



Hillrom™

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-GB

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

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

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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
Helion Rack (115V)	AC500920K
Helion Rack (230V)	AC500920K-2

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 personnel.

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

PREFACE

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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Contents

- 1 System identification 9**
- 1.1 Identification plates 9
- 1.2 Reference standards 12
- 1.3 Warranty 13
- 2 General preliminary information 14**
- 2.1 Recipients of the instructions for use 14
- 2.2 Updates 14
- 2.3 Language 14
- 2.4 Personnel qualifications 15
- 2.5 Symbols used in the instructions for use 15
- 3 Safety information 17**
- 3.1 General safety warnings 17
- 3.2 Electromagnetic compatibility 18
- 3.3 Useful life of the system 20
- 3.4 Cleaning 21
- 3.4.1 Preparing the system 21
- 3.4.2 Cleaning the system 21
- 4 System description 22**
- 4.1 Intended use 22
- 4.2 Reasonably foreseeable misuse 23
- 4.3 Use in combination with other medical devices 23
- 4.4 Obligations and prohibitions 24
- 4.4.1 Personnel prohibitions 24
- 4.5 Technical data 25
- 4.6 Measurement and weight layout 30
- 4.7 System components 35
- 4.7.1 Main unit 35
- 4.7.2 Conference unit 36
- 4.7.3 4K unit 36
- 4.7.4 4K Plus unit 36
- 4.7.5 Control software 37
- 5 Operation 38**
- 5.1 First system start 38
- 5.2 Preliminary checks 38
- 5.3 System start-up 38
- 5.4 Connection to sources 39
- 5.5 System shutdown 39
- 5.6 System start-up/shutdown by remote button 40
- 6 User Interface 41**
- 6.1 General description of the user interface 41
- 6.2 Control touchscreen 42
- 6.3 “Video Routing” function 42
- 6.3.1 Live Preview 44
- 6.3.2 Quick Access - Recording 46
- 6.3.3 Quick Access - Streaming 47
- 6.3.4 Ptz camera control 48
- 6.3.4.1 Roomcam zoom adjustment 48
- 6.3.4.2 Roomcam movement adjustment 48
- 6.3.4.3 Save camera setting (Preset) 49
- 6.3.4.4 Delete camera setting (Preset) 50

6.3.4.5	Enable camera setting (Preset)	51
6.4	“Recording” function	51
6.4.1	Image data post-processing	53
6.4.2	Selecting the signals to be recorded	53
6.4.3	Recording	54
6.4.4	Snapshot and video playback	55
6.4.5	Cutting video	56
6.4.6	Export images and videos	58
6.4.7	Delete images and videos	60
6.5	“Video Conference” function	61
6.5.1	Selecting the signals to be sent by video conference	62
6.5.2	Removing the signals to be sent by video conference	63
6.5.3	Call recipient selection	64
6.5.4	Call start	65
6.6	Additional functions	65
6.6.1	Patient data management	66
6.6.1.1	Selecting a patient in the list	67
6.6.1.2	Entering a new patient	68
6.6.1.3	Entering an emergency patient	69
6.6.1.4	Searching for a patient in a list	70
6.6.1.5	Patient master data modification	70
6.6.1.6	Accessing the worklist	71
6.6.2	Check-List	72
6.6.3	Preset	73
6.6.3.1	Preset setting	74
6.6.3.2	Enabling Preset	76
6.6.4	Multiview	77
6.6.4.1	Multiview setting	78
6.6.5	Audio control	79
6.6.5.1	Volume adjustment	80
6.6.5.2	Disabling microphones and audio	81
6.6.6	Surgical light management	82
6.6.7	Environmental control panel management	83
6.7	“Lock with PIN” function	84
6.8	“Login” function	85
7	Disposal instructions	86
8	Annex I - Getting started	87
8.1	Video Routing	87
8.2	Multiview	87
8.3	PTZ camera control	87
8.4	Recording	87
8.5	Patient data	88
8.6	Selecting the signals to be recorded	88

1 System identification













1.1 Identification plates

Helion Video Management System units are fitted with identification plates. Each plate contains the identification details of the unit which are to be quoted if required to VIDEOMED S.r.l.

The plates present are shown below:

Unit	Image
Helion Main Unit R	 <p> REF VR401111-1 Helion Main Unit R # 116001 VIDEOMED MANAGEMENT SYSTEM Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-240V~1.1-2.0A 50/60 Hz </p> <p> (01)00615521031572 (21)1234567890 (11)210811 SN 1234567890 2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T3.15A </p>
Helion Main Unit	 <p> REF VR401111-1ND Helion Main Unit # 116001 VIDEOMED MANAGEMENT SYSTEM Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-240V~1.1-2.0A 50/60 Hz </p> <p> (01)00615521031671 (21)1234567890 (11)210811 SN 1234567890 2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T3.15A </p>
Helion Main Unit RD	 <p> REF VR401111-1D Helion Main Unit RD # 116001 VIDEOMED MANAGEMENT SYSTEM Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-240V~1.1-2.0A 50/60 Hz </p> <p> (01)00615521031695 (21)1234567890 (11)210811 SN 1234567890 2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T3.15A </p>
Helion Main Unit RSD	 <p> REF VR401111-1DT Helion Main Unit RSD # 116001 VIDEOMED MANAGEMENT SYSTEM Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-240V~1.1-2.0A 50/60 Hz </p> <p> (01)00615521031688 (21)1234567890 (11)210811 SN 1234567890 2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T3.15A </p>
Helion Main Unit RS	 <p> REF VR401111-1T Helion Main Unit RS # 116001 VIDEOMED MANAGEMENT SYSTEM Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-240V~1.1-2.0A 50/60 Hz </p> <p> (01)00615521031664 (21)1234567890 (11)210811 SN 1234567890 2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T3.15A </p>
Helion Main Unit S	 <p> REF VR401111-1TND Helion Main Unit S # 116001 VIDEOMED MANAGEMENT SYSTEM Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-240V~1.1-2.0A 50/60 Hz </p> <p> (01)00615521031657 (21)1234567890 (11)210811 SN 1234567890 2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T3.15A </p>

Unit	Image
Helion Main Unit AR	<p>REF VR401111-2 Helion Main Unit AR # 116001 VIDEOMED MANAGEMENT SYSTEM</p> <p>Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy</p> <p>INPUT: 100-240V~1.1-2.0A 50/60 Hz</p>  <p>(01)00615521031640 (21)1234567890 (11)210811 SN 1234567890</p>   <p>2021-08-11 hillrom.co.uk</p>  <p>FUSES RATING: 2X 250VAC - T3.15A</p>
Helion Main Unit ARD	<p>REF VR401111-2D Helion Main Unit ARD # 116001 VIDEOMED MANAGEMENT SYSTEM</p> <p>Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy</p> <p>INPUT: 100-240V~1.1-2.0A 50/60 Hz</p>  <p>(01)00615521031633 (21)1234567890 (11)210811 SN 1234567890</p>   <p>2021-08-11 hillrom.co.uk</p>  <p>FUSES RATING: 2X 250VAC - T3.15A</p>
Helion Main Unit ARSD	<p>REF VR401111-2DT Helion Main Unit ARSD # 116001 VIDEOMED MANAGEMENT SYSTEM</p> <p>Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy</p> <p>INPUT: 100-240V~1.1-2.0A 50/60 Hz</p>  <p>(01)00615521031626 (21)1234567890 (11)210811 SN 1234567890</p>   <p>2021-08-11 hillrom.co.uk</p>  <p>FUSES RATING: 2X 250VAC - T3.15A</p>
Helion Main Unit ARS	<p>REF VR401111-2T Helion Main Unit ARS # 116001 VIDEOMED MANAGEMENT SYSTEM</p> <p>Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy</p> <p>INPUT: 100-240V~1.1-2.0A 50/60 Hz</p>  <p>(01)00615521031619 (21)1234567890 (11)210811 SN 1234567890</p>   <p>2021-08-11 hillrom.co.uk</p>  <p>FUSES RATING: 2X 250VAC - T3.15A</p>
Helion Main Unit SSD R	<p>REF VR401111-3 Helion Main Unit SSD R # 116001 VIDEOMED MANAGEMENT SYSTEM</p> <p>Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy</p> <p>INPUT: 100-240V~1.1-2.0A 50/60 Hz</p>  <p>(01)00615521031602 (21)1234567890 (11)210811 SN 1234567890</p>   <p>2021-08-11 hillrom.co.uk</p>  <p>FUSES RATING: 2X 250VAC - T3.15A</p>
Helion Conference	<p>REF CM401326 Helion Conference # 116001 VIDEOMED MANAGEMENT SYSTEM</p> <p>Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy</p> <p>INPUT: 100-240V~1.1-2.0A 50/60 Hz</p>  <p>(01)00615521031886 (21)1234567890 (11)210811 SN 1234567890</p>   <p>2021-08-11 hillrom.co.uk</p>  <p>FUSES RATING: 2X 250VAC - T1.6A</p>
Helion 4K	<p>REF VR401112 Helion 4K # 116001 VIDEOMED MANAGEMENT SYSTEM</p> <p>Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy</p> <p>INPUT: 100-240V~0.2-0.48A 50/60 Hz</p>  <p>(01)00615521031596 (21)1234567890 (11)210811 SN 1234567890</p>   <p>2021-08-11 hillrom.co.uk</p>  <p>FUSES RATING: 2X 250VAC - T1.6A</p>

Unit	Image
<p>Helion 4K Plus</p>	<p>REF VR401113 Helion 4K Plus # 116001 VIDEOMED MANAGEMENT SYSTEM  Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-240V~0.2-0.48A 50/60 Hz</p> <p>  2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T1.6A</p> <p> (01)00615521031589 (21)1234567890 (11)210811 SN 1234567890</p>
<p>Helion Rack (230V) (input voltage 220-240V)</p>	<p>REF AC500920K-2 Helion Rack (230V) # 800116 COMPONENT/ACCESSORY  Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 220-240V~ 2.6-2.9A 50/60 Hz</p> <p>  2021-09-03 hillrom.co.uk FUSES RATING: 2X 250VAC - T6.3A</p> <p> (01)00615521031893 (21)1234567890 (11)210903 SN 1234567890</p>
<p>Helion Rack (115V) (input voltage 100-120V)</p>	<p>REF AC500920K Helion Rack (115V) # 800116 COMPONENT/ACCESSORY  Videomed srl Via Cesare Battisti 31/C 35010 Limena, Italy Made In Italy INPUT: 100-120V~ 5.3-6.3A 50/60 Hz</p> <p>  2021-09-03 hillrom.co.uk FUSES RATING: 2X 250VAC - T10A</p> <p> (01)00615521031909 (21)1234567890 (11)210903 SN 1234567890</p>

⚠ CAUTION

It is strictly 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.

1.2 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: 2007/(R)2010	Medical Devices - Application Of Risk Management To Medical Devices
AAMI / ANSI / IEC 62304:2006	Medical Device Software - Software Life Cycle Processes
ANSI AAMI IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
AAMI / ANSI HE75: 2009	Human Factors Engineering - Design Of Medical Devices
AAMI / ANSI ES60601-1: 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, Mod). (General II (ES/EMC)) (U.S. Identical Adoption of Standard IEC 60601-1-2 Edition 4.0 2014-02
AAMI / ANSI / IEC 60601-1-2:2014	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 15223-1:2016	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied - Part 1: General Requirements
ISO 7010: Second edition 2011-06-01, including amendment 1 (2012) through amendment 7 (2016)	Safety Signs
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
93/42/EEC	Medical Devices Directive (MDD) and f.m. 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical devices — Quality management systems
EN ISO 14971:2012	Application of risk management to medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 60601-1:2006/A1:2013	General requirements for basic safety and essential performance
EN 60601-1-2:2015	General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
EN 60601-1-6:2010	General safety standards — Collateral standard: Usability
EN 62304:2006 + A1:2015	Medical Device Software — Software Life-cycle Processes
EN 62366-1:2015	Application of usability engineering to medical devices
WEEE 2012/19/EU	Waste electrical and electronic equipment
RoHS 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment

1.3 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 General preliminary information

2.1 Recipients of the instructions for use

The instructions for use of the Helion Video Management System are intended for operators trained and authorised to operate it. Operator training must be documented.

The instructions for use contain topics referring to correct use of the system, so as 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.

2.2 Updates

VIDEOMED S.r.l. reserves the right to update the instructions for use at any time by means of modifications and/or translations without prior notice.

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

2.3 Language

The original instructions for use have been drawn up in Italian. 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 in other 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 VIDEOMED S.r.l. Customer Service office.

2.4 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.

2.5 Symbols used in the instructions for use

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
	Caution - Refer to the operating instructions.
	Symbol used to indicate the date of manufacture.

General preliminary information

Symbol	Description
	<p>Symbol used to identify the manufacturer's name.</p>
	<p>Crossed-out bin: this product must not be disposed of as communal mixed waste, collect separately.</p>
	<p>Symbol used to indicate the VIDEOMED material number.</p>
	<p>Symbol used to indicate the serial number.</p>
	<p>Symbol used to indicate a medical device.</p>
	<p>Indicates the Unique Device Identification (UDI) code, composed of UDI-DI (01) and UDI-PI ((11) date of production (21) serial number).</p>
	<p>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)</p>
	<p>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.</p>



3 Safety information

3.1 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.

⚠ 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

RISK OF CONTAMINATION AND INFECTION OF THE PATIENT!

Free particles hidden in worn parts may end up in open wounds. A monitor with a damaged surface cannot be used in a medical environment. If the control screen is mounted on a suspension system, do not place the control screen over the sterile operating area during medical use.

⚠ 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.

3.2 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). It 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 Class A	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. 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 6 V 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

3.3 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 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.



3.4 Cleaning

⚠ CAUTION

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.

3.4.1 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.

3.4.2 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.

4 System description

4.1 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.

The intended use requires the following:

- 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.

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.



4.2 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 use”.

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.

4.3 Use in combination with other medical devices

The Helion Video Management System can be used in combination with medical devices from other manufacturers. The operation of these devices is described in the relevant operating instructions. Only medical devices (e.g. Room Camera) that are compliant with IEC standard 60601-1 can be connected to the system.

If a medical device is installed at a later date, installation must be carried out as specified in IEC standard 60601-1. The environmental requirements for the operation and storage of Helion must be observed, see the paragraph “Technical data”.

4.4 Obligations and prohibitions

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

4.4.1 Personnel prohibitions

In particular, the personnel must not:

- use the system improperly, i.e. for uses other than those indicated in the paragraph “Intended use”;
- 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 goods or persons if it is ascertained that the system has been used in one of the unapproved rooms.



4.5 Technical data

Main unit - Technical Specs

Video inputs	18 (14 DVI, 2 3G-SDI, 2 CVBS)
Monitor outputs	10 DVI over CAT6/7 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 50-60Hz 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 m
Control touchscreen	24" or 27" , 1920 x 1080, 16:9
Storage capacity	1 TB for approximately 350 hrs of video
Audio inputs	3 microphones 2 aux stereo 1 video conference
Audio outputs	2 stereo amplified 2 stereo non-amplified 1 video conference
Communication protocols	DICOM, HL7
Other connections	2 x USB 2.0 3 x USB 3.0 12 serial ports, RS232
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 50-60Hz 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 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 100Hz 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 60Hz
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 50-60Hz 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 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 60Hz
Transmission To Monitor	Optic fibre 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 m
Enclosure	IP20
Unit weight	5.5 kg



Rack unit - 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 min 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

4.6 Measurement and weight layout

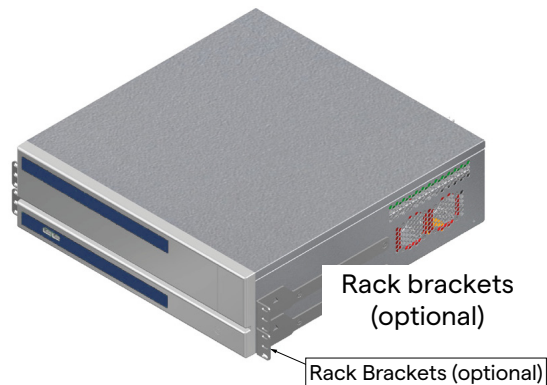
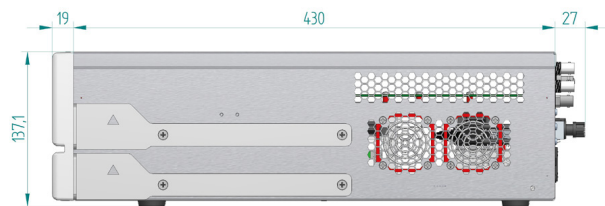
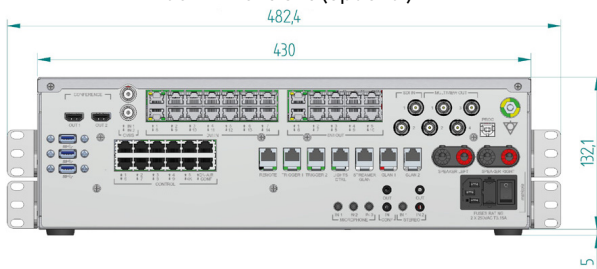
Main unit

Dimensions	133 x 430 x 450 mm
Unit weight	13.5 kg



Rack dimensions (optional)

Rack Dimensions (optional)





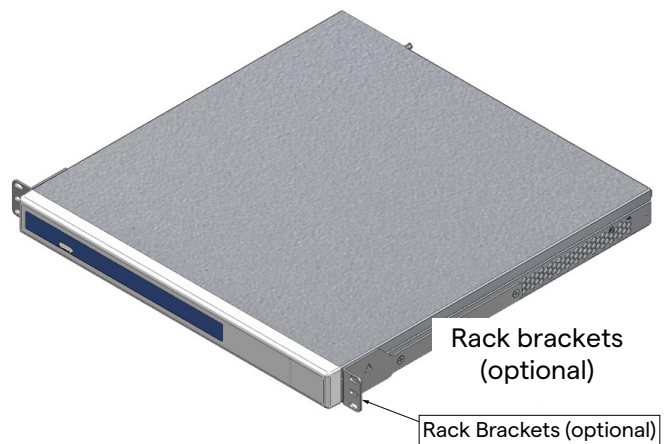
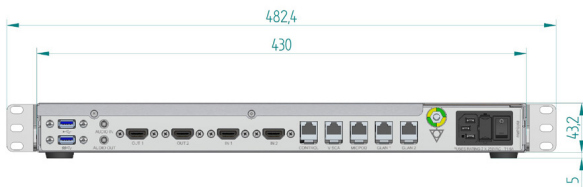
Conference unit

Dimensions	44 x 430 x 450 mm
Unit weight	8 kg



Rack dimensions (optional)

Rack Dimensions (optional)



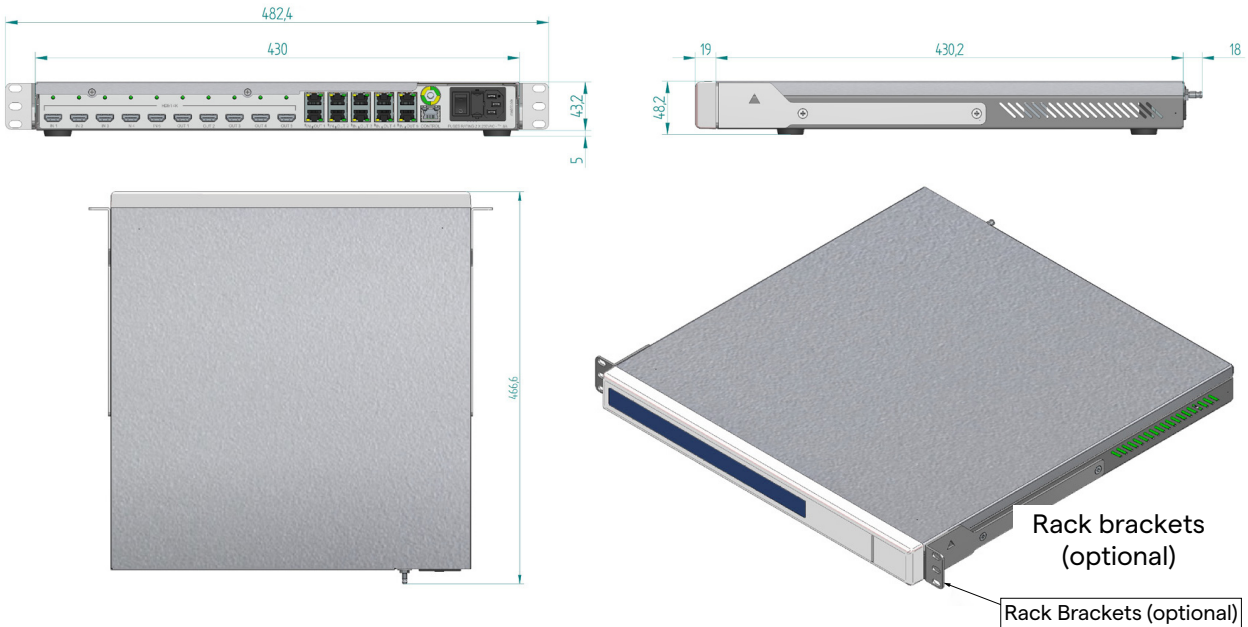
4K Unit

Dimensions	44 x 430 x 450 mm
Unit weight	5.5 kg



Rack dimensions (optional)

Rack Dimensions (optional)





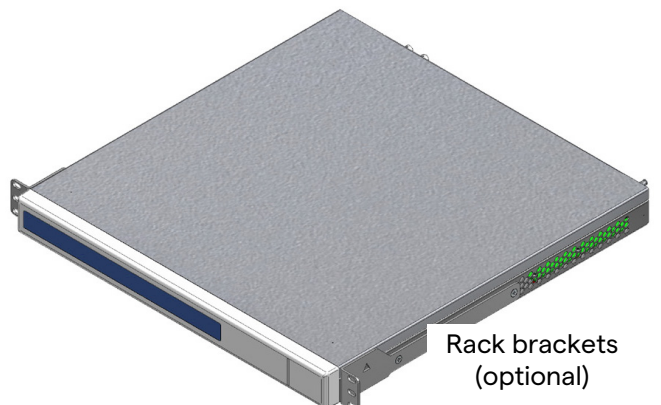
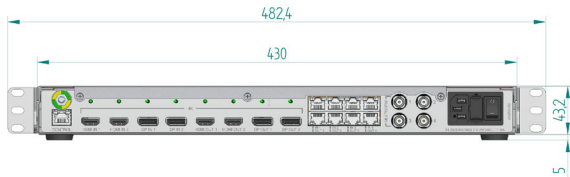
4K Plus unit

Dimensions	44 x 430 x 450 mm
Unit weight	5.5 kg



Rack dimensions (optional)

Rack Dimensions (optional)

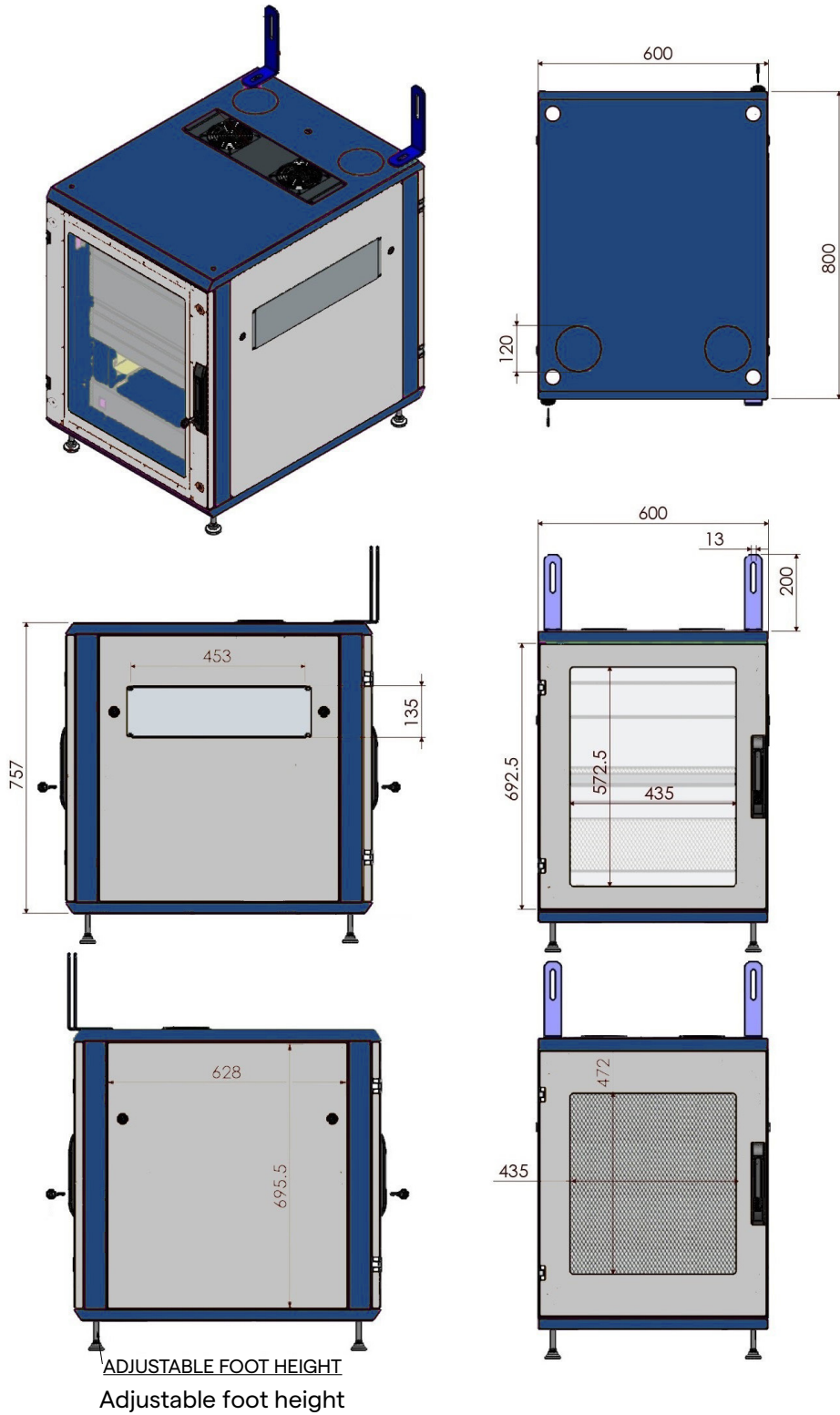


Rack brackets (optional)

Rack Brackets (optional)

Rack unit

Dimensions	800 x 600 x 757 mm
Unit weight	64 kg



4.7 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.



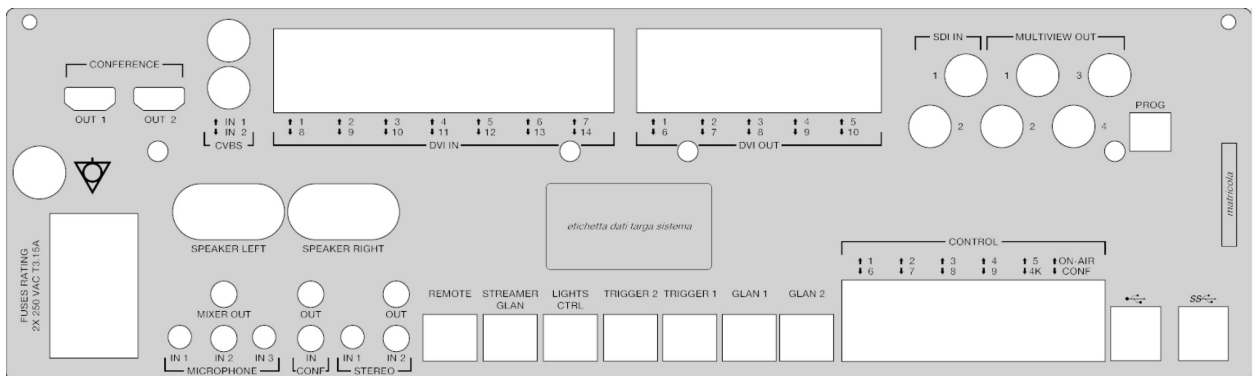
- [1] Main unit
- [2] Conference unit
- [3] 4K Unit or 4K Plus unit

4.7.1 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	It makes it possible to document operation by temporarily storing and exporting the images and videos recorded.
VIDEO STREAMING	It 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:

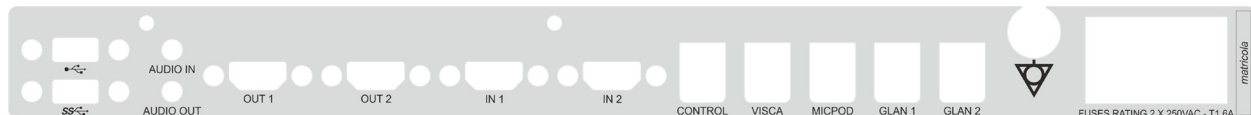


The connection cables are supplied by VIDEOMED S.r.l.

4.7.2 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.



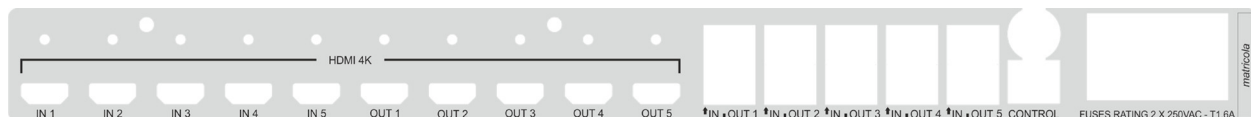
The connection cables are supplied by VIDEOMED S.r.l.

4.7.3 4K unit

The new identification plates are still missing.

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:

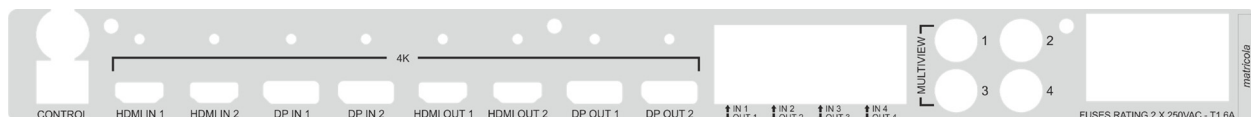


The connection cables are supplied by VIDEOMED S.r.l.

4.7.4 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:

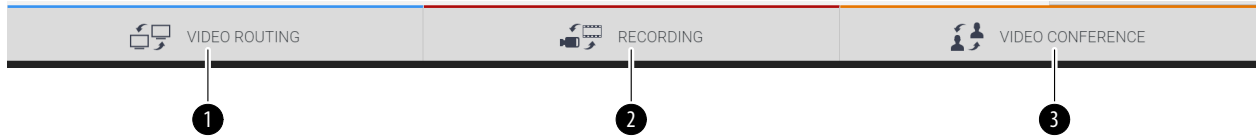


The connection cables are supplied by VIDEOMED S.r.l.




4.7.5 Control software

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

A lower selection bar (always visible) allows the software sections 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.

5 Operation

5.1 First system start

The Helion Video Management System is delivered to the operator by authorised installation 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, and also 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.

5.2 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.

5.3 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.	 A photograph of the Helion control panel. The panel has four horizontal sections. The top section is dark blue with 'Hillrom' on the left and 'Helion' on the right. The second section is dark blue with 'Service only' in the center. The third section is dark blue with 'Conference' on the right. The bottom section is dark blue with '4K' on the right. A hand is shown touching a circular touch button on the right side of the panel, which is highlighted with a dashed circle.



5.4 Connection to sources

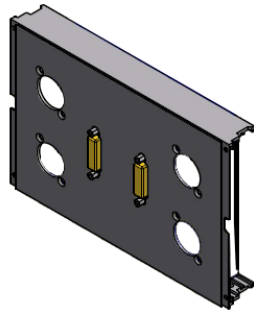
When a new video source is connected to the system, a dynamic Preview (frame) is displayed in the Source List, showing the name of the socket/line used.

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)
- VGA



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

5.5 System shutdown

To shut down the system, proceed as follows:

Step	Image
<ol style="list-style-type: none"> 1. Keep your finger on the touch button for about 5 seconds, until the frequency of flashing of the LEDs visibly increases. 2. Once the frequency changes, remove your finger from the button. 	

In the event of system shutdown, it is possible to force system deactivation by keeping 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.

5.6 System start-up/shutdown by remote button

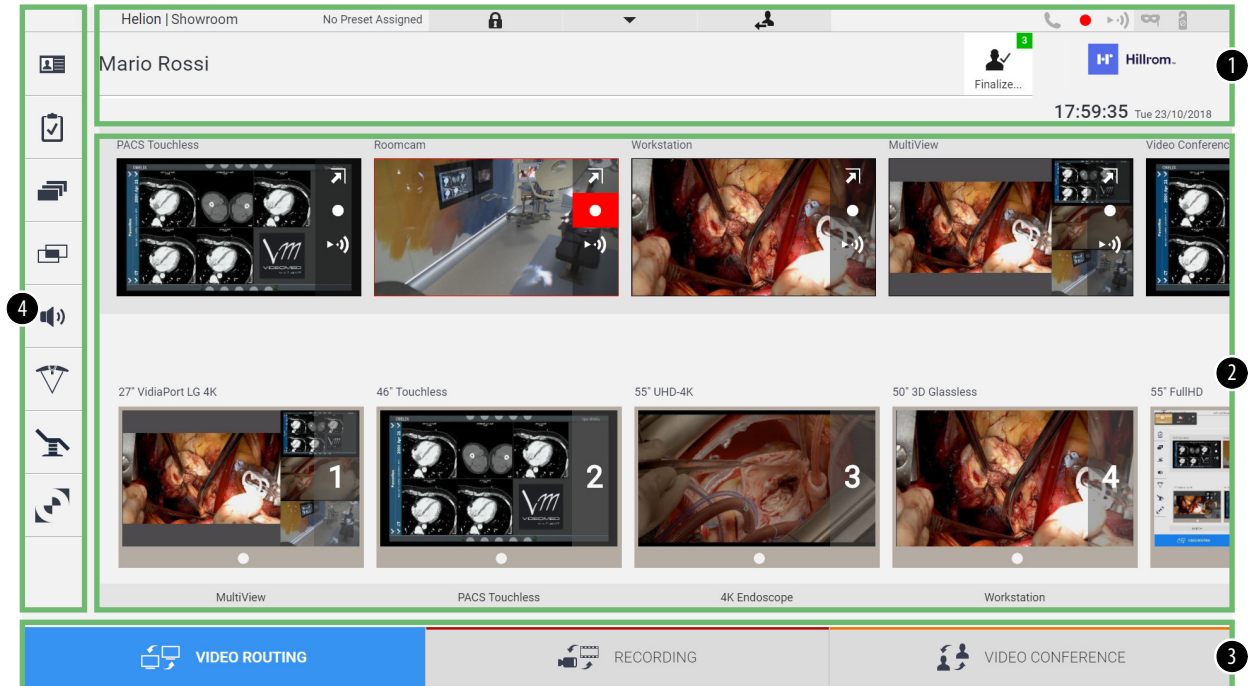
The Helion Video Management System allows units to be restarted via a remote on/off button installed inside the operating theatre (typically on a pendant panel or wall unit).

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

6 User Interface

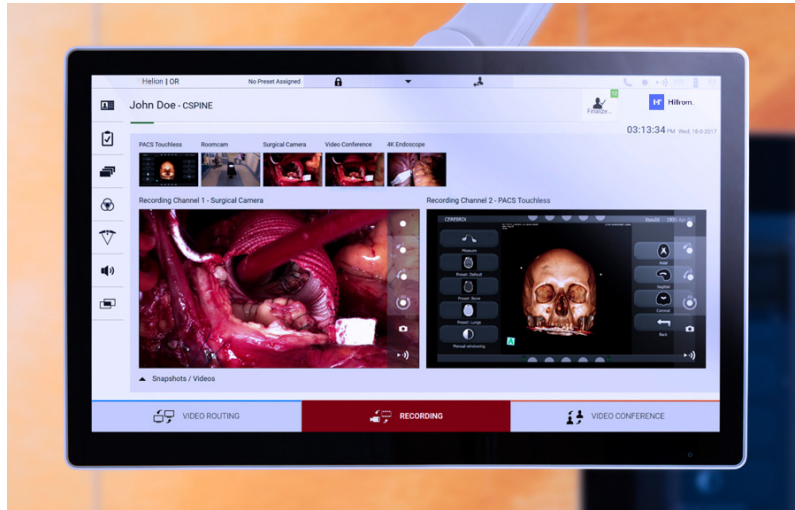
6.1 General description of the user interface

The user interface is divided up 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, video conference, streaming and advanced modes "Privacy Mode", "Do Not Disturb" and "Lecture Mode" are also present.
[2]	Main section	Source selection and monitor identification area. The structure of the area varies based on the control functions activated.
[3]	Selection bar	Bar located at the bottom of the screen, which permits 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	Bar on the left side of the screen that provides access to the setup and workflow management screens.

6.2 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.

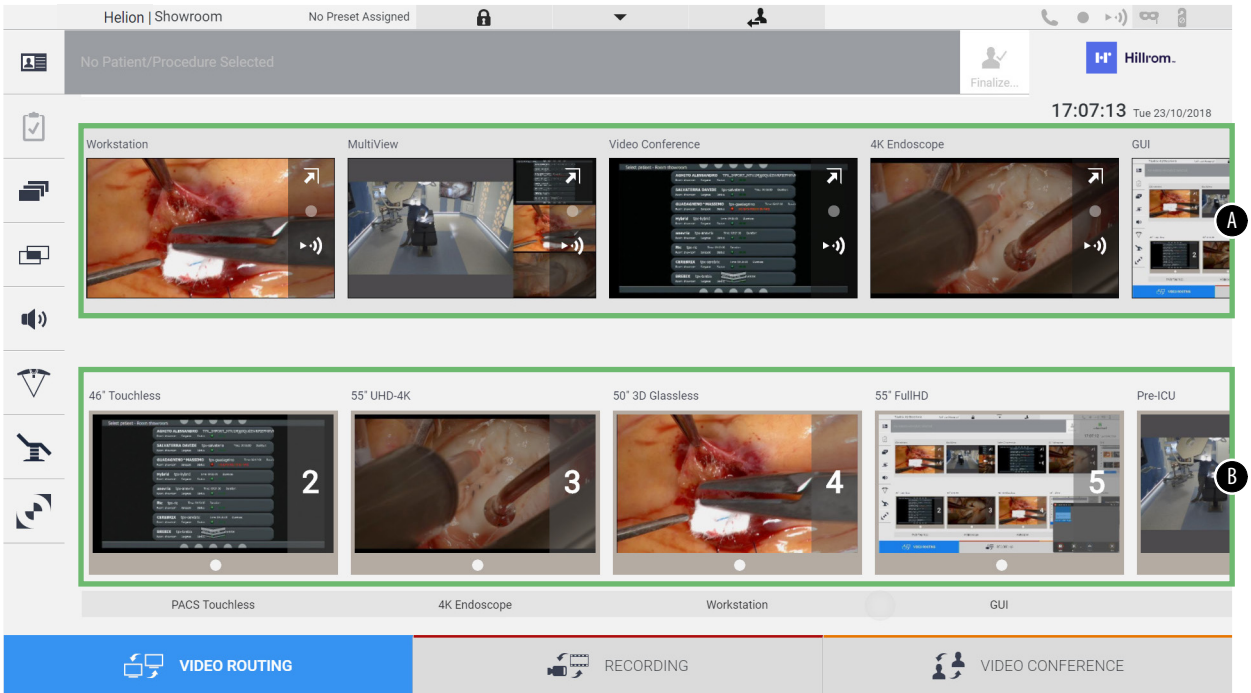
6.3 “Video Routing” function

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.

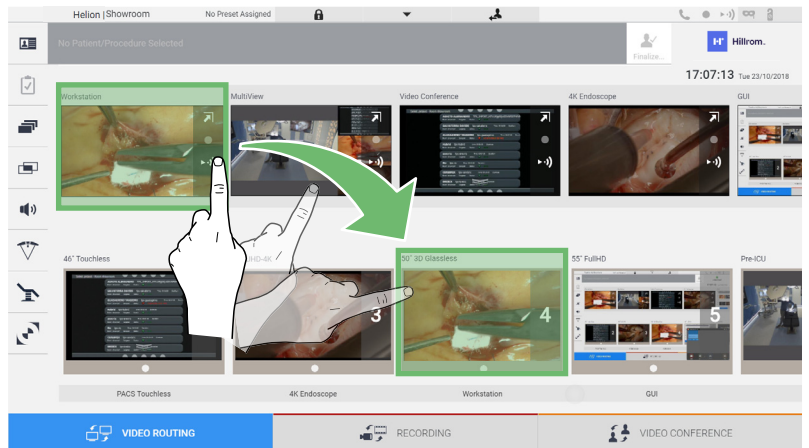
These video signals can be routed to any monitor in the operating theatre.

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.


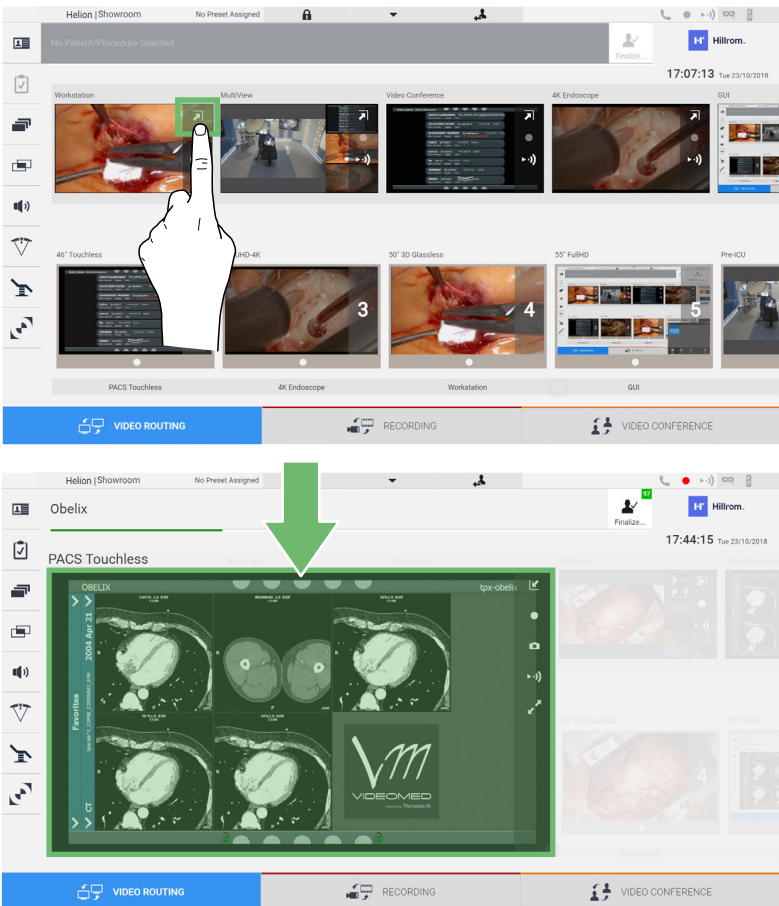




The Preview of the video signal sent will be displayed in the relative Monitor icon and updated periodically.





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

6.3.1 Live Preview

With the Live Preview function, it is possible to enlarge or reduce the preview of the video signal of each connected source. If the preview is enlarged, it will only appear momentarily on the screen. To display the Live Preview of one of the signals available in the Source list, proceed as follows:

Step	Image
<p>1. Press the  icon in the corresponding Preview. The enlarged image selected is displayed.</p>	
<p>2. Press  to return to the standard view of the Video Routing section.</p>	

The following icons are present in the Live Preview window:

Icon	Function
	<p>Makes it possible to start/stop recording of the displayed signal.</p> <p>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").</p>
	<p>Makes it possible to create snapshots of the image.</p>
	<p>Makes it possible to start/stop video signal streaming.</p>
	<p>Makes it possible to activate full-screen display, without latency, of the selected source (function is only available on certain touchscreen monitor models).</p>




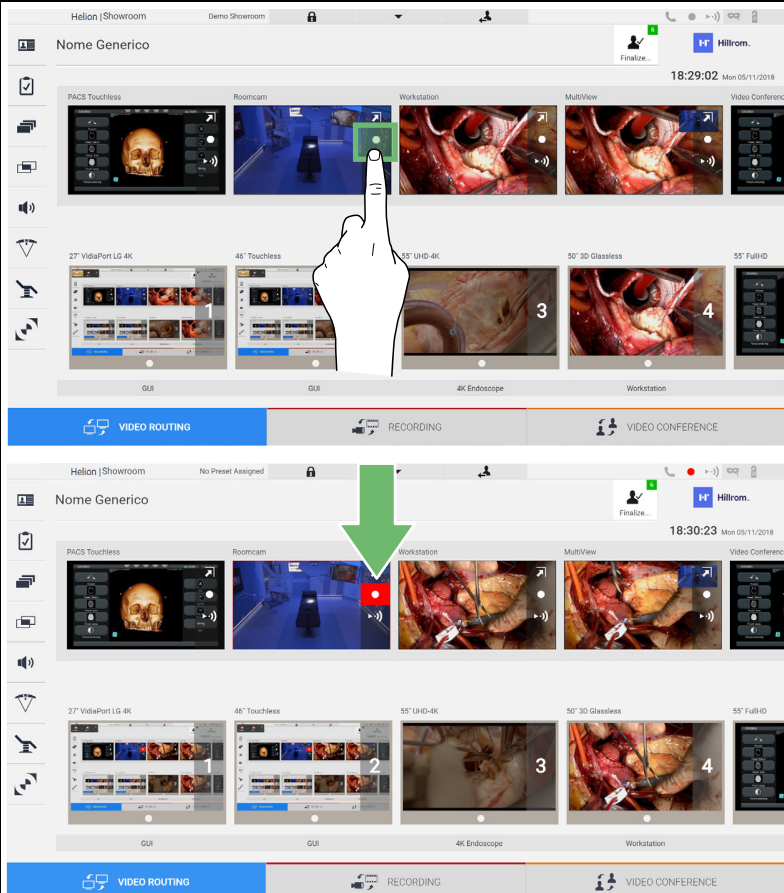
It is not possible to start recording if a reference patient is not present.

6.3.2 Quick Access - Recording

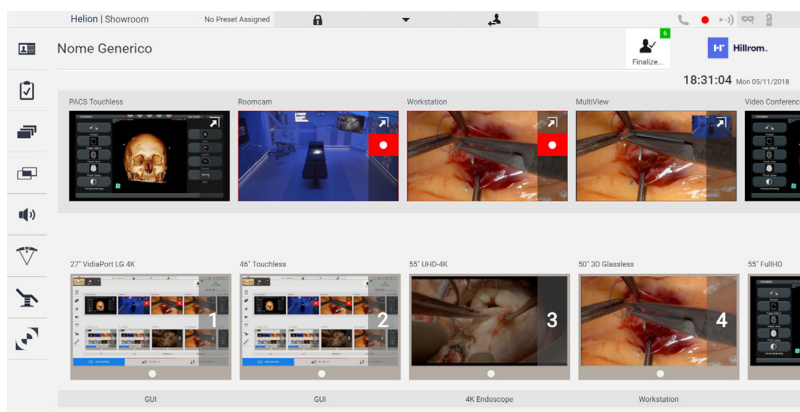
It is possible to use a quick activation system directly from the Video Routing screen to start recording. A dedicated Recording screen is available to access advanced functions.

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:





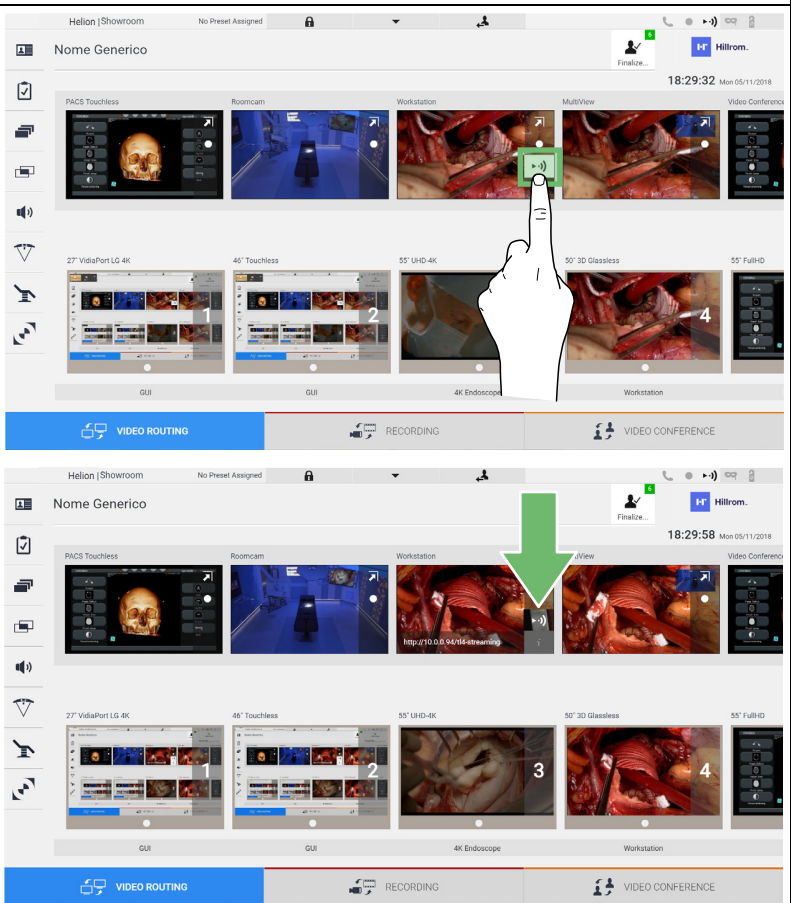
Step	Image
<p>1. Press the  icon of a Preview to start recording a signal. When recording is in progress, the button is red .</p> <p>The  icon is also present in the upper part of the screen and also remains visible when navigating through other functions (if recording is active).</p>	

In systems where the dual recording channel is enabled, this function can be activated on two sources at the same time.



6.3.3 Quick Access - Streaming

To activate streaming, proceed as follows:



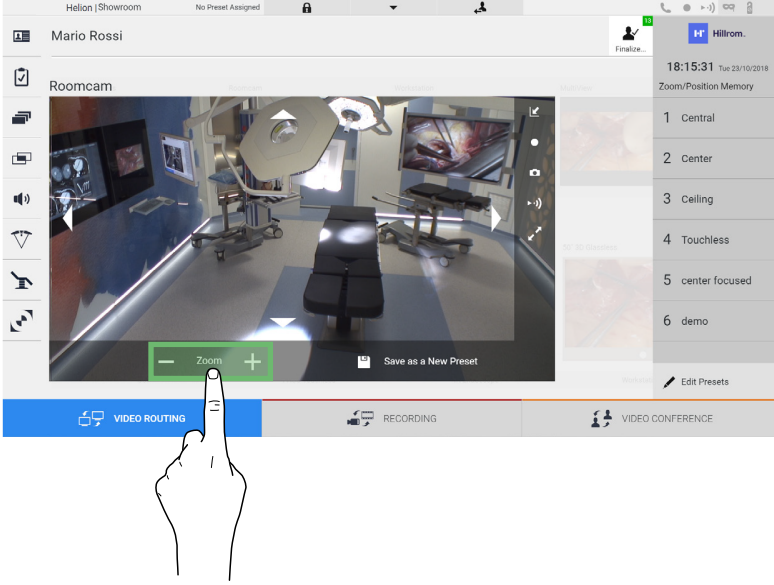
Step	Image
<p>1. Press the  icon of a Preview to start streaming the signal from one of the connected sources.</p> <p>When streaming is active, the button is in a white background  in the icon of the selected source and is disabled in the Previews of the remaining sources.</p> <p>Pressing  in a Preview 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 capable of reproducing a network flow (e.g. VLC). If the room streaming session is interrupted, communication with the outside will also be halted.</p>	 <p>The image consists of two screenshots of the Hillrom user interface. The top screenshot shows a hand clicking the streaming icon (a speaker with sound waves) on the 'Workstation' preview. The bottom screenshot shows the same interface with a green arrow pointing to the 'Workstation' preview, which now displays a URL: 'http://10.0.0.0:8080/Streaming'.</p>

6.3.4 Ptz camera control

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


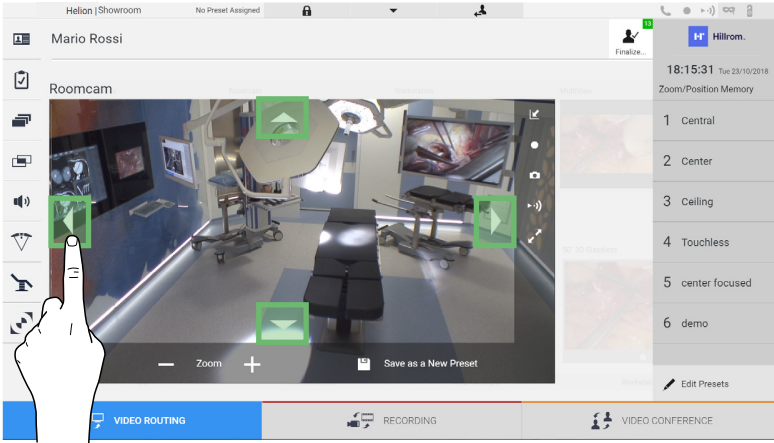
6.3.4.1 Roomcam zoom adjustment

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

Step	Image
<p>1. Use  and  to adjust the zoom to obtain the desired image (view).</p>	 <p>The screenshot shows the 'Roomcam' interface. At the bottom of the video preview window, there is a green 'Zoom' control bar with a minus sign on the left and a plus sign on the right. A hand icon is pointing to the plus sign. The interface also includes a 'Save as a New Preset' button and a list of presets on the right side.</p>

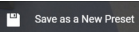
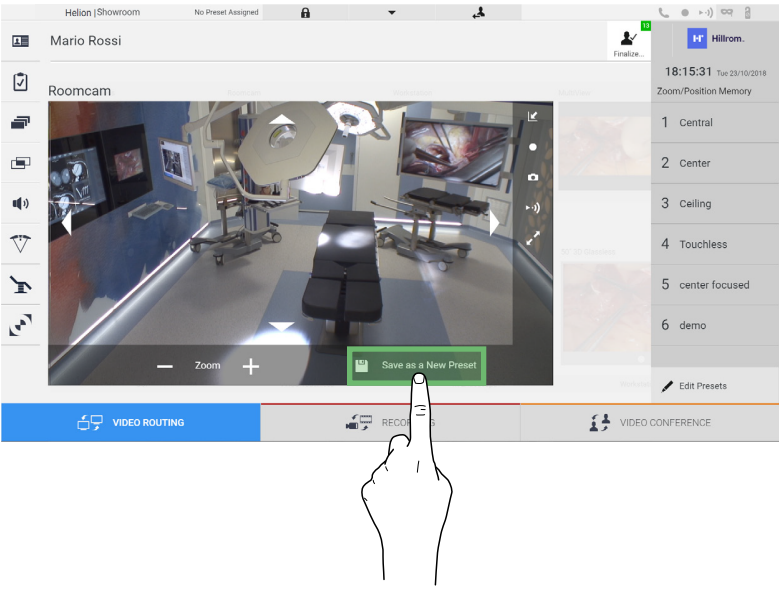
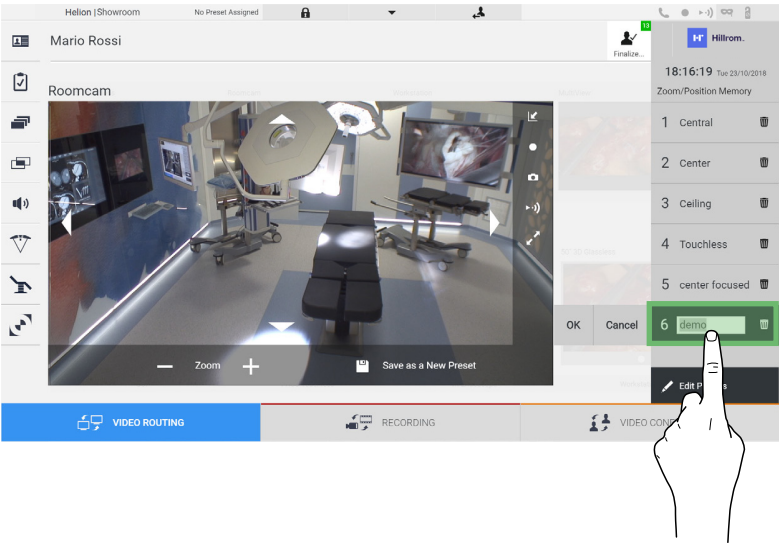
6.3.4.2 Roomcam movement adjustment

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

Step	Image
<p>1. Use the arrows  in the screen to adjust the movement of the Roomcam.</p>	 <p>The screenshot shows the 'Roomcam' interface with movement control arrows overlaid. A hand icon is pointing to the left arrow. The interface includes a 'Zoom' control bar at the bottom and a list of presets on the right side.</p>


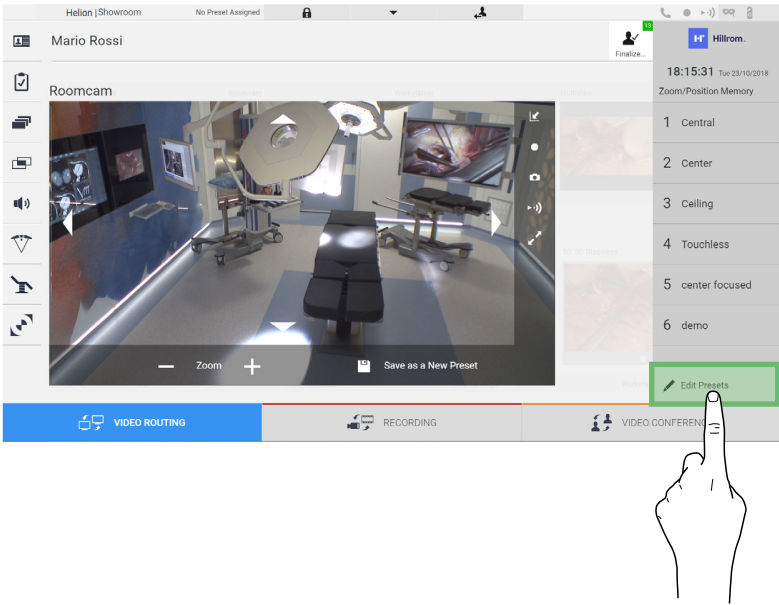

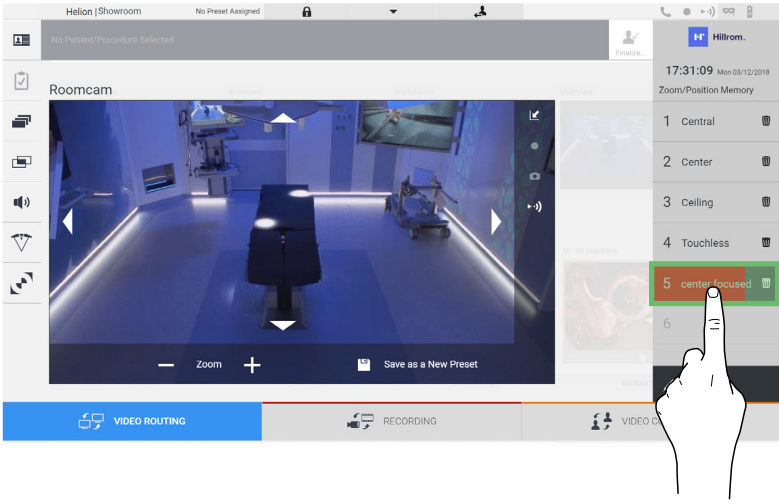
6.3.4.3 Save camera setting (Preset)

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

Step	Image
<p>1. After the video camera has been adjusted to the desired position, press .</p>	
<p>2. Enter the name to be assigned and press OK to confirm. The new Preset with the assigned name will appear on the list on the side.</p>	

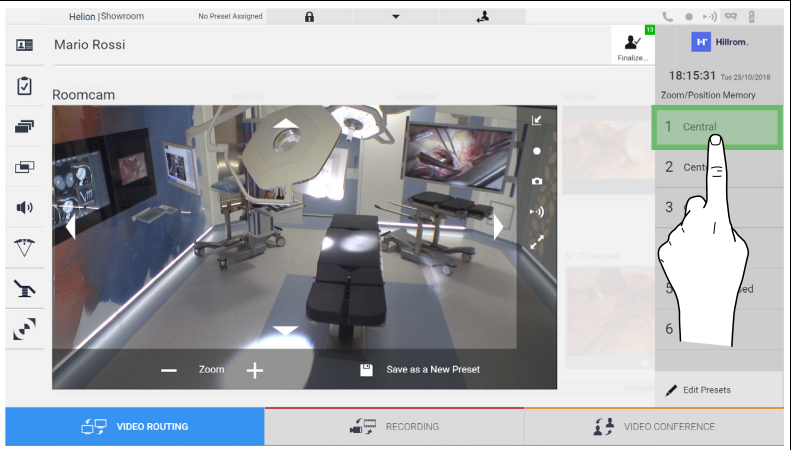
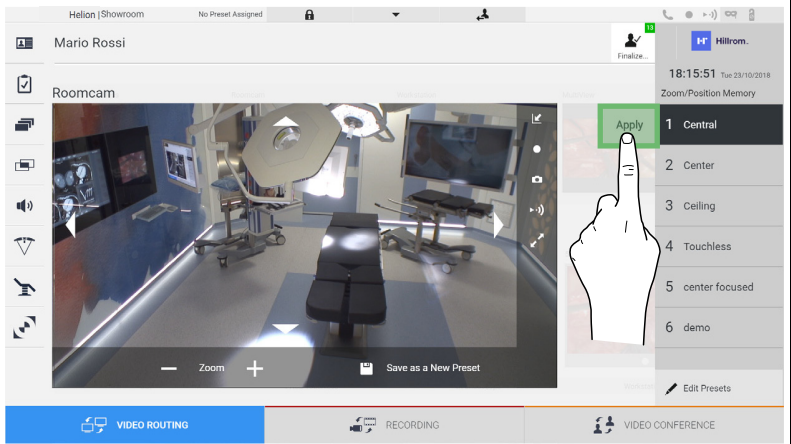
6.3.4.4 Delete camera setting (Preset)

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

Step	Image
<p>1. Press  .</p>	 <p>The screenshot shows the Helion (Showroom) interface. At the top, it displays 'Mario Rossi' and 'Roomcam'. A list of camera presets is visible on the right side, including '1 Central', '2 Center', '3 Ceiling', '4 Touchless', '5 center focused', and '6 demo'. The 'Edit Presets' button at the bottom right of the preset list is highlighted in green. A hand icon is shown pointing to this button.</p>
<p>2. Press and hold the  button until it is deleted.</p>	 <p>The screenshot shows the Helion (Showroom) interface. The '5 center focused' preset in the list is now highlighted in red, indicating it is being deleted. A hand icon is shown pointing to this preset.</p>

6.3.4.5 Enable camera setting (Preset)

To activate a video camera Preset, proceed as follows:

Step	Image
1. Press the desired Preset in the list.	 <p>The screenshot shows the Hillrom interface with a roomcam view of an operating room. On the right side, there is a list of camera presets. A hand icon is pointing to the first item, '1 Central', which is highlighted in green. The interface also shows a 'Zoom' control and a 'Save as a New Preset' button at the bottom of the roomcam view.</p>
2. Press Apply to confirm the Preset selection.	 <p>The screenshot shows the same interface as the previous step, but now the 'Apply' button is highlighted in green. A hand icon is pointing to the 'Apply' button. The preset list now shows '1 Central' as the selected preset.</p>

6.4 “Recording” function

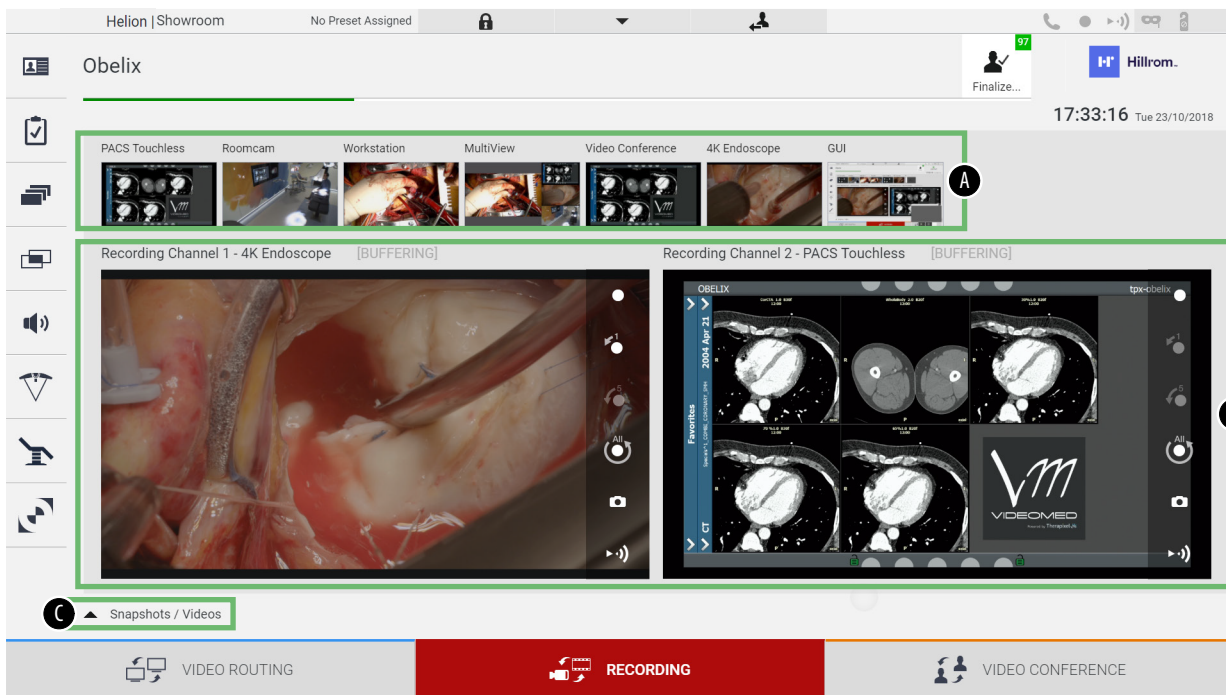
The Recording function makes it possible to capture snapshots and record video from the signals connected to the system.

It is therefore possible to save and then modify images and videos, stored on a 1TB on board support (can be optionally expanded up to 2TB). 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:

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

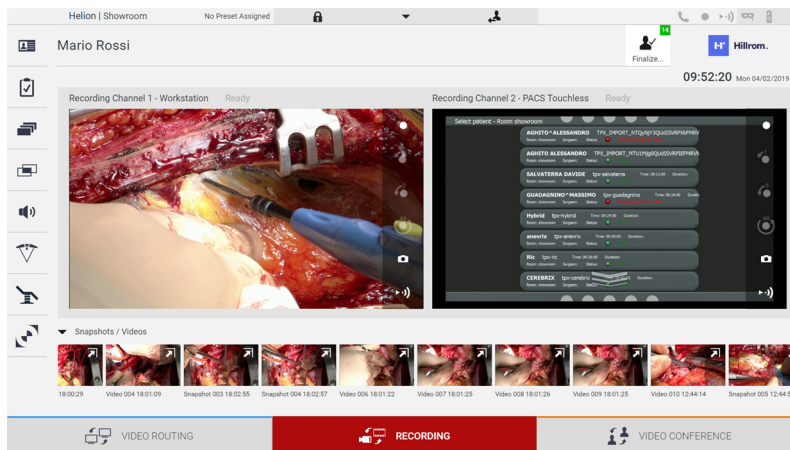
The main Recording screen is divided as follows:



- [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

▲ Snapshots / Videos . 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”.



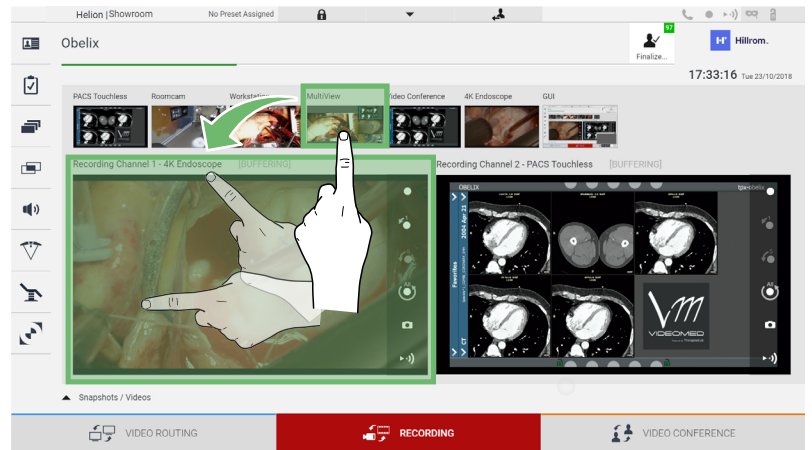
6.4.1 Image data post-processing

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.

6.4.2 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.






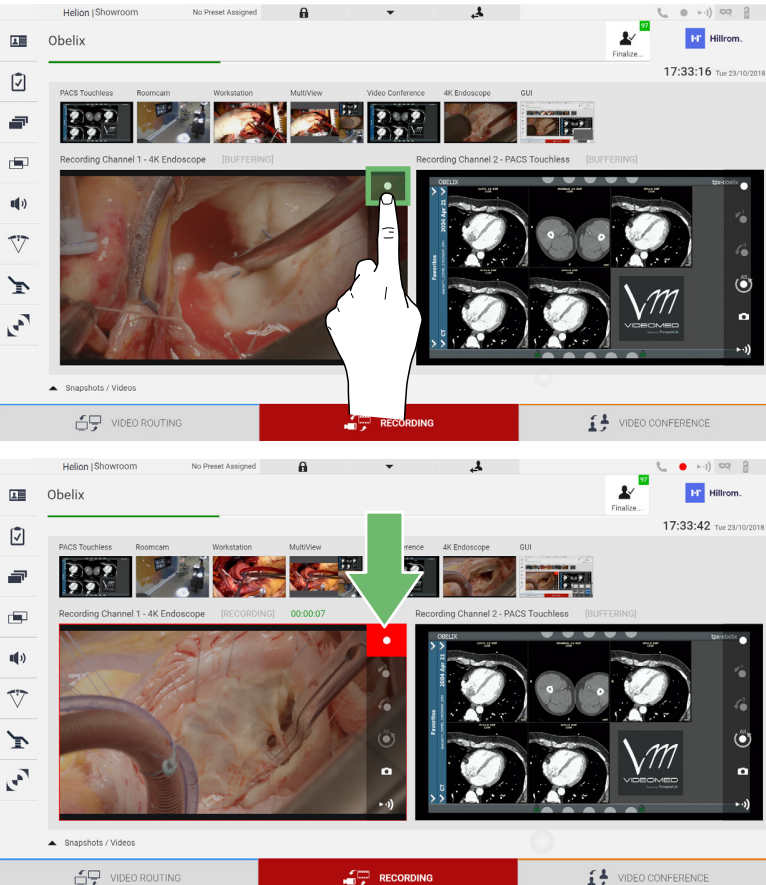
The following icons are available in the Recording Channel window:

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 stream.
	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 moment the signal was selected (up to a maximum of two 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.

6.4.3 Recording

To record from the Recording function, proceed as follows:


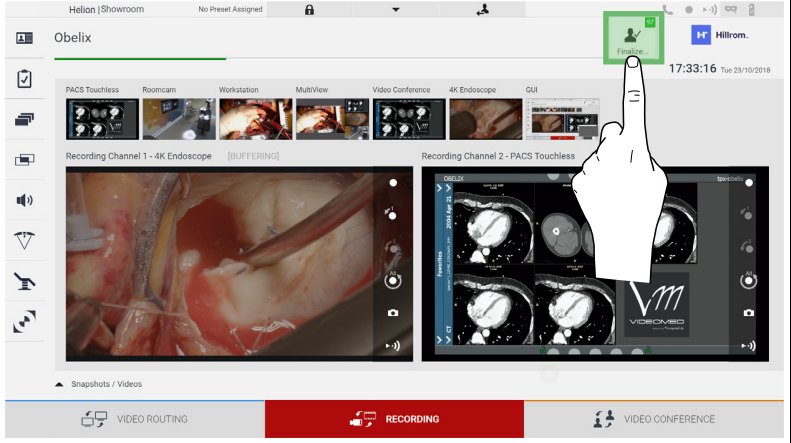

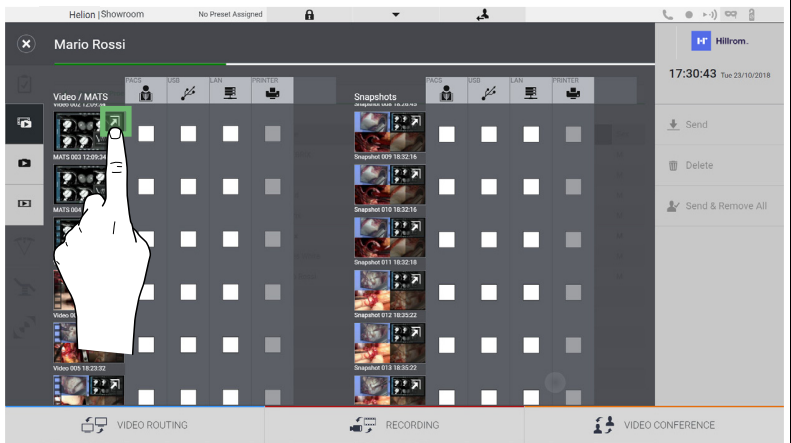














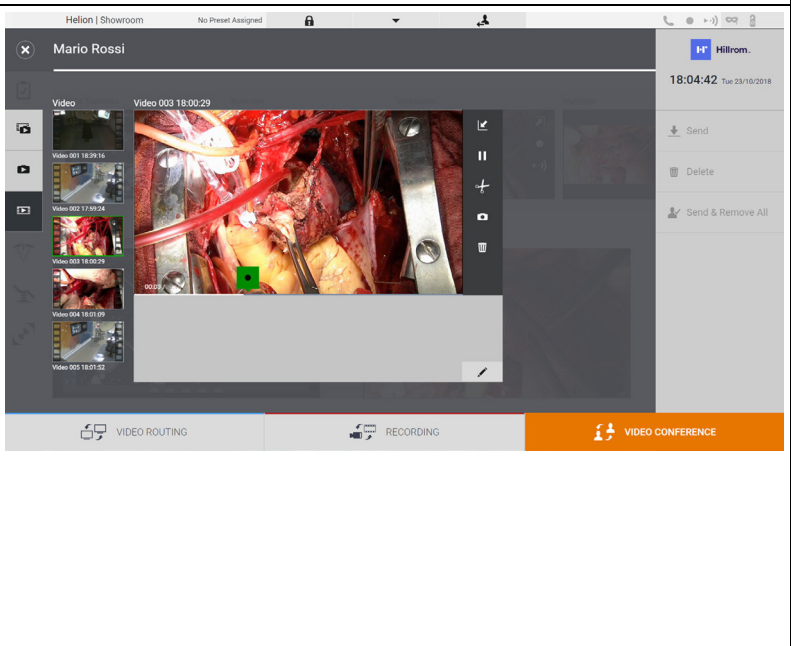







Step	Image
<p>1. Press the  icon of a Recording Channel to start recording a signal. When recording is in progress, the button is red  in the selected Recording Channel. The  icon is also present in the upper part of the screen and also remains visible when navigating through other functions (if recording is active).</p>	 <p>The image shows two screenshots of the Obelix user interface. The top screenshot shows the 'Recording Channel 1 - 4K Endoscope' button with a green circle around it and a hand icon pointing to it. The bottom screenshot shows the same button turned red with a red dot, and a green arrow pointing to it from above.</p>

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

Using the green 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.


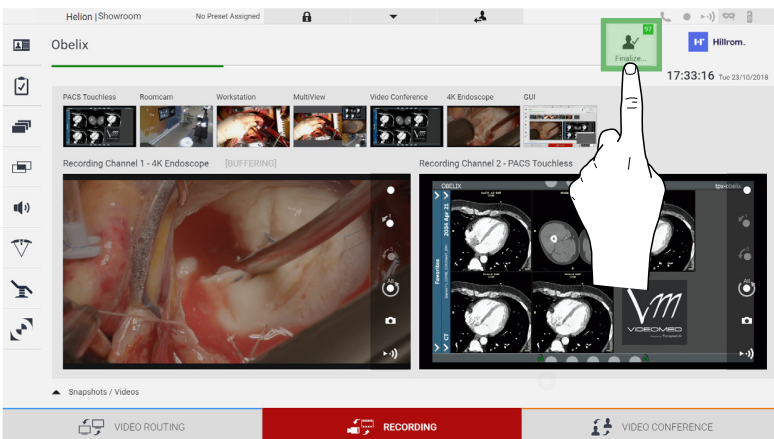

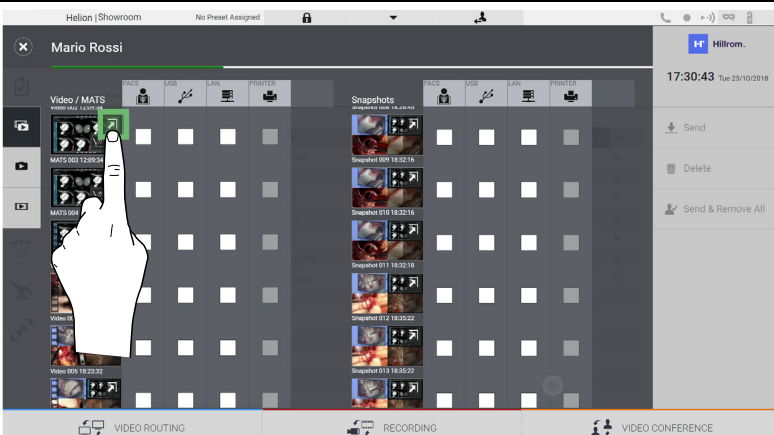

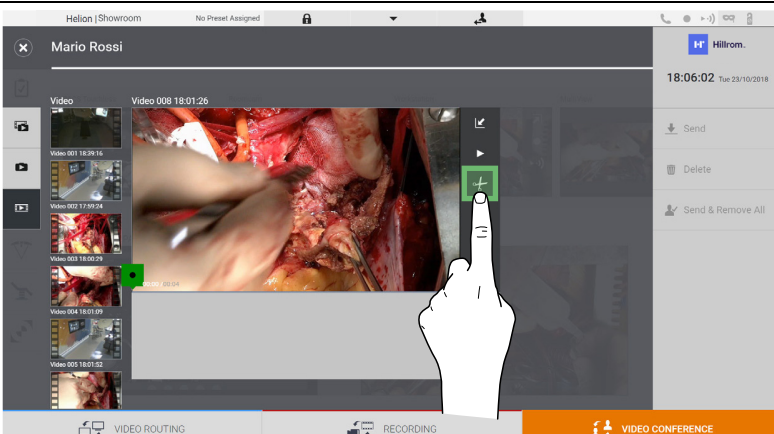
6.4.4 Snapshot and video playback

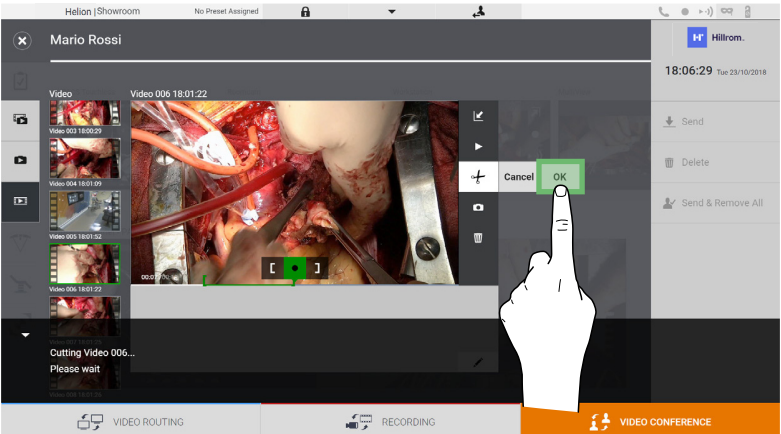
To play snapshots and videos, proceed as follows:

Step	Image																
<p>1. Press  to view all images and videos related to the selected patient.</p>																	
<p>2. Press the  icon to enlarge the individual media item.</p>																	
<p>3. A new window appears which, depending on the file selected (image or video), allows you to:</p> <table border="1" data-bbox="288 1384 683 1921"> <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.																


6.4.5 Cutting video

To cut videos, proceed as follows:

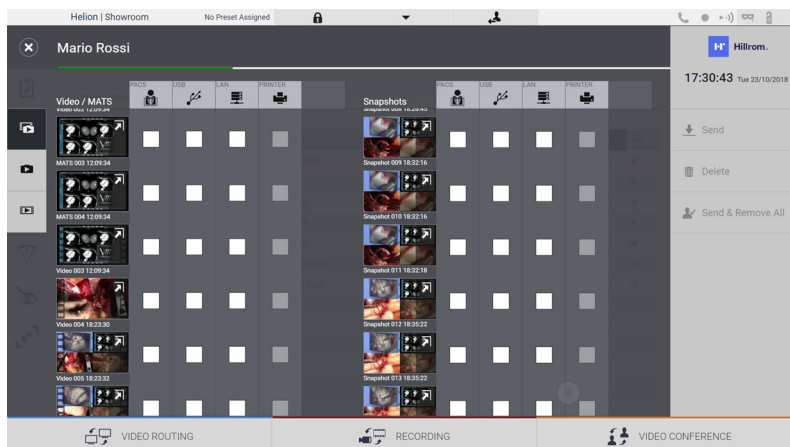
Step	Image
<p>1. Press  to view all images and videos related to the selected patient.</p>	
<p>2. Press the  icon to enlarge the single item.</p>	
<p>3. Press the  icon. A cursor appears on the progress bar. Press [to select the starting point of the video to be extracted and] for the end.</p>	

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>	




6.4.6 Export images and videos

Click on the  icon to access the folder for storing images and videos for the selected patient. This step must be performed to close the patient file and export the files.

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

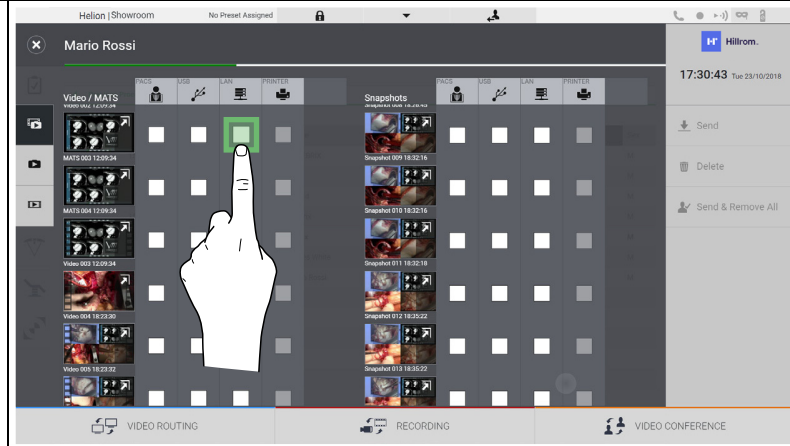


The following icons are available in the Export window:

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

The standard system configuration involves exporting to a device connected to the USB port.

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.	


Step	Image
<p>2. Press Send (on the right side of the screen) to send the files to the selected destinations.</p> <p>By pressing Send & Remove All, the files are sent to the selected destinations and the patient's session is deleted.</p>	

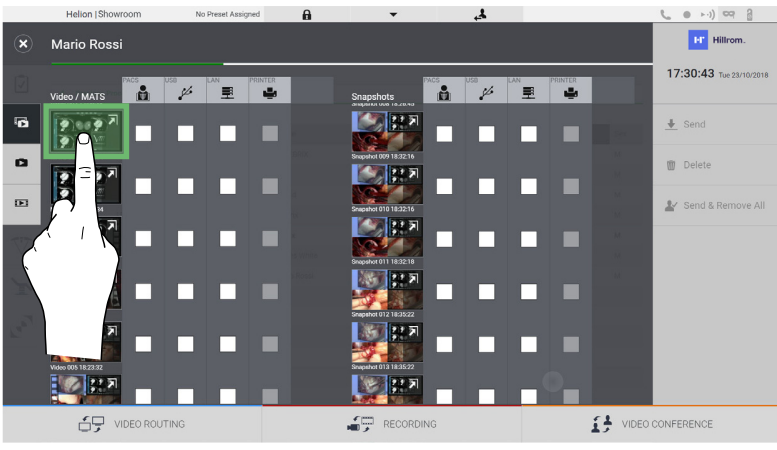

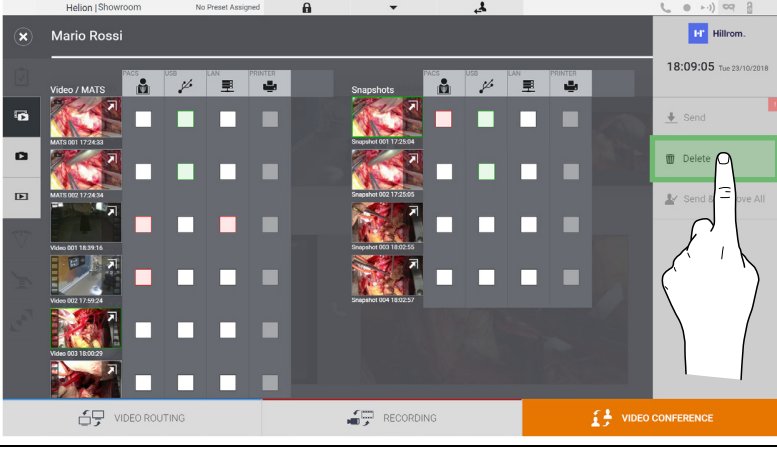

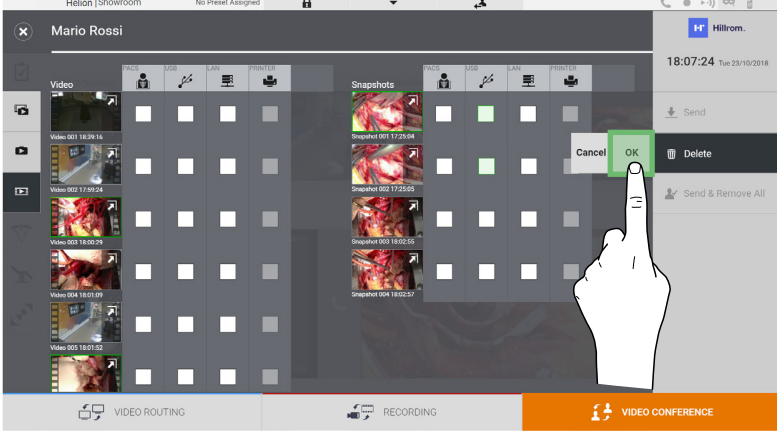
Activation of each of the export options shown above depends on settings that need to be authorised and guided by the hospital's IT managers.

If the export destination does not respond (e.g.: USB device is not present), the system displays an "EXPORT FAILED..." error message and the icon appears on the right side of the screen. The files the system failed to export are indicated with a red selection icon, as shown in the figure below.

Export failed
Check the Finalize section for details

6.4.7 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
<p>1. Select the videos or images you wish to delete by clicking directly on their thumbnails. The selected thumbnails will be outlined in green.</p>	
<p>2. Press  (on the right side of the screen) to delete the selected files.</p>	
<p>3. Press  to confirm deletion of the selected files.</p>	



6.5 “Video Conference” function

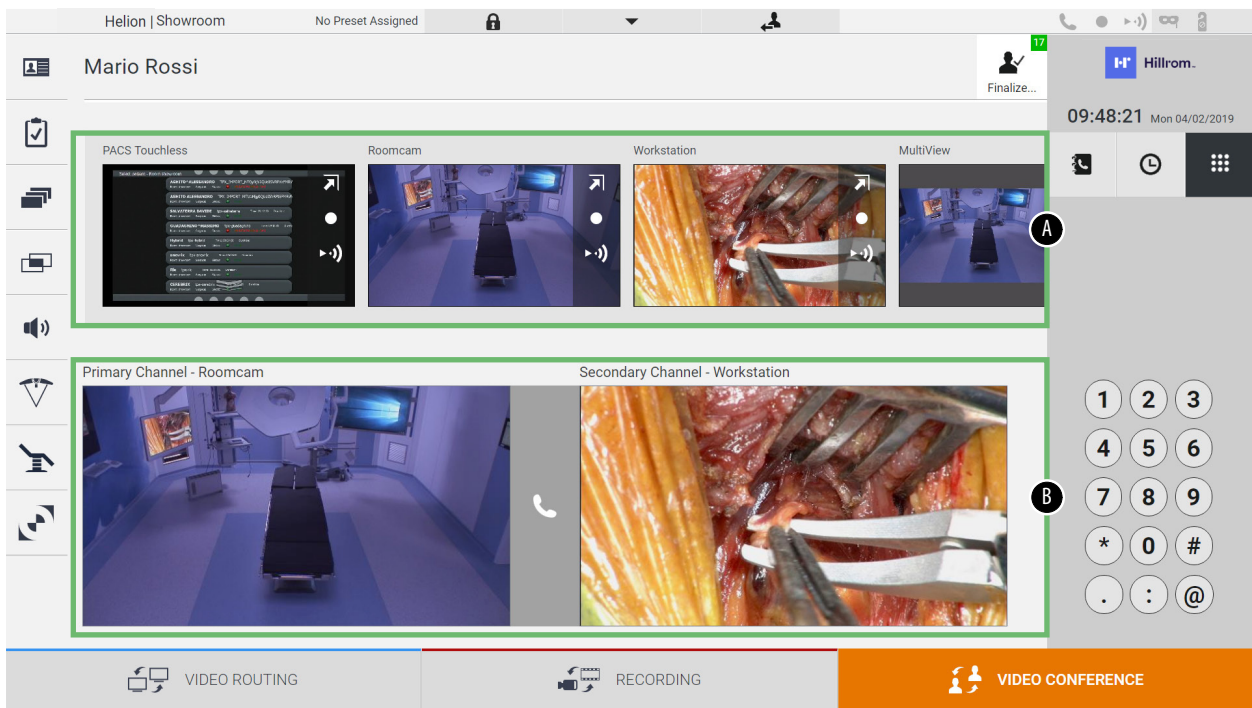
The Video Conference function allows video conferencing in a two-way audio and video connection from the operating theatre to external rooms:

- 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 change 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 .


6.5.1 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.

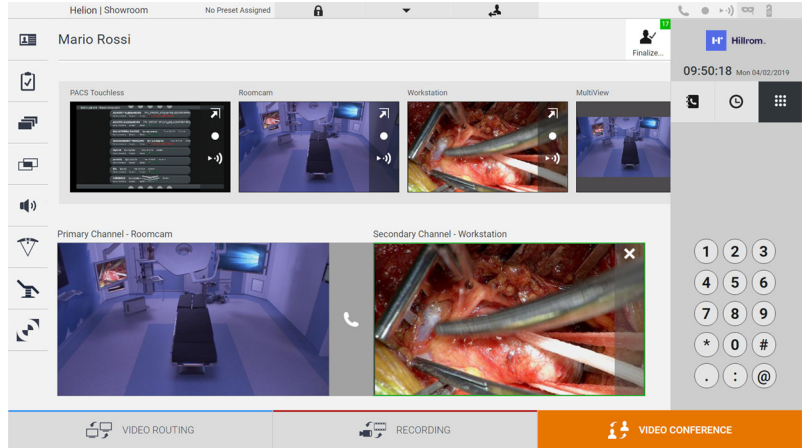







6.5.2 Removing the signals to be sent by video conference


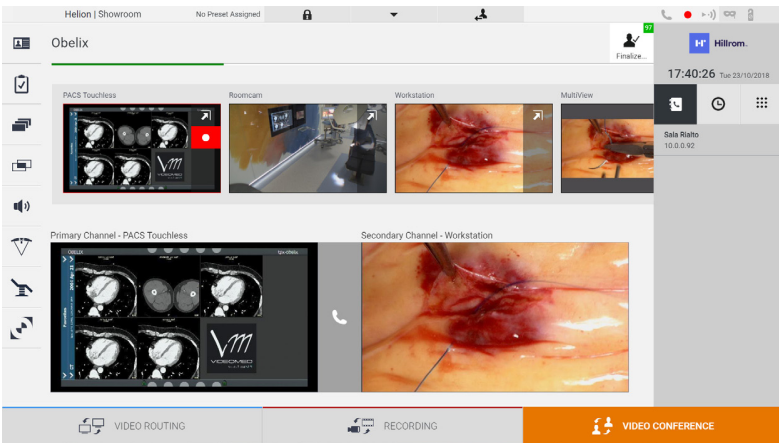

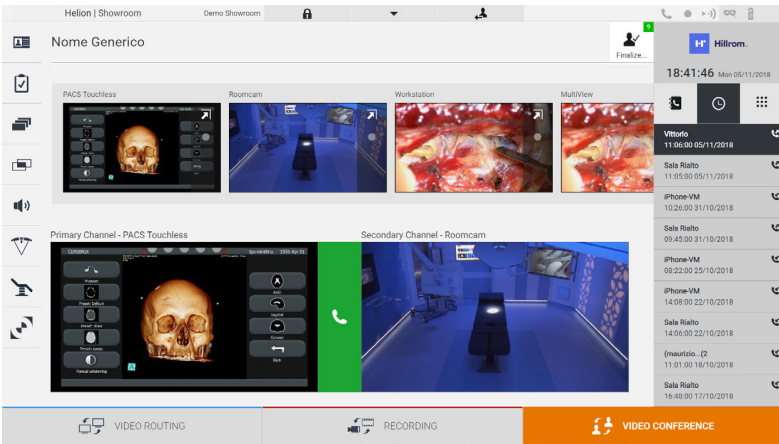

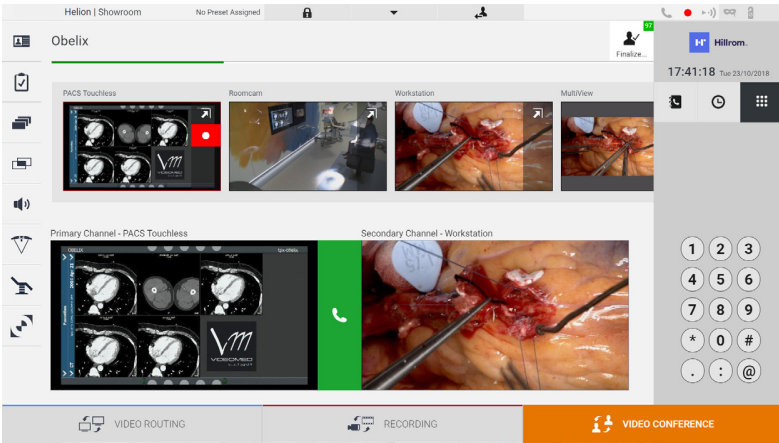
Press one of the boxes related to the primary and/or secondary video conference channel and then the icon  to be shown inside it to remove the video signal from the video conference.

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





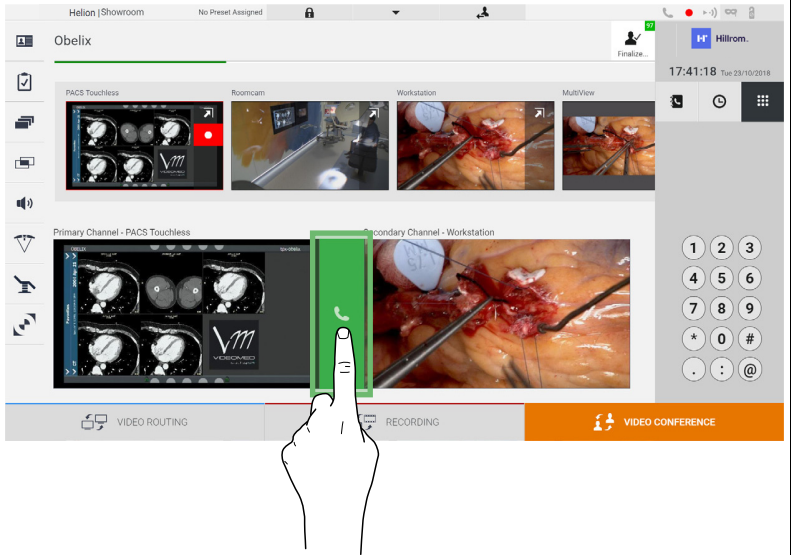
6.5.3 Call recipient selection

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

Icon	Description	Image
	<p>Enables selection of a name from the contact list.</p>	
	<p>Enables selection of a name/address from those indicated in the calls sent/received log.</p>	
	<p>Enables manual entry of the recipient's IP address using the numeric keypad.</p>	








6.5.4 Call start

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


Step	Image
<p>1. Press the green call button . The call button turns red  to indicate the option to end the call.</p>	 <p>The screenshot shows a video conference interface with multiple video feeds. A hand is pointing to a green call button in the center of the screen. The interface includes a top bar with 'Hillrom' and 'Obelix', a left sidebar with various icons, and a bottom bar with 'VIDEO ROUTING', 'RECORDING', and 'VIDEO CONFERENCE' buttons.</p>

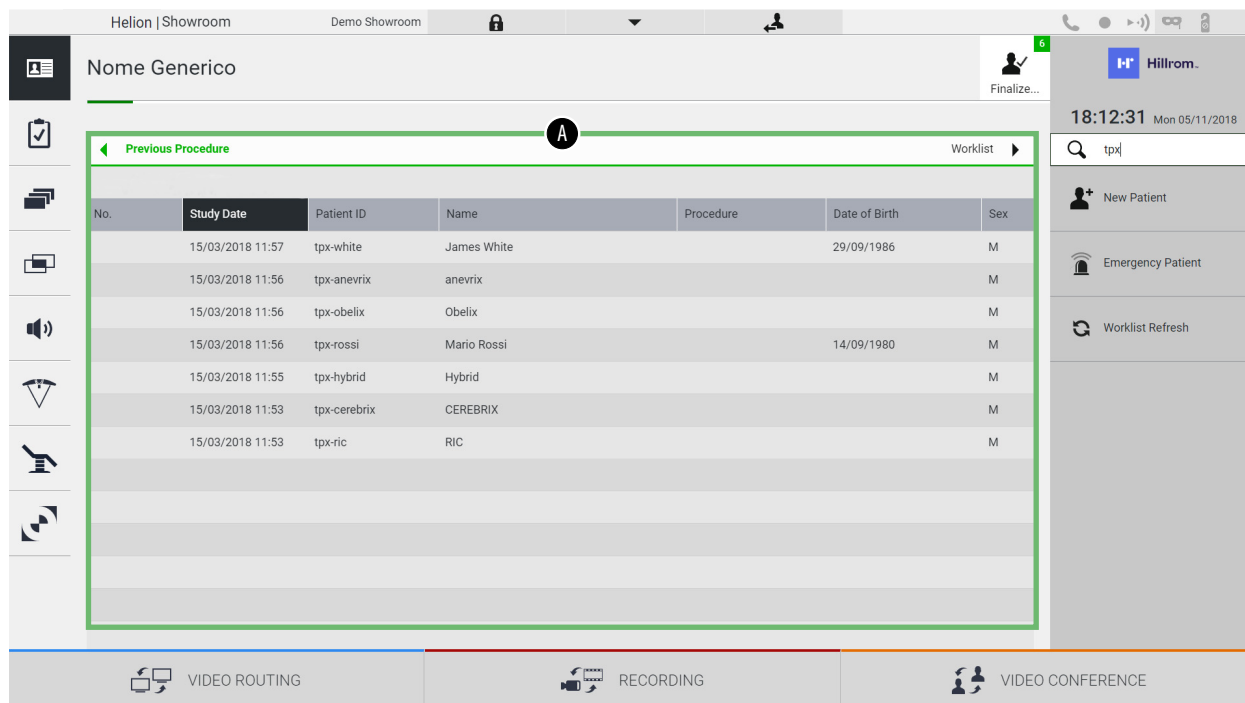
6.6 Additional functions

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 Trumpf Medical 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.

6.6.1 Patient data management

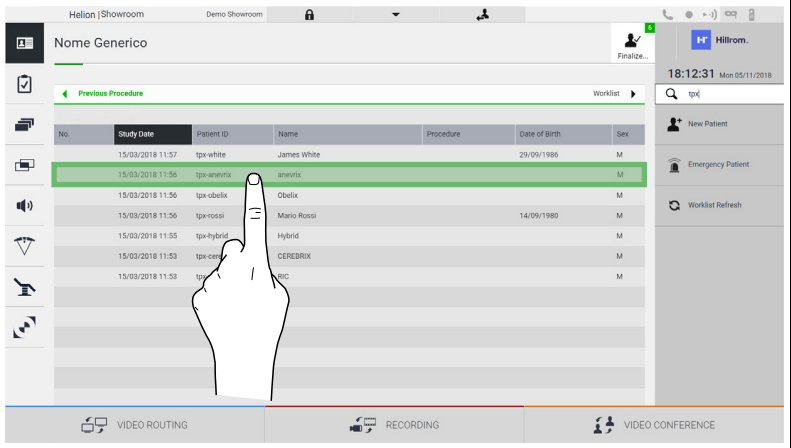

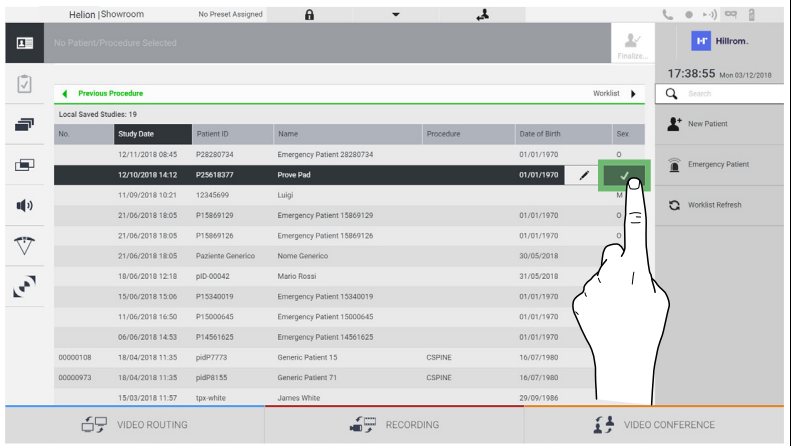
Press the  icon on the side menu to access patient data management.



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.


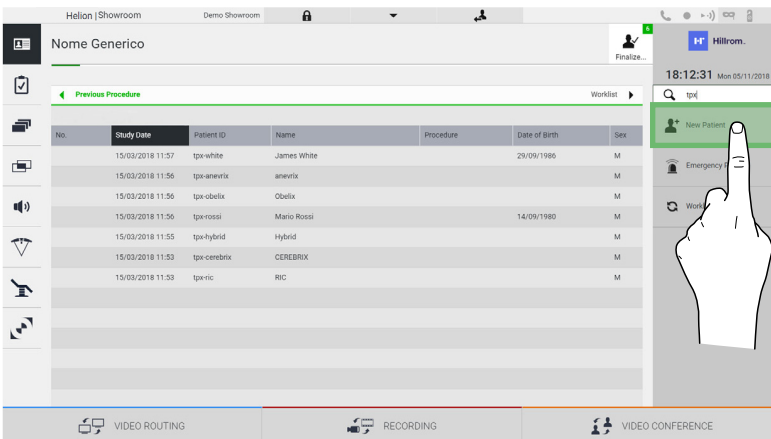
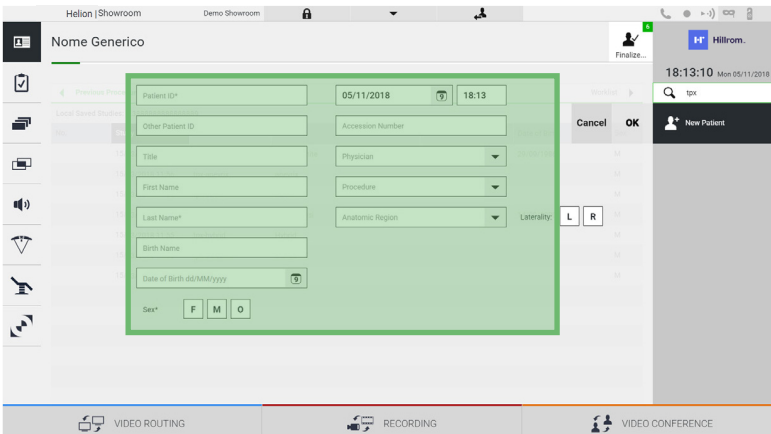
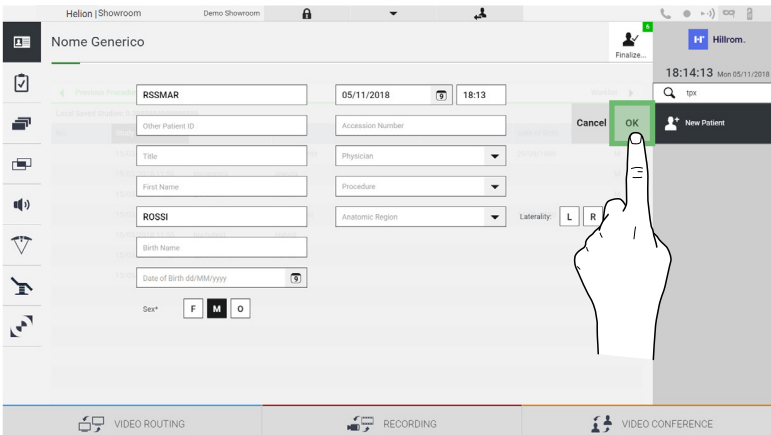
6.6.1.1 Selecting a patient in the list

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

Step	Image																																																																																																		
<p>1. Select the patient.</p>	 <p>The screenshot shows a software interface with a patient list. The list has columns for No., Study Date, Patient ID, Name, Procedure, Date of Birth, and Sex. The row for 'amevix' is highlighted in green, and a hand icon points to it.</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Study Date</th> <th>Patient ID</th> <th>Name</th> <th>Procedure</th> <th>Date of Birth</th> <th>Sex</th> </tr> </thead> <tbody> <tr> <td></td> <td>15/03/2018 11:57</td> <td>tpx-white</td> <td>James White</td> <td></td> <td>29/09/1986</td> <td>M</td> </tr> <tr style="background-color: #e0ffe0;"> <td></td> <td>15/03/2018 11:56</td> <td>tpx-amevix</td> <td>amevix</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-obelix</td> <td>Obelix</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-rossi</td> <td>Mario Rossi</td> <td></td> <td>14/09/1980</td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:55</td> <td>tpx-hybrid</td> <td>Hybrid</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:53</td> <td>tpx-cerebrix</td> <td>CEREbRIX</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:53</td> <td>tpx-cerebrix</td> <td>CEREbRIX</td> <td></td> <td></td> <td>M</td> </tr> </tbody> </table>	No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex		15/03/2018 11:57	tpx-white	James White		29/09/1986	M		15/03/2018 11:56	tpx-amevix	amevix			M		15/03/2018 11:56	tpx-obelix	Obelix			M		15/03/2018 11:56	tpx-rossi	Mario Rossi		14/09/1980	M		15/03/2018 11:55	tpx-hybrid	Hybrid			M		15/03/2018 11:53	tpx-cerebrix	CEREbRIX			M		15/03/2018 11:53	tpx-cerebrix	CEREbRIX			M																																										
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<p>2. Press  to confirm the selection.</p>	 <p>The screenshot shows the same software interface, but now the 'amevix' row is highlighted in black, and a checkmark icon is visible in the rightmost column of that row. A hand icon points to the checkmark.</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Study Date</th> <th>Patient ID</th> <th>Name</th> <th>Procedure</th> <th>Date of Birth</th> <th>Sex</th> </tr> </thead> <tbody> <tr> <td></td> <td>12/11/2018 08:45</td> <td>P28280734</td> <td>Emergency Patient 28280734</td> <td></td> <td>01/01/1970</td> <td>G</td> </tr> <tr style="background-color: #333; color: white;"> <td></td> <td>12/10/2018 14:12</td> <td>P25618377</td> <td>Prove Pad</td> <td></td> <td>01/01/1970</td> <td>M</td> </tr> <tr> <td></td> <td>11/09/2018 10:21</td> <td>12345699</td> <td>Luigi</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>21/06/2018 18:05</td> <td>P15869129</td> <td>Emergency Patient 15869129</td> <td></td> <td>01/01/1970</td> <td>G</td> </tr> <tr> <td></td> <td>21/06/2018 18:05</td> <td>P15869126</td> <td>Emergency Patient 15869126</td> <td></td> <td>01/01/1970</td> <td>G</td> </tr> <tr> <td></td> <td>21/06/2018 18:05</td> <td>Paziente Generico</td> <td>Nome Generico</td> <td></td> <td>30/05/2018</td> <td></td> </tr> <tr> <td></td> <td>18/06/2018 12:18</td> <td>pid-00042</td> <td>Mario Rossi</td> <td></td> <td>31/05/2018</td> <td></td> </tr> <tr> <td></td> <td>15/06/2018 13:06</td> <td>P13340019</td> <td>Emergency Patient 13340019</td> <td></td> <td>01/01/1970</td> <td>G</td> </tr> <tr> <td></td> <td>11/06/2018 16:50</td> <td>P15000645</td> <td>Emergency Patient 15000645</td> <td></td> <td>01/01/1970</td> <td>G</td> </tr> <tr> <td></td> <td>06/06/2018 14:53</td> <td>P14561625</td> <td>Emergency Patient 14561625</td> <td></td> <td>01/01/1970</td> <td>G</td> </tr> <tr> <td>00000108</td> <td>18/04/2018 11:35</td> <td>pidP7773</td> <td>Generic Patient 15</td> <td>CSPINE</td> <td>16/07/1980</td> <td></td> </tr> <tr> <td>00000973</td> <td>16/04/2018 11:35</td> <td>pidP8155</td> <td>Generic Patient 71</td> <td>CSPINE</td> <td>16/07/1980</td> <td></td> </tr> <tr> <td></td> <td>15/03/2018 11:57</td> <td>tpx-white</td> <td>James White</td> <td></td> <td>29/09/1986</td> <td>M</td> </tr> </tbody> </table>	No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex		12/11/2018 08:45	P28280734	Emergency Patient 28280734		01/01/1970	G		12/10/2018 14:12	P25618377	Prove Pad		01/01/1970	M		11/09/2018 10:21	12345699	Luigi			M		21/06/2018 18:05	P15869129	Emergency Patient 15869129		01/01/1970	G		21/06/2018 18:05	P15869126	Emergency Patient 15869126		01/01/1970	G		21/06/2018 18:05	Paziente Generico	Nome Generico		30/05/2018			18/06/2018 12:18	pid-00042	Mario Rossi		31/05/2018			15/06/2018 13:06	P13340019	Emergency Patient 13340019		01/01/1970	G		11/06/2018 16:50	P15000645	Emergency Patient 15000645		01/01/1970	G		06/06/2018 14:53	P14561625	Emergency Patient 14561625		01/01/1970	G	00000108	18/04/2018 11:35	pidP7773	Generic Patient 15	CSPINE	16/07/1980		00000973	16/04/2018 11:35	pidP8155	Generic Patient 71	CSPINE	16/07/1980			15/03/2018 11:57	tpx-white	James White		29/09/1986	M
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6.6.1.2 Entering a new patient

To enter a new patient, proceed as follows:


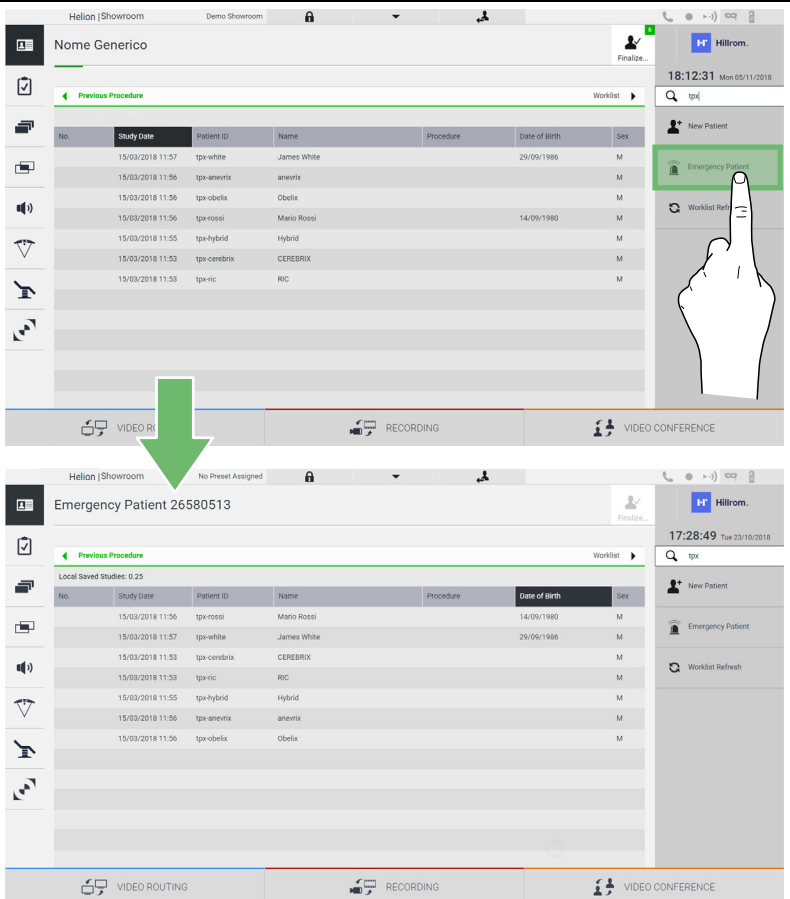
Step	Image
<p>1. Select the  New Patient icon on the right of the screen. The patient data entry window is displayed.</p>	
<p>2. Enter the data for the new patient. Fields marked with a * are mandatory.</p>	
<p>3. Once the mandatory data have been entered, the new patient can be saved by pressing OK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

6.6.1.3 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
<p>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>	 <p>The image contains two screenshots of the Hillrom software interface. The top screenshot shows the 'Nome Generico' (Generic Name) screen. It features a table with columns for 'No.', 'Study Date', 'Patient ID', 'Name', 'Procedure', 'Date of Birth', and 'Sex'. The table lists several patients, including James White, Obelix, Mario Rossi, Hybrid, CEREBRIX, and RIC. On the right side of the screen, there is a sidebar with buttons for 'New Patient', 'Emergency Patient', and 'Worklist Refresh'. A green arrow points to the 'Emergency Patient' button. The bottom screenshot shows the 'Emergency Patient 26580513' screen, which has a similar layout but with a new patient entry at the top of the table.</p>

6.6.1.4 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.	<table border="1"> <thead> <tr> <th>No.</th> <th>Study Date</th> <th>Patient ID</th> <th>Name</th> <th>Procedure</th> <th>Date of Birth</th> <th>Sex</th> </tr> </thead> <tbody> <tr> <td></td> <td>15/03/2018 11:57</td> <td>tpx-white</td> <td>James White</td> <td></td> <td>29/09/1986</td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-anevrix</td> <td>anevrix</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-obelix</td> <td>Obelix</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-rossi</td> <td>Mario Rossi</td> <td></td> <td>14/09/1980</td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:55</td> <td>tpx-hybrid</td> <td>Hybrid</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:53</td> <td>tpx-cerebrix</td> <td>CEREBRIX</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:53</td> <td>tpx-ric</td> <td>RIC</td> <td></td> <td></td> <td>M</td> </tr> </tbody> </table>	No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex		15/03/2018 11:57	tpx-white	James White		29/09/1986	M		15/03/2018 11:56	tpx-anevrix	anevrix			M		15/03/2018 11:56	tpx-obelix	Obelix			M		15/03/2018 11:56	tpx-rossi	Mario Rossi		14/09/1980	M		15/03/2018 11:55	tpx-hybrid	Hybrid			M		15/03/2018 11:53	tpx-cerebrix	CEREBRIX			M		15/03/2018 11:53	tpx-ric	RIC			M
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6.6.1.5 Patient master data modification


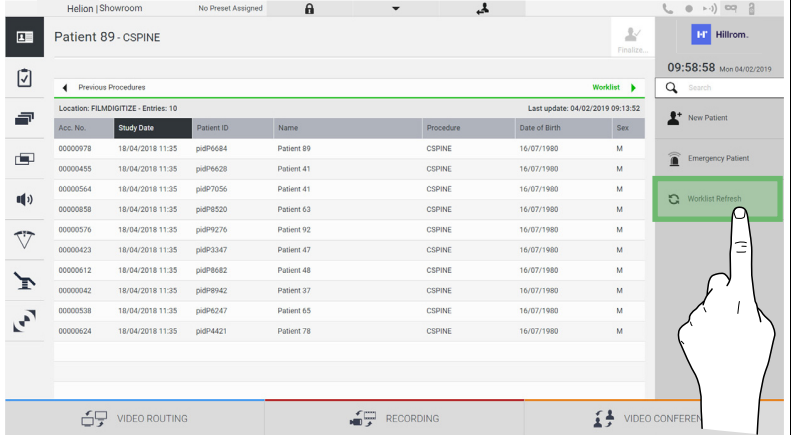
To modify a patient’s master data, proceed as follows:

Step	Image																																																																																																																
1. Search for and select the desired patient.	<table border="1"> <thead> <tr> <th>No.</th> <th>Study Date</th> <th>Patient ID</th> <th>Name</th> <th>Procedure</th> <th>Date of Birth</th> <th>Sex</th> </tr> </thead> <tbody> <tr> <td></td> <td>15/03/2018 11:57</td> <td>tpx-white</td> <td>James White</td> <td></td> <td>29/09/1986</td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-anevrix</td> <td>anevrix</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-obelix</td> <td>Obelix</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:56</td> <td>tpx-rossi</td> <td>Mario Rossi</td> <td></td> <td>14/09/1980</td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:55</td> <td>tpx-hybrid</td> <td>Hybrid</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:53</td> <td>tpx-cerebrix</td> <td>CEREBRIX</td> <td></td> <td></td> <td>M</td> </tr> <tr> <td></td> <td>15/03/2018 11:53</td> <td>tpx-ric</td> <td>RIC</td> <td></td> <td></td> <td>M</td> </tr> </tbody> </table>	No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex		15/03/2018 11:57	tpx-white	James White		29/09/1986	M		15/03/2018 11:56	tpx-anevrix	anevrix			M		15/03/2018 11:56	tpx-obelix	Obelix			M		15/03/2018 11:56	tpx-rossi	Mario Rossi		14/09/1980	M		15/03/2018 11:55	tpx-hybrid	Hybrid			M		15/03/2018 11:53	tpx-cerebrix	CEREBRIX			M		15/03/2018 11:53	tpx-ric	RIC			M																																																								
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6.6.1.6 Accessing the worklist

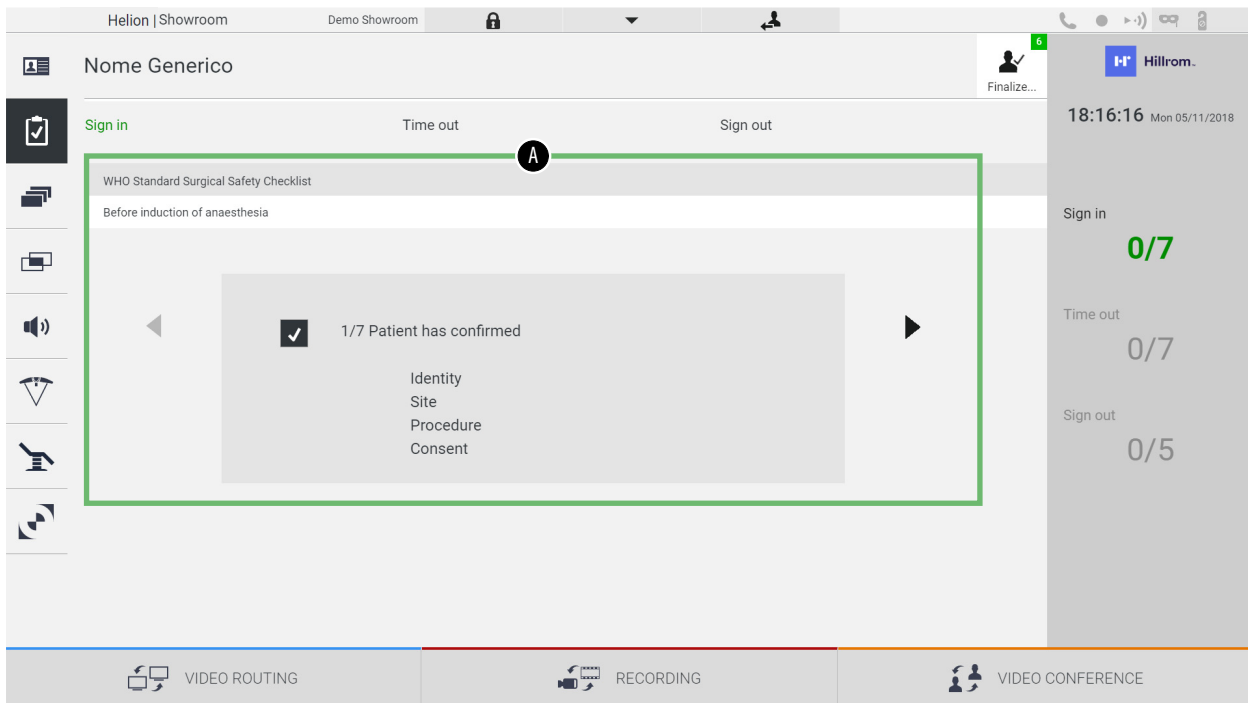
If the Helion Video Management System is configured to communicate with the centralised master data management system, the patient list for the date/room/surgeon can be called up using the  **Worklist Refresh** button.


To access the worklist, proceed as follows:

Step	Image																																																																													
<ol style="list-style-type: none"> Press the  Worklist Refresh button. Wait for the names suiting the criteria selected to appear in the list. 	 <p>The screenshot shows the Helion interface for 'Patient 89 - CSPINE'. The main area displays a table of previous procedures with columns for Acc. No., Study Date, Patient ID, Name, Procedure, Date of Birth, and Sex. The table contains 10 rows of data. On the right-hand sidebar, there are several buttons: 'New Patient', 'Emergency Patient', and 'Worklist Refresh'. A hand icon is pointing to the 'Worklist Refresh' button, which is highlighted in green.</p> <table border="1"> <thead> <tr> <th>Acc. No.</th> <th>Study Date</th> <th>Patient ID</th> <th>Name</th> <th>Procedure</th> <th>Date of Birth</th> <th>Sex</th> </tr> </thead> <tbody> <tr> <td>00000978</td> <td>18/04/2018 11:35</td> <td>pidP664</td> <td>Patient 89</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000455</td> <td>18/04/2018 11:35</td> <td>pidP628</td> <td>Patient 41</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000564</td> <td>18/04/2018 11:35</td> <td>pidP7056</td> <td>Patient 41</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000858</td> <td>18/04/2018 11:35</td> <td>pidP8520</td> <td>Patient 63</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000576</td> <td>18/04/2018 11:35</td> <td>pidP9276</td> <td>Patient 92</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000423</td> <td>18/04/2018 11:35</td> <td>pidP3347</td> <td>Patient 47</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000612</td> <td>18/04/2018 11:35</td> <td>pidP8682</td> <td>Patient 48</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000342</td> <td>18/04/2018 11:35</td> <td>pidP8942</td> <td>Patient 37</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000538</td> <td>18/04/2018 11:35</td> <td>pidP6247</td> <td>Patient 65</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> <tr> <td>00000624</td> <td>18/04/2018 11:35</td> <td>pidP4421</td> <td>Patient 78</td> <td>CSPINE</td> <td>16/07/1980</td> <td>M</td> </tr> </tbody> </table>	Acc. No.	Study Date	Patient ID	Name	Procedure	Date of Birth	Sex	00000978	18/04/2018 11:35	pidP664	Patient 89	CSPINE	16/07/1980	M	00000455	18/04/2018 11:35	pidP628	Patient 41	CSPINE	16/07/1980	M	00000564	18/04/2018 11:35	pidP7056	Patient 41	CSPINE	16/07/1980	M	00000858	18/04/2018 11:35	pidP8520	Patient 63	CSPINE	16/07/1980	M	00000576	18/04/2018 11:35	pidP9276	Patient 92	CSPINE	16/07/1980	M	00000423	18/04/2018 11:35	pidP3347	Patient 47	CSPINE	16/07/1980	M	00000612	18/04/2018 11:35	pidP8682	Patient 48	CSPINE	16/07/1980	M	00000342	18/04/2018 11:35	pidP8942	Patient 37	CSPINE	16/07/1980	M	00000538	18/04/2018 11:35	pidP6247	Patient 65	CSPINE	16/07/1980	M	00000624	18/04/2018 11:35	pidP4421	Patient 78	CSPINE	16/07/1980	M
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6.6.2 Check-List

In the side menu, press the  icon to access the Check-List screens. The Check-List is only activated after a patient has been selected.




In section [A], it is possible to manage the surgical procedure by following a sequence of questions and instructions, as defined by the World Health Organisation as default, regarding each stage of the surgical procedure. Press the  icon to scroll through the questions.

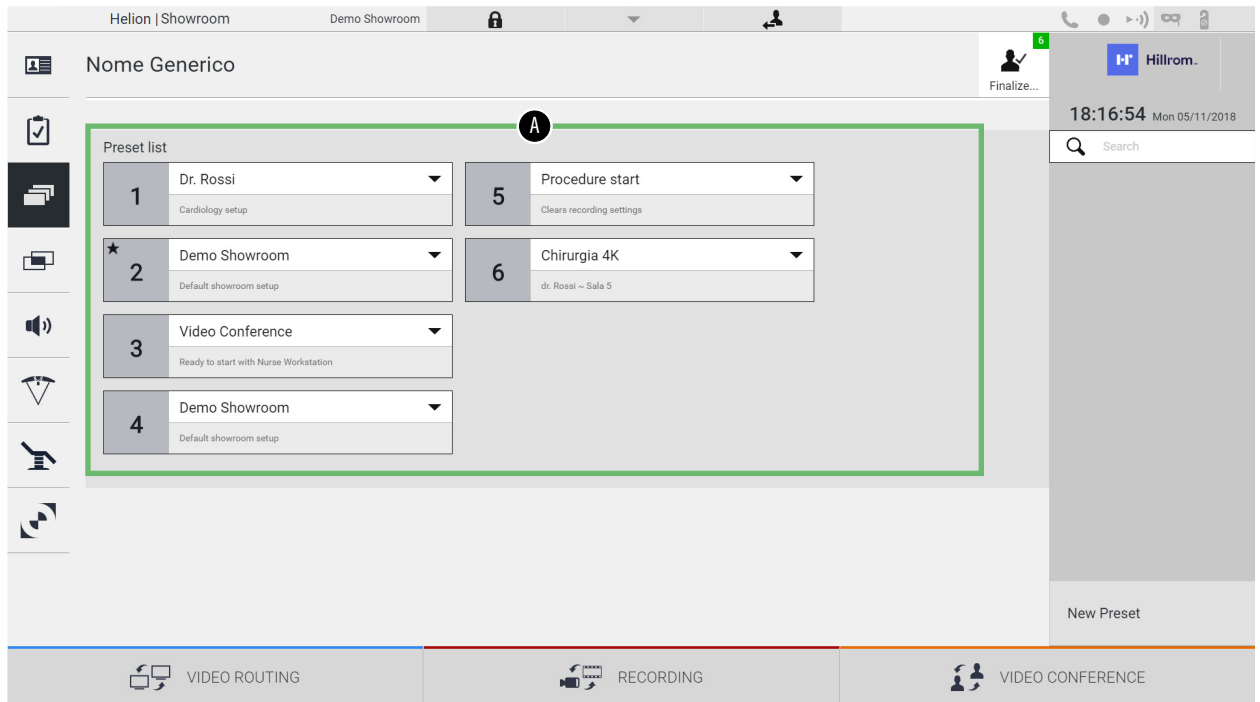
The instructions relate to the entire procedure. It will thus be possible to leave this section and return to it to check the instructions relating to the current state of the surgical activity. It will always be possible to view the entry status of the Check-List via the progress bar in the Patient Info section.

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

6.6.3 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.

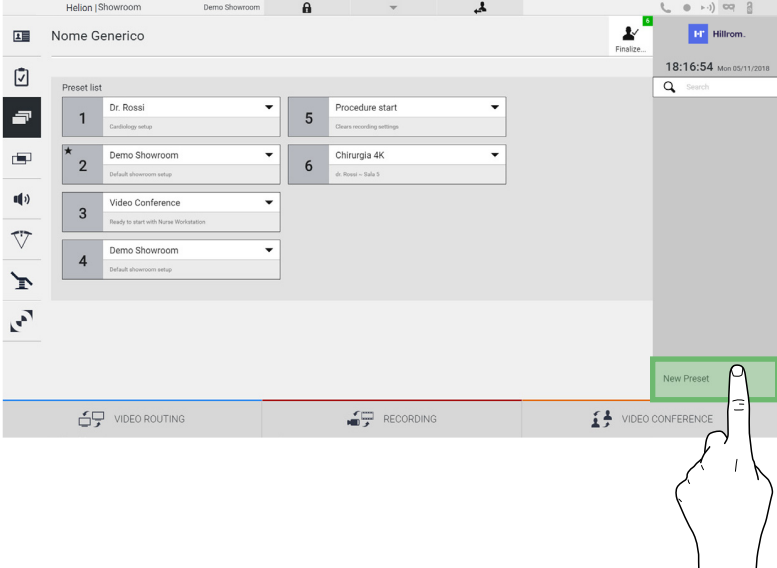
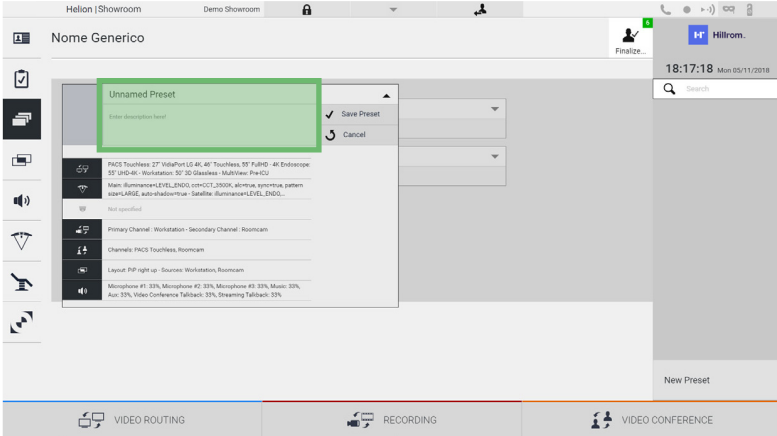
The main screen is divided as follows:



[A] Preset List

6.6.3.1 Preset setting

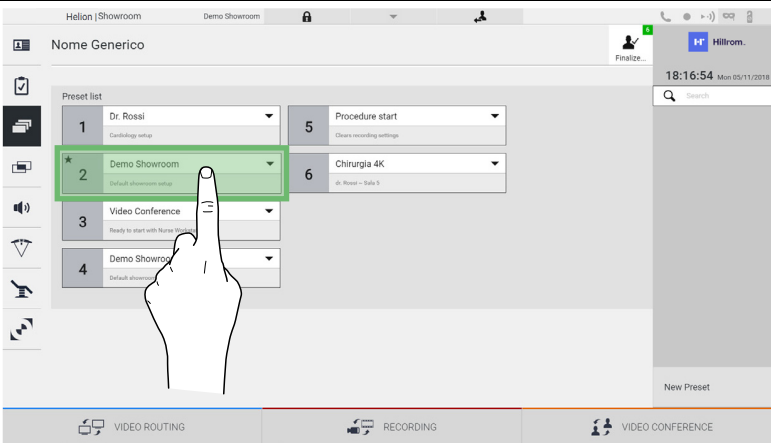
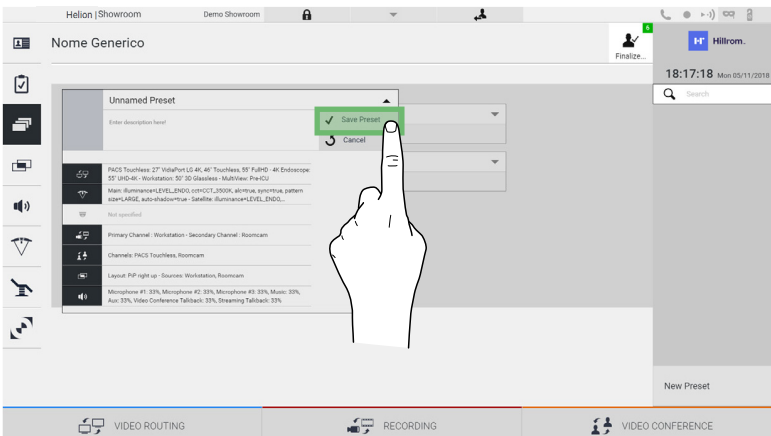
To set a new Preset, proceed as follows:

Step	Image
<p>1. Set the desired room layout (Routing Video, Recording Channel, Conference Channel, Setting Audio, Operating Light Setting).</p>	
<p>2. Press the New Preset button. The configuration window opens.</p>	 <p>The screenshot shows the Helion (Showroom) interface. At the top, there's a header with 'Helion (Showroom)' and 'Demo Showroom'. Below that, a 'Nome Generico' section contains a 'Preset list' with six items: 1. Dr. Rossi, 2. Demo Showroom, 3. Video Conference, 4. Demo Showroom, 5. Procedure start, and 6. Chirurgia 4K. At the bottom right, a 'New Preset' button is highlighted with a green box, and a hand icon is pointing to it.</p>
<p>3. Enter the name to be assigned to the new Preset and add a description in the appropriate field below (optional).</p>	 <p>The screenshot shows the Helion (Showroom) interface with the 'New Preset' configuration window open. The window has a title bar 'Unnamed Preset' and a text input field for 'Enter description here!'. Below the input field, there are several sections: 'Preset list' (with 'Procedure start' and 'Chirurgia 4K'), 'Channels' (listing 'FAC2 Touchless 27', 'Main IlluminanceLEVEL_ENDO', etc.), 'Primary Channel' (Workstation - Secondary Channel - Roomcam), 'Channels' (FACS Touchless, Roomcam), 'Layout' (PIP right up - Source: Workstation, Roomcam), and 'Microphone' (listing 'Microphone #1: 33%', 'Microphone #2: 33%', 'Microphone #3: 33%', 'Music: 33%', 'Aux: 33%', 'Video Conference Talkback: 33%', 'Streaming Talkback: 33%'). At the bottom right, a 'New Preset' button is visible. The 'Unnamed Preset' field is highlighted with a green box.</p>

Step	Image
<p>4. Select / deselect the settings to be included in the configuration by pressing the relevant icons among those listed.</p>	
<p>5. Press <input checked="" type="checkbox"/> Save Preset to confirm.</p>	


6.6.3.2 Enabling Preset

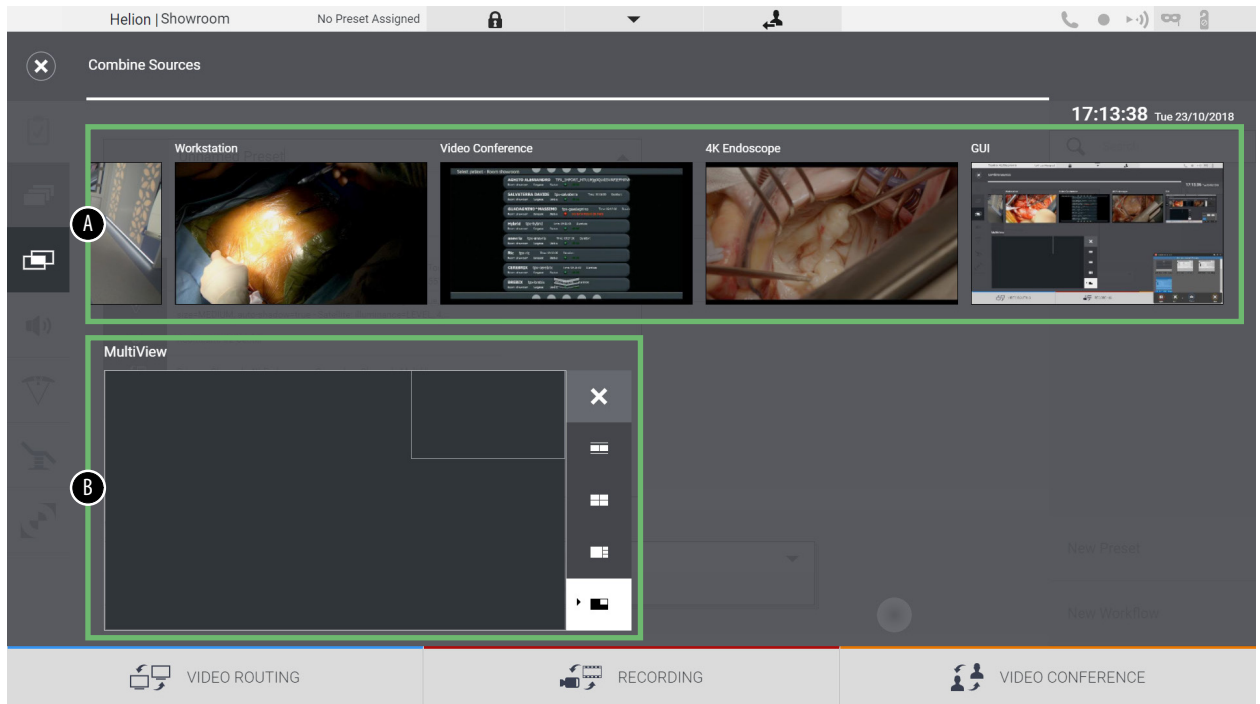
To activate a Preset in the list, proceed as follows:

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

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

6.6.4 Multiview









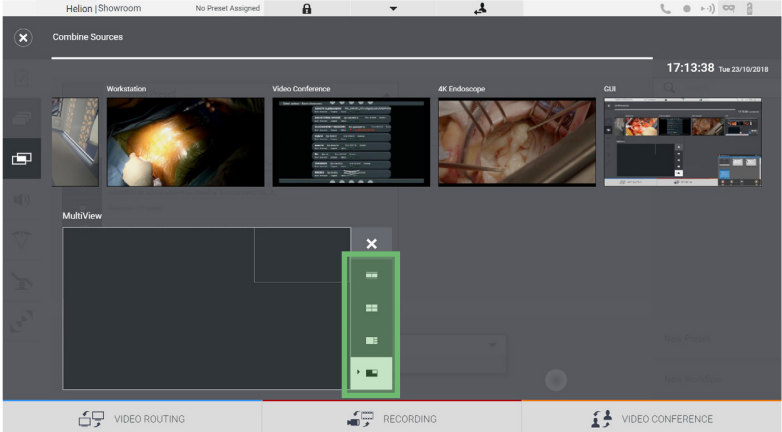





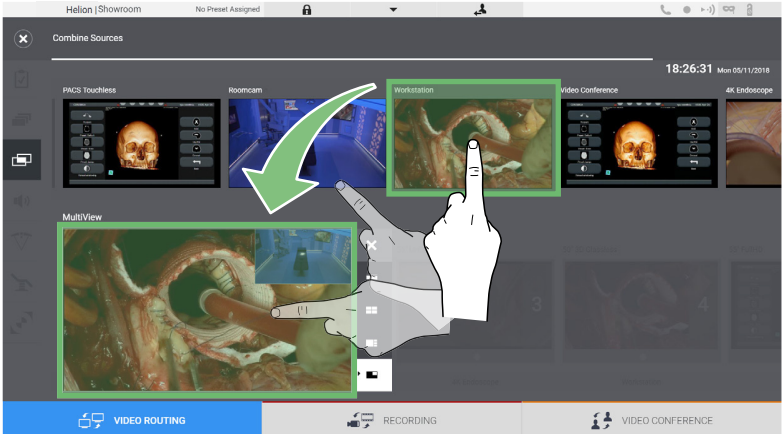

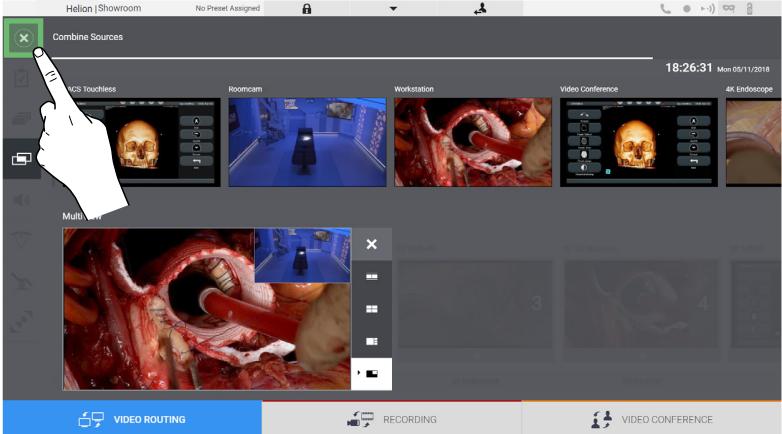
Press the  icon on the side menu to access the Multiview screen. The Multiview function makes it possible to combine multiple Inputs (up to a maximum of 4) in a single Output signal. The main screen is divided as follows:




- [A] Source List
- [B] Multiview

6.6.4.1 Multiview setting

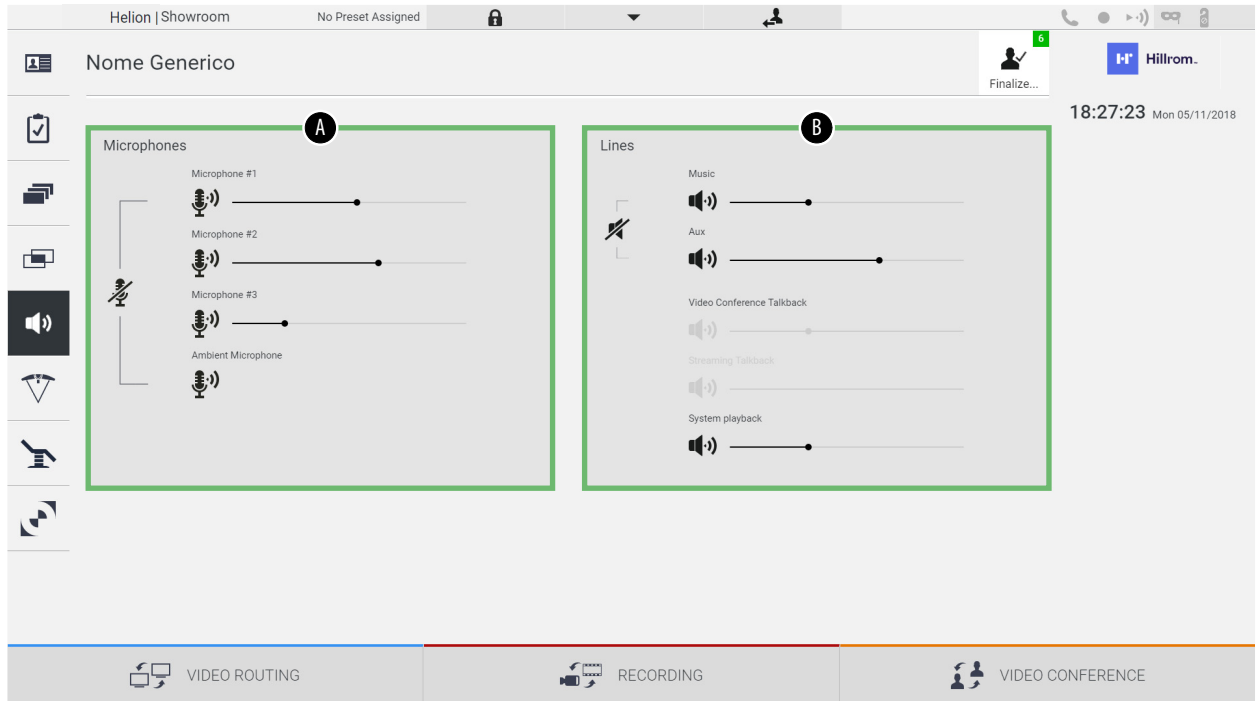
To set the Multiview, proceed as follows:

Step	Image										
<p>1. Select the desired layout from those indicated:</p> <table border="1" data-bbox="172 450 568 824"> <thead> <tr> <th data-bbox="172 450 261 488">Icon</th> <th data-bbox="261 450 568 488">Function</th> </tr> </thead> <tbody> <tr> <td data-bbox="172 488 261 566"></td> <td data-bbox="261 488 568 566">Picture and Picture</td> </tr> <tr> <td data-bbox="172 566 261 645"></td> <td data-bbox="261 566 568 645">Quadview</td> </tr> <tr> <td data-bbox="172 645 261 723"></td> <td data-bbox="261 645 568 723">Picture Over Picture</td> </tr> <tr> <td data-bbox="172 723 261 824"></td> <td data-bbox="261 723 568 824">Picture In Picture</td> </tr> </tbody> </table>	Icon	Function		Picture and Picture		Quadview		Picture Over Picture		Picture In Picture	
Icon	Function										
	Picture and Picture										
	Quadview										
	Picture Over Picture										
	Picture In Picture										
<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>											

6.6.5 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 inputs (microphones) and outputs (speakers in the room).

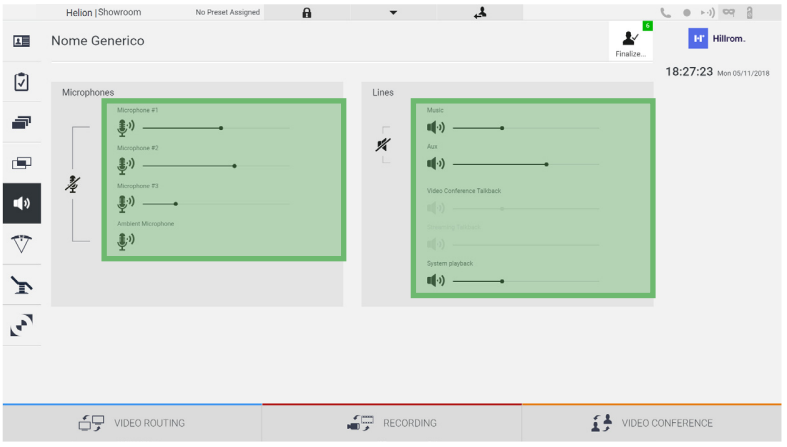
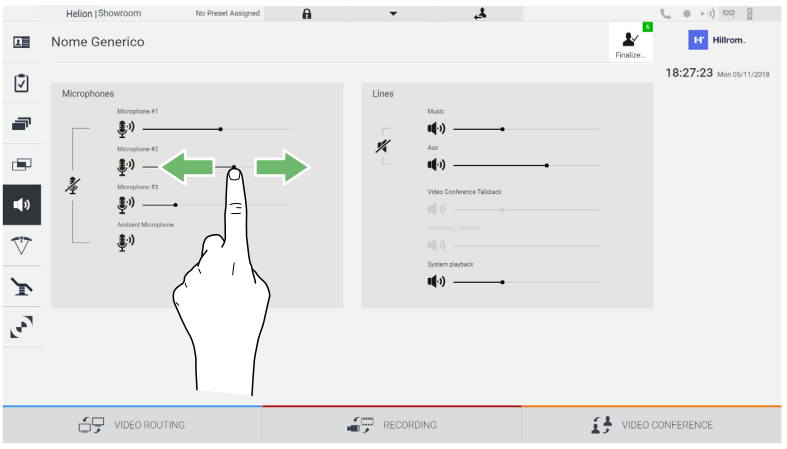
The main screen is divided as follows:



- [A] Microphone inputs
- [B] Line inputs

6.6.5.1 Volume adjustment


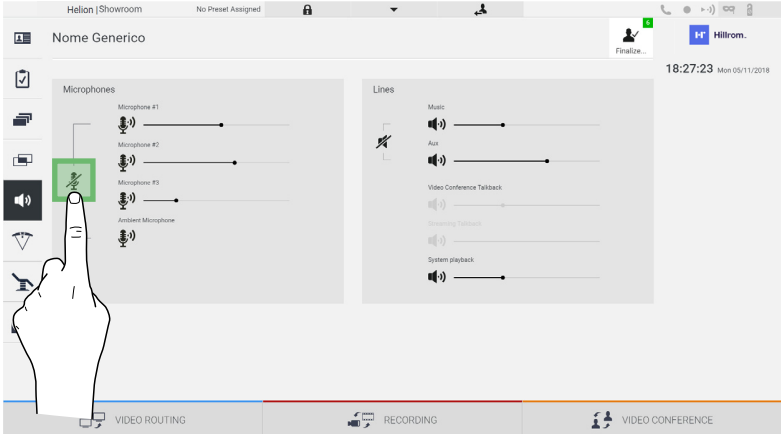

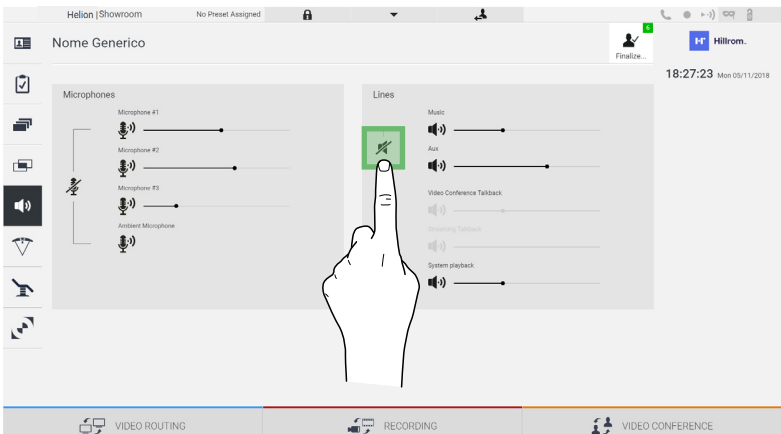
To adjust the volume of the microphones or line inputs, proceed as follows:

Step	Image
<p>1. Operate the volume bar of the microphones or line inputs based on the volume to be modified.</p>	 <p>The screenshot shows the 'Audio Control' interface. On the left, under 'Microphones', there are sliders for Microphone #1, Microphone #2, Microphone #3, and Ambient Microphone. On the right, under 'Lines', there are sliders for Music, Aux, Video Conference Talkback, Streaming Talkback, and System playback. A green box highlights the sliders for Microphone #1 and Music. The interface also shows 'VIDEO ROUTING', 'RECORDING', and 'VIDEO CONFERENCE' buttons at the bottom.</p>
<p>2. Slide the bar to increase or decrease the volume of the microphones or line inputs.</p>	 <p>This screenshot is identical to the one above, but it includes a hand icon pointing to the 'Microphone #2' slider. Two green arrows point outwards from the slider, indicating the direction of volume adjustment (increase or decrease).</p>


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.

6.6.5.2 Disabling microphones and audio

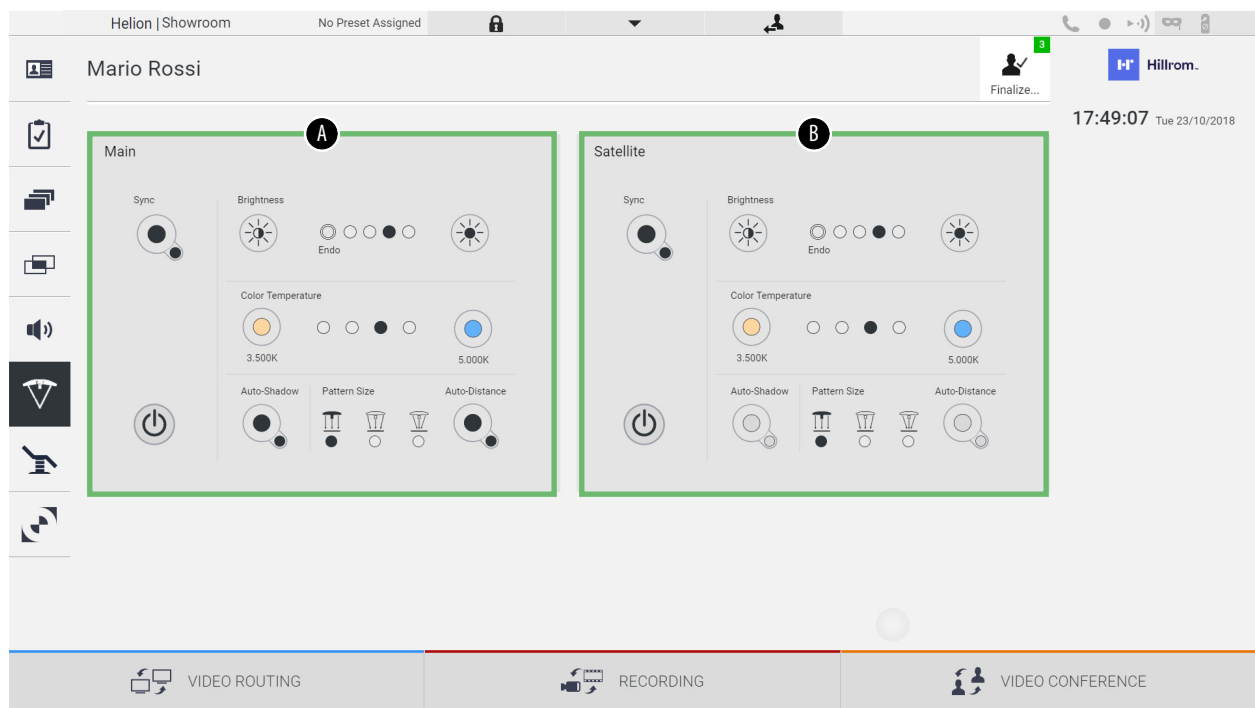
To disable the microphones or line inputs, proceed as follows:

Step	Image
<p>1. Press  to disable the microphone.</p>	
<p>2. Press  to turn off the speaker volume.</p>	

6.6.6 Surgical light management

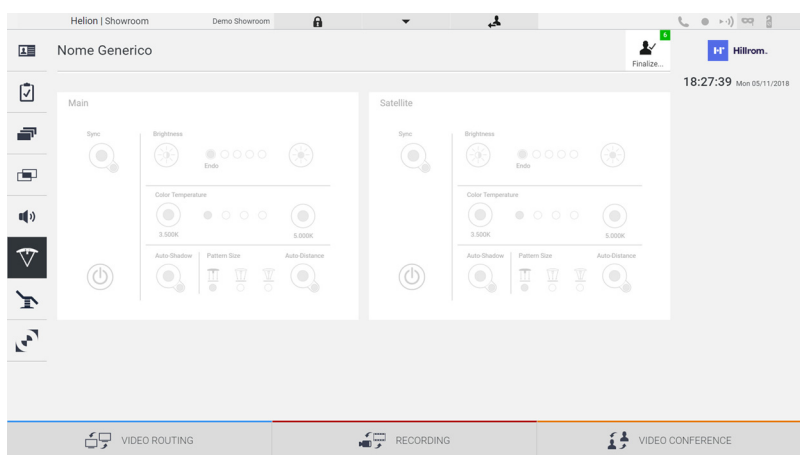
Press the  icon on the side menu to access the management screen for the devices in the operating theatre.

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



- [A] Main
- [B] Satellite

The image shows the situation where the lamp control system cannot be reached.




Helion Video Management System provides the option of controlling the Trumpf Medical surgical lights, through the reproduction of the light control console via the graphical user interface. The graphical user interface has been kept as similar to the original light control panel as possible.

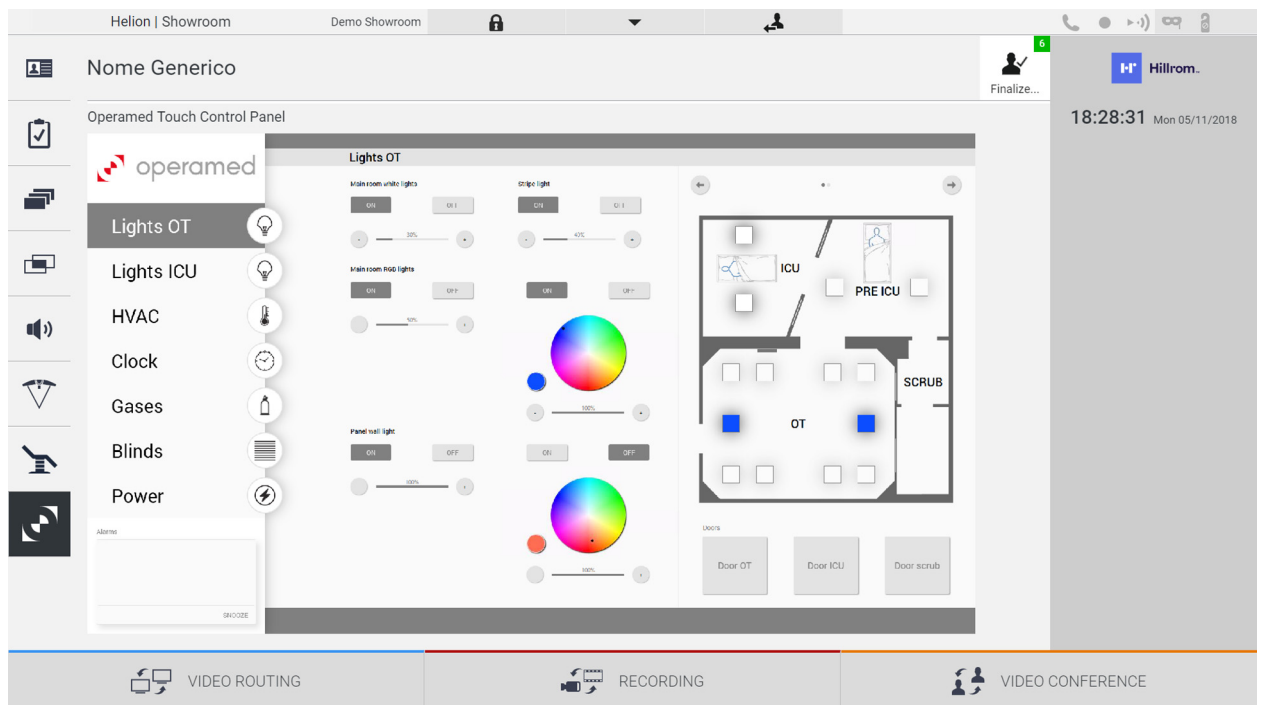
In the image, you can see that the functions accessible from the touchscreen system are:

- 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.

6.6.7 Environmental control panel management

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




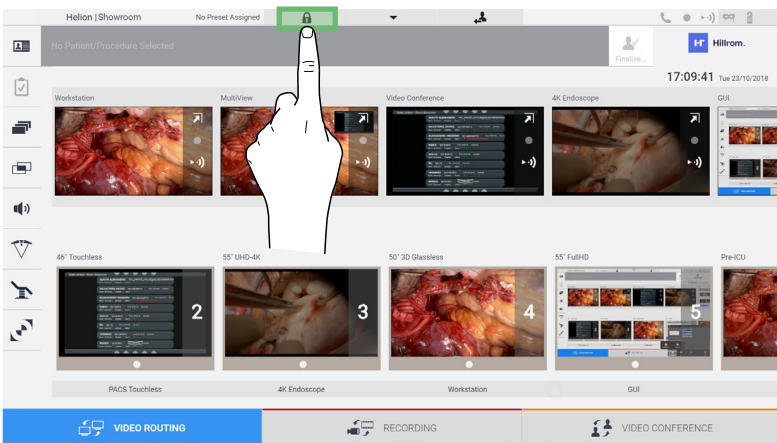
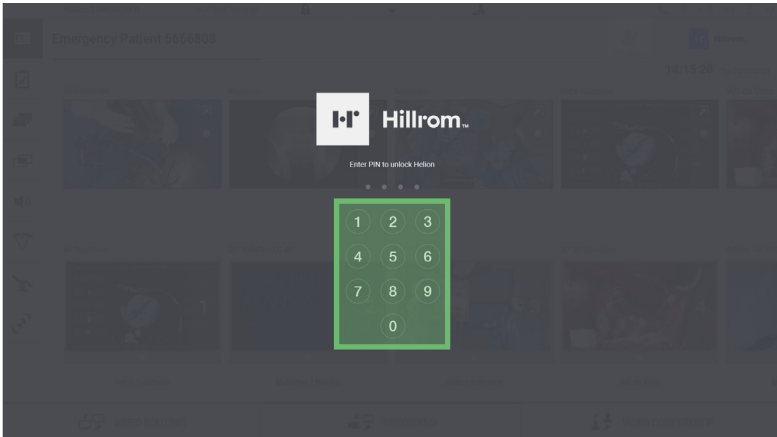
The control panel management screen can only be used if there are Operamed devices in the operating theatre.

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

6.7 “Lock with PIN” function

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

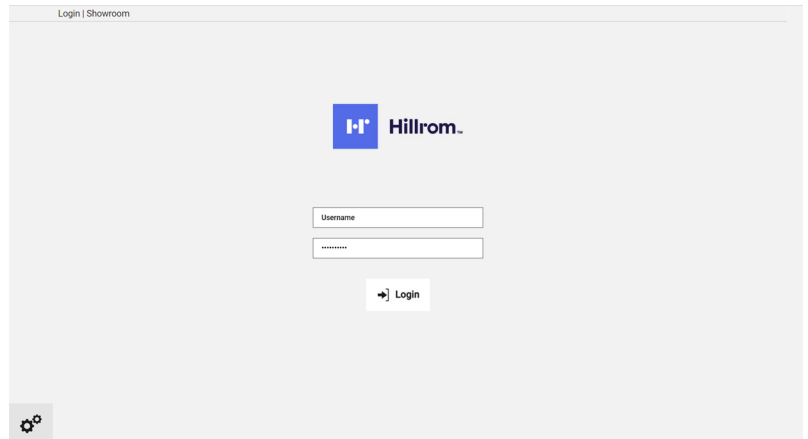
To lock the touchscreen, proceed as follows:

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



6.8 “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.

7 Disposal instructions

Electrical equipment that is no longer in use must not be disposed of as normal communal waste. The substances and materials contained 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.



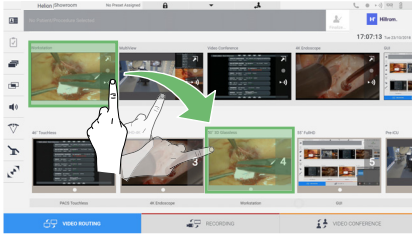
To notify the dispatch of decommissioned devices, call +39 049 9819113.

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.

8 Annex I - Getting started

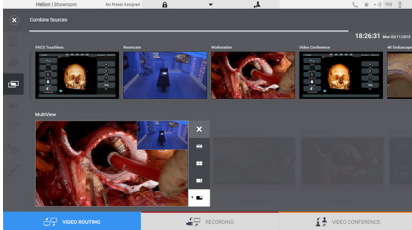
8.1 Video Routing



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**.

8.2 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.

8.3 PTZ camera control

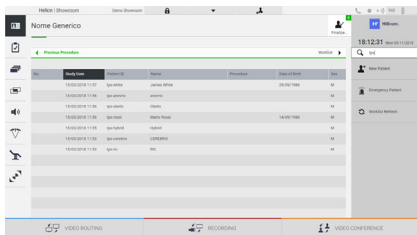


Press **↗** in the RoomCam Preview to open the Live Preview. The camera control buttons will appear. The system allows you to change the position and zoom level of the camera.

8.4 Recording

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

8.5 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).

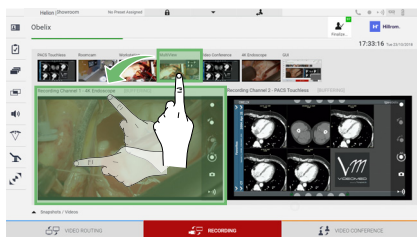
 **Worklist Refresh** **Access to the Worklist**

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.





8.6 Selecting the signals to be recorded

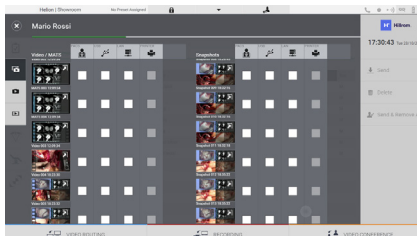


Drag the desired source into the Recording Channel box to enable basic recording functions:

 **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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