





cobas c pack opener
Operator's Manual



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Document information

<i>Revision history</i>	Manual version	Revision date	Changes
	1.0	August 2009	Initial version
<i>Edition notice</i>	Operator's Manual for users of the cobas c pack opener. Every effort has been made to ensure that all the information contained in this manual is correct at the time of printing. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as a part of ongoing product development. Any customer modification to the instrument will render the warranty or service agreement null and void.		
<i>Intended use</i>	The cobas c pack opener is a semiautomatic device designed for use with cobas [®] 8000 modular analyzer series and cobas [®] c 711 (a product used only in the Spanish market). It is intended for opening the cobas c pack (with two caps) and the cobas c pack large.		
<i>Copyright</i>	© 2009, Roche Diagnostics GmbH. All rights reserved.		
<i>Trademarks</i>	The following trademarks are acknowledged: cobas , cobas c , and LIFE NEEDS ANSWERS are trademarks of Roche.		
<i>Instrument approvals</i>	<p>The cobas c pack opener meets the protection requirements laid down in IVD Directive 98/79/EC. Furthermore, the device is manufactured and tested according to the following international standards:</p> <ul style="list-style-type: none"> • IEC 61010-1: 2001 • IEC 61010-2-101: 2003 • UL 61010-1: 2001 • CAN/CSA 22.2 No. 61010-1-04 • IEC 61326-2-6 <p>The Operator's Manual meets the requirements of European Standard EN 591. Compliance is demonstrated by the following marks:</p> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="margin-right: 20px;">  </div> <div>Complies with the IVD directive 98/79/EC.</div> </div> <div style="display: flex; align-items: center; margin-top: 20px;"> <div style="margin-right: 20px;">  </div> <div>Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.</div> </div>		

Contact address

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Conventions used in this manual

Visual cues are used to help quickly locate and interpret information in this manual. This section explains the formatting conventions used 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 (without a signal word) is used to promote awareness of generic hazards or to direct the reader to safety information provided elsewhere in the document.



The following 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

NOTICE

Indicates a hazardous situation which, if not avoided, may result in property damage.

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



Tip

Indicates additional information on correct use of the device or useful tips.

The following symbols are also used:

Symbol	Used for
▶	Start of procedure
•	List item
👁	Cross-reference

Other symbols

On the nameplate of the device you will find the following additional symbols that have not been explained so far.

Symbol	Meaning
	This device is covered by the European Directive WEEE.
	Harmonized symbol designating an in vitro diagnostic medical device.

Unpacking and assembly

The cobas c pack opener is delivered in a box. If any part was damaged during transport, inform your supplier or the carrier immediately.

► Unpacking the cobas c pack opener

- 1 Open the box as indicated.
 - 👁 Refer to the label on the box.

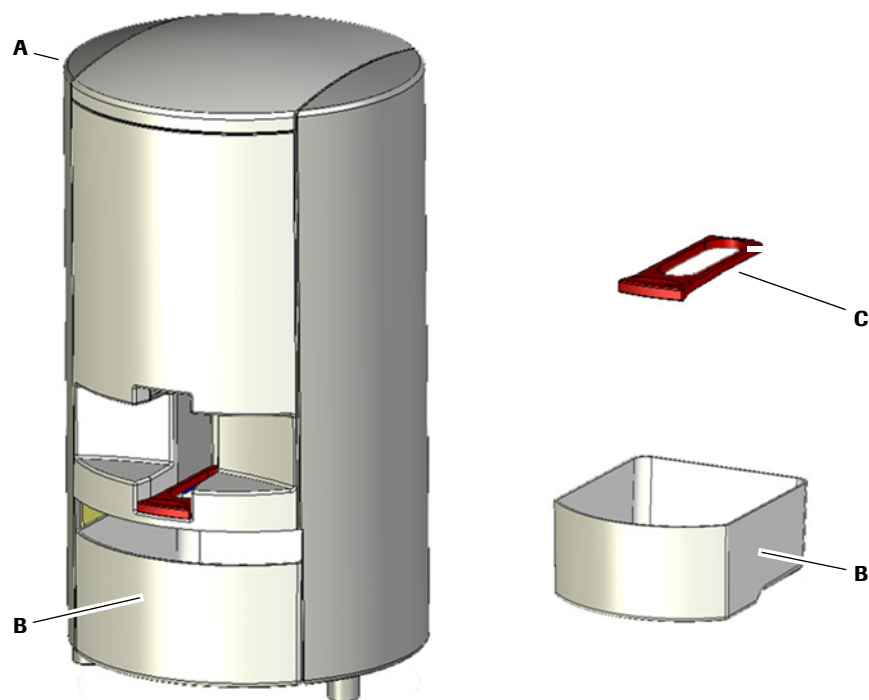


Personal injury due to heavy and slippery device

The unit may slip out of your hands.

Always hold the unit firmly.

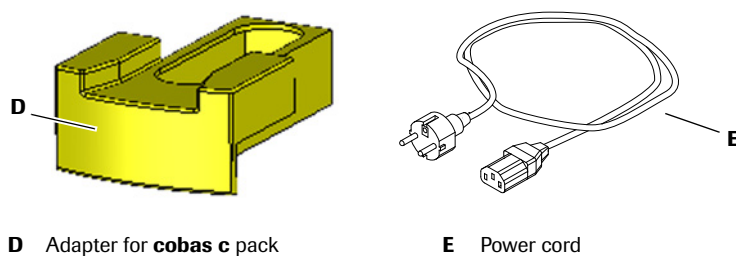
- 2 Grasp the unit firmly and remove the unit from the box.
- 3 Place the unit in an upright position on the bench.
- 4 Pull off the top foam cushion.
- 5 Separate the unit from the bottom foam cushion.
- 6 Pull off the plastic foil and remove the desiccant bag from the unit.
- 7 Place the unit on a stable, vibration-free surface, for example a bench. Do not place in direct sunlight. Comply with other environmental requirements.
 - 👁 *Technical data and specifications* on page 20
- 8 Check that the consignment is complete.



A cobas c pack opener
B Waste container

C Adapter for cobas c pack large

Figure 1 cobas c pack opener and components

**D** Adapter for **cobas c** pack**E** Power cord**Figure 2** Optional components

The adapter (C) for using **cobas c** pack large is part of the standard **cobas c** pack opener consignment.

Adapter (D) for use with standard-size **cobas c** packs is available separately (for **cobas c** 711 in the spanish market only). Please contact your local Roche representative for more details.

The device is delivered without a power cord (E). A country-specific power cord is provided separately by Roche.

If any items are missing, inform your supplier without delay.



Keep the original packaging. Transport the **cobas c** pack opener only in the original packaging.

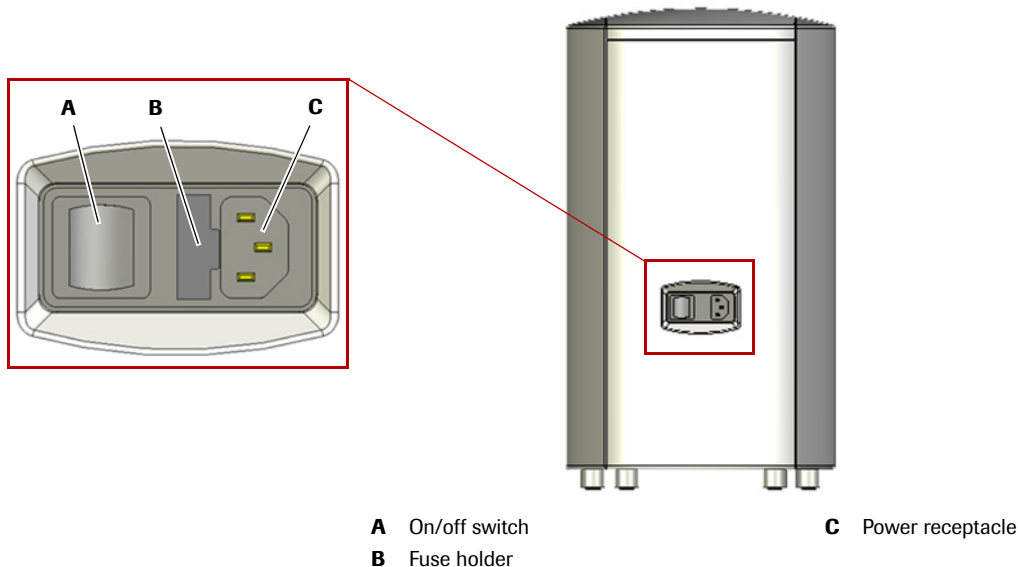
► Setting up the cobas c pack opener

- 1 Place the adapter that relates to the type of **cobas c** pack that you are using.
- 2 Connect the power cord. The **cobas c** pack opener will adjust to the local lines automatically.

Once the power cord is plugged in, the **cobas c** pack opener is ready for use.



Before using the **cobas c** pack opener, check that the power cord is connected properly!

**A** On/off switch**B** Fuse holder**C** Power receptacle**Figure 3** Rear view of the **cobas c** pack opener

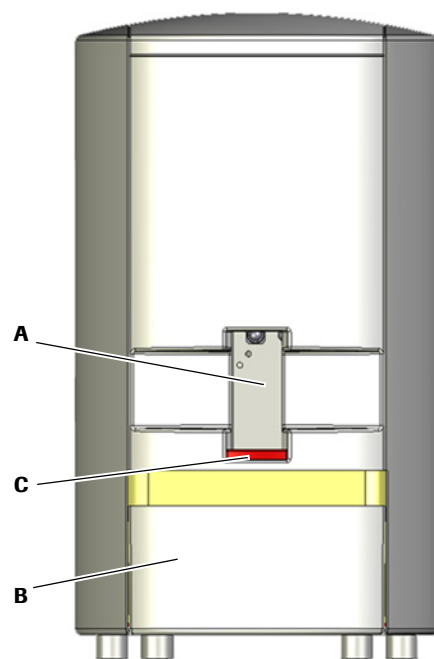
Product description

The cobas c pack opener is a semiautomatic device, designed to decap integrated reagent bottles.



Figure 4 A cobas c pack large

The cobas c pack opener is a tabletop unit that can be operated by users in a standing or seated position.



A Port for cobas c pack
B Waste container

C Adapter for cobas c pack large

Figure 5 Front view of cobas c pack opener with a standard-size adapter

- General information* A cobas c pack is inserted in the port (A) at the front of the unit. The adapter (C) is positioned directly at the bottom of the port.
- A waste container for the caps (B) is located beneath the port. The waste container is easy to empty and is dishwasher-safe up to 65°C.
- A blue light (LED) is located upside of the waste container. This light indicates that the unit is ready for use and, additionally, it illuminates the waste container.

Operator qualification

Operators are required to have knowledge of the relevant guidelines and standards as well as of the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the unit.
- Leave maintenance, installation or service that is not described in the Operator's Manual to trained Roche service personnel.
- Follow standard laboratory practice, especially when working with biohazard material.

Power on and operation



Skin irritation due to reagent traces

The **cobas c** pack caps may be contaminated by reagent splashes.

- Wear proper gloves and safety glasses.
- Do not touch your face or your eyes during operation.

► Power on

- 1 Before powering the unit on, please ensure that **no cobas c** pack is inside the c pack opener.
- 2 Power on the unit.
- 3 After a short initialization, the c pack opener will be ready for use. The blue light shine continuously.

► Opening a cobas c pack

- 1 Completely unwrap the packaging foil from a **cobas c** pack.

► To decap a cobas c pack



Use only cobas c packs with two caps

The **cobas c** pack opener is designed for **cobas c** packs with two caps exclusively.

Do not use or try **cobas c** packs with three caps!

- 1 Fully insert the **cobas c** pack by hand into the port until the motor starts and the light turns off.

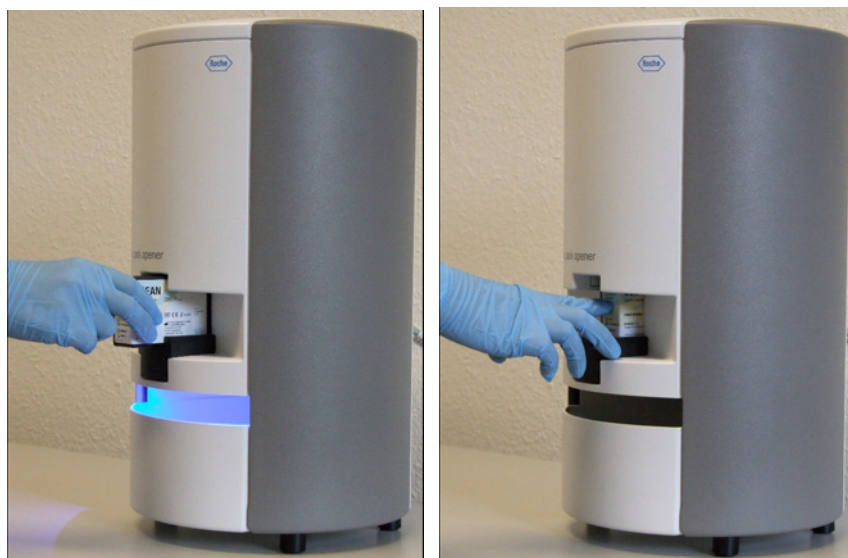


Figure 6 Inserting a **cobas c** pack by hand.



- The cap's orientation must be upwards.
- Insert only one **cobas c** pack at a time. Move the c pack to its full stop position.

- 2 Wait until the motor stops and the blue light flashes.



- 3 Remove the opened **cobas c** pack.

Ensure that no foreign object gets into the **cobas c** pack when the caps are off.

- 4 To process another **cobas c** pack, wait until the light turns on again.
- 5 Repeat steps 1 to 5.

► **Checking the waste container**

- 1 Check the level of the waste container at the end of the day.
- 2 Empty the container if it is full.

👁 *Maintenance* on page 15



Skin irritation due to reagent traces

When emptying the waste container, follow the normal precautions for handling reagents. Disposal of all waste material should be in accordance with local guidelines.

Disposal of the device



This device is covered by the European Directive WEEE.

The device must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office, waste disposal service or your local Roche Support personnel.



Personal injury due to sharp-edged parts of the device

Do not attempt to take the device apart for repair or disposal.

Maintenance

The cobas c pack opener is a maintenance-free device.

Users are responsible for cleaning the unit on a regular basis.

► Empty the waste container and clean the unit

NOTICE

Always switch off and unplug the unit prior to cleaning.

Do not allow liquids to enter the device.

Do not spray cleaning agents directly onto the device. Use a lint-free tissue or a moistened cotton bud.

- 1 Tilt the waste container and pull out.

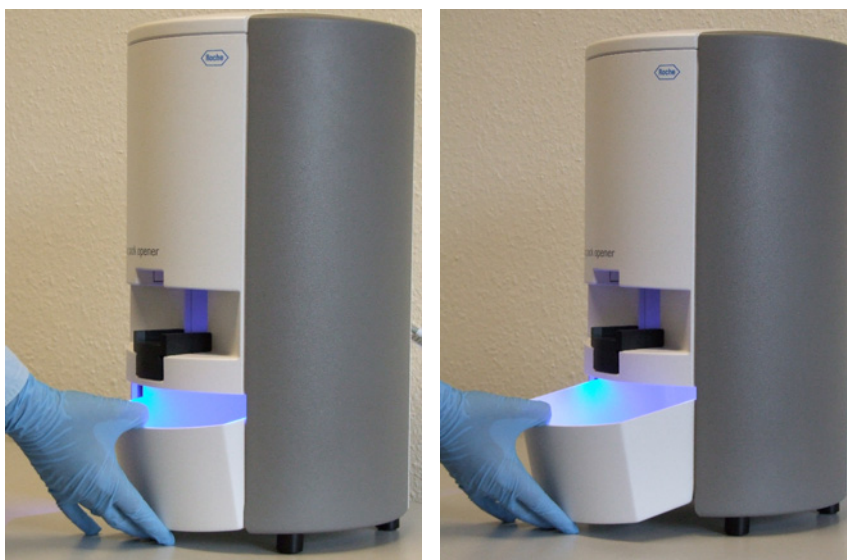


Figure 7 Emptying the waste container

- 2 Dispose of the caps in accordance with local specifications and laws.



After 100 (max. 150) **cobas c** packs, empty the waste container.

- 3 Put the waste container in the dishwasher.



The waste container is dishwasher-safe up to 65°C (149°F).

Do not put adapters into the dishwasher!

- 4 Clean surfaces of the unit with a lint-free tissue or a moistened cotton bud if necessary, using mild detergents or disinfectants, preferably 70% alcohol.

► **Changing the fuses**

- 1 Switch off the unit and disconnect the power cord.
If the power cord is still connected, you will not be able to access the fuse holder.
- 2 Using the tip of a blade screwdriver, lift the fuse holder out of the unit.



Figure 8 Lifting the fuse holder

- 3 Replace both fuses.
Make sure you are using the correct types:
(Type 2A/250V AC (5 x 20 mm) - Blow Characteristic -Time Delay).
- 4 Reconnect the power cord to the unit.
- 5 Switch on the unit.

Troubleshooting

This chapter provides information how to troubleshoot the c pack opener.

Removing a jammed c pack large

Main cause Unscrewed cap(s) fall(s) back onto of the c pack and cause(s) a jam on the top side of the **cobas c** pack large. It is not possible to remove the **cobas c** pack large manually.



Figure 9 A **cobas c** pack large jammed in a cobas c pack opener

- Remedy*
- 1 Pull out the adapter used for **cobas c** pack large.
 - 2 Pull out the waste container



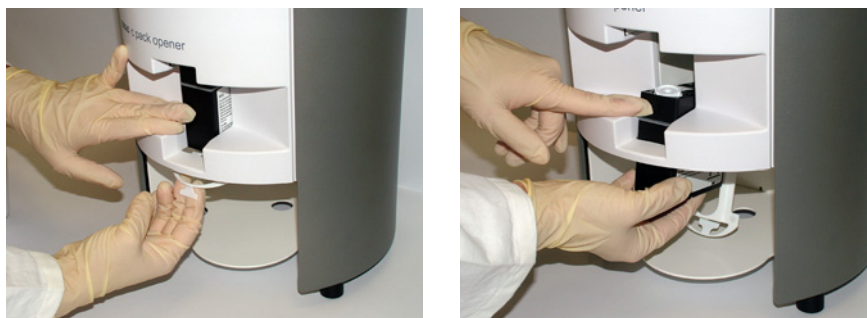
A Adapter **cobas c** pack large



B Waste container

Figure 10 Removing adapter and waste container

- 3 Pull down the emergency flap
- 4 Remove the **cobas c** pack large, moving it down step by step.



A Moving the **cobas c** pack large down

Figure 11 Removing the **cobas c** pack large

5 Remove the **cobas c** pack large and all loose caps.

NOTICE

Before using the affected c pack - manually unscrew any cap, that has been left open.

6 Move the emergency flap to its magnetic default position.

7 Reinstall adapter and waste container.

The c pack opener is ready to be used again.

Initialization does not start or is unsuccessful.

Main cause 1 A **cobas c** pack is in the port as the **cobas c** pack opener is switched on.

Remedy Pull out the **cobas c** pack. As soon as the **cobas c** pack is fully removed from the port, initialization continues

or

Main cause 2 The **cobas c** pack opener is defective.

Remedy Call service

After inserting a cobas c pack: Mechanism starts but stops almost immediately, the blue light fails to switch on again.

Main cause The **cobas c** pack is not inserted correctly.

- The **cobas c** pack was not kept in the correct position for sufficient time.
- The caps are at the bottom and not at the top.
- The plastic foil was not removed completely from the **cobas c** pack

- Remedies*
- Pull out the **cobas c** pack.
 - Check the **cobas c** pack
 - Insert it again.

After inserting a cobas c pack: Mechanism does not start, the blue light fails to switch on again.

- Main causes*
- The cobas c pack was inserted without an adapter and it was pushed up during insertion.
 - The wrong adapter was used and the cobas c pack was pushed up during insertion.
- Remedies*
- Pull out the cobas c pack.
 - Insert the proper adapter.
 - Reinsert the cobas c pack.

After inserting a cobas c pack: Mechanism does not start.

- Main cause* The cobas c pack was inserted without an adapter.
- Remedy*
- Pull out the cobas c pack completely.
 - Place the adapter.
 - Insert the cobas c pack again.

The unit does not work and the light flashes (a cobas c pack large was inserted).

- Main cause* Mechanism is stuck.
- Remedies*
- Switch off the unit.
 - Remove the adapter. The cobas c pack large drops down.
 - Pull out the cobas c pack large.
 - Replace the adapter.
 - Switch on the unit.

The unit does not work, no cobas c pack is inserted and the light is not flashing.

- Main cause* The c pack opener has no power.
- Remedies*
- Check that the power cord is connected to the power supply.
 - Switch off the unit and switch it on again.

Technical data and specifications


Dimensions (max.)	cobas c pack opener	
	• Height	460 mm
	• Diameter	255 mm
	• Weight	11 kg
	cobas c pack	
	• Height	60.7 mm
	• Width	35.4 mm
	• Depth	82.4 mm
	cobas c pack large	
	• Height	82.0 mm
• Width	35.4 mm	
• Depth	82.4 mm	
Power supply		
 WARNING	Electrical shock from electronic equipment	
	The cobas c pack opener must only be connected to an approved power source (3-wire grounded receptacle) using the specified power supply cable.	
	Supply voltage	100 - 240V (AC) ± 10%
	Frequency	50/60 Hz ±5%
	Power rating	100 VA
	Overvoltage category	II
	Pollution degree	2
	Fuse type	2A/250V AC - Type: Time Delay (5 x 20 mm) (Two fuses needed)
Environmental conditions		
	Temperature	
	Indoor use	
	Altitude	up to 2000 m
	• Operating conditions	5°C to 40°C (41°F to 104°F)
	• Transport and storage	-25°C to 70°C (-13°F to 158°F)
	Relative humidity	
	• Operating conditions	Up to 85%
	• Transport and storage	Up to 93%
Chemical resistance		
	Surface resistance	against cleaning agents typically found in laboratories and 70% isopropanol solution
	Waste container	Dishwasher-safe to max. 65°C (149°F)

Table 1 Technical data

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