VENTANA HE 600 system

User Guide
1019879EN v1.0
Software version 1.10

Publication information

Publication version	Software version	Revision date	Change description
1	1.10	November 2021	First version of the user guide with this part number. Added updates for software version 1.10 and associated hardware updates. Updated front matter for IVDR compliance. Updated List of specifications section with revised instrument measurements.

Revision history

Edition notice

This publication is intended for operators of the VENTANA HE 600 system.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **User Guide** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Configuration information

In addition, the **User Assistance** includes videos and a hardware explorer.

⚠ General attention

To avoid serious or fatal personal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

⚠ General attention

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

- Pay particular attention to all safety notices.
- Always follow the instructions in this publication.
- Do not use the software in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

⚠ Incident reporting

- Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

Training

Do not carry out operation tasks or maintenance actions unless you have received training. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Images

The images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screen shots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty

Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche Service representative, or perform such updates with their assistance.

Copyright

License information

System software is protected by contract law, copyright law, and international treaties. The system contains a user license and only authorized users may access the software and use it. Unauthorized use and distribution may result in civil and criminal penalties.

Open Source and Commercial Software

VENTANA HE 600 system software may include components or modules of commercial or open-source software.

This open source and commercial software and VENTANA HE 600 system software as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the user manual and labeling.

Please note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to the VENTANA HE 600 system software. For further information on the intellectual property and other warnings, as well as licenses pertaining to the software programs included in VENTANA HE 600 system software, refer to the Appendix.

Open source license notifications and notices (245)

Trademarks

The following trademarks are acknowledged:

VENTANA, CAREGIVER, VANTAGE, and VENTANA HE are trademarks of Roche.

All other trademarks are the property of their respective owners.

Feedback

Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals

The VENTANA HE 600 system is manufactured and compliant to the following applicable international standards:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements.

IEC 61010-2-010:2014 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 61010-2-081:2015 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.

IEC 61010-2-101:2015 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use—EMC requirements - Part 1: General requirements.

EN 62311:2008 - 1330 NFRQ licensing Radio Frequency (RF) radiators listed in Section 10 of the Roche System Component Standard (Document 4800019 Reg 001 version 05).
EN 301 489-3 V1.4.1 (2002-08) 1330 NRFQ - RF licensing
EN 302 291-1 V1.1.1 (2005-07) 1330 NRFQ - RF licensing
EN 302 291-2 V1.1.1 (2005-07) 1330 NRFQ - RF licensing
EN 301 489-1 V1.9.2 (2011-09) 1330 NRFQ - RF licensing

EN 61326-2-6:2013 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.

VENTANA HE 600 system complies with the Restriction of Hazardous Substances (RoHS) EU Directive 2015/863.

Compliance with the applicable regulation(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

IVD — For *in vitro* diagnostic use.

CE — Complies with the provisions of the applicable EU regulations.

C SA US — Issued by CSA Group for Canada and the US.

FCC information

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.

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

Contact addresses

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Roche affiliates

A list of all Roche affiliates can be found at:

www.roche.com/about/business/roche_worldwide.htm

eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service on Roche DiaLog:

www.dialog.roche.com

For more information, contact your local affiliate or Roche Service representative.

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Table of contents

Intended use

The VENTANA HE 600 system is intended to automatically stain histologic sections of formalin-fixed, paraffin-embedded (FFPE) specimens on microscope slides, with hematoxylin and eosin. The system fully automates the process of baking, deparaffinization, staining, and coverslipping of specimens on microscope slides. The VENTANA HE 600 system is intended for use in the anatomic pathology (AP) laboratory environment by trained laboratory personnel who are knowledgeable in histology processes and have basic computer operation skills.

The VENTANA HE 600 system is intended for in vitro diagnostic (IVD) use.

Symbols and abbreviations

Product names

The following product names and descriptors are used in this publication.

Product name	Descriptor
VENTANA HE 600	system
VENTANA HE 600	user interface
VENTANA HE 600	system software
VENTANA HE 600	Wash
VENTANA HE 600	Hematoxylin
VENTANA HE 600	Bluing
VENTANA HE 600	Eosin
VENTANA HE 600	Organic Solution
VENTANA HE 600	Differentiating Solution
VENTANA HE 600	Transfer Fluid
VENTANA HE 600	Cleaning Reagent
VENTANA HE 600	Cleaning Solution
VENTANA HE 600	Coverslip Activator

Product names

Symbols used in the publication

Symbol	Explanation
•	List item.
	Related topics containing further information.
	Tip. Extra information on correct use or useful hints.
▸	Start of a task.
	Extra information within a task.
→	Result of an action within a task.

Symbols used in the publication

Symbol	Explanation
	Frequency of a task.
	Duration of a task.
	Materials that are required for a task.
	Prerequisites of a task.
	Topic. Used in cross-references to topics.
	Task. Used in cross-references to tasks.
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.
	Equation. Used in cross-references to equations.
	Code example. Used in code titles and cross-references to codes.
	Search. Used on the search tab.
	Table of contents. Used on the table of contents tab.
	System explorer. Used on the system explorer tab.
	History. Used on the history tab to show previously viewed topics.
	Favorites. Used on the favorites tab and on the content panel.
	Enlarge. Button used on images.

Symbols used in the publication

Symbols used on product

Symbol	Explanation
GTIN	Global Trade Item Number.
SN	Serial number.
	Date of manufacture.
	Manufacturer.
EC REP	Authorized representative in the European Community.

Symbols used on product

Symbol	Explanation
	Indicates the entity importing the medical device into the European Union.
	Complies with the Restriction of Hazardous Substances (RoHS) EU Directive 2015/863.
	Unique device identifier.

Symbols used on product

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
AFM	Automated fluidics module
ANSI	American National Standards Institute
AP	Anatomic pathology
CFM	Cubic feet per minute
CSA	Canadian Standards Association
CSC	Customer support center
CSV	Comma-separated values
DOC	Department of Communications
dPGPE	Dipropylene glycol propyl ether
EC	European Community
EN	European standard
FCC	Federal Communications Commission
H&E	Hematoxylin and eosin
IEC	International Electrical Commission
IHC	Immunohistochemistry
ISH	In situ hybridization
ISO	International Organization for Standardization
IT	Information technology
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
LIS	Laboratory information system
PDF	Portable document format
PHI	Personal healthcare information
PPE	Personal protective equipment
QR code	Quick response code
RFID	Radio-frequency identification
RJ45	Registered jack 45
SDS	Safety data sheets
TCP/IP	Transmission control protocol/internet protocol

Abbreviations

Abbreviation	Definition
UA	User Assistance
UPS	Uninterruptible power supply
USB	Universal serial bus

Abbreviations

What is new in publication version 1.0

This section describes the changes between the *VENTANA HE 600 system User Guide* for software version 1.9.5 (1019125EN v1.0) and *VENTANA HE 600 system User Guide* for software version 1.10 (1019879EN v1.0).

Regulatory changes

Updated the following sections:

- Added the Incident reporting section.
- Updated the Images section.
- Updated the Approvals section.
- Updated the List of system specifications section.
- Updated the Supported materials section.

- Publication information (2)
- Contact addresses (7)
- Intended use (11)
- Symbols and abbreviations (11)
- List of system specifications (72)
- Supported material (75)

General changes

The following changes were made throughout the *VENTANA HE 600 system User Guide Revision 1*.

- Updated the trademarked names Caregiver remote instrument support, VENTANA HE 600 system, and Vantage workflow solution.
- Revised photos of the coverslipper fluid guard.

New topics

The following topics were added for the *VENTANA HE 600 system User Guide Revision 1*.

- Safety information for lasers (46)
- Opening User Assistance (81)
- Exploring the system and playing videos (85)
- User Management overview (167)
- Managing passwords and user accounts (173)
- Using password-protected functions (182)

Revised topics

The following topics and sections were revised for the *VENTANA HE 600 system User Guide Revision 1*.

- Data security (36)
- About the staining system (55)
- About the navigation toolbar and notification area (64)
- About the user interface (66)
- About Caregiver remote instrument support (70)
- About Vantage workflow solution (71)
- List of supported reagents and consumables (75)
- List of supported barcodes (77)
- About supported slide types (78)
- Searching in the User Assistance (83)
- List of videos in the User Assistance (87)
- VENTANA HE 600 system Best Practices (95)
- Loading slides onto a tray (103)
- Shutting down the software and initiating the cleaning cycle (121)
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- Loading coverslip cassettes (136)
- Unloading used coverslip cassettes (137)
- Replacing the coverslip activator (139)
- Emptying waste containers (144)
- About report types (146)
- Creating and printing reports (147)
- Creating and modifying staining protocols (151)
- Updating the instrument name or institution (156)
- Setting up Scheduled Start (158)
- Changing Sleep settings (161)
- Enabling database backup (162)
- Testing connectivity settings (164)
- Setting audible alerts (165)

User Assistance

The VENTANA HE 600 system user documentation is available in portable document format (PDF) as well as an interactive help system (User Assistance). The User Assistance contains unique features, which include the following:

- Hardware explorer
- Videos
- Tray recovery troubleshooter

Safety

Safety

In this chapter 1

Introduction

⚠ General attention

To avoid serious or fatal personal injury, read this publication thoroughly before you use the instrument.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.

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

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6-2011 standard. Familiarize yourself with the following meanings and icons:

⚠ Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, personal injury, or death.

These symbols and signal words are used for specific hazards:

⚠ WARNING

Warning...

- ...indicates a hazardous situation that, if not avoided, could result in death or serious personal injury.

⚠ CAUTION

Caution...

- ...indicates a hazardous situation that, if not avoided, could result in minor or moderate personal injury.

NOTICE

Notice...

- ...indicates a hazardous situation that, if not avoided, may result in damage to the system.

Important information that is not safety relevant is indicated with the following icon:

Tip...

...indicates additional information on correct use or useful tips.

Safety training

All operators must be trained in the safe use of the VENTANA HE 600 system.

After training, operators must demonstrate an 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 (SDS) for instructions for safe handling and disposal of reagents used with the instrument.
- 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.

Safety precautions

⚠ **To avoid serious or fatal personal injury, read and comply with the following safety precautions.**

In this section

About operator qualification

Insufficient training to operate the instrument

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation and maintenance unless Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche service representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow good laboratory practices, especially when you work with biohazardous material.

About safe and proper use of the system

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items:
  - Eye protection with side shields
  - Fluid-resistant laboratory coat
  - Approved lab gloves
  - Face shield if there is a chance of splashing or splattering
- Follow good laboratory practices and regularly change lab gloves to minimize the risk of contamination (especially after contact with waste or sample material).

Regular cleaning

To help prevent inaccurate results and unsafe operation of the system:

- Follow good laboratory practices for cleaning.
- Ensure that the laboratory is regularly cleaned and is maintained in an orderly manner.
- Use only approved substances for cleaning. Contact Roche Service with questions regarding the compatibility of cleaning substances with the system.

List of allowed cleaning substances (78)

Errors in installation

Only trained Roche service representatives may install the system.

- Roche personnel are responsible for appropriately installing the VENTANA HE 600 system. Roche should be consulted if any adjustments are needed after the initial installation. Roche relinquishes responsibility for any performance issues that may arise out of any unauthorized alternations from the approved installation.

Exchange or removal of parts

Unauthorized exchange or removal of system parts can damage the system or stop it from functioning correctly.

- Do not exchange or remove any part of the instrument.
- Leave replacement of instrument parts to trained Roche service representatives.

Unsuitable environmental conditions

Operation outside of the specified ranges may lead to incorrect results or malfunction of the system.

- Use the system indoors only, and avoid heat and humidity outside of the specified range.
- Make sure that the system's ventilation openings always remain unobstructed.
- To maintain the environmental conditions of the system, perform maintenance in accordance with the specified intervals.
- Keep the operating instructions undamaged and available for use. Operating instructions must be easily accessible for all users.

Environmental conditions (74)

Non-approved spare parts

Use of non-approved spare parts or devices may result in malfunction of the system and may render the warranty null and void.

- Use only spare parts and devices approved by Roche Diagnostics.

Non-specified third-party software

Installation of third-party software is not approved by Roche Diagnostics and might result in malfunction.

- Do not install third-party software without consulting your information technology (IT) department.
- See the “Warranty” topic for more information.

Warranty (3)

Non-specified consumables

Use of non-specified consumables can lead to incorrect results.

- Do not use consumables that are not intended for use with the VENTANA HE 600 system.

Miscellaneous safety precautions overview

Power interruption

A power failure or momentary drop in voltage can interrupt system operation or lead to data loss.

- It is recommended to use an uninterruptible power supply (UPS).
- Ensure regular maintenance of the UPS.
- Perform regular backup of results.

Power ratings (73)

System-performed maintenance (188)

Damage in transit

- Do not attempt to relocate or transport the system.
- Leave relocation and transportation to Roche service representatives.

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious personal injury.

- Before operating the system, read the warning messages carefully.

In this section

Electrical safety

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 remove trays, read the instructions for recovering trays in the “Errors and troubleshooting” chapter.

Errors and troubleshooting (191)

The system’s operating voltage is set during installation and can be changed only by an approved Roche service representative.

Electric shock

Removing the covers of electronic or electrical equipment increases the risk of exposure to electric shock because there are high-voltage parts inside.

- Do not attempt to work on any electronic or electrical equipment.
- Do not remove any cover of the system except those covers specified in the instructions.
- Only Roche service representatives may install, service, and repair the system.
- If the blue transportation system door or the garage access door needs to be opened for manual tray retrieval, the system immediately stops the tray transport system and advises to turn off power. Turn off the power to ensure there is no possibility of electrical shock when retrieving the trays.

Smoke due to electrical malfunction

Electrical malfunction can result in the emission of hazardous smoke. Inhaling smoke emitting from the instrument can lead to personal injury.

- If you see smoke coming from the instrument, do the following:
  - Avoid inhaling
  - Disconnect the instrument from power the supply
  - After contacting the appropriate emergency service, contact a Roche service representative.

Waste

Environmental harm

The system generates liquid waste. 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. Improper disposal may contaminate the environment.

- Dispose of waste in accordance with the local regulations.

Disposal information (47)

Instrument 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.

Moving an instrument can be dangerous to inexperienced users

Injuries and accidents can occur if you move an instrument without having the experience of a service technician.

- Only Roche service representatives should move the instrument.
- 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.

Instrument moving parts

Personal injury and infection due to sharps, rough edges, and/or moving parts

Good Laboratory Practice can reduce the risk of injury. Be aware of your laboratory environment, well-prepared, and follow the instructions for use. Some areas of the instrument may have sharps, rough edges, and/or moving parts. Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument. Your personal protective equipment should be appropriate to the degree and type of potential hazard, e.g. suitable lab gloves, eye protection, lab coat, and footwear.

Caution messages

⚠ List of caution messages

- Before operating, read the caution messages carefully. Failure to observe them may result in minor or moderate personal injury.

In this section

Burns due to hot surfaces

Hot surfaces inside

Contact with some surfaces may cause burns.

- Avoid contact with hot surfaces inside the instrument indicated with a warning label.
- No one but a Roche service representative should remove the nearby air filter or 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).

Mechanical safety

Damaged touch screen monitor

Damage to the touch screen monitor can expose sharp edges, which can cause personal injury if touched.

- Avoid touching the touch screen monitor if it is visibly damaged.
- Contact Roche support.

Touch screen monitor

Risk of personal injury when moving the touch screen monitor towards the system housing. Your hand can be pinched between the touch screen monitor and the housing.

- Use caution when moving the touch screen monitor in front of the system housing.
- Keep your fingers away from gap between the touch screen monitor and system housing when moving the touch screen monitor towards the housing.

Reagent access, coverslipper access area, and waste container doors

Risk of personal injury by colliding with an open reagent access, coverslipper access area, or waste container door.

- Close the reagent access drawer after replacing reagents.
- Close the waste container door after removing or replacing waste containers.
- Close the coverslipper access area door after handling coverslip cassettes, replacing coverslip activator, or disposing of coverslip waste.

Reagents and other working solutions

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 personal protective equipment (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.

Skin inflammation or injury

Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- When you handle reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate personal protective equipment.
- Observe the instructions given in the package insert for the test.
- Observe the information given in Material Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If reagents, detergents, or other cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water. Consult a medical professional if needed.
- During system operation, reagent drip traps may collect reagent. Thus, routine precaution should be observed.
- When working with any reagent, reagent hat, or reagent container, take appropriate precautions.
- Open reagent containers carefully.
- Avoid unnecessary contact with reagents and reagent containers.
- Always wear approved eye protection, gloves, and protective clothing when handling reagents, reagent containers, reagent hats, and slide trays.
- 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.
- 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.

Adverse impact to staining due to incorrect handling of reagents

Incorrect handling of reagents or other consumables may adversely affect staining.

- Do not use reagents that were exposed to heat, cold or to light for an extended time.
- The system does not allow the use of expired reagents.
- Adhere to the storage conditions defined in the package insert for the reagents, controls, and consumables.
- Do not manipulate reagents in any way.
- Use only Roche-supplied reagents.

Electromagnetic interference

Electromagnetic interference

Strong electromagnetic fields (originating from unshielded radio frequency sources) can interfere with proper operation and may lead to malfunction of the system and incorrect results.

- This instrument was designed and tested to IEC 61326-2-6 and complies with the emission and immunity requirements.
- Do not use this system near sources of strong electromagnetic fields because these fields can interfere with proper operation.
- Evaluate the electromagnetic environment before you operate the system.
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment this equipment may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Wireless interference

Wireless devices in the instrument may lead to malfunction.

- Do not leave mobile phones or other wireless devices inside the instrument.

Data security

Data loss or unavailability of the system due to malicious software or unauthorized system access

Malicious software or unauthorized system access can result in data loss or system unavailability.

To avoid infection by malicious software or the unauthorized access and misuse of the system, the following recommendations are essential:

- Do not install and/or execute any other software on the system.
- Make sure other computers and services on the network (for example, the LIS, archiving share, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from networks as well as measures that ensure that the connected network is free of malicious code.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, and so on).
- Make sure that system backup and archive files are protected from any unauthorized access and disaster, this includes: remote storage location; disaster discovery sites; secure transfer of backup files.
- If possible, use a firewall to restrict network traffic.

⚠ CAUTION

USB flash drives

USB flash drives can be used for several kinds of backups and restores. Wrong handling of a USB flash drive may result in data loss or malfunction of the instrument.

- Use only USB flash drives that are encrypted, tested, and installed by your local Roche support.
- At any one time only one USB device can be in use. Before inserting a USB flash drive, check that no other USB device is inserted.
- Before removing a USB flash drive, choose the Eject button in Windows.
- To prevent a virus from infecting the software, use the USB flash drive exclusively on the instrument. Do not store other data on this USB flash drive.

Roche provided firewall

To improve the security of Roche systems, a Roche provided firewall or customer provided firewall should be installed. All new systems connected to the customer network may be installed with the hardware firewall provided by Roche.

P

- Installation of the Roche provided firewall is mandatory. A Roche provided firewall is an effective method for adding an additional security layer between Roche products and the customer laboratory network.
- The use of the Roche provided firewall requires you to assign static IP addresses to Roche computers. The static IP addresses are reserved in order for the Roche computer to work properly.
- Do not move, unplug, or reconfigure the Roche provided firewall. Contact Roche support for assistance.

Notices

⚠ List of notices

Failure to observe the notices may result in damage to the system.

- Before operating, read the notices contained in this summary carefully.

Circuit breakers

Improper use may result in damage to the system.

- If the circuit breakers trip, do not attempt to operate the system before contacting Roche support.

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.

- If spills of the coverslip activator occur, ensure there are no open flames in the vicinity.
- Wipe up spills immediately to avoid slipping.
- Place mats around the system to avoid risk of slipping in the event of reagent spills or leaks.
- Place caps on waste containers before removing them from the system.

Leaks

A leak can affect the instrument performance and cause injuries if the liquid is in areas of traffic.

- Contain and wipe up leaks immediately.
- Place mats around the instrument to avoid risk of slipping in the event of reagent leaks.

Opening the blue transportation system door or garage access door

Possible tissue damage or tissue staining deficiencies.

- Only open the blue transportation system door or the garage access door whenever a manual tray retrieval is required. Opening either door immediately stops the tray transport system and arrests normal operation of the instrument. There will also be some higher risk of electrical shock. See the Electrical safety warning information for more information.

Electrical safety (29)

Incorrect power supply voltage

Severe damage may occur to the system if it is connected to an incorrect power supply voltage.

- 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.
- If the power cord needs to be replaced, it must be replaced with a Roche-approved cord rated for 30 amps.
- Observe good electrical safety practices.

Safety labels on the system

In this section

List of safety labels on the system

Warning labels are placed on the system to draw your attention to areas of potential hazard. Listed below are labels and the definitions according to the location on the system.

In addition to the safety labels on the system, there are safety notes in the corresponding parts of the user documentation.

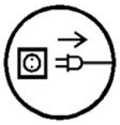
Only Roche service personnel are to replace damaged labels. For replacement labels, contact your local Roche representative.

The following symbols and formats are used to alert to a potential hazard.

General warning
Potential hazards located near this label may lead to death or serious personal injury.
Refer to the user documentation for instructions on safe operation.

Hot surface
The area near this label may be hot.
To avoid burns, do not touch this area.

Electrical
If you access a part of the system marked with this label, contact with electrical components may cause an electric shock.
Refer to the user documentation for instructions on safe operation.



Disconnect power before servicing. This symbol is at the back of the system near the power cord. It is to remind Roche service representatives to disconnect the power cord before servicing the system.

The safety messages give more detailed information about potentially hazardous situations that may arise during daily operation or when carrying out maintenance actions.

When working with the system, observe both the safety labels on the system and the safety messages in the user documentation.

Location of safety labels on the system

On the system itself, only the general warning symbol (with exclamation mark), the hot surface warning (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 are not visible to the operator.

A Waste management module

B Transportation system module

System (front, closed view)

Safety labels on the top of the transportation system module (bottom view)

Safety labels on each arm of the stainer crank and door in the transportation system module

Safety label on the waste management module

Power cord label next to the power cord on the back of the system

Safety information for lasers

The instrument includes a laser presence detector and a laser bar code reader.

- The bar code readers use LED technology with low output power.
- A laser bar code reader (class 2 laser) is used to scan the bar codes on samples.

Laser presence detector and bar code reader

This instrument contains a class 2 laser per IEC/EN 60825-1 Ed.2:2007 which can emit LED radiation. Do not view directly with optical instruments.

Safety information for disposal

Disposal information

Waste disposal

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.

Infection by a biohazardous instrument

Treat the system as biohazardous waste. It is recommended to perform decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) before reuse, recycling, or disposal of the system.

Dispose of the instrument according to the local regulations. For more information, contact Roche support.

Electronic equipment

You must dispose of electronic equipment through designated collection facilities appointed by government or local authorities.

Contact your city office, waste disposal service, or Roche support for more information about disposal of your old product.

Constraint:
It is left to the responsible laboratory organization to determine whether electronic equipment components are contaminated or not. If contaminated, treat them in the same way as the instrument.

The VENTANA HE 600 system complies with the Restriction of Hazardous Substances (RoHS) directive 2015/863.

System Description

System overview

In this chapter

2

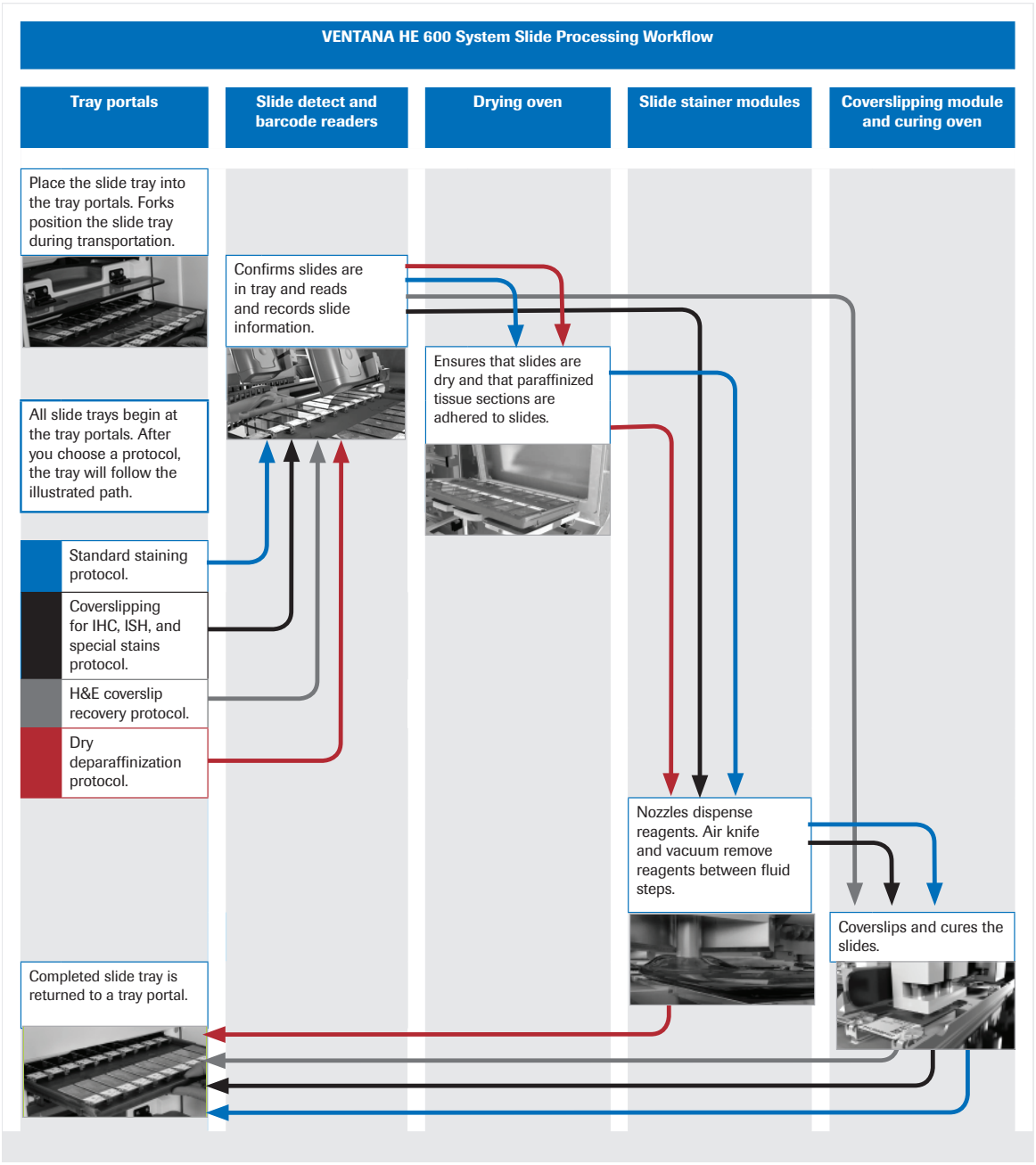
Staining process workflow

To view the journey of a slide through the VENTANA HE 600 system, view the following video.

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-SlideJourney.mp4
Title: Journey of a slide through the HE 600 system

The following diagram shows the different paths that the following slide processing protocols take through the system modules:

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


VENTANA HE 600 System Slide Processing Workflow
Tray portals
Slide detect and barcode readers
Drying oven
Slide stainer modules
Coverslipping module and curing oven
Place the slide tray into the tray portals. Forks position the slide tray during transportation.
Confirms slides are in tray and reads and records slide information.
Ensures that slides are dry and that paraffinized tissue sections are adhered to slides.
All slide trays begin at the tray portals. After you choose a protocol, the tray will follow the illustrated path.
Standard staining protocol.
Coverslipping for IHC, ISH, and special stains protocol.
H&E coverslip recovery protocol.
Dry deparaffinization protocol.
Nozzles dispense reagents. Air knife and vacuum remove reagents between fluid steps.
Coverslips and cures the slides.
Completed slide tray is returned to a tray portal.

System overview

In this section

About the staining system

The upper frame of the system includes the following components:

- Tray portal and transportation system
- Slide detect module and barcode readers
- Drying and curing ovens
- 3 stainer modules
- Coverslipper module
- Touch screen monitor

The lower frame of the system contains the automated fluidics module (AFM), which includes:

- Reagents
- Compressor
- Vacuum blower
- Waste reservoir

The waste system can drain waste to removable waste containers or directly to a drain.

For more detailed information, refer to the corresponding topics described in this publication.

The following image displays the covered system on the left and the uncovered system on the right to show the location of the internal modules.

A Slide dryer (drying oven)
B Monitor and user interface
C Transportation system
D Tray portals
E Waste capture module (optional)
F Curing oven
G Slide stainer modules
H Coverslipper
I Automated fluidics module

VENTANA HE 600 system

Related topics

- System overview (55)
- User interface overview (63)

About tray portals

Trays are loaded into tray portals to begin slide processing and unloaded from portals when processing is complete.

Status indicators on tray portals let you know when portals are ready to receive trays or when trays are ready to unload. Status indicators can also help you diagnose an issue with the portals.

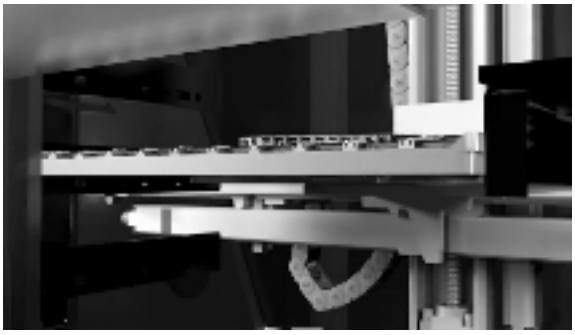
If a status indicator light is flashing yellow or is solid red, see the error log for details on the portal error.

Portal status (67)

Related topics

- About the staining system (55)
- About the transportation system (57)
- About the user interface (66)

About the transportation system



The transportation system moves slide trays between modules in the VENTANA HE 600 system.

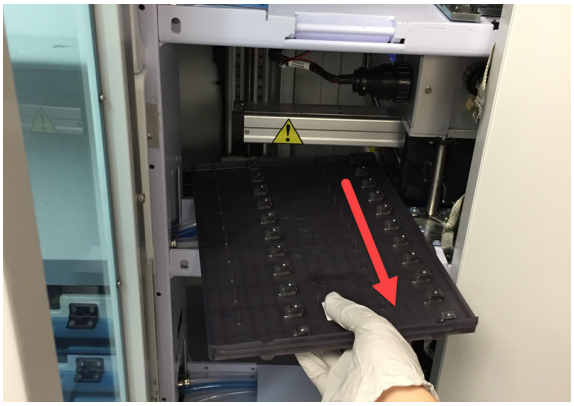
The transportation system moves the slide trays from the tray portals through the scanning, drying, staining, and coverslipper modules, and then back to the tray portal.

Forks are placed under the trays to hold them as they move between the modules.

The following video provides an overview of the transportation system.

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-TransportSystem.mp4
Title: Transportation system

About manually removing trays from the system



⚠ WARNING

Injury to operators and damage to the system

Contact with the system without powering off the system and waiting 20 minutes can result in a serious burn as some modules may be hot.

- Power off the computer and system prior to manually removing any trays.
- Wait at least 20 minutes after powering off the system to allow all trays in the slide dryer, stainers, and curing oven to cool before handling trays manually.
- Wait 20 minutes after powering off the system before touching any internal components of the system.

Be mindful of the following items when manually pulling a tray out of the system.

- Rotate the tray 90°, so that it will fit through the elevator door (also known as the blue transportation system door).
- If necessary, the transportation forks may be manually moved in either x direction to allow for tray removal.
- Be careful to avoid contact between the slide tray and other components of the system.
- Be careful to avoid spills when you remove trays. The tray and slides might have excess fluid on them.

Related topics

- About the staining system (55)
- About tray portals (57)

About the barcode reader and slide detect module

The barcode readers and slide detect module are located on the upper left corner of the system.

The slide detect module shines a beam of light onto the label ends of slides to determine where slides are located on a tray. Only positions on the tray where slides are located are processed in the subsequent stainer and coverslipper modules.

When barcodes are present on slides, the barcodes are read by the VENTANA HE 600 system barcode reader. Slides with barcodes can be tracked to ensure positive patient identification.

The barcode reader on the VENTANA HE 600 system must be enabled for the system to read barcodes. If you want to use slides with barcodes, and the barcode reader was not enabled when the system was installed, contact Roche support to enable it.

The following video provides an overview of the barcode reader and slide detect module.

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-BarCodeReader.mp4
Title: barcode reader and slide detect

Related topics

- About the staining system (55)

About the slide dryer

The slide dryer is a drying oven that ensures slides are dry and that paraffinized tissue sections are adhered to slides.

The slide dryer tilts the slide tray at an 80° angle to drain moisture from the slides. The tray is then heated in the oven at a temperature range of 72 °C +/- 3 °C.

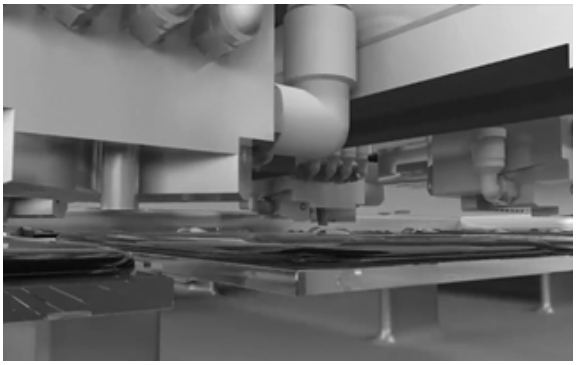
The following video provides an overview of the slide dryer.

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-DryingOven.mp4
Title: Slide dryer

Related topics

- About the staining system (55)

About the slide stainer modules



The staining modules work together to perform the H&E staining process. The staining process begins with deparaffinization and rehydration, followed by slide staining.

The slide staining module uses a patented reagent dispensing and removal process with an air knife and vacuum port to decrease times between fluid steps and reduce the need for wash steps. This process avoids the use of xylene and alcohol. Fresh reagents are used on each slide.

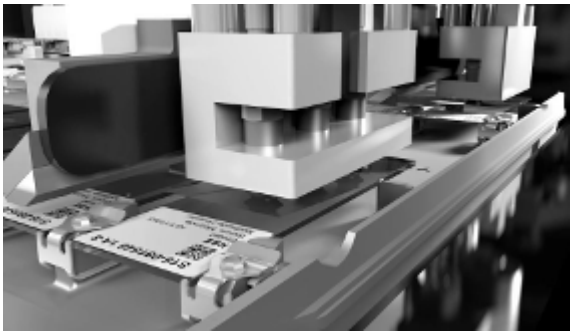
The following video provides an overview of the slide stainer modules.

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-Staining.mp4
Title: Slide stainer modules

Related topics

- About the staining system (55)

About the coverslipper module



The coverslipper module uses coverslip cassettes and coverslip activator to apply coverslips.

The activator is dispensed onto a slide, and then a coverslip is applied. The coverslip activator is a natural solvent that is dispensed from the coverslipper module.

Coverslips are dispensed from cassettes. When the cassettes are empty, they are discarded in the empty cassette bin.

If the coverslipper position needs to be adjusted to better align the coverslip or prevent bubbles on slides, contact Roche support.

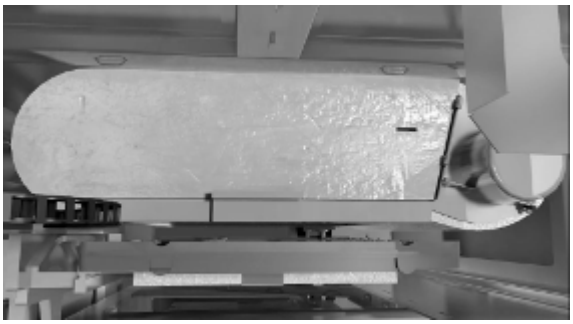
The following video provides an overview of the coverslipper module.

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-Coversliper.mp4
Title: Coverslipper

Related topics

- About the staining system (55)

About the curing oven



The curing oven cures coverslip glue and helps remove residual fluid from the slide tray.

The temperature of the oven is 92 °C +/- 3 °C. After the slides are cured, the slide tray moves to the tray portal. The tray cools in the portal before you can remove it from the system. Slides are ready for review after they are unloaded from a tray portal.

The following video provides an overview of the curing oven.

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-CuringOven.mp4
Title: Curing oven

Related topics

- About the staining system (55)

About the waste capture module

The VENTANA HE 600 system can collect liquid waste in waste containers or direct the waste to the drain.

Different laboratories have different regulations and guidance for liquid waste disposal. Laboratories that do not dispose liquid waste down a drain use an on-board waste capture module.

The waste capture module has a capacity of 9.2 L (2-5.8 L bottles each filled to 4.6 L capacity). This is enough to capture waste from approximately 350-430 slides.

The following videos provide an overview of the direct-to-drain waste and waste containers.

Video clip (.mpg, .mp4): WasteModule.mp4
Title: Direct-to-drain waste

Video clip (.mpg, .mp4): Stainers_Explorer-HE600-ReplaceWasteContainer.mp4
Title: Waste containers

Related topics

- About the staining system (55)

About the automated fluidics module

The automated fluidics module (AFM) stores and delivers the staining and cleaning reagents through a pressurized air and vacuum system. You can replace reagents by opening the AFM reagent access door.

The following video provides an overview of the AFM.

Video clip (.mpg, .mp4): AFM.mp4
Title: Automated fluidics module (AFM)

Related topics

- About the staining system (55)
- About the slide stainer modules (60)

User interface overview

In this section

About the computer and monitor

The VENTANA HE 600 system computer comes with a Windows operating system and the user interface installed.

The touch screen monitor is integrated with the computer. The monitor is mounted on the right side of the system and can swing left and right or tilt back and forth for easy access. Use your finger to navigate and select information or use the available keyboard to interact with the user interface.

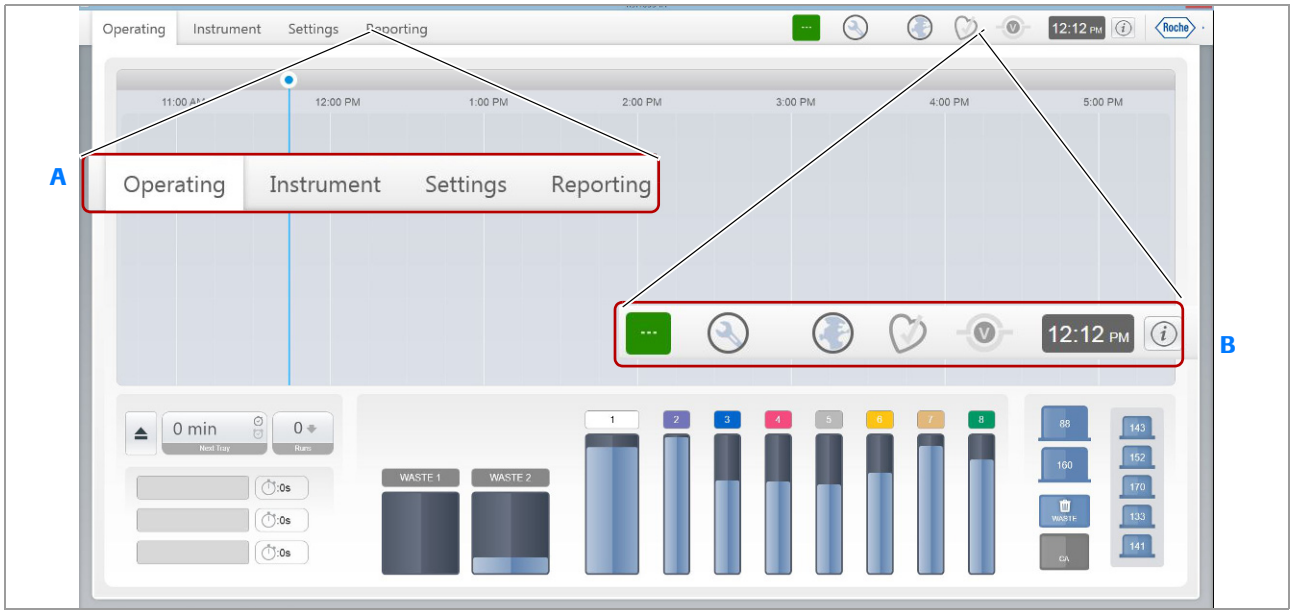
Video clip (.mpg, .mp4): Stainers_Explorer-HE600-UserInterface.mp4
Title: User interface

Related topics

- About the navigation toolbar and notification area (64)
- About the user interface (66)

About the navigation toolbar and notification area

The navigation toolbar and notification area are available from every view in the VENTANA HE 600 system software user interface. The navigation toolbar includes the tabs to the left of the screen and the notification area includes the status icons to the right of the screen.



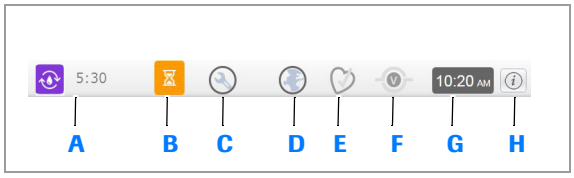
A Navigation toolbar

B Notification area

Navigation toolbar

Choose a tab to open the **Operating** view, the **Instrument** view, the **Settings** view, or the **Reporting** view.

Notification area



The image and the following table describes the functions of the icons in the notification area.

A Daily cleaning cycle and cycle time remaining.

B Instrument status

C Maintenance

D Internet connectivity

E Caregiver remote instrument support

F Vantage workflow solution

G Current time

H Information

The image displays an example of icon states that can display in the notification area. The notification area on your system displays the icons that represent the current status for your system.

If you have Scheduled Start enabled, an additional icon displays next to the Instrument status.

Symbol	Description
	If the daily cleaning cycle is in progress, this icon displays in the navigation area, along with the amount of time left for the cleaning cycle. The icon does not display when the cleaning cycle is not running.
	This icon displays the current instrument status. This is the same icon as in the Instrument view.
	To view details about the scheduled instrument start and ready times, choose the Scheduled Start icon.
	To view due or overdue maintenance items, choose the maintenance icon. The icon displays a yellow exclamation point if maintenance is due or a red exclamation point if there is overdue maintenance.
	If the internet connectivity icon changes from a dark gray to a light gray, you are not connected to the internet.
	If the Caregiver remote instrument support icon changes from a dark gray to a light gray, you are not connected to Caregiver remote instrument support.
	If the Vantage workflow solution icon changes from a dark gray to a light gray, you are not connected to Vantage workflow solution.
	To display contact, file version, and copyright information, choose the information icon.

Notification area icon key

The clock displays in the notification area, at the far right of the toolbar.

Related topics

- About the computer and monitor (63)
- About the user interface (66)
- About Caregiver remote instrument support (70)
- About Vantage workflow solution (71)
- Enabling the Scheduled Start (157)