# cobas e 411 analyzer

Operator's Manual – Version 3.3.1
Software Version 03-02
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# Publication information

| Publication version | Software version | Revision date | Change description |
|---|---|---|---|
| 1.0 | 01-01 | November 2006 | First version. |
| 1.1 | 01-01 | June 2007 | Template Updated. Changes from Addendum incorporated. |
| 2.0 | 02-01 | June 2008 | Added new software and analyzer functions. Collated Direct Drain descriptions in Appendix. |
| 2.1 | 02-02, 02-03, & 02-04 | June 2010 | New error information storage feature.<br>Updates to reflect changes to screens.<br>Added addenda.<br>Updated templates and presentation of safety information. |
| 3.0 | 02-05, 02-06, & 02-07 | November 2016 | Documentation redesigned according to the new Roche documentation concept.<br>New software features added.<br>What is new in publication version 3.0 (18) |
| 3.1 | 02-08 | April 2018 | Updated procedures for loading samples.<br>Updated information for pinch valve tubing.<br>Added maintenance tasks for cleaning racks and rack trays.<br>Added maintenance task for cleaning the input buffer and output buffer.<br>Minor revisions.<br>What is new in publication version 3.1 (17) |
| 3.2 | 03-01 | February 2019 | Added UltraVNC section.<br>What is new in publication version 3.2 (17) |
| 3.3 | 03-02 | June 2021 | Addendum 1, 2, and 3 of version 3.2 implemented.<br>IVDR implemented.<br>Processing QC for individual tests added.<br>Minor corrections.<br>What is new in publication version 3.3 (16) |
| 3.3.1 | 03-02 | August 2021 | Title corrected from "Complete User Documentation" to "Operator's Manual" on front cover and page footers of Operator's Manual. |

Revision history

**Edition notice**

This publication is intended for users of the **cobas e** 411 analyzer.

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 Assistance** / **Online Help** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Software reference
- Configuration information
- Background information

The **Safety Guide** contains important safety information. You must read the Safety Guide before operating the analyzer.

The **Operator's Manual** focuses on routine operation and maintenance. The content is organized according to the normal operation workflow.

**cobas**® e-library provides access to important updates, Method Sheets, Value Sheets, and other important documents from Roche.

The original version of this document is in English. All translations of this document have been translated from the original version in English. You can find the original and translated versions of this document at: *www.dialog.roche.com*.

Contact your local affiliate or Roche Service representative for more information.

The **cobas e** 411 analyzer can be used with all released tests. Tests approved for use on the instrument are available under eLabDoc on the Roche DiaLog website: *www.dialog.roche.com*.

**Privacy notice** When you use User Assistance online, viewing events (topics viewed and searches performed) and IP addresses are logged. The data collected is for Roche internal use only and is never forwarded to third parties. It is anonymized, and after one year it is automatically deleted. Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

**General attention**

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

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the analyzer in a way that is not described in this publication.
- Store all publications in a safe and easily accessible 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 from Roche Diagnostics. 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 screenshots, 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**

The **cobas e** 411 analyzer software is protected by contract law, copyright law, and international treaties. The **cobas e** 411 analyzer contains a user license between F. Hoffmann-LaRoche Ltd. and a license holder, and only authorized users may access the software and use it. Unauthorized use and distribution may result in civil and criminal penalties.

**License agreement for UltraVNC software**

UltraVNC is a piece of free software for all commercial uses. It is installed on the control unit PC.

UltraVNC is installed only on control units running Windows 10.

You can redistribute the software and/or modify it under the terms of the GNU General Public License (version 2 or later), as published by the Free Software Foundation. A copy of the GNU General Public License (version 2) is stored on the control unit PC. The path for the license is *C:\Program Files\uvnc bvba\UltraVNC*.

The software is distributed without warranty. There is no implied warranty of merchantability or fitness for a particular purpose. For more information, see the GNU General Public License at *http://www.gnu.org/licenses*.

The source code for the software is stored on the control unit PC. To view the source code under *C:\DriversAndTools\UltraVNC*, contact your Roche Service representative.

**Open source and commercial software**

The **cobas e** 411 analyzer may include components or modules of commercial or open-source software. For further information on the intellectual property and other warnings, as well as licenses pertaining to the software programs included in the **cobas e** 411 analyzer, refer to the electronic distribution included with this product.

This open source and commercial software and the **cobas e** 411 analyzer as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the corresponding user documentation and labeling.

Note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to the **cobas e** 411 analyzer.

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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 **cobas e** 411 analyzer complies with the following directives and regulations:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

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.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

Compliance of specific instruments with the respective directives or regulations is provided by means of the Declarations of Conformity where applicable.

Check the serial number of the instruments to identify the applicable directives and/or regulations.

All documents are available under eLabDoc on the Roche DiaLog website: *www.dialog.roche.com*.

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Compliance is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance.

Complies with the provisions of the applicable EU regulations.

For *in vitro* diagnostic use.

Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Issued by CSA Group for Canada and the US.

**Instrument approvals**

Furthermore, the instrument is manufactured and tested according to the following international safety standards:

- IEC 61010-1
- IEC 61010-2-101

The instrument complies with the emission and immunity requirements described in standard IEC 61326-2-6/ EN 61326-2-6.

# Contact addresses

**Inside the European Union and EFTA member states**

Manufacturer of the instrument

Hitachi High-Tech Corporation
1-17-1 Toranomon Minato-ku,
Tokyo, 105-6409 Japan

EC REP

Authorized representative and Importer

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

**Outside the European Union and EFTA member states**

| | |
|---|---|
| Manufactured by: | Hitachi High-Tech Corporation |
| Manufactured for: | Roche Diagnostics GmbH<br>Sandhofer Strasse 116<br>68305 Mannheim<br>Germany |
| Distributed in USA by: | Roche Diagnostics<br>9115 Hague Road Indianapolis,<br>Indiana, USA |

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# Table of contents

## Advanced operation



## Troubleshooting



## Appendix

# Intended use and intended purpose

**Intended use for US only**

The **cobas e** 411 analyzer is an automated, random-access, multichannel analyzer for immunological analysis. It is designed for both quantitative and qualitative in vitro determination of a wide range of analytes by use of electrochemiluminescence (ECL) technology.

**Supporting information for US only**

This analyzer is designed for clinical immunological test analysis using water-soluble samples and reagents. Other analyses may not be applicable to this analyzer. For clinical tests, the analyzer should be used under the management of a doctor or clinical inspector.

**Intended purpose for EU/EFTA and outside US**

The **cobas e** 411 analyzer is an automated analyzer including software, intended for running qualitative, semi-quantitative and quantitative immunochemistry assays.

**Supporting information for EU/EFTA and outside US**

It is an IVD device intended to be used in combination with assays for screening, monitoring (aid in monitoring), diagnosis (aid in diagnosis) and prognosis; additionally, the device can be used to run companion diagnostic tests.

The specific disorder and testing populations are covered by the applicable assays running on the instrument. The type of specimen to be used includes serum, urine, cerebrospinal fluid, oral fluid, hemolysate and plasma that are used for detecting and/or measuring analytes covered by the specific assays.

The intended users of this device are trained laboratory technicians and trained field service engineers (professional use only).

# Symbols and abbreviations

### Product names

Except where the context clearly indicates otherwise, the following product names and descriptors are used.

| Product name | Descriptor |
|---|---|
| **cobas e** 411 analyzer | analyzer, system |
| **cobas e** 411 software | software |

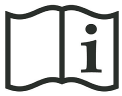
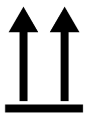
Product names

### 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 |
| ℹ | Extra information within a task |
| ➔ | Result of a user action within a task |
| | 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. |
| √xy | Equation. Used in cross-references to equations. |
| REF | Material reference number |

Symbols used in the publication

## Symbols used on products

| Symbol | Explanation |
|---|---|
| GTIN | Global Trade Item Number |
|  | Consult instructions for use on this website: *www.dialog.roche.com* |
| Cont. | Quantity contained in the package |
| CONTENT | Quantity contained in the package |
| Prod. Order | Product order |
| SN | Serial number |
|  | Date of manufacture |
|  | Manufacturer |
|  | Orientation of the package during transportation |
| EC REP | Authorized representative in the European Community |
|  | Indicates the entity importing the medical device into the European Union |
| RoHS | Complies with the directives on the restriction of hazardous substances |

Symbols used on products

| Symbol | Explanation |
|---|---|
| UDI | Unique device identifier |
| ~ | Indicates that the equipment is suitable foralternating current only |
| REF | Catalogue number |
| LOT | Lot number |
|  | Single use |
|  | Use by date |
|  | Humidity limit |
|  | Temperature limit |
|  | Caution |

Symbols used on products

**Abbreviations**

The following abbreviations are used.

| Abbreviation | Definition |
|---|---|
| AD | Amplification and detection |
| ADC | Analog-digital converter |
| ANSI | American National Standards Institute |
| CFR | Code of Federal Regulations |
| CSA | Canadian Standards Association |
| CSV | Comma-separated values |
| CV | Coefficient of variation |
| DIL | Diluent |
| EC | European Community |
| ECL | Electrochemiluminescence |
| EFTA | European Free Trade Association |
| EN | European standard |
| EU | European Union |
| FCC | Federal Communications Commission |
| GNU | GNU’s Not Unix! |
| HIS | Hospital information system |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardization |
| IVD | In vitro diagnostic |
| IVDR | In vitro diagnostics regulation: Regulation (EU) 2017/746 |
| LIS | Laboratory information system |
| LLD | Liquid level detection |
| n/a | Not applicable |
| PSM | Pre-analytics system manager |
| QC | Quality control |
| RoHS | Restriction of Hazardous Substances |
| SD | Standard deviation |
| sdta | Sample disk tube adapter |
| SLLD | Sample liquid level detection |
| SOP | Standard operating procedure |
| STAT | Short turn-around time |
| UL | Underwriters Laboratories Inc. |
| USB | Universal serial bus |
| WEEE | Waste Electrical and Electronic Equipment |

Abbreviations

# What is new in publication version 3.3

This section provides an overview of all major changes in this publication and the software.

**IVDR update**

The following sections have been updated to comply with the latest in-vitro diagnostics regulation:


- Publication information (2)
- Contact addresses (8)
- Intended use and intended purpose (11)
- Symbols and abbreviations (12)
- Accessories and consumables (75)


**Protection of personal data and software security**

The General Data Protection Regulation (GDPR) is a regulation on data protection and privacy for all citizens of the European Union (EU) and the European Economic Area (EEA). The regulation also covers the processing of personal data outside the EU and EEA.

**Sharps, rough edges, and/or moving parts**

A warning message has been added to the Safety Guide.

**Processing QC for individual tests**

You can perform QC measurements for individual tests. For example, if you have been working with only some tests during operation, perform QC measurements for these tests at the end of operation. This ensures the measurement accuracy for these tests during the entire operation.


- Processing QC for individual tests (147)


**Replacing the pinch valve tubing**

There is an extended maintenance interval for replacing pinch valve tubing under certain specific conditions.


- Maintenance schedule (219)
- Types of pinch valves (242)


**Direct drain system**

The direct drain system is no longer available. The description of the direct drain system has been removed.

# What is new in publication version 3.2

**Added UltraVNC information**

UltraVNC software is installed on control units running Windows 10.

Publication information (2)

# What is new in publication version 3.1

**Updated procedures for loading samples**

The procedures for loading routine and STAT samples have been updated.

Loading routine and STAT samples with barcodes (173)
Loading routine and STAT samples without barcodes (177)

**Updated information for pinch valve tubing**

There are two types of pinch valve that can be installed on the analyzer.

Replacing the pinch valve tubing (241)

**New maintenance actions**

There is a new maintenance action for cleaning the input buffer and output buffer.

There are new maintenance actions for cleaning rack trays and racks.

Cleaning the input buffer and output buffer (231)
Cleaning the rack trays (267)
Cleaning the sample racks (270)

# What is new in publication version 3.0

The following list contains a short description of all the major changes in software versions 02-05, 02-06, and 02-07.

**USB flash drive as a storage device**

A USB flash drive can be used as a storage device for backup and restoration of analyzer data.

**Deleting applications**

Applications you no longer use can be deleted.

**Storing count data**

Count data is no longer lost when the analyzer is rebooted.

**Simplified backup function**

You can backup analyzer data for storage and troubleshooting purposes using a single process, instead of separate processes.

**Diluent on the Reagent Level Check dialog box**

Diluents are now handled in the same way as assay reagents on the **Reagent Level Check** dialog box.

**Indication of accessibility of AssayTip and AssayCup trays**

Identifying when you can reload AssayTips and AssayCups from the **System Overview** window is simpler. The software now marks inaccessible trays as red.

**Improved QC result deletion**

QC results can be deleted from either the **QC View** window or the **IndividualQC** window. After you delete the results the change is reflected in the corresponding window. This functionality is similar to the functionality used by the **cobas**® 6000 analyzer series.

**Extended test number range**

Application test numbers and user test numbers can now have four-digits.

**Corrected lot number for QC in CSV file**

The software exports the correct lot number data to a CSV file, even if the data contains multiple lot numbers for the same control type.

# System description

# Overview of the analyzer

## In this chapter

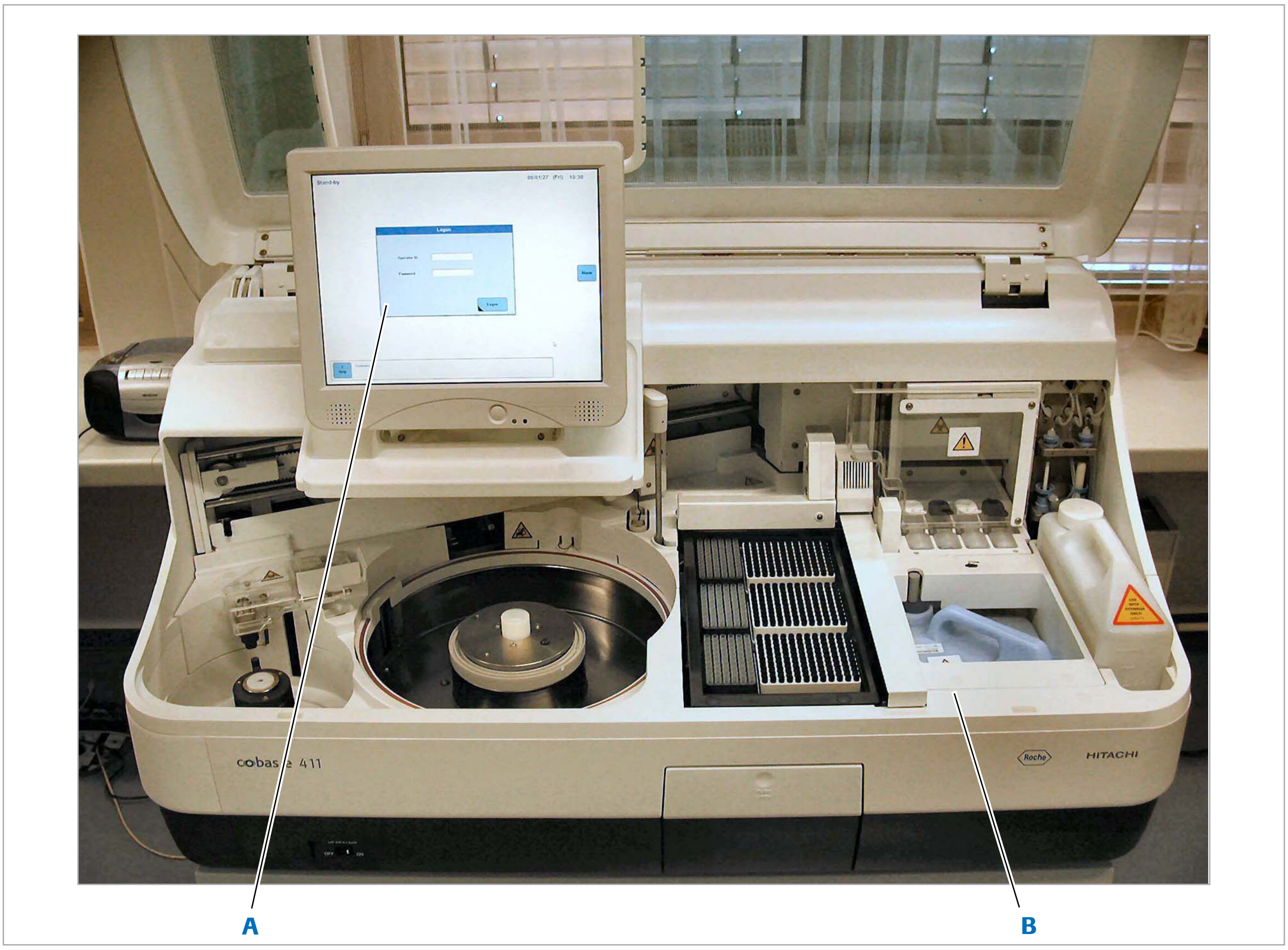
1

# About the cobas e 411 analyzer

The Roche Diagnostics **cobas e** 411 analyzer is an automated system for immunological analysis. The analyzer uses electrochemiluminescence (ECL) technology to provide a wide variety of tests.

The **cobas e** 411 analyzer consists of the two units below.

- Analyzer unit - either rack or disk based
- Control unit




**A** Control unit

**B** Analytical unit

Disk system

To save space, the **cobas e** 411 analyzer can be placed on a bench top. The analyzer unit performs all the functions required for fully automated sample and assay processing. The control unit controls the analyzer unit through user software.

The software performs the tasks below.

- Controls data transmission to and from the analyzer unit
- Evaluates results
- Produces documentation
- Implements quality control
- Manages data between a connected LIS/PSM (Pre-Analytic Systems Manager) and the **cobas e** 411 analyzer.

The Pre-Analytic Systems Manager is not available in all countries.

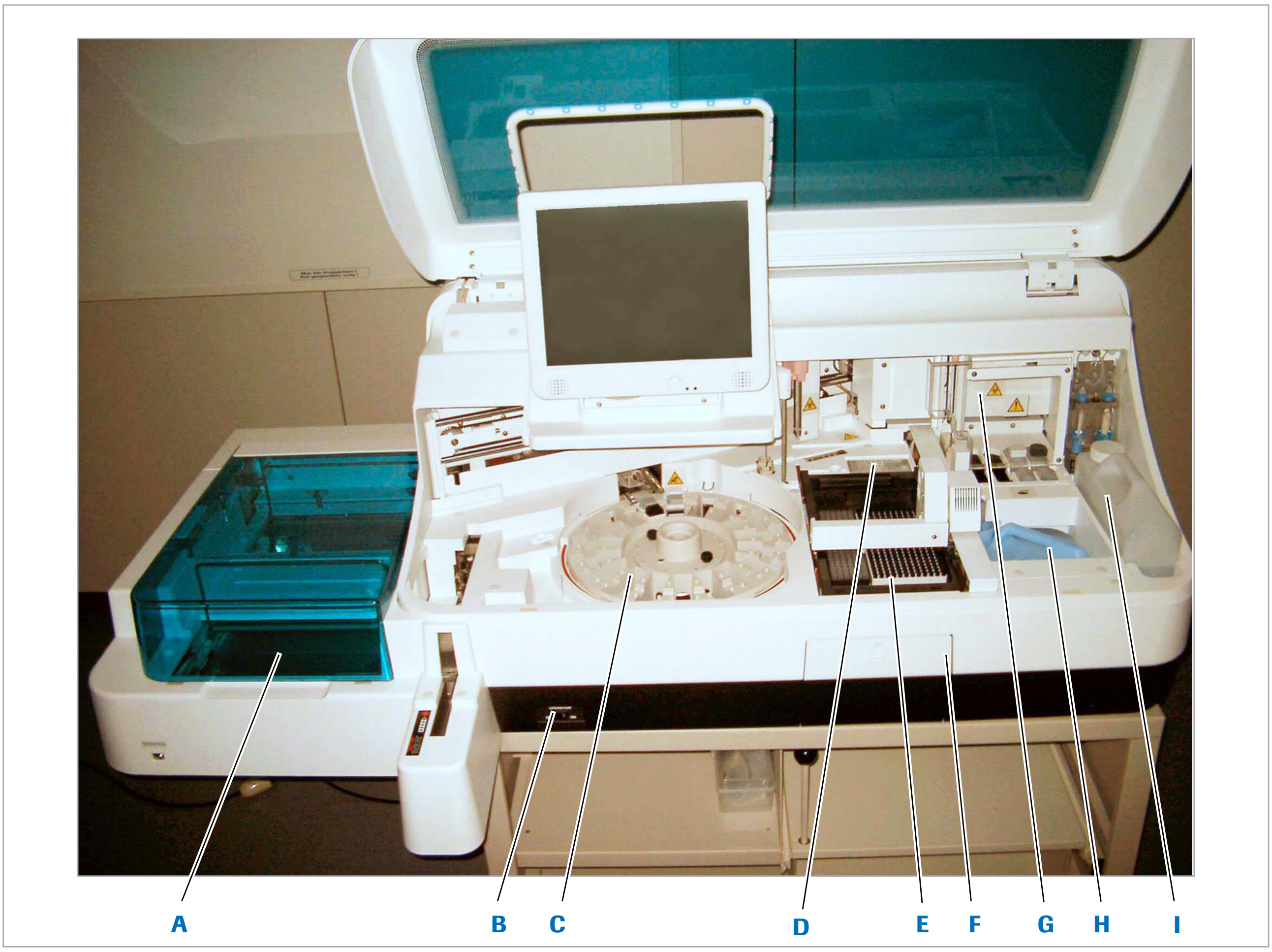
Both the rack and disk system have a throughput of approximately 86 tests per hour.

# Overview of the analyzer unit

The **cobas e** 411 analyzer is available as a rack system or a disk system. Both systems are standalone devices. The difference between the two systems is in the sample area.


**A** Sample area
**B** Operation switch
**C** Reagent area
**D** Incubation area
**E** Solid waste area
**F** Consumables area
**G** Liquid waste container
**H** Measuring area
**I** System water container

Analyzer unit (disk system)




**A** Sample area
**B** Operation switch
**C** Reagent area
**D** Incubation area
**E** Consumables area
**F** Solid waste area
**G** Measuring area
**H** Liquid waste container
**I** System water container

Analyzer unit (rack system)

**In this section**



# Sample area components

The sample area of the disk system comprises the components below.

- Sample disk and sample disk protective cover
- Disk sample barcode reader
- Sample/reagent (S/R) probe

The sample area of the rack system comprises the components below.

- Rack sampler and cover
- Rack barcode reader and sample sensor
- Sample/reagent (S/R) probe

**Sample disk**

The sample disk has 30 positions for samples, calibrators, and controls. Place patient samples in sample tubes or sample cups. Built-in adapters allow intermixing of different-sized primary sample tubes.

Place sample cups directly on the sample disk or on top of 16 mm primary sample tubes. Use 13 mm sample disk tube adapters (13 mm sdta) for 13 mm primary sample tubes.

**⚠ CAUTION**

**Damage to the analyzer due to the use of microcups**

Microcups have a smaller diameter than sample tubes or sample cups, and so do not fit correctly on the sample disk. They may collide with the sample/reagent probe and cause damage.

- Only use sample tubes or sample cups.

Using a 13 mm sdta (168)

**Rack sampler**

The rack sampler consists of six areas.

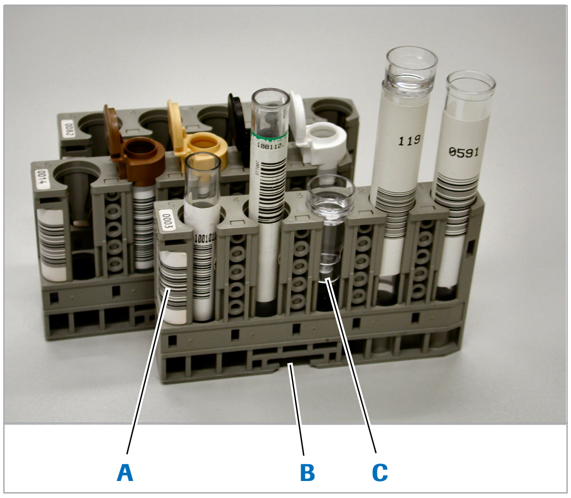
- A-Line
- Input buffer
- B-Line
- Output buffer
- C-Line
- STAT (Short Turn Around Time)

**⚠ WARNING**

**Personal injury due to racks moving at high speed on the rack lines**

Racks move at high speed in the rack lines. Contact with a moving rack on the A-Line or C-Line of the rack sampler may cause personal injury.

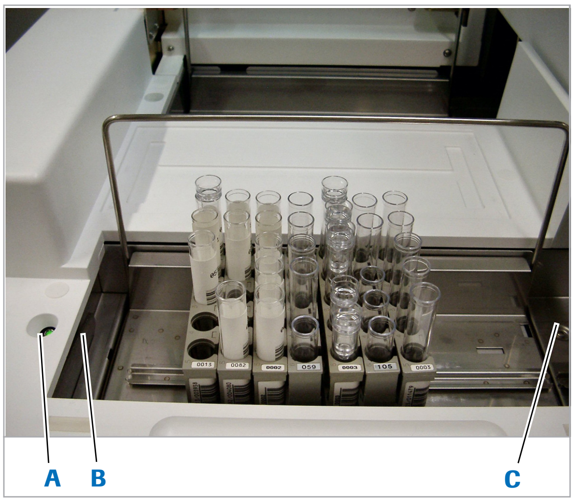
- When the analyzer is in operation, do not open the cover of the rack sampler.




**A** Rack ID barcode
**B** Tray guide
**C** Slot for tube

Each rack can hold a maximum of five samples. You can load sample cups, primary sample tubes. calibrator vials, or control vials. If you use a small primary sample tube, then use an adapter.

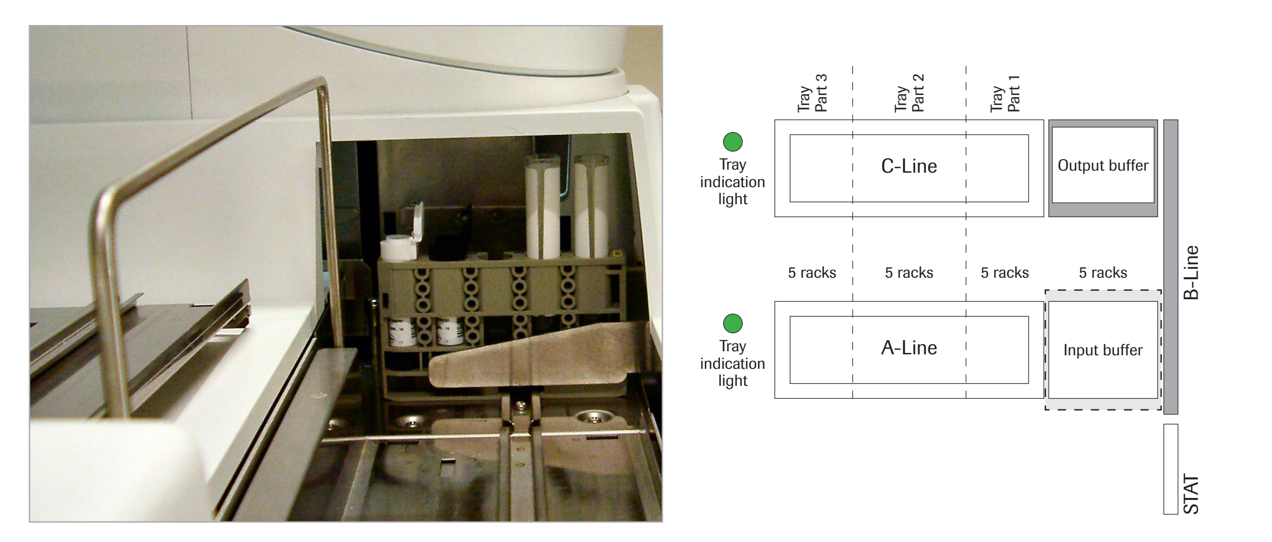
Place the cups, tubes, or vials into the rack. Ensure that the barcode reader can read the barcode on the cup, tube, or vial. Each rack has a unique barcode on the back end of the rack. The barcode reader reads this ID, then the analyzer displays it in the software and on the reports.




**A** Tray indication light
**B** Rack pusher arm
**C** Input buffer (hidden)

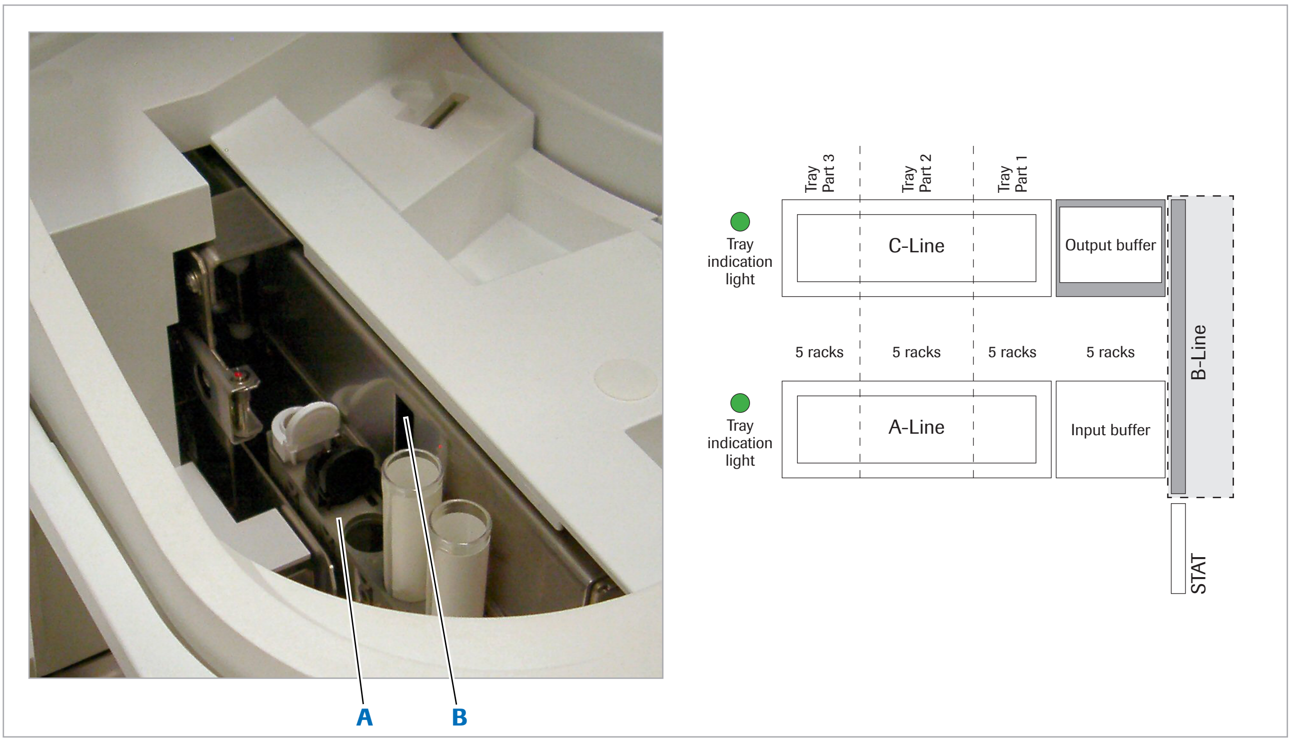
Place samples to be analyzed into the five-position racks. Then load each rack onto the tray. A tray can hold a maximum of 15 racks. When the analyzer is in operation, you can add additional racks, one at a time.

When the tray indication light is lit, you can place the tray on the A-Line of the rack sampler. When the tray indication light is off, the pusher arm prepares to push the racks into the input buffer.




Input buffer of the rack sampler

The input buffer has space for five racks. In total, you can load 20 racks, or 100 samples, onto the analyzer at one time.

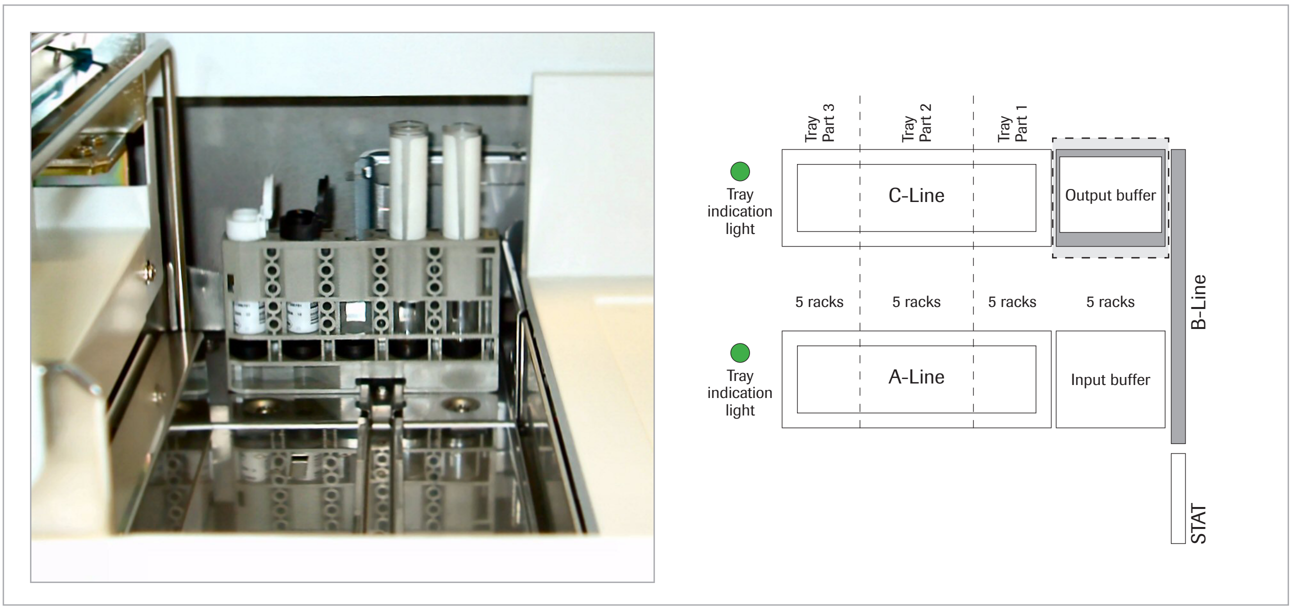



**A** Rack in B-Line

**B** Rack barcode reader

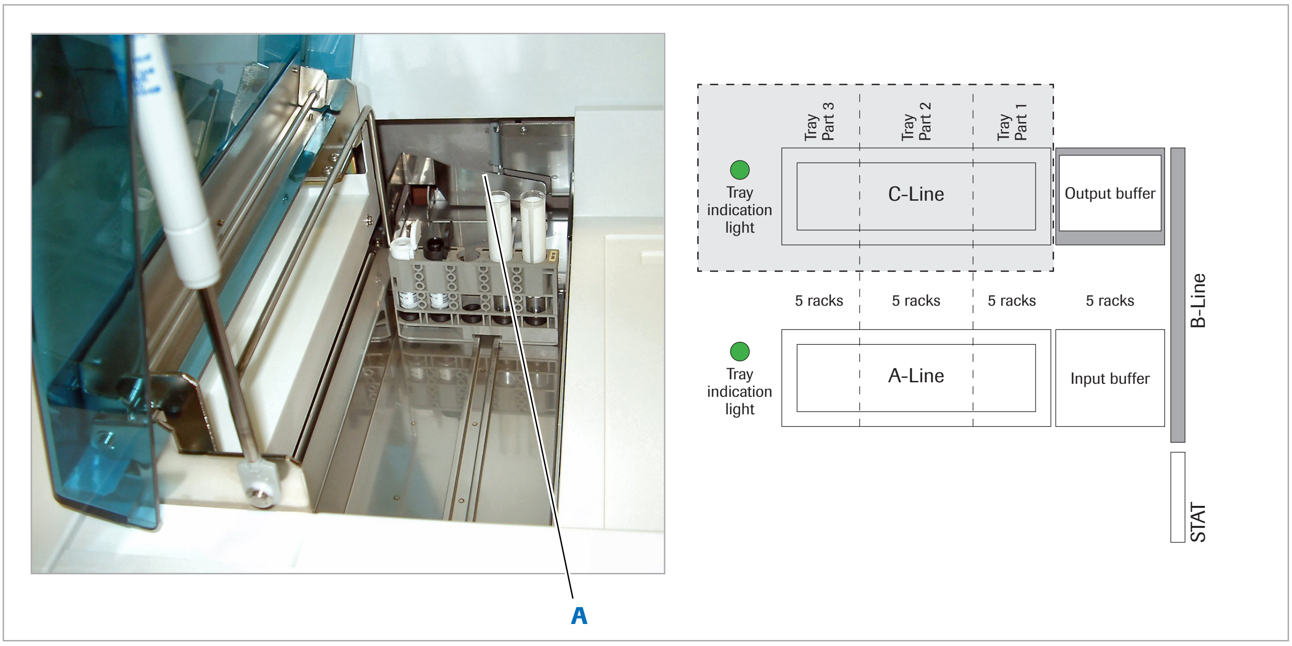
B-Line of the rack sampler

The B-Line transports the racks to the rack barcode reader. The rack barcode reader scans each sample for a sample barcode. When all samples in the rack have been scanned, the barcode reader scans the rack ID. After the barcode reader scans all the barcodes, the samples are sampled so that tests can be performed.




Output buffer of the rack sampler

The analyzer off-loads racks from the B-Line into the C-Line. When the C-Line is full, the system issues an alarm and any following racks stay in the output buffer until the C-Line has been emptied.

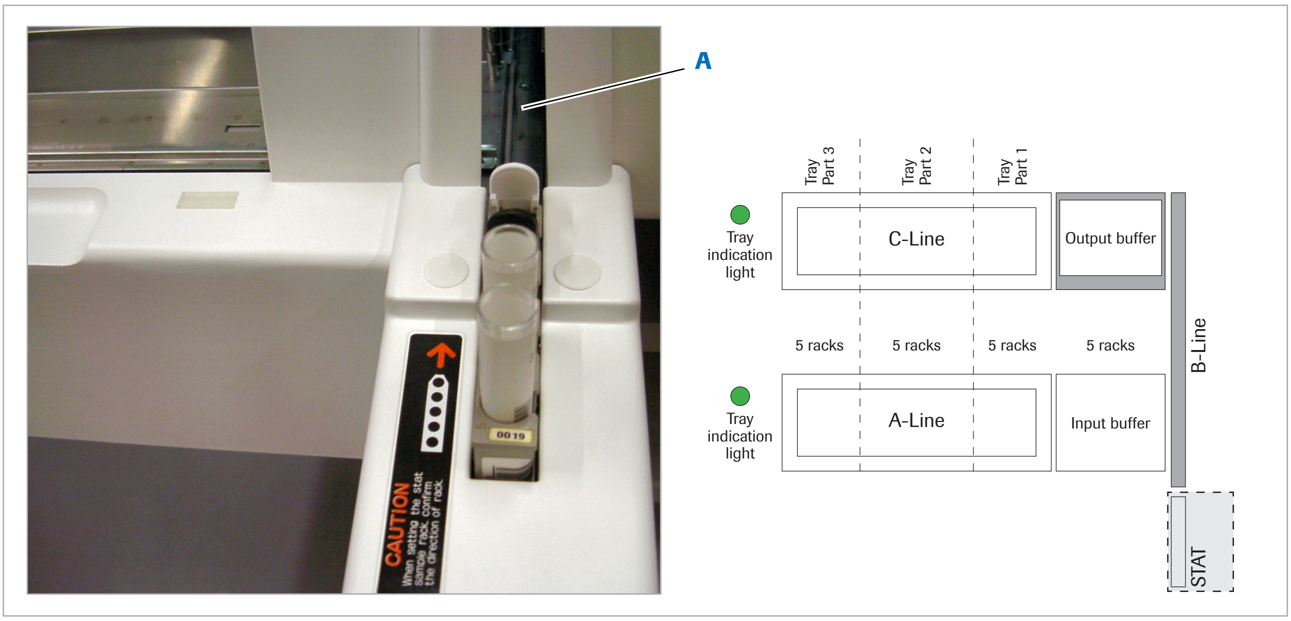



**A** Output buffer

C-Line of the rack sampler

Racks are pushed out of the output buffer onto the C-Line tray. When the tray indication light is lit, you can remove a tray from the C-Line. If the tray indication light is off, then the pusher arm is preparing to push the racks forward off the output buffer onto the tray.

While the tray is removed, racks are stored on the output buffer. If the output buffer contains five racks, and there is no tray on the C-Line, then the analyzer issues an alarm and stops sampling racks.



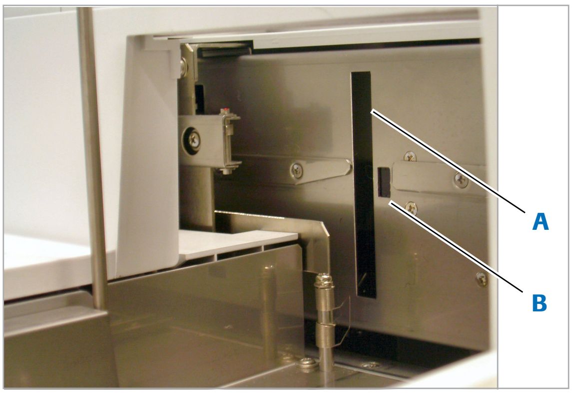

**A** STAT position

STAT rack position of the rack sampler

The STAT (Short Turn Around Time) rack position is at the front of the analyzer and feeds directly into the B-Line. Load STAT samples into a STAT rack and then load the rack onto the analyzer. Ensure that the narrower end of the STAT rack is closest to the B-Line. When the rack currently on the B-Line has been sampled and ejected into the C-Line, the STAT rack enters the B-Line.

### Rack barcode reader and sample sensor

The rack barcode reader reads both sample barcode labels and rack barcode labels.




**A** Barcode reader slot **B** Sample sensor window

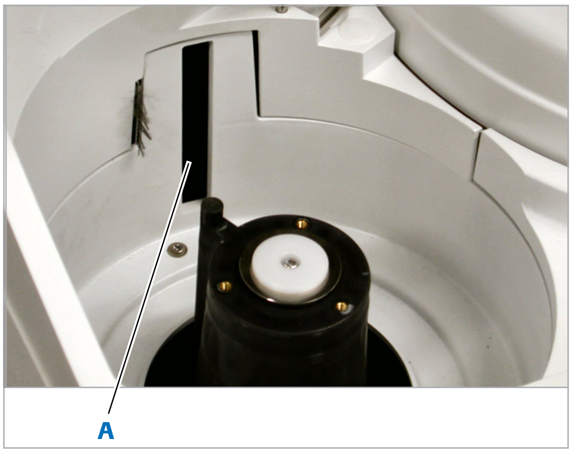
The rack barcode reader can read the barcode types below.

- NW7 (Codabar)
- Code 39
- Code 128
- Interleaved 2 of 5

The sample sensor is located to the right of the barcode reader. The sample sensor detects if there is a sample tube in the rack at that position.

**Disk sample barcode reader**

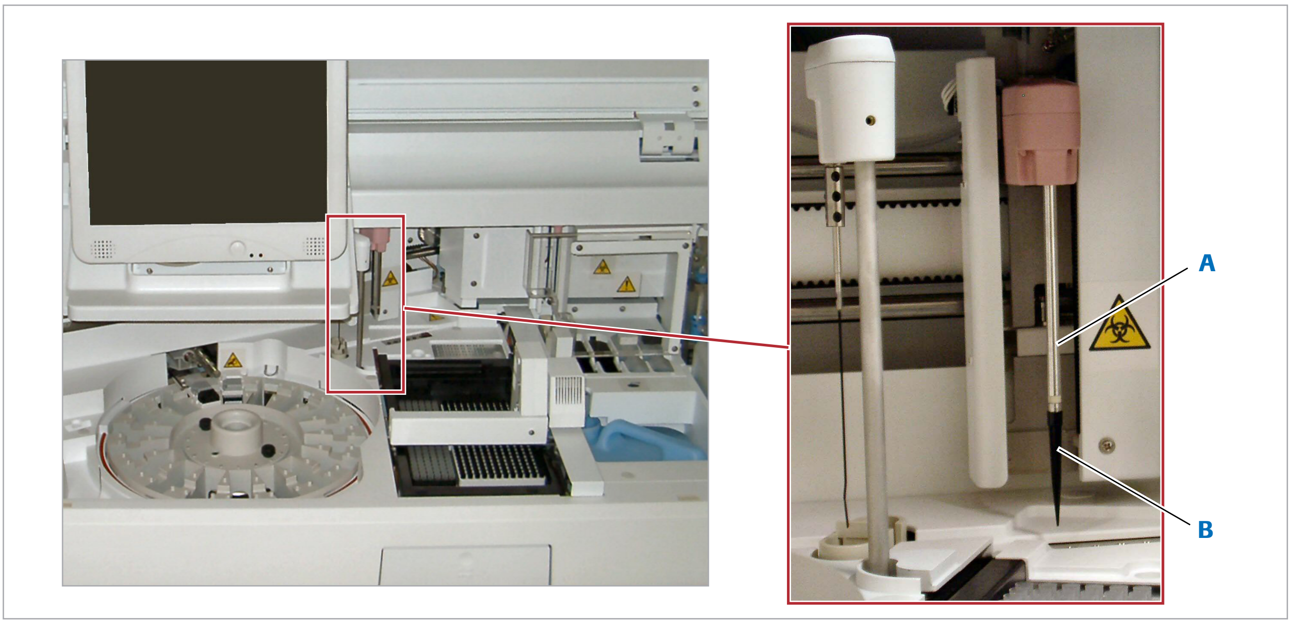
The disk system has a barcode reader, which reads the barcodes on sample tubes, calibrators, or controls. The barcode reader is located in the sample disk.




**A** Barcode reader slot

**Sample/reagent (S/R) probe**

The S/R probe transfers sample and reagent around the analyzer. The S/R probe is mounted on the S/R arm, which moves the probe between the sample disk or rack and the pipetting station. To perform liquid level detection, the S/R probe uses capacitance measurement. To perform clot detection, the S/R probe uses a pressure transducer.




**A** S/R probe **B** AssayTip

S/R probe with AssayTip

To avoid sample carryover, the S/R probe uses disposable AssayTips. The S/R probe uses a new AssayTip at the start of each of the events below.

- Pipetting sequence
- Sample dilution step
- Pretreatment step

Between aspiration steps, the analyzer washes the AssayTip in the rinse station.

**NOTICE**

**Incorrect results due to surface foam**

If there is foam on the sample or reagent, then the analyzer may not extract the correct amount of liquid.

- Ensure that the sample and reagents are settled with no foam or bubbles on the surface.

**Sample disk protective cover**

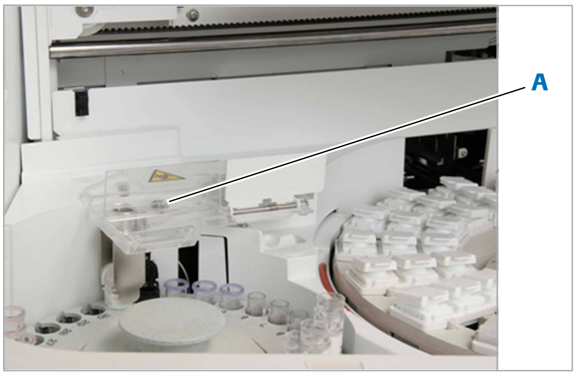
The sample disk protective cover is at the back of the analyzer. The protective cover prevents carryover from the S/R probe as it moves to and from the sample disk.

**⚠ CAUTION**

**Incorrect results due to contamination of samples**

If you do not close the sample disk protective cover before you start analysis, then the S/R probe will crash, causing damage to the analyzer and sample spillage.

- Before you start analysis, close the sample disk protective cover.




**A** Sample disk protective cover

# Reagent area components

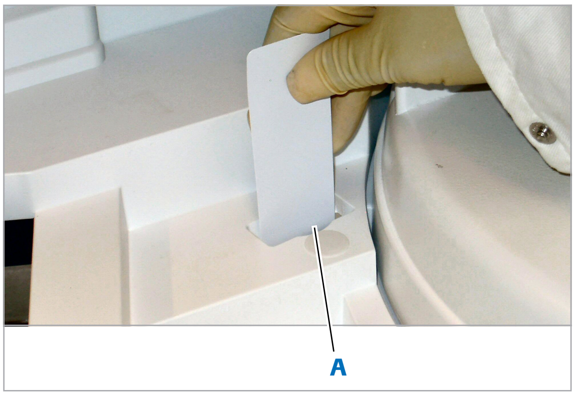
The reagent area of the analyzer comprises the components below.

- Barcode card reader station
- Reagent rotor
- Cap opener
- Microbead mixer
- Rinse stations for the S/R probe and microbead mixer
- Sample/reagent (S/R) pipetter

**Barcode card reader station**

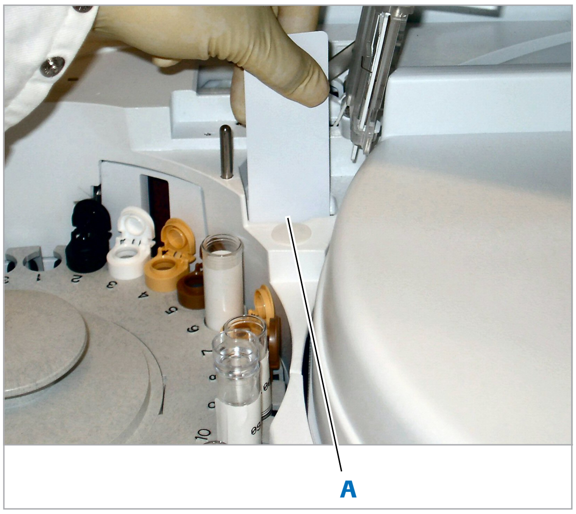
The barcode card reader scans information from the calibrator barcode card or control barcode card. These barcode cards are part of the calibrator and control kits. When you insert a barcode card in the barcode reader, ensure that the barcode faces the back of the analyzer.

On the rack system, the barcode card reader station is located near the reagent rotor on the left-hand side.




**A** Barcode card reader station on the rack system

On the disk system, the barcode card reader station is located between the sample disk and the reagent rotor.




**A** Barcode card reader station on the disk system

**Reagent rotor**

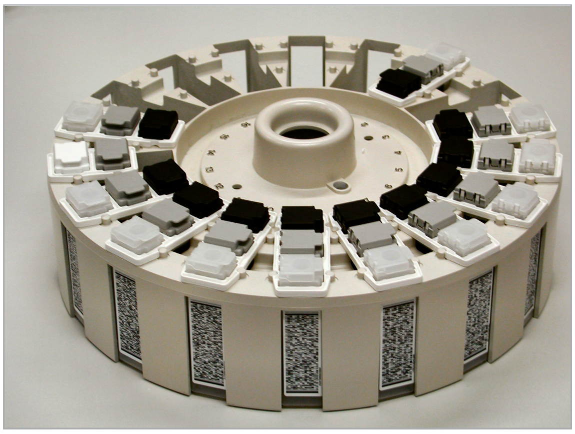
The reagent rotor contains 18 positions for assay, diluent, or pretreatment reagents. You can use the 18 positions in any combination.

You can load multiple reagent packs of each type onto the reagent rotor, up to a maximum of:

- 18 assay reagent packs
- 8 diluent reagent packs
- 9 pretreatment reagent packs

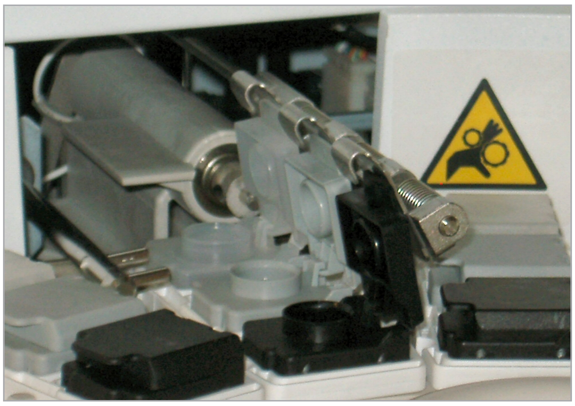
You can load more than one reagent pack onto the reagent rotor for each test.

The reagent rotor is temperature controlled at 20 ± 3 °C.



**Cap opener**

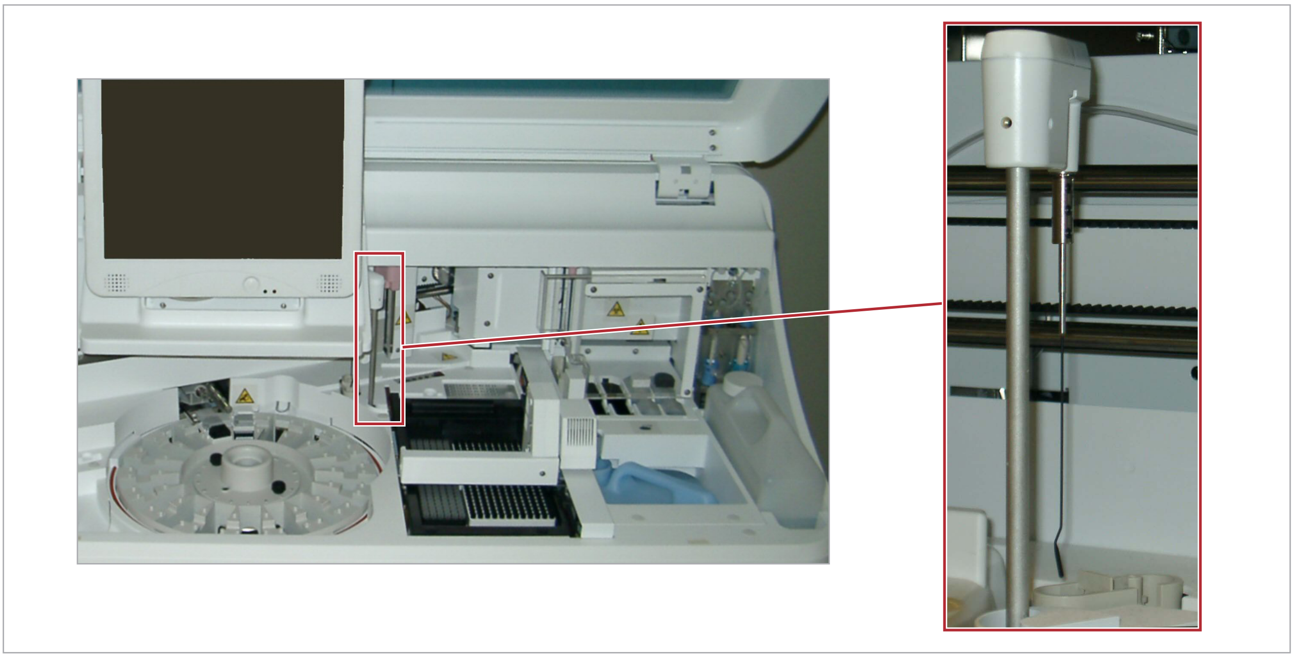
When the analyzer is in operation, the reagent rotor uses a cap opener. The cap opener reduces the amount of evaporation and promotes ease-of-use. The cap opener is on the back wall of the reagent rotor compartment.



The analyzer opens reagent caps before pipetting or mixing. After pipetting or mixing is complete, the analyzer closes reagent caps.

**Microbead mixer**

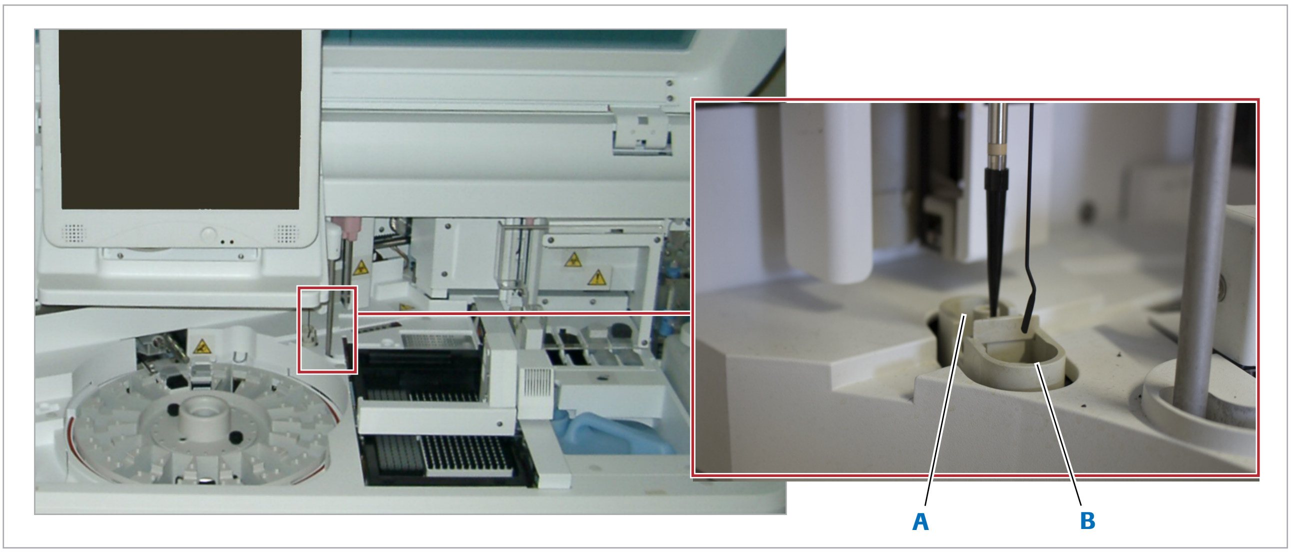
The microbead mixer mixes the microbeads to ensure a homogeneous suspension before aspiration. The home position of the microbead mixer is between the reagent rotor and the S/R probe.



Microbead mixer

**Rinse stations for the S/R probe and microbead mixer**

The rinse stations wash the microbead mixer and the AssayTip on the S/R probe between aspirations, and before and after microbead mixing.



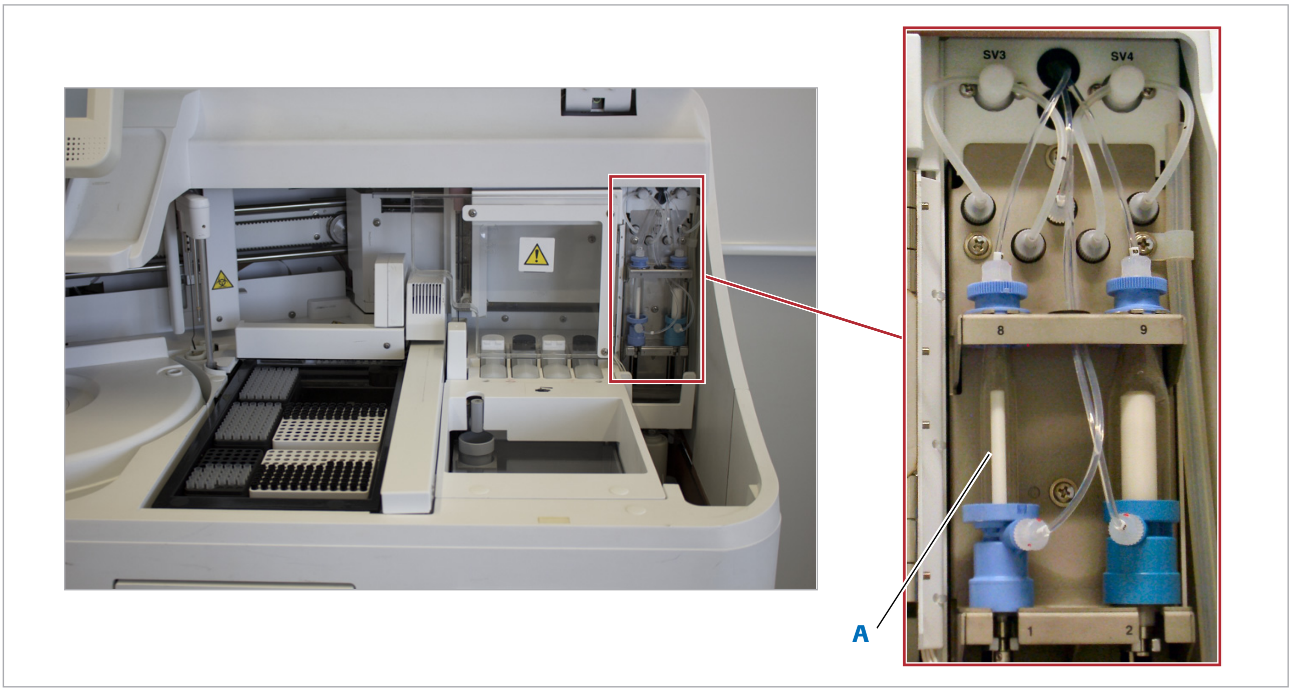

**A** S/R probe rinse station

**B** Microbead mixer rinse station

Rinse stations for the microbead mixer and the S/R probe

**Sample/reagent (S/R) pipetter**

To aspirate and dispense samples and reagents from the S/R probe, the S/R pipetter uses positive displacement of the system water. The S/R pipetter is on the right-hand side of the analyzer at the back.




**A** S/R pipetter

S/R pipetter location

# Consumables area components

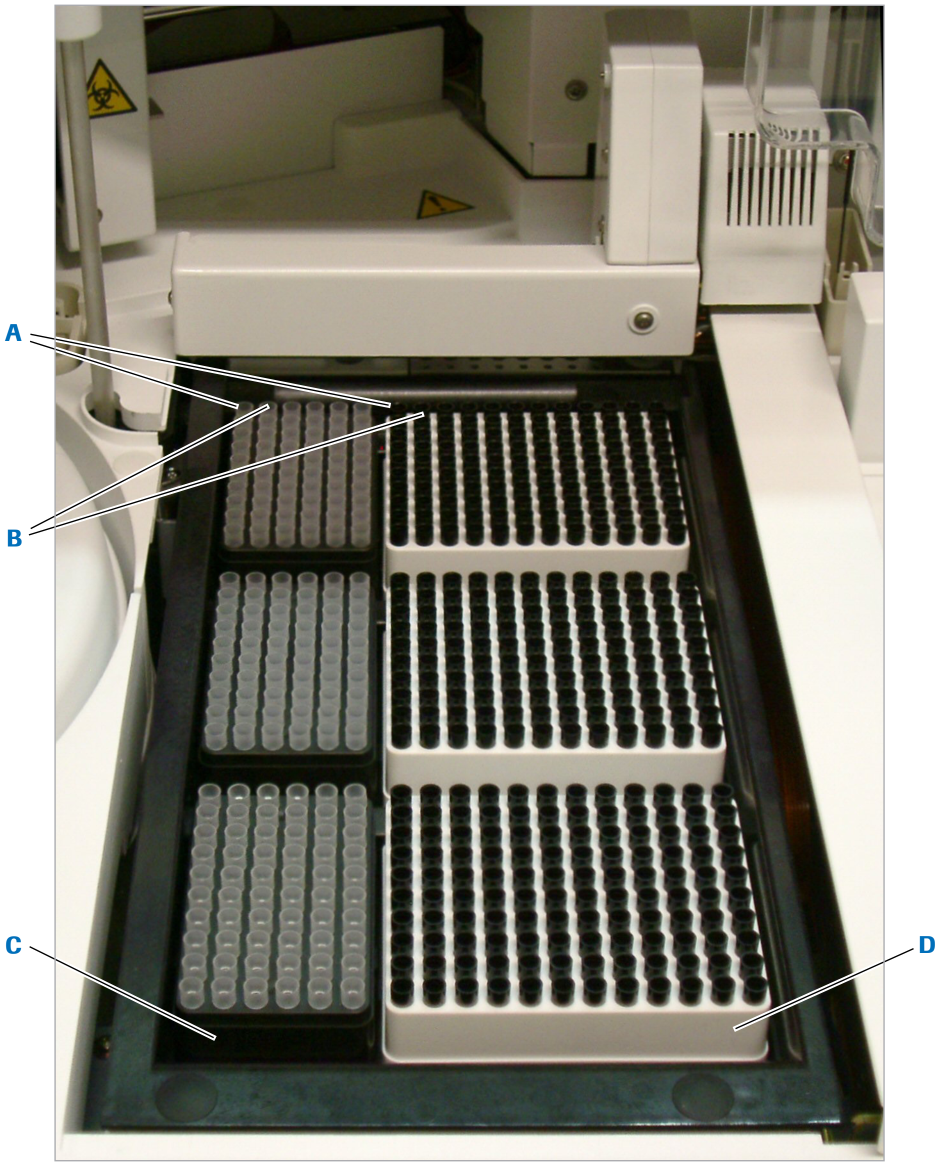
The consumables area of the analyzer comprises the components below.

- Gripper unit
- Pipetting station
- System water container
- Liquid waste container
- Solid waste tray and Clean-Liner

**Gripper unit**

The gripper takes an AssayTip or an AssayCup from the associated tray and delivers it to the pipetting station.

Samples are pipetted into the AssayCup. When the AssayCup contains the sample, the gripper moves the AssayCup to the incubator. The incubator heats the sample and then the gripper moves the heated sample to the aspiration station. The sample is pipetted out of the AssayCup and measured. The gripper picks up the used AssayCup and drops it into the AssayCup disposal opening.




**A** First position that AssayTip and AssayCups are taken from

**B** Second position that AssayTip and AssayCups are taken from

**C** Tray of AssayCups

**D** Tray of AssayTips

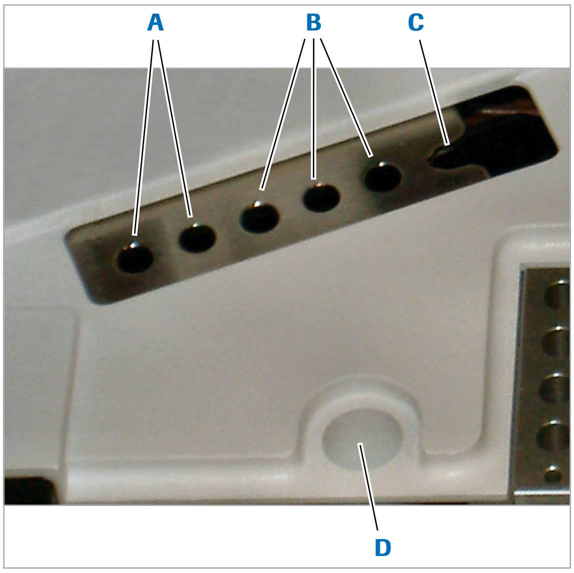
Gripper unit and trays

Each AssayCup tray holds up to 60 AssayCups. Each AssayTip tray holds up to 120 AssayTips. As there are three tray positions in front of the gripper unit, you can place a total of 360 AssayTips and 180 AssayCups on the analyzer.

If all trays are full, then the gripper takes the first AssayTip and AssayCup from the trays closest to the front of the analyzer. The gripper takes the next AssayTip or AssayCup from the space to the right. The gripper takes each AssayTip or AssayCup in turn until it empties the trays.

**Pipetting station**

The five-position pipetting station is located to the back-left of the incubator.




**A** AssayTip positions 1-2
**B** AssayCup positions 3-5
**C** AssayTip eject station
**D** AssayCup disposal opening

The gripper moves AssayCups and AssayTips to the pipetting station. At the pipetting station, the analyzer performs sample pipetting, reagent pipetting, sample dilution, and sample pretreatment.

Positions 1 and 2 of the pipetting station hold AssayTips. Positions 3 and 4 of the pipetting station hold AssayCups for dilution or pretreatment. Position 5 of the pipetting station holds AssayCups for when the S/R probe pipettes samples and reagents.

After use, the AssayTips are discarded at the AssayTip eject station. After use, the gripper picks up the AssayCups and places them into the AssayCup disposal opening.

**System water container**

The system water container is located in front of the pipetter syringes. The system water container contains deionized or distilled water mixed with SysWash. The SysWash helps to prevent bacterial growth and reagent carryover.


Under the system water container, there is an inlet valve that suppliers the system water to the system and to a reservoir. The inlet valve is fitted with a float mechanism sensor, which triggers an alarm when the system water is running low.

**Liquid waste**

The analyzer has a liquid waste container.

The liquid waste container is located in front of the ProCell and CleanCell reagents. The container holds up to 4 liters of waste, and sits on a weight-sensitive mechanism. The mechanism moves down as waste is added. In the compartment of the liquid waste container is a photosensor. The photosensor is triggered if the liquid waste container is in the wrong position or if it is three-quarters full.

**NOTICE**

**Unscheduled E.Stop due to removing the liquid waste container during operation**

If you remove the liquid waste container during operation, then the analyzer performs an E.Stop.

- Do not remove the liquid waste container while the analyzer is in operation.
- Ensure that the liquid waste container is correctly positioned.

### Solid waste tray and Clean-Liner

The solid waste tray and Clean-Liner is located behind the front access door on the analyzer. The AssayTips and AssayCups from the pipetter station are discarded into the solid waste tray.

The Clean-Liner is a disposable item that slides into the solid waste tray. The Clean-Liner has a sliding cover which prevents potential splashing and keeps the AssayCups and AssayTips inside. When the analyzer is in operation, the sliding cover is open to allow access to the solid waste. The analyzer shakes the solid waste tray periodically to ensure that the waste is evenly distributed.

A photosensor in the solid waste tray compartment ensures that the solid waste tray is correctly inserted. The software records how many AssayCups and AssayTips have been put into the solid waste tray. The software registers an alarm when the Clean-Liner is full or when the solid waste tray and Clean-Liner are missing.

**NOTICE**

**Unscheduled E.Stop due to removing the solid waste tray during operation**

If you remove the solid waste tray during operation, then the analyzer performs an E.Stop.

- Do not remove the solid waste tray while the analyzer is in operation.
- Ensure that the solid waste tray and Clean-Liner are correctly positioned.

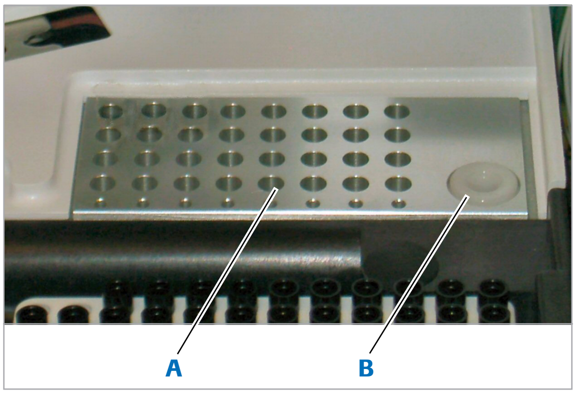
# Measuring area components

The measuring area of the analyzer comprises the components below.

- Incubator
- Sipper probe and rinse station
- Sipper pipetter
- System reagents (ProCell and CleanCell)
- Detector unit

**Incubator**

The incubator is at the back of the analyzer to the right of the pipetting station. The incubator has 32 positions. To the right of these positions is the aspiration station.




**A** Incubator positions **B** Aspiration station

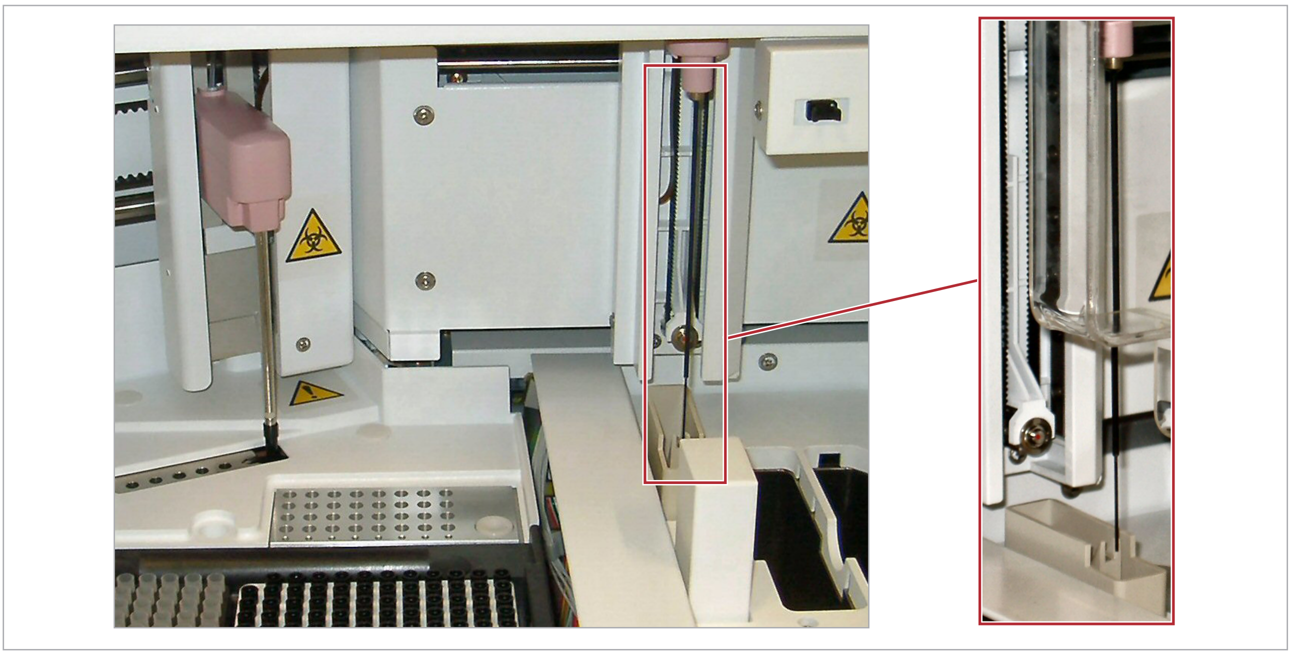
The incubator maintains a temperature of 37.0 °C ± 0.3 °C in its 32 positions. This incubator temperature is required to cause the reaction between the sample and the reagent in the AssayCup.

When the reaction has occurred, the gripper moves the AssayCup to the aspiration station. The sipper probe then transfers the reaction mixture into the detector unit.

The aspiration station is not temperature controlled.

**Sipper probe and rinse station**

The sipper probe is located to the right-hand side of the incubator.



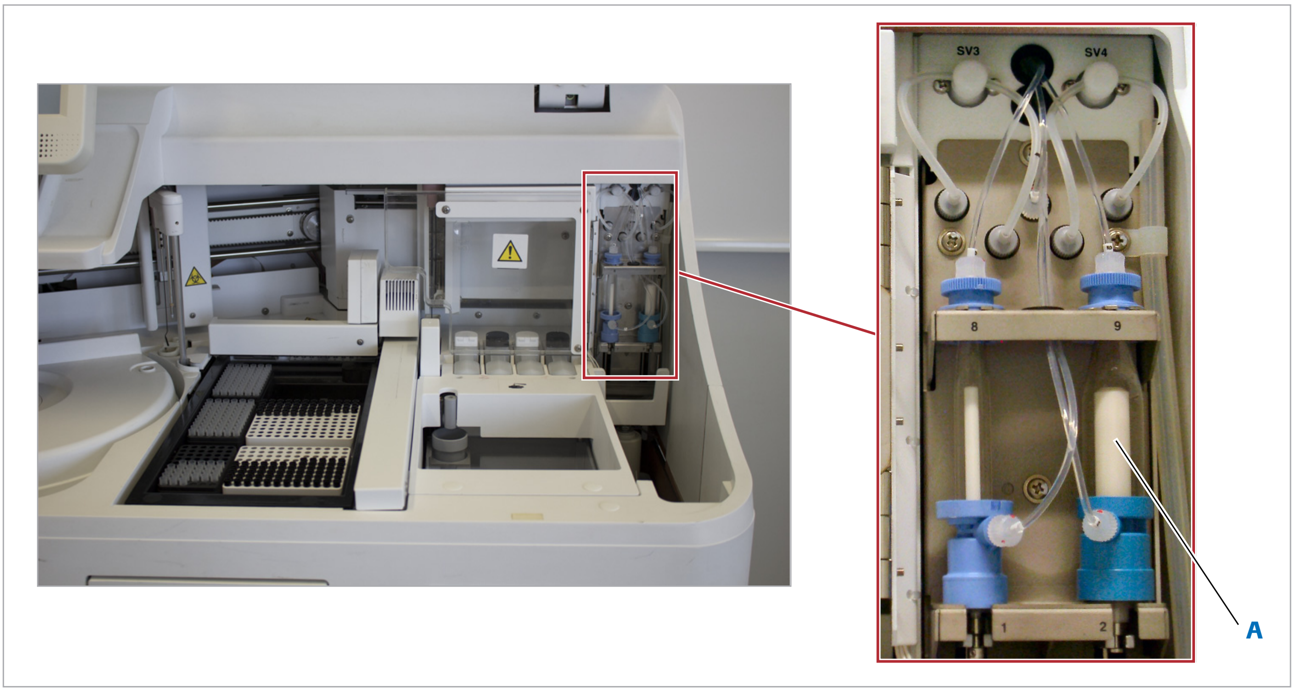
Sipper probe and rinse station

The sipper probe pipettes the reaction mixture into the measuring cell. The sipper probe also aspirates reagent from the ProCell and CleanCell.

The rinse station of the sipper probe washes the outside of the sipper probe with system water. The home position of the sipper probe is above the rinse station.

**Sipper pipetter**

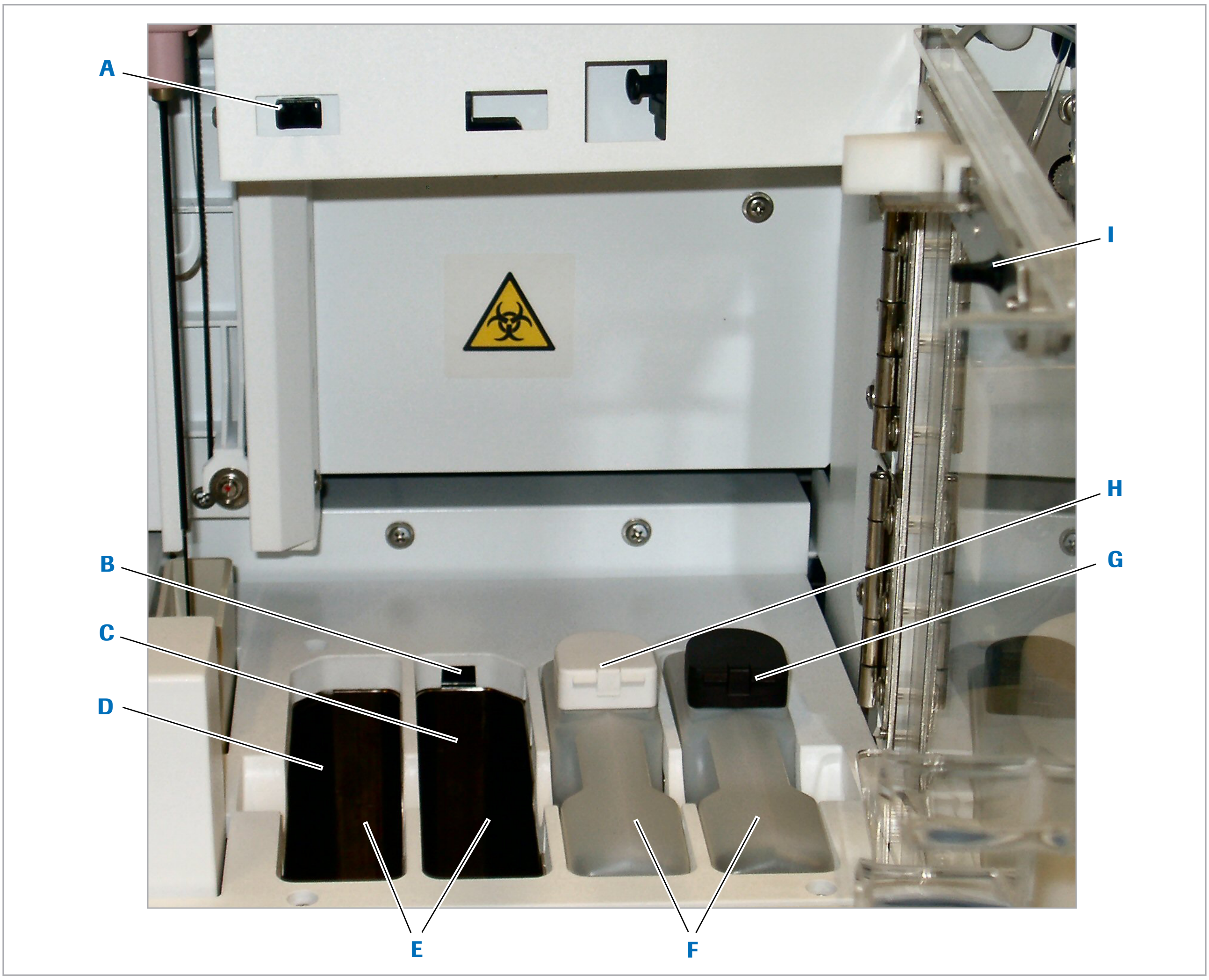
The sipper pipetter is located directly to the right of the S/R pipetter, behind the liquid waste container.




**A** Sipper pipetter location

### System reagents (ProCell and CleanCell)

The ProCell and CleanCell are located in bottles in the pipetter area, behind the liquid waste container. To access the pipetter area, open the transparent sipper shield.




**A** Sipper shield latch
**B** Photosensor
**C** Position 2 (CleanCell position) of bottle set 2. Shown with bottle removed.
**D** Position 1 (ProCell position) of bottle set 2. Shown with bottle removed.
**E** Bottle set 2
**F** Bottle set 1
**G** Position 2 (CleanCell position) of bottle set 1.
**H** Position 1 (ProCell position) of bottle set 1.
**I** Open sipper shield

ProCell is a buffer solution that contains tripropylamine (TPA). ProCell bottles have white caps.

CleanCell is a cleaning solution that the analyzer uses to clean the measuring cell after measurement. CleanCell bottles have black caps.

Two bottles of each reagent are stored on the analyzer, temperature controlled at 28.0 °C ± 2.0 °C. The keyed shape of the reagent compartment ensures that the reagent bottles can only be placed in the proper position.

At the back of each ProCell and CleanCell compartment is a photosensor. The photosensors check for the presence of the ProCell and CleanCell bottle set.

To open the sipper shield, press the PUSH OPEN indentation. Close the sipper shield before operating the analyzer. The analyzer does not operate with the sipper shield open.

**⚠ CAUTION**

**Unscheduled alarm due to opening the sipper shield during operation**

If you open the sipper shield during operation, then the analyzer stops and issues an alarm.

- Do not open the sipper shield while the analyzer is in operation.

**⚠ CAUTION**

**Equipment damage due to incorrect opening of the sipper shield**

If you open the sipper shield without releasing the latch, then the sipper shield latch can be damaged,

- To open the sipper shield, push the area marked PUSH OPEN to release the latch.

**⚠ CAUTION**

**Damage or damp on the photosensors**

Damp or damaged photosensors do not detect the presence of the ProCell/CleanCell bottle set.

- Take care not to scratch or smear the photosensors in compartment position 2 for each bottle set.
- If the photosensors become wet, then use a cotton swab to dry them.

When starting from standby, the sipper probe always attempts to use ProCell and CleanCell from bottle set 1 first. If the quantity is insufficient, then the analyzer uses bottle set 2. When starting from S.Stop or R.Stop, the bottle set that the analyzer previously used is pipetted.

**Detector unit**

The detector unit receives the incubated reaction mixture aspirated from the sipper probe.

For more information on the detector unit measuring cell, refer to the Compendium of background information.

# Overview of the control unit

The control unit is at the top left of the analyzer. The control unit includes the items below.

- Touchscreen monitor
- Connections for data storage, an external printer, and a host interface.

**Touchscreen monitor**

The 39 cm (15 inch) color touchscreen monitor is on the top left of the analyzer. Use the touchscreen to perform the tasks below.

- Display information
- Navigate through the software
- Initiate analyzer functions


**A** On/Off button

You can tilt the monitor to provide the best view. Use your finger or a stylus to select the required buttons and fields. Do not press too hard with your finger or the stylus as you could damage the touchscreen.

If you do not touch the touchscreen for 30 minutes the back light turns off. To reactivate the touchscreen monitor, touch the screen.

**Data storage**

The analyzer uses flash memory, memory cards, and a USB port for data storage. You can read data from the DVD-ROM, but you cannot write to it.

The memory locations described above contain the data files necessary for the software and analyzer to work together.

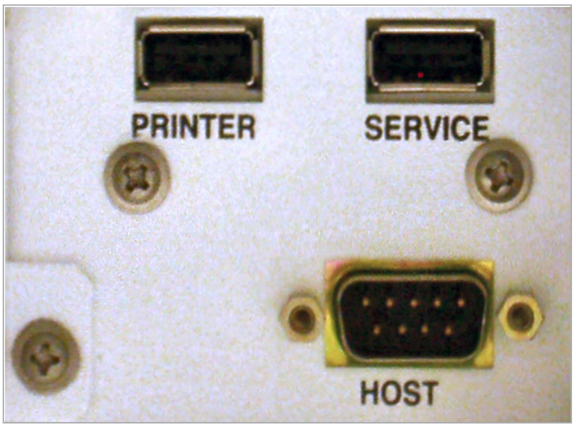
| Data type | Information stored |
|---|---|
| Reagent data | Up to 300 reagent packs |
| Sample data | Up to 2000 test records |
| Calibration data | Up to 160 calibrators |

Data files

| Data type | Information stored |
|---|---|
| QC data | Up to 100 controls |
| Parameter data | 60 parameters for assays<br>5 parameters for calculated tests<br>Up to 20 operator IDs<br>Analyzer serial number |
| Log data | Up to 20 000 daily alarm blocks<br>Up to 1000 operator ID logs<br>Up to 180 logs for each maintenance action<br>Up to 5 MB host communication log |

Data files

**External printer**




You can use one of the printers listed below with the analyzer.

- HP LaserJet 1320
- HP LaserJet P2015n
- HP LaserJet 2035
- Lexmark MS310d

**NOTICE**

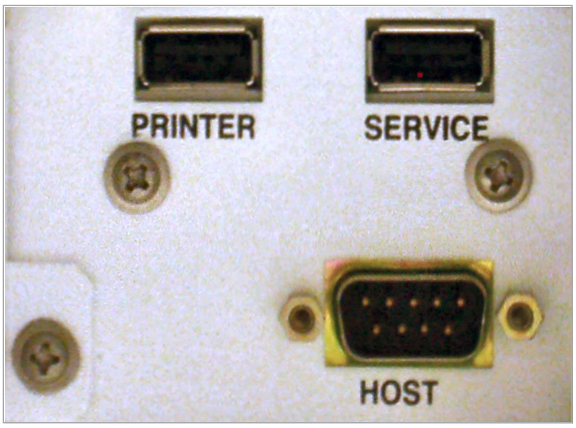
**Unapproved printers**

Roche Diagnostics does not support unapproved printers.

- Only use the printers in the list above, which have been tested and approved for use with the **cobas e** 411 analyzer.

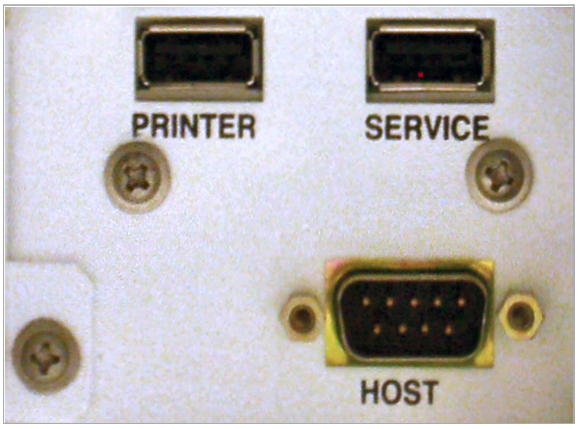
Connect the printer to the port on the left-hand side of the analyzer.

**Service interface**



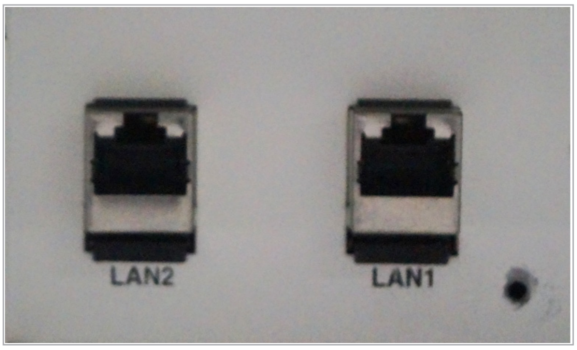

Use the Service port to connect to an external DVD-RAM disk drive or USB flash drive. You can back up information on the analyzer to either a DVD-RAM disk or a USB flash drive. Contact Roche Diagnostics Technical Support for more information.

**Host interface**




Use the Host port to connect to external host software. Contact Roche Diagnostics Technical Support for more information.

**LAN ports**




Use the LAN ports to connect to the **cobas**® link platform. Contact Roche Diagnostics Technical Support for more information.

# Overview of the power components

**Operation switch**

The operation switch for the analyzer is on the lower-left front side of the analyzer.


The operation switch controls power to the analyzer and the touchscreen monitor. The operation switch does not switch off power to the reagent rotor and system reagent compartment heaters.

**Circuit breakers**

There are two circuit breakers on the rack system and one circuit breaker on the disk system.

Both systems have a circuit breaker, which controls the power supplied to the reagent rotor and system reagent compartment heaters. When you connect or disconnect the host cable, power off the analyzer at the circuit breaker only.

The rack system has a second circuit breaker. This circuit breaker controls power to the rack sampler. The rack sampler circuit breaker should always be left on.

# cobas® link

In this chapter 2

# About cobas® link

The **cobas®** link provides a method to retrieve and distribute information from the Roche Remote Service infrastructure.

The **cobas®** link is not available in all countries.

Use the **cobas®** link to perform the actions below.

- Automatically download recent information on applications, calibrators and controls from the Roche Remote Service infrastructure to your system
- Access the **cobas®** e-library to view instructions for use and value sheets for calibrators and controls
- Archive **cobas®** e-library package inserts and analyzer parameters
- Automatically back up data to the **cobas®** link data station
- Upload statistical data from your system, to monitor performance and for QC management
- Share screens with a Roche Service representative, for troubleshooting and support

**Roche Remote Service infrastructure**

The Roche Remote Service infrastructure uses a secure internet connection to provide information services for you and your **cobas®** systems.

The infrastructure consists of the **cobas®** e-services below.

| cobas e-service | Function |
|---|---|
| **cobas®** e-library | Automatically download test parameters and information on applications, calibrators, and controls |
| **cobas®** e-support | Share screens with a Roche Service representative, for troubleshooting and support |
| **cobas®** e-LabPerformance | Upload statistical data from your system, to monitor performance and for QC management |

**cobas®** e-services

**cobas® link**

The **cobas®** link is a dedicated computer in the laboratory that runs the **cobas®** link software package. A **cobas®** link connects one or more **cobas®** systems to the Roche Remote Service infrastructure.

The **cobas**® link is connected to the control unit of the **cobas e** 411 analyzer.

A Roche Service representative sets up and configures the **cobas**® link.

The **cobas**® link includes the software components below.

| Software component | Function |
|---|---|
| Configurator | The Roche Service representative uses the configurator to set up and administrate the **cobas**® link. |
| Roche Connectivity Layer, or RCL | Manages the information flow between the **cobas**® link and the Roche Remote Service infrastructure |
| Hitachi driver, or HHT | Manages the information flow between the **cobas**® link and the **cobas**® systems |
| Human-Readable Data, or HRD, viewer | User interface of the **cobas**® e-library |

Software components of the **cobas**® link

The **cobas**® link releases electronic barcodes to the systems in your laboratory. The **cobas**® link stores back ups of the system data.

Use update DVDs to update the **cobas**® link. Use update CDs to update the **cobas**® e-library.

The **cobas**® link can download or upload information.

**Offline mode**

In offline mode, the **cobas**® link has no connection to the internet. The **cobas**® link cannot download or upload information.

**Online mode**

In online mode, the **cobas**® link has a stable connection to the internet. The **cobas**® link connects the systems in your laboratory with the Roche Remote Service infrastructure.

# About the cobas® link information flow

Download **cobas**® e-library packages from the Roche Remote Service infrastructure to the **cobas**® link.

**cobas**® e-library packages contain e-library package inserts and e-barcodes.

**Access to cobas® e-library**

You can access the **cobas**® e-library on the **cobas**® link data station.

**Content of cobas® e-library**

For each application, calibrator, and control, the **cobas**® e-library contains the latest version of the e-library package and the preceding version. Any older **cobas**® e-library packages are deleted from the **cobas**® e-library.

The **cobas**® e-library is updated daily via an automatic download from the Roche Remote Service infrastructure.

**cobas® e-library package inserts**

**cobas**® e-library package inserts contain the items below:

- Instructions for use
- Value sheets for calibrators and controls
- Important notes, for example, about reassigned control values
- Announcements from technical support

To read **cobas**® e-library package inserts, use the **cobas**® e-library application on the **cobas**® link.

**e-barcodes**

e-barcodes contain machine-readable information for **cobas**® systems, for example, the items below:

- Test-specific analyzer parameters
- Lot-specific analyzer parameters
- Values of calibrators and controls

**Parameter downloads from cobas® link**

If you need to download new e-barcodes from the **cobas**® link to a **cobas**® system, then the software on the system notifies you.

Updating calibrator or control information (55)

**Archiving information**

Accredited laboratories must archive package inserts and analyzer settings for many years.

Regularly copy documents that must be archived from the **cobas**® e-library to an archive server.

For data security, observe the guidelines below.

- Dedicate an external storage device, for example, a USB flash drive, to the data transfer from the **cobas**® link to the archive server.
- Before you use the storage device on the **cobas**® link, check the storage device with an antivirus program on a different PC.

**List of new entries**

In the **New Entries** menu, the list of new entries is limited to 200 entries. Entries are not older than 30 days.

You can filter the list, for example, for unread documents related to your **cobas**® system.

To find entries older than 30 days, search the **cobas**® e-library archive.

**Other features of cobas® e-library**

Other features of the **cobas**® e-library are below.

| | |
|---|---|
| **Comment** | Comment on documents, for example, with your initials, to mark a document you have read. |
| **Search** | Search for documents, for example, via the catalogue number on a reagent pack. |
| **Preferences** | Define preferences about documents that you want to see displayed in the **New Entries** menu. |

**Related topics**

- Installing calibrator lots with **cobas**® link (123).
- Installing control lots with **cobas**® link (143)

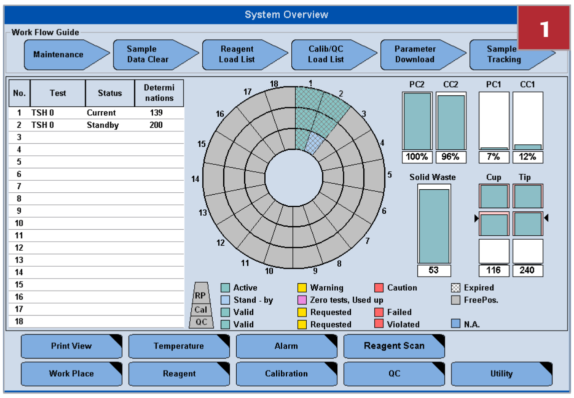
# Updating calibrator or control information

When information is updated in **cobas**® link, download it to update the analyzer.

Every time **cobas**® link is updated

1 minute

### To update calibrator or control information



1 From the **System Overview** window, choose the **Parameter Download** button.

2 Choose the **Calibrator** tab or the **Control** tab.

3 Select the required information.

4 Choose the **Download** button.

# Specifications

## In this chapter

3

# Technical data

**Analyzer plate**

A plate on the right side of the analyzer displays the part number, serial number, and power requirements.


**Analyzer dimensions**

| Analyzer Type | Height | Depth | Width | Weight |
|---|---|---|---|---|
| Disk | 31.4 in (includes touchscreen) | 28.7 in | 47.2 in | 397 lbs |
| | 80 cm (includes touchscreen) | 73 cm | 120 cm | 180 kg |
| | 43 in or 109 cm with top cover opened | | | |
| Rack | 31.4 in (includes touchscreen) | 37.4 in (includes STAT position) | 67 in | 551 lbs |
| | 80 cm (includes touchscreen) | 95 cm (includes STAT position) | 170 cm | 250 kg |
| | 43 in or 109 cm with top cover opened | | | |

Analyzer dimensions

# Environment

## Electrical requirements

| Requirements | Details |
|---|---|
| Installation requirements | The analyzer complies with the safety requirements of:<br>IEC 61010-1<br>IEC 61010-2-101<br>Pollution degree: 2 (IEC 61010-1)<br>Overvoltage category: II (IEC 664)<br>The **cobas e** 411 analyzer complies with the emission and immunity requirements described in the standard IEC 61326-2-6 / EN 61326-2-6.<br>The **cobas e** 411 analyzer must be connected to a three-wire power supply cord with a safety ground. |
| AC Cord Set ratings:<br>Countries requiring UL and CSA:<br>115 V<br>208 or 240 V<br>Temperature rate<br>Whole length<br>Safety standard<br>Europe<br>220 to 240 V<br>Temperature rate<br>Whole length<br>Safety standard | <br><br><br>AC125V-15A / SJT type 3X14AWG<br>AC250V-10A / SJT type 3X16AWG<br>Minimum 60 °C<br>2500 ± 50 mm<br>UL817 / CSA C22.2 No.21<br>The AC Cord must be marked "HAR"<br>AC250V-10A / 3X1.16AWG<br>Minimum 60 °C<br>2500 ± 50 mm<br>CENELEC HD21 |
| Connector type to e 411 inlet | IEC320 / EN60320 type |
| Supply voltage/frequency | 100 - 240V AC, 50/60 Hz single phase.<br>The power supply voltage is automatically detected by the system. |
| Main supply voltage fluctuation | ± 10% of nominal voltage (90V AC to 264V AC) |
| Power consumption | Disk system - 1000 V A<br>Rack system - 1250 V A (Analyzer unit: 1000 V A; rack sampler unit: 250 V A) |
| Heat generation (approximate) | Disk system:<br>2879 kJ/hresp<br>688 kcal/hresp<br>2730 Btu/hr<br>Rack system:<br>3778 kJ/hresp (Rack sampler unit: 899 kJ/hr resp)<br>903 kcal/hresp (Rack sampler unit: 215 kcal/hr resp)<br>3583 Btu/hr (Rack sampler unit: 853 Btu/hr) |

Electrical specifications

## Environmental conditions

The analyzer is designed for indoor use only.

| Requirement | Details |
|---|---|
| Temperature | Operation: 18 to 32 °C<br>Storage and transport: -20 to 75 °C |
| Temperature variation | Maximum ± 2 °C/h |
| Humidity (indoor use only) | Operation: 20 - 80% (non-condensing)<br>Storage and transport: 5 to 95% (non-condensing, <80% average per year) |
| Altitude | Operation up to 2000 m |

Environmental conditions

### Noise level

| Requirement | Details |
| --- | --- |
| Noise level requirement | EN ISO 11202:2010 |
| Operation level (maximum (time average)) | 70 dBA(1) |

Noise level

(1) The A-weighted emission sound pressure level is measured at the following positions: at the touch screen of the control unit, at the sample loading positions, and 1m away from the system.

### Water supply

| Requirement | Details |
| --- | --- |
| Water container | 3 L |
| Water requirements | < 10 µS/cm or > 0.1 megohm, bacteria free (SysWash is added, with a dilution 100+1) |
| Water consumption (approximate) | 3 L for 250 tests<br>12 mL/cycle |

Water supply

# Analyzer system

**Control unit**

| Requirement | Details |
|---|---|
| Type | Integral PC unit with touchscreen monitor |
| Data storage | Compact flash card |
| System interfaces | Standard PC ports (USB, ethernet, and serial) for other communication devices (remote access, cobas link) |
| Host interface | CCITT V. 24/RS-232-C (bidirectional) |
| External printer | Connection through a USB port |
| Touchscreen monitor | 39 cm (15 in) color TFT-LCD, XGA |
| Operating system | Microsoft Windows XP (embedded version) or Microsoft Windows 10 (embedded version) |

Control system

**Measuring System**

| Requirement | Details |
|---|---|
| Measuring method | Integral measuring of an electrochemiluminescence signal |
| Calibration mode | 2-point calibration |
| ProCell consumption | Approximately 2 mL per cycle |
| CleanCell consumption | Approximately 2 mL per cycle |
| Cycle time | 42 s |
| Temperature | 28.0 °C ± 0.3 °C |

Measuring system

**Incubation system**

| Requirement | Details |
|---|---|
| Incubator capacity | 32 AssayCups |
| Volume of AssayCups | 200 µL |
| Incubation temperature | 37.0 °C ±0.3 °C |

Incubation system

**Sampling system**

| Requirement | Details |
|---|---|
| Sample / reagent pipetter principle | Conductive disposable AssayTip handling |
| Sample volume per test | 10 to 50 µL |
| Sample / reagent pipetter precision | For 10 µL volumes, the coefficient of variance is <1.2% at an ambient temperature of 18 to 25 °C and <2.4% at an ambient temperature of 25 to 32 °C.<br><0.8% CV for 50 µL volumes. |
| Sample detection | Liquid level detection and clot detection. |
| Sample loading capacity | Disk system:<br>30 positions for samples, controls, and calibrators.<br>Rack system:<br>Rack tray - 15 racks with five positions each = 75 positions<br>Input buffer - 5 racks with five positions each = 25 positions<br>Total - 100 positions for samples, controls, and calibrators. |

Sampling system

| Requirement | Details |
|---|---|
| STAT capacity | Disk system:<br>Any unoccupied position on the sample disk.<br>Rack system:<br>STAT rack position at the front of the analyzer. |
| Barcode symbologies | The barcode symbologies that can be read include the following:<br>PDF417<br>NW7 (Codabar)<br>Code 39<br>Code 128<br>Interleaved 2 of 5 |
| Assay tips | 360 AssayTips (3 trays, with 120 AssayTips/tray) |
| Assay cups | 180 AssayCups (3 trays, with 60 AssayCups/tray) |
| Sample cups(1),(2) | Roche-certified 2 mL sample cups<br>Do not use micro cups |
| Primary sample tubes(2))<br>(external diameter x height) | 13 x 75 mm and 16 x 75 mm<br>13 x 100 mm and 16 x 100 mm |

Sampling system

(1) Single use containers.

(2) For the expiration date, refer to the product label of the respective containers.

### Throughput rate

| Requirement | Details |
|---|---|
| Assay measurements | Up to 86 tests/hour |

Throughput rate

# Waste

**Liquid waste**

| Requirement | Details |
|---|---|
| Liquid waste container | Capacity: 4 L, with overflow detection. |

Liquid waste

**Solid waste**

| Requirement | Details |
|---|---|
| Disposable solid waste container | Capacity: 420 AssayCups and 680 AssayTips, or 1100 items. |

Solid waste

# Residual volume

### Residual volume (disk system)

| Sample container | Tube height | "Normal" residual volume | "Reduced" residual volume |
|---|---|---|---|
| Sample cup directly on the sample disk | - | 200 µL | 100 µL |
| Sample cup on top of a primary sample tube (16 mm diameter) | 75 mm | 200 µL | 150 µL |
| Sample cup on top of a primary sample tube (16 mm diameter) | 100 mm | 200 µL | 150 µL |
| Primary sample tube (13 mm diameter) | 75 mm | 600 µL | - |
| Primary sample tube (13 mm diameter) | 100 mm | 600 µL | - |
| Primary sample tube (16 mm diameter) | 75 mm | 1000 µL | - |
| Primary sample tube (16 mm diameter) | 100 mm | 1000 µL | - |
| Calibrator vial / control vial:<br>The distinction "Normal" or "Reduced" does not apply for the residual volumes of calibrator or control vials | - | 150 µL | - |

Sample container residual volume (disk system)

### Residual volume (rack system)

| Sample container | Tube height | "Normal" residual volume | "Reduced" residual volume |
|---|---|---|---|
| Sample cup directly on the sample rack | - | 200 µL | 100 µL |
| Sample cup on top of a primary sample tube (16 mm diameter) | 75 mm | 200 µL | 100 µL |
| Sample cup on top of a primary sample tube (16 mm diameter) | 100 mm | 200 µL | 100 µL |
| Primary sample tube (13 mm diameter) | 75 mm | 600 µL | - |
| Primary sample tube (13 mm diameter) | 100 mm | 600 µL | - |
| Primary sample tube (16 mm diameter) | 75 mm | 1000 µL | - |
| Primary sample tube (16 mm diameter) | 100 mm | 1000 µL | - |
| Calibrator vial/ control vial:<br>The distinction "Normal" or "Reduced" does not apply for the residual volumes of calibrator or control vials. | - | 150 µL | - |

Sample container residual volume (rack system)

### Residual volume using a Roche-certified false bottom tube

| Sample container | "Normal" residual volume | "Reduced" residual volume |
|---|---|---|
| RD Standard False Bottom Tube, from Roche | 200 µL | 200 µL |
| Sarstedt False Bottom Tube, from Sarstedt | 200 µL | 200 µL |
| On a disk system, false bottom tubes may only be used in conjunction with a 13 mm sdta.<br>On a rack system, false bottom tubes may only be used in conjunction with a Roche rack cup adapter. | | |

Residual volume of Roche-certified false bottom tubes

⚠ **CAUTION**

**Incorrect results when using non-certified false bottom tubes**

Non-certified 13 mm false bottom tubes from other manufacturers may cause inaccurate sample pipetting, which may lead to incorrect results.

- Only use false bottom tubes that are certified by Roche.

⚠ **CAUTION**

**Working with low sample volumes**

If the volume of a sample is insufficient, then the analyzer may not be able to perform the test.

- To achieve a reduced residual volume of 200 µL on a disk system, use a Roche-certified false bottom tube in a 13 mm sdta.
- To achieve a reduced residual volume of 200 µL on a rack system, use a Roche-certified false bottom tube in a Roche rack cup adapter.

**NOTICE**

**Working with 13 mm sdtas or Roche rack cup adapters**

13 mm sdtas and Roche rack cup adapters are for use with 13 mm tubes and specified false bottom tubes.

- Do not use a 13 mm sdta or Roche rack cup adapter with any of the following containers.
    - Control vials
    - Calibrator vials
    - Roche-certified sample cups, for example, the 2 mL Hitachi Standard Cup or the 2 mL Roche Sample Cup (catalog number 10 394 246 001)

# Reagent system

### Assay Reagent system

| Requirement | Details |
|---|---|
| Reagent rotor temperature | 20 °C ± 3 °C |
| Reagent capacity | Up to 18 assays, 9 pretreatments, or 8 diluents in 18 reagent positions |
| R1/R2 consumption | 50 to 80 µL per reagent, dependent on the assay |
| Microbead consumption | 30 to 50 µL dependent upon the assay |
| Reagent detection | Liquid level detection |
| Positive reagent identification | Two-dimensional barcode (PDF417) |
| Automatic dilution | Available up to 1:100 (for applicable assays) |
| Evaporation protection | Reagent lids are automatically opened and closed |

Assay reagent system

### System Reagent system

| Requirement | Details |
|---|---|
| Temperature | 28 °C ±2 °C |
| Inventory control | Automatic based on counting (reagent rotor) or liquid level detection (ProCell / CleanCell) |
| ProCell consumption | Approximately 2 mL per cycle |
| CleanCell consumption | Approximately 2 mL per cycle |

System reagent system

# Control kits

**Control kits**

For most tests, controls for the Elecsys reagents come packaged separately, for example Elecsys PreciControl Universal. Each kit contains barcoded control vials for use on the analyzer.

Most of the controls are lyophilized in glass bottles and must be reconstituted before being transferred into plastic barcode-labeled vials. Empty barcode-labeled vials are packaged in these kits with lyophilized controls. You can store reconstituted controls in the plastic vials after transfer.


**A** Empty control vials to be filled with level 2 controls(1),(2)

**B** Empty control vials to be filled with level 1 controls(1),(2)

**C** Bottles containing level 2 controls to be reconstituted according to the package inserts

**D** Bottles containing level 1 controls to be reconstituted according to the package inserts

**E** Control barcode card

**F** Package inserts

**G** Extra labels for control aliquots that should be kept separately

(1) Single use containers.

(2) For the expiration date, refer to the product label of the respective containers.

PreciControl Universal kit

Controls also have color-coded caps to assist you in identification. A level 1 control has a light brown cap and a level 2 control has a dark brown cap. Read the package insert to check the color of the caps on the level 1 and level 2 controls.

Each control bottle has a linear barcode label that contains an identifier. The identifier links it to information encoded in the reagent barcode label and the control barcode card.

**Control barcode cards**

Each control kit comes with control barcode cards. These cards are in the PDF417 format and must be used with the corresponding controls.


A control barcode includes, but is not limited to, the information below.

- Test number
- Control lot number
- Control number
- Control code, for example, PC U1
- Lot identifier for control barcode labels
- Target or assigned values
- Control ranges
- Expiration date

When you use a new control lot, scan the new control barcode cards or download the information from **cobas**® link.

# Calibrator kits

**Calibrator kits**

For most tests, calibrators for the Elecsys reagents can be ordered separately, for example the Elecsys FT3 or Troponin-T CalSet. Each kit contains barcoded calibrator vials. Some calibrators are in ready to use liquid form, and can be inserted into the sample disk or rack when a calibration is necessary.


**A** Empty calibrator vials to be filled[(1),(2)]

**B** Bottles containing calibrators to be reconstituted according to the package insert

**C** Calibrator barcode card

**D** Package inserts

**E** Extra labels for calibrator aliquots that should be kept separately

(1) Single use containers.

(2) For the expiration date, refer to the product label of the respective containers.

Calibrator kit

A few of the calibrators are lyophilized in glass bottles and must be reconstituted before being transferred into plastic barcode-labeled vials. Empty barcode-labeled vials are included in kits with lyophilized calibrators. You can store reconstituted calibrators in the plastic vials after transfer.

Calibrators have color-coded caps to assist you in identification. Level 1 calibrators have white caps, and level 2 calibrators have black caps. Each calibrator bottle has a traditional linear barcode label. This label contains an identifier which links it to information encoded in the reagent barcode label and the calibrator barcode card.

**Calibrator barcode cards**

Each calibrator kit comes with calibrator barcode cards. The barcode cards are in the PDF417 format and must be used with the corresponding calibrators. A calibrator barcode includes, but is not limited to, the information below.

- Test number
- Calibrator lot number
- Lot identifier for calibrator barcode labels
- Target or assigned values
- Expiration date

Roche Diagnostics produces a factory master calibration for each calibration lot. The results are encoded into the corresponding reagent barcode. When you use a new calibrator lot, scan the new calibrator barcode cards or download the information from **cobas**® link.

Performing calibration (118)

# Reagent kits

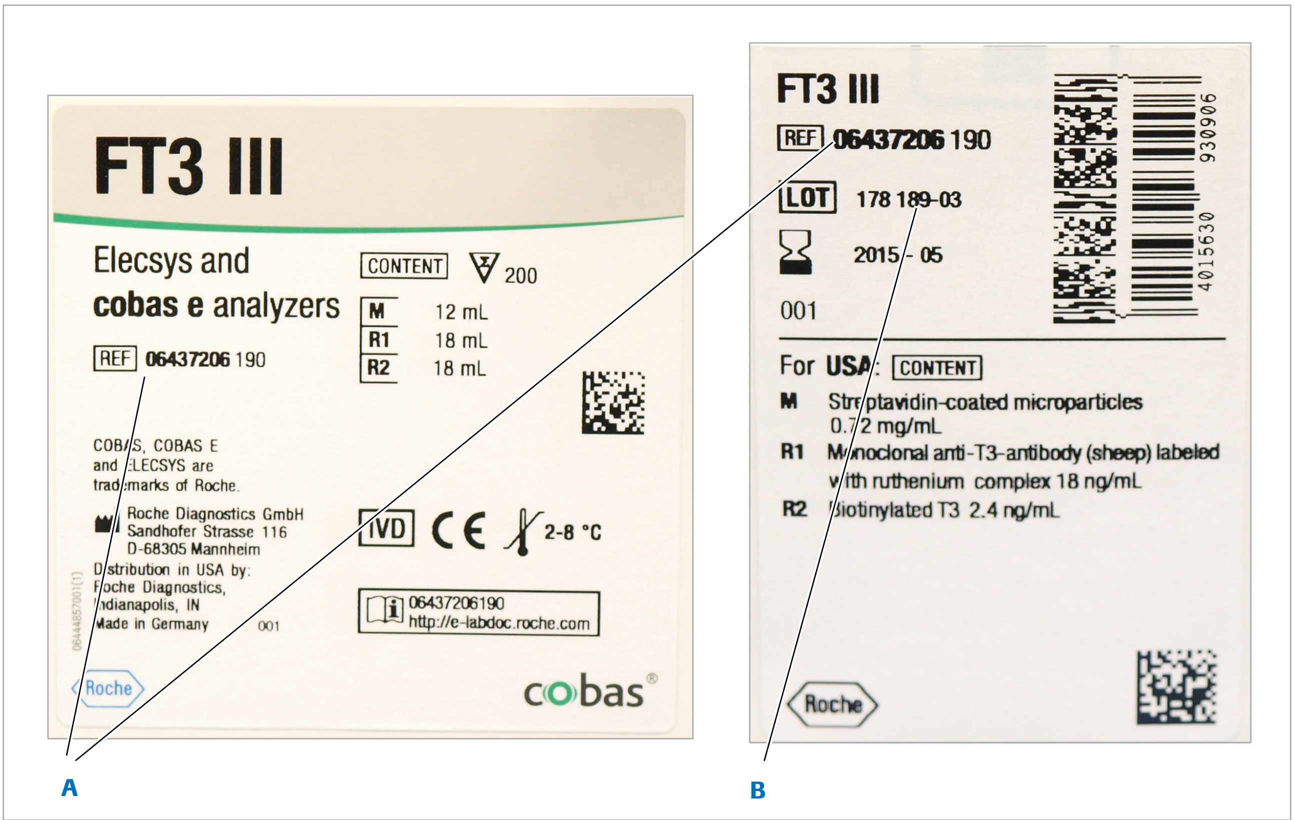
**Reagent kit box labels**

Reagent packs are supplied as part of a reagent kit. The large label on the reagent kit box gives the details below.

- Intended use
- Storage temperature
- List of box contents
- Catalogue number of the kit

The label on the side of reagent kit box gives the details below.

- Lot number
- Expiration date
- Barcode number

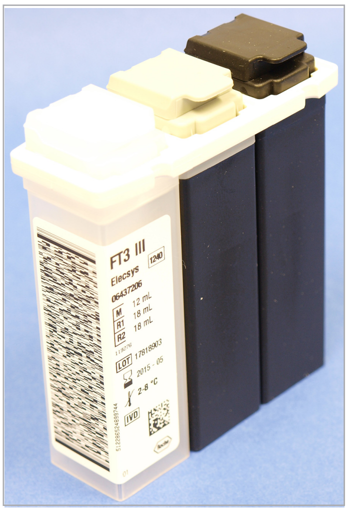



**A** Kit catalog number

**B** Reagent pack lot number

Reagent box labels

### Reagent packs




Each reagent pack is a single ready to use unit that consists of the three bottles listed below.

- A transparent bottle, with a transparent lid, which contains suspended paramagnetic microbeads (M)
- A black bottle, with a grey lid, which contains reagent 1 (R1)
- A black bottle, with a black lid, which contains reagent 2 (R2)

The reagent pack and reagent rotor are keyed to prevent you from placing reagents on the analyzer incorrectly.

### Reagent barcode label

Reagent packs have a barcode label that contains information required to run the assay on the analyzer. A reagent barcode includes, but is not limited to, the information below.

- Test number
- Lot number
- Master calibration curve parameters (for example, Rodbard parameters)
- Analyzer settings
- Calibrator lot numbers and assigned values
- Expiration date
- Calibration frequency
- Sample volume
- Measuring range
- Number of determinations

### Package inserts

Each test has a package insert or method sheet, which can be found on GRIPS, that provides detailed information required to perform the assay. A package insert includes, but is not limited to, the information below.

- Intended use
- Test principle
- Reagent handling and stability
- Calibration and QC information
- Measuring range
- Dilution
- Expected values

# External storage devices

To backup and restore data, or export test results for further analysis, you can use DVD-RAM disks or USB flash drives.

**External storage devices**

| Requirement | Details |
|---|---|
| DVD-RAM supported formats | UDF2.01, recommended UDF2.00 UDF1.50 |
| DVD-RAM supported speed | 1-5 times speed |
| DVD-RAM disk / USB flash drive supported formats | NTFS, recommended FAT32<br>USB flash drive is 32 GB or less |
| External storage device notes | This system does not support security functionality on the external storage device, for example passwords or anti-virus applications. The system does not support more than one external storage device at a time. |

External storage devices

# Accessories and consumables

A list of globally available accessories and consumables can be found under eLabDoc on the Roche DiaLog website:

*www.dialog.roche.com*

If you are unable to access Roche DiaLog, contact your local Roche Sales representative.

# Operation and maintenance

# Overview of operation

**In this chapter** 4

# Overview of the software

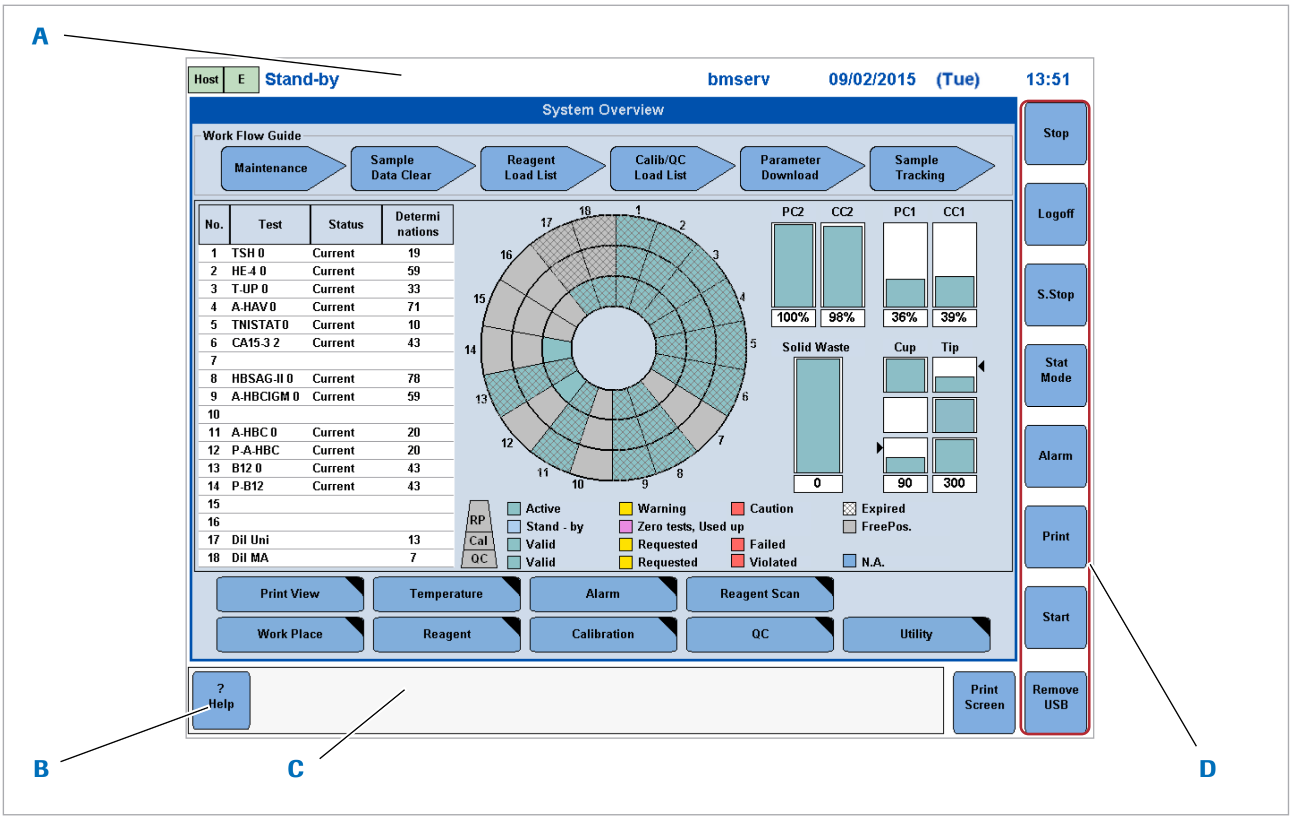
To control the analyzer, and view information and results, use the software installed on the control unit PC.

**NOTICE**

**Screen representations in the manual**

The screens shown in the manual may not show valid results. The screens may also show items which depend on different access levels.

- Look at the software on your analyzer.
- Review the software descriptions in the Online Help.




**A** Status line

**B** Online Help

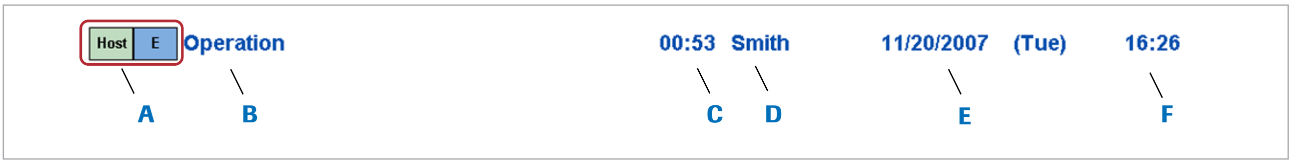
**C** Guidance prompt with no message displayed

**D** Global buttons

Screen configuration

**Status line**

The status line is shown at the top of the software. The information shown changes to reflect the status of the system.




**A** System overview button
**B** Current operational mode
**C** Sample reception mode remaining time
**D** Operator ID
**E** Date
**F** Time

Status line

The **System Overview** button on the left of the status line changes color to indicate the operational status of the analyzer. Choose this button at any time to display the **System Overview** window.

| Icon | Color | Meaning |
|---|---|---|
| Host | Blue | Host communication is Off |
| | Green | Host communication is On |
| E | Blue | The analyzer is in Initialization, Operation, or Maintenance mode |
| | Green | The analyzer is in Standby mode |
| | Yellow | An alarm has been issued with a caution level |
| | Red | An alarm of Stop, S.Stop, or E.Stop has been issued |

System Overview button color codes.

The status line displays the operational mode to the right of the **System Overview** button.

| Mode | Description |
|---|---|
| Start Up | Follows power-on. The analyzer prepares for operation. |
| Stand By | The power is on, but no sample analysis or maintenance procedures can be performed. |
| Initialization | The analyzer resets mechanisms to their home position and then enters Operation mode. |
| Operation | The analyzer processes samples. |
| Maintenance | The analyzer performs maintenance procedures. |
| Reset | The analyzer returns all mechanical parts to their home position. |

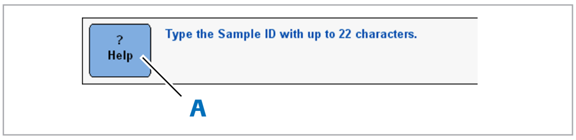
Operational modes

| Mode | Description |
|---|---|
| R.Stop (Rack Stop)<br>S.Stop (Disk Stop) | The analyzer comes to a controlled stop. No new samples are pipetted but existing samples are completed.<br>If the analyzer is in sample reception mode, then the analyzer does not enter Standby mode until the time interval elapses or the operator stops the analyzer. |
| CF Access | The analyzer reads the CF card. |
| Scan BC Card | The analyzer scans a calibrator or control barcode card. |
| Reagent Scan | The analyzer scans a reagent located in the reagent rotor. |
| Sleep | The analyzer is at rest and cannot immediately start processing requests. |

Operational modes

### Online Help system

To access the Online Help system of the analyzer, choose the **? Help** button. The Online Help displays the relevant software description for the current window or dialog box.



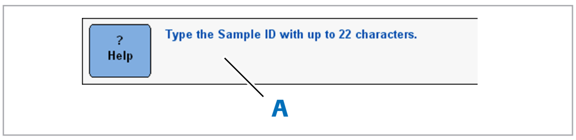

**A** Online Help button

To see different information, perform one of the steps below.

- Select the relevant item from the contents area on the left-hand side of the screen
- Select one of the related links
- Use the search or index areas on the left-hand side of the screen

Online Help links and searches work the same way as links or searches within the Internet.

### Guidance prompt

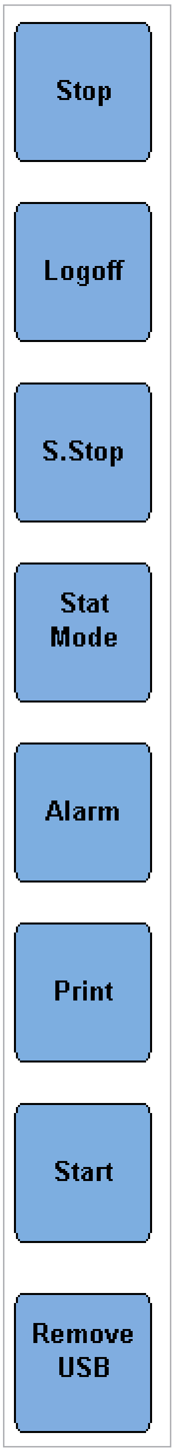



**A** Guidance prompt screen area

The guidance prompt area displays messages about what information you can enter or actions you can take. The message displayed relates to the text box or button you have selected in the software.

### Global buttons

There are eight global buttons on the right-hand side of the software.




| Button | Function |
|---|---|
| **Stop** | The analyzer stops at the end of the current mechanical cycle. |
| **Logoff** | The analyzer opens a dialog box so you can log off, change operator, or shut down the analyzer. |
| **S.Stop** | The analyzer comes to a controlled stop. The analyzer does not pipette any new samples, but completes all existing samples.<br>If the analyzer is in sample reception mode, then the analyzer does not enter Standby mode until the time interval elapses or the operator stops the analyzer. |
| **Stat Mode** | The analyzer enters STAT mode. The analyzer processes any STAT samples. |
| **Alarm** | The analyzer displays the **Alarm** window. |
| **Print** | The analyzer displays the **Print** window. |
| **Start** | The analyzer starts processing samples identified on the **Start Conditions** window. |
| **Remove USB** | If a USB flash drive is connected to the Service port, then the software checks the USB flash drive is not in use. When it is safe to remove the USB flash drive from the Service port, the software displays a message. |

Global buttons

**Main menu windows**

The main menu windows are displayed in the large middle section of the screen. There are six main windows which you use to control the analyzer.

The access level of the user restricts access to some software windows.

| Window name | Function |
|---|---|
| **System Overview** | • View the status of reagents, calibrations, and quality control<br>• Check the quantities of consumables available |
| **Workplace** | • Make, edit, and delete test selections<br>• Assign position numbers to samples<br>• Review and delete data. |
| **Reagent** | • View reagent information and add new reagents |
| **Calibration** | • Request, view, install, and define calibrations |
| **QC** | • Install, view, and edit control target values<br>• Evaluate and accumulate QC results |
| **Utility** | • Enter system settings or application parameters<br>• Perform maintenance or service functions |

Main Menu windows and their functions

Some buttons that are displayed on tabs or dialog boxes have a black triangle in the upper-right or lower-left corner.

If you press a button with a black triangle in the upper-right corner, then a new dialog box displays.

If you press a button with a black triangle in the lower-left corner, then the specified function is performed and the dialog box closes.

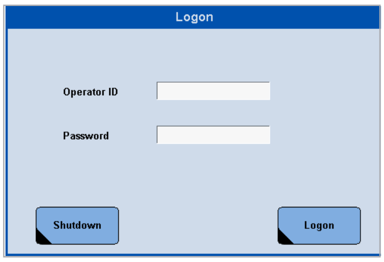
**Related topics**


- Quick start guide (86)
- Checklist for daily operation (91)

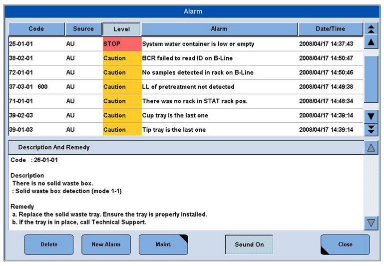
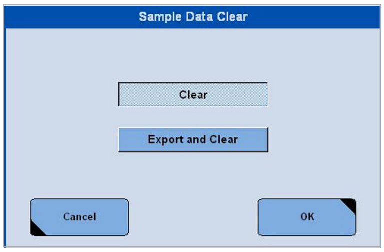
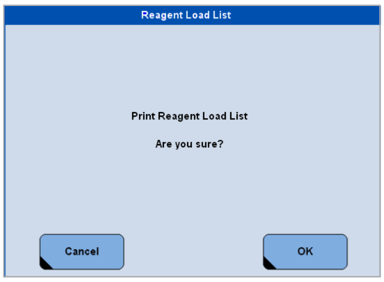
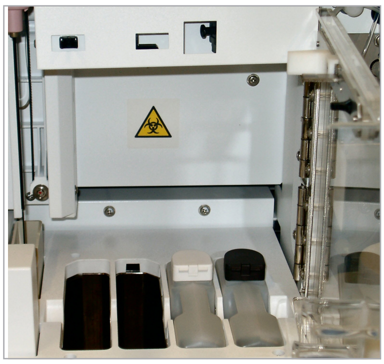
# Quick start guide

Perform a set of routine tasks every day. These tasks ensure you prepare the system, analyze samples, and maintain the system. The **System Overview** window has a workflow guide, which gives you a guide to the tasks required.

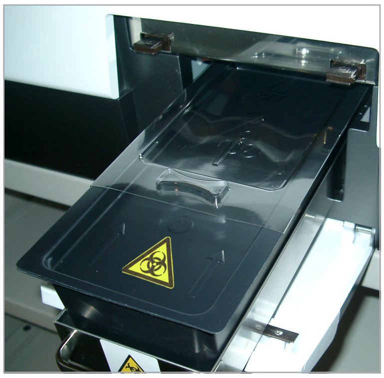
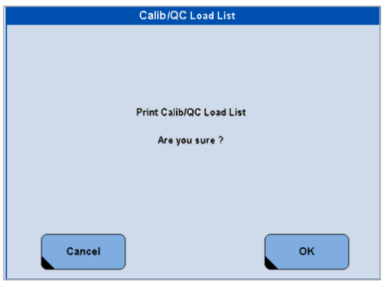
The quick start guide provides a recommended guide for routine operation.

<table>
<tr><th>Step</th><th></th><th>User action</th></tr>
<tr><td>1 Perform pre-start inspection</td><td></td><td>Check the items below:<br>1. The surfaces of the analyzer are clean.<br>2. The probes are clean and undamaged.<br>3. The pinch valve tubing is not worn out or damaged.<br>4. The pipetter syringes and tubing have no bubbles.<br>5. There are no waste materials in the analyzer.</td></tr>
<tr><td>2 Switch on the system</td><td><br></td><td>Switch on the items below:<br>1. The printer.<br>2. The analyzer.<br>3. The rack sampler, if the system is a rack system.</td></tr>
<tr><td>3 Enter your logon details</td><td><br></td><td></td></tr>
<tr><td>4 Open the lids on the ProCell and CleanCell bottles</td><td></td><td></td></tr>
</table>

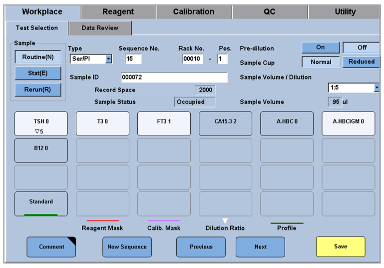
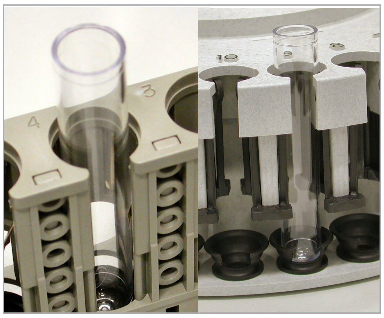
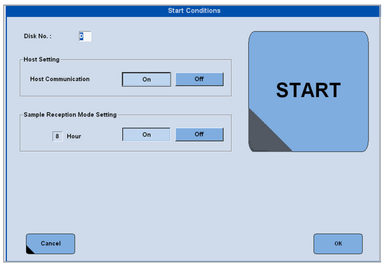
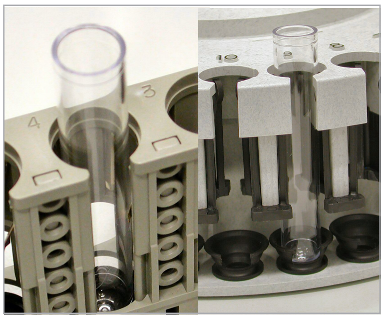
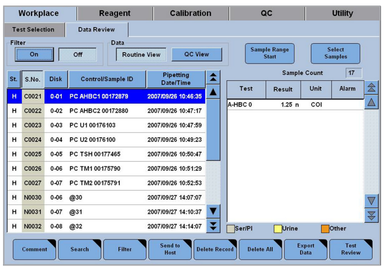
Quick start guide

<table>
<tr><th>Step</th><th></th><th>User action</th></tr>
<tr><td>5 Check system alarms and troubleshoot if necessary</td><td></td><td>1. Choose the Alarm global button.<br>2. To view the alarm description, choose the alarm.<br>3. Perform the remedy steps in the Description And Remedy panel.</td></tr>
<tr><td>6 Clear sample data every day</td><td></td><td>1. From the System Overview window, choose the Sample Data Clear button.<br>2. Choose the Clear button.<br>3. Choose the OK button</td></tr>
<tr><td>7 Print a Reagent Load List</td><td></td><td>1. From the System Overview window, choose the Reagent Load List button.<br>2. Choose the OK button.</td></tr>
<tr><td>8 Replace required reagent packs</td><td></td><td>1. Remove the cover of the reagent rotor.<br>2. Close the reagent pack lids.<br>3. Remove the old reagent packs.<br>4. Load new reagent packs.<br>5. Open the lids of the reagent packs.<br>6. Replace the reagent rotor cover.<br>7. From the System Overview window, perform a reagent scan.</td></tr>
<tr><td>9 If necessary, replace system reagents</td><td></td><td>1. Open the sipper shield.<br>2. Close the lids of all the CleanCell and ProCell bottles.<br>3. If the set 2 bottles have reagent in them, then move them to the set 1 position.<br>4. If the set 2 bottles do not have reagent in them, then replace the set 1 bottles with new system reagent.<br>5. Replace the set 2 bottles with new system reagent.<br>6. Open the lids of all the CleanCell and ProCell bottles.<br>7. Close the sipper shield.<br>8. Wait 15 minutes for the system reagents to be at the correct temperature.<br>9. If necessary, update the inventory set. Choose Reagent > Inventory Set, and then enter the new lot numbers.</td></tr>
</table>

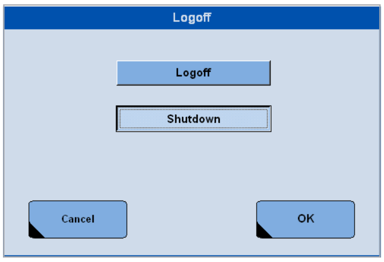
Quick start guide

| Step | | User action |
|---|---|---|
| **10** If necessary, replace AssayCup and AssayTip trays |  | 1. Lift out trays which need changing.<br>2. Insert full trays. |
| **11** Fill the system water container with distilled water and SysWash |  | 1. Lift the system water container out of the analyzer.<br>2. Empty the system water container and rinse it.<br>3. Fill the container with deionized water.<br>4. Add 35 mL of SysWash to the deionized water.<br>5. Return the system water container to the analyzer. |
| **12** If necessary, empty the solid waste container |  | 1. Open the door of the solid waste tray compartment.<br>2. Slide the tray out and place it onto the work surface.<br>3. Remove and dispose of the Clean-Liner.<br>4. Place a new Clean-Liner into the solid waste tray. Ensure the open side of the Clean-Liner is placed at the back of the solid waste compartment.<br>5. Slide the waste tray into the compartment.<br>6. Close the door to the compartment. |
| **13** Perform calibration and QC validation |  | 1. To check if calibration or QC is requested by the system, choose the **Calib/QC Load List** button.<br>2. Check if calibration renewal is due on each reagent pack.<br>3. If necessary, prepare calibrator and control material.<br>4. Insert calibrators or controls into the disk or rack. Either use barcodes or manually assign positions.<br>5. To measure calibrators, choose the global **Start** button and start the run. When sampling is complete, remove the calibrators and place them into the refrigerator.<br>6. Perform QC.<br>7. To validate calibration and control results, choose **Calibration > Status** and ensure there are not any failed calibrations. If there are failed calibrations, then recalibrate as necessary. |

Quick start guide

| Step | | User action |
|---|---|---|
| **14** Program patient samples |  | If the sample does not have a barcode, then program the information in.<br>1. On the **System Overview** window, choose **Workplace > Test Selection**.<br>2. Check that the **Routine** button is selected.<br>3. If appropriate, print a work list report.<br>4. Program in the tests from the work list report or laboratory list. |
| **15** Load patient samples |  | 1. Dilute samples, if necessary.<br>2. Print barcodes and attach to tubes, if necessary.<br>3. Slide tubes into the racks or disk.<br>4. Ensure the barcodes can all be read.<br>5. Load racks or the sample disk onto the analyzer. |
| **16** Start processing |  | 1. Choose the global **Start** button.<br>2. Check the settings on the **Start Conditions** dialog box.<br>3. On the **Start Conditions** dialog box, choose the **Start** button. |
| **17** Finish a run |  | 1. Remove samples from the analyzer.<br>2. Store or dispose of the samples as per laboratory protocol. |
| **18** Evaluate the results |  | Review results<br>1. Review as per laboratory protocols.<br>Print reports<br>1. From the **System Overview** window, choose **Workplace > Data Review**.<br>2. From the **S.No.** column, choose a sample.<br>3. From the **Data Review** window, choose the sample results to print.<br>4. From the **System Overview** window, choose **Print > Workplace**.<br>5. From the **Workplace Items** column, choose the **Result Report** option.<br>6. From the **Print Format** group box, choose to view on the monitor or print the report.<br>7. Choose the **Print** button. |

Quick start guide

| Step | | User action |
|---|---|---|
| **19** At the end of the day or shift, switch off the analyzer or put it to sleep |  | Switch off the analyzer<br>1. Choose the **Logoff** global button.<br>2. Choose the **Shutdown** button.<br>3. Choose the **OK** button.<br>Put the system to sleep<br>1. Switch the  switch to OFF.<br>2. The analyzer enters Sleep mode. |
| **20** Clean the analyzer |  | Close system reagents to prevent evaporation<br>1. Open the sipper shield.<br>2. Move the sipper arm out of the way.<br>3. Close the lids of the ProCell and CleanCell bottles.<br>4. Close the sipper shield.<br>Clean the S/R probe<br>1. Move the S/R probe to an accessible position.<br>2. Wipe the outer surfaces of the probe with lint free cloth.<br>Check the analyzer for condensation<br>1. Open the reagent rotor cover and remove the reagent rotor.<br>2. Inspect and dry the reagent rotor compartment.<br>3. Inspect and dry the system reagent components.<br>4. Return the reagent rotor to the compartment and replace the reagent rotor cover. |

Quick start guide

**Related topics**

- Checklist for daily operation (91)

# Checklist for daily operation

To perform daily operation, refer to the checklist below.

| Procedure | See |
|---|---|
| Pre-start inspection | Checking the system before startup (95) |
| Startup procedures<br>1. Switch on the analyzer<br>2. Log on<br>3. Open the lids on the ProCell and CleanCell bottles<br>4. Check system alarms<br>5. If necessary, perform troubleshooting on any alarms | Starting the system (97)<br>System alarms (101) |
| Pre-routine operation<br>1. Clear sample data every day<br>2. Print a reagent load list<br>3. Replace required reagent packs<br>4. If necessary, replace ProCell and CleanCell reagents<br>5. If necessary, replace AssayCup and AssayTip trays<br>6. Fill the system water container with distilled water and SysWash<br>7. If necessary, empty waste containers | Deleting documented patient results (200)<br>Printing a reagent load list (107)<br>Replacing reagent packs (108)<br>Replacing system reagents (110)<br>Loading consumables (181)<br>Cleaning and inspecting the valve of the system water container (250)<br>Emptying the solid waste tray (264) |
| Analyzer calibration and quality control<br>1. Check if calibration or QC is requested by the system<br>2. Check if calibration renewal is due on each reagent pack<br>3. If necessary, prepare calibrator and control material<br>4. Load required calibrators and controls<br>5. Measure calibrators and controls<br>6. Validate calibration and control results | Printing a Calib/QC load list (117)<br>Overview of reagents (105)<br>Performing calibration (118)<br>Performing QC (138)<br>Validating calibration results (134)<br>Validating QC results (152) |
| Sample processing<br>1. If necessary, program patient samples<br>2. Load patient samples<br>3. Start processing<br>4. Track processing | Overview of orders (155) |
| Result evaluation<br>1. Review results<br>2. If necessary, print reports<br>3. If necessary, delete documented samples | Results (191) |
| Daily maintenance<br>1. If necessary, perform finalization maintenance<br>2. Switch off the analyzer<br>3. Clean the S/R probe | Preparing the analyzer for an idle period (272)<br>Daily maintenance actions (205)<br>Cleaning the sample and reagent probe (221) |

Checklist for daily operation

**Related topics**

- Quick start guide (86)

# Before operation

## In this chapter 5

# Checking the system before startup

Before you start the system, check it is clean and not damaged.

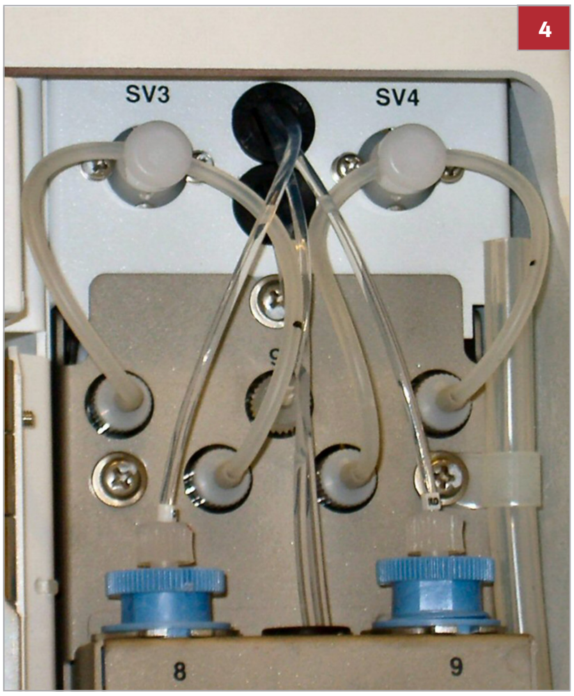
☐ The analyzer is off

## To check the system before startup


1 Lift the top cover of the analyzer.

2 Check the surfaces of the analyzer are clean.
   - If the surfaces of the analyzer are dirty, then clean them (263).


3 Check the probes are clean and not damaged.
   - If a probe is damaged, then contact your Roche Service representative.
   - If the sample and reagent probe is dirty, then clean it (221)
   - If the sipper probe is dirty, then clean it (227).




**4** Check the pinch valve tubing is not bent or pinched.

- If the pinch valve tubing is bent or pinched, then replace it (241).

**5** Check the pipetter syringes and tubing have no bubbles.

- If a pipetter syringe contains bubbles, then remove them.

**6** Remove any waste materials from the analyzer.

**7** Close the top cover of the analyzer.

**Related topics**

- Bubbles in syringes (310)

# Starting the system

Before you set up the analyzer to run tests, power it up and log on to the software.

**In this section**



## Switching on the printer

If you are using a printer, then before you switch on the analyzer, switch on the printer.

1 minute

☐ Printer paper

### ▸ To switch on the printer

1 Load paper into the supply tray of the printer.

2 To switch on the printer, refer to the printer documentation.

**Related topics**

▪ Switching on the analyzer (97)

## Switching on the analyzer

After you check the system, switch on the analyzer.

If the analyzer is in Sleep mode, then perform the same steps to wake up the analyzer.

Sleep mode and Shutdown (207)

To maintain the temperature of the reagents, leave the analyzer circuit breakers switched on.

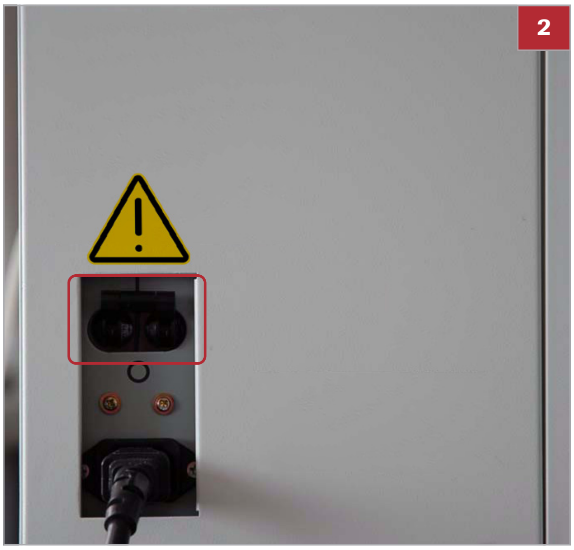
5 minutes

☐ The checks before startup are complete

Checking the system before startup (95)

### To switch on the analyzer

1 If the analyzer circuit breakers are off, then switch them on.




2 If the rack circuit breaker is off, then switch it on.


3 Switch the switch to ON.
→ The system starts and the mechanical parts move to their standby positions.

**Related topics**

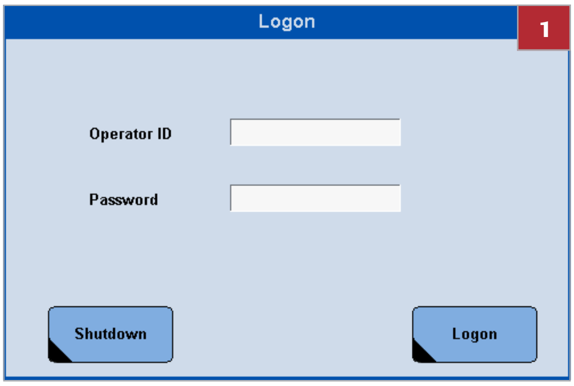
- Logging on to the software (98)
- Switching on the printer (97)

## Logging on to the software

To use the software on the system, log on to the software with your operator ID and password.

If the touchscreen monitor is blank, then switch on the touchscreen monitor.

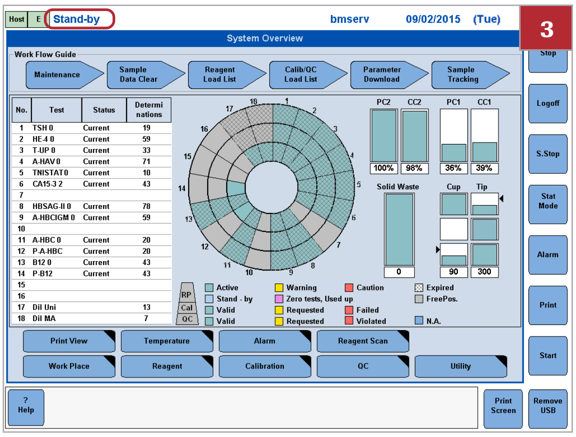
1 minute




### To log on to the software

1 From the **Logon** dialog box, fill in the **Operator ID** field and the **Password** field.

2 Choose the **Logon** button.




3 In the top left corner of the window on the touchscreen monitor, wait until the software displays **Stand-by**.

**Related topics**

- Switching on the analyzer (97)
- Logging off from the software (206)

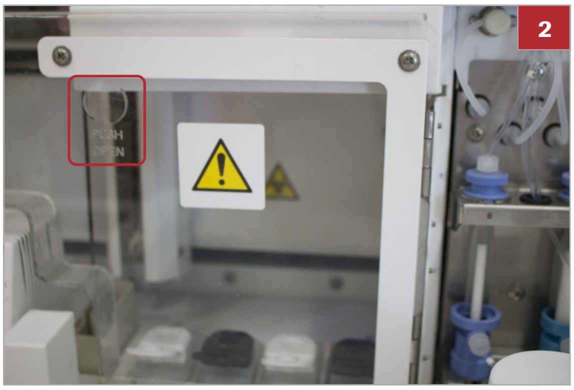
# Opening the lids of the system reagents

Before operation, open the lids of the system reagents.

☐ ProCell and CleanCell loaded on the analyzer
☐ The system is in Standby mode
Replacing system reagents (110)

## To open the lids of the system reagents


1 Lift the top cover of the analyzer.




2 To open the sipper shield, push the PUSH OPEN label.


3 Open the lids of the ProCell and CleanCell bottles.

4 To close the sipper shield, push the PUSH OPEN label until you hear a click.

5 Close the top cover of the analyzer.

**Related topics**


- Overview of reagents (105)
- Replacing system reagents (110)

# System alarms

System alarms can interrupt the operation of the system. Ensure there are no outstanding alarms before you start daily operation.

**In this section**



## About system alarms

When a system alarm occurs, the global **Alarm** button is highlighted. The **Alarm** window displays a list of current alarms.

The software uses colors to indicate the different alarm levels.

| Color | Definition |
|---|---|
| Yellow | Yellow alarm, which indicates caution<br>You can continue system operation |
| Red | Red alarm, which indicates error<br>The system stops operation until you resolve the alarm |

Colors for alarm levels

To resolve a system alarm, perform the remedy steps displayed in the **Alarm** window.

**Related topics**

- Checking system alarms (101)

## Checking system alarms

When a system alarm occurs, resolve it.

### To check system alarms

1 Choose the global **Alarm** button.
→ The **Alarm** window displays a list of alarms.


**2** To sort the **Alarm** table by different column headers, choose a column header.

**3** To view a description of an alarm, choose an alarm from the **Alarm** table.

**4** To resolve an alarm, perform the remedy steps in the **Description And Remedy** panel.

🛈 For more information about troubleshooting alarms, see the Troubleshooting chapter.

### Related topics

- About system alarms (101)
- General analyzer problems (305)
- Resolving data alarms (318)
- Chemistry problems (341)

# Reagents

## In this chapter

6

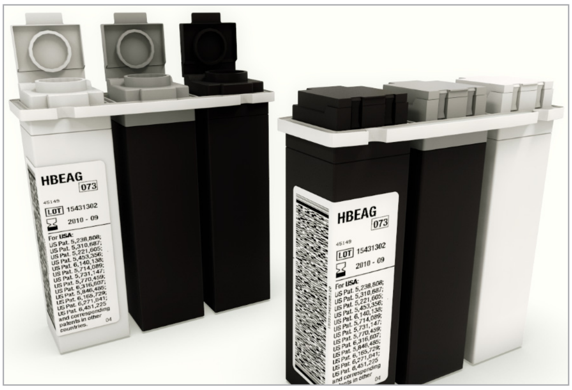
# Overview of reagents

The **cobas e** 411 analyzer uses the two types of reagents listed below.

- Reagent packs
- System reagents

**Reagent packs**

Reagent packs hold the reagents and diluents to perform tests. Each test has a specific reagent pack, or packs. A reagent pack comprises between one and three containers of reagent.

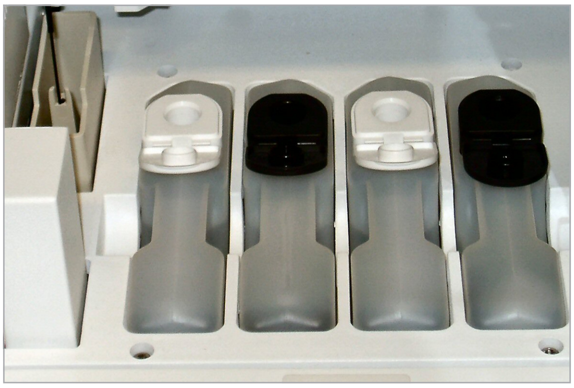



The label of each reagent pack shows the lot number and expiry date of the pack. The system identifies the reagent packs by the barcode on the label.

You load reagent packs into the reagent rotor and monitor the status of reagents on the **System Overview** window.

**System reagents**

System reagents are not specific to tests. The two system reagents are ProCell and CleanCell.

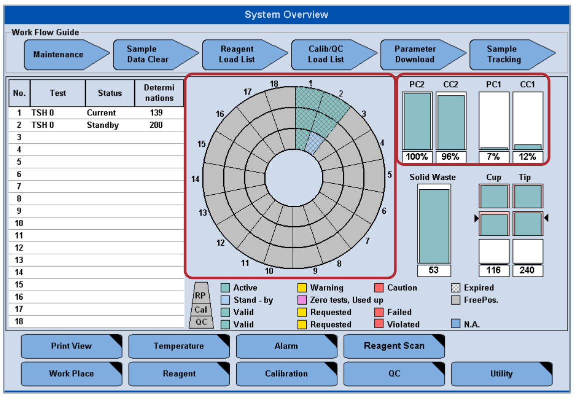


- ProCell transports the reaction mixture to the measuring cell and aids the ECL detection technology
- CleanCell conditions the electrodes, and rinses the measuring cell and flow tubes between measurements

You load system reagents to the right of the analyzer, behind the sipper shield, and monitor the status of reagents on the **System Overview** window.

**Reagent status**

The reagent overview area of the **System Overview** window contains a reagent rotor graphic. The reagent rotor graphic is divided into 18 segments, which represent the 18 reagent positions within the rotor.




To view details about a reagent on the system, choose a segment.

The **System Overview** window also displays two sets of bar charts. The bar charts display the amounts of ProCell and CleanCell left in each set of bottles, as a percentage.

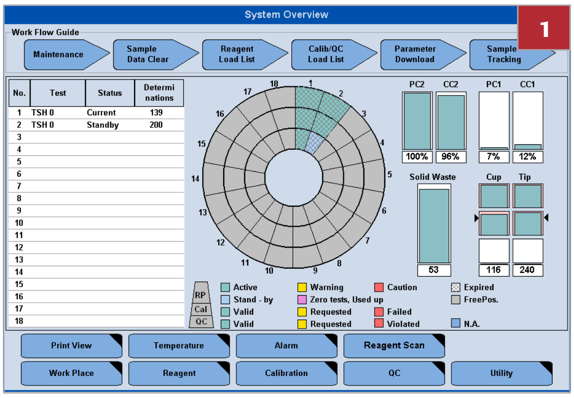
**Related topics**

- Replacing reagent packs (108)
- Replacing system reagents (110)

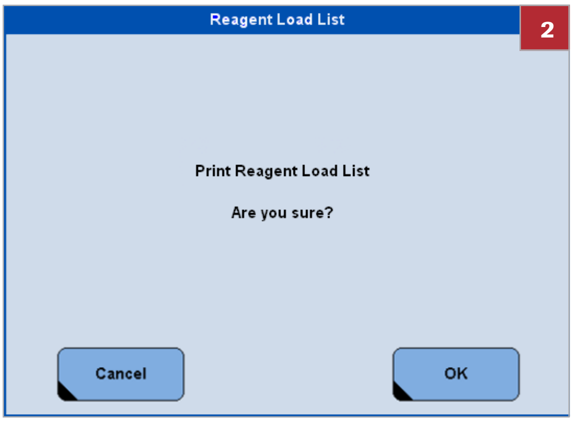
# Printing a reagent load list

To view or print a list of all the reagent packs and reagent bottle sets currently loaded on the analyzer, choose the **Reagent Load List** option.

## To print a reagent load list




1 From the **System Overview** window, choose the **Reagent Load List** button.




2 From the **Reagent Load List** dialog box, choose the **OK** button.

🛈 You can also print the reagent load list from the **Print** window.

**Related topics**

- Replacing reagent packs (108)
- Replacing system reagents (110)

# Replacing reagent packs

Use the reagent load list to identify reagent packs to replace.

Printing a reagent load list (107)

Before you start analysis, allow new reagent packs to reach the reagent rotor temperature of 20 ± 3 °C.

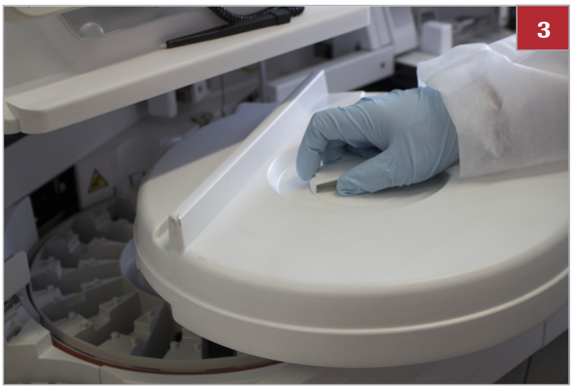
- ☐ New reagent packs
- ☐ Reagent load list

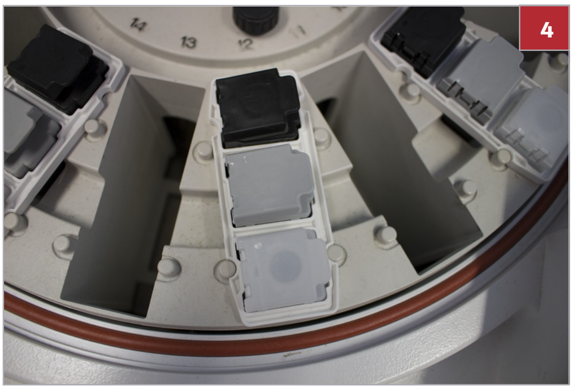
## To replace a reagent pack

1 Check that the analyzer is in Standby mode.

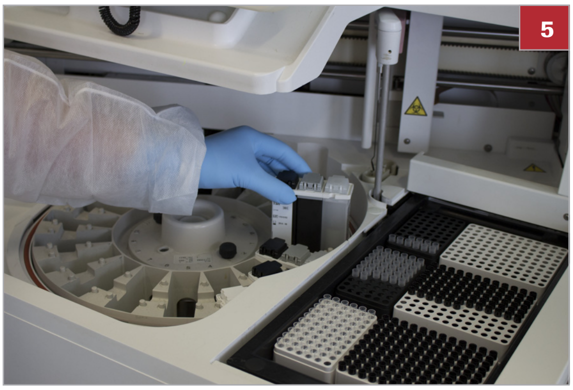
2 Lift the top cover of the analyzer.


3 To remove the cover of the reagent rotor, rotate the handle on the cover counterclockwise and then lift it.






4 Close the reagent pack lids.




5 Remove the reagent packs to be replaced.

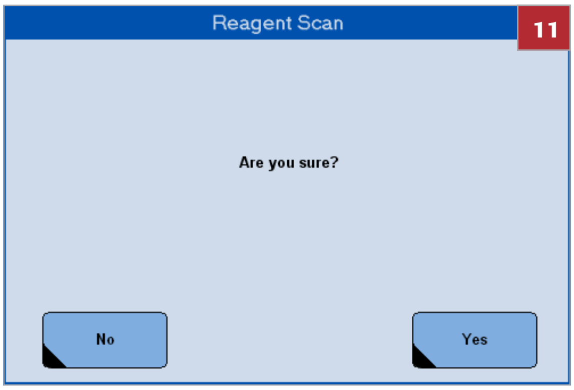
6 Check the expiry dates of the new reagent packs.

7 Load the new reagent packs in the reagent rotor.
   - ❶ Check that the reagent packs are correctly oriented.

8 Open the lids of the reagent packs.

9 Close the reagent rotor cover.
   - ❶ The reagent rotor cover is keyed. Check that the cover is correctly oriented, and then turn the cover clockwise.

10 Close the top cover of the analyzer.




11 From the **System Overview** window, choose **Reagent Scan > Yes**.
   - → The system scans all the reagent packs and updates their status on the **System Overview** window.

**Related topics**

- Overview of reagents (105)
- Replacing system reagents (110)

# Replacing system reagents

The analyzer uses the system reagents ProCell and CleanCell. Use the reagent load list to identify system reagents to replace.

To replace system reagents, perform the two actions below.

1. Remove ProCell and CleanCell bottles to be replaced and load new ones.
2. If you load a ProCell bottle with a new lot number, then update the Inventory Set.

To remove and load a system reagent ▶ (110)
To update the inventory set ▶ (112)

☐ New ProCell and CleanCell bottles

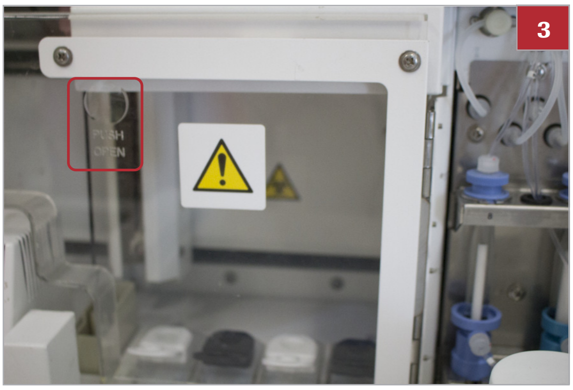
## ▶ To remove and load a system reagent

**1** Check that the analyzer is in Standby mode.

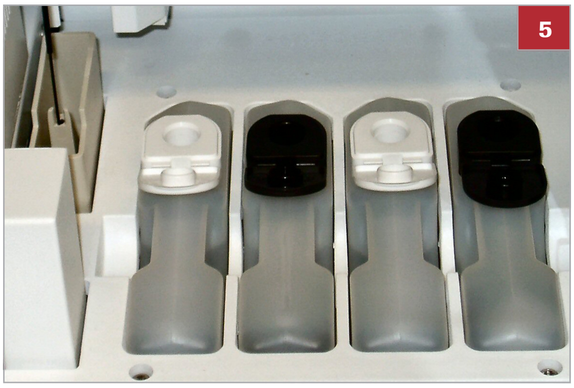
**2** Lift the top cover of the analyzer.


2

**3** To open the sipper shield, push the PUSH OPEN label.


3


4 Move the sipper arm to the left as far as possible.

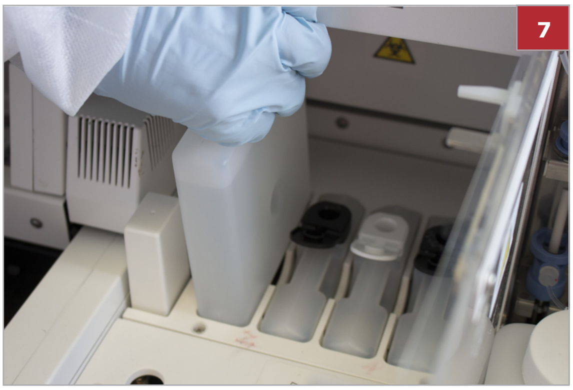



5 Close the lids of all ProCell and CleanCell bottles.

6 If you are replacing the bottles on the right, then perform the steps below.

- Move the bottles from the left position, Set 2, to the right position, Set 1
- Then load the new bottles in the left position, Set 2

🛈 The bottles on the right, Set 1, are consumed first.




7 Remove the ProCell and CleanCell bottles to be replaced from their compartments.

🛈 Always remove and replace ProCell and CleanCell bottles as sets. Each set comprises one ProCell and one CleanCell bottle.

8 Load new ProCell and CleanCell bottles in the relevant compartments.


9 Open the lids of all the ProCell and CleanCell bottles.

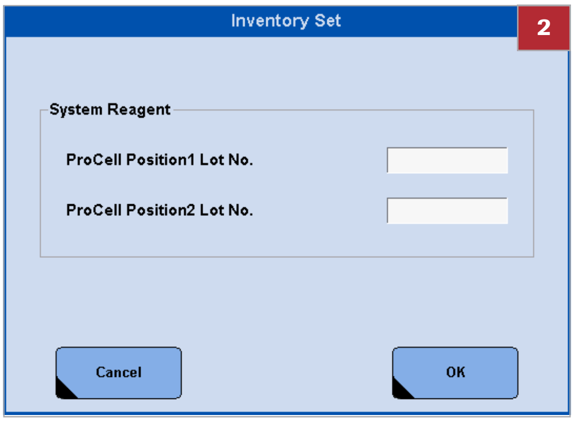
10 To close the sipper shield, push the PUSH OPEN label until you hear a click.

11 Close the top cover of the analyzer.

12 Wait 15 minutes to allow the system reagents to reach the required temperature.

🛈 If you try to operate the system during this time, then a system alarm occurs.

13 If you loaded a ProCell bottle with a new lot number, then update the Inventory Set.




## To update the inventory set

1 From the **System Overview** window, choose **Reagent > Inventory Set**.

2 From the **Inventory Set** dialog box, enter the new ProCell lot number or numbers.

3 Choose the **OK** button.

**Related topics**

- Overview of reagents (105)
- Replacing reagent packs (108)

# Calibration

## In this chapter

7

# About calibration

Perform calibration to ensure accurate analysis of samples.

The values you measure depend on environmental factors and reagents, and may deviate over time. Perform calibrations regularly. Roche recommends that you perform quality control every day.

**Lot calibration**

Lot calibration is when you perform calibration on a new reagent lot or an expired lot calibration for the same lot. A lot calibration is valid for all reagent packs from the same lot.

For a new lot, perform calibration within 24 hours of when you load a reagent pack. To recalibrate the current lot, Roche recommends that you do so according to the recommendation in the respective method sheet.

**Reagent pack calibration**

Reagent pack calibration is when you perform calibration more than 24 hours after you load a reagent pack from a new lot. Or when a pack from the current lot has been on board for more than 24 hours. A reagent pack calibration is valid for a specific reagent pack.

**Validation**

After you perform a calibration, the system validates it. To view calibration results, use the **Calibration > Status > Calibration Trace** dialog box.

For more information about calibration, see the Compendium of background information.

**Related topics**

- About QC (137)
- Performing calibration (118)

# About calibration requests

The system can request calibration automatically, or you can request calibration manually.

The cause of the calibration request is displayed on the **Calibration > Status** window.

| Cause | Description |
|---|---|
| Changeover | You load a new reagent pack with no valid lot calibration on the system |
| Daily | The calibration is defined as required daily |
| Failed | The calibration fails one or more quality criteria |
| Manual | A manual request for calibration by the operator |
| QC Violation | The QC results are outside the confidence limits |

Calibration requests

**Related topics**


- About calibration (115)
- Validating QC results (152)

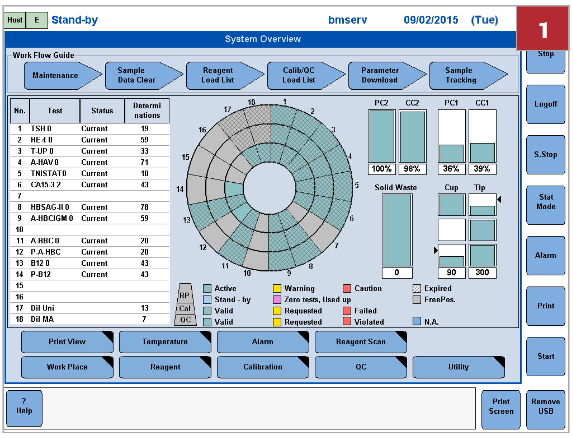
# Printing a Calib/QC load list

Before you load control samples onto the disk or rack, print the Calib/QC load list.

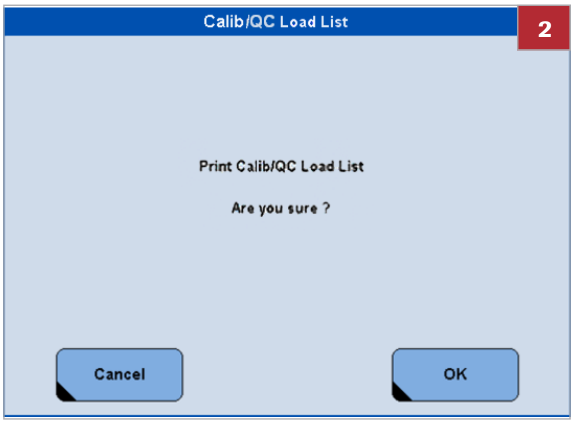
The Calib/QC load list displays the calibrators and controls that you must load and run. It also displays the positions to use on the rack or disk.

1 minute

## To print a Calib/QC load list




1 From the **System Overview** window, choose the **Calib/QC Load List** button.




2 From the **Calib/QC Load List** dialog box, choose the **OK** button.

**Related topics**

- Performing calibration (118)

# Performing calibration

## In this section



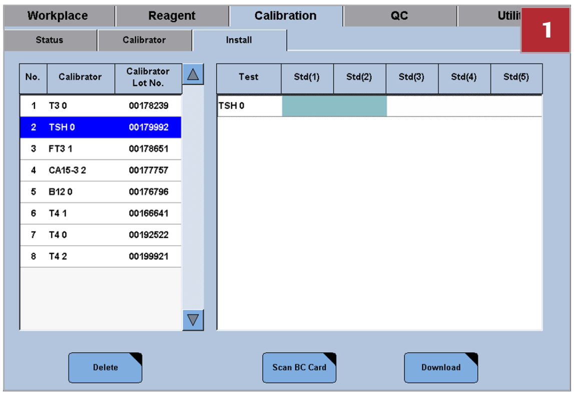
## Preparing calibrators

Most calibrators are supplied ready to use, but some require preparation before use.

As stated in the method sheet

- ☐ Package insert from calibrator
- ☐ Calib/QC load list
- Printing a Calib/QC load list (117)

### To prepare calibrators




1 To identify which calibrators are already installed, choose **Calibration > Install**.

2 Get the calibrators listed in the Calib/QC load list.

3 To check if preparation of a calibrator is required, see the package insert.

4 If preparation of a calibrator is required, then follow the instructions in the package insert.

# Assigning positions to calibrators

The system uses the barcode information to assign calibrators to positions. If a calibrator does not have a barcode, or if the system cannot read the barcode, then manually assign a position to the calibrator.

**NOTICE**

**Barcodes override manual assignments**

If the system reads a barcode at a position that has a manual assignment, then the system ignores the manual assignment.

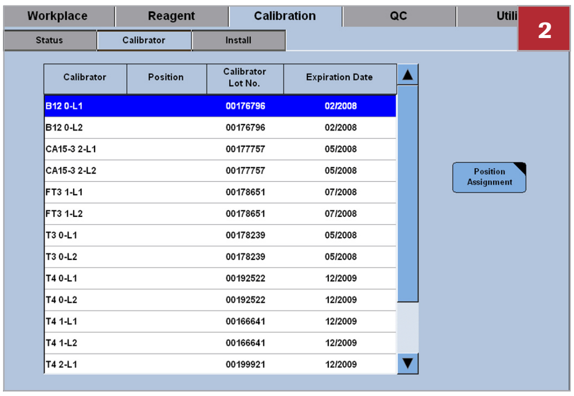
1 minute

☐ The calibrator is installed

☐ If applicable, the rack is assigned to calibrators in the **Utility > System** window

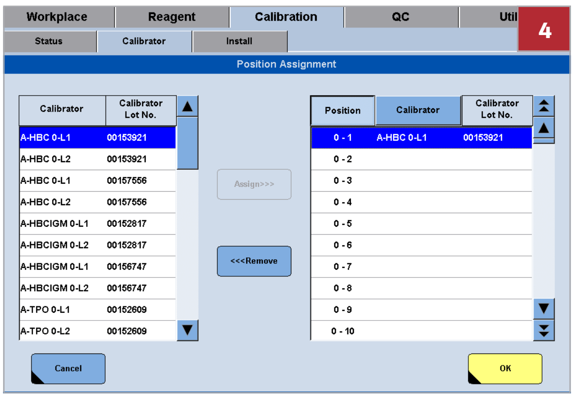
## ▸ To assign calibrators to positions

1 From the **System Overview** window, choose **Calibration > Calibrator**.




2 From the **Calibrator** table, choose a calibrator.

3 Choose the **Position Assignment** button.




4 From the **Calibrator** table on the left-hand side of the window, choose a calibrator.

5 From the **Position** table on the right-hand side of the window, choose a position.

6 Choose the **Assign>>>** button.

ℹ You can assign a calibrator to only one position.

7 Repeat steps **4** to **6** until you have assigned all new calibrators.

8 Choose the **OK** button.

# Loading calibrators

After you prepare calibrators, load them on the analyzer.

5 minutes

- ☐ Calibrators
- ☐ Calib/QC load list

Printing a Calib/QC load list (117)

## To load calibrators on a disk system


1 Lift the top cover of the analyzer.


2 NOTICE Incorrect placement of a calibrator can cause errors or incorrect results. Ensure you load calibrators in the correct positions.

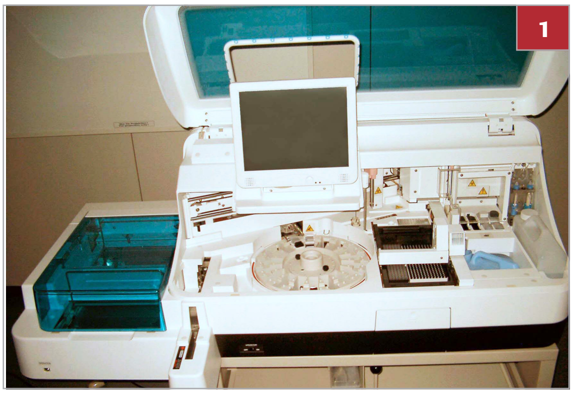
To load the calibrator onto the disk, use the positions in the Calib/QC load list.

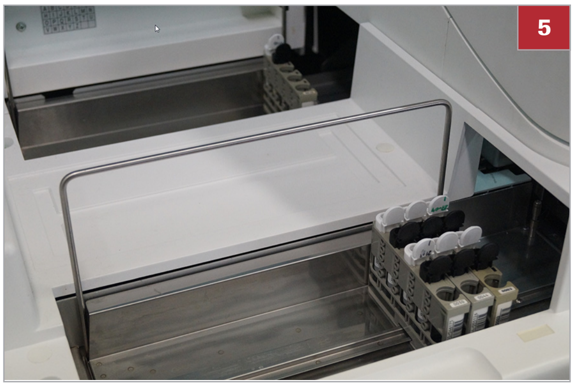
Position the calibrators so that the barcodes face outwards.

3 If a calibrator does not have a barcode, or if the system cannot read the barcode, then manually assign a position to the calibrator (119).

4 Open each vial lid to a vertical position.

5 Close the top cover of the analyzer.




### To load calibrators on a rack system

1 Lift the top cover of the rack feeder.

2 NOTICE Incorrect placement of a calibrator can cause errors or incorrect results.

To load the calibrator onto the rack, use the positions in the Calib/QC load list.

Position the calibrators so that the barcodes are visible through the gaps in the rack.

3 Load the rack on a tray.

4 Open each vial lid to a vertical position.

5 Place the tray on the A-Line.

6 Close the top cover of the rack feeder.

**Related topics**


- Printing a Calib/QC load list (117)
- Correct placement of sample tubes on a sample disk (166)
- Correct placement of sample tubes on a rack (167)
- Assigning positions to calibrators (119)


# Installing calibrator lots with barcode cards

When you load a new calibrator lot, scan the barcode card for the lot.

You do not need to scan barcode cards or e-barcodes for in-pack calibrators, which are provided as part of reagent kits.

If you do not have a barcode card, then use **cobas**® link.

**cobas**® link is not used in all countries.

Installing calibrator lots with **cobas**® link (123)

1 minute

☐ Barcode card for the new calibrator lot

- ☐ You must have administrator level access
- ☐ Calibrators are loaded on the analyzer

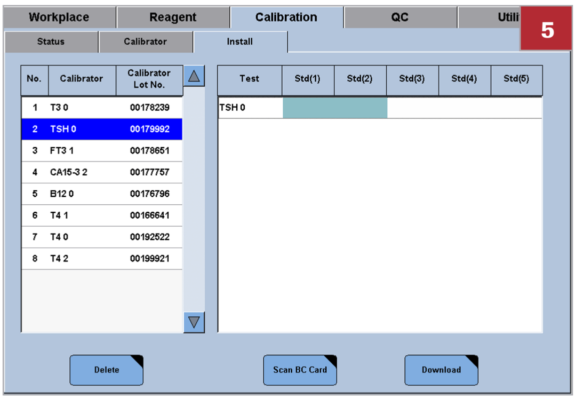
### To install a calibrator lot with a barcode card


1 Lift the top cover of the analyzer.

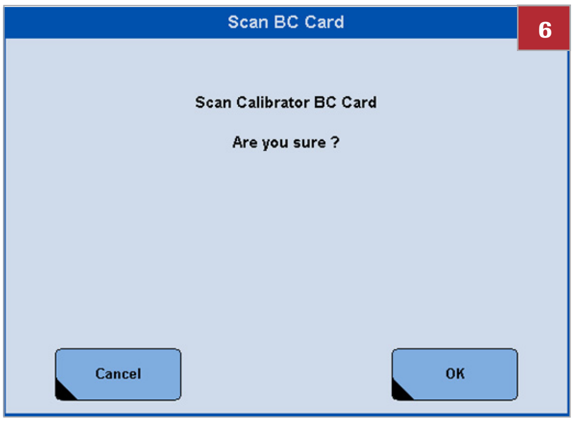

2 With the barcode facing the back of the analyzer, insert the barcode card into the barcode reading station.

3 Push the card in until it stops.

4 From the System Overview window, choose **Calibration > Install**.




5 To scan the barcode, choose the **Scan BC Card** button.




6 From the **Scan BC Card** dialog box, choose the **OK** button.

➔ If the scan is successful, then the barcode reader beeps.

7 When the analyzer is in Standby mode, remove the barcode card.

8 If you have more than one barcode card, then repeat steps **2** to **7**.

9 Close the top cover of the analyzer.

**Related topics**

- Installing calibrator lots with **cobas**® link (123)

# Installing calibrator lots with cobas® link

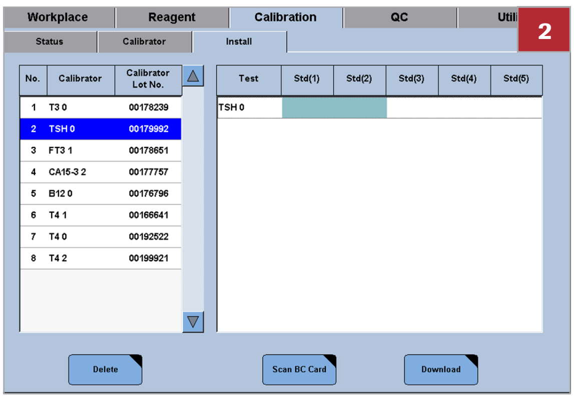
If you have **cobas**® link, then you can download calibrator barcode information from the **cobas**® e-library.

3 minutes

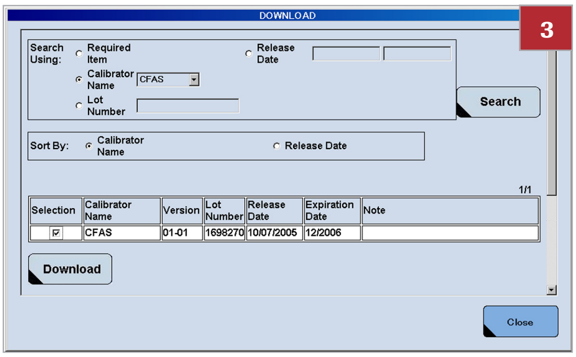
☐ Calibrators loaded on the analyzer
☐ You must be logged on as an administrator

## To install a calibrator lot with cobas® link

1 From the **System Overview** window, choose **Calibration > Install**.




2 Choose the **Download** button.




3 From the **Search Using** group box, select a search option.

4 Choose the **Search** button.

5 From the **Sort by** group box, select a sort option.

6 From the table of results, select the check boxes for the items to download.

7 NOTICE Deletion of an installed calibrator lot due to installing a new calibration lot. For quantitative tests, only one calibrator lot can be installed per test. When you install a new calibrator lot, any previously installed calibrator lots are overwritten.

Choose the **Download** button.

8 From the **Confirmation** dialog box, choose the **OK** button.

9 Choose the **Close** button.

**Related topics**

- Installing calibrator lots with barcode cards (121)

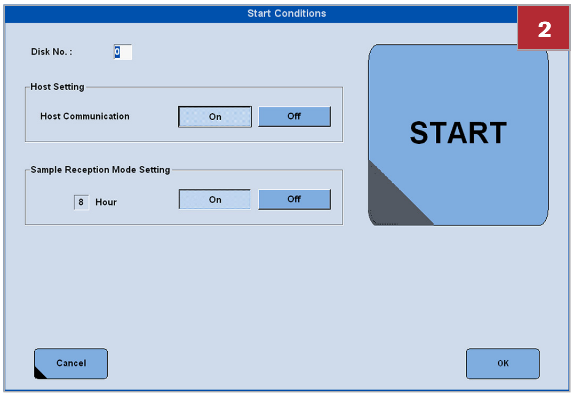
# Running calibrators

After you load the calibrators on the analyzer, perform calibration.

Assay dependent, but possibly every day

Assay dependent, but about 1 minute

☐ Calibrators loaded on the analyzer




## ▸ To measure calibrators

**1** Choose the global **Start** button.

**2** Check the settings on the **Start Conditions** dialog box.

- If you use a disk system, then check the value in the **Disk No.** field is the correct disk.
- If you use a host connection, then from the **Host Communication** group box, choose the **On** button.

**3** NOTICE A slow host connection could cause calibrators to be untested. If the host does not respond within 15 seconds, then the system advances to the next sample.

From the **Start Conditions** dialog box, choose the **Start** button.

➔ After initializing the run, the system processes the loaded calibrators. If you have selected automatic printout, then the results print.

**4** When sampling is complete, close the lids of the calibrators on the sample disk or rack.

**5** Remove the calibrators from the sample disk or rack.

**6** Place the calibrators in a refrigerator.

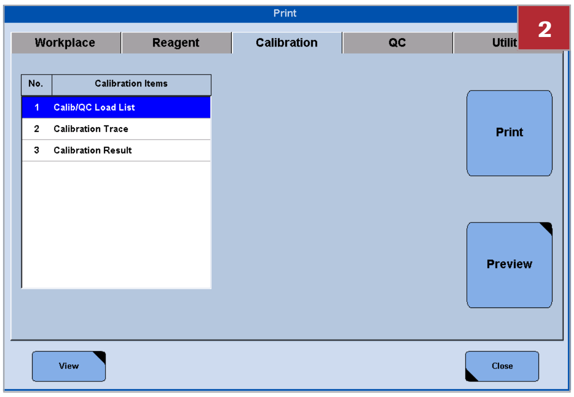
**7** If you have not selected automatic printout, then print the calibration report.

**Related topics**


- Assigning positions to calibrators (119)
- Loading calibrators (120)
- Changing documentation settings (295)
- Printing a calibration report (126)

# Printing a calibration report

To view information about a calibration, print a calibration report.




## ▸ To print a calibration report

1 From the **System Overview** window, choose **Print > Calibration**.

2 From the **Calibration Items** table, choose the **Calibration Result** option.

3 Choose the **Print** button.

# About quantitative calibration results

To identify the reasons for unsuccessful quantitative calibrations, review calibration results.

The analyzer uses a number of quality criteria to determine whether a quantitative calibration is valid. For each calibration, the calibration result report displays values for specific quality criteria.

- Missing values
- Monotony of curve
- Factor
- Minimum signal
- Minimum acceptable difference
- Deviation of duplicates
- System errors

To view or print the calibration result report, choose **Print > Calibration > Calibration Result** from the **System Overview** window.

**Missing values**

The analyzer tests each calibrator in the CalSet (Cal1 and Cal2) in duplicate. The analyzer uses the measured values to adjust the master calibration curve. For a valid calibration, all four tests must be successful.

On a report for quantitative assays, this field shows ten values. The first four values show the results for the CalSet tests. The analyzer only uses two calibrators, so only has four values.

If a calibration is successful, then the first four values in the field are shown as dashes. If a calibration fails, then a **1** or **2** is displayed in the values which correspond to the CalSet that has failed.

| Field display | Number of successful tests | Result |
|---|---|---|
| - - - - - - - - - - | 4 | Successful calibration |
| 1 - - - - - - - - - | 3 | Failed calibration |
| - 1 - - - - - - - - | 3 | Failed calibration |
| - - 2 - - - - - - - | 3 | Failed calibration |
| - - - 2 - - - - - - | 3 | Failed calibration |
| 1 1 - - - - - - - - | 2 | Failed calibration |
| - - 2 2 - - - - - - | 2 | Failed calibration |
| 1 - 2 - - - - - - - | 2 | Failed calibration |
| 1 - - 2 - - - - - - | 2 | Failed calibration |
| - 1 2 - - - - - - - | 2 | Failed calibration |
| 1 1 2 - - - - - - - | 1 | Failed calibration |
| 1 1 - 2 - - - - - - | 1 | Failed calibration |

Missing values results for quantitative assays

| Field display | Number of successful tests | Result |
|---|---|---|
| 1 - 2 2 - - - - - - | 1 | Failed calibration |
| - 1 2 2 - - - - - - | 1 | Failed calibration |
| 1 1 2 2 - - - - - - | 0 | Failed calibration |

Missing values results for quantitative assays

**Monotony of curve**

For a calibration to be valid, measured values for the CalSet must be in ascending or descending order.

If a calibration has achieved monotony, then five dashes are shown in the **Monotony of curve** field. The five dashes represent up to five calibrators. If a **1** (Cal1) or **2** (Cal2) is displayed, then the calibration is unsuccessful. As the analyzer only uses two calibrators, the remaining dashes which are displayed are not required.

If calibrators are in the incorrect vials without barcode labels, then they can fail this test.

**Factor**

To determine the factor, the analyzer checks the most recent lot calibration against the calibration curve position. Each new lot calibration has a factor of 1. For all subsequent reagent packs a new factor is calculated.

| Factor (x) | Result |
|---|---|
| x = 0.8 - 1.2 | Successful calibration |
| x = < 0.8 | Failed calibration (Red range) |
| x = > 1.2 | Failed calibration (Red range) |

Factor results

**Minimum signal**

The analyzer tests each calibrator in the CalSet (Cal1 and Cal2) twice. For a successful calibration, the signal value for all four tests must be above a minimum value.

The four dashes at the beginning of the **Minimum signal** field show the results for the CalSet tests. As the analyzer only uses two calibrators, the remaining dashes which are displayed are not required.

If an < symbol is shown in this field in the Calibration result printout, then the BCR1 signal value is out of range. The word **Min** is shown on the **Calibration Result** window if the check has failed.

If a calibration is successful, then the first four values in the field are shown as dashes. If a calibration fails, then a **1** or **2** is displayed in the values which correspond to the CalSet that has failed.

| Field display | Number of successful tests | Result |
|---|---|---|
| - - - - - - - - - - | 4 | Successful calibration |
| 1 - - - - - - - - - | 3 | Failed calibration |
| - 1 - - - - - - - - | 3 | Failed calibration |
| - - 2 - - - - - - - | 3 | Failed calibration |
| - - - 2 - - - - - - | 3 | Failed calibration |
| 1 1 - - - - - - - - | 2 | Failed calibration |
| - - 2 2 - - - - - - | 2 | Failed calibration |
| 1 - 2 - - - - - - - | 2 | Failed calibration |
| 1 - - 2 - - - - - - | 2 | Failed calibration |
| - 1 2 - - - - - - - | 2 | Failed calibration |
| 1 1 2 - - - - - - - | 1 | Failed calibration |
| 1 1 - 2 - - - - - - | 1 | Failed calibration |
| 1 - 2 2 - - - - - - | 1 | Failed calibration |
| - 1 2 2 - - - - - - | 1 | Failed calibration |
| 1 1 2 2 - - - - - - | 0 | Failed calibration |

Minimum signal results

**Minimum acceptable difference**

This is the percentage difference between the two calibrators. For a successful calibration, the difference must be at least 30%. A successful calibration is indicated by five dashes.

| Field display | Result |
|---|---|
| - - - - - | Successful calibration |
| 1 2 - - - | Failed calibration |

Minimum acceptable difference for quantitative assays

**Deviation of duplicates**

The system tests each calibrator in the CalSet (Cal1 and Cal2) in duplicate. The tests for each calibrator are compared, and if the difference between the signal values is too great, the calibration is unsuccessful.

To set the maximum variation between duplicated calibration tests, choose **Utility > Application > Calib.** from the **System Overview** window.

A successful calibration is shown by five dashes, Any failed tests are shown by a **1** or **2**, which corresponds to the calibrators that have failed.

| Field display | Result |
|---|---|
| - - - - - | Successful calibration |

Deviation of duplicates results for quantitative assays

| Field display | Result |
|---|---|
| 1 - - - - | Failed calibration |
| - 2 - - - | Failed calibration |
| 1 2 - - - | Failed calibration |

Deviation of duplicates results for quantitative assays

**System errors**

A hardware error occurred during calibration. If either **1** (Cal1) or **2** (Cal2) appears in this field, then the calibration is unsuccessful.

Quantitative assays have five values.

| Field display | Result |
|---|---|
| - - - - - | Successful calibration |
| 1 - - - - | Failed calibration |
| - 2 - - - | Failed calibration |
| 1 2 - - - | Failed calibration |

System errors for quantitative assays

**Related topics**

- About qualitative calibration results (131)

# About qualitative calibration results

To identify the reasons for unsuccessful qualitative calibrations, review calibration results.

The analyzer uses a number of quality criteria to determine whether a qualitative calibration is valid. For each calibration, the calibration result report displays values for specific quality criteria.

- Missing values
- Slope
- Minimum or maximum signal
- Minimum acceptable difference
- Deviation of duplicates
- System errors

To view or print the calibration result report, choose **Print > Calibration > Calibration Result** from the **System Overview** window.

**Missing values**

The analyzer tests each calibrator in the CalSet (Cal1 and Cal2) in duplicate. The analyzer uses the measured values to adjust the master calibration curve. For a valid calibration, all four tests must be successful.

If a calibration is successful, then the four values in the field are shown as dashes. If a calibration fails, then a **1** or **2** is displayed in the values which correspond to the CalSet that has failed.

| Field display | Number of successful tests | Result |
|---|---|---|
| - - - - | 4 | Successful calibration |
| 1 - - - | 3 | Failed calibration |
| - 1 - - | 3 | Failed calibration |
| - - 2 - | 3 | Failed calibration |
| - - - 2 | 3 | Failed calibration |
| 1 1 - - | 2 | Failed calibration |
| - - 2 2 | 2 | Failed calibration |
| 1 - 2 - | 2 | Failed calibration |
| 1 - - 2 | 2 | Failed calibration |
| - 1 2 - | 2 | Failed calibration |
| 1 1 2 - | 1 | Failed calibration |
| 1 1 - 2 | 1 | Failed calibration |
| 1 - 2 2 | 1 | Failed calibration |
| - 1 2 2 | 1 | Failed calibration |
| 1 1 2 2 | 0 | Failed calibration |

Missing values results for qualitative assays

**Slope**

All measured calibrator values must fall in ascending (sandwich or bridging principle) or descending (competition principle) order. The slope of the current calibration is listed as **OK** for successful calibrations or **NG** (Not Good) for unsuccessful calibrations.

**Min / Max signal**

The measured signal of the calibrator should be between the designated minimum and maximum signal. Minimum and maximum signals are test dependent and are encoded in the reagent barcode.

If a calibration is successful, then the first four values in the field are displayed as dashes. If a calibration fails, then a **<** or **>** symbol is displayed in the values which correspond to the measurement that has failed.

| Field display | Result |
|---|---|
| - - - - | Successful calibration |
| < - - - | Failed calibration |
| < < - - | Failed calibration |
| < < < - | Failed calibration |
| < < < < | Failed calibration |
| > - - - | Failed calibration |
| > > - - | Failed calibration |
| > > > - | Failed calibration |
| > > > > | Failed calibration |

Min/Max signal errors

If the BCR1 signal value is out of range, then **Min** or **Max** is displayed on the **Calibration Result** window if the check has failed.

**Minimum acceptable difference**

The difference between the negative and positive calibrator signal values must be greater than the allowable value limit. This limit is test dependent and is encoded in the reagent barcode. The **Minimum acceptable difference** field displays **OK** for successful calibrations, and **NG** (Not Good) for unsuccessful calibrations.

**Deviation of duplicates**

The analyzer tests each calibrator in the CalSet (Cal1 and Cal2) in duplicate. The tests for each calibrator are compared, and if the difference between the signal values is too great, the calibration is unsuccessful.

A successful calibration is shown by two dashes. Any failed tests are shown by a **1** or **2**, which corresponds to the calibrators that have failed.

| Field display | Result |
|---|---|
| - - | Successful calibration |
| 1 - | Failed calibration |
| - 2 | Failed calibration |
| 1 2 | Failed calibration |

Deviation of duplicates results for qualitative assays

**System errors**

A hardware error occurred during calibration. If either **1** (Cal1) or **2** (Cal2) appears in this field, then the calibration is unsuccessful.

Qualitative assays have two values.

| Field display | Result |
|---|---|
| - - | Successful calibration |
| 1 - | Failed calibration |
| - 2 | Failed calibration |
| 1 2 | Failed calibration |

System errors for qualitative assays

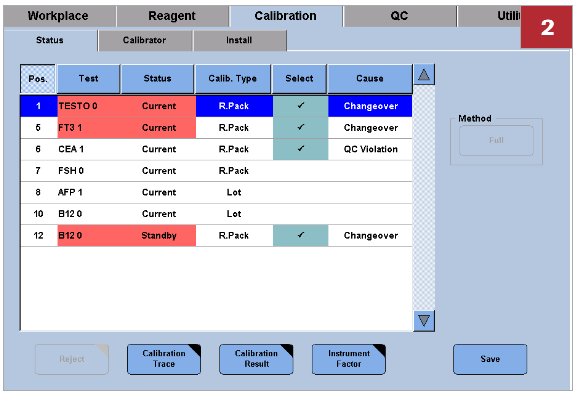
**Related topics**

- About quantitative calibration results (127)

# Validating calibration results

After you measure calibrators, validate the results.

2 minutes




## To validate calibration results

1 From the **System Overview** window, choose **Calibration > Status**.

2 If there are no failed calibrations in the **Status** table, then you can measure patient samples.

Failed calibrations have a red background color.

3 If there is a failed calibration in the **Status** table, then view more information about the calibration.

- To view the calibration results, choose the calibration, and then choose the **Calibration Result** button.
- To view the calibration trace, choose the calibration, and then choose the **Calibration Trace** button.

4 To reject a failed calibration, choose the calibration and then choose the **Reject** button.

5 Print a new Calib/QC load list (117).

6 Repeat the calibration (124).

### Related topics

- Data alarm list (316)
- Troubleshooting chemistry problems (339)

# Quality control

## In this chapter

8

# About QC

To monitor the performance of the analyzer and verify calibration, perform quality control.

⚠ **CAUTION**

**Performing QC**

Using the analyzer without performing QC may cause incorrect results.

- Before you test patient samples, perform QC to check the performance of the analyzer.

---

When in normal operation, Roche recommends that you perform QC tests before you process patient samples. However, you can measure controls at any time.

**Validation**

After you perform QC tests, validate them.

For more information about QC, see the Compendium of background information.

**Related topics**

- Performing QC (138)

# Performing QC

**In this section**



## Preparing controls

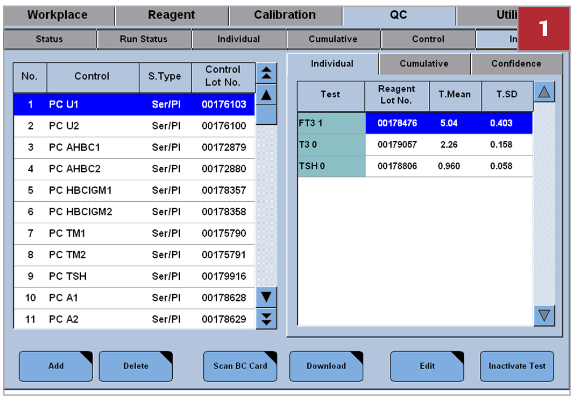
Most controls are supplied ready to use, but some require preparation before use.

As stated in the method sheet. Each Assay has a different standing time of between 30 and 60 minutes

- ☐ Package insert from control
- ☐ Calib/QC load list

Printing a Calib/QC load list (117)

### To prepare controls




1. To identify which controls are already installed, choose **QC > Install**.
2. Get the controls listed in the Calib/QC load list.
3. To check if preparation of a control is required, see the package insert.
4. If preparation of a control is required, then follow the instructions in the package insert.

# Assigning positions to controls

If a control does not have a barcode, or if the system cannot read the barcode, then manually assign a position to the control.

**NOTICE**

**Barcodes override manual assignments**

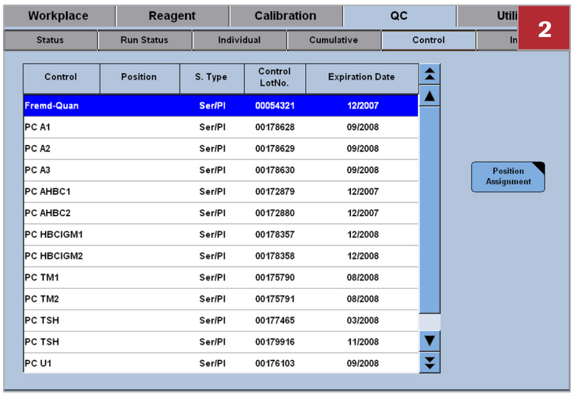
If the system reads a barcode at a position that has a manual assignment, the system ignores the manual assignment.

1 minute

- ☐ The control is installed
- ☐ If applicable, the rack is assigned to controls in the **Utility > System** window

## ▸ To assign controls to positions

1 From the **System Overview** window, choose **QC > Control**.




2 From the **Control** table, choose a control.

3 Choose the **Position Assignment** button.

4 From the **Control** table on the left-hand side of the window, choose a control.

5 From the **Position** table on the right-hand side of the window, choose a position.

6 Choose the **Assign>>>** button.

  ❶ You can assign a control to only one position.

7 Repeat steps **4** to **6** until you have assigned all new controls.

8 Choose the **OK** button.

# Loading controls

After you prepare controls, load them on the analyzer.

**NOTICE**

**Incorrect QC measurement due to controls loaded next to a calibrator set**

If you load controls next to a calibrator set, then the system uses the controls for that calibration only. The controls are only used if they are assigned to the same test. If the controls are assigned to a different test, then no control measurement takes place.

- To use the controls for all the activated and available tests, leave an empty position between the calibrator and control.

5 minutes

- ☐ Controls
- ☐ Calib/QC load list

## To load controls on a disk system

1 Lift the top cover of the analyzer.

2 NOTICE Incorrect placement of a control can cause errors or incorrect results.

To load the control onto the disk, use the positions in the Calib/QC load list.

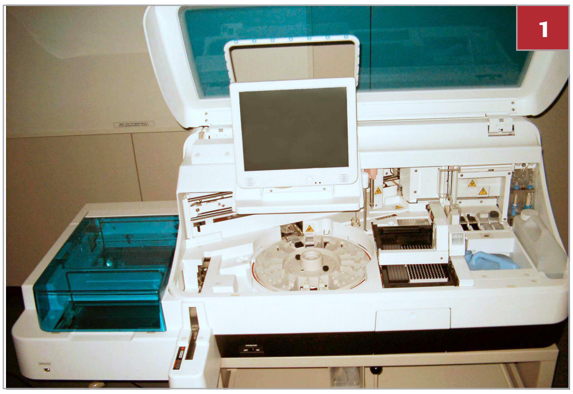
Position the controls so that the barcodes face outwards.

3 If a control does not have a barcode, or if the system cannot read the barcode, then manually assign a position to the control (139).

4 Open each vial lid to a vertical position.

5 Close the top cover of the analyzer.

### To load controls on a rack system




1 Lift the top cover of the rack feeder.

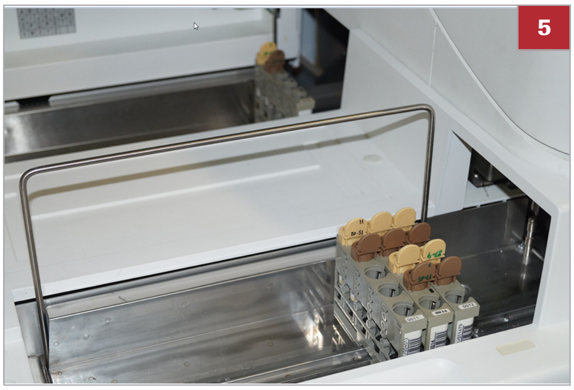
2 NOTICE Incorrect placement of a control can cause errors or incorrect results.

To load the control onto the rack, use the positions in the Calib/QC load list.

- Position the controls so that the barcodes face outwards.

3 Load the rack on a tray.

4 Open each vial lid to a vertical position.




5 Place the tray on the A-Line.

6 Close the top cover of the rack feeder.

**Related topics**

- Correct placement of sample tubes on a sample disk (166)
- Correct placement of sample tubes on a rack (167)
- Assigning positions to controls (139)

# Installing control lots with barcode cards

When you load a new control lot, scan the barcode card for the lot.

If you do not have a barcode card, then use the **cobas**® link.

The **cobas**® link is not used in all countries.

Installing control lots with **cobas**® link (143)

1 minute

☐ Barcode card for the new control lot

- ☐ You must have administrator level access
- ☐ Controls are loaded on the analyzer

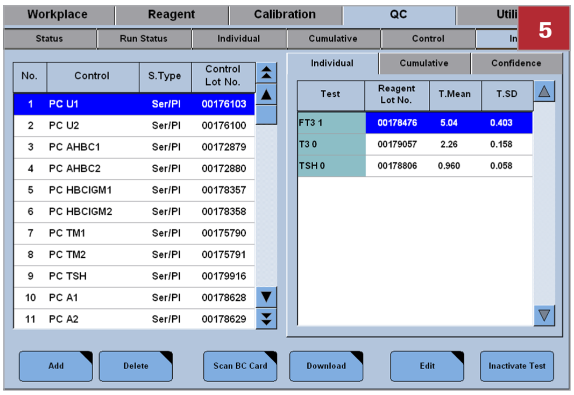
## ▸ To install a control lot with a barcode card


1 Lift the top cover of the analyzer.

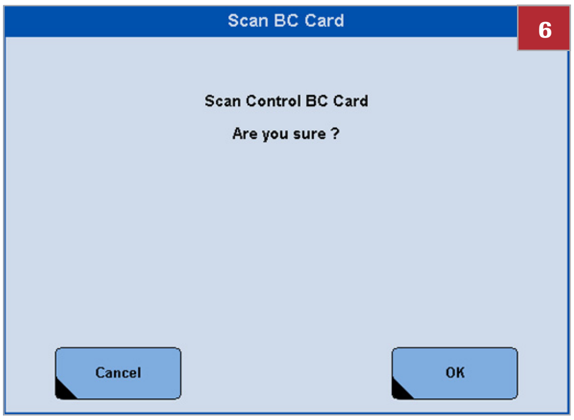

2 With the barcode facing the back of the analyzer, insert the barcode card into the barcode reading station.

3 Push the card in until it stops.

4 From the **System Overview** window, choose **QC > Install**.




5 To scan the barcode, choose the **Scan BC Card** button.




6 From the **Scan BC Card** dialog box, choose the **OK** button.
   → If the scan is successful, then the barcode reader beeps.

7 When the analyzer is in Standby mode, remove the barcode card.

8 If you have more than one barcode card, then repeat steps **2** to **7**.

9 Close the top cover of the analyzer.

**Related topics**

- Installing control lots with **cobas**® link (143)

# Installing control lots with cobas® link

If you have **cobas**® link, then you can download control barcode information from the **cobas**® e-library.

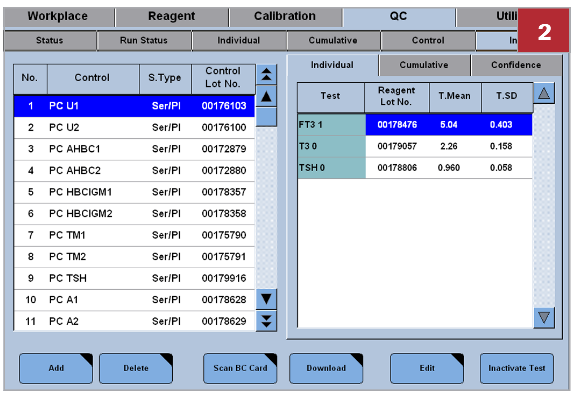
The **cobas**® link is not used in all countries.

3 minutes

- ☐ Controls loaded on the analyzer
- ☐ You must be logged on as an administrator

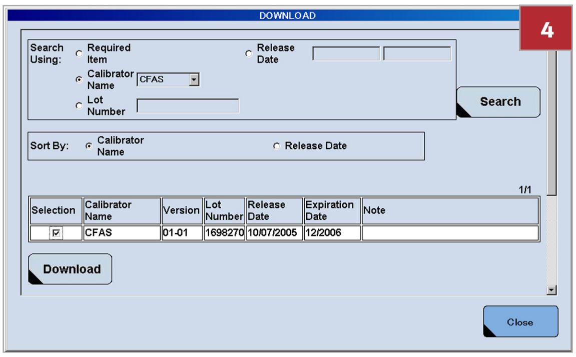
## ▸ To install a control lot with cobas® link

1 From the **System Overview** window, choose **QC > Install**.




2 From the **Control** table, choose an empty row.

3 Choose the **Download** button.




4 From the **Search Using** group box, select a search option.

5 Choose the **Search** button.

6 From the **Sort by** group box, select a sort option.

7 From the table of results, select the check boxes for the items to download.

8 Choose the **Download** button.

9 From the **Confirmation** dialog box, choose the **OK** button.

10 Choose the **Close** button.

**Related topics**

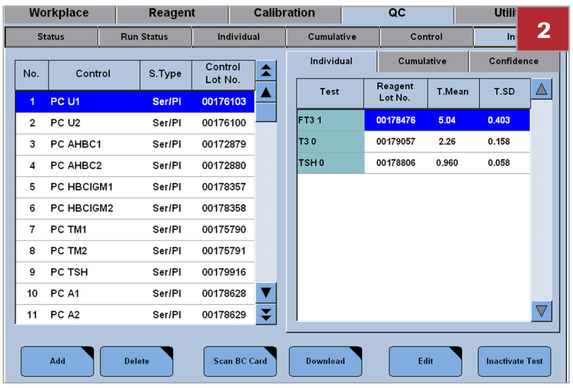
- Installing control lots with barcode cards (141)

# Activating and deactivating QC tests

When you load a new control, activate the tests.

1 minute

## To activate and deactivate QC tests




1 From the **System Overview** window, choose the **QC > Install** tab.

2 From the **Control** table, select the new control.

3 From the **Test** table, select a test.

4 To activate the selected test, choose the **Activate Test** button.

→ The legend on the **Activate Test** button changes to **Inactivate Test**.

5 To deactivate the selected test, choose the **Inactivate Test** button.

# Editing QC target values and ranges

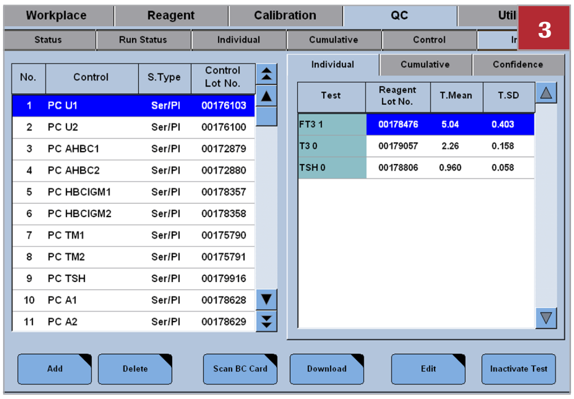
To edit QC target values and ranges, use the package insert.

1 minute

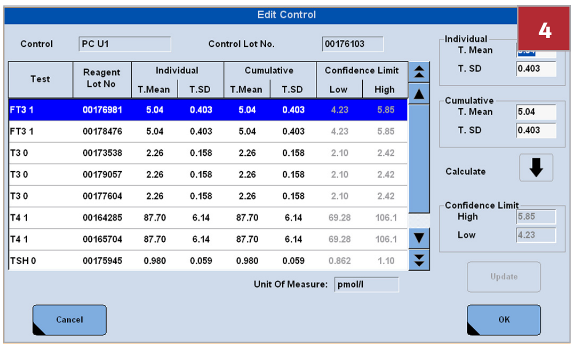
## To edit QC target values and ranges

1 From the **System Overview** window, choose **QC > Install**.

2 From the **Control** table, choose the required control.




3 Choose the **Edit** button.




4 From the **Test** table, choose a test.

5 From the **Individual** group box, fill in the **T.Mean** and **T.SD** fields.

- Use the target mean and target standard deviation values in the package insert.

6 From the **Cumulative** group box, fill in the **T.Mean** and **T.SD** fields.

- Use the target mean and target standard deviation values in the package insert.

7 Choose the **Calculate** button.

→ The new confidence values are displayed in the **Confidence Limit** group box and the **Test** table.

8 Choose the **OK** button.

# Processing standby bottle QC

To avoid sending out results from an uncontrolled reagent pack, process the QC for all standby reagents currently on the analyzer. This procedure minimizes reagent change over time.

If your current reagent pack is used up, then the system starts to use standby reagent packs.

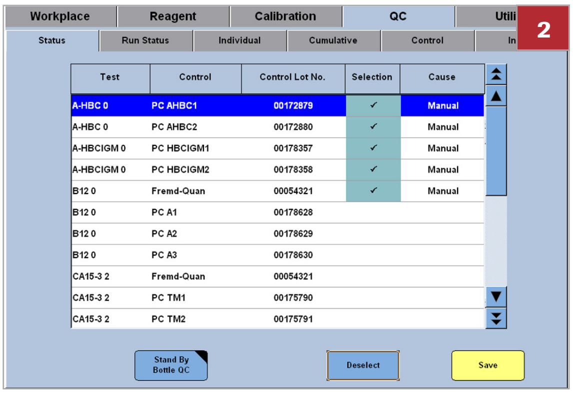
The **Individual QC Chart** window displays the standby QC measurements, but the measurements are excluded from statistical analysis.

1 minute

## ▸ To process standby bottle QC

1 From the **System Overview** window, choose **QC > Status**.

2 Choose the **Stand By Bottle QC** button.

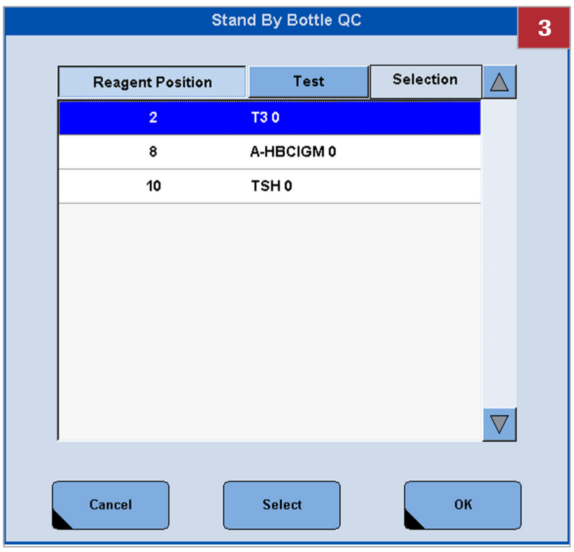



3 From the **Reagent Position** table, select the reagent.

4 Choose the **Select** button.
➔ The system displays a check mark in the **Selection** column.

5 To add further selections, repeat steps **3** to **4**.

6 Choose the **OK** button.

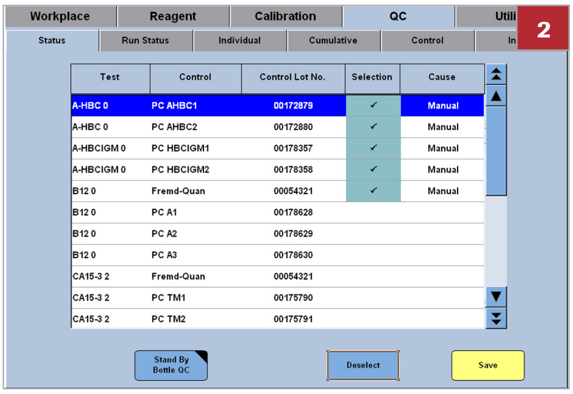


# Processing QC for individual tests

You can perform QC measurements for individual tests. For example, if you have been working with only some tests during operation, perform QC measurements for these tests at the end of operation. This ensures the measurement accuracy for these tests during the entire operation.

1 minute

## To process QC for individual tests




1 From the **System Overview** window, choose **QC > Status**.

2 Select the desired tests and controls and choose the **Select** button.
   → A green bar is displayed in the **Selection** column.
   → *Manual* is displayed in the **Cause** column.
   → The **Select** button toggles to **Deselect**.

3 Choose the **Select** button.
   → The system displays a check mark in the **Selection** column.

4 To add further selections, repeat steps **2** to **3**.

5 Choose the **Save** button.

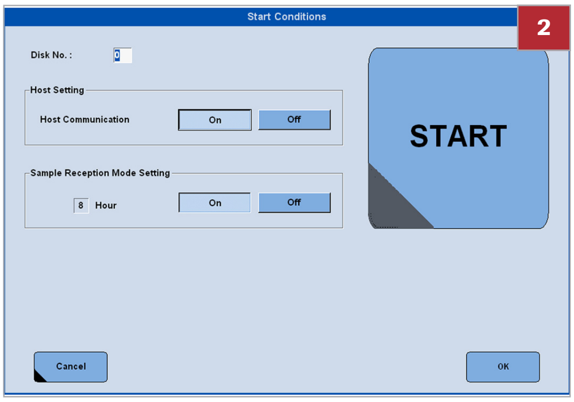
# Running controls

When in normal operation, Roche recommends that you perform QC tests before you process patient samples. However, you can measure controls at any time.

Every day

1 minute

- ☐ Controls loaded on the analyzer
- ☐ The required tests are active




## To measure controls

1 Choose the global **Start** button.

2 On the **Start Conditions** dialog box, check the settings.
   - If you use a disk system, then check the value in the **Disk No.** field is the correct disk.
   - If you use a host connection, then from the **Host Communication** group box, choose the **On** button.

3 NOTICE A slow host connection could cause controls to be untested. If the host does not respond within 15 seconds, then the system advances to the next sample.

   From the **Start Conditions** dialog box, choose the **Start** button.

   → After initializing the run, the system processes the loaded controls. If you have selected automatic printout, then the results print.

4 When sampling is complete, close the lids of the controls on the sample disk or rack.

5 Remove the controls from the sample disk or rack.

6 Place the controls in a refrigerator.

7 If you have not selected automatic printout, then print the QC report.

# Printing QC results

When QC tests are complete, you can view or print a chart that shows the results for a specific control or for all controls.

**In this section**



## Printing results for a specific control or all controls

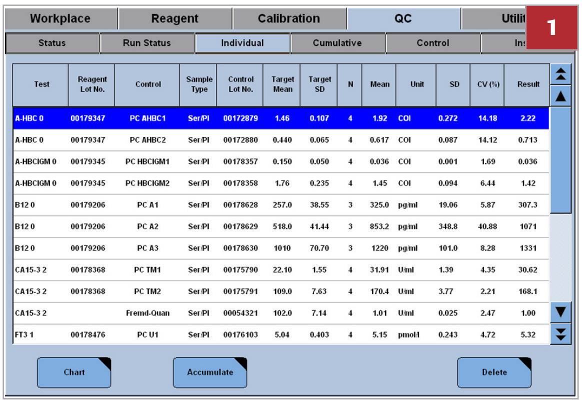
You can print QC results for a specific control or for all controls.

As-needed

1 minute

☐ Results for the required control

### ▸ To print results for a specific control



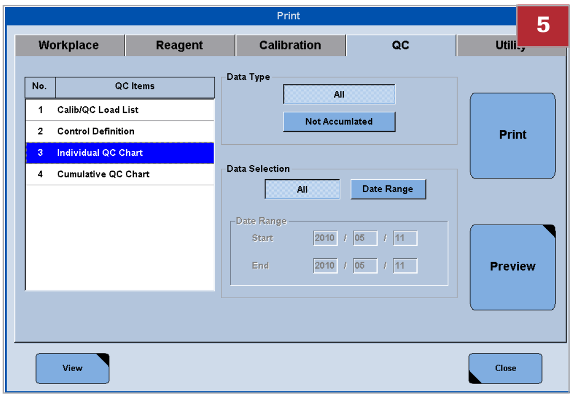

1 From the **System Overview** window, choose **QC > Individual**.

2 From the **Individual** window, choose the row that displays the required control.

   ❶ You can sort the table by the **Test** column or the **Control** column.

3 Choose **Print > QC**.

4 From the **QC Items** column, choose the **Individual QC Chart** option.

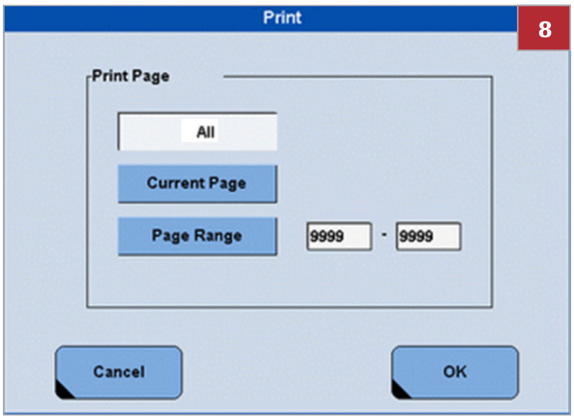



5 From the **Data Type** group box, choose whether to print all or only unaccumulated results for the control.

6 To only print results for a specific date range, perform the steps below.

- From the **Data Selection** group box, choose the **Date Range** button.
- Then in the **Date Range** group box, enter a start and end date.

7 Choose the **Print** button.

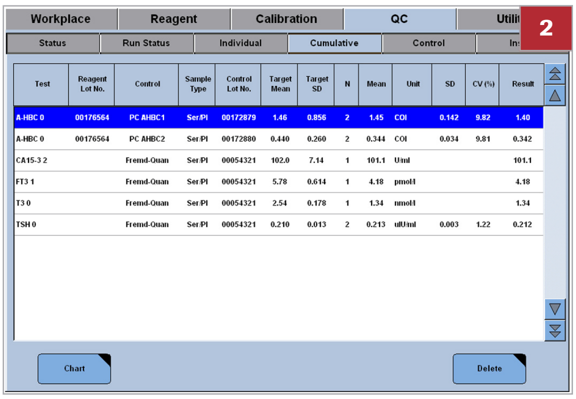



8 From the **Print** dialog box, choose to print all pages, the current page, or a page range.

9 Choose the **OK** button.

## To print cumulative results for controls

1 From the **System Overview** window, choose **QC > Cumulative QC Chart**.

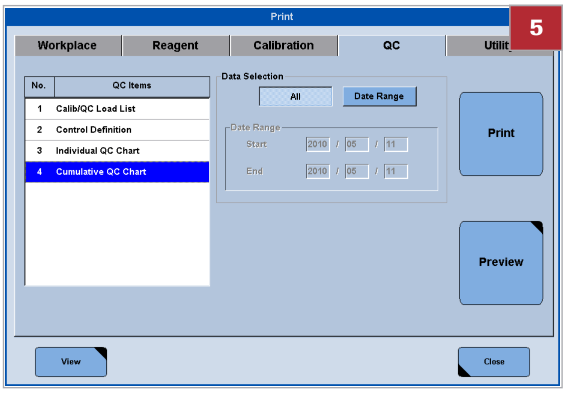



2 From the **Cumulative** window, choose the row that displays the required control.

- 🛈 You can sort the table by the **Test** column or the **Control** column.

3 Choose **Print > QC**.

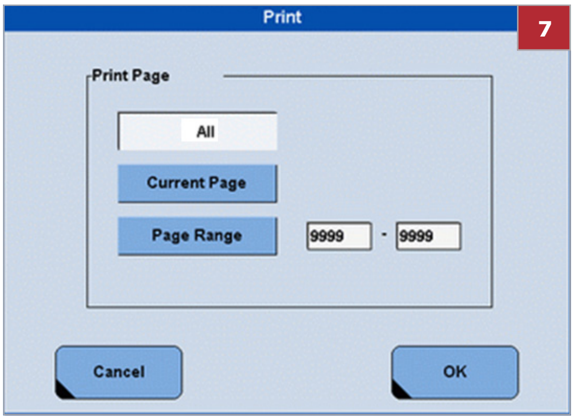
4 From the **QC Items** column, choose the **Cumulative QC Chart** option.




5 To only print results for a specific date range, perform the steps below.

- From the **Data Selection** group box, choose the **Date Range** button.
- Then, in the **Date Range** group box, enter the start and end date.

6 Choose the **Print** button.




7 From the **Print** dialog box, choose to print all pages, the current page, or a page range.

8 Choose the **OK** button.

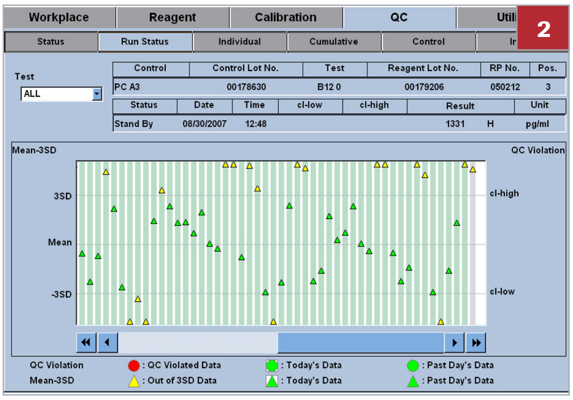
### Related topics

- Activating and deactivating QC tests (144)
- Loading controls (140)
- Assigning positions to controls (139)
- Processing standby bottle QC (146)
- Changing documentation settings (295)

# Validating QC results

After you measure controls, validate the results.

2 minutes




## ▶ To validate QC results

1 From the **System Overview** window, choose **QC > Run Status**.

2 From the **Test** drop-down list, choose a test.
   ➔ Check the QC data points are within the appropriate standard deviation range.

3 If a QC result falls outside of the expected range, then review the data alarm.
   ℹ If a QC violation occurs, then the system can automatically recommend a calibration for the test. The system can only recommend a calibration if the **QC Violation** setting is enabled in the **Utility > Application > Calib.** window.

4 Print a new Calib/QC load list (117).

5 Repeat the QC measurements (147).

**Related topics**

- Data alarm list (316)

# Orders and results

## In this chapter 9

# Overview of orders

Orders are the list of tests to be run on each sample. Most laboratories program these tests into a Laboratory Information System (LIS), which is connected to the **cobas e** 411 analyzer.

The **cobas e** 411 analyzer is linked to the LIS via the Host connector. The LIS is also called the Host in this manual.

To identify the orders to perform, use the laboratory work order list. Ensure that you have the samples, reagents, and calibrators required to run the tests. Program the information into the **cobas e** 411 analyzer. Then load the samples into the **cobas e** 411 analyzer, and run the tests.

When the tests have been run, the **cobas e** 411 analyzer saves the results. You can then, review the reports, print the reports, upload the results to the host, and delete results which have been printed or uploaded.

# Programming orders

Before you load samples on the analyzer, program the tests to perform on each sample.

**In this section**



## Programming routine samples on an interfaced system

To program routine samples on an interfaced system, use the Host system.

10 minutes

### To program samples with barcodes on an interfaced system

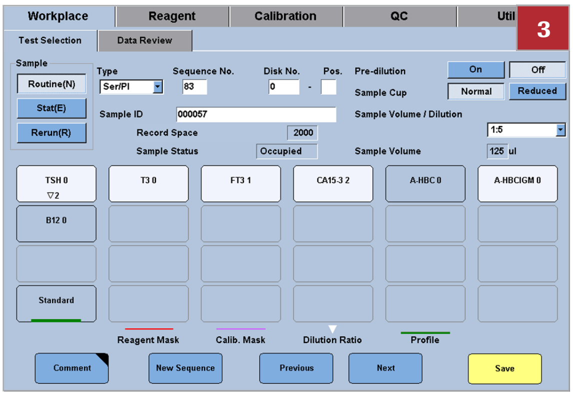
1 Enter the tests required into the Host system.
  → The analyzer automatically receives the information.

2 Ensure that the barcode labels have been printed and attached to the sample tubes.

### To program samples without barcodes on an interfaced system

1 Enter the tests required into the Host system.
  → The analyzer automatically receives the information. A sequence number is assigned to each sample ID.

2 Ensure that the information on the analyzer includes the disk or rack ID and the position number.




3 From the **System Overview** window, choose **Workplace > Test Selection**.

4 Check that the **Routine** button is selected.

5 On a disk system, print a work list report.

ℹ There is no work list report print out available for the rack system.

**Related topics**

- Placing barcode labels on containers and vials (164)
- Printing a work list report (161)

# Programming STAT samples on an interfaced system

The system processes STAT (short turnaround time) samples before routine samples.

5 minutes

☐ The system must be in Operation mode, Standby mode, or S.Stop mode

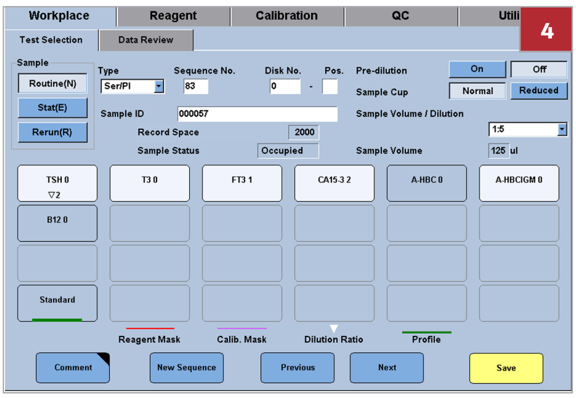
## To program STAT samples on an interfaced disk system

1 Enter the tests required into the Host system.

→ The analyzer automatically receives the information.

2 Ensure that the information on the analyzer includes the disk or rack ID and the position number.

3 From the **System Overview** window, choose **Workplace > Test Selection**.




4 From the **Sample** group box, choose the **Stat** button.

5 In the **Disk No.** and **Pos.** fields, enter the empty position for the STAT sample. The position must be after the stop barcode.

6 If the STAT samples do not have barcode labels, then enter the sample ID in the **Sample ID** field.

### To program STAT samples on an interfaced rack system

1 Enter the tests required into the Host system.
→ The analyzer automatically receives the information.

2 If the STAT samples do not have barcode labels, then program the sample manually.
→ The work list, available on the disk system, shows the assigned sample positions.

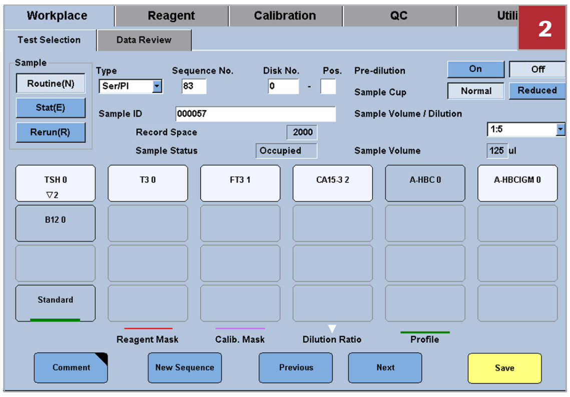
## Programming routine samples on a non-interfaced system

A non-interfaced system is not connected to the Host. You must manually enter the details of how to test the sample.

10 minutes

### To program samples with barcodes on a non-interfaced system

1 From the **System Overview** window, choose **Workplace > Test Selection**.




2 From the **Sample** group box, choose the **Routine** button.

3 From the **Type** drop-down list, choose the sample type.

4 In the **Sample ID** field, enter the ID of the sample.

5 If the sample has been manually diluted, then from the **Pre-dilution** group box, choose the **On** button.

6 If the sample has a reduced volume, then from the **Sample Cup** group box, choose the **Reduced** button.

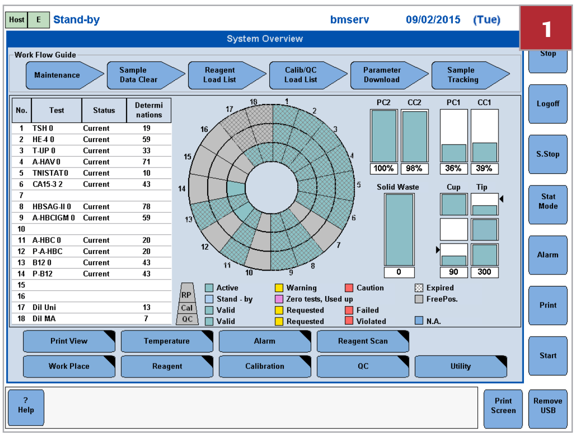
7 NOTICE Risk of the wrong dilution factor being used. The selected dilution factor remains after a test has been chosen. Reset the dilution factor before choosing the next test.

If the sample needs automatic dilution, then from the **Sample Volume / Dilution** drop-down list, choose a dilution factor.

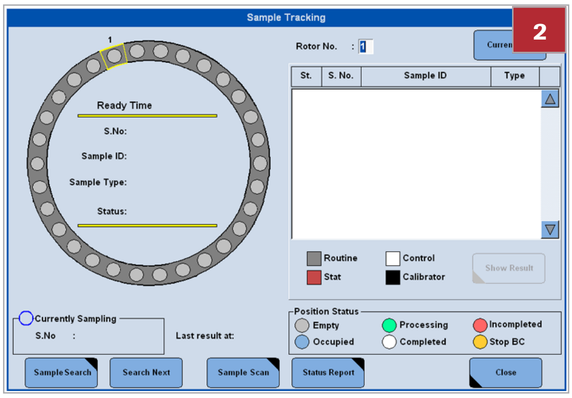
8 From the test matrix, select tests and test profiles for the sample.

9 Choose the **Save** button.

### ▸ To program samples without barcodes on a non-interfaced system



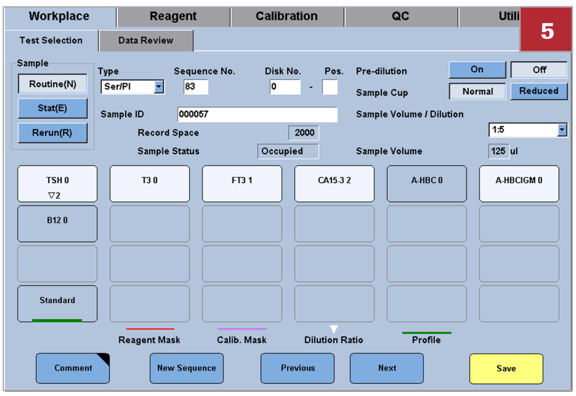

1 From the **System Overview** window, choose the **Sample Tracking** button.




2 On a disk system, from the **Sample Tracking** dialog box, choose the **Sample Scan** button.

3 Wait until the analyzer is in Standby mode.

4 Choose **Workplace > Test Selection**.




5 From the **Sample** group box, choose the **Routine** button.

6 From the **Type** drop-down list, choose the sample type.

7 If you have a disk system, then enter the disk number in the **Disk No.** field.

8 If you have a rack system, then enter the rack number in the **Rack No.** field.

9 In the **Pos.** field, enter the position number.

10 In the **Sample ID** field, enter the ID of the sample.

11 If the sample has been manually diluted, then from the **Pre-dilution** group box, choose the **On** button.

12 If the sample has a reduced volume, then from the **Sample Cup** group box, choose the **Reduced** button.

13 If the sample needs automatic dilution, then from the **Sample Volume / Dilution** drop-down list, choose a dilution factor.

14 From the test matrix, select tests and test profiles for the sample.

15 Choose the **Save** button.

# Programming STAT samples on a non-interfaced system

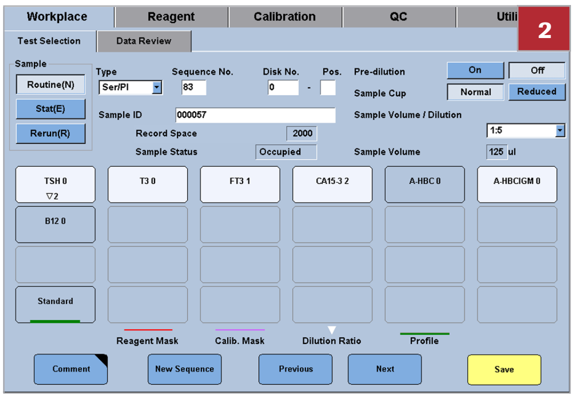
The system processes STAT (short turnaround time) samples before routine samples. Before you load STAT samples, program them on the system.

10 minutes

☐ The system must be in Operation mode, Standby mode, or S.Stop mode.

## To program STAT samples on a non-interfaced system

1 From the **System Overview** window, choose **Workplace > Test Selection**.




2 From the **Sample** group box, choose the **Stat** button.

3 If you have a disk system, then in the **Disk No.** field, enter the disk number.

4 If you have a rack system, then in the **Rack No.** field, enter the rack number.

5 In the **Pos.** field, enter the position number.

ℹ If you have a disk system, then the position must be after the stop barcode.

6 If the STAT samples do not have barcodes, then in the **Sample ID** field, enter the sample ID.

7 If the sample has been manually diluted, then from the **Pre-dilution** group box, choose the **On** button.

8 If the sample has a reduced volume, then from the **Sample Cup** group box, choose the **Reduced** button.

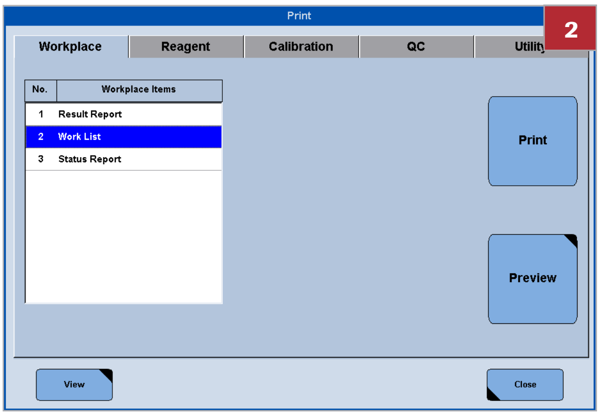
9 In the test matrix, select tests and test profiles for the sample.

10 Choose the **Save** button.

# Printing a work list report

After you program samples, view and print the work list report.

1 minute




## To print a work list report

1 Choose the global **Print** button.

2 Select **Workplace > Work List**.

3 Perform either of the steps below.
   - To print the report, choose the **Print** button.
   - To view the report before you print it, choose the **Preview** button

# Preparing samples

Before you load samples, you may need to manually dilute them, or print barcode labels.

**In this section**



## Diluting samples

If a result exceeds the measuring range of the assay, then dilute the sample.

Before you start a test run, you can perform either of the steps below.

- Manually dilute a sample.
- Select automatic dilution for the sample.

**In this section**



### Manually diluting a sample

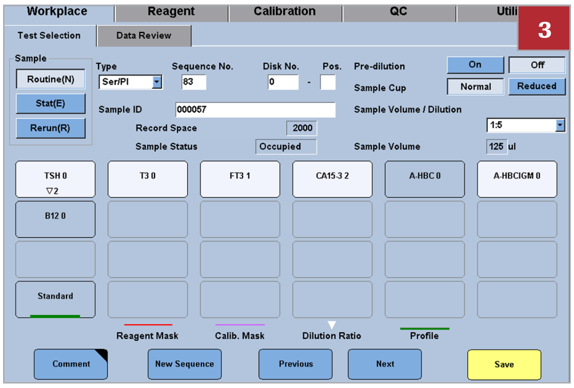
If you manually dilute a sample, then the calculated results do not include the dilution factor.

1 minute

☐ Suitable diluent

#### ▸ To manually dilute a sample

1. Before you load the sample onto the analyzer, manually dilute it.
2. From the **System Overview** window, choose **Workplace > Test Selection**.




3 From the **Pre-dilution** options, choose the **On** button.

4 Program the sample as normal.

5 Choose the **Save** button.

**Related topics**

- Programming orders (156)

## Selecting automatic dilution for a sample

If you select automatic dilution, then the calculated results include the dilution factor.

1 minute

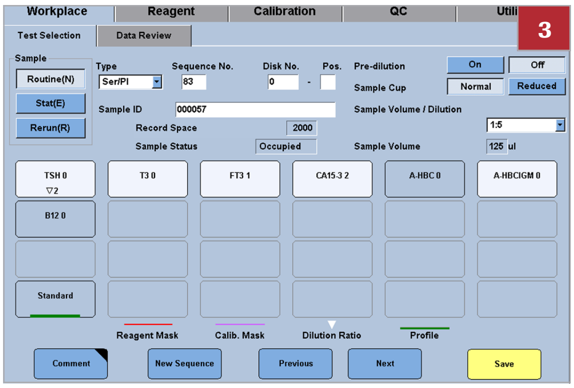
☐ The reagent barcode identifies the assays as suitable for dilution

☐ A bottle of suitable diluent is in the reagent rotor

### To select automatic dilution for a sample

1 From the **System Overview** window, choose **Workplace > Test Selection**.

2 Program the sample as normal.




3 From the **Sample Volume / Dilution** drop-down list, choose the required dilution factor.

4 From the test matrix, choose the tests for the sample.

5 Choose the **Save** button.

→ If dilution can be applied to this test, then the dilution factor is displayed under the test name.

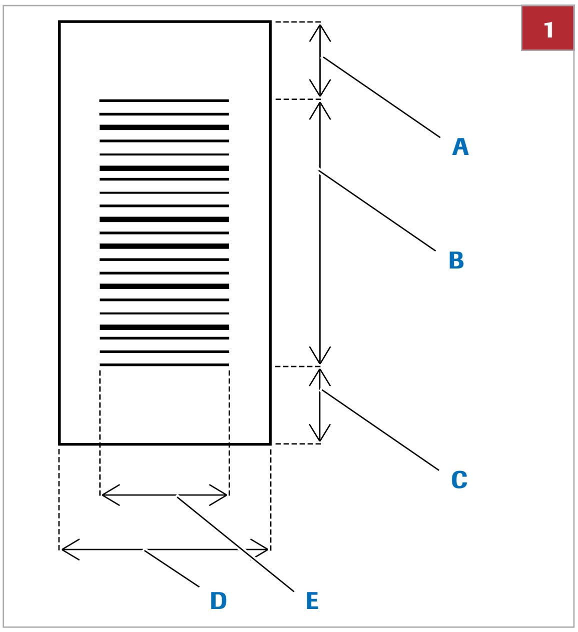
# Placing barcode labels on containers and vials

The analyzer may not read incorrectly positioned or sized barcode labels.

1 minute

☐ Barcode labels of the correct size

### ▶ To place a barcode label on a container or vial




**A** Quiet zone 5 mm minimum

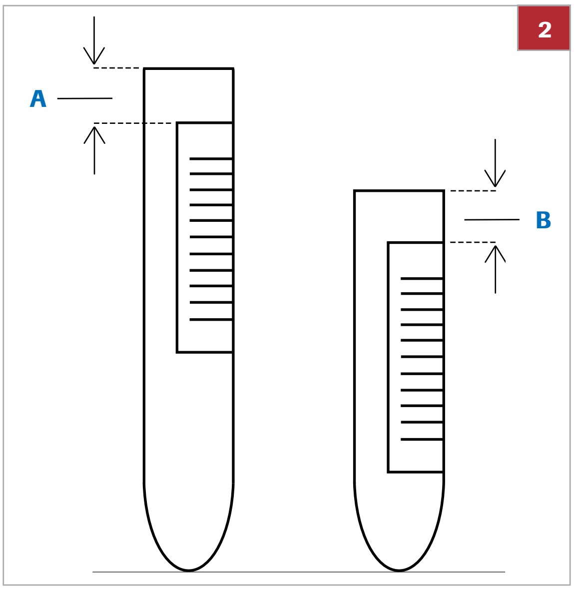
**B** Barcode zone 50 mm maximum for 100 mm tubes, 38 mm maximum for 75 mm tubes

**C** Quiet zone 5 mm minimum

**D** Label width 16 mm maximum

**E** Barcode width 12 mm maximum

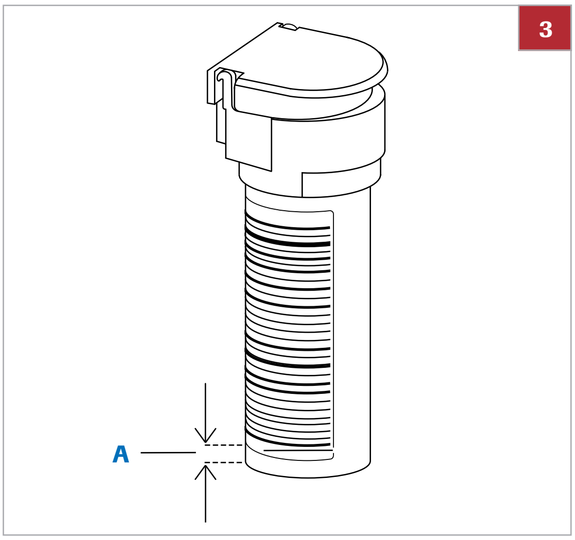
1 Check that the barcode dimensions comply with the diagram.




**A** Upper margin 12 mm minimum

**B** Upper margin 12 mm minimum

2 If the container is a sample tube, then place the barcode according to the diagram.




**A** Lower margin 2.5 ±1 mm minimum

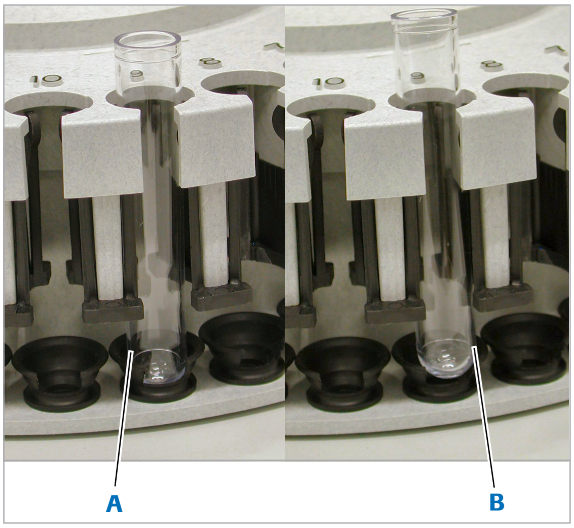
3 If the container is a calibrator vial or control vial, then place the barcode according to the diagram.

4 To check the edges of the barcode label are firmly stuck to the container, press the barcode label evenly.

# Correct placement of sample tubes on a sample disk

Incorrect placement of a sample tube can cause errors or faulty results.

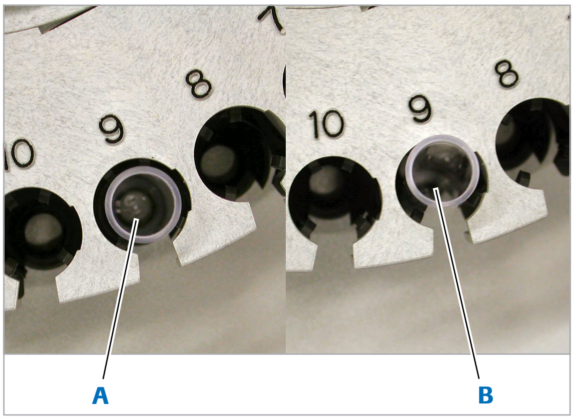
Place the sample tubes correctly in the grommet at the base of the sample disk. Check each sample tube is vertical.




**A** Tube is correctly seated in the grommet

**B** Tube is incorrectly seated

To improve the alignment of 13 mm tubes, use 13 mm sdtas.




**A** Tube is correctly positioned

**B** Tube is incorrectly positioned

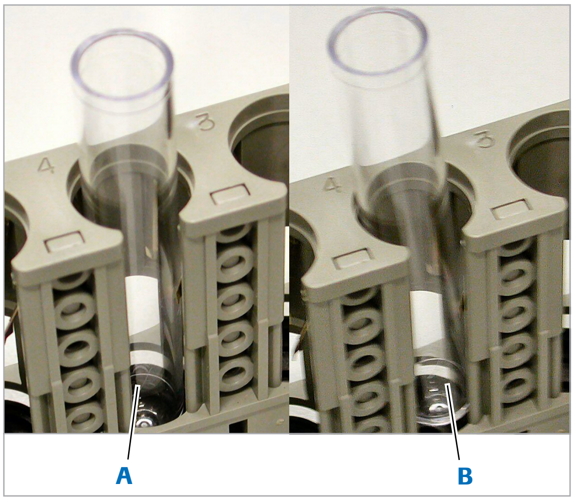
### Related topics

- Using a 13 mm sdta (168)

# Correct placement of sample tubes on a rack

Incorrect placement of a sample tube can cause errors or faulty results.

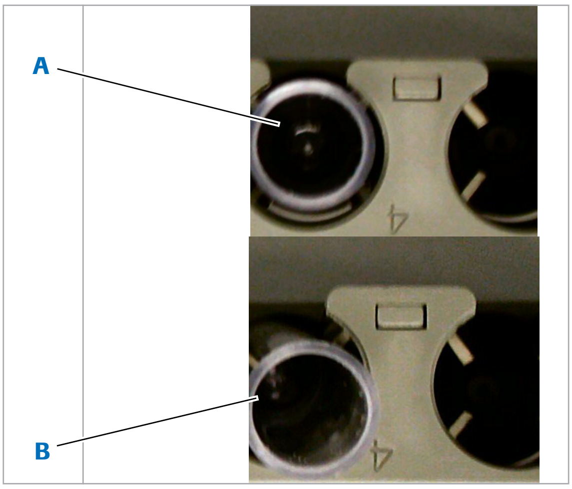
Place the tubes correctly in the grommet at the base of the rack. Check each tube is vertical.




**A** Tube is correctly seated

**B** Tube is incorrectly seated

To improve the alignment of 13 mm tubes, use Roche cup adapters.




**A** Tube is correctly positioned

**B** Tube is incorrectly positioned

**Related topics**

- Inserting a Roche rack cup adapter into a rack (171)

# Using a 13 mm sdta

Use 13 mm sdtas to improve the alignment of 13 mm tubes.

⚠ **WARNING**

**Incorrect results and errors due to misaligned sample tubes**

Not using a 13 mm sdta with 13 mm tubes or incorrect use of a 13 mm sdta may cause incorrect results or errors.

- Always use 13 mm sdtas with 13 mm tubes.
- Ensure that sample tubes are straight.
- Ensure that barcode labels are not damaged and that the barcode scanner can read them.
- Ensure that 13 mm sdtas are not exposed to direct sunlight.
- If a larger diameter tube is left inserted in a 13 mm sdta for more than 3 days, then the adapter may become distorted. Do not insert smaller diameter tubes into distorted adapters as they may not align correctly.

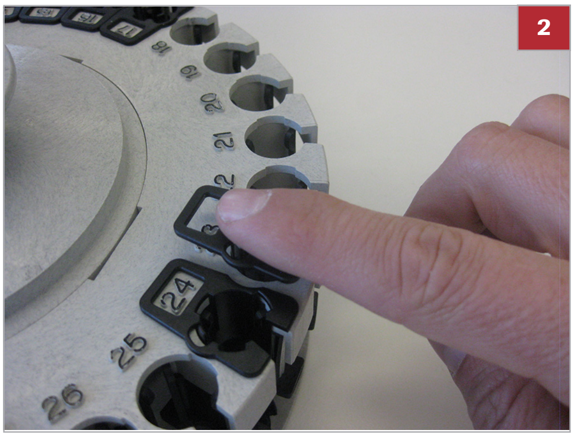
5 minutes to insert or remove thirty 13 mm sdtas

☐ 13 mm sdta

☐ The sample disk is removed from the analyzer

### To insert a 13 mm sdta into a sample disk


1 Place the 13 mm sdta into the sample disk.
   🛈 Ensure that the number on the sample disk is visible through the rectangular window of the 13 mm sdta.




**2** Gently push down on the 13 mm sdta until it clicks into place.


**3** NOTICE Incorrect placement of a 13 mm sdta may cause barcode reading errors.

To prevent rotation, ensure that the 13 mm sdta has at least one neighboring 13 mm sdta.

## To remove a 13 mm sdta from a sample disk

**1** Remove the sample tube from the 13 mm sdta.


**2** Gently push and hold the pin of the 13 mm sdta inwards.


**3** Lift the 13 mm sdta out of the sample disk.

# Inserting a Roche rack cup adapter into a rack

Use Roche rack cup adapters to improve the alignment of 13 mm tubes.

⚠ **WARNING**

**Incorrect results and errors due to misaligned sample tubes**

Not using a Roche rack cup adapter with 13 mm tubes or incorrect use of a Roche rack cup adapter may cause incorrect results or errors.

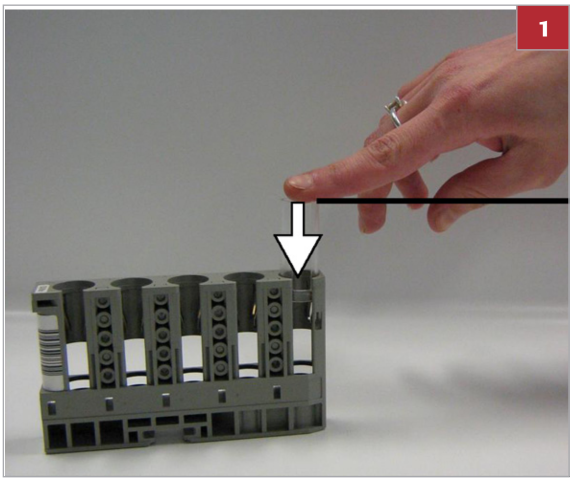
- Always use Roche rack cup adapters with 13 mm tubes.
- Ensure that sample tubes are straight.

If you insert a tube with an outside diameter greater than 13 mm into a Roche rack cup adapter, then you can damage the barcode label. Ensure the barcode label is undamaged and can be read by the barcode scanner.

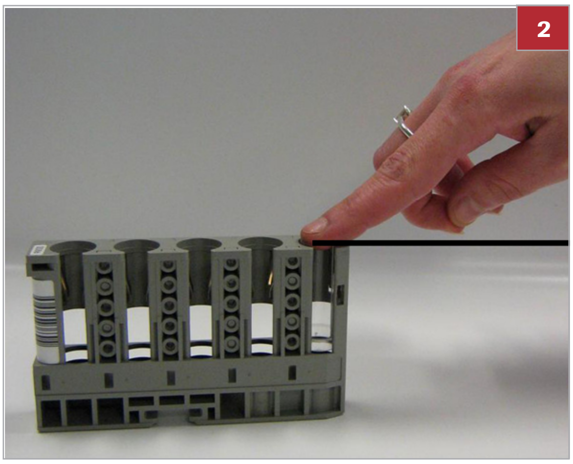
30 seconds

☐ Roche rack cup adapter

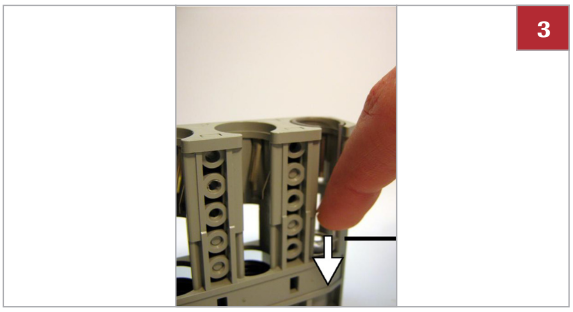
## To insert a Roche rack cup adapter



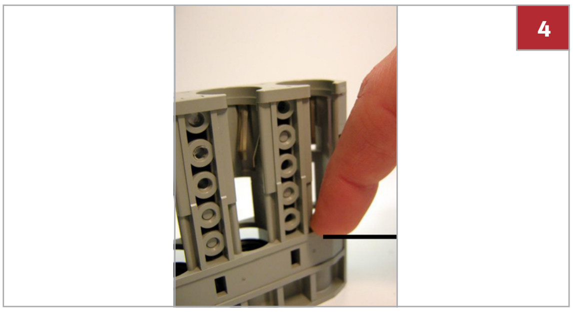

1 Gently push the Roche rack cup adapter down into the rack.




2 When your finger touches the top of the rack, stop pushing the Roche rack cup adapter.




3 Push the Roche rack cup adapter towards the bottom of the rack.




4 When the depth-stop on the Roche rack cup adapter touches the body of the rack, stop pushing the adapter.

**Related topics**

- Correct placement of sample tubes on a rack (167)

# Loading routine and STAT samples with barcodes

To perform tests on the analyzer, place the samples into the correct rack or disk position. Ensure that the barcodes on the sample tube or container can be read.

**⚠ WARNING**

**Incorrect results due to sample mismatch**

You may need to manually assign a sample to a position on a rack or sample disk. This may be due to an unreadable barcode or a non-barcoded container.

- Before you manually assign a position to a sample, ensure that the position is not already assigned to another sample.
- Do not manually assign calibrator vials with barcodes to racks or sample disks.

**In this section**



## Loading routine and STAT samples with barcodes on a disk system

Before you process samples, you must load them onto the analyzer.

**⚠ CAUTION**

**Incorrect results due to sample mismatch of additional samples**

Loading additional samples on a sample disk after testing has already begun may cause incorrect results.

- Do not load new samples in positions that are assigned to samples with outstanding measurements.

2 minutes

- ☐ Stop barcode
- ☐ Samples
- ☐ Sample disk

- ☐ Work list report printed
- ☐ Any manual dilution required has been performed
- ☐ Barcode labels printed and attached

## ▸ To load routine samples with barcodes on a disk system


**1** Lift the top cover of the analyzer.


**2** NOTICE Incorrect placement of a sample tube can cause errors or incorrect results.

Place the first sample in the position with the lowest number on the sample disk.

ⓘ Make sure that the barcodes face outwards.

**3** Place the remaining samples in the next open positions.

**4** NOTICE Omitting the stop barcode can cause incorrect results.

Place a stop barcode in the next open position.

**5** Close the top cover of the analyzer.

## ▸ To load STAT samples with barcodes on a disk system

**1** If the analyzer is processing samples, then choose the **S.Stop** button.

**2** Lift the top cover of the analyzer.

3 Load the STAT samples at the positions you specified in the **Disk No.** and **Pos.** fields.

4 Close the top cover of the analyzer.

**Related topics**

- Starting a run of tests for routine samples (183)
- Starting a run of tests for STAT samples (184)
- Correct placement of sample tube s on a sample disk (166)
- Manually diluting a sample (162)

# Loading routine and STAT samples with barcodes on a rack system

Before you can process samples, you must load them onto the analyzer.

2 minutes

- ☐ Samples
- ☐ Rack
- ☐ Tray

### To load routine samples with barcodes on a rack system

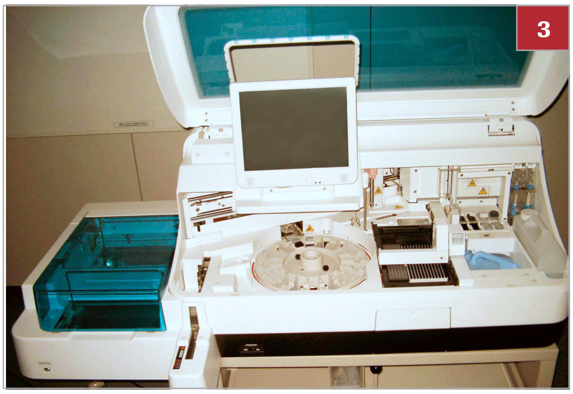
1 NOTICE Incorrect placement of a sample tube on a rack can cause errors or incorrect results.

Load the samples on a rack.

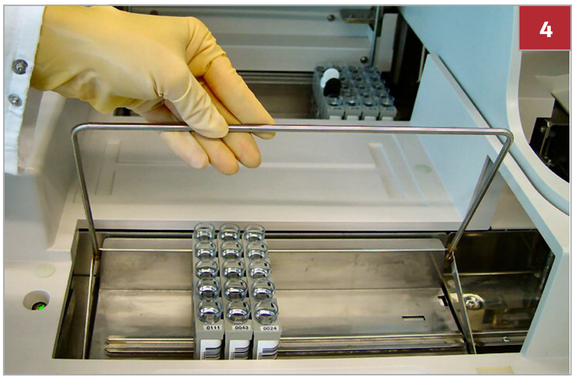
Ensure that sample barcode labels are visible through the gaps in the rack.

2 Load the racks on a tray.

To identify where to place the samples, use the work list report.




**3** Lift the top cover of the rack feeder.




**4** Place the tray on the A-Line.

**5** Check that there is an empty tray on the C-Line.

**6** Close the top cover of the rack feeder.

## ▸ To load STAT samples with barcodes on a rack system

**1** Load the STAT samples in a rack.

- ❶ Ensure that sample barcode labels are visible through the gaps in the rack.


**2** Load the rack in the STAT rack position on the analyzer.

**Related topics**

- Starting a run of tests for routine samples (183)
- Starting a run of tests for STAT samples (184)
- Correct placement of sample tubes on a rack (167)

# Loading routine and STAT samples without barcodes

Samples without barcode labels must either have barcode labels applied, or the tests programmed into the analyzer.

**In this section**



## Loading routine and STAT samples without barcodes on a disk system

Before you process samples, load them onto the analyzer.

2 minutes

- ☐ Samples
- ☐ Work list report

### To load routine samples without barcodes on a disk system


1 Lift the top cover of the analyzer.


**2** NOTICE Incorrect placement of a sample tube can cause errors or incorrect results.

Load the samples onto the disk, according to the work list report.

**3** NOTICE Omitting the stop barcode can cause incorrect results.

Place a stop barcode in the next open position.

**4** Close the top cover of the analyzer.

## To load STAT samples without barcodes on a disk system

**1** If the analyzer is processing samples, then choose the **S.Stop** button.

**2** Lift the top cover of the analyzer.

**3** Load the STAT samples at the positions you specified in the **Disk No.** and **Pos.** fields.

**4** Close the top cover of the analyzer.

**Related topics**


- Starting a run of tests for routine samples (183)
- Starting a run of tests for STAT samples (184)
- Printing a work list report (161)

# Loading routine and STAT samples without barcodes on a rack system

Before you process samples, load them onto the analyzer.

2 minutes

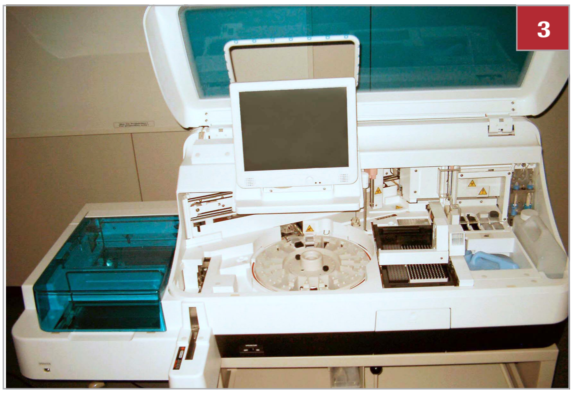
- ☐ Samples
- ☐ Rack
- ☐ Tray

## ▸ To load routine samples without barcodes on a rack system

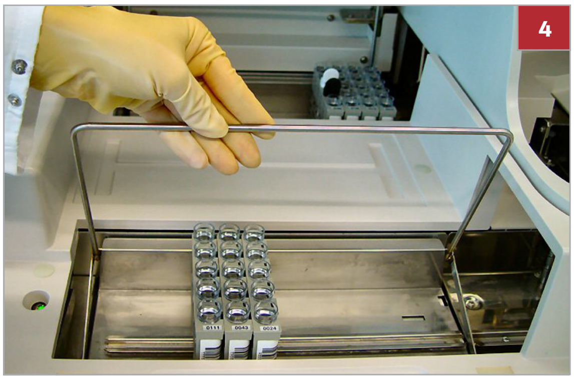
1 NOTICE Incorrect placement of a sample tube can cause errors or incorrect results.

Load the the samples on a rack, according to the work list report.

2 Load the racks on a tray.




3 Lift the top cover of the rack feeder.




4 Place the tray on the A-Line.

5 Check that there is an empty tray on the C-line.

6 Close the top cover of the rack feeder.


## To load STAT samples without barcodes on a rack system

1 Load the STAT samples in a rack, according to the work list report.

2 Load the rack in the STAT rack position on the analyzer.

**Related topics**

- Starting a run of tests for routine samples (183)
- Starting a run of tests for STAT samples (184)
- Printing a work list report (161)

# Loading consumables

When you perform tests, the analyzer uses AssayCups and AssayTips. Ensure that you load additional AssayCups and AssayTips onto the analyzer when required.

**In this section**



## Loading trays of AssayTips or AssayCups

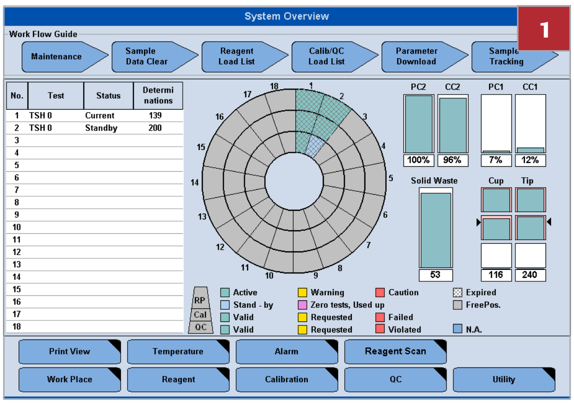
The **System Overview** window shows which trays are being used and how many AssayCups and AssayTips are loaded.

As needed

2 minutes

☐ Loaded AssayTip and AssayCup trays

### To identify which tray to access




1 Look at the gripper positions and number of AssayCups or AssayTips used on the **System Overview** screen.

2 If the background of the tray in the software is white, then you can replace the tray.

### To replace trays of AssayCups or AssayTips

1 Lift the top cover of the analyzer.

2 Lift out the AssayCup tray or AssayTip tray you want to change.

3 Insert a full AssayCup tray or AssayTip tray.
   ❶ Trays are keyed for proper placement.

4 To load additional trays, repeat steps **2** and **3**.

5 Close the top cover of the analyzer.

# Running tests

When you have programmed and loaded the **cobas e** 411 analyzer, start a run of tests.

**In this section**



## Starting a run of tests for routine samples

After you load samples, start a run of tests.

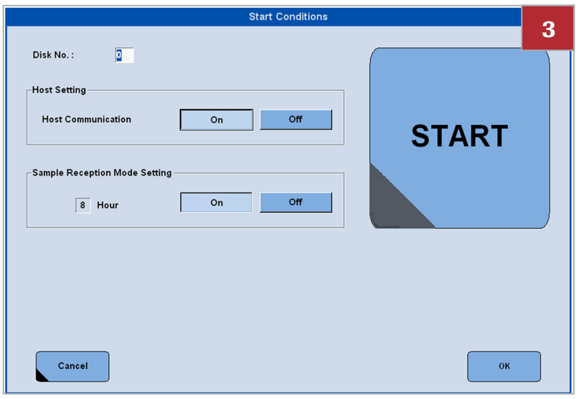
For rack systems, the analyzer automatically assigns the sequence number, rack ID, and rack position when it processes the samples.

1 minute

- ☐ The required samples are loaded
- ☐ The required tests are ordered

### To start a run of tests for routine samples

1. If you use batch mode for host communication, then check that all requests are loaded from the host to the analyzer.
2. Choose the global **Start** button.




**3** Check the settings on the **Start Conditions** dialog box.

- If you are using a disk system, then check the **Disk No.** field.
- If you are using a host connection, then choose the **On** button in the **Host Communication** panel.

**4** NOTICE A slow host connection could cause samples to be untested. If the host does not respond within 15 seconds, then the system advances to the next sample.

From the **Start Conditions** dialog box, choose the **Start** button.

➔ After initializing the run, the system processes the selected samples.

**Related topics**


- Programming orders (156)
- Starting a run of tests for STAT samples (184)
- Tracking samples (189)


# Starting a run of tests for STAT samples

After you load samples, start a run of tests.

For rack systems, the analyzer automatically assigns the sequence number, rack ID, and rack position when it processes the samples.

1 minute

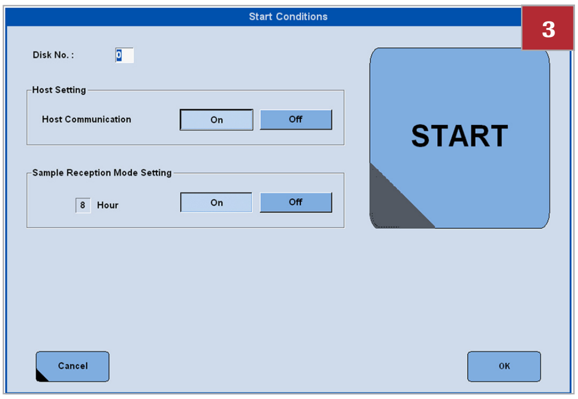
- ☐ The STAT samples are loaded
- ☐ The required tests are selected

## To start a run of tests for STAT samples on a disk system

**1** Choose the global **Stat Mode** button.

➔ If the analyzer is in operation, S.Stop or initialization, then the color of the **Stat Mode** button changes to yellow.

**2** Choose the global **Start** button.




3 Check the settings on the **Start Conditions** dialog box.

- If you are using a disk system, then check the **Disk No.** field.
- If you are using a host connection, then choose the **On** button in the **Host Communication** panel.

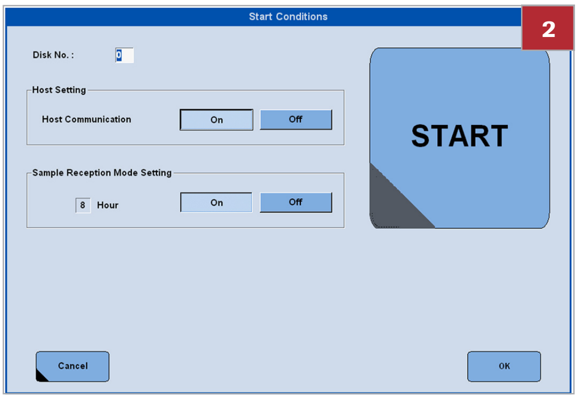
4 NOTICE A slow host connection could cause samples to be untested. If the host does not respond within 15 seconds, then the system advances to the next sample.

On the **Start Conditions** dialog box, choose the **Start** button.

➔ The analyzer continues to process any open requests for the current routine sample, then processes the STAT samples.

## To start a run of tests for STAT samples on a rack system

1 Choose the global **Start** button.




2 Check the settings on the **Start Conditions** dialog box.

- If you are using a disk system, then check the **Disk No.** field.
- If you are using a host connection, then choose the **On** button in the **Host Communication** panel.

3 NOTICE A slow host connection could cause samples to be untested. If the host does not respond within 15 seconds, then the system advances to the next sample.

On the **Start Conditions** dialog box, choose the **Start** button.

➔ The analyzer performs an initial preparation process.

4 Choose the global **Stat Mode** button.

➔ The color of the **Stat Mode** button changes to yellow and the STAT rack enters the analyzer.

5 If you need to load another STAT rack, load the rack in the STAT rack position and then choose the global **Stat Mode** button again.

**Related topics**


- Programming orders (156)
- Starting a run of tests for routine samples (183)
- Tracking samples (189)

# Finishing a run

If the analyzer is in Sample reception mode, then when it finishes a run it enters S.Stop mode. Otherwise the analyzer goes into Standby mode.

When a run finishes, unload the samples.

- ☐ Samples tested

## To unload samples from the rack system

1 If the tray indication light at the end of the C-Line is lit, then lift the analyzer lid and remove the tray.

2 If the tray indication light at the end of the C-Line is off, then wait until the light is green.

3 Remove samples from the rack and then store or dispose of them as per laboratory protocol.

## To unload samples from the disk system

1 Check that all samples in the disk have been tested and the analyzer has stopped.

2 Lift the top cover of the analyzer.


3 Remove samples from the disk and then store or dispose of them as per laboratory protocol.

4 Close the top cover of the analyzer.

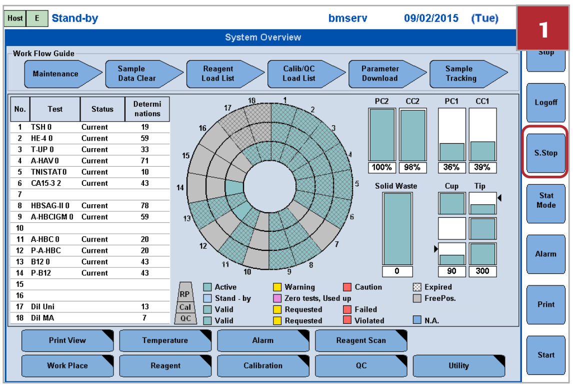
# Canceling a run

If you cancel a run, then the analyzer stops processing new samples. The analyzer completes the current sample and calculates the results.

1 minute

☐ The analyzer is processing samples

## To cancel a run




1 Choose the global **S.Stop** button.
   → The analyzer enters S.Stop mode and issues an alarm.

2 To cancel the alarm, choose the global **Alarm** button.

**Related topics**

- Continuing a run ▶ (187)

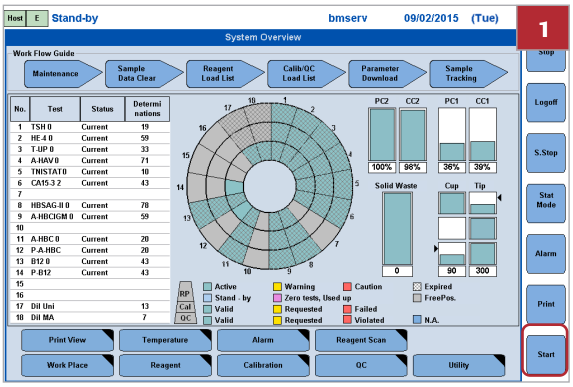
# Continuing a run

If the system is in S.Stop mode, then you can continue the run.

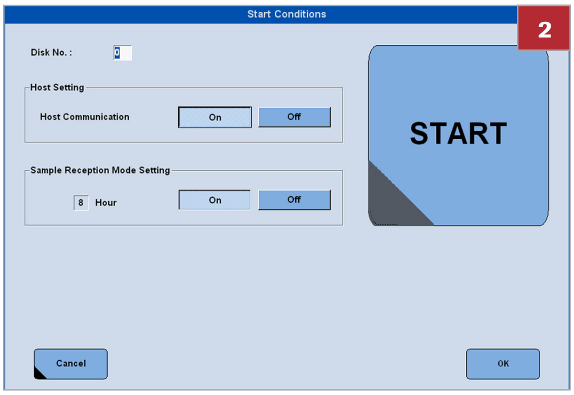
1 minute

☐ The system is in S.Stop mode

## To continue a run




1 Choose the global **Start** button.




2 Check that the settings on the **Start Conditions** screen are correct.

3 From the **Start Conditions** screen, choose the **Start** button.

➔ The analyzer continues processing the selected samples.

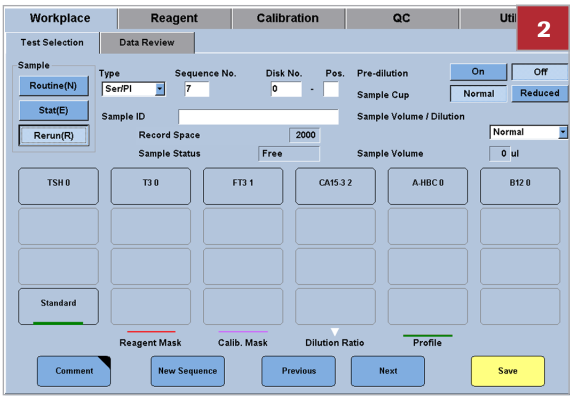
**Related topics**

- Canceling a run (187)
- Starting a run of tests for routine samples (183)

# Rerunning a sample

If you rerun a sample, then you must program it manually. The analyzer does not link the tests which have been taken with reruns.

- ☐ Sample which has been previously tested
- ☐ Details of the tests required




## To rerun a sample

1 From the **System Overview** window, choose **Workplace > Test Selection**.

2 Choose the **New Sequence** button.

3 From the **Sample** group box, choose the **Rerun** button.

4 In the **Sample ID** field, enter the sample ID.
   You can reuse the sample ID from the last time the test was run.

5 In the test matrix, select the tests that to run and the test profiles for this sample.

6 Choose the **Save** button.

**Related topics**

- Programming orders (156)
- Starting a run of tests for routine samples (183)

# Tracking samples

You can track samples as they are processed through the analyzer.

Regular intervals throughout the day

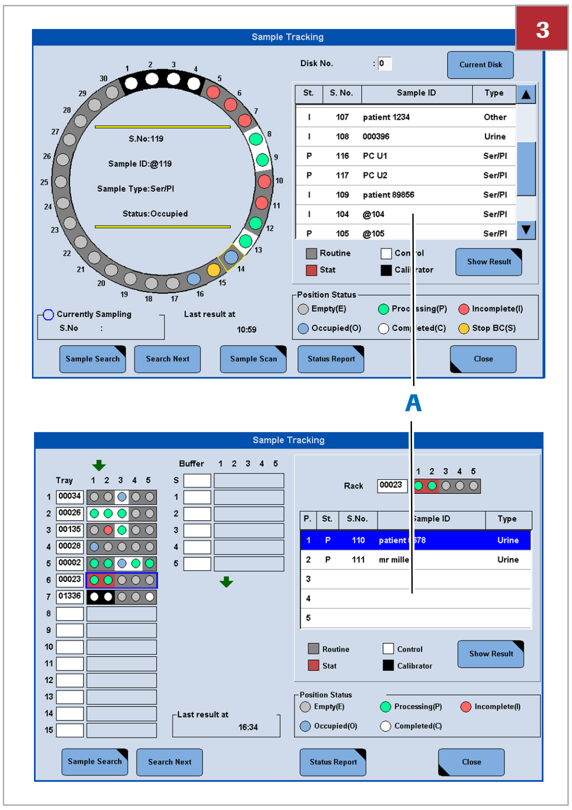
1 minute

☐ Samples processing through the analyzer

## To track a sample on the system


1 Choose the graphical icon representing the system in the status line.

2 From the **System Overview** window, choose the **Sample Tracking** button.
   The Disk and Rack systems display different **Sample Tracking** windows. These windows are described in more detail in the User Assistance.




**A** List of specific samples

3 To see information relating to a specific sample, select the sample on the right.

4 Choose the **Show Result** button.

# Results

As results are generated on the **cobas e** 411 analyzer, they are saved in the database. The database stores up to 2000 results.

When results have been generated, you can perform the actions below.

- View the results
- Print the results
- Upload the results to the Host system
- Export the results
- Delete the results

**NOTICE**

**Database may become full and results deleted automatically**

Unless you have uploaded or exported the results, they may not be available.

- Upload data daily to the host or perform a data export, then delete the results from the **cobas e** 411 analyzer.

When results are printed or uploaded, the **cobas e** 411 analyzer marks them as documented. Documented samples display an H at the top of the row in the **Data Review** dialog box.

**In this section**



## View patient results

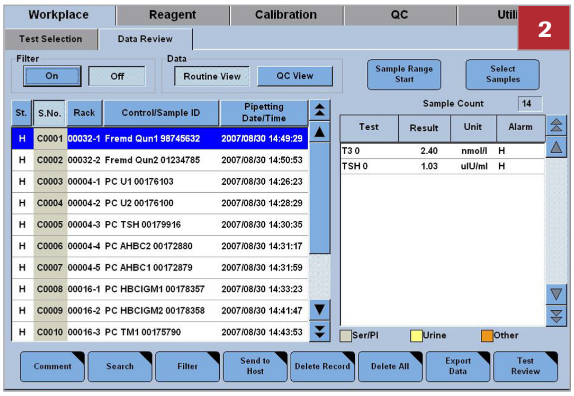
When tests are complete, view the patient results.

☐ Patient results

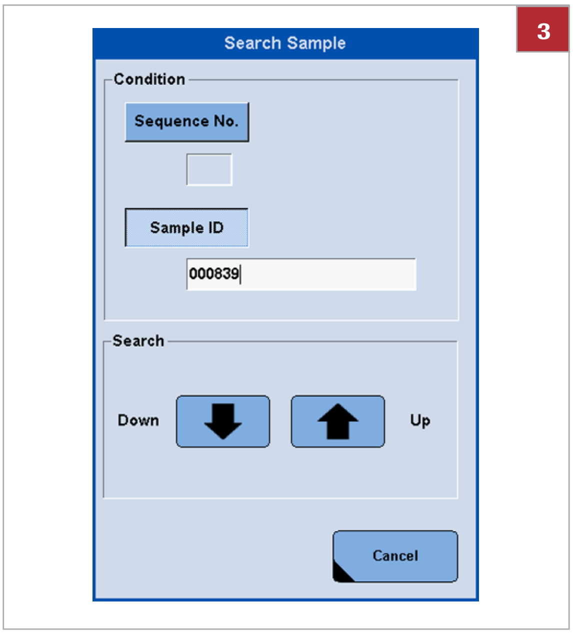
## To view patient results

1 From the **System Overview** window, choose **Workplace > Data Review**.

➔ The **Data Review** window displays routine results, STAT results, and QC results.




2 From the **Data Review** window, choose the **Search** button.




3 From the **Condition** group box, choose the search conditions.

- To search by sequence number, choose the **Sequence No.** button and enter a sequence number.
- To search by sample ID, choose the **Sample ID** button and enter a sample ID.

4 From the **Search** group box, choose to search downwards or upwards from the currently selected sample.

🛈 Choose the button repeatedly until you find the correct sample.

5 When you have found the correct sample, choose the **Cancel** button.

➔ The sample is highlighted in the **Data Review** window.

**Related topics**

- Filter patient results (192)
- Printing a result report (194)

# Filter patient results

To view, upload, or print specific sample results, filter patient results.

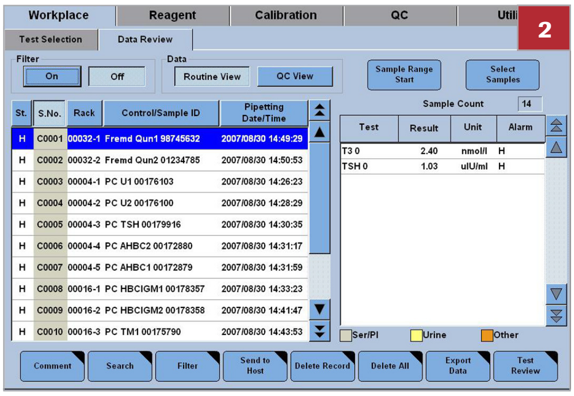
When you view patient results on the **Data Review** window, the default filter setting is **Off**.

☐ Patient results

## To filter patient results

1 From the **System Overview** window, choose **Workplace > Data Review**.

2 From the **Data Review** window, choose the **Filter** button.



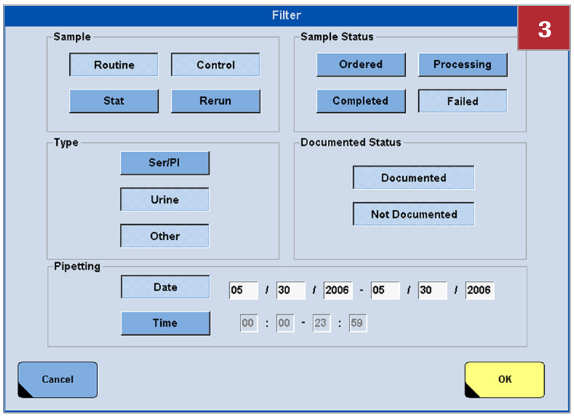

3 From the **Sample** group box, choose the samples to include.

4 From the **Sample Status** group box, choose the sample statuses to include.

5 From the **Type** group box, choose the sample types to include.

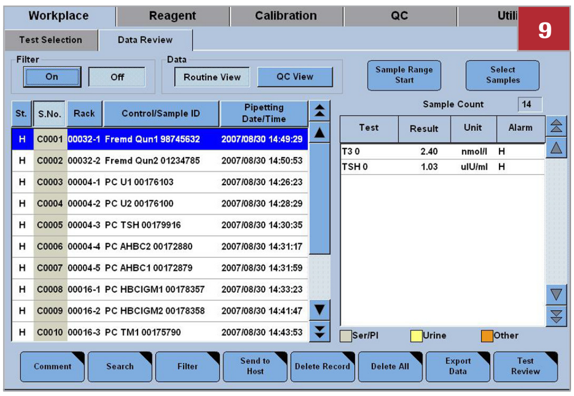
6 From the **Documented Status** group box, choose the type of results to include.

7 From the **Pipetting** group box, choose the date or time range for samples to include.




8 Choose the **OK** button.

→ The **Data Review** window is displayed.




9 From the **Filter** group box, choose the **On** button.

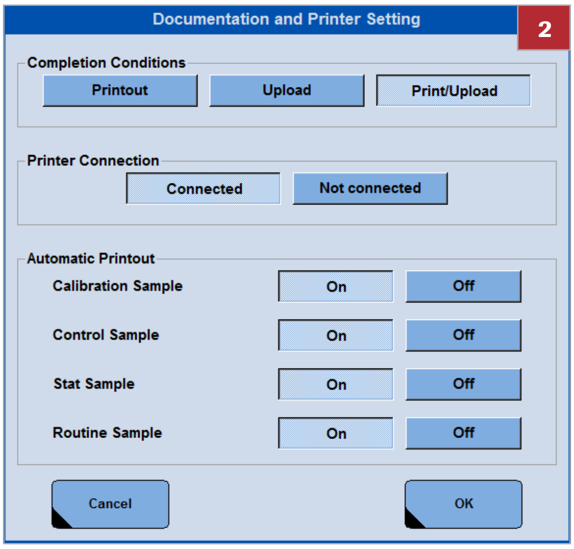
→ The software filters the results.

### Related topics


- View patient results (191)
- Printing a result report (194)

# Configure print and upload settings

When tests are complete, you can print or upload patient results automatically.




### To configure print and upload settings

1 From the **System Overview** window, choose **Utility > System > Page 2/3 > Documentation Setup**.

2 From the **Completion Conditions** group box, choose to send reports to the printer or to the host.

   ❶ If you choose the **Upload** button or the **Print/Upload** button when the host communication is off on the **Start Conditions** window, then a system alarm occurs.

3 From the **Printer Connection** group box, choose the status of the printer.

4 From the **Automatic Printout** group box, choose the sample results to automatically print.

5 Choose the **OK** button.

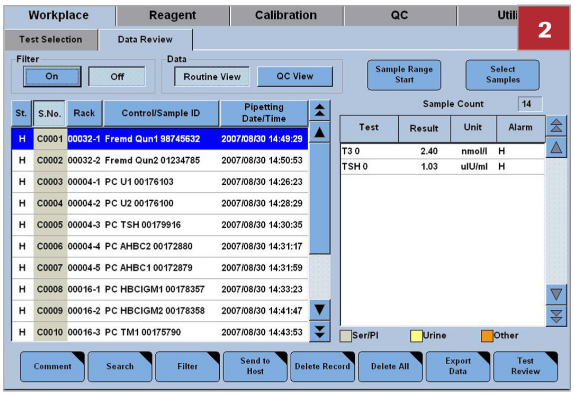
# Printing a result report

When tests are complete, you can print results.

☐ Patient results

## To print a result report

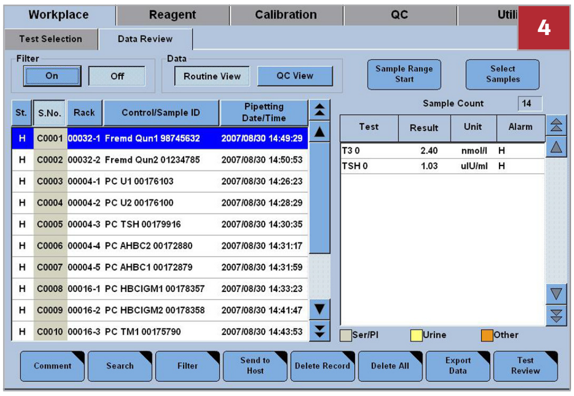
1 From the **System Overview** window, choose **Workplace > Data Review**.




2 From the **S.No.** column, choose a sample.

3 From the **Data Review** window, choose the sample results to print.

- To print results for multiple non-consecutive samples, go to step **4**.
- To print results for a range of samples, go to step **7**.
- To print results for the selected sample only, go to step **10**.

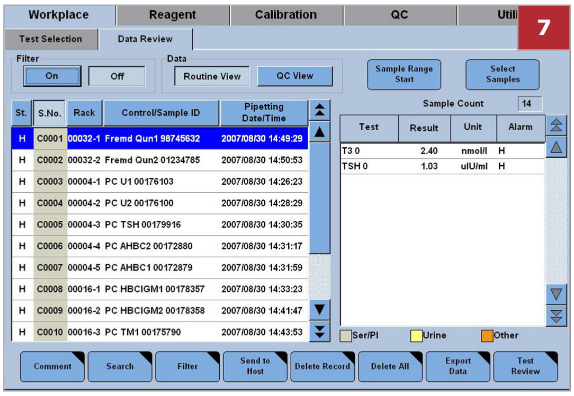



4 Choose the **Select Samples** button.

→ The **Select Samples** button changes color to white.

5 From the **S.No.** column, choose the next sample.

6 To choose more samples, repeat steps **4** and **5**. Then go to step **10**.




7 Choose the **Sample Range Start** button.

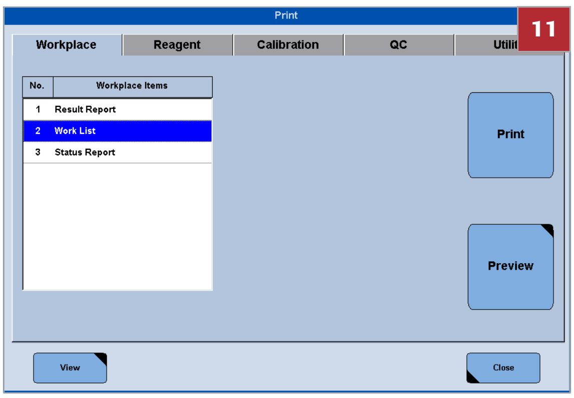
→ The button text changes to **Sample Range End**.

8 From the **S.No.** column, choose the sample at the end of the range.

9 Choose the **Sample Range End** button.

→ The samples between the start and end of the range are selected.

10 Choose **Print > Workplace**.




11 From the **Workplace Items** column, choose the **Result Report** option.

12 From the **Print Format** group box, choose to view on the monitor or print the report.

13 Choose the **Print** button.

→ The result report prints or displays on the monitor.

**Related topics**

- View patient results (191)
- Filter patient results (192)

# Exporting results

When tests are complete, you can export a copy of the results for further analysis.

The analyzer can only export the results to a DVD-RAM or USB flash drive. The results are saved as a .CSV file. Use a suitable program on a separate PC to open the file and view the results.

About exported results (198)

**⚠ CAUTION**

**Incorrect use of USB flash drives**

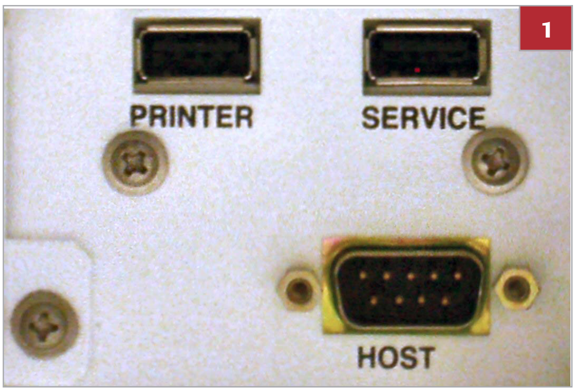
Incorrect use of USB flash drives may result in data loss or analyzer malfunction.

- Only insert or remove a USB flash drive when in Standby mode.
- Use only one USB flash drive at a time.
- Before removing a USB flash drive, choose the **Remove USB** button.
- To prevent a virus from infecting the software, only use the USB flash drive for the analyzer. Do not store any other data on the device.

☐ Patient results

☐ USB flash drive, or DVD-RAM drive with a disk

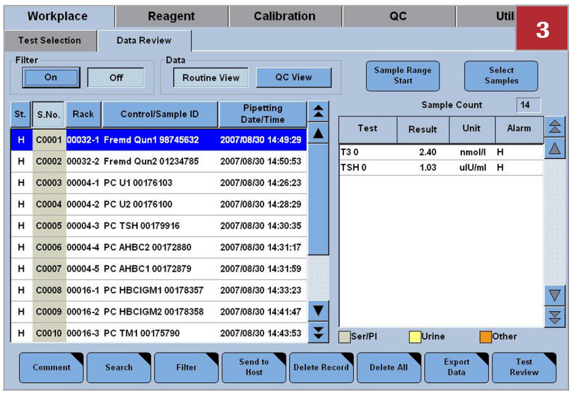
## To export results




1 Connect the DVD-RAM disk drive with disk or USB flash drive to the Service port at the left side of the analyzer.

   If you try to export results to a DVD-RAM or USB flash drive that is not ready, or is the incorrect format, then the software displays an error message.

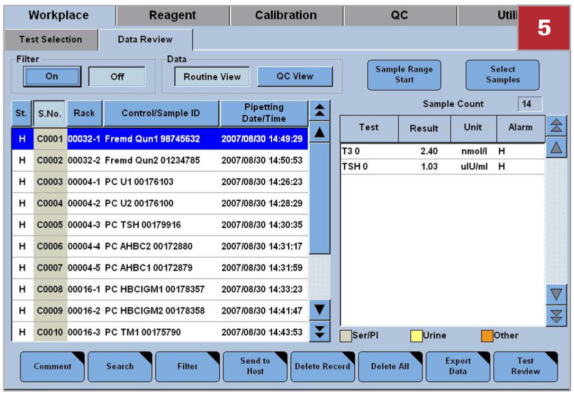
2 From the **System Overview** window, choose **Workplace > Data Review**.




**3** From the **Data** group box, choose the **Routine View** button.

**4** From the **Data Review** window, choose the sample results to export.

- From the **S.No.** column, choose the first sample you need results for.
- To export results for multiple non-consecutive samples, go to step **5**.
- To export results for a range of samples, go to step **8**.
- To export results for the selected sample only, go to step **11**.

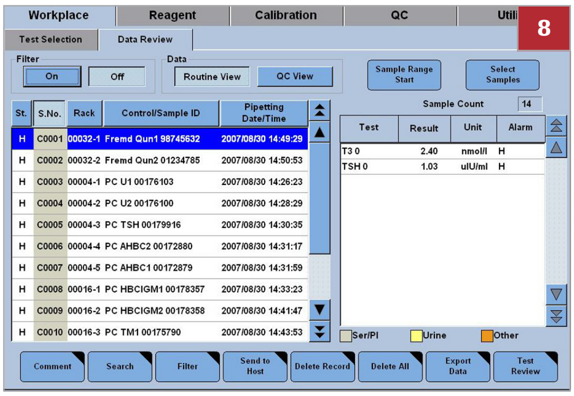



**5** Choose the **Select Samples** button.

→ The **Select Samples** button changes color to white.

**6** From the **S.No.** column, choose the next sample you need results for.

**7** To choose more samples, repeat steps **5** and **6**. Then go to step **11**.



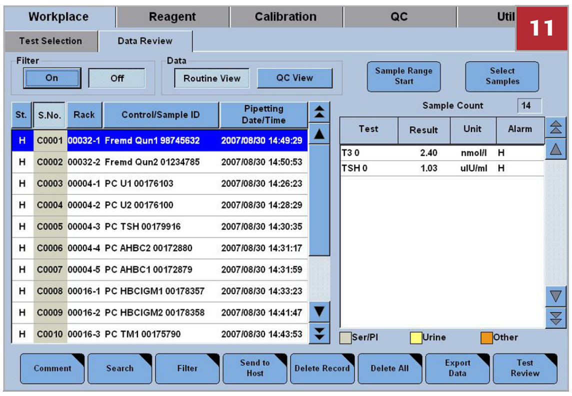

**8** Choose the **Sample Range Start** button.

→ The button text changes to **Sample Range End**.

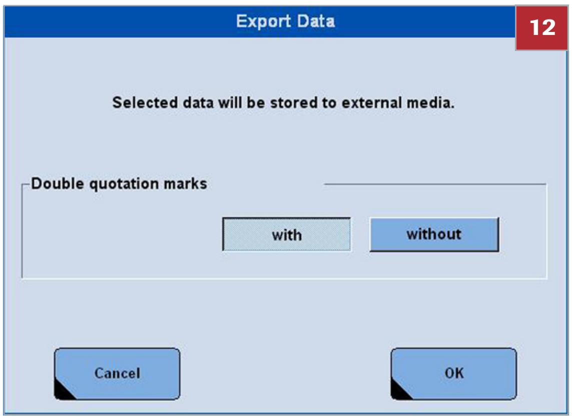
**9** From the **S.No.** column, choose the sample at the end of the range.

**10** Choose the **Sample Range End** button.

→ The samples between the start and end of the range are selected.



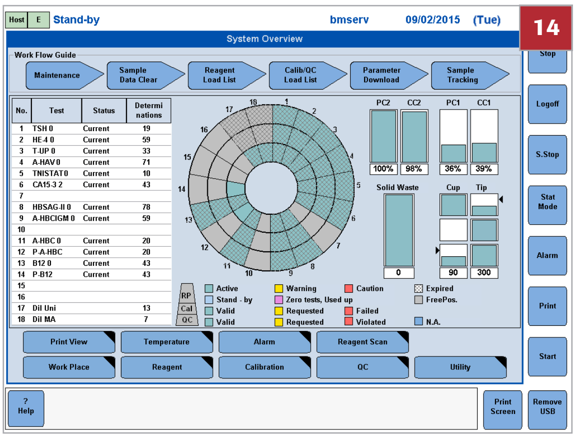

**11** Choose the **Export Data** button.




**12** From the **Double quotation marks** group box, choose whether you want data elements to be separated by double quotation marks.

**13** Choose the **OK** button.

➔ The test results are saved to the external drive in the file "E:\e411_CSV\backup-YYYY-MM-DD-hh-mm.csv", where E is the drive letter. Under certain circumstances, the drive letter can be F or G.




**14** To remove a USB flash drive, when the export is complete, perform the steps below.

- Choose the **Remove USB** button from the global buttons.
- Disconnect the USB flash drive from the Service port.

### Related topics


- About exported results (198)
- View patient results (191)
- Printing a result report (194)


# About exported results

The system saves exported results as comma-separated value (CSV) files, which can be viewed in spreadsheet software.

```
3,1,1,1,0,3,"PC CARD1    00176714  ",2015/04/30 11:37:08,,,,,,,,,,1,"",0,,,,,,,,,,,,,    5.61,"ng/ml
",," ",,"E1-1",,,,,,,,,,,,,,,,,,,
```

Example of an exported result

When opening a CSV file in spreadsheet software, use the comma delimiter to split columns and view the exported results as a table.

| Column header | Content | Detail | Field type |
|---|---|---|---|
| R_Type1 | Sampling mode | 1: Routine<br>2: Stat<br>3: Control | Number |
| R_Type2 | First/rerun | 1: First<br>2: Rerun | Number |
| S_Type | Sample type | 1: Ser/Pl<br>2: Urine<br>5: Other | Number |

List of exported result columns

*n/a: Column not used for the **cobas e** 411 analyzer.

| Column header | Content | Detail | Field type |
| --- | --- | --- | --- |
| S_No. | Sequence | 1-9999 | Number |
| R_No. | Rack number/Disk number | 1-9999 (rack system)<br>0-9 (disk system) | Number |
| Pos. | Position number | 1-5 (rack system)<br>1-30 (disk system) | Number |
| S_ID | Sample ID | Sample name (alphanumeric) | Character string |
| A_Date | Pipetting time | Format: *YYYY/MM/DD HH:MM:SS*, where:<br>YYYY: year; MM: month; DD: day; hh: hour (00-23); mm: minute (00-59); ss: second (00-59) | Date/Time |
| Age | Age | Not applicable* | Number |
| A_Unit | Unit for age | Not applicable* | Number |
| Sex | Sex | Not applicable* | Number |
| S_Date | Blood collecting date | Not applicable* | Date/Time |
| C1 | Comment 1 | Not applicable* | Character string |
| C2 | Comment 2 | Not applicable* | Character string |
| C3 | Comment 3 | Not applicable* | Character string |
| C4 | Comment 4 | Not applicable* | Character string |
| C5 | Comment 5 | Not applicable* | Character string |
| Cup | Type of sample cup | 1: Standard<br>2: Reduced | Number |
| Ope_ID | Operator ID | Operator ID during measurement | Character string |
| Pre_Dil | Predilution | 0: Not prediluted<br>1: Manual | Number |
| Value | Result value | Test result | Number |
| V_Unit | Unit | e.g. *COI*, *pmol/l* | Character string |
| D_Alm | Data alarm | e.g. *L*, *<Test* | Character string |
| R_Msg | Result message | e.g. *r*=reac.; *n*=non-reac | Character string |
| Dil | Dilution ratio | 0: Not diluted<br>1: Diluted 1:2<br>2: Diluted 1:5<br>3: Diluted 1:10<br>5: Diluted 1:20<br>7: Diluted 1:50<br>9: Diluted 1:100<br>12: Diluted 1:400 manually and barcode requested dilutions | Number |
| Module | Module code | Always *E1-1* for **cobas e** 411 analyzer | Character string |

List of exported result columns

*n/a: Column not used for the **cobas e** 411 analyzer.

### Related topics

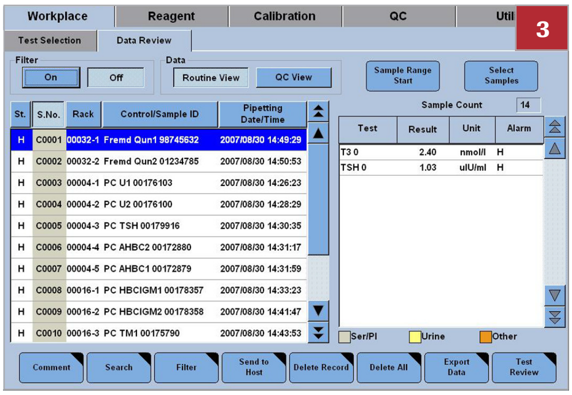
- Exporting results (196)

# Deleting a record

When you delete a record, the system deletes the sample ID or control, together with all associated records, tests, and results.

## To delete a record

1 From the **System Overview** window, choose **Workplace > Data Review**.

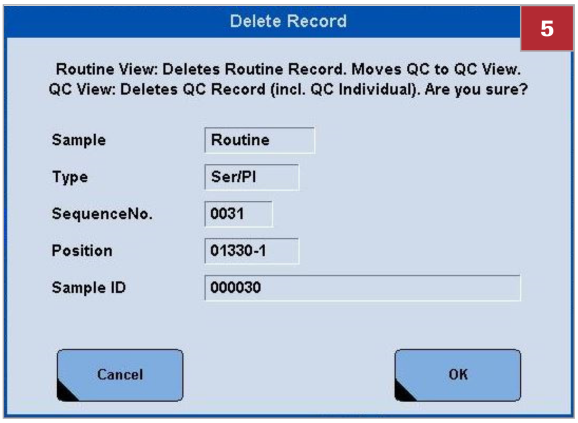



2 From the **Data** group box, choose the type of records to view.

- To view patient samples, choose the **Routine View** button.
- To view controls, choose the **QC View** button.

3 Select a sample ID or control to delete.

4 Choose the **Delete Record** button.




5 From the **Delete Record** dialog box, choose the **OK** button.

**Related topics**

- View patient results (191)
- Deleting documented patient results (200)
- Exporting results (196)

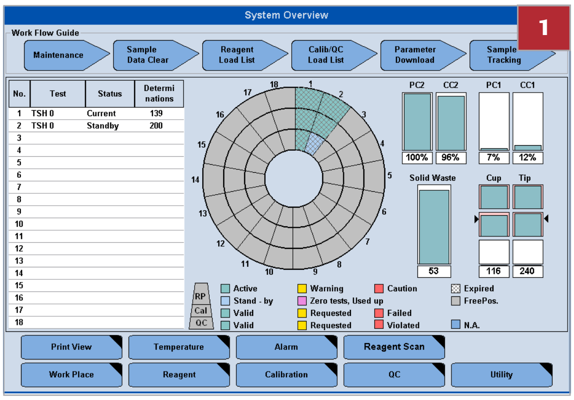
# Deleting documented patient results

When results are printed or uploaded, the **cobas e** 411 analyzer marks them as documented. To create space on the database, delete documented patient samples.

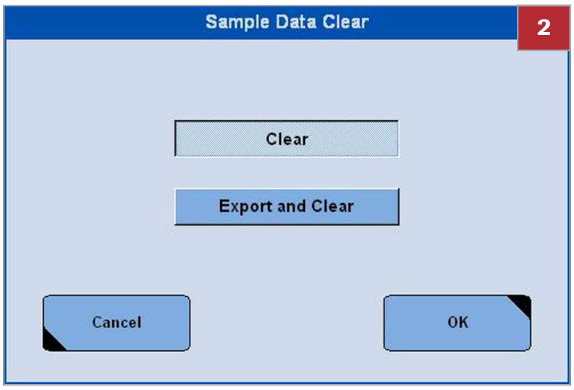
When you delete documented results, filter settings have no effect.

☐ Documented patient results

### To delete documented patient results




1 From the **System Overview** window, choose the **Sample Data Clear** button.




2 From the **Sample Data Clear** dialog box, choose the **Clear** button.

3 Choose the **OK** button.

➔ The system deletes sample results and moves control results to the **Data Review > QC View** window.

**Related topics**

- Deleting QC results (201)

## Deleting QC results

To create space on the database, delete documented QC samples.

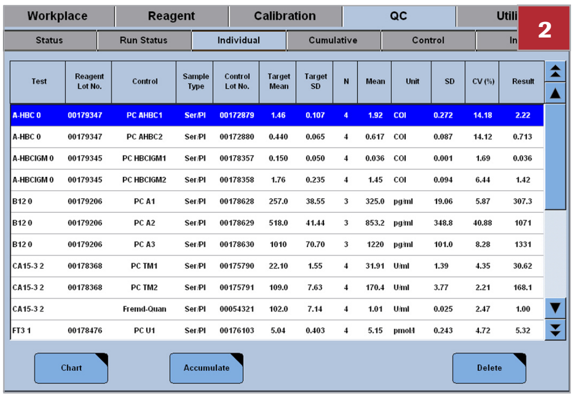
☐ Documented QC results

### To delete all QC results

1 From the **System Overview** window, choose **Workplace > Data Review > QC View**.

2 From the **QC View** dialog box, choose the **Delete All** button.

➔ The system deletes all QC results from the **QC View** window and the **QC > Individual** window. Only accumulated QC results remain.




## To delete individual QC results

1 From the **System Overview** window, choose **QC > Individual**.

2 From the **Control** table, choose the QC result to delete.

3 Choose the **Delete** button.

→ The system deletes the selected results from the **QC > Individual** window, **Workplace > Data Review > Routine View** window, and **Workplace > Data Review > QC View** window. Only accumulated QC results remain.

**Related topics**

- Deleting documented patient results (200)

# After operation

In this chapter 10

# Daily maintenance actions

At the end of each day, or at the end of routine operation, complete all outstanding maintenance actions.

Some of the maintenance actions in the maintenance schedule may not apply to your system.

**Scheduled maintenance**

Check the maintenance schedule and complete any outstanding actions.

**Daily maintenance**

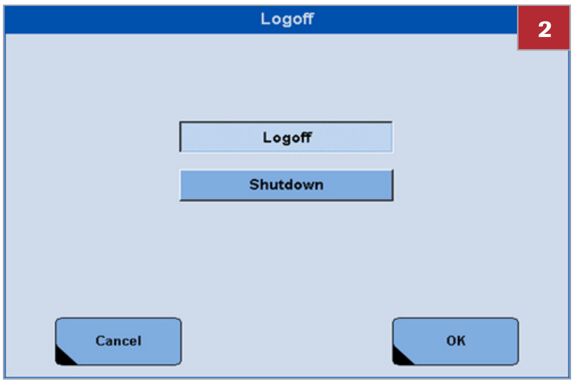
Complete the actions below every day.

Cleaning the sample and reagent probe (221)
Checking the analyzer compartments for condensation (223)

**Related topics**

- Maintenance schedule (219)
- Periodic maintenance actions (219)

# Logging off from the software




When you finish your shift, or when you want to change operators, log off from the software.

## To log off from the software

1 Choose the global **Logoff** button.

2 From the **Logoff** dialog box, choose the **Logoff** button.

3 Choose the **OK** button.

**Related topics**

- Putting the system in Sleep mode (207)
- Shutting down the system (208)
- Logging on to the software (98)

# Sleep mode and Shutdown

When routine operation is complete, and all outstanding maintenance actions have been performed, you can either put the system in Sleep mode or shut it down.

**Sleep mode**

In Sleep mode, power consumption is reduced. Power is still supplied to the reagent rotor and system reagent compartments to keep them cool.

**Shutdown**

When the analyzer is shut down, no power is supplied to it. The reagent rotor and system reagent compartments are not kept cool, and reagent packs must be refrigerated.

Under normal circumstances, you do not need to shut down the system.

**In this section**



## Putting the system in Sleep mode

Put the system in Sleep mode to reduce power consumption.

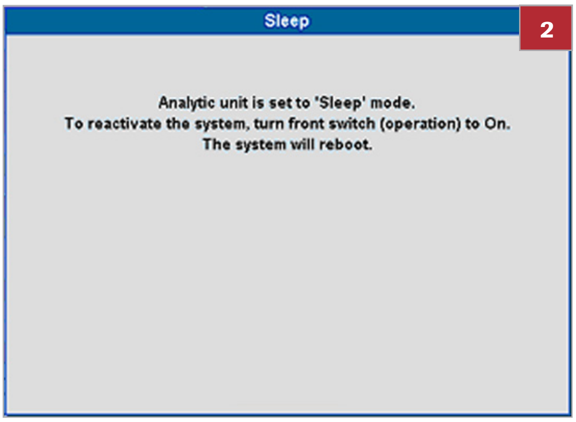
Every day, or after routine operation is complete

5 minutes

☐ Daily maintenance is complete


### To put the system in Sleep mode

1 Switch the switch to OFF.
  ➔ The system goes into Sleep mode, and the **Sleep** dialog box is displayed.




2 Wait for a few minutes until the touchscreen monitor screen goes blank.
  ➔ The system enters Sleep mode.

**Related topics**


- Preventing evaporation of the system reagents (210)
- Starting the system (97)


# Shutting down the system

When routine operation is complete, and all outstanding maintenance actions have been performed, shut down the system.

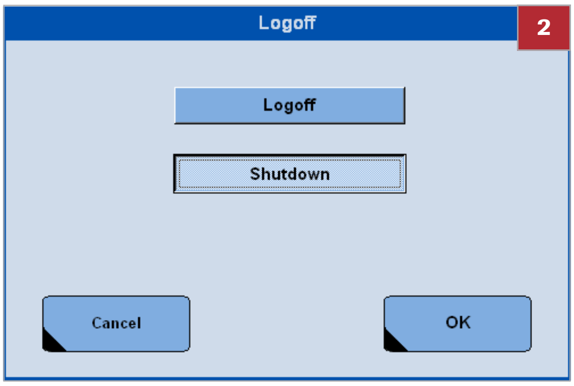
Every day, or after routine operation is complete

5 minutes

☐ Daily maintenance is complete

### To shut down the system

1 Choose the global **Logoff** button.




2 From the **Logoff** dialog box, choose the **Shutdown** button.

3 Choose the **OK** button.


4 Switch off the circuit breaker on the right side of the analyzer.


5 Switch off the circuit breaker on the rack feeder.

**Related topics**

- Preventing evaporation of the system reagents (210)
- Starting the system (97)

# Preventing evaporation of the system reagents

To prevent evaporation, close the lids of the ProCell and CleanCell bottles.

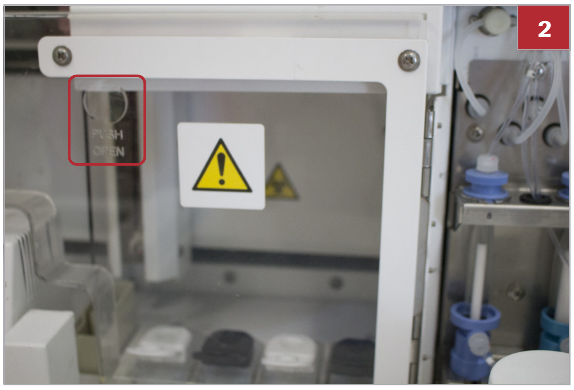
Every day, or after routine operation is complete

2 minutes

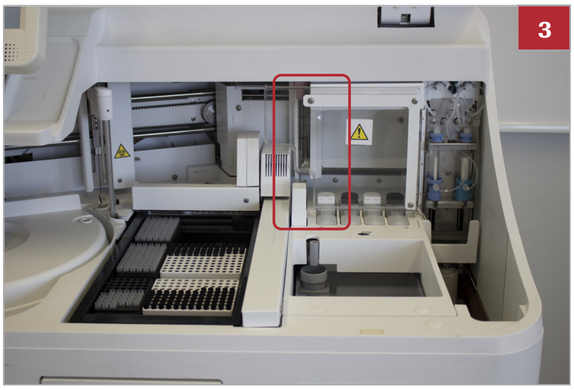
- ☐ Daily maintenance is complete
- ☐ The analyzer is in Sleep mode or shutdown

### ▶ To close the lids of the ProCell and CleanCell bottles

1 Lift the top cover of the analyzer.




2 To open the sipper shield, push the PUSH OPEN label.




**3** Move the sipper arm to the left as far as possible.


**4** Close the lids of all four ProCell and CleanCell bottles.

**5** Close the sipper shield. Push the PUSH OPEN label until you hear a click.

**6** Close the top cover of the analyzer.

**Related topics**

- Overview of reagents (105)
- Replacing system reagents (110)

# Maintenance

## In this chapter

11

# Overview of maintenance actions

Maintenance actions are divided into software-controlled maintenance and operator-controlled maintenance. Measure control samples after each maintenance action to ensure that the analyzer operates properly. Inaccurate results may cause a wrong diagnosis.

**Software-controlled maintenance**

Maintenance actions that the analyzer performs without operator interaction.

**Operator-controlled maintenance**

Maintenance actions that require operator interaction, for example, cleaning the sample and reagent probe.

**Related topics**


- Overview of software-controlled maintenance actions (217)
- Periodic maintenance actions (219)

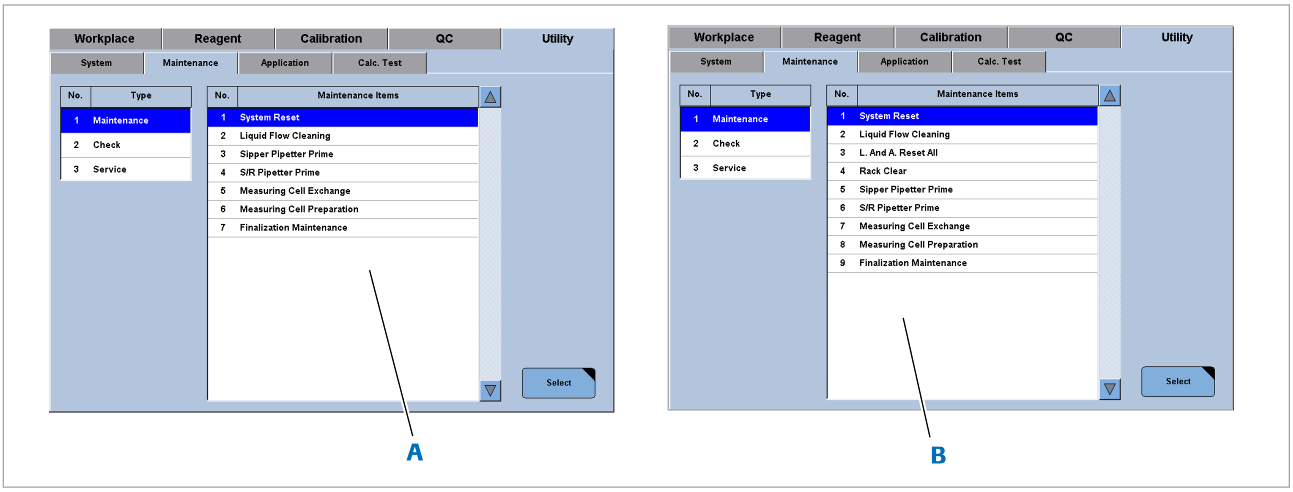
# List of cleaning solutions

When cleaning or decontaminating the system, Roche recommends that you use the substances below.

- Alcohol (e.g. 70% solution of isopropyl alcohol, or ethanol)
- 2% EcoTergent solution
- Laboratory disinfectant
- SysClean
- SysWash
- Deionized water
- Tap water

# Overview of software-controlled maintenance actions

The rack and disk systems have a list of maintenance actions set up on the **Utility > Maintenance** window. When a software-controlled maintenance action needs to be performed as part of an operator-controlled maintenance action, it is described in the task.




**A** Disk System maintenance actions

**B** Rack System maintenance actions

**System Reset**

The System Reset action returns all mechanical parts to their home or standby positions. The System Reset action does not reset any of the line mechanisms on a rack system.

**Liquid Flow Cleaning**

The Liquid Flow Cleaning action uses SysClean to wash the sipper flow paths and the measuring cell.

**L. And A. Reset All (rack system only)**

The L. And A. Reset All action starts the System Reset action, and resets the A- B-, and C- lines to their home positions.

**Rack Clear (rack system only)**

The Rack Clear action moves any racks which are on the B-Line to the C-Line.

**Sipper Pipetter Prime**

The Sipper Pipetter Prime action primes the sipper flow paths with system water. The water purges the paths of air for a specified number of cycles.

**S/R Pipetter Prime**

The S/R Pipetter Prime action purges the sipper flow paths of air for a specified number of cycles.

**Measuring Cell Exchange**

The Measuring Cell Exchange action purges the tubing.

**Measuring Cell Preparation**

The Measuring Cell Preparation action conditions the measuring cell for the specified number of cycles.

**Finalization Maintenance**

The Finalization Maintenance action primes the system with water, and fills the measuring cell with ProCell. The analyzer can stand unused for several hours, or overnight, when primed with water.

**Related topics**


- Performing software-controlled maintenance actions (221)
- Overview of maintenance actions (215)
- Periodic maintenance actions (219)

# Periodic maintenance actions

These maintenance recommendations are based on using the system 8 hours per day, 5 days per week. You can adjust your maintenance frequency based on your laboratories actual use.

Perform maintenance actions according to the maintenance schedule. Each maintenance action indicates which parts are required, including any spare parts. The task highlights any precautions you must take and indicates how long the task takes to complete.

It is important that you keep to the recommended schedule for all maintenance actions. A list of where you can find detailed descriptions of the maintenance actions is given below.

**In this section**



# Maintenance schedule

Perform maintenance actions according to the maintenance schedule.

Some of the maintenance actions in the maintenance schedule may not apply to your system.

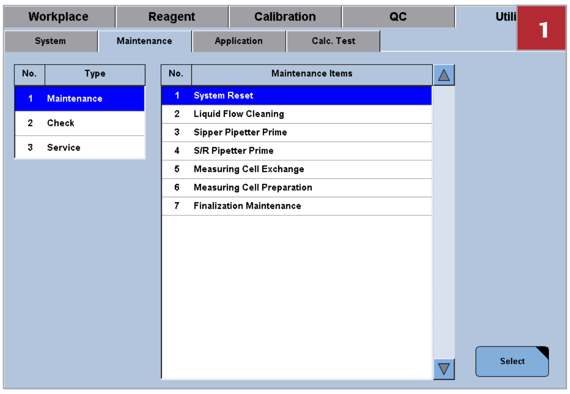
| Frequency | Operator time (min) | System time (min) | Maintenance action |
|---|---|---|---|
| Every day | 1 | 0 | Cleaning the sample and reagent probe (221) |
| | 5 | 0 | Checking the analyzer compartments for condensation (223) |
| Every week | 1 | 0 | Cleaning the sipper probe (227) |
| | 5 | 0 | Cleaning the incubator and aspiration station (229) |
| | 5 | 0 | Cleaning the input buffer and output buffer (231) |
| Every two weeks | 4 | 4 | Cleaning the sipper probe system - Liquid Flow Cleaning (234) |
| | 7 | 17 | Cleaning the rinse stations (238) |
| Every month | 5 | 15 | If the system is run in sample reception mode(1):<br>Replacing the pinch valve tubing (241) |
| Every two months | 5 | 15 | If the system is *not* run in sample reception mode(1):<br>Replacing the pinch valve tubing (241) |
| As-needed | 15 | 0 | Cleaning a 13 mm sdta (249) |
| | 10 | 0 | Cleaning and inspecting the valve of the system water container (250) |
| | 5 | 0 | Cleaning the liquid waste container (253) |
| | 2 | 0 | Cleaning the microbead mixer (255) |
| | 5 | 0 | Cleaning the ProCell and CleanCell compartments (257) |
| | 15 | 0 | Cleaning the reagent rotor and compartment (259) |
| | 5 | 0 | Cleaning the analyzer surfaces (263) |
| | 2 | 0 | Emptying the solid waste tray (264) |
| | 0.5 | 3.5 | Preparing the analyzer for an idle period (272) |
| | Dependant on number to clean | 0 | Cleaning the rack trays (267) |
| | | 0 | Cleaning the sample racks (270) |

Maintenance schedule

(1) If your analyzer is running version 03-02 software or later and your pinch valves have black dots on them, your Roche Service representative will replace the pinch valve tubing during the yearly maintenance visit.

# Performing software-controlled maintenance actions

Software-controlled maintenance actions are automatic items that the analyzer performs. They are used within operator-controlled maintenance actions.




### To perform maintenance actions

1 From the **System Overview** window, choose **Utility > Maintenance**.

2 From the **Type** column, choose the **Maintenance** option.

3 From the **Maintenance Items** column, choose the maintenance action.

4 From the dialog box, define the parameters.

5 Choose the **Start** button.
→ The system performs the maintenance action and then returns to Standby mode.

**Related topics**

- Overview of software-controlled maintenance actions (217)

# Every day

**In this section**



## Cleaning the sample and reagent probe

Dirt can build up on the sample and reagent probe and affect results.

Every day

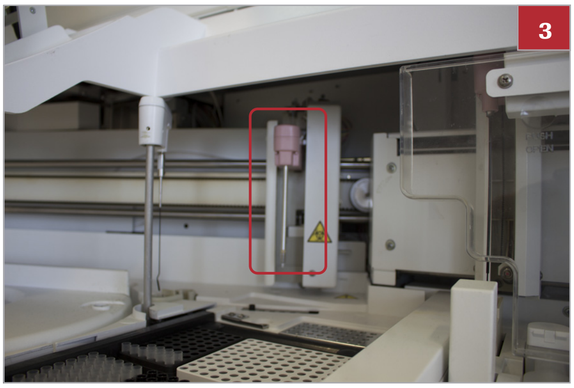
1 minute

- ☐ Lint-free cloth
- ☐ 70% solution of isopropyl alcohol, or ethanol
- ☐ Deionized water

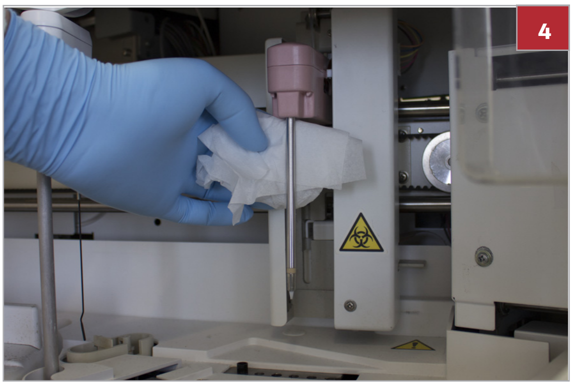
### To clean the sample and reagent probe


1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.




3 Gently move the sample and reagent probe into an accessible position.



**4** NOTICE Risk of bending the sample and reagent probe. Wipe the sample and reagent probe gently.

Use lint-free cloth moistened with deionized water to wipe the outer surfaces of the sample and reagent probe.

**5** If you see dirt on the sample and reagent probe, then wipe the outer surfaces of the probe.

- Use lint-free cloth moistened with alcohol
- Then use lint-free cloth moistened with deionized water

ℹ Wipe downwards towards the tip of the probe.

**6** Remove any waste materials from the analyzer.

**7** Close the top cover of the analyzer.

**8** Switch the switch to ON.

→ The system restarts and the mechanical parts return to their standby position.

## Checking the analyzer compartments for condensation

Condensation inside the reagent rotor and system reagent compartments can cause the analyzer to malfunction.

To inspect and dry the reagent compartment, you must perform three maintenance actions.

1. Open the reagent rotor cover and remove the reagent rotor.
2. Inspect and dry the reagent rotor compartment and the system reagent compartments.
3. Return the reagent rotor to its compartment and replace the cover.

For more information, see:

To remove the reagent rotor from its compartment ▶ (224)
To check the compartments for condensation ▶ (225)
To return the reagent rotor to its compartment ▶ (226)

Every day

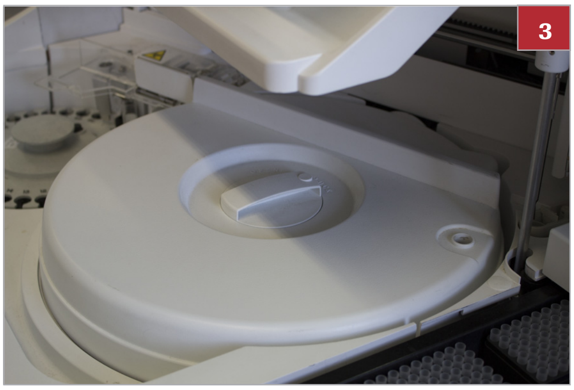
5 minutes

☐ Lint-free cloth

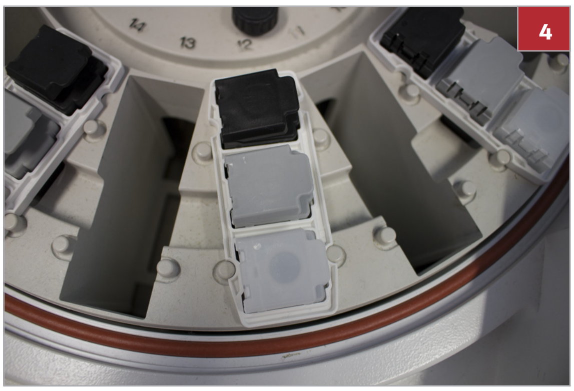
## To remove the reagent rotor from its compartment


1 Switch the switch to OFF.

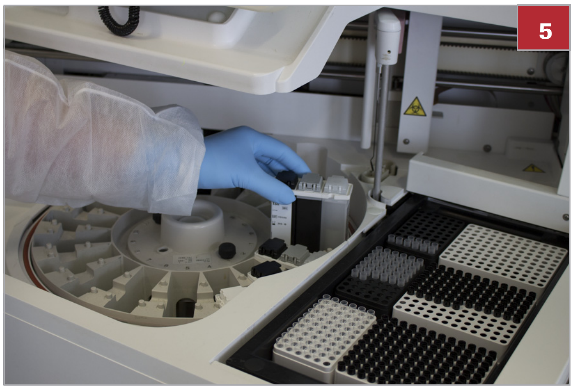

2 Lift the top cover of the analyzer.



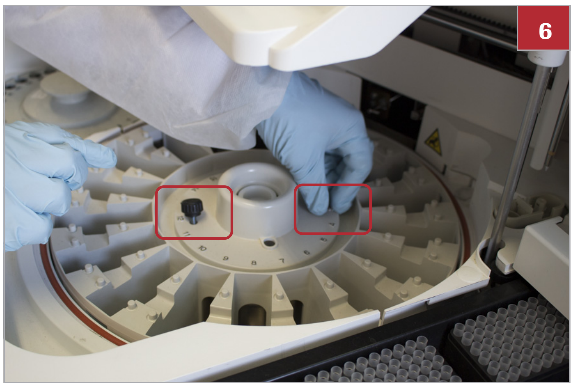

3 To remove the cover of the reagent rotor, rotate the handle of the cover counterclockwise and then lift it.




4 Close the lids of the reagent packs.



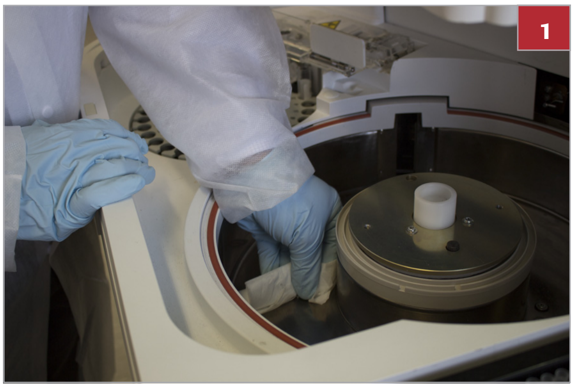

**5** Remove the reagent packs.



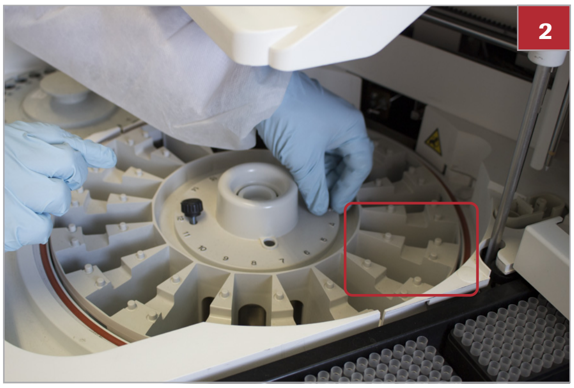

**6** Remove the black thumbscrews from the center of the reagent rotor.

**7** Lift the reagent rotor out of the reagent rotor compartment.

### ▸ To check the compartments for condensation

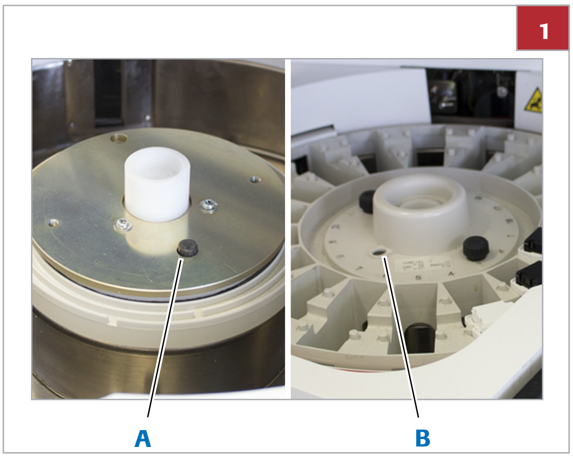



**1** Inspect the compartment of the reagent rotor. If there is any condensation, then use lint-free cloth to dry the compartment.




**2** Inspect the compartments of the system reagent. If there is any condensation, then use lint-free cloth to dry the compartment.

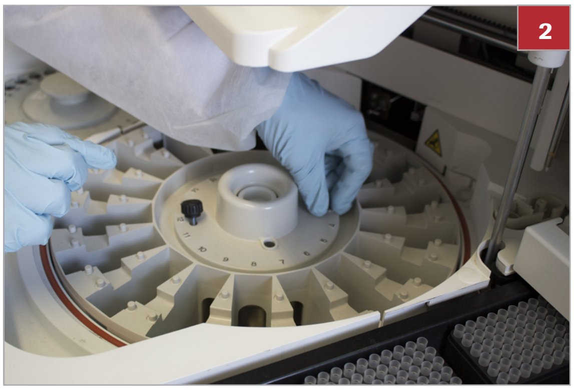
## ▶ To return the reagent rotor to its compartment




**A** Pin on the center plate **B** Hole on the rotor

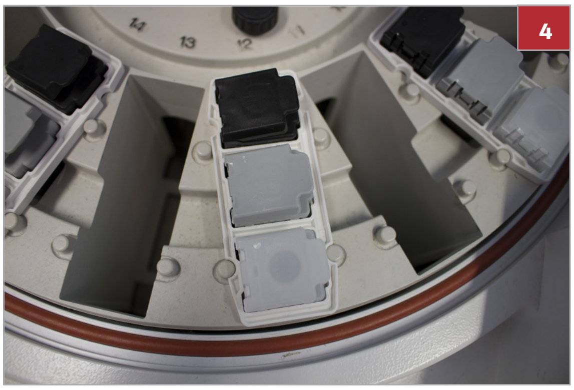
1 NOTICE Risk of damage to mechanical parts. Align the pin on the compartment center plate with the hole on the rotor.

Return the reagent rotor to the reagent rotor compartment.

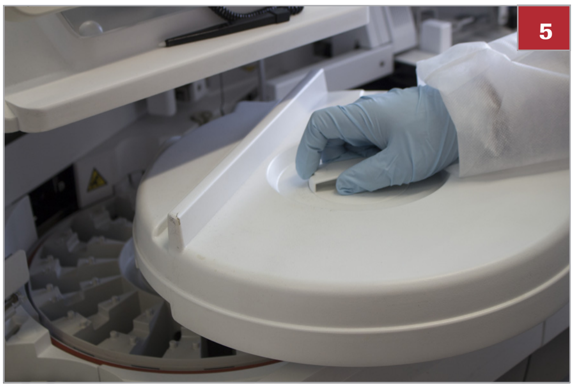



2 Replace and tighten the black thumbscrews.

3 Return the reagent packs to the reagent rotor.




4 Open the caps of the reagent packs.




5 To replace the cover of the reagent rotor, return it to the reagent rotor and rotate the handle of the cover clockwise.

6 Remove any waste materials from the analyzer.

7 Close the top cover of the analyzer.

8 Switch the switch to ON.
→ The system restarts and the mechanical parts return to their standby position.

# Every week

**In this section**



## Cleaning the sipper probe

Dirt can build up on the sipper probe and affect results.

Every week

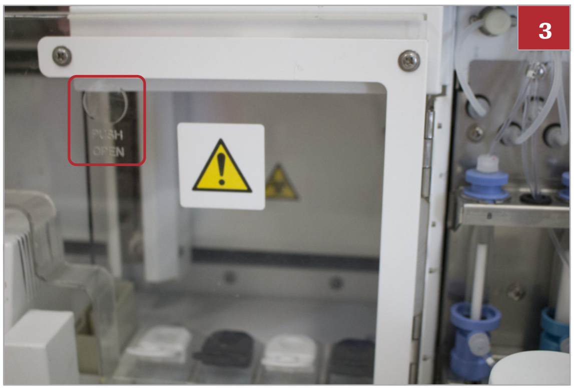
1 minute

- ☐ Lint-free cloth
- ☐ 70% solution of isopropyl alcohol, or ethanol
- ☐ Deionized water

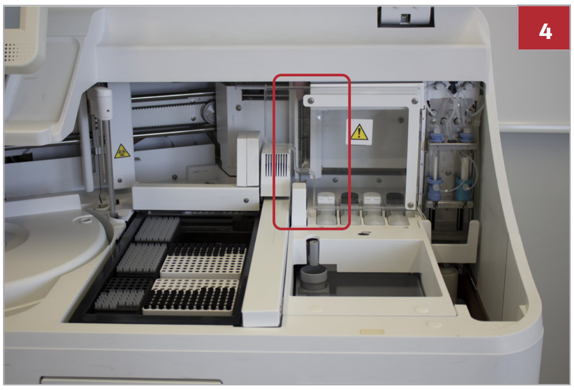
### ▸ To clean the sipper probe


1 Switch the switch to OFF.

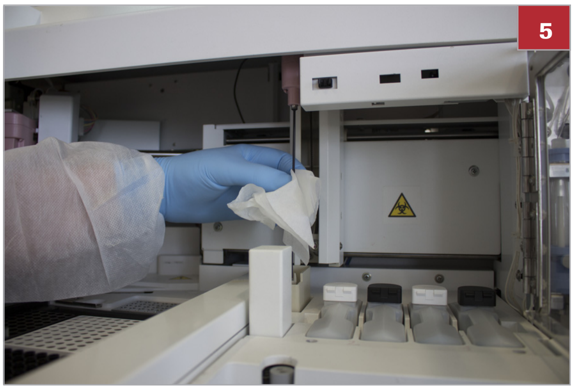

**2** Lift the top cover of the analyzer.




**3** To open the sipper shield, push the PUSH OPEN label.




**4** Gently move the sipper probe into an accessible position.




**5** NOTICE Risk of bending the sipper probe. Wipe the sipper probe carefully.

Wipe the sipper probe.

- Use lint-free cloth moistened with alcohol
- Then use lint-free cloth moistened with deionized water

🛈 Wipe downwards towards the tip of the sipper probe.

**6** Close the sipper shield. Push the PUSH OPEN label, until you hear a click.

**7** Remove any waste materials from the analyzer.

**8** Close the top cover of the analyzer.

**9** Switch the switch to ON.
➔ The system restarts and the mechanical parts return to their standby position.

## Cleaning the incubator and aspiration station

Contamination of the incubator can affect the movement of the gripper.

To clean the incubator and aspiration station, you must perform two maintenance actions.

1. Arrange the mechanical parts to make the incubator and aspiration station accessible.
2. Clean the incubator and aspiration station.

For more information, see:

To prepare the incubator and aspiration station for cleaning ▶ (229)
To clean the incubator and aspiration station ▶ (230)

Every week

5 minutes

- ☐ Lint-free cloth
- ☐ Cotton swabs
- ☐ Deionized water

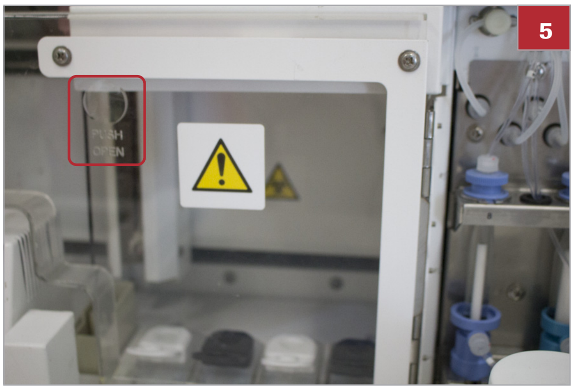
### ▶ To prepare the incubator and aspiration station for cleaning


**1** Switch the switch to OFF.


**2** Lift the top cover of the analyzer.

**3** Move the sample and reagent arm to the far left, over the sampling position.

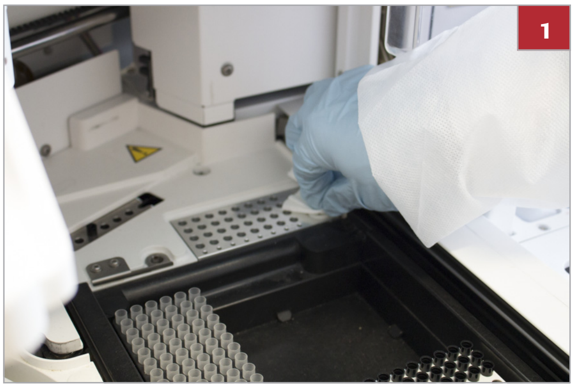
**4** Move the gripper to the front.



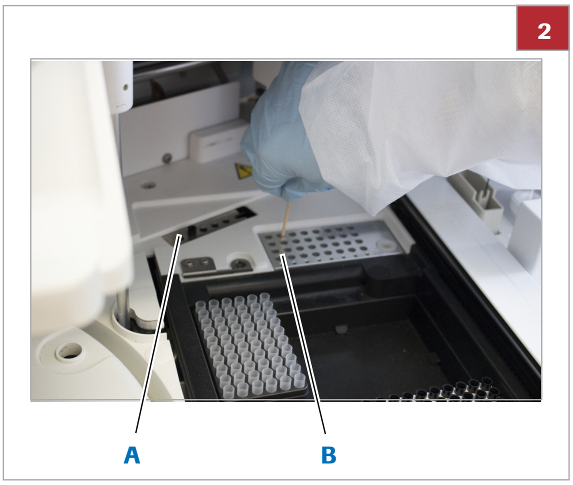

**5** To open the sipper shield, push the PUSH OPEN label.

**6** Move the sipper arm to the far right, over the CleanCell bottle from bottle set 1.

## To clean the incubator and aspiration station




**1** Use lint-free cloth moistened with deionized water to wipe the incubator and aspiration station.




**A** Aspiration station **B** Incubator

2 Use cotton swabs moistened with deionized water to clean each position in the incubator.

3 Use cotton swabs moistened with deionized water to clean the aspiration station.

4 Dry the incubator with a lint-free cloth.

5 Remove any waste materials from the analyzer.

6 Close the top cover of the analyzer.

7 Switch the ▮ switch to ON.
→ The system restarts and the mechanical parts return to their standby position.

## Cleaning the input buffer and output buffer

You must clean the input buffer and output buffer every week.


**A** Rack tray
**B** Rack tray
**C** Output buffer
**D** Input buffer

Overview of the rack sampler

⚠ **WARNING**

**Personal injury and infection due to edges on the input buffer and output buffer**

The edges on the input buffer and output buffer may cause personal injury and infection.

- Avoid contact with all edges, even when wearing lab gloves.
- Wear personal protective equipment such as lab gloves.
- Carefully observe all instructions given in this task.

Every week

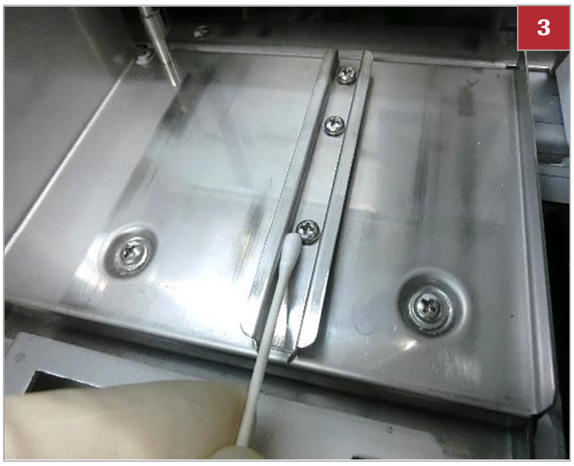
- ☐ Lint-free cloth
- ☐ Cotton swab
- ☐ Alcohol

- ☐ The system is in Standby mode, Sleep mode, or shutdown

## To clean the input buffer and output buffer

1 Use personal protective equipment when cleaning the input buffer and output buffer.

2 Remove the rack trays from the rack sampler.




3 Wipe the rail center on the input buffer in both directions with a cotton swab moistened with alcohol.
- If there is sticking and crystallized dirt on the input buffer, scrape it with a cotton swab.

ℹ Take care not to injure yourself on the rail edges.


**4** Wipe the rail edges on the input buffer in both directions with a cotton swab moistened with alcohol.

- If there is sticking and crystallized dirt on the input buffer, scrape it with a cotton swab.

🛈 Take care not to injure yourself on the rail edges.


**5** Wipe the rail grooves on the input buffer in both directions with a cotton swab moistened with alcohol.

- If there is sticking and crystallized dirt on the input buffer, scrape it with a cotton swab.

🛈 Take care not to injure yourself on the rail edges.


**6** Wipe the surface of the input buffer, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with alcohol.

🛈 Take care not to injure yourself on the rail edges.

**7** Repeat steps **3** to **6** for the output buffer.

🛈 Take care not to injure yourself on the rail edges.

**8** Replace the rack trays to the rack sampler.

# Every two weeks

**In this section**

## Cleaning the sipper probe system - Liquid Flow Cleaning

Contamination in the sipper probe system can degrade sample accuracy and precision or block the measuring cell flow.

To clean the flow path, perform the following steps:

1. Fill the SysClean adapter with SysClean and insert it into the analyzer.
2. Perform the Liquid Flow Cleaning maintenance action.
3. Remove the SysClean adapter and restart the system.

For more information, see:
To insert the SysClean adapter into the system ▶ (234)
To perform the Liquid Flow Cleaning maintenance action ▶ (236)
To remove the SysClean adapter from the system ▶ (237)

Every 2 weeks, or after 2500-3000 tests

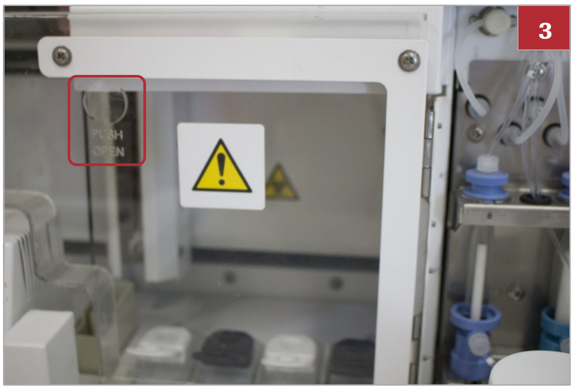
4 minutes

- ☐ SysClean adapter - REF 11933159001
- ☐ SysClean
- ☐ Deionized water

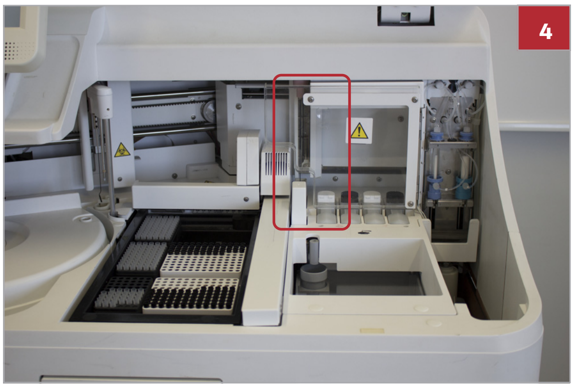
### ▶ To insert the SysClean adapter into the system


**1** Switch the switch to OFF.

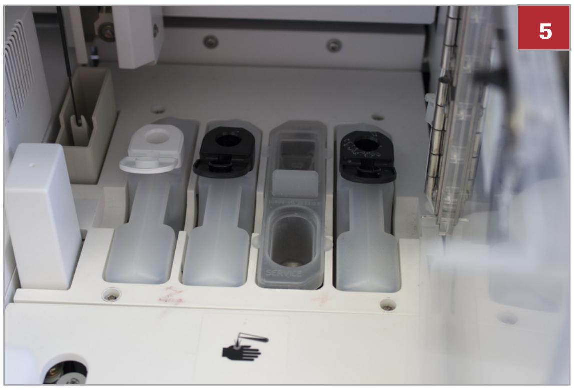

**2** Lift the top cover of the analyzer.



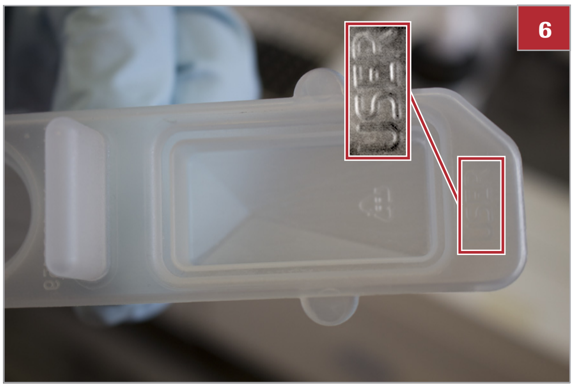

**3** To open the sipper shield, push the PUSH OPEN label.



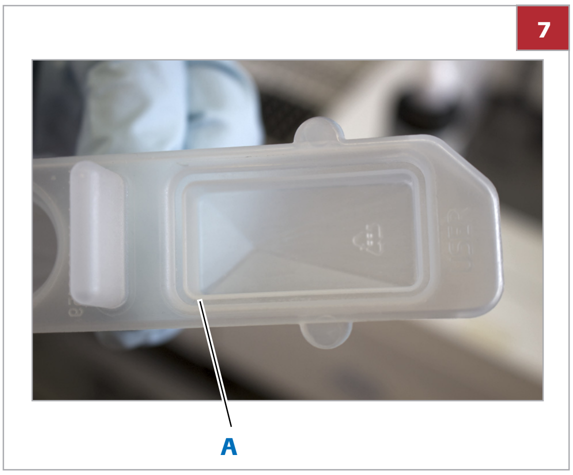

**4** Move the sipper arm to the left as far as possible.




**5** Remove the ProCell bottle from bottle set 1 of the system reagent compartment.




6 Place the adapter, with the USER label facing the back of the analyzer, into the system reagent compartment.




**A** Ledge in the SysClean adapter

7 Pour SysClean into the USER compartment of the SysClean adapter. Fill it up to the ledge.
   - ❶ The compartment holds 9 mL of liquid.

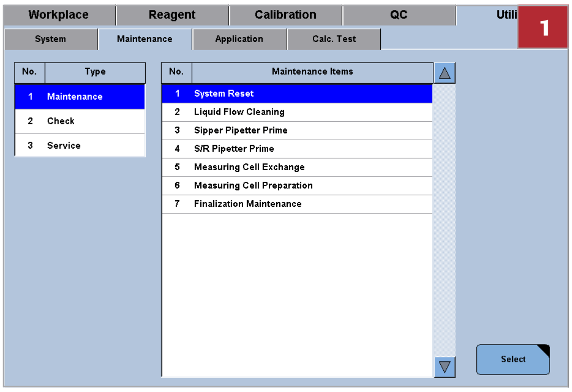
8 Close the sipper shield. Push the PUSH OPEN label, until you hear a click.

9 Remove any waste materials from the analyzer.

10 Close the top cover of the analyzer.

11 Switch the switch to ON.
   - → The system restarts and the mechanical parts return to their standby position.

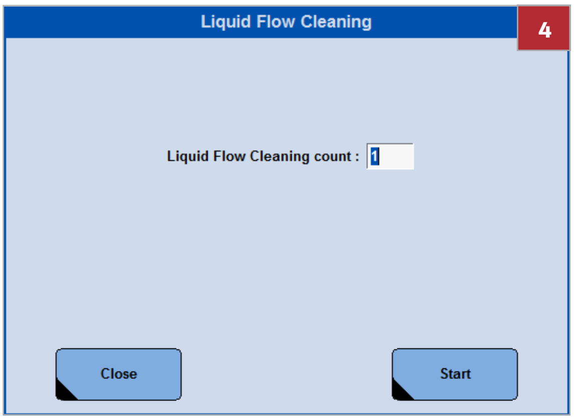
## ▶ To perform the Liquid Flow Cleaning maintenance action




1 From the **System Overview** window, choose **Utility > Maintenance**.

2 From the **Type** column, choose the **Maintenance** option.

3 From the **Maintenance Items** column, choose **Liquid Flow Cleaning > Select**.




**4** In the **Liquid Flow Cleaning count** field, enter "1".

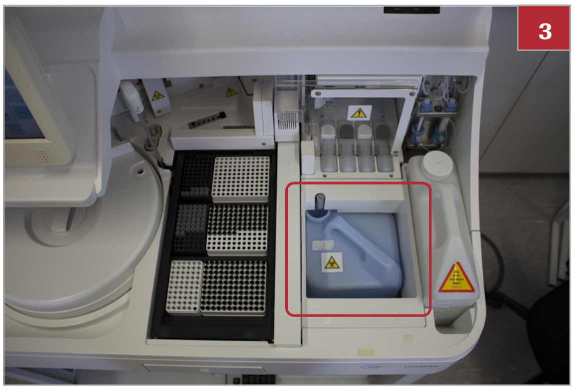
**5** Choose the **Start** button.

→ Once complete, the system returns to standby.

### To remove the SysClean adapter from the system


**1** Switch the  switch to OFF.


**2** Lift the top cover of the analyzer.




**3** Remove the liquid waste container and rinse it with deionized water.

**4** Return the empty liquid waste container to its compartment.


**5** To open the sipper shield, push the PUSH OPEN label.


**6** Remove the SysClean adapter from the ProCell position of bottle set 1.

**7** If the SysClean adapter contains SysClean, then dispose of the SysClean according to your local rules.

**8** Use deionized water to rinse the SysClean adapter.

**9** Return the ProCell bottle to the ProCell position of bottle set 1.

**10** Close the sipper shield. Push the PUSH OPEN label until you hear a click.

**11** Remove any waste materials from the analyzer.

**12** Close the top cover of the analyzer.

**13** Switch the switch to ON.

→ The system restarts and the mechanical parts return to their standby position.

## Cleaning the rinse stations

Contamination of the rinse stations can affect results.

To clean the rinse stations, you must perform the maintenance procedures below.

1. Arrange mechanical parts to make the rinse stations accessible.
2. Clean the rinse stations for the microbead mixer, S/R probe, and sipper probe.

For more information, see:

To prepare the rinse stations for cleaning ▶ (239)
To clean the rinse stations ▶ (240)

Every 2 weeks

7 minutes

- ☐ 2 x syringe with attached tubing
- ☐ Cotton swabs
- ☐ A 70% solution of ethanol or isopropyl alcohol
- ☐ Deionized water

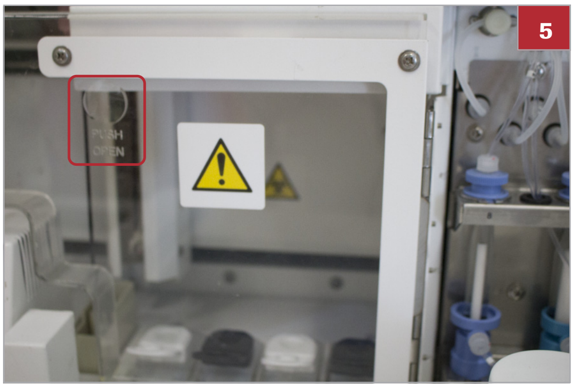
## ▶ To prepare the rinse stations for cleaning


1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.

3 Move the arm of the S/R probe to the far left, over the sampling area.

4 Move the microbead mixer to a safe position.




5 To open the sipper shield, push the PUSH OPEN label.

6 Move the sipper arm to the far right.

### To clean the rinse stations

1 Use a syringe and tubing to remove water from the rinse stations for the microbead mixer and S/R probe.

2 Use a cotton swab to clean the rinse stations. Take care when using the cotton swab as the cotton tip may come loose.
   - Use a cotton swab moistened with alcohol
   - Then use a cotton swab moistened with deionized water

3 Use a syringe filled with deionized water to refill the rinse stations.

4 Use a syringe to remove the water from the rinse stations.

5 Use a syringe filled with deionized water to refill the rinse stations.

6 Use a cotton swab to clean the rinse station for the sipper probe. Take care when using the cotton swab as the cotton tip may come loose.
   - Use a cotton swab moistened with alcohol
   - Then use a cotton swab moistened with deionized water

7 Use a syringe filled with deionized water to rinse the rinse station.

8 Remove any waste materials from the analyzer.

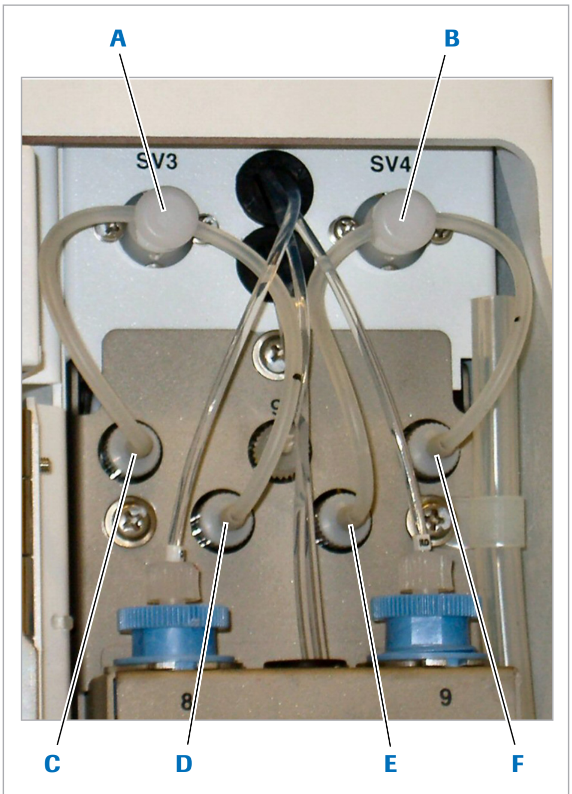
9 Close the top cover of the analyzer.

10 Switch the switch to ON.
   → The system restarts and the mechanical parts return to their standby position.

# Every month

**In this section**

## Replacing the pinch valve tubing




**A** Left-hand pinch valve
**B** Right-hand pinch valve
**C** Left-hand fitting
**D** Left-hand fitting
**E** Right-hand fitting
**F** Right-hand fitting

Damaged pinch valve tubing can cause leaks. Leakage can affect the volume pipetted and cleaning of the measuring cell.

To replace the pinch valve tubing, you must perform the maintenance procedures below.

1. Purge the pinch valve tubing.
2. Remove the pinch valve tubing.
3. If necessary, replace any broken fittings.
4. Fit new pinch valve tubing.
5. Purge air from the sipper pipetter.
6. Purge air from the measuring cell.

For more information, see:

To purge the tubing ▶ (244)

To remove the tubing ▶ (244)

To replace a broken fitting ▶ (246)

To fit new tubing ▶ (247)

To prepare the sipper system ▶ (247)

To prepare the measuring cell ▶ (248)

**⚠ WARNING**

**Infection due to contact with reaction mixture from pinch valve tubing**

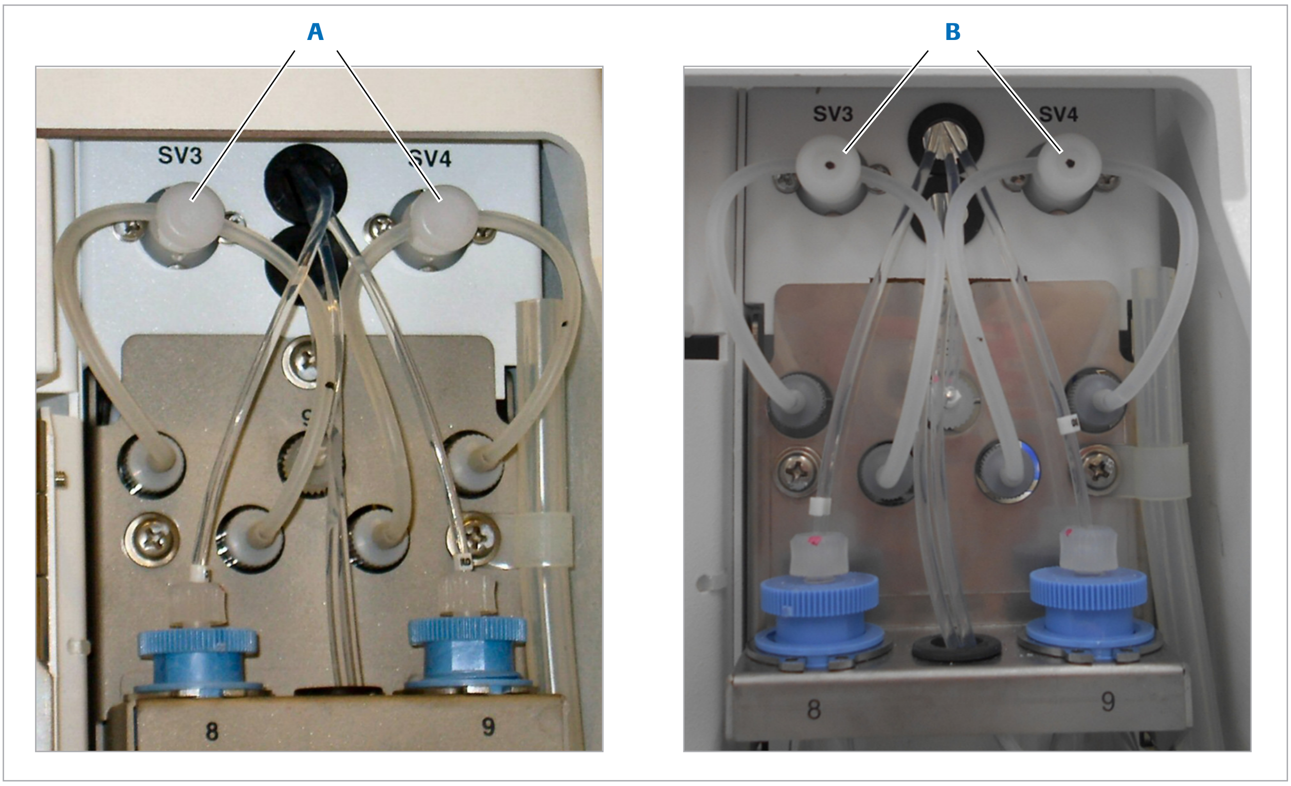
Damaged or incorrectly connected pinch valve tubing can cause reaction mixture to leak out from the tubing or fittings.

- When you replace the pinch valve tubing, ensure that you correctly fit the new tubing.
- Ensure that all pinch valve tubing and connectors are secure.
- Avoid contact with any residual liquid remaining in old pinch valve tubing or fittings. The residual liquid comes from the measuring cell and is potentially biohazardous.

- When replacing the pinch valve tubing, do not crimp the tubing, and take care not to damage the fittings.
- The procedure to replace a broken fitting is optional.

**Types of pinch valves**

The analyzer can have two types of pinch valves installed indicated by whether there are black dots on the pinch valves or not.




**A** Pinch valves without black dots

**B** Pinch valves with black dots

How often you need to replace the pinch valve tubing is determined by the following conditions:

- Type of pinch valve (without black dot / with black dot)
- Analyzer software version (Software version 03-02 or later / Software version 03-01 or earlier)
- Analyzer is run in sample reception mode (yes / no)

| Type of pinch valve | Software version 03-02 or later | | Software version 03-01 or earlier | |
|---|---|---|---|---|
| | SRM[1]=yes | SRM[1]=no | SRM[1]=yes | SRM[1]=no |
|  | 1 month | 2 months | 1 month | 2 months |
|  | 1 year[2] | 1 year[2] | 1 month | 2 months |

Replacing the pinch valve tubing: maintenance intervals

(1) SRM = Sample reception mode

(2) Your Roche Service representative will replace the pinch valve tubing during the yearly maintenance visit.

Software version 03-02 or later:

- If the pinch valves do not have black dots on them: - Every month if the system is run in sample reception mode. - Every two months if the system is not run in sample reception mode.
- If the pinch valves have black dots on them: - Every year regardless of whether the analyzer is run in sample reception mode or not. Your Roche Service representative will replace the pinch valve tubing during the yearly maintenance visit.

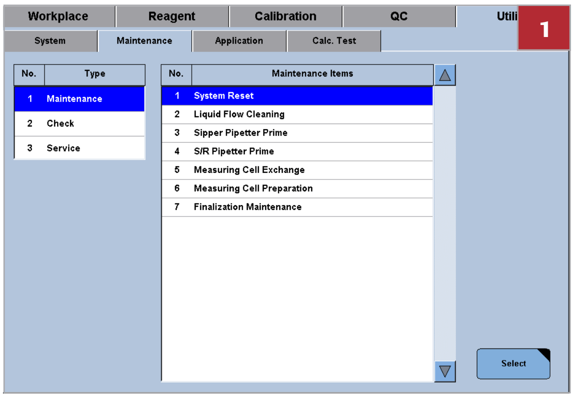
Software version 03-01 or earlier:

- Every month if the system is run in sample reception mode.
- Every two months if the system is not run in sample reception mode.

15 minutes

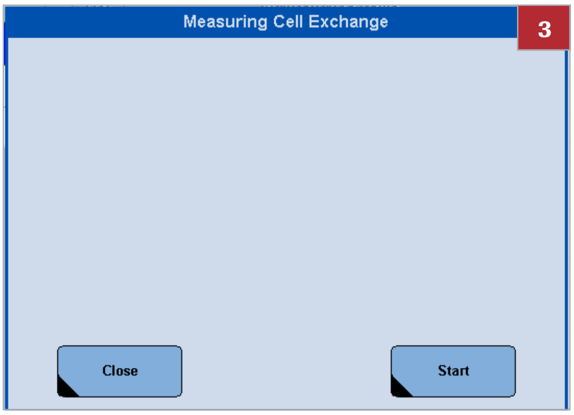
- ☐ Tube joint B
- ☐ 2 x 180 mm lengths of pinch valve tubing
- ☐ Fitting, if necessary
- ☐ Disposable cloth
- ☐ Lint-free cloth

## To purge the tubing




1 From the **System Overview** window, choose **Utility > Maintenance > Maintenance**.

2 From the maintenance actions list, choose **Measuring Cell Exchange > Select**.



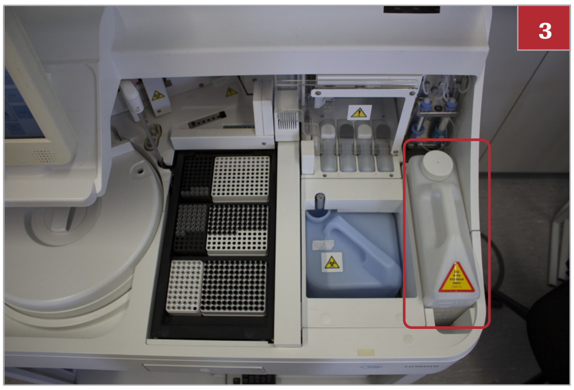

3 From the **Measuring Cell Exchange** dialog box, choose the **Start** button.
→ Liquid is purged from the tubing.

4 Wait until the system is in Standby mode.

## To remove the tubing


1 Switch the  switch to OFF.

2 Lift the top cover of the analyzer.



3 Lift the system water container out of its compartment.

4 Place disposable cloth beneath the pipettes to prevent contamination.


5 Place lint-free cloth under each tube fitting to prevent contamination.

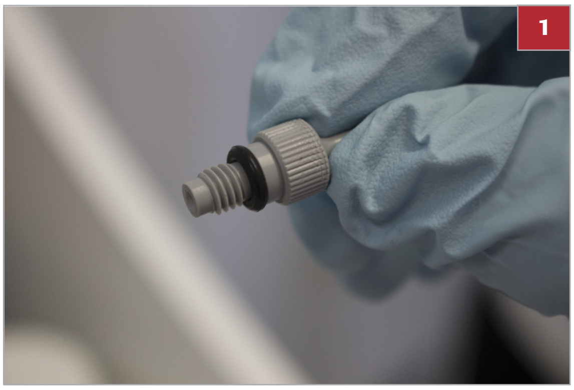
6 Carefully pull the tubing from the two left-hand fittings.


7 Remove the tubing from the pinch valve. Discard the tubing.

8 Repeat steps **6** and **7** for the two right-hand fittings.

9 Inspect the four fittings.
   - If a fitting is broken, then replace the fitting.
   - If there are no broken fittings, then fit the new tubing.

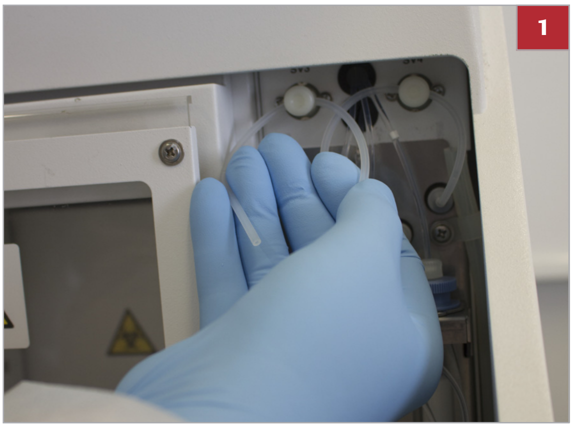
## To replace a broken fitting



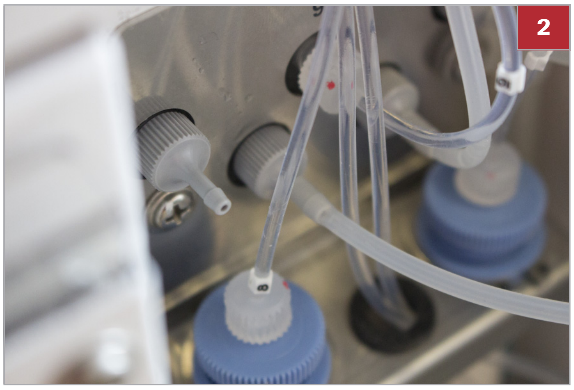

1 To remove a broken fitting, turn it counterclockwise.

2 Insert a new fitting and turn it clockwise.

## To fit new tubing




1 Insert a 180 mm piece of tubing through the left-hand pinch valve.




2 Push the ends of the tubing over the two left-hand fittings.

3 Repeat steps **1** and **2** for the right-hand pinch valve.

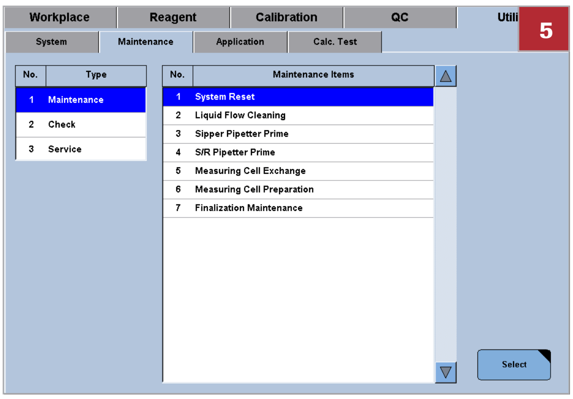
## To prepare the sipper system

1 Return the system water container to its compartment.

2 Remove any waste materials from the analyzer.

3 Close the top cover of the analyzer.

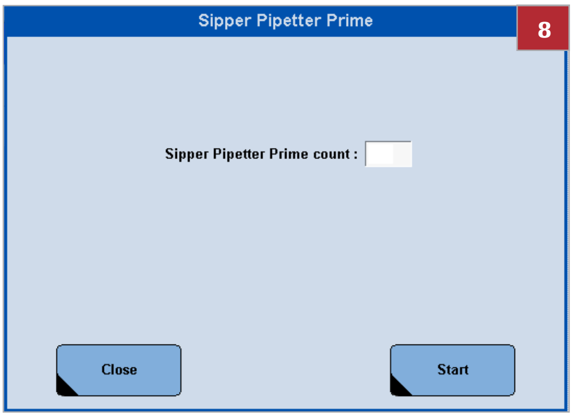
4 Switch the switch to ON.
→ The system restarts and the mechanical parts return to their standby position.




5 From the **System Overview** window, choose **Utility > Maintenance > Maintenance**.

6 From the **Maintenance Items** list, choose the **Sipper Pipetter Prime** option.

7 Choose the **Select** button.




8 In the **Sipper Pipetter Prime count** field, enter "10".

9 Choose the **Start** button.
➔ Air is purged from the sipper system.

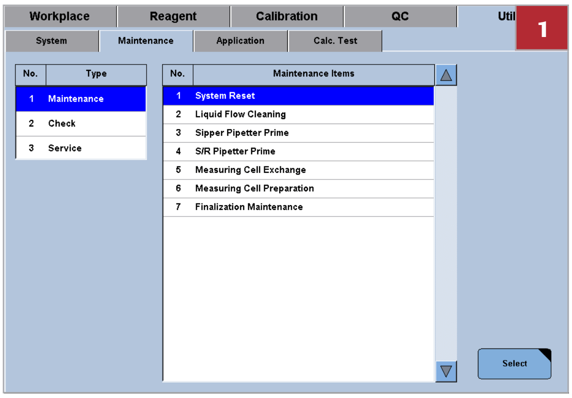

10 Lift the top cover of the analyzer.

11 Check there are no leaks from the new tubing.

12 Close the top cover of the analyzer.

13 Wait until the system is in Standby mode.

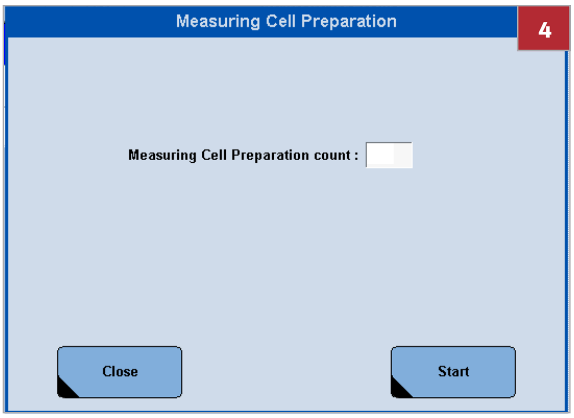
## To prepare the measuring cell




1 From the **System Overview** window, choose **Utility > Maintenance > Maintenance**.

2 From the maintenance actions list, choose the **Measuring Cell Preparation** option.

3 Choose the **Select** button.




4 In the **Measuring Cell Preparation count** field, enter "10".

5 Choose the **Start** button.
➔ Air is purged from the measuring cell.


**6** Lift the top cover of the analyzer.

**7** Check there are no leaks from the new tubing.

**8** Close the top cover of the analyzer.

**9** Wait until the system is in Standby mode.

# As-needed

**In this section**



## Cleaning a 13 mm sdta

Dirt can build up on the sample disk and the 13 mm sdta. Accumulated dirt can affect the upright position of sample tubes.

As-needed

15 minutes for thirty 13 mm sdtas

- ☐ Lint-free cloth
- ☐ One of the cleaning agents below.
  - 70% solution of ethanol
  - 100% solution of propanol
  - 100% solution of isopropanol
  - 10% solution of sodium hypochlorite
  - mikrozid® AF liquid for spray disinfection
  - mikrozid® AF wipes for wipe disinfection
  - Bacillol® AF for spray disinfection
  - Bacillol® AF Tissues for wipe disinfection
- ☐ If necessary, dish washer (commercial wash program at maximum temperature of 65 °C)

### ▸ To clean a 13 mm sdta

1 Remove the 13 mm sdta from the sample disk (168).

2 Use a cleaning agent to clean the 13 mm sdta.
  - If you use a dish washer, then disinfect the 13 mm sdta before you load it in the dish washer. To prevent damage to the 13 mm sdta, place it in a special compartment in the dish washer.

3 When the 13 mm sdta is fully dry, insert it into the sample disk (168).

## Cleaning and inspecting the valve of the system water container

Contamination of the system water container can affect results. Damage to the valve on the system water container can cause water leaks.

To clean the valve of the system water container, you must perform two maintenance actions.

1. Remove the water container and inspect the valve.
2. Clean and refill the system water container.

For more information, see:

To empty the system water container and inspect the valve ▸ (251)
To clean and refill the system water container ▸ (252)

As-needed

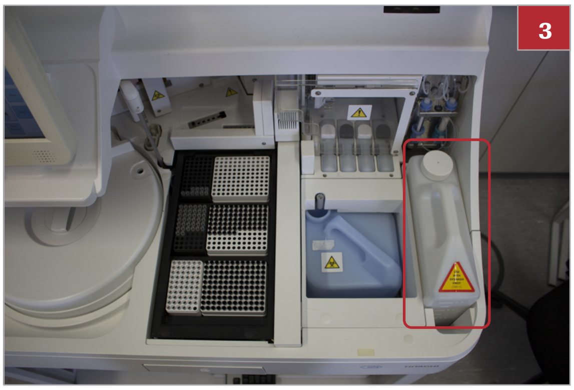
10 minutes

- ☐ Cleaning brush
- ☐ Replacement valve, optional
- ☐ Lint-free cloth
- ☐ Paper towels, or disposable cloths
- ☐ 70% solution of isopropyl alcohol, or ethanol
- ☐ SysWash
- ☐ Deionized water

### ▸ To empty the system water container and inspect the valve


1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.




3 Lift the system water container out of its compartment.

4 Remove the cap of the system water container.

5 Dispose of the system water according to your local rules.

6 Position the system water container so that you can see the valve.


**7** To remove the valve from the system water container, turn the valve counterclockwise.

**8** Inspect the valve.

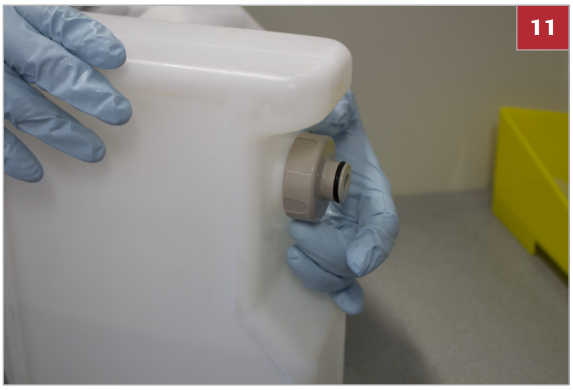
- If the valve is not damaged, then go to step **9**.
- If the valve is damaged, then get a new valve and go to step **11**.

**9** Clean the valve with water.

- Use a cleaning brush and tap water
- Then rinse the valve with deionized water

**10** If the valve is still dirty, then clean it with alcohol.

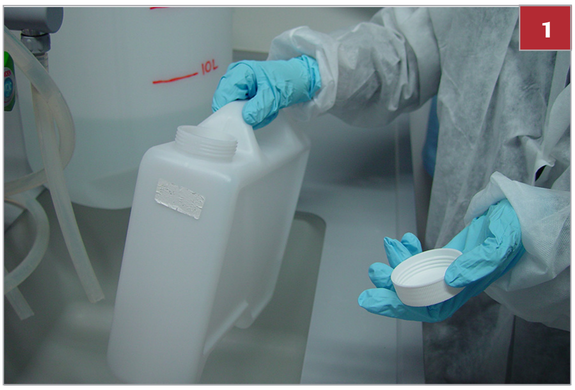
- Use a cleaning brush and alcohol
- Then rinse the valve with deionized water




**11** NOTICE Risk of damage to the valve. Do not overtighten the valve. Turn until you meet moderate resistance.

To attach the valve to the system water container, turn the valve clockwise.

## To clean and refill the system water container




**1** Rinse the system water container.

- Use tap water
- Then use deionized water

**2** If the system water container is dirty, then clean it.

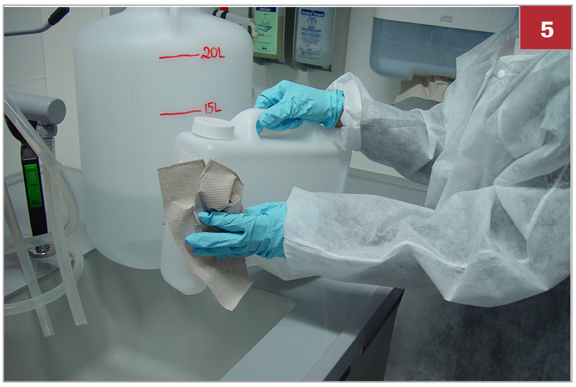
- Use a cleaning brush and alcohol
- Then rinse the container with deionized water

**3** Fill the system water container with deionized water.


4 NOTICE Risk of air bubbles. Pour the SysWash slowly.

Add 35 mL of SysWash to the deionized water in the system water container.

- This amount gives a SysWash dilution of 1+100.




5 Dry the outside of the system water container with paper towels.

6 Replace the cap on the system water container.


7 Wipe the aspiration inlet for the deionized water with a lint-free cloth.

8 Return the system water container to its compartment.

9 Remove any waste materials from the analyzer.

10 Close the top cover of the analyzer.

11 Switch the switch to ON.

→ The system restarts and the mechanical parts return to their standby position.

## Cleaning the liquid waste container

A full liquid waste container interrupts the operation of the system.

As-needed

5 minutes

- ☐ Paper towels, or disposable cloths
- ☐ 70% solution of isopropyl alcohol, or ethanol
- ☐ Germicidal agent, pH 9
- ☐ Tap water

## ▸ To clean the liquid waste container


1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.


3 Pull the liquid waste container towards you.

4 Replace and tighten the cap on the liquid waste container.

5 Lift the liquid waste container out of the compartment.
   ❶ Avoid the liquid waste outlet.

6 To absorb liquid, place paper towels under the liquid waste outlet.

7 Remove the cap on the liquid waste container.

8 Dispose of the liquid waste according to your local rules.

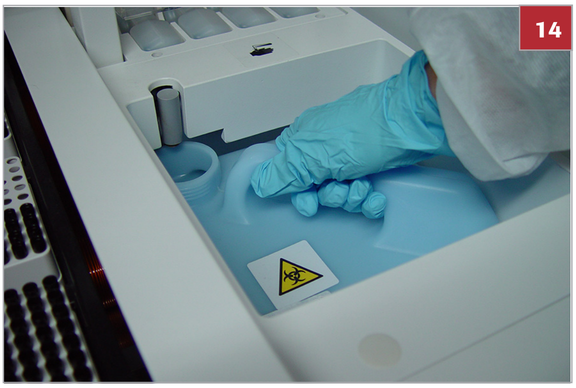
9 Rinse the liquid waste container with tap water.

**10** If the liquid waste container is dirty, then rinse it.
- Use alcohol
- Then use tap water


**11** Wipe the compartment of the liquid waste container with paper towels.

**12** If you add pH 9 germicidal agent to the liquid waste container, then follow the instructions on the product label.
This step is optional.

**13** Remove the paper towels from under the waste outlet.




**14** Return the liquid waste container to the compartment.

**15** Remove any waste materials from the analyzer.

**16** Close the top cover of the analyzer.

**17** Switch the switch to ON.
→ The system restarts and the mechanical parts return to their standby position.

## Cleaning the microbead mixer

Dirt can build up on the microbead mixer and affect results.

As-needed

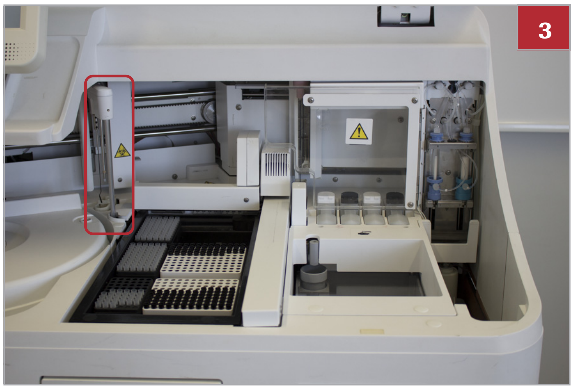
2 minutes

- ☐ Lint-free cloth
- ☐ 70% solution of isopropyl alcohol, or ethanol
- ☐ Deionized water

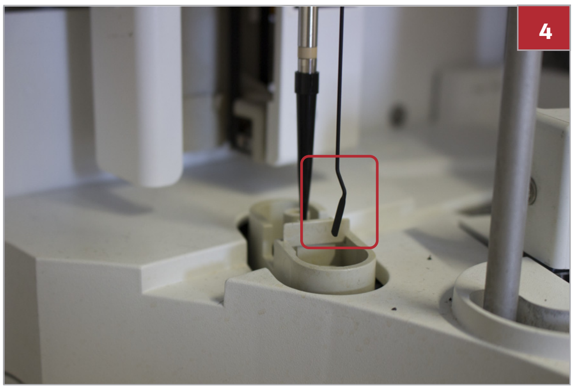
## To clean the microbead mixer


1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.




3 Move the microbead mixer arm into an accessible position.




4 NOTICE Risk of bending the microbead mixer paddle. Wipe the microbead mixer paddle carefully.

Wipe the microbead mixer paddle.

- Use lint-free cloth moistened with alcohol
- Then use lint-free cloth moistened with deionized water

5 Remove any waste materials from the analyzer.

6 Close the top cover of the analyzer.

7 Switch the switch to ON.

→ The system restarts and the mechanical parts return to their standby position.

## Cleaning the ProCell and CleanCell compartments

Liquids and residue spilt from the ProCell and CleanCell reagents can affect results.

As-needed

5 minutes

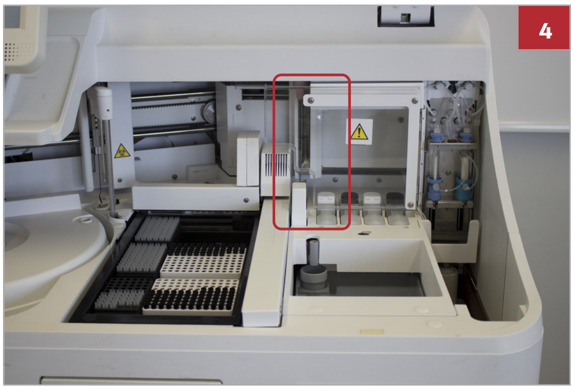
- ☐ Lint-free cloth
- ☐ Cotton swabs
- ☐ 70% solution of isopropyl alcohol, or ethanol
- ☐ Deionized water

### ▸ To clean the ProCell and CleanCell compartments

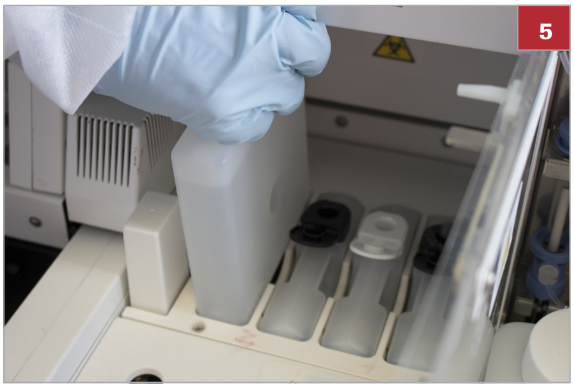

1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.


**3** To open the sipper shield, push the PUSH OPEN label.




**4** Move the sipper arm to the left as far as possible.




**5** Close the lids of all four ProCell and CleanCell bottles.

**6** Remove all the ProCell and CleanCell bottles from their compartments.

**7** Wipe and dry the sipper shield.

- Use lint-free cloth moistened with deionized water.
- Then use dry lint-free cloth.

**8** NOTICE Risk of damaging photosensors. Do not wet photosensors. If they are wet, then dry them with a cotton swab.

Wipe and dry the compartments.

- Use lint-free cloth moistened with deionized water
- Then use dry lint-free cloth
- If the compartments are still dirty, then use lint-free cloth moistened with alcohol

🛈 Do not allow water to pool in the compartments.

**9** Return the ProCell and CleanCell bottles to their compartments.

**10** Close the sipper shield. Push the PUSH OPEN label, until you hear a click.

**11** Remove any waste materials from the analyzer.

**12** Close the top cover of the analyzer.

**13** Switch the switch to ON.

→ The system restarts and the mechanical parts return to their standby position.

## Cleaning the reagent rotor and compartment

Dirt on the reagent rotor and compartment can affect the efficiency of the analyzer.

To clean the reagent rotor and compartment, you must perform three maintenance actions.

1. Open the reagent cover and remove the reagent rotor.
2. Clean the reagent rotor and its compartment.
3. Return the reagent rotor to its compartment and replace the cover.

For more information, see:

To remove the reagent rotor from its compartment ▶ (259)
To clean the reagent rotor and compartment ▶ (261)
To return the reagent rotor to its compartment ▶ (262)

As-needed

15 minutes

- ☐ Lint-free cloth
- ☐ Lint-free paper towels
- ☐ 70% solution of isopropyl alcohol, or ethanol
- ☐ Deionized water

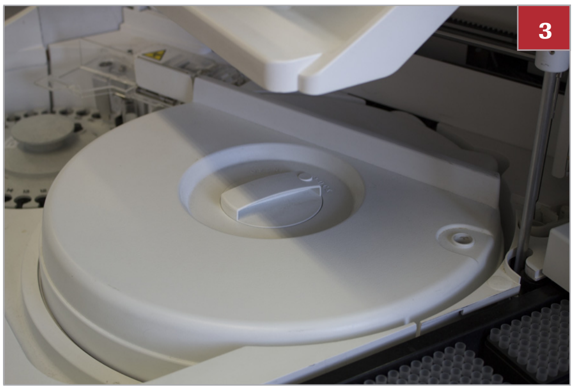
### ▶ To remove the reagent rotor from its compartment


**1** Switch the switch to OFF.

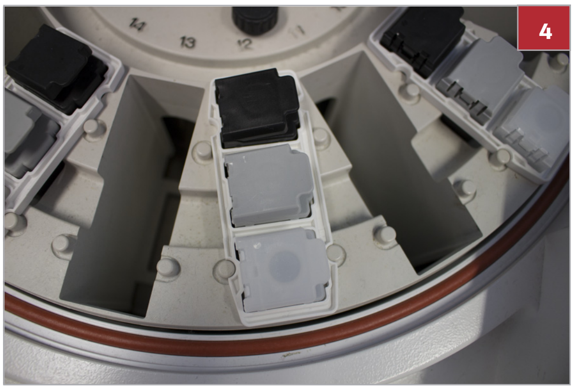


11 Maintenance

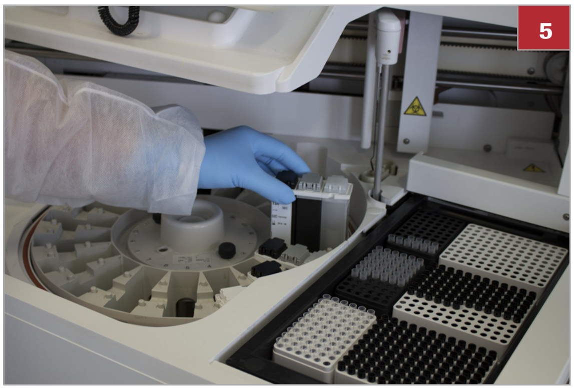

2 Lift the top cover of the analyzer.



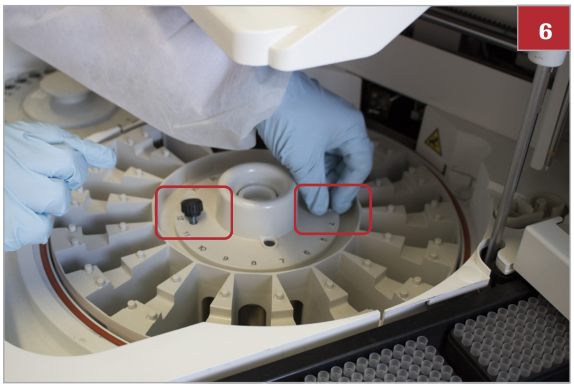

3 To remove the cover of the reagent rotor, rotate the handle on the cover counterclockwise and then lift it.




4 Close the lids of the reagent packs.



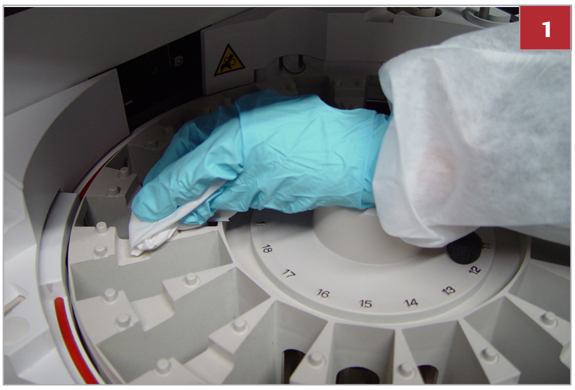

5 Remove the reagent packs.




6 Remove the black thumbscrews from the center of the reagent rotor.

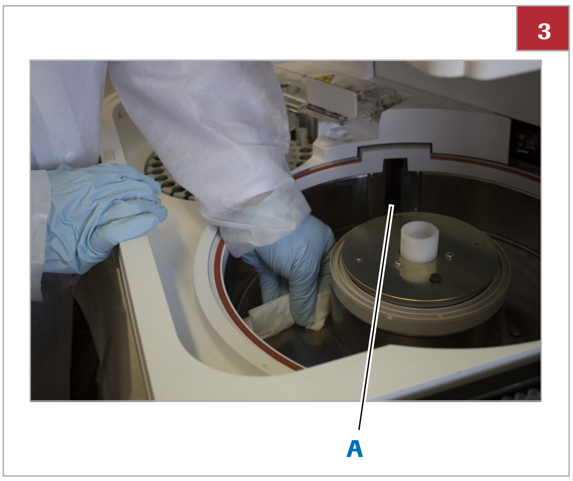
7 Lift the reagent rotor out of the reagent rotor compartment.

### To clean the reagent rotor and compartment




1 If the reagent rotor is dirty, then clean it.
- Use lint-free cloth moistened with alcohol
- Then use lint-free cloth moistened with deionized water
- Use lint-free paper towels to dry the reagent rotor

2 If there is condensation in the reagent rotor compartment, then use lint-free cloth to dry it.

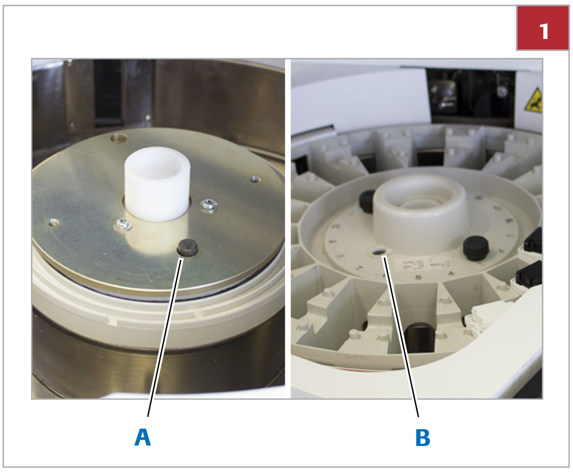



**A** Barcode reader

3 CAUTION! Risk of damage to the window of the barcode reader. Clean the window of the barcode reader gently.

If the reagent rotor compartment, or barcode reader, is dirty, then clean it.
- Use lint-free cloth moistened with alcohol
- Then use lint-free cloth moistened with deionized water
- Then use lint-free paper towels to dry the reagent rotor compartment and barcode reader

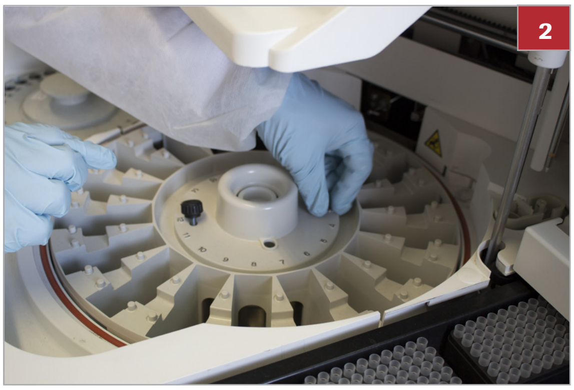
## To return the reagent rotor to its compartment




**A** Pin on the center plate **B** Hole on the rotor

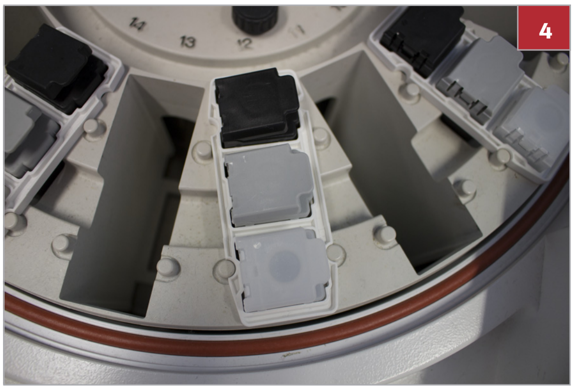
1 NOTICE Risk of damage to mechanical parts. Align the pin on the compartment center plate with the hole on the rotor.

Return the reagent rotor to the reagent rotor compartment.

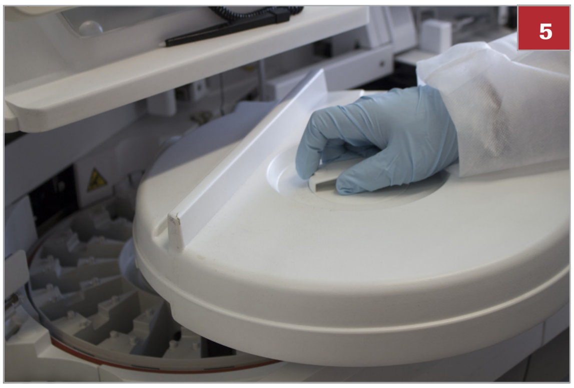



2 Replace and tighten the black thumbscrews.

3 Return the reagent packs to the reagent rotor.




4 Open the caps of the reagent packs.




5 To replace the cover of the reagent rotor, return it to the reagent rotor and rotate the handle of the cover clockwise.

6 Remove any waste materials from the analyzer.

7 Close the top cover of the analyzer.

8 Switch the switch to ON.
→ The system restarts and the mechanical parts return to their standby position.

## Cleaning the analyzer surfaces

Contamination of the analyzer surfaces can be hazardous or can damage the analyzer surfaces.

As-needed

5 minutes

- ☐ Lint-free cloth
- ☐ Laboratory disinfectant
- ☐ Deionized water

### ▸ To clean the analyzer surfaces


1 Switch the switch to OFF.


**2** Lift the top cover of the analyzer.

**3** NOTICE Risk of damage to analyzer surfaces. Do not use bleach or alcohol on the analyzer surfaces.

Use lint-free cloth moistened with disinfectant to clean the analyzer surfaces.

**4** If you spill disinfectant, then use lint-free cloth to remove it.

**5** Close the top cover of the analyzer.

**6** Switch the switch to ON.

→ The system restarts and the mechanical parts return to their standby position.

## Emptying the solid waste tray

A full solid waste tray interrupts the operation of the system.

**NOTICE**

**Equipment malfunction due to a full solid waste tray**

The software counts the number of disposable items that the analyzer uses. When you remove the solid waste tray, the software assumes that you empty the tray.

- If you remove the solid waste tray, then fit a new, empty Clean-Liner.

To empty the solid waste tray, you must perform three maintenance actions.

1. Remove the solid waste tray from its compartment.
2. Empty the solid waste tray and fit a new Clean-Liner.
3. Return the solid waste tray to its compartment.

For more information, see:

To remove the solid waste tray from its compartment ▶ (265)
To empty the solid waste tray ▶ (266)
To return the solid waste tray to its compartment ▶ (266)

As-needed

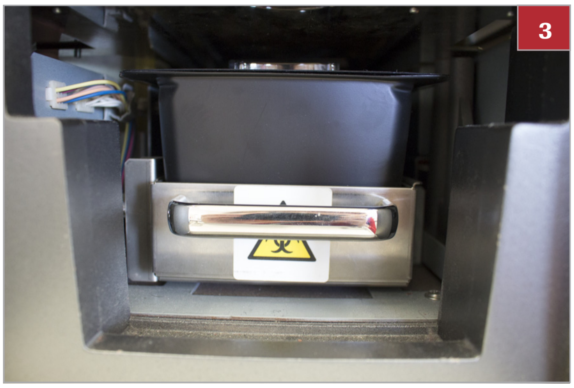
2 minutes

☐ Clean-Liner

### To remove the solid waste tray from its compartment


1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.

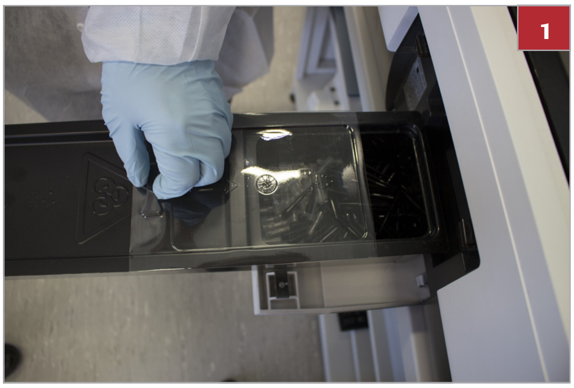



3 Open the door of the solid waste tray compartment.


**4** Pull the solid waste tray towards you.

**5** Place the solid waste tray on a suitable work surface.

## ▶ To empty the solid waste tray




**1** Slide the transparent lid of the solid waste tray over the opening of the Clean-Liner, to close the Clean-Liner.

**2** Remove the Clean-Liner from the solid waste tray.

**3** Dispose of the Clean-Liner according to your local rules.

**4** Place a new Clean-Liner in the solid waste tray.

ℹ Ensure the open side of the Clean-Liner is at the back of the solid waste tray.

**5** Ensure the transparent lid of the solid waste tray does not cover the opening of the new Clean-Liner.

## ▶ To return the solid waste tray to its compartment


**1** Push the solid waste tray into the solid waste tray compartment.

**2** Close the door of the solid waste tray compartment.

➔ On the **System Overview** window, the solid waste counter resets to zero.

**3** Switch the switch to ON.

➔ The system restarts and the mechanical parts return to their standby position.

## Cleaning the rack trays

Spills on the rack tray surfaces can be biohazardous. Clean up all spills immediately.

**⚠ WARNING**

**Personal injury and infection due to the edges on the rack tray's center guide rail**

The edges on the rack tray's center guide rail may cause personal injury and infection.

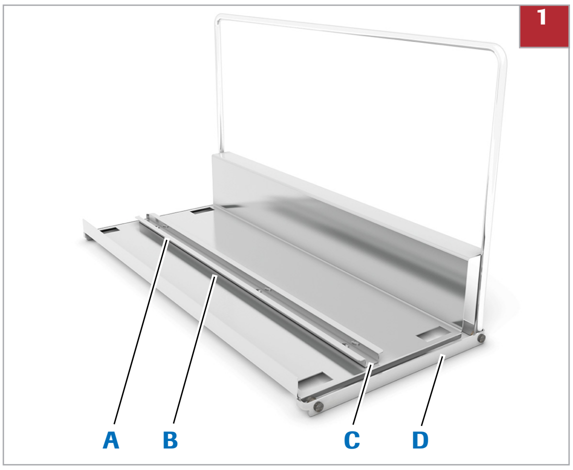
- Avoid contact with all edges, even when wearing lab gloves.
- Wear personal protective equipment such as lab gloves.
- Carefully observe all instructions given in this task.

☐ Lint-free cloth
☐ Cotton swab
☐ Alcohol

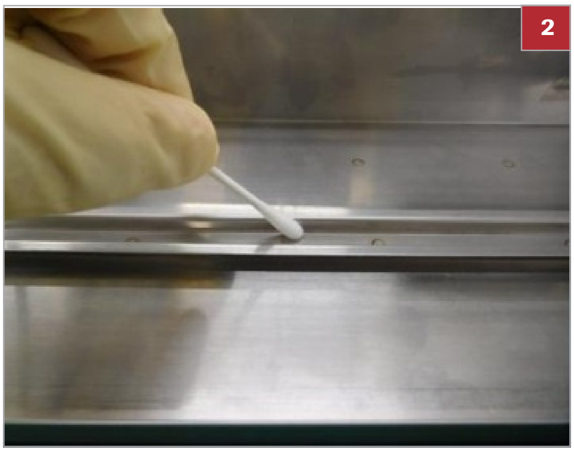
☐ The system is in Standby mode, Sleep mode, or shutdown

### To clean the rack trays

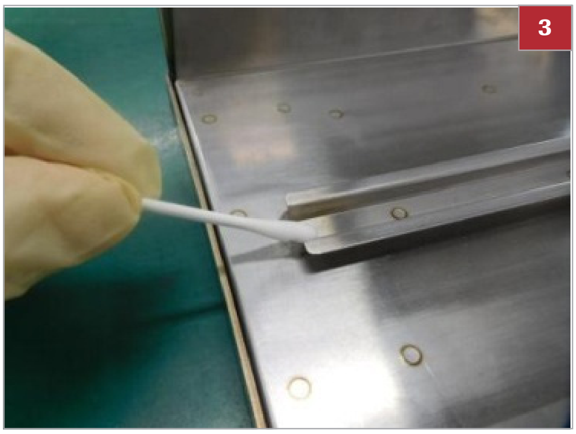
1 Use personal protective equipment when cleaning the rack tray.



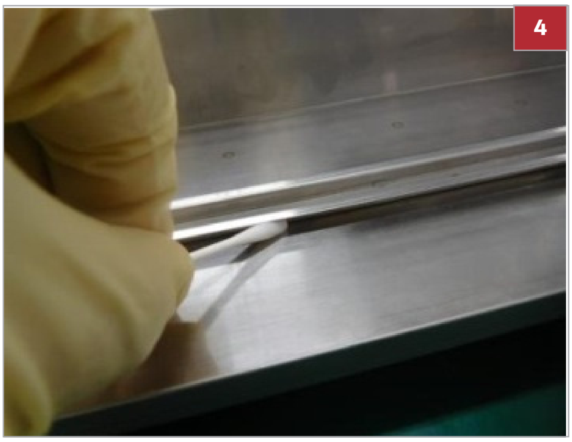

| | |
|---|---|
| **A** Rail edge | **C** Rail center |
| **B** Rail groove | **D** Rack tray |




2 Wipe the rail center in both directions with a cotton swab moistened with alcohol.
  - If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.
  - ❶ Take care not to sustain injuries by coming into contact with the edges.



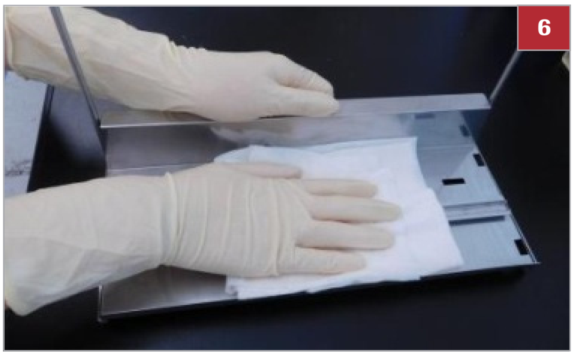

3 Wipe the rail edge in both directions with a cotton swab moistened with alcohol.
  - If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.
  - ❶ Take care not to sustain injuries by coming into contact with the edges.




4 Wipe the rail groove in both directions with a cotton swab moistened with alcohol.
  - If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.
  - ❶ Take care not to sustain injuries by coming into contact with the edges.

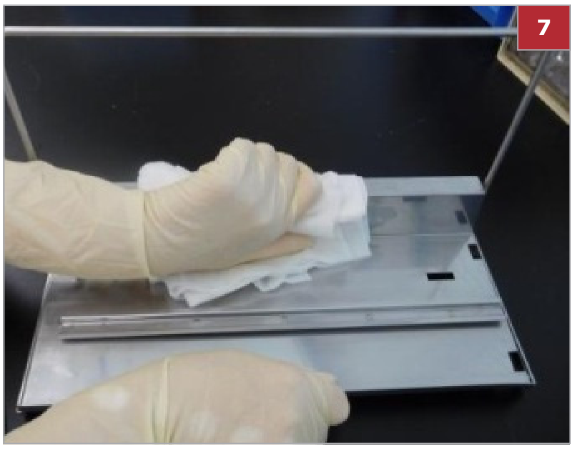

5 Wipe the edges on the bottom of the rack tray in both directions with a cotton swab moistened with alcohol.
- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.

ⓘ Take care not to sustain injuries by coming into contact with the edges.



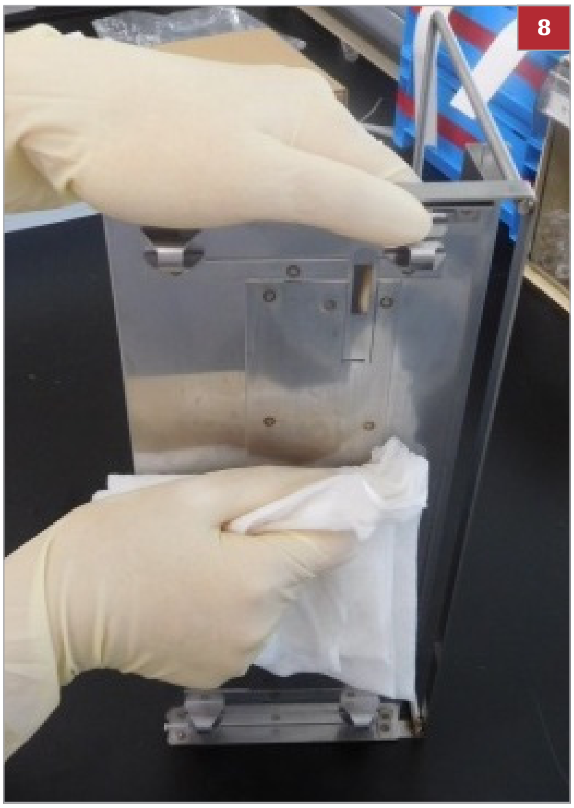

6 Wipe the surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with alcohol.
- Hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.

ⓘ Take care not to sustain injuries by coming into contact with the edges.




7 Wipe the rear surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with alcohol.
- Hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.

ⓘ Take care not to sustain injuries by coming into contact with the edges.




**8** Wipe the bottom surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with alcohol.

- Hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.
- Take care not to sustain injuries by coming into contact with the edges.

**9** Visually check the rack trays.

- Make sure that there is no textile remaining on the rack tray.
- Make sure that there are no wet areas on the rack tray.

**Related topics**


- Maintenance schedule (219)
- Cleaning the sample racks (270)


## Cleaning the sample racks

Spills or sample material on a sample rack can be hazardous. If a sample rack is dirty, then clean it.

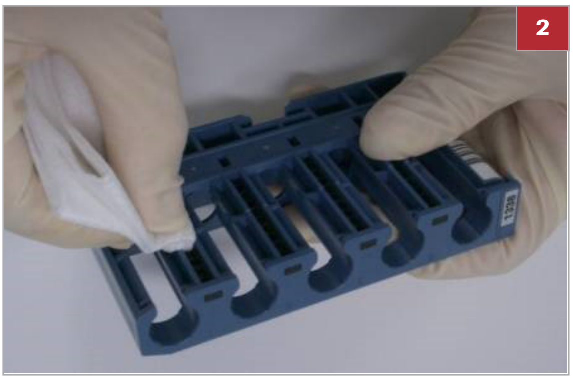
Do not use ethanol or deionized water to clean the sample racks, as they may damage the barcode label.

- ☐ Lint-free cloth
- ☐ Cotton swab
- ☐ 2% EcoTergent solution (1:50 dilution)
- ☐ Deionized water

- ☐ The system is in Standby mode, Sleep mode, or shutdown

## ▸ To clean the sample racks

1 Use personal protective equipment when cleaning the sample rack.



2 Wipe all surfaces of the sample rack with a lint-free cloth moistened with EcoTergent solution.
  - Take care when cleaning the barcode label on the sample rack. Gently wipe the surface of the barcode label only and do not wipe the label edges.
  - ❶ When you clean the sample rack, make sure you do not damage the metal grippers.

3 To clean the tops of each position in the sample rack, use a lint-free cloth moistened with EcoTergent solution and wipe in a circular motion.
  - ❶ When you clean the sample rack, make sure you do not damage the metal grippers.

4 To clean areas of the sample rack that you cannot reach with the lint-free cloth, use a cotton swab moistened with EcoTergent solution.
  - ❶ When you clean the sample rack, make sure you do not damage the metal grippers.

5 Wipe the EcoTergent off from all surfaces. Use a lint-free cloth moistened with deionized water or a cotton swab moistened with deionized water.
  - ❶ When you wipe the sample rack, make sure you do not damage the metal grippers.

6 Dry all surfaces of the sample rack with a dry lint-free cloth or a cotton swab.
  - ❶ When you dry the sample rack, make sure you do not damage the metal grippers.

7 Visually check the sample rack.
  - Make sure that there is no textile remaining on the sample rack.
  - Check the barcode label on the sample rack is not damaged and not peeling off of the rack.
  - ❶ If the barcode label is damaged, then do not use the sample rack

**Related topics**

- Maintenance schedule (219)
- Cleaning the rack trays (267)

11 Maintenance

# Preparing the analyzer for an idle period

If the analyzer is to remain idle for less than 7 days, then no special shutdown is needed.
If the analyzer is to remain idle for more than 7 days, then you must perform the correct shutdown action.

**NOTICE**

**Damage to the analyzer due to incorrect shutdown**

A long idle period can damage the measuring cell.

- Perform the correct shutdown action before a long idle period.

**In this section**



## Performing finalization maintenance before the analyzer is idle for several hours

Finalization maintenance prepares the analyzer for an idle period of several hours. The analyzer automatically performs finalization maintenance before it enters Standby mode.

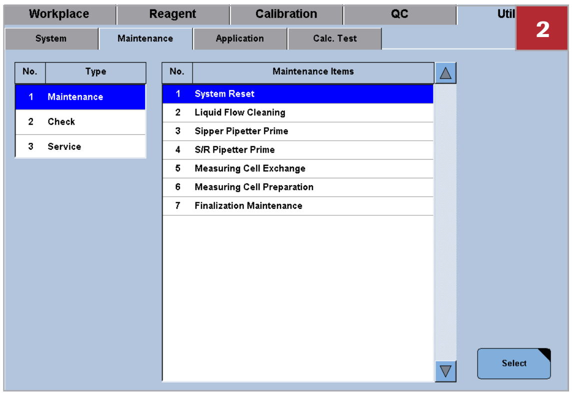
If finalization maintenance was not performed automatically, then initiate it manually.

To enter Standby mode without performing finalization maintenance, choose the **S.Stop** button.

As-needed

4 minutes

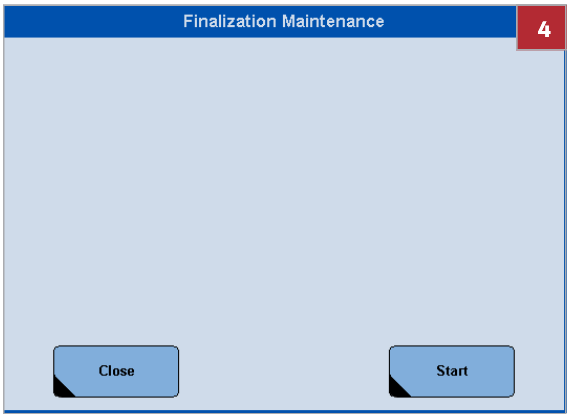
### To perform finalization maintenance




1 From the **System Overview** window, choose **Utility > Maintenance**.

2 From the **Maintenance Items** list, choose the **Finalization Maintenance** option.

3 Then choose the **Select** button.




4 On the **Finalization Maintenance** dialog box, choose the **Start** button.

5 Wait until the system enters Standby mode.

# Shutting down the analyzer for one to four weeks

To protect the analyzer while it is idle, you must shut it down correctly.

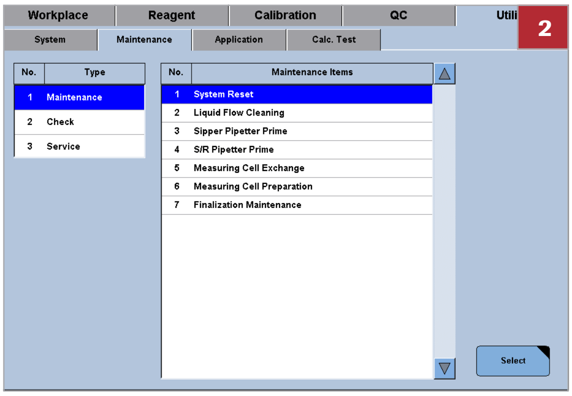
Perform this task if the system will be idle for one to four weeks.

As-needed

3 minutes

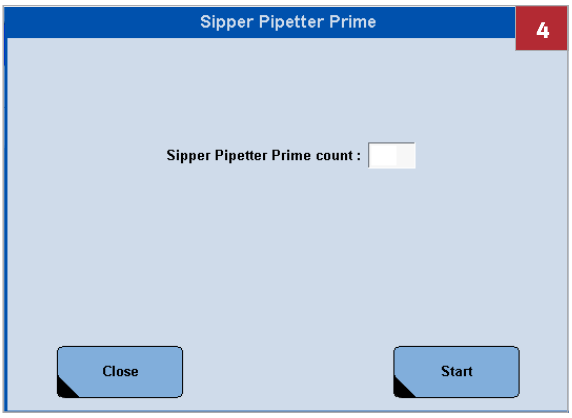
### To fill the measuring cell with system water

1 From the **System Overview** window, choose **Utility > Maintenance**.




2 From the **Maintenance Items** list, choose the **Sipper Pipetter Prime** option.

3 Choose the **Select** button.




4 In the **Sipper Pipetter Prime count** field, enter "10".

5 Choose the **Start** button.
→ Water is added to the sipper flow paths.

6 Perform steps **2** to **5** another four times.

7 Switch off the analyzer.

**Related topics**

- Shutting down the system ▶ (208)

# Shutting down the analyzer for longer than four weeks

To protect the analyzer while it is idle, you must shut it down correctly.

To prepare the analyzer for an idle period that is longer than four weeks, you must perform two maintenance actions.

1. Fill the measuring cell with system water.
2. Seal the sipper probe.

For more information, see:

To fill the measuring cell with system water ▶ (274)
To seal the sipper probe (276)

To restart the analyzer, contact your Roche Support Representative.

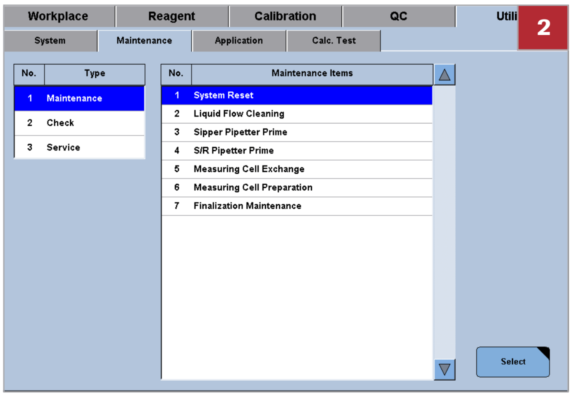
As-needed

10 minutes

☐ Deionized water

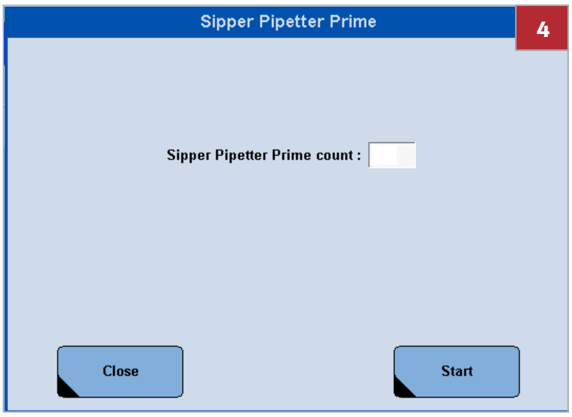
## ▸ To fill the measuring cell with system water

1 From the **System Overview** window, choose **Utility > Maintenance**.




2 From the **Maintenance Items** list, choose the **Sipper Pipetter Prime** option.

3 Choose the **Select** button.




4 In the **Sipper Pipetter Prime count** field, enter "10".

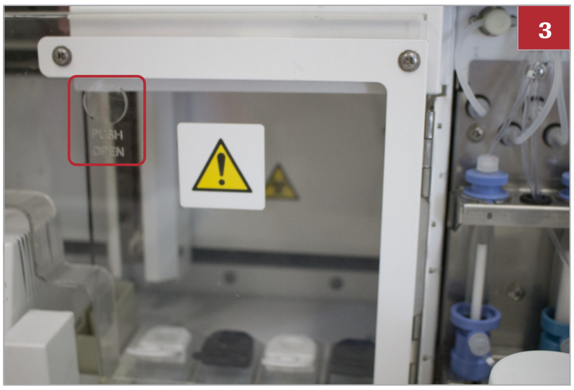
5 Choose the **Start** button.
➔ Water is added to the sipper flow paths

6 Perform steps **2** to **5** another four times.

### To seal the sipper probe


1 Switch the switch to OFF.


2 Lift the top cover of the analyzer.




3 To open the sipper shield, push the PUSH OPEN label.

4 Remove the ProCell and CleanCell bottles.

5 Fill an empty ProCell or CleanCell bottle with deionized water and put it into a compartment.

6 Gently move the sipper probe into ProCell or CleanCell bottle filled with deionized water.

7 Close the sipper shield. Push the PUSH OPEN label, until you hear a click.

8 Remove any waste materials from the analyzer.

9 Close the top cover of the analyzer.

# Advanced operation

# Advanced operation

## In this chapter

12

# Changing test settings

The system records different parameters for a test. You can update the parameter settings at any time.

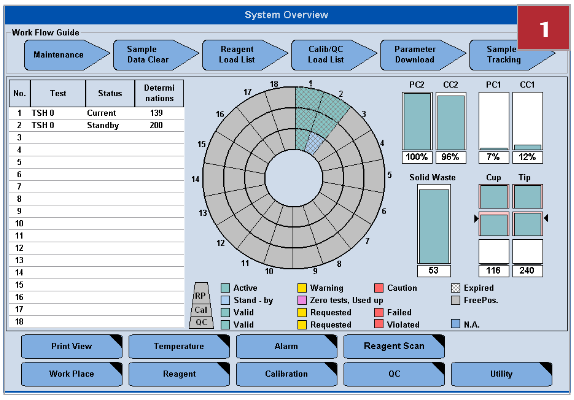
Test parameters are embedded in the reagent barcode, so any changes would be entered with the assistance of a Roche service representative. If the measuring unit is different, or there is a change in the user test number required for LIS connectivity, then the parameters can be changed.

7 As-needed

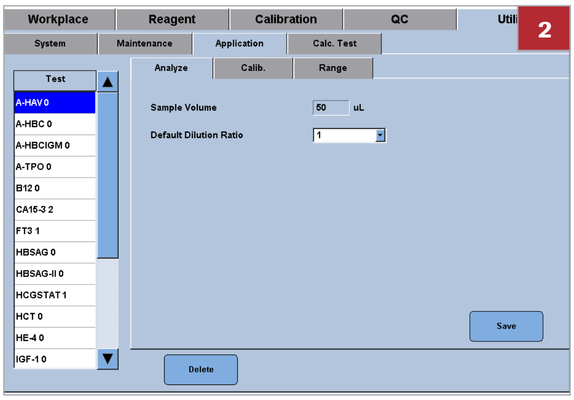
2 minutes

- ☐ Test number is known
- ☐ Dilution ratio is known
- ☐ Expected measured values, as a range, are known

## ▸ To change test settings




1 From the **System Overview** window, choose **Utility > Application > Analyze**.




2 From the **Test** table, choose a test.

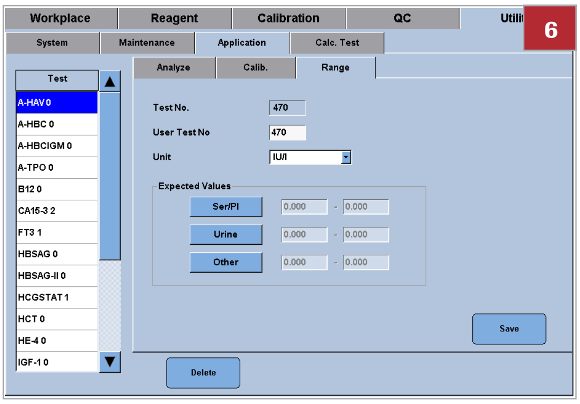
3 CAUTION! Risk of incorrect test results. When you change the default dilution ratio to any value other than 1, all samples you run are diluted.

From the **Default Dilution Ratio** drop-down list, choose a default dilution ratio.

🛈 Use the recommended dilution ratio in the reagent package insert.

4 Choose the **Save** button.

5 From the **Application** tab, choose the **Range** tab.




**6** Enter up to 4 digits in the **User Test No** field. Valid entries are 1 to 9999.

- If you install a new test, the analyzer defaults the **User Test No** to the test number of the new test. The **User Test No** determines the test order on sample printouts, the test pipetting sequence, and the test button order in the **Test Selection** window.

**7** From the **Unit** drop-down list, choose a unit for the test.

**8** From the **Expected Values** group box, fill in the **Ser/Pl** fields, the **Urine** fields, and the **Other** fields.

- The information is pre-coded in the reagent bar code, and printed as expected values on the method sheet.

**9** Choose the **Save** button.

# Overview of auto masking

To skip tests that require calibration, or that have failed calibration, use auto masking.

When active, auto masking is applied to the selected tests until it is made inactive or a successful calibration takes place.

**In this section**



## Activating auto masking

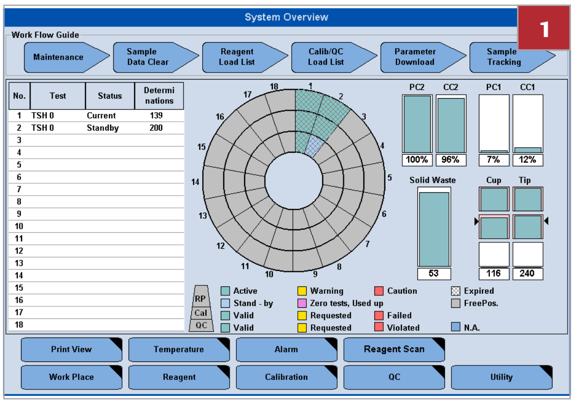
To use auto masking you must activate it, and then apply it to a test.

Applying auto masking to a test (284)

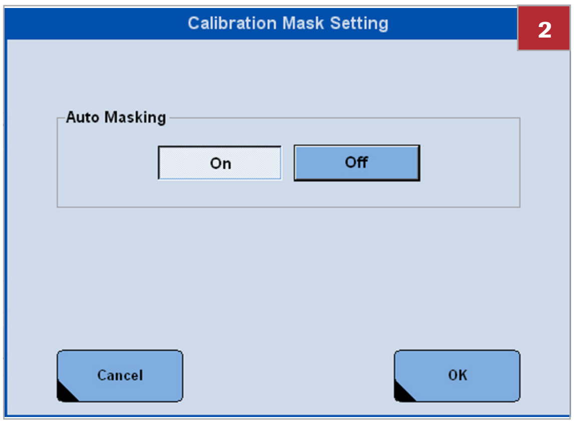
As-needed

1 minute

### To activate auto masking




1 From the **System Overview** window, choose **Utility > System > Calib.Mask Setting**.




2 From the **Auto Masking** group box, choose the **On** button.

3 Choose the **OK** button.

# Applying auto masking to a test

Before you apply auto masking to a test, you must activate it.

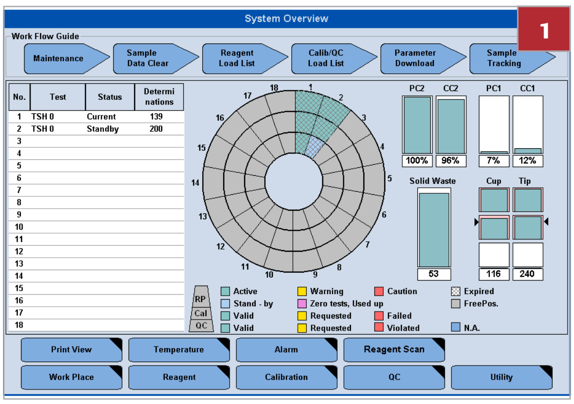
Activating auto masking (283)

As-needed

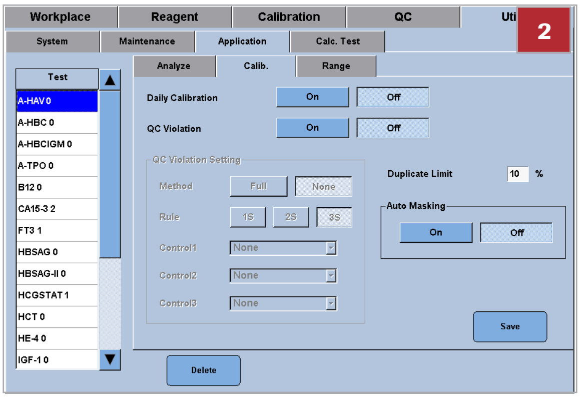
1 minute

☐ Auto masking is active

## To apply auto masking to a test




1 From the **System Overview** window, choose **Utility > Application > Calib.**.




2 From the **Test** table, choose a test.

3 From the **Auto Masking** group box, choose the **On** button.

4 Choose the **Save** button.

# Defining rack ranges

To assign calibrator and control positions, you must define rack ranges for the positions.

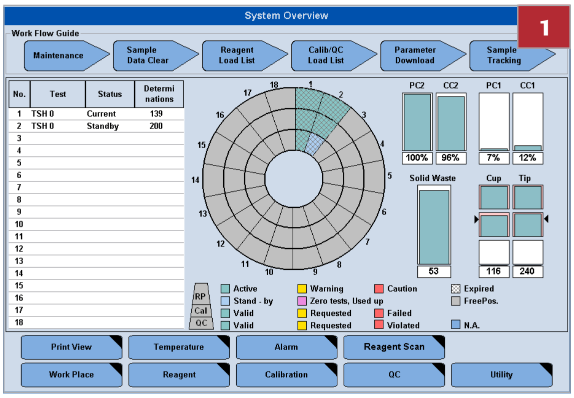
Assigning positions to calibrators (119)

Assigning positions to controls (139)

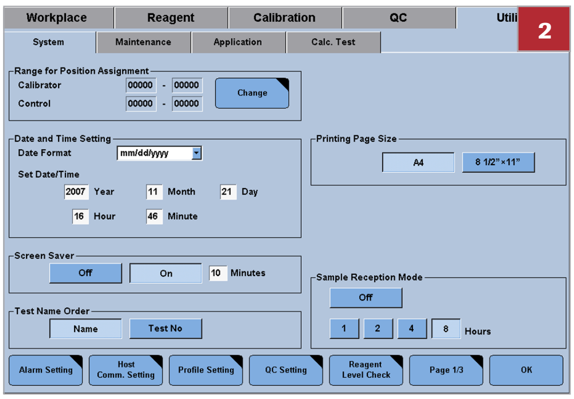
As-needed

5 minutes

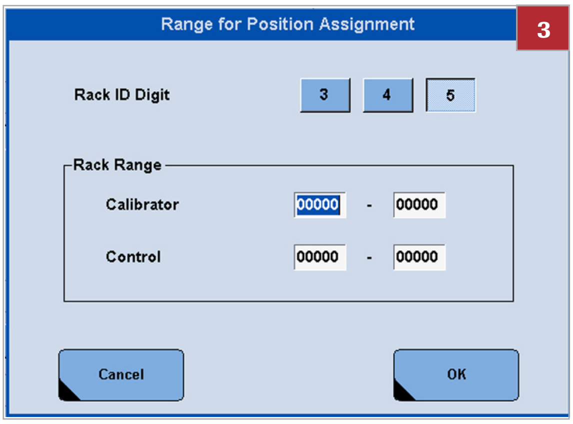
### To define rack ranges




1 From the **System Overview** window, choose **Utility > System**.




2 From the **Range for Position Assignment** group box, choose the **Change** button.




**3** From the **Rack ID Digit** dialog box, choose the **5** button.

ℹ If the **Rack ID Digit** is not set to 5, then the system does not recognize the rack ID.

**4** From the **Rack Range** group box, fill in the **Calibrator** fields and the **Control** fields.

- In the left-hand field, enter the lowest rack ID of the range.
- In the right-hand field, enter the highest rack ID of the range.

ℹ Do not enter ranges for calibrators and controls that overlap.

**5** Choose the **OK** button.

# Overview of Sample Reception mode

To process samples automatically at the end of a run, use sample reception mode.

When Sample Reception mode is active, the system remains in Operation mode after it processes the last available sample.

If one of the events below occurs, then the system enters Standby mode.

- The specified time interval ends
- You choose the **S. Stop** button
- A red alarm occurs

### In this section



## Configuring Sample Reception mode

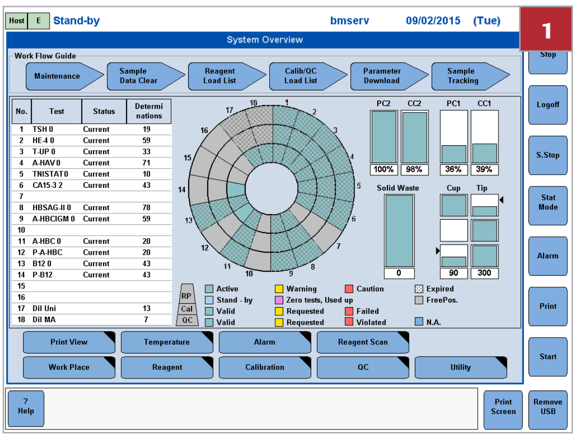
Before activating Sample Reception mode, you must configure the time interval. The time interval is the number of hours that the system remains in sample reception mode before it enters Standby mode.

Activating Sample Reception mode (289)

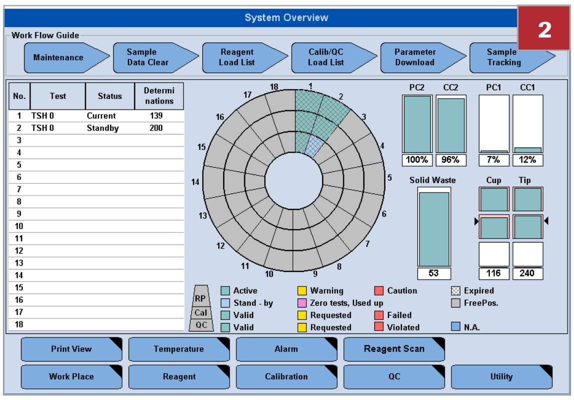
As-needed

1 minute

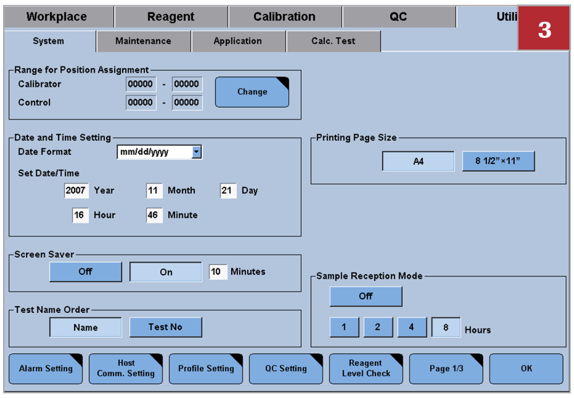
### To configure Sample Reception mode




1 Choose the **S. Stop** button.
   → All sampling stops, and the system enters Standby mode.



2 From the **System Overview** window, choose **Utility > System**.



3 From the **Sample Reception Mode** group box, choose a time interval.

- The time interval is the number of hours that the system remains in Sample Reception mode before it enters Standby mode.

4 Choose the **OK** button.

# Activating Sample Reception mode

To process samples automatically at the end of a run, use Sample Reception mode.

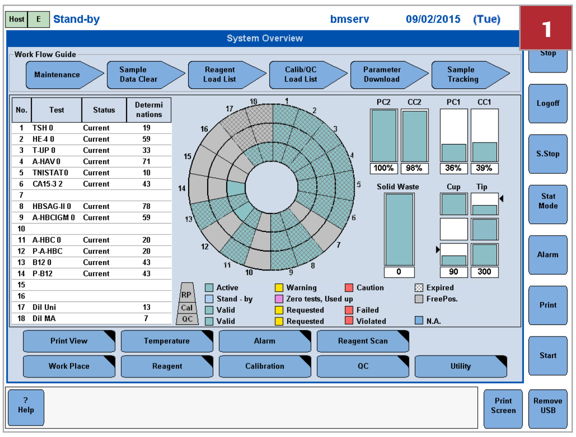
Configuring Sample Reception mode (288)

As-needed

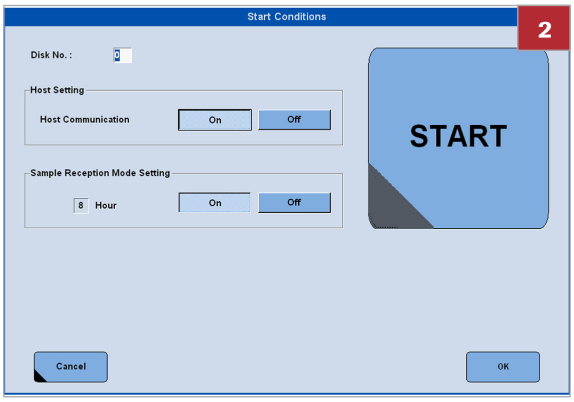
1 minute

☐ Sample Reception mode is configured

## ▸ To activate Sample Reception mode




1 From the **System Overview** window, choose the **Start** button.




2 From the **Sample Reception Mode Setting** group box, choose the **On** button.

3 Choose the **OK** button.

# Changing the sample disk mode

You can use Multiple sample disk mode to increase the number of samples the analyzer can process. Multiple disks can be loaded, ready to be placed on the analyzer. As soon as the test run for one sample disk is complete, a new one can begin.

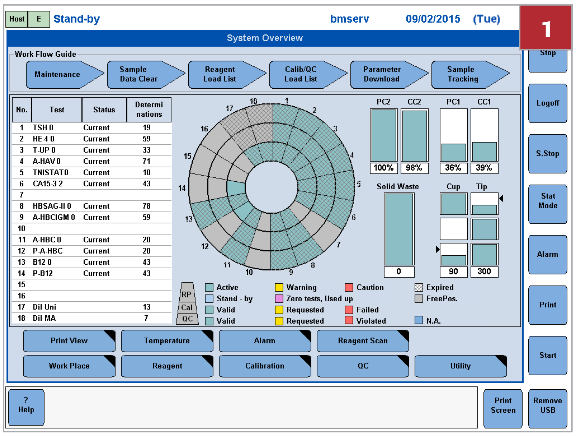
Before you change the sample disk mode, complete all open requests and delete all samples from the **Data Review** window.

When you change the sample disk mode, the system deletes data related to incomplete test requests.

As-needed

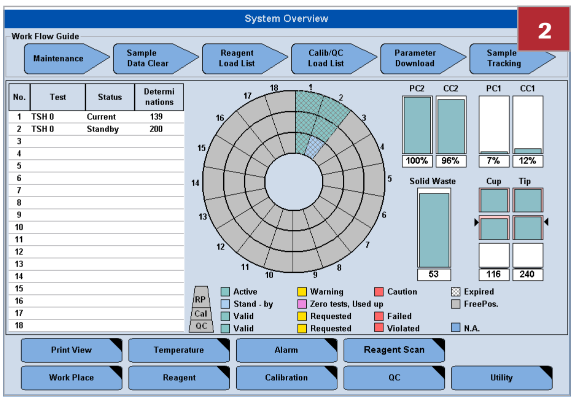
5 minutes

## To change the sample disk mode

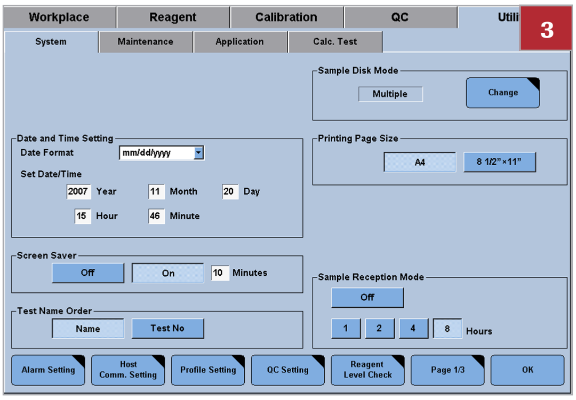



1 Choose the **S. Stop** button.

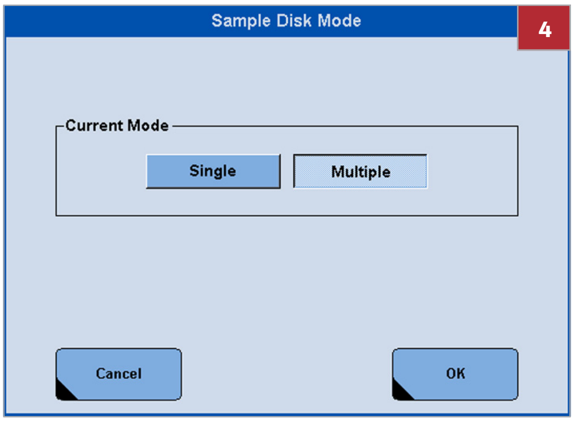
→ All sampling stops, and the system enters Standby mode.




2 From the **System Overview** window, choose **Utility > System**.




3 From the **Sample Disk Mode** group box, choose the **Change** button.




4 From the **Current Mode** group box, choose the sample disk mode.

5 Choose the **OK** button.

6 From the **Confirmation** dialog box, choose the **OK** button.

→ The **Sample Disk Mode** dialog box displays, and the **OK** button is highlighted yellow.

7 Choose the **OK** button.

→ The **OK** button changes color to blue.

8 Change the disk number if needed.

- From the **System Overview** window, choose the **Start** button.
- Then fill in the **Disk No.** field.
- Then choose the **OK** button.

# Adding operator IDs

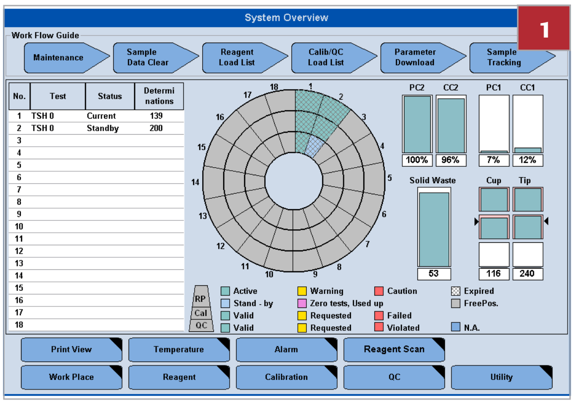
When password protection mode is active, you need an operator ID to log on to the software.

As-needed

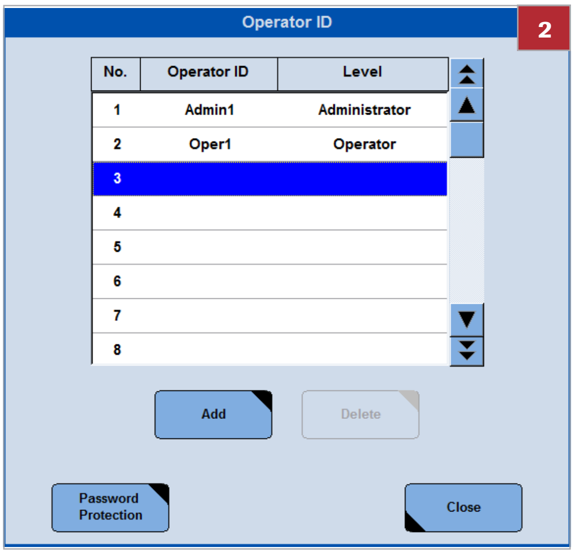
2 minutes

☐ Administrator access

## To add an operator ID

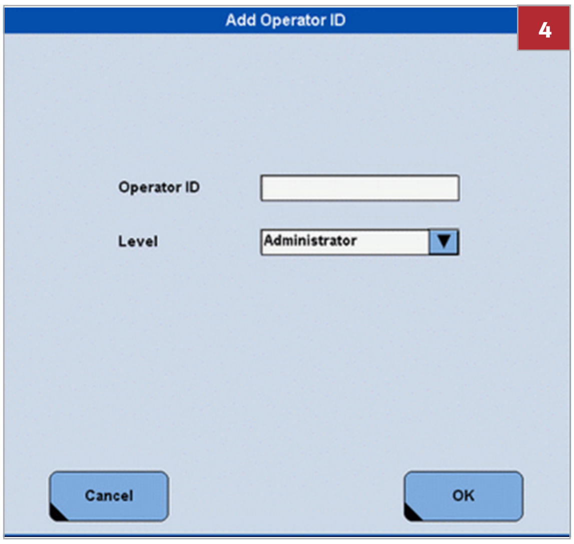



1 From the **System Overview** window, choose **Utility > System > Page 2/3 > Operator ID**.




2 From the **Operator ID** table, choose an empty row.

3 Choose the **Add** button.




4 From the **Add Operator ID** dialog box, fill in the **Operator ID** field.

5 From the **Level** drop-down list, choose an access level.

6 Choose the **OK** button.

# Changing documentation settings

When the communication link with the host fails, change the documentation settings to print the results without an upload to the host.

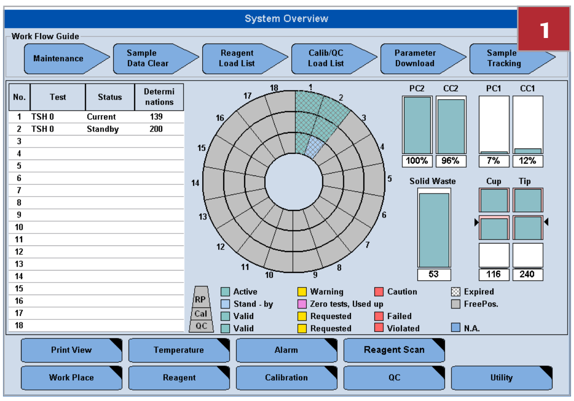
> One result is printed per page for all types of sample results selected in the **Automatic Printout** group box.

As-needed

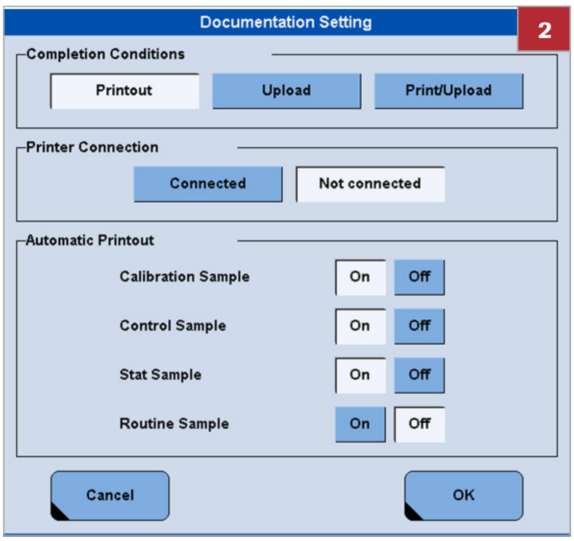
2 minutes

☐ External printer connected to the analyzer

## ▸ To change documentation settings




1 From the **System Overview** window, choose **Utility > System > Page 2/3 > Documentation Setup**.




2 From the **Completion Conditions** group box, choose the **Printout** button.

3 From the **Automatic Printout** group box, choose the **On** button next to each type of sample result you want to print.

4 Choose the **OK** button.

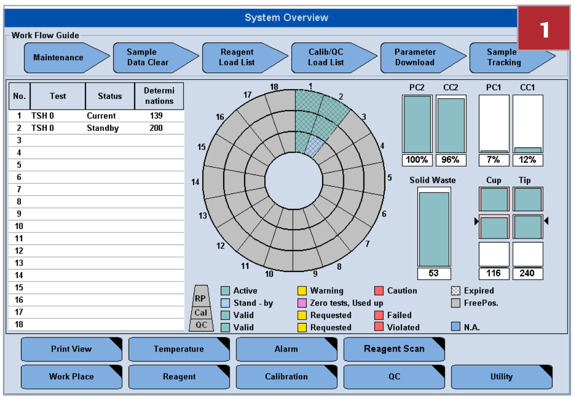
# Defining new profiles

To speed up manual test selections, group tests into profiles.

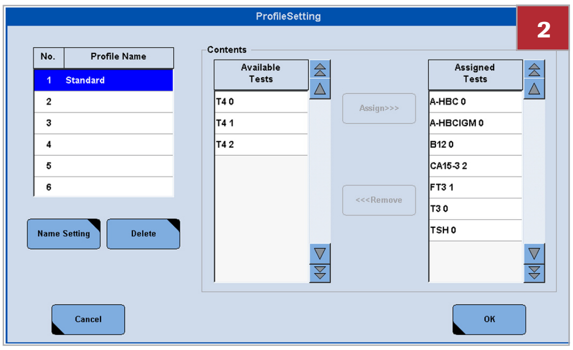
As-needed

10 minutes

## To define a new profile




1 From the **System Overview** window, choose **Utility > System > Profile Setting**.



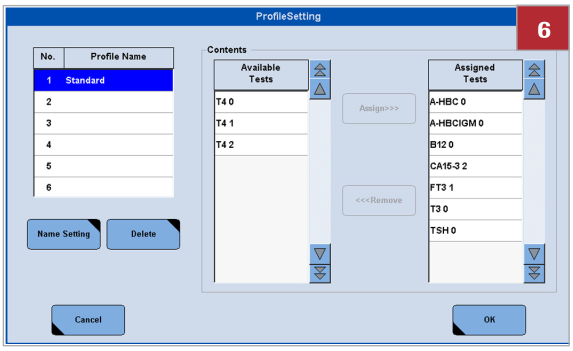

2 From the **Profile Name** table, choose an empty row.

3 Choose the **Name Setting** button.

4 From the **Profile Name Setting** dialog box, fill in the **New Profile Name** field.

5 Choose the **Update** button.

➔ The software adds the profile to the **Profile Name** table.




6 To add a test to the profile, perform the steps below.

- From the **Available Tests** table, choose a test.
- Then choose the **Assign** button.

7 To remove a test from the profile, perform the steps below.

- From the **Assigned Tests** table, choose a test.
- Then choose the **Remove** button.

8 Choose the **OK** button.

ℹ The software assigns the profile to a test key in the test matrix on the **Test Selection** window.

# Overview of saving and restoring data

To avoid the risk of data loss, regularly back up system data.

You can back up data to either the internal storage device, or one of the external storage devices below.

- DVD-RAM
- USB flash drive

⚠ **CAUTION**

**Data loss due to incorrect use of USB flash drives**

Incorrect use of USB flash drives may result in data loss.

- Only insert or remove a USB flash drive when the analyzer is in Standby mode.
- Use only one USB flash drive at a time.
- Before removing a USB flash drive, choose the **Remove USB** button.

⚠ **CAUTION**

**Analyzer malfunction due to virus infection**

A virus on a USB flash drive can result in analyzer malfunction.

- To prevent a virus from infecting the software, only use the USB flash drive for the analyzer. Do not store any other data on the USB flash drive.

If data is lost, a copy of all data saved during a backup can be restored to the system ready for use.

**In this section**



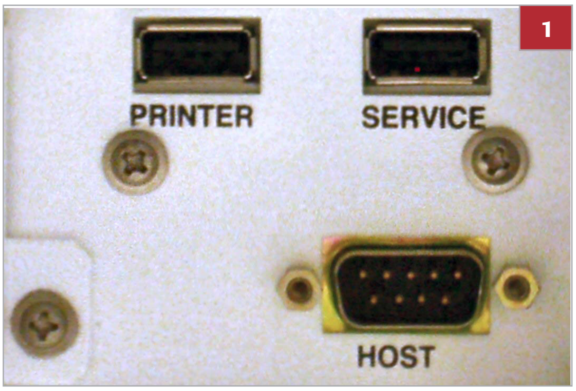
## Backing up the database

To prevent loss of data, back up the database.

As-needed

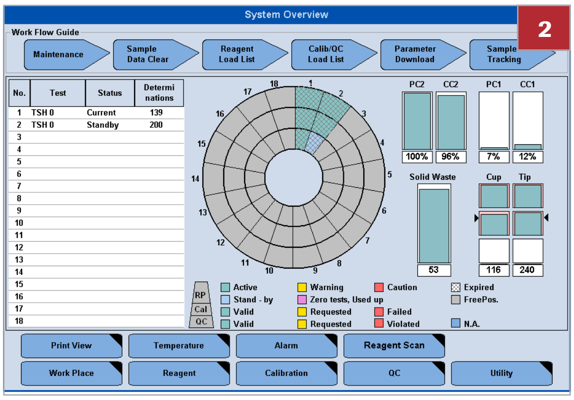
5 minutes

## To back up the database

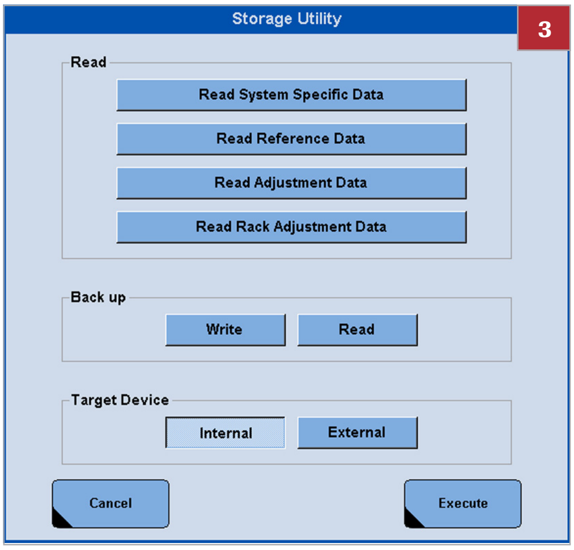



1 To back up the database to either a DVD-RAM or USB flash drive, connect the device to the Service port at the left of the analyzer.

   ❶ If you attempt to backup the database to a DVD-RAM or USB flash drive that is not ready, or is not the correct format, then the software displays an error message.




2 From the **System Overview** window, choose **Utility > System > Storage Utility**.




3 From the **Backup** group box, choose the **Write** button.

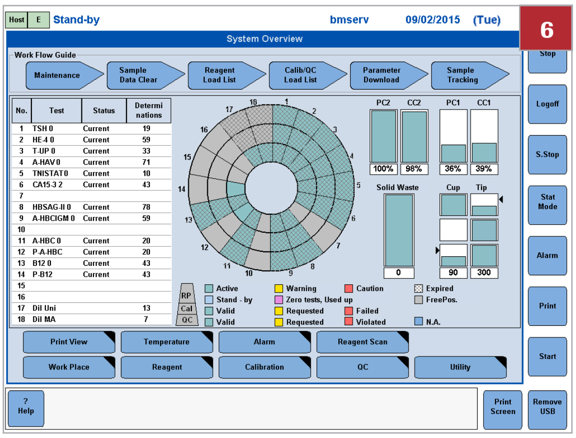
4 From the **Target Device** group box, choose to back up the database to an internal storage device or an external storage device.

   ❶ You can store two backups on the internal storage device. If you store a backup when the internal storage device is full, then the system deletes the oldest backup.

5 Choose the **Execute** button.

   - For internal storage devices, the system backs up to the folder "D:\e411\backup-YYYY-MM-DD-hh-mm\", where D is the drive letter.
   - For external storage devices, the system backs up to the folder "E:\e411\backup-YYYY-MM-DD-hh-mm\", where E is the drive letter. Under certain circumstances, the drive letter can be F or G.

   ❶ All database and log files are also backed up to the folder "D:\e411\getlog\", where D is the drive letter. Information in these files can help Roche Service representatives to investigate analyzer problems.




6 To remove a USB flash drive, when the export is complete, perform the steps below.

- Choose the **Remove USB** button from the global buttons.
- Disconnect the USB flash drive from the Service port.

# Restoring the database from a backup

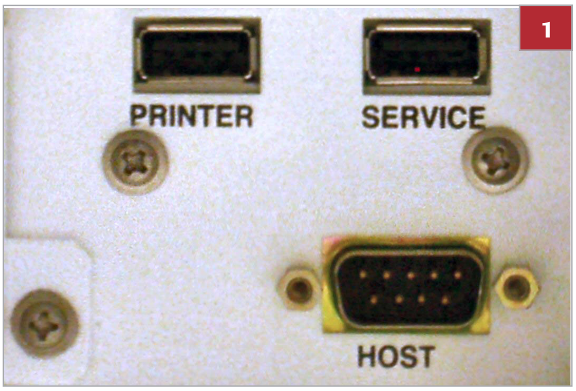
To use a backed-up database, restore the database.

Backing up the database (297)

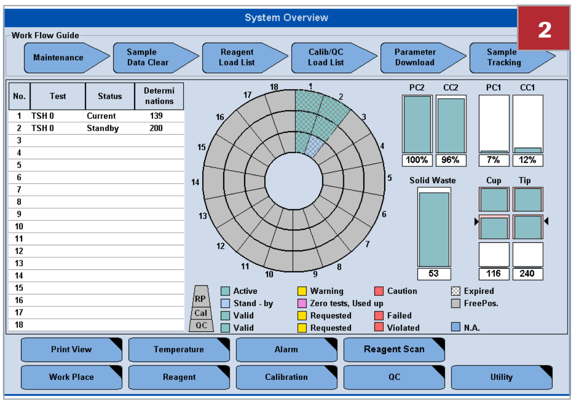
As-needed

5 minutes

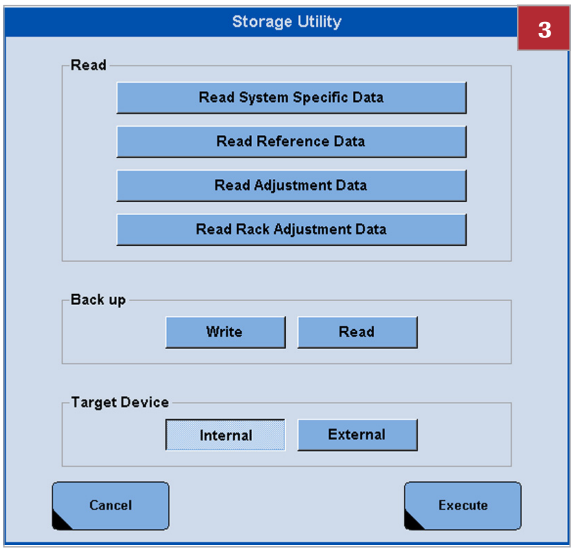
### To restore the database from a backup




1 To restore the database from a DVD-RAM disk or USB flash drive, connect the device to the Service port at the left of the analyzer.




2 From the **System Overview** window, choose **Utility > System > Storage Utility**.



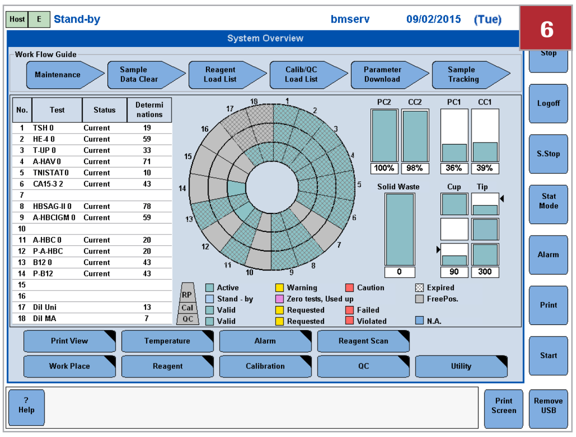

3 From the **Backup** group box, choose the **Read** button.

4 From the **Target Device** group box, choose to restore the database from an internal storage device or an external storage device.

- ℹ When the system reads data from the target storage device, it deletes all data on the device.

5 Choose the **Execute** button.

- ℹ The system restores the database, and then restarts. An error message is displayed if any files are missing from the backup, and the database cannot be restored.




6 To remove a USB flash drive, when the export is complete, perform the steps below.

- Choose the **Remove USB** button from the global buttons.
- Disconnect the USB flash drive from the Service port.

# Troubleshooting

# Troubleshooting analyzer problems

## In this chapter

13

# General analyzer problems

This chapter contains troubleshooting procedures for problems that affect the analyzer as a whole, including what to do if the analyzer does not power on.

Remedies are described for each problem. If you follow the recommended remedies, and your problem remains unresolved, call the Roche service representative.

Before you begin troubleshooting, print an alarm trace report to help you to resolve any known issues.

**Related topics**


- About data alarms (315)
- Chemistry problems (341)
- General troubleshooting (363)


## Mechanical problems and alarms


When a mechanical problem occurs within the analyzer, it immediately triggers an alarm. An audible alarm sounds, if enabled, and the alarm indicator on the global **Alarm** button lights. To display the alarm details, choose the global **Alarm** button. The **Alarm** window is displayed, listing all current alarms with the details below.

- Alarm code
- Date and time the alarm occurred
- Alarm description

Select an alarm to display more details, including a recommended remedy.

If a mechanical problem could affect the analyzer's performance, the system enters Stop or Sampling Stop mode. If the problem affects all samples, then the analyzer enters Stop mode, and all sample processing is immediately terminated.

If sample processing is unaffected by the failure, then the analyzer enters Sampling Stop mode, and already pipetted samples are processed. No more samples are pipetted until the problem is resolved.

⚠ **WARNING**

**Damage to the system or reporting of erroneous test results**

Certain analyzer problems may not cause the system to issue an alarm.

- Investigate all erroneous control measurements. Do not process samples until you have corrected the cause of the erroneous control measurement.
- If an analyzer problem occurs during operation, then perform a risk assessment before continuing to process samples.

**Related topics**


- Troubleshooting data problems (313)
- Troubleshooting chemistry problems (339)
- Unresolved problems (361)


# Analyzer does not power on

**Description** The analyzer does not switch on.

| Cause | Remedy |
|---|---|
| Analyzer is unplugged. | Connect the power cord to the analyzer, then plug it into a power socket. |
| Analyzer power switch is switched to OFF. | Switch the power switch to ON. |
| Circuit breaker (right side of analyzer) is in the OFF position. | Switch the circuit breaker to the ON position. |
| Rack sampler power cord is unplugged. | Connect the power cord to the rack sampler (left side). |
| A circuit in your laboratory circuit breaker is in the OFF position. | Ask the facility electrician to check the circuit breaker in the laboratory distribution box. |

Analyzer does not power on

**Related topics**


- Overview of the power components (48)
- Starting the system (97)


# Touchscreen monitor does not switch on

**Description**

The touchscreen monitor does not come on when the analyzer is switched on.

| Cause | Remedy |
|---|---|
| Monitor power switch is switched to OFF. | Switch the monitor power switch to ON. |
| Monitor cable is unplugged. | Firmly connect the monitor cable. |

Touchscreen monitor does not switch on

**Related topics**

- Overview of the control unit (45)

# Difficult to see content on the touchscreen monitor

**Description** It is difficult to see content on the touchscreen monitor.

| Cause | Remedy |
|---|---|
| Touchscreen monitor is dirty. | Wipe the touchscreen monitor surface with a dry cloth. |
| Ambient lighting is too bright. | • Reduce the brightness of ambient lighting.<br>• Turn the monitor face away from the light source. |

Difficult to see content on the touchscreen monitor

# Cannot access another software window

**Description** You cannot navigate to any other parts of the analyzer software.

| Cause | Remedy |
|---|---|
| Analyzer is still in Start Up mode. | Wait until the analyzer enters Standby mode. (The **E** icon in the Status Line at the top of the window turns green.) |
| A system error occurred. | Switch the circuit breaker to the OFF position, then the ON position. |

Cannot access another software window

**Related topics**

- Overview of the software (81)
- Starting the system (97)

# Reagent rotor cover does not open or close

**Description** It is difficult to open or close the reagent rotor cover.

| Cause | Remedy |
|---|---|
| Reagent rotor cover is incorrectly fitted. | The reagent rotor cover is keyed to help you fit it correctly. Reposition the cover to fit into the key. |
| An obstacle is stopping you from moving the reagent rotor cover. | Remove any objects from around the cover. |

Reagent rotor cover does not open or close

**Related topics**

- Replacing reagent packs (108)

# Sample disk does not move properly

**Description** During operation, the sample disk is not moving properly.

| Cause | Remedy |
|---|---|
| Sample disk is not seated correctly. | Remove and reposition the sample disk. |
| An obstacle is too close to the sample disk. | Remove any objects from around the sample disk. |

Sample disk does not move properly

# Problems replacing an AssayTip or AssayCup tray

**Description** You are having problems loading an AssayTip or AssayCup tray on to the gripper unit.

| Cause | Remedy |
|---|---|
| AssayTip/AssayCup tray is being incorrectly fitted. | AssayTip and AssayCup trays are keyed to help you fit them correctly. Remove and reposition the tray to fit into the key. |
| An obstacle is too close to the AssayTip/AssayCup tray. | Remove any objects from around the tray. |
| AssayTip/AssayCup tray is damaged or deformed. | Replace the tray. |

Problems replacing an AssayTip or AssayCup tray

**Related topics**

- Loading trays of AssayTips or AssayCups (181)

# Problems replacing the reagent pack

**Description** You are having problems placing a reagent pack correctly on the reagent rotor.

| Cause | Remedy |
|---|---|
| Reagent pack is being incorrectly fitted. | The reagent pack is keyed to help you fit it correctly. Remove and reposition the reagent pack to fit into the key. The transparent cap and barcode should be facing you. |
| An obstacle is underneath the reagent rotor. | Remove any objects from under the reagent rotor. |
| Reagent pack is damaged. | Replace the reagent pack. |

Problems replacing the reagent pack

**Related topics**

- Replacing reagent packs (108)

# Problems replacing a system reagent (ProCell or CleanCell)

**Description** You are having problems placing a ProCell or CleanCell bottle correctly on the analyzer.

| Cause | Remedy |
|---|---|
| System reagent bottle is being fitted incorrectly. | System reagent bottles are keyed to help you fit them correctly. Remove and reposition the bottle to fit into the key. |
| System reagent bottle is not in the correct position. | ProCell bottles must only be in positions 1 and 3, and CleanCell bottles in positions 2 and 4. Remove and reposition any bottles that are incorrectly placed. |
| An obstacle is underneath the system reagent bottle. | Remove any objects from under the bottle. |
| System reagent bottle is damaged or deformed. | • If the sides of the reagent bottle are bulging, try opening the cap before fitting the bottle.<br>• Replace the system reagent bottle. |

Problems replacing a system reagent (ProCell or CleanCell)

**NOTICE**

**Risk of damage to analyzer**

The analyzer can operate with only one set of ProCell and CleanCell bottles. The set of bottles must be positioned correctly to avoid erroneous results.

- Make sure that you use either of the following arrangements:
  - ProCell in position 1 and CleanCell in position 2
  - ProCell in position 3 and CleanCell in position 4

**Related topics**


- Replacing system reagents (110)


# Probes do not descend to the liquid surface

**Description** The S/R probe or sipper probe tip hovers above the sample.

| Cause | Remedy |
|---|---|
| Bubbles on surface of sample. | Remove any bubbles using an applicator stick. |
| An object touching the probe. | Remove any objects close to the probe. |
| Sample cup is incorrectly fitted. | Make sure that the sample cup is upright. |

Probes do not descend to the liquid surface

**Related topics**


- Loading routine and STAT samples with barcodes (173)
- Loading routine and STAT samples without barcodes (177)

# Bubbles in syringes

**Description** There are air bubbles in the S/R pipetter syringe or sipper pipette syringe.

| Cause | Remedy |
|---|---|
| Sipper pipetter syringe needs priming. | Prime the sipper pipetter syringe.<br>1. Choose **Utility > Maintenance > Maintenance**.<br>2. From the maintenance actions list, choose the **Sipper Pipetter Prime** option.<br>3. Choose the **Select** button.<br>4. In the **Sipper Pipetter Prime count** field, enter "10".<br>If air bubbles remain in the syringe, then repeat the process. |
| S/R pipetter syringe needs priming. | Prime the S/R pipetter syringe.<br>1. Choose **Utility > Maintenance > Maintenance**.<br>2. From the maintenance actions list, choose the **S/R Pipetter Prime** option.<br>3. Choose the **Select** button.<br>4. In the **S/R Pipetter Prime count :** field, enter "10".<br>If air bubbles remain in the syringe, then repeat the process. |

Bubbles in syringes

**Related topics**

- Overview of software-controlled maintenance actions (217)

# Solid waste tray does not come out or produces unusual sounds

**Description** It is difficult to remove the solid waste tray, or unusual sounds are coming from this area.

| Cause | Remedy |
|---|---|
| Solid waste tray or Clean-Liner is not seated correctly. | Reseat waste tray and Clean-Liner. |
| Stray AssayCups or AssayTips are behind the waste tray. | 1. Remove the solid waste tray.<br>2. Remove any stray AssayCups and AssayTips.<br>3. Return the solid waste tray with a new Clean-Liner. |

Solid waste tray does not come out or produces unusual noises

# Problems replacing the solid waste tray

**Description** You are having problems inserting the solid waste tray.

| Cause | Remedy |
|---|---|
| Clean-Liner does not fit properly. | Refit the Clean-Liner. Make sure that the sliding door of the solid waste tray is fully open. The opening must be towards the back of the analyzer. |
| Clean-Liner is damaged or bent. | Fit a new Clean-Liner. |
| An obstacle is blocking the solid waste tray. | Remove any obstacles close to the tray. |
| Solid waste tray is damaged or deformed. | Replace the solid waste tray. |

Problems replacing the solid waste tray

# Problems replacing the system water container

**Description** You are having problems fitting the system water container.

| Cause | Remedy |
|---|---|
| System water container is being incorrectly fitted. | Refit the system water container.<br>1. If necessary, lift the container out of its compartment.<br>2. Turn it so that the cap is closest to the back of the analyzer.<br>3. Return the container to its compartment.<br>4. Gently push down until it clicks into place. |
| An obstacle is too close to the system water container. | Remove any obstacles from around the container. |
| System water container is damaged or deformed. | Replace the system water container. |

Problems replacing the system water container

**Related topics**

- Cleaning and inspecting the valve of the system water container (250)

# Empty liquid waste container causes an alarm

**Description** A system alarm states that the liquid waste container is full even though it is empty.

| Cause | Remedy |
|---|---|
| An obstacle is triggering the alarm. | The liquid waste container sits on a tray with a sensor underneath. Remove any obstacles that are resting on the tray. They could be triggering the alarm. |

Empty liquid waste container causes an alarm

**Related topics**

- Cleaning and inspecting the valve of the system water container (250)

# Results do not print automatically

**Description** Test results are not printing automatically.

| Cause | Remedy |
|---|---|
| Printer is not switched on. | Switch on the printer. |
| Printer has run out of paper. | Make sure that there is enough paper in the printer tray. |
| Printer is not connected to analyzer. | Connect the printer to the USB port marked PRINTER (on the left side of the analyzer). |
| Automatic printing is not set up. | Make sure that automatic printing is set up correctly.<br>1. Choose **Utility > System > Page 2/3 > Documentation Setup**.<br>2. From the **Printer Connection** group box, choose the **Connected** button.<br>3. From the **Automatic Printout** group box, choose the **On** button next to each type of test that needs automatic printing. |

Results do not print automatically

**Related topics**

- Overview of the control unit (45)

# Troubleshooting data problems

## In this chapter

14

# About data alarms

If the system detects any irregular measuring results or conditions, it issues a data alarm. Data alarms do not automatically stop the analyzer. When a data alarm that will affect subsequent measurements is issued, the analyzer also issues a system alarm.

To view data alarms, view either of the dialog boxes below.

- **Workplace > Data Review**
- **Workplace > Data Review > Test Review**

Data alarms are also marked on the printed reports.

In each of these places, the analyzer displays data alarms with a flag, with up to six characters.

# Data alarm list

All data alarms are listed below. When a data alarm occurs, the alarm flag is displayed in the software and in printed reports.

| Flag | Alarm | Described on page |
|---|---|---|
| >AB | AB level range over | >AB (318) |
| >Curr | Measuring cell current range over | >Curr (318) |
| <SigL | Low-level signal | <SigL (319) |
| >Test | Measurement range (upper) | >Test (320) |
| <Test | Measurement range (lower) | <Test (320) |
| AB.E | AB level check error | AB.E (321) |
| ADC.E | ADC abnormal | ADC.E (321) |
| Cal.E | Calibration result abnormal | Cal.E (322) |
| Calc.? | Calculation not possible | Calc.? (322) |
| Cancel [Power Fail/Power Off Cancel] | Power Fail/Power Off Cancel | Cancel [Power Fail/Power Off Cancel] (323) |
| Cancel [E.STOP Cancel] | E.STOP Cancel | Cancel [E.STOP Cancel] (323) |
| Cancel [STOP Cancel] | STOP Cancel | Cancel [STOP Cancel] (324) |
| Cancel [P.STOP/A.STOP Cancel] | P.STOP/A.STOP Cancel | Cancel [P.STOP/A.STOP Cancel] (324) |
| Cancel [S.STOP Cancel] | S.STOP Cancel | Cancel [S.STOP Cancel] (325) |
| Cancel [Recovery Cancel] | Recovery Cancel | Cancel [Recovery Cancel] (325) |
| Cancel [Sample ID Error Cancel] | Sample ID Error Cancel | Cancel [Sample ID Error Cancel] (326) |
| CarOvr | Potential microparticle carryover | CarOvr (326) |
| Cell.T | Cell temperature | Cell.T (327) |
| ClcT.E | Calculated test error | ClcT.E (327) |
| Curr.E | Measuring cell current check | Curr.E (328) |
| FacA | Instrument factor A reset | FacA (328) |
| H | Outside of the expected value (upper) | H (328) |
| Inc.T | Incubator temperature | Inc.T (329) |
| L | Outside of the expected value (lower) | L (329) |
| ReagEx | Reagent expired | ReagEx (330) |
| Reag.F | Assay reagent film detected; Diluent film detected; Pretreatment film detected | Reag.F (330) |
| Reag.H | Assay reagent hovering; Diluent hovering; Pretreatment hovering | Reag.H (331) |
| Reag.S | Assay reagent short; Diluent short; Pretreatment short | Reag.S (332) |
| Reag.T | Abnormal reagent rotor temperature | Reag.T (332) |
| Samp.C | Sample clot | Samp.C (333) |
| Samp.S | Sample short | Samp.S (333) |
| SLLD.E | Sample LLD abnormal | SLLD.E (334) |
| SLLD.N | Sample LLD noise | SLLD.N (334) |

List of data alarms

| Flag | Alarm | Described on page |
|---|---|---|
| SysR.S | System reagent short | SysR.S (334) |
| SysR.T | System reagent temperature | SysR.T (335) |
| SysR.U | System reagent temperature unstable | SysR.U (335) |

List of data alarms

# Resolving data alarms

This section provides more information about each data alarm, including causes and remedies. If you follow the recommended remedies for an alarm and it remains or recurs, then contact your Roche Service representative.

## >AB

**Alarm** AB level range over

**Description** During run preparation, the ProCell count level was out of range (the ProCell signal was <200 or >400 counts).

**Cause** The ProCell has evaporated or may be contaminated.

**Remedy**

1. Replace each ProCell bottle that has air bubbles or a low liquid volume.
2. Rerun all affected samples.
3. If the alarm recurs, contact your Roche Service representative.

**Related topics**


- Replacing reagent packs (108)


## >Curr

**Alarm** Measuring cell current range over

**Description** The measuring cell current was out of range when checked during run preparation.

**Cause** Abnormal measuring cell condition.

**Remedy**

1. Perform the Liquid Flow Cleaning maintenance action.
   1) From the **System Overview** window, choose **Utility > Maintenance**.
   2) From the **Type** column, choose the **Maintenance** option.
   3) From the **Maintenance Items** column, choose **Liquid Flow Cleaning > Select**.
   4) In the **Liquid Flow Cleaning count** field, enter "1".
   5) Choose the **Start** button. The system returns to Standby mode.
2. Rerun all affected samples.
3. If the alarm recurs, contact your Roche service representative.

**Related topics**


- Cleaning the sipper probe system - Liquid Flow Cleaning (234)
- Overview of software-controlled maintenance actions (217)


# <SigL

**Alarm**

Low-level signal

**Description**

The signal is lower than the specified lower limit value encoded in the reagent pack barcode.

**Cause**

For qualitative and quantitative assays:

- The ProCell has expired.
- The calibrator solution did not reach room temperature.
- There is not enough reaction mixture in the AssayCup.
- There are clots in the reaction mixture.
- There is an abnormal measuring cell condition.

**Remedy**

1. Replace each ProCell bottle.
2. Rerun the affected sample.
3. If the alarm recurs, contact your Roche service representative.

**Cause**

For a competitive assay:

- The sample concentration is too high.

**Remedy**

1. Manually dilute the sample.
2. Rerun the sample.
3. If the alarm recurs, contact your Roche Service representative.

**Related topics**

- Replacing system reagents (110)
- Manually diluting a sample (162)

# >Test

**Alarm** Measurement range (upper)

**Description** The measured value is above the upper limit of the measuring range encoded on the reagent pack barcode.

**Cause** The sample concentration is too high.

**Remedy**

1. Manually dilute the sample.
2. Rerun the sample.
3. If the alarm recurs, contact your Roche Service representative.

The sample can be diluted using the recommended dilution factor given in the Method Sheet for each Test. You can request the dilution on the system. Then the system will dilute the sample accordingly and take the dilution into account when reporting the result.

**Related topics**

- Manually diluting a sample (162)

# <Test

**Alarm** Measurement range (lower)

**Description** The measured value is below the lower limit of the measuring range encoded on the reagent pack barcode.

**Cause** The sample concentration is too low. No sample result is reported.

**Remedy** Record the result as lower than the detection limit for the test. No rerun is required.

# AB.E

**Alarm** AB level check error

**Description** The ProCell levels check failed.

**Cause** There is not enough ProCell available for the selected tests.

**Remedy**

1. Check the amount of liquid in each ProCell bottle.
2. Replace each bottle that has a low volume.
3. Rerun all affected samples.
4. If the alarm recurs, contact your Roche Service representative.

**Related topics**

- Replacing system reagents (110)

# ADC.E

**Alarm** ADC abnormal

**Description** The analog-digital converter data is abnormal.

**Cause**

- Abnormal numerical conversion
- Abnormal cell count

**Remedy**

1. Correct any outstanding alarm conditions.
2. Perform the System Reset maintenance action.
   1) From the **System Overview** window, choose **Utility > Maintenance**.
   2) From the **Type** column, choose the **Maintenance** option.
   3) From the **Maintenance Items** column, choose **System Reset > Select**. All mechanical parts return to their home or standby positions.
3. If the alarm recurs, contact your Roche Service representative.

**Related topics**

- Overview of software-controlled maintenance actions (217)

# Cal.E

**Alarm** Calibration result abnormal

**Description** There is no valid calibration data in the system for the reagent pack and the new test.

Until you resolve the problem, the Cal.E alarm flag appears on each patient sample and control for the affected test.

**Cause**

- No calibration data is available for this test.
- The current calibration for a test has failed. Previous calibration data was used to calculate the result.
- This is seen if calibration masking is not set on the system.

**Remedy**

1. Perform calibration.
2. If calibration fails, replace reagent packs and calibrators as required. Recalibrate.
3. Rerun all samples for the affected test.

**Related topics**


- Replacing system reagents (110)
- Performing calibration (118)


# Calc.?

**Alarm** Calculation not possible

**Description** The denominator becomes zero during calculation.

**Cause** An internal calculation error occurred.

**Remedy** Rerun the sample.

# Cancel [Power Fail/Power Off Cancel]

**Alarm** Power failure - operation stopped

**Description** The test concerned was canceled by power fail or power off.

**Cause** The analyzer was powered off or there was a power failure.

**Remedy**

1. Resolve the problem that caused the power off or power failure.
2. Restart the analyzer.
3. Review the results printout.
4. Rerun any samples that were not measured.

**Related topics**

- Analyzer does not power on (306)

# Cancel [E.STOP Cancel]

**Alarm** E.STOP - operation stopped

**Description** The test concerned was canceled by E.Stop.

**Cause** The system performed an emergency stop (E.Stop) due to a hardware failure or because a safety device requested one.

**Remedy**

1. Resolve any outstanding problems.
2. Perform the System Reset maintenance action.
   1) From the **System Overview** window, choose **Utility > Maintenance**.
   2) From the **Type** column, choose the **Maintenance** option.
   3) From the **Maintenance Items** column, choose **System Reset > Select**. All mechanical parts return to their home or standby positions.
3. Review the results printout.
4. Rerun any samples that were not measured.

**Related topics**

- General analyzer problems (305)

# Cancel [STOP Cancel]

**Alarm** STOP - operation stopped by operator

**Description** Operation stopped by operator or the test concerned was canceled by Stop.

**Cause** The operator pressed the **Stop** button.

**Remedy**

1. Resolve any outstanding problems.
2. Perform the System Reset maintenance action.
   1) From the **System Overview** window, choose **Utility > Maintenance**.
   2) From the **Type** column, choose the **Maintenance** option.
   3) From the **Maintenance Items** column, choose **System Reset > Select**. All mechanical parts return to their home or standby positions.
3. Review the results printout.
4. Rerun any samples that were not measured.

**Related topics**

- General analyzer problems (305)
- Overview of software-controlled maintenance actions (217)
- Resolving data alarms (318)

# Cancel [P.STOP/A.STOP Cancel]

**Alarm** P.STOP/A.STOP - operation stopped

**Description** The test concerned was canceled by P.Stop.

**Cause** All system operations, including sample processing, were stopped because of a system alarm.

**Remedy**

1. Correct the system alarm condition.
2. Perform the System Reset maintenance action.
   1) From the **System Overview** window, choose **Utility > Maintenance**.
   2) From the **Type** column, choose the **Maintenance** option.
   3) From the **Maintenance Items** column, choose **System Reset > Select**. All mechanical parts return to their home or standby positions.
3. Review the results printout.
4. Rerun any samples that were not measured.

**Related topics**

- Overview of software-controlled maintenance actions (217)

# Cancel [S.STOP Cancel]

**Alarm** S.STOP - operation stopped

**Description** Operation stopped by operator or the test concerned was canceled by S.Stop.

**Cause** The system was put into sampling stop mode. No new samples were pipetted. Samples already pipetted were processed.

**Remedy**

1. Correct any outstanding alarm conditions.
2. Resume operation. Any remaining test samples will be pipetted and processed.

**Related topics**

- General troubleshooting (363)

# Cancel [Recovery Cancel]

**Alarm** Analyzer handling error - determination not performed

**Description** Determination not performed.

**Cause** The test was canceled because of an analyzer handling error.

**Remedy**

1. Review the results printout.
2. Rerun any samples that were not measured.

# Cancel [Sample ID Error Cancel]

**Alarm** Sample ID Error Cancel

**Description** Sample ID scanning was not successful.

**Cause** The ID of the sample scanned just before pipetting does not match the ID scanned before the test run. All tests for this sample were canceled.

**Remedy** Rerun any affected samples. Before removing a sample from the analyzer, check the status is complete.

To check the status access the **Workplace > Data Review** dialog box. The St column will show:

- O - Ordered
- P - Processing
- H or Blank - Sample complete
- I - Incomplete

**Related topics**

- Tracking samples (189)
- Finishing a run (186)

# CarOvr

**Alarm**

Potential microparticle carryover

**Description** The signal level of this sample is low.

**Cause** Carryover between tests.

**Remedy** Rerun the sample.

Do not rerun samples for the following assays:

- Qualitative assays that are negative.
- Quantitative assays that are below the lower limit of clinical decision.

**Related topics**

- Tracking samples (189)
- Finishing a run (186)

# Cell.T

**Alarm** Abnormal measuring cell temperature

**Description** Measuring cell temperature is out of range.

**Cause**

- Radiation of heat does not work normally.
- The room temperature is out of range.

**Remedy**

1. Verify temperature of ProCell/CleanCell on the analyzer.
2. Check that the fans at the back of the analyzer are operating normally.
3. Check that room temperature is between 18°C and 32°C.
4. Resume operation, rerun the sample.
5. If the alarm recurs, call Technical Support.

# ClcT.E

**Alarm** Calculated test error

**Description** Data flag is attached if one or both of two tests are flagged.

**Cause** A test calculation cannot be completed. Data alarms exist for one or both of the tests needed for the calculation.

**Remedy**

1. Correct any data alarms that exist for the two tests.
2. Perform calibration.
3. Rerun the sample.

**Related topics**


- Performing calibration (118)

# Curr.E

**Alarm** Measuring cell current check

**Description** The measuring cell current check failed.

**Cause**

- There is not enough ProCell for the selected test.
- There is a problem with the ProCell liquid level check.

**Remedy**

1. Check the amount of liquid in each ProCell bottle.
2. Replace each bottle that has a low volume.
3. Rerun all affected samples.
4. If the alarm recurs, contact your Roche Service representative.

**Related topics**


- Replacing system reagents (110)


# FacA

**Alarm** Instrument factor A reset

**Description** The instrument factor A was set to 1.0 by the system.

**Cause** For information only.

**Remedy** Contact a Roche Service Representative to perform BlankCell calibration.

# H

**Alarm** Outside of the expected value (upper)

**Description**

- For patient samples, the calculated concentration is greater than the upper limit of the expected value range.
- For control samples, a concentration exceeded the three SD values specified on **QC > Install**.

**Cause**

- The sample concentration is higher than the expected value for this test.
- The expected value range is incorrect.

**Remedy**

1. Follow laboratory protocol for high sample concentrations.
2. Set a proper value range.
   1) From the **System Overview** window, choose **Utility > Application > Range**.
   2) Update the range values in the **Expected Values** group box.

This sample alarm does NOT cause an incomplete sample status alarm.

**Related topics**

- Changing test settings (281)

# Inc.T

**Alarm** Abnormal incubator temperature

**Description** Incubator temperature is out of range.

**Cause**

- Radiation of heat does not work normally.
- The room temperature is out of range.

**Remedy**

1. Check that the fans at the rear are operating normally and are free of obstructions.
2. Check that room temperature is between 18°C and 32°C.
3. Resume operation, rerun the sample.
4. If the alarm recurs, call Technical Support.

# L

**Alarm** Outside of the expected value (lower)

**Description**

- For patient samples, the calculated concentration is less than the lower limit of the expected value range.
- For control samples, a concentration was less than the three SD values specified on **QC > Install**.

**Cause**

- The sample concentration is lower than the expected value for this test.
- The expected value range is incorrect.

**Remedy**

1. Follow laboratory protocol for low sample concentrations.
2. Set a proper value range.
   1) From the **System Overview** window, choose **Utility > Application > Range**.
   2) Update the range values in the **Expected Values** group box.

This sample alarm does NOT cause an incomplete sample status alarm.

**Related topics**

- Changing test settings (281)

# ReagEx

**Alarm** Reagent expired

**Description** An expired reagent was used for measurement.

**Cause** The analyzer detected an expired reagent.

**Remedy** This is an informational alarm. As the system accepts expired reagents, you can continue to test. To stop the alarm displaying:

1. Replace any expired reagents.
2. Rerun the test.

**Related topics**

- Replacing reagent packs (108)
- Validating QC results (152)

# Reag.F

**Alarm** Assay reagent film detected; Diluent film detected; Pretreatment film detected

**Description** Foam or film was detected above the reagent.

**Cause** Foam or film was detected above one of the following:

- Reagent
- Diluent
- Pretreatment reagent
- ProCell/CleanCell

**Remedy**

1. Check the reagent, diluent, pretreatment reagent, or ProCell/CleanCell for foam or air bubbles.
2. Remove any foam or bubbles using an applicator stick.
3. Rerun the sample.

# Reag.H

**Alarm** Assay reagent hovering; Diluent hovering; Pretreatment hovering

**Description** The reagent probe hovers over the reagent rotor.

**Cause** A premature liquid level detection (LLD) signal was detected during reagent pipetting, causing the S/R probe to hover over the reagent pack.

**Remedy**

1. Check the affected reagent pack.
2. Remove any bubbles using an applicator stick.
3. Dry the lids of the reagent pack.
4. Perform the System Reset maintenance action.
   1) From the **System Overview** window, choose **Utility > Maintenance**.
   2) From the **Type** column, choose the **Maintenance** option.
   3) From the **Maintenance Items** column, choose **System Reset > Select**. All mechanical parts return to their home or standby positions.
5. If the alarm recurs, contact your Roche Service representative.

**Related topics**

- Overview of software-controlled maintenance actions (217)

# Reag.S

**Alarm** Assay reagent short; Diluent short; Pretreatment short

**Description** The liquid level cannot be detected in the reagent pack.

**Cause**

- The reagent pack is empty.
- There is not enough reagent, diluent, or pretreatment for the selected test.

**Remedy**

1. Replace any assay reagent, diluent, or pretreatment that has a low volume. If reagents are replaced, perform a reagent scan.
2. Verify the reagent volumes. From the **System Overview** window, choose the **Reagent** tab. The **Remaining Determinations** column displays how much of each reagent is available.
3. Resume operation.
4. Rerun the sample.
5. If the alarm recurs, contact your Roche Service representative.

The system can be set to notify user when reagents are running low. Use the **Reagent Level Check** dialog box to trigger a caution alarm when the number of tests that has been set is reached. For example 10 or 20 tests left.

**Related topics**

- Replacing reagent packs (108)

# Reag.T

**Alarm** Abnormal reagent rotor temperature

**Description** Reagent rotor temperature is out of range.

**Cause**

- Radiation of heat does not work normally.
- The room temperature is out of range.

**Remedy**

1. Verify that the reagent rotor cover is securely in place.
2. Follow reagent handling procedures.
3. Check that the fans at the rear are operating normally and are free of obstructions.
4. Check that room temperature is between 18°C and 32°C.
5. Check the reagents on board by performing QC, then rerun the samples.
6. If the alarm recurs, call Technical Support.

# Samp.C

**Alarm** Sample clot

**Description** A sample clot is detected during aspiration.

**Cause**

- There is not enough liquid in the sample container.
- There are clots in the sample.

**Remedy**

1. Check the sample volume. If insufficient, fill the sample container to the required level.
2. Remove any fibrin clots.
3. Rerun the sample.

# Samp.S

**Alarm** Sample short

**Description** The sample volume is insufficient or missing.

**Cause**

- The sample is missing from the sample disk.
- There is not enough liquid in the sample container.

**Remedy**

1. Load the sample if it is missing.
2. Check the sample volume.
   - If insufficient, fill the sample container to the required level.
   - If sufficient, contact your Roche Service representative.
3. Rerun the sample.

# SLLD.E

**Alarm** Sample LLD abnormal

**Description** The S/R probe does not start liquid level detection (LLD) or LLD is not completed.

**Cause** The S/R probe is wet or dirty.

**Remedy**

1. Clean and dry the S/R probe.
2. Resume operation.
3. If the alarm recurs, contact your Roche Service representative.

**Related topics**

- Cleaning the sample and reagent probe (221)

# SLLD.N

**Alarm** Sample LLD noise

**Description** The S/R probe detects noise.

**Cause** There are bubbles in the sample container.

**Remedy**

1. Remove any bubbles using an applicator stick.
2. Rerun the sample.

# SysR.S

**Alarm** System reagent short

**Description** Liquid short signal is detected, or the liquid level cannot be detected in the ProCell reservoir.

**Cause** There is not enough ProCell and CleanCell for the selected test.

**Remedy**

1. Check there is enough liquid in each ProCell/CleanCell bottle.
2. Replace each bottle that has a low volume.
3. Rerun all affected samples.
4. If the alarm recurs, contact your Roche Service representative.

The system reagents should be checked and replaced at the beginning of the day if necessary. The ProCell and CleanCell will move between sets when one set is empty. If no other set is setup on system, then the analyze issues a Stop alarm and the system stops.

**Related topics**

- Replacing system reagents (110)

# SysR.T

**Alarm** Abnormal system reagent temperature

**Description** ProCell/CleanCell temperature is out of range.

**Cause**

- Radiation of heat does not work normally.
- The room temperature is out of range.

**Remedy**

1. Verify temperature of ProCell/CleanCell on the analyzer.
2. Check that the fans at the back of the analyzer are operating normally.
3. Check that room temperature is between 18°C and 32°C.
4. Check ProCell/CleanCell by performing QC, then rerun the samples.
5. If the alarm recurs, call Technical Support.

# SysR.U

**Alarm** System reagent temperature unstable

**Description** System reagent temperature unstable.

**Cause** The ProCell/CleanCell is not at 28 °C.

**Remedy** Ensure the ProCell/CleanCell reaches 28 °C. Try placing the reagent on the analyzer 15 minutes before operation.

# Data problems without alarms

This section provides more information about common data problems that do not generate alarms. Try following the recommended remedies for your problem. If it remains unresolved, contact your Roche Service representative.

## Result data drift

**Cause** Either the sample or standard solution has deteriorated or evaporated.

**Remedy** Rerun the sample. Minimize the time the sample is left in the sample cup.

## Incorrect operation

**Cause**

- Daily checks and maintenance actions are not being completed.
- There are clots in the sample.
- There is dust in the reagent.
- The recommended sample container was not used.

**Remedy**

1. Complete all daily checks and overdue maintenance actions.
2. Remove any fibrin clots from the sample.
3. Remove any dust from the reagent.
4. Use the recommended sample container.

**Related topics**

- Overview of maintenance actions (215)

## Poor reproducibility

**Cause**

- A maintenance action is overdue.
- Reagent handling procedures were not followed.
- The reagent has deteriorated or contains insoluble matter.
- The ProCell or CleanCell has deteriorated.
- Poor quality distilled water has been used.

**Remedy**

1. Complete all daily checks and overdue maintenance actions.
2. Follow reagent handling procedures.
3. Replace the reagent pack.
4. Replace ProCell or CleanCell bottles.
5. Check the distilled water quality. It must be 10 µS/cm (microsiemens per cm) or less.

Reagent packs are guaranteed onboard until the onboard expiry time has been reached. The onboard expiry time is test-dependent and can be anything from 1 week to 12 weeks.

ProCell and CleanCell are guaranteed for 72 hours onboard with the caps open.

**Related topics**


- Overview of maintenance actions (215)
- Replacing reagent packs (108)
- Replacing system reagents (110)


# Results are too high

**Cause**

- Reagent, control, and sample handling procedures were not followed.
- The sample or control concentration is too high.
- The ProCell or CleanCell has deteriorated.

**Remedy**

1. Follow reagent, control, and sample handling procedures.
2. Replace the ProCell or CleanCell bottles.
3. If the sample has been loaded for more than two hours, rerun the test with a fresh sample.

**Related topics**


- Replacing system reagents (110)


# Results are too low

**Cause**

- Reagent handling procedures were not followed.
- The ProCell or CleanCell has deteriorated.

**Remedy**

1. Follow reagent handling procedures.
2. Replace the ProCell or CleanCell bottles.
3. Rerun the affected tests.

**Related topics**

- Replacing system reagents (110)

# Problems with a single test

**Cause**

A control has not been prepared or setup correctly, which causes high or low results.

**Remedy**

1. Prepare a new control.
2. Replace the reagent pack.

**Related topics**

- Replacing system reagents (110)
- Preparing controls (138)

# Problems with all tests

**Cause**

- There are air bubbles in the S/R probe or sipper syringe, which causes poor reproducibility.
- Liquid is leaking from the sample or reagent syringe coupling, which causes poor reproducibility.
- The ProCell or CleanCell has deteriorated.
- The electrode in the measuring cell is contaminated or has deteriorated.

**Remedy**

1. Complete all daily checks and overdue maintenance actions.
2. Replace the ProCell or CleanCell bottles.
3. Perform the Liquid Flow Cleaning maintenance action.
   1) From the **System Overview** window, choose **Utility > Maintenance**.
   2) From the **Type** column, choose the **Maintenance** option.
   3) From the **Maintenance Items** column, choose **Liquid Flow Cleaning > Select**.
   4) In the **Liquid Flow Cleaning count** field, enter "1".
   5) Choose the **Start** button. The system returns to Standby mode.
4. If the problem recurs, contact your Roche Service representative.

**Related topics**

- Overview of maintenance actions (215)
- Replacing system reagents (110)

# Troubleshooting chemistry problems

## In this chapter

15

# Chemistry problems

All of the following issues can be indicators of a chemistry problem:

- Patient or control samples that generate data alarms
- Calibration failures
- Control sample results that are outside the expected range
- Unexpected test results

Before you start troubleshooting chemistry problems, print an alarm trace report to help you to resolve any known issues. Also, make sure that you have completed all recommended maintenance.

As not all chemistry problems generate alarms, you may need to use the following information to pinpoint, and resolve problems:

- Calibration documentation
- QC results
- Patient test results
- Checklists and remedies in this chapter

**Related topics**


- About data alarms (315)
- General troubleshooting (363)
- Resolving data alarms (318)
- General analyzer problems (305)
- Problems with reagents, calibrators, controls, and samples (342)
- Problems with test results (349)
- Problems with calibration and controls (354)
- Problems with dilution (360)

# Problems with reagents, calibrators, controls, and samples

High, low, or erratic test results do not always generate alarms. Use the checklists in this section to identify whether incorrect reagent, calibrator, control, or sample handling is the reason for unexpected test results.

**⚠ CAUTION**

**Incorrect handling of reagents**

Incorrect handling of reagents or other consumables may lead to incorrect results.

- Do not use reagents that were exposed to heat or to light for an extended time.
- Do not use reagents that have expired.
- Adhere to the storage conditions defined in the Instructions for Use for the reagents, controls, and consumables. Do not store reagents below 2 °C as the microbeads should not be frozen.
- Do not use reagents or consumables that have been dropped on the floor or compromised in any other way.
- Do not manipulate supplies in any way not specified in the user documentation or Instructions for Use.

**⚠ CAUTION**

**Foam, clots, films, or bubbles**

Incorrect results may occur due to foam, fibrin clots, films, or bubbles in reagents or samples.

- Ensure good sample preparation and reagent-handling techniques to avoid the formation of foam, clots, and bubbles in all reagents, samples, and controls.

**⚠ CAUTION**

**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 Instructions for Use for the test.
- Observe the information given in the 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 and apply a disinfectant. Then, consult a physician.

**In this section**

# Reagent-handling checklist

Use this checklist to make sure that reagents have been handled correctly.

- Has the catalog number changed?
- Have the reagent lot numbers changed?
- Do the lot numbers on the loaded reagents match the lot numbers displayed on the Reagent Detail window?
- Were the reagent packs stored correctly? Reagent packs should be stored in an upright position at between 2-8 °C.
- Were reagent packs allowed to reach the rotor temperature (20 ± 3 °C) before starting the test run?
- Have any of the reagent packs expired?
- Were the reagent packs, after opening, within allowed stability limits?
- Were the ProCell/CleanCell bottles closed overnight to prevent evaporation?
- Were system reagents replaced correctly? Move partly consumed bottles from Set 2 to Set 1 (on the right) before a new set of bottles is added.
- Was there any foam on the surface of the reagents?
- Were there any air bubbles in the S/R pipetter syringe or sipper probe syringe?

**Related topics**


- Replacing reagent packs (108)
- Replacing system reagents (110)
- General analyzer problems (305)

# Calibrator-handling checklist

Use this checklist to make sure that calibrators have been prepared and handled correctly.

- Has the calibrator lot number changed?
- Has the calibrator lot expired? Do not use expired calibrators.
- Were calibrators stored correctly? Check the details on the package insert.
- If calibrators were reconstituted, was the correct liquid volume used? Check the details on the package insert.
- Has the reconstitution material expired?
- Was fresh, bacteria-free, deionized water used for the reconstitution?
- Were volumetric pipettes used, where appropriate?
- Were the lyophilized calibrators dissolved carefully?
- Was there any foam on the surface of the calibrators?
- Was enough time allowed for reconstitution?
- After adding 1 mL of deionized water, were reconstituted calibrators allowed to stand closed for the recommended time?
- Were all calibrators allowed to reach room temperature before starting the analyzer?
- Were calibrators, after opening, within allowed stability limits?
- Were calibrators transferred to the correct CalSet barcoded vials?
- Were the calibrators on the analyzer for longer than the recommended time? Check the details on the package insert.
- Were there any droplets on the CalSet cap?
- Was there any crystallized material on the CalSet cap? Replace the affected vial.

**Related topics**

- Performing calibration (118)
- Performing QC (138)

# Control-handling checklist

Use this checklist to make sure that controls have been prepared and handled correctly.

- Has the control lot number changed?
- Has the control lot expired?
- Were controls stored correctly? Check the details on the package insert.
- If controls were reconstituted, was the correct liquid volume used? Check the details on the package insert.
- Has the reconstitution material expired?
- Was fresh, bacteria-free, deionized water used for the reconstitution?
- Were volumetric pipettes used, where appropriate?
- Were the lyophilized controls reconstituted as per package insert?
- Was enough time allowed for reconstitution?
- Was there any foam on the surface of the controls?
- Were controls, after opening, within allowed stability limits?
- Were controls transferred to the correct barcoded vials?
- Were there any droplets on the control vial cap?
- Was there any crystallized material on the control vial cap? Replace the affected vial.
- Were the controls aliquoted and frozen? Controls such as PreciControl Universal, Cardiac, and Tumor Marker should be aliquoted and frozen.

**Related topics**

- Performing calibration (118)
- Performing QC (138)

# Sample-handling checklist

For problems with a single sample:

- Can the problem be reproduced?
- Was the sample volume sufficient? Did the sample container have an adequate residual volume?
- Was sample quality maintained? Check the sample for fibrin, hemolysis, icterus, or lipemia.
- Was the correct type of sample used for the test, for example, serum, plasma, urine, or saliva?
- Was the recommended sample container used?
- Was the sample stability within the specified range? Check the details on the package insert.
- Was the sample material prepared correctly? Allow 30 minutes for clotting, and centrifuge samples before loading them.
- Were there any precipitates in the sample? Before testing, samples containing precipitates must be centrifuged at a minimum of 2500 rpm for 10 minutes. Use either primary samples tubes or sample cups.
- Were there air bubbles or foam on the surface of the sample?
- Was the sample placed correctly on the rack or sample disk?

For problems with a single test:

- Were all calibrators allowed to reach room temperature before starting the analyzer?
- Were calibrators prepared correctly?
- Have any reagents expired?
- Were the calibrators in use within stability limits?
- Have the reagent lot numbers changed?
- Do the lot numbers of the loaded reagents match the lot numbers displayed on the Reagent Detail window?

**Related topics**

- Loading routine and STAT samples with barcodes (173)
- Calibrator-handling checklist (345)
- Reagent-handling checklist (344)

# System water-handling checklist

Use this checklist to make sure that the system water has been maintained correctly.

- Was deionized water with a conductivity of 10 µS/cm or less used?
- Was the system water container refilled carefully with deionized water and SysWash to avoid creating air bubbles?
- Was the correct amount of SysWash (35 mL) added to the container?

**Related topics**

- Cleaning and inspecting the valve of the system water container (250)

# Diluent-handling checklist

Use this checklist to make sure that diluents have been handled correctly.

- Has the diluent expired?
- Was the correct diluent used for the test?
- Was the diluent, after opening, within allowed stability limits?
- Was the recommended dilution ratio used?
- After dilution, was the solution concentration still within the specified linearity?

**Related topics**

- Manually diluting a sample (162)

# Problems with test results

This section describes causes and remedies for test results that are outside the expected range.

If you follow the recommended remedies, and your problem remains unresolved, call the Roche Service representative. Make sure that you have completed all recommended maintenance before you start troubleshooting.

## Test results are too high or too low

**Description** Test results are below the detection limit or above the upper limit of the measuring range.

| Cause | Remedy |
|---|---|
| Foam on the surface of a:<br>• Sample<br>• Reagent pack<br>• System reagent (ProCell/CleanCell)<br>• Control | Remove any foam or bubbles using an applicator stick. |
| Reagent pack stressed because it was stored or transported incorrectly. | Follow all storage and transport-handling recommendations for reagent packs (on the package insert). For example, reagent packs should be stored in an upright position at between 2-8 °C. |
| Air bubbles in the system water container. | Refill the system water container.<br>1. Empty the system water container.<br>2. Rinse the container with tap water, then deionized water.<br>3. Refill the container with deionized water and 35 mL of SysWash. Pour in the SysWash slowly to avoid creating air bubbles. |
| Dirt on the gripper leads to sample contamination. | Clean the incubator and aspiration station. |
| Unstable system table. | Adjust the legs of the system table. |
| Recommended sample container was not used. | Use the recommended sample container. |
| Reagent, calibrator, and control-handling procedures were not followed. | Follow all reagent, calibrator, and control-handling procedures (on the package insert). |

Test results are too high or too low

**Related topics**


- Problems with reagents, calibrators, controls, and samples (342)
- Cleaning and inspecting the valve of the system water container (250)
- Cleaning the incubator and aspiration station (229)

# Drift in sample or control results

**Description** Sample or control results show drift over time.

| Cause | Remedy |
|---|---|
| Evaporation of a:<br>• Reagent pack<br>• System reagent (ProCell/CleanCell)<br>• Control | Replace any reagent pack, system reagent bottle (ProCell/CleanCell), or control that has a low volume. |
| Reagent pack, system reagent (ProCell/CleanCell), or controls were stored or transported incorrectly. | Follow all storage and transport-handling recommendations for reagent packs, system reagents, or controls (on the package insert). For example, reagent packs should be stored in an upright position at between 2-8 °C. |
| Reagent pack temperature is incorrect. | Before starting a test run, allow any new reagent packs to reach rotor temperature (20 ± 3 °C). |
| Correct calibration intervals have not been maintained. | Follow the recommended calibration intervals (on the package insert). |
| Reagent, calibrator, and control-handling procedures were not followed. | Follow all reagent, calibrator, and control-handling procedures (on the package insert). |

Drift in sample or control results

**Related topics**


- Problems with reagents, calibrators, controls, and samples (342)
- Replacing reagent packs (108)
- Replacing system reagents (110)
- Loading controls (140)
- Performing calibration (118)


# Erratic test results

**Description** Test results are inconsistent/erratic.

| Cause | Remedy |
|---|---|
| Foam on the surface of a:<br>• Sample<br>• Reagent pack<br>• System reagent (ProCell/CleanCell)<br>• Control | Remove any foam or bubbles using an applicator stick. |
| Reagent pack stressed because it was stored or transported incorrectly. | Follow all storage and transport-handling recommendations for reagent packs (on the package insert). For example, reagent packs should be stored in an upright position at between 2-8 °C. |
| Recommended sample container was not used. | Use the recommended sample container. |
| Reagent, calibrator, or control-handling procedures were not followed. | Follow all reagent, calibrator, and control-handling procedures (on the package insert). |

Erratic test results

**Related topics**

- Problems with reagents, calibrators, controls, and samples (342)
- Overview of the analyzer unit (25)

# Intra assay precision

**Description** The variation between results for the same test is outside the expected range.

| Cause | Remedy |
|---|---|
| Reagent packs or samples are at the incorrect temperature. | • Before starting a test run, allow any new reagent packs to reach rotor temperature (20 ± 3 °C). |
| Foam on surface of the assay reagent. | Remove any foam or bubbles using an applicator stick. |
| Air bubbles in the system water container. | Refill the system water container.<br>1. Empty the system water container.<br>2. Rinse the container with tap water, then deionized water.<br>3. Refill the container with deionized water and 35 mL of SysWash. Pour in the SysWash slowly to avoid creating air bubbles. |
| Reagent, calibrator, or control-handling procedures were not followed. | Follow all reagent, calibrator, and control-handling procedures (on the package insert). |

Intra assay precision

**Related topics**

- Problems with reagents, calibrators, controls, and samples (342)
- Cleaning and inspecting the valve of the system water container (250)

# Inter assay precision

**Description** The variation between results for different tests is outside the expected range.

| Cause | Remedy |
|---|---|
| Reagent packs or samples are at the incorrect temperature. | Before starting a test run, allow any new reagent packs to reach rotor temperature (20 ± 3 °C). |
| Foam on surface of the assay reagent. | Remove any foam or bubbles using an applicator stick. |
| Reagent pack was stored or transported incorrectly. | Follow all storage and transport-handling recommendations for reagent packs (on the package insert). For example, reagent packs should be stored in an upright position at between 2-8 °C. |
| Calibration was not performed correctly. | Recalibrate, following instructions carefully. |

Inter assay precision

| Cause | Remedy |
|---|---|
| Correct calibration intervals have not been maintained. | Follow the recommended calibration intervals (on the package insert). |
| Air bubbles in the system water container. | Refill the system water container.<br>1. Empty the system water container.<br>2. Rinse the container with tap water, then deionized water.<br>3. Refill the container with deionized water and 35 mL of SysWash. Pour in the SysWash slowly to avoid creating air bubbles. |
| Reagent, calibrator, or control-handling procedures were not followed. | Follow all reagent, calibrator, and control-handling procedures (on the package insert). |

Inter assay precision

**Related topics**


- Replacing reagent packs (108)
- Cleaning and inspecting the valve of the system water container (250)
- Performing calibration (118)
- Performing QC (138)
- Problems with reagents, calibrators, controls, and samples (342)


# Measuring differences between systems

**Description** Control and sample results vary when measured on different systems.

| Cause | Remedy |
|---|---|
| Calibration was not performed correctly. | Recalibrate, following instructions carefully. |
| Reagent, calibrator, or control-handling procedures were not followed. | Follow all reagent, calibrator, and control-handling procedures (on the package insert). |

Measuring differences between systems

**Related topics**


- Performing calibration (118)
- Performing QC (138)
- Problems with reagents, calibrators, controls, and samples (342)
- Data problems without alarms (336)

# Method differences between systems

**Description** Test results vary when measured on competitor's analyzers.

| Cause | Remedy |
|---|---|
| System to system variance. | Not applicable. |
| Different measuring standards are used. | Not applicable. |
| Different antibodies are used, for example, HCG on Elecsys. | Not applicable. |
| Different units are used. Competitors may use different conversion factors between units. | Not applicable. |
| Different sample material ± anticoagulants. | Not applicable. |
| Correct calibration intervals have not been maintained. | Follow the recommended calibration intervals (on the package insert). |
| Calibrator-handling procedures were not followed. | Perform a new calibration for the test using a new CalSet. Follow all calibrator-handling procedures carefully (on the package insert). |
| Insufficient test results to make a valid comparison. | • Compare larger sets of sample results.<br>• Compare sets of samples with a wider range of results. |
| Reagent lot to lot variance. | Keep the same reagent lot. |
| Reagent, calibrator, or control-handling procedures were not followed. | Follow all reagent, calibrator, and control-handling procedures (on the package insert). |

Method differences between systems

**Related topics**


- Performing calibration (118)
- Performing QC (138)
- Problems with reagents, calibrators, controls, and samples (342)

# Problems with calibration and controls

This section describes causes and remedies for calibration and control results that are outside the expected range.

If you follow the recommended remedies, and your problem remains unresolved, contact your Roche Service representative. Make sure that you have completed all recommended maintenance before you start troubleshooting.

## Calibration has not been performed

**Description** Calibration measurements have not been requested or cannot be taken.

| Cause | Remedy |
|---|---|
| Calibration has not been requested. | Request calibration.<br>1. Choose the global **Start** button.<br>2. Check the settings on the **Start Conditions** dialog box. Make any necessary adjustments.<br>3. Choose the global **Start** button. The previous window is displayed and the calibration and control run begins. |
| Calibrator has not been loaded. | 1. Print and check the Calib/QC load list.<br>2. Load any missing calibrators.<br>3. Make sure that all manually assigned calibrators are in the correct positions. |
| Reagent pack has not been loaded. | 1. Print and check the reagent load list.<br>2. Load any missing reagent packs. |
| Calibrator has expired. | Replace any expired calibrators. |
| Barcodes on the calibrator vial, calibrator lot-specific barcode card, or reagent pack cannot be read. | • Make sure that none of the barcodes are damaged or in the incorrect position.<br>• Make sure that calibrator vials are dry.<br>• Wipe the surface of the barcode reader to remove any dust. |
| Incorrect barcode card has been scanned. | Make sure that the barcode card is from the correct calibrator kit. |
| No data links the reagent pack and CalSet combination. | • Check Product Notification for generation changes.<br>• Ensure correct Calset information is listed.<br>• Replace Calset and Reagent with newer lots. |
| Cal1 and Cal2 vials from the same CalSet are not on the same rack or are not next to each other. | Position the CalSet vials so that they are next to each other on a sample rack, or on the sample disk. |
| A diluent (for example, CA15-3) has not been loaded. | 1. Print and check the Reagent Load List.<br>2. Load any missing diluents. |

Calibration has not been performed

**Related topics**

- Performing calibration (118)
- Printing a Calib/QC load list (117)
- Printing a reagent load list (107)
- Loading calibrators (120)
- Replacing reagent packs (108)

# Duplicates are outside of limits

**Description** Calibration failed because the results for duplicate calibrations were outside the set limits.

| Cause | Remedy |
|---|---|
| Foam on surface of the calibrator or assay reagent. | Remove any foam or bubbles using an applicator stick. |
| Calibrator-handling procedures were not followed. | Perform a new calibration for the test using a new CalSet. Follow all calibrator-handling procedures carefully (on the package insert). |
| Air bubbles in the system water container. | Refill the system water container.<br>1. Empty the system water container.<br>2. Rinse the container with tap water, then deionized water.<br>3. Refill the container with deionized water and 35 mL of SysWash. Pour in the SysWash slowly to avoid creating air bubbles. |
| Reagent and control-handling procedures were not followed. | Follow all reagent and control-handling procedures carefully (on the package insert). |

Duplicates are outside of limits

**Related topics**

- Performing calibration (118)
- Cleaning and inspecting the valve of the system water container (250)
- Problems with reagents, calibrators, controls, and samples (342)

# Monotony or minimum acceptable difference is not met

**Description** Calibration failed because values for monotony and minimum acceptable difference did not meet set limits.

| Cause | Remedy |
|---|---|
| Calibrators are in the incorrect vials. For example, the calibrator for Cal1 has been placed in the vials for both Cal1 and Cal2. | Perform a new calibration for the test using a new CalSet. Follow all calibrator-handling procedures carefully (on the package insert). |
| Vials without barcodes have been placed in incorrect positions on the sample rotor or rack. | 1. Print and check the Calib/QC load list.<br>2. Make sure that all manually assigned calibrators are in the correct positions. |
| Reagent and control-handling procedures were not followed. | Follow all reagent and control-handling procedures carefully (on the package insert). |

Monotony or minimum acceptable difference is not met

**Related topics**

- Performing calibration (118)
- Printing a Calib/QC load list (117)
- Assigning positions to calibrators (119)
- Problems with reagents, calibrators, controls, and samples (342)

# Missing calibration values

**Description** Calibration failed because there are missing calibration values.

| Cause | Remedy |
|---|---|
| Foam on surface of the calibrator. | Remove any foam or bubbles using an applicator stick. |
| One or more calibrator vials are empty or have a low volume. | Replace any calibrator vials that are empty or have a low volume. Follow instructions for preparing calibrators (on the package insert), and make sure each CalSet is complete. |
| Either a Cal1 or Cal2 vial is missing from a CalSet. | 1. Print and check the Calib/QC load list.<br>2. Load any missing calibrators. Make sure each CalSet is complete.<br>3. Make sure that all manually assigned calibrators are in the correct positions. |
| Cal1 and Cal2 vials from the same CalSet are not next to each other on a sample rack, or on the sample disk. | Position the CalSet vials so that they are next to each other on a sample rack, or on the sample disk. |

Missing calibration values

**Related topics**

- Printing a Calib/QC load list (117)
- Loading calibrators (120)
- Assigning positions to calibrators (119)

# Calibration values are outside of limits

**Description**

Calibration failed for one of the following reasons:

- The signal value was below the lower limit (for quantitative and qualitative assays).
- The signal difference between Cal1 and Cal2 vials was above the upper limit (for qualitative assays only).

| Cause | Remedy |
|---|---|
| Reagent pack stability, after opening, is not within allowed limits. | Replace the affected reagent pack. |
| Reagent pack has expired. | Replace any expired reagent packs. |
| Reagent pack stressed because it was stored or transported incorrectly. | Follow all storage and transport-handling recommendations for reagent packs (on the package insert). For example, reagent packs should be stored in an upright position at between 2-8 °C. |
| Reagent pack temperature is incorrect. | Before starting a test run, allow any new reagent packs to reach rotor temperature (20 ± 3 °C). |
| Foam on the surface of a:<br>• Reagent pack<br>• System reagent (ProCell/CleanCell)<br>• Calibrator | Remove any foam or bubbles using an applicator stick. |
| Calibrator stability, after opening and reconstituting, is not within allowed limits. | Replace the affected CalSet. |
| Calibrator has expired. | Replace any expired calibrators. |
| Calibrator-handling procedures were not followed. | Follow all calibrator-handling procedures carefully (on the package insert). |
| Calibrators are in the incorrect vials. For example, the calibrator for Cal1 has been placed in the vials for both Cal1 and Cal2. | Perform a new calibration for the test using a new CalSet. |
| Calibrator temperature is incorrect. | Before starting a test run, allow calibrators to reach room temperature. |
| Reagent and control-handling procedures were not followed. | Follow all reagent and control-handling procedures carefully (on the package insert). |

Calibration values are outside of limits

**Related topics**


- Replacing reagent packs (108)
- Loading calibrators (120)
- Performing calibration (118)
- Problems with reagents, calibrators, controls, and samples (342)

# Factor is outside of limits

**Description**

Calibration failed because factor measurements for reagent packs were outside the set limits.

Only quantitative assays are affected.

| Cause | Remedy |
|---|---|
| Reagent pack stability, after opening, is not within allowed limits. | Replace the affected reagent pack. |
| Reagent pack has expired. | Replace any expired reagent packs. |
| Reagent pack stressed because it was stored or transported incorrectly. | Follow all storage and transport-handling recommendations for reagent packs (on the package insert). For example, reagent packs should be stored in an upright position at between 2-8 °C. |
| Reagent pack temperature is incorrect. | Before starting a test run, allow any new reagent packs to reach rotor temperature (20 ± 3 °C). |
| Foam on the surface of a:<br>• Reagent pack<br>• System reagent (ProCell/CleanCell)<br>• Calibrator | Remove any foam or bubbles using an applicator stick. |
| Calibrator stability, after opening and reconstituting, is not within allowed limits. | Replace the affected CalSet. |
| Calibrator has expired. | Replace any expired calibrators. |
| Calibrator-handling procedures were not followed. | Follow all calibrator-handling procedures carefully (on the package insert). |
| Calibrators are in the incorrect vials. For example, the calibrator for Cal1 has been placed in the vials for both Cal1 and Cal2. | Perform a new calibration for the test using a new CalSet. |
| Calibrator temperature is incorrect. | Before starting a test run, allow calibrators to reach room temperature. |

Factor is outside of limits

**Related topics**


- Replacing reagent packs (108)
- Loading calibrators (120)
- Problems with reagents, calibrators, controls, and samples (342)
- Performing calibration (118)

# Control values are outside of range

**Description** Control values are above or below the measuring range for this test.

| Cause | Remedy |
|---|---|
| Controls are at incorrect temperature. | Controls should be at room temperature before measurement. |
| Controls are not within allowed stability limits. | Replace the affected controls. |
| One or more controls have expired. | Replace any expired controls. |
| Foam on the surface of a:<br>• Reagent pack<br>• System reagent (ProCell/CleanCell)<br>• Controls | Remove any foam or bubbles using an applicator stick. |
| Control-handling procedures were not followed. | Follow all control-handling procedures carefully (on the package insert). |
| Reagent packs are at incorrect temperature. | Before starting a test run, allow any new reagent packs to reach rotor temperature (20 ± 3 °C). |
| Reagent packs are not within allowed stability limits. | Replace the affected reagent packs. |
| Reagent pack has expired. | Replace any expired reagent packs. |
| Reagent pack was stored incorrectly. | Follow all storage and transport-handling recommendations for reagent packs (on the package insert). For example, reagent packs should be stored in an upright position at between 2-8 °C. |
| Correct calibration intervals have not been maintained. | Follow the recommended calibration intervals (on the package insert). |
| Calibration was not performed correctly. | Recalibrate, following instructions carefully. |

Control values are outside of range

**Related topics**


- Loading calibrators (120)
- Loading controls (140)
- Replacing reagent packs (108)
- Problems with reagents, calibrators, controls, and samples (342)
- Performing calibration (118)
- Performing QC (138)

# Problems with dilution

This section describes a specific cause and remedy for when auto dilution is not working.

If you follow the recommended remedy, and your problem remains unresolved, then contact your Roche service representative.

## Auto dilution is not working

**Description**

Auto dilution is not being performed even though the correct diluent is loaded on the analyzer.

| Cause | Remedy |
| --- | --- |
| Elecsys Universal diluent bottle or Elecsys Diluent MultiAssay reagent pack has been incorrectly placed on the reagent rotor. | Position the Elecsys Universal diluent bottle or Elecsys Diluent MultiAssay reagent pack so that the **cobas e** 411 analyzer (Elecsys) barcode is read.<br>(If the diluent bottle or reagent pack is positioned incorrectly, the MODULAR ANALYTICS barcode can be read. This stops auto dilution.) |

Auto dilution is not working

**Related topics**

- Changing test settings (281)

# Unresolved problems

In this chapter 16

# General troubleshooting

This chapter provides advice on what to do when you have attempted to troubleshoot a problem but the problem remains unresolved.

As part of basic troubleshooting, you should have reviewed all alarms, and attempted to isolate and correct the problem using the following information.

**Related topics**


- Chemistry problems (341)
- About data alarms (315)
- General analyzer problems (305)

# Contacting your Roche service representative

If you cannot resolve an analyzer problem or need further advice when troubleshooting, then contact your Roche service representative. Be prepared with the information outlined in the following checklists. You can use the Technical support information form to record all information related to a problem.

Technical support information form (367)

**In this section**



## General information checklist

Provide the information listed below for all types of problems.

- Account number / customer ID number
- A contact name and telephone number
- Analyzer serial number
- Software version
- Description of the problem including relevant alarms
- When did the problem first occur, for example, after a reagent pack lot was changed?
- Does the same problem occur on different systems?
- Copies of any printouts that could be relevant. Send any printouts by e-mail or fax.

You should also perform a backup.

**Related topics**

- Overview of saving and restoring data (297)

# Chemistry problems checklist

Provide the following information for chemistry problems.

- Does the problem affect one or all tests?
- Which tests were affected, and which other tests were on board the analyzer at the same time?
- Does the problem affect one or all samples?
- Control results and ranges from recent QC tests
- Sample type: serum; plasma; urine; saliva
- Details for the type of sample tube that was used:
  - Manufacturer
  - Tube diameter
  - Was it a primary or secondary tube?
- Was SysWash added to the system water container?
- Elapsed time between specimen collection and measurement
- Details for the reagent pack that was used:
  - Catalog number
  - Lot number
  - Expiry date
- Details for the calibrators and controls that were used:
  - Catalog number
  - Lot number
  - Expiry dates
- Calibration signals (HetIA) from recent calibrations
- Reagent, calibration, and control-handling details
- When was the reagent loaded onto the analyzer?
- When did you last perform liquid flow cleaning?

**Related topics**

- Chemistry problems (341)
- Reagent-handling checklist (344)
- Calibrator-handling checklist (345)
- Control-handling checklist (346)

# Software problems checklist

Provide the following information for software problems.

- Details for the installed reagent packs:
  - Lot numbers
  - Sequence numbers
- Language installed
- Software version and date of installation
- Date when the analyzer was installed
- Version number of the reference data file
- Version number of the internationalization CD
- Complete set of backup files
- Any relevant screen captures, printouts, or descriptions.

**Related topics**

- Overview of saving and restoring data (297)

# Analyzer problems checklist

Provide the following information for analyzer problems.

- Are you using a rack or disk system?
- Analyzer maintenance and service history
- Is a host or Pre-Analytic Systems Manager (PSM) connected to the analyzer?
- Number of tests performed
- Any error codes or descriptions
- Print out of an alarm trace report
- Any other relevant maintenance or analyzer-related information

PSM is not available in all countries.

**Related topics**

- General analyzer problems (305)

# Technical support information form

| | |
|---|---|
| | Day/Month/Year: |
| *Customer information* | |
| Account number or customer ID number | |
| Contact name and telephone number | |
| *General information* | |
| Analyzer serial number | |
| Version number of the reference data file | |
| Version number of the internationalization CD | |
| Description of the problem, including relevant alarm(s) and alarm code numbers | |
| When the problem first occurred (for example after reagent lot pack change) | |
| Whether the problem was observed with just one system or with all systems | |
| Copies of the original analyzer printouts (sent by fax or email) | |
| *Problem category (check box)* | |
| Immunoassay problems | Complete the details below for Immunoassay problems |
| Software problems | Complete the details below for Software problems |
| Analyzer problems | Complete the details below for Analyzer problems |
| *Immunoassay problems* | *Details* |
| Whether the problem was observed with just one assay or with all assays | |
| Whether the problem was observed with just one sample type or with all sample types | |
| Control results and ranges from the last few controls performed | |
| Sample type used (serum, plasma, urine, or saliva) | |
| Sample tube used (manufacturer, diameter, primary or secondary tube) | |
| Elapsed time between specimen collection and measurement | |
| Patient results (with correlation results, if relevant) | |
| Test(s) affected and other tests on board | |
| Whether SysWash was added to the system water container | |
| Catalog number, lot numbers, and expiration dates of reagents | |
| Catalog number, lot numbers, and expiration dates of calibrators and controls | |
| Calibration signals (HetIA) from the last few calibrations performed | |
| Details of reagent/calibrator/control handling (such as calibration frequency, stability, ambient temperature, foam and evaporation) | |
| When the reagent was loaded onto the system | |
| When liquid flow cleaning was last performed | |
| *Software problems* | *Details* |
| The version of software installed | |

Technical support information form

| | |
|---|---|
| The lot and sequence numbers of the reagent packs | |
| The language currently installed | |
| Software version number and date of installation | |
| The date the analyzer was initially installed | |
| *Analyzer problems* | *Details* |
| Analyzer serial number | |
| Rack or disk system | |
| Analyzer maintenance and service history | |
| Whether a host or a Pre-Analytic Systems Manager (PSM) was connected | |
| Number of tests performed | |
| Other analyzer or maintenance related information | |
| Error code and error description | |
| Printout of the alarm trace report | |

Technical support information form

# Appendix

# Glossary

**2-dimensional barcode** A type of barcode on reagent packs, calibrators, and control barcode cards or sheets. These matrix barcodes, which use PDF417 symbology, contain more information than traditional linear barcodes.

**accuracy** The absolute deviation of a result from a pre-defined target value in percent or absolute units.

**adequate sample volume** A starting sample volume that exceeds the combination of the volume of sample. that will be required for assays and the residual volume specified for the container that holds the sample.

**air purge** The removal of air from the hydraulic tubing between the probes (reagent or sample) and their respective pipetters.

**alarm** A visual or audible operator notification of any system irregularity.

**alarm code** The classification number for an alarm. Each alarm has a major classification code and a minor classification code.

**alarm level** A level that identifies the source and severity of a problem. There are five levels: data alarm, warning, sampling stop, stop, and emergency stop. A system uses the alarm levels to determine how to respond to any problem that generates alarms.

**A-Line** A section of the input buffer where samples or racks are placed for processing.

**aliquot** Portion of sample material.

**alphanumeric sorting** The listing of information, in a printout or in the software, in a pre-defined order by letters or numbers.

**analyte** The constituent in the sample that is to be determined.

**analytical sensitivity** The lowest analyte concentration that can be distinguished from zero. It is calculated as the concentration of two or three standard deviations above the lowest standard used in the master calibration. Roche Diagnostics uses master calibrators to determine the lower detection limit (LDL).

**analytical unit** The hardware unit containing the sampling, reagent, incubator, gripper, and measuring cell components.

**analyzer** A device or a combination of devices used to carry out an analytical process.

**analyzer alarm** A displayed alarm that indicates an unusual analyzer condition, such as an abnormal reaction bath temperature or a mechanical malfunction. Also called system alarm.

**application sheet** A document that lists all the information necessary to perform a specific assay or test on an analyzer.

**arbitrary units** A result classification using 1+, 2+, and 3+ classes instead of numerical concentration results.

**ASCII** Abbreviation for American Standard Code for Information Interchange. A character code used by most computers.

**aspiration station** A position located next to the incubator. Here an AssayCup containing the reaction mixture is placed for aspiration into the measuring cell by the sipper probe.

**assay** This is either a specific test or the process of measuring a substance.

**AssayCup** A plastic vessel that is used to hold the assay reaction mixture. An alternative term is reaction vessel.

**AssayCup disposal opening** The opening to the left of the incubator where used AssayCups are transferred into the solid waste tray.

**AssayTip** A disposable pipette tip made of black, conductive plastic. AssayTips are used by the S/R probe.

**assigned value (Roche-defined)** Roche-defined concentration for calibrator material that is encoded on the calibrator barcode card or transfer sheet. See also target value.

**ASTM** Abbreviation for American Society for Testing and Materials, a US organization that develops and proposes industry standards.

**ASTM protocol** A host interface protocol according to the American Society for Testing Materials standard.

**Automated Download (ADL)** A service that provides the information necessary for analysis, for example analytical parameters or concentration information from the data center. ADL is a **cobas** TeleService application. See also TeleService.

**automatic calibration** :

1. Automatic time-out calibration. A calibration of a parameter performed if a specified time interval expires. The calibration can be defined for each method separately.
2. Automatic calibration after bottle or lot exchange. A calibration performed if a new bottle or lot is registered. The calibration can be defined for each method separately.
3. Automatic calibration on QC failure. A calibration request is generated by the system if a QC value is outside a pre-defined range. The calibration can be defined for each method separately.

**automatic QC** A quality control function that takes sample measurements by moving the dedicated QC rack to the sample line from the rack rotor.

**automatic start-up** The automatic start of analyzer or system initialization and priming functions without operator intervention. See also maintenance pipe.

**backup** :

1. The saving of data onto supplementary storage media such as disks or tape. If such data is required again but is no longer available from the main storage (analyzer hard disk), it can be restored from a backup copy.
2. An internal analyzer-specific process to establish the data for a backup; only used in a case of routine analyzer break down. See also restore.

**backup operation** A function that performs measurement using the analysis unit when a problem occurs in the rack sampler and a rack cannot be conveyed.

**bandwidth** :

1. A network's capacity to carry data.
2. Also used in optics to characterize a photometer.

**barcode** A numeric or alphanumeric code used on sample tubes, racks, and reagent packs to identify the samples, racks, and reagents. Different barcode standards are available. See also barcode type.

**barcode card** A card bearing a barcode that encodes either assigned values (calibrator card) or target values and ranges (control card) for assays.

**barcode labeler** A pre-analytical analyzer or module for the automatic labeling of sample tubes.

**barcode reader** The device that reads the code from sample or reagent barcode labels or reagent pack barcodes. This term also applies to handheld barcode readers.

**barcode scan** The process of reading barcode information into the memory of an analyzer.

**barcode type** Typical sample barcode types used in the IVD industry are Code 39, NW7 (Codabar), ITF, and Code 128.

**batch mode/operation** :

1. A computing technique in which a number of data transactions are collected over a period of time and aggregated for sequential processing at a given time.
2. The operation of an analyzer in such a way that one or more analytical processes must be completed for a sequence of samples before the next sequence can be started.

**batch registration** A function to register the test-selection information of a set of routine samples.

**baud** A unit of transmission speed equal to the number of discrete conditions or signal events per second.

**BC** Abbreviation for barcode.

**BC card scan** A scan to read the information from the two-dimensional calibrator barcode card or control barcode card.

**BCR** Abbreviation for barcode reader.

**biohazardous** A classification used to identify material that poses a health threat. For example, something contaminated with biological material.

**bit** The smallest addressable unit of computer memory.

**blank cell** Calibration procedure for ECL analyzers performed by Roche Diagnostics service staff.

**B-line** The transport line that moves racks from the STAT port, or A-Line to the sample barcode reader and then to the sampling position.

**blocked result** A result can be blocked by the operator (B) or the system (S). A blocked result is printed or uploaded to the host with the respective flag (B or S).

**bottle** A container with a lid used for liquids. Some bottles may be used directly on systems.

**bottle set 1** The set of ProCell/CleanCell bottles that occupies positions 1 and 2 (position on the right) in the system reagent compartment.

**bottle set 2** The set of ProCell/CleanCell bottles that occupies positions 3 and 4 (position on the left) in the system reagent compartment.

**bound/free separation** The physical separation of reagent or sample that is bound to a solid phase, the microbeads, from free reagent or sample.

**Bracketing** A mode of operation in which patient results have to be surrounded by successful control results before they are released.

**bridging principle** One of three test principles that can be applied to ECL immunoassays. It is used to detect antibodies (such as IgG, IgM, or IgA) in the sample. See competitive principle, and sandwich principle.

**buffer** The temporary storage of data by any software in a defined section of the computer memory.

**button** A button is found on windows or dialog boxes in the software. It can be touched either to initiate an action or to move to a different area of the software.

**calculated result** See calculated test.

**calculated test** A test result calculated from different individual analytical methods with a given formula, such as ratio A/B.

**calibration** The set of operations that establish, under specified conditions, the relationship between values indicated by the analyzer and the corresponding known values of an analyte.

**calibration curve** A plot of known concentrations of calibrators against their signals, established during calibration.

**calibration frequency** A specified interval at which an assay should be calibrated. Typically found on reagent package inserts.

**calibration function** Also known as calibration mode. The type of calibration, for example, Rodbard function, linear function, or cutoff function, is a mathematical model. The model describes the relationship between a signal and a concentration in the calibration curve. See calibration curve.

**calibration monitor** A function that prints the measured absorbance of the standard solution and the factors, at the time of calibration, for every measurement item.

**calibration quality criteria** Criteria applied to the auto-validation of every calibration on the analyzer.

**calibration trace** A function for checking day-to-day changes by saving calibration results for the same item.

**calibration type** :

1. The kind of standard solution used in calibration including 1-point, 2-point, span, and full. The factors updated differ depending on which type of calibration is performed.
2. In electrochemiluminescence it is lot calibration, L-Cal, or reagent pack calibration, R-Cal.
3. In clinical chemistry it is bottle or cassette calibration.

**calibration validation** Analysis, performed by software, to check a calibration dataset against specific criteria encoded in a reagent barcode. Calibration validation results are successful or failed.

**calibration verification** A procedure required by HCFA and CLIA. Calibration verification is the assaying of calibration materials. This assaying is done in the same manner as patient samples to confirm that the calibration of the analyzer kit or test system has remained stable. For example, Elecsys CalChecks.

**calibrator** :

1. A material of known composition or properties that can be presented to the analyzer for calibration purposes.
2. The test portion or test solution used for calibration of an analytical procedure.

**calibrator code** The identification number of the standard solution in calibration measurement.

**capacitance** The property of an electrical non-conductor that provides the basis for liquid level detection in the S/R probe and sipper probes. The probes carry a high-frequency, low-voltage electrical charge. Frequency and electrical charge characteristics are altered and sensed when the probe touches liquid.

**CapTwist** An opener to aid the manual removal of ProCell and CleanCell bottle caps.

**carryover** A process by which materials are carried into a reaction mixture where they do not belong.

**CC** Abbreviation for clinical chemistry and for CleanCell.

**cell holder** A container holding the electrode in the electrode measurement unit.

**channel** :

1. The number of reagent positions on an analyzer.
2. A specific reagent position.

**check digit** A verification number used in barcodes and software.

**check sum** The result of a mathematical procedure to validate the integrity of a set of data.

**circuit breaker**

1. The main power switch on the analyzer. It controls the power to the Peltier elements and, consequently, controls the temperature in the reagent rotor, incubator, and measuring detection unit.
2. A switch that controls power to the Peltier elements, thereby controlling the temperature in the reagent rotor, incubator, system reagent compartment, and measuring cell.

**CleanCell** An auxiliary reagent used to rinse the tubing system and measuring cell after each measurement. This reagent also conditions the electrodes in the measuring cell.

**cleaning solution** See wash solution.

**Clean-Liner** A disposable liner used in the solid waste tray of the analyzer.

**client/server** A network in which computer processing is distributed among many individual PCs, clients, and a more powerful, central computer, server.

**C-line** The transport line that receives racks from the B-Line via the output buffer.

**clot detection** :

1. A device built into the pipetting system to detect clots and to avoid false pipetting.
2. The procedure of detecting a clot.

**cobas®** A modular range of in vitro diagnostics analyzers from Roche Diagnostics and Hitachi High-Technologies.

**cobas® data station** The infrastructure of network connections that enables cobas TeleService to exchange information between the Roche service network and a customer's laboratory.

**cobas® link data station** A specific desktop computer, located in the laboratory, that has been configured to act as a gateway between Roche systems and the Internet. As well as providing a communication link, the data station also stores data and documentation for assay processing and can provide a data archive.

**cobas® TeleService** The set of software applications that use cobas® link to exchange service information between the Roche service network and a customer's laboratory. cobas TeleService provides remote monitoring and diagnosis, hotline support, and software and documentation updates.

**cobas e pack** The name given to a reagent cassette used on cobas e systems and Elecsys systems.

**Code39** A barcode type for sample tubes that can be read by the barcode reader.

**coefficient of variation** A statistical measure used to describe imprecision. Often abbreviated to CV.

**communication** The exchange of data between different computers.

**compensated test** A test that has the result modified by a formula that takes account of known or defined interference factors.

**competitive principle** One of three test principles that can be applied to ECL immunoassays. It is used to detect analytes of low molecular weight for example, FT3. See bridging principle, and sandwich principle.

**Complete** A sample status found in the software indicating that all requested determinations have been completed.

**conditioning** The process of letting serum-type liquid flow through the flow path before electrolyte measurement.

**consumables** A generic term for items that are used during test processing and must be replaced on a regular basis by the operator. Examples of consumables include AssayCups, printer paper, and reaction cells.

**consumables area** The area of an analyzer where the consumables, such as AssayCups and AssayTips, are stored.

**container** See sample container.

**continuous access** The analyzer function that enables an operator to permanently access the sample loading area of an analyzer.

**continuous loading/access** The ability to load (or unload) sample or reagents at any time.

**control ID** The abbreviated name for a control material, for example PC U1 or PC TSH. Control IDs are used on software screens and windows where limited space prevents the use of longer names.

**control material** A material used to assess the performance of an analytical procedure or part of an analytical procedure. Also called the control sample.

**control name** The name of a control material, for example PreciControl Universal.

**control SD value** The acceptable standard deviation value of a quality control sample.

**control unit** An external PC or printer by which an analytical system is controlled. The control unit also serves as the user interface.

**correction item** A function that corrects the measurement result of one item by using figures or the measurement result of other tests.

**CPU** The Central Processing Unit of the system or computer.

**cross-reactivity** The reaction of an antibody with an antigen other than the one that elicited its formation as a result of shared, similar, or identical antigenic determinants.

**CSF** Abbreviation for cerebral spinal fluid. A sample type for clinical analysis.

**cumulative QC** The accumulated data and associated statistics of individual QC data.

**cup-on-tube** The placement of a smaller secondary sample container, for example a Hitachi Cup, on top of a primary sample tube.

**CV** See coefficient of variation.

**cycle** The analyzer time interval during which pipetting or measurement can be carried out.

**cyclic QC** Control tests run at fixed intervals.

**DAT** Abbreviation for Drugs of Abuse Testing. The abbreviation DAU is also used.

**data alarm** An alarm that occurs if a measurement result or calibration result is abnormal.

**database** A piece of software where all analyzer, assay, and patient-relevant data is processed and stored.

**database management system** A software system that provides the necessary procedures and programs to collect, create, organize, store, retrieve, and maintain databases or data files with security and integrity.

**data entry field** A field in the software where a user can enter or edit data.

**data field** A field in the software that contains information. There is no user access to this type of field.

**data flags** Printed or displayed alarms or flags that indicate unusual reaction or analyzer conditions, for example insufficient sample, or reagent, or substrate depletion.

**DAU** Drug of Abuse in Urine. The old term for DAT or Drugs of Abuse Testing.

**DB** Abbreviation for database.

**DBMS** Abbreviation for database management system.

**default value** A set value registered in advance, initial setting.

**deionized water supply** A device that produces purified water.

**demographics** Patient-related data such as name, date of birth, and gender.

**detection unit** A hardware unit comprising a photomultiplier tube, Peltier elements, flow-through measuring cell, magnet drive assembly, and an amplifier circuit board.

**determination** The process of quantifying analytes.

**deviation** A value minus its reference value.

**deviation of duplicate measurements** See duplicate limit.

**Diagnostics** The status that is required to perform system diagnostics and hardware error tracking actions. The field service engineer may request a system to go to Diagnostics mode to perform such procedures. The system may require initialization afterwards to resume normal operation.

**diluent (DIL)** A liquid agent used to reduce the concentration of a sample.

**dilute waste solution** A waste solution resulting after rinsing with water.

**dilution factor** A software preset or manually assigned dilution ratio that is used by the analyzer to perform a requested dilution.

**disk position** A dedicated position on the reagent or sample disk.

**dispense** The process of adding sample material or reagents by the pipetter probe into a reaction vessel or cell.

**dispenser technology** A technique in which a rinsed probe transfers reagents into a reaction vessel. The reagent container is directly connected to the pipetter probe.

**disposable** Typically a plastic tip, vessel, or cuvette that is discarded after a single use.

**DMS** Abbreviation for data management system.

**document (to ...)** The process of printing or uploading a result report to a LIS.

**download** The process of receiving data from Roche by a network link.

**down time** The period of non-operation between an analyzer failure and the resumption of operation.

**dual value method** A mode of expression of the control chart in real-time quality control. For X-axis and Y-axis, measure simultaneously the average and the standard deviation of control of a low value and a high value, and display them by X and Y coordinates, respectively.

**duplicate limit** A calibration quality criterion. For a successful calibration, duplicate measurements must be within a specified limit.

**dynamic range** The reportable range of an assay. This range extends from the lower detection limit to the limit of linearity.

**e-barcode (e-BC)** An electronic barcode received via the cobas® link.

**ECL** Abbreviation for electrochemiluminescence, the detection technology used on immunoassay analyzers.

**electromotive force (EMF)** The physical principle that provides the basis for electrolyte measurement.

**emergency stop** An alarm that immediately stops all analyzer functions.

**endpoint assay** An analytical technique taking measurements after a reaction is completed or has been halted.

**error handling** A process during which the analyzer attempts to recover from an error condition (for example, an AssayTip is not picked up from the tray). If the analyzer cannot successfully recover from error, an alarm is issued and the analyzer is halted.

**E-stopped** A status indicating that the system has performed an emergency stop (E.Stop). This could be due to hardware failure or because any of the safety devices have requested an emergency stop. The system requires either complete power off, or at least initialization, to resume normal operation.

**expected range** The pre-defined range of test result values expected for a defined group of healthy patients or materials. Also known as normal range or reference range.

**expected value** A value for a test result that can be considered as a normal result.

**expiration date** Also called the expiry date. The end of a period until which Roche Diagnostics guarantees product claims for its reagents, calibrators, and controls.

**extended dynamic range** The measuring range for an assay at its highest dilution.

**factor (calibration)** :

1. In electrochemiluminescence: one of the six calibration quality criteria used to verify the validity of a calibration. This criterion is only used for reagent pack calibrations. It is derived by comparing two different calibrations. A factor of 1.0 is achieved when two calibrations are equal. A successful calibration has a factor of 0.8-1.2.
2. In clinical chemistry: the slope of a calibration curve, only applicable to linear calibrations. One of the factors used to create a calibration curve - S1Abs, K, A, B, C.

**FDA** Abbreviation for Food and Drug Administration. A US government-controlled agency responsible for regulating diagnostic and pharmaceutical products.

**FIFO** Abbreviation for first in, first out. A logistic process for handling goods or data.

**filter** A process that sorts data for viewing, documenting, or printing according to pre-defined criteria.

**first registration** The date and time when a reagent pack or sample was first recognized by the barcode reader.

**fixing knob** A screw lid that fixes the reaction disk.

**flag** An identifier used to call an operator's attention to a result.

**float sensor** A sensor that detects the surface of solutions. The sensor position moves up and down depending on the surface level.

**front access panel** A door behind which the solid waste tray is located.

**functional sensitivity** The concentration of an analyte at which a pre-defined level of imprecision is obtained.

**global button** A button that allows access to the global software windows and that can be used at any time.

**gripper** A technical device that transports AssayCups and AssayTips to their required destination on the analyzer (for example, to the incubator). The gripper moves in three directions (X, Y, and Z).

**GUI** Abbreviation for graphical user interface.

**hardware (HW)** The mechanical and electrical components of a computer and its peripheral devices.

**Het IA** Abbreviation for heterogeneous immunoassay.

**HIA** Abbreviation for homogeneous immunoassay.

**HIS** Abbreviation for Hospital Information System. A computer system that manages the hospital's overall information processing. Sometimes also (incorrectly) referred to as LIS (Laboratory Information System).

**Hitergent** :

1. A detergent, with antibacterial properties, that can be added to the reaction bath where it acts as a surfactant, reducing the formation of foam.
2. A surfactant diluted for use in some cleaning procedures.

**home position** The position to which a certain part of the analyzer returns on reset. The start position of a mechanism.

**homogeneous immuno assay (HIA)** An analytical technique employing antigens and antibodies. An HIA uses assay protocols similar to clinical chemistry without a bound-free separation (for example, latex assays).

**host communication** Data exchange with a clinical laboratory information system (LIS).

**host computer** :

1. A computer used for overall management and control of the computer network.
2. A clinical laboratory computer that stores and processes patient requests and results. A host is able to communicate with analytical systems.

**host interface protocol** A technical description that defines data transfer between a host computer and an analytical system. See also ASTM protocol.

**IA** Abbreviation for immunoassay.

**IC** Abbreviation for immunochemistry.

**ID** A unique alphanumerical set of data that clearly identifies a patient sample or rack. Also known as an ID no.

**incubator** A temperature controlled aluminum block for AssayCups on cobas and Elecsys systems.

**initial BlankCell procedure** The calibration procedure for ECL systems performed by Roche Diagnostics service staff when setting up an ECL-based analyzer for the first time.

**Initialization** Also known as Initializing. The operational mode of an analyzer that occurs immediately after switching on and during which the analyzer prepares itself for operation.

**In-pack calibrator** A calibrator provided with the associated reagent pack.

**input buffer** A section of an analyzer where samples are loaded by using a rack or rack tray. See also rack loader.

**Instrument Manager** Typically, PC-based software that controls or supervises one or more analytical systems.

**interface** See parallel interface, user interface.

**intranet** An access-restricted network used internally in an organization.

**inventory control** The real-time monitoring of the quantities of all consumable items (liquid and solid) on an analyzer.

**in vitro qualitative assay** A determination outside the living body of constituents of a substance without regard to quantity.

**in vitro quantitative assay** A determination outside the living body of constituents of a substance with regard to a specified number or amount.

**IVD** Abbreviation for in vitro diagnostics. A diagnostic procedure performed outside the living body with specimen body fluid.

**IVDD** Abbreviation for In Vitro Diagnostics Directive. A set of rules and regulations laid out by the EU commission to ensure the safety of IVD products.

**lab automation** The process of managing the entire analytical process with minimal operator intervention.

**LDL** Abbreviation for lower detection limit. See analytical sensitivity.

**level detection** A check for the availability of sufficient liquid in a container.

**LIMS** Abbreviation for Laboratory Information Management System. See LIS.

**linear barcode** A conventional one-dimensional barcode with limited data capacity.

**liquid level detection (LLD)** The ability of an analyzer to sense liquid by using the sample or reagent probes.

**liquid waste container** A reservoir for liquid waste generated by an analyzer; its size and location vary between analyzers.

**LIS** Abbreviation for Laboratory Information System. A clinical laboratory computer system for the management and storage of patient data and results. An LIS communicates with analyzers.

**loader** A section of an analyzer that hold trays and racks waiting to be processed. Also known as the input buffer or the A-line.

**loading capacity** The maximum number of samples that can be loaded onto the input buffer.

**local area network (LAN)** A computer network covering a limited area, such as an office or a home.

**log file** A set of data, typically stored in the control unit, that traces analyzer-related or operator-related activities such as maintenance.

**log off** The procedure of terminating access to a system. Also known as log out or logoff. The reverse procedure is known as log on or log in.

**log on** The procedure of gaining access to a system by entering a user name and, if required, a password. Also known as log in or logon. The reverse procedure is known as log out or log off.

**lot calibration (L-cal)** A mandatory calibration when a new lot of reagents is introduced to an analyzer.

**maintenance item** A maintenance procedure performed by the system or the operator.

**maintenance key** A button for position movement, used for a probe position check.

**maintenance procedure** A procedure that must be performed on a regular basis (for example daily, weekly, monthly, or every three months) to secure reliable operation of the analyzer.

**manual dilution** An off-system, pre-analytical step performed by laboratory staff to reduce the analyte concentration in a sample.

**master calibration** A reference standardization that uses master test kit reagents and certified reference standard material measured at Roche Diagnostics. For example, World Health Organization reference material. The resulting reference standard curve, typically using 10 to 12 points, is the basis for the production of in-house master calibrators.

**master curve** A lot-specific master calibration curve (n=5 or 6) measured at Roche Diagnostics using lot-specific test-kit reagents and master calibrators. The shape of the lot-specific master curve is characterized by a four-parameter Rodbard function. The data characterizing this curve is stored in the lot-specific reagent barcode. Lot-specific, calibrator-assigned values (CalSet-assigned values) are read from the lot-specific master calibration curve and encoded in the CalSet calibrator barcode transfer sheet.

**Material Safety Data Sheets (MSDS)** Documents that list components of chemical solutions and precautions for the handling and disposal of the solutions.

**mean** The sum of values divided by the number of values.

**measure point** Time at which absorbance reading is taken and used to calculate results.

**measuring cell** A flow-through device that is used to generate light during the ECL detection process.

**measuring range** See reportable range.

**message** In computing, a defined set of alphanumeric data that transfers information from computer to computer or from an analyzer to the operator.

**microbead mixer** A paddle that thoroughly mixes the microbead reagent to ensure resuspension before use.

**microbeads** Paramagnetic streptavidin-coated microparticles used as the solid phase for heterogeneous immunoassays in the Elecsys format.

**Microcup** A secondary sample cup made by Hitachi with a small dead (residual) volume

**microparticle** See microbead.

**minimum sample volume** The smallest volume of sample required to ensure faultless sample aspiration. In practice this is the sum of the residual volume plus the volume required to assay all requested tests.

**minimum signal** In ECL assays, a calibration quality criterion. A pre-defined, assay-specific signal level that must be achieved to establish a valid calibration.

**missing value** In ECL assays, a calibration quality criterion. All calibrator values must be available for a successful calibration.

**mode** Defined states of operation of an analyzer.

**monochromatic** Absorbance measurement at one (primary) wavelength.

**monotony of curve** A calibration quality criterion. All measured calibrator values must fall in either ascending (sandwich or bridging principle) or descending (competition principle) order for a successful calibration.

**nipple** A part for connecting a syringe and the flow path.

**normal range** See expected values.

**nozzle** A pipe or tube of varying diameter that is used to direct or modify the flow of a liquid or gas.

**nozzle head** The cover of the device holding multiple rinse nozzles.

**nozzle seal** A seal placed between the tube and the probe to connect them.

**nozzle tip** A tip attached to the end of the nozzle that sucks up rinse water remaining after a reaction cuvette has been washed.

**onboard** :

1. A technical device or function that is part of the analyzer and can be used by the analyzer at any time.
2. The availability of reagents and consumables on an analyzer for use at any time.

**one-way serial processing** The sample flow and processing along a single, serial process lane that allows no bypass function and no rerun.

**online help** On-screen documentation that a user can request in a context-sensitive manner and search for any given term.

**online support** A service that supports the preparation for analysis and maintenance management by exchanging information over networks. See also TeleService.

**open request** See pending requests.

**Operate** The operational mode during which the analyzer processes samples.

**operating system** A software program that controls all basic functions of a computer (for example, Windows, or Linux).

**operator** The person who uses and controls the analyzer or a computer system.

**operator ID** An alphanumeric ID that a system uses to identify a particular operator. Access levels differ for operators, administrators, and service personnel.

**order** Also called a request. A test selected for a specific sample or control.

**order date/time** A field used to maintain the arrival date and time of an order in the laboratory. The date/time data may be entered manually or transmitted by LIS protocols.

**order ID** The sample order identification refers to a number of sample tubes (one or more specimen types) of a given patient collected for a panel of different tests. Typically, the sample order identification is printed on order sheets.

**output buffer** A section of an analyzer to which samples are moved on completion of the analytical process and from which they can be unloaded. See also rack unloader.

**parallel interface** The interface (Centronics type) through which the analyzer can be connected to an external printer.

**paramagnetic** A property of microbeads that do not exhibit magnetic forces themselves but are capable of becoming magnetic. The microbeads become magnetic in the presence of a magnet or magnetic field used with ECL technology.

**parameters** A set of criteria or definitions used to establish how an assay is performed. Examples of parameters include sample and reagent volumes and incubation times and temperatures. Such information is typically encoded on reagent barcode labels and cannot be changed by the operator.

**password** A form of authentication that uses secret data to control access to a resource.

**patient ID** A set of alphanumeric data that unmistakably identifies a particular patient. For example, a social security number and a sample ID.

**pending requests** Also known as open requests. The results for a sample are partially available; other tests have not yet been performed or completed.

**photomultiplier** A light-sensitive tube that collects and amplifies emitted photons from the ECL reaction and converts them into an electric signal.

**photon** A quantum of electromagnetic energy, having both particle and wave behavior, that carries the light emitted from the ECL reaction.

**pinch valve** A valve that pinches the suction tube and switches the flow path.

**pipette (to …)** The process of aspirating and dispensing sample and reagents performed by an appropriate probe.

**pipetter** A device used for pipetting a fixed amount of sample or reagent.

**pipetter technology** A technique used to transfer reagents into a reaction vessel by using a rinsed probe or a disposable tip. Reagents are aspirated from cassettes, bottles, or reagent packs.

**pipetting station** The part of the analytical unit that performs all pipetting-related functions. See also pipetter.

**plunger** A rod that connects with the drive arm and moves up or down, depending on the pipetting amount.

**pop-up window** A small screen window that contains additional information or additional options required for making entries or decisions.

**positive displacement** Water in the pipetter that is displaced by the plunger during an aspirate/dispense cycle. The positive displacement is equal to the amount of sample or reagent that is aspirated or dispensed by the probe.

**post-analytical** The sample management process, typically storage and archiving, after results have been reported.

**potentiometric assay** An assay in which analytes (for example Na, K, or Cl) are measured in millivolts by ion-selective electrodes.

**Power Up** The system status while it is loading programs, performing self-checks, and so on.

**PPID** Abbreviation for Positive Patient Identification.

**pre-analytical** The sample management process before the analytical phase. Pre-analytical processing typically involves actions such as sorting and aliquoting.

**Pre-Analytic Systems Manager** PC-based software in a laboratory environment connected to one or more pre-analytic or analytical devices. A PSM controls the sample flow and offers extended data management. PSM software is not available in all countries.

**precision** The closeness of agreement between independent test results obtained under prescribed conditions.

**PreClean** A phosphate buffer used to wash and resuspend the microbeads during the pre-wash step.

**pre-dilution** A dilution step performed before samples are analytically processed on the analyzer.

**PRID** Abbreviation for Positive Reagent Identification.

**primary tube** The original tube containing the sample that has been drawn from the patient.

**ProCell** An auxiliary reagent that transports the reaction mixture from an AssayCup into the measuring cell and aids the ECL detection technology.

**profile** A user-defined set of test requests.

**protocol** :

1. A convention or standard that controls or enables the connection, communication, and data transfer between two computing end points. Protocols can be implemented by hardware, software, or a combination of the two.
2. A set of rules that guide how an activity should be performed.

**PSD** Abbreviation for Primary Sample Distribution.

**PSID** Abbreviation for Positive Sample Identification.

**PSM** Abbreviation for Pre-Analytic Systems Manager.

**pushing spring** A spring that applies pressure to a seal to close it.

**QC error** An alarm generated in real-time when either a low value or a high value exceeds the limit of 3 SD - QC error 1, or 2.5 SD - QC error 2.

**qualitative assay** An assay that does not allow the determination of the concentration of an analyte, only a classification of the analyte. For example, positive or negative.

**qualitative measurement** The analysis of a substance, or its characteristics, without measurement of quantity or numerical value.

**Quality Assurance (QA)** A part of quality management focusing on providing confidence that quality requirements will be fulfilled.

**Quality Control (QC)** The operational techniques and activities that are used to fulfill requirements for quality.

**quantitative assay** An assay that allows the determination of the concentration of an analyte.

**quantitative measurement** The determination of a substance by calculating and reporting the concentration with a quantitative assay.

**query download** A communication process between analyzer PC and LIS by which a pre-defined data set is transmitted upon request of the analyzer.

**RA** Abbreviation for random access.

**rack** A sample carrier device that holds sample cups or primary sample tubes. This includes cups or tubes for routine samples, standard and washing solutions, quality control, STAT, and rerun samples. Different rack types can be distinguished by their differing colors.

**rack circuit breaker** A technical device controlling the power to the rack sampler unit.

**rack ID** A one-dimensional, or binary, barcode at the end of the rack that unmistakably identifies the rack.

**rack loader** Area where you place filled racks. 15 racks can be placed on the rack tray and 15 racks on the input buffer.

**rack pusher arm** An arm, located on the A-line, which pushes the racks onto the B-line.

**rack sampler** A sample-handling device that presents sample tubes, in racks, to the analytical unit.

**rack tray** A device for carrying many racks and setting them in a rack sampler.

**RAM** Abbreviation for random access memory. RAM is a type of computer memory that can be accessed randomly. When you switch off the analyzer all information stored in the RAM is deleted.

**random access** The ability of an analyzer to process requests from a patient sample in any order. That is, it could do test 4, then 2, then 1, then 3 using the same sample.

**reaction mixture** The mixture of reagents and sample material.

**reagent** A composition of chemicals used to determine the concentration of substances in a sample.

**reagent cap open/close mechanism** A mechanism that prevents evaporation by automatically opening and closing the reagent pack caps.

**reagent compartment** A temperature controlled section on an analyzer that holds reagents and diluents.

**reagent pack** A complete set of physically combined and ready-to-use reagent bottles for Elecsys assays. The components of a reagent pack cannot be interchanged with another reagent pack. See also cobas e pack.

**reagent pack calibration (R-cal)** The calibration performed when a reagent has been onboard the analyzer for more than 25 hours. A reagent pack calibration is valid for one specific reagent pack.

**reagent pack number** A unique number on the reagent bottle label that identifies each reagent pack.

**reagent probe** The probe used to transfer reagents from reagent bottles to reaction cells.

**reagent probe rinse station** The probe used to transfer reagents from reagent bottles to reaction cells.

**reagent probe rinse station** The area located between the reagent rotors and reaction disk where reagent probes are rinsed internally and externally with water.

**reagent rotor** Rotating device in the reagent compartment which holds the reagent packs.

**reagent rotor cover** The cover that closes the reagent compartment.

**reagent rotor position** One of the positions on the reagent rotor.

**reagent scan** A scan of the reagent packs held in the reagent rotor. The scan reads information from the reagent barcodes into the analyzer and updates the inventory.

**real time** The display of information on the monitor at the very moment a change to such information occurs.

**recalibration** The repetition of a calibration.

**repeat** The performance of the same test on a sample again under unchanged conditions.

**reportable range** The range of results that can be reported for the assay. It stretches from the lower detection limit to the high end of the calibration curve.

**request** See order.

**Reset** The operational mode during which the analyzer sets and aligns all mechanical parts to their home positions.

**residual volume** The volume at the bottom of the sample tube that cannot be aspirated by the sample probe.

**restore** The command for reloading data from a storage device onto the hard disk of the analyzer PC. See also backup.

**result** The value reported by an analytical device during or after the assay of a sample or control.

**Result Date/Time** The analyzer fills the result date and time after the result calculation is finished. It may be maintained by work area management systems for information purpose.

**rinse bath** See reagent probe rinse station.

**rinse nozzle** A nozzle that supplies or drains the detergent or water used for rinsing a reaction cell.

**rinse station** A technical device that cleans disposable tips or probes with deionized water or cleaning solutions to avoid contamination and carryover.

**Rodbard function** A mathematical algorithm used to convert measured signals into concentrations. It uses four parameters to define the shape and the position of the calibration curve.

**ROM** Abbreviation for read-only memory. Semiconductor memory devices used in computers. ROM content remains when a computer is switched off.

**ruthenium** A rare metallic chemical element of the platinum group that is employed in electrochemiluminescent (ECL) reactions.

**ruthenium complex** $[Ru(byp)_3^{2+}]$ N-hydroxysuccinimide (NHS) ester. This chemical complex is employed in the ECL detection technology.

**S/R arm** See sample/reagent arm.

**S/R pipetter** See sample/reagent pipetter.

**S/R probe** See sample/reagent probe.

**S. Stop button** Abbreviation for sampling stop. A button used to stop the pipetting of samples but process already scheduled activities without interruption or loss.

**S1Abs** The absorbance of standard solution 1. The displayed value is 10 000 times greater than the actual measured absorbance.

**sample/reagent (S/R) probe** The probe that transfers sample material from the sample disks to the reaction cells.

**sample blank** A control solution used to determine the background measurements, such as turbidity or color, of test samples.

**sample container** A device in which sample material is transported or stored. Also referred to as sample tube.

**sample cup** A small container that is used for samples and also for calibrator and control material. A sample cup can be placed on specific racks, sample tubes, and other inserts. Sample cups allow the use of smaller liquid volumes and so reduce the residual volume.

**sample disk** A rotor that holds the samples, only used on the disk system.

**sample ID** A set of alphanumeric data that unmistakably identifies a particular sample. See also patient ID.

**sample scan** A scan of the samples loaded in the analyzer. The scan reads the information from the barcode labels on the primary sample tubes into the analyzer.

**sample splitting** The act of making one or more aliquots from a primary or secondary specimen.

**sample tube** A container for liquid samples to be used with the system. It can have a barcode label, which is be used for positive sample identification. If the sample tube does not have a barcode label you must enter the details into the analyzer manually. A sample tube contains one specific sample type.

**sample type** One of four types of sample that can be analyzed: serum, plasma, cerebrospinal fluid, or urine.

**sampling stop** An alarm that indicates a problem with the sampling system. See also S.Stop.

**sandwich principle** One of three test principles that can be applied to ECL immunoassays. It is used to detect higher molecular weight analytes, such as TSH. See bridging principle, and competitive principle.

**scan** See barcode scan.

**SD** Abbreviation for standard deviation.

**secondary tube** A sample tube that contains an aliquot.

**sequence number** A number automatically assigned to each sample by the analyzer and used to track samples and orders.

**Service** The analyzer mode needed to perform a maintenance action. See maintenance item, maintenance procedure.

**shut down** The process of powering off the analyzer.

**signal** The emission of light converted into an electrical signal that is subsequently converted into an analyte concentration.

**sipper arm** A horizontally moving arm that holds the sipper probe.

**sipper pipetter** A device, filled with deionized water, that uses positive displacement to aspirate and dispense from the sipper probe.

**sipper probe** The probe that transfers reaction mixture from the AssayCup into the measuring cell. This probe also transfers ProCell and CleanCell reagents.

**Sleep mode** The mechanical and electrical status of the e 411 analyzer during which no immediate processing can be initiated by the operator.

**software** A computer-operated program that processes data in a defined manner. Software is usually intellectual property of the software supplier or its licensee.

**solid waste tray** A metal waste container holding a liner that collects discarded solid waste.

**standard** Traceable reference material used to create the master calibration curve.

**standard deviation (SD)** A statistic used as a measure of the dispersion or variation in a distribution of data.

**standard rack** A standardized transportation device for a maximum of five sample containers on Roche Diagnostics analyzers.

**standard tray** A metal device that holds and carries multiple standard racks and that can be placed directly in the sample reception area of an analyzer.

**Standby** An operational mode of the analyzer during which power is on but no sample analysis or maintenance procedures are being performed.

**Startup** An operational mode of an analyzer, following power-on, during which the analyzer prepares itself for operation.

**STAT** Was an abbreviation for statim – latin for urgent, immediate. Now used to indicate short turn around time.

**STAT application** A special test application, for example, reduced incubation time, for STAT samples to achieve faster result reporting. See also STAT.

**STAT port** Special entry area for STAT samples, which are processed with priority.

**STAT sample** Emergency sample. Results should be available within shortest possible time. See also STAT.

**stop barcode** A special barcode used on disk systems to halt sample scanning.

**SysClean** A reagent used for the periodic cleaning of the measuring cell.

**system alarm** A displayed alarm that indicates an unusual analyzer condition, such as an abnormal reaction bath temperature or a mechanical malfunction. Also called analyzer alarm.

**systematic error** A reproducible error which is constantly in the same direction. That is all results would be slightly higher or lower than expected.

**system cleaning solution** See wash solution.

**system error** :

1. A calibration quality criterion that originates from a hardware failure while a calibration measurement is performed.
2. The general term for a case of analyzer-related problems.

**system reagent** A non-test specific reagent that is needed to perform testing on an analyzer.

**SysWash** A system-specific agent used to avoid reagent carryover. It also prevents bacterial growth.

**target range** The allowed range of recovery for an analyte in a control material.

**target value** The mean of all participant responses after removal of outlying values.

**TDM** Abbreviation for Therapeutic Drug Monitoring.

**technical limit** The dynamic range of an assay.

**test code** The abbreviated name for a test. This code is displayed on test buttons shown in the software.

**test principle** A technique that serves as the basis for designing an assay to detect or quantify analytes.

**test protocol** The sequence of test steps used to perform an assay. For example, volumes and timings.

**timeout calibration** An analyzer mode that automatically generates a calibration request after a pre-defined interval.

**tip** See AssayTip.

**tip eject station** An opening in the analyzer housing through which AssayCups and AssayTips are discarded.

**transaction** The smallest unit of interaction between two computers. One computer, a host computer or Instrument Manager, sends a message, then the receiving computer returns a reply.

**tray indication light** A light, at the left side of both the A-Line and C-Line. This light indicates the mode of operation.

**trend** An upward or downward tendency in data values after the exclusion of the random error and cyclic effects.

**tripropylamine (TPA)** One of two electrochemically active substances used in the ECL reaction.

**turnaround-time** :

1. The time between the decision to perform a test and the time when the doctor receives the result and can act on it.
2. Inside the laboratory (Lab-TAT): Time between receiving a sample and sending out the validated result.

**two-way processing** Sample flow in two directions. Typically a main lane to feed analytical modules with samples, and a return line to handle rerun and reflex testing.

**unit** A chosen reference quantity of an analyte used to compare quantities of the same dimension. For example, mol/L, g/L, or U/L.

**upload** The process of sending data to Roche by a network link.

**user interface** The part of a system exposed to an operator. In a computer system, the operator typically interacts with an operating system or with application software.

**validation** The process of checking results or data against defined rules or ranges in clinical laboratories. Validation can be against technical or clinical criteria.

**vial** A small sample container with flip-top lid, mainly used for calibrator and control material.

**WAM** Workarea management. PC-based software that controls and monitors sample tracking and offers extended data management for a defined workarea in a clinical laboratory environment.

**waste** Anything discarded by the analyzer. Waste can be liquid or solid.

**water level sensor** A sensor that monitors the water level of temperature controlled water.

**work list** A report generated by an analyzer. A work list aids a user by listing calibrators, controls, and samples currently loaded on the sample disk.

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