

# Connected Surgery Software

User Manual

Original user manual version is created in English language. Manual is translated into French, German, Italian, Spanish, and Turkish by:

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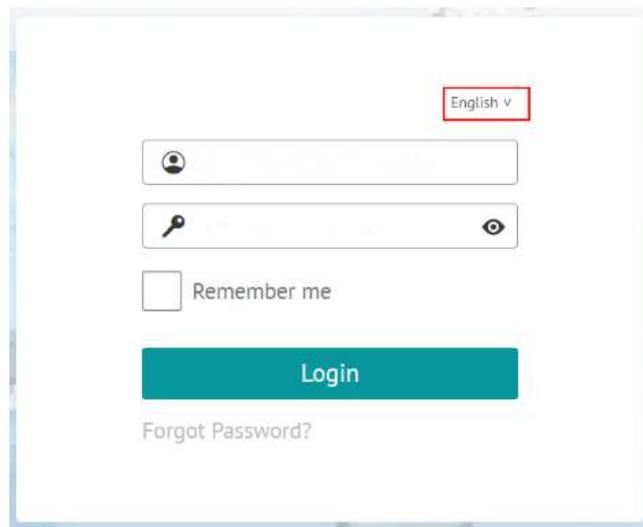
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# Log On

1. Open your internet browser.
2. Select the **Connected Surgery** bookmark (or type in the provided web URL).

**Note:** If you do not have a bookmark and have not been provided with a web URL to access **Connected Surgery**, please contact your local IT helpdesk.

3. If you want to use a different language for the user interface (UI), select that language from the dropdown menu.



**Figure 1: Language selection**

4. Enter your assigned login information to access the system.

**Connected Surgery** starts and opens the **WORKLIST** screen.

If your enterprise system does not provide integrated authentication with Caresyntax products, a message appears, requiring you to change your password.

1. Select a password with a minimum of twelve characters. The password must also meet three of these requirements:
  - Upper case alphabet (A-Z)
  - Lower case alphabet (a-z)
  - Numbers (0-9)
  - Special characters (@\*#&%\$)
2. The log on screen returns. Use your new password to log on.
3. After a maximum of 180 days, you will be asked to change your password.

# SURGERY tab

**Connected Surgery** opens at the **SURGERY** tab in the primary navigation bar. There are two menus available:

- **Settings menu**
- **User menu**



**Figure 2: Surgery Tab with SETTINGS menu and User Settings menu**

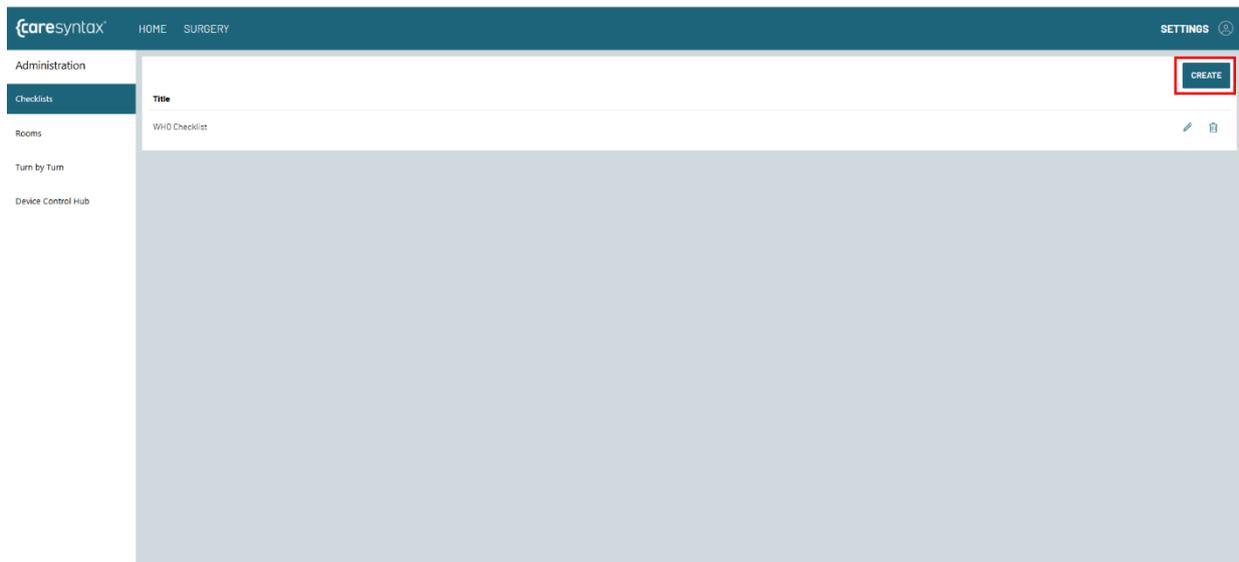
## Settings menu

The **Settings** menu enables a user to create custom checklists and to configure sources and displays for a room. The menu opens at **Checklists**.

## Checklists

Checklists allow a user to create custom checklists.

1. Select **Create** to create a new checklist.



**Figure 3: Checklists**

2. Create a new checklist.

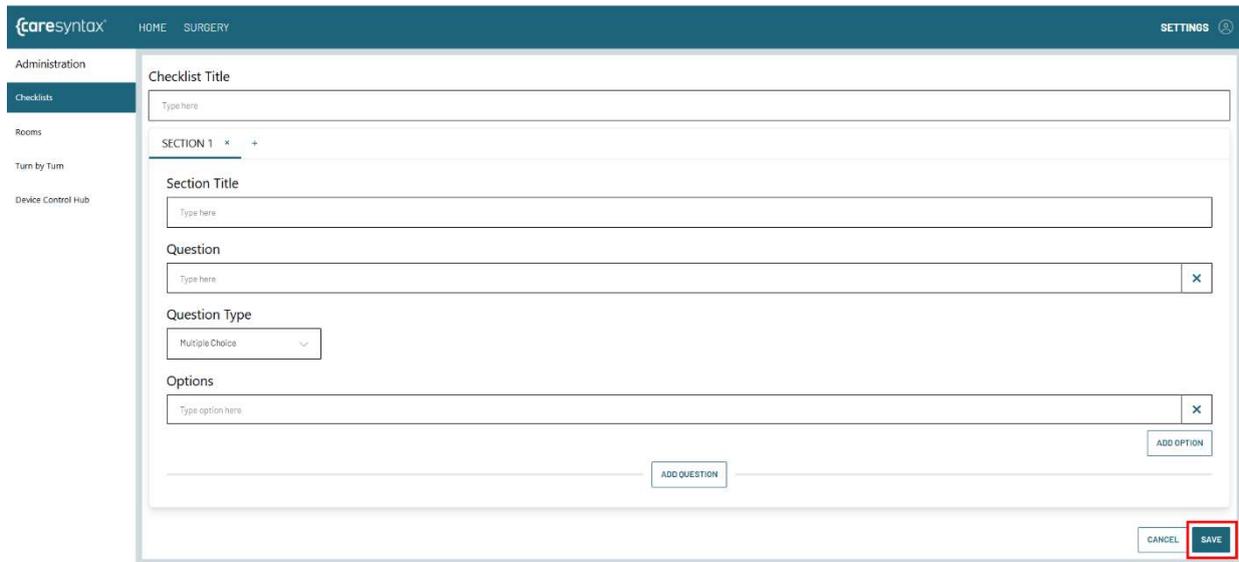


Figure 4: Checklist

3. Select **SAVE** to save the new checklist.

## Rooms

This allows you to configure sources and displays for a room.

1. Select **Start in room tool** for the room you want to configure.

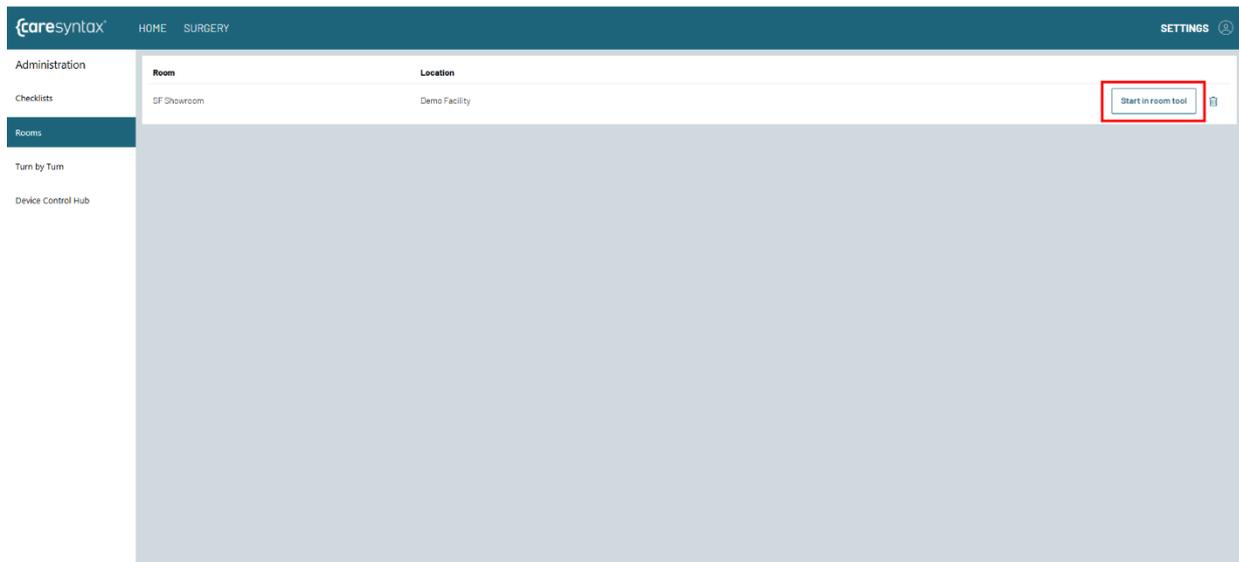


Figure 5: Rooms

The **In Room Configuration** modal window appears.



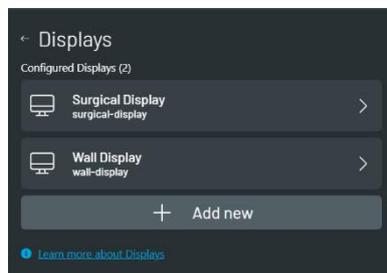
**Figure 6: In Room Configuration modal window**

2. Select **Displays**.



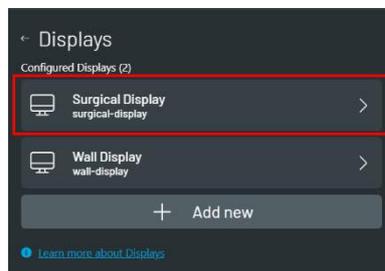
**Figure 7: Displays**

The **Displays** modal window appears.



**Figure 8: Displays modal window**

3. Select the display.



**Figure 9: Select a display**

The **Display Details** modal window appears.

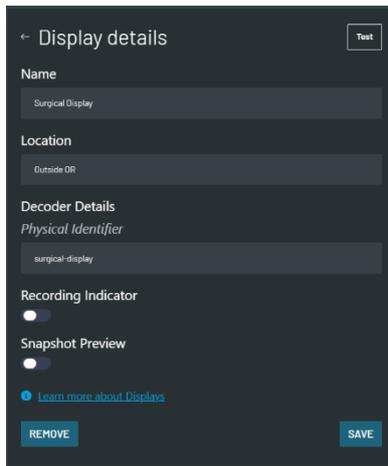


Figure 10: Display Details modal window

4. Make changes. Select **SAVE**.

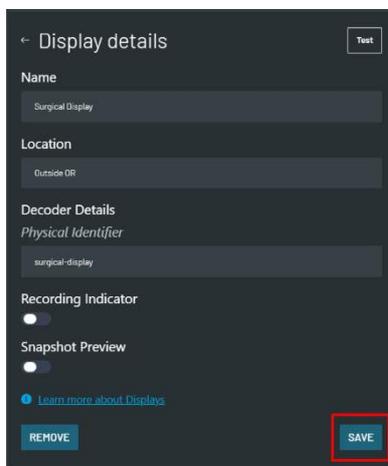


Figure 11: Select SAVE

The **Displays** modal window appears.

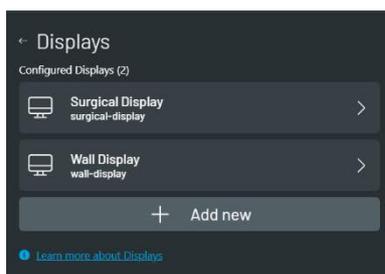


Figure 12: Displays modal window

5. Select the back arrow.

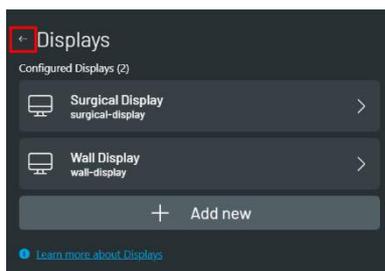


Figure 13: Select the back arrow

The **In-Room Configuration** modal window appears.



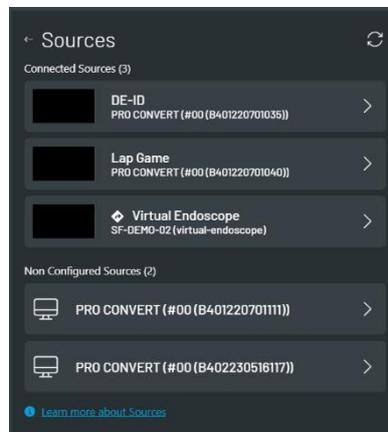
**Figure 14: In Room Configuration modal window**

6. Select Sources.



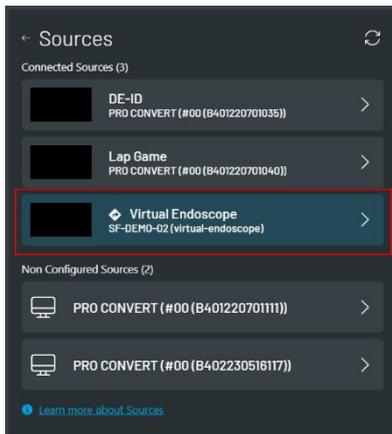
**Figure 15: Select Sources**

The **Sources** modal window appears.



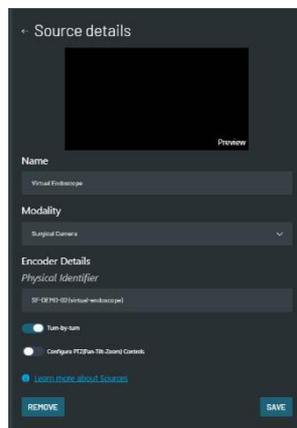
**Figure 16: Sources modal window**

7. Select a source.



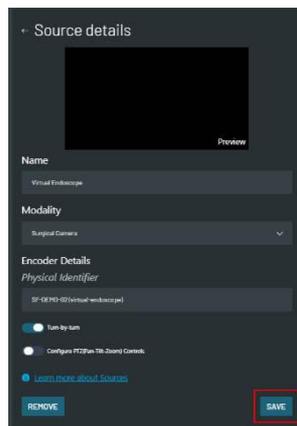
**Figure 17: Select a source**

The **Source details** modal window appears.



**Figure 18: Source Details**

8. Select **SAVE** to save the configuration.



**Figure 19: Select SAVE**

The **In Room Configuration** modal window appears.



Figure 20: In Room Configuration modal window

9. Select the back arrow to return to the **Settings** menu.



Figure 21: Select the back arrow

## Turn-by-Turn

You may use this tab to create custom Turn-by-Turn options as well as maintain and update those options.

**Note:** At this release version, customizations are only available for laparoscopic cholecystectomy procedures.

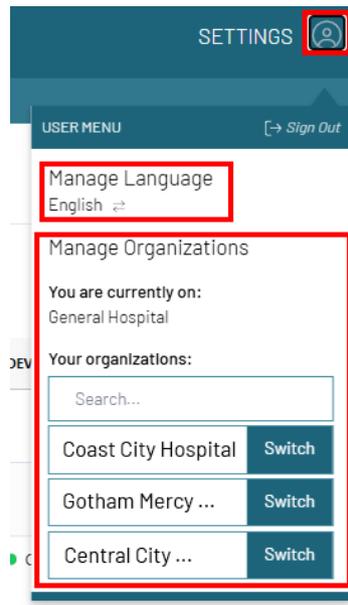
## Device Control Hub

Caresyntax uses this tab to manage firmware updates to encoders and decoders in the operating rooms.

**Note:** Non-Caresyntax personnel do not have access to this tab.

## User Menu

Select the user menu icon to open the **User Menu**.



**Figure 22: USER MENU**

**Manage Language** allows you to cycle through the available languages to set the language for your user interface (UI).

**Manage Organizations** allows you to select another organization with which you are associated. If the organization is not on the short list, use the search function to find the other organization.

# WORKLIST tab

**Connected Surgery** opens at the **WORKLIST** tab in the secondary navigation bar. The **WORKLIST** tab allows access to all the information provided within the **Surgical Worklist**.

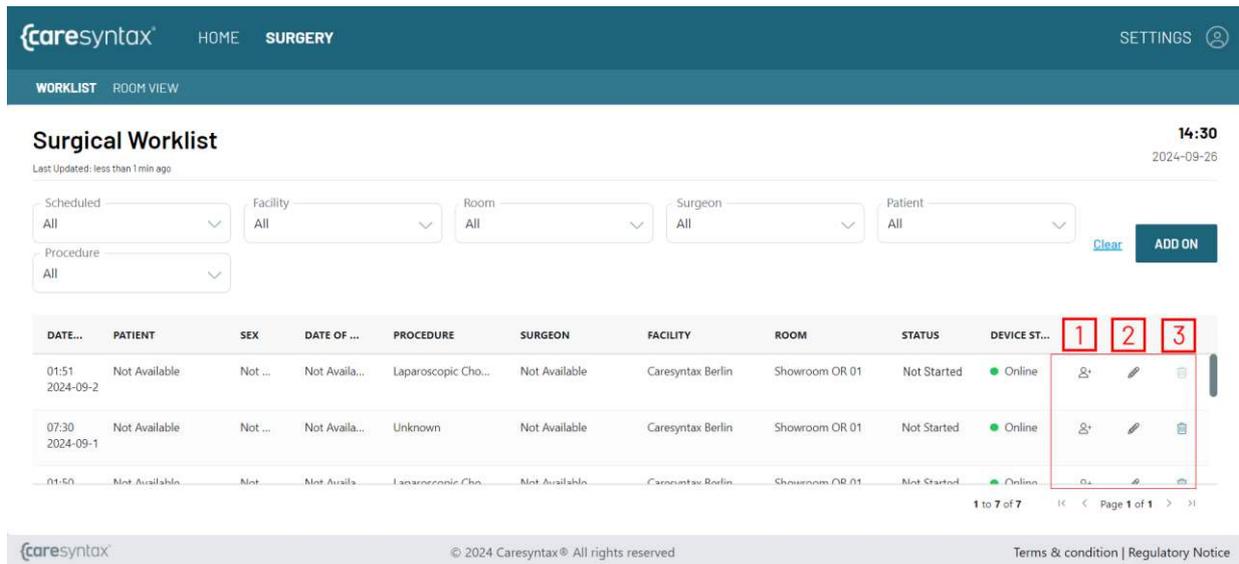
**Figure 23: WORKLIST tab**

Callout	Description
1	Filters
2	<b>ADD ON</b> button
3	Procedure rows

The **Surgical Worklist** allows the user to perform these functions:

- Apply filters to the **Surgical Worklist** to show only the procedures which meet the selected criteria. These filters are persistent with the browser, meaning that if you log out and log in again on the same device and browser, the surgical worklist will be already filtered against the last selected filters.
- Use **ADD ON** to quickly create a new scheduled procedure, often as a response to an emergency or last-minute change.
- Select a procedure row to launch an OR session for a scheduled procedure.

# Procedure row icons



**Figure 24: Procedure row icons**

Number	Description
1	Manage participants
2	Edit procedure entry
3	Delete

## Manage Participants

If you want to invite other people to view or remotely participate in the procedure, use this form to obtain an invitation link to add to a meeting invitation.

- The invitation link will not be sent automatically and must be manually sent to the intended recipient.

Manage participants
✕

Participants

Add

+

Invitation Link

📄

CANCEL
SAVE

**Figure 25: Manage participants**

## Edit a procedure entry

Use this feature to make changes to a specific procedure entry.

ROOM	STATUS	DEVICE STATUS			
Showroom OR 01	Not Started	● Online	👤		
Showroom OR 01	Not Started	● Online	👤		
Showroom OR 01	In Progress	● Online	2 👤		

**Figure 26: In Progress**

You can edit a procedure that is **Not Started**.

If you accidentally select a procedure, that procedure begins and appears as **In Progress**. To change the procedure back to **Not Started**, follow these steps:

1. Close the surgical room session, if it is open. The screen returns to the **Surgical Worklist**.
2. Select **Edit**.
3. Change the **STATUS** from **In Progress** to **Not Started**.
4. Select **Save**.

**Note:** You are not able to make any other changes to a procedure that has a **STATUS** of **IN PROGRESS**.

## Delete

**Delete** permanently removes the surgical procedure entry.

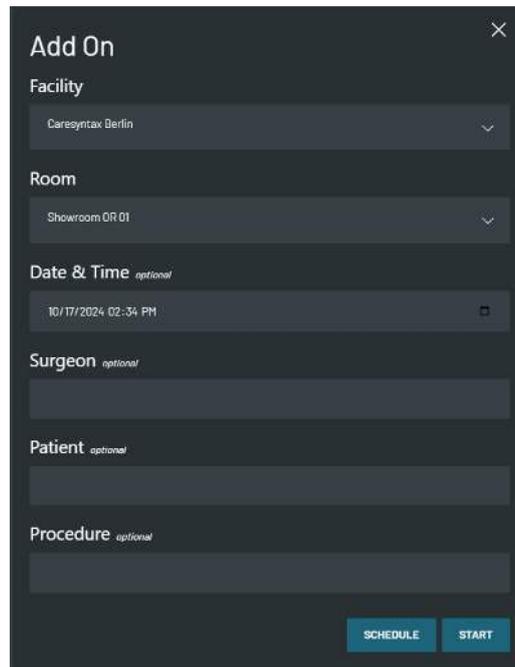
You cannot delete a session that is **In Progress** or **Completed**.

ROOM	STATUS	DEVICE STATUS			
Showroom OR 01	Not Started	● Online	👤		
Showroom OR 01	Not Started	● Online	👤		
Showroom OR 01	In Progress	● Online	2 👤		

**Figure 27: Delete**

## Add on workflow

The **Add on** modal window allows you to quickly create a new item in the surgical worklist.



**Figure 28: Add on modal window**

1. Enter the available information into the appropriate fields.

**Note:** **Facility** and **Room** are required fields. If **Facility** is not pre-populated, you must enter the facility name before you can select a room.

2. Select **START** or **SCHEDULE**.

- **START** immediately launches a surgical procedure session.
- **SCHEDULE** creates a surgical worklist item for later and returns you to the **WORKLIST**.

**Note:** Select the **x** icon to close the modal window and return to the **WORKLIST** without saving any information.

# Surgical Session UI Overview

When you begin a surgical session, a modal screen appears, allowing you to verify that you are entering into a session for the expected patient and room.



Figure 29: Verification modal window

When you begin a surgical session, the user interface (UI) opens at the **Routing** screen.

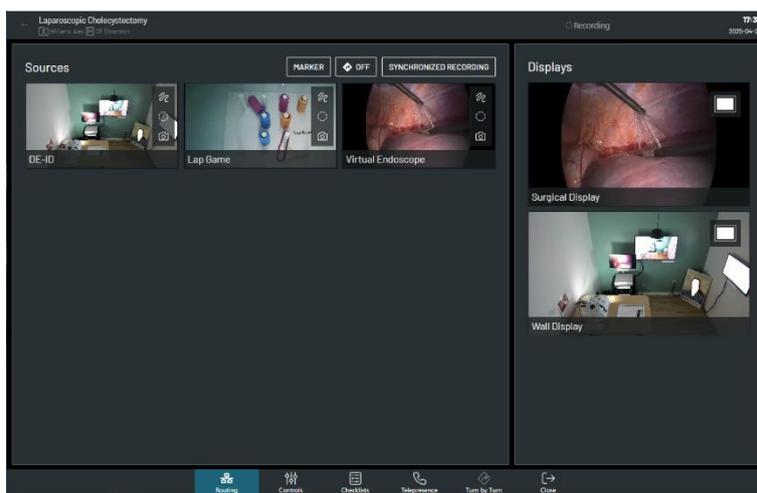
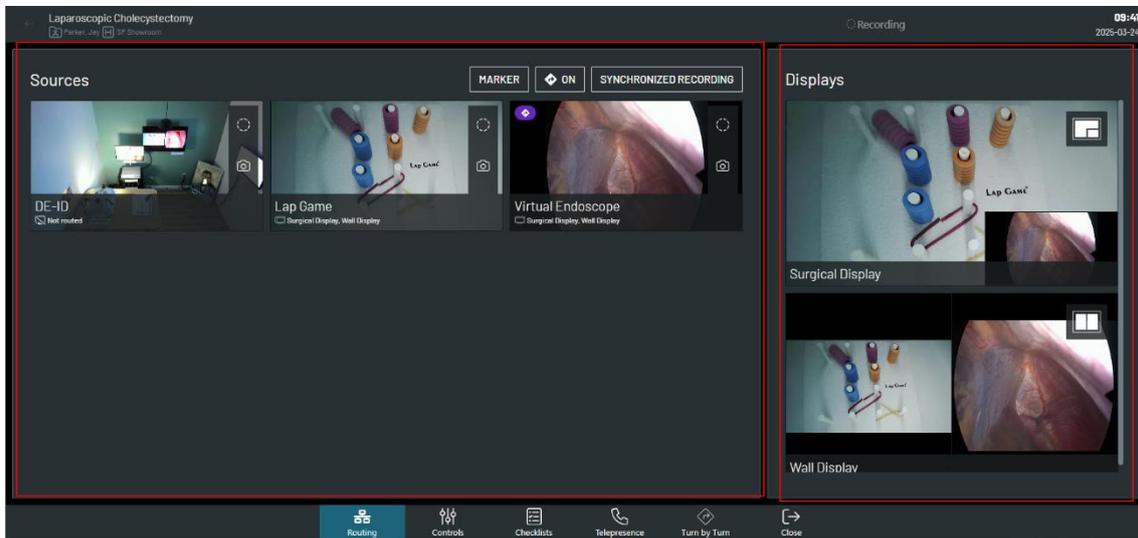


Figure 30: Routing Screen

# Routing

The Routing screen has two main subsections:

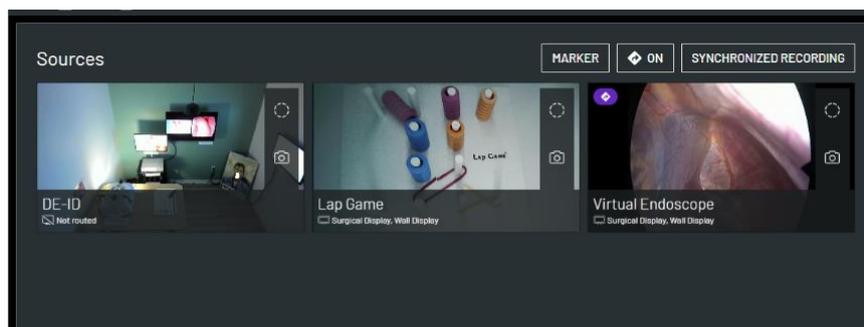
- **Sources**
- **Displays**



**Figure 31: Sources and Displays**

## Sources

The **Sources** window contains a window for each video source and several function buttons.



**Figure 32: Sources window**

## Source Windows

Each source window has three icons

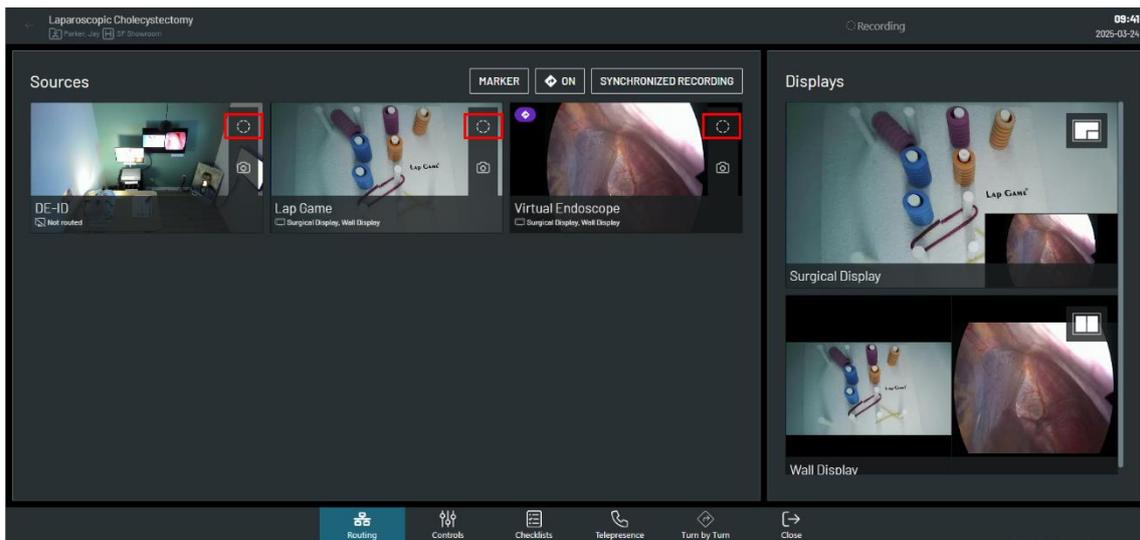
- The drawing icon (top) allows telepresence users to draw on a screen.
- The recording icon (middle) starts or stops the recording for that source window.
- The camera icon (bottom) takes an image of that source window at that specific point in time.



**Figure 33: Drawing, Recording, and Camera Icons**

## Recording

If you select sources individually, the recording for each video source starts when you select the dashed circle icon (**RECORD**) for that source.

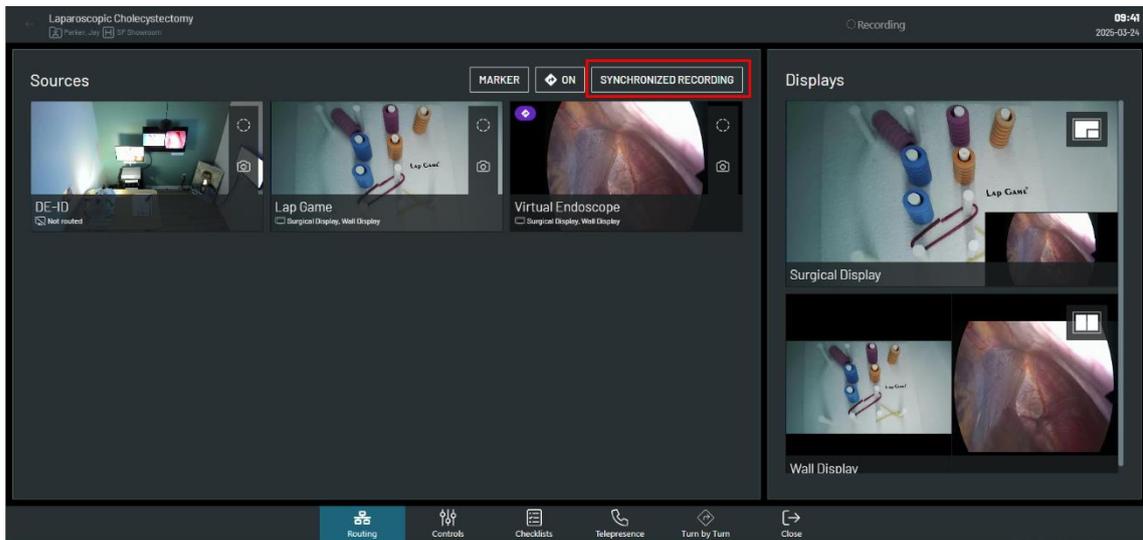


**Figure 34: Select the Dashed Circle Icon (RECORD)**

## Synchronized Recording

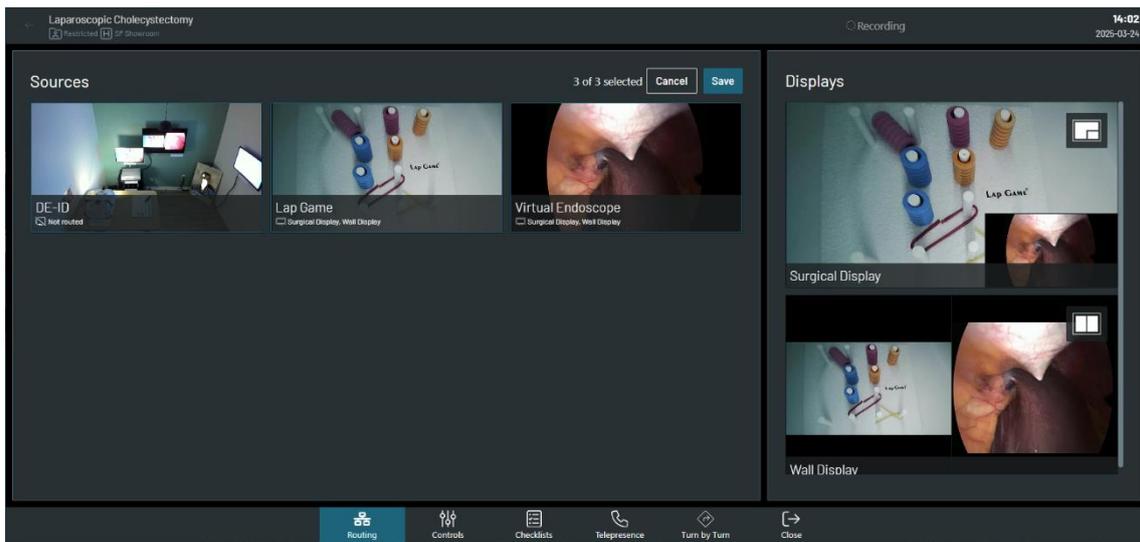
Use the **Synchronized Recording** feature to record up to four sources simultaneously.

1. Select **Synchronized Recording**.



**Figure 35: Select SYNCHRONIZED RECORDING**

2. Select up to four sources and select **Save**.



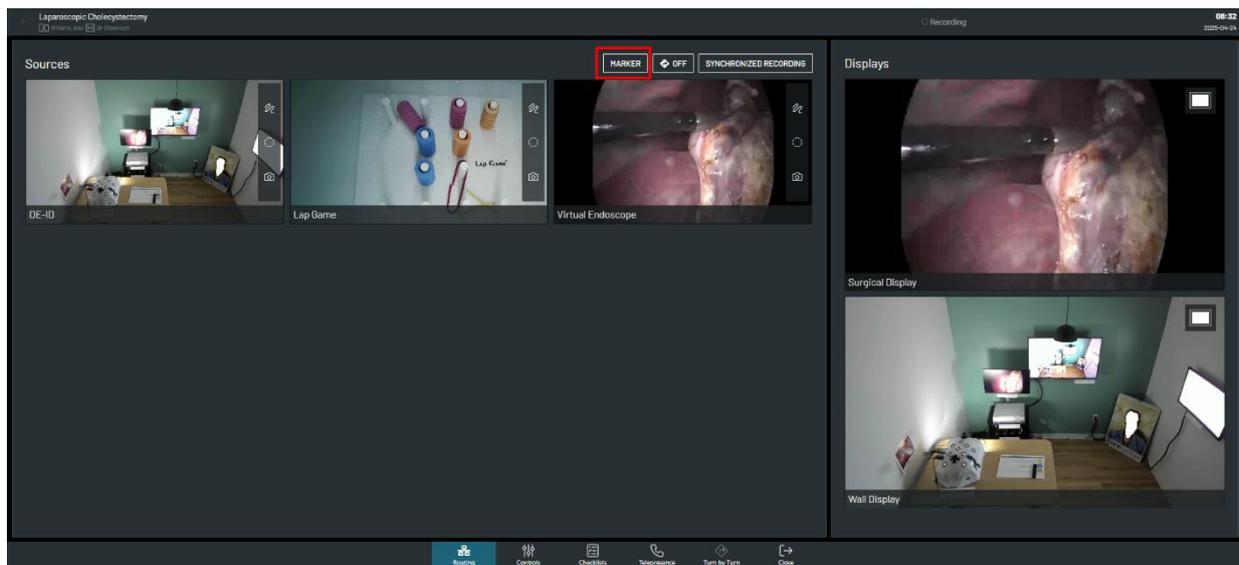
**Figure 36: Select Sources and Save**

The recording starts simultaneously for the selected sources.

3. Select **Confirm Selection** to begin recording on all the selected sources at the same time.

## Marker

This feature enables you to add a marker to any video sources being recorded.



**Figure 35: Add Marker**

Select **Add Marker** to add a marker on a video source that is being recorded.

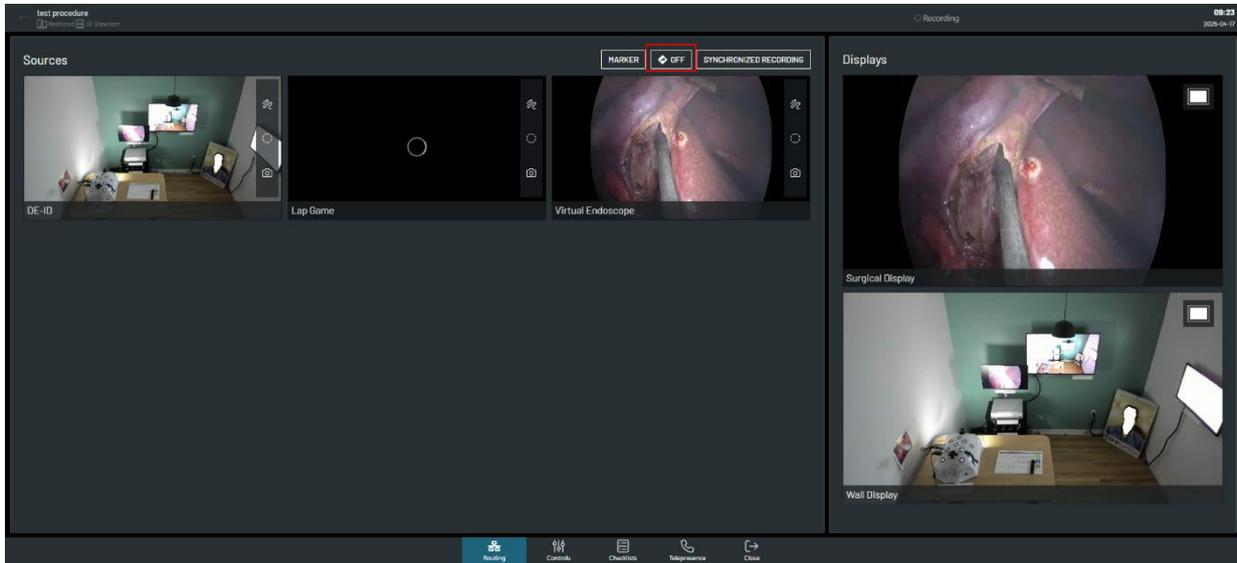
If the video source is not being recorded and you want to record the surgery, go to the **Sources** section on the **Routing** page to start the recording.

## Turn by Turn

The Turn by Turn feature provides information about the current phase of a surgical procedure on the **Turn by Turn** screen. Refer to [Turn by Turn in the Surgical Session UI Overview](#) for further information.

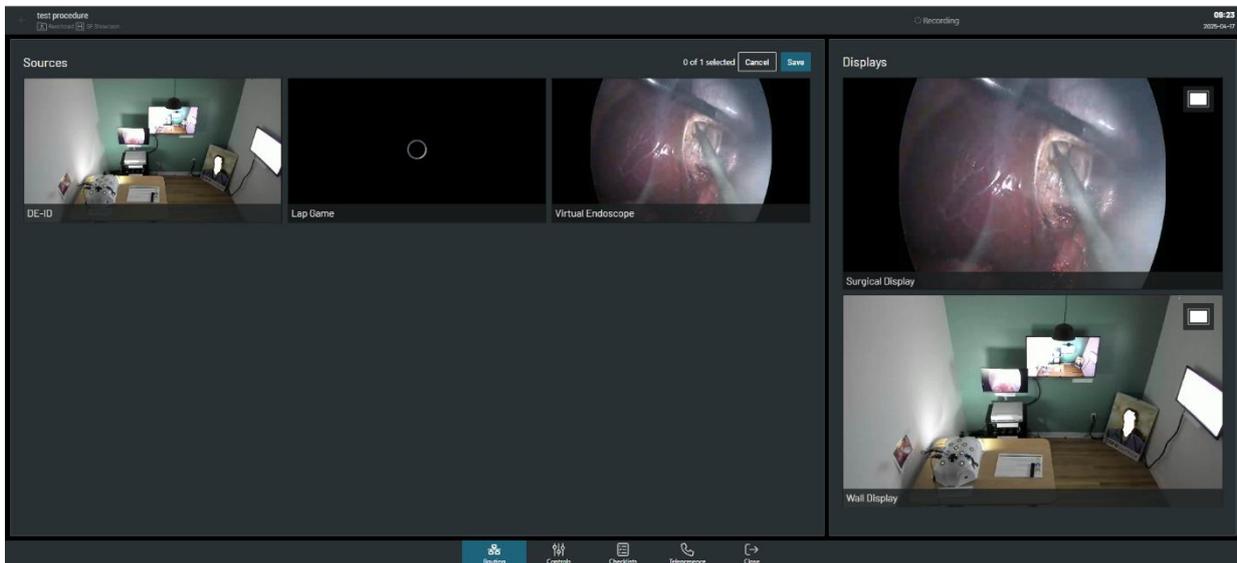
To enable the Turn by Turn feature, follow these steps.

1. Select the Turn-by-Turn icon.



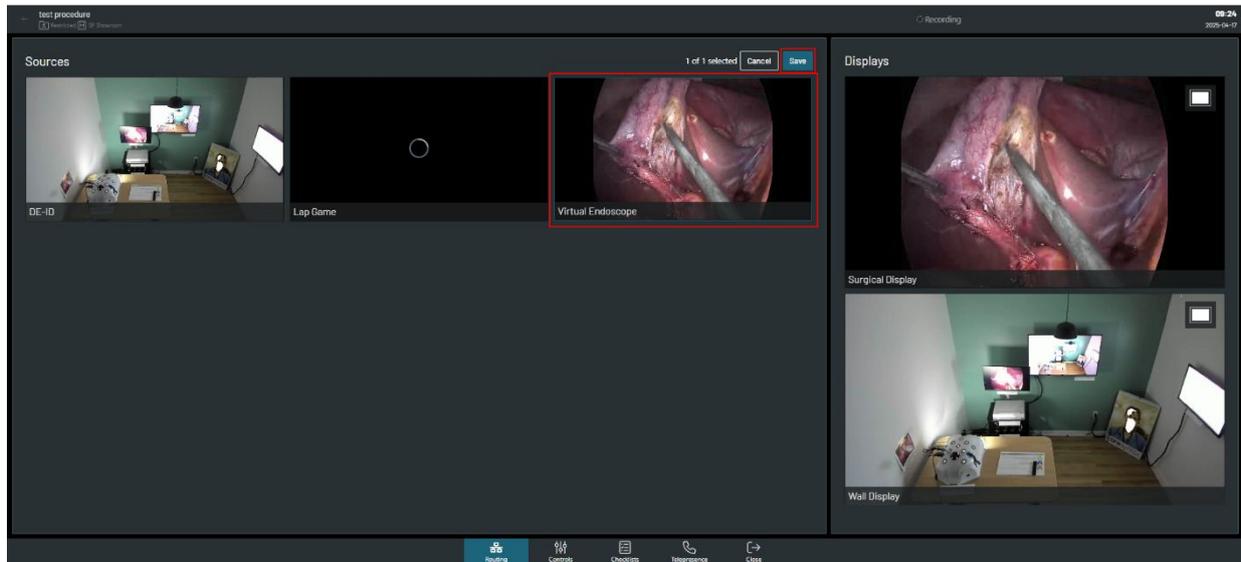
**Figure 36: Select the Turn-by-Turn icon**

The Select Source screen appears.



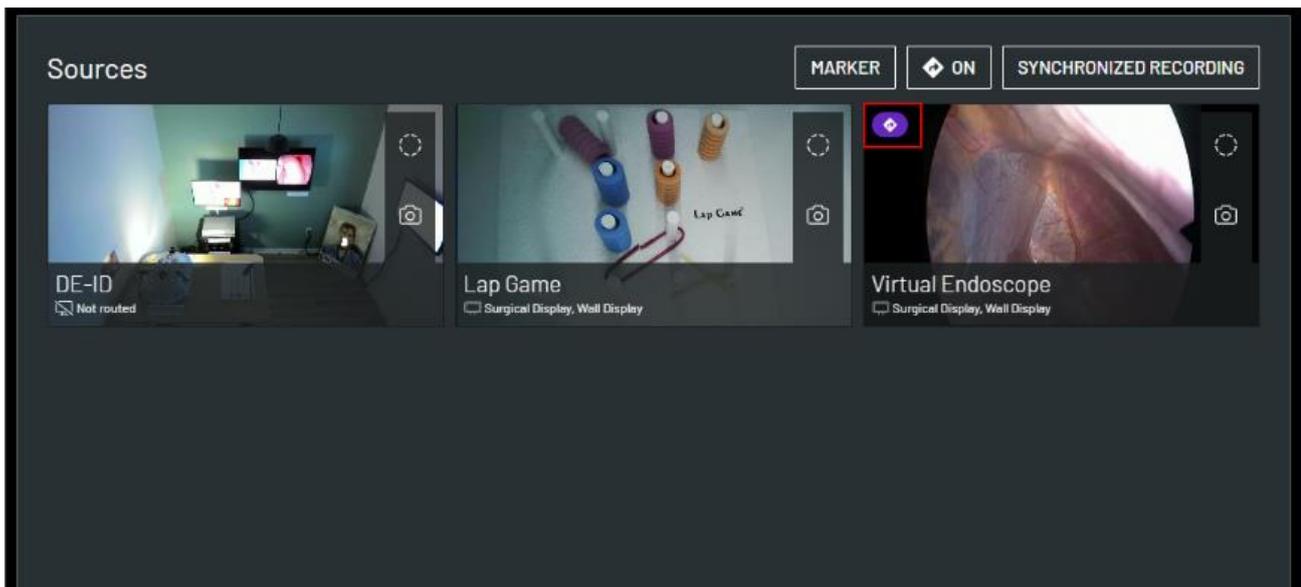
**Figure 37: Select Source screen**

1. Select the endoscope and select **Save**.



**Figure 38: Select the Endoscope and Save**

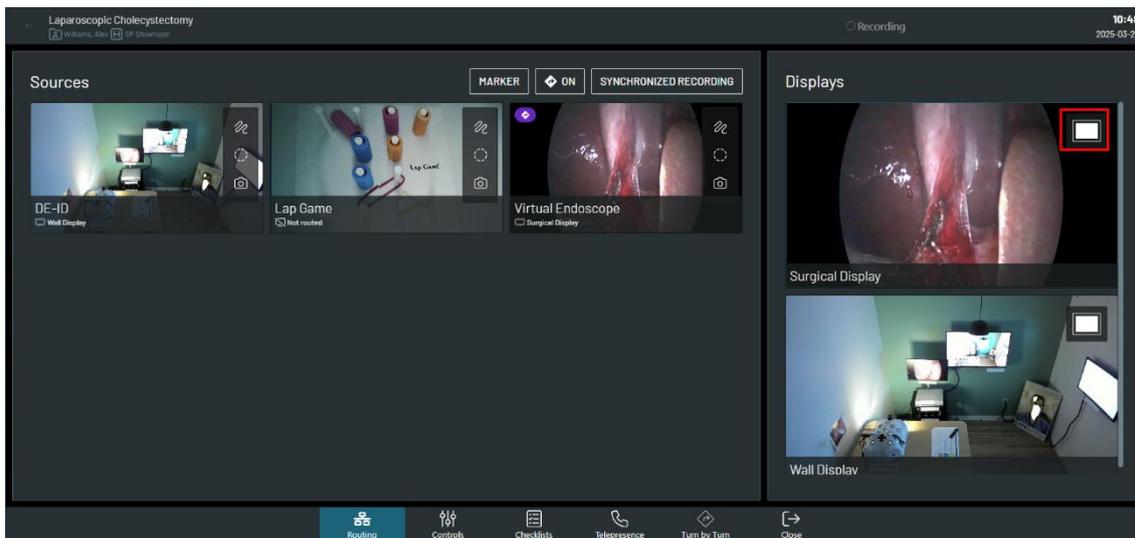
The Sources screen returns with the purple turn-by-turn icon showing the source with Turn-By-Turn capability activated.



**Figure 39: Turn by Turn icon activated on endoscope**

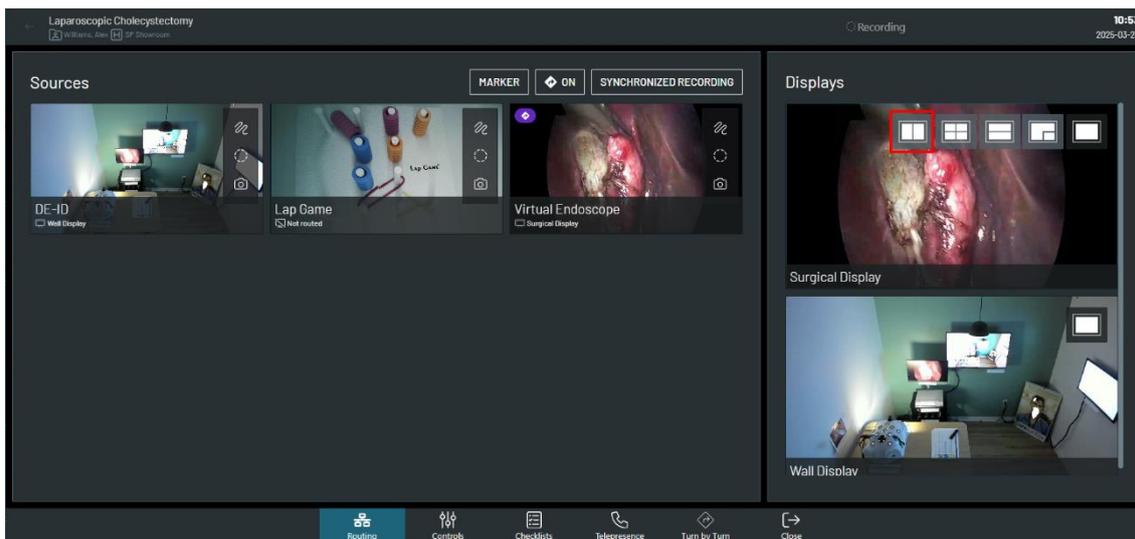
# Displays

1. Select the display configuration icon.



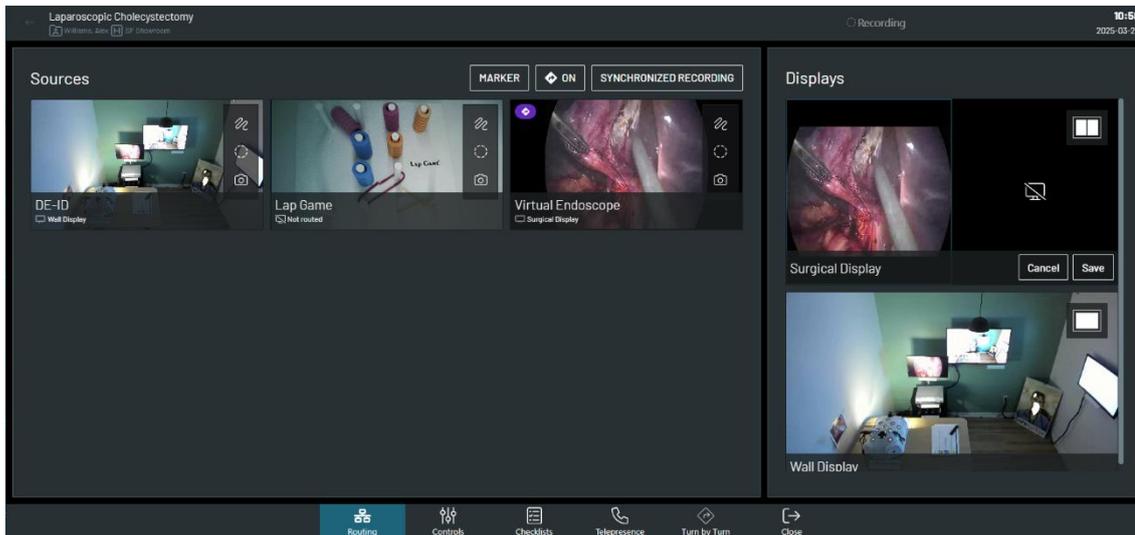
**Figure 40: Select the Display Configuration Icon**

2. Select the desired display configuration.



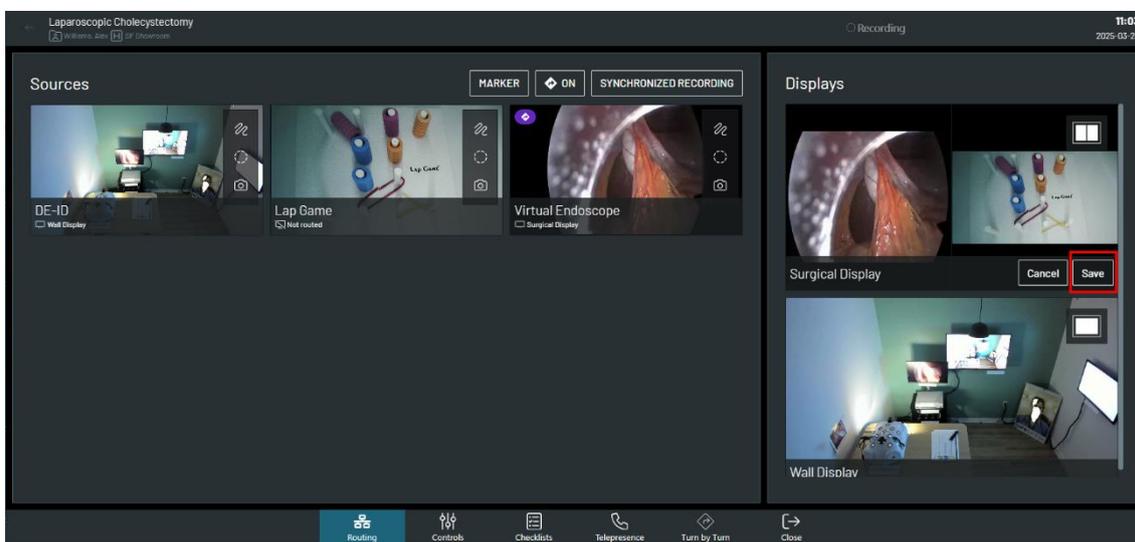
**Figure 41: Select the Desired Display Configuration**

The screen shows the selected configuration.

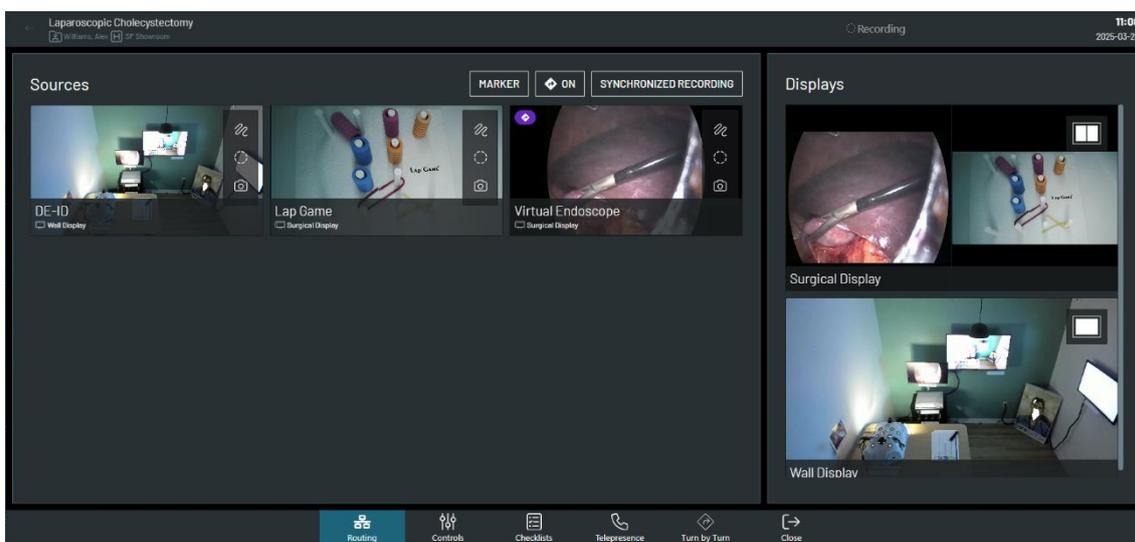


**Figure 42: Configuration Selected**

3. Drag and drop the desired source to the empty frame and then select **Save**.



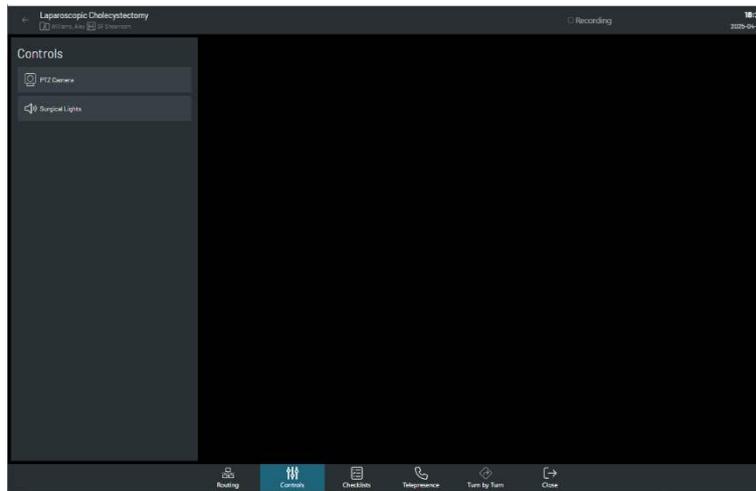
**Figure 43: Drag and Drop, then Save**



**Figure 44: Configuration Saved**

# Controls

This screen enables you to manage the camera and lights controls within the operating room.

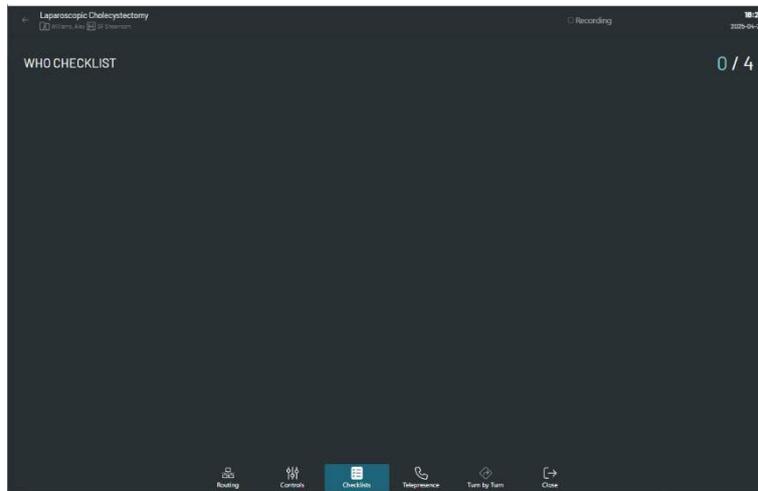


**Figure 45: Controls screen**

[**Note:** This screen’s functionality is not ready for unrestricted public release.]

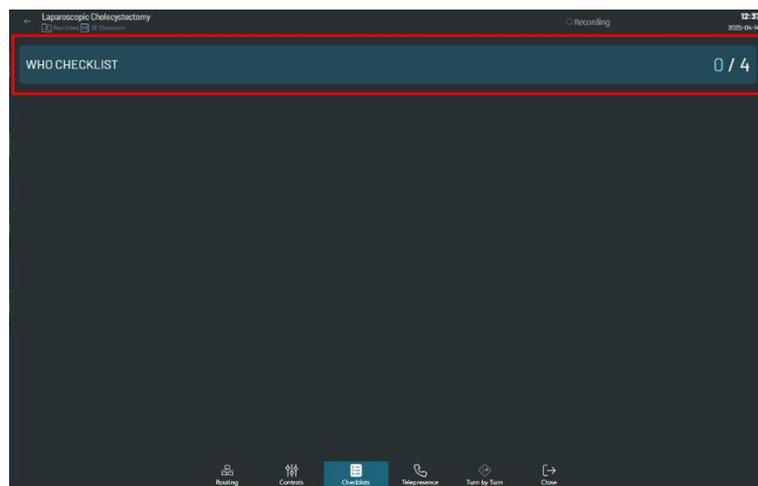
# Checklists

The **Checklists** menu enables you to complete organizational checklists for each procedure.



**Figure 46: Checklists menu**

1. Select the row of the checklist type to navigate into the checklist.



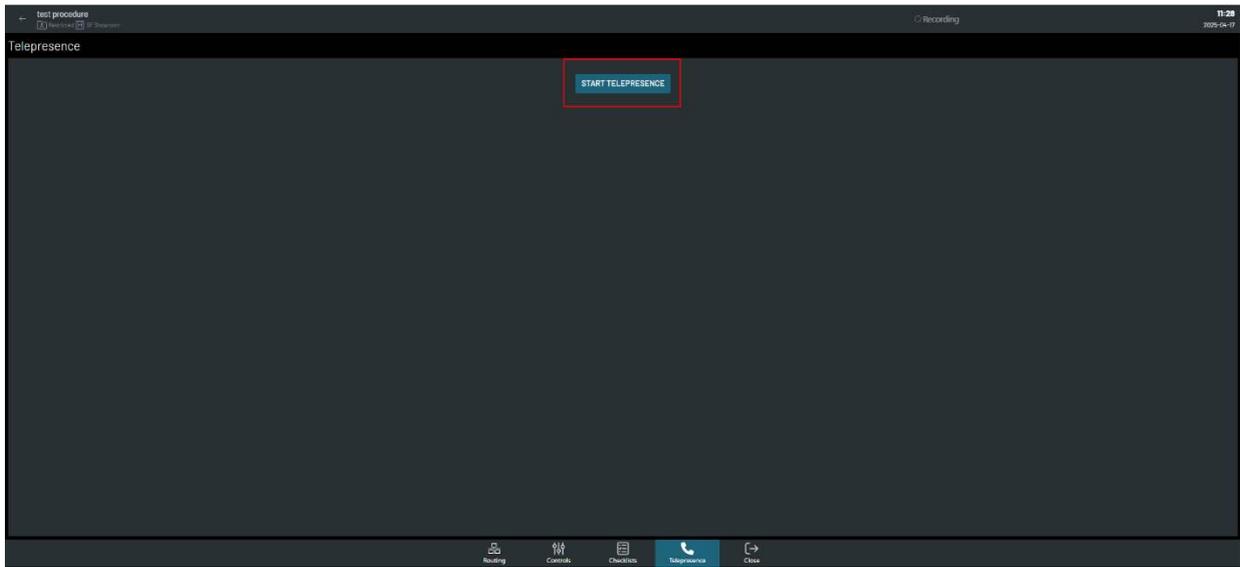
**Figure 47: Select WHO checklists**

2. After completing the checklist, move to another checklist or select **HOME** to use other functions.

**Note:** Complete checklists as needed for each individual procedure.

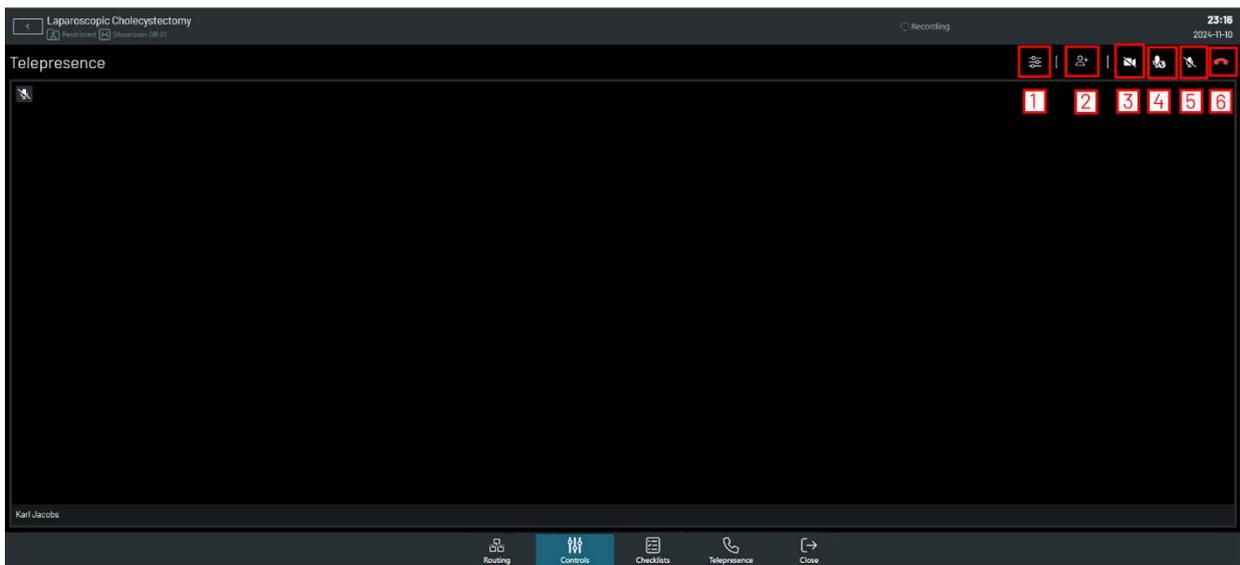
# Telepresence Screen

Select **Telepresence** and then select **START TELEPRESENCE** to begin a telepresence session.



**Figure 48: Starting a telepresence session**

The telepresence screen appears.



**Figure 49: Telepresence main screen**

Callout	Description
1	Video and audio settings
2	Manage participants
3	Camera
4	Global mute
5	Local mute
6	End call

## Manage Participants

**Figure 50: Manage participants**

If you want to invite other people to view or remotely participate in the procedure, use this form to obtain an invitation link to add to a meeting invitation.

## Turn by Turn

The Turn-by-Turn feature provides information about the current phase of a surgical procedure on the **Turn by Turn** screen.

**Figure 51: Current Phase Information**

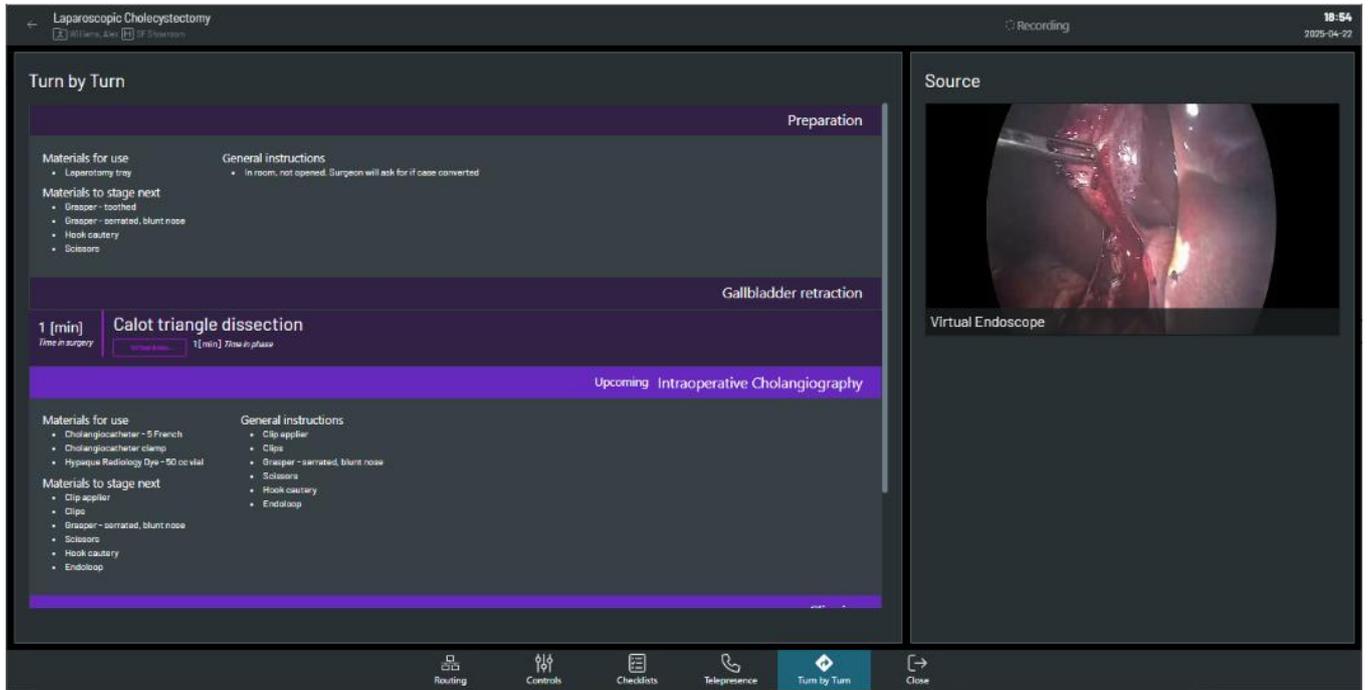
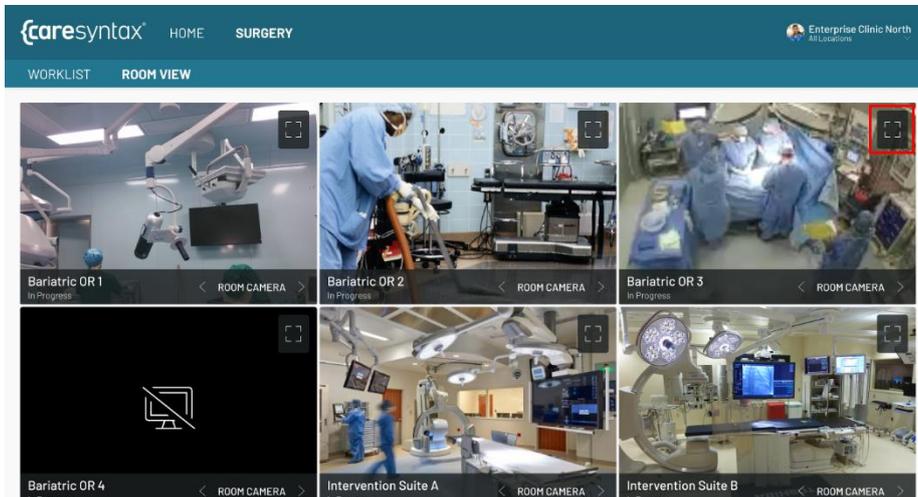


Figure 52: Upcoming Phase Information

# Room view

**ROOM VIEW** in the secondary navigation tab shows all the rooms that you have access to.

1. Select the expand view icon in the corner of a room.



**Figure 53: Overview**

2. Select the back arrow icon to return to the overview.



**Figure 54: View a specific room**

## Appendix: List of Applicable Standards

Applicable standards, laws and guidelines to the Connected Surgery standalone software:

<b>Standard</b>	<b>Title</b>
DIN EN ISO 13485:2016	Quality Management Systems – Requirements
2017/745/EEC (MDR)	Regulation (EU) 2017/745 of the European Parliament and of the council of medical devices (MDR, cons. version)
DIN/EN 14971:2020	Medical Devices – Application of Risk Management to Medical Devices
ISO 15223-1:2022	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
IEC 62304:2015	Medical Device-Software – Software-Lifecycle processes
EN 82304-1:2017	Health Software – general requirements for product safety
EN 62366-1:2021	Medical Products – Application of Usability to Medical Products
IEC 80001-1:2021	Application of Risk Management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities

## Appendix: General Information

This user manual offers step-by-step instructions and explanations of the intended uses of the Connected Surgery Software with screenshots to provide examples. Your ability to use all or only certain Connected Surgery Software functions depends on the specific configuration that you have purchased.

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

E-mail: [service@caresyntax.com](mailto:service@caresyntax.com)

## Target Group

This manual is aimed at medical and technical personnel, i.e. doctors and nurses, who are involved in operating the Connected Surgery Software in the operating room (OR).

## Copyright

The software 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 behalf of the manufacturer.

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## General Operating Concept

The Connected Surgery Software operating concept is based on web-based operations. The following operating instructions always apply:



The Back button will return backwards, step-by-step, through the paths you had previously navigated in the application, until you reach the **Routing** page. Once you follow the path back to the start of your session, the Back button will no longer be selectable.

## Device Description and Intended Use

Connected Surgery Software is a web-based stand-alone software. Connected Surgery Software 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, and forward 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.

### Intended use

Connected Surgery Software is a stand-alone application that is intended to;

- Communicate surgical imaging data
- Archive surgical imaging data

## Indications / contra indications

Connected Surgery Software can be used during any type of procedure, it applies for every patient, independent of the medical indication. Connected Surgery Software allows the user to display, view, record, and forward medical images and videos within the operating room. There are no contraindications.

## Exclusion

Connected Surgery Software is not to be used for active patient monitoring.

## Characterization of Users

Typical users of Connected Surgery Software are circulating nurses, clinicians, OR managers, ICU managers and biomedical IT professionals. These are well-trained professionals.

Connected Surgery software functions are usually performed by circulating nurses, since they are usually working from a non-sterile field and can access and control the main Connected Surgery Software interface. Connected Surgery Software 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 Connected Surgery Software. General experience and understanding of modern IT is helpful, but not required to operate Connected Surgery Software.

## General Environment

With the users described, typical use environments are the Operating Room (OR), and offices / wards.

## Physical Parameters

The physical parameters shall be those of a standard OR. Visibility of the user interface is key to the proper use of Connected Surgery Software. This includes, but is not limited to, brightness of the display, dust/debris on the screen, and any electromagnetic interferences possibly induced by third-party equipment.

## Combinations and Connections

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.

## Important Information

The software is installed by the Caresyntax service staff commissioned to do this task. In the event of modifications by third parties, Caresyntax accepts no liability for any errors in Connected Surgery Software.

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.

## CONNECTED SURGERY

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

Store the user manual for Connected Surgery Software somewhere easily accessible and ensure compliance with all the information contained.

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.

## Label



Figure 55: Connected Surgery Software Label

### Label Icons

Icon	Description
	Reorder
	Manufacturer's company logo
	Medical Device Classification
	Unique Device Identification
	Manufacturer's contact information
	Country of Manufacture
	Refer to the Instructions for Use
	CE-Mark
	Authorized representative for the Swiss market

## Version lifetime

The lifetime of each major release version of software is defined by the release of its successive major release. The lifetime for software version 1.X release ends two years after the release of software version 2.0. The expected lifetime per major release is four years.