cobas b 101 system

Version 1.0

Operator's Manual (Canada)

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Document information

Revision history

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Edition notice

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Symbols

On the packaging and on the identification plate of the instrument you may encounter the following symbols, shown here with their meaning:

Symbol	Used for
	Caution, consult accompanying documents. Refer to safety-related notes in the instructions for use accompanying this product.
	Consult instructions for use
	Temperature limitation (Store at)
	Humidity limitation (Store at)
	Power supply connection
	Use by
	Manufacturer
	Batch code / Lot number
REF	Catalog number
	In vitro diagnostic medical device
	This product fulfills the requirements of the European Directives 98/79/EC on in vitro diagnostic medical devices
	The system fulfills the Canadian and U.S. safety requirements (UL LISTED, in accordance with UL 61010A-1:02 and CAN/CSA-C22.2 No.61010-1-04)

Table 1 Symbols on the packaging and on the identification plate of the instrument

Screen content

All depictions of screen content are for illustration purposes only, and the content does not necessarily represent realistic values.

Abbreviations The following abbreviations are used:

Abbreviation	Meaning
BUH	Base Unit Hub
CHOL	Total cholesterol
DMS	Data management system
eAG	Estimated average glucose
ff	And the following
Hb	Hemoglobin
HbA1c	Glycosylated hemoglobin type A1c
HDL	High density lipoprotein
IFCC	International Federation of Clinical Chemistry
LAN	Local area network
LDL	Low density lipoprotein
NGSP	National Glycohemoglobin Standardization Program
QC	Quality control
STAT	Short turn around test
TG	Triglyceride

Table 2 Abbreviations used in this documentation

Table of contents

1 Introduction

1.1 Before you start

1.1.1 Intended use

The **cobas b** 101 system is intended for professional use in a clinical laboratory setting or point-of-care (PoC) locations.

1.1.2 Important information regarding use

Read this operator's manual, as well as the package inserts for all relevant consumables, before using the instrument for the first test.

You must configure the **cobas b** 101 system according to your needs *before* initial use. You can configure the instrument either directly or by using a suitable data management system. Refer to *Setting up the instrument* on page 31.

Be sure to read the *Safety Information* on page 14 ff before operating the instrument.

1.1.3 If you need help

Information about using the instrument, the screen menus, and on performing tests can be found in this operator's manual.

Error messages that appear on-screen include information or instructions on how to correct the error.

For all questions about the **cobas b** 101 system that are not answered in this manual, contact your Roche representative (see *Contact information for Roche* on page 172). In order to expedite troubleshooting, please have ready your instrument, its serial number, this manual, and all related consumables when you call. If you suspect a communication error beyond the instrument, also have your Base Unit Hub serial number ready to help assist our customer care group in troubleshooting.

1.1.4 What can the instrument do for you?

The **cobas b** 101 system has the following functions and properties:

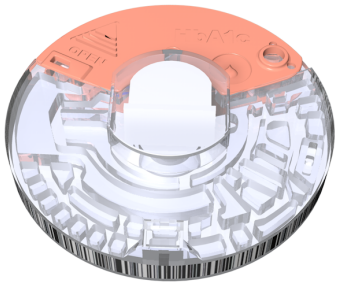
- Perform patient tests for HbA1c, Lipid Panel, and control tests using QC solutions for HbA1c and Lipid Panel.
- Automatically record all relevant data for the tests, including:
  - Time and date of test
  - IDs for operators and patients
  - Information about QC solutions, optical check disc, and tests
  - Test results and comments
- For purposes of quality assurance, information on the following areas can be collected, stored, and transferred:
  - Instrument
  - Test discs
  - QC solutions
  - Optical check disc
  - Test results

1.1.5 Test principles

All auxiliary materials such as diluents and enzymes that are required to perform the tests are contained in the test discs.

The following sections explain the main steps required for the two test types HbA1c and the Lipid Panel.

HbA1c



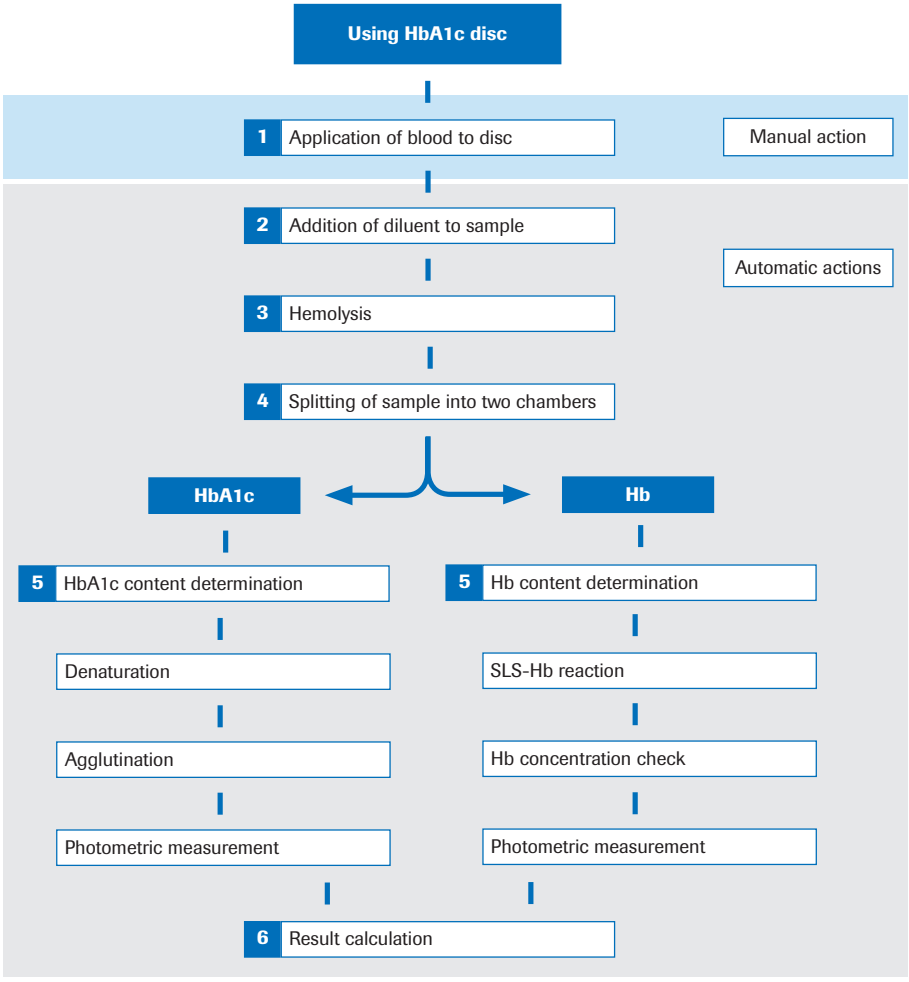


Figure 1 HbA1c test principles

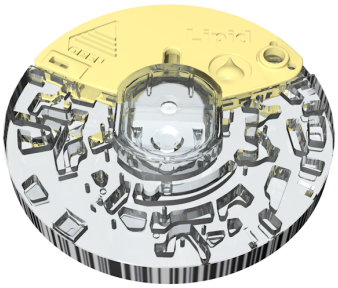
The blood sample is diluted and mixed with TRIS buffer to release hemoglobin from the erythrocytes. The hemoglobin precipitates. A fraction of the sample is conveyed into a reaction chamber where it is mixed with sodium lauryl sulfate (SLS). SLS is used to oxidize the hemoglobin forming the complex, sodium lauryl sulfate, chromophore. Since the extent of color development at 525 nm is proportional to the concentration of total hemoglobin in the sample, this can be determined from the transmissivity of the sample. The other fraction of the diluted hemoglobin is denaturated in a first step. An agglutinator (synthetic protein containing multiple copies of the immunoreactive portion of HbA1c) causes agglutination of latex coated with HbA1c specific monoclonal antibodies. This agglutination reaction causes increased scattering of light, which is measured as an increase in absorbance at 531 nm. HbA1c in whole blood specimens competes for the limited number of antibody-latex binding sites causing an inhibition of agglutination and a decreased scattering of light. The decreased scattering is measured as a decrease in absorbance at 625 nm.

The HbA1c concentration is then quantified using a calibration curve of transmissivity versus HbA1c concentration.

The percent HbA1c in the sample is then calculated as follows:

$$\%\text{HbA1c} = \frac{\text{HbA1c}}{\text{total Hemoglobin}} \times 100$$

Lipid Panel



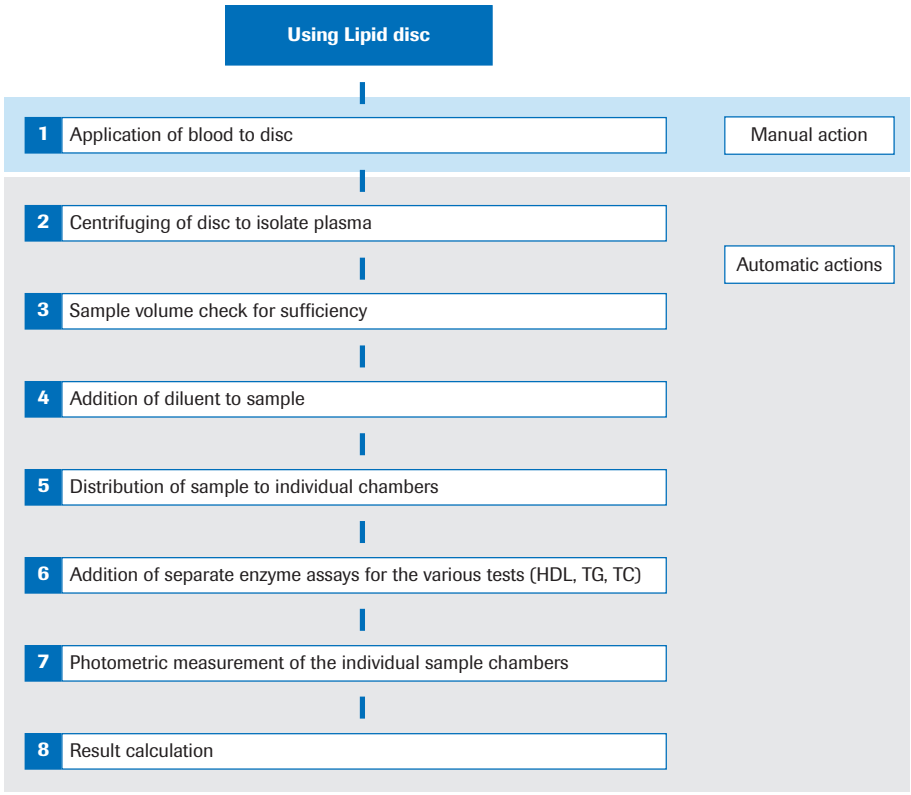


Figure 2 Lipid test principles

After application of the blood sample to the disc and closing the hinge cover, an onboard dilution container is pierced releasing phosphate buffered saline into a mixing chamber. The erythrocytes of the capillary or venous blood sample are separated from the plasma by centrifugation. In the next step, the buffer is mixed with the plasma sample and transferred through fluidic channels to the reaction chambers. The **cobas b** 101 system determines total cholesterol and HDL-cholesterol by an enzymatic method.

The triglycerides test is an enzymatic end-point method that makes use of different enzymes.

Where the concentration of triglycerides is < 400 mg/dL, the low density lipoprotein (LDL) is calculated using the Friedewald formula:

$$\text{LDL} = \text{CHOL} - \text{HDL} - \frac{\text{TG}}{5} \quad \text{(measured in mg/dL).}$$

Where the concentration of triglycerides is ≥ 400 mg/dL, the LDL-cholesterol is not calculated.

1.2 Safety classification

This section explains how precautionary information is presented in this manual.

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

The safety alert symbol by itself (without a signal word) is used to promote awareness to hazards which are generic or to direct the reader to related safety information.

These symbols and signal words are used for specific hazards:

WARNING

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

CAUTION

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

Indicates a hazardous situation which, if not avoided, may result in damage to the instrument.

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

Indicates additional information on correct use or useful tips.

1.3 Safety Information

Operator qualification

Only healthcare professionals may operate the **cobas b** 101 system.

WARNING

Protection against infection

There is a potential risk of infection. Operators of the **cobas b** 101 system must be aware that any object coming into contact with human blood is a potential source of infection.

- Use gloves.
- Use single-use only disposable blood lancets.
- Dispose of used lancets in a sturdy sharps container with lid.
- Dispose of used test discs according to your facility's infection control policy.
- Follow all health and safety regulations in force locally.

CAUTION

Protection against injury

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

- Only use the instrument in the manner specified by the manufacturer.

NOTICE

Malfunction of instrument and incorrect results due to interfering electromagnetic fields

Strong electromagnetic fields may interfere with the proper function of the instrument.

- Do not use this device in close proximity to sources of strong electromagnetic irradiation (e.g. unshielded intentional RF sources).

1.3.1 Instrument approvals

This equipment complies with the emission and immunity requirements described in IEC 61326-2-6.

- The electromagnetic environment should be evaluated prior to operation of the device.
- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

Class B FCC rule compliance: This equipment has been tested and found to comply with the limits for Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interferences when the equipment is operated in a residential area. However, this equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the present manual, may cause harmful interference to radio communications.

1.3.2 Disposal of the instrument

WARNING

Infection by a potentially biohazardous instrument

The **cobas b** 101 system or its components must be treated as potentially biohazardous waste. Decontamination (i.e., a combination of processes including cleaning, disinfection and/or sterilization) is required before reuse, recycling, or disposal.

- Dispose of the instrument or its components according to the appropriate local regulations.

1.3.3 General care

NOTICE

Malfunction and instrument failure due to improper handling

Using unsuitable solutions may result in incorrect operation and possible instrument failure.

- Clean the instrument only with recommended solutions.
- Do not let cleaning solution enter the instrument.
- Make sure that the items are thoroughly dried after cleaning or disinfecting.
- Do not perform any maintenance actions or repairs other than those described in this manual.

1.3.4 Touch screen

NOTICE

Impaired usability of screen due to improper use

Using pointed or sharp-edged objects can damage the touch screen.

Direct sunlight may reduce the life expectancy and functionality of the display.

- Use only your finger (even when wearing gloves) or special pens designed for use with touch screens to touch the screen elements.
- Avoid prolonged exposure to direct sunlight.

1.3.5 Operating conditions

To ensure that the instrument functions properly, please observe the following guidelines:

- Only use the instrument at an ambient temperature between +15 °C and +32 °C (59 °F and 90 °F).
- Only use the instrument at a relative humidity between 10% and 85%, non-condensing.
- Only use a voltage of 100 V to 240 V AC (+/-10%), 50/60 Hz.
- When performing tests, place the instrument on a level (within 3 degrees), vibration-free surface.
- Only use the instrument in appropriate light conditions:
  - Below 20 kLux. (Do not expose the instrument to bright light such as sunlight or spotlight.)
  - Sufficiently bright to see clearly what you are doing, for example when applying blood.

1.3.6 Quality control

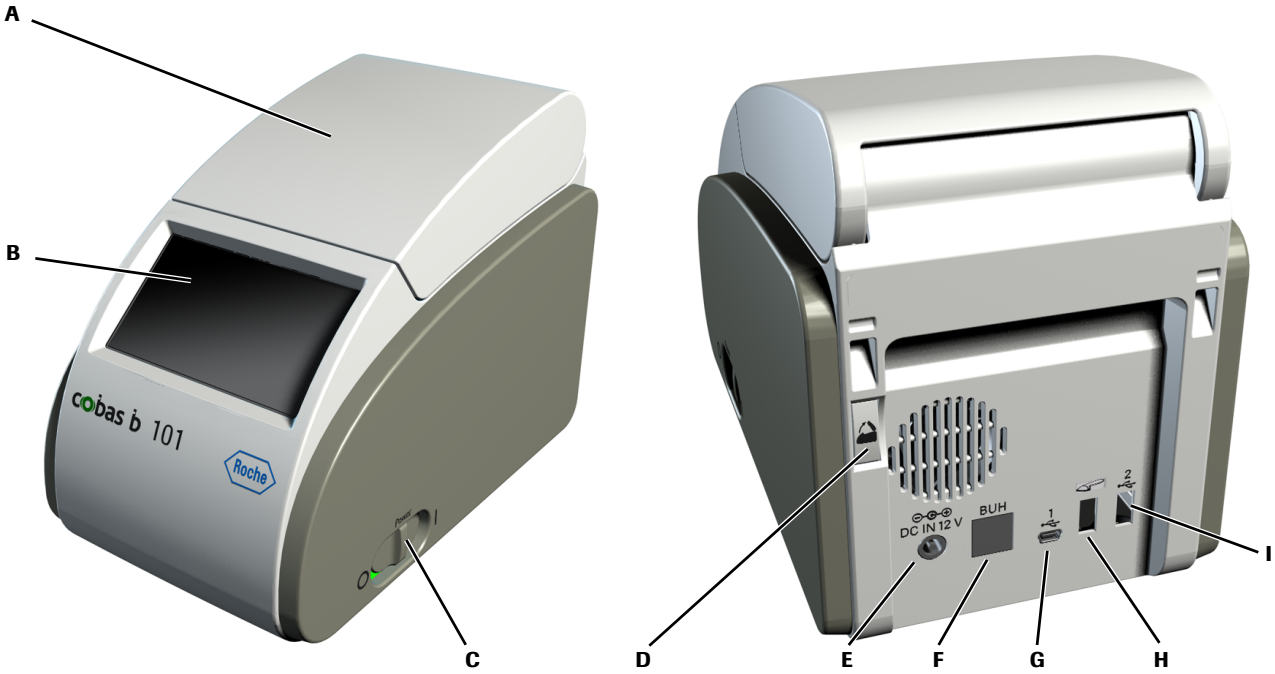
The instrument has the following built-in quality control functions:

- A self-test of the electronic and mechanical components and functions is performed every time the instrument is powered on.
- The test disc temperature is checked while a test is in progress.
- The expiry date and lot information of the test disc are checked.

Roche offers liquid controls and an optical check as well as the option for proficiency testing. These controls are provided to assist with meeting locally applicable regulatory compliance requirements.

2 The cobas b 101 system

2.1 Overview of the instrument elements



A Lid. Use the **Open** button on the screen e.g. to insert a test disc for measurement. Keep this lid closed during measurement.

B Touch screen. Shows buttons, icons, information, and test results.
To use a function, tap the button on the screen lightly.

C Power on/off switch.

D Lid button. Use this button to open the lid when the instrument is switched off.

E DC IN 12 V terminal. Connect the power cable from the power adapter to supply 12 V DC power to the instrument.

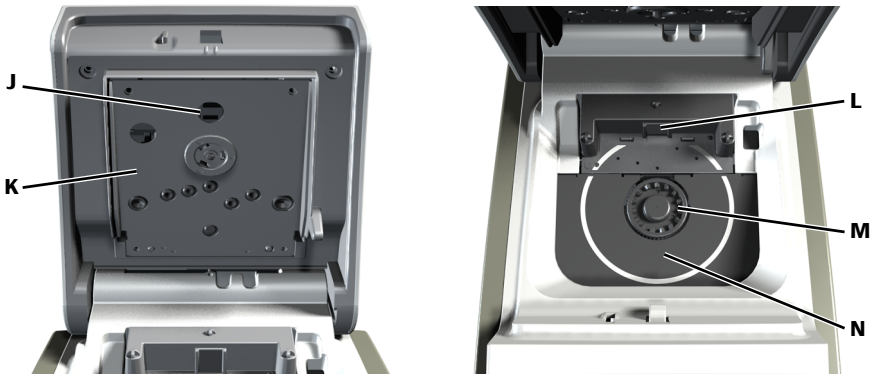
F BUH terminal. Connection to a network through a Base Unit Hub.

G USB 1 terminal. Connection to a personal computer.

H Barcode scanner terminal.

I USB 2 terminal. Connection to USB memory stick or a printer.

Figure 3 Main hardware elements of the instrument



J Temperature sensor

K Upper heater

L Barcode sensor

M Turntable. Holds and rotates the disc during processing.

N Lower heater

Figure 4 Main hardware elements inside the instrument

CAUTION

Injury to skin due to prolonged exposure to heated surface

Exposing skin to the heat of the upper heater (K) and lower (N) heater for a long period of time may cause low-temperature burns.

- Do not expose the skin to the upper heater (K) or lower heater (N) for a long period of time when the power is turned on.

NOTICE

Damage to the instrument by incorrect power supply

Only use the power supply equipment delivered with the instrument.

See *General product specifications* on page 167.

- In areas with weak or unstable power supply, Roche recommends the use of an uninterruptible power supply unit.

NOTICE

Damage to the instrument by inappropriate handling

- Do not forcefully open the lid. Choose **Open** on the screen when the instrument is switched on, use the button at the back of the instrument when it is switched off. If the lid cannot be opened using **Open**, e.g. because the disc was not inserted correctly, switch off the instrument and press firmly the button at the back of the instrument.
- Do not move or lift the instrument by its lid.
- Do not forcefully push the lid in its open position.
- Do not forcefully close the lid.
- Do not place objects on top of the instrument.

NOTICE

Malfunction due to using multiport USB hub

- Do not use a multiport hub.

NOTICE

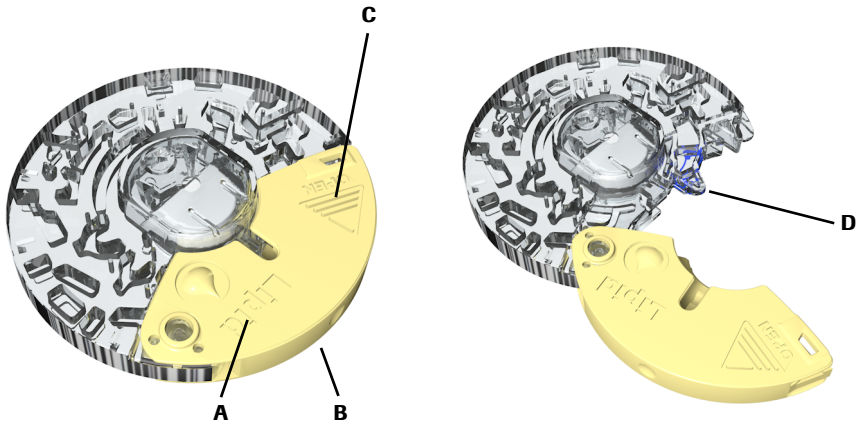
Malfunction due to connecting unsuitable devices

- Do not connect unsuitable devices such as phones to the RS422 (BUH) terminal.
- Make sure to connect the devices to the appropriate connectors.

NOTICE

Damage to the instrument by short circuiting

- Make sure no foreign substances such as liquids reach the sockets and plugs.



A Test type indication
B Use the underside of the hinge cover for writing information, e.g. the patient ID
C Open the disc on this side
D Suction point (at the underside of the disc)

Figure 5 Test disc, example for lipid test panel

- There are various optical surfaces on the disc. Therefore, when handling a disc make sure to hold it by its hinge cover and side only, do not touch the transparent surfaces.
- When writing on the disc, e.g. the patient name, make sure only to use the dedicated area. Do not affix labels to the disc.
- The imprinted side must face up when inserting the disc.

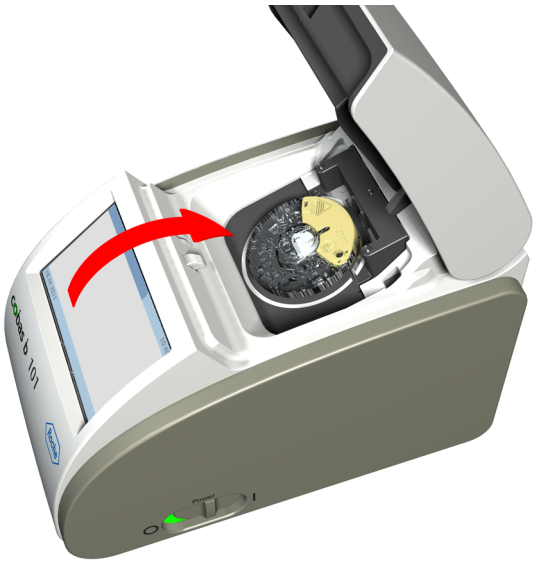


Figure 6 Inserting a test disc

For details on using test discs, see *Preparing a disc* on page 109.

2.2 Buttons and icons overview

The buttons and icons that are displayed during normal operation are shown here, along with their respective meanings.

Button/Icon	Meaning
	OK. Save setting.
	Cancel. Discard setting.
	Return (to previous menu).
	Delete last character in data entry box.
	Reduce/increase the value displayed. Move screen contents.
	**Patient Test** menu.
	**Control Test** menu.
	**Review Results** menu.
	**Setup** menu.
	Log off.
	Go to **Main Menu**.
	Print results.
	List the results for a specific patient.
	Enter patient information.
	Enter a comment.
	Edit patient information.
	Enter information using the barcode scanner.
	Enter information using the keyboard.

Table 1 Buttons and icons used on-screen

Button/Icon	Meaning
	Add an item to the list.
	Delete the selected list item.
	Edit the selected list item.
	Move the selected list item up.
	Move the selected list item down.
[Hi]	The result in the chosen measuring unit is above the accepted range.
[Lo]	The result in the chosen measuring unit is below the accepted range.
	The result in the chosen measuring unit is above the user specified range.
	The result in the chosen measuring unit is below the user specified range.
NGSP	The HbA1c results were calculated using the NGSP reference method.
IFCC	The HbA1c results were calculated using the IFCC reference method.
	There is a comment for this result.
	The instrument is connected to a printer.
	The instrument is connected to a scanner.
	The instrument is connected to a USB stick.
	The instrument is connected to an external computer.
	Wait until the action is complete.

Table 1 Buttons and icons used on-screen (Continued)

2.3 Icons on information screens

Button/Icon	Category	Meaning
	Notice	Notification for information purposes only. Operation may proceed after confirming the notification.
	Decision	Notification as a decision point. A choice is provided as to how to proceed.
	Mandatory	Notification of mandatory steps. If you accept, the mentioned actions must be performed.

Table 2 Icons used on information screens

2.4 Icons on error messages

Button/Icon	Category	Meaning
	Error	• Hardware problem codes. Operation has stopped. • Software problem codes. Operation has stopped.
	Warning	Application problem codes. The operator may need to repeat the test with a new panel.
	Information	User handling codes. Suggests an alternate workflow. Operation can continue.

Table 3 Severity icons used on error message screens

Button/Icon	Subject the message is related to
	Space for patient data, administrator data, operator data, event records
	Test result space
	QC result space
	Temperature
	Control lot expiry
	Disc lot expiry
	Operator or patient information
	Measurement (range, failure)

Table 4 Subject icons used on error message screens

Button/Icon	Subject the message is related to
DD:MM:YY	Date
	Disc status
	Disc error
	Disc presence
	Printer connection
	USB stick connection
	Scanner connection
	Tilted instrument
	Shock to instrument

Table 4 Subject icons used on error message screens (Continued)

2.5 Symbols on the instrument case

Button/Icon	Meaning
DC IN 12V	DC IN 12 V terminal
BUH	Base Unit Hub terminal
	USB 1 terminal. Connection to a personal computer
	USB 2 terminal. Connection to USB memory stick or a printer
	Barcode scanner terminal

Table 5 Symbols on the instrument case

3 Putting the instrument into operation

3.1 Installation

3.1.1 Unpacking the instrument

Please keep the shipping box for reuse if you plan to transport the instrument and supplies to other sites.

► To unpack the instrument

1 Open the box using a pair of scissors or a knife to cut the tape.

Be careful not to damage the contents when using a cutting instrument.

2 Remove and unpack all the items.

3 Check the delivered items against the following list.

- ☐ **cobas b** 101 system
- ☐ Power adapter
- ☐ Power cable
- ☐ Optical check disc

4 Check the items for damage.

5 If items are missing or damaged, report the missing and damaged items to your local supplier.

■

Consumables are not supplied with the instrument.

See *Materials supplied by Roche* on page 169.

3.1.2 Placing the instrument

► To place the instrument

1 Observe the required ambient conditions.

See *General product specifications* on page 167.

2 Place the instrument on a level (maximum 3 degrees incline), stable surface (table).

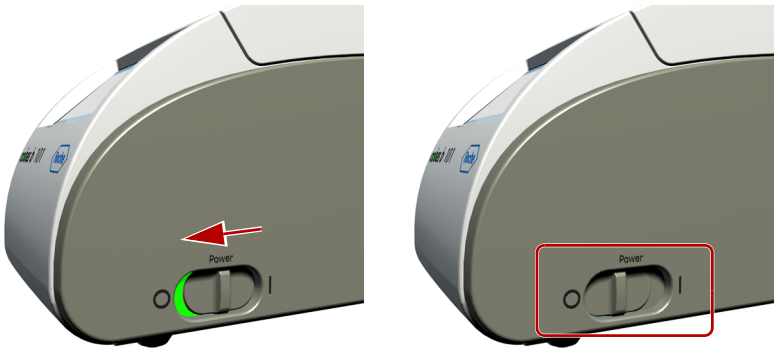
3 Make sure there is sufficient space around the instrument so that the ventilation openings at the front and back are not obstructed and that there is sufficient space for connecting devices such as a USB stick to the back of the instrument.

■

3.1.3 Power supply

► **To connect the instrument to the mains power**

1 Make sure the instrument is switched off.



When the power switch is in off position, the green background color of the power switch is not visible.

2 Connect the adapter cable to the **DC IN 12 V** terminal on the instrument.

3 Connect the power cables to the adapter and to the mains supply.

■

NOTICE

Damage to the instrument by incorrect power supply

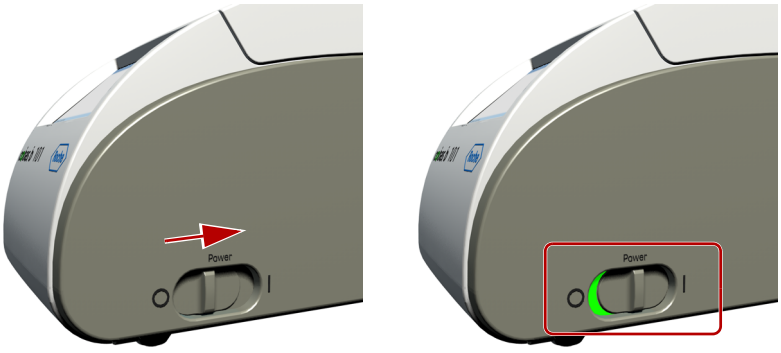
Only use the power supply equipment delivered with the instrument.

See *General product specifications* on page 167.

3.1.4 Starting the instrument

► **To start the instrument for the first time**

1 Switch on the instrument.



When the self-tests and warm-up have successfully been completed, the **Touch Screen Calibration** screen is displayed.

If at the moment you are not sure about the following settings just accept the default values, you can change them later.

2 Perform the touch screen calibration. Follow the instructions on screen.

For details see *Calibrating the touch screen* on page 91.

When you have confirmed the settings, the **Language** screen is displayed.

3 Define which language you want to work in.

For details see *Choosing the language* on page 88.

When you have confirmed the settings, the **Date Format** screen is displayed.

4 Define how you want the date to be displayed on screen.

For details see *Setting the date* on page 88.

When you have confirmed the settings, the **Date** screen is displayed.

5 Define the current date.

For details see *Setting the date* on page 88.

When you have confirmed the settings, the **Time Format** screen is displayed.

6 Define how you want the time to be displayed on screen.

For details see *Setting the time* on page 89.

When you have confirmed the settings, the **Time** screen is displayed.

7 Define the current time.

For details see *Setting the time* on page 89.

When you have confirmed the settings, the **HbA1c** screen is displayed.

8 Define which units should be used for **HbA1c** results.

For details see *Result Units* on page 44.

When you have confirmed the settings, the **eAG** screen is displayed.

9 Define which units should be used for eAG reporting.

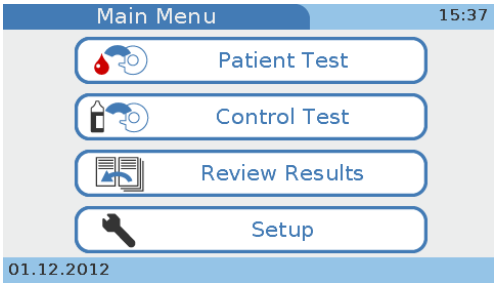
For details see *Result Units* on page 44.

When you have confirmed the settings, the **Lipid** screen is displayed.

10 Define which units should be used for **Lipid** results.

For details see *Result Units* on page 44.

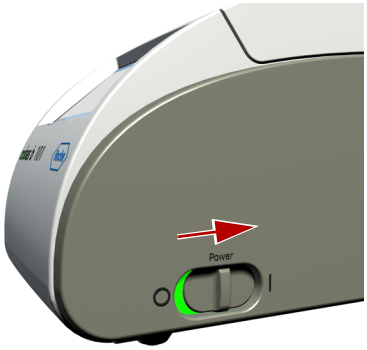
After 3 -5 minutes, the **Main Menu** is displayed.



■

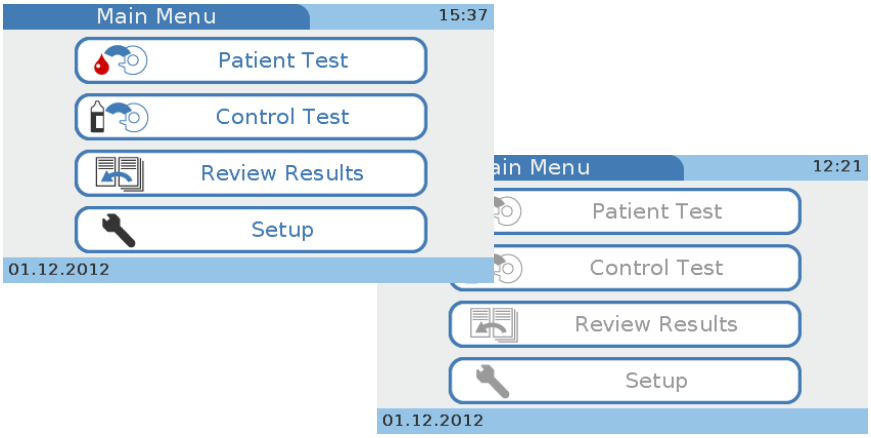
► To start the instrument for routine testing

1 Switch on the instrument.



Several screens are displayed, informing you of the startup actions that are being performed.

When the self-tests and warm-up have successfully been completed, the **Main Menu** is displayed.



Depending on whether you work with operator information, functions may not be available and you may have to log on first.

For information on on-screen messages, see *Error messages* on page 159.

■

3.1.5 Switching off the instrument

CAUTION

Loss of sample due to inappropriate switching off

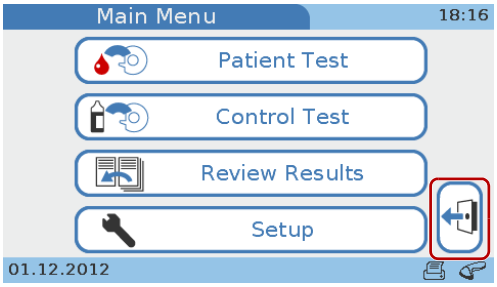
Switching off the instrument results in immediate processing stop and you need to repeat the test that was being processed when you switched off the instrument, requiring new sample and disc.

- Do not switch off the instrument while it is processing.

► To switch off the instrument

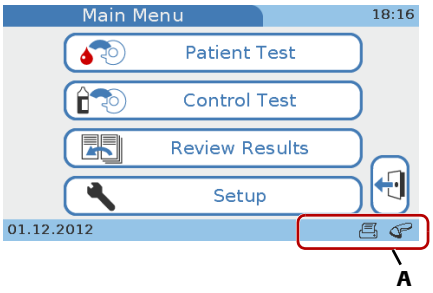
1 Make sure the instrument is not processing.

2 If you logged on at the beginning of the session, choose to log off.

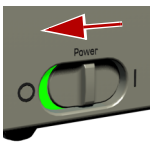


You can define automatic logoff after a certain period of inactivity. See *To define that automatic logoff should be used* on page 60.

It is safe to switch off when the **Main Menu** is displayed and there are no flashing status icons (A), when the screen-saver screen is displayed, and when you are asked on screen to switch off.



3 Switch off the instrument using the power switch.



■

4 Setting up the instrument

Presentation of screen elements in this manual

- Buttons are screen prompts that cause something to happen when chosen. The names of buttons are either **highlighted like this** or the button icon is shown (for example ✔ for OK).
- Names of screens, tabs, and parts of screens, and headings of tables and lists are shown **highlighted like this**.
- Values you need to choose or enter are *highlighted like this*.

Using buttons

- The term *choose* means that you should lightly tap the screen where for example a button is displayed.
- In some instances, for example when changing a value using ↓, keeping your finger on the button results in repeated change of the value.

For information on the meaning of the button symbols and the associated functions, see *Table 1* on page 20.

4.1 Using setup screens

All setup screens have the same basic structure and use the same buttons.

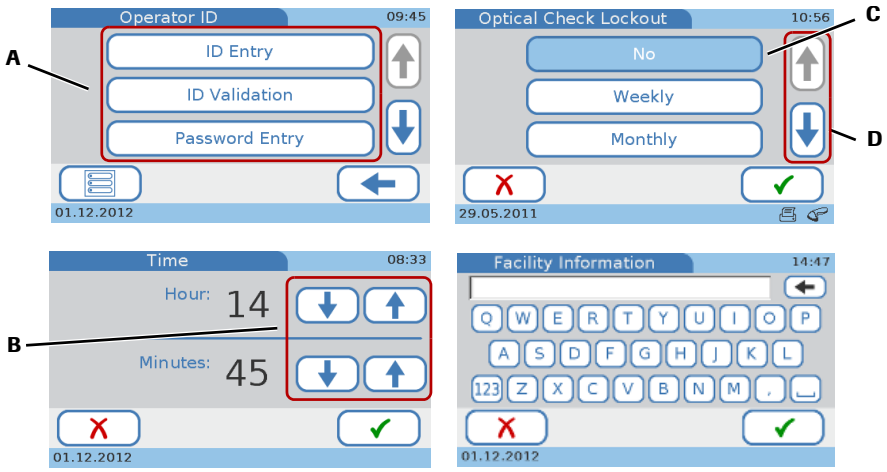


Figure 7 Typical setup screens

The available choices are represented by buttons (A), whose text describes the underlying function.

Selected choices are displayed blue (C). Choose a button to either select it or make it inactive.

Buttons with blue edge and gray content indicate choices or functions that are not available because a condition is not met that requires user input, for example an ID must be supplied.

Buttons in gray indicate choices or functions that are not available due to the current instrument setup.

Use this button to display the options that are not visible at the moment (D). This function is available if there are more list items (choices) further up in the list.

Use this button also to increase a value (B).

Use this button to display the options that are not visible at the moment (D). This function is available if there are more list items (choices) further down in the list.

Use this button also to decrease a value (B).

Use this button to display the screen that was previously displayed.

Use this button to return to the **Main Menu**.

Use this button to cancel the changes and definitions you have just made and close the screen without saving them.

Use this button to save the changes and definitions you have just made and close the screen.

Use this button to delete the last character in a data entry box.

4.1.1 Using the virtual keyboard

Use the virtual keyboard to enter text.

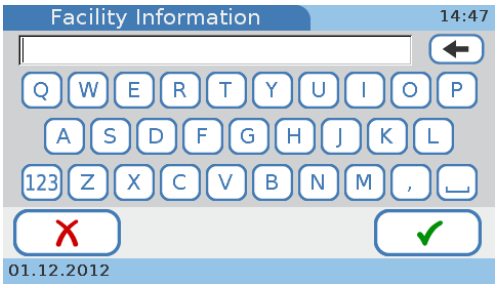


Figure 8 Using the virtual keyboard

Use ← to delete the current text.

Use 123 to display the numeric keyboard and ABC to display the alphabetic keyboard.

Choose ✓ to save the text.

Choose ✗ to cancel the entries you have just made and close the screen without saving them.

Choose ␣ to insert a space between characters.

4.2 Settings summary

☞ **Main Menu** > **Setup**

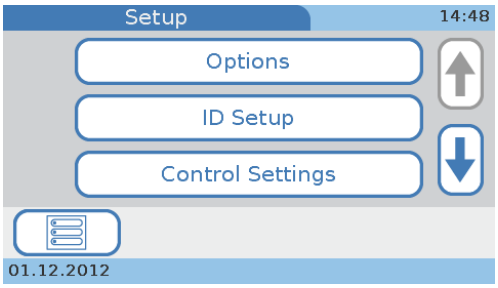


Figure 9 **Setup** screen

The following tables list the available screen items and give the possible values that can be selected or entered for them.

4.2.1 Options setup

☞ **Main Menu** > **Setup** > **Options**

Setup item	Navigation		Possible values	Default value
Sort Results			• Date/Time • Patient ID • Patient Name	Date/Time
Comments	Setting	Patient	• No • Optional • Required • Required (Out of Range)	Optional
		Control	• No • Optional • Required • Required (Out of Range)	Optional
	Edit	Patient	• Up to 10 comments • Up to 20 characters per comment	"" (blank)
		Control	• Up to 10 comments • Up to 20 characters per comment	"" (blank)
	Sequence	Patient	• NA	NA
		Control	• NA	NA
Dual Test			• Disabled • Enabled	Disabled

Table 6 **Options** settings

Setup item	Navigation			Possible values	Default value
Parameter	HbA1c			• HbA1c • eAG	HbA1c
	Lipid			• CHOL • TG • HDL • LDL	CHOL TG HDL LDL
				• Non-HDL • CHOL/HDL	Non-HDL CHOL/HDL
Result Unit	HbA1c			• NGSP • IFCC	NGSP IFCC
	eAG			• mg/dL • mmol/L	mg/dL
	Lipid			• mg/dL • mmol/L	mg/dL
Custom Normal Ranges	Disabled				Disabled
	Enabled				
		HbA1c	NGSP	• Min: 4.0-14.0%	4.0
				• Max: 4.0-14.0%	14.0
			IFCC	• Min: 20-130 mmol/mol	20
				• Max: 20-130 mmol/mol	130
		eAG		• Min: 95-299 mg/dl (5.28-16.57 mmol/L)	95 (5.28)
				• Max: 95-299 mg/dl (5.28-16.57 mmol/L)	299 (16.57)
		Lipid	CHOL	• Min: 50-500 mg/dl (1.28-12.95 mmol/L)	50 (1.28)
				• Max: 50-500 mg/dl (1.28-12.95 mmol/L)	500 (12.95)
			TG	• Min: 45-650 mg/dl (0.50-7.35 mmol/L)	45 (0.50)
				• Max: 45-650 mg/dl (0.50-7.35 mmol/L)	650 (7.35)
			HDL	• Min: 15-100 mg/dl (0.38-2.60 mmol/L)	15 (0.38)
				• Max: 15-100 mg/dl (0.38-2.60 mmol/L)	100 (2.60)
			LDL	• Min: 1-477 mg/dl (0.01-12.34 mmol/L)	1 (0.01)
				• Max: 1-477 mg/dl (0.01-12.34 mmol/L)	477 (12.34)
			Non-HDL	• Min: 1-486 mg/dl (0.01-12.57 mmol/L)	1 (0.01)
				• Max: 1-486 mg/dl (0.01-12.57 mmol/L)	486 (12.57)
			CHOL/HDL	• Min: 1.0-34.5	1.0
				• Max: 1.0-34.5	34.5
Alarm				• 0-4	2

Table 6 **Options** settings (Continued)

Setup item	Navigation		Possible values	Default value
Key Click			• 0-4	2
Auto Off			• Disabled	Disabled
			• Enabled (1-999 min)	
Computer			• Disabled • USB • BUH	Disabled
Service	Information		No values to be defined	
	Data Handling	Anonymize Patient Info.		
		Audit Trail Log File		
		Error Log File		
		Import Configuration		
		Export Configuration		
		Initialize Configuration		
	Error History			
	Software Update			
	Language Update			

Table 6 **Options** settings (Continued)

4.2.2 ID Setup

☞ **Main Menu** > **Setup** > **ID Setup**

Setup item	Navigation			Possible values	Default values	
Operator ID	ID Entry	No				No
		Required	ID Entry Mode	• Keyboard	Keyboard Barcode	
				• Barcode		
				• List		
			Length	• Min: 1-20	1	
				• Max: 1-20	20	
			Auto Logoff Time	• Enabled 1-60 min	Enabled 20	
				• Disabled		
	ID Validation			• No		No
				• Length		
				• List		
	Password Entry			• Disabled		Disabled
				• Enabled		
	Password Expiry	Disabled				Disabled
		Enabled		• 1-365 days	90	
	Administrator			• Disabled		Disabled
				• Enabled		
	Edit Operator List			One set of operator information per operator		
	Change Password			NA	NA	

Table 7 **ID Setup** settings

Setup item	Navigation			Possible values	Default values	
Patient ID	ID Entry	No				No
		Optional	ID Entry Mode	• Keyboard	Keyboard Barcode	
				• Barcode		
				• List		
			Length	• Min: 1-20	1	
				• Max: 1-20	20	
		Required	ID Entry Mode	• Keyboard	Keyboard Barcode	
				• Barcode		
				• List		
			Length	• Min: 1-20	1	
				• Max: 1-20	20	
	Name Entry			• Disabled		Disabled
				• Enabled		
	Date of Birth Entry			• Disabled		Disabled
				• Enabled		
	ID Validation			• No		No
				• Name		
				• Date of Birth		
	Edit Patient List			One set of patient information per patient		

Table 7 **ID Setup** settings (Continued)

4.2.3 Control Settings

☞ **Main Menu** > **Setup** > **Control Settings**

Setup item	Navigation		Possible values	Default values	
Operator Lockout			• No		No
			• Weekly		
			• Monthly		
			• Every X Months (Range 1-12)	3	
QC Lockout	Interval		• No		No
			• Daily		
			• Weekly		
			• Monthly		
			• Every X Days (Range 1-60)	14	
	New Lot	HbA1c	• Disabled		Disabled
			• Enabled		
		Lipid	• Disabled		Disabled
			• Enabled		

Table 8 **Control** settings

Setup item	Navigation			Possible values	Default values	
Optical Check Lockout				• No		No
				• Daily		
				• Weekly		
				• Monthly		
				• Every X Months (Range 1-12)	3	
STAT Test				• Disabled		Enabled
				• Enabled (1-9 tests)	5	
QC Result Format				• Physical Value		Physical and Target Value
				• Physical and Target Value		
				• Target Value Deviation		
QC Range	HbA1c	Default Range	NGSP		NGSP	Default Range
			IFCC		IFCC	
		Custom Range	NGSP	0-±21%	±21%	
			IFCC	0-±34%	±34%	
	Lipid	Default Range				Default Range
		Custom Range	CHOL	0-±18%	±18%	
			TG	0-±24%	±24%	
			HDL	0-±22%	±22%	

Table 8 **Control** settings (Continued)

4.2.4 Screen setup

☞ **Main Menu** > **Setup** > **Screen**

Setup item	Navigation	Possible values	Default value
Contrast		• 1-5	3
Language		List of available languages	English
Date/Time	Date Format	• DD.MM.YYYY • MM/DD/YYYY • YYYY-MM-DD	DD.MM.YYYY
	Date	• 01.01.2012 - 31.12.2050	NA
	Time Format	• 12 h • 24 h	24 h
	Time	• 0:00-23:59 (12:00AM-11:59PM)	NA
Facility Information		• 0-60 characters	"" (blank)
Touch Screen Calibration		NA	NA

Table 9 **Screen** settings

4.3 Options setup

Use these functions to define how you want to use the instrument.

☞ **Main Menu** > **Setup** > **Options**.

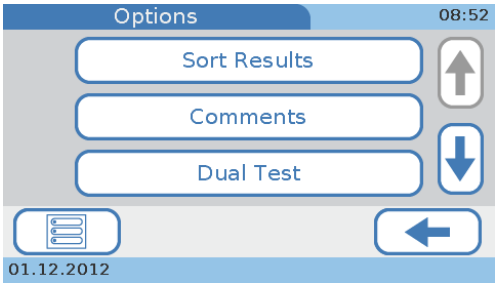


Figure 10 **Screen Setup** screen

The following buttons are available:

- Use **Sort Results** to define the order in which result information is displayed in the result screens.
- Use **Comments** to define whether and in which situations predefined comments should be added to results, and to write and change such comments.
- Use **Dual Test** to define whether HbA1c and Lipid Panel tests are performed separately or immediately following each other without displaying the results of the first test.
- Use **Parameter** to define which parameters will be reported.
- Use **Result Units** to set the units in which results will be reported.
- Use **Custom Normal Ranges** to customize the normal ranges for each test.
- Use **Alarm** to adjust the acoustic signal that is generated in certain critical situations, for example when a measurement is complete or when an exceptional situation was registered by the instrument.
- Use **Key Click** to adjust the acoustic signal that is generated when you choose a button on the screen.
- Use **Auto Off** to save energy by reducing the back lighting of the LCD display and switching off the heater after a certain time of inactivity.

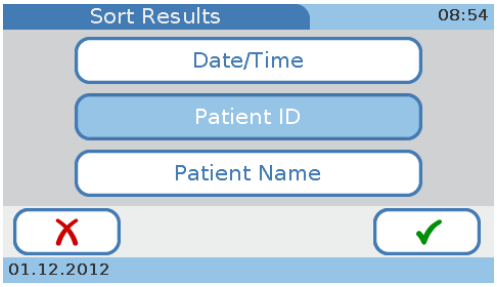
  When the system goes into this off mode, the screen saver screen is displayed. By touching the screen, the system is activated again.
- Use **Computer** to define how the instrument is connected to an external computer or a network.
- Use **Service** to perform service related activities.

4.3.1 Sort Results

Use this function to define the order in which result information is displayed in the result review screens.

► To define how results are sorted

1 Choose **Setup** > **Options** > **Sort Results**.



Use **Date/Time** if you want the results sorted by date and time when they were created.

Use **Patient ID** if you want the results to be sorted by their associated patient IDs.

Use **Patient Name** if you want the results to be sorted by their associated patient names. (This button is active if name entry is enabled. See *To define how operator related information should be handled* on page 58.)

2 Choose one of the buttons.

3 Choose ✓ to save the settings and to close the screen.

■

4.3.2 Comments

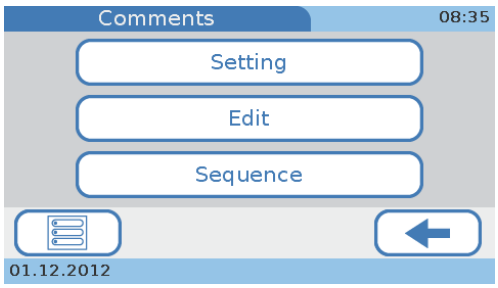
Use the comments functions to define whether and in which situations predefined comments should be added to results, and to write and change such comments.

You can define up to 10 patient and up to 10 control result comments, each containing up to 20 characters.

► To display the basic comments options

1 Choose **Setup** > **Options** > **Comments**.

The **Comments** screen is displayed.



2 Choose a button.

- Choose **Setting** to define whether comments are required for each result.
  See *To choose whether a comment should be displayed with results* on page 40.
- Choose **Edit** to edit existing comments or to add a new comment.
  See *To write (predefine) a result comment or change it* on page 41.
- Choose **Sequence** to change the order in which the comments are displayed in the **Comments** list that is for example displayed when you add a comment to a result.
  See *To define the sequence in which patient result comments are listed in the comments list* on page 42.

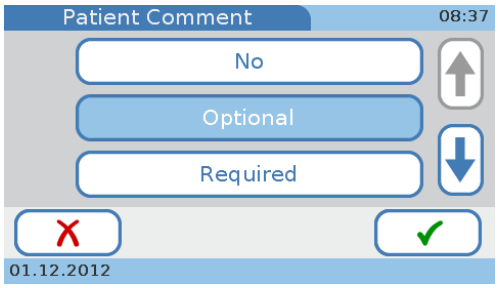
■

► To choose whether a comment should be displayed with results

1 Choose **Setup** > **Options** > **Comments** > **Setting** > **Patient** or **Control**.

The procedure is the same for defining patient and control result comments.

The **Patient** or **Control** screen is displayed.



2 Choose a button.

- Choose **No** if you do not want to use comments.
- Choose **Optional** if adding a comment should be optional.
- Choose **Required** if a comment must be added to all results.
- Choose **Required (Out of Range)** if a comment must be added to results that are outside predefined ranges.

3 Choose ✓ to save the choices and to close the screen.

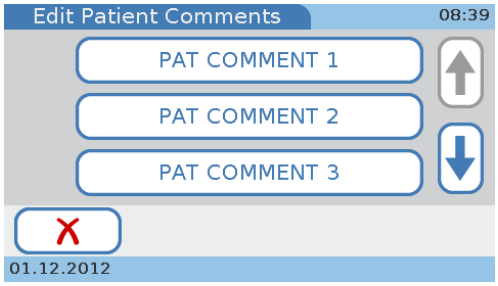
■

► To write (predefine) a result comment or change it

1 Choose **Setup** > **Options** > **Comments** > **Edit** > **Patient** or **Control**.

The procedure is the same for defining patient and control result comments.

The **Edit Patient Comments** or **Edit Control Comments** screen is displayed.



Existing comments are displayed in the buttons.

2 Choose a button.

- To edit an existing comment, choose its button.
- To add a new comment, choose a blank button.

  If you cannot see a blank button, choose ↓ repeatedly until you see one, then choose it.

The **Edit** screen is displayed.

3 Use the keyboard to enter the information. Use the 123 button to switch to the numeric keyboard for entering numbers. Use the ABC button to return to the alphabetic keyboard. Use ← to delete the last character in the data entry box.

You can enter up to 20 characters.

4 Choose ✓ to save the information and to close the screen.

■

► To delete a result comment

1 Choose **Setup** > **Options** > **Comments** > **Edit** > **Patient** or **Control**.

The procedure is the same for deleting patient and control result comments.

The **Edit Patient** or **Edit Control** screen is displayed.

Existing comments are displayed in the buttons.

2 Choose the button of the comment that you want to delete.

The **Edit** screen is displayed.

3 Use ← to delete all characters in the data entry box.

4 Choose ✓ to save the information and to close the screen.

The comment is no longer contained in the **Edit Patient Comment** or **Edit Control Comment** list.

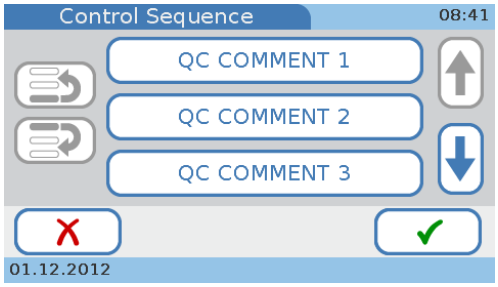
■

► To define the sequence in which patient result comments are listed in the comments list

1 Choose Setup > **Options** > **Comments** > **Sequence** > **Patient** or **Control**.

The procedure for defining the sequence is the same for both the patient and control result comments.

The **Patient Sequence** or **Control Sequence** screen is displayed.



2 Choose a comment button.

3 Move the button up or down in the list.

- Choose to move the button up by one position in the list. Choose it again to move it up another position.
- Choose to move the button down by one position in the list. Choose it again to move it down another position.

4 Choose ✓ to save the settings and to close the screen.

■

4.3.3 Dual Test

Use this function to define whether HbA1c and Lipid Panel tests can be performed immediately following each other without displaying the results of the first test.

► To define whether dual testing will be used

1 Choose **Setup** > **Options** > **Dual Test**.

The **Dual Test** screen is displayed.

2 Choose one of the buttons.

Choose **Disabled** to prevent dual testing from being used.

Choose **Enabled** if you want to be able to use dual testing.

3 Choose ✓ to save the settings and to close the screen.

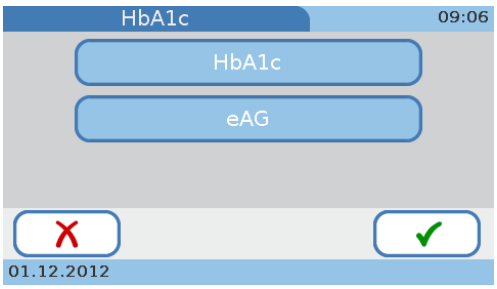
■

4.3.4 Parameter

Use this screen to define which parameters are reported.

► To choose which HbA1c parameters are reported

1 Choose **Setup** > **Options** > **Parameter** > **HbA1c**.



2 Choose one or both buttons.

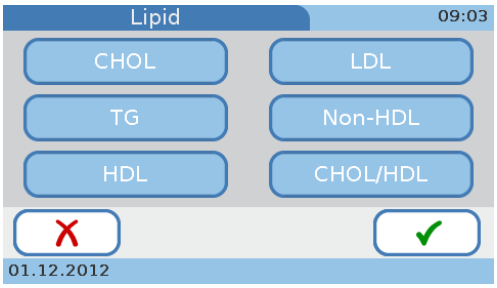
- Choose **HbA1c** if you want the results to be reported as HbA1c values.
- Choose **eAG** if you want the results to be reported as estimated average glucose values (eAG).

3 Choose ✓ to save the settings and to close the screen.

■

► To choose which parameters are reported

1 Choose **Setup** > **Options** > **Parameter** > **Lipid**.



The following parameters are available:

- CHOL
- TG
- HDL
- LDL
- Non-HDL
- CHOL/HDL

2 Choose the buttons of all parameters for which you want to display the results.

3 Choose ✓ to save the settings and to close the screen.

■

4.3.5 Result Units

Use this screen to choose the units in which results are reported.

You need to enable a parameter before you can define its units. See *Parameter* on page 43.

HbA1c

► **To set the units for the HbA1c tests**

1 Choose **Setup** > **Options** > **Result Units**.

2 Choose **HbA1c**.

A screen for selecting the units is displayed.

3 Choose up to three units you want to use.

4 Choose ✔ to save the settings and to close the screen.

■

eAG

► **To set the units for eAG reporting**

1 Choose **Setup** > **Options** > **Result Units**.

2 Choose **eAG**.

A screen for selecting the unit is displayed.

3 Choose either **mg/dL** or **mmol/L**.

4 Choose ✔ to save the settings and to close the screen.

■

Lipid

► **To set the units for the Lipid Panel**

1 Choose **Setup** > **Options** > **Result Units**.

2 Choose **Lipid**.

A screen for selecting the unit is displayed.

3 Choose either **mg/dL** or **mmol/L**.

4 Choose ✔ to save the settings and to close the screen.

■

4.3.6 Custom Normal Ranges

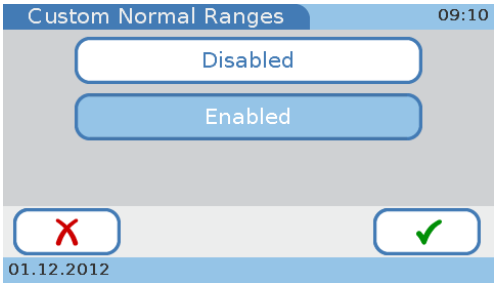
Use this function to customize the normal ranges for each test. Make sure your values comply with the legal requirements that apply to your facility.

- You need to enable tests before you can customize their ranges. See *Parameter* on page 43.
- The normal ranges are described in *Table 6* on page 33 ff.

► To disable the use of customized ranges

1 Choose **Setup** > **Options** > **Custom Normal Ranges**.

The **Custom Normal Ranges** screen is displayed.



2 Choose **Disabled** to define that customized normal ranges will not be used. In this case the default values apply.

3 Choose ✓ to save the settings and to close the screen.

■

► To define normal ranges

1 Choose **Setup** > **Options** > **Custom Normal Ranges**.

The **Custom Normal Ranges** screen is displayed.

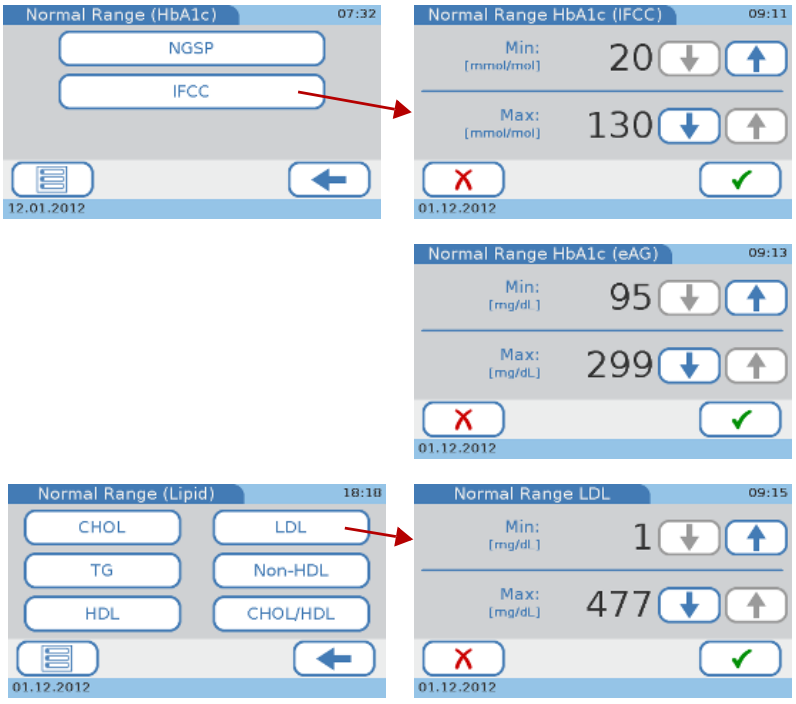
2 Choose **Enabled**.

3 Choose ✓.

4 Choose one of the parameters.

5 If you choose **HbA1c** or **Lipid** you need to choose one of the reference methods.

If you choose **eAG** the screen for defining the values is displayed directly.



6 Define the minimum and maximum values.

Use ↑ and ↓ to increase and decrease the values.

7 Choose ✓ to save the settings and to close the screen.

■

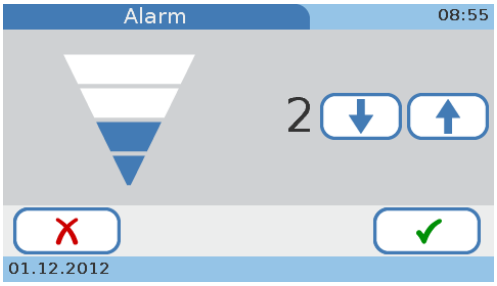
4.3.7 Alarm

Use this function to adjust the acoustic signal that is generated in certain situations, for example when a measurement is complete or when an exceptional situation was registered by the instrument.

Roche recommends not to turn off the acoustic signal.

► **To adjust the acoustic signal**

1 Choose **Setup** > **Options** > **Alarm**.



2 Use ↑ and ↓ to increase or decrease the value.

You can choose a value between 0 and 4. Choosing the value 0 (zero) turns off the acoustic signal.

3 Choose ✓ to save the settings and to close the screen.

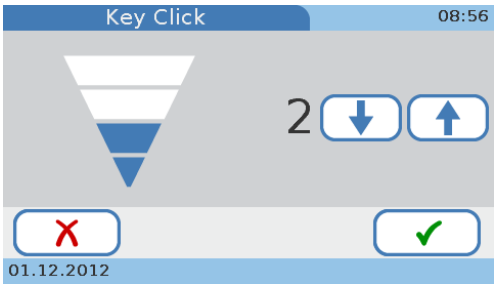
■

4.3.8 Key Click

Use this function to adjust the acoustic signal that is generated when you choose a button on the screen.

► **To adjust the acoustic signal**

1 Choose **Setup** > **Options** > **Key Click**.



2 Use ↑ and ↓ to increase or decrease the value.

You can choose a value between 0 and 4. Choosing the value 0 (zero) turns off the acoustic signal.

3 Choose ✓ to save the settings and to close the screen.

■

4.3.9 Auto Off

Use this function to save energy by reducing the back lighting of the LCD display and switching off the heater after a certain time of inactivity.

- When the system goes into **Auto Off** mode the screen saver screen is displayed. By touching the screen, the system is activated again.
- If you work with automatic logoff (see *To define that automatic logoff should be used* on page 60) you are automatically logged off when the system goes into **Auto Off** mode.

► To turn off the energy saving function

1 Choose **Setup** > **Options** > **Auto Off**.

The **Auto Off** screen is displayed.

2 Choose **Disabled**.

3 Choose ✓ to save the settings and to close the screen.

■

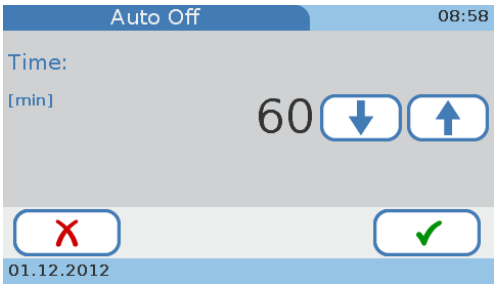
► To define the time after which the energy saving function sets in

1 Choose **Setup** > **Options** > **Auto Off**.

The **Auto Off** screen is displayed.

2 Choose **Enabled**.

3 Choose ✓.



4 Use ↑ and ↓ to increase and decrease the value.

You can set a time between 1 to 999 minutes.

5 Choose ✓ to save the settings and to close the screen.

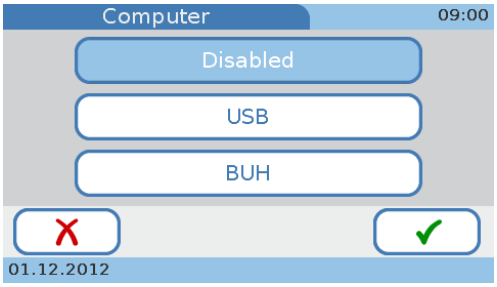
■

4.3.10 Computer

Use this function to define how the instrument is connected to an external computer or a network.

► **To define the data connection**

1 Choose **Setup** > **Options** > **Computer**.



2 Choose one of the buttons.

Use **Disabled** if you do not intend to connect the instrument to an external computer or a Base Unit Hub.

Use **USB** if you want to use the USB port to connect an external computer.

Use **BUH** (Base Unit Hub) if you want to use the BUH port to connect the instrument to a network or a data management system.

- Connect the data management system according to standard POCT1-A.
- For details on how to set up such connections see the user documentation for the respective hardware and software products and contact your Roche representative.

3 Choose ✓ to save the settings and to close the screen.

■

4.3.11 Service

Use these functions to perform service related activities.

☞ **Setup** > **Options** > **Service**

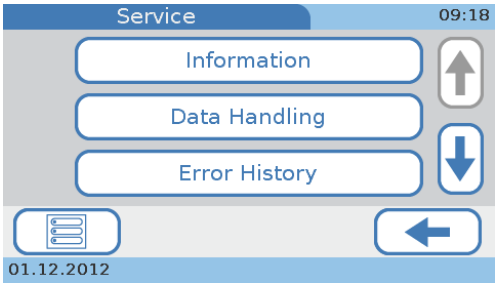


Figure 11 **Service** screen

- Use **Information** to display status information on the instrument.

👁 See *Information* on page 50.

- Use **Data Handling** to perform the following tasks:
  - Deleting the patient information (**Anonymize Patient Info**).

    Use this function to delete the patient names and dates of birth in all results. Results then are identified by an ID only. You would typically use this function if the instrument needs to be returned to your Roche representative for troubleshooting purposes.

    See *Anonymize Patient Info* on page 51.
  - Exporting the audit trail log file.

    Use this function when required for regulatory reasons or to provide your Roche representative with the necessary information to perform effective troubleshooting. It generates a historic record of events and actions performed on the instrument.

    See *Audit Trail Log File* on page 51.
  - Exporting the error log file.

    Use this function to provide your Roche representative with the necessary information to perform effective troubleshooting. It generates a record of the error messages generated by the instrument.

    See *Error Log File* on page 52.
  - Importing configuration settings.

    Use this function when for example setting up a further or a replacement instrument. (To be able to import a configuration, it must previously have been exported from a **cobas b** 101 system instrument that runs the same software as the current instrument.)

    See *Import Configuration* on page 53.
  - Exporting the configuration settings.

    Use this function to create a copy of your setup. You can use this file for setting up a further or a replacement instrument.

    See *Import Configuration* on page 53.
  - Initializing the configuration.

    Use this function to set all setup information back to their factory values.

    See *Initialize Configuration* on page 54.
- Use **Error History** to display a chronological list of messages that were generated, together with their code.

  See *Error History* on page 54.
- Use **Software Update** to install a new software version of the system software.

  See *Software Update* on page 54.
- Use **Language Update** to load additional user interface languages.

  The instrument is delivered with a set of languages, and you can work with any of these. Additional languages may be available from Roche, you can use these after you have installed them on the instrument using the **Language Update** function.

  See *Language Update* on page 55.

File names The file names for the various import and export functions have predefined formats:

- For software and language update files the format is as follows:

	Content type S = System software L = Language software	Major version	Minor version	Revision	Build (year)	Build (number)	Extension
Example:	L	1	1	3	12	01	bin

Table 10 File name example for language update file: L1131201.bin

- For files that were generated by the instrument the format is as follows:

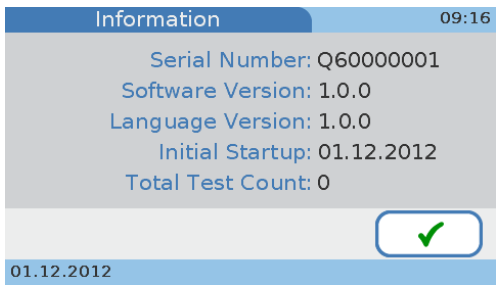
	Content type A= Audit trail file E = Error log file B = Backup of system settings	Year (YY)	Month (MM)	Day (DD)	Index (to distinguish between files that were generated on the same day)	Extension
Example:	E	12	12	01	A	csv

Table 11 File name example for error log file: E121201A.csv

Information Use this function to check the current status of the instrument.

► **To display the current instrument status information**

1 Choose **Setup** > **Options** > **Service** > **Information**.



The **Total Test Count** refers to patient tests, it does not include control tests.

2 Choose ✔ to close the screen.

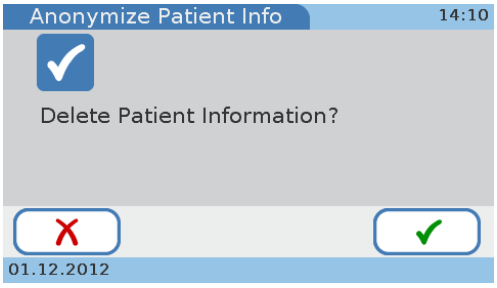
■

Anonymize Patient Info

Use this function to delete the patient names and dates of birth in all results. Results then are identified by an ID only. You would typically use this function if the instrument needs to be returned to your Roche representative for troubleshooting purposes.

► To delete patient information

1 Choose **Setup** > **Options** > **Service** > **Data Handling** > **Anonymize Patient Info**.



2 Choose ✔.

3 A screen is displayed for confirming the deletion.

4 Choose ✔.

The patient names and dates of birth for all results are deleted.

5 When a message is displayed confirming the successful deletion, choose ✔ to close the screen.

■

Audit Trail Log File

This function generates a historic record of up to 1000 events and actions performed on the instrument. Use this function to back up event data, which may be required for regulatory reasons or by your Roche representative to perform effective troubleshooting.

When the log file is full (1000 events) the oldest entries are replaced with the new ones. Therefore, you need to periodically export the audit trail log file.

► To export the audit trail log file

1 Choose **Setup** > **Options** > **Service** > **Data Handling** > **Audit Trail Log File**.

You are asked to insert a USB stick.

2 Insert a USB stick in the USB port at the back of the instrument.

See Figure 4 on page 17.

3 Choose ✔.

4 Wait until a message informs you that the export of the audit trail log file is complete.

5 Choose ✔ to close the screen.

■

Error Log File

This file can contain up to 100 error records. Use this function to back up the error records, which may be required by your Roche representative to perform effective troubleshooting.

When the log file is full (100 error records) the oldest entries are replaced with the new ones. Therefore, you need to periodically export the error log file.

► To export the error log file

1 Choose **Setup** > **Options** > **Service** > **Data Handling** > **Error Log File**.

You are asked to insert a USB stick.

2 Insert a USB stick in the USB port at the back of the instrument.

See Figure 4 on page 17.

3 Choose ✓.

4 Wait until a message informs you that the export of the error log file is complete.

5 Choose ✓ to close the screen.

■

Export Configuration

You typically use this function if you need to replace the current instrument or to create a backup before you retire the current instrument.

The following information is exported:

- Setup parameters
- Operator list
- Comment list
- Patient list
- Patient results
- Control results
- QC Info Disc information

► To export the current configuration settings

1 Choose **Setup** > **Options** > **Service** > **Data Handling** > **Export Configuration**.

You are asked to insert a USB stick.

2 Insert a USB stick in the USB port at the back of the instrument.

See Figure 4 on page 17.

3 Choose ✓.

4 Wait until a message informs you that the export is complete.

5 Choose ✓ to close the screen.

■

Import Configuration You typically use this function if you need to replace the current instrument or to access results that were generated on a retired instrument.

Existing results are deleted

When importing configuration data, existing patient and control results are deleted and replaced.

To be able to import a configuration, it must previously have been exported from a **cobas b** 101 systeminstrument that runs the same software as the current instrument. See *To export the current configuration settings* on page 52.

► To import configuration settings

1 Choose **Setup** > **Options** > **Service** > **Data Handling** > **Import Configuration**.

You are asked to insert a USB stick.

2 Insert a USB stick in the USB port at the back of the instrument.

👁 See Figure 4 on page 17.

3 Choose ✔.

You are asked to confirm the import.

4 Choose ✔ to confirm.

5 Wait until a message informs you that the import is complete.

6 Choose ✔ to close the screen.

■

► To access results that were generated on a different (retired) instrument

1 Export the data of the current instrument.

👁 See *To export the current configuration settings* on page 52.

2 Import the data that were generated on the retired instrument.

👁 See *To import configuration settings* on page 53.

All existing results are overwritten!

3 Find the required data and print them if required.

4 Import the data that were generated in step 1.

👁 See *To import configuration settings* on page 53.

■

► To install the configuration data of a different (retired) instrument

1 Export the data of the instrument you are going to retire.

👁 See *To export the current configuration settings* on page 52.

2 Install the new instrument and import the data that were generated in step 1.

👁 See *To import configuration settings* on page 53.

■

Initialize Configuration

Use this function to set all setup information back to their factory values. This does not affect the language, date, and time settings.

► To initialize the configuration settings

1 Choose **Setup** > **Options** > **Service** > **Data Handling** > **Initialize Configuration**.

2 Choose ✔.

You are asked to confirm the initialization.

3 Choose ✔.

4 Wait until a message informs you that the initialization is complete.

5 Choose ✔ to close the screen.

■

Error History

Use this function to check for messages that were generated by the instrument. The list is chronologically sorted.

► To check for messages

1 Choose **Setup** > **Options** > **Service** > **Error History**.

A list is displayed that contains the most recent messages that were generated by the instrument.

Use ↑ and ↓ to display items that are currently not displayed.

2 Note the error code and refer to *Table 18* on page 160 for details.

3 Choose ✔ to close the screen.

■

Software Update

Use this function for installing a new version of the system software.

This task takes about 5 minutes.

Only install original Roche software.

► To update the system software

1 Choose **Setup** > **Options** > **Service** > **Software Update.**

You are asked to insert a USB stick.

2 Insert a USB stick in the USB port at the back of the instrument.

See Figure 4 on page 17.

You are asked to confirm the update.

3 Choose ✔.

The instrument performs checks and then installs the software.

4 Wait until a message informs you that the update is complete.

Do not remove the USB stick or switch off the instrument during the installation procedure.

5 Switch off the instrument.

6 Remove the USB stick.

7 Switch on the instrument.

■

Language Update

The instrument is delivered with a set of languages, and you can work with any of these. Additional languages may be available from Roche, you can use these after you have installed them on the instrument using the **Language Update** function. You can install up to 18 languages.

This task takes about 5 minutes.

► To add a new user interface language

1 Choose **Setup** > **Options** > **Service** > **Language Update.**

You are asked to insert a USB stick.

2 Insert a USB stick in the USB port at the back of the instrument.

See Figure 4 on page 17.

3 Choose ✔.

4 Wait until a message informs you that the installation is complete.

Do not remove the USB stick or switch off the instrument during the installation procedure.

5 Switch off the instrument.

6 Remove the USB stick.

7 Switch on the instrument.

■

4.4 ID setup

Use the **ID Setup** functions to define how operator and patient related information is handled.

☞ **Main Menu** > **Setup** > **ID Setup**.

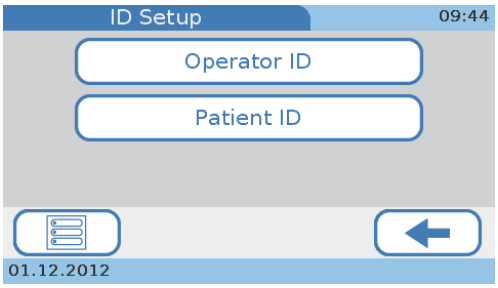


Figure 12 **ID Setup** screen

You can operate the instrument without using operator and patient data.

Use the **Operator ID** functions to define and organize operator access to the various functions of the instrument.

See *Operator ID* on page 56.

Use the **Patient ID** functions to define whether you want to work with demographic patient data, and if you do so, to define such data.

See *Patient ID setup* on page 69.

4.4.1 Operator ID

Use the **Operator ID** functions to define and organize operator access to the various functions of the instrument. If you choose to work without operator information, anyone can use the instrument and perform all possible functions; by using operator information, you can limit access to the instrument to specific persons, and you can assign them to the Operator or Administrator user group. Members of the Operator group can perform all functions required to perform day-to-day testing, members of the Administrator group can additionally use the functions required for managing the instrument.

The following illustration shows the logical relations between the various definitions and settings.

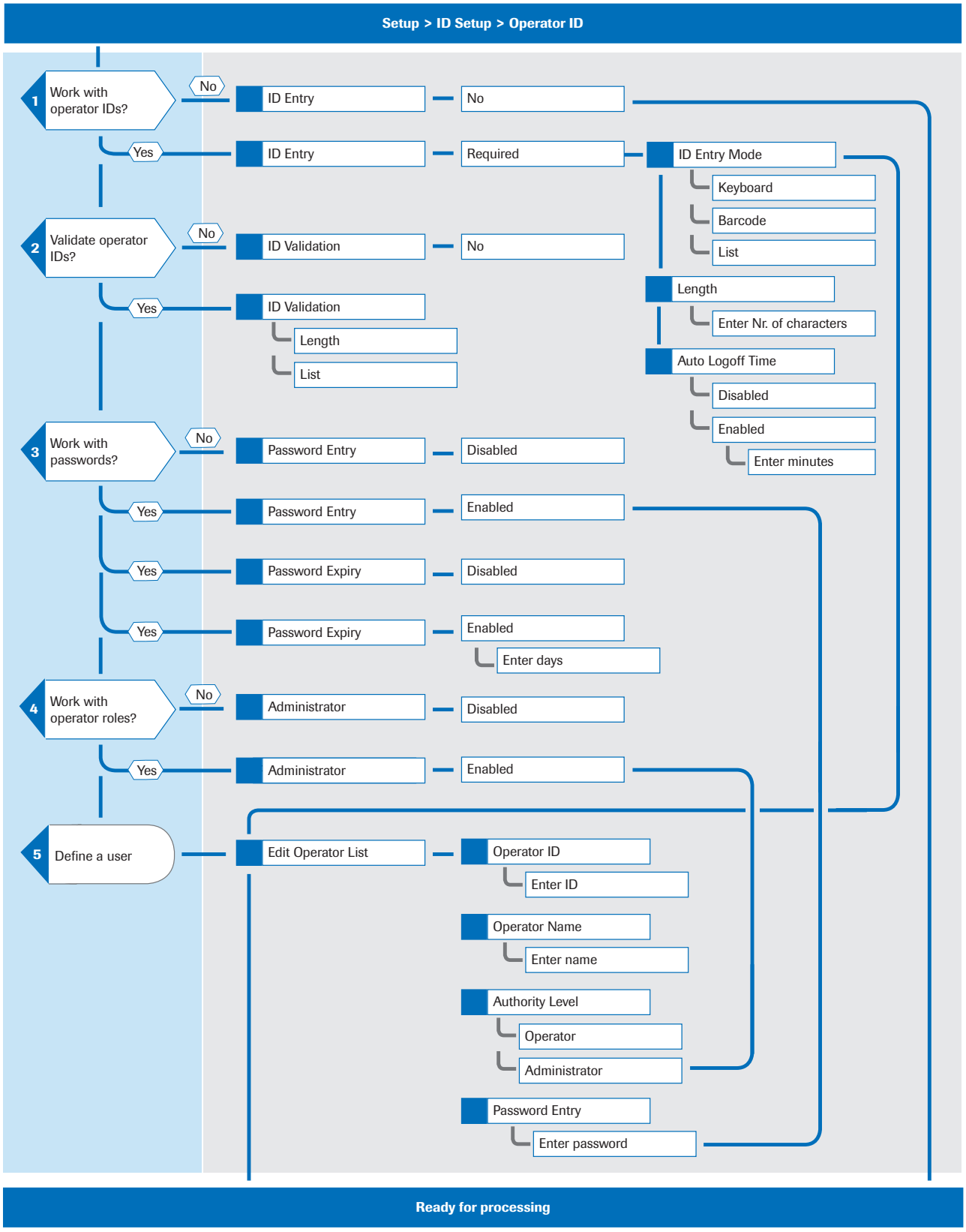
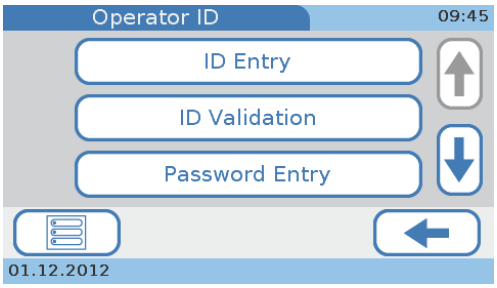


Figure 13 Logical overview of using the **Operator ID** functions

► To define how operator related information should be handled

1 Choose **Setup** > **ID Setup** > **Operator ID.**



- Use **ID Entry** to define whether and how the IDs should be entered, how long they should be and whether a user should be logged off automatically after a certain period of inactivity.
  See *ID Entry* on page 58.
- Use **ID Validation** to define whether the IDs should be validated and against which values (length, information defined in the **Edit Operator List**).
  See *ID Validation* on page 61.
- Use **Password Entry** to define whether users must enter passwords.
  See *Password Entry* on page 62.
- Use **Password Expiry** to define whether a password should expire and if so after how many days.
  See *Password Expiry* on page 62.
- Use **Administrator** to define whether the instrument should be managed by a dedicated administrator.
  See *Administrator* on page 63.
- Use **Edit Operator List** to define and change user information such as ID, name, password, and user rights (**Administrator**, **Operator**, **Training Mode**).
  See *Edit Operator List* on page 64.
- Use **Change Password** to change your current password. This function is available if you work with password identification (**Password Entry**).
  See *Change Password* on page 67.

2 Choose one of the buttons.

■

4.4.2 ID Entry

Use this function to define whether and how the IDs should be entered, how long they should be and whether users should be logged off automatically after a certain period of inactivity.

► To define that operator IDs should not be used

1 Choose **Setup** > **ID Setup** > **Operator ID** > **ID Entry**.

The **Operator ID Entry** screen is displayed.

2 Choose **No**.

3 Choose ✓ to save the settings and to close the screen.

■

Working without operator IDs has the following major consequences:

- Everyone can use the instrument and perform tests.
- There is no record of who has performed a certain test.

► To define how the operator IDs should be entered and used

1 Choose **Setup** > **ID Setup** > **Operator ID** > **ID Entry**.

The **Operator ID Entry** screen is displayed.

2 Choose **Required** to define that users should identify themselves before they can use the instrument.

3 Choose ✓.

A list is displayed.

4 Choose **ID Entry Mode**.

A list is displayed to select how IDs can be entered.

5 Choose a button.

- Choose **Keyboard** to allow the users to type their ID using the on-screen keyboard.
- Choose **Barcode** to allow the users to use the handheld barcode scanner to enter their user ID.
- Choose **List** to allow the user to select their ID from the **Edit Operator List** list.

- If you select **Keyboard** you can additionally select **Barcode** and vice versa.
- If you select **List** more than one operator must be defined in the **Edit Operator List**. See *Edit Operator List* on page 64.

6 Choose ✓ to save the settings and to close the screen.

The **Operator ID Entry** screen is displayed again.

■

► To define how long IDs should be

1 Choose **Setup** > **ID Setup** > **Operator ID** > **ID Entry**.

The **Operator ID Entry** screen is displayed.

2 Choose **Required**.

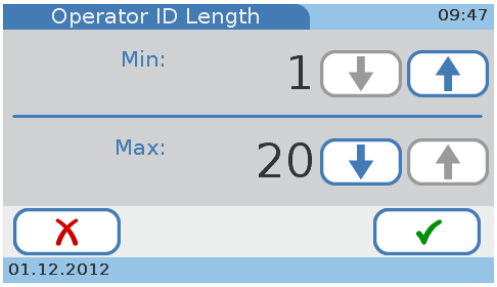
3 Choose ✓.

A list is displayed.

4 Choose **Length**.

The **Operator ID Length** screen is displayed.

5 Define the minimum and maximum length.



Use ↑ and ↓ to increase and decrease the values.

6 Choose ✓ to save the settings and to close the screen.

The **Operator ID Entry** screen is displayed again.

■

► To define that automatic logoff should be used

1 Choose **Setup** > **ID Setup** > **Operator ID** > **ID Entry**.

The **Operator ID Entry** screen is displayed.

2 Choose **Required**.

3 Choose ✓.

A list is displayed.

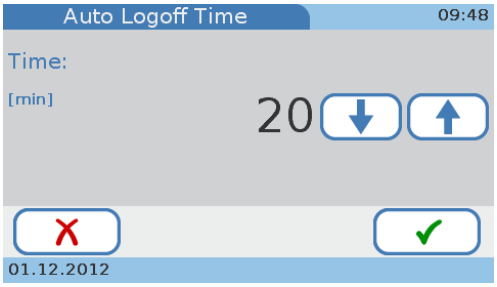
4 Choose **Auto Logoff Time**.

The **Auto Logoff Time** screen is displayed.

5 Choose **Enabled**.

6 Choose ✓.

A screen is displayed for defining the period of inactivity after which the user should be logged off automatically.



7 Define a value between 1 and 60 minutes. Use ↑ and ↓ to increase and decrease the values.

8 Choose ✓ to save the settings and to close the screen.

The **Operator ID Entry** screen is displayed again.

■

When the user is logged off, the screen saver screen is displayed. By touching the screen, the system is activated again.

► **To define that automatic logoff should not be used**

1 Choose **Setup** > **ID Setup** > **Operator ID** > **ID Entry**.

The **Operator ID Entry** screen is displayed.

2 Choose **Required** to define that users should identify themselves before they can use the instrument.

3 Choose ✔.

A list is displayed.

4 Choose **Auto Logoff Time**.

5 Choose **Disabled**.

6 Choose ✔ to save the settings and to close the screen.

The **Operator ID Entry** screen is displayed again.

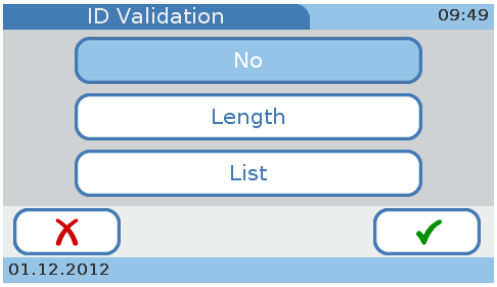
■

4.4.3 ID Validation

Use this function to define whether the IDs should be validated and if so against which of the values defined in the **Edit Operator List**.

► **To define whether IDs should be validated, and if so against which values**

1 Choose **Setup** > **ID Setup** > **Operator ID** > **ID Validation**.



2 Choose one of the following buttons:

- Choose **No** to define that IDs should not be validated.
- Choose **Length** if you want the IDs checked against the permissible length.
- Choose **List** if you want the IDs checked against the IDs defined in the **Edit Operator List**.

See *Edit Operator List* on page 64.

3 Choose ✔ to save the settings and to close the screen.

The **Operator ID** screen is displayed again.

■

4.4.4 Password Entry

Use this function to define whether users must enter passwords.

► To define whether passwords must be entered

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Password Entry**.

The **Operator Password Entry** screen is displayed.

2 Choose one of the buttons:

- Choose **Disabled** if users should not require password identification.
- Choose **Enabled** if users should identify themselves with their password when they start up the instrument or when the user had or was logged off.

3 Choose ✓ to save the settings and to close the screen.

The **Operator ID** screen is displayed again.

■

4.4.5 Password Expiry

Use this function to define whether a password should expire and if so after how many days.

► To define that passwords should not expire

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Password Expiry**.

The **Password Expiry** screen is displayed.

2 Choose **Disabled**.

3 Choose ✓ to save the settings and to close the screen.

The **Operator ID** screen is displayed again.

■

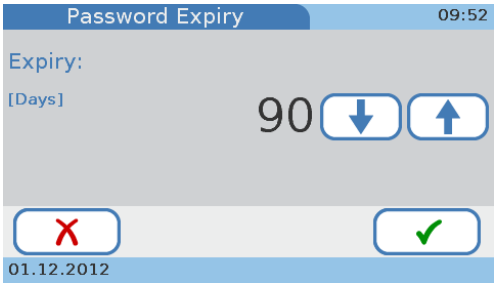
► To define the password expiry period

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Password Expiry**.

The **Password Expiry** screen is displayed.

2 Choose **Enabled**.

3 Choose ✓.



4 Define a value between 1 and 365 days. Use ↑ and ↓ to increase and decrease the value.

5 Choose ✔ to save the settings and to close the screen.

The **Operator ID** screen is displayed again.

■

4.4.6 Administrator

Use this function to define whether the instrument is managed by one or several dedicated administrators. If you choose to work with the Administrator role, the administrator can perform all functions on the instrument, but users with the Operator role assigned to them can only perform the functions for routine testing and maintenance. If you work without the Administrator role, all users can perform all functions.

Users with the Operator role assigned to them can perform the following functions, in addition to performing patient and control tests:

- Enable/disable dual testing
- Define how results are sorted (date/time, patient ID, patient name)
- Add new patients to the patient list
- Adjust the loudness of the acoustic alarm
- Adjust the loudness of key click sound
- Adjust the touch screen contrast
- Calibrate the touch screen
- Change the screen language
- Change their own password
- Enable/disable USB and BUH connections
- View the system information
- View the error history

If administrators have forgotten their password, they can contact their Roche representative and request a *password of the day*. If you work with operator information but not with the Administrator role, all users can request such a password.

► To define whether there are dedicated users for managing the instrument

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Administrator**.

The **Administrator** screen is displayed.

2 Choose one of the buttons.

- Use **Disabled** if all users should be able to perform all functions.
- Use **Enabled** if the instrument management should be performed by dedicated users.

3 Choose ✔ to save the settings and to close the screen.

The **Operator ID Entry** screen is displayed again.

■

4.4.7 Edit Operator List

Use this function to define and change user information such as ID, name, role (**Administrator**, **Operator**, **Training Mode**), and password. You can define up to 50 sets of user information, five of them can be administrators.

For preconditions, see Figure 16 on page 79.

► To define a new user

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Edit Operator List**.

2 Choose .

3 Do one of the following:

If …	Do this
You want to enter the ID manually	1. Enter the operator ID using the keyboard. 2. Choose ✓. The **Operator Name** screen is displayed.
You want to use the barcode scanner	1. Choose . A screen is displayed, asking you to scan the barcode. 2. Scan the barcode. A screen is displayed for checking the ID. 3. Choose ✓ to confirm. (If the information is not correct, choose ✗. A screen is then displayed, asking you to scan the barcode again. Scan the barcode again.) The **Operator Name** screen is displayed.

4 Enter the operator name using the keyboard.

5 Choose ✓.

The **Authority Level** screen is displayed.

6 Choose one of the buttons.

- Choose **Operator** if the user should be able to perform only the functions required for performing routine testing.
- Choose **Administrator** if the user should be able to perform all functions.
- Choose **Training Mode** if the user should be able to perform control tests as part of the instrument setup.

The **Add New Operator** screen is displayed, which allows you to review the information you entered.

7 Choose ✗ if you need to change the information. Otherwise proceed with step 8.

After choosing ✗ the **Operator ID** screen is displayed again. Make the required changes as described in the previous steps.

8 Choose ✓.

The definitions are displayed.

9 If you work with passwords, you are asked to define the password.

- Choose ✓ and define the password.
- Choose ✓ and enter the identical password again.

The password can contain up to 20 alphanumeric characters.

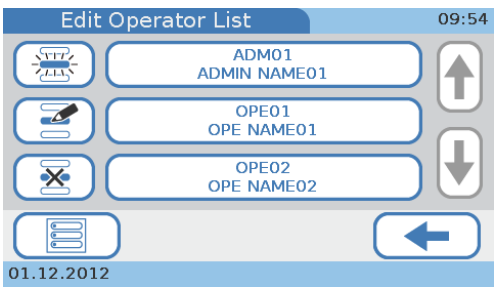
10 Choose ✓ to save the settings and to close the screen.

The **Edit Operator List** screen is displayed again.

■

► To change user information

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Edit Operator List**.



2 Choose an operator from the list.

3 Choose .

4 Use ← to delete the characters in the entry box and enter the new information.

If you want to use the barcode scanner to define the ID, choose and read the barcode.

5 Choose ✓.

The **Operator Name** screen is displayed.

6 Use ← to delete the characters in the entry box.

7 Enter the new information.

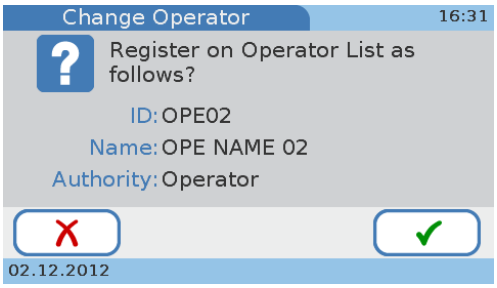
8 Choose ✓.

The **Authority Level** screen is displayed.

9 Choose one of the buttons.

- Choose **Operator** if the user should be able to perform only the functions required for performing routine testing.
- Choose **Administrator** if the user should be able to perform all functions.
- Choose **Training Mode** if the user should be able to perform control tests as part of the instrument setup.

The **Change Operator** screen is displayed, which allows you to review the information you entered.



10 Choose ✗ if you need to change the information. Otherwise proceed with step 11.

After choosing ✗ the **Operator ID** screen is displayed again. Make the required changes as described in the previous steps.

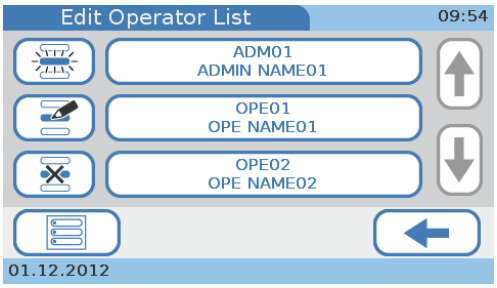
11 Choose ✓ to save the settings and to close the screen.

The **Edit Operator List** screen is displayed again.

■

► To delete a user

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Edit Operator List**.



2 Choose the button of the user whose information you want to delete.

3 Choose .

A screen is displayed for confirming the deletion.

4 Choose ✓ to delete this set of user information.

The **Edit Operator List** screen is displayed again.

■

4.4.8 Change Password

All users can change their own password, users who are members of the Administrator role can also change (reset) the password of other users. The **Change Password** function is available if you work with password identification. See *Password Entry* on page 62.

► To change your password

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Change Password**.

2 Enter the existing password and choose ✓.

3 Enter the new password and choose ✓.

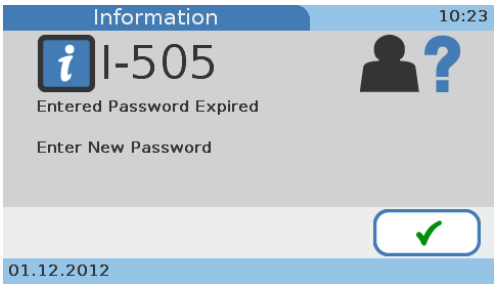
4 Enter the new password again and choose ✓.

■

Password expiry If you work with password expiry (see *Password Expiry* on page 62) you must change the password when it has expired.

► To change your password when it has expired

1 If you log on after your password has expired a screen is displayed to inform you of this fact.



2 Choose ✓.

3 Enter the new password and choose ✓.

4 Enter the new password again and choose ✓.

■

► To reset a password

1 Choose **Setup** > **ID Setup** > **Operator ID** > **Edit Operator List**.

2 Choose the user's button and choose .

3 Choose ✓ to confirm the operator ID.

4 Choose ✓ to confirm the operator name.

5 Choose ✓ to confirm the authority level.

6 Choose ✓ to confirm the operator information.

7 Choose ✓ to confirm that you want to change the password.

8 Enter the new password and choose ✓.

9 Enter the new password again and choose ✓.

■

4.5 Patient ID setup

Use the **Patient ID** functions to define whether you want to work with demographic patient data, and if so to define such data.

If you choose to work with patient information, a patient ID must be assigned to every result. (Note that if you choose to work without patient information, the instrument still automatically assigns an ID to each result, but no demographic patient data will be associated with it.) Working with patient information enables you to list all results of a certain patient. You can define up to 500 sets of patient information.

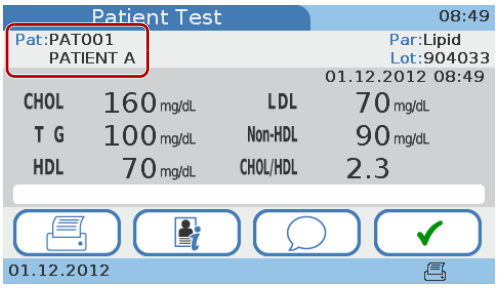


Figure 14 Patient information in result display

The following illustration shows the logical relations between the various definitions and settings.

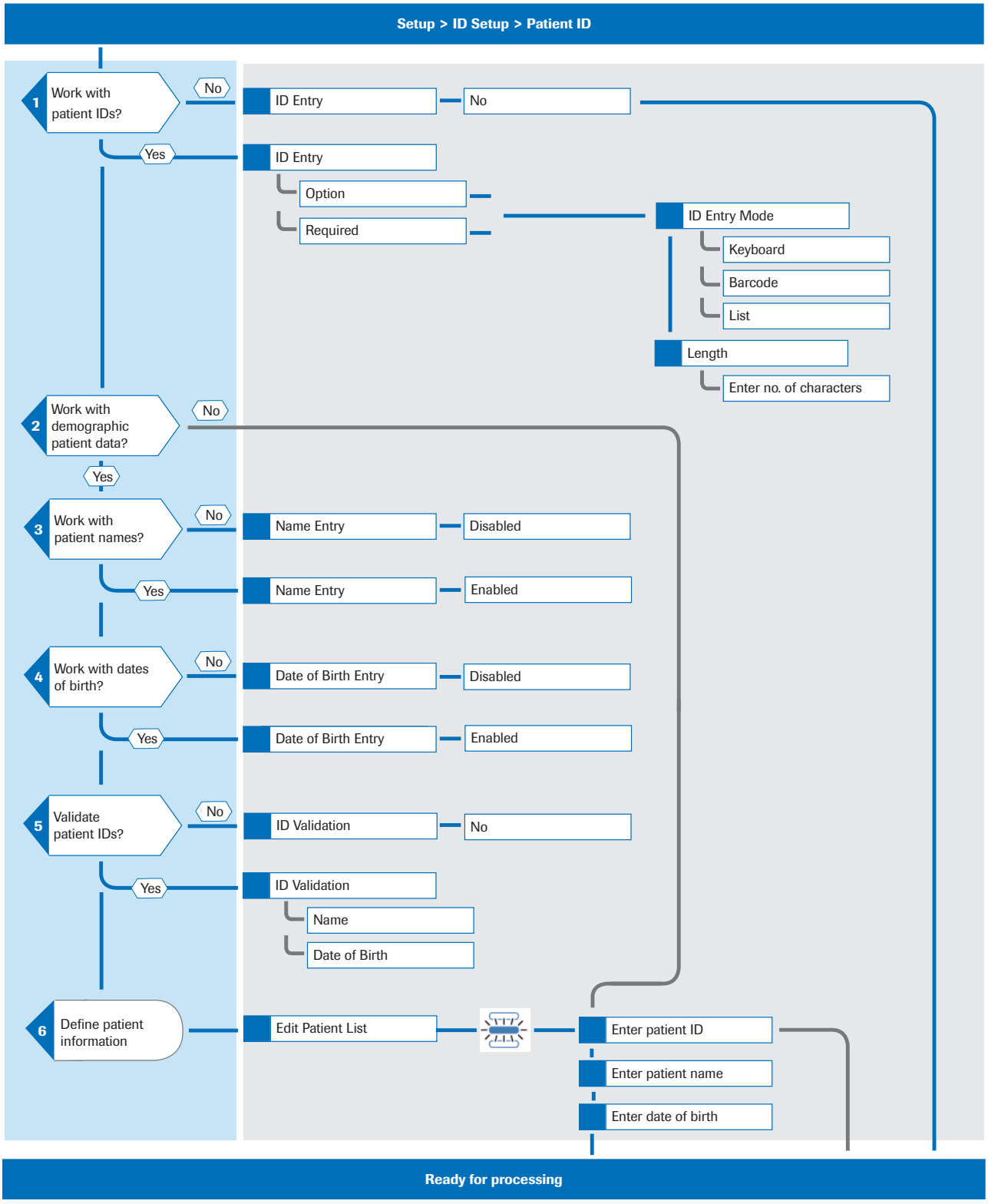
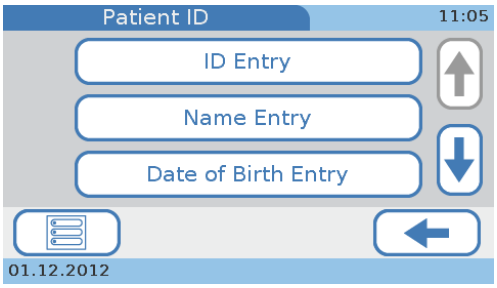


Figure 15 Logical overview of using the **Patient ID** functions

► To define how patient information should be handled

1 Choose **Setup** > **ID Setup** > **Patient ID.**



- Use **ID Entry** to define whether and how the IDs should be entered.
  See *ID Entry* on page 71.
- Use **Name Entry** to define whether you want to work with patient names. If you don't, tests and results will be anonymous on the instrument.
  See *Name Entry* on page 73.
- Use **Date of Birth Entry** to define whether the date of birth should be added to the patient ID.
  See *Date of Birth Entry* on page 74.
- Use **ID Validation** to define whether the IDs should be validated and if so against which values (patient name, date of birth).
  See *ID Validation* on page 74.
- Use **Edit Patient List** to define and change patient information such as ID, name, and date of birth.
  See *Edit Patient List* on page 75.

2 Choose one of the buttons.

■

4.5.1 ID Entry

Use this function to define whether and how the IDs should be entered.

Each result has a patient ID assigned to it, even if you work without patient information. If you work with patient information, results for the same patient have the same patient ID; if you work without patient information, each result, regardless of whether there are several for the same patient, has its unique ID assigned to it.

► To define that you want to work without patient information

1 Choose **Setup** > **ID Setup** > **Patient ID** > **ID Entry**.

The **ID Entry** screen is displayed.

2 Choose **No**.

- If you choose **No**, the instrument will automatically assign an ID (running number) to each result.
- The lifespan of the instrument is limited to 12240 patient or control tests. Messages will warn you in time when this limit is approached.

3 Choose ✓ to save the settings and to close the screen.

■

► To define that you want to work with mandatory patient information

1 Choose **Setup** > **ID Setup** > **Patient ID** > **ID Entry**.

The **ID Entry** screen is displayed.

2 Choose **Required**.

3 Proceed with step 3 in *To determine how to define patient information* on page 72.

■

► To define that you want to optionally work with patient information

1 Choose **Setup** > **ID Setup** > **Patient ID** > **ID Entry**.

The **ID Entry** screen is displayed.

2 Choose **Optional** to define that you can define patient information for a test.

3 Proceed with step 3 in *To determine how to define patient information* on page 72.

■

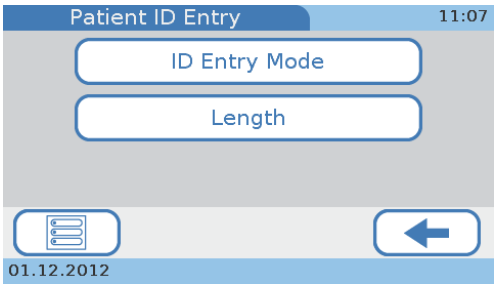
► To determine how to define patient information

1 Choose **Setup** > **ID Setup** > **Patient ID** > **ID Entry**.

The **ID Entry** screen is displayed.

2 Choose **Optional** or **Required**.

3 Choose ✔.



4 Choose **ID Entry Mode**.

A list is displayed where you can select how patient information can be entered.

5 Choose one of the buttons.

- Choose **Keyboard** to allow the users to type the patient information using the on-screen keyboard.
- Choose **Barcode** to allow the users to use the handheld barcode scanner to enter patient IDs.
- Choose **List** to allow the users to select patient information from the **Edit Patient List**.

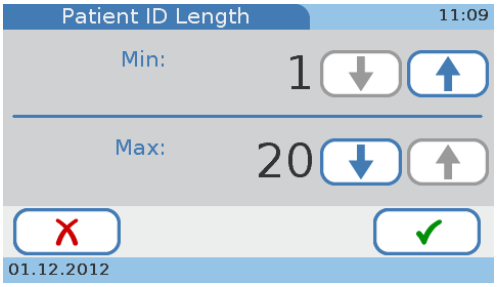
See *Edit Patient List* on page 75.

If you choose **Keyboard** you can additionally select **Barcode** and vice versa.

6 Choose ✔ to save the settings and to close the screen.

The **ID Entry** screen is displayed again.

7 Choose **Length** to define how long a patient ID should be.



8 Use ↑ and ↓ to increase and decrease the values.

9 Choose ✓ to save the settings and to close the screen.

The **ID Entry** screen is displayed again.

■

4.5.2 Name Entry

Use this function to define whether you want to work with patient names. If you don't, tests and results will be anonymous on the instrument, identified by their patient ID only.

► **To define that you want to work with patient names**

1 Choose **Setup** > **ID Setup** > **Patient ID** > **Name Entry**.

The **Name Entry** screen is displayed.

2 Choose **Enabled**.

3 Choose ✓.

A screen is displayed, informing you that using this function means that the patient data will not be anonymous.

4 Choose ✓ to save the settings and to close the screen.

The **Patient ID** screen is displayed again.

■

► **To define that you do not want to work with patient names**

1 Choose **Setup** > **ID Setup** > **Patient ID** > **Name Entry**.

The **Name Entry** screen is displayed.

2 Choose **Disabled**.

3 Choose ✓ to save the settings and to close the screen.

The **Patient ID** screen is displayed again.

■

4.5.3 Date of Birth Entry

Use this function to define whether the date of birth should be added to the patient information. (The date of birth is contained in the result printout but not displayed with on-screen results. You can, however, view the full set of patient results from the results display.)

► **To define whether to include the date of birth with the patient information**

1 Choose **Setup** > **ID Setup** > **Patient ID** > **Date of Birth Entry**.

The **Date of Birth Entry** screen is displayed.

2 Choose one of the buttons.

- Choose **Disabled** if you want to work without date of birth information.
- Choose **Enabled** if you want to work with date of birth information.

3 Choose ✓ to save the settings and to close the screen.

The **Patient ID** screen is displayed again.

■

4.5.4 ID Validation

Use this function to define whether patient information should be validated and if so against which of the values defined in the **Edit Patient List** (patient name, date of birth).

► **To define whether patient ID validation should be used**

1 Choose **Setup** > **ID Setup** > **Patient ID** > **ID Validation**.

The **ID Validation** screen is displayed.

2 Choose one of the buttons.

- Choose **No** if you want to work without ID validation.
- Choose **Name** if the patient name should be validated against the name defined in the **Edit Patient List**.

👁 See *Edit Patient List* on page 75.

- Choose **Date of Birth** if the patient's date of birth should be validated against the date of birth defined in the **Edit Patient List**.

👁 See *Edit Patient List* on page 75.

If you choose **Name** you can additionally select **Date of Birth** and vice versa.

3 Choose ✓ to save the settings and to close the screen.

The **Patient ID** screen is displayed again.

■

4.5.5 Edit Patient List

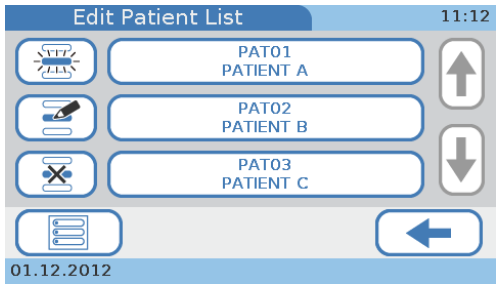
Use this function to define and change patient information such as ID, name, and date of birth. You can define up to 500 sets of patient information.

The following procedures are based on a setup that works with patient ID, patient name, and date of birth information. If you do not work with names or dates of birth, the corresponding functions are not available and the screens are not displayed.

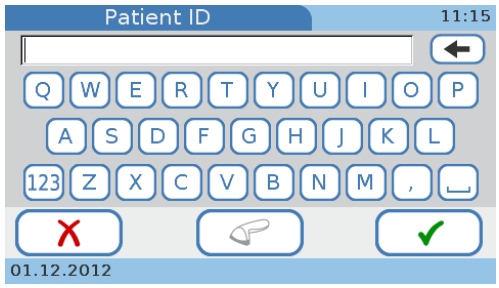
► To define a new patient

1 Choose **Setup** > **ID Setup** > **Patient ID** > **Edit Patient List**.

The **Edit Patient List** screen is displayed. Each currently defined patient is represented by a button.



2 Choose .



3 To define the patient ID, do one of the following:

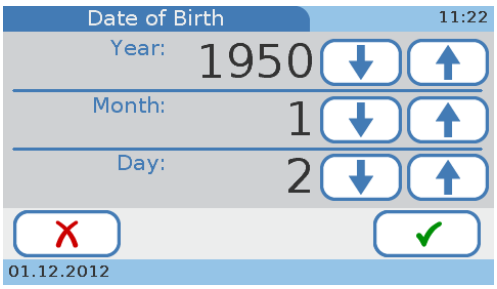
Whether the following functions are available depends on how the **ID Entry Mode** is defined. See *To define how patient information should be handled* on page 71.

If …	Do this
You want to enter the ID manually	1. Enter the patient ID using the keyboard. 2. Choose ✔. The **Patient Name** screen is displayed.

If …	Do this
You want to use the barcode scanner	1. Choose . A screen is displayed, asking you to scan the barcode. 2. Scan the barcode. A screen is displayed for checking the ID. 3. Choose ✓. (If the information is not correct, choose ✗. A screen is then displayed, asking you to scan the barcode again. Scan the barcode again.) The **Patient Name** screen is displayed.

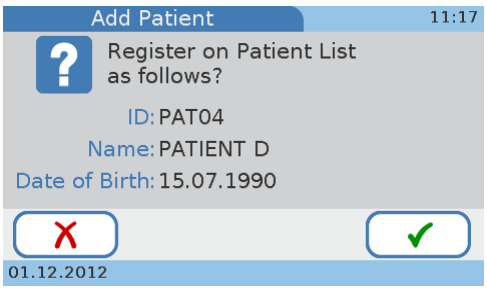
4 Enter the patient name using the keyboard.

5 Choose ✓.



6 Define the date of birth. Use ↑ and ↓ to increase and decrease the values.

7 Choose ✓.



8 Review the information.

Choose ✗ if you need to change the information. Otherwise proceed with step 9.

When choosing ✗ the **Patient ID** screen is displayed again. Make the required changes as described in the previous steps.

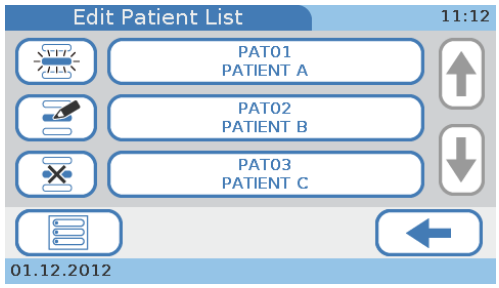
9 Choose ✓ to save the settings and to close the screen.

The **Edit Patient List** screen is displayed again.

■

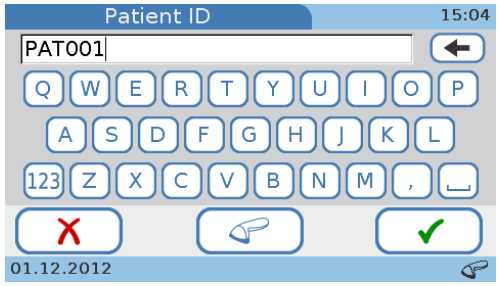
► To change patient information

1 Choose **Setup** > **ID Setup** > **Patient ID** > **Edit Patient List**.



2 Choose one of the patient buttons.

3 Choose .

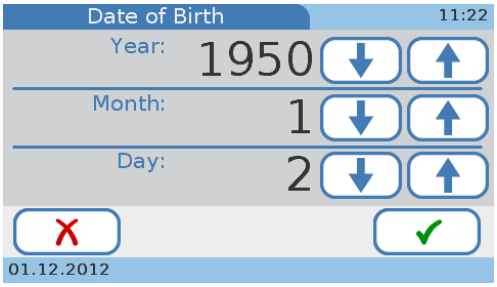


4 To change the patient ID, do one of the following:

If …	Do this
You want to change the ID manually	1. Use ← to delete the current text. Enter the patient ID using the keyboard. 2. Choose ✓. The **Patient Name** screen is displayed.
You want to use the barcode scanner	1. Choose . A screen is displayed, asking you to scan the barcode. 2. Scan the barcode. A screen is displayed for checking the ID. 3. Choose ✓. (If the information is not correct, choose ✗. A screen is then displayed, asking you to scan the barcode again. Scan the barcode again.) The **Patient Name** screen is displayed.

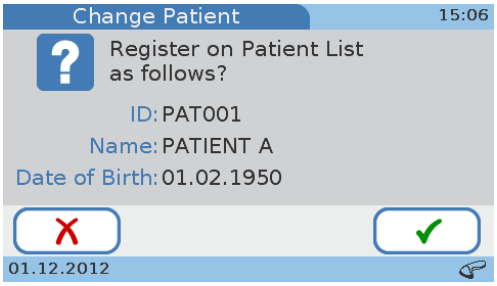
5 Enter the patient name using the keyboard.

6 Choose ✔.



7 Define the date of birth. Use ↑ and ↓ to increase and decrease the values.

The **Change Patient** screen is displayed, which allows you to review the information you entered.



8 Choose ✗ if you need to change the information. Otherwise proceed with step 9.

When choosing ✗ the **Patient ID** screen is displayed again. Make the required changes as described in the previous steps.

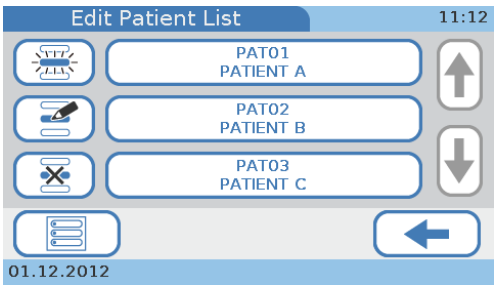
9 Choose ✔ to save the settings and to close the screen.

The **Edit Patient List** screen is displayed again.

■

► To delete patient information

1 Choose **Setup** > **ID Setup** > **Patient ID** > **Edit Patient List**.



2 Choose the button.

3 Choose .

A screen is displayed for confirming the deletion.

4 Choose ✔ to delete this set of patient information.

The **Edit Patient List** screen is displayed again.

■

4.6 Control Settings

☞ **Main Menu** > **Setup** > **Control Settings**.

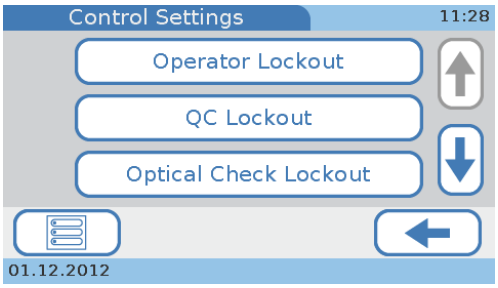


Figure 16 **Control Settings** screen

Use the **Control Settings** functions to define how control results are displayed and what effect results have that are outside the predefined ranges. You can also define your own result ranges.

Separate QC solutions are used for HbA1c tests and the Lipid Panel, and for each two levels are available (Level 1 and Level 2). You can either test both levels in one procedure or test one of the levels at a later stage.

An optical check disc is used to check the functioning of the optical unit.

Use the *Lockout* functions to define how frequently control measurements should be performed. If the results are out of date or outside the defined ranges either the current user or the complete instrument is blocked from performing patient tests until a valid control result is available.

- Use the **Operator Lockout** function to define after what period of time new QC tests must be performed by a specific operator to be able to perform routine patient tests.

  👁 See *Operator Lockout* on page 80.
- Use the **QC Lockout** functions to define after what period of time control results are no longer valid and whether QC tests must be performed when you use a test disc of a new lot. If one of the latest control results is no longer valid, patient test processing is blocked on the instrument until the respective QC test has been performed successfully.

  👁 See *QC Lockout* on page 81.
- Use the **Optical Check Lockout** functions to define whether you want the instrument to check the expiry of optical check control results and if so how frequently.

  👁 See *Optical Check Lockout* on page 82.
- Use the **STAT Test** function to define whether you want to work with STAT tests and if so how many of them can be performed. (You typically use this function when testing is blocked due to no longer valid control results and there is no time to first perform the necessary control tests.)

  If a control test failed, no patient tests can be performed until the control test is successfully completed.

  👁 See *STAT Test* on page 83.
- Use the **QC Result Format** functions to define how the control results are displayed (result values, target value deviation) and whether the target value should be displayed with the results.

  👁 See *QC Result Format* on page 84.

- Use the **QC Range** function to define whether you want to work with the result ranges as defined by the manufacturer of the controls or whether you want to define your own ranges, if the latter is the case you can also define these ranges here.

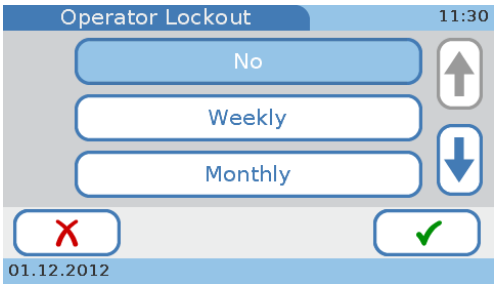
  See *QC Range* on page 85.

4.6.1 Operator Lockout

Use this function to define after what period of time new QC tests must be performed by a specific operator to be able to perform routine patient tests.

► To define how often an operator must perform QC tests

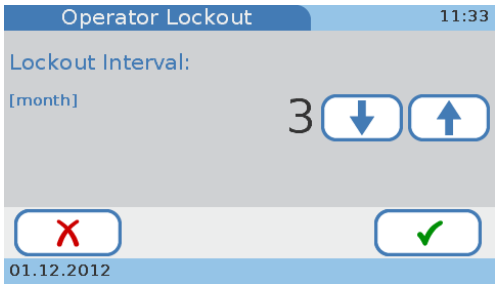
1 Choose **Setup** > **Control Settings** > **Operator Lockout.**



2 Choose one of the buttons.

- Choose **No** if you do not want the instrument to check the expiry of control results.
- Choose **Weekly** if you want the control results to be valid for one week.
- Choose **Monthly** if you want the control results to be valid for one month.
- Choose **Every X Months** if you want the control results to be valid for a specific number of months.

  If you choose this option choose ✓ and a screen for entering the number of months is displayed.



  Define an interval between 1 and 12 months. Use ↑ and ↓ to increase and decrease the values.

3 Choose ✓ to save the settings and to close the screen.

The **Control Settings** screen is displayed again.

■

4.6.2 QC Lockout

Use this function to define after what period of time control results are no longer valid and whether QC tests must be performed when you use a test disc of a new lot. If one of the latest control results is no longer valid, patient test processing is blocked on the instrument until the respective QC test has been performed successfully.

► To define how often QC tests should be performed

1 Choose **Setup** > **Control Settings** > **QC Lockout.**

The **QC Lockout** screen is displayed.

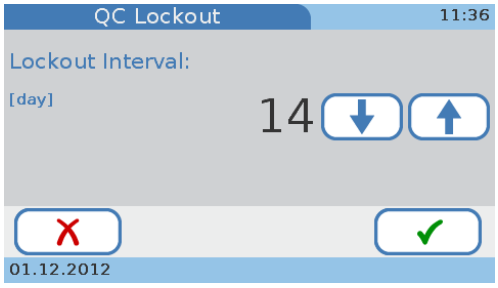
2 Choose **Interval**.

A screen is displayed for defining the period of time after which new QC tests should be performed.

3 Choose one of the buttons.

- Choose **No** if you do not want the instrument to check the expiry of control results.
- Choose **Daily** if you want the control results to be valid for one day.
- Choose **Weekly** if you want the control results to be valid for one week.
- Choose **Monthly** if you want the control results to be valid for one month.
- Choose **Every X days** if you want the control results to be valid for a specific number of days.

  If you choose this option choose ✓ and a screen for entering the number of days is displayed.



  Define an interval between 1 and 60 days. Use ↑ and ↓ to increase and decrease the values.

4 Choose ✓ to save the settings and to close the screen.

The **Control Settings** screen is displayed again.

■

► To define whether QC tests should be performed when using a test disc of a new lot

1 Choose **Setup** > **Control Settings** > **QC Lockout.**

The **QC Lockout** screen is displayed.

2 Choose **New Lot**.

The **QC Lockout New Lot** screen is displayed.

3 Choose either **HbA1c** or **Lipid**.

4 Choose one of the buttons.

Choose **Disabled** if you do not want that a QC test must be performed when using a disc of a new lot.

Choose **Enabled** if you want that a QC test must be performed when using a disc of a new lot.

5 Choose ✔ to save the settings and to close the screen.

The **QC Lockout New Lot** screen is displayed again.

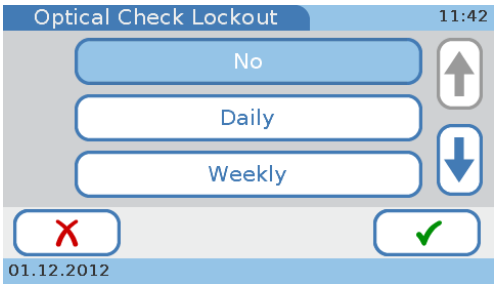
■

4.6.3 Optical Check Lockout

Use this function to define whether you want the instrument to check the expiry of optical check results and if so how frequently.

► **To define how to use optical check control results**

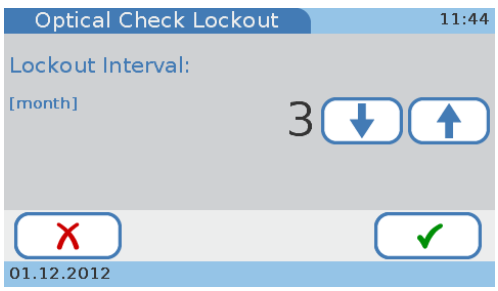
1 Choose **Setup** > **Control Settings** > **Optical Check Lockout**.



2 Choose one of the buttons.

- Choose **No** if you do not want the instrument to check the expiry of optical check results.
- Choose **Daily** if you want the optical check results to be valid for one day.
- Choose **Weekly** if you want the optical check results to be valid for one week.
- Choose **Monthly** if you want the optical check results to be valid for one month.
- Choose **Every X Months** if you want the optical check results to be valid for a specific number of months.

  If you choose this option choose ✔ and a screen for entering the number of months is displayed.



Define an interval between 1 and 12 months. Use ↑ and ↓ to increase and decrease the values.

3 Choose ✔ to save the settings and to close the screen.

The **Control Settings** screen is displayed again.

■

4.6.4 STAT Test

STAT (short turn around time) tests are tests that are performed in situations of operator or QC lockout, i.e. when QC results are not or no longer valid and there is no time to perform the necessary control tests first.

Use this function to define whether you want to work with STAT tests and if so how many of them can be performed.

WARNING

Incorrect results due to expired quality control results

Quality control measures are performed to ensure that the instrument and your technique used in testing give accurate results of patient tests.

Performing patient tests when the current control test results are not or no longer valid may lead to incorrect patient results.

- Do not perform patient tests with invalid quality control except in emergencies.
- Always perform control tests as soon as they are due.

In the following situations STAT tests are not available:

- When the optical check test has failed neither HbA1c nor lipid patient tests are available.
- When the HbA1c QC test has failed, HbA1c STAT tests are not available.
- When the Lipid QC test has failed, lipid STAT tests are not available.

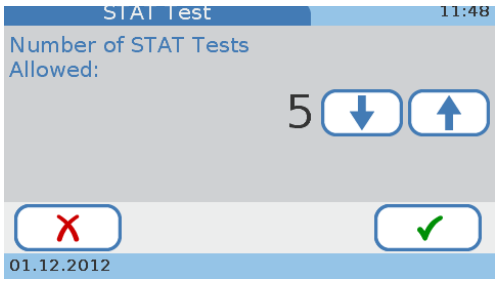
► To define how to use STAT tests

1 Choose **Setup** > **Control Settings** > **STAT Test**.

2 Choose one of the buttons.

- Choose **Disabled** if you do not want to use STAT tests.
- Choose **Enabled** if you want to allow STAT tests.

  If you choose this option choose ✔ and a screen is displayed for entering the number of STAT tests you want to be able to perform, even if patient testing is blocked.



Define a value between 1 and 9. Use ↑ and ↓ to increase and decrease the values.

With each test that is performed, the counter is decreased by one, regardless who is logged on as operator.

3 Choose ✔ to save the settings and to close the screen.

The **Control Settings** screen is displayed again.

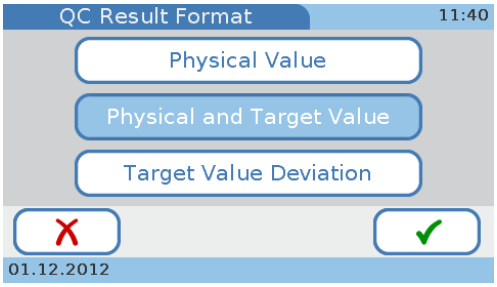
■

4.6.5 QC Result Format

Use this function to define how the control results are displayed (result values, target value deviation) and whether the target values should be displayed with the results.

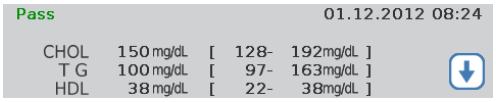
► **To define how control results should be displayed**

1 Choose **Setup** > **Control Settings** > **QC Result Format**.

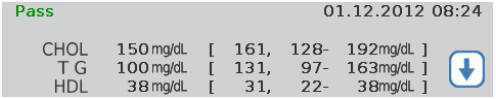


2 Choose a button from the list.

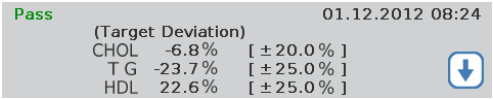
- Choose **Physical Value** if you want the results to show the actually measured value and the defined range.



- Choose **Physical and Target Value** if you want the results to include the actually measured value, the target value, and the defined range.



- Choose **Target Value Deviation** if you want the results to show the deviation (percentage) from the target values and the allowed range (percentage).



The **Pass** or **Fail** information is always displayed, even if you do not choose any of the buttons.

3 Choose ✔ to save the settings and to close the screen.

The **QC Result Format** screen is displayed again.

■

4.6.6 QC Range

Use this function to define whether you want to work with the result ranges as defined by the manufacturer of the controls (**Default Range**) or whether you want to define your own ranges (**Custom Range**), if the latter is the case you can also define these ranges here.

You can only change the ranges within the limits defined in the respective QC info disc.

► To define the range for HbA1c tests

1 Choose **Setup** > **Control Settings** > **QC Range**.

A screen is displayed for choosing the test type.

2 Choose **HbA1c**.

3 Define whether to work with the manufacturer's ranges or with your own.

- If you want to work with the result ranges as defined by the manufacturer of the controls, chose **Default Range** and then ✔.

  A screen for selecting the test is displayed.

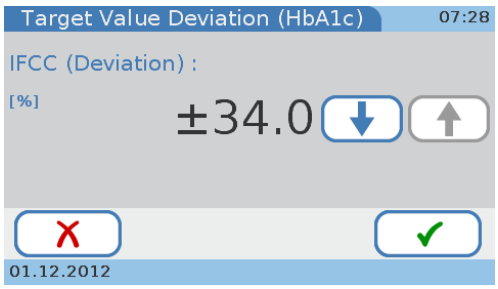
  Choose a test and continue with step 4.

or

- If you want to adjust the ranges, chose **Custom Range** and then ✔.

  A screen for selecting a test is displayed.

  Choose a test and then ✔.



Define the deviation using ↑ and ↓ to increase and decrease the percentage.

4 Choose ✔ to save the settings and to close the screen.

The **QC Range** screen is displayed again.

■

► To define the range for lipid tests

1 Choose **Setup** > **Control Settings** > **QC Range**.

A screen is displayed for choosing the test type.

2 Choose **Lipid**.

3 Define whether to work with the manufacturer's ranges or with your own.

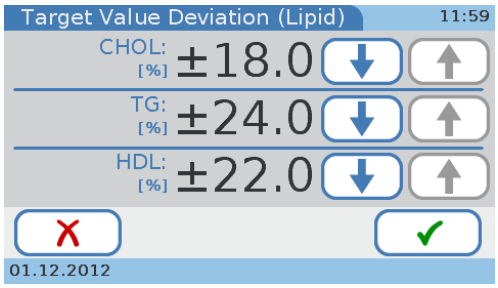
- Choose **Default Range** to define that you want to work with the result ranges as defined by the manufacturer of the controls.

  Continue with step 4.

or

- Choose **Custom Range** to adjust the ranges.

  Choose ✓.



Adjust the deviations using ↑ and ↓ to increase and decrease the percentages.

4 Choose ✓ to save the settings and to close the screen.

The **QC Range** screen is displayed again.

■

4.7 Screen setup

☞ **Main Menu** > **Setup** > **Screen**.

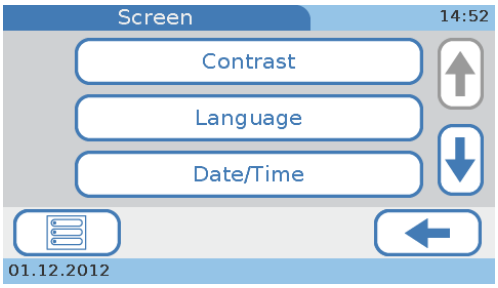


Figure 17 **Screen Setup** screen

Use ↑ and ↓ to display buttons that cannot currently be seen.

The following buttons are available:

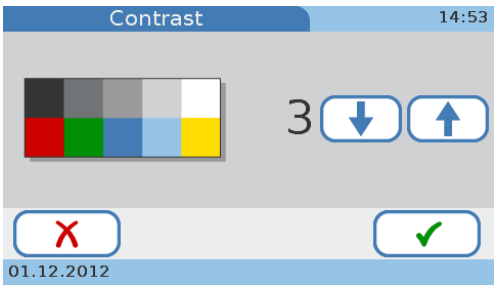
- Use **Contrast** to adjust the display to your ambient light condition to make it easier to read.
- Use **Language** to set of language you want to work in.
- Use **Date/Time** to define the formats in which date and time are displayed and to set the current date and time.
- Use **Facility Information** to record any information about your institution (practice, laboratory etc.) that you want to be displayed with the result printouts.
- Use **Touch Screen Calibration t**o make sure that choosing a button on screen actually initiates the function associated with this button.

4.7.1 Adjusting the screen contrast

Use this function to adjust the display to your ambient light conditions to make it easier to read.

► **To adjust the contrast**

1 Choose **Setup** > **Screen** > **Contrast**.



2 Use ↑ and ↓ to increase and decrease the contrast respectively. There are five levels available.

3 Choose ✓ to confirm the change and to close the screen.

■

4.7.2 Choosing the language

The instrument is delivered with a set of languages, you can work with any of these. Additional languages may be available from Roche, you can use these as soon as you have installed them on the instrument. (See *Language Update* on page 55.)

► To choose the language

1 Choose **Setup** > **Screen** > **Language**.

The **Language** screen is displayed.

The language name is displayed in its native spelling.

2 Choose the button that displays the language you want to use.

Use ↑ and ↓ to display buttons that cannot currently be seen.

3 Choose ✓ to confirm the change and to close the screen.

■

4.7.3 Setting the date

To set the current date you first choose the format in which the date should be displayed, then you set the date.

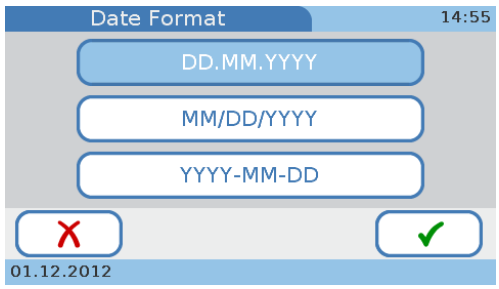
When you switch on the instrument for the first time, the screens for defining the date format and the date itself are automatically displayed. You need to define both.

You can change these settings later.

► To select the date format

1 Choose **Setup** > **Screen** > **Date/Time** > **Date Format**.

The **Date Format** screen is displayed.



Example for the **DD.MM.YYYY** format: 01.12.2012 (1 December 2012).

Example for the **MM/DD/YYYY** format: 12/01/2012 (1 December 2012).

Example for the **YYYY-MM-DD** format: 2012-12-01 (1 December 2012).

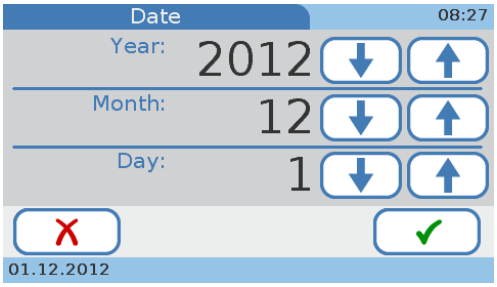
2 Choose the format you want to use.

3 Choose ✓ to confirm the change and to close the screen.

■

► **To define the date**

1 Choose **Setup** > **Screen** > **Date/Time** > **Date**.



2 Use ↑ and ↓ to increase and decrease the values.

3 Choose ✓ to confirm the change and to close the screen.

■

4.7.4 Setting the time

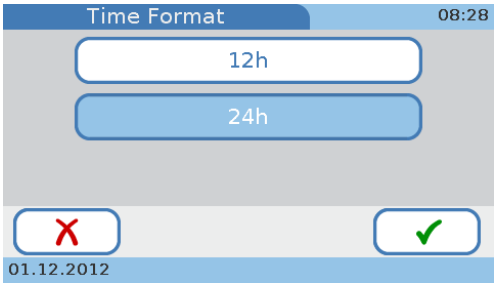
To set the current time you first choose the format in which the time should be displayed, then you set the time.

When you switch on the instrument for the first time, the screens for defining the time format and the time itself are automatically displayed. You need to define both.

You can change these settings later.

► **To select the time format**

1 Choose **Setup** > **Screen** > **Date/Time** > **Time Format**.



Example for the **12h** format: 01:30 pm.

Example for the **24h** format: 13:30.

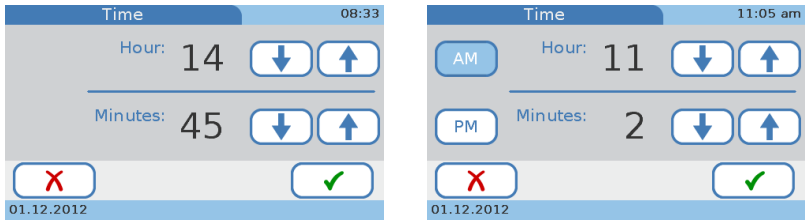
2 Choose the format you want to use.

3 Choose ✓ to confirm the change and to close the screen.

■

► To define the time

1 Choose **Setup** > **Screen** > **Date/Time** > **Time**.



2 Use ↑ and ↓ to increase and decrease the values. For the 12 hour format, make sure to choose **AM** or **PM** correctly.

3 Choose ✓ to confirm the change and to close the screen.

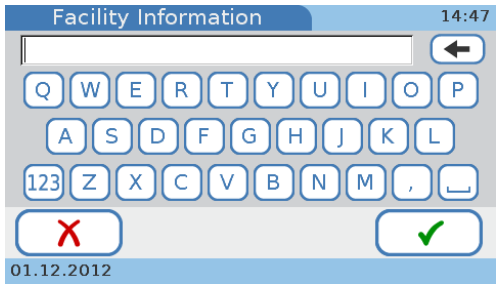
■

4.7.5 Writing facility information

Use this function to record any information about your facility (practice, laboratory etc.) that you want to have displayed with the result printouts. You can enter up to 60 characters.

► To enter facility information

1 Choose **Setup** > **Screen** > **Facility Information**.



2 Use the keyboard to enter the information. Use the 123 button to switch to the numeric keyboard for entering numbers. Use the ABC button to return to the alphabetic keyboard. Use ← to delete the last character in the data entry box.

3 Choose ✓ to save the text and to close the screen.

■

4.7.6 Calibrating the touch screen

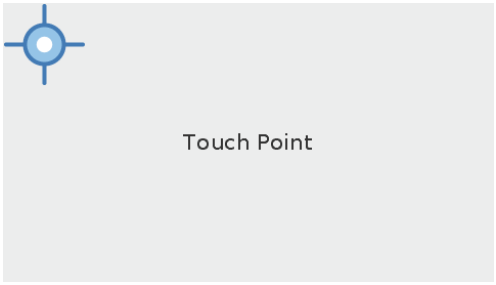
Use this function to make sure that choosing a button on screen actually initiates the function associated with this button.

When you switch on the instrument for the first time, the screens for calibrating the touch screen are automatically displayed.

► To calibrate the touch screen

1 Choose **Setup** > **Screen** > **Touch Screen Calibration**.

The first screen of the calibration wizard is displayed.



2 Follow the instructions on screen.

When touching the point, make sure to touch it exactly in the center of the target symbol.

You are asked to confirm completion of the calibration.

3 Choose ✓ to confirm completion, save the settings, and to close the screen.

■

5 Testing samples

5.1 What you need

- ☐ **cobas b** 101 system.
- ☐ **cobas** HbA1c Test or **cobas** Lipid Panel disc.
- ☐ Single-use only disposable blood lancets, e.g. Accu-Chek Safe-T-Pro Plus.
- ☐ Pipette or capillary tube with plunger if you take sample from a blood collection tube.

  For HbA1c tests use pipettes with a pipetting volume of at least 2.0 µL, for lipid tests with a volume of at least 19.0 µL.
- ☐ External printer (if you want to print the results).
- ☐ Handheld barcode scanner (if you want to read operator or patient information from barcodes).
- ☐ Powder-free gloves.
- ☐ Cotton balls and alcohol wipes.

5.2 Important notes regarding blood testing

WARNING

Protection against infection

There is a potential risk of infection. Operators of the **cobas b** 101 system must be aware that any object coming into contact with human blood is a potential source of infection.

- Use gloves.
- Use single-use only disposable blood lancets.
- Dispose of used lancets in a sturdy sharps container with lid.
- Dispose of used test discs according to your facility's infection control policy.
- Follow all health and safety regulations in force locally.

5.2.1 Always …

Make sure the following conditions are met before and during performing tests:

- The ambient temperature must be between +15°C and +32°C (59 to 90°F).

  Do not operate an air conditioning system near the instrument.

  Do not place the instrument near another heat emitting device.
- The ambient relative humidity must be between 10% and 85% non condensing.

  Do not operate a humidifier or dehumidifier near the instrument.
- The ambient environment must not contain high levels of dust.
- The instrument must be placed on a level (maximum 3 degrees incline), stable surface (table).
- Do not knock or move the instrument during processing.
- For correct handling of test discs, follow the information contained in the package insert.

- If the test discs are stored in a refrigerator, they must be kept—in their sealed foil pouch—at an ambient temperature between +15 °C and +32 °C (59 °F and 90 °F)) for at least 20 minutes before being used for performing tests.
- Apply blood to the disc immediately after lancing.
- Use a disc within 20 minutes of opening its pouch.
- The turntable, its surroundings, and the touch screen must be clean.

5.2.2 Never …

Observe the following precautions:

- Do not disconnect the power supply or switch off the instrument while the instrument is processing.
- Do not disconnect the printer, computer, or BUH while the instrument is processing a test or performing other activities such as printing or transferring data.
- Do not take blood from a patient who has wet hands (residues of water, sweat, hand cream, alcohol).

CAUTION

Accuracy and precision of measured results

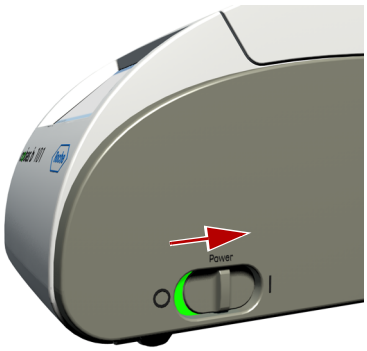
Failure to comply with the above precautions may lead to inaccurate results, which in turn may influence the result interpretation by the health care professional.

5.3 Preparing the instrument

5.3.1 Starting the instrument

► **To start the instrument**

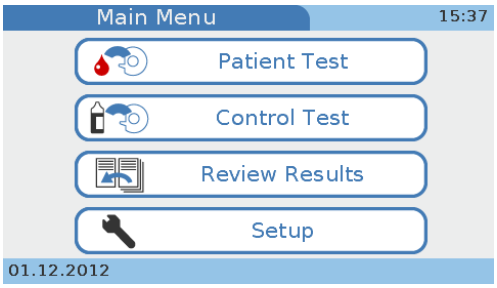
1 Switch on the instrument.



The instrument automatically performs self-tests and warm-up.

If an error message is displayed, note its ID and refer to section *Error messages* on page 159.

When they are successfully completed the **Main Menu** is displayed.



■

5.3.2 User identification

The instrument can be set up so that users must log on (enter identification information) before they can use the instrument. This is done to restrict access to the instrument.

The following identification functions are available:

- Operator ID
  See *Edit Operator List* on page 64.
- Operator name
  See *Edit Operator List* on page 64.
- User role (authority)
  See *Edit Operator List* on page 64.
- Password
  See *Password Entry* on page 62 and *Password Expiry* on page 62.

► To log on

1 You are automatically presented with the appropriate logon screens as soon as you choose one of the buttons. Which ones they are and which information you need to supply depends on the instrument setup.

2 Enter the logon information as requested.

Which screen is displayed now depends on which button you chose at the beginning.

■

5.4 Preparing the sample

5.4.1 Getting a good capillary blood sample

To get a suitable drop of blood:

- Use single-use only disposable blood lancets.
- Warm the hand. Have the patient hold it under his or her arm or use a hand warmer.
- Wash your hands with soap to remove fatty substances. Warm water helps to stimulate the blood flow. Rinse the fingers extensively to remove all traces of soap. Dry your hands.

  (Hand cream and soap might contain substances such as glycerides, glycerol and ethylene glycol, which can result in false high triglyceride results.)
- Have the patient let that arm hang down by his or her side before lancing a finger.
- Choose an area on the side of the middle or ring finger of either hand and disinfect it with an alcohol wipe (i.e. 70% Isopropanol or Ethanol, emollient free!) and dry with a clean swab or paper tissue.
- Immediately after lancing, skim the finger smoothly from the palm's end towards 1 cm before the puncture site several times to obtain a good drop of blood. Wipe off this first drop of blood, as it may contain tissue fluid, then obtain another drop of blood in the same way.
- Immediately apply the drop of blood directly to the suction point of the test disc.
- Wipe the puncture site with a clean swab or paper tissue. If bleeding continues, slightly press on the puncture site and cover it with a protective plaster.

For details on obtaining a blood sample, see *To use a fingerstick* on page 111.

For an overview of performing a test, see *Short guide* on page 97.

CAUTION

When washing or disinfecting the patient's finger, allow it to dry thoroughly. Residues of water or disinfectant on the skin can dilute the drop of blood and so produce false results. Residues of hand cream on skin influence the triglyceride results.

5.4.2 Getting a good result from venous blood or plasma samples

Instead of performing a test with capillary blood you can use venous whole blood or plasma sample.

Always use venous blood and plasma with anticoagulant as stated in the respective method sheet of the test.

CAUTION

Incorrect results due to using inappropriate anticoagulants

Using inappropriate anticoagulants may interfere with the reagents and lead to incorrect results.

- Only use anticoagulants or other additives that are stated in the method sheet of the respective test.

5.5 Performing patient tests

CAUTION

Keep the lid closed and in place while the instrument is operating.

Only open the lid when instructed to do so or when the instrument is switched off.

CAUTION

Incorrect results due to wrong liquid

Make sure you use patient sample and not control solution.

NOTICE

Wear powder-free gloves while operating the **cobas b** 101 system instrument. (Powder may adversely affect the optical unit in the instrument or the disc.)

Due to the possible difference between the internal clock and local time (time zones), the actual disc expiry dates can vary to beyond the date printed on the pouch.

The following procedures depend on whether you work with or without operator IDs.

- For information on the effect of the various operator ID definitions, see Figure 13 on page 57.
- For information on the effect of the various patient ID definitions, see Figure 15 on page 70.
- For a detailed procedure when working *without* operator and patient information, see *Performing a test (no operator and patient information, single testing)* on page 116.
- For a detailed procedure when working *with* operator and patient information, see *Performing the tests (with operator and patient information, dual testing)* on page 118.

5.5.1 Short guide

The following table provides an overview of how to perform a single mode patient test with capillary blood.

For details on individual steps, see the subsequent sections.

Step	Task		Procedure, comment
1	Precondition the discs.	  20 min  15 to 32°C (59 to 90°F)	1. Discs must have a temperature between +15 °C and +32 °C (59 °F and 90 °F) when being used. If you store them in a refrigerator, remove them from the refrigerator at least 20 minutes before you want to use them.

Table 12 Short guide for performing a single mode patient test (capillary blood)

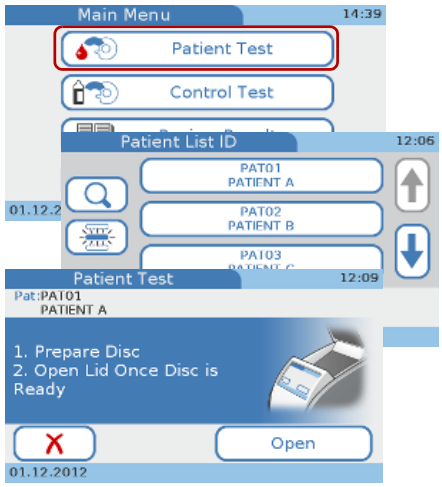
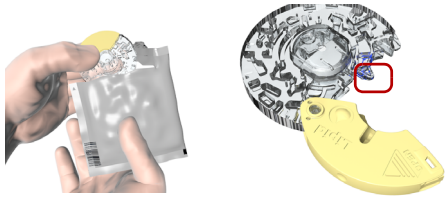
Step	Task		Procedure, comment
2	Start the test on the instrument.		1. Choose **Main Menu** > **Patient Test**. 2. If you are asked to provide an operator ID and possibly a password, enter them. 3. If you are asked to provide patient information (e.g. a patient ID), enter it. When the instrument is ready to perform the test you are asked to prepare the disc and to open the lid. For details on using operator information, see *Using operator information* on page 102. For details on using patient information, see *Using patient information* on page 106.
3	Prepare the disc.		1. Tear open the pouch at the notch on the edge of the foil pouch. Make sure to open the whole length of the pouch so the disc can easily be removed.
4	Remove the disc from the pouch and open it.		1. Remove the disc from its pouch and place it on a clean surface. Make sure not to touch the suction point and the transparent surfaces.

Table 12 Short guide for performing a single mode patient test (capillary blood) (Continued)

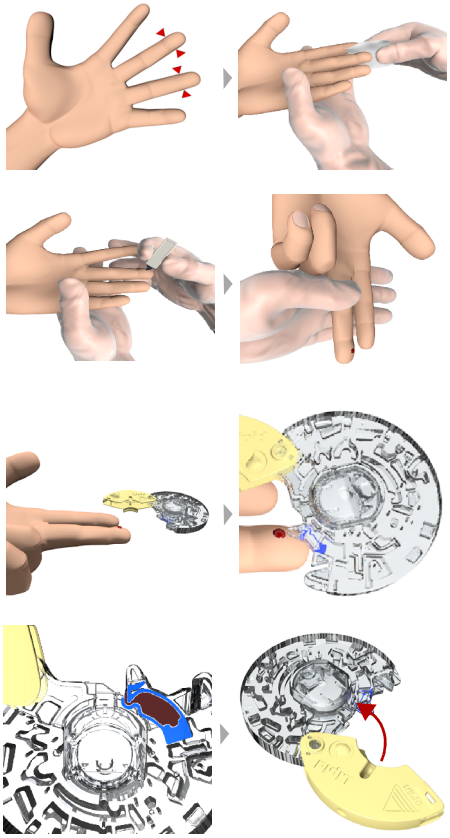
Step	Task		Procedure, comment
5	Apply a fingerstick and transfer the capillary blood to the disc		1. Wash the hands with soap. Rinse the fingers extensively, then dry them thoroughly. 2. Choose an area on the side of the middle or ring finger of either hand 3. Clean the chosen area with an alcohol wipe (i.e. 70% Isopropanol or Ethanol, emollient free!), then dry it with a clean swab or paper tissue. 4. Firmly prick the chosen area with a lancet. 5. Skim the finger smoothly from the palm's end up to 1 cm before the puncture site several times to obtain a large drop of blood. Wipe off this first drop of blood, as it may contain tissue fluid. Squeeze the finger gently again until a second large drop of blood forms. 6. With the imprinted side of the disc facing upwards, position the disc's suction point above the drop of blood. 7. Apply blood and observe that it has filled the marked area. Check the sample volume: turn the disc on its backside. The area marked in blue has to be filled completely with blood. 8. Press the hinge cover down firmly to close the disc. 9. Ensure that the disc is free from blood outside the sample application zone and the hinge cover. 10. Wipe the puncture site with a clean swab or paper tissue. If bleeding continues, slightly press on the puncture site and cover it with a protective plaster.
6	Insert the disc in the instrument		1. Open the lid of the instrument. 2. Place the disc on the turntable. Make sure to have the imprinted side up and not to touch the transparent surfaces. 3. Close the lid. The instrument automatically starts processing the test.

Table 12 Short guide for performing a single mode patient test (capillary blood) (Continued)

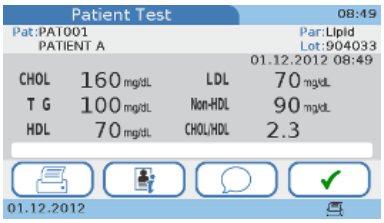
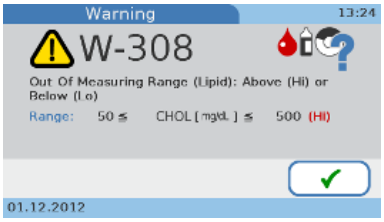
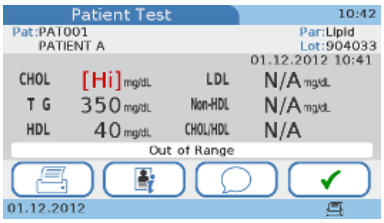
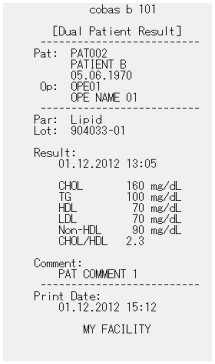
Step	Task		Procedure, comment
7	Review the results		When the test is complete, the results are displayed on screen. The possible actions that follow depend on the instrument setup. For details on reviewing patient results, see *Reviewing patient results* on page 138.
	Enter a comment		1. Choose . 2. Choose one of the predefined comment buttons or define a new one. 3. Choose ✔ to accept the comment. For details on defining comments, see *Adding comments to results* on page 120 4. Choose ✔ to accept the result.
	Exceptional situations		If the result is outside a range a message is displayed.
			When you confirm this message, the result screen is displayed.
		[Hi]	The result in the chosen measuring unit is above the accepted range.
		[Lo]	The result in the chosen measuring unit is below the accepted range.
			The result is above the user defined range.
			The result is below the user defined range.
8	Print the results		If your instrument is connected to an external printer you can now print the results. 1. Choose . The result is printed using a predefined layout. You cannot alter this.

Table 12 Short guide for performing a single mode patient test (capillary blood) (Continued)

Step	Task		Procedure, comment
9	Remove the disc from the instrument and dispose of it		1. Choose **Open**. 2. Remove the disc and dispose of it in accordance with the regulations that apply to your facility. 3. Close the lid.

Table 12 Short guide for performing a single mode patient test (capillary blood) (Continued)

5.5.2 Single testing vs. dual testing

The instrument offers two testing modes: single and dual testing. Single testing allows measuring one disc at a time, either the HbA1c or the Lipid disc. Dual testing allows measuring an HbA1c and a Lipid disc immediately following each other with all results displaying after the second test.

For details on setting up the test mode, see *Dual Test* on page 42.

	Single testing	Dual testing
1	Prepare the disc.	
2	Apply a fingerstick.	
3	• Transfer the sample to the disc. • Insert the disc in the instrument and close the lid. The instrument starts testing automatically.	• Transfer the sample first to the Lipid then to the HbA1c disc. • Insert the HbA1c disc in the instrument immediately after applying sample and close the lid. The instrument starts testing automatically. • When the test is complete, remove the HbA1c disc and insert the Lipid disc. The instrument starts testing automatically.
4	Review and print the results.	
5	Remove the disc.	

Table 13 Single vs. dual testing

- Testing of discs must start immediately after applying the sample.
- In the case of dual testing, testing of the Lipid disc must start as soon as the HbA1c test is complete.

5.5.3 Using operator information

Test procedures depend on whether your instrument is configured to work with or without operator and patient information, and also on the test mode (single or dual testing).

For details on defining operator information, see *ID setup* on page 56 ff.

Working with operator information has the following purpose:

- Each test result is identified by the ID and name of the operator who has performed the test. This may be a legal requirement for result archiving purposes.
- You can limit instrument access to specifically trained persons.
- You can specify certain users for setup and maintenance of the instrument.

For the operator, the main consequence of working with user information is the fact that they have to identify themselves (enter the operator ID and possibly password) before they can use the instrument.

The instrument offers several ways of entering your operator information:

- You can use the on-screen keyboard for entering all information (ID, password).
  See *To enter your operator information using the barcode scanner* on page 104.

- You can use the handheld barcode scanner to enter your operator ID.

  This function speeds up information entry and prevents input errors. It is particularly suitable for environments where barcodes are generally used, e.g. on patient records.

  See *To enter your operator information using either the keyboard or the scanner* on page 105.

- You can use a list of predefined users (**Edit Operator List**) to enter your operator ID and name.

  This function is designed to make the ID entry easy.

  See *To enter your operator information using the operator list* on page 105.

For security reasons, passwords can only be entered using the keyboard.

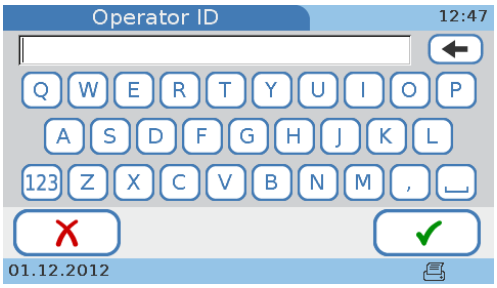
► To enter your operator information using the keyboard

The following procedure is based on the assumption that you work with operator IDs and passwords. If you do not work with passwords, the respective screens are not displayed.

1 On the **Main Menu**, choose any button.

A screen for entering your operator ID is displayed.

2 Enter your operator ID.



Use 123 to display the numeric keyboard and ABC to display the alphabetic keyboard.

3 Choose ✓.

A screen is displayed for entering your password.

4 Enter your password.

Choose ✓.

Which screen is displayed now depends on the button you chose in step 1.

5 You can now proceed to work with the instrument.

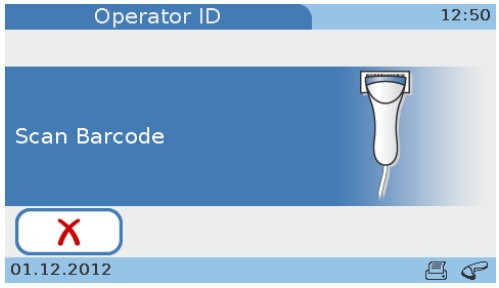
■

► To enter your operator information using the barcode scanner

The following procedure is based on the assumption that you work with operator IDs and passwords. If you do not work with passwords, the respective screens would not be displayed.

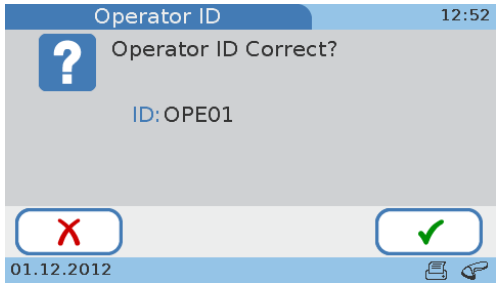
1 On the **Main Menu**, choose any button.

A screen for entering your operator ID is displayed.



2 Scan your operator ID.

A screen is displayed that shows the ID.



3 Check the ID and choose ✓.

If the information is not correct, choose ✗, and you can scan it again. If the information is still not correct, see *Troubleshooting* on page 155.

A screen for entering your password is displayed.

4 Enter your password.

Choose ✓.

Which screen is displayed now depends on the button you chose in step 1.

5 You can now proceed to work with the instrument.

■

► To enter your operator information using either the keyboard or the scanner

The following procedure is based on the assumption that you work with operator IDs and passwords and that a barcode scanner is connected the instrument. If you do not work with passwords, the respective screens are not displayed.

1 On the **Main Menu**, choose any button.

A screen is displayed asking you to scan the barcode.

2 Do one of the following:

- Scan the barcode using the handheld barcode scanner.
  See *To enter your operator information using the barcode scanner* on page 104.
- Choose ✗ and enter the ID using the keyboard.
  See *To enter your operator information using the keyboard* on page 103.

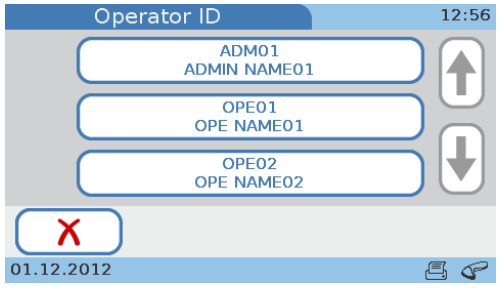
■

► To enter your operator information using the operator list

- The following procedure is based on the assumption that you work with operator IDs and passwords. If you do not work with passwords, the respective screens are not displayed.
- To be able to use the operator list at least one operator must be defined.

1 On the **Main Menu**, choose any button.

A list is displayed for selecting your operator ID.



Use ↑ and ↓ to display your button if you cannot see it.

2 Choose the button that contains your operator ID.

A screen is displayed for entering your password.

3 Enter your password.

Choose ✓.

Which screen is displayed now depends on the button you chose in step 1.

4 You can now proceed to work with the instrument.

■

5.5.4 Using patient information

Your instrument can be set up to work without patient information, to optionally work with or without patient information, or to make patient information mandatory. You can also configure how you want to enter this information: using the keyboard, the barcode scanner, or a list of predefined patient information.

For information on how to set up patient information handling, see
Patient ID setup on page 69
Logical overview of using the Patient ID functions on page 70
To determine how to define patient information on page 72

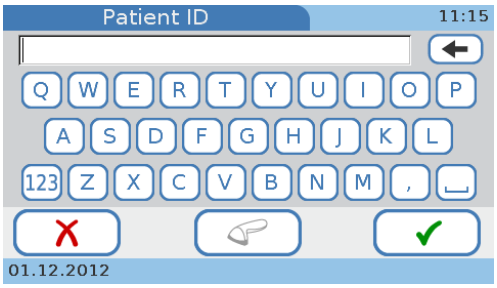
Typically, patient information is added when you start the test. If patient information is optional, you can enter it either when you start the test or add it to the results later.

- If you work without patient information, the instrument automatically assigns an ID to each result.
- You can always add patient information to a result, irrespective of the patient ID definitions. See *Adding patient information to results* on page 142.
- Patient information always includes the patient ID. Depending on the instrument setup, the patient name and the date of birth may be included as well.

The following procedures assume that you work with patient ID, name and date of birth. If you do not work with name or date of birth, the corresponding screens would not be displayed.

► To enter patient information using the keyboard

1 Choose **Patient Test**.



If patient information is optional you can choose ✗ and add the ID to the result later, if required. See *Adding patient information to results* on page 142.

2 Enter the ID.

3 Choose ✓.

The **Patient Name** screen is displayed.

4 Use the keyboard to enter the name and choose ✓.

The **Date of Birth** screen is displayed.

5 Adjust the values using ↑ and ↓ to increase and decrease the values, then choose ✓.

The **Patient Information** screen is displayed, which contains all patient information.

6 Choose ✗ if you need to change the information. Otherwise proceed with the next step.

When choosing ✗ the **Patient ID** screen is displayed again. Make the required changes as described in the previous steps.

7 Choose ✓ to save the settings and to close the screen.

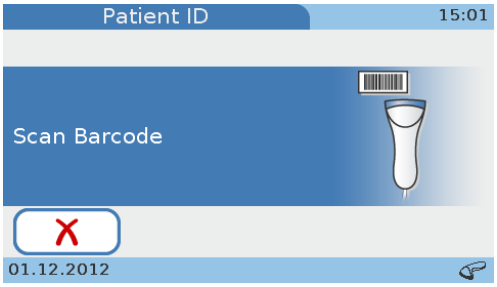
The patient information will be contained in result screen.

8 Continue with the test.

■

► To enter patient information using the barcode scanner

1 Choose **Patient Test**.



If patient information is optional you can choose ✗ and add it to the result later, if required. See *Adding patient information to results* on page 142.

2 Scan the patient barcode.

The **Patient Name** screen is displayed.

3 Use the keyboard to enter the name.

4 Choose ✓.

The **Date of Birth** screen is displayed.

5 Adjust the values using ↑ and ↓ to increase and decrease the values.

6 Choose ✓.

The **Patient Information** screen is displayed, which contains all patient information.

7 Choose ✗ if you need to change the information. Otherwise proceed with the next step.

When choosing ✗ the **Patient ID** screen is displayed again. Choose , scan the patient barcode and make the required changes as described in the previous steps.

8 Choose ✓ to save the settings and to close the screen.

The patient information will be contained in result screen.

9 Continue with the test.

■

► To enter patient information using either the keyboard or the scanner

The following procedure is based on the assumption that you work with patient name and date of birth. If you do not work with patient name or date of birth, the respective screens would not be displayed.

1 Choose **Patient Test**.

A screen is displayed asking you to scan the barcode.

2 Do one of the following:

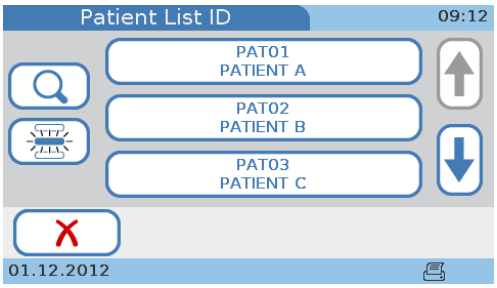
- Scan the barcode using the handheld barcode scanner.
  See *To enter patient information using the barcode scanner* on page 107.
- Choose ✗ and enter the ID using the keyboard.
  See *To enter patient information using the keyboard* on page 106.

■

► To enter patient information using the patient list

To use the patient list, at least one patient must be defined.

1 Choose **Patient Test**.



If patient information is optional you can choose ✗ and add it to the result later, if required. See *Adding patient information to results* on page 142.

2 Do one of the following:

- Choose a patient from the list.

or

- To search for a particular patient, choose 🔍, type the first few characters of the patient name or ID, choose ✓, and then choose the patient from the list.

The **Patient Information** screen is displayed, which contains all patient information that is defined in the patient list for this particular patient.

3 Choose ✗ if you need to change the information. Otherwise proceed with the next step.

When choosing ✗ the **Patient List ID** screen is displayed again. Choose the appropriate patient button.

4 Choose ✓ to save the settings and to close the screen.

The patient information will be contained in result screen.

5 Continue with the test.

■

5.5.5 If the control results are no longer valid

If your instrument is configured to check the validity of control results (see *Operator Lockout* on page 80 and *QC Lockout* on page 81) you may not be able to perform patient tests.

You can see this on the **Main Menu**:

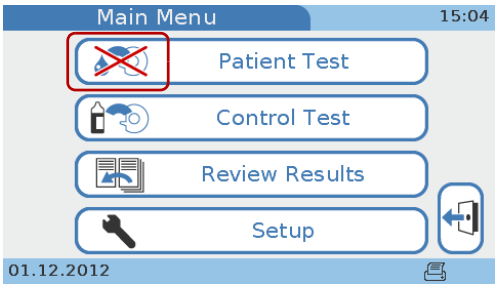


Figure 18 **Main Menu** with locked **Patient Test** function

If you choose **Patient Test,** a message will inform you that you cannot proceed.

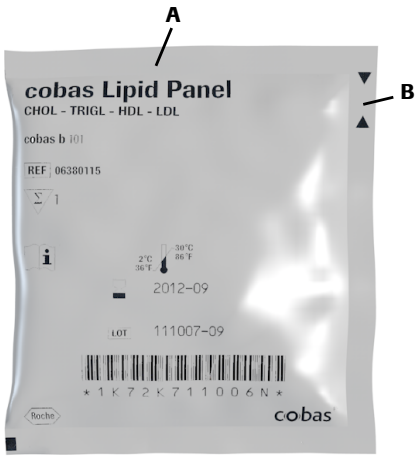
See *Operator and QC lockout (the control results are no longer valid)* on page 156.

5.5.6 Preparing a disc

- If the test discs are stored in a refrigerator, they must be kept—in their sealed foil pouch—at an ambient temperature between +15 °C and +32 °C (59 °F and 90 °F) for at least 20 minutes before being used for performing tests.
- Do not open the foil pouch during this warming up period.
- Do not affix any labels to the disc, this may interfere with testing mechanisms.
- Do not try to disassemble the disc.

► To prepare a disc

1 Take a disc that has been stored at an ambient temperature between +15 °C and +32 °C (59 °F and 90 °F) for at least 20 minutes.



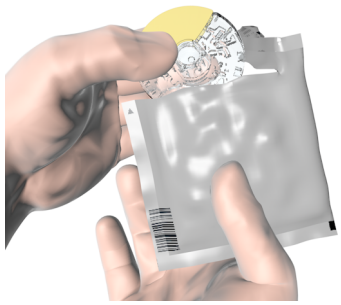
The type of disc (HbA1c, Lipid) is indicated on the foil (A).

2 Inspect the unopened foil pouch for tears and punctures.

Do not use a disc from a damaged pouch.

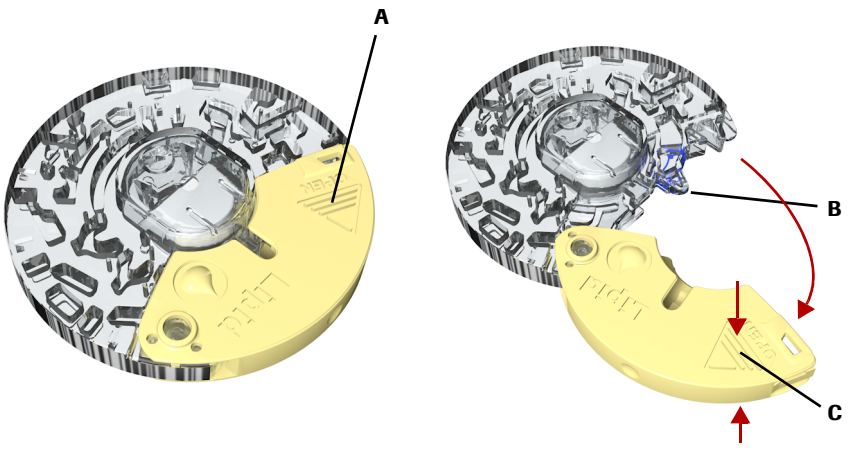
3 Tear open the pouch at the notch on the edge of the foil pouch (B).

4 Remove the test disc from the pouch holding the hinge cover of the disc with thumb and forefinger or thumb and middle finger.



- Make sure not to touch the transparent surfaces of the test disc. Roche recommends to always place the disc in a pouch when it is not currently being used, even for small periods of time and also after it has been used.
- Make sure to place the disc on a clean surface only.
- If you drop the unpacked disc, do not use it, dispose of it and use a new disc.
- Do not place the disc in direct sunlight. For details, see its package insert.
- You must use the disc within 20 minutes after opening the pouch. For details, see its package insert.

5 Open the hinge cover.



Hold the hinge cover with two fingers at the position of the arrow (A) and open the hinge cover to the maximum opening angle. You experience a click when it is properly opened.

- Do not open the hinge cover to more than the maximum opening angle by applying excess force, and do not grip the hinge cover too tightly with your two fingers (C); the hinge cover may come off.
- Do not close the hinge cover before applying blood sample. Once the hinge cover has been closed it cannot be opened again. Do not use force to open it again.
- Do not contaminate the suction point (B).

■

Do not refrigerate a test disc once its pouch has been opened.

5.5.7 Using a fingerstick

This task is only required if you test capillary blood.

CAUTION

Use single-use only disposable blood lancets. Follow the manufacturer's instructions for the device.

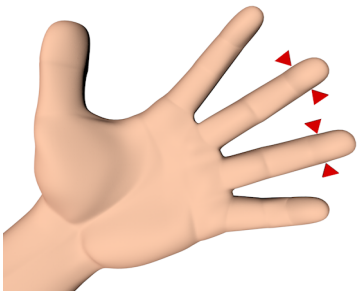
► To use a fingerstick

1 Warm the hand. Have the patient hold it under his or her arm or use a hand warmer.

2 Wash the hand with soap to remove fatty substances. Warm water helps to stimulate the blood flow. Rinse the fingers extensively to remove all traces of soap. Dry the hand.

(Hand cream and soap might contain substances such as glycerides, glycerol and ethylene glycol, which can result in false high triglyceride results.)

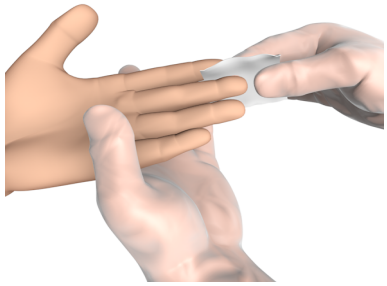
3 Choose an area on the side of the middle or ring finger of either hand.



Generally, the middle or ring finger are chosen because they tend to bleed the best and are less sensitive to pain than other fingers. The index finger may have increased sensitivity to pain. Therefore, avoid using it when possible.

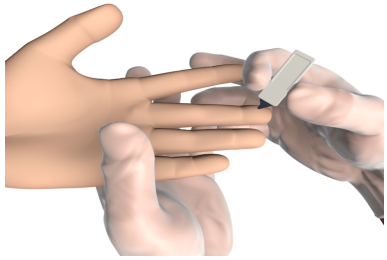
Do not use a finger that is swollen or edematous. Avoid recent incision sites and open cuts on the fingers.

4 Disinfect the area with an alcohol wipe (i.e. 70% Isopropanol or Ethanol, emollient free!) and dry with a clean swab or paper tissue.



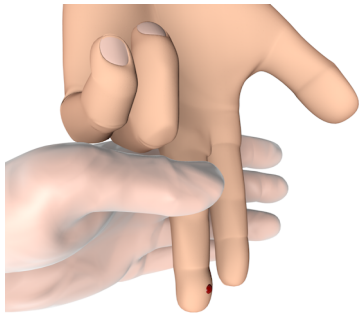
It is important to thoroughly dry off the alcohol because it may cause hemolysis of the sample.

5 Firmly prick the chosen area with a lancet.



For details on using the lancet, see its package inset.

6 Immediately after lancing, skim the finger smoothly from the palm's end towards 1 cm before the puncture site several times to obtain a good drop of blood. Wipe off this first drop of blood, as it may contain tissue fluid, then obtain another drop of blood i the same way.



Do not squeeze or milk the area around the puncture, the sample may become hemolytic or contain tissue fluid, which potentially affects sample results.

7 Immediately apply the drop of blood directly to the suction point of the test disc.

8 Wipe the puncture site with a clean swab or paper tissue. If bleeding continues, slightly press on the puncture site and cover it with a protective plaster.

■

5.5.8 Applying sample to a disc

The procedure depends on whether you use capillary blood or venous blood from a blood collection tube.

Incorrect results due to soiled disc

Sample or any other liquid that is spilled on the disc casing may lead to incorrect results.

- Do not use discs that had any liquid spilled on their casing. Dispose of them and start with a new disc.

Incorrect results due to deteriorated sample or wrong sample temperature

Sample whose temperature is too high or that was stored in inappropriate conditions may deteriorate.

Testing sample that had been frozen and not brought up to a temperature between +15 °C and +32 °C (59 °F and 90 °F) before application may lead to incorrect results.

- Make sure the sample is fresh and has the correct temperature.
- Roche recommends not to use previously frozen sample for Lipid Panel tests. When using previously frozen blood for HbA1c testing, make sure the blood temperature has reached room temperature before application.

Incorrect results due to inappropriate sample handling

Air bubbles in the sample may adversely affect capillary forces and lead to low fill volume.

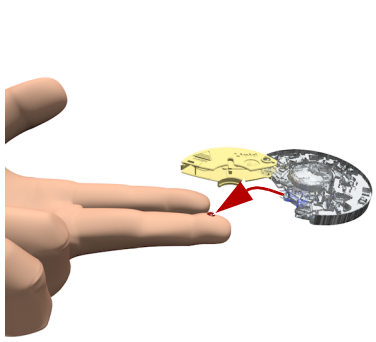
- Make sure the sample is free of air bubbles.

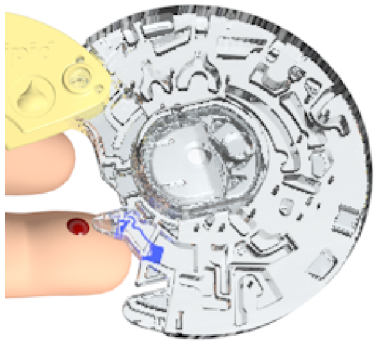
- Apply the blood immediately after lancing to prevent clotting.
- Do not apply blood to a disc directly from a syringe with needle.
- The sample must be tested within the time limits defined in the respective package insert.

► To apply capillary blood sample

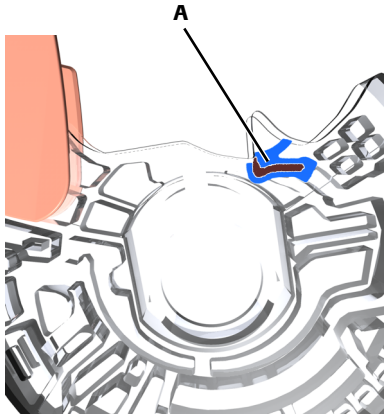
1 Immediately after pricking the finger, apply the drop of blood directly to the suction point of the test disc.

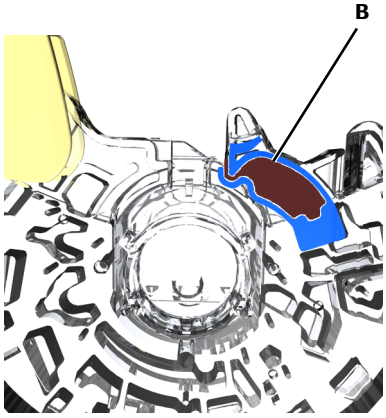
2 With the imprinted side of the disc facing upwards, position the disc's suction point above the blood drop. Apply blood and check that it has filled the marked area.





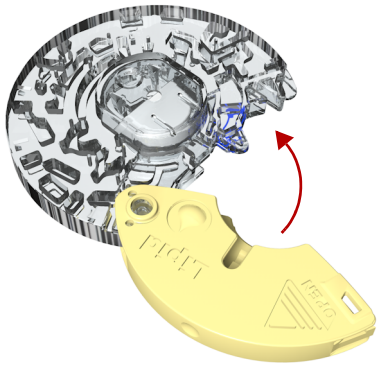
Turn the disc on its back. The area marked in blue has to be filled completely with blood (A: HbA1c disc, B: Lipid disc), and also make sure not to overdose (> 20 µL for HbA1c disc, > 40 µL for Lipid disc).





If there is insufficient blood, do not use a second fingerstick and apply the blood to the same disc; this may lead to clotting. Instead, continue with the procedure and if an error message points to underdosing obtain a new blood sample and apply it to a new disc.

3 Press the hinge cover down firmly to close the disc.



Once closed correctly the hinge cover cannot be opened again.

Do not use a disc for testing whose hinge cover has been forcibly removed. Dispose of such a disc and prepare a new disc.

4 Wipe the puncture site with a clean swab or paper tissue. If bleeding continues, slightly press on the puncture site and cover it with a protective plaster.

5 If you want to write information such as a patient name on the disc, use a felt pen and write it on the underside of the hinge cover.

■

The sample must be tested within the time limits defined in the respective disc package insert.

► To apply venous sample from a blood collection tube

1 Mix the blood well before applying it to the disc.

CAUTION

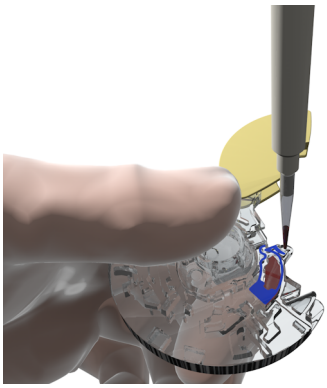
Incorrect results due to insufficient mixing of the anticoagulated whole blood or plasma

Insufficient mixing of the anticoagulated whole blood or plasma prior to applying it may lead to incorrect results.

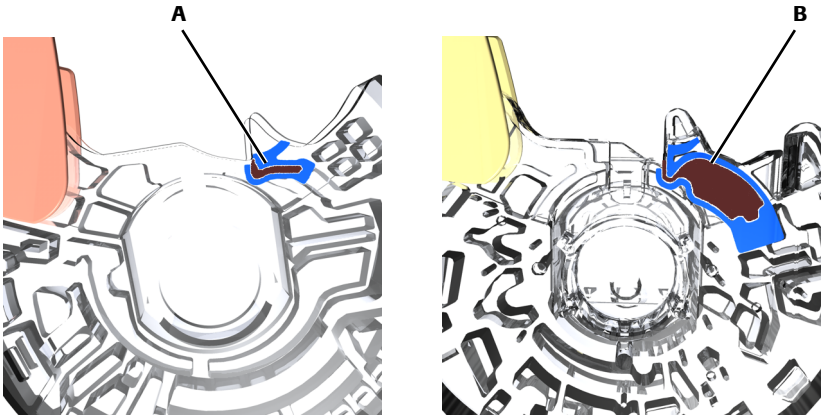
- Always mix the anticoagulated whole blood or plasma well before applying it.

2 Collect the blood from a vial by using a pipette, capillary tube or similar.

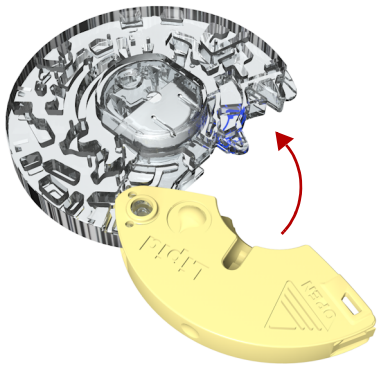
3 With the imprinted side of the disc facing downwards, apply the blood sample to the suction point.



4 Check the sample volume: The area marked in blue has to be filled completely with blood (A: HbA1c disc, B: Lipid disc), and also make sure not to overdose (> 20 µL for HbA1c disc, > 40 µL for Lipid disc).



5 Press the hinge cover down firmly to close the disc.



Once closed correctly the hinge cover cannot be opened again.

6 If you want to write information such as a patient name on the disc, use a felt pen and write it on the underside of the hinge cover.

■

The sample must be tested within the time limits defined in the respective disc package insert.

5.5.9 Performing a test (no operator and patient information, single testing)

Test procedures depend on whether your instrument is configured to work with or without operator and patient information, and also on the test mode (single or dual testing).

The following procedure is based on the following configuration:

- You work without operator information and without patient information. (Note that the instrument automatically assigns an ID to each test.)
- You work in single test mode.

► To perform a test

1 On the **Main Menu**, choose **Patient Test**.

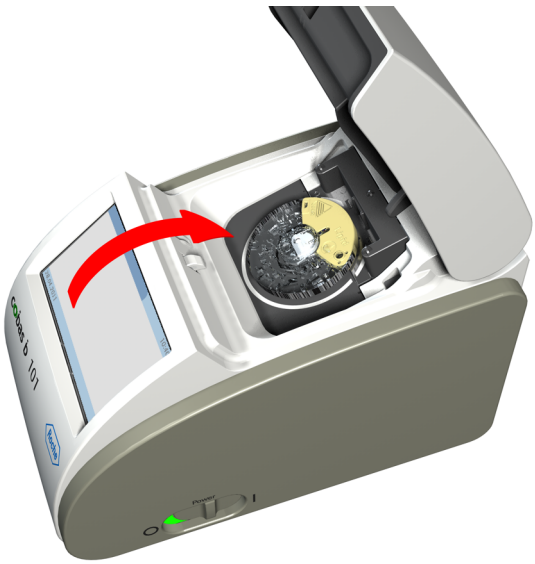
An instruction screen is displayed.

2 Choose **Open**.

The lid opens automatically.

A screen is displayed, asking you to place the disc and to close the lid.

3 Place the disc on the turn-table.



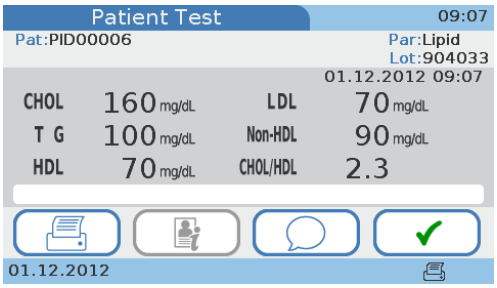
Do not insert a disc whose hinge cover has been forcibly removed. Dispose of such a disc and prepare a new disc.

4 Make sure that the imprinted side is facing up.

5 Close the lid slowly, you can feel it click when it is closed.

The measuring process starts automatically.

Messages are displayed to inform you about the progress. When the test is complete, the results are displayed.



6 If the instrument is configured to allow comment entry, you may now add a comment to the result by choosing and then selecting a predefined comment or writing a new one.

For details on writing and adding comments, see *Adding comments to results* on page 120.

For details on reviewing results, see *Reviewing patient results* on page 138.

7 Choose ✔.

A screen is displayed, asking you to open the lid.

8 Choose **Open**.

A screen is displayed, asking you to remove the disc and close the lid.

9 Remove the disc, store it in its pouch, and dispose of it according to the rules for handling biohazardous waste that apply to your facility.

The results are now available on the **Review Results** screens.

10 Close the lid.

The **Main Menu** is displayed again.

■

5.5.10 Performing the tests (with operator and patient information, dual testing)

Test procedures depend on whether your instrument is configured to work with or without operator and patient information, and also on the test mode (single or dual testing).

The following procedure is based on the following configuration:

- You work with operator information and patient information.
- You work with patient name information.
- You work with password identification.
- You work in dual test mode.

► To perform a test

1 On the **Main Menu**, choose **Patient Test**.

If you have just started the instrument or this is your first action of a work session, a screen for entering your operator ID is displayed.

2 Enter the operator ID.

For the different methods of entering information, see *Using operator information* on page 102.

3 Choose ✓.

A screen for entering your password is displayed.

4 Enter your password.

5 Choose ✓.

A screen for entering the patient ID is displayed.

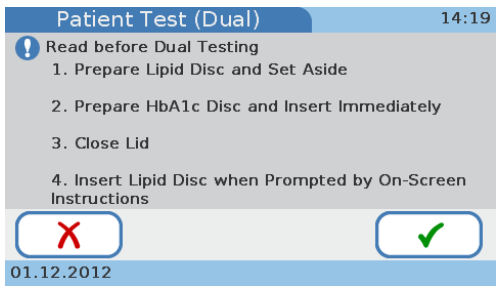
6 Enter the patient information

For details on entering patient information, see *Using patient information* on page 106.

A screen is displayed for selecting single or dual testing.

7 Choose **Dual Testing**.

An instruction screen is displayed.



8 Read the instructions carefully and choose ✔.

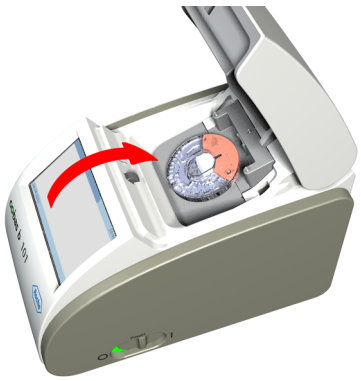
A screen with step-by-step instructions is displayed.

9 Follow the instructions on screen.

10 Choose **Open**.

The lid opens automatically and a screen is displayed, asking you to place the HbA1c disc and to close the lid.

11 Place the HbA1c disc on the turn-table.



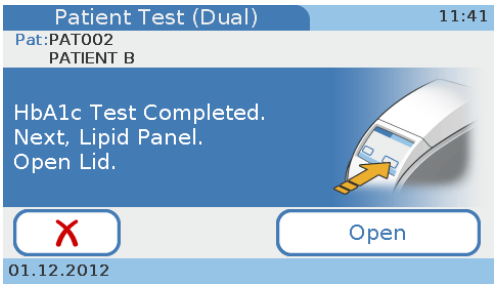
Do not insert a disc whose hinge cover has been forcibly removed. Dispose of such a disc and prepare a new disc.

12 Make sure that the imprinted side is facing up.

13 Close the lid slowly, you can feel it click when it is closed.

The measuring process starts automatically.

Messages are displayed to inform you about the progress. When the test is complete, a screen is displayed, asking you to replace the HbA1c disc with the Lipid disc.



14 Choose **Open**.

A screen is displayed, asking you to replace the HbA1c disc with the Lipid disc.

15 Remove the HbA1c disc and place the Lipid disc on the turn-table.

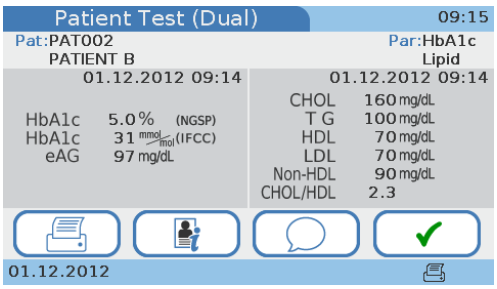
16 Close the lid slowly, you can feel it click when it is closed.

The measuring process starts automatically.

(If the Lipid disc is not inserted within 60 seconds after completion of HbA1c measurement, a screen is displayed informing you that the sample stability period has been exceeded and that you need to repeat the lipid tests with a fresh disc. The

test is aborted, confirm the message, remove the disc, obtain a fresh sample and Lipid disc, then perform a single lipid test.)

Messages are displayed to inform you about the progress. When the test is complete, the results are displayed.



17 If the instrument is configured to allow comment entry, you may now add a comment to the result by choosing 💬 and then selecting a predefined comment or entering a new one.

Note that comments are entered separately for both the HbA1c and Lipid results.

👁 For details on writing and adding comments, see *Adding comments to results* on page 120.

18 Choose ✔.

A screen is displayed, asking you to open the lid.

19 Choose **Open**.

A screen is displayed, asking you to remove the disc and close the lid.

20 Remove the disc, store it in its pouch, and dispose of it according to the rules for handling biohazardous waste that apply to your facility.

The results are now available on the **Review Results** screens.

21 Close the lid.

The **Main Menu** is displayed again.

■

5.5.11 Adding comments to results

Typically, you would add a comment as part of reviewing the result. Whether you can or even must add a comment to the results depends on how your instrument is configured.

👁 For information on defining predefined comments, see *To write (predefine) a result comment or change it* on page 41.
For information on configuring the commenting functions, see *Comments* on page 39.

💡 If you work with dual testing, comments are added to both results separately.

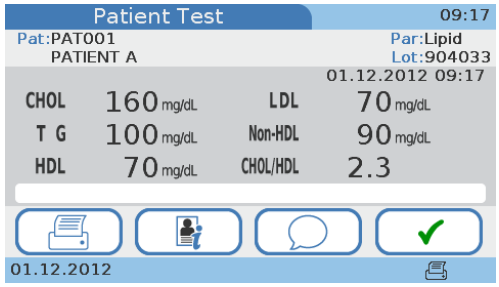
► To add a comment to a result while performing a test

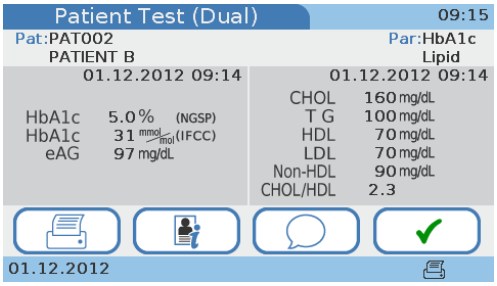
1 Perform a test.

👁 See *Performing a test (no operator and patient information, single testing)* on page 116

👁 See *Performing the tests (with operator and patient information, dual testing)* on page 118

When the test is complete, the results are displayed.





2 Choose 💬.

The **Comments** list is displayed, which contains all predefined comments.

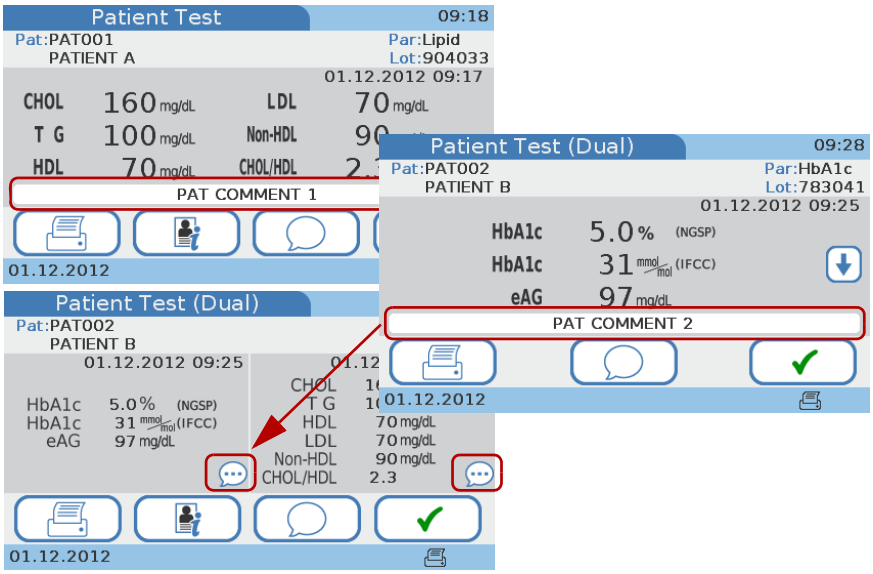
If your instrument is configured to always require comments and you do not enter a comment at this stage, a message is displayed, reminding you that you need to add a comment.

3 Do one of the following:

If …	Do this
You want to add a predefined comment	• Choose one of the comment buttons and choose ✔.

If …	Do this
You want to change and add a predefined comment	1. Choose one of the comment buttons and choose ⌨. 2. Change the comment. Use ← to delete the current text. Use the keyboard to enter the new text. Use 123 to display the numeric keyboard and ABC to display the alphabetic keyboard. 3. Choose ✔.
You want to add a new comment	1. Choose ⌨, 2. Enter the comment. Use 123 to display the numeric keyboard and ABC to display the alphabetic keyboard. 3. Choose ✔.

The **Patient Result** screen is displayed again, containing the comment.



4 Choose ✔ to continue with the task.

■

► **To add a comment to a result as part of separate result validation**

1 See *Adding and changing comments* on page 140.

■

5.5.12 Adding patient information

Typically, patient information is added when you start the test.

👁 See *Using patient information* on page 106.

If patient information is optional, you can enter it either when you start the test or add it to the results later.

👁 See *Adding patient information to results* on page 142.

5.5.13 Printing results

- To be able to print results your instrument must be connected to an external printer.
- Only connect the instrument to one of the recommended printers. See *Accessories* on page 169.
- Do not disconnect the printer from the instrument while printing is in progress.

What exactly is included in the result printout depends on the instrument configuration. Basically, what is displayed is printed. With dual testing, the results for both the HbA1c and the Lipid Panel tests are printed.

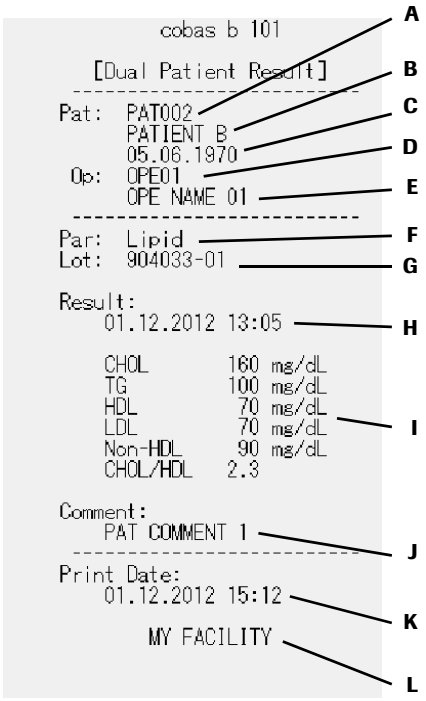
► To print a result

1 Display the result.

If you are in the process of performing a test, the results will be displayed automatically.

2 Choose .

The results are printed.



A Patient ID
B Patient name
C Patient date of birth
D Operator ID
E Operator name
F Test name
G Disc lot number
H Date and time when result was generated
I Results
J Comment
K Date and time when result was printed
L Facility information

■

The instrument displays a message if printing was not successful.

NOTICE

Unreadable results due to fading

Results printed with a thermal printer can fade over time and become unreadable.

- Do not use old discolored thermal printer paper and only use the paper specified for your printer.
- If you need to archive printed results make sure to store the paper in a dark place away from direct light.

5.6 Performing STAT tests

STAT tests are tests that are performed in situations of operator or QC lockout, i.e. when QC results are not or no longer valid and there is no time to perform the necessary control tests first.

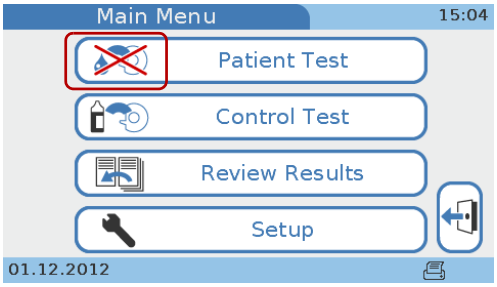
For information on setting up STAT testing, see *STAT Test* on page 83.

In the following situations STAT tests are not available:

- When the optical check test has failed neither HbA1c nor lipid patient tests are available.
- When the HbA1c QC test has failed, HbA1c STAT tests are not available.
- When the Lipid QC test has failed, Lipid STAT tests are not available.
- When *All testing function lockout* is enabled in the data management system.

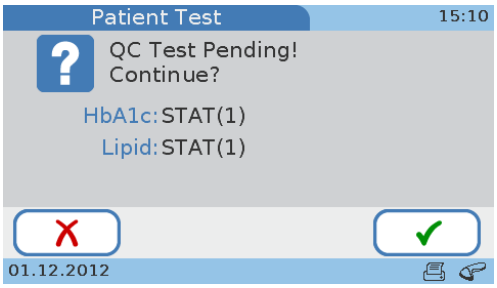
► To perform a STAT test

1 On the **Main Menu**, choose **Patient Test**.



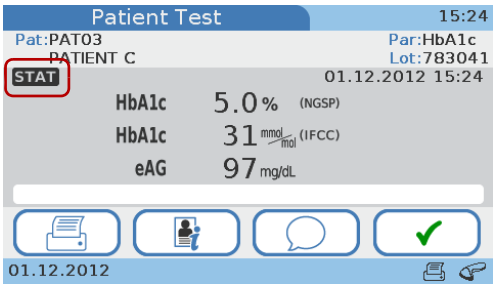
The button is marked as blocked.

2 A screen is displayed, asking you whether you want to perform a STAT test.



3 Choose ✔.

4 Continue the test as a normal patient test.



Results for STAT tests are specially marked.

■

5.7 Aborting a test

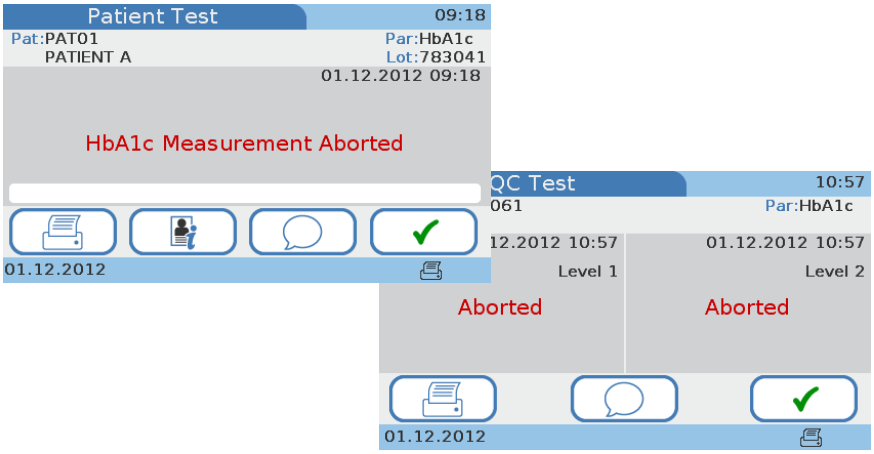
Aborting a test means to interrupt the measurement process. The process is the same for the various kinds of test.

► To abort a test

1 On the progress screen, choose ✗.

2 A screen is displayed asking you whether you really want to abort the test.

3 Choose ✓ to confirm.



4 Choose ✓ to close the screen.

A screen is displayed, asking you to open the lid.

5 Choose **Open**.

6 Open the lid and remove the disc.

7 Close the lid.

■

You cannot reuse a disc that was used for an aborted test.

6 Performing control tests

The instrument can be set up to be used with or without control testing.

See *Operator Lockout* on page 80
See *QC Lockout* on page 81
See *Optical Check Lockout* on page 82

The following sections describe working with control testing.

CAUTION

Incorrect patient results due to invalid quality control results

Quality control (QC) measurements are performed to ensure that the instrument and your technique used in testing give accurate results of patient tests.

Performing patient tests when the current control test results are not or no longer valid may lead to incorrect patient results.

- Always perform quality control measurements as soon as they are due.
- Use control tests in a manner that ensures compliance with the regulatory requirements that apply to you facility.

The following types of control test are available:

- Liquid QC tests
- Optical check test
- Proficiency test

6.1 Liquid QC tests

Observe the applicable regulations and directives of the relevant regulatory agencies when performing liquid QC tests. Accurately testing known levels of the QC solution ensures that the instrument and your technique used in testing give accurate results of patient tests. QC solutions have defined (known) values. The results for these solutions must fall within certain acceptable ranges in order to allow valid patient testing. The instrument may be configured to require control testing before patient testing is allowed. This is called QC Lockout. In this case, the instrument prevents patient and proficiency testing if the control results are not within the acceptable ranges.

Intervals

Intervals between running liquid QC tests are determined by your facility. These intervals are typically entered when the instrument is configured.

See *QC Lockout* on page 81.

When to run liquid QC tests

Liquid QC tests should be run in the following circumstances:

- Before using the instrument for patient testing the first time
- According to the liquid quality control intervals established by your facility
- When the quality control interval has been exceeded
- When using a new QC solution vial for the first time
- When using the first disc of a new lot
- If questionable test results are displayed repeatedly
- If you wish to test the performance of the instrument
- If a previous control test is out of range
-

You will be informed by messages on screen if a liquid QC test is required.

If you work with QC lockout and a control test failed, no patient tests can be performed (not even STAT tests) until a valid QC result can be produced.

See *Operator and QC lockout (the control results are no longer valid)* on page 156.

Available QC solutions

For liquid QC tests, the following QC solutions are available:

- **cobas** HbA1c Control
  - Level 1: test results within normal range
  - Level 2: test results in pathological range
- **cobas** Lipid Panel Control (CHOL,TG, HDL)
  - Level 1: low values in test results
  - Level 2: high values in test results

Information stored with control results

The following information is stored for every liquid QC test:

- Liquid QC test result
- Lot number of the QC solution
- Operator ID (if configured)
- Level of control solution (Level 1 or Level 2)
- Lot number of the test disc
- Time and date of test
- Comments (if entered)
- Out of range measurements

QC info disc

The QC info disc is supplied with each new lot of QC solution and contains the following QC information:

- Control lot number
- Expiry date of QC lot
- Parameter (HbA1c, Lipid)
- Target values for each control
- Acceptable ranges for each control

6.1.1 Performing a liquid QC test

Liquid QC tests are performed in the same manner as patient tests.

For information on performing a test, see *Testing samples* on page 93.

For information on what to do when control measurements are due, see *Operator and QC lockout (the control results are no longer valid)* on page 156.

What you need

- **cobas** HbA1c Control (Level 1 and 2 bottles)
- **cobas** Lipid Panel Control (Level 1 and 2 bottles)
- Pipette or capillary tube with plunger
- **cobas** HbA1c QC Info Disc
- **cobas** Lipid QC Info Disc
- **cobas** HbA1c Test disc
- **cobas** Lipid Panel disc
- External printer if you want to print the results
- Barcode scanner if you want to read information from barcodes
- Powder-free gloves

- Verify that the QC solution has not expired.
- Verify that the QC solution lot number matches the lot number displayed on screen.
- Make sure to use the correct parameter.
- Make sure to use the correct level.

Unpacking the test disc

The disc is handled in the same way as for single-use patient testing.

See *Preparing a disc* on page 109.

Applying QC solution

Test solution is applied using either the dropper included in control kit for HbA1c or an eyedropper for the lipid QC solutions.

See *To apply venous sample from a blood collection tube* on page 115.

Check the sample volume: turn the disc on its back. The area marked in blue has to be filled completely with blood, and also make sure not to overdose (> 20 µL for HbA1c disc, > 40 µL for Lipid disc).

You can either test both levels in one procedure or test one of the levels at a later stage.

Testing of discs must start immediately after applying the solution.

The following table shows the possible effects on the results and the locking state.

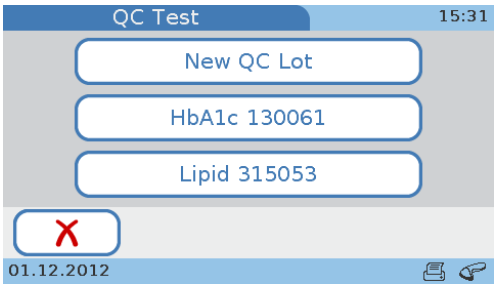
First test	Second test	Overall QC result status	Locking status
Pass	Not performed (user chose not to perform second test)	Pass	Unlock
Pass	Pass	Pass	Unlock
Pass	Fail	Fail	Lock
Pass	Aborted by user during testing	Aborted	No change
Pass	Error	Aborted	No change
Fail	Not performed (skipped by instrument)	Fail	Lock
Error	Not performed (skipped by instrument)	Aborted	No change
Aborted by user	Not performed (skipped by instrument)	Aborted	No change

Table 14 Possible effects on the results and the locking state if testing both or just one QC level

► To perform a liquid QC test of a new lot

1 Choose **Control Test** > **QC Test**.

A screen for choosing the control lot is displayed.



When performing a QC test for the first time, only the **New QC Lot** button is available.

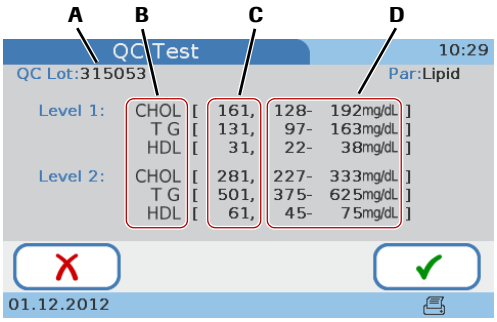
2 Choose **New QC Lot**.

A screen is displayed asking you to insert the QC info disc.

Make sure to use the QC info disc that is contained with the control kit you are going to use.

3 Choose **Open**, open the lid and load the QC info disc, then close the lid.

The test information is read into the instrument and displayed as illustrated in the following example of a Lipid QC test.



A Control lot number
B Parameters for the QC solution
C Target value for each control
D Acceptable range for each control

4 Compare the control lot number on the bottle with that of your QC info disc, they must be identical.

5 Choose ✔.

A screen is displayed for choosing a control level.

6 Choose a level and then ✔.

A screen with instructions is displayed.

7 Prepare the disc.

See *Preparing a disc* on page 109.

8 Apply the solution.

See *To apply venous sample from a blood collection tube* on page 115.

CAUTION

Incorrect results due to wrong liquid

- Make sure you use control solution and not patient sample.
- Make sure that the level you just selected and that of the solution in the disc are the same.

9 Choose **Open**, open the lid and load the disc, then close the lid.

A screen is displayed asking you to check the loaded solution.

10 Check the information displayed on screen and confirm by choosing ✔.

(If it is not correct, you can abort the test by choosing ✘ and confirming the abortion. The results are then displayed as **Aborted**.)

The test is performed. When it is complete, a screen is displayed asking you whether you want to proceed with the QC solution of the other level.

You can perform the test with the other level at a later stage and abort QC testing by choosing ✘. Choose ✔ to confirm. The results are displayed. Continue with step 16. For details on the effect on the lockout status, see *Table 14* on page 130.

11 Choose ✔ to confirm that you want to test the other level as well.

A screen with instructions is displayed.

12 Prepare the second disc.

See *Preparing a disc* on page 109.

13 Apply the solution of the other level.

See *To apply venous sample from a blood collection tube* on page 115.

Make sure that the level you just selected and that of the solution in the disc are the same.

14 Choose **Open** and replace the disc with the one containing the QC solution of the other level, then close the lid.

A screen is displayed asking you to check the loaded solution.

15 Check the information displayed on screen and confirm by choosing ✔.

(If it is not correct, you can abort the test by choosing ✗ and confirming the abortion. The results are then displayed as **Aborted**.)

The test is performed. When it is complete, the results are displayed.

How the results are displayed depends on how the control result format is defined on the instrument. See *QC Result Format* on page 84.

- The **Pass** or **Fail** information is always displayed.
- If a control test persistently fails contact your Roche representative.

16 If you want to add a comment choose 💬.

Whether you can or need to add a comment depends on how commenting is set up for control results.

For details on setting up commenting, see *Comments* on page 39.
For details on adding comments, see *Adding comments to results* on page 120.

17 Choose ✔.

A screen is displayed asking you to open the lid.

18 Choose **Open**, open the lid and remove the disc, then close the lid.

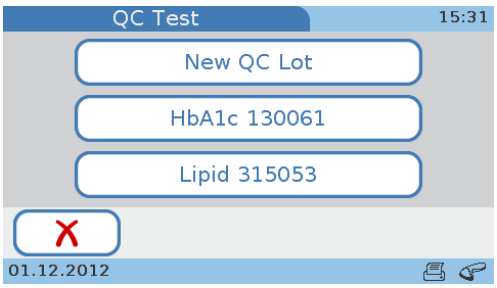
The **Main Menu** is displayed.

■

► To perform a liquid QC test of an existing lot

1 Choose **Control Test** > **QC Test**.

A screen for choosing the control lot is displayed.



2 Choose a button of an existing lot.

- Choose the **HbA1c** button to perform an HbA1c QC test.
- Choose the **Lipid** button to perform a Lipid QC test.

A screen is displayed with the defined target values and acceptable ranges.

3 Choose ✔.

A screen is displayed for choosing a control level.

4 Continue with step 6 on page 131.

■

6.2 Optical check

Observe the applicable regulations and directives of the relevant regulatory agencies when performing an optical check test. The optical check is designed to check the optical function and accuracy of the entire instrument. For the test, an optical check disc is used, which is supplied with the instrument. If the test passes successfully, the optical functions of the instrument can be considered to work normally.

When to run the optical check

The optical check should be performed in the following circumstances:

- Before the instrument is used for patient testing for the first time.
- When the test interval has been exceeded. The intervals are determined by the rules that apply to your facility.
- If a message for optical check lockout is displayed. (The instrument can be configured to block patient testing if there is no valid result for the optical check. See *Optical Check Lockout* on page 82.)
- If an error message concerning the optical system is displayed.
- If you want to check the optical function of the instrument.
- After impact on the instrument (e.g. after accidentally knocking the instrument).

Optical check disc

The optical check disc is a special disc that is supplied with the instrument. It is designed for testing the optical unit of the instrument.

CAUTION

- Take care not to soil the optical areas of the optical check disc.
- Store the optical check disc in the conditions described in its package insert. Do not store it in a refrigerator.
- Keep the disc at an ambient temperature between +15 °C and +32 °C (59 °F and 90 °F) for at least 20 minutes before using it.
- Take care not to drop the optical check.
- Do not disassemble the optical check disc.
- Do not store the optical check disc at a place subjected to direct sunlight.

6.2.1 Performing an optical check

► **To perform an optical check test**

1 Choose **Control Test** > **Optical Check**.

A screen is displayed asking you to open the lid.

2 Choose **Open**, open the lid and load the optical check disc, then close the lid.

Test cannot be performed due to improper disc placement

If the disc or the turntable are soiled, the disc may not rest flat on the turntable. This may prevent the instrument from performing the test properly.

- Make sure the disc is free of soil and rests flat on the turntable.

The test is performed. When it is complete, a screen is displayed, informing you whether the test has passed or failed.

3 If you want to add a comment choose .

Whether you can or need to add a comment depends on how commenting is set up for control results. See *Adding comments to results* on page 120.

4 Choose ✔.

A screen is displayed asking you to open the lid.

5 Choose **Open**, open the lid, remove the optical check disc and store it in its proper case.

6 Close the lid.

The **Main Menu** is displayed.

■

6.3 Proficiency test

Observe the applicable regulations and directives of the responsible regulatory agencies when performing proficiency tests.

When to run a proficiency test

Proficiency tests are run on samples whose values are unknown to the operator performing the test. These samples are provided by an outside source, and the results should be forwarded to the appropriate source after completing the test. The supplied samples are treated in the same manner as regular patient samples.

Proficiency testing provides another means to verify that your technique, reagents, system, and testing performance are as they should be. Some regulatory agencies require that these proficiency samples be tested as part of an institution's quality assurance program before certification of the institution is granted.

Proficiency tests are performed for each of the patient tests you use on the **cobas b** 101 system.

The following information is stored for every proficiency test:

- Test name
- Test results
- Proficiency test ID
- Lot number of the test disc

- Time and date of test
- Comments (if entered)
- Operator ID (if configured)

What you need

- HbA1c proficiency test sample (vial containing venous blood)
- Lipid proficiency test sample (vial containing venous blood)
- Pipette, capillary tube or similar
- **cobas** HbA1c Test disc
- **cobas** Lipid Panel disc
- Handheld barcode scanner if you want to input information from barcodes
- External printer if you want to print the results

6.3.1 Performing a proficiency test

► To perform a proficiency test

1. Choose **Control Test** > **Proficiency Test**.

   A screen is displayed asking you to open the lid.

2. Apply the sample to the suction point of the disc and then close it.

   See *Preparing the sample* on page 96 and *To apply venous sample from a blood collection tube* on page 115.

3. Choose **Open**, open the lid, insert the disc, and close the lid.

   The test is performed. When it is complete, the test results are displayed.

   Note that with these results there is no pass or fail indication

4. If you want to add a comment choose 💬.

   You can use the comment function to add information on the sample if required.

   Whether you can or need to add a comment depends on how commenting is set up for control results.

   For details on adding comments, see *Comments* on page 39.
   For details on adding comments, see *Adding and changing comments* on page 140.

5. Choose ✔.
6. Choose 🖨 if you want to print the results.
7. Choose ✔.

   A screen is displayed asking you to open the lid.

8. Choose **Open**, open the lid, remove the proficiency test disc, then close the lid.

   The **Main Menu** is displayed.

9. Forward the results to the appropriate source.

■

7 Reviewing results

The **cobas b** 101 system can store the results of up to 5000 patient and 500 control tests, as well as up to 500 sets of patient information and 50 sets of operator information. If the remaining memory capacity for results reaches 50 tests (for either patients or controls), a message is displayed, informing you of this fact. You can save the data to an external data medium.

You can review results either as a part of running the test or at a later stage. You can also print results using a dedicated external printer.

The way results are presented and how to review them depends on which units were defined to be used and how commenting is set up; with control results it also depends on how the result format was defined.

- For details on defining the result units, see *Result Units* on page 44.
- For details on configuring the commenting functions, see *Comments* on page 39.
- For details on defining how control results are displayed, see *QC Result Format* on page 84.

☞ **Main Menu** > **Review Results** > **Patient Results** or **Control Results**

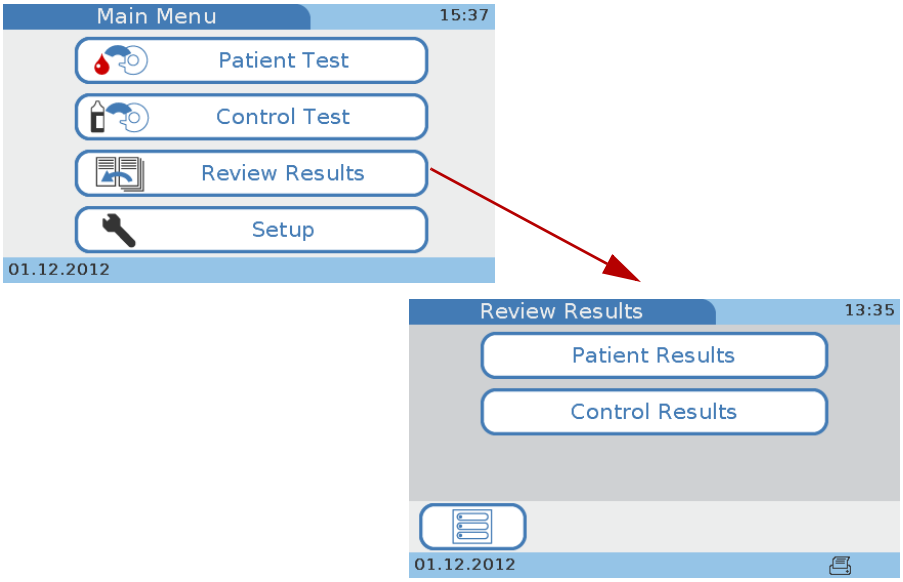
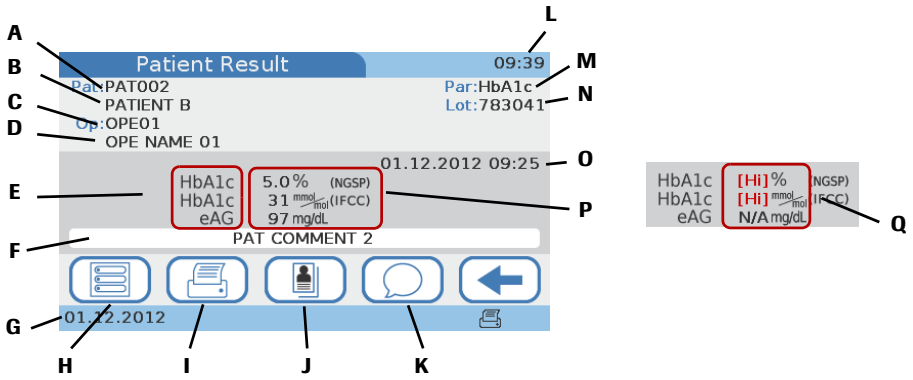


Figure 19 Displaying results

7.1 Reviewing patient results



A	Patient ID	**J**	Display or add patient information
B	Patient name	**K**	Add comment
C	Operator ID	**L**	Current time
D	Operator name	**M**	Test type
E	Test parameters	**N**	Lot number
F	Comment	**O**	Date and time when the result was generated
G	Current date		
H	Back to **Main Menu**	**P**	Results
I	Print the result	**Q**	Results are out of range

Figure 20 Overview on patient result screen

[Hi], [Lo]

If a result is outside the permissible ranges, a message is displayed, indicating the range and whether the result is above [**Hi**] or below [**Lo**] the range. On the result screen, [**Hi**] and [**Lo**] respectively are displayed instead of the result value (Q).

► To review patient results

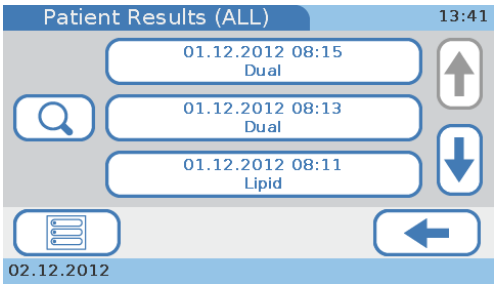
1 Choose **Main Menu** > **Review Results** > **Patient Results**.

The **Patient Results** screen is displayed.

2 Choose one of the buttons:

- Choose **All** to list all patient results.
- Choose **HbA1c** to list all results of HbA1c tests.
- Choose **Lipid** to list all results of lipid tests.

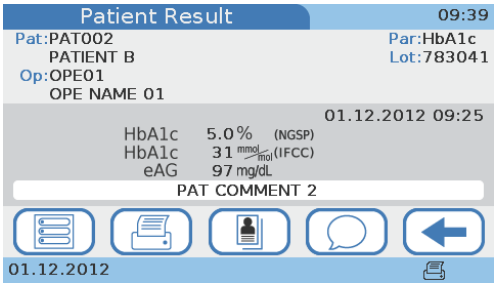
A list is displayed with a button for each result.



3 Choose one of the result buttons.

(If you work with patient information, you can choose to find all results of a particular patient. See *Finding the results of a patient* on page 139.)

The results are displayed.



4 Do one or several of the following:

(Which of the following tasks are available to you depends on how the instrument is set up, and your facility's work procedures define which to perform.)

- Use to add or change a comment.
  - See *Adding and changing comments* on page 140.
- Use to add or change patient information.
  - See *Adding patient information to results* on page 142.
- Use to print the results.
  - See *Printing results* on page 147.

■

7.1.1 Finding the results of a patient

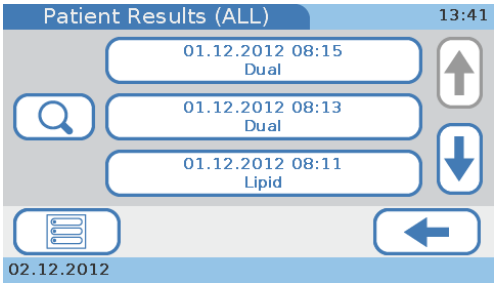
This function is available if you work with patient information.

See *Patient ID setup* on page 69.

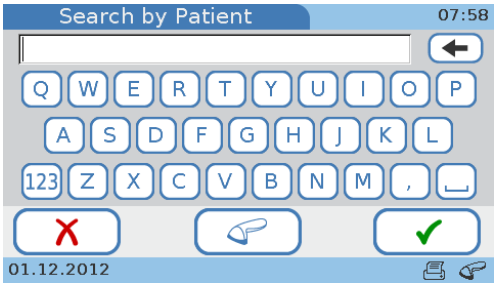
► To find the results of a certain patient

1 Display a result list.

(**Main Menu** > **Review Results** > **Patient Results** > **All** or **HbA1c** or **Lipid**.)



2 Choose .



3 Enter part of or the complete patient ID or name.

If you use the barcode scanner for entering patient information, you can choose and then scan the patient information. A list is displayed containing all the results for this patient. Choose one of the result buttons to display the result.

4 Choose ✔.

5 If more than one patient ID or name match the characters you just entered, a list is displayed containing all the matching patients. Choose one of the patient buttons, and a list is displayed containing all the results for this patient.

If only one patient ID matches the characters you just entered, a list is displayed containing all the results for this patient.

6 Choose one of the result buttons.

The results are displayed.

■

7.1.2 Adding and changing comments

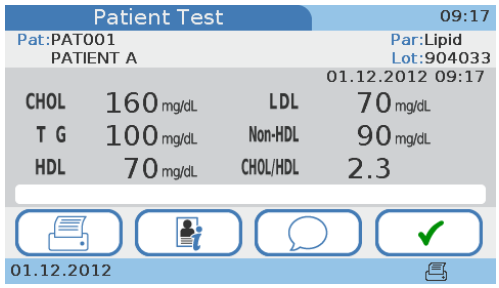
Whether this function is available and how comments are added depends on how commenting is set up on your instrument.

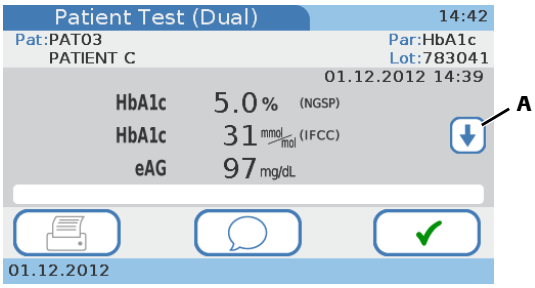
For information on setting up the commenting functions, see *Comments* on page 39.

For information on writing comments, see *To write (predefine) a result comment or change it* on page 41.

► To add a comment to a result or change an existing comment

1 Display a result.





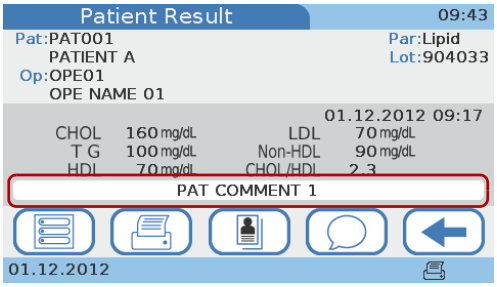
With dual testing, comments are entered separately for both the HbA1c and Lipid results. (You can use ↑ and ↓ (A) to switch between the two result sets.)

2 On the result screen, choose .

The **Comments** list is displayed, which contains all predefined comments.

3 Do one of the following:

If …	Do this
You want to add a predefined comment	• Choose one of the comment buttons and choose ✔.
You want to change and add a predefined comment	1. Choose one of the comment buttons, then choose ⌨. 2. Change the comment. Use ← to delete the current text. Use the keyboard to enter the new text. 3. Choose ✔.
You want to add a new comment	1. Choose ⌨. 2. Enter the comment. 3. Choose ✔.



■

7.1.3 Adding patient information to results

You can add patient information to results if your instrument is set up to optionally work with or without patient information. You can always change patient information that was entered previously. Your instrument setup also determines the way in which this information is entered (keyboard, scanner, from a list of predefined patients). Note that if you work with operator information and the Administrator role, you must have Administrator authority to be able to add patient information to results.

For information on how to set up patient information handling, see
Patient ID setup on page 69
Logical overview of using the Patient ID functions on page 70
To determine how to define patient information on page 72

Possible patient information items are the ID, name, and the date of birth. Patient information always includes the patient ID. Depending on the instrument setup, the patient name and the date of birth may be included as well.

The same patient information always applies to all results of a patient.

7.1.4 Searching for results of a certain patient

This function is available if you work with patient information.

See *Patient ID setup* on page 69

► To find all results of a certain patient

1 In the result list, choose .

The **Search by Patient** screen is displayed.

2 Enter part of or the complete patient ID.

If you use the barcode scanner for entering patient information, you can choose and then scan patient ID.

3 Choose ✓.

A list is displayed with all patients whose ID or name contains the characters you just entered.

4 Choose a patient name button.

A list is displayed with all the tests that were performed for this patient.

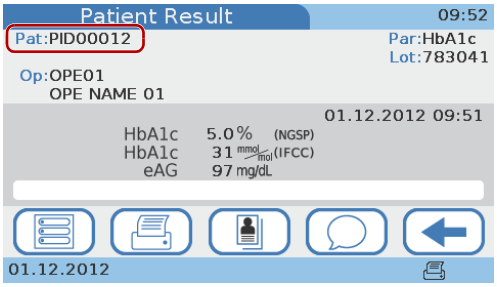
5 Choose one of the buttons from the list.

The results are displayed.

■

► To add patient information to a result

1 Display a result.



2 Choose .

A screen is displayed that lists all the results of the patient with the current patient ID.

3 Choose .

A screen is displayed, asking you whether you want to add patient information.

4 Choose ✓ to confirm.

If you use the keyboard or the scanner for entering patient information, the **Patient ID** screen is displayed.

If you use the patient list for entering patient information, the patient list is displayed.

5 Enter the information.

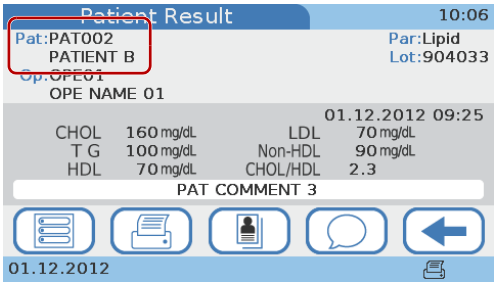
- Enter the information using the keyboard.
  See *To enter patient information using the keyboard* on page 106.
- Enter the information using the barcode scanner.
  See *To enter patient information using the barcode scanner* on page 107.
- Enter the information using the patient list.
  See *To enter patient information using the patient list* on page 108.

The ID that was assigned by the instrument is replaced by the one you just entered.

■

► To change patient information

1 Display a result.



2 Choose .

A screen is displayed that lists all the results of the patient.

3 Choose .

A screen is displayed, showing the current patient information.

4 Choose .

If you use the keyboard or the scanner for entering patient information, the **Patient ID** screen is displayed.

If you use the patient list for entering patient information, the patient list is displayed.

5 Enter the information.

- Enter the information using the keyboard.
  See *To enter patient information using the keyboard* on page 106.
- Enter the information using the barcode scanner.
  See *To enter patient information using the barcode scanner* on page 107.
- Enter the information using the patient list.
  See *To enter patient information using the patient list* on page 108.

A confirmation screen is displayed that shows the changed information.

6 Choose ✓ to save the new information.

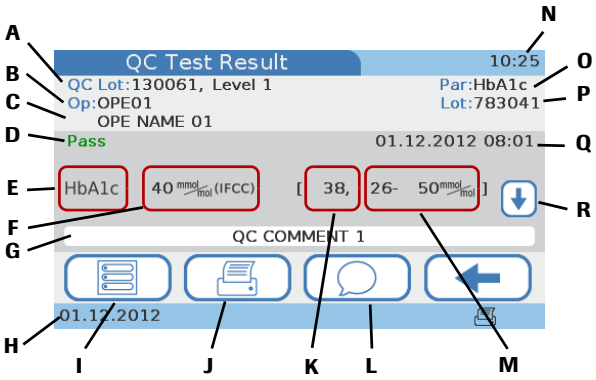
■

7.2 Reviewing control results

How the results are displayed depends on how the control result format is defined on the instrument. You cannot change the result format for the Optical Check and Proficiency control tests.

For details on defining how control results are displayed, see *QC Result Format* on page 84.

With the exception of the proficiency test results, the **Pass** or **Fail** information is always displayed.



A	Lot ID and level of the QC solution	**K**	Target value
B	Operator ID	**L**	Add comment
C	Operator name	**M**	Acceptable range
D	Pass or fail indication	**N**	Current time
E	Test parameters	**O**	Test type
F	Results	**P**	Lot ID of disc
G	Comment	**Q**	Date and time when the result was generated
H	Current date	**R**	Button for displaying the results of the other level
I	Back to **Main Menu**		
J	Print the result		

Figure 21 Overview of the QC result screen

[Hi], [Lo]

If a QC result is outside the permissible ranges, a message is displayed, indicating the range and whether the result is above **[Hi]** or below **[Lo]** the range. On the result screen, **[Hi]** and **[Lo]** respectively are displayed instead of the result value.

If a QC result is outside the defined ranges the result is flagged with an arrow.

► To review control results

1 Choose **Main Menu** > **Review Results** > **Control Results**.

The **Control Results** screen is displayed.

2 Choose one of the buttons:

- Choose **QC Test** to view all liquid QC results.
- Choose **Optical Check** to view all optical check results.
- Choose **Proficiency Test** to view all proficiency test results.

3 Display an individual result.

4 Which of the following tasks are available to you depends on how the instrument is set up, and your facility's work procedures define which to perform.

- Use to add a comment.
  See *Adding and changing comments* on page 140.
- Use to print the results.
  See *Printing results* on page 147.

■

8 Printing results

Your instrument must be connected to an external printer to be able to print results.

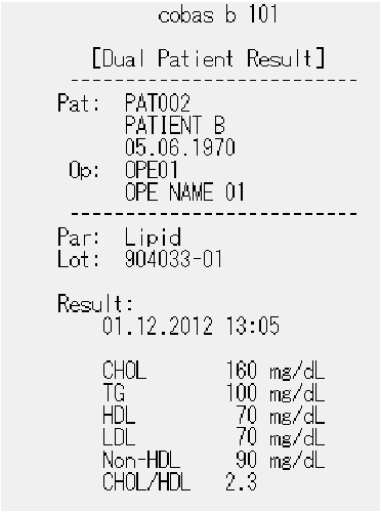
What exactly is included in the result printout depends on the instrument configuration. Basically what is displayed is printed. With dual testing, the results for both the HbA1c and the Lipid Panel tests are printed.

► To print a patient result

1 Display the result.

2 Choose .

The result is printed.



■

The instrument displays a message if printing was not successful.

NOTICE

Printed results can fade over time and become unreadable.

- If you need to archive printed results make sure to store the paper in a dark place away from direct light.
- Only use paper of the quality recommended by the manufacturer of your printer.

■

9 Cleaning and disinfecting of the cobas b 101 system

Cleaning and disinfecting the instrument is, at minimum, recommended daily. Follow recommendations from the FDA, CDC, and CMC and your facility's policies and procedures for infection control.[1] [2] [3]

9.1 Guide to cleaning and disinfecting the cobas b 101 system

Prior to cleaning and disinfecting the instrument:

- Follow the infection control procedures of your institution when handling the instrument.
- Wear gloves.
- The gloves worn during cleaning and disinfecting should be removed and hands washed thoroughly with soap and water.

Cleaning and disinfecting the instrument

- Clean the instrument to remove visible soil and organic material prior to disinfecting.[3]
- Disinfect the instrument to destroy pathogenic and other types of microorganisms. Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).[3]

When to clean and disinfect the instrument

- Clean the instrument when there are visible signs of soil or per your facility's guidelines.
- Clean and disinfect the instrument daily or per your facility's guidelines. The instrument should be cleaned prior to disinfection.

Acceptable cleaning and disinfecting agents

To purchase approved disinfecting products, please refer to your facility's guidelines, which may include instructions on direct purchase from the manufacturer or through an approved distributor.

Obtain and dispose of acceptable cleaning and disinfection solutions per facility guidelines.

Acceptable active ingredients and products for cleaning and disinfecting are:

- Sani-Cloth Plus Germicidal Disposable Wipes

  (EPA registration number 9840-6)

  Pre-moistened disinfecting cloths (active ingredient: n-alkyl dimethyl ethylbenzyl ammonium chlorides 0.125%; n-alkyl dimethyl benzyl ammonium chlorides 0.125% and isopropyl alcohol 14.85%)

(1) FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

(2) CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010). http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

(3) Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. Atlanta, Ga.

What to clean and disinfect

The following parts of the instrument may be cleaned and disinfected:

- Outside of the instrument
- Screen
- Inside of the instrument
- Barcode scanner

Technical assistance

If you notice any signs of deterioration after cleaning and disinfecting of your instrument, stop using the instrument and contact Roche Technical Service for assistance. See *Contact information for Roche* on page 172.

WARNING

Protection against infection

There is a potential risk of infection. Healthcare professionals using the **cobas b** 101 system must be aware that any object coming into contact with human blood is a potential source of infection.

- Use gloves.
- Use recommended cleaning and disinfecting materials only.
- Dispose of used cleaning and disinfecting material according to your facility's infection control policy.
- After cleaning and disinfecting the instrument, remove the gloves and wash your hands.
- Follow all health and safety regulations in force locally.

It is important to follow the procedure as described in this section. Failure to follow these procedures may cause malfunction of the instrument.

NOTICE

Damage to the instrument by using unsuitable cleaning materials

Using unsuitable solutions may result in incorrect operation and possible failure of the system.

- Clean and disinfect the instrument with recommended materials only. Make sure that the instrument is thoroughly dried after cleaning and disinfecting.
- Do not use any abrasive cleaning and disinfecting substances or pointed implements for cleaning and disinfecting the instrument.

Always use Sani-Cloth Plus Germicidal Disposable Wipes. Do not use any other cleaning or disinfecting solutions. Using solutions other than the Sani-Cloth Plus could result in damage to the system components.

NOTICE

Damage to the instrument by liquids reaching critical parts

Liquids reaching electrical parts such as sockets and plugs may lead to short-circuiting. Liquids entering internal parts may lead to their disfunctioning.

- Make sure no foreign substances such as liquids reach the sockets and plugs.
- Make sure no liquid enters internal components.
- Do not use spray of any sort.
- Ensure the swab or cloth is only damp, not wet.
- Remove excessive moisture, if necessary.
- Do not allow pooling of liquid on touch screen. Remove immediately with dry lint-free cloth.

NOTICE

The inside and outside of the instrument must be kept clean at all times. If there is a spillage, clean and disinfect immediately using a Sani-Cloth Plus Germicidal Disposable Wipe. Dispose of the wipe according to your facility's infection control policy.

9.2 Cleaning and disinfecting the screen and outside of the instrument

Immediately clean and disinfect the screen and outside of the instrument whenever it is visibly soiled or whenever a spillage occurs.

Clean and disinfect at least once a day.

► To clean the screen and outside of the instrument

1 Switch off the instrument (A). Disconnect the power cable from the instrument (B).

When using a Sani-Cloth Plus Germicidal Disposable Wipe, *squeeze off excess cleaning and disinfecting solution* or blot dry on a paper towel to remove any excess cleaning solution before cleaning the surface of the instrument.

2 To clean, use a Sani-Cloth Plus Germicidal Disposable Wipe to gently wipe the screen and the outside of the instrument. Dry the screen and the outside of the instrument thoroughly with a dry cloth or gauze.

The instrument should be cleaned prior to each disinfection step.

3 To disinfect, use a fresh Sani-Cloth Plus Germicidal Disposable Wipe by gently wiping the screen and the outside of the instrument. Allow the screen and the outside of the instrument to remain damp with the recommended cleaning and disinfecting solution for a contact time of greater than 3 minutes.

The screen and the outside of the instrument should stay moist for the entire contact time.

4 Dry the screen and the outside of the instrument thoroughly with a dry cloth or gauze. Visually verify that no solution is seen anywhere on the instrument at the completion of cleaning and disinfecting. *Ensure that the instrument is thoroughly dried after cleaning and disinfecting* (see safety message *Damage to the screen by using unsuitable materials* in this section).

5 Reconnect the power cable.

6 Switch on the instrument and check that the startup procedure works without an error message.

■

NOTICE

Damage to the screen by using unsuitable materials

Using unsuitable materials may damage the surface of the screen.

- Do not use any abrasive cleaning substances or pointed implements for cleaning the screen.

NOTICE

Damage to the instrument due to short-circuiting

Liquids reaching electrical parts such as sockets and plugs may lead to short-circuiting.

- Make sure no foreign substances such as liquids reach the sockets and plugs.

9.3 Cleaning and disinfecting the inside of the instrument

Immediately clean and disinfect the inside of the instrument whenever it is visibly soiled or whenever a spillage occurs.

Clean and disinfect at least once a day.

► To clean and disinfect the inside of the instrument

1 Switch off the instrument (B). Disconnect the power cable from the instrument (C).

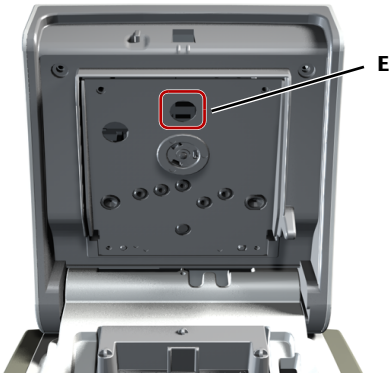
When using a Sani-Cloth Plus Germicidal Disposable Wipe, *squeeze off excess cleaning and disinfecting solution* or blot dry on a paper towel to remove any excess cleaning solution before cleaning the surface of the instrument.

2 Press the lid button (A) at the rear of the instrument and open the lid.

3 To clean, use a Sani-Cloth Plus Germicidal Disposable Wipe to gently wipe the inside of the instrument and disc insertion area (D). Dry the inside of the instrument and disc insertion area thoroughly with a dry cloth or gauze.

The instrument should be cleaned prior to each disinfection step.

Pay particular attention to the temperature sensor window (E).



CAUTION

Incorrect results due to soiled temperature sensor

A soiled temperature sensor may lead to malfunction and incorrect results.

- Do not touch the temperature sensor with your fingers.

4 To disinfect, use a fresh Sani-Cloth Plus Germicidal Disposable Wipe by gently wiping the inside of the instrument and disc insertion area. Allow the inside of the instrument and disc insertion area to remain damp with the recommended cleaning and disinfecting solution for a contact time of greater than 3 minutes.

The inside of the instrument and disc insertion area should stay moist for the entire contact time.

5 Dry the inside of the instrument and disc insertion area thoroughly with a dry cloth or gauze. Visually verify that no solution is seen anywhere on the instrument at the completion of cleaning and disinfecting. *Ensure that the instrument is thoroughly dried after cleaning and disinfecting* (see safety message *Damage to the instrument due to liquid entering internal components* in this section).

6 Close the lid.

7 Reconnect the power cable.

8 Switch on the instrument and check that the startup procedure works without an error message.

■

Damage to the instrument due to liquid entering internal components

Liquids entering internal components may damage them and lead to their disfunctioning.

- Make sure no liquid enters internal components.
- Do not immerse in liquid the instrument or any parts of it.

9.4 Cleaning and disinfecting the barcode scanner

The internal barcode scanner is used for reading the disc barcodes.

Immediately clean and disinfect the barcode scanner of the instrument whenever it is visibly soiled or whenever a spillage occurs.

Clean and disinfect at least once a day.

► To clean and disinfect the barcode scanner

👁 See safety message *Damage to the sensor surface by using unsuitable materials* in this section.

When using a Sani-Cloth Plus Germicidal Disposable Wipe, *squeeze off excess cleaning and disinfecting solution* or blot dry on a paper towel to remove any excess cleaning solution before cleaning the barcode scanner.

1 To clean, use a Sani-Cloth Plus Germicidal Disposable. Wipe to gently wipe the barcode scanner.

The instrument should be cleaned prior to each disinfection step.

2 To disinfect, use a fresh Sani-Cloth Plus Germicidal Disposable Wipe by gently wiping the barcode scanner. Allow the barcode scanner to remain damp with the recommended cleaning and disinfecting solution for a contact time of greater than 3 minutes.

The barcode scanner should stay moist for the entire contact time.

3 Dry the barcode scanner thoroughly with a dry cloth or gauze. Visually verify that no solution is seen anywhere on the barcode scanner at the completion of cleaning and disinfecting. *Ensure that the barcode scanner is thoroughly dried after cleaning and disinfecting.*

■

NOTICE

Damage to the sensor surface by using unsuitable materials

Using unsuitable materials may damage the surface of the sensor.

- Do not use any abrasive cleaning and disinfecting substances or pointed implements for cleaning or disinfecting the sensor surface.

10 Troubleshooting

10.1 Exceptional situations not indicated on screen

The following sections describe how to deal with some exceptional situations that are not indicated on screen.

If a problem persists, contact your Roche service representative.

The instrument display does not come on

Perform the following checks and actions:

- Switch off the instrument, wait 10 seconds and switch on the instrument again.
- Check whether the power on/off switch is damaged and you can slide it to the On and Off positions.
- Check whether the power cable are properly connected.
- Check whether the correct power adapter is used.
- Check whether the power LED on the adapter lights up and the power adapter is working.
- Check the voltage at your mains power outlet.

The touch screen backlight does not function properly

Perform the following checks and actions:

- Check whether any display elements are visible on the screen.
- Check whether the instrument is positioned in an exceptionally bright environment, e.g. in direct sunlight or near strong fluorescent lighting.
- Check whether the display is improved by changing the contrast setting in the setup.

The instrument's touch screen does not work properly

Perform the following checks and actions:

- Check for any signs of damage on the screen such as splotches, punctures, cracks, or ink marks.
- Check whether the instrument has been exposed to extreme temperatures.
- Check whether all the segments are visible and the contrast adjustment works properly.
- When entering characters using the keyboard, check whether anything different than the characters are displayed.

The screen saver (moving white cobas logo on black screen) is displayed

Perform the following checks and actions:

- Check whether Auto Off or Auto Logout are active.
  See *Auto Off* on page 47 and *To define that automatic logoff should be used* on page 60.
- Check that touching the screen results in the work screen being displayed.

The instrument does not generate an acoustic signal when buttons are touched

Perform the following checks and actions:

- Check whether the volume level for **Key Click** is set to zero.
  See *Key Click* on page 46.

The instrument does not generate an acoustic signal when a measurement is complete and or an error occurs

Perform the following checks and actions:

- Check whether the volume level for **Alarm** is set to zero.
  See *Alarm* on page 46.

The instrument displays information in the wrong language

Perform the following checks and actions:

- Check whether the setup for **Language** is set to your language.
  See *Choosing the language* on page 88.

10.2 Exceptional situations indicated on screen

10.2.1 Operator and QC lockout (the control results are no longer valid)

If your instrument is configured to check the validity of control results (see *Operator Lockout* on page 80 and *QC Lockout* on page 81) you may not be able to perform patient tests.

For emergency situations, you can define that a certain number of so-called STAT (short turn around time) tests can be performed even if testing is blocked. See *STAT Test* on page 83.

Note that in the following situations STAT tests cannot be performed either:

- When the optical check test has failed neither HbA1c nor lipid patient tests are available
- When the HbA1c QC test has failed, HbA1c STAT tests are not available
- When the Lipid QC test has failed, lipid STAT tests are not available
- When *All testing function lockout* is enabled in the data management system

Locked testing is indicated on the **Main Menu**:

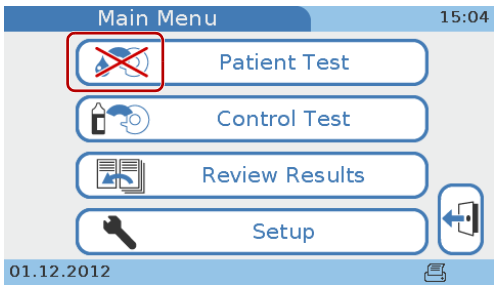


Figure 22 **Main Menu** with locked **Patient Test** function

If you attempt to perform a test you will be informed by messages on screen about the reason why the test cannot currently be performed.

The following table lists examples of screen information related to lockout situations and provides some further explanations.

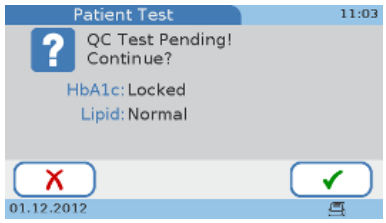
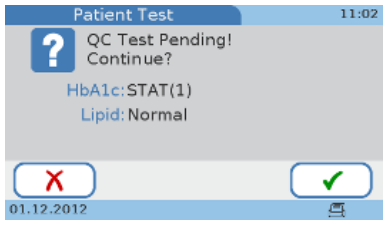
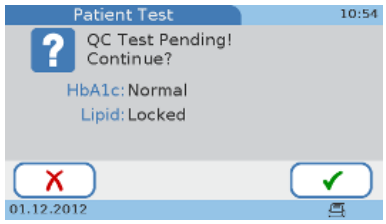
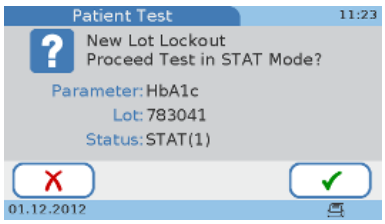
Message	Comment
	You can still perform lipid patient tests, but you need to perform a HbA1c QC test before you can perform another HbA1c patient test.
	You can perform lipid patient tests as normal but HbA1c testing is blocked. Because you work with STAT testing you can perform - in this example - one more HbA1c test. See *To perform a STAT test* on page 124.
	You can still perform HbA1c patient tests, but you need to perform a Lipid QC test before you can perform another lipid patient test.
	Because you work with STAT testing you can perform the HbA1c test as a STAT test, even though the disc is of a new lot and you work with New Lot Lockout. See *To perform a STAT test* on page 124.

Table 15 Lockout situations

The following table lists error messages related to lockout situations and provides some further explanations.

ID	Message text	Comment
I-226	Operator Lockout Run QC Test to Proceed	You cannot perform any tests before you have successfully completed the QC test. You work with operator lockout and the logged-in operator has not performed the QC test within the given interval and the number of allowed STAT tests is zero.
I-227	QC Lockout Run QC Test to Proceed	You cannot perform any tests before you have successfully completed the QC test. You work with QC lockout and the QC test has not been performed within the given interval, and the number of allowed STAT tests is zero.
I-228	Failed QC Lockout Run QC Test to Proceed	You cannot perform any tests before you have successfully completed QC test. The results of the last QC test are not valid (Fail).

Table 16 Messages related to lockout situations

ID	Message text	Comment
I-229	Optical Check Lockout Run Optical Check to Proceed	You cannot perform any tests before you have successfully completed an Optical Check test.
I-230	QC Lockout	Contact System Administrator
I-233	New Lot Lockout Test Control Level 1 and 2 With This Disc Lot to Proceed	You cannot perform any tests before you have successfully completed the QC test. You work with New Lot Lockout and you inserted a disc of a new lot, and the number of allowed STAT tests is zero.
I-234	Failed Optical Check Lockout Run Optical Check to Proceed	You cannot perform any tests before you have successfully completed an Optical Check test. The results of the last Optical Check test are not valid (Fail).
I-405	Wrong Disc (Lipid) Inserted and New Lot Lockout	Test Control Level 1 and 2 With This Disc Lot to Proceed. Repeat Dual Test

Table 16 Messages related to lockout situations (Continued)

10.2.2 Barcode cannot be read

► **To deal with a barcode reading problem**

1. If a barcode cannot be read properly, a message is displayed. Follow the instructions in the message.
2. If the problem persists, perform an optical check test.

   👁 See *Performing an optical check* on page 134.
3. If the problem persists clean the barcode scanner sensor surface.

   👁 See *Cleaning and disinfecting of the cobas b 101 system* on page 149.
4. If the problem persists, check that a supported barcode type is used.

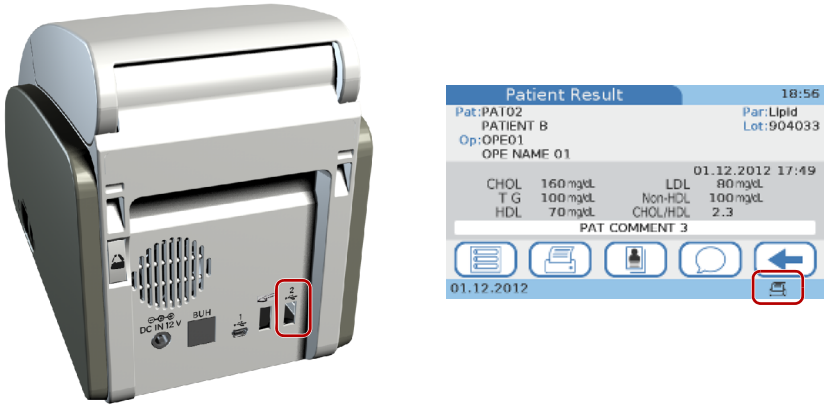
   👁 See *Barcodes* on page 170.
5. If the problem still persists, contact your Roche service representative.

■

10.2.3 Printing is not working

► **To check the printing**

1 Check the connection between the instrument and the printer. (🖶)



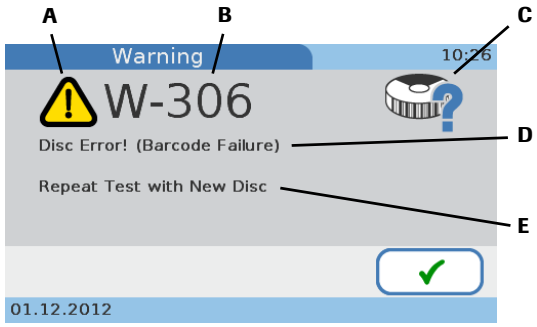
2 Follow the instructions in the printer documentation.

3 If the problem persists contact your Roche service representative.

■

10.3 Error messages

In exceptional situations error messages are displayed. These messages have a distinct structure: The following is an example of a warning message.



A Icon indicates the severity of the issue
B Message ID
C Subject icon
D Description of issue
E Proposed action to resolve the issue

Figure 23 Example of an error message

Use the various information items as follows:

- The icon (A) indicates the severity of the issue, i.e. whether you need to intervene.

Button/Icon	Category	Meaning
	Error	• Hardware problem codes. Operation has stopped. • Software problem codes. Operation has stopped.
	Warning	Application problem codes. The operator needs to repeat the test with a new disc.
	Information	User handling codes. Suggests an alternate workflow. Operation can continue.

Table 17 Icons used on error message screens

- Use the message ID (B) to locate the message text in *Table 18* on page 160 and quote it when contacting your Roche service representative.
- Use the subject icons (C) to get a rough idea of what the message refers to.

  For details, see *Table 4* on page 22.
- Read the description (D) carefully to understand the issue.
- Follow the instructions given in the proposed solution (E).

Error messages

The following table list the error messages, sorted according to their message ID

ID	Message text	Comment
E-001	Software Failed	Execute Software Update
E-002	Instrument Error! (Internal)	Re-Start System or Contact Technical Service
E-003	Battery Down	Contact Technical Service
E-004	Battery Down	Contact Technical Service
E-005	Internal Memory Error (Patient Results)	Contact Technical Service
E-006	Internal Memory Error (QC Results)	Contact Technical Service
E-007	Internal Memory Error (Settings)	Contact Technical Service
E-008	Software Update Failed	Retry Software Update
E-009	Language Update Failed	Retry Language Update
E-100	Unexpected Software Error	Re-Start System or Contact Technical Service
E-101	Unexpected Software Error	Re-Start System or Contact Technical Service
E-102	Data Writing Failed	Format USB Memory Stick and Retry
E-209	Instrument Error! (Internal)	Re-Start System or Contact Technical Service
E-210	Instrument Error! (Temp.Control)	Re-Start System or Contact Technical Service
E-211	Instrument Error! (Optics)	Re-Start System or Contact Technical Service
E-212	Instrument Error! (Lid)	Re-Start System or Contact Technical Service
E-216	Shock During Measurement	Repeat Test with New Disc
E-217	Liquid Detection!	Contact Technical Service
I-200	Ambient Temperature Too High or Low	Turn Off Instrument. Make Sure that the Ambient Temperature Falls Within Specified Limits.
I-201	Disc Temperature Too High or Low	Use New Disc Within Specified Temperature Limits

Table 18 Error messages

ID	Message text	Comment
I-202	Disc Present	Remove Disc
I-203	Disc Present	Remove Disc
I-204	Barcode Scanner Not Connected	Connect Barcode Scanner
I-205	USB Memory Stick Not Connected	Connect USB Memory Stick
I-206	Printer Not Connected	Connect Printer.
I-207	Printer Out Of Paper	Check Printer Paper
I-208	Invalid Installation Condition (Tilt)	Turn Off Instrument and Set Instrument on Plane Surface
I-218	Invalid Barcode Scanner Connected	Connect Recommended Barcode Scanner or Contact Technical Service
I-219	Invalid Operator Barcode	Scan Valid Operator Barcode or Contact System Administrator
I-220	Invalid Patient Barcode	Scan Valid Patient Barcode or Contact System Administrator
I-221	Invalid USB Memory Stick	Connect Valid USB Memory Stick or Contact System Administrator
I-222	USB Memory Stick Disconnected During Processing	Connect USB Memory Stick and Retry Procedure
I-223	Printer Error	Contact Technical Service
I-224	Invalid Printer Connected	Connect Recommended Printer or Contact Technical Service
I-225	All Parameters Disabled	Enable Parameters Before Test
I-226	Operator Lockout	Run QC Test to Proceed
I-227	QC Lockout	Run QC Test to Proceed
I-228	Failed QC Lockout	Run QC Test to Proceed
I-229	Optical Check Lockout	Run Optical Check to Proceed
I-230	QC Lockout	Contact System Administrator
I-232	Comment Required for this Result	Enter Comment
I-233	New Lot Lockout	Test Control Level 1 and 2 With This Disc Lot to Proceed
I-234	Failed Optical Check Lockout	Run Optical Check to Proceed
I-235	Disc Rotation Error!	Remove Disc in Instrument if Disc Exists
I-236	Disc Rotation Error!	Close Disc Hinge Cover and Re-Insert Disc or Contact System Administrator
I-237	Barcode Sensor Window Dirty	Clean Window
I-300	Invalid Disc Inserted (Hinge Cover Open)	Close Hinge Cover and Insert Disc Again
I-301	Used Disc Inserted	Replace Disc
I-302	Invalid Disc Inserted	Replace Disc
I-303	Disc Lot Expired	Use Non-Expired Disc
I-304	Control Lot Expired	Use Non-Expired Control Lot
I-305	Wrong Disc (HbA1c) Inserted!	Inserted Disc is Not Corresponding to QC Info Disc. Retry QC Test with Correct Lot
I-313	Optical Check Disc Expired	Use Non-Expired Optical Check Disc

Table 18 Error messages (Continued)

ID	Message text	Comment
I-314	Wrong Disc (Lipid) Inserted!	Inserted Disc is Not Corresponding to QC Info Disc. Retry QC Test with Correct Lot
I-400	Wrong Disc (Lipid) Inserted!	Repeat HbA1c Test with New Disc
I-401	Wrong Disc (HbA1c) Inserted!	Remove HbA1c Disc and Insert Lipid Disc Immediately
I-404	Wrong Disc (Lipid) Inserted and Disc Lot Expired.	Repeat Dual Test with Non-Expired Disc
I-405	Wrong Disc (Lipid) Inserted and New Lot Lockout	Test Control Level 1 and 2 With This Disc Lot to Proceed. Repeat Dual Test
I-500	Invalid Date	Re-Enter Date
I-501	Operator ID Not Found	Contact System Administrator
I-502	Invalid Operator ID Length	Re-Enter Operator ID
I-503	Invalid Password	Re-Enter Password or Contact System Administrator
I-504	Password Confirmation Failed	Re-Enter Password
I-505	Entered Password Expired	Enter New Password
I-506	Invalid Patient ID Length	Re-Enter Patient ID
I-507	Invalid Patient ID	Re-Enter Patient ID
I-508	Entered Patient Name is Not in List	Re-Enter Patient Name
I-509	Entered Date of Birth is Not in List	Re-Enter Date of Birth
I-510	Invalid Software Update File	Connect USB Memory Stick with Valid Software Update File
I-511	Invalid Range	Re-Enter Range: Max. Must Be Greater Than Min.
I-513	Operator ID Already Defined	Re-Enter Operator ID
I-514	Do Not Delete Own Operator ID	-
I-515	No Patient Name in List	Register Patient Name or Contact System Administrator
I-516	No Date of Birth in List	Register Date of Birth or Contact System Administrator
I-518	Patient ID Already Defined	Re-Enter Patient ID
I-519	Software Update Version Invalid	Connect USB Memory Stick with Valid Software Update File
I-520	Language File Invalid	Connect USB Memory Stick with Valid Language File
I-521	Database Full (Audit Trail)	Oldest Entries Will be Overwritten. Save Audit Trail Log File to USB Memory Stick or DMS.
I-523	Database Full (Operator)	Contact System Administrator
I-524	Database Full (Administrator)	Contact System Administrator
I-525	Database Full (Patient)	Contact System Administrator
I-526	Invalid Password	Re-Enter Password

Table 18 Error messages (Continued)

ID	Message text	Comment
I-527	No Operator Defined	Register Operator or Contact System Administrator
I-528	No Login is Possible When The Operator is Deleted	Register Operator or Contact System Administrator
I-529	No Valid Operator Defined	Register Operator with Valid ID Length
I-530	No Valid Operator Defined	Confirm ID Length of Registered Operator
I-531	No Login is Possible When The Operator is Deleted	Confirm ID Length of Registered Operator
I-532	No Administrator Defined	Register Administrator or Contact System Administrator
I-533	No Login is Possible When The Operator is Deleted	Register Administrator or Contact System Administrator
I-534	No Patient Name and Date of Birth in List	Register Patient Name and Date of Birth or Contact System Administrator
I-535	Invalid Patient Name	Name Must be at Least One Character. Re-Enter Patient Name.
I-536	Entered Operator ID Expired	Contact System Administrator
I-537	Database Full (Patient Test Results)	Contact System Administrator
I-538	Database Full (Control Test Results)	Contact System Administrator
I-539	Database Almost Full (Patient Test Results)	Contact System Administrator
I-540	Database Almost Full (Control Test Results)	Contact System Administrator
I-541	Database Almost Full (Audit Trail)	Save Audit Trail Log File to USB Memory Stick or DMS
I-542	3 Patient Tests Possible Until Database Full	Contact System Administrator
I-543	2 Patient Tests Possible Until Database Full	Contact System Administrator
I-544	1 Patient Test Possible Until Database Full	1 Single Patient Test is Possible But No Dual Test
I-545	3 Patient Tests Possible Until Database Full	After 3 Patient Tests Oldest Result Will be Overwritten Automatically
I-546	2 Patient Tests Possible Until Database Full	After 2 Patient Tests Oldest Result Will be Overwritten Automatically
I-547	1 Patient Test Possible Until Database Full	After 1 Patient Test Oldest Result Will be Overwritten Automatically
I-548	Database Full (Patient Test Results)	Oldest Result Will be Overwritten Automatically
I-549	3 Control Tests Possible Until Database Full	Contact System Administrator
I-550	2 Control Tests Possible Until Database Full	Contact System Administrator
I-551	1 Control Test Possible Until Database Full	QC Test is Not Available

Table 18 Error messages (Continued)

ID	Message text	Comment
I-552	3 Control Tests Possible Until Database Full	After 3 Control Tests Oldest Result Will be Overwritten Automatically
I-553	2 Control Tests Possible Until Database Full	After 2 Control Tests Oldest Result Will be Overwritten Automatically
I-554	1 Control Test Possible Until Database Full	After 1 Control Test Oldest Result Will be Overwritten Automatically
I-555	Database Full (Control Test Results)	Oldest Result Will be Overwritten Automatically
I-556	Invalid Backup File	Connect USB Memory Stick with Valid Backup File
I-557	No Patient Test Possible in Training Mode	Contact System Administrator
I-559	Test Count Limit: Max.1250 Remaining Tests.	Contact Technical Service
I-560	Test Count Limit: Max.750 Remaining Tests	Contact Technical Service
I-561	Test Count Limit: Max.250 Remaining Tests.	Contact Technical Service
I-562	Test Count Limit: Max.50 Remaining Tests.	Contact Technical Service
I-563	Test Count Limit: 2 Tests Possible Until Count Limit.	Contact Technical Service
I-564	Test Count Limit: 1 Test Possible Until Count Limit.	Contact Technical Service
I-565	End of Test Count. Thank You for Using cobas b101.	Contact Technical Service
I-566	No Valid Administrator Defined	Modify ID Length of Registered Administrator
W-306	Disc Error! (Barcode Failure)	Repeat Test with New Disc
W-308	Out Of Measuring Range (Lipid): Above (Hi) or Below (Lo)	[display of range]
W-309	Out Of Measuring Range (HbA1c): Above (Hi) or Below (Lo)	[display of range]
W-310	Interference in Sample	[display of detected interference]
W-315	Dust Detected	Repeat Optical Check with New Optical Check Disc
W-316	Disc Error! (Reaction Failure)	Repeat Test with New Disc
W-317	Disc Error! (Reaction Failure: HbA1c)	Repeat Test with New Disc
W-318	Sample Stability Time Exceeded or No Sample in Disc	Repeat Test with New Disc
W-319	Abnormally High Hemoglobin	—
W-320	Abnormally Low Hemoglobin	—
W-321	Disc Error! (Reaction Failure: Lipid)	Repeat Test with New Disc

Table 18 Error messages (Continued)

ID	Message text	Comment
W-322	Large Sample Volume	Repeat Test with New Disc
W-323	Insufficient Sample Volume	Repeat Test with New Disc
W-403	Sample Stability Time Is Exceeded	Repeat Lipid Panel with New Disc

Table 18 Error messages (Continued)

11 General product specifications

11.1 Technical data

Operating temperature range for operation	+15°C to +32°C (59°F to 90°F), indoor use
Temperature range for storage and transport	-25°C to +60°C (-13°F to +140°F)
Relative humidity for operation	10-85%, (non condensing)
Relative humidity for storage and transport	10-90%, (non condensing)
Maximum altitude for operation	3,000m (9,843 feet)
Position	Place the analyzer on a level, vibration-free surface
Memory	• 5,000 patient test results • 500 control test results • 500 sets of patient information • 50 sets of operator information, including 5 for administrators
Interface	• USB interface for PC • USB interface for barcode scanner • USB interface for printer or USB stick • RS422 interface for Base Unit Hub
Printer	Optional (via USB) See *Accessories* on page 169.
Barcode scanner	Optional (via USB) See *Accessories* on page 169.
Base Unit Hub (BUH)	Optional (via RS422) See *Accessories* on page 169.
Power connection	Overvoltage Category II Pollution Degree 2 IEC/UL 61010-1 Power supply adapter: Input 100 ~ 240 V AC; 50/60 Hz; Output 12V DC. ⊖-C-⊕ Power consumption: Max. 60 VA
Noise emission	Max. 65 dB (A)
User interface	Touch screen and barcode scanner

Dimensions Width: 135 mm (5.31 in)

Height: 184 mm (7.24 in)

Depth: 234 mm (9.21 in)

Weight 2.0 kg (without power supply adapter)

11.1.1 Measuring ranges

The measuring ranges depend on the test parameters.

HbA1c

Parameter	Range
NGSP	4.0-14.0%
IFCC	20-130 mmol/mol

Table 19 Measuring ranges for HbA1c tests

eAG Calculated.

Lipid

Parameter	Range mmol/L	Range mg/dl
CHOL	1.28-12.95	50-500
TG	0.50-7.35	45-650
HDL	0.38-2.60	15-100
LDL	Calculated	
Non-HDL	Calculated	
CHOL/HDL	Calculated	

Table 20 Measuring ranges for lipid tests

11.2 Sample materials

HbA1c test

Sample type	Capillary whole blood, venous whole blood with anticoagulant (EDTA or heparin)
Sample size	At least 2 µL
Interferences	Refer to the HbA1c disc package insert

Table 21 Sample materials for HbA1c tests

CAUTION

Incorrect results due to using inappropriate anticoagulants

Using inappropriate anticoagulants may interfere with the reagents and lead to incorrect results.

- Do not use inappropriate anticoagulants.

Lipid test

Sample type	Capillary whole blood, venous whole blood with anticoagulant (EDTA), plasma with anticoagulant (EDTA)
Sample size	At least 19 µL
Interferences	Refer to the Lipid disc package insert

Table 22 Sample materials for lipid tests

11.3 Further Information

11.3.1 Materials supplied by Roche

The following materials are available through Roche. For details contact your local Roche representative.

- **cobas** HbA1c Test
- **cobas** Lipid Panel
- **cobas** HbA1c Control
- **cobas** Lipid Control

11.3.2 Other materials

- Accu-Chek Safe-T-Pro Plus (single-use disposable lancets)
- Sani-Cloth Plus Germicidal Disposable Wipes
- Powder free gloves
- Cotton swabs
- Lint-free cloths

11.3.3 Accessories

Item	Comment
External printer	• TPL2824 (Zebra) • CT-S281L (Citizen Systems) • Printer paper and labels
Barcode scanner	MS180-1UVG (Unitech corporation) The barcode scanner must be able to read at least one of the following barcode formats: • Code 128 (ISO/IEC15417, JIS-X-0504) • Code 93 (USS-CODE93) • Code 39 (ISO/IEC16388, JIS-X-0503) • Interleaved 2 of 5 (ISO/IEC16390,JIS-X-0505) • codabar [NW-7] (ANSI/AIM BC3-1995, JIS-X-0506) Make sure you use one of the above barcode formats for your barcodes.
Base Unit Hub	Required for stand-alone network connection.
Optical Check Disc	Replacement disc if damaged or lost.

Table 23 Accessories

11.3.4 Product limitations

For details on product data and limitations, refer to the information in the package insert supplied with each test disc.

11.3.5 Barcodes

Operator and patient ID barcode masks

Barcode mask character	Definition
A-Z, 0-9	If not preceded by the Caret (“^”), the scan data character must be the same as the mask character. This character is not saved as part of the ID. If the characters are not the same, the scan data is not a valid ID.
Dollar (“$”)	The scan data character in this position is kept as part of the ID.
Asterisk (“*“)	The scan data character in this position is not kept as part of the ID.
Tilde (“~”)	The scan data character in this position must be a number, 0-9, and it is not kept as part of the ID. If the scan data character is not a number, the scan data is not a valid ID.
Plus (“+”)	The scan data character in this position must be an alphabetic character, A – Z, and it is not kept as part of the ID. If the scan data character is not an alphabetic character, the scan data is not a valid ID.
Caret (“^”)	This mask character denotes that the scan data character must be equal to the next character in the barcode mask after the “^”, and that the scan data character is kept as part of the ID. If the scan data character is not equal to the mask character following the “^”, the barcode reading is invalid as an ID.

Table 24 Barcode masks

Acceptable characters

You can use all characters from the on-screen keyboard, with the exception of characters with diacritic marks, for example: Á, Ç, É, Í, Ñ, Ó, Ú, Ü.

Effective scanning size

80 mm

Samples of recommended barcodes

Barcode	Description
 1234567890	Codabar (ANSI/AIM BC3-1995, JIS-X-0506)
 1234567890	Code 39 (ISO/IEC16388,JIS-X-0503)
 1234567890	Code 93 (USS-CODE93)

Table 25 Sample barcodes

Barcode	Description
 1234567890	Code 128 (ISO/IEC15417,JIS-X-0504)
 1234567890	Interleaved 2 of 5 (ISO/IEC16390,JIS-X-0505)

Table 25 Sample barcodes (Continued)

11.4 Warranty

The statutory guarantee provisions on rights in consumer goods sales in the country of purchase shall apply.

11.5 Contact information for Roche

For all questions about the **cobas b** 101 system that are not answered in this operator's manual, contact your Roche representative.

► **To find your Roche contact details**

1 Visit our website at www.roche.com.

2 Choose **Roche Worldwide** at the top of the page.

3 Choose your country to find the appropriate local office contact information.

■

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