cobas® Synergy software

For use with **cobas**® 6800/8800 Systems, **cobas**® 5800 System, Microlab® STAR IVD, and Microlab® STARlet IVD

Safety Guide

Publication version 6.0

Software version 1.5

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0	December 2015	First version
1.1	1.0	May 2016	Use of complete product name (following changes in the User Assistance)
2.0	1.1	December 2016	Terminology adapted
3.0	1.2	August 2017	Intended use
4.0	1.3	January 2019	The **cobas**® **Synergy** software version 1.3 can be used together with **cobas**® 6800/8800 Systems software versions 1.2.14 and 1.3.9.
5.0	1.4	December 2019	Update for **cobas**® **Synergy** software version 1.4 to be used together with analytic software versions 1.3.9 and 1.4.
5.1	1.4	November 2020	Update for **cobas**® **Synergy** software version 1.4 patch 1 to be used together with analytic software versions 1.3.9 and 1.4.7.
6.0	1.5	December 2021	Update for **cobas**® **Synergy** software version 1.5 to be used together with analytic software versions 1.4.7 (**cobas**® 6800/8800 Systems) and 1.0 (**cobas**® 5800 System).

Revision history

Edition notice

This publication is intended for operators of the **cobas**® **Synergy** software for use with **cobas**® 6800/8800 Systems, **cobas**® 5800 System, Microlab® STAR IVD, and Microlab® STARlet IVD.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **User Assistance** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- A software reference
- Configuration information
- Background information

The **Safety Guide** contains important safety information. You must read the Safety Guide before operating the Microlab® STAR IVD and Microlab® STARlet IVD.

The **User Guide** focuses on routine operation and maintenance. The chapters are organized according to the normal operation workflow.

For information about the **cobas**® 6800/8800 Systems and the **cobas**® 5800 System, refer to the respective User Assistance.

For test-specific information, refer to the **Instructions for Use** of the respective tests.

For information about the optional pre-analytical systems, refer to the respective user documentation.

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Contact adresses

For **cobas**® **Synergy** software:
Biomedical Data Solutions
Centrum Point
Third Avenue
Centrum 100
Burton upon Trent
DE14 2WD
United Kingdom

The manufacturer of the Microlab® STAR IVD and Microlab® STARlet IVD is HAMILTON Bonaduz AG (Via Crush 9, CH-7402 Bonaduz, Switzerland).
Refer to the manufacturer's user manual of the respective instruments for contact addresses and approvals information.

Advena Ltd.
Tower Business Centre, 2nd Flr.
Tower Street
Swatar
BKR 4013 Malta

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Distributed in the United States by:
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256
USA

Roche affiliates

A list of all Roche affiliates can be found at:

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

eLabDoc

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

dialogportal.roche.com

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

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Intended use

The **cobas® Synergy** software is intended to be used for the management of data regarding samples to be processed for individual testing and pooling. The software collects data for samples that have been pooled and analyzed, which allows the user to review results against individual samples and samples that have been pooled, creating output files from the data that can be sent to a laboratory information system.

cobas® Synergy software is intended for use by laboratory staff who are trained in its use and are familiar with the associated test and instruments.

Symbols and abbreviations

Product names

Except where the context clearly indicated otherwise, the following product names and descriptors are used.

Product name	Descriptor
cobas® Synergy solution	solution
cobas® Synergy core	core
cobas® Synergy software	software
Microlab® STAR IVD	pooling instrument
Microlab® STARlet IVD	pooling instrument
cobas® 6800/8800 Systems	analytic system
cobas® 5800 System	analytic system

Product names

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ANSI	American National Standards Institute
CSA	Canadian Standards Association
EC	European Community
EN	European standard
IEC	International Electrical Commission
IVD	In vitro diagnostic
LIS	Laboratory information system
n/a	not applicable
RF	radio frequency
UPS	Uninterruptible power supply

Abbreviations

Abbreviation	Definition
WEEE	Waste Electrical and Electronic Equipment

Abbreviations

Introduction

⚠ General attention

To avoid serious or fatal injury, read this publication thoroughly before you use the pooling instrument.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the pooling instrument in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use.
  This publication must always be easily accessible.

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6-2011 standard. Familiarize yourself with the following meanings and icons:

⚠ Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the components of the **cobas® Synergy** solution, injury, or death.

These symbols and signal words are used for specific hazards:

⚠ WARNING!

Warning...

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

⚠ CAUTION!

Caution...

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

NOTICE!

Notice...

- ...indicates a hazardous situation that, if not avoided, may result in damage to the system.

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

Tip...

...indicates additional information on correct use or useful tips.

Safety precautions

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

In this section

Operator qualification

Insufficient knowledge and skills

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation and maintenance unless Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche Service representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow good laboratory practices, especially when you work with biohazardous material.

Safe and proper use of the pooling instrument

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items:
  - Eye protection with side shields
  - Fluid-resistant lab coat
  - Approved lab gloves
  - Face shield if there is a chance of splashing or splattering
- Follow good laboratory practices and regularly change lab gloves to minimize the risk of infection and contamination (especially after contact with waste or sample material).

Installation

Risk of personal injury or damage to the pooling instrument.

- Installation must be performed by trained Roche Service representatives only.

Correct use

- Use the pooling instrument only as described in the **cobas® Synergy** software User Assistance.

Operating conditions

Operation outside of the specified ranges may lead to incorrect results or malfunction of the pooling instrument.

- During operation, the pooling instrument must be shielded from sunlight and intense artificial light.
- Position the pooling instrument in the laboratory in a way permitting personnel to access the front and sides of the pooling instrument.
- Maintenance (daily maintenance, weekly maintenance, and periodic verification performed by Roche Service representatives) is a mandatory part of the work routine.
- Keep the user documentation in a safe place to ensure it is not damaged and remains available for use. The documentation must be easily accessible at all times.

Approved parts

Use of nonapproved parts or devices may result in malfunction of the pooling instrument and may render the warranty null and void.

- Only use parts and devices approved by Roche Diagnostics.
- Only certified technicians are authorized to perform mechanical maintenance on the pooling instrument.

Authorized access

Unauthorized access to the components of the **cobas® Synergy** solution can result in data loss, solution damage or solution unavailability.

- Only authorized persons may access solution components.

Miscellaneous safety precautions

Power interruption

A power failure or momentary drop in voltage may damage the pooling instrument or lead to data loss.

- Perform regularly backups of measurement results.
- An uninterruptible power supply (UPS) is recommended.

Electromagnetic fields

Although the pooling instrument conforms to European norms with regards to interference immunity, exposure to electromagnetic RF fields, or direct discharge of static electricity can negatively affect liquid level detection ability.

- Keep the pooling instrument away from equipment that emits electromagnetic RF fields in the laboratory.
- Minimize static electricity in the immediate environment of the pooling instrument.

Relocation and transportation

Risk of personal injury or damage to the pooling instrument.

- Never lift a fully installed pooling instrument to transport it from one place to another. It must be reinstalled in the new work location by an authorized Roche Service representative.

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before operating the solution, read the warning messages carefully.

In this section

Electrical safety

Electric shock

Removing the covers or panels of electronic equipment can cause electric shock due to high-voltage parts inside.

- Do not attempt to work on any electronic equipment.
- Do not remove any cover or panel of the pooling instrument.
- Only Roche Service representatives may install, service, and repair the pooling instrument.

Related topics

- Safety labels on the pooling instrument (25)

Optical safety

Blindness due to intense barcode reader light

The intense light of a laser or LED barcode reader may severely damage your eyes or result in exposure to hazardous radiation.

- Do not stare into the beam of a laser or LED barcode reader.
- Do not remove the housing from barcode readers.
- Do not perform any maintenance actions on barcode readers. If you experience problems with the barcode readers, contact your Roche Service representative.
- Perform only the procedures described in operating instructions. Performing unauthorized procedures may result in exposure to hazardous radiation.

Biohazardous materials

Infectious samples

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples containing material of human origin are potentially biohazardous.

- Follow good laboratory practices, especially when working with biohazardous material.
- Keep all covers closed while the pooling instrument is operating.
- Wear appropriate personal protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If sample or waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Operator infection and injury

Contact with pooling instrument mechanisms or with the pooling instrument chassis or covers may result in personal injury and infection.

- Whenever possible, keep the front cover of the pooling instrument closed.
- Always ensure that the pooling instrument is off or in **Maintenance** status, before you work with an opened cover (for example, for cleaning or maintenance).
- Do not open the front cover while the pooling instrument is performing maintenance.
- Be careful not to hit your head when the covers are open.
- Pay attention to the covers during automatic movement, check for obstructions and keep out of reach.
- Do not touch any parts of the pooling instrument other than those specified.
- Never reach into the pooling instrument while parts are moving.
- Carefully observe all instructions given in this publication.

Infection by biohazardous material

- Do not eat, drink, or smoke in laboratory work areas.
- Wear personal protective equipment whenever preparing consumables or when cleaning.
- Change lab gloves frequently.
- Wear eye protection when handling samples. Wash hands thoroughly afterwards.

Smoke due to electrical malfunction

Electrical malfunction can result in the emission of hazardous smoke. Inhaling smoke emitting from the pooling instrument can lead to personal injury.

- If you see smoke coming from the pooling instrument:
  - Avoid inhaling
  - Disconnect from power supply
  - Contact Roche Service immediately

Troubleshooting procedures

Corrective measures in troubleshooting procedures can result in exposure to biohazardous materials.

- Always follow the troubleshooting procedures given in software wizards and/or in the user documentation.
- Wear appropriate personal protective equipment when implementing corrective measures.

Waste

Infectious waste

Contact with solid waste may result in infection. All materials and mechanical components associated with the solid waste unit are potentially biohazardous.

- Wear appropriate personal protective equipment. Take extra care when working with lab gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Environmental harm

The pooling instrument generates solid waste. Solid waste is potentially biohazardous. Improper disposal may contaminate the environment.

- Treat solid waste as infectious waste.
- Dispose of waste in accordance with the local regulations.

Related topics

- Safety labels on the pooling instrument (25)
- Safety information for disposal (28)

Explosion and fire

Fire risk through use 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 pooling instrument is connected to the power supply and do not use sprays in the vicinity of the pooling instrument.
- Do not spray directly at the autoload unit or at electrical boards or connectors.
- Do not clean the pooling instrument in the vicinity of open flames or devices that can create sparks.
- Do not use hot air blowers to dry the pooling instrument. The liquids used for cleaning are flammable.

Caution messages

⚠ List of caution messages

- Before operating, read the caution messages carefully. Failure to observe them may result in minor or moderate injury.

In this section

Mechanical safety

Moving parts

Contact with moving parts may result in personal injury.

- Keep all covers closed and in place while the pooling instrument is operating. An interlock system prevents operation of moving parts when the covers are open.
- Always ensure that the pooling instrument is off or in **Maintenance** status, before you work with an opened cover (for example, for cleaning or maintenance).
- Do not touch any parts of the pooling instrument except those parts specified. Keep away from moving parts during operation.
- During operation and maintenance, carefully follow the instructions.

Related topics

- Safety labels on the pooling instrument (25)

Proper identification

Incorrect data caused by exchanging sample positions

Exchanging positions of sample tubes or switch aliquot plates after they have been identified by the barcode reader can result in incorrect test data or a hardware error.

- Do not exchange positions of sample tubes or switch aliquot plates after they have been identified by the barcode reader.

Contamination

Contamination due to improper loading

Incorrect loading of the pooling instrument can result in contamination.

- Handle any one-track carrier (such as a sample carrier) with particular care, as this type of carrier can fall over and cause injury or contamination.
- Make sure the carriers are inserted completely until they touch the stop hooks on the autoload tray.
- Make sure there are no carriers loaded on the same tracks as already loaded carriers on deck.
- Perform weekly maintenance if any parts of the pooling instrument, carriers, or racks become contaminated.

Collection media and other working solutions

Skin inflammation or injury

Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- When you handle reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate personal protective equipment.
- Observe the instructions given in the Instructions for Use for the test.
- Observe the information given in Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If reagents, detergents, or other cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Contaminated samples, foam, clots, films, or bubbles

Incorrect results may occur due to insoluble contaminants, foam, fibrin clots, films, or bubbles in samples.

- Ensure good sample preparation and handling techniques to avoid the formation of foam, clots, and bubbles in all samples.
- Make sure that the samples contain no insoluble contaminants, such as fibrin or dust.

Evaporation of samples

Evaporation of samples may lead to incorrect or invalid results.

- Sample material may evaporate if left open. Do not leave samples open for any length of time.
- For information about sample stability, see the applicable *Instructions for Use*.

Incorrect results due to reuse of container caps

Reuse of caps for containers and tubes can lead to contamination, resulting in an incorrect result.

- Do not reuse caps.

Fatigue due to long hours of operation

Fatigue due to long hours of operation

Looking at the monitor over an extended time may lead to eye strain or body fatigue.

- Take a break to relax, in accordance with your laboratory's standard operating procedures or local regulations.

Electromagnetic interference

Electromagnetic interference

Strong electromagnetic fields (originating from unshielded radio frequency sources) can interfere with proper operation and may lead to malfunction of the pooling instrument and incorrect results.

- Do not use this pooling instrument near sources of strong electromagnetic fields because these fields can interfere with the proper operation.
- Evaluate the electromagnetic environment before you operate the pooling instrument.
- Take measures to mitigate the interference.

IT security

Data loss or unavailability of the solution due to malicious software or unauthorized access

Malicious software or unauthorized access can result in data loss or solution unavailability.

To avoid infection by malicious software or the unauthorized access and misuse of the solution, the following recommendations are essential:

- Do not install and/or execute any other software on the solution.
- Make sure other computers and services on the network (for example, the LIS, archiving share, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- The Roche-provided firewall is mandatory and part of the solution.
- Make sure that system backup and archive files are protected from any unauthorized access and disaster, this includes: remote storage location; disaster recovery sites; secure transfer of backup files.
- Prevent credential theft.
  - Use strong passwords.
  - Do not share passwords.
  - Do not write passwords down.
  - Do not use the same credentials on multiple pooling instruments.

Disclosure of confidential data due to entry in the comment field

Adding personal health information of patients to open text fields increases the risk of privacy incidents and exposure of sensitive data. If you enter confidential data (such as patient data, test results interpretation, service account credentials) into the comment field, it can be viewed by unauthorized users.

- Do not enter any confidential patient-relevant information into a comment field. There is the risk of unauthorized access to patient data.

Disclosure of confidential data due to patient information being returned by the LIS

Any data not requested in the order query can be recorded in a communication log file.

- Set up the LIS so that it does not return patient information in addition to the data requested by the LIS.

Notices

List of notices

Failure to observe the notices may result in damage to the solution.

- Before operating, read the notices contained in this summary carefully.

In this section

Moving parts

Damage to the pooling instrument due to contact with moving parts

Contact with moving parts may bend the pipette tips or damage some component.

- Keep all covers closed and in place while the pooling instrument is operating.
- Do not remove carriers from the pooling instrument until they have been transferred back to the autoload tray.
- Whenever it is necessary to move pipetting channels on the x-arm, move them gently by pushing close to their y-slide (carrier that allows pipetting channels to move away from and towards the operator). Never force them as this may lead to damage. If possible, switch on the pooling instrument as this will result in a smoother motion when pipetting channels have to be moved on the x-arm.

Circuit breakers and fuses

Circuit breakers and fuses

Improper use may result in damage to the pooling instrument.

- If one of the circuit breakers or fuses blows, do not attempt to operate the pooling instrument before contacting your Roche Service representative.

Pipetting channels

Damage to the pooling instrument due to improper use

Leaving pipette tips on the pipetting channels for a long period of time may cause damage to the pipetting channel O-rings.

- Do not leave pipette tips on the pipetting channels for a long period of time (for example, overnight).
- Remove the pipette tips with daily maintenance.

Proper loading and handling of the pooling instrument

Damage to the pooling instrument due to improper loading

Incorrect loading of the pooling instrument can result in damage.

- Aliquot plates must be placed on the carrier so that well A1 is in the position defined in the user documentation.
- 5-position racks must be placed on the 5-position rack carrier so that the first rack is located immediately next to the carrier barcode label.

Interference due to incorrect handling

If the pooling instrument is positioned on a table containing storage cabinets, attempting to access cabinets underneath the pooling instrument during a run may interfere with automatic loading and unloading of carriers.

- Do not access cabinets underneath the pooling instrument during operation.

Spillage

Spilled liquid

Any liquid spilled on the pooling instrument may result in malfunction or damage.

- Place samples, reagents, or any other liquid only at the intended positions.
  Do not place samples, reagents, or any other liquid on the covers or other surfaces of the pooling instrument.
- When you remove or replace consumables, do not spill any liquid on the pooling instrument.
- If liquid does spill on the pooling instrument, wipe it up immediately and follow the applicable decontamination procedure. Wear appropriate personal protective equipment.
  Dispose of waste according to the local regulations.

Decontamination procedures are described in the *Decontamination* section in the User Assistance.

Safety labels on the pooling instrument

In this section

List of safety labels on the pooling instrument

Warning labels are placed on the pooling instrument to draw your attention to areas of potential hazard. Listed below are labels and the definitions according to the location on the pooling instrument.

The safety labels on the pooling instrument comply with the following standards: ANSI Z535, IEC 61010-1, IEC 60417, ISO 7000, or ISO 15223-1.

In addition to the safety labels on the pooling instrument, there are safety notes in the corresponding parts of the user documentation.

Only Roche Service representatives are to replace damaged labels. For replacement labels, contact your local Roche Service representative.

Electrical
If you access a part of the pooling instrument marked with this label, contact with electrical components may cause an electric shock.
Refer to the user documentation for instructions on safe operation.

General warning
Potential hazards located near this label may lead to death or serious injury.
Refer to the user documentation for instructions on safe operation.

Laser transmitter
There is a danger of contact with laser light or severe damage to the eyes.
Do not stare into the laser transmitter.

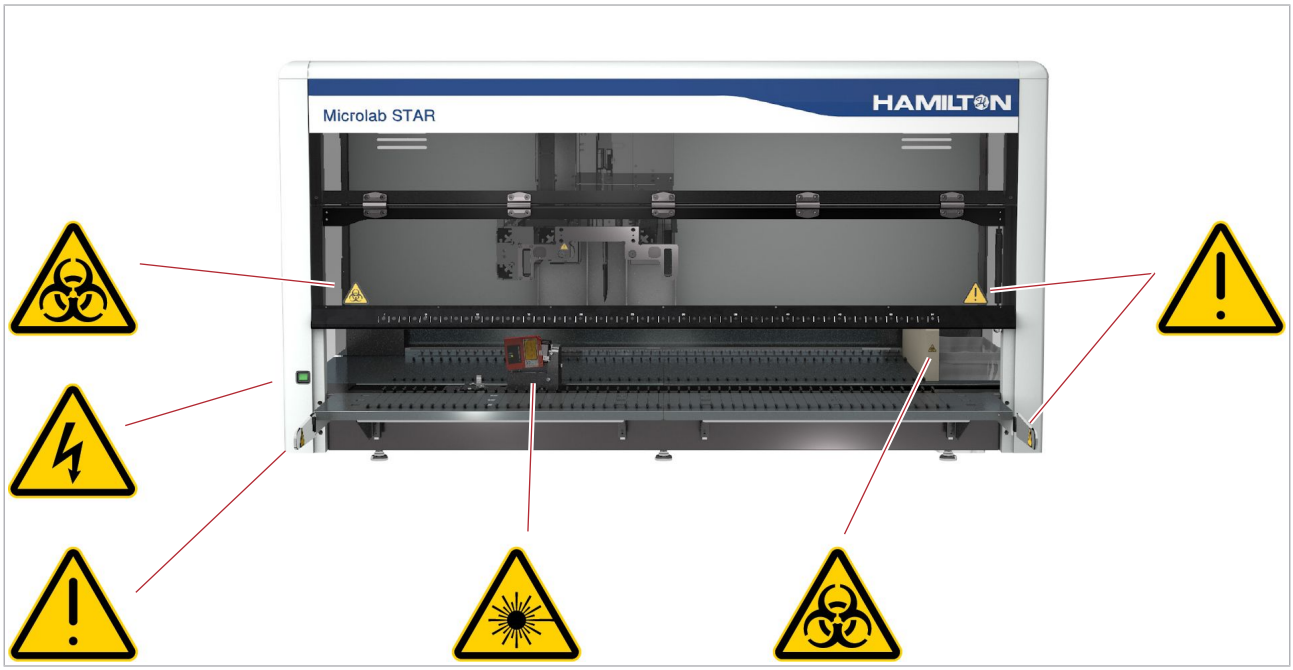
Biohazard
Potentially biohazardous materials are used near this label.
Observe relevant good laboratory practices on safe usage.

The safety messages give more detailed information about potentially hazardous situations that may arise during daily operation, or when carrying out maintenance actions.

When working with the pooling instrument, observe both the safety labels on the pooling instrument and the safety messages in the user documentation.

Location of safety labels on the pooling instrument

The image below shows the location of the safety labels on the Microlab® STAR IVD. The safety labels on the Microlab® STARlet IVD are placed on the same places.



Location of safety labels on the Microlab® STAR IVD

Safety information for lasers

The pooling instrument includes a barcode reader. The pooling instrument is a class 2 laser product. Do not stare into the beam.

The mentioned classes refer to the standard IEC 60825-1:

- Class 1: Eye-safe under normal operating conditions.
- Class 2: Visible lasers. Eye-safe for accidental viewing. It may not be safe to deliberately stare into the laser beam, overcoming the natural aversion response to the bright light.

Module	Wavelength	Operating voltage	Max. output	Remark
Barcode reader	650–690 nm	10–30 V(DC)	1.3 mW	Class 2 laser

Lasers on the pooling instrument

Safety information for disposal

Disposal information

Infection by a biohazardous pooling instrument

- Treat the pooling instrument as biohazardous waste. Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the pooling instrument.
- Dispose of the pooling instrument according to the local regulations. For more information, contact your Roche Service representative.

Electronic equipment

Disposal of electronic equipment
This symbol appears on any component of the **cobas® Synergy** solution that is covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE).

You must dispose of these items through designated collection facilities appointed by government or local authorities.

Contact your city office, waste disposal service, or your Roche Service representative for more information about disposal of your old product.

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

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Switzerland

www.roche.com