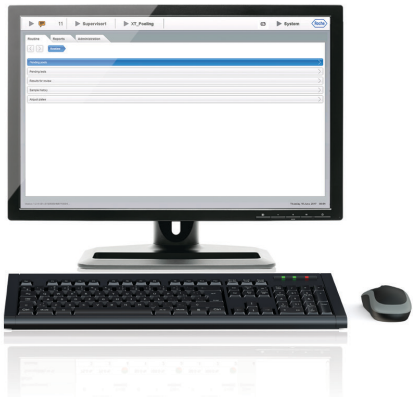
cobas Synergy software

For use with **cobas**® 6800/8800 Systems (software version 1.2.13) and Microlab® STAR IVD
Safety Guide Version 3.0

Software version 1.2



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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

Revision history

Edition notice

This publication is intended for operators of the **cobas Synergy** software for use with **cobas**® 6800/8800 Systems (software version 1.2.13) and Microlab® STAR 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 pooling instrument.

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, 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.

Contact addresses

For **cobas Synergy** software:
Stratec Biomedical UK Limited
Centrum Point
Third Avenue
Centrum 100
Burton upon Trent
DE14 2WD
United Kingdom

For Microlab® STAR IVD:
HAMILTON Bonaduz AG
Via Crusch 8
CH-7402 Bonaduz
Switzerland
Made in Switzerland

Distributed by:
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana
USA

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Preface

Intended use

cobas Synergy software manages samples to be processed on pre-analytic instruments as a front-end to the **cobas**® 6800/8800 Systems. The **cobas Synergy** solution collects data from pooling and analyzer instruments which allows the user to review results against individual samples and samples which 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 blood establishment personnel who are trained in its operation and are familiar with the associated tests and instruments.

Conventions used in this publication

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
cobas® 6800/8800 Systems	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

Abbreviations

Abbreviation	Definition
RF	radio frequency
UL	Underwriters Laboratories Inc.
UPS	Uninterruptible power supply
WEEE	Waste Electrical and Electronic Equipment

Abbreviations

Introduction

⚠ General attention

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

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the 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 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 instrument.

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

Correct use

- Use the Microlab® STAR IVD only for pooling samples as described in the **cobas Synergy** core user documentation.

Operating conditions

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

- During operation, the instrument must be shielded from sunlight and intense artificial light.
- Position the instrument in the laboratory in a way permitting personnel to access the front and sides of the 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 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 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 instrument or lead to data loss.

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

Electromagnetic fields

Although the Microlab® STAR IVD 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 Microlab® STAR IVD away from equipment that emits electromagnetic RF fields in the laboratory.
- Minimize static electricity in the immediate environment of the Microlab® STAR IVD.

Relocation and transportation

Risk of personal injury or damage to the instrument.

- Never lift a fully installed 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 instrument.
- Only Roche Service representatives may install, service, and repair the instrument.

Related topics

- Safety labels on the instrument (24)

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 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 instrument mechanisms (for example, sample pipetter, reagent pipetter, main handler, transfer module handler, processing module handler, reagent cassette handler, etc.) or with the instrument chassis or covers may result in personal injury and infection.

- Whenever possible, keep the front cover of the instrument closed.
- Always ensure that the 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 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 instrument other than those specified.
- Never reach into the 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 instrument can lead to personal injury.

- If you see smoke coming from the 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 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 instrument (24)
- Safety information for disposal (27)

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 instrument is connected to the power supply and do not use sprays in the vicinity of the instrument.
- Do not spray directly at the autoload unit or at electrical boards or connectors.
- Do not clean the instrument in the vicinity of open flames or devices that can create sparks.
- Do not use hot air blowers to dry the 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 instrument is operating. An interlock system prevents operation of moving parts when the covers are open.
- Always ensure that the 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 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 instrument (24)

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 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 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 instrument and incorrect results.

- Do not use this instrument near sources of strong electromagnetic fields because these fields can interfere with the proper operation.
- Evaluate the electromagnetic environment before you operate the 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 instruments.

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 instrument due to contact with moving parts

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

- Keep all covers closed and in place while the instrument is operating.
- Do not remove carriers from the Microlab® STAR IVD 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 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 instrument.

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

Pipetting channels

Damage to the instrument due to improper use

Leaving pipette tips on the pipetting channels for a long period of time may cause damage to the pipette tip 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

Damage to the instrument due to improper loading

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

- Do not access cabinets underneath the instrument during operation.

Spillage

Spilled liquid

Any liquid spilled on the 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 instrument.
- When you remove or replace consumables, do not spill any liquid on the instrument.
- If liquid does spill on the 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 documentation.

Safety labels on the instrument

In this section

List of safety labels on the instrument

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

The safety labels on the 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 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 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.

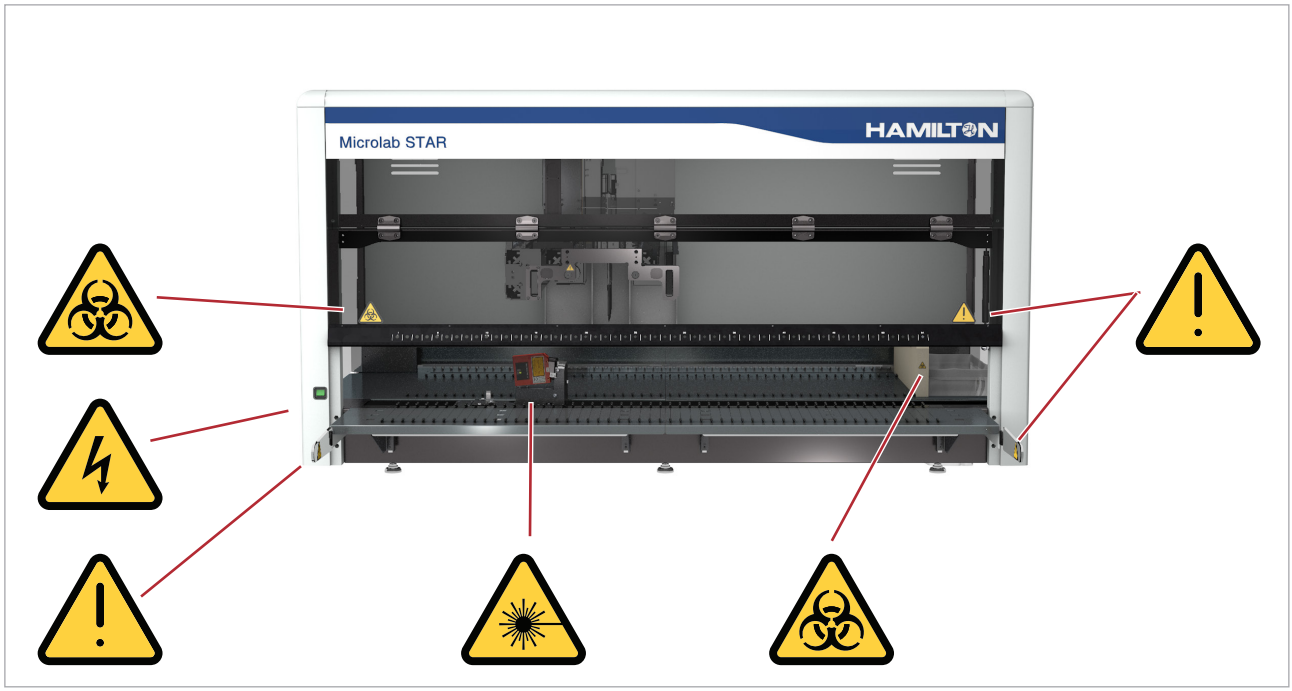
Laser transmitter
There is a danger of contact with laser light or severe damage to the eyes.
Do not stare into the laser transmitter.

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 instrument, observe both the safety labels on the instrument and the safety messages in the user documentation.

Location of safety labels on the instrument



Location of safety labels on the Microlab® STAR IVD

Safety information for lasers

The instrument includes a barcode reader. The 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 for longer than 0.25 s, 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 instrument

Safety information for disposal

Disposal information

Infection by a biohazardous instrument

- Treat the instrument as biohazardous waste. Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the instrument.
- Dispose of the 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 instrument.

Safety information for disposal

Disposal information