Instructions for use

Helion

Video Management System

Read the instructions for use carefully prior to using the product and keep them safe for future reference.

ENGLISH
en-AU

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Videomed S.r.l. is a company of the Hill-Rom Holdings Group. The manufacturer is hereinafter referred to as Videomed S.r.l.

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Technical Customer Service

The contact details for the current Technical Customer Service hubs in the individual countries are listed on the Internet at www.hillrom.com.

Information about the document

Instructions for use

This document is identified by a code which indicates its version and update status. The user is responsible for ensuring that the most recent version is used.

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This document applies to the following units sold:

Product designation	**REF**
Helion Main Unit R	VR401111-1
Helion Main Unit	VR401111-1ND
Helion Main Unit RD	VR401111-1D
Helion Main Unit RSD	VR401111-1DT
Helion Main Unit RS	VR401111-1T
Helion Main Unit S	VR401111-1TND
Helion Main Unit AR	VR401111-2
Helion Main Unit ARD	VR401111-2D
Helion Main Unit ARSD	VR401111-2DT
Helion Main Unit ARS	VR401111-2T
Helion Main Unit SSD R	VR401111-3
Helion 4K	VR401112
Helion 4K Plus	VR401113
Helion Conference	CM401326

Optional sales items for the Helion video management system. Not all products are available in all countries.

Product designation	**REF**
Helion Rack (115V)	AC500920K
Helion Rack (230V)	AC500920K-2
Helion Rack (115V) - Permanent Install.	AC500920K-3
Auxiliary Rack (115V) - Plug&Play Install.	AC500920KB
Auxiliary Rack (230V) - Permanent Install.	AC500920KB-2
Auxiliary Rack (115V) - Permanent Install.	AC500920KB-3
Delrin Rack Spacer Kit	AC500919
On Air Lamp	AC300601
Back cover for monitor 24IN /31IN	AC500634
STD Single Plate 2xDVI 2xNEUTRIK	CS201580
STD Double Plate 4xNeutrik	CS201582
Transmission Set Single Display	CS201584
DVI Line Transmission	CS201585
STD Double Plate 4xDVI 2xNeutrik	CS201586
STD Single Plate 4xNEUTRIK	CS201592
STD Single Plate 2x NEUTRIK	CS201593
STD Single Plate 2xDVI	CS201594
Helion HR Surgical Lights Control SW	DC500103
Helion Recording Endotrigger Interface	AC500716

The manual is provided by Videomed S.r.l. in electronic PDF format on digital media. A hard copy of the manual is available upon request for qualified technical and medical staff.

Videomed S.r.l. waives any liability for improper use of the system and/or for damage caused as a result of operations not covered by the technical documentation.

PREFACE

The manufacturer is in no way responsible for the consequences of any incorrect operations carried out by the user.

PUBLISHER'S NOTE

This documentation is specifically intended for clinically trained system users.

The Publisher is in no way responsible for the information and data contained in this manual all information contained herein has been provided, checked and approved by the manufacturer for verification.

The Publisher is in no way responsible for any consequences of any incorrect operations carried out by the user.

Product and label images are for illustrative purposes only. Actual product and label may vary.

GENERAL CONSIDERATIONS

All operating instructions and recommendations provided in this manual must be complied with.

Clinical personnel must be trained in all operating procedures and safety standards prior to using the system.

SIGNAL WORDS

Residual dangers that may occur while using the product are identified in the document by the use of a signal word. The required safety measures and the potential consequences of failing to take these are listed. A corresponding signal word provides an indication of the severity of the danger:

Signal word	Meaning
DANGER	The signal word indicates a dangerous situation that will immediately lead to death or serious injury if no precautionary measures are taken.
WARNING	The signal word indicates a dangerous situation that may lead to death or serious injury if no precautionary measures are taken.
CAUTION	The signal word indicates a dangerous situation that may lead to moderate to slight injury if no precautionary measures are taken.
NOTICE	The signal word indicates a dangerous situation that may lead to material damage or damage to the environment if no precautionary measures are taken.

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Contents

1 General preliminary information

1.1 Operator's responsibility

The instructions for use of the Helion Video Management System are intended for operators trained and authorised in its operation. The management of the medical site is responsible for training staff in the use of the medical device.

The instructions for use provide instructions on the correct use of the system, which will help maintain its functional and qualitative characteristics over time. All information and warnings concerning correct, fully safe use are also provided.

The instructions for use, like the CE conformity certificate, are an integral part of the system and must always accompany it in the event of movement or resale. The user is responsible for keeping this documentation intact, so that it may be consulted throughout the entire lifespan of the system. The instructions for use must be stored in a way that ensures that the user can access the information required for using the medical device at any time.

NOTICE

The user and/or patient should report any serious incidents that have occurred in relation to the device to the manufacturer and the competent authority of the country in which the user and/or patient is established/located.

1.2 Updates

Videomed S.r.l. reserves the right to update the instructions for use at any time with modifications and/or translations without prior notice.

Contact the Customer Service office of Videomed S.r.l. for the latest version of the instructions.

1.3 Language

The original instructions for use have been drawn up in American English.

Any translations into additional languages must be made on the basis of the original instructions.

The manufacturer is responsible for the information contained in the original instructions; translations into different languages cannot be completely verified, and therefore, if an inconsistency is detected, it is required to follow the text in the original language or to contact the Videomed S.r.l. Customer Service office.

1.4 Personnel qualifications

Consult the following table in order to establish personnel skills and qualifications:

Qualification	Description
Operator	Natural or legal person (for example, a doctor or a hospital) who owns and uses the Helion Video Management System. They must provide a safe system and adequately instruct the user in the intended and permitted use of the system.
User	A suitably trained person who, thanks to their professional qualification, is authorised to operate and use the Helion Video Management System for as required. They are responsible for correct and safe operation of the system and for ensuring that it is used solely for the intended purpose.
Qualified Personnel	Authorised persons who are generally employees of the manager or have acquired their skills through professional training in the medical sector, are able to evaluate their work and recognise potential risks based on their professional experience and knowledge of safety regulations. Where required, qualified personnel must certify their qualifications through a valid document.

1.5 Symbols

The Helion Video Management System units are fitted with device labels. Each device label contains the identification details of the unit.

The device label must be undamaged and attached at the specified locations on the product. Any damaged, illegible or missing device labels must be replaced. Device labels must not be changed or removed.

Symbol	Description
	Symbol used to indicate the need to consult the instructions for use prior to using the equipment.
	Symbol of compliance with Regulation (EU) 2017/745 on medical devices.
	Equipotential: symbol for ‘potential equalisation’.
	Protective earth (ground)
N	Connection point for the neutral conductor on PERMANENTLY INSTALLED equipment

Symbol	Description
	Symbol used to indicate the date of manufacture.
	Symbol used to identify the manufacturer's name.
	Crossed-out bin: this product must not be disposed of as communal mixed waste, collect separately.
	Symbol used to indicate the Videomed S.r.l. material number.
	Symbol used to indicate the serial number.
	Symbol used to indicate a medical device.
 (01)00615521031626 (21)123456789012 (11)210212	Indicates the Unique Device Identification (UDI) code; it is composed of: – a device identifier (UDI-DI) (01); – a production identifier (UDI-PI) (serial number (21), date of production (11)).
	Medical – General medical equipment Defined in relation to electrical shock, fire and mechanical hazards only in accordance with AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including Amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
	Consult the instructions for use (IFU). A copy of the IFU is available on the website indicated on the symbol. A printed copy of the IFU can be ordered from Hillrom for delivery within 7 calendar days.
	Only valid for US. Caution: According to US federal law, this device may only be sold by or on the order of a licensed healthcare practitioner.
	Symbol used to indicate the model number.
	China RoHS symbol

1.6 Product certification

CE

The Helion Video Management System is a Class I medical device according to Regulation 2017/745/EU on medical devices, and is compliant with the version of the regulation currently in force at the time of sale of the product. Videomed S.r.l. declares that Helion conforms to the general safety and performance requirements according to Regulation 2017/745/EU on medical devices, Annex I. A conformity assessment procedure required for Class I devices shall be carried out in accordance with Article 52 (7), taking into account a quality management system in accordance with Annex IX, Chapter 1. The manufacturer confirms conformity with the CE marking.

1.7 Warranty

The complete warranty clauses are provided in the sales contract.

Videomed S.r.l. assures the safety and functional reliability of the system provided the following:

- the system is used, managed and repaired solely as described in these instructions for use;
- installation, modification and repair are carried out exclusively by Videomed S.r.l. assistance services;
- only spare parts and accessories authorised by the manufacturer are used;
- no structural changes are made to the devices.

The system status following system testing must be recorded in an installation protocol. Commissioning is used as proof of the start of the warranty period.

Further details may be provided in the commercial contract.

The conditions required by the commercial contract (should they differ) take priority over what is stated in this section.

2 Safety information

2.1 General safety warnings

The Helion Video Management System must be operated by suitably trained personnel.

⚠ DANGER

ELECTRIC SHOCK FROM DAMAGED MAINS POWER CABLE!

Check the mains power cable before connecting it and do not use it if it has been crushed or the insulation is damaged.

⚠ DANGER

ELECTRIC SHOCK FROM EXPOSED LIVE PARTS!

It is also recommended to periodically check the integrity of the parts of the device, to check for the presence of exposed parts following an impact or fall and to avoid using the device in case of damage to the structure or to its components.

⚠ DANGER

ELECTRIC SHOCK FROM INCORRECT POWER CONNECTION PROCEDURE!

The Helion system must be powered and earthed from the same electrical panel that powers the operating theatre. All equipment connected to the Helion system must also be powered and earthed from the same electrical panel that powers the operating theatre.

⚠ WARNING

This product can expose you to chemicals including lead and Di(2-ethylhexyl) phthalate (DEHP), which are known by the State of California to cause cancer, and lead and Di(2-ethylhexyl) phthalate (DEHP), which are known by the State of California to cause birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

⚠ CAUTION

All safety information must be complied with to ensure safe use of the Helion Video Management System.

⚠ CAUTION

To avoid complications due to electrostatic balancing charges between parts of the device and the patient, the user must not touch the metal parts of the system and the patient at the same time.

⚠ CAUTION

COMPULSORY MEASUREMENT OF DISPERSAL CURRENTS

It is necessary to measure leakage currents with circuits downstream of the Helion system open. Otherwise, the leakage currents of these circuits will be added to those of the Helion system.

⚠ CAUTION

It is absolutely forbidden to remove the device labels and/or replace them with other labels. If any device label is damaged or removed, the customer must notify the manufacturer.

2.2 Security considerations

The security best practices to be followed are listed below:

User access management:

Security best practices for user account management should be followed, including those listed below:

- The principle of least privilege should be followed while creating user accounts.
- Shared user accounts should not be created.
- Use a strong password according to the healthcare provider's password policy.

Authentication:

Authentication can be enforced to access the product. Authentication is usually in the form of a username and a password. The following steps are therefore recommended:

- Do not write your password in a public workspace.
- Do not save the password in the browser.
- Verify the URL before entering the credentials.
- Log out and close the browser window or the application after accessing the product.

Remote connection support:

- Utilising a VPN or equivalent technologies with multi-factor authentication is advisable for remote connection via a public network.
- The remote connection must be used over a secure, encrypted connection.
- Following the principle of least privilege is recommended when configuring remote connection support.

Browser security:

It is recommended to use the latest supported browser with up-to-date security patches as per the healthcare provider's security policy.

The browser should be used in a private mode to protect against data leaks. If not, then it is recommended to clear data such as cookies, cache, history, etc. when closing the browser.

Data protection:

- It is recommended that organisations must implement strict access control to protect sensitive information such as PHI stored locally in a system.
- Implement physical security to prevent unauthorised physical access to the system.
- It is recommended to use the latest supported browser with up-to-date security patches as per the healthcare provider's security policy.

  The browser should be used in private mode to protect against data leaks. If not, then it is recommended to clear data such as cookies, cache, history, etc. when closing the browser.

Updates and patches:

- Updates and patches should be installed by a trained service technician authorised by Baxter following the installation directions.
- Do not initiate an update during product usage.
- It is recommended not to install any service packs or updates related to the operating system that are not required for the product to operate.
- Only security updates and patches are recommended.
- Do not install unnecessary software of unknown sources and off-the-shelf (OTS) software on the system.

Logging:

The retention time for the system as well as the software shall be set as per local regulations / the healthcare provider's policies.

Secure configuration:

- The healthcare provider must ensure that the network the product is connected to is secure.
- The product should be secured against:
  - unauthorised access to system files;
  - unauthorised software program installation;
  - unauthorised physical access.
- Network and physical access controls should be implemented to reduce the likelihood of system compromise.
- Firewalls or equivalent technologies must be implemented to protect the system.
- Utilise secure deployment measures such as device isolation and network segmentation.

User training:

Security awareness training by the users' healthcare provider to maintain and access the product securely is recommended.

Malware protection:

The product is delivered without any pre-installed antivirus and anti-malware system. It is possible to install an enterprise antivirus or anti-malware client on it. The client can use anti-malware with some precautions, such as excluding critical directories from the real-time scan.

2.3 Privacy considerations

Types of data processed by the device:

The system processes various types of data, some of which may be subject to applicable privacy and data protection laws.

Data that may be processed by the system:

- Patient identifiers: Patient registration information like names, dates of birth, gender, and patient IDs for accurate patient selection and data association as determined by the customer's systems.
- Patient treatment information: Including medical data such as surgical worklists, medical conditions, details of the surgery, and audio and video recordings of the surgery.
- Medical images: Images from PACS (e.g., MRI, CT scans, X-rays).
- Helion system user data (Healthcare providers (HCPs) and customer support staff): Full names, user or network IDs, account passwords for login, audio and image data extracted from surgery videos.
- Annotations and comments: Annotations and comments to medical images that can be made by users and are stored only within the system. They may contain surgery details and other related data, and should not contain any unnecessary personally identifiable information.
- User access and activity logs: Login information, timestamps, actions, and data changes for system security and audit trails.
- System metadata: Data transfer logs, cache information, and performance metrics for system maintenance.

User responsibilities:

- Ensure compliance with all applicable privacy laws and regulations.
- For the related data processing activities, the customer acts as a data controller while Baxter acts as a data processor. If required, the responsibility for obtaining any necessary consent from data subjects lies with the customer. The same goes for appropriate transparency notices to patients and HCPs.
- Utilise all system capabilities to ensure the highest possible level of privacy.
- Avoid any situation that may increase the risk of a breach of data privacy.

Privacy features in the product:

The Product has features that help protect patient data.

- Local storage: Data is only temporarily stored on the Helion system, which is hosted on-premises at the customer's facility and is then transferred to the customer's system and servers. The system stores videos and images from video sources in the operating theatre locally on the customer's servers, ensuring that patient data remains on-premises at the customer's facility.
- Encryption: Databases containing patient health information (PHI) or personal data are encrypted.

- User authentication: To ensure that only authorised users can access patient data, it is necessary to enable user authentication for the product. The Authentication Application is designed to authenticate authorised users only by requiring them to prove their identity through a secure web application. The system also maintains a record of user activity and permissions to ensure compliance with regulations and policies.
- Automatic logouts: Administrators can set up timeouts, which log users out automatically after a certain time. This helps reduce the risk of someone getting into the system without permission.
- Secure workflows: The system has built-in workflows that make sure data is only shown to the right users.

Privacy best practices that should be followed are listed below:

Access management:
To protect sensitive information, such as personal data or Protected Health Information (PHI) that is stored locally on the system, strict access controls should be implemented.

Monitoring and updates:
Regularly monitor and update the product to address potential privacy vulnerabilities and to comply with the latest privacy and data protection regulations and standards.

User training:
Users and the operator of the product are responsible for keeping patient, staff, and user data private and protected.

- Privacy awareness training for the users on privacy best practices and how to handle sensitive data in accordance with your organisation's policies and applicable laws is recommended.
- Users should be trained on the product's privacy features and the privacy and data protection laws that apply to the product.

Data use and retention:

- Data should be collected and used only to the extent required to fulfil the purpose of the product and its associated services.
- The operator should establish internal data retention policies to ensure that sensitive data is not stored any longer than necessary. Implement secure data disposal methods when required.
- The operator should ensure personal data is kept up to date and accurate. Any outdated or unnecessary data should be deleted. The operator should also establish data protection protocols and internal deletion and retention policies to safeguard personal data.

Regular privacy audits:
The operator should conduct regular privacy audits to identify and address potential vulnerabilities, ensuring that the product remains compliant with privacy and data protection laws and standards.

Third-party compliance:
The operator should verify that any third-party systems or services integrated with the product comply with data protection laws and maintain adequate privacy safeguards.

Responsible disclosure / Report a security or a privacy issue:
If a security or privacy issue relating to the product is noticed, the healthcare provider should report the issue to Baxter as soon as possible. Go to Product Security | Baxter (https://www.baxter.com/product-security) for information on how to report a potential issue.

2.4 Useful life of the system

Provided that all applicable safety and maintenance regulations are strictly observed, the video management system has been designed to guarantee a useful life of 8 years.

The life cycle includes a guarantee of the functionality of the product when used in compliance with the specific instructions for use, the provision of the customer assistance service, and the availability of spare parts.

Videomed S.r.l. applies a certified quality management system in accordance with EN ISO 13485 to all its business processes, which guarantees:

- highest quality;
- product and accessory reliability;
- ease of use;
- functional design;
- optimisation for the intended purpose.

2.5 Cleaning

NOTICE

Risk of material damage

Excess liquid may cause damage to the internal electronics.

- Do not apply or spray liquid directly onto the housing.
- Apply liquid to the cleaning cloth.

NOTICE

Risk of material damage

Do not clean the Helion unit's rear connector panel, or any of its connectors or buttons. This may cause damage to the connectors, buttons, and internal electronics.

- Call Baxter service.

NOTICE

Risk of material damage

Abrasive materials may cause damage to the devices.

- Use a soft cloth.

2.5.1 Cleaning agents

When selecting the cleaning agents, ensure that they do not contain any of the following components:

- organic, mineral, and oxidising acids;
- bases;
- organic solvents (e.g., ether, ketones, benzines);
- halogens (chlorine, iodine, bromine);
- aromatic/halogenated hydrocarbons;
- any other substance that is chemically aggressive to plastics.

The housings and plates have been tested for resistance to the following product: general purpose glass cleaner.

2.5.2 Preparing the devices

Before cleaning the devices, proceed as follows:

- Power off the devices.
- Pull the power plugs out of the sockets.
- For permanent installations, turn off the main switch located on the front panel of the rack.

2.5.3 Cleaning the devices

To clean the front of the devices, proceed as follows:

1. Moisten a soft cloth lightly with a recognised cleaning product.
2. Clean the front of the housing.
3. Wipe dry with a dry soft cloth.
4. Inspect the surface to determine that it is visually clean. Repeat if necessary.

2.6 Preventive maintenance

Maintenance must be carried out on an annual basis to ensure components remain intact and in good working order.

The products may only be serviced by qualified maintenance technicians. Contact details for service technicians are available from Technical Customer Service.

Videomed S.r.l. recommends that a maintenance agreement be concluded so that maintenance can be performed in a reliable, timely manner.

3 System description

3.1 Intended purpose

The Helion Video Management System is a medical video communication system used exclusively to display and manage existing audio-video sources, and to control an operating light within the specifications established by the manufacturer.

3.2 Intended medical indication

As the device is not used for diagnostics, medical decision making etc. (see intended use / contraindications), it has no immediate medical indication.

3.3 Device contact site

The medical device has no contact with patients.

3.4 Patient population

The device can be used with any patient population in the operating theatre at the discretion of the facility. It does not require differentiated use according to the patient being treated.

3.5 Intended users

Operating theatre personnel are medical or paramedical users such as surgeons, nurses, physicians, and biomedical engineers who have completed user training for the system. They are responsible for preparing and performing surgical procedures.

3.6 Use environment

The device's environment of use is the surgical operating theatre. This includes but is not limited to:

- operating theatres in hospitals;
- outpatient surgery centres.
- In the offices of physicians in private practice and other operating theatre-like environments, when the video conference function is used.
- **Note:** If Helion is placed on a boom shelf, maintain a distance of 1.5 m or more to the surgical area during surgery.

3.7 Normal use

- The system is used exclusively to display and manage existing audio-video sources.
- Signals are controlled via a touch screen monitor.
- Analogue and digital signals are distributed to different video outputs.
- Data is exported to other devices (not part of the MD).
- Interventions are documented via temporary archiving.

- Information is exchanged by video conference with the operating theatre by sharing high resolution images and videos with the world outside the room.
- The MD is regularly maintained by qualified service technicians in accordance with the defined maintenance intervals.
- It is initially operated by the operator.
- The MD must be repaired and disposed of as required by qualified service technicians.
- To control the on/off state and intensity of compatible surgical lights.

3.8 Contraindications

- The system shall not be used for findings and diagnostics.
- The system shall not be used to check vital body functions.
- The system shall not be used to make reports.
- The product has not been designed to store clinical data for medical-legal purposes.
- The system shall not be used as a system for precision or measurement of life support function.
- The system shall not be use to correct the administration of medicinal products.
- The system shall not be used as a system for monitoring the patient's condition.
- The system shall not be used as an alarm system.
- The system shall not be used for a specific treatment. In the event that incorrect information may lead to inappropriate treatment of the patient:
- The system (or monitors connected to the system) shall not be used as the primary information source.

3.9 Reasonably foreseeable misuse

Cases of reasonably foreseeable misuse, which are strictly prohibited, are listed below:

- using the system in areas at risk of explosion;
- using the system near strong electromagnetic fields;
- using the system in a different way to what is required in the paragraph 'Intended purpose'.

Any other use of the system with regard to the intended use must be authorised by the manufacturer in writing in advance. Any use that does not comply with the conditions specified above shall be considered 'misuse'. In the event of such misuse, the manufacturer declines any liability for damage caused to things or persons and deems any type of warranty for the system void.

Improper use of the system disclaims any liability on the part of the manufacturer.

3.10 Use in combination with other devices

3.10.1 Combination with other Baxter products

Product designation	REF
FCS Plate S 1xDVI	CS201560
FCS Plate S 4xNEUTRIK	CS201561
FCS Plate 2xDVI	CS201562
FCS Plate 4xNEUTRIK	CS201563
FCS Plate 1xDVI 4xNEUTRIK	CS201564
FCS Plate 8xNEUTRIK	CS201565
FCS Plate 2xDVI 4xNEUTRIK	CS201568
iLED7 Ceiling Single	4068110
iLED7 Mobile	4068120
iLED7 Pendant	4068140
iLED7 Ceiling Duo	4068210
iLED7 Ceiling Trio	4068310
iLED7 Ceiling Quad	4068410
TV HD Wireless Camera (in combination with iLED 7)	1940442
TV HD Wireless Receiver (in combination with iLED 7)	1940747
TruLight 5000 / 3000 Ceiling Single	4038110
TruLight 5000 / 3000 Mobile	4038120
TruLight 5000 / 3000 Wall	4038130
TruLight 5000 / 3000 Pendant	4038140
TruLight 5000 / 3000 Ceiling Duo	4038210
TruLight 5000 / 3000 Ceiling Trio	4038310
TruLight 5000 / 3000 Ceiling Quad	4038410
TV HD 2000 (in combination with Trulight)	2072249

3.10.2 Combination with products of other manufacturers

The Helion Video Management System can be used in combination with devices from other manufacturers.

Only install devices in the patient environment that have been approved in accordance with standard IEC 60601-1.

Outside the patient environment, devices approved in accordance with standard IEC 62368-1 are also allowed.

If a device is installed at a later stage, installation must be performed as specified in standard IEC 60601-1 and in line with the specifications provided by the manufacturer.

Videomed S.r.l. does not take any responsibility for the combination of the video management system with third-party products.

Pay attention to operating temperature of individual third-party devices.

It is also possible to use a medical FHD Touch screen Monitor that is not included in the catalogue. Please contact Technical Customer Service (www.hillrom.com) for compatibility information.

3.11 Obligations and prohibitions

The management of the medical site is responsible for training staff on the use of the medical device. The training may be conducted initially by the staff of the manufacturer. However, the training of new staff and the refreshing of the training remain the responsibility of the medical site.

3.11.1 Personnel prohibitions

In particular, the personnel must not do the following:

- use the system improperly, i.e. for uses other than those indicated in the paragraph 'Intended purpose';
- replace or modify system components without the manufacturer's permission;
- use the system as a support point even if not in operation (resulting in a risk of falling and/or damaging the system itself);
- use the system outside the permitted room conditions (see the paragraph 'Technical data').

⚠ CAUTION

Videomed S.r.l. is not liable for damage caused to objects or persons if it is ascertained that the system has been used in a room in which its use is not permitted.

3.12 Technical data

Main unit – Technical Specs

Video inputs	18 (14 DVI, 2 3G-SDI, 2 CVBS)
Video outputs	10 FullHD DVI
Supported resolutions	Standard video PAL (720 x 576), NTSC (720 x 480) HDTV (1280 x 720) Full HDTV (1920 x 1080) PC resolution (1024 x 768, 1280 x 1024, 1600 x 1200, 1920 x 1200) UHD / 4K option with 4K unit
Dimensions	133 x 430 x 450 mm
Power supply	100 – 240 V 50 – 60 Hz AC
Power consumption	160 W
Protection	Short circuit protection Overload protection Overvoltage protection
Insulation voltage	Input/Output 4,000 V AC Input/FG 1500 V AC
Enclosure	IP20

Main unit – Technical Specs

Environmental conditions	Operating temperature: +10/+40°C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70°C Storage relative humidity range: 10% to 100%, including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa
Max. operation altitude	5,000 m
Control touch screen	21”, 24” or 27”, 1920 x 1080, 16:9
Storage capacity	2 TB
Audio inputs	3 x microphones 2 x Aux stereo 1 x video conference
Audio outputs	1 x stereo amplified 1 x stereo non-amplified 1 x video conference 2 x speaker terminal out (L/R)
Communication protocols	DICOM HL7 (Only with an additional gateway provided through a partner third-party vendor.)
Other connections	2 x USB 2.0 3 x USB 3.0 12 x serial ports RS232 (2 x serial ports RS232 reserved for the manufacturer)
Unit weight	13.5 kg
Recording function *1	Time shift recording Movie around the snapshot 2 x Recording channel Endotrigger recording compatibility

*1 All digital video signals are recorded with 16:9 aspect ratio. 3D side-by-side only.

Conference Unit – Technical Specs

Standard video	H.263, H.263+, H.263++, H.264, H.264 High Profile, H.264 SVC. Encoding up to 1920 x 1080p 60fps
Video inputs *1	2 inputs: – 2 x HD video in (1080p60/720p60)
Dimensions	44 x 430 x 450 mm
Power supply	100 – 240 V 50 – 60 Hz AC
Video outputs	2 outputs: – 2 x HD video out (1080p60/720p60)
Power consumption	34 W

Conference Unit – Technical Specs

Protection	Short circuit protection Overload protection Overcurrent protection Overvoltage protection
Insulation voltage	Input / output 4,000 V AC Input / FG 1500 V AC
Environmental conditions	Operating temperature: +10/+40°C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70°C Storage relative humidity range: 10% to 100%, including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa
Max. operation altitude	5,000 m
Enclosure	IP20
HD audio	MicPod 100 Hz – 16 kHz Mute button
Unit weight	8 kg

*1 3D side-by-side only

4K Unit – Technical Specs

Video inputs	5 HDMI ports
Video outputs	5 HDMI ports
Supported resolutions	Up to 4096 x 2160 at 60 Hz
Transmission To Monitor	Fibre-optic cabling
Additional ports	5 x DVI over CAT 6/7 output scaled to FullHD 1080 5 x DVI over CAT 6/7 pass-through input (FullHD 1080)
Dimensions	44 x 430 x 450 mm
Power supply	100 – 240 V 50 – 60 Hz AC
Power consumption	30 W
Protection	Short circuit protection Overload protection Overcurrent protection Overvoltage protection
Insulation voltage	Input / output 4,000 V AC Input / FG 1500 V AC

4K Unit – Technical Specs

Environmental conditions	Operating temperature: +10/+40°C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70°C Storage relative humidity range: 10% to 100%, including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa
Max. operation altitude	5,000 m
Enclosure	IP20
Unit weight	5.5 kg

4K Plus Unit – Technical Specs

Video inputs	2 HDMI ports 2 display ports
Video outputs	2 HDMI ports 2 display ports
Supported resolutions	Up to 4096 x 2160 at 60Hz
Transmission To Monitor	Fibre-optic cabling
Additional ports	4 x DVI over CAT 6/7 output scaled to FullHD 1080 4 x DVI over CAT 6/7 pass-through input (FullHD 1080)
Dimensions	44 x 430 x 450 mm
Power supply	100 – 240 V 50 – 60 Hz AC
Power consumption	30 W
Protection	Short circuit protection Overload protection Overcurrent protection Overvoltage protection
Insulation voltage	Input / output 4,000 V AC Input / FG 1500 V AC
Environmental conditions	Operating temperature: +10/+40°C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70°C Storage relative humidity range: 10% to 100%, including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa
Max. operation altitude	5,000 m
Enclosure	IP20
Unit weight	5.5 kg

Rack Unit (optional) – Technical Specs

Dimensions	800 x 600 x 757 mm
Colour	RAL 7016 puckered
Environmental conditions	Operating temperature: +10/+40°C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 70.0 kPa to 106.0 kPa Storage temperature: -40/+70°C Storage relative humidity range: 10% to 100%, including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa
Rack internal component	Two fans, forced ventilation produced minimum 2410 Cubic Meters per Minute (CMM) each Isolation transformer, power 1,000 VA
Max. operation altitude	3,000 m
Enclosure	IP20
Unit weight	64 kg

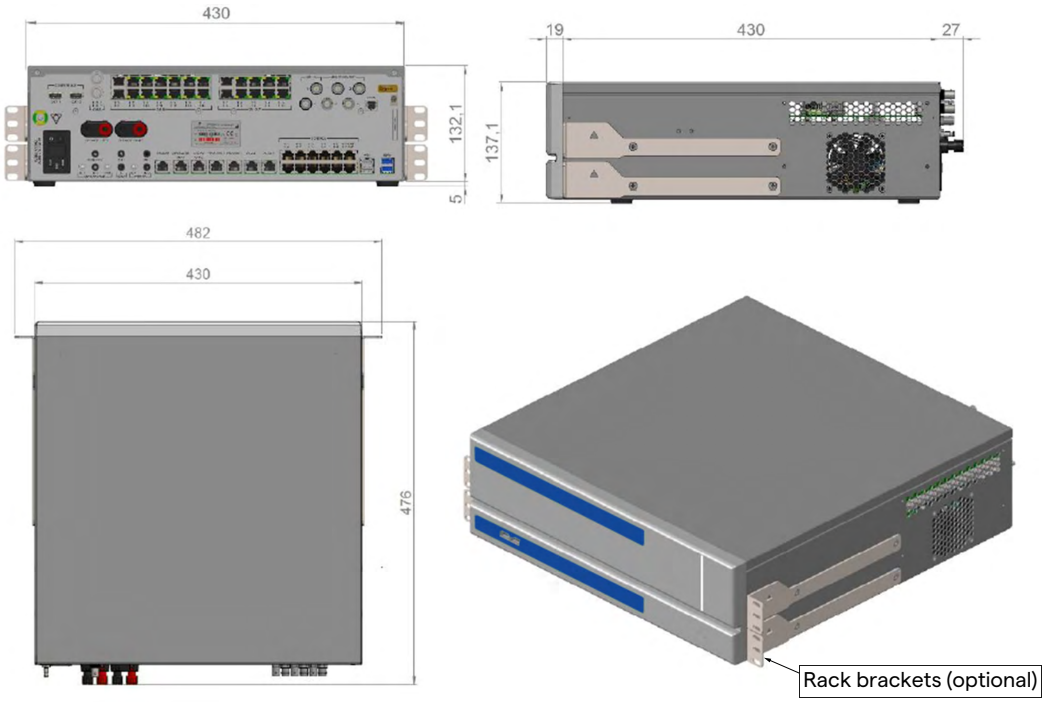
Rack Unit (Video-over-IP configuration) – Technical Specs

Dimensions	800 x 600 x 757 mm
Colour	RAL 7016 puckered
Environmental conditions	Operating temperature: +10°C/+30°C (1,000 m) / +26.6°C (2,000 m) / +18.6°C (3,000 m) Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 70.0 kPa to 106.0 kPa Storage temperature: -20/+50°C Storage relative humidity range: 15% to 93% non-condensing Storage atmospheric pressure range: 60.0 kPa to 106.0 kPa
Rack internal component	Two fans, forced ventilation produced minimum 2410 Cubic Meters per Minute (CMM) each Isolation transformer, power 1,000 VA
Max. operation altitude	3,000 m
Enclosure	IP20
Unit weight	64 kg

3.13 Measurement and weight layout

Main Unit	
Dimensions	133 x 430 x 450 mm
Unit weight	13.5 kg

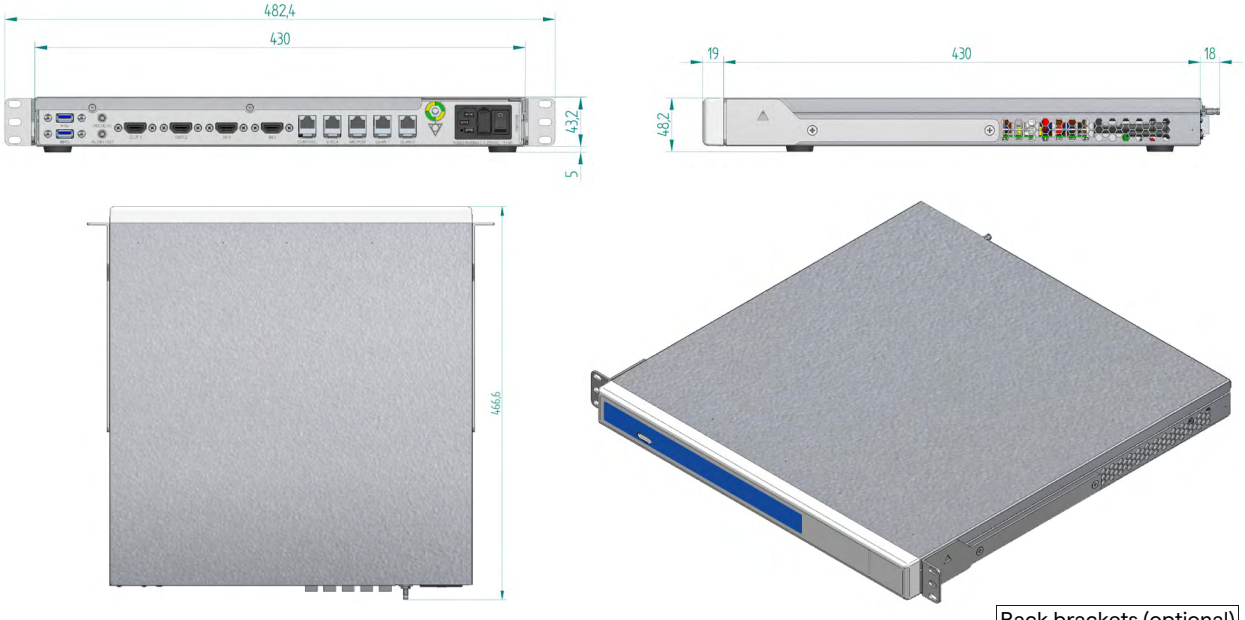
Rack dimensions (optional)



Conference Unit

Dimensions	44 x 430 x 450 mm
Unit weight	8 kg

Rack dimensions (optional)

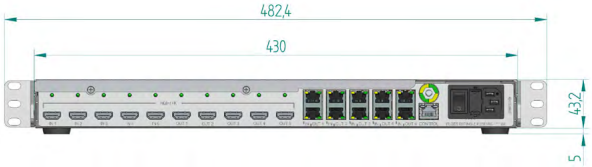


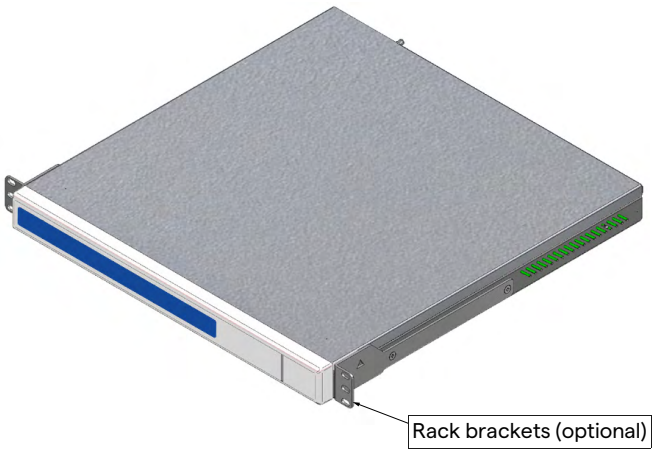
Rack brackets (optional)

4K Unit

Dimensions	44 x 430 x 450 mm
Unit weight	5.5 kg

Rack dimensions (optional)

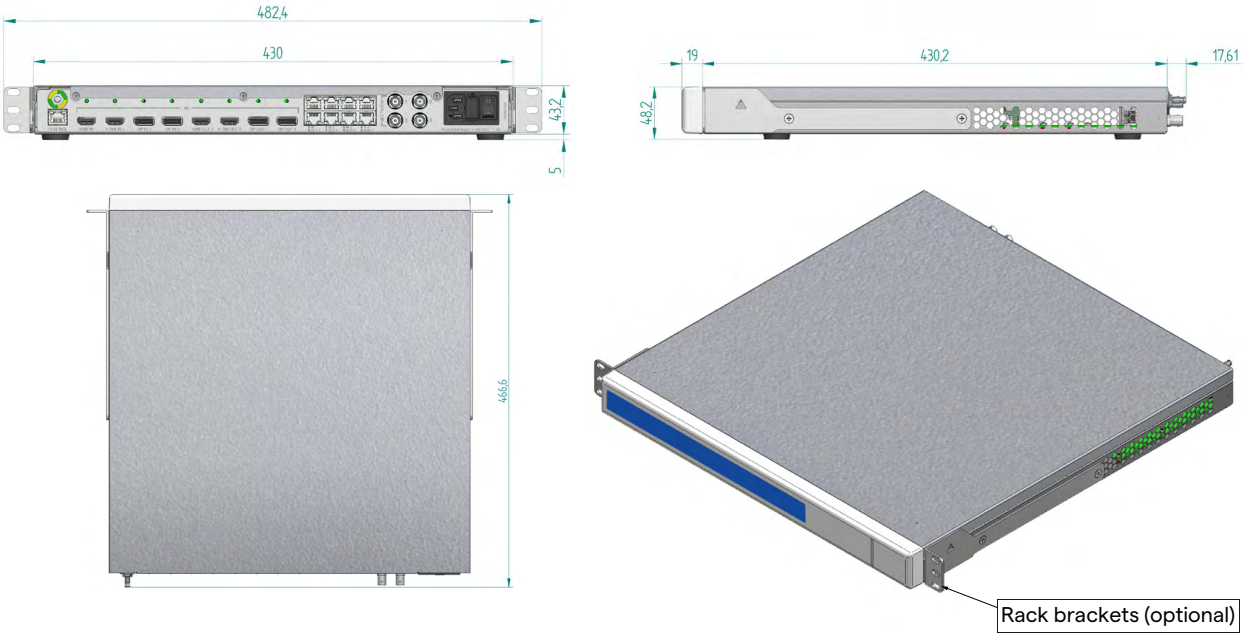




4K Plus Unit

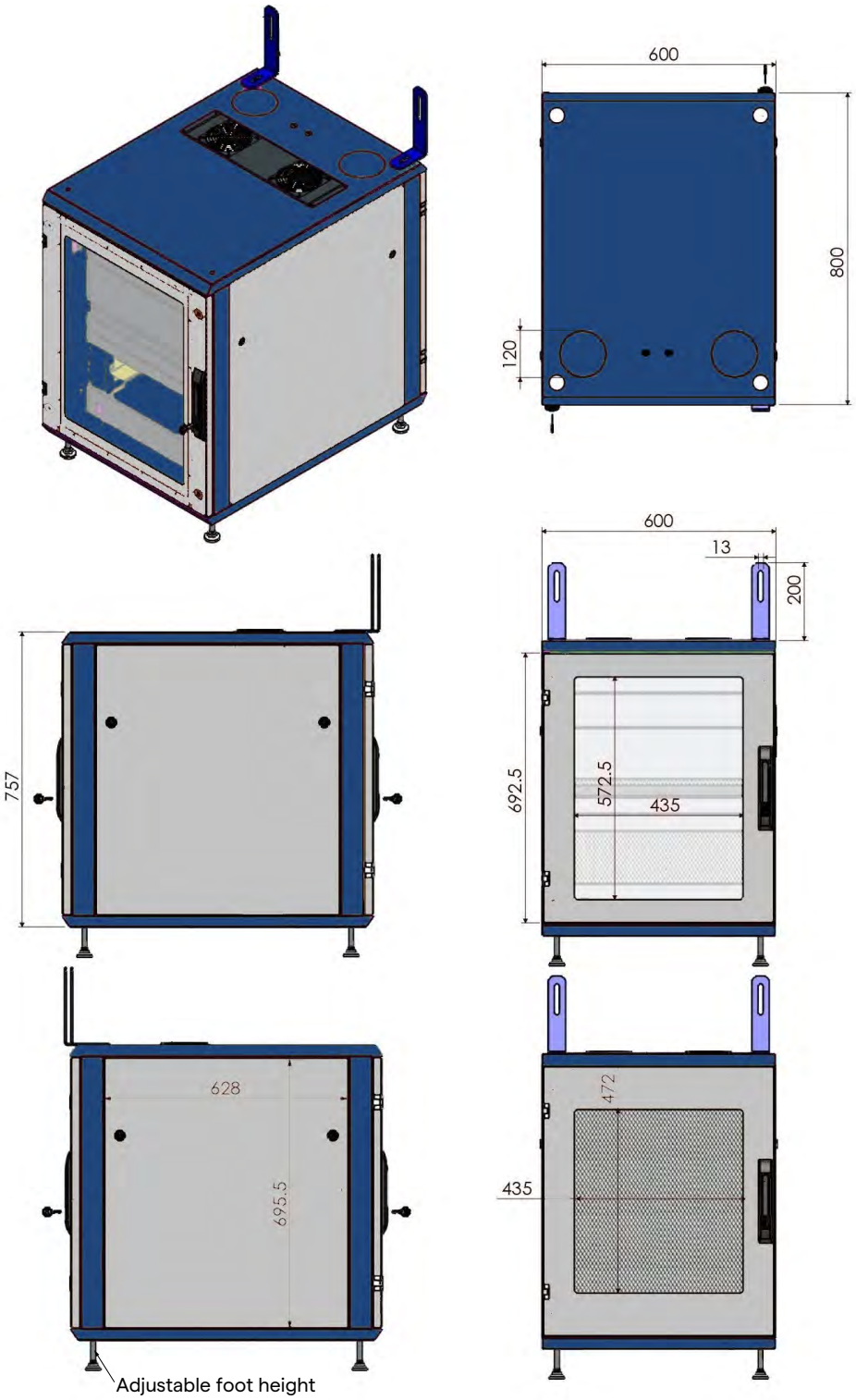
Dimensions	44 x 430 x 450 mm
Unit weight	5.5 kg

Rack dimensions (optional)



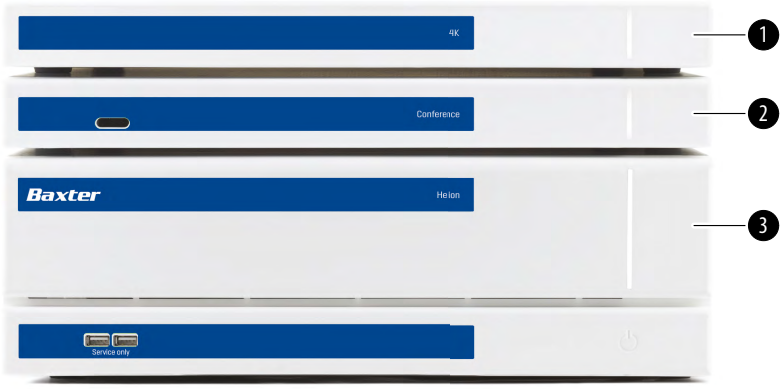
Rack Unit

Dimensions	800 x 600 x 757 mm
Unit weight	64 kg



3.14 System components

The Helion Video Management System has a modular structure composed of 3 operating units that can be used simultaneously. The only unit that can operate independently is the Main unit.



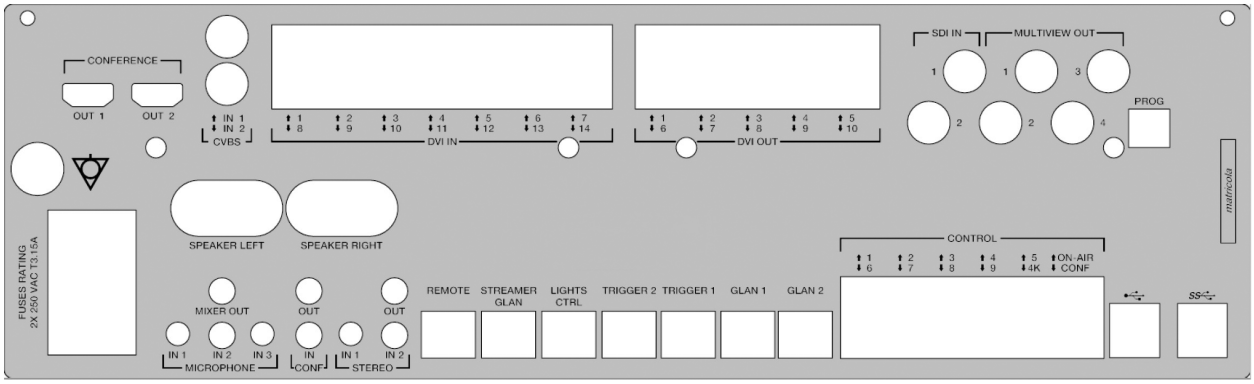
[1] 4K Unit or 4K Plus Unit
[2] Conference Unit
[3] Main Unit

3.14.1 Main Unit

The following functions are available via the Main unit.

Function	Description
ROUTING	Enables the distribution of the different sources present in the room to the recipient monitors.
PROCEDURE DOCUMENTATION	Enables documentation of the operation by temporarily storing and exporting the images and videos recorded.
VIDEO STREAMING	Enables the sharing of information outside the operating theatre via an HD streaming system.

The following connection ports can be found on the back of the unit. They are divided into the following sections:

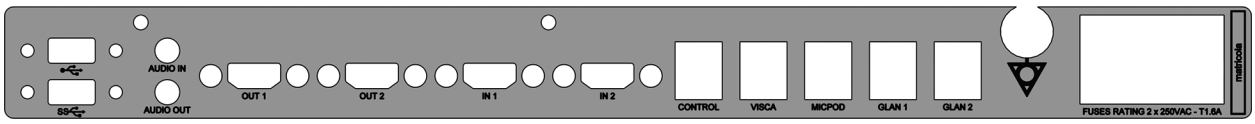


Connection cables are supplied by Videomed S.r.l.

3.14.2 Conference Unit

The Conference unit is equipped with Full HD video conference technology that allows the exchange of information in video conference with the operating theatre by sharing high-resolution images and videos outside the room.

The following connection ports can be found on the back of the unit.

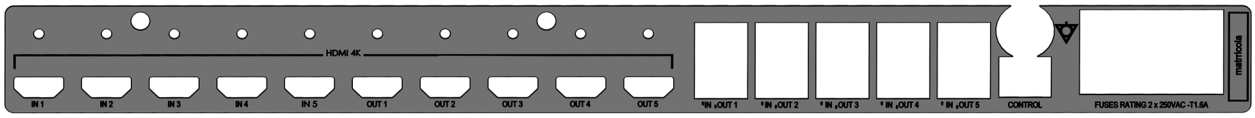


Connection cables are supplied by Videomed S.r.l.

3.14.3 4K Unit

The 4K Unit allows for the full management of signals with 4K/Ultra HD resolution.

The following connection ports can be found on the back of the unit. They are divided into the following sections:

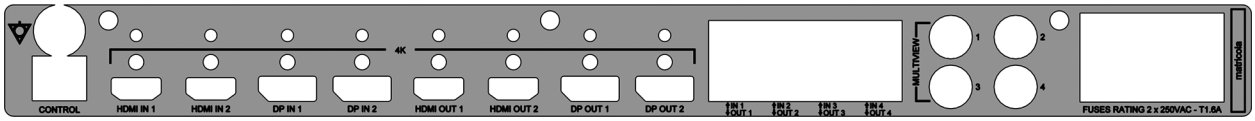


Connection cables are supplied by Videomed S.r.l.

3.14.4 4K Plus Unit

The 4K Plus unit allows full management of 4K/Ultra HD resolution signals (at Ultra HD standard resolution).

The following connection ports can be found on the back of the unit. They are divided into the following sections:

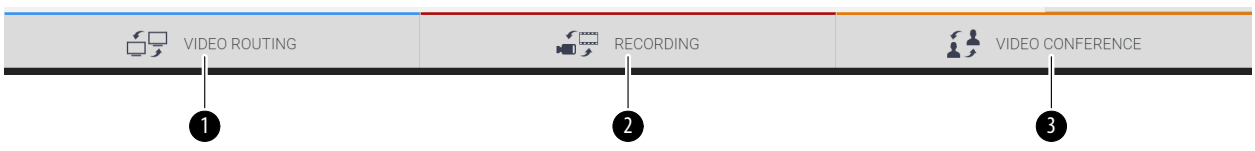


Connection cables are supplied by Videomed S.r.l.

3.14.5 Control software

The user interface of the Helion Video Management System allows each functional unit to be controlled and managed.

A lower selection bar (always visible) allows the sections of the software to be uniquely identified based on the function performed.



The sections of the selection bar are described below:

No	Function	Description	Image
[1]	VIDEO ROUTING	The BLUE button identifies the section of the VIDEO ROUTING function. This function allows the distribution of video signals to all monitors installed in the operating theatre.	
[2]	RECORDING	The RED button identifies the section of the VIDEO RECORDING function. This function enables the recording of images and videos.	
[3]	VIDEO CONFERENCE	The ORANGE button identifies the section of the VIDEO CONFERENCE function. This function enables two-way audio/ video communication.	

The Helion Video Management System also ensures control and management of the main devices installed in the operating theatre:

- PTZ Roomcam;
- surgical lights with surgical video camera.

All of the functions available in the Control Software are described in detail in the ‘User interface’ chapter of these instructions for use.

4 Operation

4.1 First system start

The Helion Video Management System is delivered to the operator by authorised installer technical personnel from Videomed S.r.l.

System commissioning requires for the operator to be adequately trained on the functional and visual controls, on the adjustments and calibration, on system cleaning and maintenance, and on the applicable user instructions.

Delivery of the Helion Video Management System is validated by a document signed by the operator.

Once the system has been commissioned, the instructions included in this manual are binding for the user.

4.2 Preliminary checks

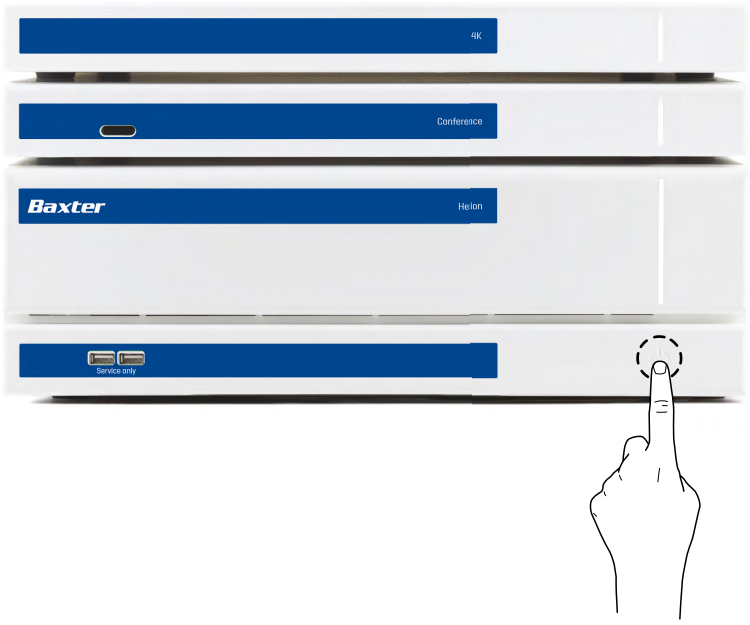
Before each use, check the components of the control screen, paying attention to:

- monitor assembly stability;
- loose parts on the monitor body;
- visible damage, in particular abrasion of plastic surfaces or damage to paint.

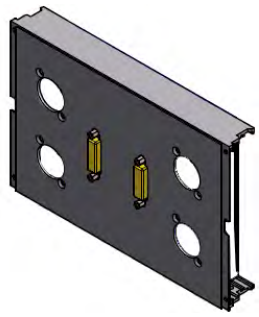
Cleaning is carried out during maintenance.

4.3 System startup

In order to start the system, proceed as follows:

Step	Image
1. Place your finger on the touch button until the front LEDs turn on. The LEDs will start to flash.	

4.4 Connection to sources



When a new video source is connected to the system, a dynamic Preview (frame) is displayed in the Source List, showing the name of the socket/line used.

The Preview updates periodically as long as the signal remains active.

To connect new video sources to the system, simply connect the desired source to one of the compatible video connections on the connection plates installed on the pendant panels.

Based on the configuration installed, the following connections may be present:

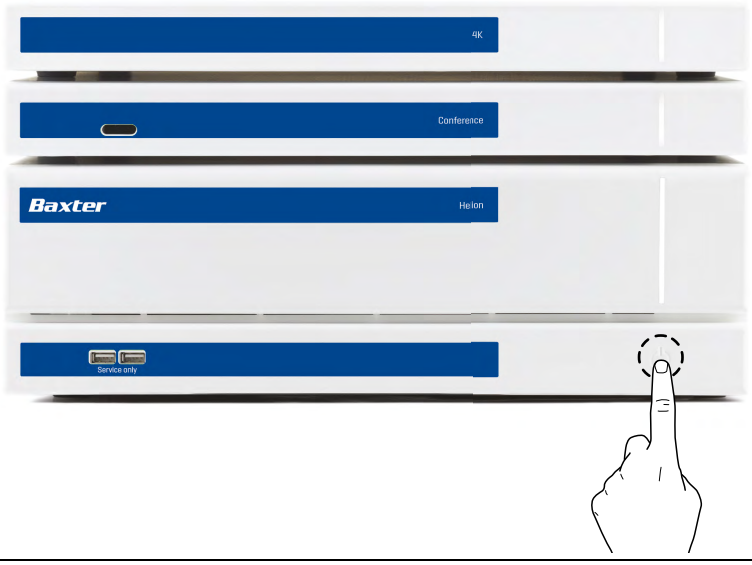
- DVI
- 3G/HD/SD-SDI
- CVBS (Composite)

The technical drawing shows an example of the connection plates installed on the pendant panels.

In case of Helion Video over IP configuration, Neutrik universal port connectors will be supplied and installed to connect video sources to Helion.

4.5 System shutdown

To shut down the system, proceed as follows:

Step	Image
1. Keep your finger on the touch button for about 5 seconds, until the frequency of flashing of the LEDs visibly increases. 2. Once the frequency changes, remove your finger from the button.	

In the event of system shutdown, it is possible to force system deactivation by keeping your finger on the button until it is completely switched off and then restarting the device by following the startup procedure outlined in the paragraph ‘System startup’.

It is recommended that forced shutdown only be used in an emergency, as this procedure may cause data loss.

Should it be necessary to interrupt communication between Helion and any controlled devices, proceed to shut down the system.

4.6 System startup/shutdown with remote button

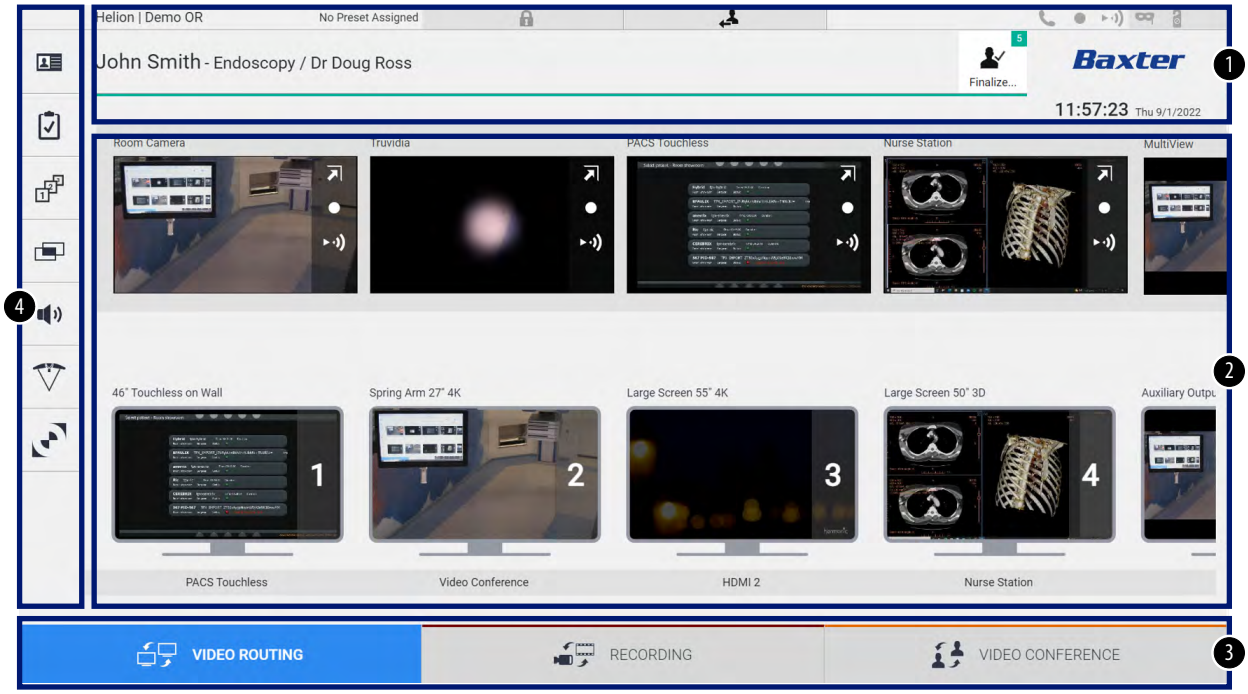
The Helion Video Management System allows units to be restarted via a remote on/off button installed inside the operating theatre (typically on a pendant panel or wall unit).

Using this solution, the operator can manage the entire video management system without needing to access the Technical rack. The units inside the Rack can therefore only be switched off by technical and authorised/trained VIDEOMED personnel for service or maintenance sessions.

5 User interface

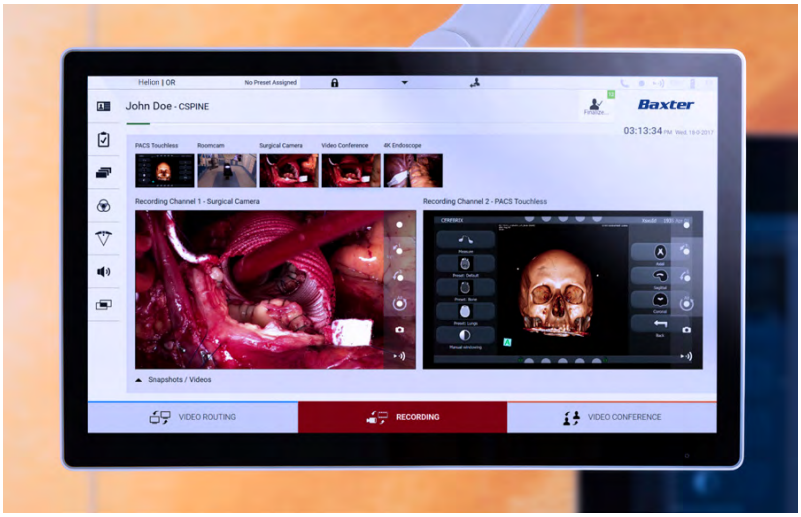
5.1 General description of the user interface

The user interface is divided up as follows:



No	Element	Description
[1]	STATUS BAR	Contains important information such as the patient's name and the number of recorded media related to them. Information such as the date and time and a dashboard showing the status of the recording, video conference, streaming and advanced modes 'Privacy Mode', 'Do Not Disturb' and 'Lecture Mode' are also provided.
[2]	MAIN SECTION	Source selection and monitor identification area. The structure of the area varies based on the control functions activated.
[3]	SELECTION BAR	A bar located at the bottom of the screen, which allows selection of the following functions: – Video Routing (marked in blue); – Recording (marked in red); – Video Conference (marked in orange).
[4]	SIDE MENU	A bar on the left side of the screen that provides access to the setup and workflow management screens.

5.2 Control touch screen



The control screen is a high-resolution touch screen. The user interface buttons are activated by a brief touch of the finger, or by swiping.

The control screen has its own setup menu to access the monitor settings:

- brightness: intensity of the entire display screen;
- contrast: the difference in brightness between the different light and dark areas of the screen.

The menu control settings are located to the side or at the bottom of the monitor, depending on the model purchased.

Refer to the user manual of the touch screen monitor for further information.

Information regarding the serial number identifying the model can be found on the back of the screen.

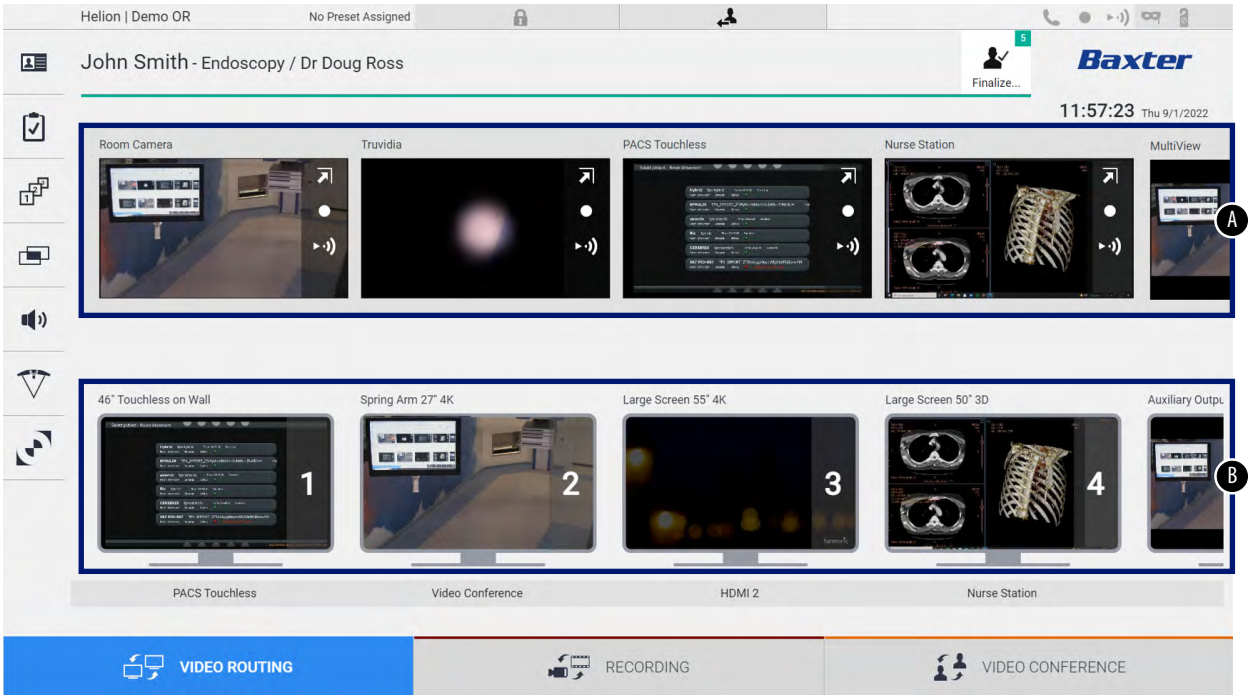
5.3 'Video Routing' function

The Video Routing function allows you to manage images from the various sources present in the operating theatre, such as:

- endoscope;
- surgical video camera;
- roomcam.

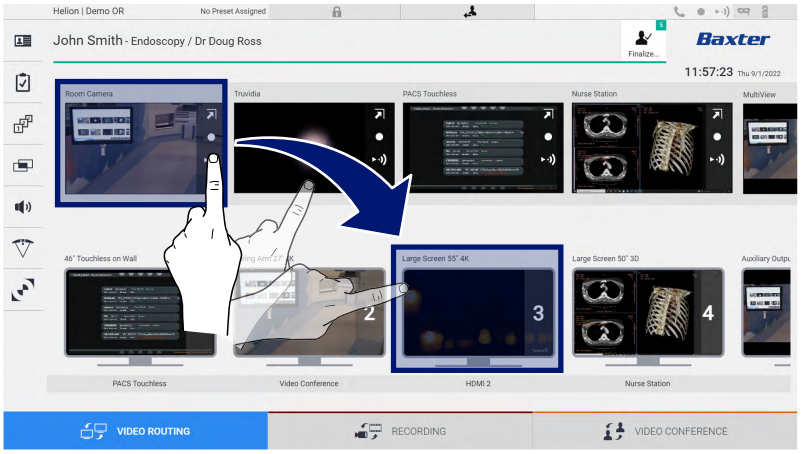
These video signals can be routed to any monitor in the operating theatre.

The main Video Routing screen is divided as follows:



[A] list of sources connected;
[B] list of monitors enabled.

To send a video signal to a monitor, drag the relevant image from the Source List [A] available and drop it into one of the enabled monitors [B] using drag&drop.



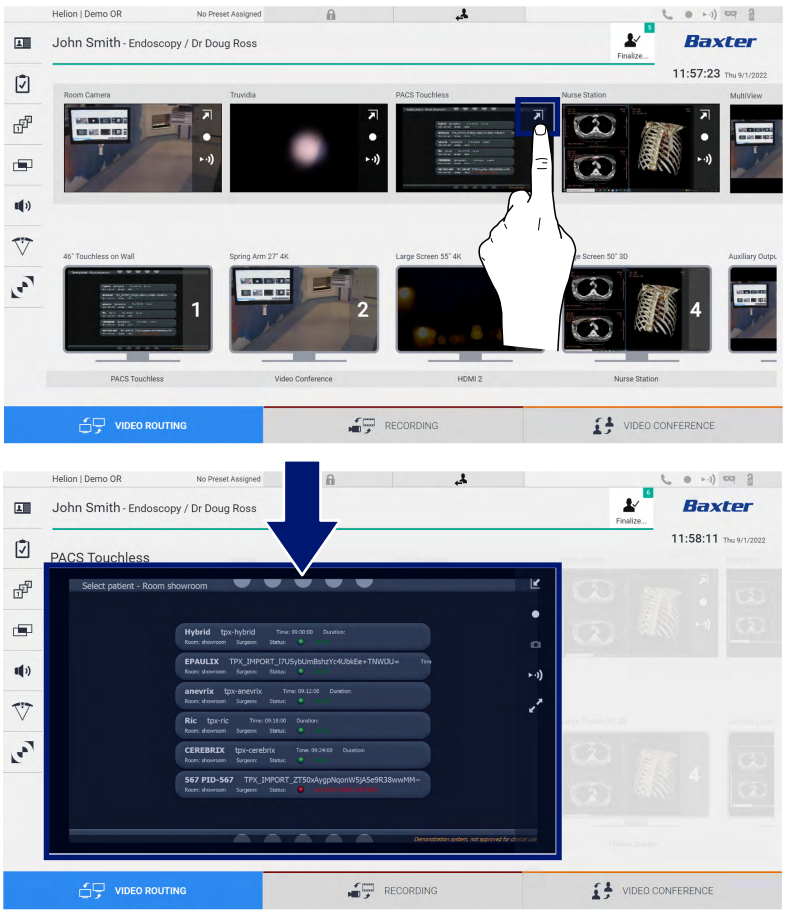
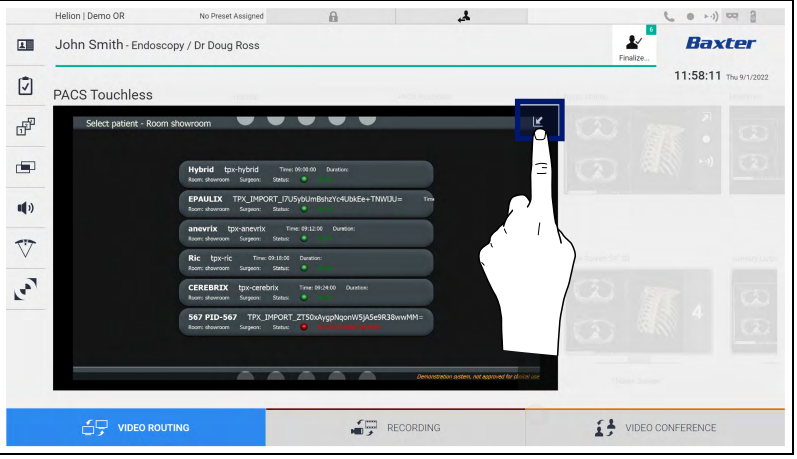
The Preview of the video signal sent will be displayed in the relative monitor icon and updated periodically.

To remove the signal from a monitor, select it from the Monitor List and press ✕.

5.3.1 Live Preview

The Live Preview function can be used to enlarge or reduce the preview of the video signal of each connected source.

To display the Live Preview of one of the signals available in the Source list, proceed as follows:

Step	Image
1. Press the icon in the corresponding Preview. An enlarged version of the selected image is displayed.	
2. Press to return to the Video Routing section standard view.	

The following icons are present in the Live Preview window:

Icon	Function
	Starts/stops recording of the displayed signal. If the icon is greyed out, this indicates that the function is not active. To activate the function, select a patient from the list (refer to paragraph 'Selecting a patient from the list').
	Creates snapshots of the image.
	Starts/stops video signal streaming.
	Activates the full-screen display function, without latency, of the selected source (function available only on some touch screen monitor models).

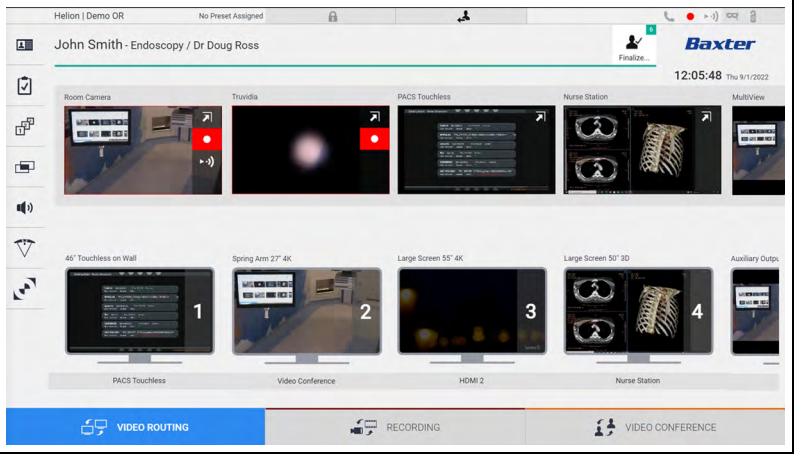
It is not possible to start recording if a reference patient is not present.

5.3.2 Quick Access – Recording

It is possible to use a quick activation system directly from the Video Routing screen to start recording. A dedicated Recording screen is available to access advanced functions.

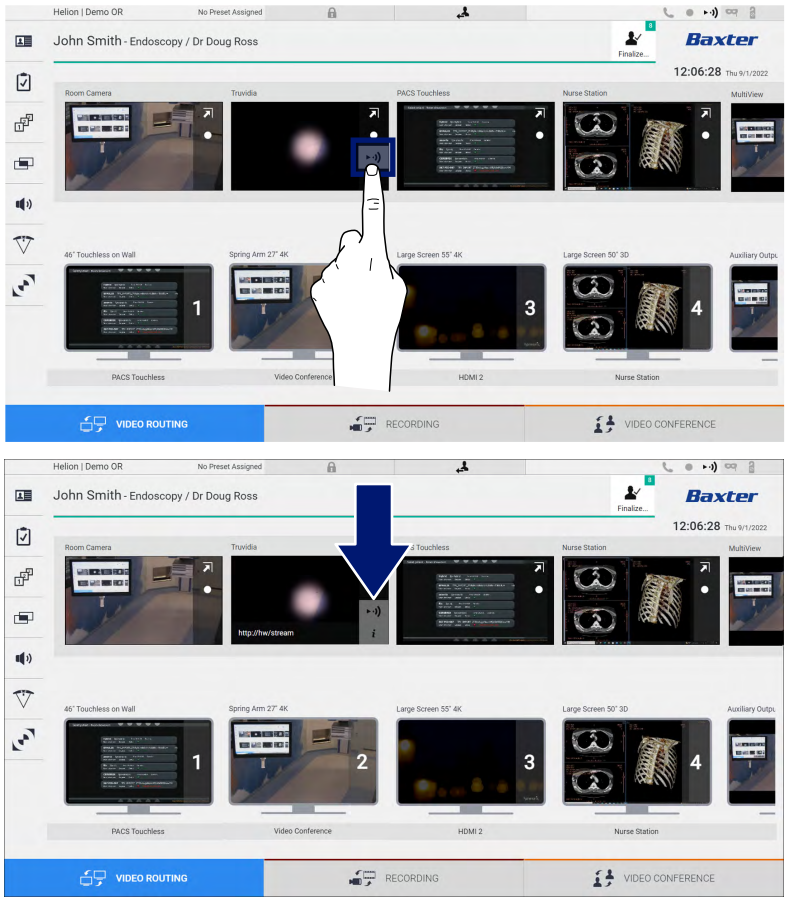
A dedicated Recording function enables recording. In any case, it is possible to use an additional quick activation system from the Video Routing function.

To record using the Video Routing function, proceed as follows:

Step	Image
1. Press the ● icon of a Preview to start recording a signal. When recording is in progress, the button is red ●. The ● icon is also present in the upper part of the screen and also remains visible when navigating through other functions (if recording is active).	
2. In systems where the dual recording channel is enabled, this function can be activated on two sources at the same time.	

5.3.3 Quick Access – Streaming

To activate streaming, proceed as follows:

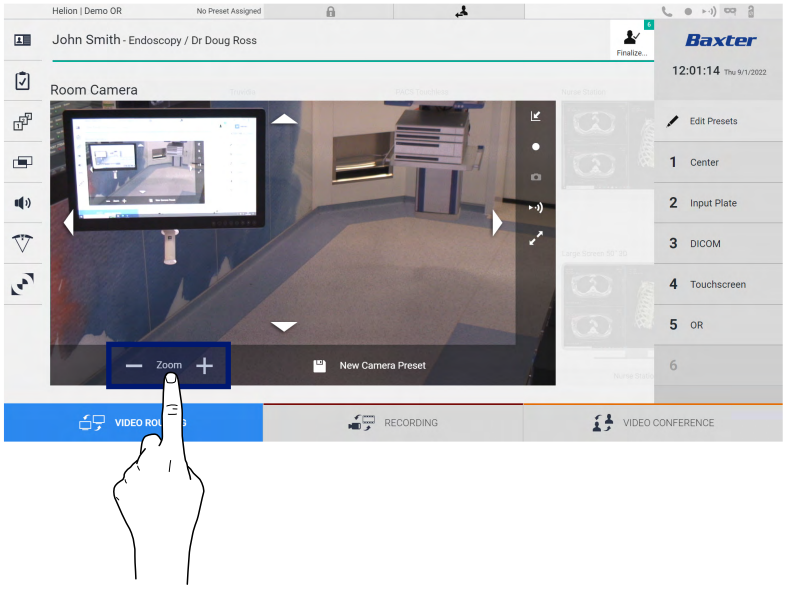
Step	Image
1. Press the icon of a Preview to start streaming the signal from one of the connected sources. When streaming is active, the button appears with a white background in the Preview box of the selected source, and is disabled for the remaining source Previews. Pressing in a Preview box also activates the icon that shows the user the link to connect to the streaming session. Using this link, each user can therefore connect to the streaming session by using applications that are capable of reproducing a network video stream (e.g. VLC). If the room streaming session is interrupted, external communication will also be interrupted.	

5.3.4 PTZ camera control

If activated on a controllable camera signal, the Live Preview function will allow access to its movement controls.

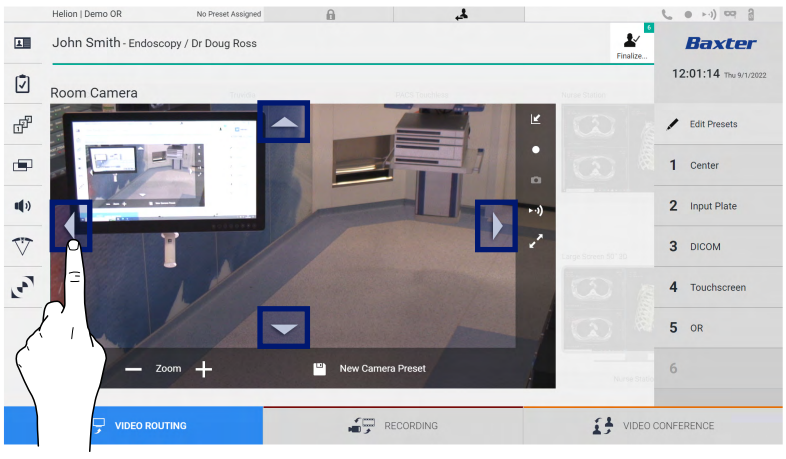
5.3.4.1 Roomcam zoom adjustment

To adjust the zoom of the Roomcam, proceed as follows:

Step	Image
1. Use ▬ and ✚ to adjust the zoom to obtain the desired image (view).	

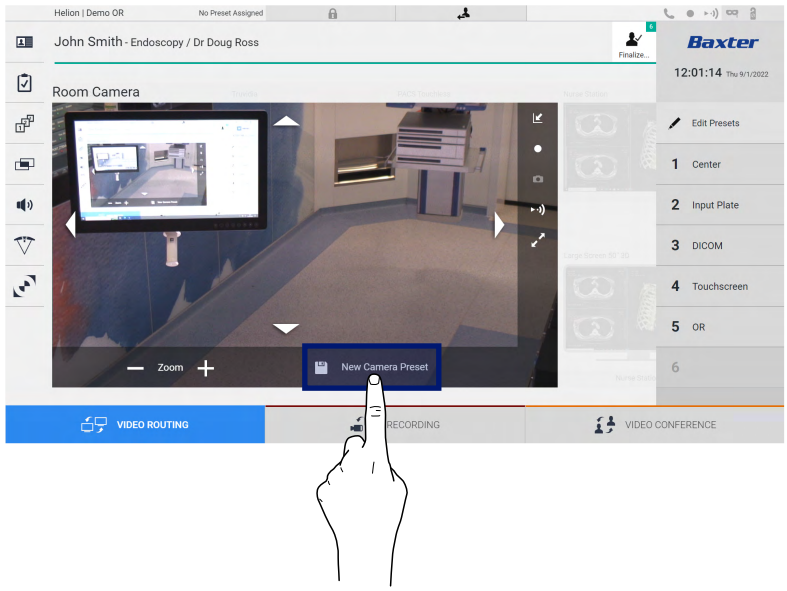
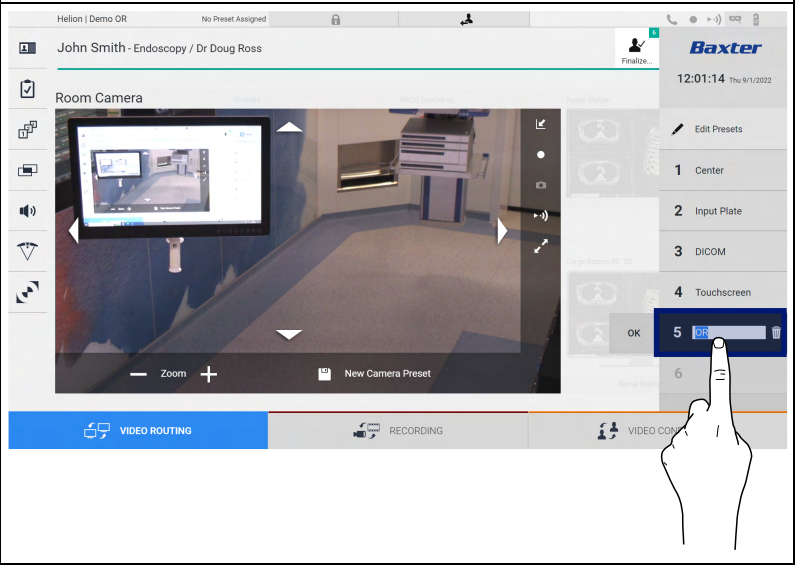
5.3.4.2 Roomcam movement adjustment

To adjust the movement of the Roomcam, proceed as follows:

Step	Image
1. Use the arrows ◀ on the screen to adjust the movement of the Roomcam.	

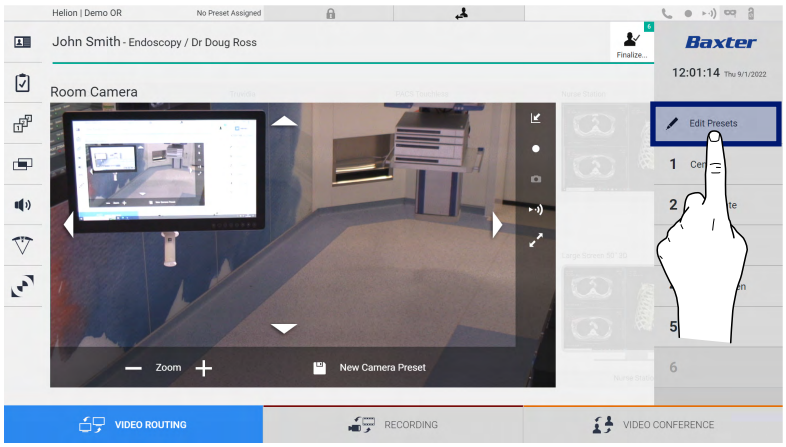
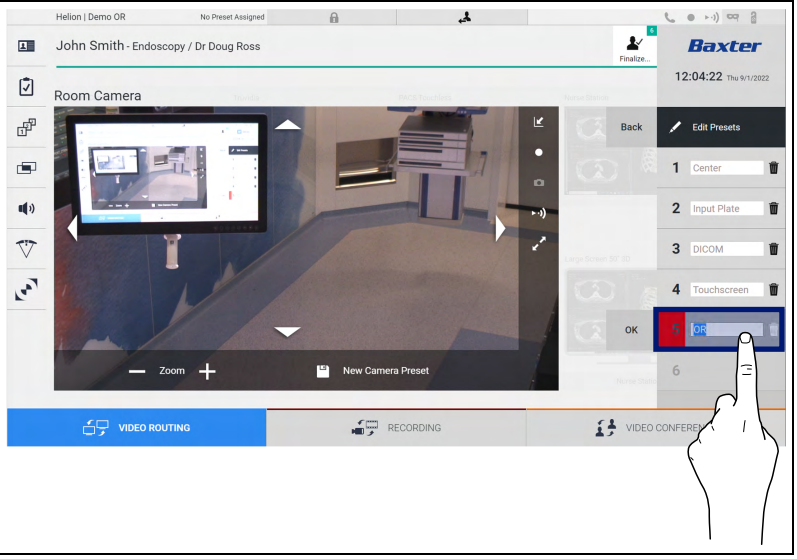
5.3.4.3 Saving a camera setting (Preset)

To save a specific video camera setting (Preset), proceed as follows:

Step	Image
1. After the video camera has been adjusted to the desired position, press Save as a New Preset.	
2. Give it a name and press OK to confirm. The new named Preset will appear on the list on the side.	

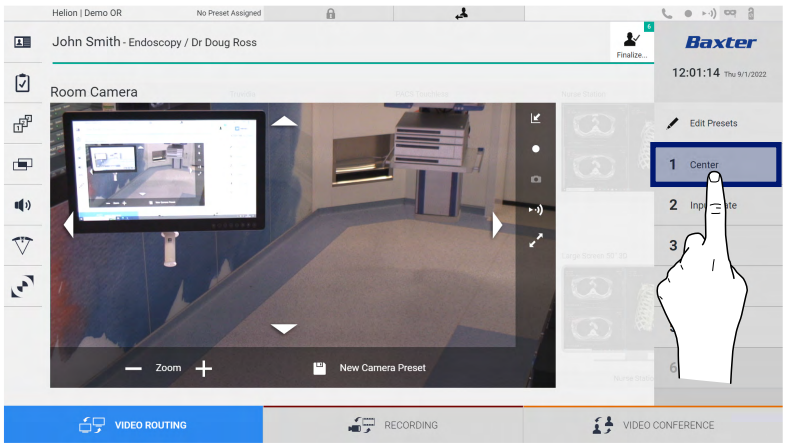
5.3.4.4 Deleting a camera setting (Preset)

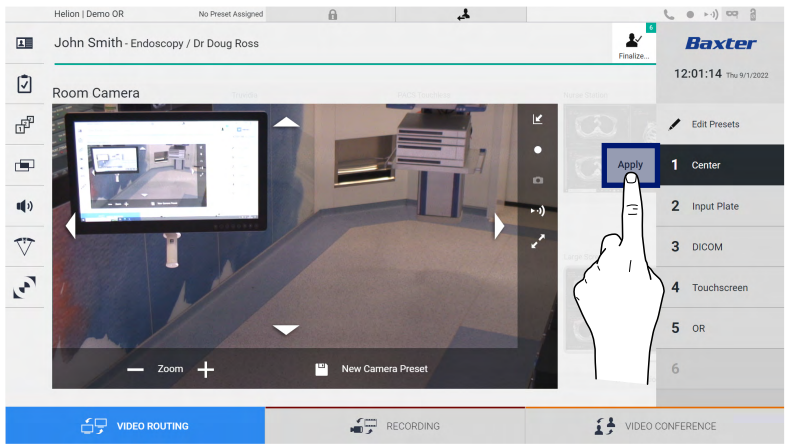
To delete a video camera setting from the Preset list, proceed as follows:

Step	Image
1. Press Edit Presets.	
2. Press and hold the 5 center focused button until it is deleted.	

5.3.4.5 Enabling a camera setting (Preset)

To activate a video camera Preset, proceed as follows:

Step	Image
1. Press the desired Preset in the list.	

Step	Image
2. Press Apply to confirm the Preset selection.	

5.4 'Recording' function

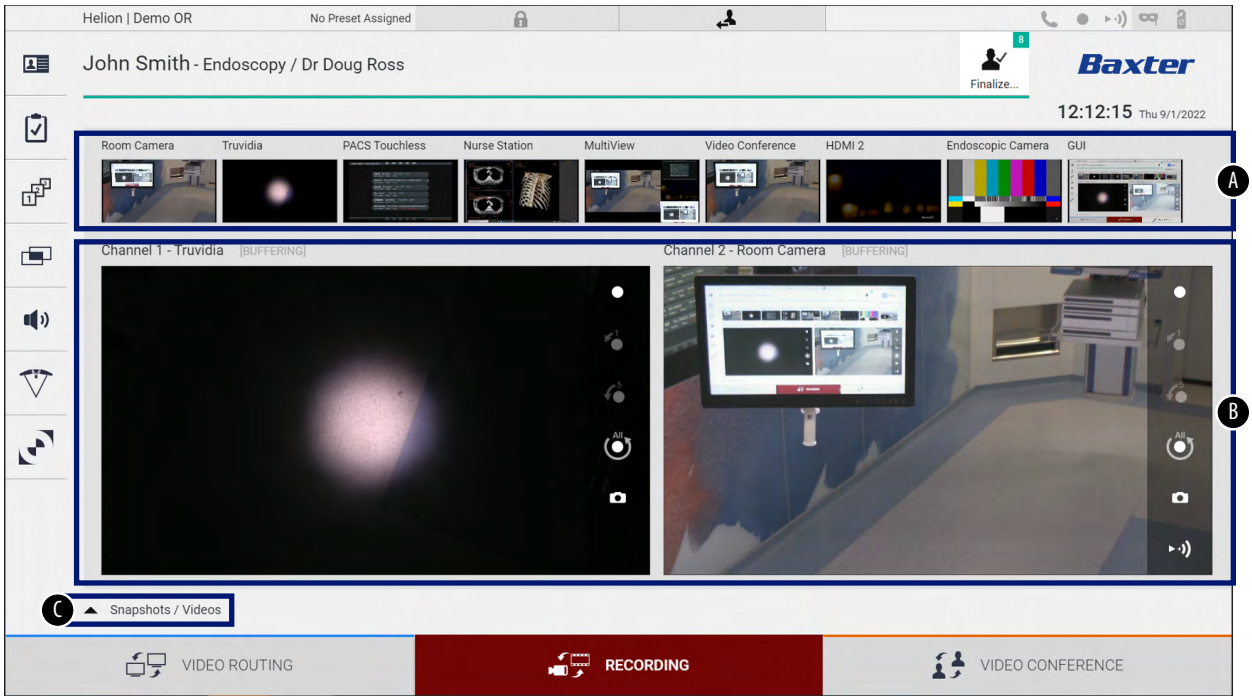
The Recording function enables capture snapshots and video recording from the signals connected to the system.

This enables users to save images and videos to the system and then edit them. Recorded material can then be sent to a dedicated server (connected storage systems such as PACS, network or mobile storage media).

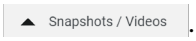
The Recording function includes:

- capturing still images;
- video recording (audio included);
- image and video post-processing.

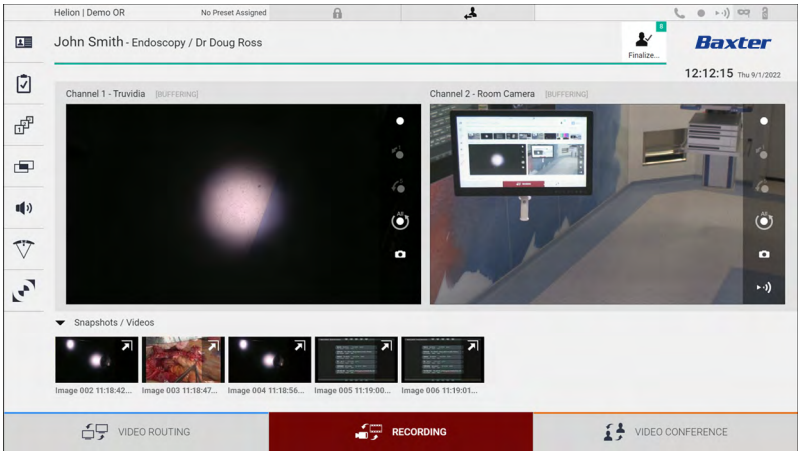
The main Recording screen is divided as follows:



[A] source list;
[B] view of the two recording channels;
[C] list of screenshots and videos stored.

The user may view and reproduce any material stored during the surgical activity (images and video) at any time by pressing the icon 

. In this way, a list will appear on the screen containing all previews of stored files, which can then be reproduced and processed using the functions described in the paragraph ‘Snapshot and video playback’.



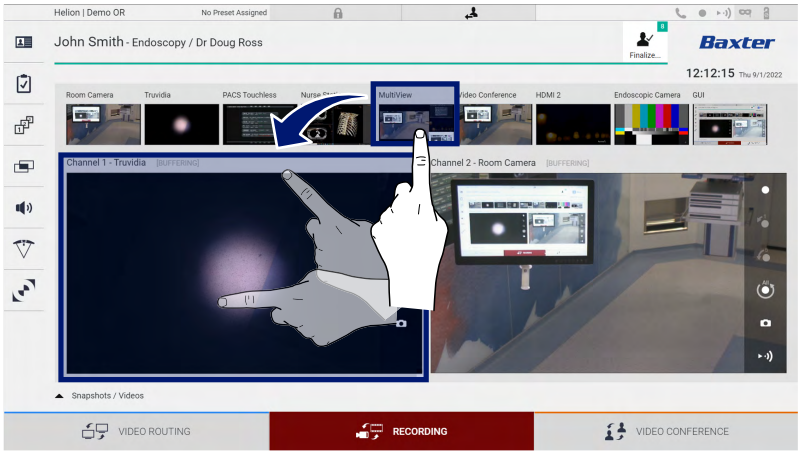
5.4.1 Image data post-processing

By using locally stored data, it is possible to:

- create video sequences out of screenshots saved during the operation (MATS – Movie Around The Snap);
- create still images generated from previously recorded video;
- create annotations on video clips or text information on images;
- add annotations to videos and images captured.

5.4.2 Selecting the signals to be recorded

Drag the source you wish to record a video or capture snapshots from into the Recording Channel box, where you will get a Live Preview of the signal and the basic and advanced recording functions will be enabled.



The following icons are available in the Recording Channel window:

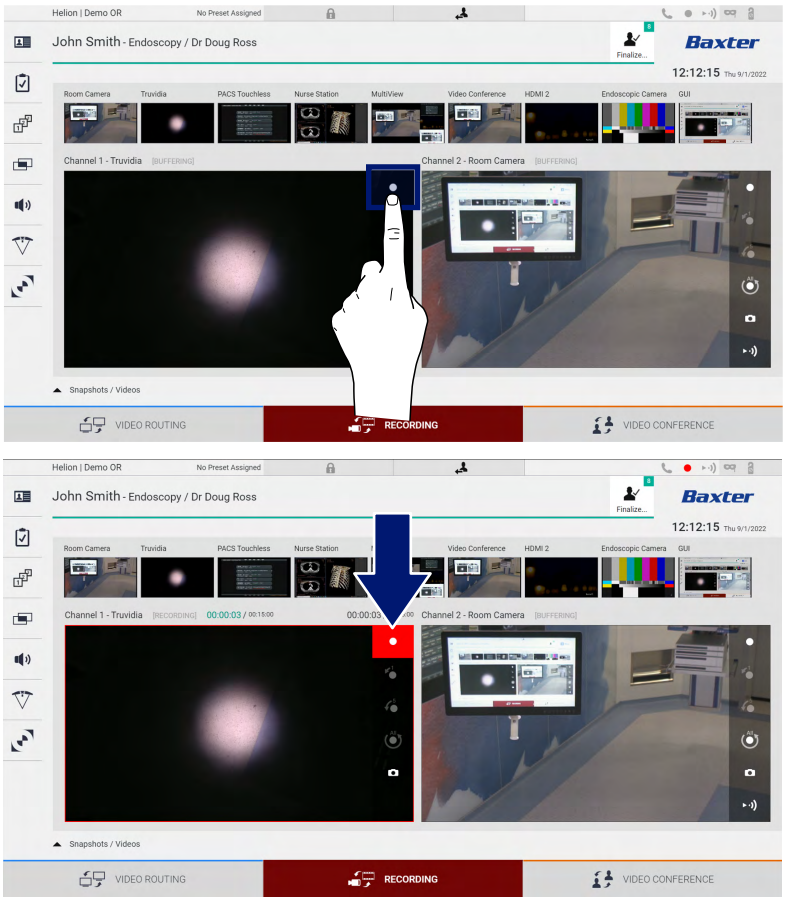
Icon	Function
	Starts/stops recording of the displayed signal. If the icon is greyed out, this indicates that the function is not active. To activate the function, select a patient from the list (refer to paragraph 'Selecting a patient from the list').
	Creates snapshots of the video source.
	Starts/stops video signal streaming.
  	Starts recording: – 1 minute before; – 5 minutes before; – the entire buffer available (up to a limit configurable by the technician).

Channel selection and recording will in no way affect the signals sent to the monitors via Video Routing.

It is not possible to start recording if a reference patient is not present.

5.4.3 Recording

To record from the Recording function, proceed as follows:

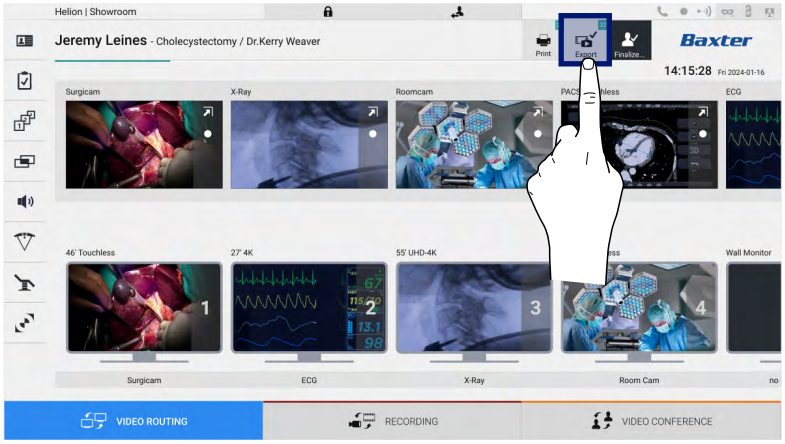
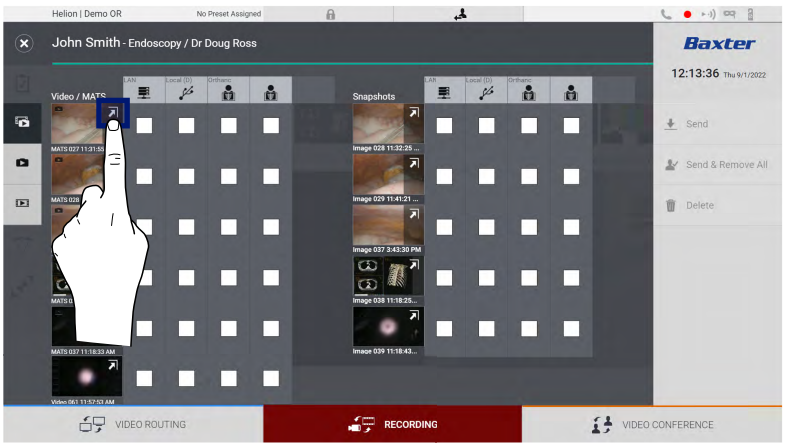
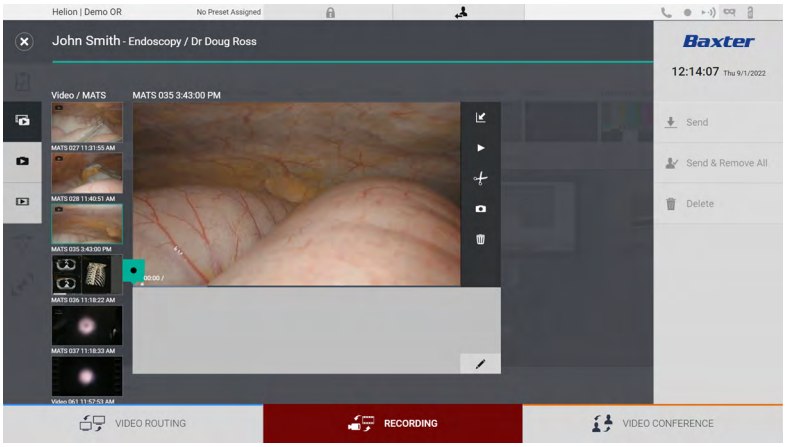
Step	Image
1. Press the ● icon of a Recording Channel to start recording a signal. When recording is in progress, the button is red ● in the selected Recording Channel. The ● icon is also present in the upper part of the screen and also remains visible when navigating through other functions (if recording is active).	

All videos and images related to the patient will be saved in the dedicated folder.

The number in the Finalize... icon shows how many media items have been associated with that patient. Press the icon to access the storage folder.

5.4.4 Snapshot and video playback

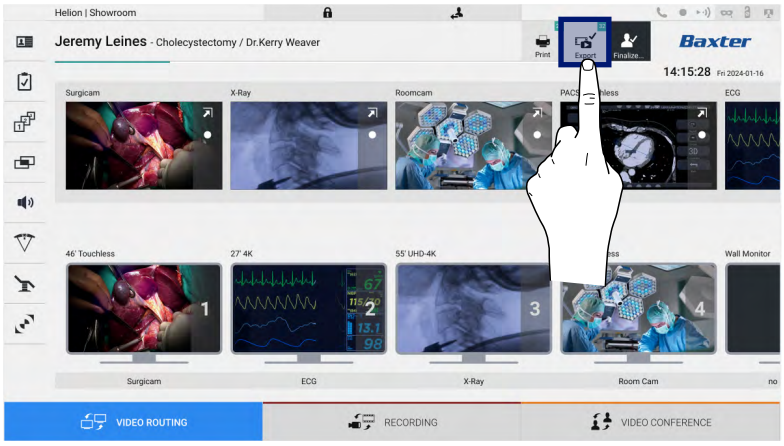
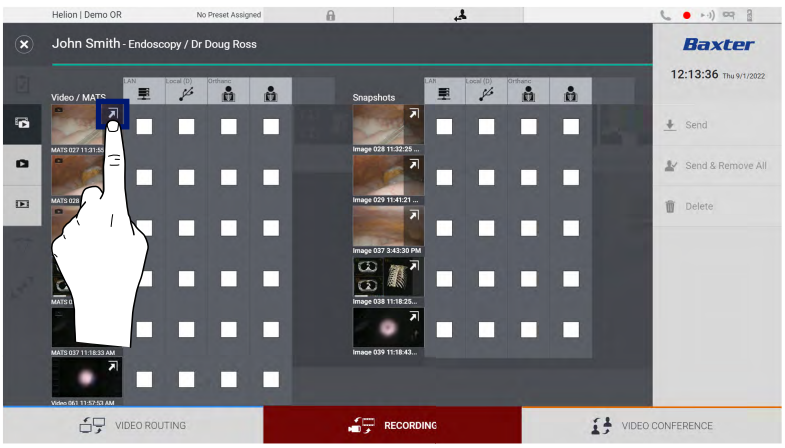
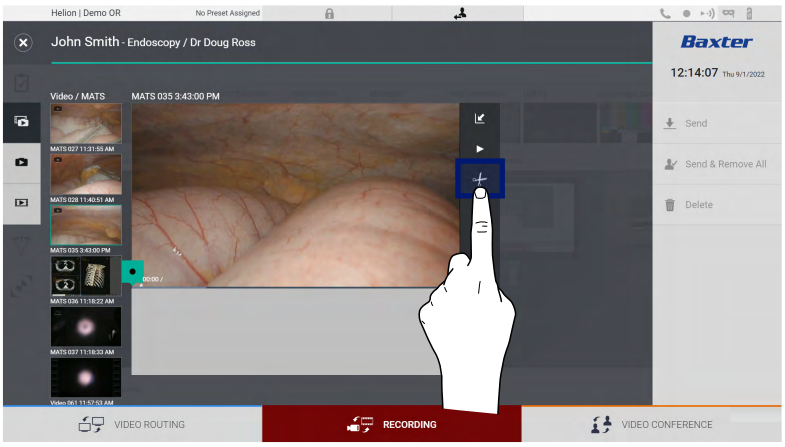
To play snapshots and videos, proceed as follows:

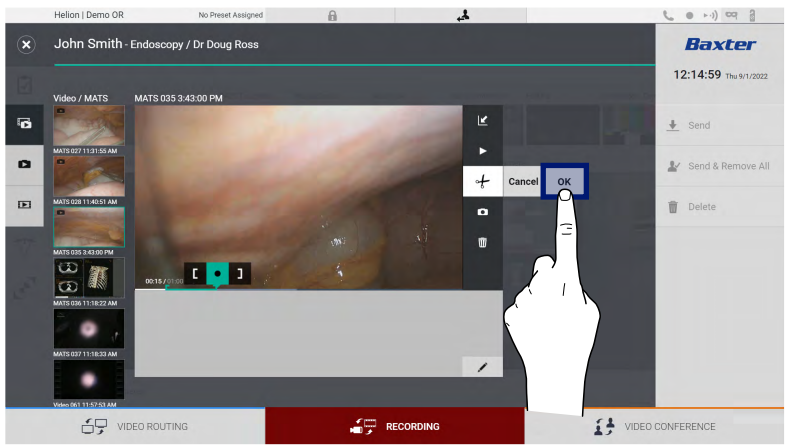
Step	Image
1. Press Finalize and then Export (or simply press Export if the printing function is not enabled) to view all images and videos related to the selected patient.	
2. Press the icon to enlarge the selected media item.	
3. A new window appears which, depending on the file selected (image or video), allows you to:	

Icon	Function
	Delete the file.
	Add a comment.
	Play the video.
	Interrupt video playback.
	Extract a part of the video.
	Return to the full view of available functions.
	Create a snapshot from the video being played.

5.4.5 Cutting video

To cut videos, proceed as follows:

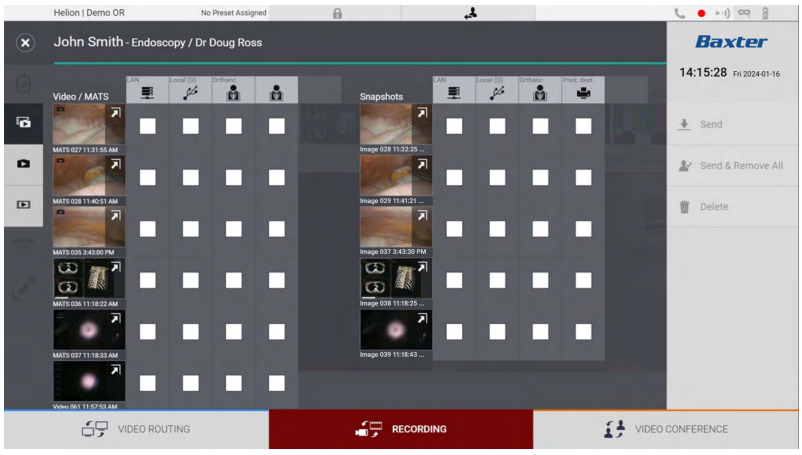
Step	Image
1. Press Finalize... and then Export (or simply press Export if the printing function is not enabled) to view all images and videos related to the selected patient.	
2. Press the icon to enlarge the selected media item.	
3. Press the icon. A cursor appears on the progress bar. Press [to select the starting point of the video to be extracted and] for the end.	

Step	Image
4. Once the cutting points are determined, extract the cropped video by pressing OK. A new video appears in the photo/video list for the same patient.	

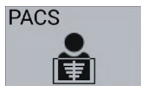
5.4.6 Export images and videos

Press Finalize and then Export (or simply press Export if the printing function is not enabled) to access the folder for exporting images and videos of the selected patient. This operation must be performed to export the media and, optionally, close the patient file.

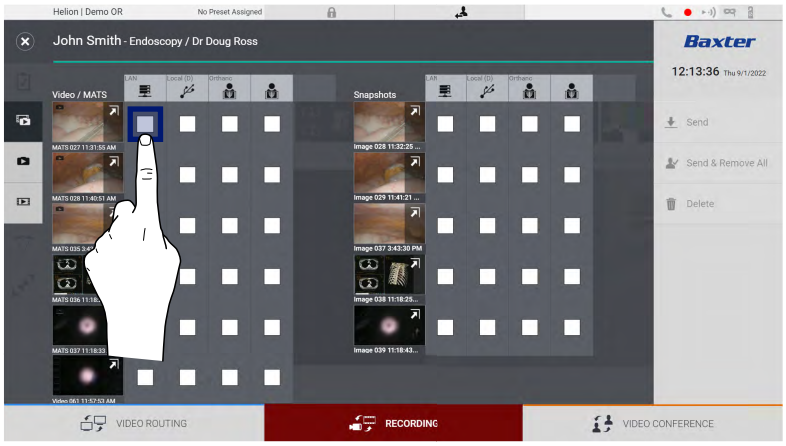
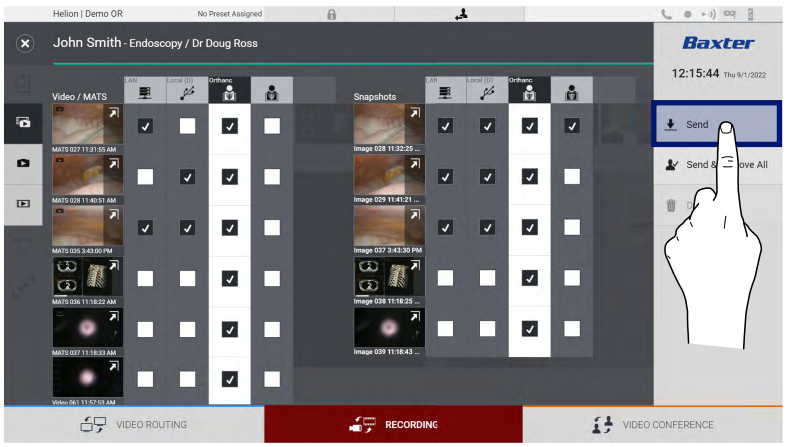
A screen will display all the captured images and videos.



The following icons are available in the Export window:

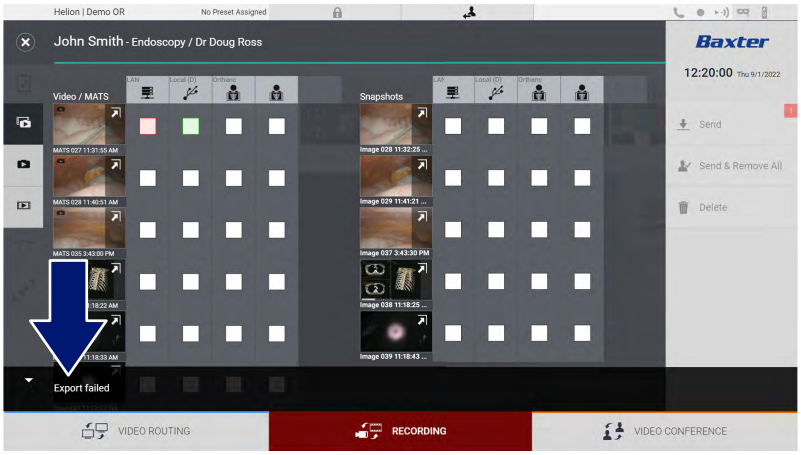
Icon	Function
	Exports via LAN to another device.
	Saves on a device connected to the USB port.
	Exports to the PACS system.
	Exports via LAN to a network destination connected to an external printer.

To export, proceed as follows:

Step	Image
1. Select the export destination. This must be done in order for the images or videos to be exported.	
2. Press Send (on the right side of the screen) to send the files to the selected destinations. Pressing Send & Remove All sends the files to the selected destinations and deletes the patient's session.	

The activation of each of the export options shown above depends on settings that must be authorised and guided by the hospital's IT managers.

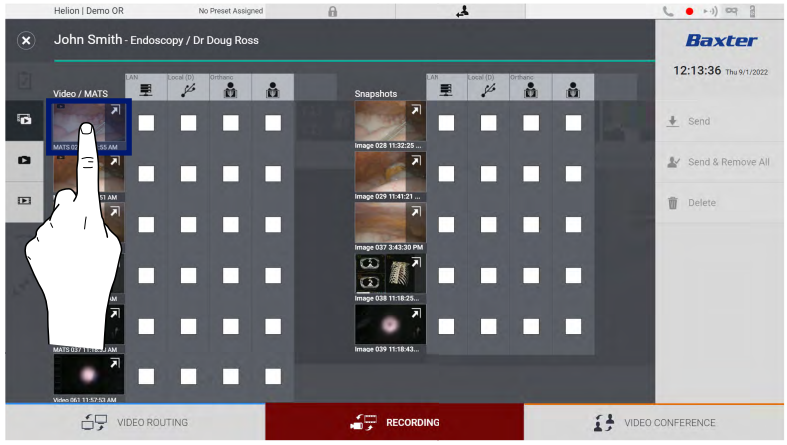
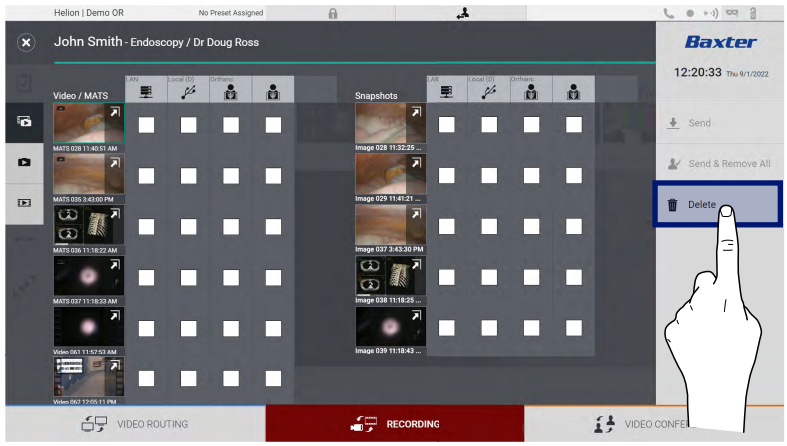
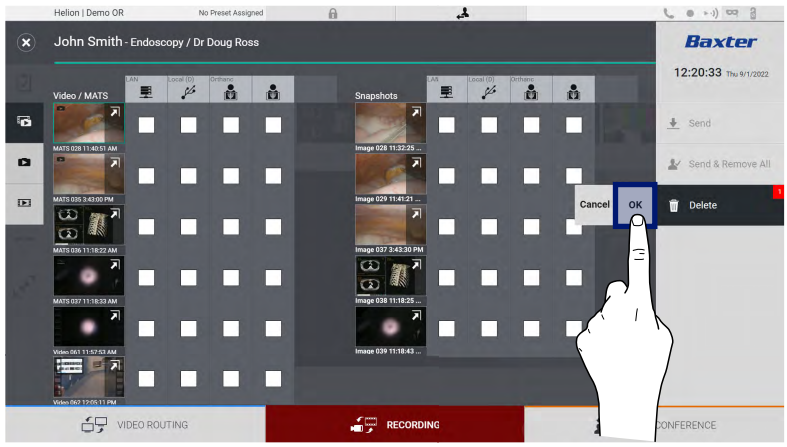
If the export destination does not respond (e.g., USB device not present), the system displays an 'EXPORT FAILED...' error message and the icon ! appears on the right side of the screen. A red checkbox is displayed for each destination to which the selected file could not be exported, as shown in the figure below.



5.4.7 Delete images and videos

Press Finalize and then Export (or simply press Export if the printing function is not enabled) to access the folder for storing images and videos of the selected patient.

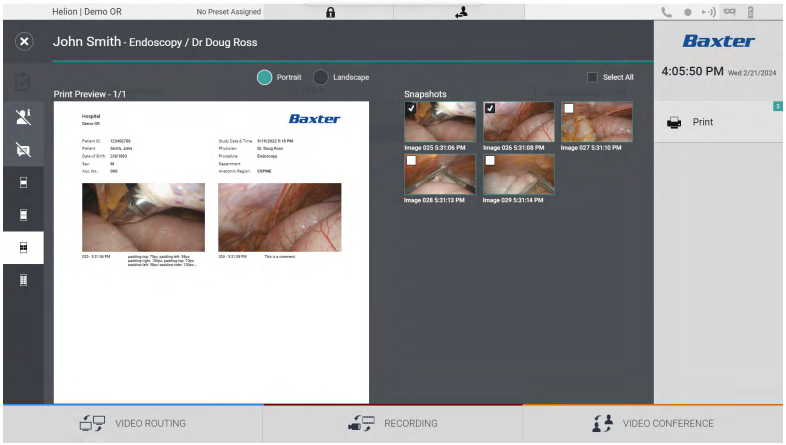
To delete images and videos, proceed as follows:

Step	Image
1. Select the videos or images you wish to delete by clicking directly on their thumbnails. The selected thumbnails will be outlined in green.	
2. Press Delete (on the right side of the screen) to delete the selected files.	
3. Press OK to confirm deletion of the selected files.	

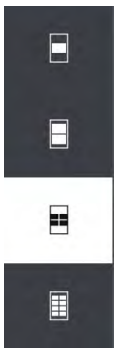
5.4.8 Printing function

The Printing function enables users to print images of the selected patient directly from the Helion UI.

Click on  icon and then on  icon to access the printing section. A screen with all the captured images is displayed, where you can select those you wish to print and the layout to be used.



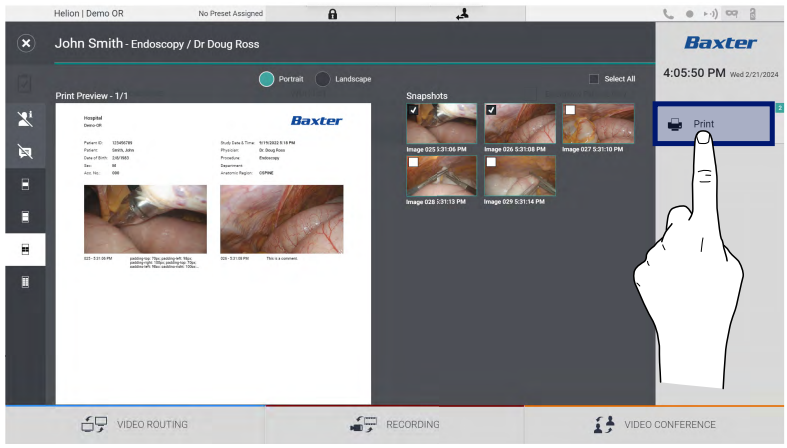
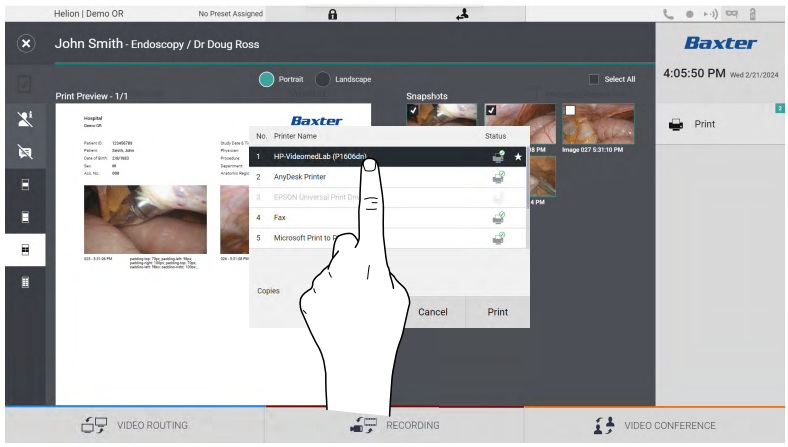
The following options are available in the printing area:

Icon	Function
	Choose the orientation: portrait or landscape.
	Choose the number of images per page, according to the selected printing orientation. For portrait: 1, 2, 4, or 8 images per page are possible.
	Choose the number of images per page, according to the selected printing orientation. For landscape: 1, 2, 4, or 6 images per page are possible.
	Hides or shows comments of each media.

Icon	Function
	Hides or shows sensitive patient data *1.

*1 Sensitive data can be defined in the configuration section by an authorised technician.

To print, proceed as follows:

Step	Image
1. Chose a print layout, using the options mentioned before.	
2. Select the image(s) to be printed. Select 'All' to select all the images.	
3. Press  to open the Printer Selection Dialog.	
4. Select a printer from the list of available printers. Select the number of copies and press 'Print' to send to the printer. The printing workflow described refers to the touch screen user experience. The web user experience may vary according to the browser used.	

This function is available only after the selected printer(s) has/have been installed and configured on Helion by qualified service personnel.

5.5 'Video Conference' function

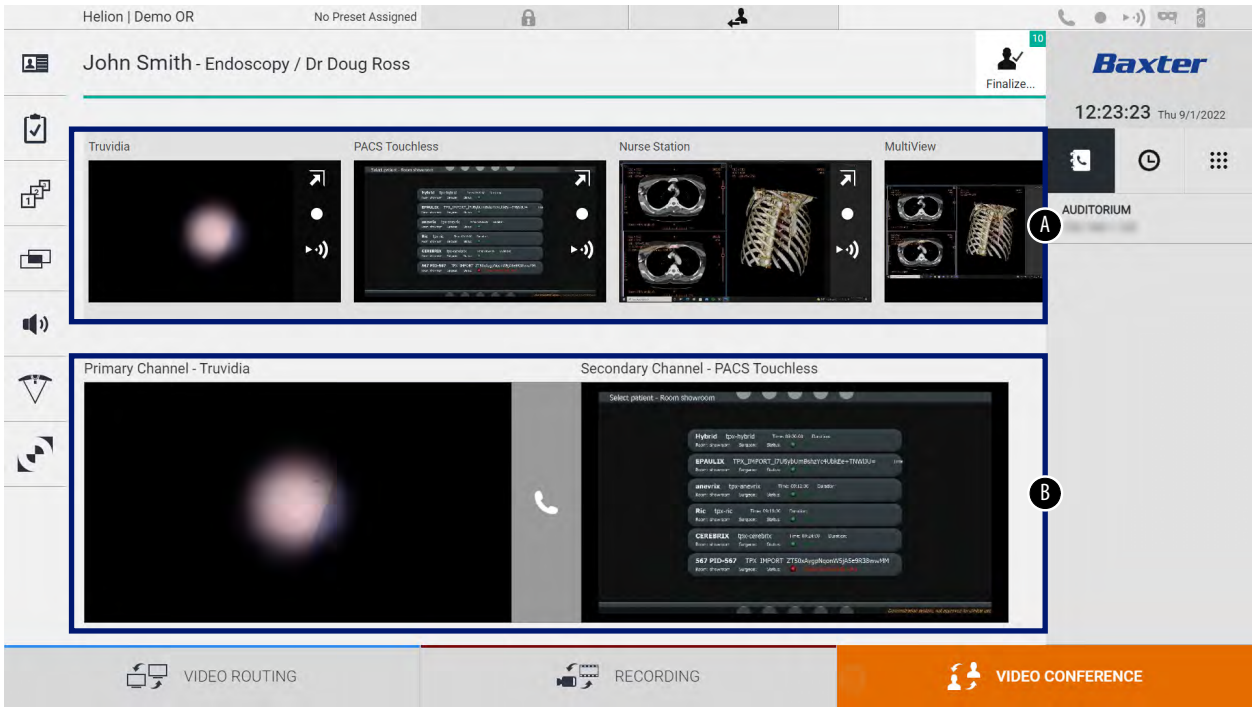
The Video Conference function enables video conferencing in a two-way audio and video connection from the operating theatre to external rooms:

- external participants located in other rooms or areas of the building are connected to the device via LAN connection;
- external participants who are in other locations can connect to the system online.

The following modes are available:

Mode	Description
Preview of the transmission channel	Enables viewing of one, or in the case of multi-channel video conferencing, both connected transmission channels.
Images or video sources	All connected sources are displayed in the input signal bar.
Swap button	During a conference, it is possible to exchange the signals displayed in the selected layout.
Layout button	During a multi-channel conference, it is possible to have various live Previews of the video signals concerned, for example PiP and PaP.
Participant selection/ Contact list	Video conference participants can be selected using the button provided: – by using the contact list; – by using the list of recent participants (log); – by entering the recipient's IP address directly via the keyboard.
Participant display	Shows which participants (name, IP address) are currently connected or with whom a video conference is about to start after assigning a transmission device and a signal source.

The main Video Conference screen is divided as follows:

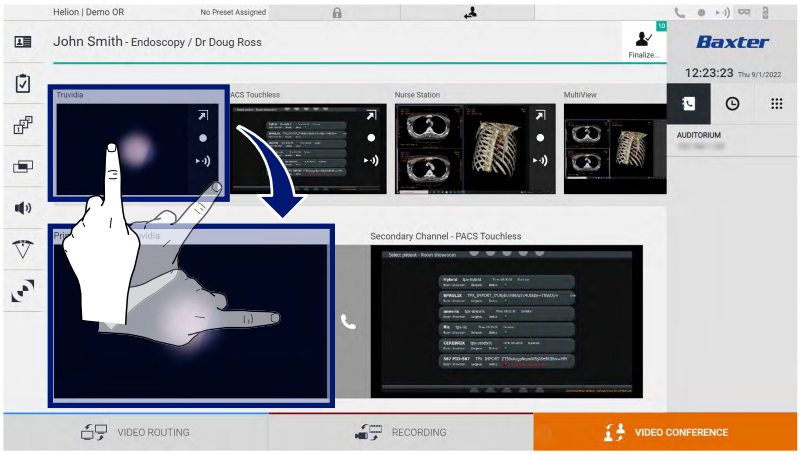


[A] source list;
[B] view of the two video conference channels.

When the video conference is active, the dashboard receiver icon turns green .

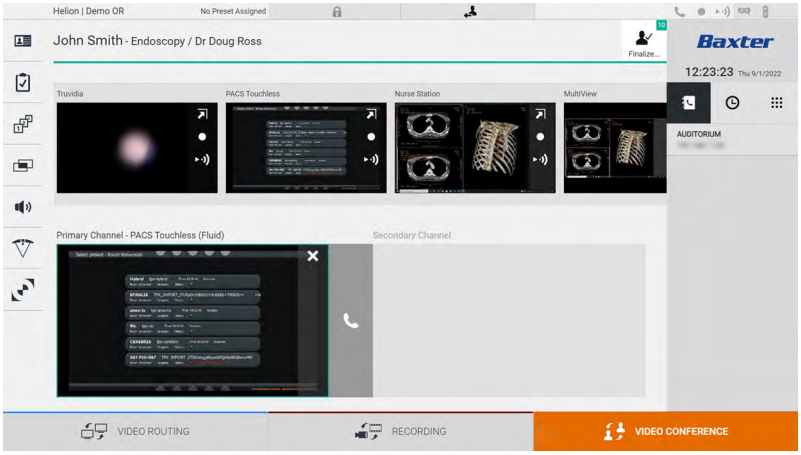
5.5.1 Selecting the signals to be sent by video conference

From the Source List, drag the source you wish to send via video conference into the Primary Channel (or Secondary Channel) box.



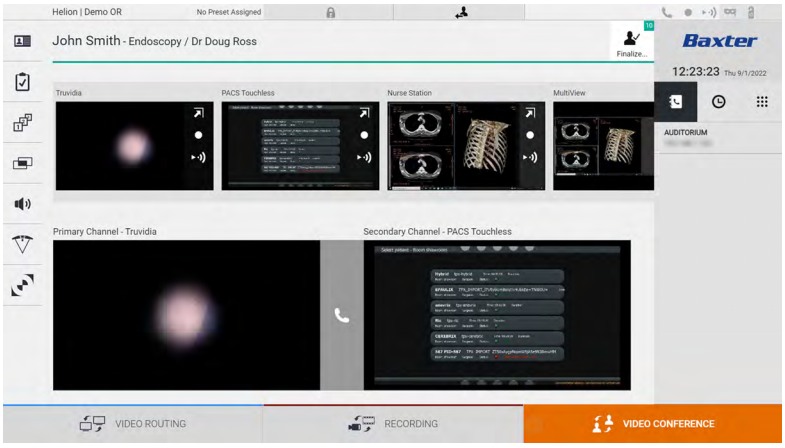
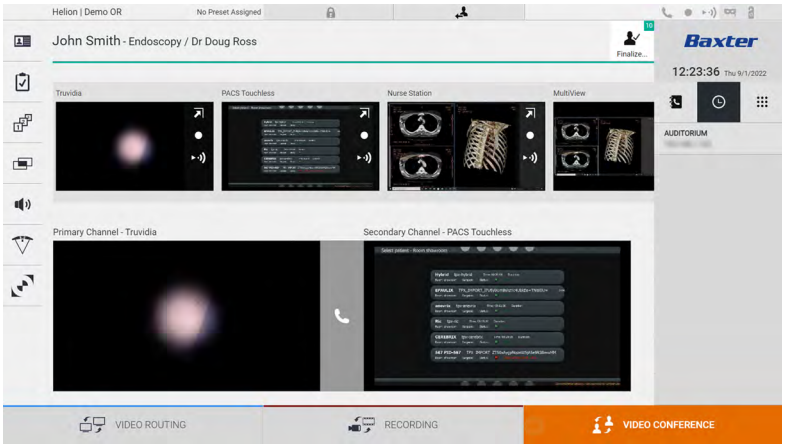
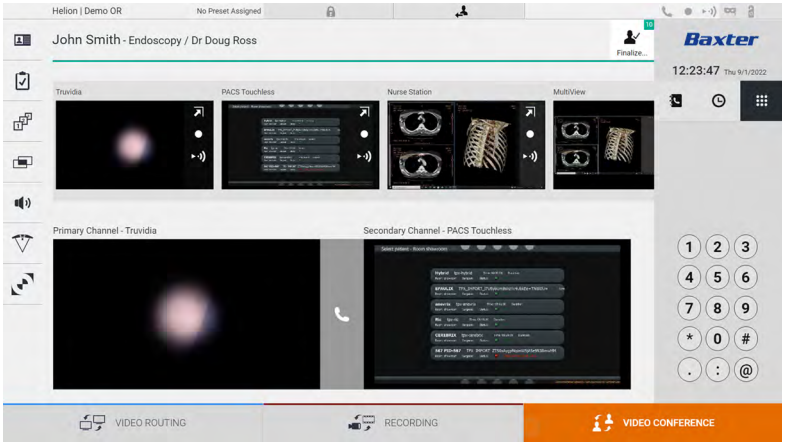
5.5.2 Removing the signals to be sent by video conference

Press one of the boxes related to the primary and/or secondary video conference channel and then the icon shown inside it to remove the video signal from the video conference.
The video signal that was just removed will no longer be shared with video conference participants.



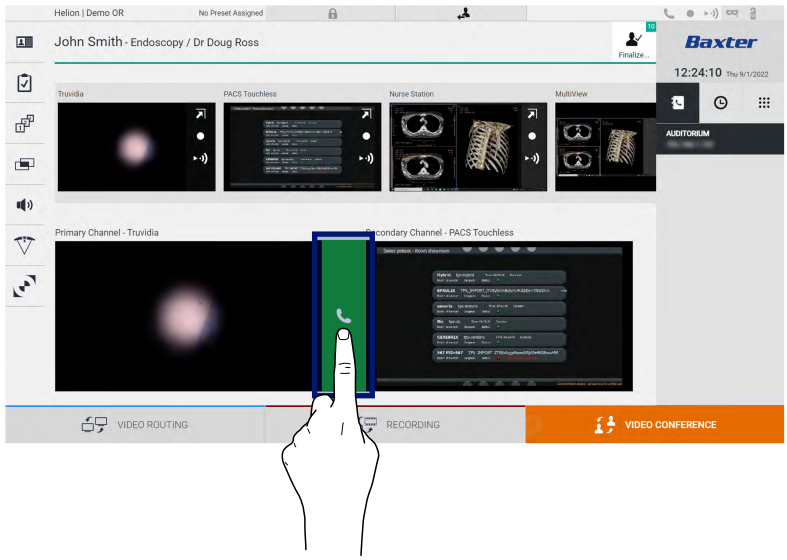
5.5.3 Call recipient selection

To select the call recipient, press the respective icon  (depending on the mode) on the right side of the screen. The icons are described below:

Icon	Description	Image
	Select a name from the contact list.	
	Select a name/address from the calls sent/ received log.	
	Manually enter the recipient's IP address using the numeric keypad.	

5.5.4 Call start

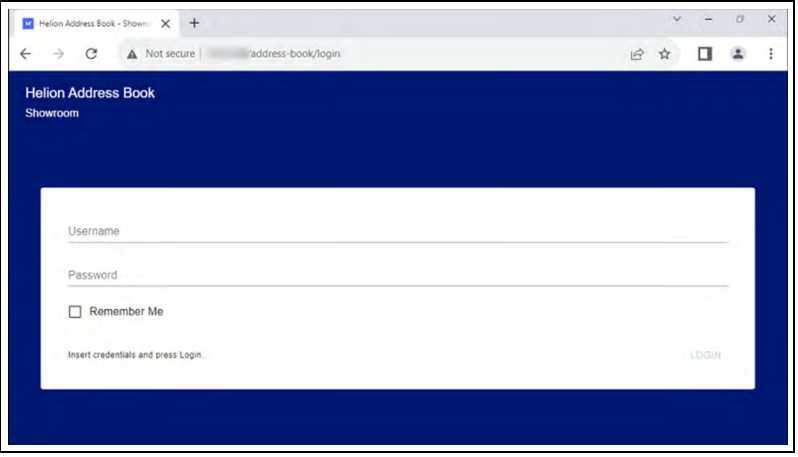
Once the call recipient has been selected, the call can be started. To start the call, proceed as follows:

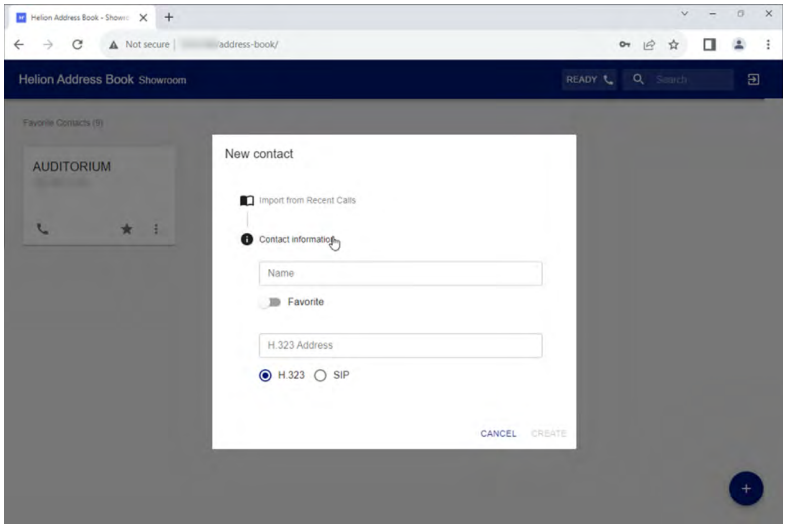
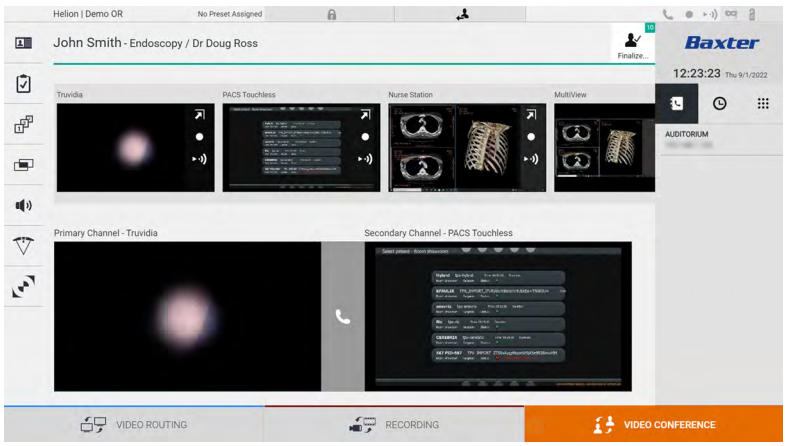
Step	Image
1. Press the green call button . The call button turns red to indicate the option of ending the call.	

5.5.5 Call H.323/SIP recipient

The following instructions outline the steps required to:

- access the Helion system address book;
- call into a H.323/SIP meeting via the Helion system.

Step	Image
1. On a PC with Helion network access, open a modern web browser and type the Helion Address Book address: https://<ip-address>/address-book **Note:** Replace <ip-address> with the actual IP address/ FQDN of the Helion Main Unit. 2. Enter the same user credentials to access the Helion GUI.	

Step	Image
3. Click + in the bottom-right corner of the page to bring up the New Contact form. 4. Type the name of a contact into the Name field. 5. Select either the H.323 or the SIP radio button according to the platform you are using. 6. Enter the H.323/SIP link address in the H.323/SIP address field. **Note:** You can mark a contact as a 'Favourite' to make it appear at the top of the list, in alphabetical order. 7. Click CREATE.	
8. Log into the Helion System user interface. 9. Navigate to the Video Conference tab and review the saved contacts in the address book on the right-hand side of the screen for the contact you just created. 10. Select and call the contact you created.	

5.6 ON AIR lamp

The ON AIR lamp turns on in the following scenarios:

- video recording function started;
- conference call started;
- streaming session started.

5.7 Additional functions

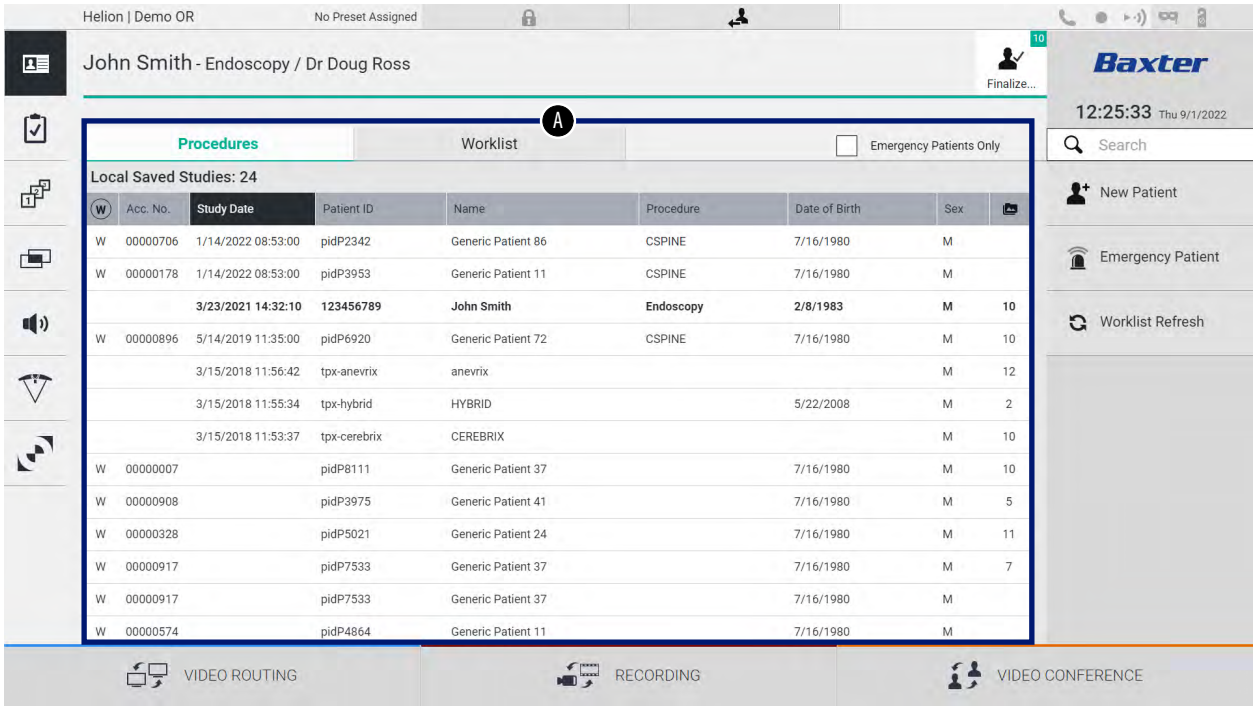
The following optional functions can be accessed via the side menu:

Icon	Description
	Access the screens related to patient data management.
	Access the Checklist screens relating to the surgery.

Icon	Description
	Access the Preset & Workflows screens of the Room configuration.
	Access the Multiview setup screens.
	Access the Audio setup screens.
	Access the management screen of the operating lights in the operating theatre. This function can only be used if the associated Baxter devices are present.
	Access the control screen of the lights in the operating theatre. This function can only be used if the associated Operamed devices are present.

5.7.1 Patient data management

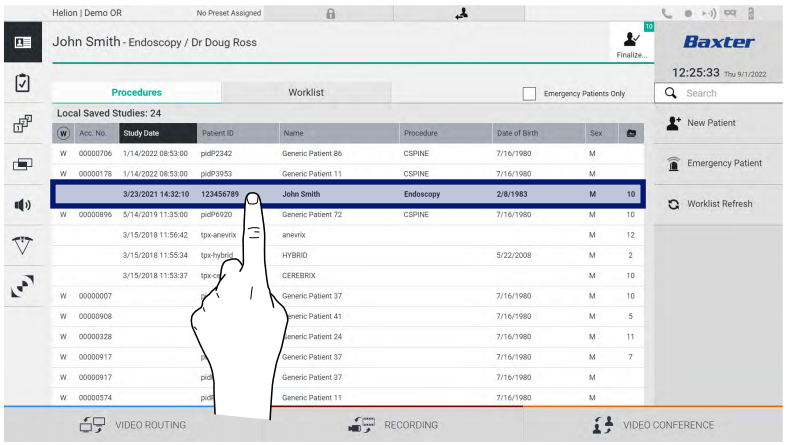
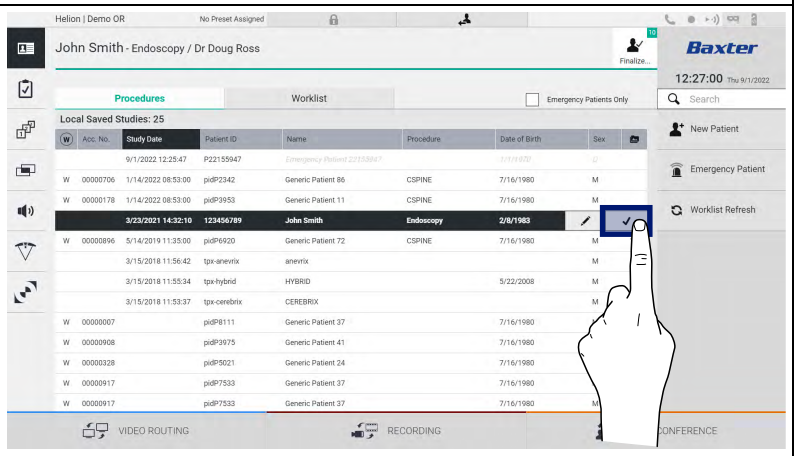
Press the  icon on the side menu to access patient data management.



When the icon is pressed, a screen will display the list of previously entered patients [A]. This list is split between patients imported via the Worklist (if present), and those who where manually selected or inserted.

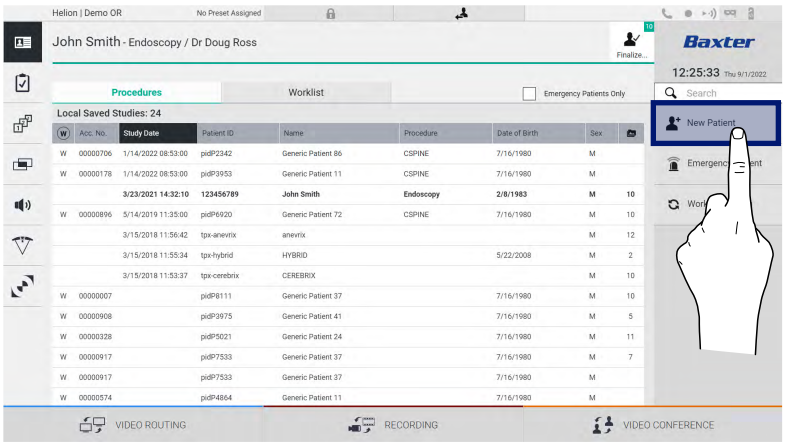
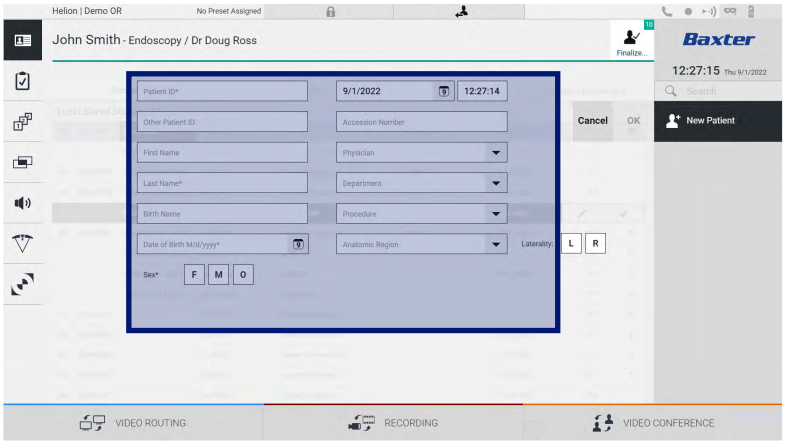
5.7.1.1 Selecting a patient from the list

To select a patient who is already in the list, proceed as follows:

Step	Image
1. Select the patient.	
2. Press ✓ to confirm the selection.	

5.7.1.2 Entering a new patient

To enter a new patient, proceed as follows:

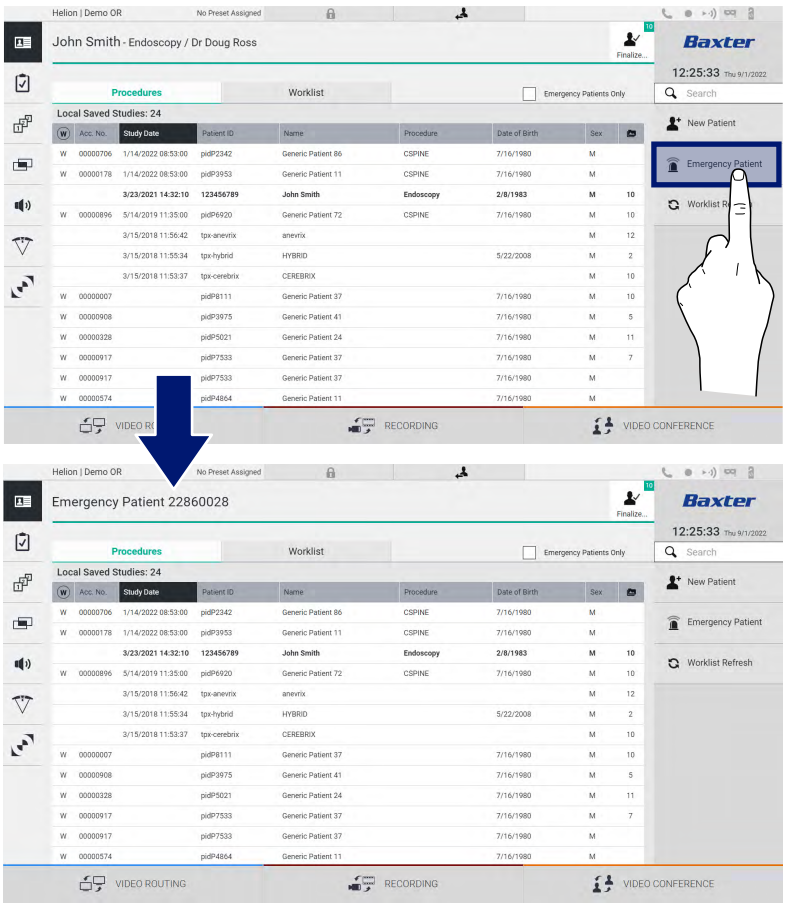
Step	Image
1. Select the New Patient icon on the right of the screen. The patient data entry window is displayed.	
2. Enter the data for the new patient. Fields marked with a * are mandatory.	
3. Once the mandatory data has been entered, the new patient can be saved by pressing OK or cancelled using Cancel.	

5.7.1.3 Entering an emergency patient

If the conditions do not allow new patient data to be entered completely manually, this option can be used to quickly create a patient with the name Emergency Patient plus a random ID.

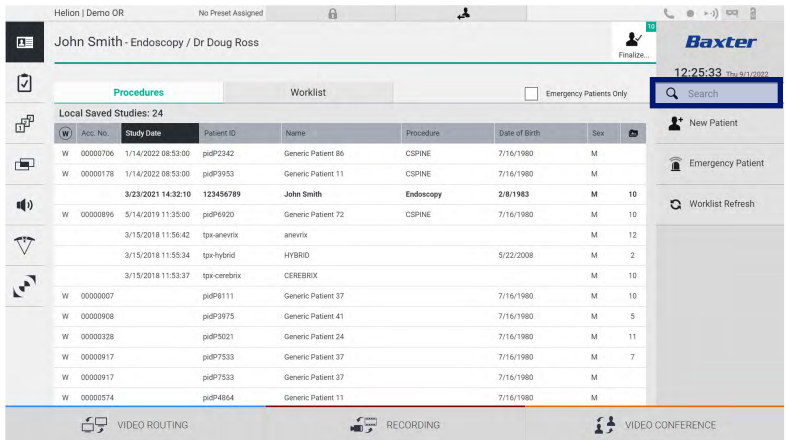
In terms of available functionalities and management, emergency patients are similar to any patient entered manually or by calling up the Worklist.

To enter an emergency patient, proceed as follows:

Step	Image
1. Select the Emergency Patient icon on the right of the screen. A new line is displayed with the name 'Emergency Patient XXXX' where XXXX indicates a progressive identification number.	

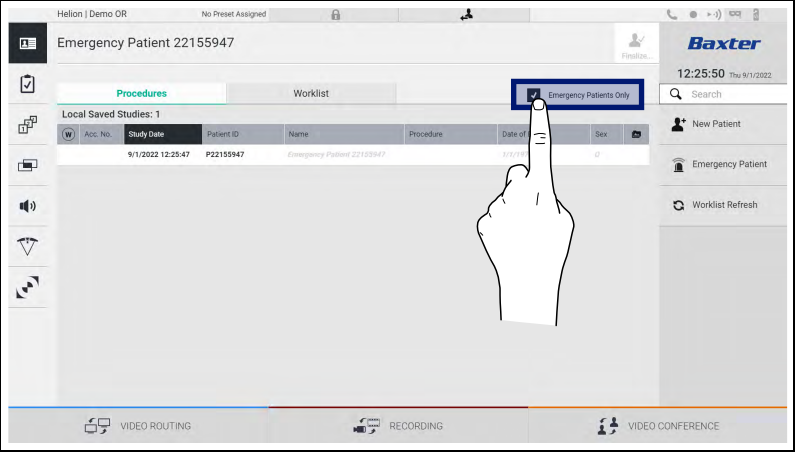
5.7.1.4 Searching for a patient from a list

To search for a patient already in the list, proceed as follows:

Step	Image
1. Enter their surname or ID in the specific field in the section on the right.	

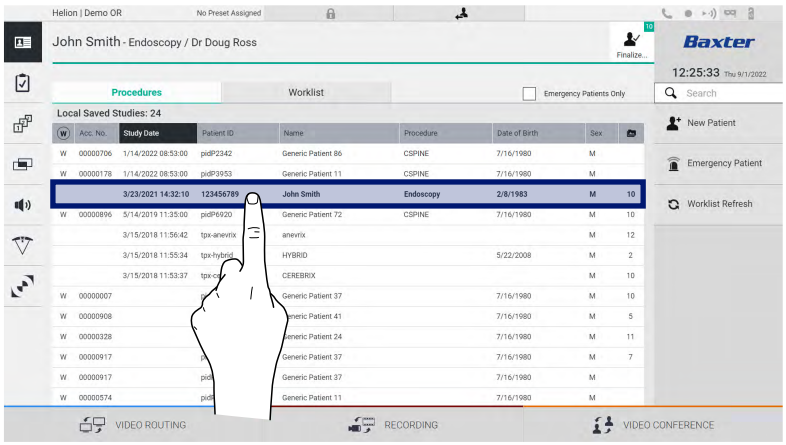
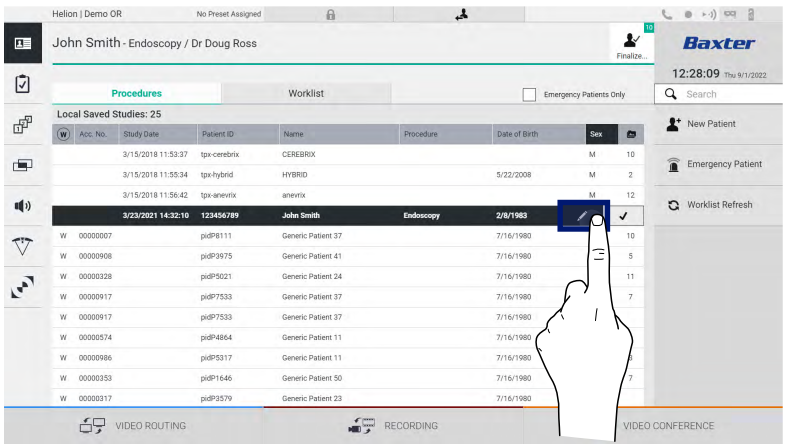
5.7.1.4.1 Emergency patient filter

Patients created as ‘Emergency Patient’ can be displayed only by applying the Emergency Patient Only filter:

Step	Image
1. Select the icon at the top of the screen. Helion will then only display the list of emergency patients.	

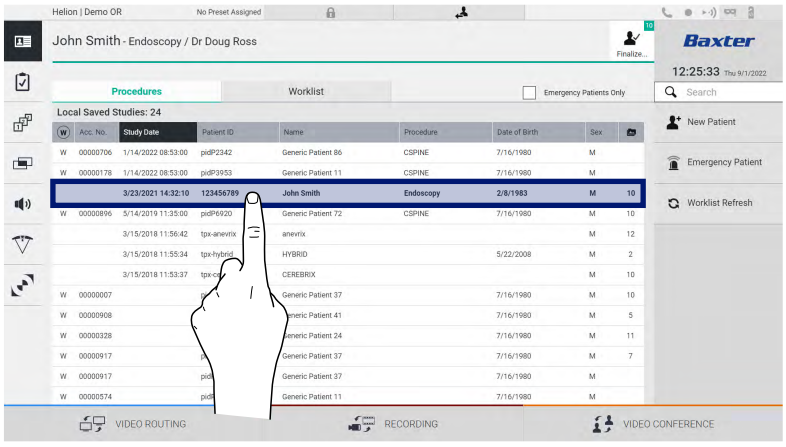
5.7.1.5 Modifying patient master data

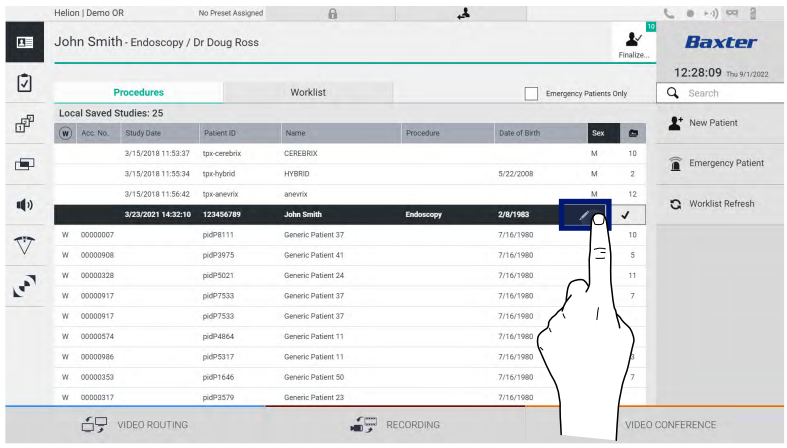
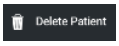
To modify a patient's master data, proceed as follows:

Step	Image
1. Search for and select the desired patient.	
2. Press  to change the selected patient's master data. This option is not available for patients in the Worklist section.	

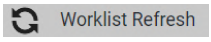
5.7.1.6 Deleting a patient

To delete a patient's master data, proceed as follows:

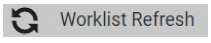
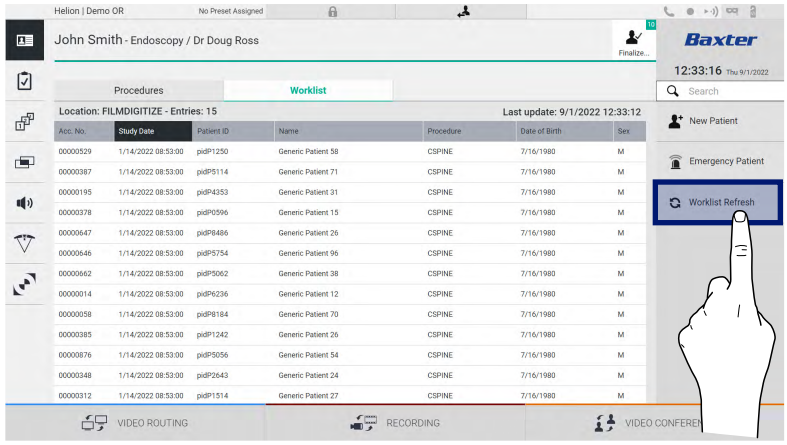
Step	Image
1. Search for and select the desired patient.	

Step	Image
2. Press  to change the selected patient's master data. This option is not available for patients in the Worklist section.	
3. Press  and confirm the action by pressing to delete the patient. **Note**: Deleting a patient will delete all media linked to the patient.	

5.7.1.7 Accessing the worklist

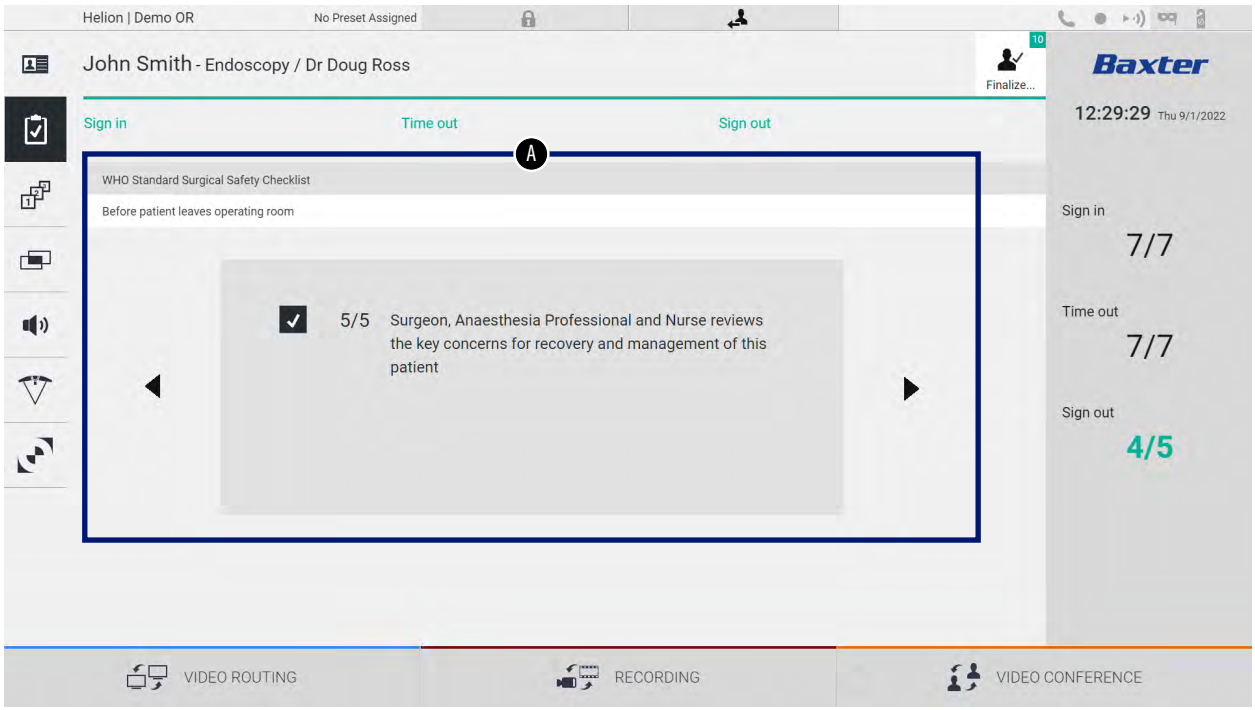
If the Helion Video Management System is configured to connect to a centralised master data management system, the list of patients related to a given date/room/surgeon can be retrieved using the  button.

To access the worklist, proceed as follows:

Step	Image
1. Press the  button. This operation will trigger updating of the worklist. 2. Wait for the names that meet the selected criteria to appear in the list. **Alternatively:** Press the 'Worklist' tab at the top of the list (this will not cause the worklist to update).	

5.7.2 Surgical Checklist

Press the icon on the side menu to access the Surgical Checklist screens. The Surgical Checklist is only activated after a patient has been selected.



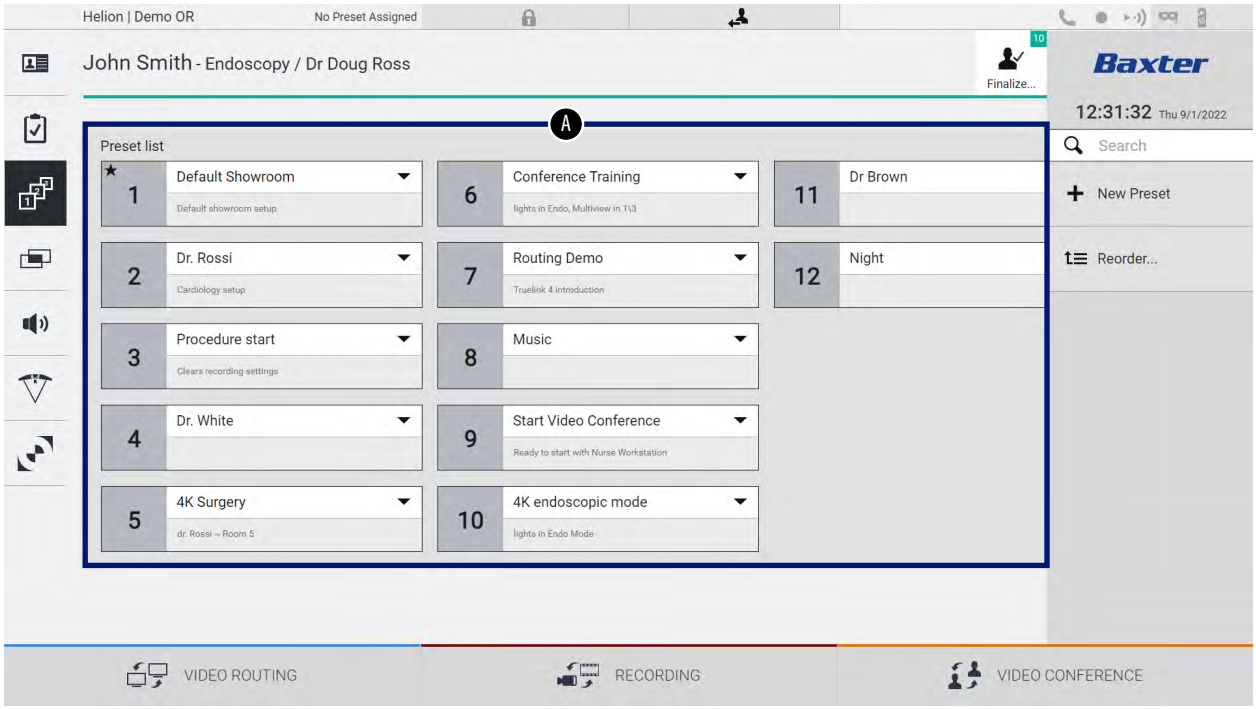
In section [A], you can go through the surgical procedure by following a sequence of questions and instructions on each stage of the procedure. Press the ▶ icon to navigate through the questions.

The steps refer to the entire procedure. You can then exit this section and return to it to continue filling out the Surgical Checklist when necessary. You can check the Surgical Checklist progress at any time using the bar in the Status Bar.

Once the Checklist has been completed in full, a window will open for the operator to enter notes.

5.7.3 Preset

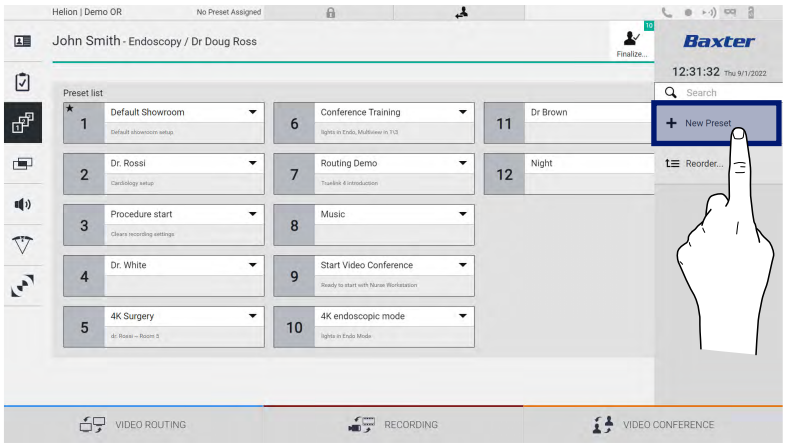
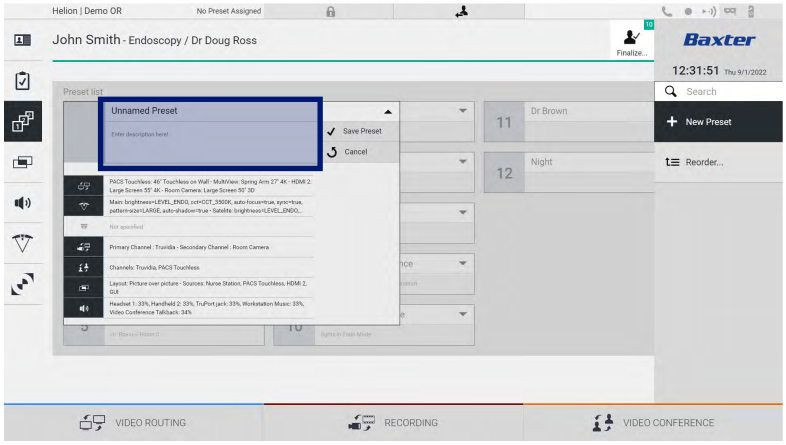
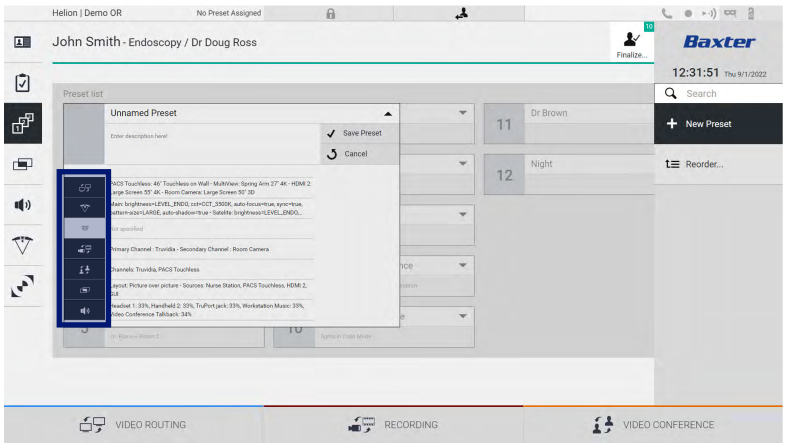
Press the icon on the side menu to access the Preset screens.
Presets are used to save room settings configurations. With Presets, you can recall the configurations by pressing the related icons.
The main screen is divided as follows:

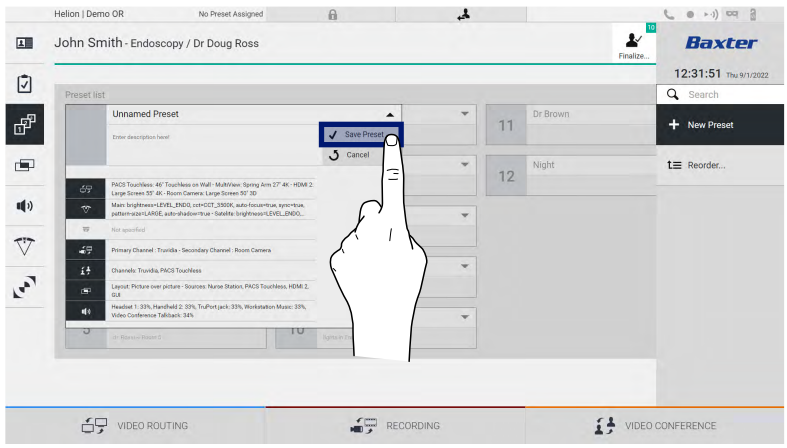


[A] Preset List

5.7.3.1 Setting Presets

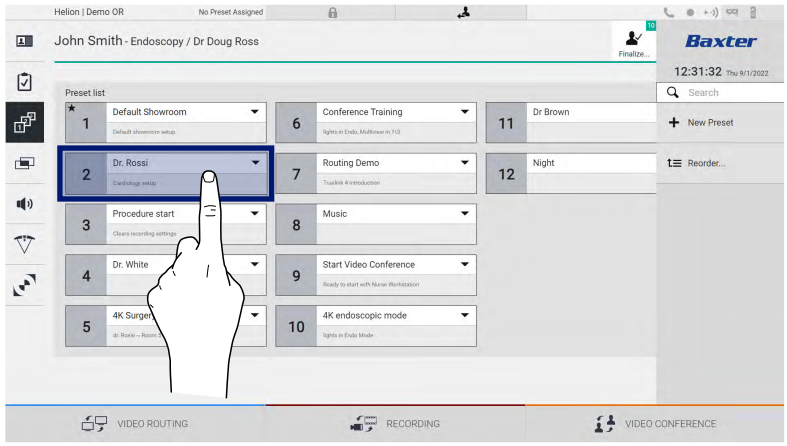
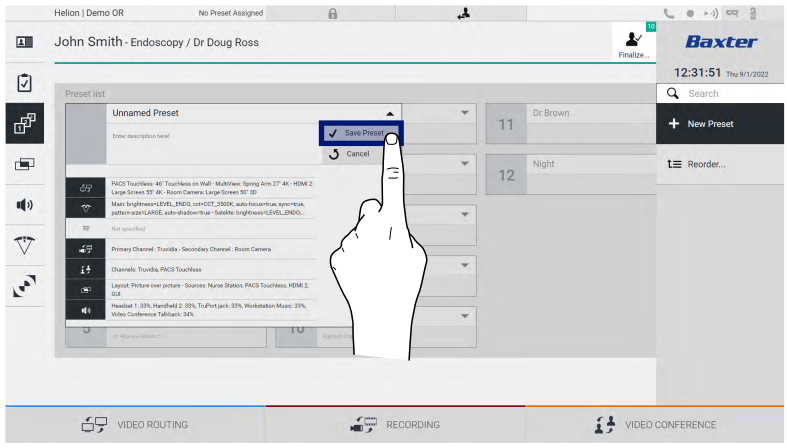
To set a new Preset, proceed as follows:

Step	Image
1. Set the desired room layout (Routing Video, Recording Channel, Conference Channel, Setting Audio, Operating Light Setting).	
2. Press the New Preset button. The configuration window opens.	
3. Enter a name for the new Preset and add a description in the appropriate field below (optional).	
4. Select / deselect the settings to be included in the configuration by pressing its icon from among those listed.	

Step	Image
5. Press ✓ Save Preset to confirm.	

5.7.3.2 Enabling Presets

To activate a Preset in the list, proceed as follows:

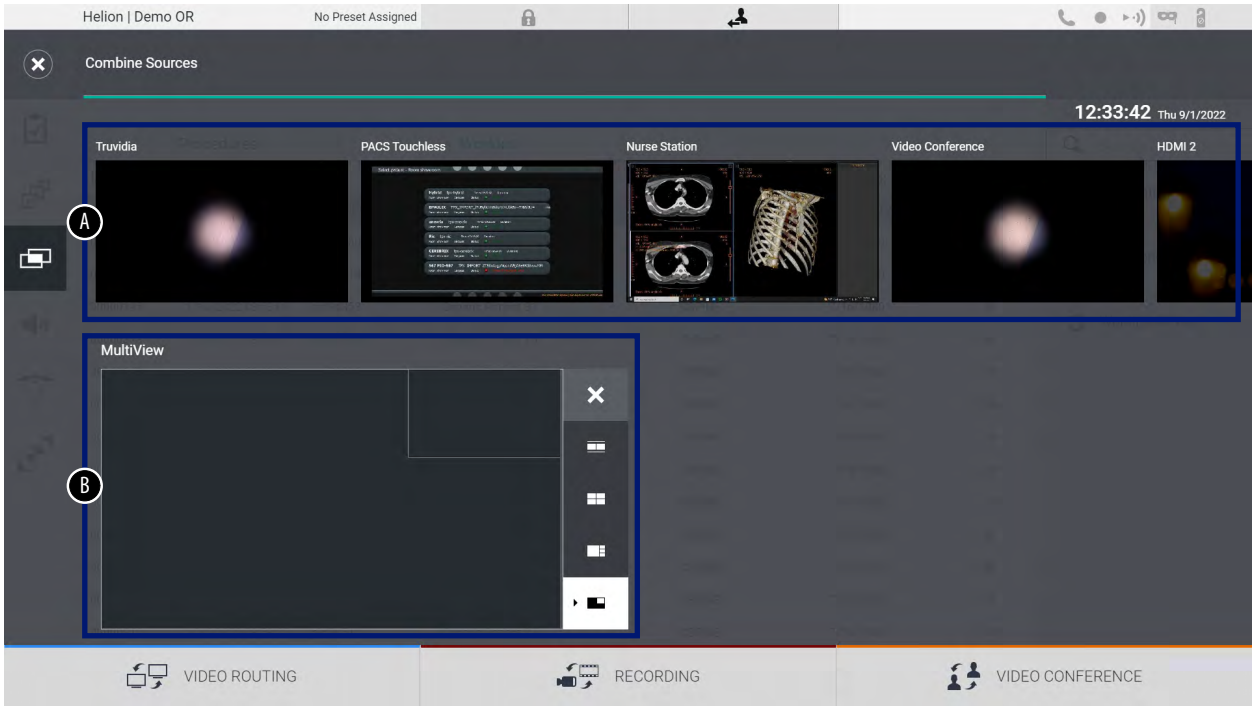
Step	Image
1. Select the desired Preset from the Preset List. The configuration window opens.	
2. Apply the Preset by pressing ✓ Apply Preset. Press ✎ Edit Preset to make changes to the Preset. Save the changes by pressing ✓ Save Preset.	

Press the ★ Mark Favorite icon to automatically activate the Preset each time the system is started.

5.7.4 Multiview

Press the icon on the side menu to access the Multiview screen. The Multiview function combines multiple Inputs (up to a maximum of 4) into a single Output signal.

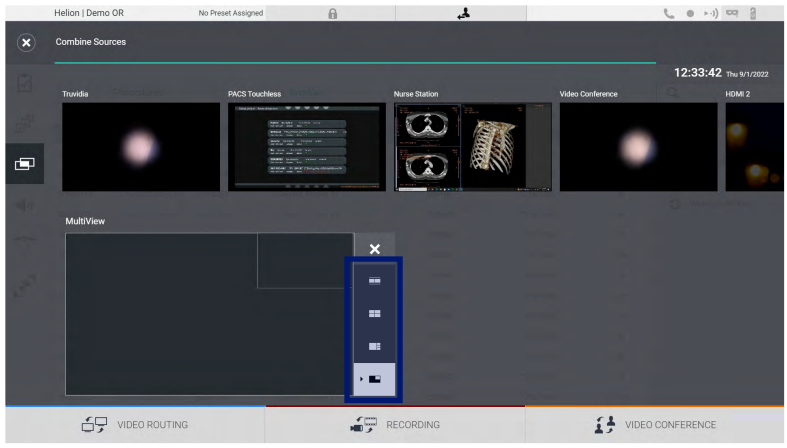
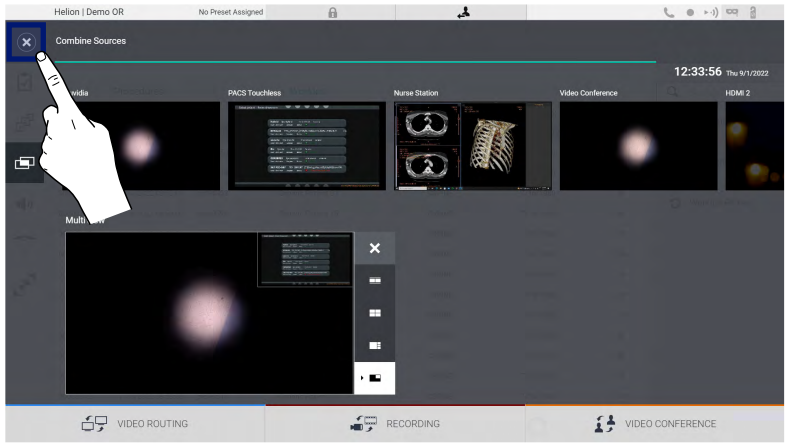
The main screen is divided as follows:



[A] Source List
[B] Multiview

5.7.4.1 Multiview setting

To set the Multiview, proceed as follows:

<table>
<tr><th colspan="2">Step</th><th>Image</th></tr>
<tr><td>1.</td><td>Select the desired layout from those indicated:
<table><tr><th>Icon</th><th>Function</th></tr><tr><td></td><td>Picture and Picture</td></tr><tr><td></td><td>Quadview</td></tr><tr><td></td><td>Picture over Picture</td></tr><tr><td></td><td>Picture in Picture (up to 4 different Picture in Picture layouts)</td></tr></table></td><td> 
</td></tr>
<tr><td>2.</td><td>Drag the images (one at a time) from the Source List and drop them into the corresponding boxes.
Press ✕, which appears at the top right of the box once selected, to remove the image from the box.</td><td> 
</td></tr>
<tr><td>3.</td><td>Once the grid has been filled in, close the Multiview section by pressing ✕. The grid will be available in the Source List.</td><td> 
</td></tr>
</table>

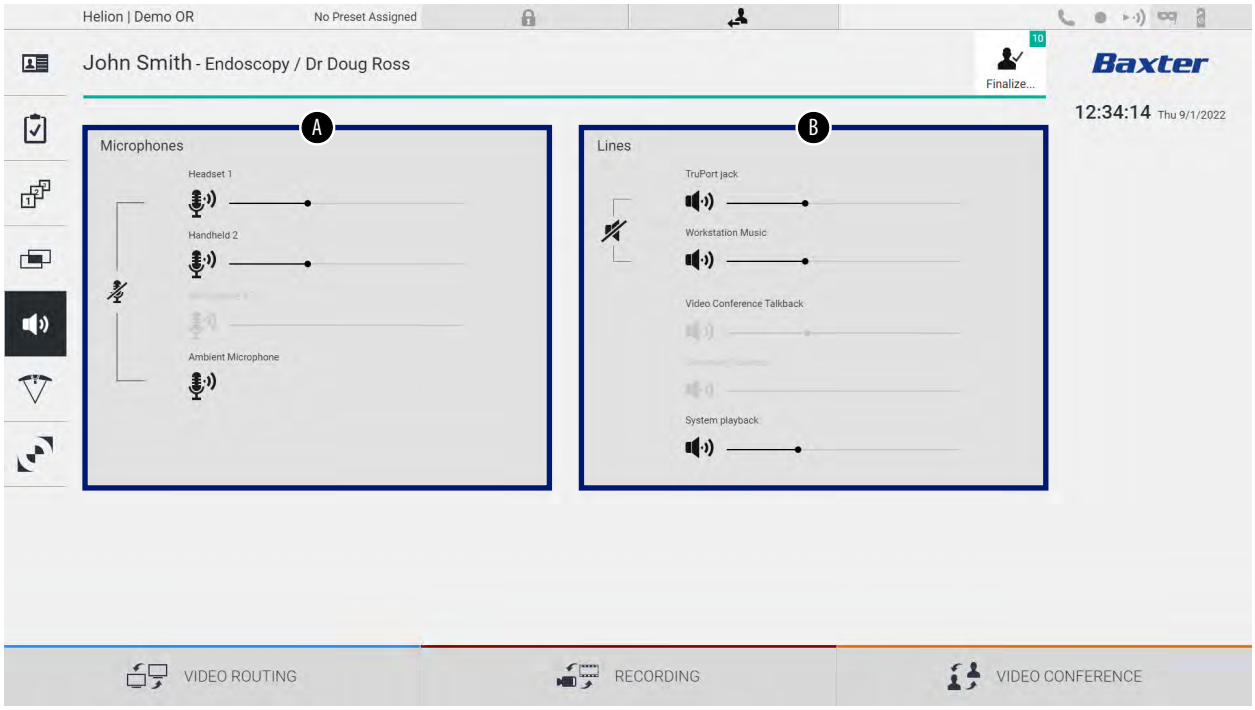
5.7.5 Audio control

Press the icon on the side menu to access the Audio Control screen. In the Audio Control section, you can set the volume levels of the microphones and auxiliary lines.

The 'Microphones' settings will affect the audio level recorded or sent to a remote location via Streaming or Video Conference (please note that Ambient Microphone only works for Video Conference).

The 'Lines' settings will affect the audio mix sent to the speakers in the operating theatre.

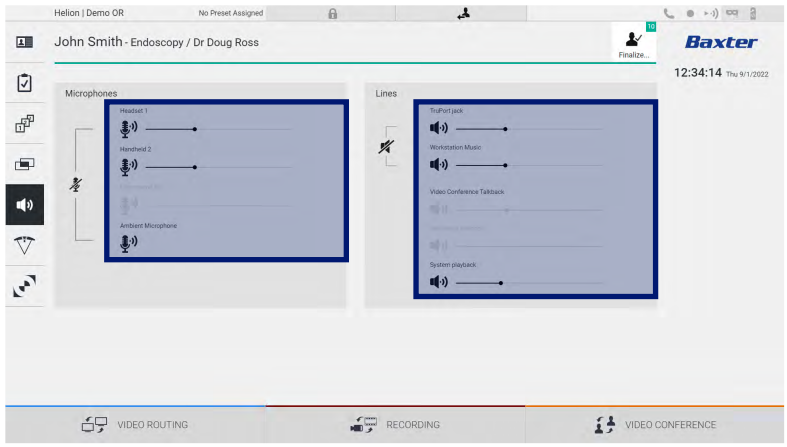
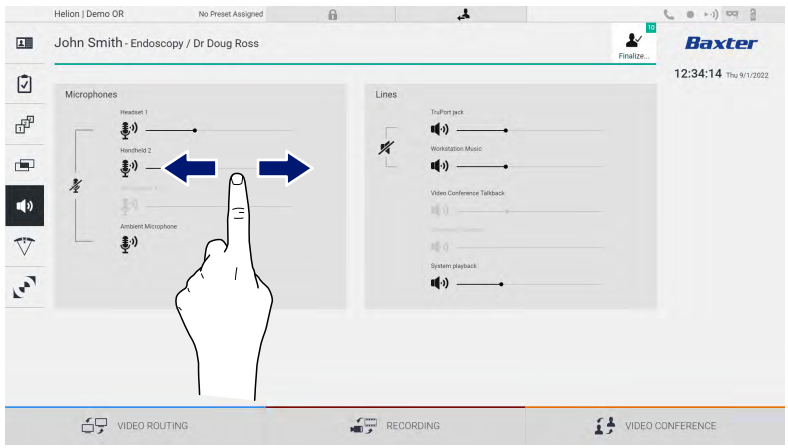
The main screen is divided as follows:



[A] Microphone inputs
[B] Line inputs

5.7.5.1 Volume adjustment

To adjust the volume of the microphones or line inputs, proceed as follows:

Step	Image
1. Operate the volume bar of the microphones or line inputs based on the volume to be modified.	
2. Slide the bar to increase or decrease the volume of the microphones or line inputs.	

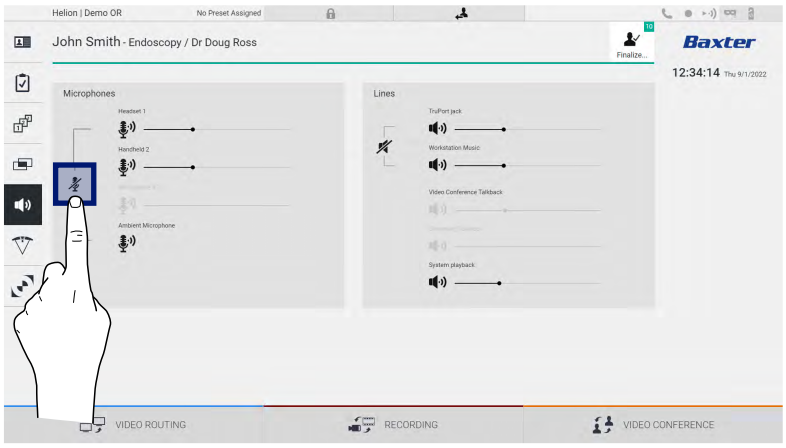
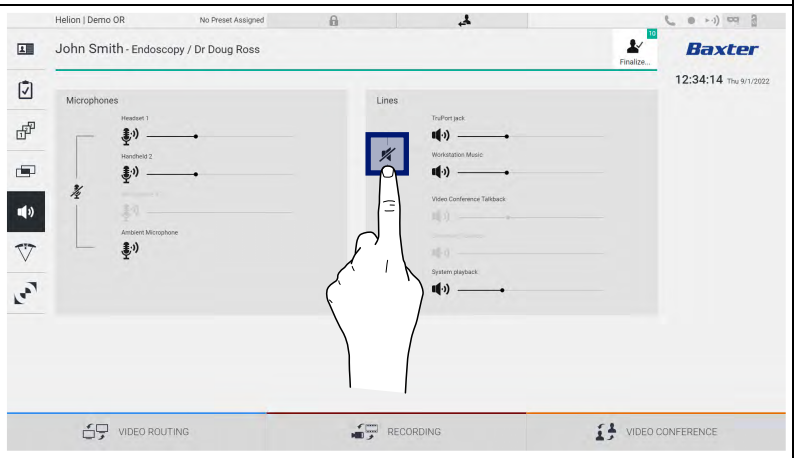
It is possible to independently change the audio channel from inputs AUX1, AUX2 and video conference/streaming.

In the event that the system receives a video conference connection request, the system will automatically silence lines AUX1/AUX2 and activate the video conference line.

This option is set by default. If you wish to disable it, contact the Assistance service Videomed S.r.l.

5.7.5.2 Disabling microphones and audio

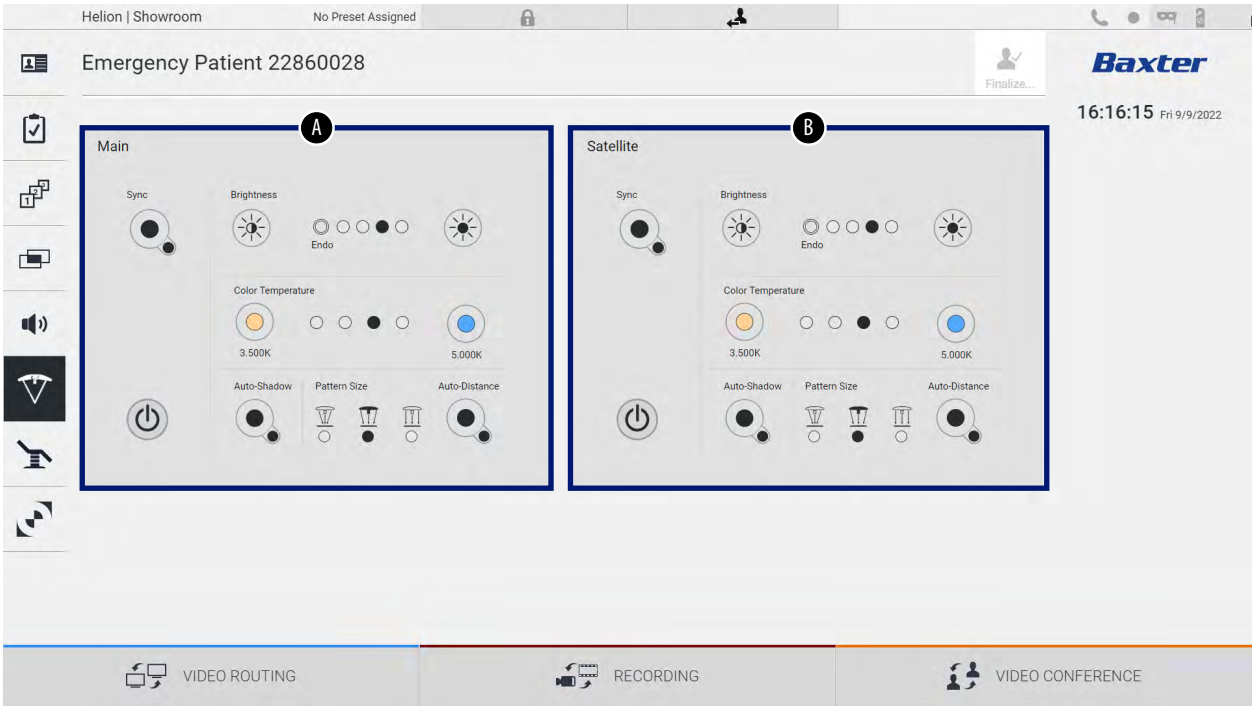
To disable the microphones or line inputs, proceed as follows:

Step	Image
1. Press to disable the microphone.	
2. Press to turn off the speaker volume.	

5.7.6 Surgical light management

Press the icon on the side menu to access the management screen for the devices in the operating theatre.

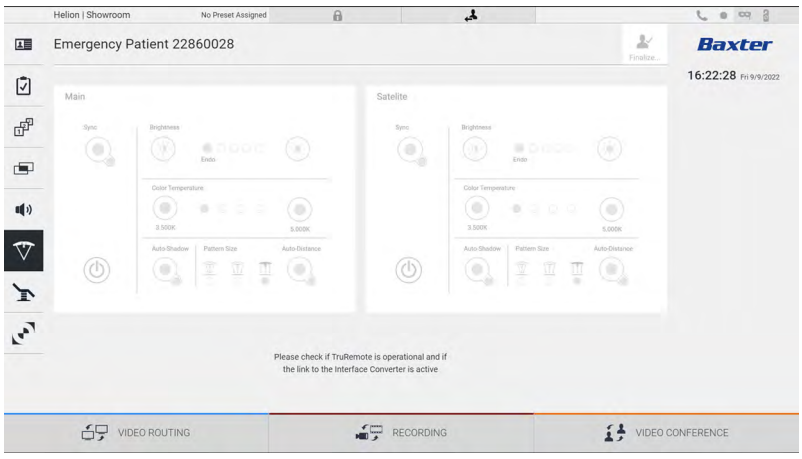
The main screen is divided into 2 sub-control areas respectively for the 2 operating lights installed in the operating theatre:



* the image may differ depending on the surgical light installed

[A] Light 1
[B] Light 2

The screen below shows a case where the surgical lights control system cannot be reached.



The Helion Video Management System provides the option of controlling the Baxter surgical operating lights (see chapter 3.10.1), using a reproduction of the light control console via the graphical interface.

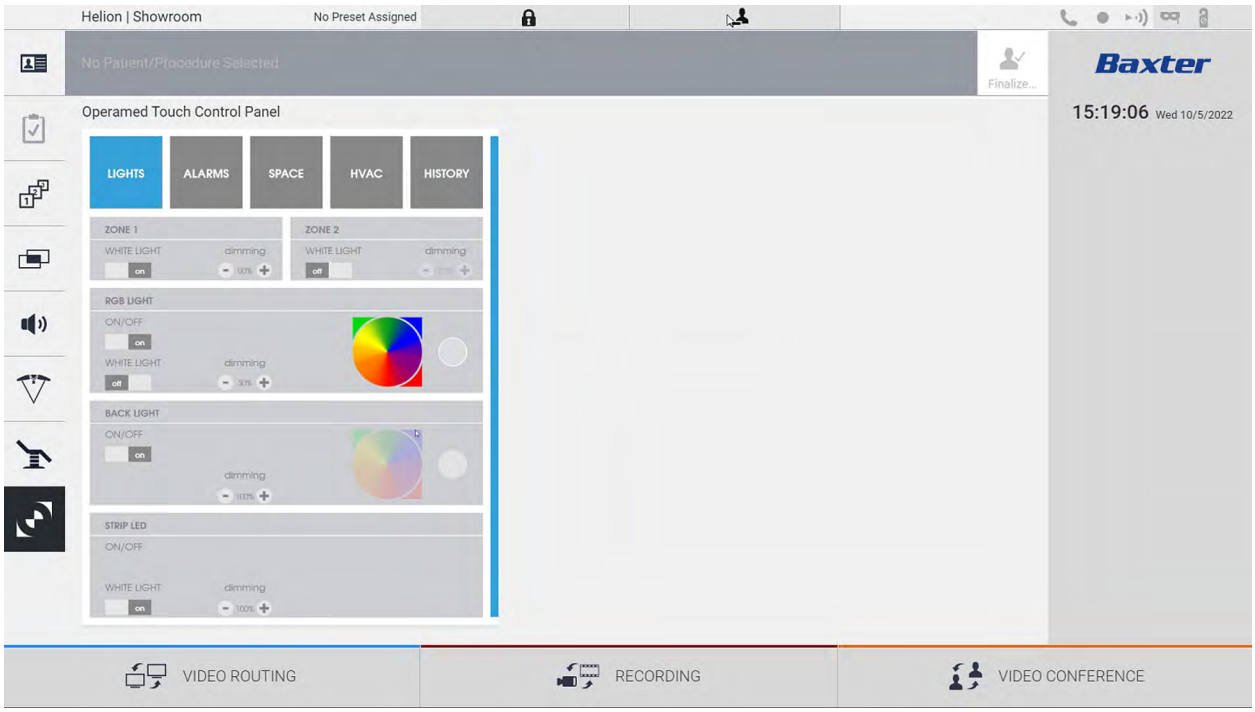
The image shows the functions that can be accessed from the touch screen device, namely:

- light on/off;
- enable sync function (synchronisation of the 2 lights);
- adjust light brightness level;
- adjust light colour temperature;
- set focus (automatic function can also be activated)*;
- light beam size*;
- set shadow (automatic function can also be activated)*.

* the function may vary based on the light model installed.

5.7.7 Environmental control panel management

Press the icon on the side menu to access the operating theatre control panel management screen.



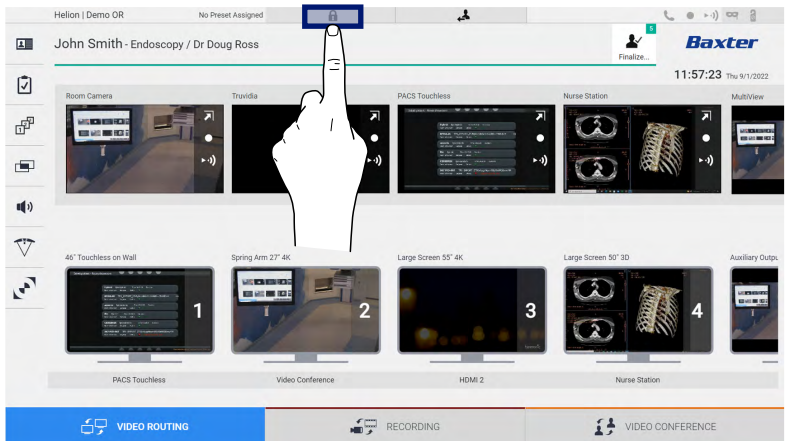
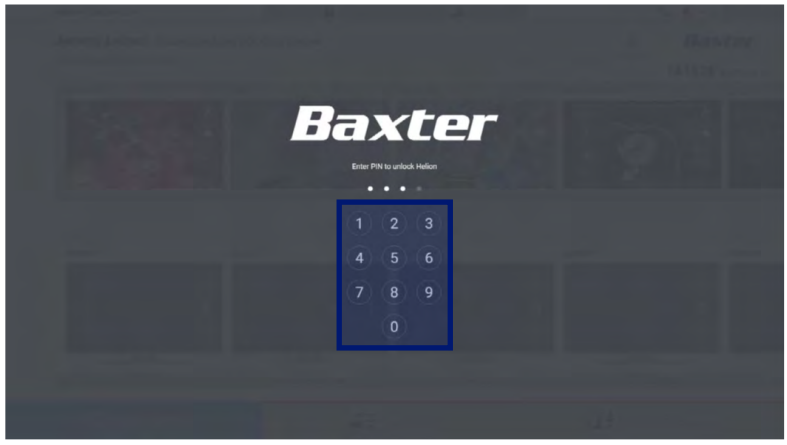
The control panel management screen can only be used if there are Operamed devices in the operating theatre.

The Helion Video Management System from Videomed S.r.l. only enables the association of Operamed control panels.

5.8 'Lock with PIN' function

The Helion Video Management System includes a Lock function for locking the touch screen using a PIN.

To lock the touch screen, proceed as follows:

Step	Image
1. Press to lock the screen.	
2. Enter the PIN code to unlock the touch screen, using the numeric keypad highlighted in the image.	

5.9 'Login' function

The Helion Video Management System includes a Login/Logout function for managing user access. The Login function can be set as active by default at system startup or only following a Logout. The Login screen requires the completion of 2 mandatory fields, Username and Password, in order to access the system.

Once the correct credentials have been entered, the system will show the initial Helion graphical user interface (Video Routing interface).

Press the icon to log out and be redirected to the credentials screen.

6 Electromagnetic compatibility

The Helion Video Management System supplied contains electronic components subject to Electromagnetic Compatibility regulations, which are affected by conducted and radiated emissions.

The emission values comply with regulatory requirements thanks to the use of components compliant with the Electromagnetic Compatibility Directive, suitable connections and the installation of filters where required.

The Helion Video Management System is thus compliant with the Electromagnetic Compatibility (EMC) directive.

⚠ CAUTION

Any maintenance activities on the electrical equipment that are carried out in a non-compliant manner or incorrect replacement of components may compromise the efficiency of the solutions adopted.

The Helion product is a Class A electromedical device according to IEC 60601-1-2 (CISPR 11), which is suitable for use in a specific electromagnetic environment. The customer and / or user of the product must ensure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guide
Radiated and conducted RF emissions CISPR 11	Group 1	The Helion system only uses RF (radio-frequency) energy for its internal operation. Therefore, the RF emissions are very low and should not cause interference in adjacent electronic devices.
	Class A	Helion is suitable for use in all buildings, except for residential buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – Electromagnetic immunity

The product is suitable for use in a specific electromagnetic environment. The customer and / or user of the product must ensure that it is used in an electromagnetic environment as described below:

IMMUNITY test	IEC test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV in contact ±2, ±4, ±8, ±15 kV in the air	IEC 60601-1-2 Test level	The floor must be made of wood, concrete, or ceramic tiles. If the floors are covered with synthetic material, relative humidity must be at least 30%. Temporary signal loss is possible (a few seconds).
Radiated electromagnetic fields IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should not be used near any part of the EUT. This includes cables. Minimum distance: 30 cm.

IMMUNITY test	IEC test level	Compliance level	Electromagnetic environment – guidance
Fast electrical transients (burst) IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input / output lines > 3 m	IEC 60601-1-2 Test level	The quality of the mains power supply should be typical for a commercial or hospital environment.
Pulses IEC 61000-4-5	±0.5, ±1 kV differential mode ±0.5, ±1, ±2 kV in common mode	IEC 60601-1-2 Test level	The quality of the mains power supply should be typical for a commercial or hospital environment.
Conducted disorders, induced by RF fields IEC 61000-4-6	3 V 150 kHz to 80 MHz 6V ISM frequencies	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should not be used near any part of the EUT. This includes cables. Minimum distance: 30 cm.
Network frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should have the characteristic levels for a typical location in a standard commercial or hospital environment.
Voltage dips, brief interruptions and voltage variations on power input lines IEC 61000-4-11	10 ms – 0% at 0°, 45°, 90°, 135°, 180°. 225°, 270°, 315° 20 ms – 0% at 0° 500 ms – 70% at 0° 5 s – 0%	IEC 60601-1-2 Test level	The quality of the mains voltage should be typical for a commercial or hospital environment. If the user of the appliance requires it to continue operating even when the mains power supply is interrupted, it is recommended to power the appliance with an uninterruptible power supply (UPS) or batteries.

Guidance and manufacturer's declaration – Range and frequency level: RF wireless communication equipment

Test frequency (MHz)	Modulation	Minimum IMMUNITY level (V / m)	Applied IMMUNITY level (V / m)
385	** Pulse modulation: 18 Hz	27	27
450	☐ * FM + 5 Hz deviation: 1 kHz sine ☒ ** Pulse modulation: 18 Hz	28	28
710 745 780	** Pulse modulation: 217 Hz	9	9
810 870 930	** Pulse modulation: 18 Hz	28	28
1720 1845 1970	** Pulse modulation: 217 Hz	28	28
2450	** Pulse modulation: 217 Hz	28	28
5240 5500 5785	** Pulse modulation: 217 Hz	9	9

Test frequency (KHz)	Modulation	Minimum IMMUNITY level (A / m)	Applied IMMUNITY level (A / m)
134.2	Pulse modulation: 2.1 kHz	65	65
13560	Pulse modulation: 50 kHz	7.5	7.5

7 Disposal instructions

Electrical equipment that is no longer in use must not be disposed of as normal communal waste. The substances and materials contained therein must be disposed of separately in an appropriate manner. This ensures that they can be recycled for the production of new products. Videomed S.r.l. offers a waste collection and environmentally sustainable disposal service for all Videomed S.r.l. products.

Recycling and disposal are performed by Videomed S.r.l. at no additional cost to the operator.

To notify the dispatch of decommissioned devices, call +39 049 9819113.

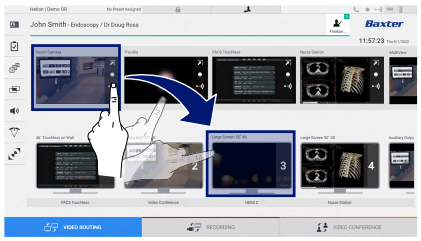
Assistance is always available to clarify any doubts regarding the recycling and disposal of products.

Electrical and electronic equipment waste must be disposed of according to national laws and regulations in force.

8 SVHC (Substance of very high concern)

According to Article 33 of the REACH regulation (EC) no. 1907/2006, the products may contain components with reportable substances in concentrations exceeding 0.1 mass percent. A list of affected components will be provided by Videomed S.r.l. on request. The list can also be viewed online at hillrom.com.

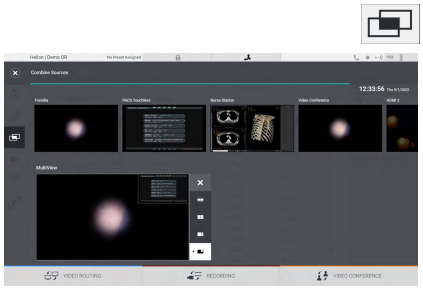
9 Annex I – Getting started



Video Routing

To send a video signal to a monitor, drag the relevant image from the list of available sources and drop it into one of the enabled monitors. The Preview of the video signal sent will be displayed in the relevant Monitor icon and updated periodically.

To remove the signal from a monitor, select it from the Monitor List and press ✕.

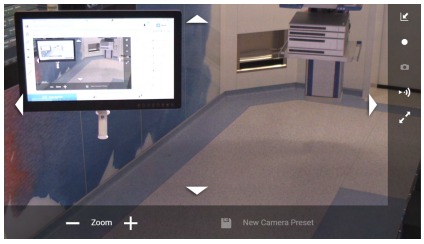


Multiview

In the Multiview section, it is possible to create a composition of 2 or 4 images among those available in the Source List.

Select the desired layout from PiP, PaP, PoP and Quadview. Then proceed to populate this layout by dragging the images of the sources and dropping them into the relative boxes, one at a time.

To remove an image from a frame, press ✕ which appears at the top right of the frame once selected. Once the grid has been set up, return to the Video Routing section by pressing the relevant blue icon.

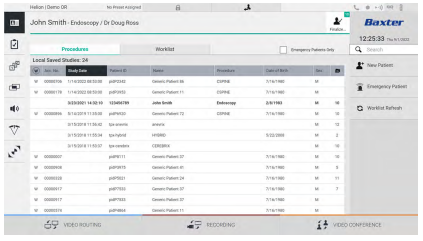


PTZ camera control

Press ↗ in the RoomCam Preview to open the Live Preview. The camera control buttons will appear. The system allows you to change the position and zoom level of the camera.

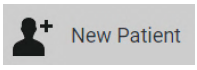
Recording

To record a video or take a photo, select / insert a patient in the appropriate section.



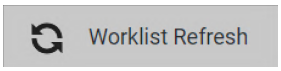
Patient data

The list of previously created patients is displayed on the main screen. To insert a new patient, select one of the options in the section on the right:



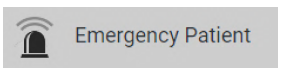
Adding manually

Enter the data concerning the new patient (fields marked with a * are mandatory).



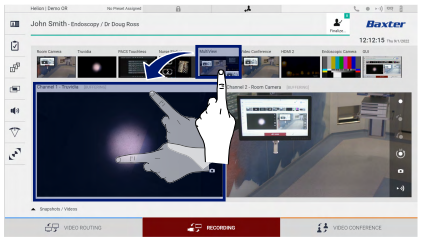
Accessing the Worklist

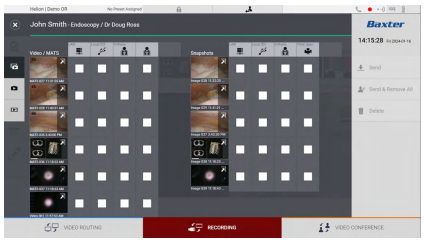
Press Worklist Refresh to download the patient list in automatic mode.



Inserting an emergency patient

Using this option, it is possible to create a study with a random ID name called Emergency Patient.





Selecting the signals to be recorded

Drag the desired source into the Recording Channel box to enable basic recording functions:

Recording start / stop

Instant capture

Press Finalize and then Export (or simply press Export if the printing function is not enabled) to close the patient record and export the files.

Select the elements to be exported, then export Send, delete Delete or choose to export the selected data and then delete the patient from the patient list Send & Remove All.

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Baxter

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