**Document information**

**Revision history**

<table>
<thead>
<tr>
<th>Manual version</th>
<th>Software version</th>
<th>Revision date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>1.0</td>
<td>July 2009</td>
<td></td>
</tr>
</tbody>
</table>

**Edition notice**

This manual is for users of the cobas® 4800 system.

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 Ltd reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument or analyzer will render the warranty or service agreement null and void.

Software updates are done by Roche Service representatives.

**Intended use**

The cobas® 4800 system is intended to be used as a diagnostic or screening system providing sample preparation, amplification and detection of specific targets from human samples. Initial diagnostic targets are Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) and human papillomavirus (HPV).

It is important that the operator read this manual thoroughly before using the system.

The cobas® 4800 system is to be used by laboratory professionals trained in laboratory techniques and by instruction on the use of the system.

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**Trademarks**

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All other trademarks are the property of their respective owners.
**Instrument approvals**

The cobas x 480 instrument and the cobas z 480 analyzer meet the protection requirements laid down in IVD Directive 98/79/EC. Furthermore, the cobas z 480 analyzer is manufactured and tested according to the following international standards:

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

The Operator’s Manual meets the European Standard EN 591. Compliance is demonstrated by the following marks:

- Complies with the IVD directive 98/79/EC.

- Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

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Preface

The cobas® 4800 system integrates fully automated total nucleic acid isolation directly from primary and secondary sample tubes, automated PCR setup, and real-time PCR. This manual covers the complete cobas® 4800 system comprised of the cobas® 4800 software, the cobas x 480 instrument used for sample preparation, and the cobas z 480 analyzer used for amplification and detection using real-time PCR.

How to use this manual

To help you find information quickly, there is a table of contents at the beginning of the manual and each chapter. In addition, a complete index can be found at the end.

Conventions used in this manual

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

Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Used for</th>
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<tbody>
<tr>
<td>➤</td>
<td>Start of procedure</td>
</tr>
<tr>
<td>■</td>
<td>End of procedure</td>
</tr>
<tr>
<td>•</td>
<td>List item</td>
</tr>
<tr>
<td>❙</td>
<td>Cross-reference</td>
</tr>
<tr>
<td>☰</td>
<td>Call-up (software reference)</td>
</tr>
<tr>
<td>☽</td>
<td>Tip</td>
</tr>
<tr>
<td>🔴</td>
<td>Safety alert</td>
</tr>
</tbody>
</table>

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

The following abbreviations are used:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>A</td>
<td>ANSI: American National Standards Institute</td>
</tr>
<tr>
<td>C</td>
<td>cc: cubic centimeter</td>
</tr>
<tr>
<td></td>
<td>cLLD: Capacitive Liquid Level Detection</td>
</tr>
<tr>
<td>CT</td>
<td>CT: Chlamydia Trachomatis</td>
</tr>
<tr>
<td>CSA</td>
<td>CSA: Canadian Standards Association</td>
</tr>
<tr>
<td>D</td>
<td>dBA: decibel weighted against the A-frequency response curve. This curve approximates the audible range of the human ear.</td>
</tr>
<tr>
<td>DIL</td>
<td>DIL: Diluent</td>
</tr>
<tr>
<td>DWP</td>
<td>DWP: Deepwell Plate</td>
</tr>
<tr>
<td>E</td>
<td>EC: European community</td>
</tr>
<tr>
<td></td>
<td>e.g.: exempli gratia – for example</td>
</tr>
<tr>
<td>EMC</td>
<td>EMC: ElectroMagnetic Compatibility</td>
</tr>
<tr>
<td>EN</td>
<td>EN: European standard</td>
</tr>
<tr>
<td>H</td>
<td>HPV: Human Papillomavirus</td>
</tr>
<tr>
<td>I</td>
<td>i.e.: id est – that is to say</td>
</tr>
<tr>
<td>IEC</td>
<td>IEC: International Electrical Commission</td>
</tr>
<tr>
<td>iSWAP</td>
<td>iSWAP: internal Swivel Arm Plate handler</td>
</tr>
<tr>
<td>IVD</td>
<td>IVD: In Vitro Diagnostic</td>
</tr>
<tr>
<td>K</td>
<td>KVA: kilovolt-Ampere</td>
</tr>
<tr>
<td>L</td>
<td>LED: Light Emitting Diode</td>
</tr>
<tr>
<td></td>
<td>LIS: Laboratory Information System</td>
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<tr>
<td>M</td>
<td>MWP: MicroWell Plate</td>
</tr>
<tr>
<td>N</td>
<td>n/a: not applicable</td>
</tr>
<tr>
<td>NG</td>
<td>NG: Neisseria Gonorrhoeae</td>
</tr>
<tr>
<td>P</td>
<td>PC: PreservCyt®</td>
</tr>
<tr>
<td>PCR</td>
<td>PCR: Polymerase Chain Reaction</td>
</tr>
<tr>
<td>Q</td>
<td>QC: Quality Control</td>
</tr>
<tr>
<td>S</td>
<td>SD: Standard Deviation</td>
</tr>
<tr>
<td>SP</td>
<td>SP: SurePath™</td>
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<tr>
<td>U</td>
<td></td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td>UL</td>
<td>Underwriters Laboratories Inc.</td>
</tr>
<tr>
<td>UT</td>
<td>UniTrans (cobas PCR Media)</td>
</tr>
<tr>
<td>UUT</td>
<td>Urine UniTrans (urine stabilized with cobas PCR Media)</td>
</tr>
<tr>
<td>W</td>
<td>Waste Electrical and Electronic Equipment</td>
</tr>
<tr>
<td>WEEE</td>
<td>Waste Electrical and Electronic Equipment</td>
</tr>
<tr>
<td>X</td>
<td>Extensible Markup Language</td>
</tr>
<tr>
<td>XML</td>
<td>Extensible Markup Language</td>
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# System description

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General safety information

In this chapter, you will find information on the safe operation of the cobas® 4800 system.

In this chapter

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<th>In this chapter</th>
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<td>Operator qualification</td>
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<td>Safe and proper use of the instrument and analyzer</td>
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<td>Miscellaneous safety precautions</td>
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<td>Safety summary</td>
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<td></td>
<td>Warning messages</td>
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<td></td>
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<td></td>
<td>Waste</td>
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<td></td>
<td>Explosion and fire risk</td>
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<td></td>
<td>Caution messages</td>
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<td></td>
<td>Mechanical safety</td>
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<td></td>
<td>Reagents</td>
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<td></td>
<td>Insoluble contaminants in samples</td>
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<tr>
<td></td>
<td>Evaporation of samples or reagents</td>
</tr>
<tr>
<td></td>
<td>Cross contamination</td>
</tr>
<tr>
<td></td>
<td>Hot surfaces</td>
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<td>Data security</td>
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<td>Notices</td>
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<td>Spillage</td>
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<td>Safety labels on the system</td>
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<td>Safety labels on cobas x 480 instrument</td>
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<tr>
<td></td>
<td>Safety labels on cobas z 480 analyzer</td>
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<tr>
<td></td>
<td>Disposal of the cobas x 480 instrument and the cobas z 480 analyzer</td>
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</table>
Safety classifications

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:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>WARNING Indicates a hazardous situation which, if not avoided, could result in death or serious injury.</td>
</tr>
<tr>
<td>!</td>
<td>CAUTION Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.</td>
</tr>
<tr>
<td></td>
<td>NOTICE Indicates a hazardous situation which, if not avoided, could result in damage to equipment.</td>
</tr>
<tr>
<td>⚡</td>
<td>Tip Indicates additional information on correct use of the system or useful tips.</td>
</tr>
</tbody>
</table>

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 safety information provided elsewhere in the document.

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, could result in damage to equipment.

For more information about the product safety labels, see "Safety labels on the system" on page A-16.

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

**Tip**

Indicates additional information on correct use of the system or useful tips.
Safety precautions

Particular attention must be paid to the following safety precautions. If these safety precautions are ignored, the operator may suffer serious or fatal injury. Each precaution is important.

Operator qualification

Operators are required to have a sound knowledge of relevant guidelines and standards as well as 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 cobas x 480 instrument and the cobas z 480 analyzer.
- Leave maintenance, installation, or service that is not described in the Operator’s Manual to trained Roche Service personnel.
- Follow standard laboratory practices, especially when working with biohazardous material.

Safe and proper use of the instrument and analyzer

Personal protective equipment

- Be sure to wear appropriate protective equipment, including, but not limited to, safety glasses with side shields, fluid resistant lab coat, and approved disposable gloves.
- Wear a face shield if there is a chance of splash or splatter.

Accuracy/precision of measured results

- Do not use reagents that have exceeded their expiration date, otherwise inaccurate data may be obtained.
- For diagnostic purposes always assess the results in conjunction with the patient’s medical history, clinical examination, and other findings.
- Each laboratory must verify that instrument, analyzer, and reagent performance meets the published specifications.

Installation

- Installation must be performed by trained Roche Service personnel only.
- Leave installation that is not described in the Operator’s Manuals to trained Roche Service personnel.

Correct use

Use the cobas x 480 instrument only for preparing liquid samples with the provided reagents.
Safety precautions

Operating conditions

- Operation outside of the specified ranges may lead to incorrect results or malfunction of the instrument or analyzer.
- Use the instrument and analyzer as indicated in the technical specifications.
- Make sure that the instrument’s and analyzer’s ventilation openings remain unobstructed at all times.
- Perform maintenance according to the specified intervals to maintain the operating conditions of the instrument and analyzer.
- Keep the Operator’s Manual in a safe place to ensure that it is not damaged and remains available for use. This manual must be easily accessible at all times.

Approved parts

Use of non-approved parts or devices may result in malfunction of the instrument or analyzer and may render the warranty null and void. Only use parts and devices approved by Roche Diagnostics.

Third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior of the cobas® 4800 system or the cobas® 4800 software. Do not install any non-approved software.

Miscellaneous safety precautions

Power interruption

A power failure or momentary drop in voltage may damage the instrument or analyzer or lead to data loss. Perform regular backups of measurement results. Operation with an uninterruptible power supply (UPS) is recommended.

Electromagnetic fields

Devices that emit electromagnetic waves may cause the instrument or analyzer to malfunction. Do not operate the following devices in the same room where the instrument or analyzer are installed:

- Mobile phone
- Transceiver
- Cordless phone
- Other electrical devices that generate electromagnetic fields

Relocation and transportation

Do not attempt to relocate or transport the instrument or analyzer. Leave relocation and transportation to personnel trained or authorized by Roche.

For additional details, see Disposal of the cobas x 480 instrument and the cobas z 480 analyzer on page A-19.
Safety summary

This safety summary contains the most important and general warning and caution messages. Additionally, you will find specific safety information at the beginning of Part Operation and Part Maintenance.

Warning messages

List of warning messages
Before operating the system, read the warning messages contained in this summary carefully. Failure to observe them may result in death or serious injury.

Electrical safety

Electrical shock by electronic equipment
- Do not attempt to work in any electronic compartment.
- Do not remove any cover of the instrument or analyzer other than those specified in this Operator’s Manual.
- Do not touch any parts of the instrument or analyzer other than those specified. Especially do not touch any power supply parts.
- Never remove the middle grounding prong from the power cable or defeat its purpose by using an ungrounded adapter.
- Installation, service, and repair must only be performed by personnel authorized and qualified by Roche.
- Observe the system safety labels as illustrated in section Safety labels on the system on page A-16.

Optical safety

Loss of sight due to staring into laser beam
The barcode scanner on the autoloader of the cobas x 480 instrument contains a class II laser diode.
Do not stare into the laser transmitter beam as eyesight may be severely damaged.
Biohazardous materials

Infection by samples and associated materials

Samples processed on the instrument and analyzer are provided in media that inactivate potentially biohazardous material. However, as with all human-derived specimens, universal precautions should be taken when handling and processing samples. Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Follow standard laboratory practices, especially when working with biohazardous material.
- Keep the main cover closed and in place while the cobas x 480 instrument is operating.
- When working with the main cover open while the cobas x 480 instrument is powered on (e.g., for cleaning or maintenance), always put the cobas x 480 instrument in Maintenance mode or in Shutdown status first.
- Be sure to wear appropriate protective equipment, including, but not limited to, safety glasses with side shields, fluid resistant lab coat, and approved disposable gloves.
- Wear a face shield if there is a chance of splash or splatter.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If sample or waste solution comes into contact with your skin, wash it off immediately with soap and water and apply a disinfectant. Consult a physician.

Infection and injury due to sharp objects

When wiping sharp objects, use several layers of gauze.

- Be careful to not puncture yourself.
- Be sure to wear appropriate protective equipment, for example gloves.
1 General safety information

Safety summary

Waste

Infection by biohazardous waste

Liquid and solid waste originate from samples collected in media that inactivate potentially biohazardous material. However, as with all human-derived solutions, universal precautions should be taken when handling waste.

Contact with waste solution or used pipetting tips may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult immediately a physician.
- Observe the system safety labels as illustrated in section Safety labels on the system on page A-16.

Contamination of the environment by liquid waste and solid waste

The waste of the cobas x 480 instrument and the cobas z 480 analyzer is potentially biohazardous.

- When disposing of any liquid or solid waste generated by the cobas x 480 instrument or cobas z 480 analyzer, do so according to the appropriate local regulations.

For information about disposal of the instrument and analyzer, see Disposal of the cobas x 480 instrument and the cobas z 480 analyzer on page A-19

Explosion and fire risk

Explosion through sparks

Hazard of explosion through sparks.

- Keep all potentially flammable or explosive material (e.g. anesthetic gas) away from the instrument and analyzer.

Fire risk through usage of sprays

Spraying liquid on the power supply parts can cause a short circuit and result in a fire.

- Keep the cover closed while the instrument and analyzer is connected to the main power supply, and do not use sprays in the vicinity of the instrument and analyzer.
- During fire-fighting operations disconnect the instrument, analyzer, and the control unit from the main power supply.
Caution messages

List of caution messages
Before operating the system, read the caution messages contained in this summary carefully. Failure to observe them may result in minor or moderate injury.

Mechanical safety

Personal injury due to contact with moving parts
The pipetting head of the cobas x 480 instrument moves rapidly during sample preparation. The main cover is locked during operation, protecting the user from moving parts.

- Keep the main cover closed and in place while the cobas x 480 instrument is operating.
- When working with the main cover open while the cobas x 480 instrument is powered on (e.g., for cleaning or maintenance), always put the cobas x 480 instrument in Maintenance mode or in Shutdown status first.
- Do not touch any parts of the cobas x 480 instrument other than those specified. Keep away from moving parts during cobas x 480 instrument operation.
- During operation and maintenance of the cobas x 480 instrument, proceed according to the instructions.
- Observe the system safety labels as illustrated in section Safety labels on the system on page A-16.
1 General safety information

Reagents

**Skin inflammation or injury caused by reagents**
Direct contact with reagents, detergents, or cleaning solutions may cause skin irritation, inflammation, or burns.

- When handling reagents, exercise the precautions required for handling laboratory reagents. Be sure to wear protective equipment (such as goggles, gloves).
- Observe the cautions given in the package insert and observe the information given in the Material Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.
- If a reagent or detergent comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult a physician immediately.

**Invalid results due to incorrect reagent volume**
Incorrect reagent handling may cause an undetectable loss of reagent.

- Store reagents always according to specified storage conditions.
- Partially used reagents should not be used on other cobas® 4800 systems.
- Avoid foam on top of reagents in filled reagent reservoirs and in reagent vials that are placed on reagent carriers.

**Invalid results due to expired reagents**
Data obtained using expired reagents are not reliable. Reagents are supplied with a label that indicates the expiration date.

- Do not use reagents that have exceeded their expiration dates. Replace expired reagent with unexpired reagents before sample processing.

Insoluble contaminants in samples

**Invalid results due to interfering substances**
Interferring substances in samples or foam on top may cause clogging or pipetting volume errors and lead to incorrect results.

Evaporation of samples or reagents

**Pipetting errors due to evaporation of samples or reagents**
Evaporation of samples or reagents may lead to pipetting errors.

- Do not leave opened sample containers on the system for any considerable length of time.
  
  ▶️ For additional details, refer to assay-specific package inserts.
- Processing of the samples must commence within specified time after reagent barcodes have been scanned as indicated in the cobas® 4800 software.
- Do not use expired reagents.
Cross contamination

Incorrect results due to carryover
Traces of analytes or reagents may be carried over from one test to the next.

- Take adequate measures to prevent cross contamination and to avoid potentially false results.
- When any indication of potential sources of contamination is seen (e.g., leaking tips, spilled reagents or samples, etc.) proper decontamination services must be performed.

Hot surfaces

Personal injury due to hot surface
The heater/shaker cradle on the cobas x 480 instrument and the microwell plate holder, the thermal block cycler, the block cycler cover, and the Xenon lamp on the cobas z 480 analyzer are hot while operating.

- Do not touch hot surfaces.
Data security

Unauthorized access and data loss due to malicious software and hacker attacks
Portable storage media can be infected with and transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The cobas® 4800 system is not protected against malicious software and hacker attacks. The customers are responsible for IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks. Failure to do so may result in data loss or render the cobas® 4800 system unusable.

Roche recommends the following precautions:

- Allow connection to authorized external devices only.
- Ensure that all external devices are protected by appropriate security software.
- Ensure that access to all external devices is protected by appropriate security equipment. cobas IT firewall must be used when the cobas® 4800 system is integrated into a network.
- Do not copy or install any software on the cobas® 4800 software control unit unless it is part of the system software or you are instructed to do so by a Roche Service representative.
- If additional software is required, contact your Roche Service representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless you are instructed to do so by official user documentation or a Roche Service representative.
- Exercise utmost care when using external storage devices such as USB flash drives, CDs, or DVDs. Do not use them on public or home computers while connecting to the cobas® 4800 system.
- Keep all external storage devices in a secure place and ensure that they can be accessed by authorized persons only.
 Notices

**NOTICE**

**List of notices**

Before operating the system, read the notices contained in this summary carefully. Failure to observe them may result in damage to equipment.

### Moving parts

**Damage to the cobas x 480 instrument due to contact with moving parts**

Contact with moving parts may damage some components.

- Keep all covers closed and in place while the **cobas x 480** instrument is operating.
- Do not touch any parts of the **cobas x 480** instrument other than those specified. Keep away from moving parts during **cobas x 480** instrument operation.

### Circuit breakers and fuses

**Damage to the instrument or analyzer due to improper use**

Should one of the instrument or analyzer circuit breakers or fuses blow, do not attempt to operate the instrument or analyzer before contacting either your Roche Service representative or technical support.

### Spillage

**Malfunction due to spilled liquid**

Any liquid spilled on the instrument or analyzer may result in malfunction, or damage of the instrument or analyzer.

- Do not place samples, reagents, or any other liquid on the surface of the instrument or analyzer other than in designated areas.
- If liquid does spill on the instrument or analyzer, wipe it up immediately and apply disinfectant. Be sure to wear protective equipment.
Safety labels on the system

Warning labels have been placed on the cobas x 480 instrument and the cobas z 480 analyzer to draw your attention to areas of potential hazard. The labels and their definitions are listed below according to their location on the instrument and analyzer.

The safety labels on the cobas x 480 instrument and on the cobas z 480 analyzer comply with the following standards: ANSI Z535, EN 980, IEC 61010-1, or ISO 7000.

If the labels are damaged, they must be replaced by Roche Service personnel. For replacement labels, contact your local Roche representative.
Safety labels on cobas x 480 instrument

1 Biohazard warning
Instrument deck may contain biohazardous or chemically contaminated materials.

2 Power connection
Connect only to earth-grounded outlet.
Connection to PC
Use only the appropriate shielded cables.
USB connection
Having a total cable distance of more than 5 m, signals can be interfered.

3 Pipetting Arm
Do not move pipetting arm by hand.

4 Barcode scanner laser beam
Do not stare into beam of class 2 laser.

5 Moving parts
Moving arm inside transparent cover. Aborts the run if cover is opened.

6 Biohazard warning
Waste may contain biohazardous or chemically contaminated materials.

Table A-1 Description of safety labels on the cobas x 480 instrument
Safety labels on cobas® 4800 system

Safety labels on the system

1 General safety information

Safety labels on the system

In addition to safety labels on the cobas® 4800 system and the cobas z 480 analyzer there are safety notes in the corresponding parts of the Operator’s Manual.

For more information, see Part Operation on page B-1 and Part Maintenance on page C-1.

These safety notes give more detailed information about potentially hazardous situations that may arise during daily operation or when carrying out maintenance procedures.

When working with the cobas® x 480 instrument and the cobas® z 480 analyzer, be sure to observe both the safety labels and the safety notes in the Operator’s Manual.

### Table A-2

<table>
<thead>
<tr>
<th>Label</th>
<th>Meaning</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Alert symbol]</td>
<td>Consult the Operator’s Manual</td>
<td>On the analyzer type plate.</td>
</tr>
<tr>
<td>![Hot symbol]</td>
<td>Hot surface</td>
<td>On the margin of the microwell plate loader. On the surface of the block cycler cover. On the surface of the block cycler unit. On the Xenon lamp unit.</td>
</tr>
<tr>
<td>![Biohazard symbol]</td>
<td>Biohazard warning</td>
<td>On the margin of the microwell plate loader.</td>
</tr>
<tr>
<td>![WEEE symbol]</td>
<td>WEEE</td>
<td>On the analyzer type plate.</td>
</tr>
</tbody>
</table>

Read the safety information contained in this manual.

Do not touch hot surfaces.

Take adequate precautions when working with potentially infectious material.

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.
Disposal of the cobas x 480 instrument and the cobas z 480 analyzer

Infection by a potentially biohazardous instrument and analyzer

The instrument and analyzer must be treated as potentially biohazardous waste. Decontamination (i.e., a combination of processes including cleaning and disinfection) is required before reuse, recycling, or disposal of the instrument or analyzer.

If you want to dispose of the instrument or analyzer contact your Roche representative.

Disposal of control unit components

Components of your control unit (such as the computer, monitor, keyboard) which are marked with this symbol are covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE, 2002/96/EC).

These items must be disposed of via designated collection facilities.

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

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

Disposal of the cobas x 480 instrument and the cobas z 480 analyzer
# Overview

In this chapter you get a basic overview about the whole cobas® 4800 system including the cobas x 480 instrument, the cobas z 480 analyzer, the cobas® 4800 software, and the reagents.

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<th>In this chapter</th>
<th>Chapter</th>
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<td>cobas x 480 instrument</td>
<td>A–24</td>
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<tr>
<td>cobas z 480 analyzer</td>
<td>A–25</td>
</tr>
<tr>
<td>cobas® 4800 software and control unit</td>
<td>A–25</td>
</tr>
<tr>
<td>LIS</td>
<td>A–26</td>
</tr>
<tr>
<td>cobas® 4800 Work Order Editor</td>
<td>A–26</td>
</tr>
<tr>
<td>Reagents</td>
<td>A–27</td>
</tr>
<tr>
<td>Consumables</td>
<td>A–27</td>
</tr>
<tr>
<td>Run types, tests, and media types</td>
<td>A–28</td>
</tr>
<tr>
<td>Run types</td>
<td>A–28</td>
</tr>
<tr>
<td>Tests</td>
<td>A–29</td>
</tr>
<tr>
<td>Subtests</td>
<td>A–29</td>
</tr>
<tr>
<td>Media types</td>
<td>A–30</td>
</tr>
</tbody>
</table>
System overview

The cobas® 4800 system provides a platform to perform qualitative in vitro nucleic acid amplification tests for the detection of Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG), and Human Papilloma Virus (HPV) in clinical specimens.

The cobas® 4800 system integrates fully automated total nucleic acid isolation directly from primary and secondary sample tubes, automated PCR setup, and real-time PCR. The main features are:

- Fully integrated sample preparation
- Amplification and detection using real-time PCR
- Minimal hands-on time
- Multiple sample types
- Multiple tests in one kit
- CT/NG and HPV testing
- HPV genotyping
- Intuitive operation by an easy to use workflow wizard

The cobas® 4800 system combines the following components:

![Diagram of cobas® 4800 system components]

---
**Figure A-2** cobas® 4800 system overview

Roche Diagnostics
Operator’s Manual - Version 1.0
A-23
**cobas x 480 instrument**

The cobas x 480 instrument prepares the samples. The cobas x 480 instrument is loaded with samples, consumables and reagents. After sample preparation, the microwell plate with the PCR-ready samples is unloaded, sealed, and transferred to the cobas z 480 analyzer for amplification and detection using real-time PCR.

The procedure for sample preparation is as follows:

1. Media-specific processing
2. Generic binding, washing, and elution
3. Working master mix preparation and PCR-setup

![cobas x 480 instrument](image)
cobas® 4800 system

2 Overview

System overview

cobas z 480 analyzer

The cobas z 480 analyzer utilizes fluorescence signal to detect nucleic acids amplified by using real-time PCR methodology. Loading and unloading the microwell plate is the only manual intervention.

Figure A-4  cobas z 480 analyzer

cobas® 4800 software and control unit

The cobas® 4800 software runs on a dedicated control unit. The cobas® 4800 software guides the user through the entire process from sample preparation to amplification and detection and result interpretation.

A handheld barcode scanner is connected to the control unit. It is used to scan reagent and reagent reservoir barcodes during loading of reagents as well as sample barcodes to setup the work order file.

For details about the control unit and the handheld barcode scanner, see Control unit on page A-66
LIS

The cobas® 4800 system can be connected to a Laboratory Information System (LIS). Orders are downloaded automatically from the LIS after samples are loaded onto the cobas x 480 instrument. After reviewing of the final results, results have to be manually uploaded to the LIS using the export function in the Results work area.

- Using result export, all results of the selected runs are exported to the LIS. It is not possible to export individual results.
- PCR Only runs are not supported by the LIS. Use the cobas® 4800 Work Order Editor to create the orders for a PCR Only run.

For information about the LIS host protocols, refer to the cobas® 4800 Host Interface Manual.

cobas® 4800 Work Order Editor

The cobas® 4800 Work Order Editor is used for manual order creation. Orders are created separately from the cobas® 4800 software and are stored in an XML-based work order file.

The cobas® 4800 Work Order Editor and work order files are only used when the cobas® 4800 system is not connected to an LIS or if the LIS is not working.
Reagents

**Kit sizes**  Individual reagent kits are available for the following run sizes:

- 10 runs with 24 samples (up to 22 patient specimen plus 2 controls)
- 10 runs with 96 samples (up to 94 patient specimen plus 2 controls)

**NOTICE**

- Make sure that the kit size corresponds to the intended run size. Although not an optimal use of reagents, a 96-kit can be used in a 24-run.
- For the most efficient reagent utilization it is advisable to maximize the number of patient specimens processed within a run. Remaining reagents can not be used later for another run.

**Reagent handling**  Some reagents are poured into reagent reservoirs and then placed onto their dedicated positions on the reagent reservoir carriers.

Other reagents are ready to use. They are decapped and then placed onto their dedicated positions on the reagent carrier.

_for instructions on handling and storage of reagents, refer to assay-specific package inserts._

**Controls**  Two external controls (Positive Control and Negative Control) are provided in a Control Kit for each assay. Controls are always processed on position A1 and B1 of the deepwell and microwell plate.

All controls are homogeneous and do not require vortexing or shaking prior to loading on the cobas x 480 instrument.

_for instructions on handling and storage of controls, refer to assay-specific package inserts._

Controls are loaded on the reagent carrier not the sample carrier.

Consumables

The cobas® 4800 system requires the following consumables:

- Pipetting tips
- Reagent reservoirs (200 mL and 50 mL)
- Deepwell plate
- Microwell plate and sealing film
- Small and large waste bags for tips
- Waste chute
- Waste container

_for details about the consumables, see Consumables on page A-55_
Run types, tests, and media types

Run types

Two different run types are supported. The run type is defined in the work order file and has to be selected at the start of a new run.

**Full workflow**

The full workflow covers sample preparation on the cobas x 480 instrument and amplification and detection on the cobas z 480 analyzer.

**PCR Only workflow**

The PCR Only workflow supports amplification and detection on the cobas z 480 analyzer for samples previously prepared on the cobas x 480 instrument.

The PCR Only workflow is intended for repeat amplification from the remaining eluate in the deepwell plate (extraction plate). For the PCR Only workflow, the microwell plate (AD plate) is manually prepared with working master mix and eluate from the deepwell plate. The PCR Only run is only validated to work with extract from a cobas x 480 instrument.

For stability of eluates, refer to the assay-specific package inserts.

A sample preparation only workflow is not supported.
Tests

The **cobas® 4800** system runs the following tests:

- Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG)
- Human papillomavirus (HPV)

Tests are run in batches. While CT and NG tests can be performed in a single run, neither test can be combined with HPV tests in a single run.

Subtests

The **cobas® 4800** analyzer can simultaneously detect signal from one or more detection channels, which makes it possible to obtain more information from a single reaction. This provides multiple subtests for each test type.

Subtests can be ordered for each sample individually using the **cobas® 4800 Work Order Editor**.

For information about the **cobas® 4800 Work Order Editor**, see **cobas® 4800 Work Order Editor** on page B-55.

The following subtests are available:

<table>
<thead>
<tr>
<th>Main test type</th>
<th>Subtests</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT/NG</td>
<td>CT and NG in combination</td>
<td>CT/NG</td>
</tr>
<tr>
<td></td>
<td>CT only</td>
<td>CT</td>
</tr>
<tr>
<td></td>
<td>NG only</td>
<td>NG</td>
</tr>
<tr>
<td>HPV</td>
<td>HPV high risk panel</td>
<td>High risk HPV</td>
</tr>
<tr>
<td></td>
<td>HPV high risk panel and genotyping for HPV type 16 and 18</td>
<td>Other high risk HPV, HPV16, HPV18</td>
</tr>
</tbody>
</table>

**Table A-3** Subtests for CT/NG and HPV
Media types

The following media types are supported:

- CT/NG assay supports endocervical swab and urine samples collected in cobas PCR Media
- HPV assay supports cervical samples collected in liquid-based cytology media (PreservCyt, SurePath™, or cobas® PCR Cell Collection Media).

<table>
<thead>
<tr>
<th>Test type</th>
<th>Specimen type</th>
<th>Abbreviation</th>
<th>Carrier used</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT/NG</td>
<td>• Swab UT</td>
<td>• UT</td>
<td>• 24-position sample carrier</td>
</tr>
<tr>
<td></td>
<td>• Urine UUT</td>
<td>• UUT</td>
<td></td>
</tr>
<tr>
<td>HPV</td>
<td>• PreservCyt®</td>
<td>• PC</td>
<td>PreservCyt carrier (primary tubes)</td>
</tr>
<tr>
<td></td>
<td>• cobas® PCR Cell Collection Media</td>
<td>• 24-position sample carrier (secondary tubes)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SurePath™</td>
<td>• SP</td>
<td>24-position sample carrier (secondary tubes)</td>
</tr>
</tbody>
</table>

Table A-4  Media types for CT/NG and HPV

NOTICE

Use only media types that are approved by Roche.

Secondary sample tubes

When a secondary sample tube is needed on the cobas x 480 instrument, use the 13 mL round bottom base 16.5 x 101 mm PP tube from Sarstedt (e.g. US part number 60.541.122 or EU part number 60.540.500 and 60.540.014). Use of any other tube may lead to incorrect results or processing failures.
Hardware

In this chapter you get an introduction into the cobas x 480 instrument and the cobas z 480 analyzer.

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<thead>
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<th>cobas x 480 instrument</th>
<th>Chapter 3</th>
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<td>LEDs</td>
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<td>Instrument deck</td>
<td>A–35</td>
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<td>Autoload unit</td>
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<tr>
<td>Pipetting arm</td>
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<td>iSWAP</td>
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<td>Teaching needles</td>
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<td>Waste station</td>
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<tr>
<td>Carriers</td>
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<tr>
<td>Sample carriers</td>
<td>A–45</td>
</tr>
<tr>
<td>Reagent carriers</td>
<td>A–46</td>
</tr>
<tr>
<td>Plate carrier</td>
<td>A–49</td>
</tr>
<tr>
<td>Tip rack carriers</td>
<td>A–51</td>
</tr>
<tr>
<td>Stationary carrier</td>
<td>A–52</td>
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<tr>
<td>Consumables</td>
<td>A–53</td>
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<tr>
<td>Pipetting tips</td>
<td>A–54</td>
</tr>
<tr>
<td>Reagent reservoirs</td>
<td>A–55</td>
</tr>
<tr>
<td>Deepwell plate</td>
<td>A–56</td>
</tr>
<tr>
<td>Microwell plate</td>
<td>A–57</td>
</tr>
<tr>
<td>Consumables for tip waste</td>
<td>A–58</td>
</tr>
<tr>
<td>Technical specifications of the cobas x 480 instrument</td>
<td>A–60</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cobas z 480 analyzer</th>
<th>A–62</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEDs</td>
<td>A–63</td>
</tr>
<tr>
<td>Main building blocks</td>
<td>A–64</td>
</tr>
<tr>
<td>Technical specifications of the cobas z 480 analyzer</td>
<td>A–65</td>
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<tr>
<td>Control unit</td>
<td>A–66</td>
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<tr>
<td>Handheld barcode scanner</td>
<td>A–67</td>
</tr>
<tr>
<td>Technical specification of the control unit</td>
<td>A–68</td>
</tr>
</tbody>
</table>
cobas x 480 instrument

The cobas x 480 instrument is an automated multi-channel pipetting instrument used to extract, purify, and prepare target nucleic acid for subsequent PCR testing on the cobas z 480 analyzer. The cobas x 480 instrument is configured to perform CT/NG and HPV sample preparations and is able to process up to 96 samples (94 patient specimens plus two controls) in a single run.

The main parts of the cobas x 480 instrument are shown in Figure A-6.
Covers

The following figure shows the covers of the cobas x 480 instrument.

![Covers of the cobas x 480 instrument](image)

**Figure A-7**  Covers of the cobas x 480 instrument

The front cover protects you from moving parts inside the cobas x 480 instrument. The front cover can be opened for user intervention during maintenance. Always close the front cover when you have finished maintenance work. During a run, the front cover must be closed.

**NOTICE**

The front cover is locked during a run. While it is possible to force the front cover open during a run, doing so will cause an emergency stop. The run will be aborted and all on-board reagents and in-process samples will be lost. Do not attempt to start the run with cover open.
LEDs

The loading status on the instrument deck is indicated by a LED bar above the autoload tray. The status LEDs inform you where to place the carriers on the autoload tray and which tracks on the instrument deck are occupied by a carrier.

![LED bar indicating loading status](image)

**Figure A-8** LED bar with status LEDs

<table>
<thead>
<tr>
<th>LED status</th>
<th>Meaning</th>
<th>User action</th>
</tr>
</thead>
<tbody>
<tr>
<td>No light</td>
<td>No carrier loaded.</td>
<td>No action necessary.</td>
</tr>
<tr>
<td>Green light steady</td>
<td>Carrier on board at that position.</td>
<td>No action necessary.</td>
</tr>
<tr>
<td>Green light blinking</td>
<td>Indicates the track positions in which the carrier must be loaded.</td>
<td>Place the carrier at the indicated positions on the autoload tray and insert the carrier until the stop hooks.</td>
</tr>
</tbody>
</table>

**Table A-5** Status LEDs on LED bar
**Instrument deck**

The work area of the cobas x 480 instrument is called *instrument deck*. The instrument deck holds:

- removable carriers for samples, reagents, plates, and consumables.
- a stationary carrier used for sample processing. The stationary carrier is not removable and holds heater and shaker unit, magnet plate, and the plate holders for the deepwell plate and the microwell plate.

*Instrument deck layout*  
The instrument deck is divided into 54 equal tracks. The tracks are numbered so that you can readily identify the location where a carrier must be loaded. The track positions are stamped on the surface of the autoload tray. A corresponding LED on the LED bar above the autoload tray indicates the loading status of each track.

Track assignment is fixed. It is the same for CT/NG and HPV sample preparation. The instrument deck layout below shows you the dedicated areas for each carrier type.

---

**Figure A-9**  
Instrument deck layout of *cobas x 480* instrument
**Track positions**  The following table summarizes the dedicated track positions on the instrument deck.

<table>
<thead>
<tr>
<th>Track position</th>
<th>Used for carrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-6</td>
<td>Plate carrier</td>
</tr>
<tr>
<td>7-10</td>
<td>Not used</td>
</tr>
<tr>
<td>11-16</td>
<td>Left tip carrier</td>
</tr>
<tr>
<td>17-34</td>
<td>Sample loading area</td>
</tr>
<tr>
<td>35-40</td>
<td>Right tip carrier</td>
</tr>
<tr>
<td>41-47</td>
<td>Stationary carrier for sample preparation</td>
</tr>
<tr>
<td>48-49</td>
<td>200 mL reagent reservoir carrier</td>
</tr>
<tr>
<td>50</td>
<td>50 mL reagent reservoir carrier</td>
</tr>
<tr>
<td>51</td>
<td>Reagent carrier</td>
</tr>
<tr>
<td>52-54</td>
<td>Not used</td>
</tr>
</tbody>
</table>

**Table A-6**  Track positions on instrument deck of the cobas x 480 instrument

**Sample loading area**  The sample loading area can hold any combination of sample carriers.

*For additional details about sample carriers, see Sample carriers on page A-46*
Autoload unit

The autoload unit consists of the autoload tray - the platform where the carriers are placed - and the autoloader. The autoloader detects waiting carriers with their tubes and containers and scans the barcodes.

The autoload unit is used to automatically load carriers onto the cobas x 480 instrument. The carriers are inserted by the operator into their designated position on the autoload tray. The correct loading position is indicated by a blinking LED on the LED bar above the autoload tray.

For details about the status LEDs, see Table A-5 on page A-35.

After correct placement the carriers are loaded automatically onto the instrument deck by the cobas x 480 instrument. During loading, the barcode scanner on the autoloader scans the carrier barcode and the barcodes of the supplies on the carrier (samples, reagents, and disposables).

## Inserting carriers on autoload tray

The autoload tray contains slide blocks that engage tracks in the carriers to guide the carriers when they are loaded. When inserting a carrier onto the autoload tray, be sure that the tracks on the carrier properly engage the slide blocks. Insert the carriers into their designated position on the autoload tray until they touch the stop hooks on the far side of the tray.

Insert the carriers into the tracks between the front and rear slide blocks of the Autoload tray until they touch the stop hooks on the far side of the tray.

**NOTICE**

Make sure the carriers are inserted completely until they touch the stop hooks on the autoload tray. Exercise care when inserting the carriers - do not push carriers against the stop hooks with excessive force.
Safety guards

The autoload tray has safety guards attached on each side. Extend the safety guards to avoid bumping into the carriers on the autoload tray.

---

**CAUTION**

**Personal injury due to bumping into carriers on autoload tray**

Keep safety guards on both sides of the autoload tray extended to avoid bumping into carriers on the autoload tray.

---

Autoloader with barcode scanner

During loading, the barcode scanner on the autoloader scans the barcode of the carrier and those of the supplies on the carrier (samples, reagents, and disposables).

The following barcode types are supported:

- Codabar (without check sum)
- Code 39 (without check sum)
- Code 128, subset B and C (with check sum)

For details about barcode specifications, see Barcode scanner on page A-61

---

**WARNING**

**Loss of sight due to staring into laser beam**

The barcode scanner contains a class II laser diode. Do not stare into the laser transmitter beam as your eyesight may be severely damaged.

---

**CAUTION**

**Personal injury due to touching moving parts**

Keep hands away from the moving barcode scanner while the **cobas x 480 instrument** is operating. Be sure that the front cover is closed whenever the **cobas x 480 instrument** is operating. Do not disable the front cover interlock.

---

**NOTICE**

**Damage to the cobas x 480 instrument due to incorrect handling**

In the event that the autoloader does not respond or the barcode scanner blocks removal of a carrier, DO NOT attempt to move the barcode scanner by hand. Severe damage to the autoloader will result. If the barcode scanner must be moved, perform daily maintenance.
Pipetting arm

The cobas x 480 instrument is equipped with a pipetting arm containing eight pipetting channels and the iSWAP device. During operation, the pipetting arm moves left-and-right (x-direction), picks up the required number of disposable pipetting tips, aspirates, dispenses, and mixes the liquids, and then ejects the used tips into the tip waste bag.

Each air-displacement pipetting channel can move forward-and-back (y-direction) and up-and-down (z-direction) during the pipetting operation. A disposable pipetting tip is picked up by each pipetting channel at the beginning of a pipetting cycle. The pipetting tip is ejected into the tip waste bag at the completion of pipetting for that cycle.

For additional details, see Weekly maintenance on page C-12.
iSWAP

The landscape iSWAP is a robotic arm that picks up deepwell plates and microwell plates and moves them to the desired location on the instrument deck during a run. The iSWAP is mounted on the pipetting arm.

Teaching needles

The cobas x 480 instrument uses eight teaching needles to automatically check (and adjust if necessary) z-positioning and over- and under-pressure of each pipetting channel at the appropriate time. The teaching needles are stored near the waste station, next to the tip waste. The teaching needles are cleaned during the Roche preventive maintenance visit.
Waste station

Make sure that you have read and understood the chapter General safety information. The following safety messages in particular are relevant:

- **Warning messages:**
  - Infection by biohazardous waste on page A-10
  - Contamination of the environment by liquid waste and solid waste on page A-10

---

**Tip waste**

Waste bags hold used pipetting tips after they have been ejected by the pipetting arm. The cobas x 480 instrument can be installed on either a bench top or on a trolley that accommodates a larger waste bag.

- If the cobas x 480 instrument is installed on a bench top, a small waste bag is used. This waste bag has a capacity for tips of at most one full run.

---

**NOTICE**

Exchange the small waste bag each time before starting a new run to avoid overfilling of the tip waste.

- For details about replacing the small waste bag, see Daily maintenance on page C-7 and Weekly maintenance on page C-12

---

![Diagram of waste station](image)

**Figure A-15**

Small waste bag

A Initialization/waste block
B Support frame
C Small waste bag with a capacity for tips of at most one full run
If the cobas x 480 instrument is installed on a special trolley, a plastic waste chute is used in place of the waste bag and the tip waste is directed into a waste box on the trolley that holds a large waste bag. The large waste bag holds tips of at most three full runs.

- Waste chute and waste box can be reused and need to be replaced only if required.
- If required, replace the waste chute in the same way as the small tip waste bag.
- If required, fold up a new waste box as indicated in Figure A-17 on page A-43

For details about replacing the large waste bag, see Daily maintenance on page C-7 and Weekly maintenance on page C-12.

![Figure A-16](image)

**Figure A-16** Waste box with large waste bag

The waste box can be used several times. Fold up a new waste box in the following way:

![Figure A-17](image)

**Figure A-17** Folding a new waste box
Liquid waste

The liquid waste from the cobas x 480 instrument is collected in an external waste container. The level of the liquid waste is monitored by the system and a warning is issued when it is not possible to do a full run. In this case, it is not possible to start the run.

The liquid waste is emptied during daily or weekly maintenance. The liquid waste container is reusable.

For details about emptying the liquid waste container, see Daily maintenance on page C-7 and Weekly maintenance on page C-12.
Carriers

The following carriers are used:

<table>
<thead>
<tr>
<th>Carrier for</th>
<th>Carrier</th>
<th>Used for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples</td>
<td>24-position sample carrier</td>
<td>PCR Medium tubes and secondary sample tubes.</td>
</tr>
<tr>
<td></td>
<td>PreservCyt carrier</td>
<td>PreservCyt primary sample tubes</td>
</tr>
<tr>
<td></td>
<td>200 mL reagent reservoir carrier</td>
<td>200 mL reagent reservoirs</td>
</tr>
<tr>
<td></td>
<td>50 mL reagent reservoir carrier</td>
<td>50 mL reagent reservoirs</td>
</tr>
<tr>
<td></td>
<td>Reagent carrier</td>
<td>Reagent and control vials (in adapter)</td>
</tr>
<tr>
<td>Plates</td>
<td>Plate carrier</td>
<td>Deepwell plate and microwell plate</td>
</tr>
<tr>
<td>Tips</td>
<td>Tip carrier</td>
<td>Pipetting tip racks</td>
</tr>
<tr>
<td>Sample preparation</td>
<td>Stationary carrier</td>
<td>Heater/shaker unit, magnet plate, holders for plates</td>
</tr>
</tbody>
</table>

Table A-7 Carriers used in the cobas® 4800 system
Sample carriers

Two different sample carriers allow the use of samples in primary and secondary sample tubes.

A total of 94 patient specimens can be loaded onto the cobas x 480 instrument per run.

The sample barcodes must face to the right of the carrier.

Each run requires a positive and a negative control. Both controls are loaded together with the reagents onto the reagent carrier.

Barcode dimensions

![Barcode dimensions diagram]

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Minimal</th>
<th>Maximal</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Label length</td>
<td>-</td>
<td>80 mm</td>
</tr>
<tr>
<td>B Code length</td>
<td>-</td>
<td>74 mm</td>
</tr>
<tr>
<td>C Quiet zone</td>
<td>3 mm</td>
<td>-</td>
</tr>
<tr>
<td>D Label width</td>
<td>12 mm</td>
<td>-</td>
</tr>
<tr>
<td>E Code width</td>
<td>12 mm</td>
<td>-</td>
</tr>
<tr>
<td>F Distance from code to label edge</td>
<td>-</td>
<td>1 mm</td>
</tr>
</tbody>
</table>

Figure A-20 Barcode dimensions

Positioning barcode labels on secondary sample tubes

The barcode must fit within a range of between 20 mm and 100 mm from the bottom of the tube.

Make sure the bars are perpendicular to the tube.

For additional details about barcode types and specifications, see Barcode scanner on page A-61
**HPV assay**  The HPV assay runs on liquid-based cytology samples only. The following sample carriers can be used in any combination in a single run for HPV testing:
- PreservCyt carrier with PreservCyt primary sample tubes
- 24-position sample carrier with secondary sample tubes

**CT/NG assay**  The CT/NG assay runs on swab samples and on urine samples stabilized with cobas PCR Media only. The following sample carrier can be used for CT/NG testing:
- 24-position sample carrier with primary cobas PCR Media tubes

**24-position sample carrier**  The 24-position sample carrier holds up to 24 cobas PCR Media tubes or 13 mL round bottom base 16.5 x 101 mm PP tubes from Sarstedt.
- Use cobas PCR Media tubes as primary sample tubes.
- Use 13 mL round bottom base 16.5 x 101 mm tubes from Sarstedt as secondary sample tubes and transfer an aliquot from the primary sample tube if necessary.

For additional details, see [Secondary sample tubes](#) on page A-30

The 24-position sample carrier uses one track on the instrument deck.

---

**NOTICE**  Handle any 1-track carrier (such as a sample carrier) with particular care, as this type of carrier can fall over and cause injury or contamination. Position it on the autoload tray or place several carriers together to minimize this risk.

---

![24-position sample carrier](image)

**Figure A-22**  24-position sample carrier

- **A**  Carrier barcode
- **B**  cobas PCR Media tubes or appropriate secondary sample tubes (see [Secondary sample tubes](#) on page A-30)
PreservCyt carrier

The PreservCyt carrier is optionally available and holds up to 12 PreservCyt primary sample tubes. The minimal sample volume in the PreservCyt primary sample tubes is 2.4 mL.

This carrier uses two tracks on the instrument deck.

NOTICE

Open the PreservCyt containers before inserting the carrier on the autoloading tray.

---

**Figure A-23** PreservCyt carrier

A  Carrier barcode
B  PreservCyt primary sample tube
Reagent carriers

The reagent reservoir carriers hold the reagent reservoirs. The reagent reservoir carriers are available in two sizes:

- 200 mL reagent reservoir carrier for 200 mL reservoirs
- 50 mL reagent reservoir carrier for 50 mL reservoirs

The required reagents are poured into the reagent reservoirs which are then placed onto their dedicated positions on the reagent reservoir carriers. The reagent reservoir barcodes must face to the right of the carrier.

For details about reagents and the placement on reagent reservoir carriers, see Reagents on page A-27 and Load the reagents on page B-33.

![200 mL reagent reservoir carrier](image1)

**Figure A-24** 200 mL reagent reservoir carrier

![50 mL reagent reservoir carrier](image2)

**Figure A-25** 50 mL reagent reservoir carrier
Reagent carrier

The reagent carrier holds the assay specific reagents for sample processing and PCR setup (controls, master mix, metal co-factor(s), and so on).

The required reagents are decapped and then placed onto their dedicated positions on the reagent carrier. The reagent barcodes must face to the right of the carrier.

For details about reagent placement on reagent carriers, see Load the reagents on page B-33.

The reagent carrier is the same carrier as the 24-position sample carrier.
The plate carrier holds the deepwell plate and the microwell plate. The deepwell plate is used to process the samples. The microwell plate is used to hold the final prepared samples that are ready for PCR.

Place the deepwell plate on position 1 and the microwell plate on position 3 of the plate carrier. The other positions on the carrier are not used. The deepwell plate barcode must face to the right of the carrier. The deepwell plate barcode is read during loading of the plate carrier. The microwell barcode is read after loading being brought in front of the barcode scanner on the autoloader by the iSWAP.

At the end of the run, the plates are placed back on the plate carrier. Unload the plate carrier, seal the microwell plate and dispose of the deepwell plate according to the local regulations unless further off-the-system use is intended.
Tip rack carriers

The tip rack carriers hold the tip racks with the disposable pipetting tips (1mL tips with filter). Two tip rack carriers are loaded for a single run holding a total of 10 tip racks.

The tip rack barcodes must face to the right of the carrier.

There is no tracking of tip usage from run to run. In addition, the total number of tips per run varies and depends on several criteria (assay type, sample media, run size, and so on). Therefore, to avoid running out of tips during processing, fully load both tip rack carriers for each run.
Stationary carrier

The stationary carrier is the area where the samples are processed. It is mounted on the instrument deck and is not removable. The stationary carrier holds four units:

- heater/shaker unit
- magnet plate
- deepwell plate holder
- microwell plate holder

**Heater/shaker unit**

The heater/shaker unit provides consistent and reliable heating and shaking during sample processing.

The heater/shaker unit is powered from an external controller box located outside of the cobas x 480 instrument. The heater/shaker unit must be switched on and off on the external controller box.

- Do not forget to switch on the heater/shaker unit on its external controller box.
- Always switch off the heater/shaker unit before unplugging it.
3 Hardware

Magnet plate
The magnet plate immobilizes magnetic glass particles during sample processing.

Be aware, that the magnets are not affixed to the plate so any metal can remove the magnets from its holder.

Holders for deepwell plate and microwell plate
The holders for the deepwell plate and the microwell plate are where the washing and PCR setup occurs during sample processing.
Consumables

NOTICE

- Use only Roche consumables designed for use on the cobas® 4800 system. Use of non-Roche consumables may damage the cobas x 480 instrument or lead to incorrect results.
- Do not reuse consumables. All consumables are designed for one time use only.
- Inspect consumables before use. Do not use damaged consumables.

Pipetting tips

Disposable 1 mL pipetting tips with filters are used for pipetting of all liquids during sample processing. The pipetting tips are available in tip racks of 96 tips each. Tip racks are placed into tip rack carriers.

For details about tip rack carriers, see Tip rack carriers on page A-52

NOTICE

Use only disposable tips that are specified by Roche. Non-Roche tips may cause contamination or damage pipetting channels.

Figure A-32 Tip rack with 96 disposable pipetting tips
Reagent reservoirs

The reagent reservoirs hold the reagents used for sample preparation. The reagent reservoirs are barcoded and are filled manually by the operator (scan-scan-pour principle) for each run.

Scan-scan-pour principle
To minimize handling errors the reagent reservoirs are filled and placed using the scan-scan-pour principle:

1. Scan the barcode of the required reagent using the handheld barcode scanner.
2. Scan the barcode of an unused reagent reservoir using the handheld barcode scanner.
3. Pour the reagent in the scanned reagent reservoir.
4. Place the filled reagent reservoir onto the required position of the reagent reservoir carrier as indicated in the wizard.

Reagent reservoir sizes
The reagent reservoirs are available in two sizes:

- 200 mL reagent reservoirs
- 50 mL reagent reservoirs

Reagent reservoirs are placed in reagent reservoir carriers.

For details about reagent reservoir carriers, see Reagent reservoir carriers on page A-49

- The reagent reservoirs are designed for one time use. The cobas® 4800 software tracks the use of the reservoirs and rejects previously used reagent reservoirs.
- Do not fill reagent reservoirs above the maximal fill height. A sign within the reagent reservoir indicates the maximal fill height.
- Always pour the entire reagent vial in the scanned reagent reservoir to avoid underfilling.
- Handle filled reservoirs with particular care to avoid splashes and tipping over.
- It is advisable to pour the reagent into the reservoir in a lengthwise movement to minimize the risk of splashing and resulting reagent loss.
- Do not pour reagents into reservoirs that are already placed onto a reagent rack. Always follow the scan-scan-pour principle.

![Reagent reservoirs](image)

A 200 mL reagent reservoir  B 50 mL reagent reservoir.

Figure A-33  Reagent reservoirs
Deepwell plate

The deepwell plate (extraction plate 1.6 mL) is used for sample processing. The deepwell plate holds up to 96 samples.

The deepwell plate is placed in the plate carrier on position 1 prior to a run.

- The deepwell plate is barcoded and designed for one time use. The cobas® 4800 software tracks the use of the plate and rejects previously deepwell plates.
- Open the primary packaging of the deepwell plate before use. Open the packaging only in a clean environment to prevent contamination of the plate.
- Never touch the wells of a deepwell plate to avoid contamination.

NOTICE

Use only deepwell plates designed for the cobas® x 480 instrument.
Microwell plate

The microwell plate (AD-plate 0.3 mL) holds the processed samples mixed with working master mix reagent and is used for amplification and detection on the cobas z 480 analyzer.

The microwell plate is placed in the plate carrier on position 3 prior to a run.

⚠️ For details about the plate carrier, see Plate carrier on page A-51

After final sample processing on the cobas x 480 instrument the microwell plate is placed back on the plate carrier by the iSWAP. Unload the plate carrier and seal the microwell plate using the sealing film.

⚠️ For details about sealing of the microwell plate, see Unload and seal the microwell plate on page B-40

- The microwell plate is barcoded and designed for one time use. The cobas® 4800 software tracks the use of the plate and rejects previously used microwell plates.
- Open the primary packaging of the microwell plate before use. Open the packaging only in a clean environment to prevent contamination of the plate.
- Never touch the wells of a microwell plate to avoid contamination.

NOTICE

Use only microwell plates designed for the cobas x 480 instrument.
Consumables for tip waste

The following consumables are used for the tip waste. The required consumables depend on the implemented waste solution.

- **Small waste solution**
  - Small waste bag for tips

- **Large waste solution**
  - Large waste bag for tips
  - Waste chute
  - Waste box

💡 Waste chute and waste box can be reused and need to be replaced only if required.

💡 For additional details, see Waste station on page A-42
## Technical specifications of the cobas x 480 instrument

### NOTICE

Every effort has been made to ensure that all the information contained in these specifications is correct at the time of printing. However, Roche reserves the right to make any changes necessary without notice as part of ongoing product development.

### Physical dimension

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width</td>
<td>166.5 cm (65.55 in)</td>
</tr>
<tr>
<td>Depth</td>
<td>101 cm (39.76 in)</td>
</tr>
<tr>
<td></td>
<td>120 cm (47.2 in)</td>
</tr>
<tr>
<td>Height</td>
<td>90.5 cm (35.6 in)</td>
</tr>
<tr>
<td>Weight</td>
<td>Approximately 180 kg (397 lb)</td>
</tr>
</tbody>
</table>

### Power requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Line voltage</td>
<td>115 VAC (-15%) to 230 VAC (+10%)</td>
</tr>
<tr>
<td>Line frequency</td>
<td>50 or 60 Hz (±5 Hz)</td>
</tr>
<tr>
<td>Power consumption</td>
<td>Max. 600 VA</td>
</tr>
<tr>
<td>Installation category</td>
<td>II</td>
</tr>
<tr>
<td>Fuses (delayed action)</td>
<td>115 V~: 6.3 A</td>
</tr>
<tr>
<td></td>
<td>230 V~: 3.15 A</td>
</tr>
</tbody>
</table>

### System principles

The cobas x 480 instrument is an automated multi-channel pipetting instrument used to extract, purify, and prepare target nucleic acid for subsequent real-time PCR testing on the cobas z 480 analyzer.

### Environmental conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Running conditions: 15-30°C (59-86°F)</td>
</tr>
<tr>
<td></td>
<td>Transport and storage: -25 to +70°C (-13 to +158°F)</td>
</tr>
<tr>
<td>Humidity</td>
<td>Running conditions: 15-85%, without condensation</td>
</tr>
<tr>
<td>Noise</td>
<td>&lt;65dBA</td>
</tr>
<tr>
<td>Pollution</td>
<td>Level 2 (EN 61010-1, IEC 60664-1)</td>
</tr>
<tr>
<td>Altitude</td>
<td>30-2000 m (100-6500 ft) above sea level</td>
</tr>
</tbody>
</table>

### Throughput

| Throughput     | Daily: 282 HPV and 376 CT/NG tests per day        |

### Samples

<table>
<thead>
<tr>
<th>Sample type</th>
<th>For test-specific samples types refer to the package inserts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-board capacity</td>
<td>A total of 94 patient specimen can be loaded per run. Two different sample carriers allow the use of samples in primary and secondary sample tubes.</td>
</tr>
</tbody>
</table>

### Controls

| Kit controls   | One positive and one negative control per run |

---

Roche Diagnostics

A-60  Operator’s Manual · Version 1.0
### Barcode scanner

**Barcode types**
- Codabar (without check sum)
- Code 39 (without check sum)
- Code 128, subset B and C (with check sum)

**String length**
Max. 20 characters, excluding start, stop and check characters. Depends on label length.

**Code density tolerance**
Best reading performance with X dimension between 0.19 mm (0.0075 in) and 0.25 mm (0.01 in)

**Quiet zone**
≥ 10 times the X dimension, at least 3 mm (0.12 in).

**Print quality**
- Printing with ANSI / CEN / ISO grade A or B is required.
- Suitable for offset, typographic, intaglio and flexographic printing.
- Not suitable for mechanical dot-matrix and thermomatrix printing.

### Interfaces

**User interface**
cobas® 4800 software running on the cobas® 4800 software control unit.

**Instrument interface**
The cobas x 480 instrument is connected to the cobas® 4800 software control unit through a USB connection.
Place the cobas® 4800 software control unit close to the cobas x 480 instrument. Use the originally delivered USB cable only.

### Waste

**Solid waste**
- Small waste bag holds used pipetting tips of at most one full run.
- Large waste bag holds used pipetting tips of at most three full runs.

**Liquid waste**
Liquid waste container holds liquid waste.

### Consumables

**Transport temperature**
All consumables are designed to be transported without the need for refrigeration at a temperature range between -15°C to 55°C (5°F to 131°F).

**Storage temperature**
Microwell plate and deepwell plate are designed to be stored at a temperature range between 15°C to 25°C (59°F to 77°F).

Pipe tips can be stored at a temperature range between -15°C to 55°C (5°F to 131°F)

### Heater/shaker unit

**Line voltage**
100-240 VAC

**Line frequency**
50-60 Hz

**Power consumption**
70 VA
cobas z 480 analyzer

The cobas z 480 analyzer is a rapid thermal block cycler with integrated real-time detection capabilities.

Simultaneous detection on four detection channels allows analysis of signals from multiple dyes in multiplex real-time PCR assays. As a benefit of this, multiple results can be reported from a single run.

⚠️ For more details about tests and subtests, see Tests on page A-29

---

**NOTICE**

- Before loading the microwell plate into the cobas z 480 analyzer, it has to be sealed properly with the self-adhesive sealing film. Sealing the plate is crucial to eliminate evaporation at high temperatures. Use only the recommended foil.

⚠️ For details about sealing of the microwell plate, see To seal the microwell plate on page B-41

- It is not necessary to centrifuge the sealed plate before loading it into the cobas z 480 analyzer.
The front of the cobas z 480 analyzer provides two status LEDs which inform the user of the hardware status. The load button for opening and closing the microwell plate loader is located next to the two LEDs.
Main building blocks

The main building blocks of the cobas z 480 analyzer are the following:

**Block cycler unit**
- Thermal block cycler with block cycler cover, ventilation, microwell plate loader, and microwell plate barcode scanner

**Detection unit**
Consisting of the following:
- Lamp unit housing the Xenon excitation lamp
- Optics unit, including the liquid light guide, emission and detection filter wheel, and the CCD camera.

![Diagram of cobas z 480 analyzer building blocks](image)

**Legend**
- A Lamp unit
- B Housing
- C Detection unit
- D Filter wheels
- E Status LED
- F Load button
- G Thermal block cycler
- H Microwell plate loader
- I Block cycler door (open) with ventilation fans

**Figure A-38** cobas z 480 analyzer building blocks
## Technical specifications of the cobas z 480 analyzer

### NOTICE
Every effort has been made to ensure that all the information contained in these specifications is correct at the time of printing. However, Roche reserves the right to make any changes necessary without notice as part of ongoing product development.

### Physical dimension

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width</td>
<td>57.4 cm (22.6 in)</td>
</tr>
<tr>
<td>Depth</td>
<td>58.8 cm (23.1 in)</td>
</tr>
<tr>
<td>Height</td>
<td>49.7 cm (19.6 in)</td>
</tr>
<tr>
<td>Weight</td>
<td>55 kg (121.25 lb)</td>
</tr>
</tbody>
</table>

### Power requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Line voltage</td>
<td>200-240 VAC</td>
</tr>
<tr>
<td>Line frequency</td>
<td>50 or 60 Hz</td>
</tr>
<tr>
<td>Power consumption</td>
<td>1500 VA</td>
</tr>
<tr>
<td>Primary fuses</td>
<td>250 V / T10 A</td>
</tr>
<tr>
<td>Secondary fuses</td>
<td>F1: 250 V / T3.15 A</td>
</tr>
<tr>
<td></td>
<td>F2: 250 V / T8 A</td>
</tr>
<tr>
<td></td>
<td>F3: 250 V / T16 A</td>
</tr>
<tr>
<td>Lamp fuse</td>
<td>250 V / T2.5 A</td>
</tr>
</tbody>
</table>

### System principles

The cobas z 480 analyzer performs real-time PCR amplification and detection using real-time PCR.

### Environmental conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Running conditions: 15-32°C (59-90°F)</td>
</tr>
<tr>
<td></td>
<td>Transport and storage: -25 to +60°C (-13 to +140°F)</td>
</tr>
<tr>
<td>Humidity</td>
<td>Running conditions:</td>
</tr>
<tr>
<td></td>
<td>Max. 80% at 32°C, without condensation</td>
</tr>
<tr>
<td></td>
<td>Min. 30% at 15°C to 32°C</td>
</tr>
<tr>
<td>Noise</td>
<td>&lt;60 dBA</td>
</tr>
<tr>
<td>Altitude</td>
<td>0 to 2000 m (0 to 6500 ft) above sea level</td>
</tr>
</tbody>
</table>

### Throughput

<table>
<thead>
<tr>
<th>Sample</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples per run</td>
<td>94 samples and 2 controls</td>
</tr>
</tbody>
</table>

### Interfaces

<table>
<thead>
<tr>
<th>Interface Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User interface</td>
<td>cobas® 4800 software running on the cobas® 4800 software control unit.</td>
</tr>
<tr>
<td>Instrument interface</td>
<td>The cobas z 480 analyzer is connected to the cobas® 4800 software control unit through an Ethernet LAN.</td>
</tr>
</tbody>
</table>

### Consumables

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport</td>
<td>The microwell plate is designed to be transported without the need for refrigeration at a temperature range between -15°C to 55°C (5°F to 131°F).</td>
</tr>
<tr>
<td>Storage</td>
<td>The microwell plate is designed to be stored at a temperature range between 15°C to 25°C (59°F to 77°F).</td>
</tr>
</tbody>
</table>
Control unit

A dedicated control unit runs the cobas® 4800 software and the cobas® 4800 Work Order Editor and controls the cobas x 480 instrument and the cobas z 480 analyzer.

**NOTICE**

- Use only manufacturer’s original installation CD-ROM or DVD sets for the operating system, and the original cobas® 4800 software.
- Any manipulation of cobas® 4800 system data files or other information determining or affecting cobas® 4800 system functions can result in erroneous results or cobas x 480 instrument or cobas z 480 analyzer failure.
- Only use the control unit that is supplied with the cobas® 4800 system.

![Control unit with display gooseneck](image)

**Figure A-39** Control unit with display gooseneck

A Display
B Display gooseneck
C Control unit
Handheld barcode scanner

The handheld barcode scanner is used to scan reagent and reagent reservoir barcodes during loading of reagents as well as sample barcodes to setup the work order file. In addition, the handheld barcode scanner could be used when an error message indicates that a specified reagent or sample barcode label could not be read.

**Supported barcode types**

The following barcode types are supported:

- Codabar
- Code 39
- Code 128, subset B and C
- Data matrix

**Usage**

The barcode label is read by holding the head of the barcode scanner in close proximity to the barcode label and then pressing the button on the barcode scanner. The barcode ID is then automatically read and displayed on the screen.

**NOTICE**

Be sure to hold the head of the handheld barcode scanner over the correct barcode label. It is recommended to visually verify the displayed scanned characters with the human readable characters on the barcode label.

---

Figure A-40  Handheld barcode scanner
Technical specification of the control unit

<table>
<thead>
<tr>
<th>NOTICE</th>
<th>Note that the type and specification of the control unit and the barcode scanner is subject to change without notice. The specifications listed below apply to the type and specification provided at the time of publishing of this Operator’s Manual.</th>
</tr>
</thead>
</table>

### Hardware

<table>
<thead>
<tr>
<th>Control unit</th>
<th>HP Compaq dc7800</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPU</td>
<td>Intel Pentium Dual Core E8400 Processor 3.0 GHz</td>
</tr>
<tr>
<td>Memory</td>
<td>4 GB</td>
</tr>
<tr>
<td>Hard disk</td>
<td>1x160 GB (RAID1, disks are mirrored)</td>
</tr>
<tr>
<td></td>
<td>1x250GB (used for data archiving)</td>
</tr>
<tr>
<td>Optical drive</td>
<td>16x CD-/RWD</td>
</tr>
<tr>
<td>Display</td>
<td>19” LC-Display with Sound</td>
</tr>
</tbody>
</table>

### Software

<table>
<thead>
<tr>
<th>Operating system</th>
<th>Microsoft Windows XP Professional, SP 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Database</td>
<td>Oracle Database Enterprise Edition</td>
</tr>
</tbody>
</table>

### Handheld barcode scanner

<table>
<thead>
<tr>
<th>Type</th>
<th>IT4600</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interface</td>
<td>The handheld barcode scanner is connected to the control unit through the keyboard interface.</td>
</tr>
<tr>
<td>Skew angle</td>
<td>±40 degrees</td>
</tr>
<tr>
<td>Pitch angle</td>
<td>±40 degrees</td>
</tr>
<tr>
<td>Motion tolerance</td>
<td>10 cm (4 in) per second</td>
</tr>
<tr>
<td>Scan contrast</td>
<td>45% minimum for Matrix codes</td>
</tr>
<tr>
<td></td>
<td>37,5% minimum for all others</td>
</tr>
<tr>
<td>Temperature</td>
<td>Operating: 0-50°C (32-122°F)</td>
</tr>
<tr>
<td></td>
<td>Storage: -40 to +70°C (-40 to +158°F)</td>
</tr>
<tr>
<td>Humidity</td>
<td>0-95% non-condensing</td>
</tr>
</tbody>
</table>
In this chapter the software basics are explained.

**In this chapter**

<table>
<thead>
<tr>
<th>Introduction</th>
<th>Basic software elements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Colors</td>
</tr>
<tr>
<td></td>
<td>Tabs</td>
</tr>
<tr>
<td></td>
<td>Buttons</td>
</tr>
<tr>
<td></td>
<td>Lists</td>
</tr>
<tr>
<td></td>
<td>Organizing lists</td>
</tr>
<tr>
<td></td>
<td>Sort by column</td>
</tr>
<tr>
<td></td>
<td>Column header context menu</td>
</tr>
<tr>
<td></td>
<td>Displaying and hiding columns</td>
</tr>
<tr>
<td></td>
<td>Filter drop-down menu</td>
</tr>
<tr>
<td></td>
<td>Custom AutoFilter</td>
</tr>
<tr>
<td></td>
<td>Managing filters and advanced filtering</td>
</tr>
<tr>
<td></td>
<td>Filter builder</td>
</tr>
<tr>
<td></td>
<td>Wizard</td>
</tr>
<tr>
<td></td>
<td>Database</td>
</tr>
<tr>
<td></td>
<td>Audit trail</td>
</tr>
</tbody>
</table>
The **cobas® 4800 software** is used to manage the whole **cobas® 4800 system workflow**. The screen of the **cobas® 4800 software** is divided into the following dedicated areas making the software easy to understand and intuitive to use:

- Status area
- Tab navigation bar
- Main work area
- Global action bar
- Alarm area

The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The screens do not necessarily show valid data.

---

**Figure A-41**  
**cobas® 4800 software screen**

A The **status area** displays the status of the **cobas x 480** instrument, the **cobas z 480** analyzer, the currently logged in user and date and time.

B The **tab navigation bar** displays the tabs. Click a tab to open it. In the first row of the navigation bar the tabs of the main work areas are displayed. In the second row the subtabs belonging to the currently selected work area are displayed.

C This is the **main work area**. It displays the content of the currently selected tab.

D The **global action bar** contains buttons used for general software functions. These buttons are always available.

E The **alarm area** displays the most recent alarms that are not yet confirmed by the operator. Select an alarm in the list and click the Alarm button on the left to get more details about the selected alarm.
Basic software elements

Colors

The **cobas® 4800** software uses the familiar *traffic light* color scheme.

<table>
<thead>
<tr>
<th>Color</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>Normal condition. The status is OK.</td>
</tr>
<tr>
<td>Yellow</td>
<td>Warning condition. Status is not OK, but immediate intervention is not required.</td>
</tr>
<tr>
<td>Red</td>
<td>Alarm condition. Immediate intervention is required. Operation may have stopped.</td>
</tr>
<tr>
<td>Blue</td>
<td>The item is selected or active.</td>
</tr>
</tbody>
</table>

Table A-8  Color concept

Tabs

Tabs are used to group information and software functions into units that can be displayed on one screen. The second row of tabs represent subgroups of the one selected in the first row.

Navigating within the **cobas® 4800** software needs only one or two clicks.

1. Click a main tab in the first tab row. Here you have access to the five main work areas **Overview**, **Workplace**, **Results**, **Messages**, and **Utilities**.
2. Click a subtab in the second row. Here you have access to all tabs of the selected work area.

The **Workplace** tab is displayed only if a run is active.

![Tabs Diagram](image-url)

**Figure A-42**  Main tabs and subtabs
Buttons

**Text buttons**  
Click a button to start the associated function. Some text buttons have a triangular marking in a corner. This triangle tells you what exactly happens on screen if you click the button.

<table>
<thead>
<tr>
<th>Button</th>
<th>Behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Search" /></td>
<td>Performs a specified action in the current window.</td>
</tr>
<tr>
<td><img src="image" alt="Abort" /></td>
<td>A triangle in the top right corner of a button tells you that a new dialog box will be displayed when you click the button.</td>
</tr>
<tr>
<td><img src="image" alt="Abort" /></td>
<td>A triangle in the bottom left corner of a button tells you that the current window or dialog box will be closed when you click the button.</td>
</tr>
</tbody>
</table>

**Table A-9**  
Triangular markings in text buttons

**Global action buttons**  
On the right of the cobas® 4800 software screen the global action buttons are available. They are always visible and perform the following functions:

<table>
<thead>
<tr>
<th>Button</th>
<th>Name</th>
<th>Use for...</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="New Run" /></td>
<td>New Run</td>
<td>Starting a new run. A wizard will guide you through the whole run.</td>
</tr>
<tr>
<td><img src="image" alt="Abort" /></td>
<td>Abort</td>
<td>Aborting a run. The Abort Run dialog box is displayed when several runs are active. Select the run you want to abort.</td>
</tr>
<tr>
<td><img src="image" alt="Exit" /></td>
<td>Exit</td>
<td>Exiting the cobas® 4800 software. Do not exit the cobas® 4800 software during a run. The run will be aborted.</td>
</tr>
<tr>
<td><img src="image" alt="Print" /></td>
<td>Print</td>
<td>Printing results, messages, and alarms. A preview window is displayed allowing to configure the report to be printed.</td>
</tr>
<tr>
<td><img src="image" alt="Log on, Log off" /></td>
<td>Log on, Log off</td>
<td>Logging on and off.</td>
</tr>
<tr>
<td><img src="image" alt="Info" /></td>
<td>Info</td>
<td>Accessing the Operator’s Manual and for displaying the installed SW versions.</td>
</tr>
</tbody>
</table>

**Table A-10**  
Global action buttons
To abort a run

1. Click the Abort button in the global action bar.
2. If more than one run is active, select the run you want to abort. A confirmation dialog box is displayed.
3. Confirm the message.
4. In the wizard, click Next to abort the run.

Lists

The cobas® 4800 software provides powerful sorting and filtering tools for information displayed in tables. These allow a lengthy list to be condensed in ways that provide fast access to items of interest. It is also possible to hide certain columns, display additional columns, and change their left-to-right order.

Organizing lists

The sorting and filtering tools are accessed by right- or left-clicking the respective column headings.

Sort by column

Click a column header to sort the table by the entries of this column. Successive clicks switch between ascending and descending sort order, the order is indicated by the arrow that appears in the header.
Column header context menu

Right-click any column header to display a context menu with further sorting and grouping options.

![Column header context menu diagram]

- A: Select the sort order, or clear any sorting
- B: Group listed items by the values of this column (click + or - next to individual groups to reveal or hide the items they contain)
- C: Display a box with a graphic representation of the grouped items. Create nested groups by dragging column headings to the display box above the list (click + or - to expand/collapse nested levels and show/hide items within a level)
- D: Display the Customization dialog box for adding information items to the table or for removing them
- E: Auto-adjust the selected column for optimum display width
- F: Clear the filter settings
- G: Display the Filter Builder dialog box for defining complex filter criteria
- H: Auto-adjust all columns for optimum display width

**Figure A-44** Column sort and group context menu

Displaying and hiding columns

Right-click any column header and select Column Chooser.

![Column Chooser dialog box]

**Figure A-45** Column Chooser dialog box

The Column Chooser dialog box contains all available information items that are not included in the table. Which items are available depends on the table from which you started the Column Chooser.

To add a column (information item) to the table, select the item in the Column Chooser and drag it to the appropriate place in the table header.

To remove a column from the table, select its header and drag it into the Column Chooser.
Filter drop-down menu

A filter symbol (funnel icon) is displayed in the column header of all columns that can be filtered. Right-click the filter symbol and a drop-down menu appears.

A Select the item that should serve as a filter criterion
B Select Custom to display the Custom AutoFilter dialog box for refining the filter criterion
C Click the filter symbol to display the filter context menu.

When a filter criterion is applied, its details are displayed in a bar at the bottom of the list (A).

To return to the full view at any time (no filtering), click the close button in the filter details bar. Previously used filter settings remain accessible from the filter history.

For additional details, see Managing filters and advanced filtering on page A-77
**Custom AutoFilter**

With the help of the **Custom AutoFilter** you can apply one or two filter conditions, logically linked by AND or OR.

Click the filter icon in a column heading and select (Custom) to display the **Custom AutoFilter** dialog box.

![Custom AutoFilter Dialog Box](image)

- **A** Primary filter condition
- **B** Secondary filter condition (optional)
- **C** Box for typing a value
- **D** Logical operator linking the two filter conditions

**Figure A-48**  Custom AutoFilter

**Managing filters and advanced filtering**

When a filter criterion is applied, its details are displayed in a bar at the bottom of the list. This bar allows convenient selection of previously selected filter conditions (filter history) as well as disabling and enabling the criteria respectively.

Clicking the **Edit Filter** button on the right of the bar displays the **Filter Builder** dialog box for advanced definition of filter criteria.

![Filter Control Bar](image)

- **A** Click to close the filter details bar and remove all filters
- **B** Click to switch current filter on and off
- **C** Current filter condition
- **D** Click to display previously used filters (filter history)
- **E** Filter history list: Click a filter entry to apply this previously used filter
- **F** Click **Edit Filter** to display the **Filter Builder** dialog box for advanced definition of filter criteria

**Figure A-49**  Filter control bar
Filter builder

The Filter Builder dialog box provides powerful editing and extension of the currently selected filter conditions.

A Click to display a list of all available logical operators  
B Click to add another filter  
C Click to display a list of all available information items  
D Click to display a list of all available operators  
E Click to display a box for typing values  
F Click to apply the definitions and close the dialog box.  
G Click to close the dialog box without applying the changes  
H Click to apply the changes without closing the dialog box

Figure A-50  Filter Builder dialog box
Wizard

Performing a cobas® 4800 system run requires the coordination of operator, instrument, and software interactions. A wizard guides the operator through all processing steps and helps keeping track of all necessary operator actions. The wizard is started by clicking the New Run button and ends with the display of the final PCR results. The run wizard is accessible through the Workplace tab. A new run can be started as soon as the sample preparation step is finished.

A run goes through a series of steps. The next step can only be accessed if the current step is successfully finished. A full CT/NG or HPV run includes the following steps:

![Figure A-51 Steps in a run](image)

**NOTICE**

There is no way to go back to a previous step in a run. Follow the guidelines outlined in this manual to avoid losing reagents, samples, or disposables.

![Figure A-52 Working with the wizard](image)

**A** Run name  
**B** Run information  
**C** Instructional area. Guides the operator through all steps and gives feedback to the operator.  
**D** Step timeline  
**E** Button area for starting instrument and analyzer actions and aborting the run.
Database

All data of the cobas® 4800 system are stored in an Oracle database. The database has a storage capacity of 100’000 results. A warning message is displayed when the database size exceeds 100’000 results. The purge and archive function is used to archive results and purge them from the database to free up space in the database for new results. Purge and archive should be done much earlier before the database limit is reached.

For additional details about purge and archive function, see Archiving on page B-74

NOTICE

No run can be started when the database has reached the maximal size. Use the purge and archive function to limit the database size.

The purge and archive function does only cover results. Messages are kept in the cobas® 4800 software until they are deleted manually. Therefore, it is recommended to manually delete confirmed messages from time to time to free up additional space in the database.

The actual size of the database is displayed in the System tab.
Audit trail

The cobas® 4800 software provides a secure, computer-generated, time-stamped audit trail to record user activities including:

- Operator log on and log off
- Result acceptance, purging, and archiving
- Configuration changes, including changes in user accounts

The audit trail can be accessed by Roche Service only.

The cobas® 4800 software audit trail is designed based on guidelines in CFR Title 21, Part 11 Electronic Records, Electronic Signatures.

This is the last page of Part A.
In this chapter the different workflows are described.

### In this chapter

- **Introduction** ................................................................. B–5
- **Full run with LIS** ...................................................... B–6
  - *cobas® 4800 system full run (with LIS) short guide* .......... B–7
- **Full run without LIS** .................................................. B–10
  - *cobas® 4800 system full run (without LIS) short guide* .... B–11
- **PCR Only run** ............................................................ B–15
  - *PCR Only run short guide* ........................................ B–16
Introduction

The following workflow types are available. All workflows can be used with all test types and batch sizes.

<table>
<thead>
<tr>
<th>Workflow</th>
<th>Description</th>
<th>Ordering</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full run with LIS</td>
<td>Sample preparation and amplification and detection</td>
<td>LIS</td>
</tr>
<tr>
<td>Full run without LIS</td>
<td>Sample preparation and amplification and detection</td>
<td>Work order file</td>
</tr>
<tr>
<td>PCR Only</td>
<td>Amplification and detection</td>
<td>Work order file</td>
</tr>
</tbody>
</table>

Table B-1 Workflow types
The workflow for a full run with LIS is shown below.

Figure B-1  cobas® 4800 system workflow for a full run with LIS

- Do not eat, drink, or smoke in laboratory work areas.
- Wear protective disposable gloves and laboratory coats whenever preparing consumables, reagents, samples, or when cleaning.
- Wear eye protection when handling samples. Wash hands thoroughly afterwards.
cobas® 4800 system full run (with LIS) short guide

The following short guide is summary of the workflow without any details.

For a complete and detailed description of the workflow, see Performing a full run on page B-22

<table>
<thead>
<tr>
<th>Step</th>
<th>User action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Start up cobas® 4800 system.</td>
</tr>
<tr>
<td>2</td>
<td>Perform cobas x 480 instrument maintenance.</td>
</tr>
<tr>
<td>3</td>
<td>Remove samples and reagents from storage.</td>
</tr>
<tr>
<td>4</td>
<td>Start new run.</td>
</tr>
<tr>
<td>5</td>
<td>Load samples.</td>
</tr>
</tbody>
</table>

Start up and log on to cobas® 4800 software
1. Switch on the monitor and control unit.
2. Log on to the cobas® 4800 software.

Perform cobas x 480 instrument maintenance.
1. Select Overview tab and check maintenance status of the cobas x 480 instrument.
   - If weekly maintenance is due, click Run Weekly Maintenance.
   - If daily maintenance is due, click Run Daily Maintenance.
   Follow the online guidance

Remove samples and reagents from storage.
For instructions on storage and handling of reagents, samples and controls, refer to assay-specific package inserts.

Start new run.
1. Click .
2. Select test type.
3. Type run name (optional).
4. Click OK.

Load samples.
1. Decap samples.
2. Place samples on corresponding carrier.
3. Insert sample carriers on autoload tray.
4. Click Load Samples.

Table B-2  cobas® 4800 system full run short guide (with LIS)
5 Workflow cobas® 4800 system

Full run with LIS

<table>
<thead>
<tr>
<th>Step</th>
<th>User action</th>
</tr>
</thead>
</table>
| 6    | **Load consumables.**  
1. Place listed consumables on appropriate carriers.  
2. Insert carriers on autoload tray.  
3. Click Load Consumables. |
| 7    | **Load reagents.**  
200 mL reagent reservoir carrier  
1. Load Wash Buffer on 200 mL reagent reservoir carrier as indicated in the wizard (scan-scan-pour).  
2. Insert carrier on autoload tray.  
3. Click Load Reagents.  
50 mL reagent reservoir carrier  
1. Load reagents on 50 mL reagent reservoir carrier as indicated in the wizard (scan-scan-pour).  
2. Insert carrier on autoload tray.  
3. Click Load Reagents.  
Reagent carrier  
1. Open reagent vials and load them on reagent carrier as indicated in the wizard.  
2. Insert carrier on autoload tray.  
3. Click Load Reagents. |
| 8    | **Start sample preparation run.**  
1. Click Start Run.  
The sample preparation starts.  
2. Check the timer in the wizard. |
| 9    | **Unload and seal microwell plate.**  
1. Click Sample Prep Results to review the results of the sample preparation.  
2. Click Unload.  
3. Seal the microwell plate as indicated on screen. |
| 10   | **Remove used reagents, samples, and deepwell plate**  
1. Remove used reagents, samples, and deepwell plate from the cobas x 480 instrument. |

Table B-2 cobas® 4800 system full run short guide (with LIS) (continued)

Roche Diagnostics

B-8 Operator’s Manual · Version 1.0
**Full run with LIS**

1. **Load microwell plate on cobas z 480 analyzer.**
   - Press load button on the cobas z 480 analyzer.
   - Place the sealed microwell plate into the extended loader.
   - Press load button again.
   - The amplification and detection run starts automatically.
   - Check the timer in the wizard.

2. **Review and accept results.**
   - Click Show Results.
   - Review and accept results in Results work area.
   - Select results and click \(\text{重要} \) to print the results report, if required.

3. **Export results to LIS.**
   - In the Results work area select the runs to be exported to the LIS.
   - Select a result and click Export.
   - All results of the selected runs are exported to the LIS.

4. **Unload the cobas z 480 analyzer.**
   - Unload the cobas z 480 analyzer.
Full run without LIS

The workflow for a full run without LIS is shown below.

1. Startup cobas® 4800 system
2. Perform cobas x 480 instrument maintenance
3. Remove samples and reagents from storage
4. Create work order file
5. Start new run
6. Load samples and work order file
7. Load consumables (deepwell plate, microwell plate, tip racks)
8. Load reagents
9. Start sample preparation run
10. Unload and seal microwell plate
11. Remove used reagents, samples, and deepwell plate
12. Load microwell plate on cobas z 480 analyzer
13. Review and accept results
14. Unload cobas z 480 analyzer

CAUTION

- Do not eat, drink, or smoke in laboratory work areas.
- Wear protective disposable gloves and laboratory coats whenever preparing consumables, reagents, samples, or when cleaning.
- Wear eye protection when handling samples. Wash hands thoroughly afterwards.
cobas® 4800 system full run (without LIS) short guide

The following short guide is summary of the workflow without any details.

For a complete and detailed description of the workflow, see Performing a full run on page B-22

<table>
<thead>
<tr>
<th>Step</th>
<th>User action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Start up cobas® 4800 system.</td>
</tr>
<tr>
<td></td>
<td>Switch on cobas® z 480 analyzer, heater/shaker unit, and cobas® x 480 instrument</td>
</tr>
<tr>
<td></td>
<td>2. Switch on the cobas® z 480 analyzer.</td>
</tr>
<tr>
<td></td>
<td>3. Switch on heater/shaker unit.</td>
</tr>
<tr>
<td></td>
<td>4. Switch on the cobas® x 480 instrument.</td>
</tr>
<tr>
<td></td>
<td>Start up and log on to cobas® 4800 software</td>
</tr>
<tr>
<td></td>
<td>1. Switch on the monitor and control unit.</td>
</tr>
<tr>
<td></td>
<td>2. Log on to the cobas® 4800 software.</td>
</tr>
<tr>
<td>2</td>
<td>Perform cobas® x 480 instrument maintenance.</td>
</tr>
<tr>
<td></td>
<td>1. Select Overview tab and check maintenance status of the cobas® x 480 instrument.</td>
</tr>
<tr>
<td></td>
<td>• If weekly maintenance is due, click Run Weekly Maintenance.</td>
</tr>
<tr>
<td></td>
<td>• If daily maintenance is due, click Run Daily Maintenance.</td>
</tr>
<tr>
<td></td>
<td>Follow the online guidance</td>
</tr>
<tr>
<td>3</td>
<td>Remove samples and reagents from storage.</td>
</tr>
<tr>
<td></td>
<td>For instructions on storage and handling of reagents, samples and controls, refer to assay-specific package inserts.</td>
</tr>
<tr>
<td>4</td>
<td>Create work order file.</td>
</tr>
<tr>
<td></td>
<td>Select run type and test type.</td>
</tr>
<tr>
<td></td>
<td>1. Open cobas® 4800 Work Order Editor.</td>
</tr>
<tr>
<td></td>
<td>2. Select run type and test type.</td>
</tr>
<tr>
<td></td>
<td>3. Click Add.</td>
</tr>
<tr>
<td></td>
<td>Add sample orders and save work order file.</td>
</tr>
<tr>
<td></td>
<td>1. Select subtest and media type.</td>
</tr>
<tr>
<td></td>
<td>2. Enter number of samples and click Add.</td>
</tr>
<tr>
<td></td>
<td>3. Change to Edit mode.</td>
</tr>
<tr>
<td></td>
<td>4. Click in Barcode field and scan all sample barcodes.</td>
</tr>
<tr>
<td></td>
<td>5. Add supplementary sample information or modify subtest or media type for selected samples, if required.</td>
</tr>
<tr>
<td></td>
<td>6. Click Save.</td>
</tr>
</tbody>
</table>

Table B-3  cobas® 4800 system full run short guide (without LIS)
### 5 Workflow

**Full run without LIS**

<table>
<thead>
<tr>
<th>Step</th>
<th>User action</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td><strong>Start new run.</strong></td>
</tr>
<tr>
<td></td>
<td>1. Click <img src="image1.png" alt="Image" />.</td>
</tr>
<tr>
<td></td>
<td>2. Select test type.</td>
</tr>
<tr>
<td></td>
<td>3. Type run name (optional).</td>
</tr>
<tr>
<td></td>
<td>4. Click OK.</td>
</tr>
</tbody>
</table>

| 6    | **Load samples and work order file.** |
|      | ![Image](image2.png) **Load samples** |
|      | 1. Decap samples. |
|      | 2. Place samples on corresponding carrier. |
|      | 3. Insert sample carriers on autoload tray. |
|      | 4. Click Load Samples. |
|      | ![Image](image3.png) **Load work order file** |
|      | 1. Click ![Image](image4.png). |
|      | 2. Select appropriate work order file. |
|      | 3. Click Next. |

| 7    | **Load consumables.** |
|      | ![Image](image5.png) | 1. Place listed consumables on appropriate carriers. |
|      | 2. Insert carriers on autoload tray. |
|      | 3. Click Load Consumables. |

**Table B-3**  
**cobas® 4800 system full run short guide (without LIS)**  (continued)
## 5 Workflow

### Full run without LIS

<table>
<thead>
<tr>
<th>Step</th>
<th>User action</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td><strong>Load reagents.</strong></td>
</tr>
<tr>
<td></td>
<td><img src="image1" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td><strong>200 mL reagent reservoir carrier</strong></td>
</tr>
<tr>
<td></td>
<td>1. Load Wash Buffer on 200 mL reagent reservoir carrier as indicated in the wizard (scan-scan-pour).</td>
</tr>
<tr>
<td></td>
<td>2. Insert carrier on autoload tray.</td>
</tr>
<tr>
<td></td>
<td>3. Click <strong>Load Reagents</strong>.</td>
</tr>
<tr>
<td></td>
<td><strong>50 mL reagent reservoir carrier</strong></td>
</tr>
<tr>
<td></td>
<td>1. Load reagents on 50 mL reagent reservoir carrier as indicated in the wizard. (scan-scan-pour).</td>
</tr>
<tr>
<td></td>
<td>2. Insert carrier on autoload tray.</td>
</tr>
<tr>
<td></td>
<td>3. Click <strong>Load Reagents</strong>.</td>
</tr>
<tr>
<td></td>
<td><strong>Reagent carrier</strong></td>
</tr>
<tr>
<td></td>
<td>1. Open reagent vials and load them on reagent carrier as indicated in the wizard.</td>
</tr>
<tr>
<td></td>
<td>2. Insert carrier on autoload tray.</td>
</tr>
<tr>
<td></td>
<td>3. Click <strong>Load Reagents</strong>.</td>
</tr>
<tr>
<td>9</td>
<td><strong>Start sample preparation run.</strong></td>
</tr>
<tr>
<td></td>
<td><img src="image2" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td>1. Click <strong>Start Run</strong>. The sample preparation starts.</td>
</tr>
<tr>
<td></td>
<td>2. Check the timer in the wizard.</td>
</tr>
<tr>
<td>10</td>
<td><strong>Unload and seal microwell plate.</strong></td>
</tr>
<tr>
<td></td>
<td><img src="image3" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td>1. Click <strong>Sample Prep Results</strong> to review the results of the sample preparation.</td>
</tr>
<tr>
<td></td>
<td>2. Click <strong>Unload</strong>.</td>
</tr>
<tr>
<td></td>
<td>3. Seal the microwell plate as indicated on screen.</td>
</tr>
<tr>
<td>11</td>
<td><strong>Remove used reagents, samples, and deepwell plate</strong></td>
</tr>
<tr>
<td></td>
<td><img src="image4" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td>1. Remove used reagents, samples, and deepwell plate from the cobas x 480 instrument.</td>
</tr>
</tbody>
</table>

---

**Table B-3**  cobas® 4800 system full run short guide (without LIS)  (continued)
## Full run without LIS

### Step 12: Load microwell plate on cobas z 480 analyzer.

1. Press load button on the cobas z 480 analyzer.
2. Place the sealed microwell plate into the extended loader.
3. Press load button again.
   - The amplification and detection run starts automatically.
4. Check the timer in the wizard.

### Step 13: Review and accept results.

1. Click Show Results.
2. Review and accept results in Results work area.
3. Select results and click **Print** to print the results report.

### Step 14: Unload the cobas z 480 analyzer.

1. Unload the cobas z 480 analyzer.

---

**Table B-3**

<table>
<thead>
<tr>
<th>Step</th>
<th>User action</th>
</tr>
</thead>
</table>
| 12   | 1. Press load button on the cobas z 480 analyzer.  
      | 2. Place the sealed microwell plate into the extended loader.  
      | 3. Press load button again.  
      |   - The amplification and detection run starts automatically.  
      | 4. Check the timer in the wizard. |
| 13   | 1. Click Show Results.  
      | 2. Review and accept results in Results work area.  
      | 3. Select results and click **Print** to print the results report. |
| 14   | 1. Unload the cobas z 480 analyzer. |
The workflow for a PCR Only run is shown below.

The PCR Only workflow is intended for repeat amplification from the remaining eluate in the deepwell plate (extraction plate). For the PCR Only workflow, the microwell plate (AD plate) is manually prepared with working master mix and eluate from the deepwell plate. The PCR Only run is only validated to work with extract from a cobas x 480 instrument.

**Figure B-3** cobas® 4800 system workflow for a PCR Only run

- Do not eat, drink, or smoke in laboratory work areas.
- Wear protective disposable gloves and laboratory coats whenever preparing consumables, reagents, samples, or when cleaning.
- Wear eye protection when handling samples. Wash hands thoroughly afterwards.
The following short guide is summary of the workflow without any details.

⚠️ For a complete and detailed description of the workflow, see Performing a PCR Only run on page B-46

PCR Only runs are not supported by the LIS. Use the cobas® 4800 Work Order Editor to create the orders for a PCR Only run.

**Step** | **User action**
--- | ---
1 | Create work order file.

Retrieving information from result export file.

1. In the Results work area select the run that needs to be repeated.
2. In the Test Results area select a result.
3. Click Export and save the file.
4. From the result export file retrieve the information for test type, specimen barcode, media type, subtest type, and plate position.

Create work order file - step 1.

1. Open cobas® 4800 Work Order Editor.
2. Select PCR workflow only run type.
3. Select test type.
4. Scan microwell plate barcode.
5. Click ✅.

Create work order file - step 2.

1. Change to Edit mode.
2. Enter control barcodes (for details, see Define control barcodes for a PCR Only run on page B-48).
3. Change to Create mode.
4. For each sample select subtest type, media type, and plate position, enter sample barcode and press Enter. Use the data from the result export file.
5. Click Save.

2 | Setup microwell plate.

1. Perform manual PCR setup as described in the assay-specific package insert.
2. Seal the microwell plate.
3. Centrifuge the microwell plate in a swing bucket centrifuge for at least 5 seconds at 3000 rpm.

3 | Start new run.

1. Click ◼️.
2. Select test type (PCR Only workflow).
3. Type run name (optional).
4. Click OK.

Table B-4 cobas® 4800 system PCR Only run short guide
<table>
<thead>
<tr>
<th>Step</th>
<th>User action</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>** Load microwell plate on **&lt;br&gt;<strong>cobas z 480 analyzer.</strong>&lt;br&gt;1. Press load button on the <strong>cobas z 480 analyzer.</strong>&lt;br&gt;2. Place the sealed microwell plate into the extended loader.&lt;br&gt;3. Press load button again.</td>
</tr>
<tr>
<td>5</td>
<td><strong>Load work order file</strong>&lt;br&gt;1. Click <img src="image" alt="Open" />.&lt;br&gt;2. Navigate to the appropriate directory, select the work order file and click <strong>Open</strong>.&lt;br&gt;3. Click <strong>Next</strong>.&lt;br&gt;The amplification and detection run starts automatically.</td>
</tr>
<tr>
<td>6</td>
<td><strong>Review and accept results.</strong>&lt;br&gt;1. Click <strong>Show Results</strong>.&lt;br&gt;2. Review and accept results in <strong>Results</strong> work area.&lt;br&gt;3. Select results and click <img src="image" alt="Print" /> to print the results report.</td>
</tr>
<tr>
<td>7</td>
<td>**Unload the **&lt;br&gt;<strong>cobas z 480 analyzer.</strong>&lt;br&gt;1. Unload the <strong>cobas z 480 analyzer.</strong></td>
</tr>
</tbody>
</table>

**Table B-4** *cobas® 4800 system PCR Only run short guide (continued)*
Operation

In this chapter the operation of the cobas® 4800 system is described.

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# 6 Operation

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Safety information

Make sure that you have read and understood the chapter General safety information. The following safety messages in particular are relevant:

Warning messages:
- Loss of sight due to staring into laser beam on page A-8
- Infection by samples and associated materials on page A-9
- Infection and injury due to sharp objects on page A-9
- Infection by biohazardous waste on page A-10
- Contamination of the environment by liquid waste and solid waste on page A-10

Caution messages:
- Personal injury due to contact with moving parts on page A-11
- Skin inflammation or injury caused by reagents on page A-12
- Personal injury due to hot surface on page A-13

Safety precautions:
- Operator qualification on page A-6

Observe the system safety labels illustrated and described starting on page A-16.
Performing a full run

The following procedures guide you through all required steps to perform a full run with sample preparation on the cobas® x 480 instrument and amplification and detection on the cobas® z 480 analyzer. The procedures cover both working modes: with and without LIS. Steps that only apply to one working mode are indicated accordingly.

Perform startup procedures

To start up the cobas® 4800 system, you need to perform the following steps:

1. Switch on the cobas® z 480 analyzer.
2. Switch on the heater/shaker unit.
3. Switch on the cobas® x 480 instrument.
4. Start up the cobas® 4800 software.

**NOTICE**
To prevent hardware damage, follow the steps in the exact order outlined when starting up the cobas® 4800 system.

**To switch on the cobas® z 480 analyzer**

1. Switch on the cobas® z 480 analyzer. The main switch is located at the back of the analyzer.

   The cobas® z 480 analyzer is powered on and initializes.

![Switching on the cobas® z 480 analyzer](image)
To switch on the heater/shaker unit

1. Switch on the heater/shaker unit. The switch is located at the front of the heater/shaker controller box.

![Main switch of heater/shaker controller box](image1)

**A** Main switch of heater/shaker controller box

---

To switch on the cobas x 480 instrument

1. Switch on the cobas x 480 instrument. The main switch is located at the front of the instrument.

The cobas x 480 instrument is powered on and initializes.

![Main switch of the cobas x 480 instrument](image2)

**A** Main switch of the cobas x 480 instrument

---
Performing a full run

To start up and log on to the cobas® 4800 software

1 Power on the monitor and control unit.
   First the Windows XP operating system and then the cobas® 4800 software starts automatically.
   The cobas® 4800 software displays the System tab.
2 Click to log on and enter your assigned user ID and password.
3 Click OK.

- The user ID is not case sensitive.
- The password is case sensitive. The password displays as asterisks when typed to maintain security.

Perform maintenance

Periodic maintenance needs to be performed in order to ensure safe and reliable operation of the cobas x 480 instrument.

NOTICE
- Performing daily and weekly maintenance is mandatory. A sample preparation run can only be started when maintenance is done.
- If any parts of the cobas x 480 instrument or carriers have become contaminated, the weekly maintenance procedure must be performed.
- Counters are reset to twenty-four hours when daily maintenance is performed. If weekly maintenance is being performed, daily maintenance is not required on that day.

To perform daily or weekly maintenance on the cobas x 480 instrument

1 Click the cobas x 480 tab to check the maintenance status.
2 Do one of the following:
Performing a full run

- If the weekly maintenance is due, click Run Weekly Maintenance and follow the online instructions.
  - For additional details about weekly maintenance, see Weekly maintenance on page C-12
- If the daily maintenance is due, click Run Daily Maintenance and follow the online guidance.
  - For additional details about daily maintenance, see Daily maintenance on page C-7

Create a work order file

The cobas® 4800 Work Order Editor and work order files are only used when the cobas® 4800 system is not connected to an LIS or if the LIS is not working.

Orders for the cobas® 4800 system are loaded from a work order file. Work order files are created in the cobas® 4800 Work Order Editor. Creating orders in the cobas® 4800 Work Order Editor can be done at any time independently of the cobas® 4800 software.

- For details about creating a work order file for a full run, see Defining work order files for full runs on page B-57

Remove the samples and reagents from storage

Which reagents are required depends upon the test type (HPV or CT/NG) and the run size (24 or 96 runs).

- For instructions on storage and handling of reagents, samples and controls, refer to assay-specific package inserts.
**Start a new run**

A wizard guides you through the entire run, from sample preparation on the cobas x 480 instrument to amplification and detection on the cobas z 480 analyzer.

**NOTICE**

- Do not disconnect the network cable during a run. The run will be aborted immediately.
- There is no way to go back to a previous step in a run. Follow the guidelines outlined in this manual to avoid losing reagents, samples, or disposables.
- If the cobas x 480 instrument is installed on a bench top, a small waste bag is used. This waste bag has a capacity for tips of at most one full run. Exchange the small waste bag each time before starting a new run to avoid overfilling of the tip waste.
- For details about replacing the small waste bag, see Daily maintenance on page C-7 and Weekly maintenance on page C-12

**To start a new run**

1. Click 🔄.

   The New Run dialog box is displayed.

   ![New Run dialog box](image)

   A Select a run type

   **Figure B-7 New Run dialog box**

2. Select a test type from the list.

   The following test types for full runs are available:

   - CT/NG workflow
   - HPV workflow

3. Enter a name for the run in the Run name (optional) field.

   The system generates a generic run name if you leave the field empty. The generic run name is composed of date and time when the run was started (e.g. "28-May-2009 11:57 AM").

4. Click OK.

   The Workplace is displayed showing the wizard for the new run. The cobas x 480 instrument initializes. This can take some time.
Load samples and work order file

- Samples can be loaded in barcoded primary or secondary tubes. Up to 22 or 94 patient specimen can be loaded for a single run. Two positions on the plates are reserved for controls. Controls are not loaded together with samples. They are loaded onto the reagent carrier during reagent loading.
  - For a list of sample types, refer to the assay-specific package inserts.
  - For more details about samples and sample carriers, see Sample carriers on page A-46
- After sample loading you are requested to load the corresponding work order file, if no LIS is used. Be sure that the work order file matches with the loaded sample.
  - For more details about creating work order files, see cobas® 4800 Work Order Editor on page B-55

- The cobas® 4800 Work Order Editor and work order files are only used when the cobas® 4800 system is not connected to an LIS or if the LIS is not working.
- If an LIS is used, order information is loaded automatically from the LIS after samples are loaded onto the cobas x 480 instrument.
- If a work order file and the loaded samples do not match, both the work order file and the samples must be reloaded. It is not possible to choose another work order file and leave the samples loaded.
- Samples can be loaded in any order as long as they match the set of samples listed in the work order file.
- Whenever the operator decides to unload the samples to correct any errors (e.g. barcode reading or work order mismatch), all sample carriers are unloaded, not only those with errors.
- Be careful not to load samples onto the 24-position carrier used for loading reagent as they will not be processed. Reagent carriers with samples cannot be unloaded unless the run is aborted.
- To maximize processing throughput with mixed media types, the total number of patient samples plus controls should be an even multiple of eight (e.g. 80, 88, 96).
- Do not overfill sample tubes to avoid spillage and contamination during loading.
- Sample barcodes can be 3 to 20 characters long.
To load samples

Preparing samples

1. Decap the sample tubes or primary sample containers and place the samples on the appropriate carrier. The sample barcodes must face to the right of the carrier.

   For details about sample placement, see Sample carriers on page A-46

2. Insert all sample carriers into their designated track positions on the autoload tray. The correct loading position is indicated by blinking LEDs on the LED bar above the autoload tray.

   For details about carrier loading, see Sample carriers on page A-46

A Sample carrier  B Tracks 17 through 34 are reserved for sample carriers  C Sample barcodes facing to the right

Figure B-8 Loading samples
Loading samples 3 Click **Load Samples** when you have placed all sample carriers on the indicated track positions on the autoload tray.

Check that all sample carriers are placed correctly before loading the samples.

![Figure B-9](image.png)

**Figure B-9** Wizard > Load Samples

The sample carriers are loaded automatically onto the cobas x 480 instrument. During loading, the barcode scanner scans the carrier barcode and the sample barcodes.

If the cobas x 480 instrument is connected to an LIS the orders are downloaded automatically from the LIS after the samples are loaded.

4 Follow the online instructions in case a sample barcode can not be read.

⚠️ For details about barcode error handling, see *Barcode reading errors* on page D-10
Performing a full run

Importing the work order file

After successful loading, the wizard asks for the corresponding work order file, if no LIS is connected.

This step can be skipped if working with an LIS.

To load work order file

1. Click `Open`. An Open dialog box is displayed.

2. Navigate to the appropriate directory, select the work order file and click `Open`. A summary of the work order file is displayed.

3. Click Next. The work order file information is cross-checked against the loaded samples. Run and test types, number of samples, sample types, and barcode IDs must match.

4. Follow the online instructions in case the work order file and the loaded samples do not match.

Figure B-10 Loading work order file

A Summary of selected work order file
Load the consumables

One deepwell plate, one microwell plate and two full tip rack carriers are used for each run.

All consumables are barcoded and designed to be used only once. The cobas® 4800 software tracks the use of the consumables and rejects already used consumables.

- There is no tracking of tip usage from run to run. In addition, the total number of tips per run varies and depends on several criteria (assay type, sample media, run size, and so on). Therefore, to avoid running out of tips during processing, fully load both tip rack carriers for each run.
- Whenever the operator decides to unload a consumable carrier to correct any errors (e.g. barcode reading), all consumable carriers are unloaded, not only those with errors.

To load the consumables

1. Place the listed consumables on the appropriate carrier. The barcodes must face to the right of the carrier.
   
   ☀️ For details about carrier loading, see Plate carrier on page A-51 and Tip rack carriers on page A-52

2. Insert all consumable carriers into their designated track positions on the autoload tray. The correct loading position is indicated by blinking LEDs on the LED bar above the autoload tray.

   Use the following tracks:
   - Plate carrier: tracks 1 through 6
   - Left tip carrier: tracks 11 through 16
   - Right tip carrier: tracks 35 through 40

3. Click Load Consumables when you have placed all consumables carriers on the indicated track positions on the autoload tray.

   Check that all consumable carriers are placed correctly before loading the consumables.
Performing a full run

The consumable carriers are loaded automatically onto the cobas x 480 instrument. During and after loading, the barcode scanner scans the carrier barcodes and the consumable barcodes.

4 Follow the online instructions in case a consumables barcode can not be read or a consumable is recognized as already used.

For details about barcode handling and inventory errors, see Barcode reading errors on page D-10

After successful loading of consumables the wizard asks for loading the reagents.
Load the reagents

The reagent reservoirs are barcoded and need to be filled manually by the operator (scan-scan-pour principle) for each run.

Scan-scan-pour principle

To minimize handling errors the reagent reservoirs are filled and placed using the scan-scan-pour principle:

1. Scan the barcode of the required reagent using the handheld barcode scanner.
2. Scan the barcode of an unused reagent reservoir using the handheld barcode scanner.
3. Pour the reagent in the scanned reagent reservoir.
4. Place the filled reagent reservoir onto the required position of the reagent reservoir carrier as indicated in the wizard.

The reagent reservoirs are available in the two sizes: 200 mL and 50 mL. The reagent reservoir barcodes must face to the right of the carrier.

The reagent carrier holds the assay specific reagents for sample processing and PCR setup (controls, master mix, metal co-factor(s), and so on). The required reagents and controls are manually decapped and then placed onto their dedicated positions on the reagent carrier. The reagent barcodes must face to the right of the carrier.

For instructions on handling and storage of reagents and controls, refer to assay-specific package inserts.

- All reagents and reagent reservoirs are barcoded and designed to be used only once. The cobas® 4800 software tracks the use of the reagents and reagent reservoirs and rejects partially used reagents or previously used reagent reservoirs.
- An acoustic signal is issued and an error message is displayed in the alarm area when the cobas® 4800 system does not accept a scanned reagent barcode.
- To minimize the risk of contamination, it is highly recommended to change gloves between handling patient samples and loading reagents onto cobas x 480 instrument.
- Make sure that the kit size corresponds to the intended run size. Although not an optimal use of reagents, a 96-kit can be used in a 24-run.
- For the most efficient reagent utilization it is advisable to maximize the number of patient specimens processed within a run. Remaining reagents can not be used later on in another run.
- The reagent inventory marks a reagent as used as soon as it is assigned to a reservoir. From this time point on the reagent is dedicated to this run and cannot be used later on another run even if the reagent is not used due to aborting the run.
- Each reagent has a specific location assigned to it on the carriers. Even though each reagent is uniquely identified by barcodes, it must be placed at the correct location, otherwise an error message will be generated and loading will not proceed. Therefore, always place the reagent reservoirs and the reagent vials in the indicated positions on the carriers.
- There is a limited time window between scanning the reagents and initiating the cobas x 480 instrument run. This window is called reagent on-board time and is assay specific. Refer to assay-specific package insert for exact values. The timer starts when the wash buffer reagent vial is scanned. The cobas® 4800 system checks if the reagent on-board time is elapsed when the run is started.
- All controls are homogeneous and do not require vortexing or shaking prior to loading on the cobas x 480 instrument.
For instructions on storage and handling of reagents and controls, refer to the assay-specific package inserts.

The following tables show the reagent positions on the different carriers.

### Reagent loading for CT/NG

<table>
<thead>
<tr>
<th>Carrier type</th>
<th>Position</th>
<th>Reagents</th>
</tr>
</thead>
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<tr>
<td>200 mL reagent reservoir carrier</td>
<td>1 through 3</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Wash Buffer</td>
</tr>
<tr>
<td>50 mL reagent reservoir carrier</td>
<td>1 through 3</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>MGP</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Elution Buffer</td>
</tr>
<tr>
<td>Reagent carrier</td>
<td>1 through 16</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>Internal control</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>Positive control</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Negative control</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>Control Diluent</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>Master Mix (for 96-sample runs only)</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>Master Mix</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>Metal Ion Reagent</td>
</tr>
</tbody>
</table>

### Table B-5  Placement of CT/NG reagents

### Reagent loading for HPV

<table>
<thead>
<tr>
<th>Carrier type</th>
<th>Position</th>
<th>Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mL reagent reservoir carrier</td>
<td>1 through 3</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Wash Buffer</td>
</tr>
<tr>
<td>50 mL reagent reservoir carrier</td>
<td>1</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>SDS</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Lysis Buffer</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>MGP</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Elution Buffer</td>
</tr>
<tr>
<td>Reagent carrier</td>
<td>1 through 13</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>Proteinase K (for 96-sample runs only)</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>Proteinase K</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>Positive control</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Negative control</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>Not used</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>Master Mix (for 96-sample runs only)</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>Master Mix</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>Metal Ion Reagent</td>
</tr>
</tbody>
</table>

### Table B-6  Placement of HPV reagents
To load the reagents

200 mL reagent reservoir carrier

1. Scan the barcode of the wash buffer using the handheld barcode scanner.
   The reagent in the list is highlighted in dark green.

   Scanning the barcode of the wash buffer vial starts the internal reagent on-board timer in the cobas® 4800 software. The cobas x 480 instrument run must be started within a pre-defined time window. Refer to the assay-specific package insert for exact time.

2. Scan the barcode of an unused 200 mL reagent reservoir using the handheld barcode scanner.
   The reagent in the list is checked and highlighted in light green.

3. Pour the entire reagent vial in the scanned reagent reservoir.

   - It is advisable to pour the reagent into the reservoir in a lengthwise movement to minimize the risk of splashing and resulting reagent loss.
   - Do not pour reagents into reservoirs that are already placed onto a reagent rack. Always follow the scan-scan-pour principle.
   - Do not fill reagent reservoirs above the maximal fill height. A sign within the reagent reservoir indicates the maximal fill height.
   - Handle filled reservoirs with particular care to avoid splashes and tipping over.

4. Place the filled reagent reservoir onto position 4 of the 200 mL reagent reservoir carrier as indicated.

5. Insert the 200 mL reagent reservoir carrier into its designated track positions on the autoload tray. The correct loading position is indicated by blinking LEDs on the LED bar above the autoload tray.

   Use the following tracks:
   - 200 mL reagent reservoir carrier: tracks 48 through 49

6. Click Load Reagents when you have placed the 200 mL reagent reservoir carrier on the indicated track positions on the autoload tray.

   Check that the 200 mL reagent reservoir carrier is placed correctly before loading it.

   A. Click Load Reagents when carrier is ready for loading.
Performing a full run

The 200 mL reagent reservoir carrier is loaded automatically onto the cobas® 480 instrument. During loading, the barcode scanner scans the carrier barcode and the reagent reservoir barcode.

7 Follow the online instructions in case a barcode can not be read or a reagent is recognized as already used.

⚠️ For details about barcode handling and inventory errors, see Barcode reading errors on page D-10

After successful loading, the wizard asks for loading the reagents for the 50 mL reagent reservoirs.

50 mL reagent reservoir carrier

8 Scan the barcode of one of the reagents in the list using the handheld barcode scanner.

The reagent in the list is highlighted in dark green.

9 Scan the barcode of an unused 50 mL reagent reservoir using the handheld barcode scanner.

The reagent in the list is checked and highlighted in light green.

10 Pour the entire reagent vial in the scanned reagent reservoir.

💡

- It is advisable to pour the reagent into the reservoir in a lengthwise movement to minimize the risk of splashing and resulting reagent loss.
- Do not pour reagents into reservoirs that are already placed onto a reagent rack. Always follow the scan-scan-pour principle.
- Do not fill reagent reservoirs above the maximal fill height. A sign within the reagent reservoir indicates the maximal fill height.
- Handle filled reservoirs with particular care to avoid splashes and tipping over.

11 Place the filled reagent reservoir into the indicated position of the 50 mL reagent reservoir carrier.

12 Repeat step 8 to 11 for all reagents in the list.

13 Insert the 50 mL reagent reservoir carrier into its designated track position on the autoload tray. The correct loading position is indicated by a blinking LED on the LED bar above the autoload tray.

Use the following track:

- 50 mL reagent reservoir carrier: track 50

14 Click Load Reagents when you have placed the 50 mL reagent reservoir carrier on the indicated track position on the autoload tray.

Check that the 50 mL reagent reservoir carrier is placed correctly before loading it.
Performing a full run

The 50 mL reagent reservoir carrier is loaded automatically onto the cobas® 4800 instrument. During loading, the barcode scanner scans the carrier barcode and the reagent reservoir barcodes.

15 Follow the online instructions in case a barcode can not be read or a reagent is recognized as already used.

For details about barcode handling and inventory errors, see Barcode reading errors on page D-10.

After successful loading the wizard asks for loading the reagents for the reagent carrier.

16 Open the listed reagent vials and place them onto the indicated positions on the reagent carrier.

The reagent barcode must face to the right of the carrier.

Open the reagent vials before placing them onto the reagent carrier to minimize the risk of contamination.

17 Insert the reagent carrier into its designated track position on the autoload tray. The correct loading position is indicated by a blinking LED on the LED bar above the autoload tray.

Use the following track:

- reagent carrier: track 51

18 Click Load Reagents when you have placed the reagent carrier on the indicated track position on the autoload tray.

Check that the reagent carrier is placed correctly before loading it.
Performing a full run

The reagent carrier is loaded automatically onto the cobas® 480 instrument. During loading, the barcode scanner scans the carrier barcode and the reagent vial barcodes.

Follow the online instructions in case a barcode can not be read or a reagent is recognized as already used.

For details about barcode handling and inventory errors, see Barcode reading errors on page D-10

After successful loading the wizard shows the instrument deck. Loaded samples, reagents and disposables are highlighted in green. The cobas® 480 instrument is now ready to be started.
Start the sample preparation run

The loading is now complete and the cobas x 480 instrument is ready to be started. The loaded instrument deck is shown with all loaded samples, reagents, and consumables highlighted in green.

The loaded reagents have limited on-board stability. Sample preparation should be started as soon as practical. This is especially important when maximum system throughput is desired. The on-board reagent expiration time is indicated on screen.

Never attempt to start and/or operate the cobas x 480 instrument with the front cover open. Keep hands away from all moving parts while the cobas x 480 instrument is in use.

To start the sample preparation run

1. Click Start Run.
   The sample preparation is started. After starting the run, the estimated completion time is indicated on the screen.

2. Check the timer in the wizard.
   After a successful run the Sample Prep Results and the Unload buttons become available.

   • The indicated completion time is only an estimate.
   • After sample preparation is completed, there is a limited time before the amplification and detection process must be started. An expiration timer is displayed in the Workplace tab. Refer to the appropriate assay-specific package insert for specific time between completion of the sample preparation and the start of the amplification and detection run.

![Figure B-14](image.png)

**Figure B-14** Ready to start the run

- **A** Estimated completion time
- **B** On-board reagent expiration time
- **C** Start Run
6 Operation

Performing a full run

Unpack and seal the microwell plate

After completion of the sample preparation the microwell plate is transported back to the plate carrier by the iSWAP. After unloading the microwell plate must be sealed and then manually transferred to the cobas z 480 analyzer for amplification and detection. The results of the prepared samples can be reviewed in the Sample Prep Results dialog box.

The prepared samples with working master mix have a limited stability. Amplification and detection should be started as soon as practical. The expiration time is indicated on screen.

To review the sample preparation results

1. Click Sample Prep Results to review the results of the sample preparation.

   The Sample Prep Results dialog box is displayed.

   Sample preparation results are intermediate results. They cannot be saved or transmitted to the LIS.

   - For flagged sample preparation results, see Chapter 10 Result flags

2. Click Close to close the Sample Prep Results dialog box.

3. Click Unload to unload the plate carrier.

   - Allow the cobas x 480 instrument to unload all the carriers. Do not pull them out manually. This would interrupt the unload process and crash the cobas x 480 instrument.
   - If the cobas x 480 instrument encounters a problem during unloading an error message is displayed. Confirm the error message.
   - In both cases the cobas x 480 instrument must be unloaded manually. After unloading seal the microwell plate and start the amplification and detection run on the cobas z 480 analyzer. The results will be flagged (X9 flag).
Sealing the microwell plate

On the plate carrier seal the microwell plate properly with a sealing film. Sealing the microwell plate is crucial to eliminate evaporation at high temperatures.

Incorrect results due to evaporation of samples or sample contamination

- Follow the outlined procedure to seal the microwell plate to prevent leakage of the sealing film or contamination of samples. Plate leakage can contaminate the cobas z 480 analyzer. If contamination is suspected, contact Roche Service.
- Examine the microwell plate after amplification and detection. An indication of a leak is if the sealing film is bent into the wells of the plate.

To seal the microwell plate

1. Remove the protection layer from the sealing film.

   Do not touch the foil on the clean side and handle the foil only at the sides.

2. Cover the microwell plate with the clean side of the sealing film.

3. Firmly press the sealing film to the plate surface using the sealing film applicator.

   To ensure a strong seal, use the provided sealing film applicator.

4. Remove both ends of the sealing film alongside the perforation.

   Do not lift the sealing film from the plate while tearing off the ends of the foil.

5. In the cobas® 4800 software, click Next.

   The screen for loading the microwell plate onto the cobas z 480 analyzer is displayed.
Performing a full run

Remove used reagents, samples, and deepwell plate

To optimize throughput used reagents, samples and the deepwell plate can be removed and the cobas x 480 instrument can be prepared for the next run as soon as the amplification and detection run on the cobas z 480 analyzer has been started.

Run scheduling

The cobas® 4800 software manages the scheduling of the runs. The second run on the cobas x 480 instrument can only be started a certain amount of time after the cobas z 480 analyzer run has started to avoid any working master mix time out. Trying to start too early will create an error message.

Start amplification and detection run

The sealed microwell plate has to be manually transferred to the cobas z 480 analyzer for amplification and detection.

The amplification and detection will start immediately after loading.

- The prepared samples with working master mix have a limited stability. Therefore, be sure not to wait too long before starting the amplification and detection run. Refer to the appropriate assay-specific package insert for specific time between completion of the sample preparation and the start of the amplification and detection run. The expiration time is indicated on the screen.
- After starting amplification and detection on the cobas z 480 analyzer the cobas x 480 instrument is ready for the next preparation run.
- Before starting a run, check the Overview tab if the Xenon lamp needs replacement. Replace the Xenon lamp, if required.

For details about Xenon lamp replacement, see Exchanging the Xenon lamp on page C-18

To load the prepared microwell plate into the cobas z 480 analyzer

1. Press the load button on the cobas z 480 analyzer.

   ![Figure B-15 Loading prepared microwell plate](image)

   A Load button  B Extended plate loader

   The microwell plate loader opens.

2. Place the sealed microwell plate into the loading frame of the loader.
3 Press the load button again to close the loader.
   The loader is retracted. The run starts immediately.

**NOTICE**

Do not turn off the cobas® 480 analyzer power during a run.

4 Check the timer in the wizard.
   When the run is finished, in the cobas® 4800 software, the **Show Results** button becomes available.

---

**Review and accept results**

Test results are displayed in the **Results** work area as soon as the cobas z 480 analyzer has finished amplification and detection.

1 In the **Workplace** work area, click the **Show Results** button.

The **Results** work area is displayed.

2 Review and accept results in the **Results** work area.
   - For details, see *Accepting and printing results* on page B-63

3 Select results and click ▶️ to print the results report.
   - For details, see *Accepting and printing results* on page B-63

---

A Fluorescence growth curves of the positive (+) and negative (-) controls of all channels

B **Show Results** button
Export results to LIS

After review test results have to be exported to the LIS.

- This step can be skipped if working without LIS.
- Using result export, all results of the selected runs are exported to the LIS. It is not possible to export individual results.

To export results to the LIS

1. Click the Results tab to display the Results work area.
2. Using the dropdown list in the Runs area, select whether you want to display all runs or only HPV or CT/NG runs.
3. Select one or more runs.
   - Use the Ctrl key to select several nonadjacent runs.
   - Use the Shift key to select a range of adjacent runs.

   If necessary, use first the standard filtering and sorting methods to filter and sort the displayed runs.
   - For additional details, see Lists on page A-74
4. In the Test Results area, select a result.
5. Click the Export button.

All results of the selected runs are exported to the LIS.

- No confirmation is displayed after successful result export to the LIS.
- An error message is displayed if the result export to the LIS failed.
- Exported results are kept in the Results work area. They are not deleted from the results database.
Unload the cobas z 480 analyzer

Unload the microwell plate as soon as practical after the run has finished to prevent plate leakage and contamination of the cobas z 480 analyzer.

To unload the cobas z 480 analyzer

1. When the run has finished, open the plate loader to remove the microwell plate.
2. Examine the microwell plate after amplification and detection.
3. Discard the plate according to the appropriate local regulations.

CAUTION

Incorrect results due to evaporation of samples or sample contamination

Plate leakage can lead to incorrect results or can contaminate the cobas z 480 analyzer. If contamination is suspected, contact Roche Service.

- Unload the microwell plate as soon as practical after the run has finished and check the microwell plate for indications of leakage.

- Discard the plate according to the appropriate local regulations.
Performing a PCR Only run

The following procedures guide you through all required steps to perform a PCR Only run with amplification and detection on the cobas z 480 analyzer.

The PCR Only workflow is intended for repeat amplification from the remaining eluate in the deepwell plate (extraction plate). For the PCR Only workflow, the microwell plate (AD plate) is manually prepared with working master mix and eluate from the deepwell plate. Only specimens successfully processed on the cobas x 480 instrument can be amplified/detected using the PCR Only run.

⚠️ PCR Only runs are not supported by the LIS. Use the cobas® 4800 Work Order Editor to create the orders for a PCR Only run.

Create a work order file for a PCR Only run

Orders for the cobas® 4800 system are loaded from a work order file. The work order file is created in the cobas® 4800 Work Order Editor. The information necessary to create a PCR Only work order can be derived from the results of the run that needs to be recovered. This information can be accessed either by exporting or printing the run results. To print the results, click the Print button.

⚠️ There is no system surveillance for sample tracking between the deepwell plate (extraction plate) and the microwell plate (AD plate). Ensure that the eluate is transferred correctly from the deepwell plate to the microwell plate and that the work order file correctly reflects the plate layout.

Exporting run results

To export results of a run

1. In the Results work area, select the run that needs to be repeated.
2. In the Test Results area, select a result of that run.
3. Click the Export button.
   A Windows dialog box for saving files is displayed.
4. Select the directory where you want to save the file to.
5. Enter a telling name for the result file.
6. Click Save.
Performing a PCR Only run

Creating a work order file for a PCR Only run

Open the result export file (using a text or XML editor) or refer to the result printout and retrieve the information for test type, sample barcode, media type, subtest type, and plate position.

To create a work order file for a PCR Only run

1. Start the cobas® 4800 Work Order Editor.
2. Select the PCR workflow only run type.
3. Select the test type.
4. Scan or enter the microwell plate barcode (PlateID).
   Ensure that the correct microwell plate ID is entered.
5. Click Next.
   The next window of the cobas® 4800 Work Order Editor is displayed.
6. Change to Edit mode.
7. Enter control barcodes for position A1 and B1 (for details, see Define control barcodes for a PCR Only run on page B-48).
   Positions A1 and B1 on the microwell plate are reserved for the positive and negative controls respectively in any work order file. These positions cannot be changed or re-assigned.
8. Change to Create mode.
9. For each sample order select subtest type, media type, and plate position. Then enter sample barcode and press Enter. Use the data from the result export file or printout.
10. Click Save.
   A Windows dialog box for saving files is displayed.
11. Select the directory where you want to save the file to.
12. Enter a telling name for the result file.
13. Click Save.
Define control barcodes for a PCR Only run

For the positive and negative controls, enter the barcode as shown in the result export file or printout but modify the last four digits as follows:

- First digit = the current month code from the following table:

<table>
<thead>
<tr>
<th>Month</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>A</td>
</tr>
<tr>
<td>February</td>
<td>B</td>
</tr>
<tr>
<td>March</td>
<td>C</td>
</tr>
<tr>
<td>April</td>
<td>D</td>
</tr>
<tr>
<td>May</td>
<td>E</td>
</tr>
<tr>
<td>June</td>
<td>F</td>
</tr>
<tr>
<td>July</td>
<td>G</td>
</tr>
<tr>
<td>August</td>
<td>H</td>
</tr>
<tr>
<td>September</td>
<td>I</td>
</tr>
<tr>
<td>October</td>
<td>J</td>
</tr>
<tr>
<td>November</td>
<td>K</td>
</tr>
<tr>
<td>December</td>
<td>L</td>
</tr>
</tbody>
</table>

*Table B-7  Month codes used in control barcode*

- Second and third digits = the current day represented as two digits (e.g. 01 through 31).
- Fourth digit = unique number to indicate PCR Only runs for that day (e.g. 1, 2, 3, 4,…).

*Examples* Four digit code for the first PCR Only run performed on 27-May-2009 would be E271 and the third PCR Only run that day would be E273.

Setup microwell plate

Setup the microwell plate for the PCR Only run in the following way:

1. Perform manual PCR setup
2. Seal microwell plate
3. Centrifuge microwell plate

*NOTICE*  
- Only specimens successfully processed on the *cobas®* 4800 instrument can be amplified/detected using the PCR Only run. Do not use extract from any other source.
- There is no system surveillance for sample tracking between the deepwell plate (extraction plate) and the microwell plate (AD plate). Ensure that the eluate is transferred correctly from the deepwell plate to the microwell plate and that the work order file correctly reflects the plate layout.
- Use only Roche consumables designed for use on the *cobas®* 4800 system. Use of non-Roche consumables may damage the *cobas®* 4800 analyzer or lead to incorrect results.
- The microwell plate is barcoded and designed to be used only once. The *cobas®* 4800 software tracks the use of the plate and rejects previously used microwell plates.
Performing manual PCR setup

Perform manual PCR setup as described in the assay-specific package insert.

The prepared samples added to working master mix have limited stability. Amplification and detection should be started as soon as practical. Refer to the appropriate assay-specific package insert for exact timing window.

Sealing the microwell plate

To prevent evaporation the microwell plate needs to be sealed using the appropriate sealing film.

**CAUTION**

Incorrect results due to evaporation of samples or sample contamination

- Follow the outlined procedure to seal the microwell plate to prevent leakage of the sealing film or contamination of samples. Plate leakage can contaminate the *cobas z 480* analyzer. If contamination is suspected, contact Roche Service.
- Examine the microwell plate after amplification and detection. An indication of a leak is if the sealing film is bent into the wells of the plate.

► **To seal the microwell plate**

1. Remove the protection layer from the sealing film.
   
   Do not touch the foil on the clean side and handle the foil only at the sides.

2. Cover the microwell plate with the clean side of the sealing film.

3. Firmly press the sealing film to the plate surface using the sealing film applicator.

   To ensure a strong seal, use the provided sealing film applicator.

4. Remove both ends of the sealing film alongside the perforation.
   
   Do not lift the sealing film from the plate while tearing off the ends of the foil.
Centrifuging the microwell plate

After sealing, centrifuge the sealed microwell plate in a swing bucket centrifuge for at least 5 seconds at 3000 rpm.

Start a new run

To start a new run

1 In the cobas® 4800 software, click .

The New Run dialog box is displayed.

2 Select a test type from the list.

The following test types for PCR Only runs are available:

- CT/NG PCR Only workflow
- HPV PCR Only workflow

3 Enter a name for the run in the Run name field (optional) field.

The system generates a generic run name if you leave the field empty. The generic run name is composed of date and time when the run was started (e.g. "28-May-2009 11:57 AM").

4 Click OK.

The Workplace is displayed showing the wizard for the new run.
Load microwell plate

To load the prepared microwell plate into the cobas z 480 analyzer

1. Press the load button on the cobas z 480 analyzer.

The microwell plate loader opens.

2. Place the sealed microwell plate into the loading frame of the loader.

3. Press the load button again to close the loader.

The loader is retracted.

After successful loading, the wizard asks for the corresponding work order file.
Performing a PCR Only run

Load work order file

To load the work order file

1. Click ...

   An Open dialog box is displayed.

2. Navigate to the appropriate directory, select the work order file and click Open.

   A summary of the work order file is displayed.

   ![Summary of selected work order file](image)

   **Figure B-18** Loading work order file

3. Click Next.

   The work order file information is cross-checked against the loaded microwell plate. The plate ID must match the one in the work order file. Follow the online instructions in case the check fails.

   The amplification and detection run starts automatically.

   When the run is finished, in the cobas® 4800 software, the Show Results button becomes available.
Review and accept results

Test results are displayed in the Results work area as soon as the cobas z 480 analyzer has finished amplification and detection.

**To review and accept results**

1. In the Workplace work area, click the Show Results button.

   Once the **Show Results** button is clicked, the control growth curves can no longer be viewed.

   ![Fluorescence growth curves of the positive (+) and negative (-) controls of all channels](image)

   **A** Fluorescence growth curves of the positive (+) and negative (-) controls of all channels
   
   **B** **Show Results** button

   The Results work area is displayed.

2. Review and accept results in the Results work area.

   For details, see Accepting and printing results on page B-63

3. Select results and click **Save** to print the results report.

   For details on result handling, see Results on page B-60.
Unload the cobas z 480 analyzer

Unload the microwell plate as soon as practical after the run has finished to prevent plate leakage and contamination of the cobas z 480 analyzer.

**To unload the cobas z 480 analyzer**

1. When the run has finished, open the plate loader to remove the microwell plate.
2. Examine the microwell plate after amplification and detection.

---

**Incorrect results due to evaporation of samples or sample contamination**

Plate leakage can lead to incorrect results or can contaminate the cobas z 480 analyzer. If contamination is suspected, contact Roche Service.

- Unload the microwell plate as soon as practical after the run has finished and check the microwell plate for indications of leakage.

3. Discard the plate according to the appropriate local regulations.

---
cobas® 4800 Work Order Editor

The cobas® 4800 Work Order Editor is an independent standalone software application. It is used to create and edit work order files for the cobas® 4800 system. The work order file is an XML-file that contains all orders for a single run on the cobas® 4800 system.

The cobas® 4800 Work Order Editor and work order files are only used when the cobas® 4800 system is not connected to an LIS or if the LIS is not working.

The work order file is loaded into the cobas® 4800 software at the beginning of a run. For each run, the information in the work order file must match the loaded samples on the cobas® 4800 system.

- If a work order file and the loaded samples do not match, both the work order file and the samples must be reloaded. It is not possible to choose another work order file and leave the samples loaded.
- Samples can be loaded in any order as long as they match the set of samples listed in the work order file.
- Do not use the prefix “SP” or “PC” in a sample barcode. Sample barcodes using these prefixes cannot be modified in the cobas® 4800 Work Order Editor.

A Select Create New to create a new work order file.
Select Edit Existing to open an already existing work order file for editing.
B Select a run type and test type. Both are unique for a single run on a cobas® 4800 system.
C Click Next to open the next window for adding orders.

Figure B-19 cobas® 4800 Work Order Editor (Startup window)
A Define the order information for each sample in the order. Fields marked with an asterisk (*) are mandatory.

B Enter the number of samples and click Add to add them to the order list on the right.

C Switch between Create and Edit mode. Use Create mode to add new orders. Use Edit mode to edit existing order entries.

D List of sample orders.

E Click save to save the work order file.

Figure B-20 cobas® 4800 Work Order Editor (Order window)
Defining work order files for full runs

When defining a work order file there are basically three ways of doing it:

- Define each order one sample at a time.
  For additional details, see Create the work order file for full runs (one sample at a time) on page B-57
- Create a number of generic orders and then complete them.
  For additional details, see Create the work order file for full runs (batch mode) on page B-58
- Edit an existing work order file.
  For additional details, see Edit an existing work order file for full runs on page B-59

Create the work order file for full runs (one sample at a time)

To create a new work order file for full runs (one sample at a time)

1. Start the cobas® 4800 Work Order Editor.
   The startup window of the cobas® 4800 Work Order Editor is displayed.
2. Enter the user name.
3. Select Create New.
4. Select Full for a full workflow with sample preparation, amplification and detection.
5. Select the test type.
6. Click Next.
   The next window of the cobas® 4800 Work Order Editor is displayed.
7. Select the subtest.
8. Click in the Barcode field and scan the sample barcode.
9. Select the media type.
10. Click Add.
    The order is created in the order list on the right.
11. Repeat step 7 through 10 for all of your samples in the run.
12. Click Save.
    The Save As dialog box is displayed. The default location is the one that is defined in the Configuration tab (Utilities > Configuration > System Settings).
13. If necessary, change the path.
14. Enter a meaningful file name and click Save.
    Follow the file naming conventions defined for your laboratory.
Create the work order file for full runs (batch mode)

To create a new work order file for full runs (batch mode)

1. Start the cobas® 4800 Work Order Editor.
   The startup window of the cobas® 4800 Work Order Editor is displayed.
2. Enter the user name.
3. Select Create New.
4. Select Full for a full workflow with sample preparation, amplification and detection.
5. Select the test type.
6. Click Next.
   The next window of the cobas® 4800 Work Order Editor is displayed.
7. Select the subtest.
8. Select the media type.
9. Enter the number of samples in the run and click Add.
   The corresponding number of generic orders are created in the order list on the right.
10. From the Mode list, select the Edit mode.
11. Scan all sample barcodes.
12. Click Save.
   The Save As dialog box is displayed. The default location is the one that is defined in the Configuration tab (Utilities > Configuration > System Settings).
13. If necessary, change the path.
14. Enter a meaningful file name and click Save.
   Follow the file naming conventions defined for your laboratory.
Edit an existing work order file for full runs

To edit a work order file for full runs

1 Start the cobas® 4800 Work Order Editor.
2 Enter the user name.
3 Select Edit Existing.
4 Click Browse.
   The Browse XML Work Order File dialog box is displayed.
5 Navigate to the location where your work order file is stored and select the work order file.
6 Click Open.
7 Click Next.
8 To edit existing orders, select the order and perform the necessary changes.
9 To add a new order do the following:
   • From the Mode list, select the Create mode.
   • Select the necessary subtest, media type, and well position.
   • Click in the Barcode box and scan the sample barcode.
   • Click Add.
10 Click Save.
11 Select the existing file name if you want to overwrite the current file or enter a different name if you want to keep both versions.
12 If necessary, change the path.
13 Click Save.

Defining work order files for PCR Only runs

For a description how to define a work order file for a PCR Only run, see Create a work order file for a PCR Only run on page B-46
The Results work area gives access to all runs and test results of the cobas® 4800 system. Use the Results work area to review, accept, print, and export results.

A Runs
In this area all runs are displayed. Select a test type from the list and use the sorting and filter functions in the column headers to limit the runs that are listed.
Select one or more runs to display the associated test results in the Test Results list on the right.

B Test Results
In this area the test results of the selected run(s) are listed. Use the sorting and filter functions in the column headers to limit the results that are listed.

C Detail
In this area more detailed information on a selected result is provided. Details about result flags and Ct values can be accessed.

D Result report
Click Print to print a report of the selected results or the selected run(s).

E Result handling
Click Detail to display the Detail area for viewing information about flags and Ct Values.
Click Search to open the search dialog box for searching for particular results.
Click Export to export the selected results.
Click Accept to accept the selected results.

Figure B-21 Results work area
Viewing results

The Test Results area only displays the results of the runs that are selected in the Runs area.

Powerful filtering functions can further limit the displayed runs and results.

- For additional details, see Lists on page A-74

The layout of the Results window can be customized. Customization includes:

- Sorting and grouping of runs and results.
- Changing the column orders and hiding selected columns in the Runs and Test Results areas.

- For additional details, see Lists on page A-74

Customization of the result view in the Results work area does not influence result printouts and result export. The details per result that are included in reports and export files are independent of what is displayed on screen.

- When a user customizes the view of the Results work area, the new view will be saved for all users.

To display results of selected runs

1. Using the dropdown list in the Runs area, select whether you want to display all runs or only HPV or CT/NG runs.

2. Select one or more runs.

   - Use the Ctrl key to select several nonadjacent runs.
   - Use the Shift key to select a range of adjacent runs.

If necessary, use first the standard filtering and sorting methods to filter and sort the displayed runs.

- For additional details, see Lists on page A-74

In the Test Results area, all results of the selected runs are displayed.

3. Click the Detail button to display result details of the selected result. Flag details and Ct values are available.
Searching results

Use the search function to search for certain results. The search function searches the whole result database not only the results that are currently displayed.

**NOTICE**

There are certain limitations in the search functionality.

Search is case sensitive. For example enter “Failed” in the Test Results box to find Failed results. Entering “failed” would not work.

The use of the following wildcards is possible:

- Use the question mark (?) as placeholder for a single character.
- Use the asterisk (*) as placeholder for a range of characters (e.g. searching for a sample ID “AD2*” will find all sample IDs starting with “AD2”).

▶ To search for results

1. Click the Search button.

   The Search for Sample Results dialog box is displayed.

2. Enter the search criteria.

3. Click the OK button to start the search.

   If necessary, use the standard filtering and sorting methods to further limit the displayed results.

   📘 For additional details, see Lists on page A-74

Filtering, grouping, and sorting runs and results

Runs and results that are displayed in the Results work area can be filtered, grouped, and sorted.

📘 For additional details, see Lists on page A-74
Accepting and printing results

Use the Results work area to do the following tasks:

- Accepting results
- Printing results
  
  Printing of individual results or whole runs is possible.
- Exporting results
  
  Results are exported in XML-format.

To accept results

1. Using the dropdown list in the Runs area, select whether you want to display all runs or only HPV or CT/NG runs.
2. Select one or more runs.
   
   - Use the Ctrl key to select several nonadjacent runs.
   - Use the Shift key to select a range of adjacent runs.
   
   If necessary, use first the standard filtering and sorting methods to filter and sort the displayed runs.
   
   For additional details, see Lists on page A-74
3. Click Detail.
   
   The detail area is displayed.
4. In the Test Results area, select a result you want to review.
5. Review the results data.
   
   For details about flags, see Chapter 10 Result flags
6. Click Accept.
   
   The accepted result is marked with a checkmark.
To print selected results

1 Using the dropdown list in the Runs area, select whether you want to display all runs or HPV or CT/NG only runs.

2 Select one or more runs.
   • Use the Ctrl key to select several nonadjacent runs.
   • Use the Shift key to select a range of adjacent runs.

If necessary, use first the standard filtering and sorting methods to filter and sort the displayed runs.

For additional details, see Lists on page A-74

3 In the Test Results area, select all test results to be printed.
   • Use the Ctrl key to select several nonadjacent results.
   • Use the Shift key to select a range of adjacent results.

4 Click the Print button.

The selected results are printed on the default printer.

To print results of selected runs

1 Using the dropdown list in the Runs area, select whether you want to display all runs or HPV or CT/NG only runs.

2 Select one or more runs.
   • Use the Ctrl key to select several nonadjacent runs.
   • Use the Shift key to select a range of adjacent runs.

If necessary, use first the standard filtering and sorting methods to filter and sort the displayed runs.

For additional details, see Lists on page A-74

3 Click the Print button.

The results of the selected runs are printed on the default printer.

The details per result that are included in the report are independent of what is displayed on screen. Structure and layout of reports cannot be changed by the user.
Exporting results

The export function works in two ways:

- If no LIS is connected to the cobas® 4800 system, the export function exports the results data of the selected runs to an export file. Results are exported in XML format.
- If an LIS is connected to the cobas® 4800 system the export function uploads the results data of the selected runs to the LIS.

To export results to an export file

1. Using the dropdown list in the Runs area, select whether you want to display all runs or HPV or CT/NG only runs.
2. Select one or more runs.
   - Use the Ctrl key to select several nonadjacent runs.
   - Use the Shift key to select a range of adjacent runs.
   If necessary, use first the standard filtering and sorting methods to filter and sort the displayed runs.
3. In the Test Results area, select a result.
4. Click the Export button.
   A Windows dialog box for saving files is displayed.
5. Select the directory where you want to save the file to.
6. Enter a telling name for the result file.
   Follow the naming conventions defined for your laboratory.
7. Click Save.
   All results of the selected runs are exported in XML format. Each run is stored as separate export file.
   Exported results are kept in the Results work area. They are not deleted from the results database.

- To export results to LIS

For details about result upload to the LIS, see Export results to LIS on page B-44
In this chapter the configuration of the system is described.

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<td>.......................................</td>
</tr>
<tr>
<td>Password rules</td>
<td>.......................................</td>
</tr>
</tbody>
</table>

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Roche Diagnostics

Operator’s Manual - Version 1.0

B-67
Introduction

The accessible configuration settings are dependent on the user group of the logged in operator.

The configuration tasks are divided into the following areas:

- System configuration
  - For additional details, see For additional details, see User management on page B-76 on page B-69

- User management
  - For additional details, see User management on page B-76
Configuration

System Settings

Utilities > Configuration > System Settings

Use the System Settings group to define the default import path for work orders files. Work order files are only used when the cobas® 4800 system is not connected to an LIS or if the LIS is not working.

![System Settings group](image)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workorder import path</td>
<td>Path name</td>
<td>Location where the system looks for work order files. Type the full path and use Windows naming conventions (e.g. C:\Temp\Workorders)</td>
</tr>
</tbody>
</table>

![System Settings parameters](image)
Reporting

Utilities > Configuration > Reporting

Use the Reporting group to enable or disable the header of the result report and to set the maximal number of entries in a report.

![Figure B-23 Reporting group](image)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
<th>Comment</th>
</tr>
</thead>
</table>
| Show Lab Header on Reports       | ![checkmark] | Defines whether the specified header in the reports will be displayed or not.  
The report header can only be defined by administrators. |
| Maximum Entries                  | Number | Defines the maximum number of result entries in a report.               |

Table B-9 Reporting parameters
Tests

Utilities > Configuration > Tests

Use the Tests group to enable or disable test and run types on the cobas® 4800 system. Disabled tests cannot be run on the cobas® 4800 system.

![Tests group](image)

**Table B-10 Tests parameters**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT/NG workflow</td>
<td>✔️</td>
<td>Select a box to enable the test for use on the cobas® 4800 system, clear the box to prevent it from being used.</td>
</tr>
<tr>
<td>CT/NG PCR Only workflow</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>HPV workflow</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>HPV PCR Only workflow</td>
<td>✔️</td>
<td></td>
</tr>
</tbody>
</table>

Figure B-24 Tests group
Instruments

→ Utilities > Configuration > Instruments

Use the Instruments group to define maintenance settings and the displayed names for the cobas x 480 instrument and the cobas z 480 analyzer.

![Image of Instruments group](image)

**Figure B-25 Instruments group**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>cobas z 480 name</td>
<td>Alphanumeric characters</td>
<td>Enter the displayed name for the cobas z 480 analyzer.</td>
</tr>
<tr>
<td>cobas z 480 Lamp changed date</td>
<td>Date</td>
<td>Enter the date when the Xenon lamp of the cobas z 480 analyzer was exchanged. Use the calendar to select a date.</td>
</tr>
<tr>
<td>cobas x 480 name</td>
<td>Alphanumeric characters</td>
<td>Enter the displayed name for the cobas x 480 instrument.</td>
</tr>
<tr>
<td>cobas x 480 maintenance days</td>
<td>Number between 7 and 360</td>
<td>Number of days between two consecutive preventive maintenance visits. Preventive maintenance is done by Roche Service. Do not change this setting!</td>
</tr>
</tbody>
</table>

| Table B-11 Instruments parameters |
Archiving

Utilities > Configuration > Archiving

Use the Archiving group to define the settings for purging and archiving results. The purge and archive function is used to archive results and purge them from the results database. This will free up space for new results in the database. Results are archived at regular intervals in a password protected ZIP-file at a predefined location. Each run is archived in a separate ZIP-file.

- No manual intervention is necessary. The cobas® 4800 system performs purging and archiving of results automatically based on the settings in Utilities > Configuration > Archiving.
- Ensure that the archive directory is included in the backup plans.
- Contact Roche Service if result archives need to be viewed or restored.
- The purge and archive function does only cover results. Messages are kept in the cobas® 4800 software until they are deleted manually. Therefore, it is recommended to manually delete confirmed messages from time to time to free up additional space in the database.
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imported files archiving time</td>
<td>Number between 10 and 10000</td>
<td>Number of days after which downloaded LIS orders will be deleted.</td>
</tr>
<tr>
<td>Purge &amp; Archive</td>
<td>☑ ☐</td>
<td>Select the box to enable the purge &amp; archive function.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Deselect the box to disable the purge &amp; archive function.</td>
</tr>
<tr>
<td>Purge &amp; Archive Directory</td>
<td>Directory path</td>
<td>Location where the cobas® 4800 system archives results. The archive directory can be located on a server. Type the full path to the archive directory and use Windows naming conventions. (e.g. D:\Archive)</td>
</tr>
<tr>
<td>Maximum age of Results</td>
<td>Number</td>
<td>Enter the time interval in days when results should be archived and purged from the database. All results that are older than the specified days will be archived and purged.</td>
</tr>
</tbody>
</table>

**Table B-12 Archiving parameters**
User management

Utilities > Users

There are three groups of functions available for managing users:

- Changing passwords
- Managing user accounts
- Setting up rules for passwords and user accounts

- Only users that are assigned as Supervisors can manage users and can set up rules for passwords and user accounts.
- Users assigned as Operators can change their password only.
- Keep user access information on a secure place and do not make it public to prevent unauthorized access to the cobas® 4800 system.

Password management

The initial password is defined during set up of a user account.

For details, see To define a new user account on page B-78.

Changing a password

Any user can change his/her password. Supervisors can change the passwords of all users. The password must follow the password rules that are defined on the cobas® 4800 system.

For details, see Password rules on page B-81.

To change the password

1 Choose Utilities > Users and click Change Password.
   
   The Change Password dialog box is displayed.

2 In the Old Password box, type the current password.

3 In the New Password box, type the new password.

4 In the Confirm new Password box, type the new password again.

5 Click the Apply button.
To change the password of another user

1. Choose Utilities > Users.
2. Select a user in the list.
3. Click the Reset Password button.
4. In the Password box, type the new password.
5. In the Confirm Password box, type the new password again.
6. Click the Apply button.

User account management

The following functions are available:
- Creating new user accounts
- Changing and deleting existing user accounts
- Unlocking user accounts

User rights

A user assigned to the Operator group has the following user rights:
- Starting and aborting runs
- Viewing result details and accepting, exporting, printing, and purging results
- Performing daily and weekly maintenance
- Confirming messages

A user assigned to the Supervisor group has the same user rights as the Operator group plus:
- Editing configuration settings
- Managing user accounts and editing account rules
- Deleting messages
Creating user accounts

User name and password must be unique.

To define a new user account


2. Type the User ID.
The user ID must be unique on the system.

3. Type the User Name.
The user name must be unique on the system.

4. Type the password and confirm it.
The password must follow the password rules that are defined on the system.

5. Assign the User Group.
   To each group, a set of user rights is assigned.

6. Select Log off user on inactivity to make sure that the user will be automatically logged off after a certain period of inactivity on the system.
   For details, see Account rules on page B-80.

7. Select Change Password on next logon to ensure that the user changes his or her password during the next log on.

8. Clear Account is enabled if you are preparing a new user account to be ready for a later date.

9. Clear Password never expires if the user should change the password periodically.
   For details, see Account rules on page B-80.

10. Click the Apply button.
    This button is only active if all necessary definitions have been made.
Changing user accounts

► To change a user account
1 Choose Utilities > Users
2 Select a user from the list.
3 Click the Edit button.
4 Make the necessary changes in the User Account area.
5 Click the Apply button.

Deleting user accounts

► To delete a user account
1 Choose Utilities > Users
2 Select a user from the list.
3 Click the Delete button.

A confirmation dialog box is displayed.
4 Click OK to confirm the deletion.
Unlocking user accounts

User accounts become locked after a number of unsuccessful login attempts. Locked users are indicated in the Users list.

➤ To unlock a locked user account

1. Choose Utilities > Users
2. Select the locked user from the list.
3. Click the Unlock button.

Rules

➔ Utilities > Users > click Rules

There are two sets of rules, one for user accounts and one for passwords.

Enter zero to switch off a rule.

Account rules

<table>
<thead>
<tr>
<th>Item</th>
<th>Values</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Password expires after [days]</td>
<td>Number (0...999)</td>
<td>Select or type the number of days after which the user must change the password.</td>
</tr>
<tr>
<td>Auto log off user after [min]</td>
<td>Number (0...999)</td>
<td>Select or type the number of minutes of inactivity on the system after which the user is automatically logged off.</td>
</tr>
<tr>
<td>User locked after wrong logins</td>
<td>Number (0...999)</td>
<td>Select or type the number of failed login attempts before the system automatically locks the account.</td>
</tr>
</tbody>
</table>

Table B-13  User account settings
### Password rules

<table>
<thead>
<tr>
<th>Item</th>
<th>Values</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>have a minimum length of</td>
<td>Number</td>
<td>Select or type the minimum number of characters a password must consist of. The minimal required value is automatically set by the system based on the values of the other password rules.</td>
</tr>
<tr>
<td>contain at least uppercase characters (A through Z)</td>
<td>Number</td>
<td>Select or type the minimum number of uppercase characters a password must contain.</td>
</tr>
<tr>
<td>contain at least lowercase characters (a through z)</td>
<td>Number</td>
<td>Select or type the minimum number of lowercase characters a password must contain.</td>
</tr>
<tr>
<td>contain at least digits (0 through 9)</td>
<td>Number</td>
<td>Select or type the minimum number of digits a password must contain.</td>
</tr>
<tr>
<td>contain at least nonalphanumeric characters (e.g., !, $, %)</td>
<td>Number</td>
<td>Select or type the minimum number of non-alphanumeric characters a password must contain.</td>
</tr>
</tbody>
</table>

This is the last page of Part B.
# Maintenance

In this chapter the required maintenance procedures are described.

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<td>Perform start up procedures</td>
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<td>C–12</td>
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<tr>
<td>cobas z 480 analyzer maintenance</td>
<td>C–17</td>
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<td></td>
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<td>C–17</td>
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<td>Exchanging the Xenon lamp</td>
<td>C–18</td>
</tr>
<tr>
<td>Exchanging the ventilation dust filters</td>
<td>C–23</td>
</tr>
<tr>
<td>Exchanging fuses</td>
<td>C–25</td>
</tr>
</tbody>
</table>
Safety information

Make sure that you have read and understood the chapter *General safety information*. The following safety messages in particular are relevant:

Warning messages:
- *Electrical shock by electronic equipment* on page A-8
- *Loss of sight due to staring into laser beam* on page A-8
- *Infection by samples and associated materials* on page A-9
- *Infection and injury due to sharp objects* on page A-9
- *Infection by biohazardous waste* on page A-10
- *Contamination of the environment by liquid waste and solid waste* on page A-10
- *Explosion through sparks* on page A-10
- *Fire risk through usage of sprays* on page A-10

Caution messages:
- *Personal injury due to contact with moving parts* on page A-11
- *Skin inflammation or injury caused by reagents* on page A-12
- *Personal injury due to hot surface* on page A-13

Safety precautions:
- *Operator qualification* on page A-6

Observe the system safety labels illustrated and described starting on page A-16.

Before performing any maintenance, read the safety messages carefully. If you ignore safety messages, you may suffer serious or fatal injury.
Maintenance for the cobas x 480 instrument is initiated and managed directly from the cobas® 4800 software. The System tab shows the actual maintenance status of the cobas x 480 instrument. Maintenance is started from the cobas x 480 tab.

Periodic maintenance must be performed in order to ensure safe and reliable operation of the cobas x 480 instrument. A maintenance procedure is completed once the procedure has been fully executed and the results are within the specifications.

Aborting maintenance procedures
A maintenance procedure must always be finalized. Do not abort a maintenance procedure. Aborting a maintenance procedure will lead to a failed status, and maintenance will need to be started again. After aborting a maintenance procedure, switch off the cobas x 480 instrument and switch it on again after 10 seconds.

The following maintenance intervals have to be followed:

**Daily maintenance**
Recommended daily after cobas x 480 instrument start up.

**Weekly maintenance**
Recommended at the end of the week before shutting down the cobas x 480 instrument.

If an error is encountered during a maintenance procedure, try to resolve the problem and re-start the maintenance procedure. If you cannot resolve the error yourself, call Roche Service.

**Preventive maintenance**
As part of the preventive service program two scheduled preventive maintenance service visits per year will be required. Preventive maintenance is performed by Roche Service. The duration of each preventative maintenance procedure will be approximately 4 hours.

**WARNING**
- Always wear disposable gloves during maintenance. Pay special attention to the sharp edges on the iSWAP and the pipetting channels.
- Do not clean the cobas x 480 instrument in the vicinity of open flames or devices which could create sparks. Do not use hot air blowers to dry the cobas x 480 instrument. The liquids used for cleaning are flammable.
- Perform only the maintenance tasks described in the daily and weekly maintenance procedures. No other maintenance is allowed on any module of the cobas x 480 instrument.

**NOTICE**
- Performing daily and weekly maintenance is mandatory. A run can only be started when maintenance is complete.
- If any parts of the cobas x 480 instrument or carriers have become contaminated, the weekly maintenance procedure must be performed.
- Do not shut down the control unit or the cobas® 4800 software during a running maintenance procedure.
- Counters are reset to twenty-four hours when daily maintenance is performed. If weekly maintenance is performed, daily maintenance is not required on that day.
- There is no processing icon like an hourglass or progress bar displayed during maintenance.
Perform start up procedures

The cobas® 4800 system control unit is normally left on, except for a daily restart (e.g. as part or before starting the daily maintenance).

It is strongly recommended to restart the cobas® 4800 system daily.

For startup procedures, if the control unit is powered off, see Perform startup procedures on page B-22

Daily maintenance

The following tasks are part of the daily maintenance:

1. Shutdown and restart the cobas® 4800 system control unit.
2. Check if instrument deck is clean.
3. Empty the tip waste and the liquid waste container and clean the tip eject plate.
4. The cobas x 480 instrument automatically checks the tightness of the pipetting channels.
5. The cobas x 480 instrument automatically verifies the functioning of the liquid level detection.

Tools and material required

- Tip waste bag
- Disposable latex gloves
- Protective glasses
- Lab coat
To perform daily maintenance

1. Shutdown and restart the cobas® 4800 system control unit.
2. Logon to the cobas® 4800 software.
3. Select the Overview tab and then the cobas x 480 tab.

The cobas x 480 instrument initializes. The pipetting arm and the autoloader move to the left hand side. A message box displays the first daily maintenance procedure that must be performed.

The operator now has access to the instrument deck to check if cleaning is required.

5. Open the front cover and inspect that all the parts of the cobas x 480 instrument or carriers are clean.
   - If the instrument deck is clean continue with step 6.
   - If the instrument deck requires cleaning, stop daily maintenance. Perform weekly maintenance. To stop daily maintenance, click Cancel in the message box.

6. Click OK.

The next message box is displayed.

7. Replace the tip waste bag as described below.
   - For additional details about the tip waste, see Waste station on page A-42

The tip waste, the tip eject plate, and the plastic waste chute must always be considered as biohazardous.
Replacing small waste bag

If a small waste bag is used access the tip waste bag by lifting the cobas x 480 instrument front cover. Remove a full waste bag from the cobas x 480 instrument by removing the support frame from the initialization/waste block.

When replacing the small waste bag, place the bottom portion of the waste bag inside the support frame, fold the top over the frame and then place the support frame into the initialization/waste block. Dispose of either waste bag and contents according to the appropriate local regulations.
Replacing large waste bag

If a waste container is used remove the large waste bag from the waste container and replace it with a new one. Close the large waste bag with a binder and dispose of either waste bag and contents according to the appropriate local regulations.

- Waste chute and waste container can be reused and need to be replaced only if required.
- If required, replace the waste chute in the same way as the small tip waste bag.
- If required, fold up a new waste container as indicated in Figure A-17 on page A-43

8 Remove the tip eject plate of the tip waste station (see Figure C-1 on page C-9) and clean it with disinfectant solution. Put the clean tip eject plate back in place.

9 Check the status of the liquid waste container. Empty the waste container if it requires emptying. Dispose of the liquid waste according to the appropriate local regulations.

For additional details, see Liquid waste on page A-44
The procedure continues with the tightness check of the pipetting channels. The pipetting arm will move to the right hand side to pick up the teaching needles.

Two checks are done with the pipetting channels, the over-pressure and the under-pressure check.

For the capacitive liquid level detection check the needles are picked-up again. One channel to the next is checked for the proper functioning of the liquid level detection.

If the automatic tightness or liquid level detection checks fail, repeat twice, then call Roche Service.

The pipetting arm and the autoloader move to the right hand side and the end of the daily maintenance wizard is displayed.

Click OK.

The daily maintenance process status is saved.
Weekly maintenance

If weekly maintenance is being performed, daily maintenance is not required on that day.

The following tasks are part of the weekly maintenance:

1. Shutdown and restart the cobas® 4800 system control unit.
2. Clean the instrument deck and the carriers.
3. Empty the tip waste and the liquid waste container and clean the tip eject plate, the covers and the autoload protecting ribbon.
4. The cobas x 480 instrument automatically checks the tightness of the pipetting channels.
5. The cobas x 480 instrument automatically verifies the functioning of the liquid level detection.

Tools and material required

- Tip waste bag
- Disposable latex gloves
- Protective glasses
- Lab coat
- Paper towels
- Lint-free cloths or Q-tips
- Ethanol (70%)
- De-ionized water
- Decontamination liquid

**NOTICE**

Use proper decontamination liquid according to the advice of Roche Service.

► **To perform weekly maintenance**

1. Shutdown and restart the cobas® 4800 system control unit.
2. Logon to the cobas® 4800 software.
3. Select the Overview tab and then the cobas x 480 tab.
4. Click Run Weekly Maintenance.

The cobas x 480 instrument initializes and a message box is displayed.
5 Remove all carriers from the autoload tray and then click OK.

The instrument deck is unloaded automatically. The procedure continues with the tightness check of the pipetting channels. The pipetting arm moves to the right hand side to pick up the teaching needles.

Two checks are done with the pipetting channels, the over-pressure and the under-pressure check.

For the capacitive liquid level detection check the needles are picked-up again. One channel to the next is checked for the proper functioning of the liquid level detection.

If the automatic tightness or liquid level detection checks fail, repeat twice, then call Roche Service.

A message box displays.

6 Clean all carriers with decontamination liquid and leave them to dry.

7 Open the front cover and wipe the instrument deck with a cloth saturated with decontamination liquid. The slide blocks - the guides on the autoload tray for proper insertion of the carriers - in particular must be checked for cleanliness.

8 Click OK.

The pipetting arm and the autoloader move to the left hand side of the instrument deck and the next message box is displayed.

9 Replace the tip waste bag as described below.

For additional details about the tip waste, see Waste station on page A-42

The tip waste, the tip eject plate, and the plastic waste chute must always be considered as biohazardous.
Replacing small waste bag

If a small waste bag is used access the tip waste bag by lifting the cobas® x 480 instrument front cover. Remove a full waste bag from the cobas® x 480 instrument by removing the support frame from the initialization/waste block.

![Diagram](image)

<table>
<thead>
<tr>
<th>A</th>
<th>Tip eject plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>Support frame</td>
</tr>
<tr>
<td>C</td>
<td>Initialization/waste block</td>
</tr>
<tr>
<td>D</td>
<td>Waste bag or waste chute</td>
</tr>
</tbody>
</table>

**Figure C-4** Removing waste bag or waste chute

When replacing the small waste bag, place the bottom portion of the waste bag inside the support frame, fold the top over the frame and then place the support frame into the initialization/waste block. Dispose of either waste bag and contents according to the appropriate local regulations.
Replacing large waste bag

If a waste container is used remove the large waste bag from the waste container and replace it with a new one. Close the large waste bag with a binder and dispose of either waste bag and contents according to the appropriate local regulations.

- Waste chute and waste container can be reused and need to be replaced only if required.
- If required, replace the waste chute in the same way as the small tip waste bag.
- If required, fold up a new waste container as indicated in Figure A-17 on page A-43.

10 Remove the tip eject plate of the tip waste station (see Figure C-4 on page C-14) and clean it with disinfectant solution. Put the clean tip eject plate back in place.

11 Check the laser scanner window of the barcode scanner on the autoloader and clean it with a lint-free cloth or Q-tips lightly soaked in ethanol (70%) to prevent unreliable barcode scanning.

**NOTICE**

The laser scanner window must be completely dry and free from dust and fibers before the cobas x 480 instrument can be reused.

12 Clean the front and side cover with a lint-free cloth soaked in disinfectant solution and wipe dry.

13 Clean the autoload protecting ribbon with a lint-free cloth soaked in disinfectant solution and wipe without exerting pressure.
14 Check the status of the liquid waste container. Empty the waste container if it requires emptying. Dispose of the liquid waste according to the appropriate local regulations.

notEmpty Empty the waste container if it requires emptying. Dispose of the liquid waste according to the appropriate local regulations.

For additional details, see Liquid waste on page A-44

15 Click OK.

The pipetting arm and the autoloader move to the right hand side and the end of the weekly maintenance wizard is displayed.

16 Click OK.

The weekly maintenance process status is saved.
cobas z 480 analyzer maintenance

No user maintenance is required for the cobas z 480 analyzer. General cleaning of the cobas z 480 analyzer and exchanging the Xenon lamp, the ventilation dust filters, and the fuses are described below.

- Never clean the cobas z 480 analyzer without turning the analyzer power switch off and disconnecting the power cable.
- Do not pour fluids into the thermal block cycler, the compartment of the block cycler unit, or the interior of the analyzer.
- As with all potentially biohazardous specimens, universal safety precautions should be taken when handling and processing samples. Spills should be immediately disinfected with an appropriate disinfectant solution to avoid spreading contamination to laboratory personnel or equipment. Handling and disposal of infectious material should be performed according to local safety guidelines.

General cleaning

Regular cleaning of the cobas z 480 analyzer and the accessories is not required. If necessary, clean the housing of the cobas z 480 analyzer, the thermal block cycler, and the block cycler cover with 70% ethanol.

Ventilation inlets

The ventilation inlets of the cobas z 480 analyzer should be checked regularly, to ensure an unrestricted air flow. If required, replace the ventilation dust filters.

For details, see Exchanging the ventilation dust filters on page C-23

To clean the cobas z 480 analyzer block cycler unit

1. Pipette 125 µL of 70%-ethanol or isopropanol into all wells (96-well block).
2. After 15 minutes pipette up and down several times.
3. Remove the liquid and let the block cycler unit dry before using again.

Take care not to destroy the block coating.
Exchanging the Xenon lamp

The cobas z 480 analyzer automatically and continually measures the intensity of the Xenon lamp to ensure optimal detection of the fluorescent signals during real-time PCR. If the lamp intensity falls below 50% of its initial intensity, a warning is issued by the cobas® 4800 software that the Xenon lamp must be exchanged. The Xenon lamp is available as a spare part from Roche. Please contact your local Roche representative for details.

- Use only the exchange Xenon lamp available directly from Roche.
- Never exchange the Xenon lamp without turning the cobas z 480 analyzer power switch off and disconnecting the power cable. Non-compliance poses the danger of electric shock and damage to the eyes by the bright light of the lamp.
- Before exchanging the Xenon lamp, make sure you have waited an appropriate period of time (approximately 20 minutes) after you shut down the cobas z 480 analyzer to allow the lamp to cool. Directly after completion of a run, the lamp is hot enough to cause an immediate burn.
- In its cold state the lamp has a high internal pressure (as much as 20 bar). During operation the internal pressure is around three times higher than in the cold state. The lamp is extremely unlikely to explode but the possibility cannot be entirely ruled out. Therefore, when handling the Xenon lamp always use the protective jacket or cap supplied. When installing the lamp, remove the protective jacket or cap and always take the following precautions: wear goggles and gloves and protect your neck (e.g., with a thick scarf). Take the same precautions when removing the lamp.
- Do not get finger marks, grease, paint, or the like on the bulb. Before using the lamp, remove any such marks with isopropanol, ethanol, or any other suitable agent that leaves no residues on the bulb.
- The Xenon lamp does not contain any materials which are harmful to the environment so they are not subject to special waste disposal regulations. Prior to disposal, the old lamp should be stored in their protective jacket or cap where it cannot be easily accessed. Where possible, the lamp should be disposed off by a specialist waste management company. If this is not possible, put on protective clothing, wrap the lamp completely in leather or thick cloth, smash the lamp, including the discharge tube, with a suitable implement and dispose off the pieces.
To exchange the Xenon lamp

1. Remove the right panel of the cobas z 480 analyzer as shown below.

2. Move the cover of the cobas z 480 analyzer to the right to access to the lamp unit.
3  Unscrew the lamp unit cover and open it.

4  The Xenon lamp is fixed by a clip which itself is secured by a screw. Unscrew the clip and open it.

![Xenon lamp with clip](image)

**Figure C-7**  Xenon lamp with clip

A  Safety clip  
B  Xenon lamp
5 Press the safety clip to lift the Xenon lamp out of its clamp and remove the two conductors.

![Figure C-8](image1.png)

**Figure C-8** Press the safety clips

![Figure C-9](image2.png)

**Figure C-9** Remove the conductors

A Conductor (-)  B Conductor (+)
6 Install the new Xenon lamp. First attach the (-) conductor and then the (+) conductor.

7 Complete installing by following the above mentioned steps 4 to 1 exactly in the reverse order.

**NOTICE**

Make sure the (-) conductor points upward while fixing the new Xenon lamp into the clamp.

**NOTICE**

After you exchanged the Xenon lamp, make sure to reset the lamp counter on the cobas z 480 tab by clicking Reset values after Lamp Change. The cobas z 480 analyzer will read and save the intensity of the lamp as the starting intensity value. During operation, the cobas z 480 analyzer compares this saved value to the actual lamp intensity to determine the loss of lamp intensity. When the lamp intensity reaches 50% of its starting intensity, you will be informed and prompted to exchange the lamp.
Exchanging the ventilation dust filters

The electronic rack of the cobas z 480 analyzer is cooled by ventilation. Two ventilation inlets are located in the lower right corner of the right side of the cobas z 480 analyzer (right beside the block cycler compartment) and in the back of the cobas z 480 analyzer. To avoid any contamination of the cobas z 480 analyzer interior by dust particles, these ventilation inlets carry dust filters.

**NOTICE**
The dust filters should be exchanged when indicated on the cobas z 480 tab of the cobas® 4800 software. You can order exchange dust filters directly from Roche.

► **To exchange the ventilation dust filters**

1. Remove the right instrument panel as shown below to access the lateral ventilation inlet.

2. Remove the ventilation dust filter carrier.

![Ventilation dust filter next to the block cycler door](image)
3 In the same way, remove the dust filter carrier from the rear ventilation inlet.

![Rear ventilation dust filter](image1)

**Figure C-11** Rear ventilation dust filter

4 Remove the used dust filters from each carrier and insert new filters.

![Dust filters](image2)

**Figure C-12** Dust filters

5 Replace each dust filter carrier on the corresponding ventilation inlet and reassemble the cobas z 480 analyzer panel by following the above mentioned steps 3 to 1 exactly in the reverse order.
Exchanging fuses

The cobas z 480 analyzer contains eight fuse types. Fuses must be exchanged when they are blown.

**Electrical shock by electronic equipment**

Always turn off the cobas z 480 analyzer, then unplug the main cable before replacing fuses.

---

**Primary fuses**

![Primary fuses on the power box](image)

**A** High-breaking capacity (T 10A H / 250V)

**Table C-1** Primary fuses

<table>
<thead>
<tr>
<th>Labeling</th>
<th>Amperage/Voltage</th>
<th>Consumer load</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUSES LINE INPUT</td>
<td>2 × T 10A H / 250V</td>
<td>Line input cobas z 480 analyzer</td>
</tr>
<tr>
<td>2 × T 10A H / 250V</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Secondary fuses

![Secondary fuses](image)

To access secondary fuses F1 – F5, remove the right panel of the cobas z 480 analyzer.

<table>
<thead>
<tr>
<th>Labeling</th>
<th>Amperage/Voltage</th>
<th>Consumer load</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>T 3.15A / 250V</td>
<td>Detection unit</td>
</tr>
<tr>
<td>F2</td>
<td>T 8A / 250V</td>
<td>Block cycler unit</td>
</tr>
<tr>
<td>F3, F4, F5</td>
<td>T 16A / 250V</td>
<td>Thermal block cycler Peltier elements</td>
</tr>
</tbody>
</table>

**NOTICE**

Xenon lamp fuse

![Xenon lamp fuse](image)

To access the Xenon lamp fuse, remove the cover of the cobas z 480 analyzer.

<table>
<thead>
<tr>
<th>Labeling</th>
<th>Amperage/Voltage</th>
<th>Consumer Load</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 x T 2.5A / 250V</td>
<td>Xenon lamp</td>
<td></td>
</tr>
</tbody>
</table>

**NOTICE**

Table C-2
Secondary fuses

Table C-3
Xenon lamp fuse
To exchange a primary or secondary fuse

1. Turn off the cobas z 480 analyzer, then unplug the main cable.
2. Unscrew the cover of the fuse chamber by using a screwdriver.
3. Remove the cover together with the fuse attached from the chamber.
4. Exchange the blown fuse with a replacement fuse and place it back in the chamber.
5. Screw up the cover again.

To exchange the Xenon lamp fuse

1. Turn off the cobas z 480 analyzer, then unplug the main cable.
2. Remove the cover of the cobas z 480 analyzer.
3. The Xenon lamp fuse is located above the mains socket of the Xenon lamp module.
4. Using forceps, press the clamps of the left and right side of the fuse holder inward. Pull the fuse holder out of its chamber.
5. Exchange the blown fuse with a replacement fuse and place the fuse holder back in the chamber.
6. Re-assemble and close the instrument cover.

This is the last page of Part C.
Troubleshooting

9  Troubleshooting and messages ..........................  D–3
10  Result flags .............................................  D–17
In this chapter alarm and troubleshooting information help to deal with exceptional situations.

In this chapter

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<tr>
<th>In this chapter</th>
<th>Chapter</th>
</tr>
</thead>
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<td>D–5</td>
</tr>
<tr>
<td>Messages work area</td>
<td>D–7</td>
</tr>
<tr>
<td>Viewing and confirming new alarms</td>
<td>D–9</td>
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<tr>
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<tr>
<td>Barcode reading errors</td>
<td>D–10</td>
</tr>
<tr>
<td>Connection errors</td>
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<tr>
<td>cobas x 480 instrument connection problems</td>
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<tr>
<td>Error messages</td>
<td>D–14</td>
</tr>
</tbody>
</table>
Overview

The cobas® 4800 system records all activities that are performed and any cobas® 4800 software, cobas x 480 instrument, or cobas z 480 analyzer problems that are encountered. These activity records can be viewed in the alarm area at the bottom of the screen and in the Messages work area.

**Figure D-1**  Alarm area

A The **alarm area** displays the most recent alarms that are not yet confirmed by the operator. Select an alarm in the list and click the **Alarm** button on the left to get more details about the selected alarm.
### Alarm area

The color of the alarm button changes depending on the severity of the alarms listed in the alarm area.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Error Icon" /></td>
<td>The alarm area contains at least one error.</td>
</tr>
<tr>
<td><img src="image" alt="Warning Icon" /></td>
<td>The alarm area only contains warnings but no errors.</td>
</tr>
<tr>
<td><img src="image" alt="Empty Icon" /></td>
<td>The alarm area is empty.</td>
</tr>
</tbody>
</table>

#### Table D-1  Alarm button

### Message and alarm icons

The severity of the alarms and messages is indicated by the following icons:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Error Icon" /></td>
<td>Designates an error message (red icon). The error must be resolved before additional samples can be run. A problem report is generated automatically.</td>
</tr>
<tr>
<td><img src="image" alt="Warning Icon" /></td>
<td>Designates a warning (yellow icon) indicating an error was detected but the system can still be run.</td>
</tr>
<tr>
<td><img src="image" alt="Informational Icon" /></td>
<td>Designates an informational message.</td>
</tr>
</tbody>
</table>

#### Table D-2  Message and alarm icons
Messages work area

There are two tabs in the Messages work area.

<table>
<thead>
<tr>
<th>Tab</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarms</td>
<td>Contains all new alarms from the cobas x 480 instrument, the cobas z 480 analyzer, or the cobas® 4800 software.</td>
</tr>
<tr>
<td>Messages</td>
<td>Contains confirmed error and warning messages.</td>
</tr>
</tbody>
</table>

The purge and archive function does only cover results. Messages are kept in the cobas® 4800 software until they are deleted manually. Therefore, it is recommended to manually delete confirmed messages from time to time to free up additional space in the database.

A All unconfirmed alarms are listed in the Alarms tab. Alarms are moved to the Messages tab after confirmation.
B Alarm details. Select an alarm in the list to see the alarm details.
C Click Delete to delete the selected alarm.
D Click Confirm to confirm the selected alarm or click or Confirm All to confirm all alarms of the Alarms tab. Confirmed alarms are deleted from the Alarms tab and moved to the Messages tab.

Figure D-2 Alarms tab
9 Troubleshooting and messages

Messages work area

A Use the sort, filter, and group functions in the column headers to customize the list of messages.
B Click **Delete** to delete the selected message.
C Click **Confirm** to confirm the selected message.

Figure D-3 Messages tab

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity</td>
<td>Contains an icon to indicate whether the message is an error, warning, or information message.</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Displays the date and time that the message was generated.</td>
</tr>
<tr>
<td>Code</td>
<td>Displays the message code.</td>
</tr>
<tr>
<td>Text</td>
<td>Displays an abbreviated description of the error or situation that occurred.</td>
</tr>
<tr>
<td>Confirmation date and user</td>
<td>Displays date and time of confirmation and the operator who has confirmed the message.</td>
</tr>
</tbody>
</table>

Table D-4 Fields in Messages tab
Viewing and confirming new alarms

All alarms should be confirmed.

The selected alarm(s) are removed from the Alarms tab and transferred to the Messages tab.

Click the Print button to print the contents of the Alarms or Messages tab.

▲ To confirm a new alarm

1. Click the Messages tab and then the Alarms tab or double-click the alarm in the alarm area at the bottom of the screen.

2. Select the alarm to be confirmed.

To select more than one alarm, hold the Ctrl key down and click the desired alarm. Alternatively, to select adjacent alarms hold down the Shift key while selecting the starting and ending alarm or use the sort and filter functions in the column headings.

3. Click Confirm or Confirm All.
Troubleshooting

Barcode reading errors

If one or more barcode labels could not be read, the error dialog box below is displayed. The reason for this error may be poor-quality, damaged, or missing barcode labels. There are several options for handling barcode errors.

**NOTICE**

Exactly follow the procedure outlined below to resolve barcode reading errors. Deviating from this procedure might abort the run.

**Figure D-4**  
Barcode error message

---

**To resolve barcode errors**

1. Do one of the following:
   - Click **Repeat** and wait until the carrier is unloaded. Click **Execute**. The carrier is unloaded and loaded again without any further user intervention. This time the carrier is loaded slower to facilitate barcode reading.
   - Click **Unload carrier**. The carrier is unloaded and the barcode problem can be resolved. Click **Repeat** and then **Execute** to load the carrier again.
   - Click **Unload carrier** to unload the carrier and enter the barcode manually by clicking the **Barcode...** button. Type in the barcodes in double blind entry mode. Do not use the barcode scanner here as this will produce an error message.
After this is done, the error dialog turns green for all positions with a manually entered barcode. Click the Execute button. The carrier is loaded again using manually typed barcodes at the corresponding positions.

### Connection errors

**cobas x 480 instrument connection problems**

*NOTICE*

If the connection between the cobas® 4800 software and the cobas x 480 instrument is broken or if the cobas x 480 instrument was switched off the run status may not be displayed correctly until the connection has been reestablished.

If the connection between the control unit and the cobas x 480 instrument is interrupted (i.e. the USB connector is disconnected), the cobas x 480 instrument will immediately abort the run. The status of the cobas x 480 instrument changes to Error, however the status of the run in the cobas® 4800 software will only be updated after the connection is reestablished. The same is true for the display of the associated error message in the alarm area. An error message will only be issued after the connection to the cobas x 480 instrument is reestablished.

After a connection error the cobas x 480 instrument has to be unloaded manually.

*⃣* For details, see Unloading the cobas x 480 instrument deck manually on page D-12
Run recovery

If the run control is lost by the cobas® 4800 software an automatic run recovery process is started. Depending at what time point in a run the run control was lost the recovery process continues the run or aborts it. Run control can be lost for reasons like power drops, shutdown of the control unit, or connection or hardware problems.

Results of such runs are flagged with flag M6. The flag only indicates that run recovery was initiated but does not indicate if the run could be recovered by the cobas® 4800 system or not. To decide if the result is reportable analyze the result itself and all associated flags as you would do with any result.

Unloading the cobas x 480 instrument deck manually

All carriers have to be manually unloaded from the instrument deck if a run was aborted and the carriers are not automatically unloaded.

Take adequate precautions if the instrument deck has to be unloaded manually. The instrument deck or the carriers could be contaminated.

Make sure that you have read and understood the chapter General safety information. The following safety messages in particular are relevant:

Warning messages:
- Infection by samples and associated materials on page A-9
- Infection and injury due to sharp objects on page A-9

Caution messages:
- Skin inflammation or injury caused by reagents on page A-12

To manually unload the cobas x 480 instrument after a cobas x 480 instrument abort

1 In the wizard, click the Unload button.
2 If carriers are not unloaded automatically switch off the cobas x 480 instrument.
3 Clear all obstructions and remove carefully all carriers from the instrument deck.

   Be careful not to break the stop hooks. Unloading carriers manually causes stop hooks to break easily.
   Call Roche Service if there are any obstructions that can not be cleared.
4 Clean the instrument deck.
5 Switch on the cobas x 480 instrument.

   Check before switching on the cobas x 480 instrument that no obstructions are left on the instrument deck.
6 Perform daily maintenance.

   Do not manually remove tips from the pipetting channels. Call Roche Service if there are still tips on the pipetting channels after daily maintenance.

   ➤ For additional details, see Daily maintenance on page C-7
Problem reports

Each time a new error message is generated a problem report is created by the cobas® 4800 system. Problem reports are used by Roche Service to assist in troubleshooting cases. Problem reports are stored as ZIP-files in a predefined folder where they can be retrieved and sent to Roche Service when required. Problem reports older than 30 days are deleted automatically.

► To retrieve a problem report

1. Open Windows File Explorer and go to “C:\Documents and Settings\{CURRENT_USER}\Application Data\Roche Diagnostics\MTS {RELEASE_VERSION}\FseReport”.
2. Copy the requested problem report to a portable storage device.
3. Send the problem report to Roche Service together with a detailed problem description.

Remote support using cobas® link

The cobas® link is a remote support tool that allows remote access to the cobas® 4800 system in troubleshooting cases. In a remote support session the cobas® 4800 software is remotely operated by Roche Service. Call Roche Service to initiate a remote support session.

NOTICE

Do not operate the cobas® 4800 software during a remote support session.

► To initiate a remote support session

1. Request a remote support session at Roche Service.
   Roche Service initiates a remote session. A message is displayed on screen asking to allow remote access on this computer.
2. Confirm the displayed message.
   The remote support session starts. The session is terminated by Roche Service.
## Error messages

The source of a message is indicated in the message code as outlined in the following table.

<table>
<thead>
<tr>
<th>Message code</th>
<th>Message source</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5.10.xx</td>
<td>Messages created by the cobas® 4800 system.</td>
<td>2.5.10.22</td>
</tr>
<tr>
<td>2.5.20.xx</td>
<td>Messages created by the cobas x 480 instrument or the cobas z 480 analyzer.</td>
<td>2.5.20.13</td>
</tr>
<tr>
<td>2.5.30.xx</td>
<td>Messages created by the calculation module.</td>
<td>2.5.30.19</td>
</tr>
</tbody>
</table>

### Table D-5  
Message source

The following table lists the messages as they are displayed in the cobas® 4800 software.

- If there is no user action stated in the message table call Roche Service.
- Placeholders in the message table are printed in italic (e.g. xy).

**Table D-6 cobas® 4800 system messages**

<table>
<thead>
<tr>
<th>ID</th>
<th>Severity</th>
<th>Message</th>
<th>Solution / Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5.10.22</td>
<td>Error</td>
<td>Cannot start a new Run.</td>
<td>Check the state of the instruments.</td>
</tr>
<tr>
<td>2.5.20.10</td>
<td>Error</td>
<td>Instrument xy is not ready.</td>
<td>Check if the instrument is powered up and initialized.</td>
</tr>
<tr>
<td>2.5.20.11</td>
<td>Error</td>
<td>Wrong cobas z 480 Software Version: xy.</td>
<td>Check the instrument for the correct software version.</td>
</tr>
<tr>
<td>2.5.20.12</td>
<td>Error</td>
<td>Wrong cobas z 480 Instrument Filters installed: xy.</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>2.5.20.13</td>
<td>Error</td>
<td>Wrong cobas z 480 Instrument Block: xy</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>2.5.20.14</td>
<td>Error</td>
<td>Sample preparation cannot be started at this time because z480 is busy and will not be available in time for amplification/detection run.</td>
<td>Wait and try to start the run later. ☢️ For details, see Run scheduling on page B-42</td>
</tr>
<tr>
<td>2.5.30.13</td>
<td>Error</td>
<td>Scanned barcode xy is already used before.</td>
<td>The scanned barcode has already been used in this or in a previous run. Use new reagents, reservoirs, and consumables.</td>
</tr>
<tr>
<td>2.5.30.14</td>
<td>Error</td>
<td>The reagent has been expired at xy.</td>
<td>It is not allowed to use expired reagents. Use reagents that are not expired.</td>
</tr>
<tr>
<td>2.5.30.19</td>
<td>Error</td>
<td>Scanned barcode xy at position yz at track zx has been used before.</td>
<td>The scanned barcode has already been used in this or in a previous run. Use new reagents, reservoirs, and consumables.</td>
</tr>
<tr>
<td>2.5.30.20</td>
<td>Error</td>
<td>Wrong MWP loaded. Expected MWP: xy.</td>
<td>Mismatch occurred between loaded and expected microwell plate. Load the microwell plate xy into the cobas z 480 analyzer.</td>
</tr>
<tr>
<td>2.5.30.26</td>
<td>Error</td>
<td>The reagent xy has expired at yz.</td>
<td>It is not allowed to use expired reagents. Use reagents that are not expired.</td>
</tr>
<tr>
<td>2.5.30.29</td>
<td>Error</td>
<td>The run was aborted by the user.</td>
<td>Unload the instrument.</td>
</tr>
<tr>
<td>2.5.10.31</td>
<td>Error</td>
<td>On xy is yz of zx free (yz% full).</td>
<td>Archive and delete old data.</td>
</tr>
<tr>
<td>2.5.20.21</td>
<td>Error</td>
<td>Processing on cobas x 480 was aborted by the instrument.</td>
<td>Check the messages for further details.</td>
</tr>
<tr>
<td>2.5.20.22</td>
<td>Error</td>
<td>Error on cobas x 480.</td>
<td>Error state xy found. Check the messages for further details.</td>
</tr>
</tbody>
</table>
## Error messages

<table>
<thead>
<tr>
<th>ID</th>
<th>Severity</th>
<th>Message</th>
<th>Solution / Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5.20.23</td>
<td>Error</td>
<td>Error on <strong>cobas x 480</strong>.</td>
<td>The instrument is not switched on, not connected or defective. Check connections between instrument and control unit or switch on the instrument. Then click on the <strong>Refresh</strong> button.</td>
</tr>
<tr>
<td>2.5.30.31</td>
<td>Error</td>
<td>Processing on <strong>cobas x 480</strong> was aborted by the user.</td>
<td>User abort.</td>
</tr>
<tr>
<td>2.5.30.32</td>
<td>Error</td>
<td>An unhandled exception in <strong>cobas x 480</strong> RunFsm occurred: <code>xy</code></td>
<td>Check the messages for further details.</td>
</tr>
<tr>
<td>2.5.30.33</td>
<td>Error</td>
<td>An exception in <strong>cobas z 480</strong> UpdateRocessResults occurred: <code>xy</code></td>
<td>Error while updating acquisition records from the instrument.</td>
</tr>
<tr>
<td>2.5.20.32</td>
<td>Error</td>
<td>Instrument error has occurred: <code>xy</code>.</td>
<td>Instrument must be restarted.</td>
</tr>
<tr>
<td>2.5.20.33</td>
<td>Error</td>
<td>Software error has occurred: <code>xy</code>.</td>
<td>Instrument must be restarted.</td>
</tr>
<tr>
<td>2.5.20.35</td>
<td>Error</td>
<td>Hardware problem on the Instrument has occurred: <code>xy</code>.</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>2.5.20.40</td>
<td>Error</td>
<td>The run was aborted by the user.</td>
<td>Unload the instrument.</td>
</tr>
<tr>
<td>2.5.20.41</td>
<td>Error</td>
<td>The run was aborted by the instrument.</td>
<td>Unload the instrument.</td>
</tr>
<tr>
<td>2.5.20.42</td>
<td>Error</td>
<td>Error on <strong>cobas z 480</strong>.</td>
<td>Error state <code>xy</code> found. Check the messages for further details.</td>
</tr>
<tr>
<td>2.5.10.25</td>
<td>Fatal</td>
<td>File: <code>xy</code> has been modified!</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>2.5.20.31</td>
<td>Fatal</td>
<td>The <strong>cobas z 480</strong> assay file: <code>xy</code> is missing or corrupted.</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>2.5.20.20</td>
<td>Information</td>
<td>The <code>xy</code> has started on the <strong>cobas x 480</strong> device.</td>
<td></td>
</tr>
<tr>
<td>2.5.10.20</td>
<td>Warning</td>
<td>Wrong screen dpi-setting.</td>
<td>The current screen DPI-setting is <code>xy</code> dpi. Change DPI-setting to 96 dpi.</td>
</tr>
<tr>
<td>2.5.10.21</td>
<td>Warning</td>
<td>Wrong screen resolution.</td>
<td>The current screen resolution is <code>ab x cd</code>. Change screen resolution to 1280 x 1024.</td>
</tr>
<tr>
<td>2.5.10.23</td>
<td>Warning</td>
<td>'ShortDate' format is set incorrectly in Regional and Language Settings for the operating system.</td>
<td>In the <strong>Regional and Language Options</strong> in the <strong>Control Panel</strong> set the <strong>ShortDate</strong> format so that the day and the month have 2 digits or less and the year has at most 4 digits. Example MM/DD/YYYY or 06/01/2009.</td>
</tr>
<tr>
<td>2.5.10.24</td>
<td>Warning</td>
<td>'Decimal symbol' and 'Digit grouping symbol' are the same in Regional Options of the operating system.</td>
<td>Define the number and decimal separator differently in <strong>Regional Options</strong> in the <strong>Control Panel</strong>. Example: 1’000.00 not 1,000,0.</td>
</tr>
<tr>
<td>2.5.20.16</td>
<td>Warning</td>
<td>Lifetime of Lamp exceeded.</td>
<td>Exchange the Xenon lamp and restart the <strong>cobas z 480</strong> analyzer.</td>
</tr>
<tr>
<td>2.5.20.17</td>
<td>Warning</td>
<td>Lamp intensity is too low.</td>
<td>Exchange the Xenon lamp and restart the <strong>cobas z 480</strong> analyzer.</td>
</tr>
<tr>
<td>2.5.30.10</td>
<td>Warning</td>
<td>Reagent kit size does not match.</td>
<td>Expected kit size is 96. Using reagents from a 24 kit is not sufficient for this run. Use reagents from a 96 kit.</td>
</tr>
<tr>
<td>2.5.30.11</td>
<td>Warning</td>
<td>Scanned barcode (<code>xy</code>) is invalid.</td>
<td>Please use a valid <strong>cobas</strong>® 4800 reagent or consumable.</td>
</tr>
</tbody>
</table>

*Table D-6 cobas® 4800 system messages (continued)*
## 9 Troubleshooting and messages

### Error messages

<table>
<thead>
<tr>
<th>ID</th>
<th>Severity</th>
<th>Message</th>
<th>Solution / Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5.30.12</td>
<td>Warning</td>
<td>Scanned barcode (xy) identifies an object not requested here.</td>
<td>Scanned barcode (xy) does not match. The barcode of samples, reagents, reservoirs, or consumables required in this step. Check to ensure that the correct ones are used.</td>
</tr>
<tr>
<td>2.5.30.15</td>
<td>Warning</td>
<td>Incorrect reagent for this loading step.</td>
<td>The wrong reagent was scanned. Scan the correct reagent.</td>
</tr>
<tr>
<td>2.5.30.17</td>
<td>Warning</td>
<td>The consumable (xy) of type (yz) at position (zx) on track (zy) is not a cobas(^{®}) 4800 consumable.</td>
<td>Replace consumable (xy) of type (yz) at position (zx) on track (zy) with a valid cobas(^{®}) 4800 consumable.</td>
</tr>
<tr>
<td>2.5.30.18</td>
<td>Warning</td>
<td>Barcode (xy) at position (yz) on track (zx) is not valid.</td>
<td>Scan valid barcode (xy) at position (yz) on track (zx).</td>
</tr>
<tr>
<td>2.5.30.22</td>
<td>Warning</td>
<td>MWP barcode could not be read.</td>
<td></td>
</tr>
<tr>
<td>2.5.30.24</td>
<td>Warning</td>
<td>This reagent reservoir (xy) is not a cobas(^{®}) 4800 consumable.</td>
<td>This reagent reservoir type was scanned. Replace the incorrect reagent reservoir type.</td>
</tr>
<tr>
<td>2.5.30.25</td>
<td>Warning</td>
<td>This reagent reservoir is not required in this reagent loading step.</td>
<td>This reagent reservoir type was scanned. Replace the incorrect reagent reservoir type.</td>
</tr>
<tr>
<td>2.5.30.27</td>
<td>Warning</td>
<td>Barcode is not specified.</td>
<td>Check if barcode is according to specification.</td>
</tr>
<tr>
<td>2.5.30.28</td>
<td>Warning</td>
<td>Barcode (xy) is invalid.</td>
<td>Check if barcode is according to specification.</td>
</tr>
<tr>
<td>2.5.30.29</td>
<td>Warning</td>
<td>On (xy) is (yz) of (zx) free ((yz)% full).</td>
<td>Archive and delete old data.</td>
</tr>
<tr>
<td>2.5.30.34</td>
<td>Warning</td>
<td>No connection to cobas (x) 480.</td>
<td>The instrument is not switched on, not connected, or defective. Check connections between instrument and control unit or switch on the instrument. Then click on the Refresh button.</td>
</tr>
</tbody>
</table>
| 2.5.30.34 | Warning  | The test method has been aborted by the instrument, but after SamplePrepFinished was sent. This means all samples are valid and process will continue. | Error type: \(xy\)  
Error description: \(yz\) |
| 2.5.30.36 | Warning  | Operator advice message occurred: \(xy\).                             |                                                                                   |

### Table D-6  cobas\(^{®}\) 4800 system messages (continued)
Result flags

In this chapter the result flags are explained.

In this chapter

About result flags ................................................................. D–19
List of result flags .............................................................. D–21
About result flags

Flags are automatically generated with results if during processing certain technical checks were not passed, if the result exceeds or does not reach predefined limits, or if technical or mechanical problems occurred on the cobas x 480 instrument or the cobas z 480 analyzer during a run.

The flags may originate from either the cobas x 480 instrument, the cobas z 480 analyzer, the cobas® 4800 software, or the calculation step.

For details on individual flags, see List of result flags on page D-21.

Results that did not have flags associated with them can be considered as technically correct. However, not all results that had flags associated with them are incorrect. Some flags are warnings rather than error messages and do not necessarily invalidate the result(s).

Flags are displayed and printed together with the results in a special Flags column.

To display result flag information

1. Click the Results tab.
2. Select a run.
3. In the Test Results area, select a result that has a flag entry in the Flags column and click the Detail button.
   - The Detail area is displayed.
4. In the Detail area, click the Flags tab.
All flags that were generated for this result are displayed.

Each flag is identified by its unique ID, and information on the nature of the reason for each flag is displayed.
List of result flags

The source of a flag is indicated in the flag code as outlined in the following table.

<table>
<thead>
<tr>
<th>Flag code</th>
<th>Flag source</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>Calculation</td>
<td>C1</td>
</tr>
<tr>
<td>M</td>
<td>Multiple or other reasons</td>
<td>M6</td>
</tr>
<tr>
<td>R</td>
<td>Result interpretation</td>
<td>R20</td>
</tr>
<tr>
<td>X</td>
<td>cobas x 480 instrument</td>
<td>X2</td>
</tr>
<tr>
<td>Z</td>
<td>cobas z 480 analyzer</td>
<td>Z1</td>
</tr>
</tbody>
</table>

**Table D-7** Flag source

The following table lists all result flags of the cobas® 4800 system that are user relevant.

<table>
<thead>
<tr>
<th>Flag code</th>
<th>Severity</th>
<th>Description</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Error</td>
<td>General exception raised.</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>C2 ... C322</td>
<td>Calculation flag.</td>
<td></td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>M1</td>
<td>Error</td>
<td>Software error. Additional information can be found in the alarm messages and the trace log files.</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>M2</td>
<td>Error</td>
<td>Aborted by the user.</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>M5</td>
<td>Warning</td>
<td>PCR-only workflow.</td>
<td>None. Flag is for information only.</td>
</tr>
<tr>
<td>M6</td>
<td>Warning</td>
<td>Cobas 4800 application was temporarily unavailable during the run. Run results were retrieved by data recovery process.</td>
<td>None. Flag is for information only. For details, see Run recovery on page D-12</td>
</tr>
<tr>
<td>R1</td>
<td>Error</td>
<td>General exception raised.</td>
<td>Contact Roche Service.</td>
</tr>
<tr>
<td>R2 ... R19</td>
<td>Result interpretation flag.</td>
<td></td>
<td>Contact Roche Service.</td>
</tr>
</tbody>
</table>
| R20       | Warning  | The positive external control is invalid. | 1. Repeat the run.  
2. If the problem persists, contact Roche Service. |
| R21       | Warning  | The negative external control is invalid. | 1. Repeat the entire run.  
2. If the problem persists, contact Roche Service. |
| X1        | Error    | The run was aborted due to one or more instrument error(s). | 1. Check if instrument deck is contaminated or if there are lost tips on the instrument deck.  
   For details how to unload the cobas x 480 instrument manually, see Unloading the cobas x 480 instrument deck manually on page D-12  
2. Contact Roche Service. |
| X2        | Info     | Patient sample barcode was entered manually. | None. Flag is for information only. |
| X3        | Error    | Clot detected. Sample is not processed | 1. Check the sample for clots.  
2. For CT/NG swab samples, remove swab from sample vial.  
3. Rerun the sample. |
| X4        | Error    | Processing of the sample was aborted due to one or more pipetting error(s). | Insufficient sample volume is the most likely reason.  
1. Make sure there is enough sample volume.  
2. For CT/NG swab samples, remove swab from sample vial.  
3. Rerun the sample. |
**List of result flags**

<table>
<thead>
<tr>
<th>Flag code</th>
<th>Severity</th>
<th>Description</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>X5</td>
<td>Error</td>
<td>The run was aborted because the allowed reagent onboard time was exceeded.</td>
<td>Repeat the entire run with fresh reagents.</td>
</tr>
<tr>
<td>X6</td>
<td>Error</td>
<td>The run was aborted because Working Master Mix with extract timed out after sample preparation had finished.</td>
<td>Repeat the entire run with fresh reagents.</td>
</tr>
<tr>
<td>X7</td>
<td>Error</td>
<td>The run was aborted because one or more pipetting error(s) prevented proper processing of positive or negative control.</td>
<td>Insufficient reagent volume is the most likely reason. Repeat the entire run with fresh reagents.</td>
</tr>
</tbody>
</table>
| X8        | Error    | Sample was not processed due to mechanical error in pipetting channel. | 1. Perform daily maintenance.  
2. Rerun the sample.  
3. If the problem persists, contact Roche Service. |
| X9        | Info     | An error occurred during the unload process of cobas x 480. | 1. Manually unload the cobas x 480 instrument.  
2. Check the cobas x 480 instrument for damages and restart the cobas x 480 instrument.  
3. Continue the run on the cobas z 480 instrument. |
| X10       | Error    | The run was aborted because insufficient number of tips was loaded. | Repeat the entire run. |
| X11       | Error    | The run was aborted because cover was opened or a carrier was removed manually during the run. | Repeat the entire run. |
| Z1        | Error    | Hardware or software error from the instrument. The run was aborted. | Contact Roche Service. |

Table D-8  List of cobas® 4800 system flags  (continued)
Glossary

A

Amplification  The process of producing many DNA copies from one original DNA or RNA target region. PCR is a nucleic acid amplification technique.

Anneal  The biochemical process of hybridizing or binding two segments of complementary nucleic acid.

Autoloader  The hardware assembly on the cobas x 480 instrument that enables automatic loading of carriers placed on the loading deck. It consists of a loading head movable in the Y direction, which draws the items into the cobas x 480 instrument and can read the barcodes on them.

C

Controls  Reagent formulated to produce known results that are processed like samples. The cobas® 4800 software monitors control results. Each run requires a positive and a negative control.

Control unit  A personal computer that runs the Microsoft Windows XP Professional operating system and the cobas® 4800 software.

Ct value  The amplification/detection cycle where the growth curve crosses a specific fluorescence level and the growth rate can be observed.

Deepwell plate  Plate used for extraction on the cobas x 480 instrument.

Denaturation  The process of separating double stranded DNA into single strands by breaking the hydrogen bonds.

Detection  Obtaining measurements to determine whether a sample is reactive for the target analyte. Fluorescence measurements are made at selected temperatures and times during the amplification process. When the run is complete data are analyzed to determine the presence of the amplified products from the target and internal control nucleic acid sequences.

DNA  Deoxyribonucleic Acid (DNA) is the genetic material that is passed from parent to progeny and propagates the characteristics of the species in the form of genes it contains and the proteins for which it codes. DNA contains the following four nucleotides: dATP, dCTP, dTTP, and dGTP.

I

Instrument deck  The work surface of the cobas x 480 instrument, where pipetting takes place. It is organized as a left-to-right series of tracks, into which the autoloader draws carriers.

L

LAN  Local Area Network. The cobas® 4800 system control unit is connected to the cobas x 480 instrument and the cobas z 480 analyzer.

LED  Light Emitting Diode.

LIS  Laboratory Information System. A computerized system for entering, managing and reporting laboratory information. Information includes but is not limited to patient demographics, test orders, and test results.

Loading deck  The external shelf at the front of the cobas x 480 instrument. It provides a surface onto which carriers can be placed before the autoloader draws them into the instrument.

M

Magnetic glass particles  Used in combination with other reagents to bind nucleic acids, allowing separation of impurities during washing.

MGP  see Magnetic Glass Particles.

Microwell plate  Plate used for amplification and detection. The 96-well plate is barcoded and has to be sealed with a special sealing film before inserting into the cobas z 480 analyzer.
**Glossary**

**PCR** - XML

**PCR**  
Polymerase Chain Reaction. The in vitro process used to amplify short specific target nucleic acid sequences. PCR is performed by cycling the temperature of the amplification mixture according to a set profile. The profile generally consists of denaturation and annealing.

**Pipetting channel**  
A hardware assembly mounted on the pipetting arm. It can pick up and eject tips, aspirate and dispense liquid, and detect liquid level in tubes. There are 8 pipetting channels working in parallel.

**Plate carrier**  
Carrier for deepwell plate and microwell plate on the cobas x 480 instrument.

**Reagent reservoir**  
The reagent reservoirs hold the reagents used for sample preparation. The reagent reservoirs are barcoded and are filled manually by the operator (scan-scan-pour principle) for each run. Reagent reservoirs are available in two sizes: 200 mL and 50 mL.

**Sample carrier**  
Used to load unprocessed samples onto and to unload processed samples from the cobas x 480 instrument.

**Scan-scan-pour principle**  
To minimize handling errors the reagent reservoirs are filled and placed using the scan-scan-pour principle.  
1. Scan the barcode of the reagent vial.  
2. Scan the barcode of the reagent reservoir.  
3. Pour the reagent in the scanned reagent reservoir.  
4. Place the filled reagent reservoir onto the reagent reservoir carrier.

**Target**  
The DNA or RNA target region that is detected and amplified during PCR.

**Teaching needles**  
Eight titanium pipette tips on the cobas x 480 instrument that are used to automatically check of each pipetting channel. The teaching needles are stored near the waste station, next to the tip waste bag.

**Thermal block cycler**  
Programmable temperature block in the cobas z 480 analyzer. The thermal cycler rapidly changes temperature according to the amplification profile.

**Tip**  
A disposable tip for pipetting. The tips used by the cobas x 480 instrument are capable of transferring up to 1000 microliters of liquid per pipetting operation. The tip includes a built-in filter that prevents the possibility of liquid inside the tip entering the pipetting channel hardware.

**Tip rack carrier**  
The tip rack carriers on the cobas x 480 instrument hold the tip racks with the disposable pipetting tips.

**Tip rack**  
The tip racks on the cobas x 480 instrument holding the disposable pipetting tips (CORE Tips with filter 1mL).

**UPS**  
Uninterrupted power supply.

**XML**  
Extensible Markup Language.
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