

Instructions for use

Helion

Video Management System



This page is intentionally blank.



Manufacturer VIDEOMED S.r.l.

Via C. Battisti, 31/C 35010 Limena (Pd)

Italy

Telephone: +39 049 9819113 Fax: +39 0434 030689

surgical@hillrom.com

hillrom.com

 $\label{thm:company} \textit{VIDEOMED S.r.l.} \ is a company of the \textit{Hill-Rom Holdings Group.} \ The$

manufacturer is hereinafter referred to 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.

Information about the document

Instructions for use

This document is identified by a code indicating its version and update status. It is the user's responsibility to ensure the most recent version is used.

Document number: 80028000
Language ID: 030
Version: C
Material number: 773607
Date of publication: 2021-09-01

This document applies to the following sales units:

| Product designation | REF |
|------------------------|---------------|
| Helion Main Unit R | VR401111-1 |
| Helion Main Unit | VR401111-1ND |
| Helion Main Unit RD | VR401111-1D |
| Helion Main Unit RSD | VR401111-1DT |
| Helion Main Unit RS | VR401111-1T |
| Helion Main Unit S | VR401111-1TND |
| Helion Main Unit AR | VR401111-2 |
| Helion Main Unit ARD | VR401111-2D |
| Helion Main Unit ARSD | VR401111-2DT |
| Helion Main Unit ARS | VR401111-2T |
| Helion Main Unit SSD R | VR401111-3 |
| Helion 4K | VR401112 |
| Helion 4K Plus | VR401113 |
| Helion Conference | CM401326 |
| 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 paper copy of the manual is available upon request for qualified technical and medical personnel.

VIDEOMED S.r.l. declines any liability for improper use of the 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 personal use by the buyer, without the express written permission of the Manufacturer.

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

PUBLISHER'S NOTE

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

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

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

GENERAL CONSIDERATIONS

All operating instructions and recommendations described in this manual must be complied with. Clinical personnel must be trained on all operating procedures and safety standards prior to using the system.

SIGNAL WORDS

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

| Signal word | Meaning |
|-------------|---|
| DANGER | The signal word indicates a dangerous situation that will immediately lead to death or serious injury if no precautionary measures are taken. |
| WARNING | The signal word indicates a dangerous situation that may lead to death or serious injury if no precautionary measures are taken. |
| CAUTION | The signal word indicates a dangerous situation that may lead to moderate to 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. |

© 2021 VIDEOMED S.r.I.

This page is intentionally blank.



Contents

| 1 | System identification | |
|--------------------|---|-------------|
| 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 | |
| 2.2 | Updates | |
| 2.3 | Language | |
| 2.4 | Personnel qualifications | |
| 2.5 | Symbols used in the instructions for use | |
| 2.0 | Symbols used in the instructions for use | 10 |
| 3 | Safety information | 17 |
| 3.1 | General safety warnings | 17 |
| 3.2 | Electromagnetic compatibility | |
| 3.3 | Useful life of the system | |
| 3.4 | Cleaning | |
| 3.4.1 | Preparing the system | |
| 3.4.2 | Cleaning the system | |
| J. 4 .2 | Clearling the system | |
| 4 | System description | 22 |
| 4.1 | Intended use | |
| 4.2 | Reasonably foreseeable misuse | |
| 4.3 | Use associated with other medical devices | |
| 4.4 | Obligations and prohibitions | |
| 4.4.1 | Personnel prohibitions | |
| 4.4.1 4.5 | | |
| | Technical data | |
| 4.6 | Measurement and weight layout | |
| 4.7 | System components | |
| 4.7.1 | Main unit | |
| 4.7.2 | Conference unit | |
| 4.7.3 | 4K unit | . 36 |
| 4.7.4 | 4K Plus unit | . 36 |
| 4.7.5 | Control software | . 37 |
| 5 | Operation | 70 |
| 5 5.1 | · | |
| | First system start | |
| 5.2 | Preliminary checks | |
| 5.3 | System start-up | |
| 5.4 | Connection to the sources | |
| 5.5 | System shutdown | |
| 5.6 | System start-up/shutdown with remote button | . 40 |
| 6 | User Interface | / 11 |
| 6 .1 | General description of the user interface | |
| 6.2 | Control touchscreen | |
| | | |
| 6.3 | "Video Routing" function | |
| 6.3.1 | Live Preview | |
| 6.3.2 | Quick Access - Recording | |
| 6.3.3 | Quick Access - Streaming | |
| 6.3.4 | Ptz camera control | |
| 6.3.4.1 | Roomcam zoom adjustment | |
| 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 |
| | | |

Contents

| 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 | |
| 6.4.3 | Recording | |
| 6.4.4 | Snapshot and video playback | |
| 6.4.5 | Crop video | |
| 6.4.6 | Export images and videos | |
| 6.4.7 | Delete images and videos | |
| 6.5 | "Video Conference" function | 61 |
| 6.5.1 | Select 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 present in the list | 66 |
| 6.6.1.2 | Entering a new patient | 67 |
| 6.6.1.3 | Entering an emergency patient | 68 |
| 6.6.1.4 | Searching for a patient present in a list | |
| 6.6.1.5 | Patient master data modification | 69 |
| 6.6.1.6 | Accessing the worklist | 70 |
| 6.6.2 | Check-List | 71 |
| 6.6.3 | Preset | 72 |
| 6.6.3.1 | Preset setting | 73 |
| 6.6.3.2 | Enabling Preset | 74 |
| 6.6.4 | Multiview | |
| 6.6.4.1 | Multiview setting | |
| 6.6.5 | Audio control | |
| 6.6.5.1 | Volume adjustment | |
| 6.6.5.2 | Disabling microphones and audio | |
| 6.6.6 | Management of surgical lights | |
| 6.6.7 | Environmental control panel management | |
| 6.7 | "Lock with PIN" function | |
| 6.8 | "Login" function | 83 |
| 7 | Disposal instructions | 84 |
| 8 | Annex I - Short manual | 85 |
| 8.1 | Video Routing | 85 |
| 8.2 | Multiview | 85 |
| 8.3 | PTZ camera control | 85 |
| 8.4 | Recording | 85 |
| 8.5 | Patient data | 86 |
| 8.6 | Selection of signals to be recorded | 86 |



1 System identification

1.1 Identification plates

The Helion Video Management System units are fitted with identification plates. Each plate contains the identification details of the unit to be quoted in case of need to VIDEOMED S.r.l.

The plates present are shown below:

| Unit | Image |
|----------------------|--|
| Helion Main Unit R | 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 (01)00615521031572 (21)1234567890 (11)210811 SN 1234567890 (11)210811 Tod 2021-08-11 hillrom.co.uk FUSES RATING: 2X 250VAC - T3.15A |
| Helion Main Unit | 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 (01)00615521031671 (21)1234567890 (11)210811 SN 1234567890 (11)210811 FUSES RATING: 2X 250VAC - T3.15A |
| Helion Main Unit RD | REF VR401111-1D (01)00615521031695 (21)1234567890 |
| Helion Main Unit RSD | 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 (01)00615521031688 (21)1234567890 (11)210811 SN 1234567890 (11)210811 FUSES RATING: 2X 250VAC - T3.15A |
| Helion Main Unit RS | 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 (01)00615521031664 (21)1234567890 (11)210811 SN 1234567890 (11)210811 To d 35070 Limena, Italy FUSES RATING: 2X 250VAC - T3.15A |
| Helion Main Unit S | REF VR401111-1TND |

| Unit | Image |
|------------------------|--|
| Helion Main Unit AR | REF VR401111-2 |
| Helion Main Unit ARD | # 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 (01)00615521031633 (21)1234567890 (11)210811 SN 1234567890 (11)210811 FUSES RATING: 2X 250VAC - T3.15A |
| Helion Main Unit ARSD | Comparison |
| Helion Main Unit ARS | Comparison |
| Helion Main Unit SSD R | REF VR401111-3 |
| Helion Conference | Continue |
| Helion 4K | REF VR401112 Helion 4K # 116001 VIDEOMED MANAGEMENT SYSTEM Videomed srl Videomed srl Videomed srl Videomed srl Wade In Italy Made In Italy INPUT: 100-240V-0.2-0.48A 50/60 Hz REF VR401112 (01)00615521031596 (21)1234567890 (11)210811 SN 1234567890 Videomed srl Videomed srl SN 1234567890 FUSES RATING: 2X 250VAC - T1.6A |



| Unit | Image |
|--|--|
| Helion 4K Plus | REF VR401113 |
| Helion Rack (230V) (input voltage 220-240V) | 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 (01)00615521031893 (21)1234567890 (11)210903 SN 1234567890 (2021-09-03 hillrom.co.uk FUSES RATING: 2X 250VAC - T6.3A |
| Helion Rack (115V) (input voltage 100-120V) | REF AC500920K Helion Rack (115V) # 300116 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 (01)00615521031909 (21)1234567890 (11)210903 (11)210903 (11)210903 (11)20903 |

▲ CAUTION

It is absolutely forbidden to remove the identification plates and/or replace them with other plates. If the plates are damaged or removed, the customer must notify the Manufacturer.

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) countries:

| Standard | Description |
|--|--|
| 21 CFR Part 820 | Quality System Regulation |
| 21 CFR Part 821 | Medical Device Tracking Requirements |
| 21 CFR Part 803, 806, 807 | Medical Device Reporting, |
| | Medical Device Reports of Corrections and Removals, |
| | Establishment Registration and Device Listing for Manufacturers and initial Importers of Devices |
| 21 CFR Part 801 | Labeling |
| 19 CFR Part 134 | Country of origin marking. |
| AAMI / ANSI / ISO 14971: 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 | Medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, Mod). (General II (ES/EMC)) |
| and A2:2010/(R)2012 | (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 | 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 provided by the manufacturer of medical devices |
| EN ISO 13485:2016 | Management systems for the quality of medical devices |
| EN ISO 14971:2012 | Applying risk management to medical devices |
| EN ISO 15223-1:2016 | Symbols to be used in medical device labels, labelling and information to be provided — Part 1: General requirements |
| EN 60601-1:2006/A1:2013 | General requirements for fundamental safety and essential performance |
| EN 60601-1-2:2015 | General requirements relating to fundamental safety and essential performance - Collateral standard: Electromagnetic compatibility |
| EN 60601-1-6:2010 | General safety standards — Collateral rule: Usability |
| EN 62304:2006 + A1:2015 | Medical Device Software — Software Lifecycle Processes |
| EN 62366-1:2015 | Application of user characteristics 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 the safety and functional reliability of the system provided that:

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

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

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

2 General preliminary information

2.1 Recipients of the instructions for use

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

The instructions for use contain the topics that refer to a correct use of the system, in order to maintain its functional and qualitative characteristics unchanged over time. All the information and warnings for a correct use in full safety are also provided.

The instructions for use, like the CE conformity certificate, are an integral part of the system and must always accompany it in any movement or resale. It is the user's responsibility to keep this documentation intact, so that it may be consulted, throughout the entire lifespan of the system.

2.2 Updates

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

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

2.3 Language

The original instructions for use have been written in Italian.

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

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



2.4 Personnel qualifications

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

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

2.5 Symbols used in the instructions for use

| Symbol | Description |
|-----------|--|
| | Symbol used to indicate the need to consult the instructions for use before using the equipment. |
| CE | Symbol of compliance with Regulation (EU) 2017/745 on medical devices. |
| \bigvee | Equipotential: symbol for "potential equalization". |
| | Protective earth (ground) |
| N | Connection point for the neutral conductor on PERMANENTLY INSTALLED equipment |
| i | Caution - Refer to the operating instructions. |
| <u>~</u> | Symbol used to indicate the date of manufacture. |

| Symbol | Description |
|--|---|
| | Symbol used to identify the manufacturer's name. |
| | Barred bin: this product must not be disposed of as municipal mixed waste, collect separately. |
| REF | Symbol used to indicate the VIDEOMED material number. |
| SN | Symbol used to indicate the serial number. |
| MD | Symbol used to indicate a medical device. |
| (01)00615521031626 (21)123456789012 (11)210212 | Indicates the Unique Device Identification UDI code, is composed of UDI-DI (01) and UDI-PI ((11) date of production (21) serial number). |
| C UL US EXXXXXX | MEDICAL — GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014) |
| hillrom.co.uk | Consult instructions for use (IFU). A copy of the IFU is available on this website. A printed copy of the IFU can be ordered from Hillrom for delivery within 7 calendar days. |



3 Safety information

3.1 General safety warnings

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

A DANGER

ELECTRIC SHOCK FROM DAMAGED MAINS POWER CABLE! Check the mains power cable before connecting it and do not use it if it has been crushed or if the insulation is damaged.

A DANGER

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

A WARNING

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

▲ CAUTION

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

▲ CAUTION

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

▲ CAUTION

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

MEASUREMENT OF DISPERSAL CURRENTS!

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

3.2 Electromagnetic compatibility

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

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

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

▲ CAUTION

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

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

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



Guidance and manufacturer's declaration - Electromagnetic immunity

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

| IMMUNITY test | IEC test level | Compliance level | Electromagnetic environment – guidance |
|--|---|--|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV in contact ±2, ±4, ±8, ±15 kV in the air | IEC 60601-1-2 Test level | The floor must be in wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity must be at least 30%. Temporary loss of the signal is possible (a few seconds). |
| Radiated electromagnetic fields IEC 61000-4-3 | 3 V/m from 80 MHz to 2,7 GHz | IEC 60601-1-2 Test level | Portable and mobile RF communications equipment should be used no closer to any part of the EUT. including cables. Minimum distance 30 cm. |
| Fast electrical transients (burst) IEC 61000-4-4 | ± 2 kV for power lines ± 1 kV for input / output lines > 3 m | IEC 60601-1-2 Test level | The quality of the mains supply must be that typical of a commercial and / or hospital environment. |
| Pulses IEC 61000-4-5 | ±0.5, ±1 kV differential mode ±0.5, ±1, ±2 kV in common mode | IEC 60601-1-2 Test level | Mains power quality should be typical of a commercial or hospital environment. |
| Conducted disorders, induced by RF fields IEC 61000-4-6 Network frequency magnetic field (50/ 60 Hz) | 3 V 150 kHz to 80 MHz 6V ISM frequencies 30 A/m | IEC 60601-1-2 Test level IEC 60601-1-2 Test level | Portable and mobile RF communications equipment should be used no closer to any part of the EUT. including cables. Minimum distance 30 cm. Power frequency magnetic fields should have the characteristic levels of a typical location in a typical commercial or hospital environment. |
| IEC 61000-4-8 Voltage dips, brief | 10 ms – 0% a 0°, | IEC 60601-1-2 | The quality of the mains voltage should be |
| interruptions and voltage variations on the power input lines IEC 61000-4-11 | 45°, 90°, 135°, 180°. 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0% | Test level | that typical of commercial or hospital environments. If the user of the appliance requires it to continue to operate even when the mains power supply is interrupted, it is recommended to power the appliance with an uninterruptible power supply (UPS) or with batteries. |

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

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

3.3 Useful life of the system

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

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

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



3.4 Cleaning



Do not use any cleaning products.

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

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

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

3.4.1 Preparing the system

Pull the plug of the power cord out of the socket. For permanent installations turn off the main switch place on the front panel of the rack.

3.4.2 Cleaning the system

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

4 System description

4.1 Intended use

The Helion Video Management System is a medical videocommunication system used exclusively for displaying and managing already existing audio-video sources, and to control an operating light within the specifications established by the manufacturer.

Intended use entails the following:

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

Contraindications:

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

4.2 Reasonably foreseeable misuse

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

using the system in areas at risk of explosion;



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

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

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

4.3 Use associated with other medical devices

The Helion Video Management System can be used 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) 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. Environmental conditions for the operation and storage of Helion must be met, see "Technical data" paragraph.

4.4 Obligations and prohibitions

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

4.4.1 Personnel prohibitions

In particular the personnel must not:

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

▲ CAUTION

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



4.5 Technical data

MAIN UNIT - Technical Specs

| WAIN ONLY - Lectifical | opecs |
|----------------------------|---|
| Video Inputs | 18 (14 DVI, 2 3G-SDI, 2 CVBS) |
| Monitor Outputs | 10 DVI over CAT6/7 or optic fiber |
| Supported Resolutions | Standard video PAL (720 x 576) HDTV (1280 x 720) Full HDTV (1920 x 1080p) PC resolution (1024 x 768, 1280 x 1024, 1600 x 1200, 1920 x 1200) UHD / 4K option with 4K unit |
| Dimensions | 133 x 430 x 450 mm |
| Power Supply | 100-240 V 50-60Hz AC |
| Power Consumption | 160 W |
| Protection | Short circuit protection Overload protection Overvoltage protection |
| Insulation Voltage | Input/Output 4000 V AC Input/FG 1500 V AC |
| Enclosure | IP20 |
| Environmental conditions | Operating temperature: +10/+40 °C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70 °C Storage relative humidity range: 10% to 100% including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa |
| Max Operation Altitude | 5000 mt |
| Control Touchscreen | 24" or 27" , 1920 x 1080, 16:9 |
| Storage Capacity | 1 TB for approximately 350hrs 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

| COM ENLINCE ONLY | ecimical opecs |
|--------------------------|---|
| Standard Video | H.263, H.263+, H.263++, H.264, H.264 High Profile, H.264 SVC. Encoding up to 1920 x 1080p 60fps |
| Video Inputs | 2 Inputs: |
| | - 2 x HD video in (1080p60/720p60) |
| Dimensions | 44 x 430 x 450 mm |
| Power Supply | 100-240 V 50-60Hz AC |
| Video Outputs | 2 Outputs: |
| | - 2 x HD video out (1080p60/720p60) |
| Power Consumption | 34 W |
| Protection | Short circuit protection |
| | Overload protection |
| | Overcurrent protection |
| | Overvoltage protection |
| Insulation Voltage | Input / Output 4000 V AC |
| | Input / FG 1500 V AC |
| Environmental conditions | Operating temperature: +10/+40 °C |
| Conditions | Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa |
| | Storage temperature: -40/+70 °C |
| | Storage relative humidity range: 10% to 100% including |
| | condensation |
| | Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa |
| Max Operation Altitude | 5000 mt |
| Enclosure | IP20 |
| HD Audio | MicPod 100Hz fino a 16 kHz |
| | Mute button |
| Unit Weight | 8 kg |
| | |



4K UNIT - Technical Specs

| Video Inputs | 5 HDMI Ports |
|----------------------------|---|
| Video Outputs | 5 HDMI Ports |
| Supported Resolutions | Up to 4096 x 2160 at 60Hz |
| Transmission To Monitor | Optic Fiber Cabling |
| Additional Ports | 5 x DVI over CAT 6/7 output scaled to FullHD 1080 5 x DVI over CAT 6/7 pass-through input (FullHD 1080) |
| Dimensions | 44 x 430 x 450 mm |
| Power Supply | 100-240 V 50-60Hz AC |
| Power Consumption | 30 W |
| Protection | Short circuit protection Overload protection Overcurrent protection Overvoltage protection |
| Insulation Voltage | Input / Output 4000 V AC Input / FG 1500 V AC |
| Environmental conditions | Operating temperature: +10/+40 °C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70 °C Storage relative humidity range: 10% to 100% including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa |
| Max Operation Altitude | 5000 mt |
| Enclosure | IP20 |
| Unit Weight | 5.5 kg |

4K PLUS UNIT - Technical Specs

| 4K PLOS ONIT - 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 Fiber cabling | |
| Additional Ports | 4 x DVI over CAT6/7 output scaled to FullHD 1080 4 x DVI over CAT6/7 pass-through input (FullHD 1080) | |
| Dimensions | 44 x 430 x 450 mm | |
| Power Supply | 100-240 V 50-60Hz AC | |
| Power Consumption | 30 W | |
| Protection | Short circuit protection Overload protection Overcurrent protection Overvoltage protection | |
| Insulation Voltage | Input / Output 4000 V AC Input / FG 1500 V AC | |
| Environmental conditions | Operating temperature: +10/+40 °C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70 °C Storage relative humidity range: 10% to 100% including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa | |
| Max Operation Altitude | 5000 mt | |
| Enclosure | IP20 | |
| Unit Weight | 5.5 kg | |



RACK UNIT - Technical Specs

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

4.6 Measurement and weight layout

MAIN UNIT

Dimensions 133 x 430 x 450 mm

Unit Weight 13.5 kg









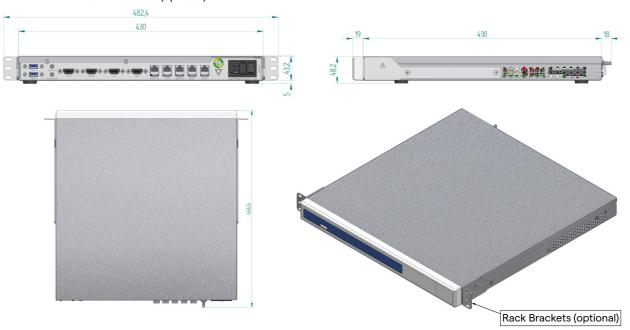
CONFERENCE UNIT

Dimensions 44 x 430 x 450 mm

Unit Weight 8 kg



Rack Dimensions (optional)



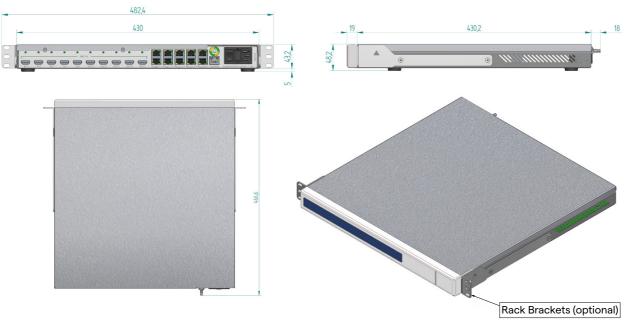
4K UNIT

Dimensions 44 x 430 x 450 mm

Unit Weight 5.5 kg



Rack Dimensions (optional)





4K PLUS UNIT

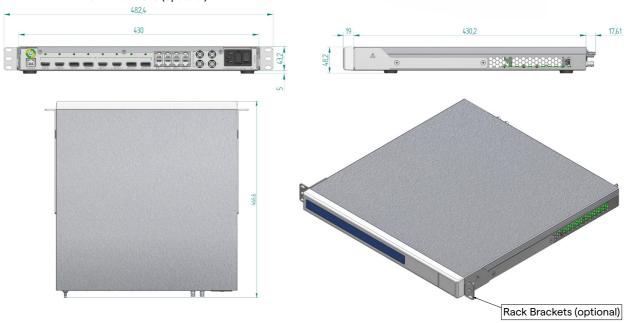
| Dimensions | 44 x 430 x 450 mm |
|------------|-------------------|
| Dimensions | 44 X 430 X 450 mm |

Unit Weight 5.5 kg



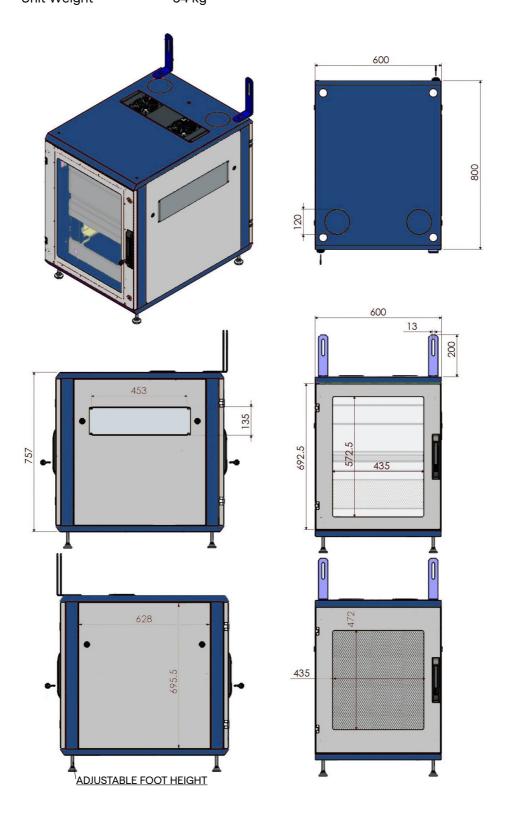


Rack Dimensions (optional)



RACK UNIT

Dimensions 800 x 600 x 757 mm
Unit Weight 64 kg





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.



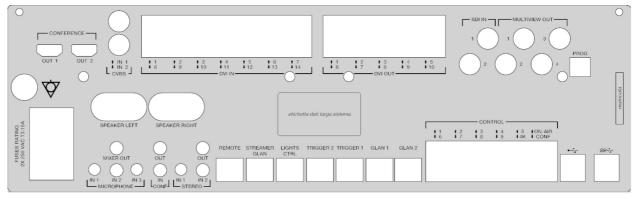
- [1] MAIN UNIT
- [2] CONFERENCE UNIT
- [3] 4K UNIT or 4K PLUS UNIT

4.7.1 Main unit

The following functions are available via the Main unit.

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

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

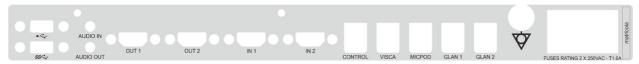


The connection cables are supplied VIDEOMED S.r.l.

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

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



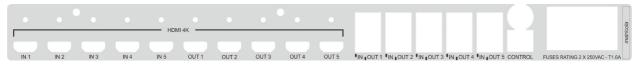
The connection cables are supplied VIDEOMED S.r.l.

4.7.3 4K unit

The new identification plates are still missing.

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

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

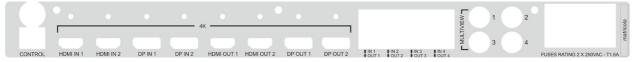


The connection cables are supplied VIDEOMED S.r.l.

4.7.4 4K Plus unit

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

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



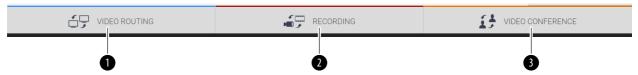
The connection cables are supplied VIDEOMED S.r.l.



4.7.5 Control software

The management software of Helion Video Management System allows to control and manage each functional unit.

There is a lower selection bar (always visible) which allows the software sections to be uniquely identified according to the function performed.



The sections of the selection bar are described below:

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

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

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

The complete functions present in the Control Software are described in detail in the "User Interface" chapter of these instructions for use.

5 Operation

5.1 First system start

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

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

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

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

5.2 Preliminary checks

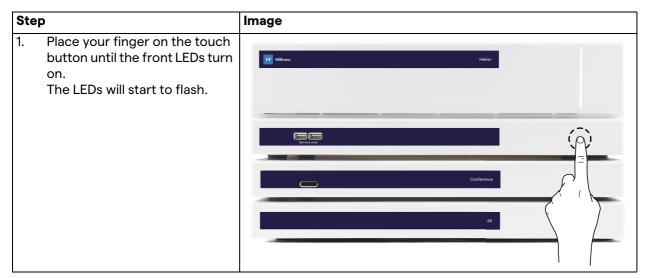
Before each use, check the components of the control screen, in regards to:

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

Cleaning is done during maintenance.

5.3 System start-up

To start the system, proceed as follows:





5.4 Connection to the sources

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

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

To connect new video sources to the system, simply connect the desired source to one of the compatible video connections present on the connection plates installed on the pendant panels. Depending on the configuration installed, the following connections may be present:

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

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

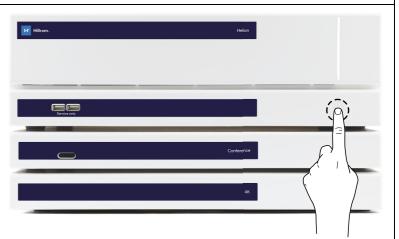


5.5 System shutdown

To shut down the system, proceed as follows:

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

Image



In the event of system shutdown, it is possible to force system deactivation by keeping the finger on the button until it is completely switched off and then restart the device by following the start-up procedure described in paragraph "System start-up". It is recommended to use forced shutdown only in case of an emergency, as this procedure may cause data loss.

5.6 System start-up/shutdown with remote button

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

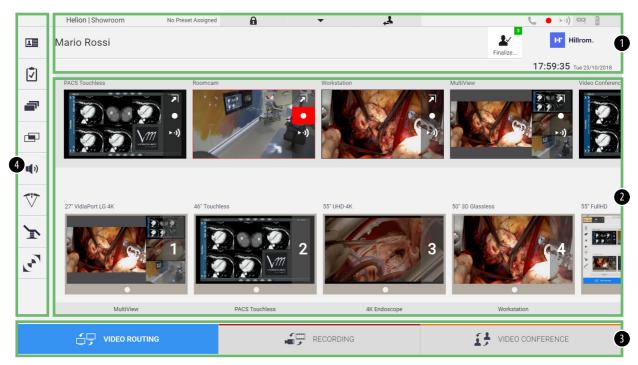
Thanks to this solution, the operator can manage the entire video management system without having to access the Technical rack. The switch-off of the units inside the Rack will therefore be reserved for technical and authorized/trained VIDEOMED personnel for service or maintenance sessions.



6 User Interface

6.1 General description of the user interface

The user interface is divided as follows:



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

6.2 Control touchscreen



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

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

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

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

Refer to the user manual of the touchscreen monitor for further information.

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



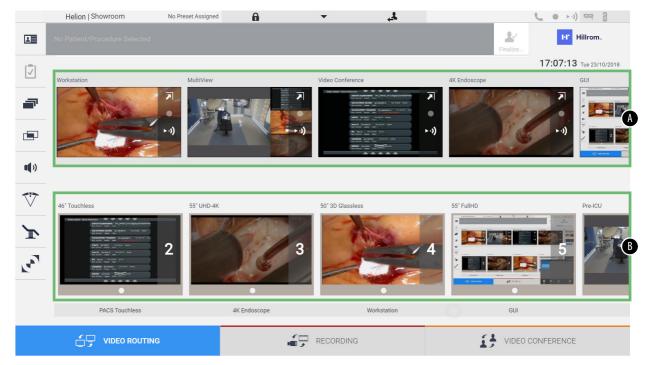
6.3 "Video Routing" function

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

- endoscope,
- surgical video camera,
- roomcam.

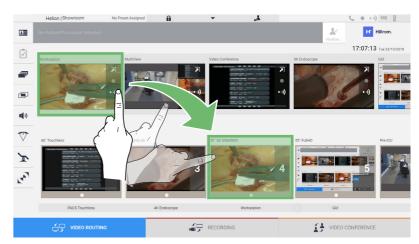
These video signals can be routed to any monitor in the operating room.

The main Video Routing screen is divided as follows:



- [A] list of sources connected
- [B] list of monitors enabled

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

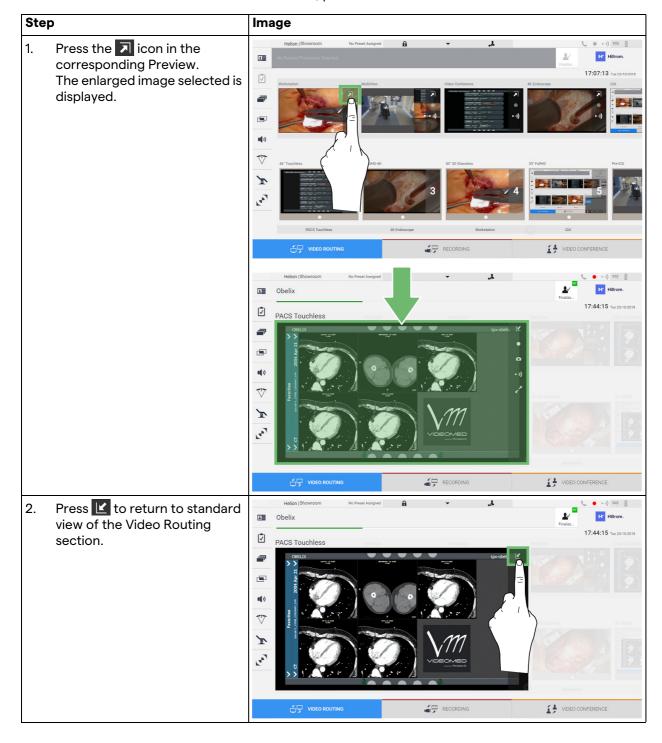


The Preview of the video signal sent will be displayed in the relative Monitor icon and updated periodically.

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

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:





The following icons are present in the Live Preview window:

| Icon | Function |
|-------------|--|
| | Enables to start/stop recording of the displayed signal. |
| | If the icon is gray, it indicates that the function is not active. To activate the function it is required to select a patient from the list (refer to paragraph "Selecting a patient present in the list"). |
| | Enables to create snapshots of the image. |
| ►·1) | Enables to start/stop video signal streaming. |
| E 34 | Enables to activate the full-screen display function, without latency, of the selected source (function available only on some touchscreen monitor models). |

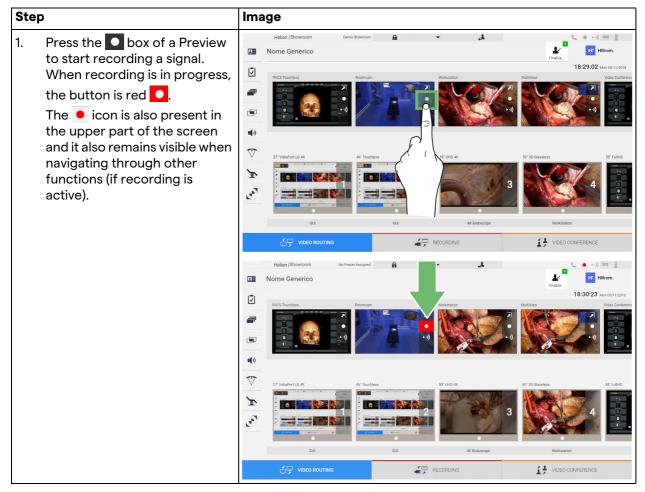
It is not possible to start recording if a reference patient is not present.

6.3.2 Quick Access - Recording

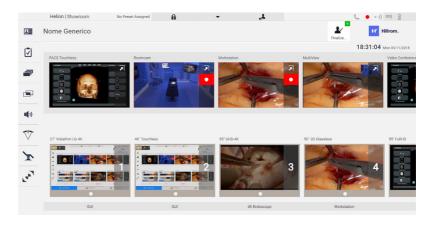
To start the recording it is possible to use a quick activation system directly from the Video Routing screen. There is a dedicated Recording screen to access the advanced functions.

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

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



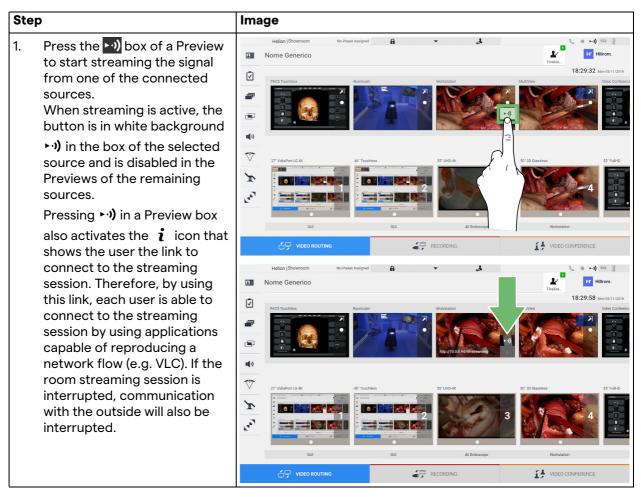
In systems where the dual recording channel is enabled, this function can be activated on two sources at the same time.





6.3.3 Quick Access - Streaming

To activate the streaming session, proceed as follows:

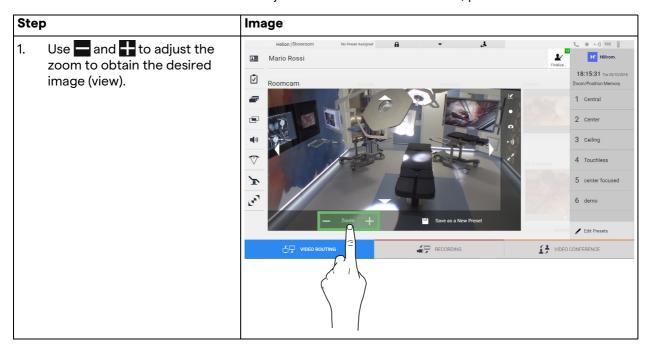


6.3.4 Ptz camera control

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

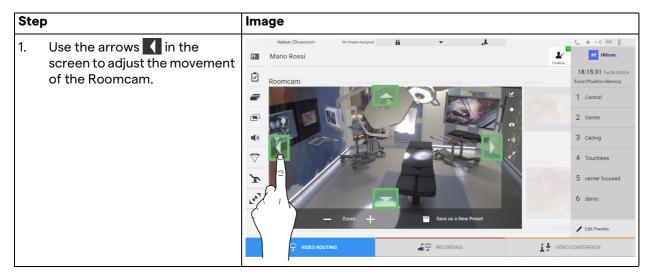
6.3.4.1 Roomcam zoom adjustment

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



6.3.4.2 Roomcam movement adjustment

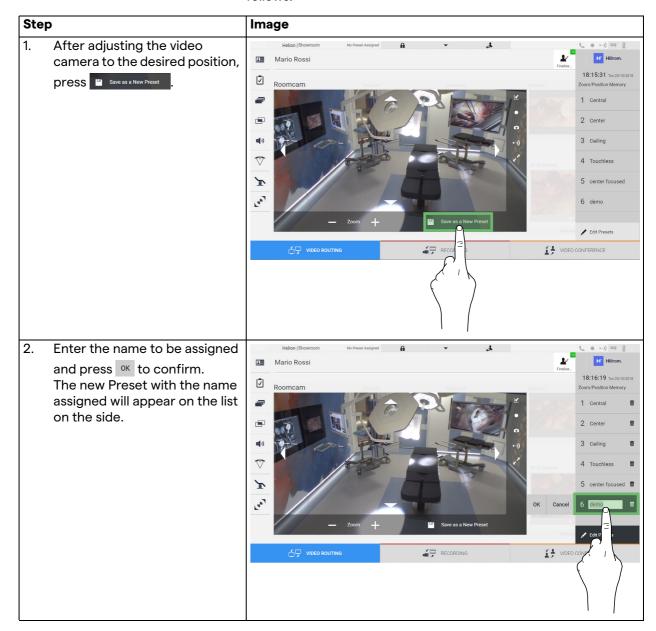
To adjust the movement of the Roomcam, proceed as follows:





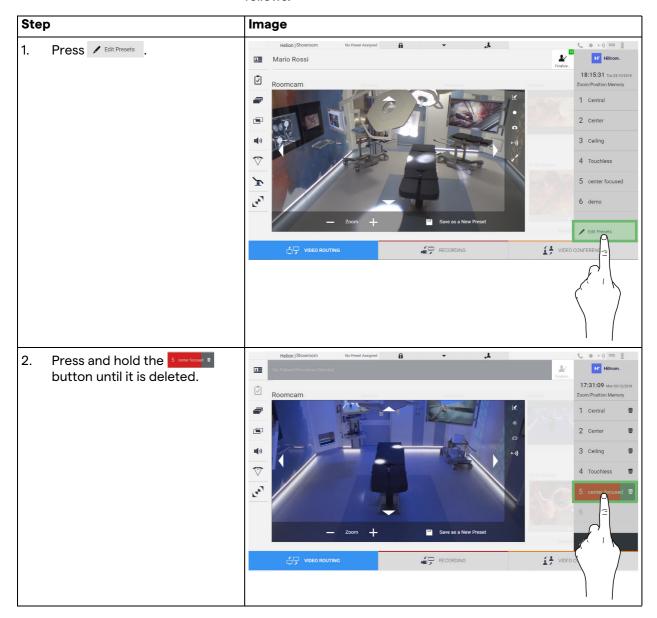
6.3.4.3 Save camera setting (Preset)

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



6.3.4.4 Delete camera setting (Preset)

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





6.3.4.5 Enable camera setting (Preset)

To activate a video camera Preset, proceed as follows:



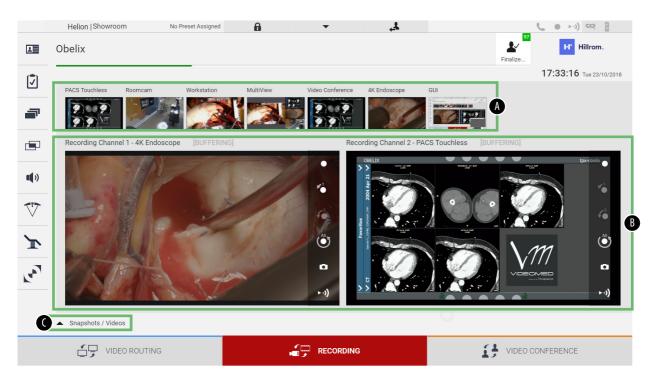
6.4 "Recording" function

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

IT IS therefore possible to save and then modify images and videos, stored on a 1TB on board support (expandable up to 2TB as an option). 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.



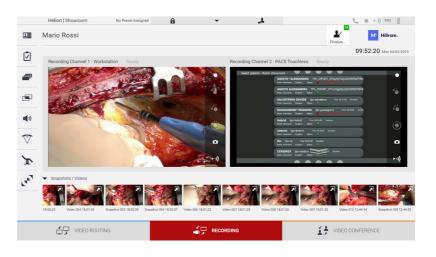
The main Recording screen is divided as follows:

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

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

Snapshots / Videos

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





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 will get a Live Preview of the signal and the basic and advanced recording functions will be enabled.



The following icons are present in the Recording Channel window:

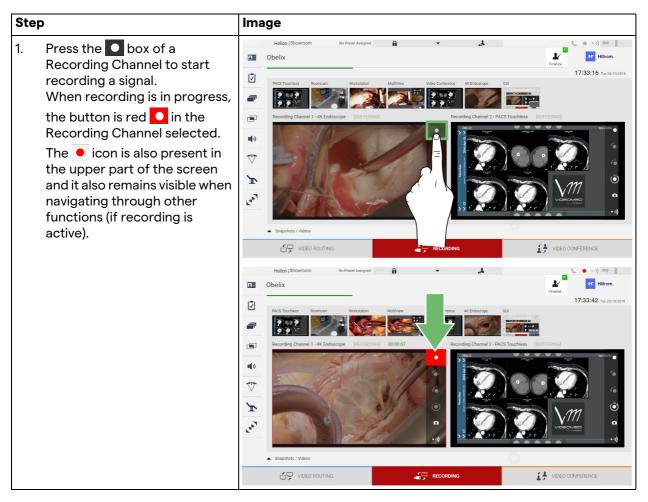
| Icon | Function |
|-----------------------|--|
| | Enables to start/stop recording of the displayed signal. |
| | If the icon is gray, it indicates that the function is not active. To activate the function it is required to select a patient from the list (refer to paragraph "Selecting a patient present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



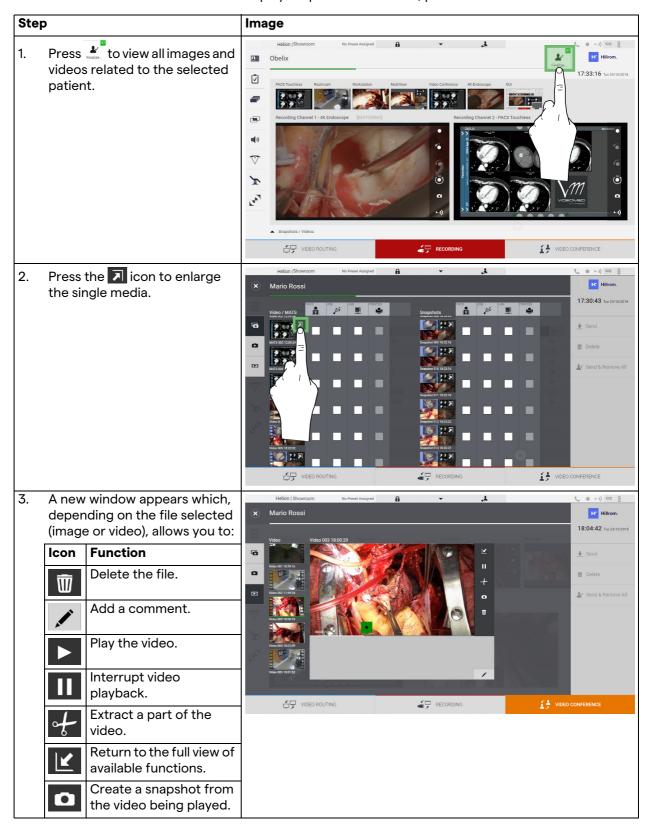
All videos and images related to the patient will be saved in the folder dedicated to them.

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



6.4.4 Snapshot and video playback

To play snapshots and videos, proceed as follows:



6.4.5 Crop video

To cut the videos, proceed as follows:





6.4.6 Export images and videos

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

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

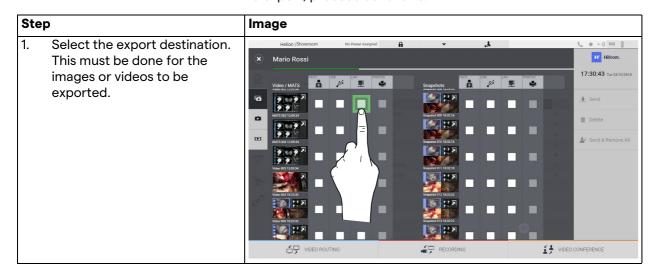


The following icons are present in the Export window:

| Icon | Function |
|------|--|
| PACS | It enables to export to the PACS system. |
| USB | Enables to save on a device connected to the USB port. |
| LAN | It enables 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:



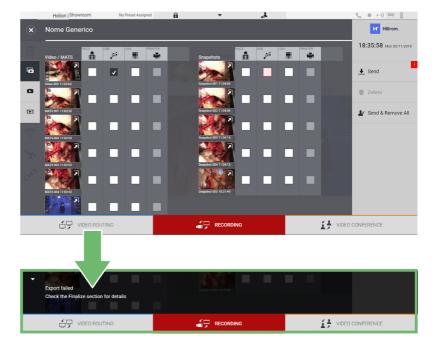


Step 2. Press ★ Send (on the right side of the screen) to send the files to the selected destinations. By pressing ★ Send & Remove All the files are sent to the selected destinations and the patient's session will be deleted. | Tright | Trigh

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

If the export destination does not respond (e.g.: USB device not present), the system displays an "EXPORT FAILED..." error message and the icon present on the right side of the screen.

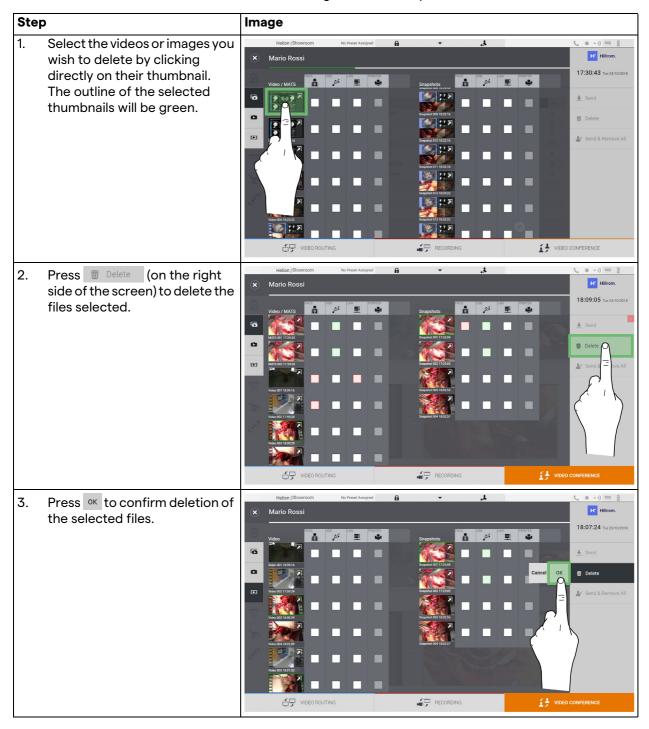
message and the icon papears on the right side of the screen. The files that the system failed to export are indicated with a red selection icon, as shown in the figure below.



6.4.7 Delete images and videos

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

To delete images and videos, proceed as follows:





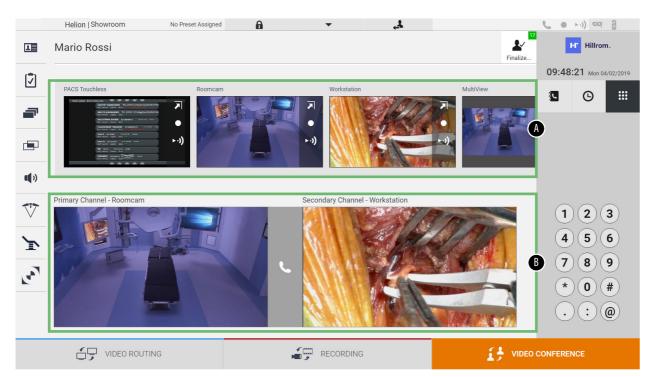
6.5 "Video Conference" function

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

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

The following modes are available:

| Mode | Description |
|--|---|
| Preview of the transmission channel | It enables to view one, or in case of multi-channel video conferencing, both connected transmission channels. |
| Images or video sources | All connected sources are displayed in the input signal bar. |
| Swap Button | During a conference it is possible to change the signals displayed in the layout selected. |
| Layout Button | During a multi-channel conference it is possible to have various live Previews of the video signals involved, for example PiP and PaP. |
| Participant selection/ Contact list | The video conference participants can be selected through the specific button: - by using the contact list, - by using the list of recent participants (log), - by entering the recipient's IP address directly from the |
| Participant display | keyboard. 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

6.5.1 Select the signals to be sent by video conference

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





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 to the icon \times which will be shown inside it to remove the video signal from the video conference.

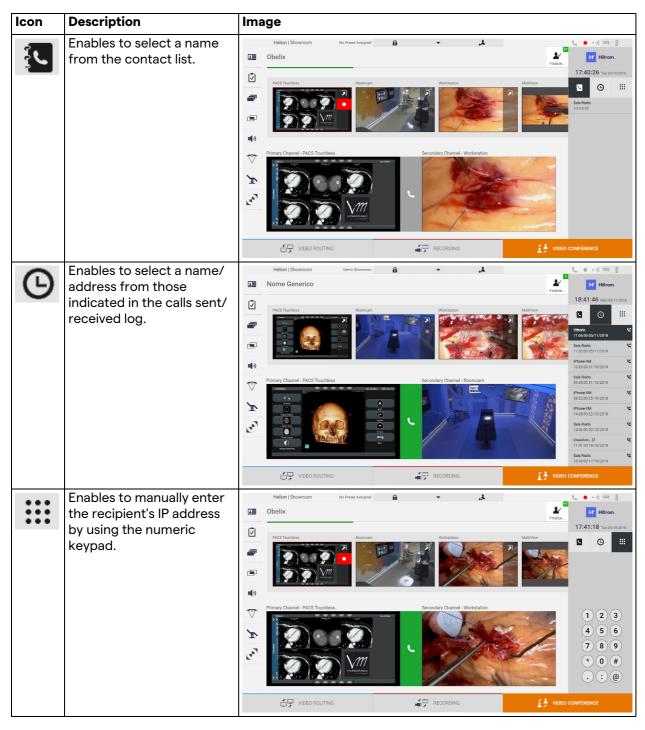
The video signal thus removed will no longer be shared with video conference participants.



6.5.3 Call recipient selection

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

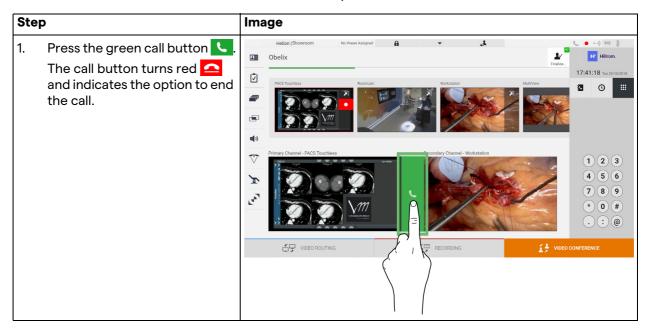
(depending on the mode) on the right side of the screen. The icons are described below:





6.5.4 Call start

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



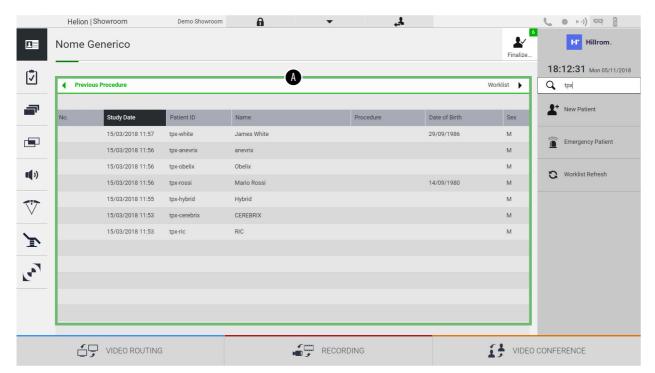
6.6 Additional functions

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

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

6.6.1 Patient data management

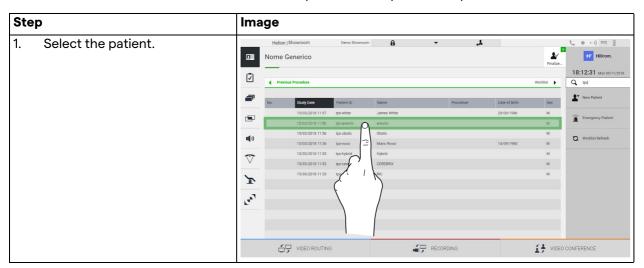
On the side menu, press the licon to access patient data management.



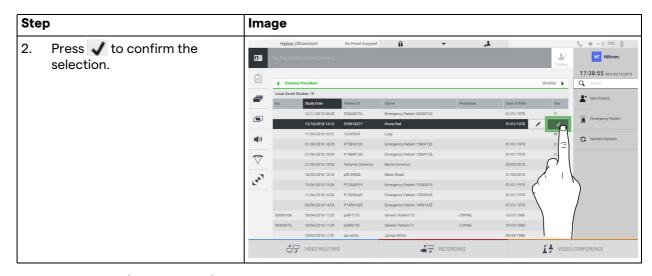
On the screen displayed, when the icon is pressed, the list of patients [A], already entered and divided between those imported by the Worklist (if present), and those previously manually selected or inserted, is displayed.

6.6.1.1 Selecting a patient present in the list

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

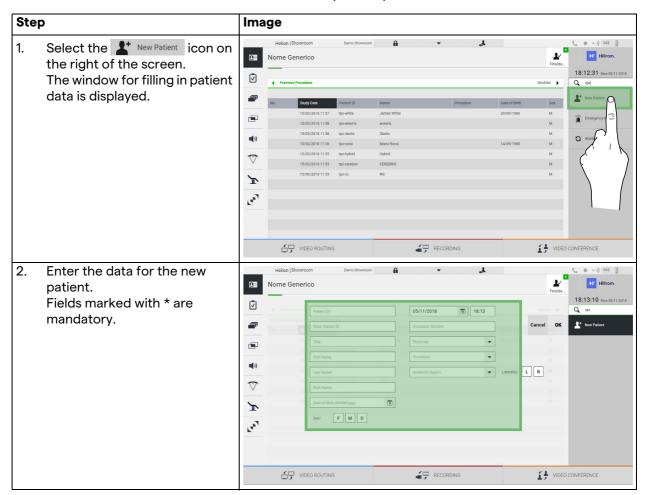


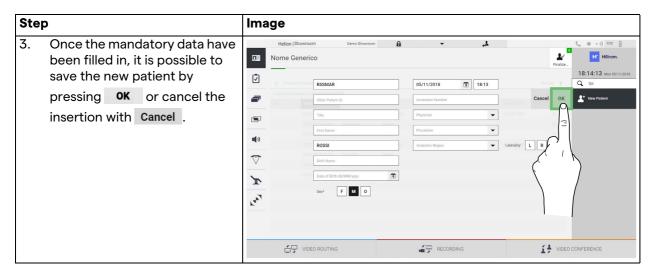




6.6.1.2 Entering a new patient

To enter a new patient, proceed as follows:



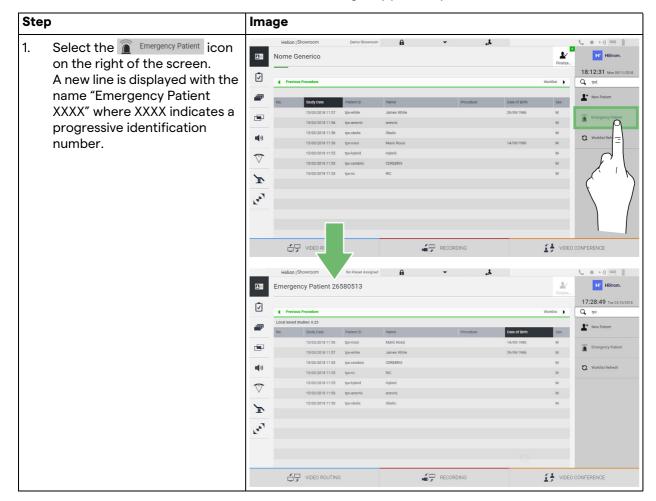


6.6.1.3 Entering an emergency patient

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

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

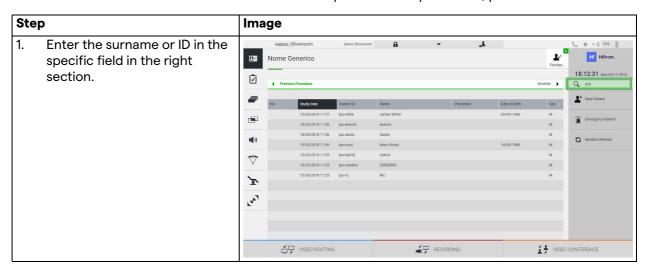
To enter an emergency patient, proceed as follows:





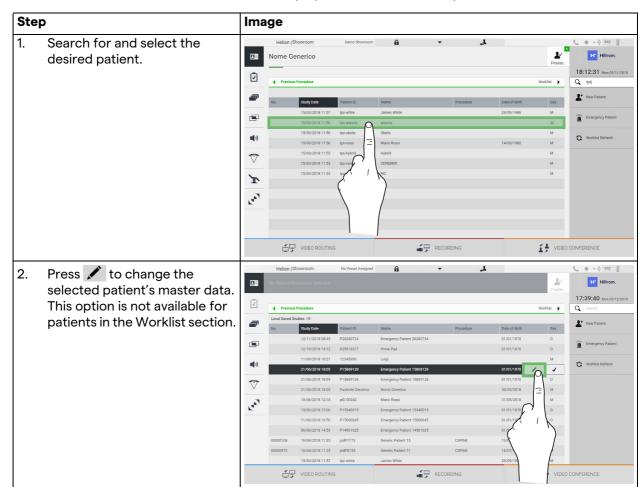
6.6.1.4 Searching for a patient present in a list

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



6.6.1.5 Patient master data modification

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

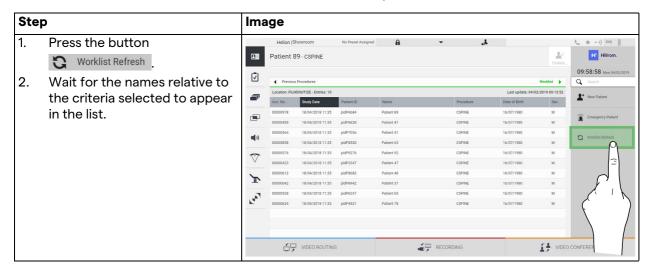


6.6.1.6 Accessing the worklist

If the Helion Video Management System is configured to dialogue with the centralized master data management system, the patient list relative to the date/room/surgeon can be called up by using

the Worklist Refresh button.

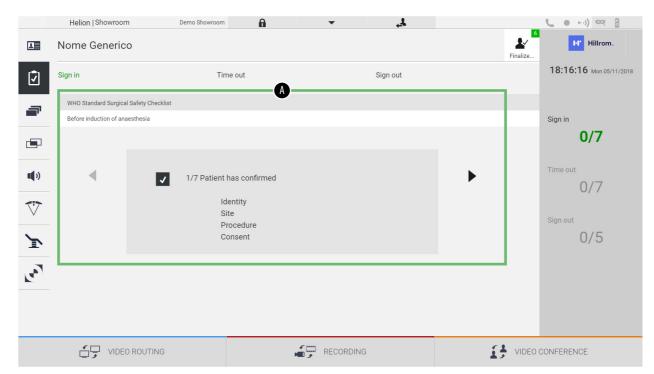
To access the worklist, proceed as follows:





6.6.2 Check-List

On the side menu, press the icon to access the Check-List screens. The Check-List only activates after selecting a patient.



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

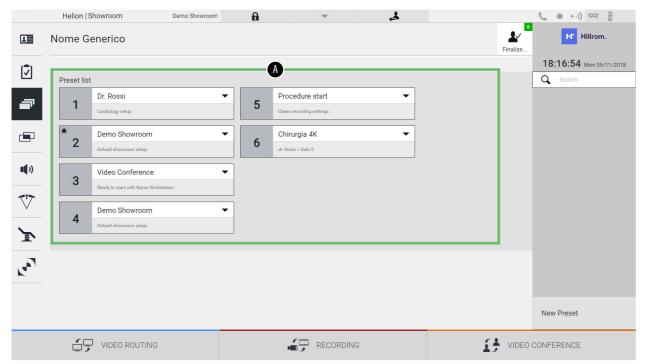
The instructions refer to the entire procedure, it will therefore be possible to exit this section and return to it to validate the instructions relating to the current state of the operating activity. It will always be possible to view the fill-in status of the Check-List via the progress bar in the Patient Info section.

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

6.6.3 Preset

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

The main screen is divided as follows:

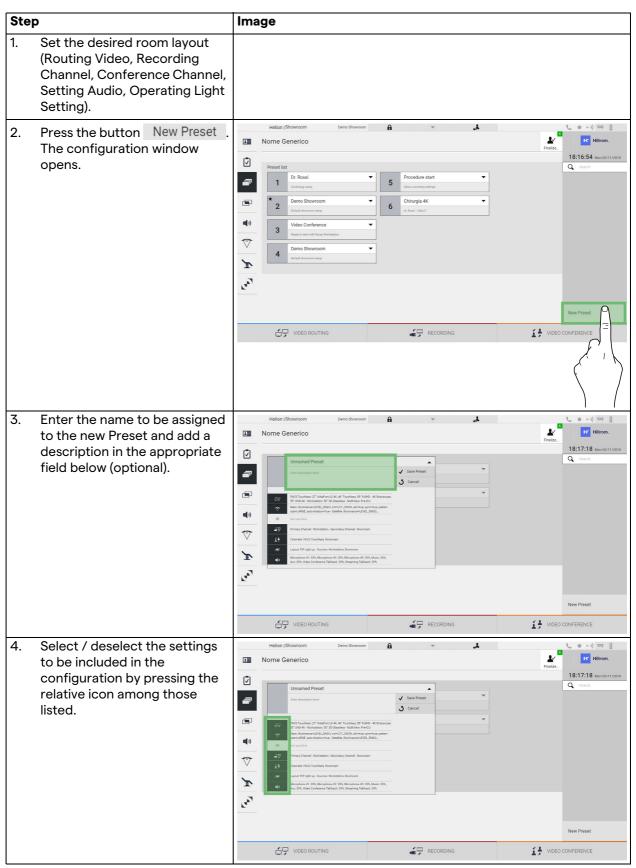


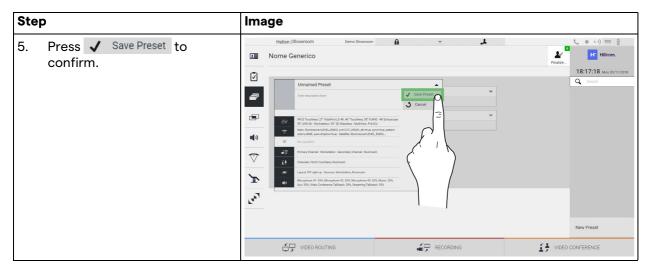
[A] Preset List



6.6.3.1 Preset setting

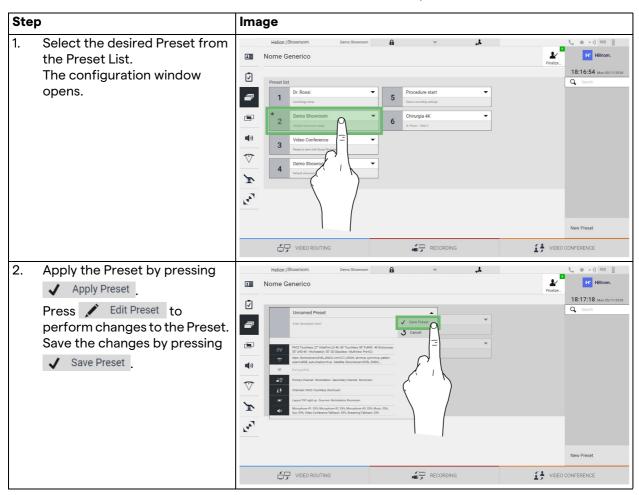
To set a new Preset, proceed as follows:





6.6.3.2 Enabling Preset

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



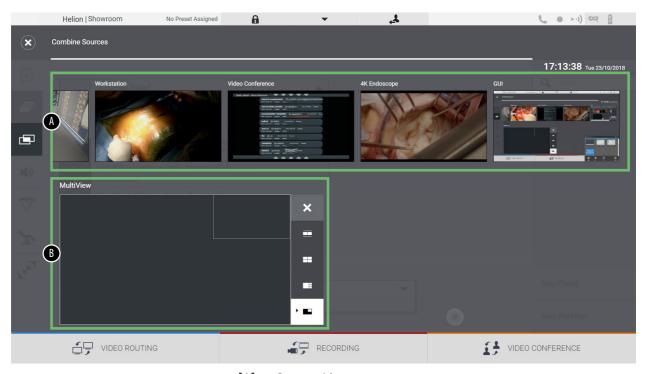
Press the * Mark Favorite* icon to automatically activate the Preset each time the system is started.



6.6.4 Multiview

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

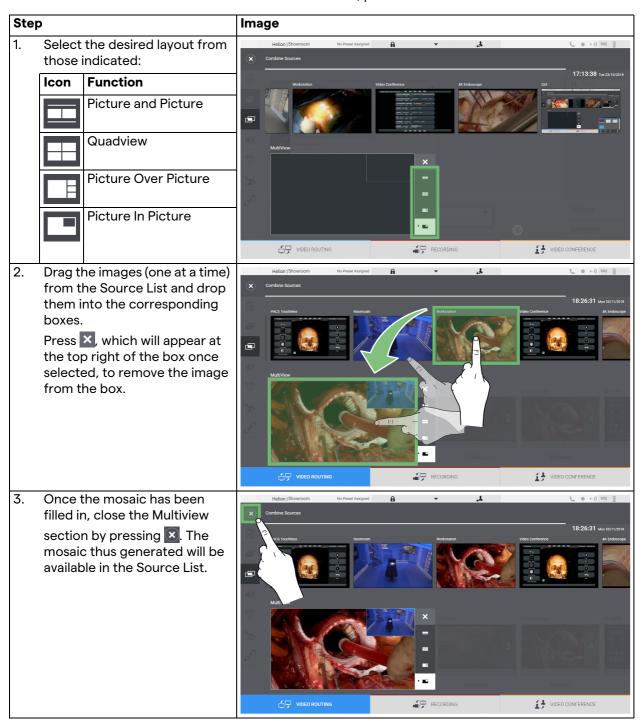
The main screen is divided as follows:



- [A] Source List
- [B] Multiview

6.6.4.1 Multiview setting

To set the Multiview, proceed as follows:

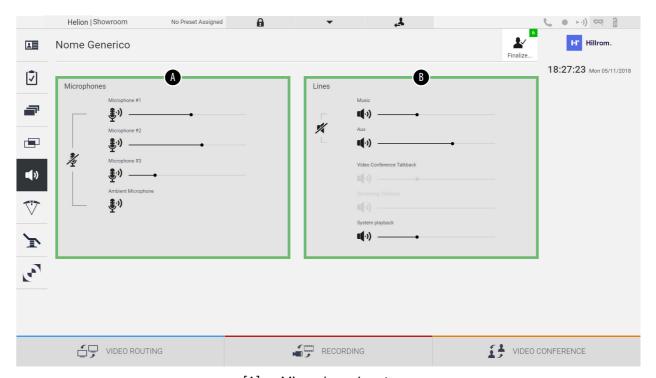




6.6.5 Audio control

On the side menu, press the (1) icon to access the Audio Control screen. In the Audio Control section it is possible to set the volume levels of the 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:



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

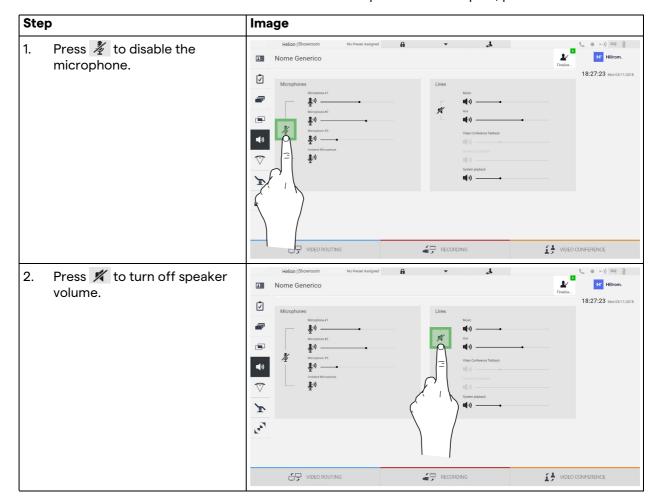
In the event that the system receives a connection request in video conference, the system will automatically silence lines AUX1/AUX2 and activate the video conference line.

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



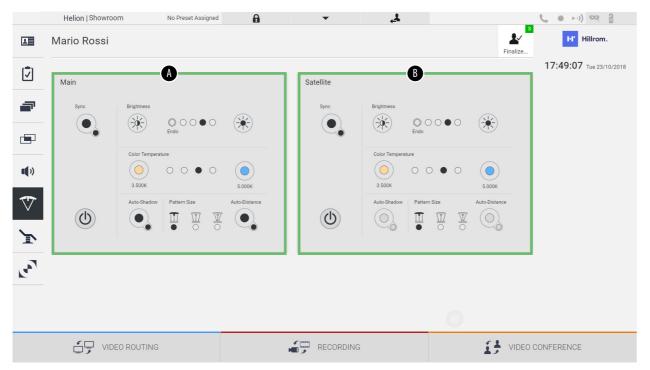
6.6.5.2 Disabling microphones and audio

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



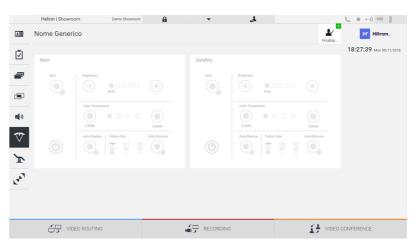
6.6.6 Management of surgical lights

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



- [A] Main
- [B] Satellite

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



Helion Video Management System assures the option of controlling the Trumpf Medical surgical operating lights, thanks to reproduction of the light control console through the graphic interface. The graphic interface has been kept as similar to the original light control panel as possible.



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

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

6.6.7 Environmental control panel management

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



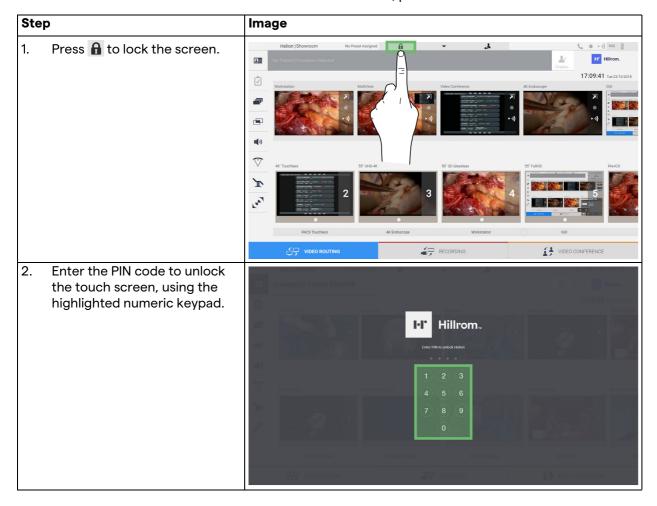
The control panel management screen can be used only if Operamed devices are present in the operating room.

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

6.7 "Lock with PIN" function

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

To lock the touchscreen, proceed as follows:





6.8 "Login" function

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



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

Press the _____ icon to Logout and be redirected to the credentials screen.

7 Disposal instructions

Electrical equipment that is no longer in use must not be disposed of as normal urban waste. The substances and materials contained in them must be disposed of separately in an appropriate way, so that they can be recycled for the production of new products. VIDEOMED S.r.l. offers a waste collection and environmentally sustainable disposal service for all products VIDEOMED S.r.l. Recycling and disposal is performed by VIDEOMED S.r.l. at no additional cost to the operator.



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

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

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



8 Annex I - Short manual

8.1 Video Routing



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

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

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 populate this layout by dragging, one at a time, the images of the sources and releasing them in the relative boxes.

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

8.3 PTZ camera control



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

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:



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

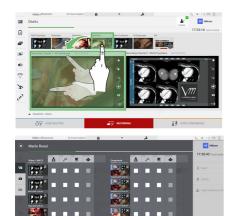


Press Worklist Refresh to download the patient list in automatic mode.



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

8.6 Selection of 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 elements to be exported and proceed with the export Send, deletion Delete or export of the selected elements and subsequent deletion of the patient from the patient list Send & Remove All.

This page is intentionally blank.

