VENTANA HE 600 System
Operator Manual

Ventana Medical Systems, Inc.

www.roche.com

www.ventana.com

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IVD

CE

VENTANA HE 600 System Operator Manual

The VENTANA HE 600 system software is protected by contract law, copyright laws, and international treaties.

The VENTANA HE 600 system software is licensed for use between Ventana Medical Systems, Inc. and a licensee, and only users authorized there under are permitted to access and use the software. Unauthorized use and distribution may result in civil and criminal penalties.

Open Source and Commercial Software

Portions of the VENTANA HE 600 system software might include one or more Open Source or Commercial Software programs. For copyright and other notices and licensing information regarding such software programs included with VENTANA HE 600 system software see *Open Source License Notifications and Licenses on page 102* and the product online help pages included with the product.

The product and the VENTANA HE 600 system software as a whole may form a regulated device in accordance with the applicable laws – refer to this Operator Manual and the labeling for details. Please note that the respective authorization in accordance with the applicable laws lapse in case of any unauthorized changes to the VENTANA HE 600 system software.

Warranty

Any customer modification to the system will render the warranty or service agreement null and void. For conditions of warranty, please contact your local sales representative or refer to your warranty contract partner. Software updates must be performed by or with the assistance of a Roche Service Representative.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES. VENTANA DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ALL WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Revision History

Guide Revision	Revision Date	Changes
B	September 2015	First manual
C	May 2016	Updated software version
		Updated protocol selection
		Updated Maintenance and Troubleshooting chapter
		Updated warranty
		Added operator language to footers
D	November 2016	Updated Intended Use Statement
		Added System Setting Sleep
		Added System Settings Alerts
		Updated Maintenance and Troubleshooting chapter

Contact

Ventana Medical Systems, Inc.
a Member of the Roche Group
1910 E. Innovation Park Drive
Tucson, Arizona 85755
USA

+1 520 887-2155
+1 800 227-2155 (USA)

 www.ventana.com

Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany

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Preface

Welcome

The VENTANA HE 600 system is an *in vitro* diagnostic (IVD) automated hematoxylin and eosin (H&E) staining system. It integrates ovens, stainers, and reagents with a computer and touchscreen to automate processing of H&E slides from drying to glass coverslipping. The touchscreen monitor allows the operator to monitor reagent use and daily workflow.

1. Compliance and Safety

Compliance with Regulatory Standards

The VENTANA HE 600 system is manufactured and certified per the following applicable international standards.

EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements.
IEC 61010-2-010	Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 2-010: Particular requirements for laboratory equipment for the heating of materials.
IEC 61010-2-081	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.
EN 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
EN 61326-1	Electrical equipment for measurement, control and laboratory use—EMC requirements - Part 1: General requirements.
EN 61326-2-6	Electrical equipment for measurement, control, and laboratory use - EMC requirements – Part 2-6: Particular requirements - *in vitro* diagnostic (IVD) medical equipment.
EN ISO 18113-1:2011	In vitro diagnostics medical devices - Information supplied by the manufacturer (labeling) - Part I: Terms, definitions, and general requirements.
EN ISO 18113-1:2011	In vitro diagnostics medical devices - Information supplied by the manufacturer (labeling) - Part II: In vitro diagnostic reagent for professional use.
EN ISO 18113-1:2011	In vitro diagnostics medical devices - Information supplied by the manufacturer (labeling) - Part III: In vitro diagnostic instruments for professional use.

Regulatory compliance is demonstrated by the following marks:

CE Complies with the European Union Directive 98/79/EC.

C SA US Issued by CSA.

Intended Use

The VENTANA HE 600 system is a platform consisting of an instrument, software, and reagents, used for hematoxylin and eosin staining of histologic sections from formalin-fixed, paraffin-embedded tissues. The system's intended use environment includes anatomic pathology (AP) laboratories and histology facilities located within hospital, clinic, reference, or private lab settings. The platform is to be operated by qualified users in the AP laboratory who are trained on the VENTANA HE 600 system.

FCC Information

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the Federal Communications Commission (FCC) rules. These limits are designed to provide reasonable protection against interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy; if not installed and used in accordance with the operator manual, it may cause interference to radio communications. Operation of this equipment in a residential area is likely to cause interference, in which case users will be required to correct the interference at their own expense. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a different circuit from the one the receiver is connected to.
- Consult the dealer or an experienced radio/TV technician for help.

CAUTION: Changes or modifications not expressly approved by the party responsible for compliance with Part 15 of the FCC rules could void the user's authority to operate the equipment.

Canadian DOC Information

This digital apparatus does not exceed the Class A limits for radio noise emissions from digital apparatuses as set out in the Radio Frequency Regulations of the Department of Communications (DOC).

Safety

All safety-related regulations, local codes, and instructions that appear in the operator manual or on equipment must be observed to ensure personal safety and to prevent damage to the system or equipment connected to it. If equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment could be impaired.

Safety Symbols

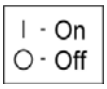
The following symbols and formats are used to alert to a potential hazard. On the system itself, only the **General Caution** symbol (with exclamation mark), the **Hot Surface Caution** (behind the waste compartment door on the system left front), and the **Disconnect Power Symbol** (at the back of the system next to the power cord) are visible. The other symbol stickers are on the inside of the system, and not visible to the operator.

CAUTION: REFER TO ACCOMPANYING DOCUMENTS
Consult accompanying document for proper use of this device.

CAUTION: If the power cord needs to be replaced, it must be replaced with a Roche-approved cord rated for 30 amps.

CAUTION: This symbol is a caution for the Roche Service Representative, who might encounter hot surfaces upon removing this panel. No one but a Service Representative should remove the nearby air filter, nor insert a hand or finger into the instrument at this location. A hot surface is present behind the heat exchanger (accessible when the filter is removed).

CAUTION: DISCONNECT POWER BEFORE SERVICING



ON AND OFF SYMBOL ON POWER SWITCH

Biological and Chemical Hazards

When working with any reagent or reagent container, take appropriate precaution. Reagents are not formulated with biological content, nor do they promote or support biological growth. However, there is some possibility that the user environment may inadvertently introduce biological material to the system, which may then appear as waste.

The reagent SDS should be consulted to ensure operators are aware of the content, in order to manage the reagents in accordance with any national, state, or local regulations.

There are chemical hazards that could result in minor hazards such as skin sensitivity or eye irritation. It is for these reasons that the use of suitable PPE is recommended when handling the system reagents or waste containers.

Reagent may collect around the container lid during transit and storage and be released when the reagent lid is opened. Open containers carefully.

Because some reagents present a skin irritation, it is recommended that affected skin is washed after exposure to any reagent.

CAUTION: During system operation reagent drip traps may collect reagent. Thus, routine precaution should be observed.

CAUTION: When working with any reagent, reagent hat, or reagent container, take appropriate precautions.

CAUTION: Open reagent containers carefully.

CAUTION: Avoid unnecessary contact with reagents and reagent containers.

CAUTION: Always wear approved eye protection, gloves, and protective clothing when handling reagents, reagent containers, reagent hats, and slide trays.

CAUTION: If the system is supplied with the VENTANA HE 600 system waste capture option where emptying waste containers is periodically necessary, always wear approved eye protection, gloves, and protective clothing when changing the waste containers.

CAUTION: If the system's waste is direct-to-drain, the direct-to-drain system should be installed by a Roche Service Representative. Roche should then be consulted for any adjustments necessary after the initial installation.

Cleaning and Maintenance

Contact Roche Service with questions regarding the compatibility of cleaning agents with the system.

Spills

Clean spills with an absorbent material in combination with a mild detergent.

Hematoxylin and eosin stains can be removed with a 10% solution of chloride bleach.

CAUTION: If spills of the Coverslip Activator occur, ensure there are no open flames in the vicinity.

CAUTION: Wipe up spills immediately to avoid slipping.

CAUTION: Place mats around the system to avoid risk of slipping in the event of reagent spills or leaks.

CAUTION: Place caps on waste containers before removing them from the system.

System Location

The system is very heavy and is not designed to be moved by the operator. Contact an approved Roche Service Representative if the system needs to be relocated. This system is for indoor use only.

CAUTION: The system should be moved only by approved Roche Service Representatives.

CAUTION: The system uses fans at the rear and top-right side to ensure it operates at the optimum internal temperature. Take care not to impede the airflow from these fans. Never store items on top of the system, which could block the fan outlet.

Safety Training

All operators must be trained in the safe use of the VENTANA HE 600 system. After training, operators must demonstrate understanding of the following:

- The system must be connected to a grounded outlet.
- The system must be connected to a voltage source that complies with the rating label.
- Using the system in a manner not specified by Roche may impair protection provided by the equipment.
- Operators must keep their hands clear of potential pinch points.
- Operators must consult the Safety Data Sheets for instructions on safe handling and disposal of reagents used with the system.
- In the rare event the system suffers a major malfunction and the interior must be accessed to manually recover trays, operators must turn off power to the system via the power switch, located on the left side panel of the system.

Electrical Hazards

Dangerous voltages are present inside the system. Only approved Roche Service Representatives should remove system covers or access internal system components unless the operator needs to manually recover trays.

If the operator needs to manually recover trays, read *Troubleshooting on page 68*.

The system's operating voltage is set during installation and can be changed only by an approved Roche Service Representative.

CAUTION: In the unusual circumstance that the system supply voltage is to change, contact a Roche Service Center for recommendations on a suitable transformer setup for the system. Severe damage may occur to the system if it is connected to an incorrect power supply voltage.

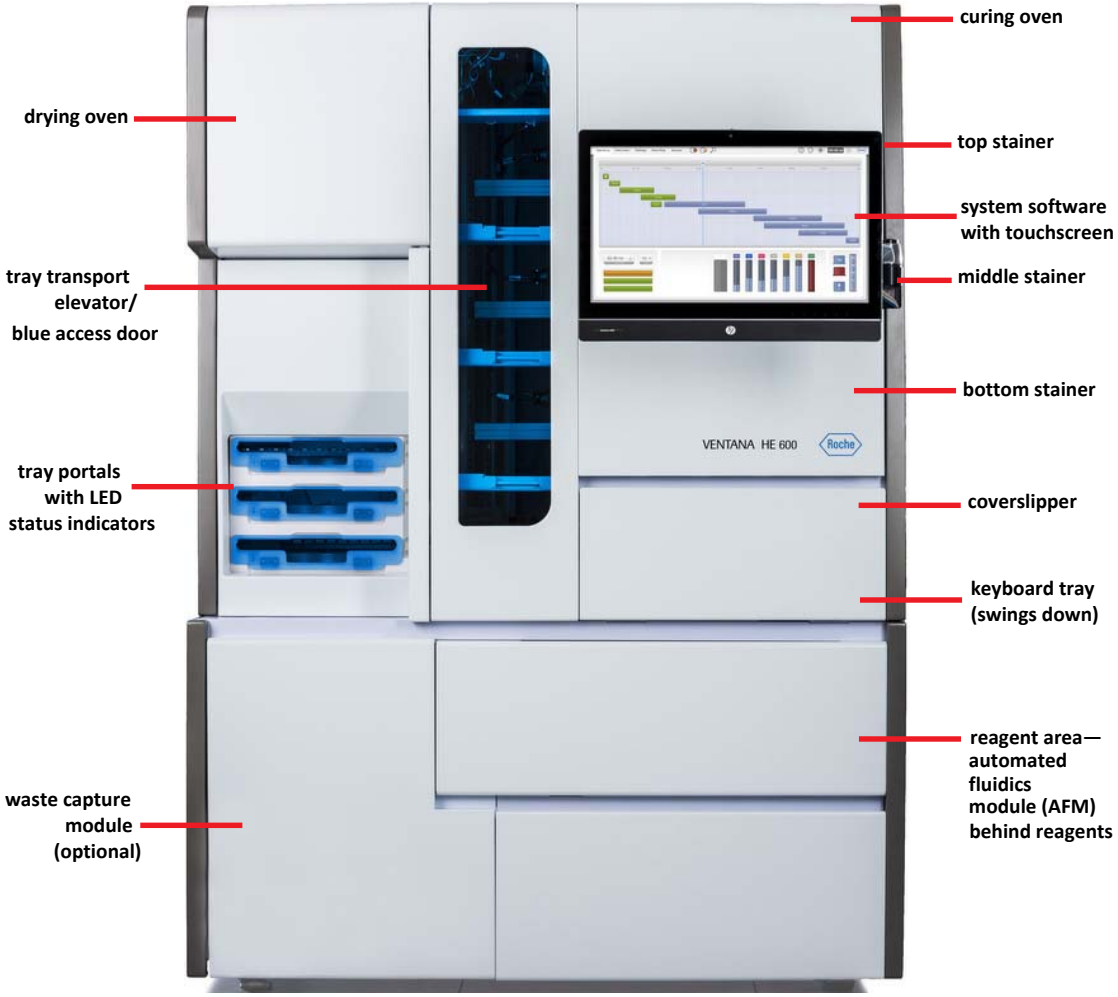
CAUTION: Observe good electrical safety practices.

WARNING: If the VENTANA HE 600 system blue access door or the garage access door is opened, the system will immediately stop the tray transport system, and advise to turn off power.

CAUTION: If the power cord needs to be replaced, it must be replaced with a Roche-approved cord rated for 30 amps.

2. System Overview

System



The system's upper frame is where trays and slides are processed. Located here is the tray portal and transportation system, the barcode reader for detecting the position and number of slides, a drying oven and a curing oven, three stainer modules, the coverslipper module, and the computer and touchscreen monitor.

The lower frame is the automated fluidics module (AFM), including reagents, the waste reservoir, the compressor, and the vacuum blower. If the system is not configured as waste direct-to-drain, it will also have a waste module with removable waste containers.

Tray Portals

The tray portals on the VENTANA HE 600 system are the primary interface point for insertion and removal of trays loaded with patient specimens. The three tray portals have LEDs associated with each, which indicate available for use, busy, and tray completed status.

Solid green means the portal is ready to receive a tray. Amber indicates the portal is busy. A flashing green means a tray is completed and ready for pathology review.

Transportation System

The transportation system on the VENTANA HE 600 system is responsible for moving trays of patient specimens between modules. Forks are used under trays, with ball-and-socket connections, to hold trays during transportation upward and downward to and from all modules.

Barcode Reader/Slide Detect

The system detects slides on a tray via barcode or slide detect. Barcode slides can be tracked to ensure positive patient identification. The system can read many types of barcodes, however it has been optimized for use with the five most common: Interleaved 2 of 5, Code 128, Data matrix, PDF417, and QR code.

The barcode reader/slide detector is located on the upper left corner of the system.

Drying Oven

The drying oven ensures that slides are dry and that paraffinized tissue sections are adhered to slides.The oven employs three methods to do both: orientation (80° tilt to improve wicking), conduction, and convection. The drying oven temperature range is 72°C +/- 3°C.

Stainers

Three staining modules work together to perform the complete H&E staining process (deparaffinization, rehydration, staining, differentiation, dehydration, clearing, etc.) through either a progressive or regressive process.

Precise dispensing of reagents reduces overall system waste. A patented reagent dispensing and removal process uses an air knife and vacuum port to decrease times between fluid steps and reduce the need for wash steps. The system uses a proprietary, more environmentally sensitive, organic deparaffinization solution, eliminating the need for xylene, toluene, or other potentially harmful solvents.

Coverslipper

The system has one coverslipping module to cover slides with glass coverslips after the H&E staining process. Coverslip Activator is dispensed onto a slide, and then coverslips are applied.

Curing Oven

The curing oven is used to cure coverslip glue and evaporate residual fluid from the tray. This ensures slides are ready for immediate pathology review when removed from the system. The oven's temperature is 92°C +/- 3°C. After curing, the tray is moved to the portal.

Waste Capture Module

The VENTANA HE 600 system is designed either to send liquid waste directly down the drain or to capture waste in an on-board waste capture module. An on-board waste capture module is available for laboratories that choose to not dispose liquid down a drain. Use of the waste module is an after-market system option. Waste must be managed in accordance with all applicable national, state, and local regulations, including applicable municipal codes. The laboratory is responsible for determining the appropriate waste disposal option, and ensuring the waste disposal method complies with all local and municipal regulations, codes, and guidance.

Automated Fluidics Module (AFM)

The VENTANA HE 600 system houses one AFM that stores and delivers all system staining and cleaning reagents, provides an interface point for easy reagent exchange, and delivers pressurized air and vacuum to the system.

The AFM uses eight reagents necessary for staining tissue and cleaning reagent lines. Pumps are used to transfer each reagent from its bottle to reservoirs to stainers, providing continuous access to all reagents.

The system software provides the status of all consumables, including alerts when it is time to replace reagents or coverslips and when to empty consumables.

Software

The all-in-one PC, with VENTANA HE 600 system software and a touchscreen monitor, is mounted on the right side of the system, and can swing left and right and tilt back and forth to accommodate different operators. The PC uses the Microsoft Windows 10 operating system.

NOTE The VENTANA HE 600 system is compatible with Microsoft BitLocker and has been tested to ensure compliance. Customers may enable BitLocker on their VENTANAHE 600 system PC if wanted to do so. Customers should work with their local IT resources to enable BitLocker on their system.

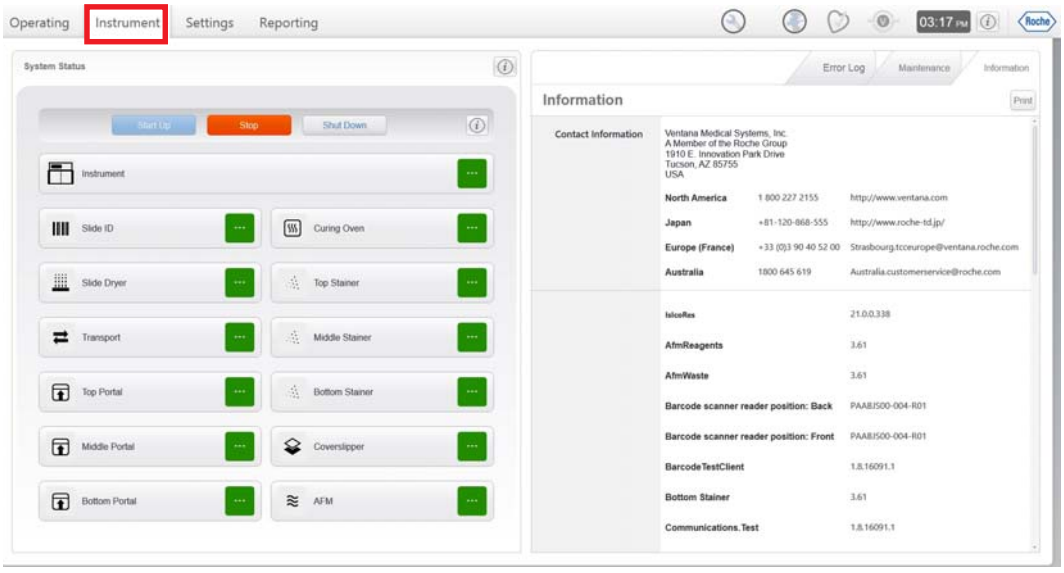
Within the software are four tabs that enable different ways to interact with or monitor the system:

Operating View

This is an overview of all trays currently in the system. Tap a tray icon to get more detailed status of a tray or slides on a tray. Also view the current status of consumables: reagents, coverslip cassettes, coverslip cassette waste, and waste containers (if applicable). Each consumable corresponds to an icon. View the status at a glance, or tap an icon for additional information.

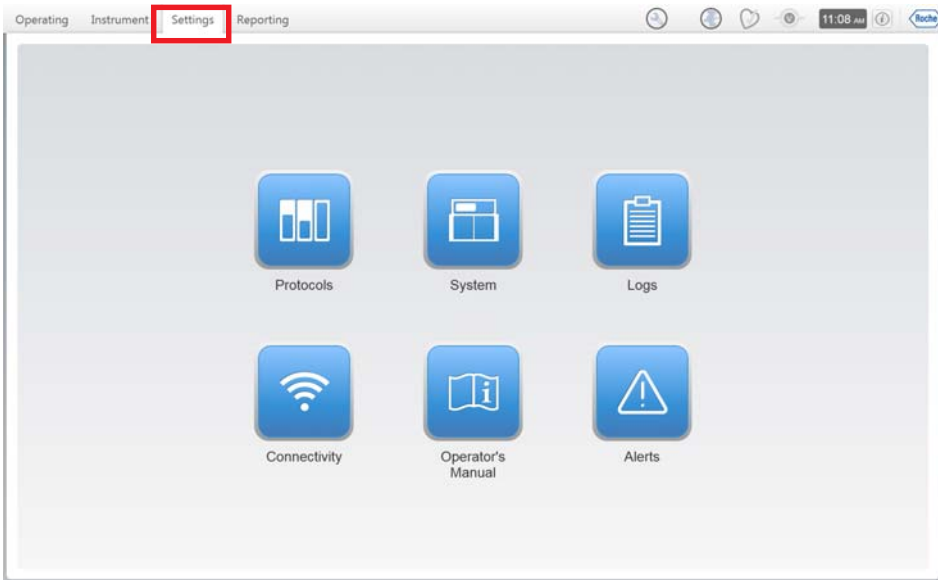
Instrument View

From the Instrument tab view, on the left pane, is an overview of the instrument status—slide scanner, slide dryer, transport system, portals, curing oven, stainers, coverslipper, and AFM. From the right pane, view error logs, instrument information, and a maintenance schedule.



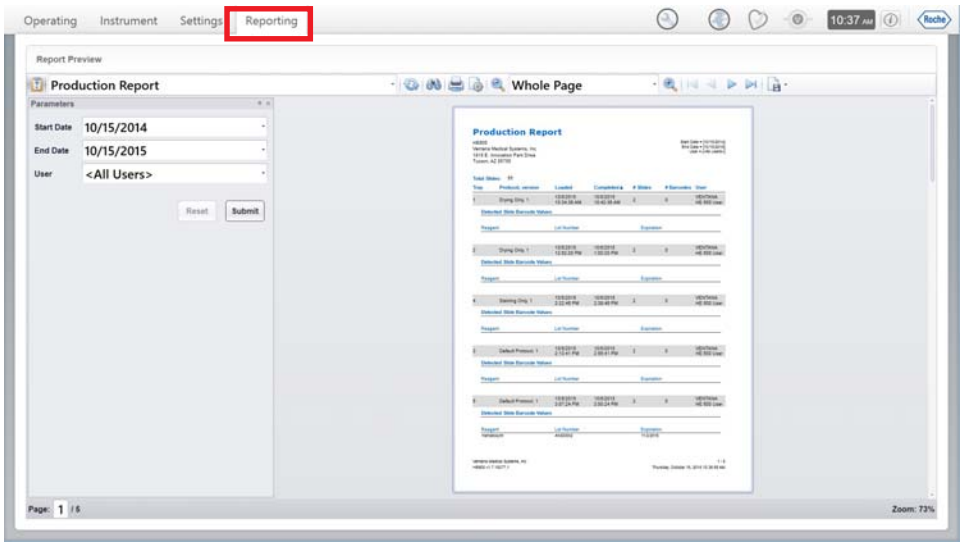
Settings View

From the Settings home page, tap Protocols, System, Logs, Connectivity, and Alerts to customize settings for each. Tap Operator Manual to open this manual from the touchscreen.



Reporting View

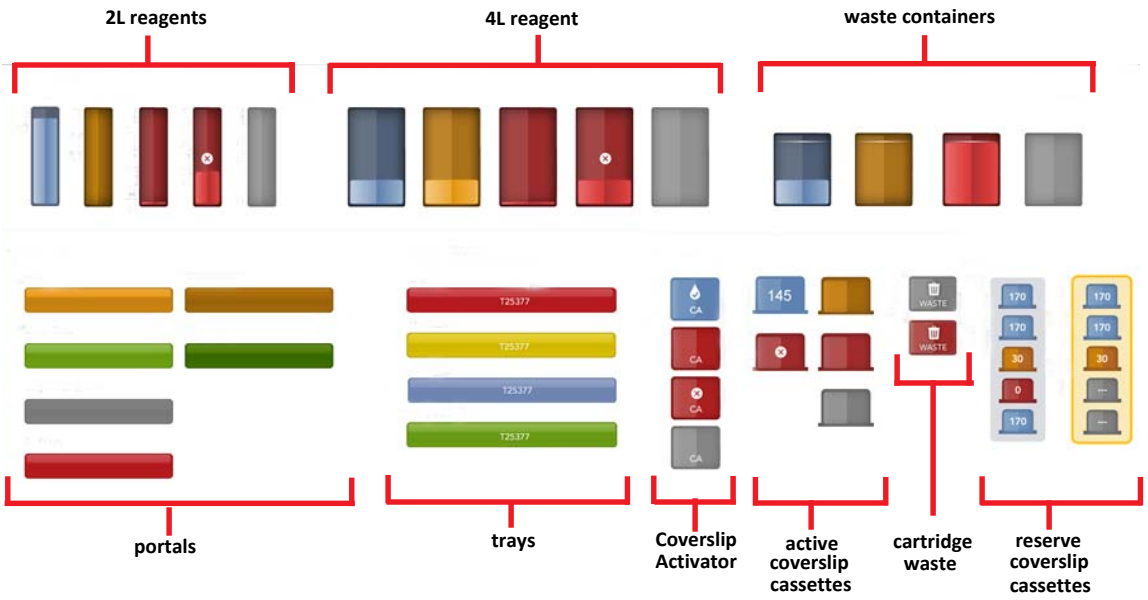
Go to the Reporting tab to view a choice of reports that can be generated and printed. Reports include Inventory, Operators, Preventive Maintenance, Production, and Protocols.



Software Color Key

The software uses consistent colors to communicate the same state of processing in trays, coverslips, and consumables.

- blue—tray is processing or consumable level is adequate.
- amber—tray is aborted, consumable level is low and can be refilled, or portal is busy.
- red—tray error or consumable is empty or, if accompanied by an **x**, expired.
- green—tray finished processing or portal is ready for a tray.
- grey—consumable not detected.
- yellow background surrounding cassettes—more cassettes needed.



VENTANA CAREGIVER Remote Support

The VENTANA HE 600 system offers integration with VENTANA CAREGIVER Remote Support, providing an interface between Roche Service Representatives and the VENTANA HE 600 customer computer, to help with technical services in real time. CAREGIVER Remote Support uses a web-based interface and toolset to remotely identify, understand, and repair performance problems with connected systems. The ability to remotely share screens and performance data, speeds the recovery process with connected Roche Tissue Diagnostics systems. Additionally, CAREGIVER Remote Support provides automated software downloads and proactive error messaging monitoring to drive laboratory efficiency.

NOTE The software is not intended for patient data assessment or diagnosis, therapy, or treatment decisions. CAREGIVER remote support does not collect or transmit any personal healthcare information (PHI).

NOTE Please contact a Roche Service Representative for details regarding connection and security.

VANTAGE Workflow Solution

The VENTANA HE 600 system offers integration with the VENTANA VANTAGE system. The VANTAGE system is a workflow solution that leverages Lean Six Sigma principles to improve sample identification, enhance sample tracking, integrate quality reporting, and use informatics for greater visibility into the histology workflow. The integration with the VENTANA VANTAGE system is designed to improve quality, patient safety and efficiency throughout the H&E and histology process.

Reagents

Below is an overview of each reagent. Use only Roche-supplied reagents.

Position	Reagent	Function	Design	Bottle Color	Label Color	Volume
1	Wash	Dispensed in between all other reagents for surface preparation and rinsing, washing, and differentiating	Surfactant in propylene glycol and water solution	clear	white	4L
2	Hematoxylin	Stains nuclear details	Proprietary formulation based on Gills hematoxylin	black	purple	2L
3	Bluing	Shifts the color of the hematoxylin stained features from red/purple to purple/blue	Tris base in propylene glycol and water solution (pH 8.0-9.0)	clear	blue	2L
4	Eosin	Stains cytoplasmic details (RBCs, smooth muscle, and collagen)	Eosin Y in propylene glycol, acid, and water solution (pH 3.65-4.25	black	pink	2L
5	Organic solution	Removes paraffin from tissue and prepares slide for coverslipping	Mixture of 2 aliphatic hydrocarbons (Linpar and Drakesol)	clear	gray	2L
6	Differentiating solution	Reduces hematoxylin intensity and mucin staining	Acetic acid in propylene glycol and water solution (pH2.9-3.1)	clear	yellow	2L
7	Transfer fluid	Used to transition back and forth from organic to aqueous states	Dipropylene glycol propyl ether (dPGPE)	clear	tan	2L
8	Cleaning solution	Used to clean hematoxylin lines and stainer manifold during daily maintenance	Diluted hydrochloric acid in propylene glycol and water solution	clear	green	2L
	Coverslip Activator	Dispensed during coverslipping to activate coverslip glue	limonene	brown	white	120 mL

Reagent Storage Requirements and Expiration Dates

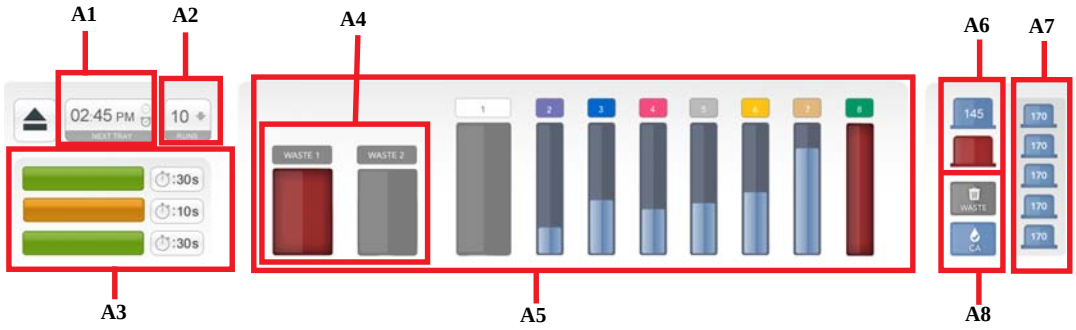
Position	Reagent	Storage Requirements	Expiration Date (From When Opened/ Registered)	Expiration Date (From When Manufactured/ Unopened)
1	VENTANA HE 600 Wash	15°C to 30°C	28 days	24 months
2	VENTANA HE 600 Hematoxylin	15°C to 30°C	28 days	12 months
3	VENTANA HE 600 Bluing	15°C to 30°C	28 days	24 months
4	VENTANA HE 600 Eosin	15°C to 30°C	28 days	24 months
5	VENTANA HE 600 Organic solution	15°C to 30°C	28 days	24 months
6	VENTANA HE 600 Differentiating solution	15°C to 30°C	28 days	24 months
7	VENTANA HE 600 Transfer fluid	15°C to 30°C	28 days	24 months
8	VENTANA HE 600 Cleaning solution	15°C to 30°C	28 days	24 months
	VENTANA HE 600 Coverslip Activator	15°C to 30°C	28 days	18 months
	VENTANA HE 600 Coverslips	15°C to 30°C	28 days	12 months

3. Daily Operation

This chapter contains information on performing everyday tasks on the VENTANA HE 600 system, including staining slides and maintaining consumables.

Verifying System Readiness

From the touchscreen, verify whether the system is ready for trays to be loaded. Tap each consumable or tray portal icon to get further details.



A1	Next tray—toggle between time of next tray and time remaining until next tray is finished.	A5	Consumable container level—colors and numbers reflect packaging.
A2	Trays in system—number of trays in the system.	A6	Active coverslip cassettes—count and status indicator. Red cassette indicates the cassette is empty. The system will automatically eject the cassette as long as the cassette waste is not full. When the red cassette is ejected, the blue cassette will move into the system.
A3	Portal monitor—replicates state of portal LEDs.	A7	Cassette conveyor—count indicator.
A4	Waste containers— these will not be visible on the screen if the system is using direct-to-drain waste disposal. Red and grey status indicator.	A8	Coverslip waste—grey status indicator. Coverslip Activator—blue status indicator.

Portal Status

LEDs at each portal indicate whether the portal is ready for use.

Solid green indicates a portal is available.

Flashing green indicates a portal contains a tray ready to be unloaded.

Solid amber indicates either a tray has been loaded successfully,

OR

the portal is about to receive a completed tray from the system,

OR

a tray is cooling in the portal.

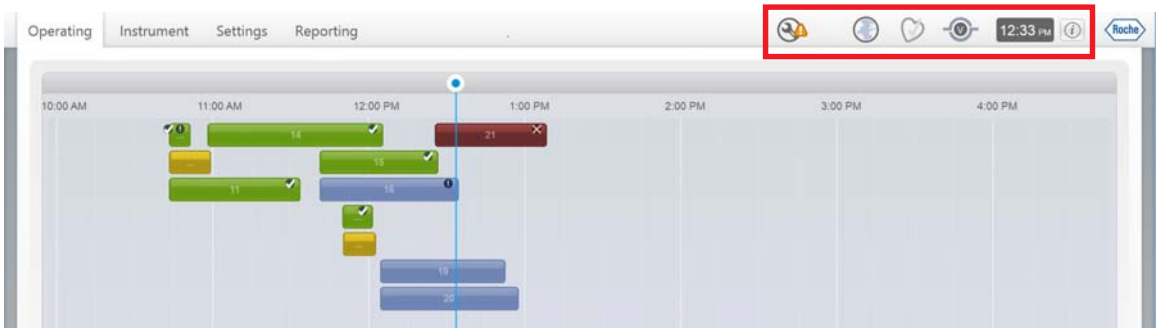
Flashing amber indicates a tray has been loaded backwards. An error message appears on the touchscreen.

LED OFF indicates a portal has been disabled, or the system is off.

Solid red indicates a portal error. Refer to the touchscreen for details.

Icons at the Top of the Touchscreen

Icons shown below are visible at the top of the touchscreen no matter what tab view is selected. See the icon key below the screenshot.



Maintenance icon—when an exclamation point shows within the orange triangle, tap the icon to view upcoming maintenance.

When an exclamation point shows within a red circle, tap the icon to view overdue maintenance.

Internet Connection icon—shows internet connectivity.

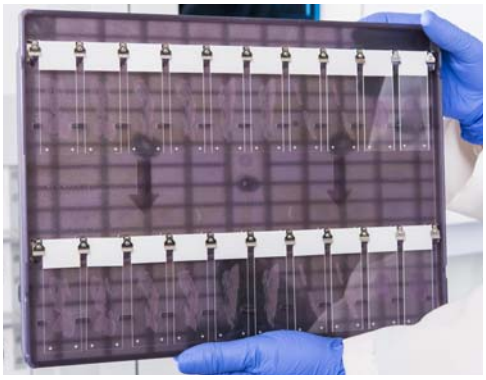
CAREGIVER Remote Support Connection icon—indicates status of CAREGIVER software connectivity, for use with Roche Remote Support.

VANTAGE Workflow Solution icon—indicates a connection with the (optional) VANTAGE Workflow Solution. VANTAGE monitors the entire workflow for the laboratory, including full tracking. Reports can be downloaded within VANTAGE.

01:10 PM Clock—Can be set to different time zones.

Information icon—Tap to view contact information, file version, and copyright information.

Working with Trays



The VENTANA HE 600 system automates slide-staining protocols by moving trays, populated with slides, through the system.

Trays are stackable, with or without loaded slides.

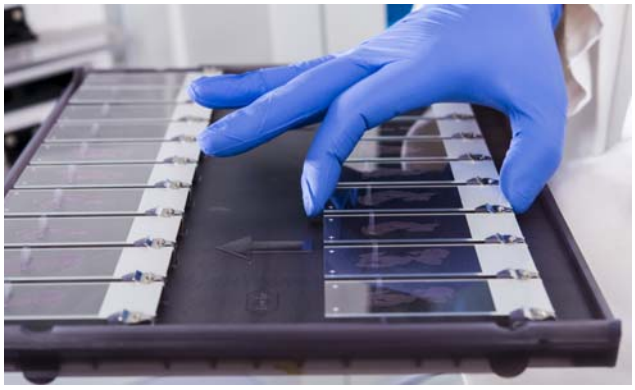
To insert a slide on a tray:

IMPORTANT The tray and its clips are designed to allow a minimum of force when inserting slides. The clips have rounded edges to prevent cut hazards. However, care should always be taken when inserting slides. Broken slides and excessive force could result in a minor cut. If a slide breaks, exercise care when retrieving broken pieces of glass from the tray. Safety gloves will aid in preventing cuts.

1. Choose any open position on the tray. Slide position has no given order.
2. Holding the slide at the top and bottom with the thumb and forefinger, insert the label end of the slide between the metal clips, and push forward until the slide is securely seated.

   TIP The position on the tray is not important, but the slide must be inserted in the correct orientation, with the label between the clips.
3. Visually inspect the slides on the tray to ensure they are vertically and horizontally level and aligned.

   IMPORTANT If slides are not aligned properly within the tray, improper staining and/or improper placement of the coverslip can occur.



To remove a slide from a tray:

- Holding the slide at the top and bottom with the thumb and forefinger, remove the slide from the clip.

Loading Trays into the Portal

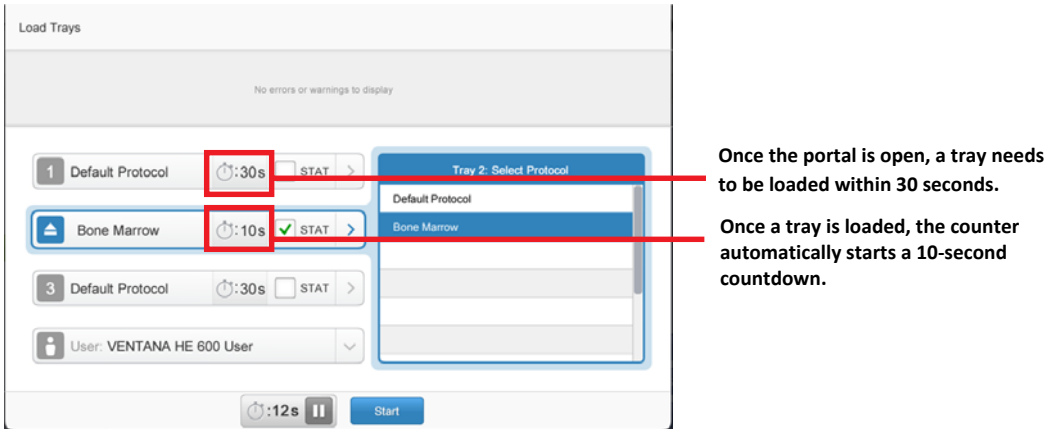
Trays can be processed only when loaded correctly—be sure the tray is not backward (if it happens, an error message will appear). Trays rest in the portal via a ball-and-groove kinematic coupling on the underside, and when seated properly, are detected via a detection cable.

IMPORTANT Portal doors should not be impeded in their operation. Do not insert hands, fingers, or foreign objects that might interfere with portal door opening or closing.

Tray directional arrow points toward system

1 Once an LED is green next to a portal, tap the Eject button on the touchscreen, and slide the tray into the open portal, with the tray directional arrow pointing toward the available portal.

Once the portal is open, a 30-second countdown begins in which time the tray needs to be placed in the portal. However, once a tray is loaded into the portal, the countdown is reset to 10 seconds. After the 10 seconds have expired, the tray(s) will be taken to the appropriate system modules for processing.



The portal door closes automatically. A solid amber bar confirms the tray is placed correctly .

2 To choose a protocol other than default, or to give the tray STAT status, tap Pause in the Load Trays dialog, and continue with *Selecting a Protocol*.

To run the default protocol without STAT status, do nothing further. The tray will begin processing after a countdown. The countdown timing can be adjusted, depending on lab needs.

Selecting a Protocol

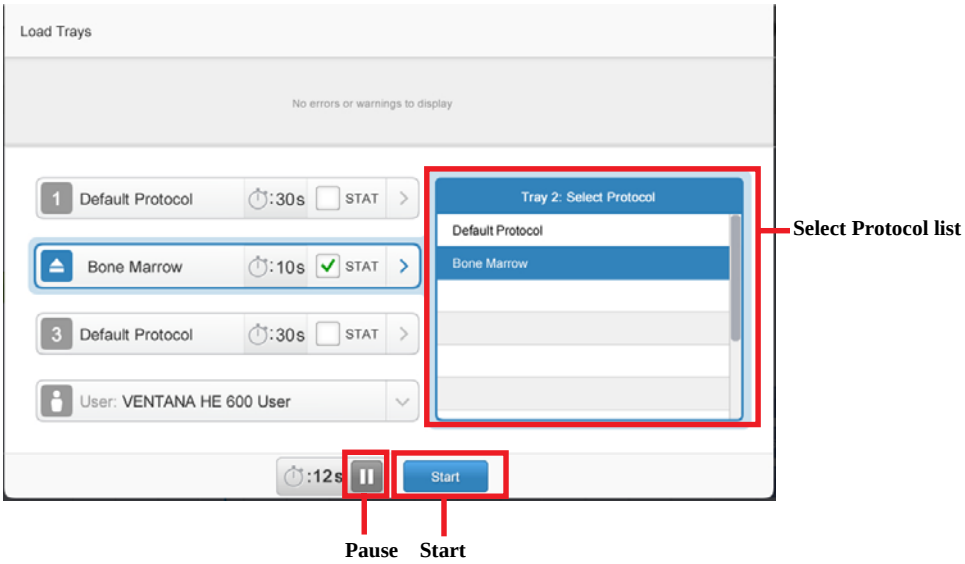
1 From the scroll-down list on the Select Protocol screen, select a protocol for the designated tray.

2 Tap Start, or let the counter count down to zero.

If AutoStart is selected, the tray begins processing the selected protocol.

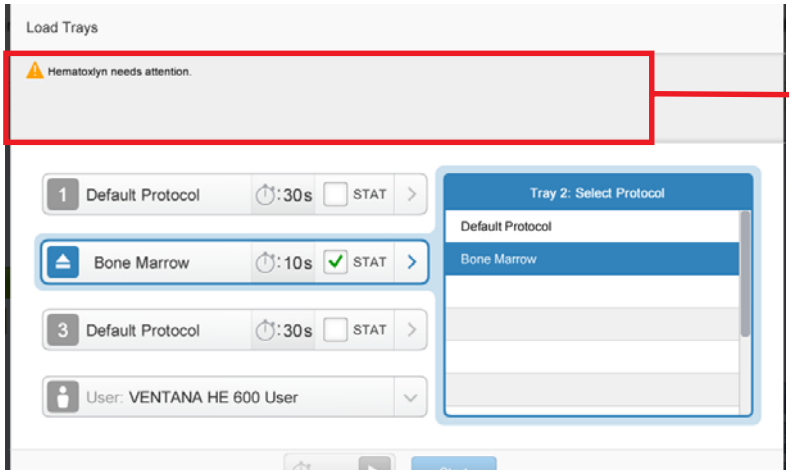
IMPORTANT If AutoStart is not selected, you must tap Start to begin processing trays.

NOTE: Tapping Pause will provide more time to select a protocol if the default protocol is not the correct protocol for the tray.



Error Messages

If a protocol is selected in the Load Trays dialog, but the system detects a problem with the protocol, it won't proceed until the error is addressed. For example, all reagents have to be loaded and have sufficient reagent for a tray to be accepted by the portal.

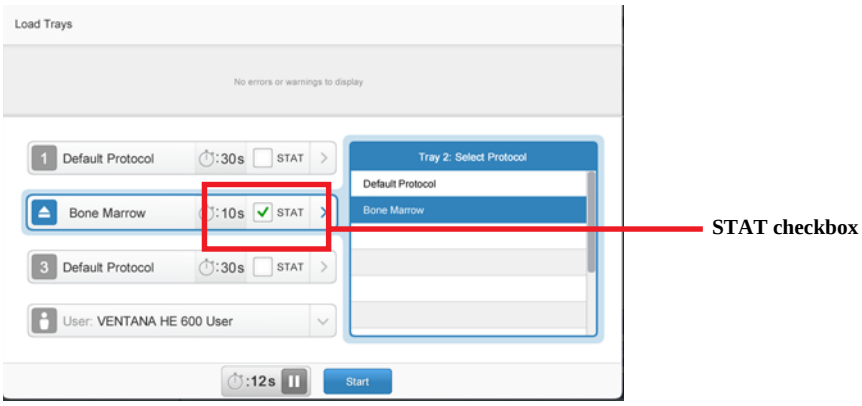


STAT Status

If a tray is designated as STAT, that tray has priority status in the system. The system will move a STAT tray ahead as long as no other tray's processing is compromised.

1. Load the tray into the portal.
2. (Optional) Tap Pause .
3. From the Load Trays dialog, tap the checkbox next to STAT in the protocol field.
4. Tap Start.

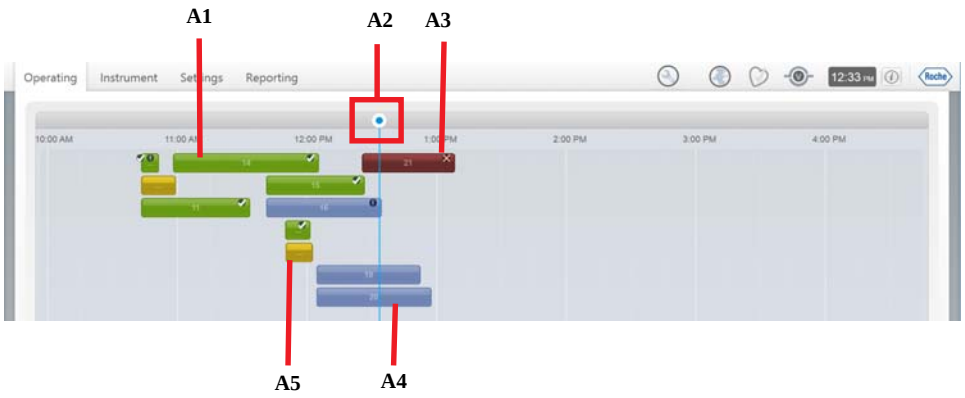
TIP If the STAT checkbox is tapped before the countdown ends, there is no need to tap Pause or Start. Tap the STAT checkbox, and the tray processing will automatically start after the countdown.



Monitoring a Tray in the System

From the touchscreen, view all trays currently in the system. Using the tip of your finger, drag horizontally back and forth to adjust the time of day the screen is showing. Eight hours of tray activity is visible at one time.

Tap a tray icon to get more detailed status. See *Tray Details*.

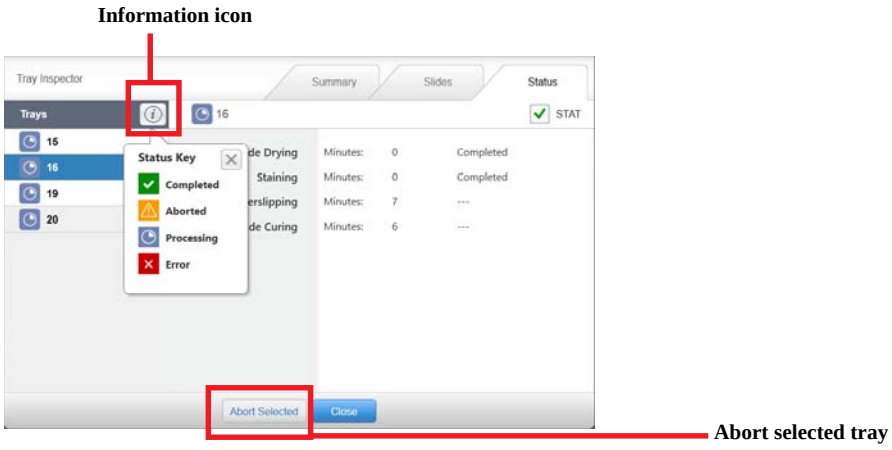


A1	**Green tray**—Tray complete. Tap tray icon to open the Tray Inspector for details.
A2	**Now handle**—Shows the current time of day.
A3	**Red tray**—Error with tray.
A4	**Blue tray**—Tray is processing. Tap tray span icon to open the Tray Inspector for details.
A5	**Amber tray**—Tray was aborted.

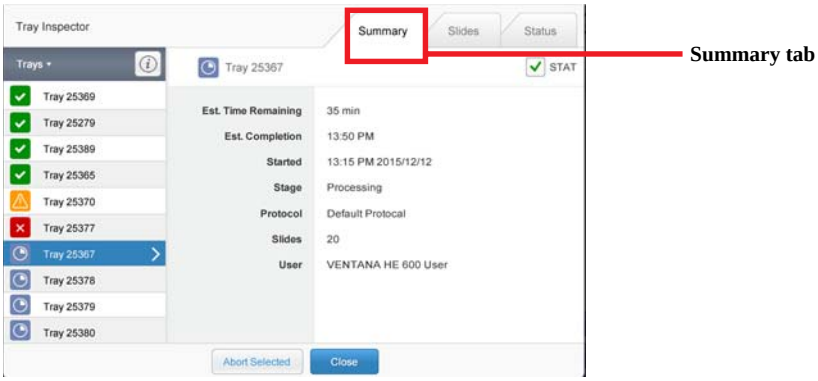
Tray Details

Tap any tray icon on the touchscreen, and the Tray Inspector dialog opens. Find details on each tray from three tabs—Summary, Slides, and Status. Trays can also be aborted from any of the three tab views.

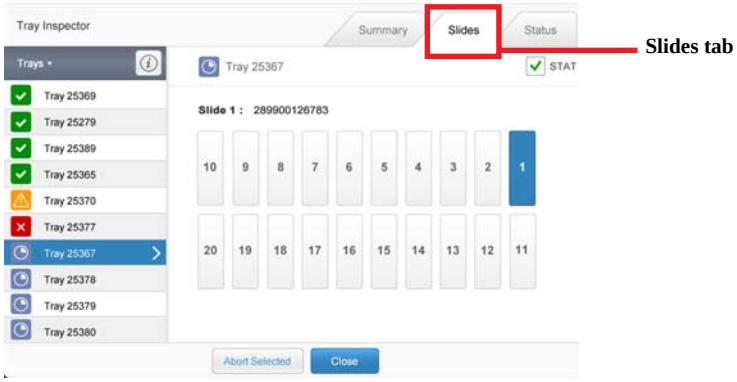
The icons in the left pane give a quick status of each tray. Tap the information icon for a status icon key.



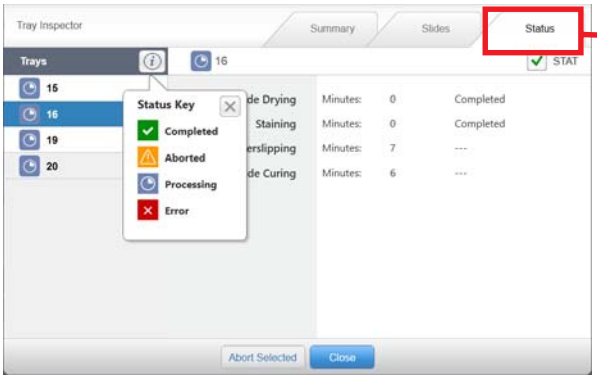
Tap the Summary tab to view details about the selected tray.



Tap the Slides tab to view details about the slides on the selected tray. If the slides on the tray have a barcode, the slide ID will be available for viewing on the View Details tab. If there is no barcode on the slides, the position of the slide will be read, but without the slide ID.



Tap the Status tab to view more details about the status of slides in the selected tray.



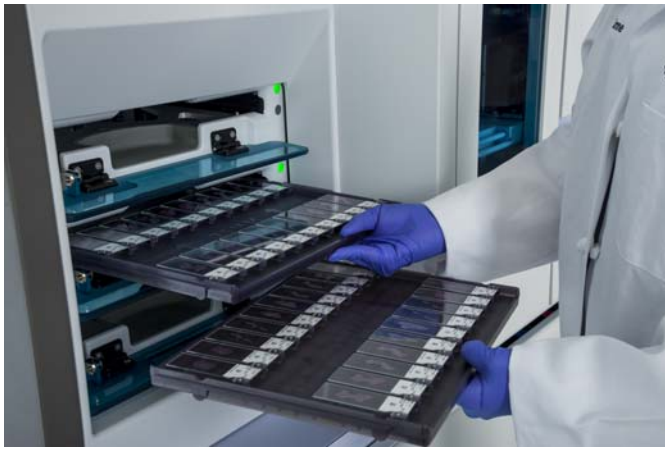
Unloading Trays

The green light flashes next to any portal that is ready to be unloaded.

- Tap the eject button, and remove the tray from the open portal.

Hot-Swapping Trays

When a tray is ready to be unloaded, a hot-swap saves time, if a new tray is ready to be loaded.



1. Have the tray ready to be loaded into the system in one hand.
2. Tap the Eject button on the touchscreen to open the portal.
3. When a portal opens, remove the processed tray from the portal with your other hand.
4. Immediately insert the unprocessed tray into the same portal.
5. Choose a protocol and tap Start, or if it is the default protocol, the tray will be automatically processed after the countdown.

Maintaining Consumables

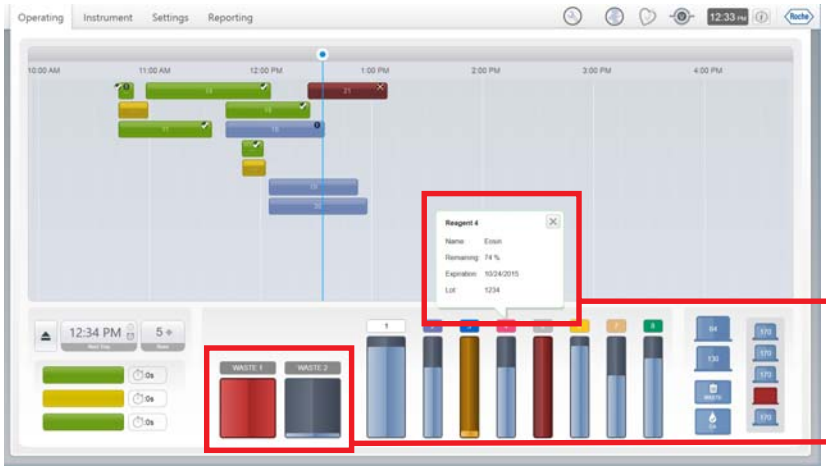
Some reagents used in the VENTANA HE 600 system are flammable and/or may be considered an irritant. Always follow good clinical practices when handling reagents.

When trays are run, a variety of consumables are required for the assigned protocols. Ensure that the VENTANA HE 600 system has adequate required consumables.

IMPORTANT The system does not need to be paused to replace consumables.

Viewing Consumable Status

On the touchscreen, view the current status of reagents and coverslip cassettes. Each VENTANA HE 600 system consumable corresponds to an icon. View the current status at a glance, or tap an icon to view a popup with additional information.



Tap a consumable icon to get further details. Tap the X at top right to close the popup.

If the system is using direct-to-drain waste disposal, these icons will not be visible.

Reagents

For most efficient reagent use, replace reagent containers only when their icons show red on the touchscreen.

Container is properly installed and has sufficient contents.

Container is properly installed and its contents are low—only 20% of reagent is left. Replace this container soon.

Container is properly installed but it is either empty (solid red) or its contents have expired (red with an **X**—the lighter red shows reagent left, but that reagent has expired). Replace immediately.

No container is currently installed for this reagent, or a reagent container is installed but its information tag cannot be read.

Replacing Reagent Containers

VENTANA HE 600 system reagent containers have a bottle-and-hat assembly. Remove the reusable hat from the empty reagent bottle and place it on the new bottle before installing it.

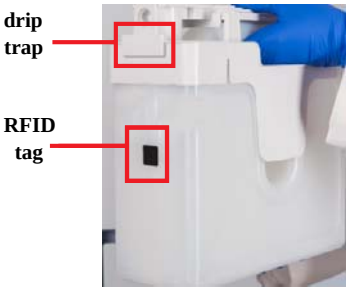
Do not unload a reagent container until its touchscreen icon turns red and is empty, which will prevent spilling.

The AFM uses pumps to transfer each reagent from its bottle to reservoirs to stainers, providing continuous access to all reagents.

Reagents are shipped and stored in disposable bottles with colored and numbered labels. Those labels match the color and number on the reagent hat assembly, and on its touchscreen icon.

Reagent bottle hats are also physically key coded, so that each hat won't fit properly in the system if in the wrong position.

In addition, each bottle has an RFID to ensure it is placed accurately.



CAUTION Do not carry a full reagent container by its hat alone. Hold the bottom of the reagent container as well as the top of the hat.

To remove a reagent container:

Have the replacement reagent bottle nearby and ready to install.

1 Open the reagent access door to access the reagent that will be replaced.

IMPORTANT The reagent door can also be used as a shelf to temporarily place reagent bottles on, to facilitate the reagent bottle change process. Do not overload the shelf; no more than 5 bottles should be placed on it at one time.

2 Press down on the locking tab on the reagent container hat with your index finger looped around the bottle handle, and pull it straight back from its mount on the system.

To disassemble a bottle-and-hat:

- Grasp the sides of the hat with one hand and squeeze the release bands until the bottle disengages. Pull the bottle off with your other hand if needed.

To assemble a bottle-and-hat:

1. Ensure the hat and the bottle are for the same reagent—colors and number identifications match.
2. Unscrew and remove the bottle cap on the new reagent bottle.

   TIP Use this cap to put on the empty reagent bottle, and discard or recycle.
3. Guide the hat tube into the replacement bottle mouth and press the hat down over the bottle until it snaps into place.

   TIP To avoid spills, keep assembled bottle-and-hat containers upright.

To install a reagent container:

1. Align the bottle-and-hat with its mount—slide the container into the automated fluidics module (AFM) until the locking tab engages.

   The touchscreen shows the reagent icon as blue—it is properly installed and levels are sufficient.
2. Close the door to the AFM.

Coverslip Cassettes

IMPORTANT Do not attempt to load a new coverslip cassette unless there is an open position.

Active—coverslip cassette is properly installed and in use by the system. (A new coverslip cassette holds 170 coverslips.)

Cassette is properly installed but it is either empty (solid red) or its contents have expired (red with an X). Replace immediately.

Cassette is properly installed and its contents are low (35 coverslips remaining).

No coverslip cassette is installed in this location, or it isn't being detected. Load a new cassette.

Coverslip Waste

IMPORTANT When a coverslip waste cassette icon turns red, no more empty coverslip cassettes can be moved to the cassette waste bin, because the cassette waste bin is full—immediately remove empty cassettes.

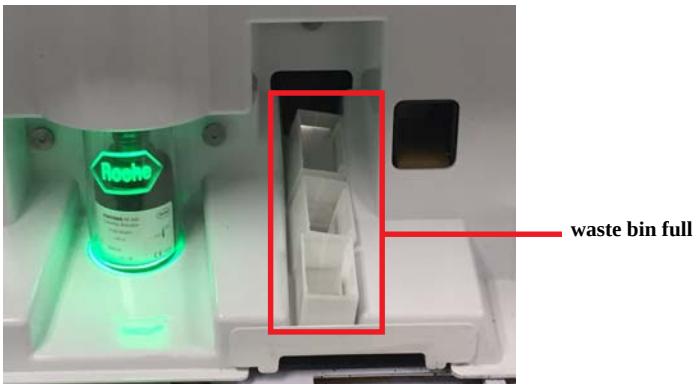
CAUTION: The coverslip waste may contain broken coverslips. Proceed with caution when disposing of coverslip waste to avoid minor cuts. Use safety gloves to aid in the prevention of cuts.

On the lower-right side of the touchscreen, view each coverslipper slide count currently on the conveyor.

When the cassettes are outlined in yellow, load cassettes immediately.

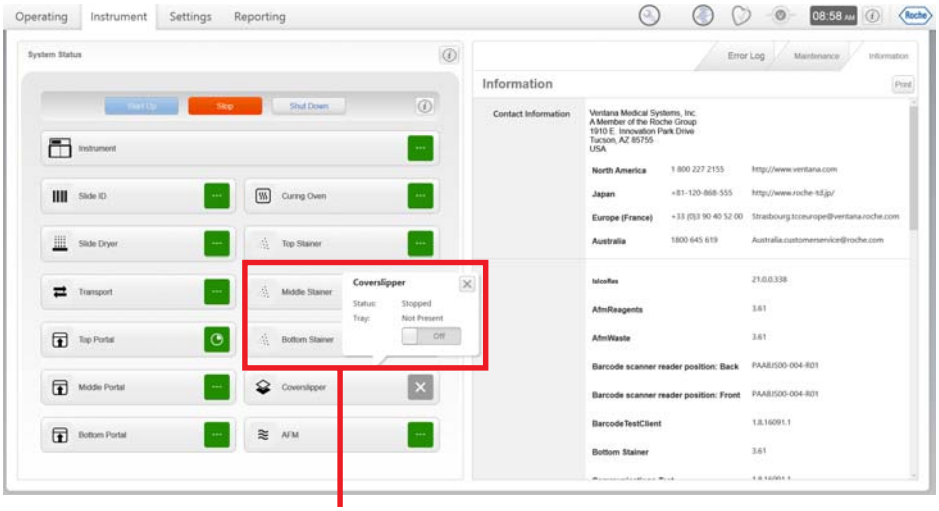
Coverslip Waste Logic

Once the cassette waste bin becomes full and the coverslipper finishes coverslipping the current tray, the coverslipper will disable itself. The coverslipper disables itself to make sure another cassette is not ejected and causes damage to the coverslipper. Once the operator empties the coverslipper waste bin, enabling the coverslipper will be necessary to begin processing trays.



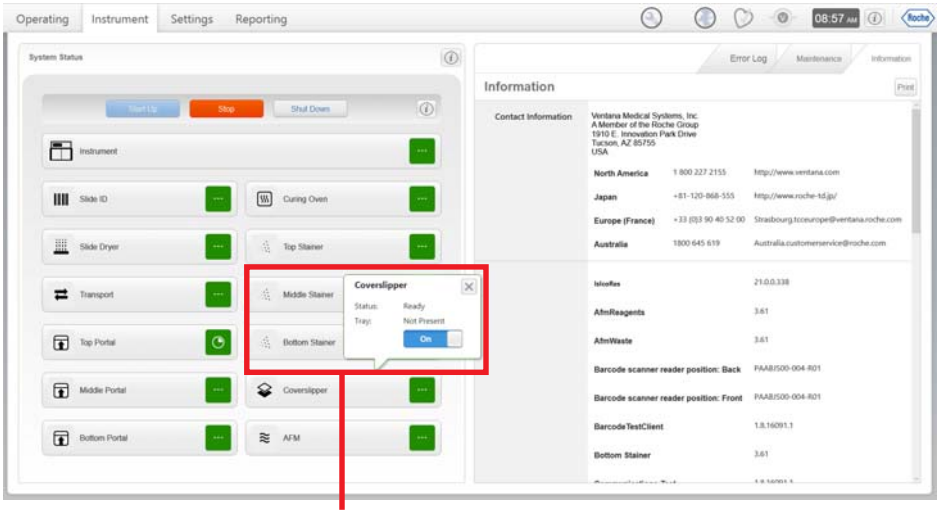
To enable the coverslipper:

1 In the Instrument view, tap Coverslipper.



disabled coverslipper

2 In the pop-up, swipe On to enable the coverslipper.



enabled coverslipper

Replacing Coverslip Cassettes

To prepare a coverslip cassette for loading:

VENTANA HE 600 system coverslip cassettes contain pre-glued coverslips. Do not attempt to use alternative coverslip cassettes in the VENTANA HE 600 system.

The cassettes should be stored flat, horizontally on their side with labels facing up, in a clean dry area and should remain sealed in their plastic bags until they are loaded into the system. Do not use a cassette if it contains broken or cracked coverslips.

1. Remove the cassette from its plastic bag.
2. Remove the tape covering the top of the cassettes.
3. Ensure that the desiccant pouches are removed along with the tape.

To load coverslip cassettes:

Two coverslip cassettes will be used simultaneously by the system at a time. Do not attempt to load a new coverslip cassette unless there is an open position.

1. Open the door to the coverslip cassette module.
2. Place cassettes to be loaded on the belt, with the cassette label on the right. Insert the cassette until it is detected by the belt sensor.

   The belt will start moving and the cassette will be positioned by the system.

   NOTE Coverslip cassettes are key-coded and can be loaded in one direction only.

To unload coverslip cassettes:

When a cassette is empty, it is automatically moved into the empty cassette bin.

1. Open the door to the coverslip cassette module.
2. Remove empty cassettes from the bin.
3. Close the door to the coverslip cassette module.

coverslip waste dispensary

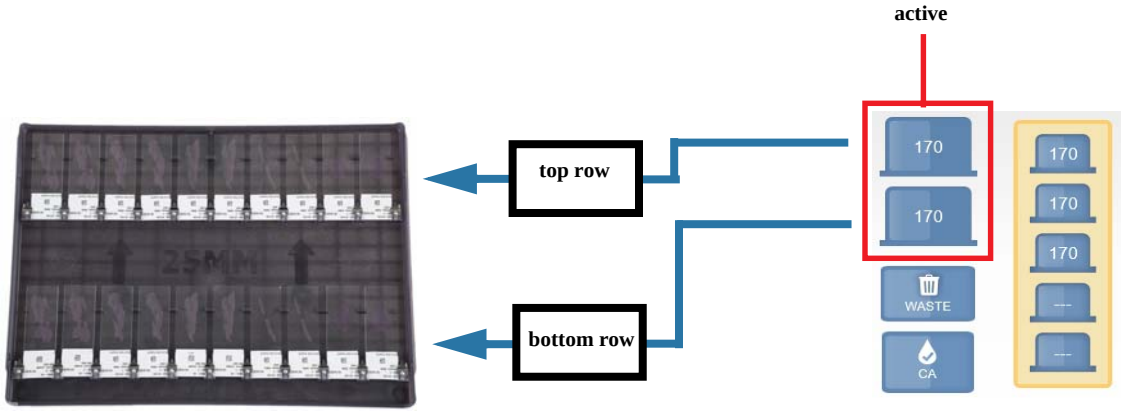
IMPORTANT Coverslip cassette shipping packages should be stacked horizontally, never vertically.

IMPORTANT The VENTANA HE 600 system does not have the ability to process VENTANA SYMPHONY coverslips. Do not place VENTANA SYMPHONY coverslips in the VENTANA HE 600 system.

IMPORTANT Remove cassettes before three pile up on the cassette bin, as the coverslipper may become disabled.

Coverslip Cassettes Logic

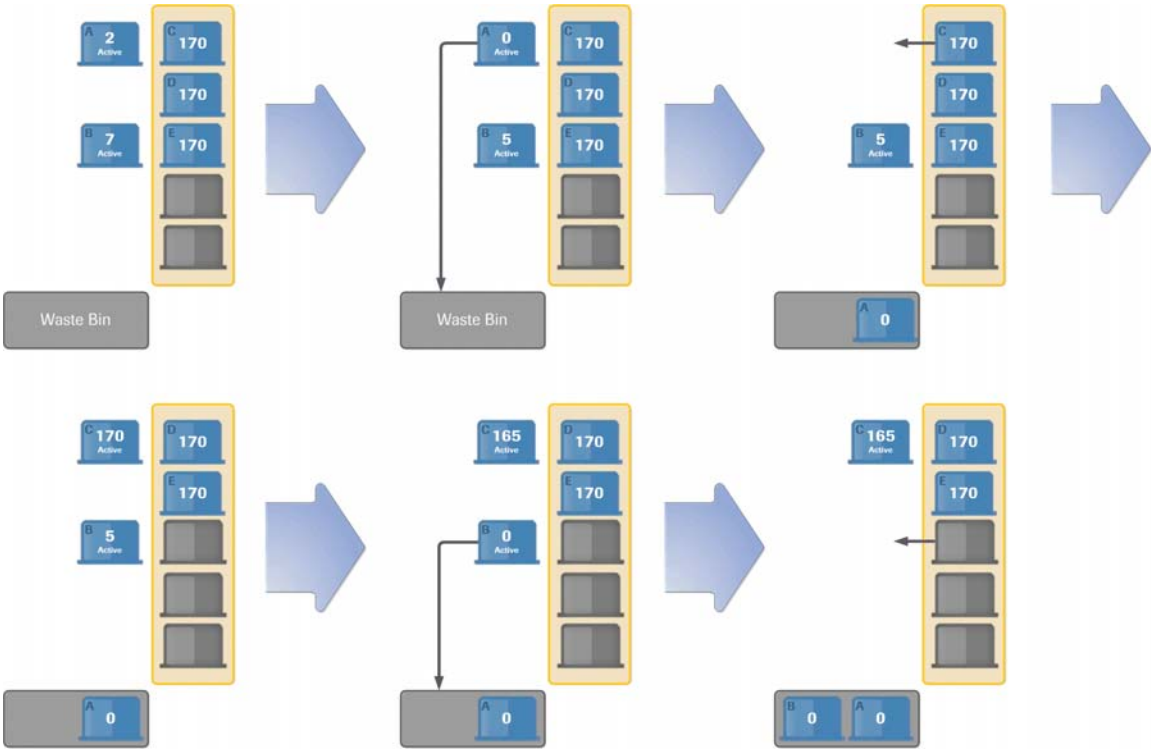
The VENTANA HE 600 system allows the operator to load up to seven coverslip cassettes at one time. Two of the possible seven coverslip cassettes will be actively used by the system to coverslip any given tray. The top active coverslip cassette coverslips the top row of a tray only while the bottom coverslip cassette coverslips the bottom row of a tray only.



The system requires a minimum of five coverslip cassettes loaded in the coverslipper in order to continue processing and loading additional trays. This eliminates the possibility a) the coverslipper running out of coverslips, b) the coverslipper coverslipping a partial tray, c) tissue drying out as trays wait for a new cassette to be loaded for coverslipping and d) the coverslipper not having a backup for all active coverslipping positions at all times.

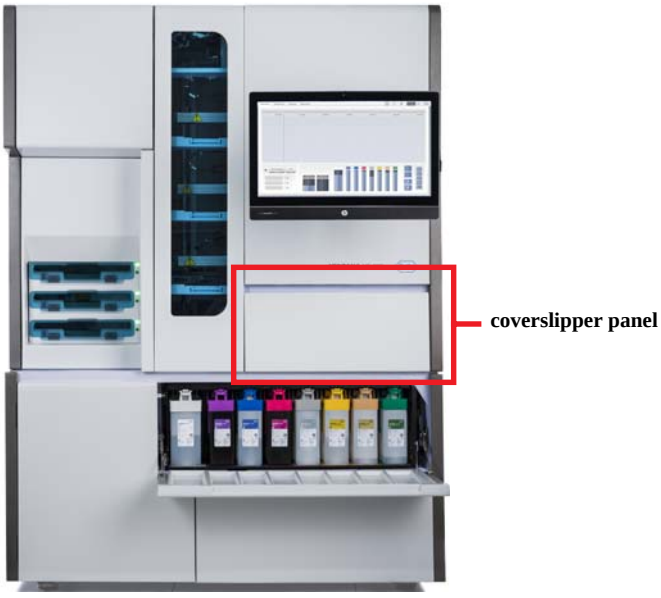
Coverslip cassettes software logic example:

1. A tray with 20 slides enters the coverslipper.
2. After two slides are coverslipped, cassette (A) is left empty and is discarded tot eh waste bin.
   - Cassette (A) is replaced by cassette (C)
   - Cassette (C) is replaced by cassette (D)
   - Cassette (D) is replaced by cassette (E)
3. After seven slides are coverslipped, cassette (B) becomes empty and is discarded to the waste bin.
   - In this scenario there are no available cassette to replace cassette (B)
   - The tray will not be able to complete coverslipping of all 10 slides for the bottom row (7 out of 10 are coverslipped)
   - The tray in the coverslipper, partially coverslipped, would sit in the coverslipper until a new cassette is loaded in which the tissue has the potential to dry out



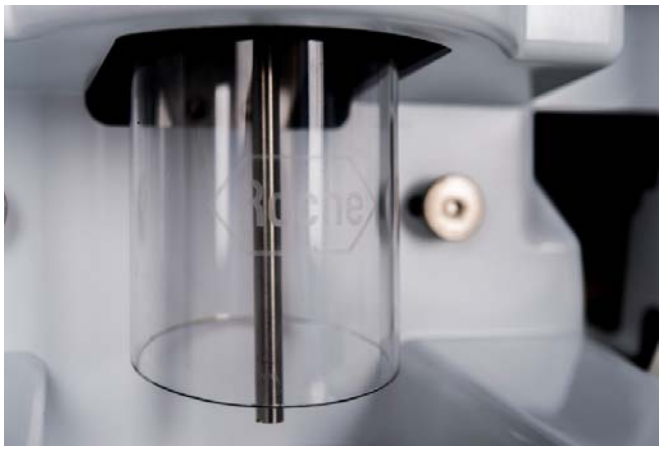
Replacing the Coverslip Activator

1 Open the coverslipper door to provide access to the coverslipper module. Have a bottle of Coverslip Activator nearby to install.



2 Verify that the Roche clear plastic cover is fully elevated, and not processing.

The Roche logo will display green when the system is processing the Coverslip Activator.



3 Uncap the VENTANA HE 600 Coverslip Activator bottle.

4 Insert the bottle below the Roche plastic cover.

5 When the bottle is in place, the plastic cover will descend and cover the entire bottle. The Roche logo will light green when the system is using the reagent.

6 When the Activator has been consumed by the system, the Roche plastic cover will automatically elevate.

7 Remove the bottle to replace it with a new one.

CAUTION: Move hands and body parts away from the Roche plastic cover as it comes down.

Maintaining Waste Containers (If Applicable)

The VENTANA HE 600 system is designed to send liquid waste directly down the drain or to capture waste in an on-board waste capture module. An on-board waste capture module is available for laboratories that choose not to dispose liquid down a drain. Use of the waste module is an after-market system option. Waste must be managed in accordance with all applicable national, state, and local regulations, including applicable municipal codes. The laboratory is responsible for determining the appropriate waste disposal option, and ensuring the waste disposal method complies with all local and municipal regulations, codes, and guidance.

IMPORTANT Ensure that the VENTANA HE 600 system can always dispose of waste. The system does not need to be paused to empty waste. Empty waste as directed by the system.

Waste Containers

When a lock appears above a waste container on the waste capture module (on the system), the waste container is being used by the system and should not be unloaded. Tap the waste container icon on the touchscreen to get a popup with more details.

Waste container is properly installed and has sufficient available space.

Waste container is properly installed and 20% space is available. The container will need to be emptied soon.

Waste container is properly installed but has no available space. Empty this container immediately.

No waste container is currently installed in this position. If the system does not use direct-to-drain, load an empty container.

Emptying Waste Containers

Each VENTANA HE 600 system waste container (optional) includes an ultrasonic sensor that determines waste level. Only VENTANA HE 600 system waste containers can be used—the interior volume and shape of the container is necessary for the system to accurately monitor waste levels.

IMPORTANT If any other waste containers are used besides VENTANA HE600 system containers, the system will not function.

1 Open the door to access the waste storage module.

If the waste container needs to be emptied, note that the lock button has been turned off and the red waste container light is on.

2 Remove the container, keeping it upright.

3 Dump the waste in accordance with local regulations.

4 Place the empty container back in the waste storage module, and close the door.

System LED Waste Indicator Location

The indicators directly above the waste containers show whether each container is locked, and how full they are.

System LED Waste Status

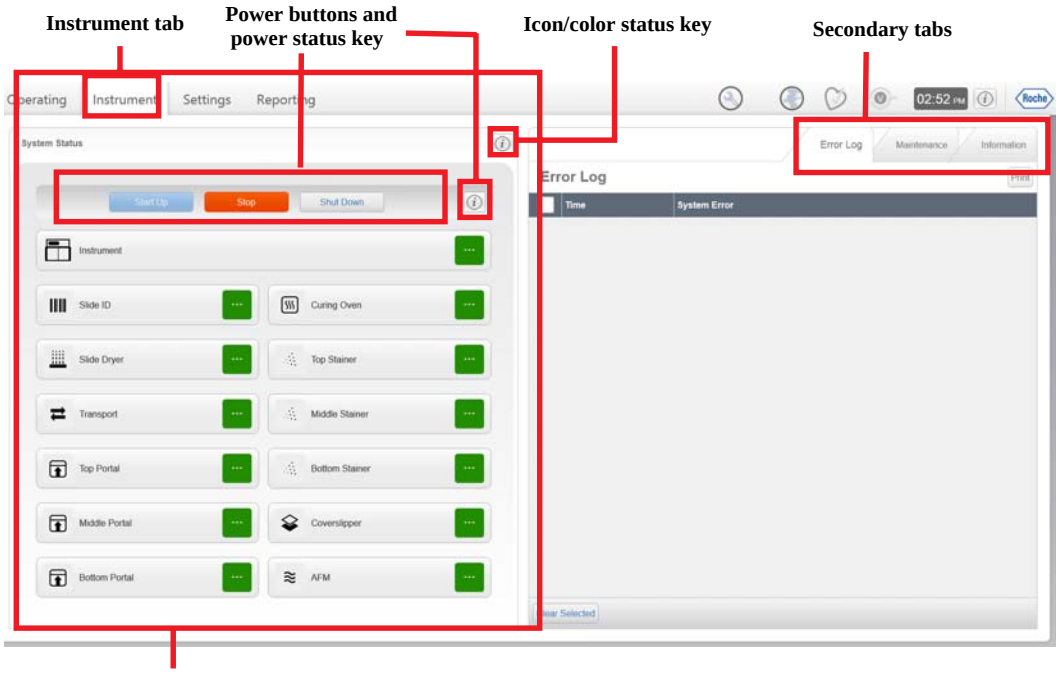
	Green light on lock symbol indicates the waste container is locked and cannot be removed from system.		Amber light on waste container symbol indicates the waste level is approaching full. The number one indicates this is waste container number 1.
	No light on lock symbol indicates the waste container is unlocked and can be removed from system.		Red light on waste container symbol indicates the waste level is full and waste container is no longer accepting waste.
	Green light on waste container symbol indicates the waste level is low. The number two indicates this is waste container number 2.		Unlit icon indicates there is no container in that position. The number two indicates this is waste container number 2.

4. Instrument Status

Generally, daily workflow happens in the Operating tab view. Lab administrators and specific lab personnel will use the Instrument tab to view maintenance and error logs, and system information.

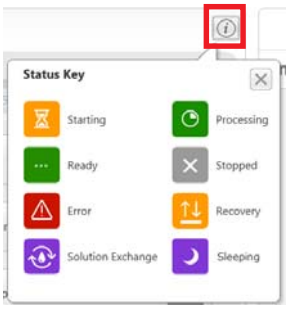
From the Instrument tab view, left pane, view an overview of the instrument status—slide scanner, slide dryer, transport system, portals, ovens, and stainers.

On the right half of the screen, tap a secondary tab to view an error log, a maintenance schedule, or system information.

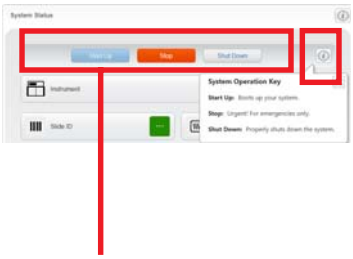


Instrument Status Keys

Colored icons give system status at a glance. Tap the top information icon ⓘ to view the icon/color status key.



Icon button key and info icon



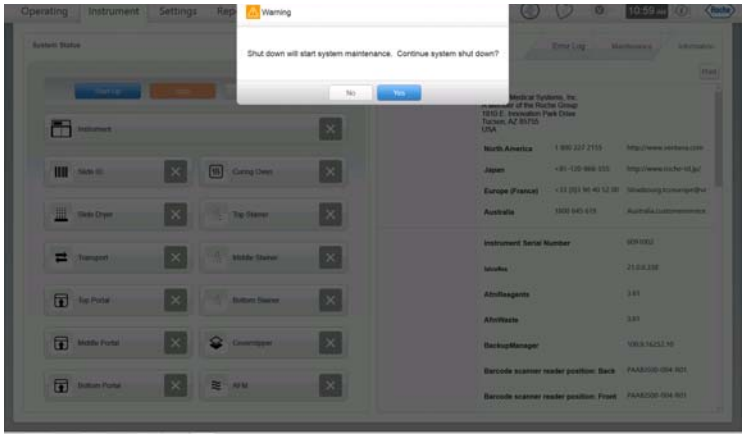
Power buttons and info icon

Power Buttons

Tap the information icon ⓘ next to the power buttons to view a power status key.

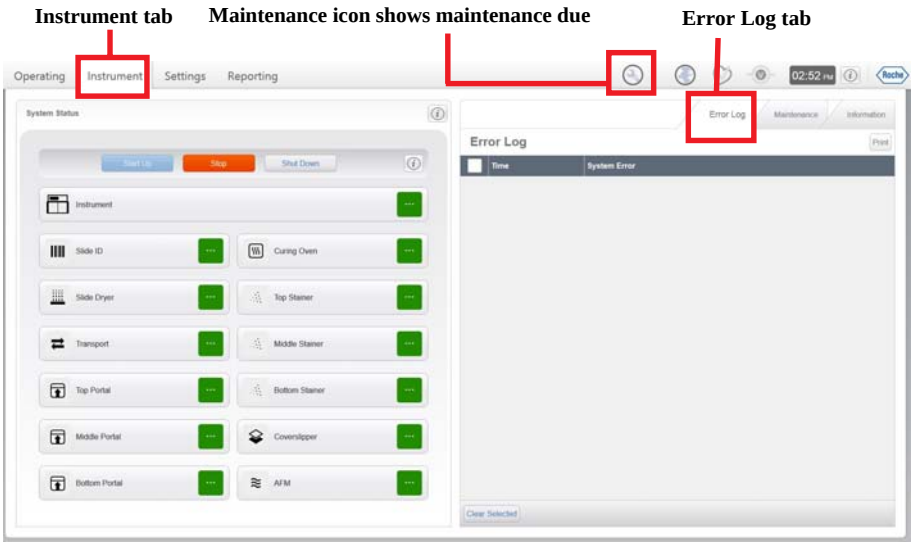
Power buttons and info icon

- **Start Up**—The operator will go to the Instrument tab and tap the Start Up button. The system goes through a process to ready itself for running trays.
- **Stop**—All trays will stop processing. Once the system is restarted, the system will recover the trays to the portal. If trays are being processed when the Stop button is pressed, the system will let you know trays are being processed and ask you to verify whether you want to continue system stop.
- **Shut Down**—the operator taps Shut Down to power off the system. A cleaning cycle will occur once the system is shut down. If Shut Down is pressed, the system will ask you to verify that you want to continue to shut down.



Instrument Error Log View

1. Tap the Instrument tab on the upper left of the touchscreen.
2. If the Error Log tab view is not selected, tap it to view a current error log at the right half of the touchscreen. In the following screen, there are no errors.



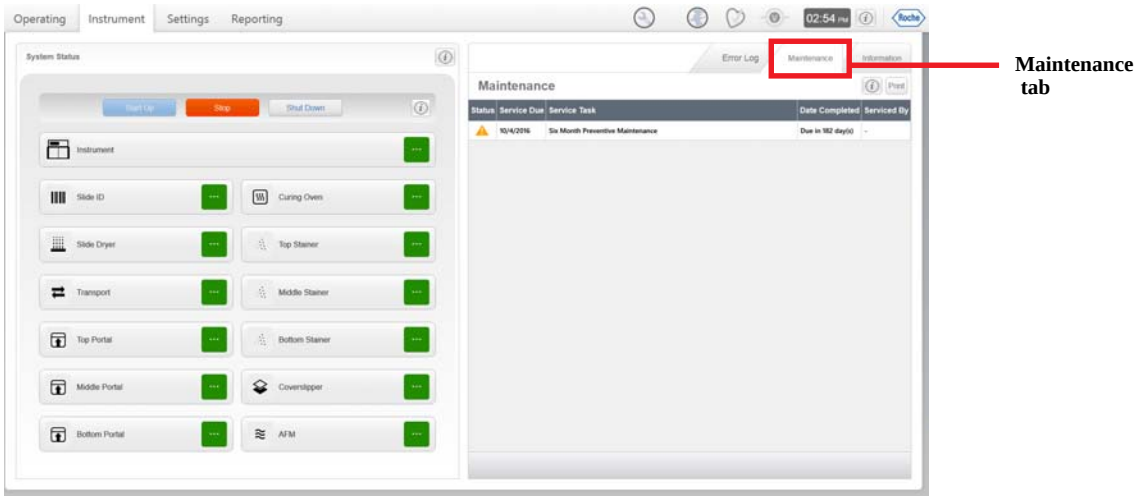
3 To delete an error, tap its checkbox to the left of the error, and then tap the Clear Selected button.

4 To clear the entire error log, tap the Select All box, and then tap the Clear Selected button.

Instrument Maintenance View

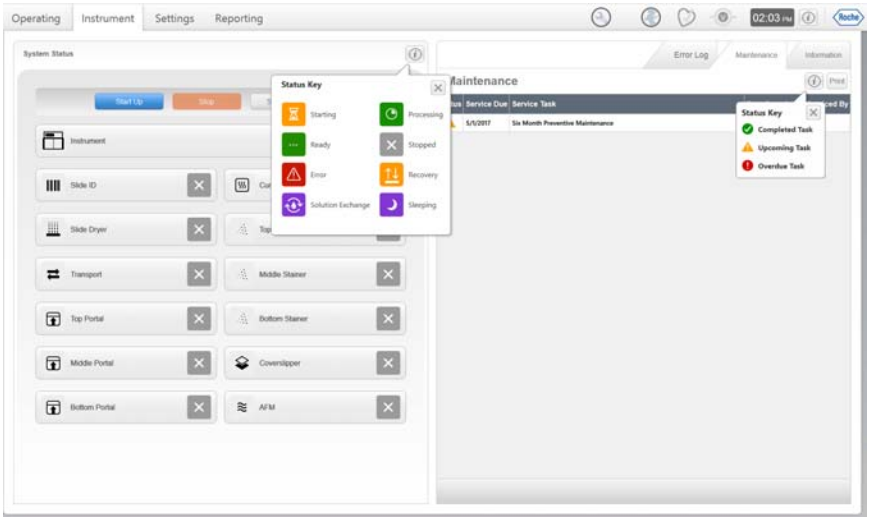
1 From the Instrument tab view of the touchscreen, tap the Maintenance tab on the top right.

2 From here, view the upcoming instrument maintenance schedule, maintenance that has been completed, and what is incomplete.



IMPORTANT The VENTANA HE 600 system currently requires a preventive maintenance service performed every 6 months (182 days) or 2,500 trays processed, whichever occurs first.

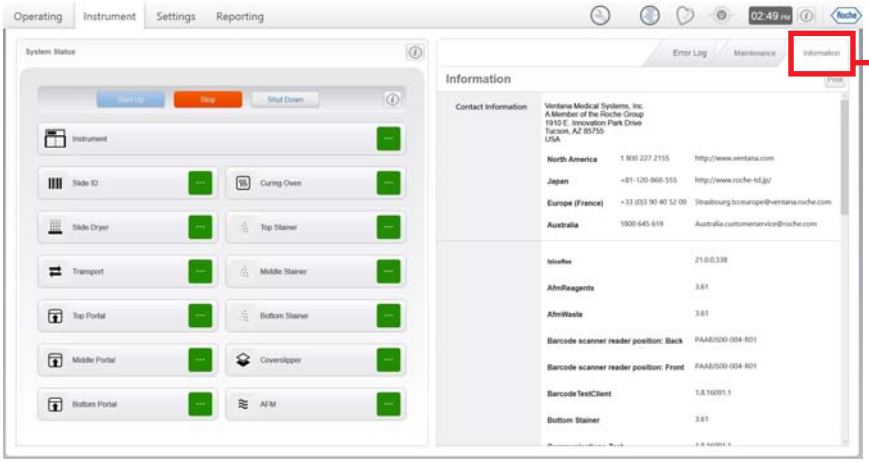
3 Tap elements on the touchscreen to view popups with more detailed information, including icon/color status keys.



Instrument Information View

1 From the Instrument tab view, tap the Information tab on the top right.

From here, view VENTANA HE 600 system contact information as well as current software versions of the system, subsystems, and copyright information.

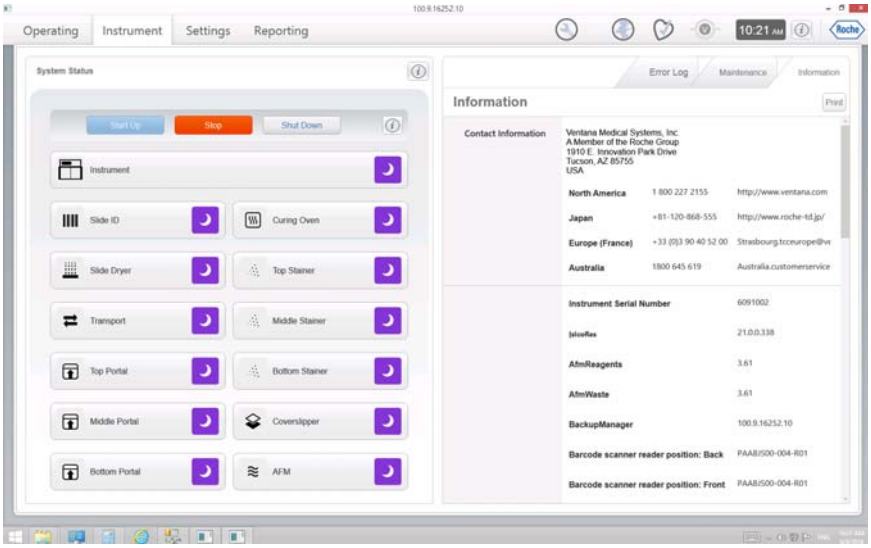


Instrument Information View—Sleep Mode (Optional)

1 In the Instrument tab, sleep mode can be viewed if the Sleep option is selected in System Settings (see *Settings > System on page 56*.)

When the Sleep option is selected, the system will enter sleep when either no trays have been loaded in the system or a minimum of one minute has passed since the last tray finished processing.

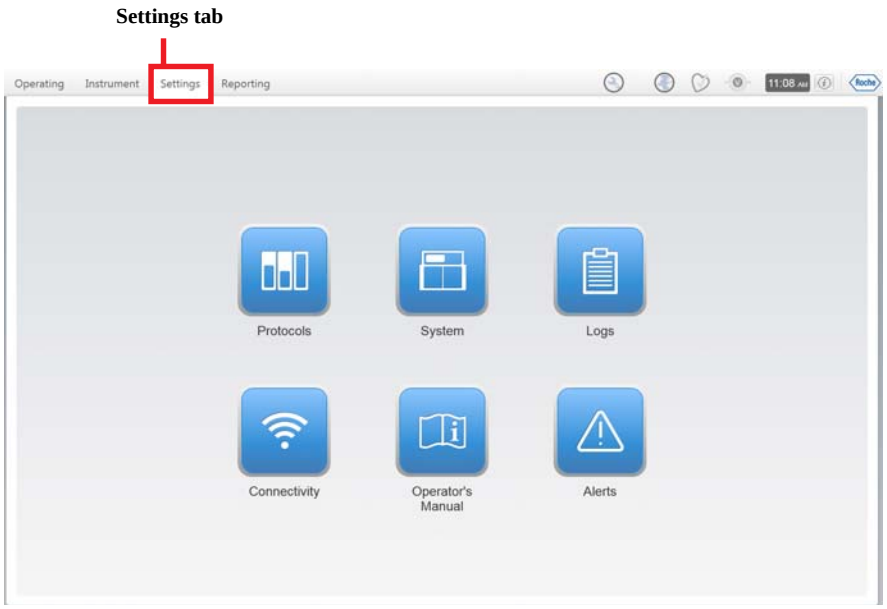
NOTE The time of inactivity before sleep mode is enabled is configurable in 1, 5, 10, or 15 minute increments. See *Settings > System on page 56* for instructions on configuring this setting.



5. System Settings and Reports

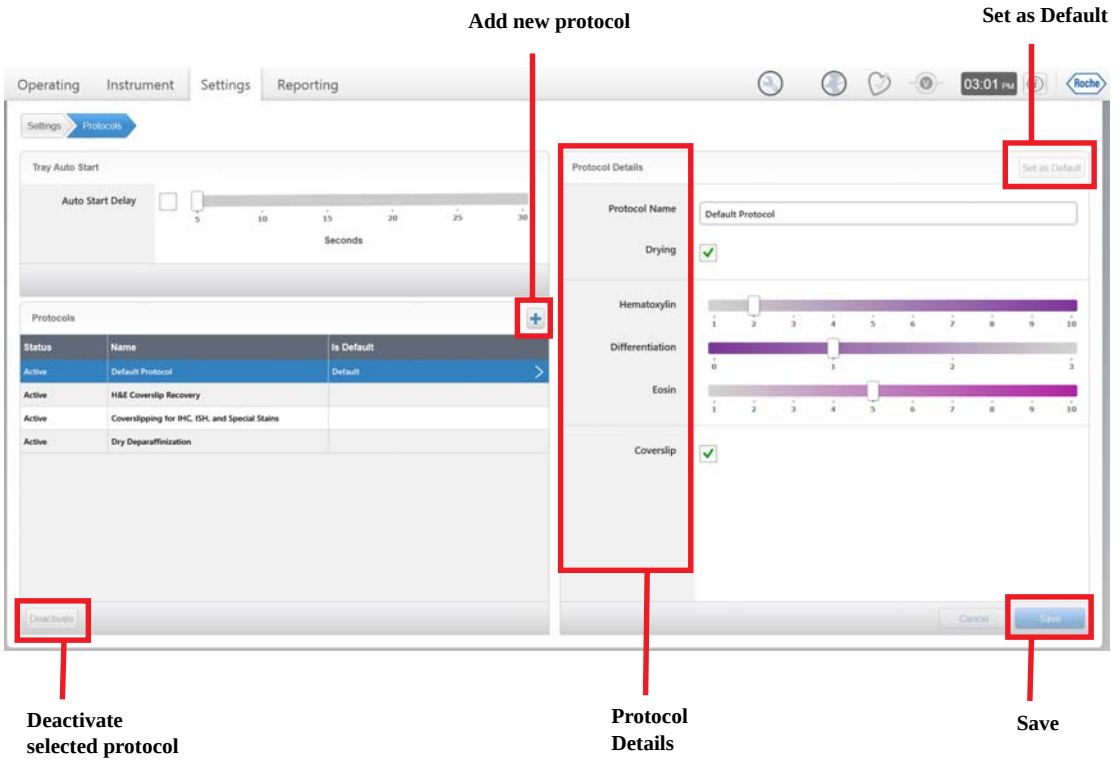
System Settings

On the touchscreen, tap the Settings tab to view the Settings home page. From the home page, tap Protocols, System, Logs, Connectivity, and Alerts to customize settings for each. Tap Operator Manual to open this manual from the touchscreen.



Settings > Protocols

Create or modify staining protocols by selecting staining options and staining intensities.



IMPORTANT An exception exists for the Hematoxylin Protocol screen above. Normally, Hematoxylin staining levels are 1-10, and Differentiation levels are 0-3. However, if the Hematoxylin level is set to 1, the Differentiation level now has 6 levels instead of 4. This is in the case, for example, of very light staining levels.

To create a new staining protocol:

1. Tap the Add new protocol button + and enter a new protocol name in the Protocol Name field.
2. Choose Auto Start Delay. (Optional—available only for the default protocol)
3. Change protocol details as needed.
4. Tap Save.

   The new staining protocol is added to the Protocols list on the left.

To modify a staining protocol:

1. Select the protocol to be modified in the protocol list on the left.
2. In Protocols Details on the right, modify protocol options, drying, staining intensities, and coverslipping as needed.
3. Tap Save.

To deactivate staining protocols:

1. In the protocol list on the left, select a protocol to be deactivated.
2. Tap Deactivate.

Roche-Supplied Protocols

The VENTANA HE 600 system offers three Roche-supplied protocols:

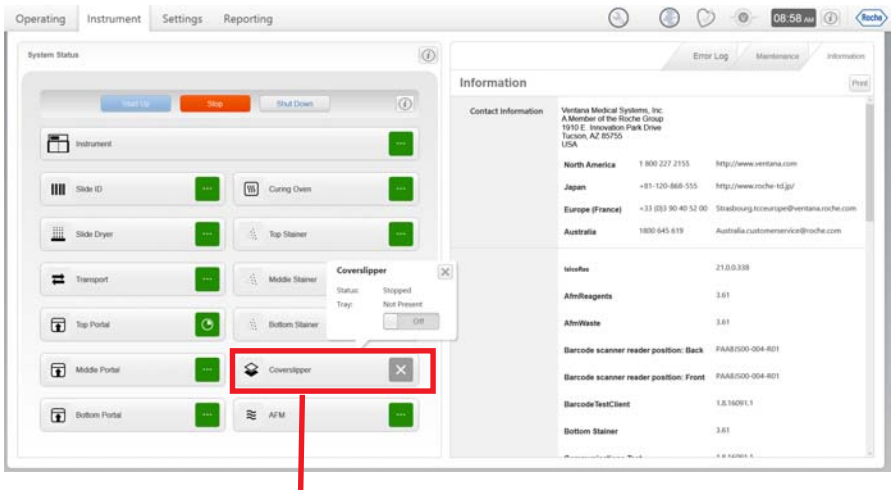
- H&E Coverslip Recovery
- Coverslipping for IHC, ISH, and Special Stains
- Dry Deparaffinization

H&E Coverslip Recovery Protocol

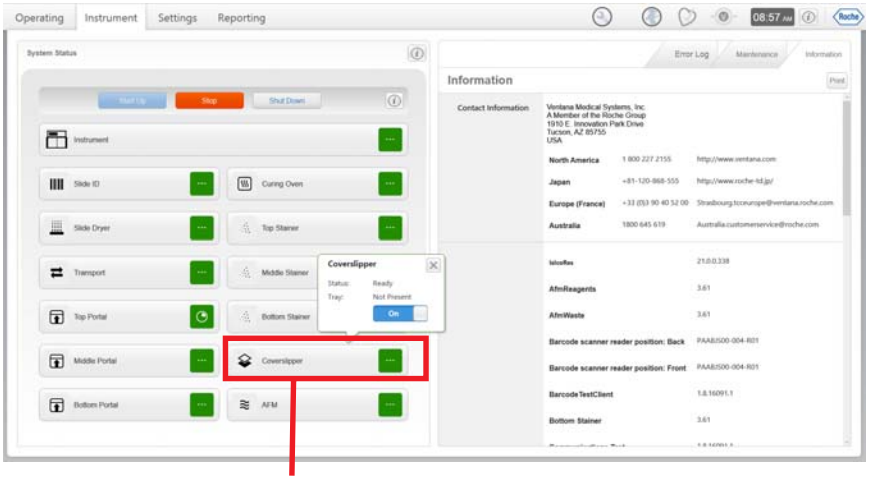
The H&E Coverslip Recovery protocol is to be used when the coverslipper becomes disabled for any reason and does not coverslip a VENTANA HE 600 tray with slides.

IMPORTANT The operator will need to enable the coverslipper prior to using this protocol.

1. In the Instrument view, tap Coverslipper.



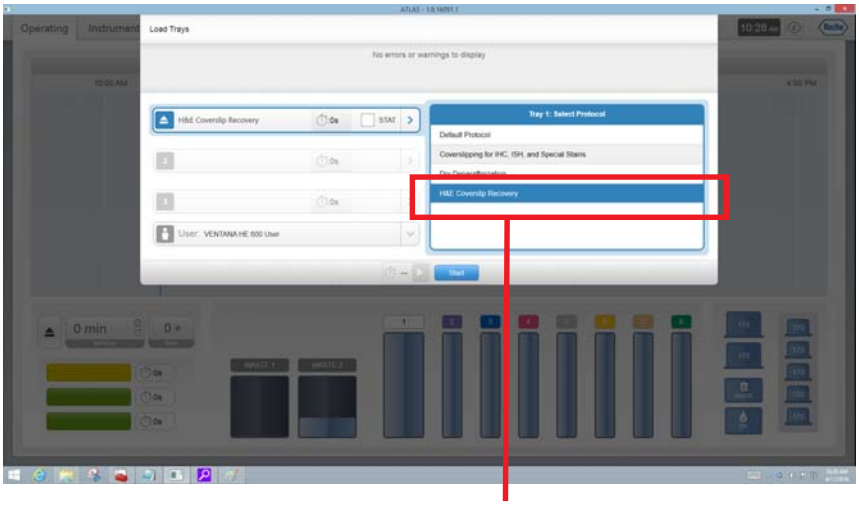
2 In the pop-up, swipe On to enable the coverslipper.



Enabled Coverslipper

3 Insert a tray into the portal that was not coverslipped.

4 From the scroll-down list at the right of the Select Protocol screen, select H&E Coverslip Recovery Protocol.



H&E Coverslip Recovery Protocol selected

5 Tap Start.

The system will start processing the H&E Coverslip Recovery protocol.

Coverslipping for IHC, ISH, and Special Stains Protocol

The Coverslipping IHC, ISH, and Special Stains protocol is to be used to coverslip slides after they have gone through the IHC, ISH, or Special Stains staining process from a Roche Tissue Diagnostic system. The Coverslipping IHC, ISH, and Special Stains protocol was tested on Roche IHC, ISH, and Special Stain

systems. During the Coverslipping IHC, ISH, and Special Stains protocol, the slides get dehydrated in the stainer prior to coverslipping.

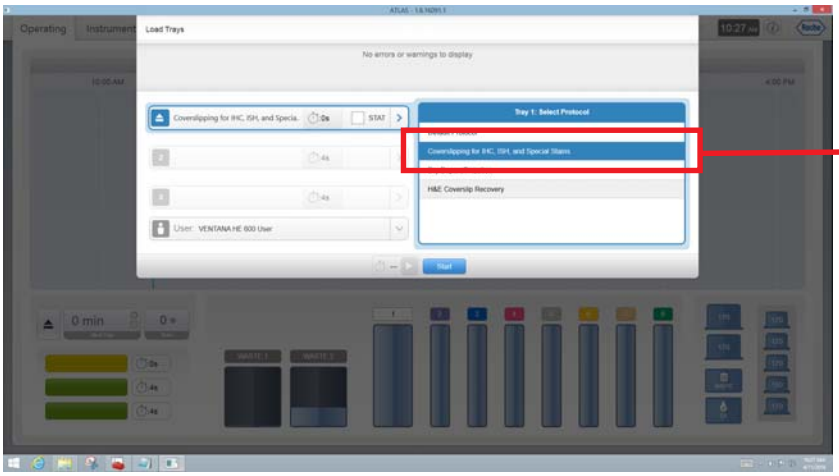
NOTE The VENTANA HE 600 system dispenses reagent gently onto a slide, thus the liquid coverslip from Roche IHC and ISH staining systems will not be fully removed. Therefore, the following recommended procedure should be followed before using the VENTANA HE 600 system for coverslipping.

1. Perform the staining run on a Roche Tissue Diagnostic-IHC, -ISH, or -special stains platform.
2. At the completion of the IHC, ISH, or special stains run, remove the slide from the system.
3. For IHC and ISH slides, wash in a mild dishwashing detergent or alcohol to remove the liquid coverslip solution.

   IMPORTANT Rinsing of special stains in any solution after run completion may result in lighter staining results.
4. Rinse the slides in deionized water to remove any detergent.

   IMPORTANT For any slides stained using red detection chemistry, the slides need to be completely dry before they are placed into the VENTANA HE 600 system. Follow the Package Insert for post-processing instructions.
5. Load the slides onto a tray.
6. Insert the tray into the VENTANA HE 600 system portal.
7. From the scroll-down list at the right of the Select Protocol screen, select Coverslip IHC, ISH, and Special Stains Protocol.

   IMPORTANT Review each detection kit package insert for exceptions or special dehydration recommendations.



8. Tap Start.
9. The system begins processing the Coverslip IHC, ISH, or Special Stains Protocol.

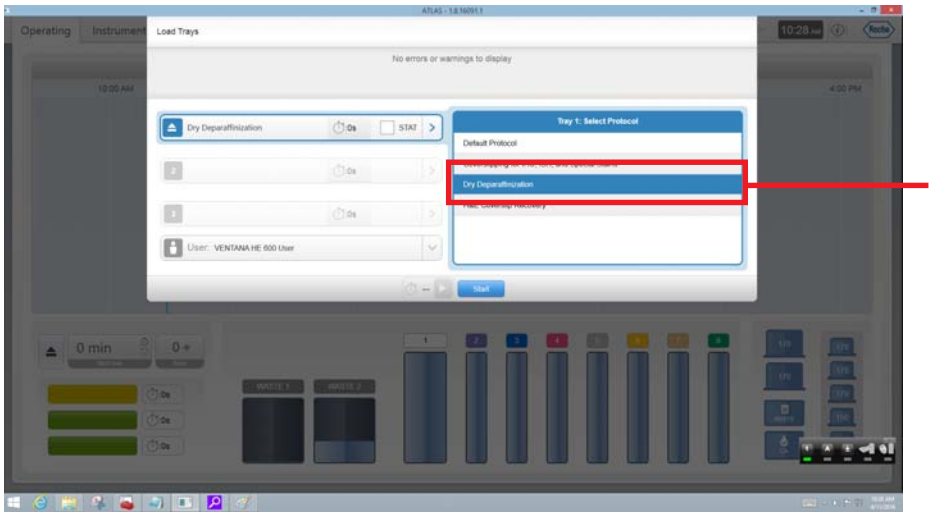
   IMPORTANT When inserting a tray or trays, review each selected tray to ensure proper protocol is selected.

Dry Deparaffinization Protocol

The dry deparaffinization protocol is used to dry and de-wax slides before loading the slides onto a Roche Tissue Diagnostic system without deparaffinization capabilities.

1 Insert the tray into the portal.

2 From the scroll-down list at the right of the Select Protocol screen, select Dry Deparaffinization.

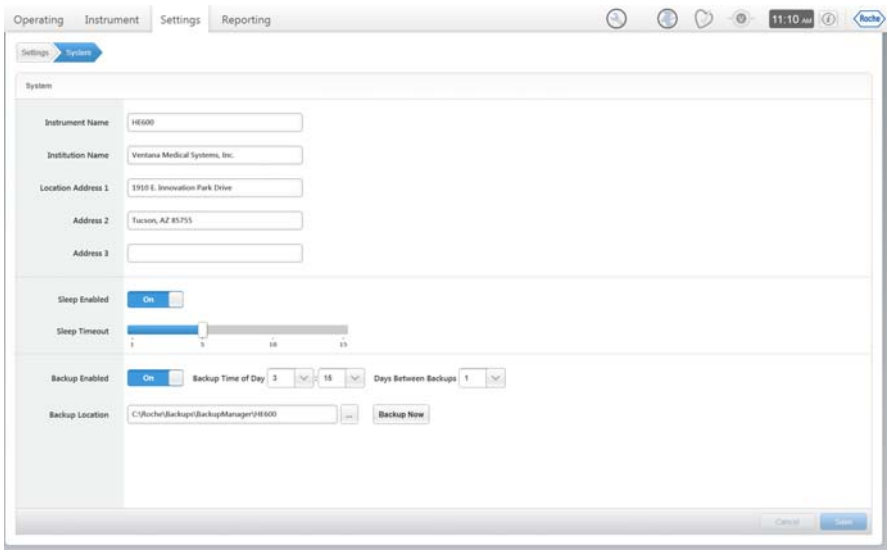


3 Tap Start.

4 The system will begin processing the Dry Deparaffinization Protocol.

Settings > System

The System Settings view is where you view the instrument name and the institution name and customer information. Additionally, Sleep and Backup are enabled or disabled in the System Settings view.



To change the instrument name, institution name, or location address in System Settings, tap a field and enter the new data.

Sleep

1. Swipe On to enable Sleep.
2. Select inactivity period of 1, 5, 10, or 15 minutes.
3. Tap Save.

   When the sleep option is enabled, the system will enter sleep after it is initialized and either no trays have been loaded or a minimum of one minute has passed since the last tray finished processing. The system will not enter sleep if trays are processing, the system is performing its daily cleaning cycle, modules are initializing, modules are in process of stopping, or a critical error has occurred.

State of Modules During Sleep

- Transport system—Stopped
- Portals—Doors are open and stopped. LEDs stay in the state prior to entering Sleep
- Barcode Reader/Slide Detect—Remains enabled
- Slide dryer—Remains enabled
- Stainers—Remains enabled
- Coverslipper—Solvent shield is lowered, Load Cassettes buttons on the touchscreen are disabled and coverslipper is stopped
- AFM—Stopped
- Modules—The UI to enable or disable modules is disabled. Modules cannot be enabled or disabled while the system is in Sleep

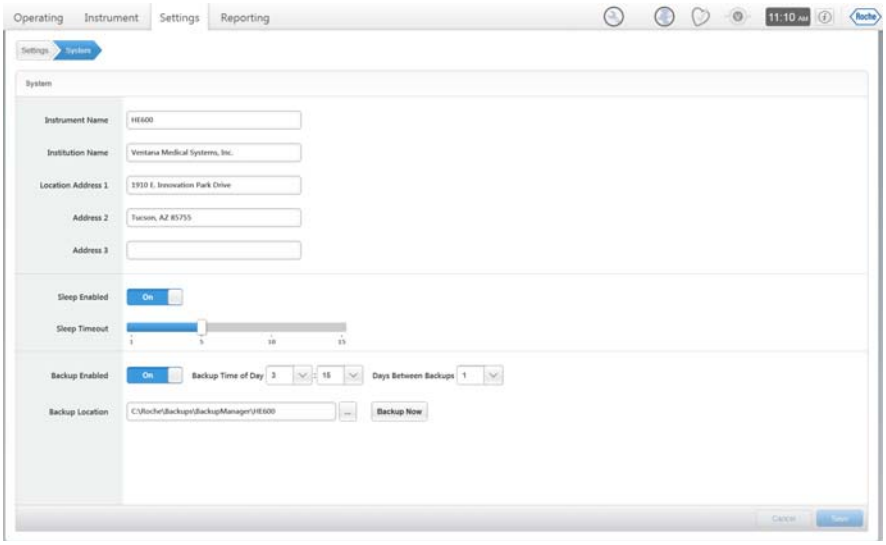
Exiting Sleep

The system will wake and ready itself to process trays when the operator inserts a new tray into the portal, removes a processed tray from the portal, or taps the Eject button on the touchscreen. Additionally, if the operator presses Stop or Shut Down, the system will be taken out of Sleep, and then performs its designated operation.

NOTE It takes the system approximately 2 minutes to begin processing trays once it is taken out of sleep.

Backup and Restore

The VENTANA HE 600 system database is backed up periodically by the Backup function, which facilitates the recovery of files in a recovery scenario.



1. Swipe On to enable Backup.
2. Select backup time of day.
3. Select days between backups.
4. Select backup location.
5. (Optional) Tap Backup Now.
6. Tap Save.

IMPORTANT By default, the VENTANA HE 600 application creates a backup of the database once a day to a path on the local drive. It is recommended that a local network be used to back up the database. Work with your local IT support to determine a network location to be used. Another option to backup the VENTANA HE 600 system is to connect a USB on the back of the VENTANA HE 600 computer to continuously backup data.

NOTE It is recommended that backup occurs during a time of infrequent activity. Therefore, the backup is scheduled to occur at 3:15 AM by default. This is to coincide with the default 3:00 AM time scheduled for the cleaning cycle.

Settings > Logs

By tapping Logs in the Settings home page, you can view a thorough list of system activities. On the System Log page are System, Maintenance, and Script tabs. Additionally, a search can be executed in the Logs directly. Generally, the Logs view will be used by Service Representatives.

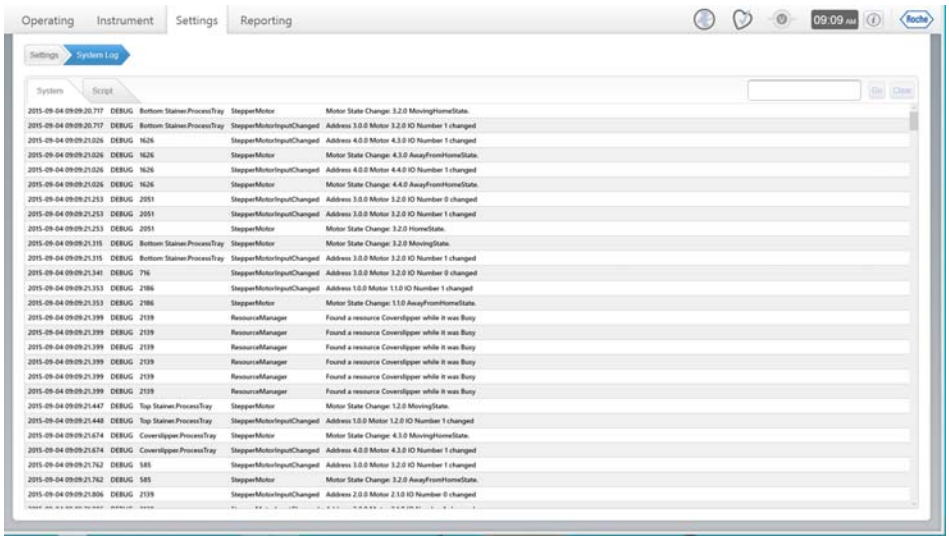
To search in the logs:

1. Tap on the Search box.
2. Enter a keyword.
3. Tap OK.

To return to the full list after searching a keyboard:

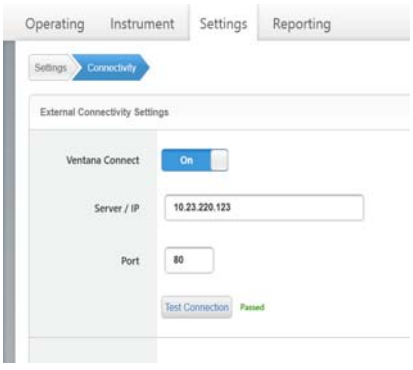
1. Tap Clear.

   The full log list appears.



Settings > Connectivity

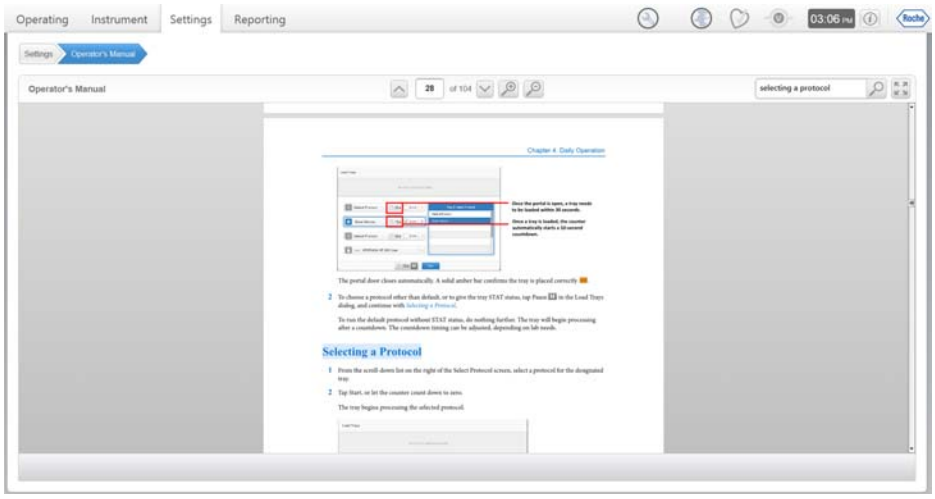
In the Connectivity view you can change whether VENTANA CONNECT or VENTANA VANTAGE is on or off, test whether the connection is working, as well as configure which Server/IP address and which port.



1. Tap any field to modify information, or to test connections.
2. If you made changes, tap Save.

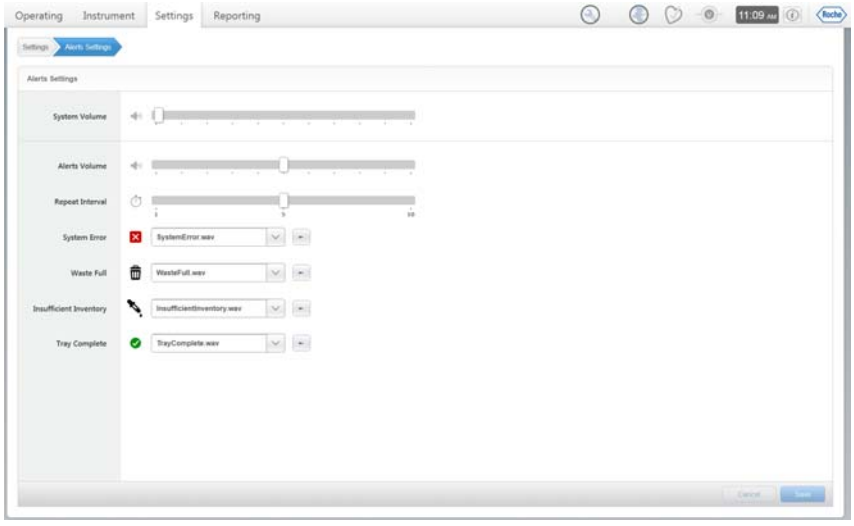
Settings > Operator Manual

To view the VENTANA HE 600 System Operator Manual, tap Operator Manual in the Settings tab view.



Settings > Alerts

By tapping Alerts in the Settings home page, you can view a list of the available audible alerts. On the System Alerts pane are System Volume, Alerts Volume, Repeat Interval, System Error, Waste Full, Insufficient Inventory, and Tray Complete. All alerts can be changed by the operator at any time, or turned off completely, from the drop-down menus. The play button to the right of the drop-down gives a short playback example of the sounds.



1. Tap Alerts in the Settings tab.
2. Select System Volume.
3. Select Alert Volume.
4. Select a Repeat Interval of 1, 5, or 10 minutes.

5 Select System Error.

6 Select Waste Full.

7 Select Insufficient Inventory.

8 Select Tray Complete.

9 Tap Save.

NOTE Alerts Volume is based off System Volume selected. Adjust System and Alert Volumes as needed.

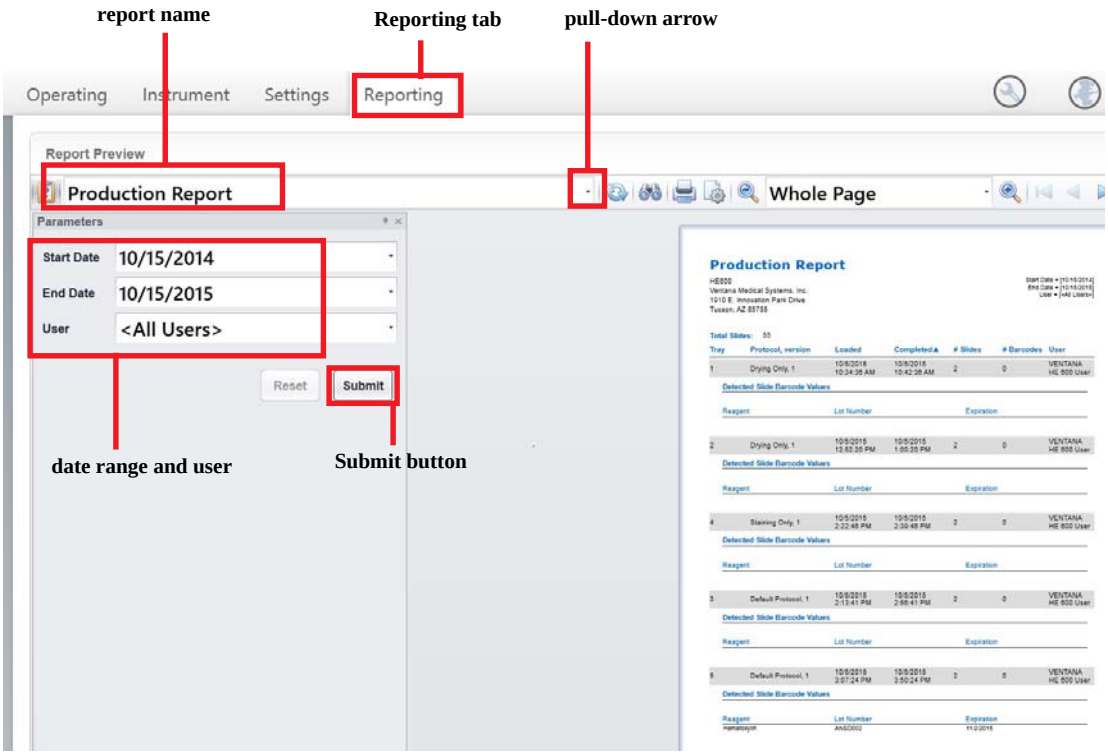
All alerts repeat at the selected interval except for the Tray Complete alert which repeats only once. The alerts will continue to repeat at the selected interval until the alert condition is addressed or until a higher priority alert is triggered. The system prioritizes alerts as follows: System Error, Waste Full, Insufficient Inventory, and Tray Completion.

NOTE The VENTANA HE 600 system has the ability to accept custom audible alerts. Please contact your Roche Customer Support to set this feature. The custom sound must be in a .wma, mp3 or .wav file to be supported by the VENTANA HE 600 system.

Reports

Go to the Reporting tab to view any of the following reports: Inventory, Operators, Preventive Maintenance, Production, and Protocols.

1 Tap the Reporting tab on the upper left of the touchscreen.



1 In the left panel, tap the pull-down arrow to choose from the following reports:

- Inventory
- Operators
- Preventive Maintenance
- Production
- Protocol

2 If applicable, tap the User field to choose a user or All Users.

3 Tap the Parameters field to define the timeline.

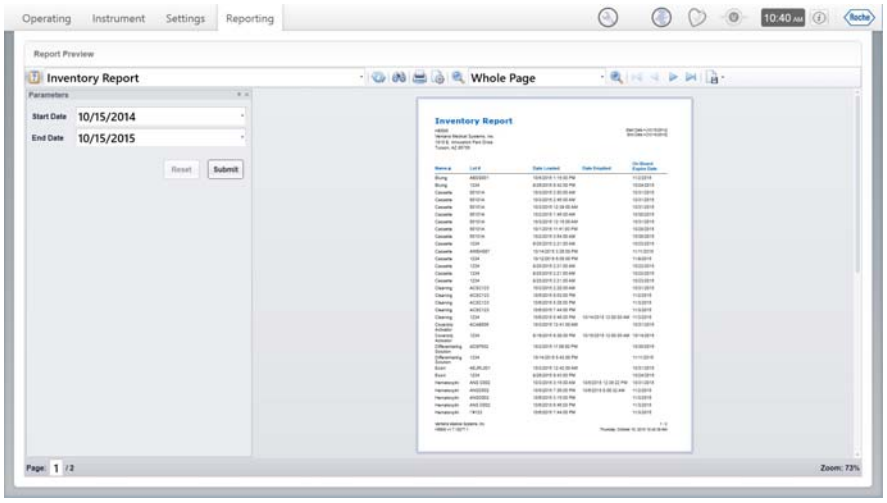
4 Tap Submit.

The report will show in the Report Preview to the right.

Print the report or save it as a PDF or CSV, or view it in full screen view.

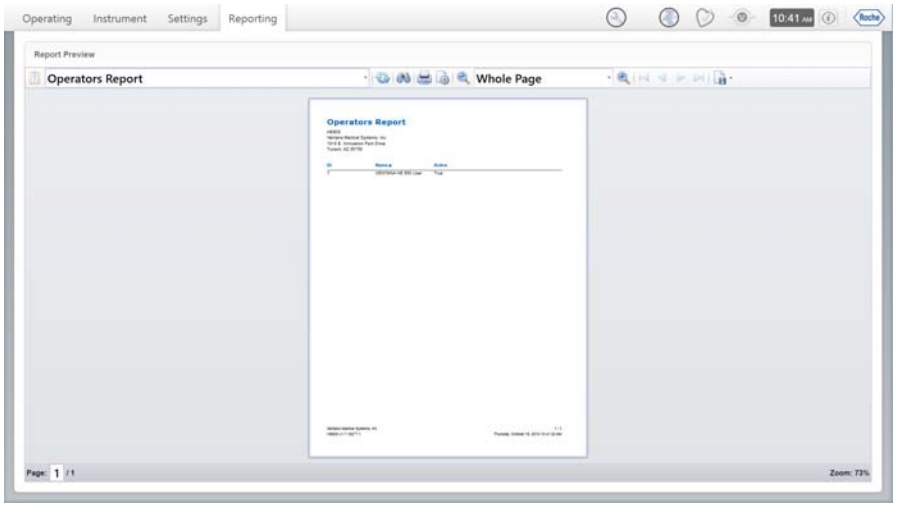
Inventory Report

The Inventory report gives an overall view of reagents and cassettes. The report shows a table of the reagent name, lot number, date loaded, date expired, and expiration date from when opened.



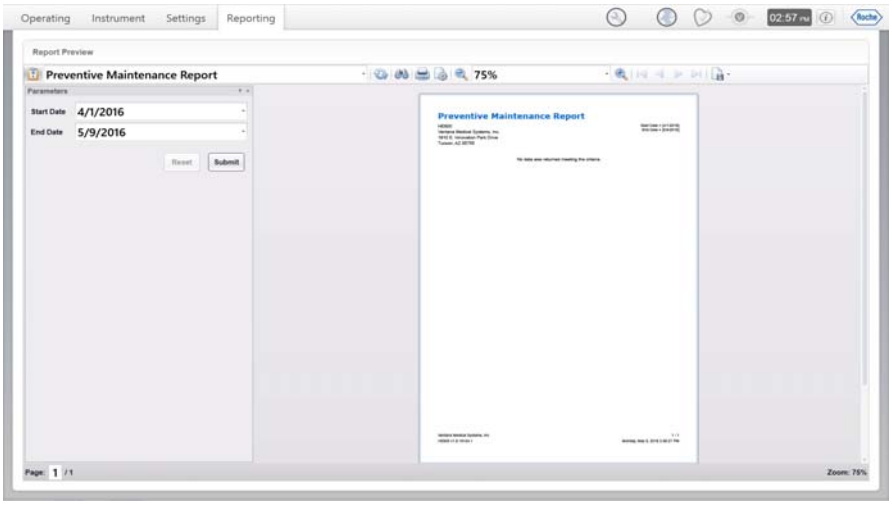
Operator Report

The Operator Report is sorted by user and shows the User ID, User name, and whether that person is an active user.



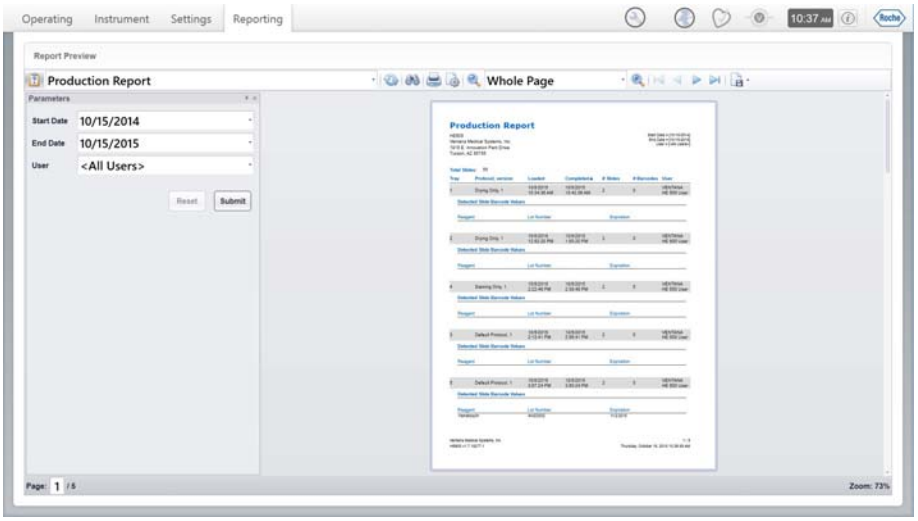
Preventive Maintenance Report

The Preventive Maintenance report is sorted by date performed, in descending order. It gives the dates the maintenance was performed, who it was performed by, and task details. There is also a notes section for the Roche Service Representative to give further details.



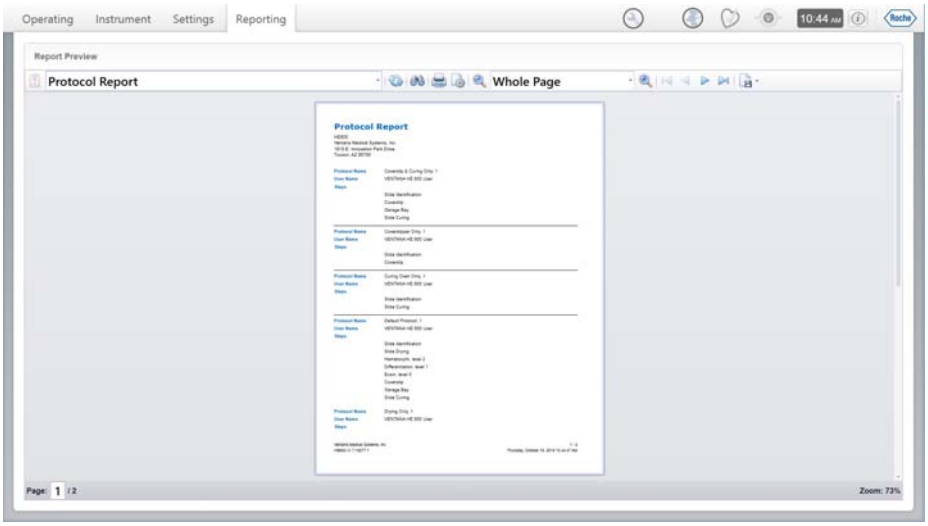
Production Report

The Production report is sorted by Tray Completed Date and Time. It has detailed information about each tray put in the system. View the tray number, the number of slides in the tray, the total number of slides run, the protocol name and version, the user name at the time the tray was run, the date and time loaded and completed, and the number of barcodes read with detected barcode values for each slide.



Protocol Report

The Protocol report is sorted by protocol name. It gives a list of the protocol name and version, the user name at the time the protocol was assigned.



6. Maintenance and Troubleshooting

Preventive Maintenance

The VENTANA HE 600 system was designed to minimize the amount of user-required maintenance. Roche Preventive Maintenance (PM) for the system will be performed every 6 months (182 days) or 2,500 trays processed, whichever occurs first, unless a Roche Service Representative determines otherwise.

The projected downtime for preventive maintenance of the system is 8 hours. These downtimes include the testing procedures required to verify that the system is functioning after maintenance.

Daily Maintenance

Check the Coverslip Waste Dispensary

Each day, remove the coverslip waste dispensary located at the base of the coverslip module and remove any glass debris that has collected in the dispensary.

IMPORTANT Dispose of the broken glass according to your facility procedure for handling glass waste.

Daily Shutdown

Your Roche Service Representative may set a daily time for system shutdown to occur automatically.

Ask your Representative for details. If this scheduled time occurs during a staining run, the system will automatically reschedule the shutdown when no slides are being processed.

Manually initiating a daily shutdown (if it is not scheduled)

1. Tap the Instrument tab.
2. Tap Shutdown.

IMPORTANT Manually shutting down the system will initiate a cleaning cycle that lasts for a minimum of one hour.

As-Needed Maintenance

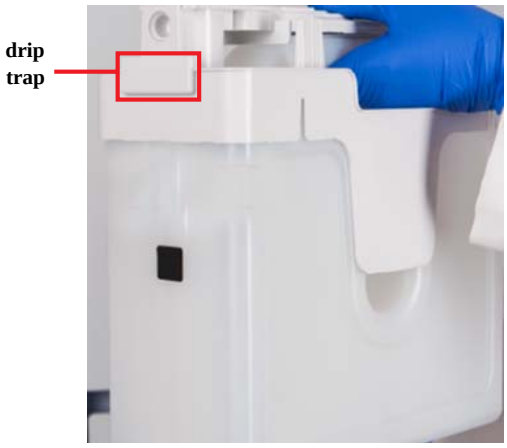
Trays

Check trays regularly to ensure they are in optimal condition. Discard trays that show any sign of damage—do not use damaged trays in the system. Trays should be cleaned using DI water only.

IMPORTANT Do not put trays in dishwasher.

Reagent Hats

During system operation, reagent drip traps (located on the reagent hats) may collect reagent. Empty reagent drip traps as necessary.



CAUTION: When working with any reagent, reagent hat, or reagent container, take appropriate precautions.

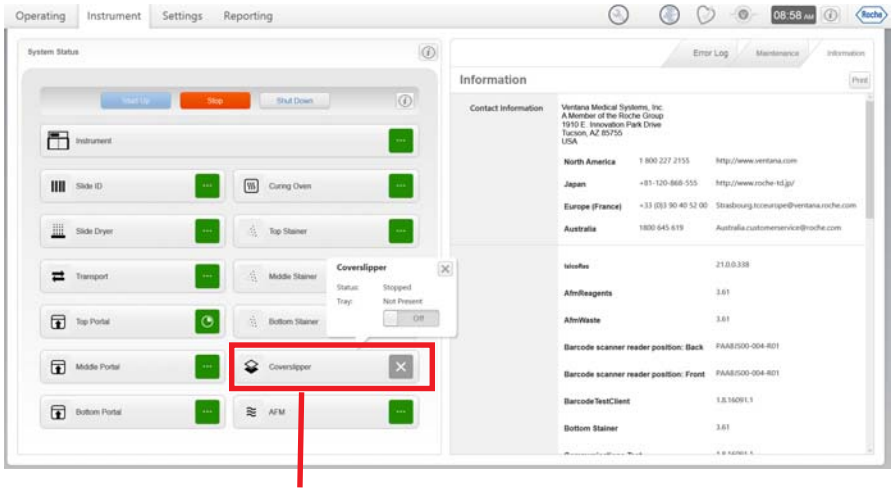
CAUTION: Always wear approved eye protection, gloves, ad protective clothing when handling reagents, reagent containers, reagent hats, and slide trays.

Removing Coverslip Cassette

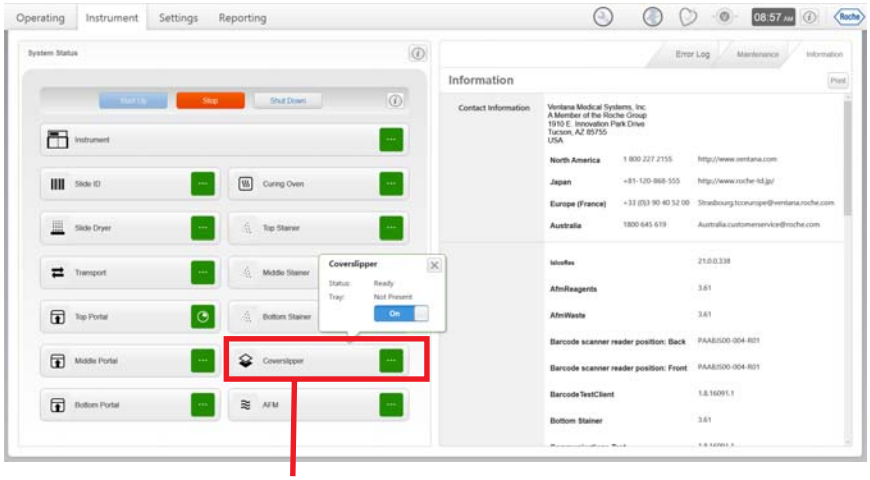
Empty coverslip cassettes will be ejected into the cassette discard bin to the left of the entry belt. Empty cassettes should be removed and discarded. The system detects the presence of empty cassettes.

IMPORTANT If the cassette discard bin is full of empty cassettes, the coverslip module will become disabled and stop operation until the discard bin is emptied.

1 In the Instrument view, tap Coverslipper.



2 Tap On to enable the coverslipper.



Troubleshooting

Recovering Trays

In the event that an error occurs that requires trays to be removed from the VENTANA HE 600 system, precautions are required to prevent injury to operators and damage to the system.

WARNING: Power off the computer and system prior to removing any trays.

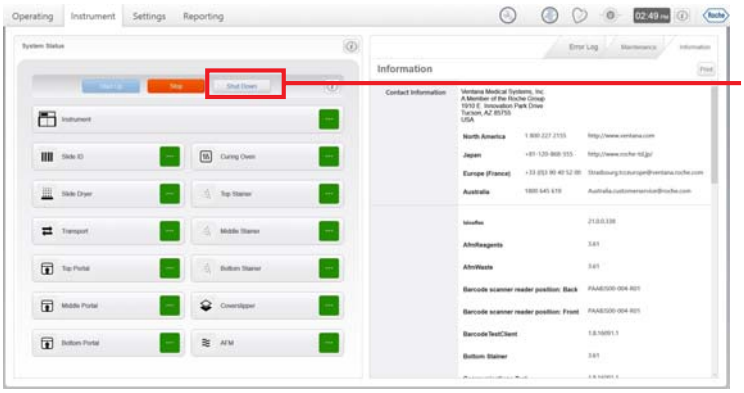
WARNING: Wait at least 20 minutes after powering off the system to allow all trays in the slide drying oven, stainers, and curing oven to cool before handling trays manually.

WARNING: Wait 20 minutes after powering off the system before touching any internal components of the system. Some modules may be hot.

Preparing to Recover Trays

Shut down the system:

1 In the Instrument view tab, tap Shut Down.



2 Wait for the VENTANA HE 600 system application to automatically close.

3 Tap the Windows icon.

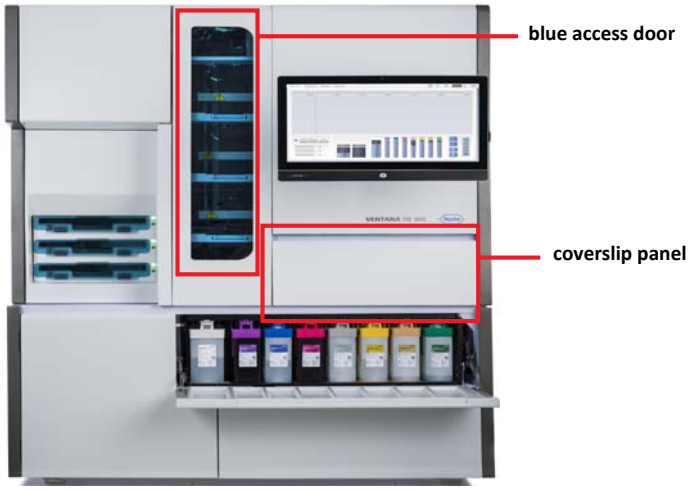
4 Tap Shut Down to turn off the computer.

5 Turn the power switch from I to O to power off the system.

NOTE: If the blue access door is opened prior to turning off the system, the system will automatically stop and shut down. If trays are inside the system when the blue access door is opened, they will be recovered to the portal once the blue access door is closed and the system is operational.

6 Locate the blue access door.

7 Open the coverslip panel.



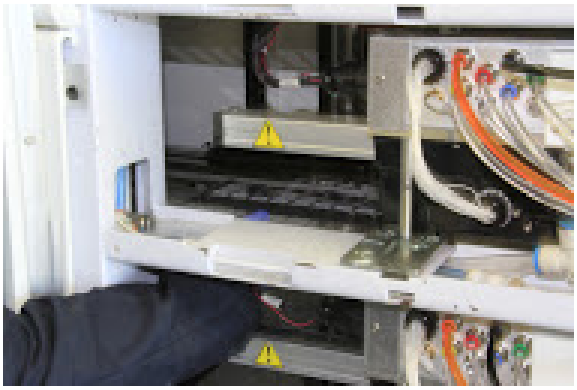
8 Have the hex key ready to use.

9 Align the hex key with the blue access door interlock hatch.

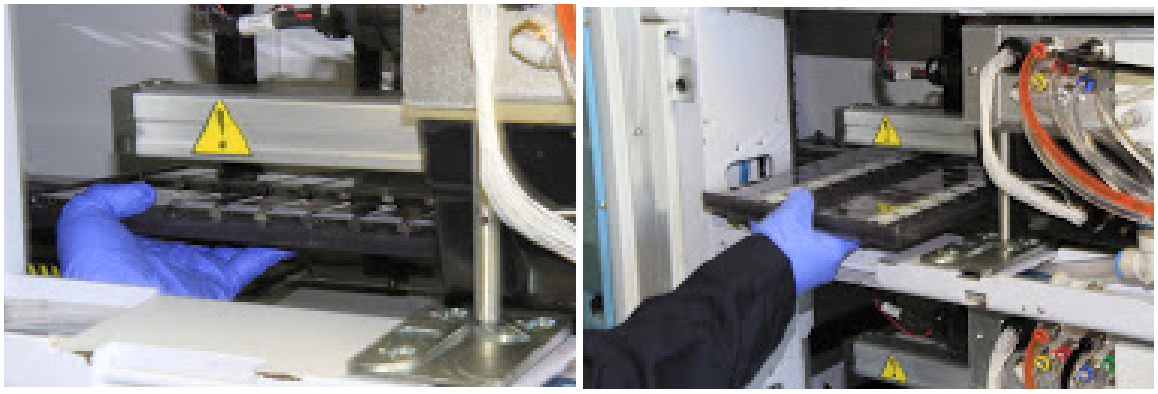
10 Turn the hex key counterclockwise until the door releases.

11 Check the transport system for a tray.

12 Locate the transportation fork; it could have stopped in any position.



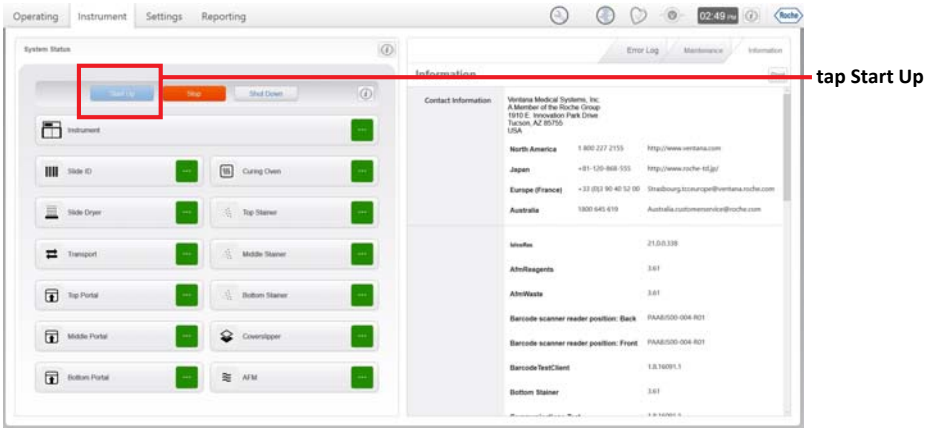
13 Carefully remove the tray from the transportation fork.



14 Close the blue access door, and then the coverslip panel.

15 Turn the power switch from O to I to power on the system.

16 In the Instrument view tab, tap Start Up.



17 If system shutdown and restart fails to recover all trays, call your Roche Customer Support Center to report a service call, and then use the following procedure to manually recover trays from each module.

Manually Recovering Trays from the Portal

1. Repeat steps 1–11 in *Preparing to Recover Trays on page 68*.
2. To prevent injury, ensure trays are cool to the touch prior to removing them from the portal.
3. Once the system is powered off, the portal doors open automatically.
4. Reach under the tray, and pick up the tray so it clears the portal.

5. Pull out the tray.

Manually Recovering Trays from the Garage

1. Repeat steps 1–11 in *Preparing to Recover Trays on page 68*.
2. Have the hex key ready to use.

3 Locate the garage interlock, which is visible once the blue access door is open.

4 Turn the hex key counterclockwise until the Garage interlock opens.

5 Open the garage door until all Garage slots are visible.

NOTE: Use caution; the blue access door needs to be closed as the garage door is being opened.

6 Pull trays out of garage slots 1–8.

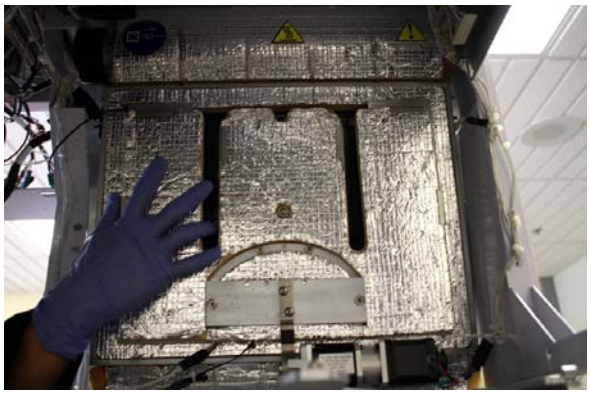
7 To reach slots 9–10, reach through the blue access door to pull the trays out of the system.

8 Once the tray has been reached, carefully pull the tray out of the system.

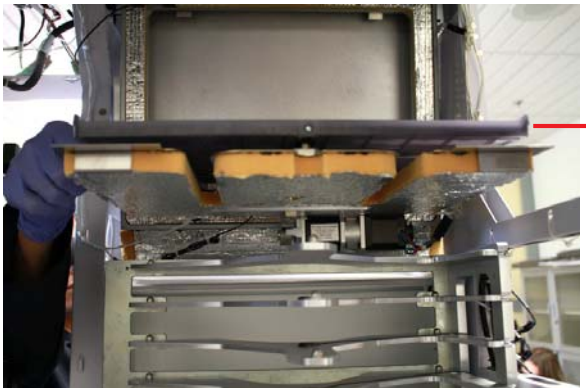
9 Close the garage door firmly, ensuring that the top and bottom of the door is closed.

Manually Recovering Trays from the Drying Oven

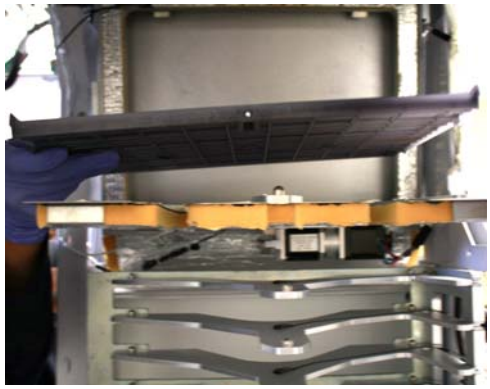
1. Repeat steps 1–11 in *Preparing to Recover Trays on page 68*.
2. To prevent injury, ensure the oven is cool to the touch prior to removing trays from the drying oven.
3. Open the drying oven, reaching through the blue access door to grasp the oven door.



4. Pull down the oven door until it fully opens.



5. Remove the tray from the oven by first lifting up the tray slightly.

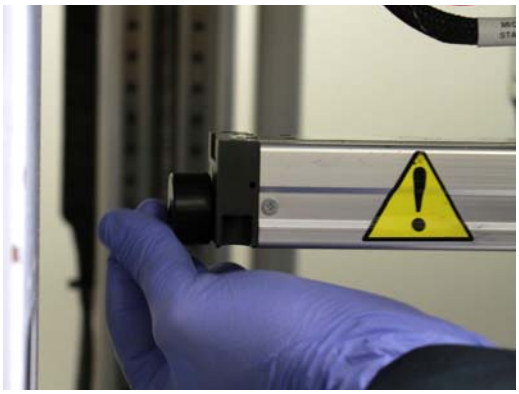


6. Pull the tray out of the system.

Manually Recovering Trays from the Stainers

1. Repeat steps 1–11 in *Preparing to Recover Trays on page 68*.
2. Locate the VENTANA HE 600 Stainer Crank.

3. Insert the stainer crank into the stainer release.
4. Turn the crank clockwise until the tray and the tray mount are fully out of the stainer.



5. Remove the tray from the stainer and carefully take it out of the system.

6. Reinsert the stainer crank into the stainer release.
7. Turn the stainer crank counterclockwise until the tray mount is inside the stainer.

Manually Recovering Trays from the Coverslipper

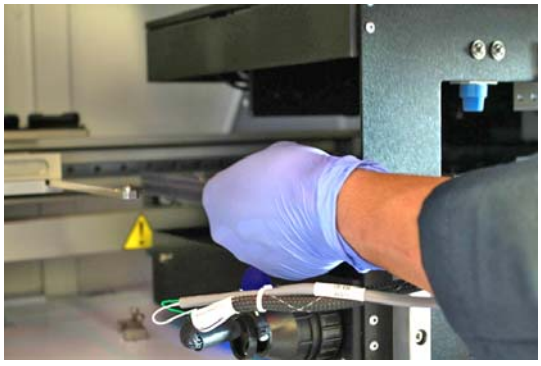
1 Repeat steps 1–11 in *Preparing to Recover Trays on page 68*.

2 Locate the air relief valve.

IMPORTANT Releasing the air from the coverslipper will lower the tray to allow for safe removal of trays.

3 Open the air relief valve by turning counterclockwise.

4 Carefully pull out the tray from the coverslipper.



5 Close the air relief valve by turning it clockwise until it is shut.

IMPORTANT The operator must close the air relief valve for the coverslipper to work properly.

Manually Recovering Trays from the Curing Oven

1. Repeat steps 1–11 in *Preparing to Recover Trays on page 68*.
2. To prevent injury, ensure the oven is cool to the touch prior to removing trays from the curing oven.

   NOTE: Once the system shuts down, the curing oven will slowly open as pressure is released from the oven. Wait approximately 10 minutes for the door to fully open.
3. When the curing oven is open, remove the tray by lifting up slightly, and pulling the tray out of the oven.

4. When the tray has been removed, carefully take the tray out of the system.
5. After all trays have been removed from the system, ensure all panels and doors are closed.

   NOTE: Call your Roche Representative if you need assistance.

System Non-Use

The VENTANA HE 600 system should be placed in the following states, depending on the expected time of non-use of the system.

Days of Non-Use	Storage Stage	Instrument Setting	Reagent Bottle State	Coverslip Cassette State
1–6	VENTANA HE 600 Cleaning Solution in Hematoxylin lines (exchange process)	Power on or shut down	Leave reagents on AFM	Leave cassettes on-board in the Coverslipper
7–30	VENTANA HE 600 Cleaning Solution in Hematoxylin lines (exchange process)	Power on or shut down	Remove reagents from the AFM, cap reagents, and store reagents	Leave cassettes on-board in the Coverslipper
>30	All fluids de-installed from system, filters discarded and replaced	Shut down	All reagents removed from the AFM and disposed of following laboratory regulations	Discard cassettes

Error Messages

Error Code	Error Text	Reason or Solution
0	An unknown error has occurred.	Contact your local support for help.
1004	Tray pickup from transport failed.	The instrument is attempting recovery.
1009	Tray drop-off by transport failed.	The instrument is attempting recovery.
1024	Transport failed to initialize.	Contact your local support for help.
1026	The attempt to move to a safe location in the elevator failed.	Contact your local support for help.
1040	The communications port that controls motion failed to open. The motion control is now disabled.	Contact your local support for help.
1050	The motion system move failed on the X axis.	Contact your local support for help.
1051	The motion system move failed on the Z axis.	Contact your local support for help.
1052	The transport station failed to pick up the tray.	Contact your local support for help.
1053	The transport station failed to drop off the tray.	Contact your local support for help.
1054	The elevator may not be clear.	Ensure elevator is clear. Contact your local support for help, if needed.
1055	This instrument is allowing the transport to move beyond its allowable boundaries.	Contact your local support for help.
1056	A transportation move was requested while a prior move is in process.	Contact your local support for help.
1057	Tray lost during transportation move.	Contact your local support for help.
1058	Transport motor stall detected on (0) axis.	Contact your local support for help.
11000	There is an issue with the RFID: Unable to connect to reader on port {0:D}.	Contact your local support for help.
11001	There is an issue with the RFID: Unable to read from the tag on port {0:D}.	Contact your local support for help.
11002	There is an issue with the RFID: Unable to update the tag on port {0:D}.	Contact your local support for help.
1101	Tray {1} failed at {0} due to internal {2}.	Restart the instrument or contact your local support.
1102	Tray {1} failed due to an {0} error.	Contact your local support for help.
1103	Tray move failed at station {0}.	Contact your local support for help.

11100	Expiration date check: {0} will expire in {1} days. The expiration date is {2} and the open date is {3}.	Replace expired reagent.
11101	Consumable {0} has expired. The expiration date is {1} and the open date is {2}.	Replace expired reagent.
11102	Invalid consumable {0} found at position {1}.	Contact your local support for help.
12006	Unable to schedule a job.	Contact your local support for help.
12008	Unable to abort schedule process, and it will continue.	Contact your local support for help.
13000	There is an error communicating with the database.	Contact your local support for help.
13001	There is an issue with saving information to the database.	Contact your local support for help.
14024	The message could not be found.	Contact your local support for help.
14025	There is an issue with starting communications.	Contact your local support for help.
14026	There is an issue connecting to the serial network provider.	Restart the instrument or contact your local support for help.
14029	The message was not sent due to a timeout issue. Details: {0}.	Contact your local support for help.
14030	The message was not sent due to an error. More details: firmware command {0}. Message content: {1}.	Contact your local support for help.
14031	There is an error in a firmware command response from Address: {0} Error Code: {1} Command: {2} Received Data: {3}.	Restart the instrument or contact your local support for help.
14032	There is an incorrect firmware version.	Contact your local support for help.
14033	There is an incorrect FPGA version.	Contact your local support for help.
14034	An incorrect version of M-Code is being used.	Contact your local support for help.
14035	An incorrect version of firmware for the translation motor firmware is being used.	Contact your local support for help.
19003	Unable to connect with the VENTANA Connect Web service.	Contact your local support for help.
20000	The attempted tray recover failed.	Contact your local support for help.
20001	Unable to disable station: {0}.	Contact your local support for help.

20002	Resource information for {0} could not be found.	Contact your local support for help.
20003	Some of the data used for this operation is missing information due to a system error.	Contact your local support for help.
20004	Unable to load protocols.	Contact your local support for help.
20005	Unable to select or perform the protocol on the tray.	Contact your local support for help.
20006	A process is unable to run because it has invalid data due to a system error.	Contact your local support for help.
20009	Unable to cancel the tray.	Try restarting the instrument. If it does not work, contact your local support for help.
20010	The tray could not be created in the system.	Contact your local support for help.
20011	This station is unable to recover after avoiding a possible collision.	Contact your local support for help.
20012	This station is not allowing a move to occur to avoid a possible collision.	Contact your local support for help.
20013	{0} is unable to recover after avoiding a possible collision.	Contact your local support for help.
20014	The {0} door appears to be open.	Power down the Instrument before proceeding. If this error appears again, contact your local support for help.
20015	An error was detected with the {0} door sensor.	Contact your local support for help.
20016	The prerequisites to perform a reagent exchange have not been met.	Check that all reagents have the appropriate amount of fluid to perform the exchange.
20017	The instrument was unable to schedule the reagent exchange.	Contact your local support for help.
20018	A reagent exchange process is currently in progress.	Wait until the exchange process completes.
20019	The time to complete a Cleaning Solution soak time has not finished.	Wait until cleaning solution soak has completed.
2006	The instrument could not drain the fluid from the pressure trap.	Restart the instrument or contact your local support for help.
2009	The instrument does not detect a waste container.	Replace the waste container and restart the instrument.
2011	The waste cannot be purged because of a timeout issue.	Contact your local support for help.
2014	A sensor has detected an overflow of the waste reservoir.	Contact your local support for help.
2015	Wash reservoir is empty.	Replace empty reagent.

2016	Transfer Fluid reservoir is empty.	Replace empty reagent.
2018	The instrument could not fill the bulk fluid due to an error.	Contact your local support for help.
2026	The waste pressure exceeded the threshold.	Restart the instrument or contact your local support for help.
2027	The waste containers have reached capacity.	Empty the full containers.
2029	The sensor on the pressure trap float is registering as high.	Restart the instrument or contact your local support for help.
2032	There is an error with the {0} reservoir float. The low sensor reports empty while the top sensor reports full.	Restart the instrument or contact your local support for help.
2033	There is an error with the waste reservoir float. The top sensor reports full and the bottom sensor reports empty.	Sensors may be stuck or a failure has occurred. Restart the instrument or contact your local support for help.
2034	There was an error starting the macro that controls reagent filling.	Contact your local support for help.
2035	The accumulator pressure is too high.	Restart the instrument or contact your local support for help.
2036	The accumulator pressure is too low.	Restart the instrument or contact your local support for help.
2037	The reagent dispense pressure is too high.	Restart the instrument or contact your local support for help.
2038	The reagent dispense pressure is too low.	Restart the instrument or contact your local support for help.
2039	The air knife pressure is too high.	Restart the instrument or contact your local support for help.
2040	The air knife pressure is too low.	Restart the instrument or contact your local support for help.
2041	The waste manifold pressure is too high.	Restart the instrument or contact your local support for help.
2042	The vacuum is too high.	Restart the instrument or contact your local support for help.
2043	The vacuum is too low.	Restart the instrument or contact your local support for help.
2044	There is an error with the {0} reagent reservoir float. The top sensor reports full while the bottom sensor reports empty.	Sensors may be stuck or a failure has occurred. Restart the instrument or contact your local support for help.
2045	The instrument was unable to empty the accumulator.	Restart the instrument or contact your local support for help.

2046	Cannot start the bulk reagent prime process.	Restart the instrument or contact your local support for help.
2048	{0} reagent prime failed, continuing to fill.	Restart the instrument or contact your local support for help.
2049	The time it took to empty the waste was {0} seconds. This is too long.	Restart the instrument or contact your local support for help.
2050	The waste cannot be purged because of a timeout issue.	Restart the instrument or contact your local support for help.
2055	Unable to switch to a waste container - it cannot be found.	Replace the waste containers or contact your local support for help.
2056	Failed to fill reagent {0}.	Replace empty reagent.
2057	{0} is empty.	Replace empty reagent.
2058	{0} waste container has an invalid fluid condition and will be disabled.	Restart the instrument or contact your local support for help.
2059	Reagent startup (checking fluid volume and RFID tags) has failed.	Restart the instrument or contact your local support for help.
2060	A leak was detected in the waste reservoir.	Contact your local support for help.
2061	A leak was detected for reagent {0}.	Contact your local support for help.
2062	Waste volume estimation exceeded {0} float condition.	Restart the instrument or contact your local support for help.
2063	Reagent startup (starting RFID reader) has failed.	Restart the instrument or contact your local support for help.
2064	Reagent startup (configuring RFID reader) has failed.	Contact your local support for help.
22000	Unable to create station: {0}.	Restart the instrument or contact your local support for help.
22001	There is an invalid station configuration.	Restart the instrument or contact your local support for help.
22002	There is an invalid device configuration. Restart the instrument or contact local support for help.	Restart the instrument or contact your local support for help.
22003	Unable to find {0} in instrument.	Restart the instrument or contact your local support for help.
22004	Operator manually enabled {0}.	Contact your local support for help.
23000	A tray is lost in {0}.	Contact your local support for help.
27000	There is an invalid IO type.	Contact your local support for help.

27001	There is an invalid process that is trying to run.	Contact your local support for help.
27002	There is an invalid Device IO Definition.	Contact your local support for help.
27003	There is an invalid Device Macro Definition.	Contact your local support for help.
27004	There is an invalid Device.	Contact your local support for help.
27005	There was an error starting a macro.	Contact your local support for help.
27006	The instrument experienced an issue with memory access.	Contact your local support for help.
27007	A failed macro operation occurred.	Contact your local support for help.
27008	Unable to update device input / output.	Contact your local support for help.
28000	System start up (starting script and code execution) has failed.	Contact your local support for help.
28001	System startup (script translation) has failed.	Contact your local support for help.
29000	Unable to obtain a reservation.	Contact your local support for help.
3000	{0} failed to Prepare for Handoff.	Contact your local support for help.
3001	{0} failed to complete tray handoff.	Contact your local support for help.
3002	{0} failed to Process Tray.	Contact your local support for help.
3003	{0} startup has failed.	Restart the instrument or contact your local support for help.
3004	{0} failed to stop processing.	Contact your local support for help.
3007	{0} failed to Abort process.	Contact your local support for help.
3008	{0} failed to detect tray.	Contact your local support for help.
3009	{0} Disable process failed.	Contact your local support for help.
3010	{0} vacuum pressure is too low.	Restart the instrument or contact your local support for help.
3011	{0} vacuum pressure is too high.	Restart the instrument or contact your local support for help.
3012	{0} vacuum pressure is detected.	Restart the instrument or contact your local support for help.

3014	{0} door close failed.	Contact your local support for help.
3015	{0} door open failed.	Contact your local support for help.
3016	{0} transport failed to go to home.	Contact your local support for help.
3017	{0} airknife failed to go to home.	Contact your local support for help.
3018	{0} door failed to go to home.	Contact your local support for help.
3019	{0} temperature is too low (below threshold).	Contact your local support for help.
3020	{0} temperature is too high (above threshold).	Contact your local support for help.
3021	{0} cannot start up with tray present.	Contact your local support for help.
3022	{0} temperature is extremely high (above extreme threshold).	Contact your local support for help.
3023	{0} carriage move error occurred.	Contact your local support for help.
3024	{0} carriage encoder read retry.	Contact your local support for help.
3025	{0} dispenser move error occurred.	Contact your local support for help.
3026	{0} dispenser encoder read retry.	Contact your local support for help.
3027	Fluid overflow detected in {0}.	Contact your local support for help.
4000	{0} Maintenance failed.	Contact your local support for help.
4001	Coverslipper failed to Complete Handoff.	Contact your local support for help.
4002	Coverslipper failed to Process Tray.	Contact your local support for help.
4003	Coverslipper failed to Recover Tray.	Contact your local support for help.
4004	Invalid cassette specified.	Contact your local support for help.
4005	Coverslip Activator reservoir failed to fill.	Contact your local support for help.
4006	Coverslip Cassette failed to eject.	Restart the instrument or contact your local support for help.
4007	Coverslipper abort process failed.	Contact your local support for help.
4008	The coverslipper calibration values are not available.	Contact your local support for help.

4009	Coverslipper disable process failed.	Restart the instrument or contact your local support for help.
4010	Coverslipper start up failed.	Restart the instrument or contact your local support for help.
4011	Coverslipper failed to detect tray.	Contact your local support for help.
4012	The coverslipper pressure is above the operating limits.	Restart the instrument or contact your local support for help.
4013	The coverslipper pressure is below the operating limits.	Restart the instrument or contact your local support for help.
4014	The coverslipper pressure is in the high warning range.	Contact your local support for help.
4015	The coverslipper pressure is in the low warning range.	Contact your local support for help.
4016	The coverslipper tray carrier is not in the correct position.	Restart the instrument or contact your local support for help.
4017	The Coverslip Cassette failed to reach the waste bin.	Contact your local support for help.
4019	A Coverslip Cassette is unable to load because there are no cassettes present. Add more cassettes.	Contact your local support for help.
4020	Coverslipper pressure is too high or too low.	Restart the instrument or contact your local support for help.
4021	The coverslipper waste bin is full. Remove empty cassettes from the waste bin.	Contact your local support for help.
4022	Coverslipper front vacuum went low during transport.	Restart the instrument or contact your local support for help.
4023	Coverslipper rear vacuum went low during transport.	Restart the instrument or contact your local support for help.
4024	Coverslipper carriage move to dispense position exceeded 0.005 inch variance.	Contact your local support for help.
4025	Coverslipper carriage move to dispense position exceeded 0.01 inch variance.	Contact your local support for help.
4026	Initial coverslip lay-down move exceeded 0.01 inch variance on the rear head.	Contact your local support for help.
4027	Initial coverslip lay-down move exceeded 0.02 inch variance on the rear head.	Contact your local support for help.

4028	Initial coverslip lay-down move exceeded 0.01 inch variance on the front head.	Contact your local support for help.
4029	Initial coverslip lay-down move exceeded 0.02 inch variance on the front head.	Contact your local support for help.
4030	Coverslipper carriage move to coverslip lay-down position exceeded 0.005 inch variance.	Contact your local support for help.
4031	Coverslipper carriage move to coverslip lay-down position exceeded 0.01 inch variance.	Contact your local support for help.
4032	Final coverslip lay-down move exceeded 0.01 inch variance on the front head.	Contact your local support for help.
4033	Final coverslip lay-down move exceeded 0.02 inch variance on the front head.	Contact your local support for help.
4034	Final coverslip lay-down move exceeded 0.01 inch variance on the rear head.	Contact your local support for help.
4035	Final coverslip lay-down move exceeded 0.01 inch variance on the rear head.	Contact your local support for help.
4036	Front coverslip pickup timed out on initial contact with sufficient vacuum.	Contact your local support for help.
4037	Front coverslip pickup timed out due to head motor stall.	Restart the instrument or contact your local support for help.
4038	Front coverslip pickup timed out due to head contact with top of cassette.	Contact your local support for help.
4039	Front coverslip pickup timed out on initial contact with insufficient vacuum.	Contact your local support for help.
4040	Coverslip head failed to enter front cassette. Load new cassette.	Contact your local support for help.
4041	Coverslipper front head motor stalled after 10 attempts. Coverslipping has stopped.	Restart the instrument or contact your local support for help.
4042	Front coverslip pickup failed after 3 attempts with 2 cassettes. Coverslipping has stopped.	Restart the instrument or contact your local support for help.
4043	Front coverslip pickup failed after 3 attempts.	Contact your local support for help.
4044	Front coverslip pickup failed. Retrying pickup.	Contact your local support for help.
4045	Front coverslip pickup failed and coverslip was placed on waste belt.	Contact your local support for help.
4046	Rear coverslip pickup timed out on initial contact with sufficient vacuum.	Contact your local support for help.

4047	Rear coverslip pickup timed out due to head motor stall.	Restart the instrument or contact your local support for help.
4048	Rear coverslip pickup timed out due to head contact with top of cassette.	Contact your local support for help.
4049	Rear coverslip pickup timed out on initial contact with insufficient vacuum.	Contact your local support for help.
4050	Coverslip head failed to enter rear cassette. Load new cassette.	Contact your local support for help.
4051	Coverslipper rear head motor stalled after 10 attempts. Coverslipping has stopped.	Restart the instrument or contact your local support for help.
4052	Rear coverslip pickup failed after 3 attempts with 2 cassettes. Coverslipping has stopped.	Restart the instrument or contact your local support for help.
4053	Rear coverslip pickup failed after 3 attempts.	Contact your local support for help.
4054	Rear coverslip pickup failed. Retrying pickup.	Contact your local support for help.
4055	Rear coverslip pickup failed and coverslip was placed on waste belt.	Contact your local support for help.
4056	The coverslipper carriage did not return to home.	Restart the instrument or contact your local support for help.
4057	The coverslipper carriage did not return to home during tray recovery.	Restart the instrument or contact your local support for help.
4058	The coverslipper front vacuum head did not return to home.	Restart the instrument or contact your local support for help.
4059	The coverslipper front vacuum head did not return to home during tray recovery.	Restart the instrument or contact your local support for help.
4060	The coverslipper rear vacuum head did not return to home.	Restart the instrument or contact your local support for help.
4061	The coverslipper rear vacuum head did not return to home during tray recovery.	Restart the instrument or contact your local support for help.
4062	The Coverslip Cassette belt exit sensor is not working.	Restart the instrument or contact your local support for help.
4063	The vacuum in the coverslipper (front vacuum pump location) is too high before coverslipper pickup.	Restart the instrument or contact your local support for help.
4064	The vacuum in the coverslipper (rear vacuum pump location) is too high before coverslipper pickup.	Restart the instrument or contact your local support for help.

4070	The vacuum in the coverslipper (front vacuum pump location) is too low.	Restart the instrument or contact your local support for help.
4071	The vacuum in the coverslipper (front vacuum pump location) is too low.	Restart the instrument or contact your local support for help.
4072	The vacuum in the coverslipper (front vacuum pump location) is too high.	Restart the instrument or contact your local support for help.
4073	The vacuum in the coverslipper (front vacuum pump location) is too high.	Restart the instrument or contact your local support for help.
4074	The vacuum in the coverslipper (rear vacuum pump location) is too low.	Restart the instrument or contact your local support for help.
4075	The vacuum in the coverslipper (rear vacuum pump location) is too low.	Restart the instrument or contact your local support for help.
4076	The vacuum in the coverslipper (rear vacuum pump location) is too high.	Restart the instrument or contact your local support for help.
4077	The vacuum in the coverslipper (rear vacuum pump location) is too high.	Restart the instrument or contact your local support for help.
4078	The vacuum in the coverslipper (front label cup location) is too low.	Restart the instrument or contact your local support for help.
4079	The vacuum in the coverslipper (front label cup location) is too low.	Restart the instrument or contact your local support for help.
4080	The vacuum in the coverslipper (front label cup location) is too high.	Restart the instrument or contact your local support for help.
4081	The vacuum in the coverslipper (front label cup location) is too high.	Restart the instrument or contact your local support for help.
4082	The vacuum in the coverslipper (rear label cup location) is too low.	Restart the instrument or contact your local support for help.
4083	The vacuum in the coverslipper (rear label cup location) is too low.	Restart the instrument or contact your local support for help.
4084	The vacuum in the coverslipper (rear label cup location) is too high.	Restart the instrument or contact your local support for help.
4085	The vacuum in the coverslipper (rear label cup location) is too high.	Restart the instrument or contact your local support for help.
4086	The vacuum in the coverslipper (front center cup location) is too low.	Restart the instrument or contact your local support for help.
4087	The vacuum in the coverslipper (front center cup location) is too low.	Restart the instrument or contact your local support for help.

4088	The vacuum in the coverslipper (front center cup location) is too high.	Restart the instrument or contact your local support for help.
4089	The vacuum in the coverslipper (front center cup location) is too high.	Restart the instrument or contact your local support for help.
4090	The vacuum in the coverslipper (rear center cup location) is too low.	Restart the instrument or contact your local support for help.
4091	The vacuum in the coverslipper (rear center cup location) is too low.	Restart the instrument or contact your local support for help.
4092	The vacuum in the coverslipper (rear center cup location) is too high.	Restart the instrument or contact your local support for help.
4093	The vacuum in the coverslipper (rear center cup location) is too high.	Restart the instrument or contact your local support for help.
4094	The vacuum in the coverslipper (front distal cup location) is too low.	Restart the instrument or contact your local support for help.
4095	The vacuum in the coverslipper (front distal cup location) is too low.	Restart the instrument or contact your local support for help.
4096	The vacuum in the coverslipper (front distal cup location) is too high.	Restart the instrument or contact your local support for help.
4097	The vacuum in the coverslipper (front distal cup location) is too high.	Restart the instrument or contact your local support for help.
4098	The vacuum in the coverslipper (rear distal cup location) is too low.	Restart the instrument or contact your local support for help.
4099	The vacuum in the coverslipper (rear distal cup location) is too low.	Restart the instrument or contact your local support for help.
4100	The vacuum in the coverslipper (rear distal cup location) is too high.	Restart the instrument or contact your local support for help.
4101	The vacuum in the coverslipper (rear distal cup location) is too high.	Restart the instrument or contact your local support for help.
4102	The vacuum in the coverslipper (front trough location) is too low.	Restart the instrument or contact your local support for help.
4103	The vacuum in the coverslipper (front trough location) is too low.	Restart the instrument or contact your local support for help.
4104	The vacuum in the coverslipper (front trough location) is too high.	Restart the instrument or contact your local support for help.
4105	The vacuum in the coverslipper (front trough location) is too high.	Restart the instrument or contact your local support for help.
4106	The vacuum in the coverslipper (rear trough location) is too low.	Restart the instrument or contact your local support for help.

4107	The vacuum in the coverslipper (rear trough location) is too low.	Restart the instrument or contact your local support for help.
4108	The vacuum in the coverslipper (rear trough location) is too high.	Restart the instrument or contact your local support for help.
4109	The vacuum in the coverslipper (rear trough location) is too high.	Restart the instrument or contact your local support for help.
4110	The Coverslip Activator shield failed to move.	Restart the instrument or contact your local support for help.
4111	Coverslipper motor {0} move failed.	Contact your local support for help.
4112	Unable to run Coverslip Cassette belt while ejecting a cassette.	Restart the instrument or contact your local support for help.
4113	An unopened Coverslip Cassette is detected in the front position. Remove and then open the cassette before reinserting into the coverslipper.	Contact your local support for help.
4114	An unopened Coverslip Cassette is detected in the rear position. Remove and then open the cassette before reinserting into the coverslipper.	Contact your local support for help.
4115	Recovery from unopened Coverslip Cassette failed.	Restart the instrument or contact your local support for help.
4116	Coverslipper failed to transition to standby.	Restart the instrument or contact your local support for help.
5000	Slide Dryer failed to prepare for handoff.	Contact your local support for help.
5001	Slide Dryer failed to complete handoff.	Contact your local support for help.
5002	Slide Dryer failed to process tray.	Contact your local support for help.
5003	Slide Dryer initialization failed.	Contact your local support for help.
5004	No tray is detected in Slide Dryer.	Contact your local support for help.
5005	Slide Dryer temperature is out of range.	Restart the instrument or contact your local support for help.
5006	Slide Dryer temperature is out of range.	Restart the instrument or contact your local support for help.
5007	Slide Dryer blower speed is inadequate, attempting recovery.	Contact your local support for help.

5008	Slide Dryer could not reach operating temperature.	Restart the instrument or contact your local support for help.
5009	Slide Dryer heater is too hot (over temperature).	Restart the instrument or contact your local support for help.
5010	Slide Dryer air temperature sensor failed.	Restart the instrument or contact your local support for help.
5011	Slide Dryer heater temperature sensor failed.	Restart the instrument or contact your local support for help.
5012	Slide Dryer could not reach the correct blower speed.	Contact your local support for help.
5014	The slide dryer door failed to open and is attempting recovery.	Contact your local support for help.
5015	The slide dryer door failed to open.	Contact your local support for help.
5016	The slide dryer door failed to close and is attempting recovery.	Contact your local support for help.
5017	The slide dryer door failed to close.	Contact your local support for help.
5018	The slide dryer door is not in the correct position. Restart the instrument or contact your local support for help.	Restart the instrument or contact your local support for help.
5019	No tray is detected in the Slide Dryer after the door is closed.	Contact your local support for help.
5020	Slide Dryer tray presence stuck on.	Contact your local support for help.
5021	Slide Dryer failed to stop processing.	Contact your local support for help.
5555	AC voltage detected by the power management and distribution controller is out of range.	Contact your local support for help.
6000	Curing Oven failed to prepare for handoff.	Contact your local support for help.
6001	Curing Oven failed to complete handoff.	Contact your local support for help.
6002	Curing Oven failed to process tray.	Contact your local support for help.
6003	The curing oven's process could not start.	Contact your local support for help.
6004	The curing oven's heater sensor is reporting the incorrect temperature.	Restart the instrument or contact your local support for help.
6005	The curing oven's heater sensor is reporting the incorrect temperature.	Restart the instrument or contact your local support for help.

6006	The curing oven's heater sensor is reporting the incorrect temperature.	Restart the instrument or contact your local support for help.
6007	The curing oven's blower speed is too low. The instrument is trying to fix it.	Contact your local support for help.
6008	The curing oven's sensor is reporting a lower than normal temperature.	Restart the instrument or contact your local support for help.
6009	The curing oven's sensor is reporting a temperature that is above normal.	Restart the instrument or contact your local support for help.
6010	The curing oven's air sensor is reporting the incorrect temperature.	Restart the instrument or contact your local support for help.
6011	The curing oven's heater sensor is reporting the incorrect temperature.	Restart the instrument or contact your local support for help.
6012	The curing oven could not reach the correct blower speed.	Contact your local support for help.
6014	The door to the curing oven would not open. The instrument is trying to open it.	Contact your local support for help.
6015	The door to the curing oven would not open.	Restart the instrument or contact your local support for help.
6016	The door to the curing oven would not close. The instrument is trying to open it.	Contact your local support for help.
6017	The door to the curing oven would not close. The instrument is trying to open it.	Contact your local support for help.
6018	The curing oven will not shut down.	Restart the instrument or contact your local support for help.
7000	The slide ID process failed.	Contact your local support for help.
7001	The barcode scanner failed.	Contact your local support for help.
7002	The verification of the barcode scanner configuration failed.	Contact your local support for help.
7003	The verification of the barcode scanner failed.	Contact your local support for help.
8001	During recovery, the portal door closed.	Restart the instrument or contact your local support for help.
8002	The portal door failed to open.	Contact your local support for help.
8003	The portal door failed to close.	Contact your local support for help.
8004	The tray is not properly loaded in portal bay {0}. Reinsert tray correctly.	Contact your local support for help.
13002	Error occurred creating system backup {0}.	Contact your local support for help.

13003	Attempted to execute backup/restore operation, while existing backup/restore operation in progress.	Contact your local support for help.
13004	Error occurred restoring system from backup.	Contact your local support for help.
13007	System backup completed. Backup was copied to fallback output location because copying to primary location failed: {0}	Contact your local support for help.
13008	System backup completed. Old backup files could not be purged.	Contact your local support for help.
27009	Calibration time stamp command {0} failed.	Contact your local support for help.
31000	Update file not found for module controller update.	Contact your local support for help.
31001	Erase failed on module controller update.	Contact your local support for help.
31002	Write failed on module controller update.	Contact your local support for help.
31003	Unrecoverable bootloader checksum mismatch on module controller update.	Contact your local support for help.
31004	Successful recovery from bootloader checksum mismatch on module controller update.	Contact your local support for help.

Technical Specifications

General

Automation	Fully automated baking, staining, coverslipping, and curing of H&E specimens
Slide transportation	20 slides per tray
Throughput	Approximately 180-200 slides per hour, depending on the protocol
Consumables	Nine reagents plus coverslips
Slides	**NOTE** Charged slides are not necessary.
External DI water supply	Not necessary
Lab-provided reagents	None **NOTE** The VENTANA HE 600 system accepts only reagents supplied by Roche Diagnostics.
Configuration	Floor unit

Physical

Size (H x D x W)	79.5 x 27.5 x 56 in (202 x 69 x 142 cm)
Weight	1370 lb (621 kg)—direct-to-drain system 1422 lb (645 kg)—waste collection system
Venting (optional but recommended)	60-70 CFM (1222-1426 ft/min) The ventilation connection should be within 15 feet of the top of the instrument. Refer to site requirements documentation for further ventilation requirements.

Electrical

	U.S. and Canada	Japan	Europe
Voltage	120V	100V	230V (240V exceptions do occur)
Peak Power	5 kW	5 kW	5 kW
Average Power	3.5 kW	3.5 kW	3.5 kW
Frequency	50/60 Hz	East Japan 50 Hz West Japan 60 Hz	50 Hz
General power cords and transformers (Consult your local service center for further details regarding your installation needs.)	Transformer required if 230V not available	Transformer required if 230V not available	System supplied with standard power cord, plugs, and sockets to allow a standard 230V +/- 10%, 30A installation worldwide when 230V is available.

NOTE The system has some limited capability to function outside the specified voltage and frequency range listed above. It has no power storage capability, and extreme voltage fluctuations in the supply may result in the system going offline until voltage comes back into regulation. In that case, the system will automatically reinitialize and recover normal operation. If the operator wants uninterrupted operation, the system must be supplied with an Uninterruptible Power Supply source with the listed capability.

NOTE The 5kW power rating shown above is a peak power draw for the system. The 30A, above and elsewhere in this manual is the rating for the electrical power cord and main circuit breaker, and represents the worst-case current that can exist before the system's circuit breaker will operate.

Communication

Recommended Connectivity	Standard Category 5, RJ-45 network port located within 14 ft (426.7 cm) of the left side of the system; with network port with TCP/IP ports 80 and 443 open

NOTE: Neither the USB or the Ethernet cable should be longer than 9.84 feet (3 meters) to help minimize electromagnetic interference.

Environmental Requirements

Operating Temperature Range	15°C to 32°C (59°F to 90°F). The system may be unable to maintain proper reaction temperature if laboratory ambient temperature exceeds the specified temperature range.
Operating Humidity	10% - 80%, non-condensing
Location	Maximum altitude 6,000 ft (1828 m) above sea level

Barcodes

The VENTANA HE 600 system is able to identify specimens by barcode. The barcode reader has been optimized to decode the following barcodes:

Code 128

Interleaved 2 of 5

Data Matrix

PDF 417

QR Code

The barcode reader is also capable of decoding (though the system is not optimized for) the following barcode symbologies.

One-Dimensional Symbologies

UPC/EAN	ISBT 128	Code 11	Matrix 2 of 5
Bookland EAN	Code 39	Discrete 2 of 5	Korean 3 of 5
UCC Coupon Code	Trioptic Code 39	Codabar	Inverse 1D
ISSN EAN	Code 32	MSI	GS1 DataBar
GS1-128	Code 93	Chinese 2 of 5	Composite Codes

Two-Dimensional Symbologies

MicroPDF417	MicroQR	Aztec Inverse
Data Matrix Inverse	QR Inverse	
Maxicode	Aztec	

NOTE:

- Barcodes must have an element size greater than 5 millimeters and must be printed at a resolution of 300 dpi or higher.
- Slides on the system must use only one type of barcode.
- Barcodes must be 1mm away from the tray clip for the barcode reader to read the barcode.

Slides

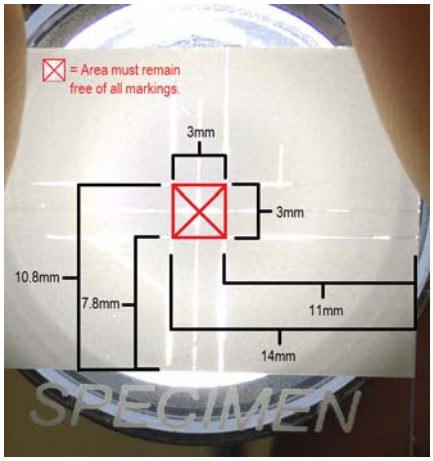
- 25mm x 75mm or 26mm x75mm (ISO-Certified)
- Slides must contain a label or an opaque painted end for proper slide identification or recognition

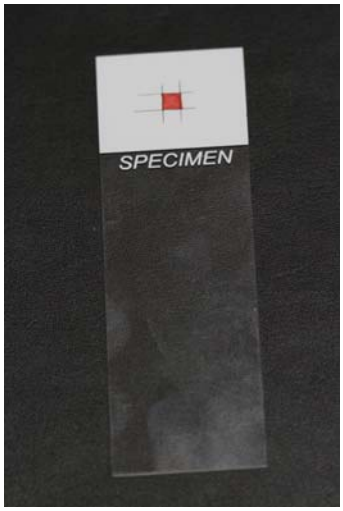
NOTE If possible, avoid using slides with green labels or a green-painted end, as the slide identification technology struggles with identifying the color green.

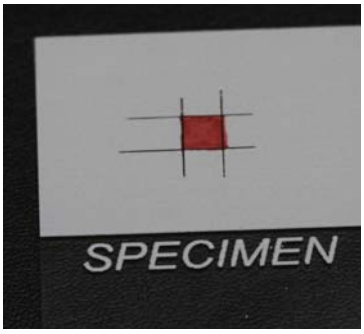
Slide Labels

If the barcode reader is not used, the VENTANA HE 600 system uses a slide detect option to verify where slides are located on each tray. The slide detect option reads the frosted or opaque area on each slide. Without a barcode, no slide will be detected by the slide detect unless the slide has a frosted or opaque area.

To achieve appropriate barcode and slide detect reading, it is necessary to leave the center of the label or frosted area clear of any markings. See examples below to find the area to avoid.







NOTE The system slide detect is calibrated only for a label and a frosted or opaque painted-end slide that is not green.

The system slide detect beam may be unable to see the light reflecting off extraneous markings and thus consider the position empty and skip processing the particular slide.

IMPORTANT If reformatting the information on the label end is not an option, contact your Roche Customer Support as it may be necessary to adjust the slide detect location.

Slide Archival

VENTANA HE 600 stained slides can be archived 24 hours after coverslipping.

IMPORTANT Archive slides at room temperature in a dry, dark environment.

Delivery Access

All entryways and doors leading from the receiving area to the final system location must be wider than 1.72 meters (28 inches) and higher than 2.03 meters (80 inches).

Receptacle Location

The location of the electrical receptacle must be within 8 feet (2.44 meters) of the left side of the system.

Waste Management Requirements

Waste must be managed in accordance with all applicable national, state and local regulations.

The VENTANA HE 600 system is designed to send waste directly down the drain. The location of the drain must be within 15 feet (4.57 meters) of the right side of the system and not exceed 3 feet (.91 meters) in height.

System Leveling

The VENTANA HE 600 system must be leveled after:

- The system has been placed in its planned footprint
- Venting (recommended) has been installed
- The system is moved in any way.

A Roche Service Representative will ensure proper system leveling at the time the system is installed.

Fixative Specifications

Tissue should be fixed according to each laboratory's current process. The following fixatives were tested during the development of the VENTANA HE 600 system and are acceptable.

Fixative	Manufacturer	Ingredients
Acid Zinc Formalin	Newcomer/Supply	Formalin, glacial acetic acid, zinc chloride, distilled water
Bouin's Solution	Richard-Allen Scientific	picric acid, formaldehyde, acetic acid
EverFix	Ever Scientific	halogenated carboxylic acid, inorganic metallic salt, aldehydes
Fix-All	Surgipath	DI water, isopropanol, formaldehyde, barium chloride, FDC Yellow #5
Shandon Glyo-Fixx	Thermo Electron Co	ethanol, glyoxal, methanol, isopropanol, acetic acid
GTF	StatLab	ethanol, glyoxal, buffer, water
IBF	Surgipath	DI water, isopropanol, formaldehyde, methanol, barium chloride, eosin (for tint)
10% NBF	BDH/VWR	formaldehyde solution, methanol, disodium and monosodium phosphate buffer
O-Fix	Surgipath	alcohol, formalin, acetic acid
Stat-Fix	StatLab	formaldehyde, methanol, ethanol
Z-5 (aka Z-Fix)	Anatech	isobutyl ketone, isopropanol, formaldehyde, ionized zinc, buffer, indicator
Zinc Formalin	Polysciences, Inc.	acetic acid, acetic sodium salt, formaldehyde, water, zinc chloride

Disposal at End of Useful Life

The VENTANA HE 600 system is not intended to process infectious or potentially infectious material, and the reagents do not contain infectious or potentially infectious materials of human or animal origin. However the system will reside in laboratories which may be exposed to biological hazards. Therefore disposal of the system at end of life must be carefully controlled. Please contact your local Roche Service Representative at end of life for advice.

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