

Molecular Lab Overview

User Guide

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Software version 1.0



Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0	July 2025	First version

☰ Revision history

Edition notice

This publication is intended for users of the Molecular Lab overview.

The Molecular Lab overview is a non-MD/IVD stand-alone software.

We have made every effort to make sure 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. A new version of this publication is then created.

Where to find information

The **User Assistance** and the **User Guide** contain information about the product, including:

- Safety information
- Background information
- Routine operation information
- Troubleshooting information

Privacy notice

When you use User Assistance online, viewing events (topics viewed and searches performed) and IP addresses are logged.

The data collected is for Roche internal use only. It is never forwarded to third parties. It is anonymized, and after one year it is automatically deleted.

Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

General note

General note

Make sure that you are familiar with the instructions before you use the software.

- ▶ Pay particular attention to all safety precautions.
- ▶ Always follow the instructions in this publication.
- ▶ Do not use the system in a way that is not described in this publication.
- ▶ Store all publications in a safe and easily retrievable place.

Incident reporting **Incident reporting**

- ▶ Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

Training

Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics.

Images

The images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

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

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This open-source and commercial software and Molecular Lab overview as a whole can form a device regulated in line with applicable law. For more information, refer to the corresponding user documentation and labeling.

Note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to the software.

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Molecular Lab Overview is compliant with IEC 62304.

Feedback

We have made every effort to make sure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. If you have any such feedback, use the feedback function under every topic in the User Assistance. Your feedback is transferred to the responsible person for this user documentation. You can also contact your Roche representative.

Contact addresses

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876
USA
Made in Switzerland

Distributed in the United States by
Roche Diagnostics
9115 Hague Road
Indianapolis
Indiana, USA



Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Roche affiliates

A list of all Roche affiliates can be found at:

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eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service on navify Portal:

www.navifyportal.roche.com

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

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Intended use

Lab overview application software is displayed on a local or remote user screen and is intended to be used for the following:

- Observing the status of multiple x800 systems with information such as processing, error, or maintenance.
- Getting additional information from the instrument (e.g. sample processing progress or maintenance tasks).

Product names, symbols, and abbreviations

Product names

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

Product name	Descriptor
Molecular Lab Overview	software
cobas [®] 6800 instrument	instrument
cobas [®] 8800 instrument	instrument
x800 Data Manager	data manager
☰ Product names and abbreviation	

Symbols used in the publication

The following symbols are used:

Symbol	Explanation
•	List item
☰	Table, used in table titles and cross-references to tables
💡	Tip, used for extra information on correct use or for useful hints
ⓘ	Extra information within a task
➔	Result of an action within a task
☰ Symbols used in the publication	

Abbreviations

The following abbreviations are used:

Abbreviation	Definition
ANSI	American National Standards Institute
IVD	In vitro diagnostic
LAN	Local area network
MD	Medical device
VPN	Virtual private network

☰ Abbreviations

Safety

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Safety information

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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 system, injury, or death.

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

Tip...

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

Data security

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

Malicious software or unauthorized system access can result in data loss or system unavailability. To avoid infection by malicious software or the unauthorized access and misuse of the system, protect attached systems from malicious software and security threats.

To inform Roche about potential cybersecurity vulnerabilities affecting the Molecular Lab Overview refer to the following links:

U.S.: Inform the US local safety officer: indianapolis.csc@roche.com. For additional information on vulnerability and incident handling: <https://www.diagnostics.roche.com/us/en/about-us/vulnerability-and-incident-handling-policy.html>

Outside the U.S.: Refer to the list of Roche affiliates: www.roche.com/worldwide. On the web page, choose your country. For the phone number, depending on your country, choose the contact link or tab.

- ▶ Make sure that your computer or electronic device with all applications is securely configured.
- ▶ Make sure that security patches are regularly applied on your computer or electronic device.
- ▶ Make sure that an up-to-date antivirus software is running on your computer or electronic device.
- ▶ Make sure that a local firewall is protecting your computer or electronic device.
- ▶ Make sure that any external storage devices (such as USB flash drives or external hard drives) connected to your computer or electronic device are free of malicious software.
- ▶ Make sure that other computers, electronic devices, and services on the network are properly secured and protected against malicious software and unauthorized access.
- ▶ Secure LANs for all connected devices and workstations and ensure access only through, for example, VPNs when accessing from outside the customer network.
- ▶ Make sure that attached networks and IT system are secure. Customers are responsible for the security of their local network, and IT systems, especially in protecting it against malicious software and attacks. This protection might include measures, such as a

Data loss or unavailability of the system due to disclosed passwords

firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.

- ▶ Restrict physical access to your computer, electronic device, and all attached IT infrastructure (cables, network equipment, and so on).
- ▶ Do not use shared user accounts.
- ▶ Delete or deactivate user accounts for users no longer requiring access to the system.

Disclosing passwords can result in unauthorized access.

Unauthorized access can result in loss of data integrity or system unavailability. Manage, handle, and use passwords and credentials for authentication appropriately.

- ▶ Always use strong passwords.
- ▶ Always enter your password unobserved.
- ▶ Do not disclose your password to unauthorized users.
- ▶ Do not write down your password.
- ▶ Store passwords in a password manager.
- ▶ If you ever disclose your password to anyone, change it immediately after.
- ▶ If you think anyone else has access to your account, contact your local IT support immediately.

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System description

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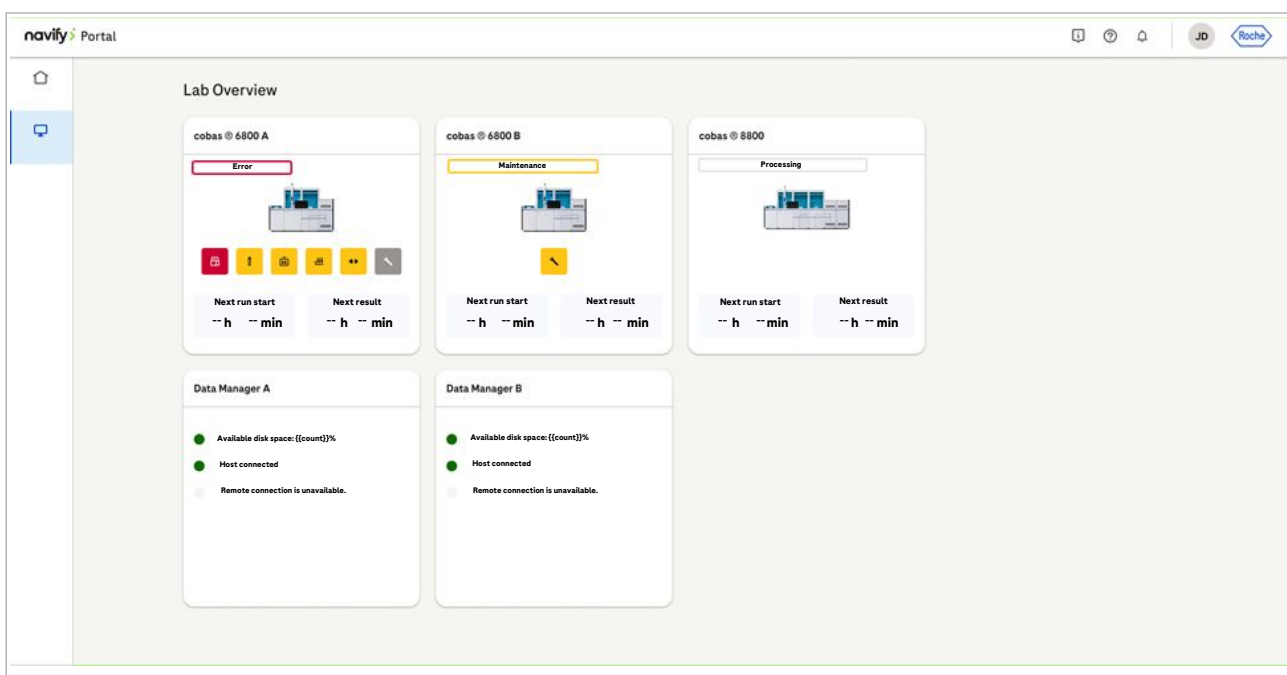
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About the software

Molecular Lab Overview software is built on navify technology. It offers data source cards specific to the **cobas**® 6800/8800 systems and x800 Data Manager. For each instrument or x800 Data Manager a data source card is displayed on the Molecular Lab Overview dashboard.

The software receives and presents information from the following components:

- **cobas**® 6800 instrument software version 2.01 upwards
- **cobas**® 8800 instrument software version 2.01 upwards
- x800 Data Manager version 2.2 upwards.



Lab overview layout on a desktop pc

Functions

The software collects and displays information from 1 or multiple connected data sources close to real time.

The software provides the following information of the connected instruments:

- Instrument name
- Instrument status
- Instrument connection status to the x800 Data Manager.
- Missing supplies
- Transfer and order errors
- Errors in output location
- Hardware notifications

- Required maintenance actions
- Postponed runs
- Next run start
- Next result

The software provides the following information of the connected x800 Data Manager:

- Serial number of the data manager
- Data manager disk space
- Host or middleware connection status
- Remote connection status
- Indication if there are results to be reviewed.



Use Molecular Lab Overview only to view information. You cannot control the instruments with the application.

User interface layout and supported devices

On the user interface, each instrument and each data manager has its own data source card.

The user interface layout changes according to the device you are using.

The following devices are supported:

- Mobile phone
- Tablet
- **cobas**[®] mobile solution device
- Personal computer
- Projection screen

Color coding








The status color in the card is the same as the status light of the corresponding instrument.

Accessibility

You access Molecular Lab Overview from the **navify**[®] Portal. The log on screen, the profile settings, and language settings are available via the **navify**[®] Portal user interface.

List of user interface icons

Depending on the occurrence, the following icons are displayed on the instrument cards.

Icons	Color of icon	Explanation
	yellow	Connection to the data manager lost
	yellow	Errors in the output location
	red	Hardware notifications
	gray	Maintenance due
	yellow	Maintenance overdue
	yellow	Missing supplies: reagents and consumables
	yellow	Sample errors

 User interface icons

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Operation

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Accessing the software

You can access the Molecular Lab Overview software via the **navify**[®] Portal.



- Access rights to **navify**[®] Portal and Molecular Lab Overview software.

▶ To access the software

- 1 Choose <https://navifyportal.roche.com>.
- 2 Log on to the **navify**[®] Portal.
- 3 Choose **Overview > Molecular Lab Overview**.

Viewing detailed information of each connected instrument

The data source cards of the instrument are interactive. If you choose the card, the software displays detailed information for the instrument:

- Instrument-specific name
- Instrument status
- Instruments connection status to the x800 Data Manager
- Next run start
- Next result
- Sample processing information
- Number of pipetting errors
- Number of order errors
- List of missing supplies
- Hardware notifications
- Maintenance notifications
- Number of errors in output location


► To view detailed information of each connected instrument

- 1 Choose any area on the instrument card or choose the **See details** button.
 - On the right side of the screen, detailed information for the instrument is displayed.
- 2 To close the detailed view, choose the **×** button.

Filtering the data sources

To view only your preferred data sources, you can apply a filter.

► To filter the data sources

- 1 Depending on your device, on the **Molecular Lab Overview** screen, choose the **Filter by** drop-down list or the  drop-down list.
- 2 From the drop-down list, choose the check boxes of the data sources you want to view. If all data sources are activated, deactivate the data sources you want to remove from your view.
- 3 Choose the **Apply** button.

Organizing the cards on the screen

On the **Molecular Lab Overview** screen, you can organize the cards of the data sources according to your preferred sequence.

The default order is as follows:

1. cards of **cobas**® 6800 instrument
2. cards of **cobas**® 8800 instrument
3. cards of x800 Data Manager

► To organize the cards on the screen

- 1 Choose the card and move it to the position you prefer.
- 2 At the preferred position, drop the card.
 - The order of the cards is now connected to your profile. With every logon the same order is displayed.

Viewing Molecular Lab Overview in full screen mode

The full screen mode is designed for projection screens and optimized for a monitor without user interaction. The cards are presented on the **Molecular Lab Overview** screen with the summarized information of the connected data sources.

Features of full-screen mode:

1. Display-only view:
 - The full-screen mode renders the cards in an enlarged format for better visibility from a distance.
 - No user interactions are possible with the cards while in full screen mode.
2. Automatic pagination and toggling:
 - If the software has more than 8 cards, the full-screen mode automatically creates additional pages.
 - The pages toggle sequentially in a carousel format, ensuring all cards are displayed over time.

► To view the Molecular Lab Overview in full-screen mode

- 1 On the **Molecular Lab Overview** screen, choose the **View full screen** button.
- 2 To exit the full screen mode, choose the **Exit full screen** button.

Activating push notifications in navify® Portal

Push notifications inform you about any changes on the instruments or data manager connected to the **Molecular Lab Overview**.

To receive push notifications, in the settings of the following software, notifications must be enabled:

- **navify®** Portal
- Browser
- Operating system
 - PC: Windows or Apple
 - Mobile device: Android or IOS



For information on enabling notifications in your browser or operating system, consult the online help of the respective browser or operating system.



- Notifications are activated in your browser and operating system
- Logon credentials available

▶ Activating push notifications in navify® Portal

- 1 Open your browser.
- 2 In your browser, delete cookies from the site navifyportal.roche.com.
 - ❗ For information how to delete third-party cookies in your browser, check the online help of your browser.
- 3 Log on to **navify®** Portal.
 - A dialog box is displayed.
- 4 In the dialog box, activate notifications.
 - A dialog box is displayed.
- 5 In the dialog box, allow **navify®** Portal to send notifications.
 - You receive notifications according to your notification settings in the **navify®** Portal.

Troubleshooting

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Resolving connectivity issues between the instrument and Molecular Lab Overview

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Resolving a connection loss between the data source and the software for more than 1 hour (42)

Handling a connection loss between the data source and the software for less than 1 hour

If the data between the data source and the software is not synchronized for more than 5 minutes and less than 1 hour, the card is marked as **Information outdated**. The connection loss does not affect the functionality of the instrument or the data manager.

The issue can occur in the following cases:

- A communication issue between the instrument or data manager and the Unified Gateway.
- Issue of the software components of the Unified Gateway.
- A connectivity issue between the Unified Gateway and the Roche cloud.

The system is designed with a buffering mechanism that helps mitigate the impact of short-term connection losses.

- Messages of a connected data source are saved for up to 1 hour from the last event published by the data source.
- If the connection between the data source and the software is reestablished within less than 1 hour, the buffered information can be retrieved. There is no loss in the data continuity.
- If the disconnection lasts longer than 1 hour, the software cannot recover the buffered data. After the connection is enabled again, the current data source status is displayed.

► **To handle a connection loss between the data source and the software for less than 1 hour**


- 1 Check the network stability. Make sure that the communication network between the data source, the **Molecular Lab Overview** software, and the Unified Gateway is stable.
- 2 If the issue is resolved within 1 hour, compare the **Molecular Lab Overview** screen with the instrument screen or data manager screen. Check if the status and the displayed information are consistent.
- 3 If the connection is not restored within 1 hour, proceed with the following procedure: [Resolving a connection loss between the data source and the software for more than 1 hour \(42\)](#).

Resolving a connection loss between the data source and the software for more than 1 hour

If the data between the data source and the software is not synchronized for more than 1 hour, the instrument status is marked as **Information unreliable. Contact your Roche Service representative**. The data displayed in the software can be incorrect due to the connection loss.

The lost information cannot be recovered.

The issue can occur in the following cases:

- A communication issue between the instrument or data manager and the Unified Gateway.
 - Issue of the software components of the Unified Gateway.
 - A connectivity issue between the Unified Gateway and the Roche cloud.
-  • To restart the data manager, you must have the **Administrator** user role.

► **To resolve a connection loss between the data source and the software**

- 1 If the connection loss affects an instruments, restart the instrument.

- ❶ If the instrument is in **Processing** status, wait until the run is complete and then perform a restart.

 - After the instrument restart, the information displayed on the data source card is up to date.
- ❷ If the connection loss affects the data manager, restart the data manager.

 - After the data manager restart, the information displayed on the data source card is up to date.
- ❸ If after the restart the data between the data source and the lab software is not synchronized, contact your Roche Service representative.

Resolving an issue with push notifications

If push notifications are activated in **navify**® Portal but you do not receive any, usually your browser or operating system disables the notification.



- Push notifications are activated in **navify**® Portal

► To resolve an issue with push notifications

- 1 Check in the settings of your browser if push notifications are activated.
- 2 Check in the settings of your operating system if push notifications are activated.

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Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland

www.roche.com