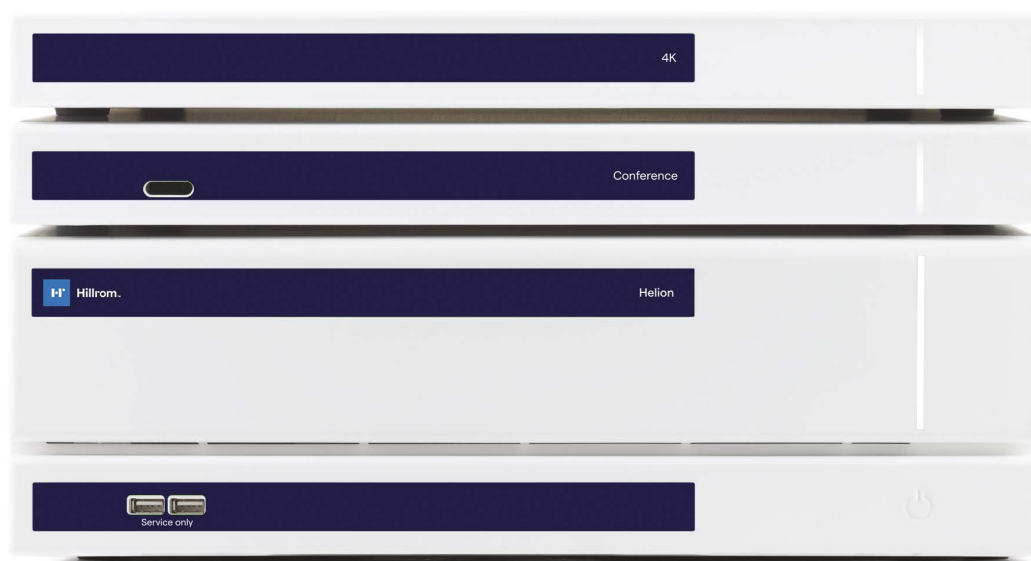




Instructions for use

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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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
SDI/Composite Video Input	CS201534
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
STD Single Plate 2xDVI 2xNEUTRIK	CS201580
STD Plate 1xVGA 1xDVI 2xNEUTRIK	CS201581
STD Double Plate 4xNeutrik	CS201582
DVI Line Transmission	CS201585
STD Double Plate 4xDVI 2xNeutrik	CS201586
VGA Video Input	CS201587
3.5mm Audio Jack Input	CS201588
STD Single Plate Pass Throught	CS201589
USB Universal Input	CS201591
STD Single Plate 4xNEUTRIK	CS201592
STD Single Plate 2x NEUTRIK	CS201593
STD Single Plate 2xDVI	CS201594
HDMI Video Input	CS201595
PLATE 2XNEUTRIK PENSILI LEGRAND	CS201596
PLATE 2XDVI PENSILI LEGRAND	CS201597
RJ45 NETWORK INPUT	CS201598
STD Plate 1XRemote ON/OFF	CS201599
Tedisel Medical Plate 2XDVI	CS201600
Tedisel Medical Plate 2XNEUTRIK	CS201601

Product designation	REF
504 STD Plate 1XDVI 1X NEUTRIK	CS201602
Helion HR Surgical Lights Control SW	DC500103

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.

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PREFACE

All rights reserved. No part of this publication may be copied, distributed, translated into other languages or transmitted by any electronic or mechanical means, including photocopying, recording or any other storage and retrieval system, for other purposes that are not exclusively the buyer's personal use, without the manufacturer's express written permission.

The Manufacturer is in no way responsible for the consequences resulting from 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 resulting from incorrect operations carried out by the user.

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 potential consequences of failure 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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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 the training of staff in the use of the medical device.

The instructions for use cover subjects referring to correct use of the system, in order to keep its functional and qualitative characteristics unchanged 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 case of any 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 by modifications and/or translations without prior notice.

Contact the Customer Service office of Videomed S.r.l. to be updated on 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 fully verified, therefore, if an inconsistency is detected, it is necessary to follow the text in the original language or to contact the Customer Service office of Videomed S.r.l.

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

Helion Video Management System units are fitted with identification plates. Each plate contains the unit's identification details.

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)
	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, composed of UDI-DI (01) and UDI-PI ((11) date of production (21) serial number).
	MEDICAL — GENERAL MEDICAL EQUIPMENT FOR ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS, ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014)
 7d hillrom.co.uk	Consult the instructions for use (IFU). A copy of the IFU is available on this website. A printed copy of the IFU can be ordered from Hillrom for delivery within 7 calendar days.
R_x ONLY	Only valid for US. Caution: US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
#	Symbol used to indicate the model number.

1.6 Reference standards

Videomed S.r.l. declares that the Helion Video Management System complies with the specific standards of the medical sector.

Legislation and rules applicable to the United States of America (USA):

Standard	Description
21 CFR Part 820	Quality System Regulation
21 CFR Part 821	Medical Device Tracking Requirements
21 CFR Part 803, 806, 807	Medical Device Reporting, Medical Device Reports of Corrections and Removals, Establishment Registration and Device Listing for Manufacturers and initial Importers of Devices
21 CFR Part 801	Labeling
19 CFR Part 134	Country of origin marking.
AAMI / ANSI / ISO 14971	Medical Devices - Application Of Risk Management To Medical Devices
AAMI / ANSI / IEC 62304	Medical Device Software - Software Life Cycle Processes
ANSI AAMI IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
AAMI / ANSI HE75	Human Factors Engineering - Design Of Medical Devices
AAMI / ANSI ES60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, Mod). (General II (ES/EMC))
AAMI / ANSI / IEC 60601-1-2	Medical electrical equipment -- part 1-2: general requirements for basic safety and essential performance -- Collateral standard: Electromagnetic disturbances -- Requirements and tests. (General II (ES/EMC))
AAMI / ANSI / ISO 15223-1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied - Part 1: General Requirements
California Proposition 65	Safe Drinking Water and Toxic Enforcement Act of 1986

Legislation and rules applicable to European Union (EU) countries:

Standard	Description
Regulation (EU) 2017/745	The regulation on medical devices amending Directive 93/42/ EEC will enter into force on 26 May 2021
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices — Quality management systems
EN ISO 14971	Application of risk management to medical devices
EN ISO 15223-1	Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 60601-1	General requirements for basic safety and essential performance
EN 60601-1-2	General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
EN 60601-1-6	General safety standards — Collateral standard: Usability

Standard	Description
EN 62304	Medical Device Software — Software Life-cycle Processes
EN 62366-1	Application of usability engineering to medical devices
WEEE 2012/19/EU	Waste electrical and electronic equipment
Directive 2011/65/EU, as amended by Commission Delegated Directive (EU) 2015/863	Restriction of the use of certain hazardous substances in electrical and electronic equipment

1.7 Product certification



The Helion video management system is a Class I medical device according to Regulation 2017/745/EU concerning medical devices, which is compliant with the version of the regulation currently in force at the time of sale of the product. Videomed S.r.l. declares the conformity of Helion with the general safety and performance requirements according to Regulation 2017/745/EU concerning 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.

1.8 Warranty

The complete warranty clauses are provided in the sales contract. Videomed S.r.l. assures system safety and functional reliability provided that:

- 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 used 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 PRESENCE OF 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 receive protective earth from the same electrical panel as the one that powers the operating theatre. In addition, all equipment connected to the Helion system must be powered and receive protective earth from the same electrical panel as the one 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 simultaneously touch the metal parts of the system and the patient.

⚠ 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

Removal of the identification plates and/or replacement of them with other plates is absolutely forbidden. If the plates are damaged or removed, the customer must notify the Manufacturer.

2.2 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 finished in wood, concrete or ceramic tiles. If the floors are covered with synthetic material, relative humidity must be at least 30%. Temporary signal loss may occur (for 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 be used no closer to any part of the EUT, including cables. Minimum distance: 30 cm.
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 supply must be typical for a commercial and / 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 be used no closer to any part of the EUT, including 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% a 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	IEC 60601-1-2 Test level	The quality of the mains voltage supply should be typical for commercial or hospital environments. 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	<input type="checkbox"/> * FM + 5 Hz deviation: 1 kHz sine <input checked="" type="checkbox"/> ** 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

2.3 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 guaranteeing the functionality of the product in accordance with the specific instructions for use, supply of 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.

2.4 Cleaning



Do not use any cleaning products.

This paragraph describes how to clean the Helion system.

Cleaning shall be performed on a regular basis (at least once a week) to ensure components remain intact and in good working order.

Use personal protective equipment for any maintenance and cleaning activities. Required protective devices: closed shoes, sturdy long trousers made of fabric, tunic, gloves. Check personal protective equipment to make sure it is in proper condition. Inform the operator of any defects.

2.4.1 Preparing the system

Pull the plug of the power cord out of the socket. In case of permanent installations, turn off the main switch located on the front panel of the rack.

2.4.2 Cleaning the system

1. Wear the required personal protective equipment.
2. Using suitable means, remove coarse dirt from the rack or units for installation without rack.
3. With a clean dry cloth, wipe all residue from the rack or units. First wipe the top and then the sides of the rack or units.
4. Visually inspect the surfaces of the system. The surfaces must be free of residue. Particular attention must be paid to places where the fan grilles are positioned for optimal air recirculation. Clean once more any surfaces with still visible residue.

2.5 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 the Technical Customer Service.

Videomed S.r.l. recommends concluding a maintenance agreement so that maintenance can be performed reliably and in time.

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, as well as to control an operating light within the specifications established by the manufacturer.

3.2 Normal use

- The system is used exclusively to display and manage existing audio-video sources;
- Signals are controlled via a touchscreen monitor;
- Analogue and digital signals are distributed to different video outputs;
- Data are 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;
- Control of turning on, off and intensity of compatible surgical lights.

3.3 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 (monitors connected to the system) shall not be used as the primary information source.

3.4 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 paragraph “Intended purpose”.

Any other use of the system with regard to 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 such cases, the Manufacturer waives any liability for damage caused to goods or persons and deems any type of system warranty to be void.

Improper use of the system rules out any liability on the part of the manufacturer.

3.5 Use in combination with other medical devices

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

3.6 Obligations and prohibitions

The Videomed S.r.l. Helion system may only be used by medical and paramedical staff with the necessary professional qualifications, who have read these instructions for use and have been adequately trained in the use of the system. Training is certified through participation in the training course entitled “Training for healthcare personnel in the use of Helion”. This training must be documented.

3.6.1 Personnel prohibitions

In particular, the personnel must not:

- 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”).



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 an unapproved room.

3.7 Technical data

MAIN UNIT - Technical Specs

Video inputs	18 (14 DVI, 2 3G-SDI, 2 CVBS)
Monitor outputs	10 DVI over CAT 7 or optic fibre
Supported resolutions	Standard video PAL (720 x 576) HDTV (1280 x 720) Full HDTV (1920 x 1080p) 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 4000 V AC Input/FG 1500 V AC
Enclosure	IP20
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	5000 m
Control touchscreen	21", 24" or 27" , 1920 x 1080, 16:9
Storage capacity	2 TB as default (can be expanded up to 4 TB)

MAIN UNIT - Technical Specs

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
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

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	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
Protection	Short circuit protection Overload protection Overcurrent protection Overvoltage protection
Insulation voltage	Input / output 4000 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	5000 m
Enclosure	IP20
HD audio	MicPod 100 Hz up to 16 kHz Mute button
Unit weight	8 kg

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	Optic fibre 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 4000 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	5000 m
Enclosure	IP20
Unit weight	5.5 kg

4K PLUS UNIT - Technical Specs

Video inputs	2 HDMI ports 2 display port
Video outputs	2 HDMI ports 2 display port
Supported resolutions	Up to 4096 x 2160 at 60 Hz
Transmission To Monitor	Optic fibre 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 4000 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	5000 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, with forced ventilation produced 2410 minimum cubic metres per minute (CMM) each
Rack internal component	Isolation transformer, power 1000 VA
Max. operation altitude	3000 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 (1000 m) / +26.6 °C (2000 m) / +18.6 °C (3000 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, producing 2410 minimum cubic metres of forced ventilation per minute (CMM) each
Rack internal component	Isolation transformer, power 1000 VA
Max. operation altitude	3000 m
Enclosure	IP20
Unit weight	64 kg

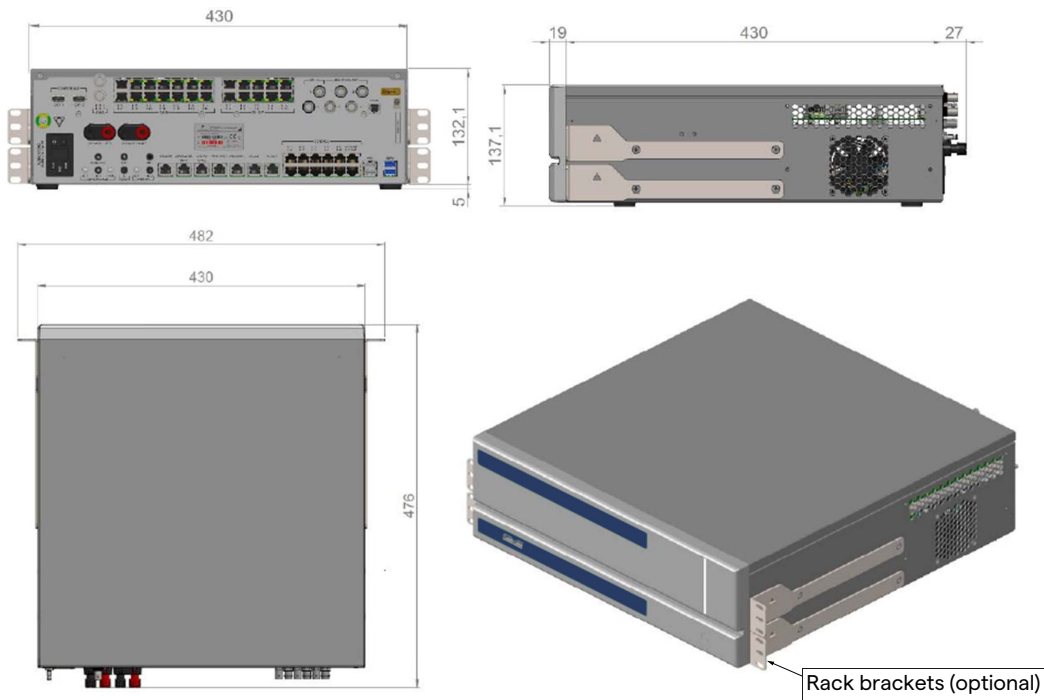
3.8 Measurement and weight layout

MAIN UNIT

Dimensions	133 x 430 x 450 mm
Unit weight	13.5 kg



Rack dimensions (optional)

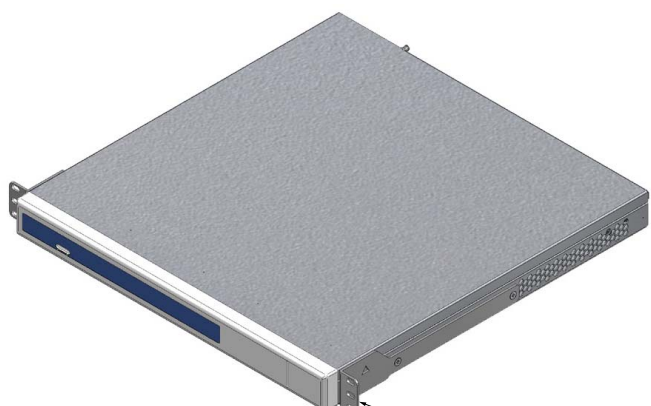
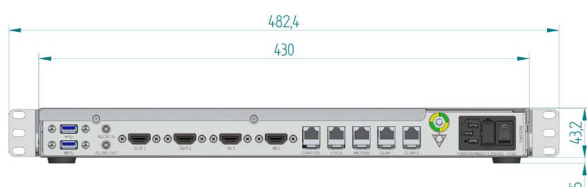


CONFERENCE UNIT

Dimensions	44 x 430 x 450 mm
Unit weight	8 kg



Rack dimensions (optional)



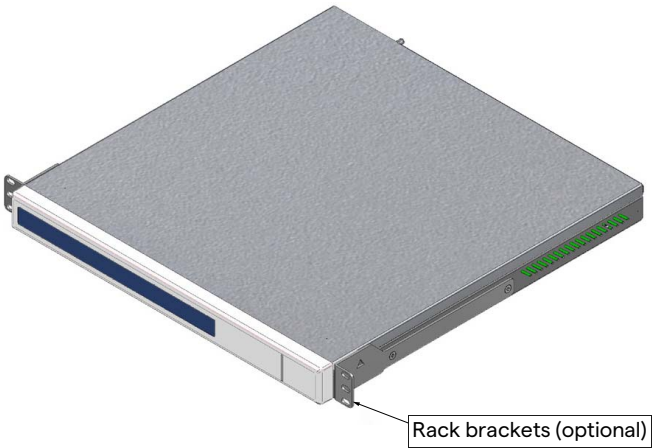
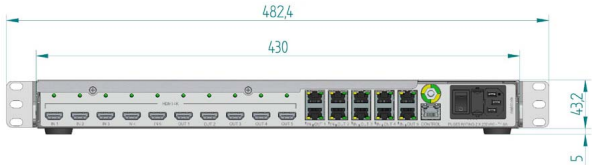
Rack brackets (optional)

4K UNIT

Dimensions	44 x 430 x 450 mm
Unit weight	5.5 kg



Rack dimensions (optional)



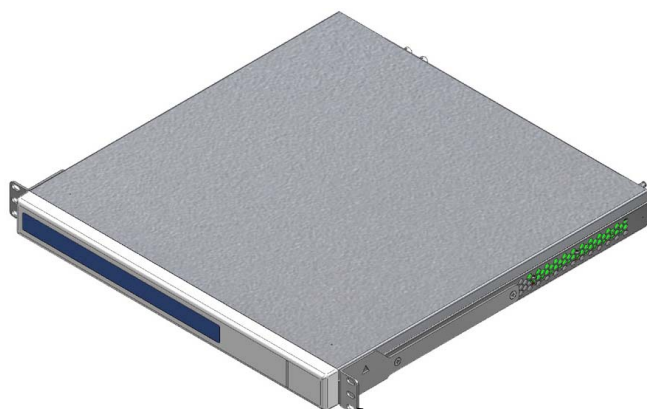
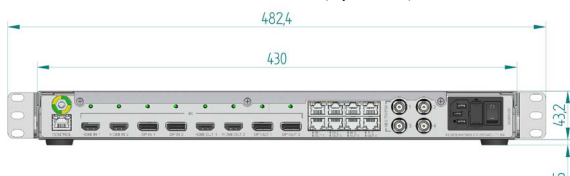
Rack brackets (optional)

4K PLUS UNIT

Dimensions	44 x 430 x 450 mm
Unit weight	5.5 kg



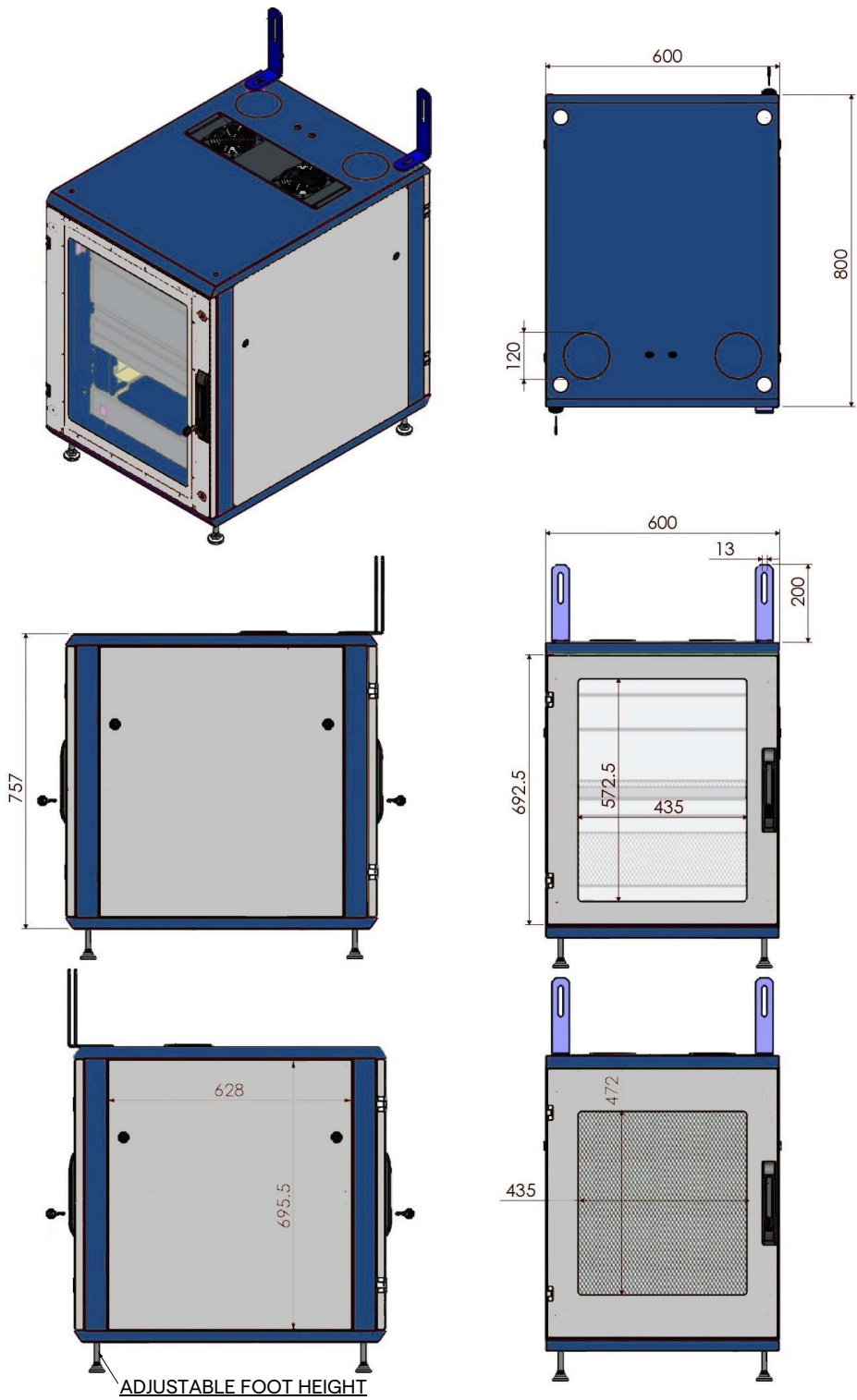
Rack dimensions (optional)



Rack brackets (optional)

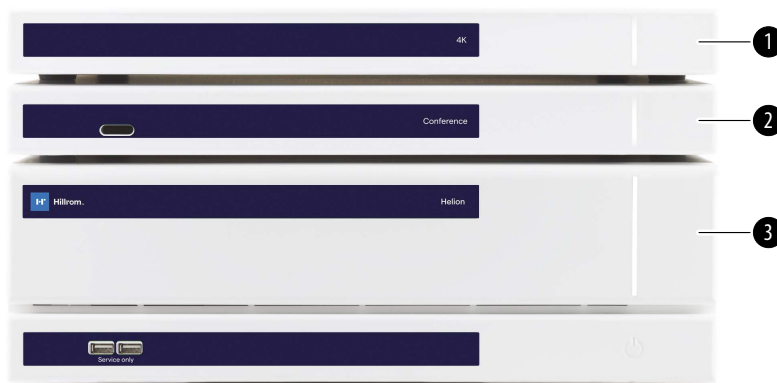
RACK UNIT

Dimensions	800 x 600 x 757 mm
Unit weight	64 kg



3.9 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.



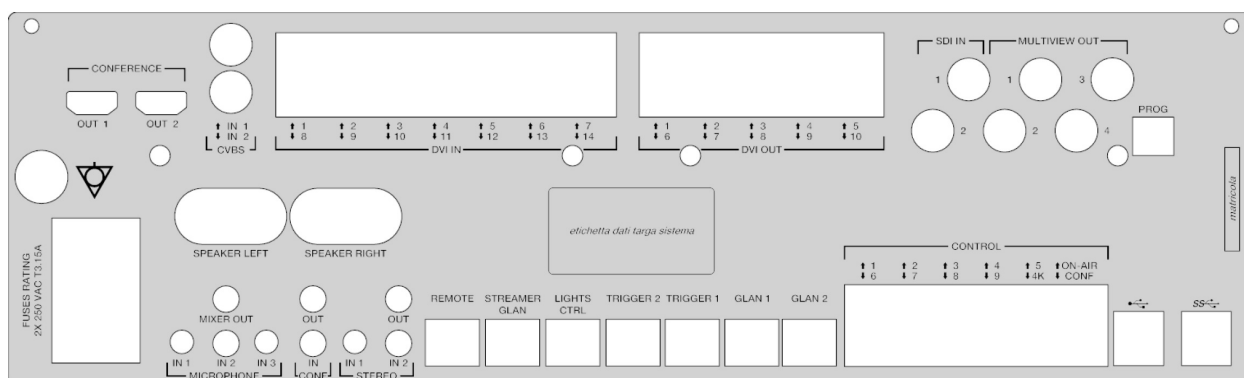
- [1] 4K Unit (4K UNIT) or 4K PLUS Unit (4K PLUS UNIT)
- [2] Conference unit (CONFERENCE UNIT)
- [3] Main unit (MAIN UNIT)

3.9.1 Main unit

The following functions are available via the Main unit.

Function	Description
ROUTING	Makes it possible to distribute the different sources present in the room to the recipient monitors.
PROCEDURE DOCUMENTATION	Makes it possible to document operation by temporarily storing and exporting the images and videos recorded.
VIDEO STREAMING	Makes it possible to share 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:

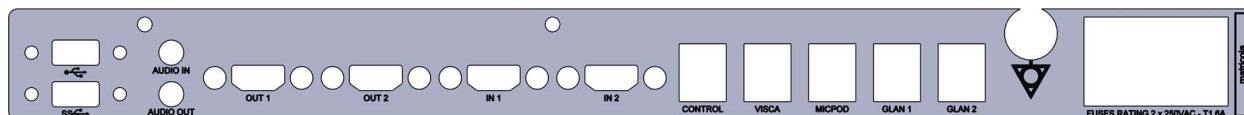


Connection cables are supplied by Videomed S.r.l.

3.9.2 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.

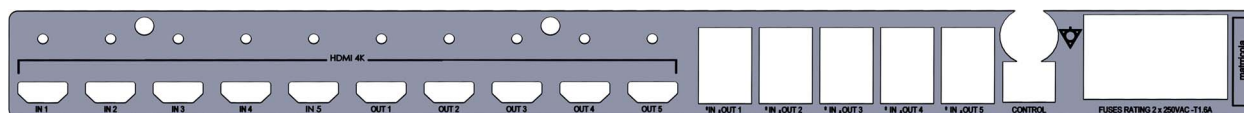


Connection cables are supplied by Videomed S.r.l.

3.9.3 4K unit

The 4K unit allows full management of 4K/Ultra HD resolution signals.

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

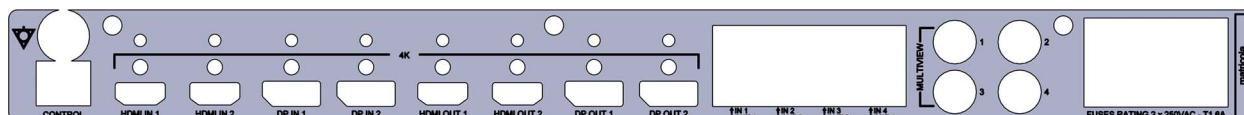


Connection cables are supplied by Videomed S.r.l.

3.9.4 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:

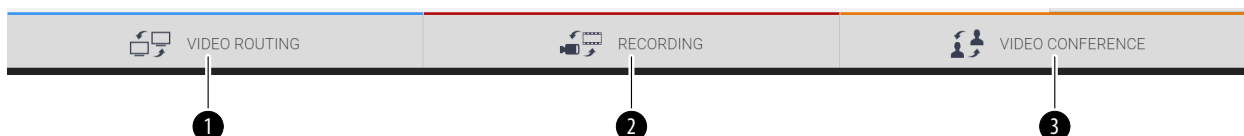


Connection cables are supplied by Videomed S.r.l.

3.9.5 Control software

The user interface of the Helion Video Management System makes it possible to control and manage each functional unit.

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 allows 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 the operator to be adequately trained in the functional and visual controls, adjustments and calibration, cleaning and maintenance of the system, as well as in 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

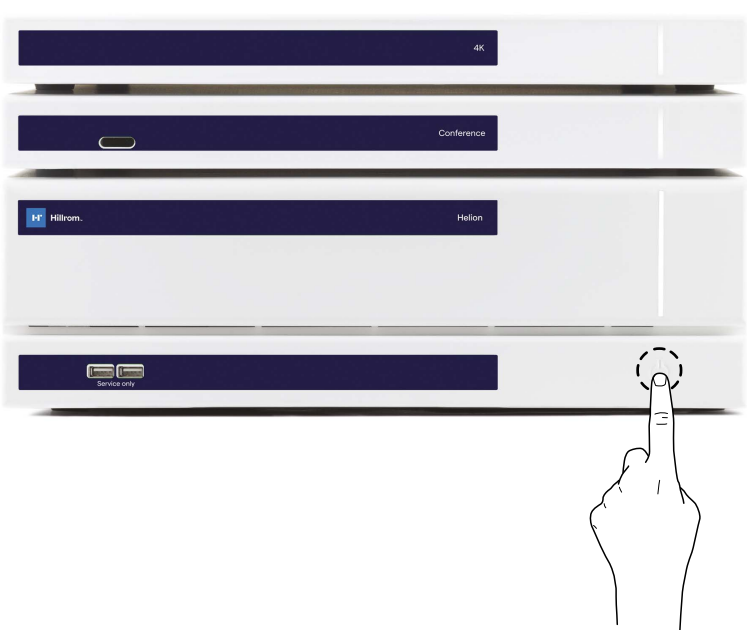
Before each use, check the components of the control screen in terms of:

- 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 start-up

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.

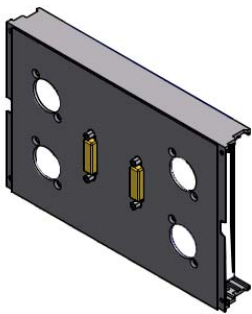
To connect new video sources to the system, simply connect the desired source to one of the compatible video connections on the connection plates installed on the pendant panels.

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
<div>1. Keep your finger on the touch button for about 5 seconds, until the frequency of flashing of the LEDs visibly increases.</div> <div>2. Once the frequency changes, remove your finger from the button.</div>	A screenshot of the Helion control interface. It shows a dark blue header bar with '4K' on the right. Below it are several horizontal bars: 'Conference', 'Hillrom Helion', and a 'Service only' button at the bottom. A hand icon is shown pressing the 'Service only' button, which is circled with a dashed line.

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

It is recommended to only use forced shutdown in an emergency, as this procedure may cause data loss.

4.6 System start-up/shutdown by remote button

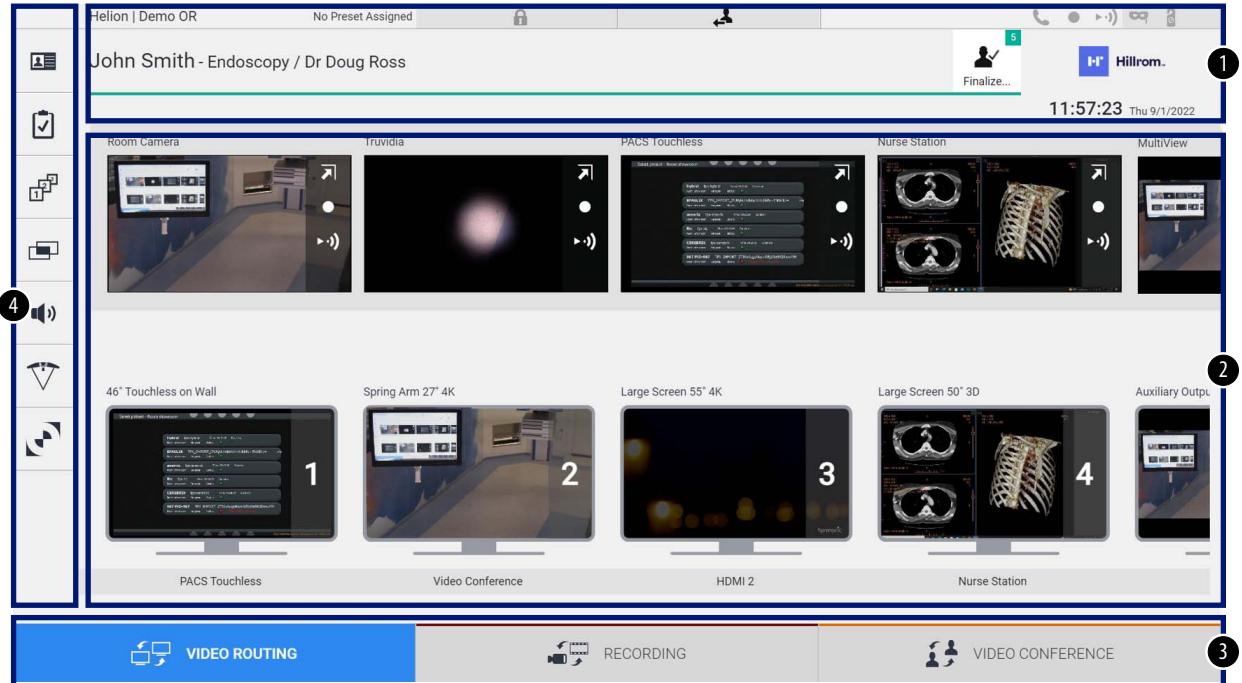
The Helion Video Management System allows units to be restarted via a remote on/off button installed inside the operating theatre (typically on a pendant panel or wall unit).

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

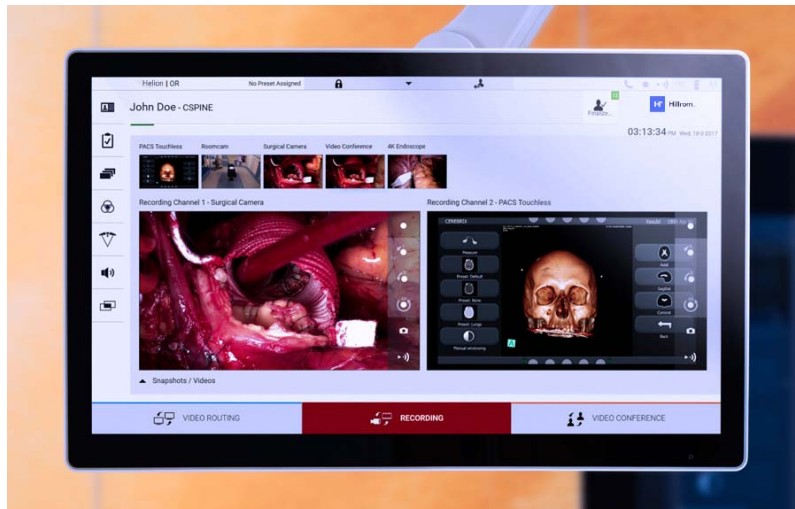
5.1 General description of the user interface

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: <ul style="list-style-type: none"> – 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 touchscreen



The control screen is a high-resolution touchscreen. 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 touchscreen monitor for further information.

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

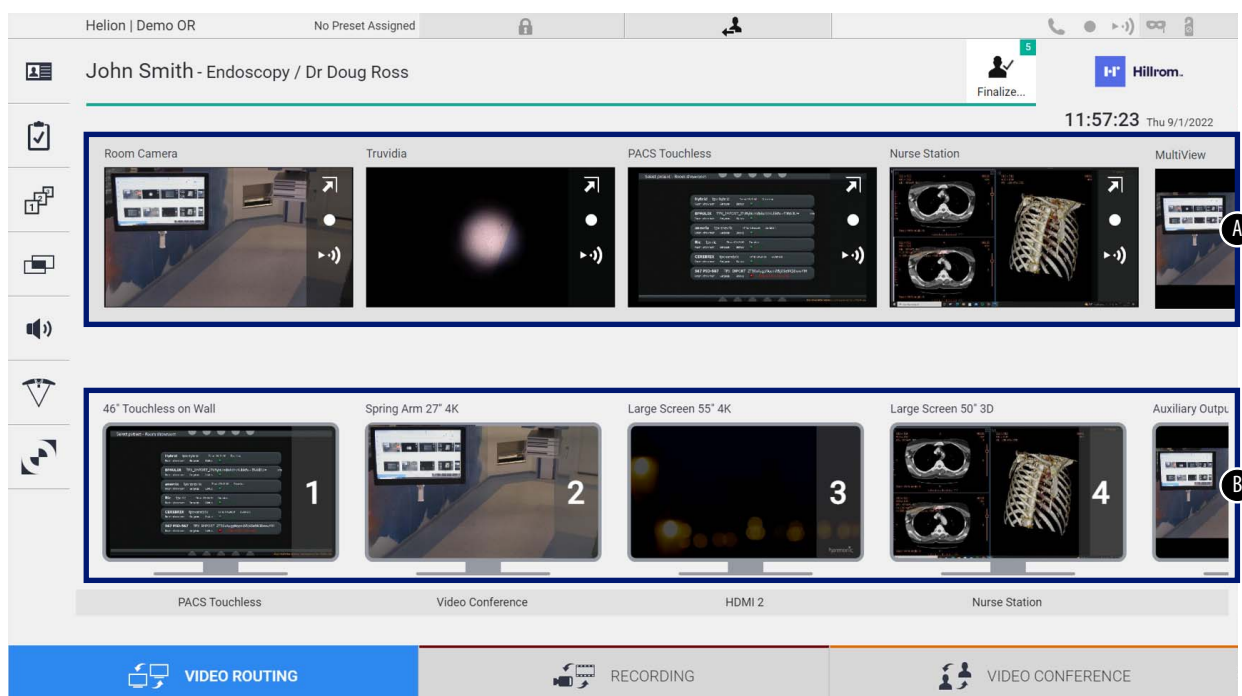
5.3 “Video Routing” function

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.

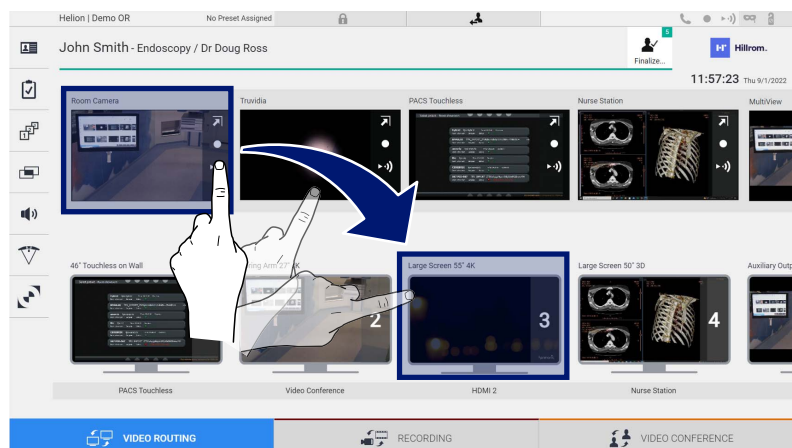
These video signals can be routed to any monitor in the operating theatre.

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] by drag&drop.


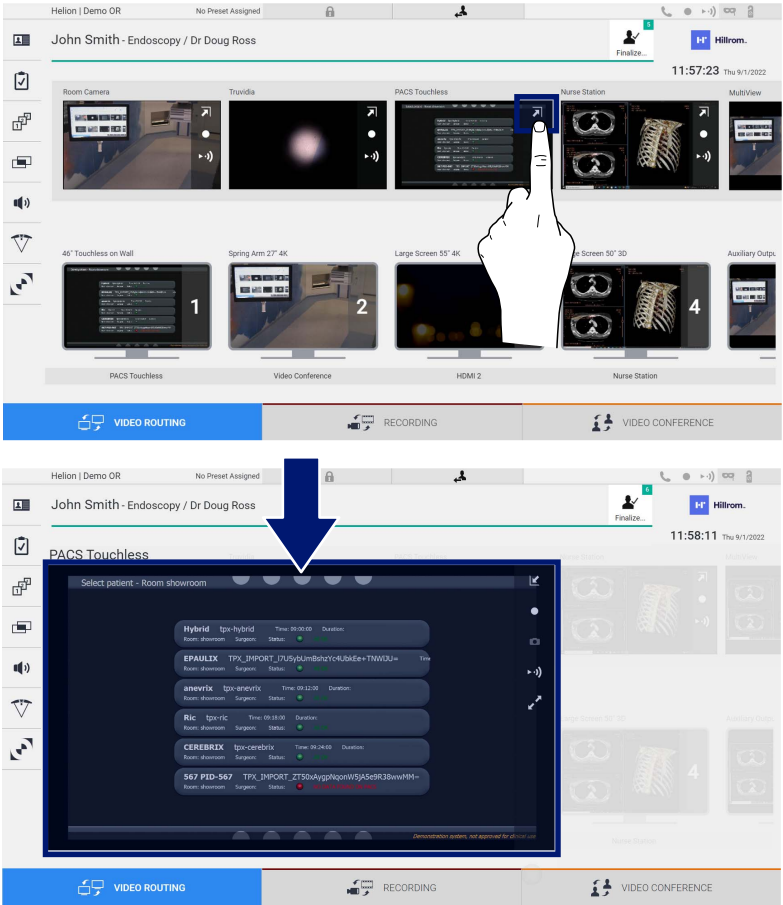

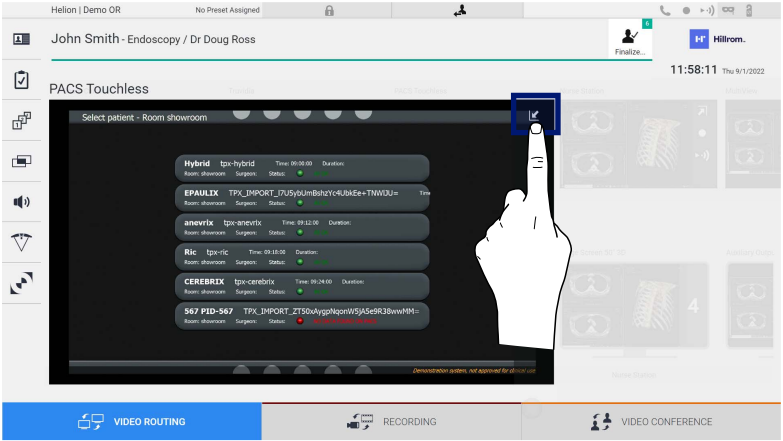


The Preview of the video signal sent will be displayed in the relative Monitor icon and updated periodically.





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

5.3.1 Live Preview

With the Live Preview function, it is possible 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. The enlarged image selected is displayed.	
2. Press  to return to the standard view of the Video Routing section.	

The following icons are present in the Live Preview window:

Icon	Function
	Makes it possible to start/stop recording of the displayed signal. If the icon is grey, this indicates that the function is not active. To activate the function, it is necessary to select a patient from the list (refer to the paragraph "Selecting a patient in the list").
	Makes it possible to create snapshots of the image.
	Makes it possible to start/stop video signal streaming.
	Makes it possible to activate full-screen display, without latency, of the selected source (function is only available on certain touchscreen monitor models).




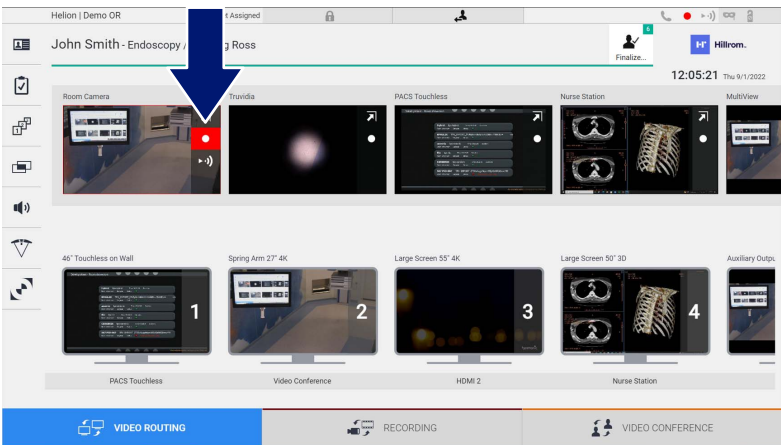
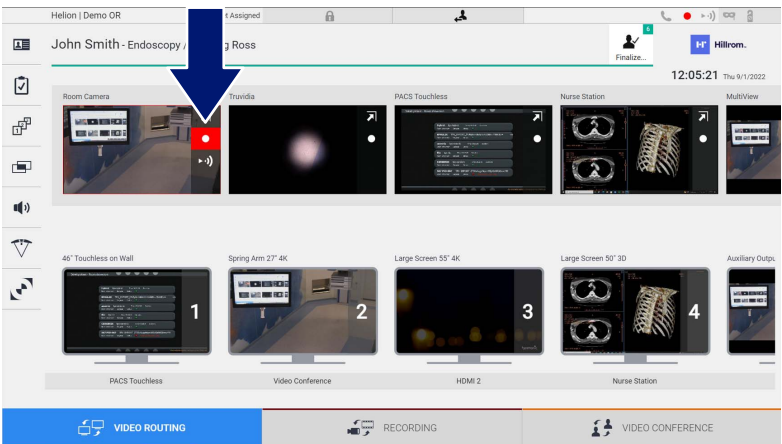
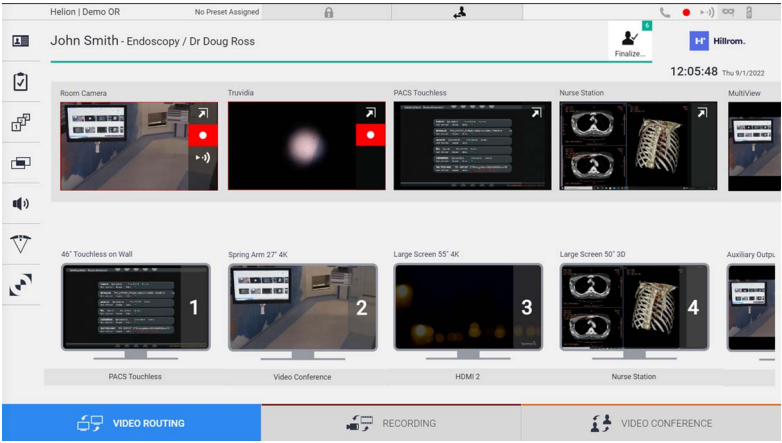
It is not possible to start recording if a reference patient is not present.

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:



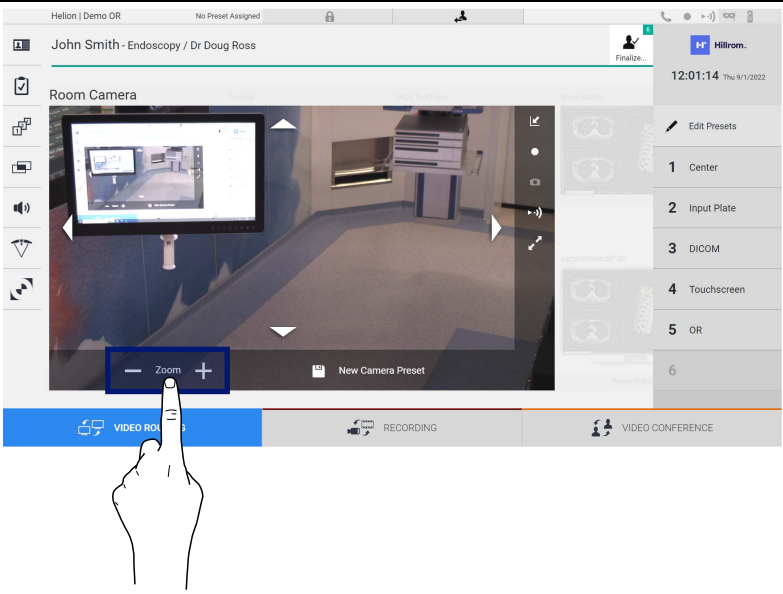
Step	Image
<p>1. Press the  icon of a Preview to start streaming the signal from one of the connected sources.</p> <p>When streaming is active, the button is in a white background  in the icon of the selected source and is disabled in the Previews of the remaining sources.</p> <p>Pressing  in a Preview box also activates the  icon that shows the user the link to connect to the streaming session. Therefore, by using this link, each user can 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, communication with the outside will also be halted.</p>	

5.3.4 Ptz camera control

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


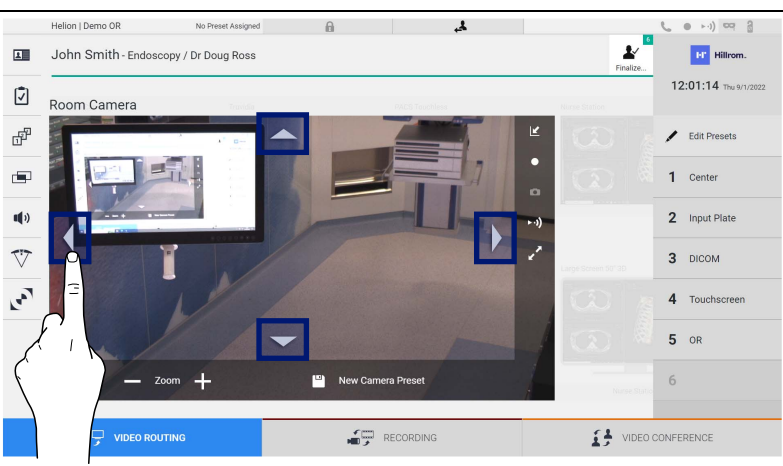
5.3.4.1 Roomcam zoom adjustment

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).	

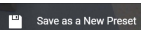
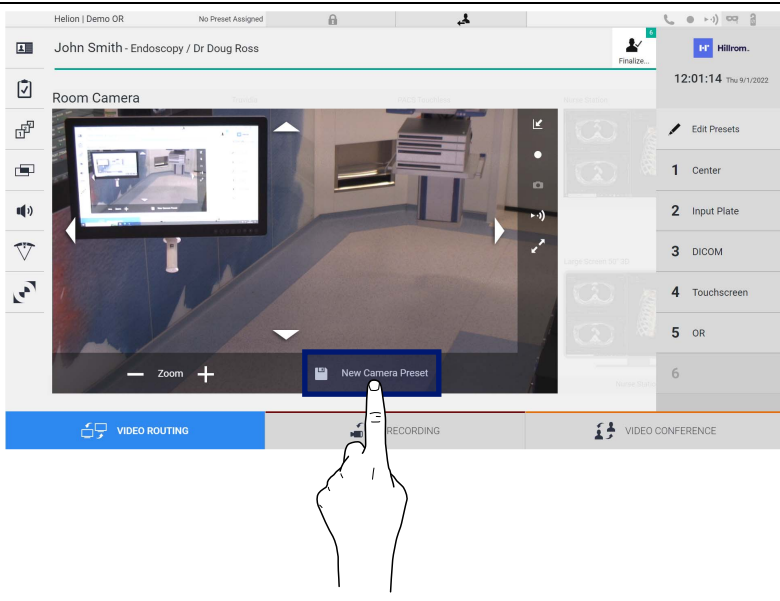

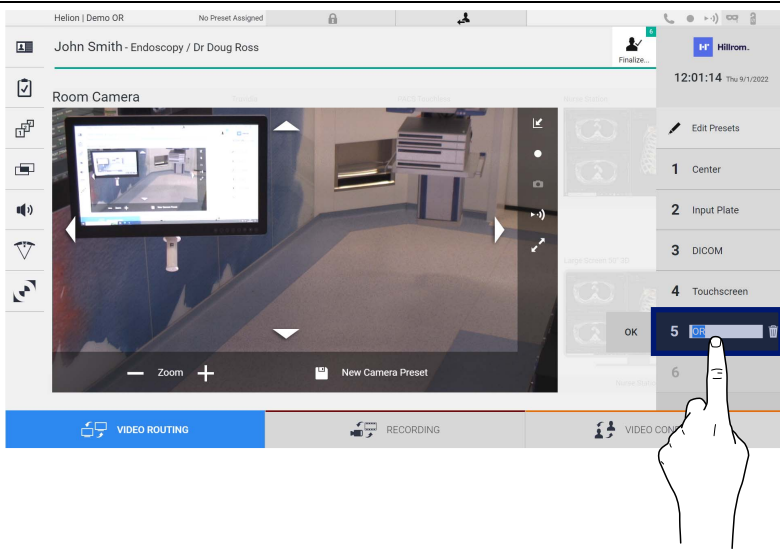
5.3.4.2 Roomcam movement adjustment

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

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


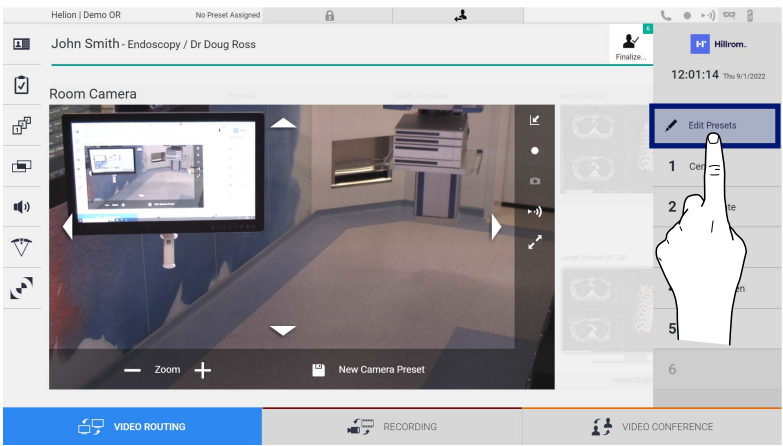

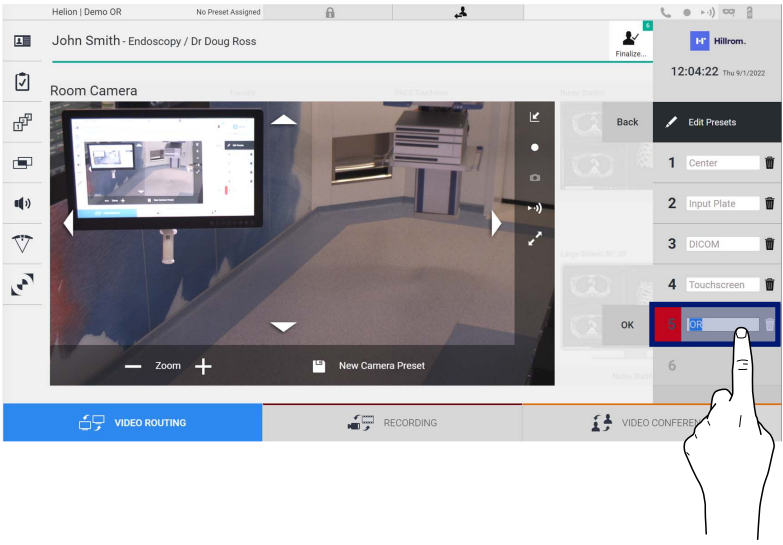
5.3.4.3 Save camera setting (Preset)

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  .	
2. Enter the name to be assigned and press  to confirm. The new Preset with the assigned name will appear on the list on the side.	

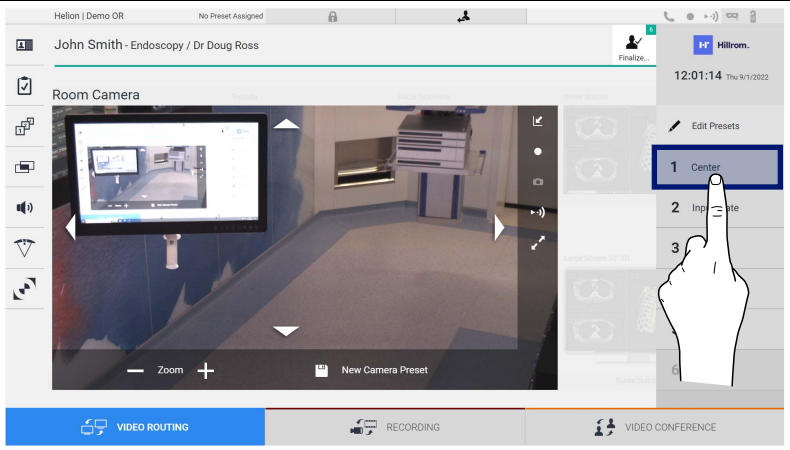
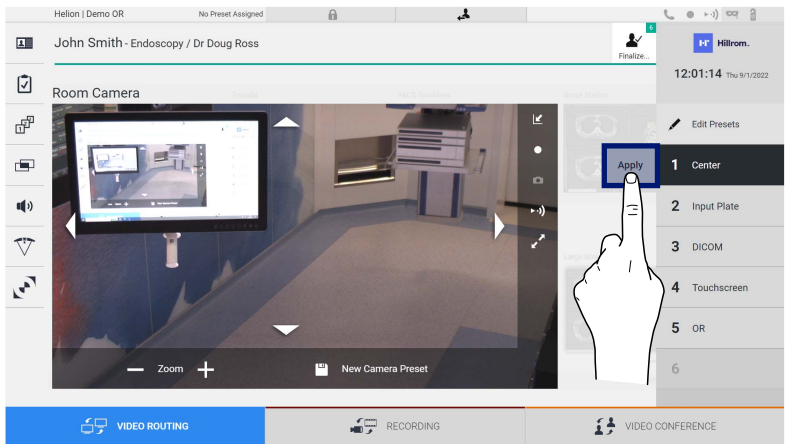
5.3.4.4 Delete camera setting (Preset)

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

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

5.3.4.5 Enable camera setting (Preset)

To activate a video camera Preset, proceed as follows:

Step	Image
1. Press the desired Preset in the list.	 The screenshot shows the 'Room Camera' interface. At the top, it says 'No Preset Assigned'. Below that is a list of presets: '1 Center', '2 Input Plate', '3 DICOM', '4 Touchscreen', '5 OR', and '6'. A hand icon is pointing to the '1 Center' preset. The main video area shows a room with a monitor and a camera. The bottom bar has 'VIDEO ROUTING', 'RECORDING', and 'VIDEO CONFERENCE' buttons.
2. Press Apply to confirm the Preset selection.	 The screenshot shows the same 'Room Camera' interface. The 'Apply' button is now highlighted in blue. A hand icon is pointing to the 'Apply' button. The preset list remains the same.

5.4 “Recording” function

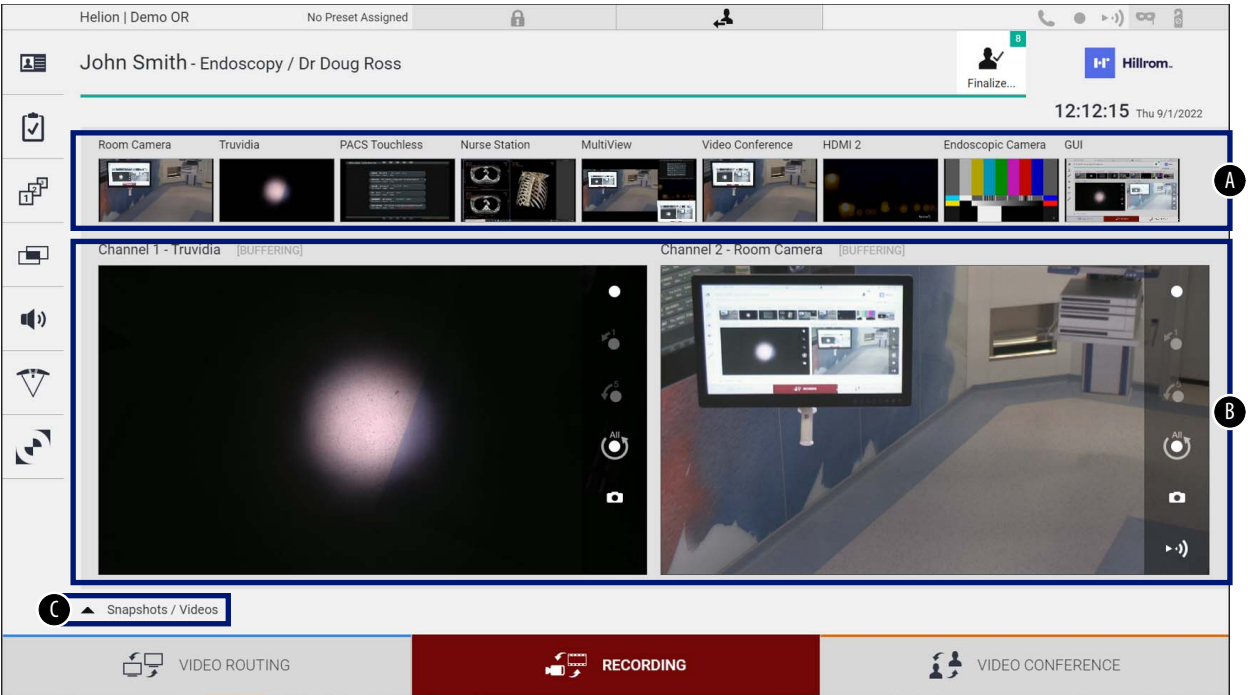
The Recording function makes it possible to capture snapshots and record video from the signals connected to the system.

It is thus possible to save and then modify images and videos that are stored in the system. The 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:

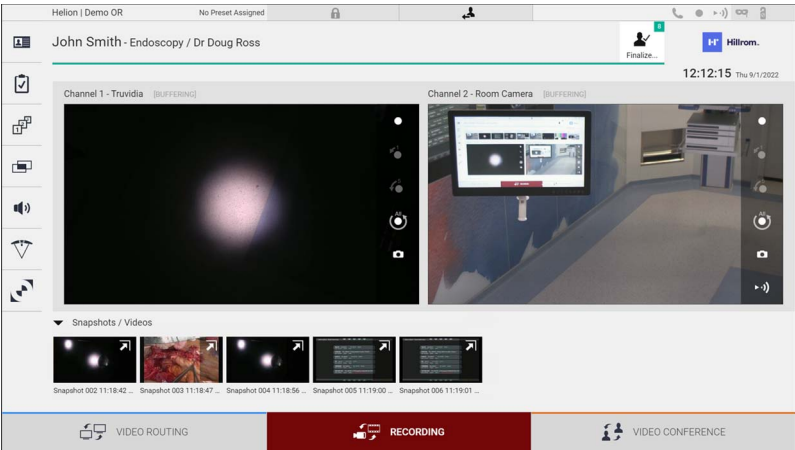
- capturing still images,
- video recording (audio included),
- image and video post-processing.

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”.



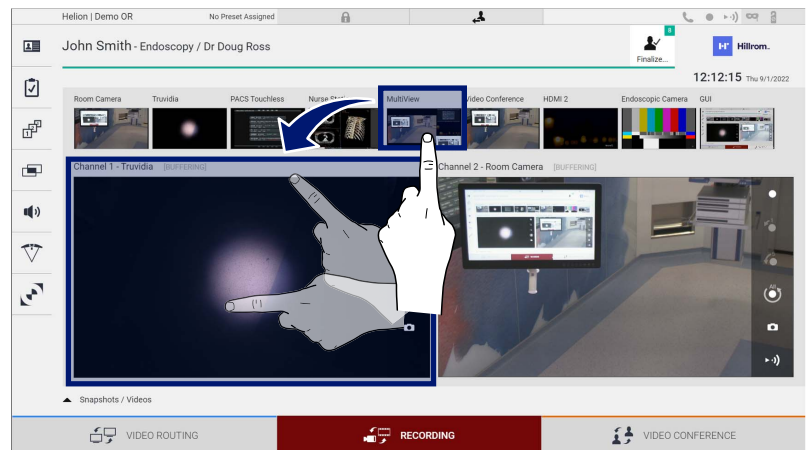
5.4.1 Image data post-processing

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






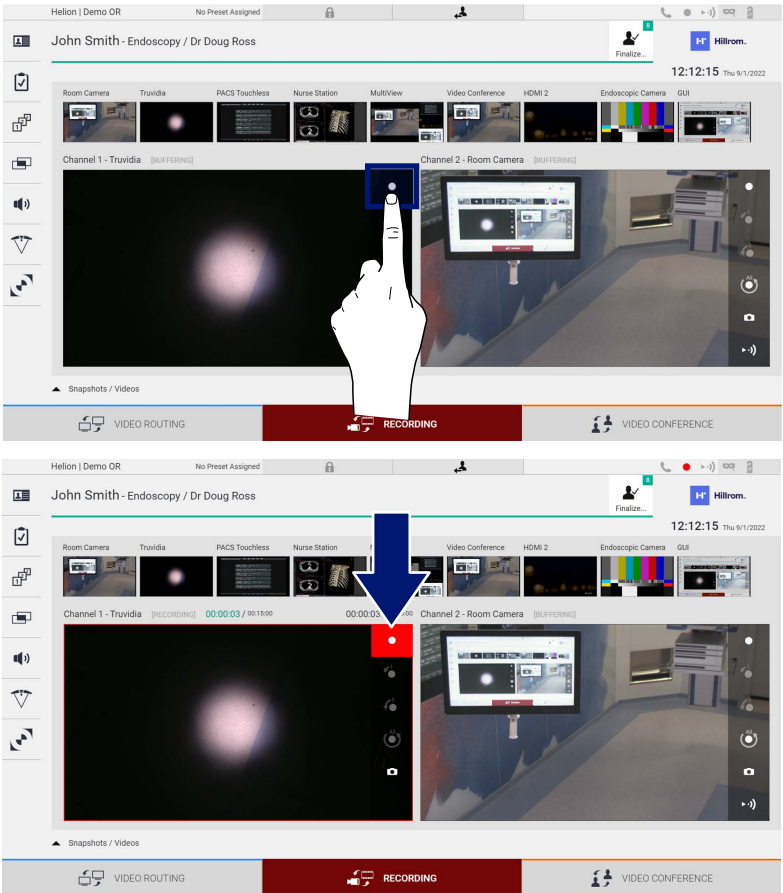
The following icons are available in the Recording Channel window:

Icon	Function
	Makes it possible to start/stop recording of the displayed signal. If the icon is grey, this indicates that the function is not active. To activate the function, it is necessary to select a patient from the list (refer to the paragraph "Selecting a patient in the list").
	Makes it possible to create snapshots of the video source.
	Makes it possible to start/stop video signal streaming.
	Makes it possible to start recording: <ul style="list-style-type: none"> – 1 minute before, – 5 minutes before, – the entire available buffer (up to a maximum of 2 hours).


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:


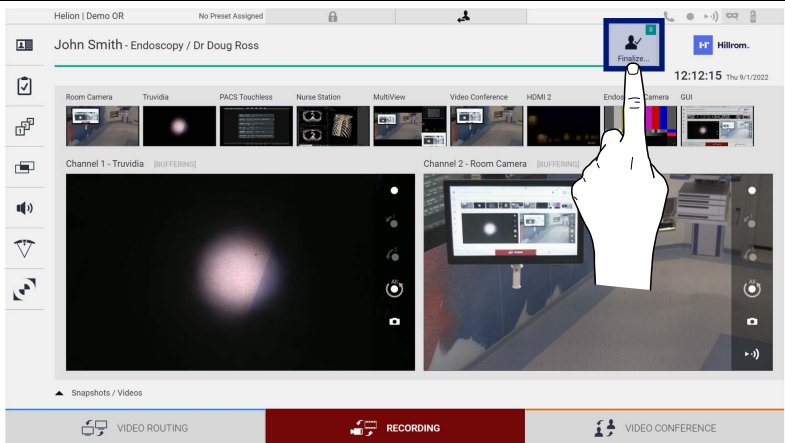

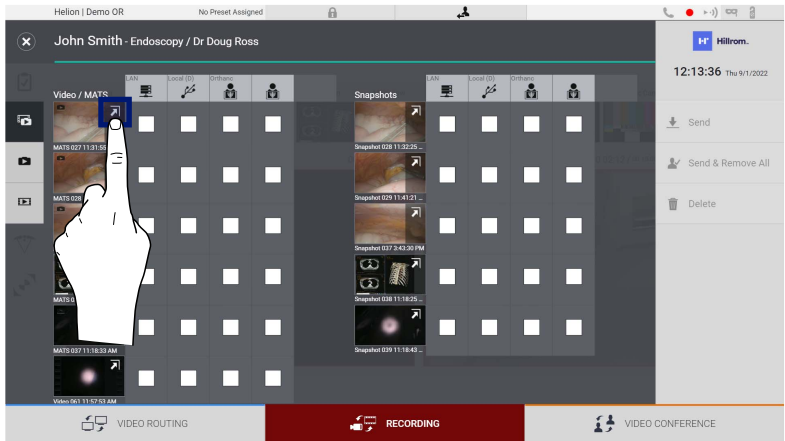
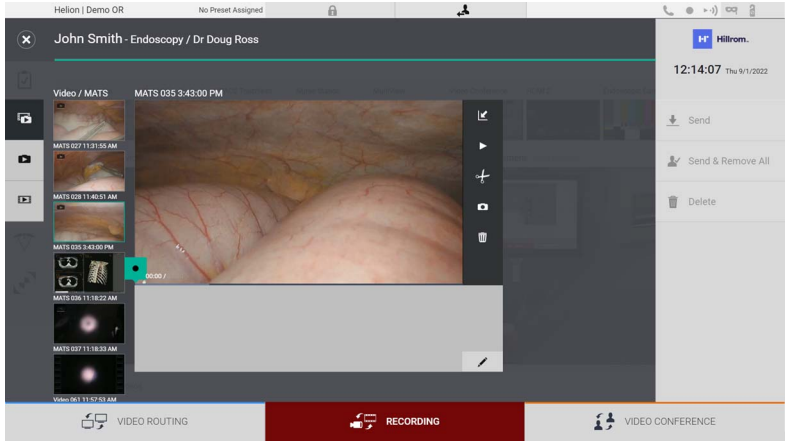





















Step	Image
1. Press the  icon of a Recording Channel to start recording a signal. When recording is in progress, the button is red  in the selected Recording Channel. The  icon is also present in the upper part of the screen and also remains visible when navigating through other functions (if recording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

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

Using the number in the  icon, it will be possible to see how many media items have been associated with that patient. Click on the icon to access the storage folder.


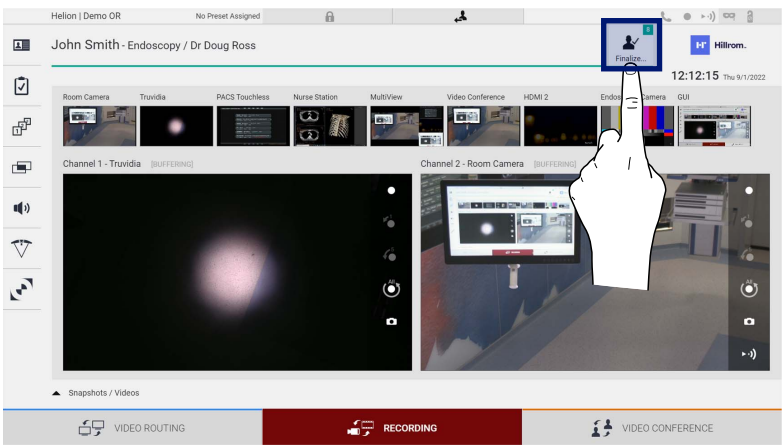

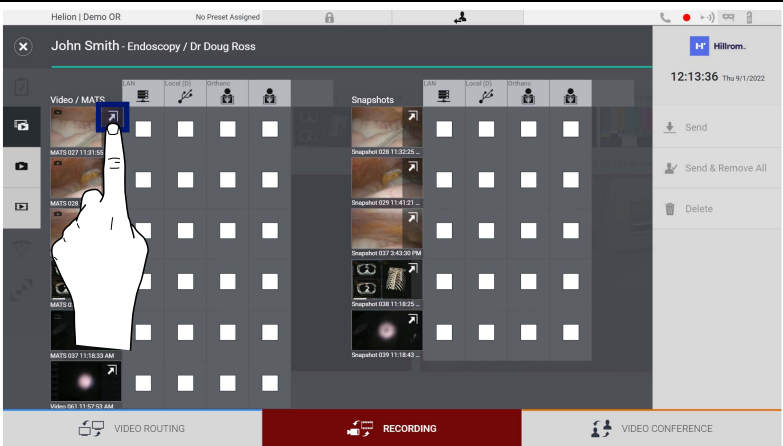



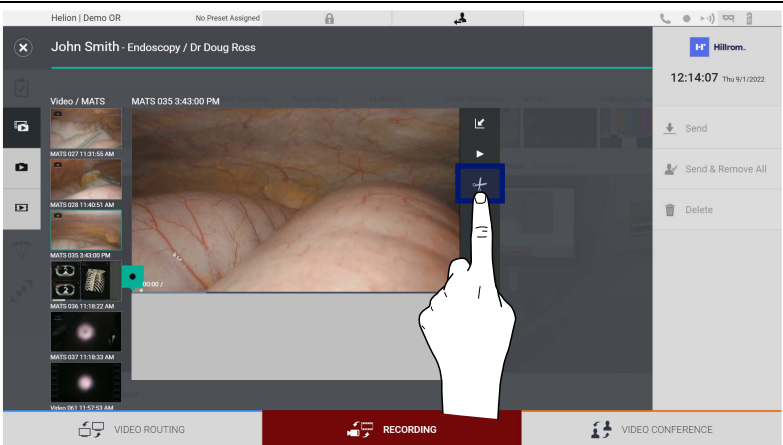
5.4.4 Snapshot and video playback

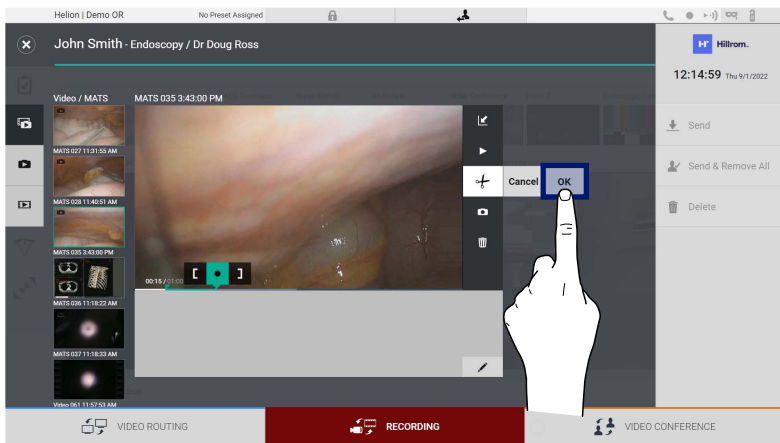
To play snapshots and videos, proceed as follows:

Step	Image																
1. Press  to view all images and videos related to the selected patient.																	
2. Press the  icon to enlarge the individual media item.																	
3. A new window appears which, depending on the file selected (image or video), allows you to:																	
<table border="1"> <thead> <tr> <th>Icon</th><th>Function</th></tr> </thead> <tbody> <tr> <td></td><td>Delete the file.</td></tr> <tr> <td></td><td>Add a comment.</td></tr> <tr> <td></td><td>Play the video.</td></tr> <tr> <td></td><td>Interrupt video playback.</td></tr> <tr> <td></td><td>Extract a part of the video.</td></tr> <tr> <td></td><td>Return to the full view of available functions.</td></tr> <tr> <td></td><td>Create a snapshot from the video being played.</td></tr> </tbody> </table>	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.	
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

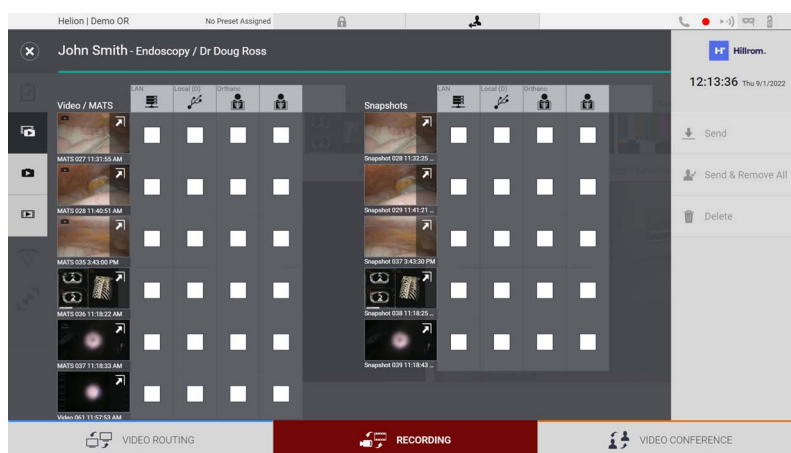
To cut videos, proceed as follows:

Step	Image
1. Press  to view all images and videos related to the selected patient.	
2. Press the  icon to enlarge the single 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.	

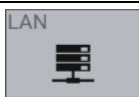

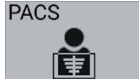
Step	Image
<p>4. Once the cutting points have been determined, extract the portion of the video by pressing OK.</p> <p>A new video appears in the photo/video list for the same patient.</p>	

5.4.6 Export images and videos

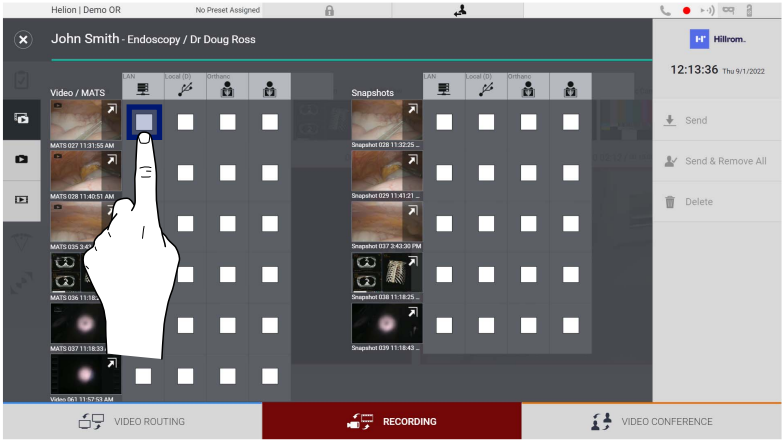
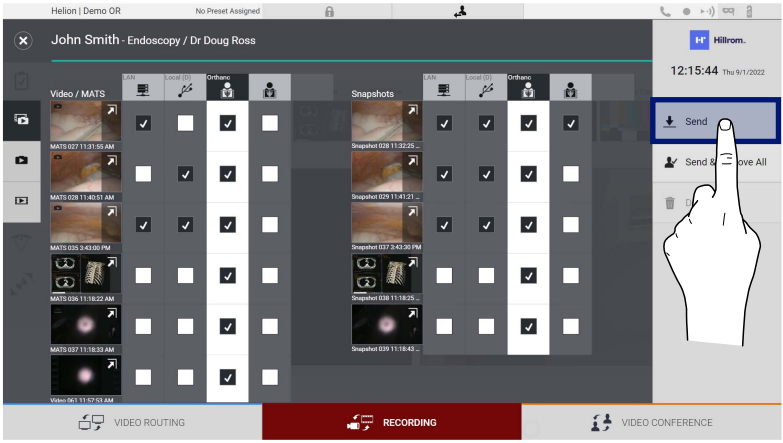
Click on the  icon to access the folder for exporting images and videos of the selected patient. This operation must be performed to export the media and, optionally, close the patient file. All the captured images and videos are displayed on a screen.




The following icons are available in the Export window:

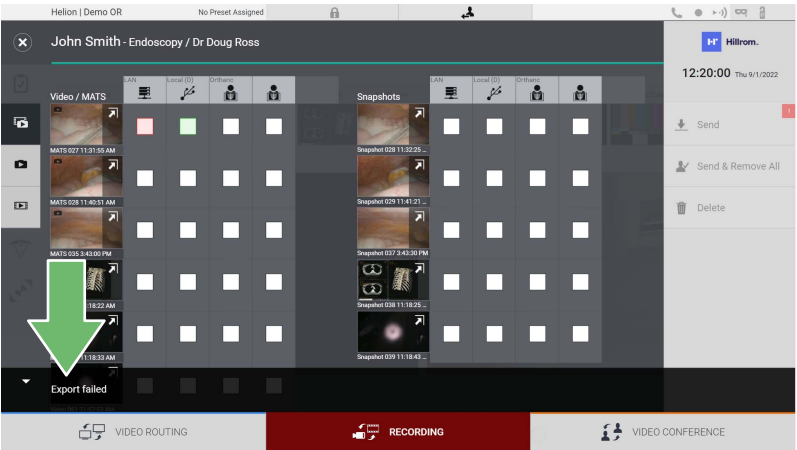
Icon	Function
	Makes it possible to export via LAN to another device.
	Makes it possible to save to a device connected to the USB port.
	Makes it possible to export to the PACS system.

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. By pressing Send & Remove All , the files are sent to the selected destinations and the patient's session is deleted.	

Activation of each of the export options shown above depends on settings that need to be authorised and guided by the hospital's IT managers.

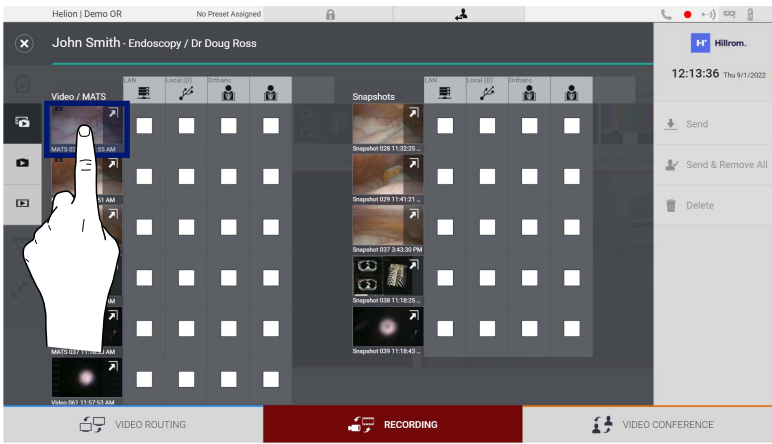

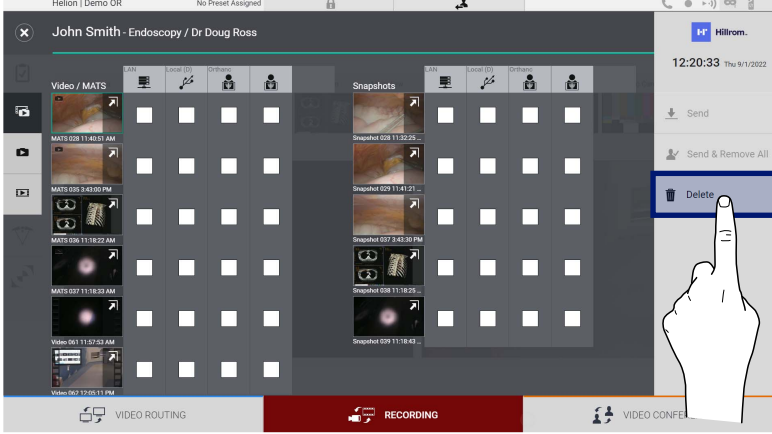

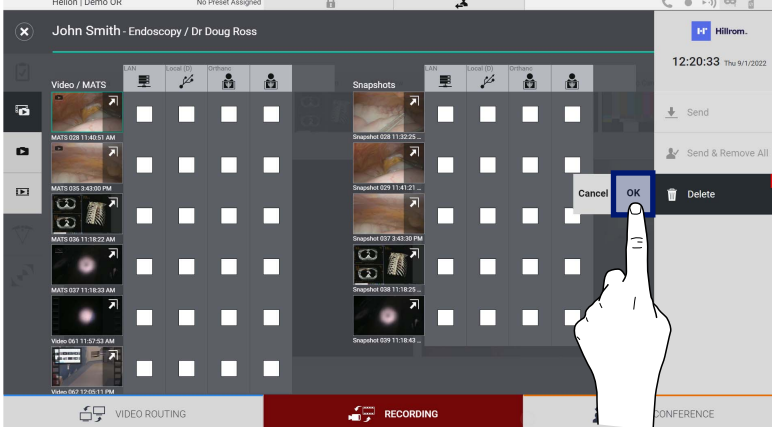
If the export destination does not respond (e.g.: USB device not present), the system displays an "EXPORT FAILED..." error message and the icon  appears on the right side of the screen. A red checkbox is displayed for each destination to which the selected file could not be exported, as shown in the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



5.4.7 Delete images and videos

Click on the  icon to access the folder for storing images and videos for 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  to confirm deletion of the selected files.	

5.5 “Video Conference” function

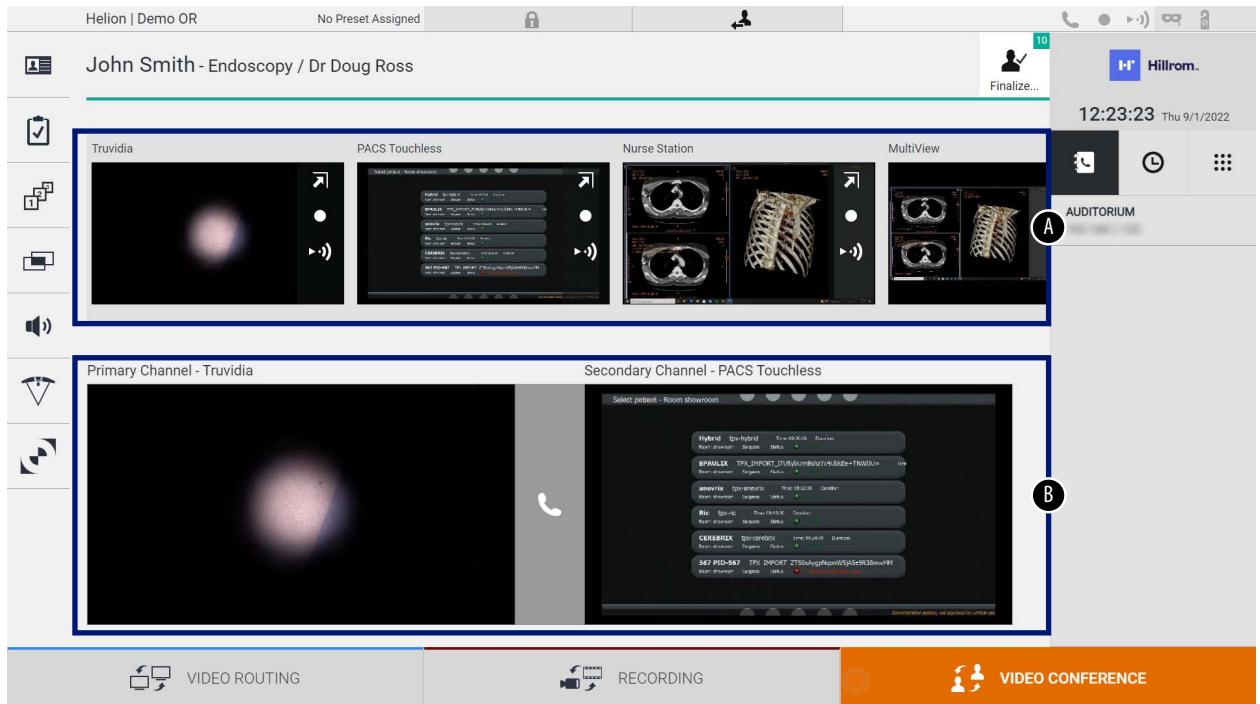
The Video Conference function allows video conferencing in a two-way audio and video connection from the operating theatre to external rooms:

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


The following modes are available:

Mode	Description
Preview of the transmission channel	This enables viewing of one, or in 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: <ul style="list-style-type: none">– 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:

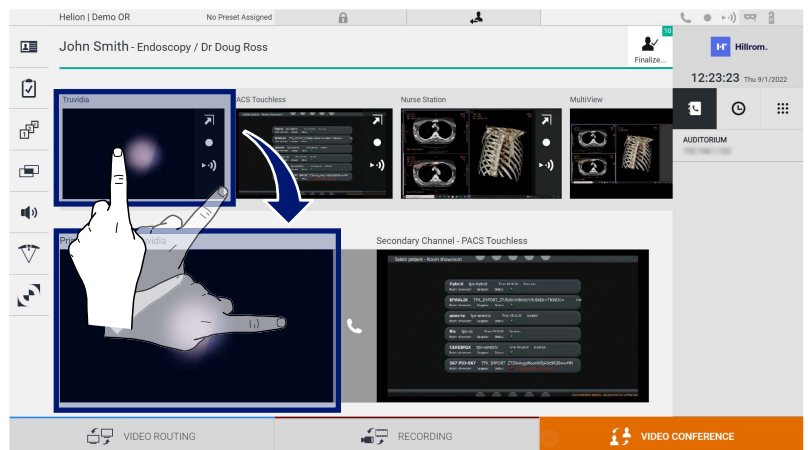


- [A] source list
- [B] view of the two video conference channels


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

5.5.1 Selecting the signals to be sent by video conference

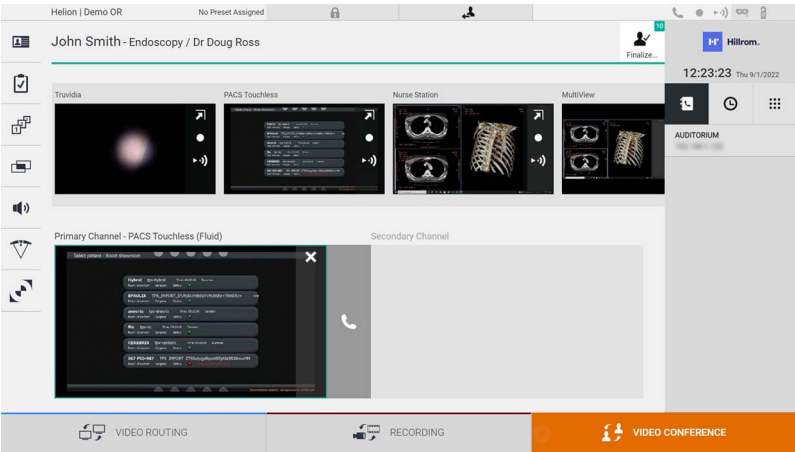
From the Source List, drag the source you wish to send via video conference in the Primary Channel (or Secondary Channel) box.




5.5.2 Removing the signals to be sent by video conference


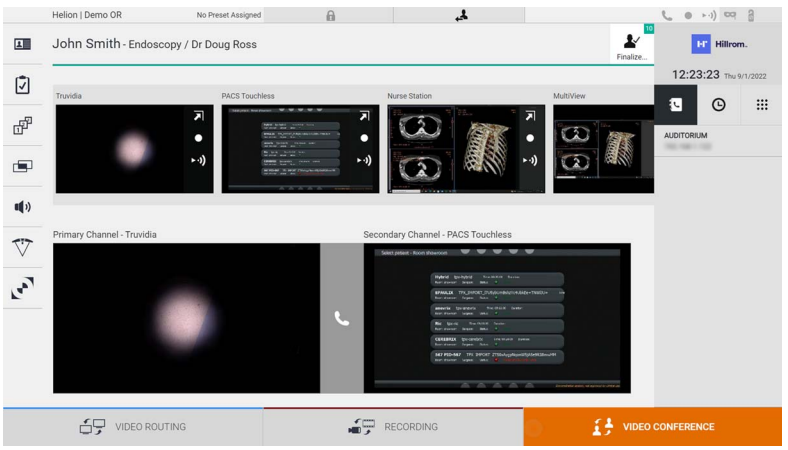
Press one of the boxes related to the primary and/or secondary video conference channel and then the icon  to be shown inside it to remove the video signal from the video conference.


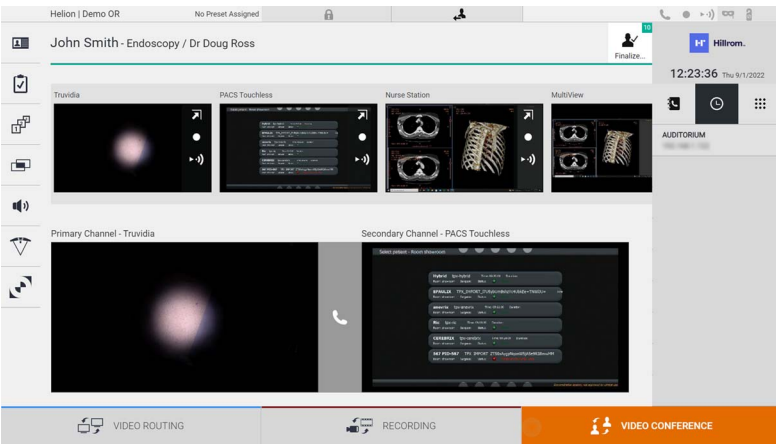

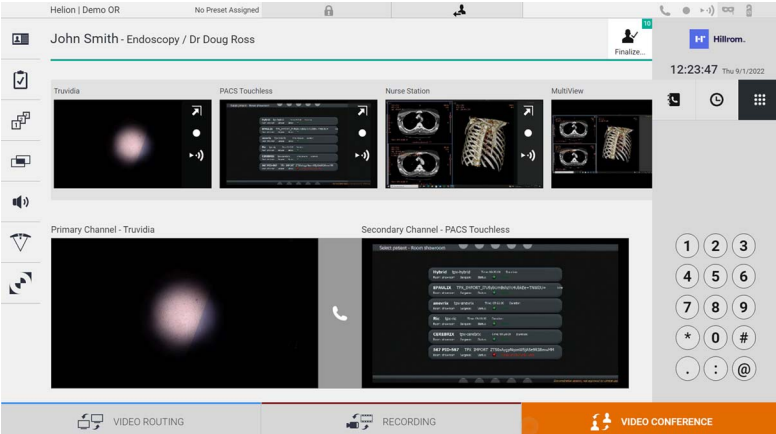
The thus removed video signal will no longer be shared with video conference participants.



5.5.3 Call recipient selection



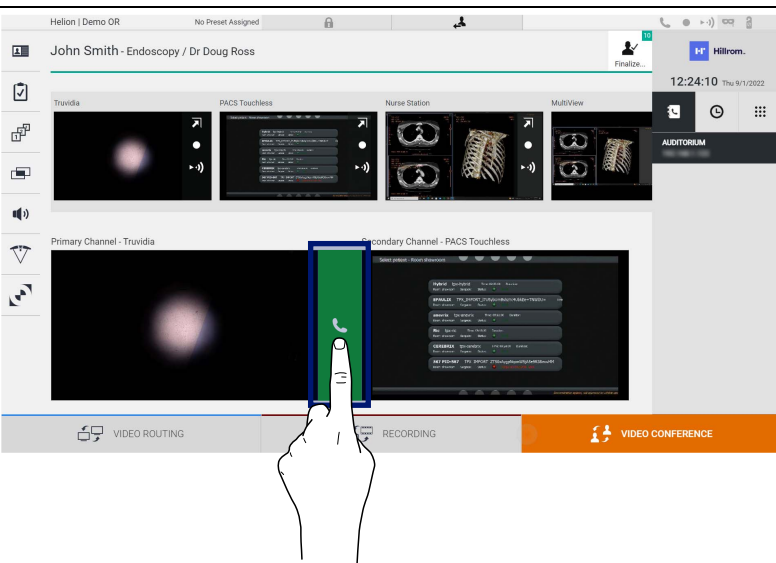
To select the call recipient, press the respective icon  (depending on the mode) on the right side of the screen. The icons are described below:

Icon	Description	Image
	Enables selection of a name from the contact list.	

Icon	Description	Image
	Enables selection of a name/address from those indicated in the calls sent/received log.	
	Enables manual entry of 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 to end the call.	

5.5.5 Call H.323/SIP recipient








The following instructions outline the steps required to:

- Access the Helion system Address book section
- Call into a H.323/SIP meeting via the Helion system


Step	Image
<p>1. On a PC from which Helion can be reached via network, open an up-to-date web browser and type the Helion Address book address: https://<ip-address>/address-book</p> <p>Note: Replace <ip-address> with the actual IP address/FQDN of the Helion Main Unit.</p> <p>2. Enter the same user credentials to access the Helion GUI.</p>	
<p>3. Click  in the bottom-right corner of the page to bring up the New Contact form.</p> <p>4. Type the name of a contact into the Name field.</p> <p>5. Select the SIP/H.323 radio button based on the platform you are using.</p> <p>6. Enter the SIP/H.323 link address into the SIP/H.323 address field.</p> <p>Note: You can mark a contact as a "Favourite" to make it appear at the top of the list, in alphabetical order.</p> <p>7. Click .</p>	
<p>8. Log into the Helion System user interface.</p> <p>9. Navigate to the Video Conference tab and review the saved contacts in the address book on the right-hand side of the screen to find the named contact you just created.</p> <p>10. Select and call the contact you created.</p>	

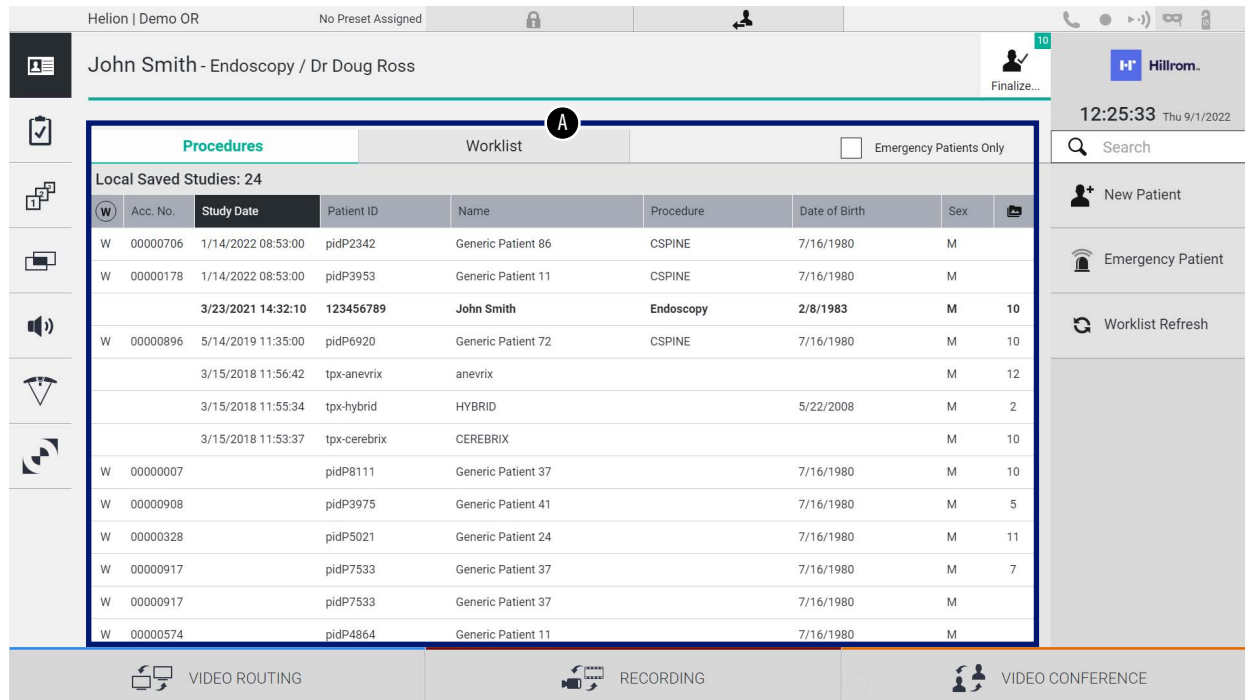
5.6 Additional functions

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

Icon	Description
	Allows access to the patient data management-related screens.
	Allows access to the Check-List screens relating to the surgery.
	Allows access to the Preset & Workflows screens of the Room configuration.
	Allows access to the Multiview setup screens.
	Allows access to the Audio setup screens.
	Allows access to the management screen of the operating lights in the operating theatre. This function can only be used if the associated Baxter devices are present.
	Allows access to the control screen of the lights in the operating theatre. This function can only be used if the associated Operamed devices are present.

5.6.1 Patient data management

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



Helion | Demo OR No Preset Assigned

John Smith - Endoscopy / Dr Doug Ross

Finalize...

12:25:33 Thu 9/1/2022

Search

New Patient

Emergency Patient

Worklist Refresh

VIDEO ROUTING RECORDING VIDEO CONFERENCE

W	Acc. No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex	
W	00000706	1/14/2022 08:53:00	pidP2342	Generic Patient 86	CSPINE	7/16/1980	M	
W	00000178	1/14/2022 08:53:00	pidP3953	Generic Patient 11	CSPINE	7/16/1980	M	
		3/23/2021 14:32:10	123456789	John Smith	Endoscopy	2/8/1983	M	10
W	00000896	5/14/2019 11:35:00	pidP6920	Generic Patient 72	CSPINE	7/16/1980	M	10
		3/15/2018 11:56:42	tpx-anevrix	anevrix			M	12
		3/15/2018 11:55:34	tpx-hybrid	HYBRID		5/22/2008	M	2
		3/15/2018 11:53:37	tpx-cerebrix	CEREBRIX			M	10
W	00000007		pidP8111	Generic Patient 37		7/16/1980	M	10
W	00000908		pidP3975	Generic Patient 41		7/16/1980	M	5
W	00000328		pidP5021	Generic Patient 24		7/16/1980	M	11
W	00000917		pidP7533	Generic Patient 37		7/16/1980	M	7
W	00000917		pidP7533	Generic Patient 37		7/16/1980	M	
W	00000574		pidP4864	Generic Patient 11		7/16/1980	M	


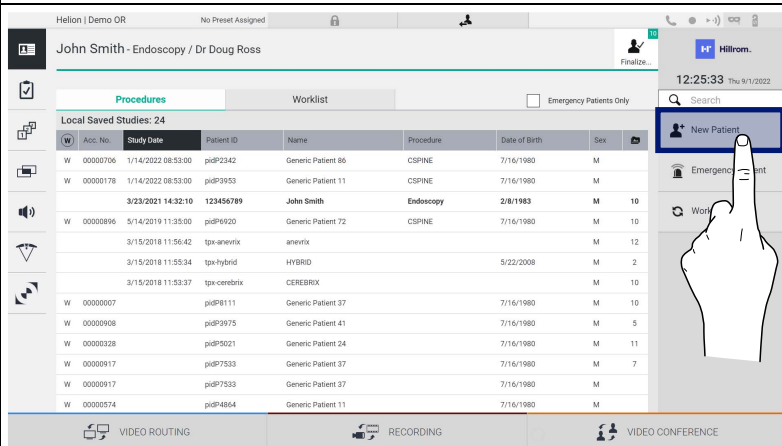
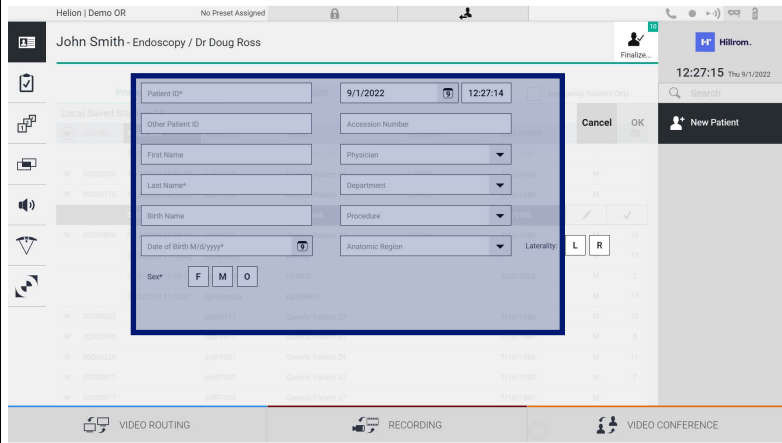
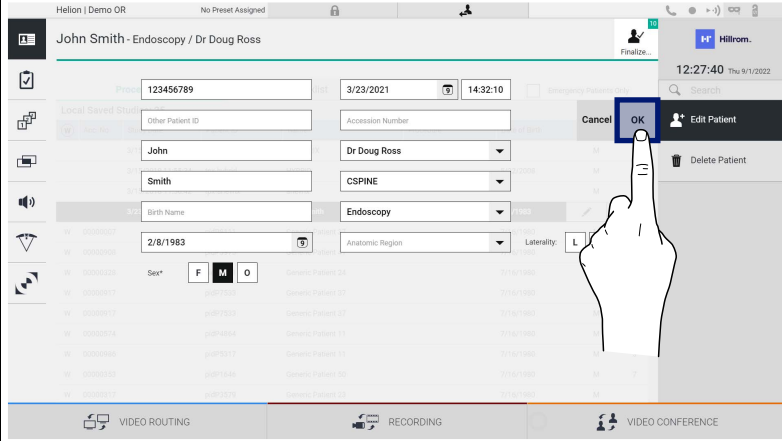
On the screen displayed, after pressing the icon, the list of patients [A], already entered and divided between those imported by the Worklist (if present), and those previously manually selected or inserted, is displayed.

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

65

5.6.1.2 Entering a new patient

To enter a new patient, proceed as follows:


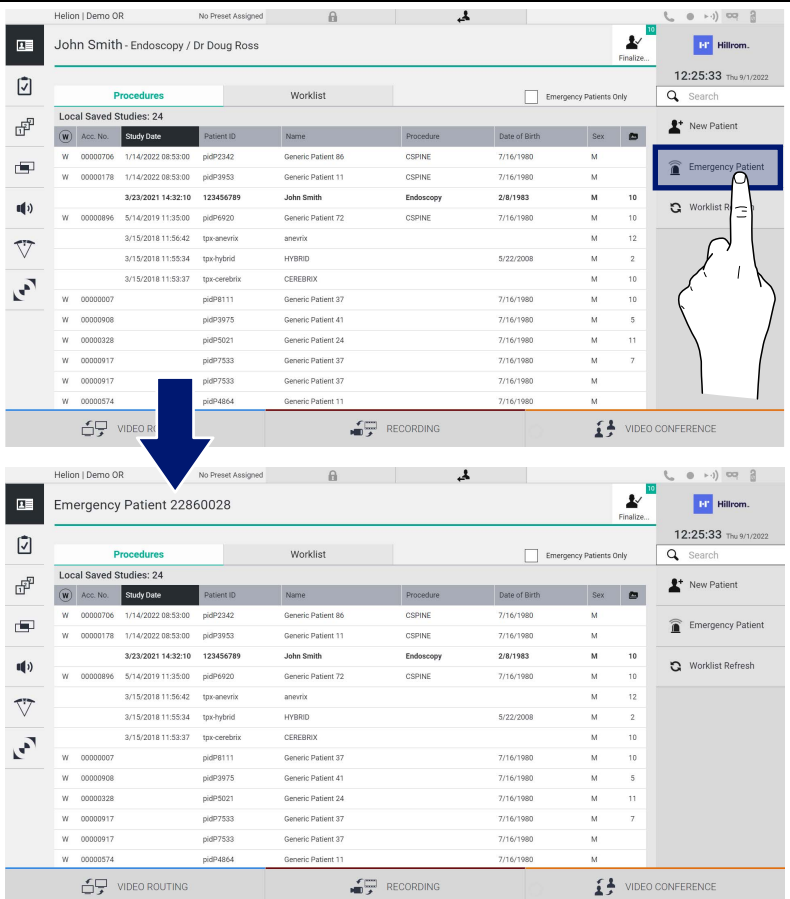
Step	Image
1. Select the  New Patient icon on the right of the screen. The patient data entry window is displayed.	
2. Enter the data for the new patient. Fields marked with a * are mandatory.	
3. Once the mandatory data have been entered, the new patient can be saved by pressing OK or cancelled using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

5.6.1.3 Entering an emergency patient

If the conditions do not allow new patient data to be entered completely manually, using this option, it is possible to quickly create a name with a random ID called Emergency Patient.

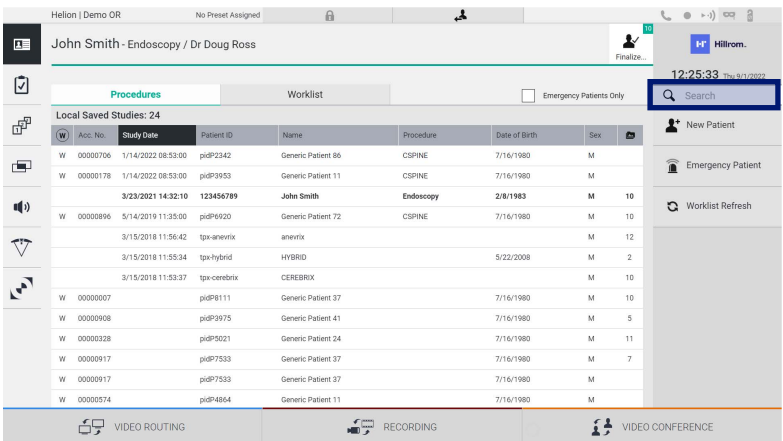
In terms of available functionalities and management, the Emergency Patient is similar to any patient entered manually or by calling up the Worklist.

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.	 <p>The screenshot shows the Baxter user interface. The top bar displays 'Helion Demo OR' and 'No Preset Assigned'. The main area shows a patient list with columns: Acc. No., Study Date, Patient ID, Name, Procedure, Date of Birth, Sex, and Age. The patient list includes 'John Smith - Endoscopy / Dr Doug Ross' and several 'Generic Patient' entries. On the right-hand side, there is a vertical menu with options: 'New Patient', 'Emergency Patient', 'Worklist Refresh', and 'Worklist'. The 'Emergency Patient' option is highlighted with a blue box and a blue arrow pointing to it. Below the patient list, there are buttons for 'VIDEO ROUTING', 'RECORDING', and 'VIDEO CONFERENCE'.</p>

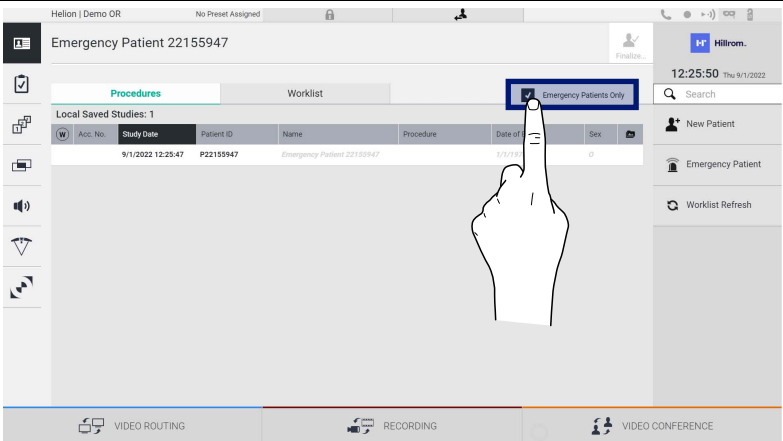
5.6.1.4 Searching for a patient in a list

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.	 <p>The screenshot shows the Helion interface with a patient list. A search bar is highlighted on the right side of the screen. The patient list includes columns for Acc. No., Study Date, Patient ID, Name, Procedure, Date of Birth, and Sex. The patient John Smith is highlighted in the list.</p>

5.6.1.4.1 Emergency Patient filter

Patients created as “Emergency Patient” can be displayed only by applying the Emergency Patient filter:

Step	Image
1. Select the icon at the top of the screen. Helion will automatically only display the list of emergency patients.	 <p>The screenshot shows the Helion interface with the Emergency Patient filter selected. A hand icon points to the 'Emergency Patients Only' button. The patient list is filtered to show only emergency patients, with one patient, P22155947, displayed.</p>

5.6.1.5 Patient master data modification

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


Step

1. Search for and select the desired patient.

Image

The screenshot shows the Hilrom software interface. At the top, it says "Helion | Demo OR" and "No Preset Assigned". Below this, the patient name "John Smith - Endoscopy / Dr Doug Ross" is displayed. The main area is divided into two tabs: "Procedures" and "Worklist". The "Procedures" tab is active, showing a table of "Local Saved Studies: 24". A hand icon points to the row for "John Smith" with ID "123456789" and procedure "Endoscopy". The table has columns for "Acc. No.", "Study Date", "Patient ID", "Name", "Procedure", "Date of Birth", and "Sex".


Acc. No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex
W 00000706	1/14/2022 08:53:00	pid2342	Generic Patient 86	CSPINE	7/16/1980	M
W 00000178	1/14/2022 08:53:00	pid3953	Generic Patient 11	CSPINE	7/16/1980	M
W 00000896	3/23/2021 14:32:10	123456789	John Smith	Endoscopy	2/8/1983	M
W 00000908	5/14/2019 11:35:00	pid6920	Generic Patient 72	CSPINE	7/16/1980	M
3/15/2018 11:56:42	tpx-aneurix	aneurix				M
3/15/2018 11:55:34	tpx-hybrid	HYBRID			5/22/2008	M
3/15/2018 11:53:37	tpx-cerebrox	CEREBROX				M
W 00000007			Generic Patient 37		7/16/1980	M
W 00000908			Generic Patient 41		7/16/1980	M
W 00000328			Generic Patient 24		7/16/1980	M
W 00000917			Generic Patient 37		7/16/1980	M
W 00000917			Generic Patient 37		7/16/1980	M
W 00000574			Generic Patient 11		7/16/1980	M

2. Press  to change the selected patient's master data. This option is not available for patients in the Worklist section.


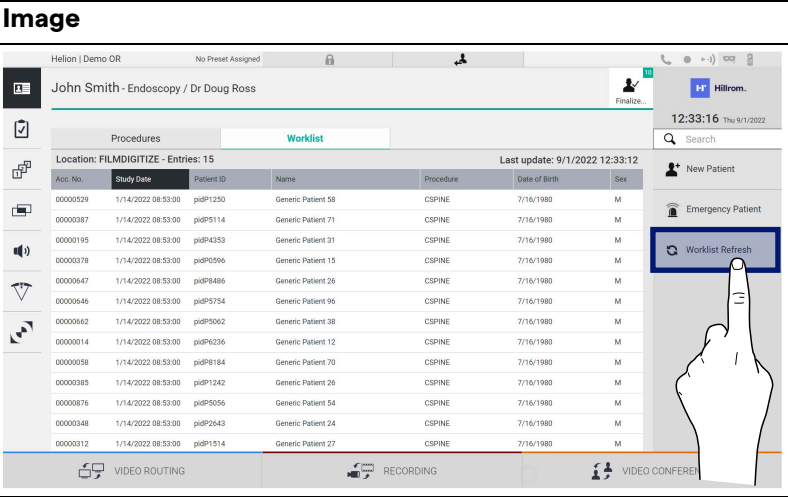
The screenshot shows the Hilrom software interface, similar to the first one. The "Procedures" tab is active, and the "John Smith" row is still highlighted. A hand icon points to the pencil icon in the action column of this row. The table now shows "Local Saved Studies: 25".

Acc. No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex
3/15/2018 11:53:37	tpx-cerebrox	CEREBROX				M
3/15/2018 11:55:34	tpx-hybrid	HYBRID			5/22/2008	M
3/15/2018 11:56:42	tpx-aneurix	aneurix				M
3/23/2021 14:32:10	123456789	John Smith	Endoscopy	2/8/1983		10
W 00000007		pid8111	Generic Patient 37		7/16/1980	10
W 00000908		pid2975	Generic Patient 41		7/16/1980	5
W 00000328		pid5021	Generic Patient 24		7/16/1980	11
W 00000917		pid7533	Generic Patient 37		7/16/1980	7
W 00000917		pid7533	Generic Patient 37		7/16/1980	7
W 00000574		pid4884	Generic Patient 11		7/16/1980	7
W 00000986		pid5317	Generic Patient 11		7/16/1980	7
W 00000353		pid1646	Generic Patient 50		7/16/1980	7
W 00000317		pid3579	Generic Patient 23		7/16/1980	7


5.6.1.6 Accessing the worklist

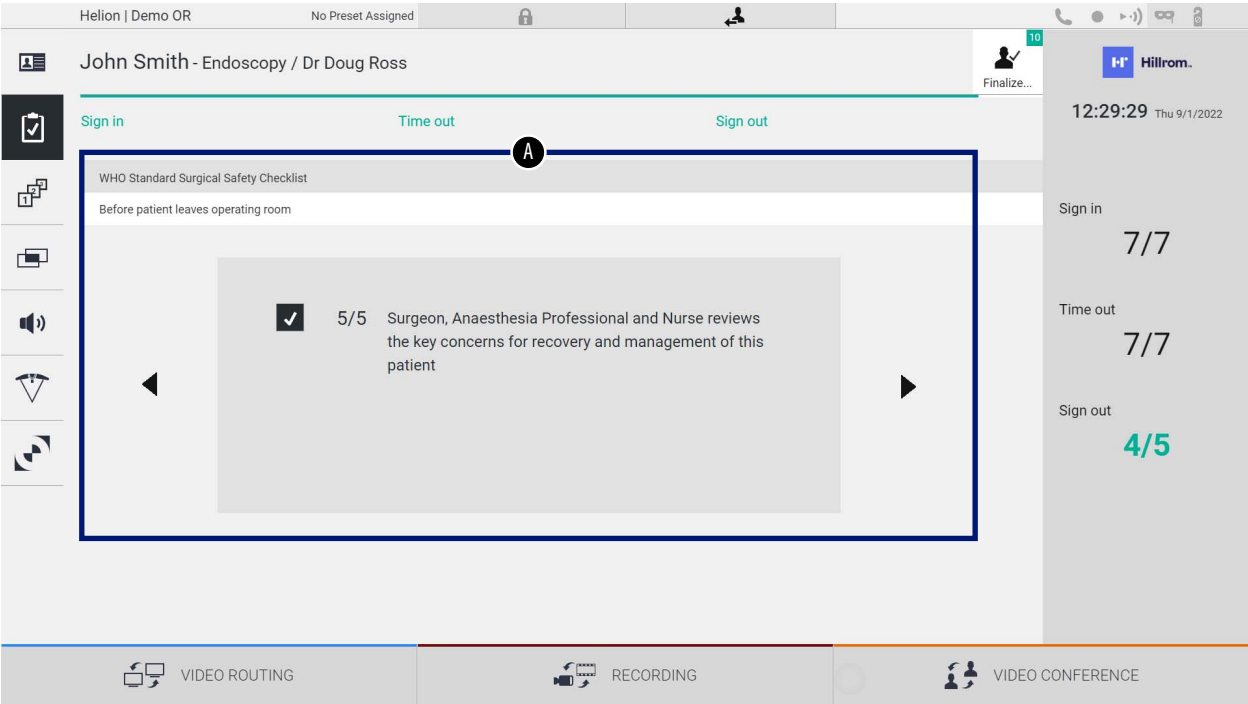
If the Helion Video Management System is configured to connect to a centralised master data management system, the list of patients related to a given date/room/surgeon can be retrieved using the  **Worklist Refresh** button.

To access the worklist, proceed as follows:

Step	Image
<div>1. Press the  Worklist Refresh button. This operation will trigger updating of the worklist.</div> <div>2. Wait for the names that meet the selected criteria to appear in the list.</div> <div>Alternatively: Press the “Worklist” tab at the top of the list (this will not trigger updating of the worklist).</div>	

5.6.2 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.



WHO Standard Surgical Safety Checklist


Before patient leaves operating room

5/5 Surgeon, Anaesthesia Professional and Nurse reviews the key concerns for recovery and management of this patient

Sign in 7/7

Time out 7/7


Sign out 4/5

In section [A], it is possible to manage the surgical procedure by following a sequence of questions and instructions concerning each stage of the surgical procedure. Press the  icon to navigate through the questions.

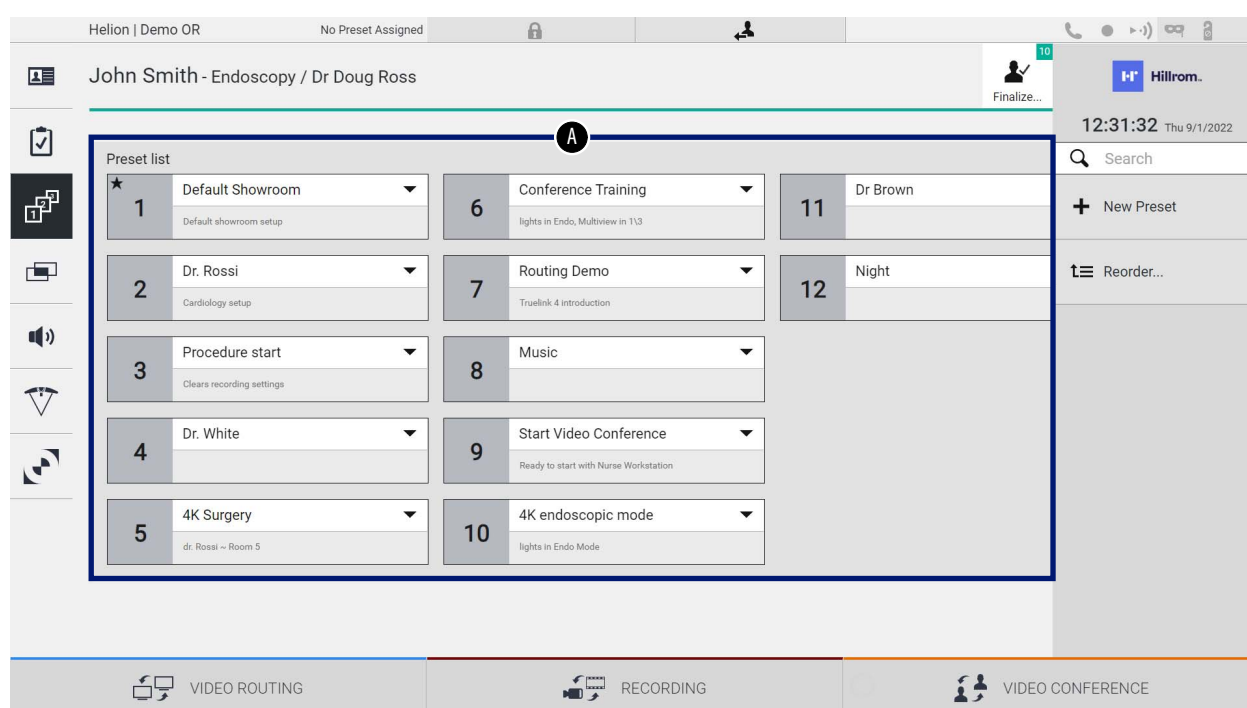
The steps refer to the entire procedure. You can exit this section and return to it to continue filling out the Surgical Checklist when necessary. The entry status of the Check-List can always be viewed using the progress bar in the Status bar.

Once entry is complete, a window will open for the operator to be able to enter Notes.

5.6.3 Preset

Press the  icon on the side menu to access the Preset screens. The Preset makes it possible to save room setting configurations. It will then be possible to recall the configurations by pressing the relevant icons.

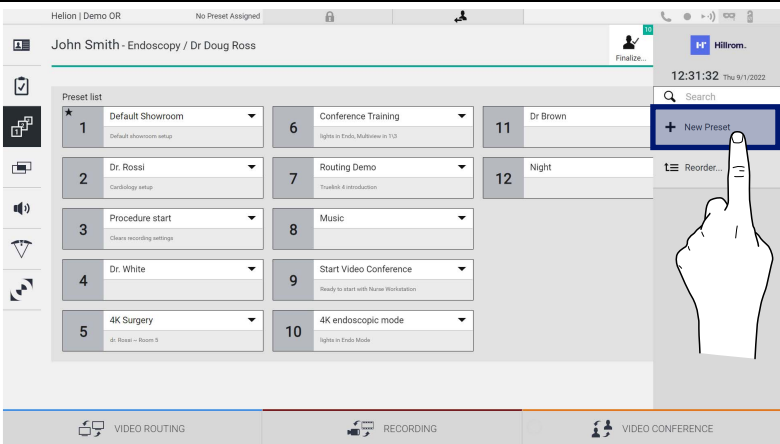
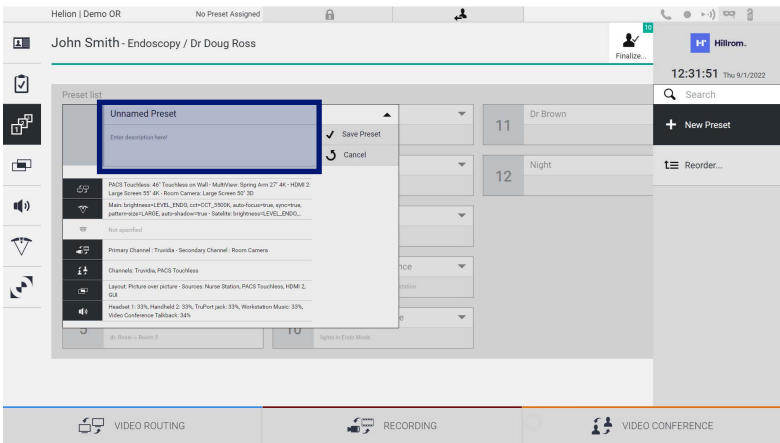
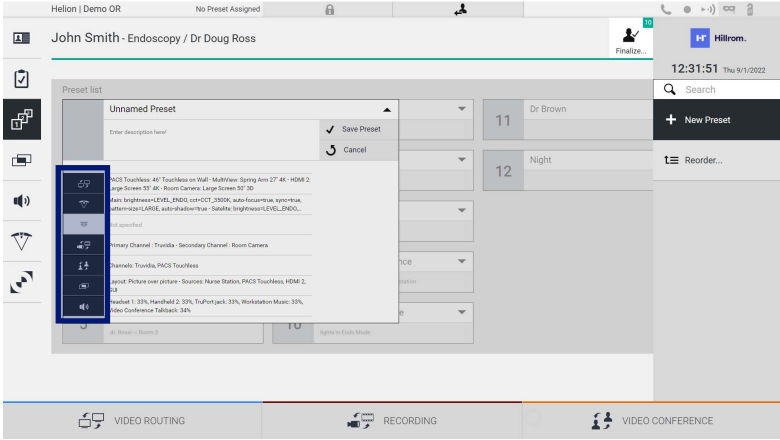
The main screen is divided as follows:

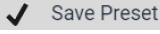
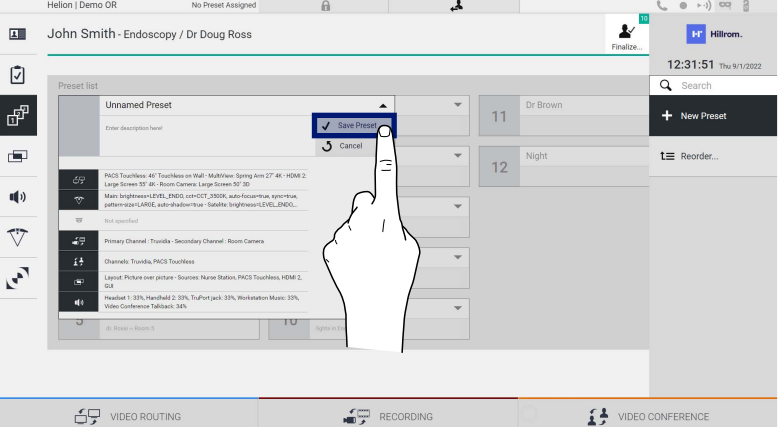


[A] Preset List

5.6.3.1 Preset setting

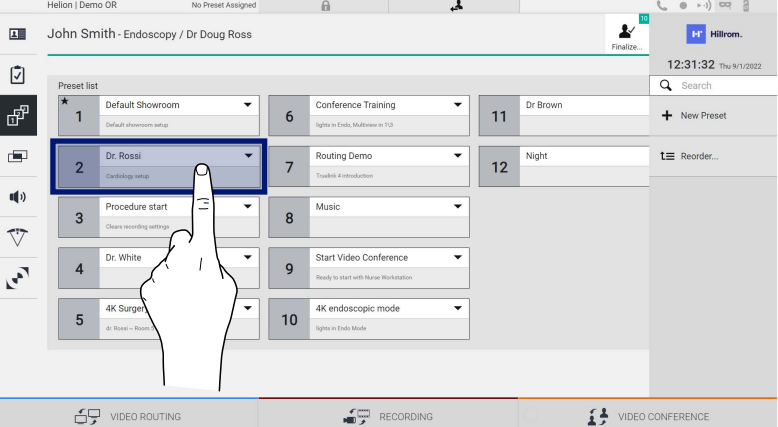

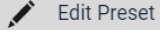

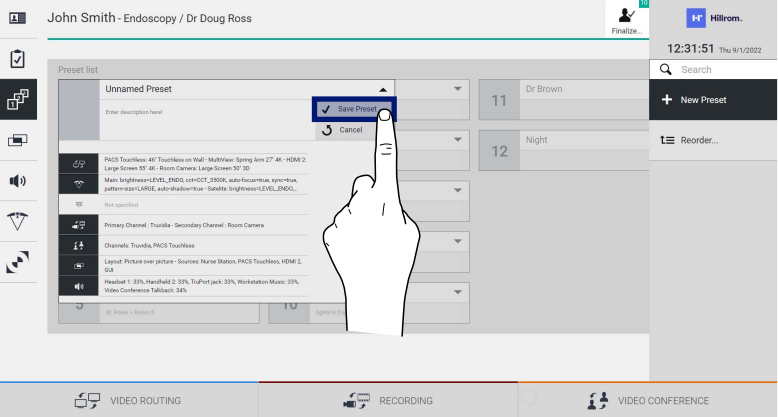
To set a new Preset, proceed as follows:


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 the name to be assigned to 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 the relevant icons among those listed.	

Step	Image
5. Press  to confirm.	


5.6.3.2 Enabling Preset

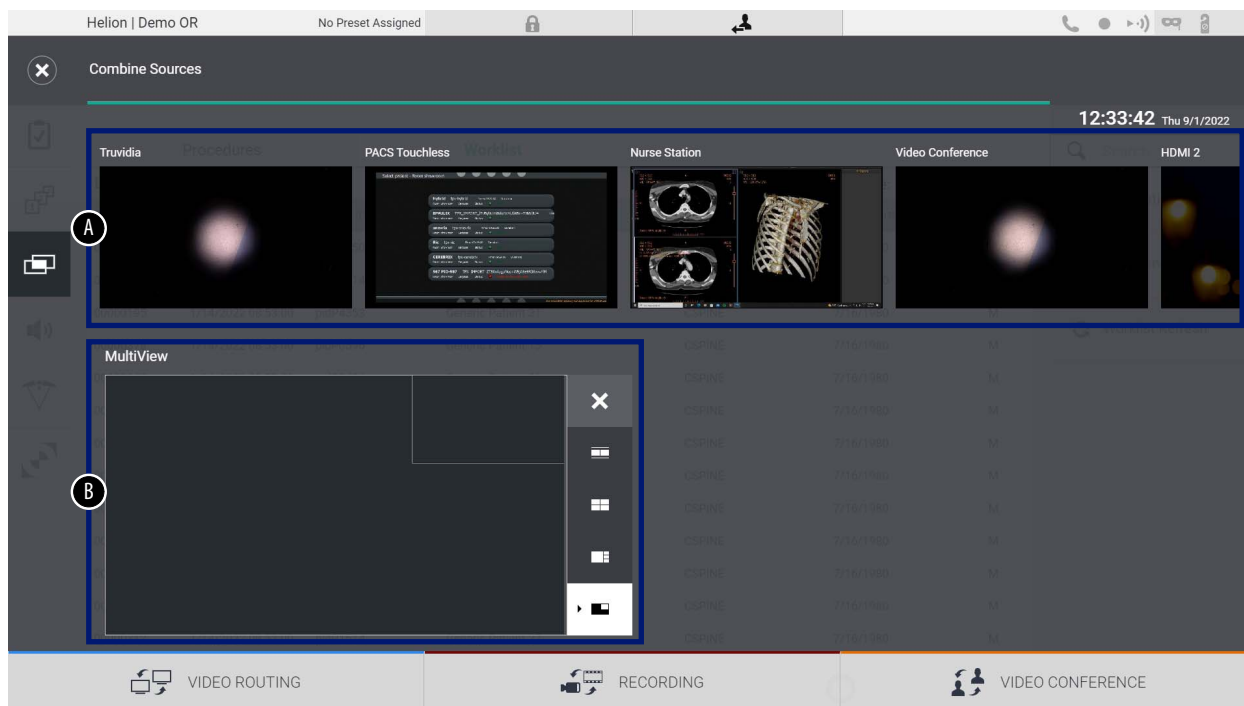
To activate a Preset in the list, proceed as follows:

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

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

5.6.4 Multiview

Press the  icon on the side menu to access the Multiview screen. The Multiview function makes it possible to combine multiple Inputs (up to a maximum of 4) in a single Output signal. The main screen is divided as follows:




- [A] Source List
- [B] Multiview

5.6.4.1 Multiview setting

To set the Multiview, proceed as follows:

Step	Image										
<p>1. Select the desired layout from those indicated:</p> <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>	Icon	Function		Picture and Picture		Quadview		Picture Over Picture		Picture In Picture (up to 4 different Picture in Picture layouts)	
Icon	Function										
	Picture and Picture										
	Quadview										
	Picture Over Picture										
	Picture In Picture (up to 4 different Picture in Picture layouts)										
<p>2. Drag the images (one at a time) from the Source List and drop them into the corresponding boxes.</p> <p>By pressing , which will appear at the top right of the box once selected, the image can be removed from the box.</p>											
<p>3. Once the mosaic has been filled in, close the Multiview section by pressing . The mosaic thus generated will be available in the Source List.</p>											

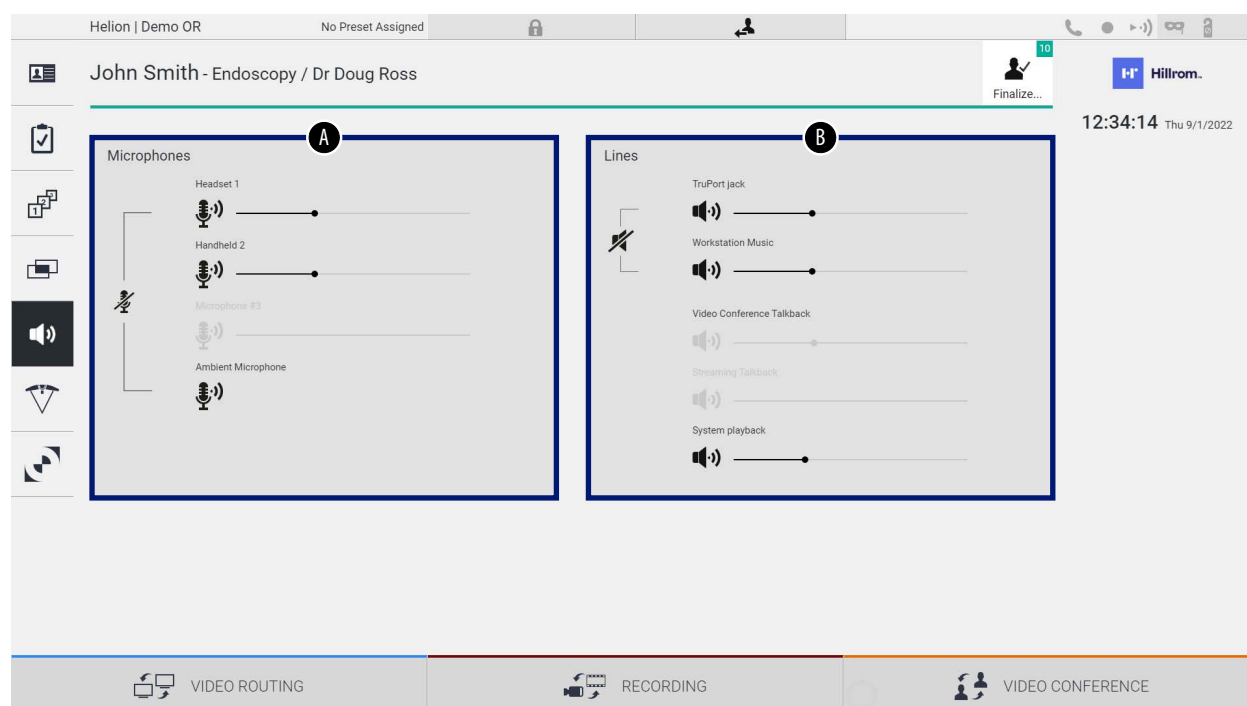
5.6.5 Audio control

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

The “Microphones” setting 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

5.6.5.1 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.	


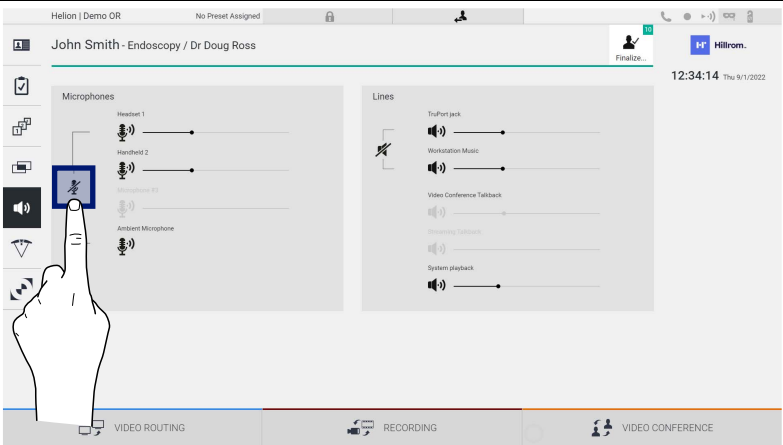

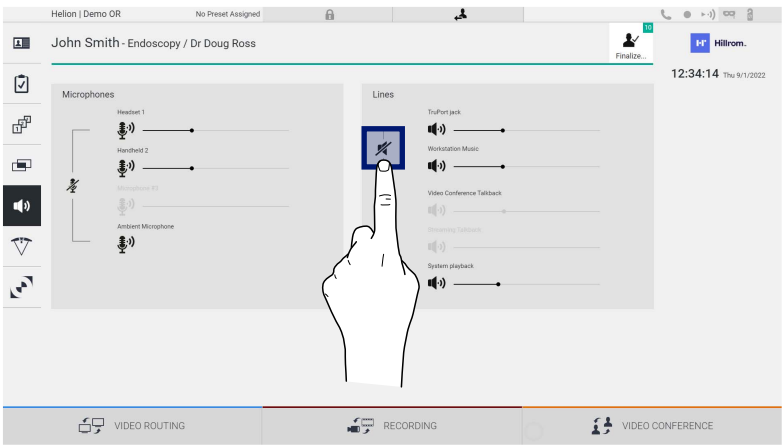
It is possible to independently change the audio channel from inputs AUX1, AUX2 and video conference/streaming.

If the system receives a connection request in video conference, the system will automatically mute 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 of Videomed S.r.l.

5.6.5.2 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.	

5.6.6 Surgical light management

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

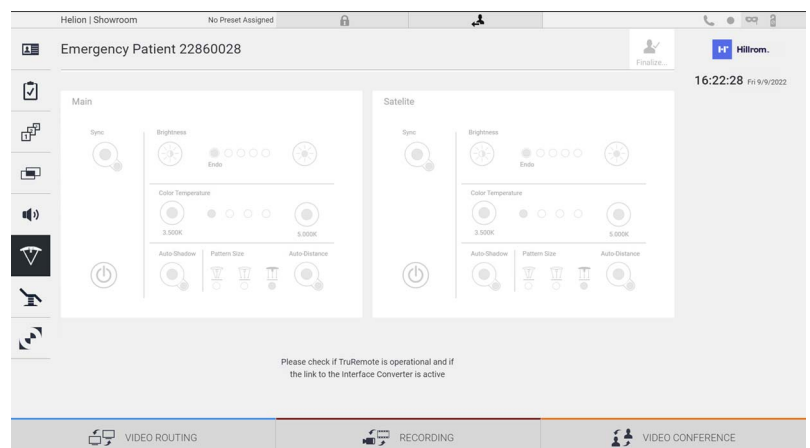
The main screen is divided into 2 sub-control areas respectively for the 2 operating lights installed in the operating theatre:



* the image may differ depending on the surgical light installed

- [A] Light 1
- [B] Light 2

The image shows the case in which the surgical light control system cannot be reached.




The Helion Video Management System provides the option of controlling the Baxter surgical lights through the reproduction of the light control console via the graphical user interface.

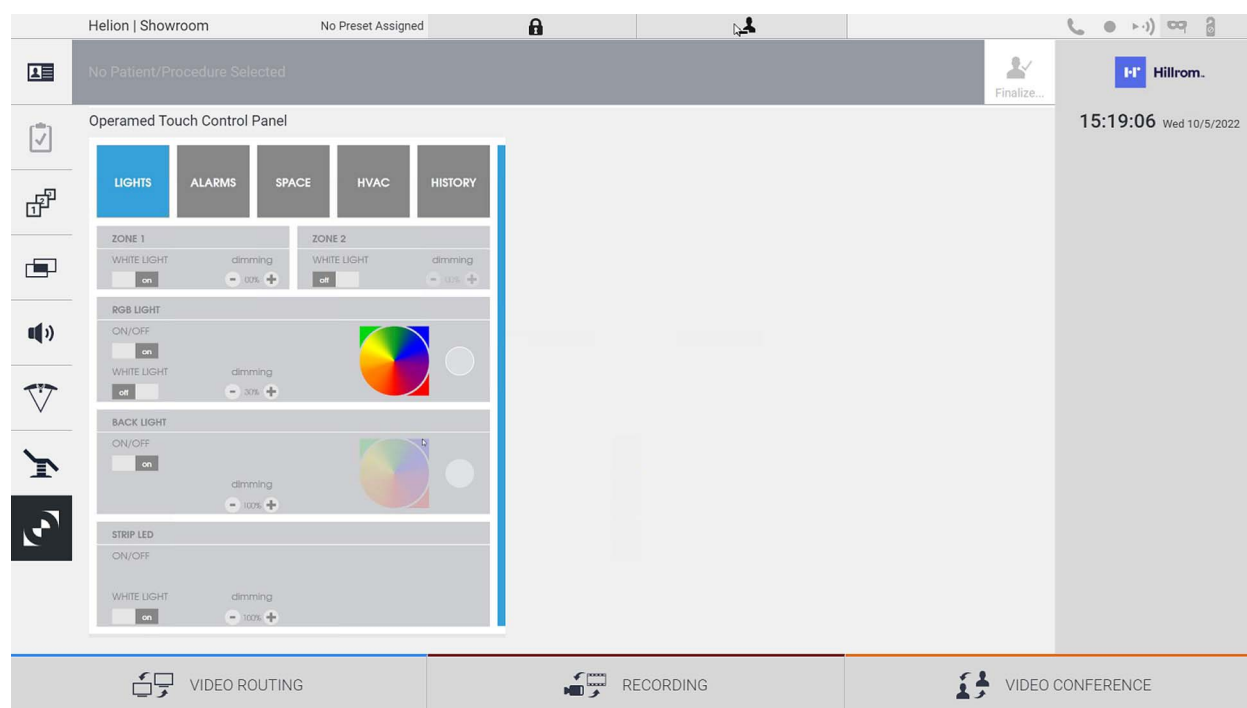
In the image, you can see that the functions that can be accessed from the touchscreen system are:

- 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.

5.6.7 Environmental control panel management

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




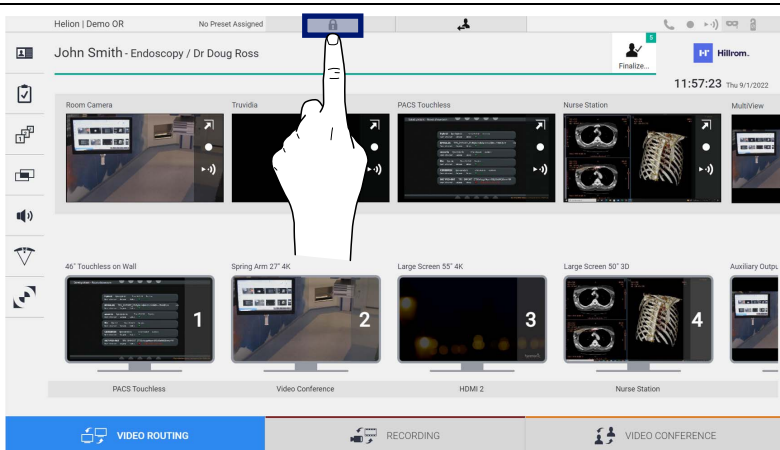
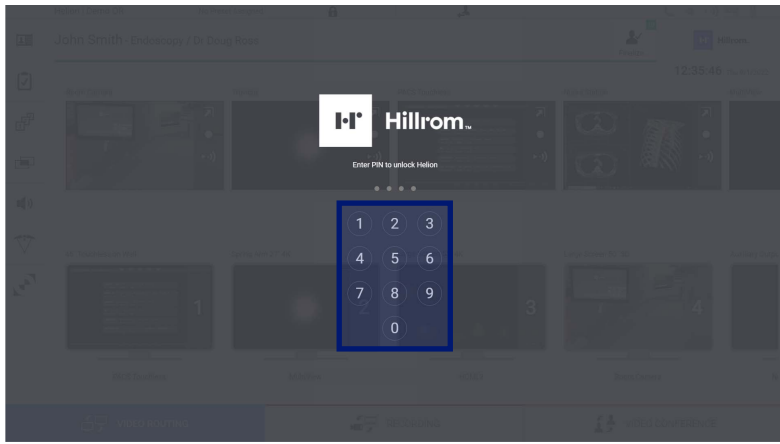
The control panel management screen can only be used if there are Operamed devices in the operating theatre.

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

5.7 “Lock with PIN” function

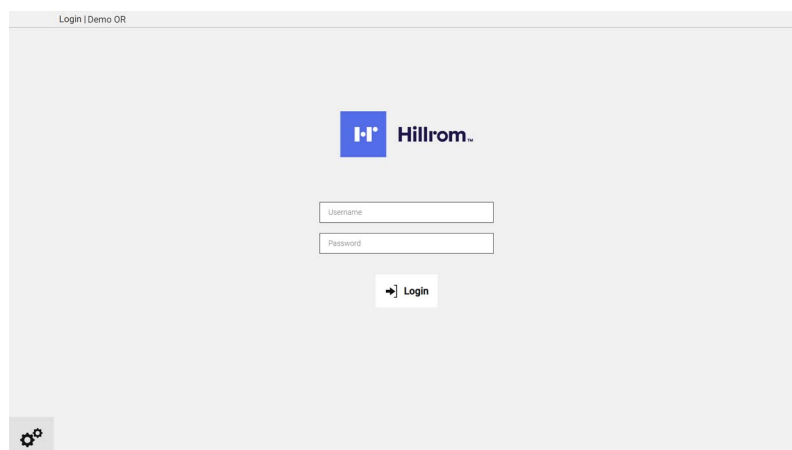
The Helion Video Management System includes a Lock function for locking the touchscreen using a PIN.

To lock the touchscreen, proceed as follows:

Step	Image
1. Press  to lock the screen.	
2. Enter the PIN code to unlock the touchscreen using the highlighted numeric keypad.	

5.8 “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 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 Logout and be redirected to the credentials screen.

6 Disposal instructions

Electrical equipment that is no longer in use must not be disposed of as normal communal waste. The substances and materials contained in them must be disposed of separately in an appropriate manner, so 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.

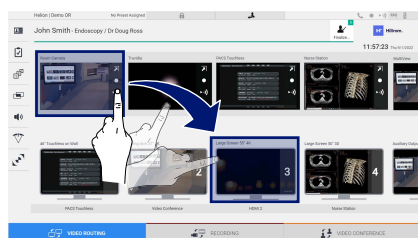


To notify the dispatch of decommissioned devices, call +39 049 9819113.

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.

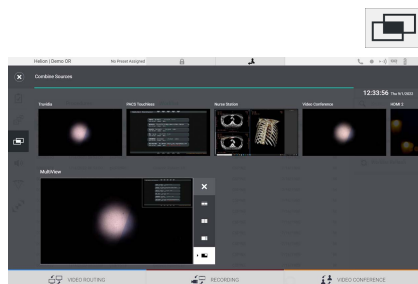
7 Annex I - Getting started



Video Routing

To send a video signal to a monitor, drag the relevant image from the list of available sources and drop it in 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 **X**.



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 populating this layout by individually dragging the images of the sources and releasing them in the relevant boxes.

To remove an image from a frame, press **X** which will appear at the top right of the frame once selected. Once the composition of the mosaic is complete, return to the Video Routing section by pressing the relevant blue icon.



PTZ camera control

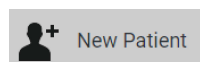
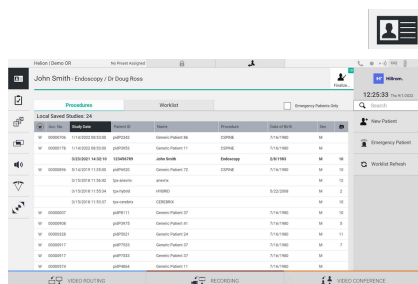
Press **Live Preview** in the RoomCam Preview to open the Live Preview. The camera control buttons will appear. The system allows you to change the position and zoom level of the camera.

Recording

In order to record a video or photo, it is necessary to select / insert a patient in the appropriate section.

Patient data

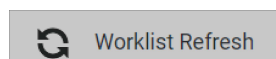
The list of previously created patients is displayed on the main screen. To insert a new patient, select one of the options in the right section:



New Patient

Manual insertion

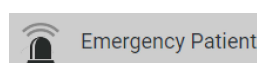
Enter the data concerning the new patient (fields marked with a * are mandatory).



Worklist Refresh

Access to the Worklist

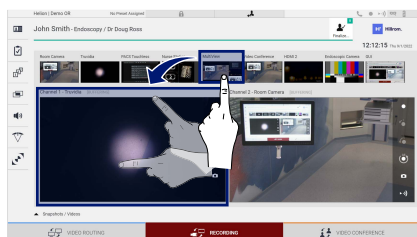
Press Worklist Refresh to download the patient list in automatic mode.



Emergency Patient

Urgent insertion

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



Selecting the signals to be recorded

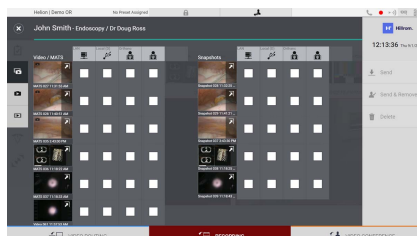
Drag the desired source into the Recording Channel box to enable basic recording functions:







Recording start / stop



Instant capture



Press  to proceed with closing the patient record and exporting the files. Select the items to be exported and proceed with the export  Send, deletion  Delete or export of the selected items and subsequent deletion of the patient from the patient list  Send & Remove All.

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Baxter