cobas c 111

Installation Manual

Version 3.0

29-Sep-2009

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CONTENT:

1. Preface

1.1 Revision history

Version	Revision date	Comments
0.1	May 2005	Draft version
0.2	June 2005	Improved draft
0.5	January 2006	Improved draft 2
0.9	May 2006	Improved draft 3
1.0	June 2006	First release version
1.1	July 2006	Corrected version (procedure)
1.2	August 2006	Regulatory corrections
1.3	March 2007	Update of procedures
1.4	October 2007	Update of procedures
2.0	April 2008	Update of procedure for deinstallation ISE
2.1	Sep 2008	Update of instrument placement & prep.
2.2	April 2009	New transport protection Installation procedure ISE adjusted
3.0	September 2009	Generally remarks concerning Data base and applications added (empty Database)

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Questions or comments regarding the contents of this Manual can be directed to the address below or to your Roche representative.

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Switzerland

Every effort has been made to ensure that all the information contained in the **cobas c** 111 Installation Manual is correct at the time of printing.
However, Roche Diagnostic Ltd. reserves the right to make any changes necessary without notice as part of ongoing product development.

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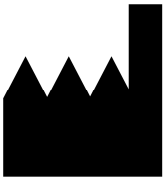

Manufacturer

Roche Diagnostics Ltd.
Forrenstrasse
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Switzerland

1.4 Intended use

The **cobas c** 111 instrument is a continuous random-access analyzer intended for the in-vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine or whole blood. (Only HbA1c application)
It is important that the operators read this manual thoroughly before using the system. Any disregard of the instructions in this or the Operator's Manual may result in a safety risk.

2. About this manual

This manual is to be used for unpacking, installing and registering the **cobas c** 111. For detailed instrument information, see the **cobas c** 111 Operator's Manual.

2.1 Conventions used in this manual

The conventions used in this manual are as follows:

1., 2., 3., represents sequential steps in a procedure. You should follow these steps in order.

2.1.1 Symbol listing

Caution: Refer to accompanying documents.

Manufacturer of device

These symbols are provided on the type plate of the instrument

Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE. The symbol denotes that the equipment must not be disposed of in the municipal waste system.
(WEEE = Directive 2002/96/EC of the European Parliament and the council of 27 January 2003 on waste electrical and electronic equipment.)

2.1.2 Abbreviations

The following abbreviations are used:

Units	
cm	Centimeters
in	Inches
lb	Pounds (weight)
psi	Pounds per square inch
VA	Volt- Amperes
VAC	Volts (alternating current)
MΩ	Megohm (10^6 ohms)

Acronyms

UL	Underwriters Laboratories Inc.
IEC	International Electro technical Commission
CSA	Canadian Standard Association
LED	Light emitting diode
CB	Certification body
FCC	Federal Communications Commission
EN	European Norm

3. Safety information

Before operating the **cobas c** 111, it is essential that you read and understand the safety information listed here.

3.1 Safety classifications

The safety precautions and important user notes are classified according to ANSI Z535 resp. ISO 3864 standards. You must familiarize yourself with following signs and their meanings:

Danger

- Indicates a direct danger that, if not avoided, may result in death or serious injury.

Warning

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

Caution

- Indicates a possibly hazardous situation that, if not avoided, may result in slight or minor injury or may result in damage to equipment.

General warning symbol on the analyzer

- The triangular warning symbol on the analyzer is a general reminder that users should read the safety information contained in this manual. Users must be able to identify specific hazards and take appropriate action to avoid them.

3.2 Safety notices

Read the Roche Diagnostics safety notices carefully and make sure you understand them. This information should be made available to new employees and kept for future reference.

Electrical safety

Danger

- Danger of electric shock. Keep the side panels closed while the analyzer is connected to the main power supply!
- The **cobas c** 111 is designed in accordance with safety standard EN/IEC 61010-1. Grounding of the instrument and those surfaces the user can come into contact with is provided by a grounded cable in accordance with protection class 1 (IEC). Users should not perform any servicing except as specifically stated in the **cobas c** 111 Operator's Manual.

Biological safety

- Liquid waste and cuvette waste are potentially biological hazardous. Always wear gloves when handling those materials. Do not touch parts of the analyzer other than those specified. If sample is spilled on the analyzer, wipe up immediately and apply disinfectant. Consult your laboratory protocol for handling biohazard materials.

Software virus warning

Warning

- Roche does not provide any anti-virus Software. Therefore, it is essential to take precautions to ensure that any software loaded onto the system is virus-free.
  Do not load any software that is not approved by Roche Diagnostics!

Recommendations

Check any data carrier (e.g. USB memory stick) with an anti-virus program (on another computer) to ensure that they are virus free before using them on the **cobas c** 111.

Optical Safety

Warning

- **Loss of sight!** The intense light of the LEDs may severely damage your eyes. Do not stare into the LEDs! Scanning equipment using LED technology is covered by the international standard IEC 60825-1 LED safety: Class 1

Instrument Service & Maintenance

The **cobas c** 111 is an electromechanical device that has no internal electrical parts serviceable by the user. For preventive maintenance, contact your Roche Service representative who is trained and qualified to perform the necessary maintenance.
Any unauthorized modification to the system shall render the warranty or service agreement null and void.

User safety

Read the following list to familiarize yourself with the potential hazards and the precautions for operating the **cobas c** 111.

Electrical safety
Danger of electric shock if you touch any power supply parts.
Do not access any electrical parts while the analyzer is connected to the main power supply.
Users may replace fuses if they follow the procedures described in this manual. Any other electrical modification is not allowed and may render any warranties on the **cobas c** 111 null and void.

Fire risk
Danger of explosion through sparks. Keep all potentially flammable or explosive material (for example, anesthetic gas) away from the analyzer.
Spraying liquid on the power supply parts can cause a short circuit and result in a fire. Keep the cover closed while the analyzer is connected to the main power supply and do not use sprays in the vicinity of the **cobas c** 111.
During fire-fighting operations disconnect the **cobas c** 111 from the main power supply.

Analyzer in use
Danger of hands injury by moving parts. Keep all covers closed during initialization or operation.

Samples
Danger from infectious sample material can cause severe illness. Avoid direct contact with sample material. Clean contaminated surfaces immediately and dispose of waste according to local regulations. Please refer to your local safety regulations regarding handling sample material.

Waste
Danger from infectious waste material can cause severe illness. Avoid direct contact with waste. Dispose of the waste according to local regulations.

Quality control
Danger of false results. Patients can be put at risk if false results lead to incorrect diagnosis and therapy. Carry out quality controls according to the local regulations.

Correct use
Use the **cobas c** 111 only for measuring liquid sample material with the specified Roche reagents. Sample material can be serum, plasma, urine.

User qualification
Danger from incorrect operation. The **cobas c** 111 should only be used by a qualified operator experienced in the use of such equipment.

Environmental conditions
Incorrect location can cause incorrect results and damage to the equipment parts. Follow the installation instructions carefully. Moving the **cobas c** 111 must be performed only by qualified personnel.

Location
The **cobas c** 111 is designed for indoor use and the instrument must be located on a stable and level surface that is not subject to vibration. The instrument should not be placed in a position where strong or variable light conditions exist (e.g. direct sunlight). Avoid locations where other equipment may create interference from high frequency or high voltage electromagnetic fields.
Allow sufficient space around the instrument for convenient working.

Environmental conditions

The **cobas c** 111 is designed to operate in a controlled environment. In particular the room temperature, relative humidity and atmospheric pollution conditions must be maintained within the limits specified above (par. 4.3). Operation outside of the specified ranges may cause erratic operation or, in exceptional circumstances, component failure.

Protective grounding

The protective grounding is done via the mains power cord. There are no special provisions for protective grounding required.

Warning

Any break in the electrical ground wire, whether inside or outside the analyzer, or disconnection of the electrical ground connection, may create a hazardous condition.

Under no circumstances should the user attempt to modify or deliberately override the safety features of this system.

Risk of infection from contaminated samples!

Fluid and cuvette waste is potentially biologically hazardous.

Samples containing material of human origin must be treated as potentially infectious. Always wear protective gloves when handling this material.

Do not touch parts of the analyzer other than those specified.

The whole inside of the system may be contaminated with potentially infectious or toxic material.

Always wear protective gloves when cleaning the following parts:

Waste area, Sample Area, Pipetting System e.g., probes,

Battery may explode if mistreated!

Do not recharge, disassemble or dispose of the battery in fire.
Servicing of the battery circuit and replacement of the lithium battery must not be done by the user.
Only authorized persons are allowed to replace the lithium battery.
Replace Battery with type Sonnenschein SL-360/S only.
Use of another battery may present a risk of fire or explosion.

User maintenance actions and internal cleaning

All internal cleaning must be performed according to the instructions given in the ***cobas c** 111 Operator's Manual.*

Danger of damaging the Touch-Screen Display

Excessive use of liquid cleaner may damage the Touch-Screen display! Do not spray any cleaner liquid directly onto the screen! Please clean the surface of the monitor with a cloth that is moistened with cleaner liquid.

4. Overview

4.1 Introduction

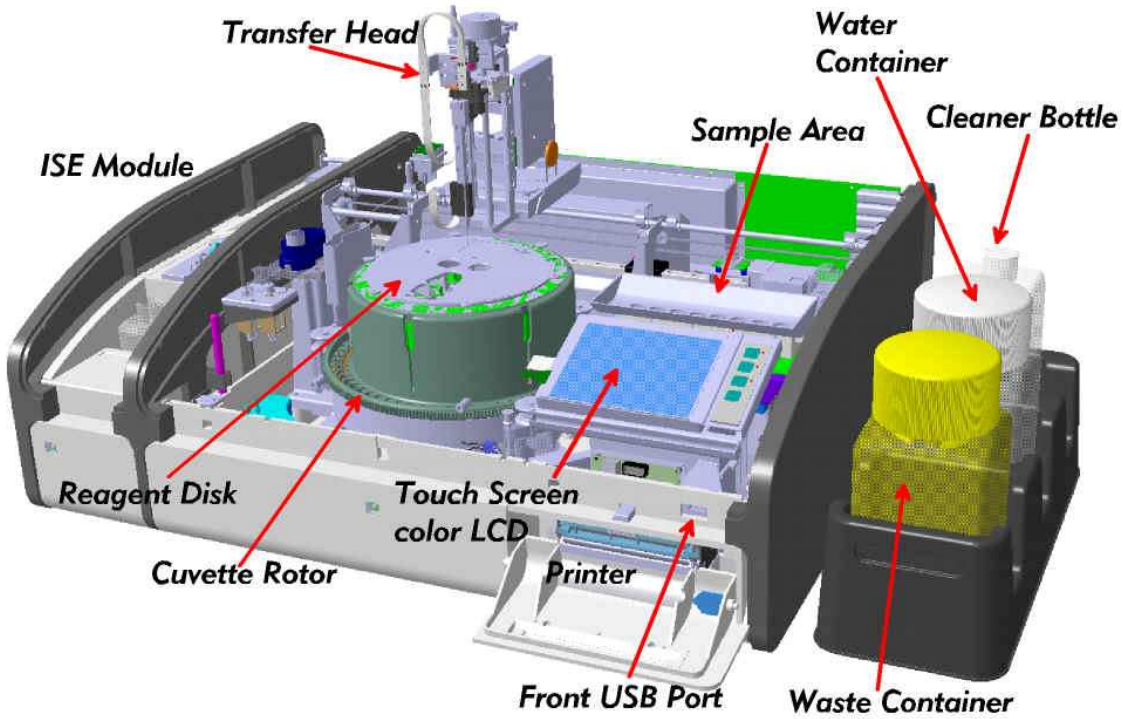
The **cobas c** 111 analyzer is intended for in vitro quantitative or qualitative determination of a wide range of analytes in serum, plasma and urine. (Whole blood only with HbA1c application.)
The **cobas c** 111 is intended for professional use only.

The primary functions of the **cobas c** 111 analyzer include:

- Manual loading of various primary and secondary sample tubes onto the instrument providing 8 positions.
- Sample volume per test from 2 ... 15 µl
- Manual and/or computer-interfaced test ordering
- Cooled storage area for Roche reagents. 27 reagent bottles per reagent disk and up to 8 reagent disks can be handled. Using reagents manufactured by Roche Diagnostics ensures best quality of stable and reliable results.
- Bar-coded reagent bottles for easy handling.
- Absorbance Photometry measurements with 12 wavelengths ranging from 340 nm up to 659 nm
- Ion Selective Electrode (ISE) measurements for Na, K, and Cl, using the indirect method. Dilution of the sample 1:6.
- Result memory can keep up to 300 patient results.
- Optional formats for data interchange via RS-232 (ASTM-protocol)
- Sample identification with handheld barcode scanner
- Internal thermal printer (112 mm paper width)

4.2 Instrument internal layout

The major components of the analyzer are shown below in fig 1.



4.3 Technical specifications

Software and data handling	Operating System	LINUX VX Works
	Memory DM- Module PXA 255	32 MB Flash ROM 32 MB DRAM
	Memory RT-CPU PXA 255	32 MB Flash ROM 32 MB DRAM 2 MB SRAM
	Communication between DM and RT	10/100 BaseT Ethernet (for internal use only)
	Communication between RT-CPU and µC boards	TegiLink Bus (RS485)
Mass Storage	➢ internal	Flash ROM
	➢ external (data share)	USB Memory Stick
	Interfaces (external)	
	➢ 2 x USB 1.1/2.0	Memory stick, Modem
	➢ 2 x RS-232	- Host - Barcode Reader
	Display	5.7 in. color LCD, (¼ VGA - 320 x 240 pixels); passive matrix touch screen.
	Printer	Internal thermal printer (112 mm paper width)
Samples	Sample handling	Direct tube placement manually by user
	Incubation time	Max. 12 min. / 40 cycles
	Typical time to result	ABS: 4 min. to 12 min. ISE: 90 sec. (Na, K, Cl)
	Instrument cycle time	18 sec.
Reagent bottles	Content	20 ml maximum
	Identification	Barcode 2-d, Format PDF417
	Number of tests	50-200 depending of test
Calibration	Use of Roche test-specific calibrator fluids	CFAS, ISE Calibrator, etc.
	Use of recommended QC material	PreciNorm, PreciPath, etc.
Cuvette handling	6 segments of 10 cuvettes each. Single use only	Manual handling of cuvette segments during standby.
	Incubation Temperature	37°C ± 0.2°C
Measuring Unit	Absorbance photometer	20 W halogen lamp
	12 Wavelengths	340 nm ... 659 nm
	Sensor	Photosensitive diode array

ISE	Ion-Selective Electrode	Indirect measurement
	Sample volume	15 µl (Dilution 1:6)
	OMNI©-Style Electrodes	Na, K, Cl, Reference

Physical dimensions (max.)	Width /(with ISE)	590 mm / (720 mm)
	Depth / (with ISE)	550 mm / (550 mm)
	Height / (with ISE)	480 mm / (480 mm)
	Weight / (with ISE)	32 kg (35 kg)
Packing dimensions	Width	850 mm
	Depth	700 mm
	Height	850 mm
	Weight	58 kg
Power require-ments w/o ISE	Line voltage	100 – 250 V~ 4 A max.
	Line frequency	47 – 63 Hz
	Power consumption	250 VA
This unit must be connected to a grounded mains outlet!		
	Insulation coordination	Category II (IEC 61010-1)
	Main Fuse	T6.3A H 250V
	Secondary Fuses (4x)	T3.15A 250V
	Battery	 Replace Battery with type Sonnenschein SL360 only Not to be replaced by user!
ISE unit Data (Option)	External Power Supply UL-listed QQGQ/7 or EPBU/7	Input Voltage: 100 – 240 V~ 50 - 60 Hz Output Voltage: 19 – 24 Vdc, Min. 4 A
	Weight	3 kg
	Insulation coordination	Category II (IEC 61010-1)
	Power consumption	70 VA max.
Environmental conditions	Temperature/Humidity Transport and Storage	-25 °C to 60 °C 10-95% rH, non condensing
	Temperature/Humidity Operating	15-32°C, 30-80% rH, non condensing
	Pollution	Degree 2 (IEC 61010-1)
	Altitude	2000m above sea level

Safety approval

UL 61010-1
EN/IEC 61010-1
EN/IEC 61010-2-101
CAN/CSA C22.2 No. 61010-1

Regulatory compliance

CE:	*Complies with European Union (EU) Directive 98/79/EC (in vitro medical device)*
FCC:	*This equipment complies with the requirement in part 15 of FCC rules for a class A computing device. Operation of this equipment in a residential area may cause unacceptable interference to radio and TV reception requiring the operator to take whatever steps are necessary to correct the interference.*
UL	*Underwriters' Laboratories (USA)*
IEC	*International Electro technical Commission*

5. Delivery, unpacking and set-up of the analyzer

This section describes the state of the analyzer on delivery, how to unpack and set-up the instrument. The installation and set-up, however, must be performed by a certified person. Please ask your local representative if you have any questions regarding the installation.

5.1 Delivery

The **cobas c** 111 analyzer is shipped in a specially designed container.
On delivery, carefully inspect the container. Make a note of any indications of physical damage and record your observations in the accompanying shipping documents. It is essential that you report any suspected damage immediately to Roche Diagnostics, and to the shipping agent, before accepting the unit.
Please also note the Installation Report Feedback Form at the end of this document.

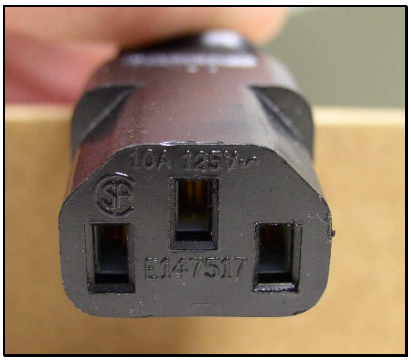
5.1.1 Packing list

The actual version of the analyzer (as delivered), together with a list of the accessories for your configuration, are detailed in the accompanying packing list. That list specifies the part numbers and quantities supplied. Please check the items supplied against the packing list and retain the list for future reference.

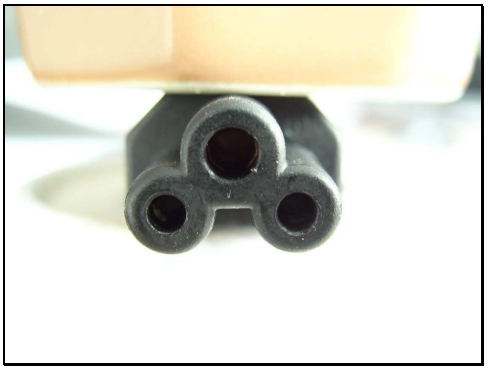
5.2 Additional items required

To be able to install and set up the **cobas c** 111 correctly it is necessary to provide the following additional items:

- Power supply cord, either:
  US-Type: Cable Power Mains US STD: No. 25565608001 (rated 15A, 125V. Cable SJT, 3x16 AWG. Connector type 13V (10A, 250V; 15A, 125V)
  or
  Euro-Type: Cable Power Mains, No. 25565607001 (3 x 1mm^2) rated 10A, 250V, or equivalent.
  For other country specific power connectors equivalent conditions apply.
  See also the pictures 3 & 4 below.
- Operator Manual
- Ordering of additional material to operate the instrument like cuvette segments, reagents, calibrator material, QC material, suitable sample tubes, cleaner etc. Please contact your local sales representative for further details.



cobas c111 instrument connector


ISE Unit Power Supply Connector

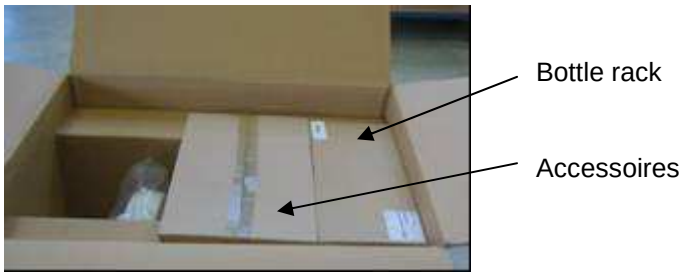
5.3 Unpacking

Important: Do not allow unqualified personnel to unpack, set up, or perform first time operation of the **cobas c** 111. Unauthorized action taken by the customer in this regard could void the warranty on the analyzer.
The original shipping containers must be transferred unopened to the installation site.

Unpack the instrument and check that all items mentioned on the packing list are present. If the package is damaged or parts are missing please report immediately to your local Roche Diagnostics representative and file a report with the shipping agent.

5.3.1 Unpacking procedure for instrument with ISE:

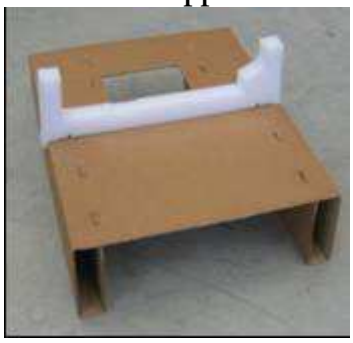
1. Open the box at the top. (On the upper cardboard cover inside the box you can find the standard accessories of the system).



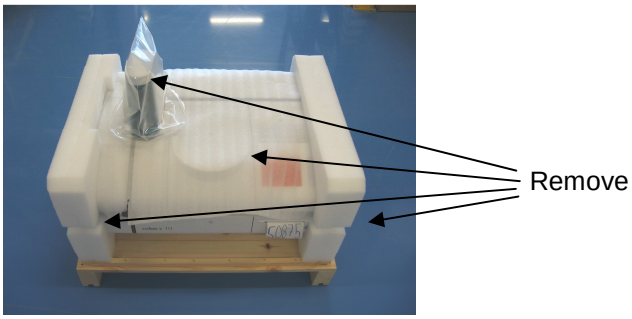
2. Remove the standard accessories.

3. Lift the carton off the pallet to get access to the instrument.

4. **Remove the upper cardboard cover.**



5. Remove the plastic transport protection covering the instrument.



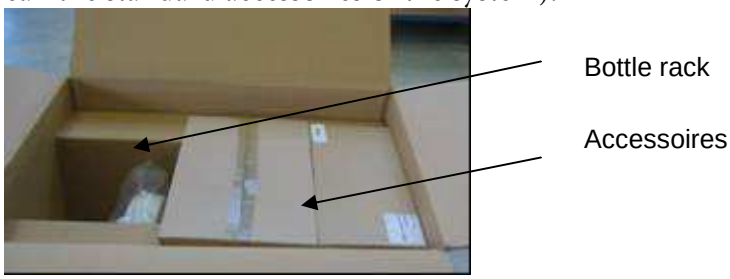
Lift the **cobas c** 111 instrument from the pallet.
Caution: The instrument weighs around 38 kg (~80 lbs.)

6. Place the **cobas c** 111 on flat and stable surface.

Notice: Keep the packing pieces in a safe place to use again whenever the instrument has to be transported any significant distance.

5.3.2 Unpacking procedure for instrument without ISE:

1. Open the box at the top. (On the upper cardboard cover inside the box you can the standard accessories of the system).

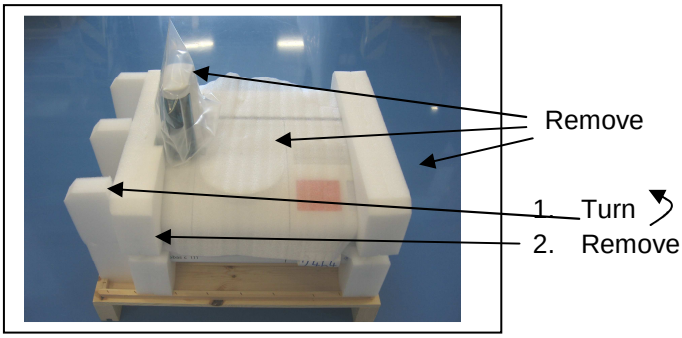


2. Remove the standard accessories and the upper cardboard cover.

3. Lift the carton off the pallet to get access to the instrument.

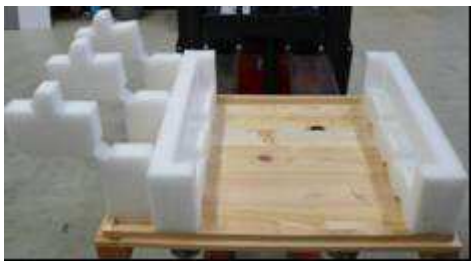
4. Remove the upper cardboard cover

5. Remove the plastic transport protection covering the instrument.



Plastic transport protection

6. Lift the **cobas c** 111 instrument from the pallet.
Caution: The instrument weighs around 35 kg (~75 lbs.)



Empty palette

7. Place the **cobas c** 111 on flat and stable surface.

Notice: Keep the packing pieces in a safe place to use again whenever the instrument has to be transported any significant distance.

5.4 Location of switches and connectors

Locations and use of all the switches, fuses and connectors are listed here, (See also Fig. 2 below)

Main switch

The main switch is on the left side on top of the analyzer.
Press 1 to switch on the analyzer, press 0 to switch it off.
If an ISE unit is attached, the ISE power supply will be on as long as it is connected to a mains power outlet. The constant powering of the ISE unit is intended due to functional reasons.

Caution

Damage to electrodes and possible tubing blockage.
Do not unplug or switch off the ISE Power Supply. Periodic flow of solutions must be given at all times.

Power cable

The power supply socket is located at the rear of the instrument.

<u>Important:</u> Only use an approved power supply cord in good condition!
Do not touch mains cables if your hands are wet.

Warning

Do not attempt to connect or disconnect the mains cables, if the analyzer is switched on.
If any power connector becomes worn or frayed, it must be replaced immediately with an approved cable.

Location of fuses

The Mains power fuse is located at the rear of the instrument inside the power supply socket. The internal power supply fuses are accessible on rear right side of the instrument. The fuse for ISE unit is located inside and is to be replaced by authorized service engineers.

Fluid Connections:

On the right side of the instrument is the Fluid Connector Terminal. It holds the a) Water Connector; b) Waste Connector; c) Cleaner Tubing Connector.

USB connection

A USB connector is located at the right front side of the instrument, which is intended for connecting to a USB memory stick. Any USB memory device that supports the USB v1.1 standard can be used on this USB port.
A USB connection exists at the rear right side of the instrument, which is intended for connecting an analog modem.

RS232 Serial connectors

There are 2 serial interface connectors intended for use with a Barcode scanner and Host interface respectively. Please refer to the **cobas c** 111 Operator Manual and the corresponding instructions before attempting to connect up.

cobas c 111 external connections

6. Start-up of the Instrument

6.1 Instrument with ISE unit

6.1.1 Instrument placement & preparation:

1. Follow all steps of procedure 6.2.1 below (see Instrument without ISE Unit)
2. Connect the ISE power supply cable into an appropriate AC wall socket.
3. Follow all steps of procedure 6.1.2 below.

6.1.2 Starting the instrument & setup of ISE

Notice: All operator-related instructions on how to handle the instruments during the following procedure are described in the Operator's Manual.

1. Before switching on the instrument, make sure that the Transfer Head can move smoothly, and all covers are closed properly.
2. Switch on the instrument by pressing the mains power switch to "I"
3. The instrument will perform an initialization and check all vital components. Please wait until the instrument will show the status "Standby".
4. Log in as admin

Notice: Upon delivery, the instrument is drained of water, so eventually an error message "Air detected in the fluid system" will appear. Ignore it until you performed step 6. Otherwise you have to check the fluid tubing for leakages.

5. Check the Reagent Disk. If there is none inside, please insert one. (The description on how to insert a Reagent Disk is found in the Operator's Manual)

Notice: If there is a Reagent Disk inside, but is not detected by the software, then check for correct identification by the flags. Exactly one of these flags needs to be broken away for correct ID.

6. Use the Diagnostic function "Fill and empty fluid system" to fill the fluid system. Watch closely the water and cleaner fluids flowing through the tubing. Remove the transfer head cover for this purpose.
7. Use the Maintenance function "Deproteinize Probe" to activate the probe for correct pipetting. This process needs 2 "False bottom"-cups, (or any other suitable cup) one filled with 1.5 ml of ISE Deproteinizer, and one filled with 1 ml of Activator. Those tubes have to be prepared before starting this maintenance function. Follow the instructions given by the software, when and how to place these tubes.
8. Check the correct setting of time and date.
9. Perform ISE Applications Import and installation if not yet done.
   To do so, access to Utilities > Applications > Laboratory Parameters > select then Add Tab click (+). As next "Import Application" tab will be displayed and by clicking on it the System will ask for the BTS or for an upload using the USB Stick. After providing this information select the Add Tab again click (+) and click in Install Application. The installation will be performed. Once the installation is successfully done, the brackets which were surrounding the application name previously won't be visible anymore.
   For example:[K] installation not yet done. ; K installation already done.

Notice: There will be no Applications which will be ready to install. All wanted Applications must be imported first (via BTS or USB Stick) to be ready to install them. With Software Version 3.0 and higher the database will be delivered empty. The only to Profiles which will be available are ISE-I and ISE –U.

10. Prepare the additional material required to run the ISE, like electrodes, calibrator indirect, reference solution, solution 1 and solution 2.
11. Check the correct placement of all pre-mounted ISE tubing.
12. Mount all ISE valve caps (and clamps if necessary). Do this using the diagnostic function “Check ISE valves”. Use this function to open the valves first, to avoid bending of the valve shafts.
13. Check that sample inlet tube is correctly mounted to the mixing tower holder inside the base instrument.
14. Read in the barcode from the Reference Fluid and Calibrator indirect bottle and place the bottles into the ISE module. Insert the respective tubing into the bottle.
15. Insert the reference electrode, using the system SW. At the step where it is requested to insert the electrode insert also all the other electrodes.

Notice: Take care to avoid air bubbles in the electrolyte at the lower end of the electrode body.

16. Read in the barcodes of Na, K and CL (Dummy electrode) accordingly.
17. Check the electrodes, the valves and the tubing for correct placement. During the following step watch the valves to operate correctly.
18. Check if the peristaltic pump cover is closed.
19. Use the maintenance action “Prime ISE calibrator and reference” to prime the tubing.
20. Use the maintenance action “Initialize ISE reference sensor” to set the controller SW properly recognizing air bubbles in the reference tubing. (Please follow the procedure given by the SW).
21. Close all covers.
22. Use the maintenance action “Condition Tubing”. For this action you will need Activator prepared in a HHT-Cup.
23. Use the maintenance action “Initialize ISE” to initialize the ISE unit. This action needs Activator.
24. Selecting the ISE status button and the “>>”-Button, you will be guided to perform an “Electrode Service” now, which needs Activator, Etcher and Deproteinizer on board.
25. Read the barcode of the ISE Calibration Kit and install the desired ISE tests in the Applications Menu.
26. As a general function test run a single CHECK test first. For this purpose Import and install the CHECK test application and order a single test only, like as you would order any other test. Check that the result is within the range printed on the CHECK test solution bottle. Later on you may disable the CHECK test.

Notice: The calibration result for the CHECK test that is stored in the database cannot be deleted, as it is always used as reference.

27. Reset Maintenance Counter: Please choose “Utilities -> Diagnostics -> Analyzer -> Installation Completed”
28. Calibrate now all ISE tests. The calibrations must be flag free.
29. Prepare the requested reagent bottles and insert them into the instrument.
30. Prepare the calibrators and QC material accordingly and calibrate all tests.
31. Check the test performance by running controls.

32. Complete the installation report form.

Warning

*Any factory-set calibration data found on the instrument may be outdated and therefore cause wrong results! Cross-check the calibration results and the application producing correct results by running qualified control material. Refer to the **cobas c** 111 Operator's Manual for more handling information.*

6.2 Instrument without ISE unit

6.2.1 Instrument placement & preparation:

1. Place the instrument in a suitable position for operation (refer to location and environmental conditions above).
2. Unpack all accessory components like Water and Waste Reservoir, Reagent Disk, Barcode Scanner, Printer paper, etc.
3. Preposition all additional parts as appropriate power cord, cuvettes, reagents, calibrators, etc.
4. Insert a roll of printer paper as instructed in the Operator's Manual. The printer paper (thermal paper) is heat-sensitive and must be kept away from direct sunlight and high temperatures.
5. Mount the probe onto the Transfer Head.
6. Place the Fluid Rack to the right side of the instrument. Place a new bottle of cleaner, fill the Water Container with de-ionized water (CLSI Grade II) and check that the Waste Container is empty.
7. As next step Connect the Cleaner Protection pipe.

Notice: Make sure the two internal Seals which are located in the interior of the black protection pipe were mounted previously as shown on the picture above.

Attention: To avoid seals damaging, push pipe carefully to end position. Consider to grease previously both seals, to assure an easier operation.

8. Mount the Fluid Water and Waste tubing sets to the respective lids.
9. Connect the tubing connectors to their respective counterparts at the Fluid connector terminal at the right side of the instrument.
10. Place the lids on top of their bottles. White -> water; yellow -> waste; red -> cleaner.
11. Plug the cable of the barcode scanner into the COM2 port. (This is the port named with Scanner)
12. Connect the cross wired LAN cable to the RJ45 connectors (named DM and IC)

cobas c 111 external connections

13. Plug one end of the power connector cable into the power socket at the rear of the instrument and the other end into an appropriate AC wall socket.

6.2.2 Starting the instrument

Notice: All operator-related instructions on how to handle the instruments during the following procedure are given in the Operator's Manual.

1. Before switching on the instrument, make sure that the Transfer Head can move smoothly and all covers are closed properly.
2. Switch on the instrument by pressing the mains power switch to "I"
3. The instrument will perform an initialization and check all vital components. Please wait until the instrument will show the status "Standby".
4. Log in as admin.

Notice: As the instrument is drained of water when delivered, eventually an error message "Air detected in the fluid system" will appear. Ignore it until you performed step 6. Otherwise you have to check the fluid tubing for leaks.

5. Check the Reagent Disk. If there is none inside, please insert one.

Notice: If there is a Reagent Disk inside, but is not detected by the software, then check for correct identification by the flags. Exactly one of these flags needs to be broken away for correct ID.

6. Use the Diagnostic function "Fill and empty fluid system" to fill the fluid system. Watch closely the water and cleaner fluids flow through the tubing. Remove the transfer head cover for this purpose. Replace the cover afterwards
7. Use the Maintenance function "Deproteinize Probe" to activate the probe for correct pipetting. This process needs 2 "False bottom"-cups, (or any other suitable cup) one filled with 1.5 ml of ISE Deproteinizer, and one filled with 1 ml of Activator. Those tubes have to be prepared before starting this maintenance

function. Follow the instructions given by the software, when and how to place these tubes.

8. Check the correct setting of time and date.
9. As a general function test run a single CHECK test first. For this purpose Import and Install the CHECK test application and order a single test only, like you would order any other test. Check that the result is within the range printed on the CHECK test solution bottle. Later you may disable the CHECK test.

Please note: *The calibration result for the CHECK test that is stored in the database can not be deleted, as it is always used as reference.*

10. Reset Maintenance Counter: Please choose "Utilities -> Diagnostics -> Analyzer -> Installation Completed"
11. Prepare the requested reagent bottles and insert them into the instrument.
12. Prepare the calibrators and QC material accordingly and calibrate all tests.
13. Check the test performance by running controls.
14. Complete the installation report form.

Warning

Any factory-set calibration data found on the instrument may be outdated and therefore cause wrong results! Cross-check the calibration results and the application producing correct results by running qualified control material. Refer to the ***cobas c*** *111 Operator's Manual for more handling information.*

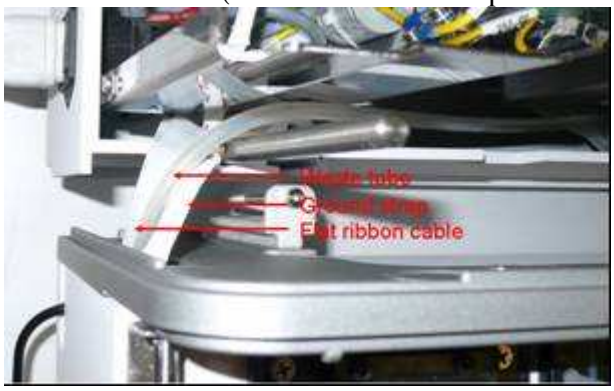
6.3 Single ISE unit

6.3.1 Attaching the ISE unit to the base instrument (if applicable)

1. Unpack the ISE unit and preposition all ISE accessory parts, like Electrodes, Calibrator indirect, Reference solution and Solution 1-2.
2. Remove left and right side panel of the base instrument.
3. Move the transfer head to the sample area and remove the left side panel and main cover.
4. Remove the transfer head cover.
5. Remove the screws on the left and right side that holds the rear service flap and fold it backwards.

Fixation of rear panel

6. Remove the complete ISE Cover and left side panel of the ISE unit.
7. Route the flat ribbon cable from the instrument into the ISE. Route the ground strap from the ISE into the instrument. Route the waste tube from the ISE into the instrument (the end with the quick fit connector belongs into the ISE).



Routing of ISE connections

8. Fit the right side of the ISE unit to the left side of the instrument by inserting the rails into the guides. There are 2 screws that attach the ISE unit to the base instrument.

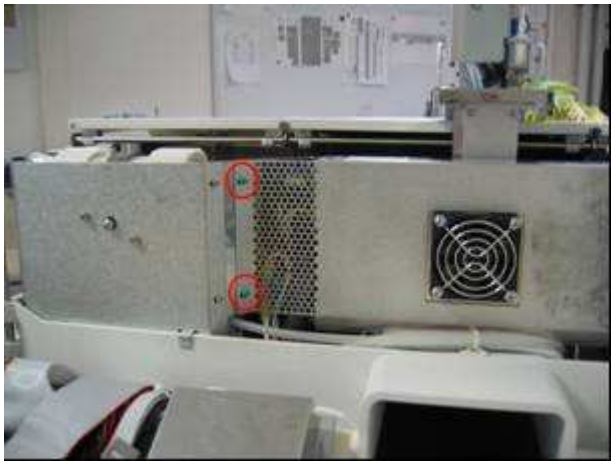
Notice: Take care not to squeeze the waste tube at any position!

ISE Module fixation screws

9. Connect the flat ribbon cable to the PCB ISE Controller J2.

Flat ribbon cable connection

10. Remove the power box guard plate.



Power box guard plate fixation

11. Connect the ground strap using the provided screw and serrated lock washer.

ISE ground strap fixation

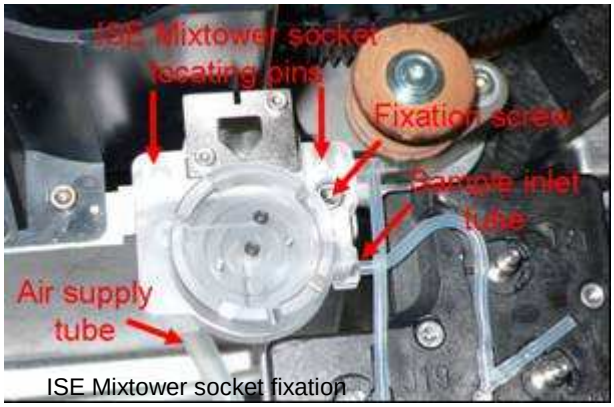
12. Connect the waste tube to the corresponding plug.

ISE waste connection

13. Connect the low voltage end cable to the connector of the PCB ISE Control. Then fix the cable with the pull relief.

ISE power supply

14. Mount the power box guard plate back into place.
15. Fold the Rear Service Flap into normal position and fix it with the 2 screws.
16. Put the right side panel back into place.
17. If not yet mounted fix the air tube to the mixtower socket. Mount the sample inlet tube to the socket. Mount now the socket to its location.



ISE Mixtower socket fixation

18. Mount now the waste tube to the internal waste tank. Push the round black waste outlet into the tube holder until the stopper. Mount afterwards the cover back to the waste tank.

Connection ISE waste to waste tank

Notice: Take care not to squeeze the waste tube at any position!

19. Mount the tube from the ISE tower overflow adaptor to the rear connector of the internal waste tank.

Connection of overflow adaptor to waste tank

20. Finally mount the waste tube to ISE tower, mount the tower itself and lock the ring. Apply the overflow adapter at the end.

Mounted ISE tower

21. Connect the ISE power supply cable into an appropriate AC wall socket.
22. Switch on the instrument
23. Follow now steps 9-27 of chapter 6.1.2 (Starting instrument & Setup of ISE) above.

7. Running the analyzer and everyday tasks

Refer to the ***cobas c** 111 Operator's Manual* to see what tasks you must do each day before running tests and for information on day-to-day running of the analyzer.

8. Shutting down

After completion of work the instrument should be allowed to enter the "Standby" status and the waste should then be emptied.
You may use the "End of shift" wizard, guiding you through various procedures to prepare the instrument to be switched off for a longer time, e.g. overnight, weekend, etc.
The instrument can then be switched off by the On/Off switch at the top left side.
After switching off please ensure that the instrument is cleaned according to the instructions in the Operator Manual to avoid the build up of contamination.
Another way to shutdown the instrument is to press the STOP button, then on the touch screen press "shutdown". The instrument will shut down, after that switch off the instrument by the Power Switch

9. Preparing for transportation

9.1 Drain the instrument with ISE of water and cleaner.

1. Perform the Diagnostic function "Drain ISE Unit", follow its instructions
2. Store the valve caps and clamps and the electrodes in separate bags at the place of the calibrator and reference bottles.
3. Now follow all the steps from procedure 9.2 below.

Always use the approved packaging for transportation of the **cobas c** 111 analyzer.
Before transporting or disposing of an instrument, carry out a Shutting down procedure and a full decontamination according to local regulations.

9.2 Drain the instrument without ISE of water and cleaner.

1. Remove the nozzle out of the external cleaner bottle and place on a paper tissue. Close the cleaner bottle and store it at a safe place.
2. Empty the water container. Leave it in place.
3. Perform the diagnostic action "Fill and empty fluid system".
4. Empty the waste container.
5. Now the fluid tubing can be disconnected.
6. Remove all cuvette segments from the rotor.
7. Remove all reagents from disk, by using the System SW.
8. Remove the reagent disk from the instrument.

Always use the approved packaging for transportation of the **cobas c** 111 analyzer.
Before transporting or disposing of an instrument, carry out a Shutting down procedure and a full decontamination according to local regulations.

9.3 Packing procedure for instrument with ISE:

Notice: Use only the original packing pieces to prevent any damage of the instrument.

Notice: The packing instructions are also shown on a label outside of the box

Packing instruction

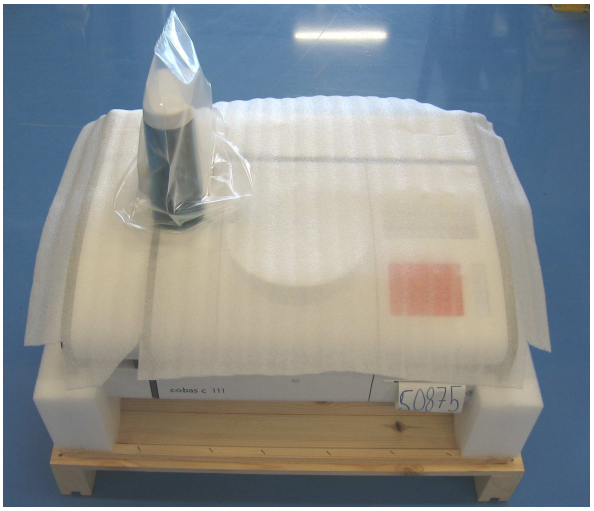
1. Start with preparing the palette.

Empty palette

2. Lift the **cobas c** 111 instrument and place it into the cellular material
Caution: The instrument weighs around 38 kg (~80 lbs.)

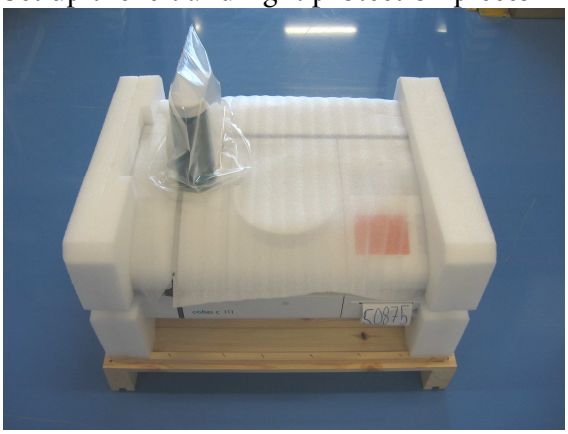
Palette with C111 instrument

3. Apply the protection plastic foil and the plastic bag over the transfer head



Instrument with protection foil

4. Set up the left and right protection pieces



Instrument with protection plastic pieces

5. Impose on the surrounding carton.

Packed in surrounding carton

6. Put on the cardboard cover.

Cardboard cover

Applied Cardboard cover

Make sure to have the transfer head protection correctly mounted

Transfer head protection

7. Pack the accessories in the box as shown and the fluid rack incl. remaining fluid bottles into the other box.

Accessoires box

Packed accessories + fluid rack boxes

8. If the TIP-N-TELL indicator applied on the cardboard cover (iniside box) and outside are still ok, leave them, otherwise cancel the corresponding one with a pen (??).

TIP-N-TELL (inside)

TIP-N-TELL (outside)

9. If possible apply new straps as shown below, or apply cords.

Finished packing with straps

9.4 Packing procedure for instrument without ISE:

Notice: Use only the original packing pieces to prevent any damage of the instrument.

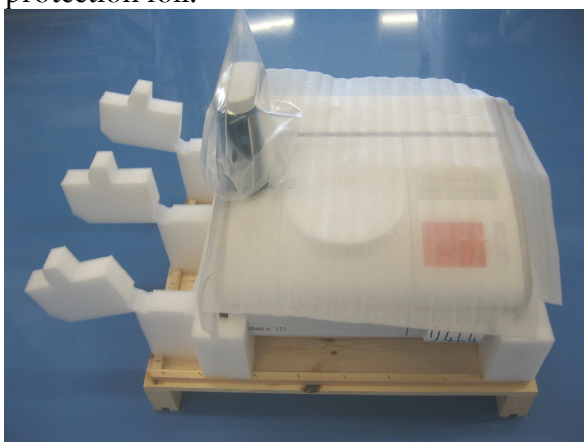
Notice: The packing instructions are also shown on a label outside of the box

Packing instruction

1. Start with preparing the palette.

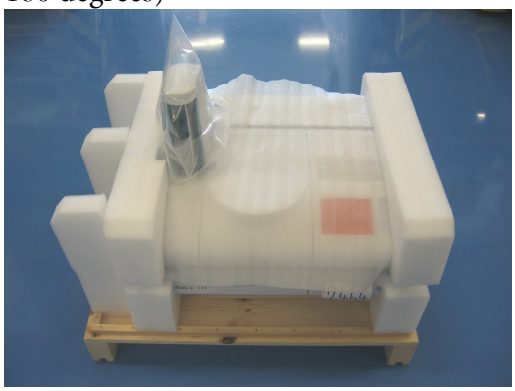
Empty palette

2. Lift the **cobas c** 111 instrument and place it into the cellular material
Caution: The instrument weighs around 35 kg (~75 lbs.) and mount the protection foil.



Palette with C111 instrument and protection foil

3. Apply the protection plastic foil and the plastic bag over the transfer head. Set up the left and right protection pieces (just turn the one on the left side by 180 degrees)



Instrument with protection plastic pieces

4. Impose on the surrounding carton.

Packed in surrounding carton

5. Put on the cardboard cover.

Cardboard cover

Imposed on Cardboard cover

Make sure to have the transfer head protection correctly mounted

Transfer head protection

6. Pack the accessories in the box as shown and the fluid rack incl. remaining fluid bottles into the other box.

Accessoires box

Packed accessories + fluid rack boxes

7. If the TIP-N-TELL applied on the cardboard cover (inside box) and outside are still ok, leave them, otherwise cancel the corresponding one with a pen.

TIP-N-TELL (inside)

TIP-N-TELL (outside)

8. If possible apply new straps as shown below or cords.

Finished packing with straps

10. Disposal of the instrument

If the instrument is to be scrapped then all parts maybe disassembled according to the procedures in the service manual to allow separate disposal of differing materials according to local regulations.

- The instrument must be treated as biologically contaminated-hazardous waste. Final disposal must be organized in a way that does not endanger the waste handlers. As a rule, such equipment must be sterile before it is passed on for final disposal.

For more information contact your Local Safety Officer.

10.1 Disposal of external components

External components such as the scanner and the ISE power supply, which are marked with the crossed-out wheeled bin symbol, are covered by the European directive 2002/96/EC (WEEE)
These items must be disposed of via designated collection facilities appointed by government or local authorities.

(WEEE) Directive 2002/96/EC of the European Parliament and the Council of 27 January 2003 on waste electrical and electronic equipment

For more information about disposal of your old products, contact your city office, waste disposal service or your Local Safety Officer.

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

11. Installation Report Form

For Field Service Engineer: Your feedback is needed!

Please fill in the Installation Report and send it back to the Customer Support Team

by Fax: ++41 41 798 72 18

by Mail: Roche Diagnostics Ltd.
GSS cobas c 111
Forrenstrasse
CH-6343 Rotkreuz
Switzerland

by E-Mail: rotkreuz.gsscdiric@roche.com

12. Installation Report cobas c 111

Instrument Serial No.	**Installation Date:**	**Country:** **City:**
Responsible FSE:	**Main Power Supply** Voltage: Frequency:	

Subject:	**Not OK.**	**OK.**	**Comments:**
Package			
Accessories			
Chassis / Housing			
Robotic Transfer			
Fluid / Pipetting			
Internal Printer			
Analyzer Assembly **Reagent Disk**			
Power Supply			
Cooling Unit			
Display Unit **Touch Screen**			
ISE Unit **(option)**			
ISE Unit power supply **(option)**			
Host Interface Connection **(option)**			
Other comments or findings:			