

cobas® development channel file creator

General Information

User Assistance

Publication version 6.0

Software version 3.4



Publication information

Publication version	Software version	Revision date	Change description
1.0	2.0	October 2018	First version
2.0	2.1	September 2019	▶ What is new in publication version 2.0 (13)
3.0	2.2	January 2020	▶ What is new in publication version 3.0 (12)
4.0	3.0	October 2020	▶ What is new in publication version 4.0 (12)
5.0	3.1 or later	May 2021	▶ What is new in publication version 5.0 (11)
6.0	3.4 or later	October 2023	▶ What is new in publication version 6.0 (11)

☰ Revision history

Edition notice

This publication is intended for users of the **cobas**[®] development channel file creator.

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 **cobas**[®] development channel file creator **User Assistance** “General Information” contains basic information how to access the **cobas**[®] development channel file creator and describes some basic features.

Refer to a dedicated **cobas**[®] development channel file creator **User Assistance** for an individual analyzer or system to get information how to create and handle e-barcodes for that analyzer or system.

General attention

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

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

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.

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 unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Images

The screenshots 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.

Warranty

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

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The **cobas**[®] development channel file creator may include components or modules of commercial or open-source software.

Trademarks

The following trademarks are acknowledged:

COBAS, COBAS C, and COBAS T are trademarks of Roche.

All other trademarks are the property of their respective owners.

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. Contact your Roche representative, should you have any such feedback.

Approvals

The **cobas**[®] development channel file creator meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Compliance with the applicable regulation(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:



For *in vitro* diagnostic use.



Complies with the provisions of the applicable EU regulations.

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A list of all Roche affiliates can be found at:

www.roche.com/worldwide

eLabDoc

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

<https://navifyportal.roche.com>

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

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Table of contents

Publication information	2
Contact addresses	4
Intended use	9
Symbols and abbreviations	9
What is new in publication version 6.0	11
What is new in publication version 5.0	11
What is new in publication version 4.0	12
What is new in publication version 3.0	12
What is new in publication version 2.0	13

Safety

1 General safety information

Warning messages	19
Caution messages	20
General data protection regulation	22

Application description

2 Overview of the CDC File Creator

Introduction	29
About the workspace manager	30
About generic CDC File Creator functions	31

3 Specifications

List of system specifications	37
-------------------------------	----

Operation

4 Operation

Logging on to the navify [®] Portal	43
Selecting a workspace	44

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Intended use

The cobas development channel (CDC) File Creator is a software device (accessory) intended to be used for creating customer-specific test applications. Such applications must be validated by the customer, especially if they are intended for use in IVD procedures. The specific disorder or testing population is dependent upon the customer assay used.

The CDC File Creator is intended for use in combination with empty cobas c packs, DC vials and Roche analyzers running clinical chemistry analytical units, coagulation analyzers and molecular analyzers. It is intended for professional use only.

Intended users

Supervisor	Creation of e-barcodes and UCAPs which are required on the analyzer or module to run non-Roche validated tests.
Lab Manager	
Department Supervisor	
Lab Coordinator	
Head of Operations	
Field Service Engineer	First level customer support and training.
Customer Support	Second level customer support and training.

Symbols and abbreviations

Product names

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

Product name	Descriptor
cobas [®] development channel file creator	CDC File Creator

 Product names

Symbols used in the publication

Symbol	Explanation
●	List item.
	Context search. Used on the context search tab.
	Search. Used on the search tab.
	Table of contents. Used on the table of contents tab.
	Symbols used in the publication

Symbol	Explanation
	History. Used on the history tab to show previously viewed topics.
	Favorites. Used on the favorites tab and on the content panel.
	Enlarge. Button used on images.
	Settings. Button used to open the settings dialog.
	Contact. Used in the User Assistance. Functionality currently unavailable.
	Tip. Extra information on correct use or useful hints.

 Symbols used in the publication

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ACN	Application code number
CDC	cobas [®] development channel
ID	Identifier
IVDR	In vitro diagnostics regulation
n/a	Not applicable

 Abbreviations

Symbols used on product

Symbol	Explanation
	Catalog number.
	Global Trade Item Number.
	Unique device identifier.
	Manufacturer.
	Date of manufacture.
	In vitro diagnostic medical device.
	Complies with the provisions of the applicable EU regulations.

 Symbols used on product

Symbol	Explanation
	Consult Instructions for Use.
	Caution. Consult Instructions for Use.
	Symbols used on product

What is new in publication version 6.0

Frontmatter	The frontmatter content was updated.
Intended use	The intended use section was updated and information about the intended users has been added. <ul style="list-style-type: none"> ▶ Intended use (9)
Workspaces without e-barcode functionality	Updated workspace description with workspaces without e-barcode functionality (e.g. for LightCycler® PRO). They are used to download system specific tools and software. <ul style="list-style-type: none"> ▶ About the workspace manager (30)
Minor changes	Minor changes have been implemented throughout the publication.

What is new in publication version 5.0

Regulatory adaptations	The following information was added as part of the adaptation to the EU regulation 2017/746 on in vitro diagnostic medical devices: <ul style="list-style-type: none"> • Information about incident reporting • Approvals and compliance • Link to the worldwide list of Roche affiliates • Link where the electronic user documentation can be downloaded • Symbols used on product ▶ Publication information (2) ▶ Contact addresses (4)
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	<ul style="list-style-type: none"> ▸ Symbols used on product (10)
IT security	<p>A new section about IT security was added to prevent the risk of privacy incidents and exposure of sensitive data.</p> <ul style="list-style-type: none"> ▸ IT security (21)
General data protection regulation	<p>A section about the general data protection regulation was added.</p> <ul style="list-style-type: none"> ▸ General data protection regulation (22)
About box	<p>A new About box informs you about the installed software version and the build number. In addition, information about copyright, trademark, license, contact address and the included OTSS components and modules is available.</p> <ul style="list-style-type: none"> ▸ About box (32)

What is new in publication version 4.0

Workspace for cobas® 5800 system	<p>A new workspace for cobas® 5800 system was added.</p> <p>Use the download button on the cobas® 5800 system workspace to download the RFID tool and the optimization software for local installation. These tools are used in addition to the CDC File Creator to generate specific UCAPs which are required to run tests on a cobas® 5800 system.</p> <ul style="list-style-type: none"> ▸ About the workspace manager (30)
Specifications	<p>The specification for the Microsoft Edge web browser was updated.</p> <ul style="list-style-type: none"> ▸ List of system specifications (37)

What is new in publication version 3.0

General changes	<p>The publication was migrated to the new Roche publication format.</p>
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Intended use The intended use was extended with the **cobas**[®] c 303 analytical unit.

What is new in publication version 2.0

- General changes**
- Some screenshots have been updated.
 - The naming of a few software functions has been changed.
 - Act on behalf of extended to all workspaces.
 - [Act on behalf \(31\)](#)

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Safety

1	General safety information.....	17
---	---------------------------------	----

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General safety information

In this chapter

1

Warning messages	19
Data security	19
Caution messages	20
Data security	20
IT security	21
General data protection regulation	22

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Warning messages

List of warning messages

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

- ▶ Before operating the system, read the warning messages carefully.

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.

- ▶ Prevent credential theft:
 - Use strong passwords.
 - Do not share passwords.
 - Do not write passwords down.
 - Do not use the same credentials on multiple instruments.
 - Do not share user accounts.
 - Always enter your password unobserved.

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

Data security (20)

IT security (21)

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, the following recommendations are essential:

- ▶ Ensure that your computer with all applications is securely configured.
- ▶ Ensure that security patches are regularly applied on your computer.
- ▶ Ensure that an up-to-date anti-virus software is running on your computer.
- ▶ Ensure that a local firewall is protecting your computer.
- ▶ Ensure that any external storage devices (such as USB flash drives or external hard drives) connected to your computer are free of malicious software.
- ▶ Make sure other computers and services on the network are properly secured and protected against malicious software and unauthorized access.
- ▶ Ensure that attached networks are secure. Customers are responsible for the security of their local 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.
- ▶ Restrict physical access to your computer and all attached IT infrastructure (cables, network equipment, etc.).

IT security

Disclosure of confidential data due to entry in free-text fields

Adding personal confidential patient-relevant information to free-text fields increases the risk of privacy incidents and exposure of sensitive data.

- Do not enter any confidential patient-relevant information into free-text fields.

General data protection regulation

What is the GDPR?

This regulation lays down the rules for protecting EU citizens and residents with regard to the processing of personal data and rules relating to the free movement of personal data. In addition, it protects fundamental rights and freedoms of natural persons and, in particular, their right to the protection of personal data.

Who is affected by the GDPR?

This regulation applies to the controlling and processing of personal data carried out by organizations operating within the EU. It also applies to organizations outside the EU that offer goods and services to individuals in the EU.

This regulation does not apply to certain activities, such as processing for national security purposes or processing carried out by individuals purely for personal and household activities.

What information does the GDPR apply to?

This regulation applies to two categories of information:

- Personal data: Any information relating to an identifiable person who can be directly or indirectly identifies in particular by reference to an identifier.
- Sensitive personal data: Special categories of personal data, such as genetic and biometric data, which can be used to uniquely identify someone if processed.

What are the lawful bases for collecting and processing personal data?

One of the following lawful bases has to apply whenever you collect and process personal data:

- Consent: The data subject has to give clear consent for the data controller to process their personal data for a specific purpose.
- Contract: The processing has to be necessary for a contract the data controller has with the data subject, or because the data subject have asked the data controller to take specific steps before entering into a contract.
- Legal obligation: The processing is necessary for the data controller to comply with the law (not including contractual obligations).
- Vital interests: The processing is necessary to protect someone's life.
- Public task: The processing is necessary for the data controller to perform a task in the public interest or for the official functions of the data controller, and the task or function has a clear basis in law.

Who are data controllers, processors and subjects in the GDPR?

- Legitimate interests: The processing is necessary for the legitimate interests of the data controller or the legitimate interests of a third party unless there is a good reason to protect the individual's personal data, which overrides those legitimate interests.

Data controllers are the principal party who decides why, how and what personal data needs to be collected and processed. Data controllers are expected to ensure that contracts with data processors comply with the EU GDPR.

Data processors are entities that handle personal data on behalf of data controllers. Specific legal obligations are placed on data processors. For example, you are required to maintain records of personal data and processing activities.

Data subjects are all individuals whose personal data is collected, managed and processed by data controllers and data processors.

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Application description

2	Overview of the CDC File Creator	27
3	Specifications	35

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Overview of the CDC File Creator

In this chapter

2

Introduction.....	29
About the workspace manager	30
About generic CDC File Creator functions.....	31

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Introduction

The **cobas**[®] development channel file creator is a web-based solution which enables the user to generate customer specific e-barcodes and UCAPs which are required in combination with specified accessories to run customer specific (non-Roche validated) tests on Roche analyzers. Such tests need to be validated by the customer.

About the workspace manager

The workspace manager allows you to select and access your workspaces. It gives an overview of type and number of all created e-barcodes in the workspace. Choose a workspace to get directly to the e-barcode manager.

Not all workspaces might be accessible. The workspace assignment is done in the user configuration.



Always use the navigation features of the CDC File Creator. Do not use the navigation features of the web browser (for example Back and Forward buttons).

The screenshot shows a grid of workspace cards. Each card contains the following information:

- Workspace Name:** Coagulation, cobas t 511, cobas t 711, cobas pro, cobas c 503, cobas pure, cobas c 303, cobas 6000, cobas c 501, cobas 8000, cobas c 502, Molecular, LightCycler Pr..., cobas 5800.
- Data Concept:** Data concept 8.00, Data concept 8.00, Data concept 1.11, Data concept 1.00, Data concept 4.21, Data concept 1.00, Data concept 1.00.
- E-barcode Counts:** Application, Calibrator, Container, Diluent, Valid until, Library access.
- Buttons:** Information (i), Download (D), and Library access (E).

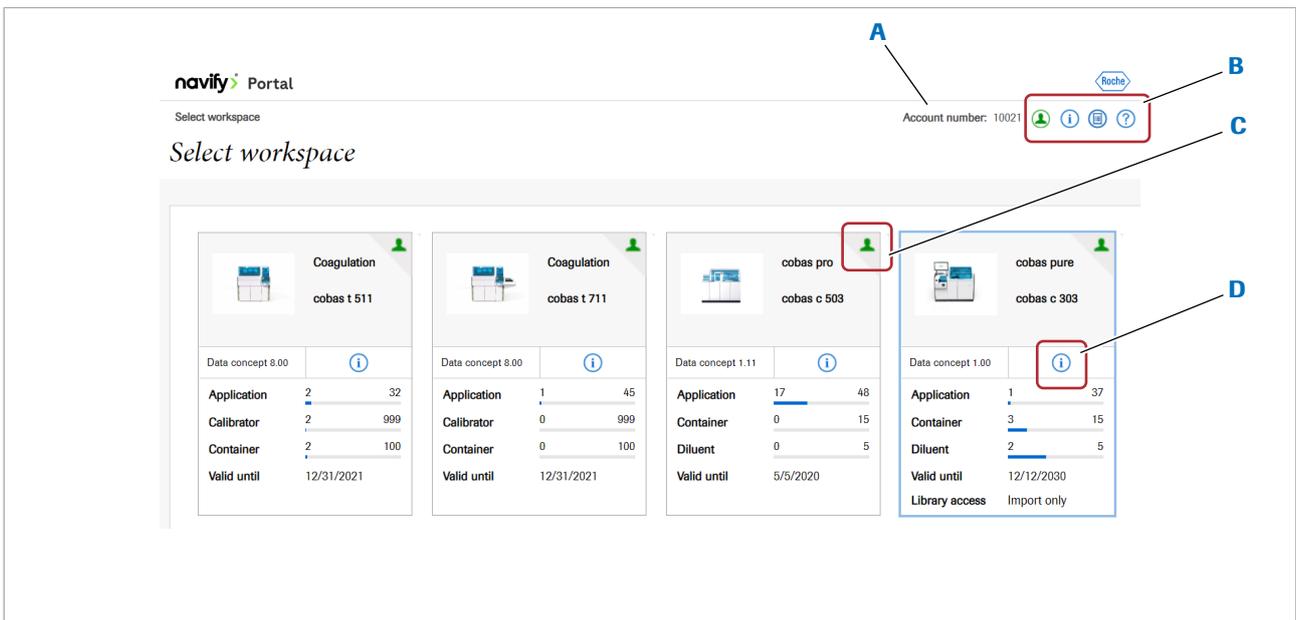
- A** Workspace
- B** Total number of available and already used e-barcodes in this workspace.
- C** System information. Choose the system to display the workspace.
- D** Download button for downloading tools and software for local installation. These tools are used in addition to the CDC File Creator for some systems.
- E** Workspace without e-barcode functionality. Use this workspace to download system specific tools and software.
- F** Workspace expiry date and e-barcode library access rights (**Import only**, **Export only**, and **Import and export**).
- G** Software version of the analytical unit supported by this workspace. Choose this button to display the version details.
- H** Data concept version supported by this workspace.

Workspace manager

About generic CDC File Creator functions

On the top right of the workspace manager, you find some buttons to access the following generic CDC File Creator functions:

- Act on behalf
- CDC File Creator version information
- Audit trail
- User Assistance



A Account number

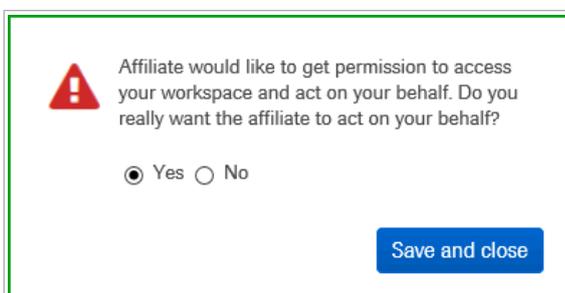
B Buttons for the generic CDC File Creator functions

C Act on behalf indicator

D Software version information

Account number and generic CDC File Creator functions

Act on behalf



You can delegate e-barcode creation to your Roche affiliate.

When your Roche affiliate asks for permission to act on your behalf, choose the button and choose the **Yes** option to grant your Roche affiliate access to your workspace.

At any time you can change the access right and reject permission to act on your behalf. To do this, choose the button and choose the **No** option.

Data concept 1.11		
Application	17 / 48	
Container	0 / 15	
Diluent	0 / 5	
Valid until	5/5/2020	

When you delegate e-barcode creation to your Roche affiliate the workspace is marked with an indicator

CDC File Creator version information

Version information		
Workspace version		
6.0.0.012		
Analyzer software version		
01-03		
01-04		

Use the button to access the CDC File Creator version information. It displays the CDC File Creator version. In addition, for each workspace the data concept version and the software version of the corresponding analyzer or analytical unit is listed. e-barcodes created with one of these workspaces are compatible with the listed SW versions.

About box

Use the button to access the **About box**. Here you can view the installed software version and the build number. In addition, information about copyright, trademark, license, contact address and the included OTSS components and modules is available.

Audit trail



The screenshot shows a dialog box titled "Create audit trail report" with a close button (X) in the top right corner. The dialog contains the following elements:

- A "Date" label followed by a horizontal line.
- "From" and "To" labels, each followed by an empty text input field.
- A "File type" label followed by a horizontal line.
- Two radio button options: "PDF file" and "CSV file".
- A "Cancel" button in the bottom left corner.
- A "Download" button in the bottom right corner.

Use the button  to create an audit trail report. In the audit trail all essential activities in the CDC File Creator are tracked with a date and time stamp.

User Assistance

Use the button  to access the User Assistance.

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Specifications

In this chapter

3

List of system specifications	37
Computer	37
Display	37
Web browser	37

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List of system specifications

In this section

Computer (37)

Display (37)

Web browser (37)

Computer

The CDC File Creator requires a commercially available desktop computer for accessing the web-based application. To view the reports, an Acrobat PDF reader or an equivalent application is required.

The CDC File Creator is not compatible with mobile devices.

Display

Item	Requirement
Display resolution	For an optimal display of the CDC File Creator, the display should have a minimal width of 1280 pixels.

☰ Display specifications

Web browser

The CDC File Creator requires an installed web browser on a computer to access the web-based application.

Browser	Recommended version
Google Chrome	Latest available version is recommended.
Microsoft Edge	Latest Chromium based version is recommended. The non-Chromium version of Microsoft Edge is not supported from CDC File Creator version 3.0 onwards.

☰ Web browser specifications

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Operation

4	Operation.....	41
---	----------------	----

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Operation

In this chapter

4

Logging on to the navify ® Portal.....	43
Selecting a workspace	44

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Logging on to the navify® Portal

You can access the CDC File Creator via the **navify®** Portal once your account has been activated by your Roche representative.

► To log on to the navify® Portal

- 1** In the global information area, on the top of the page, choose the **Log on** button.
- 2** In the dialog box, enter your email address and password and choose the **Log in** button.
 - The **navify®** Portal with the **CDC File Creator** tab is displayed.
- 3** Choose the **CDC File Creator** tab.
 - The CDC File Creator is displayed.

Already have an Account?

[Forgot password?](#)

Don't have an account yet? [Register now](#)

Selecting a workspace

Your workspaces are displayed once you are logged in. Select the workspace you want to access to get to the e-barcode manager.

Not all workspaces might be accessible. The workspace assignment is done in the user configuration by your Roche representative.

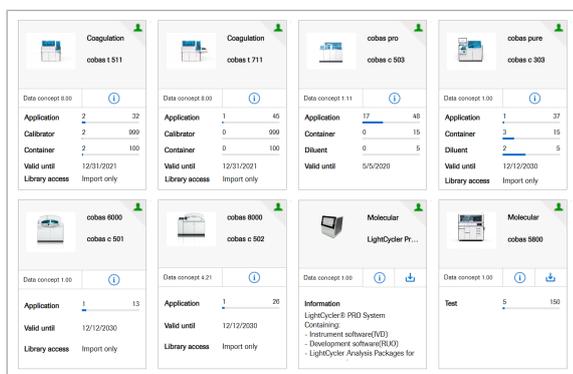
► To select a workspace

1 In the Roche Dialog portal, choose the **CDC File Creator** tab.

→ All available workspaces are displayed.

2 On the **Select workspace** panel, choose a workspace to access.

→ The e-barcode manager of the chosen workspace is displayed.



Published by

Roche Diagnostics International Ltd
CH-6343 Rotkreuz
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www.roche.com