Roche

cobas u 411 urine analyzer
Operator's Manual
Version 3.0

Software Versions 3.2 and 3.3

US Publication information

Edition notice This publication is intended for operators of the ***cobas u 411 urine analyzer***.

The contents of this document, including all graphics and photographs, are the property of Roche. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of Roche.

Every effort has been made to ensure that the information is correct at the time of publishing. Not all functionality described in this manual may be available to all users. Roche Diagnostics reserves the right to change this publication as necessary and without notice as part of ongoing product development. Such changes may not immediately be reflected in this document.

Screenshots Any screenshots in this publication are added exclusively for the purpose of illustration. Configurable and variable data such as parameters, results, path names etc. visible therein must not be used for laboratory purposes.

Intended use *This document is intended for the US market only.*
CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Trademarks The following trademarks are acknowledged.

COBAS, COBAS U and CHEMSTRIP are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

Distribution Roche Diagnostics, Indianapolis, IN USA 46256
This operator's manual is printed in the US.

Feedback This document was created by Roche Diagnostics GmbH (operator manual content) and the Roche Diagnostics Engineering Operations department. Direct questions or concerns regarding the contents of this document :

Roche Diagnostics Corporation
Engineering Operations Department
9115 Hague Road
Indianapolis, IN 46256
USA

Document availability This document is available on the Roche Diagnostics USA website at dialog.roche.com

Request additional copies of this document by sending an email to indianapolis.rsn_documentation@roche.com. Request the US order number listed in the footer.

Warranty for the instrument

Roche warrants the instrument against defects in materials and workmanship (except for consumable items and lamps) for a period of one year (90 days in the case of parts in direct contact with reagents). Roche, at its option, either replaces or repairs free of charge, on an f.o.b. Indianapolis, Indiana basis, all instruments and parts which prove to be defective and are subject to such warranty.

Field-installed options, modifications, and used equipment carry a ninety (90) day parts and labor warranty. Any component part(s) and labor necessary to complete a repair are guaranteed for thirty (30) days. Some replacement components, such as printers, monitors, etc., may carry a longer warranty.

This warranty does not apply to instruments not installed by a Roche Field Service Representative/Field Application Specialist (or authorized agent of Roche) and/or not used according to instructions or damaged by accident, alteration, misuse, tampering, and/or abuse.

We warrant that the services provided under a Roche Warranty or Service Agreement are free from defects in workmanship for a period of thirty (30) days from the date of service.

Warranty for the reagent

Roche warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label.

WE HEREBY DISCLAIM ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE EQUIPMENT, REAGENTS AND SERVICES PROVIDED, EXCEPT THE LIMITED WARRANTY SET FORTH ABOVE. WE ARE NOT LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO, LOST PROFITS OR REVENUES, LOSS OF THE USE OF THE CAPITAL, COST OF SUBSTITUTE EQUIPMENT, REAGENTS, FACILITIES OR SERVICES AND/OR DOWN-TIME COSTS RESULTING FROM OR ARISING IN CONNECTION WITH THE PERFORMANCE, DELAY IN PERFORMANCE OR NONPERFORMANCE OF ANY TERM OR CONDITION OF A ROCHE WARRANTY OR SERVICE AGREEMENT OR FROM THE USE OR MISUSE OF THE INSTRUMENT (OR ANY SUBSTITUTE THEREFORE) OR REAGENTS OR ANY MATERIALS OR WORKMANSHIP DELIVERED HEREUNDER, EVEN IF WE HAVE BEEN ADVISED, KNEW OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES. YOUR EXCLUSIVE REMEDY WITH RESPECT TO OUR WARRANTY OF ANY EQUIPMENT, REAGENTS OR PARTS SHALL BE REPAIR OR REPLACEMENT OF THE DEFECTIVE ITEM(S), AT OUR OPTION. AS YOUR EXCLUSIVE REMEDY FOR ANY SERVICE PERFORMED UNDER THIS LIMITED WARRANTY WE SHALL RE-PERFORM ANY SERVICE WHICH WAS DEFECTIVE.

OS-02994-01

Limited warranty and limitation of liability for software

The software described in this Operator's Manual (the "Software") is provided "as is" without warranty of any kind, either express or implied, including, but not limited to the implied warranties of merchantability or fitness for a particular purpose. ROCHE SPECIFICALLY DISCLAIMS ALL WARRANTIES TO THE FULLEST EXTENT PERMITTED BY LAW. The entire risk as to the quality and performance of the Software is with Customer should the Software prove to be defective. Customer assumes the entire costs of all necessary servicing, repair or correction of the Software. However, Roche warrants that the program media on which the Software is furnished is and will remain free from defects in materials and workmanship under normal use for a period of ninety (90) days from the date of delivery.

If the Software application program media is found defective, Roche's sole obligation under this warranty is to remedy such defect in a manner consistent with Roche's regular business practices. In the event that Roche is unable to remedy such defect within a reasonable amount of time, Roche may terminate the license for the Software granted in the Operator's Manual by written notice to Customer, in which event Customer shall be entitled to a refund of the unamortized portion of any applicable license fee actually paid by Customer to Roche for the Software. In such an event, Customer must return the defective program media to Roche as a condition to receipt of Customer's refund. The foregoing obligations to remedy defects and to refund license fees do not apply if the Software has been altered by Customer or has not been installed, operated, repaired or maintained in accordance with any written instructions provided by Roche. Any service provided by Roche to remedy problems due to Customer's errors or system and network inadequacies shall be billed at Roche's standard time and material charges.

IN NO EVENT WILL ROCHE OR ANY OF ROCHE'S AFFILIATES (OR THEIR RESPECTIVE OFFICERS, EMPLOYEES, CONSULTANTS, ATTORNEYS OR AGENTS) BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO DAMAGE TO COMPUTER SOFTWARE OR HARDWARE (WHETHER OR NOT PROVIDED BY ROCHE), LOST PROFITS, LOST DATA OR INFORMATION, LOSS OF USE OF THE SOFTWARE, BUSINESS INTERRUPTION, LOSS OF BUSINESS REPUTATION OR GOODWILL, DOWNTIME COSTS, OR ANY OTHER COMMERCIAL DAMAGES OR LOSSES WHICH CUSTOMER MAY INCUR OR EXPERIENCE, DIRECTLY OR INDIRECTLY, ARISING OUT OF OR RELATING TO THE SOFTWARE, HOWEVER CAUSED AND REGARDLESS OF THE THEORY OF LIABILITY, EVEN IF ROCHE OR ANY OF ITS AFFILIATES HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ROCHE'S TOTAL LIABILITY FOR ALL DAMAGES ARISING OUT OF OR RELATING TO THE USE OF THE SOFTWARE BY CUSTOMER SHALL BE LIMITED, AT ROCHE'S OPTION, TO REPLACEMENT OF THE SOFTWARE OR A REFUND BY ROCHE OF ANY LICENSE FEES RECEIVED FROM CUSTOMER WITH RESPECT TO THE SOFTWARE.

Contact Support and/or Service Representatives

Roche provides 24 hour-a-day, 365 day-a-year telephone assistance. In addition, on-site service is provided in a timely manner. In order for us to comply with federal record keeping requirements, if you need to contact your Roche Diagnostics service representative, call the appropriate Customer Support Center number listed below. They, in turn, notify your representative to contact you.

Chemistry, Immunology, Automation & Urinalysis products
1-800-428-2336

The Customer Support Center answers all calls pertaining to Roche products. If the Customer Support Center cannot resolve a problem by phone, a Roche representative is dispatched.

Service policy questions
Questions relating to your service policy can be referred to your local Roche representative or the regional service manager by calling number above.

Customer Education

Roche Diagnostics offers training options for both instrument and IT solutions which can be found in Roche Diagnostics University (RDU). Please contact your Roche Diagnostics representative about online availability and RDU access.

Ordering Information

Order replacement parts, consumable materials, reagents, standards, calibrators and controls as necessary from Roche. Please use the catalog number and reference name for each item when placing an order with Roche Order Fulfillment.

Roche Order Fulfillment
1-800-428-5030

Contacting Sales Representatives

If you wish to contact your sales representative, he or she may be reached by calling Roche Order Fulfillment or by leaving a message on their voice mail.

Roche Order Fulfillment
1-800-428-5076

Voice mail
1-800-845-7355

Enter the appropriate mailbox number or press # to spell the name.

Customer Communications

As the need arises, you will receive various customer communications concerning information about your system. These updates are usually in one of the following forms.

Customer communications can also be viewed on the internet. Some documentation is available online only. Go to dialog.roche.com and select **Documentation**.

Bulletins

Bulletins (Reagent, Software, or Analyzer) are printed on Roche Diagnostics letterhead. Bulletins contain information that is vital to the performance of your system. Communicate bulletin information internally to all analyzer operators. Keep bulletins on file until the reagent expires, you receive updated labeling or you are notified by Roche Diagnostics to discard them.

Urgent Medical Device Correction or Removal

Urgent Medical Device Correction or Removal is printed on Roche Diagnostics letterhead with the words **Urgent Medical Device Correction** or **Urgent Medical Device Removal**. These require immediate attention by the analyzer operator and are to be filed for reference until further notice.

Customer Letters

Customer Letters are printed on Roche letterhead and contain general information or attachments that you may place in your files. You may discard Customer Letters after reading and following any applicable instructions contained in them.

Product Announcement

Product Announcements are usually announcing product launches. They contain specific details about a new product such as features and benefits, kit configuration and pricing. Product Announcements may or may not be discarded depending on your laboratory's preference.

CLIA/CLSI Compliance

Roche documentation, which includes this operator's manual, methods sheets and active customer bulletins, conforms with the guidelines in effect at the time of publication listed in the Code of Federal Regulations (CFR) and the Clinical Laboratory Standards Institute (CLSI) General Laboratory Practices and Safety Guidelines. Documentation also meets the Centers for Medicare and Medicaid Services, formerly known as Health Care Financing Administration, interpretation of the requirements for the Clinical Laboratory Improvement Amendments (CLIA '88).

To Change Mailing Addresses or Contact Names

There are several ways to change your mailing address or the contact name for your account. You may:

- send an email or
- go to dialog.roche.com

Provide your name and account number when contacting us. Your account number is provided to you by a Roche representative when your analyzer is installed.

Email

indianapolis.marcom-tech_pubs@roche.com

dialog.roche.com

Contact > Contact Change Form

This page intentionally left blank.

cobas u 411 system

Operator's Manual

Version 3.0

Publication information

Edition notice	This publication is intended for users of the **cobas u** 411 urine 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.

General attention

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

- *Pay particular attention to all safety precautions.*
- *Always follow the instructions in this publication.*
- *Do not use the instrument in a way that is not described in this publication.*
- *Store all publications in a safe and easily 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   © 2007-2021, Roche Diagnostics GmbH. All rights reserved.

License information   The **cobas u** 411 urine analyzer software is protected by contract law, copyright law, and international treaties. The **cobas u** 411 urine analyzer contains a user license between F. Hoffmann-La Roche 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.

Open source and commercial software	The **cobas u** 411 urine analyzer may include components or modules of commercial or open source software.
	This open source and commercial software and the **cobas u** 411 urine 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 u** 411 urine analyzer.
Trademarks	The following trademarks are acknowledged:
	COBAS, COBAS U, COMBUR-TEST, and CHEMSTRIP are trademarks of Roche.
	All other trademarks are the property of their respective owners.
	Combur^{10}Test M test strips are marketed in the US as Chemstrip 10 UA test strips.
	Control-Test M calibration strips are marketed in the US as Chemstrip Calibration Strips.
Feedback	Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.
Approvals	The **cobas u** 411 system meets the requirements laid down in:
	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.
	Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity.
	The following marks demonstrate compliance:

IVD	For *in vitro* diagnostic use.
$C\,E$	Complies with the provisions of the applicable EU regulations.
EAC	Eurasian Conformity. Demonstrates that the product meets the Eurasian Economic Union (EAEU)'s regulations and standards for customs clearance and trading.
c(UL)us LISTED	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Contact addresses

Manufacturer   Roche Diagnostics GmbH
                                     Sandhofer Strasse 116
                                     68305 Mannheim
                                     Germany

                                     Made in Switzerland

Distributed by   Roche Diagnostics
                                     9115 Hague Road
                                     Indianapolis, Indiana
                                     USA

Roche affiliates   A list of all Roche affiliates can be found at:

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

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

                       www.dialog.roche.com

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

Table of contents

Intended use

The **cobas u** 411 urine analyzer is a semi-automated, benchtop analyzer. It is designed to read the **Combur[10]Test M test strips which are marketed in the United States as the Chemstrip 10 UA test strips and Chemstrip 10 MD test strips** for urinalysis. This analyzer is intended for the measurement of bilirubin, blood, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen and color (if selected). These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Tests performed using the **cobas u** 411 are intended for prescription, in vitro diagnostic use only. Only trained personnel working in a professional laboratory environment may operate the **cobas u** 411 analyzer.

How to use this manual

- *Keep this manual in a safe place where it will not be damaged and is available for reference.*
- *This Operator's Manual should be accessible at all times.*

The table of contents at the start of the manual and of every chapter makes it easy to find the subject you are looking for. You will also find a comprehensive index of key words at the end of the manual.

The manual is divided into the following parts:

Part A – System Description The System Description contains information on the safe operation of the **cobas u** 411 analyzer. It also provides an overview of the analyzer. Finally, this section explains the analyzer's hardware components with the technical specifications as well as the software components.

Part B – Operation This section defines the installation procedure as well as the daily and special operations of the **cobas u** 411 analyzer in a step-by-step guide.

Part C – Maintenance This section provides details on all of the general maintenance actions.

Part D – Troubleshooting This section contains information on how to respond to data and instrument alarms, and provides troubleshooting guidelines for alarms that cannot be solved by the operator.

Part E – Glossary and Index This section contains the glossary and the index.

Symbols and abbreviations

Symbols are used to help quickly locate and interpret information in this manual. This section explains the formatting conventions used in this manual.

Symbols used in the publication

Symbol	Explanation
►	Instruction
•	Bullet point
👁	Cross-reference
☞	Commands used to call up a screen or a specific function
💡	Note
❗	Caution
⚠	Warning
☣	Biological hazard

Symbols used on product

Symbol	Explanation
⚠	Caution, consult accompanying documents. Refer to safety-related notes in the instructions for use accompanying this product.
📖i	Consult instructions for use.
IVD	For *in vitro* diagnostic use.
REF	Catalogue number
SN	Serial number
UDI	Unique device identifier
∼	Suitable for alternating current only.
🏭	Manufacturer

Symbol	Explanation
GTIN	Global trade item number
	Date of manufacture
$C \in$	Complies with the provisions of the applicable EU regulations.
c(UL)us LISTED	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.
EAC	Eurasian Confirmity
	Biological hazard
	Protective earth; protective ground.
	Temperature limits
	Humidity range
	This way up.
	Fragile, handle with care.
	Keep dry.
	Stacking limit

Abbreviations The following abbreviations are used:

Abbreviation	Definition
A	
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing Material
B	
BIL	Bilirubin
C	
C/D	Check digit
CLA	Clarity
COL	Color
COM	Compensation pad
csv	comma separated values
E	
EN	European Standard
ERY	Erythrocytes
G	
GLU	Glucose
I	
ID	Identification number
IEC	International Electrotechnical Commission
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
K	
KET	Ketones
L	
LED	Light Emitting Diode
LEU	Leukocytes
N	
neg	Negative
NIT	Nitrite
nm	Nanometer
norm	Normal
P	
pos	Positive
PRO	Protein
Q	
QC	Quality Control
R	
RAM	Random access memory
Rem	Remission (= Reflectance)
ROM	Read only memory

Abbreviation	Definition
S	
SG	Specific gravity
SI	Standard International
SW	Software
U	
UBG	Urobilinogen

System description $\quad$ **A**

Safety information

This chapter contains information on the safe operation of the **cobas u** 411 analyzer.

In this chapter   *Chapter* **1**

Safety classifications

Before operating the **cobas u** 411 analyzer, it is essential that the warnings, cautions, and safety requirements contained in this manual are read and understood by the user. This section explains how precautionary information is formatted in the manual.

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

Warning

Indicates a possibly hazardous situation which, if not avoided, may result in death or serious injury.

Examples of a "serious injury" include loss of eyesight, burn (high temperature, low temperature), electric shock, bone fracture, or poisoning. These injuries require medical assistance.

Caution

Indicates a possibly hazardous situation which, if not avoided, may result in slight or minor injuries, damage to equipment., inaccurate results or loss of result data.

"Minor injury" refers to injuries that may require medical assistance.
"Equipment" refers to extended damage to buildings, furniture, and so on.

Safety precautions

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

The hazard warnings in the Operator's Manual and on the instrument cannot cover every possible case, as it is impossible to predict and evaluate all circumstances beforehand.

Just following the given directions may, therefore, be inadequate for operation. Always be alert and use your common sense.

Safe and proper use of the instrument

Electrical safety

Connect the analyzer to grounded power outlets only (protection class 1).
*All peripheral devices that are connected to the **cobas u** 411 analyzer must comply with the safety standards for information technology equipment, or with the safety requirements for laboratory use instruments and the particular requirements for in vitro diagnostic (IVD) medical equipment.*

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

Good Laboratory Practice can reduce the risk of injury. Be aware of your laboratory environment, well-prepared, and follow the instructions for use. Some areas of the instrument may have sharps, rough edges, and/or moving parts.

- *Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument.*

- *Your personal protective equipment should be appropriate to the degree and type of potential hazard, e.g. suitable lab gloves, eye protection, lab coat, and footwear.*

User qualification

Only appropriately trained operators are qualified to operate the analyzer.

Correct use

*Any disregard of the instructions in the Operator's Manual may result in a safety risk. Use the **cobas u** 411 analyzer to analyze urine samples only. It is not intended for any other application.*

Environmental conditions

*The **cobas u** 411 analyzer is approved for indoor use only.*

Test strip handling

Do not bend test strip. Dip the test strip briefly (1 sec) in the urine sample. Draw the long edge of the strip along the rim of the specimen container to remove excess urine.

Biological safety

Strip waste is potentially biologically hazardous.

Samples containing material of human origin must be treated as potentially infectious.

- *Always wear protective gloves when handling this material.*
- *Do not touch parts of the analyzer other than those specified.*

Particular care must be taken when performing the following actions:

- *Preparing and processing samples (routine and control)*
- *Cleaning the test strip pusher, the test strip transfer and the test strip tray and waste area*
- *Disposing of used test strips*

Consult your laboratory protocol for handling biohazard materials.

Spilling and cleaning

If a sample is spilled on the analyzer, wipe it up immediately and apply disinfectant.

Consult your laboratory protocol for handling biohazard materials.

Radio interference

The **cobas u** *411 analyzer is a class B device. In residential areas it may cause radio interference. The user must take precautions as required.*

Installation

Follow the specified installation instructions carefully. Otherwise, inaccurate results or damage to the analyzer may occur.

Electromagnetic waves

Devices that emit electromagnetic waves may affect measured data or cause the analyzer to malfunction. Do not operate the following devices in the same room where the analyzer is installed: mobile phone, transceiver, cordless phone, other electrical devices that generate electromagnetic waves.

Safety precautions

Protection of personal data and software security

The General Data Protection Regulation (GDPR) is a regulation in EU law 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.

If this regulation or any other privacy protection regulation is applicable for your country, observe the following safety messages to prevent data breaches and to meet the GDPR:

Access control

Unauthorized access may lead to data breaches.

- *Implement physical access controls to ensure that only authorized personnel operate the system at all times.*
- *Assign a personal, unique user ID to each user for system access.*
- *Assign access rights to each user only as high as required for the tasks of the user.*
- *Delete user IDs from the system for users who no longer work on the system.*
- *Delete all results, user ID's, and sample ID's before the instrument is taken out of a protected environment, e.g., for disposal or shipping.*

Corrupt data due to a disclosed password

The security of the system and its data depends on the password-protected access. If an unauthorized person discovers your user ID and password, they could compromise this security.

- *Always enter your password unobserved.*
- *Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer.*
- *Do not disclose your password to anyone. Roche will never ask you for your password.*
- *If you ever disclose your password to anyone, change it immediately afterwards.*
- *Contact your local Roche affiliate if you think your account has been compromised.*

Network security

Malicious software and hacker attacks may impair IT security. The laboratory is responsible for the IT security of their IT infrastructure.

- *Secure all devices and services used in the lab infrastructure against malicious software and unauthorized access.*
- *Secure the network environment to be resilient against traffic redirection and eavesdropping.*

Data entry and data transfer

Writing patient sensitive information in comment fields can violate protection laws for protected health information.

- *Do not write any patient sensitive information into comment fields.*
- *Do not use patient identifiers as part of the Sample ID.*
- *Do not download patient identifiers from any host system (e.g., LIS, middleware, or HIS) onto the system. Data transfer using any host protocol is not encrypted; data is transferred as plain text and readable with IT tools like Sniffer.*

Secure data storage

Unauthorized access to data backups and archive files can violate data protection laws.

- *Any data backup or data archive that has been exported from the instrument must be physically stored in a secured location.*

- *Ensure only authorized persons may access the secure data storage. This includes the data transfer to remote storage locations and disaster recovery.*

- *Data backups must not be taken from the secure data storage. Do not take external storage devices outside the lab environment.*

Cybersecurity and privacy awareness

Insufficiently informed employees can endanger security.

- *Perform regular cybersecurity and privacy awareness trainings for staff handling personal data. Instruct staff how to handle data in a compliant way and according the privacy principles as mandated by customer regulations.*

- *Check your instrument for suspicious activity and report any suspected compromise to your local Roche representative immediately.*

- *Update to the latest software versions provided by Roche as soon as possible.*

- *Exercise care when using external storage devices. Do not connect to the system any external storage device that you use on public or home computers. Failure to do so may result in data loss and render the instrument unusable.*

Use of storage devices

Incorrect handling of external storage devices may result in data loss or system malfunction.

- *Only insert or remove an external storage device after the data export is finished.*

- *At any one time only one external storage device can be in use. Before inserting an external storage device into a USB port, check that no other external storage device is connected.*

Computer viruses

If you detect an unexpected operation or program/data damage, the instrument may be infected with a computer virus.

- *To avoid virus infections, scan removable storage devices by an antivirus program before using them on the system.*

- *Never use a program or external storage device that is suspected of containing a virus.*

- *If you think your instrument is infected with a computer virus, call your local Roche Service representative. Your local Roche Service representative will check your system for proper functionality.*

Data backup

Data may get lost due to instrument failure or damage.

- *Back up your data (measurement results and system parameters) at regular intervals.*

- *Use the backup function periodically to store relevant data on an external storage device.*

- *Make a backup copy if you have changed any system parameters.*

Non-approved third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior by the system.

- *Do not copy or install any software or software patches on the system unless it is part of the system software or your Roche Service representative advises it.*

Disposal recommendations

All electrical and electronic products should be disposed separately from the municipal waste system. Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

Disposal of the instrument

Used test strips and instruments must be treated as biologically contaminated-hazardous waste. Final disposal of waste (strips) and instrument must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed on for final disposal.

For more information contact your Roche Service representative.

Disposal of control unit components

Components of your control unit such as the computer, monitor, keyboard, etc., which are marked with the crossed out wheeled bin symbol are covered by the European Directive on Waste of Electrical and Electronic Equipment (WEEE).

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office, waste disposal service or your Roche Service representative.

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

Operation and maintenance

Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the analyzer. Leave maintenance of other areas to your Roche Service representative.

Calibration

Calibrate the analyzer once a month to ensure the analyzer operates optimally. Failure to do so may lead to inaccurate results.

Test strips

Handle and store test strips according to the instructions provided by Roche Diagnostics. Refer to the instructions in the package insert of the Combur^{10}Test M (see Trademarks on page 5) test strips.

Safety labels of the analyzer and their significance

Risk of infection from contaminated samples!

Strip waste is potentially biologically hazardous.

Samples containing material of human origin must be treated as potentially infectious.

- *Always wear protective gloves when handling this material.*
- *Do not touch parts of the analyzer other than those specified.*

The whole inside of the analyzer may be contaminated with potentially infectious or toxic material. Always wear protective gloves when cleaning the following parts:

- 👁 *Test strip transfer system on page A-27*
- *Test strip pusher*
- *Test strip transporter*
- *Test strip tray and -waste area*

Figure A-1   Safety labels of the analyzer

Safety labels of the analyzer and their significance
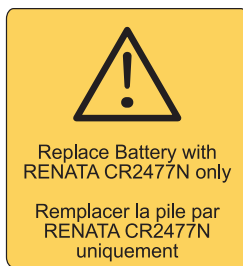
Battery may explode if mistreated!

- *Do not recharge, disassemble or dispose of the battery in fire.*

- *Servicing of the battery circuit and replacement of the lithium battery must not be done by the user. Only authorized persons are allowed to replace the lithium battery.*

- *Replace battery with RENATA CR2477N only. Use of another battery may present a risk of fire or explosion.*
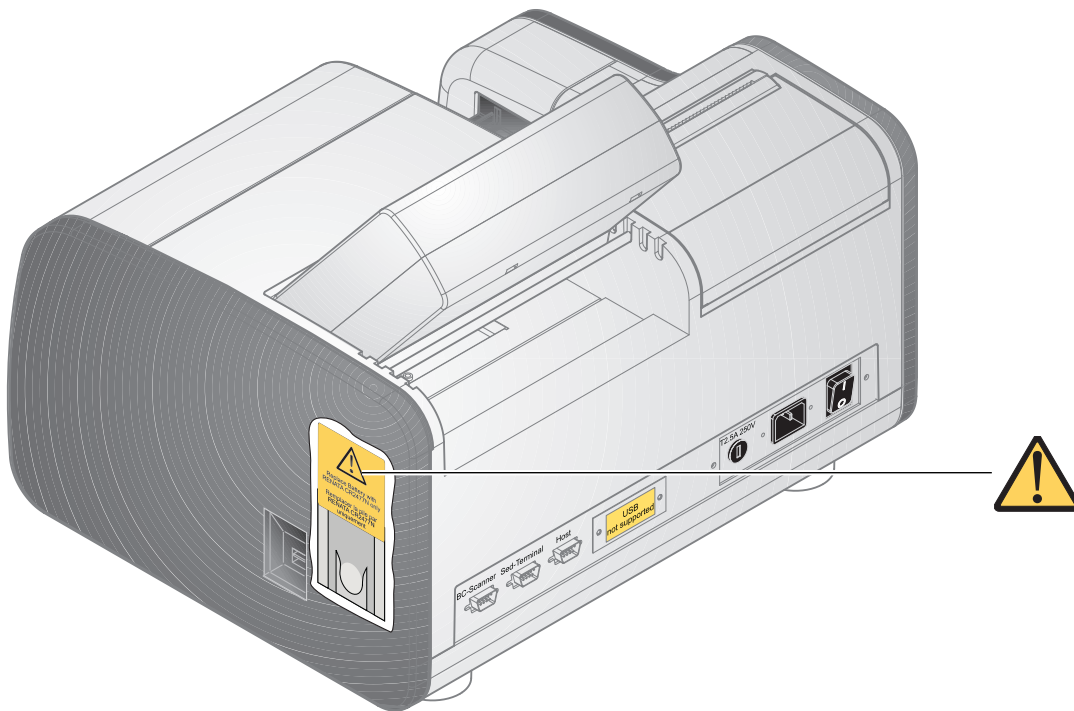
Figure A-2   Safety labels of the analyzer

Introduction to the system

This chapter contains an introduction to the **cobas u** 411 analyzer.

In this chapter   *Chapter* **2**

Overview of the analyzer

The **cobas u** 411 analyzer is a semiautomatic urinalysis system intended for in vitro qualitative or semi-quantitative determination of urine analytes, including specific gravity (SG), pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, and erythrocytes and color. Only trained personnel working in a professional laboratory environment may operate the **cobas u** 411 analyzer.

The primary functions of the **cobas u** 411 analyzer include:

- Sample identification (with optional barcode scanner only)
- Controlled incubation period
- Photometric measurements
- Result memory
- Optional formats for data output

The **cobas u** 411 analyzer uses Combur^{10}Test M (see *Trademarks* on page 5) test strips. Each test strip has ten or eleven individual test pads that are used to test for different substances or characteristics (including color compensation pad). The test strips are analyzed as they move automatically through the analyzer. One strip is used per sample. The test results are based on the measurement of reflected light intensity.

Sample processing

► **To process samples using the cobas u 411 analyzer**

Place the wet test strip correctly on the test strip tray.

- The photoelectric sensor recognizes the test strip.

The test strip pusher draws the test strip into the analyzer.

- The test strip is drawn into the transporter within a cycle time of approx. 6 seconds. The test strip transporter now takes over the test strip.

The test strip transporter carries the test strip into the measuring position.

- Once the test strip transporter has taken over the test strip, it carries the test strip into the measuring position. This takes about 10 cycles (approx. 55 seconds).
- The **cobas u** 411 analyzer will measure the test strips 11 cycles (approx. 60 seconds) after the strip was positioned.

The photometer performs a reference measurement.

- Before every measurement, the photometer is located in its home position above the reference test strip.
- Once a test strip has reached the measuring position, a comparison measurement of the reference test strip is performed.

The photometer measures the sample test strip.

- Once the comparison measurement of the reference test strip has been performed, the photometer moves into position over the sample test strip.
- The test strip is now exposed to each of the three different wavelengths in quick succession.
- The photodiode detector measures the light reflected by each wavelength.
- The measured values are then converted into concentration results.

The sample test strip is transported to the waste container.

- The test strip transporter carries the test strip to the waste container in the next cycle.

Measuring principle

The first part of this section contains an overview of how the **cobas u** 411 analyzer evaluates the test strip measurements.

Reflected light is measured electro-optically, and the process is illustrated in the following figure:

- - - ▶ **Optical transmission**   ━━━▶ **Electronic transmission**

A   LED   **D**   Analog-to-digital converter
B   Test pad   **E**   Computer
C   Photodiode detector   **F**   Result
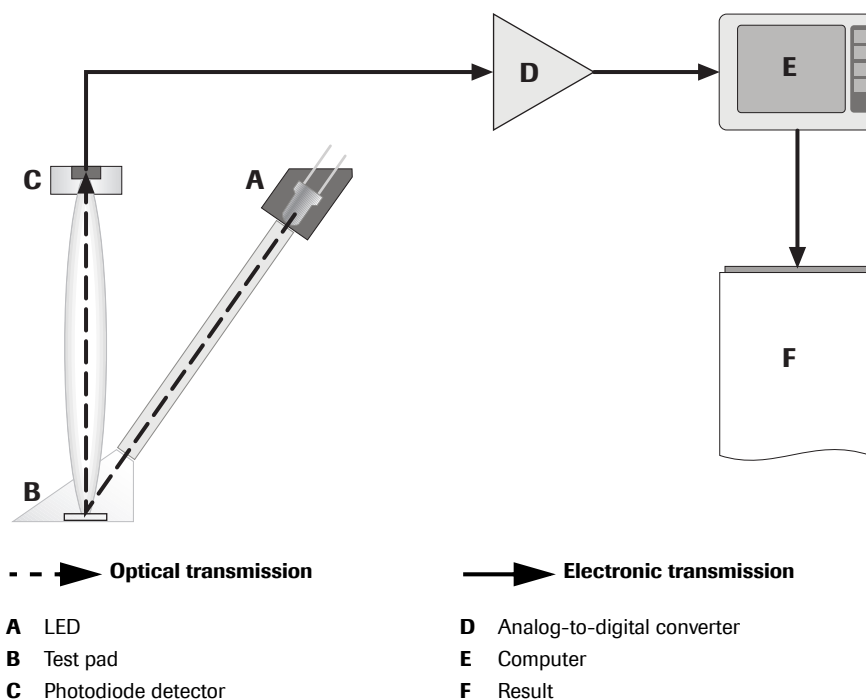
Figure A-3   Process of measuring

Several LEDs (**A**) use a light pipe to transmit light of a defined wavelength onto the surface of all test pads (**B**).

The light that hits the test pad is reflected with an intensity that is dependent on the color of the test pads. A photodiode detector (**C**) positioned directly above the test pad receives the reflected light.

The photodiode detector transmits an analog electrical signal to the analog-to-digital converter (**D**), which changes the analog signal to a digital value.

The computer (**E**) then converts the digital value into the semi-quantitative result (**F**).

The following sections contain more details on the processing of the signal and the measured value.

Signal processing in the reflectance photometer

The LEDs' wavelengths are optimized for the color development that occurs on the test pads.

The light from the LEDs (**A**) is directed through the light pipe onto the entire test strip (**B**) with its 11 test pads. The reflected light is then transferred onto the photodiode detector (**C**) via a lens. Every test pad has its own lens and its own photodiode. This means that every test pad is evaluated individually.

Measuring the reference test strip

Before every measurement, the photometer is located in its home position above the reference test strip. Once a test strip has reached the measuring position, a measurement of the reference test strip is taken. This also guarantees the integrity of the measurement system for every measurement.

Measuring the sample test strip

The photometer then moves into position over the sample test strip. The test strip is now exposed to each of the three different wavelengths in quick succession.

Dark value

To exclude the influences of ambient light, a so-called dark value is taken into account every time the reference and the sample test strip are measured. The dark value is measured when the LEDs are switched off.

Signal processing in the photometer

The 11 photodiodes measure the light reflected by each wavelength.

The photodiode signals are processed electronically and converted into digital values by an analog-digital converter. In digital form, the computer can use these measured values to calculate the concentration result.

The following section describes how the concentration results are calculated.

👁 *Processing measured values by computer* on page A-19

The following table lists the wavelengths that are used to measure the parameters.

Test parameters	Measuring wavelength (nm)
Specific gravity	620
pH	555, 620
Leukocytes	555
Nitrite	555
Protein	620
Glucose	555
Ketones	555
Urobilinogen	555
Bilirubin	555
Erythrocytes	555, 620
Color	470, 555, 620

Table A-1   Wavelengths used to measure the reflectance values

Processing measured values by computer

The following block diagram illustrates the individual steps involved in processing the measured values:
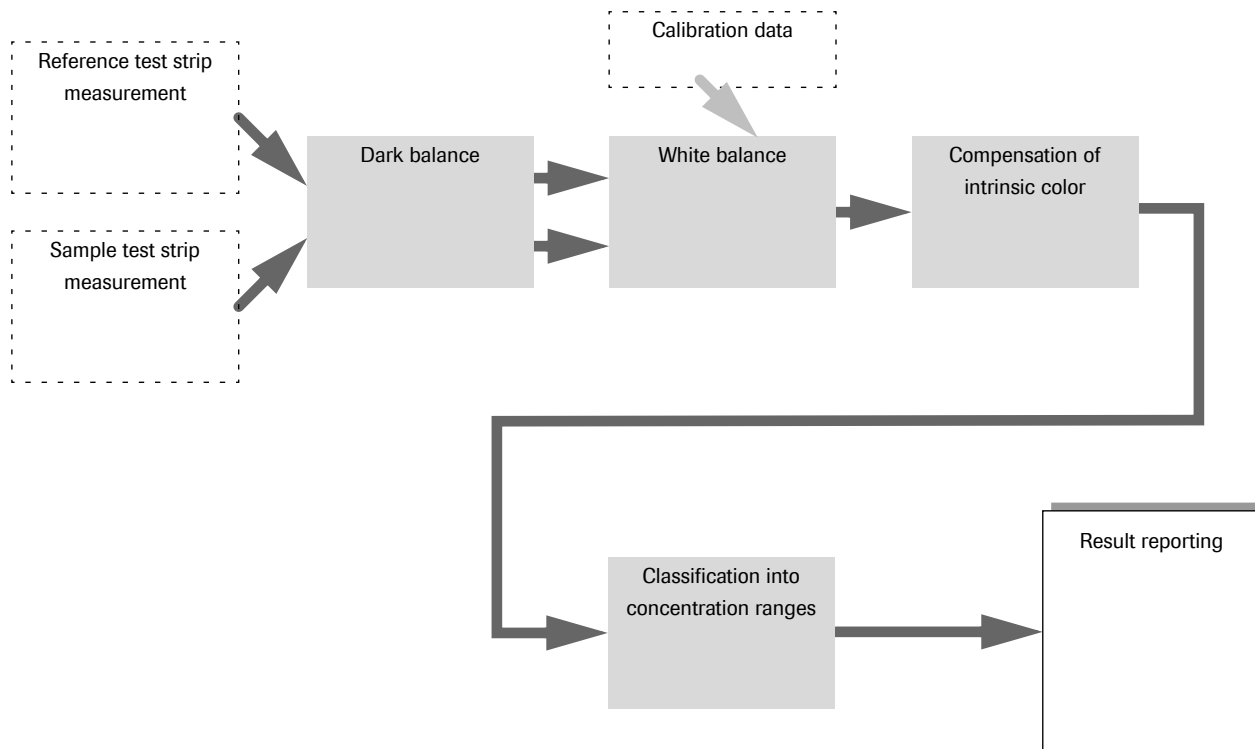
Figure A-4   Processing measured values

Dark balance   The dark balance is conducted within the photometer. Each individual measured value is adjusted by the dark value to exclude influences from the ambient light.

After the signal has been processed by the photometer, the measured values for the reference test strip and the sample test strip that have been adjusted by the dark value are available as digital values for each individual test pad.

Calibration and white balance   To be able to measure absolute reflectance, the measurement system must be calibrated using a test strip with a known reflectance value. To this end, the system is calibrated using the same reference test strip that is installed in the analyzer.

👁 *Calibrating the analyzer* on page B-70

For the white balance, the measured values for the reference test strip and the sample test strip are offset against the calibration values and the target reflectance values.

This means that there are three results for each test pad on the measured sample test strip; one for each wavelength.

Compensation of intrinsic urinary color   The intrinsic urinary color, which is a recognized interfering factor, can be taken into account by measuring a compensation pad on the test strip when calculating the result. The compensation pad assists in the prevention of false positives when a urine sample is strongly colored.

The **cobas u** 411 analyzer determines the urine color by evaluating the reflectance values of all 3 measuring wavelengths (470 nm, 555 nm, and 620 nm) on the

compensation pad. Color results are reported as pale yellow, yellow, amber, brown, orange, red, green and others.

Classification into concentration ranges

To determine the concentration of a parameter from the previously calculated reflectance values, the reflectance values are classified into concentration ranges with the help of a classification table (range table).

👁 *Range table* on page B-87

The range table is divided into up to 8 concentration ranges. A reflectance value is allocated to every concentration range as a limiting value that defines the concentration range. The calculated reflectance values are now compared with the limiting values. The final result is the allocation of every test pad to a concentration range. The measured value is thereby converted into a semi-quantitative result.

The results are stored in the memory and can be printed, stored on an USB stick, or sent to another computer.

👁 The full list of concentration range values for all test parameters is shown in: Table A-5 on page A-42

Operating states

This section contains a description of the operating states of the **cobas u** 411 analyzer. The operating states are displayed in the status bar of the screen.

A   Status bar

Figure A-5   [Overview] tab - operating states

During operation, the analyzer changes in different operating states:

- Initialization
- Stand-by
- Operation
- Utilities
- Stop

The operating states displayed in the status bar of the screen correspond with the LEDs colors of the global action buttons <Start>, <Stop> and <Alarm>.

The following table shows the operating states, the corresponding global action buttons, a short description of the operating states and the states to which the analyzer can change to.

Operating state	Global action button	Description	...can lead up to the following operating states
Initialization	⬡ <Stop> (red)	After the analyzer is switched on, the software and the hardware initializes. The analyzer is in Initialization state. When initialization is finished, the analyzer is in Stand-by state. The analyzer also changes to Initialization state, when the front cover has been closed.	• Stand-by: When the initialization is finished successfully. • Initialization (new): If the front cover is opened during initialization. • Stop: If an error occurs during initialization.
Stand-by	◈ <Start> (green)	In Stand-by state the analyzer is ready for operation. When the analyzer is started for the first time after installation, be sure to perform the calibration.	• Operation: If a test strip is positioned on the test strip tray. • Utilities: If any screen in the [Utilities] tab except for [Utilities > Tools] is selected. • Stop: If a system error occurs.
Operation	◈ <Start> (green)	After a test strip is positioned on the test strip tray, the analyzer changes to Operation state. Until the last test strip has been analyzed and disposed in the waste area, the analyzer remains in Operation state. Then it changes to Stand-by.	• Stand-by: When the analysis is finished. • Stop: If the front cover is opened, the global action button <Stop> is pressed, or an system error occurs.
Utilities	◈ <Start> (green)	If you select any screen in the [Utilities] tab except for [Utilities > Tools], the analyzer changes to Utilities state. As long as the analyzer is in Operation state, you cannot change to Utilities state. The analyzer has to be in Stand-by. In Utilities state you cannot analyze test strips.	• Stand-by: When the [Overview] tab or the [Workplace] tab is selected. The analyzer only changes to Stand-by, if all screens in the [Utilities] tab are closed and the main screen of the [Utilities] tab is displayed.
Stop	⬡ <Stop> (red) ❶ <Alarm> (yellow, red)	Stop signalizes an error. Stop state can be caused by the following user actions: opening of the front cover or pressing <Stop>. When the analyzer changes to Stop state, it performs the following steps: • All test strips on the test strip tray will be disposed in the waste area. • The corresponding samples, controls and calibrators are deleted. • The sequence number of the samples are released. They can be reused for new samples. Stop state can also be caused by a system error. If a system error has occurred, <Alarm> lights up.	• Initialization/Stand-by: After opening of the front cover or pressing <Stop> the analyzer changes to Initialization an then Stand-by. On some system errors the analyzer does not initialize automatically. You first have to acknowledge or remedy the error, if possible. 👁 For more information about system errors see *Instrument alarms (messages)* on page D-7

Table A-2   Overview of the operating states

Hardware

This chapter contains a description of the analyzer hardware.

In this chapter   *Chapter* **3**

System overview

The **cobas u** 411 analyzer is optimized for workloads of between 30 and 100 urine samples per day.

The **cobas u** 411 analyzer consists of several major components:

- Test strip transfer system for the automated processing of test strips
- 3-wavelength reflectance photometer
- Operator control panel
- Internal thermal printer
- Buffered memory
- USB port used for data transfer (results, configuration, database, logfiles) as well as for software loading with recommended USB-stick
- Interfaces for the connection of external equipments
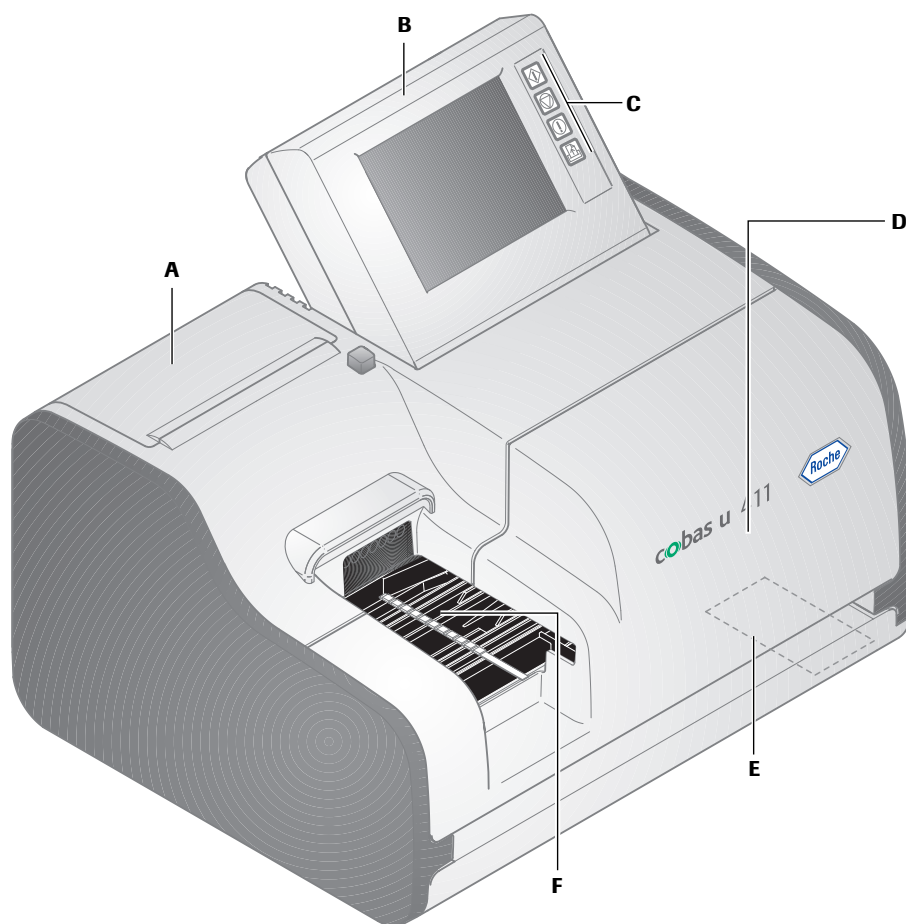
A	Printer	**D**	Front cover
B	Operator control panel with touch screen	**E**	Type plate – below the black cover of the base plate (drip tray)
C	Global action buttons	**F**	Area for test strips on the test strip tray

Figure A-6   The **cobas u** 411 analyzer – front view
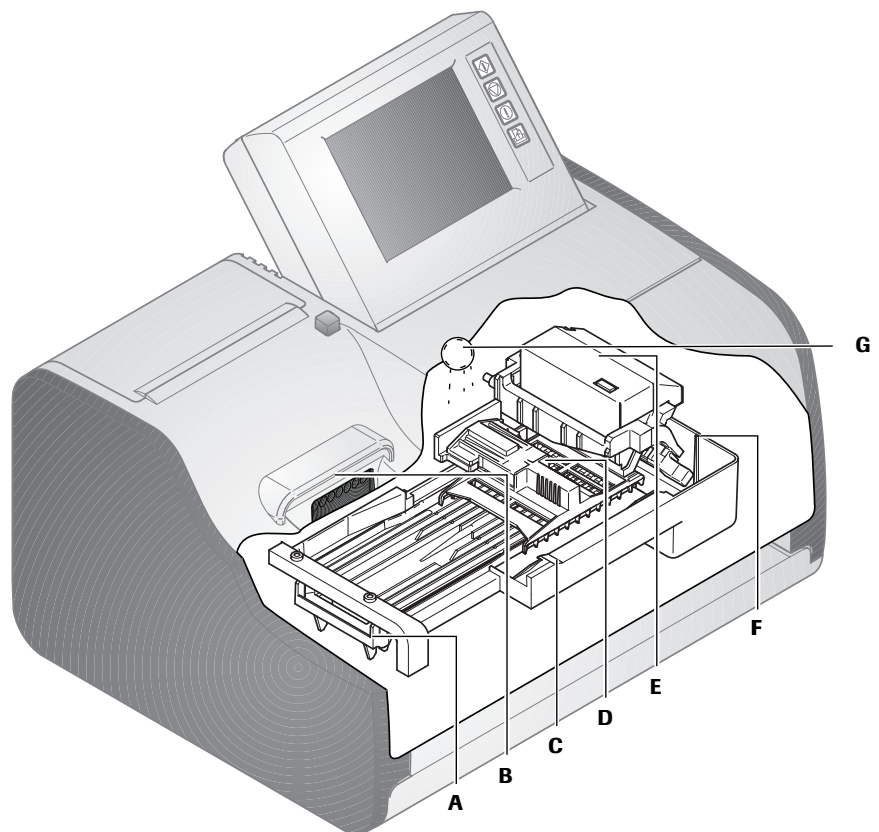
A	Test strip pusher	**E**	Photometer unit
B	Test strip sensor 1	**F**	Test strip waste area
C	Test strip tray	**G**	Test strip sensor 2 (behind the Test strip
D	Test strip transporter		transporter)

Figure A-7   The **cobas u** 411 analyzer – parts behind the front cover

A	USB port	**C**	Mains power connection
B	Battery for data buffering	**D**	Power switch
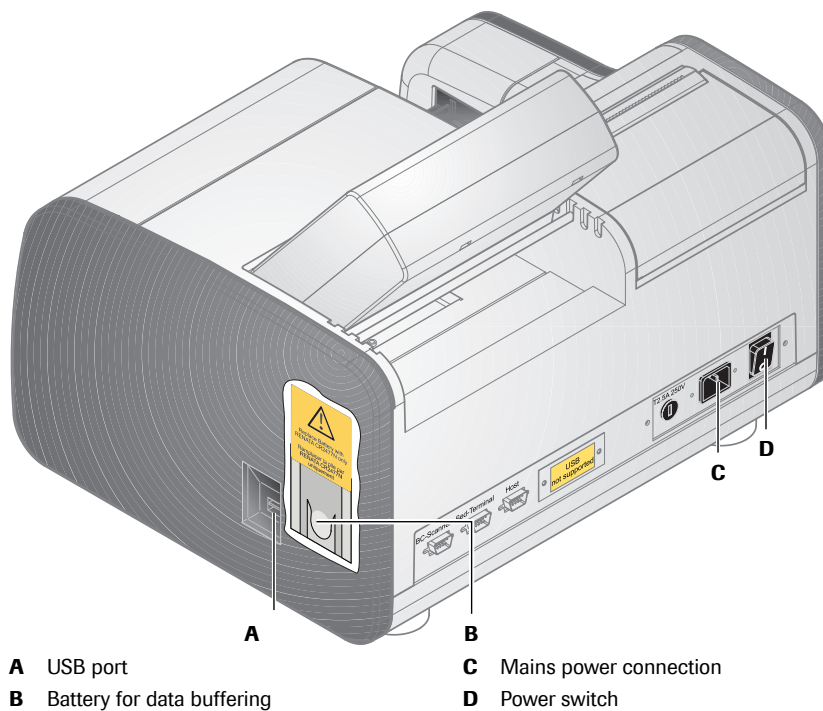
Figure A-8   The **cobas u** 411 analyzer - rear view

System description

The System Description contains information on the major components in the analyzer.

Test strip transfer system

The test strip transfer system comprises the following components:

- Test strip tray with test strip area and integrated waste area
- Test strip pusher
- Test strip transporter

A	Test strip transporter	**D**	Test strip area
B	Test strip tray	**E**	Test strip waste area
C	Test strip pusher		
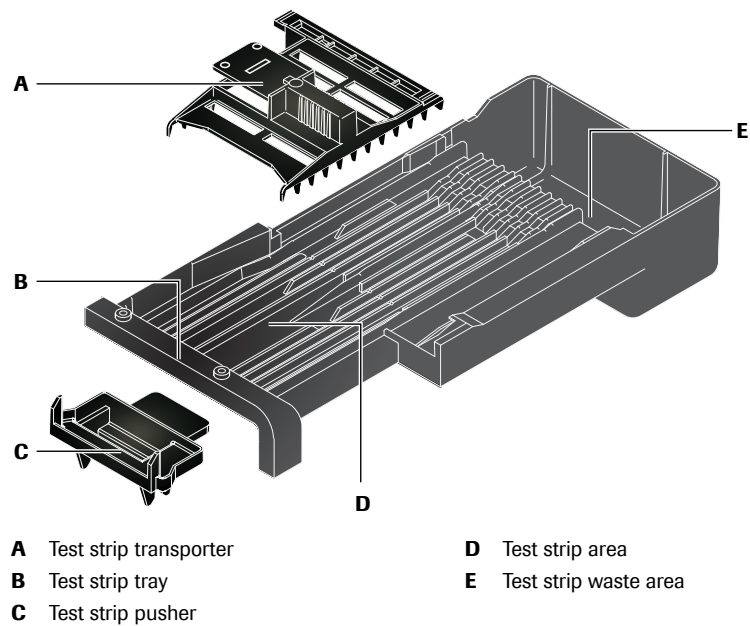
Figure A-9 Test strip transfer system

Test strip tray The test strip tray is a complete plastic tray that can be removed for cleaning. It has an integrated waste area.

Test strip pusher The test strip pusher can also be removed for cleaning. When installed, the pusher reaches up from beneath the transfer tray and draws the test strip from the test strip area into the device.

Test strip transporter The test strip transporter can also be removed for cleaning. When installed, it is positioned above the transfer tray. It transports the test strip into the measurement position.

Reflectance photometer

The **cobas u** 411 analyzer is equipped with a 3-wavelength reflectance photometer.

A	Photometer unit	**E**	Light pipe
B	Reference test strip	**F**	Lens for reflected light
C	Photosensor	**G**	Test strips
D	LED		
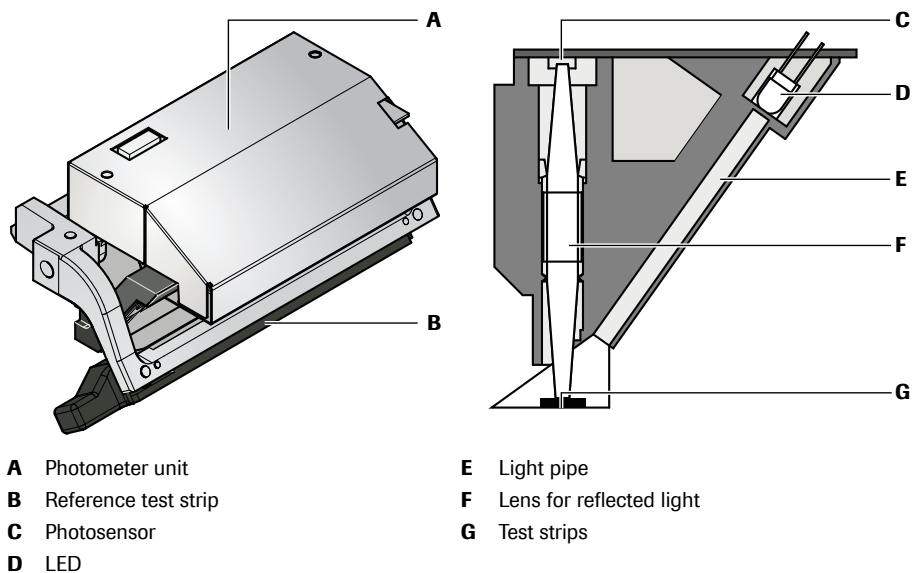
Figure A-10   Photometer unit

The photometer has an arrangement of 20 LEDs. Measurements are taken at the following wavelengths:

- 470 nm
- 555 nm
- 620 nm

The light from the LEDs is directed through a light pipe onto the test strips. The reflected light is transmitted through a lens onto the photosensor.

System description

Operator control panel

The operator control panel of the **cobas u** 411 analyzer consists of a built-in computer with touch screen and global action buttons.

A	Operator control panel	**C**	Global action buttons
B	Touch screen	**D**	Control panel rest for adjusting the angle of the operator control panel (on the rear)
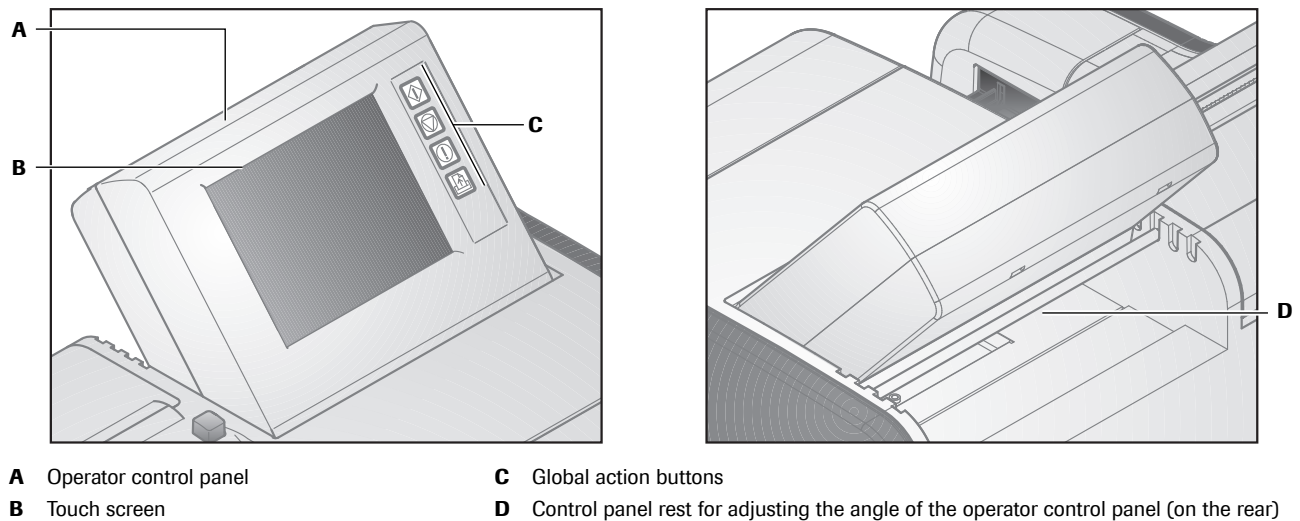
Figure A-11 Operator control panel

The angle of the operator control panel can be adjusted using the control panel rest on the rear of the operator control panel. The operator control panel contains the device's major electronic components and the touch screen.

The operator control panel also contains the global action buttons that allow you to call up functions directly.

👁 *Global action buttons* on page B-21

Printer

The **cobas u** 411 analyzer is equipped with an internal thermal printer.
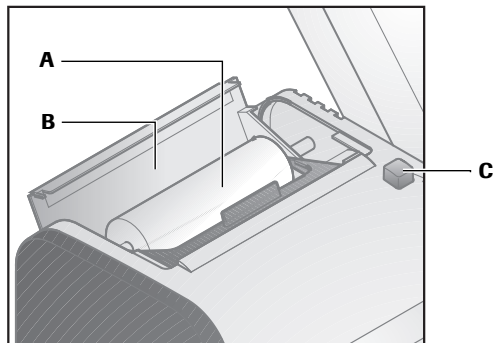
| **A** | Printer | **C** | Release button for printer panel and paper |
| **B** | Printer panel | | stay |

Figure A-12   Internal printer

The thermal printer is equipped with 112 mm paper rolls.

Press the release button to open the printer panel and replace the printer's paper roll.

👁 *Inserting printer paper* on page B-9

USB port

The **cobas u** 411 analyzer's USB port is located on the right-hand side of the device.

👁 Figure A-8 on page A-27

You can use the USB port to store and load your data and settings on an USB stick and to install the user software as well as the operating system software whenever needed.

👁 *Updating the user software* on page B-76

👁 *Storing and loading system, test and sediment parameters* on page B-77

System description

Buffered memory

The internal memory of the **cobas u** 411 analyzer is built in to the computer. The device also features an 32 MB Flash-Memory (Read/Write) and a 32 MB DRAM (Random Access Memory).

The Flash-Memory is a permanent memory that retains data even when the device is switched off or during a power failure. It contains the operating system, the device's system software and the database with the test results and settings.

The DRAM is the device's internal memory. It contains the programs and data that are required for operation of the device.

In the event of a power failure, the **cobas u** 411 analyzer is protected by a capacitor. All important data (system settings and patient results) are written to the Flash-Memory.

When the device is unplugged from the mains, the system battery supplies the power for the internal real-time clock. The system battery is located behind the right-hand cover of the device.

Power supply unit and interfaces

Power supply unit   The **cobas u** 411 analyzer can be operated with a supply voltage from 100 V to 125 V and 200 V to 240 V and a frequency of either 50 Hz or 60 Hz. No adjustment is necessary. It supplies an internal voltage of 24 V.

The power supply unit, the power switch and the fuse are located on the rear of the device.
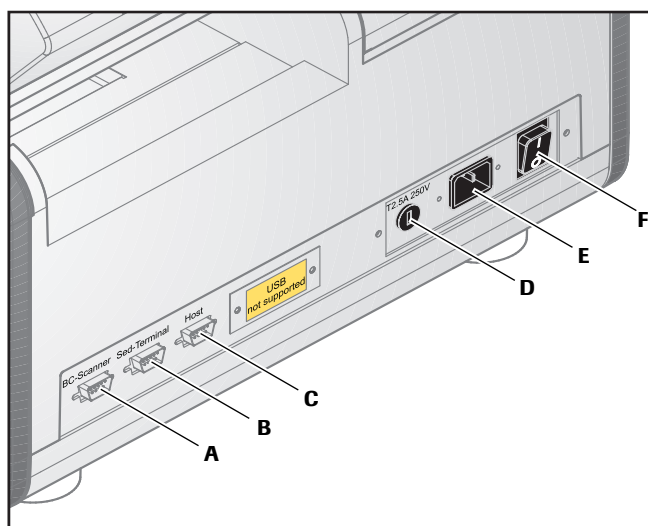
A	Barcode scanner interface		**D**	Fuse
B	Sediment Terminal interface		**E**	Mains power connection
C	Host interface		**F**	Power switch

Figure A-13   Power supply unit and interfaces

Interfaces   The **cobas u** 411 analyzer is equipped with the following serial interfaces:

- Sediment Terminal (see *Trademarks* on page 5)

  This interface is used for connecting the Sediment Terminal.

- Barcode scanner

  This interface is used for connecting the hand-held barcode scanner, which can be ordered as an additional item.

- Host interface

  This interface is used to connect the **cobas u** 411 analyzer to a PC or a laboratory data processing system.

  👁 For more information on working with a host, see:

!   **Danger of damage for the interface devices!**

Only connect the intended devices to the corresponding interface.

If you connect another device to the corresponding interface, the device may be damaged e. g. because of wrong voltage

- *To interface (**A**) only connect the hand-held barcode scanner which is recommended by Roche.*

- *To interface (**B**) only connect the Sediment Terminal.*

- *To interface (**C**) only connect the host system.*

List of available accessories and consumables

Below is a list of globally available accessories and consumables. For ordering information, contact your local sales representative.

Consumables

Consumable	**REF** (catalog number)
Combur10 Test M test strips	11379208191
	11379208077
	11442848171

Standard accessories

The standard accessories that accompany the **cobas u** 411 analyzer are:

Accessory (*catalog name*)	**REF** (catalog number)
Fuses	26213047001
Multi-Tool (for fuse replacement)	28097429001
1 pack printer paper (5 rolls)	04352483001
1 spindle for printer paper roll (*1 holder printer paper roll*)	03535401001
2nd set of test strip transfer system consisting of:	04343255001
• Test strip tray with test strip area and integrated waste area.	
• Test strip pusher	
• Test strip transporter	
Touch pen	04893565001
Control panel rest (*Holder display bar*)	03541002001

Additional accessories

Items that are necessary or optional for the installation and operation of the **cobas u** 411 analyzer, but are not supplied with the analyzer, are:

Accessory (*catalog name*)	**REF** (catalog number)
Serial interface (host) cable	04481810001
USB stick as storage medium	08468761001
Power cord (approved local equivalent)	
Sediment Terminal	04581725001
Barcode scanner (*Barcode Reader Datalogic QD2131*)	08145571001

Sediment Terminal

The Sediment Terminal is used to enter microscopic results for the sample of the corresponding test strip.

If your **cobas u** 411 analyzer is connected with a Sediment Terminal, you should configure the analyzer's sediment parameters.

👁 *Sediment Parameters* on page A-78

---

*If you enter alphanumerical sample IDs on the **cobas u** 411 analyzer, a Sediment Terminal can display them. But you can only search for numerical sample IDs on Sediment Terminal, because a Sediment Terminal has only a numerical keyboard.*

Barcode scanner

Roche Diagnostics markets a barcode scanner for the **cobas u** 411 analyzer as an optional item.

The barcode scanner's accessory package consists of a barcode scanner with RS-232 cable and a holder. We strongly recommend using the barcode scanner with the delivered holder. Using any other holder might interfere with the functionality of the barcode scanner.
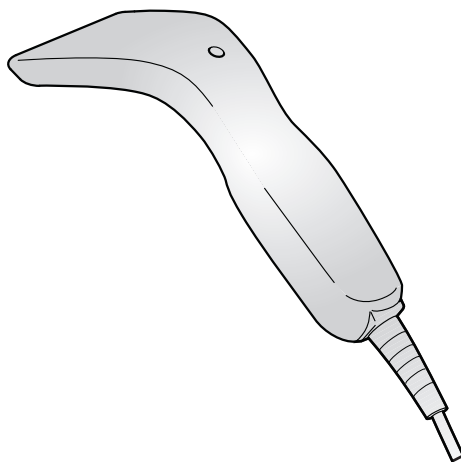
Figure A-14   Barcode scanner

The barcode scanner can read all conventional barcodes.

Roche Diagnostics supports the following barcodes.

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

For details of the barcodes refer to the barcode specifications supported by this scanner.

👁 *Barcode specifications* on page A-41

👁 Documentation included with the barcode scanner

Barcode Scanner Checksum   The activation of the checksum is recommended when using the barcode scanner. The checksums are used to control the readings.

The checksum is activated by default. If it is not activated, refer to the documentation of the barcode scanner provided by the manufacturer.

Technical specifications

This section contains information on:

- Analyzer specifications
- Barcode specifications
- Concentration ranges

Analyzer specifications

System description	Continuous load urine analyzer, to use with test strips	Combur^{10}Test M (see *Trademarks* on page 5) test strips. Parameters: • Spec. gravity • pH • Leukocytes • Nitrite • Protein • Glucose • Ketone • Urobilinogen • Bilirubin • Erythrocytes • Color
Precision	Intra-System Precision	
	• Control Test M	$\leq$ 0.5% Remission
	Inter-System Precision	
	• Control Test M	$\leq$ 1.5% Remission
Robustness	accepted bending of test strips	
	- wet	4 mm
	- dry	2 mm

Table A-3   Technical specifications (Sheet 1 of 3)

Software and data handling	CPUs	Software version 3.2: • Intel XScale PXA255 • Cygnal 8051 Software version 3.3: • Intel XScale PXA168 • Cygnal 8051
	Operating System	LINUX
	Memory	Software version 3.2: • 32 MB Flash-Memory • 32 MB DRAM Software version 3.3: • 128 MB Flash-Memory • 128 MB DRAM
	Bus architecture	CAN fieldbus
	Data storage	
	• internal	Flash-Memory
	• external (data share)	USB port
	Interfaces	1 x USB
		3 x RS232 (Sediment Terminal, Barcode Scanner, Host)
	Display	Software version 3.2:
		5.7 inch (¼ VGA - 320 x 240 pixels) passive matrix touch screen, blue/white.
		Software version 3.3:
		5.7 inch (¼ VGA - 320 x 240 pixels) passive matrix touch screen color.
	Printer	Internal thermal-printer (112 mm)
Samples	Sample handling	manually by user
	Throughput (theoretical throughput)	600 test strips per hour
	Incubation time	60 sec.
	Instrument cycle time	6.0 sec.
Calibration	Reference Strip on board for internal calibration	Control Test M
	Recommended calibration with calibration strip: once a month	Control Test M
Measuring unit	Light source	20 LEDs
	Wavelength	470 nm, 555 nm, 620 nm
	Sensor	11 wide range photo sensors

Table A-3   Technical specifications (Sheet 2 of 3)

Roche Diagnostics

A-38   Operator's Manual · Version 3.0

OS-02597-01

Physical dimensions (max.)	Height Width — 425 mm	Depth — 340 mm
	Height Width — 425 mm	Depth — 375 mm
	Weight	approx. 12 kg
Power requirements	Line voltage	100 V – 125 V (-15% / +10%) and 200 V – 240 V (-15% / +10%)
	Line frequency	50 Hz (+/- 5%) or 60 Hz (+/-5%)
	Power consumption	60 VA
	Overvoltage Category	II (IEC 61010-1)
	Fuse	T 2.5A 250V
Environmental conditions	Temperature	
	• Running conditions	• 15 – 32 °C (59 – 89,6 °F)
	• Transportation and storage	• -25 – 60 °C (-13 – 140 °F)
	Humidity	10% – 95% at no condensation
	• Running conditions	• 30% - 80%, non condensing
	• Transportation and storage	• 10% - 95%, non condensing
	Pollution degree	2 (IEC 61010-1)
	Altitude	0 – 2000 m, airpressure 80 to 106 kPa
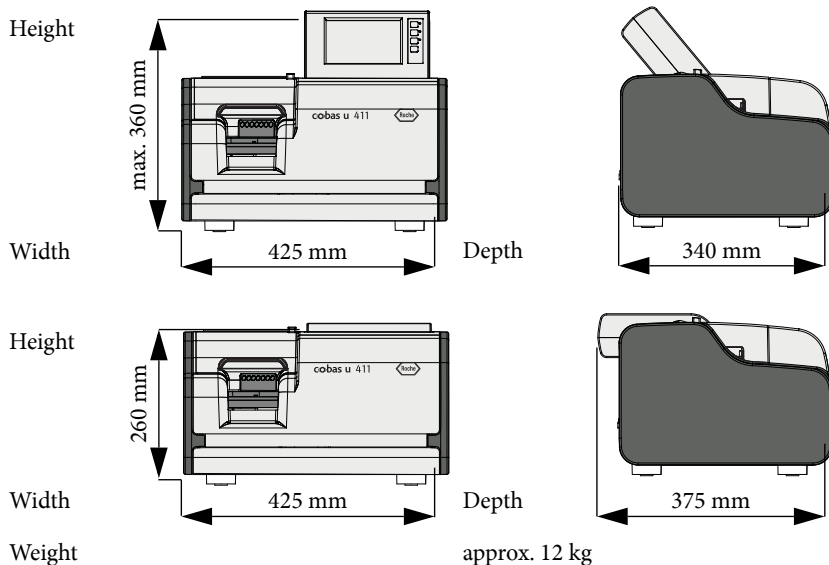
Table A-3   Technical specifications (Sheet 3 of 3)

Barcode specifications

Reading method	Scanning via LED and CCD sensor
Barcode types used	Codabar, Code 39, ITF (Interleaved 2 of 5), Code 128
Check digit	Usable
Codabar	Modulus 16
Code 39	Modulus 43
ITF	Modulus 10/weight 3
Code 128	Modulus 103
Number of ID digits	
Codabar	5 to 13 digits (no check digit); 5 to 13 digits + 1 digit (check digit)
Code 39	5 to 13 digits (no check digit); 5 to 13 digits + 1 digit (check digit)
ITF	8, 10, or 12 digits (no check digit); 9, 11, or 13 digits (with check digit)
Code 128	5 to 13 digits + 2 digits (check digit)
Characters usable	
Codabar	0 to 9, -, /, $, +
Code 39	0 to 9, space, A to Z, -, ., /, $, %, +
ITF	0 to 9
Code 128	Alphanumerical function characters and communication characters are excluded.

Table A–4   Barcode specifications

Concentration ranges

Test parameters	Default values		
	Range (conventional)	**Range (SI)**	**Range (arbitrary)**
SG	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
PH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	8	8	8
	9	9	9
LEU	neg	neg	neg
	25 /µl	25 /µl	1+
	100 /µl	100 /µl	2+
	500 /µl	500 /µl	3+
NIT	neg	neg	neg
	pos	pos	pos
PRO	neg	neg	neg
	15 mg/dl	0.15 g/l	1+
	30 mg/dl	0.30 g/l	2+
	100 mg/dl	1.00 g/l	3+
	500 mg/dl	5.00 g/l	4+
GLU	norm.	norm.	neg
	50 mg/dl	3 mmol/l	1+
	100 mg/dl	6 mmol/l	2+
	250 mg/dl	15 mmol/l	3+
	1000 mg/dl	56 mmol/l	4+
KET	neg	neg	neg
	5 mg/dl	0.5 mmol/l	1+
	15 mg/dl	1.5 mmol/l	2+
	50 mg/dl	5.0 mmol/l	3+
	150 mg/dl	15.0 mmol/l	4+
UBG	norm.	norm.	neg
	1 mg/dl	17 µmol/l	1+
	4 mg/dl	68 µmol/l	2+
	8 mg/dl	135 µmol/l	3+
	12 mg/dl	203 µmol/l	4+

Table A-5   Range values for all test parameters (Sheet 1 of 2)

Test parameters	Default values		
	Range (conventional)	**Range (SI)**	**Range (arbitrary)**
BIL	neg	neg	neg
	1 mg/dl	17 µmol/l	1+
	3 mg/dl	50 µmol/l	2+
	6 mg/dl	100 µmol/l	3+
ERY	neg	neg	neg
	10 /µl	10 /µl	1+
	25 /µl	25 /µl	2+
	50 /µl	50 /µl	3+
	150 /µl	150 /µl	4+
	250 /µl	250 /µl	5+
COL	p. yel.	p. yel.	p. yel.
	yellow	yellow	yellow
	amber	amber	amber
	brown	brown	brown
	orange	orange	orange
	red	red	red
	green	green	green
	other	other	other

Table A-5   Range values for all test parameters (Sheet 2 of 2)

Software

This chapter describes the **cobas u** 411 analyzer software.

In this chapter

Chapter **4**

Software overview

You should familiarize yourself with the operating basics before working with the software.

👁 *Basic operational procedures* on page B-21

Not all functions described in this manual are available for all user levels.

👁 *User rights* on page B-27

In this chapter, we use the following designation system to describe the calling up of a certain screen:

☞ Workplace > Sample Entry > Color

stands for:

- Call up the [Sample Entry] screen from the [Workplace] tab.
- Press the <Color> button to access the appropriate screen.

Work areas   The **cobas u** 411 analyzer software encompasses the following work areas:

- Log-in
- Overview
- Workplace
- Utilities

The following illustrations show the menu structure of the various work areas.

Log-in and overview
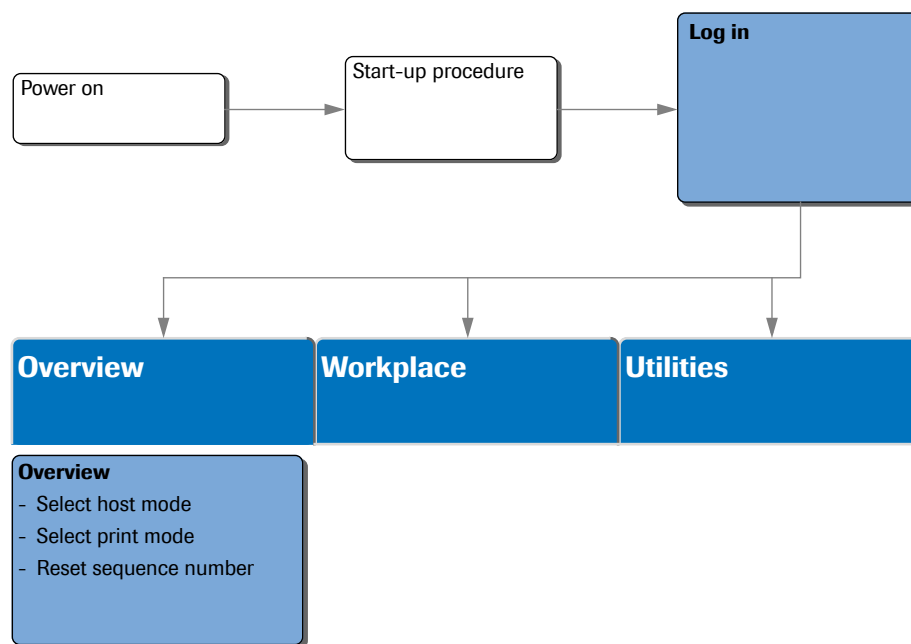
Figure A-15   Menu structure of [Login] and [Overview]

Workplace
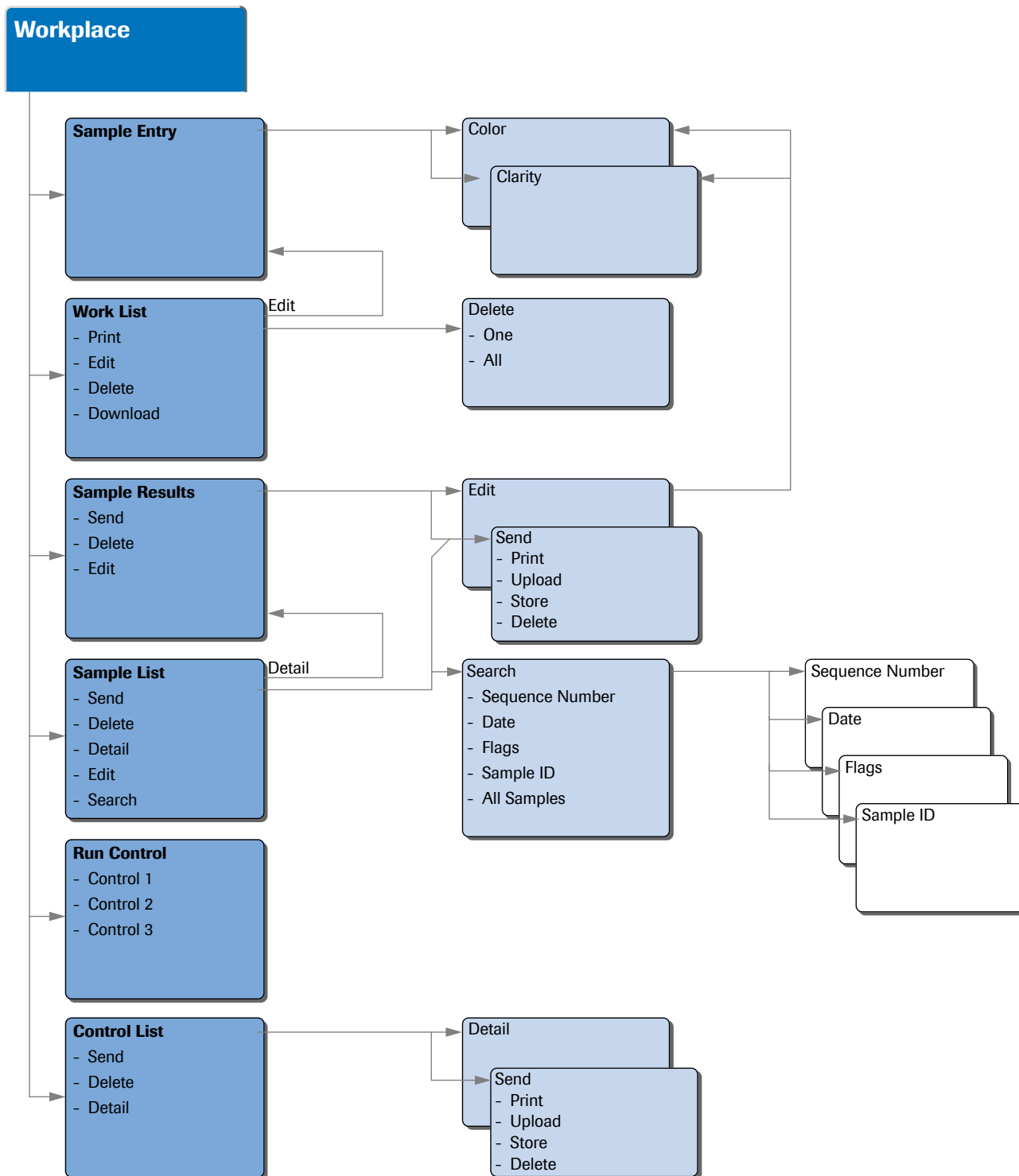
Figure A-16   Menu structure of [Workplace]

OS-02597-01
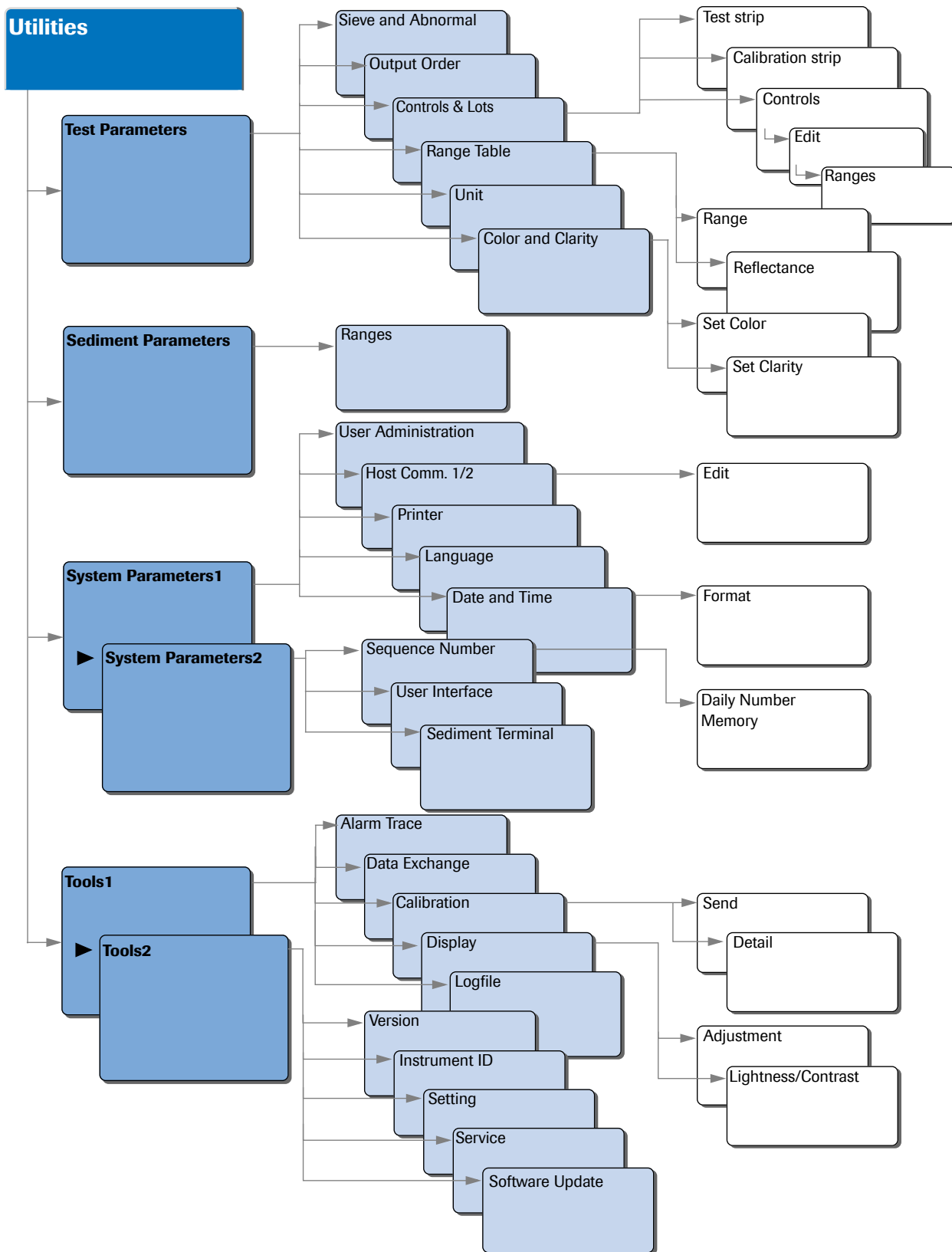
Utilities

Figure A-17   Menu structure of [Utilities]

OS-02597-01

Log-in

The [Log-in] screen appears after you switch the **cobas u** 411 analyzer on.
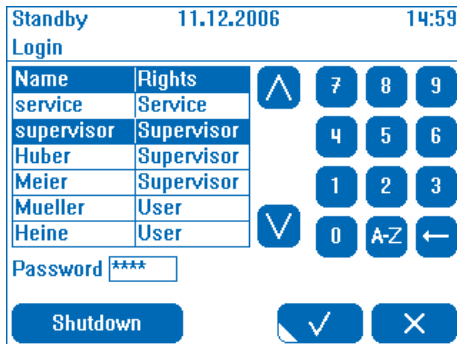
Figure A-18   [Log-in] screen

Log in to the analyzer on the [Log-in] screen by selecting a user or your name from the list and entering your password.

Shutdown   Select Shutdown to switch off the analyzer.

You can create other users for your analyzer on the [User Admin] screen.

👁 *User Admin on page A-80*

Only a user with supervisor rights has access to the [User Admin] screen to create new users.

Overview

The [Overview] tab will appear after you have logged on using the [Log-in] screen. You can call up the [Overview] tab from any screens by selecting the appropriate tab.

Figure A-19   [Overview] tab

The [Overview] tab displays various system information. You can enable or disable the host mode, select a print mode and reset the sequence number.

User   Displays the user logged on to the analyzer.

Waste   Displays the number of test strips processed since the waste container was last emptied.

> *When there are 90 test strips in the waste container, alarm no. 69 is displayed in the alarm monitor. When there are 100 test strips in the waste container, no further test strips will be analyzed. The alarm no. 70 is displayed.*

👁 For more information about instrument alarms see:
    Overview about alarms on page D-9
    Instrument alarm list on page D-12

Next free Seq. No.   Displays the next available sequence number.

The analyzer can be set in such a manner that the sequence numbers automatically start again with 1 after the date has changed.

👁 *Sequence Number* on page A-85

Host   The display field indicates the present status of the host connection. Possible settings are the following:

- Off: Host transmission is disabled.
- On: Host transmission is enabled.
- Upload only: Host transmission is only for upload.

Pressing **<** or **>** changes the status of host connection.

👁 *Host Comm. 1* on page A-81

Print Mode   The display field displays which results are to be printed automatically:

- Off
- All
- Abnormal
- Sieve
- Sieve & Abnormal
- Normal

Pressing **<** or **>** selects a different print mode.

Reset Sequence No.   Resets the sequence number to 1.

> *A reset is only possible, when all results have been reported (printed or sent to host). If there are unreported results, a message is displayed. You have to report the results first, before you can reset the sequence number.*
>
> *If the option <Memory> is selected, you have to delete the results manually before the sequence number can be reset to 1.*
>
> 👁 *Memory* on page A-85
>
> 👁 *Printing, uploading to the host, storing or deleting several results* on page B-52
>
> *If there are pending samples in the work list, the sequence number is reset to the next available sequence number.*

👁 For more information about the result memory see *Working with results* on page B-43

Log off   You can log off with this button. The [Log-in] screen appears.

Workplace

You can call up the [Workplace] tab from any screen by selecting the appropriate tab.
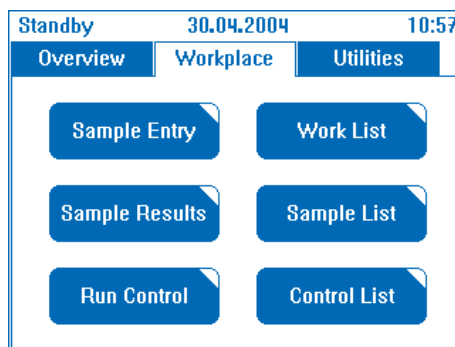
Figure A-20   [Workplace] tab
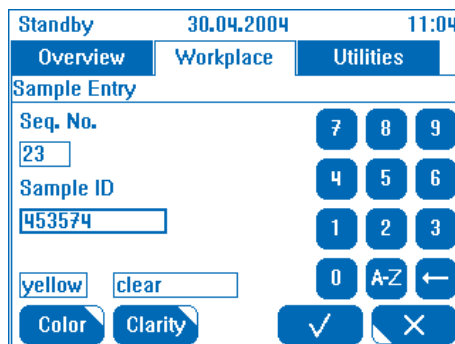
From the [Workplace] tab, you can call up the various screens which you work with during daily operation.

Sample Entry   Enter information for a new sample on this screen.

Work List   This screen displays a work list of all samples entered.

Sample Results   This screen displays the results for a sample.

Sample List   This screen displays a list of the samples, with their corresponding results which have been stored on the analyzer.

Run Control   The analyzer is informed for analysis of a control sample on this screen.

Control List   This screen displays a list of all control results which have been stored on the analyzer.

Sample Entry

☞ Workplace > Sample Entry.

Figure A-21   [Sample Entry] screen

Enter information for a new sample on this screen.

Seq. No.   The next free sequence number is displayed in this field.

Sample ID   The sample ID is displayed in this field. You can either enter the sample ID manually in this field, scan it with a barcode scanner or transmit it from the host.

Color   This button calls up the [Sample Entry > Color] screen. You can assign a color to a sample here.

👁 *Color* on page A-52

Clarity   This button calls up the [Sample Entry > Clarity] screen. You can assign a clarity to a sample here.

👁 *Clarity* on page A-52

The <Color> button is disabled, when the analyzer is set to Color measurement <Automatic>.

👁 *Color and Clarity* on page A-76

Color

☞ Workplace > Sample Entry > Color.
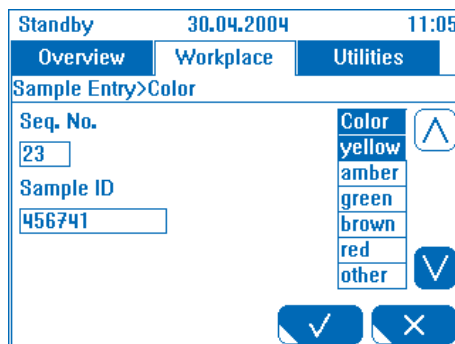
Figure A-22   [Sample Entry > Color] screen

You can select and assign the visually determined color of the sample from the menu on this screen.

Clarity

☞ Workplace > Sample Entry > Clarity.
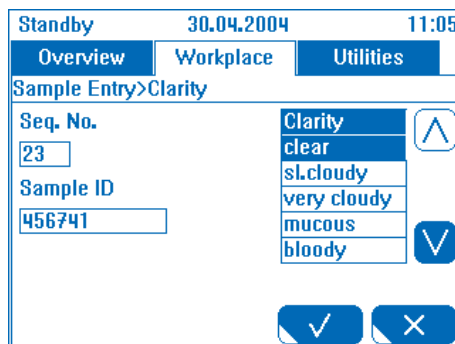
Figure A-23   [Sample Entry > Clarity] screen

You can select and assign the visually determined clarity of the sample from the menu on this screen.

Work List

☞ Workplace > Work List.
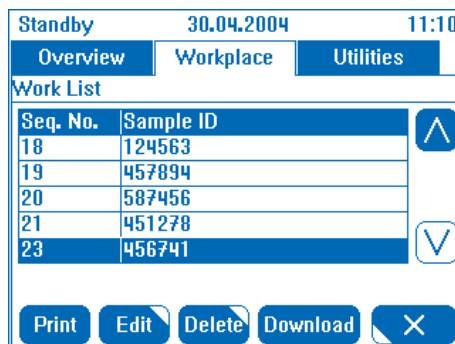
Figure A-24   [Work List] screen

This screen displays all samples that were transmitted from the host, samples for which you scanned in the barcode and samples which you entered manually in the [Sample Entry] screen.

A new sample is added to the end of the list. If a sample from the work list is scanned via barcode scanner, the sample is moved to the top of the list and must be analyzed next.
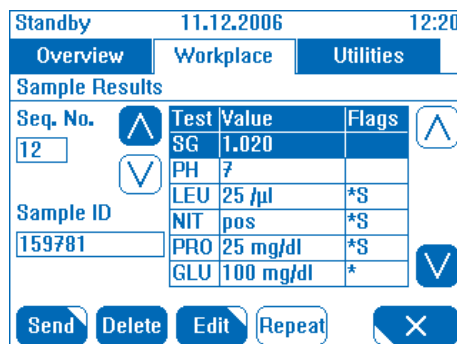
👁 For more information, see:
   Analyzing barcoded samples downloaded from a host on page B-41

Seq. No.   The sequence number of the sample is displayed in this column.

Sample ID   The sample ID is displayed in this column.

Print   Press this button to print the work list.

Edit   This button calls up the [Work List > Edit] screen. This screen is identical with the [Sample Entry] screen. You can change sample information here (e. g. sample ID, color, clarity).

   👁 *Sample Entry* on page A-51

Delete   This button displays the [Work List > Delete] screen. You can delete the samples highlighted in the work list (One) or all samples of the work list (All).

Download   This button downloads the samples from the host into the work list.

Sample Results

☞　Workplace > Sample Results.

Figure A-25　　　　[Sample Results] screen

This screen displays the results of the last sample.

Seq. No.　　　The sequence number of the sample is displayed in this field.

⋀ ⋁　　　You can switch to the previous / next sample (sequence number) using these buttons.

Sample ID　　　The sample ID is displayed in this field, if assigned.

Table　　　The table displays the results for the individual parameters and the result flags of the selected sample.

Send　　　This button calls up the [Sample List > Send] screen for sending samples to the printer, host, USB stick or waste bin.

　　　◉　*Send* on page A-57

Delete　　　This button deletes the complete sample.

Edit　　　This button calls up the [Sample Results > Edit] screen.

If you have selected any parameter except for COL (color) or CLA (clarity) from the table, the [Sample Results > Edit] screen is called up. You can then edit the result of the selected parameter.

　　　◉　*Edit* on page A-55

If you have selected the COL (color) parameter from the table, the [Sample Results > Color] screen is called up using the [Edit] button. You can then edit the color or add the color to the results of the sample.

　　　◉　*Color* on page A-52
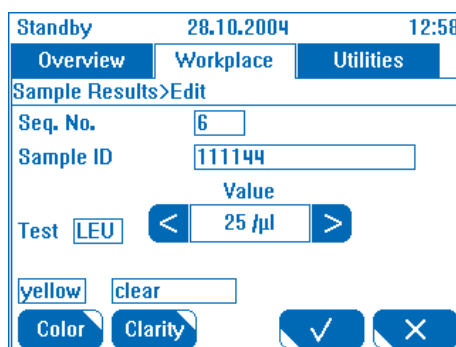
If you have selected the CLA (clarity) parameter from the table, the [Sample Results > Clarity] screen is called up using the [Edit] button. You can then edit the clarity or add the clarity to the results of the sample.

　　　◉　*Clarity* on page A-52

Repeat　　　The selected sample can be measured again with the same sequence number or sample ID. This button is only active, if the selected sample has a T-flag.

Edit

☞ Workplace > Sample Results > Edit.

Figure A-26 [Sample Results > Edit] screen

You can edit the results of a sample on this screen.

Seq. No. The sequence number of the sample is displayed in this field.

Sample ID The sample ID is displayed in this field.

Test The test selected is displayed in this field.

Value The test result of the selected test is shown in the <Value> field. You can decrease or increase the test result by pressing ◄ or ►. You can change the test result by the ranges defined for the parameter.

👁 *Concentration ranges* on page A-42

👁 For more information see *To alter range limits* on page B-87

Color This button calls up the [Sample Results > Edit > Color] screen. You can assign a color to a sample here.

👁 *Color* on page A-52

Clarity This button calls up the [Sample Results > Edit > Clarity] screen. You can assign a clarity to a sample here.

👁 *Clarity* on page A-52

The <Color> button is disabled, when the analyzer is set to Color measurement <Automatic>.

👁 *Color and Clarity* on page A-76

Sample List

☞ Workplace > Sample List.

Figure A-27   [Sample List] screen

This screen displays a list of the samples which have been stored on the analyzer.

Screen hierarchy line   To the right of the screen hierarchy, the search criteria for the selected samples are displayed. If <All Samples> is selected as search criteria, no information is displayed.

👁 *Search* on page A-58

Seq. No.   The sequence number of the sample is displayed in this column.

Sample ID   The sample ID, if defined, is displayed in this column.

Flags   All flags for the sample are displayed in this column. All flags which have occurred for the various parameters are displayed here. You can see which parameters the flags apply to by selecting the <Detail> button.

Send   This button calls up the [Sample List > Send] screen.

👁 *Send* on page A-57

You can send the results

- to host
- to printer
- to USB stick
- to waste bin

S. List   This button prints the sequence number and sample ID of samples with sieve flag, which have to be analyzed. The S. List button is only active, if at least one sample in the result list has a sieve flag.

Detail   This button calls up the [Sample List > Detail] screen. This screen is identical to the [Sample Results] screen.

👁 *Sample Results* on page A-54

Search   This button calls up the [Sample List > Search] screen.

👁 *Search* on page A-58

Send

☞ Workplace > Sample List > Send.
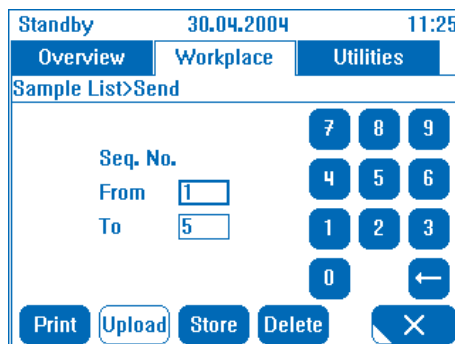
Figure A-28 [Sample List > Send] screen

Results can be printed, sent to the host, stored or deleted from this screen.

◉ See *To print results, upload results to the host, store results or delete them* on page B-52

From / To   Select the corresponding input fields and enter the first sequence number and the last sequence number of the sample results you want to print, send to the host, store or delete.

Print   This button prints the samples on the internal printer.

Upload   This button uploads the samples to the host.

Store   This button stores the samples on an USB stick as <Instr. No.>_Sample<No.>.csv (e.g. 2575_Controls6.csv). In this format the data can be processed with another application for example a spread sheet application.

Delete   This button deletes the samples.

Search

☞ Workplace > Sample List > Search.
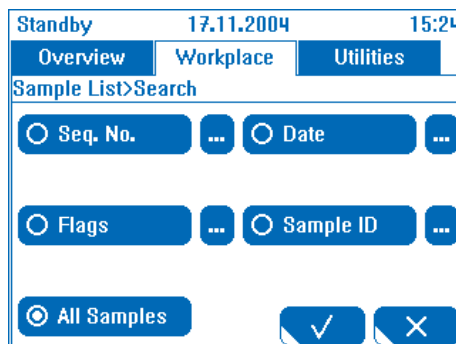
Figure A-29   [Sample List > Search] screen

You can search for results on this screen. The selected search mode (<Seq. No.>, <Date>, <Flags>, <Sample ID> or <All Samples>) and the search criteria set for the search mode (e.g. *1 - 1* for <Seq. No.>, *01.01.1970-01.01.1970* for <Date>) are displayed. If <All Samples> is selected, no search criteria are displayed.

The button of the selected search mode is marked (◉). If you press the button of another search mode, the corresponding search mode is marked.

If you press [...] on the right of a search mode, the corresponding screen is called up where you can define search criteria. The selected search criteria are displayed below the corresponding button.

Seq. No [...]   This button calls up the [Sample List > Search > Sequence No] screen.

    👁 *Search > Seq. No.* on page A-59

Date [...]   This button calls up the [Sample List > Search > Date] screen.

    👁 *Search > Date* on page A-59

Flags [...]   This button calls up the [Sample List > Search > Flags] screen.

    👁 *Search > Flags* on page A-60

Sample ID [...]   This button calls up the [Sample List > Search > Sample ID] screen.

    👁 *Search > Sample ID* on page A-60

All Samples   This is the default selection. All sample results are selected to be displayed. If <All Samples> is selected, no search criteria are displayed.

    👁 *Sample List* on page A-56

Search > Seq. No.

☞ Workplace > Sample List > Search > Seq. No.

Figure A-30   [Sample List > Search > Seq. No.] screen

On this screen you can set a range of sequence numbers for searching results.

From / To   Select the corresponding input field and enter the sequence number of the first and last sample results you want to search.

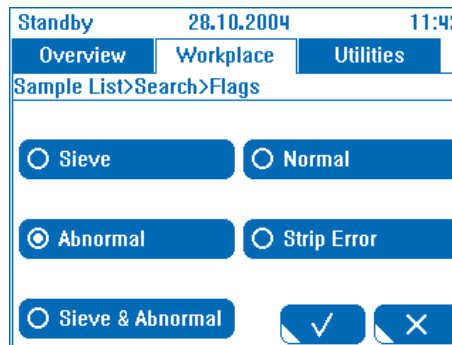## Search > Date

☞ Workplace > Sample List > Search > Date.
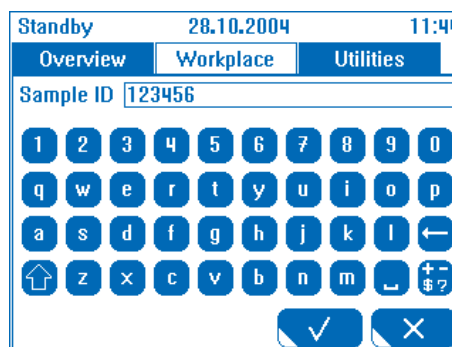

Figure A-31   [Sample List > Search > Date] screen

On this screen you can set a range of dates for searching results.

From / To   Select the corresponding input field and enter the date of the first and last sample results you want to search.

Search > Flags

☞ Workplace > Sample List > Search > Flags.

Figure A-32   [Sample List > Search > Flags] screen

On this screen you can set a flag for searching results.

Sieve / Normal / Abnormal /   Use these buttons to select the flag of the sample results you want to search for.
Strip error / Sieve & Abnormal

Search > Sample ID

☞ Workplace > Sample List > Search > Sample ID.

Figure A-33   [Sample List > Search > Sample ID] screen

On this screen you can set a range of sample IDs for searching results.

Run Control

☞ Workplace > Run Control.

Standby	28.10.2004	13:00

| Overview | Workplace | Utilities |

Run Control

Control 1:	Urine-1
Control 2:	Urine-2
Control 3:	

☒
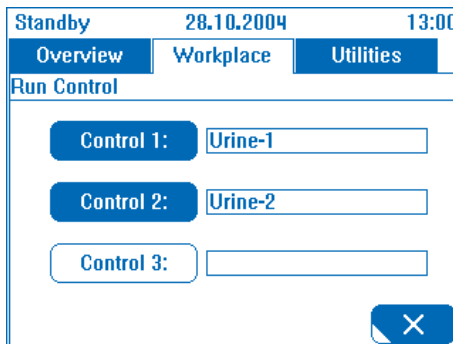
Figure A-34   [Run Control] screen

You can select the control which you are going to analyze next on this screen. The name of the control is displayed on the right of the button.

Before you analyze any control samples, you must configure the control samples used.

👁 See *To configure the control samples for your analyzer* on page B-85
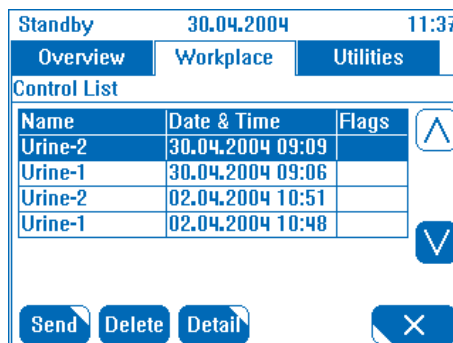
It is possible to analyze control samples as normal samples. But the results are then stored with the normal sample results and will be handled as samples.

Control List

☞ Workplace > Control List.

Figure A-35   [Control List] screen

This screen displays a list of all control results which have been stored on the analyzer.

The controls are displayed in the order in which they were measured. The most recent measurement is at the top of the list.

Name The name of the control sample is displayed in this column.

Date & Time This column shows the date and time on which the control sample was analyzed.

Flags All flags for the control are displayed in this column.

Error text A detailed error text for the selected control is displayed below the list with the controls in case of C-flags or T-flags.

Send This button calls up the [Control List > Send] screen.

👁 *Send* on page A-63
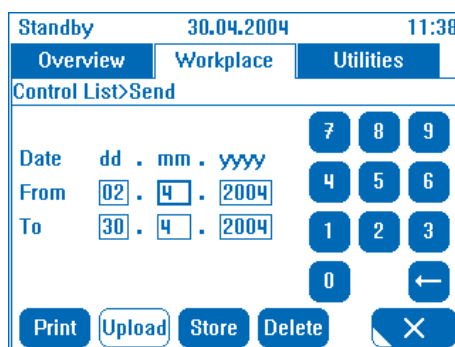
Delete This button deletes the selected control with all results.

Detail This button calls up the [Control List > Detail] screen.

👁 *Detail* on page A-64

Send

☞ Workplace > Control List > Send.

Figure A-36   [Control List > Send] screen

Results can be printed, sent to the host, stored or deleted from this screen.

👁 *Printing, storing and uploading control sample results to the host* on page B-66

From / To   Select the corresponding input field and enter the date of the first and last control sample results you want to print, upload to the host, store ore delete.

Print   This button prints the controls on the internal printer.

Upload   This button uploads the controls to the host.

An upload of control results is only possible, if <ASTM> is selected as protocol.
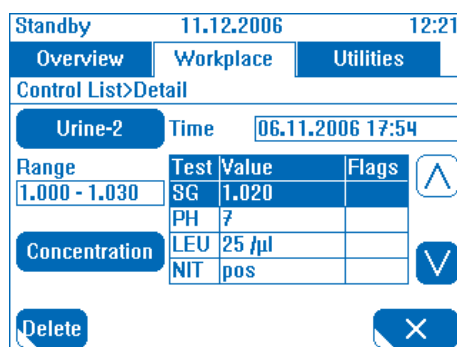
👁 For more information about the available protocols see *Host Comm. 1* on page A-81

Store   This button stores the controls on an USB stick as <Instr. No.>_Calibration<No.>.csv (e.g. 2575_Calibration6.csv). In this format the data can be processed with another application for example a spread sheet application.

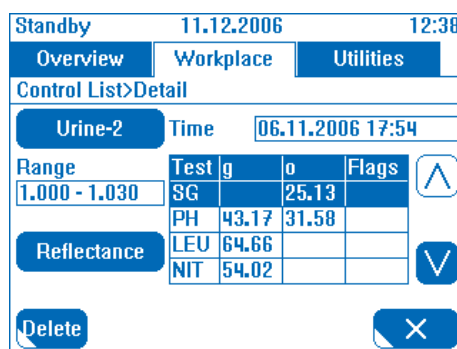*Delete*   This button deletes the controls.

Detail

☞ Workplace > Control List > Detail.

Figure A-37   [Control List > Detail] screen (concentration)

Figure A-38   [Control List > Detail] screen

This screen displays the results for a control sample.

Control name   This button toggles between different controls.

    👁 *Viewing the results of the control samples* on page B-64

Range   The expected range of the parameter which you have selected in the table is displayed
in this field, if configured.

    👁 *To configure the control samples for your analyzer* on page B-85

Concentration/Reflectance   With this button the units of the results are selected. This has an influence on the
details of the table, the upload function and the printout. This button toggles between
concentration and reflectance.

- Concentration: semi-quantitative values (e.g. 25 Ery/ul)
- Reflectance: compensated reflectance values (e.g. Ery: 43.2%)

After every new start of the analyzer this button toggles to Concentration.

*Time*   The date and time of the analysis are displayed in this field.

Table   The table displays the results for the individual parameters and the result flags for the
selected control sample analysis.

Delete   This button deletes all results of the measured control sample.

Utilities

You can call up the [Utilities] tab from any screen by selecting the appropriate tab, depending on the state of the analyzer.

👁 For more information about the operating states see: *Operating states* on page A-20
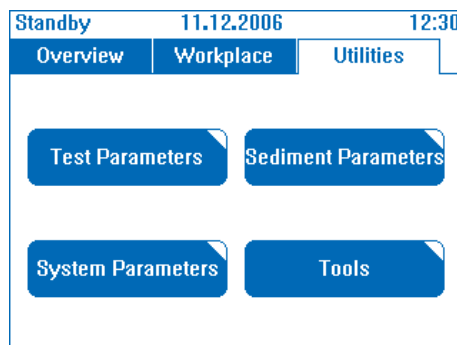
Figure A-39   [Utilities] tab

From the [Utilities] tab, you can call up the various screens on which you can configure the analyzer or adjust analyzer settings.

Test Parameters   The [Test Parameters] screen shows an additional menu with the following options:

- Sieve & Abnormal
- Output Order
- Controls & Lots
- Range Table
- Unit
- Color and Clarity

Sediment Parameters   If your **cobas u** 411 analyzer is connected with a Sediment Terminal (see *Trademarks* on page 5), this screen can be used to configure the analyzer's sediment parameters.

System Parameters 1+2   The [System Parameters] functions are displayed on two screens, [System Parameters 1] and [System Parameters 2]. The [System Parameters] screens show additional menus with the following options:

System Parameters 1
- User Admin
- Host Comm. 1
- Printer
- Language
- Date & Time

System Parameters 2
- Sequence Number
- Date & Time
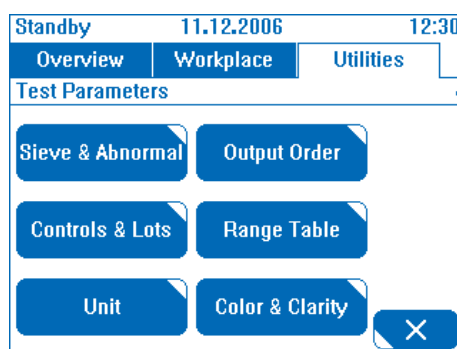- User Interface
- Sed. Terminal

Tools   The [Tools] functions are displayed on two screens, [Tools1] and [Tools2]. The [Tools] screens show additional menus with the following options:

Tools1   • Alarm Trace

         • Data Exchange

         • Calibration

         • Display

Tools2   • Version

         • SW Update

         • Instrument ID

         • Service

         • Setting

Test Parameters

☞ Utilities > Test Parameters
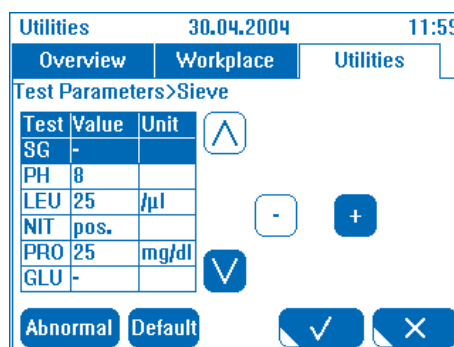

Figure A-40   [Test Parameters] screen

From the [Test Parameters] screen, you can call up the various screens on which you can adjust the settings for test parameters, controls and printouts.

Sieve & Abnormal   The criteria for sieve settings and abnormal values can be defined on this screen.

Output Order   The order of the test parameters on the display and on the result printout can be set on this screen.

Controls & Lots   This screen can be used to configure the controls & lots.

Range Table   The analyzer's concentration and reflectance ranges can be configured on this screen.

Unit   This screen can be used to indicate which type of unit should be used to report the results.

Color and Clarity   The analyzer's color and clarity settings can be configured on this screen.

Sieve & Abnormal

☞ Utilities > Test Parameters > Sieve & Abnormal

Figure A-41	[Test Parameters > Sieve/Abnormal] screen

The criteria for sieve settings and abnormal values can be defined on this screen.

These sieve settings can be used to identify urine samples which need to be examined by additional methods such as sediment microscopy.

The settings for abnormal values can be used to identify urine samples with potentially pathological values.

For a detailed description of the configuration of sieve criteria and abnormal values, refer to:

👁 *Sieve and abnormal values* on page B-81

Table   The screen hierarchy (above the table) indicates which criteria are currently displayed in the table.

- Test Parameters > Sieve
- Test Parameters > Abnormal

The table displays the concentration values of the individual parameters for sieve or abnormal values.

The concentration values represent the lower limits of the concentration ranges at which test parameter results are flagged.

Sieve/Abnormal   You can switch between sieve values and abnormal values by pressing this button.

Default   This button resets the sieve/abnormal criteria to the default settings, after confirmation.

Output Order

☞ Utilities > Test Parameters > Output Order
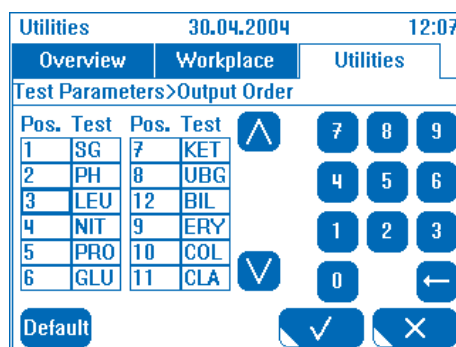
Figure A-42   [Test Parameters > Output Order] screen

The order of the test parameters on the display and on the result printout can be set on this screen.
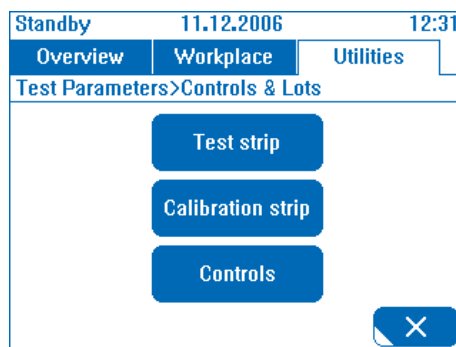
For detailed instructions on configuring the output order, refer to:

👁 *Output order* on page B-82

Default   This button resets the analyzer to the default output order. The default output order is in the same order as the test pads on the strip.

Controls & Lots

☞ Utilities > Test Parameters > Controls & Lots

Figure A-43   [Test Parameters > Controls & Lots] screen

From the [Controls & Lots] screen, you can call up the various screens on which you can adjust the settings for Test strips, Calibration strip and controls.

Test strip   This screen can be used to enter the lot number and expiry date of the test strips.

Calibration strip   This screen can be used to enter the lot number and expiry date of the calibration strips.

Controls   This screen can be used to configure the analyzer's controls.

Test strip

☞ Utilities > Test Parameters > Controls & Lots > Test strip

Figure A-44   [Test Parameters > Controls & Lots > Test strip] screen

The [Test strip] screen can be used to enter lot number and expiry date of the test strips.

Lot number   This field displays the lot number of the used test strips.

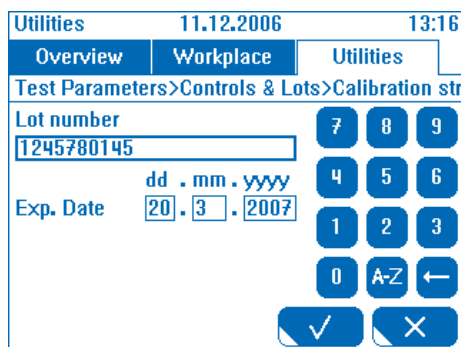*The lot number must not consist of more than 13 characters.*

Exp. date   This field displays the expiry date of the used test strips. If the date is reached, a pop-up window appears after every measurement with the warning: "Expiry date of test strips exceeded!".

Keyboard   To change lot number or expiry date, use the touch screen keyboard.

Calibration strip

☞ Utilities > Test Parameters > Controls & Lots > Calibration strip

Utilities	11.12.2006	13:16
Overview	Workplace	Utilities

Test Parameters>Controls & Lots>Calibration str

Lot number

1245780145

dd . mm . yyyy

Exp. Date   20 . 3 . 2007

7 8 9
4 5 6
1 2 3
0 A-Z ←

√   ✕

Figure A-45   [Test Parameters > Controls & Lots > Calibration strip] screen

The [Calibration strip] screen can be used to enter lot number and expiry date of the calibration strips.

Lot number   This field displays the lot number of the calibration strips.

The lot number must not consist of more than 13 characters.

Exp. date   This field displays the expiry date of the used calibration strips. If the date is reached, a pop-up window appears after every measurement with the warning: "Expiry date of calibration strips exceeded!".

Keyboard   To change lot number or expiry date, use the touch screen keyboard.

Controls

☞ Utilities > Test Parameters > Controls & Lots > Controls

Utilities	11.12.2006		18:52
Overview	Workplace		Utilities

Test Parameters>Controls & Lots>Controls

Control	Name	Lot number	
1	Urine-1	14562312	∧
2	Urine-2	12567852	
3			∨

Edit Delete   ✕

Figure A-46	[Test Parameters > Controls & Lots > Controls] screen

This screen can be used to configure the analyzer's controls. You can configure 3 different controls for the analyzer.

For detailed instructions on configuring controls, refer to:

👁 *Controls & Lots* on page B-83

Edit   This buttons calls up the screen on which the name, the lot number and the control ranges can be configured.

👁 *Controls > Edit* on page A-72

Delete   This button deletes the selected control, after confirmation.

Controls > Edit

☞ Utilities > Test Parameters > Controls & Lots > Controls > Edit

Figure A-47   [Test Parameters > Controls & Lots > Controls > Edit] screen

This screen can be used to configure the name and the lot number of the control. The ranges can be configured via the <Ranges> button.

Name   Input field for the name of the control. You can enter the name of the selected control using the touch screen keyboard.

👁 *Important operating elements* on page B-26

Lot Number   Input field for the lot number of the control. You can enter the lot number of the selected control using the touch screen keyboard.

👁 *Important operating elements* on page B-26

*The lot number must not consist of more than 13 characters.*

Exp. date   This field displays the expiry date of the controls. If the date is reached, a pop-up window appears after every measurement with the warning: "Expiry date of controls exceeded!". You can enter the expiry date of the selected control using the touch screen keyboard.

Ranges   This buttons calls up the screen on which the control ranges can be configured.

👁 *Controls > Edit > Ranges* on page A-73

Controls > Edit > Ranges

☞ Utilities > Test Parameters > Controls & Lots > Edit > Ranges
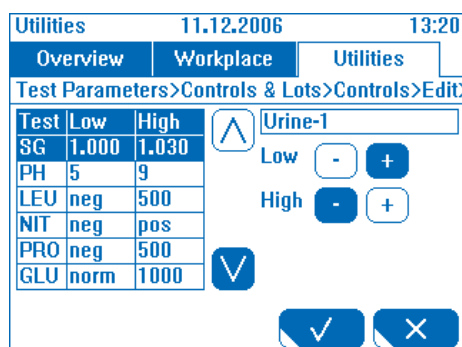
Figure A-48   [Test Parameters > Controls & Lots > Edit > Ranges] screen

This screen can be used to configure the target value and/or expected ranges

👁 see also package insert of the controls.

⋀ ⋁   Selects the previous / next parameter. The selected parameter is displayed in the field <Control Name>.

Low ⊞ ⊟   Increases / decreases the lower limit of the control. The next value, which is configured for the parameter in the range table, is displayed.

👁 *Range Table* on page A-74

High ⊞ ⊟   Increases / decreases the upper limit of the control. The next value, which is configured for the parameter in the range table, is displayed.

👁 *Range Table* on page A-74

If you try to decrease the upper limit below the lower limit, then the lower limit is decreased together with the upper limit.

If you try to increase the lower limit above the upper limit, then the upper limit is increased together with the lower limit.

Range Table

☞ Utilities > Test Parameters > Range Table

Figure A-49   [Test Parameters > Range Table] screen

The analyzer's concentration ranges, reflectance ranges and colors for automatic color measurement can be configured on this screen. The colors for manual color entry can be configured on the following screen:

👁 *Color and Clarity* on page A-76

The **cobas u** 411 analyzer provides semi-quantitative results. This means that the medically important concentration range for a test parameter is divided into certain ranges. In pH values, for example, 6 ranges are used in the concentration range from pH 5 to pH 9: 5 - 6 – 6.5 - 7 - 8 - 9. A certain reflectance has been assigned to each of these ranges. The analyzer measures the reflectance and assigns level 1 reflectance to the level 1 pH value.

The SG and pH ranges are factory-set. They cannot be changed by the user.

For detailed instructions on configuring the range table, refer to:

👁 *Range table* on page B-87

Default   This button resets the range table to the default settings.

Range   This button calls up the [Test Parameters > Range Table > Range] screen. You can set the concentration ranges here.

👁 *Range Table > Range* on page A-75

Refl.   This button calls up the [Test Parameters > Range Table > Reflectance] screen. You can set the reflectance ranges here.

👁 *Range Table > Reflectance* on page A-75

Range Table > Range

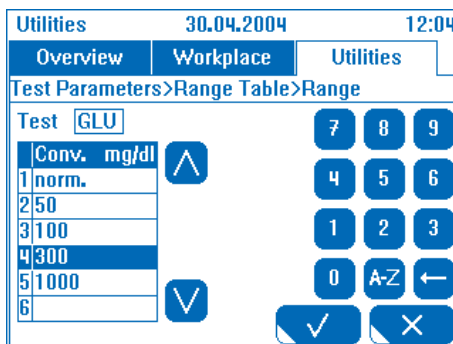☞ Utilities > Test Parameters > Range Table > Range

Figure A-50   [Test Parameters > Range Table > Range] screen

You can define the individual increments within the concentration range for the selected test on this screen.

Range Table > Reflectance
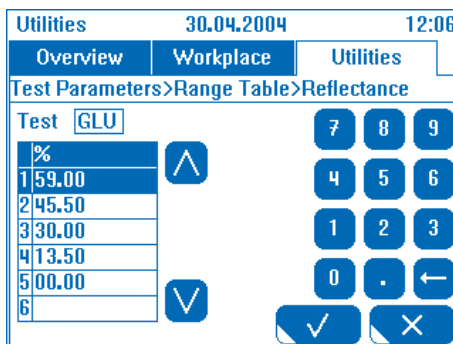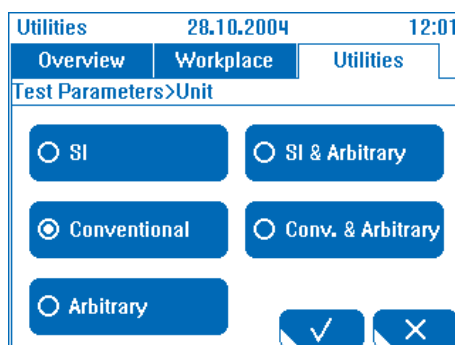
☞ Utilities > Test Parameters > Range Table > Refl.

Figure A-51   [Test Parameters > Range Table > Reflectance] screen

You can define the individual increments within the reflectance range for the selected test on this screen.

OS-02597-01

Unit

☞ Utilities > Test Parameters > Unit

Figure A-52   [Test Parameters > Unit] screen

This screen can be used to indicate which type of unit should be used to report the results.

Press one of the <SI>, <SI & Arbitrary>, <Conventional>, <Conv. & Arbitrary>, <Arbitrary> buttons to select the unit preferred.

Color and Clarity

☞ Utilities > Test Parameters > Color & Clarity.
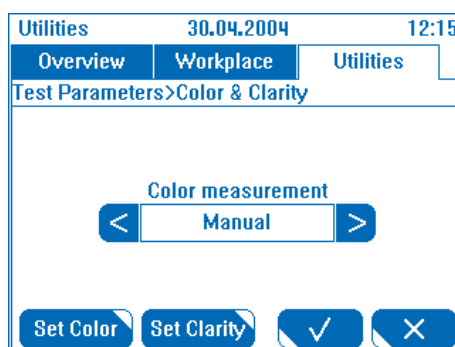
Figure A-53   [Test Parameters > Color & Clarity] screen

The analyzer's color and clarity settings for manual entry can be configured on this screen. The colors for automatic color measurement can be configured on the following screen:

👁 *Range Table* on page A-74

Color measurement   Use ◄ or ► to enable or disable the analyzer's automatic color determination function.

Set Color   This button calls up the [Test Parameters > Color & Clarity > Set Color] screen. You can set user-defined values for colors here.

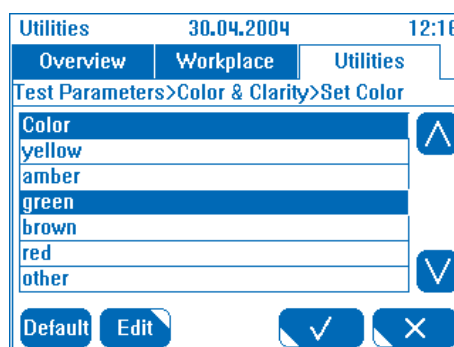👁 *Color and Clarity > Set Color* on page A-77

This button is disabled, if the color is determined automatically.

Set Clarity   This button calls up the [Test Parameters > Color & Clarity > Set Clarity] screen. You can set user-defined values for clarity here.

      👁 *Color and Clarity > Set Clarity* on page A-77

Color and Clarity > Set Color

    ☞ Utilities > Test Parameters > Color & Clarity > Set Color

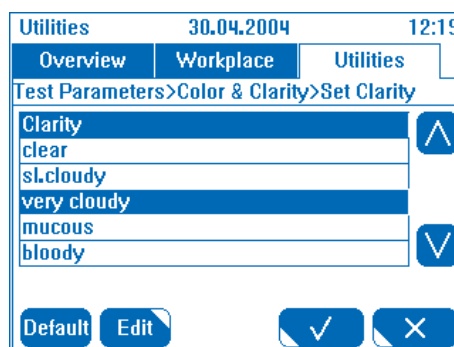**Figure A-54**   [Test Parameters > Color & Clarity > Set Color] screen

This screen can be used to configure the analyzer's color settings.

Default   This button resets the color settings to the default settings.

Edit   This button calls up the touch screen keyboard. You can enter the color designations of your choice here.

Color and Clarity > Set Clarity

    ☞ Utilities > Test Parameters > Color & Clarity > Set Clarity

Figure A-55   [Test Parameters > Color & Clarity > Set Clarity] screen

This screen can be used to configure the analyzer's clarity settings.

Default   This button resets the clarity settings to the default settings.

Edit   This button calls up the touch screen keyboard. You can enter the clarity designations of your choice here.

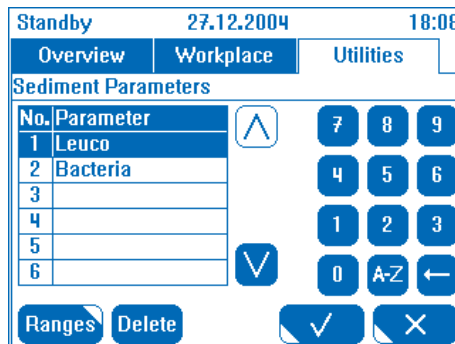# Sediment Parameters

☞ Utilities > Sediment Parameters

Figure A-56   [Sediment Parameters] screen

If your **cobas u** 411 analyzer is connected with a Sediment Terminal, this screen can be used to configure the analyzer's sediment parameters.

No. / Parameter The table shows the number and the name for the each sediment parameter that you have defined. Up to 30 sediment parameters can be defined here.

Ranges This button calls up the [Sediment Parameters > Ranges] screen. You can define up to 5 ranges here for each sediment parameter.

Delete This button deletes the selected sediment parameter and the corresponding ranges.

Ranges

☞ Utilities > Sediment Parameters > Ranges
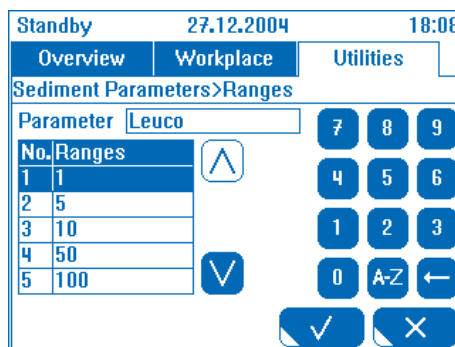
Figure A-57   [Sediment Parameters > Ranges] screen

This screen is used to define the ranges for each sediment parameter.

Parameter This field displays the selected sediment parameter.

No. / Ranges The table shows the number and the range for the selected sediment parameter. You can define up to 5 ranges for each sediment parameter here. You can also use alphanumerical characters to describe the ranges.

System Parameters 1

☞ Utilities > System Parameters
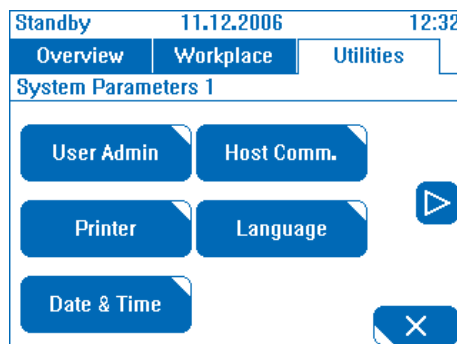
Figure A-58   [System Parameters 1] screen

The System Parameters functions are called up via 2 different [System Parameters] screens: [System Parameters 1] and [System Parameters 2]. When you call up <System Parameters>, the [System Parameters 1] screen is always displayed first. From the [System Parameters] screen, you can call up the various screens on which some analyzer parameters can be configured.

User Admin   This screen is used to manage the users. You can change and delete users here or add new users.

Host Comm. 1   You can configure host settings and enable host communication on this screen.

Printer   This screen is used to configure printer settings.

Language   This screen can be used to install 2 different languages and to set the language of the analyzer display.

Date & Time   You can enter the date and time for the analyzer on this screen.

▷   Displays the [System Parameters 2] screen.

User Admin

☞ Utilities > System Parameters 1 > User Admin
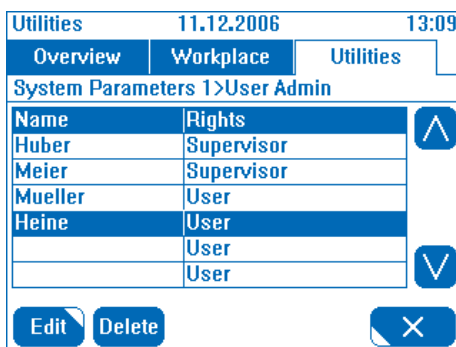
Figure A-59   [System Parameters 1 > User Admin] screen

This screen is used to manage the users. You can change and delete users here or add new users. In the left column of the table, the user name is displayed. In the right column of the table, the access rights (supervisor or user) of the user are displayed.

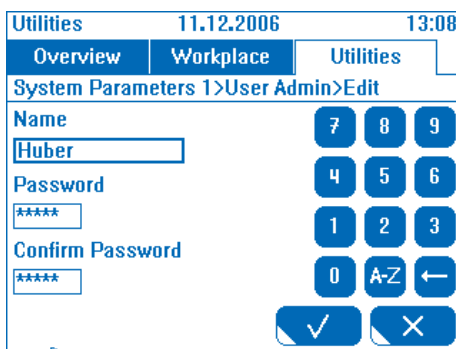👁 For more information see *Setting up users* on page B-11

Edit   This button calls up the [System Parameters > User Admin> Edit] screen.

👁 *User Admin > Edit* on page A-80

Delete   This button deletes the selected user after confirmation.

User Admin > Edit

☞ Utilities > System Parameters 1 > User Admin > Edit

Figure A-60   [System Parameters 1 > User Admin > Edit] screen

This screen is used to enter the name and the password for the user.

Name   You can enter or edit the user name via the touch screen keyboard here.

Password / Confirm Password   You can enter the password or the confirmation password for the user via the touch screen keyboard here. The password and the confirmation password must be identically.

Host Comm. 1

☞ Utilities > System Parameters 1 > Host Comm.
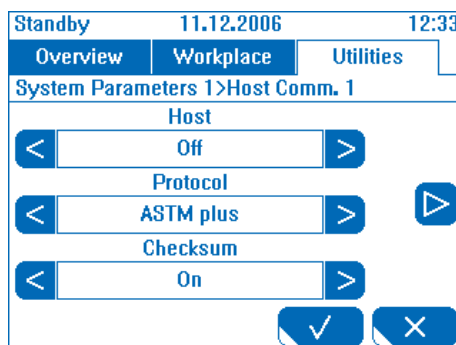
Figure A-61   [System Parameters 1 > Host Comm.] screen

The host communication functions are called up via 2 different [Host Comm.] screens: [Host Comm. 1] and [Host Comm. 2]. When you call up <Host Comm.>, the [Host Comm. 1] screen is always displayed first.

You can select the host protocol and configure check sum on this screen.

Host   The display field indicates the present status of the host connection.

👁 *Host* on page A-49

The following protocol types are available:

- ASTM plus
- ASTM Urisys 2400

▷ Displays the [Host Comm. 2] screen.

👁 *Host Comm. 2* on page A-81

Host Comm. 2

☞ Utilities > System Parameters 1 > Host Comm. > ▷
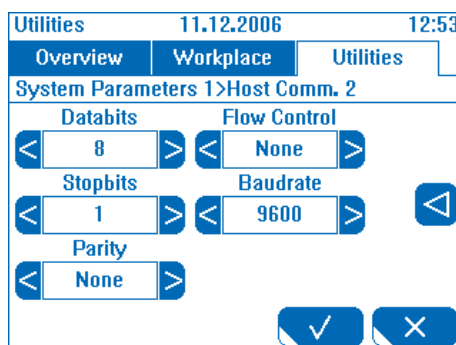
Figure A-62   [System Parameters 1 > Host Comm.] screen

You can configure host settings and enable host communication on this screen.

◁ Displays the [Host Comm. 1] screen.

👁 *Host Comm. 1* on page A-81

OS-02597-01

Printer

☞ Utilities > System Parameters 1 > Printer
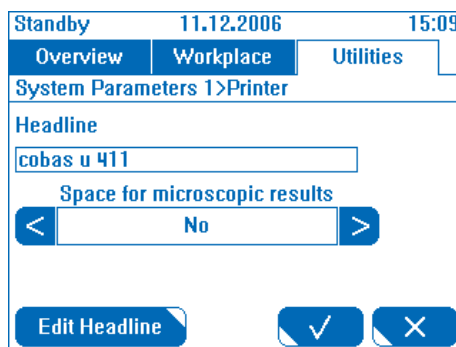
Figure A-63   [System Parameters 1 > Printer] screen

This screen is used to configure printer settings.

*Headline*   This field displays the headline that appears on all printouts.

Space for microscopic results   The buttons ◁ or ▷ enable or disable the space for microscopic results. If you have enabled the space for microscopic results, the printout will contain a section where you can enter the results of your microscopic examination by hand below the analysis results.

Edit Headline   This button calls up the touch screen keyboard. The touch screen keyboard can be used to enter the text for the headline on the printout.

👁 *Important operating elements* on page B-26

Date & Time

☞ Utilities > System Parameters 1 > Date & Time
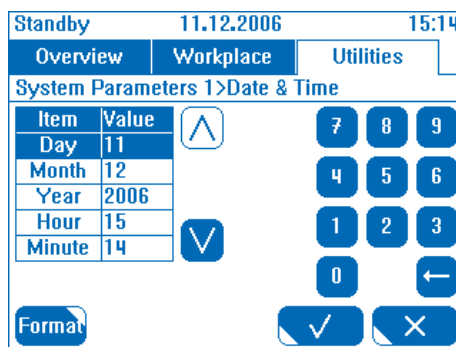
Figure A-64   [System Parameters 1 > Date & Time] screen

You can enter the date and time for the analyzer on this screen. The system will automatically reboot.

Format   This button calls up the [System Parameters > Date & Time > Format] screen. You can set the date format here.

Date & Time > Format

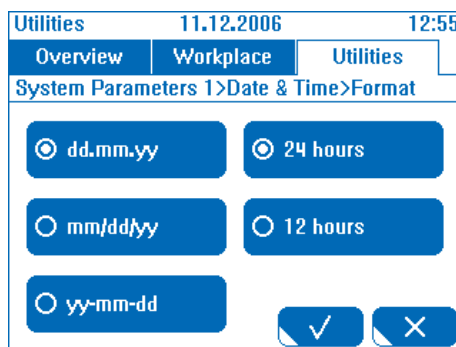☞ Utilities > System Parameters 1 > Date & Time > Format

Figure A-65   [System Parameters 1 > Date & Time > Format] screen

You can set the date format for the analyzer on this screen.

Language

☞ Utilities > System Parameters 1 > Language

Figure A-66   [System Parameters 1 > Language] screen

This screen can be used to install 2 different languages and to set the language of the analyzer display. The selected language is marked (⊙).

The analyzer is always delivered with the English language installed as the first language. It is possible to install your preferred language as a second language or to replace the English language.

👁 For more information see *Installing another language* on page B-14

Install 1 / Install 2   These buttons call up the [System Parameters 1 > Language > Install] screen. You can install the first / second language here.

System Parameters 2

☞ Utilities > System Parameters > ▷
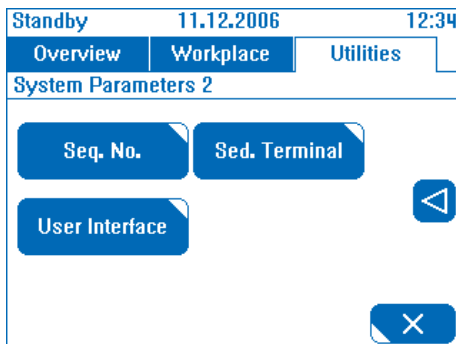
Figure A-67 [System Parameters 2] screen

From the [System Parameters] screen, you can call up the various screens on which some analyzer parameters can be configured.

Sequence Number This screen is used to configure the handling of the sample results. The analyzer can be set in such a manner, that the sequence number automatically starts again with 1 after the date has changed or that the sequence number is counted up to 1,000.

User Interface This screen is used to configure the status bar (date, sample ID or sequence number) and to turn on or off the barcode sorting.

Sed. Terminal This screen is used to turn on or off the Sediment Terminal.

◁ Displays the [System Parameters 1] screen.

👁 *System Parameters 1* on page A-79

Sequence Number

☞ Utilities > System Parameters 2 > Seq. No.
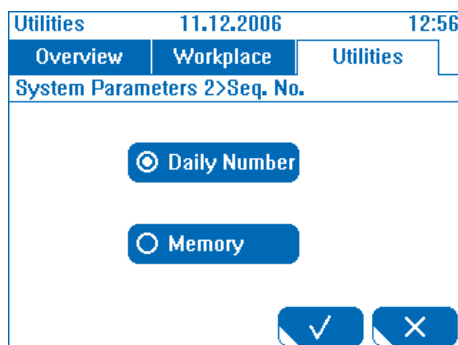
Figure A-68   [System Parameters 2 > Seq. No.] screen

The analyzer can be set in such a manner that the sequence number automatically starts again with 1 after the date has changed or that the sequence number is counted up to 1,000.

Daily number   If this option is marked (⊚), the sequence number automatically starts every day with 1.

All reported results will be automatically deleted. If unreported results are in the database, the user will be informed. If unprocessed samples are in the work list the sequence number will not be reset to 1 automatically and the user will be informed too. You can process or delete the pending samples and then reset the sequence number manually.

Reset Sequence No. on page A-49

Memory   If this option is marked (⊚), the sequence number will not be reset and the results will be kept in the system until the memory is full.

When the result memory has 950 entries, alarm number 51 is displayed in the alarm monitor. When there are 1,000 entries in the memory alarm number 52 is displayed. No further test strips will be analyzed. Then you are asked to delete the results.

👁 For more information about the result memory see *Working with results* on page B-43

👁 For more information about the instrument alarms see *Instrument alarm list* on page D-12

User Interface

☞ Utilities > System Parameters 2 > User Interface
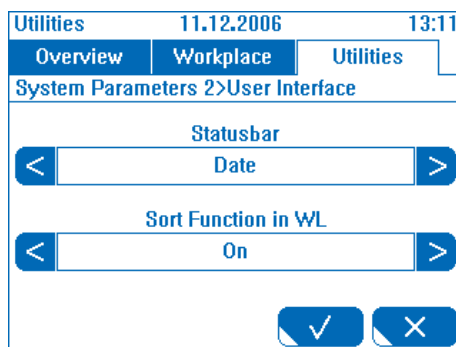
Figure A-69   [System Parameters 2 > User Interface] screen

This screen is used to configure the status bar (date, sample ID or sequence number) and to turn on or off the barcode sorting.

Statusbar   This toggle-button defines the configuration of the statusbar (date, sample ID or sequence number).

Sort Function in WL   This button configures the barcode sorting of the Worklist (WL). Possible values are *On* or *Off*.

Sediment Terminal

☞ Utilities > System Parameters 2 > Sed. Terminal
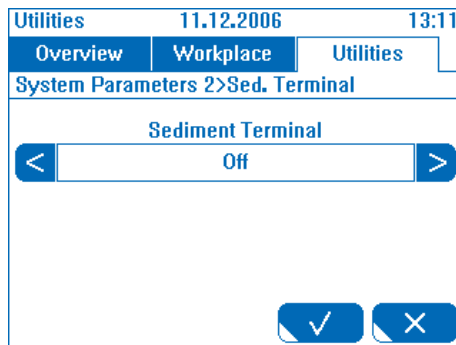
Figure A-70   [System Parameters 2 > Sed. Terminal] screen

This screen is used to turn on or off the Sediment Terminal.

Off   The Sediment Terminal is not active although it is connected with the analyzer.

Tools1

☞ Utilities > Tools (Tools1)
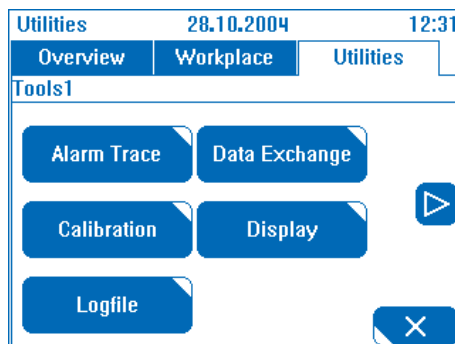
Figure A-71   [Utilities > Tools1] screen

The tools functions are called up via 2 different [Tools] screens: [Tools1] and [Tools2]. When you call up <Tools>, the [Tools1] screen is always displayed first.

From the [Tools1] screen, you can call up various screens on which some analyzer parameters can be configured.

Alarm Trace   Displays the [Alarm Trace] screen.

Data Exchange   This screen can be used to store and restore data.

Calibration   You can calibrate the analyzer on this screen and manage the calibration results.

Display   This screen can be used to adjust the position of the touch screen and to set the lightness and the contrast of the screen.

Logfile   Displays the [Logfile] screen.

▷   Displays the [Tools2] screen.

Alarm Trace

☞ Utilities > Tools (Tools1) > Alarm Trace

Utilities	28.10.2004	12:35
Overview	Workplace	Utilities

Tools1>Alarm Trace

250/250 28.10.2004 12:26
Error 53800: <LibIOUtil> Error Controller does not answer

∧

∨

Print Print All Store Del All ✕
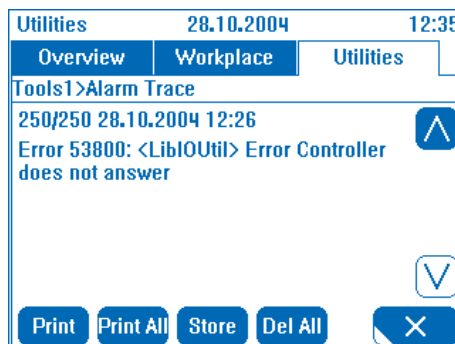
Figure A-72   [Tools1 > Alarm Trace] screen

This screen displays information about the last alarm that has occurred. It displays the following information about an alarm:

- Number of the displayed alarm / total number of alarms
- Date and time of the occurrence of the alarm
- Severity, ID and information text about the alarm

👁 For more information about alarms see *Instrument alarms (messages)* on page D-7

You can display the last 250 entries using the ∨ or ∧ buttons. If more than 250 alarms have occurred, the oldest alarm is deleted first (FIFO principle: first in - first out). The next alarm will be assigned to number 1.

The ID and the information text about the alarm in the [Tools1 > Alarm Trace] screen is different from the ID and the information text in the [Alarm Monitor]. It gives more detailed information about the alarm.

👁 *Alarm monitor* on page D-10

The ID and the information text is helpful when you contact your Roche Service representative.

Print   This button prints the last 20 alarm on the internal printer.
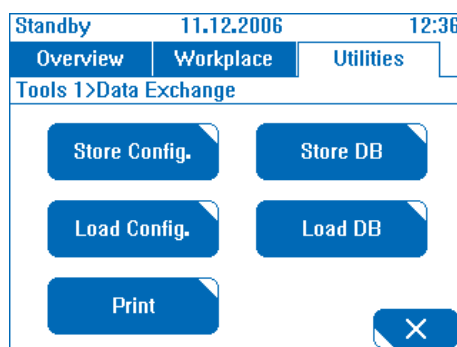
Print All   This button prints all alarms of the alarm trace.

Store   This button stores all alarms of the alarm trace on an USB stick.

Del All   This button deletes all alarms of the alarm trace after confirmation.

Data Exchange

☞ Utilities > Tools (Tools1) > Data Exchange

Standby 11.12.2006	12:36

Figure A-73   [Tools1 > Data Exchange] screen

From this screen system, test and sediment parameters can be printed, loaded from an USB stick or stored on an USB stick.

You can use this function to transfer the data from one **cobas u** 411 analyzer to another or to print data for documentation.

Store Config.   This button stores the configuration parameters (system, test and sediment parameters) on an USB stick as Config?.csv (.csv-format).

Load Config.   Use this button to load the configuration parameters which are stored with [Store Config] from an USB stick on the analyzer. These configuration parameters are stored in a database.

For more information about this screen see:
Storing and loading system, test and sediment parameters on page B-77

Store DB   Use this button to store the whole database on an USB stick.

Load DB   Use this button to load the database which is stored with [Store DB] from an USB stick on the analyzer.

Print   Use this button to print the configuration parameters.

Calibration

☞ Utilities > Tools (Tools1) > Calibration

Figure A-74   [Tools1 > Calibration] screen

This screen displays the current valid calibration and up to the last 4 calibrations which have been stored on the analyzer.

The currently used calibration is indicated by the symbol ▶ in front.

Every measurement is displayed with its corresponding date and time. The most recent measurement is at the top of the list.

Send   This button calls up the [Tools1 > Calibration > Send] screen.

👁 *Calibration > Send* on page A-91

Detail   This button calls up the [Tools1 > Calibration > Detail] screen.

👁 *Calibration > Detail* on page A-92

Calibrate   Use this button to start a new calibration.

👁 For more information see *To calibrate the analyzer* on page B-71

Calibration > Send

☞ Utilities > Tools (Tools1) > Calibration > Send

| **Figure A-75** | [Tools1 > Calibration > Send] screen |

Results can be printed or stored from this screen.

From / To   Select the corresponding input field and enter the date of the first and last calibration results you want to print or store.

Print   This button prints the results on the internal printer.

Store   This button stores the results on an USB stick as Config?.csv (.csv-format). In this format the data can be processed with another application for example a spread sheet application.

Calibration > Detail

☞ Utilities > Tools (Tools1) > Calibration > Detail

Figure A-76 [Tools1 > Calibration > Detail] screen

This screen displays the results for the calibration selected in the [Tools1 > Calibration] screen. The date and time of the selected calibration is displayed above the table.

The table shows all results of the selected calibration:

- The first column shows the test name including compensation field for color determination.

- The second column shows the wavelength of the measurement.

- The third column shows reflectance values (the reflectance values of the calibration currently used are shown in brackets).

Print This button prints the results on the internal printer.

Display

☞ Utilities > Tools (Tools1) > Display

| Standby | 30.04.2004 | 12:23 |

Overview | Workplace | **Utilities**

Tools1>Display

Adjustment

Lightness/Contrast

✕
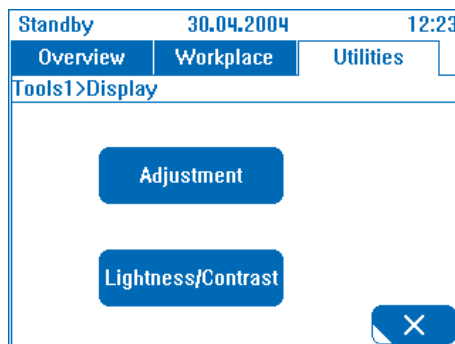
Figure A-77   [Tools1 > Display] screen

This screen can be used to adjust the position of the touch screen and to set the lightness and the contrast of the display.

Adjustment   This button calls up a screen to adjust the touch-sensitive surface of the touch screen.

👁 *Display > Adjustment on page A-94*

Lightness/Contrast   This button calls up a screen to set the lightness and the contrast of the display.

👁 *Display > Lightness/Contrast on page A-94*

Display > Adjustment

☞ Utilities > Tools (Tools1) > Display > Adjustment

Please touch the cross!
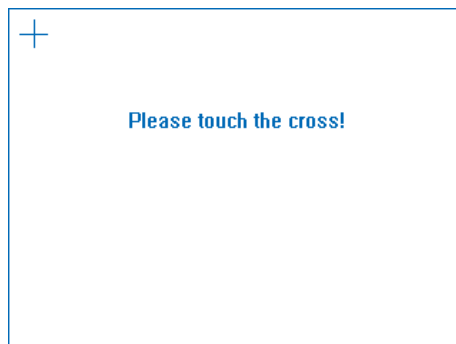
Figure A-78   [Tools1 > Display > Adjustment] screen

The touch screen can be adjusted on this screen.

The touch screen has a touch-sensitive surface over the key display. The touch screen must be adjusted when the position of the touch-sensitive surfaces of the touch screen no longer corresponds with the keys displayed.

The need for touch screen adjustment will become evident when a key responds only when you touch the screen slightly to the side of the key.

A total of 5 crosses are shown in succession. You must touch the crosses one after the other. This position of the cross is then re-saved.
When you have touched all 5 crosses, in software version 3.2, the [Tools1 > Display] screen appears again.
In software version 3.3 and higher you have to reboot the system to make the change effective.

Display > Lightness/Contrast

☞ Utilities > Tools (Tools1) > Display > Lightness/Contrast

Standby	30.04.2004	12:29
Overview	Workplace	Utilities

Tools1>Display>Lightness/Contrast

Lightness
< 253 >

Contrast
< 170 >

✓   ✕
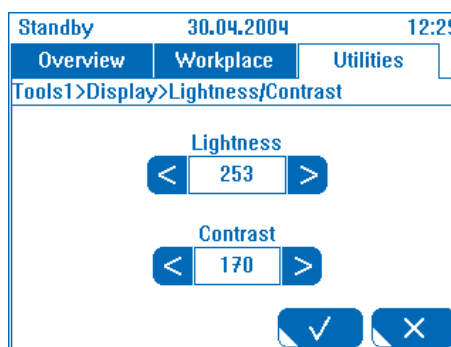
Figure A-79   [Tools1 > Display > Lightness/Contrast] screen

This screen can be used to set the lightness and the contrast of the display.

Lightness < >   Decreases / increases the lightness of the display.

Contrast < >   Software version 3.2: Decreases / increases the contrast of the display.
Software version 3.3: This function is inactive.

Logfile

☞ Utilities > Tools (Tools1) > Logfile
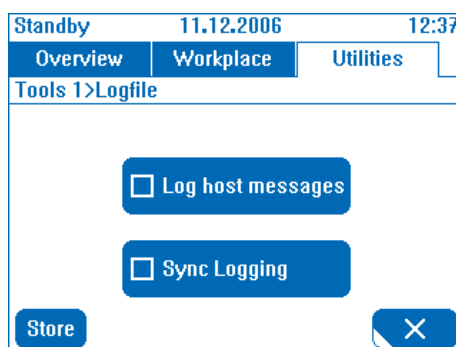


Figure A-80 [Tools1 > Logfile] screen

This screen can be used to trace the analyzer actions for troubleshooting.

If you have troubles with the analyzer, the your Roche Service representative will instruct you to select this function and to store the system trace into a log file on an USB stick. The log file contains important information that helps your Roche Service representative locating the error causes.

Log host messages If this checkbox is activated additional host information will be logged. This function is deactivated after every new start.

Sync Logging Software version 3.2: If this checkbox is activated the log file is saved to the flash memory on regular time intervals. This function is deactivated after every new start.

Software version 3.3: This function is inactive. The system trace is automatically saved into a log file to the USB stick using the store function.

Store This button stores the system trace into a log file on the USB stick.

Tools2

☞ Utilities > Tools > ▷
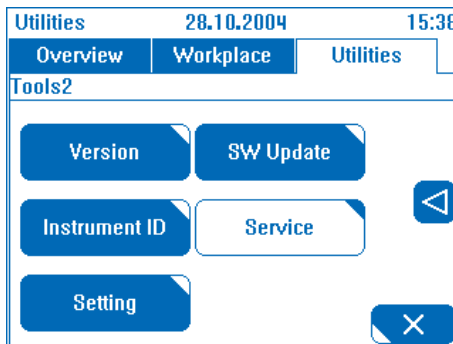
Figure A-81   [Utilities > Tools2] screen

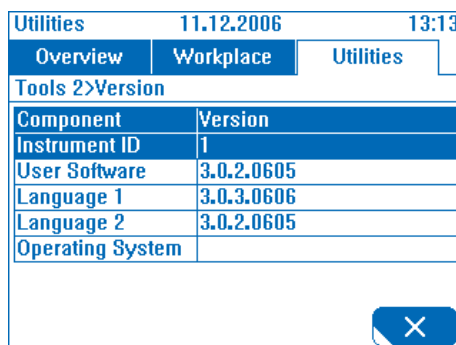From the [Tools2] screen, you can call up various screens on which some analyzer parameters can be configured.

Version   This screen displays all important version information about the different components of **cobas u** 411 analyzer.

SW Update   This button starts the update of the software. A confirmation window with further instructions for the update of the software is displayed.

    👁 For more information see *Updating the user software* on page B-76

Instrument ID   This button calls up a screen to enter the Instrument ID. If you use more than one **cobas u** 411 analyzer in your laboratory, the instrument ID can be used to identify the analyzer. Roche recommends to enter the serial number of the analyzer as Instrument ID.

    👁 Fore more information, see:
      Instrument ID on page A-97

Service   The functions called up with this button are accessible for your Roche Service representative only. They are not covered in this Operator's Manual.

Setting   This button calls up a screen to change the range settings according to laboratory needs.

    👁 *Setting* on page A-98

◁   Displays the [Tools1] screen.

    👁 *Tools1* on page A-87

Version

☞ Utilities > Tools > ▷ (Tools2) > Version

Utilities	11.12.2006	13:13
Overview	Workplace	Utilities

Tools 2>Version

Component	Version
Instrument ID	1
User Software	3.0.2.0605
Language 1	3.0.3.0606
Language 2	3.0.2.0605
Operating System	

Figure A-82   [Tools2 > Version] screen

This screen displays all important version information about the different components of **cobas u** 411 analyzer.

Instrument ID

☞ Utilities > Tools > ▷ (Tools2) > Instrument ID

Utilities	28.10.2004	12:45
Overview	Workplace	Utilities

Tools2>Instrument ID

Instrument ID

123456
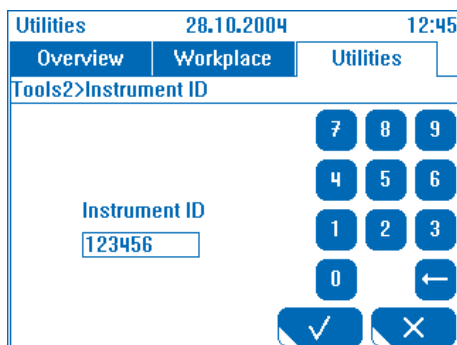
Figure A-83   [Tools2 > Instrument ID] screen

If you use more than one **cobas u** 411 analyzer in your laboratory, the instrument ID can be used to identify the analyzer. On this screen you can enter the Instrument ID.

Setting

👉 Utilities > Tools > ▷ (Tools2) > Setting

Figure A-84   [Tools2 > Setting] screen

On this screen you can change the range settings according to laboratory needs.

OS-02597-01

Operation **B**

Installation

This chapter provides information on the installation of the **cobas u** 411 analyzer.

In this chapter   *Chapter* **5**

As-delivered condition and accessories

As-delivered condition   The **cobas u** 411 analyzer is delivered with the english version of user software installed. Installation of another language is outlined in the following chapter:

👁 *Installing another language* on page B-14

Standard accessories   The **cobas u** 411 analyzer normally is supplied with the following standard accessories:

- Fuses set
- Multi-Tool (for fuse replacement)
- 1 pack printer paper (5 rolls)
- 1 spindle for printer paper roll
- 2nd set of test strip transfer system consisting of:
  - Test strip tray with test strip area and integrated waste area.
  - Test strip pusher
  - Test strip transporter
- Touch pen
- Control panel rest for adjustment of the operator control panel

The standard accessories supplied with the system is listed in the packing list which is delivered with the system.

Additional items   Items that are necessary or optional for the installation and operation of the **cobas u** 411 analyzer, but are not supplied with the analyzer, are:

- Serial interface (host) cable
- USB stick as storage medium
- Power cord (approved local equivalent)
- Barcode scanner

Installing the analyzer

Installation of the **cobas u** 411 analyzer consists of just a few steps. To work with the **cobas u** 411 analyzer, perform the following steps:

- Unpacking and assembling the analyzer
- Set-up and connection

Unpacking and assembling the analyzer

► **To unpack the analyzer**

1 Open the box.

On the upper cardboard cover inside the box you can find the standard accessories of the system.

2 Remove the standard accessories and the upper cardboard cover.

3 Remove the **cobas u** 411 analyzer and the package.

4 Open the front cover of the **cobas u** 411 analyzer and remove the transportation locks. The removable bottom plate inside the analyzer is fixed with two adhesive strips.

You can now continue setting up the analyzer.

!

Installation

Follow the specified installation instructions carefully. Otherwise, inaccurate results or damage to the analyzer may occur.

Electromagnetic waves

Devices that emit electromagnetic waves may affect measured data or cause the analyzer to malfunction. Do not operate the following devices in the same room where the analyzer is installed: mobile phone, transceiver, cordless phone, other electrical devices that generate electromagnetic waves.

Set-up and connection

After unpacking the unit, you can set it up and connect it.

The **cobas u** 411 analyzer must be used in an environment that meets the following conditions:

- Approximately 10 cm (4 inches) of space on either side of and behind the analyzer for good accessibility
- Free from excessive dust
- Well-ventilated area
- Not exposed to direct sunlight
- Floor that is level (with an inclination of less than 1.5 degrees in every direction) and firm
- Ambient temperature ranging according to technical specifications
- Relative humidity according to technical specifications, without moisture condensation
- Free from vibrations
- Power supply according to technical specifications
- Well-distanced from a machine generating a high frequency voltage (for example, a centrifuge)
- Free from electromagnetic wave interference

👁 *Technical specifications* on page A-38

The following figure shows the ports and switches on the rear of the analyzer:
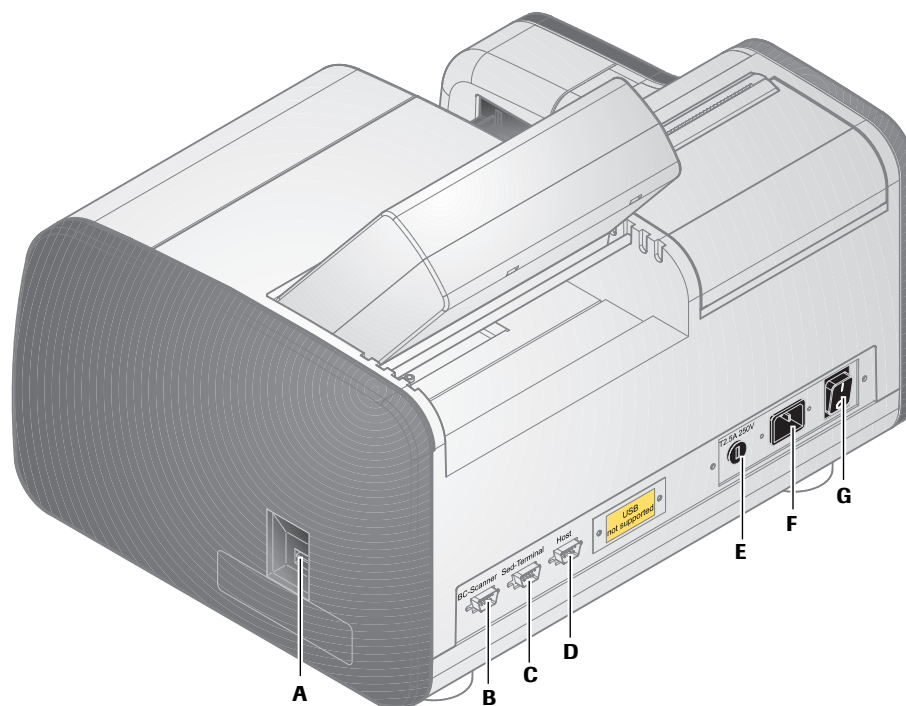
A	USB port	**E**	Fuse
B	Barcode scanner interface	**F**	Mains power connection
C	Sediment Terminal interface	**G**	Power switch
D	Host interface		

Figure B-1   Power supply unit and interfaces

► **To connect the analyzer to the power supply**

The **cobas u** 411 analyzer can be operated with a supply voltage from 100 V or 240 V and a frequency of either 50 Hz or 60 Hz. No adjustment is necessary.

👁 For more detailed information see *Technical specifications* on page A-38

1 Plug one end of the power cord into the connector (**F**).

2 Plug the other end of the power cord into the wall outlet.

► **To connect the analyzer with other optional units via the serial interfaces**

The **cobas u** 411 analyzer features the following serial interfaces:

- Sediment terminal (**C**) (see *Trademarks* on page 5)
- Barcode scanner (**B**)
- Host interface (**D**)

1 Connect the serial cable to the corresponding connector of the **cobas u** 411 analyzer.

2 Configure the **cobas u** 411 analyzer and the connected unit for operation.

- The **cobas u** 411 analyzer needs to be configured for operation with a Sediment Terminal.

  👁 For further information, see *Activating Sediment Terminal* on page B-13.

  👁 For further information on working with a Sediment Terminal, please consult the Sediment Terminal operating instructions.

- You must configure the barcode specifications in order to operate the barcode scanner.

  👁 For further information, see:
  Barcode specifications on page A-41
  Documentation included with the barcode scanner

- Operation with a host system requires information on the host system in your laboratory.

- Information on configuration of the **cobas u** 411 analyzer for operation with a host system can be found in the following locations.

  👁 *Host Comm. 1* on page A-81

If you have any questions on configuration that you cannot answer with the help of these instructions, please contact your Roche Service representative.

Risk of damage to the USB interface (on the back side)!

Do not remove the USB label.

Do not connect any device to the USB interface.

Inserting printer paper

The **cobas u** 411 analyzer is equipped with an internal thermal printer for 112 mm paper rolls.

► **To insert the paper into the printer**
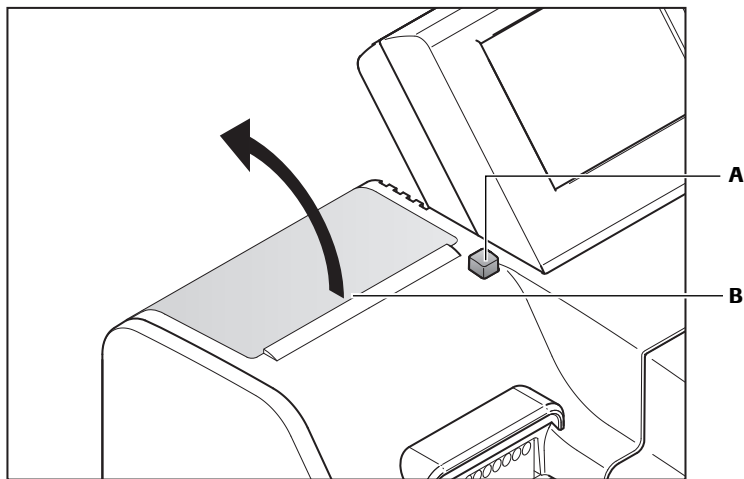
| **A** | Release button for the paper stay | **B** | Printer panel |

Figure B-2   Open the printer

1 Press the release button (**A**) to open the printer panel and release the paper stay.

2 Open the printer panel (**B**) by hand.
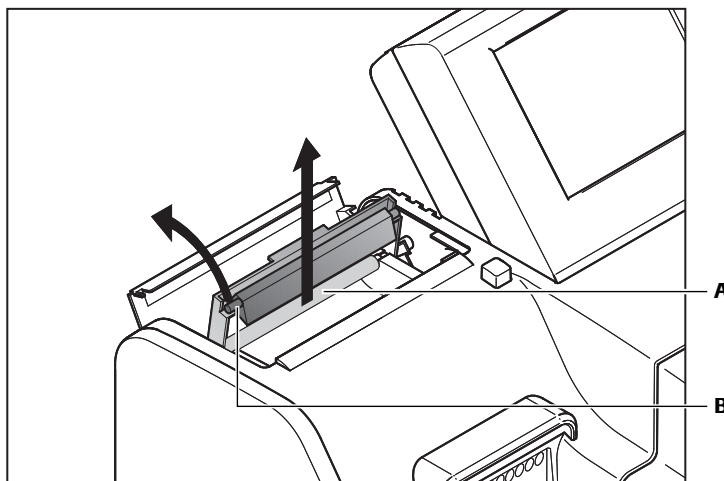
| **A** | Paper spindle | **B** | Paper stay |

Figure B-3   Removing the old paper roll

3 Fold back the paper stay (**B**).

4 Lift up and remove the spindle (**A**) for the paper roll.
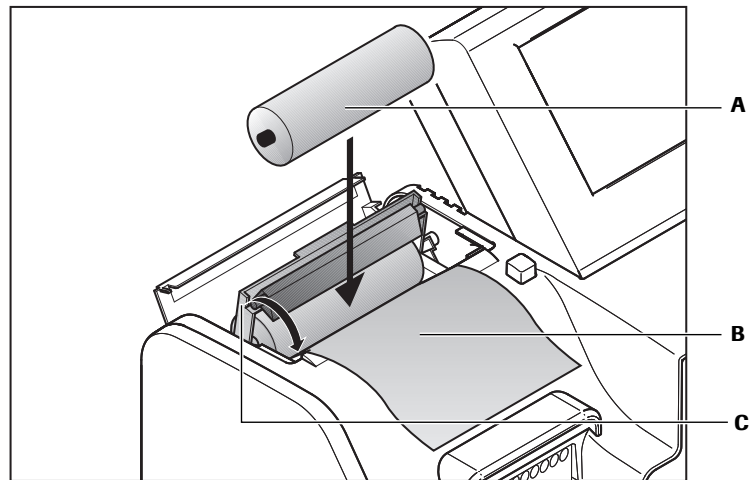
A	Paper roll	**B**	Feed direction of paper
		C	Paper stay

Figure B-4   Removing the old paper roll

5 Slide the paper roll (**A**) onto the spindle and replace the spindle in its mount.

The paper feed (**B**) must be as indicated in Figure B-4.

6 Let the paper hang over in the front about 10 cm (4 in.).

7 Fold down the paper stay (**C**) forward and press it down until it snaps into place.

The paper is automatically transported (self check) if the analyzer is switched on.
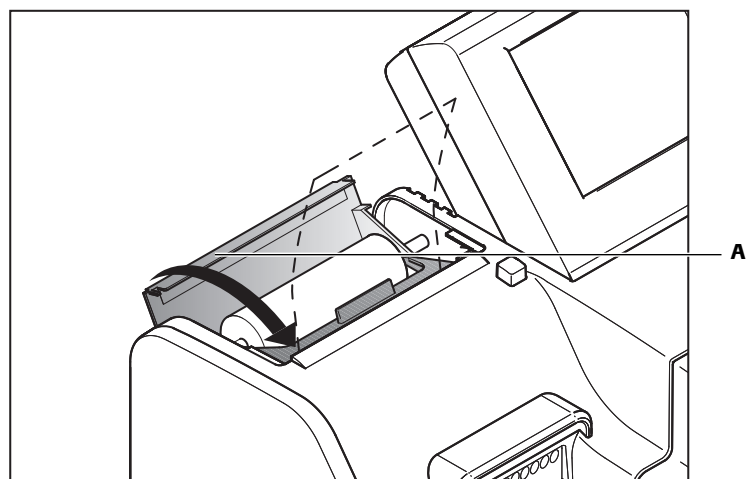
A	Printer panel

Figure B-5   Replacing the paper roll

8 Close the printer panel (**A**).

The printer is now ready to use.

Setting up users

The analyzer is delivered with a predefined supervisor. The person in charge of your laboratory will be informed about the supervisor password. He has to install the users for your laboratory.

👁 *User rights* on page B-27

You should familiarize yourself with the operating basics before working with the software.

👁 *Basic operational procedures* on page B-21

► **To set up a new user**

1 Turn the power switch to the ON (|) position.
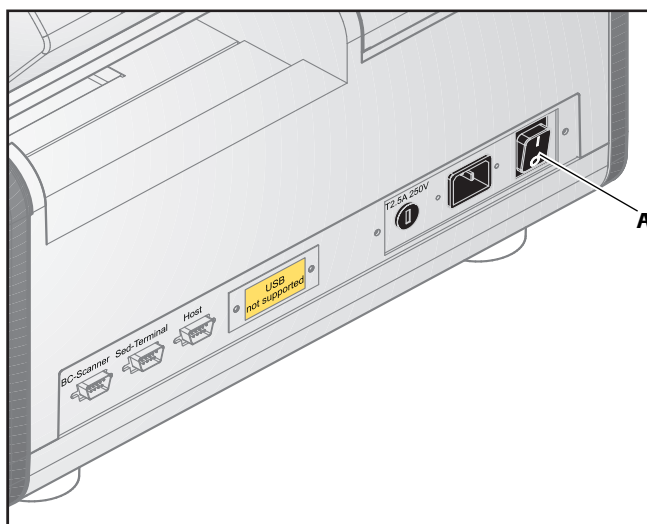
A Power switch

Figure B-6 Power switch on the rear of the analyzer

The [Login] screen appears once the system software has been loaded. The analyzer is initialized and enters into Stand-by state.
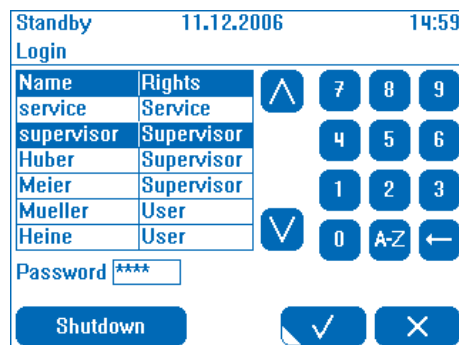
Figure B-7 [Login] screen

2 Select the predefined supervisor using the ∨ or ∧ buttons.

3 Enter the password and confirm your entry by pressing ☑ .

A message will appear: "No instrument calibration available. Please calibrate first!"

4 Call up the [System Parameters 1> User Admin] screen from the [Utilities] tab.

Utilities	11.12.2006	13:09

| Overview | Workplace | **Utilities** |

System Parameters 1>User Admin

Name	Rights
Huber	Supervisor
Meier	Supervisor
Mueller	User
Heine	User
	User
	User

Edit Delete   ✕
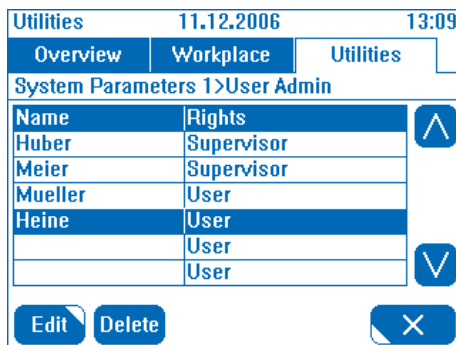
Figure B-8   [System Parameters 1 > User Admin] screen

This screen is used to manage the users. You can change and delete users here or add new users. In the left column of the table, the user name is displayed. In the right column of the table, the right (supervisor or user) of the user are displayed.

Up to 2 users with supervisor rights can be defined and up to 20 user with user rights.

5 Select an empty row with user rights from the list by pressing ☒ or ☒.

6 Press <Edit> to open the [System Parameters > User Admin > Edit] screen.

Utilities	11.12.2006	13:08

| Overview | Workplace | **Utilities** |

System Parameters 1>User Admin>Edit

Name
Huber

Password
★★★★★

Confirm Password
★★★★★

7 8 9
4 5 6
1 2 3
0 A-Z ←
✓ ✕
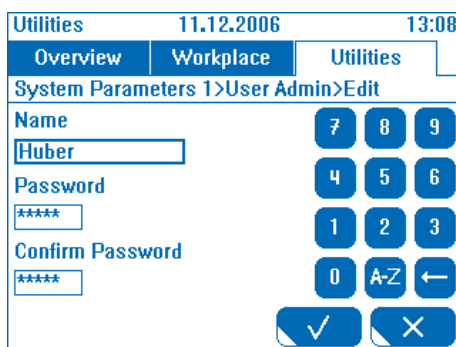
Figure B-9   [System Parameters > User Admin > Edit] screen

7 Select <Name> and enter the name of the new user with the touch screen keyboard.

8 Enter the password for the new user twice in the fields <Password> and <Confirm Password>.

9 Confirm the new user by pressing ☑ .

Activating Sediment Terminal

If you use the Sediment Terminal, you have to turn on the Sediment Terminal.

►   **To turn on the Sediment Terminal**

1   Call up the [System Parameters 2> Sed. Terminal] screen from the [Utilities] tab.
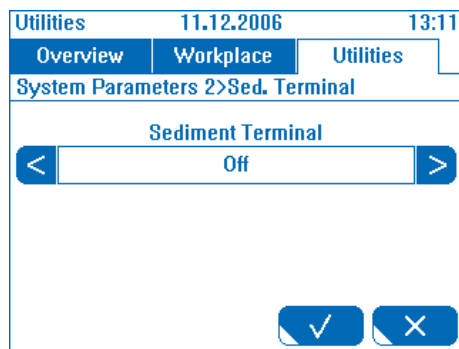
Figure B-10   [System Parameters 2 > Sed. Terminal] screen

2   Use the <Sediment Terminal> selector buttons ◄ or ► to turn on the Sediment Terminal.

Installing another language

The analyzer is always delivered with the English-language version installed as the first language. It is possible to install the version for your national language as a second language or to replace the English-language version by the version for your national language.

► **To install your national language**

1 Call up the [System Parameters > Language] screen from the [Utilities] tab.

Figure B-11   [System Parameters > Language] screen

The selected language is marked (⊚).

2 Press <Install 1> or <Install 2> and confirm the pop-up window.

- If you want to replace the English-language version with the version for your national language press <Install 1>.

- If you want to install your national language as a second language press <Install 2>.

3 Follow the instructions given on the screen.

4 Select the installed language by pressing the corresponding button.

The selected language is marked (⊚).

5 Press ✕ to close the screen.

!

The default settings of color and clarity are not updated automatically!

To update the internal stored default settings of color and clarity into the requested language you have to assign the default color and clarity values, after changing the language.

► **To update the default settings of color and clarity into the requested language**

1 Call up the [Test Parameters > Color & Clarity] screen from the [Utilities] tab.
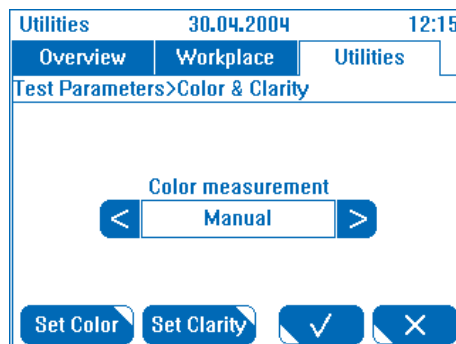
Figure B-12   [Test Parameters > Color & Clarity] screen

2 Verify that color measurement is set to <Manual>.

👁 *Color and clarity* on page B-91

3 Press <Set Color> to call up the [Test Parameters > Color & Clarity > Set Color] screen.
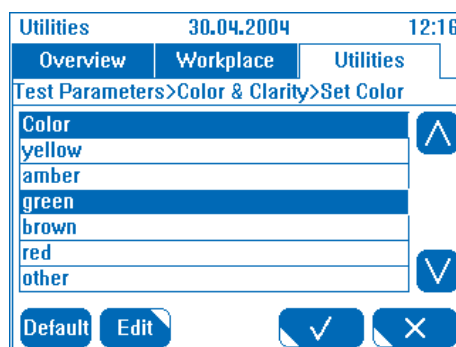
Figure B-13   [Test Parameters > Color & Clarity > Set Color] screen

4 Press <Default> and confirm the pop-up window.

5 Apply the new settings by pressing [✓].

This closes the screen.

6 Press <Set Clarity> to display the [Test Parameters > Color & Clarity > Set Clarity] screen.

7 Press <Default> and confirm the pop-up window.

8 Apply the new settings by pressing [✓].

This closes the screen.

9 Change the color measurement to <Automatic> on the [Test Parameters > Color & Clarity] screen.

10 Call up the [Test Parameters > Range Table] screen from the [Utilities] tab.

Figure B-14   [Test Parameters > Range Table] screen

11 Select the test <COL> from the left-hand list.

12 Press <Default> and confirm the pop-up window.

► **To update the user software**

If there is a new version of the user software for the **cobas u** 411 analyzer available, you can update the software.

👁 *Updating the user software* on page B-76

Using the analyzer for the first time

After you have set up and connected the analyzer, set up users, and optionally installed another language you are ready to begin using the analyzer.

► **To use the analyzer for the first time**

No further action, apart from calibrating the analyzer, is required to begin using the analyzer in its default configuration.

◉ *Calibrating the analyzer* on page B-70

When the analyzer is calibrated, it is ready to analyze test strips.

◉ *Starting the analyzer* on page B-28

If you wish to change the default configuration, you may edit the following settings:

- Adjust range table
    - ◉ *Range table* on page B-87
- Define print sequence
    - ◉ *Output order* on page B-82
- Define units as required in your laboratory
    - ◉ *Unit* on page A-76
- Automatic determination for sample color
    - ◉ *Color and Clarity* on page A-76
- Automatic printout of results
    - ◉ *Print Mode* on page A-49
- Configure sieve and abnormal values
    - ◉ *Sieve and abnormal values* on page B-81

In addition to the basic settings, you can make additional adjustments to the work in your laboratory:

- Configure controls
    - ◉ *Controls & Lots* on page B-83
- Configure sediment parameters
    - ◉ *Sediment Parameters* on page A-78
- Configure host operation
    - ◉ *Host Comm. 1* on page A-81
- Configure printer
    - ◉ *Printer* on page A-82
- Configure barcode scanner (optional)
    - ◉ Documentation included with the barcode scanner
- Set date and time format
    - ◉ *Date & Time* on page A-82
- Set instrument ID
    - ◉ *Instrument ID* on page A-97

Disposal of the analyzer

Disposal

Used test strips and instruments must be treated as biologically contaminated-hazardous waste. Final disposal of waste (strips) and instrument must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed on for final disposal.

For more information contact your Roche Service representative.

Daily operation

This chapter describes the procedures that are necessary for the daily operation of the **cobas u** 411 analyzer.

In this chapter   *Chapter* **6**

Basic operational procedures

This chapter is an introduction to the basic operational procedures for the **cobas u** 411 analyzer.

Operator control panel

The operator control panel of the **cobas u** 411 analyzer consists of a built-in computer with touch screen and global action buttons.

A	Operator control panel	**C**	Global action buttons
B	Touch screen	**D**	Control panel rest for adjusting the angle of the operator control panel (on the rear)
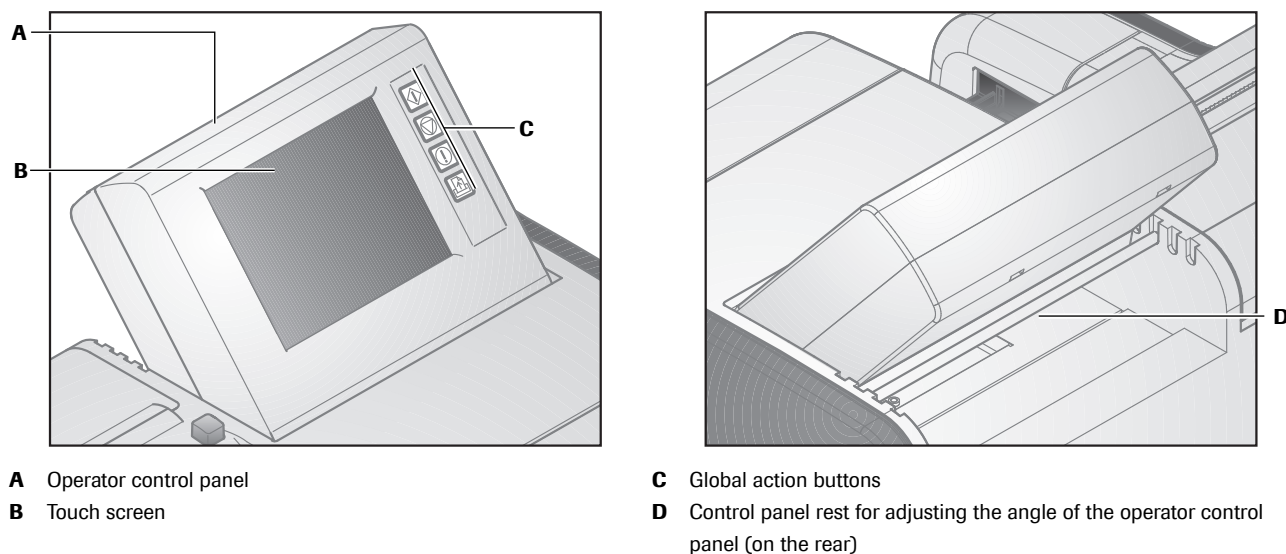
Figure B-15   Operator control panel

The touch screen allows for the easy operation of each screen. Press the buttons on the touch screen once to perform the various functions. Operators wearing gloves can easily use the touch screen. The included touch pen can be used to operate the keyboard displayed on the touch screen, if necessary. The angle of the operator control panel can be adjusted using control panel rest on the rear of the unit.

Global action buttons

The **cobas u** 411 analyzer has 4 global action buttons. These global action buttons display the operating states. Alternatively, you can use them to execute functions directly.

Start ⬦   The LED of this key lights up green when the analyzer is ready for operation.

Stop ⬡   The LED of this key lights up red when a system error occurs and the analyzer cannot continue operations or when the operator presses this key.

When this key is pressed, the analysis stops immediately. All test strips on the test strip tray are disposed in the waste area. The corresponding samples, controls and calibrators are deleted.

Alarm ⓘ The LED of this key lights up when an alarm has been triggered. It lights up yellow or red depending on the severity of the alarm. Press this key to display a list of alarms.

    👁 *Handle alarms* on page D-11

    👁 *Instrument alarms (messages)* on page D-7

Line Feed 🔼 Press this key to move the printer paper forward (not in Operation state).

Working with the software

Some of the software's operating elements are used on numerous screens. The significance and operation of these elements is described in the next section.

The following designations are used to indicate screens and buttons in this manual:

[Name of the screen]	Name of screen (in square brackets) e. g. „The [Sample Entry] screen is displayed"
<Button designation>	Name of the button (in angle brackets) e. g. „Press the <Edit> button"

Overview of structure and functions

The [Overview] tab appears when you log on to the analyzer.

    👁 For more information see *To start the cobas u 411 analyzer* on page B-28
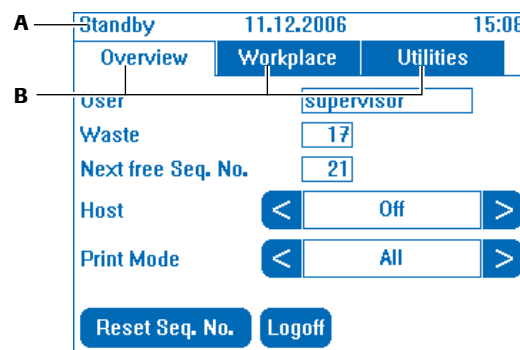
A	Status bar	**B**	Tabs

Figure B-16   [Overview] tab

(**A**) *Status bar* Displays information such as date, time and operating state (Initialization, Stand-by, Operation, Utilities, Stop).

    👁 For more information about operating states see *Operating states* on page A-20

(**B**) *Tab* The **cobas u** 411 analyzer software is divided into three workspaces:

- Overview
- Workplace
- Utilities

You can call up each of these workspaces by simply pressing the required tab.

The main screen of the [Workplace] and [Utilities] tabs each contain buttons to call up more screens or to start functions.

A	Status bar	**C**	Buttons
B	Tabs		
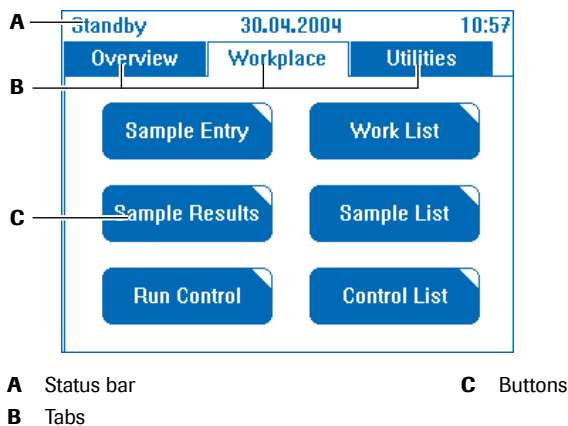
Figure B-17   [Workplace] tab

*(**C**) Buttons*   Since the **cobas u** 411 analyzer has a touch screen, we refer to the control elements as buttons. You can select buttons by touching them or, to put it another way, by pressing them.

👁 For an overview of the software structure, please refer to *Software overview* on page A-45
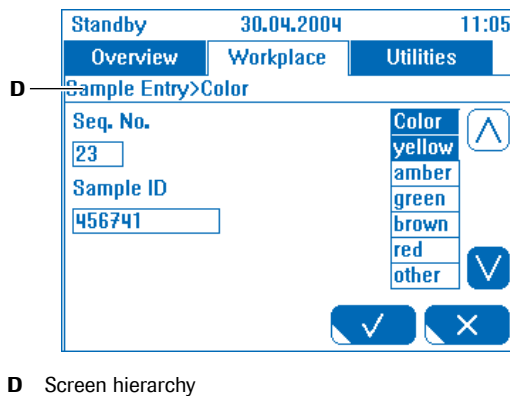
D   Screen hierarchy

Figure B-18   [Workplace] tab

*(**D**) Screen hierarchy*   Below the tabs, the screen hierarchy is displayed. The screen hierarchy indicates the name of the screen and the menu hierarchy of the screen.

► **To call up a different workspace (tab)**

To switch workspaces, press the tab of another workspace. The analyzer notices which screen is displayed for each tab. If you press the tab of another workspace and then return to the initial tab, the last screen of this tab is displayed again.

Example   You have called up the [Sample Entry] screen in the [Workplace] tab

Figure B–19   [Sample Entry] screen

1   Press the [Utilities] tab to call up the corresponding workspace.

Figure B–20   [Utilities] tab

The main screen of the [Utilities] tab is displayed.

2   To switch workspaces again, press the [Workplace] tab.

The [Sample Entry] screen in the [Workplace] tab is displayed again.

Figure B–21   [Sample Entry] screen

► **To access a screen**

You can access screens by pressing the buttons in a tab or another screen.

Example   You have called up the [Sample Entry] screen in the [Workplace] tab

Figure B-22   [Sample Entry] screen

You can call up a new screen by pressing the <Color> or <Clarity> buttons.

1 Press <Color> to display the corresponding screen.
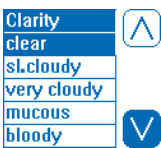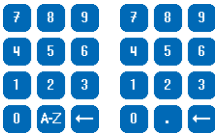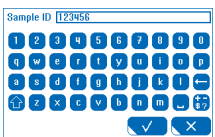
Figure B-23   [Sample Entry > Color] screen

2 Press [✓] to accept your entries and close the screen

or

press [✗] to reject the entries and close the screen.

Important operating elements

There are a number of buttons that consistently appear on the screens. The following table summarizes these buttons and their functions.

Element	Designation	Function
	Action button	Executes a function on the current screen.
	Inactive button	This button is inactive currently.
	Open buttons	Buttons with an upper right-hand corner allow you to call up a new screen.
	Close buttons	Buttons with an lower left-hand corner allow you to close screens.
✓	OK button	Allows you to apply changes in fields and close the screen.
✕	Cancel button	Allows you to reject changes in fields and/or close the screen.
		On some screens, this button just closes the screen.
Clarity / clear / sl.cloudy / very cloudy / mucous / bloody	Drop-down list	You can select an entry from this list using the ∨ or ∧ buttons or by pressing the list entry directly on the touch screen.
7 8 9 / 4 5 6 / 1 2 3 / 0 A-Z ←	Numerical keyboards	Use the numerical keyboard, to enter numerics in input fields. Use the ← button to delete entries in a input field. Use the A-Z button to call up the touch screen keyboard.
Sample ID 123456 (touch keyboard)	Touch screen keyboard	Use the touch screen keyboard, to enter free text in input fields. Use the ⇧ button to toggle between upper and lower case letters. Use the ← button to delete entries in a input field. Use the _ button to enter a space character. Use the $% button to open the ASCII special character keyboard.
LEU 25 - +	-/+ buttons	You can increase or decrease values in the given increments using the − or + buttons.
< 25 /µl >	Selector buttons	You can select between different values using the < or > buttons.

Table B-1   Important operating elements

User rights

The **cobas u** 411 analyzer has 3 different user types with different user rights:

- User
- Supervisor
- Service

User The user has rights to perform all tasks which are necessary for the daily routine.

Supervisor The supervisor, in addition to the user, has the following rights:

- Create and to edit a new user or supervisor
- Edit the range table, sediment parameters and color & clarity
- Update the user software
- Install another language

Service The service level is not accessible for laboratory personnel. The service level, in addition to the supervisor, has rights to perform diagnosis functions on the **cobas u** 411 analyzer.

Starting the analyzer

► **To start the cobas u 411 analyzer**

The power switch is located on the rear of the analyzer. The OFF position is represented by O.

1 Turn the power switch to the ON (|) position.
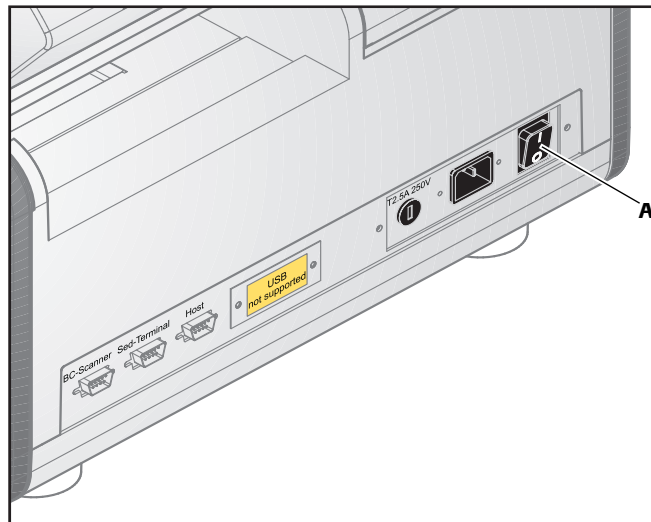
A Power switch

Figure B-24 Power switch on the rear of the analyzer

The [Login] screen appears once the analyzer software has been loaded. The analyzer is initialized and enters into Stand-by state.
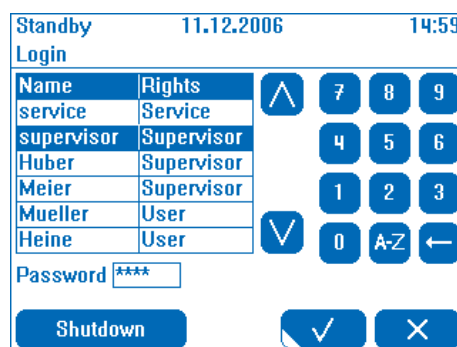
Figure B-25 [Login] screen

When installing the analyzer, the person in charge of your laboratory has to set up new users.

◉ *Setting up users* on page B-11.

2 Select a user or select your name using the ⋁ or ⋀ buttons.

3 Enter your password and confirm your entry by pressing ✓.

The [Overview] screen is displayed.

Standby	11.12.2006	15:08

Figure B-26   [Overview] screen

The [Overview] screen displays important information, e. g. user, next available sequence number, host status, and print mode.

4 Host: By pressing < or > you can change the host status.

5 Print Mode: By pressing < or > you can change the print mode:

- Automatic result printout is performed if you select:
  - All
  - Abnormal
  - Sieve
  - Sieve & Abnormal
  - Normal
- No automatic result printout is performed if you select:
  - Off

If the host status is <On> the results will be sent to the host automatically. For any print mode except <Off> the results will be printed accordingly.

Preparing samples

Risk of infection from contaminated samples

The analyzer processes urine (including control urine) samples.

Wear protective gloves when preparing samples and placing samples onto the analyzer.

If the sample contacts the operator's skin, wash the affected area immediately with a large volume of water.

Analyze samples within two hours of the time that the urine samples were obtained.

Do not expose samples to direct sunlight.

Do not add any preservatives to the samples.

Samples should be at room temperature.

Use fresh urine that has not been centrifuged. The urine specimen should not stand for more than two hours before being analyzed. In case of longer standing, mix the sample before use.

Observe the instructions in the test strip package insert.

► **To prepare a sample for analysis**

1   Remove the test strip from the vial and close the vial with the vial cap containing the desiccant.

2   Always dip all test pads of the test strip completely in the sample and wipe off excessive urine on the edge of the sample tube.

Do not bend test strips

If a test strip is strongly bent, the strip check sensor of the instrument will not be able to detect the presence of the test strip. If you are using a work list and a deformed strip is not measured, the results of the next test strip will be assigned to the sample ID of the test strip that could not be measured.
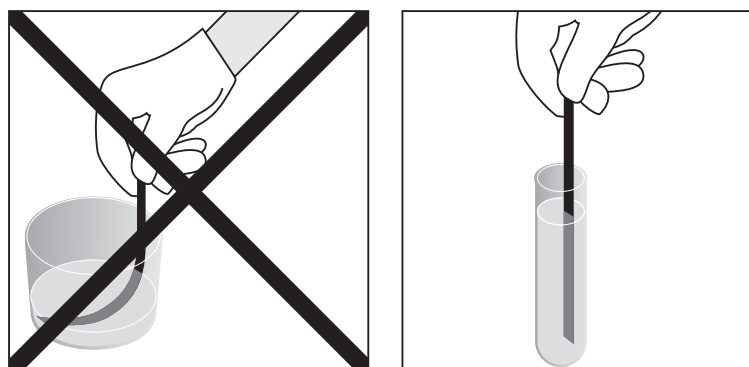
Figure B-27   Test strip handling

3   Position the test strip on the test strip tray for analysis.

Analyzing samples

Depending on how you intend to use the **cobas u** 411 analyzer in your laboratory, there are various workflows of analyzing samples.

The following procedures are described in the next sections:

- Quick analysis using sequence numbers
- Analyzing samples using sample ID numbers
  - Analyzing individual samples
  - Analyzing samples from a work list
- Analyzing barcoded samples downloaded from a host

In case of a defective Test strip sensor 2 (behind the Test strip transporter) no alarm message is generated. A defective Test strip sensor 2 can be recognized as follows:

- *When the test strips are transported but no results are obtained (processed strips are transported to the waste without measurements).*
- *The sample sequence number is not changing.*

Quick analysis using sequence numbers

For quick analysis of samples, samples are processed without any further entries in the analyzer.

You can position the sample once the **cobas u** 411 analyzer is ready for operation. The analysis starts automatically.

The analyzer must be in Stand-by state or Operation state.

👁 *Operating states* on page A-20

You can enter details about the sample, e. g. color and clarity in the [Sample Result] screen.

👁 For more information see *To edit individual results* on page B-45

Figure B-28   [Sample Entry] screen

For quick analysis of samples you can only work with the sequence number. The sequence number is used to allocate the samples to the results.

If the host status is <On> the results will be sent to the host automatically. For any print mode except <Off> the results will be printed accordingly.

👁 *[Overview] screen* on page B-29

You can also view the results of the analyses on the [Sample Results] screen.

Figure B-29   [Sample Results] screen

👁 *Viewing individual results* on page B-44

▶ **To perform a quick sample analysis**

1 Dip a test strip in the sample.

2 Position the test strip on the corresponding area of the test strip tray.

!

Do not remove a test strip after you have positioned it on the test strip tray!

When the analyzer has recognized the test strip, a new sequence number (e.g. 23) is assigned to it. If you remove the test strip and then put it back, the next new sequence number (24) will be assigned to the test strip. The previous sequence number (23) will nevertheless be processed and consequently produce a T-Flag.

A	Test strip sensor 1	**C**	Test strip
B	Area for test strips on the test strip tray		

Figure B-30   Positioning samples

The sample is drawn into the analyzer for analysis.

The next available sequence number will automatically be used for the sample.

!

Do not open the front cover of the analyzer during the analysis of the test strips!

If you open the front cover, processing of the test strips is interrupted. The results of all test strips in process are lost.

3 Repeat steps 1 through 2 for the next samples.

The next sequence number will be used for the next sample.

Analyzing samples using sample ID numbers

When analyzing samples using sample ID numbers, you can process a series of samples from a work list. The **cobas u** 411 analyzer also allows you to process individual samples with sample barcodes.

Analyzing individual samples

► **To analyze individual samples using sample ID numbers**

To analyze individual samples using sample ID numbers, enter the sample ID number for every sample in the [Sample Entry] screen.

1 Call up the [Sample Entry] screen from the [Workplace] tab.


Figure B–31   [Sample Entry] screen

<Seq. No>, the next available sequence number, will now be displayed.

2 If requested, select the input field for the sequence number and enter a new sequence number.

You can only enter a sequence number which is not used by another sample. You can use this function to remeasure a sample in case of a faulty measurement (e. g. if you have forgotten to dip the test strip). Then you must first delete the sample of the faulty measurement.

3 Enter the <Sample ID> using the touch screen keyboard.

4 If requested, enter the data for color and clarity.

👁 For more information see *To enter the color and clarity of a sample* on page B-36

5 Store the sample data by pressing ✓ .

6 Dip a test strip in the sample.

7 Position the test strip on the test strip tray area.
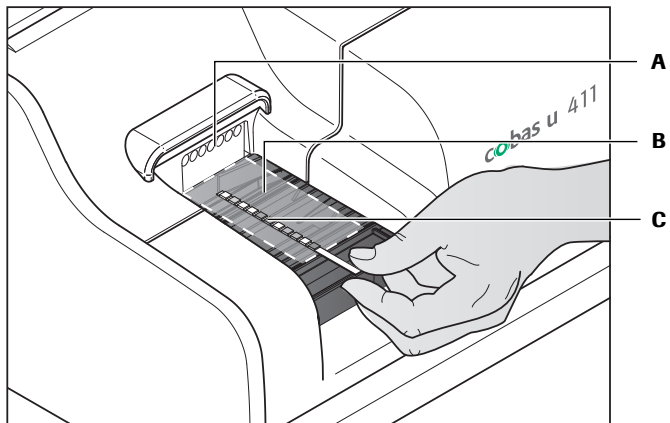
A	Test strip sensor 1	**C**	Test strip
B	Area for test strips on the test strip tray		

Figure B-32   Positioning samples

The sample is drawn into the analyzer for analysis.

8 Repeat steps 1 through 7 for the next samples.

If the host status is <On> the results will be sent to the host automatically. For any print mode except <Off> the results will be printed accordingly.

👁 *[Overview] screen* on page B-29

You can also view the results of the analyses on the [Sample Results] screen from the [Workplace] tab.

👁 *Viewing individual results* on page B-44

► **To enter the color and clarity of a sample**

You have the option of entering the color and clarity of the sample.

1 Call up the [Sample Entry > Color] or [Sample Entry > Clarity] screen.

Figure B–33   [Sample Entry > Color] screen

Figure B–34   [Sample Entry > Clarity] screen

2 Select the color or clarity of the sample using ▽ or △.

3 Apply your selection by pressing ✓.

This closes the screen and displays the selected color and clarity on the [Sample Entry] screen.

The selected color and clarity is only adopted by the analyzer if a sample ID has been entered on the [Sample Entry] screen.

Color and clarity can also be entered via [Sample Result] screen or via [Sample List] screen

👁 *Working from the [Sample Results] screen (individual results) on page B-44*

👁 *Working from the [Sample List] screen on page B-49*

The analyzer usually determines the color of the sample using the compensation pad on the test strip. If you want to enter the color of the sample manually, you have to enable the corresponding function.

👁 *Color and clarity on page B-91*

Analyzing samples from a work list

To analyze samples from a work list, first enter the samples that you want to process into a work list.

You have several options to enter samples into a work list:

- Entering samples manually into the work list via [Sample Entry] screen.
- Scanning the samples into a work list using a barcode scanner
- Downloading samples from a host

▶ **To enter samples manually and via Barcode Scanner into the work list**

To add samples to the work list manually, enter each sample in the [Sample Entry] screen. From here, the sample is automatically added to the work list. By using the barcode scanner the sample ID will be displayed in the corresponding field in the [Sample Entry] screen and will be listed in the work list.

1 Call up the [Sample Entry] screen from the [Workplace] tab.

Figure B-35   [Sample Entry] screen

<Seq. No>, the next available sequence number, will now be displayed.

2 If requested, select the input field for the sequence number and enter a new sequence number.

You can only enter a sequence number which is not used by another sample. You can use this function to remeasure a sample in case of a faulty measurement (e. g. if you have forgotten to dip the test strip). Then you must first delete the sample of the faulty measurement.

3 Enter the <Sample ID>.

4 If necessary, enter the data for color and clarity.

   👁 For more information see *To enter the color and clarity of a sample* on page B-36
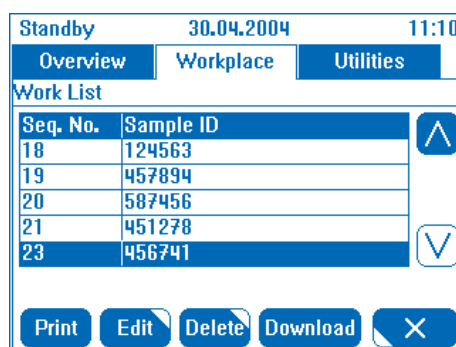
5 Store the sample data by pressing ☑ .

   The sample is added to the work list. The next sequence number will be used for the next sample and so on.

6 Repeat steps 3 through 5 for the next samples.

7 Once you have entered all of the samples, you can close the screen with ✕ and start the analysis.

   👁 For more information on analyzing samples, see:
   To analyze samples from a work list on page B-39

▶   **To scan samples into a work list using a barcode scanner**

If you scan a sample ID, the sample is added to the work list. The next available sequence number is allocated to the sample and the scanned barcode is entered.

To keep an overview of which samples have already been scanned, use the [Work List] screen while scanning the samples.

1   Call up the [Work List] screen from the [Workplace] tab.

Standby	30.04.2004	11:10
Overview	Workplace	Utilities

Work List

Seq. No.	Sample ID
18	124563
19	457894
20	587456
21	451278
23	456741

Print   Edit   Delete   Download   ✕

Figure B-36   [Work List] screen

2   Scan the sample ID numbers using the barcode scanner.

3   If you want to enter color and clarity, press <Edit> and then <Color> or <Clarity>.

   👁 For more information see *To enter the color and clarity of a sample* on page B-36

Once you have entered all of the samples, you can start the analysis.

   👁 For more information on analyzing samples, see:
   To analyze samples from a work list on page B-39

If you scan the sample barcode of a sample that already exists in the work list again, the sample ID is put to the top of the list.

   👁 For more information see:
   Analyzing barcoded samples downloaded from a host on page B-41

► **To load samples from a host into a work list**

1 Call up the [Work List] screen from the [Workplace] tab.

Standby	30.04.2004	11:10
Overview	**Workplace**	Utilities

Work List

Seq. No.	Sample ID	
18	124563	∧
19	457894	
20	587456	
21	451278	
23	456741	∨

Print Edit Delete Download ✕

Figure B-37   [Work List] screen

2 Press <Download>.

The samples are downloaded from the host. The screen shows all samples that have not yet been analyzed. You can now start the analysis.

👁 For more information on analyzing samples, see:
To analyze samples from a work list on page B-39

► **To analyze samples from a work list**

If the work list contains all samples that you want to analyze in a sequence, you can start analyzing the samples.

Please observe the order of samples when performing the analysis.

If you analyze samples from a work list, number the samples in a suitable manner to avoid mixing up the samples. It is the operator's responsibility to ensure the samples are analyzed in the correct order.

- *Print out the work list before starting the analysis and sort the samples in the order of the work list to avoid mixing up samples.*

- *Analyze the samples in the order given on the work list.*

1 Call up the [Work List] screen from the [Workplace] tab.

Standby	30.04.2004	11:10
Overview	**Workplace**	Utilities

Work List

Seq. No.	Sample ID	
18	124563	∧
19	457894	
20	587456	
21	451278	
23	456741	∨

Print Edit Delete Download ✕

Figure B-38   [Work List] screen

The screen shows all samples that have not yet been analyzed.

Use ∨ or ∧ to scroll up and down the list to display more samples.

2 Dip a test strip in the first sample displayed in the list.

3 Position the test strip on the test strip tray area.

The test strip is allocated to the first sample on the list. The sample is now being processed and disappears from the work list.

A	Test strip sensor 1	**C**	Test strip
B	Area for test strips on the test strip tray		

Figure B-39 Positioning samples

The sample is drawn into the analyzer for analysis. The sample ID number of the next sample that must be positioned on the test strip tray now appears at the top of the work list.

4 Repeat steps 2 through 3 for all the samples in the work list.

Work list must be completed!

If you enter new samples, they will be added to the end of the work list. This means that you cannot enter a sample to be processed between two existing samples.

The analyzer can be set in such a manner that the sequence numbers automatically start again with 1 after the date has changed.

👁 *Sequence Number* on page A-85

The analyzer cannot reuse a sequence number until the results have either been printed or transmitted to the host. In this case, an error message will appear on the screen. When this happens, you must either print the results or transmit them to the host before continuing.

If the host status is <On> the results will be sent to the host automatically. For any print mode except <Off> the results will be printed accordingly.

👁 *[Overview] screen* on page B-29

You can view the results of the analyses on the [Sample Results] screen.

👁 *Viewing individual results* on page B-44

Analyzing barcoded samples downloaded from a host

If you are analyzing only barcoded samples that have been downloaded from the host, you do not have to follow the order of the samples in the work list. If you scan a sample that is already in the work list, the work list is re-sorted. The scanned sample is moved to the top of the work list and can be analyzed immediately.

For working with the re-sort function the sort function in worklist (WL) must be activated.

 👁 *Sort Function in WL on page A-86*

► **To load samples from a host into a work list**

1 Call up the [Work List] screen from the [Workplace] tab.

Figure B-40   [Work List] screen

2 Press <Download>.

The samples are downloaded from the host. The screen shows all samples that have not yet been analyzed. You can now start the analysis.

► **To analyze samples from a work list using a barcode scanner**

1 Call up the [Work List] screen from the [Workplace] tab.

Figure B-41   [Work List] screen

The screen shows all samples that have not yet been analyzed.

2 Scan the sample ID number of the next sample you want to analyze using the barcode scanner.

If the sample ID already exists on the work list, it is moved to the top of the work list and the sequence numbers of all samples are reassigned.

3 Dip a test strip in the sample that you just scanned.

4 Position the test strip on the test strip tray area.

The test strip is assigned to the first sample on the list.
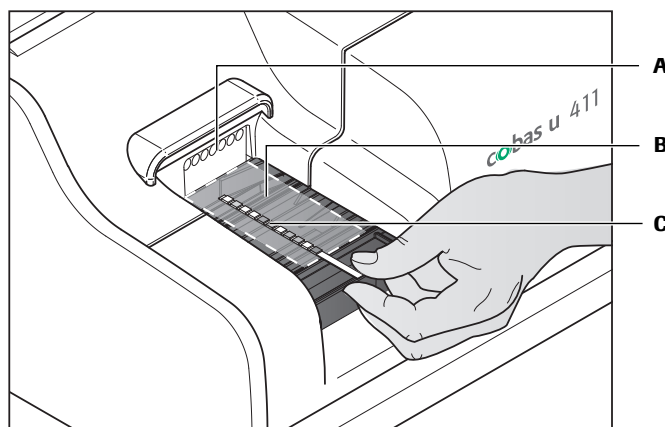
A	Test strip sensor 1	**C**	Test strip
B	Area for test strips on the test strip tray		

Figure B-42   Positioning samples

The sample is drawn into the analyzer for analysis. The corresponding entry disappears from the work list. The work list moves up by one entry.

5 Repeat steps 2 through 4 for all the samples in the work list.

If you scan the barcode of a sample that is not in the work list, the sample is added to the end of the work list. If you wish to analyze the sample immediately, scan the sample barcode again and put the sample directly on the test strip tray of the analyzer.

If the host status is <On> the results will be sent to the host automatically. For any print mode except <Off> the results will be printed accordingly.

You can view the results of the analyses on the [Sample Results] screen.

Working with results

This section contains the following information on working with results.

- Working from the [Sample Results] screen (individual results)
- Working from the [Sample List] screen

From both screens the operator has the following options to work with results:

- Viewing
- Editing
- Sending
  - ○ Printing
  - ○ Uploading
  - ○ Storing
  - ○ Deleting
- Deleting

In addition the [Sample List] screen contains a search function. Search can be performed for:

- Date
- Flags
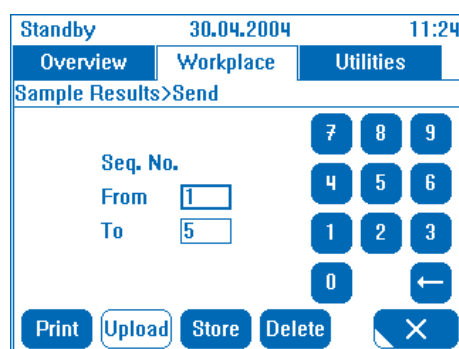- Sequence number
- Sample ID

The cobas u 411 analyzer is equipped with a memory for 1,000 entries.

This memory is used for the pending samples in the work list and for the results of already analyzed samples.

- *When the database contains 950 entries (pending samples and results), a warning message is displayed in the alarm monitor. Analysis can be continued.*

- *When the database contains 1,000 entries, the reported results (results, which are printed or sent to the host) are automatically deleted. If there are unreported results, a confirmation window is displayed, asking you to delete the unreported results.*

- *If the option <Daily Number> is selected, the reported results are deleted after the date has changed and the sequence number is automatically reset to 1.*

  - 👁 *Daily number on page A-85*

- *If there are 1,000 unreported results and pending samples in the database, analysis cannot be continued. You first have to delete unreported results. It is recommended to report the results before deleting them.*

- *The pending samples are not deleted together with the unreported results. They can only be deleted on the [Work List] screen.*

  - 👁 *Work List on page A-53*

Working from the [Sample Results] screen (individual results)

The [Sample Results] screen offers you a quick access to the results of the last measured sample and you can scroll through all samples. It shows you the individual results of a sample.

If you are only interested in specific sample Id's or samples with flags we recommend working with the [Sample List] screen.

► **To work with individual results**

1 Call up the [Sample Results] screen from the [Workplace] tab.

Figure B-43   [Sample Results] screen

The screen shows the results of the last sample.

You can view the results as soon as the test strip analysis is completed.

Viewing individual results

► **To view individual results**

1 On the [Sample Results] screen use ⌄ or ⌃ (to the right of <Seq. No.>) to select the sequence number of the required sample.

The results of the sample are displayed in the table:

- Test (test name/parameter)
- Value of the individual result
- Flags of individual result

The displayed result value is shown in the unit, which is selected. If a combination of two units (e.g. SI and arbitrary is selected) only the SI will be shown.

Editing individual results

► **To edit individual results**

1 On the [Sample Results] screen use ∨ or ∧ (to the right of the table with results) to select the required parameter from the list.

2 Pressing <Edit> calls up the [Sample Results > Edit] screen or the [Sample Results > Color] screen or the [Sample Results > Clarity] screen depending on the parameter you have selected.

Edit any parameter except for COL or CLA

If you have selected any parameter except for COL (color) or CLA (clarity) from the table, the [Sample Results > Edit] screen is called up.

Standby	28.10.2004	12:58
Overview	Workplace	Utilities

Sample Results>Edit
Seq. No.   6
Sample ID   111144
                  Value
Test LEU   <   25 /µl   >

yellow   clear
Color   Clarity   ✓   ✕

Figure B-44   [Sample Results > Edit] screen

3 Use the <Value> selector buttons < or > to allocate the new result to the selected test.

4 Apply these changes by pressing ✓.

The screen is now closed and the modified result is displayed on the [Sample Results] screen with a flag.

Once you have edited the result, it will be marked with an "!". This flag indicates that the result has been modified.

👁 *Flags on result printout on page D-5*

If you have edited a result, the sample is reevaluated according to the sieve and abnormal criteria.

👁 *Sieve and abnormal values on page B-81*

Edit or add color or clarity   If you have selected the COL (color) parameter from the table, the [Sample Results > Color] screen is called up.
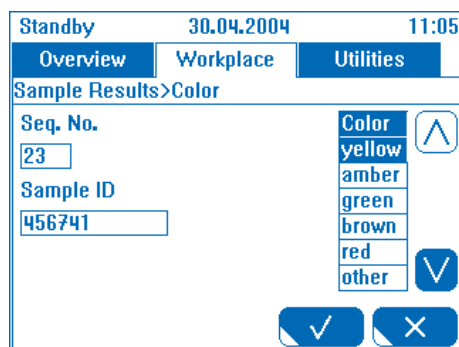
Figure B-45   [Sample Results > Color] screen

If you have selected the CLA (clarity) parameter from the table, the [Sample Results > Clarity] screen is called up.
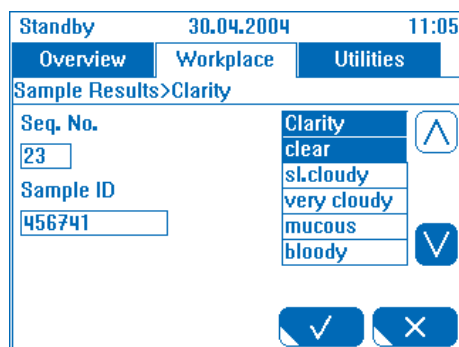
Figure B-46   [Sample Results > Clarity] screen

5   Select the color or clarity of the sample using [V] or [∧].

6   Apply your selection by pressing [✓].

This closes the screen and displays the selected color and clarity on the [Sample Results] screen.

Printing, uploading to the host, storing or deleting several results

If the host status is <On> the results will be sent to the host automatically. For any print mode except <Off> the results will be printed accordingly.

👁 *[Overview] screen* on page B-29

You can print results, upload results to the host, store results or delete results on the [Sample Results > Send] screen. To this end, enter the first and last sequence number and select what you want to do with the results.

When printing, you cannot use the display. The display is frozen.

► **To print results, upload results to the host, store results or delete them**

1 On the [Sample Results] screen, use <Send> to call up the [Sample Results > Send] screen.

Standby	30.04.2004	11:24

| Overview | **Workplace** | Utilities |

Sample Results>Send

Seq. No.

From [1]

To [5]

7	8	9
4	5	6
1	2	3
0		←

Print Upload Store Delete ✕

Figure B-47   [Sample Results > Send] screen

2 Select <From> and enter the first sample sequence number.

3 Select <To> and enter the last sample sequence number.

4 Select <Print>, <Upload>, <Store> or <Delete>, depending on what you want to do with the results.

- <Print> prints the results using the internal printer.
- <Upload> uploads the results to the host.
- <Store> stores the results on an USB stick as <Instr. No>_Sample<No.>.csv (e.g. 2575_Controls6.csv). In this format the data can be processed with another application for example a spread sheet application.
- <Delete> deletes the results.

5 If necessary, confirm the pop-up window.

6 If you have finished your work on this screen, you can close the screen with ✕ and return to the [Sample Results] screen.

Working with results

Deleting individual samples

► **To delete individual samples**

1   Call up the [Sample Results] screen from the [Workplace] tab.

Figure B-48   [Sample Results] screen

2   Use ∨ or ∧ (to the right of <Seq. No.>) to select the sequence number of the required sample.

3   Press <Delete> to delete all results of the selected sample and confirm the pop-up window.

Repeating individual samples

The selected sample can be measured again with the same sequence number or sample ID. The <Repeat> button is only active, if the selected sample has a T-flag.

► **To repeat individual samples**

1   Call up the [Sample Results] screen from the [Workplace] tab.

Figure B-49   [Sample Results] screen

2   Use ∨ or ∧ (to the right of <Seq. No.>) to select the sequence number of the required sample.

3   Press <Repeat> to repeat the selected sample and confirm the pop-up window.

4   Place the proper test strips to repeat the measurement.

Working from the [Sample List] screen

The sample list is used to manage results. Here you can review only the samples of your interest (e.g. flagged samples).

It is also possible to search for a specific sample or for specific flags.

Once you have located the required sample, you can display the results of the individual parameters.

You can also use the sample list to print, store and delete results or upload them to the host.

Viewing results from the sample list

► **To view results from the sample list**

1   Call up the [Sample List] screen from the [Workplace] tab.

Figure B-50   [Sample List] screen

2   Use ∨ or ∧ to select the required sample.

3   Call up the [Sample List > Detail] screen by pressing <Detail>.

Figure B-51   [Sample List > Detail] screen

The screen shows the results of the selected sample.

The [Sample List > Detail] screen is identical to the [Sample Results] screen.

4   Use ∨ or ∧ (to the right of <Seq. No.>) to select the sequence number of the required sample.

The results of the sample are displayed in the table:

- Test (test name/parameter)
- Value of the individual result
- Flags of individual result

The displayed result value is shown in the unit, which is selected. If a combination of two units (e.g. SI and arbitrary is selected) only the SI will be shown.

Editing individual results

► **To edit individual results**

1 On the [Sample List > Detail] screen use ∨ or ∧ (to the right of the table with results) to select the required parameter from the list.

2 Pressing <Edit> calls up the [Sample List > Detail > Edit] screen or the [Sample Results > Color] screen or the [Sample Results > Clarity] screen depending on the parameter you have selected.

Edit any parameter except for COL or CLA

If you have selected any parameter except for COL (color) or CLA (clarity) from the table, the [Sample List > Detail > Edit] screen is called up.

Figure B-52   [Sample List > Detail > Edit] screen

3 Use the <Value> selector buttons < or > to allocate the new result to the selected test.

4 Apply these changes by pressing ✓ .

The screen is now closed and the modified result is displayed on the [Sample List > Detail] screen with a flag.

Once you have edited the result, it will be marked with an "!". This flag indicates that the result has been modified.

👁 *Flags on result printout* on page D-5

If you have edited a result, the sample is reevaluated according to the sieve and abnormal criteria.

👁 *Sieve and abnormal values* on page B-81

Edit or add color or clarity   If you have selected the COL (color) parameter from the table, the [Sample List > Detail > Color] screen is called up.
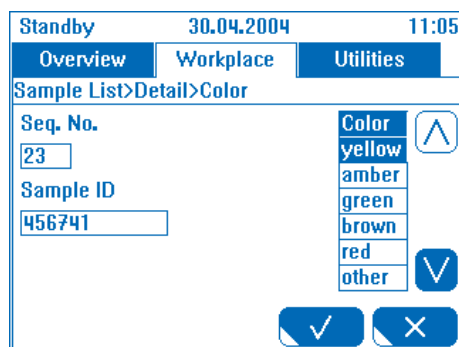
Figure B-53   [Sample List > Detail > Color] screen

If you have selected the CLA (clarity) parameter from the table, the [Sample List > Detail > Clarity] screen is called up.
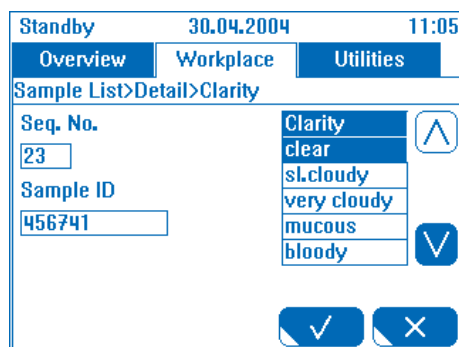
Figure B-54   [Sample List > Detail > Clarity] screen

5 Select the color or clarity of the sample using ⌄ or ⌃.

6 Apply your selection by pressing ✓.

This closes the screen and displays the selected color and clarity on the [Sample List > Detail] screen.

Printing, uploading to the host, storing or deleting several results

If the host status is <On> the results will be sent to the host automatically. For any print mode except <Off> the results will be printed accordingly.

👁 *[Overview] screen* on page B-29

You can print results, upload results to the host, store results or delete results on the [Sample List > Send] screen. To this end, enter the first and last sequence number and select what you want to do with the results.

When printing, you cannot use the display. The display is frozen.

► **To print results, upload results to the host, store results or delete them**

1 On the [Sample List] screen or on the [Sample List > Detail] screen, use <Send> to call up the [Sample List > Send] screen.
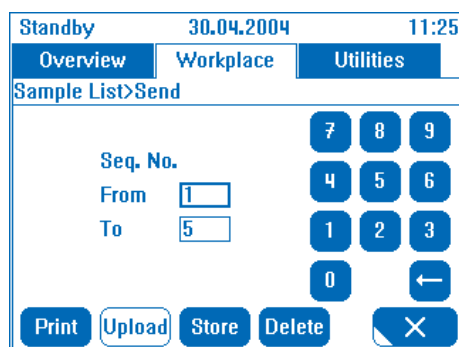
Figure B-55   [Sample List > Send] screen

2 Select <From> and enter the first sample sequence number.

3 Select <To> and enter the last sample sequence number.

4 Select <Print>, <Upload>, <Store> or <Delete>, depending on what you want to do with the results.

- <Print> prints the results using the internal printer.
- <Upload> uploads the results to the host.
- <Store> stores the results on an USB stick as <Instr. No.>_Sample<No.>.csv (e.g. 2575_Controls6.csv). In this format the data can be processed with another application for example a spread sheet application.
- <Delete> deletes the results.

5 If necessary, confirm the pop-up window.

6 If you have finished your work on this screen, you can close the screen with [×] and return to the [Sample List] screen or the [Sample List > Detail] screen.

Deleting individual results

You can delete individual results on the [Sample List > Detail] screen.

► **To delete individual samples on the [Sample List > Detail] screen**

1 Call up the [Sample List] screen from the [Workplace] tab.

2 Use ⌄ or ⌃ to select the required sample.

3 Press the <Detail> button to call up the [Sample List > Detail] screen.
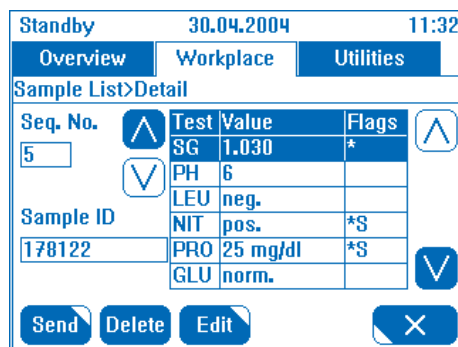
Figure B-56   [Sample List > Detail] screen

4 Press the <Delete> button to delete the selected sample and confirm the pop-up window.

5 To delete further samples, use ⌄ or ⌃ (to the right of <Seq. No.>) to select the sequence number of the required sample.

OS-02597-01

Searching for Samples

From the [Sample List] screen you can also search for samples.

► **To search for samples in the sample list**

1 On the [Sample List] screen, use <Search> to call up the [Sample List > Search] screen.
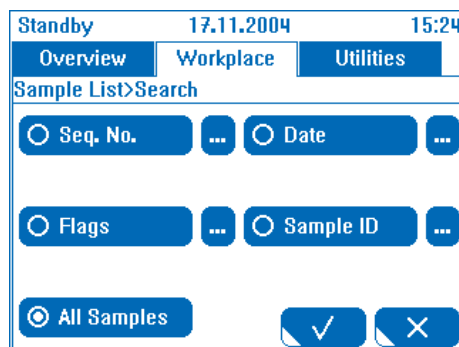
Figure B-57   [Sample List > Search] screen

On this screen you can search for a specific sample directly without having to scroll through the sample list.

The button of the selected search mode (<Seq. No.>, <Date>, <Flags>, <Sample ID>, or <All Samples>) is marked (⊚). The search criteria set for the search mode (e.g. *1 - 1* for <Seq. No.>, or *Strip Error* for <Flags>) are displayed. If All Samples is selected, no search criteria are displayed.

2 Press the corresponding button to set the criteria for the desired search mode.

If you press ... on the right of a search mode, the corresponding screen is called up where you can define search criteria. The selected search criteria are displayed below the corresponding button.

Seq. No. ... This button calls up a screen where you can set a range of sequence numbers for searching samples.
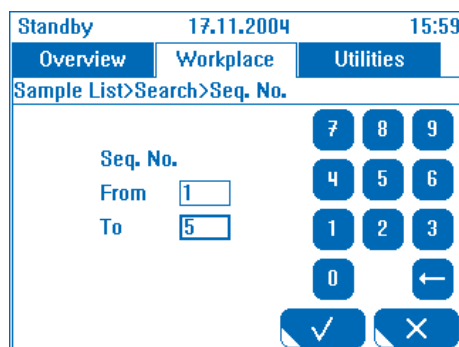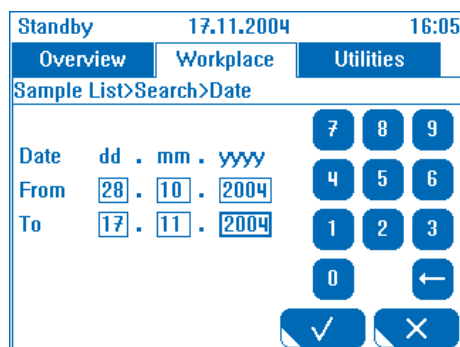
Figure B-58   [Sample List > Search > Seq. No.] screen

- Select the corresponding input field and enter the sequence number of the first and last sample results you want to search.
- Press ✓ to return to the [Sample List > Search] screen.

Date ⋯   This button calls up a new screen where you can set a date range for searching samples.

Figure B-59   [Sample List > Search > Date] screen

- Select the corresponding input field and enter the date of the first and last sample results you want to search.
- Press ✓ to return to the [Sample List > Search] screen.

Flags ⋯   This button calls up a screen where you can set a flag for searching samples.
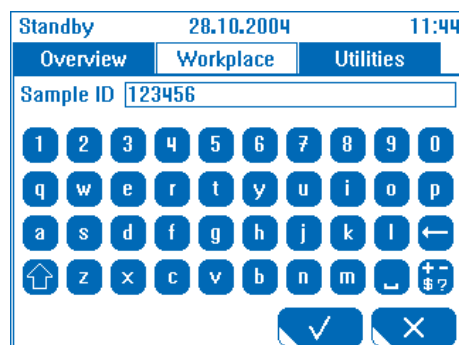
Figure B-60   [Sample List > Search > Flags] screen

Use the corresponding button to select the flag of the sample results of which you want to search.

- Press <Sieve>, <Normal>, <Abnormal>, <Strip error>, or <Sieve&Abnormal> to select the flag of the results of which you want to search.
- Press ✓ to return to the [Sample List > Search] screen.

- For more information about the search criteria, see:
  Sieve and abnormal values on page B-81
  Sample flags on page D-5
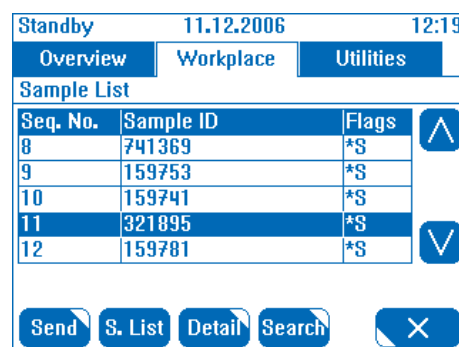
Sample ID [...]   This button calls up a screen where you can enter a single sample ID.

Figure B-61   [Sample List > Search > Sample ID] screen

- Enter the sample ID of the sample you want to search.

- Press [✓] to return to the [Sample List > Search] screen.

If you have selected the desired search mode and entered the required criteria, you can close the [Sample List > Search] screen with [✓] and return to the [Sample List] screen.

Figure B-62   [Sample List] screen

The selected results are displayed in the [Sample List] screen now. To the right of the screen hierarchy line (Sample List), the search criteria for the selected samples are displayed.

If <All Samples> is selected as search criteria on the [Sample List > Search] screen, no search criteria is displayed to the right of the screen hierarchy line (Sample List) and all samples are displayed.

Presentation of results on the printout

The operator can determine the order of the test parameters on the printout.

👁 *Output order* on page B-82

The operator can also enter text for the headline and determine whether the printout should contain an empty space for microscopic results.

👁 *Printer* on page A-82

The printout includes the following information:

- Headline
- Software version
- Range setting (International, Japan, or USA)
- Sample sequence number
- Sample ID
- User ID
- Date and time of analysis
- Lot number
- Expiration date
- Sample flags
- Test parameter results with result flags
    - 👁 Table D-1 and Table D-2 on page D-5
- Section for microscopic results (if enabled)

<pre>
                    ┌──────────────────────────────────┐
                    │   urine analyzer   │
                    └──────────────────────────────────┘
                    Analytical Report   V3.3.0.0000/
                                                   Intern.

                    Seq. No.   2
                    Sample ID   759568
                    User   supervisor
                    Date/Time   01.03.2013 11:15
                    Lot No.   21208102
                    Exp. Date   31.05.2013
                    Flags

                    Chemical Analysis
                    SG   1.005
                    PH   8   *S
                    ...
                    ...
                    ERY   neg
                    Color   yellow
                    Clarity   clear

                    Microscopic Report   (Space for handwritten results)
                    LEU   6 - 10
                    ERY   4 - 9
                    LEU. CASTS.   Few
                    HYAL. CASTS.   Many
                    TRICHOM.   Abundant
</pre>

Figure B-63   Example of a result printout for a patient sample

Switching off the analyzer

The **cobas u** 411 analyzer must be in Stand-by state when it is switched off. Never switch off the analyzer when it is in any other operating state.

👁 *Operating states* on page A-20

► **To complete work and switch off the analyzer**

1 Wait until the analysis of all test strips has been completed and all samples have been printed. The end of the analysis is indicated by Stand-by state in the status bar.

👁 *(A) Status bar* on page B-22

Otherwise results for test strips which have not yet been measured will be lost. However, results not yet printed will still be kept in the analyzer.

2 Perform the required daily maintenance procedures.

👁 General maintenance, *Daily* on page C-6

3 Press [Overview > Logoff] to attain the [Login] screen.

4 Press <Shutdown> on the [Login] screen to switch off the analyzer.

5 Switch off the analyzer.

Special Operation

This chapter contains a description of special **cobas u** 411 analyzer operations that do not fall into the category daily operations.

To perform the operations described in this chapter, you must be thoroughly familiar with the basic operation of the **cobas u** 411 analyzer.

👁 *Basic operational procedures* on page B-21

In this chapter   *Chapter* **7**

Analyzing control samples

The **cobas u** 411 analyzer offers the possibility to define controls and set ranges for their target values. When the result of a control is out of these ranges, the result is marked with the flag (*).

Of course you can analyze control samples as normal samples. But the results are then not stored as control results, they are stored with the normal sample results.

If the feature of storing control results separately and flagging the results by the software automatically is requested, it is necessary to define the controls in advance.

👁 For more information see *To configure the control samples for your analyzer* on page B-85

► **To analyze control samples**

1 Call up the [Run Control] screen from the [Workplace] tab.
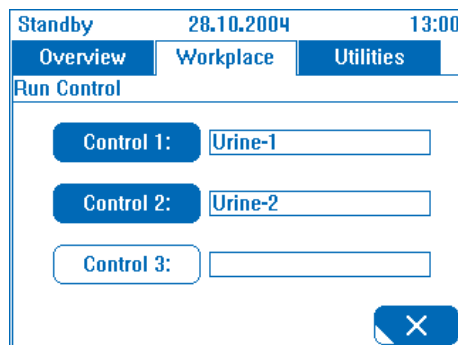
Figure B-64   [Run Control] screen

2 Select the control that you want to analyze by pressing the corresponding button.

3 Dip a test strip in the control sample material.

4 Press <Ok> in the pop-up window and then position the test strip on the test strip tray area.
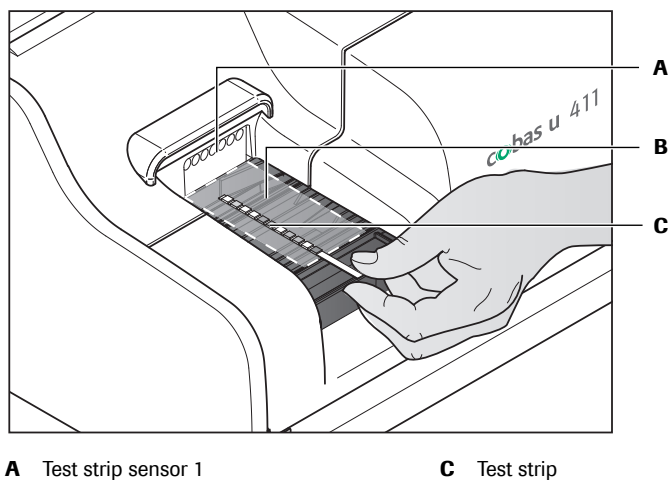
A	Test strip sensor 1	**C**	Test strip
B	Area for test strips on the test strip tray		

Figure B-65   Positioning samples

The sample is drawn into the analyzer for analysis.

You can view the results of the analyses on the [Control List] screen of the [Workplace] tab.

Working with control sample results

This section contains the following information on working with results.

- Viewing the results of the control samples
- Printing, storing and uploading control sample results to the host
- Deleting results
- Presentation of results on the printoutPresentation of results on the printout

The cobas u 411 analyzer is equipped with a circular memory for 100 control samples per control.

When the memory is full, the 10 oldest results are deleted. A message will appear for confirmation to document the old control results or not.

You can store old results on an USB stick and delete them in the analyzer.

Viewing the results of the control samples

The [Control List] screen is used to manage the control sample results. Here you can see a list of all control results that are stored in the analyzer. The results of the individual parameters are not displayed here.

Here you can select a specific control sample or look for results with flags.

Once you have selected the required control sample, you can display the results of the individual parameters.

You can print, store or transmit results to the host from the [Control List] screen.

▶ **To select a control sample**

1   Call up the [Control List] screen from the [Workplace] tab.

Figure B-66   [Control List] screen

It gives an overview of several control samples. The name of the control sample is displayed in the first column, the date and time of the analysis in the second column, and the flags that indicate errors that occurred during analysis in the third column. Below the list with the control results an error text for the selected result is displayed, if a test strip error (T) or a calibration exceeded error (C) has occurred.

👁 For more information see *Flags on result printout* on page D-5

2   Use ▽ or △ to select the required control result.

▶ **To view individual results**

1   Use <Detail> to access the [Control List > Detail] screen.

Figure B-67   [Control List > Detail] screen

The screen displays the values of the individual parameters of the control sample that you selected on the [Control List] screen.

2   Use ▽ or △ to select the required parameter.

The result of the analysis is displayed after the parameter. The concentration range that was configured for the control is displayed in the <Range> field.

👁 *To configure the control samples for your analyzer* on page B-85

3   Use <Control name> to display the current result of the next control.

Pressing <Control name> always displays the current result of the next control. If you wish to display a previous result of another control, you have to select the result from the [Control List] screen.

Printing, storing and uploading control sample results to the host

If automatic result printout is enabled, the results will be printed automatically.

👁 *[Overview] screen* on page B-29

You can print or store results on the [Control List > Send] screen. To this end, enter the first and last date and time of analysis and select what you want to do with the results.

When printing, you cannot use the display. The display is frozen.

► **To print and store control sample results from the sample list**

1   Call up the [Control List] screen from the [Workplace] tab.

Standby	30.04.2004	11:37
Overview	**Workplace**	Utilities

Control List

Name	Date & Time	Flags
Urine-2	30.04.2004 09:09	
Urine-1	30.04.2004 09:06	
Urine-2	02.04.2004 10:51	
Urine-1	02.04.2004 10:48	

Send Delete Detail   ✕
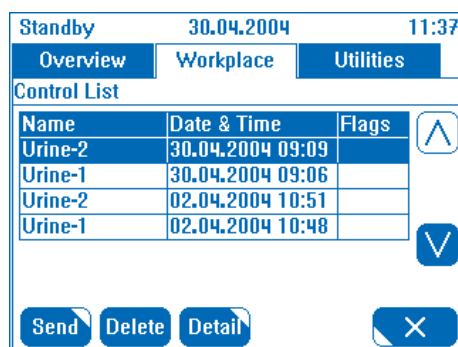
Figure B-68   [Control List] screen

2   Use ⋁ or ⋀ to select the required control.

3   Use <Send> to access the [Control List > Send] screen.

Standby	30.04.2004	11:38
Overview	**Workplace**	Utilities

Control List>Send

Date	dd . mm . yyyy
From	02 . 4 . 2004
To	30 . 4 . 2004

7 8 9
4 5 6
1 2 3
0 ←

Print Upload Store Delete   ✕
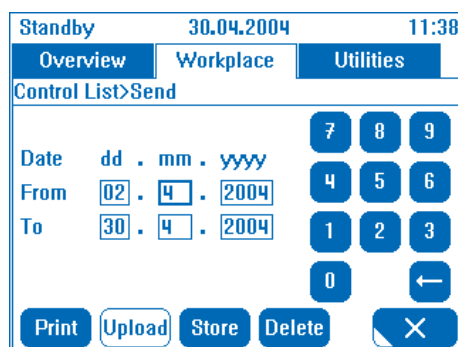
Figure B-69   [Control List > Send] screen

4   Select the corresponding input field for day, month or year.

5   Enter the date of the first and last analysis you want to print, upload or store.

6 Select <Print>, <Upload> or <Store>, depending on what you want to do with the results.

- <Print> prints the results using the internal printer.
- <Upload> transmits the results to the host.
- <Store> stores the results on an USB stick as <Instr. No.>_Calibration<No.>.csv (e.g. 2575_Controls6.csv). In this format the data can be processed with another application for example a spread sheet application.

Deleting results

► **To delete the results for a control sample**

1 Call up the [Control List] screen from the [Workplace] tab.
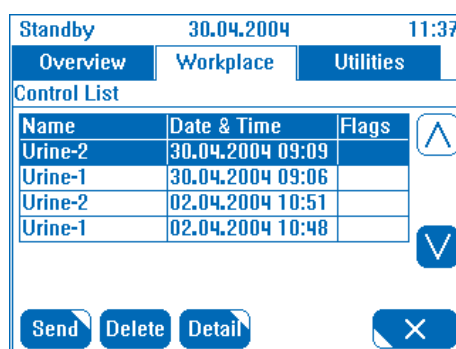
Figure B-70   [Control List] screen

2 Use ∨ or ∧ to select the required control.

3 Press <Delete> and confirm the pop-up window.

This deletes the results of the selected control sample.

► **To delete the results for a specific period**

1 Press the <Send> button on the [Control List] screen to access the [Control List > Send] screen.
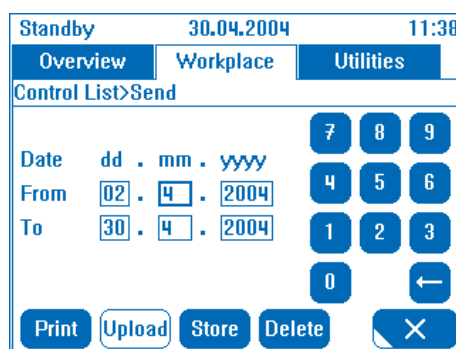
Figure B-71   [Control List > Send] screen

2 Select the corresponding input field for day, month or year.

3   Enter the date of the first and last analysis you want to delete.

4   Press <Delete> and confirm the pop-up window.

This deletes all control results for the period you entered.

► **To delete the results of a control measurement**

1   Press the <Detail> button on the [Control List] screen to access the [Control List > Detail] screen.
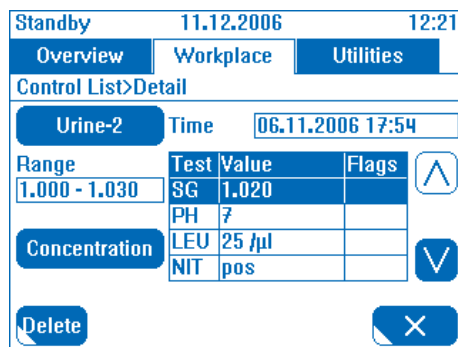
Figure B-72   [Control List > Detail] screen

2   Press <Delete> and confirm the pop-up window.

This deletes all results of the selected measurement.

► **To change units of the results of a control measurement**

1   Press the <Detail> button on the [Control List] screen to access the [Control List > Detail] screen.
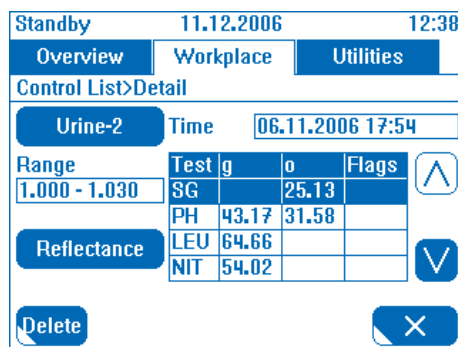
Figure B-73   [Control List > Detail] screen

2   Press <Concentration/ Reflectance> to toggle between reflectance and concentration.

The second column changes to two columns of compensated reflectance values.

Presentation of results on the printout

The output order of the test parameter results is identical to the order selected for routine samples.

👁 *Output order* on page B-82

The printout includes the following information:

- Headline
- Software version
- Range setting (International, Japan, or USA)
- Control name
- Lot number of the control
- Expiration date of control
- Lot number of test strip
- Expiration date of test strip
- User ID
- Date and time of analysis
- Sample flags
- Test parameter results (with result flags and ranges - if defined)
    - 👁 Table D-1 and Table D-2 on page D-5

urine analyzer		
Quality Control Report	V3.3.0.0000 / Intern.	
Control name	Control-1	
Lot No. Control	23145683	
Exp. Date Control	31.10.2014	
Lot No. Strip	21220101	
Exp. Date Strip	30.09.2013	
User	supervisor	
Date/Time	01.03.2013 09:24	
Flags		
Chemical Analysis		
ERY	250	(150 - 250)
LEU	500 *	(25 - 100)
NIT	pos	(pos - pos)
PRO	500	(25 - 500)
PH	7	(6 - 8)
GLU	1000	(100 - 1000)
KET	150 *	(5 - 50)
UBG	12	(4 - 12)
BIL	6	(1 - 6)
SG	1.010	(1.005 - 1.020)
Color	other	(amber - amber)

Figure B-74   Example of a result printout for control samples

Calibrating the analyzer

The operator can calibrate the **cobas u** 411 analyzer using the [Tools1 > Calibration] screen of the [Utilities] tab.

Calibration is based on the analysis of a calibration strip with known reflectance values. This must only be performed using the Control-Test M calibration strip manufactured by Roche Diagnostics. The calibration strip is made of gray plastic material of constant reflectance characteristics.

Under routine conditions, the **cobas u** 411 analyzer should be calibrated once a month.

Calibration procedure

The remission values analyzed for each elevated area of the calibration strip are compared with the previous user calibration values analyzed and the values of the internal calibration strip.

Calibration tests
For each calibration strip positioned on the test strip tray the following tests are performed:

- The values of the calibration strip must not deviate by more than ±15% from the values of the internal reference strip. Otherwise a calibration error is displayed. This tests prevents that the analyzer is calibrated with an accidentally positioned test strip.

- The values of the calibration strip must not deviate by more than ±10% (relative deviation) from the values of the actually stored calibration. This tests also detects an accidentally positioned test strip and wrong positioned calibration strips.

- The values of the calibration strip must not deviate by more than ±1% (Rem) from the values of the actually stored calibration.

- The values of 2 consecutive calibration strips must not deviate by more than ±1% (Rem).

The following calibrations are possible with combination of these tests:

Initial Calibration
If you put the analyzer into operation for the first time, no calibration values are stored. You must perform an initial calibration. At an initial calibration the values of 2 consecutive calibration strips must not deviate by more than ±1% (Rem). In addition, the values must not deviate by more than ±15% from the values of the internal reference strip. You will be prompted to position a new calibration strip, until these conditions are accomplished. The values of the calibration strip are stored as actual calibration values.

Re calibration
For re calibration of the analyzer, there are two possibilities:

- If the calibration values are within ±1% (Rem) of the actually stored values and the deviation between the values of the calibration strip and the internal reference strip is not greater than ±15%, the actually stored calibration values are still used.

- If the calibration values deviate by more than ±1% (Rem) from the actually stored values, you will be prompted to position a second calibration strip on the test strip tray. The values of the second calibration strip must not deviate by more than ±1% (Rem) from the values of the first calibration strip. You will be prompted to

position a new calibration strip, until 2 consecutive calibration strips do not deviate by more than ±1% (Rem) or you cancel the calibration.

Only start analyzing samples if the calibration was successful. If calibration continues to fail after several attempts, please contact your Roche Service representative.

Handle and store the Control-Test M calibration strips according to the instructions in the calibration strip package insert.

Performing a calibration

The test strip tray must be clean and dry before you start a new calibration!

The calibration results may be imprecise if the calibration strip is polluted or not dry.

Before calibration, clean and dry the test strip tray.

► **To calibrate the analyzer**

1   Call up the [Tools1 > Calibration] screen from the [Utilities] tab.

Figure B-75   [Tools1 > Calibration] screen

The screen displays a list of the last calibration results and the current valid one.

2   Press the <Calibrate> button to prepare the calibration.

A confirmation window is displayed.

3   If you want to cancel the calibration procedure, press ⟨ × ⟩.

If you want to perform the calibration, press ⟨ ✓ ⟩ and position the calibration strip on the test strip tray area.

Please ensure that the area by which you hold the calibration strip is pointing towards the front of the analyzer and that the elevated areas on the calibration strip are facing upwards.
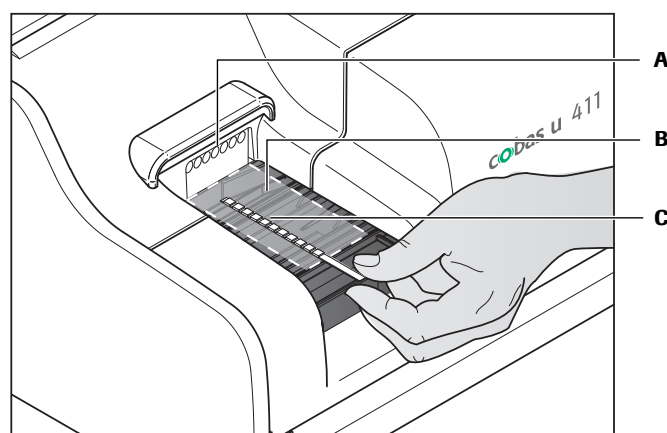
OS-02597-01

A	Test strip sensor 1	**C**	Calibration strip
B	Area for test strips on the test strip tray		

Figure B-76   Positioning the calibration strip

The calibration strip is drawn into the analyzer for measurement. A message appears once the calibration has been successfully completed.

For more information on the calibration results, please refer to:

👁 *Working with calibration results* on page B-73

Exceeding the calibration intervals

If the recommended calibration interval of once a month is exceeded, a warning message appears when starting the analyzer or when the date changes over night.

Close the pop-up window and calibrate as described above.

👁 For more information see *To calibrate the analyzer* on page B-71

! *You should not analyze samples without a new calibration. The accuracy of results may be impaired by performing samples after the recommended calibration interval is exceeded. The operator is responsible for verifying the proper function of the test strips, e.g. by analysis of normal and abnormal urine controls.*

💡 *Results of routine and control samples will be marked with a C-flag on the display, printout and host protocol until a new calibration is executed.*

👁 *Flags on result printout* on page D-5

Working with calibration results

This section contains the following information on working with calibration results.

- Viewing calibration results
- Printing and storing results
- Presentation of results on the printout

The cobas u 411 analyzer stores the last 4 calibration results and the current valid one.

When the memory for calibration results is full, you will be prompted to store the old results on an USB stick. Store the old results on an USB stick, if required by any regulatory issues.

If you do not store these results on an USB stick, they will be overwritten by more recent calibration results.

Viewing calibration results

The [Tools1 > Calibration] screen is used to manage the calibration results. It gives an overview of several calibration results. The results of the individual parameters are not displayed here.

Here you can select a specific calibration result and display calibration details.

You can also print and store results.

► **To view calibration results**

1 Call up the [Tools1 > Calibration] screen from the [Utilities] tab.
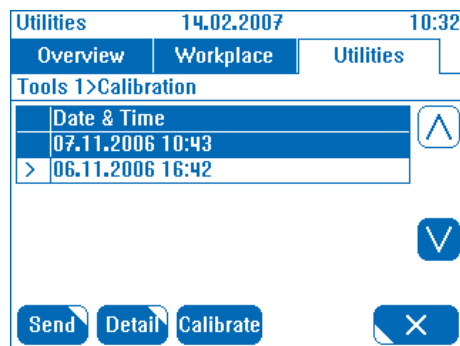
Figure B-77   [Tools1 > Calibration] screen

The screen displays a list of the last 5 calibration results.

2 Use ∨ or ∧ to select the required calibration.

3 Use <Detail> to call up the [Tools1 > Calibration > Detail] screen.
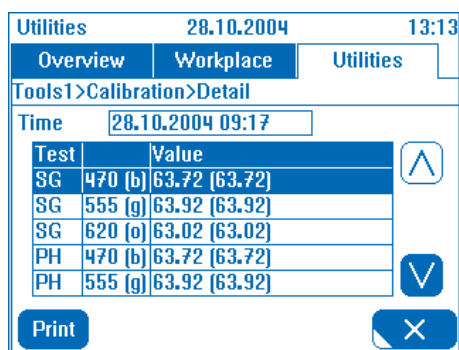
Figure B-78   [Tools1 > Calibration > Detail] screen

This screen displays the results for the calibration selected in the [Tools1 > Calibration] screen. Above the table the date and time of the selected calibration is displayed.

The table shows all results of the selected calibration:

- The first column shows the test name and the wavelength of the measurement.
- The second column shows reflectance values (the reflectance values of the actually used calibration are shown in brackets).

Printing and storing results

If automatic result printout is enabled, the results will be printed automatically.

👁 *[Overview] screen* on page B-29

You can print or store results on the [Tools1 > Calibration > Send] screen. To this end, enter the date of the first and last calibration and select what you want to do with the results.

When printing, you cannot use the display. The display is frozen.

► **To print or store calibration results**

1   On the [Tools1 > Calibration] screen, use <Send> to access the [Tools1 > Calibration > Send] screen.
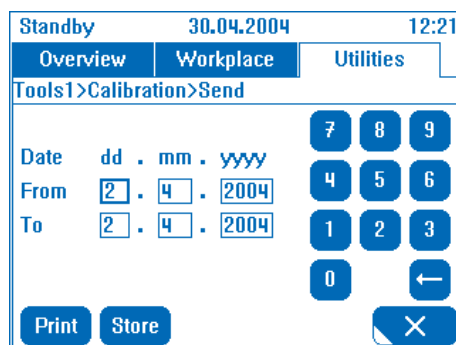
Figure B-79   [Tools1 > Calibration > Send] screen

2 Select the corresponding input field for day, month or year.

3 Enter the date of the first and last calibration you want to print or store.

4 Select <Print> or <Store>, depending on what you want to do with the results, and confirm the pop-up window.

- <Print> prints the results using the internal printer.
- <Store> stores the results on an USB stick as <Instr. No.>_Sample<No.>.csv (2575_Controls6.csv). In this format the data can be processed with another application for example a spread sheet application.

Presentation of results on the printout

The printout includes the following information:

- Headline
- Software version
- User ID
- Date and time of analysis
- Calibration date and time
- Lot number of calibration strip
- Expiration date of calibration strip
- Calibration results for each parameter and wavelength

```
            urine analyzer

Calibration Report      V3.3.0.0000
User                    supervisor
Current Date            01.03.2013  11:15
Calibration Date        16.02.2013  09:24
Lot No. calib. strip    21219501
Exp. Date calib. strip  31.08.2016

Calibration ok

              470 (b)  555 (g)  620 (o)
SG            63.72    63.92    63.02
PH            63.72    63.92    63.02
LEU          61.35    61.37    61.47
NIT          62.18    62.60    61.46
PRO          61.96    62.04    61.36
GLU          62.50    62.55    62.03
KET          62.63    62.13    62.27
UBG          62.72    62.75    61.20
BIL          64.04    63.42    63.12
ERY          64.13    64.21    62.73
COM          64.54    64.42    62.79
```

Figure B-80   Example of a result printout for a calibration

Updating the user software

When a new user software is released for the **cobas u** 411 analyzer, you can update the software.

All results and system parameters might be lost, when updating the user software!

Depending on the changes in the user software, all data on the analyzer may be deleted. When an new software is released, the release notes will inform you on how to update your analyzer.

To prevent losing results or system settings, observe the following precautions:

- *Report all your results.*
  - 👁 *Printing, uploading to the host, storing or deleting several results* on page B-47
  - 👁 *Printing, storing and uploading control sample results to the host* on page B-66
- *Print and store all system settings*
  - 👁 *Storing and loading system, test and sediment parameters* on page B-77

► **To update the user software**

1 Call up the [Tools2] screen from the [Utilities] tab.

2 Press ▷ to display the [Tools2] screen.
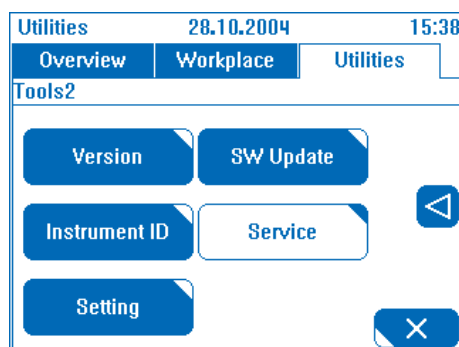
Figure B-81　　　　[Utilities > Tools2] screen

3 Press <SW Update> to start the update of the software.

A confirmation window with further instructions for the update of the software is displayed.

4 Follow the instructions displayed on the confirmation windows.

Storing and loading system, test and sediment parameters

If you want to transfer data from one **cobas u** 411 analyzer to another or to make a backup of your system settings you can store system, test, and sediment parameters on an USB stick.

▶ **To store system, test and sediment parameters on USB stick**

1   Call up the [Tools1 > Data Exchange] screen from the [Utilities] tab.
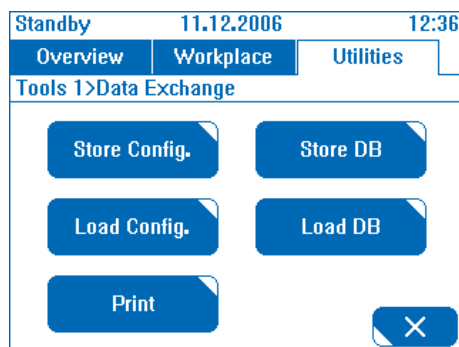
Figure B-82   [Tools1 > Data Exchange] screen

2   Insert an USB stick in the USB port.

3   Press <Store Config.>.

4   Follow the instructions displayed on the confirmation window.

    The parameters are stored on USB stick in file <Instr. No.>_Config<No.>.csv.

    The data can only be loaded by an **cobas u** 411 analyzer.

▶ **To load system, test and sediment parameters from an USB stick to the analyzer**

1   Call up the [Tools1 > Data Exchange] screen from the [Utilities] tab.

2   Insert the USB stick containing the system, test, and sediment parameters in the USB port.

3   Press <Load Config.>.

    The parameters are loaded from the USB stick to your analyzer.

Configuration

This chapter contains a description of those configuration procedures that are often adjusted individually by the user.

- Sieve and abnormal values
- Output order
- Controls & Lots
- Range table
- Units
- Color and clarity

The following chapter contains a brief description of the other screens:

👁 Chapter 4, *Software*, *Utilities* on page A-65

In this chapter   *Chapter* **8**

Sieve and abnormal values

Use the sieve settings to define the criteria for a flag (S) on the corresponding test parameter result. These flags can be used to identify urine samples to be examined by additional methods, for example, sediment microscopy.

Use the abnormal settings to define the criteria that indicate potentially pathological values. An asterisk (*) flags the corresponding test parameter results.

👁 *Result flags* on page D-5

The concentration values which are specified on the screen represent the lowest concentration ranges from which on the test parameter results are flagged.

▶ **To set the criteria for defining sieve and abnormal values**

1 Call up the [Test Parameters > Sieve / Abnormal] screen from the [Utilities] tab.
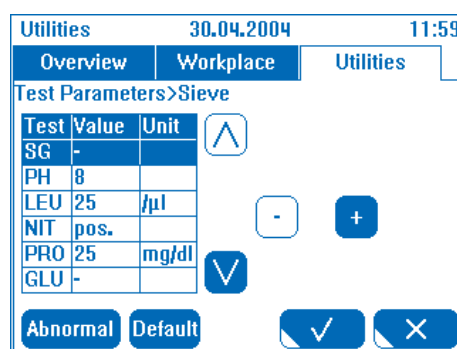
Figure B-83   [Test Parameters > Sieve / Abnormal] screen

This screen lists the criteria for sieve or abnormal settings for each individual test.

2 Press <Sieve>/<Abnormal> to toggle between the display criteria for sieve or abnormal settings. The screen hierarchy (above the table) indicates which criteria you can define:

- Test Parameters > Sieve
- Test Parameters > Abnormal

3 Use ∨ or ∧ to select the required test parameter.

4 Use − or + to allocate a new lower limit to the selected test parameter.

If the result exceeds this lower limit, it will be flagged.

5 Repeat steps 2 through 4 for the next parameters.

Pressing <Default> resets the sieve/abnormal values to the default settings.

6 Apply the changes as new criteria for sieve and abnormal values by pressing ✓ .

This closes the screen.

The sediment parameters are entered via the Sediment Terminal.

👁 For more information see *Sediment Terminal* on page A-36

For more information about working with the *Sediment Terminal,* refer to the *Operators Manual of the Sediment Terminal*

OS-02597-01

Output order

The operator can define the order of the test parameters on the display and on the result printout.

► **To set the output order**

1   Call up the [Test Parameters > Output Order] screen from the [Utilities] tab.
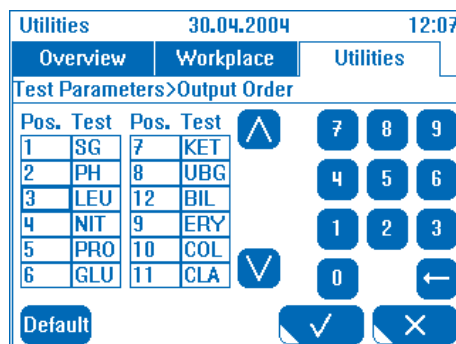
Figure B-84   [Test Parameters > Output Order] screen

The 2 lists contain the available tests. The number to the left of the test indicates the position on the printout.

2   Select the required test from the list by pressing ⌄ or ⌃.

3   Enter the position of the test on the printout via the touch screen keyboard.

Make sure, that no position has been assigned to more than one test.

Pressing <Default> resets the output order to the default settings. The default output order is in the same order as the test pads on the strip.

4   Apply the new output order by pressing ✓ .

This closes the screen.

Controls & Lots

The Controls & Lots window contains three buttons: <Test strip>, <Calibration strip> and <Controls>.
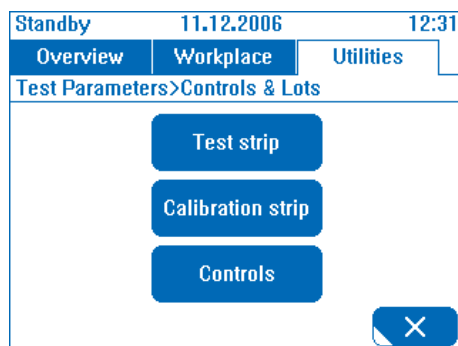
Figure B-85   [Test Parameters > Controls & Lots] screen

Test strip   Press <Test strip> to call up the screen and enter lot number and expiry date of the test strips.

Calibration strip   Press <Calibration strip> to call up the screen and enter lot number and expiry date of the calibration strips.

Controls   Press <Controls> to call up the screen and configure the analyzer's controls.

Controls (QC) should be run after using the calibration strip, after maintenance or service and when changing operators.

Test strip

The operator can enter lot number and expiry date of test strips on this screen.

▶ **To configure test strips for your analyzer**

1 Call up the [Test Parameters > Controls & Lots > Test strip] screen from the [Utilities] tab.

Figure B-86   [Test Parameters > Controls & Lots > Test strip] screen

2 Press <Lot Number> input field and use the touch screen keyboard to enter the test strip lot.

3 Press the corresponding input field <dd, mm, yyyy> and use touch screen to enter the expiry date of the test strip.

Calibration strip

The operator can enter lot number and expiry date of calibration strips on this screen.

▶ **To configure calibration strips for your analyzer**

1 Call up the [Test Parameters > Controls & Lots > Calibration strip] screen from the [Utilities] tab.

Figure B-87   [Test Parameters > Controls & Lots > Calibration strip] screen

2 Press <Lot Number> input field and use the touch screen keyboard to enter the calibration strip lot.

3 Press the corresponding input field <dd, mm, yyyy> and use touch screen to enter the expiry date of the calibration strip.

Controls

Before you can analyze control samples, you must configure the control samples you use in your laboratory. Up to 3 controls can be configured on the analyzer.

Of course you can analyze control samples as normal samples. But the results are then stored and deleted with the normal sample results.

► **To configure the control samples for your analyzer**

1   Call up the [Test Parameters > Controls & Lots > Controls] screen from the [Utilities] tab.

Figure B-88   [Test Parameters > Controls & Lots > Controls] screen

2   Use ∨ or ∧ to select Control 1, 2 or 3, depending on the control you want to configure.

3   Press the <Edit> button to access the [Test Parameters > Controls & Lots > Controls > Edit] screen.

Figure B-89   [Test Parameters > Controls & Lots > Controls > Edit] screen

4   Press the <Name> input field and use the touch screen keyboard to enter the name of the control sample.

5   Press <Lot Number> input field and use the touch screen keyboard to enter the control sample lot.

6   Press the corresponding input field <dd, mm, yyyy> and use touch screen to enter the expiry date of the control sample.

7 Press the <Ranges> button to access the [Test Parameters > Controls & Lots > Controls > Edit > Ranges] screen.

Figure B-90   [Test Parameters > Controls & Lots > Controls > Edit > Ranges] screen

8 Enter the ranges for the various control sample parameters:

- Use [V] or [Λ] to select the parameter you want to configure.
- Use [-] or [+] to allocate a new low value or high value to the selected parameter.

  The next value from the default range table, is displayed.

  👁 *Range table* on page B-87

9 Apply the new range limits temporarily by pressing [√].

This closes the screen and displays the [Test Parameters > Controls & Lots > Controls > Edit] screen.

The new range limits are not applied until [√] is pressed on the [Test Parameters > Controls & Lots > Controls > Edit] screen.

10 Repeat steps 2 through 9 for the next controls.

Once you have defined the controls, you only have to alter the lot number and adjust the ranges (if necessary) when using a different lot.

If you try to delete a control definition, a pop-up window will inform you that all corresponding control results will be deleted automatically. However you will be asked whether the control results should be reported or stored on USB stick before deletion.

👁 For more information, see *Analyzing control samples* on page B-63

Range table

The operator can view the concentration ranges and reflectance values for each test parameter. Editing of ranges is allowed for supervisors only.

The SG and pH ranges are factory-set. They can only be changed by your Roche Service representative.

Editing ranges leads to concentration results that deviate from the default concentration ranges shown in the table referred to below.

👁 *Range values for all test parameters* on page A-42

Test parameter results for altered reflectance values are marked with the hash symbol (#).

👁 *Result flags* on page D-5

! *Changing reflectance values leads to different evaluation sensitivities of the respective test parameters. Lowering the reflectance value of the negative (neg) range leads to a decrease of the sensitivity of the test evaluation, and vice versa. In this way, the sensitivity can be adjusted to the requirements of the individual laboratory.*

The accuracy of results obtained after the supervisor has altered the ranges or reflectance values is not warranted by Roche Diagnostics. The supervisor is responsible for validating the consistency of results after changes have been made.

For measuring control samples the default ranges are used, even if the ranges are changed by the operator.

▶ **To alter range limits**

1 Call up the [Test Parameters > Range Table] screen from the [Utilities] tab.
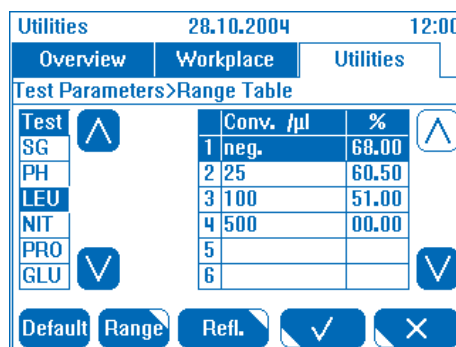
Figure B–91   [Test Parameters > Range Table] screen

The left-hand list contains the available tests. The right-hand list displays the concentration range limits and the relevant reflectance values in % for the selected test. You can scroll up and down the right-hand list using ⌄ or ⌃ to display the top or the bottom part of the range.

The entire concentration range can be subdivided into range boundaries. A range boundary is limited by the range limits. When a range limit is exceeded, the measured value is allocated to the next range boundary. A range limit is exceeded

when the measured reflectance value is lower than the reflectance value that has been defined as the range limit for a range boundary.

Example: If the reflectance value for Glucose is less than 59.00%, the measured value will be allocated to the second boundary (50 mg/dl).

The concentration values are displayed in the unit you have defined for your analyzer: SI, conventional, or arbitrary.

👁 *Units* on page B-90

If you want to reset the analyzer to the default range settings, press <Default> and confirm the pop-up window.

2   Select the required test from the left-hand list by pressing ⋁ or ⋀.

Alter range values   **3**   Press <Range> to call up the screen and edit the range values.
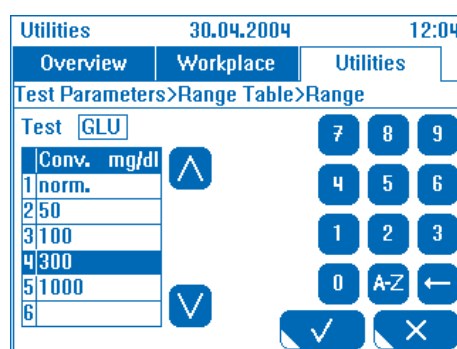
Figure B-92   [Test Parameters > Range Table > Range] screen

The name of the selected test is displayed above the list. The unit of the values is displayed above the first value in the list.

The following units are available for concentration values:

- SI
- Conventional
- Arbitrary

4   Use ⋁ or ⋀ to select the range limit that you want to alter from the list.

5   You can overwrite the selected entry with the keys or use ⬅ to delete the current value.

6   Enter the new value using the numeric touch screen keyboard.

If you want to enter a term, call up the alphanumeric touch screen keyboard using A-Z. Enter the term and close the touch screen keyboard using the ✓ button.

7   Repeat steps 4 through 6 to alter other range limits.

8   Apply the new range limits by pressing ✓.

This closes the screen.

Old results will not be recalculated after changing the ranges.

- *For ERY and Color you must not add or delete concentration ranges. It is only possible to change the ranges.*
- *Changing color ranges in the range table is only possible if automatic color determination is selected.*
- *For all other parameters, except for SG and pH, you can configure up to 8 ranges per parameter.*

Alter reflectance values   **9**   Press <Refl.> to call up the screen and edit the reflectance values.
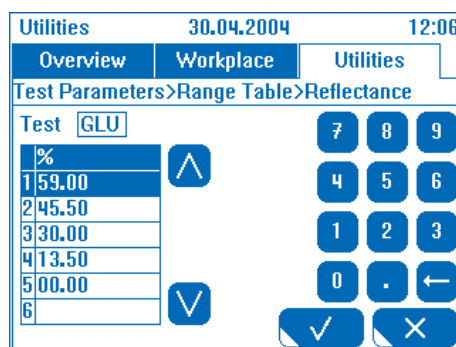
Figure B-93   [Test Parameters > Range Table > Reflectance] screen

The name of the selected test is displayed above the list. The unit of the values is displayed above the first value in the list. Reflectance is displayed in %.

10 Use ⌄ or ⌃ to select the range limit that you want to alter from the list.

11 You can overwrite the selected entry with the keys or use ← to delete the current value.

12 Enter the new value using the numeric touch screen keyboard.

13 Repeat steps 10 through 12 to alter other range limits.

14 Apply the new range limits by pressing ✓ .

This closes the screen.

Storing new range and   **15** Store the new range and reflectance values by pressing ✓ on the
reflectance values   [Test Parameters > Range Table] screen.

The values are checked for correctness.

Units

The operator can define which type of unit should be used to report the results.

► **To set the type of unit**

1   Call up the [Test Parameters > Unit] screen from the [Utilities] tab.
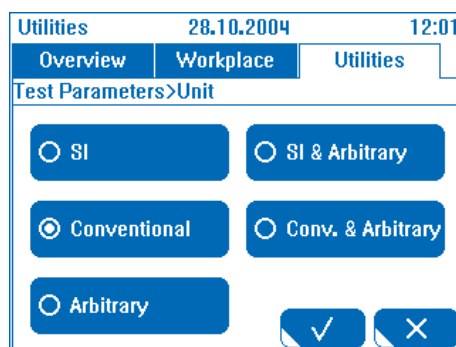
Figure B-94   [Test Parameters > Unit] screen

2   Press one of the <SI>, <SI & Arbitrary>, <Conventional>, <Conv. & Arbitrary>,
    <Arbitrary> buttons to select the unit used.

3   Apply the new unit by pressing ✓.

    This closes the screen.

- *Old results will not be recalculated after changing the unit.*

- *If you change the unit, you must redefine the control ranges and check the values of the range table.*

- *If you want to change the presentation of the arbitrary units to your lab specific requirements, you have to select < Arbitrary> in this screen and then adapt the Range table.*

    👁 *Controls & Lots on page B-83*

    👁 *Range table on page B-87*

Color and clarity

You can set whether the analyzer determines the color of the sample automatically using the compensation pad on the test strip, or if you select the color manually.

The clarity of the sample cannot be determined by the analyzer.

The colors for automatic color measurement can be configured on the following screen:

👁 *Range table* on page B-87

The analyzer's color and clarity settings for manual entry can be configured on the [Test Parameters > Color & Clarity] screen.

► **To change the Color and Clarity settings for manual entry**

1 Call up the [Test Parameters > Color & Clarity] screen from the [Utilities] tab.
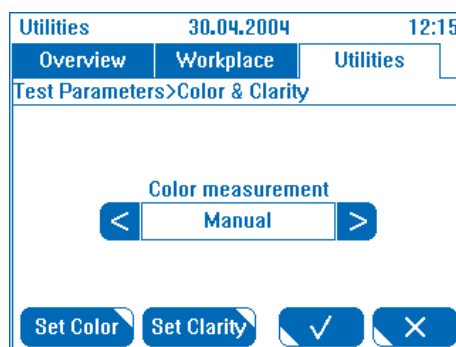
Figure B-95   [Test Parameters > Color & Clarity] screen

2 Select <Manual> for color measurement by pressing [<] or [>] to enable the analyzer's manual color determination function.

Alter color settings 3 Press <Set Color> to call up the [Test Parameters > Color & Clarity > Set Color] screen.

The <Set Color> button can only be selected if the color measurement is set to <Manual>.
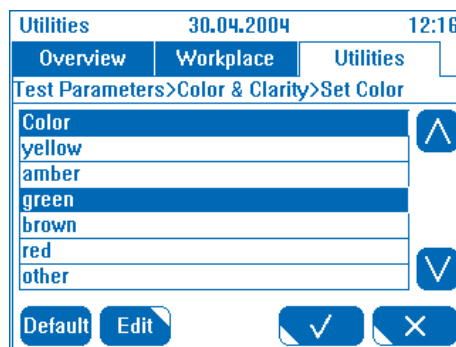
Figure B-96   [Test Parameters > Color & Clarity > Set Color] screen

4 Use [V] or [Λ] to select the color that you want to alter from the list.

Roche Diagnostics

OS-02597-01

5 Press <Edit> to call up the touch screen keyboard.

You can enter the color designations of your choice here.

If you want to reset the analyzer to the default color settings, press <Default> and confirm the pop-up window.

6 Apply the new settings by pressing ✓ .

This closes the screen.

Alter clarity settings **7** Press <Set Clarity> to call up the [Test Parameters > Color & Clarity > Set Clarity] screen.
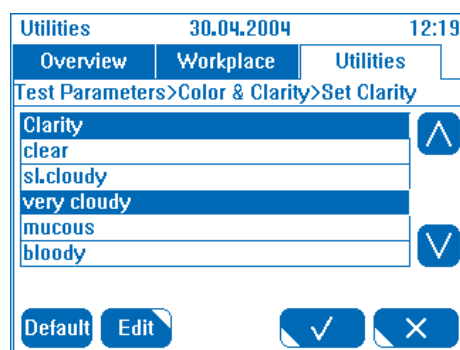
Figure B-97   [Test Parameters > Color & Clarity > Set Clarity] screen

8 Use ∨ or ∧ to select the clarity that you want to alter from the list.

9 Press <Edit> to call up the touch screen keyboard.

You can enter the clarity designations of your choice here.

If you want to reset the analyzer to the default clarity settings, press <Default> and confirm the pop-up window.

10 Apply the new settings by pressing ✓ .

This closes the screen.

Maintenance   **C**

General maintenance

This chapter explains general maintenance procedures for the **cobas u** 411 analyzer.

In this chapter   *Chapter* **9**

OS-02597-01

Safety precautions

To prevent excessive contamination of your **cobas u** 411 analyzer and keep it functioning reliably, maintenance should be carried out regularly and carefully.

Risk of infection from contaminated samples!

The test strip transfer system (test strip tray with integrated waste area, test strip pusher, and test strip transporter) may be contaminated with potentially infectious or toxic material.

Always wear protective gloves when handling its parts.

Please observe the laws governing the handling of waste!

Handle used test strips properly and in accordance with the laws governing water pollution and the treatment of drainage and waste matter.

The analyzer can be damaged by spilled samples or chemicals!

The analyzer can be damaged if liquids flow into the measurement system or into power connections.

Wipe up any lost or spilled chemicals or samples immediately!

Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the analyzer.

There are no maintenance actions required by the field service engineers for the cobas u 411.

Daily

Perform the following maintenance tasks daily:

- Empty the waste area of the test strip tray.
- Clean the test strip transfer system:
  - Test strip tray with integrated waste area
  - Test strip pusher
  - Test strip transporter

Emptying the test strip waste area

The test strip tray is a complete plastic tray that can be removed for cleaning. It has an integrated waste area.

Empty the waste area at least at the end of daily measurements, or when an alarm message is generated. When there are 90 test strips in the waste container, an alarm will sound. When there are 100 test strips in the waste container, no further test strips will be analyzed. Empty the waste container. If you don't empty the test strip waste container, no further measurements are possible.

! **If the front cover is opened during analysis, results will be lost!**

If you open the front cover during analysis, the analyzer will stop immediately and switch over to Stop mode. The results for test strips that are still being processed will be lost.

Do not open the front cover during operation!

When you take out the test strip tray, you must empty the waste area!

When you remove and re-insert the test strip tray, the waste counter will be reset to zero.

You must empty the waste area of the test strip tray whenever you remove it from the unit!

► **To empty the test strip waste container**
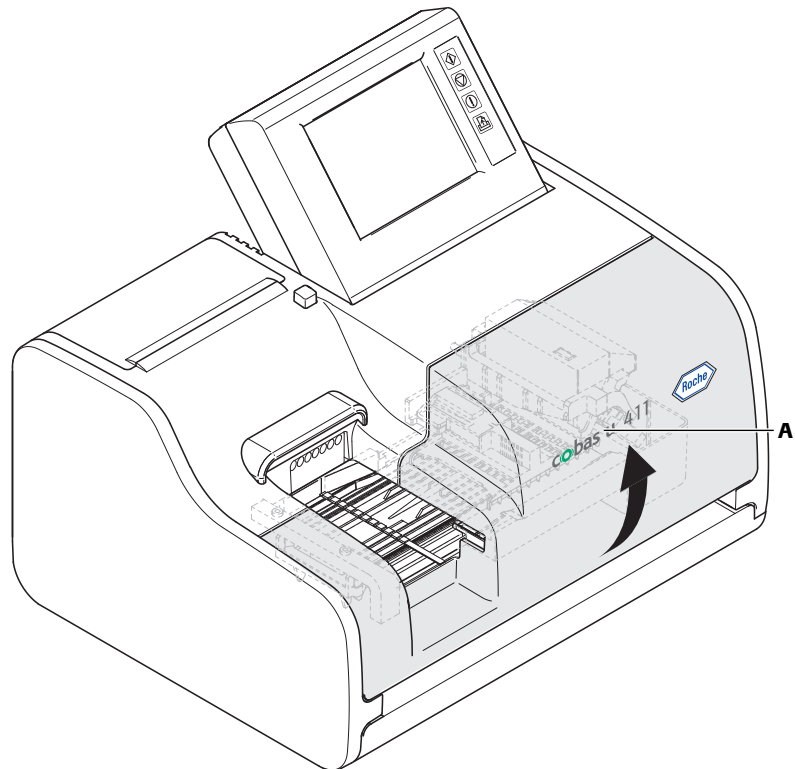
A   Front cover

Figure C–1   Opening the front cover

1   Wait until the **cobas u** 411 analyzer is in Stand-by state.

2   Open the front cover (**A**).
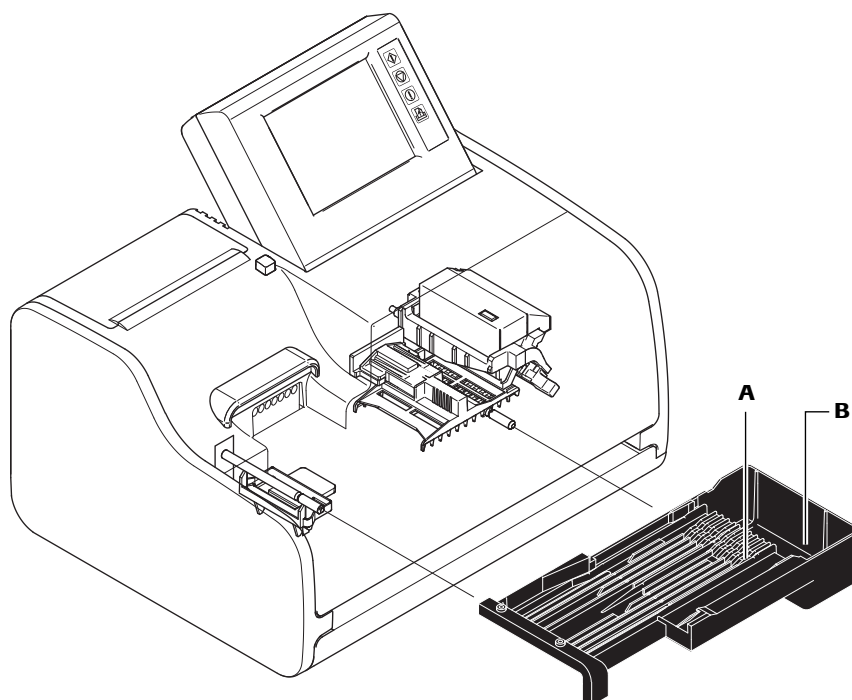
A Test strip tray	**B** Test strip waste area

Figure C-2 Pulling out the test strip tray

3 Pull out the test strip tray (**A**).

The test strip tray is locked in its working position.

4 Empty the waste area (**B**) of the test strip tray.

5 Re-insert the test strip tray.

The test strip tray will snap into its working position. This will reset the waste counter to zero.

6 Close the front cover of the **cobas u** 411 analyzer.

Cleaning the test strip transfer system

When cleaning the test strip transfer system, the analyzer must be in Stand-by state.

The test strip transfer system must be cleaned every day to prevent contamination and deposits, and to ensure that test strips are processed accurately.

► **To clean the test strip transfer system**
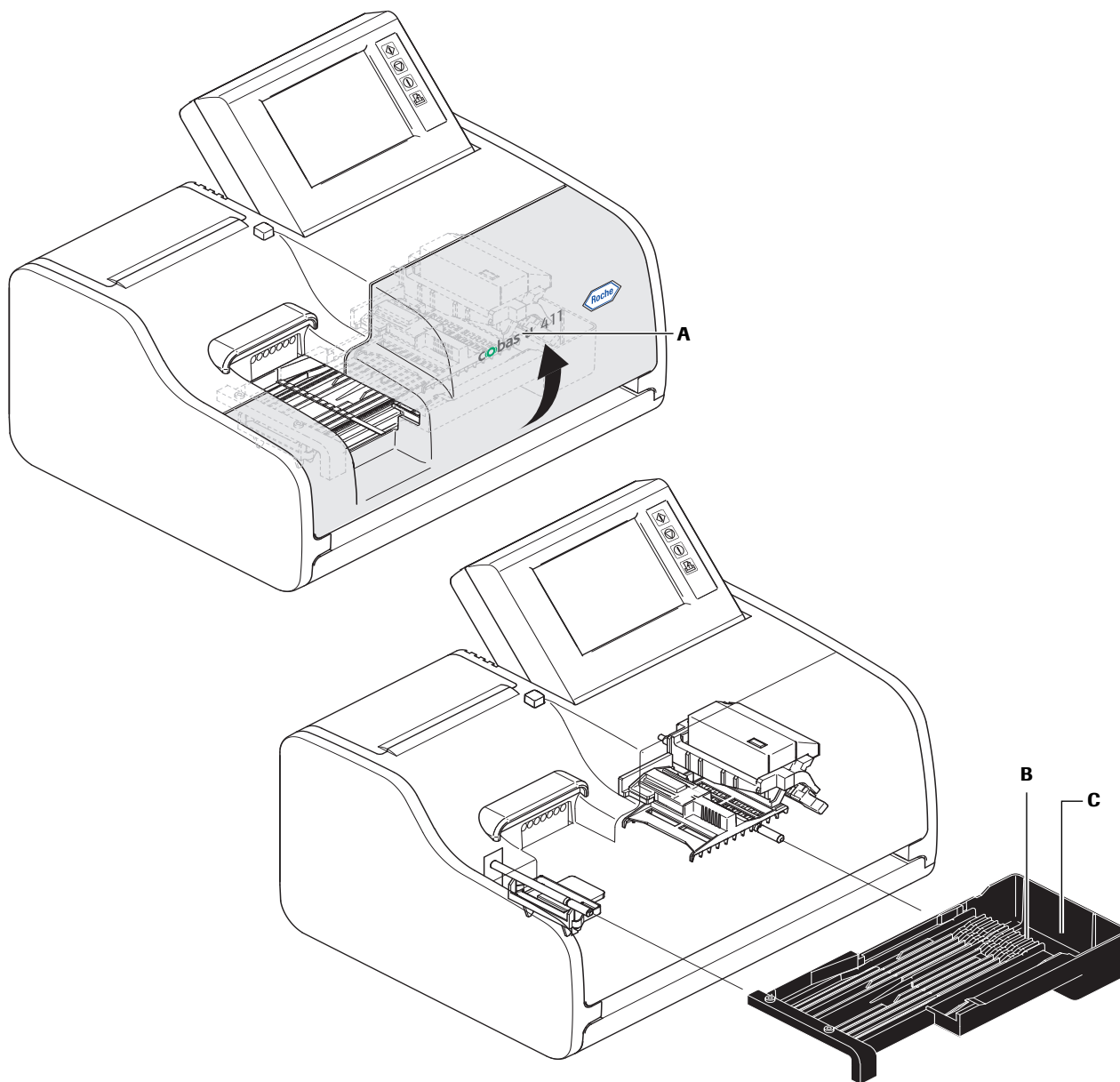
| **A** | Front cover | **B** | Test strip tray | **C** | Test strip waste area |

Figure C-3   Opening the front cover and pulling out the test strip tray

1 Open the front cover (**A**) of the **cobas u** 411 analyzer.

2 Pull out the test strip tray (**B**).

   The test strip tray is locked in its working position.

3 Empty the waste area (**C**) of the test strip tray.
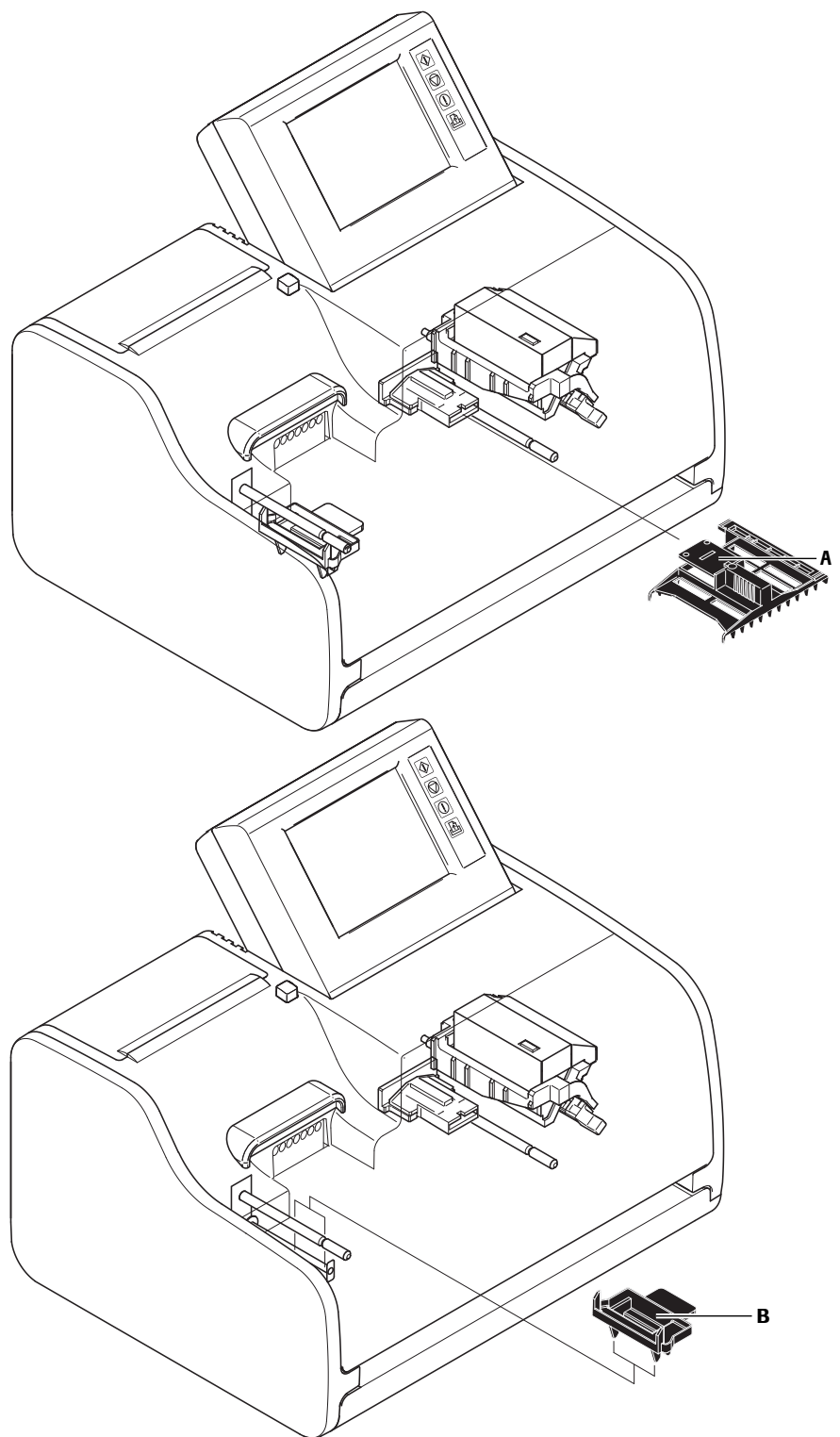
A	Test strip transporter	**B**	Test strip pusher

Figure C-4   Pulling out the test strip transporter and the test strip pusher

The test strip transporter (**A**) is locked in its working position.

4   Squeeze sides to release the test strip transporter and pull it out.

5 Raise the test strip pusher (**B**) slightly and pull it out.
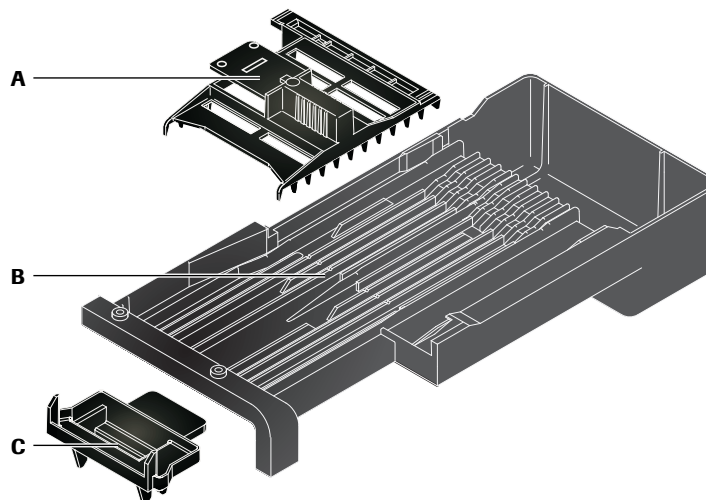
A   Test strip transporter
B   Test strip tray
C   Test strip pusher

Figure C-5   Parts of the test strip transfer system

6 Clean the parts under running water. If necessary, wipe them with a cloth or gauze moistened with a neutral detergent. Wipe the grooves with a cotton swab. Apply a disinfectant if necessary.

Risk of damage to the test strip transfer system!

Acid or alkaline detergents can corrode the parts of the test strip transfer system.

Do not use acid or alkaline detergents. Do not scratch the surface of the test strip transfer base.

7 Dry the parts with a lint-free cloth if analysis is to continue immediately after cleaning.

You can also clean the parts in the dishwasher. If the parts of the test strip transfer system are washed in the dishwasher (80°C), they should cool down to room temperature before use.

The test strip tray, test strip pusher and test strip transporter should always be cleaned together.

8 Re-insert the test strip pusher first, then the test strip transporter, and finally the test strip tray.

The test strip transporter and the test strip tray will snap into their working position.

9 Close the front cover of the **cobas u** 411 analyzer.

Monthly

Perform the following maintenance tasks monthly:

- Clean the interior of the analyzer.
- Clean the outer parts (housing) of the analyzer.

Cleaning the interior of the analyzer

You must wipe down the interior of the analyzer once a month, or more often where there is heavy contamination.

Perform the daily cleaning as described, but do not re-insert the test strip transfer system parts yet. This will give you better access to the other parts in the interior of the analyzer.

!

Risk of short-circuit by the use of liquids for cleaning the analyzer!

The photometric unit and the switches in the interior of the analyzer are not splash-proof.

Use only a moistened cloth clean the interior of the analyzer.

► **To clean the interior of the analyzer**

1 Before cleaning the analyzer, turn off the power switch on the rear of the analyzer.

2 Remove the parts of the test strip transfer system during daily cleaning.

   👁 *Cleaning the test strip transfer system* on page C-8, step 1 through step 7

3 Wipe down the interior of the analyzer.

   - Bottom of unit
   - Sides
   - Other contaminated parts

   Use a cloth moistened with water or with a liquid cleaning agent to clean the outer surface of the analyzer. Use a disinfectant when necessary.

4 Re-insert the test strip pusher first, then the test strip transporter, and finally the test strip tray.

   The test strip transporter and the test strip tray will snap into their working position.

5 Close the front cover of the **cobas u** 411 analyzer.

Cleaning the exterior of the analyzer

► **To clean the exterior of the analyzer**

   1 Before cleaning, turn off the power switch on the rear of the analyzer.

   2 Wipe down all exterior parts of the analyzer except for the touch screen with a damp cloth.

     Use a cloth moistened with water or with a liquid cleaning agent to clean the outer surface of the analyzer. Use a disinfectant when necessary.

► **To clean the touch screen**

   1 Before cleaning, turn off the power switch on the rear of the analyzer.

   2 Wipe the touch screen with a dry cloth.

     If contamination is heavy, clean with a cloth moistened with a neutral detergent.

!

Risk of damage to the touch screen!

Do not use volatile solvents such as benzene.

Do not scratch the surface of the touch screen.

Once a year

Replacing the internal calibration strip

The internal calibration strip must be replaced at least once a year or if the **cobas u** 411 analyzer cannot be calibrated despite several attempts.

👁 For more information see *To calibrate the analyzer* on page B-71

► **To replace the internal calibration strip**

| **A** Front cover | **B** Protective cover | **C** Internal calibration strip |
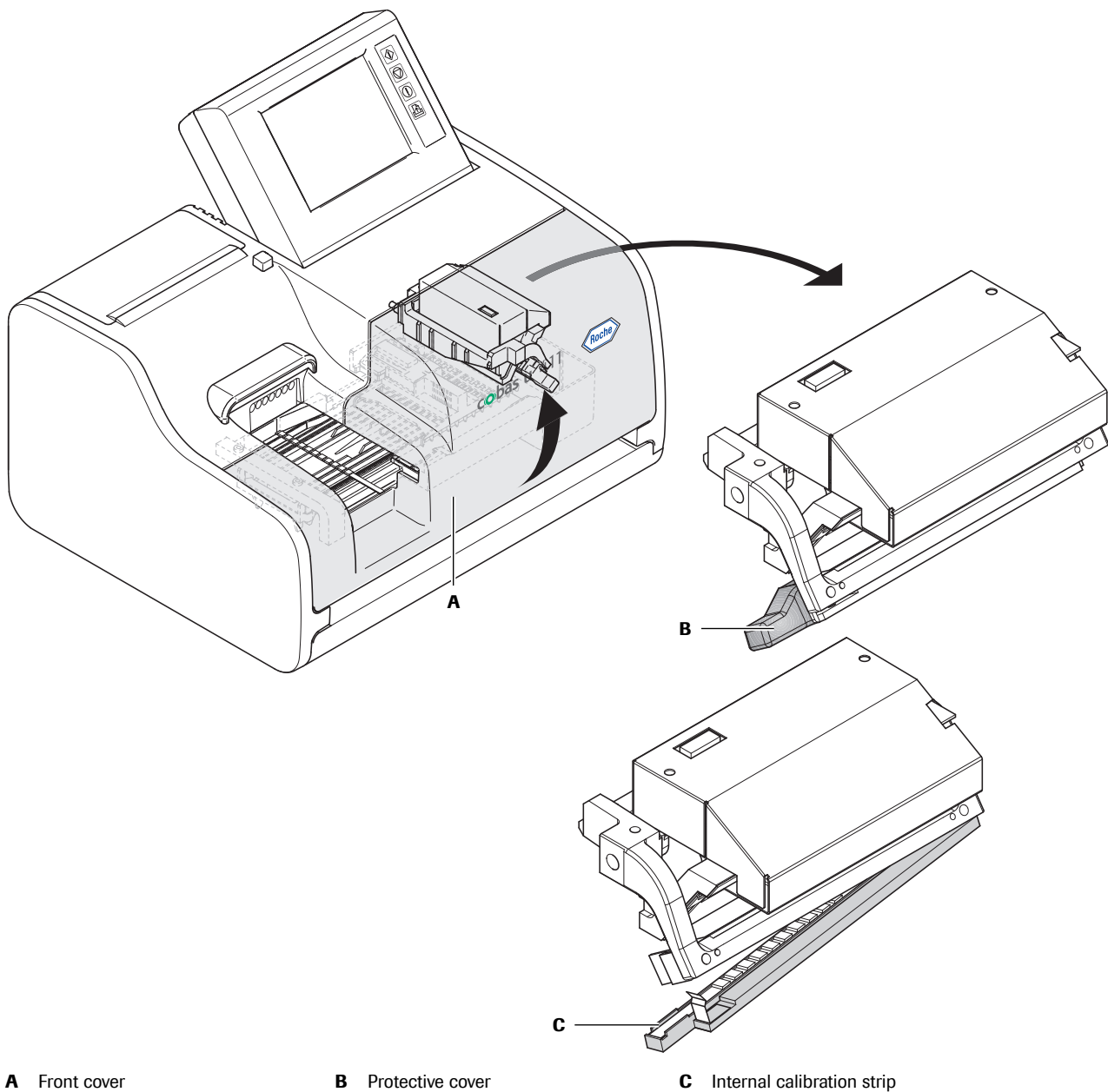
Figure C-6 Replacing the Internal Calibration Strip

Once a year

1 Open the front cover (**A**) of the **cobas u** 411 analyzer.

2 Remove the test strip tray.

3 Remove the protective cover (**B**) from the calibration strip by pulling towards you.

4 Remove the calibration strip (**C**).

5 Insert a new calibration strip with the measuring field side up.

6 Put the protective cover back over the calibration strip.

7 Re-install the test strip tray.

8 Close the front cover of the **cobas u** 411 analyzer.

9 Recalibrate the analyzer.

👁 For more information see *To calibrate the analyzer* on page B-71

As required

Replacing the main fuse

The main fuse must be replaced when the analyzer can no longer be turned on and the fuse is defective.

► **To replace the main fuse**
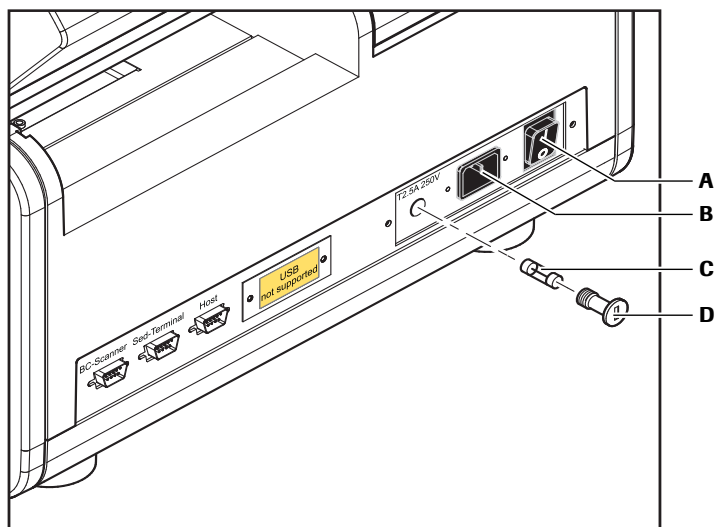
A	Power switch	**C**	Fuse
B	Power supply connector	**D**	Fuse socket

Figure C-7 Replacing a fuse

1 Turn off the power switch (**A**) on the rear of the analyzer.

2 Unplug the power cord at the analyzer's power supply connection (**B**).

3 Unscrew the fuse socket (**D**) with the multi-tool.

4 Replace the fuse (**C**) if it is defective.

5 Screw the fuse socket back in.

6 Reinsert the power cord into the power supply connection of the analyzer and set the main switch to ON.

Risk of damage to the analyzer!

Using fuses designed for other capacities may damage the unit.

Use only fuses that are specified in this Operator Manual (see Power requirements on page A-40).

Troubleshooting ◼ **D**

Data alarms (flags)

This chapter describes the data alarms (flags) that appear on printouts.

In this chapter   *Chapter* **10**

Flags on result printout

The result data that are printed must be checked for flags. There can be different flags next to the data, in order to bring some of the values to the attention of the operator. Flags on result printout are outlined below.

Result flags

Flag	Result flags	Explanation	Appearance on printout
S	Sieve	Test parameter result corresponds to sieve criteria settings	After the value
*****	Abnormal	For patient samples test parameter result corresponds to abnormal criteria settings. For control samples it means out of range.	After the value
#	Changed reflectance value	Initial range table is changed	After the value
!	Edited Result	Data have been edited	After the value

Table D-1   Result flags

Sample flags

Flag	Sample flags	Explanation	Appearance on printout
T	Test strip	Error during measurement of a test strip or a reference strip. Possible reasons: • Strip upside down • Strip incomplete wet • Strip complete dry • Strip missing or wrong positioning • Wrong strip (e.g. Combur^{10}Test strip instead of Combur^{10}Test M strip) • Calculation not possible	In the flag row
C	Calibration exceeded	Calibration interval of once a month is exceeded. 👁 For more information, see *Calibrating the analyzer* on page B-70	In the flag row

Table D-2   Sample flags

Instrument alarms (messages)

This chapter describes the instrument alarms, and explains how to handle alarms.

In this chapter   *Chapter* **11**

Overview about alarms

This section gives an overview about alarms. It describes:

- How does the analyzer signal an alarm
- How can you remedy an alarm

If the instrument shows no error message but the test strip is not transported, there is a problem with the test strip sensor 1.

If the test strip is transported but the system stops later respectively the samples of the worklist are not processed and the test strip sensor 2 is defective.

Occurrence of an alarm   When an alarm has been triggered on the analyzer, the alarm is announced by the LED of the global action button and a buzzer.
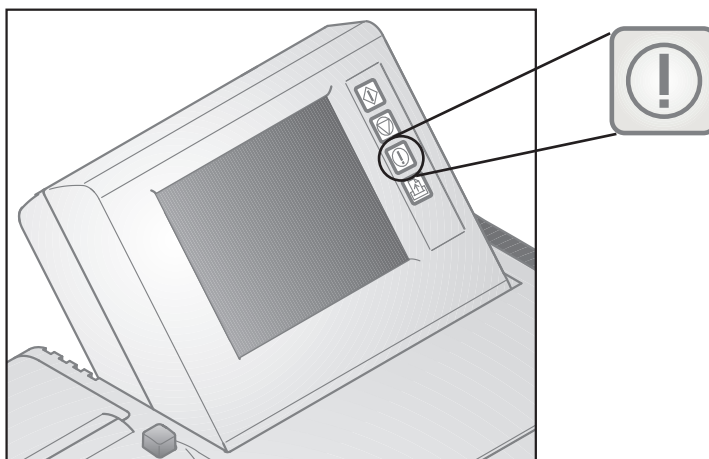
Figure D-1   Global action button Alarm

The LED lights up yellow or red depending on the severity of the alarm. Press this global action button to display the alarm monitor.

Yellow	Signalizes a warning (e.g. waste: 90 samples). The analyzer remains ready for analysis.
Red	Signalizes an error. Depending on the error, the analyzer changes the operating state to Stop. A stop error must be remedied before continuing analysis.

Alarm monitor   Pressing the global action button Alarm opens the [Alarm Monitor]. On the [Alarm
Alarm trace   Monitor] warnings and errors are recorded for the user. For additional error diagnosis warnings and errors are recorded, on the [Tools1 > Alarm Trace] screen. The [Tools1 > Alarm Trace] screen is only accessible for supervisors.

Data alarms   Data alarms are not recorded on the [Alarm Monitor] and [Tools1 > Alarm Trace] screen. Data alarms are reported together with the results.

👁 Chapter 10 *Data alarms (flags)* on page D-3

Instrument alarms   The [Alarm Monitor] only shows the number and the name of the error. A description of the error and countermeasures can be found in the following section:

- 👁 *Instrument alarm list* on page D-12

Alarm monitor

Pressing the global action button Alarm opens the [Alarm Monitor] and switches off the buzzer.

Initialization	29.10.2004	15:55
Overview	Workplace	Utilities

Alarm Monitor

250/250 29.10.2004 15:35
Error 58: Internal communication error

☑ Buzzer
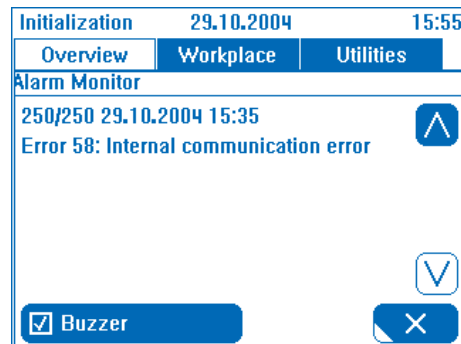
Figure D-2   [Alarm Monitor] screen

This screen displays the last alarm which has occurred. To view previous alarms, it may be necessary to display them using the ⋁ or ⋀ buttons.

The following information about an alarm are displayed:

- Number of the displayed alarm / total number of alarms
- Date and time of the occurrence of the alarm
- Severity, ID and name of the alarm

You can display the last 250 entries using the ⋁ or ⋀ buttons.

You can disable the buzzer on the alarm monitor using <Buzzer>.

The buzzer remains off until you switch the buzzer on again or after restart of the analyzer.

When you close the [Alarm Monitor] by pressing ⟨ × ⟩, the alarm is acknowledged and the LED of the global action button Alarm turns off, even if the error has not been remedied yet. The LED only signals, that an alarm has been acknowledged.

The alarm monitor displays only the most recent alarm which has occurred. To view and acknowledge other alarms it may be necessary to scroll up ⋁ or down ⋀. The LED lights up until all alarms have been acknowledged on the alarm monitor, even after restart of the analyzer.

Alarm trace

For additional error diagnosis warnings and errors are recorded in the [Tools1 > Alarm Trace] screen. The [Tools1 > Alarm Trace] screen is only accessible for supervisors.

👁 *Alarm Trace* on page A-88

Handle alarms

When an alarm has been triggered on the analyzer, the alarm is announced by the LED of the global action button and a buzzer.

► **To fix an alarm which has occurred on the analyzer**

1   Press the global action button Alarm to display the alarm monitor.

Figure D-3   [Alarm Monitor] screen

2   Read the ID and name of the alarm.

A description of the error and countermeasures can be found in the following section:

👁 *Instrument alarm list* on page D-12

3   Confirm the alarm by pressing [×]. This closes the [Alarm Monitor].

The LED of the global action button Alarm turns off, even if the error has not been remedied yet.

4   If necessary remedy the error cause as described in the instrument alarm list.

The LED lights up until all alarms have been acknowledged even after restart of the analyzer. To view and acknowledge other alarms, it may be necessary to open the [Alarm Monitor] screen again and to scroll up ☑ or down ☑.

Instrument alarm list

This list shows the alarm messages that can be acted on by the operator. If the screen shows an alarm code that is not mentioned in this list, contact your Roche Service representative.

The column checks and countermeasures shows different levels of countermeasures. Always start with the 1st level.

Alarm no.	Alarm name	Checks and countermeasures
17	Selected language not supported for the sediment terminal	1. Load alternative language using the appropriate Language Disk File LDF [Utilities > System Parameters > Language]. 2. Call the service support.
18	Sediment parameters error	1. Define sediment parameters [Utilities > Sediment Parameters]. 2. Check that the Sediment Terminal cable is properly connected to Sediment Terminal serial port at the back of the instrument. 3. Restart the system (Switch the instrument off/on). 4. Call the service support.
19	Sediment Terminal connection error	1. Check that the Sediment Terminal cable is properly connected to Sediment Terminal serial port at the back of the instrument. 2. Restart the system (Switch the instrument off/on). 3. Call the service support.
20	Sediment terminal error	1. Restart the system. (Switch the instrument off/on). 2. Check that the Sediment Terminal cable is properly connected to Sediment Terminal serial port at the back of the instrument. 3. Call service support.
21	Host connection error	1. Check correct host connection (the cable should be connected to the host serial port at the back of the instrument). 2. Restart the system (Switch the instrument off/on). 3. Check that the correct host interface protocol is selected and configured [Utilities > System Parameters > Host Comm.]. 4. Call the service support.
22	Barcode label or connection error	1. Make sure that you are using the barcode scanner recommended by Roche (other types are not supported). 2. Restart the system (Switch the instrument off/on). 3. Check that the barcode scanner is properly connected to the BC-Scanner serial port at the back of the instrument. 4. Check that the correct barcode label type is used (Codabar, Code 39, ITF (Interleaved 2 to 5), Code 128). 5. Call the service support.
23	Serial Interface connection error	1. not used
30	Electronic error	1. Restart the system (Switch the instrument off/on). 2. Call the service support.
32	Power supply error	1. Restart the system (Switch the instrument off/on). 2. Call the service support.
33	Time-out error (blockages)	1. Check that the test strip transfer set parts (tray, pusher, transporter) are properly placed. 2. Restart the system (Switch the instrument off/on). 3. Call the service support.

Table D-3   Instrument Alarm List

Roche Diagnostics

Alarm no.	Alarm name	Checks and countermeasures
34	Time-out error	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the Software. 4. Call the service support.
35	Hardware error	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the Software. 4. Call the service support.
37	HW Controller error	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the Software. 4. Call the service support.
38	HW communication error	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the Software. 4. Call the service support.
39	Strip Detection error	1. Check for light affecting Strip loading area. 2. Restart the system (Switch the instrument off/on). 3. Call the service support.
40	Low Battery	1. Call the service support.
43	Photometer electronic error	1. Restart the system (Switch the instrument off/on). 2. Call the service support.
44	Photometer initialization error	1. Check for blockages in the photometer movement. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the Software. 5. Call the service support.
46	Photometer error	1. Ensure that the test strip tray is clean. 2. Replace the reference strip with a new one. 3. Call the service support.
47	Photometer out of range	1. Ensure that the test strip tray is clean. 2. Replace the reference strip with a new one. 3. Call the service support.
50	Software error	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the software. 4. Call the service support.
51	Memory nearly full	1. Delete unnecessary data and reset sequence number. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the software. 5. Call the service support.
52	Memory full	1. Delete unnecessary data and reset sequence number. 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the software. 4. Call the service support.

Table D-3   Instrument Alarm List (continued)

Alarm no.	Alarm name	Checks and countermeasures
53	Database error	1. Save the configuration [Utilities > Tools > Data Exchange > Store Config.] on an USB stick and then reload them again [Utilities > Tools > Data Exchange > Load Config.]. 2. Reinstall the software. 3. Call the service support.
54	Host error	1. Check the correct host connection (the cable should be connected to the host serial port at the back of the instrument). 2. Restart the system (Switch the instrument off/on). 3. Check that the correct host protocol is selected and configured [Utilities > System Parameters > Host Comm.]. 4. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 5. Reinstall the software. 6. Call the service support.
55	SW error (measurement)	1. Restart the system (Switch the instrument off/on). 2. Save the configuration parameters [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the software. 4. Call the service support.
56	Control results Memory	1. Check alarm trace [Utilities > Tools > Alarm Trace] for the 5 digit message "Please delete control results of control %i!" and delete the corresponding control results. 2. Restart the system (Switch the instrument off/on). 3. Call the service support.
58	Internal communication error	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.] on an USB stick and then reload them again [Utilities > Tools > Data Exchange > Load Config.]. 3. Reinstall the software. 4. Call the service support.
59	Switch OFF and ON Fatal SW-error occurred	1. Restart the system (Switch the instrument off/on). 2. Check the printer paper. 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.] on an USB stick and then reload them again [Utilities > Tools > Data Exchange > Load Config.]. 4. Reinstall the software. 5. Call the service support.
60	SW inconsistency	1. Delete unnecessary data and reset the sequence number. 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.] on an USB stick and then reload them again [Utilities > Tools > Data Exchange > Load Config.]. 3. Reinstall the software. 4. Call the service support.
61	Printer power failure	1. Restart the system (Switch the instrument off/on). 2. Call the service support.
62	Printer error	1. Print mode is off [Overview > Print Mode]. 2. Printer out of paper. 3. Printer head open. 4. Restart the system (Switch the instrument off/on). 5. Call the service support.
63	Error accessing USB stick	1. Ensure that a USB stick is properly plugged in. 2. Reconnect the USB stick and try again. 3. Restart the system (Switch the instrument off/on). 4. Try with another USB stick. 5. Call the service support.

Table D-3   Instrument Alarm List (continued)

Roche Diagnostics

Alarm no.	Alarm name	Checks and countermeasures
65	Sediment terminal SW error	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.] on an USB stick and then reload them again [Utilities > Tools > Data Exchange > Load Config.]. 3. Call the service support.
67	SW language file error	1. Reinstall the language using the appropriate Language Disk File LDF [Utilities > System Parameters > Language]. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the software. 5. Call the service support.
69	Waste almost full	1. Empty the waste container. 2. Call the service support.
70	The waste is full. No new strips can be processed.	1. Empty the waste container. 2. Call the service support.
72	Display unit ventilator failure	1. Restart the system (Switch the instrument off/on). 2. Call the service support.
73	Instrument overheating	1. Switch the system off to cool down. 2. Check the ambient temperature (15-32° C). 3. Restart the system (Switch the instrument off/on). 4. Call the service support.
75	Front cover open	1. Information only
76	Front cover closed	1. Information only
77	Test Strip Tray inserted	1. Information only
78	Test Strip Tray removed	1. Information only
79	Invalid system status	1. Restart the system (Switch the instrument off/on). 2. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 3. Reinstall the software.
80	Invalid barcode received	1. Check correct barcode lengths (max.13 digits). 2. Check that the correct barcode label type is used (Codabar, Code 39, ITF (Interleaved 2 of 5), Code 128). 3. Restart the system (Switch the instrument off/on). 4. Call the service support.
82	SW could not identify sample type	1. Repeat the sample measurement. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the software. 5. Call the service support.
83	Sample measurement interrupted	1. Sequence number will be automatically reset. 2. Repeat the sample measurement. 3. Restart the system (Switch the instrument off/on). 4. Call service support.

Table D-3   Instrument Alarm List (continued)

Alarm no.	Alarm name	Checks and countermeasures
84	Control measurement interrupted	1. Repeat the control measurement. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the software. 5. Call the service support.
85	Control and sample measurement interrupted	1. Sequence number will be automatically reset. 2. Repeat the sample and control measurement. 3. Restart the system (Switch the instrument off/on). 4. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 5. Reinstall the software. 6. Call the service support.
86	Calibration measurement interrupted	1. Repeat the calibration. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the software. 5. Call the service support.
87	Calibration strip exceeded tolerance	1. Ensure that the test strip tray is clean. 2. Repeat the calibrating using new calibration strips. 3. Replace the reference strip with a new one and repeat the calibration. 4. Call the service support.
88	Error during instrument calibration.	1. Repeat the calibration. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the software. 5. Call the service support.
89	No instrument calibration available	1. Calibrate the instrument [Utilities > Tools > Calibration]. 2. Call the service support.
90	Calibration period exceeded	1. Calibrate the instrument [Utilities > Tools > Calibration]. 2. Call the service support.
91	Reference strip measurement error	1. Ensure that the reference strip is correctly placed. 2. Replace the reference strip with a new one. 3. Restart the system (Switch the instrument off/on). 4. Call the service support.
92	Test strip measurement error	1. Ensure that the usage of the correct test strip type. 2. Restart the system (Switch the instrument off/on). 3. Call the service support.
93	Test strip and reference strip measurement error	1. Ensure that the usage of the correct test strip type. 2. Ensure that the reference strip is correctly placed. 3. Replace the reference strip with a new one. 4. Restart the system (Switch the instrument off/on). 5. Call the service support.
95	Measurement inconsistency	1. Confirm correct work list sequence and Retry. 2. Restart the system (Switch the instrument off/on). 3. Save the configuration [Utilities > Tools > Data Exchange > Store Config.]. 4. Reinstall the software. 5. Call the service support.

Table D-3   Instrument Alarm List (continued)

Alarm no.	Alarm name	Checks and countermeasures
99	Software information logged	1. Information only
107	Error during database access. Database was replaced by a new (blank) one.	1. Save the logfile (Utilities > Tools > Logfile) and contact the service support.
108	Loaded Data Exchange file not fully compatible with SW version. User and sediment data converted accordingly. All other configuration data unchanged.	1. Information only: The configuration file is not fully compatible with the current software version. The user and sediment data are loaded successfully, the rest of the configuration data are not loaded.

Table D-3   Instrument Alarm List (continued)

In case of a defective test strip sensor 2 (behind the test strip transporter) no alarm message is generated. A defective test strip sensor 2 can be recognized as follows:

- *When the test strips are transported but no results are obtained (processed strips are transported to the waste without measurements).*

- *The sample sequence number is not changing.*

Glossary and Index   **E**

Glossary

A

Analyte see Urine analyte.

Analyzer The **cobas u** 411 analyzer.

Arbitrary units Result classification using 1+, 2+, 3+ classes instead of numerical concentration results.

ASTM protocol Interface protocol according to the American Society for Testing Materials standard.

B

Backup The storing of data onto storage media, such as USB sticks, other than that of the main storage. If this data is required again, it can be restored from the backup copy.

Barcode A numeric or alphanumeric code used on sample tubes and racks for sample and rack identification.

Barcode type The **cobas u** 411 analyzer can read different sample barcode types: Code39, Codabar, ITF, and Code 128.

C

Calibration To adjust the reflectance photometer to a gray standard (calibration strip) with known reflectance values.

Calibration strip Gray plastic strip used for calibrating the photometer of the **cobas u** 411 analyzer.

Clarity (CLA) Clarity is the optical appearance of the sample. The clarity can be entered manually.

Codabar A barcode type for sample tubes that can be read by the barcode scanner.

Code39 A barcode type for sample tubes that can be read by the barcode scanner.

Color (COL) Feature of urine samples determined by measurement of the compensation pad on the test strips.

Color development Color change that occurs on the test pads of the test strip as a result of a chemical reaction with the urine analyte.

Compensation pad A blank pad on the test strip used for the determination of the urine color and for the prevention of false positives when a urine sample is strongly colored.

D

Data flags Symbols that indicate values outside a specified range or an abnormality in sample or test strip processing.

E

Expiry date The date after which test strips must not be used for analysis.

H

Host computer A central computer that communicates with the **cobas u** 411 analyzer receiving sample results, control results from the analyzer and downloading a work list to the analyzer.

Host connection The connection (via a RS 232 interface) between the analyzer and the host computer. The operator can either activate or deactivate this connection, as required.

I

ITF A barcode type for sample tubes that can be read by the barcode scanner.

L

Light–emitting diode (LED) A semiconductor that emits light of a defined wavelength.

M

Maintenance procedures Procedures that must be performed on a regular basis for example daily or monthly to secure reliable operation of the analyzer.

Menu Part of the user interface that allows to select screens or functions. Menu are also called tab.

Message (alarm) Information on the touch screen of sample or test strip errors, or reasons for the analyzer stopping.

O

Operation state The analyzer processes samples in this state. Additional samples can be loaded and measured without an intermediate stop of the analyzer.

P

Parameters System and analysis configurations that can be set individually (and stored) according to customer requirements if they deviate from the default factory settings.

Parameter-specific reflectance values
Reflectance ranges stored in the analyzer that are used to convert the reflectance values of each test pad into semi-quantitative concentration results.

Password-protection The password protection provides an access restriction for certain functions that should be executed by supervisors or service personnel only.

Photodiode detector A photometer component that receives the reflected light.

Photometer An optical device (measuring head) that measures the intensity of reflected light of each test pad.

Print mode Software function in the [Overview] screen to select the category of results (all, abnormal, sieve, sieve & abnormal) to be printed in real time.

Q

Qualitative determination The measurement of analytes or features with descriptive (qualitative) result classifications such as negative/positive, clear/turbid, or yellow, amber and so on.

R

Range table Table that assigns reflectance values (obtained from test strip pads) to concentrations or qualitative results.

Reference strip Internal gray plastic strip that is measured first and used as a reference for the reflectance measurements of the test strip pads.

Reflectance value Portion of reflected light, calculated by the microprocessor and expressed as a percentage.

Reflected light intensity The amount of light that is reflected from the test pad and measured by the photodiode detector.

S

Semi-quantitative determination Measurement of analytes or features with numerical result classifications.

Sequence number Consecutive number assigned to each sample and that is increased automatically with each measurement.

Specific gravity The ratio of the density of urine to the density of water.

Stand-by state The non-operational state, that the analyzer must always be in for the processing of data, inputting of criteria, or the setting of parameters.

System parameters Analyzer settings that can be selected by the operator such as host communication parameters, and others.

T

Tab Part of the user interface that allows to select screens. Tab are also called menu.

Test parameters 1. Software menu for the definition of parameters related to sample analysis and result reporting. 2. Parameters of the test strip itself, such as glucose, protein, etc.

Test strip Chemical reagent strip containing 10 or 11 individual test pads that are used to test for different analytes or features of urine or control samples.

Touch screen An interactive screen designed to make navigation through the menus and input of data and settings consistent and convenient. Also known as user interface screen.

U

Urinalysis system A system consisting of an analyzer and reagents (test strips), designed for the chemical analysis of urine samples.

Urine analytes The constituents in the urine sample whose concentrations are to be determined.

User interface screen See Touch screen.

W

Waste area An area of the test strip tray in which used test strips are deposited.

OS-02597-01

Index

A

B

C

T

U

V

Version (of system components), A-96

W

Warning label, A-5
Warranty, 3
Waste
– display of test strips processed, A-49
– emptying the test strip waste area, C-6
Wavelengths, A-18
White balance, A-19
Work list
– analyzing samples from a work list, B-37
– enter samples manually into the work list, B-37
– work list screen, A-53
Workplace
– control list screen, A-62
– menu structure, A-46
– run control screen, A-61
– sample entry screen, A-51
– sample list screen, A-56
– sample results screen, A-54
– work list screen, A-53
– workplace tab, A-50

Revisions   F