medartis

CMX Portal

User Guide

CMX

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1 Introduction

Please read this User Guide and the corresponding Terms and Conditions carefully before using the CMX Portal. The following is the User Guide for the CMX Portal, a software application operated by Medartis AG. This User Guide is also available on the Medartis website: ifu.medartis.com.

1.1 Clinical Benefit

The clinical benefit offered by the CMX Portal is that it includes a measurement function which allows physicians to assess the preoperative and expected postoperative bone situation visualized as 3D models.

1.2 Intended Purpose

The CMX Portal is intended for professional use, containing 3D model visualization to determine patient-specific procedures and design determination for personalized devices.

1.3 Indications

Portal Case Description	Indication
CMX Orthognathics	Orthognathics
CMX Mandible	Mandible
CMX Midface	Midface
CMX Wrist	Wrist
CMX Forearm	Forearm
CMX Hand	Hand
CMX Dist. Humerus	Elbow
CMX Olecranon	Elbow
CMX Radial Head/Coronoid	Elbow
CMX Prox. Humerus	Shoulder
CMX Clavicle	Shoulder
CMX Ankle	Ankle
CMX Foot	Foot

1.4 Case Types – Non-medical Device Functionality

In addition to the indications listed in Section 1.3, the CMX Portal provides the following case types. They serve exclusively for communication and data exchange between the user and Medartis, e.g. the exchange of files and case-related information:

Portal Case Description	Function
AMSJI	Communication and data exchange only
TMJR Parametro	Communication and data exchange only
Facial Contouring	Communication and data exchange only
Orbital Floor	Communication and data exchange only
Carpitech	Communication and data exchange only

These case types are not indications within the meaning of Section 1.3. They are not part of the intended purpose (Section 1.2) and provide no clinical benefit (Section 1.1). When such a case is created, and when it is opened, the CMX Portal informs the user that the reduced functionality applies.

	ATTENTION
	The following medical device functionality is not available for the case types listed above: – the measurement function described in Section 1.1, – the CE marking and the medical device labeling of the CMX Portal software application, – the integrated screenshot functionality.

	WARNING
	For the case types listed above, images and screenshots taken from the CMX Portal must not be used in either the Design Approval document or the Case Planning and Instructions document. Use only validated third-party software for measurements and images.

	WARNING
	For the case types listed above, the 3D Model Viewer is not a certified medical product. Evaluate the geometry of the ordered products only from the images in the Design Approval document, the Case Planning and Instructions document and the CADskills design proposal document.

1.5 Contraindications

None

1.6 Intended User

The CMX Portal is intended for experienced medical professionals. Medartis, as the manufacturer, recommends that the user reads all available documents before first use and contacts other users who have practical experience with this type of treatment.

1.7 Patient Target Group

No intended patient population is defined. There are no restrictions nor contraindications defined which apply. For specific patient target groups related to each system refer to the corresponding surgical technique of the system being used. The current surgical techniques can be found on the internet at ifu.medartis.com. Responsibility for proper selection of patients rests with the surgeon, based on the specific indications and contraindications of each system and on patient-related factors (e.g. activity, occupation, mental health, age, bone quality).

2 Version

This User Guide applies to the CMX Portal Version 2.9.

2.1 Lifetime

The lifetime of the software version described in this User Guide ends with the implementation of a major or minor software version update.

3 Precautions

3.1 Compliant Use

The use of this software application is reserved depending on the role that is assigned to a user account. Any inappropriate use is forbidden.

User Role	Is reserved to
Physician	Any person authorized by national law by virtue of that person's professional qualification to issue a prescription or use or apply a medical product.
Designer	Medartis staff qualified to design personalized devices in collaboration with physicians.
Customer Service	Customer-service employees of Medartis or its distributors. This role is limited to creating cases and uploading DICOM patient images for the customers. Access to personal information is limited.
Sales Rep	Sales representatives of Medartis or its distributors. They can create cases and upload DICOM images for their customers. They have access to detailed information on their assigned cases in order to optimally support the customer.
Guest	Guests that have been invited by a physician for temporary access to anonymized case data. Usually Guests are healthcare professionals that are asked for feedback based on anonymized views on a case.
Clinical staff	Employees of clinics qualified and authorized to upload DICOM images to assigned cases.
Admin	Medartis staff qualified to perform technical administration with full access rights.
Contract Designer	Employees of third-party companies who are qualified to design personalized devices in collaboration with physicians. They have no access to user management, and cannot create case-specific documents.
Restricted Contract Designer	Contract Designers whose access to personally identifiable information (PII) is limited to the minimum necessary.

The user shall use only non-defective products and protect patients, third parties, other operators, assistants and themselves from all danger.
Only Medartis software technicians are authorized to modify or repair Medartis software products.

The software can only process medical devices from the Medartis Group.

	WARNING
	When using the software as Designer: Be aware that the platform might be offline for several days due to technical problems. Physicians may also be unable to access the application for longer periods of time due to internet connectivity, software, or hardware problems. Therefore, Designers must always have a set of alternative tools ready, in case the CMX Portal cannot be used.

	WARNING Delivered physical products (guides, implants, bone models, positioning aids) may deviate from their digitally planned counterparts.

	ATTENTION When using the case sharing functionality, please carefully check the receiver address in order not to share anonymized health data with unintended persons.

	WARNING In case you have any doubts that the anatomical orientation is defined correctly, use the delete orientation function to remove the anatomical orientation buttons and discard the current orientation information.

	WARNING When using the CMX Portal as Designer, create 3D view screenshots for Design Approval and Case Planning and Instruction documents only on supported desktop browsers, never on mobile browsers.

	WARNING As an Admin, assigning a designer qualification grants the user read and write access to personally identifiable information (PII). Verify that each user is authorized to access this data before assigning a qualification.

3.2 Safety Instructions

Operating the CMX Portal requires a functional and safe computer system with access to the internet. The safety and operational readiness of your computer system and/or network is the responsibility of the user. The user must treat any file from the CMX Portal with the necessary precautions.

3.3 Malfunction

If you notice any malfunction of the system, stop using it and contact immediately cmx.support@medartis.com.
Any complaint or adverse event that has occurred in relation to the software should be reported to the manufacturer and the respective national competent authority of the state in which the user and/or patient is established.

	WARNING In the event of abnormal operation, immediately stop using the CMX Portal and contact Medartis support.

4 Requirements

4.1 Hardware Requirements

4.1.1 Desktop

- 4 GB RAM
- 3D accelerated graphics card
- Internet connection

4.1.2 Mobile

- Display Size: 5.5 inches
- Resolution: Full HD (1080 x 1920 pixels)
- Refresh Rate: 60Hz
- RAM: 3GB

4.2 Software Requirements

4.2.1 One of the following operating systems:

- Microsoft Windows 10 or later
- macOS 10.15 or later

4.2.2 One of the following web browsers:

- Google Chrome 126 or later
- Mozilla Firefox 127 or later
- Apple Safari 17.6 or later
- Microsoft Edge 126 or later

WARNING

Use the application only with supported browsers and operating systems in order to ensure the correct and secure functionality of the CMX Portal. An incorrect visualization may lead to personalized devices which do not match with the approved specifications.

4.2.3 Mobile browser support:

Mobile browsers are not restricted from accessing the portal; however, the feature set is significantly reduced compared to the desktop version.

	ATTENTION
	Full compatibility with mobile browsers is not guaranteed. If you experience problems while using the application on a mobile browser, we recommend switching to a supported desktop browser to perform the needed tasks.

4.3 Data Input Requirements

3D Models (STL)

3D models must be provided in STL format. We support binary and ASCII encoded files. Only surface triangle information is read. We do not parse any meta information from the STL encoded file. Each file should only contain one solid. Binary files must be encoded in little-endian.
An soft upload limit is set to 15 MB per file. Uploading larger files will trigger a warning, but upload is still possible. A hard upload limit is set to 50 MB. Files of this size or larger cannot be uploaded.

Documents (PDF)

Only documents in valid PDF format can be uploaded. Currently there is no size limit for PDF documents.

Images (PNG, JPEG)

Image uploads within the Case Planning and Instructions can only be provided in PNG and JPEG format.

Medical Image Data (DICOM, ZIP)

Medical image data must adhere to the scan protocols which can be found on the Medartis website at ifu.medartis.com

- DICOM
  DICOM files can be uploaded directly by selecting the directory/drive that contains the image files. Further information on how to upload DICOM files is given in chapter 6.1.

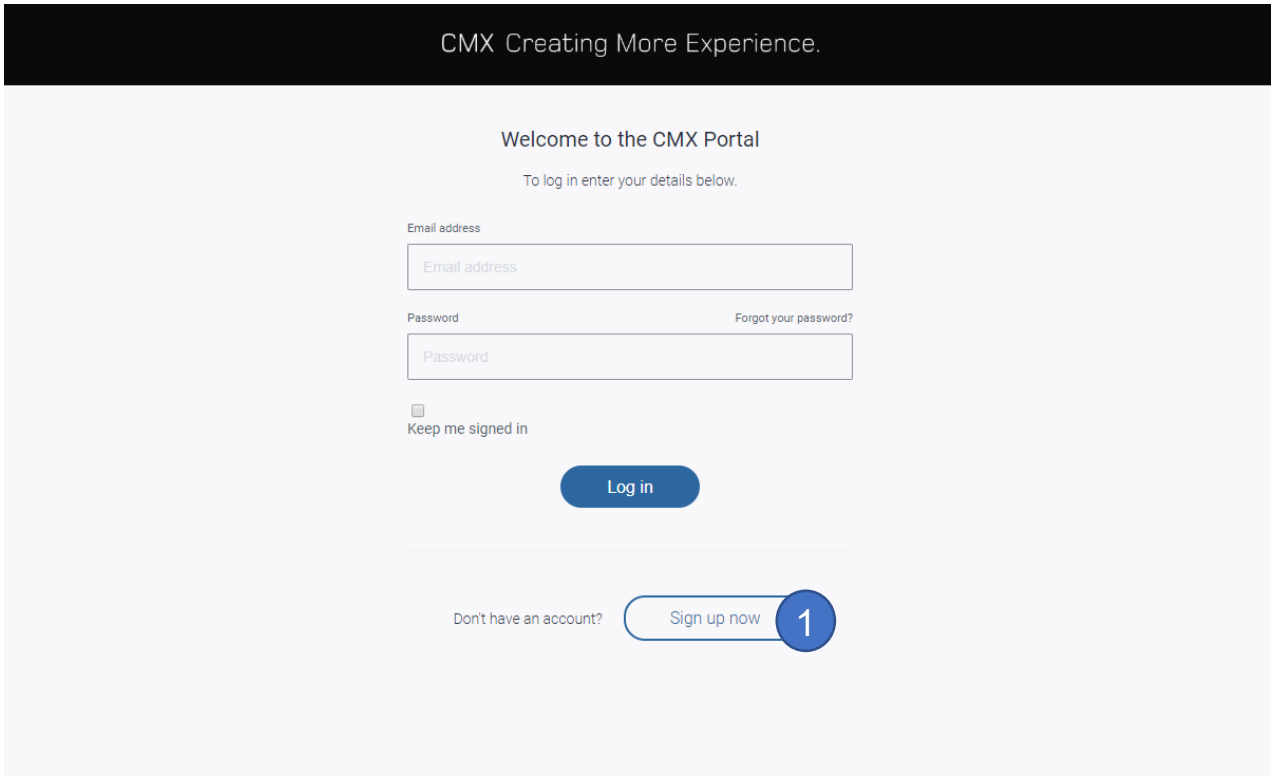
- ZIP
  DICOM and other medical image data can be provided in a packaged ZIP container. Further instructions on how to create such a container and fill it with data are described in chapter 6.1.
  The upload size of ZIP containers is limited to 6 GB.

5 Getting Started

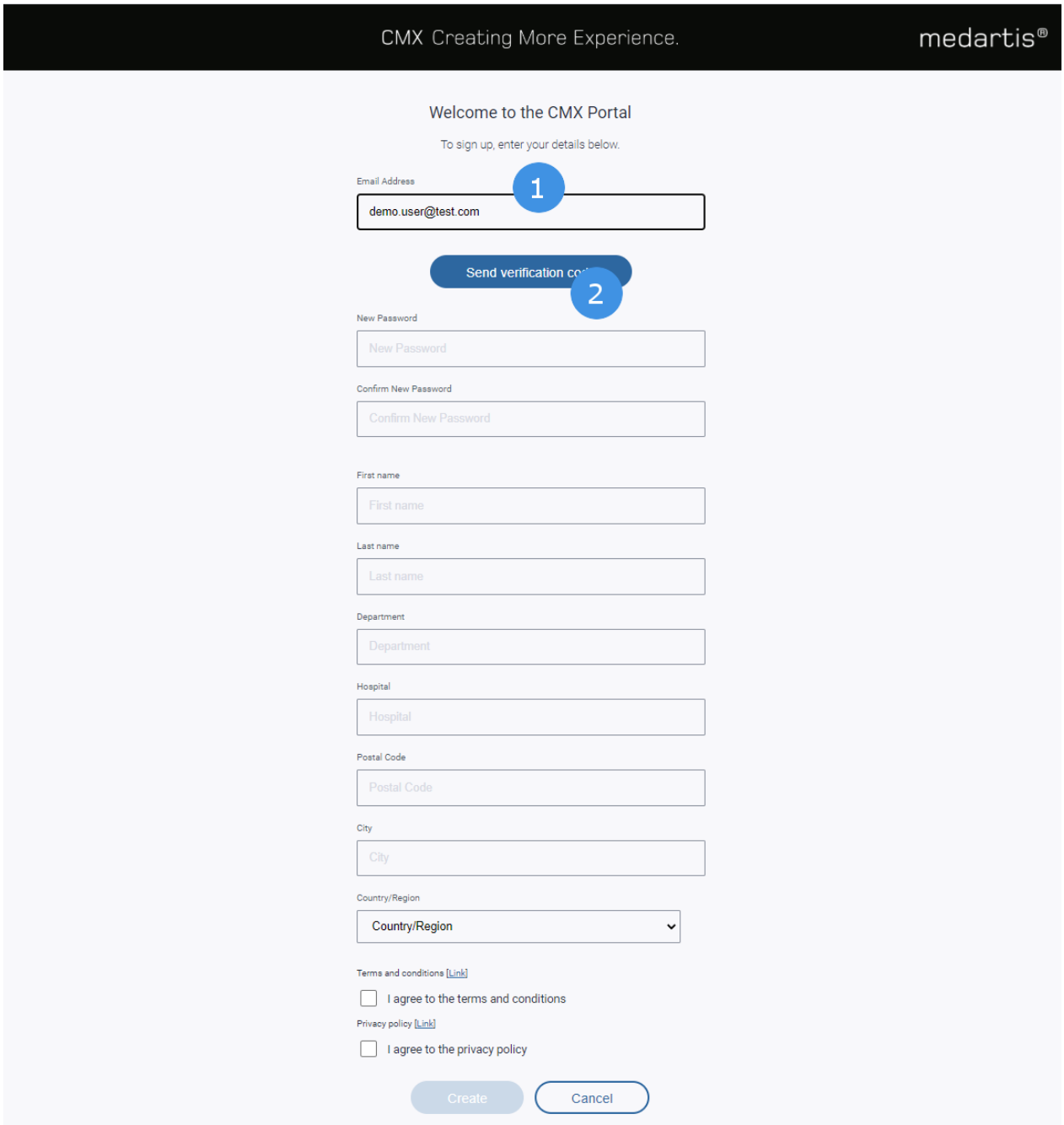
5.1 Installation/Registration

User registration:

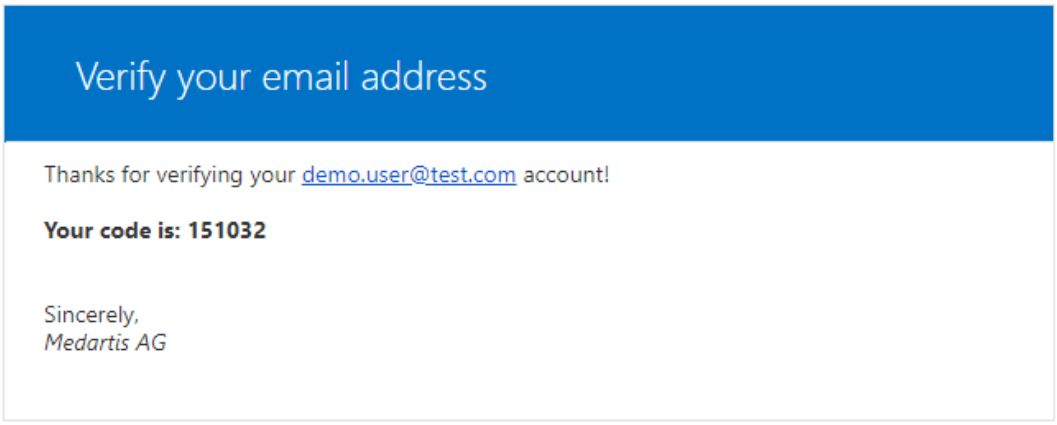
Go to cmx.medartis.com, then:



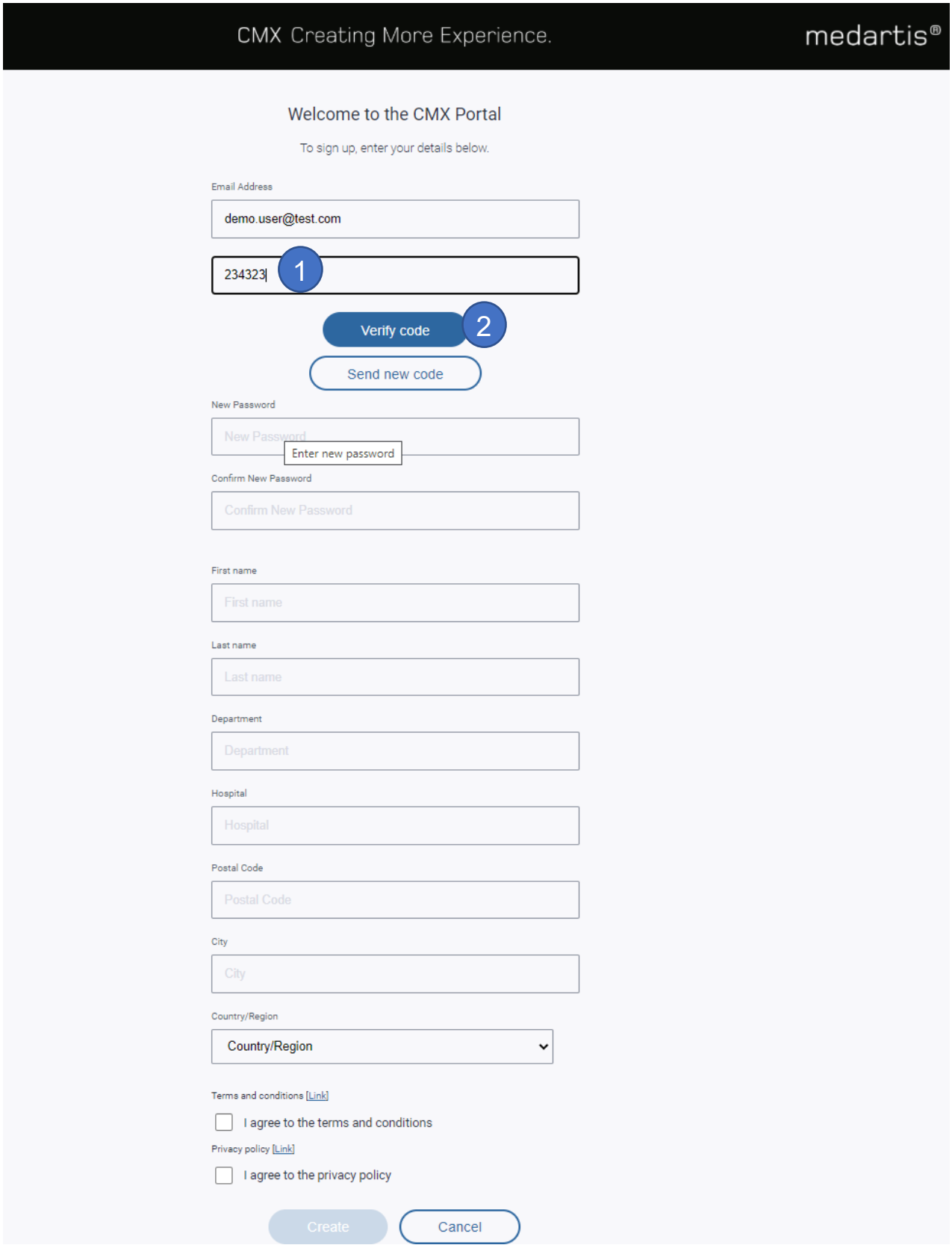
1. Click “Sign up now”.



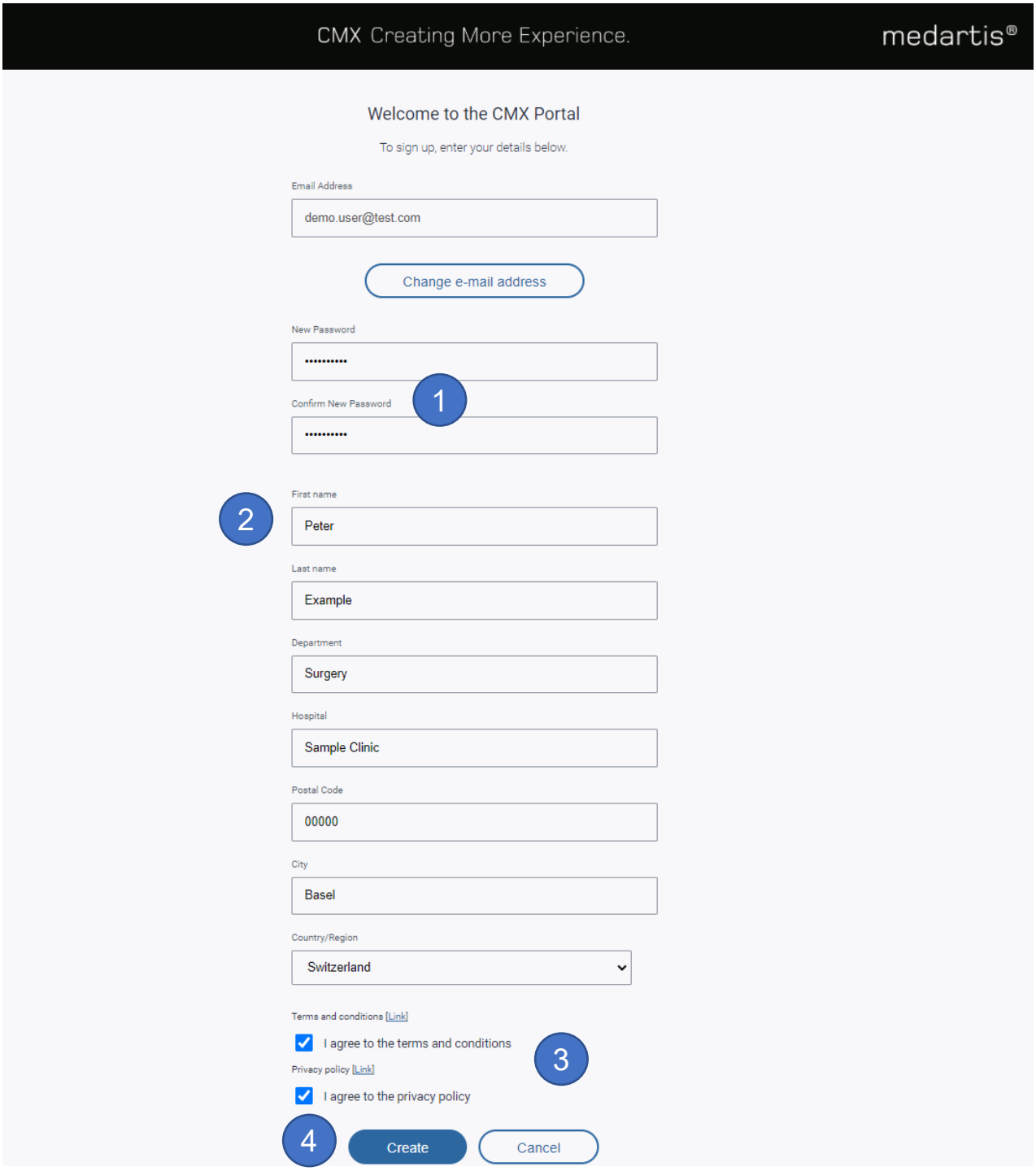
1. Add your valid email address.
2. Click the button “Send verification code” to receive the verification code to your given email address.



Open your email client, and copy/remember the received verification code.

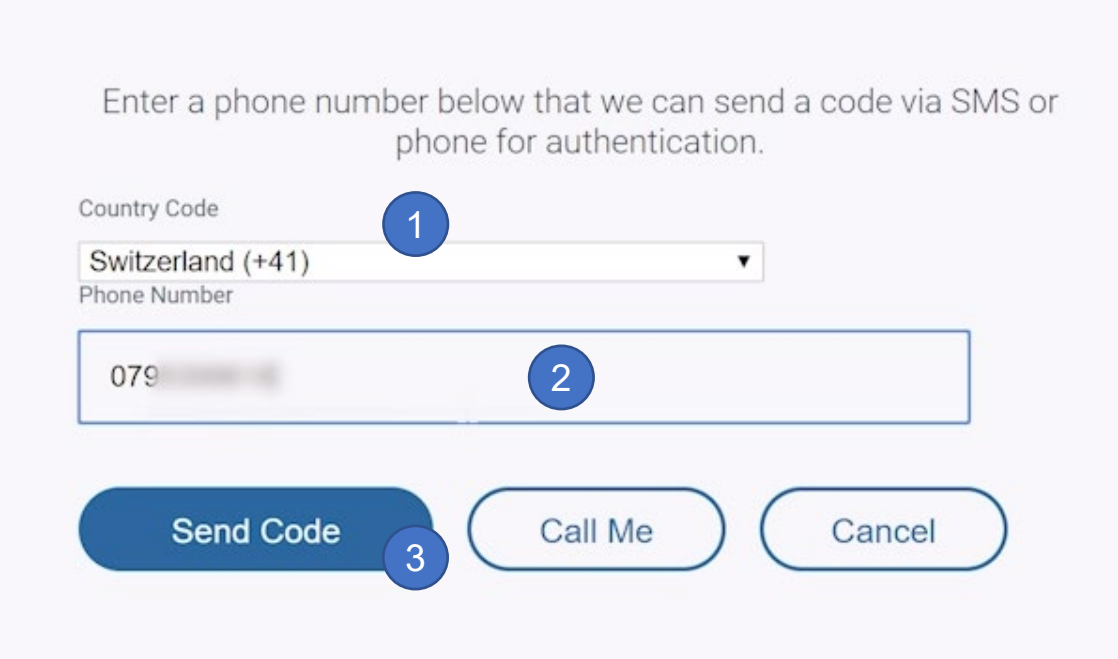


1. Specify the received verification code.
2. Click the button “Verify code”–in order to validate your email address.

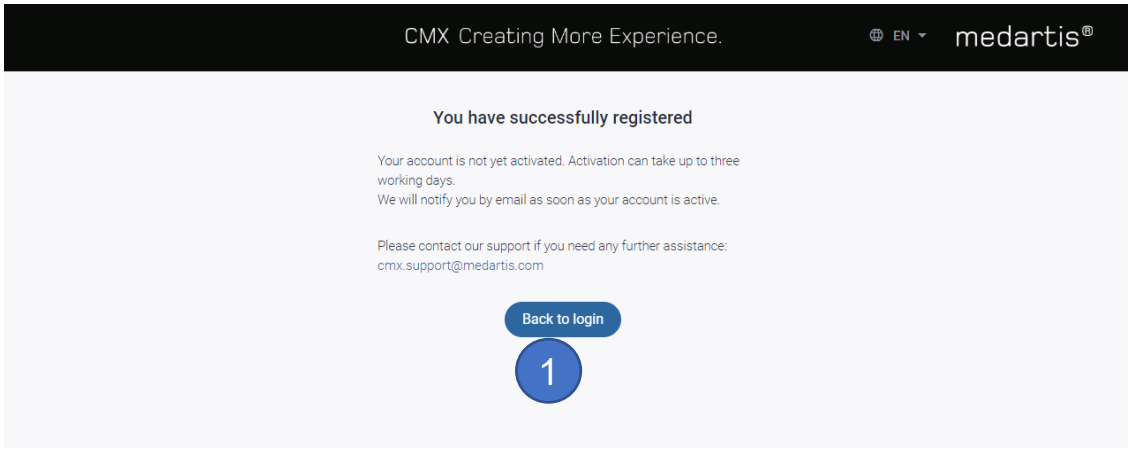

CMX Creating More Experience.
medartis®
Welcome to the CMX Portal
To sign up, enter your details below.
Email Address
demo.user@test.com
Change e-mail address
New Password
Confirm New Password
1
2
First name
Peter
Last name
Example
Department
Surgery
Hospital
Sample Clinic
Postal Code
00000
City
Basel
Country/Region
Switzerland
Terms and conditions [Link]
I agree to the terms and conditions
3
Privacy policy [Link]
I agree to the privacy policy
4
Create
Cancel

1. Specify your password. Rules are: 8–64 characters, 3 of the 4 (numbers, lower-case, upper-case, symbols) must be included.
2. Specify your personal data.
3. Accept the terms and conditions and the privacy policy. You can read them in detail by clicking “[Link]” above the according acceptance checkbox.
4. Click “Create” in order to register.

	WARNING
	Login credentials are used to authenticate you. Always use unique and strong passwords. Do not write down or share login credentials with others. Take security precautions to keep credentials secret when entering credentials in public. Shield any possible view on the keyboard while typing passwords.



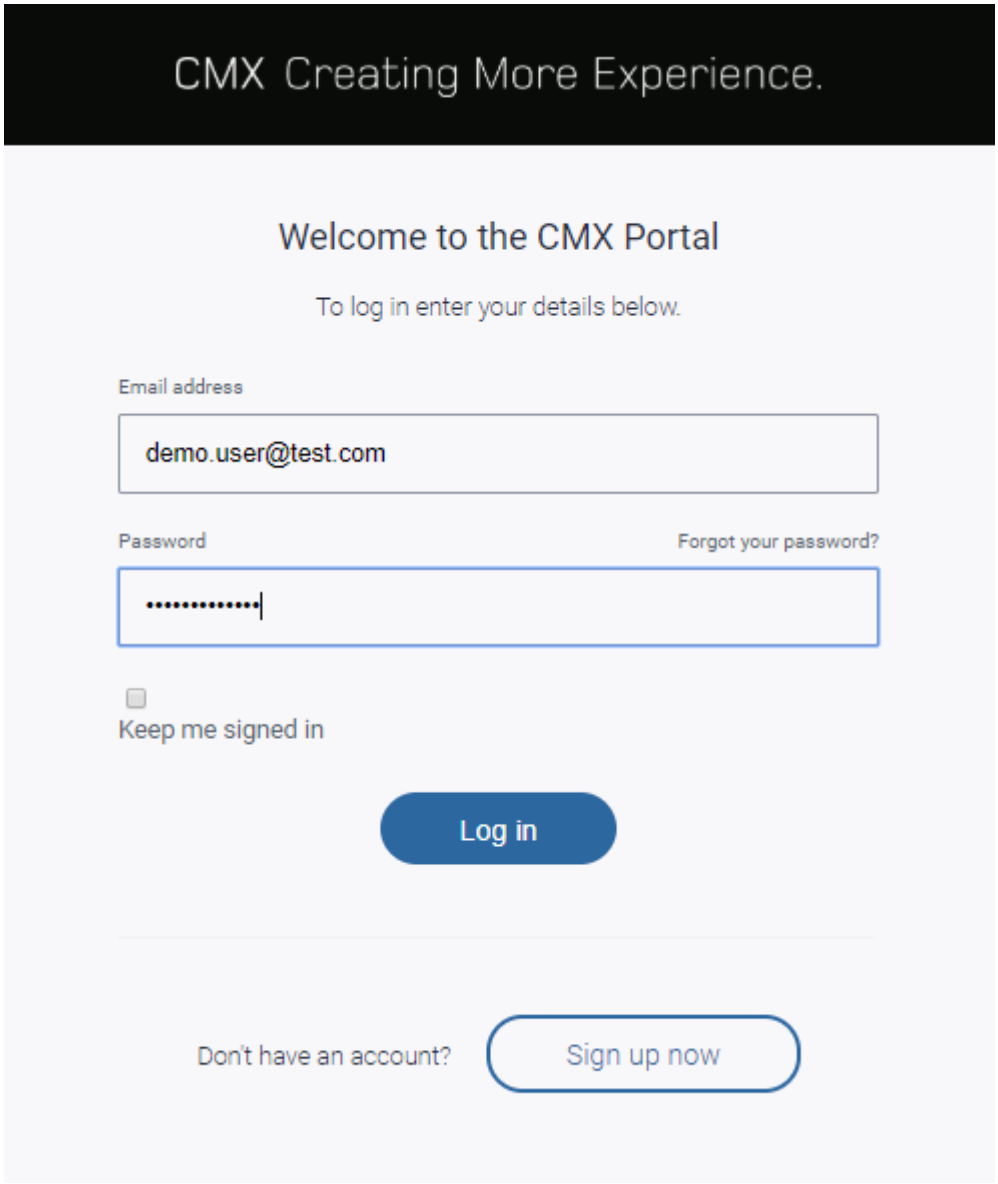
1. Select your country code.
2. Enter your mobile phone number without country code.
3. Click “Send Code” in order to receive a verification code via SMS to your phone.
4. (Not shown) Enter the received SMS code in order to validate your phone number.



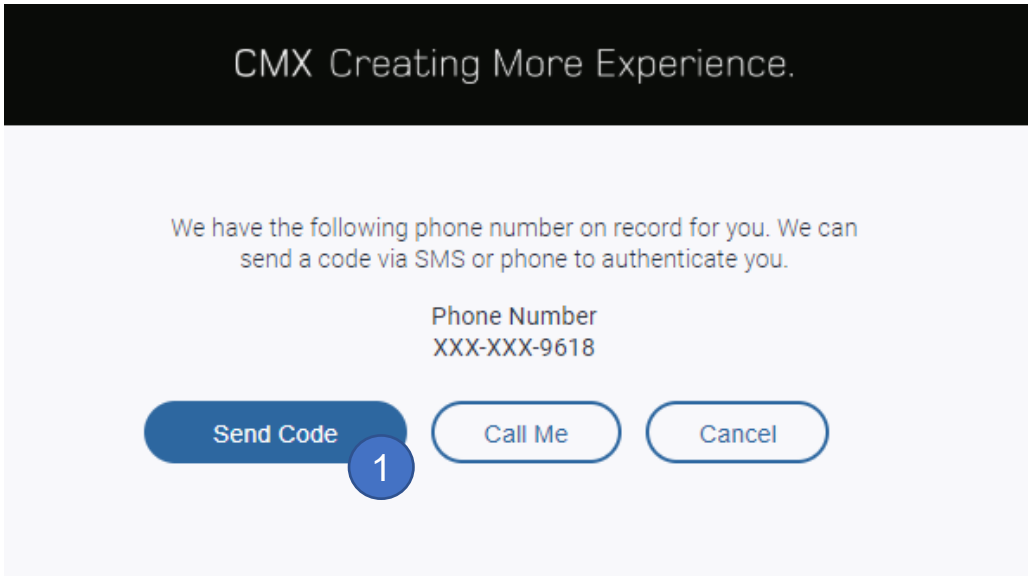
1. The registration is now finished for your part. Our support will now review your information and then activate your account. You can log out for now by clicking the button “Back to login”.

5.2 Login

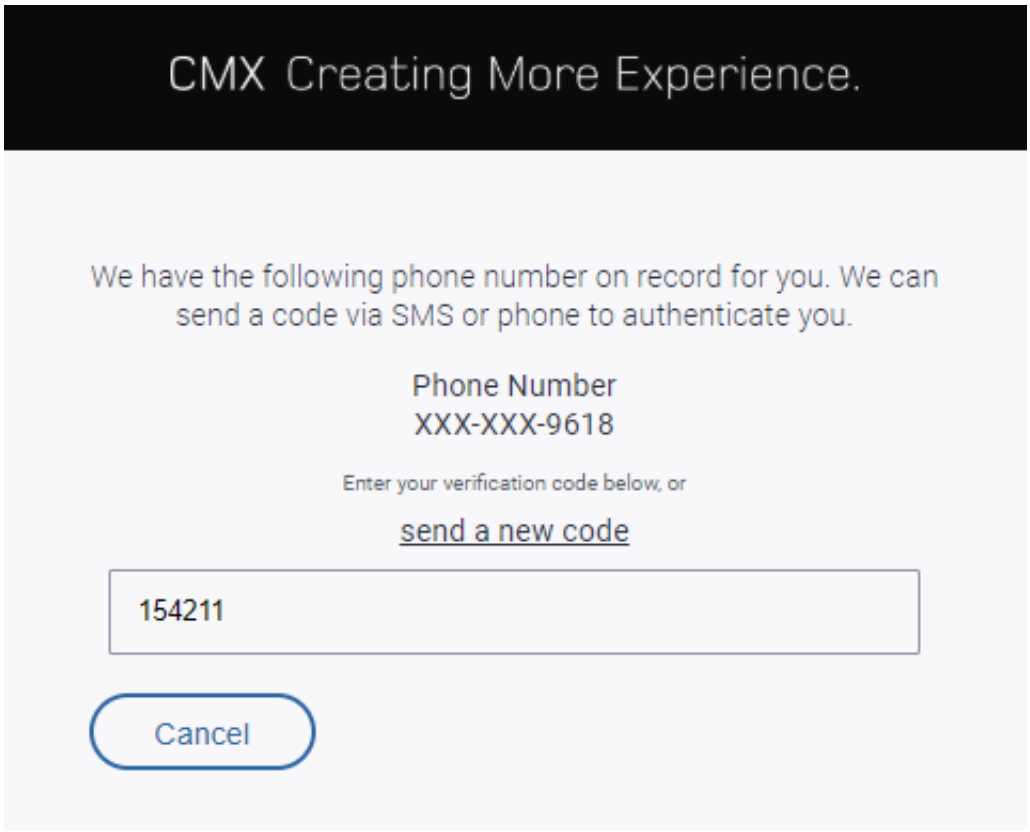
Use your web-browser to go to cmx.medartis.com.



Enter username and password.



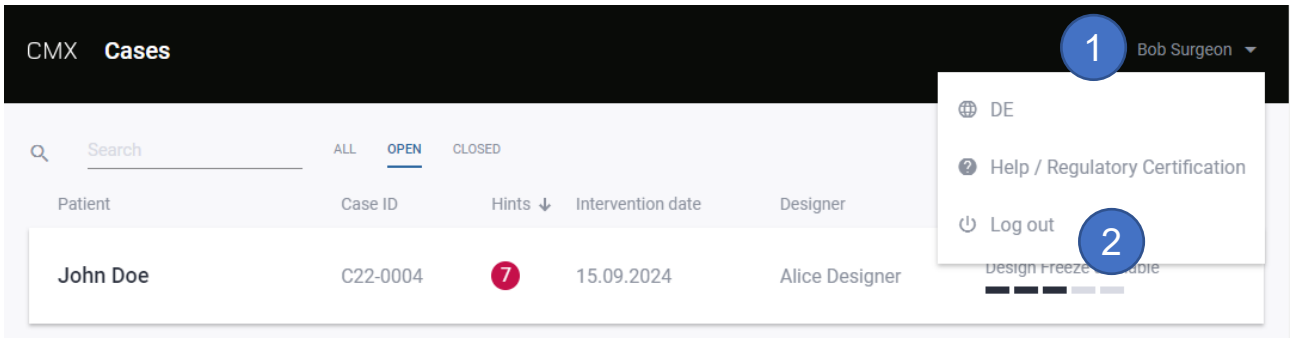
1. Click “Send Code”.
2. (Not shown) You will receive an SMS containing the verification code.



1. Enter the code you have received by SMS. You will be logged in without further interaction.

5.3 Logout

In order to log out, click your name on the top right (1) and then “Log out” (2).



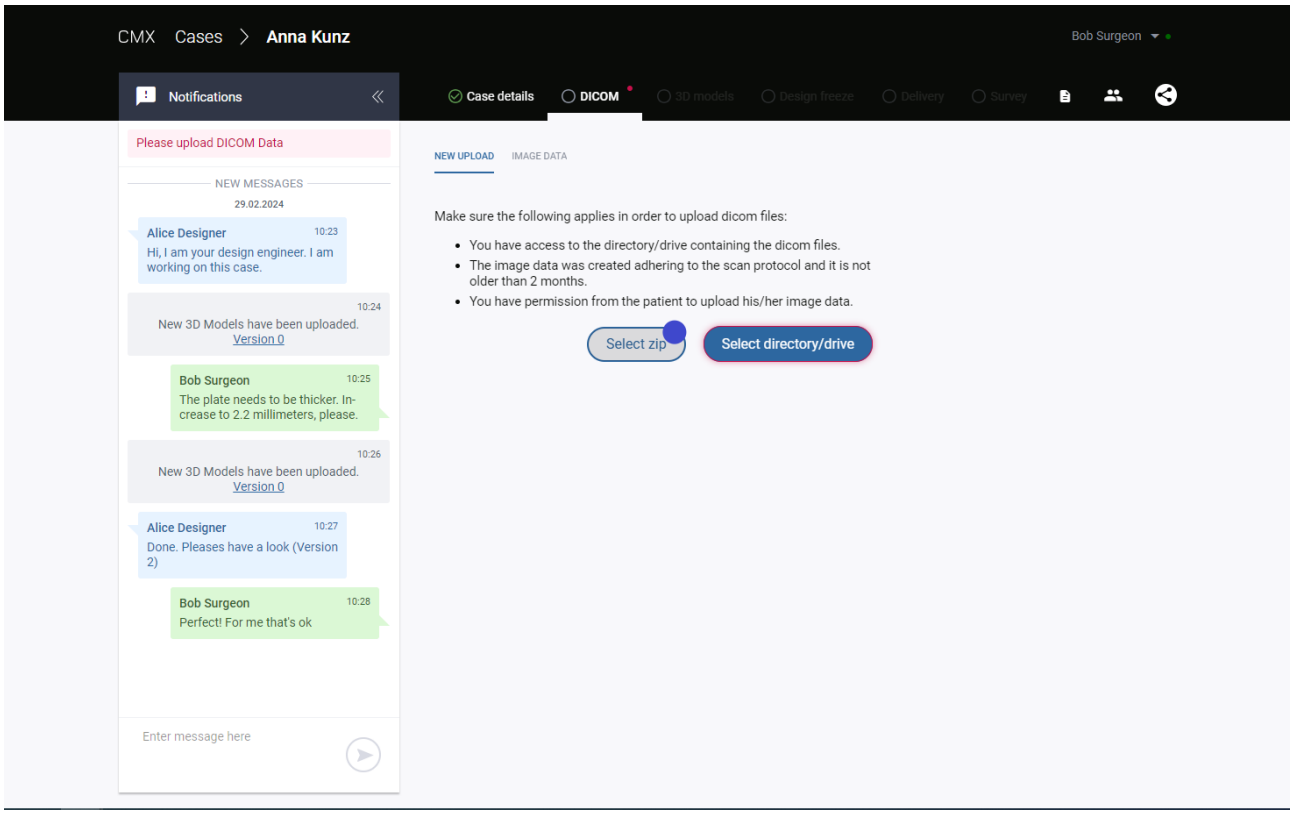
	WARNING
	To prevent others from accessing your account, always log yourself out before closing the browser or browser tab.

6 Advanced Functionality

6.1 Uploading DICOM Data

Uploading the DICOM data can be done in the DICOM view.

6.1.1 Uploading a ZIP data file



Steps:

1. After opening a case, go to the DICOM tab.
2. Click “Select zip” (marked with blue dot in the image above)
3. Read and confirm the dialog.
4. Select the “zip” file on your system.

All image data must be included in the “zip” file. The following chapters describe in detail how to create a “zip” file which includes the image data you want to upload.

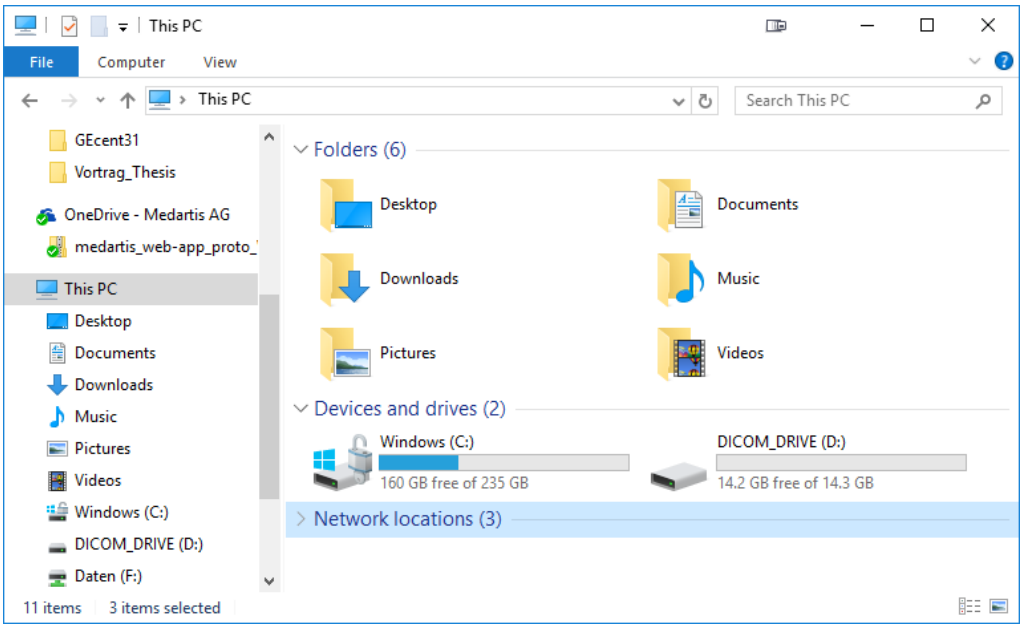
	ATTENTION
	If you need urgent assistance, urgent changes or urgent delivery immediately contact Medartis support.

	WARNING
	When using the CMX Portal as a Designer, reload the case list regularly using the browser's reload button in order to be informed about any case updates.

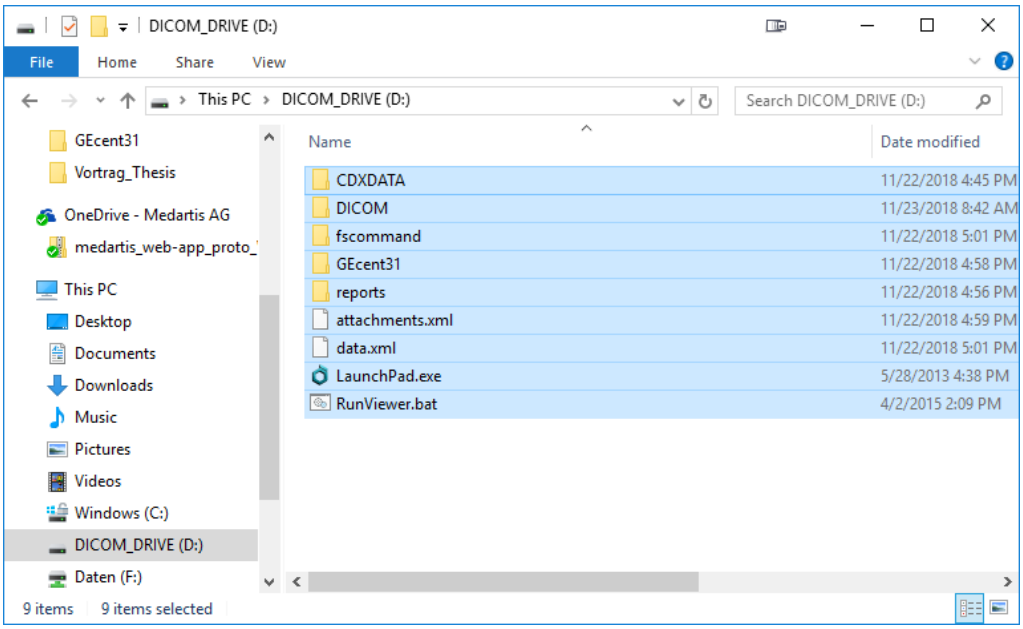
	WARNING
	When using the CMX Portal as a Designer, always check that the patient information included in the uploaded DICOM data matches the patient information provided in the case (e.g. patient name, date of birth, etc.).

Creating a ZIP file Using Windows

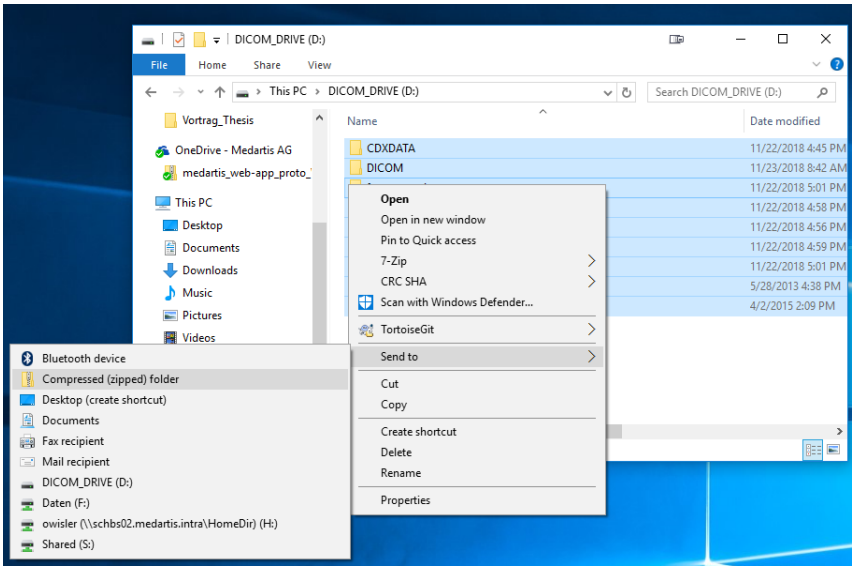
1. Insert the disc containing the DICOM data.
2. Open the Explorer and navigate to “This PC”.



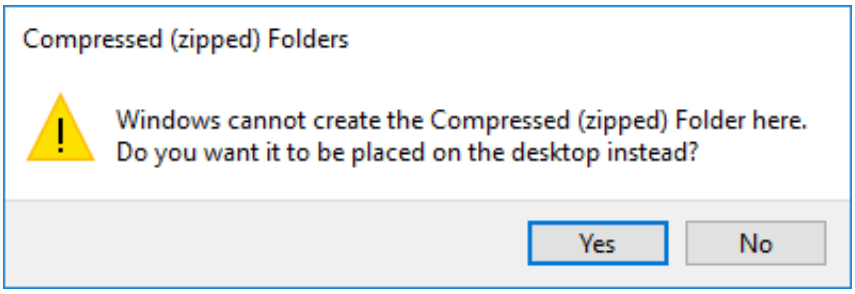
3. Navigate into the DICOM drive and mark all files.



4. Right click on the selection and choose “Send to -> Compressed (zipped) folder” in the context menu.



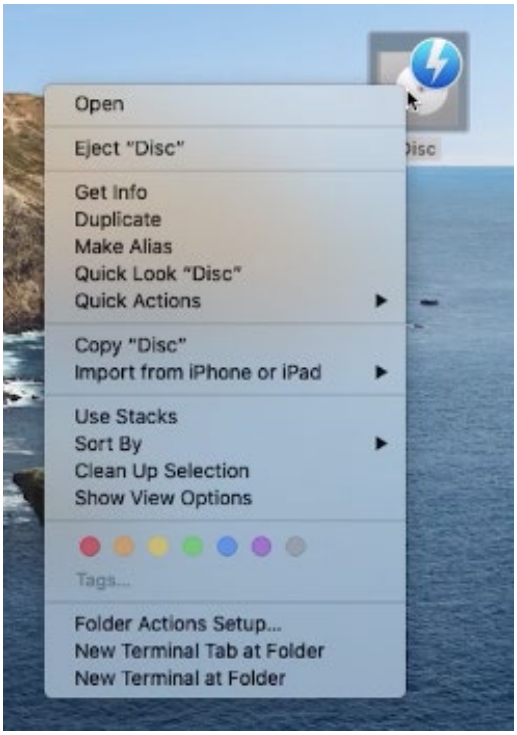
5. Choose “Yes” to create a ZIP file on your desktop.



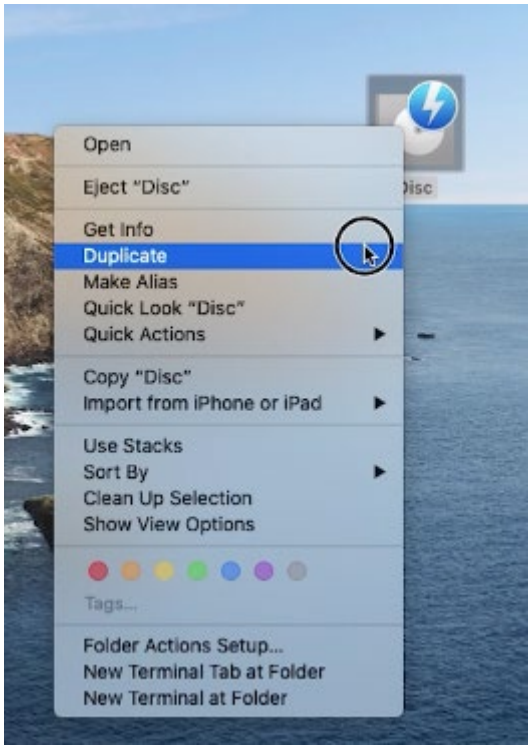
6. On your desktop the created ZIP-file will appear:

Creating a ZIP file Using macOS

1. Insert the disc containing the DICOM data.
2. Right click the disc drive (or tap it with two fingers on the trackpad).

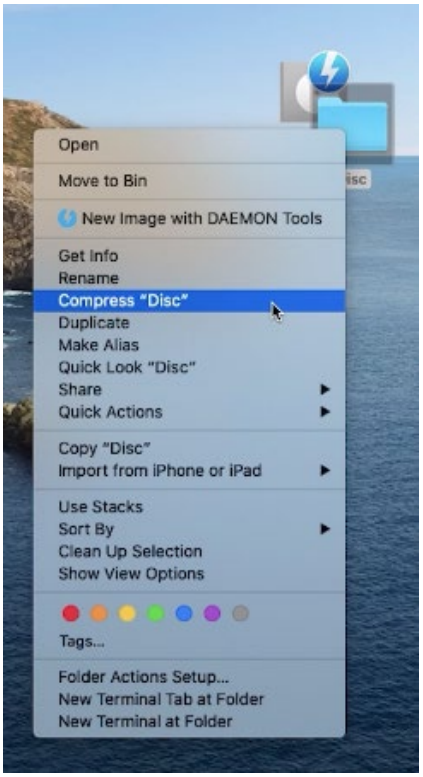


3. Duplicate the disc to your desktop drive by clicking “Duplicate”.

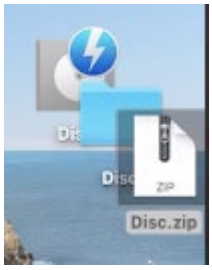


4. A new folder containing a copy of the complete disc will appear.

5. Right click the new folder and click Compress "…".



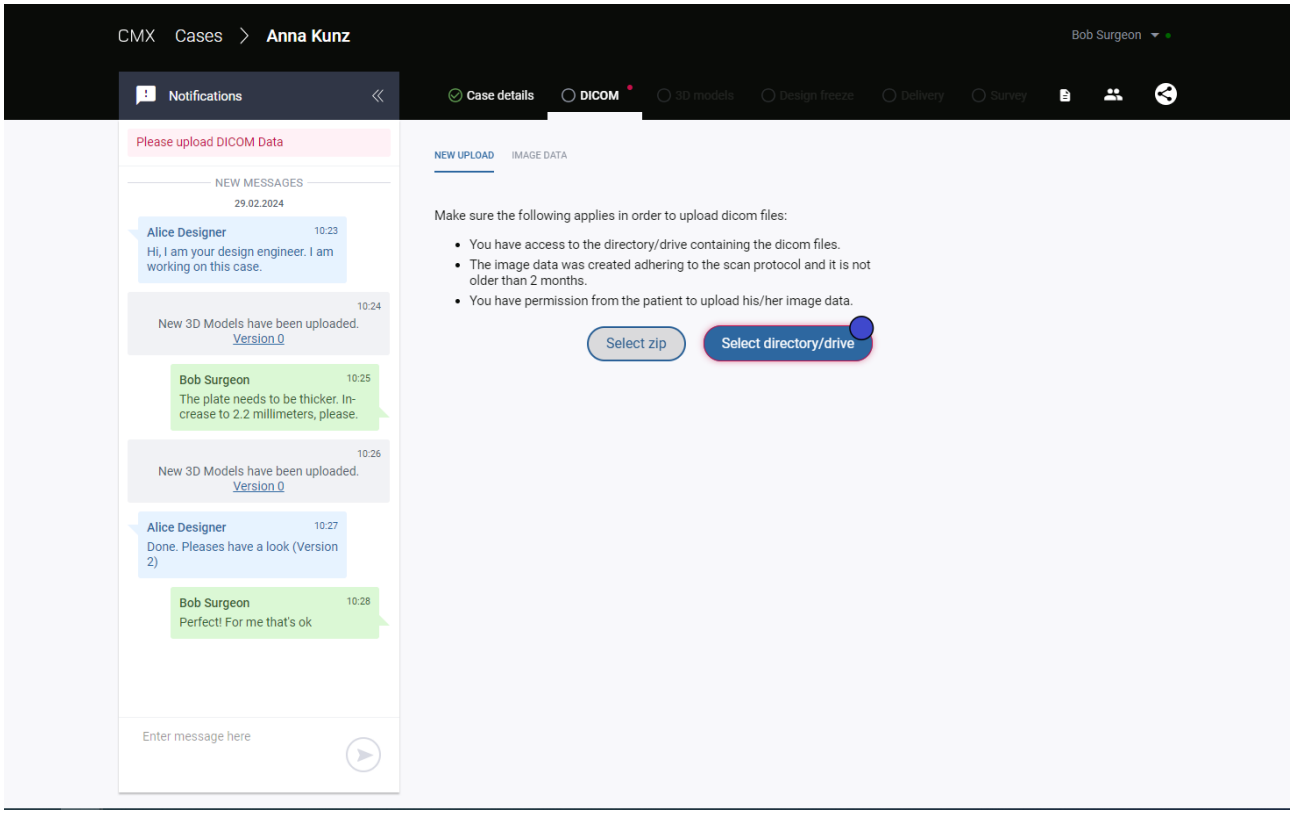
6. The created ZIP-file will appear on top.



	WARNING
	For unpacking ZIP files downloaded from the CMX Portal, use software that verifies the checksums inside the ZIP file in order have an end-to-end data integrity check. Incorrect or low-quality anatomical data may have an impact on the design of the device.

Note: Guidelines for patient scans (scan protocols).

6.1.2 Uploading a DICOM file directly



Steps:

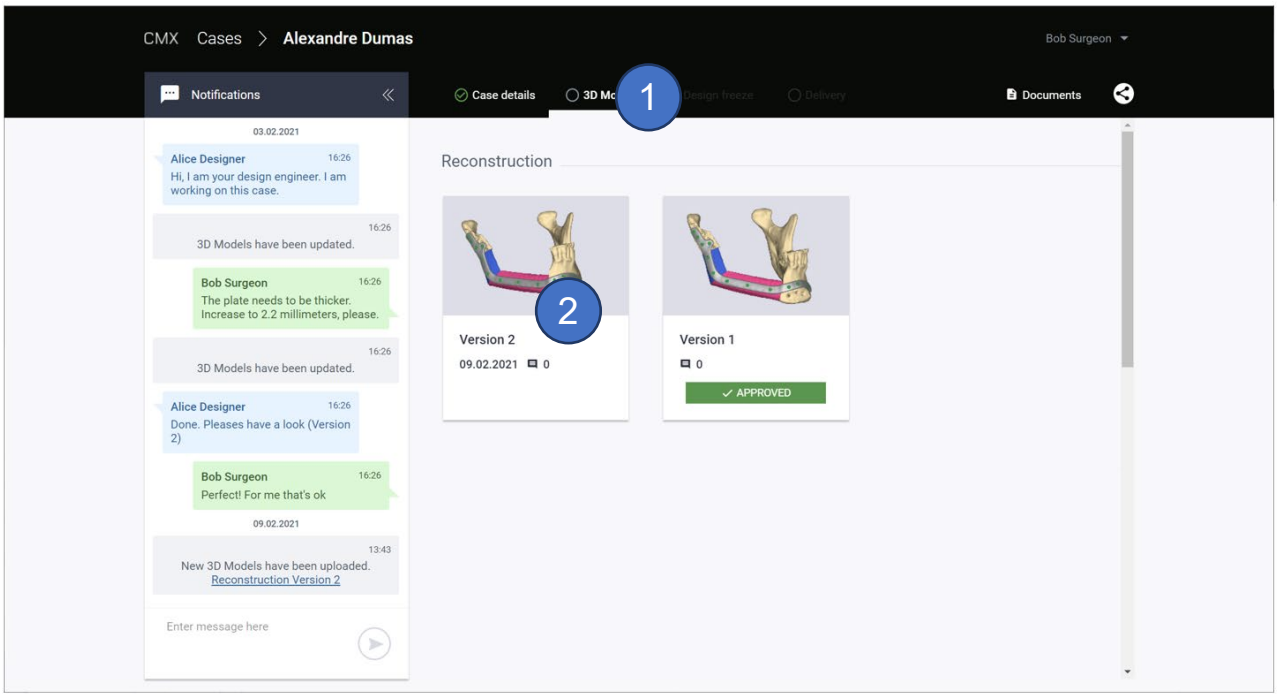
1. After opening a case, go to the DICOM tab.
2. Click “Select directory/drive” (marked with a blue dot in the image above)
3. Select the directory or drive that contains the DICOM image data. You are only able to see directories and drives. The files themselves are not visible.
4. Confirm the browser dialog. Image files are not uploaded to the server at this point. They’re only loaded locally in order to be visualized.
5. Select all DICOM series you want to upload by checking their respective checkboxes.
6. Click “Upload selected series”

	WARNING
	Do not use the DICOM viewer for diagnostic purposes. Use it only to find the correct data to upload.

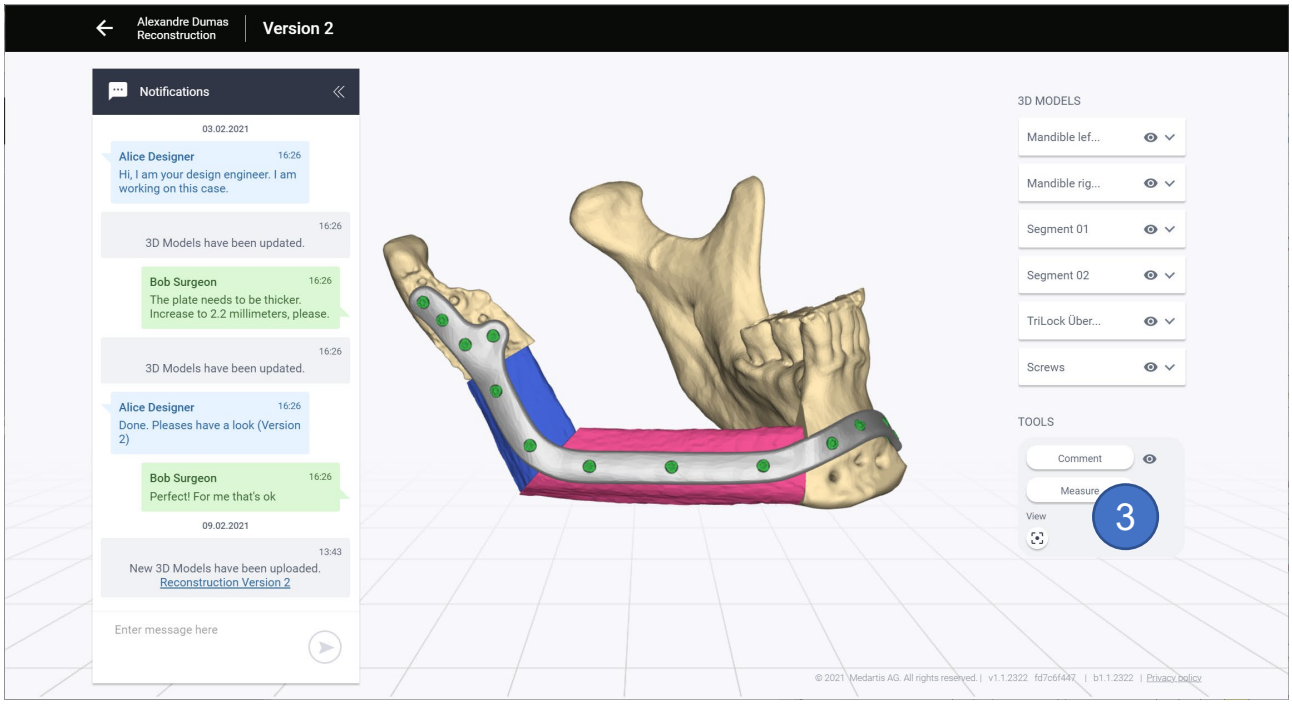
6.2 Measure Distances in 3D View

The 3D view includes a measurement tool for measuring distances between selected points on 3D model surfaces. The unit of measurement is millimeters and measurements are displayed with 1 digit after the decimal point. The measurement is solely based on the 3D model data and its accuracy in relation to real world structures is limited by the underlying data source and the segmentation. Based on an analytical research we concluded a maximum measurement deviation of ± 3.1 mm, given that the raw data satisfies our scan protocols.

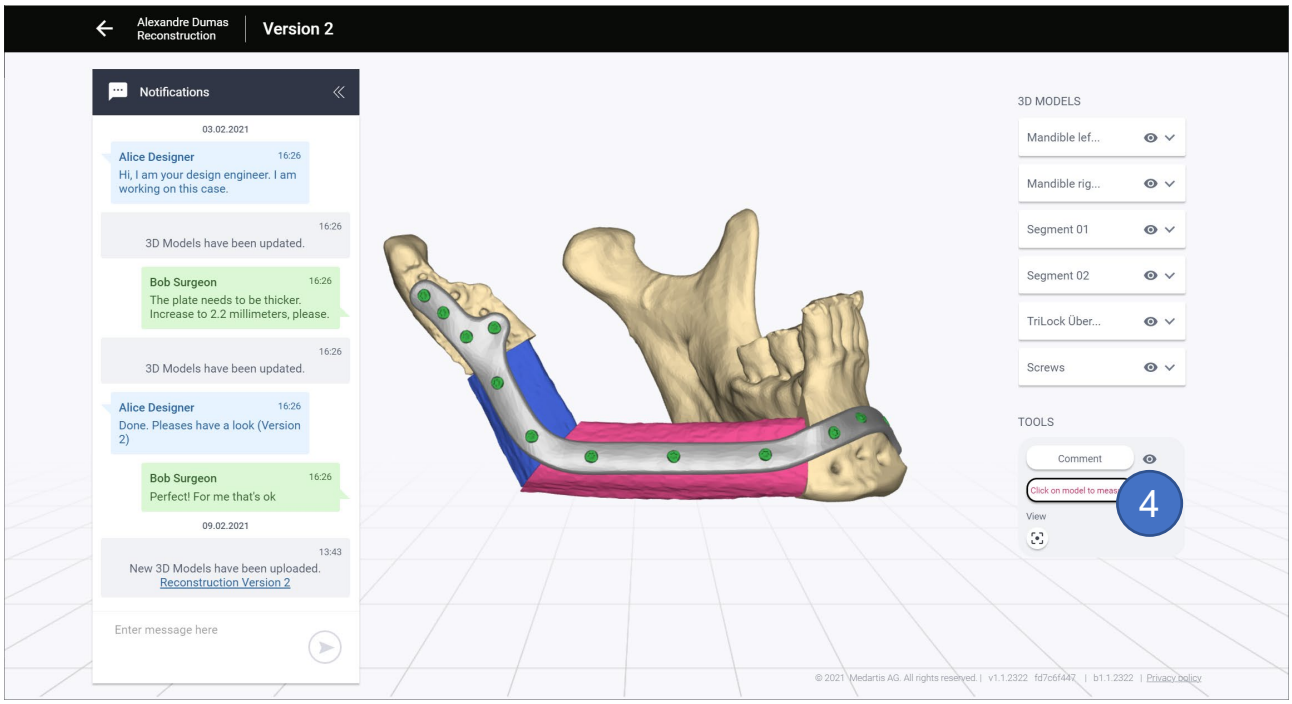
3D views open when you display the 3D Models tab (1) and click any of the versions (2):



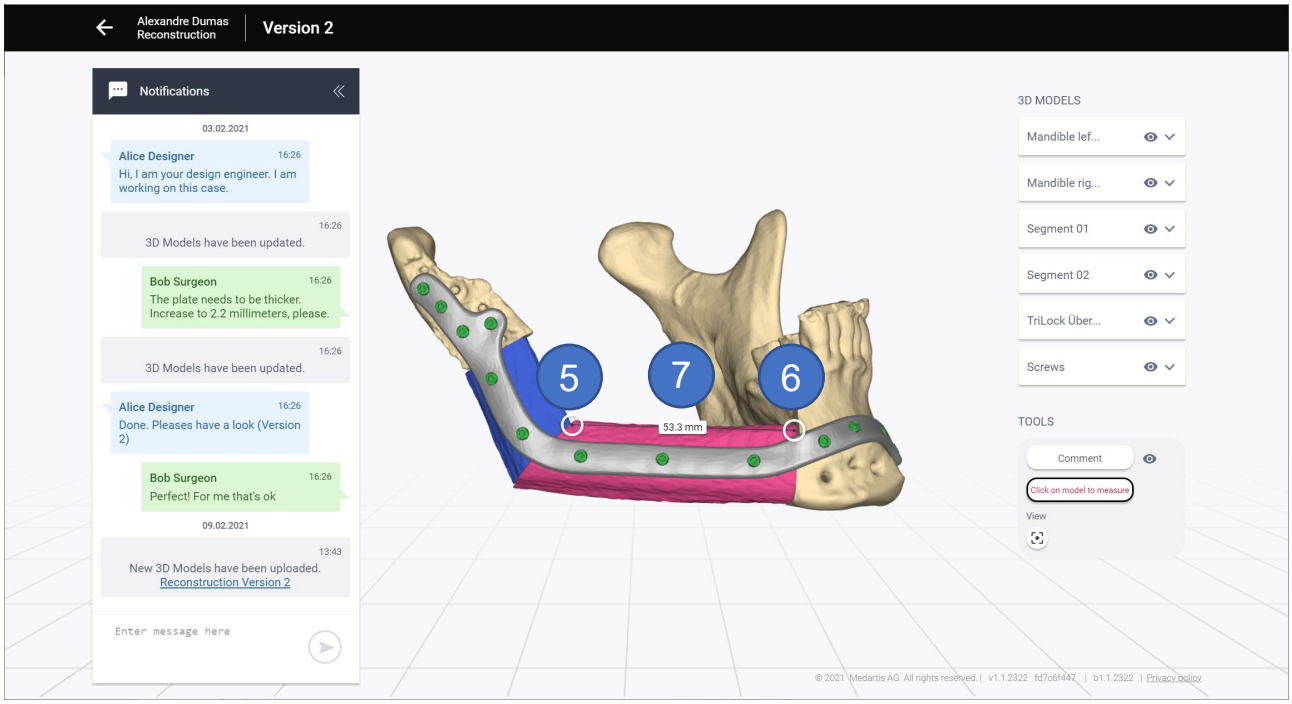
The 3D view contains a TOOLS section on the right of the screen where you find the button “Measure” (3):



Clicking the button “Measure” activates the measurement tool (4):



The first click on the 3D model defines the start location of the measurement (5). With a second click on the 3D model you define the end location of a measurement (6). After that, start and end are visualized by white circles with black dots in the center. The direct connection between the measurement points is visualized by a black line. A label in the middle of the line displays the distance measurement value in millimeters (7):



	WARNING
	Measurements match the length of the direct connecting straight line between start and end point. No surfaces or obstacles between measurement endpoints are taken into account. Incorrect measurement interpretation may influence the decision making process regarding the design of the personalized device.

	WARNING
	When using the software as a Designer, always validate that the 3D models correctly represent the real life structures (scale, resolution) before uploading.

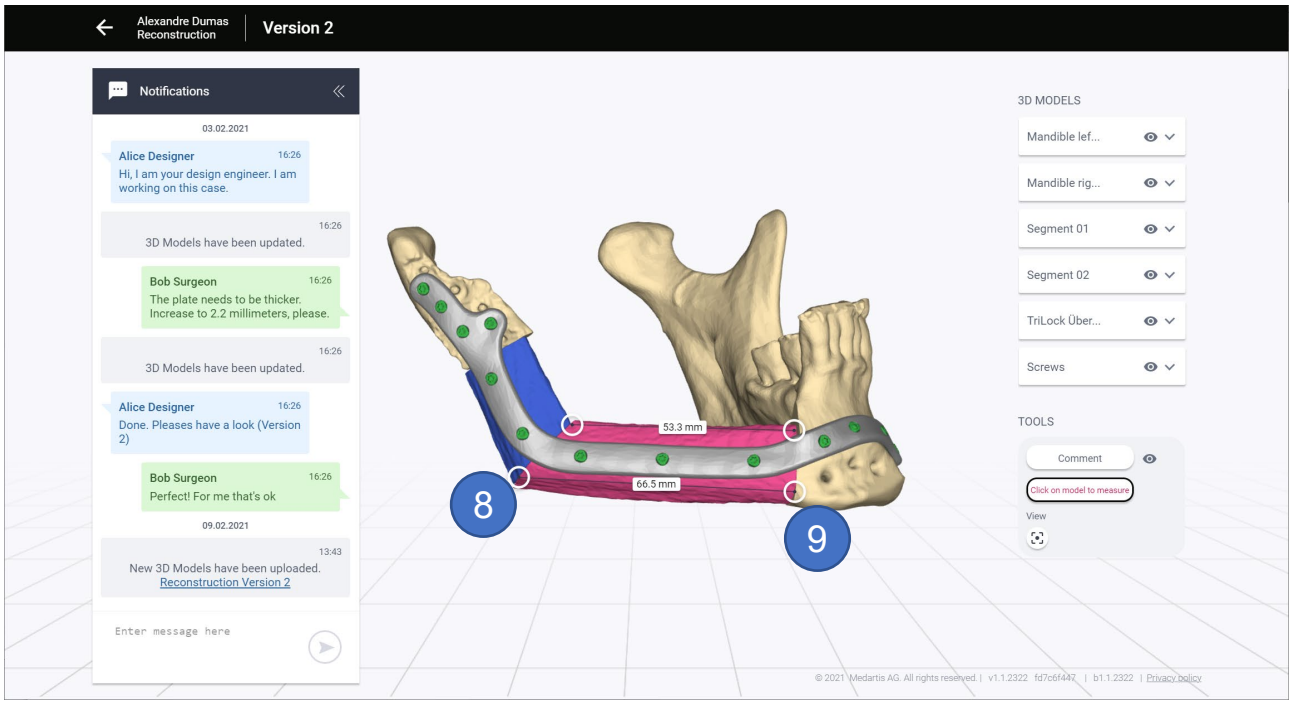
	WARNING
	The measurement is solely based on 3D model data and its accuracy in relation to real world structures is limited by the underlying data source and the segmentation. Based on analytical research, we concluded a maximum measurement deviation of ± 3.1mm, given that the raw data satisfies our scan protocols.

	ATTENTION
	Measurements are temporary and not stored persistently. They are removed when the user deactivates the measurement tool or when he closes or reloads the 3D view.

	ATTENTION
	Measurements are only visible for the current user and cannot be shared with other users of the CMX Portal.

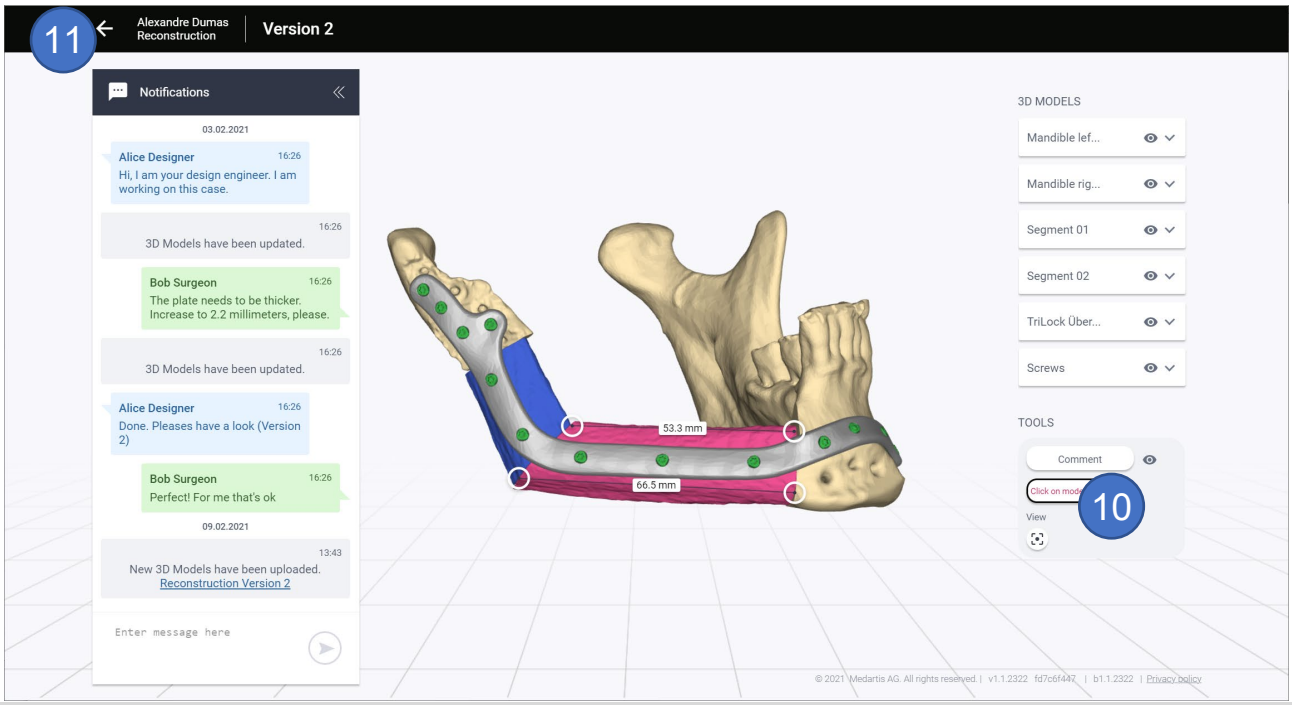
6.2.1 Multiple measurements

After placing the first measurement (see chapter 6.2), the measurement tool stays active. For subsequent measurements click again to define the next measurement start point (8) and then again for the next end point (9):



6.2.2 Deactivate the measurement tool

You can deactivate the measurement tool by clicking the measurement button again (highlighted button with red instruction text) (10). Alternatively you can also leave the 3D view using the "←" button (11). Please note that measurements are removed as soon as you leave the measurement tool or the 3D view.



7 Troubleshooting and Error Messages

In the event of abnormal operation, immediately stop using the CMX Portal and contact Medartis support.

If it is not possible to locate or eliminate the problem using this chapter, or if the dysfunction is still present, stop using the CMX Portal and contact Medartis support.

	WARNING
	In the event of abnormal operation, immediately stop using the CMX Portal and contact Medartis support.

7.1 Error Messages

Error message	Description
Server is not reachable. Please check your network settings.	This message indicates, that the communication to the backend server has been interrupted. If this message shows multiple times over a continuous time range, the client or the server might be offline.
Error Page: “CMX Portal is currently under maintenance”	This error message indicates that the server is currently offline due to maintenance. In urgent cases contact the displayed support contact information.
Please enter a valid date	This message indicates that the entered date format is incorrect. In this case, please strictly follow the requested date format.
Please specify a custom-made device type. If you choose 'Other', specify in the text field.	This message indicates that you have not chosen a device type yet.
Please enter at least … letter(s)	This message indicates that the text in the input field is too short to be accepted.
Please enter at least … character(s)	This field must be filled at least with the indicated amount of characters.
Please enter less than … letters	This message indicates that the text in the input field is too long to be accepted.
Please enter less than … characters	This message indicates that the text in the input field is too long to be accepted.
Numbers and special characters are not allowed	This message indicates that this input only accepts alphabetical letters and that the numerical/special characters need to be removed for the input to be valid.
Ooops, the page you were looking for does not exist.	This message indicates that the requested URL is not valid.
Your file is too big for the upload (over 50 MB)	This indicates that the file which has been marked for uploading is too big for the upload process to be handled. You must choose a smaller file.
Could not upload file! File has no PDF format.	This message indicates that the file that was uploaded could not be successfully uploaded as it was not a valid PDF file.

Error message	Description
Your session has timed out. Please login again.	This message indicates that the session used for authentication has expired and the user needs to login again to obtain a valid session.
Case could not be created. Please check your internet connection.	This message indicates, that the communication to the backend server has been interrupted. If this message shows multiple times over a continuous time range, the client or the server might be offline.
There was a network error. Could not upload data.	This message indicates, that the upload process has been interrupted. This could be because of an interruption in the internet connection (e.g. because of a firewall) or if the server or client might be offline.
Could not upload data. Possible causes: File too large, wrong ending, others ...	The file could not be uploaded due to the given reason.
Browser error page: Connection timed out HTTP 502 Bad Gateway	The message indicates that you are offline or there is a problem reaching the CMX Portal server or the server might be offline.

7.2 Known Issues

Issue	Cause	Solution
Silent token renewal not working on Safari 13 and ITP 2.0. Therefor the user session ends when the initial token times out. (5 min)	Safari uses ITP 2.0, intelligent tracking prevention, which drops third party cookies. These cookies from the Microsoft B2C system are needed to prolong a user session.	By default the ITP setting is enabled on Safari browser. You can disable this setting by navigating to **Preferences** -> **Privacy** and unchecking the **Prevent cross-site tracking** option.

8 Legal & Regulatory

Please refer to the Terms & Conditions of the CMX service for statements referring to disclaimers and warranty.

The measurement function of the CMX Portal is considered a clinical feature and was subjected to a conformity assessment procedure according to Regulation (EU) 2017/745. Other features of the software are not in the scope of the aforementioned regulation.

9 Symbols & General Instructions

To avoid all physical and material damage, this documentation splits safety instructions into 3 danger levels.

	ATTENTION
	Hazardous situation which can cause material damage or lead to moderate serious injury.

	WARNING
	Hazardous situation which can cause serious/ fatal injury.

	DANGER
	Hazardous situation which could immediately cause serious/fatal injury.

	Consult instructions for use
MD	Medical device
LOT	Lot number shows the version of the software as *major version.minor version* (e.g. *1.1*)
UDI	Unique device identifier
	Manufacturer

	Date of manufacture
EC REP	Authorized representative in the European Community / European Union
CE 0197	Applies only to EC risk class I devices in sterile condition, class I devices with a measuring function, class I reusable surgical instruments and class IIa and IIb devices.

10 Manufacturer Contact Information

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Disclaimer: The conformity of the Software as a Medical Device “CMX Portal” does not allow any conclusions to be drawn about the conformity of the personalized devices generated later in the higher-level manufacturing process.