Note: If automatic archiving and transfer to the LIS are enabled in the **Setup** screen, then the **Completed** list does not display.

Figure 7-12

Note: The system now expedites the routine management process. As soon as a profile for a sample displays on the Completed List, you can re-order the existing profile from the Worklist and the LIS.

Section C: Symbols to Indicate Status of Sample in Worklist and Completed List

Table 7-3 Symbol Explanation

Symbol	Status	Action Required
	Profile cancelled for sample.	None
	Profile accepted, printed, and transferred to the LIS for sample.	None
	Error on sample. For example, due to a lack of consumables.	Refer to **Status screen** for consumables to load.
	Error on result. For example, a discrepancy between ABO forward direct and reverse tests. Or discrepancy in patient information.	Edit the test result manually. Edit patient information.
	At least one result for a sample is ready to be accepted.	Accept result.
	Profile in progress for a sample.	None.
	Sample registered, but not loaded.	Load sample.
	Result accepted for sample	Transfer results to LIS or print out results. Note: On printed reports, this icon displays next to automatically and manually accepted results.
	Result to be archived.	Archive result.
	Result transferred to the LIS.	None.
	Result edited.	None.

Table 7-4 Symbols that Display in the Analysis Results Columns

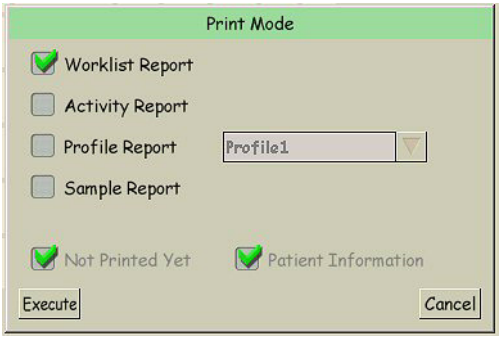
Symbol	Status
	Analysis requested, but sample not loaded.
	Analysis in progress.
	Error on analysis (for example, due to lack of consumables).
	Result rejected.
	Discrepant result in control.
	System could not interpret the result. Note: Results manually modified to a status of indeterminate display a blank field in the **Analysis Results** column.

Section D: Reports

You can print the following report formats from the **Worklist** or **Completed** list:

- Worklist: Prints the **Worklist**
- Activity: Prints samples requested, in process, and completed
- Profile: Prints details for a single test profile
- Sample: Prints details of samples displaying information one sample per page

Figure 7-13



Note: For all tests that require more than two cassettes, the system displays and prints results for all cassettes used.

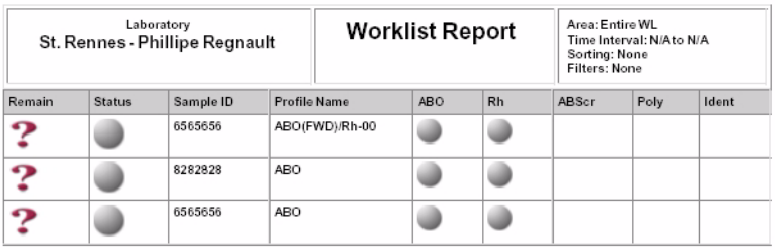
Worklist report

The report generated from the Worklist view displays information from either the Worklist or Completed views test results with a status of:

- In progress
- Completed
- Cancelled

When the report is generated from the **Completed** view, all accepted results display.

Figure 7-13



Activity report

The Activity report provides a print out of the samples requested, in process, and completed. Your lab may print this report at the end of each day to view the results obtained for the day. Information in this report includes:

- **Sample ID** – The sample ID scanned or typed into the system.
- **Profile(s)** – The test profiles run on the sample ID.
- **Result(s)** – The results for each profile.
- **Created** – The date the test request was created.
- **Completed** – The date the test result was completed.
- **User/Man** – The name of the user/if the user manually edited the result.
- **Patient information** – The patient ID, first name, last name, and birth date of the patient.

  Note: Patient information only displays if this option is enabled in the Setup screen.

Profile report

While the Activity report shows all the results processed for the day, the Profile report provides a detail view of a single profile, including the following information:

- **Sample ID** – The sample ID scanned or typed into the system.
- **Result(s)** – The results for each profile.
- **Created** – The date the test request was created.
- **Completed** – The date the test result was completed.
- **User/Man** – The name of the user/if the user manually edited the result.
- **Patient information** – The patient ID, first name, last name, and birth date of the patient.

  Note: Patient information only displays if this option is enabled in the **Setup** screen.

Sample Report

While the Activity report shows all the results processed for the day and the Profile report shows a detail view of a single profile, the Sample report provides a detailed view of results for samples including:

- The sample ID scanned or typed into the system
- Patient demographics
- Data for a single patient per printed page, with repeated patient information on continuing pages
- Results of each test in a test profile, including any modifications
- Graphic view of the wells in the cassette
- Reagent information
- For crossmatch tests, the association of a well number to a donor ID in the table of results

Note: It is possible to print a Sample report for up to 300 samples. We recommend printing large reports when sample processing is not in progress.

Print Reports

To print reports

1 On the **Worklist** screen, touch **Print Out**.

Result: The **Print Out** dialog box displays.

2 Touch the check box for the report to print:

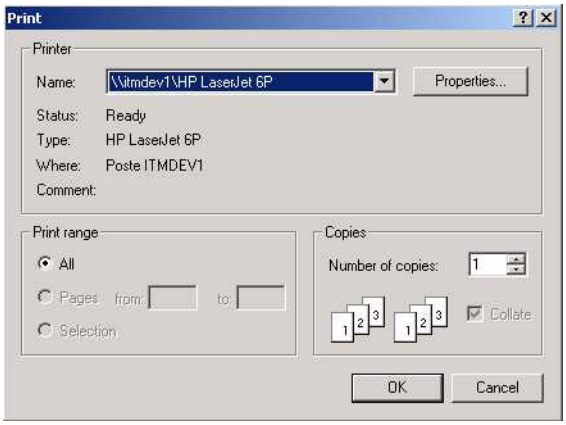
- Worklist
- Activity
- Profile
- Sample report

For the Profile report, select a profile to print.

3 Touch **Execute** to print the report or cancel to exit without printing.

Result: The Print dialog displays.

Figure 7-15



4 Touch **Ok** to print the report.

This page intentionally left blank.

8 Performing Maintenance and Quality Control Procedures

Overview

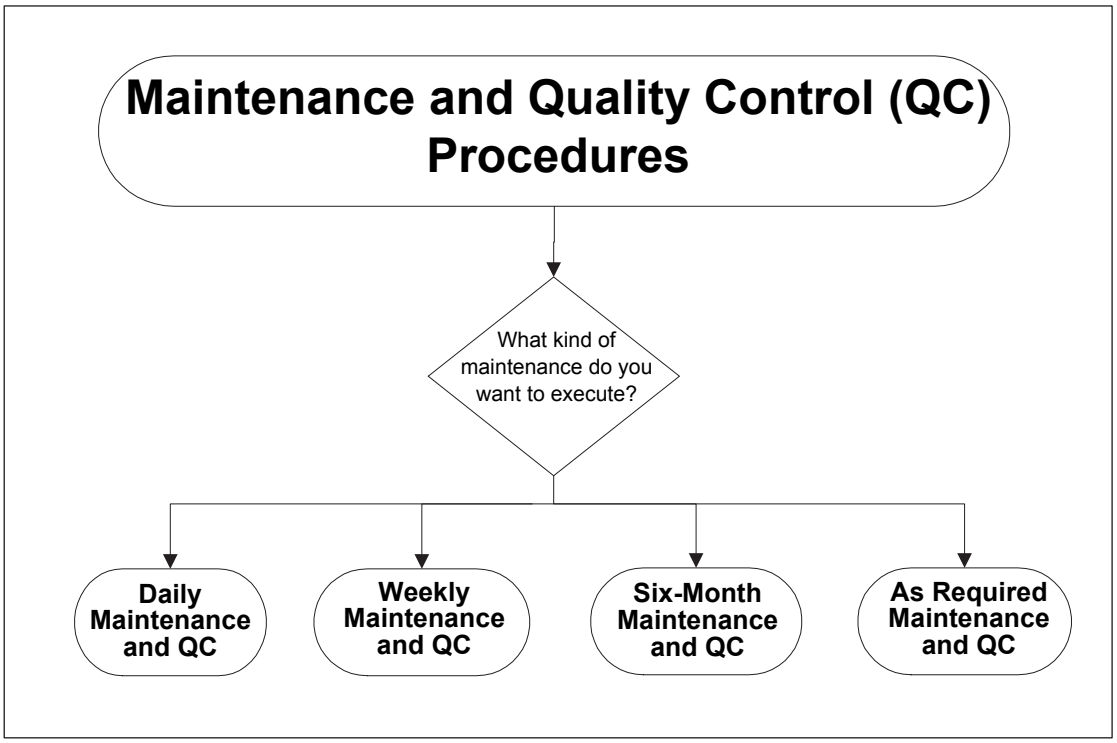
You can use the AutoVue software to track the daily, weekly, and monthly maintenance procedures you execute. The **Maintenance** screen guides you through a series of wizards that describe the steps for executing maintenance procedures. Maintenance can only be done with a log in that is in Routine Mode.

Note: OCD recommends performing the maintenance procedures according to the schedules described in this chapter to help ensure accurate test results.

Topics

Types of Maintenance Procedures to Execute

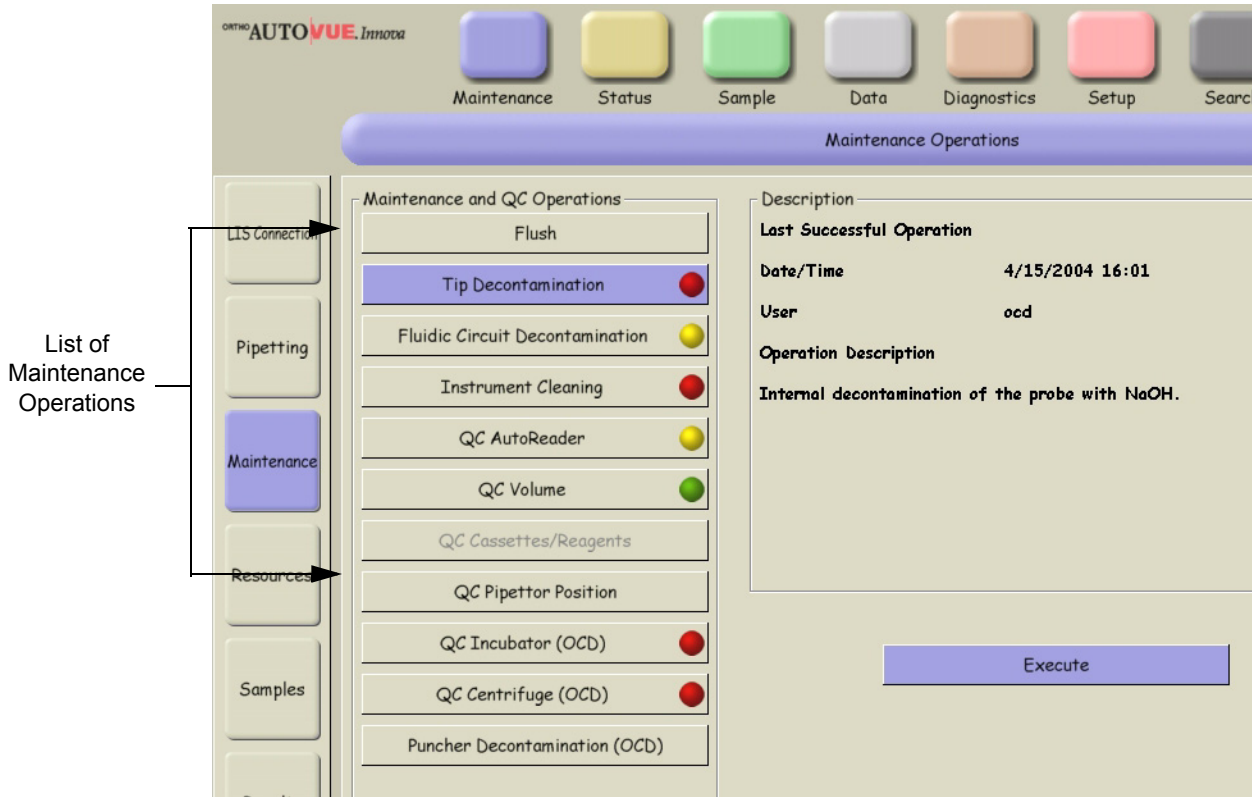
Figure 8-1



Use the Maintenance Wizards

The **Maintenance** screen displays buttons for the maintenance and quality control (QC) procedures to execute.

Figure 8-2



When you touch a maintenance operation button, a wizard that contains a series of screens displays. The wizard:

- Guides you through the steps to execute to complete the maintenance procedure
- Displays a report when the maintenance procedure is complete

Example of Wizard

Following is an example of the wizard for tip decontamination.

To execute the Tip Decontamination procedure

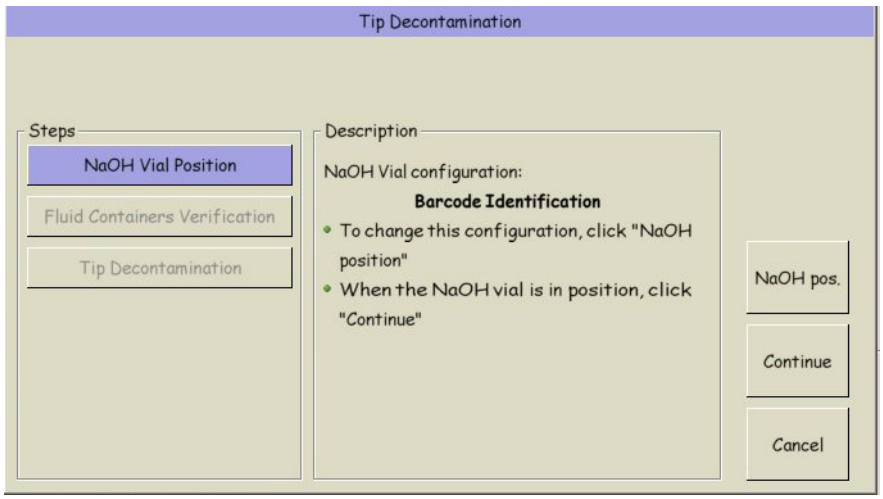
1 On the **Maintenance** tab, touch the **Tip Decontamination** button.

Result: The first screen of the **Tip Decontamination** wizard displays for the **NaOH Vial Position** and describes the steps to take in this screen.

- Touch **NaOH pos** to change the position of the NaOH vial
- Touch **Continue** to proceed to the next screen in the wizard
- Touch **Cancel** to exit the wizard

When the Tip decontamination operation is cancelled, the Main Cover may unlock. Do not open the Main Cover until the operation is fully completed.

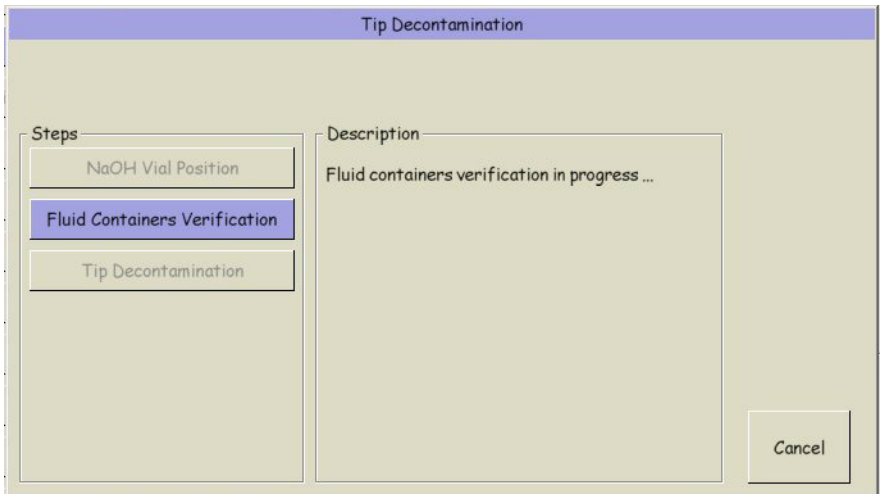
Figure 8-3



To execute the Tip Decontamination procedure (continued)

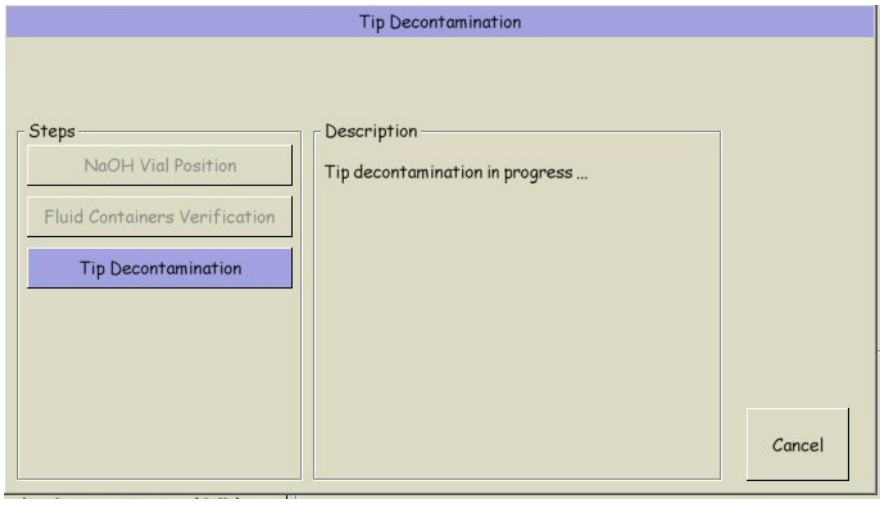
2 If you touch **Continue**, the next screen in the wizard named **Fluid Containers Verification** displays:

Figure 8-4



3 When the fluid container verification completes, the system begins tip decontamination and the **Tip Decontamination** screen displays:

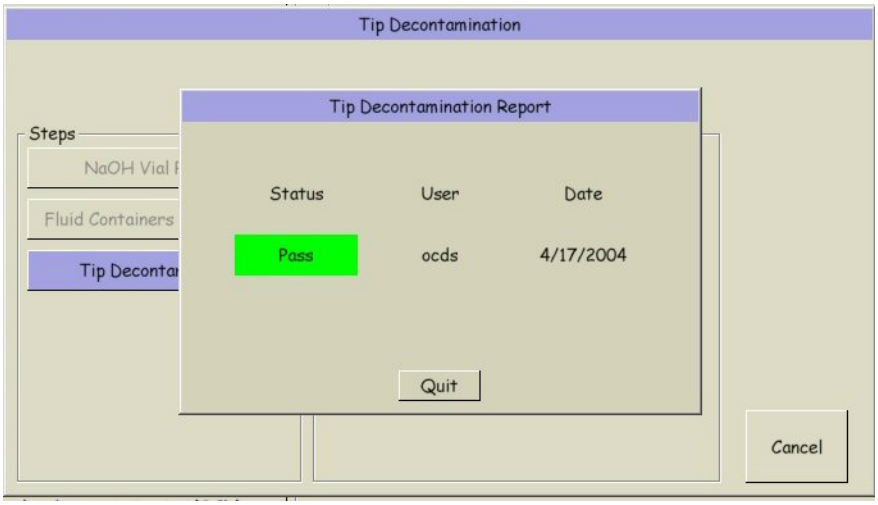
Figure 8-5



To execute the Tip Decontamination procedure (continued)

4 When the tip decontamination completes, a report with the completion status of the maintenance procedure displays. The report displays a status of **Pass** if the maintenance procedure was successful or a status of **Fail** if it was unsuccessful.

Figure 8-6



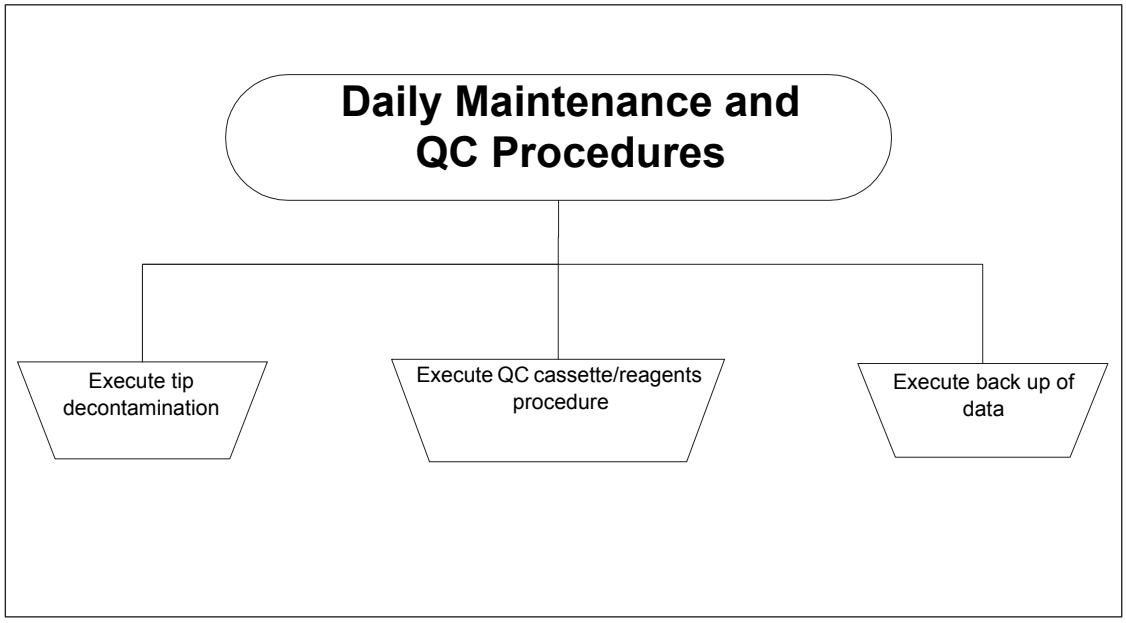
Note: You must touch **Continue** before you can open the Main Cover to remove the NaOH vial.

Section A: Daily Maintenance and QC Procedures

Execute the following procedures at the end of each testing day. The procedures include tasks to execute using the software as well as manual maintenance tasks.

⚠ Follow laboratory procedures and use protective gloves and a face shield when flushing the system with NaOH.

Figure 8-7



To perform daily maintenance and QC procedures

1 On the **Maintenance** screen, touch the **Tip Decontamination** button to execute the tip decontamination procedure. Follow the instructions as displayed on the wizard.

Result: The system decontaminates the inside of the pipette tip and the washable sections of the wash station with 0.1N NaOH.

For the deep well

Result: The system dispenses approximately 10 mL of a 0.1 N NaOH solution into the deep-dish wash station and then approximately 30 mL of distilled or deionized water.

For the shallow well

Result: The system dispenses approximately 5 mL of a 0.1 N NaOH solution into the shallow wash station and then approximately 15 mL of distilled or deionized water.

Note: Inspect for leaks during flush. Tighten all connections, if necessary. Leave instrument filled with distilled or de-ionized water overnight. The system is automatically flushed with distilled water during shut down.

2 Empty waste cassettes from the Waste Container.

3 Fill liquid containers as needed.

⚠ Ensure sufficient liquid levels in the fluid containers so that the pump and the syringe can dispense liquid properly. When liquid levels are low, the pump and syringe can splash the instrument parts causing potential contamination.

4 Touch the **QC Cassettes/Reagents** button to execute the QC procedure. Follow the instructions displayed on the wizard.

5 Ensure that a backup of data has been performed. The system automatically backups data on a daily basis. Refer to "Data Back Up/Restore and LIS Communication" on page 9-1.

Empty Waste Cassettes from the Waste Container

AutoVue tracks cassette waste by counting the number of cassettes used, and prompts you to empty the cassette waste container when it is full. This information displays in the **Status** screen, **Required** tab.

Note: Always empty the waste container before beginning a test routine. Periodically inspect the waste container during long test runs to ensure that the waste container does not overflow.

Note: If greater than 225 cassettes are in the Waste Basket, the software indicates this by highlighting this on the **Status** screen, **Resources** tab. The operator must empty the cassettes from the Waste Basket as soon as possible.

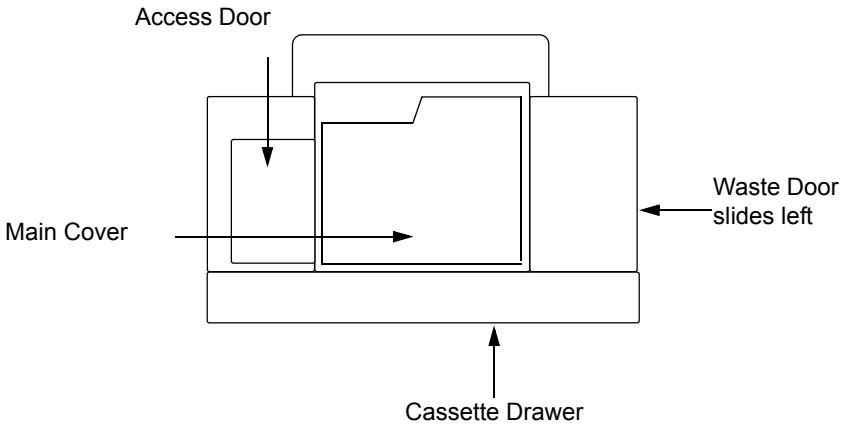
Biohazard: Use caution when emptying the waste container. Used cassettes that you review manually contain biohazardous material. Follow your laboratory's safety procedures for handling biohazardous waste when handling used cassettes.

To empty the waste container

1. Touch the **Waste Door** button to open the Waste Door.

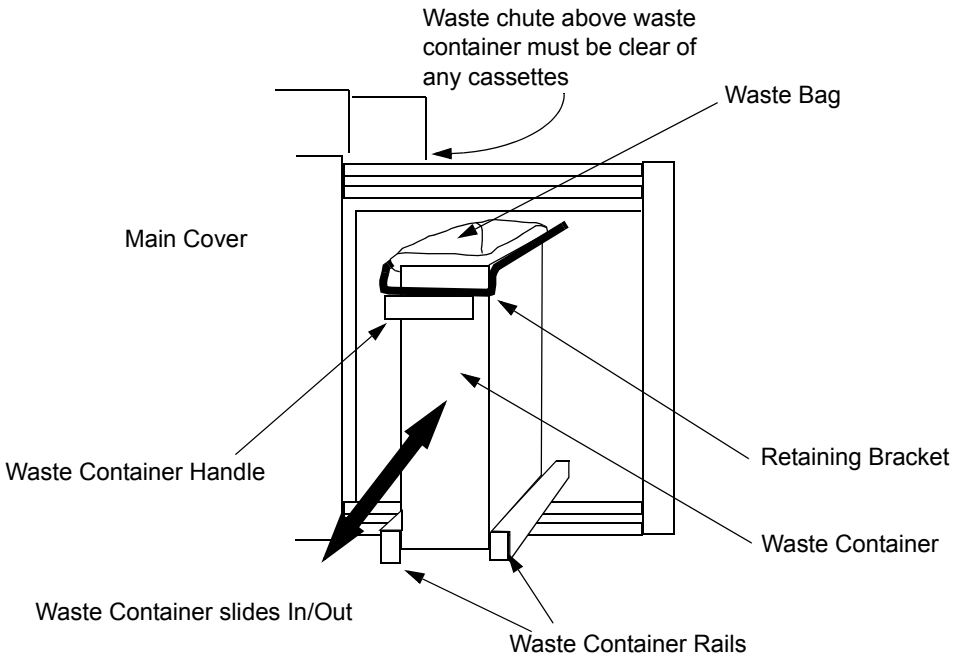
   Result: AutoVue unlocks the Waste Door.

2. Slide open the waste door to the left to reveal the waste container.



To empty the waste container (continued)

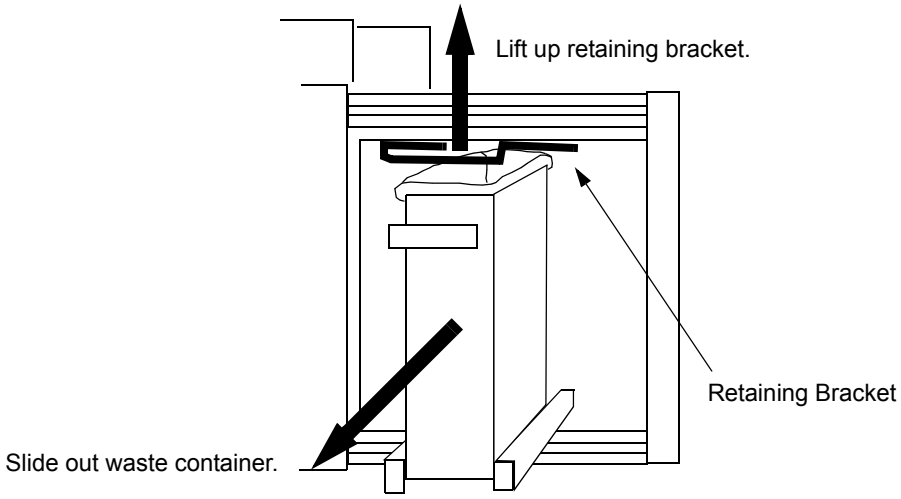
3 Slide the waste container out as shown.



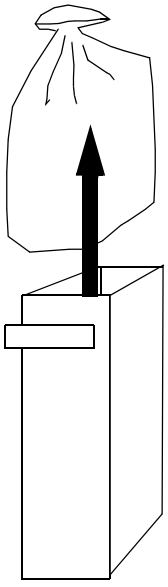
4 Ensure the waste chute is free of jammed cassettes. Remove any jammed cassettes in the chute.

To empty the waste container (continued)

5 Slide out the waste container and lift up the retaining bracket.



6 Remove the waste bag.



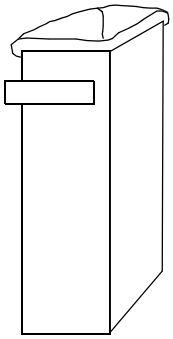
To empty the waste container (continued)

7 Discard the waste bag.

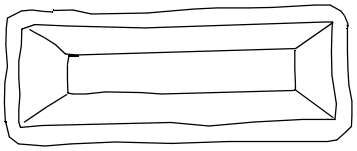
The cassette waste is a biohazard. Discard this waste according to laboratory guidelines for disposing of biohazardous waste.

8 Insert a new waste bag. Use a 20-liter waste bag.

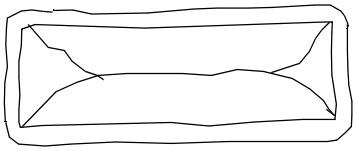
Note: Ensure the bag is inside the waste container and is close to the sides of the container as shown in the diagram. If the bag is away from the sides, the volume is reduced, and the likelihood of cassette jam is greater.



Top View - Correctly Inserted: Bag is close to sides of container

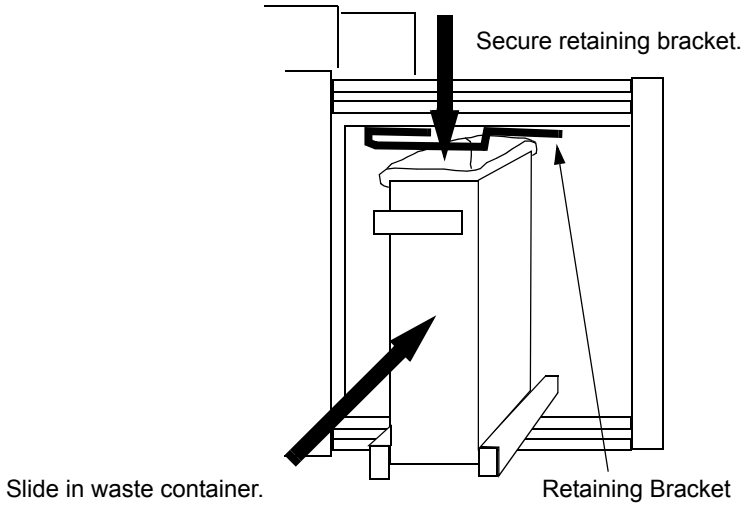


Top View - Incorrectly Inserted: Bag is away from sides of container



To empty the waste container (continued)

9 Secure the retaining bracket and slide waste container back into the instrument.



Note: The system will not detect the absence of the waste container. Ensure container is present prior to starting batches.

10 Manually close the Waste Door.

Note: The system automatically resumes sample processing after you open and close the Waste Door.

Empty Liquid Waste

Warning messages are displayed in the **Status** screen, **Required** tab to let you know that the saline/water container is empty and the waste container is full. The operator can visually inspect containers at the beginning of the day and at regular intervals to fill system liquids and empty waste for test routines.

Note: Distilled water is not used during normal test routines; therefore, AutoVue does not continuously monitor the level of distilled water. The system only checks fluid level:

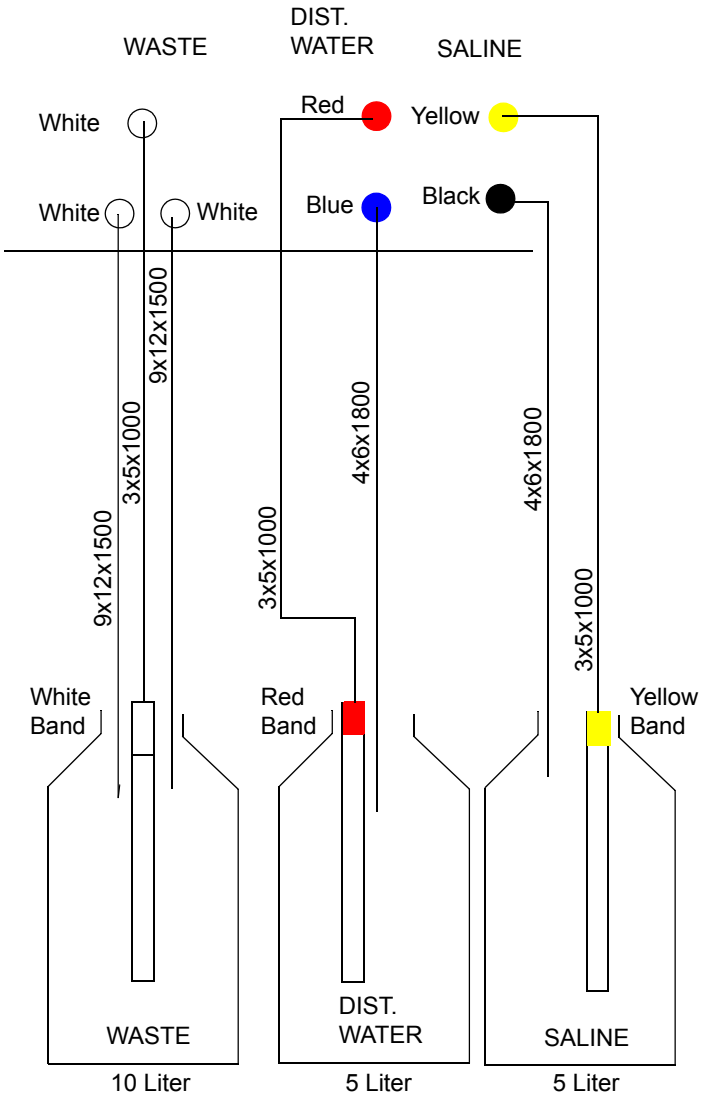
- During initialization of the system
- Prior to a flush that utilizes distilled water
- During a system shutdown

⚠ Caution: Do not intermix the fluid connections in AutoVue. Use caution when handling fluid connections. Ensure there are no leaks in tubing or connections. System fluids should not be changed while routines are running.

To empty liquid waste

1 Confirm that no test routine is running.

2 Remove the connections for the fluid waste container.



3 Dispose of the fluid waste according to your laboratory's guidelines for handling fluid waste and clean container.

4 Restore the waste fluid connections.

Section B: Quality Control Planning

Two types of QC procedures are available:

- Internal QC using controls as samples when running test routines on the system
- Cassette/reagent QC using an OCD quality control reagent kit

Ortho-Clinical Diagnostics recommends that QC procedures be performed at least once a day. Frequency and type of QC should conform to local standards of practice and local regulations.

Internal QC for Analytical Process

To use controls for internal QC, refer to "Registering and Loading Consumables and Samples/Controls" on page 6-1.

Cassette/reagent QC using and OCD Quality Control Reagent Kit

ORTHO AutoVue *Innova/Ultra* provides flexibility in performing cassette and reagent quality control based on the cassettes and reagents that a laboratory normally uses in routine testing. Therefore, many of the quality control tests perform the same function - to provide a positive control and a negative control for as many wells as possible of a specific cassette type. The type of reagent used to perform the QC test will depend upon the type of reagent a laboratory routinely uses. For example, *BRC Surg Rh-hr, BRC Sel Rh-hr, BRC Pap Rh-hr,* and *BRC Fic Rh-hr* all perform the same function - a positive and negative control for most wells of the Rh-hr (11) cassette. If a laboratory only uses a 3-cell screening test, the *BRC Surg Rh-hr* to test the Rh-hr (11) cassette would be selected.

Since positive and negative controls are needed to perform the QC Cassettes/ Reagents procedure, a laboratory's reagent inventory will not be able to cover this requirement. Ortho-Clinical Diagnostics has designed the Blood Bank Reagent Control (BRC) Kit which contains reagent red cells and antisera, and supplements a laboratory's reagent inventory for performance of the QC Cassettes/Reagents procedure.

Note: The Cassette Drawer can only accommodate up to 12 different Cassette Sleeves at one time. Therefore, all cassette types may not be included within one Cassette Drawer loading or all reagents with one Reagent Rack loading. If all are not included, the QC Cassettes/Reagents QC procedure will need to be repeated to include all cassettes and reagents.

Table 8-1 Cassettes/Reagents Required for Quality Control Groupings

QC Test for...	QC Profile or Required Single Tests for Complete Testing[a]	QC Tests in Profile	Required Consumables	
			Cassettes	Reagents
ABO-Rh/Rvs Cassette Site will select one of these four test groupings.	BRC 00 Neg BRC 00 Surg Pos	Not Applicable – Two Separate Single Tests	00	BRC-S1, BRC-S2, BRC-E3, A_1, B, Surg 1
	BRC 00 Neg BRC 00 Sel Pos	Not Applicable – Two Separate Single Tests		BRC-S1, BRC-S2, BRC-E3, A_1, B, Sel I
	BRC 00 Neg BRC 00 Pap Pos	Not Applicable – Two Separate Single Tests		BRC-S1, BRC-S2, BRC-E3, A_1, B, Pap Unt 1
	BRC 00 Neg BRC 00 Fic Pos	Not Applicable – Two Separate Single Tests		BRC-S1, BRC-S2, BRC-E3, A_1, B, Fic Unt 1
ABD Cassette Site will select one of these four tests.	BRC ABD Surg	Not Applicable – Single Test	10	BRC-E3, A_1, B, Surg 1
	BRC ABD Sel	Not Applicable – Single Test		BRC-E3, A_1, B, Sel I
	BRC ABD Pap	Not Applicable – Single Test		BRC-E3, A_1, B, Pap Unt 1
	BRC ABD Fic	Not Applicable – Single Test		BRC-E3, A_1, B, Fic Unt 1
Newborn Cassette Site will select one of these four profiles.	BRC Surg Newborn	BRC Newborn Neg BRC Newborn Surg BRC 20 B of A+B	20	BRC-E3, A_1, B, Surg 1
	BRC Sel Newborn	BRC Newborn Neg BRC Newborn Sel BRC 20 B of A+B		BRC-E3, A_1, B, Sel I
	BRC Pap Newborn	BRC Newborn Neg BRC Newborn Pap BRC 20 B of A+B		BRC-E3, A_1, B, Pap Unt 1
	BRC Fic Newborn	BRC Newborn Neg BRC Newborn Fic BRC 20 B of A+B		BRC-E3, A_1, B, Fic Unt 1
ADK Cassette Site will select one of these four profiles.	BRC Surg ADK	BRC ADK Neg BRC ADK Surg	40	BRC-E1, BRC-E3, A_1, B, Surg 1
	BRC Sel ADK	BRC ADK Neg BRC ADK Sel		BRC-E1, BRC-E3, A_1, B, Sel I
	BRC Pap ADK	BRC ADK Neg BRC ADK Pap		BRC-E1, BRC-E3, A_1, B, Pap Unt 1
	BRC Fic ADK	BRC ADK Neg BRC ADK Fic		BRC-E1, BRC-E3, A_1, B, Fic Unt 1

Table 8-1 Cassettes/Reagents Required for Quality Control Groupings (continued)

QC Test for...	QC Profile or Required Single Tests for Complete Testing[a]	QC Tests in Profile	Required Consumables	
			Cassettes	Reagents
ABO-Rh Cassette Site will select one of these four profiles	BRC Surg ABO-Rh	BRC ABO-Rh Neg BRC ABO-Rh Surg BRC ABO-Rh E BRC ABO-Rh C	44	BRC-E1, BRC-E2, BRC-E3, A_1, B, Surg 1
	BRC Sel ABO-Rh	BRC ABO-Rh Neg BRC ABO-Rh Sel BRC ABO-Rh E BRC ABO-Rh C		BRC-E1, BRC-E2, BRC-E3, A_1, B, Sel I
	BRC Pap ABO-Rh	BRC ABO-Rh Neg BRC ABO-Rh Pap BRC ABO-Rh E BRC ABO-Rh C		BRC-E1, BRC-E2, BRC-E3, A_1, B, Pap Unt 1
	BRC Fic ABO-Rh	BRC ABO-Rh Neg BRC ABO-Rh Fic BRC ABO-Rh E BRC ABO-Rh C		BRC-E1, BRC-E2, BRC-E3, A_1, B, Fic Unt 1
Reverse Cassette, A_1, and B Cells	BRC Rvs 2 cell	Not Applicable – Single Test	66	BRC-S1, BRC-S2, A_1, B
Reverse Cassette, A_1, A_2, and B Cells	BRC Rvs 3 cell	Not Applicable – Single Test		BRC-S1, BRC-S2, A_1, A_2, B
Reverse Cassette, A_1, B, and O Cells	BRC Rvs A1,B,O	Not Applicable – Single Tests		BRC-S1, BRC-S2, A_1, B, O
Reverse Cassette, A_1, A_2, B, and O cells	BRC Rvs 4 Neg BRC Rvs 4 Pos	Not Applicable – Two Separate Single Tests		BRC-S1, BRC-S2, A_1, A_2, B, O,
Reverse Cassette, A_1, A_2, B, O, and Selectogen cells	BRC Rvs 6 Neg BRC Rvs 6 Pos	Not Applicable – Two Separate Single Tests		BRC-S1, BRC-S2, BRC-S3, A_1, A_2, B, O, Sel I, Sel II
Rh-hr Cassette Site will select one of these four profiles	BRC Surg Rh-hr	BRC Rh-hr Surg Neg BRC Rh-hr Surg Pos	11	BRC-E1, BRC-E2, BRC-E3, Surg 1, Surg 2
	BRC Sel Rh-hr	BRC Rh-hr Sel Neg[b] BRC Rh-hr Sel Pos		BRC-E1, BRC-E2, BRC-E3, Sel I, Sel II
	BRC Pap Rh-hr	BRC Rh-hr Pap Neg BRC Rh-hr Pap Pos		BRC-E1, BRC-E2, BRC-E3, Pap Unt 1, Pap Unt 2
	BRC Fic Rh-hr	BRC Rh-hr Fic Neg BRC Rh-hr Fic Pos		BRC-E1, BRC-E2, BRC-E3, Fic Unt 1, Fic Unt 2
Rh/K Cassette	BRC Surg Rh/K	BRC Rh/K Surg Neg BRC Rh/K Pos	77	BRC-E1, BRC-E2, BRC-E3, Surg 1, Surg 2

Table 8-1 Cassettes/Reagents Required for Quality Control Groupings (continued)

QC Test for...	QC Profile or Required Single Tests for Complete Testing[a]	QC Tests in Profile	Required Consumables	
			Cassettes	Reagents
Site will select one of these four profiles	BRC Sel Rh/K	BRC Rh/K Sel Neg[b] BRC Rh/K Pos		BRC-E1, BRC-E2, BRC-E3, Sel I, Sel II
	BRC Pap Rh/K	BRC Rh/K Pap Neg BRC Rh/K Pos		BRC-E1, BRC-E2, BRC-E3, Pap Unt 1, Pap Unt 2
	BRC Fic Rh/K	BRC Rh/K Fic Neg BRC Rh/K Pos		BRC-E1, BRC-E2, BRC-E3, Fic Unt 1, Fic Unt 2
Poly Cassette, Surgiscreen, and BLISS	BRC Surg Poly Ltd	BRC 3 Poly Ltd BRC C3d Poly	22	BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Surg 1, Surg 2, Surg 3
Poly Cassette, Selectogen, and BLISS	BRC Sel Poly	BRC 2 Poly BRC C3d Poly		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Sel I, Sel II
Poly Cassette, Untreated Papain Cells, and BLISS	BRC Unt Pap Poly	BRC BVSP Poly Ltd BRC C3d Poly		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Pap Unt 1, Pap Unt 2, Pap Unt 3
Poly Cassette, Untreated Ficin Cells, and BLISS	BRC Unt Fic Poly	BRC BVSF Poly Ltd BRC C3d Poly		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Fic Unt 1, Fic Unt 2, Fic Unt 3
DAT/IDAT Cassette - Direct Tests[c]	BRC C3d DAT	Not Applicable – Single Test	30	BRC-E5
IAT/IDAT Cassette - Indirect Tests Site will select one of these four tests[d]	BRC IAT Surg	Not Applicable – Single Test		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Surg 1
	BRC IAT Sel	Not Applicable – Single Test		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Sel I
	BRC IAT Pap	Not Applicable – Single Test		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Pap Unt 1
	BRC IAT Fic	Not Applicable – Single Test		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Fic Unt 1
IgG Cassette, Surgiscreen, and BLISS	BRC 3 IgG Ltd	Not Applicable – Single Test	33	BLISS, BRC-S1, diluted BRC-S3, Surg 1, Surg 2, Surg 3
IgG Cassette, Selectogen, and BLISS	BRC 2 IgG	Not Applicable – Single Test		BLISS, BRC-S1, diluted BRC-S3, Sel I, Sel II

Table 8-1 Cassettes/Reagents Required for Quality Control Groupings (continued)

QC Test for...	QC Profile or Required Single Tests for Complete Testing[a]	QC Tests in Profile	Required Consumables	
			Cassettes	Reagents
IgG Cassette, Untreated Papain Cells, and BLISS	BRC BVSP IgG Ltd	Not Applicable – Single Test		BLISS, BRC-S1, diluted BRC-S3, Pap Unt 1, Pap Unt 2, Pap Unt 3
IgG Cassette, Untreated Ficin Cells, and BLISS	BRC BVSF IgG Ltd	Not Applicable – Single Test		BLISS, BRC-S1, diluted BRC-S3, Fic Unt 1, Fic Unt 2, Fic Unt 3
Poly/Neutral Cassette, Papain BioVue Screen kit, and BLISS	BRC 55 Pap Neg BRC 55 Pap Pos BRC C3d Poly/Neut	Not Applicable – Three Separate Single Tests	55	BLISS, BRC-S1, diluted BRC-S3, BRC-E5
Poly/Neutral Cassette, Papain BioVue Screen kit, and BLISS	BRC 55 Fic Neg BRC 55 Fic Pos BRC C3d Poly/Neut	Not Applicable – Three Separate Single Tests		BLISS, BRC-S1, diluted BRC-S3, BRC-E5, BioVue Screen Ficin kit - all cells
Neutral Cassette, Treated cells Papain, or Ficin	BRC 88 Pap	Not Applicable – Single Test	88	BRC-S1, BRC-S3, Pap Trt 1, Pap Trt 2, Pap Trt 3
Site will select one of these two tests	BRC 88 Fic	Not Applicable – Single Test		BRC-S1, BRC-S3, Fic Trt 1, Fic Trt 2, Fic Trt 3

a. Some required single tests are combined by Ortho-Clinical Diagnostics into a profile. However, some combinations of single tests (00 cassette, 4 and 6 cell reverse on a 66 cassette, and 55 cassette) must be independently selected. Complete QC Pass/Fail decision requires manual review of each single test and the selection of satisfactory/unsatisfactory for the cassette lot from within the last test performed for that cassette. For example: a 6 cell reverse is performed, and the BRC Rvs 6 Neg is run first followed by the BRC Rvs 6 Pos. The BRC Rvs 6 Neg result is unsatisfactory and the BRC Rvs 6 Pos result is satisfactory. An unsatisfactory result must be selected for the BRC Rvs 6 Pos in order for this cassette lot to be considered failed for use.

b. Selectogen cells may include antigens for e and c. Therefore, it is not guaranteed that a negative control will be achieved if Selectogen cells are used. If the e and c wells are positive in this test, check the antigen profile included with the lot of Selectogen cells used to determine if the positive was an expected result.

c. The DAT/IDAT cassette can be used for direct antiglobulin testing and indirect antiglobulin testing. Use one of these four QC procedures when performing direct antiglobulin testing.

d. The DAT/IDAT cassette can be used for direct antiglobulin testing and indirect antiglobulin testing. Use one of these four QC procedures when performing indirect antiglobulin testing.

Note: The optional tests all test the Anti-D in a cassette column against a D^u (weak D) cell. This testing is not required for quality control of the cassette. However, it is included as an option for those laboratories that wish to test for this affinity.

Table 8-2 Cassettes/Reagents Optional Quality Control Groupings

QC Test for...	QC Profile	QC Tests in Profile	Required Consumables	
			Cassettes	Reagents
ABO-Rh/Rvs Cassette	BRC 00 WkD	Not Applicable – Single Test	00	BRC-E4
ABD Cassette	BRC 10 WkD	Not Applicable – Single Test	10	BRC-E4
Newborn Cassette	BRC 20 WkD	Not Applicable – Single Test	20	BRC-E4
ADK Cassette	BRC 40 WkD	Not Applicable – Single Test	40	BRC-E4
ABO-Rh Cassette	BRC 44 WkD	Not Applicable – Single Test	44	BRC-E4
Rh-hr Cassette	BRC 11 WkD	Not Applicable – Single Test	11	BRC-E4

Preparation of Dilute Anti-D Reagent

The Anti-D (BRC-S3) Reagent in the Blood Bank Reagent Control (BRC) Kit must be diluted with normal saline solution for QC testing of Anti-IgG (33) and Anti-IgG, -C3d; polyspecific (22) cassettes.

To perform this test, follow instructions for using reagents without bar code labels. Refer to "Load Reagent Vial(s)" on page 6-9.

Note: Use Anti-D (BRC-S3) Reagent undiluted for other QC tests that require this reagent.

Cassettes/Reagents QC Procedure

Ortho-Clinical Diagnostics recommends QC Cassettes/Reagents be performed daily.

Note: When a QC Cassettes/Reagents procedure fails for one reagent or cassette, all reagents and cassettes in the test fail. In this case, follow the procedures of your laboratory.

Note: If the time limit for performing a BRC profile has expired, the BRC results must be accepted in the Worklist after the profile is run.

Materials required:

- Cassettes from your laboratory inventory (for each cassette type and from each lot) used in ORTHO AutoVue *Innova/Ultra* testing.
- Reagents from your laboratory inventory (of each reagent type and every lot) used in ORTHO AutoVue *Innova/Ultra* testing.
- Blood Bank Reagent Control (BRC) Kit. The lots for these controls must be registered into ORTHO AutoVue *Innova/Ultra* similar to other reagents.

  Note: Refer to Table 8-1, “Cassettes/Reagents Required for Quality Control Groupings,” on page 17.
- If the time limit for performing a BRC profile has expired, the BRC results must be accepted in the Worklist after the profile is run.

	To execute the QC Cassette/Reagents procedure
1	Load cassette sleeves in the Cassette Drawer. Refer to “Loading Cassettes” on page 6-17.
2	Load reagents on the Reagent Rack. Refer to “Registering and Loading Reagents and Dilution Plate(s)” on page 6-3.

To execute the QC Cassette/Reagents procedure (continued)

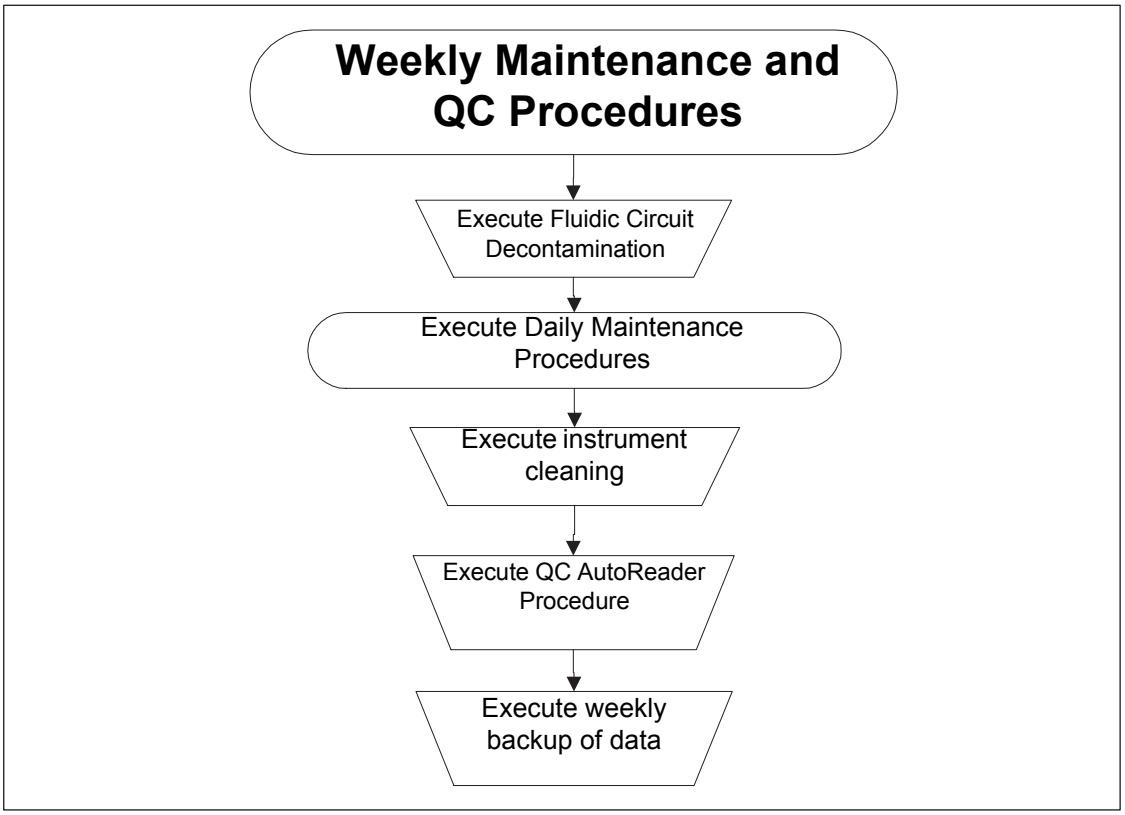
3 On the **Maintenance** screen, touch the **QC Cassette/Reagents** button to execute the maintenance procedures. Follow instructions as described in the wizard to run a BRC profile routine, integrate results, and print results.

Note: The frequency of the QC Cassette/Reagents procedure is determined by your laboratory standards and configured in AutoVue by your system administrator in the **Setup** screen, **Maintenance** tab.

Section C: Weekly Maintenance Procedure

Perform the following procedures once per week.

Figure 8-8



To perform weekly maintenance procedures

1. Perform steps 2-4 as described under Daily Maintenance Procedures on page "Daily Maintenance and QC Procedures" on page 8-7.

2. On the **Maintenance** screen, touch the **Fluidic Circuit Decontamination** button to execute the fluidic circuit decontamination procedure for cleaning fluidic lines. Follow the instructions as displayed on the screens. Some steps require user intervention.

   - Replace saline and distilled/deionized water containers with the 0.1 N NaOH containers. Perform a series of five flushes using the water line and five flushes using the saline line. See "Flush the Instrument" on page 8-48.

   ⚠ 0.1 N NaOH is a hazardous material. Refer to manufacturer's Material Safety Data Sheet for specific health and safety information prior to handling.

   - Remove the 0.1 N NaOH containers from the system and replace with two containers containing distilled/deionized water. Perform a series of ten flushes using the distilled water line and ten flushes using the saline line.

   - Replace container on saline line with a container filled with 0.9% saline.

   Note: Prior to restart of testing, make sure a minimum of two flushes has been performed with saline to completely displace all non-salt solution in the saline fluid path. See "Flush the Instrument" on page 8-48.

3. Touch the **QC AutoReader** button to execute the QC procedure. Refer to "AutoReader QC Procedure" on page 8-27.

To perform weekly maintenance procedures (continued)

4 On the Maintenance screen, touch the **Instrument Cleaning** button to execute the instrument cleaning procedures:

- Clean the waste tubing with 70% isopropanol.
- Check Teflon® coating and clean the tip gently with a cloth soaked in 70% isopropanol. If damage is noted, replace tip.
- Wipe down parts of the instrument including the wash station edges; sample/reagent rotor; CASUNCA; dilution plates area; liquid tubing; autorotor and the cassette waste container with a cloth soaked in 70% isopropanol or mild detergent.

Use the **Rotate** button on the **Sample** screen to rotate sample racks and remove them from the instrument.

5 Ensure that the weekly backup of data has been performed. The system automatically performs a weekly backup of data in addition to the daily backup. Refer to "Data Back Up/Restore and LIS Communication" on page 9-1.

AutoReader QC Procedure

The AutoReader QC procedure is used to check the calibration of the AutoReader including:

- The loss of luminosity of the lamps
- Noise of the electronic components

Wait 30 minutes after the system has initialized to start the QC AutoReader procedure.

Materials required

- ORTHO AutoVue *Innova/Ultra* System Calibration Cassette

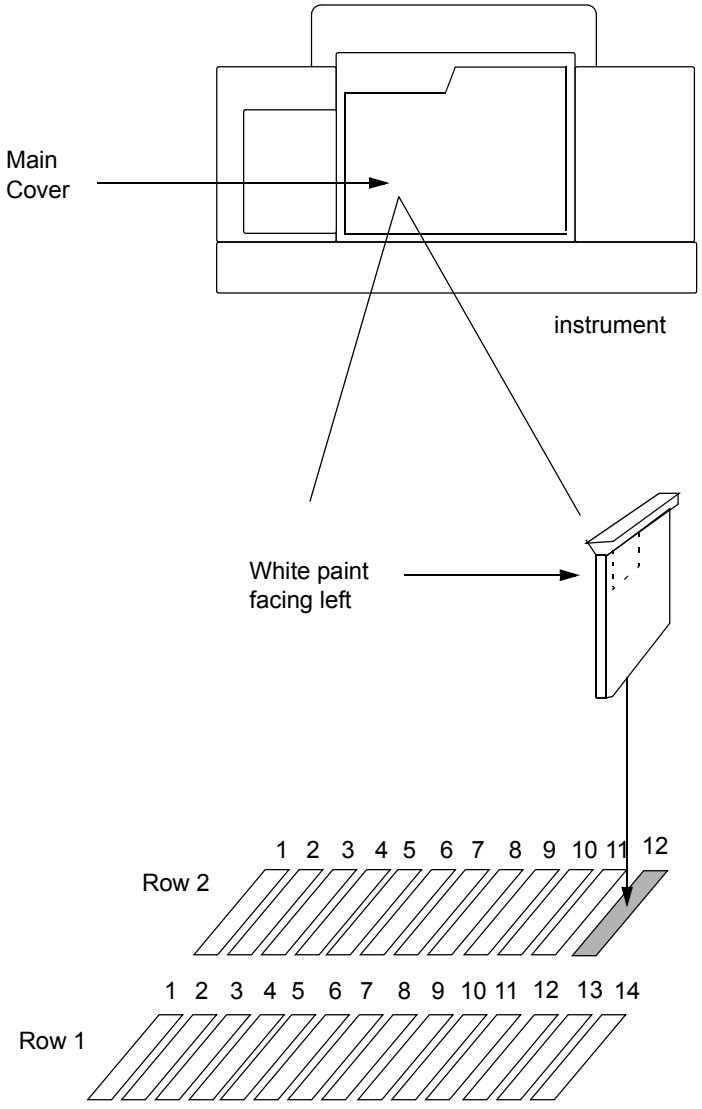
Ensure that the calibration cassette is clean before performing this procedure. Wipe the calibration cassette carefully with lens paper if necessary.

To execute the AutoReader QC procedure

1 Open the Main Cover.

2 Insert the calibration cassette into position 12 with the white paint facing left as shown.

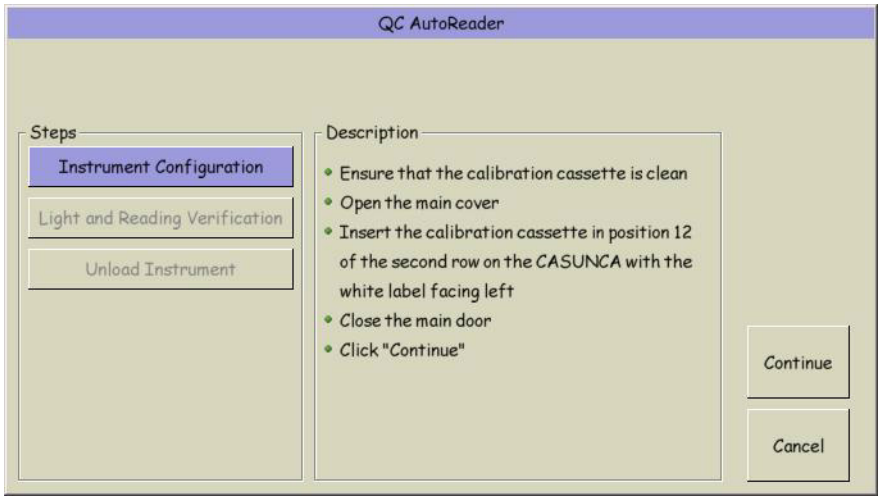
Note: Operator should wear gloves, so as not to leave finger prints on the calibration cassette



3 Manually close the Main Cover.

To execute the AutoReader QC procedure (continued)

4 On the **Maintenance** screen, touch the **QC AutoReader** button and then touch the **Execute** button to display the **QC AutoReader** dialog box. Follow the instructions on the screen to initiate the QC AutoReader procedure.



Result: AutoVue loads the calibration cassette into the AutoReader and begins the QC test.

⚠ If the glass calibration cassette is broken during AutoReader QC, follow universal and standard precautions for handling broken glass.

5 If the QC AutoReader test:

Passes: Then a “Pass” message displays.

Fails: Then a “Fail” message displays.

Note: If the AutoReader QC fails, call the local Ortho-Clinical Diagnostics service representative immediately. AutoVue testing may continue, but reading and interpretation must be verified manually.

You may be instructed to select the **Reset to Default** button in the **QC AutoReader report** window. This will reset the AutoReader gain and offset to the original default values. This will also set the QC AutoReader result to Fail, requiring that the QC procedure be repeated.

⚠ Users should not select the **Reset to Default** button unless instructed to do so by OCD personnel.

6 Remove the calibration cassette and manually close the Main Cover.

Section D: Six Month Maintenance Procedures

Ortho-Clinical Diagnostics recommends that the following procedures be performed every six months:

- QC pipettor position (Every six months *or* each time the pipette tubing or tip is replaced)
- QC pipette volume (Every six months *or* each time the pipette tubing or tip is replaced)
- QC Incubator (OCD service personnel only)
- QC Centrifuge (OCD service personnel only)
- Puncher Decontamination (OCD service personnel only)

The following error message displays if an operator with insufficient privileges attempts to execute the QC procedures mentioned above:

If you receive this error, contact an authorized individual to complete the procedures.

QC Pipettor Position Procedure

The QC pipettor position procedure is used to check the positions of the pipette including:

- The XY position
- Z position

OCD recommends that an advanced operator adjust the pipette position if the:

- Operator has changed the tip
- The tip was bent during pipetting, for example, if the cap on a reagent was not removed.

Materials required

- No additional materials are required.

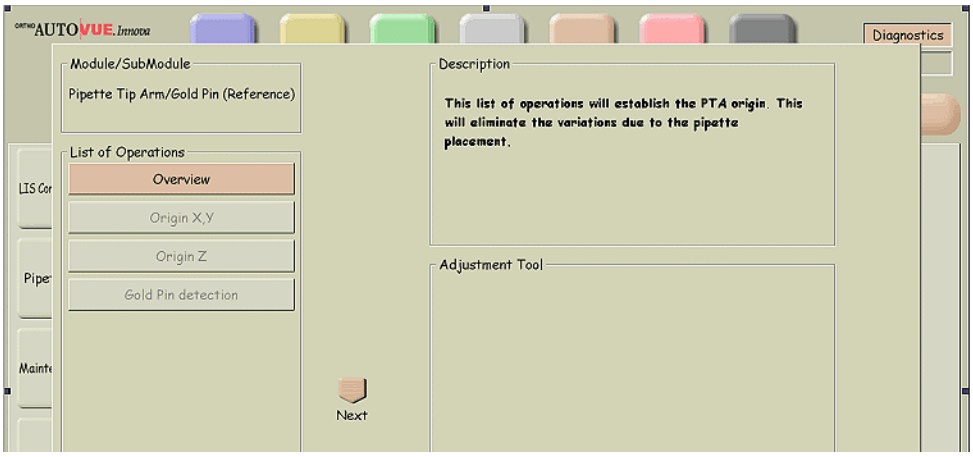
If the user is unable to adjust the pipette to the correct X, Y and Z position, the system is unavailable for testing. Contact OCD service personnel to adjust the pipette position.

To adjust the pipette position

1 Open the Main Cover.

2 When the system checks the pipette position, if the pipette tip is not positioned correctly, the software wizard for adjusting the **Pipette Tip Arm (Gold Pin reference)** automatically displays:

Figure 8-9



On this screen:

- Read an overview description of the procedure. Note that the **Overview** button is highlighted.
- Touch the **Next** button to proceed to the next screen **Origin X,Y**.

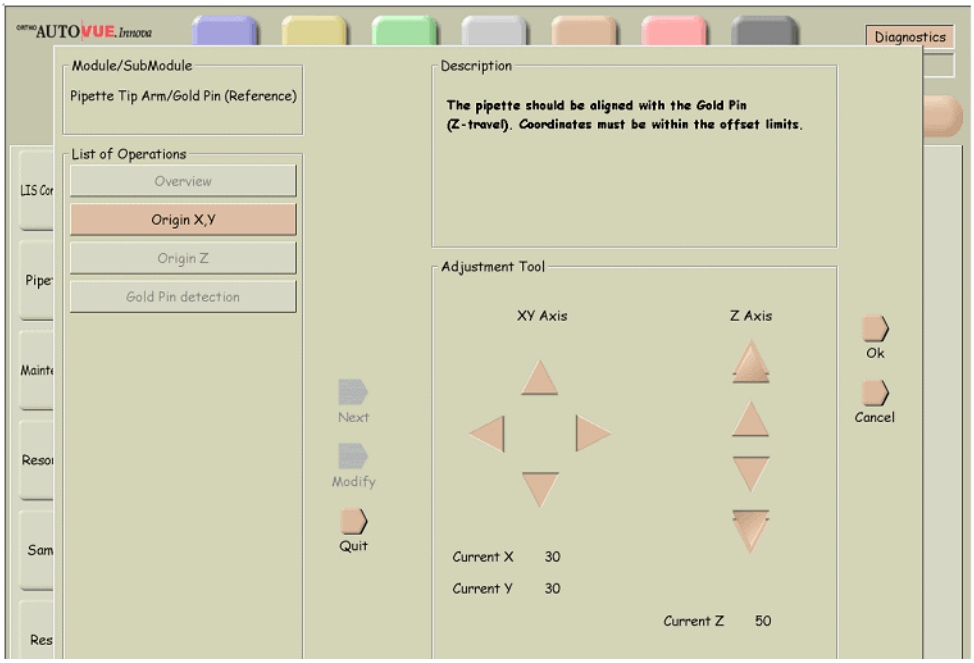
To adjust the pipette position (continued)

3 In the **Origin X,Y** screen, adjust the X and Y positions of the pipette.

Touch **Modify** and use the adjustment buttons. Touch **Ok** to accept changes.

The modified X and Y coordinates display.

Figure 8-10



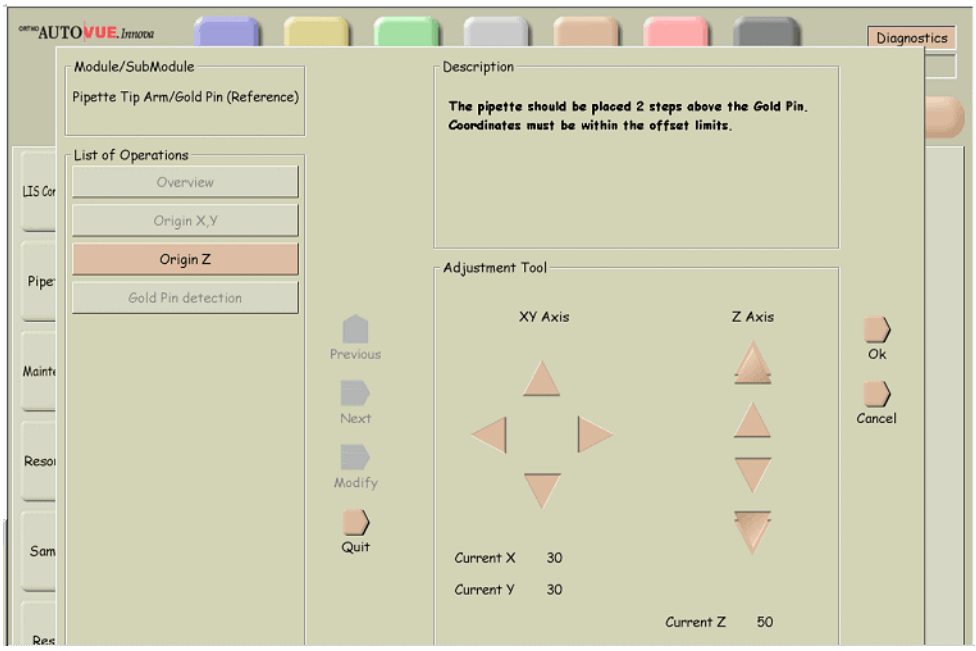
Touch **Next** to proceed to the **Origin Z** screen.

To adjust the pipette position (continued)

4 In the **Origin Z** screen, touch **Modify** to adjust the Z position of the pipette using the adjustment buttons and touch **Ok** to accept changes.

The modified Z coordinate displays.

Figure 8-11

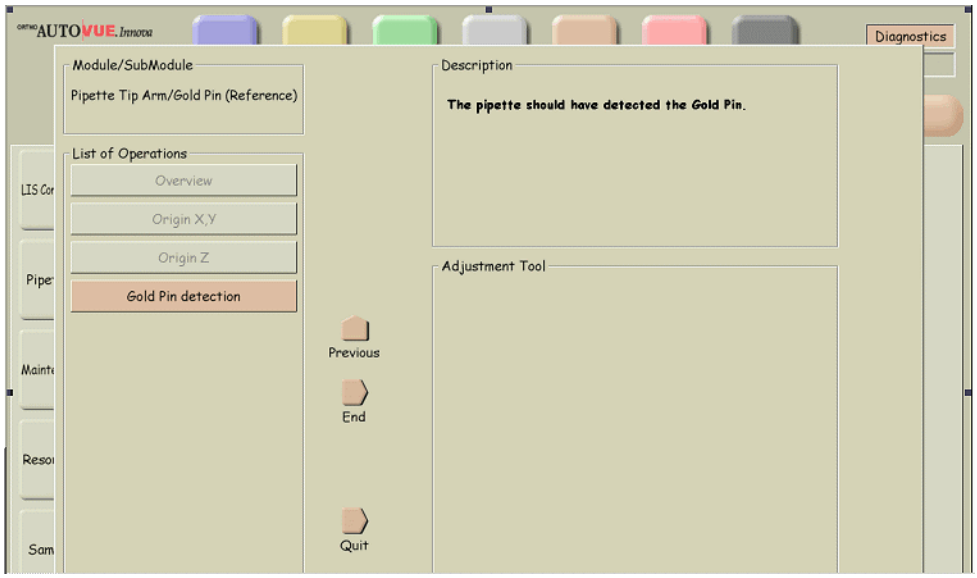


Touch **Next** to proceed to the **Gold Pin reference** screen.

To adjust the pipette position (continued)

5 Touch **End**. The system will attempt to detect the Gold Pin position again.

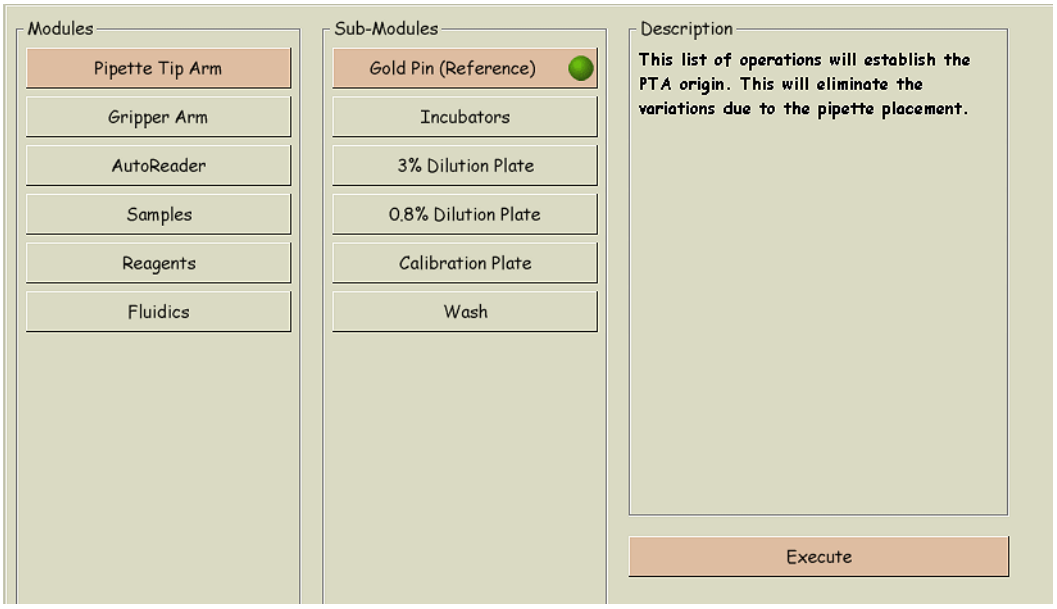
Figure 8-12



To adjust the pipette position (continued)

6 If pipette tip arm is positioned correctly, then the following screen displays with the symbol:

Figure 8-13



If the pipette tip arm is incorrectly positioned, then the message **Gold Pin Not Detected** displays and the symbol displays in the screen above.

Touch **Execute** if needed to return to the software wizard for the **Pipette Tip Arm Gold Pin (Reference)** to re-adjust the X, Y, or Z coordinates.

QC Volume Procedure

The QC Volume procedure is used to check that the system is able to dispense liquid with the expected accuracy and precision.

OCD recommends that an advanced operator perform the QC volume procedure:

- Every 6 months or
- After the pipette tip or tip tubing has been replaced

Materials required

- Calibration plate provided by OCD
- at least 2 L of saline in the fluid container
- 10 mL vial of saline

Prerequisite

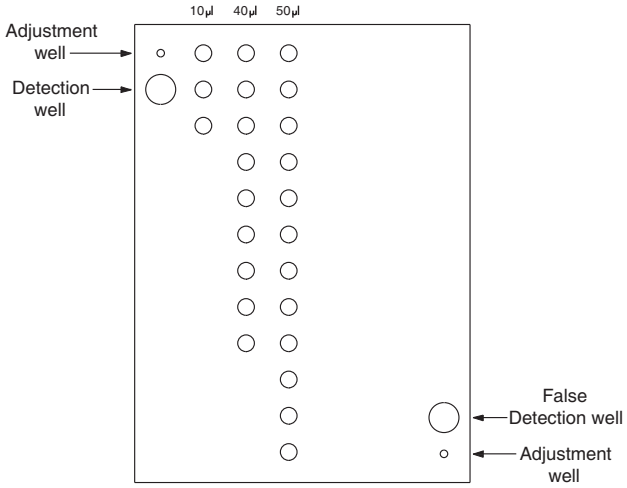
Before you begin the QC Volume procedure, complete the following:

- Power the instrument off and on
- Clean the probe using saline solution to remove any residue
- Completely dry the microplate
- Load the 10 mL vial of saline in position 14 of the Reagent Rack

To complete the QC Volume procedure, the system must first check the X, Y, and Z positions of the pipette tip arm in relation to the adjustment well position on the calibration plate provided by OCD. See Figure 8-14, on page 8-38. The adjustment well position is used by the system to check the X, Y, and Z positions of the pipette tip arm. The other wells are used to perform the QC Volume procedure.

OCD configures instruments in your laboratory for use with a specific calibration plate. This calibration plate is to be used with multiple instruments. If a new calibration plate is required, contact OCD service personnel.

Figure 8-14

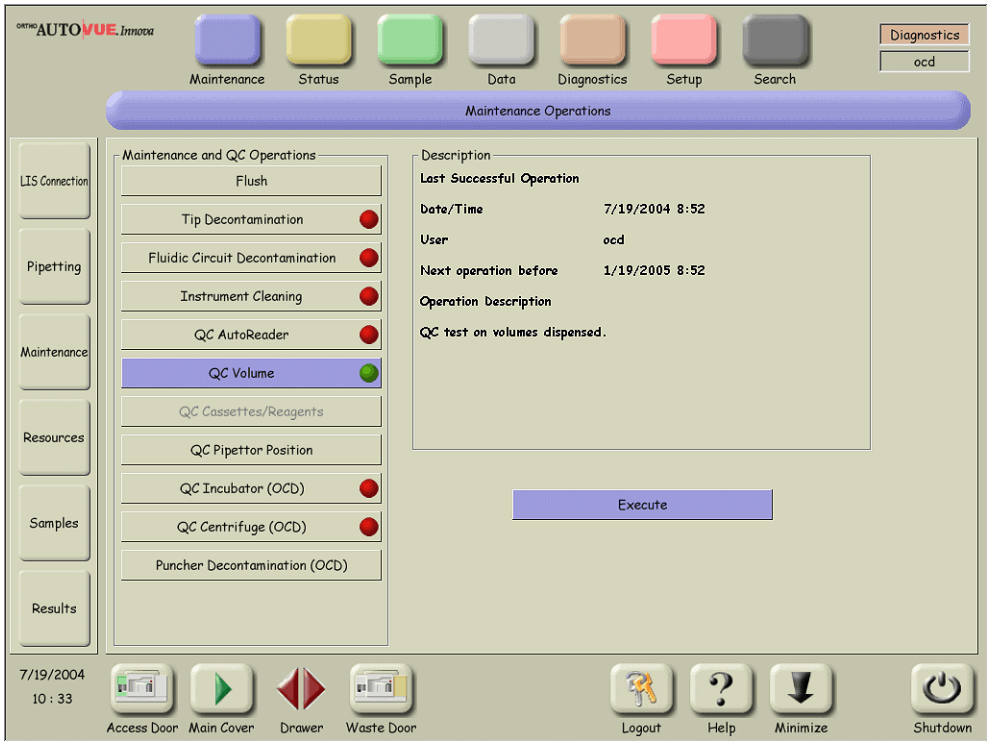


Q5076ACA

To perform the QC Volume procedure:

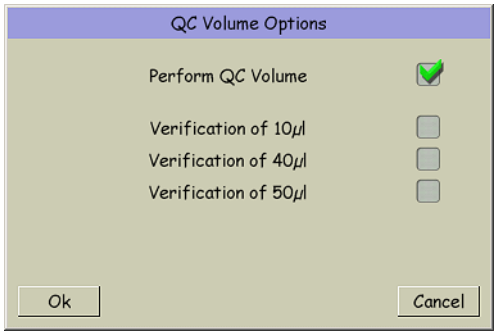
1 On the **Maintenance** screen, touch **Execute**.

Figure 8-15



2 On the dialog box that displays, touch **Ok**.

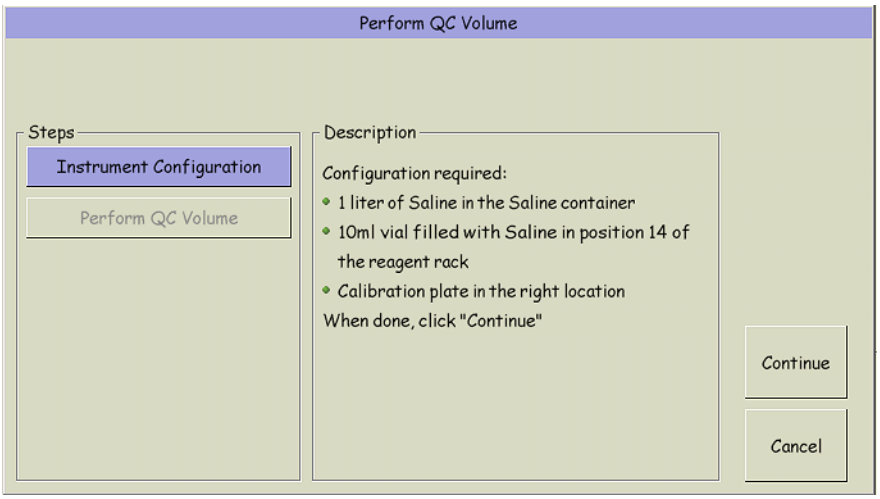
Figure 8-16



To perform the QC Volume procedure: (continued)

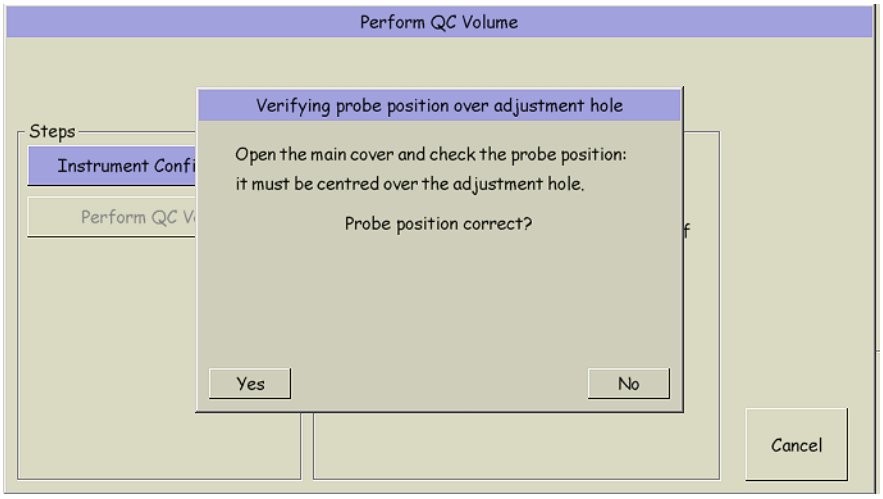
3 On the screen that displays, follow the instructions listed in the **Description** section and the touch **Continue**.

Figure 8-17



On the screen that displays, follow the instructions

Figure 8-18



4 To check that the pipettor tip is positioned correctly over the adjustment well on the calibration plate, open the Main Cover and visually verify that the pipette tip is centered directly above the adjustment well.

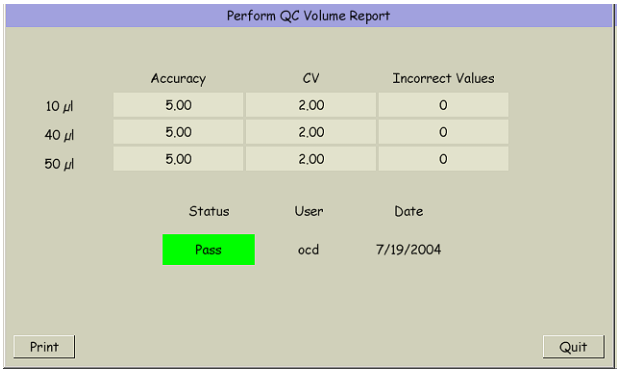
To perform the QC Volume procedure: (continued)

5 If the pipette tip is correctly positioned, touch **Yes**.

Result: The system performs the QC Volume procedure. When the procedure completes the following report displays indicating whether the procedure passed or failed.

Once the QC Volume procedure is complete, remove the calibration plate before running tests.

Figure 8-19

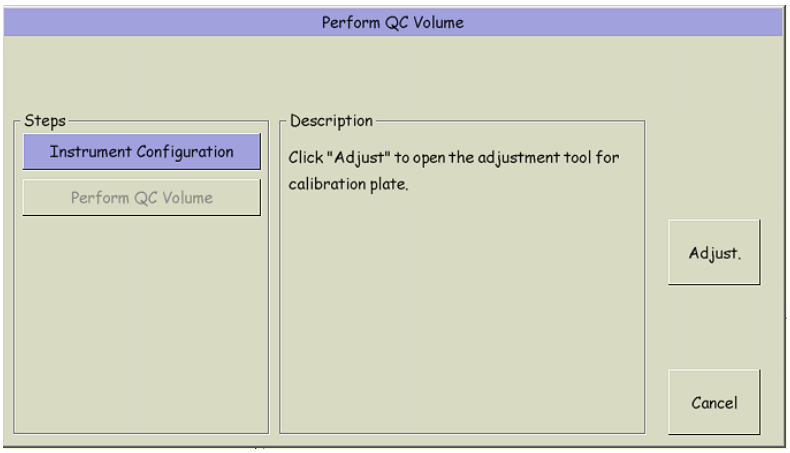


Or

If the pipette tip is incorrectly positioned, try to re-position the calibration plate. If the pipette tip is still not centered directly over the adjustment well, touch **No**.

Result: The following screen displays. Touch **Adjust** to modify the X, Y, and Z positions of the pipette tip arm.

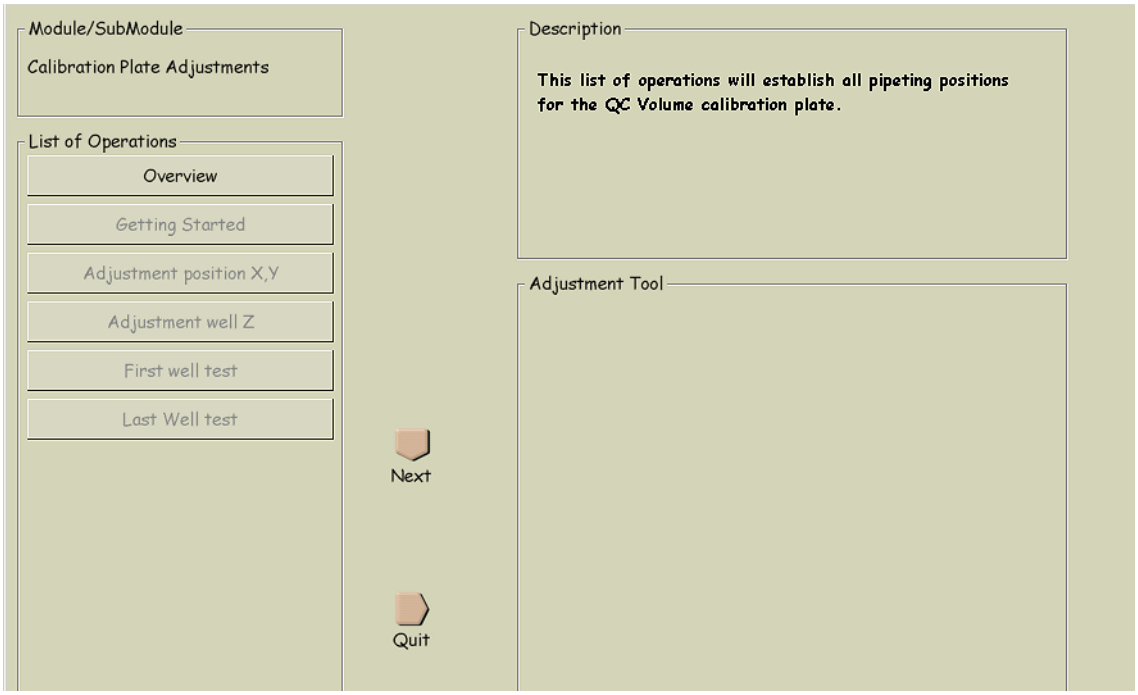
Figure 8-20



To perform the QC Volume procedure: (continued)

Result: The software wizard **Calibration Plate Adjustments** displays. Use this wizard to adjust the pipette tip position in relation to the calibration plate:

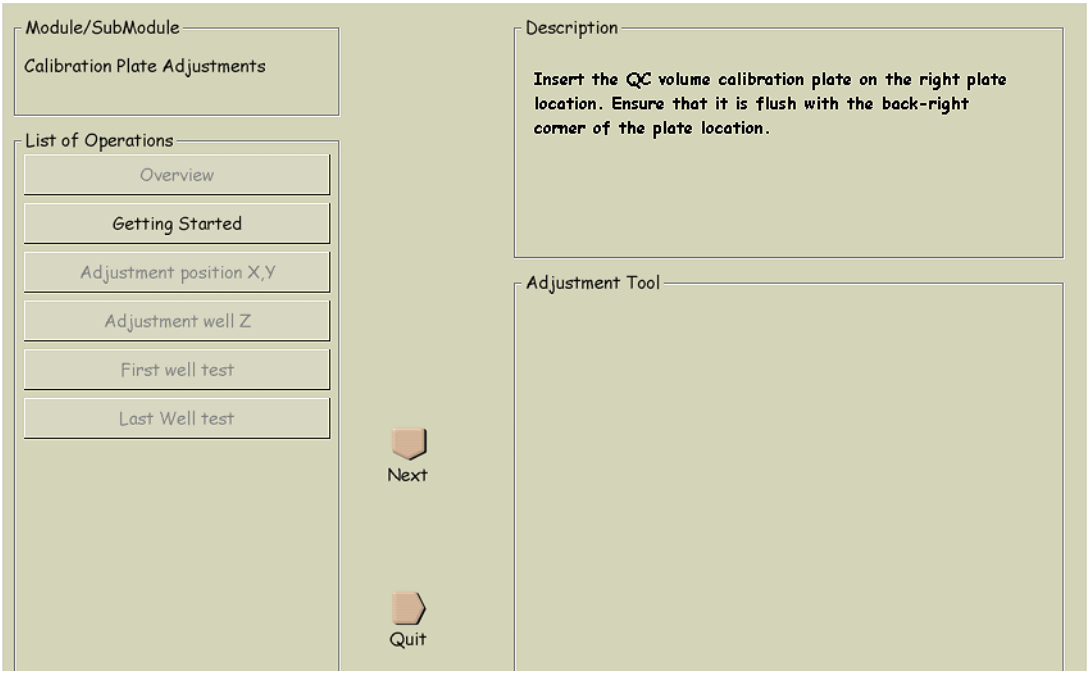
Figure 8-21



To perform the QC Volume procedure: (continued)

6 Touch **Next** to proceed to the **Getting Started** screen and follow the instructions listed in the **Description** section.

Figure 8-22



To perform the QC Volume procedure: (continued)

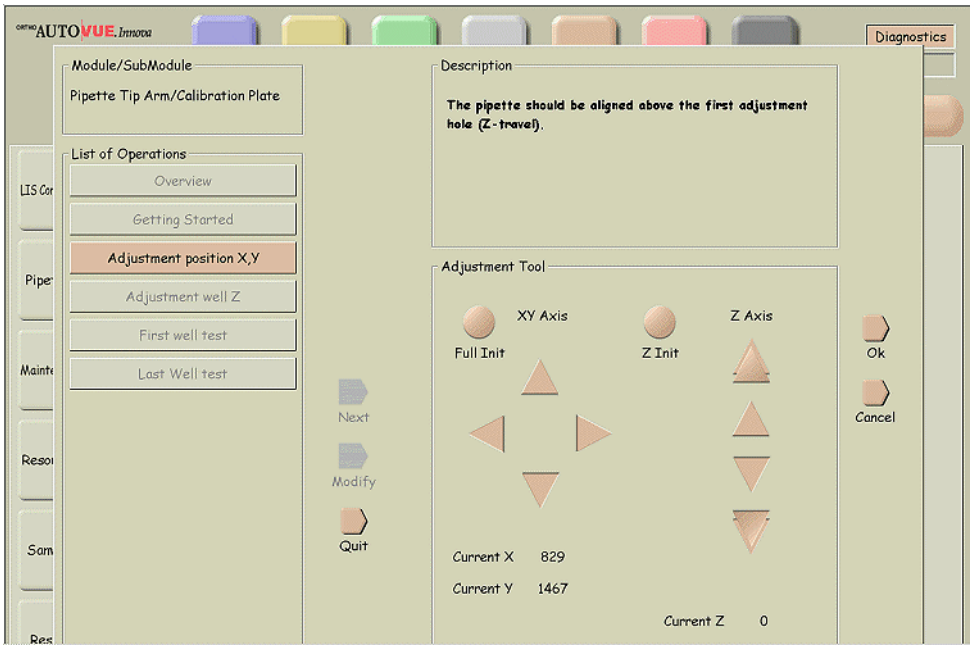
7 Touch **Next** to proceed to the **Adjustment position X,Y** screen as shown below.

Follow the instructions listed in the **Description** section.

Touch **Modify** to adjust the X, Y positions of the pipette using the adjustment buttons and touch **Ok** to accept changes.

The modified X,Y coordinates display.

Figure 8-23



To perform the QC Volume procedure: (continued)

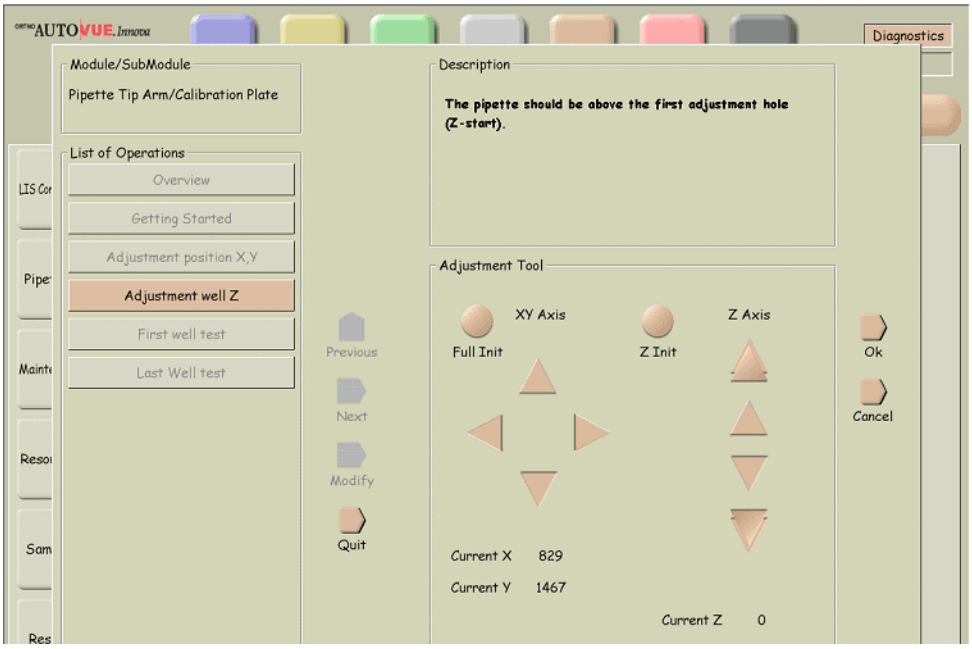
8 Touch **Next** to proceed to the **Adjustment position Z** screen as shown below.

Follow the instructions listed in the **Description** section.

Touch **Modify** to adjust the Z position of the pipette using the adjustment buttons and touch **Ok** to accept changes.

The modified Z coordinate displays on the screen.

Figure 8-24

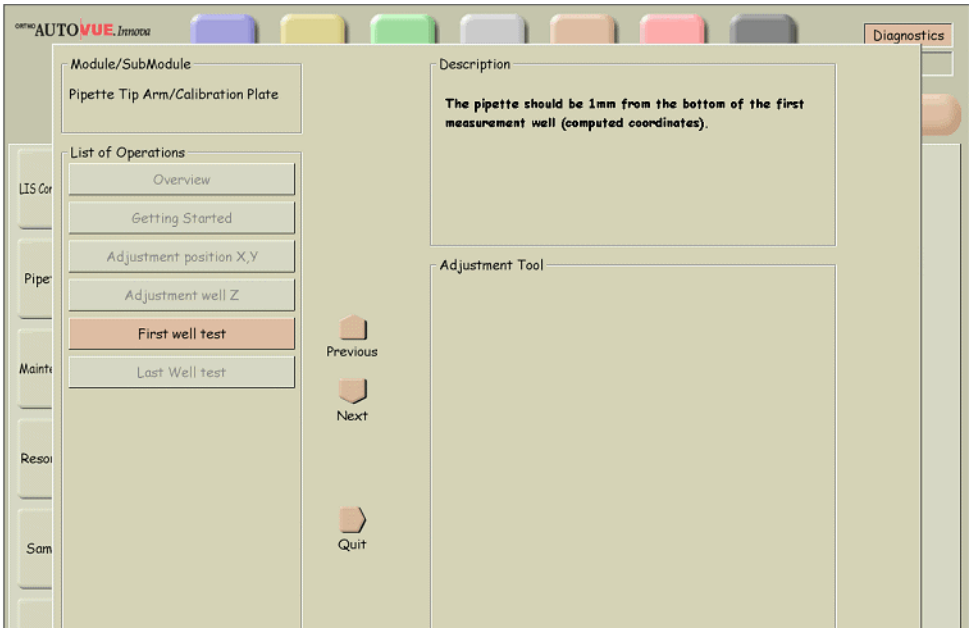


To perform the QC Volume procedure: (continued)

9 Touch **Next** to proceed to the **First well test** screen as shown below.

Follow the instructions listed in the **Description** section.

Figure 8-25



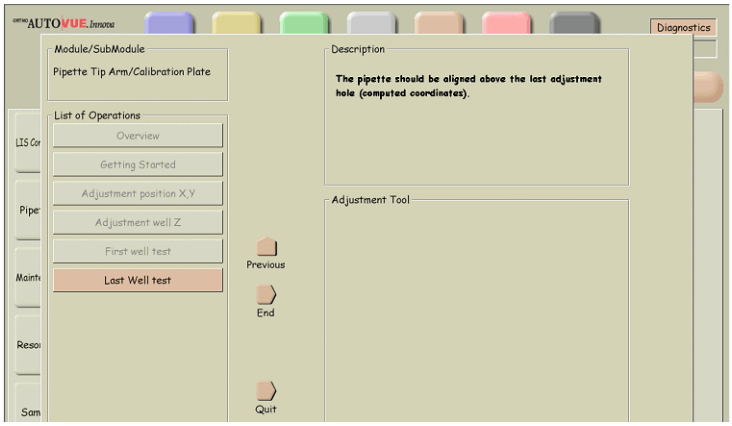
To perform the QC Volume procedure: (continued)

10 Touch **Next** to proceed to the **Last well test** screen as shown below.

Follow the instructions listed in the **Description** section.

Touch **End** to complete the procedure.

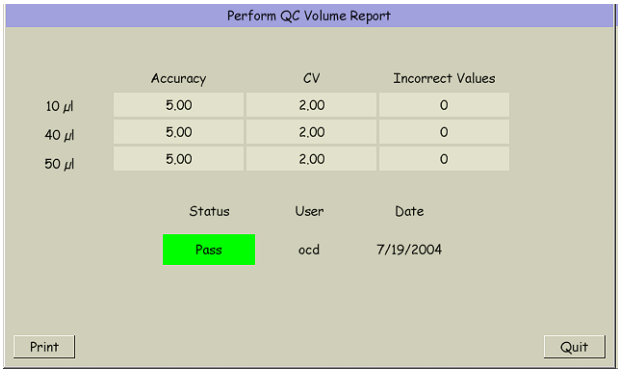
Figure 8-26



Result: The system performs the QC Volume procedure. When the procedure completes the following report displays indicating whether the procedure passed or failed.

Once the QC Volume procedure is complete, remove the calibration plate before running tests.

Figure 8-27



Refer to "Performance Criteria" on page 1-12 for expected values of QC volume.

Section E: As-Required Maintenance Procedures

The following maintenance procedures need to be performed as required:

- Flush the instrument
- Pipette tip and tube replacement
- Daylight Savings Time Adjustments

Flush the Instrument

AutoVue provides four different ways to flush the instrument and fluidic system.

- Saline
- Water

Fluidic decontamination

- NaOH and Water
- NaOH and Saline

The system will require a flush when:

- It has been idle for one hour or longer
- Operator receives an error message

NaOH system flushes (NaOH and saline, NaOH and water) require a reagent bottle filled with 0.1 N NaOH.

⚠ 0.1 N NaOH is a hazardous material. Refer to manufacturer's Material Safety Data Sheet for specific health and safety information prior to handling.

Note: If an instrument has not been used for a few days, the ability to accurately check the waste and system fluid levels may be hindered due to pressure changes and the subsequent rise of the fluid level in the detection tube. Raise detection tubes out of fluid, shake, and replace in the container.

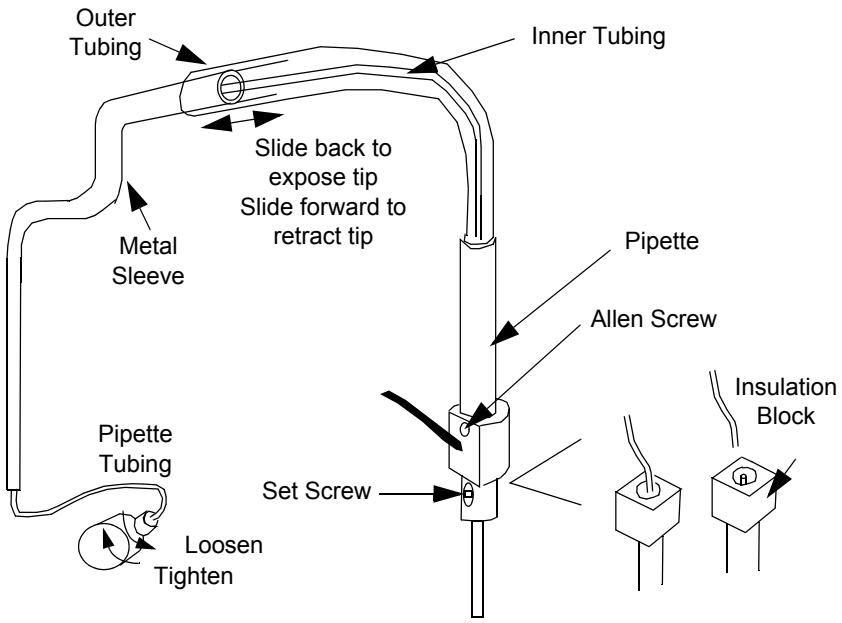
⚠ Regularly monitor the liquid level and ensure that the levels are appropriate in the fluidic containers. Low liquid levels prevent regular and consistent flow of liquid through the wash pump and syringe. This can cause the pump and syringe to splash liquid onto instrument parts.

Pipette Tip and Tubing Replacement Procedure

Perform this procedure when the tip is visibly damaged. Use the Allen wrench and screwdriver supplied with the instrument.

	To replace the pipette tip
1	Shut down the instrument.
2	Open the Main Cover of the instrument.
3	Move the pipette arm to the right and forward for easier access to the pipette tip.

Pipette Tip and Tubing Assembly



4	Loosen the Allen screw.
5	Slide the outer tubing back onto the metal sleeve about 2 cm.
6	The pipette tip assembly drops down from the holder.
7	Loosen the set screw.

	To replace the pipette tip (continued)
8	Biohazard: Use care and wear protective laboratory gloves when handling the pipette tip. Remove the tip probe from the tubing.
9	If the tubing needs replacement, disconnect the tubing from the lower connection. If the tubing is not being replaced, proceed to Step 11.
10	Pull the old tubing from the sleeve.
11	Locate new pipette tubing and insert the nonconnector end through the metal sleeve.
12	Connect the connector at the bottom of the tubing.
13	If tubing is not replaced, trim the tubing back about 0.25 cm with diagonal cutters.
14	Insert the new pipette tip into the insulation block and secure the set screw.
15	Insert the tubing onto the new pipette tip.
16	Slide the outer tubing forward on the metal tube. The pipette tip is drawn upward.
17	Insert the insulation block into the holder, and secure the Allen screw.
18	Move the pipette tip back to the home position (back and left).
19	Power up the instrument.
20	Perform a system flush. See “Flush the Instrument” on page 8-48.
21	Perform a pipette position QC procedure. Note: Initialization of tip may fail if pipette tip assembly is raised to its maximum height.

Daylight Savings Time Adjustments

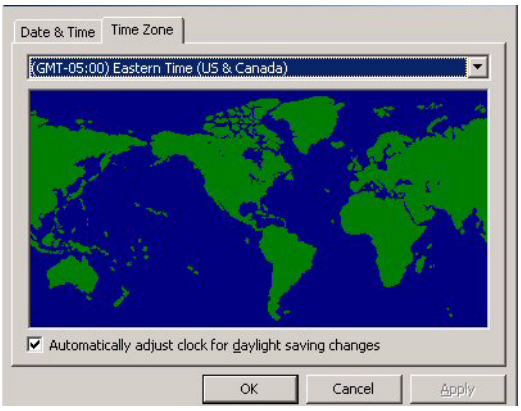
Daylight savings time changes can potentially cause erroneous results to be reported. If the software operating system is set to **automatically adjust clock for daylight savings time** and a BioVue cassette is being incubated at 37ºC when the time change occurs from daylight saving time (summer time) to the standard time (winter time) (clock set back 1 hour), the BioVue cassette may end up incubating for a total of 1 hour and 10 minutes or 1 hour and 15 minutes depending on the assay type. If this occurred, a result would be generated without an error code.

To prevent the occurrence of an erroneous result during the summer-to-fall daylight savings time change:

- Disable the automatic adjustment clock for daylight saving time.
- Manually adjust the Windows system clock for daylight saving when the system is not in operation.

To disable the Windows automatic daylight savings time adjustment

1. Close the Ortho AutoVue *Innova/Ultra* application software.
2. From the Windows XP **Start** menu, choose **Start > Settings > Control Panel**.
3. Double-click the **Date/Time** icon.
4. Select the **Time Zone** tab.

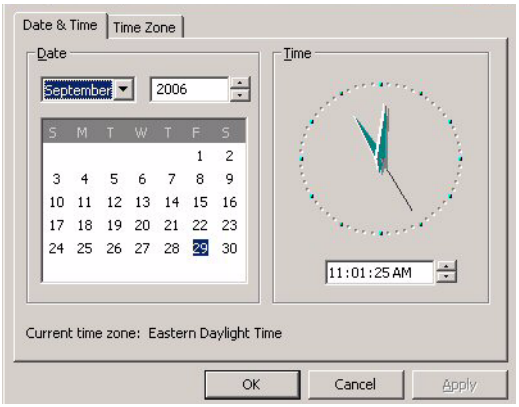


5. Clear the check box entitled **Automatically adjust clock for daylight savings changes**.
6. Click **OK**.

.

To manually adjust the Windows system clock for daylight savings time

1. Close the Ortho AutoVue *Innova/Ultra* application software.
2. From the Windows XP **Start** menu, choose **Start > Settings > Control Panel**.
3. Double-click the **Date/Time** icon.
4. Select the **Date & Time** tab.



5. Change the time one hour according to the adjusted time zone of the region in which you are located.
6. Click **OK**.

9 Data Back Up/Restore and LIS Communication

This chapter contains the information you need to back up the AutoVue database and communicate with the LIS.

Topics

Section A: Data Backup and Restore

Test data and configuration settings should be backed up to ensure against loss of data in case a software crash or hard disk failure occurs.

The backup software is a stand-alone Windows-based application that automatically launches when the operator logs onto Windows.

Backup Application Status and Icons

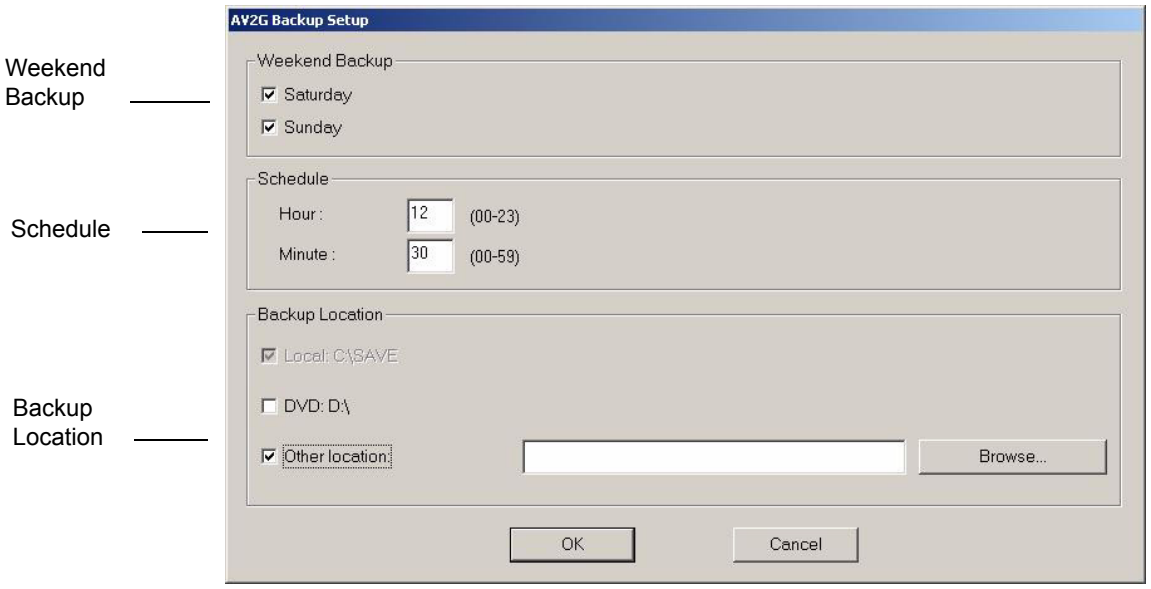
In the Windows task bar in the lower right corner on the desktop, one of the following icons displays:

Application Status	Icon
Inactive	
Running	
Backup failure	

Daily Backup

Schedule the time and specify the location(s) for creating daily backup files in the AV2G Backup Setup dialog box. To display the AV2G Backup Setup dialog box, right click on the backup application status icon in the Windows task bar and select Setup.

Figure 9-1



The Setup dialog box has three sections:

- Weekend Backup: If you wish to include Saturday and/or Sunday as part of your daily backup schedule, click the appropriate checkbox(es).
- Schedule: Use the Hour and Minute fields to enter the time each day when you wish to be prompted to create a backup.
- Backup Location: You can save your backup files to one, two, or all three of the available locations.
  - Local: C:\Save. This saves your files to your local hard drive. This is the required location and is always selected.
  - DVD: D:\ You can also save your data to a properly formatted and named DVD in the DVD drive on your computer. (See "DVD Backup Requirements" on page 9-6.)
  - Other Location. This option lets you save your data to a location you specify. This location can be on the local hard drive, on a network, or on an external hard drive. When you select the Other Location checkbox, you can click Browse to navigate to the location you want, or enter the location in the text box.

When you have entered all necessary information, click OK. At the scheduled time, the backup application will prompt you to save your data to the selected location(s).

When the backup application activates at the scheduled time, the operator has the option to cancel the procedure. If a scheduled backup is cancelled, the operator can right-click on the backup application icon at any time and select the option to initiate a backup immediately. OCD does not recommend missing daily backups.

Note: Performing a data backup while the instrument is processing samples may delay obtaining results.

Files Saved

The daily backup saves AutoVue programs and data including files in the MEDs and LOGs folders. The following files are backed up:

all files in the following folders:
C:\OCD\AV2G – system files
C:\OCD\MEDS – MEDs files

only the previous two days files in these folders:
C:\OCD\AV2G\\LOGS
C:\OCD\AV2G\\IMAGES
C:\OCD\AV2G\\FTP
C:\OCD\AV2G\\FTP\\TRACES
C:\OCD\AV2G\\KER
C:\OCD\AV2G\\KER\\TRACES
C:\OCD\AV2G\\LAN
C:\OCD\AV2G\\LAN\\TRACES

Weekly Archive Backup

The weekly archive backup automatically launches on Tuesdays. Files will be saved to the location(s) you select in the Backup Location section of the AV2G Backup Setup dialog box.

- Local: C:\Save. This saves your files to your local hard drive. This is the required location and is always selected.
- DVD: D:\ You can also choose to save your data to a DVD in the DVD drive on your computer.
- Other Location. This option lets you save your data to a location you specify. This location can be on the local hard drive, on a network, or on an external hard drive. When you select the Other Location checkbox, the text box and Browse button become active. Click Browse to navigate to the location you want, or enter the location in the text box.

At the scheduled time, the backup application activates and begins the weekly archive backup process. The operator can choose to cancel the scheduled backup. If a scheduled weekly archive backup is cancelled, the operator can right-click on the backup application icon and select the option to initiate a weekly archive backup immediately. OCD does not recommend missing weekly archive backups.

Note: Performing a data backup while the instrument is processing samples may delay obtaining results.

Note: Weekly archive backups save all data for all previous weeks.

- If the correct DVD for the archive backup is not present in the DVD-burner, the system will prompt the operator to load the correct DVD.

- The weekly archive backup saves the current AutoVue archive, including all cassette images. Use the **Setup** screen, **Data** tab, **Archiving** section to set up archiving options.

DVD Backup Requirements

If you wish to use DVDs as an additional backup option, you must have properly formatted and named DVD+RW discs.

For Daily Backups

A properly named and formatted DVD is required for each day of the week when backups are performed. Therefore, you will need five, six, or seven DVDs each year for daily backups. OCD personnel or your system administrator must format and name the DVDs using the following case-sensitive naming convention:

1. MONDAY
2. TUESDAY
3. WEDNESDAY
4. THURSDAY
5. FRIDAY
6. SATURDAY
7. SUNDAY

For Weekly Archive Backups

The weekly archive backup automatically launches on Tuesdays. Two properly named and formatted DVDs per year are required for weekly archive backups:

- 1 DVD to store data for 1 January - 30 June of the year
- 1 DVD to store data for 1 July - 31 December of the year

  Note: OCD personnel or your system administrator must format and name the 2 DVDs correctly using the following naming convention:

  1. year-1 (for example, 2007-1)
  2. year-2 (for example, 2007-2)

If the correct DVD is not present in the DVD-burner, the system will prompt the operator to load the correct DVD.

Backup Log Files

A backup log file is automatically generated each day by the backup application. These log files are text files with a .txt extension that record the date, time, and result of each backup attempt (successful or failed).

If a backup fails, the  icon displays in the Windows task bar and an HTML file automatically displays. The HTML file contains links to each daily log file so that the system administrator can review log files for unsuccessful backups. Possible reasons for unsuccessful backups include:

- The DVD is full
- The DVD is formatted or named incorrectly
- The DVD is unreadable or unwritable

Restore

In the event of a software crash or hard disk failure where data was lost, files that have been backed up on the DVDs can be restored to the AutoVue database.

To restore data from one of your backup DVDs, call OCD service personnel.

Section B: AutoVue/LIS Communication

Test results can be uploaded to the Laboratory Instrument System (LIS) from AutoVue and test requests can be downloaded from LIS to AutoVue.

LIS File Format

There are a number of file formats that can be used to transfer data between the LIS and AutoVue. See *Ortho AutoVue™ System - LIS Developers Guide and Troubleshooting Manual*. Contact your local OCD representative for additional information on the document.

Uploading Data to the LIS

You can upload data to the LIS in these groups:

- All accepted results that have not been uploaded
- All accepted results
- All partially accepted results
- All selected results

To upload data to the LIS

1. Touch **Samples** on the menu at the top of the screen and select the **Worklist** tab.
2. Touch the **Completed** check box.
3. Touch the Transfer button to display the **Transfer Mode** dialog.

To upload data to the LIS (continued)

4 Select an option from the **Transfer Mode** dialog and touch **Ok**.

Result: Selected worklist data is sent to the LIS.

or

Touch **Cancel** to exit without transferring data.

To upload selected test data to the LIS

1 Touch **Samples** on the menu at the top of the screen and select the **Worklist** tab.

2 Touch the **Completed** check box and select completed items from the Worklist to transfer to the LIS.

3 Touch the **Transfer** button.

Result: The selected Worklist data is sent to the LIS.

Reupload to the LIS

Each upload is saved in a file that is listed in the LIS Communication Log.

	To reupload to the LIS
1	Touch **Data** on the menu at the top of the screen and select the **LIS Communication Log** tab.
2	Touch the file to reupload. or Touch **Filter**, enter a sample ID, and touch **Ok**. Result: Only the files containing the entered sample ID are listed in the file list. Choose a file from the list.
3	Touch the **Retransfer** button in the **Detail of a file** dialog. Result: Selected Worklist data is sent to the LIS.

Queries

When Query mode has been set in Setup, queries are automatically sent when a new sample ID is identified during initialization of sample racks or manual registering of samples. The LIS automatically downloads information and analyses requests for the sample ID.

Downloading Data from the LIS

The AutoVue system automatically reads from the LIS on demand, and every *n* seconds as set in the **Transfer Setup** dialog. See "Set and Modify LIS Transfer Options" on page 11-32.

Additional or changed information about patients received from the LIS is accepted and stored.

Data transferred by the LIS to AutoVue can include any of the following:

- Patient ID
- Patient national ID
- Medical record
- Other ID
- Patient last name
- Patient first name
- Patient date of birth
- Patient gender
- Sample ID *(required)*
- Profile ID *(required)*
- Priority
- Requested/ordered date and time
- Action: cancel, add, or new
- Sample type *(required)*
- Setting to save all cassettes for all profiles
- Sample ID of first donor
- Sample type of first donor *(required)*
- Sample ID of second donor
- Sample type of second donor *(required)*
- Sample ID of subsequent donor(s)
- Sample type of subsequent donor(s) *(required)*

When requests are received from the LIS, they are added to the Worklist and resources are recalculated for the updated test list.

This page intentionally left blank.

10 Managing Error Messages

Overview

This chapter describes the different types of error messages and provides a procedure to troubleshoot problems uploading to the LIS.

Errors display in different ways on the screen:

- In dialog boxes that pop up
- On the Action Dashboard
- As fields that are highlighted in color
- On the Data screen, Instrument Errors tab

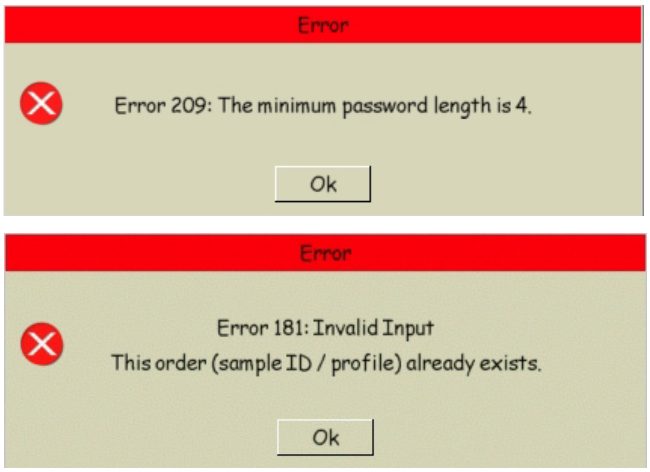
The types of errors are listed in Appendix A: Error Messages on page A-1:

- Software errors. These may require operator intervention.
- Hardware errors related to the instrument
  - Asynchronous errors display on the Data screen, Instrument Errors tab. These may require operator intervention or OCD service personnel.
  - Internal errors display in log files, but not on the screen. Internal errors are used by OCD personnel to troubleshoot the reason for an asynchronous error.

Topics

Error Dialogs

Error dialogs have red banners. Some error messages have error numbers. A complete list of numbered error messages with accompanying explanations and instructions on how to resolve the error is provided in Appendix A: Error Messages on page A-1.

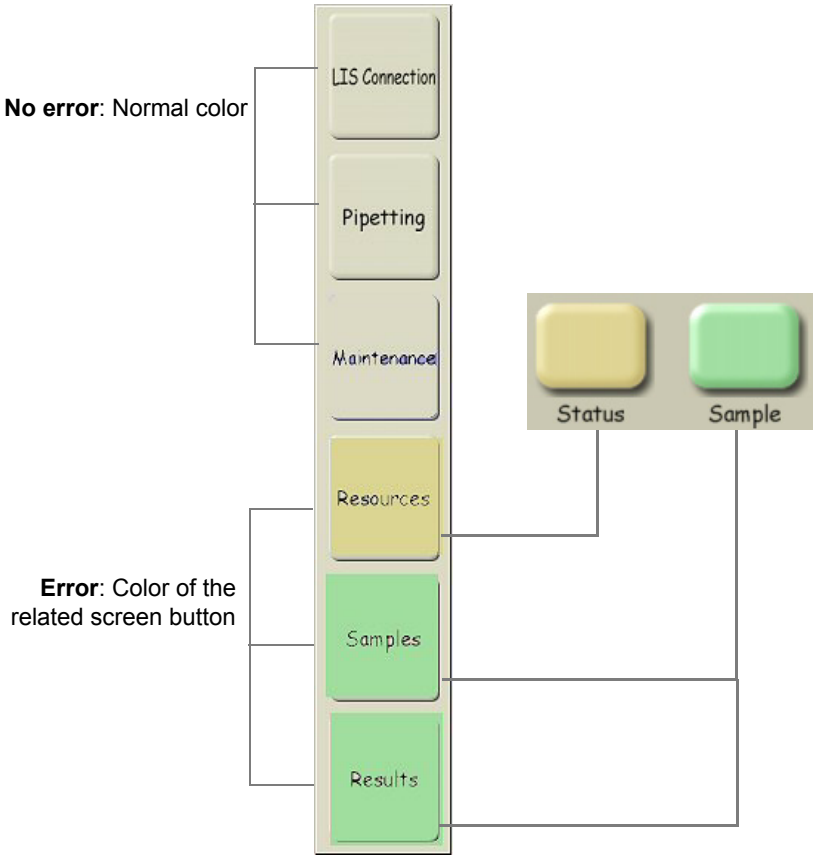


Other messages have different colors (Warning = yellow, Information = blue).

When the **Routine** status (normally green) turns RED due to an error, the software unlocks all doors to allow access to the inside of the instrument.

Action Dashboard Buttons

The Action Dashboard buttons are on the left side of the screen. When an error occurs, the button changes to the color of the related screen button and blinks. After the button is touched, it will no longer blink. After the error is corrected, the button color changes to normal.



LIS Connection Errors

When the **LIS connection** button in the Action Dashboard is flashing, follow these instructions to manage LIS Communication Log errors.

To manage LIS Communication Log errors

1. Touch the **LIS Connection** button in the Action Dashboard.

   Result: The **Data** screen **LIS Communication Log** tab displays.

2. Read the error(s) in the **Errors** section. Errors include:
   - **No communication**
   - **Patient already defined in worklist with different information**
   - **Sample already defined in worklist with a different patient ID**
   - **Sample already defined in Worklist with different sample information**
   - **Unknown information (profile name, sample type)**
   - **Wrong file format**

3. Follow the instructions for the error.

   - **No communication**
     - Check the physical connection
     - Check the **Setup**, **Data** tab, **LIS transfer** section. See "Set and Modify LIS Transfer Options" on page 11-32.
   - **Patient already defined in Worklist with different information**
     - Accept the new information.

       or
     - Select **Abort** to keep the old information.
   - **Sample already defined in Worklist with a different patient ID**
     - Archive the old order and retry.
   - **Sample already defined in Worklist with different sample information**
     - Accept or abort

To manage LIS Communication Log errors (continued)

- **Unknown information profile name or sample type**
  - Modify the sample Register/Load information. See "Registering Samples" on page 6-21.
  - Add the profile in the **Setup**, **Testing** tab, **Profiles** section.
  - Return to the **LIS errors** screen to retry the download. Touch the **Retry** button.
- **Wrong file format**
  - Contact the LIS Administrator or contact OCD service personnel.

For numbered error messages, see Appendix A: Error Messages on page A-1.

Pipetting Errors

When the Pipetting button in the Action Dashboard is blue and flashing, follow these instructions to manage Pipette errors.

	To manage Instrument errors
1	Touch the **Pipetting** button in the Action Dashboard. Result: The **Data** screen **Instrument Errors** tab displays.
2	Read the error(s) in the **Errors** section. Errors are listed with a number. See Appendix A: Error Messages on page A-1 for instructions on how to resolve pipetting errors.

Maintenance Errors

When the **Maintenance** button in the Action Dashboard is purple and flashing, follow these instructions to manage Maintenance errors.

	To manage Maintenance errors
1	Touch the **Maintenance** button in the Action Dashboard. Result: The **Maintenance** screen displays.
2	Observe the symbol beside each maintenance or quality control procedure:  = Overdue, run maintenance immediately  = Warning, maintenance is due  = No maintenance required at the moment
3	For red status, run maintenance immediately. If OCD-only maintenance, call OCD service personnel.

For numbered error messages, see Appendix A: Error Messages on page A-1.

Resource Errors

When the **Resources** button in the Action Dashboard is yellow and flashing, follow these instructions to manage Resource errors.

Required Tab

To manage Cassettes errors

1	Touch the **Resources** button in the Action Dashboard and then touch the **Required** tab. Result: The **Status** screen **Required** tab displays.
2	Observe the cassette type(s) highlighted in color in the **Cassettes** section. These are not loaded in the Cassette Drawer.
3	Load the highlighted cassette type(s) in the Cassette Drawer. Reference: See "Loading Cassettes" on page 6-17.

To manage Review Areas errors

1	Touch the **Resources** button in the Action Dashboard and then touch the **Required** tab. Result: The **Status** screen **Required** tab displays.
2	Observe the area highlighted in color in the **Review Areas** section.
3	Follow the instructions for the error. ▪ **CASUNCA** – The area is full. Remove cassettes from the CASUNCA. ▪ **Trashcan** – The area is full. Empty the Waste Basket. Reference: See "Empty Waste Cassettes from the Waste Container" on page 8-9.

To manage Reagents errors

1. Touch the **Resources** button in the Action Dashboard and then touch the **Required** tab.

   Result: The **Status** screen **Required** tab displays.

2. Observe the reagent type(s) highlighted in color in the **Reagents** section. These are not loaded in the Reagent Rotor.

3. Load the highlighted reagent type(s) in the Reagent Rotor.

   Reference: See "Registering and Loading Reagents and Dilution Plate(s)" on page 6-3.

To manage Temperature Verification errors

1. Touch the **Resources** button in the Action Dashboard and then touch the **Required** tab.

   Result: The **Status** screen **Required** tab displays.

2. Observe the area highlighted in color in the **Temperature Verification** section.

3. Call OCD Service personnel.

To manage Dilution Plates errors

1. Touch the **Resources** button in the Action Dashboard and then touch the **Required** tab.

   Result: The **Status** screen **Required** tab displays.

2. Observe the dilution plate(s) highlighted in color in the **Dilution Plates** section. There is a problem with one or more wells on the plate.

3. Replace the highlighted plate(s).
   (**Left** = shallow; **Right** = deep-well)

   Reference: See "Load Dilution Plate(s)" on page 6-13.

	To manage Fluids errors
1	Touch the **Resources** button in the Action Dashboard and then touch the **Required** tab. Result: The **Status** screen **Required** tab displays.
2	Observe the dilution plate(s) highlighted in color in the **Dilution Plates** section. There is a problem with one or more wells on the plate.
3	Follow the instructions for the error. ▪ **DW** or **Saline** – The area does not have enough liquid. Add the highlighted liquid (distilled water; saline). ▪ **Waste** – The area is full. Empty the liquid waste container. Reference: See "Empty Liquid Waste" on page 8-14.

Reagent Rack Tab

To manage Reagent Rack errors

1. Touch the **Resources** button in the Action Dashboard and then touch the **Reagent Rack** tab.

   Result: The **Status** screen **Reagent Rack** tab displays.

2. Observe the rack position(s) highlighted in color and the description of the error in the table. Errors include:
   - **Empty fixed position** – The assigned position does not contain a reagent.
   - **Fixed position with wrong reagent** – The assigned position contains the wrong reagent vial.
   - **Insufficient remaining volume to cover the needs of the current Worklist** – There is not enough reagent to complete the test.
   - **Loading time over limit** – The reagent has been on the instrument too long.
   - **Lot not usable** – The reagent lot is quarantined or blocked and is not available for use.
   - **Unreadable bar code on a non-fixed position** (bar code cannot be read) – The system cannot scan the bar code on the vial.
   - **Unknown bar code** – The system does not recognize the bar code.

To manage Reagent Rack errors (continued)

3 Follow the instructions for the error.

- **Empty fixed position** – Load the appropriate reagent vial into the assigned position.
- **Fixed position with wrong reagent** – Remove the reagent and load the correct reagent in the assigned position.
- **Insufficient remaining volume to cover the needs of the current Worklist** – Load additional reagent vials to complete the current tests.
- **Loading time over limit** – Change the reagent that has been on the instrument too long.
- **Lot not usable (quarantine or blocked)** – Change the status of the lot to Available in the **Lots** tab.
- **Unreadable bar code on a non-fixed position** (bar code cannot be read) – Check that the barcode is facing outward. Register the reagent lot in the **Lots** tab.

  Reference: See "Load Reagent Vial(s)" on page 6-9.
  See c.
- **Unknown bar code** – Register the reagent lot in the **Lots** tab.

  Reference: See "Procedure to Manually Register Reagents" on page 6-6.

Drawer Tab

To manage Drawer errors

1. Touch the **Resources** button in the Action Dashboard and then touch the **Drawer** tab.

   Result: The **Status** screen **Drawer** tab displays.

2. Observe the sleeves highlighted in color in the **Drawer Content** section. If there are no sleeves highlighted (no errors), skip to Step 5 "Observe the Quantity Errors section."

3. Touch on a sleeve to display the error description. Errors include:
   - **Lot expired**
   - **Lot in other status than "In Use."**
   - **(Review Sleeve only) Control cassette not found**
   - **Type not configured on puncher**

4. Follow the instructions for the error:
   - **Lot expired** – Replace cassette sleeve with a current sleeve.
   - **Lot in other status than "In Use."** – Change the lot status in the **Lots** tab.
   - **(Review Sleeve only) Control cassette not found** – Place a control cassette in position 20 of the cassette sleeve showing the error.

     Reference: See "Load or Replace Review Cassette Sleeve(s)" on page 6-20.
   - **Type not configured on puncher** – Call OCD service personnel to configure the puncher.

5. Observe the **Quantity Errors** section.

6. Load one or more cassette sleeves into the Drawer.

For numbered error messages, see Appendix A: Error Messages on page A-1.

Sample Errors

When the **Samples** button in the Action Dashboard is green and flashing, follow these instructions to manage Sample errors.

	To manage Samples errors
1	Touch the **Sample** button in the Action Dashboard. The **Sample** screen **Sample Racks** tab displays.
2	Observe the position in the sample rack image that displays (E). The error is described in the **Position Errors** section. Errors include: ▪ **Empty fixed position** – The assigned position does not contain a sample. ▪ **Fixed position with wrong bar code** – The wrong sample is in the fixed position. ▪ **Unknown sample** – The system does not recognize the sample. ▪ **Unreadable bar code** (bar code cannot be read) – The system does not recognize the bar code. Note: When diluent resources are unavailable to complete testing on a sample, the position of the sample displays a (U) symbol rather than a (E) symbol and the **Resources** button on the Dashboard blinks. Replenish diluent resources to resolve the error and continue the routine.
3	Follow the instructions for the error. ▪ **Empty fixed position** – Load the appropriate sample tube into the assigned position. Reference: See "Load Samples/Controls" on page 6-42. ▪ **Fixed position with wrong bar code** – Remove the sample and load the correct sample tube in the assigned position. ▪ **Unknown sample** – Register the sample. ▪ **Unreadable bar code** (bar code cannot be read) – Check that the barcode is facing outward. Manually register the sample. Reference: See "Registering Samples" on page 6-21.

For numbered error messages, see Appendix A: Error Messages on page A-1.

Results Errors

When the Results button in the Action Dashboard is green and flashing, follow these instructions to manage Result errors.

	To manage Worklist errors
1	Touch the **Results** button in the Action Dashboard. Result: The **Sample** screen **Worklist** tab displays.
2	Observe the symbols for each Sample ID.
3	Read the meaning of the symbol(s) in the referenced tables and perform the action specified. Reference: See "Symbol Explanation" on page 7-22. Reference: See "Symbols that Display in the Analysis Results Columns" on page 7-23.

For numbered error messages, see Appendix A: Error Messages on page A-1.

Trash Container and Cassette Waste Lift Errors

When the system detects a full trash container, test processing will pause and the “ASTC013 Trash Container is Full” error will display.

	To manage Trashcan Is Full error
1	Touch OK on the error message. Result: The **Resources** screen **Required** tab displays.
2	Observe the number of available cassettes is 0 and is highlighted in red. The Trashcan door is unlocked, and will remain unlocked if the user touches the Waste Door button.
3	Follow the instruction “Empty Waste Cassettes from the Waste Container” on page 8-9.
4	A message will display: “Did you empty the trashcan?” Touch Yes. Result: The trashcan door will be closed and locked, and the available number of cassettes in the Trashcan of the Review Areas will be 250. The Waste Lift will move the cassette to the Trashcan and the system returns to normal operation.

When the system detects a waste lift error, test processing will pause and the "ASCS041 Cassette Waste Lift Error" message will display.

To manage Cassette Waste Lift error

1	Touch OK on the error message. Result: The **Data** screen, **Instrument Errors** tab displays.
2	Observe the Cassette Waste Lift error entry, highlighted in the Instrument Errors list. The Trashcan door is unlocked, and will remain unlocked if the user touches the Waste Door button.
3	Open the Waste Door, remove the trash container, and remove any cassettes in the Cassette Waste Lift or in the AutoReader gripper.
4	Replace the Trashcan and close the Waste Door.
5	A message will display: "Did you remove the cassette causing the Waste Lift error?" Touch Yes. Result: The Trashcan door will be closed and locked, the Waste Lift will move the cassette to the Trashcan and the system returns to normal operation. Reference: "Empty Waste Cassettes from the Waste Container" on page 8-9

This page intentionally left blank.

11 Setting Up System Preferences and User Information

Overview

The **Setup** screen provides many features for customizing your AutoVue system. It is primarily used by the laboratory's system administrator and the OCD field engineer to set preferences for the AutoVue system and user privileges.

Figure 11-1

The **Setup** screen contains the following tabs:

Setup Tab	Contains
General	▪ Laboratory ▪ Connections ▪ Patient Information ▪ Alarms
Privileges	▪ Login Rules ▪ Actions ▪ Users
Maintenance	▪ Maintenance and QC ▪ BRC Profiles
Testing	▪ Puncher 37°C/RTHA (OCD Service Personnel only) ▪ Profiles ▪ Reagents ▪ Centblood Offset (OCD Service Personnel only)
Results	▪ Miscellaneous ▪ Saving Cassettes ▪ Result Display ▪ Thresholds
Data	▪ LIS Transfer ▪ Archiving ▪ Analyses Group

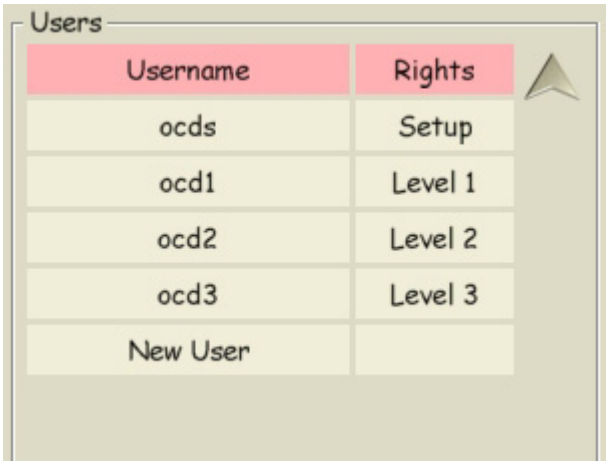
Topics

Accessing the Setup Screen

Access to the Setup screen to make changes to system configuration and settings requires:

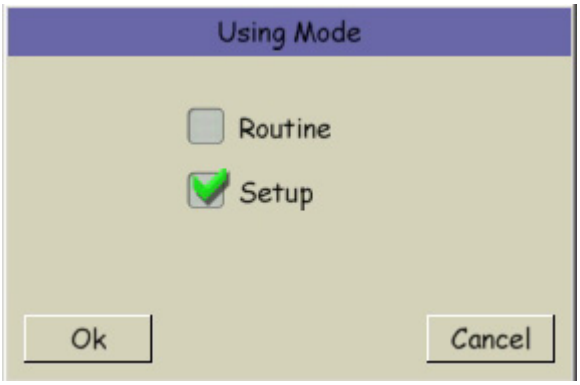
- The user has Setup privileges to prevent changes to important parameters by unauthorized personnel.

Figure 11-2



- Logging in with Setup mode

Figure 11-3



Specify Preferences in the General Tab

Use the **General** tab to specify:

- Laboratory information
- Connections to the UPS, instrument, LIS, and video channel (OCD Service Personnel)
- Required fields for entry of patient information
- System actions that will trigger an alarm

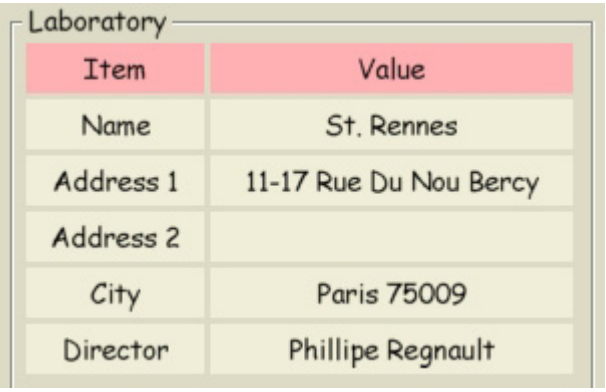
Specify and Modify Laboratory Information

Laboratory information prints in the header of reports.

To specify or edit the Laboratory Address

1 Touch **Setup** on the menu at the top of the screen and select the **General** tab. The **Laboratory** section displays the currently saved Laboratory address.

Figure 11-4



To specify or edit the Laboratory Address

2 Touch a field in the **Laboratory** section to display the Laboratory Address dialog box.

Figure 11-5

3 Type address information in the fields displayed. You can enter up to 30 characters per field.

4 Touch **Ok** to save address information.

or

Touch **Cancel** to exit without saving.

5 To edit address information, repeat this procedure.

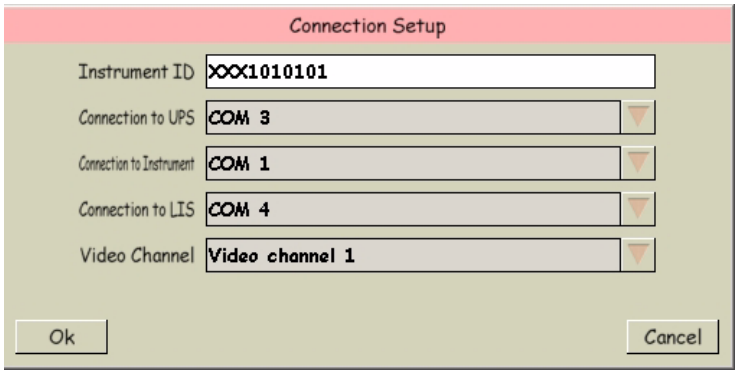
Set System Connections (OCD Service Personnel)

You must identify the machine ID and ports for communication with the UPS, Instrument, LIS, and Video Channel.

To set system connections

1. Touch **Setup** on the menu at the top of the screen and select the **General** tab. The **Connections** section allows you to identify the instrument, communications ports, and video channel.
2. Touch an item in the **Connections** section to display the **Connection Setup** dialog box for all items.
3. To setup system connections:
   - Type the Instrument ID in the field.
   - Select communications ports from the drop-down menus for the UPS, Instrument, and LIS.
   - Select the video channel from the drop-down menu.

   Figure 11-6

4. Touch **Ok** to save changes.

   Result: The **Connections** section displays the instrument ID, the communications port assignments, and the video channel assignment.

   or

   Touch **Cancel** to exit without saving.
5. To edit system connections, repeat this procedure.

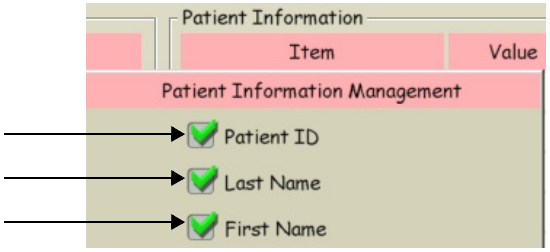
Specify and Edit Required Fields for Patient Information

You can specify which patient information fields are required for lab personnel to complete.

To specify or edit patient information

1. Touch **Setup** on the menu at the top of the screen and select the **General** tab. The **Patient Information** section displays fields with either a designation of:
   - **Yes.** The patient information for this field is required and the operator must enter a value.
   - **No.** The patient information for this field is optional.
2. Touch a field under **Patient Information** to display the Patient Information Management dialog box.
3. Touch the check boxes for fields that you want to designate as required fields.

Figure 11-7



4. Touch **Ok** to save changes.

   Result: The **Patient Information** section displays Yes next to the fields you designated as required and No next to the fields you designated as optional.

   or

   Touch **Cancel** to exit without saving.
5. To edit patient information, repeat this procedure.

Set Audio Alarms for System Events

You can set audio alarms for system events such as sample or result errors. There are two options:

- Alarms can sound on the AutoVue system you are currently operating

  or

- Alarm information can be sent as a text file to a centralized computer that manages errors

To set alarms for system events

1	Touch **Setup** on the menu at the top of the screen and select the **General** tab. The **Alarms** section allows you to set paths for network notification and sound file location, and displays a list of system events and the alarm sounds selected for those events. *Optional:* Touch **Dashboard** to enter a network path for the centralized computer that will receive a text file containing error information.
2	Touch **Sound effects location** to enter the path to the sound files. Touch **Test** to confirm the specified directory path and touch **Ok**.
3	Touch a system event in the **Alarms** section to display the **Setup Alarm** dialog box for that system event.
4	To specify an alarm: ▪ Select a sound effect from the list. ▪ Type a duration for the alarm from seconds to seconds. ▪ Type a frequency for the alarm from seconds to seconds. ▪ Check the Alarms box to enable the sound for the error.

To set alarms for system events

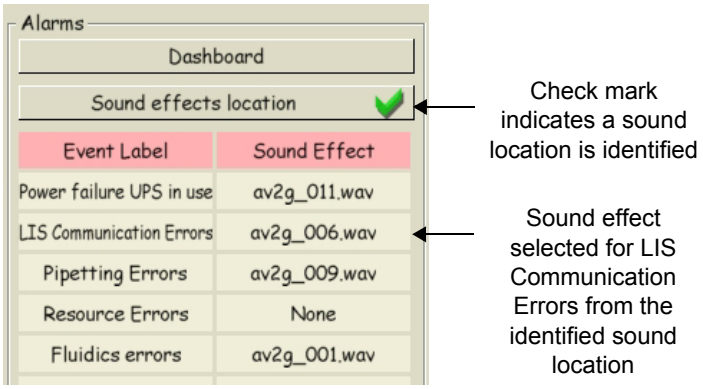
5 Touch **Cancel** to exit without saving.

or

Touch **Ok** to save changes.

Result: The **Alarms** section displays the sound you selected next to the system event. If you do not specify an alarm, None displays next to the system event.

Figure 11-8



6 To modify alarms for a system event, repeat this procedure.

Specify Operator Information in the Privileges Tab

Use the **Privileges** tab to:

- Set up and modify login rules for operators
- Assign operator levels to system actions
- Set up and modify user names and rights

  Note: The system administrator must be assigned Setup privileges.
- Reset a password

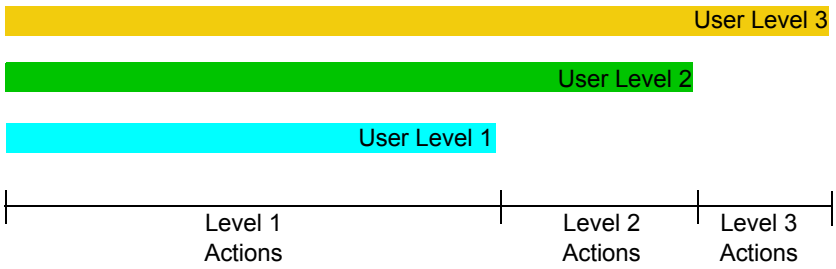
Note: To ensure that only authorized users are allowed access to the instrument and software, do not share login IDs or passwords.

Set Up and Modify Login Rules for Operators

	To specify or edit login rules
1	Touch **Setup** on the menu at the top of the screen and select the **Privileges** tab. The **Login Rules** section displays the currently saved login rules.
2	Touch a field in the **Login Rules** section to display the **Login Rules** dialog box.
3	To specify login rules: ▪ Type a minimum length (0–20) for passwords. ▪ Type the number of days (0–120) passwords remain valid. ▪ Type the number of minutes (0–120) of inactivity before the system automatically logs off the operator.
4	Touch **Ok** to save information. or Touch **Cancel** to exit without saving.
5	To edit login rules, repeat this procedure.

Assign and modify levels for system actions

You can assign a privilege level of 1, 2, or 3 for each system action displayed on the Actions list. It is up to your laboratory to select a privilege level for system actions.



- **Level 1** allows typical actions. Most actions are level 1.
- **Level 2** allows typical and higher responsibility actions such as:
  - Accepting or rejecting results
  - Modifying well results
- **Level 3** allows all actions. Only the most experienced operators in the lab can initiate and execute actions such as:
  - Adding comments in archiving
  - Editing interpretations
  - Editing lot last-used date
- **Level Setup** allows all actions and Setup privileges. Only system administrators should have access to the **Setup** screens.

To assign a privilege level of 1, 2 or 3 for each system action

1. Touch **Setup** on the menu at the top of the screen and select the **Privileges** tab. The **Actions** section displays a list of system actions and the privilege level selected for each action:
   - **Level 1.** The action is assigned a low privilege.
   - **Level 2.** The action is assigned a medium privilege.
   - **Level 3.** The action is assigned a high privilege.
2. Touch a system action in the **Actions** list to display the **Action Level** dialog box for that action.
3. Select a level from the drop-down menu.

To assign a privilege level of 1, 2 or 3 for each system action

4 Touch **Ok** to save changes.

Result: The **Actions** list displays the level you selected next to the action.

or

Touch **Cancel** to exit without saving.

5 To modify privilege levels for a action, repeat this procedure.

Set Up and Modify User Names and Rights

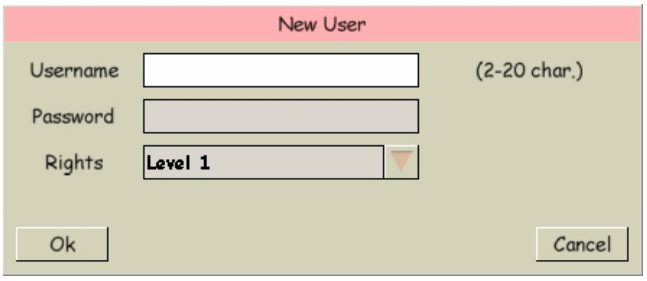
You can designate a password and one of three levels for an operator, depending on the actions you want the operator to be able to initiate.

To set up a user name and rights

1 Touch **Setup** on the menu at the top of the screen and select the **Privileges** tab. The **Users** section displays the username and rights assigned (Level 1, 2, 3 or Setup).

2 Touch **New User** to display the **New User** dialog box.

Figure 11-9



3 Enter the **Username** (2-20 characters).

Note: Each username must be unique.

Result: The **Password** is automatically assigned as the same as the user name.

4 Select a **Rights** level from the drop-down menu.

To set up a user name and rights

5 Touch **Ok** to save changes.

Result: The **Users** section displays the rights level beside the user name.

or

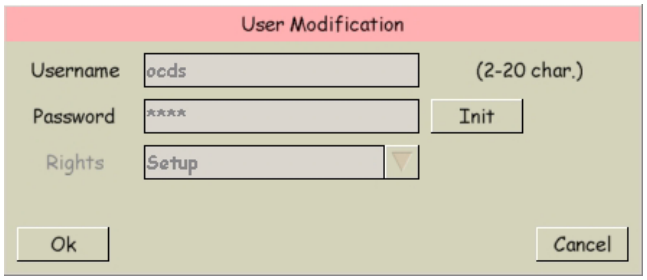
Touch **Cancel** to exit without saving.

To modify user rights

1 Touch **Setup** on the menu at the top of the screen and select the **Privileges** tab. The **Users** section displays the user name and rights assigned (Level 1, 2, or 3).

2 Touch a field under **Users** (other than New User) to display the **User Modification** dialog box.

Figure 11-10



3 Select a different **Rights** level from the drop-down menu and touch **Ok.**

To inactivate a username, select **Revoked**.

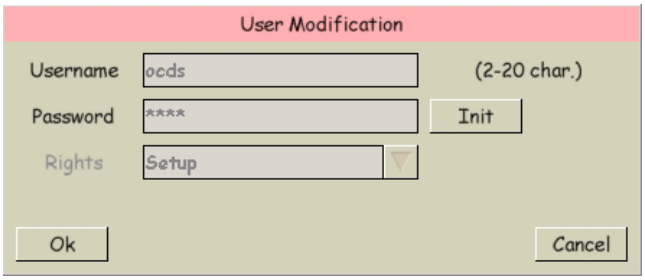
Reset a User Password

To reset a password

1 Touch **Setup** on the menu at the top of the screen and select the **Privileges** tab. The **Users** section displays the user name and rights assigned (Level 1, 2, 3, or Setup).

2 Touch the user's field under **Users** to display the **User Modification** dialog box.

Figure 11-11



3 Touch **Init** and touch **Ok** in the Warning and User Modification dialogs.

Set Preferences in the Maintenance Tab

Use the Maintenance tab to specify:

- Maintenance and quality control frequency

  Reference: For more information about recommended frequencies and step-by-step explanations of maintenance procedures see "Performing Maintenance and Quality Control Procedures" on page 8-1.

- BRC profiles

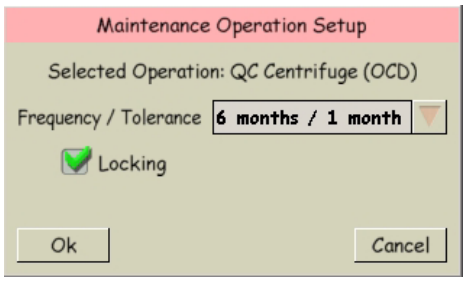
Set and Modify Maintenance and Quality Control Frequency

To set and modify maintenance and quality control frequencies

1 Touch **Setup** on the menu at the top of the screen and select the **Maintenance** tab. The **Maintenance and QC** section displays the currently saved preferences.

2 Touch a field to display the **Maintenance Operation** dialog box for the item.

Figure 11-12



3 To specify preferences:
- Select a frequency / past due time.
- Uncheck the Locking check box to indicate that you do not want the system to become unavailable for use if the maintenance procedure is not performed within the past due time limit.

To set and modify maintenance and quality control frequencies

4 Touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

5 To modify preferences, repeat this procedure.

Set Up BRC Test Profiles

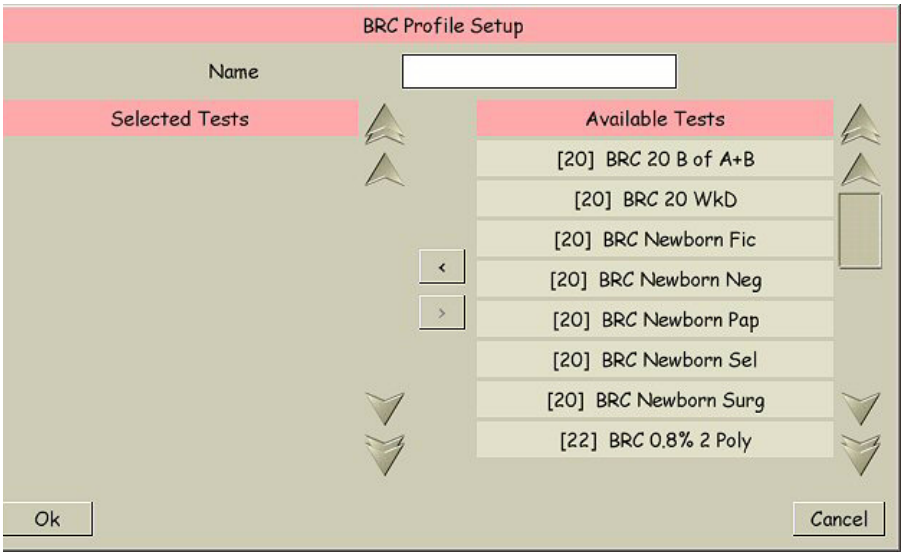
A Biological Reagent Control (BRC) test profile allows you to test reagents and cassettes as part of quality control to make certain that results are reported correctly. When running a BRC test, reagents are used instead of samples and dispensed into wells along with appropriate reagents from the BRC kits. The reported result is for the test itself (positive or negative).

To set or modify BRC profiles

1 Touch **Setup** on the menu at the top of the screen and select the **Maintenance** tab. The **BRC Profile** section displays the currently saved preferences.

2 Touch a field to display the Setup of **BRC Profile Setup** dialog box.

Figure 11-13



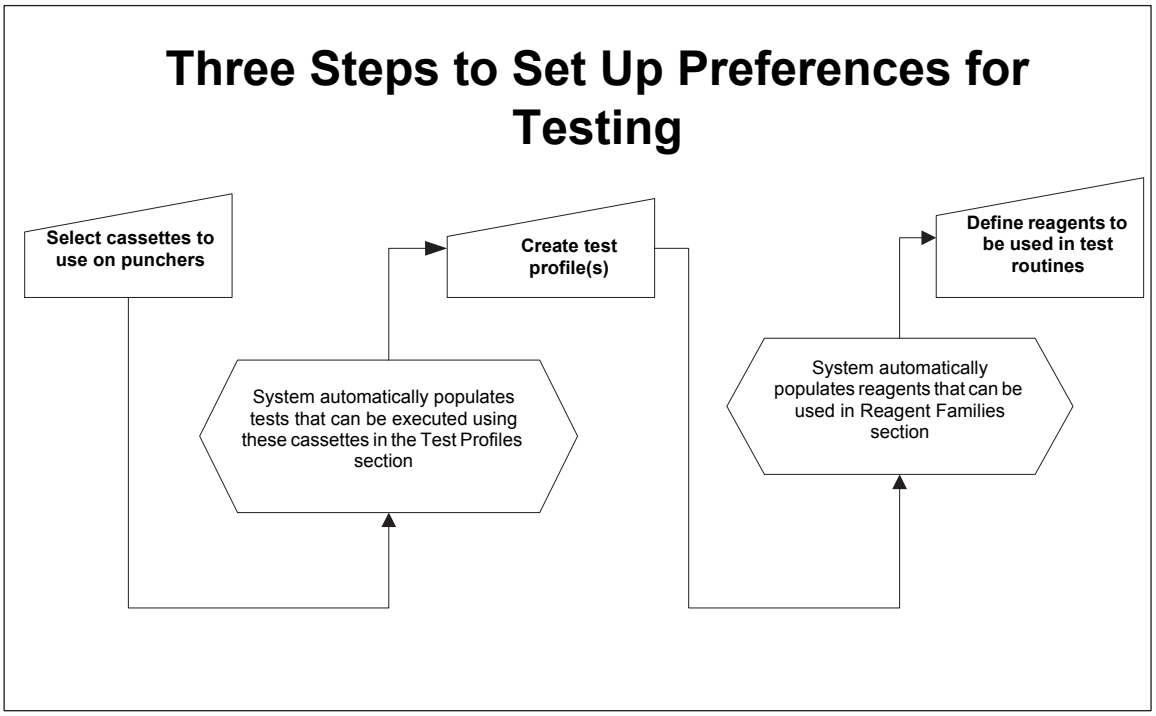
	To set or modify BRC profiles
3	To specify BRC profile: ▪ Type a name for the profile. ▪ Select a BRC test
4	To add a test to the BRC profile: ▪ Select a BRC test from the Available Tests list. ▪ Touch the (left arrow graphic) button. Result: The test is added to the **Selected tests** list.
5	To remove a test from the BRC profile: ▪ Select a BRC test from the Available Tests list. ▪ Touch the (right arrow graphic) button. Result: The test is removed from the **Selected tests** list.
6	Touch **Ok** to save information. or Touch **Cancel** to exit without saving.
7	To modify preferences, repeat this procedure.

Specify Test Configurations in the Testing Tab

Use the **Testing** tab to specify:

- Test profiles containing single or multiple tests to execute
- Reagents used in testing

Figure 11-14



Set and Modify Puncher Configurations based on Cassette Usage

OCD will set the puncher configuration based on the cassettes you use in your lab.

- 5 configurations to punch cassettes in the RTHA.
- In the 37°C punch, 3 configurations to punch cassettes among which 2 configurations permit cassettes to be punched 3 wells at a time. For example, the AHG cassette can be assigned to this punch configuration to conserve cassettes and allow partially used cassettes to be recycled into the processing flow.

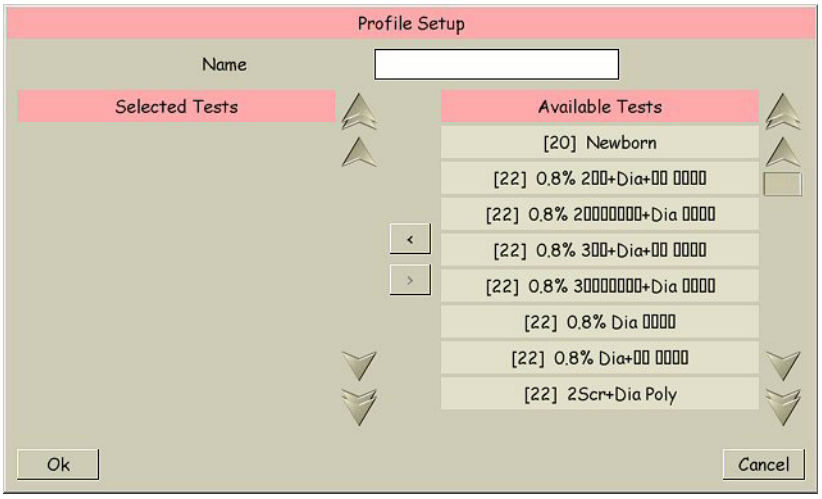
To modify the puncher configurations, contact OCD Service personnel.

Create a test profile

To create or modify a test profile

1. Touch **Setup** on the menu at the top of the screen and select the **Testing** tab. The **Profiles** section displays the currently saved preferences.
2. Touch **New Profile** to display the **Profile Setup** dialog box.

Figure 11-15



3. Type a name for the profile in the **Name** field.
4. To add a test to the profile:
   - Select a test from the **Available Tests** list.
   - Touch the < button.

   Result: The test is added to the **Selected Tests** list.
5. To remove a test from the profile:
   - Select a test from the **Selected Tests** list.
   - Touch the > button.

   Result: The test is removed from the **Selected Tests** list.

	To create or modify a test profile
6	Touch **Ok** to save modifications. Result: The system automatically adds the corresponding OCD reagent kit to the **Reagents** section. For example, if you create a profile containing the BVSP poly test, the system automatically adds the papain kit to the **Reagents** list in the **Testing** tab. or Touch **Cancel** to exit without saving modifications.
7	To create another test profile, repeat this procedure.
8	To modify a test profile, touch a profile name to display the **Profile Setup** dialog, and repeat steps 4 through 6.

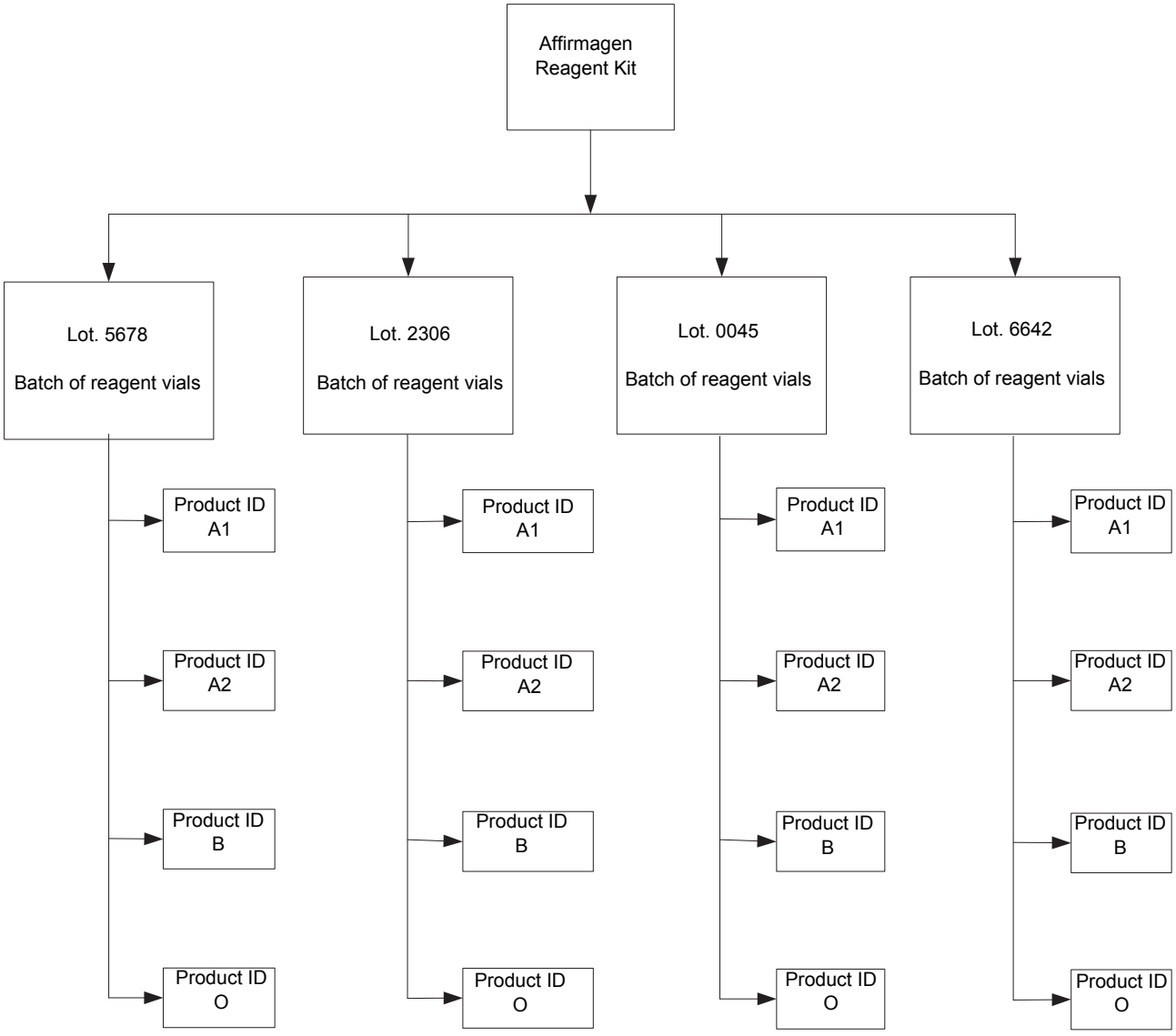
Delete a test profile

	To delete a test profile
1	Touch **Setup** on the menu at the top of the screen and select the **Testing** tab. The **Profiles** section displays the currently saved preferences.
2	Touch a profile name to display the **Profile Setup** dialog box.
3	To delete a test profile, touch **Delete**. Result: The **Warning** dialog box displays.
4	Touch **Ok** to delete the profile. Result: The system automatically deletes the corresponding OCD reagent kit from the **Reagents** section of the **Testing** tab. For example, if you delete a profile containing the BVSP poly test, the system automatically deletes the papain kit from the **Reagents** list in the **Testing** tab. or Touch **Cancel** to exit without deleting.
5	To delete another profile, repeat this procedure.

Modify a Reagent Kit

A reagent kit is a grouping of reagents. For example, Affirmagen or red cell reverse reagent Kits contain four cell types (A1, A2, B, O). A batch of the same reagent kit is labeled with a lot number. Vials of a cell type within the lot are labeled with a unique barcode.

Figure 11-16



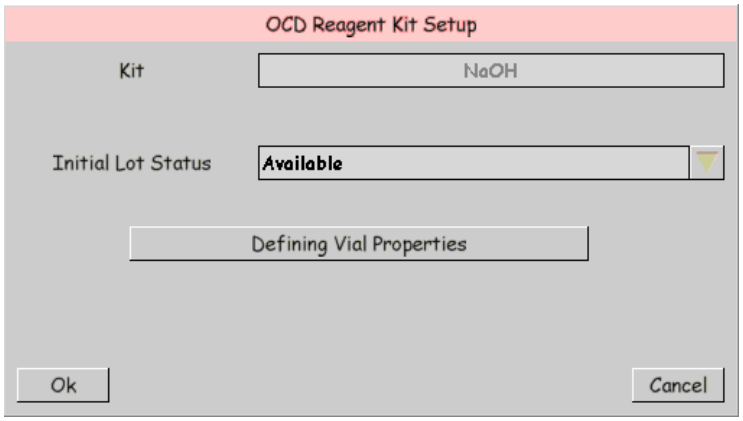
The system automatically recognizes OCD reagent vials that are placed on the reagent rack and adds them to the **Status** screen **Lots** tab.

To modify a reagent kit

1 Touch **Setup** on the menu at the top of the screen and select the **Testing** tab. The **Reagents** section displays the currently saved reagent kits.

2 Touch a reagent kit to display the **OCD Reagent Kit Setup** dialog box.

Figure 11-17



3 Select a lot status from the drop-down menu:

- **Available.** The reagent vial can be used by the system.
- **Quarantine.** The reagent vial cannot be used by the system until the lab tech enters lot information in the **Status** screen, **Lots** tab.

4 Touch the **Defining Vial Properties** button to display the **Reagent vials** dialog box.

For each volume of vial, select a vial type.

- 3mL: 3 available settings for the vial type
- 10mL: 3 available settings for the vial type
- 60mL: 2 available settings for the vial type

Note: OCD field engineers set up vial types.

5 Touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

To modify a reagent kit

6 In the **OCD Reagent Kit Setup** dialog box, touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

7 To modify another reagent kit, repeat this procedure.

Create a Non-OCD Reagent Kit

For non-OCD reagent vials without barcodes, set up reagent Kits as described below.

Note: Ortho-Clinical Diagnostics has validated the use of OCD reagents on the AutoVue system. Your institution is responsible for validating the use of non-OCD reagents on the AutoVue system.

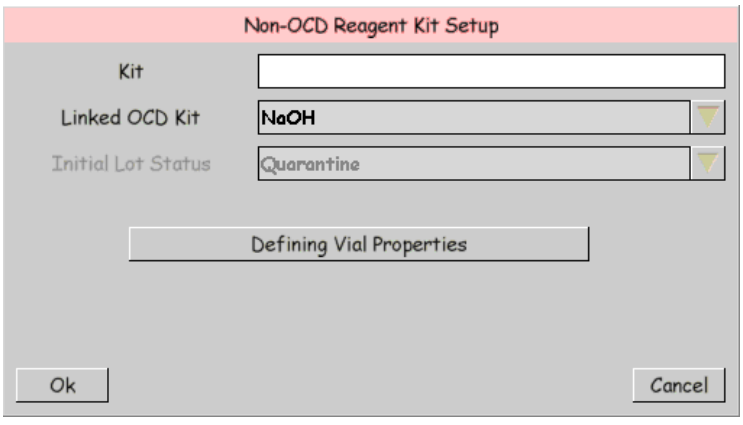
.

To create a non-OCD reagent Kit

1 Touch **Setup** on the menu at the top of the screen and select the **Testing** tab. The **Reagents** section displays the currently saved reagent kits.

2 Touch the **New Kit** field to display the **Non-OCD Reagent Kit Setup** dialog.

Figure 11-18



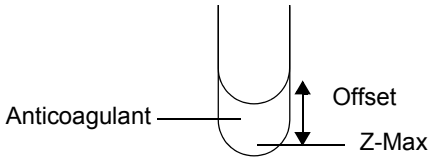
3 Type a name for the reagent kit.

	To create a non-OCD reagent Kit
4	Select a linked OCD reagent kit. For example, an OCD reagent kit that is comparable.
5	Touch the **Defining Vial Properties** button to display the **Reagent vials** dialog box. For each volume of vial, select a vial type: ▪ 3mL: 3 available settings ▪ 10mL: 3 available settings ▪ 60mL: 2 available settings Note: OCD field engineers set up vial types.
6	Touch **Ok** to save information. or Touch **Cancel** to exit without saving.
7	In the **Non-OCD Reagent Kit Setup** dialog box, touch **Ok** to save information. or Touch **Cancel** to exit without saving.
8	The reagent will have a status of **Quarantine** and will be unavailable for use. To change the status of the reagent to Available so that it can be used for testing, use the **Status** screen, **Lots** tab.
9	To create another non-OCD reagent kit, repeat this procedure.

Set Up Centblood Offset (OCD personnel only)

Centblood tubes contain an area of anticoagulant at the bottom of the tubes. These tubes can be used with typical tubes on the same sample rack at the same time.

If you are using Centblood tubes, set the offset for the RBC pipetting position (Z-position = Z-max – Offset).



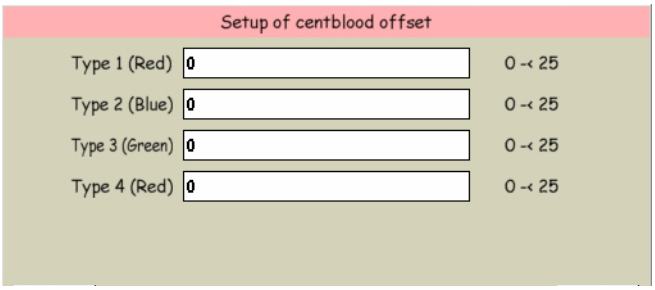
To set Centblood tube offset

1. Only OCD personnel should modify the Centblood tube offset.

   Touch **Setup** on the menu at the top of the screen and select the **Testing** tab. The **Centblood Offset** section displays the currently saved preferences.

2. Touch a sample rack type to display the **Setup of centblood offset** dialog box.

   Figure 11-19

3. Type an offset between 0mm and 25mm for one or more sample rack types.

4. Touch **Ok** to save information.

   or

   Touch **Cancel** to exit without saving.

5. To modify an offset, repeat this procedure.

Set Preferences in the Results Tab

Use the **Results** tab to specify:

- Miscellaneous
- Cassettes to save for review
- Result display preferences
- Threshold values for results

Set Miscellaneous Results Preferences

	To set miscellaneous results preferences
1	Touch **Setup** on the menu at the top of the screen and select the **Results** tab. The **Miscellaneous** section displays various results settings.
2	Touch an item to display the **Miscellaneous** dialog box.

For these items	Select or Type
Review sleeves in drawer	Select the number of cassette sleeves in the drawer that will hold saved cassettes. If you select 0, then the system will store cassettes in the CASUNCA. You can select a value from 1-4 to store saved cassettes in cassette sleeves 1-4.
User can accept own modification	▪ Touch **Yes** to accept modification changes ▪ Touch **No** to exit without saving
Acceptance mode	▪ Select **Auto** if you want results to be accepted automatically by the system. ▪ Select **Manual** if you want to review results and manually accept them. All cassettes are saved for review in this case.
Sample auto deletion period	Type the time limit (in hours) after which LIS test requests should be deleted from the Worklist because samples were not tested for these requests. The maximum time limit is 48 hours.

For these items	Select or Type
Analyses worklist display	Select the order of analyses you want to display in the Worklist.
Patient worklist display	Select the patient information fields you want to display in the Worklist.
Phenotype worklist display	Select the phenotype symbology you want to display in the Worklist.
Differentiation Patient/CQI	▪ Touch **Yes** to set the system to recognize and identify a CQI barcode. ▪ Touch **No** to set the system to not differentiate between CQI 7/9 barcodes and patient sample barcodes.
Differentiation Patient/AlbaQ-Chek J	▪ Touch **Yes** to set the system to recognize and identify an AlbaQ-Chek J barcode. ▪ Touch **No** to set the system to not differentiate between AlbaQ-Chek J barcodes and patient sample barcodes.
Review Cassettes	▪ Touch **Yes** to accept change ▪ Touch **No** to cancel change
Review Orders	▪ Touch **Yes** to accept change ▪ Touch **No** to cancel change
ABD Repipet	▪ Touch **Yes** to set the instrument so that it will make two dilutions, one for the ABO test and a separate one for the ABD confirmation. ▪ Touch **No** to use one dilution for both the ABO test and the ABD confirmation.
Enable Scheduler Optimization v1.0	▪ Allows OCD personnel to select optimal scheduler algorithm for individual labs.
Require comments for editing results	▪ Touch **Yes** to make a comment mandatory before edited results can be accepted. ▪ Touch **No** to allow edited results without entering a comment.

3 Touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

Set and Modify Preferences for Saving Cassettes to Review

In the **Saving Cassettes** section, you can specify the cassettes you would like to save in the CASUNCA or drawer to review manually. You will save the cassettes for analysis results you want to be able to review before accepting results.

You can select cassettes to save per profile or test.

All cassettes which contain at least one well with a positive grade falling within the set range will automatically be saved in the CASUNCA or drawer for review.

Note: Cassettes with indeterminate results will automatically be saved.

	To specify cassettes to save for review
1	Touch **Setup** on the menu at the top of the screen and select the **Results** tab. The **Saving Cassettes** section displays the current cassettes to save by test profile and by individual test**.** The instructions described apply to both saving a cassette by profile or by test.
2	Touch **Empty**, a profile, or a test to display the **Cassette Saving Per Profile (Test) Setup** dialog box.
3	To add a profile or test: Select a profile/test from the **Available Profiles** or **Available Tests** list and touch the left arrow ‹ button. Result: The profile/test is added to the **Selected** list.
4	To remove a profile or test: Select a profile/test from the **Selected Profiles** or **Selected Tests** list and touch the right arrow › button. Result: The profile/test is removed from the **Selected** list.
5	Touch **Ok** to save information. or Touch **Cancel** to exit without saving.

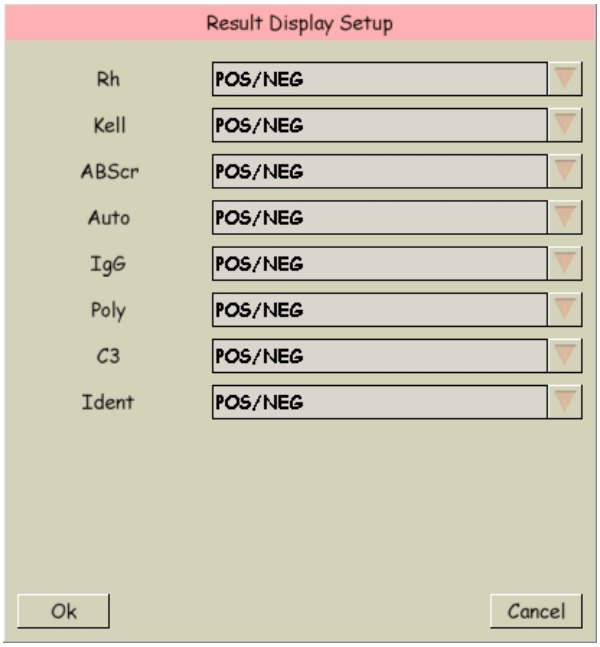
Set and Modify Results Display Preferences

To modify result display

1 Touch **Setup** on the menu at the top of the screen and select the **Results** tab. The **Result Display** section displays the currently saved preferences for each blood type **POS/NEG** or **+/-.**

2 Touch an analysis type to display the **Result Display Setup** dialog box.

Figure 11-20



3 Select a result display, either text or symbol:

Pos/Neg

+ / -

4 Touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

5 To modify result display preferences, repeat this procedure.

Set and Modify Threshold Values for Results

A threshold is a minimum value that determines whether results can be automatically accepted by the system or must be reviewed first and accepted manually.

- If results are higher than the threshold, the system will automatically accept the results.
- If results are equal to or below the threshold, then they must be reviewed and accepted manually.

For example, if you set a threshold value of 3, then any result with a value less than or equal to 3 will have to be manually accepted. A cassette containing a result with a value equal to or less than 3 will be saved for review.

Note: When two samples are processed with the same cassette, if one result is accepted manually, then the second result must also be accepted manually.

Threshold Setting Constraints

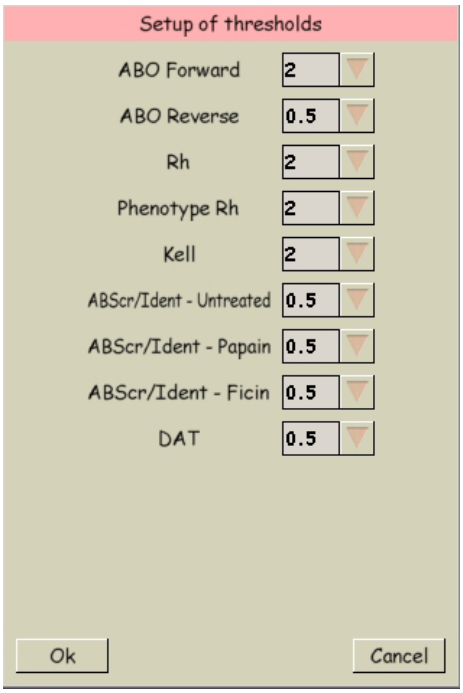
- The highest threshold that you can select is 4. A threshold of 4 means all results must be reviewed and manually accepted.
- All non-antigen typing tests have a preset threshold of 0.5. You can set these thresholds in the range from 0.5 to 4.
- All antigen typing tests have a preset threshold of 2. You can set these thresholds in the range from 2 to 4.

To set and modify result threshold values

1 Touch **Setup** on the menu at the top of the screen and select the **Results** tab. The **Thresholds** section displays the currently saved preferences for thresholds.

2 Touch a threshold value to display the **Setup of thresholds** dialog box.

Figure 11-21



3 Select a threshold value from the drop-down menu for each well type listed.

Result: The cassettes with results lower than or equal to the threshold will be saved for review rather than being discarded directly in the Waste basket.

4 Touch **Ok** to save the information.

or

Touch **Cancel** to exit without saving.

5 To modify result display preferences, repeat this procedure.

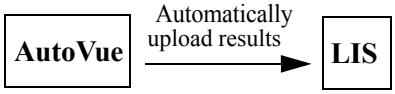
Set Preferences in the Data tab

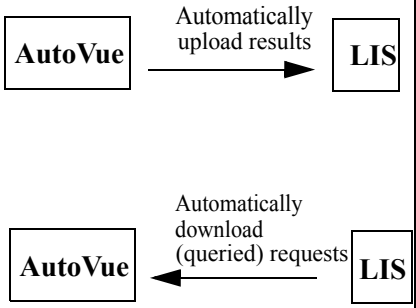
Preferences you can set for data include:

- LIS transfer options
- Data transfer by analyses groups
- Archiving preferences for data

Set and Modify LIS Transfer Options

	To specify preferences for data in the data tab
1	Touch **Setup** on the menu at the top of the screen and select the **Data** tab. The **LIS transfer** section displays the currently saved preferences**.**
2	Touch an item to display the **Transfer Setup** dialog box.

If you want to...	Then...	And....
	Select **Transfer to LIS**	▪ Type the upload path/file ▪ Check **Rejected Results Transfer** (optional) ▪ Type the Auto upload interval (0-120 min)

If you want to...	Then...	And....
	Select **Bidirectional**	▪ Type the upload path/file ▪ Type the Auto upload interval (0-120 min) ▪ Type the Auto download interval (5-600 seconds) ▪ Select Query Mode (optional)
Set a protocol	▪ Select from the list	
Set a format for the data	▪ Select from the list	
Select a character set	▪ Select from the list	

3 Touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

Set and Modify Archiving Preferences

ORTHO AutoVue *Innova/Ultra* has two types of archives:

- Short-term archive: Stores data that is less than 15 days old
- Long-term archive: Stores data that is more than 15 days old

To set or modify archiving preferences

1 Touch **Setup** on the menu at the top of the screen and select the **Data** tab.

2 Touch a row in the **Archiving** section to display the **Archiving Setup** dialog box.

3 To set automatic archiving for data, touch the **Automatic Archiving** check box.

To set or modify archiving preferences

4 Type a number between 1-6 (hours) to specify the frequency for automatic archiving. For example, type 2, for AutoVue to automatically archive data every 2 hours.

5 Touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

Set and Modify Analyses Groups

You can form a group of two or more analyses in the Analyses group setup window. If Transfer to LIS is enabled, the results for these grouped analyses will be uploaded to the LIS at the same time, i.e., the results for analyses in a group will not be uploaded until all results are available.

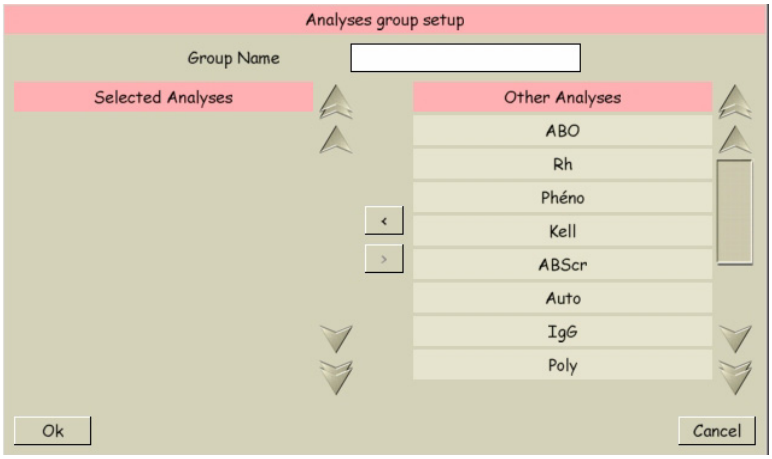
.

To set or modify analyses groups

1 Touch **Setup** on the menu at the top of the screen and select the **Data** tab.

2 Touch **New Group** in the **Analyses Group** section to display the dialog box:

Figure 11-22



3 Type a name to identify this analyses group order in the **Group Name** field.

To set or modify analyses groups

4 To add analyses to the group:

Select an analysis from the **Other Analyses** list and touch the left arrow < button.

Result: The analyses is added to the **Selected Analyses** list.

5 To remove analyses:

Select an analyses from the **Selected Analyses** list and touch the right arrow > button.

Result: The analysis is removed from the **Selected Analyses** list.

6 Touch **Ok** to save information.

or

Touch **Cancel** to exit without saving.

This page intentionally left blank.

Appendix A: Error Messages

This appendix lists the ORTHO AutoVue *Innova/Ultra* error messages and the action required.

Topics

Software Error Codes

Software errors display as 3-digit numeric codes. Some of these codes only display for OCD service personnel.

Table A-1 Software Error Codes

Error	Error Label	Customer Action Required	Only display for OCD Service Personnel
101.	Syntax Error	NA	x
102.	XML File Modified (Checksum error)	NA	x
103.	Invalid MEDs Script	NA	x
104.	Error in Actions List. Modules will be parked.	NA	x
105.	Error while parking modules. Modules will be reinitialized.	NA	x
106.	No free position on CASUNCA for this cassette.	NA	x
107.	Cassette Already Present	NA	x
108.	Cassette Already in Gripper	NA	x
109.	No cassette present in this position.	NA	x
110.	Centrifuge Not Balanced	NA	x
111.	Centrifuge door must be closed.	NA	x
112.	Centrifuge door must be opened in order to balance.	NA	x
113.	Spin door must be opened.	NA	x
114.	PTA in Wrong Position	NA	x
115.	Rack must be in pipetting position.	NA	x
116.	3-way valve in wrong position.	NA	x
117.	PTA Not Empty.	NA	x
118.	PTA is empty.	NA	x
119.	Rack is not in reading position.	NA	x
120.	Sample rack is not in home position.	NA	x
121.	Drawer incorrectly positioned.	NA	x
122.	Loaded cassette must be released.	NA	x
123.	Parameter Error	NA	x

Table A-1 Software Error Codes (continued)

Error	Error Label	Customer Action Required	Only display for OCD Service Personnel
124.	No punched cassette in this position.	NA	x
125.	Incorrect Username or Password	Enter correct username or password.	
126.	All fields must be completed.	Complete all fields.	
127.	Invalid Selection	Make valid selection.	
128.	Define a name for this new analyses group.	Enter a name in the Group Name field.	
129.	Main analyses group cannot be removed.	Do not delete Main analyses group.	
130.	Old password incorrect.	Enter correct old password.	
131.	Passwords entered do not match.	Enter correct passwords.	
132.	New and old passwords are identical.	Enter unique new password.	
133.	Invalid Input. Date entered is not valid.	Enter valid date.	
134.	Incubator must be in loading position.	NA	x
135.	Gripper incorrectly positioned.	NA	x
136.	Invalid Input. This sample is already associated to another patient.	Register a unique sample ID for the current patient.	
138.	Cannot dispense. No liquid picked up.	NA	x
139.	Invalid Input. Incorrect Sample ID.	Enter correct sample ID.	
140.	Incorrect Rack Number (1-5)	Call OCD service personnel.	x
141.	Rack Rotation Failure	Call OCD service personnel.	x
143.	Parameters for cassette type %1 (%2) do not match with current parameters. Parameter file is corrupt, or current parameters are out of date.	NA	x
144.	Parameter file seems to be corrupt.	NA	x
145.	Test structure (ref %1 name %2) is invalid. Parameter file may be corrupt	NA	x
146.	Current user cannot be revoked.	Confirm that the username is to be deleted.	
147.	The cassette type currently punched on this position is in use in a profile and cannot be changed.	Wait until test routine completes to change cassette type information.	
148.	Control already in use.	Use a control ID that is not already registered or in use.	

Table A-1 Software Error Codes (continued)

Error	Error Label	Customer Action Required	Only display for OCD Service Personnel
149.	Control already registered.	Register a unique control ID for the control.	
150.	Invalid Input. the two entries are not identical.	Enter identical entries in the fields.	
151.	This analyses group already exists.	Enter a unique analyses group.	
152.	Invalid Input. this sample ID is already defined as a control.	Register a unique sample ID.	
153.	Invalid Input. This control ID is already defined as a sample.	Register a unique control ID.	
154.	Invalid Input. Unknown Control Sample.	Register control sample.	
155.	Select an OCD reagent kit before creating a new lot.	Select an OCD reagent kit.	
156.	Select a cassette type before creating a new lot.	Select a cassette type.	
157.	Cannot create a new lot for this cassette type.	Check that the cassette type is defined in the puncher.	
158.	Invalid Input. Undecodable Barcode	Enter the correct bar code.	
159.	Invalid Input. Lot Already Defined	Enter a unique lot.	
160.	Cannot create this lot; it already exists.	Enter a unique lot.	
161.	The profile name is empty.	Enter profile name.	
162.	Cannot create an empty profile. At least one test must be added.	Add a test to the profile.	
163.	Result received for unexpected order	Call OCD service personnel.	
164.	Cannot create an empty analyses group.	Enter analyses group information.	
165.	A profile with this name already exists.	Enter a unique profile name or delete the existing profile with the same name.	
166.	A user with the same username already exists.	Enter a unique username.	
167.	This username does not exist.	Enter a correct username in the field or call your system administrator to add the username to the system.	
168.	A puncher configuration for this cassette type already exists.	Select another cassette type for the puncher configuration.	
169.	This sample is already defined with a different sample type.	Register a unique sample ID for the sample type.	

Table A-1 Software Error Codes (continued)

Error	Error Label	Customer Action Required	Only display for OCD Service Personnel
170.	Test failure on path/file name.	Inform your system administrator.	
171.	Value is out of range.	Enter a value within the valid range.	
172.	Interval entered is incorrect.	Enter a value within the valid range.	
173.	Config.inp was not found.	Call OCD service personnel.	x
174.	Invalid Input. The barcode read should not have an OCD format.	Check the bar code.	
175.	Invalid Input.	Enter valid value.	
177.	Invalid Input. This sample is already defined with a different sample type.	Register a unique sample ID for the sample type.	
178.	Invalid Input. The sample ID must be confirmed	Re-enter the sample ID or touch the **Validate** button.	
179.	Invalid Input. Unknown sample ID.	Register the sample ID.	
180.	Invalid Input. This sample is already defined with a different sample type.	Register a unique sample ID for the sample type.	
181.	Invalid Input. This order (sample ID / profile) already exists.	Register a unique sample ID.	
182.	Invalid Input. This order (control ID / profile) already exists.	Register a unique control ID.	
183.	Invalid Input. This donor ID is already defined for this patient.	Register a unique donor ID.	
184.	Invalid Input. This donor ID is already defined as a control or as a sample.	Register a unique donor ID.	
185.	Invalid Input. This control is a CQI.	Enter a non-CQI control ID.	
186.	NAA is not present.	Load Non-Agitated Area through Main door, if required.	
187.	The sample ID is empty or not valid.	Enter correct sample ID in field.	
188.	No result to be accepted.	Wait until test routine is complete and results have displayed on the **Worklist**.	
189.	This non-OCD reagent kit already exists.	Define a unique name for the non-OCD reagent kit.	
190.	This reagent kit does not exist.	Define the kit in **Setup**, **Testing** tab, **Reagents** section.	
191.	There is at least one lot associated to this kit.	Enter a unique lot ID for this kit.	

Table A-1 Software Error Codes (continued)

Error	Error Label	Customer Action Required	Only display for OCD Service Personnel
192.	This non-OCD reagent kit has the same name as an OCD reagent kit.	Define a unique name for the non-OCD reagent kit.	
193.	Manual entry not allowed.	Scan requested bar code.	
194.	No available profile.	NA	x
195.	A test cannot be included more than once in a profile.	Add a test that is not already part of the profile.	
196.	FATAL ERROR. Not enough space for display analysis results	Inform your system administrator.	
197.	The maximum barcode length cannot be greater than 20 characters.	Type a bar code that is under 20 characters.	
198.	Position not allowed.	Place the reagent in a correct position on the rack.	
199.	You cannot accept your own modifications.	Ask an authorized user to accept your modifications.	
200.	It's not the right cassette.	Scan the correct cassette bar code.	
201.	AutoRotor must be in loading position.	NA	x
202.	The selected profile is not compatible with this CQI.	Select the correct profile.	
203.	Value must be between x and x.	Type a value between 1-2.	
204.	Wrong Value. Entered value x. Admitted interval y.	Enter a value within the allowed interval.	
205.	Test failure. Entered value %1. Error detected %2.	Enter a valid value.	
206.	The Start date must be less than %1 days ago.	Enter an accurate start date.	
207.	Incoherent Period.	Enter an accurate date interval.	
208.	The user currently logged in does not have sufficient privileges to perform this action.	Log in with a username that has sufficient privileges to perform this action or contact your system administrator for more information.	
209.	The minimum password length is %1.	Enter correct password length that is at least one character.	
210.	The username and password cannot be identical.	Enter a unique password that is different from your username.	
211.	Insufficient Privileges.	Login with appropriate login mode, with a username that has sufficient privileges, or contact your system administrator.	

Table A-1 Software Error Codes (continued)

Error	Error Label	Customer Action Required	Only display for OCD Service Personnel
212.	Incorrect Barcode. The barcode expected is a reagent rack barcode.	Scan the bar code of the Reagent Rack.	
213.	Invalid Input. This sample ID is assigned to a patient.	Register a unique sample ID.	
214.	Invalid Input. Invalid Expected Result.	Enter a valid expected result.	
215.	Invalid Input. Result not allowed.	Re-enter the option or data using valid input.	
216.	Cannot add any more donors.	Do not attempt to add additional donors.	
217.	Invalid Input. This sample ID is already defined as a donor.	Enter an unused sample ID.	
218.	Invalid Input. Search Criteria Unavailable.	Enter a valid search criterion.	
219.	Password Validity Period Expired.	Login again using the Change Password feature.	
220.	BRC Cannot be integrated. See worklist.	BRC is not in the Worklist. Run a BRC and then integrate it.	
221.	Serial communication lost! Application will be closed.	Check the serial communication and restart the application.	
222.	Cassette ID %1, Lot ID %2 cannot be found.	Enter a valid cassette ID and lot ID to review the cassette.	
223.	Invalid Input. This control is an AlbaQ-Chek J.	Enter a non-AlbaQ-Chek J control ID.	
224.	The selected profile is not compatible with this AlbaQ-Chek J.	Select the correct profile.	
225.	Invalid input. This control is an AlbaQ-Chek WW	Enter a non-AlbaQ-Chek WW control ID.	
226.	The selected profile is not compatible with this AlbaQ-Chek WW	Select the correct profile.	

Hardware Error Codes

Hardware errors related to the instrument:

- Asynchronous errors display on the **Data** screen, **Instrument Errors** tab. These errors may require operator intervention or OCD service personnel.
- Internal errors display in log files, but not on the screen. These errors are viewed by OCD service personnel to determine the reasons why asynchronous errors occurred.

Asynchronous Error Codes

Asynchronous errors display when two or more independent processes are running simultaneously and an error is reported for one of the processes.

Asynchronous error codes have 7 characters:

ASBBNNN

where
AS is the abbreviation for Asynchronous
BB is the assembly as described in the table below
NNN is the error identification number

Table A-2 Assembly Designations

Assembly Code	Description	Assembly Code	Description
AO	AutoRotor	PM	Pump
AR	AutoReader	PP	Pipette
BA	Batch	RE	Reagent
CO	Special Cassette Type	RO	Reagent Rotor
CA	Cassette Area	RR	Reagent Rack
CS	Cassette	RT	Reagent Type
CT	Cassette Type	SA	Sample
CR	Cassette Loading Area	SO	Sample Rotor
CH	Channel	SP	Spin
CP	Partially Used Cassette Area	SR	Sample Rack
CU	Cassette Review Area	ST	Sample Type
DP	Diluter Position	SY	System
DR	Dilution Rack	TC	Trashcan

Table A-2 Assembly Designations (continued)

Assembly Code	Description	Assembly Code	Description
DU	Diluter	TE	Test
GP	Gripper Position	TP	Tip Position
GR	Gripper	TT	Test Type
IN	Incubator/Piercer	WH	Wash
LY	Layout	WT	Waste
OO	Image Processing System		

Table A-3 Asynchronous Error Codes

Error	Description	Cause	Action
ASAO011	AutoRotor Initialization Error	The AutoRotor could not be initialized, possibly due to something jammed, broken, or poorly adjusted.	Open the instrument cover. Remove any cassettes in the AutoRotor. Continue the system. If unable to access the instrument, switch off the instrument power. Follow the actions above. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASAO012	AutoRotor Positioning Error	The AutoRotor cannot be positioned properly, possibly due to something jammed, broken, or poorly adjusted.	Open the instrument cover. Remove the cassette causing the problem in the AutoRotor. Select the cassette Abort button. Scan the cassette bar code with the hand-held bar code scanner and select Abort. All tests associated with this cassette will be aborted. Continue the system.
ASAR011	AutoReader Initialization Error	The AutoReader could not be initialized, possibly due to something jammed, broken, or poorly adjusted.	Open the waste door and remove the trash container. Remove any cassettes in the cassette waste lift or in the AutoReader gripper. Replace the trash container. Continue the system. If unable to access the instrument, switch off the instrument power. Follow the actions above. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASAR012	AutoReader Positioning Error	The AutoReader cannot be positioned properly, possibly due to something jammed, broken, or poorly adjusted.	Open the waste door and remove the trash container. Remove any cassettes in the cassette waste lift or in the AutoReader gripper. Replace the trash container. Continue the system.
ASCH011	Cassette Drawer Initialization Error	The cassette drawer could not be initialized, possibly due to something jammed, broken, or poorly adjusted.	Open the cassette drawer. Verify that the cassettes are properly loaded. Center metal tray within the cassette drawer. Continue the system. If unable to access the instrument, switch off the instrument power. Open cassette drawer by pushing the release switch. Follow the actions above. Switch on the instrument power. Follow PCU prompts to recover from communication loss.

Table A-3 Asynchronous Error Codes (continued)

Error	Description	Cause	Action
ASCH012	Cassette Drawer Positioning Error	The cassette drawer cannot be positioned properly, possibly due to something jammed, broken, or poorly adjusted.	Open the cassette drawer. Verify cassettes are properly loaded. Center metal tray within the cassette drawer. Continue the system.
ASCH015	Cassette Expired	A cassette in the specified channel has reached its expiration date.	Open the cassette drawer. Replace the cassette(s) with cassettes that are not expired. Continue the system.
ASCH020	Unrecognizable Cassette Barcode	A cassette from the associated channel has a missing or invalid bar	If the instrument has stopped processing batches, open the instrument cover. Examine the cassettes and determine if a problem exists. Open the cassette drawer. Verify channel assignments are correct and that the correct type of cassettes are loaded. If possible, correct the problem. Continue the system. If the problem persists, contact OCD.
ASCH024	Wrong Cassette Type	The cassette type does not match the definition for the specified channel.	Open the cassette drawer. Verify channel assignments are correct and that the correct type of cassettes are loaded. Continue the system.
ASCS016	Cassette Time Elapsed	The specified cassette was incubated for too long.	The cassette and its associated test(s) will automatically be aborted. Redefine the test(s) in a new batch.
ASCS020	Unrecognizable Cassette Barcode	The cassette in the AutoReader has a missing or invalid bar	If the problem continues to occur, switch off the instrument power. Restart the instrument. If the problem persists, contact OCD.
ASCS022	Unexpected Cassette ID Number	The bar code scanner in the AutoReader has found an unexpected cassette ID number.	The cassette will be stored in the cassette review area for manual examination. The cassette will not be graded. Redefine tests. Report error to OCD.
ASCS025	Cassette Cannot be Pierced	The instrument was unable to pierce the specified cassette, possibly due to cassette deformity or positioning.	Open the instrument cover and Continue the system. If the problem persists, obtain the cassette ID number from the error message. Abort all tests to be run with this cassette.

Table A-3 Asynchronous Error Codes (continued)

Error	Description	Cause	Action
ASCS026	Cassette Cannot be Picked Up	The gripper was unable to pick up the specified cassette, possibly due to a deformed cassette box, a damaged cassette, or poor positioning.	If the problem is in the cassette drawer, open the cassette drawer and reposition or remove the cassette in question. If the problem is not in the cassette drawer, open the instrument cover. Place the cassette in question into the cassette recovery position. Continue the system.
ASCS027	Cassette Cannot be Placed	The gripper was unable to place the specified cassette, possibly due to a damaged cassette or poor positioning.	Open the instrument cover. Remove the cassette causing the error from the gripper. Place the cassette into the cassette recovery position. Continue the system. If the problem persists, abort this cassette to continue batch processing.
ASCS028	Cassette Lost	The gripper or AutoReader gripper has lost the specified cassette.	Open the instrument cover. Remove the cassette causing the error and place it into the cassette recovery position. Continue the system. If the problem persists, open the instrument cover. Select the cassette Abort button. Scan the cassette bar code with the hand-held bar code scanner and select Abort. All tests to be run with this cassette will be aborted. Continue the system.
ASCS041	Cassette Waste Lift Error	The AutoReader gripper cannot place the specified cassette into the cassette waste lift.	Open the waste door and remove the trash container. Remove any cassettes in the cassette waste lift or in the AutoReader gripper. Replace the trash container. Continue the system.
ASCS046	Serological Timing Restriction Violation	During the processing (in the incubator, centrifuge, or the AutoReader) of the specified cassette, a serological timing restriction was violated.	All tests associated with this cassette will be aborted. Defining smaller batches may eliminate the occurrence of this violation. If a serological time error occurs for one well of a cassette, all the wells of the cassette linked to the same patient will be reported as invalid.
ASCS052	Duplicate Cassette Detected in the Cassette Drawer	A duplicate cassette was detected while scanning cassette bar code labels residing in the cassette drawer.	Open the cassette drawer and examine the cassettes for unique cassette identification. The duplicate cassette will be brought up automatically by the instrument to the cassette review area.
ASCT029	No More Cassettes	There are no more cassettes of the specified type.	Open the cassette drawer. Add more cassettes. Continue the system.

Table A-3 Asynchronous Error Codes (continued)

Error	Description	Cause	Action
ASDU011	Diluter Initialization Error	The diluter could not be initialized.	Open the instrument cover and Continue the system. If the problem persists, contact OCD.
ASDU012	Diluter Positioning Error	The diluter cannot be positioned properly.	Open the instrument cover and Continue the system. If the problem persists, contact OCD.
ASGR011	Gripper Arm Initialization Error	The gripper arm could not be initialized, possibly due to the gripper arm position.	Open the instrument cover and Continue the system. Alternate action: Switch off the instrument power. Position the gripper arm near the centrifuge. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASGR012	Gripper Arm Positioning Error	The cassette gripper arm cannot be positioned properly, possibly due to the gripper arm position.	Open the instrument cover and Continue the system. Alternate action: Switch off the instrument power. Position the gripper arm near the centrifuge. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASGR245	No Balance Cassette Found	A balance cassette was not found for use in the centrifuge.	Switch the instrument power off. Open the cassette drawer by pushing the release switch. Load cassettes into the cassette drawer. Restart the instrument. Follow the PCU prompts to recover from communication loss. The problem will be corrected upon initialization of the instrument.
ASIN011	Incubator or RTHA Initialization Error	The incubator could not be initialized, possibly due to something jammed, broken, or poorly adjusted.	Open the instrument cover. Verify that all visible cassettes in the incubator and RTHA are inserted properly. Continue the system. If unable to access the instrument, switch off the instrument power. Follow the actions above. Switch on the instrument power. Follow PCU prompts to recover from communication loss. If the problem persists, contact OCD.
ASIN012	Incubator or RTHA Positioning Error	The incubator or RTHA cannot be positioned properly, possibly due to something jammed, broken, or poorly adjusted.	Open the instrument cover. Verify that all visible cassettes in the incubator and RTHA are inserted properly. Continue the system. If the problem persists, contact OCD.

Table A-3 Asynchronous Error Codes (continued)

Error	Description	Cause	Action
ASIN017	Incubator Temperature Too Low	The temperature of the incubator is too low.	All tests in the incubator will be aborted. Tests requiring the RTHA will not be affected. All new tests requiring the incubator will be delayed until the incubator meets temperature specifications.
ASIN018	RTHA or Incubator Temperature Too High	The temperature of the RTHA or the incubator is too high.	All tests in the incubator will be aborted. Tests requiring the RTHA will complete. All new tests will be delayed from starting until the RTHA and the incubator meet temperature specifications.
ASIN043	Problem Detecting Temperature	The software had a problem detecting the incubator or RTHA temperature. Running batches will be aborted. New batches will not start.	If the problem persists, contact OCD.
ASPM255	System Fluid Flow Interrupted	The application software detected that the flow of either saline or distilled water was interrupted. Some possible causes are bubbles, a clogged tip, a shaken or empty container, or squeezed, crossed, or loose tubes.	Inspect the liquid system and correct the problem. Continue the system. If the problem persists, contact OCD.
ASPP011	Pipette Arm Initialization Error	The pipette arm could not be initialized, possibly due to the pipette arm position.	Open the instrument cover and Continue the system. Alternate action: Switch off the instrument power. Position the pipette arm near the wash station. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASPP012	Pipette Arm Positioning Error	The pipette arm cannot be positioned properly, possibly due to the pipette arm position.	Open the instrument cover and Continue the system. Alternate action: Switch off the instrument power. Position the pipette arm near the wash station. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASPP030	Pipette Tip Positioned Poorly	The pipette tip position check failed, possibly due to a bent tip or poor positioning.	Adjust the pipette tip position by performing Pipette Position QC. If the problem persists, contact OCD.

Table A-3 Asynchronous Error Codes (continued)

Error	Description	Cause	Action
ASRO011	Reagent Rotor Initialization Error	The reagent rotor could not be initialized, possibly due to something jammed, broken, or poorly adjusted.	Open the instrument cover. Reposition the reagent rack. Continue the system. If unable to access the instrument, switch off the instrument power. Follow the actions above. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASRO012	Reagent Rotor Positioning Error	The reagent rotor cannot be positioned properly, possibly due to something jammed or broken.	Open the instrument cover. Reposition the reagent rack. Continue the system.
ASRR242	Reagent Rotor Mixing Error	The reagent rotor has stopped mixing, possibly due to something jammed, broken, or poorly adjusted.	Switch instrument power off. Restart the instrument. Follow PCU prompts to recover from communication loss. If the problem persists, contact OCD.
ASRT019	Reagent clot detected	A blood clot adhered to the pipette during reagent aspiration.	Test is aborted if retries to remove the clot are unsuccessful.
ASRT049	Reagent Volume Lower or Higher than Expected	The difference between the expected amount of remaining reagent and the actual amount remaining is outside of tolerance for the vial size.	Check reagent level in vial and replace if necessary.
ASSA019	Sample Clot Detected	A clot was detected in the specified sample.	Tests requiring the blood component of the sample, which generated the clot error, that have not yet received the sample will be aborted. Open the access door. Correct the problem with the sample tube. Continue the system. Redefine the sample in a new batch.
ASSA046	Serological Timing Restriction Violation	During sample distribution, a serological timing restriction was violated.	The test associated with the sample being pipetted when the timing violation occurred will be aborted. Defining smaller batches may eliminate the occurrence of this violation.

Table A-3 Asynchronous Error Codes (continued)

Error	Description	Cause	Action
ASSO011	Sample Rotor Initialization Error	The sample rotor could not be initialized, possibly due to something jammed, broken, or poorly adjusted.	Open the access door. Reposition the sample racks. Verify loaded sample tubes are completely inserted in the sample racks. Continue the system. If unable to access the instrument, switch off the instrument power. Follow the actions above. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASSO012	Sample Rotor Positioning Error	The sample rotor cannot be positioned properly, possibly due to something jammed or broken.	Open the access door. Reposition the sample racks. Verify loaded sample tubes are completely inserted in the sample racks. Continue the system.
ASSO013	Sample Rack Position Verification Error	The sample rack position could not be verified.	Ensure that test results reported during the period when the sample rack position was unverified are correct.
ASSP011	Centrifuge Initialization Error	The centrifuge could not be initialized, possibly due to something jammed or broken.	Open the instrument cover. Remove any cassettes in the centrifuge. Continue the system. If unable to access the instrument, switch off the instrument power. Follow the actions above. Switch on the instrument power. Follow PCU prompts to recover from communication loss.
ASSP012	Centrifuge Positioning Error	The centrifuge cannot be positioned properly, possibly due to something jammed or broken.	Open the instrument cover. Remove any cassettes in the centrifuge. Continue the system.
ASSP038	Centrifuge Overload	The centrifuge detected an overload condition.	All tests in the centrifuge will automatically be aborted. Open the instrument cover. Clear away any jams or loose cassettes in the centrifuge. Continue the system. If the problem persists, contact OCD.
ASSP039	Centrifuge Out of Balance	The centrifuge detected an out of balance condition.	All tests in the centrifuge will automatically be aborted. Open the instrument cover. Clear away any jams or loose cassettes in the centrifuge. Continue the system. If the problem persists, contact OCD.

Table A-3 Asynchronous Error Codes (continued)

Error	Description	Cause	Action
ASSP054	The Centrifuge spun less time than required	The centrifuge spun less time than required (configured). This can happen if the centrifuge device (hardware or firmware) malfunctions. The instrument will automatically abort all cassettes in the centrifuge and tests associated with them.	Open the cover and run Continue System. If the problem persists, call for service.
ASSR022	Incorrect Sample Rack Barcode Content	The data contained within the sample rack bar code is incorrect.	Open the access door. Replace the sample rack. Continue the system. Retain the sample rack in question and report error to OCD.
ASSY047	Hard Disk Full	The amount of available hard disk space is too low.	Contact OCD.
ASSY242	Open Door Detected	An open door was detected after the doors were locked.	Switch instrument power off. Restart the instrument. Follow PCU prompts to recover from communication loss.
ASSY253	CCU Not Connected	The CCU is not properly connected.	Contact OCD.
ASSY255	Exception Procedure Called	The application software has run into a problem. Possible reasons for this error are hardware problems, programming errors, or bad configurations.	Continue the system. If the problem persists, contact OCD.
ASTC013	Trash Container is Full	Sensor detects trashcan has reached capacity.	System will pause testing. Follow instruction "Empty Waste Cassettes from the Waste Container" on page 8-9. When message "Did you empty the trashcan?" displays, click Yes. Number of available cassettes in Resources screen, Required tab will show 250. Waste lift will move any waste cassette in process to the trashcan, and system returns to normal.

Internal Errors Codes

Internal error codes are found in log files and not seen on the screen. They are listed here for the system administrator's reference.

Table A-4 AutoRotor Error Codes

AutoRotor (ARR)	Error Description	Comments
0	No Error	
1	Initialization Error	
2	Invalid Command Memo	
3	Invalid Operand x Parameter y Argument	
4	Invalid Command Sequence	
5	Device Not Available	generated by MASTER internally
6	Time-Out Error	generated by MASTER internally
7	Device Not Initialized	Set until <PI> exec. for the 1st time
8–9	NA	
10	EEPROM Access Error	
11–13	NA	
14	Command Overflow on MODULE-1	
15	Command Overflow	New class 2 command received while a class 2 command is already busy
16–19	NA	
20	Steploss on Rotor	
21–29	NA	
30	Door Lock Monitoring Shutdown Error	
31	NA	

Table A-5 AutoReader (ARR) Error Codes

AutoReader (ARR) Error Code	Error Description	Comments
0	No Error	
1	Initialization Error	
2	Invalid Command Memo	
3	Invalid Operand x Parameter y Argument	
4	Invalid Command Sequence	
5	Device Not Available	generated by MASTER internally
6	Time-Out Error	generated by MASTER internally
7	Device Not Initialized	Set until <PI> exec. for the first time
8–9	NA	
10	EEPROM Access Error	
11–13	NA	
14	Command Overflow on MODULE-1	
15	Command Overflow	New class 2 command received while a class 2 command is already busy
16	NA	
17	Waste Bag Full	
18	Barcode Error	
19	Waste Error	
20	Steploss on Cassette Transport	
21	Position Error of Revolving Gripper	
22–29	NA	
30	Door Lock Monitoring Shutdown Error	
31	NA	

Table A-6 Arms Error Codes

Arms Error Code	Error Description	Comments	Returned
0	No Error		All commands in normal case
1	Initialization Error		By PI, XI, YI, ZI
2	Invalid Command Memo		If a wrong command is sent
3	Invalid Operand x Parameter y Argument		If a wrong operand is sent
4	Invalid Command Sequence	(not used by CCU)	Not used
5	Device Not Available	Generated by MASTER internally (CCU)	No connection
6	Time-Out Error	Generated by MASTER internally (CCU)	No response
7	Device Not Initialized	Set until <PI> exec. for the first time	If no PI was performed
8	Command Overflow		Command overflow
9	No Liquid Detected		By ZX
10	Z-Position overrun (out of defined range)		By ZR
11	Not Enough Liquid Detected		By ZX
12	No Liquid Detected		By ZZ
13	Not Enough Liquid Detected		By ZZ
14–16	NA		Not used
17	Arm Collision Avoided		by PA, XA, YA, ZA, XR, YR, ZR, XS, YS, ZS
18–19	NA		Not used
20	Steploss Detected X Axis		by PI, XI, XA, XR, XS
21	Steploss Detected Y Axis		by PI, YI, YA, YR, YS
22	Steploss Detected Z Axis		by PI, ZI, ZA, ZR, ZS, ZX, ZZ
23	Steploss Detected on the Other Arm		by SX, SY, SZ
24	ALID pulse error		by ZX, ZZ, SS
25–29	NA		Not used
30	Door Lock Monitoring Shutdown Error		Door open
31	EEPROM Write/Read Failure		by OW

Table A-7 Centrifuge Error Codes

Centrifuge Error Code	Error Description	Comments
0	No Error	
1	Initialization Error	Not used by centrifuge, initialization is controlled by the overload error number 10
2	Invalid Command	
3	Invalid Operand x Parameter y Argument	
4	Invalid Command Sequence	Not used by centrifuge
5–6	NA	
7	Device Not Initialized	Set until <PI> exec. for the first time
8	NA	
9	Excessive Centrifuge Vibration	
10	Overload	
11–14	NA	
15	Command Overflow	

Table A-8 Cassette Loading Area (CLA) Error Codes

Cassette Loading Area (CLA) Error Code	Error Description
0	No Error
1	Initialization Error
2	Invalid Command
3	Invalid Operand x Parameter y Argument
4	Invalid Command Sequence
5	Device Not Available
6	Time-Out Error
7	Device Not Initialized
8–14	NA
15	Command Overflow
16–19	NA
20	Step Loss detected
21–24	NA
25	NA

Table A-9 Incubator Error Codes

Incubator Error Codes	Error Description	Comments
0	No Error	
1	Drive Error	Use cmd. <REx> for more information
2	Invalid Command Memo	
3	Invalid Operand x Parameter y Argument	
4	NA	
5	Device Not Available	Generated by CCU internally
6	Time-Out Error	
7	Device Not Initialized	Set until <PI0> exec. for the first time and after drive errors
8	Command Overflow	Generated by CCU internally
9	NA	NA because reserved for: Device Independent Error
10	EEPROM error	New (empty) eeprom or read/write error
11	AD Converter Fail	Affects temperature measurement and control circuit INCA and RTHA
12–14	NA	
15	Command Overflow	New class 2 command received while a class 2 command is already busy
16–19	NA	
20	24V Heater Fail (VCC)	Voltage < 20V; related fuse: F2
21	24V Motor Fail (VSS)	Voltage < 20V; related fuse: F3
22–31	NA	
41	Rotor Position Error	
42	Stroke Position Error	
43	Revolver INCA Position Error	
44	Revolver RTHA Position Error	
51	Rotor Initialization Time-Out Error	
52	Stroke Initialization Time-Out Error	
53	Revolver INCA Initialization Time-Out Error	
54	Revolver RTHA Initialization Time-Out Error	

Table A-10 Internal Communication Error Codes

Internal Communication Error Codes	Error Description	Comments
0	No Error	
1	Initialization Error	
2	Invalid Command	
3	Invalid Operand x Parameter y Argument	
4	NA	Not used by I/O Module
5	NA	
6	NA	
7	Device Not Initialized	
8	NA	
9	Overload of Power Output	
10	No Liquid Flow Detected or Liquid Flow Interrupted	
11	Liquid Level Not Restored	
12	Liquid Flow Detected on Wrong Tube	
13–14	NA	
15	Command Overflow	New class 2 command received while a class 2 command is already busy

Table A-11 Pipette Error Codes

Pipette Error Codes	Error Description	Description
0	Error Free Condition	
1 (01h)	Initialization Error	Occurs when the pump fails to initialize. Check for blockages and loose connections before attempting to reinitialize. The pump will not accept commands until it has been successfully initialized.
2 (02h)	Invalid Command	Occurs when an incorrect command is issued. Correct the command and operation will continue normally.
3 (03h)	Invalid Operand	Occurs when an invalid parameter (nn) is given with a command. Correct the parameter and pump operation will continue normally.
4 (04h)	Invalid Command Sequence	Occurs when the command structure or communication protocol is incorrect. Review the information describing the communication protocol then repeat the command sequence.
7 (07h)	Device Not Initialized	Occurs when the pump is not initialized. To clear the error initialize the pump.
9 (09h)	Plunger Overload	Occurs when the syringe plunger loses steps. The pump must be reinitialized before normal operation can resume.
10 (0Ah)	Valve Overload	Occurs when the valve drive loses too many steps. Continual valve overload errors are an indication the valve should be replaced. The pump must be reinitialized before normal operation can resume.
11 (0Bh)	Plunger Move Not Allowed	When the valve is in the Bypass or Throughput position, plunger movement commands are not allowed
15 (0Fh)	Command Overflow	The buffer contains too many characters. Commands in the buffer must be executed before more commands can be sent.

Table A-12 Sample Supply Rotor (SSR) Error Codes

Sample Supply Rotor (SSR) Error Codes	Error Description	Comments
0	No Error	
1	Initialization Error	
2	Invalid Command	
3	Invalid Operand x Parameter y Argument	
4	Invalid Command Sequence	Not used by SSR
5	Device Not Available	Generated by MASTER internally (CCU)
6	Time-Out Error	Generated by MASTER internally (CCU)
7	Device Not Initialized	Set until <PI> is executed for the first time
8	NA	
9	Steploss Detected	
10	EEPROM Read / Write Error	
11	Steploss During Mix	
13	NA	
14	NA	
15	Command Overflow	New class 2 command received while a class 2 command is already busy
16–28	NA	
29	Barcode Reader Initialization Failed	This error is handled by the CCU
30	Door Lock Monitoring Shutdown Error	
31	NA	

This page intentionally left blank.

Appendix B: Supported Cassettes, Reagents, Tests, and Test Results

This appendix lists all cassettes and reagents that are currently utilized on ORTHO AutoVue *Innova/Ultra*. It also lists all available individual tests and the valid results that may be displayed for a test type.

Overview

Use the tables in this appendix to determine:

- Cassettes utilized. See “Supported Cassettes” on page B-4.
- Reagents utilized. See “OCD Reagent Kits” on page B-6.
- Tests available. See “Supported Tests” on page B-17.
- Valid results. See “Valid Test Results for Analyses” on page B-39.

Table B-1 below, lists the abbreviations used within this appendix.

Table B-1 Common Abbreviations

Abbreviation	Explanation
AHG	Anti-Human Globulin
Auto	Autologous Control
BC	Bar Code
BRC	Blood Bank Reagent Control Kit
BVS	BioVue Screen
CMP	Compatible
DAT	Direct Antiglobulin Test
Di^a or Dia	Diego A
Dnr	Donor
Enz	Enzyme
IAT	Indirect Antiglobulin Test
ID	Identification
INCMP	Incompatible
IS	Immediate spin: an immediate spin antibody detection test
NEG or Neg	Negative
PC	Personal Computing Unit
POS or Pos	Positive
Pt	Patient
QC	Quality Control
RVW	Review
Sel	Selectogen Cells
Surg	Surgiscreen Cells
Trt	Enzyme Treated Cell
Unt	Untreated Cell
XM	Crossmatch (Compatibility) Test

Section A: Supported Cassettes

Table "ORTHO BioVue™ System Cassettes Supported On ORTHO AutoVue Innova/Ultra" on page B-5, lists the cassettes that are currently supported on the system. The information included in the table is as follows:

- **Cassette Names Formal** – The formal name of the cassette as identified in the OCD manufacturing process.
- **Cassette Names Software Abbreviation** – The abbreviated name of the cassette that displays in the ORTHO AutoVue *Innova/Ultra* software.
- **BC ID** – The bar code ID number used to identify a specific cassette type
- **Lot Prefix** – The letters that are used for the lot prefix of a specific cassette type
- **Contents of Cassette Wells** – The contents of each well of a specific cassette type

Table B-2 ORTHO BioVue™ System Cassettes Supported On ORTHO AutoVue *Innova/Ultra*

Cassette Names		BC ID	Lot Prefix	Well Configuration					
Formal[a]	Software Abbreviation			1	2	3	4	5	6
ABO-Rh/Reverse	ABO-Rh/Reverse (00)	00	ABR	Anti-A	Anti-B	Anti-D	Control	Reverse Diluent	Reverse Diluent
ABD Confirmation	ABD-Confirmation (10)	10	ACC	Anti-A	Anti-B	Anti-D	Anti-A	Anti-B	Anti-D
Rh-hr	Rh-hr (11)	11	BRH	Anti-D	Anti-C	Anti-E	Anti-$\overline{c}$	Anti-e	Control
New Born	ABO-Rh/DAT new born (20)	20	ABP	Anti-A	Anti-B	Anti-A,B	Anti-D	Control	Anti-IgG[b]
Anti-Human Globulin (Polyspecific)	AHG Polyspecific (22)	22	AHC	Anti-IgG, -C3d; Polyspecific					
Anti-Human Globulin Anti-IgG (Rabbit); Anti-Human Globulin Anti-C3b, -C3d; Control (DAT/IDAT)	DAT (30)	30	DAT	Anti-IgG[c]	Anti-C3b, -C3d	Control	Anti-IgG[3]	Anti-C3b, -C3d	Control
Anti-Human Globulin (Anti-IgG)	AHG Anti-IgG (33)	33	IGC	Anti-IgG					
ADK	ADK (40)	40	ADK	Anti-A	Anti-B	Anti-D	Anti-D	Anti-K	Control
ABO-Rh	ABO-Rh (44)	44	ABE	Anti-A	Anti-B	Anti-A,B	Anti-D	Anti-CDE	Control
Anti-Human Globulin (Polyspecific)/ Neutral	AHG Polyspecific/ Neutral (55)	55	PLN	Anti-IgG, -C3d; Polyspecific			Neutral		
Reverse Diluent	Reverse diluent (66)	66	RDC	Reverse Diluent					
Rh/K	Rh/K (77)	77	RHP	Anti-C	Anti-E	Anti-$\overline{c}$	Anti-e	Anti-K	Control
Neutral	Neutral (88)	88	NEC	Neutral					
Kell	Kell (90)	90	KEL	Anti-K	Anti-K	Anti-K	Anti-K	Anti-K	Anti-K
Kell/Control	Kell/Control (95)	95	KCT	Control	Anti-K	Control	Anti-K	Control	Anti-K
ABO DD	ABODD (48)	48	ADD	Anti-A	Anti-B	Anti-AB	Anti-D	Anti-D	Control

a. These names have been taken from OCD manufacturing product specification documents. However, these names do not necessarily match the labels on the cassette box, cassette sleeve or the cassette itself.

b. Anti-IgG well in this cassette is for DAT testing only (no incubation, no BLISS).

c. Anti-IgG in this cassette is more similar to that in the Poly cassette than the IgG cassette.

Section B: OCD Reagent Kits

The OCD reagent kits and reagents are listed in this table, including:

- **Analysis** – the analysis the reagent is used for.
- **OCD Reagent Kit**
- **Reagent Description**
- **Unabbreviated Software Designation**
- **Abbreviated Software Designation** – the abbreviation that displays for a test
- **Barcode Product ID**
- **Barcode Format** – A = DDD-Y-ID-LLLL; B = DD-MM-Y-ID-LLL. (See "Reagent Bar Code Description" on page 6-4)

Table B-3 OCD Reagent Kits

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABO	Affirmagen 3mL	A_1 Cells	A1 Cells	A1 Cells	12	A
		A_2 Cells	A2 Cells	A2 Cells	13	A
		B Cells	B Cells	B Cells	14	A
		O Cells	O Cells	O Cells	15	A
	0.8% Affirmagen	0.8% A_1 Cells	0.8% A1 Cells	0.8% A1 Cells	92	A
		0.8% A_2 Cells	0.8% A2 Cells	0.8% A2 Cells	93	A
		0.8% B Cells	0.8% B Cells	0.8% B Cells	94	A
		0.8% O Cells	0.8% O Cells	0.8% O Cells	95	A

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABScr	Selectogen	Selectogen Cell I	Selectogen Cell I	Sel I	23	A
		Selectogen Cell II	Selectogen Cell II	Sel II	24	A
	0.8% Selectogen	0.8% Selectogen Cell I	0.8% Selectogen Cell I	0.8% Sel I	29	A
		0.8% Selectogen Cell II	0.8% Selectogen Cell II	0.8% Sel II	30	A
ABScr	Surgiscreen	Surgiscreen Cell 1	Surgiscreen Cell 1	Surg 1	34	A
		Surgiscreen Cell 2	Surgiscreen Cell 2	Surg 2	35	A
		Surgiscreen Cell 3	Surgiscreen Cell 3	Surg 3	36	A
	0.8% Surgiscreen	0.8% Surgiscreen Cell 1	0.8% Surgiscreen Cell 1	0.8% Surg 1	31	A
		0.8% Surgiscreen Cell 2	0.8% Surgiscreen Cell 2	0.8% Surg 2	32	A
		0.8% Surgiscreen Cell 3	0.8% Surgiscreen Cell 3	0.8% Surg 3	33	A
ABScr	BVS Papain	Untreated BioVue Screen Cell 1, Papain Kit	Papain Untreated 1	Pap Unt 1	25	A
		Untreated BioVue Screen Cell 2, Papain Kit	Papain Untreated 2	Pap Unt 2	26	A
		Untreated BioVue Screen Cell 3, Papain Kit	Papain Untreated 3	Pap Unt 3	27	A
		Papain Treated BioVue Screen Cell 1	Papain Treated 1	Pap Trt 1	37	A
		Papain Treated BioVue Screen Cell 2	Papain Treated 2	Pap Trt 2	38	A
		Papain Treated BioVue Screen Cell 3	Papain Treated 3	Pap Trt 3	39	A

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABScr	BVS Ficin	Untreated BioVue Screen Cell 1, Ficin Kit	Ficin Untreated 1	Fic Unt 1	16	A
		Untreated BioVue Screen Cell 2, Ficin Kit	Ficin Untreated 2	Fic Unt 2	17	A
		Untreated BioVue Screen Cell 3, Ficin Kit	Ficin Untreated 3	Fic Unt 3	18	A
		Ficin Treated BioVue Screen Cell 1	Ficin Treated 1	Fic Trt 1	19	A
		Ficin Treated BioVue Screen Cell 2	Ficin Treated 2	Fic Trt 2	20	A
		Ficin Treated BioVue Screen Cell 3	Ficin Treated 3	Fic Trt 3	21	A
ABScr	0.8% BVS Ficin	0.8% Untreated BioVue Screen Cell 1, Ficin Kit	0.8% Ficin Untreated 1	0.8% Fic Unt 1	87	A
		0.8% Untreated BioVue Screen Cell 2, Ficin Kit	0.8% Ficin Untreated 2	0.8% Fic Unt 2	88	A
		0.8% Untreated BioVue Screen Cell 3, Ficin Kit	0.8% Ficin Untreated 3	0.8% Fic Unt 3	89	A
		0.8% Ficin Treated BioVue Screen Cell 1	0.8% Ficin Treated 1	0.8% Fic Trt 1	96	A
		0.8% Ficin Treated BioVue Screen Cell 2	0.8% Ficin Treated 2	0.8% Fic Trt 2	97	A
		0.8% Ficin Treated BioVue Screen Cell 3	0.8% Ficin Treated 3	0.8% Fic Trt 3	98	A

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABScr	Diego Cells	Diego Reagent Red Blood Cells	Diego	Diego	73	A
	0.8% Diego	0.8% Diego Reagent Red Blood Cells	0.8% Diego	0.8% Diego	22	A
ABI	Resolve Panel A	Resolve Panel A Cell 1	Resolve Panel A Cell 1	Panel A Cell 1	01	A
		Resolve Panel A Cell 2	Resolve Panel A Cell 2	Panel A Cell 2	02	A
		Resolve Panel A Cell 3	Resolve Panel A Cell 3	Panel A Cell 3	03	A
		Resolve Panel A Cell 4	Resolve Panel A Cell 4	Panel A Cell 4	04	A
		Resolve Panel A Cell 5	Resolve Panel A Cell 5	Panel A Cell 5	05	A
		Resolve Panel A Cell 6	Resolve Panel A Cell 6	Panel A Cell 6	06	A
		Resolve Panel A Cell 7	Resolve Panel A Cell 7	Panel A Cell 7	07	A
		Resolve Panel A Cell 8	Resolve Panel A Cell 8	Panel A Cell 8	08	A
		Resolve Panel A Cell 9	Resolve Panel A Cell 9	Panel A Cell 9	09	A
		Resolve Panel A Cell 10	Resolve Panel A Cell 10	Panel A Cell 10	10	A
		Resolve Panel A Cell 11	Resolve Panel A Cell 11	Panel A Cell 11	11	A
ABI	0.8% Resolve Panel A	0.8% Resolve Panel A Cell 1	0.8% Resolve Panel A Cell 1	0.8% Panel A Cell 1	51	A
		0.8% Resolve Panel A Cell 2	0.8% Resolve Panel A Cell 2	0.8%Panel A Cell 2	52	A
		0.8% Resolve Panel A Cell 3	0.8% Resolve Panel A Cell 3	0.8% Panel A Cell 3	53	A
		0.8% Resolve Panel A Cell 4	0.8% Resolve Panel A Cell 4	0.8% Panel A Cell 4	54	A
		0.8% Resolve Panel A Cell 5	0.8% Resolve Panel A Cell 5	0.8% Panel A Cell 5	55	A
		0.8% Resolve Panel A Cell 6	0.8% Resolve Panel A Cell 6	0.8% Panel A Cell 6	56	A
		0.8% Resolve Panel A Cell 7	0.8% Resolve Panel A Cell 7	0.8% Panel A Cell 7	57	A
		0.8% Resolve Panel A Cell 8	0.8% Resolve Panel A Cell 8	0.8% Panel A Cell 8	58	A
		0.8% Resolve Panel A Cell 9	0.8% Resolve Panel A Cell 9	0.8% Panel A Cell 9	59	A
		0.8% Resolve Panel A Cell 10	0.8% Resolve Panel A Cell 10	0.8% Resolve Panel A Cell 10	60	A
		0.8% Resolve Panel A Cell 11	0.8% Resolve Panel A Cell 11	0.8% Resolve Panel A Cell 11	61	A

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABI	Resolve Panel B	Resolve Panel B Cell 12	Resolve Panel B Cell 12	Panel B Cell 12	40	A
		Resolve Panel B Cell 13	Resolve Panel B Cell 13	Panel B Cell 13	41	A
		Resolve Panel B Cell 14	Resolve Panel B Cell 14	Panel B Cell 14	42	A
		Resolve Panel B Cell 15	Resolve Panel B Cell 15	Panel B Cell 15	43	A
		Resolve Panel B Cell 16	Resolve Panel B Cell 16	Panel B Cell 16	44	A
		Resolve Panel B Cell 17	Resolve Panel B Cell 17	Panel B Cell 17	45	A
		Resolve Panel B Cell 18	Resolve Panel B Cell 18	Panel B Cell 18	46	A
		Resolve Panel B Cell 19	Resolve Panel B Cell 19	Panel B Cell 19	47	A
		Resolve Panel B Cell 20	Resolve Panel B Cell 20	Panel B Cell 20	48	A
		Resolve Panel B Cell 21	Resolve Panel B Cell 21	Panel B Cell 21	49	A
		Resolve Panel B Cell 22	Resolve Panel B Cell 22	Panel B Cell 22	50	A

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABI	0.8% Resolve Panel B	0.8% Resolve Panel B Cell 12	0.8% Resolve Panel B Cell 12	0.8% Panel B Cell 12	62	A
		0.8% Resolve Panel B Cell 13	0.8% Resolve Panel B Cell 13	0.8% Panel B Cell 13	63	A
		0.8% Resolve Panel B Cell 14	0.8% Resolve Panel B Cell 14	0.8% Panel B Cell 14	64	A
		0.8% Resolve Panel B Cell 15	0.8% Resolve Panel B Cell 15	0.8% Panel B Cell 15	65	A
		0.8% Resolve Panel B Cell 16	0.8% Resolve Panel B Cell 16	0.8% Panel B Cell 16	66	A
		0.8% Resolve Panel B Cell 17	0.8% Resolve Panel B Cell 17	0.8% Panel B Cell 17	67	A
		0.8% Resolve Panel B Cell 18	0.8% Resolve Panel B Cell 18	0.8% Panel B Cell 18	68	A
		0.8% Resolve Panel B Cell 19	0.8% Resolve Panel B Cell 19	0.8% Panel B Cell 19	69	A
		0.8% Resolve Panel B Cell 20	0.8% Resolve Panel B Cell 20	0.8% Panel B Cell 20	70	A
		0.8% Resolve Panel B Cell 21	0.8% Resolve Panel B Cell 21	0.8% Panel B Cell 21	71	A
		0.8% Resolve Panel B Cell 22	0.8% Resolve Panel B Cell 22	0.8% Panel B Cell 22	72	A

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABI	Resolve Panel C	Resolve Panel C Cell 1	Resolve Panel C Cell 1	Panel C Cell 1	71	B
		Resolve Panel C Cell 2	Resolve Panel C Cell 2	Panel C Cell 2	72	B
		Resolve Panel C Cell 3	Resolve Panel C Cell 3	Panel C Cell 3	73	B
		Resolve Panel C Cell 4	Resolve Panel C Cell 4	Panel C Cell 4	74	B
		Resolve Panel C Cell 5	Resolve Panel C Cell 5	Panel C Cell 5	75	B
		Resolve Panel C Cell 6	Resolve Panel C Cell 6	Panel C Cell 6	76	B
		Resolve Panel C Cell 7	Resolve Panel C Cell 7	Panel C Cell 7	77	B
		Resolve Panel C Cell 8	Resolve Panel C Cell 8	Panel C Cell 8	78	B
		Resolve Panel C Cell 9	Resolve Panel C Cell 9	Panel C Cell 9	79	B
		Resolve Panel C Cell 10	Resolve Panel C Cell 10	Panel C Cell 10	80	B
		Resolve Panel C Cell 11	Resolve Panel C Cell 11	Panel C Cell 11	81	B

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABI	Resolve Panel C Enz	Resolve Panel C Enz Cell 1	Resolve Panel C Enz Cell 1	Panel C Enz Cell 1	82	B
		Resolve Panel C Enz Cell 2	Resolve Panel C Enz Cell 2	Panel C Enz Cell 2	83	B
		Resolve Panel C Enz Cell 3	Resolve Panel C Enz Cell 3	Panel C Enz Cell 3	84	B
		Resolve Panel C Enz Cell 4	Resolve Panel C Enz Cell 4	Panel C Enz Cell 4	85	B
		Resolve Panel C Enz Cell 5	Resolve Panel C Enz Cell 5	Panel C Enz Cell 5	86	B
		Resolve Panel C Enz Cell 6	Resolve Panel C Enz Cell 6	Panel C Enz Cell 6	87	B
		Resolve Panel C Enz Cell 7	Resolve Panel C Enz Cell 7	Panel C Enz Cell 7	88	B
		Resolve Panel C Enz Cell 8	Resolve Panel C Enz Cell 8	Panel C Enz Cell 8	89	B
		Resolve Panel C Enz Cell 9	Resolve Panel C Enz Cell 9	Panel C Enz Cell 9	90	B
		Resolve Panel C Enz Cell 10	Resolve Panel C Enz Cell 10	Panel C Enz Cell 10	91	B
		Resolve Panel C Enz Cell 11	Resolve Panel C Enz Cell 11	Panel C Enz Cell 11	92	B
ABI	0.8% Resolve Panel C	0.8% Resolve Panel C Cell 1	0.8% Resolve Panel C Cell 1	0.8% Panel C Cell 1	21	B
		0.8% Resolve Panel C Cell 2	0.8% Resolve Panel C Cell 2	0.8% Panel C Cell 2	22	B
		0.8% Resolve Panel C Cell 3	0.8% Resolve Panel C Cell 3	0.8% Panel C Cell 3	23	B
		0.8% Resolve Panel C Cell 4	0.8% Resolve Panel C Cell 4	0.8% Panel C Cell 4	24	B
		0.8% Resolve Panel C Cell 5	0.8% Resolve Panel C Cell 5	0.8% Panel C Cell 5	25	B
		0.8% Resolve Panel C Cell 6	0.8% Resolve Panel C Cell 6	0.8% Panel C Cell 6	26	B
		0.8% Resolve Panel C Cell 7	0.8% Resolve Panel C Cell 7	0.8% Panel C Cell 7	27	B
		0.8% Resolve Panel C Cell 8	0.8% Resolve Panel C Cell 8	0.8% Panel C Cell 8	28	B
		0.8% Resolve Panel C Cell 9	0.8% Resolve Panel C Cell 9	0.8% Panel C Cell 9	29	B
		0.8% Resolve Panel C Cell 10	0.8% Resolve Panel C Cell 10	0.8% Panel C Cell 10	30	B
		0.8% Resolve Panel C Cell 11	0.8% Resolve Panel C Cell 11	0.8% Panel C Cell 11	31	B

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABI	0.8% Resolve Panel C Enz	0.8% Resolve Panel C Enz Cell 1	0.8% Resolve Panel C Enz Cell 1	0.8% Panel C Enz Cell 1	32	B
		0.8% Resolve Panel C Enz Cell 2	0.8% Resolve Panel C Enz Cell 2	0.8% Panel C Enz Cell 2	33	B
		0.8% Resolve Panel C Enz Cell 3	0.8% Resolve Panel C Enz Cell 3	0.8% Panel C Enz Cell 3	34	B
		0.8% Resolve Panel C Enz Cell 4	0.8% Resolve Panel C Enz Cell 4	0.8% Panel C Enz Cell 4	35	B
		0.8% Resolve Panel C Enz Cell 5	0.8% Resolve Panel C Enz Cell 5	0.8% Panel C Enz Cell 5	36	B
		0.8% Resolve Panel C Enz Cell 6	0.8% Resolve Panel C Enz Cell 6	0.8% Resolve Panel C Enz Cell 6	37	B
		0.8% Resolve Panel C Enz Cell 7	0.8% Resolve Panel C Enz Cell 7	0.8% Resolve Panel C Enz Cell 7	38	B
		0.8% Resolve Panel C Enz Cell 8	0.8% Resolve Panel C Enz Cell 8	0.8% Resolve Panel C Enz Cell 8	39	B
		0.8% Resolve Panel C Enz Cell 9	0.8% Resolve Panel C Enz Cell 9	0.8% Panel C Enz Cell 9	40	B
		0.8% Resolve Panel C Enz Cell 10	0.8% Resolve Panel C Enz Cell 10	0.8% Panel C Enz Cell 10	41	B
		0.8% Resolve Panel C Enz Cell 11	0.8% Resolve Panel C Enz Cell 11	0.8% Panel C Enz Cell 11	42	B

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
ABI	BioVue Top Papain	BVTP Cell 1	BVTP Cell 1	BVTP Cell 1	11	B
		BVTP Cell 2	BVTP Cell 2	BVTP Cell 2	12	B
		BVTP Cell 3	BVTP Cell 3	BVTP Cell 3	13	B
		BVTP Cell 4	BVTP Cell 4	BVTP Cell 4	14	B
		BVTP Cell 5	BVTP Cell 5	BVTP Cell 5	15	B
		BVTP Cell 6	BVTP Cell 6	BVTP Cell 6	16	B
		BVTP Cell 7	BVTP Cell 7	BVTP Cell 7	17	B
		BVTP Cell 8	BVTP Cell 8	BVTP Cell 8	18	B
		BVTP Cell 9	BVTP Cell 9	BVTP Cell 9	19	B
		BVTP Cell 10	BVTP Cell 10	BVTP Cell 10	20	B
ABI	BioVue Top Untreated	BVTU Cell 1	BVTU Cell 1	BVTU Cell 1	01	B
		BVTU Cell 2	BVTU Cell 2	BVTU Cell 2	02	B
		BVTU Cell 3	BVTU Cell 3	BVTU Cell 3	03	B
		BVTU Cell 4	BVTU Cell 4	BVTU Cell 4	04	B
		BVTU Cell 5	BVTU Cell 5	BVTU Cell 5	05	B
		BVTU Cell 6	BVTU Cell 6	BVTU Cell 6	06	B
		BVTU Cell 7	BVTU Cell 7	BVTU Cell 7	07	B
		BVTU Cell 8	BVTU Cell 8	BVTU Cell 8	08	B
		BVTU Cell 9	BVTU Cell 9	BVTU Cell 9	09	B
		BVTU Cell 10	BVTU Cell 10	BVTU Cell 10	10	B
ABI	Bromelin	Bromelin	Bromelin	Bromelin	76	A

Table B-3 OCD Reagent Kits (continued)

Analysis	OCD Reagent Kit	Reagent Description	Unabbreviated Software Designation	Abbreviated Software Designation	Bar Code Product ID	Bar Code Format
BRC		Antibody free Control Serum	BRC-S1	BRC-S1	77	A
		Anti-AB Control Serum	BRC-S2	BRC-S2	78	A
		Anti-D Control Serum	BRC-S3	BRC-S3	79	A
		O cell Ccddee, Kell NEG	BRC-E1	BRC-E1	81	A
		O cell, ccddEe	BRC-E2	BRC-E2	82	A
		O cell, ccddee, Kell POS	BRC-E3	BRC-E3	83	A
		O cell, D^u	BRC-E4	BRC-E4 and/or Du Cells	84	A
		O cell, C3d-sensitive[a]	BRC-E5	BRC-E5	85	A
		A3 4, [2]			86	A
		Diluted Anti-D Control Serum for IgG and DAT/IAT cassettes	Dilute BRC-S3-IgG	BRC-S3	90	A
		Diluted Anti-D Control Serum for Poly cassette	Dilute BRC-S3-Poly	BRC-S3	91	A
Many	NA	BLISS	BLISS	BLISS	28	A
Many	0.8% Red Cell Diluent (RCD)	0.8% Red Cell Diluent (RCD)	0.8% Red Cell Diluent (RCD)	0.8% RCD	00	A
NA	NA	0.1N NaOH	0.1N NaOH	NA	99	A

a. This is a C3d coated cell. Proper storage conditions should be maintained at all times to ensure stability of this reagent red cell.

Section C: Supported Tests

This section lists the tests currently supported by the AutoVue. Following are tables that provide information about tests. The information included is:

- **Combo (Combination)** – A group of tests utilizing the same red cells, (reagent, donor and/or patient) in an antibody screening or crossmatch test
- **Heading** – A detailed description of the test, including all necessary information to allow a person to understand the full range of a given test
- **Name in Software** – The default name that displays for a test.
- **Test Number** – The test number does not display in the software screens, but may appear in traceability logs. See table "ORTHO BioVue™ System Cassettes Supported On ORTHO AutoVue Innova/Ultra" on page B-5 and table "Test Naming Convention" on page B-18 for additional detail.
- **Reagents/Sample Added by** ORTHO AutoVue *Innova/Ultra* – Names of reagents in the OCD reagent kit. A listing of all the reagents or sample blood components that will be added by the ORTHO AutoVue *Innova/Ultra* instrument during this test. Not every reagent is necessarily added to every well of the cassette.

  Note: Serum and plasma samples are treated equivalently on ORTHO AutoVue *Innova/Ultra.* The abbreviation for both serum or plasma is PLASMA.

Information you are seeking	Found on page
Test Naming Convention Used by AutoVue Software	▪ See Table, "Test Naming Convention" on page B-18.
Supported ABO Grouping, Phenotype, and DAT Tests	▪ See Table, "ABO & Rh Grouping, Phenotype, DAT Programs" on page B-19.
Supported Antibody Screening and Compatibility Tests	▪ See Table, "Antibody Screening and Crossmatch" on page B-23.
Supported Quality Control Tests for ABO Grouping and Phenotype	▪ See Table, "ABO and Phenotype Cassette/Reagent Quality Control Tests" on page B-34.
Supported Quality Control Tests for Antibody Screening Tests	▪ See Table, "Antibody Screening Cassette/Reagent Quality Control Tests" on page B-37.

Test Naming Convention

The table "Test Naming Convention" below details the naming convention used by ORTHO AutoVue *Innova/Ultra* to distinguish individual tests. For example, **NA03-00**.

Table B-4 Test Naming Convention

Character Number	Indicator of...	Acceptable Values For...
1 For example, **N**	Group Type	N ≡ Normal Q ≡ Quality Control Test
2 For example, **A**	Test Type	A ≡ ABO and Rh_o(D) C ≡ Neonatal Testing (Cord Blood) D ≡ DAT I ≡ Antibody Identification R ≡ Rh (Phenotype) S ≡ Antibody Screen U ≡ Autologous Control X ≡ Crossmatch
3 and 4 For example, **03**	Sequence #	01, 02,...10, etc.
5 For example, -	Separator	A single dash
6 For example, **00**	Cassette Type	22, 33, etc. See BC ID column in table "ORTHO BioVue™ System Cassettes Supported On ORTHO AutoVue Innova/Ultra" on page B-5.

ABO & Rh Grouping, Phenotype, DAT Program

Table B-5 ABO & Rh Grouping, Phenotype, DAT Programs

Heading	Software Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
2 Cell ABO Reverse	ABO(RVS)-2 Cell	NA10-66	Patient Plasma, A_1, B Cells
2 Cell 0.8% ABO Reverse	8ABO(RVS)-2 Cell	NA24-66	Patient Plasma, 0.8% A_1, B Cells
3 Cell ABO Reverse: A_1, A_2, B Cells	ABO(RVS)-3 Cell	NA05-66	Patient Plasma, A_1, A_2, B Cells
3 Cell 0.8% ABO Reverse: A_1, A_2, B	8ABO(RVS)-3 Cell	NA22-66	Patient Plasma, 0.8% A_1, A_2, B Cells
3 Cell ABO Reverse: A_1, B, O Cells	ABO(RVS)-A1, B, O	NA16-66	Patient Plasma, A_1, B, O Cells
3 Cell 0.8% ABO Reverse: A_1, B, O	8ABO(RVS)-A1, B, O	NA25-66	Patient Plasma, 0.8% A_1, B, O Cell
4 Cell ABO Reverse	ABO(RVS)-4 Cell	NA08-66	Patient Plasma, A_1, A_2, B, O Cells
4 Cell 0.8% ABO Reverse	8ABO(RVS)-4 Cell	NA23-66	Patient Plasma, 0.8% A_1, A_2, B, O Cells
6 Cell ABO Reverse	ABO(RVS)-6 Cell	NA02-66	Patient Plasma, A_1, A_2, B, O Cells, Selectogen Cells
6 Cell 0.8% ABO Reverse	8ABO(RVS)-6 Cell	NA21-66	Patient Plasma, 0.8% A_1, A_2, B, O Cells, 0.8% Selectogen Cells
ABO Forward: ABO-Rh	ABO(FWD)-44	NA12-44	Patient Cells
ABO Forward: ABO-Rh/ Reverse	ABO(FWD)-00	NA11-00	Patient Cells
ABO Forward and Rh: ABO-Rh/Reverse	ABO(FWD)/Rh-00	NA01-00	Patient Cells
ABO Forward and Rh: ABO-Rh	ABO(FWD)/Rh-44	NA04-44	Patient Cells
ABO Forward and 2 Cell ABO Reverse	ABO(FWD)-44 + RVS 2	NA13-4466	Patient Plasma, A_1, B Cells, Patient Cells
ABO Forward, Rh, and 2 Cell 0.8% ABO Reverse: ABO-Rh/ Reverse	8ABO(FWD/RVS)/ Rh	NA12-00	Patient Plasma, A_1, B Cells, Patient Cells
ABO Forward and 2 Cell 0.8% ABO Reverse	8ABO(FWD)-44+ RVS 2	NA33-4466	Patient Plasma, 0.8% A_1, B Cells, Patient Cells
ABO Forward and 3 Cell ABO Reverse: A_1, A_2, B	ABO-Rh-44 + RVS 3-A2	NA05-4466	Patient Plasma, A_1, A_2, B Cells, Patient Cells
ABO Forward and 3 Cell 0.8% ABO Reverse: A_1, A_2, B	8ABO(FWD)-44+ RVS-A2	NA25-4466	Patient Plasma, 0.8% A_1, A_2, B Cells, Patient Cells
ABO Forward and 3 Cell ABO Reverse: A_1, B, O	ABO(FWD)-44 + RVS 3-O	NA17-4466	Patient Plasma, A_1, B, O Cells, Patient Cells

Table B-5 ABO & Rh Grouping, Phenotype, DAT Programs (continued)

Heading	Software Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
ABO Forward and 3 Cell 0.8% ABO Reverse: A_1, B, O	8ABO(FWD)-44+ RVS 3-O	NA37-4466	Patient Plasma, 0.8% A_1, B, O Cells, Patient Cells
ABO Forward and 4 Cell 0.8% ABO Reverse: A_1, A_2, B, O	8ABO(FWD)-44+ RVS 4	NA29-4466	Patient Plasma, 0.8% A_1, A_2, B, O Cells, Patient Cells
ABO Forward and 4 Cell ABO Reverse: A_1, A_2, B, O	ABO(FWD)-44 + RVS 4	NA09-4466	Patient Plasma, A_1, A_2, B, O Cells, Patient Cells
ABO Forward and 6 Cell ABO Reverse	ABO(FWD)-44 + RVS 6	NA01-4466	Patient Plasma, A_1, A_2, B, O Cells, Selectogen Cells, Patient Cells
ABO Forward and 6 Cell 0.8% ABO Reverse	8ABO(FWD)-44+ RVS 6	NA21-4466	Patient Plasma, 0.8% A_1, A_2, B, O Cells, 0.8% Selectogen Cells, Patient Cells
ABO Forward/Rh/K	ABO(FWD)-Rh/K	NA04-40	Patient Cells
ABO Forward/DD	ABO(FWD)/DD-48	NA01-48	Patient Cells
ABO and Rh Confirmation Test	ABD Conf	NA15-10	Patient Cells
ABO Forward, Rh, and 2 Cell ABO Reverse: ABO-Rh/ Reverse	ABO(FWD/RVS)/ Rh	NA03-00	Patient Plasma, A_1, B Cells, Patient Cells
ABO Forward/Rh and 2 Cell ABO Reverse	ABO(FWD)/Rh-44 + RVS 2	NA14-4466	Patient Plasma, A_1, B Cells, Patient Cells
ABO Forward/Rh and 2 Cell 0.8% ABO Reverse	8ABO(FWD)/Rh-44+ RVS 2	NA34-4466	Patient Plasma, 0.8% A_1, B Cells, Patient Cells
ABO Forward/Rh and 3 Cell ABO Reverse: A_1, A_2, B	ABO(FWD)/Rh-44 + RVS 3-A2	NA06-4466	Patient Plasma, A_1, A_2, B Cells, Patient Cells
ABO Forward/Rh and 3 Cell 0.8% ABO Reverse: A_1, A_2, B	8ABO(FWD)/Rh-44+ RVS 3-A2	NA26-4466	Patient Plasma, 0.8% A_1, A_2, B Cells, Patient Cells
ABO Forward/Rh and 4 Cell ABO Reverse: A_1, A_2, B, O	ABO(FWD)/Rh-44 + RVS 4	NA10-4466	Patient Plasma, A_1, A_2, B, O Cells, Patient Cells
ABO Forward/Rh and 4 Cell 0.8% ABO Reverse: A_1, A_2, B, O	8ABO(FWD)/Rh-44+ RVS 4	NA30-4466	Patient Plasma, 0.8% A_1, A_2, B, O Cells, Patient Cells
ABO Forward/Rh and 3 Cell ABO Reverse: A_1, B, O	ABO(FWD)/Rh-44 + RVS 3-O	NA18-4466	Patient Plasma, A_1, B, O Cells, Patient Cells
ABO Forward/Rh and 3 Cell 0.8% ABO Reverse: A_1, B, O	8ABO(FWD)/Rh-44+ RVS 3-O	NA38-4466	Patient Plasma, 0.8% A_1, B, O Cells, Patient Cells
ABO Forward/Rh and 6 Cell ABO Reverse	ABO(FWD)/Rh-44 + RVS 6	NA02-4466	Patient Plasma, A_1, A_2, B, O Cells, Selectogen Cells, Patient Cells
ABO Forward/Rh and 6 Cell 0.8% ABO Reverse	8ABO(FWD)/Rh-44+ RVS 6	NA22-4466	Patient Plasma, 0.8% A_1, A_2, B, O Cells,0.8% Selectogen Cells, Patient Cells
ABO Forward/Rh/K and 2 Cell ABO Reverse	ABO(FWD)/D/K-40+RVS 2	NA16-4066	Patient Plasma, A_1, B Cells, Patient Cells

Table B-5 ABO & Rh Grouping, Phenotype, DAT Programs (continued)

Heading	Software Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
ABO Forward/Rh/K and 2 Cell 0.8% ABO Reverse	8ABO(FWD)/D/K-40+ RVS 2	NA36-4066	Patient Plasma, 0.8% A_1, B Cells, Patient Cells
ABO Forward/Rh/K and 3 Cell ABO Reverse: A_1, A_2, B	ABO(FWD)/D/K-40+RVS 3-A2	NA08-4066	Patient Plasma, A_1, A_2, B Cells, Patient Cells
ABO Forward/Rh/K and 3 Cell 0.8% ABO Reverse: A_1, A_2, B	8ABO(FWD)/D/K-40+ RVS 3-A2	NA28-4066	Patient Plasma, 0.8% A_1, A_2, B Cells, Patient Cells
ABO Forward/Rh/K and 3 Cell ABO Reverse: A_1, B, O	ABO(FWD)/D/K-40+RVS 3-O	NA20-4066	Patient Plasma, A_1, B, O Cells, Patient Cells
ABO Forward/Rh/K and 3 Cell 0.8% ABO Reverse: A_1, B, O	8ABO(FWD)/D/K-40+ RVS 3-O	NA40-4066	Patient Plasma, 0.8% A_1, B, O Cells, Patient Cells
ABO Forward/Rh/K and 4 Cell ABO Reverse: A_1, A_2, B, O	ABO(FWD)/D/K-40+RVS 4	NA12-4066	Patient Plasma, A_1, A_2, B, O Cells, Patient Cells
ABO Forward/Rh/K and 4 Cell 0.8% ABO Reverse: A_1, A_2, B, O	8ABO(FWD)/D/K-40+ RVS 4	NA43-4066	Patient Plasma, 0.8% A_1, A_2, B, O Cells, Patient Cells
ABO Forward/Rh/K and 6 Cell ABO Reverse	ABO(FWD)/D/K-40+RVS 6	NA04-4066	Patient Plasma, A_1, A_2, B, O Cells, Selectogen Cells, Patient Cells
ABO Forward/Rh/K and 6 Cell 0.8% ABO Reverse	8ABO(FWD)/D/K-40+ RVS 6	NA24-4066	Patient Plasma, 0.8% A_1, A_2, B, O Cells, 0.8% Selectogen Cells, Patient Cells
ABO Forward/DD and 2 Cell ABO Reverse	ABO(FWD)/DD-48+RVS 2	NA15-4866	Patient Plasma, A_1, B Cells, Patient Cells
ABO Forward/DD and 2 Cell 0.8% ABO Reverse	8ABO(FWD)/DD-48+ RVS 2	NA35-4866	Patient Plasma, 0.8% A_1, B Cells, Patient Cells
ABO Forward/DD and 3 Cell ABO Reverse: A_1, A_2, B	ABO(FWD)/DD-48+RVS 3-A2	NA07-4866	Patient Plasma, A_1, A_2, B, Patient Cells
ABO Forward/DD and 3 Cell 0.8% ABO Reverse: A_1, A_2, B	8ABO(FWD)/DD-48+ RVS 3-A2	NA27-4866	Pt Plasma, 0.8% A_1, A_2, B, Patient Cells
ABO Forward/DD and 3 Cell ABO Reverse: A_1, B, O	ABO(FWD)/DD-48+RVS 3-O	NA19-4866	Patient Plasma, A_1, B, O Cells, Patient Cells
ABO Forward/DD and 3 Cell 0.8% ABO Reverse: A_1, B, O	8ABO(FWD)/DD-48+ RVS 3-O	NA39-4866	Patient Plasma, 0.8% A_1, B, O Cells, Patient Cells
ABO Forward/DD and 4 Cell ABO Reverse: A_1, A_2, B, O	ABO(FWD)/DD-48+RVS 4	NA11-4866	Patient Plasma, A_1, A_2, B, O Cells, Patient Cells
ABO Forward/DD and 4 Cell 0.8% ABO Reverse: A_1, A_2, B, O	8ABO(FWD)/DD-48+ RVS 4	NA31-4866	Patient Plasma, 0.8% A_1, A_2, B, O Cells, Patient Cells
ABO Forward/DD and 6 Cell ABO Reverse	ABO(FWD)/DD-48+RVS 6	NA03-4866	Patient Plasma, A_1, A_2, B, O Cells, Selectogen Cells, Patient Cells
ABO Forward/DD and 6 Cell 0.8% ABO Reverse	8ABO(FWD)/DD-48+ RVS 6	NA23-4866	Patient Plasma, 0.8% A_1, A_2, B, O Cells,0.8% Selectogen Cells, Patient Cells

Table B-5 ABO & Rh Grouping, Phenotype, DAT Programs (continued)

Heading	Software Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
ABO Forward, Rh, and DAT for newborn sample	Newborn	NC01-20	Patient Cells
Rh Phenotype with Kell	Rh/K	NR02-77	Patient Cells
Rh Phenotype with D	Rh-hr	NR01-11	Patient Cells
K1 (Kell) Typing	Kell	NR02-90	Patient Cells
K1 (Kell) Typing with Control	Kell+Control	NR02-95	Patient Cells
Direct Antiglobulin Test (DAT): Anti-IgG, -C3d; polyspecific	DAT Poly	ND01-22	Patient Cells
Direct Antiglobulin Test (DAT): Anti-IgG	DAT IgG	ND02-33	Patient Cells
Direct Antiglobulin Test (DAT): DAT/IDAT	IgG, -C3b,-C3d DAT	ND01-30	Patient Cells

Antibody Screening and Crossmatch

Table B-6 Antibody Screening and Crossmatch

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
BioVue Screen	Papain BioVue Screen AHG/Enzyme Antibody Screen	Pap ABScr	NS05-55	BLISS, BVS Papain, Patient Plasma
	Ficin BioVue Screen AHG/Enzyme Antibody Screen	Fic ABScr	NS06-55	BLISS, BVS Ficin, Patient Plasma
3 Cell (Surg) + Diego + Auto	3 Cell (Surg) + Diego + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	3Scr+Dia +Auto Poly	NU06-22	BLISS, Surgiscreen Cells, Diego Cells, Patient Plasma, Patient Cells
	3 Cell (Surg) + Diego + Auto AHG Antibody Screen: Anti-IgG cassette	3Scr+Dia +Auto IgG	NU07-33	
3 Cell (unt BioVue Screen cells) + Diego + Auto	3 Cell (BioVue Screen Papain Kit untreated cells) + Diego + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	BVSP+Dia +Auto Poly	NU11-22	BLISS, BioVue Screen Papain Kit (untreated cells), Diego Cells, Patient Plasma, Patient Cells
	3 Cell (BioVue Screen Papain Kit untreated cells) + Diego + Auto AHG Antibody Screen: Anti-IgG cassette	BVSP+Dia +Auto IgG	NU11-33	
	3 Cell (BioVue Screen Ficin Kit untreated cells) + Diego + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	BVSF+Dia +Auto Poly	NU12-22	BLISS, BioVue Screen Ficin Kit (untreated cells), Diego Cells, Patient Plasma, Patient Cells
	3 Cell (BioVue Screen Ficin Kit untreated cells) + Diego + Auto AHG Antibody Screen: Anti-IgG cassette	BVSF+Dia +Auto IgG	NU12-33	
3 Cell (Surg) + Auto	3 Cell (Surg) + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	Auto ABScr 3 Poly	NU03-22	BLISS, Surgiscreen Cells, Patient Plasma, Patient Cells
	3 Cell (Surg) + Auto AHG Antibody Screen: Anti-IgG cassette	Auto ABScr 3 IgG	NU05-33	

Table B-6 Antibody Screening and Crossmatch (continued)

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
3 Cell (unt BioVue Screen Cells) + Auto	3 Cell (BioVue Screen Papain Kit untreated cells) + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	Auto BVSP Poly	NU13-22	BLISS, BioVue Screen Papain Kit (untreated cells), Patient Plasma, Patient Cells
	3 Cell (BioVue Screen Papain Kit untreated cells) + Auto AHG Antibody Screen: Anti-IgG cassette	Auto BVSP IgG	NU13-33	
	3 Cell (BioVue Screen Ficin Kit untreated cells) + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	Auto BVSF Poly	NU14-22	BLISS, BioVue Screen Ficin Kit (untreated cells), Patient Plasma, Patient Cells
	3 Cell (BioVue Screen Ficin Kit untreated cells) + Auto AHG Antibody Screen: Anti-IgG cassette	Auto BVSF IgG	NU14-33	
3 Cell (Surg) + Diego	3 Cell (Surg) + Diego Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	3Scr+Dia Poly	NS06-22	BLISS, Surgiscreen Cells, Diego Cells, Patient Plasma, Patient Cells
	3 Cell (Surg) + Diego Antibody Screen: Anti-IgG cassette	3Scr+Dia IgG	NS07-33	
3 Cell (unt BioVue Screen cells) + Diego	3 Cell (BioVue Screen Papain Kit untreated cells) + Diego AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	BVSP+Dia Poly	NS12-22	BLISS, BVS Papain (untreated cells), Diego Cells, Patient Plasma
	3 Cell (BioVue Screen Papain Kit untreated cells) + Diego AHG Antibody Screen: Anti-IgG cassette	BVSP+Dia IgG	NS12-33	
	3 Cell (BioVue Screen Ficin Kit untreated cells) + Diego AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	BVSF+Dia Poly	NS13-22	BLISS, BVS Ficin (untreated cells), Diego Cells, Patient Plasma
	3 Cell (BioVue Screen Ficin Kit untreated cells) + Diego AHG Antibody Screen: Anti-IgG cassette	BVSF+Dia IgG	NS13-33	

Table B-6 Antibody Screening and Crossmatch (continued)

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
4 Cell ABScr	4 Cell Antibody Screen: Polyspecific	ABScr 4 Poly	NS26-22	Patient Plasma, Screening Cells, BLISS
	4 Cell Antibody Screen: Anti-IgG	ABScr 4 IgG	NS26-33	Patient Plasma, Screening Cells, BLISS
4ABScr 0.8% ABScr	4 Cell ABScr: 0.8% Antibody Screen; Polyspecific	8ABScr 4 Poly	TBD	Patient Plasma, 0.8% Screening Cells
	4 Cell ABScr: 0.8% Antibody Screen; Anti-IgG	8ABScr 4 IgG	TBD	Patient Plasma, 0.8% Screening Cells
2 Cell (Sel) + Diego + Auto	2 Cell (Sel) + Diego + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	2Scr+Dia+Auto Poly	NU08-22	BLISS, Selectogen Cells, Diego Cells, Patient Plasma, Patient Cells
	2 Cell (Sel) + Diego + Auto AHG Antibody Screen: Anti-IgG cassette	2Scr+Dia+Auto IgG	NU08-33	
3 Cell (trt BioVue Screen cells)	3 Cell (BioVue Screen Papain Kit treated cells) ENZ Antibody Screen: Neutral cassette	BVSP Neut	NS01-88	BVS Papain (treated cells), Patient Plasma
	3 Cell (BioVue Screen Ficin Kit treated cells) ENZ Antibody Screen: Neutral cassette	BVSF Neut	NS02-88	BVS Ficin (treated cells), Patient Plasma
3 Cell (unt BioVue Screen cells)	3 Cell (BioVue Screen Papain Kit untreated cells) AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	BVSP Poly	NS10-22	BLISS, BVS Papain (untreated cells), Patient Plasma
	3 Cell (BioVue Screen Papain Kit untreated cells) AHG Antibody Screen: Anti-IgG cassette	BVSP IgG	NS10-33	
	3 Cell (BioVue Screen Ficin Kit untreated cells) AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	BVSF Poly	NS11-22	BLISS, BVS Ficin (untreated cells), Patient Plasma
	3 Cell (BioVue Screen Ficin Kit untreated cells) AHG Antibody Screen: Anti-IgG cassette	BVSF IgG	NS11-33	
3 Cell (Surg)	3 Cell (Surg) AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	ABScr 3 Poly	NS02-22	BLISS, Surgiscreen Cells, Patient Plasma
	3 Cell (Surg) AHG Antibody Screen: Anti-IgG cassette	ABScr 3 IgG	NS04-33	

Table B-6 Antibody Screening and Crossmatch (continued)

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
2 Cell (Sel) + Auto	2 Cell (Sel) + Auto AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	Auto ABScr 2 Poly	NU02-22	BLISS, Selectogen Cells, Patient Plasma, Patient Cells
	2 Cell (Sel) + Auto AHG Antibody Screen: Anti-IgG cassette	Auto ABScr 2 IgG	NU04-33	
2 Cell (Sel) + Diego	2 Cell (Sel) + Diego Antibody Screen Anti-IgG,-C3d; polyspecific cassette	2Scr+Dia Poly	NS08-22	BLISS, Selectogen Cells, Diego Cells, Patient Plasma
	2 Cell (Sel) + Diego Antibody Screen Anti-IgG cassette	2Scr+Dia IgG	NS08-33	
2 Cell (Sel)	2 Cell (Sel) AHG Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	ABScr 2 Poly	NS01-22	BLISS, Selectogen Cells, Patient Plasma
	2 Cell (Sel) AHG Antibody Screen: Anti-IgG cassette	ABScr 2 IgG	NS03-33	
Diego + Auto	Diego + Auto Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	Dia+Auto Poly	NU09-22	BLISS, Diego Cells, Patient Plasma, Patient Cells
	Diego + Auto Antibody Screen: Anti-IgG cassette	Dia+Auto IgG	NU09-33	
Diego	Diego Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	Dia Poly	NS09-22	BLISS, Diego Cells, Patient Plasma
	Diego Antibody Screen: Anti-IgG cassette	Dia IgG	NS09-33	
Autologous Control	Autologous Control: Anti-IgG, -C3d; polyspecific cassette	Auto Poly	NU10-22	BLISS, Patient Plasma, Patient Cells
	Autologous Control: Anti-IgG cassette	Auto IgG	NU10-33	
Test Cell[b]	Indirect Antiglobulin Test using any red cell (reagent or patient) from a sample tube	IgG, -C3b,-C3d IAT	NU10-30	BLISS, Patient Plasma, Any reagent red blood cell or Patient Cells (all treated as patient cells)
Major	Major Crossmatch (Immediate Spin): Reverse cassette	IS XM Rvs	NX05-66	Patient Plasma, Donor Cells
	Major AHG Crossmatch: Antibody Screen: Anti-IgG, -C3d; polyspecific cassette	Maj XM Poly	NX01-22	BLISS, Patient Plasma, Donor Cells
	Major AHG Crossmatch: Antibody Screen: Anti-IgG cassette	Maj XM IgG	NX03-33	

Table B-6 Antibody Screening and Crossmatch (continued)

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
2 ABScr 0.8% Selectogen	2ABScr: 0.8% Selectogen Polyspecific	8ABScr2 Poly	NS19-22	Patient Plasma, 0.8% Selectogen Cells
	2ABScr: 0.8% Selectogen IgG	8ABScr2 IgG	NS19-33	Patient Plasma, 0.8% Selectogen Cells
3 ABScr 0.8% Surgiscreen	3ABScr: 0.8% Surgiscreen Polyspecific	8ABScr3 Poly	NS20-22	Patient Plasma, 0.8% Surgiscreen Cells
	3ABScr: 0.8% Surgiscreen IgG	8ABScr3 IgG	NS20-33	Patient Plasma, 0.8% Surgiscreen Cells
ABScr + Auto	2ABScr+Auto: 0.8% Selectogen+Auto Polyspecific	8ABScr2+Auto Poly	NU15-22	Patient Plasma, 0.8% Surgiscreen Cells
	2ABScr+Auto: 0.8% Selectogen+Auto IgG	8ABScr2+Auto IgG	NU15-33	Patient Plasma, 0.8% Selectogen Cells, Patient Cells
	3ABScr+Auto: 0.8% Surgiscreen+Auto Polyspecific	8ABScr3+Auto Poly	NU16-22	Patient Plasma, 0.8% Surgiscreen Cells, Patient Cells
	3ABScr+Auto: 0.8% Surgiscreen+Auto IgG	8ABScr3+Auto IgG	NU16-33	Patient Plasma, 0.8% Surgiscreen Cells, Patient Cells
Autocontrol 0.8%	0.8% Autocontrol Polyspecific	8Auto Poly	NU17-22	Patient Plasma, Patient Cells, 0.8% Red Cell Diluent
	0.8% Autocontrol IgG	8Auto IgG	NU17-33	Patient Plasma, Patient Cells, 0.8% Red Cell Diluent
0.8% 3ABScr Unt BVSF	3ABScr: 0.8% BioVue Screen Ficin untreated cells Polyspecific	8BVSF Unt Poly	NS24-22	Patient Plasma, 0.8% BioVue Screen untreated Cells
	3ABScr: 0.8% BioVue Screen Ficin untreated cells IgG	8BVSF Unt IgG	NS24-33	Patient Plasma, 0.8% BioVue Screen untreated Cells
	3ABScr: 0.8% BioVue Screen Ficin untreated cells+Auto IgG	8BVSF Unt+Auto IgG	NU22-33	Patient Cells, Patient Plasma, 0.8% BioVue Screen untreated Cells
	3ABScr: 0.8% BioVue Screen Ficin untreated+Auto, polyspecific	8BVSF Unt+Auto Poly	NU22-22	Patient Cells, Patient Plasma, 0.8% BioVue Screen untreated Cells
0.8% BVSF Enz	3ABScr: 0.8% BioVue Screen Ficin Enzyme Treated	8BVSF Enz Neut	NS26-88	Patient Plasma, 0.8% BioVue Screen enzyme treated Cells
0.8% BVSF	ABScr: 0.8% BioVue Screen Ficin	8Fic ABScr	NS24-55	0.8% BioVue Screen Cells, Pt Plasma

Table B-6 Antibody Screening and Crossmatch (continued)

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
ABScr Bromelin	2ABScr: Selectogen + Bromelin PLN	Bro 2ABScr PLN	NS21-55	Bromelin, Selectogen Cells, Patient Plasma
	2ABScr: Selectogen+ Bromelin Neut	Bro 2ABScr Neut	NS21-88	Bromelin, Selectogen Cells, Patient Plasma
	3ABScr: Surgiscreen + Bromelin PLN	Bro3ABScr PLN	NS22-55	Bromelin, Surgiscreen Cells, Patient Plasma
	3ABScr: Surgiscreen + Bromelin Neut	Bro 3ABScr Neut	NS22-88	Bromelin, Surgiscreen Cells, Patient Plasma
	Diego Bromelin	Bro Dia Neut	NS23-88	
	2ABScr: Selectogen+ Dia Bromelin PLN	Bro 2ABScr + Dia PLN	NS23-55	Bromelin, Selectogen and Dia Cells, Patient Plasma
	2ABScr: Selectogen+ Dia Bromelin Neut	Bro 2ABScr+ Dia Neut	NS24-88	Bromelin, Selectogen + Diego Cells, Patient Plasma
	3ABScr: Surgiscreen+ Dia Bromelin Neut	Bro 3ABScr+ Dia Neut	NS25-88	Bromelin, Surgiscreen + Diego Cells, Patient Plasma
	Autocontrol Bromelin	Bro Auto Neut	NU19-88	Bromelin, Patient Plasma, Patient Cells
	Diego+Auto Bromelin	Bro Dia+Auto Neut	NU18-88	Bromelin, Diego Cells, Patient Plasma, Patient Cells
	2ABScr: Selectogen +Auto Bromelin PLN	Bro 2ABScr+Auto PLN	NU20-55	Bromelin, Selectogen Cells, Patient Plasma, Patient Cells
	2ABScr: Selectogen+Auto Bromelin Neut	Bro 2ABScr+Auto Neut	NU20-88	Bromelin, Selectogen Cells, Patient Plasma
	3ABScr: Surgiscreen +Auto Bromelin Neut	Bro 3ABScr+Auto Neut	NU21-88	Bromelin, Surgiscreen Cells, Patient Plasma, Patient Cells
	2ABScr: Selectogen+Dia+Auto Bromelin Neut	Bro 2ABScr+DiaAuto Neut	NU22-88	Bromelin, Selectogen + Diego Cells, Patient Plasma, Patient Cells
	3ABScr: Surgiscreen+ Dia+Auto Bromelin Neut	Bro 3ABScr+Dia+ Auto Neut	NU23-88	Bromelin, Surgiscreen + Diego Cells, Patient Plasma, Patient Cells

Table B-6 Antibody Screening and Crossmatch (continued)

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
ABScr Diego	2ABScr+Dia: 0.8% Selectogen+Dia Polyspecific	0.8% 8ABScr2+8Dia Poly	NS21-22	Patient Plasma, 0.8% Selectogen, 0.8% Diego Cells
	2ABScr+Dia: 0.8% Selectogen+Dia IgG	0.8% ABScr2+Dia IgG	NS21-33	Patient Plasma, 0.8% Selectogen, 0.8% Diego Cells
	3ABScr: 0.8% Surgiscreen + Dia Polyspecific	0.8% ABScr3 + Dia Poly	NS22-22	Patient Plasma, 0.8% Surgiscreen, 0.8% Diego Cells
	3ABScr: 0.8% Surgiscreen + Dia IgG	0.8% ABScr3 + Dia IgG	NS22-33	Patient Plasma, 0.8% Surgiscreen, 0.8% Diego Cells
	0.8% Diego Polyspecific	0.8% Dia Poly	NS23-22	Patient Plasma, 0.8% Diego Cells
	0.8% Diego IgG	0.8% Dia IgG	NS23-33	Patient Plasma, 0.8% Diego Cells
	2ABScr+Dia+Auto: 0.8% Selectogen+Dia+Auto Polyspecific	0.8% ABScr2+Dia+ Auto Poly	NU18-22	Patient Plasma, 0.8% Selectogen, 0.8% Diego Cells, Patient Cells
	2ABScr+Dia+Auto: 0.8% Selectogen+Dia+Auto IgG	0.8% ABScr2+Dia+ Auto IgG	NU18-33	Patient Plasma, 0.8% Selectogen, 0.8% Diego Cells, Patient Cells
	3ABScr+Dia+Auto: 0.8% Surgiscreen+Dia+Auto Polyspecific	0.8% ABScr3+Dia+ Auto Poly	NU19-22	Patient Plasma, 0.8% Surgiscreen, 0.8% Diego Cells, Patient Cells
	3ABScr+Dia+Auto: 0.8% Surgiscreen+Dia+Auto IgG	0.8% ABScr3+Dia+ Auto IgG	NU19-33	Patient Plasma, 0.8% Surgiscreen, 0.8% Diego Cells, Patient Cells
	ABScr+Dia: 0.8% BioVue Screen Ficin + 0.8% Dia, polyspecific	8 BVSF + 8Dia Poly	NS25-88	Patient Plasma, 0.8% BioVue Screen Cells, 0.8% Diego Cells
	3ABScr+Dia+Auto: 0.8% BioVue Screen Ficin Untreated + 0.8% Dia + 0.8% Autocontrol; Polyspecific	8BVSF Unt+8Dia+8Auto Poly	NU21-22	Patient Plasma, 0.8% BioVue Screen Ficin Untreated cells, 0.8% Dia Cells, Patient Cells, 0.8% Red Cell Diluent
	ABScr+Dia: 0.8% BioVue Screen Ficin + 0.8% Dia, IgG	8 BVSF + 8Dia IgG	NS25-33	Patient Plasma, 0.8% BioVue Screen Cells, 0.8% Diego Cells

Table B-6 Antibody Screening and Crossmatch (continued)

Combo[a]	Heading	Software Abbreviation	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
ABScr Diego	0.8% Diego + 0.8% Auto Poly	8 Dia + 8 Auto Poly	NU20-22	Patient Cells, Patient Plasma, 0.8% Diego Cells, 0.8% Red Cell Diluent
	0.8% Diego + 0.8% Auto Poly	8 Dia + 8 Auto IgG	NU20-33	Patient Cells, Patient Plasma, 0.8% Diego Cells, 0.8% Red Cell Diluent
	3ABScr+Dia+Auto:0.8% BioVue Screen Ficin Untreated+0.8% Dia+0.8% Autocontrol:Anti-IgG	8BVSF Unt + 8 Dia + 8Auto IgG	NU21-33	Patient Plasma, 0.8% BioVue Screen Ficin Untreated cells, 0.8% Dia Cells, Patient Cells, 0.8% Red Cell Diluent
Crossmatch Major	0.8% Major Crossmatch Polyspecific	8 Maj XM Poly	NX06-22	Patient Plasma, Donor Cells
	0.8% Major Crossmatch IgG	8 Maj XM IgG	NX06-33	Patient Plasma, Donor Cells
	0.8% Major Crossmatch immediate spin	8 IS XM Rvs	NX06-66	Patient Plasma, Donor Cells
	Major Crossmatch Bromelin	Bro XM	NX07-88	Bromelin, Patient Plasma, Donor Cells
Crossmatch Minor	Minor AHG Crossmatch Anti-IgG, -C3d; polyspecific cassette	Min XM Poly	NX01-22_Min	BLISS, Patient Cells, Donor Plasma
	Minor AHG Crossmatch Anti-IgG cassette	Min XM IgG	NX03-33_Min	
	0.8% Minor Crossmatch Polyspecific	8Min XM Poly	NX06-22_Min	Patient Cells, Donor Plasma
	0.8% Minor Crossmatch IgG	8Min XM IgG	NX06-33_Min	

a. Papain and Ficin BioVue Screen Kits are listed in the same combination.
b. The IAT tests listed in this section of the table require the test cell to be placed in a sample tube and treated as patient red cells, even if the test cell is a reagent red blood cell.

Antibody Identification

Table B-7 Antibody Identification

Heading	Software Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
AbID Resolve Panel A Polyspecific	Panel A Poly	NI02-22	BLISS, Panel A Cells, Patient Plasma
AbID Resolve Panel A IgG	Panel A IgG	NI02-33	BLISS, Panel A Cells, Patient Plasma
AbID Resolve Panel A Immediate	Panel A IS Neut	NI02-88	Panel A Cells, Patient Plasma
AbID Resolve Panel B Polyspecific	Panel B Poly	NI03-22	BLISS, Panel B Cells, Patient Plasma
AbID Resolve Panel B IgG	Panel B IgG	NI03-33	BLISS, Panel B Cells, Patient Plasma
AbID Resolve Panel B Immediate spin	Panel B IS Neut	NI03-88	Panel B Cells, Patient Plasma
AbID Resolve Panel C Unt Polyspecific	Panel C Unt Poly	NI04-22	BLISS, Panel C untreated Cells, Patient Plasma
AbID Resolve Panel C Unt IgG	Panel C Unt IgG	NI04-33	BLISS, Panel C untreated Cells, Patient Plasma
AbID Resolve Panel C Unt Immediate spin	Panel C Unt IS Neut	NI04-88	Panel C untreated Cells, Patient Plasma
AbID BioVue Top Unt Polyspecific	BV Top Unt Poly	NI01-22	BLISS, BioVue Top untreated Cells, Patient Plasma
AbID BioVue Top Unt IgG	BV Top Unt IgG	NI01-33	BLISS, BioVue Top untreated Cells, Patient Plasma
AbID BioVue Top Unt Immediate spin	BV Top Unt IS Neut	NI01-88	BioVue Top untreated Cells, Patient Plasma
AbID 0.8% Resolve Panel A polyspecific	8 Panel A Poly	NI05-22	Patient Plasma, Panel A Cells
AbID 0.8% Resolve Panel A IgG	8 Panel A IgG	NI05-33	Patient Plasma, Panel A Cells
AbID 0.8% Resolve Panel A immediate spin	8 Panel A IS Neut	NI05-88	Patient Plasma, Panel A Cells
AbID 0.8% Resolve Panel B polyspecific	8 Panel B Poly	NI06-22	Patient Plasma, Panel B Cells
AbID 0.8% Resolve Panel B IgG	8 Panel B IgG	NI06-33	Patient Plasma, Panel B Cells
AbID 0.8% Resolve Panel B immediate spin	8 Panel B IS Neut	NI06-88	Patient Plasma, Panel B Cells

Table B-7 Antibody Identification (continued)

Heading	Software Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
AbID 0.8% Resolve Panel C Unt polyspecific	8 Panel C Unt Poly	NI07-22	Patient Plasma, Panel C untreated Cells
AbID 0.8% Resolve Panel C Unt IgG	8 Panel C Unt IgG	NI07-33	Patient Plasma, Panel C untreated Cells
AbID 0.8% Resolve Panel C Unt immediate spin	8 Panel C Unt IS Neut	NI07-88	Patient Plasma, Panel C untreated Cells
AbID Resolve Panel A +Auto Polyspecific	Panel A+Auto Poly *	NI09-22	BLISS, Panel A Cells, Patient Plasma, Patient Cells
AbID Resolve Panel A +Auto IgG	Panel A+Auto IgG *	NI09-33	BLISS, Panel A Cells, Patient Plasma, Patient Cells
AbID Resolve Panel A +Auto immediate spin	Panel A+Auto IS Neut *	NI16-88	Panel A Cells, Patient Plasma, Patient Cells
AbID Resolve Panel B +Auto Polyspecific	Panel B+Auto Poly *	NI10-22	BLISS, Panel B Cells, Patient Plasma, Patient Cells
AbID Resolve Panel B +Auto IgG	Panel B+Auto IgG *	NI10-33	BLISS, Panel B Cells, Patient Plasma, Patient Cells
AbID Resolve Panel B +Auto immediate spin	Panel B+Auto IS Neut *	NI17-88	Panel B Cells, Patient Plasma, Patient Cells
AbID Resolve Panel C Unt +Auto Polyspecific	Panel C+Auto Poly *	NI11-22	BLISS, Panel C untreated Cells, Patient Plasma, Patient Cells
AbID Resolve Panel C Unt +Auto IgG	Panel C+Auto IgG *	NI11-33	BLISS, Panel C untreated Cells, Patient Plasma, Patient Cells
AbID Resolve Panel C Unt +Auto immediate spin	Panel C+Auto IS Neut *	NI18-88	Panel C untreated Cells, Patient Plasma, Patient Cells
AbID BioVue Top Unt+Auto Polyspecific	BV Top Unt+Auto Poly	NI08-22	BLISS, BioVue Top untreated Cells, Patient Plasma, Patient Cells
AbID BioVue Top Unt+Auto IgG	BV Top Unt+Auto IgG	NI08-33	BLISS, BioVue Top untreated Cells, Patient Plasma, Patient Cells
AbID BioVue Top Unt+Auto immediate spin	BV Top Unt+Auto IS Neut	NI15-88	BioVue Top untreated Cells, Patient Plasma, Patient Cells
AbID 0.8% Resolve Panel A +Auto polyspecific	8 Panel A+Auto Poly *	NI12-22	Patient Plasma, Panel A Cells, Patient Cells
AbID 0.8% Resolve Panel A +Auto IgG	8 Panel A+Auto IgG *	NI12-33	Patient Plasma, Panel A Cells, Patient Cells
AbID 0.8% Resolve Panel A immediate spin	8 Panel A+Auto IS Neut *	NI19-88	Patient Plasma, Panel A Cells, Patient Cells
AbID 0.8% Resolve Panel B +Auto polyspecific	8 Panel B+Auto Poly *	NI13-22	Patient Plasma, Panel B Cells, Patient Cells

Table B-7 Antibody Identification (continued)

Heading	Software Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
AbID 0.8% Resolve Panel B +Auto IgG	8 Panel B+Auto IgG *	NI13-33	Patient Plasma, Panel B Cells, Patient Cells
AbID 0.8% Resolve Panel B+Auto immediate spin	8 Panel B+Auto IS Neut *	NI20-88	Patient Plasma, Panel B Cells, Patient Cells
AbID 0.8% Resolve Panel C Unt+Auto polyspecific	8 Panel C+Auto Poly *	NI14-22	Patient Plasma, Panel C untreated Cells, Patient Cells
AbID 0.8% Resolve Panel C Unt+Auto IgG	8 Panel C+Auto IgG *	NI14-33	Patient Plasma, Panel C untreated Cells, Patient Cells
AbID 0.8% Resolve Panel C Unt Auto immediate spin	8 Panel C+Auto IS Neut *	NI21-88	Patient Plasma, Panel C untreated Cells, Patient Cells
AbID Resolve Panel C Ficin Neut	Panel C Ficin Neut	NI13-88	Panel C Ficin treated Cells, Patient Plasma
AbID BioVue Top Papain	BV Top Pap Neut	NI12-88	BioVue Top Papain treated Cells, Patient Plasma
AbID 0.8% Resolve Panel C Ficin Neut	8 Panel C Ficin Neut	NI14-88	Panel C Ficin treated Cells, Patient Plasma
AbID Resolve Panel A Bromelin	Panel A+Brom Neut 37	NI09-88	Bromelin, Panel A Cells, Patient Plasma
AbID Resolve Panel B Bromelin	Panel B+Brom Neut 37	NI10-88	Bromelin, Panel B Cells, Patient Plasma
AbID Resolve Panel C Unt Bromelin	Panel C Unt+Bromelin Neut 37	NI11-88	Bromelin, Panel B Cells, Patient Plasma
AbID BioVue Top Unt Bromelin	BV Top Unt+Brom Neut 37	NI08-88	Bromelin, BioVue Top untreated Cells, Patient Plasma
AbID Resolve Panel A Bromelin+Auto	Panel A+Brom+Auto Neut 37 *	NI23-88	Patient Plasma, Bromelin, Panel A Cells
AbID Resolve Panel B+Bromelin+Auto	Panel B+Brom+Auto Neut 37 *	NI24-88	Patient Plasma, Bromelin, Panel B Cells
AbID Resolve Panel C Unt +Bromelin+Auto	Panel C Unt+Brom+Auto Neut 37 *	NI25-88	Patient Plasma, Panel C untreated Cells, Bromelin, Patient Cells
AbID BioVue Top Unt Bromelin + Auto	BV Top Unt+Brom+Auto Neut 37	NI22-88	Bromelin, BioVue Top untreated Cells, Patient Plasma, Patient Cells

* Use predefined "Panel + Auto" test profiles provided with V1.04 and above to ensure the use of 12 wells in 2 cassettes.

Cassette/Reagent Quality Control Tests

Table B-8 ABO and Phenotype Cassette/Reagent Quality Control Tests

Heading	PC Name	Tests ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
BRC QC ABO-Rh/Reverse: Negative	BRC 00 Neg	QA03-00	BRC-S1, BRC-E3, A_1, B
BRC QC ABO-Rh/Reverse: Positive Surgiscreen	BRC 00 Surg Pos	QA04-00	BRC-S2, A_1, B, Surgiscreen Cells 1
BRC QC ABO-Rh/Reverse: Positive Selectogen	BRC 00 Sel Pos	QA05-00	BRC-S2, A_1, B, Selectogen Cell I
BRC QC ABO-Rh/Reverse: Positive BioVue Screen Papain	BRC 00 Pap Pos	QA06-00	BRC-S2, A_1, B, BVS Papain Unt 1
BRC QC ABO-Rh/Reverse: Positive BioVue Screen Ficin	BRC 00 Fic Pos	QA07-00	BRC-S2, A_1, B, BVS Ficin Unt 1
BRC QC ABO-Rh/Reverse: Weak D	BRC 00 WkD	QA08-00	BRC-E4
BRC QC 2 Cell ABO Reverse, Immediate Spin Crossmatch	BRC Rvs 2 Cell	QA09-66	BRC-S1, BRC-S2, A_1, B
BRC QC 3 Cell ABO Reverse: A_1, A_2, B	BRC Rvs 3 Cell	QA10-66	BRC-S1, BRC-S2, A_1, A_2, B
BRC QC 3 Cell ABO Reverse: A_1, B, O	BRC Rvs A1,B,O	QA15-66	BRC-S1, BRC-S2, A_1, B, O
BRC QC 4 Cell ABO Reverse: Negative	BRC Rvs 4 Neg	QA11-66	BRC-S1, A_1, A_2, B, O
BRC QC 4 Cell ABO Reverse: Positive	BRC Rvs 4 Pos	QA12-66	BRC-S2, A_1, A_2, B, O
BRC QC 6 Cell ABO Reverse: Negative	BRC Rvs 6 Neg	QA13-66	BRC-S1, A_1, A_2, B, O, Selectogen Cells
BRC QC 6 Cell ABO Reverse: Positive	BRC Rvs 6 Pos	QA14-66	BRC-S2, BRC-S3, A_1, A_2, B, O, Selectogen Cells
BRC QC ABO(FWD)-Rh/K: Negative	BRC ADK Neg	QA06-40	BRC-E1, BRC-E3, A_1, B
BRC QC ABO(FWD)-Rh/K: Surgiscreen	BRC ADK Surg	QA07-40	BRC-E3, A_1, B, Surgiscreen Cells 1
BRC QC ABO(FWD)-Rh/K: Selectogen	BRC ADK Sel	QA08-40	BRC-E3, A_1, B, Selectogen Cells I
BRC QC ABO(FWD)-Rh/K: BioVue Screen Papain	BRC ADK Pap	QA09-40	BRC-E3, A_1, B, BVS Papain Unt 1
BRC QC ABO(FWD)-Rh/K: BioVue Screen Ficin	BRC ADK Fic	QA10-40	BRC-E3, A_1, B, BVS Ficin Unt 1

Table B-8 ABO and Phenotype Cassette/Reagent Quality Control Tests (continued)

Heading	PC Name	Tests ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
BRC QC ABO(FWD)-Rh/K: Weak D	BRC 40 WkD	QA13-40	BRC-E4
BRC QC ABO-Rh: Negative	BRC ABO-Rh Neg	QA06-44	BRC-E3, A_1, B
BRC QC ABO-Rh: Surgiscreen	BRC ABO-Rh Surg	QA07-44	A_1, B, Surgiscreen Cells 1
BRC QC ABO-Rh: Selectogen	BRC ABO-Rh Sel	QA08-44	A_1, B, Selectogen Cells I
BRC QC ABO-Rh: BioVue Screen Papain	BRC ABO-Rh Pap	QA09-44	A_1, B, BVS Papain Unt 1
BRC QC ABO-Rh: BioVue Screen Ficin	BRC ABO-Rh Fic	QA10-44	A_1, B, BVS Ficin Unt 1
BRC QC ABO-Rh: Anti-E	BRC ABO-Rh E	QA11-44	BRC-E2, A_1
BRC QC ABO-Rh: Anti-C	BRC ABO-Rh C	QA12-44	BRC-E1, B
BRC QC ABO-Rh: Weak D	BRC 44 WkD	QA13-44	BRC-E4
BRC QC ABD Surgiscreen	BRC ABD Surg	QA01-10	BRC-E3, A_1, B, Surgiscreen Cells 1
BRC QC ABD Selectogen	BRC ABD Sel	QA02-10	BRC-E3, A_1, B, Selectogen Cells I
BRC QC ABD BioVue Screen Papain	BRC ABD Pap	QA03-10	BRC-E3, A_1, B, BVS Papain Unt 1
BRC QC ABD BioVue Screen Ficin	BRC ABD Fic	QA04-10	BRC-E3, A_1, B, BVS Ficin Unt 1
BRC QC ABD: Weak D	BRC 10 WkD	QA05-10	BRC-E4
BRC QC Newborn: Negative	BRC Newborn Neg	QA01-20	BRC-E3, A_1, B
BRC QC Newborn: Positive Surgiscreen	BRC Newborn Surg	QA02-20	BRC-E5, A_1, B, Surgiscreen Cells 1
BRC QC Newborn: Positive Selectogen	BRC Newborn Sel	QA03-20	BRC-E5, A_1, B, Selectogen Cells I
BRC QC Newborn: Positive BioVue Screen Papain	BRC Newborn Pap	QA04-20	BRC-E5, A_1, B, BVS Papain Unt 1
BRC QC Newborn: Positive BioVue Screen Ficin	BRC Newborn Fic	QA05-20	BRC-E5, A_1, B, BVS Ficin Unt 1
BRC QC Newborn: Positive B for A, B	BRC 20 B of A+B	QA07-20	B, BRC-E5
BRC QC Newborn: Weak D	BRC 20 WkD	QA06-20	BRC-E4
BRC QC Complement (C3d): Anti-IgG, -C3d; polyspecific	BRC C3d Poly	QD01-22	BRC-E5
BRC QC DAT: QC for Direct Testing of DAT/IDAT	BRC C3d DAT	QD01-30	BRC-E5
BRC QC Complement (C3d): Anti-Human/Neutral	BRC C3d Poly/ Neut	QD01-55	BRC-E5

Table B-8 ABO and Phenotype Cassette/Reagent Quality Control Tests (continued)

Heading	PC Name	Tests ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
BRC QC Phenotype with D: Negative Surgiscreen	BRC Rh-hr Surg Neg	QR03-11	BRC-E2, BRC-E3, Surgiscreen Cells 1 and 2
BRC QC Phenotype with D: Positive Surgiscreen	BRC Rh-hr Surg Pos	QR04-11	BRC-E1, BRC-E2, Surgiscreen Cells 1
BRC QC Phenotype with D: Negative Selectogen	BRC Rh-hr Sel Neg	QR05-11	BRC-E2, BRC-E3, Selectogen Cells I and II
BRC QC Phenotype with D: Positive Selectogen	BRC Rh-hr Sel Pos	QR06-11	BRC-E1, BRC-E2, Selectogen Cells I
BRC QC Phenotype with D: Negative BioVue Screen Papain	BRC Rh-hr Pap Neg	QR07-11	BRC-E2, BRC-E3, BVS Papain Untreated Cells 1 and 2
BRC QC Phenotype with D: Positive BioVue Screen Papain	BRC Rh-hr Pap Pos	QR08-11	BRC-E1, BRC-E2, BVS Papain Untreated Cells 1
BRC QC Phenotype with D: Negative BioVue Screen Papain	BRC Rh-hr Fic Neg	QR09-11	BRC-E2, BRC-E3, BVS Ficin Untreated Cells 1 and 2
BRC QC Phenotype with D: Positive BioVue Screen Papain	BRC Rh-hr Fic Pos	QR10-11	BRC-E1, BRC-E2, BVS Ficin Untreated Cells 1
BRC QC Phenotype with D: Weak D	BRC 11 WkD	QR11-11	BRC-E4
BRC QC Phenotype with K: Positive	BRC Rh/K Pos	QR03-77	BRC-E1, BRC-E2, BRC-E3
BRC QC Phenotype with K: Negative Surgiscreen	BRC Rh/K Surg Neg	QR04-77	BRC-E2, BRC-E3, Surgiscreen Cell 1 and 2
BRC QC Phenotype with K: Negative Selectogen	BRC Rh/K Sel Neg	QR05-77	BRC-E2, BRC-E3, Selectogen Cells I and II
BRC QC Phenotype with K: Negative BioVue Screen Papain	BRC Rh/K Pap Neg	QR06-77	BRC-E2, BRC-E3, BVS Papain Untreated Cells 1 and 2
BRC QC Phenotype with K: Negative BioVue Screen Ficin	BRC Rh/K Fic Neg	QR07-77	BRC-E2, BRC-E3, BVS Ficin Untreated Cells 1 and 2

Table B-9 Antibody Screening Cassette/Reagent Quality Control Tests[a]

Combo[b]	Heading	PC Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
BioVue Screen	BRC QC BioVue Screen Papain Negative Antigen Test	BRC 55 Pap Neg	QS09-55	BLISS, BRC-S1, BVS Papain
	BRC QC BioVue Screen Papain Positive Antigen Test	BRC 55 Pap Pos	QS10-55	BLISS, diluted BRC-S3, BVS Papain
	BRC QC BioVue Screen Ficin Negative Antigen Test	BRC 55 Fic Neg	QS11-55	BLISS, BRC-S1, BVS Ficin
	BRC QC BioVue Screen Ficin Positive Antigen Test	BRC 55 Fic Pos	QS12-55	BLISS, diluted BRC-S3, BVS Ficin
BioVue Screen (treated cells)	BRC QC BioVue Screen Papain Kit Pos/Neg Antigen Test	BRC 88 Pap	QS05-88	BRC-S1, BRC-S3, BVS Papain (treated cells)
	BRC QC BioVue Screen Ficin Kit Pos/Neg Antigen Test	BRC 88 Fic	QS06-88	BRC-S1, BRC-S3, BVS Ficin (treated cells)
BioVue Screen (untreated cells)	BRC QC BioVue Screen Papain Kit: Anti-IgG, -C3d; polyspecific with no positive for BioVue Screen 3	BRC BVSP Poly Ltd	QS06-22	BLISS, BRC-S1, diluted BRC-S3, BVS Papain (untreated cells)
	BRC QC BioVue Screen Papain Kit: Anti-IgG with no positive for BioVue Screen 3	BRC BVSP IgG Ltd	QS08-33	BLISS, BRC-S1, diluted BRC-S3, BVS Papain (untreated cells)
	BRC QC BioVue Screen Ficin Kit: Anti-IgG, -C3d; polyspecific with no positive for BioVue Screen 3	BRC BVSF Poly Ltd	QS07-22	BLISS, BRC-S1, diluted BRC-S3, BVS Ficin (untreated cells)
	BRC QC BioVue Screen Ficin Kit: Anti-IgG with no positive for BioVue Screen 3	BRC BVSF IgG Ltd	QS09-33	BLISS, BRC-S1, diluted BRC-S3, BVS Ficin (untreated cells)

Table B-9 Antibody Screening Cassette/Reagent Quality Control Tests[a] (continued)

Combo[b]	Heading	PC Name	Test ID	Reagents/Sample Added by ORTHO AutoVue *Innova/Ultra*
Surgiscreen	BRC QC Surgiscreen: Anti-IgG, -C3d; polyspecific with no positive for Surg 3	BRC 3 Poly Ltd	QS03-22	BLISS, BRC-S1, diluted BRC-S3, Surgiscreen
	BRC QC Surgiscreen: Anti-IgG with no positive for Surg 3	BRC 3 IgG Ltd	QS05-33	BLISS, BRC-S1, diluted BRC-S3, Surgiscreen
	BRC QC 0.8% Surgiscreen: Polyspecific with no positive for Surg 3	BRC 0.8% 3 Poly Ltd	QS13-22	BRC-S1, diluted BRC-S3, 0.8% Surgiscreen
	BRC QC 0.8% Surgiscreen: IgG with no positive for Surg 3	BRC 0.8% 3 IgG Ltd	QS13-33	BRC-S1, diluted BRC-S3, 0.8% Surgiscreen
Selectogen	BRC QC Selectogen Anti-IgG, -C3d; polyspecific	BRC 2 Poly	QS05-22	BLISS, BRC-S1, diluted BRC-S3, Selectogen Cells
	BRC QC Selectogen Anti-IgG	BRC 2 IgG	QS07-33	BLISS, BRC-S1, diluted BRC-S3, Selectogen Cells
	BRC QC 0.8% Selectogen Polyspecific	BRC 0.8% 2 Poly	QS14-22	BRC-S1, diluted BRC-S3, 0.8% Selectogen
	BRC QC 0.8% Selectogen IgG	BRC 0.8% 2 IgG	QS14-33	BRC-S1, diluted BRC-S3, 0.8% Selectogen
Test Cell	BRC QC: Surgiscreen	BRC IAT Surg	QS01-30	BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Surgiscreen 1
	BRC QC: Selectogen	BRC IAT Sel	QS02-30	BLISS, BRC-S1, diluted BRC-S3, BRC-E5, Selectogen I
	BRC QC: Papain	BRC IAT Pap	QS03-30	BLISS, BRC-S1, diluted BRC-S3, BRC-E5, BVS Papain Untreated Cells 1
	BRC QC: Ficin	BRC IAT Fic	QS04-30	BLISS, BRC-S1, diluted BRC-S3, BRC-E5, BVS Ficin Untreated Cells 1

a. Screening tests utilizing autologous controls are considered the same as those without the auto control.
b. Papain and Ficin BioVue Screen Kits are listed in the same combination.

Valid Test Results for Analyses

This section provides a list of the valid test results.

Note: You can configure the system to display test results in different ways. For example, POS/NEG or +/-.

.

Table B-10 Valid Test Results for Analyses

ABO	$Rh_o(D)$	Phenotype	Kell	Antibody Screen	DAT	XM	Autocontrol
A	POS	CcEe	POS	POS	POS	INCMP	POS
B	NEG	ccEe	NEG	NEG	NEG	CMP	NEG
AB	D	ccee	POS				
O	d	Ccee	K+				
A	POS	CCee	K-				
B	D	CCEe					
O		CCEE					
		CcEE					
		ccEE					

This page intentionally left blank.

Appendix C: Software Versions

This guide is validated for the ORTHO AutoVue *Innova/Ultra* software version 1.05.

This page intentionally left blank.

Appendix D: Anti-Virus Software

Anti-virus software can protect your system from computer viruses, spyware and Internet worms. Tests conducted by OCD have demonstrated that the performance of the ORTHO AutoVue *Innova/Ultra* is unaffected by two anti-virus software packages:

- McAfee VirusScan® 2007
- Norton AntiVirus™ 2007

You may safely install either of these packages on your AutoVue PC.

Both the Norton AntiVirus 2007 and the McAfee VirusScan 2007 software packages also include protection against spyware and Internet worms. If you choose to install an anti-virus package other than Norton or McAfee, OCD recommends that you also install anti-spyware and anti-Internet worm software.

Anti-Virus Software Updates

Anti-virus software looks for strings of code or data that are known to be part of an identified virus or other malicious software. This requires frequent updates to the software's Signature or Definition Files in order for the software to remain current. These updates may occur daily. Usually, such updates are made via a connection between your computer and the manufacturer over the Internet, and take place with little or no user intervention.

Minor updates to the anti-virus application itself may occur less frequently, on a weekly or monthly basis. These updates also usually take place with minimal user intervention.

Major updates of the anti-virus software typically happen once a year. These updates usually require that the new version be installed on your PC to replace the old version. This installation is commonly performed by information technology staff.

Recommendations

To ensure that your system remains secure and free of any virus, spyware and Internet worms, OCD recommends the following:

- Avoid connecting directly to the Internet. Connecting directly to the Internet leaves your PC exposed to harmful viruses, spyware, and other malicious software. When you must connect to the Internet, do so only through a hardware firewall, such as a properly configured router.
- Be sure to configure your anti-virus software so that automated updates do not occur while the ORTHO AutoVue *Innova/Ultra* is processing samples. If this isn't possible, then disable automatic downloads and perform them manually on a daily basis.
- Perform both a daily and an archive backup before installing any minor or major updates to your anti-virus software.

  Note: Performing these backups is not necessary before daily updates to the software's definition or signature files.

Validation Protocol

Perform the following validation protocol when:

- you update your anti-virus software (not including an update to the definition files).
- you install any anti-virus software that has not been validated by OCD. This includes any major or minor updates to software that you previously validated.

This procedure will validate that all major modules in the ORTHO AutoVue *Innova/Ultra* software are functioning properly.

To Validate the System after Installing or Updating Anti-Virus Software

1	Restart the ORTHO AutoVue *Innova/Ultra* to initialize the system.
2	Perform one of the following maintenance operations: ▪ Flush ▪ Tip decontamination ▪ Fluidic circuit decontamination

To Validate the System after Installing or Updating Anti-Virus Software (continued)

3	Perform the following QC operations: ▪ QC Auto Reader ▪ QC Volume
4	Make sure that all reports that include result data are printing properly. Verify that the report prints completely, and that data on the printed report matches result data shown on the AutoVue screen.
5	Verify that orders are transferred completely and accurately to the AutoVue from the LIS, and that results are transferred to the LIS from the AutoVue. Make sure that results match on both the LIS and the AutoVue.
6	Process two or more samples with patient demographic data (if used), using two or more profiles. Verify that tests complete successfully.
7	Process two or more QC samples. Verify that results correspond with sample labeling.
8	Perform daily and archive backup procedures, verifying that they complete successfully.

This page intentionally left blank.

Appendix E: Revision History

2009-11-10, Software Version 1.05

Revision to Chapter/section	Page	Description
Chapter 1: Intended Use, Specifications and Limitations	1-13	▪ Added cross reference to QC AutoReader in the "Instrument Quality Control Limits" table
	1-17	▪ Added "or polypropylene" to description of acceptable dilution plates.
	1-28	▪ Added statement that recovery from an empty sample tube error includes moving tube to a new position in the sample rack.
		▪ Removed note concerning "7" appearing during a shutdown in Routine/Maintenance field. This has been corrected.
	1-28	▪ Removed note concerning risk of dropped cassettes. This has been corrected.
	1-29	▪ Added advisory to select New Search when checking test order results through the Search screen. ▪ Added statement regarding carry-over in samples with very high-titered antibody.
	1-32	▪ Expanded statement that only validated software may be installed on system computer. ▪ Added instruction to call CTS in the event of a software crash.
	1-37	▪ Added street address for OCD in Raritan.
Chapter 6: Registering and Loading Consumables and Samples/Controls	6-4	▪ Updated reagent barcode descriptions.
	6-33, 34	▪ Added statement that the system will create a Patient ID if none is entered by the user.

Revision to Chapter/section	Page	Description
Chapter 7: Monitoring Status and Managing Results	7-5	▪ Updated description and graphic: results at or below thresholds are now highlighted whether or not Review orders or Review cassettes is enabled.
	7-15, 7-20	▪ Removed redundant note concerning results at or below thresholds set by the user.
	7-14, 7-16	▪ Updated note: sample priority cannot be changed after instrument has started testing the sample.
	7-16, -17, -18	▪ Added note that if "Require Comments for Editing Results" is enabled, user must enter comment before system will accept edited result.
Chapter 8: Performing Maintenance and Quality Control Procedures	8-29	▪ Added description of Reset to Default button in QC AutoReader Report window.
Chapter 11: Setting Up System Preferences and User Information	11-21	▪ Made treatment of Lot 2306 consistent with others in diagram of Affirmagen Reagent Kit.
	11-27	▪ Added "Require Comments for Editing Results" to Set Miscellaneous Results Preferences table.
	11-30	▪ Corrected and reworded "Set and Modify Threshold Values for Results."
	11-34	▪ Corrected description of Analyses groups.
Appendix A: Error Messages	A-7	▪ Added error codes 225 and 226.
	A-15	▪ Removed ASRT046, STRV error during reagent distribution. ▪ Added ASRT019, reagent clot detected. ▪ Added ASRT049, reagent volume too low or too high.
	A-16	▪ Added ASSO013, sample rack position verification error.
Appendix B: Supported Cassettes, Reagents, Tests, and Test Results	B-6	▪ Corrected description of OCD Reagent Kit table.
	B-6 to B-15	▪ Added Barcode Format column to table of OCD Reagent kits.
	B-30 to B-32	▪ Updated Table B-7, Antibody Identification; added note to use predefined Panel+Auto test profiles to conserve cassettes.

2008-04-30, Software Version 1.04

Revision to Chapter/section	Page	Description
Cover page, inside cover, document footer	All	▪ Updated document version, date, and copyright date.
Table of Contents	All	▪ Updated for current release.

Revision to Chapter/section	Page	Description
Chapter 1: Graphic Symbols Used in this Guide and for Labeling	1-6	▪ Added graphic label required by Chinese Environmental Regulations on Hazardous Substances.
Chapter 1: Description of ORTHO AutoVue *Innova/Ultra*	1-9	▪ Added STRV to list of common abbreviations.
Chapter 1: Software Functions	1-11	▪ Added "manage incubation time of cassettes" to software control operations.
Chapter 1: Quality Control Limits	1-12	▪ Added pipette position error reference to Instrument Quality Control Limits table.
	1-13	▪ Added "Gain and Offset values" to AutoReader entry, Instrument Quality Control Limits table.
Chapter 1: System Specifications	1-15	▪ Added AlbaQ-Chek J, Ortho CQI 7 and Ortho CQI 9 to list of Reagent Types.
	1-17	▪ Added Greiner 96-well polypropylene plate to approved deep-well dilution plates.
	1-20	▪ Corrected reference to Code 39 barcode.
	1-21	▪ Added "and is read as "$$" by the system scanner" to description of Sample Rack barcodes.
Chapter 1: Serological Timing Restrictions	1-23	▪ Added "result in a Serological Timing Restriction Violation (STRV) error" to description.
Chapter 1: Instrument and Software Limitations	1-25	▪ Some reagents significantly past their expiration may erroneously be accepted as valid.
	1-26	▪ Corrected description of what happens when instrument is switched off during testing.
	1-27	▪ Removed statement that a profile must be re-created to see associated archive results using Search.
	1-28	▪ Removed references to ASRT014, ASRT037, and ASSA035. ▪ If user removes a review sleeve while system is reading a cassette and does not replace it, the system may drop a cassette into review sleeve location. ▪ If a donor sample is loaded after the corresponding crossmatch order has started running, tests for the donor sample might not be run, indicated by instrument error CCIN002. ▪ Inconsistent results for a crossmatch may occur if well result was positive but an STRV occurred, and results of re-running the test are negative.
	1-29	▪ If user requests a test before 37C incubator has heated to correct temperature, the test will not be scheduled or performed. ▪ System displays only two of possible "cassette save reasons."

Revision to Chapter/section	Page	Description
Chapter 1: Warnings and Cautions	1-32	▪ Performing a backup while the system is processing will delay results.
	1-33	▪ User should not adjust system clock while processing is underway.
Chapter 2: Main Cover	2-13	▪ Added description of Reagent Rack barcodes.
Chapter 2: Dilution Plates	2-14	▪ Added polypropylene as acceptable material for dilution plates.
	2-15	▪ Added Greiner 96-well polypropylene plate to approved deep-well dilution plates.
Chapter 2: Cassette Drawer	2-18	▪ Added recommendation to not mix cassette types or different lots in the same cassette sleeve.
Chapter 2: Waste Door	2-19	▪ Updated to 225 the threshold number of discarded cassettes resulting in prompt to empty trashcan. ▪ Corrected description of instrument behavior when trashcan is full.
Chapter 6: Load Reagents on Reagent Rack	6-8	▪ Added statement that tests conducted with verified in-date reagents are considered valid.
Chapter 6: Load Dilution Plates	6-13	▪ Deep-well dilution plate is required only if testing calls for 0.8% patient or donor red blood cell dilution.
Chapter 6: Loading Cassettes	6-18	▪ Added statement that tests conducted with verified in-date cassettes are considered valid.
Chapter 6: Buttons and Fields Used to Register and Load Samples/Controls	6-26	▪ Corrected description of Cassette Saving check box in Options field.
Chapter 6: Register and Load Samples and Controls	6-35, 6-36	▪ Added description of AlbaQ-Chek J and CQI 7/9. ▪ Added procedure for loading AlbaQ-Chek J and CQI 7/9 controls.
Chapter 7: View Results for Profiles and Tests	7-5	▪ Added note and graphic for Information window that displays when test results are at or below system thresholds.
	7-10	▪ Added Caution statement that to edit well results the cassette barcode must be scanned.
	7-13	▪ Corrected instructions for displaying Profile Detail and Test Detail screens.
Chapter 7: Edit Test Results and Well Grading Results	7-15	▪ Added note and graphic for Information window that displays when test results are at or below system thresholds.

Revision to Chapter/section	Page	Description
Chapter 7: Review Cassettes	7-18	▪ Deleted text: “or enter the ID manually and touch Validate. If you enter the ID manually, you will also need to enter the LOT ID” from step 3 in “To Review Cassettes” procedure.
	7-20	▪ Added note and graphic for Information window that displays when test results are at or below system thresholds.
Chapter 8: Empty Waste Cassettes from the Waste Container	8-9	▪ Changed threshold for waste container error to 225 cassettes.
Chapter 8: Empty Liquid Waste	8-15	▪ Changed “Confirm that the instrument is powered off” to “Confirm that no test routine is running.”
Chapter 8: Weekly Maintenance Procedure	8-25	▪ Corrected description of Fluidic Circuit Decontamination.
	8-26	▪ Corrected Instrument Cleaning instruction.
Chapter 8: QC Volume Procedure	8-37	▪ Added “or tip tubing” to bullets describing conditions calling for QC volume procedure. ▪ Changed amount of saline required for QC Volume procedure from 1 L to 2 L.
	8-47	▪ Added cross reference to Performance Criteria.
Chapter 9: Daily Backup, Weekly Archive Backup, DVD Requirements	9-3 to 9-6	▪ Updated procedure for daily and weekly backups. ▪ Added note that performing backups may slow test processing.
Chapter 10: Trash Container and Waste Lift Errors	10-18	▪ Added procedure for handling Trashcan is Full error.
	10-19	▪ Added procedure for handling Cassette Waste Lift error.
Chapter 11: Set Preferences in the Results Tab	11-27	▪ Corrected table in Set Miscellaneous Results Preferences: Differentiation Patient/CQI to reflect auto-recognition activation/deactivation. ▪ Added Differentiation Patient/AlbaQ-Chek J to table.
	11-30	▪ Corrected note to read that antigen typing threshold can be changed to values greater than 2+.
Appendix A: Table A-1: Software Error Codes	A-7	▪ Added errors 223 and 224 referring to AlbaQ-Chek J.
Appendix A: Table A-3: Asynchronous Error Codes	A-17	▪ Added “ASTC013 Trash Container is Full.”
Appendix C: Software Versions	C-1	▪ Updated to software version 1.04.
Appendix D: Anti-Virus Software	D-1 to D-3	▪ Added new appendix to describe use and validation of anti-virus software.
Index	All	▪ Updated for current release.

January 29, 2007, Software Version 1.03

Revision to Chapter/section	Page	Description
Cover page, inside cover, document footer	All	▪ Updated document version, date, and copyright date.
Table of Contents	All	▪ Updated for current release.
Book	All	Generic references to AutoVue were changed to the following: ▪ ORTHO AutoVue *Innova/Ultra*
Chapter 1: Graphic Symbols Used in this Guide and for Labeling	1-6	▪ Added graphics of labels required in the European Union to identify electrical and electronic equipment requiring separate disposal or recycling at the end of the product's life cycle.
Chapter 1: Reagent Types	1-15	▪ Updated trademark information.
Chapter 1: Reagent, Sample, and Cassette Handling	1-16	▪ Added the AutoVue's ability to reprocess partially used cassettes.
Chapter 1: Dilution Plates	1-17	▪ Added a note that dilution plates should be replaced daily. ▪ Corrected the last sentence of the second bullet to read ".....in the deep-well dilution plate".
Chapter 1: PC, Uninterruptible Power Supply, and Printer sections	1-18	▪ Added a note that the PC should be rebooted daily. ▪ Grammatical update. ▪ Updated printer description to describe the capabilities of the new printer.
Chapter 1: Supported Bar Code Types	1-20	▪ Updated bullet for clarification. ▪ Added a note that the software enables you to use all alphabetic characters in the barcode configurations.
Chapter 1: Serological Timing Restrictions	1-23	▪ Updated table to reflect new content for Minor XM tests.
Chapter 1: Instrument and Software Limitations	1-27	▪ Added a bullet explaining that when a profile is deleted in Setup, you cannot search archived results. ▪ "Interpretation" and "Result" are used interchangeably within the manual.
Chapter 1: Instrument and Software Limitations	1-28	▪ Added procedures to follow if a test is not proceeding as expected. Check to see if reagents are expired and ensure that all doors on the system are closed.
Chapter 1: Instrument and Software Limitations	1-32	▪ Clarified restrictions regarding the use of reagent red cells with the AutoVue. Reagent red cells can be used on the AutoVue for a maximum of 24 hours, in three eight-hour shifts with refrigeration overnight in between shifts. ▪ All instrument doors must be closed during testing.

Revision to Chapter/section	Page	Description
Chapter 2: Section A: Accessing the Instrument	2-3	▪ Updated graphic
Chapter 2: Sample Rotor and Racks	2-5	▪ Updated graphic
Chapter 2: Main Cover	2-6	▪ Updated graphic
Chapter 2: Main Cover	2-7	▪ Added a note indicating that following the wash operation, a small amount of fluid will be released into the wash station. This is normal operation to clear the probe of all fluid.
Chapter 2: Main Cover/Key Instruments	2-10	▪ If you try to change a puncher or delete a profile and there are results still associated with those settings, you won't be able to change/delete anything until the results have gone into the long-term archive.
Chapter 2: Reagent Rotor	2-13	▪ Updated graphic
Chapter 2: Dilution plates	2-14	▪ Added information regarding dilution plate use and restrictions. ▪ Deep Well Dilution Plates: Corrected the last sentence of the second bullet to read ".....in the deep-well dilution plate".
Chapter 2:	2-16 and 2-17	▪ Updated graphics
Chapter 2: Waste Door	2-19	▪ The system automatically resumes sample processing after you open and close the Waste Door.
Chapter 3: Section D: Software Screens	3-7	▪ If the routine does not begin as expected, open and close the Access Door. The system will be able to perform a complete routine only when all doors are closed.
Chapter 4: Tasks Involved in Running Test Routines	4-5	▪ Indicated that all doors must be closed for the system to run properly.
Chapter 6: Load Reagents on Reagent Rack	6-8	▪ Clarified restrictions regarding the use of reagent red cells with the AutoVue. Reagent red cells can be used on the AutoVue for a maximum of 24 hours, in three eight-hour shifts with refrigeration overnight in between shifts.
Chapter 6: Load Reagent Vials	6-9 and 6-10	▪ Updated graphic
Chapter 6: Load Routine Cassette Sleeves	6-18	▪ The system optimizes the use of cassettes in the Drawer. The cassette sleeve closest to expiration is used first, followed by the sleeve that has the fewest number of remaining cassettes.
Chapter 6: Registering Samples	6-21	▪ Added note: If a user is not logged in and the LIS auto-transfer feature is activated, test results uploaded to the LIS will be associated with the last user logged onto the system.

Revision to Chapter/section	Page	Description
Chapter 6: View the Samples on the Sample Rotor	6-25	▪ Moved note from other location in book to point of need: The STAT sample rack position numbers displayed in the software correspond with the position numbers on the instrument STAT Sample rack.
Chapter 6: Select Options	6-26	▪ Added note indicating that unbarcoded tubes can be used for 2-tube samples as well as the donor associated with a crossmatch test. Provided additional information for unbarcoded tubes.
Chapter 7: Overview	7-2	▪ Added Review Cassettes and Review Orders. ▪ Updated Topic References
Chapter 7: Section A: The Worklist	7-5	▪ Added Review Cassettes and Review Orders. ▪ Added information below the graphic indicating that two data display options can be selected using the Worklist and Completed check boxes.
Chapter 7: View the Worklist/ View the Completed list	7-6	▪ Moved content from front of chapter to make the chapter structure consistent with the rest of the book.
Chapter 7: Sort Data	7-8	▪ Added instruction to touch the column once to switch between ascending and descending order. ▪ Added information regarding how to handle truncated Search results.
Chapter 7: Edit Well Gradings and Test Results	7-9	▪ Added table representing polyspecific/enzyme results and the cumulative results sent to the LIS.
Chapter 7: Edit Test Results	7-11	▪ Added Review Orders information to the Edit Overall Results and/or Well Grading Results procedure.
Chapter 7: Review Cassettes	7-16 to 7-17	▪ Added procedure for reviewing cassettes.
Chapter 7: Section B: The Completed List	7-18	▪ Added note regarding expedited profile ordering.
Chapter 7: Section D: Reports	7-21	▪ Add note indicating that for all tests that require more than two cassettes, the system displays and prints results for all cassettes used.
Chapter 7: Sample Report	7-23	▪ Added additional information to the results provided on the Sample report.
Chapter 8: Use the Maintenance Wizards	8-6	▪ You must touch **Continue** before you can open the Main Cover to remove the NaOH vial.
Chapter 8: AutoReader QC Procedure	8-27	▪ Wait 30 minutes after the system has initialized to start the QC AutoReader procedure.
Chapter 8: QC Volume Procedure	8-37	▪ Updated list of Prerequisites
Chapter 8: Section E: As-Required Maintenance Procedures	8-48	▪ Added bullet for daylight savings time adjustments.

Revision to Chapter/section	Page	Description
Chapter 8: Daylight Savings Time Adjustments	8-51 to 8-52	▪ Added section with instructions on the appropriate methods for modifying the system for daylight savings time adjustments.
Chapter 9: Section A: Backup Media Required	9-3	▪ Corrected case-sensitive naming conventions for DVD formatting.
Chapter 11: Setting Up System Preferences and User Information	11-8 to 11-92	▪ Made modifications to steps 2 and 5 to clarify the procedure.
Chapter 11: Specify Operator Information in the Privileges Tab	11-10	▪ Moved information regarding setup privileges and recommendations regarding passwords and IDs from Chapter 1 to point of need in the document.
Chapter 11: Set Preferences in the Results Tab	11-26 to 11-27	▪ Added new preferences to selection table: user can accept own modification, Phenotype worklist display, Differential Patient CQI, Review Cassettes, Review Orders, ABD Repipet
Chapter 11: Set and Modify Threshold Values for Results	11-30	▪ Modified the maximum threshold for positive results: increased from 3 to 4.
Appendix A: Software Error Codes table	A-7	▪ Added Error Codes 214-222.
Appendix A: Asynchronous Error Codes table	A-12	▪ Added additional information to Serological Timing Restriction Violation (Error ASCS046)
Appendix B: Antibody Screening and Crossmatch table	B-32	▪ Added information to Crossmatch - Minor.
Index	All	▪ Updated for this release.

January 29, 2007, Software Version 1.03

Date	Section	Description
2004-09-23	All	Initial release

This page intentionally left blank.

Appendix F: Release Notes

Use this section to retain copies of ORTHO AutoVue *Innova/Ultra*-related release notes.

This page intentionally left blank.

Index

Numerics

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

Ortho Clinical Diagnostics
a Johnson & Johnson company

CE IVD

EC REP

Ortho-Clinical Diagnostics, Inc.
Johnson & Johnson
50 - 100 Holmers Farm Way
High Wycombe
Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869 USA