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CX-PRIME

User Manual

Vendor-Neutral
Medical Device & Patient Data
Automation Platform

5
Version

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1 General Information

Thank you for choosing CX-PRIME. This user manual will introduce you to the software that you have purchased and its properties. It offers step-by-step instructions and explanations on the intended uses of CX-PRIME with screenshots to provide examples. Your ability to use all or only certain CX-PRIME functions depends on the specific configuration that you have purchased.

Please read this user manual to optimize your Operating Room (OR) workflows.

We will continuously update this manual in line with any changes or upgrades to the CX-PRIME software.

We hope that this manual answers your questions. If you have any queries to which you are unable to find answers, please do not hesitate to contact our service team. Please also use this contact to report any incident to us, in addition to notifying your local health authority.

Service hotline: +49 (0)1805 722730

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If you have any general questions about CX-PRIME or would like to receive further information about the full range of caresyntax® products, please do not hesitate to contact us at the address and phone number below.

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Target Group

This manual is aimed at medical personnel, i.e. doctors and nurses, who are involved in operating the CX-PRIME software in the operating room (OR).

Copyright

CX-PRIME and the user manual may only be copied, modified, and/or passed to third parties with the authorization of the manufacturer caresyntax® GmbH.

The information contained in this manual is subject to change without prior notice in order to improve reliability, design, and function. As such, this manual does not represent a commitment on the behalf of the manufacturer.

Under no circumstances will the manufacturer be liable for direct, indirect, special, incidental, or consequential damages arising from the use or inability to use the product.

This document contains proprietary information protected by copyright. All rights are reserved.

No part of this manual may be reproduced by mechanical, electronic, or any other means without prior and explicit written permission by the manufacturer.

Icons

1 Red numbers indicate steps in instructions.

Example: **1** Click...

The squares in the figures indicate the location of control elements that are mentioned in the steps with the same number.

Information or additional helpful tips are indicated with an i.

Legal manufacturer.

Consult instructions for use.

Warning!

The term **WARNING** is used to draw attention to potential risks that can lead to endangerment, injury or even death of the patient or user.

Caution!

The term **CAUTION** is used in connection with problems that may result from proper or improper use of the device. Non-compliance may lead to program errors, or cause the full system to fail.

Button names are printed in bold. Example: Click **OK**.

General Operating Concept

The CX-PRIME operating concept is based on touch screen operations. The individual functions are stored in apps, which are further subdivided in a perioperative overview. The following operating instructions always apply:

The Back button saves the selected settings.

The Desktop button takes you back to the overview of the apps.

To confirm instructions: click the confirmation button once.

To exit pop-ups: click outside of the pop-up screen.

It is sometimes necessary to double click to confirm instructions. Such cases are specifically indicated.

Device Description and Intended Use

CX-PRIME is a stand-alone medical device software that, alongside various non-medical features, supports in the diagnosis, therapy and treatment of diseases and injuries. CX-PRIME is a modular suite of surgical workflow tools. It is a vendor-neutral OR integration platform, that collects surgical data from disparate sources, and centralizes it allowing the user to display, view, record, forward, and store medical images, videos, and other data within the operating room.

It thus helps to improve efficiency in the OR workflow, by aggregating, combining, and making available digital data related to a patient, process or medical device.

1.1.1 Intended use

CX-PRIME is a stand-alone medical device software that supports in the diagnosis, therapy and treatment of diseases and injuries by:

1. Making available surgical imaging data,
2. Export of perioperative imaging data,
3. Control of medical devices.

Making available surgical imaging data

By making available surgical imaging data on various displays in the OR, CX-PRIME enables the treatment of diseases, injuries, and / or disabilities. Through routing imaging data, the performing clinician is informed about the actual state of the current surgical procedure. Thus, CX-PRIME provides information which is used to take decisions with diagnostic and / or therapeutic purposes.

Export of perioperative imaging data

Perioperative images and videos are created via CX-PRIME and consequently exported to PACS. These images and videos can be used by clinicians for diagnostic purposes, e.g. a video recorded during a surgery may serve as input for further diagnosis of the condition of individual patients. Thus, CX-PRIME provides information which is used to take decisions with diagnostic and / or therapeutic purposes.

Control of medical devices

Via CX-PRIME, other medical devices, such as surgical lights and surgical light cameras, can be controlled.

1.1.2 Other Normal/Intended Use

Adding to the intended use outlined in chapter 1.1.1, CX-PRIME is designed to improve clinical ergonomics, workflow efficiency and quality of care. This is achieved by allowing the user to route and display patient related content on one single point-of-interest for reference purposes, rather than needing to access multiple systems separately (PACS, HIS, and other data sources). To facilitate this, CX-PRIME can be connected to other devices within the OR; moreover, it allows for interfaces with PACS or HIS to be established, to retrieve pre-operative information related to the patient. By these means, medical information and images can be displayed, viewed, (pre-)recorded, transmitted, routed, and stored.

Further non-medical functions CX-PRIME are:

- Surgical safety checklists
- Import of worklists from PACS via DICOM
- Import of studies from HIS via HL7
- Creating/deleting new studies, including ad-hoc creation of a patient database entry (“Emergency function”)
- Import of Non-DICOM images from local directory, and other media such as USB or CD
- Converting Non-DICOM images in JPEG, TIFF, PNG, and BMP format as well as non-DICOM videos in MP4 format into DICOM format
- Allocation of image and video data onto various displays in the OR (Routing)
- Recording, playback, and transmission of image and video sequences of camera-based systems during clinical procedures (e.g. Microscopes, Endoscopes, Room cameras) for the purposes of observation, documentation, and training
- Videoconferencing and video sharing capabilities to support education of clinical staff in training
- Export of image and metadata data in DICOM format to network drive, or USB
- Export of images in Non-DICOM formats to network drive, or USB
- Access to non-medical 3rd party applications (Browser, Music Players etc.)
- Timer
- User Management

CX-PRIME allows service staff and caresyntax employees to do the following:

- Installation, configuration, service and remote maintenance, incl. remote software updates
- Connectivity with accessories and other devices and products

Indications / contra indications

CX-PRIME can used be during any type of procedure, it applies for every patient, independent of the medical indication. Besides these medical functions, CX-PRIME allows the user to display, view, record, forward, and store medical images and videos within the operating room. There are no contraindications.

Exclusion

CX-PRIME is not to be used for active patient monitoring.

Characterization of Users

Typical users of CX-PRIME are circulating nurses, clinicians, OR managers, ICU managers and biomedical IT professionals. These are well-trained professionals. For typical tasks, see chapters 1.1.1 and 1.1.2.

Medical and non-medical functions are usually performed by circulating nurses, since they are usually working from a non-sterile field and can access and control the main CX-PRIME PC. In addition, clinicians may use the User Management, Routing, review the imported and created media, export the instances, and use videoconferencing / streaming. OR / ICU Managers may use the import of worklist and studies. Biomedical IT Professionals usually have access to the settings of CX-PRIME and therefore can change the configuration that supports both medical and non-medical functions of CX-PRIME.

CX-PRIME caters for the use of different languages. Regardless of the language being used, the user needs to be able to fluently read and write the respective language in a quick manner. This, along with the medical education (as outlined above), are the only intellectual capabilities required to operate CX-PRIME. General experience and understanding of modern IT is helpful, but not required to operate CX-PRIME.

CX-PRIME users must pass the training before beginning to use the device.

Characterization of Context of Use

CX-PRIME is a Class IIa medical device in the EU and FDA Class I MDDS medical device in the United States of America. Each release is tested to include verification, validation, regression, and risk mitigation.

1.1.3 General Environment

With the users described in section 1, typical use environments are the Operating Room (OR), ICU, examination rooms, and offices / wards.

1.1.4 Physical Parameters

The physical parameters shall be those of a standard O.R. Visibility of the user interface is key to the proper use of CX-PRIME. This includes, but is not limited to, brightness of the display, dust/debris on the screen, and any electromagnetic interferences possibly induced by 3rd party equipment.

The PC that CX-PRIME runs on should be physically isolated, e.g. in a caresyntax® Medical Multiconsole, or a lockable technical room.

1.1.5 Supply Engineering

CX-PRIME is dependent on the customer-specific on-site setup. However, irrespective of the specific on-site setup, the following are basic requirements that are necessary for CX-PRIME to function:

Required:

- CPU: Intel Core i5 (8th generation or newer), clock frequency > 3 GHz
- RAM: 8GB DDR4
- Capture Card: YUAN SC5C0N4 HDMI-S,4xHDMI (shielded) or YUAN PCIex1*SC5C0N1-S, DVI, SDI*shielded
- Hard Drive: 256GB SSD
- OS: Windows 10 Professional, including:
    - Auto-updating Antivirus
    - Active Firewall

Recommended:

- Connection to WSUS Update server
- OS: Windows 10 Enterprise LTSB/LTSC

Customer-specific on-site setup should be reviewed by caresyntax® GmbH service staff or trained personnel before installation.

CX-PRIME must be installed and configured by trained personnel before use.

Exclude following folders from Antivirus Scan:

- C:\Program Files\CX-PRIME
- C:\ProgramData\CX-PRIME

1.1.6 Portability

CX-PRIME can be installed on any environment meeting the criteria outlined in section 1.1.5. With this, portable use cannot be excluded. However, it will predominantly be used within the O.R. CX-PRIME is not intended to be worn on the body.

1.1.7 Combinations and Connections

CX-PRIME can be integrated with medical devices with specified communication protocols. It allows for the control of surgical lights, surgical light cameras, and room cameras. See Appendix D for current list of integrated devices.

Also, connection with digital standardized video interfaces is possible, as well as a connection to send data to PACS (via DICOM protocol), and exchange data with HIS (via HL7 protocol).

In order to fulfil its intended use, the product is intended to get information from any video sources in the OR (room cameras, surgical light cameras, endoscopic cameras), and be connected to at least one display.
Supported video interfaces (depends on video management integration – see supported video management systems in Appendix D):

- HDMI
- DVI
- Displayport
- SDI
- VGA
- S-Video
- Composite

Supported video resolutions and refresh rates (depends on video management integration – see supported video management systems in Appendix D):

- 1920x1080@50P
- 1920x1080@60P
- 1920x1080@50I
- 1920x1080@60I
- 1920x1080@25P
- 1280x720@50P
- 1280x720@60P
- 1280x720@50I
- 1280x720@60I
- 1280x720@25P
- 1280x720@50P
- 720x576@50P

- 720x576@50I
- 720x480@60P
- 720x480@60I

Important Safety Information

The software is installed by the caresyntax® GmbH service staff commissioned with this task. In the event of modifications by third parties, caresyntax® GmbH accepts no liability for any errors in CX-PRIME.

The owner/user must read the operating manual before using the software for the first time to prevent misuse.

The names and clinical pictures used in the descriptions are purely fictitious and do not relate to real people.

If changes are to be made to hardware and software systems in your hospital, please ensure that you notify caresyntax® GmbH in advance. You may only conduct system modifications following prior approval by caresyntax® GmbH. This is the only way to ensure the full functionality of CX-PRIME.

If technical interfaces are connected to CX-PRIME and CX-PRIME automatically receives and exports data via these interfaces, the data must be checked.

Store the user manual for the CX-PRIME software somewhere easily accessible and ensure compliance with all the information contained.

Hospital IT has to put in place a backup mechanism to daily replicate the database and resources of CX-PRIME to a safe location.

Hospital IT has to set the user permissions in operating system to allow read and write access in CX-PRIME installation and program data folder

(standard directories: *C:\ProgramData\CX-PRIME* and *C:\Program Files\CX-PRIME*).

Patient consent must be obtained from a patient regarding the use of patient data as well as objection and their consequence.

It is recommended to undergo training regarding usage and handling of personal data as outlined per GDPR/HIPAA.

If working with video modalities crucial to perform surgery (e.g. endoscopy systems) always have a direct connection to a display system setup.

Manufacturer and Software information

1.1.8 Label

Product name	CX-PRIME
Basic UDI-DI:	4251823900008 (with GS1)
Classification according to MDR 2017/745 (Planned)	Class IIa (Rule 11)
Legal Manufacturer	caresyntax® GmbH Kaltes Feld 16 08468 Heinsdorfergrund Germany Tel.: +49 (0)30 7130297 0 Fax: +49 (0)30 7130297 69 E-Mail: info@caresyntax.com Web: www.caresyntax.com

1.1.9 Version lifetime

The Lifetime of each major Release Version of CX-PRIME is defined by the Release of its successive major Release. The Lifetime for CX-PRIME 5.X Release ends 2 years after the Release of CX-PRIME 6.0.

2 First Steps

This section describes the basic functions of CX-PRIME such as starting and shutting down the software, logging in and out as a user, and using the emergency function.

Starting CX-PRIME

1 To start CX-PRIME, double-click the **CX-PRIME** icon on the Windows desktop.

If you cannot find this icon on your desktop, you can also start the program via the Windows start menu (see Figure 2.1).

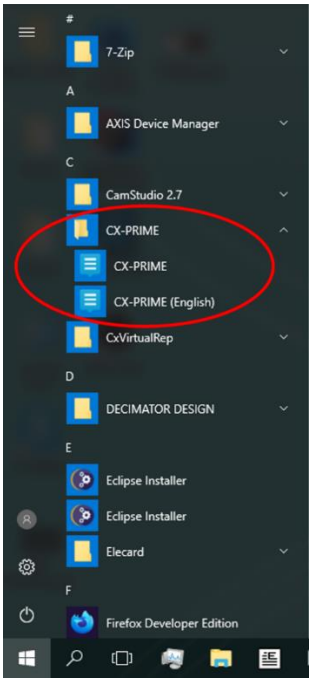


Figure 2.1: CX-PRIME in the Windows start menu.

CX-PRIME starts and the welcome screen (Figure 2.2) opens on the default monitor. A list of registered users appears on the welcome screen. Each of these users can log in under their name (see Section 2).

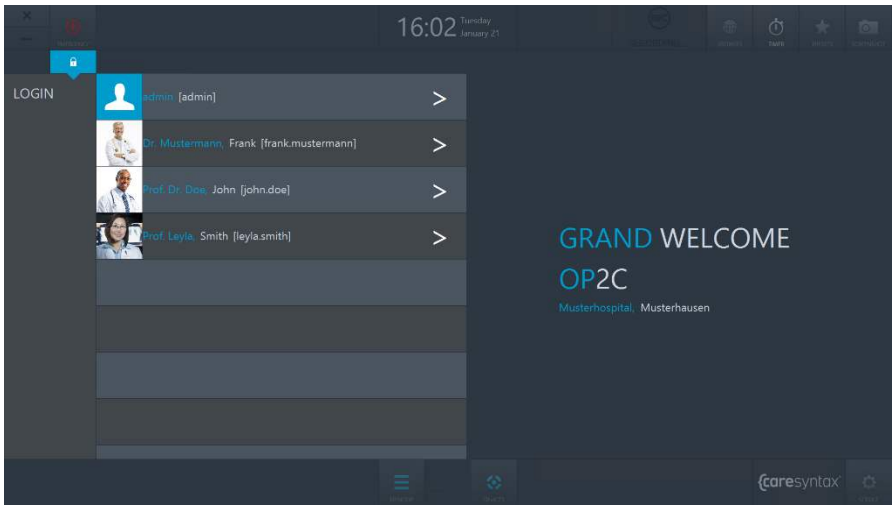


Figure 2.2: CX-PRIME welcome screen.

Shutting down CX-PRIME

1 To shut down CX-PRIME, click the **X** in the top left corner of the welcome screen.

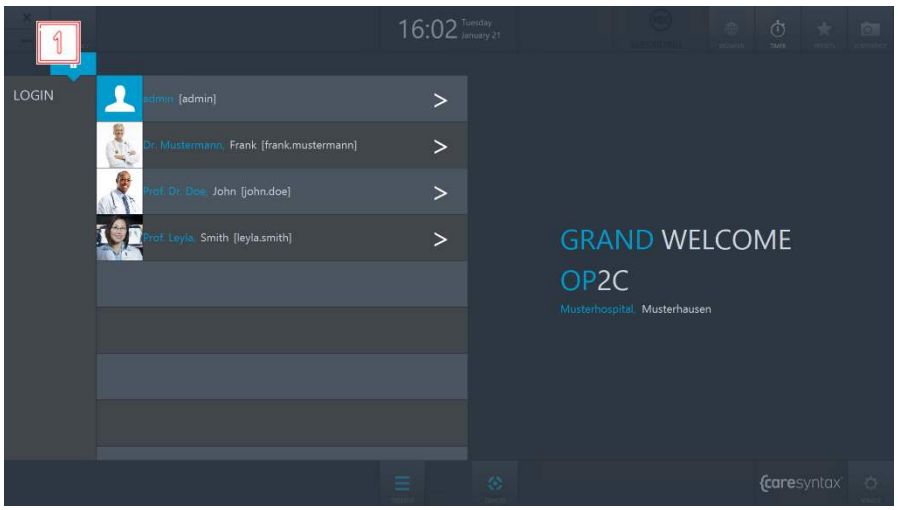


Figure 2.3: Shutting down CX-PRIME.

2 A pop-up asks you to confirm the termination of the program by clicking the green button.

If you do not actually want to shut down CX-PRIME: 3 click outside of the pop-up window to return to CX-PRIME.

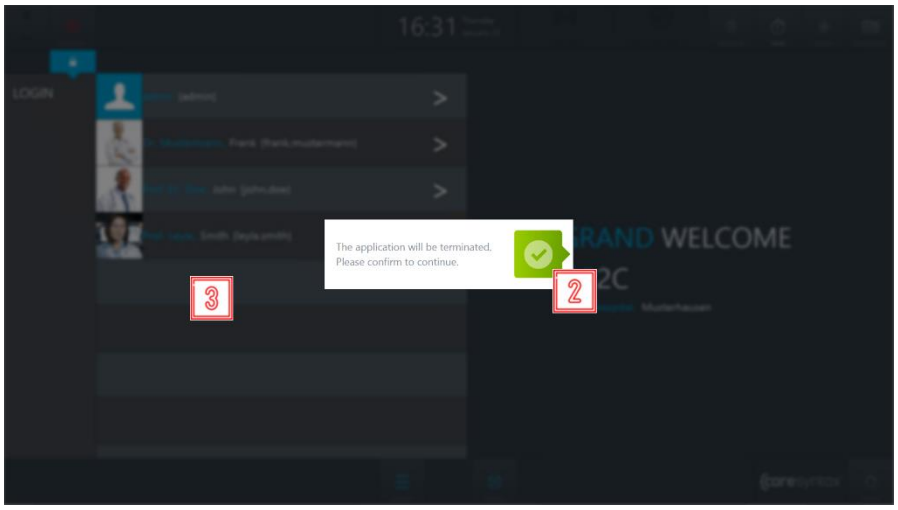


Figure 2.4: Shutting down CX-PRIME.

User Login

1 To log in as a user, click the **>** sign next to your name.

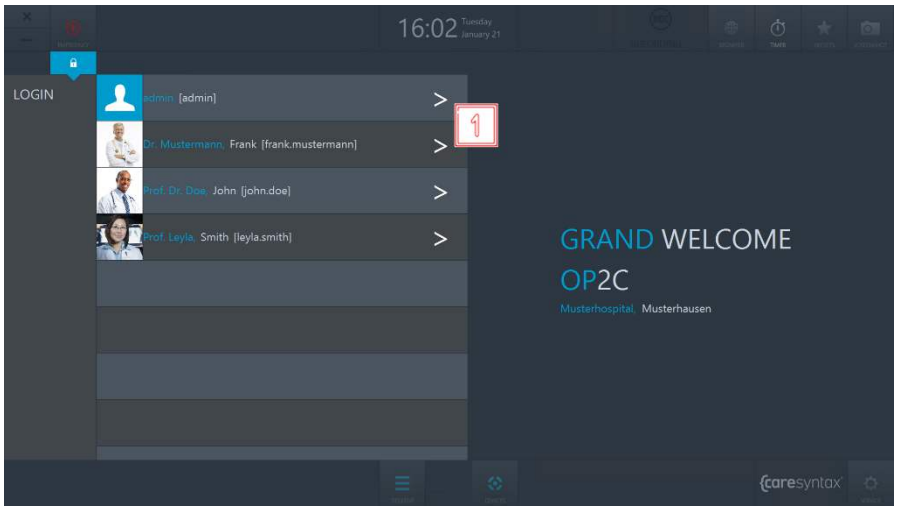


Figure 2.5: User login on the CX-PRIME welcome screen.

2 A login window opens in which you can enter your password.

3 Log in by clicking the green button on the right.

If the login window jitters slightly after you have confirmed your password, the password that you have entered is incorrect. Repeat steps 2 and 3.

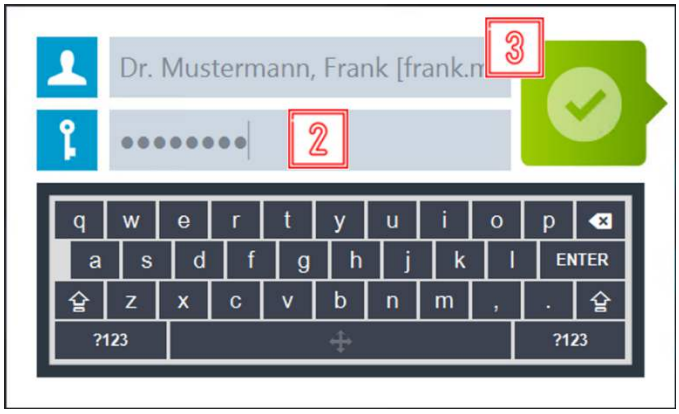


Figure 2.6: User login on the CX-PRIME welcome screen.

Upon successful login, the CX-PRIME desktop appears with the full perioperative overview. The individual operatory phases and their apps are described in Sections 4–6. Users can customize the CX-PRIME desktop and save their user-specific settings as presets. How to do this is explained in the next section.

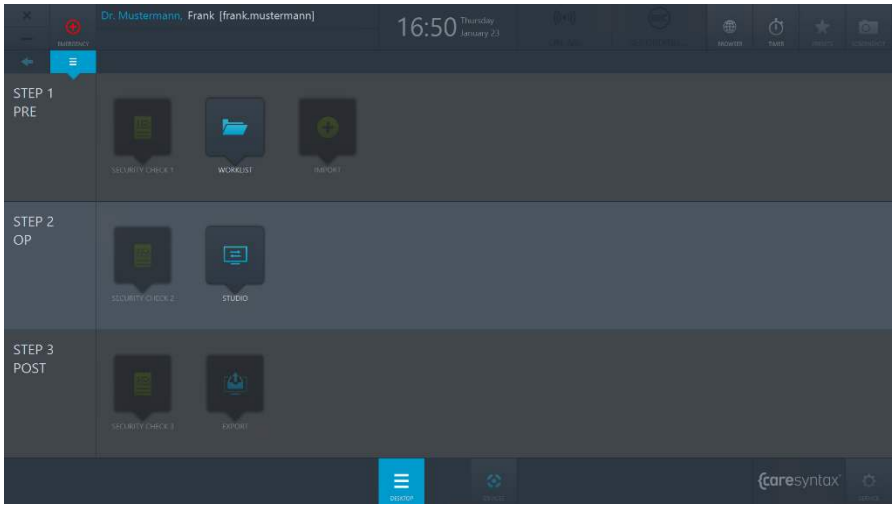


Figure 2.7: CX-PRIME desktop.

Logging Off

Please make sure to perform user logout after completing a procedure (or several consequent procedures).

1 To log off as a user, click the username on the CX-PRIME desktop.

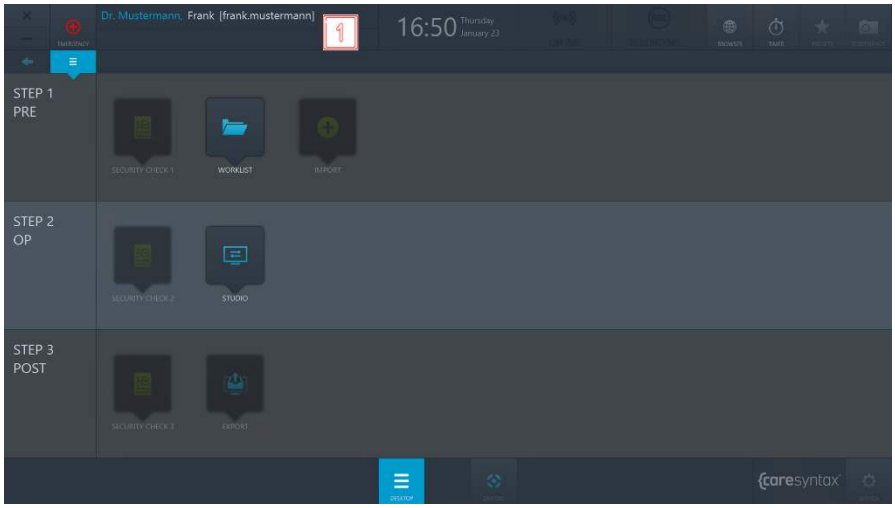


Figure 2.8: Logging off: selecting the username on the CX-PRIME desktop.

2 Click the green button to confirm that you want to log off.

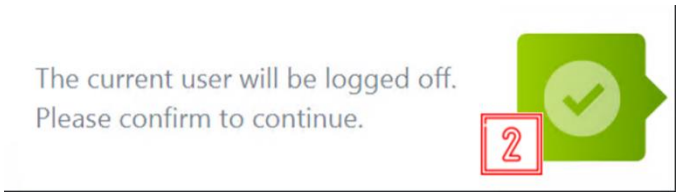


Figure 2.9: Confirming the logoff of the current user.

The CX-PRIME welcome screen with the list of users re-opens. For instructions on how to log in as a user, please return to Section 2.

Emergency Function

The emergency function enables you to take action quickly in the event of an emergency procedure. If an emergency patient arrives, you do not have to start by creating a patient file. Instead, you can create the patient in two quick steps and begin using the CX-PRIME system fully. The emergency function is therefore available for you at all times after you log in as a user, regardless of whether you are on the welcome screen or editing an app.

1 Click the **Emergency** button.

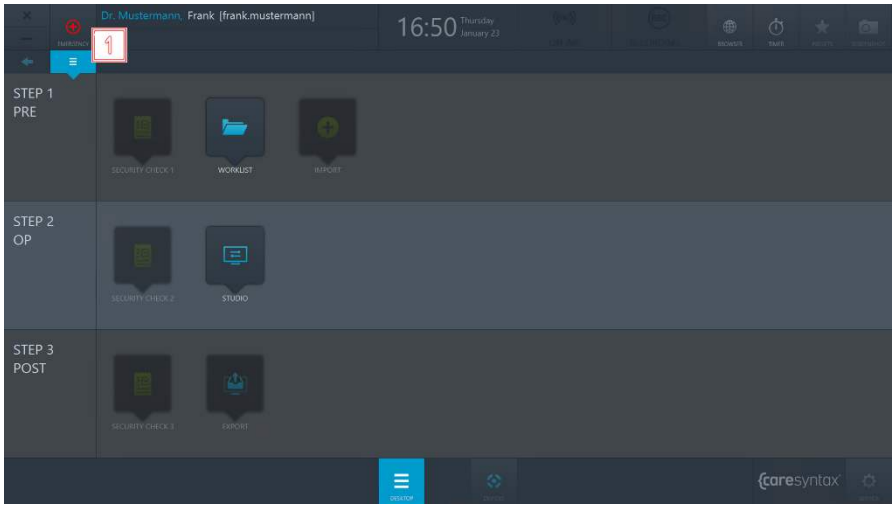


Figure 2.10: Emergency function on the CX-PRIME desktop.

2 Enter information that clearly identifies the patient and the study in the pop-up window. Enter as much information as possible so that the patient can subsequently be assigned to a study.

3 Click the green button to confirm the identification.

Figure 2.11: Entry of clear information to identify the emergency patient and confirmation of the identification.

Following the confirmation, the CX-PRIME desktop appears. The emergency patient has been automatically created in the local worklist using the identification details that you

entered and has been directly selected (see Figure 2.12). Start the operation/medical procedure directly (Section 5).

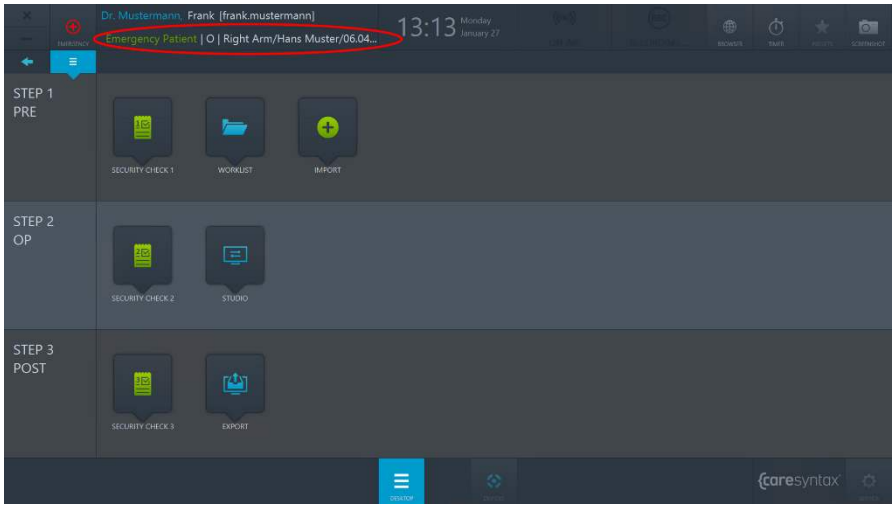


Figure 2.12: CX-PRIME desktop with the emergency patient created (red circle) and a logged-in user.

3 General Functions

Once you have logged in as a user, all the general functions of CX-PRIME are available to you. These functions can be found in the top right corner and in the bottom center of the CX-PRIME screen. You can use the desktop button at any time to come back to the CX-PRIME desktop. You can use the browser and the timer and operate the devices at any time, including when working inside a specific app. The screenshot function can only be used if a patient has been selected in the worklist. Therefore, this is only described in Section 4 after the description of the Worklist app. The following sections describe how to use the individual functions on the basis of user examples.

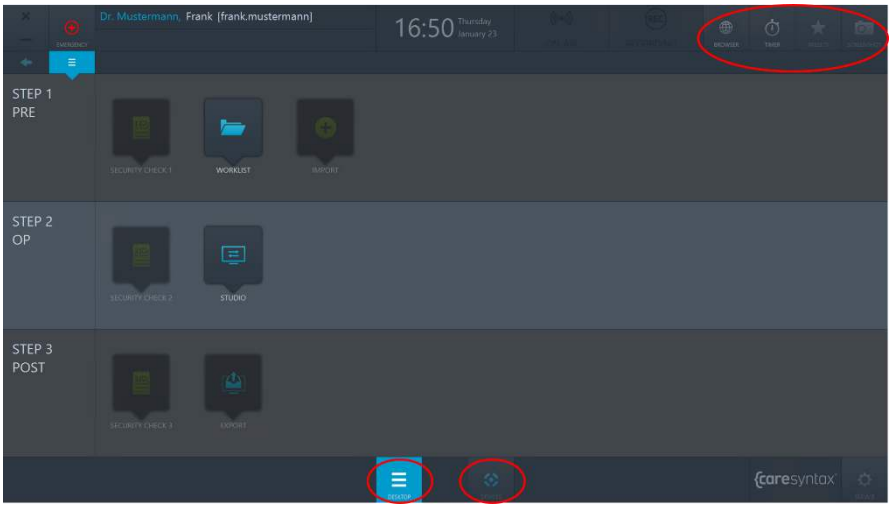


Figure 3.1: CX-PRIME desktop – General functions (red circles).

Browser

The browser enables you to access websites and web clients, for example, from PACS or EMR/EHR systems.

1 Click the **Browser** icon on the CX-PRIME desktop to open the browser.

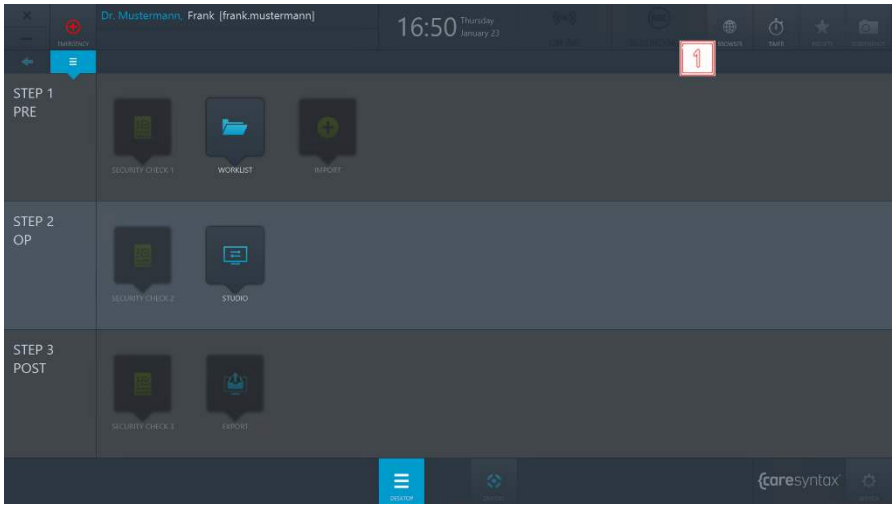


Figure 3.2: Browser on the CX-PRIME desktop.

In this example, a default PACS system URL exists (see Figure 3.3). To change the URL, follow the steps below.

2 Click in the URL field.

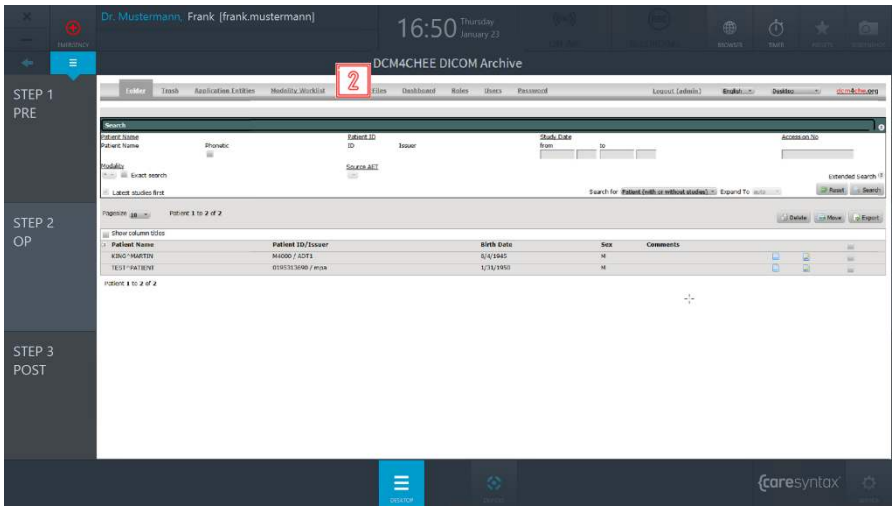


Figure 3.3: URL field.

3 Enter the desired URL, always starting with *http://*.

4 Click the green button to confirm the URL that you have entered.

Figure 3.4: URL entry.

Timer

The timer function is always available to the user and can be used for a variety of purposes inside the OR.

The use of the timer must not affect the use of other devices in the operating room. It is not intended to be used with other medical devices, such as infusion pumps, imaging equipment, or similar.

Only one timer can be set at a time. Setting a new timer while another timer is already running overwrites the existing timer.

1 Click the **Timer** icon.

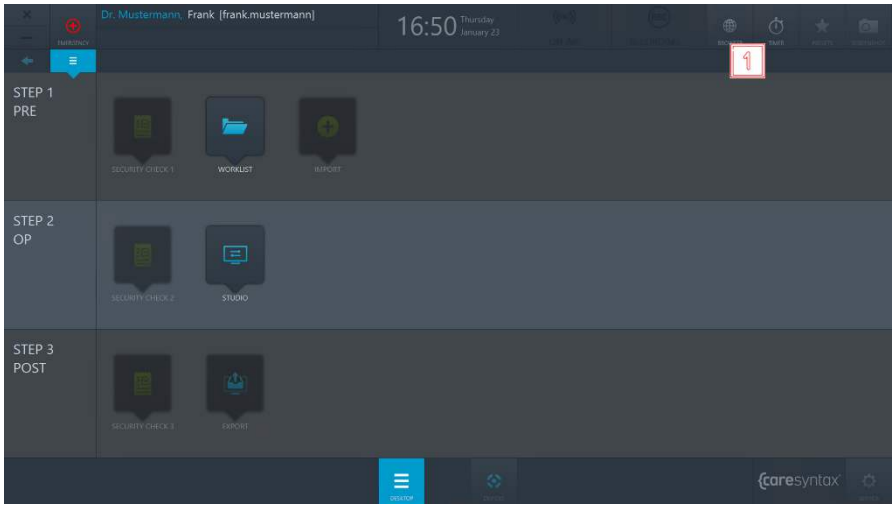


Figure 3.5: Timer function on the CX-PRIME desktop.

2 Click **New Timer** in the pop-up window.

Figure 3.6: Setting a new timer.

3 A further pop-up window appears. To use the timer, you must select between the modes 'forward' and 'backward', which indicate the direction in which the timer counts, and enter the number of minutes and/or seconds. You can also give the timer a name (optional).

4 Click the green button to confirm your entries.

Figure 3.7: Timer settings.

The timer appears in the middle of the top bar on the CX-PRIME desktop instead of the current time.

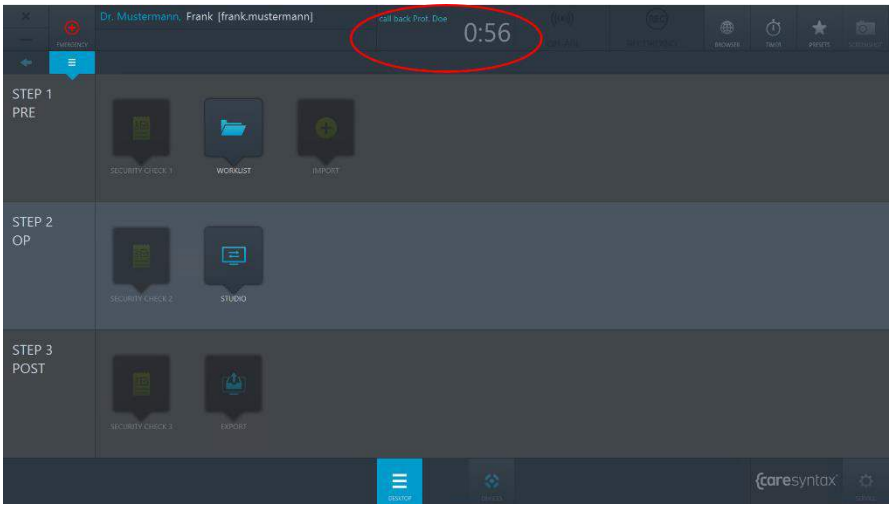


Figure 3.8: Running timer on the CX-PRIME desktop.

5 When the configured time has passed, a pop-up opens to notify you that the timer has finished. Click the green button to acknowledge this information.

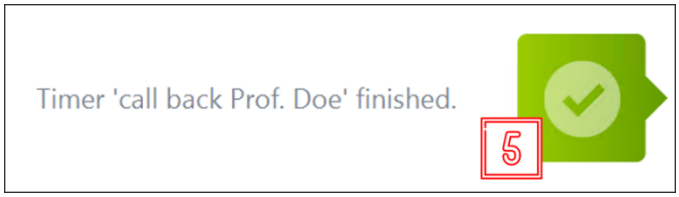


Figure 3.9: Acknowledging the finished timer.

To cancel the running timer, follow step **1** and then:

6 Click **Reset Timer**:

Figure 3.10: Resetting the timer.

If you want to leave the timer running in the background and display the clock, click the field with the running timer (see Figure 3.8). This field allows you to switch between the clock and the running timer at any time. Even if the clock is displayed, the pop-up for acknowledging the finished timer will still appear once the timer has finished.

Desktop Presets

The icons on CX-PRIME desktop are arranged by default order. You can use the Preset function in order to rearrange the icons on the Desktop.

1 Click the **Presets** button.

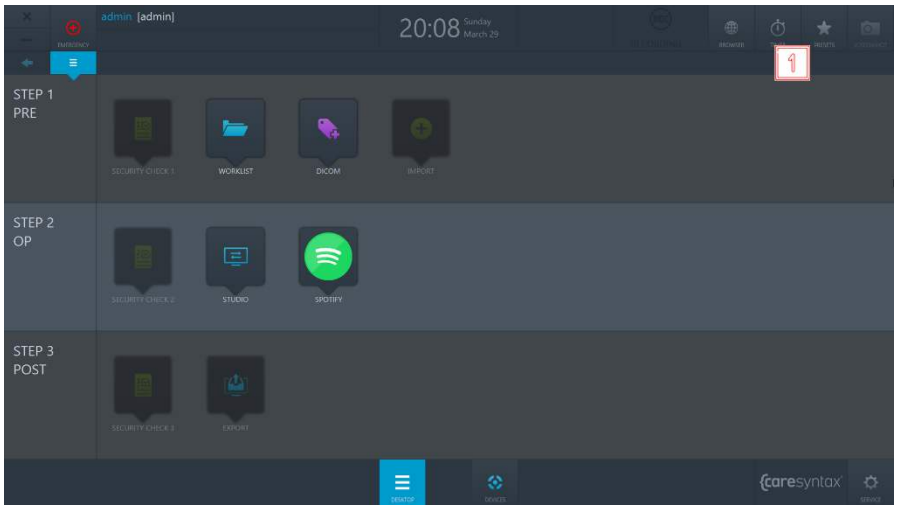


Figure 3.11: Presets button on CX-PRME desktop.

2 Click the **Edit Preset** button in order to rearrange the desktop icons.

After step 2, the icons on the Desktop will start to jitter and you can move them around.

3 When you are done rearranging the icons, repeat step 1 and click the **Save Preset** button to save your changes.

4 If you wish to restore the default icon preset, repeat step 1 and click the **Reset Preset** button.

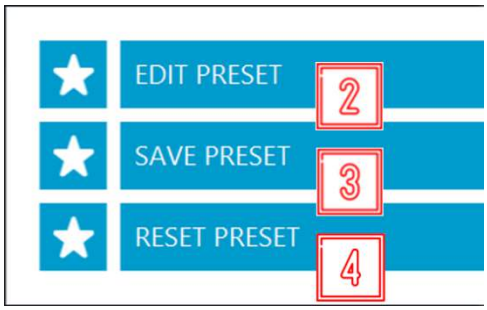


Figure 3.12: Preset actions.

Operating Integrated Devices

You can operate the devices integrated into your system at any time, i.e. on the CX-PRIME welcome screen, on the CX-PRIME desktop, or while working within a specific app. The control functions for the individual devices are described in Appendix A.

1 Click the **Devices** button.

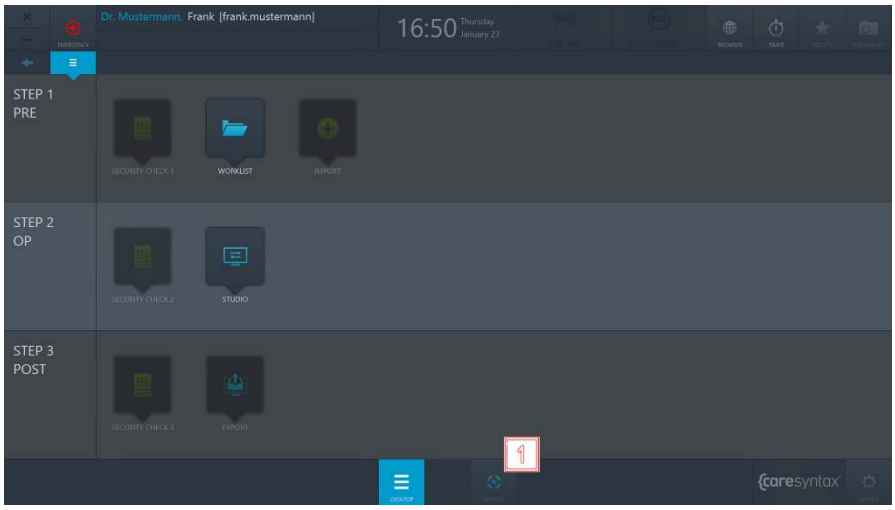


Figure 3.13: Opening the device management window.

2 Select the device that you want to operate by clicking the relevant icon.

Figure 3.14: Selecting the devices to be operated.

Third Party Applications in CX-PRIME

It is possible to configure quick access to the third party applications via CX-PRIME desktop. In the example below (Figure 3.15) quick access to Spotify and DICOM viewer is configured. Once clicking on a third party application icon, the application will open in a separate window.

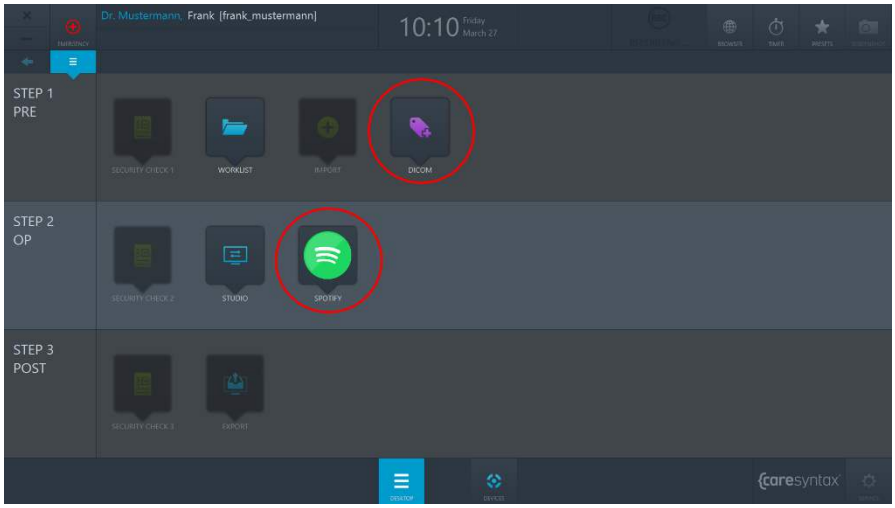


Figure 3.15: Third party applications (red circles) in CX-PRIME desktop.

3.1.1 App Routing

If the system is enabled for App Routing. Certain 3rd party Application that are opened from CX-PRIME desktop will show up as video source in Routing Menu. This will allow the specific application to be routed to a destination like Screen or Multiview. The application can also

be routed when it is running in the background of CX-PRIME. Minimized applications will be represented as a still image.

Once the application is closed the source will vanish from the Routing App until the 3rd party application is reopened.

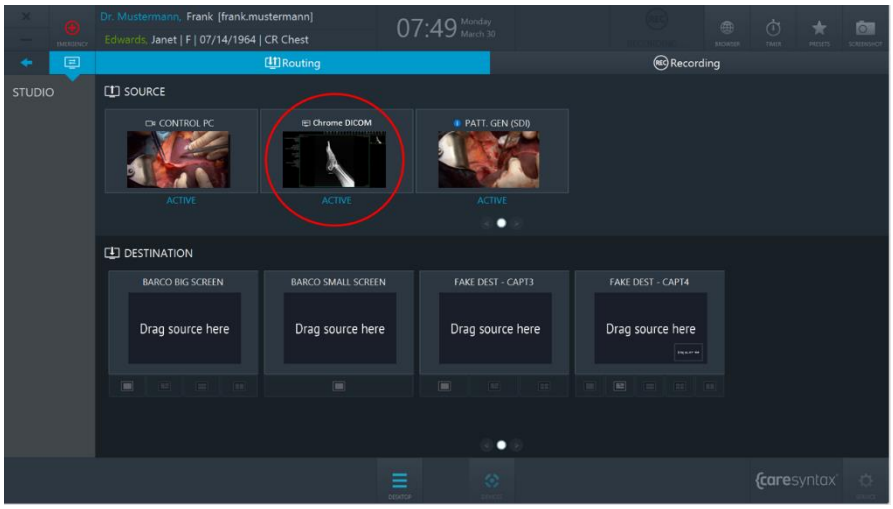


Figure 3.16: Routable third party application (red circles) in CX-PRIME Routing App.

4 Step 1: Pre-phase

The pre-operatory phase is the phase before the actual operation/medical procedure. During this phase, patient data and studies are imported from a **worklist** or manually created in a local worklist. After selecting the patient, the general **screenshot** function also becomes available. You can use this, for example, to check the system status. The first part of the **security checklist** can be filled out in this phase. The **import** app enables you to import pictures and videos in relation to patient/study data.

Worklist

The worklist contains the demographic information about the patient, the study description, and the medical modality used. Patient and study data can be imported into the worklist via DICOM modality worklist (MWL) service class providers (SPCs), via HL7 worklist or via CX-ADVANCE (if it is configured as a worklist provider). Alternatively, the data can be manually created in a local worklist.

This section starts by explaining how to start the worklist and select a study from the local worklist for the medical procedure. The subsequent sections will then describe how to select a patient from an imported worklist, create a new study in the local worklist, and delete a study.

1 Click the **Worklist** icon to open the worklist.

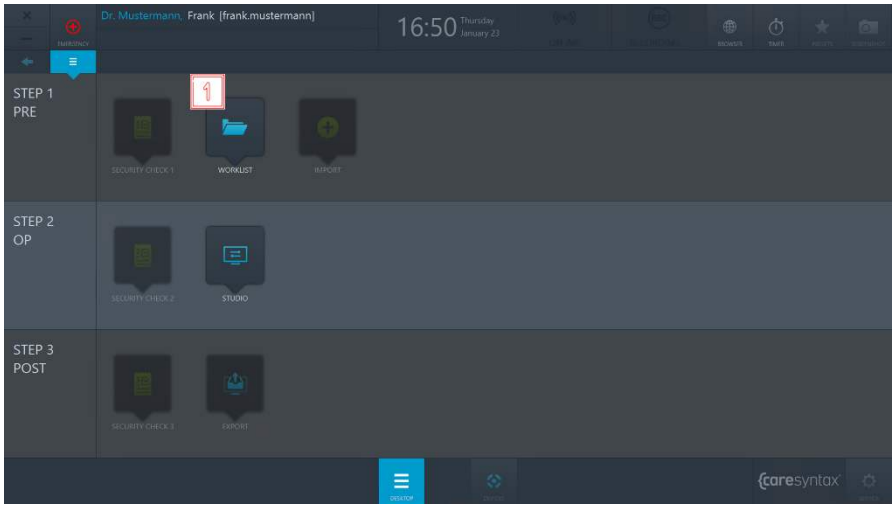


Figure 4.1: Starting the worklist app.

The last used worklist opens with the name shown in gray. The top tab shows which worklist you are in. In Figure 4.2, the current worklist is the local worklist – see red circle. The list of patient/study information is visible below the tab.

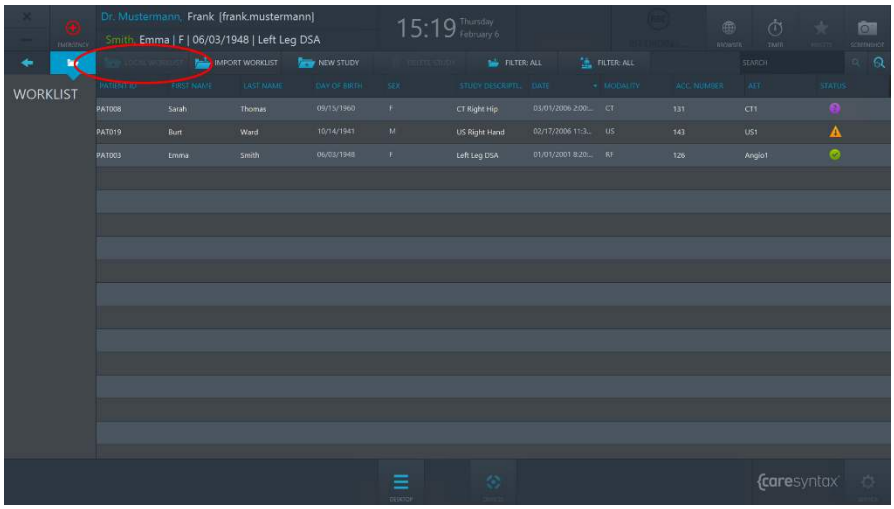


Figure 4.2: Local worklist: the currently displayed worklist is circled in red. Below this is the list of patient and study information.

The worklist contains the following elements:

- *Patient ID*: a unique, cross-institute ID that is assigned to the patient
- *Last Name*
- *First Name*
- *Sex*: M - Male, F - Female, O - Other
- *Day of Birth*
- *Study Description*: a clear description of the medical procedure
- *Modality*: the device used for the study (see Tab. 4.1)
- *Date*: the date on which the patient was created in or imported into the worklist.
- *Status*: the current study status (icons explained in Tab. 4.2)
- *Acc. Number*: the accession number from the DICOM standard, used to assign images to a procedure in the RIS/PACS.
- *AET*: the CX-PRIME device name or the OR name.

TG	Thermography
SC	Secondary Capture
RG	Radiographic Imaging
US	Ultrasonography
RF	Radio Fluoroscopy
CT	Computer Tomography
OT	Other
DX	Digital Radiography
LS	Laser Surface Scan
MR	Magnetic Resonance Imaging

Table 4.1: Worklist modalities: explanation of the abbreviations.

	Study is outstanding
	Study has begun
	Study is complete

Table 4.2: Explanation of the status icons in the worklist.

You can customize the worklist elements as desired. In order to change the position of a worklist element, press on the worklist element with the right mouse button, hold it and move it to the desired position.

In order to resize the columns of worklist elements, move the mouse over the border between two worklist elements until a two-sided arrow appears. Then press the right mouse button, hold it and move the border to the desired position. In this way you can hide worklist elements; however, this does not apply to worklist elements used for identifying the patient or procedure (e.g. Patient ID).

2 Double-click a patient to select that patient.

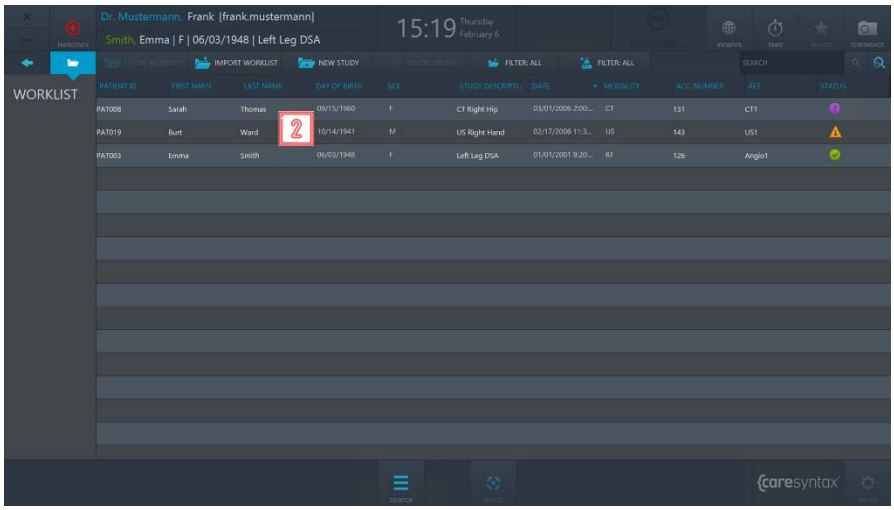


Figure 4.3: Selecting a patient/study.

If your worklist is extremely long and you are looking for a particular entry (e.g. the last name Smith), click the relevant worklist element (in this case, 'Last Name') to sort the worklist by this element. This makes it easier to find the information about the entry you are looking for.

You will then be automatically forwarded to the CX-PRIME desktop where the selected patient appears below the name of the current user. You can now use the other apps in the pre-operatory phase or switch to the operatory phase.

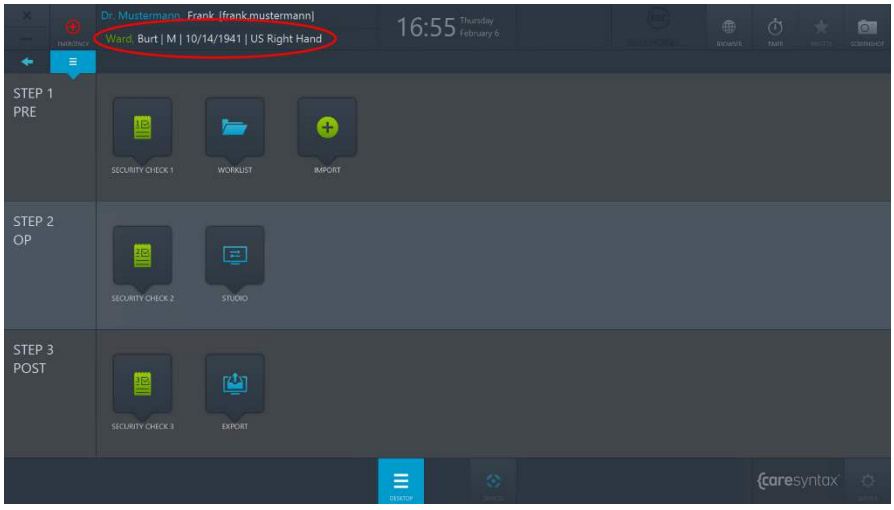


Figure 4.4: CX-PRIME desktop following patient selection. The selected patient is shown below the current user (red circle). .

If a patient has been selected and you are currently editing within another app or are on the CX-PRIME desktop, you can click the patient name displayed to go directly to the worklist.

4.1.1 Imported Worklist

Import Worklist enables you to call up the worklist provided by the PACS/HIS system, select the individual worklist entries, and import them into the local worklist.

1a In case a DICOM Modality Worklist from a PACS System is configured for your installation, click the **Import Worklist** tab to display the latest worklist entries. The Worklist will be refreshed every 60 seconds, unless configured otherwise in the Service area by an admin user.

1b In case HL7 Worklist from HIS is configured for your installation, click the **Reload** button to import the latest worklist. The Worklist will be refreshed every 60 seconds, unless configured otherwise in the Service area by an admin user.

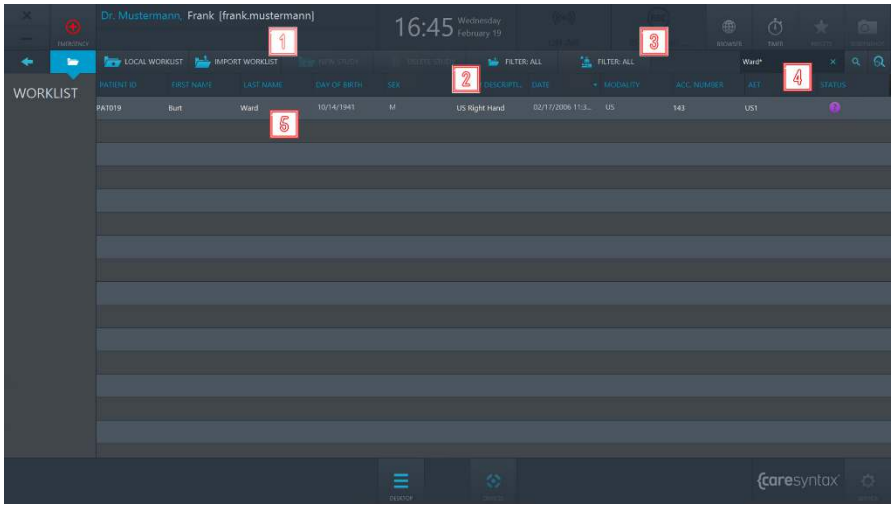
2 Use the **Date Filter** tab to select whether you want to view all worklist entries or only the entries for the current day, +/-1 day or +/-2 days (see Figure 4.6). It is also possible to add a specific time interval that is often used by your team. Ask your CX installation team how.

3 Use the **OR Filter** tab to select whether you want to view all worklist entries or only the entries that belong to a specific OR (e.g. if CX-PRIME is installed on a mobile device) (see Figure 4.7).

4 Use the **Search Field** to search for a patient name, ID, study description or accession number. Select which field you would like the search to be persormed in as shown in Figure 4.8

5 Double-click the desired patient to select him/her.

a)



b)

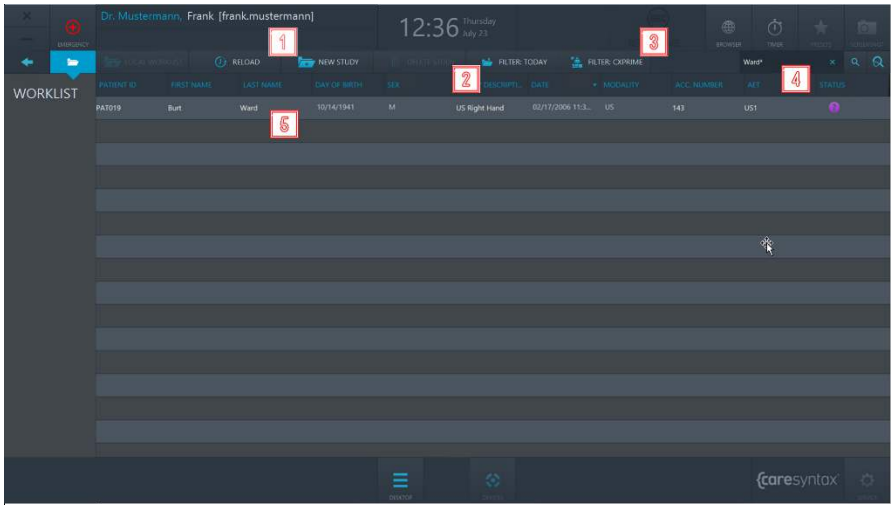


Figure 4.5: The Import Worklist tab and the worklist entry to be imported from a) the PACS system, b) the HIS system.

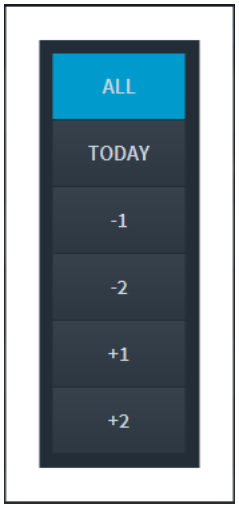


Figure 4.6: Selection of Date options for displaying the worklist entries sent from the PACS/HIS system.

Figure 4.7: Selection of OR options for displaying the worklist entries sent from the PACS/HIS system.

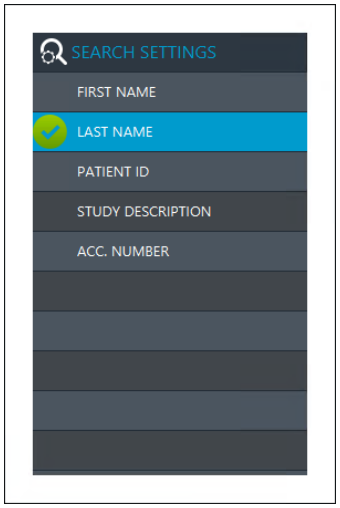


Figure 4.8: Selection of options for performing the freetext search.

After making a selection, you are forwarded directly to the CX-PRIME desktop where the selected patient is again displayed below the username (see Figure 4.9). The patient and his/her information have been simultaneously imported into the local worklist. To view the imported worklist entry in the local worklist, click the Worklist app on the CX-PRIME desktop.

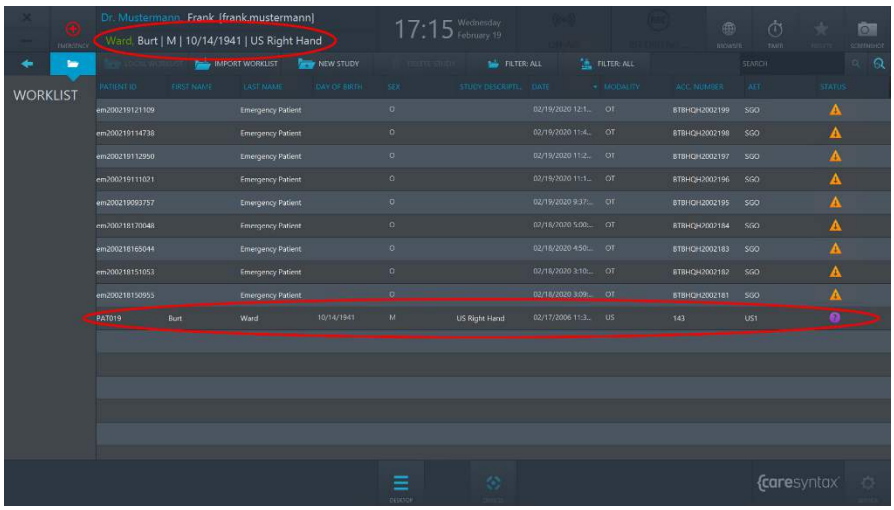


Figure 4.9: The selected patient is displayed below the user (small red circle). The imported worklist entry is also displayed in the local worklist.

4.1.2 Creating a New Worklist Entry

You can also use the local worklist to create a new patient or a new study.

If you are still in the imported worklist, the **New Study** tab is grayed out and therefore not released. You should therefore click the **Local Worklist** tab.

1 Click the **New Study** tab.

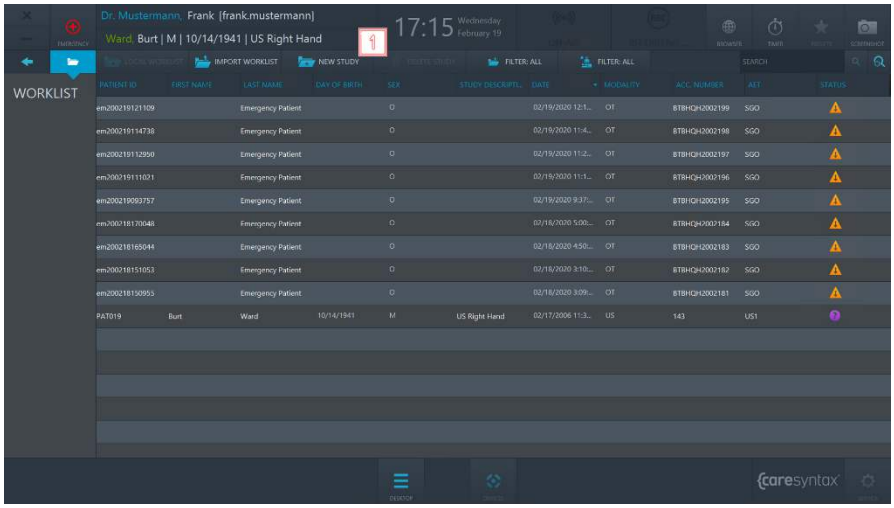


Figure 4.10: New Study tab.

2 Carefully complete all the fields in the pop-up window.

You cannot post-edit your entries.

Patient ID is a mandatory field.

3 Click the “Generate Patient ID” button for an auto-generated Patient ID.

4 Click the green button to confirm the details about the study and the patient.

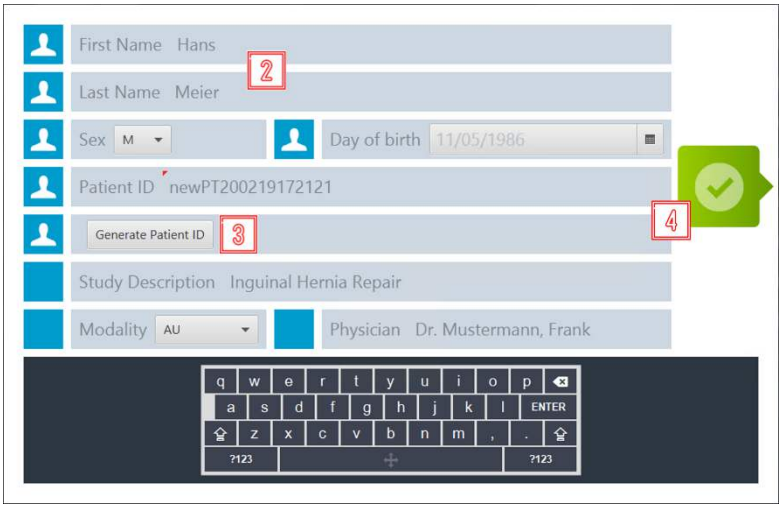


Figure 4.11: Creating a new study with the appropriate information.

The newly created study now appears in the local worklist.

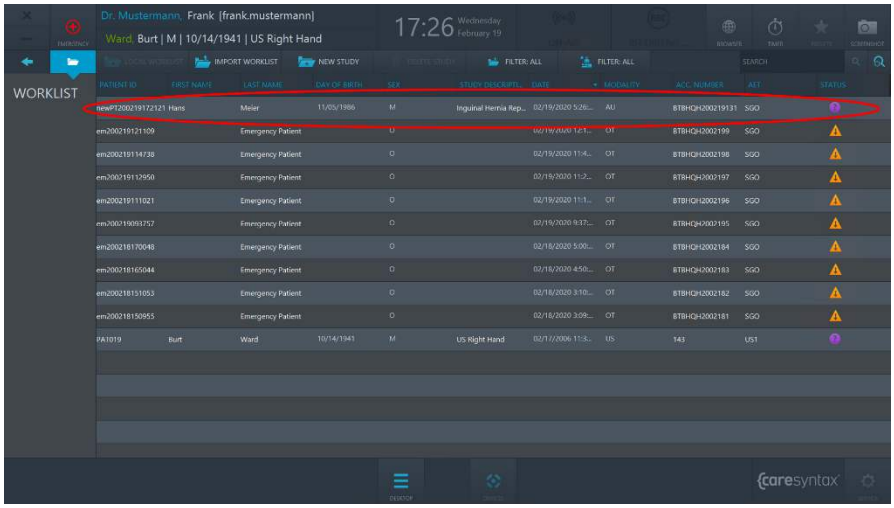


Figure 4.12: The newly created study is circled in red in the local worklist.

4.1.3 Deleting a Worklist Entry

You can individually delete worklist entries from the local worklist but:

Take great caution when using this function, because although you only delete the entry locally in CX-PRIME, there is no quick way of re-creating a deleted study.

1 Select the entry that you want to delete in the local worklist.

2 Click the **Delete Study** button.

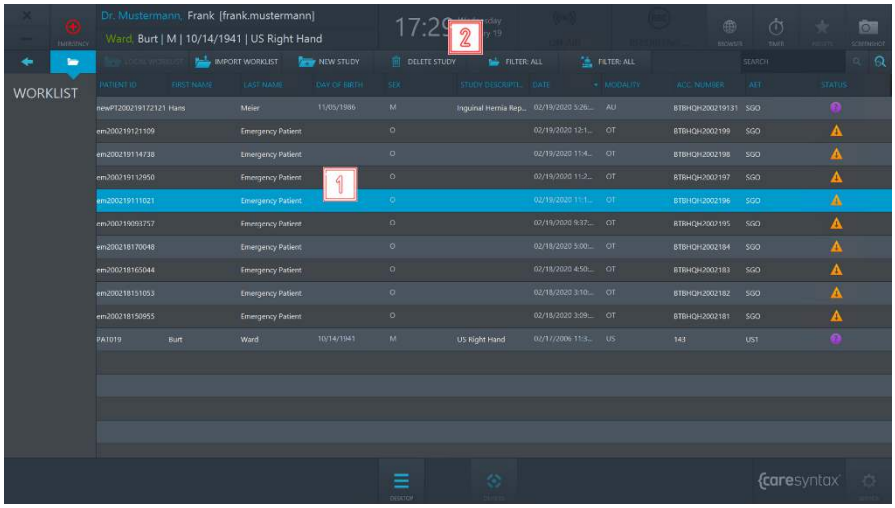


Figure 4.13: Deleting a study in the local worklist.

3 Click the green button in the pop-up window to confirm that you wish to delete the selected study.

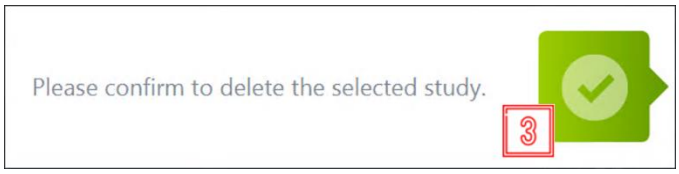


Figure 4.14: Confirming the deletion of a study.

Screenshot

The screenshot function is available as soon as you have selected a patient in the worklist. This enables you to determine the system status, as one example of a use case for this functionality.

The screenshots are stored in CX-PRIME under the selected patient and displayed in the Export (Section 6) app. Please note this when selecting the images to be exported.

You can only take a screenshot of the entire CX-PRIME screen; it is not possible to select certain areas only.

1 To take a screenshot of the CX-PRIME screen, click the Screenshot button. The screen will go light for a brief moment.

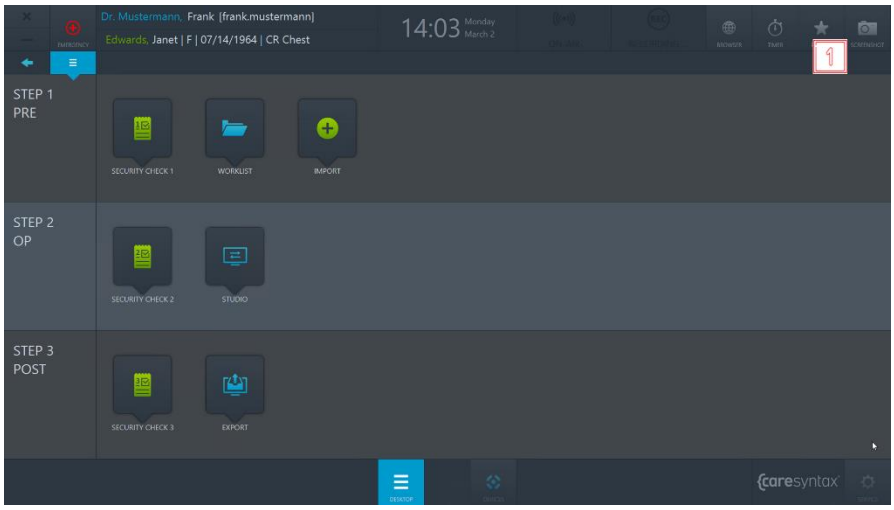


Figure 4.15: Screenshot function on the CX-PRIME desktop.

The screenshot image is displayed to you in the Studio and Exports apps (see Figure 4.16).

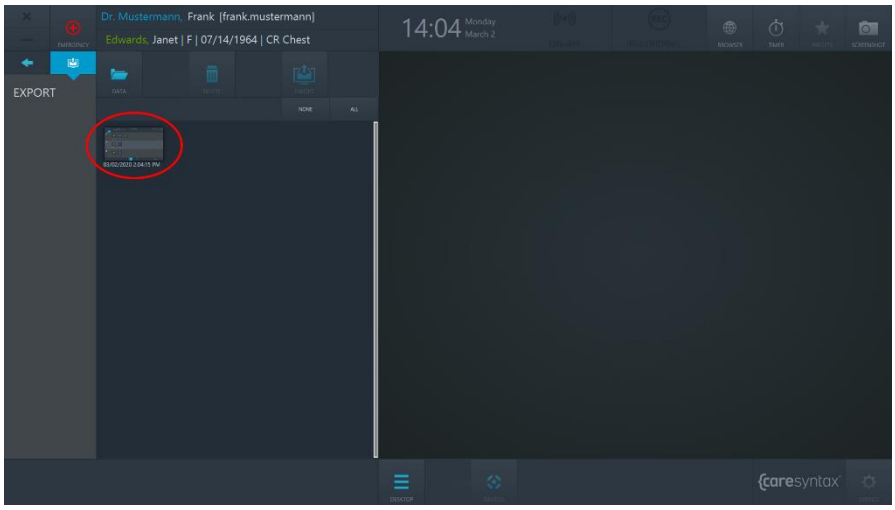


Figure 4.16: Screenshot image in the Export app.

Import

This app enables you to add non-DICOM images and videos to a patient or study. This image data can be imported from integrated network directories, local directories, CD/DVD drives, and removable media such as USB drives.

Non-DICOM images in JPEG, TIFF, PNG, and BMP format as well as non-DICOM videos in MP4 format can all be imported.

To use the Import app, you must first select a study in the worklist

(see Section 4).

Select the images to be imported carefully, as these cannot be deleted from the study again once they have been imported.

1 Click the Import icon on the CX-PRIME desktop to start the app.

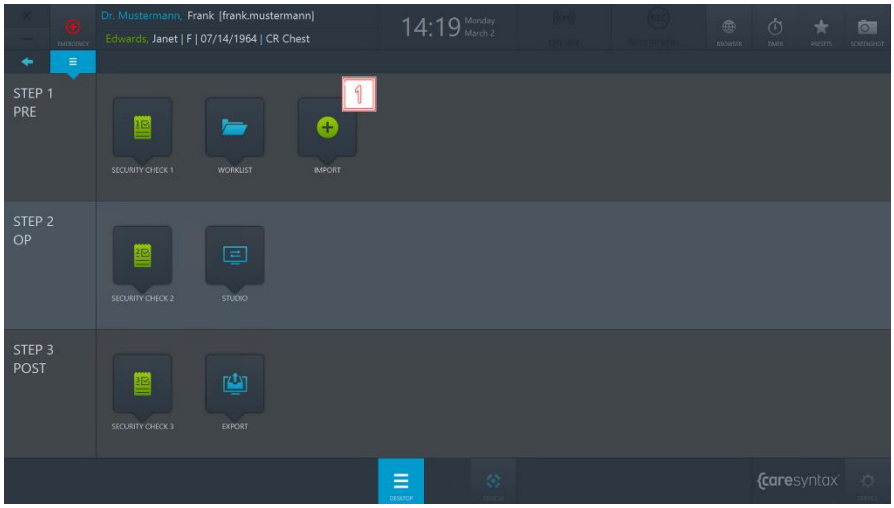


Figure 4.17: Import app on the CX-PRIME desktop.

2 At the top left of the Import app is the list of integrated directories. Select the directory with the images of the selected study. The selected directory is highlighted in blue.

3 The folders for the selected directory are located under the directory tabs. Double-click to select the folder containing the images that you wish to add to the study.

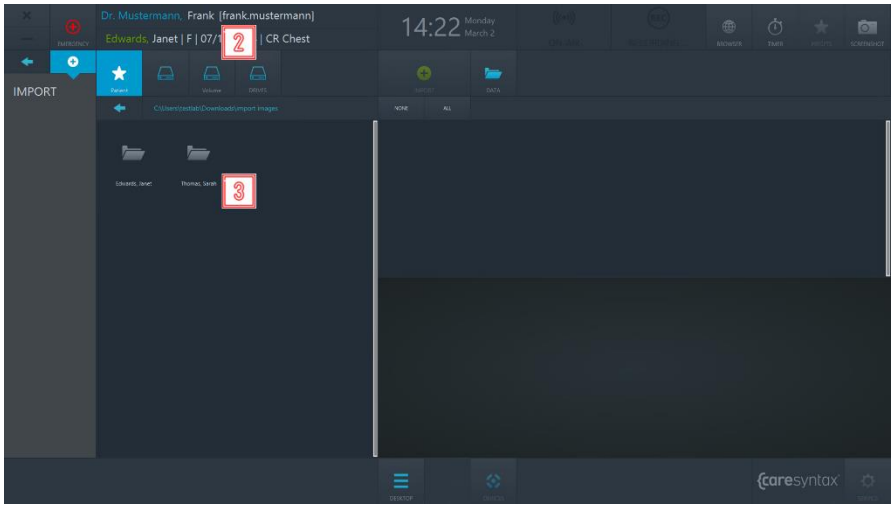


Figure 4.18: Selecting the directory and the folder containing the images to be imported.

Once you have selected the folder containing the images to be imported, the images are displayed on the right-hand side of the Import app (see Figure 4.20).

4 You can choose whether you want to view *All data*, only the *Images* or only the *Videos*.

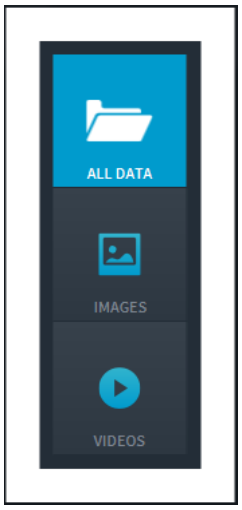


Figure 4.19: Selecting the image data to be displayed.

5 Now select the images that you want to import. You can do this by individually clicking the images. The selected images are highlighted in blue.

You can also select all images in the selected folder. To do this, click the **All** button above the image tabs (circled in red in Figure 4.20). To reset the image selection, click the **None** button.

Double-click on an image or video to view it in the embedded media player in the lower section of the Import app. Videos are also played in this media player (see Figure 4.20, bottom image circled in red).

6 Once you have selected all the desired images and videos, click the **Import** button.

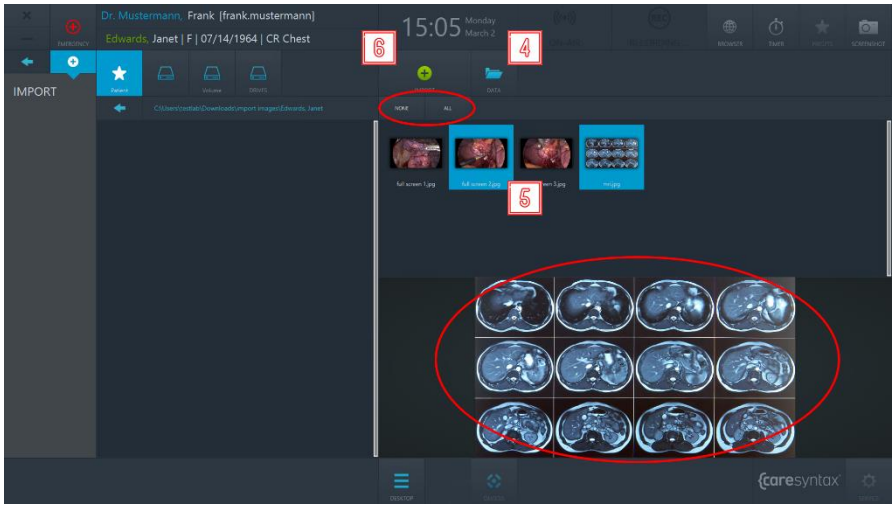


Figure 4.20: Selecting the image data to be imported. The top red circle shows the All and None tabs that can be used to select all or no image data. The lower red circle shows the embedded media player, which can be used to show images/videos by double-clicking them.

7 Click the green button in the pop-up window to confirm that you wish to import the images.

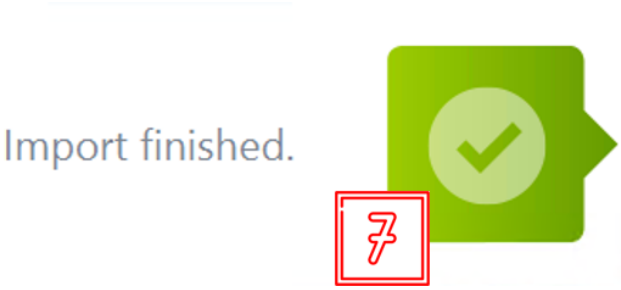


Figure 4.21: Confirmation of the imported images.

5 Step 2: OP-phase

After selecting the patient and importing imaging data into a study, the medical procedure takes place in the Operatory phase. In this phase, you can use the **Checklist** application to ensure that all the necessary precautionary steps before start of the procedure have been taken. The **Studio** application enables you to route the various video sources to various displays in the OR and to record images, videos, and clinical parameters from different sources.

Checklist

The **Checklist** app enables you to centralize and digitize the team time-out workflow within the operating room. You can use the default pre-configured checklist from the World Health Organization, or you can implement your organization's own customized version. To use a custom checklist, please contact us for configuration. You can complete and save the checklist in this app.

If there is no symbol named **Checklist** on your CX-PRIME desktop, then this application is not configured in your system. Please proceed to the next section.

Please note that the **Checklist** app is split into three phases to mirror the operatory workflow: pre-operatory, operatory, and post-operatory. Depending on your configuration, you may see all or some of the checklist phases.

1 Click the **Checklist** icon on the CX-PRIME desktop to start the app.

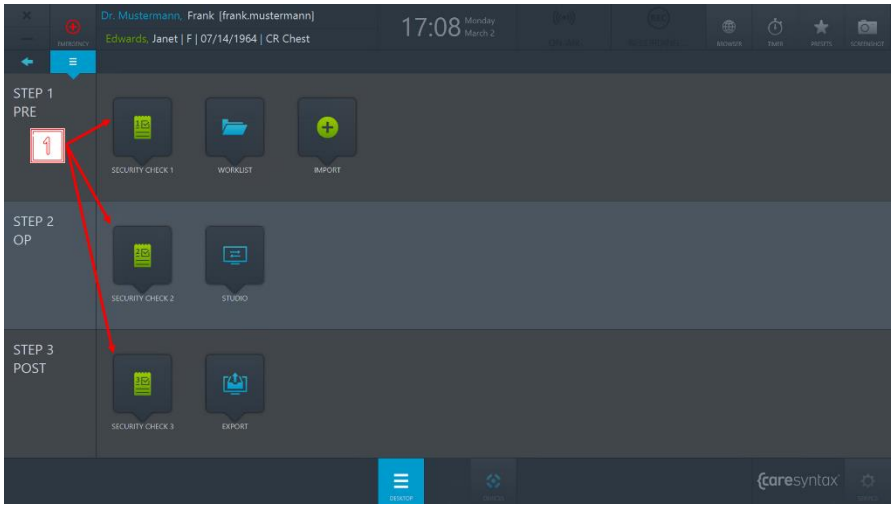


Figure 5.1: Confirmation of the imported images.

2 To mark a question as completed, click into the checkbox.

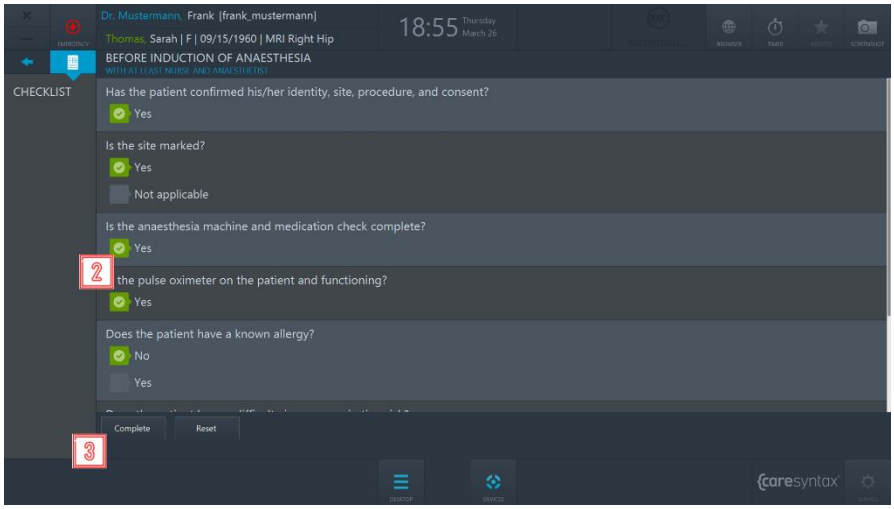


Figure 5.2: View of the Operatory Pre-op Checklist.

If you make a mistake, to un-mark the question, click on the checkmark.

3 Once you have filled out the checklist, you can click on the **Complete** button to save the checklist.

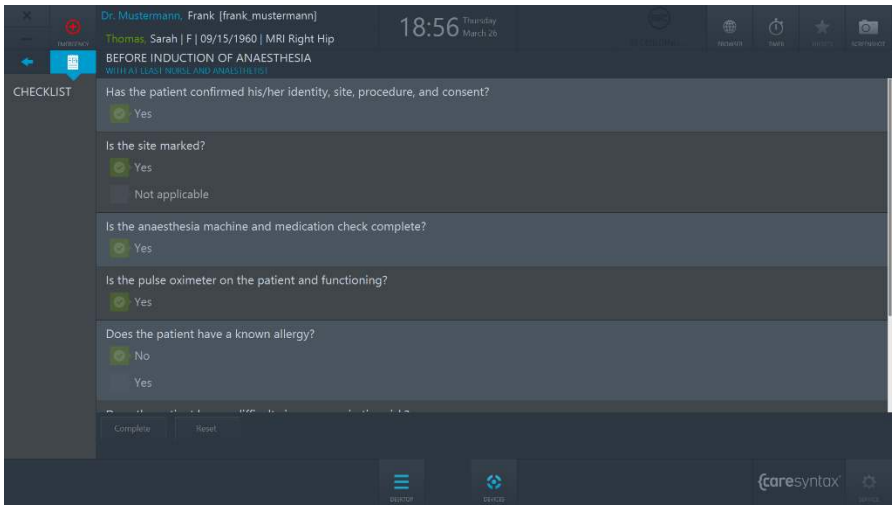


Figure 5.3: View of the completed Operatory Pre-op Checklist.

After completing all three parts of the Checklist, it will be automatically saved as a .pdf file in the pre-deficed directory. Please contact caresyntax® service team for configuring the checklist export location.

Studio

The Studio application enables you to route various video sources to various displays in the OR and to record images, videos, and clinical parameters from different sources. Respectively, the Studio application consists of two tabs: **Routing** and **Recording**.

1 Click the **Studio** icon on the CX-PRIME desktop to start the app.

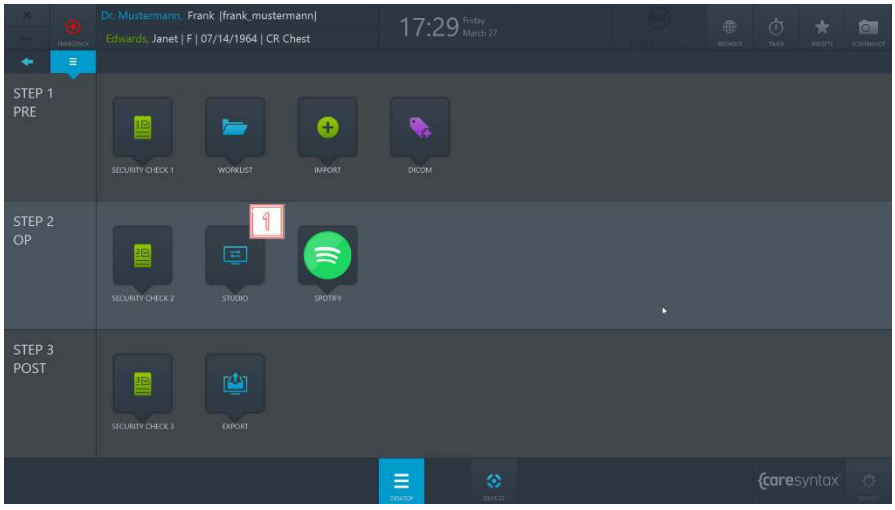


Figure 5.4: Studio app on the CX-PRIME desktop.

5.1.1 Routing

In order to access Routing, go to **Studio** application and select **Routing** tab (see Figure 5.5).

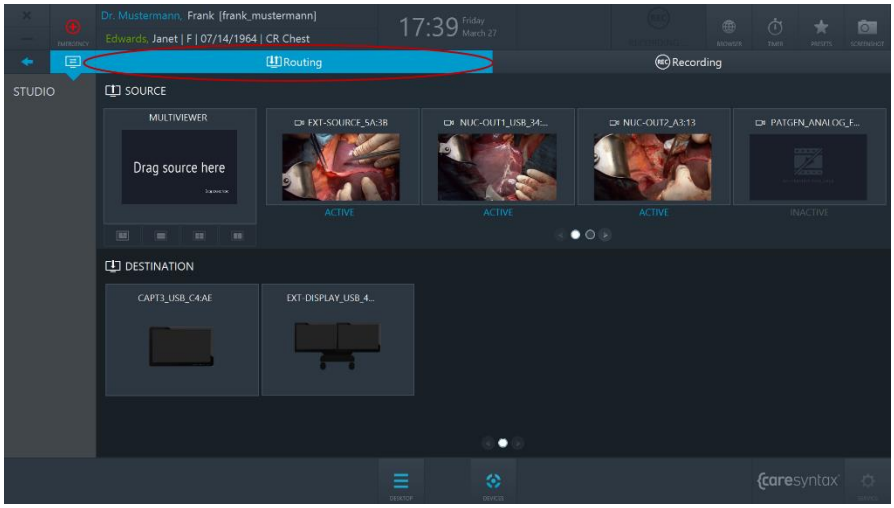


Figure 5.5: Routing tab (red circle) of the Studio app.

There are two main Routing graphic user interfaces:

a. Routing with a multiview composer (section 5.2.1.1);
b. Routing with multiview destinations (section 5.2.1.2).

The graphic user interface of the Routing application depends on the specific hardware setup in the OR. If you are not sure which one applies to your OR, please contact caresyntax® service team. Disregarding the particular graphic user interface, below are some general concepts of the Routing application.

The layout of the Routing app is divided horizontally into two parts: the upper part shows all connected video *Sources* and the lower part shows all connected displays - *Destinations*.

Sources
The sources that are connected and turned on are marked as *ACTIVE*.
The sources that are connected but turned off are marked as *INACTIVE*.

Destinations
Each Destination might have an icon, which indicates what kind of display it is:

General Display (default)	
Console	
Teleport	
Videoconferencing	

Table 5.1: Types of destination icons.

Navigation

Use the pagination buttons (Figure 5.6) or swipe the Sources row using the touch operations (Figure 5.7) in order to navigate between source pages. Do the same to navigate between destinations.

2 Click on the second pagination button in order to get to the second page.

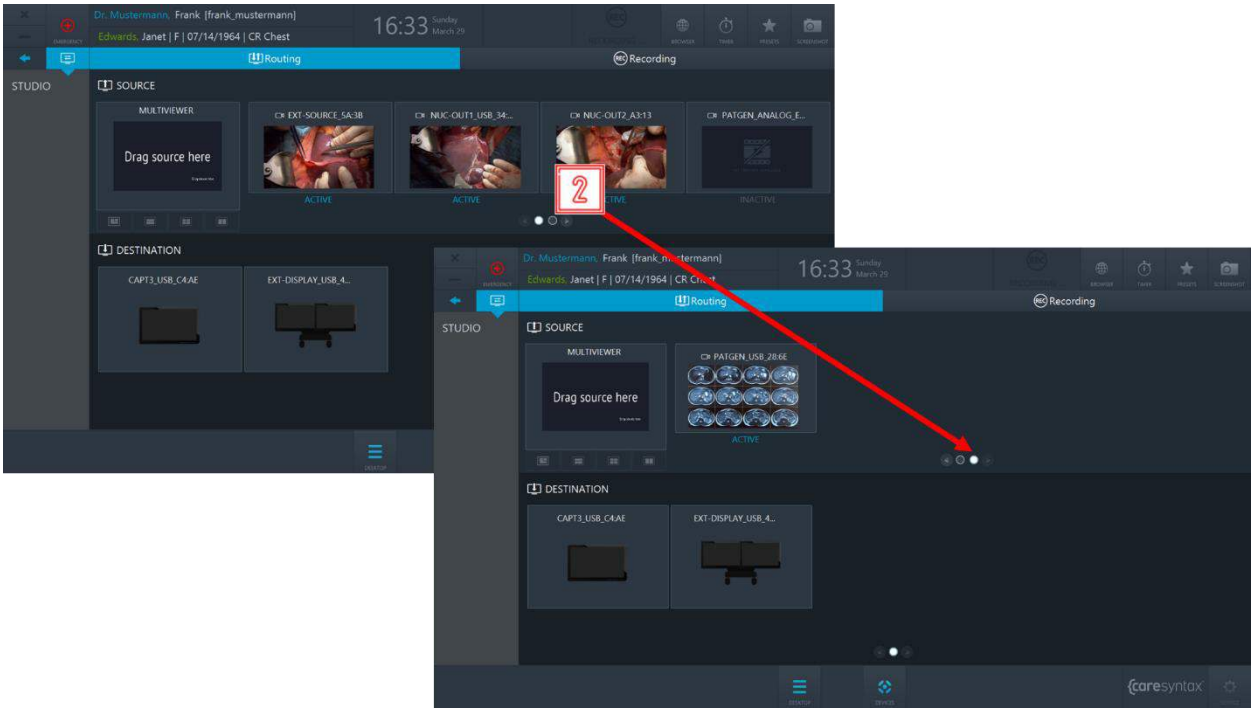


Figure 5.6: Using pagination buttons for navigation.

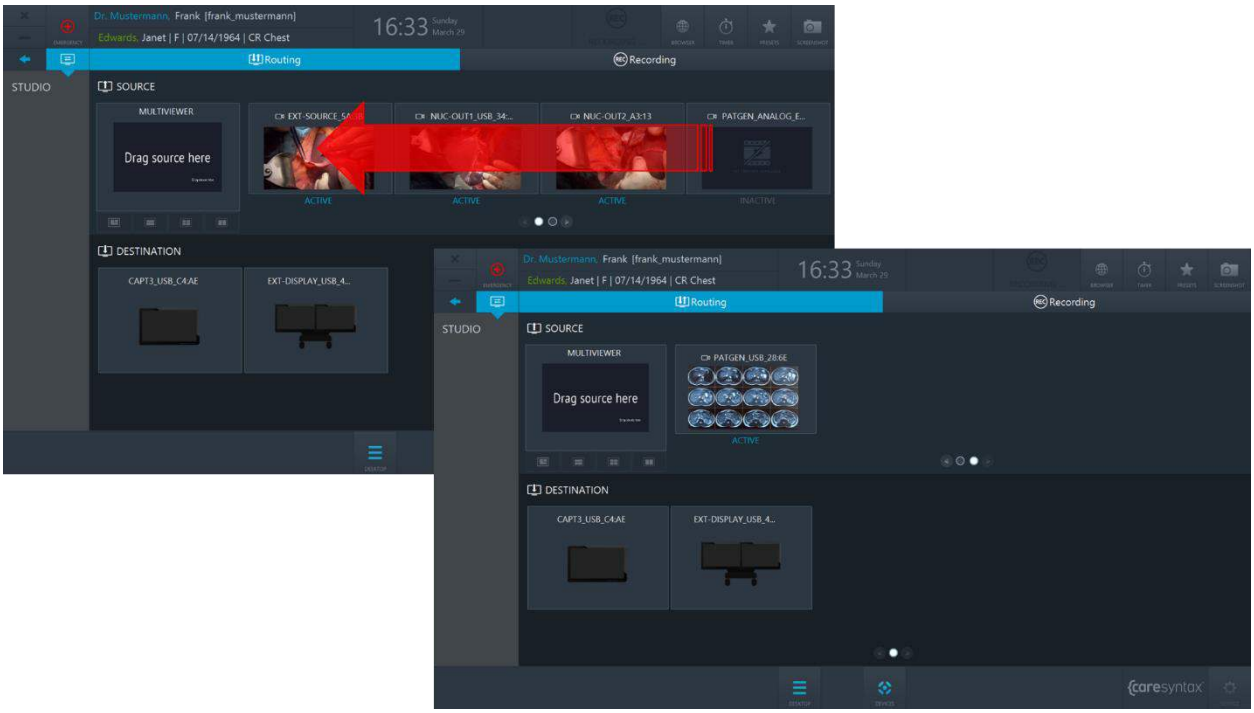


Figure 5.7: Swiping the source row in order to get to the second page.

5.1.1.1 Routing With a Multiview Composer

Routing a Source to a Destination

3 Select a source by clicking on it.

4 Click on a destination you want to rout this source to.

You can also perform routing the other way around: select a Destination first and the then click on a Source.

You can also perform Routing operations by dragging and dropping.

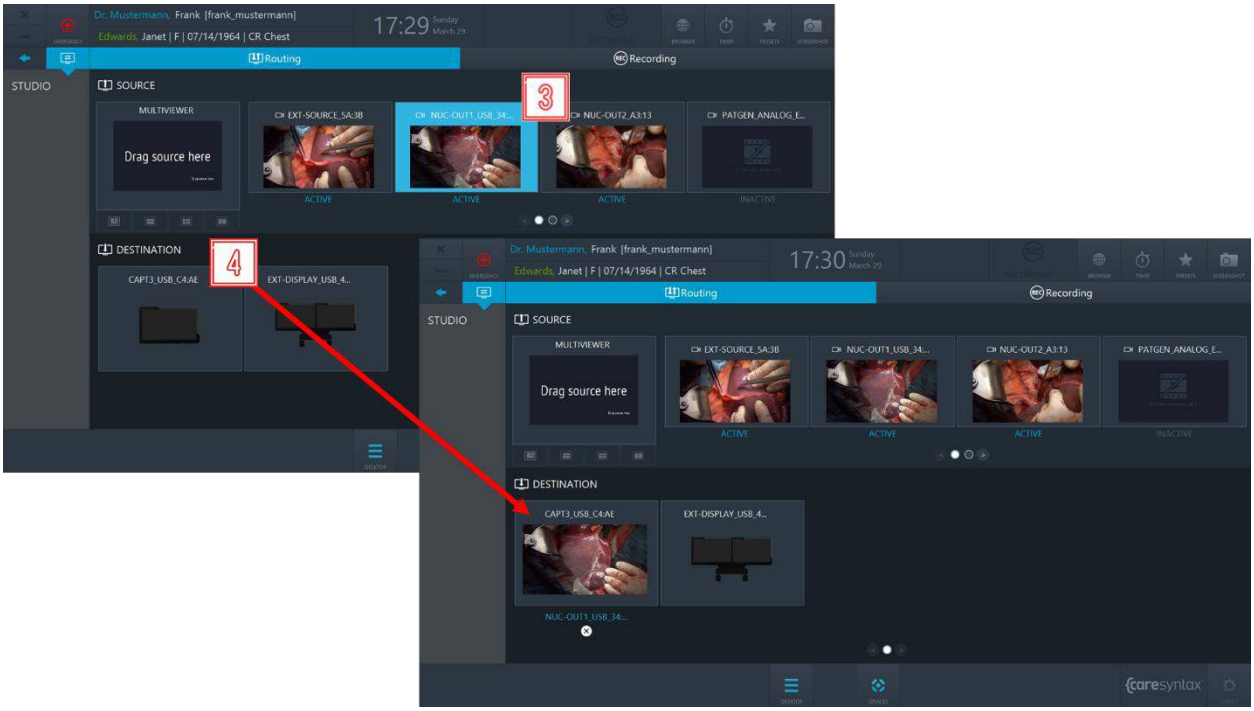


Figure 5.8: Routing a source to a destination.

Unrouting a source from a destination:

5 Click on the **X** button under a destination to clear the route.

It is also possible to override existing routes without performing the Unroute operation first.

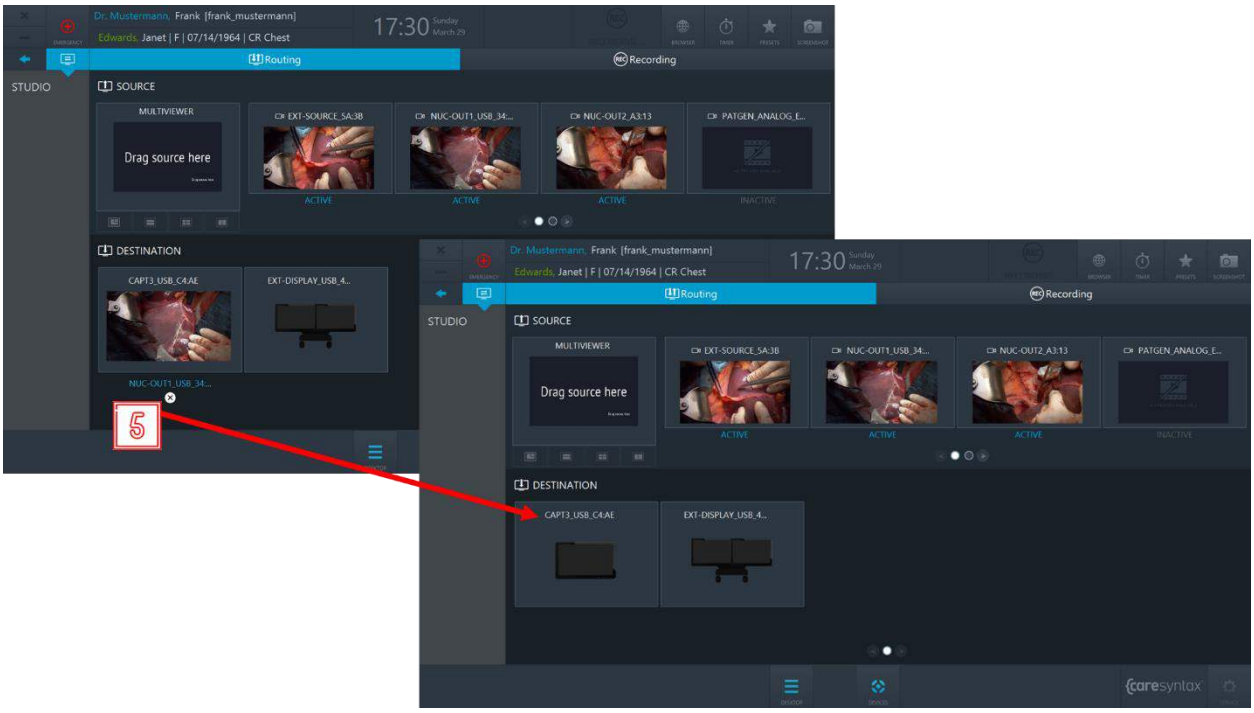


Figure 5.9: Clearing the route.

Creating and Routing a Multiview

In CX-PRIME it is possible to create a route combined of several sources, this feature is called Multiview. There are 4 Multiview layouts:

- PIP (Picture-in-Picture)
- QUAD
- POP (Picture-on-Picture)
- SBS (Side-by-Side)

Please note: the Multiview feature is only available on the Video-over-IP setups.

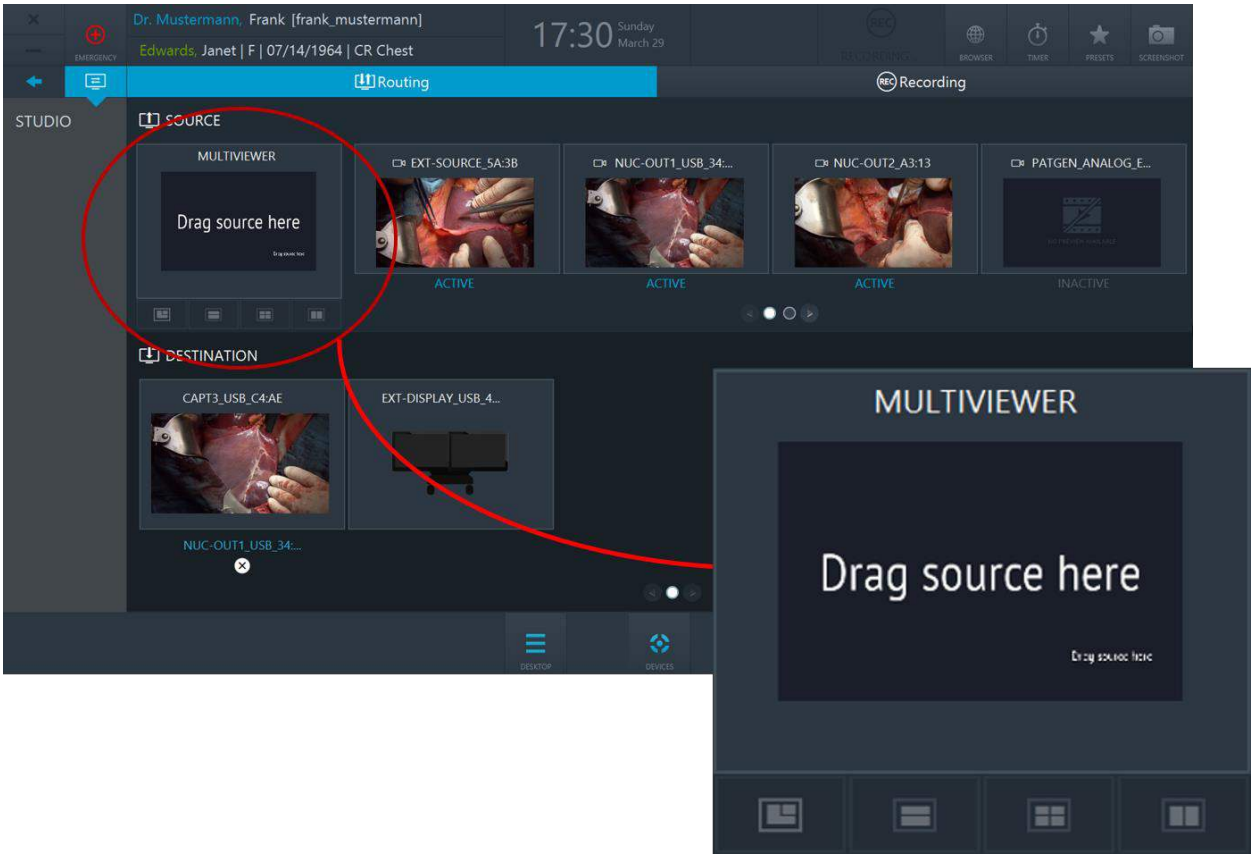


Figure 5.10: Multiviewer composer. Click on Multiviewer tabs in order to select a layout.

6 To create a multiview, connect the sources of your choice to the respective Multiviewer slots.

In order to disconnect a source from a Multiview layout, double click on it.

In order to disconnect all sources from a Multiviewer, click on the X button under the Multiviewer Composer (see Figure 5.12).

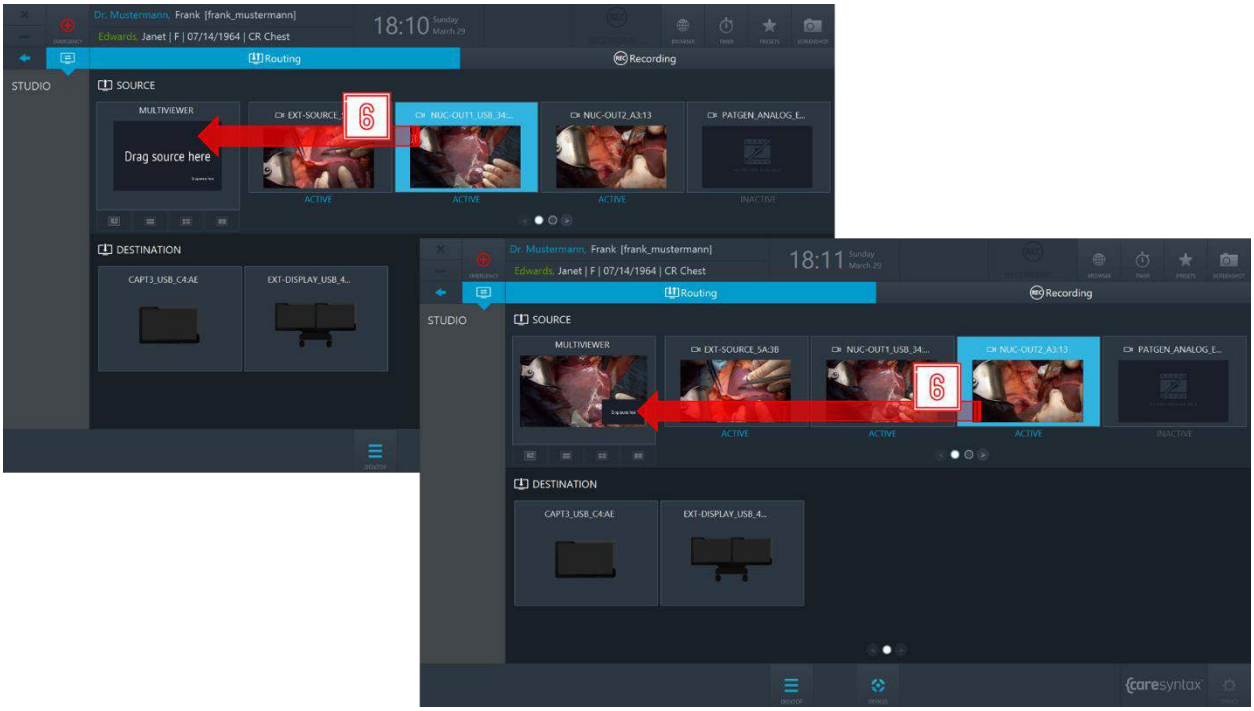


Figure 5.11: Creating a multiview: connect the sources to the Multiviewer slots.

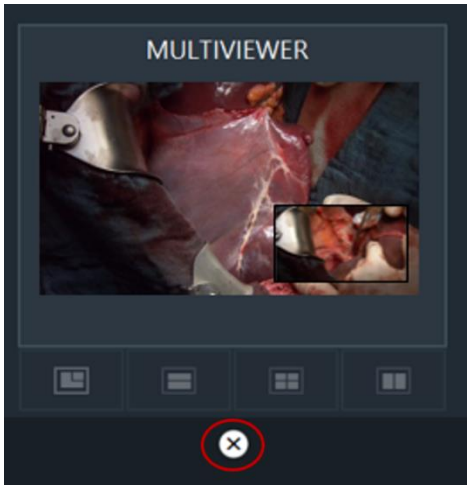


Figure 5.12: Multiview cleanup button.

7 To route a multiview, click on the Multiviewer to select it.

8 Click on a destination you want to route this multiview to.

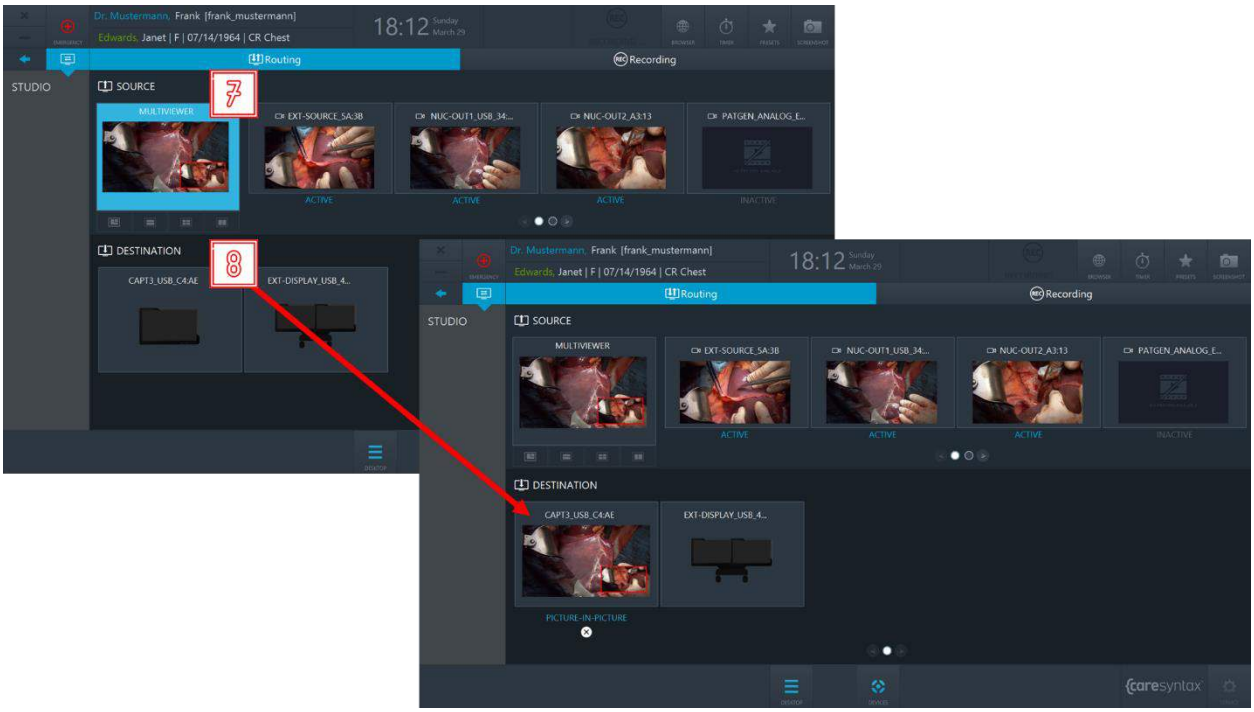


Figure 5.13: Routing a multiview.

Routing presets

Routing presets allow the OR team to save time on the routing setup: when selecting a certain preset, the pre-configured routing order will be activated.
If you would like to use routing presets in your ORs, please contact caresyntax® service team.

9 Click the **Presets** button on CX-PRIME desktop to access the list of configured presets.

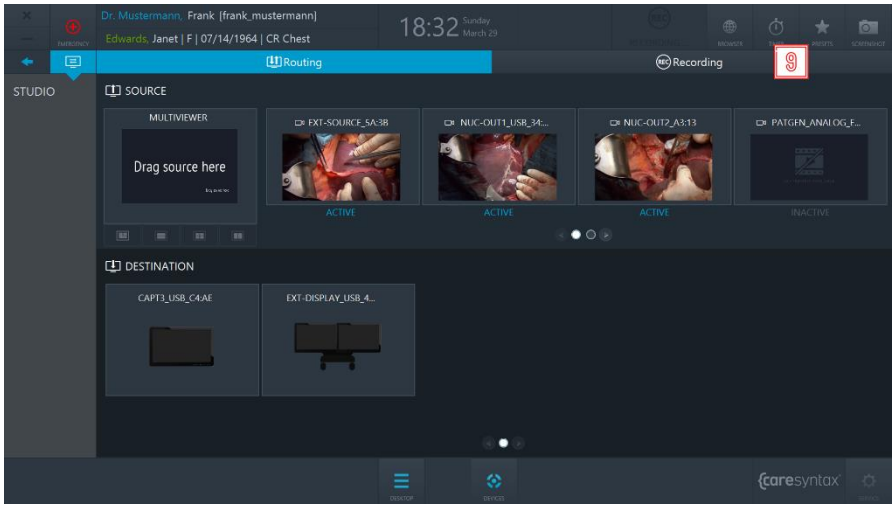


Figure 5.14: Presets button on CX-PRIME desktop.

10 Select a preset from the list → the pre-configured routing setup will be activated.

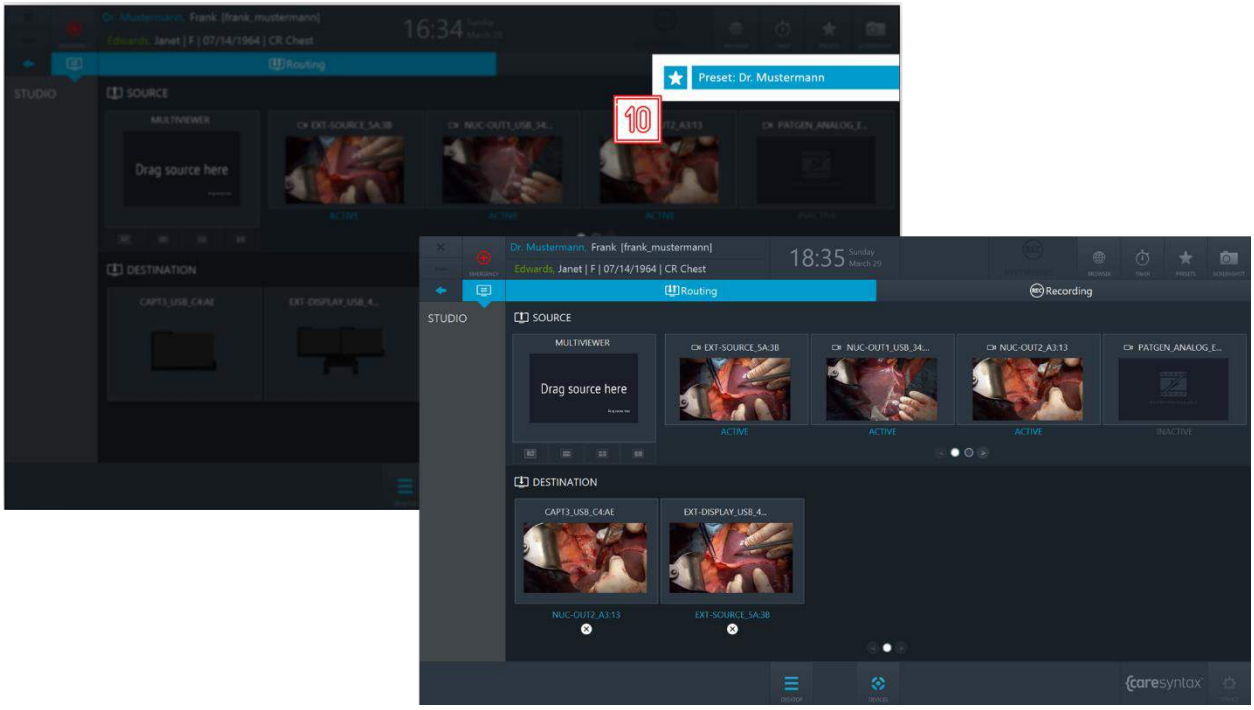


Figure 5.15: Selecting a routing preset.

5.1.1.2 Routing with Multiview Destinations

In this version of Routing application, every Destination has Multiviewer features. Therefore, destinations (depending on their hardware capabilities) support the following layouts:

- Fullscreen
- PIP (Picture-in-Picture)
- QUAD
- POP (Picture-on-Picture)
- SBS (Side-by-Side)

Navigate between the destination layouts by clicking on respective tabs.

Every destination layout consists of a certain number of **slots**, e.g. PIP has two slots: the big slot and the small slot in the bottom right corner.

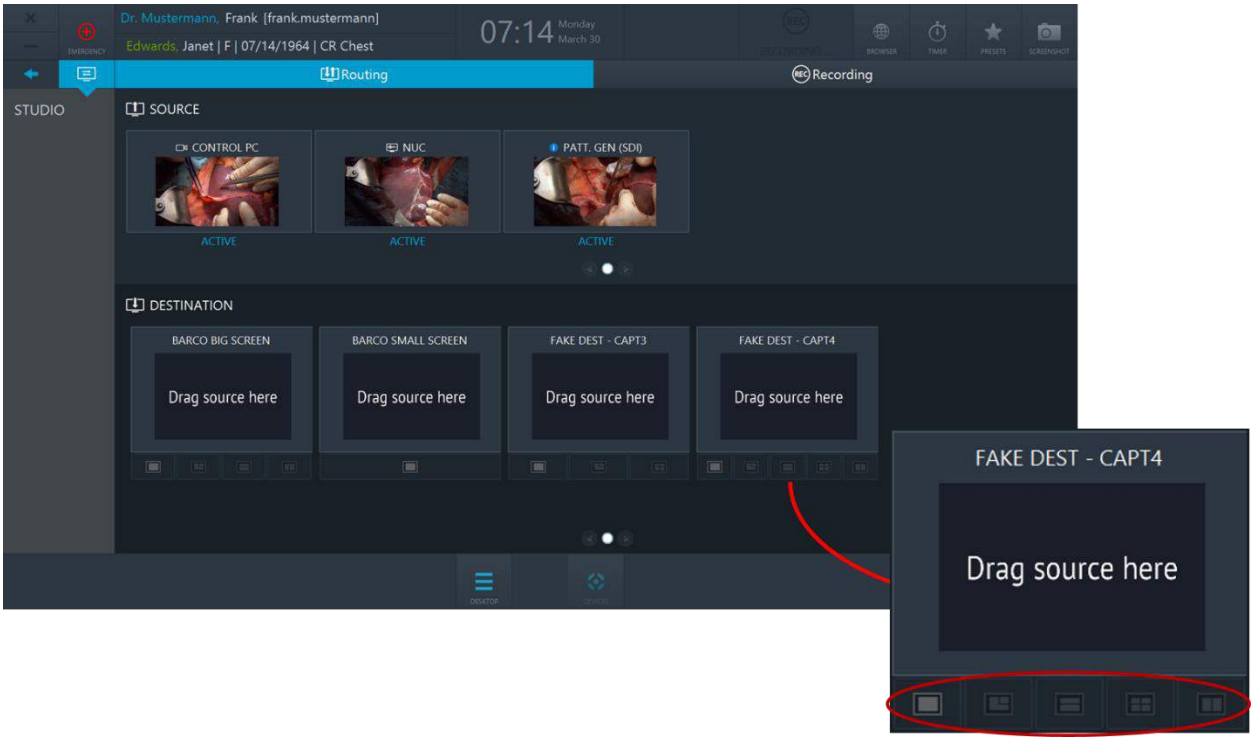


Figure 5.16: Destinations have multiview capabilities. Destination layouts are marked with red circle.

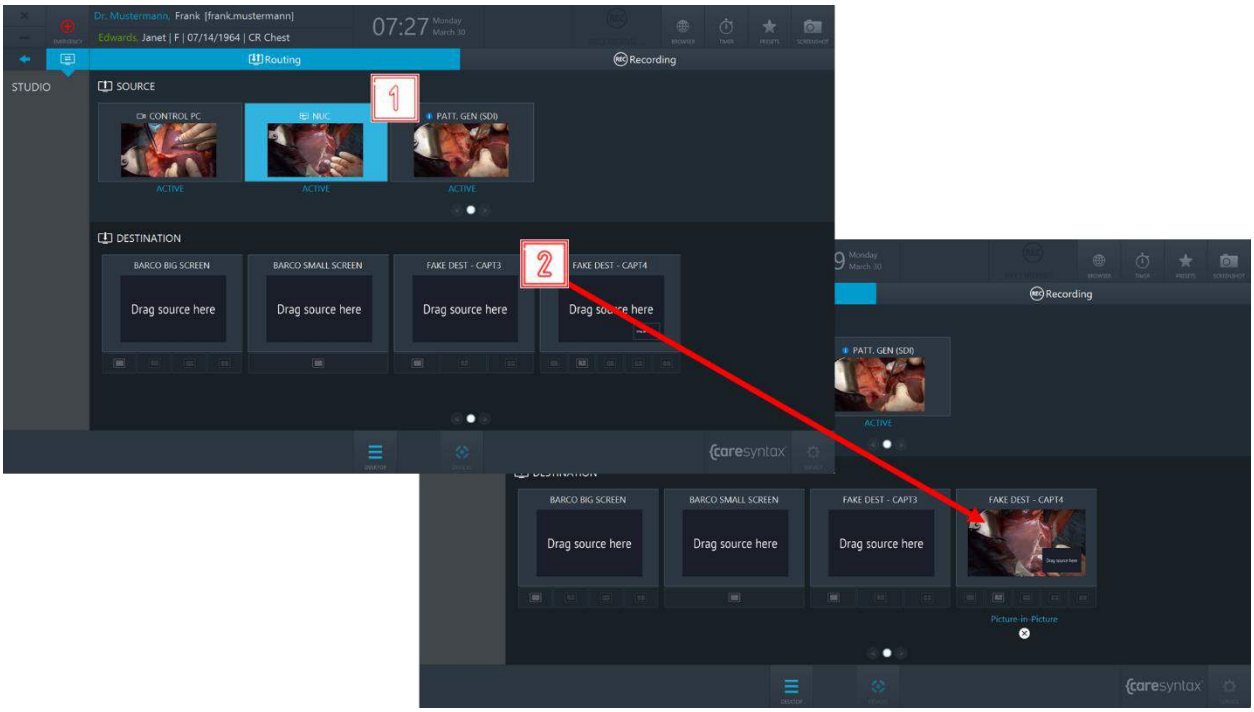
Routing a Source to a Destination

1 Select a source by clicking on it.

2 Select a destination layout and click on the slot you want to route this source to. Repeat step 1 and step 2 for the second source.

You can also perform routing the other way around: select a Destination slot first and the then click on a Source.

You can also perform Routing operations by dragging and dropping.



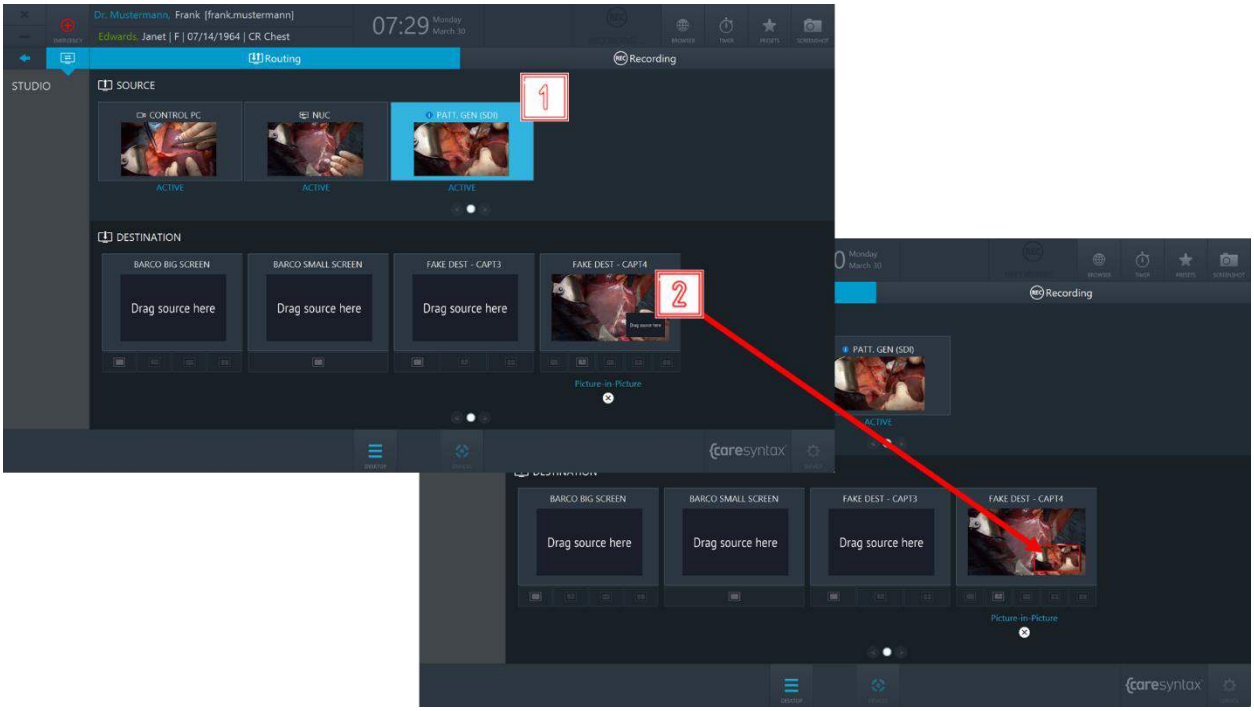


Figure 5.17: Routing a source to a destination.

Unrouting a source from a destination:

3 Click on the **X** button under a destination to clear the route.

It is also possible to override existing routes without performing the Unroute operation first.

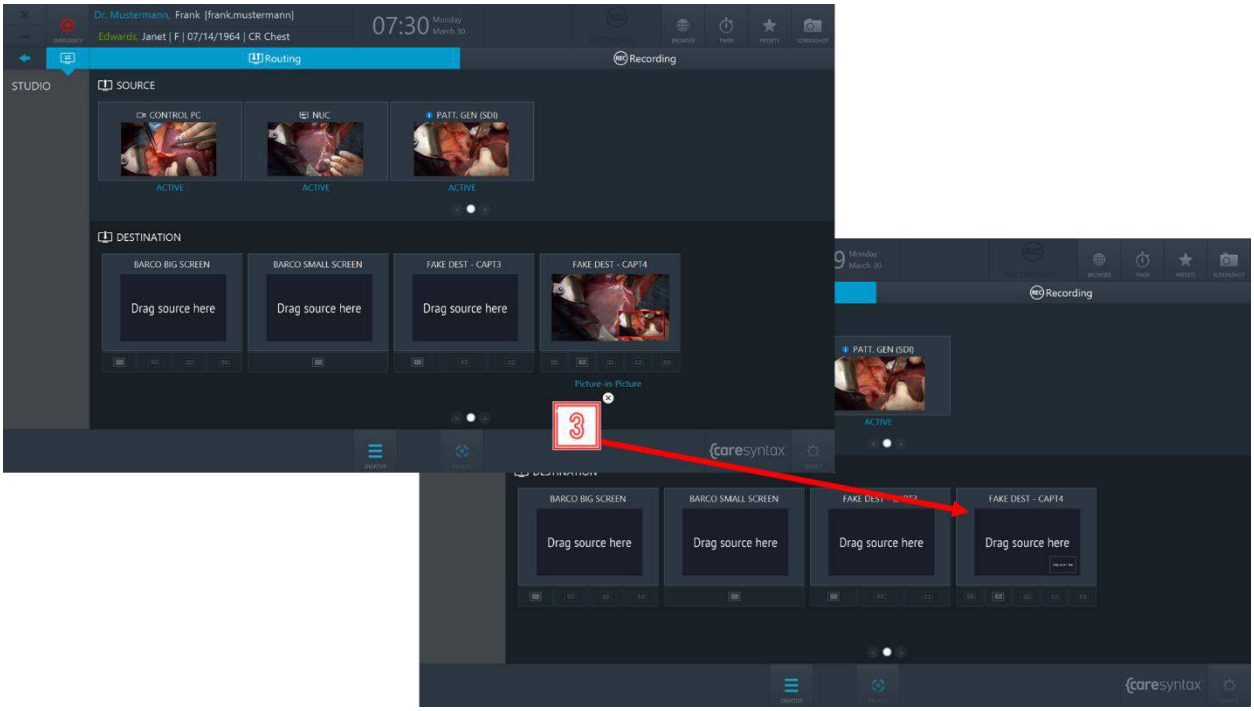


Figure 5.18: Clearing the rout.

Routing presets

Routing presets allow the OR team to save time on the routing setup: when selecting a certain preset, the pre-configured routing order will be activated.
If you would like to use routing presets in your ORs, please contact caresyntax® service team.

4 Click the **Presets** button on CX-PRIME desktop to access the list of configured presets.

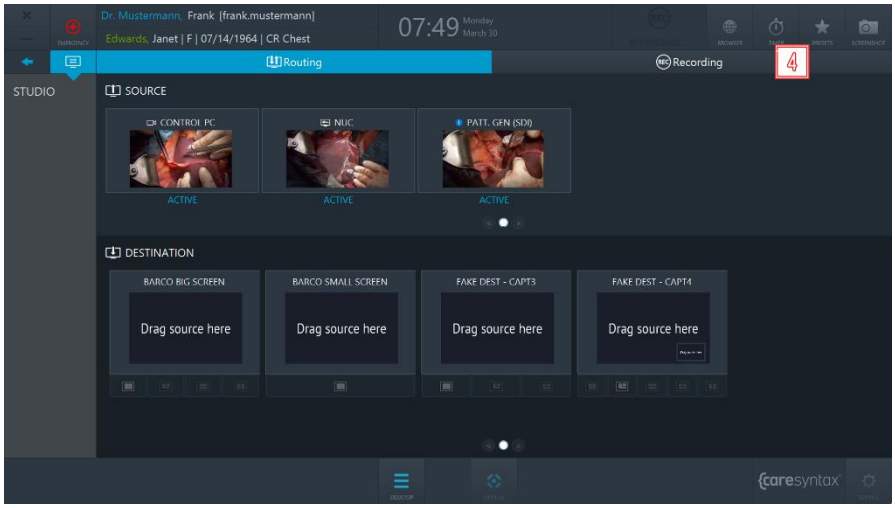


Figure 5.19: Presets button on CX-PRIME desktop.

5 Select a preset from the list → the pre-configured routing setup will be activated.

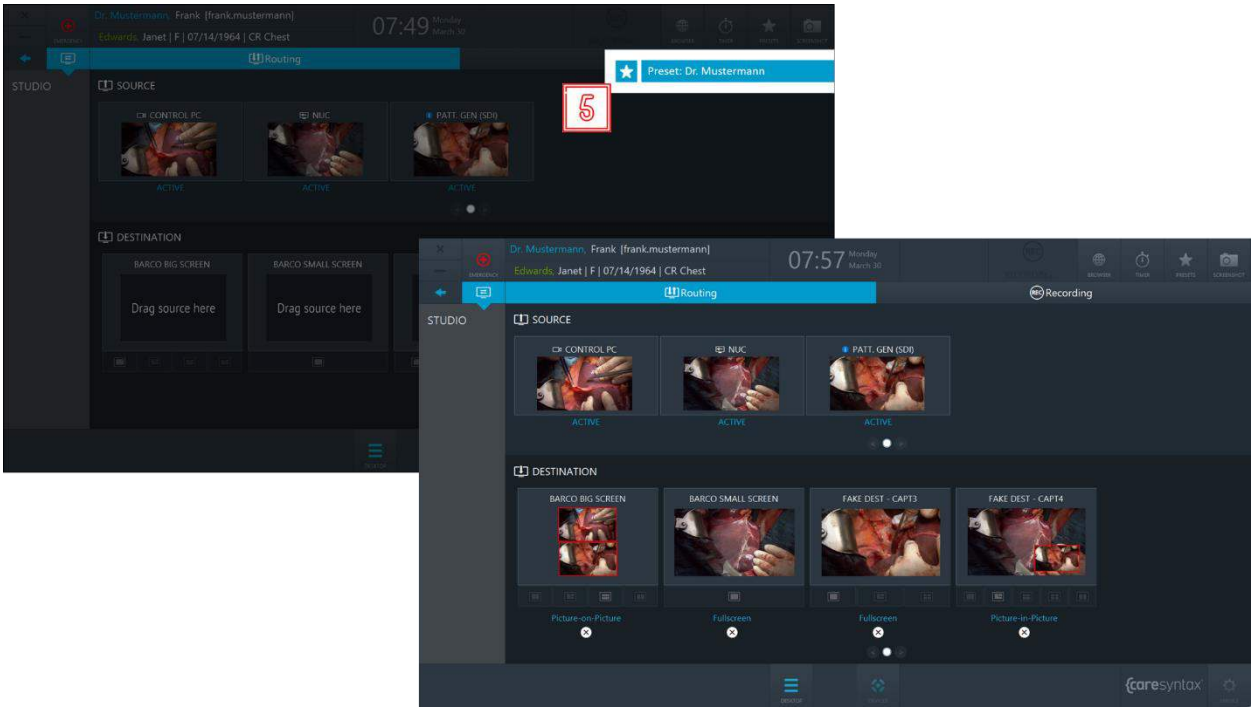


Figure 5.20: Selecting a routing preset.

5.1.1.3 Emergency Disconnect

In the event a situation were to occur during recording that would require all connections going outside of the operating room to stop, an additional button is available within the General Functions once source recording has begun to disconnect all outside connections to the case.

Figure 5.21: Emergency Disconnect button in general functions bar.

5.1.2 Recording

In the Recording tab of the Studio application individual image and video sequences can be recorded and images from the video signal can be captured simultaneously during a video recording.

The Recording application will be available for use only if a user is operating within the patient context, i.e. please select a patient from the worklist or create an emergency patient before proceeding to the recording application.

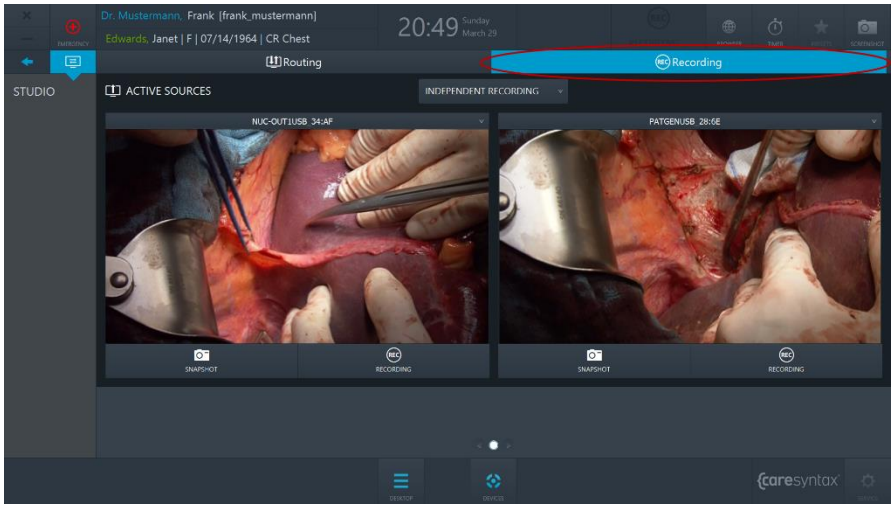


Figure 5.22: Recording tab (red circle) of the Studio app.

The current example shows 2 recorders in the recording application, however, depending on a specific hardware setup, there can be up to 4 recorders.

1 Select the video source that you want to record by clicking on the dropdown button and selecting a source in the list.

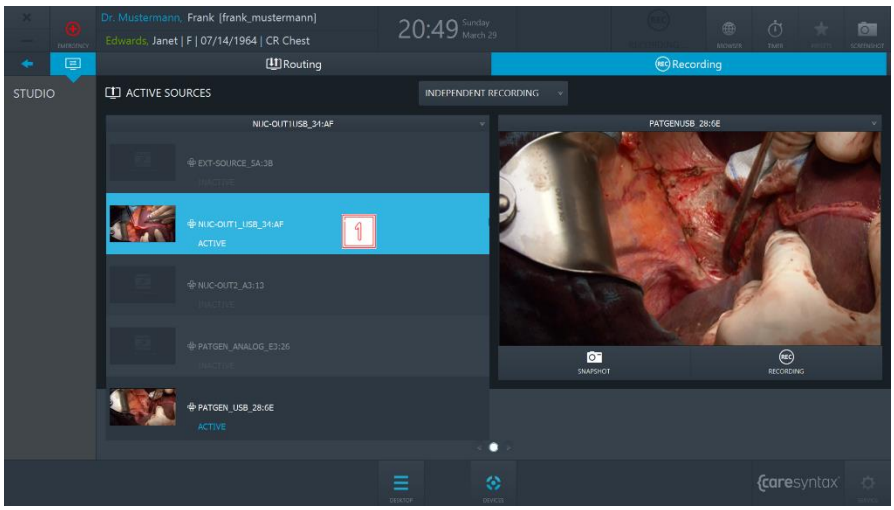


Figure 5.23: Selecting the video source.

2 To create an image of the video source, click the button **Snapshot**.

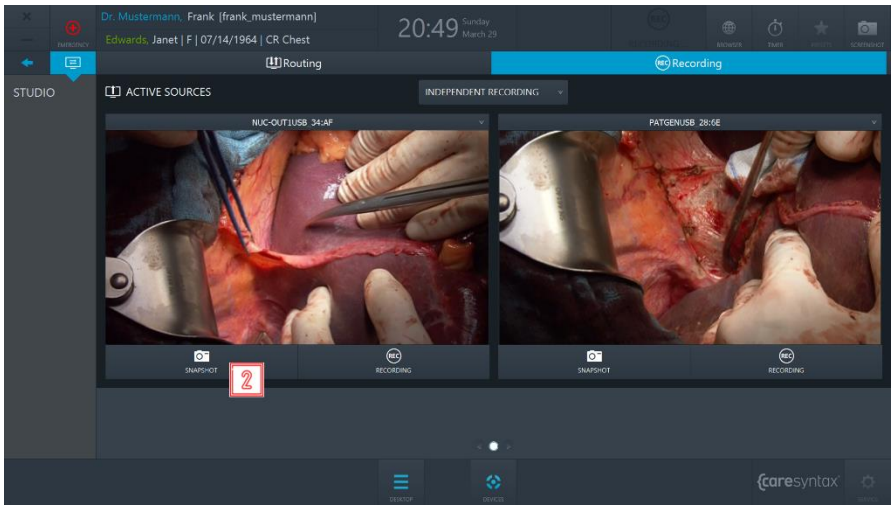


Figure 5.24: Creating a snapshot.

3 To start the recording, click the **Recording** button once. The button turns blue and a blue frame appears around the image. The Recording symbol in the header of CX-PRIME will be highlighted blue for the duration of recording. The overlay will appear on the routed destination (see section 5.1.2.2)
To stop the recording, click the button again.

During a video recording, you can simultaneously create images from the video source. To do so, follow step **3**.

The images and videos that you record during a procedure are displayed under the recorders

Images and videos can be recorded using remote actions, e.g. using camera head buttons or footswitch buttons. Please contact caresyntax® service team to inquire about this functionality and see section 5.1.2.1 for more instructions.

The pre-recording function is available, allowing for continuous recording of a short period of time before the end user clicks the **Recording** button. Please contact caresyntax® service team to inquire about this functionality.

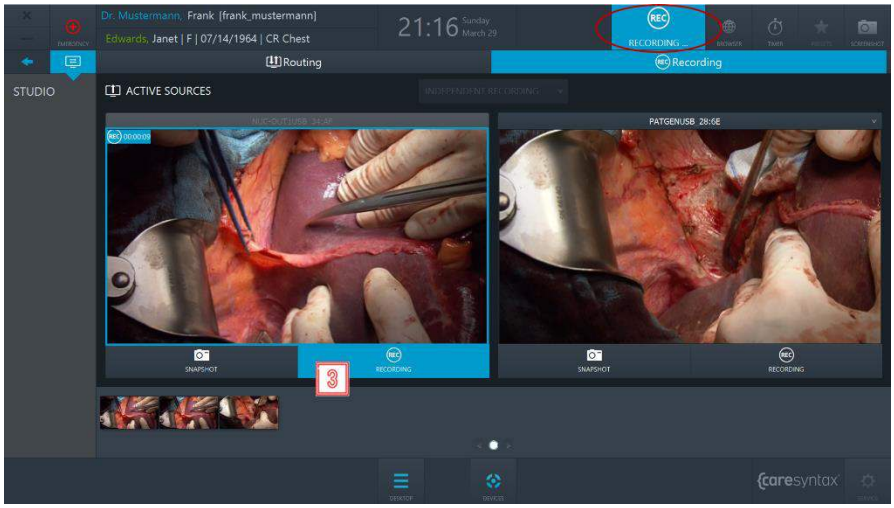


Figure 5.25: Recording a video.

The example above shows how to create snapshots and record videos of independent sources. If you want to record the sources simultaneously, you need to change the recording mode from *Independent Recording* to *Synchronized Recording*.

4 Click on the dropdown above the recorders and select **Synchronized Recording** → there will be one set of controls per two recorders and you can now create snapshots and record videos of both sources simultaneously.

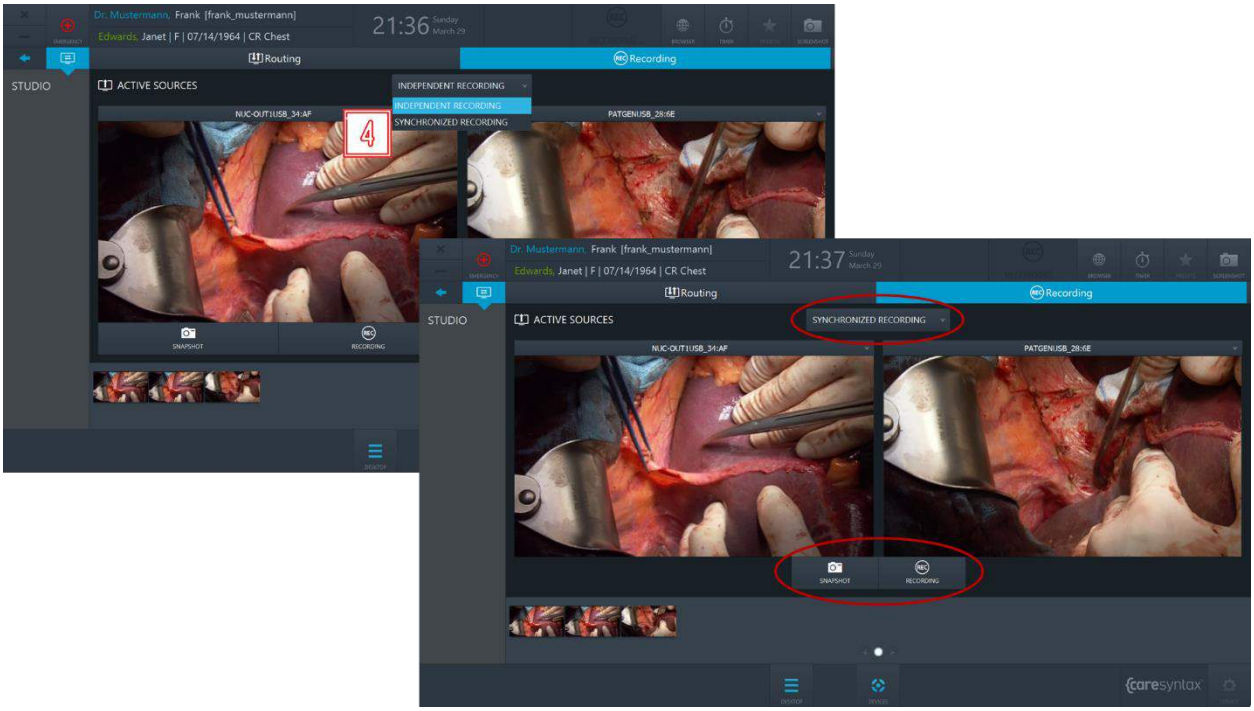


Figure 5.26: Synchronized Recording mode.

5.1.2.1 Triggering snapshots & recordings with remote buttons

Depending on the configuration of your installation, it might be possible to trigger remote actions in CX-PRIME, such as start/stop of recording and snapshot creation, with the remote buttons, such as footswitch buttons or camera head buttons. If this feature is enabled in your OR, you will be able to dynamically choose in the Recording application the video stream, which remote actions will be applied to.

1. Select the recorder, which the remote actions will be applied to by checking the radio button in the recorder dropdown. The icon in the header will signify that this recorder is now used for remote actions.
2. Select a source, which the remote actions will be applied to by selecting it from the recorder dropdown. The icon next to the source will signify that this source is now used for remote actions.

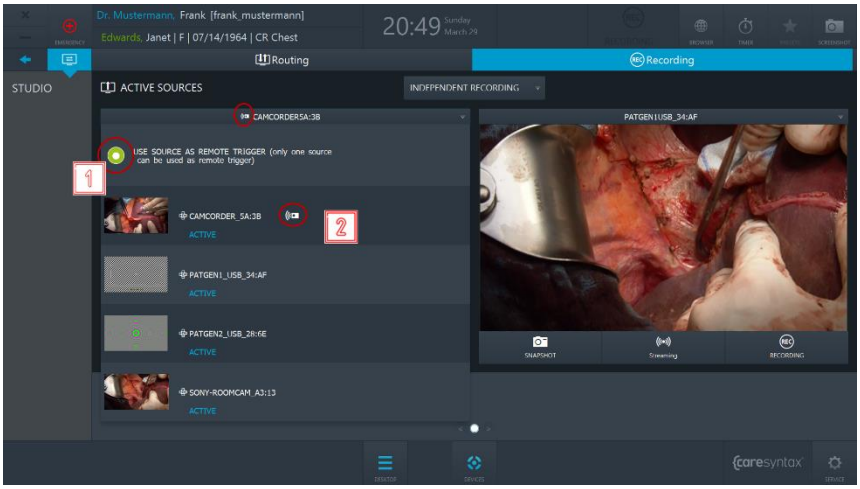


Figure 5.27: Selecting a recorder and a source for remote actions

Now, in this example, remote buttons will trigger snapshot creation or start/stop of recording for the CAMCORDER_5A:3B source of the Recorder 1.

5.1.2.2 On-screen notifications

Depending on the specific hardware setup in your ORs, the on-screen notification function may be available. Please contact caresyntax® service team to inquire about this functionality.

On-screen notifications allow the user to get visual feedback about certain actions. Two on-screen notifications exist:

a. Confirmation of an image been taken;

5 If a user creates a snapshot of a routed source, a thumbnail of the created image will appear in the corner of the display for 2 seconds.

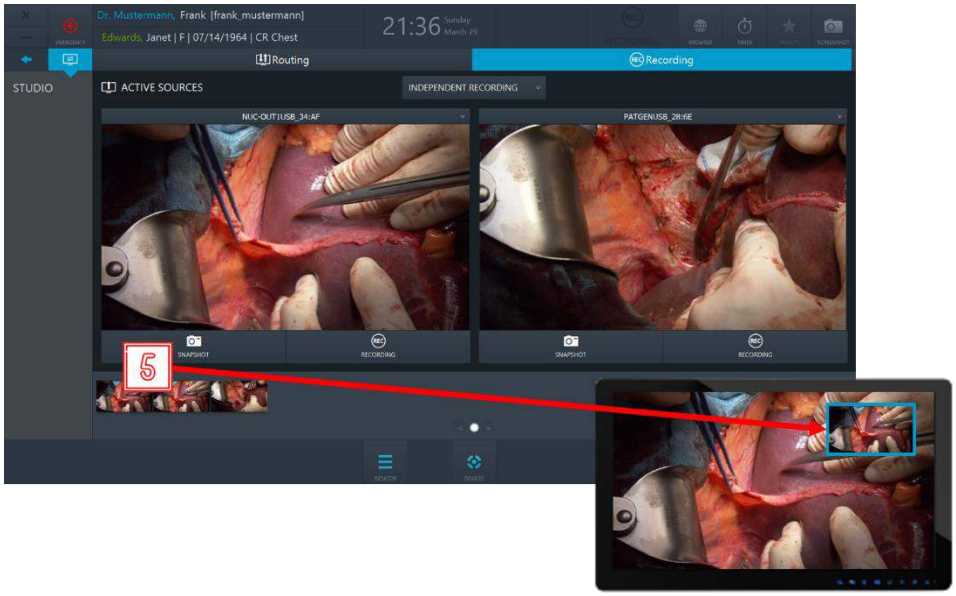


Figure 5.28: On-screen notification will appear in the corner of the display for 2 seconds as a confirmation that a snapshot of the routed source was taken.

b. Indication of recording being in progress.

6 If a user starts recording of a routed source, a blue frame will be present on the display for the duration of the recording and will disappear once the recording stops.

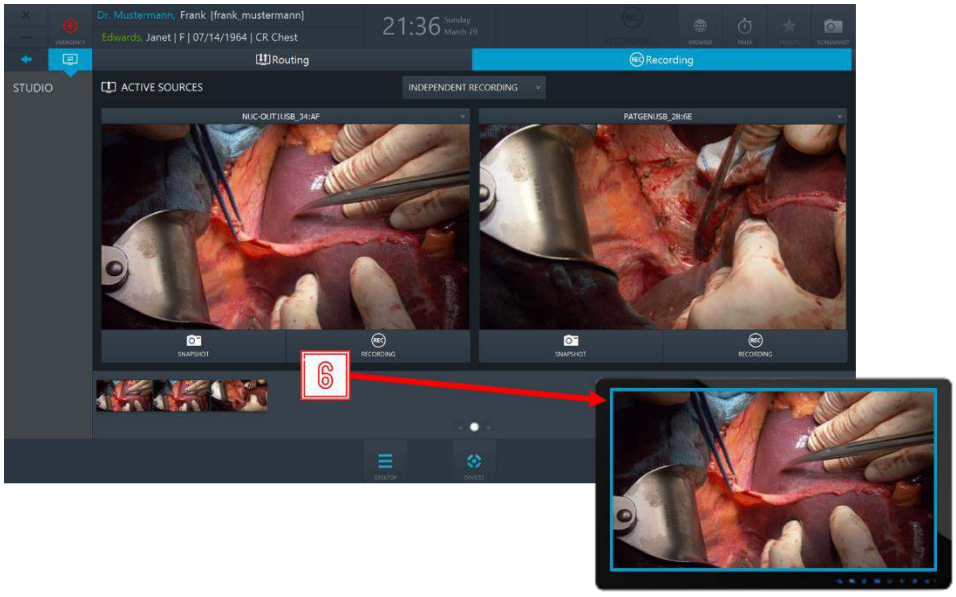


Figure 5.28: On-screen notification (blue frame) will appear on the display and will stay as long as the routed source is being recorded.

5.1.2.3 Automatic recording on patient selection

If enabled by the admin user in the Service area, recording can be automatically started at patient selection. In that case, a user would be ported to the Recording application and recording of all available sources will be started automatically.

In addition, if a source gets dynamically connected to the capture device, recording for this source will also start automatically. If a source gets disconnected from the capture device, the recording of it will be automatically stopped and a recording file will be saved as usual.

6 Step 3: Post-phase

After the operatory phase/medical procedure is complete, you can export the data recorded to a PACS system, VNA or a network directory (provided that these systems are integrated and configured), as well as to local directories or removable mediums such as USB drives or CDs/DVDs within the scope of the post-operatory phase.

Export

This app enables you to save all or some of the imported or recorded data to a selected target as Non-DICOM or DICOM data. Targets for the export can be either PACS archives, providing an archive is integrated into your configuration, or local directories, network directories, CD/DVD drives, or removable media (USB).

The CX-PRIME software does not have any functions that can be used for image processing, data analysis, or compressing/decompressing raw data recorded on other devices.

If there is no symbol named **Export** on your CX-PRIME desktop, then this application is not configured in your system. Please proceed to the next section.

1 Select **Export** on the CX-PRIME desktop to start the app.

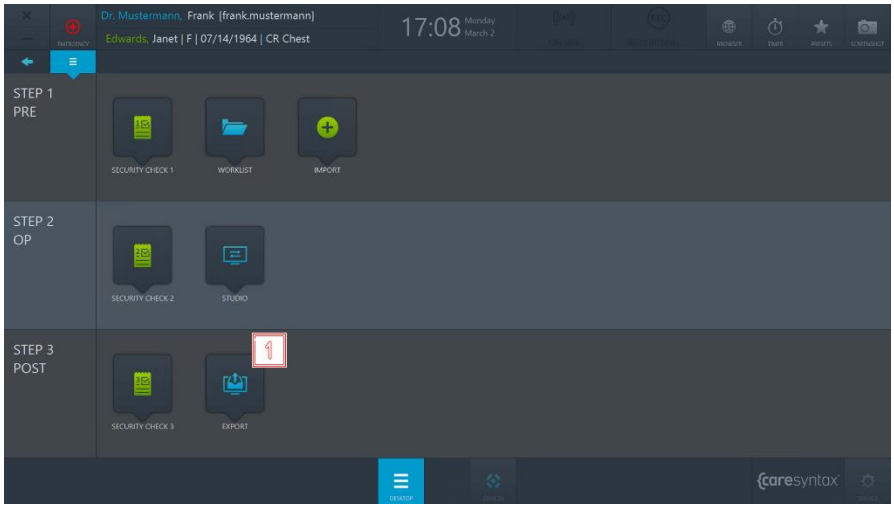


Figure 6.1: Export app on the CX-PRIME desktop.

All of the data that you have imported or recorded is now displayed in the Export app (see Figure 6.3).

2 You can choose whether you want to view Images and Videos *(DATA) or* only the *Images* or only the *Videos*.

Figure 6.2: Selecting the image data to be displayed.

3 Now select the images that you want to export. You can do this by individually clicking on the images. The selected images are highlighted in blue.

You can also select all images in the selected folder. To do this, click the **All** button above the image tabs (top red circle in Figure 6.3). To reset the image selection, click the **None** button.

Double-click an image or video to view it in the embedded media player in the right-hand section of the Export app. Videos are also played in this media player (see Figure 6.3, right-hand image circled in red).

4 Once you have selected all the desired images and videos, you now can export them. The **Fast Export** button is only shown when its and the destination paths for pictures and videos are preconfigured in the settings. When clicking the **Fast Export** button a rotating circle appears on the screen to show that the data is being exported. In the case you want to choose the destination path yourself or only the **Export** button is available, click this button and follow the instructions below.

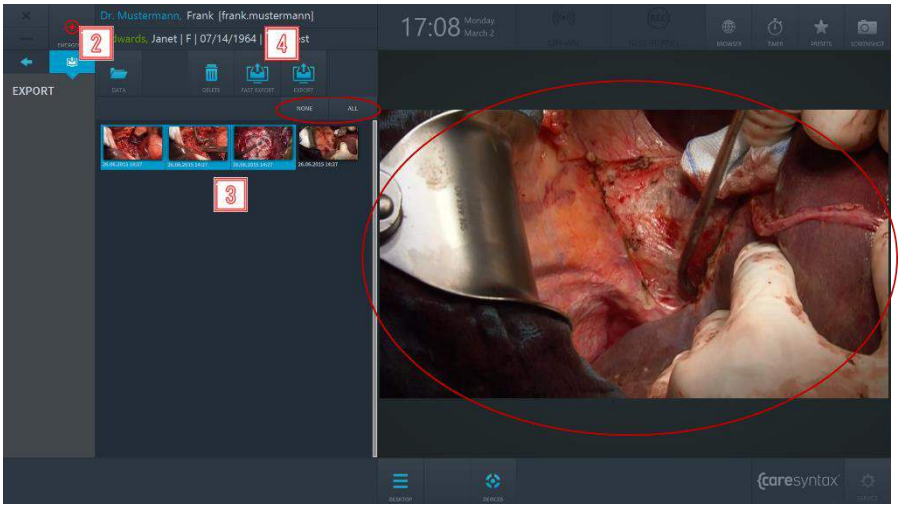


Figure 6.3: Selecting the image data to export. The top red circle shows the All and None tabs that can be used to select all or no data. Double-click an image or video to view/play it in the media player (red circle on the right).

If a pop-up window with username and password fields appears when you click the **Export** button, you do not have the necessary permissions to export images and videos. Follow the steps below to select a user who is entitled to export images and videos. If this pop-up window does not appear, go straight to step **7**.

5 Select a user with export permissions and enter his/her password.

6 Confirm the entries.

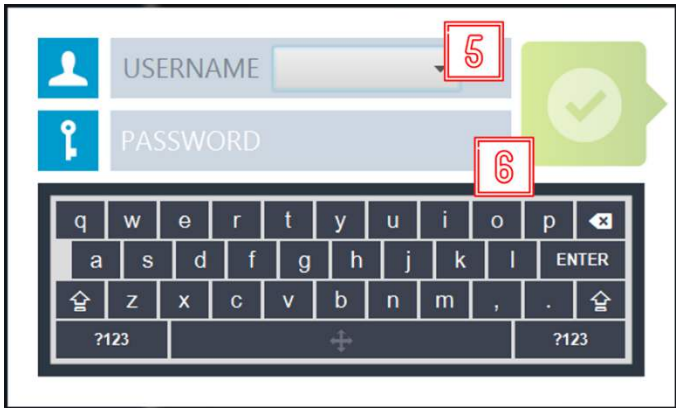


Figure 6.4: Selecting a user with export permissions.

7 A pop-up window appears in which you can select the format for the export. Click the **DICOM** button if you want to export the images/videos in DICOM format or the **NON-DICOM** button if you want to export the images/videos in the default non-DICOM format.

Figure 6.5: Selecting the export format (DICOM or NON-DICOM).

8 Select the target to which you want to save the data. Depending on the selected target and any preconfigured default paths for the export targets, different steps are now required. These are listed below:

The names of the targets used here do not have to match the names in your system. You should therefore use the icons as guidance.

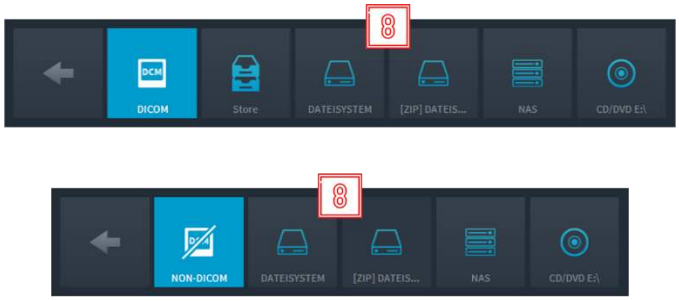


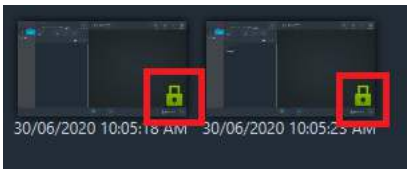
Figure 6.6: Export: selecting the target. The top figure shows the export in DICOM format and the bottom figure in non-DICOM format.

Save the DICOM data in a PACS archive.

Click the button (see Figure 6.6, here called 'Store').

The data can only be stored using the 'Store' button if there is a preconfigured and active PACS archive or VNA. If there is no integrated PACS archive, the Store button is not displayed when selecting the targets for the DICOM export.

If an instance was successfully exported to PACS, the instance thumbnail is marked with a green padlock icon:



If the PACS archive is inactive, an error message appears saying: "Export to XXX Not Successful: XXX is not reachable".

Save the DICOM/non-DICOM data in the pre-defined export format or as a ZIP file in a local directory or on a removable medium.

Click the button (see Figure 6.6, here called 'File System').

There are now two different options for the next steps:

a. If a default directory for exports has been stored in the CX-PRIME configuration, a rotating circle appears on the screen to show that the data is being exported.

b. If no default directory has been stored in the CX-PRIME configuration, Windows Explorer opens.

9 Please select the desired directory and the folder in which you want to locally save the data. Next, click the Select Folder button. A rotating circle then appears on the screen to show that the data is being exported.

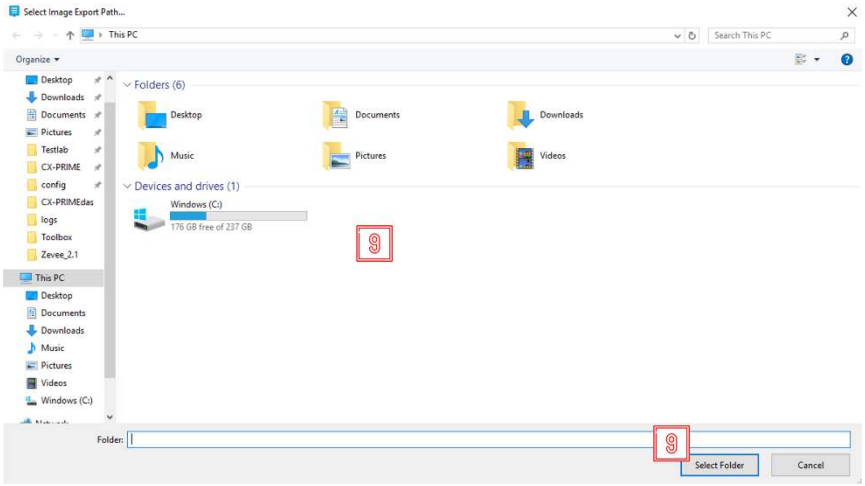


Figure 6.7: Export: selecting the local directory for the export.

In case of successful export, a similar notification will appear:

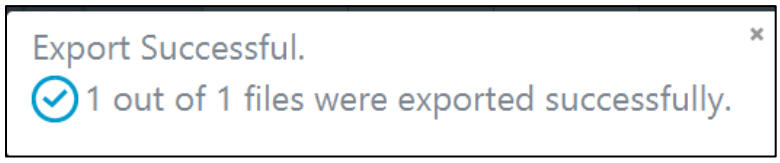


Figure 6.8: Notification about a successful export (example).

There are cases when export to a directory might fail. A user will be notified about the failed export and the reason for it in one of the following notifications (Figure 6.9-6.11):

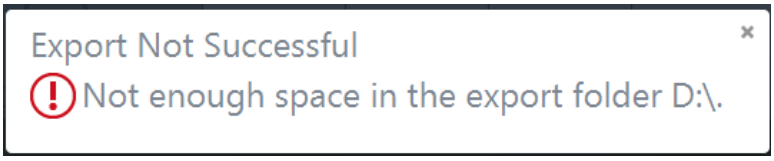


Figure 6.9: Notification about unsuccessful export due to lack of space in the export directory (example).

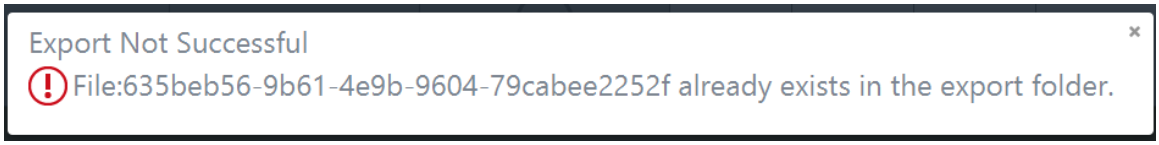


Figure 6.10: Notification about unsuccessful export due to a duplicate export (example).

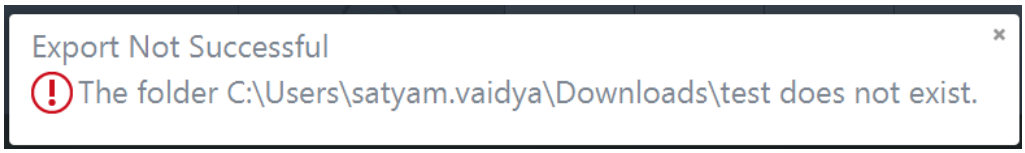


Figure 6.11: Notification about unsuccessful export due to non-existing export directory (example).

Save the DICOM/non-DICOM data in a network directory.

Click the button (see Figure 6.6, here called 'NAS').

You cannot independently select the network directory. This is configured in the CX-PRIME default settings. If this is not the case, an error message appears.

A rotating circle now appears in the Export app and a Windows screen opens.

10 In order to delete some items from the Export app, select the items and click the **Delete** button.

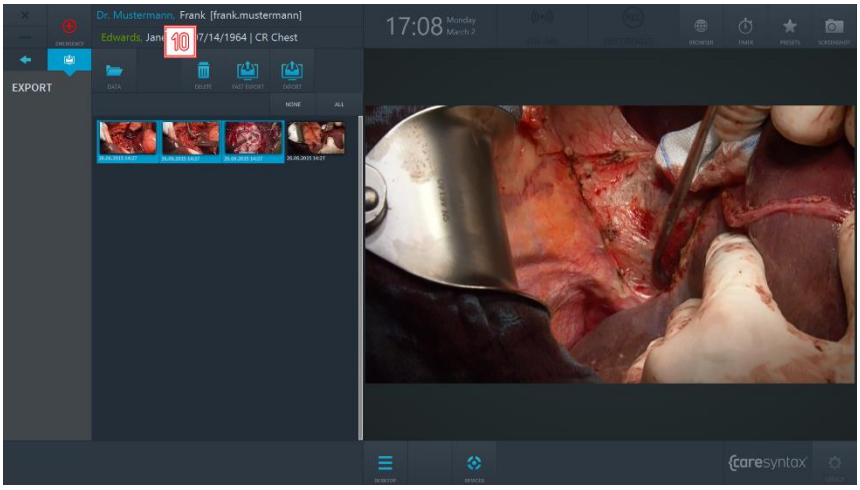


Figure 6.12: Deleting the items from the Export app.

Deleting multiple instances (50+) at once from the Export app might cause slowness of CX-PRIME or might crash it.

Printing

It is possible to print surgical images directly from the Export application of CX-PRIME.

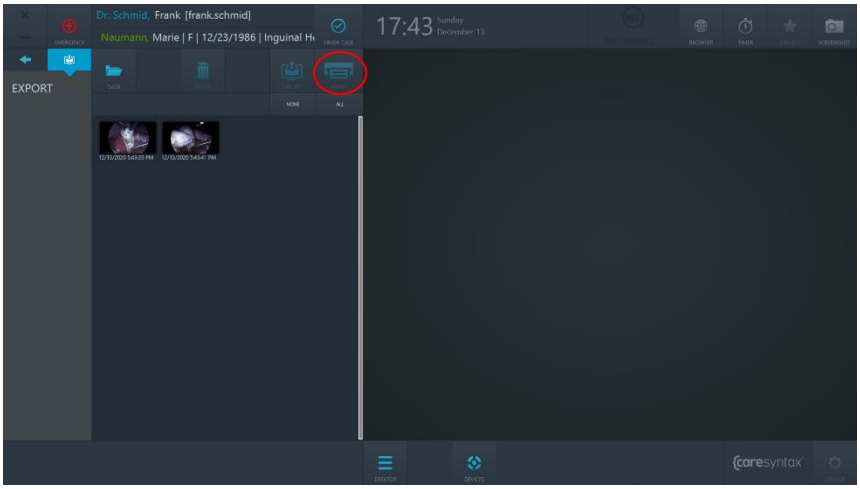


Figure 6.13: Print button in the Export application. Print button is inactive and will become active once a user selects images to be printed.

1 Select the images you would like to get printed. You can do this by individually clicking on the images. The selected images are highlighted in blue.

2 Click on the Print button: the Printing dialogue will pop up.

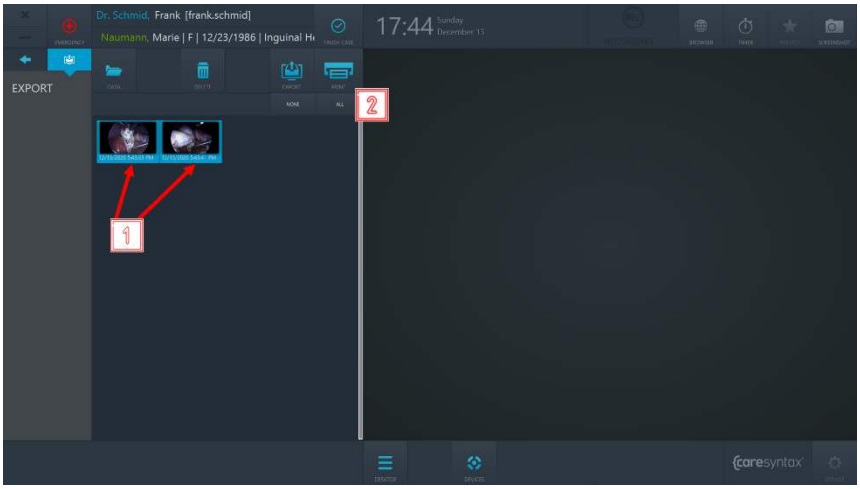


Figure 6.14: Selecting images for print and proceeding to the Printing dialogue.

3 Select the printer from the dropdown of the available devices.

4 Choose the number of images per page.

5 Choose the page orientation.

6 Choose the number of copies to print.

7 Choose the page format to print on.

8 On the right side, you can see the preview of your report. You may scroll through the preview by using touch actions or mouse buttons.

9 You may adjust the zoom of the preview by clicking on “+” or “-” buttons, or by selecting one of the zoom options from the zoom dropdown.

10 If you wish to proceed with printing, click on “PRINT” button. The printing job will start, and you will receive a notification in the upper right corner of the screen.

11 If you wish to cancel printing, click on “CANCEL” button.

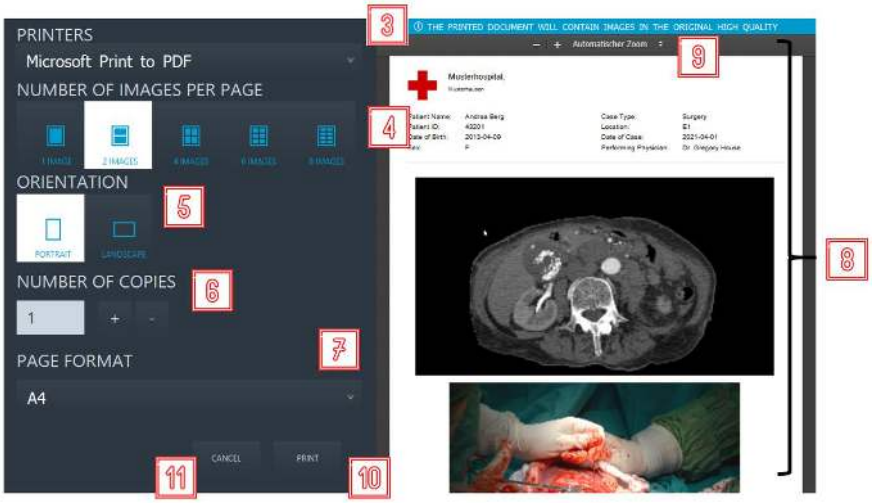


Figure 6.15: Actions with the Printing dialogue.

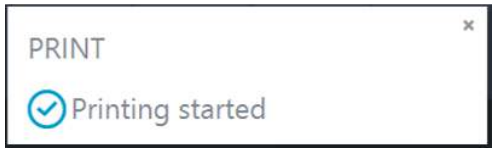


Figure 6.16: Notification about start of printing.

In addition to selected images, the printed report will contain patient and hospital information in its header.

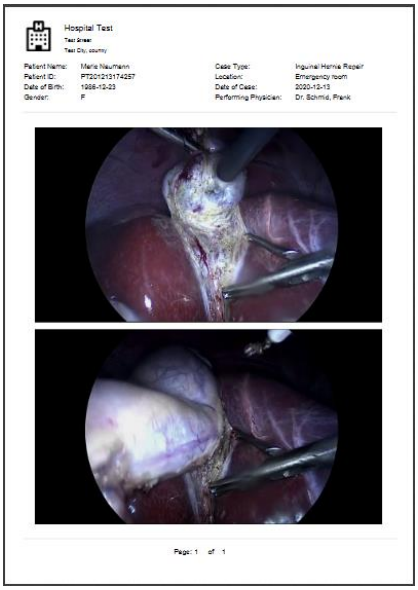


Figure 6.17: Example of a printed report.

Finishing the Case

Finishing the case in CX-PRIME can be done with the help of the Finish Case button.

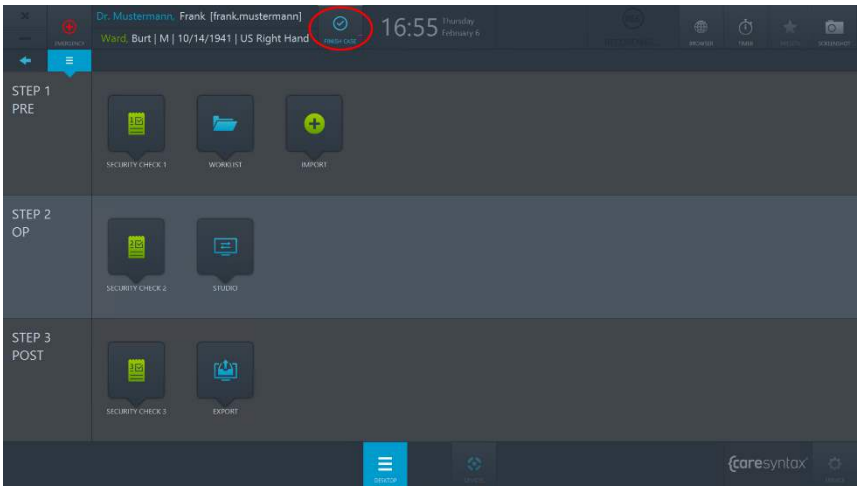


Figure 6.18: Finish Case button on the CX-PRIME desktop.

Finish Case button becomes active once a user enters the patient context i.e. selects a patient from the Worklist. In order to finish the case and all associated processes (all ongoing recording), click the Finish Case button and confirm that you really wish to finish the case. After the confirmation, all ongoing processes will be stopped, you will leave the patient context and you will be taken to the Worklist application.

A. Operating the integrated Devices

A.1 Controlling Surgical Lights

There are different surgical lights that can be controlled via CX-PRIME. The example below is based on SurgLED surgical lights.

You can switch the light on and off and adjust the illuminance, the light field diameter, the color temperature, and the presets. The section below describes the individual buttons.

Please note that the control buttons may differ depending on the integrated device and its functionality.

In case of malfunction that prevents controlling the device via CX-PRIME user interface, please make sure to have backup access to the device controls.

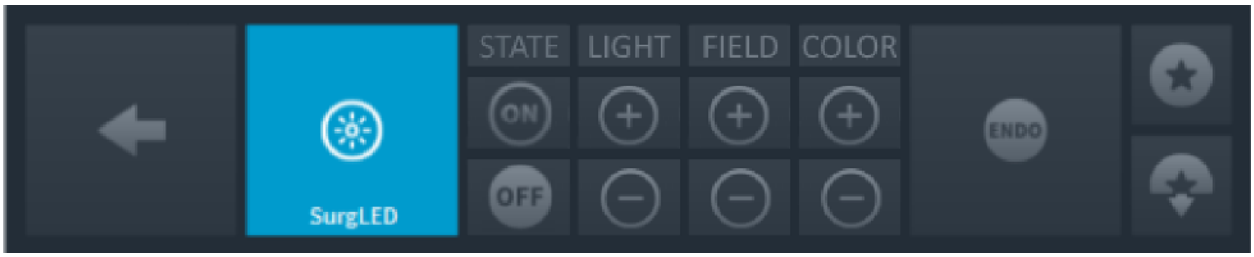
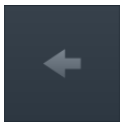


Figure A.1: OR light controls.



Back

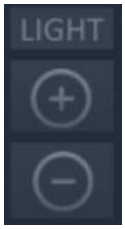
Go back to the list of devices to be managed (Figure 3.14).

Switch light on/off

Press the

button to switch on the light or the

button to switch it off.

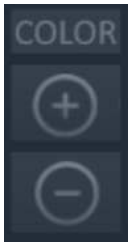


Setting the illuminance

To increase the illuminance, press the button repeatedly until the desired illuminance level is set. Press the button to reduce the illuminance.

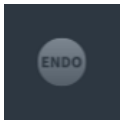
Setting the light field

There are 5 levels for setting the light field. Click the button to enlarge the light field to the desired size. Press the button to reduce the light field size.



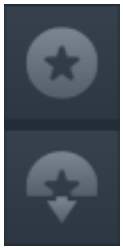
Setting the color temperature

The color temperature is set in 5 stages. Repeatedly press or press and hold the button to increase the color temperature to the desired level. To reduce the color temperature, repeatedly press or press and hold the button.



Backlight for endoscopic operations

This is a diffuse backlight that is needed during endoscopic operations and that reduces the illuminance. Press this button once to switch on the backlight. Press the button again to return to the previously set illuminance.



Saving the light parameters

To save the current settings for the light field, illuminance and color temperature, press the button. To restore the saved light parameters, press the button.

A.2 Controlling a Room Camera

Please note that the control buttons may differ depending on the integrated device and its functionality

In case of malfunction that prevents controlling the device via CX-PRIME user interface, please make sure to have backup access to the device controls.

The following functions can be used to integrate a room camera, e.g. a pan, tilt and zoom (PTZ) camera:

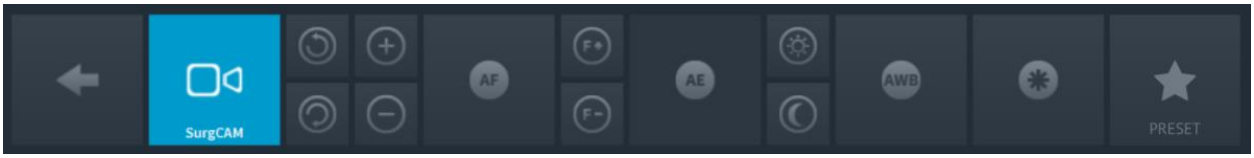
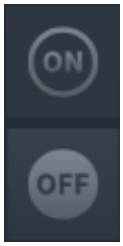


Figure A.2: Room camera controls.

Back

Go back to the list of devices to be managed (Figure 3.14).



Switch the camera on/off

Press the button to switch the camera on or the button to switch it off.

Zooming

Press the to make the camera image larger or the button to make it smaller. Repeatedly press or press and hold the respective button until you reach the desired setting.

Automatic focusing

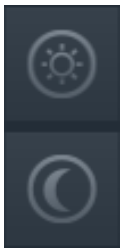
The camera supports automatic focusing. Press this button to use this function.

Manual focusing

Repeatedly press or press and hold the button to set the focus in the distance. For close-up focus, repeatedly press or press and hold the button until you reach the desired camera image sharpness.

Automatic brightness setting

This function automatically sets the aperture to achieve the optimum brightness for the image. Click the button to use this function.



Manual brightness setting

Repeatedly press the button to open the aperture and brighten the camera image. To close the aperture to obtain a darker image, repeatedly press the button.

Automatic white balance

The automatic white balance function adjusts the camera's color control to the lighting conditions in the room. Press this button to use the white balance function.

Due to the manufacturer default settings, no white balance should be conducted unless required.

Infrared filter

The infrared filter can be removed from the image in the case of increased sensitivity in low light conditions. This enables the camera to work effectively both during the day and at night. In low light conditions, the

infrared mode is switched on. This removes the infrared filter, increasing the infrared sensitivity and making the camera image monochrome.

Panning the camera

Repeatedly press or press and hold the respective arrow button to move the camera left or right until you have reached the desired camera position.

Tilting the camera

Repeatedly press or press and hold the respective arrow button to move the camera up or down until you have reached the desired camera position.

Saving and recalling a preset

Press this button to save new camera position presets or to recall existing camera preset. The preset are a defined Pan Tilt Zoom Position of the camera that can be easily recalled.

A.2.1 Preset Save

With below outlined steps you can save the current Pan Tilt Zoom position of the camera as a new preset. The preset will be available for the currently logged in CX-PRIME user only.

1 Click the **Preset** icon.

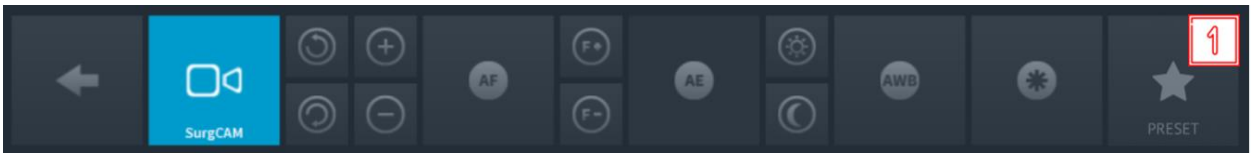


Figure A.3: Room camera controls.

2 Click **SAVE AS NEW** in the pop-up window.

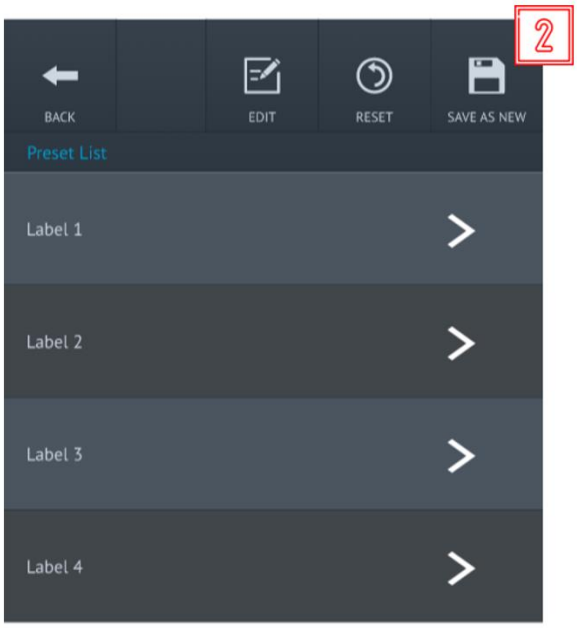


Figure A.4: Saving a new Preset

3 A further pop-up window appears. Enter a Label Name for the preset using an attached keyboard or the On-Screen Keyboard.

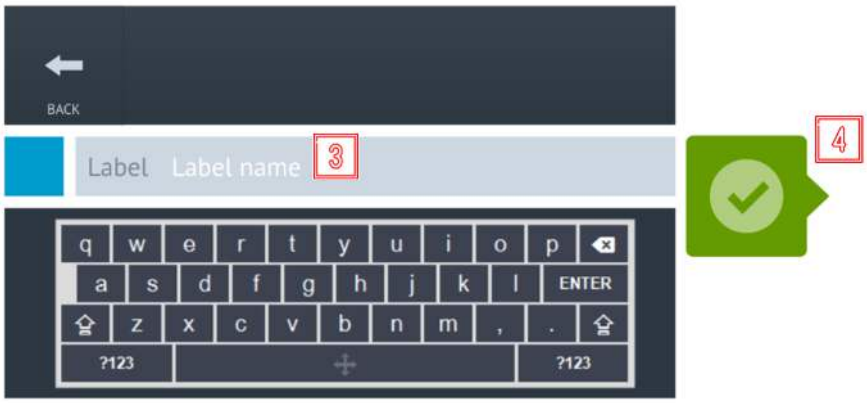


Figure A.5: Saving a new Preset

4 Click the green button to confirm your entries. The Preset will be saved in the next free Preset slot.

A.2.2 Preset Edit/Delete

With below outlined steps you can edit the name of Camera Presets or delete them.

1 Click the **Preset** icon.

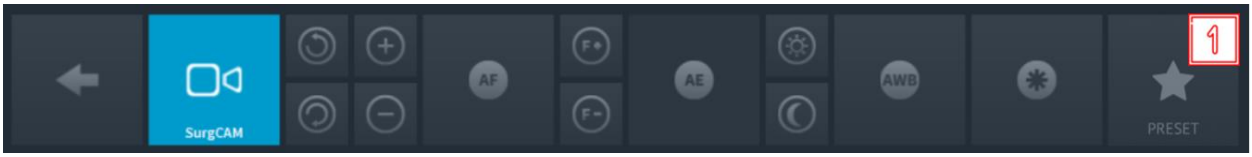


Figure A.6: Room camera controls.

2 Click **EDIT** in the pop-up window.

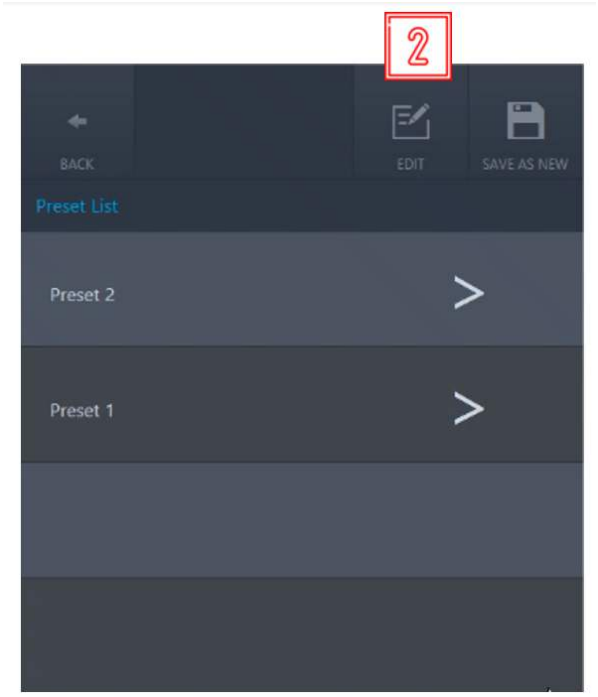


Figure A.7: Editing an existing Preset

3 A further pop-up window appears. Delete an existing Preset by clicking the delete Button.

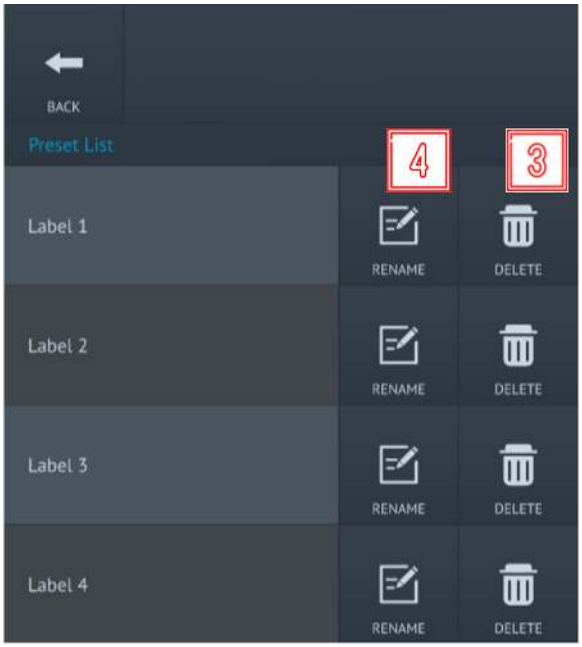


Figure A.8: Deleting or renaming a Preset

4 Click the Rename button to rename an existing Preset

5 In the upcoming pop-up enter a new Label Name for the preset using an attached keyboard or the On-Screen Keyboard.

Figure A.9: Renaming a Preset

6 Click the green button to confirm your entries. The Preset will be saved in the existing slot with a new name.

A.2.3 Preset Recall

With below outlined steps you can recall a previously saved Pan Tilt Zoom position of the camera.

1 Click the **Preset** icon.

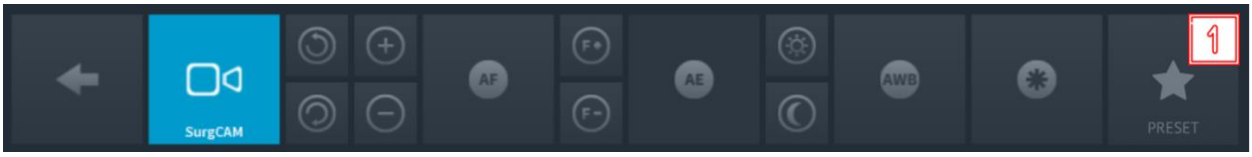


Figure A.10: Room camera controls.

2 Apply the Preset by clicking the arrow for the preset you want to recall.

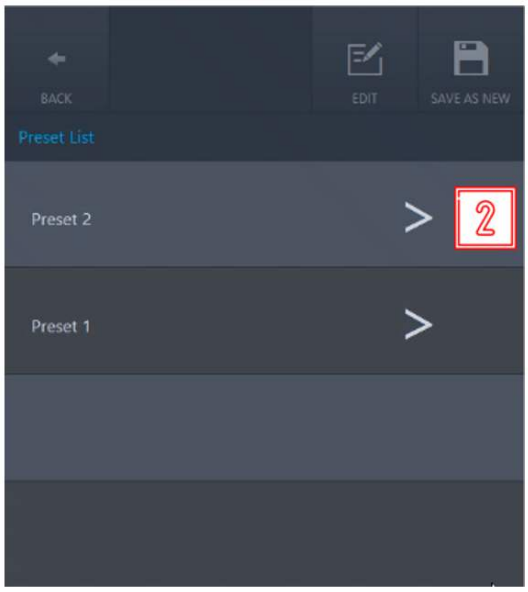


Figure A.11: Recalling a Preset

A.3 Controlling an Operating Room (OR) Light Camera

Please note that the control buttons may differ depending on the integrated device and its functionality

There are different OR light cameras that can be controlled via CX-PRIME. The example below is based on SurgCAM camera, which is integrated into an OR light.

The following control functions are available:

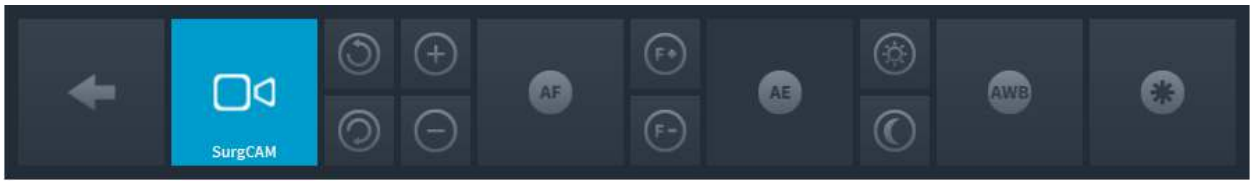


Figure A.12: OR light camera controls.

Back

Go back to the list of devices to be managed (Figure 3.14).

Rotating the camera

Press the button to rotate the camera clockwise or the button to rotate it counter-clockwise. Press and hold the relevant button until you have reached the desired image orientation.

Zooming

Press the to make the camera image larger or the button to make it smaller. Repeatedly press or press and hold the respective button until you reach the desired setting. The camera allows a 10x enlargement (10x optical zoom).

Automatic focusing

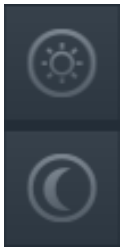
The camera supports automatic focusing. Press this button to use this function.

Manual focusing

Repeatedly press or press and hold the button to set the focus in the distance. For close-up focus, repeatedly press or press and hold the button until you reach the desired camera image sharpness.

Automatic brightness setting

This function automatically sets the aperture to achieve the optimum brightness for the image. Click the button to use this function.



Manual brightness setting

Repeatedly press the button to open the aperture and brighten the camera image. To close the aperture to obtain a darker image, repeatedly press the button.

Automatic white balance

The automatic white balance function adjusts the camera's color control to the lighting conditions in the room. Press this button to use the white balance function.

Due to the manufacturer default settings, no white balance should be conducted unless required.

Freeze frame

Press this button to create a freeze frame image.

A.4 Controlling an Audio System

Please note that the control buttons may differ depending on the integrated device and its functionality

Audio System gives the opportunity to choose pre-defined settings for optimal playback quality of audio signals for different applications. This will be explained using examples, i.e. the used examples may not match those in your system. A user can control the volume of speakers and microphones connected to the audio system via CX-PRIME.

A.4.1 Volume control

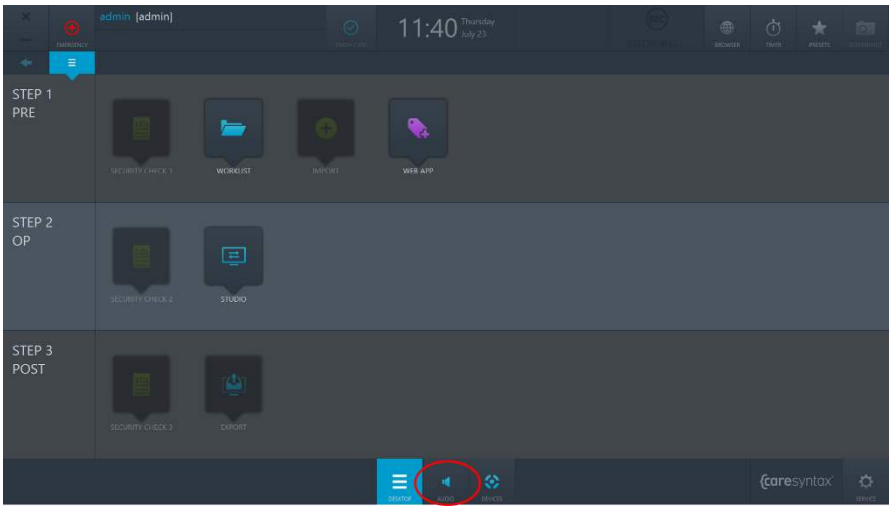


Figure A.14: Audio Control app on the CX-PRIME Desktop.

By clicking the AUDIO button on the CX-PRIME desktop, a user will access the volume faders, configured for the speakers and microphones in the OR (Figure A.15). A user can then change the volume of every device by moving the fader knob up or down. In addition, every device fader has a mute button, which makes a device silent.

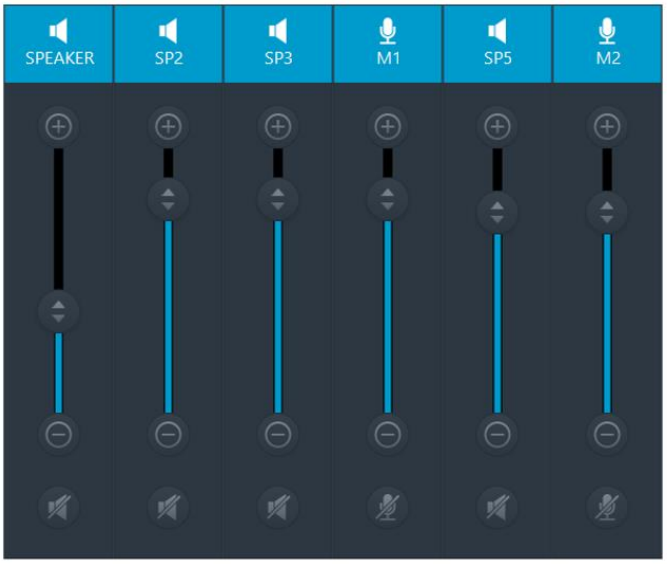


Figure A.15: Audio Control Faders and Mute Buttons.

A.4.2 Audio Preset Recall

With below outlined steps you can recall Audio Preset

1 Click the **Preset** icon.

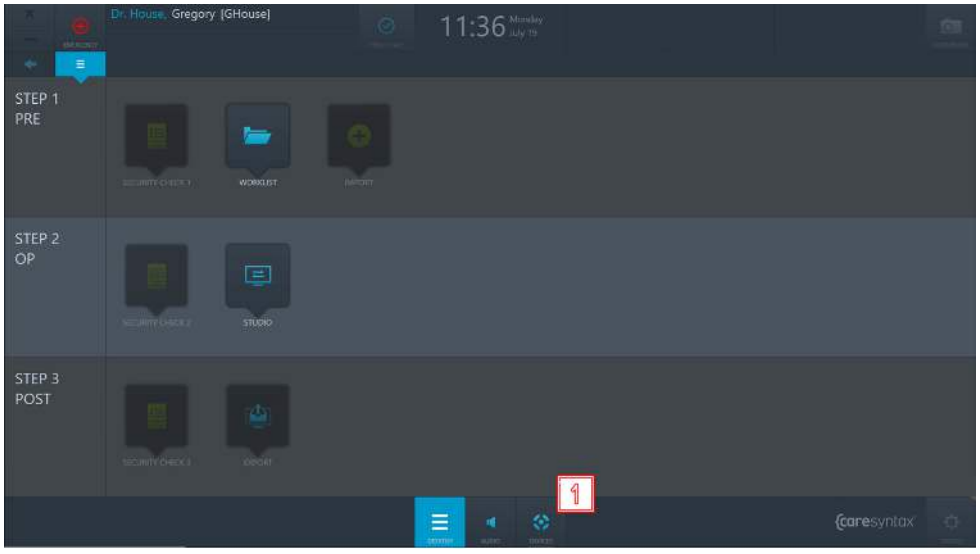


Figure A.16: CX-PRIME Desktop Devices

2 Choose the Device with the speaker icon.

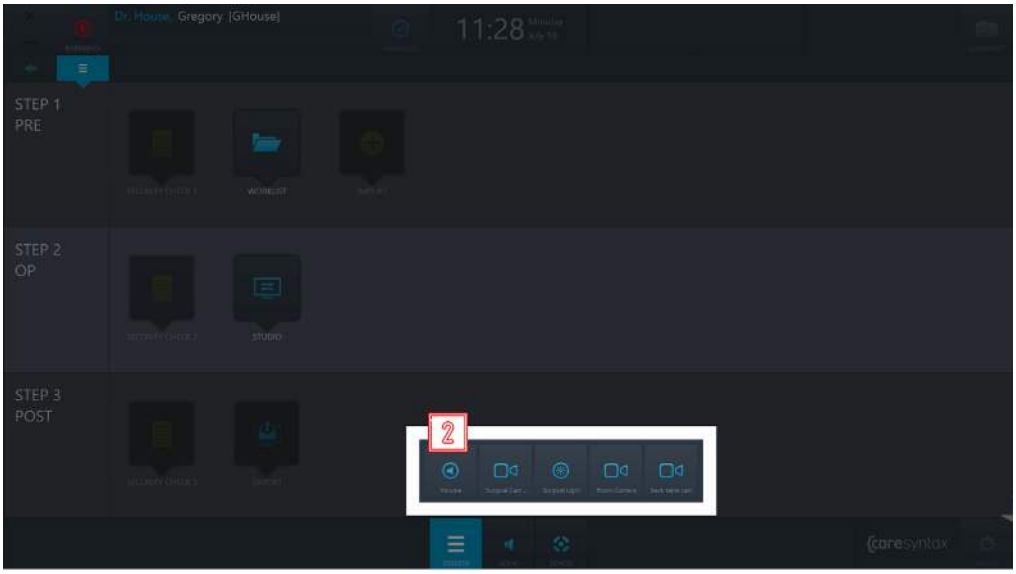


Figure A.17: Choosing Audio Preset Device

3 Click the Preset you want to recall

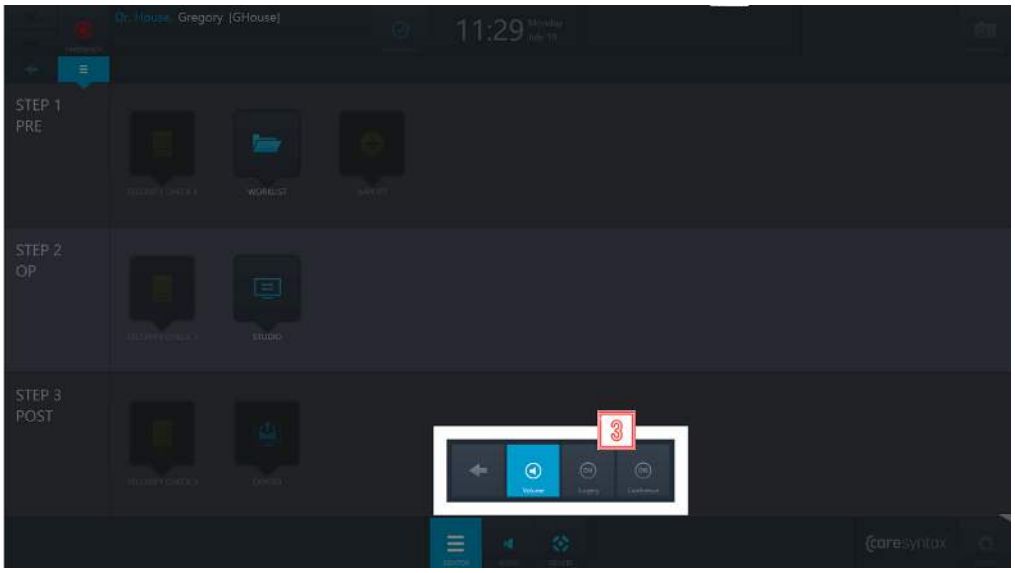


Figure A.18: Audio Preset Recall

B. FAQ

This section provides you with advice on how to resolve usage errors and error messages. The general CX-PRIME functions are listed first, followed by those for each operatory phase. This overview should help you to quickly resume your operation.

General functions/first steps

User: Why does the window jitter but then nothing happens after you have entered and confirmed your password?

The password entered is incorrect. Re-enter the password and click the green button to confirm (see Section 2). On logging in successfully, the CX-PRIME desktop appears.

Step 1: Pre-phase

Worklist: Why I am unable to select a patient when I click him/her?

You must double-click to select a patient.

Worklist: I have selected the Worklist app but can only see a blank list and I am unable to create a new study. Why?

You are most likely in the wrong worklist, i.e. the Import worklist. Click Local Worklist. You should now be able to see the patient and study data that has already been created. The New Study tab is also now active. Instructions on how to create a new study are provided in Section 4.1.2. Alternatively, you might be filtering the worklist and therefore not seeing any results. Please refer to Section 4.1.1.

Import: I cannot click the Import app; it is grayed out. Why?

Once you have selected a patient or study in the worklist, the Import app is enabled. Instructions on how to select a patient or study can be found in Section 4.

Step 2: OP-Phase

Studio: The Recording tab of the Studio app is grayed out and cannot be selected.

In this case you must first select a patient or a study in the worklist. Section 4 shows you how to select a patient/study.

Step 3: Post

Export: The Export app is grayed out and cannot be selected.

In this case you must first select a patient or a study in the worklist. Section 4 shows you how to select a patient/study.

Export: On clicking the Export button, a window appears in which a username and password need to be entered. Why?

In this case you do not have the necessary permissions to export the images/videos. Select a user who has rights to perform the export and enter his/her password (see Section 2). If you do, however, have rights to export images/videos, please contact your system administrator.

Export: On clicking the Fast Export button, an error message appears. Why?

For the Fast Export Button, the destination paths for images and videos are preconfigured in the administration area. Please contact your system administrator.

Export: The error message 'Could not connect to xxx!' appears when exporting the DICOM data to the PACS archive or VNA.

The connection to your PACS archive is inactive. Please contact your system administrator.

Export: The following error message appears when exporting the image/video data to the network directory: 'Logon failure: unknown username or bad password.'

You do not have access to the network directory. Either there is no network connection to this directory or no default path has been stored for the network directory in the CX-PRIME configuration. Please contact your system administrator.

C. List of Applicable Standards

Applicable standards, laws and guidelines to the CX-Prime standalone software:

Standard	Title
DIN EN ISO 13485:2016	Quality Management Systems – Requirements
2017/745/EEC (MDR)	Regulation 2017/745/EEC of the European Parliament and of the council of medical devices
EN 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 1041:2013	Information supplied by the manufacturer of medical devices
EN 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 62304:2015	Medical Device-Software – Software-Lifecycle processes
EN 82304:2016	Health Software - general requirements for product safety
EN 62366-1:2015	Medical Products – Application of Usability to Medical Products
EN 80001-1:2016	Application of Risk Management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities
MEDDEV 2.7/1 rev.4	Clinical Evaluation: A Guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
MPSV	Medizinprodukte Sicherheitsplanverodrnung (Ordinance on the Medical Device Safety Plan)
MPG	Medizinproduktegesetz (Act on Medical Devices)

D. List of Integrated Devices

Surgical Lights

Vendor	Model
Simeon	Sim.LED
Surgiris	Surgi LED
KLS Martin	marLED
Trumpf	iLED 3
Trumpf	iLED 5
Trumpf	iLED 7
Trumpf	Trulight 5000
Trumpf	Trulight 5000c
Dräger	Polaris 600
Maquet	PowerLED 700 (via FIBOX 40)
Amico	ICE30M

Surgical Light Cameras

Vendor	Model
Simeon	Sim.CAM SD/ HD camera
Simeon	Sim.CAM HD touch
Surgiris	SurgirisCamera
KLS Martin	SurgiCAM
Trumpf	TruVidia Wireless
Trumpf	TruVidia HD
Amico	iCE LED
Maquet	ORCHIDE HD (via FIBOX 40)
Dräger	Polaris 600

Room Cameras

- Sony PTZ
    - SRG-360SHE
    - SRG-300H
    - SRG-300SE
    - SRG-X120

- Ikegami PTZ Camera
    - MKC-700HD Camera Head and CCU
    - MPR-401 PAN/TILT Head
    - MPC-401 Controller

Displays (Input/DICOM Preset Control)

- Sony LMD-2760MD
- Sony LMD-X310MD

Video routers

Non Video Over IP

- Aja Kumo 3G-SDI Router
- FSN IPS500A

Video Over IP

- ZeeVee Zyper4K
- Barco Nexxis

Audio Matrices

- Extron
    - DMP44LC
    - DMP64
    - DMP128

Remote control devices

- Swifty USB switch interface Model: SW2

Recording devices

- Yuan HD capture solution with hardware compression