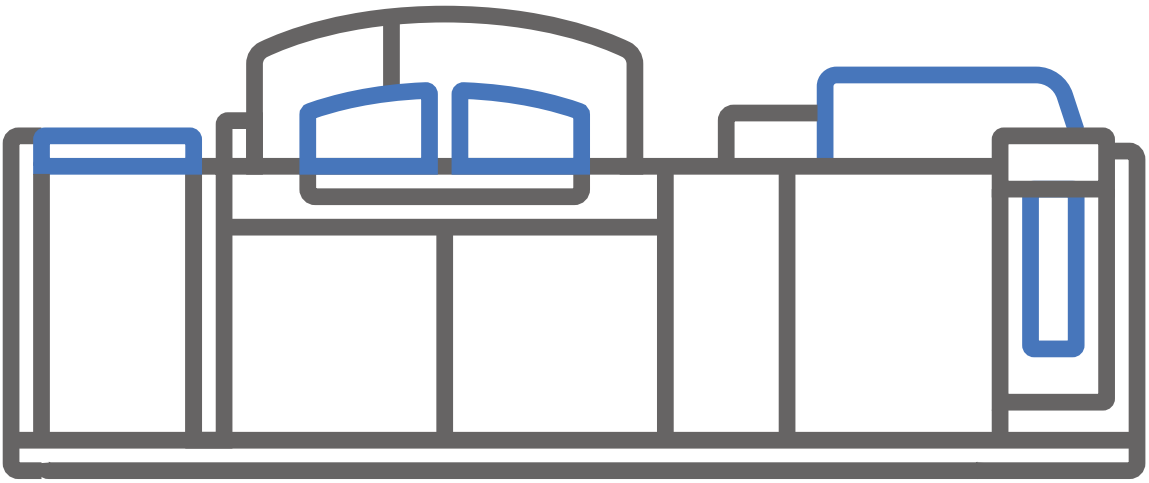
cobas® 6000 analyzer series

Addendum 1.0 to Complete User Documentation, Version 8.3
Software Version 06–03



Publication information

Revision history

Publication version	Software version	Revision date	Change description
1.0	06-03[(a)(b)(c)]	2025-05	New addendum

(a) Also valid for software version 05-02
(b) Also valid for software version 06-01
(c) Also valid for software version 06-02

Edition notice

This addendum contains supplementary information for operators of the **cobas®** 6000 analyzer series.

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: *navifyportal.roche.com*.

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Roche affiliates

A list of all Roche affiliates can be found at: *roche.com/worldwide*

eLabDoc

Electronic user documentation can be downloaded under eLabDoc on the **navify®** Portal: *navifyportal.roche.com.*

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

Table of Contents

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Disposal of the instrument

Section in Operator's Manual System description > General safety information > Disposal of the instrument

Description of revision The section *Disposal of control unit components* has been replaced with the section *Disposal of analyzer components* to comply with the new WEEE directive.

Revised section

Disposal of analyzer components

Do not discard devices marked with the crossed-out wheeled bin symbol as unsorted mixed household waste. Send these devices to separate facilities for recovery and recycling.

Before disposal, ensure that any liquid or solid waste is removed from the devices.

Before disposal, disinfect the exterior of the devices with a disinfectant solution recommended in these instructions.

If applicable, before disposal, remove used batteries and accumulators.

If applicable, before disposal, ensure that personal data is deleted from the device.

These devices must be disposed of at collection facilities designated by government or local authorities. Avoid sending EEE components to landfill.

For more information on how to dispose of your old device, contact your city office, your waste disposal service, or your Roche Service representative.

Constraint: It is left to the responsible laboratory organization to determine whether the equipment are contaminated or not. If contaminated, treat them in the same way as biologically contaminated/hazardous waste.

cobas link

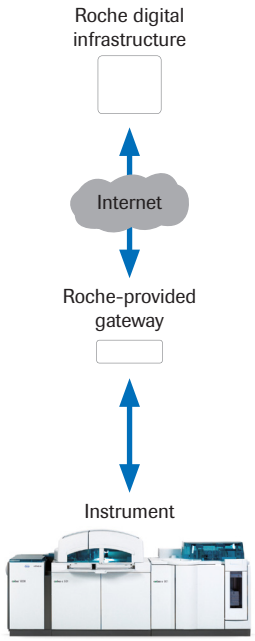
Section in Operator's Manual System description > Control unit, cobas link and core unit > cobas link

Description of revision The cobas link chapter has been rewritten to comply to the new Roche Gateway Branding.

Revised chapter (heading is now: *Overview of laboratory IT setup* instead of *cobas link*)

The software of the instrument is embedded in the laboratory IT setup. Different setups are possible

About cobas® link software



The Roche-provided gateway (e.g., **cobas**® link or Unified Gateway) provides a secure remote connection for data transfer between the instrument and the Roche digital infrastructure.

The gateway hosts the **cobas**® link software and is used to access the e-library to view Method Sheets, Value Sheets for calibrators and QC materials, and other documents.

Other functionalities provided by the gateway are:

- Automatic synchronization of recent parameters from the Roche digital infrastructure to your system:
  - Applications
  - Calibrators
  - QC materials
  - Reagents
- Archiving of Instructions for Use
- Uploading of statistical data from your system to the Roche digital infrastructure for:
  - Performance monitoring
  - QC management
  - Service

To enable access to the Roche digital infrastructure, the instrument must be connected to a Roche-provided gateway (e.g., **cobas**® link or Unified Gateway).

Roche digital infrastructure

The Roche digital infrastructure provides the following services to your system:

Electronic service	Function
e-library	Interface to access Method Sheets, Value Sheets for calibrators and QC materials, and other documents.
ThingWorx	Provides a link for Roche Service representatives for secure remote access to the instrument.
cobas® e-LabPerformance	To upload statistical data from the system, e.g., for performance monitoring and QC management. No patient names or patient IDs are transferred to or stored within the Roche digital infrastructure.

Table Z-1 **cobas**® e-services

Roche-provided gateway

The Roche-provided gateway together with its monitor, keyboard, mouse and printer is located in the laboratory. The gateway is connected via a secure internet connection to the Roche digital infrastructure and via your local network to the control unit of the instrument.

A Roche Service representative sets up and configures the **cobas**® link software installed on the gateway.

The **cobas**® link software hosts the e-library, i.e., the interface to access information on applications, calibrators, and QC materials.

The **cobas®** link software can be used either in the remote access mode or data transfer mode.

Function	Remote access mode (online mode)	Data transfer mode (offline mode)
Connection of the instrument to the Roche digital infrastructure	Yes	No
Automatic downloading of e-library packages from the Roche digital infrastructure to the gateway	Yes	To update the e-library manually, use the e-library files provided by Roche.
Automatic **cobas®** link software updates, e.g., security patches	Yes	Your Roche Service representative must maintain the security patch status of the gateway.
Automatic uploading of statistical data every 4 hours, e.g., for performance monitoring	Yes	No

Table Z-2 Differences between online and offline mode

For more information, see:
About the e-library information flow on page Z-8
About the e-library on page Z-9

Using the backup function

Instrument and process related data can be stored on the Roche-provided gateway for recovery. In order to initiate this backup function it is necessary to include the upload function *Smart. Com Essential information upload* in a daily maintenance pipe, e.g., as part of the *Power ON* pipe.

This item can only be performed in a maintenance pipe.

For more information, see:
Defining and editing maintenance pipes
Recommended maintenance pipes
Smart. Com Essential information upload

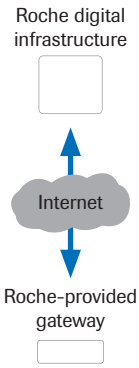
Perform daily backups to preserve the operational availability of the analyzer

Include the upload function *Smart. Com Essential information upload* in a maintenance pipe that is executed daily. If a hard disk error on the control unit occurs, the last backup can be restored from the Roche-provided gateway by a Roche Service representative.

About the e-library information flow

The information flow between the Roche digital infrastructure and the gateway, and between the gateway and the instrument is bidirectional.

Downloads from the Roche digital infrastructure



Downloads from the Roche digital infrastructure to the Roche-provided gateway are usually performed once a day and include the following items:

- e-library packages which contain product information about applications, calibrators and QC materials
- e-barcodes
- **cobas®** link software updates

e-library packages

The following documents are part of the e-library packages:

- Method Sheets
- Value Sheets for calibrators and QC materials
- Important notes, for example, about reassigned QC values
- Announcements from the local technical support

You can read these documents in the e-library application on the gateway monitor.

e-barcodes

e-barcodes contain the following machine-readable information for the instrument:

- Test-specific system parameter files
- Lot-specific application parameter files
- Calibrators and QC parameter files

e-barcodes are stored on the gateway.

Archive information

Accredited laboratories must archive Instructions for Use and system parameters for many years.

If required by the local authorities, regularly copy documents that must be archived from the e-library to an archive server.

For data security, observe the following guidelines:

- Dedicate a storage medium, e.g., a USB flash drive, for the data transfer from the gateway.
- Before you use the storage medium on the gateway, check it with an antivirus program on another PC.

For more information, see:
About cobas® link software on page Z-5
About the e-library on page Z-9

About the e-library

The e-library application is hosted on the Roche-provided gateway. In the e-library you can read the product information. The e-library is also an electronic archive.

In the e-library, check the list of new entries every day for the latest e-library inserts.

For more information about the e-library, refer to the e-library User Guide.

Access to e-library

The e-library is accessible through the Roche-provided gateway monitor.

Content of e-library

For each application, calibrator, and QC material, the e-library contains the latest version of the respective e-library package and the preceding version. Any older e-library packages are deleted from the e-library.

If the gateway has an internet connection, the e-library is updated daily via an automatic download from the Roche digital infrastructure.

In the case of no internet connection, the e-library must be updated manually. Contact your Roche Service representative for this process.

User Guide

The latest User Guide for your instrument is available for download from the e-library.

For more information, see:
About cobas® link software on page Z-5
About the e-library information flow on page Z-8

Maximum fill height

Section in Operator's Manual System description > Control unit, cobas link and core unit > Trays, racks, tubes, and cups > Sample containers > Maximum fill height

Description of revision In the section *Maximum fill height*, the illustration has been replaced to display the Hitachi micro cup (2nd from left).

Revised section

To prevent any splashing during processing of sample containers, the maximum fill height should not exceed 10 mm below the top edge of each container.

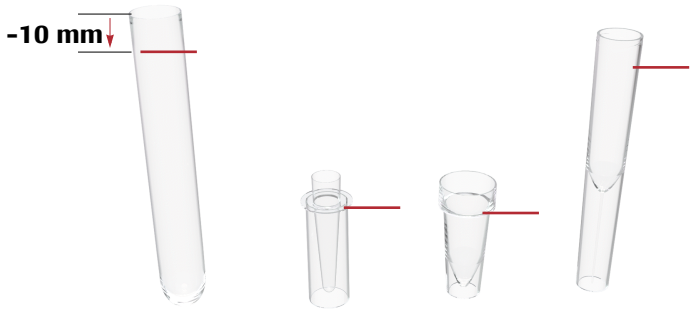


Figure Z-1 Maximum fill height for containers

>Cuvet data alarm

Section in Operator's Manual Troubleshooting > Data alarms > Data alarms c 501 (P) > >Cuvet

Description of revision The description of the data alarm >*Cuvet* has been revised as it also applies to tests without dilution.

Revised description

Alarm Cell blank abnormal

Description If a reaction cell fails the cell blank measurement, the system excludes it from any measurements. The reference is the stored value from the **(4) Cell Blank Measurement**.

However, a failed reaction cell will be used with >*Cuvet* alarm in the following two cases:

1. For a diluted test, the cell blank value of the second reaction cell exceeds the reference by more than 0.1 Abs.

   For diluted tests the system uses 2 reaction cells:

   - 1st reaction cell: Contains sample and diluent.
   - 2nd reaction cell: Used for discharging diluted sample from the first reaction cell, adding reagent, and performing the measurement.

   The >*Cuvet* alarm indicates a failed cell blank measurement for the 2nd reaction cell.

2. For a large pipetting volume test (≥20.1 µL), the cell blank value of the reaction cell exceeds the reference by more than 0.1 Abs.

   The >*Cuvet* alarm indicates a failed cell blank measurement for the reaction cell.

Cause Reaction cells are contaminated or damaged.

Remedy

1. Check that the reaction cell is not contaminated or cracked.
2. Choose **Utility** > **Maintenance** and perform maintenance item **(7) Wash Reaction Parts**.
3. Ensure that there is no excessive foaming or particles in the incubator bath.

   If you notice excessive foaming or particles, perform maintenance item **(5) Incubation Water Exchange**.
4. Wipe the outside of the reaction cells with a gauze pad moistened with incubator bath water.
5. Resume operation. If alarm recurs, ensure there is adequate rinse water and cell blank water from the rinse mechanism. The cells must be completely filled.
6. Choose **Utility** > **Maintenance** and perform maintenance item **(5) Incubation Water Exchange**.

7. Resume operation. If alarm recurs, choose **Utility** > **Maintenance** and perform maintenance item **(4) Cell Blank Measurement**.

   If an **Abnormal Cell List** is displayed on the **Cell Blank Measurement** report, the cell blank failed. For the cells listed in the **Abnormal Cell List**, the cell blank value differs more than ± 1000 (± 0.1 Abs) compared to cell no. 1. These cells need to be inspected (or replaced) and the **(4) Cell Blank Measurement** must be performed again.

   For further instructions, see:
   To perform a cell blank measurement
   Replacing reaction cells

8. Resume operation. If alarm recurs, call Roche Service representative.

ISE, results are erratic

Section in Operator's Manual Troubleshooting > Troubleshooting > c 501 (ISE) troubleshooting > ISE, results are erratic

Description of revision Step **4** of the troubleshooting action has been revised: number of cycles added, information on Ref electrode deleted and information on other electrodes revised.

Revised step 4

4 Perform maintenance check *(2) ISE Check* (30 cycles).

Make sure that there is no alarm and the difference of the measured voltages for each electrode stays within the following limits:

Electrode	Criterion
Na^+, K^+, Cl^-	±0.2 mV from cycle to cycle after the first 10 cycles among 30 cycles.

Table Z-3 Stability criterion during ISE Check

- If the difference of the measured voltages is greater than ±0.2 mV, perform another ISE check.
- Calibrate the ISE units before you resume routine analysis.
- If results are not within range, replace the ISE reference cartridge.

ISE, high internal standard values

Section in Operator's Manual Troubleshooting > Troubleshooting > c 501 (ISE) troubleshooting > ISE, high internal standard values

Description of revision Step **5** of the troubleshooting action has been revised: number of cycles added, information on Ref electrode deleted, and information on other electrodes revised.

Revised step 5

5 Perform maintenance check (2) ISE Check (30 cycles).

Make sure the difference of the measured voltages for each electrode stays within the following limits:

Electrode	Criterion
Na^+, K^+, Cl^-	±0.2 mV from cycle to cycle after the first 10 cycles among 30 cycles.

Table Z-4 Stability criterion during ISE Check

- If all values (Na^+, K^+, and Cl^-) are too high or too low, replace the reference cartridge. An *ISE.E* data alarm is displayed in the printout adjacent to the respective EMF if the following limits are exceeded:

  Na^+: -90 to -10 mV;

  K^+: -90 to -10 mV

  Cl^-: 80 to 160 mV

- If only single values (Na, K or Cl) are outside the range, replace the respective electrode.

ISE Check report explanation

Section in Operator's Manual Software description > Global screens > Reports Printed from Utility > Maintenance > ISE Check report explanation

Description of revision The description of some parameters has been revised: for *NA EMF*, *K EMF*, and *Cl EMF* the first 10 cycles must be discarded, for *KCL RMF* the range information concerning the reference electrode has been deleted.

Revised parameter descriptions

NA EMF This column displays the electromotive force (mV) values of the sodium electrode for each ISE check performed. The number should fall within the range of -90 to -10 mV.

Within 30 cycles the difference from measurement to measurement should not exceed ±0.2 mV from cycle to cycle after discarding the first 10 cycles. Over the total cycle range the difference should not exceed 2 mV.

K EMF This column displays the electromotive force (mV) values of the potassium electrode for each ISE check performed. The number should fall within the range of -90 to -10 mV.

Within 30 cycles the difference from measurement to measurement should not exceed ±0.2 mV from cycle to cycle after discarding the first 10 cycles. Over the total cycle range the difference should not exceed 2 mV.

Cl EMF This column displays the electromotive force (mV) values of the chloride electrode for each ISE check performed. The number should fall within the range of 80 to 160 mV.

Within 30 cycles the difference from measurement to measurement should not exceed ±0.2 mV from cycle to cycle after discarding the first 10 cycles. Over the total cycle range the difference should not exceed 2 mV.

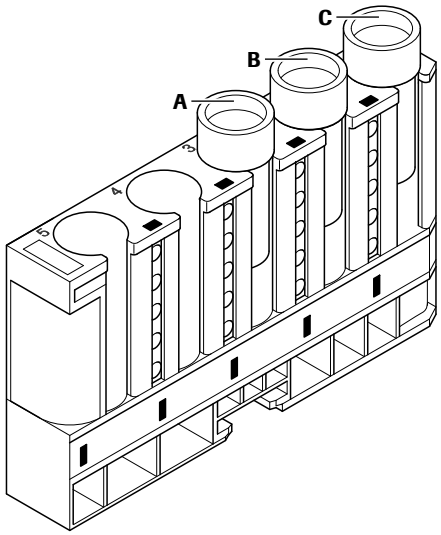
KCL EMF This column displays the electromotive force (mV) values of the reference electrode for each ISE check performed.

Preparing the wash rack and checking the number of cycles

Section in Operator's Manual Maintenance > Maintenance c 501 with ISE > Daily maintenance > Processing green wash rack > Preparing the wash rack and checking the number of cycles

Description of revision The illustration in step **1** of the maintenance action has been revised: the callout letters below the image were wrongly given as **E**, **F**, and **G** and have been corrected to **A**, **B**, and **C**.

Revised illustration



A Activator (for conditioning) **B** SysClean **C** Sample Cleaner 1

Figure Z-2 Green rack with reagents for daily ISE maintenance

Linearity limit check (>Lin)

Section in Operator's Manual Basic analytical principles > Data alarm rules > Linearity limit check (>Lin)

Description of revision In section *6-16 measuring points* and section *17 or more measuring points*, the formulas that describe under which conditions a data alarm is issued have been revised using absolute values.

Revised paragraph in section *6-16 measuring points*

The percentage of nonlinearity is the difference between the slope of the initial part of the curve and the slope of the final part of the curve scaled to the overall slope. An alarm is issued, if $(|v_i - v_f|/|v_x|) * 100 > LL_1$, where LL_1 is the value of the first box in the **Linearity Limit** line on **Utility** > **Application** > **Analyze**.

Revised paragraph in section *17 or more measuring points*

An alarm is issued, if $(|v_i - v_f|/|v_x|) * 100 > LL_2$, where LL_2 is the value of the second box in the **Linearity Limit** line on **Utility** > **Application** > **Analyze**.

Term revisions

The following terms in the Operator's Manual have been revised.

Roche-provided gateway instead of *cobas link* (and other gateway names)

Several different hardware gateways are now in use to connect analyzers with the Roche digital infrastructure, e.g., Connect 2+, **cobas** link, and Unified Gateway. The term *Roche-provided gateway* has been introduced as a generic term for all of these gateways.

The revision affects numerous sections in the Operator's Manual which cannot all be outlined in this addendum.

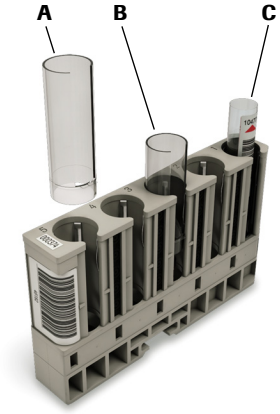
Therefore, refer to the following section in this addendum as an example on how the term is now used:

See *cobas link* on page Z-5.

Tube adapter instead of *cup adapter*

The term *cup adapter* has been replaced with the term *tube adapter*. The material number, however, remains unchanged: 05463190001.

The following illustration from the Operator's Manual explains the new term:



A Roche Diagnostics tube adapter
B Insert tube adapter into rack
C 13 mm tube placed in a rack position with tube adapter

Figure Z-3 Placing a tube adapter into a rack

The revision affects the following sections in the Operator's Manual:

- System description > Control unit, cobas link and core unit > Trays, racks, tubes, and cups > Racks > Rack types
- System description > Control unit, cobas link and core unit > Trays, racks, tubes, and cups > Racks > Correct alignment of sample tubes on a rack
- System description > Specifications > General system specifications > Sample cups and tubes
- Operation > Daily operation > Routine operation

IS measurement instead of *one-point calibration/single-point calibration*

For the ISE module, the term *one-point calibration* and the term *single-point calibration* have been replaced with the term *IS measurement*.

For photometric modules, the terminology remains unchanged.

The revision affects the following sections in the Operator's Manual:

- System description > c 501 module > ISE area components > Flow of an ISE analysis (2nd paragraph)
- Operation > Reagents > Reagent concept – c 501 > Reagents for ISE applications > Reagents
- Operation > Calibration > Calibration concept – c 501 > Calibration concept - ISE applications
- Basic analytical principles > Measurement technology > ISE technology > Measurement sequence
- Basic analytical principles > Test principles > ISE unit - Ion selective electrode principles > Introduction (3rd paragraph)
- Basic analytical principles > Calibration principles > ISE unit - Ion selective electrode calibration > One-point calibration