

Instructions for use

Helion

Video Management System



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Instructions for use

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This document applies to the following sales units:

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 paper copy of the manual is available upon request for qualified technical and medical personnel.

Videomed S.r.l. declines any liability for improper use of the

Videomed S.r.l. declines 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 personal use by the buyer, without the express written permission of the Manufacturer.

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

PUBLISHER'S NOTE

This documentation is expressly intended for clinically trained users of the system.

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 deriving from incorrect operations carried out by the user.

GENERAL CONSIDERATIONS

All operating instructions and recommendations described in this manual must be complied with. Clinical personnel must be trained on 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 with a signal word. The safety measures required and potential consequences of failing to take these are listed. A corresponding signal word provides information about 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 s 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 Helion Video Management System are intended for operators trained and authorized to handle it. The management of the medical site is responsible for the training of the staff on the use of the medical device.

The instructions for use contain the topics that refer to a correct use of the system, in order to maintain its functional and qualitative characteristics unchanged over time. All the information and warnings for a correct use in full safety 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 any movement or resale. It is the user's responsibility to keep 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 has 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.

1.2 Updates

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

Contact the Customer Service office of Videomed S.r.l. to be updated on the latest version of the instructions.

1.3 Language

The original instructions for use have been written in American English.

Any translations into additional languages must be made starting from the original instructions.

The Manufacturer is responsible for the information contained in the original instructions; translations in different languages cannot be completely verified, therefore if an inconsistency is detected it is required 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 the 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	Person suitably trained or who, thanks to their professional qualification, is authorized to operate and use the Helion Video Management System in the activities required. They are responsible for the correct and safe operation of the system and ensures that it is used solely for the intended purpose.
Qualified Personnel	Authorized persons who are generally employees of the manager or who have acquired their skills through professional training in the medical sector, who are able to evaluate their work and recognize potential risks based on their professional experience and knowledge of safety regulations. Where required, qualified personnel must certify their qualifications by means of a valid document.

1.5 Symbols

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

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

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



Symbol	Description
س	Symbol used to indicate the date of manufacture.
	Symbol used to identify the manufacturer's name.
	Barred bin: this product must not be disposed of as municipal mixed waste, collect separately.
REF	Symbol used to indicate the Videomed S.r.l. material number.
SN	Symbol used to indicate the serial number.
MD	Symbol used to indicate a medical device.
(01)00615521031626 (21)123456789012 (11)210212	Indicates the Unique Device Identification UDI code, is composed of UDI-DI (01) and UDI-PI ((11) date of production (21) serial number).
C UL US EXXXXXX	MEDICAL — GENERAL MEDICAL EQUIPMENT AS TO 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)
hillrom.co.uk	Consult 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	Valid only for US. Caution: Federal law (United States of America) 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) countries:

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	Regulation on medical devices amending Directive 93/42/EEC will enter into force on 26 May 2021
EN 1041	Information provided by the manufacturer of medical devices
EN ISO 13485	Management systems for the quality of medical devices
EN ISO 14971	Applying risk management to medical devices
EN ISO 15223-1	Symbols to be used in medical device labels, labelling and information to be provided — Part 1: General requirements
EN 60601-1	General requirements for fundamental safety and essential performance
EN 60601-1-2	General requirements relating to fundamental safety and essential performance - Collateral standard: Electromagnetic compatibility
EN 60601-1-6	General safety standards — Collateral rule: Usability
EN 62304	Medical Device Software — Software Lifecycle Processes
EN 62366-1	Application of user characteristics 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, and is compliant with the version of the regulation currently in force at the time of product sale. 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 the safety and functional reliability of the system provided that:

- the system is used, managed and repaired exclusively as described in these instructions for use;
- installations, modifications and repairs are carried out exclusively by the Videomed S.r.l. assistance services
- only spare parts and accessories authorized by the Manufacturer are used;
- no structural changes to the devices are carried out.

The system status after 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 present in the commercial contract.

The conditions required by the commercial contract (if different) have priority over what is provided in this section.



2 Safety information

2.1 General safety warnings

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

A 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 if the insulation is damaged.

A DANGER

ELETRIC SHOCK FROM PRESENCE OF LIVE PARTS EXPOSED! It is also recommended to periodically check the integrity of the parts of the device, to detect the presence of parts exposed following an impact or a fall and not to use the device in the presence of damage to the structure or to the its components.

A DANGER

ELECTRIC SHOCK FROM WRONG POWER CONNECTION PROCEDURE!

The Helion system must be powered and receive protective earth from the same electrical panel that powers the operating room. Also all equipment connected to the Helion system must be powered and receive protective earth from the same electrical panel that powers the operating room.

A WARNING

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

▲ CAUTION

All safety information must be complied with for a 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

MEASUREMENT OF DISPERSAL CURRENTS!

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

A CAUTION

It is absolutely forbidden to remove the identification plates and/or replace them with other plates. 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 the Electromagnetic Compatibility regulations, 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 installation of filters where required.

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

A CAUTION

Any maintenance activities on the electrical equipment 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), it is suitable for use in a specific electromagnetic environment. The customer and / or the 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 emission CISPR 11	Group 1	Helion uses RF (radio-frequency) energy only 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,
Harmonic emissions IEC 61000-3-2	Not applicable	except domestic buildings and those direct connected to the public low-voltage power supply network that supplies buildings used
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	for domestic purposes.



Guidance and manufacturer's declaration - Electromagnetic immunity

The product is suitable for use in a specific electromagnetic environment. The customer and / or the 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 in wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity must be at least 30%. Temporary loss of the signal is possible (a few seconds).
Radiated electromagnetic fields IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should 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 that typical of 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	Mains power quality should be typical of a commercial or hospital environment.
Conducted disorders, induced by RF fields IEC 61000-4-6 Network frequency magnetic field (50/ 60 Hz) IEC 61000-4-8	3 V 150 kHz to 80 MHz 6V ISM frequencies 30 A/m	IEC 60601-1-2 Test level 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. Power frequency magnetic fields should have the characteristic levels of a typical location in a typical commercial or hospital environment.
Voltage dips, brief interruptions and voltage variations on the 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 should be that typical of commercial or hospital environments. If the user of the appliance requires it to continue to operate even when the mains power supply is interrupted, it is recommended to power the appliance with an uninterruptible power supply (UPS) or with batteries.

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

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

2.3 Useful life of the system

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

The life cycle includes guaranteeing the functionality of the product in compliance with the specific instructions for use, the supply of the assistance service and the availability of spare parts; Videomed S.r.l. applies a certified quality management system according to EN ISO 13485 to all its business processes which is a guarantee of:

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



2.4 Cleaning



Do not use any cleaning products.

This paragraph indicates how to perform the cleaning on the Helion system.

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

Use personal protective equipment for any maintenance and cleaning activities. List of protective devices: closed shoes, sturdy long trousers in fabric, tunic, gloves. Check personal protective equipment to make sure they are 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. For permanent installations turn off the main switch place on the front panel of the rack.

2.4.2 Cleaning the system

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

2.5 Preventive maintenance

Maintenance must be carried out annually to ensure the components remain in good working order and intact.

The products must be serviced by qualified maintenance technicians only. The contact details for service technicians are available from the Technical Customer Service.

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

3 System description

3.1 Intended use

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

3.2 Normal use

- The system is used exclusively for displaying and managing already existing audio-video sources;
- Controlling signals via a touchscreen monitor;
- Distributing analogue and digital signals to different video outputs;
- Export data into other devices (not part of the MD);
- Document the intervention through temporary archiving
- Exchange of information by video conference with the operating room by sharing images and videos with the world outside the room in high resolution;
- Regular maintenance of the MD in accordance with the defined maintenance intervals by qualified service technicians;
- Initial operation by the operator;
- Repair and disposal of the MD must be performed by qualified service technicians as required;
- To control the on, off and intensity of compatible surgical lights.

3.3 Contraindications

- The system shall not be used for the purpose of findings and diagnostics;
- The system shall not be used for checking vital body functions;
- The system shall not be used to make reports;
- The product has not been designed for storing clinical data for medical-legal purposes;
- The system shall not be used as a system of precision or measurement of the function of life support;
- The system shall not be use to correct administration of drugs;
- The system shall not be used as a monitoring system of 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 for the patient;
- The system (monitors connected to the system) shall not be used as the primary source of information.



3.4 Reasonably foreseeable misuse

The reasonably foreseeable misuses, which are to be considered strictly prohibited, are listed below:

- using the system in areas at risk of explosion;
- using the system near strong electromagnetic fields;
- using the system differently from what is required in paragraph "Intended use".

Any other use of the system with respect to the intended use must be previously authorized in writing by the Manufacturer. Any use that does not comply with the conditions specified above shall be considered "misuse"; therefore the Manufacturer declines any liability for damage caused to things or persons and deems any type of warranty for the system void.

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

3.5 Use associated with other medical devices

The Helion Video Management System can be combined with devices from other manufacturers.

In the patient environment, only install devices approved in accordance with standard IEC 60601-1.

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

If a device is installed at a later stage, the installation must be performed as specified in standard IEC 60601-1 and in keeping 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.I. Helion system must only be used by medical and paramedical personnel with the necessary professional qualifications, who have read these instructions for use and who have been adequately trained in the use of the system. The training is certified through participation in the training course called "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 paragraph "Intended use";
- replace or modify system components without the permission of the Manufacturer;
- use the system as a support point even if not operational (resulting in the risk of falling and/or damaging the system itself);
- use the system outside the room conditions permitted (see paragraph "Technical data").

A CAUTION

Videomed S.r.l. is not liable for damage caused to things or persons if it is ascertained that the system has been used in one of the room not permitted.



3.7 Technical data

MAIN UNIT - Technical Specs

	•	
Video Inputs	18 (14 DVI, 2 3G-SDI, 2 CVBS)	
Monitor Outputs	10 DVI over CAT7 or optic fiber	
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 50-60Hz 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 mt	
Control Touchscreen	21", 24" or 27" , 1920 x 1080, 16:9	
Storage Capacity	2 TB by default (expandable up to 4 TB)	
Audio Inputs	3 x Microphones 2 x Aux Stereo 1 x Video conference	
Audio Outputs	1 x Stereo amplified 1 x Stereo non-amplified 1 x Video conference 2 x Speakers 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

COM ENLINCE ONLY	ecimical opecs
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 50-60Hz 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	Operating temperature: +10/+40 °C
conditions	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 mt
Enclosure	IP20
HD Audio	MicPod 100Hz fino a 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 60Hz
Transmission To Monitor	Optic Fiber 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 50-60Hz 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 mt
Enclosure	IP20
Unit Weight	5.5 kg

4K PLUS UNIT - Technical Specs

4K PLUS UNII - Technic	cal 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 60Hz
Transmission To Monitor	Optic Fiber cabling
Additional Ports	4 x DVI over CAT6/7 output scaled to FullHD 1080 4 x DVI over CAT6/7 pass-through input (FullHD 1080)
Dimensions	44 x 430 x 450 mm
Power Supply	100-240 V 50-60Hz 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 mt
Enclosure	IP20
Unit Weight	5.5 kg



RACK UNIT (optional) - Technical Specs

Dimensions	800 x 600 x 757 mm
Color	RAL 7016 puckered
Environmental conditions	Operating temperature: +10/+40 °C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 70.0 kPa to 106.0 kPa Storage temperature: -40/+70 °C Storage relative humidity range: 10% to 100% including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa
Rack internal component	Two fans, forced ventilation produced min. 2410 Cubic Meters per Minute (CMM) each
Rack internal component	Isolation transformer, power 1000 VA
Max Operation Altitude	3000 mt
Enclosure	IP20
Unit Weight	64 kg

RACK UNIT (Video-over-IP configuration) - Technical Specs

Dimensions	800 x 600 x 757 mm
Color	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, forced ventilation produced 2410 min Cubic Meters per Minute (CMM) each
Rack internal component	Isolation transformer, power 1000 VA
Max Operation Altitude	3000 mt
Enclosure	IP20
Unit Weight	64 kg

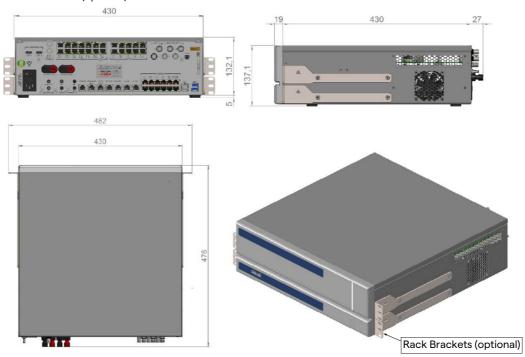
3.8 Measurement and weight layout

MAIN UNIT

Dimensions	133 x 430 x 450 mm
Unit Weight	13.5 kg



Rack Dimensions (optional)



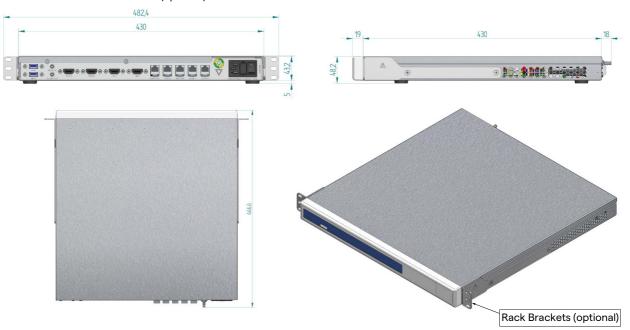


CONFERENCE UNIT

Unit Weight 8 kg



Rack Dimensions (optional)



4K UNIT

Dimensions 44 x 430 x 450 mm

Unit Weight 5.5 kg



Rack Dimensions (optional)





4K PLUS UNIT

Dimensions 44 x	(430 x 450 mm
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Unit Weight 5.5 kg



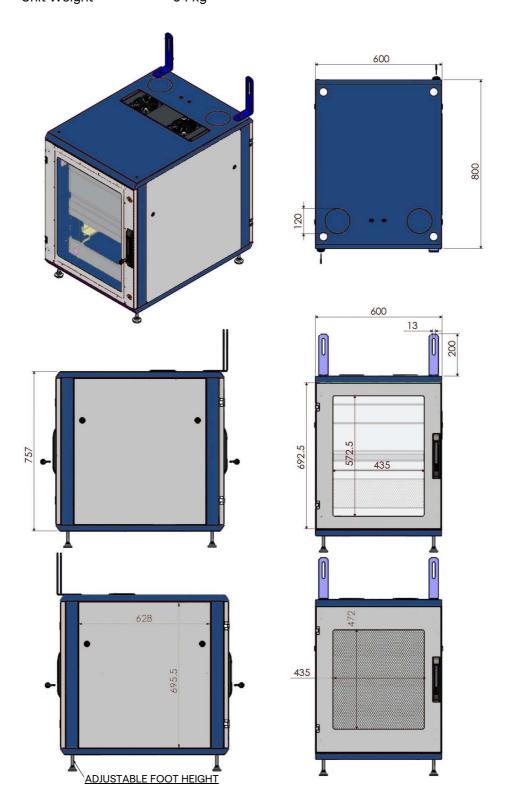


Rack Dimensions (optional)



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.



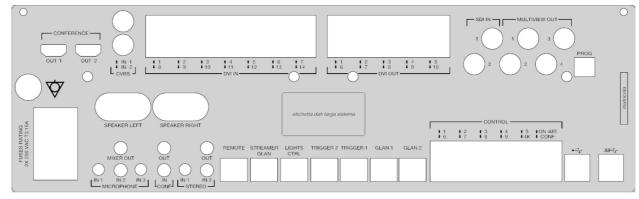
- [1] 4K UNIT or 4K PLUS UNIT
- [2] CONFERENCE UNIT
- [3] MAIN UNIT

3.9.1 Main unit

The following functions are available via the Main unit.

Function	Description
ROUTING	Enables to distribute the different sources present in the room to the recipient monitors.
PROCEDURE DOCUMENTATION	It enables to document the operation by temporarily storing and exporting the images and videos recorded.
VIDEO STREAMING	It enables to share information outside the operating room with an HD streaming system.

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



The 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 room by sharing high resolution images and videos outside the room.

The following connection ports are located on the back of the unit.

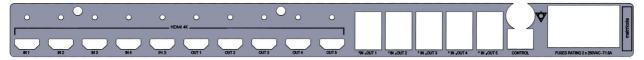


The connection cables are supplied Videomed S.r.l.

3.9.3 4K unit

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

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

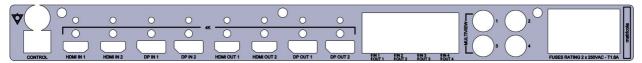


The connection cables are supplied Videomed S.r.l.

3.9.4 4K Plus unit

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

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



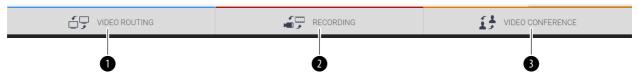
The connection cables are supplied Videomed S.r.l.



3.9.5 Control software

The User Interface of Helion Video Management System allows to control and manage each functional unit.

There is a lower selection bar (always visible) which allows the software sections to be uniquely identified according to 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.	Fy VIDEO ROUTING
		This function allows the distribution of video signals connected to all monitors installed in the operating room.	
[2]	RECORDING	The RED button identifies the section of the VIDEO RECORDING function.	RECORDING
		This function enables to record images and videos.	
[3]	VIDEO CONFERENCE	The ORANGE button identifies the section of the VIDEO CONFERENCE	VIDEO CONFERENCE
		function. This function allows two-way audio/video communication.	

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

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

The complete functions present 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 the authorized installer technical personnel from Videomed S.r.l.

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

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

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

4.2 Preliminary checks

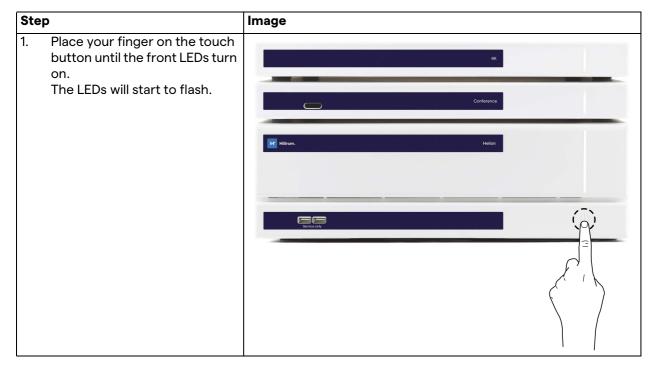
Before each use, check the components of the control screen, in regards to:

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

Cleaning is done during maintenance.

4.3 System start-up

To start the system, proceed as follows:





4.4 Connection to the sources

When a new video source is connected to the system, its dynamic Preview (frame) is displayed in 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 present on the connection plates installed on the pendant panels. Depending 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 1. Keep your finger on the touch button for about 5 seconds, until the flashing frequency of the LEDs increases visibly. 2. Once the frequency has changed, remove your finger from the button.

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 restart the device by following the start-up procedure described in paragraph "System start-up". It is recommended to use forced shutdown only in case of an emergency, as this procedure may cause data loss.

4.6 System start-up/shutdown with remote button

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

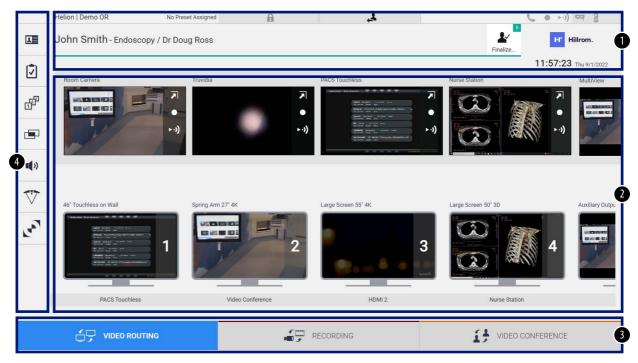
Thanks to this solution, the operator can manage the entire video management system without having to access the Technical rack. The switch-off of the units inside the Rack will therefore be reserved for technical and authorized/trained Videomed S.r.l. personnel for service or maintenance sessions.



5 User Interface

5.1 General description of the user interface

The user interface is divided as follows:



No.	Element	Description
[1]	STATUS BAR	It contains important information such as the patient's name and the number of recorded media related to them. Information such as the date, time and a dashboard showing the status of the recording, the video conference, the streaming and the advanced modes "Privacy Mode", "Do Not Disturb" and "Lecture Mode" are also present.
[2]	MAIN SECTION	Area for the functions to select the source and identify the monitors. The structure of the area varies according to the control functions activated.
[3]	SELECTION BAR	Bar located at the bottom of the screen, with which the following functions can be selected: - Video Routing (identified with blue), - Recording (identified with red), - Video Conference (identified with orange)
[4]	SIDE MENU	Bar on the left side of the screen that allows access to setup and workflow management screens.

5.2 Control touchscreen



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

The control screen has its own setup menu from which the monitor settings can be accessed:

- 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.



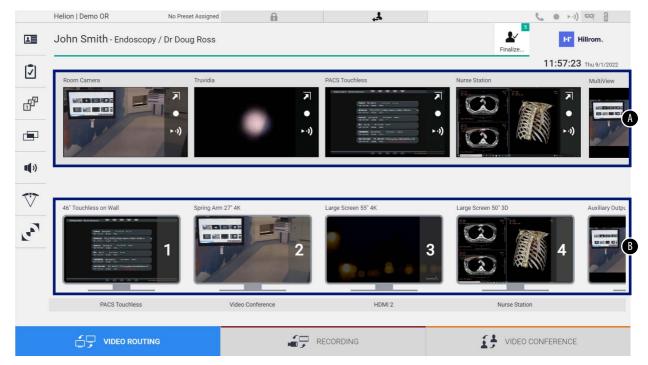
5.3 "Video Routing" function

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

- endoscope,
- surgical video camera,
- roomcam.

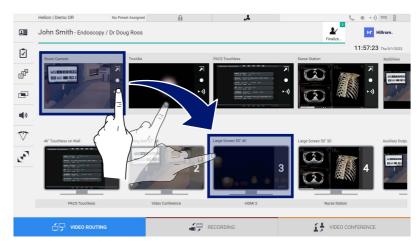
These video signals can be routed to any monitor in the operating room.

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 using the Drag&Drop system.

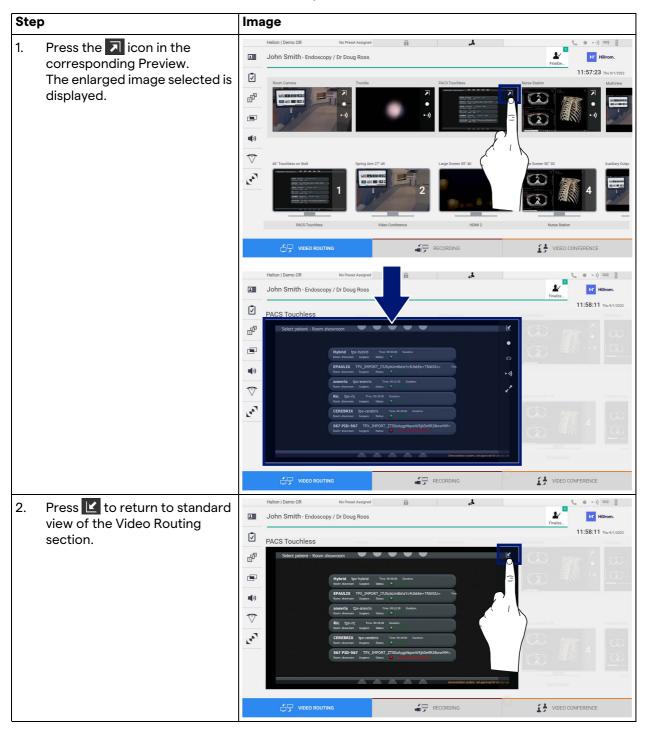


The Preview of the video signal sent will be displayed in the relative Monitor icon and updated periodically.

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

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:





The following icons are present in the Live Preview window:

Icon	Function
	Enables to start/stop recording of the displayed signal.
	If the icon is gray, it indicates that the function is not active. To activate the function it is required to select a patient from the list (refer to paragraph "Selecting a patient present in the list").
	Enables to create snapshots of the image.
►·1)	Enables to start/stop video signal streaming.
2.7	Enables to activate the full-screen display function, without latency, of the selected source (function available only on some touchscreen monitor models).

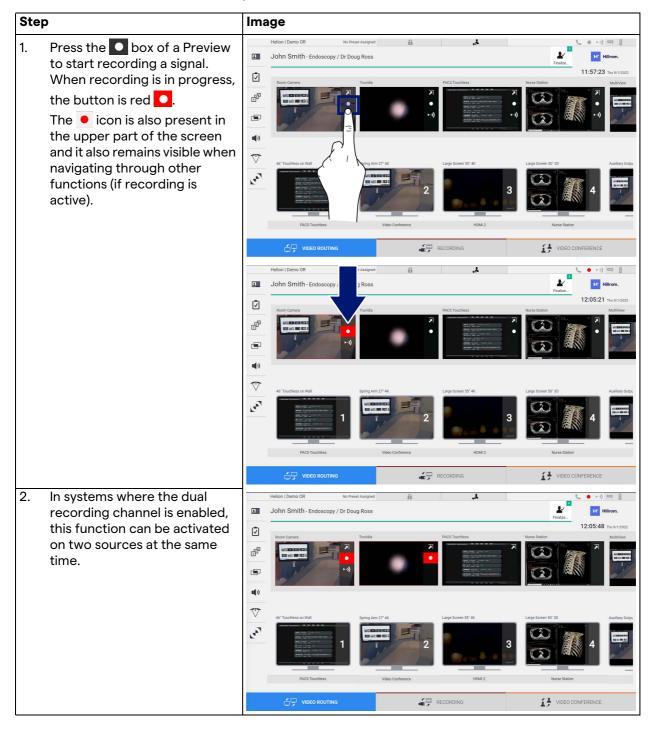
It is not possible to start recording if a reference patient is not present.

5.3.2 Quick Access - Recording

To start the recording it is possible to use a quick activation system directly from the Video Routing screen. There is a dedicated Recording screen to access the advanced functions.

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

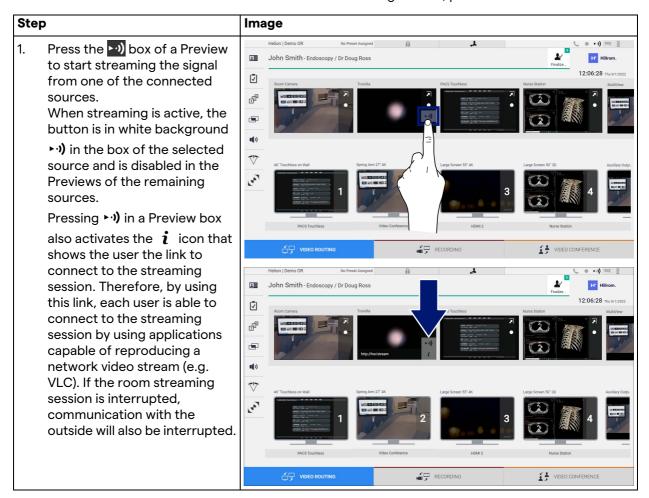
To perform the recording from the Video Routing function, proceed as follows:





5.3.3 Quick Access - Streaming

To activate the streaming session, proceed as follows:

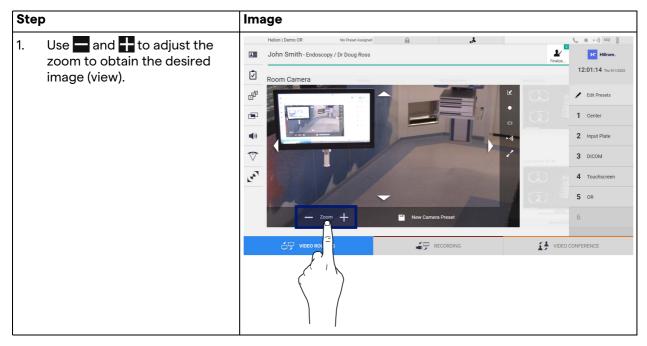


5.3.4 Ptz camera control

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

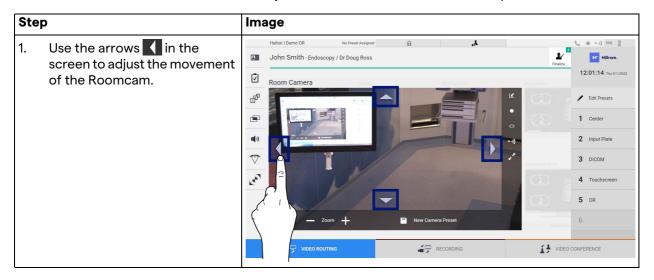
5.3.4.1 Roomcam zoom adjustment

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



5.3.4.2 Roomcam movement adjustment

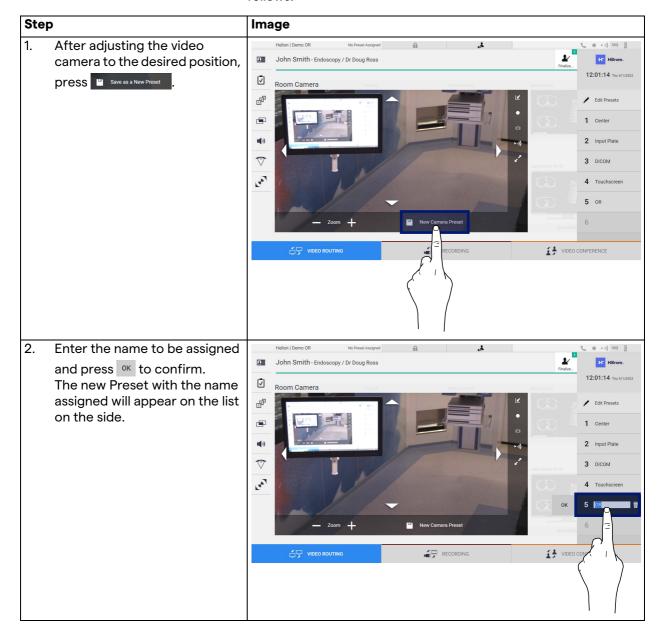
To adjust the movement of the Roomcam, proceed as follows:





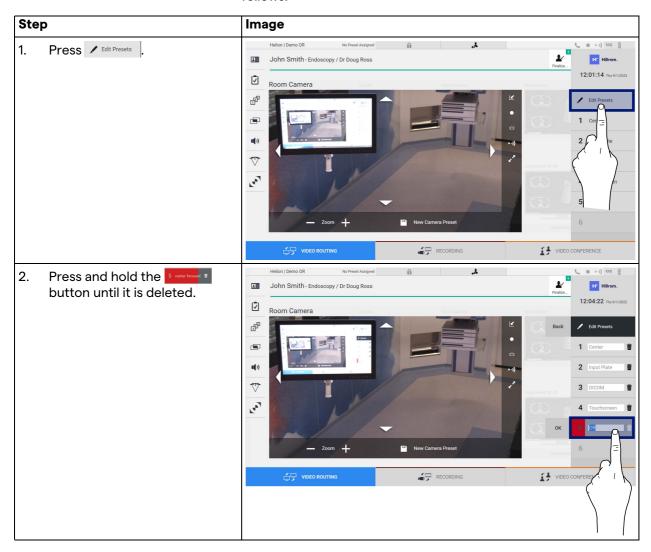
5.3.4.3 Save camera setting (Preset)

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



5.3.4.4 Delete camera setting (Preset)

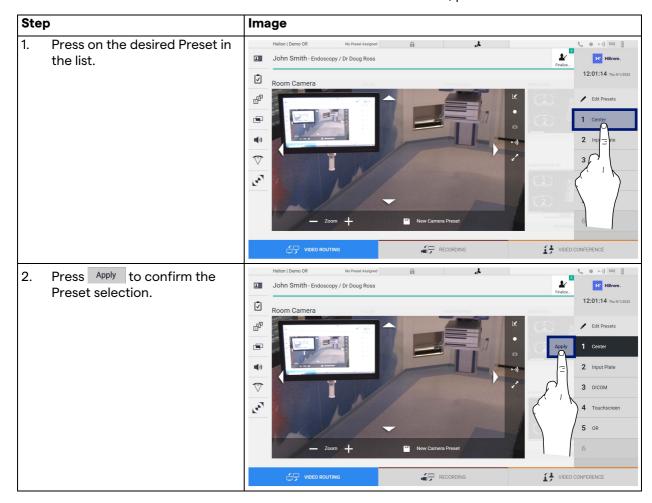
To delete a video camera setting from the Preset list, proceed as follows:





5.3.4.5 Enable camera setting (Preset)

To activate a video camera Preset, proceed as follows:



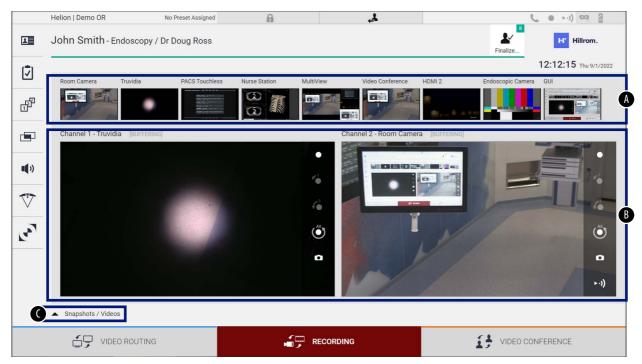
5.4 "Recording" function

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

It is therefore possible to save and then modify images and videos, stored in the system. It is then possible to send the recorded material 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.



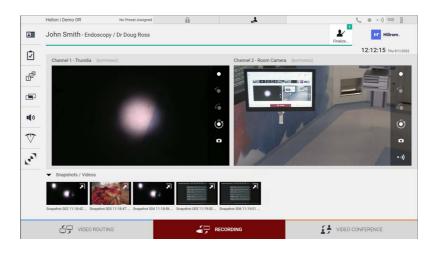
The main Recording screen is divided as follows:

- [A] source list
- [B] view of the two recording channels
- [C] list of snapshots 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

Snapshots / Videos

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





5.4.1 Image data post-processing

By using locally stored data it is possible to:

- create video sequences from 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 will get a Live Preview of the signal and the basic and advanced recording functions will be enabled.



The following icons are present in the Recording Channel window:

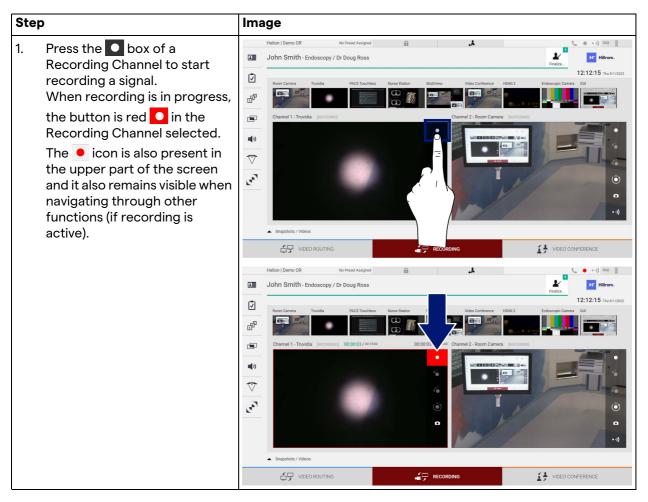
Icon	Function	
	Enables to start/stop recording of the displayed signal.	
	If the icon is gray, it indicates that the function is not active. To activate the function it is required to select a patient from the list (refer to paragraph "Selecting a patient present in the list").	
	Enables to create snapshots of the video source.	
►·1)	Enables to start/stop video signal streaming.	
1	Enables to start recording:	
	– 1 minutes before,	
1 5	- 5 minutes before,	
	 the entire buffer available (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 perform the recording from the Recording function, proceed as follows:



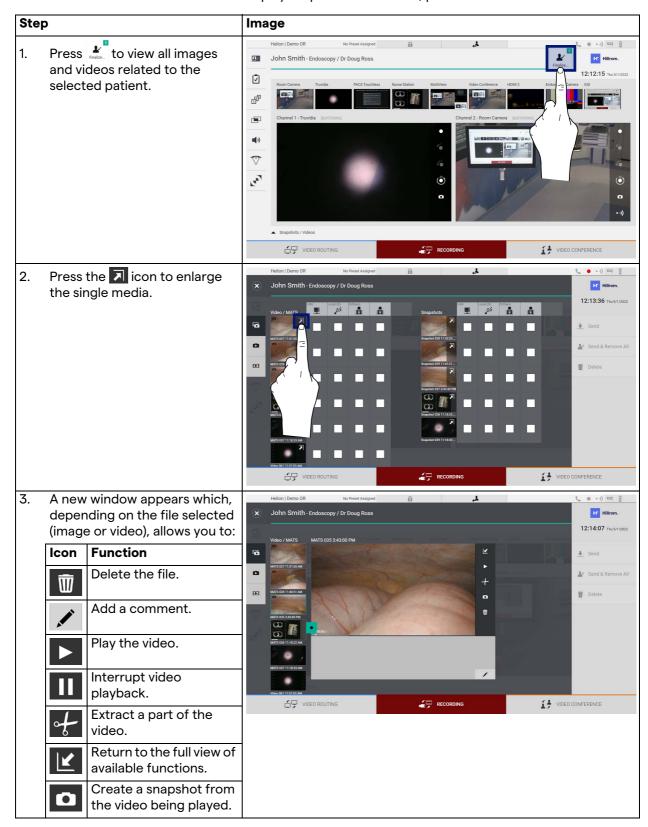
All videos and images related to the patient will be saved in the folder dedicated to them.

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



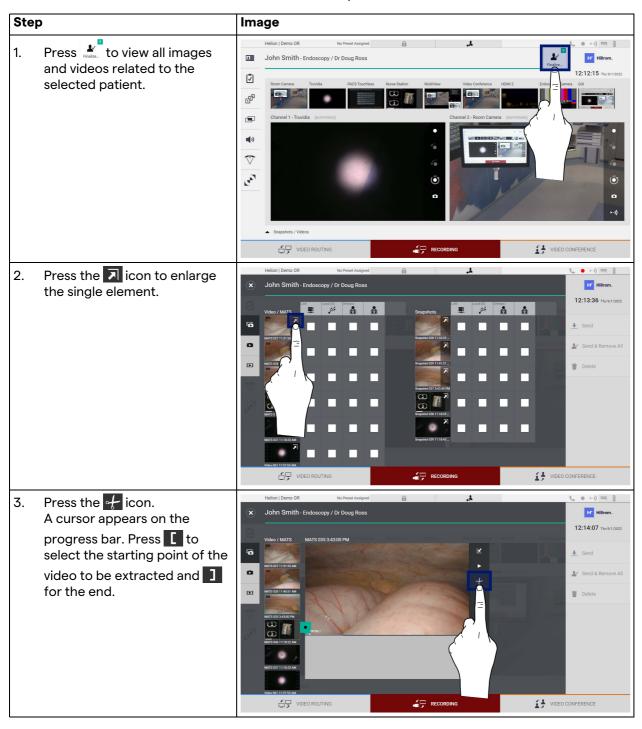
5.4.4 Snapshot and video playback

To play snapshots and videos, proceed as follows:



5.4.5 Crop video

To cut the videos, proceed as follows:





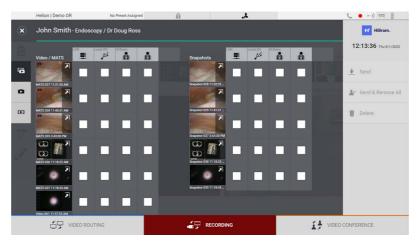
4. Once the cutting points are determined, extract the portion of the video by pressing OK. A new video appears in the photo/video list of the same patient.

€ RECOR

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.

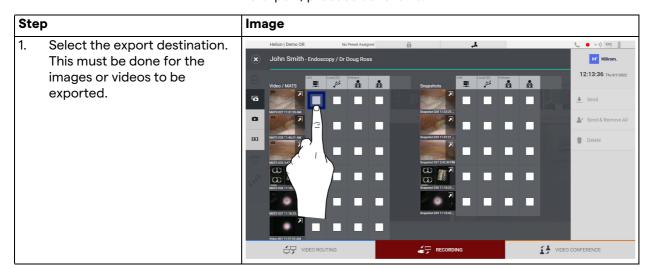
A screen with all the captured images and videos is displayed.



The following icons are present in the Export window:

Icon	Function
LAN	It enables to export via LAN to another device.
Local (D)	Enables to save on a device connected to the USB port.
PACS	It enables to export to the PACS system.

To export, proceed as follows:

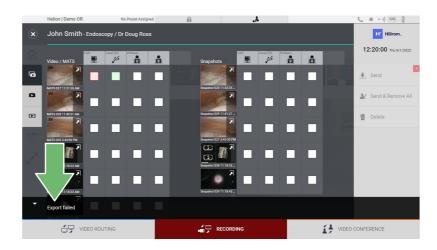




Step **Image** 2. John Smith - Endoscopy / Dr Doug Ross of the screen) to send the files 12:15:44 ты to the selected destinations. IN ILocal (D) Orthano coal (0) Orthano 1 1 By pressing & Send & Remove All the files are sent to the selected **√** 1 destinations and the patient's session will be deleted. 1 1 1 VIDEO CONFERENCE

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

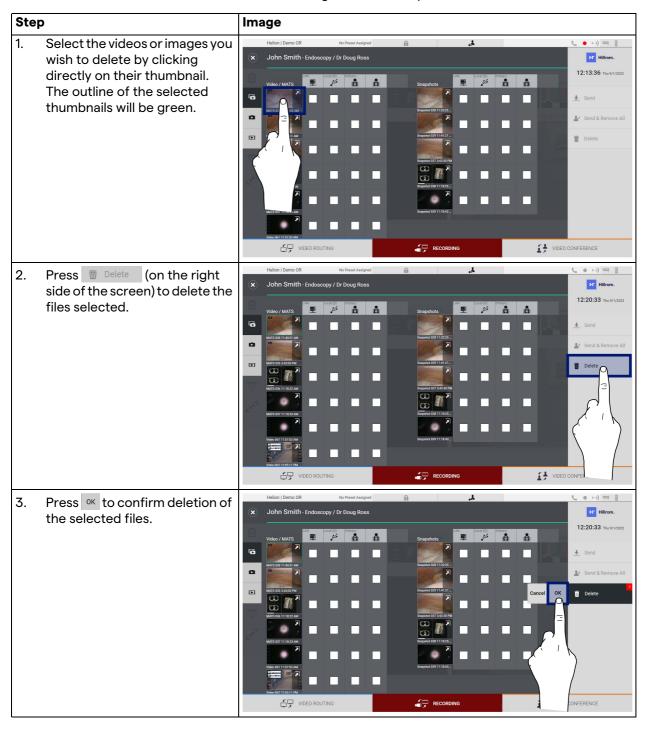
If the export destination does not respond (e.g.: USB device not present), the system displays an "EXPORT FAILED..." error message and the icon papears on the right side of the screen. A red checkbox is displayed for each destination to which the selected file could not be exported, as shown in the figure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



5.4.7 Delete images and videos

Click on the icon to access the folder for storing images and videos of the selected patient.

To delete images and videos, proceed as follows:





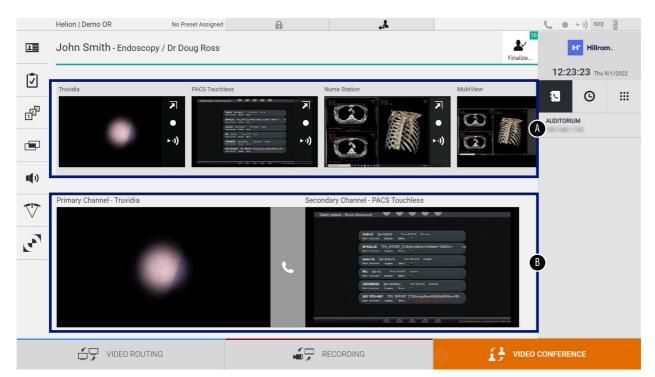
5.5 "Video Conference" function

The Video Conference function allows video conferencing in twoway audio and video connection from the operating room to external rooms:

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

The following modes are available:

Mode	Description
Preview of the transmission channel	It enables to view 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 layout selected.
Layout Button	During a multi-channel conference it is possible to have various live Previews of the video signals involved, for example PiP and PaP.
Participant selection/ Contact list	The video conference participants can be selected through the specific button: - by using the contact list, - by using the list of recent participants (log), - by entering the recipient's IP address directly from 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.

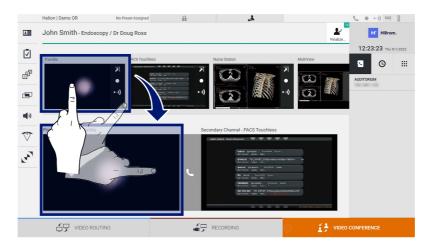


The main Video Conference screen is divided as follows:

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

5.5.1 Select the signals to be sent by video conference

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

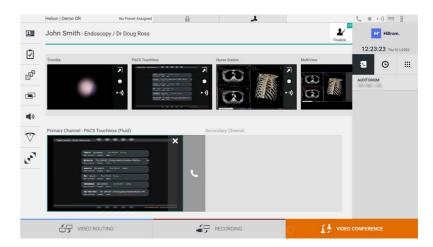




5.5.2 Removing the signals to be sent by video conference

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

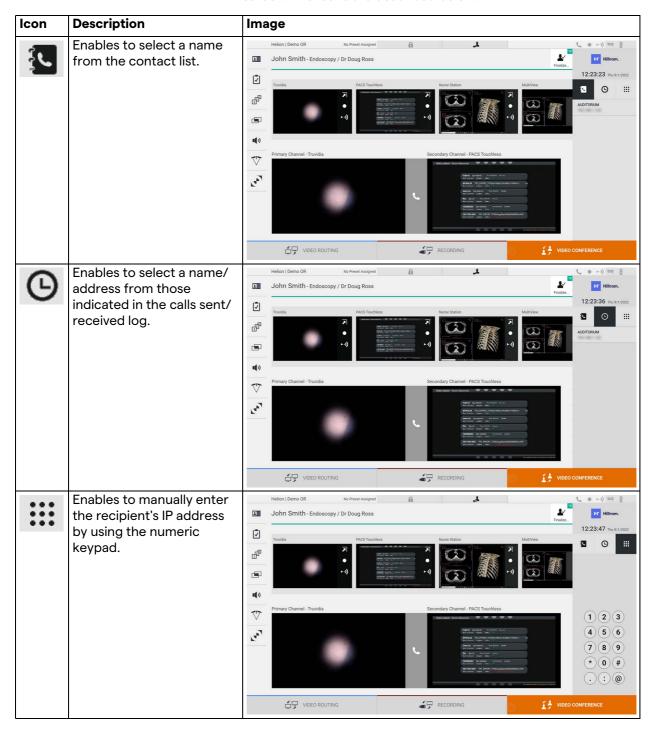
The video signal thus removed will no longer be shared with video conference participants.



5.5.3 Call recipient selection

To select the recipient of the call, press the respective icon

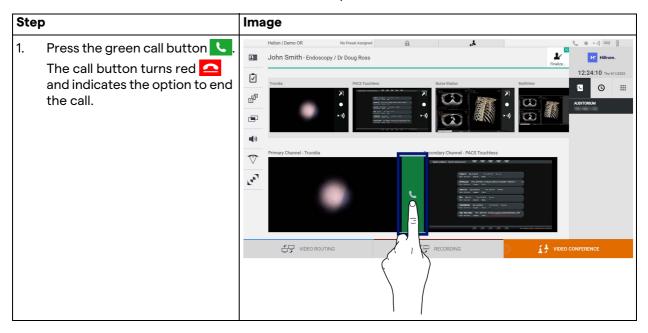
(depending on the mode) on the right side of the screen. The icons are described below:





5.5.4 Call start

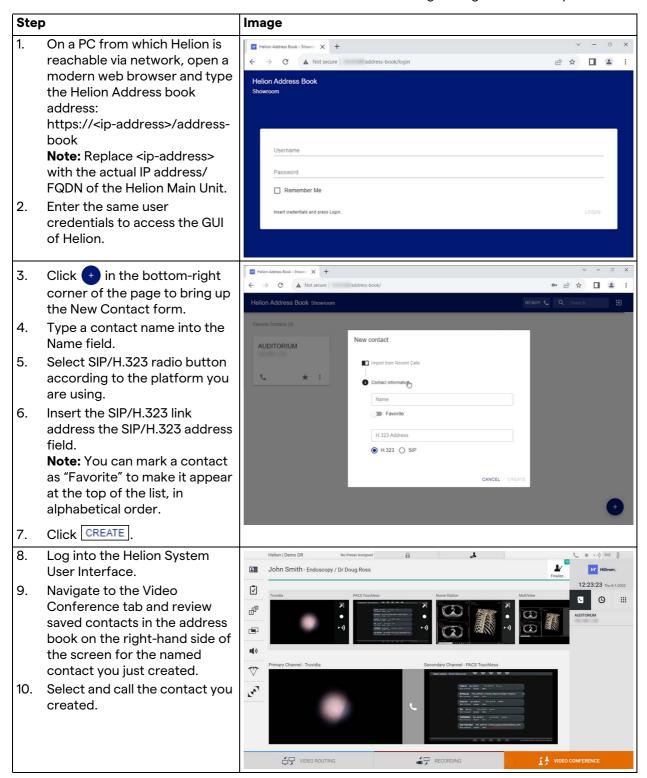
Once the call recipient has been selected, the call can be started. To start the call, proceed as follows:



5.5.5 Call H.323/SIP recipient

The following instructions provide the steps required to:

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





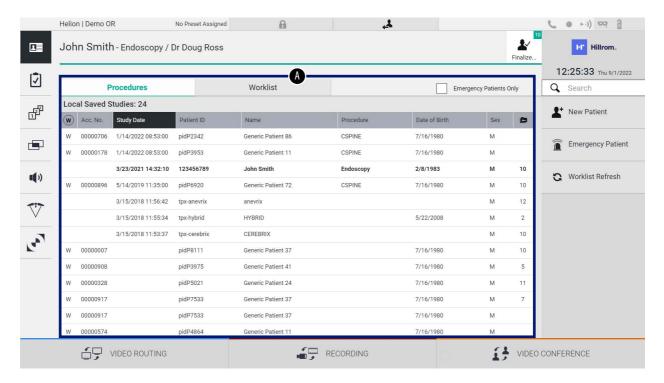
5.6 Additional functions

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

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

5.6.1 Patient data management

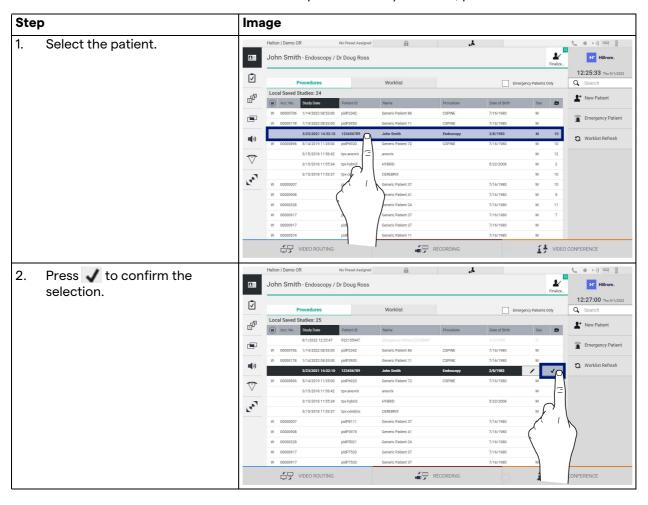
On the side menu, press the less icon to access patient data management.



On the screen displayed, when the icon is pressed, 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.

5.6.1.1 Selecting a patient present in the list

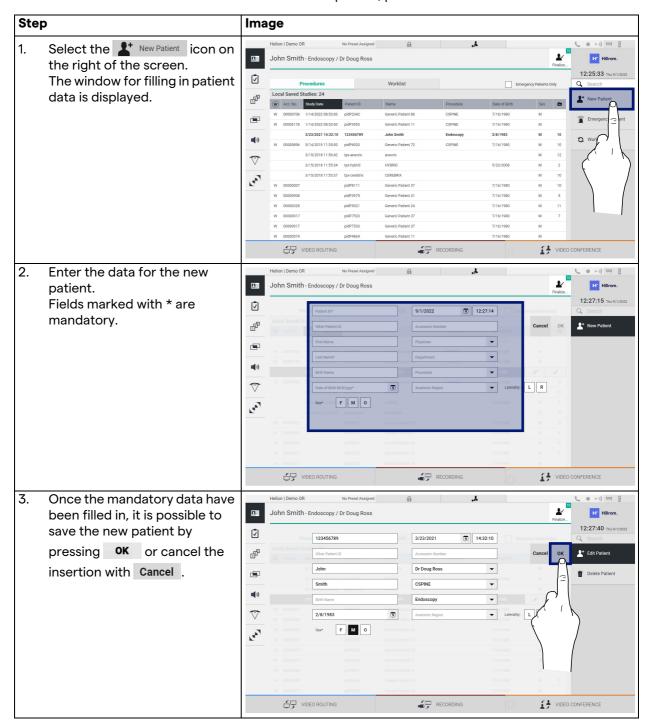
To select a patient already in the list, proceed as follows:





5.6.1.2 Entering a new patient

To enter a new patient, proceed as follows:

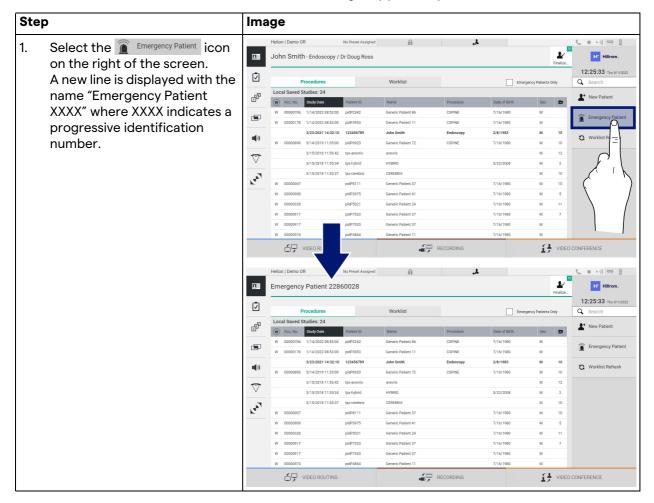


5.6.1.3 Entering an emergency patient

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

In regards to functionalities available and management, the Emergency Patient is comparable to any patient manually entered or by recalling the Worklist.

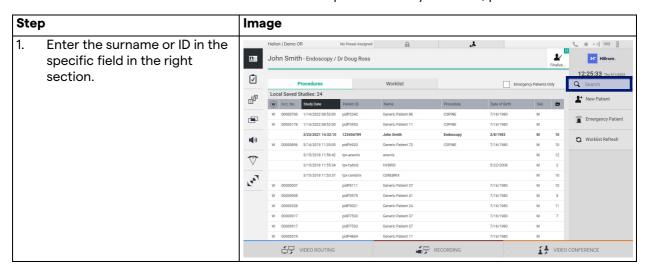
To enter an emergency patient, proceed as follows:





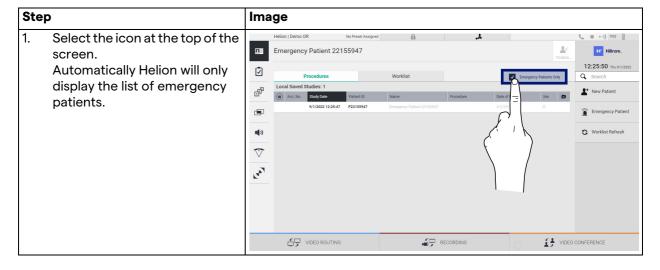
5.6.1.4 Searching for a patient present in a list

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



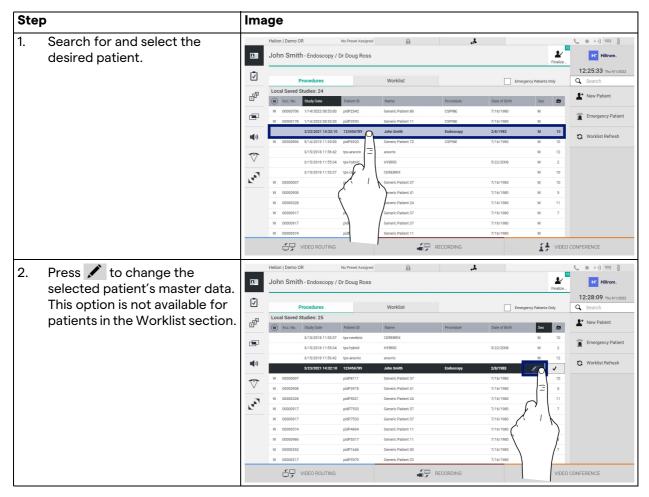
5.6.1.4.1 Emergency patient Filter

It is possible to display only patients created as "Emergency Patient" by applying the Emergency Patient filter:



5.6.1.5 Patient master data modification

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

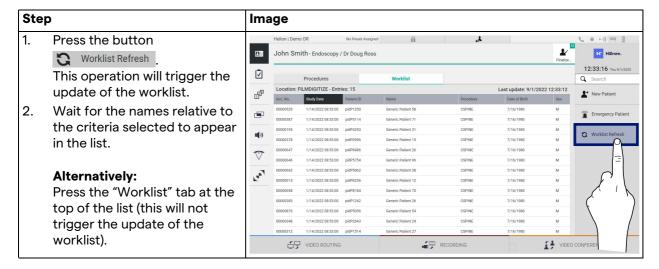


5.6.1.6 Accessing the worklist

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

Worklist Refresh button.

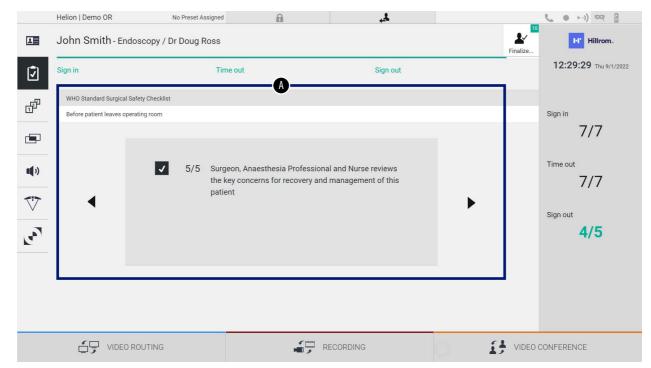
To access the worklist, proceed as follows:





5.6.2 Surgical Checklist

On the side menu, press the 📝 icon to access the Surgical Checklist screens. The Surgical Checklist only activates after selecting a patient.



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

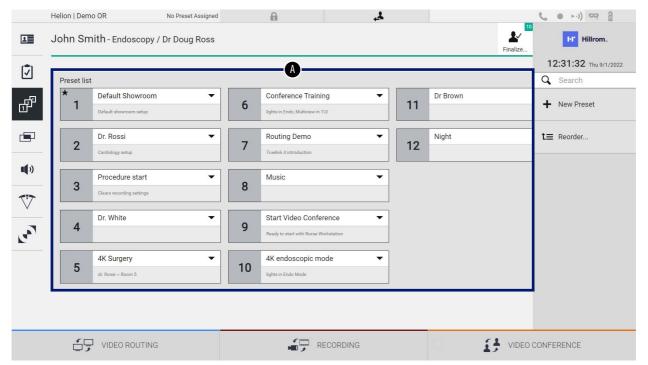
The steps refer to the entire procedure, you will then be able to exit this section and return to it to continue filling out the Surgical Checklist when necessary. It will always be possible to view the fillin status of the Surgical Checklist by looking at the progress bar in the Status Bar.

Once fill-in is complete, a window dedicated to entering Notes by the operator will open.

5.6.3 Preset

On the side menu, press the F icon to access the Preset screens. The Preset enable to save room settings configurations. It will then be possible to recall the configurations by pressing the relative icons.

The main screen is divided as follows:

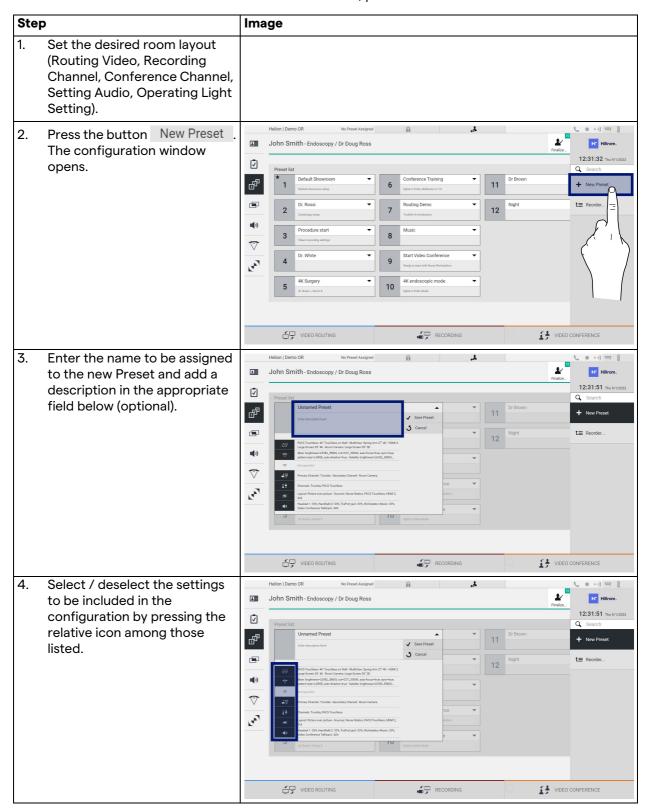


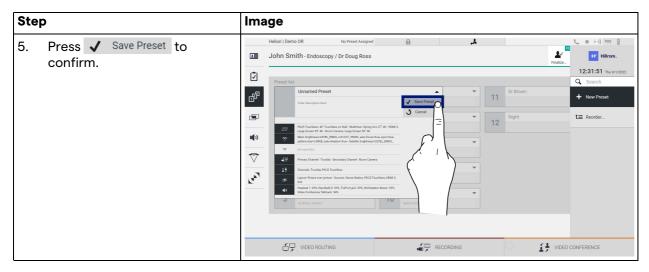
[A] Preset List



5.6.3.1 Preset setting

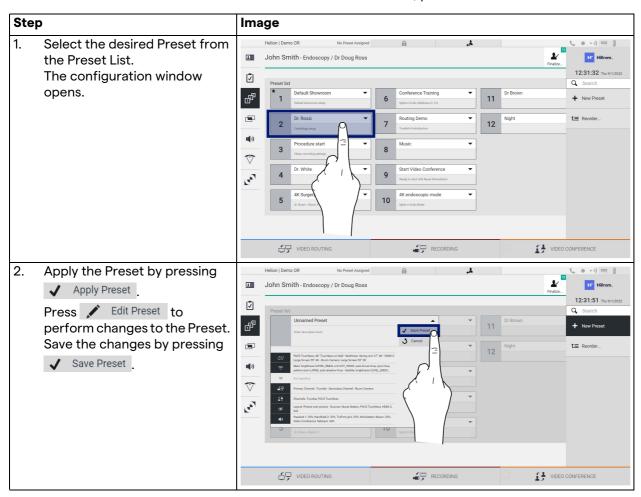
To set a new Preset, proceed as follows:





5.6.3.2 Enabling Preset

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



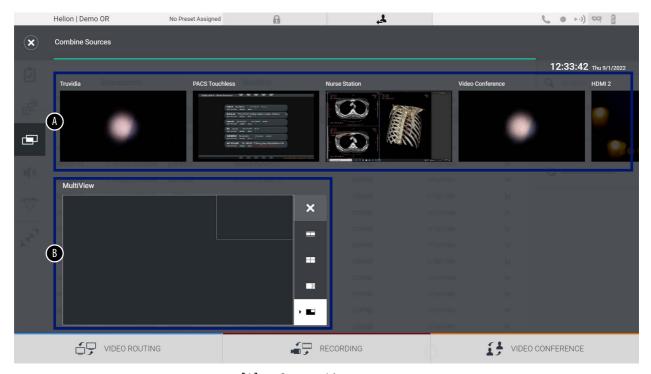
Press the * Mark Favorite* icon to automatically activate the Preset each time the system is started.



5.6.4 Multiview

On the side menu, press the icon to access the Multiview screen. The Multiview function enables to combine multiple Inputs (up to a maximum of 4) into a single Output signal.

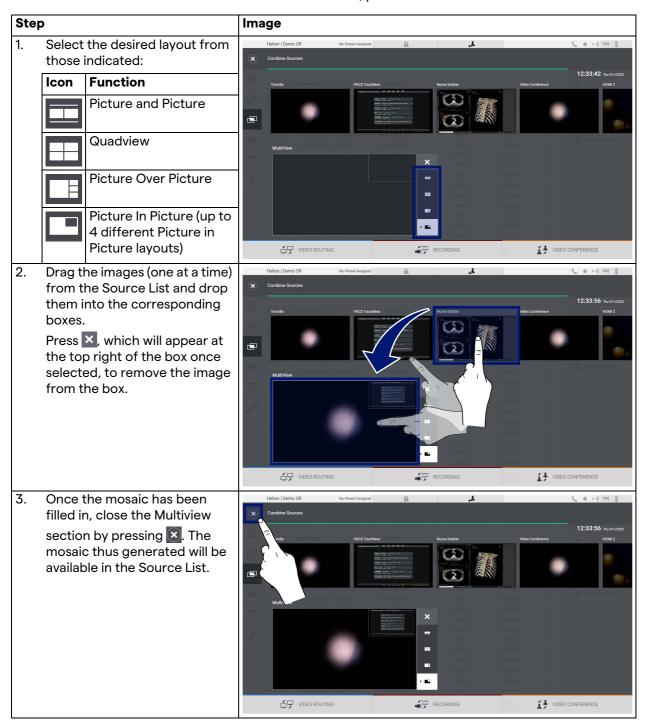
The main screen is divided as follows:



- [A] Source List
- [B] Multiview

5.6.4.1 Multiview setting

To set the Multiview, proceed as follows:





5.6.5 Audio control

On the side menu, press the (1) icon 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.

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

"Lines" settings will affect the audio mix that is sent to the speakers in the operating room.

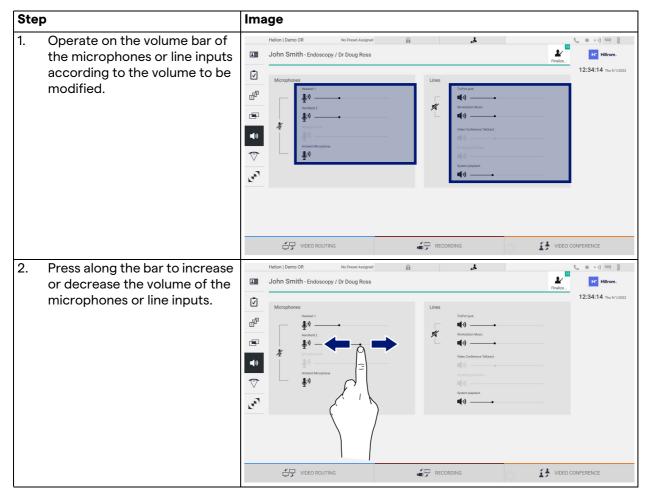
The main screen is divided as follows:



- [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:



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

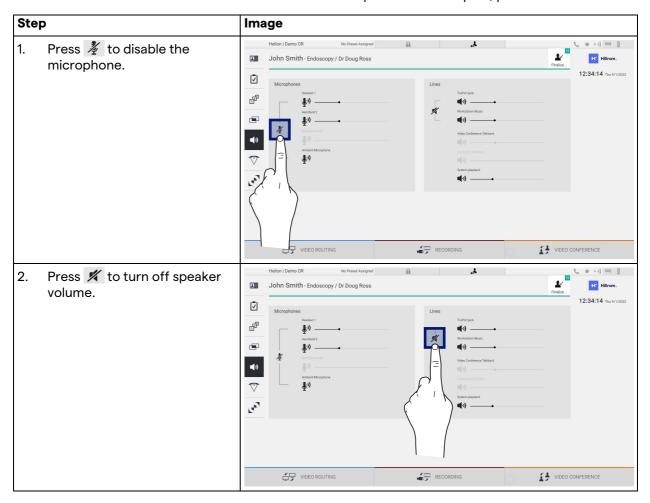
In the event that the system receives a connection request in video conference, the system will automatically silence lines AUX1/AUX2 and activate the video conference line.

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



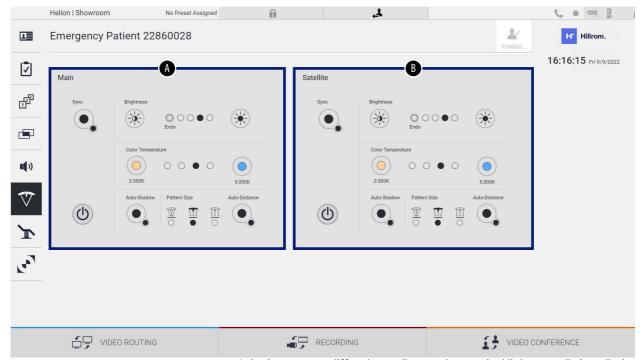
5.6.5.2 Disabling microphones and audio

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



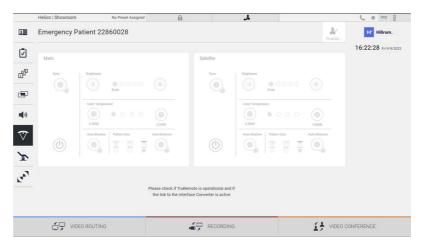
5.6.6 Management of surgical lights

The main screen is divided into 2 sub-control areas dedicated respectively to the 2 operating lights installed in the operating room:



- * the image may differ depending on the surgical light actually installed
- [A] Light 1
- [B] Light 2

The image shows the case where the surgical lights control system cannot be reached.



Helion Video Management System assures the option of controlling the Baxter surgical operating lights, thanks to reproduction of the light control console through the graphic interface.

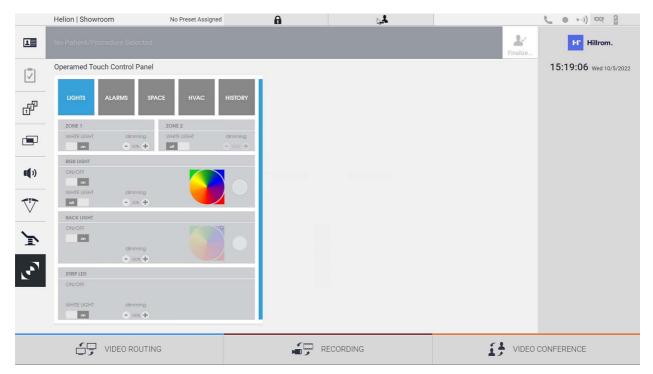


From the image you can see that the functions accessible from the touchscreen system are:

- Light on/off;
- Sync function enabling (synchronization of the 2 lights);
- Light brightness level adjustment;
- Light color temperature adjustment;
- Focus setting (the automatic function can also be activated)*;
- Light beam size*;
- Shadow setting (the automatic function can also be activated)*.
- * the function may vary based on the light model installed.

5.6.7 Environmental control panel management

On the side menu, press the icon to access the operating room control panel management screen.



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

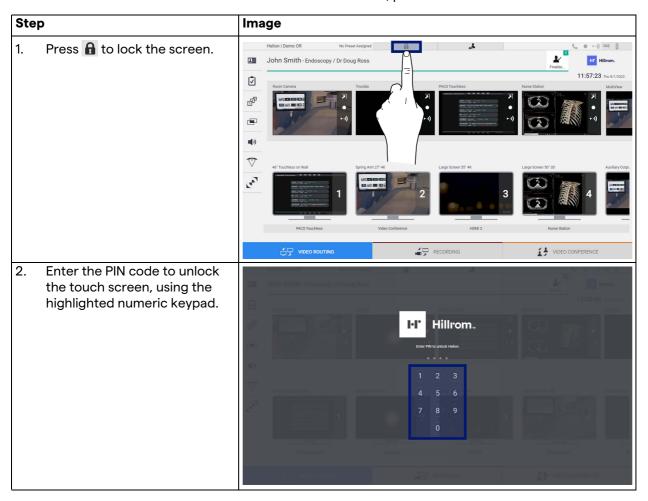
The Helion Video Management System of Videomed S.r.l. enables only Operamed control panels to be associated.

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5.7 "Lock with PIN" function

Helion Video Management System includes a Lock function to lock the touchscreen by using a PIN.

To lock the touchscreen, proceed as follows:





5.8 "Login" function

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



Once the correct credentials have been entered, the system will show the initial Helion graphical 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 urban waste. The substances and materials contained in them must be disposed of separately in an appropriate way, 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 products Videomed S.r.l. Recycling and disposal is performed by Videomed S.r.l. at no additional cost to the operator.



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

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

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



7 Annex I - Short manual



Video Routing

To send a video signal to a monitor, drag the relative 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 inside the relative Monitor icon and updated periodically.

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



Multiview

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

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

To remove an image from a frame, press the x which will appear at the top right of the frame once selected. Once the composition of the mosaic has been completed, return to the Video Routing section by pressing the relative blue icon.

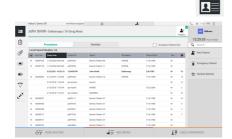


PTZ camera control

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



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:



Enter the data relating to the new patient (the fields marked with * are mandatory).



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



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





Selection of signals to be recorded

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



Instant capture

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

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