



OR Integration Quick User Guide

5

Version

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1 General Information

Thank you for choosing CX-PRIME. This quick user guide will introduce you to first steps of the software that you have purchased. It offers step-by-step instructions and explanations on the main usage of CX-PRIME with screenshots to provide examples.

It will also guide you through some of the standard hardware that you might face in a CX-PRIME integrated OR and the handling of this hardware.

Your ability to use all or only certain CX-PRIME functions depends on the specific configuration that you have purchased.

Please also read the full CX-PRIME user manual to optimize your OR workflows.

If you have any queries to which you are unable to find answers also in the full user manual, 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 this quick user guide 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 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.

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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.



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**.

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 full 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.

2 Base system components overview

The integration hardware built around the CX-PRIME software in video-over IP based setups consists of several core components that will be lined out in the following section.

For further info on devices and connections on your specific setup please refer to the individual project documentation.

OR integration setup architecture

Each Video Source like Endoscope, Room camera, Surgical light etc. is enabled for Routing and Recording using CX-PRIME application. To be routed signals are converted to a Video-over-IP data stream. This conversion is handled through Encoders that each video device will be equipped with.

Some displays are integrated with an internal Decoder. Accordingly, the backwards conversion from Video-over-IP data stream to raw video is handled internally in the Display. Displays that are not equipped with an internal Decoder require an external device to facilitate this function.

To enable a data connection between all video sources (Encoders) and displays (Decoders) a central network switch connects all data streams.

With CX-PRIME the user can define which Video source is to be shown on which display. Furthermore CX-PRIME can record the video streams connected to the system. CX-PRIME is running on a central PC.

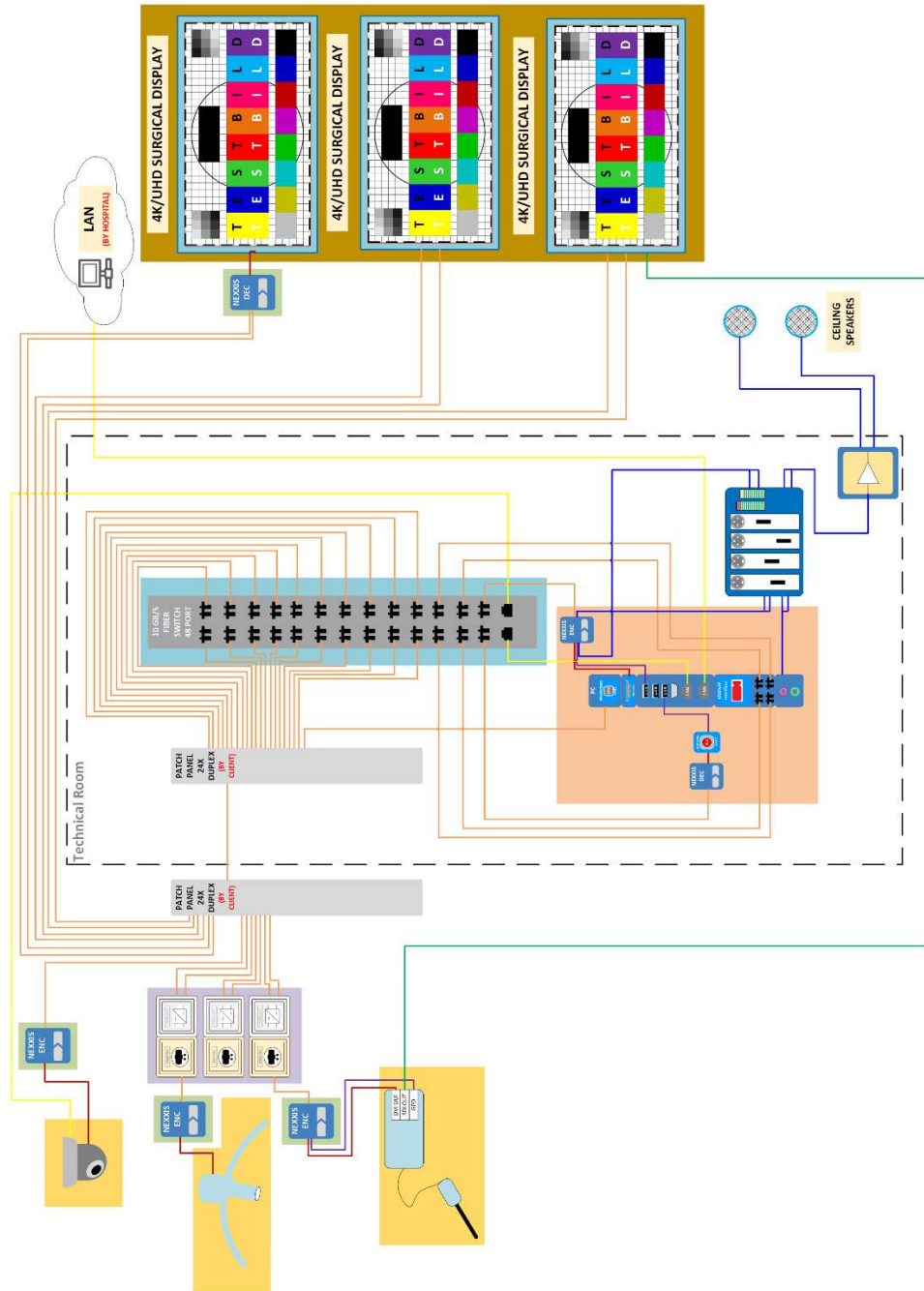
The central switch as well as the CX-PRIME control PC is located in a technical rack usually outside of the operating room environment.

Find a high level OR integration hardware schematic below.

The following main devices can be seen:

- **Encoder/Decoders:** Encoders and Decoders that enable the conversion between raw video (e.g. provided via HDMI signal) and Video-over-IP data streams
- **Single Plug Patch Panels:** Patch Panels where mobile devices can easily be connected via their Encoder to the OR integration setup
- **Video sources:** Video Sources such as Room camera, Surgical Light, Endoscope that are connected via an Encoder to the System integration setup
- **Video destinations:** Video destinations such as Displays needed for displaying Video feeds of connected devices. Some Displays require an external Decoder and some have this device integrated

- **Network Switch:** A central network switch that enables connection between all Video devices
- **CX-PRIME Control PC:** The Control PC runs CX-PRIME and is used to control the System integration setup



Encoder

Depending on the video output the video source provides, different Encoders are available for connection of the Video source. All those devices convert the raw video stream to a Video-over-IP data stream. The devices are connected to the System integration setup via a single plug connection cable. The Single Plug connection cable enables both data transfer as well as powering the Encoder device.



Figure 1: Video-over-IP Encoder

Decoder

All Decoders convert the Video-over-IP data stream to a raw video stream via HDMI interface. This is needed to connect Video destinations (Displays) to the OR integration setup. Some displays have the Decoder integrated. Accordingly, they do not need a separate device.



Figure 2: Video-over-IP Decoder

Single Plug Patch Panel and cable

For connection of mobile devices that are used in multiple ORs such as endoscope systems, the Integrated operating room is equipped with Patch Panels. Connecting the Single Plug cable to this Encoder will make the video source available in the CX-PRIME Routing application. For convenience, only devices connected to the system are displayed in the CX-PRIME user interface.



Figure 3: Single Plug Patch Panel with Single Plug cable



Figure 4: Single Plug cable

Network Switch

The uncompressed video transmission between Encoders and Decoders is enabled by a central network switch with a per port bandwidth of 10 Gb/s. The Switch is usually housed in a technical rack outside of the operating room environment.



Figure 5: 10 Gb/s network switch

Central Control PC

The central control PC is running the CX-PRIME application and enables all functionality to control the integrated operating room setup.



Figure 6: Control PC

3 Usage of CX-PRIME application

Preparation

As preparation for usage of the CX-PRIME application please make sure that all devices in the system such as Surgical-Lights, Endoscopes, Displays, PCs etc. are powered up.

Connect all mobile sources via the Single Plug Cable to available Patch Panels. This will power up the Encoder on these devices. For convenience only devices connected to the system are displayed in the CX-PRIME user interface.



Figure 7: Single Plug Patch Panel with Single Plug cable

Login

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.

3.1.1 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.

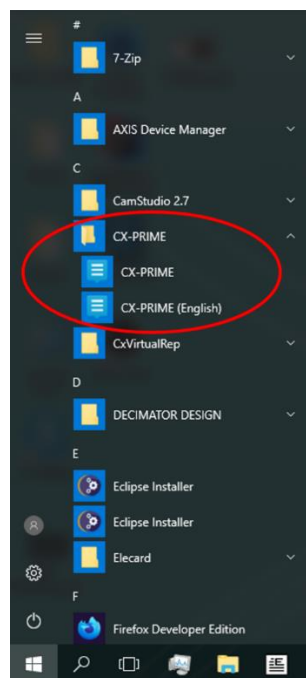


Figure 8: CX-PRIME in the Windows start menu.

CX-PRIME starts and the welcome screen 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.

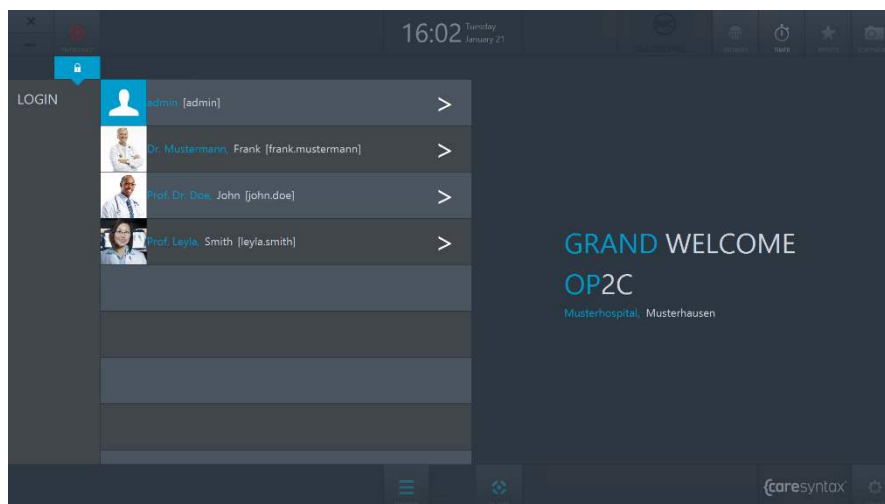


Figure 9: CX-PRIME welcome screen

3.1.2 Shutting down CX-PRIME

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

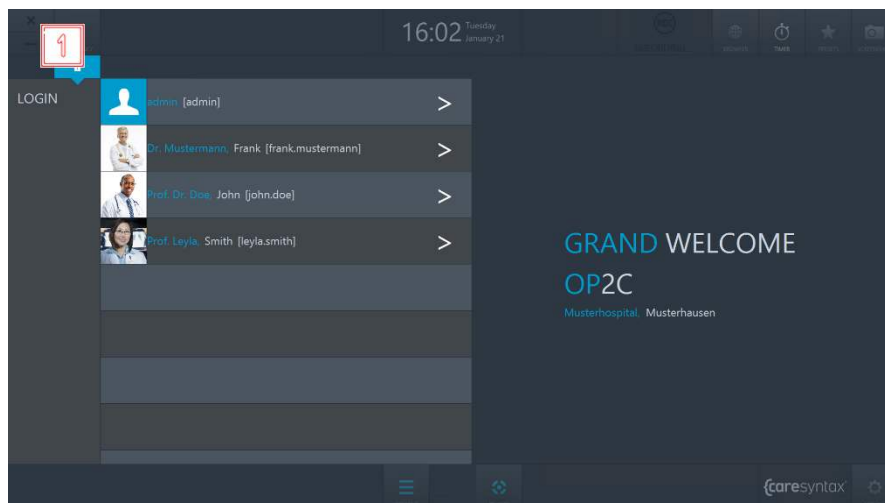


Figure 10: Shutting down CX-PRIME

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



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

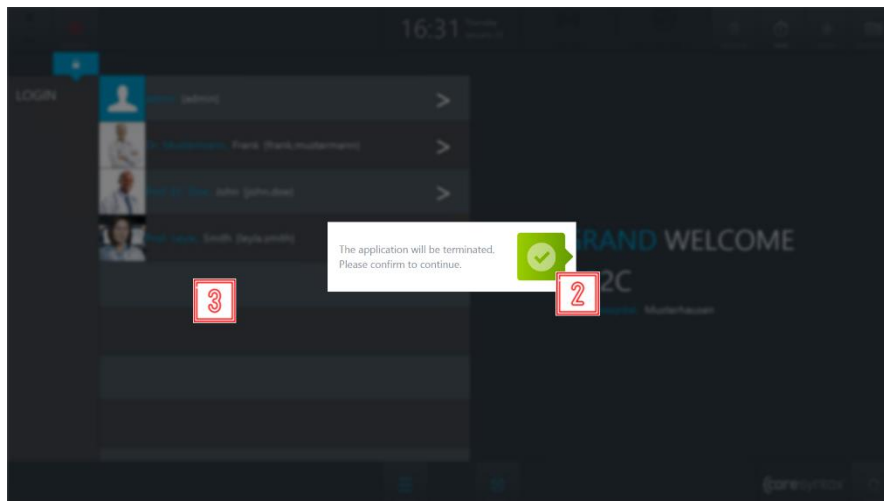


Figure 11: Shutting down CX-PRIME

3.1.3 User Login

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

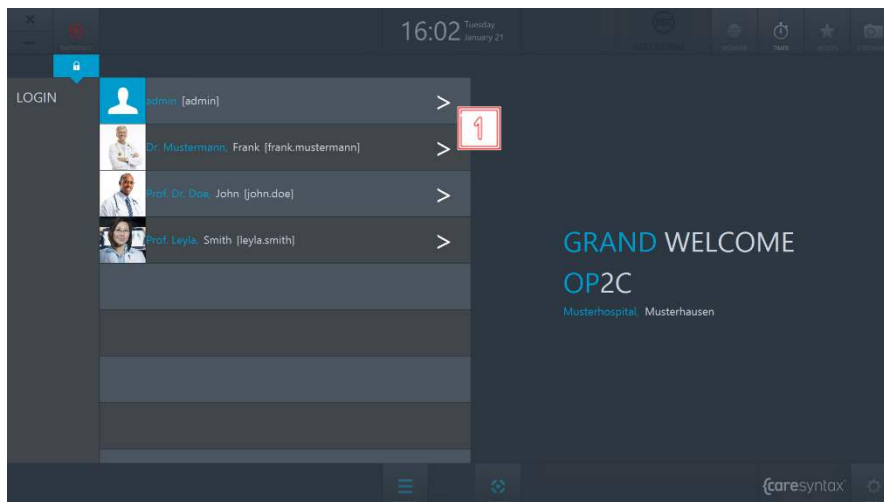



Figure 12: User login on the CX-PRIME welcome screen

- 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**.

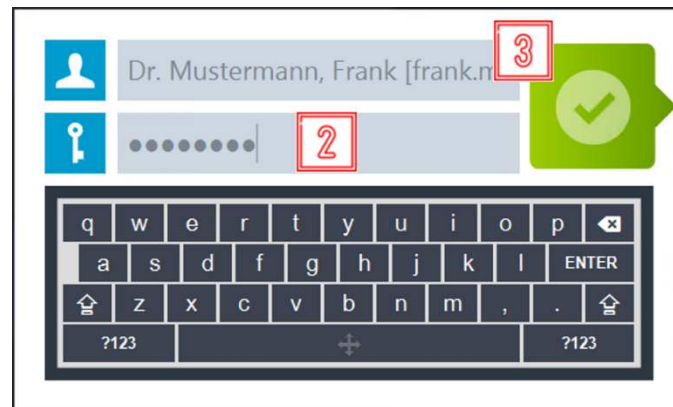


Figure 13: User login on the CX-PRIME welcome screen

Upon successful login, the CX-PRIME desktop appears with the full perioperative overview. The individual operatory phases and their apps are described in following pages.

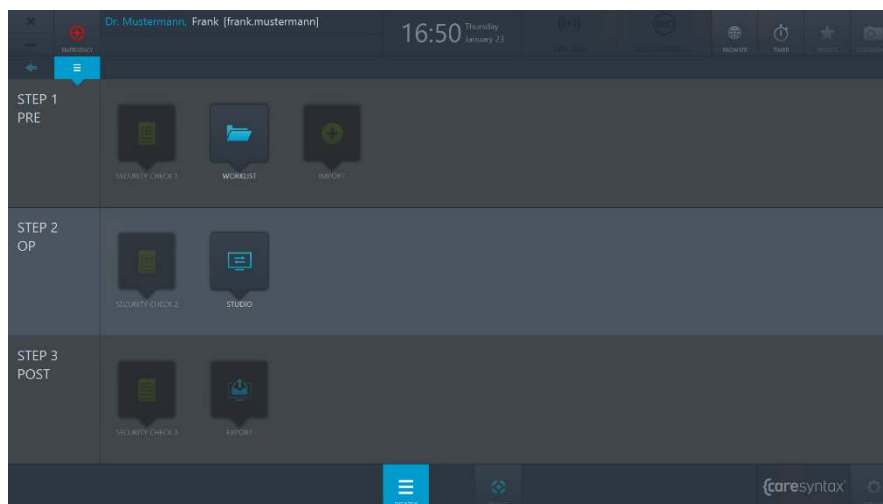


Figure 14: CX-PRIME desktop

3.1.4 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.

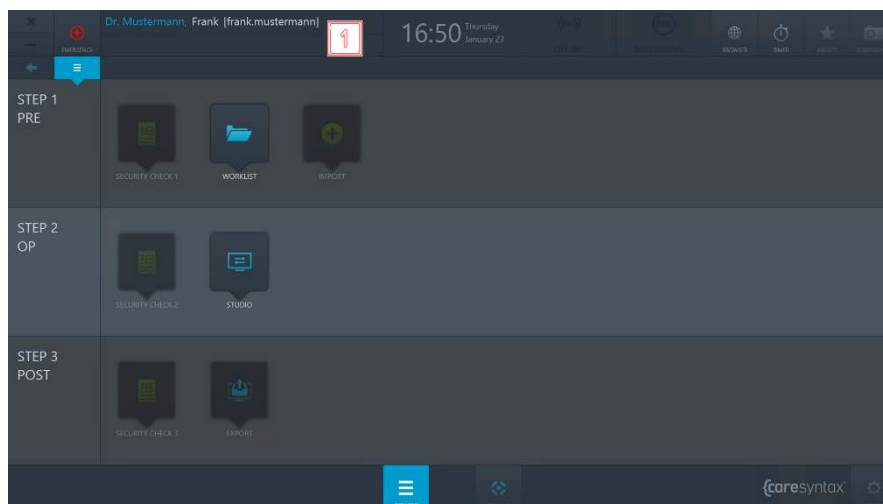


Figure 15: Logging off: selecting the username on the CX-PRIME desktop

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

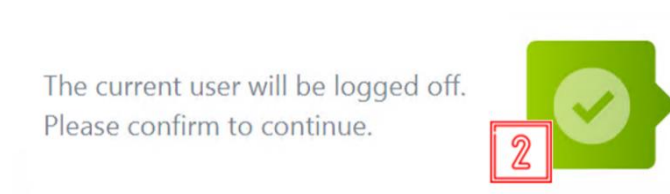


Figure 16: Confirming the logoff of the current user

The CX-PRIME welcome screen with the list of users re-opens.

Step 1: Pre-phase

The pre-operative 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 **security checklist** and **import** become available.

3.1.5 Worklist

This section starts by explaining how to start the worklist and select a study from the worklist for the medical procedure.

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

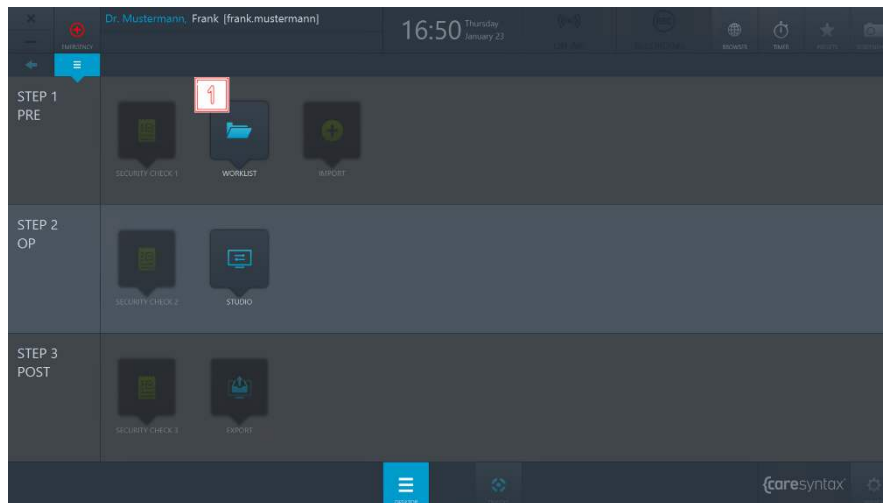


Figure 17: Starting the worklist app

- 2 Double-click a patient to select that patient.

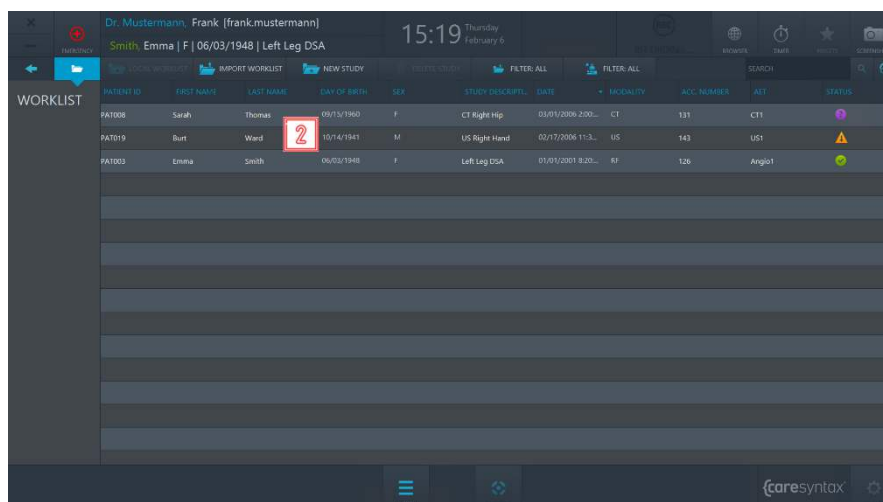


Figure 18: Selecting a patient/study

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-operative phase or switch to the operatory phase.

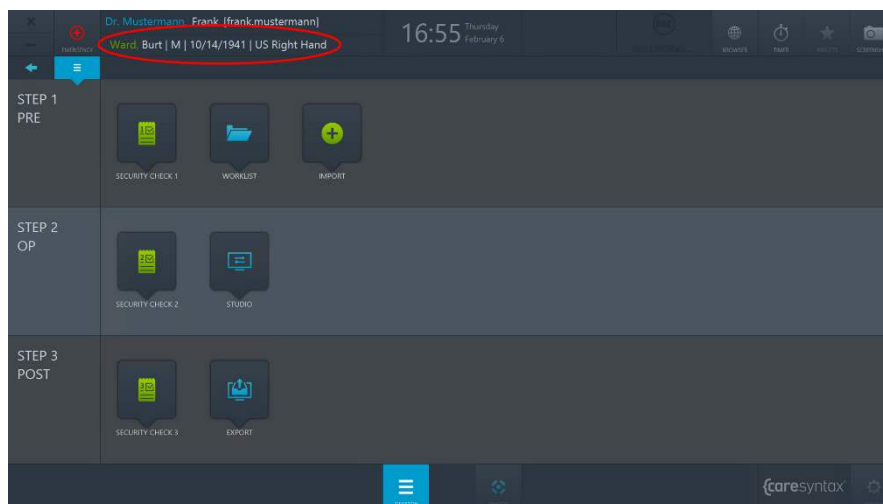


Figure 19: CX-PRIME desktop following patient selection. The selected patient is shown below the current user (red circle).



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.

3.1.6 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



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.

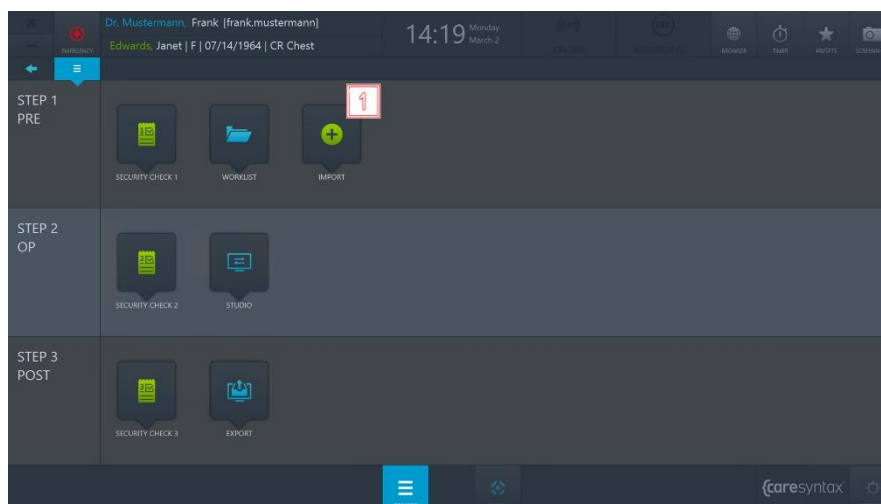


Figure 20: Import app on the CX-PRIME desktop

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.

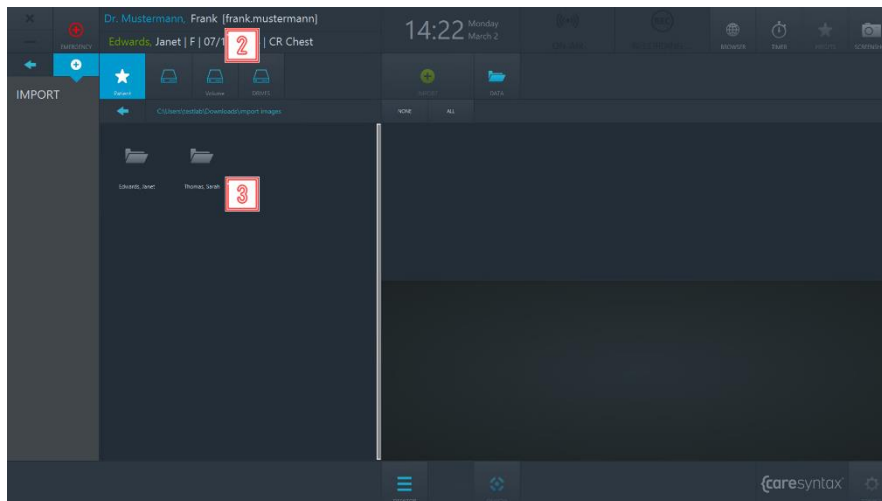


Figure 21: Selecting the directory and the folder containing the images to be imported

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.

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

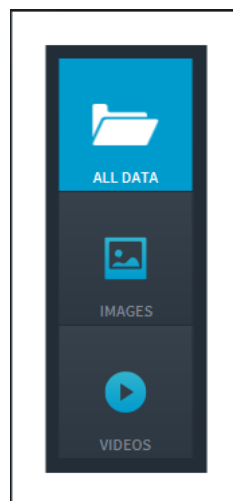




Figure 22: Selecting the image data to be displayed

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

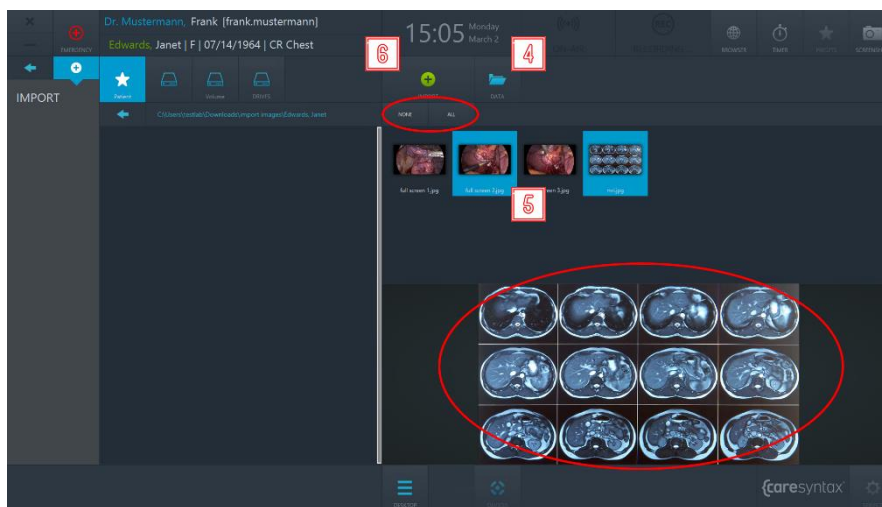


Figure 23: Selecting the image data to be imported. The top red circle shows the All and None tabs that can be used to select all or no image data. The lower red circle shows the embedded media player, which can be used to show images/videos by double-clicking them

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

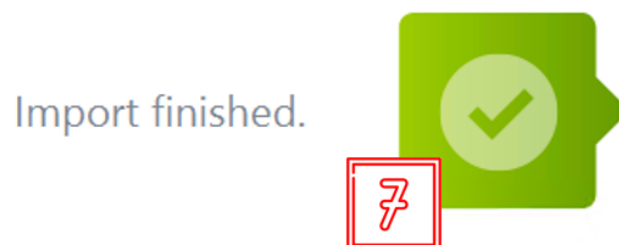


Figure 24: Confirmation of the imported images

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.

3.1.7 Checklist

The **Checklist** app enables you to centralize and digitize the team time-out workflow within the operating room.



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.

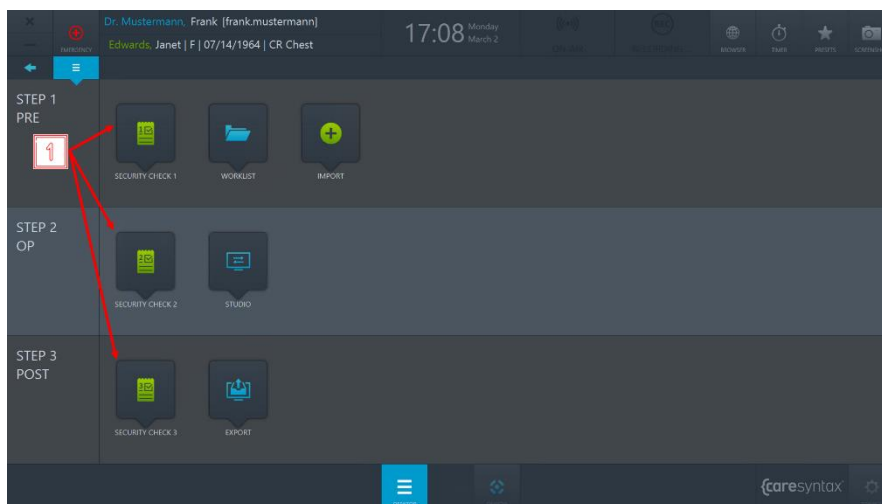


Figure 25: Checklist items on CX-PRIME desktop

2

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

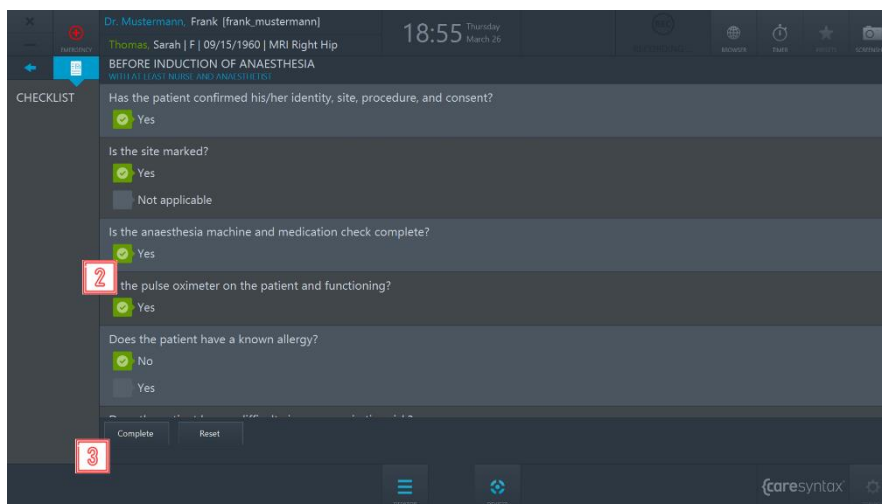


Figure 26: View of the Operatory Pre-op Checklist



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.

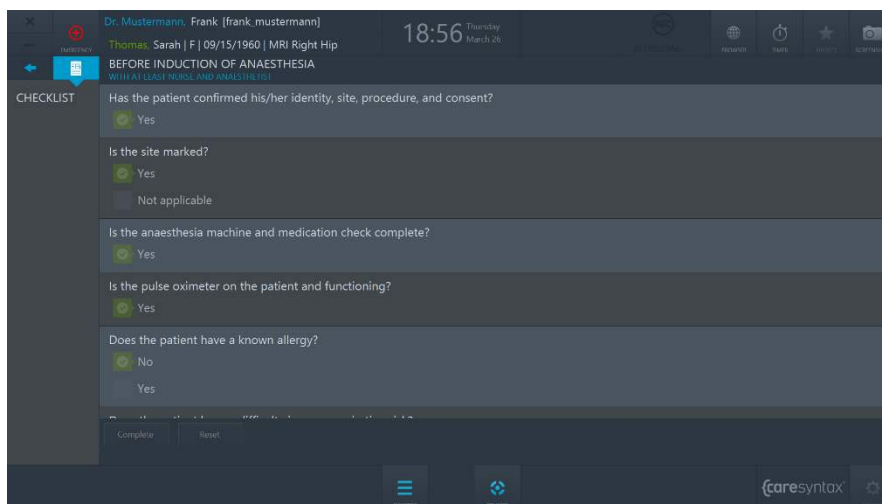


Figure 27: View of the completed Operator Pre-op Checklist

3.1.8 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.

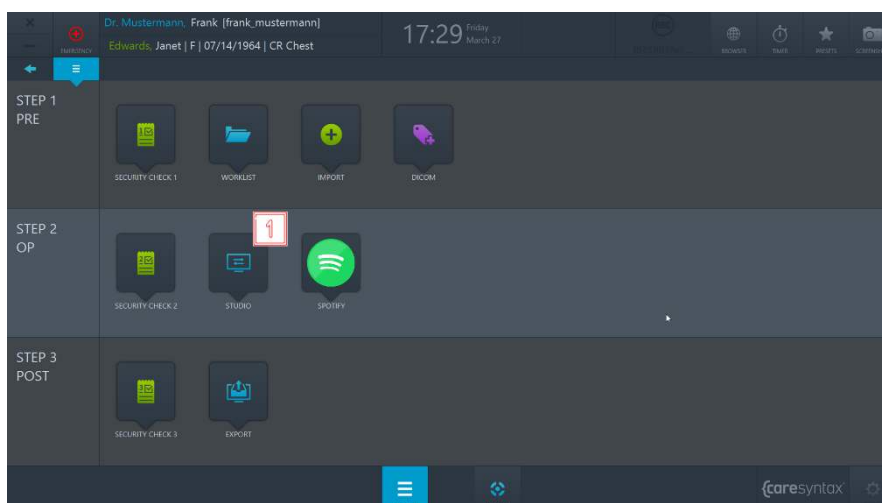


Figure 28: Studio app on the CX-PRIME desktop

3.1.8.1 Routing

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

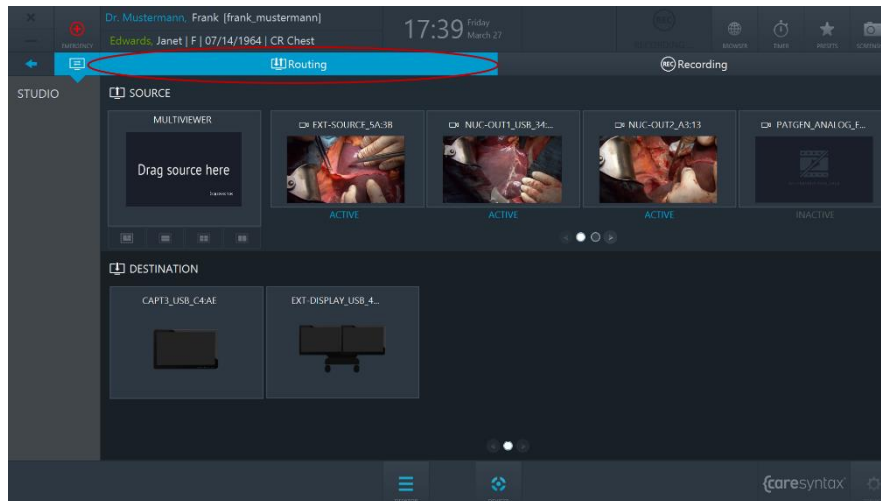


Figure 29: Routing tab (red circle) of the Studio app

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.

Navigation

Use the pagination buttons or swipe the Sources row using the touch operations 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.

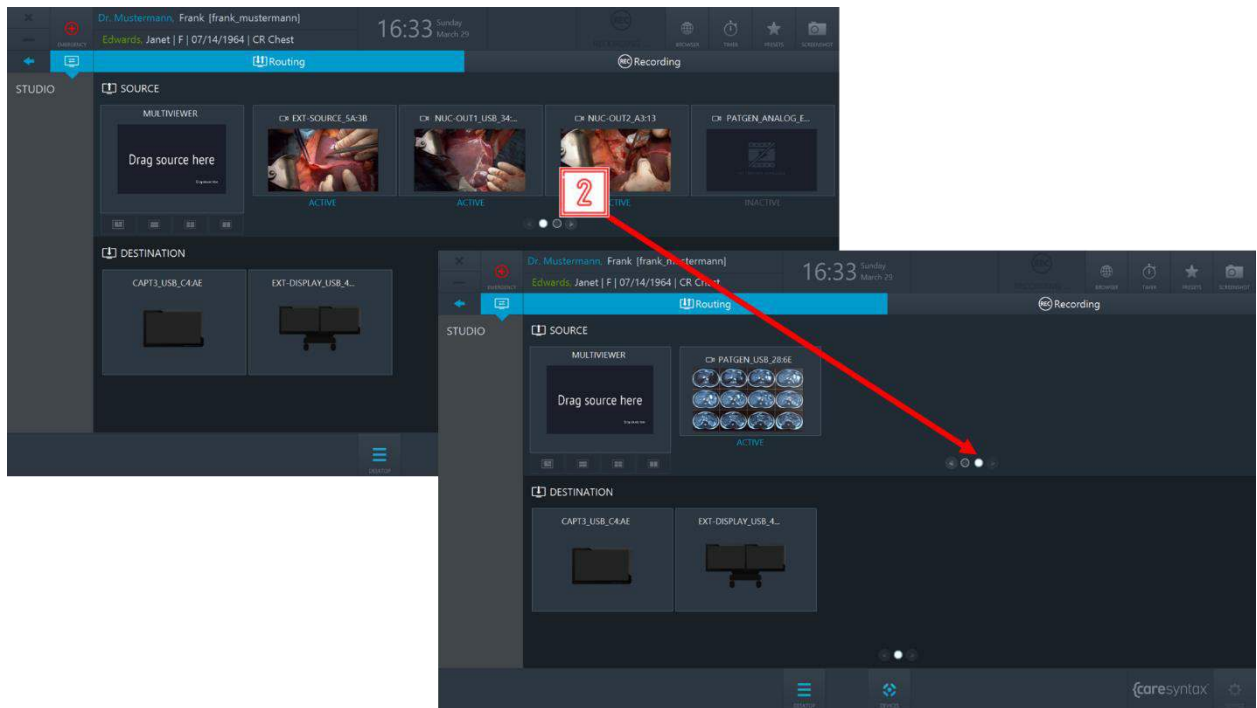


Figure 30: Using pagination buttons for navigation

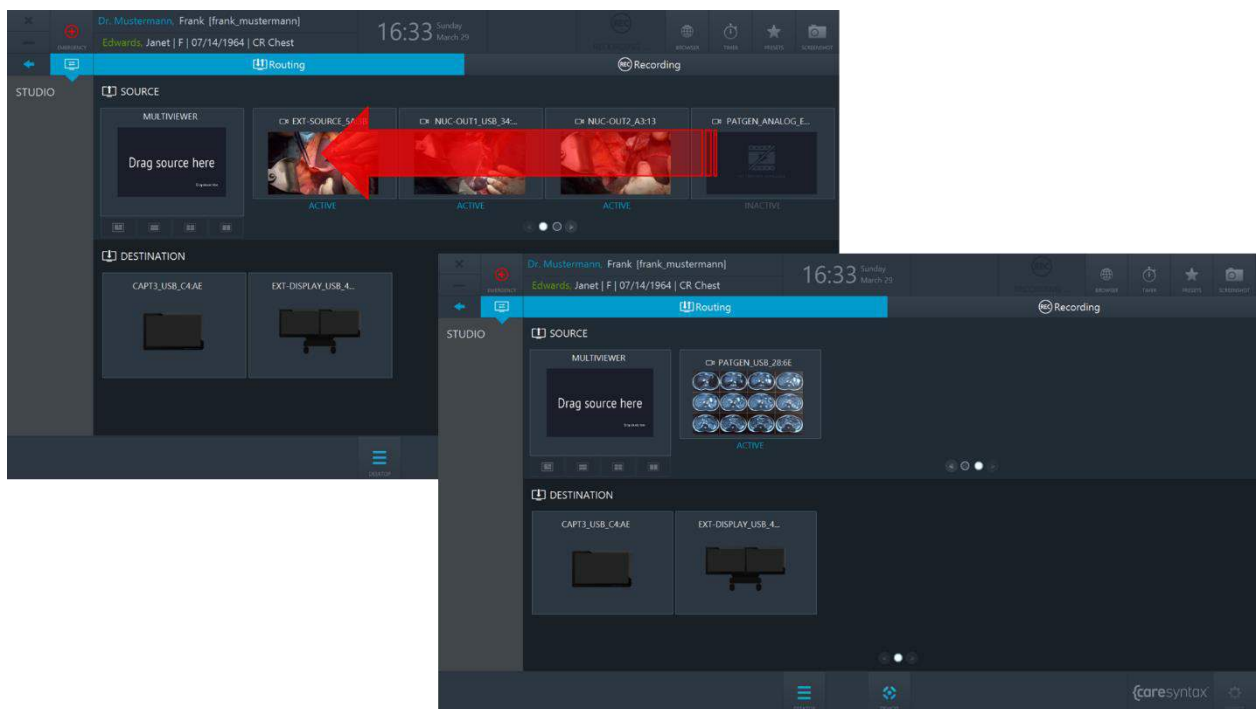


Figure 31: Swiping the source row in order to get to the second page

Routing a Source to a Destination

Some Destinations have 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.

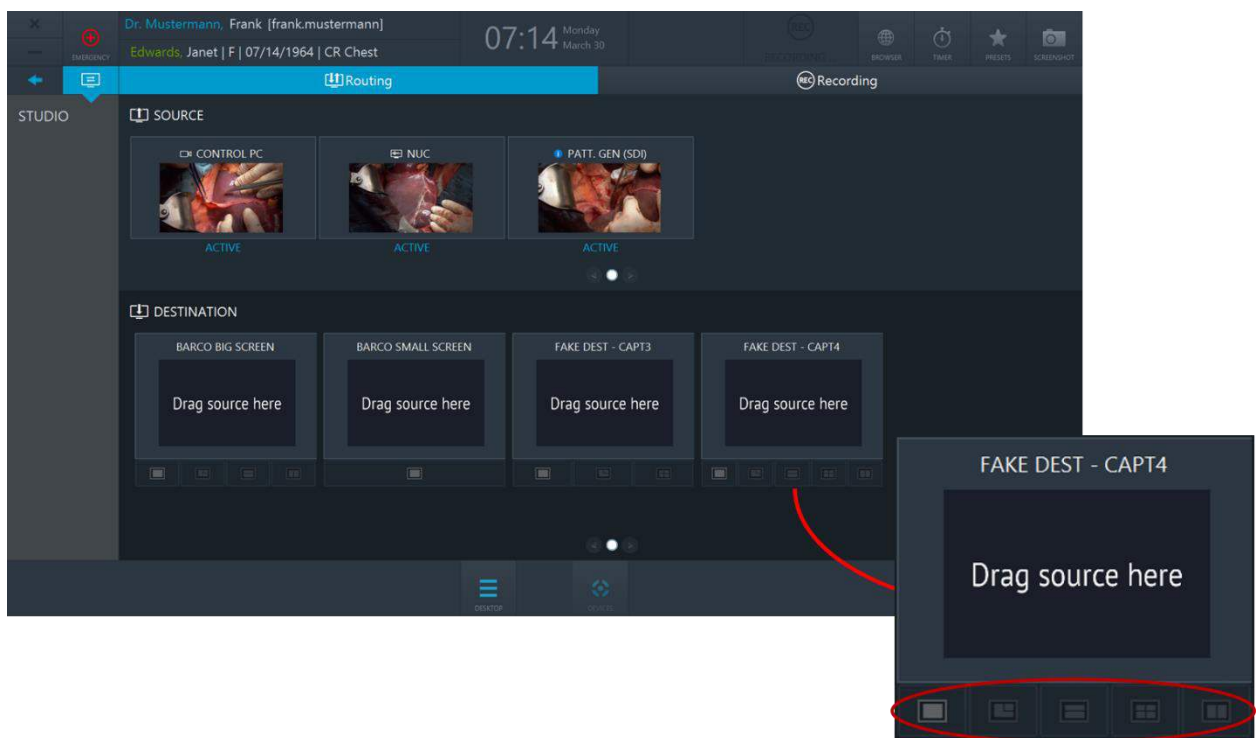


Figure 32: Destinations have multiview capabilities, destination layouts are marked with red circle

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 then click on a Source.



You can also perform Routing operations by dragging and dropping.

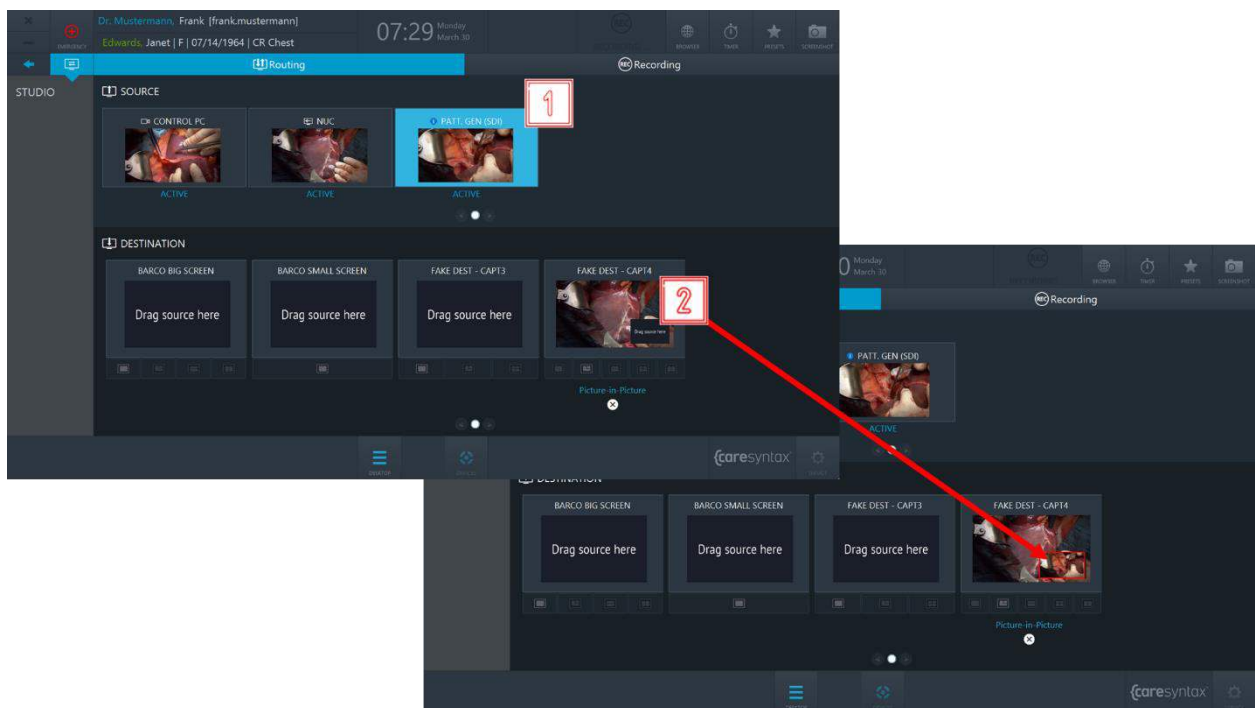


Figure 33: Routing a source to a destination.

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.

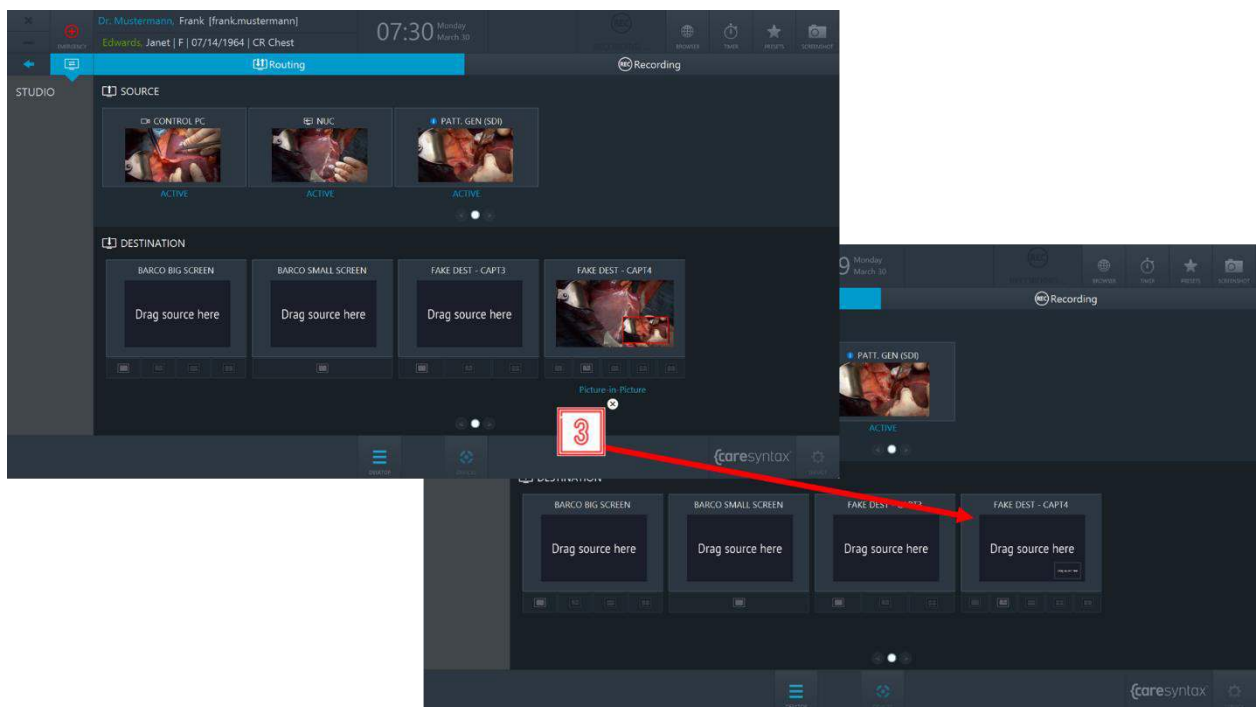


Figure 34: Clearing the route

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.

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

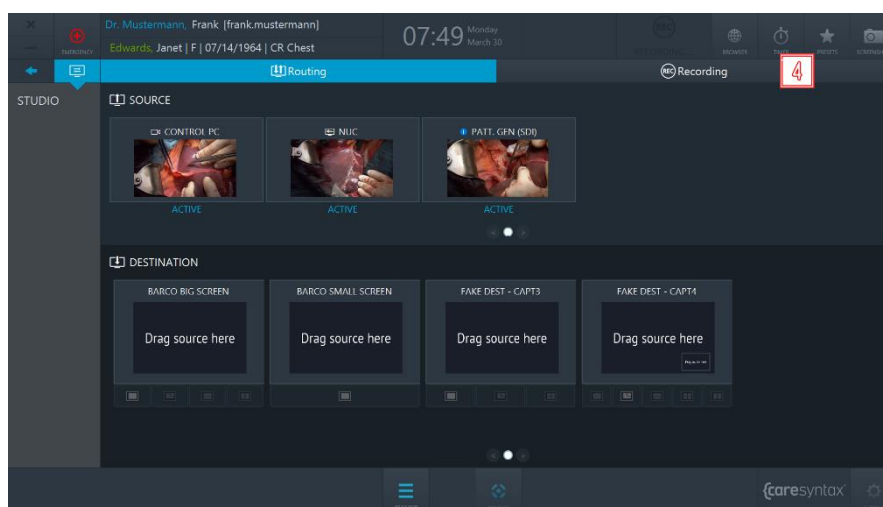


Figure 35: Presets button on CX-PRIME desktop

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

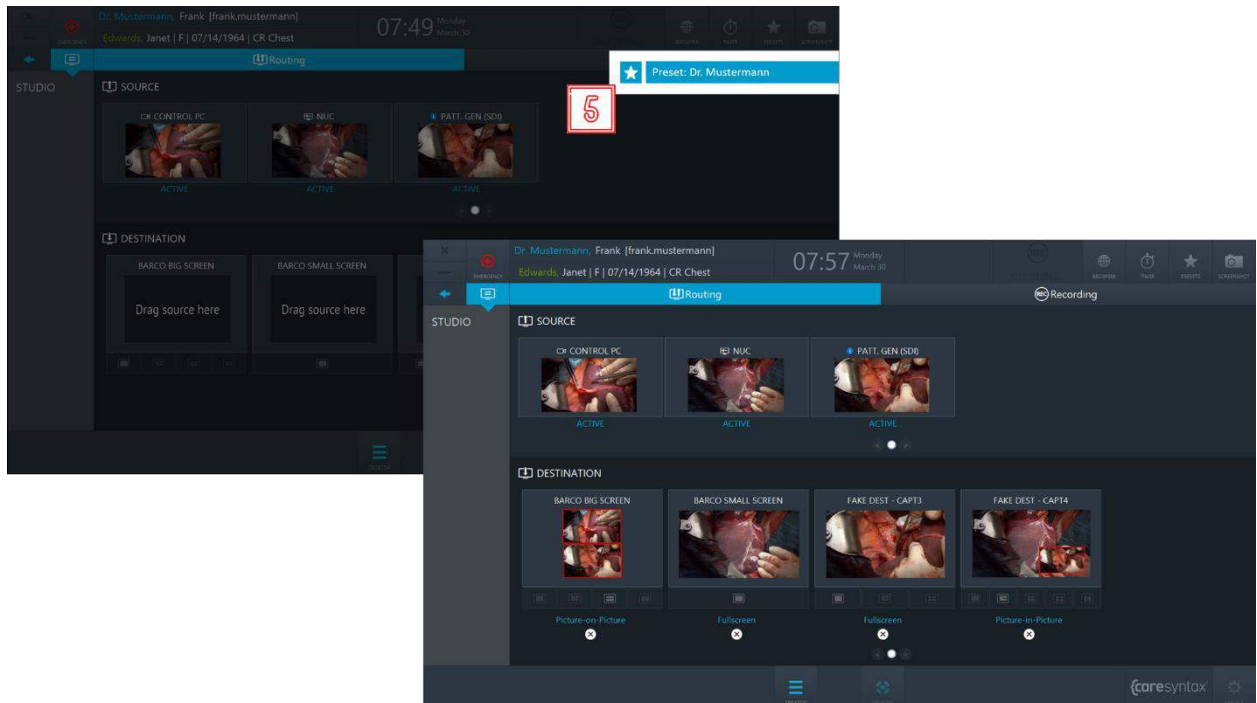


Figure 36: Selecting a routing preset

3.1.8.2 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.

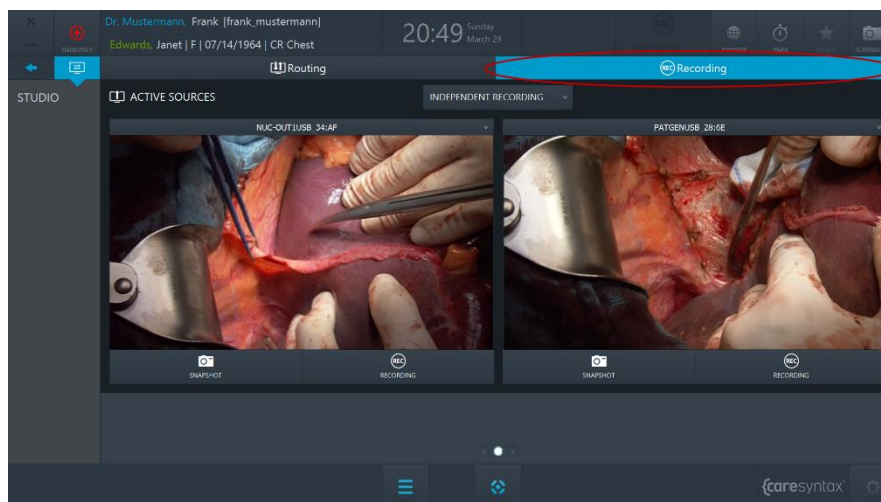


Figure 37: Recording tab (red circle) of the Studio app



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.

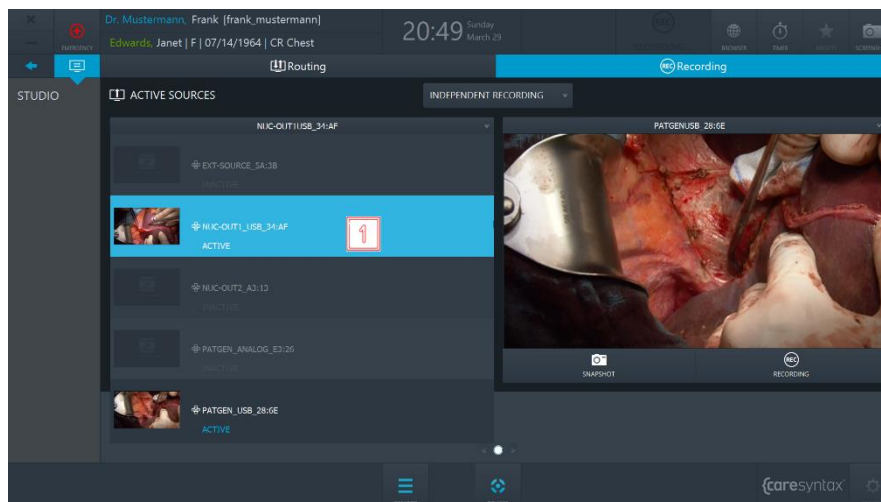


Figure 38: Selecting the video source

2

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

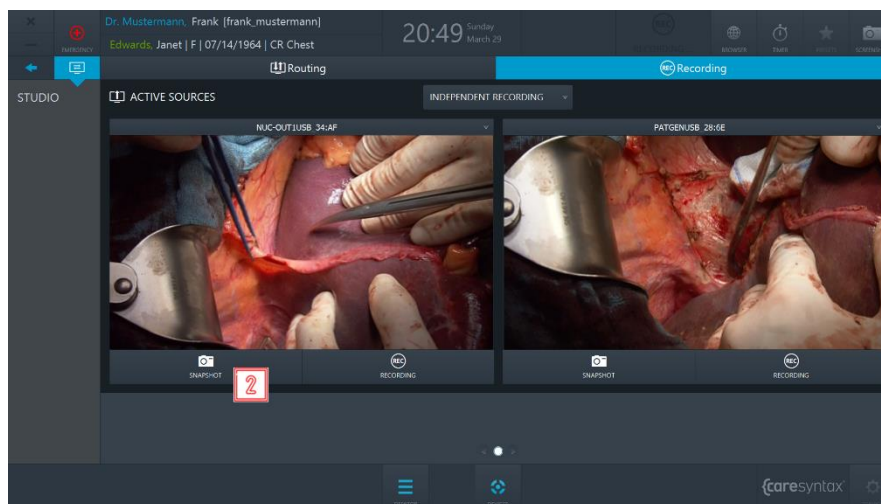


Figure 39: Creating a snapshot

- 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. 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 endoscopic head buttons or footswitch buttons.



The pre-recording function is available, allowing for continuous recording of a short period of time before the end user clicks the **Recording** button.

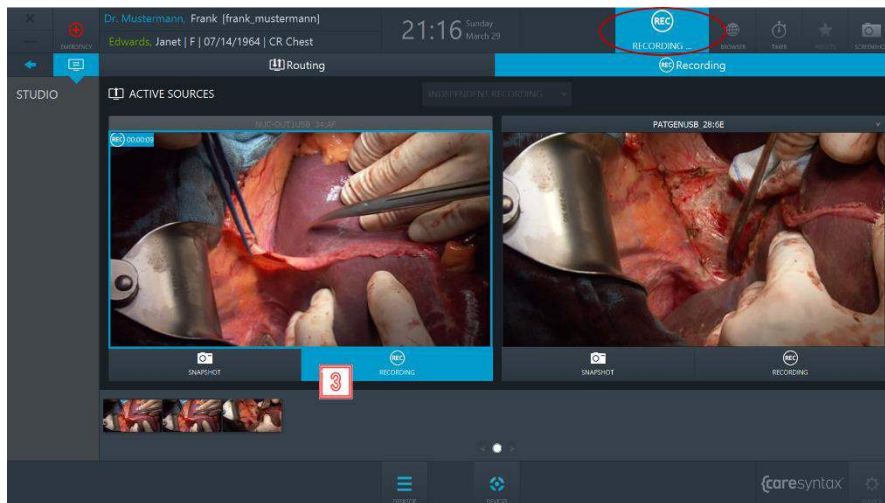


Figure 40: Recording a video

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.

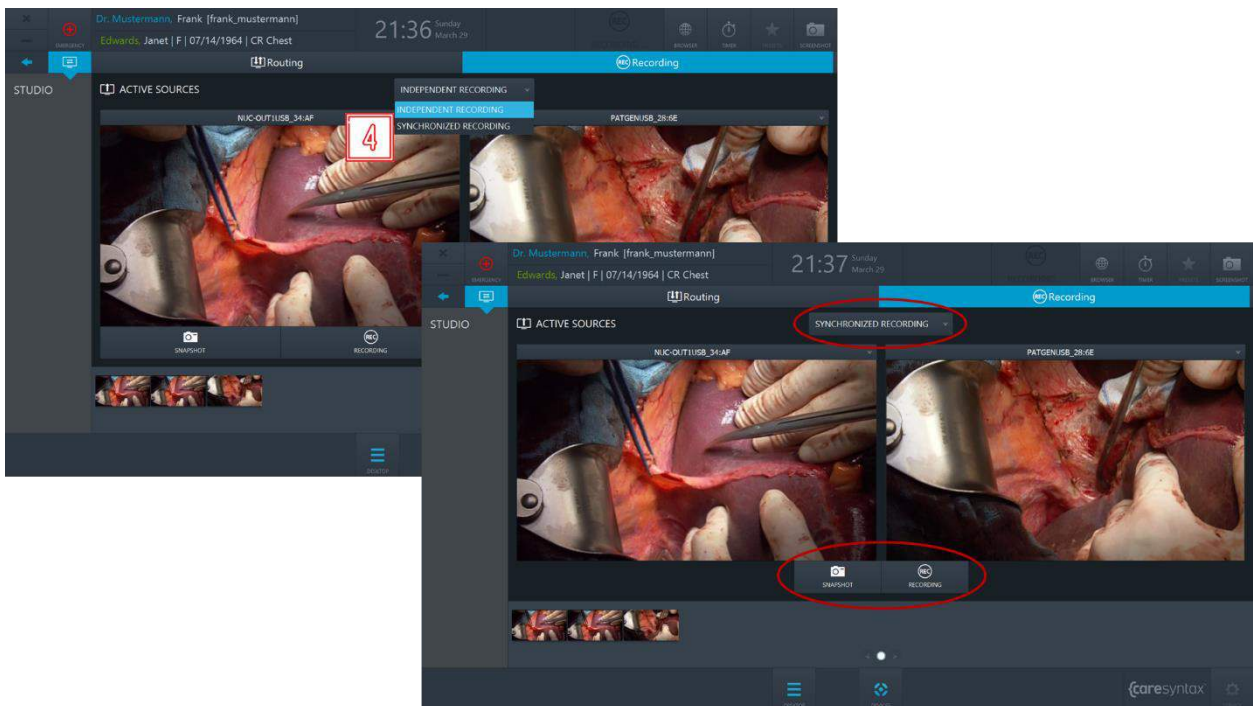


Figure 41: Synchronized Recording mode

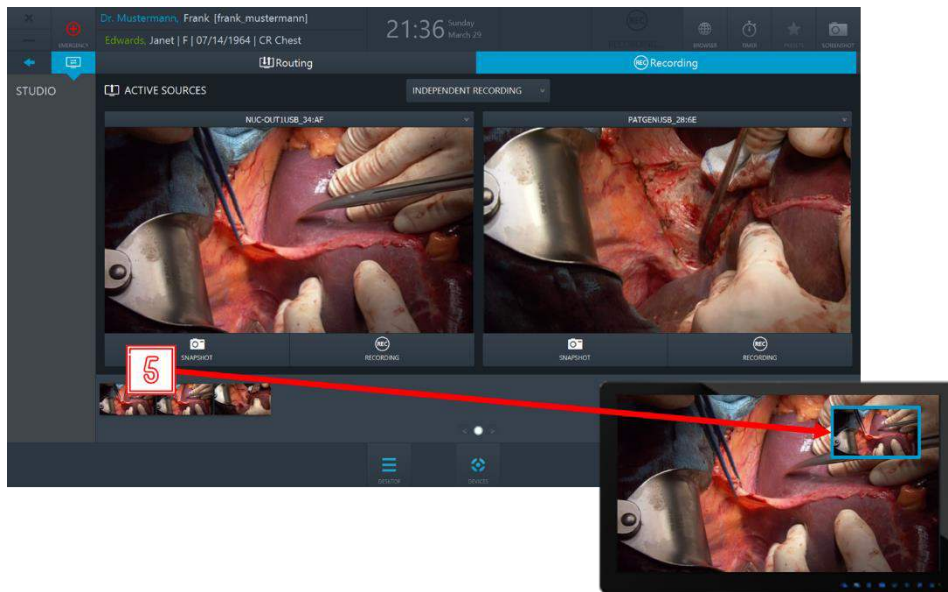


Figure 42: On-screen notification will appear in the corner of the display for 2 seconds as a confirmation that a snapshot of the routed source was taken

a. 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.

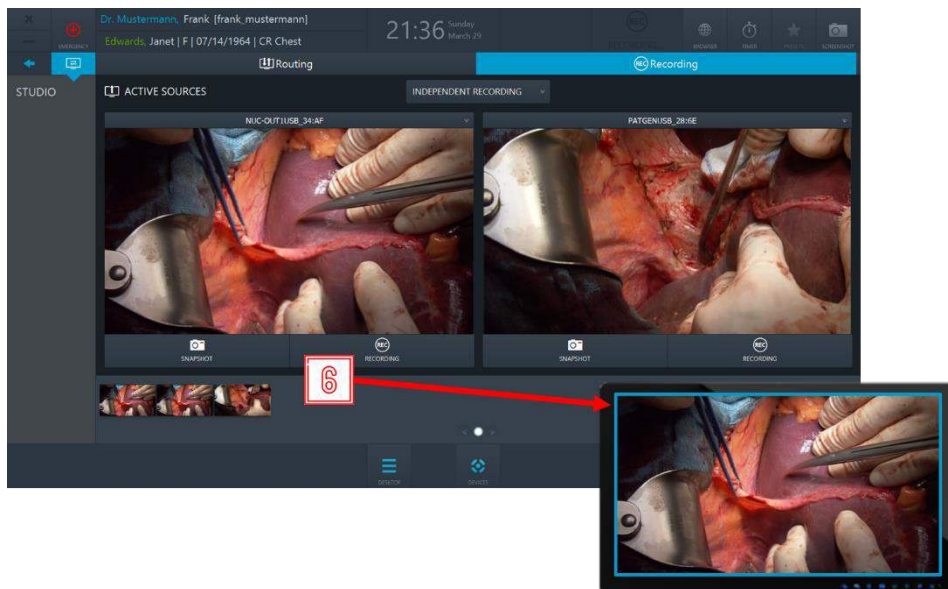


Figure 43: On-screen notification (blue frame) will appear on the display and will stay as long as the routed source is being recorded

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.

3.1.9 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.

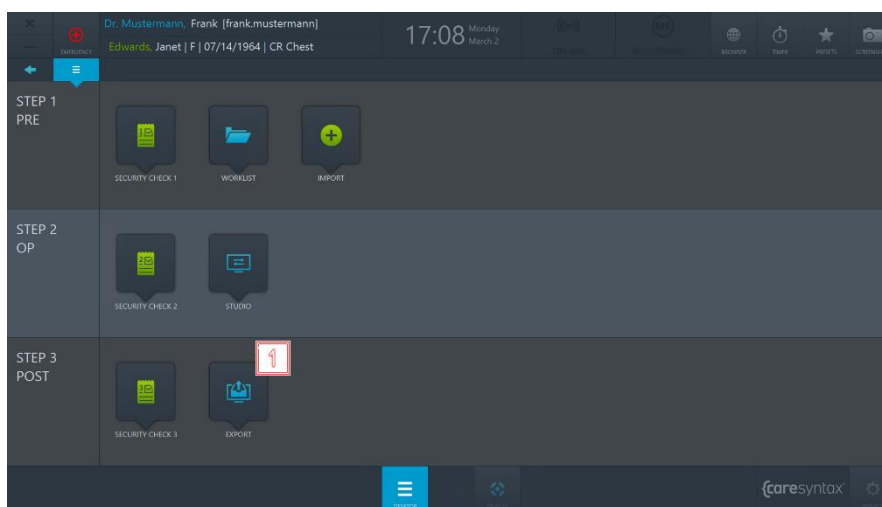


Figure 44: Export app on the CX-PRIME desktop

All of the data that you have imported or recorded is now displayed in the Export app

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

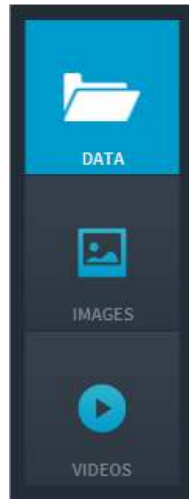


Figure 45: Selecting the image data to be displayed

- 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. 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.

- 4 Once you have selected all the desired images and videos, you now can export them. 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.

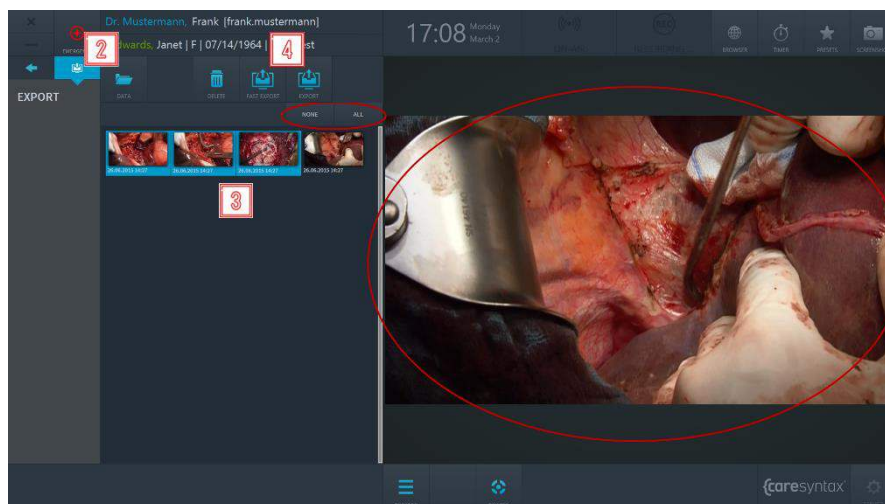


Figure 46: Selecting the image data to export. The top red circle shows the All and None tabs that can be used to select all or no data. Double-click an image or video to view/play it in the media player (red circle on the right)

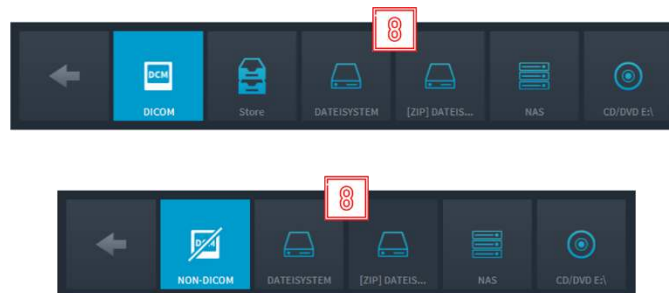


Figure 47: Export: selecting the target. The top figure shows the export in DICOM format and the bottom figure in non-DICOM format.

3.1.10 Printing

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

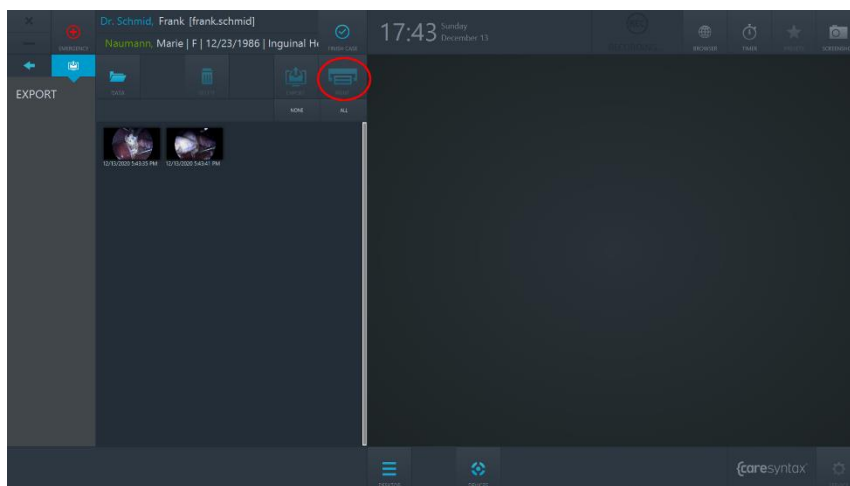


Figure 48: Print button in the Export application. Print button is inactive and will become active once a user selects images to be printed.

- 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.

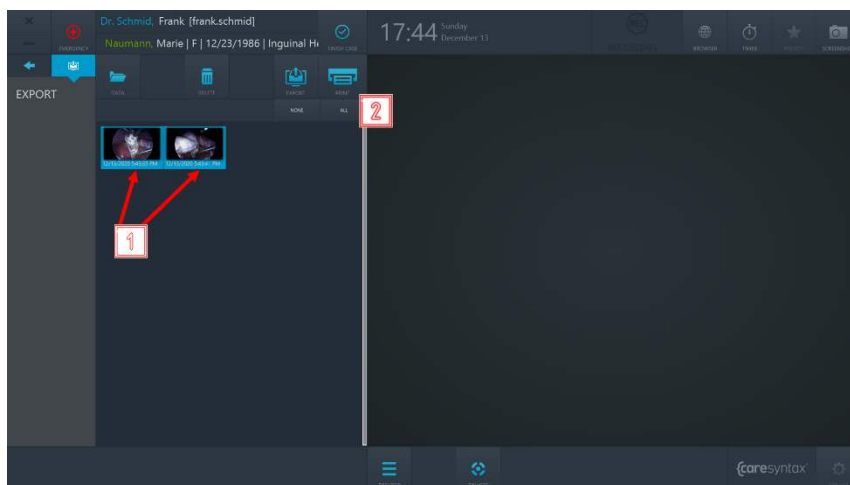


Figure 49: Selecting images for print and proceeding to the Printing dialogue

- 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

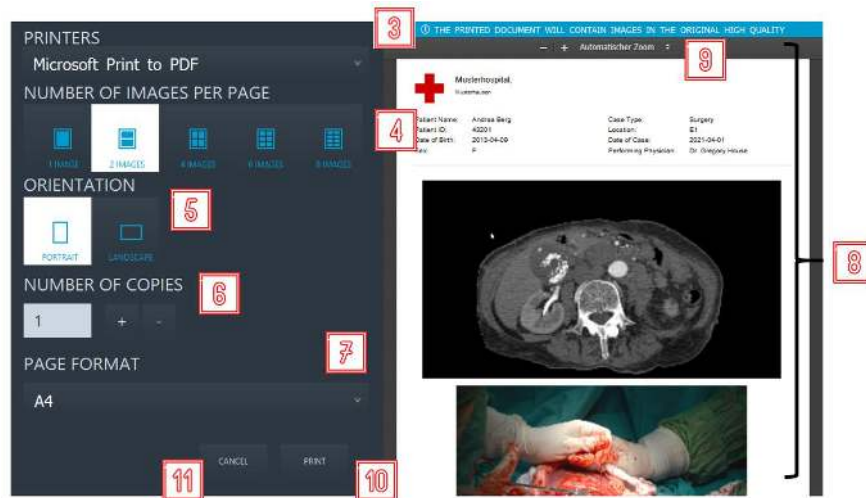


Figure 50: Actions with the Printing dialogue

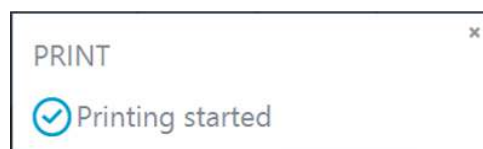


Figure 51: Notification about start of printing

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

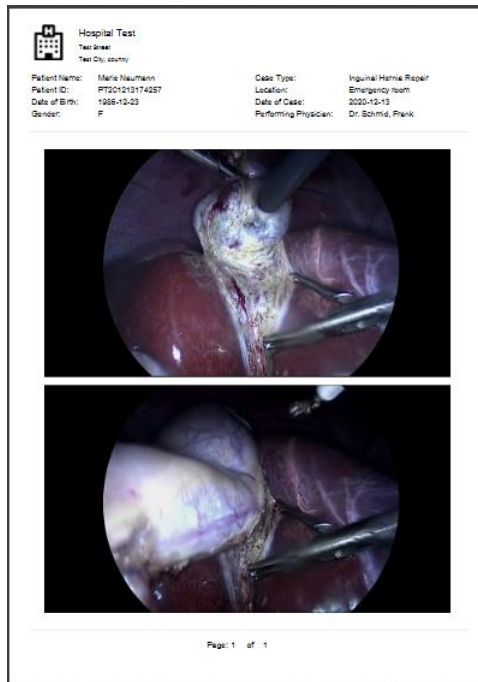


Figure 52: Example of a printed report

3.1.11 Finishing the Case

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

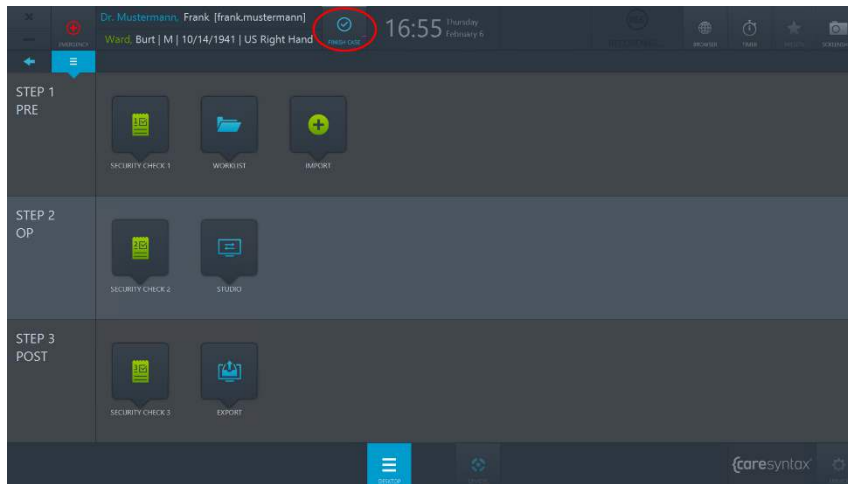


Figure 53: Finish Case button on the CX-PRIME desktop

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, pre-recording, and streaming), 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.

Other 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. The following sections describe how to use the main functions on the basis of user examples.

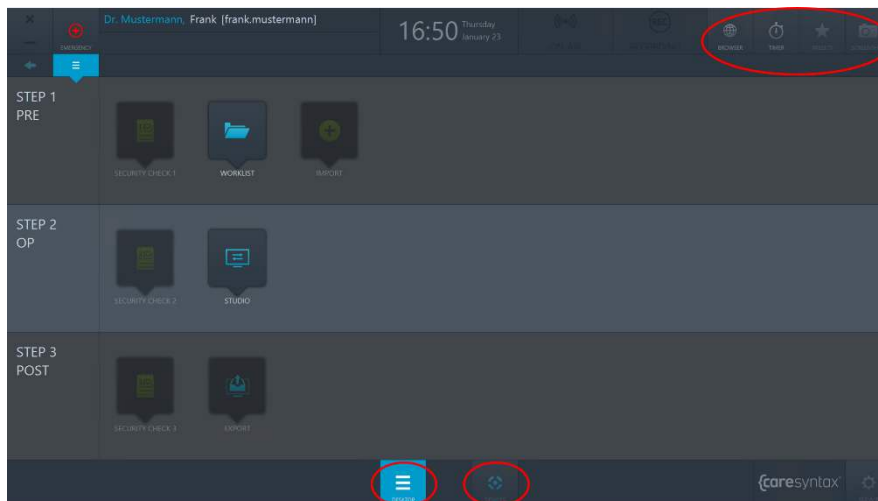


Figure 54: CX-PRIME desktop – General functions (red circles)

3.1.12 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.

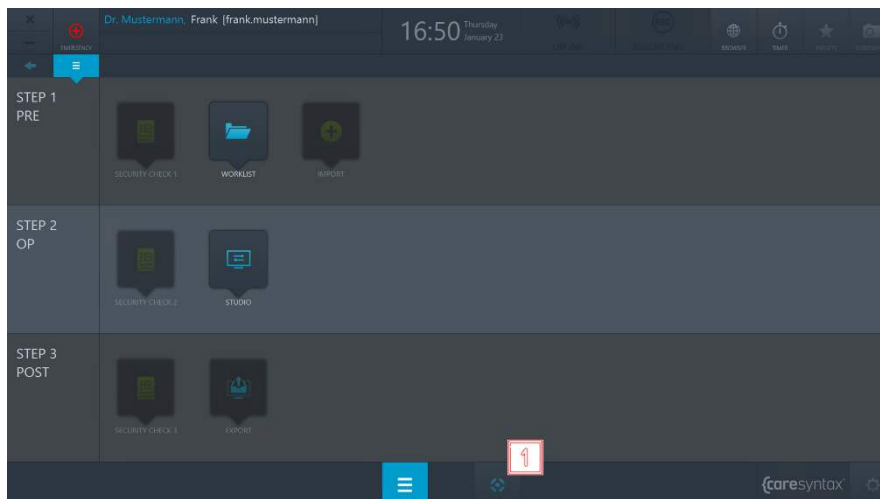


Figure 3.13: Opening the device management window.

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

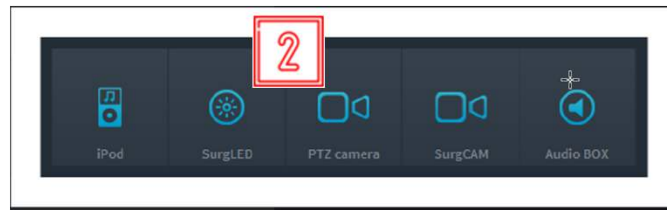
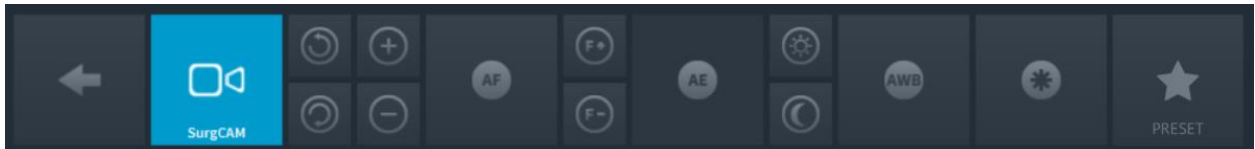


Figure 3.14: Selecting the devices to be operated.

3 Use the available Buttons to control the selected device



3.1.13 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 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.

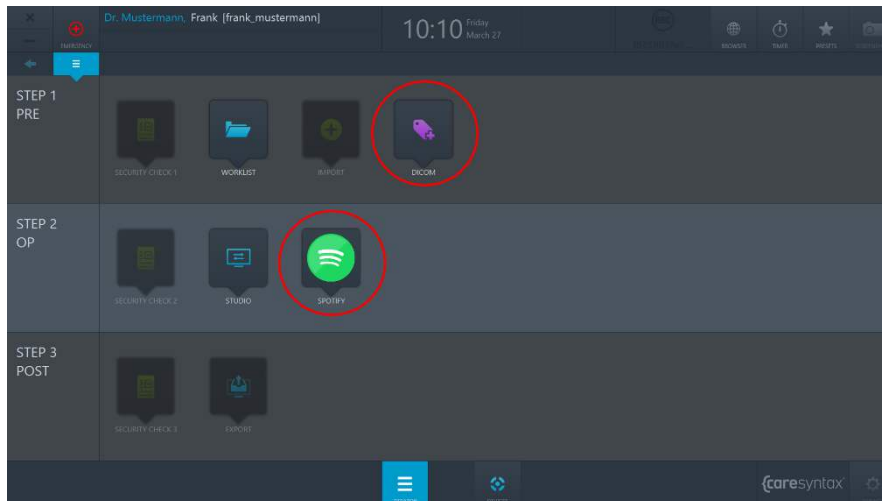


Figure 3.15: Third party applications (red circles) in CX-PRIME desktop.