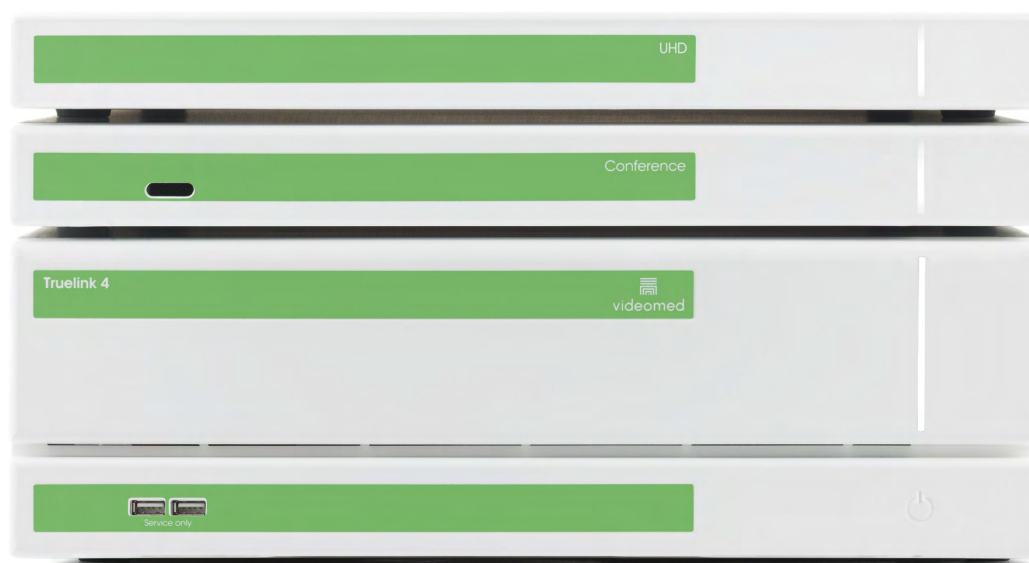




Instructions for use

Truelink 4

Video Management System



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

ENGLISH
en-US

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This document applies to the following sales units:

Product designation	REF
Truelink 4 Main Unit R	TVR401111-1
Truelink 4 Main Unit	TVR401111-1ND
Truelink 4 Main Unit RD	TVR401111-1D
Truelink 4 Main Unit RSD	TVR401111-1DT
Truelink 4 Main Unit RS	TVR401111-1T
Truelink 4 Main Unit S	TVR401111-1TND
Truelink 4 Main Unit AR	TVR401111-2
Truelink 4 Main Unit ARD	TVR401111-2D
Truelink 4 Main Unit ARSD	TVR401111-2DT
Truelink 4 Main Unit ARS	TVR401111-2T
Truelink 4 Main Unit SSD R	TVR401111-3
Truelink 4 UHD	TVR401112
Truelink 4 UHD Plus	TVR401113
Truelink 4 Conference	TCM401326

Optional sales items for the Truelink 4 video management system.
Not all products are available in all countries.

Product designation	REF
Truelink 4 Rack (115V)	TAC500920K
Truelink 4 Rack (230V)	TAC500920K-2
Delrin Rack Spacer Kit	AC500919
On Air Lamp	AC300601
Back cover for monitor 24IN /31IN	AC500634
STD Single Plate 2xDVI 2xNEUTRIK	CS201580
STD Double Plate 4xNeutrik	CS201582
Transmission Set Single Display	CS201584
DVI Line Transmission	CS201585
STD Double Plate 4xDVI 2xNeutrik	CS201586
STD Single Plate 4xNEUTRIK	CS201592
STD Single Plate 2x NEUTRIK	CS201593
STD Single Plate 2xDVI	CS201594
Truelink 4 HR Surgical Lights Control SW	TDC500103
Helion Recording Endotrigger Interface	AC500716

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.

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

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.

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Contents

1	General preliminary information	9
1.1	Operator's responsibility	9
1.2	Updates	9
1.3	Language	9
1.4	Personnel qualifications	10
1.5	Symbols	10
1.6	Product certification	11
1.7	Warranty	12
2	Safety information	13
2.1	General safety warnings	13
2.2	Security considerations	14
2.3	Privacy considerations	16
2.4	Useful life of the system	18
2.5	Cleaning	18
2.5.1	Cleaning agents	19
2.5.2	Preparing the devices	19
2.5.3	Cleaning the devices	19
2.6	Preventive maintenance	19
3	System description	20
3.1	Intended use	20
3.2	Intended medical indication	20
3.3	Device contact site	20
3.4	Patient population	20
3.5	Intended users	20
3.6	Use environment	20
3.7	Normal use	20
3.8	Contraindications	21
3.9	Reasonably foreseeable misuse	21
3.10	Use associated with other devices	22
3.10.1	Combination with other Baxter products	22
3.10.2	Combination with products of other manufacturers	22
3.11	Obligations and prohibitions	23
3.11.1	Personnel prohibitions	23
3.12	Technical data	23
3.13	Measurement and weight layout	28
3.14	System components	33
3.14.1	Main unit	33
3.14.2	Conference unit	34
3.14.3	UHD unit	34
3.14.4	UHD Plus unit	34
3.14.5	Control software	34
4	Operation	36
4.1	First system start	36
4.2	Preliminary checks	36
4.3	System start-up	36
4.4	Connection to the sources	37
4.5	System shutdown	37
4.6	System start-up/shutdown with remote button	38
5	User Interface	39
5.1	General description of the user interface	39
5.2	Control touchscreen	40

5.3	“Video Routing” function	40
5.3.1	Live Preview	42
5.3.2	Quick Access - Recording	44
5.3.3	Quick Access - Streaming	45
5.3.4	Ptz camera control	46
5.3.4.1	Roomcam zoom adjustment	46
5.3.4.2	Roomcam movement adjustment	46
5.3.4.3	Save camera setting (Preset)	47
5.3.4.4	Delete camera setting (Preset)	48
5.3.4.5	Enable camera setting (Preset)	48
5.4	“Recording” function	49
5.4.1	Image data post-processing	50
5.4.2	Selecting the signals to be recorded	50
5.4.3	Recording	52
5.4.4	Snapshot and video playback	53
5.4.5	Crop video	54
5.4.6	Export images and videos	55
5.4.7	Delete images and videos	57
5.4.8	Printing function	58
5.5	“Video Conference” function	60
5.5.1	Select the signals to be sent by video conference	61
5.5.2	Removing the signals to be sent by video conference	62
5.5.3	Call recipient selection	62
5.5.4	Call start	63
5.5.5	Call H.323/SIP recipient	64
5.6	On air lamp	65
5.7	Additional functions	65
5.7.1	Patient data management	66
5.7.1.1	Selecting a patient present in the list	66
5.7.1.2	Entering a new patient	67
5.7.1.3	Entering an emergency patient	68
5.7.1.4	Searching for a patient present in a list	69
5.7.1.4.1	Emergency patient Filter	69
5.7.1.5	Patient master data modification	70
5.7.1.6	Deleting a patient	70
5.7.1.7	Accessing the worklist	71
5.7.2	Surgical Checklist	72
5.7.3	Preset	73
5.7.3.1	Preset setting	73
5.7.3.2	Enabling Preset	75
5.7.4	Multiview	76
5.7.4.1	Multiview setting	77
5.7.5	Audio control	78
5.7.5.1	Volume adjustment	79
5.7.5.2	Disabling microphones and audio	80
5.7.6	Management of surgical lights	81
5.7.7	Environmental control panel management	82
5.8	“Lock with PIN” function	83
5.9	“Login” function	84
6	Electromagnetic compatibility	85
7	Disposal instructions	88
8	SVHC (Substance of very high concern)	88
9	Annex I - Short manual	89

1 General preliminary information

1.1 Operator's responsibility

The instructions for use of Truelink 4 Video Management System are intended for operators trained and authorized to handle it. The management of the medical site is responsible for the training of the staff on the use of the medical device.

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

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

NOTICE

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

1.2 Updates

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

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

1.3 Language

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

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

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

1.4 Personnel qualifications






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












Qualification	Description
Operator	Natural or legal person (for example a doctor or a hospital) who owns and uses the Truelink 4 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 Truelink 4 Video Management System in the activities required. They are responsible for the correct and safe operation of the system and ensures that it is used solely for the intended purpose.
Qualified Personnel	Authorized persons who are generally employees of the manager or who have acquired their skills through professional training in the medical sector, who are able to evaluate their work and recognize potential risks based on their professional experience and knowledge of safety regulations. Where required, qualified personnel must certify their qualifications by means of a valid document.

1.5 Symbols

The Truelink 4 Video Management System units are fitted with device labels. Each device label contains the identification details of the unit.

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

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

Symbol	Description
	Symbol used to indicate the date of manufacture.
	Symbol used to identify the manufacturer's name.
	Barred bin: this product must not be disposed of as municipal mixed waste, collect separately.
	Symbol used to indicate the Videomed S.r.l. material number.
	Symbol used to indicate the serial number.
	Symbol used to indicate a medical device.
 (01)00615521031626 (21)123456789012 (11)210212	Indicates the Unique Device Identification UDI code, is composed of UDI-DI (01) and UDI-PI ((11) date of production (21) serial number).
	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)
	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.
	Symbol used to indicate the model number.
	China RoHS symbol

1.6 Product certification



The Truelink 4 video management system is a Class I medical device according to Regulation 2017/745/EU concerning medical devices, and is compliant with the version of the regulation currently in force at the time of product sale. Videomed S.r.l. declares the conformity of Truelink 4 with the general safety and performance requirements according to Regulation 2017/745/EU concerning medical devices, Annex I. A conformity assessment procedure required for Class I devices shall be carried out in accordance with Article 52 (7), taking into account a quality management system in accordance with Annex IX, Chapter 1. The manufacturer confirms conformity with the CE marking.

1.7 Warranty

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

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

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

Further details may be present in the commercial contract.

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

2 Safety information

2.1 General safety warnings

The Truelink 4 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 if the insulation is damaged.

DANGER

ELECTRIC 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 its components.

DANGER

ELECTRIC SHOCK FROM WRONG POWER CONNECTION PROCEDURE!

The Truelink 4 system must be powered and receive protective earth from the same electrical panel that powers the operating room. Also all equipment connected to the Truelink 4 system must be powered and receive protective earth from the same electrical panel that powers the operating room.

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 Truelink 4 Video Management System.

CAUTION

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

⚠ CAUTION

MEASUREMENT OF DISPERSAL CURRENTS!

It is necessary to measure the leakage currents with the circuits downstream of the Truelink 4 system open. Otherwise, the leakage currents of these circuits will be added to those of the Truelink 4 system.

⚠ CAUTION

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

2.2 Security considerations

Below are the security best practices that should be followed:

User access management:

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

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

Authentication:

Authentication can be enforced to access the product. Usually, the authentication is in the form of a username and a password. Therefore, the following steps are recommended:

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

Remote connection support:

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

Browser security:

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

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

Data protection:

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

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

Updates and patches:

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

Logging:

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

Secure configuration:

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

User training:

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

Malware protection:

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

2.3 Privacy considerations

Types of data processed by the device:

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

Data that may be processed by the system:

- Patient identifiers: Patient registration information like names, birthdates, gender, and patient IDs for accurate patient selection and data association as determined by the customer's systems.
- Patient treatment information: Including medical data such as surgical worklists, medical conditions, details of the surgery, and audio and video recordings of the surgery.
- Medical images: Images from PACS (e.g., MRI, CT scans, X-rays).
- Truelink 4 system user data (Healthcare providers (HCPs) and customer support staff): Full names, user or network IDs, account passwords for login, audio and image data extracted from surgery videos.
- Annotations and comments: Annotations and comments to medical images that can be made by users and are stored only within the system. They may contain surgery details and other related data, and should not contain any unnecessary personally identifiable information.
- User access and activity logs: Login information, timestamps, actions, and data changes for system security and audit trails.
- System metadata: Data transfer logs, cache information, and performance metrics for system maintenance.

User responsibilities:

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

Privacy features in the product:

The Product has features that help protect patient data.

- Local storage: Data is only temporarily stored on the Truelink 4 system, which is hosted on-premises at the customer's facility and is then transferred to the customer's system and servers. The system locally stores videos and images from video sources in the operating room on the customer's servers, ensuring that patient data remains on-premises at the customer's facility.
- Encryption: Databases containing patient health information (PHI) or personal data are encrypted.

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

Below are privacy best practices that should be followed:

Access management:

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

Monitoring and updates:

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

User training:

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

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

Data use and retention:

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

Regular privacy audits:

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

Third-party compliance:

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

Responsible disclosure / Report a security or a privacy issue:

In case a security or privacy issue about the product is observed, the healthcare provider should report the issue to Baxter as soon as possible. Go to [Product Security | Baxter \(https://www.baxter.com/product-security\)](https://www.baxter.com/product-security) for information on how to report a potential issue.

2.4 Useful life of the system

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

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

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

2.5 Cleaning

NOTICE

Risk of material damage

Excess liquid may cause damage to internal electronics.

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

NOTICE

Risk of material damage

Do not clean the Truelink 4 unit's rear connector panel, or any of its connectors or buttons. This may cause damage to the connectors, buttons, and internal electronics.

- Call Baxter service.

NOTICE

Risk of material damage

Abrasive materials may cause damage to the devices.

- Use a soft cloth.

2.5.1 Cleaning agents

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

- Organic, mineral, and oxidizing acids
- Bases
- Organic solvents (e.g., ether, ketones, benzines)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons
- Any other substance that is chemically aggressive to plastics

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

2.5.2 Preparing the devices

Before cleaning the devices, proceed as follows:

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

2.5.3 Cleaning the devices

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

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

2.6 Preventive maintenance

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

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

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

3 System description

3.1 Intended use

The Truelink 4 Video Management System is a medical video communication system used exclusively to display and manage existing audio-video sources, and to control an operating light within the specifications established by the manufacturer.

3.2 Intended medical indication

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

3.3 Device contact site

The medical device has no contact with patients.

3.4 Patient population

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

3.5 Intended users

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

3.6 Use environment

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

- Surgical theaters in hospitals
- Outpatient surgery centers
- In the offices of physicians in private practice and other operating room-like environments, when the video conference function is used.
- **Note:** If Truelink 4 is placed on a boom shelf, keep a distance of 1.5 m or more to the surgical area during surgery.

3.7 Normal use

- The system is used exclusively for displaying and managing already existing audio-video sources.
- Controlling signals via a touchscreen monitor
- Distributing analogue and digital signals to different video outputs
- Export data into other devices (not part of the MD)
- Document the intervention through temporary archiving

- Exchange of information by video conference with the operating room by sharing images and videos with the world outside the room in high resolution
- Regular maintenance of the MD in accordance with the defined maintenance intervals by qualified service technicians
- Initial operation by the operator
- Repair and disposal of the MD must be performed by qualified service technicians as required
- To control the on/off state and intensity of compatible surgical lights

3.8 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 used to correct the 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 (or monitors connected to the system) shall not be used as the primary source of information.

3.9 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". In the event of such misuse, the manufacturer declines any liability for damage caused to things or persons and deems any type of warranty for the system void.

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

3.10 Use associated with other devices

3.10.1 Combination with other Baxter products

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

3.10.2 Combination with products of other manufacturers

The Truelink 4 Video Management System can be combined with devices from other manufacturers.

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

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

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

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

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

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

3.11 Obligations and prohibitions

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

3.11.1 Personnel prohibitions

In particular, the personnel must not the following:

- 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”)



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

3.12 Technical data

MAIN UNIT - Technical Specs

Video Inputs	18 (14 DVI, 2 3G-SDI, 2 CVBS)
Video Outputs	10 FullHD DVI
Supported Resolutions	Standard video PAL (720 x 576), NTSC (720 x 480) HDTV (1280 x 720) Full HDTV (1920 x 1080p) PC resolution (1024 x 768*, 1280 x 1024*, 1600 x 1200*, 1920 x 1200) UHD / 4K option with UHD unit * Routing only
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

MAIN UNIT - Technical Specs

Enclosure	IP20
Environmental conditions	Operating temperature: +10/+40 °C Operating relative humidity range: 30% to 75% Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa Storage temperature: -40/+70 °C Storage relative humidity range: 10% to 100% including condensation Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa
Max Operation Altitude	5000 mt
Control Touchscreen	21", 24" or 27" , 1920 x 1080, 16:9
Storage Capacity	2 TB
Audio Inputs	3 x Microphones 2 x Aux Stereo 1 x Video conference
Audio Outputs	1 x Stereo amplified 1 x Stereo non-amplified 1 x Video conference 2 x Speakers terminal out (L/R)
Communication Protocols	DICOM HL7 (Only with an additional gateway provided through a partner third-party vendor.)
Other Connections	2 x USB 2.0 3 x USB 3.0 12 x Serial ports RS232 (2 x Serial ports RS232 reserved for the manufacturer)
Unit Weight	13.5 kg
Recording function ^{*1}	Time shift recording Movie Around The Snapshot 2x Recording channel Endotrigger recording compatibility

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

CONFERENCE UNIT - Technical Specs

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

CONFERENCE UNIT - Technical Specs

Protection	Short circuit protection Overload protection Overcurrent protection Overvoltage protection
Insulation Voltage	Input / Output 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
HD Audio	MicPod 100Hz fino a 16 kHz Mute button
Unit Weight	8 kg

*1 3D side-by-side only.

UHD 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

UHD UNIT - Technical Specs

Max Operation Altitude 5000 mt

Enclosure IP20

Unit Weight 5.5 kg

UHD 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 Fiber cabling

Additional Ports 4 x DVI over CAT6/7 output scaled to FullHD 1080
4 x DVI over CAT6/7 pass-through input (FullHD 1080)

Dimensions 44 x 430 x 450 mm

Power Supply 100-240 V 50-60Hz AC

Power Consumption 30 W

Protection Short circuit protection
Overload protection
Overcurrent protection
Overvoltage protection

Insulation Voltage Input / Output 4000 V AC
Input / FG 1500 V AC

Environmental conditions Operating temperature: +10/+40 °C
Operating relative humidity range: 30% to 75%
Operating atmospheric pressure range: 54.0 kPa to 106.0 kPa
Storage temperature: -40/+70 °C
Storage relative humidity range: 10% to 100% including condensation
Storage atmospheric pressure range: 50.0 kPa to 106.0 kPa

Max Operation Altitude 5000 mt

Enclosure IP20

Unit Weight 5.5 kg

RACK UNIT (optional) - Technical Specs

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

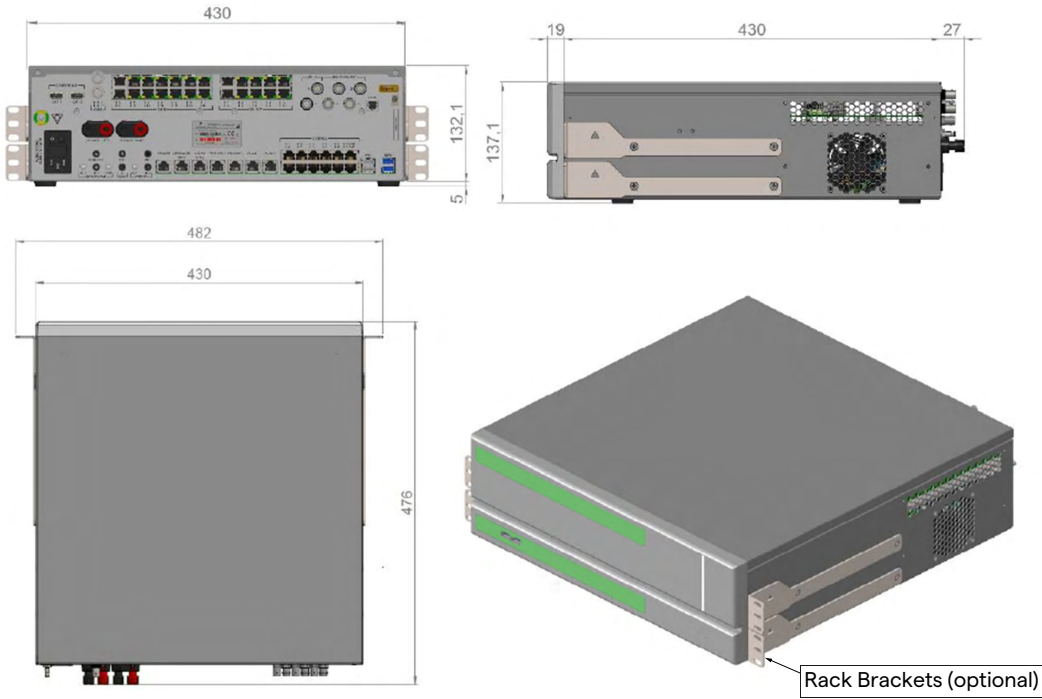
3.13 Measurement and weight layout

MAIN UNIT

Dimensions	133 x 430 x 450 mm
Unit Weight	13.5 kg



Rack Dimensions (optional)

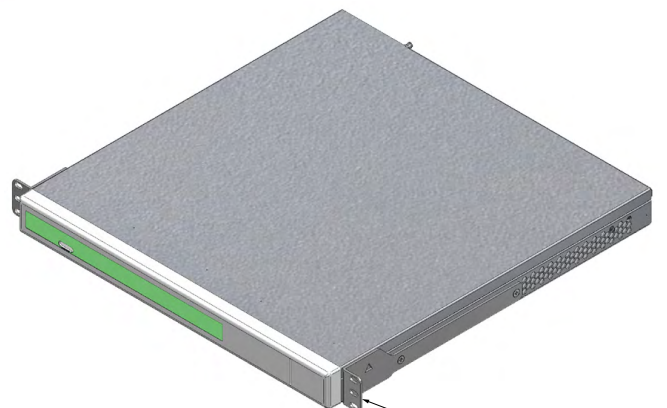


CONFERENCE UNIT

Dimensions	44 x 430 x 450 mm
Unit Weight	8 kg



Rack Dimensions (optional)



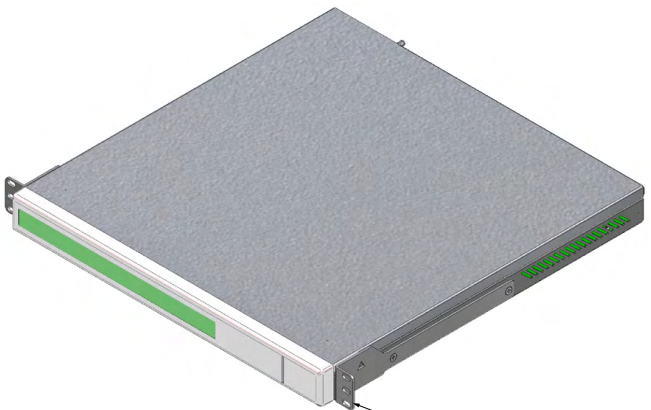
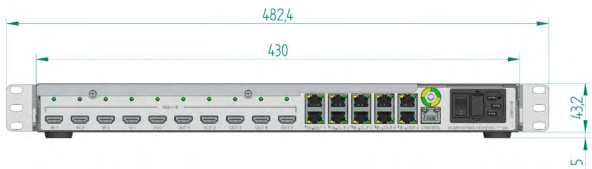
Rack Brackets (optional)

UHD UNIT

Dimensions	44 x 430 x 450 mm
Unit Weight	5.5 kg



Rack Dimensions (optional)



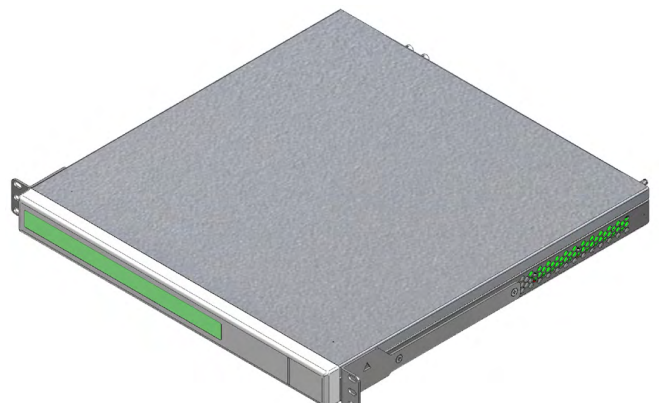
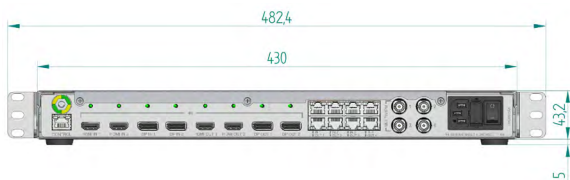
Rack Brackets (optional)

UHD PLUS UNIT

Dimensions	44 x 430 x 450 mm
Unit Weight	5.5 kg



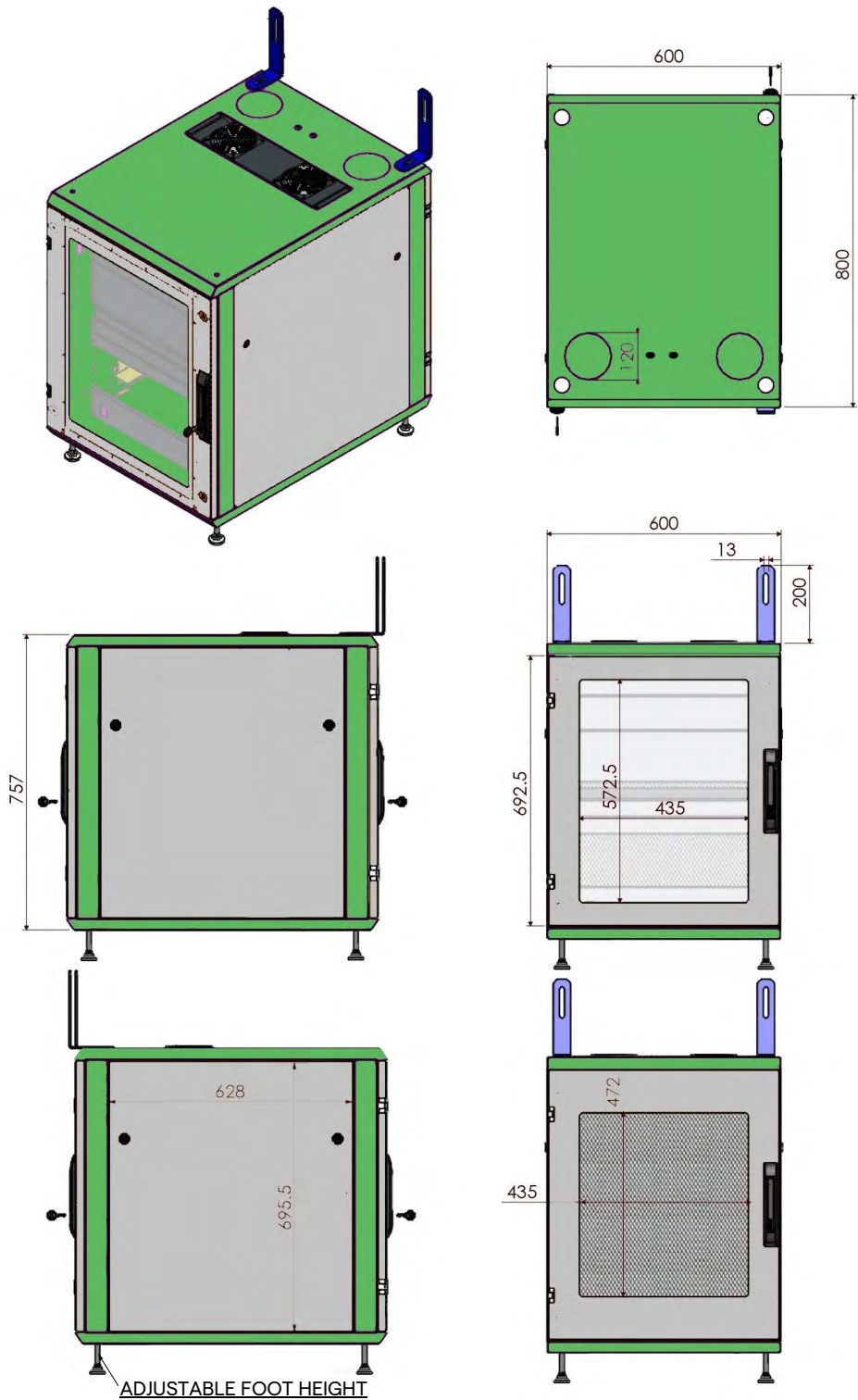
Rack Dimensions (optional)



Rack Brackets (optional)

RACK UNIT

Dimensions	800 x 600 x 757 mm
Unit Weight	64 kg



3.14 System components

The Truelink 4 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.



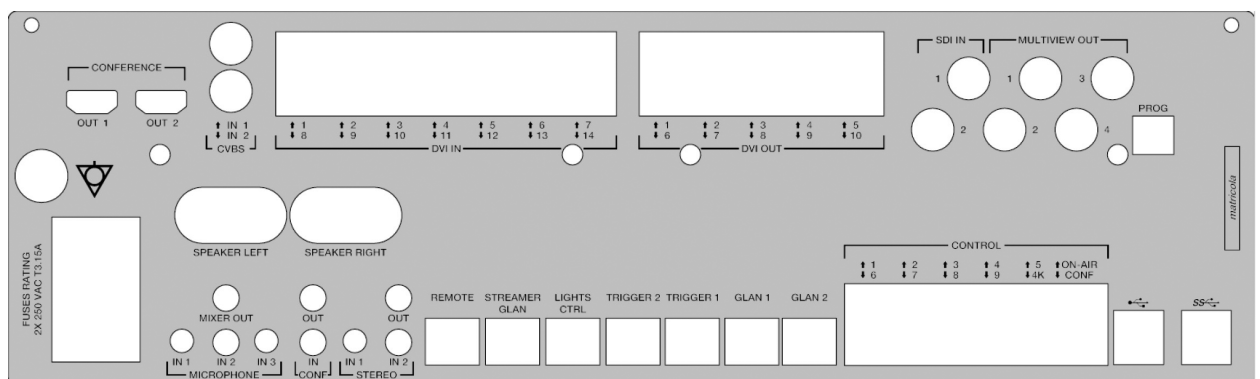
- [1] UHD UNIT or UHD PLUS UNIT
- [2] CONFERENCE UNIT
- [3] MAIN UNIT

3.14.1 Main unit

The following functions are available via the Main unit.

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

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

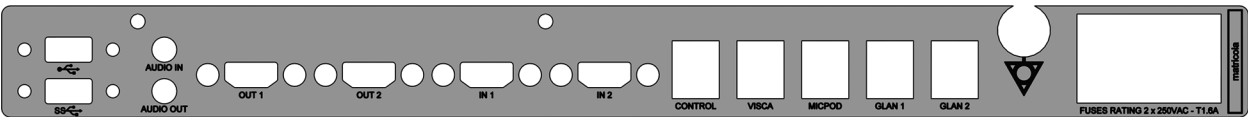


The connection cables are supplied by Videomed S.r.l.

3.14.2 Conference unit

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

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

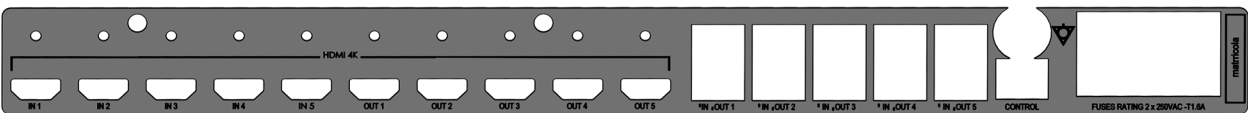


The connection cables are supplied Videomed S.r.l.

3.14.3 UHD unit

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

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

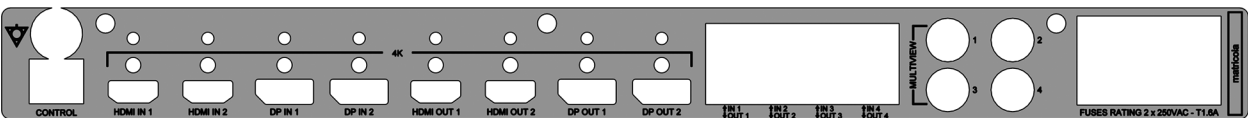


The connection cables are supplied Videomed S.r.l.

3.14.4 UHD Plus unit

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

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

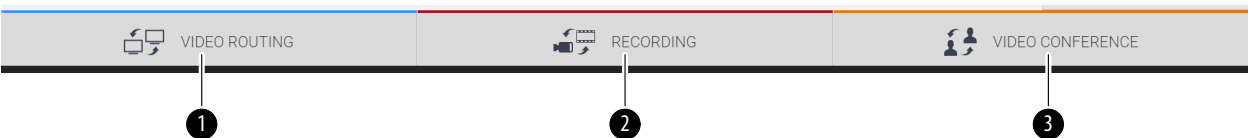


The connection cables are supplied Videomed S.r.l.




3.14.5 Control software

The User Interface of Truelink 4 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. 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. This function enables to record 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 Truelink 4 Video Management System also assures control and management of the main devices installed in the operating room:

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

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

4 Operation

4.1 First system start

The Truelink 4 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 Truelink 4 Video Management System is validated by a document signed by the operator.

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

4.2 Preliminary checks

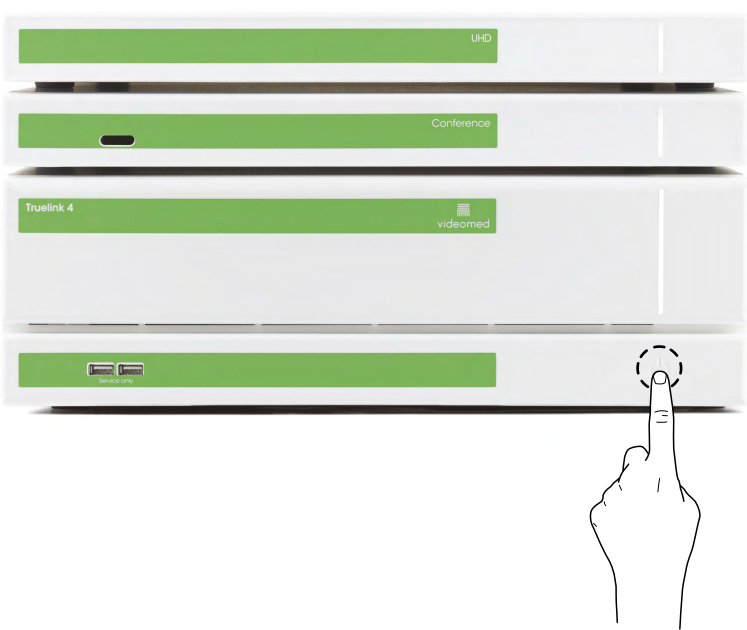
Before each use, check the components of the control screen, in regards to:

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

Cleaning is done during maintenance.

4.3 System start-up

To start the system, proceed as follows:

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

4.4 Connection to the sources

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

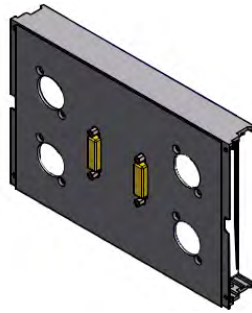
The Preview updates periodically as long as the signal remains active.

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

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


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

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



4.5 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 flashing frequency of the LEDs increases visibly. 2. Once the frequency has changed, remove your finger from the button. 	

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

In case it is necessary to interrupt communication between Truelink 4 and any controlled devices, proceed to shut down the system.

4.6 System start-up/shutdown with remote button

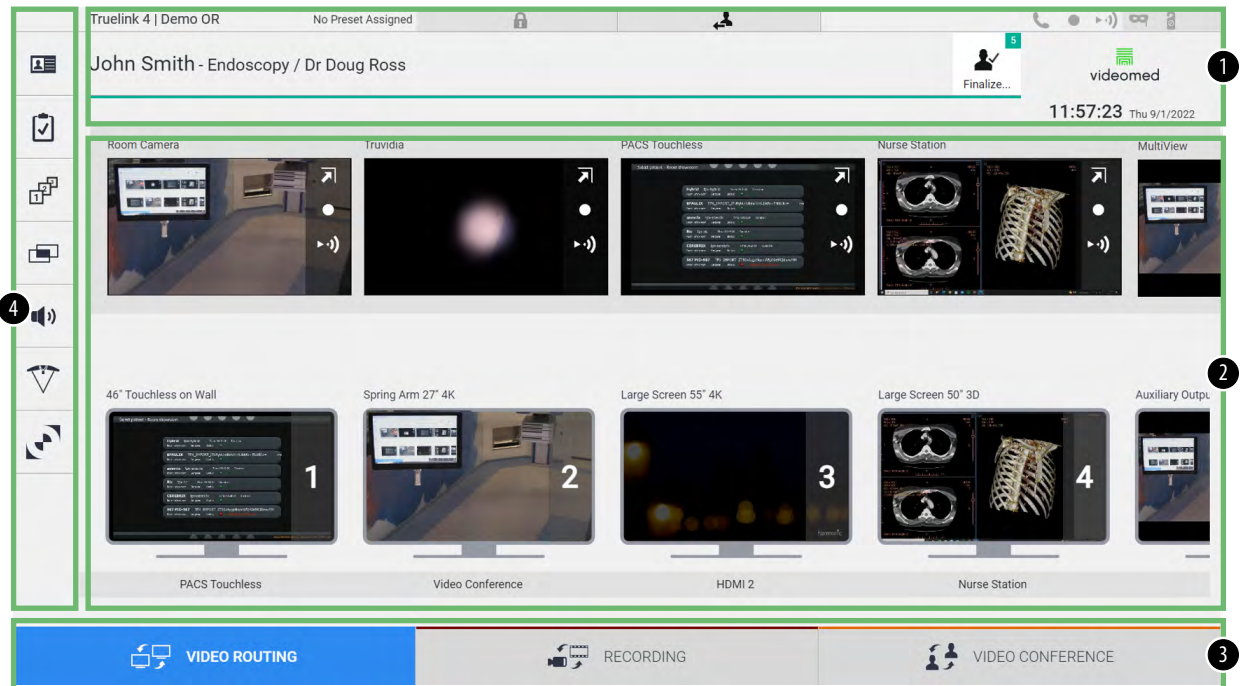
The Truelink 4 Video Management System allows the units to be restarted via a remote on/off button installed inside the operating room (typically on a pendant panel or wall unit).

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

5 User Interface

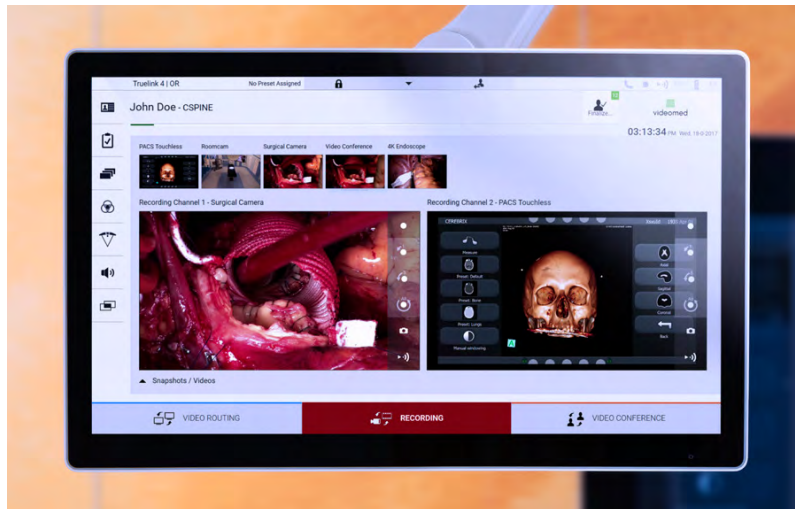
5.1 General description of the user interface

The user interface is divided as follows:



No.	Element	Description
[1]	STATUS BAR	It contains important information such as the patient's name and the number of recorded media related to them. Information such as the date, time and a dashboard showing the status of the recording, the video conference, the streaming and the advanced modes "Privacy Mode", "Do Not Disturb" and "Lecture Mode" are also present.
[2]	MAIN SECTION	Area for the functions to select the source and identify the monitors. The structure of the area varies according to the control functions activated.
[3]	SELECTION BAR	Bar located at the bottom of the screen, with which the following functions can be selected: <ul style="list-style-type: none"> – Video Routing (identified with blue), – Recording (identified with red), – Video Conference (identified with orange)
[4]	SIDE MENU	Bar on the left side of the screen that allows access to setup and workflow management screens.

5.2 Control touchscreen



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

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

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

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

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

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

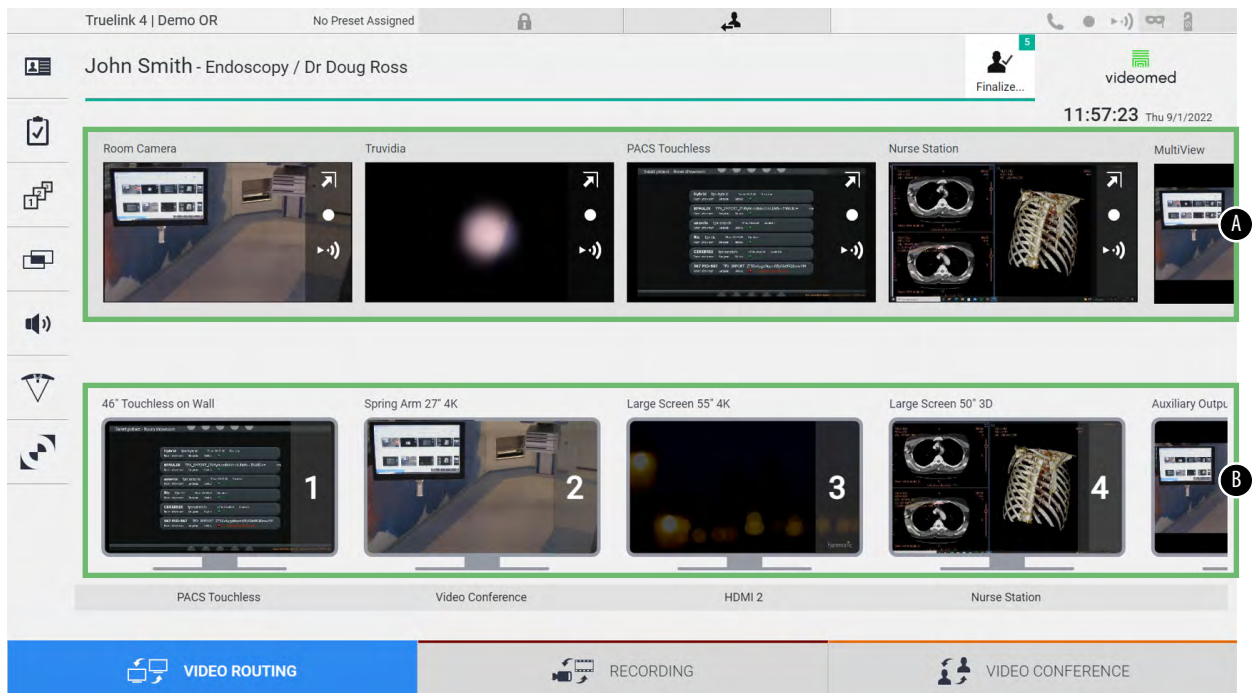
5.3 “Video Routing” function

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

- endoscope,
- surgical video camera,
- roomcam.

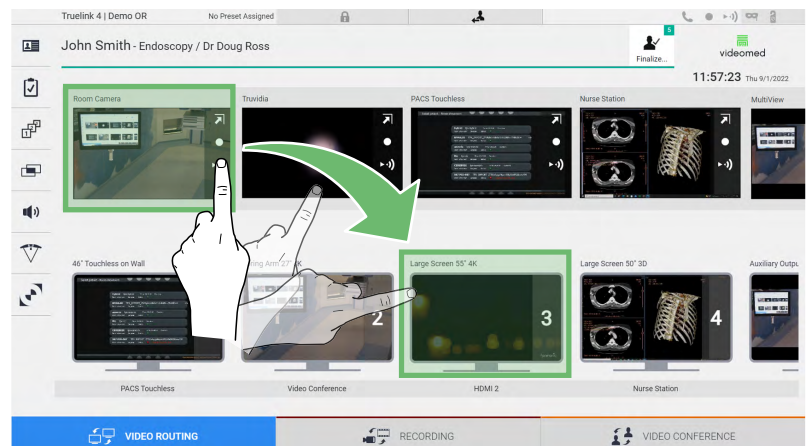
These video signals can be routed to any monitor in the operating room.

The main Video Routing screen is divided as follows:



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

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


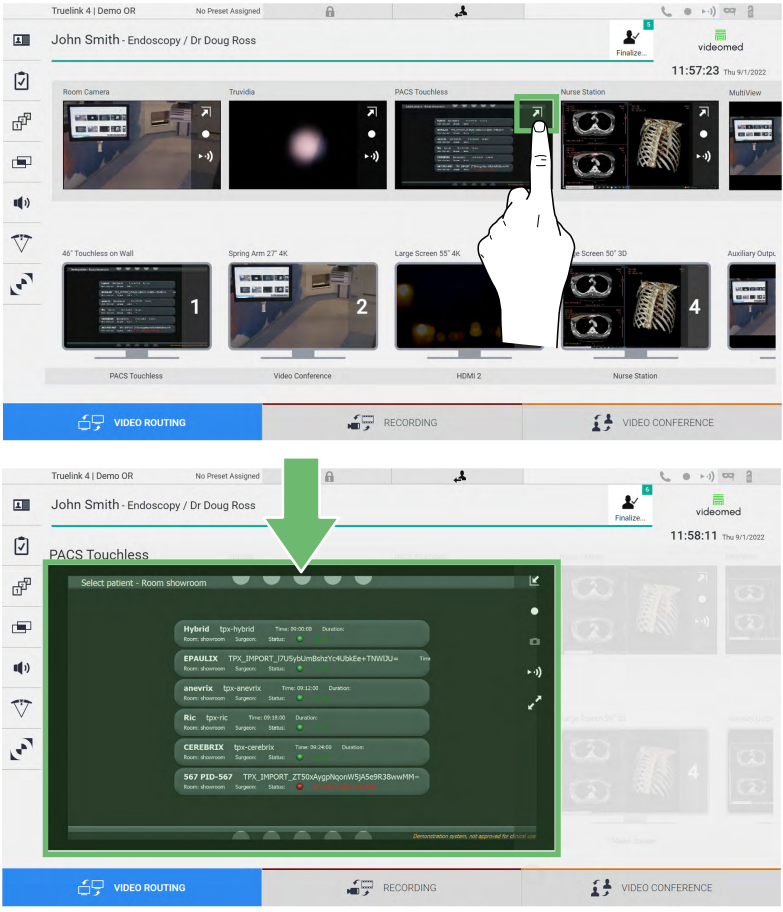

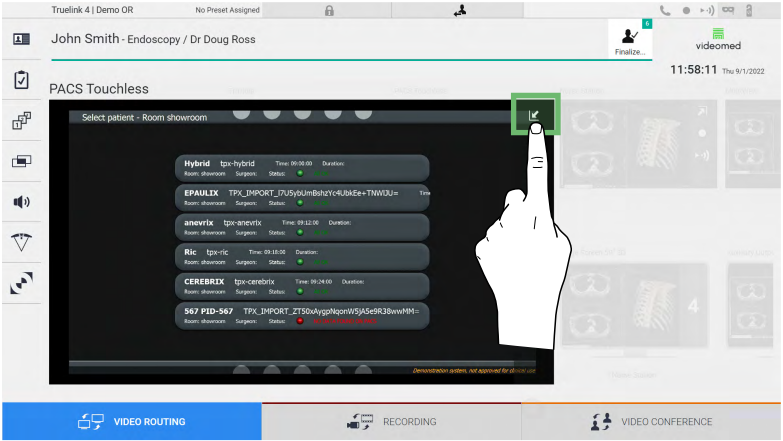


The Preview of the video signal sent will be displayed in the relative Monitor icon and updated periodically.





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

5.3.1 Live Preview

With the Live Preview function it is possible to enlarge or reduce the preview of the video signal of each connected source. To display the Live Preview of one of the signals available in the Source List, proceed as follows:

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

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.
	Enables to start/stop video signal streaming.
	Enables to activate the full-screen display function, without latency, of the selected source (function available only on some touchscreen monitor models).




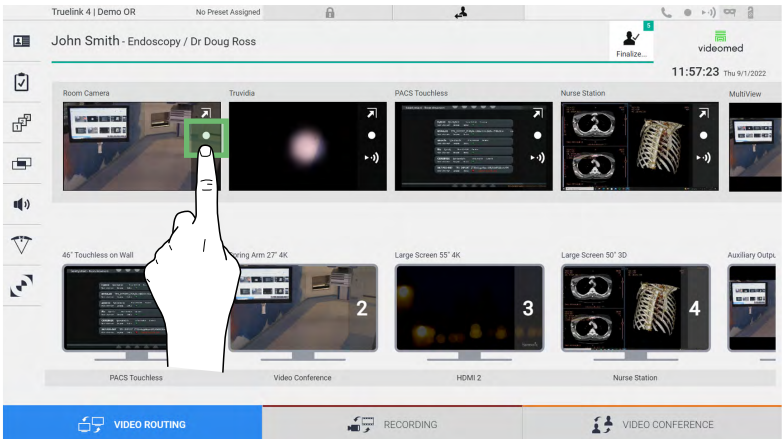
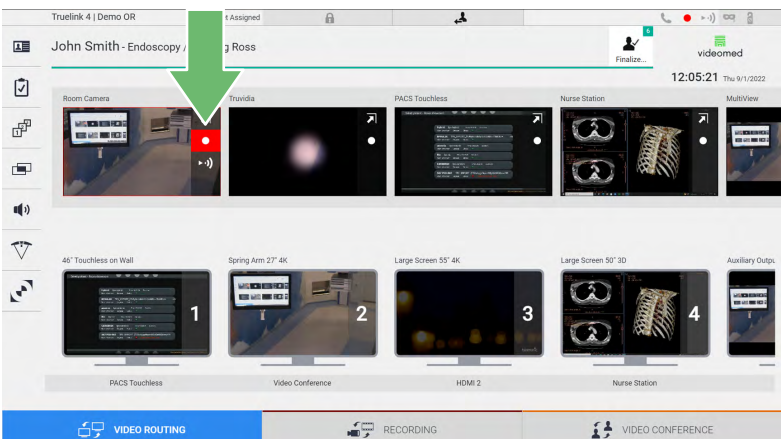
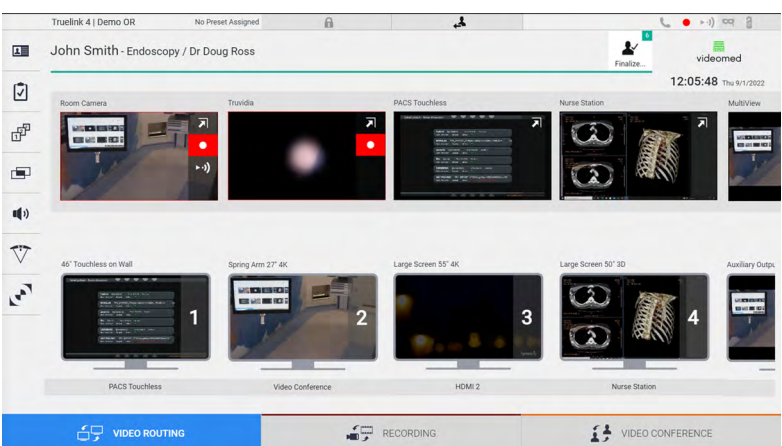
It is not possible to start recording if a reference patient is not present.

5.3.2 Quick Access - Recording

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





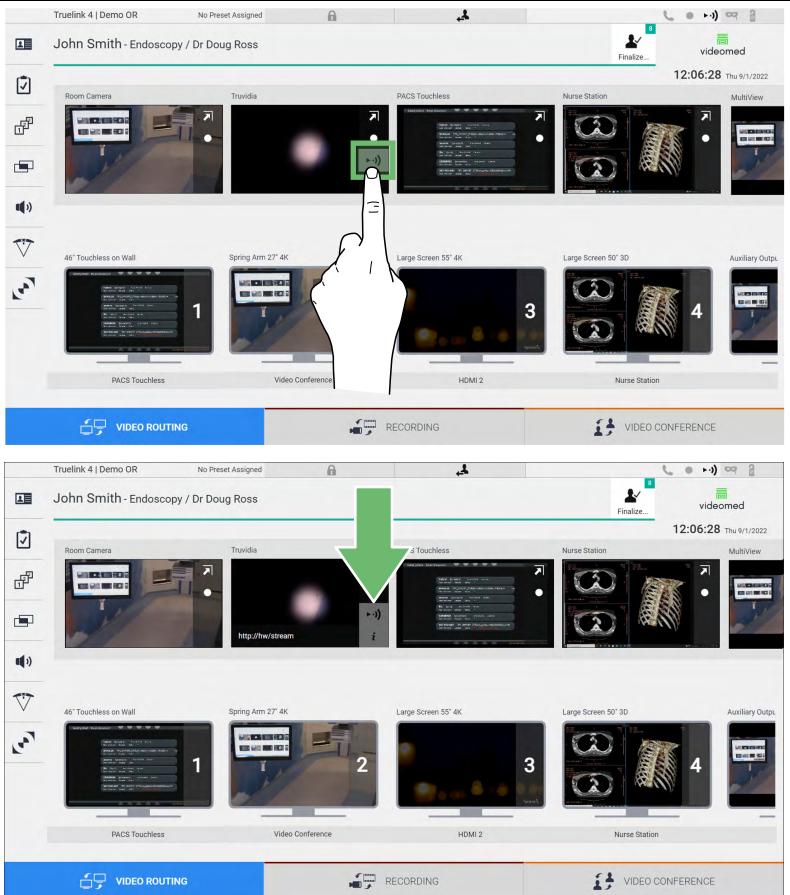
There is a dedicated Recording function to perform the recording. In any case, it is possible to use an additional quick activation system from the Video Routing function.

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

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

5.3.3 Quick Access - Streaming

To activate the streaming session, proceed as follows:



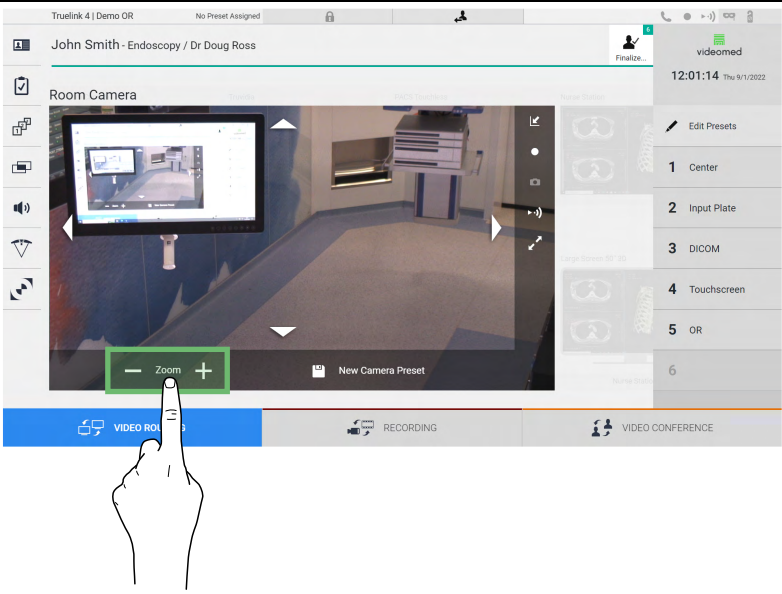
Step	Image
<p>1. Press the  box of a Preview to start streaming the signal from one of the connected sources.</p> <p>When streaming is active, the button is in white background  in the box of the selected source and is disabled in the Previews of the remaining sources.</p> <p>Pressing  in a Preview box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

5.3.4 Ptz camera control

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


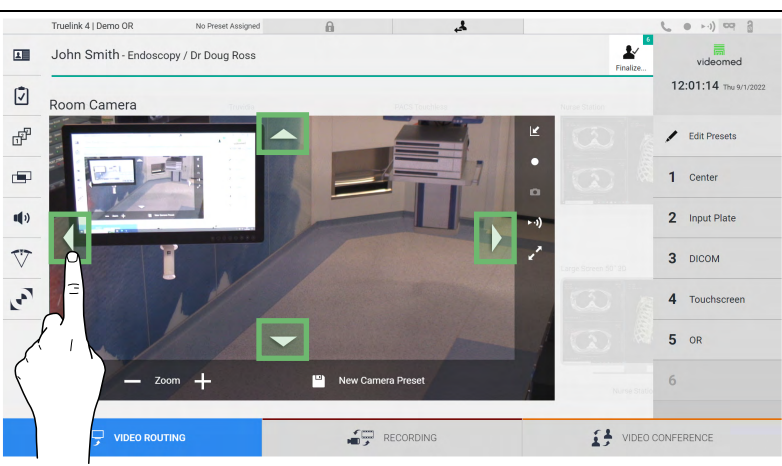
5.3.4.1 Roomcam zoom adjustment

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

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

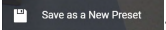
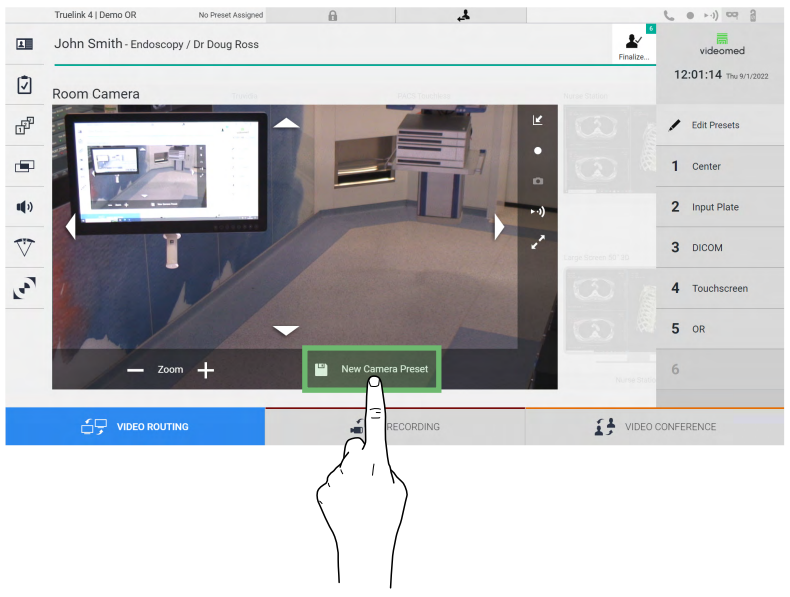

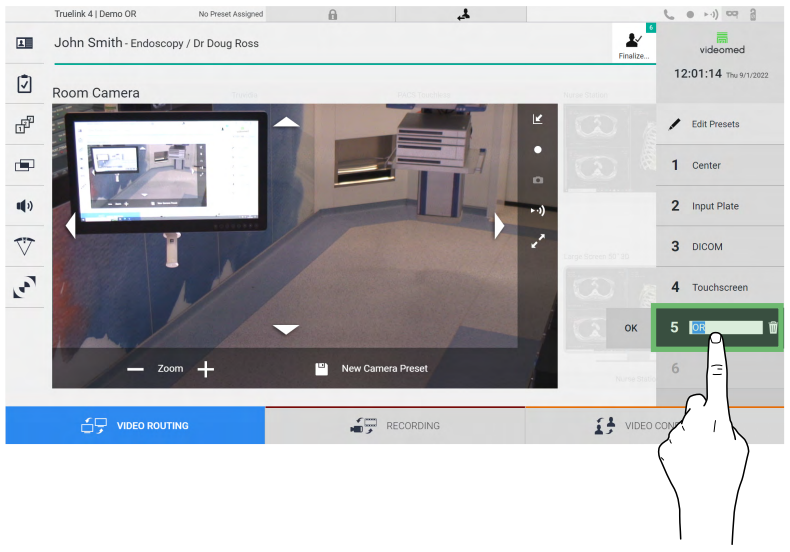
5.3.4.2 Roomcam movement adjustment

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

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


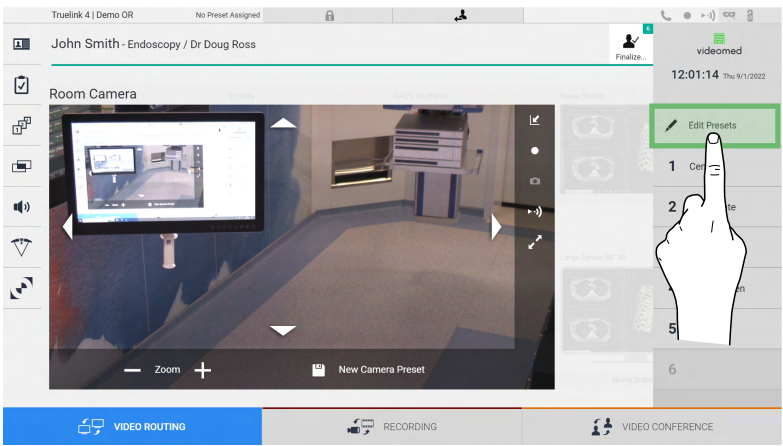

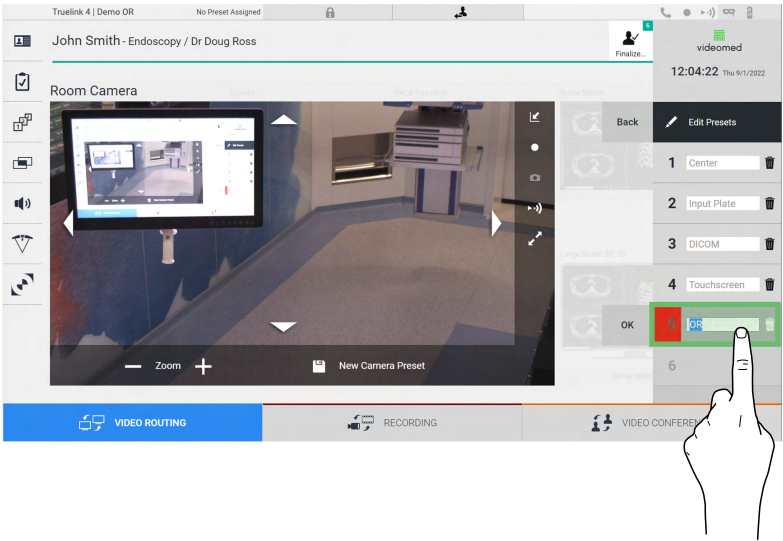
5.3.4.3 Save camera setting (Preset)

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

Step	Image
1. After adjusting the video camera to the desired position, press  .	
2. Enter the name to be assigned and press  to confirm. The new Preset with the name assigned will appear on the list on the side.	

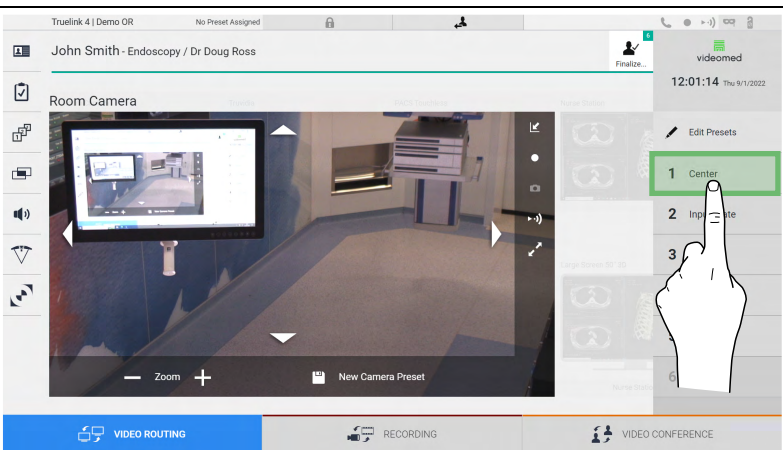
5.3.4.4 Delete camera setting (Preset)

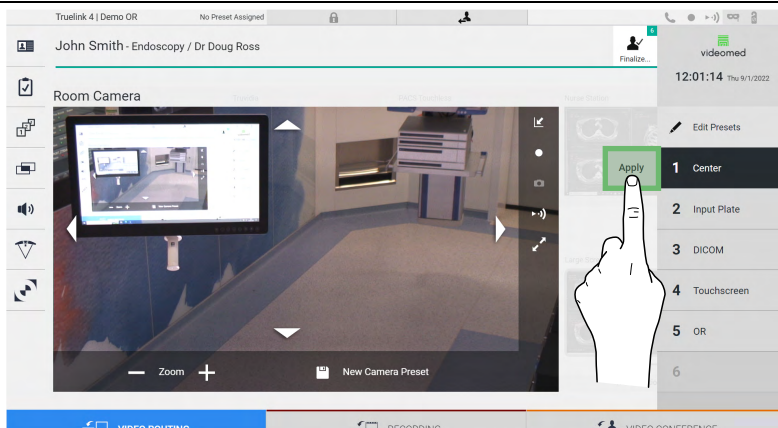
To delete a video camera setting from the Preset list, proceed as follows:

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

5.3.4.5 Enable camera setting (Preset)

To activate a video camera Preset, proceed as follows:

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

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

5.4 “Recording” function

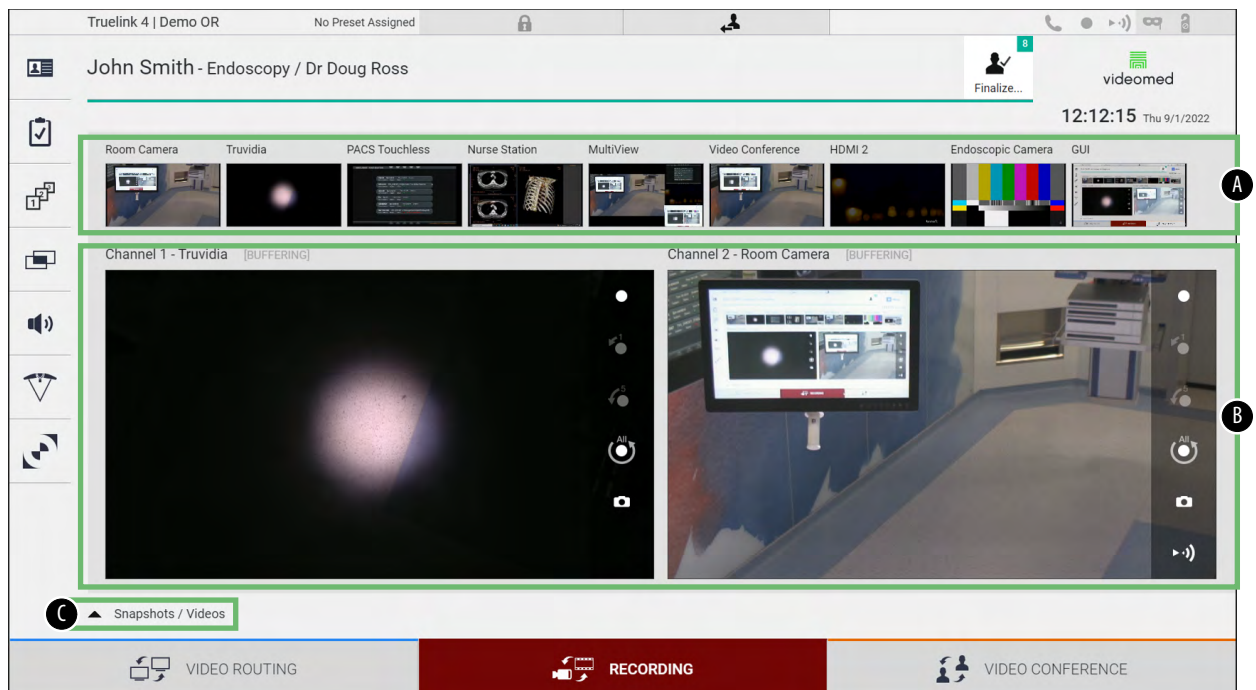
The Recording function enables to capture snapshots and record video from the signals connected to the system.

It is therefore possible to save and then modify images and videos, stored in the system. It is then possible to send the recorded material to a dedicated server (connected storage systems such as PACS, network or mobile storage media).

The Recording function includes:

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

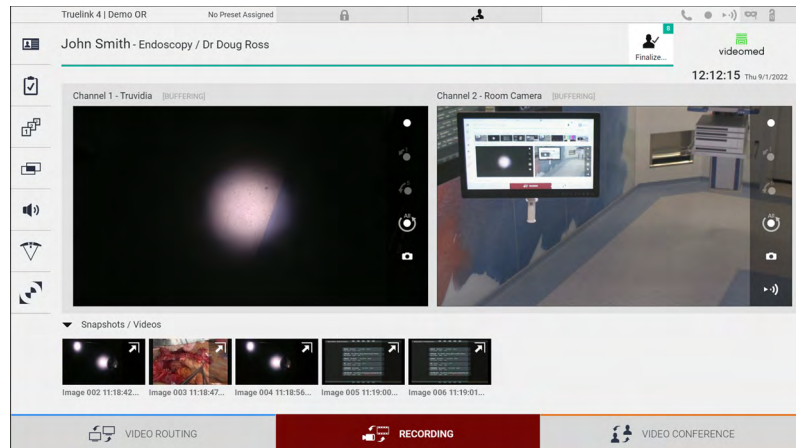
The main Recording screen is divided as follows:



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

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

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



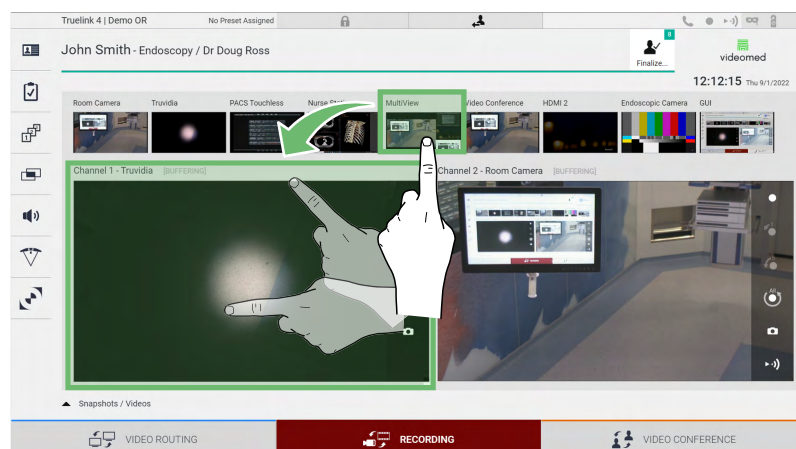
5.4.1 Image data post-processing

By using locally stored data it is possible to:







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

5.4.2 Selecting the signals to be recorded

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



The following icons are present in the Recording Channel window:




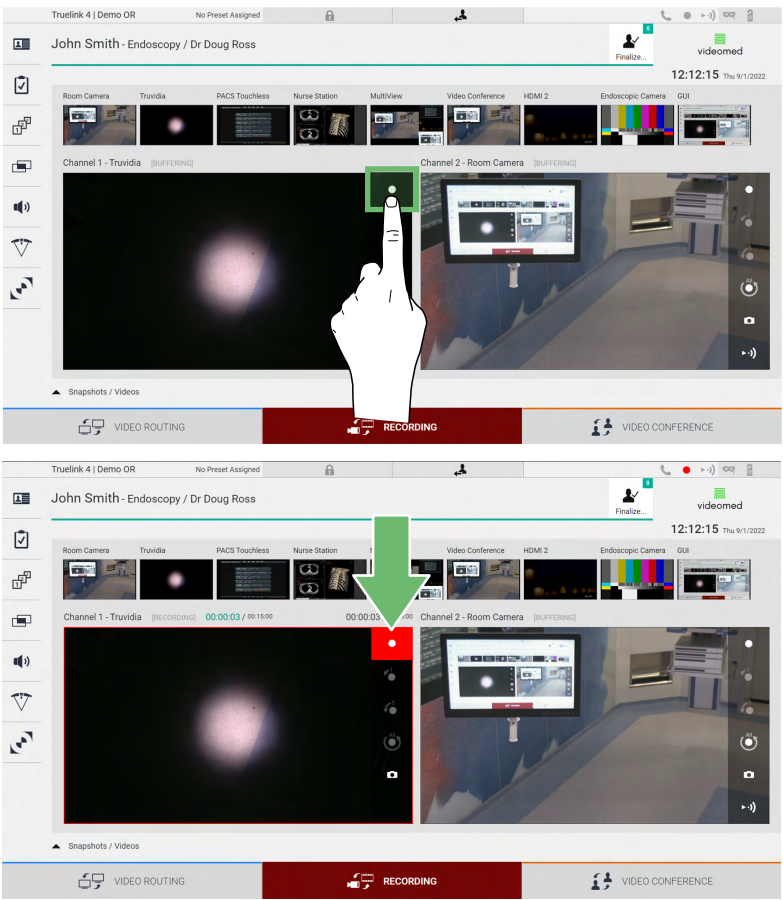
Icon	Function
	Enables to start/stop recording of the displayed signal. If the icon is gray, it indicates that the function is not active. To activate the function it is required to select a patient from the list (refer to paragraph "Selecting a patient present in the list").
	Enables to create snapshots of the video source.
	Enables to start/stop video signal streaming.
  	Enables to start recording: <ul style="list-style-type: none"> – 1 minutes before, – 5 minutes before, – the entire buffer available (up to a limit configurable by the technician).

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


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

5.4.3 Recording

To perform the recording from the Recording function, proceed as follows:




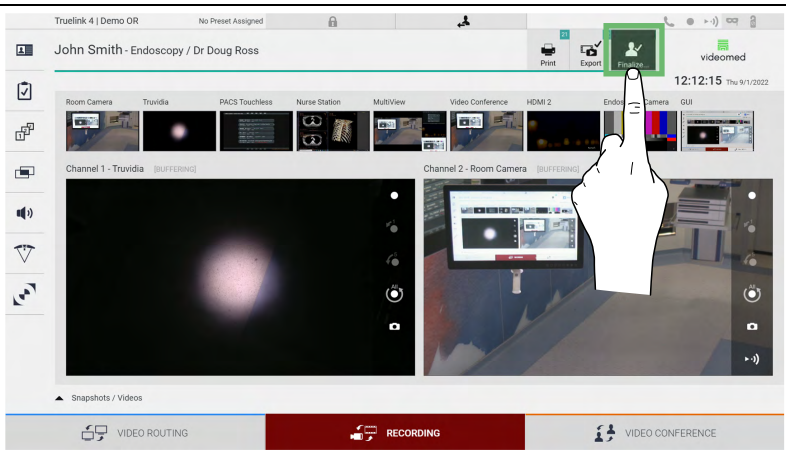

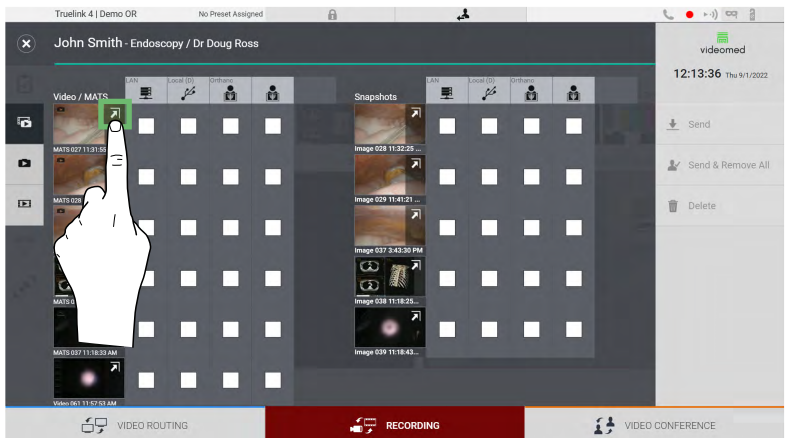
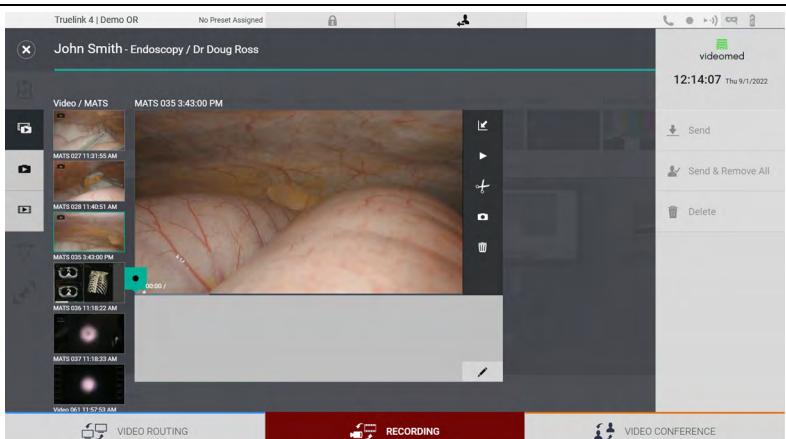





















Step	Image
1. Press the  box of a Recording Channel to start recording a signal. When recording is in progress, the button is red  in the Recording Channel selected. The  icon is also present in the upper part of the screen and it also remains visible when navigating through other functions (if recording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

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

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




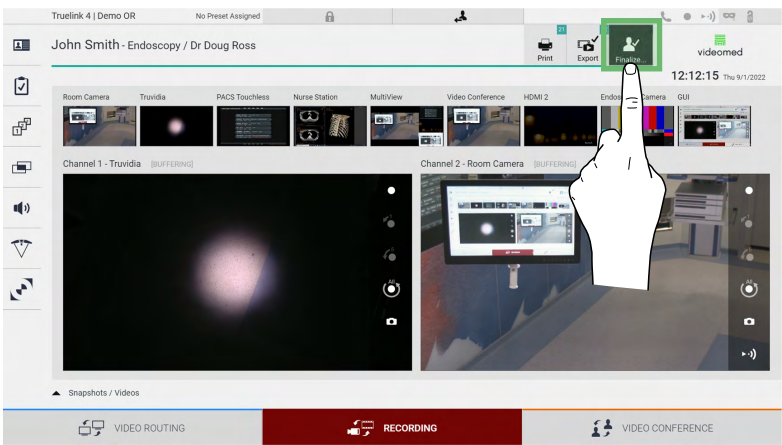

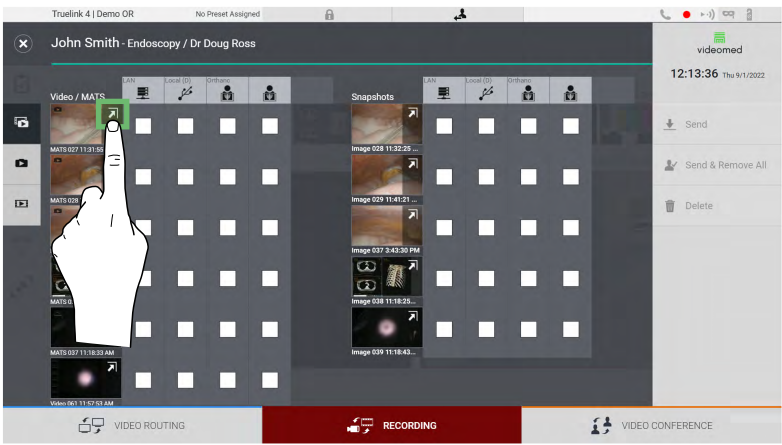



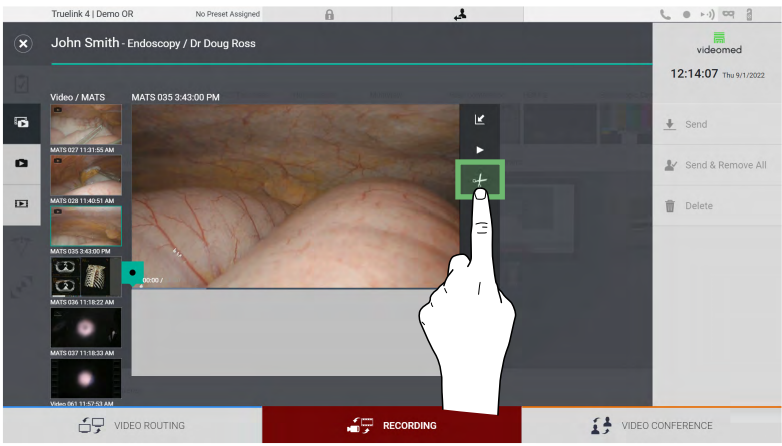
5.4.4 Snapshot and video playback

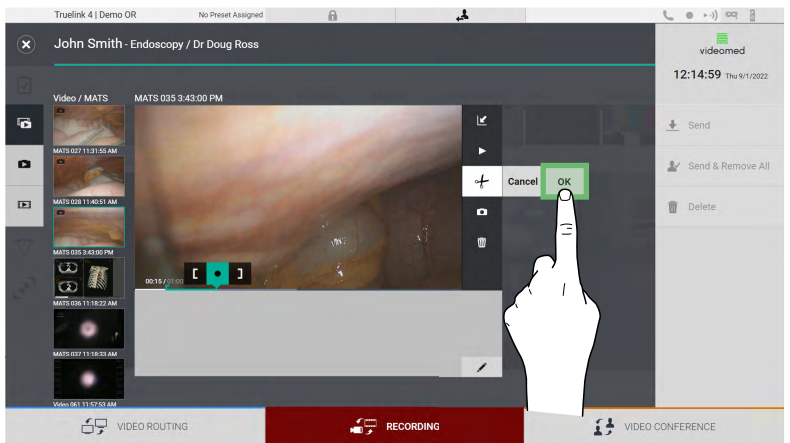
To play snapshots and videos, proceed as follows:

Step	Image																
1. Press  and then  (or simply press  if the printing function is not enabled) to view all images and videos related to the selected patient.																	
2. Press the  icon to enlarge the single media.																	
3. A new window appears which, depending on the file selected (image or video), allows you to:																	
<table border="1"> <thead> <tr> <th>Icon</th><th>Function</th></tr> </thead> <tbody> <tr> <td></td><td>Delete the file.</td></tr> <tr> <td></td><td>Add a comment.</td></tr> <tr> <td></td><td>Play the video.</td></tr> <tr> <td></td><td>Interrupt video playback.</td></tr> <tr> <td></td><td>Extract a part of the video.</td></tr> <tr> <td></td><td>Return to the full view of available functions.</td></tr> <tr> <td></td><td>Create a snapshot from the video being played.</td></tr> </tbody> </table>	Icon	Function		Delete the file.		Add a comment.		Play the video.		Interrupt video playback.		Extract a part of the video.		Return to the full view of available functions.		Create a snapshot from the video being played.	
Icon	Function																
	Delete the file.																
	Add a comment.																
	Play the video.																
	Interrupt video playback.																
	Extract a part of the video.																
	Return to the full view of available functions.																
	Create a snapshot from the video being played.																




5.4.5 Crop video

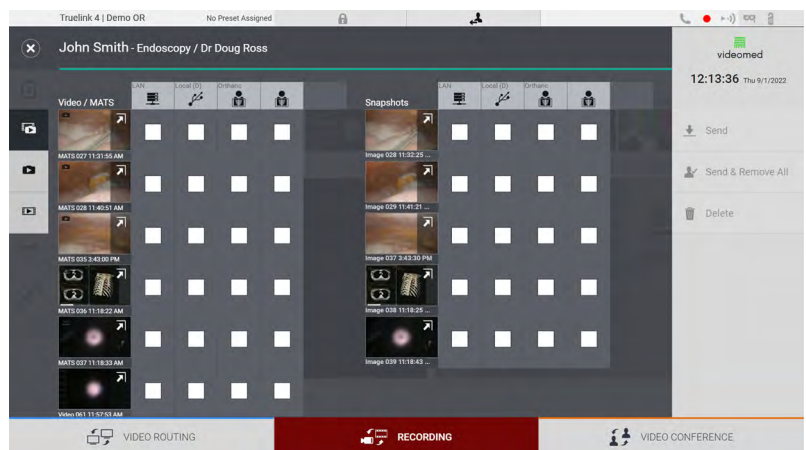
To cut the videos, proceed as follows:

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


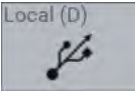
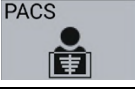
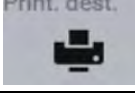
Step	Image
<p>4. Once the cutting points are determined, extract the portion of the video by pressing OK.</p> <p>A new video appears in the photo/video list of the same patient.</p>	

5.4.6 Export images and videos

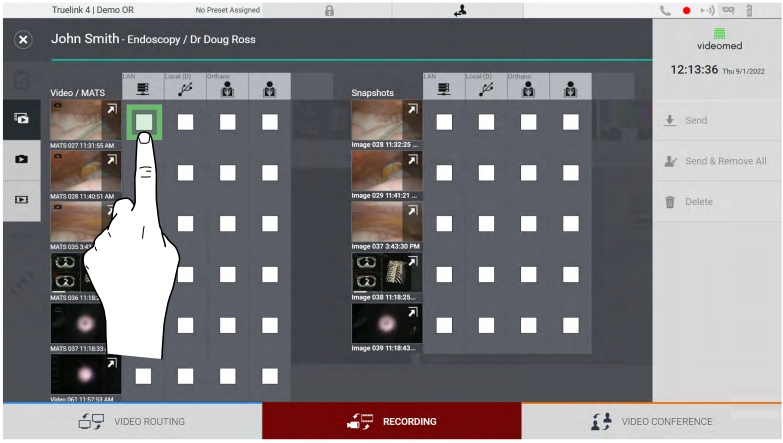
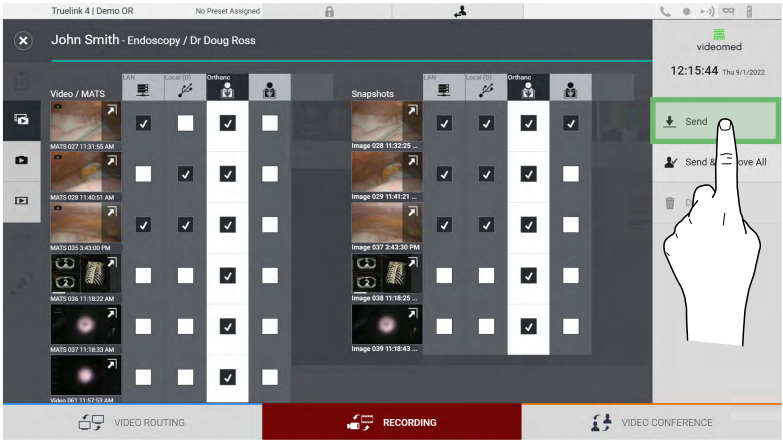
Press  and then  (or simply press  if the printing function is not enabled) to access the folder for exporting images and videos of the selected patient. This operation must be performed to export the media and optionally close the patient file. A screen with all the captured images and videos is displayed.




The following icons are present in the Export window:

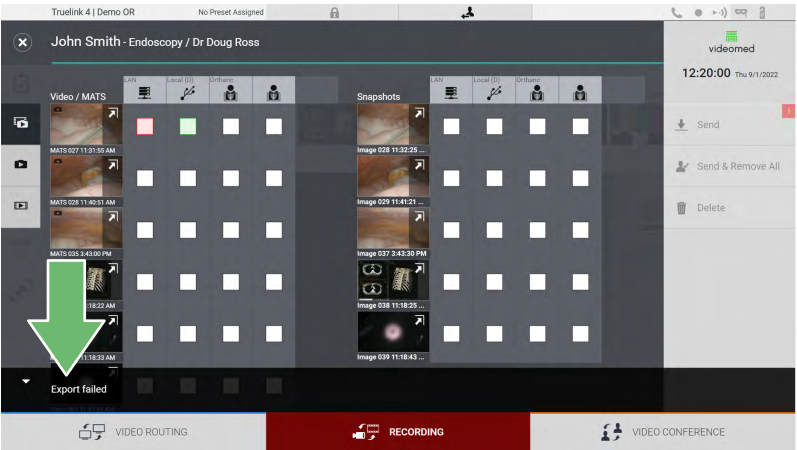
Icon	Function
	It enables to export via LAN to another device.
	Enables to save on a device connected to the USB port.
	It enables to export to the PACS system.
	It enables to export via LAN to a network destination connected to an external printer.

To export, proceed as follows:




Step	Image
1. Select the export destination. This must be done for the images or videos to be exported.	
2. Press Send (on the right side of the screen) to send the files to the selected destinations. By pressing Send & Remove All the files are sent to the selected destinations and the patient's session will be deleted.	

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.

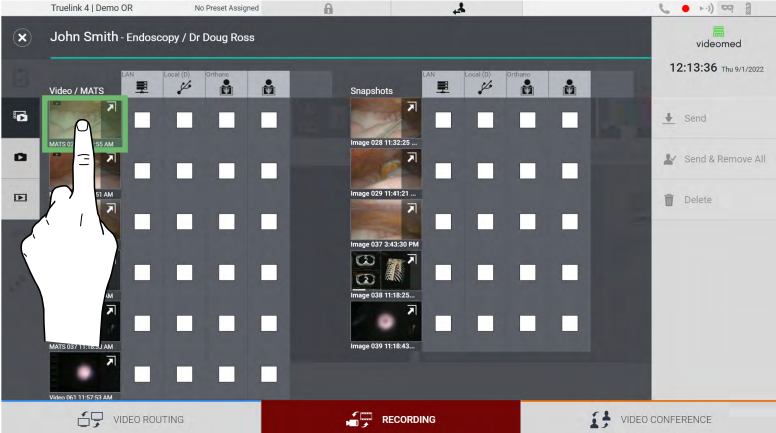

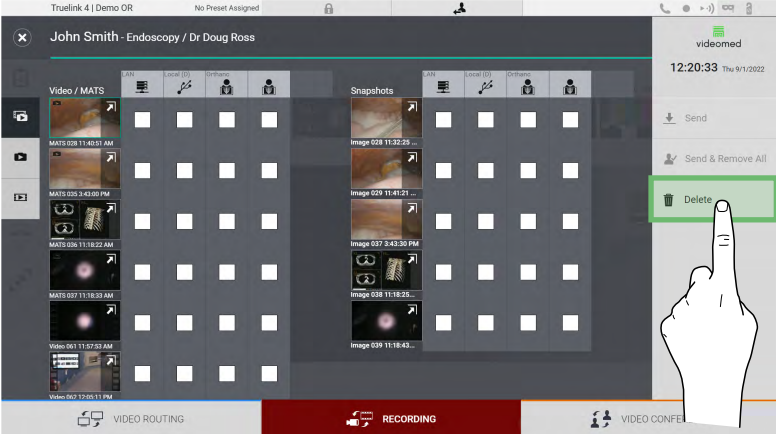

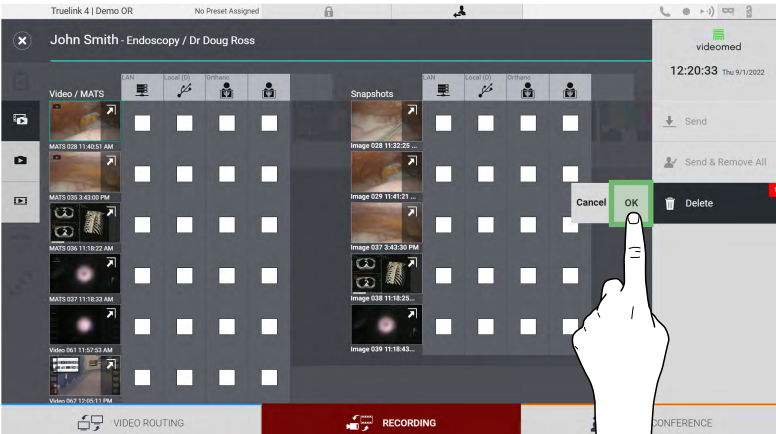
If the export destination does not respond (e.g.: USB device not present), the system displays an “EXPORT FAILED...” error message and the icon  appears on the right side of the screen. A red checkbox is displayed for each destination to which the selected file could not be exported, as shown in the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



5.4.7 Delete images and videos



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

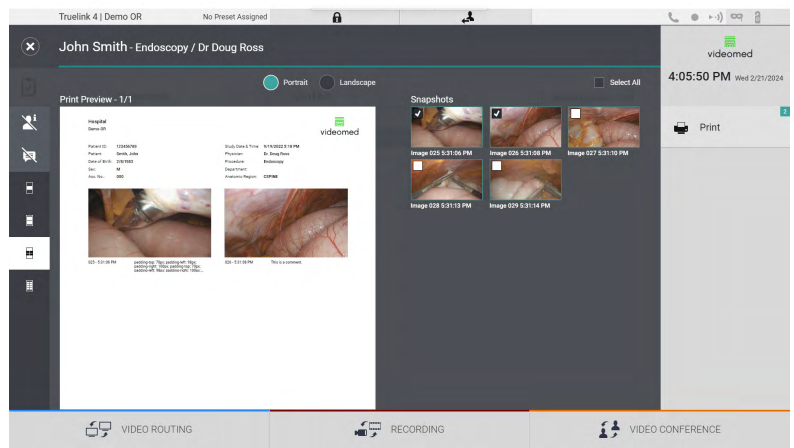
To delete images and videos, proceed as follows:

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


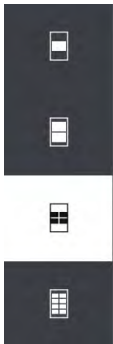


5.4.8 **Printing function**


The Printing function allows to print images of the selected patient directly from the Truelink 4 UI.

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




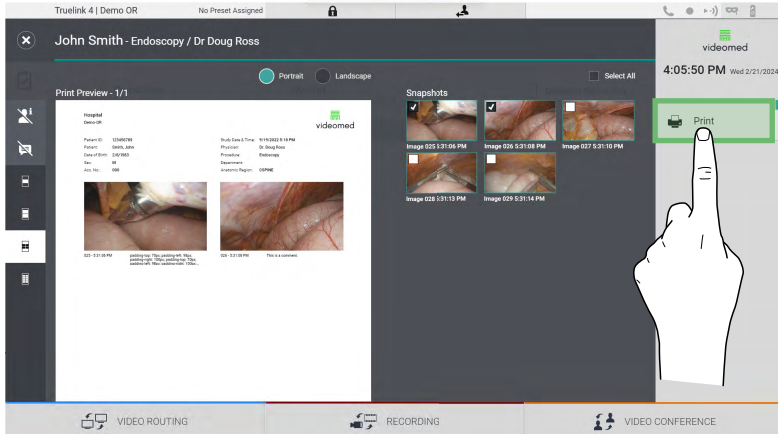
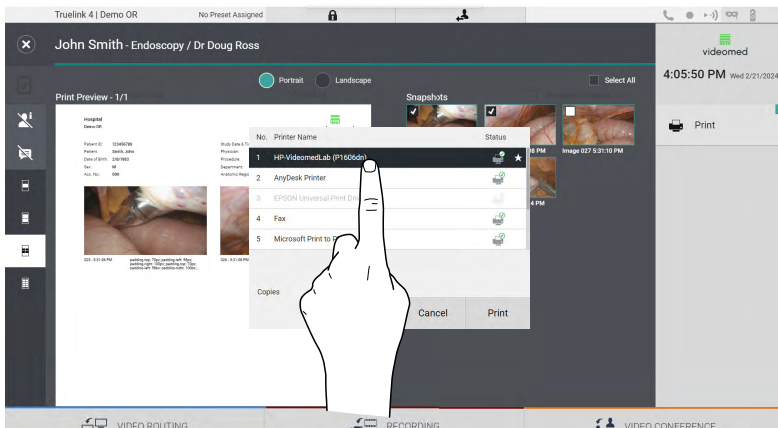
The following options are available in the printing area:

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

Icon	Function
	Hides or shows patient sensitive data ^{*1} .

^{*1} Sensitive data can be defined in the configuration section by an authorized technician.

To print, proceed as follows:

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

This function is available only after the selected printer(s) have been installed and configured on Truelink 4 by qualified service personnel.

5.5 “Video Conference” function

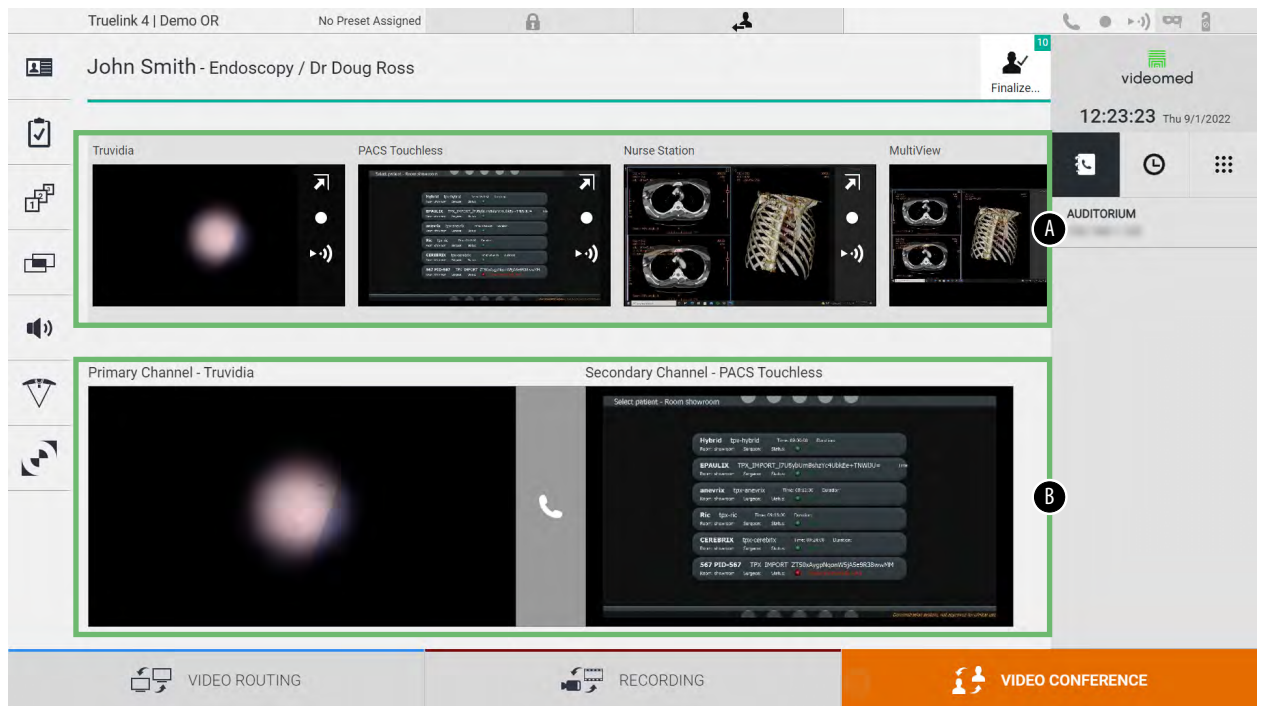
The Video Conference function allows video conferencing in two-way audio and video connection from the operating room to external rooms:

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


The following modes are available:

Mode	Description
Preview of the transmission channel	It enables to view one, or in case of multi-channel video conferencing, both connected transmission channels.
Images or video sources	All connected sources are displayed in the input signal bar.
Swap Button	During a conference it is possible to exchange the signals displayed in the layout selected.
Layout Button	During a multi-channel conference it is possible to have various live Previews of the video signals involved, for example PiP and PaP.
Participant selection/ Contact list	The video conference participants can be selected through the specific button: <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 from the keyboard.
Participant display	Shows which participants (name, IP address) are currently connected or with whom a video conference is about to start after assigning a transmission device and a signal source.

The main Video Conference screen is divided as follows:

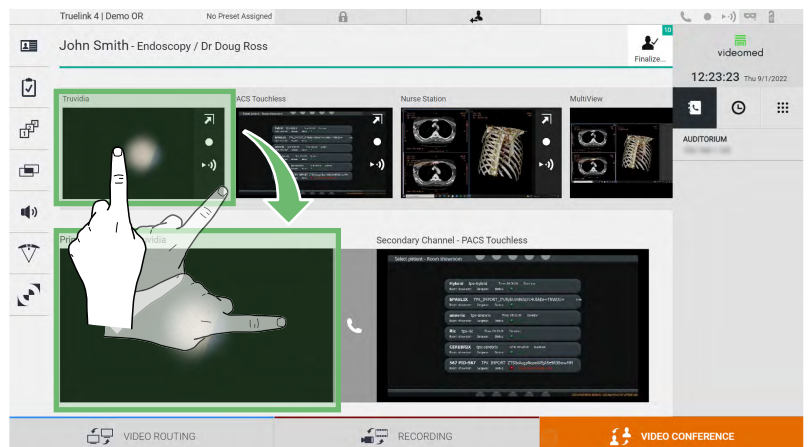


- [A] source list
[B] view of the two video conference channels


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

5.5.1 Select the signals to be sent by video conference

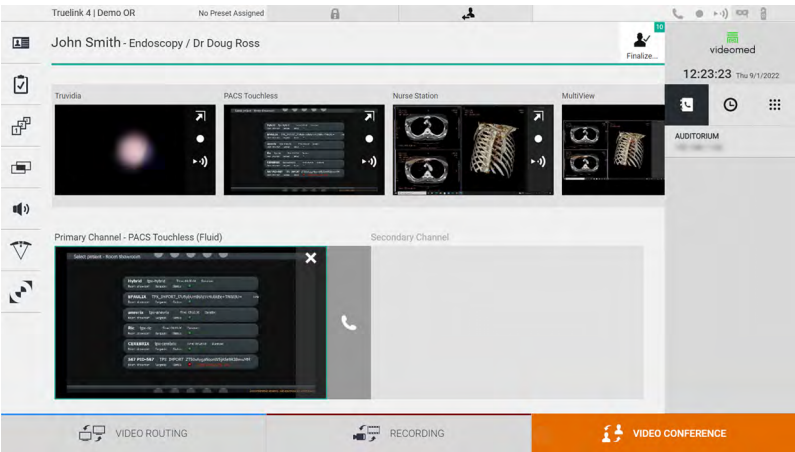
From the Source List, drag the source you wish to send in video conference in the Primary Channel (or Secondary Channel) box.






5.5.2 Removing the signals to be sent by video conference


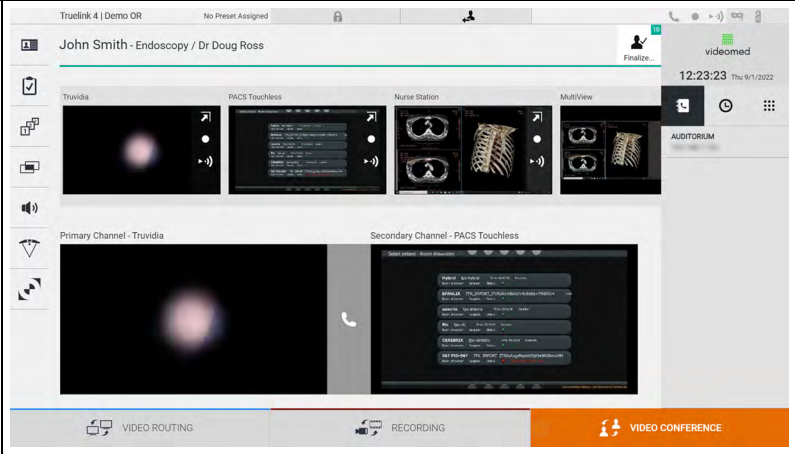
Press one of the boxes related to the primary and/or secondary video conference channel and then to the icon  which will be shown inside it to remove the video signal from the video conference.


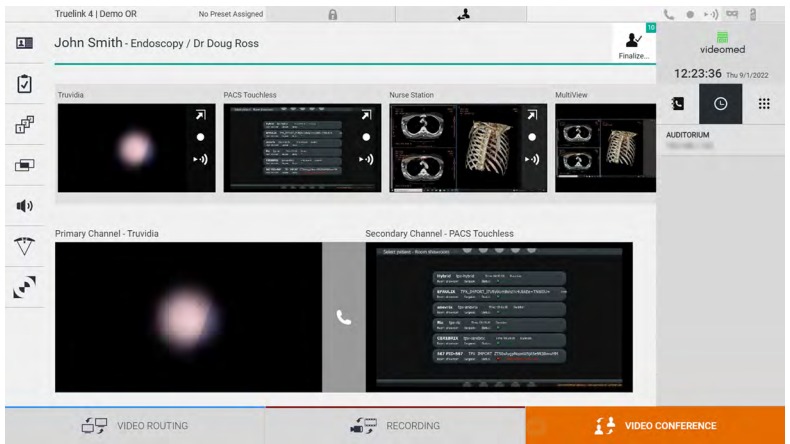

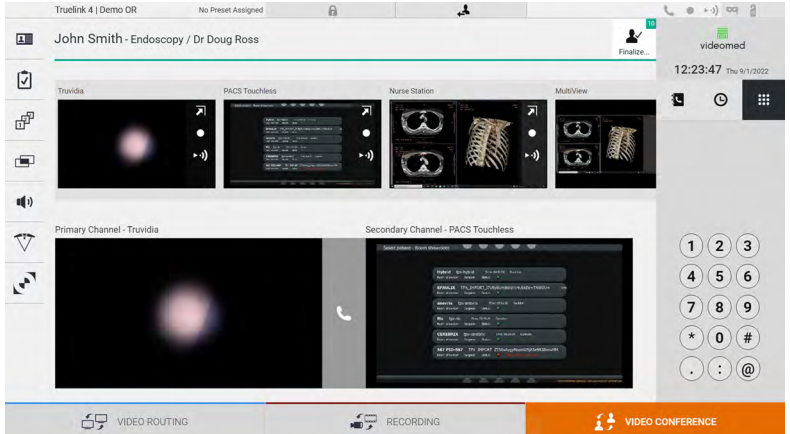
The video signal thus removed will no longer be shared with video conference participants.



5.5.3 Call recipient selection



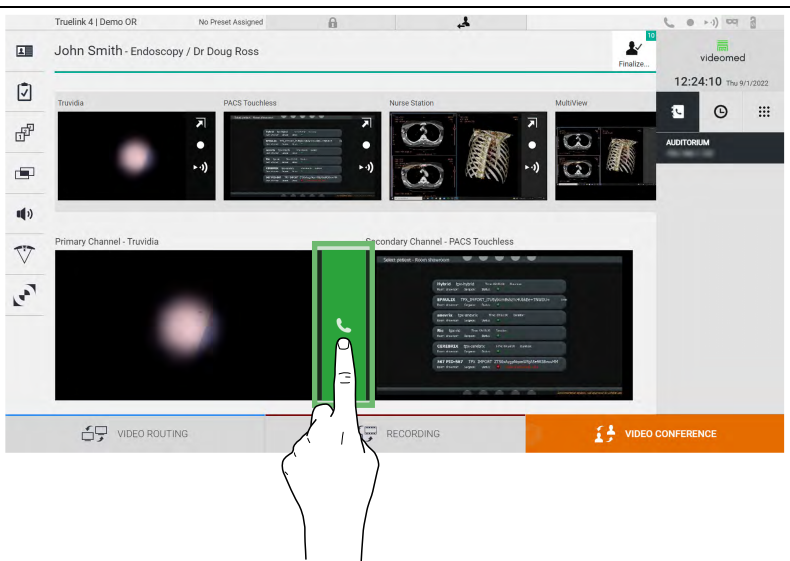
To select the recipient of the call, press the respective icon    (depending on the mode) on the right side of the screen. The icons are described below:

Icon	Description	Image
	Enables to select a name from the contact list.	

Icon	Description	Image
	Enables to select a name/address from those indicated in the calls sent/received log.	
	Enables to manually enter the recipient's IP address by using the numeric keypad.	

5.5.4 Call start


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

Step	Image
1. Press the green call button  . The call button turns red  and indicates the option to end the call.	

5.5.5 Call H.323/SIP recipient

The following instructions provide the steps required to:

- Access the Truelink 4 system Address book section
- Call into a H.323/SIP meeting through the Truelink 4 system

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

5.6 On air lamp










The ON AIR lamp turns on in the following scenarios:

- Video recording function started
- Conference call started
- Streaming session started

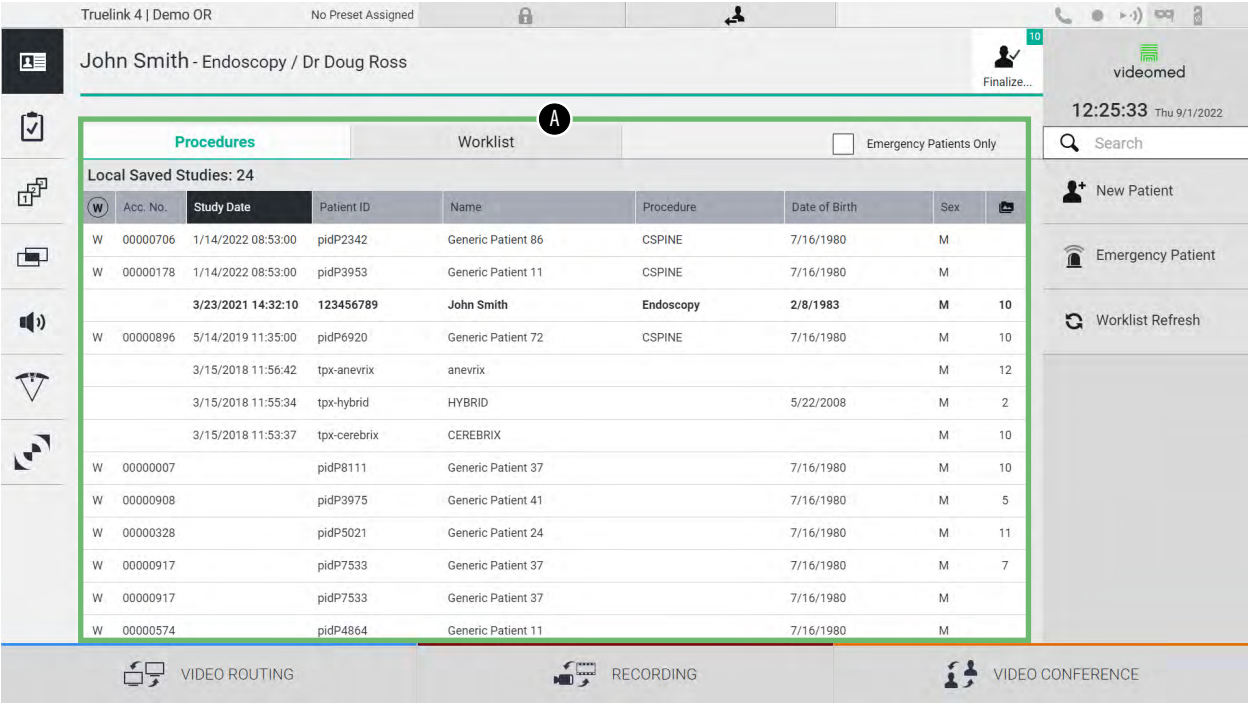
5.7 Additional functions

The following optional functions can be accessed 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 Baxter devices are present.
	Allows access to the control screen of the lights in the operating room. This function can only be used if associated Operamed devices are present.

5.7.1 Patient data management

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


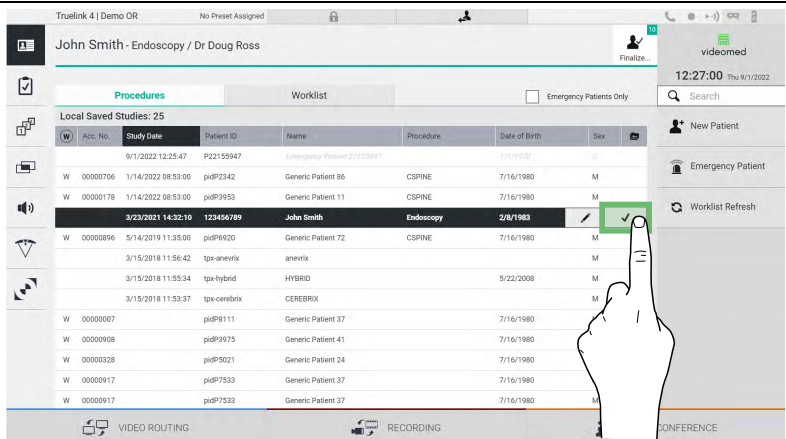


On the screen displayed, when the icon is pressed, the list of patients [A], already entered and divided between those imported by the Worklist (if present), and those previously manually selected or inserted, is displayed.

5.7.1.1 Selecting a patient present in the list


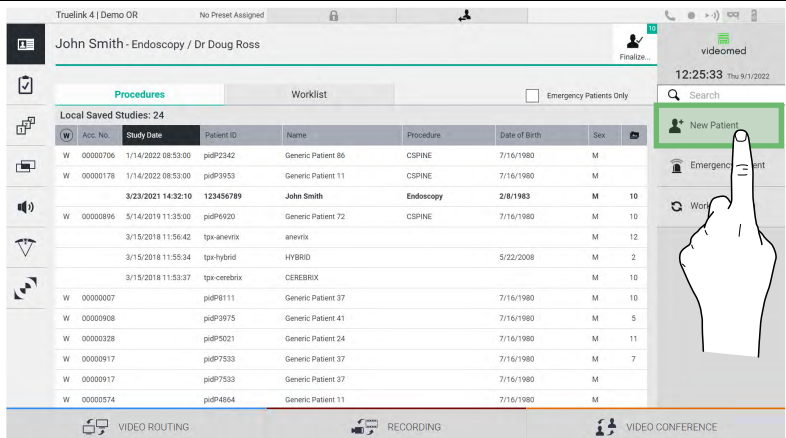
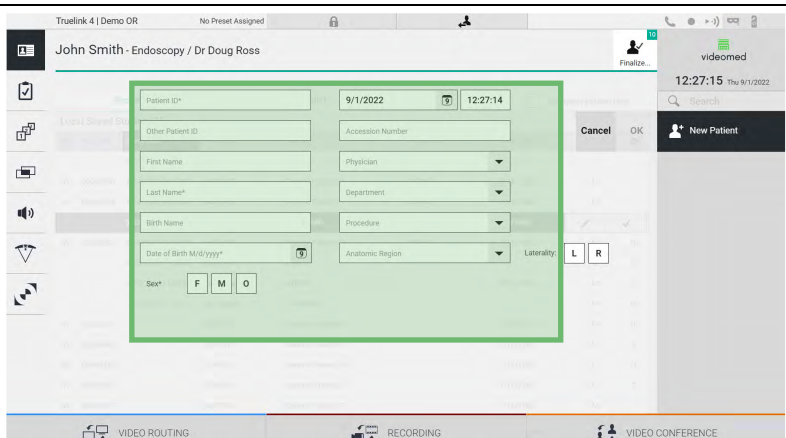
To select a patient already in the list, proceed as follows:

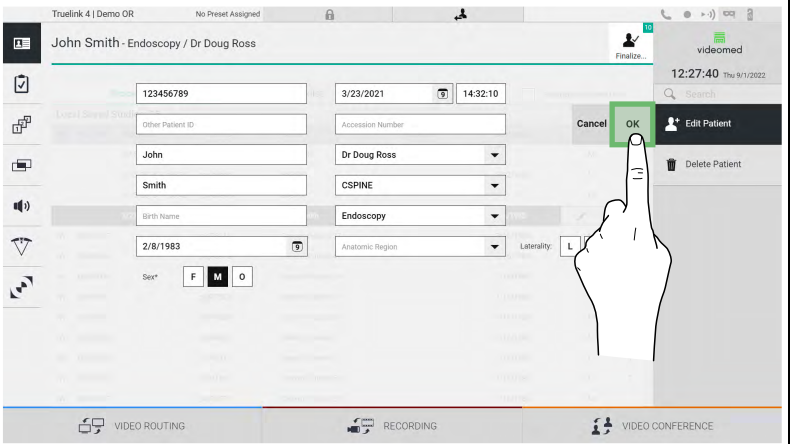
Step	Image
1. Select the patient.	

Step	Image
2. Press  to confirm the selection.	

5.7.1.2 Entering a new patient

To enter a new patient, proceed as follows:

Step	Image
1. Select the  New Patient icon on the right of the screen. The window for filling in patient data is displayed.	
2. Enter the data for the new patient. Fields marked with * are mandatory.	


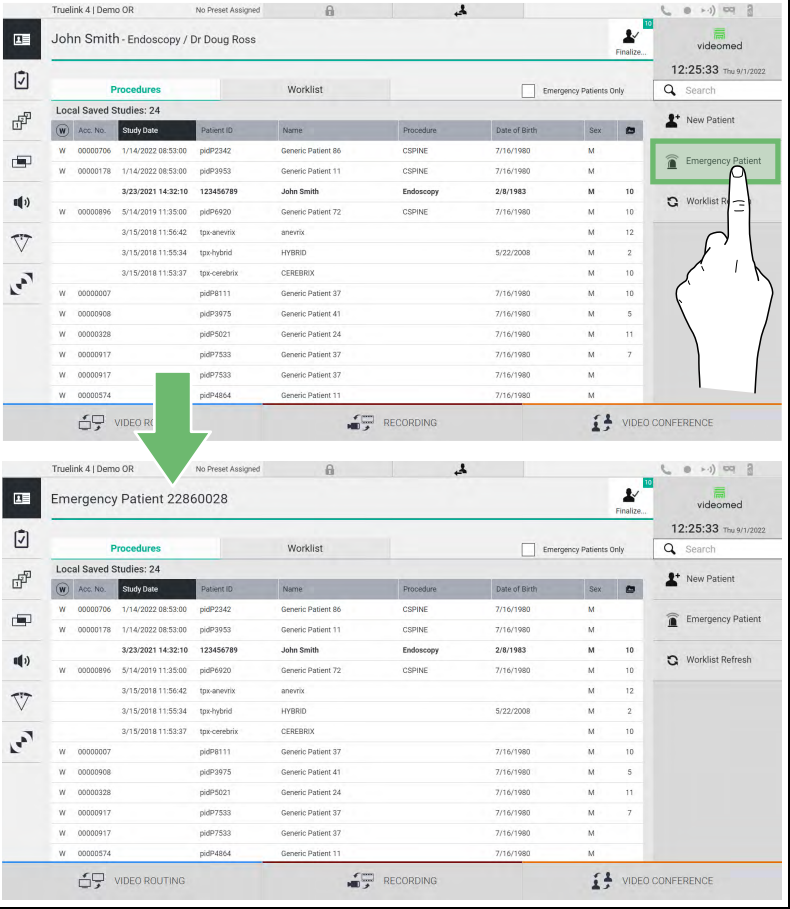
Step	Image
3. Once the mandatory data have been filled in, it is possible to save the new patient by pressing OK or cancel the insertion with Cancel .	

5.7.1.3 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.

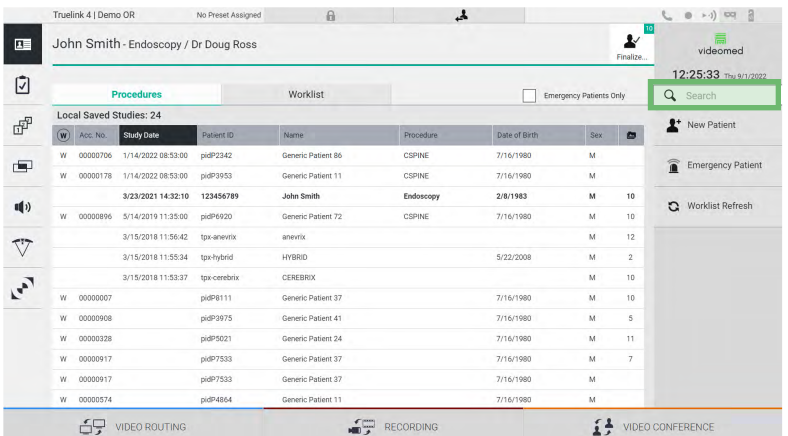
In regards to functionalities available and management, the Emergency Patient is comparable to any patient manually entered or by recalling the Worklist.

To enter an emergency patient, proceed as follows:

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

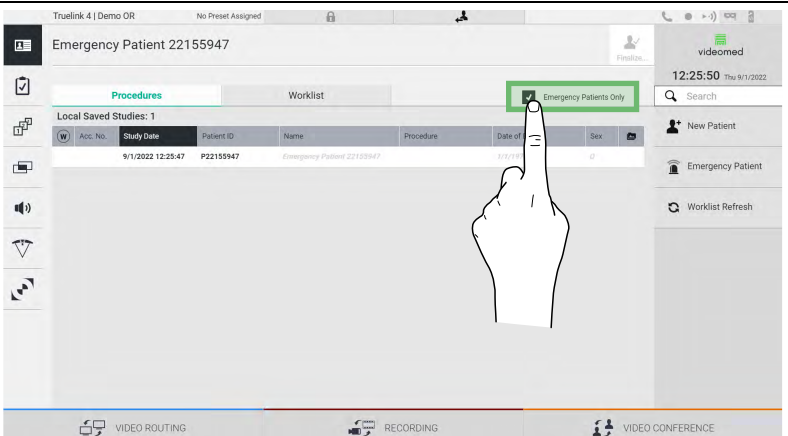
5.7.1.4 Searching for a patient present in a list

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

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

5.7.1.4.1 Emergency patient Filter

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

Step	Image
1. Select the icon at the top of the screen. Automatically Truelink 4 will only display the list of emergency patients.	

5.7.1.5 Patient master data modification

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

Step

1. Search for and select the desired patient.


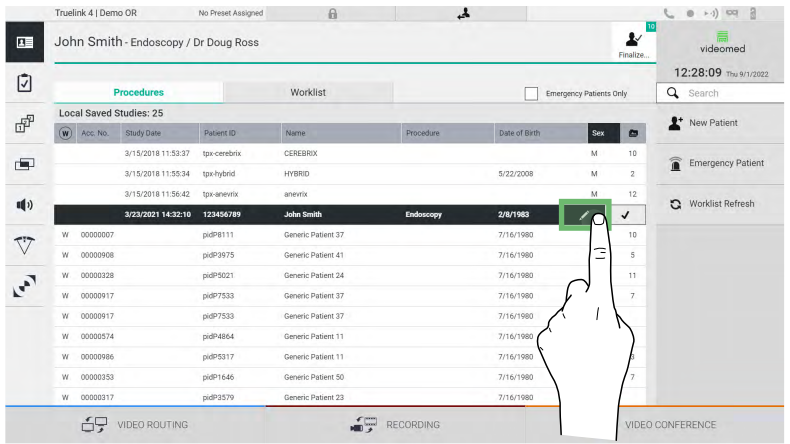


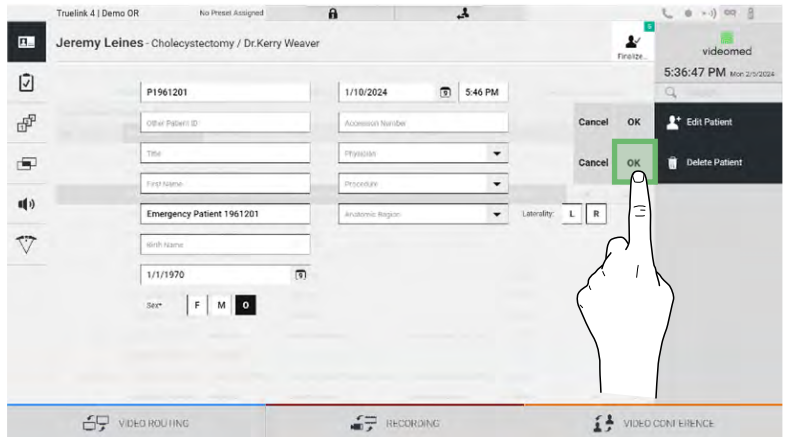
2. Press to change the selected patient’s master data. This option is not available for patients in the Worklist section.

5.7.1.6 Deleting a patient


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

Step


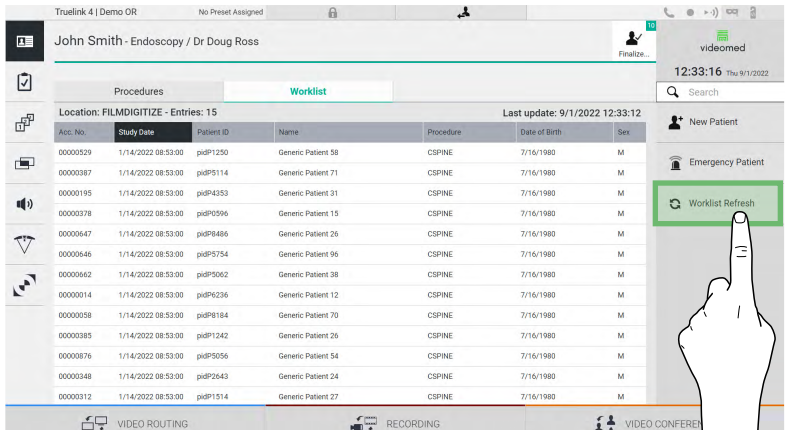
1. Search for and select the desired patient.

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


5.7.1.7 Accessing the worklist

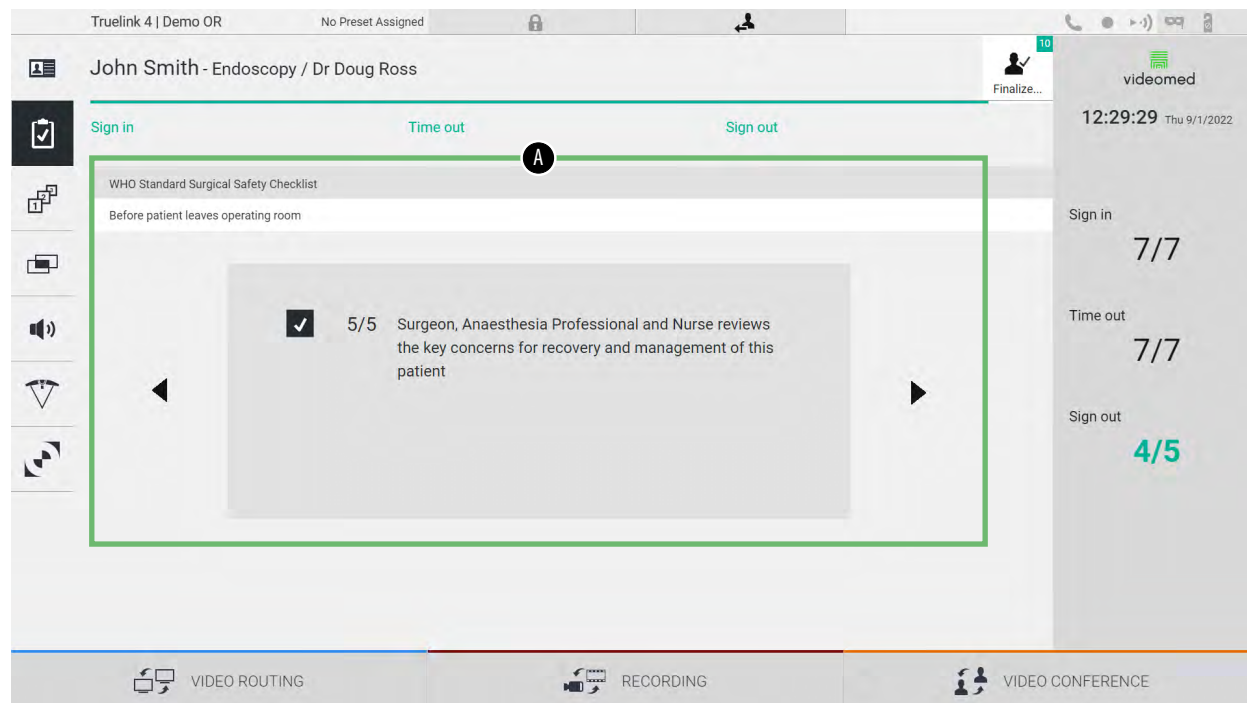
If the Truelink 4 Video Management System is configured to connect to a centralized master data management system, the list of patients related to date/room/surgeon can be retrieved using the  **Worklist Refresh** button.


To access the worklist, proceed as follows:

Step	Image
<p>1. Press the button  Worklist Refresh. This operation will trigger the update of the worklist.</p> <p>2. Wait for the names relative to the criteria selected to appear in the list.</p> <p>Alternatively: Press the "Worklist" tab at the top of the list (this will not trigger the update of the worklist).</p>	

5.7.2 Surgical Checklist

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




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

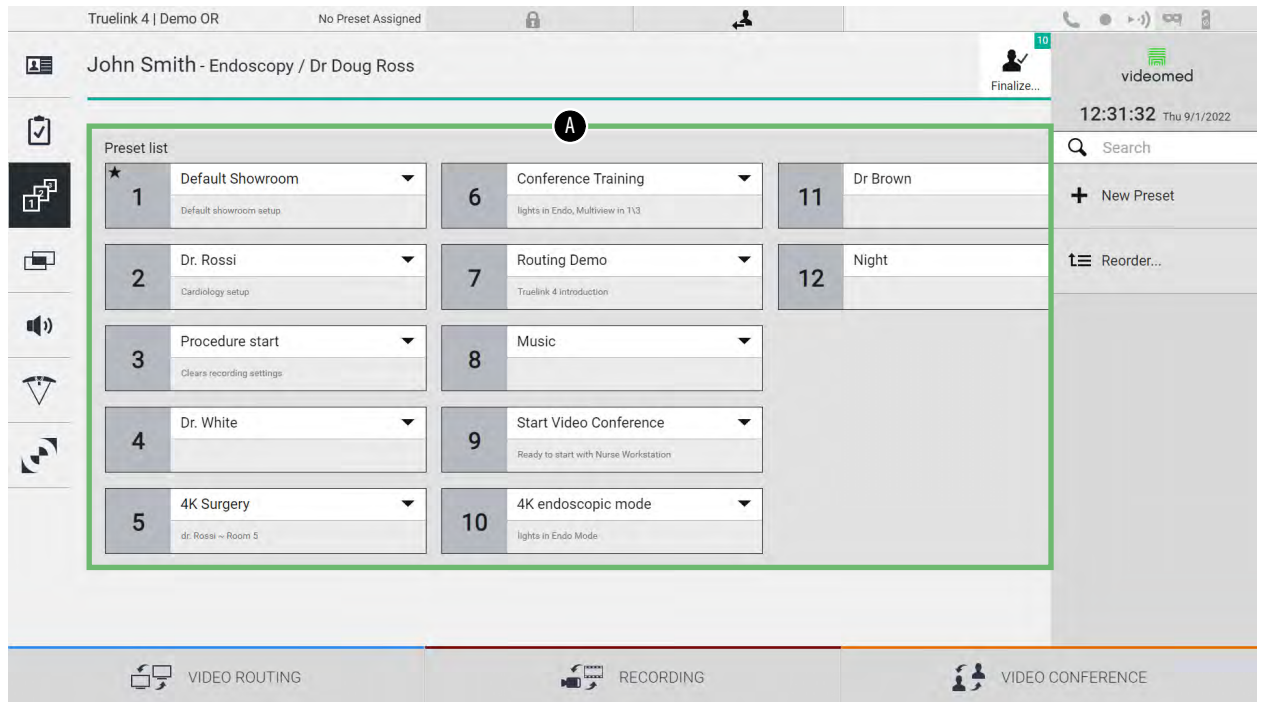
The steps refer to the entire procedure, you will then be able to exit this section and return to it to continue filling out the Surgical Checklist when necessary. It will always be possible to view the fill-in status of the Surgical Checklist by looking at the progress bar in the Status Bar.

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

5.7.3 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.

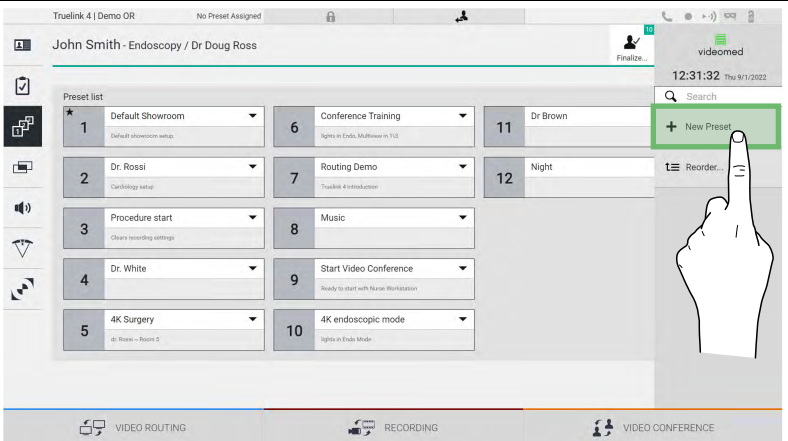
The main screen is divided as follows:

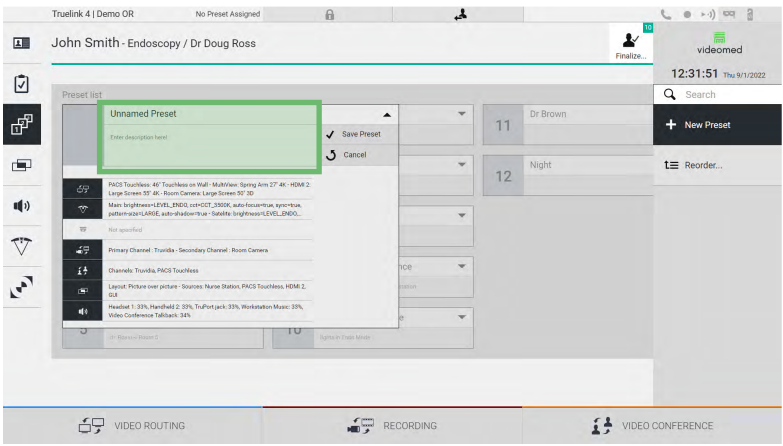
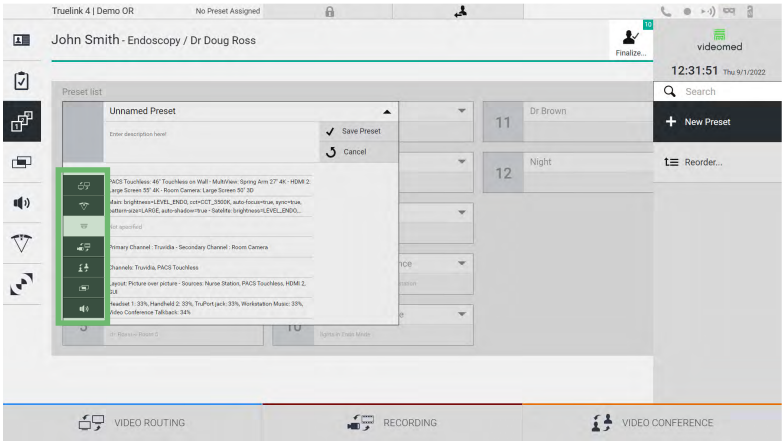

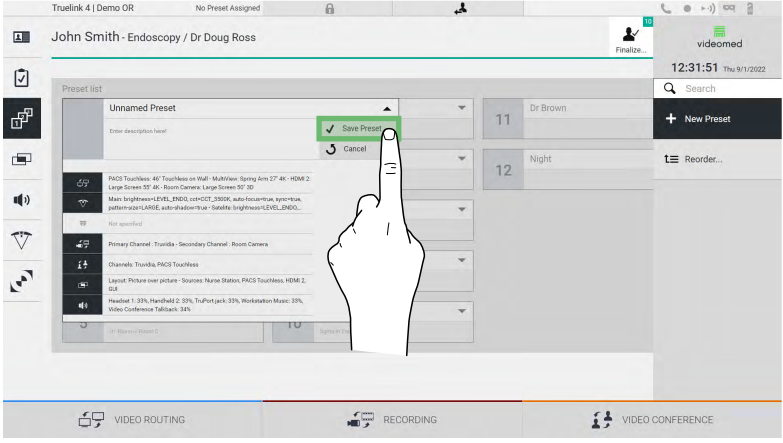


[A] Preset List

5.7.3.1 Preset setting

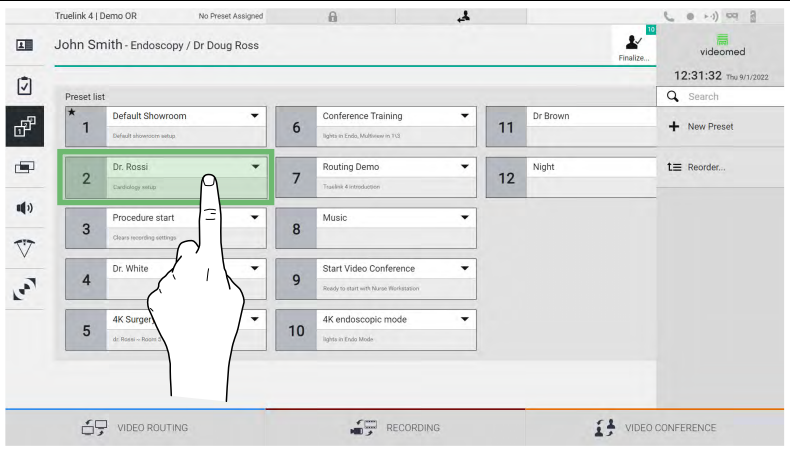
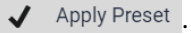


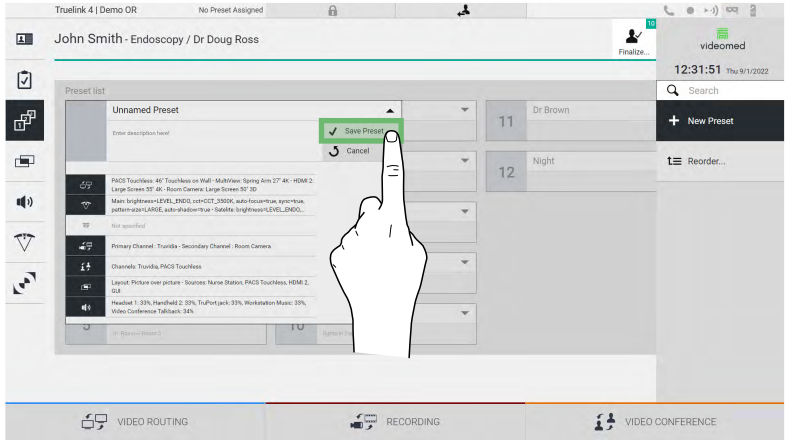
To set a new Preset, proceed as follows:


Step	Image
1. Set the desired room layout (Routing Video, Recording Channel, Conference Channel, Setting Audio, Operating Light Setting).	
2. Press the button New Preset . The configuration window opens.	

Step	Image
3. Enter the name to be assigned to the new Preset and add a description in the appropriate field below (optional).	
4. Select / deselect the settings to be included in the configuration by pressing the relative icon among those listed.	
5. Press  Save Preset to confirm.	

5.7.3.2 Enabling Preset

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

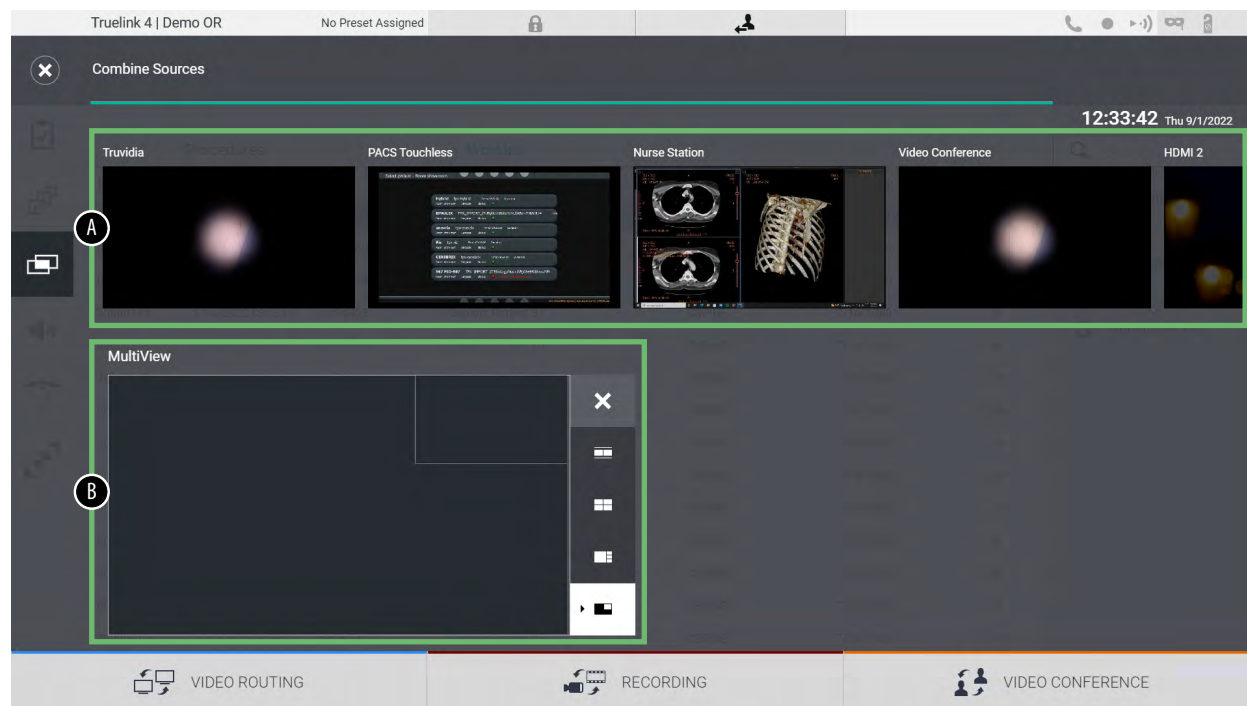
Step	Image
1. Select the desired Preset from the Preset List. The configuration window opens.	
2. Apply the Preset by pressing  . Press  to perform changes to the Preset. Save the changes by pressing  .	

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

5.7.4 Multiview

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









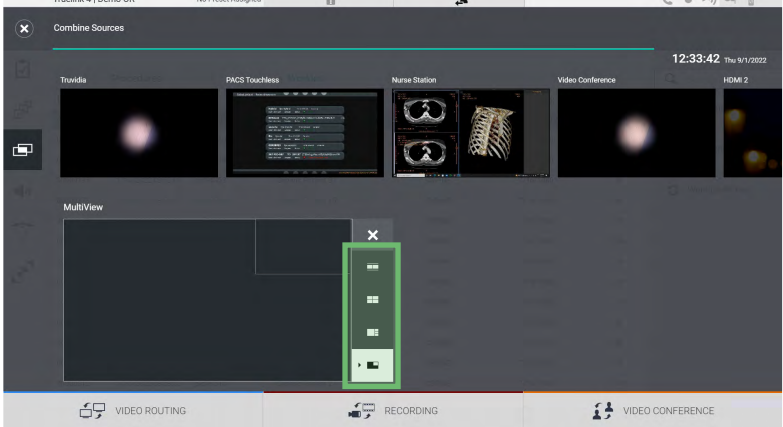




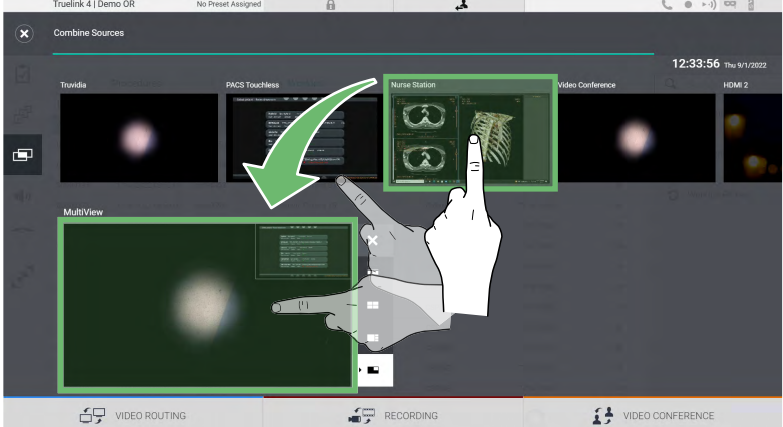
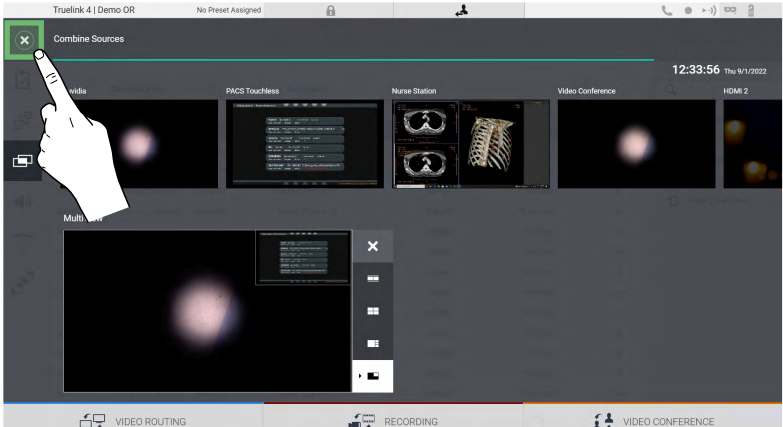
The main screen is divided as follows:




- [A] Source List
- [B] Multiview

5.7.4.1 Multiview setting

To set the Multiview, proceed as follows:

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

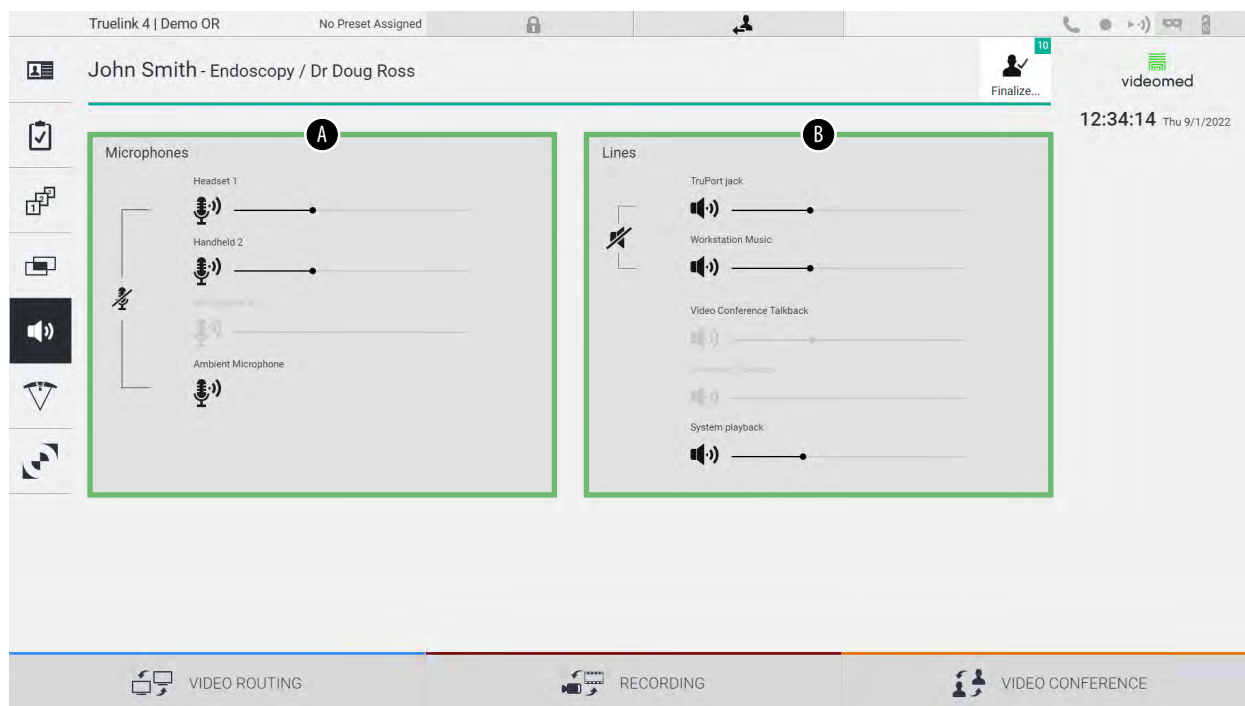
5.7.5 Audio control

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

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

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

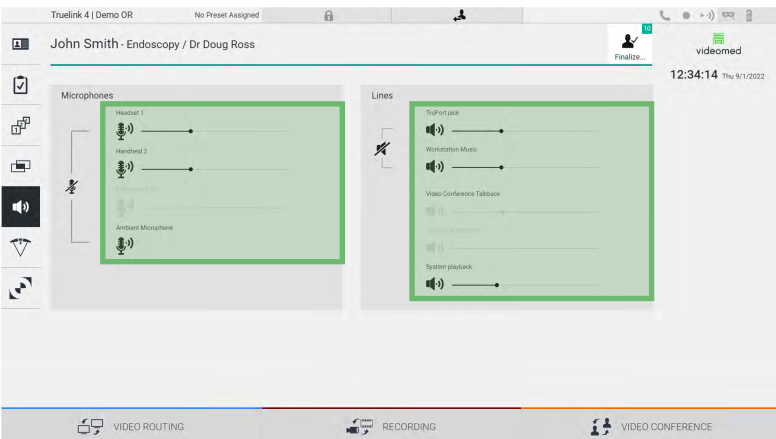
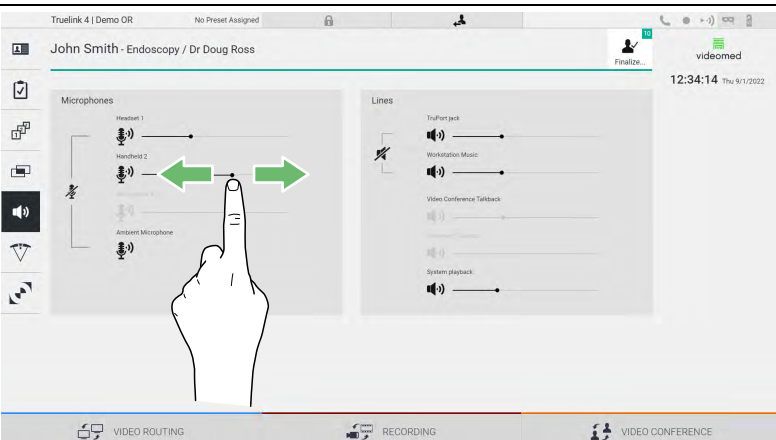
The main screen is divided as follows:



- [A] Microphone Inputs
- [B] Line Inputs

5.7.5.1 Volume adjustment

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

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


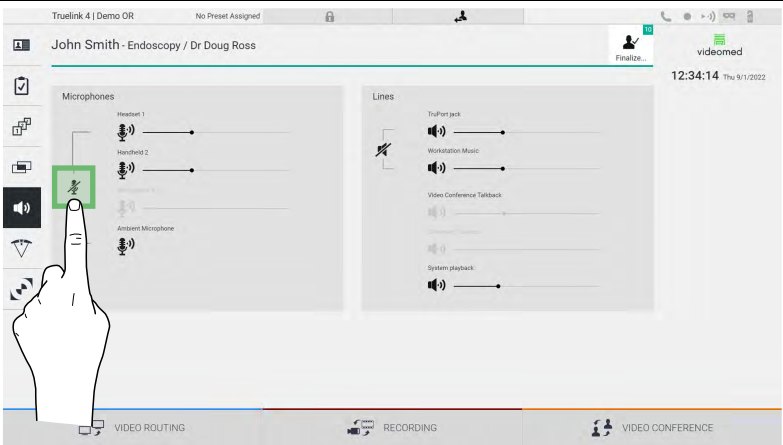

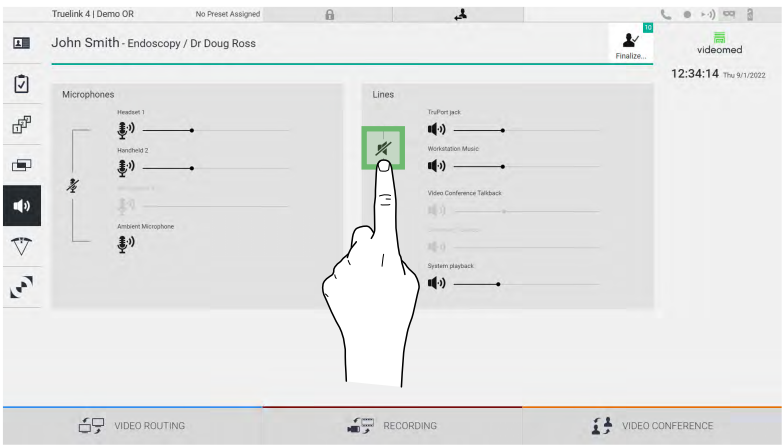
It is possible to independently change the audio channel coming from inputs AUX1, AUX2 and video conference/streaming.

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

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

5.7.5.2 Disabling microphones and audio

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

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

5.7.6 Management of surgical lights

On the side menu, press the  icon to access the management screen for the devices in the operating room.

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

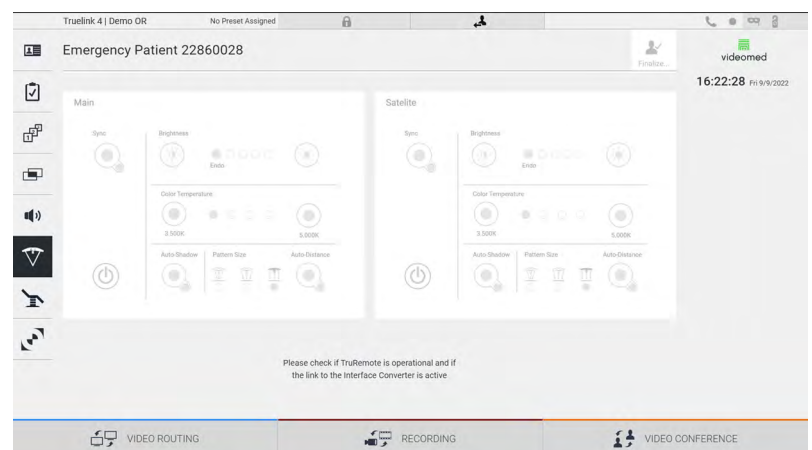


* the image may differ depending on the surgical light actually installed

[A] Light 1

[B] Light 2

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



Truelink 4 Video Management System assures the option of controlling the Baxter surgical operating lights (see chapter 3.10.1), using a reproduction of the light control console via the graphical interface.

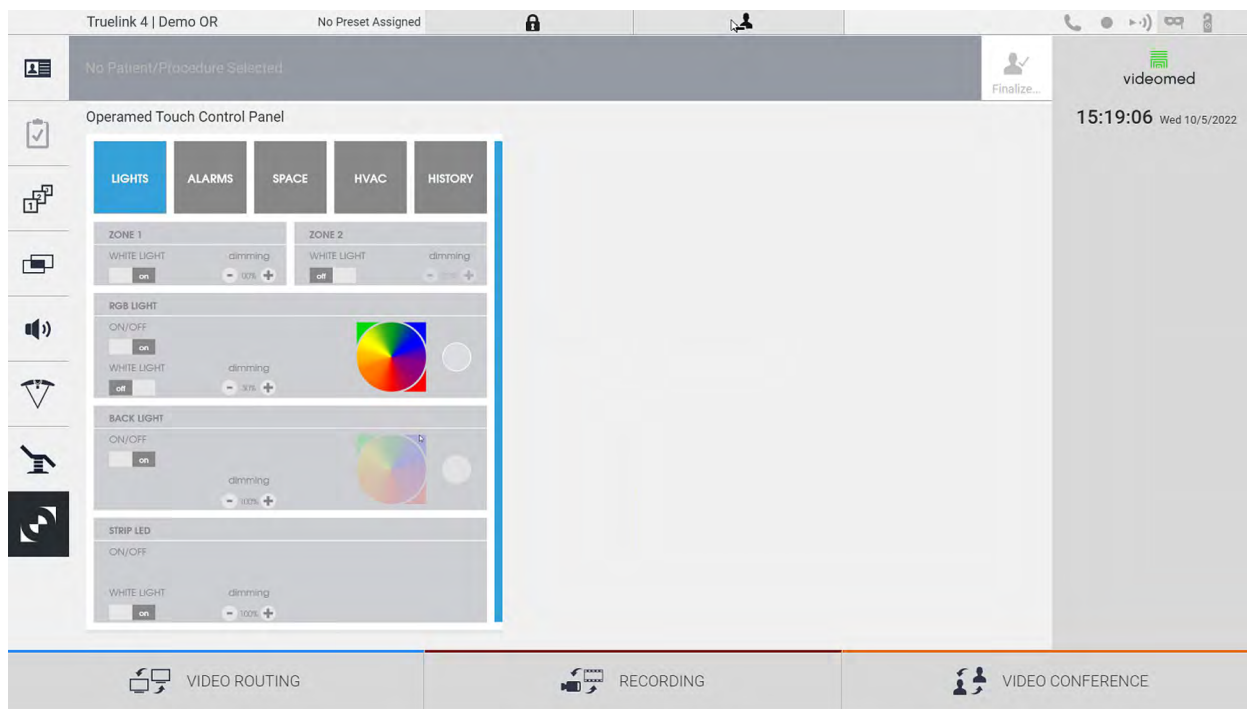
From the image you can see that the functions accessible from the touchscreen system are:

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

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

5.7.7 Environmental control panel management

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


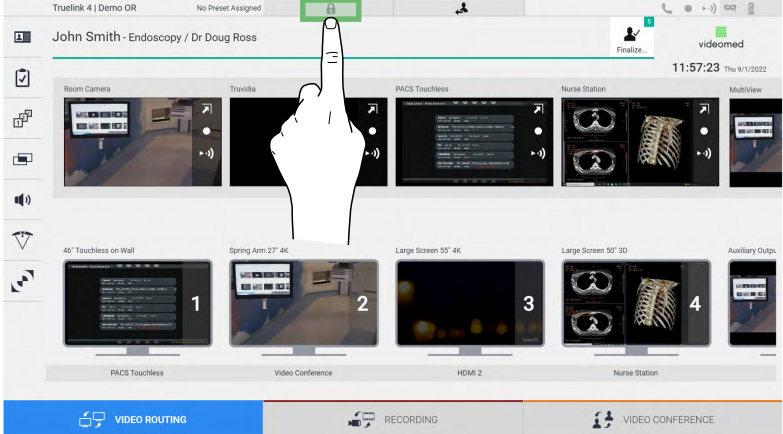
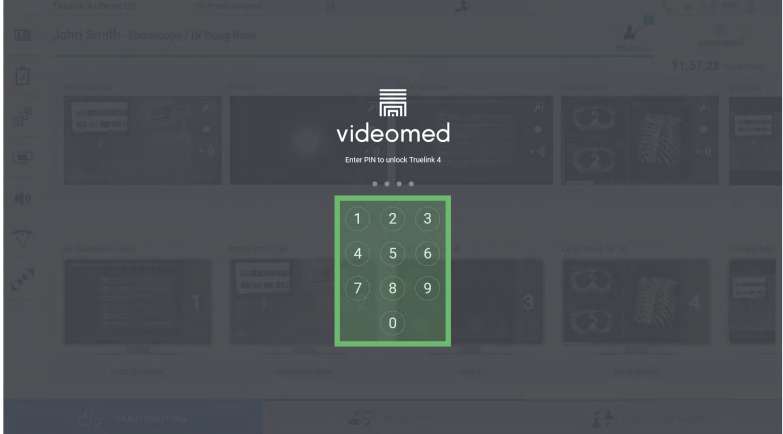


The control panel management screen can be used only if Operamed devices are present in the operating room. The Truelink 4 Video Management System of Videomed S.r.l. enables only Operamed control panels to be associated.

5.8 “Lock with PIN” function

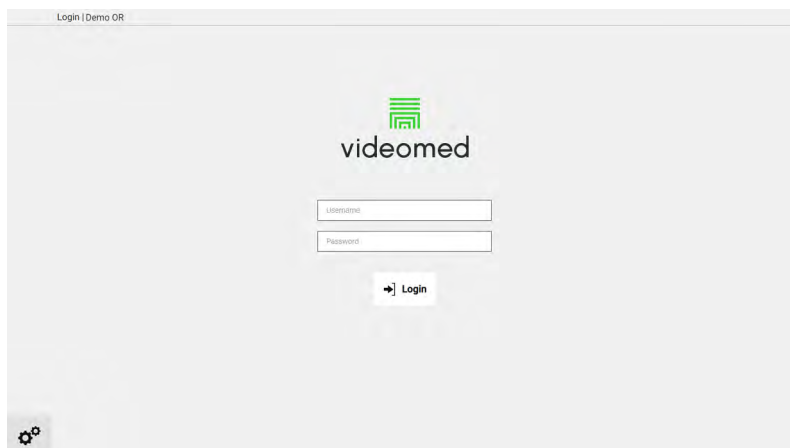
Truelink 4 Video Management System includes a Lock function to lock the touchscreen by using a PIN.

To lock the touchscreen, proceed as follows:

Step	Image
1. Press  to lock the screen.	 A screenshot of the Truelink 4 Video Management System interface. The top bar shows 'Truelink 4 Demo OR' and 'No Preset Assigned'. A green box highlights the lock icon in the top right corner. Below the top bar, the interface displays various video feeds and controls. A hand icon is pointing at the lock icon.
2. Enter the PIN code to unlock the touch screen, using the highlighted numeric keypad.	 A screenshot of the Truelink 4 Video Management System interface showing the lock screen. The screen is dark with the 'videomed' logo and the text 'Enter PIN to unlock Truelink 4'. A green box highlights the numeric keypad in the bottom right corner.

5.9 “Login” function

Truelink 4 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 Truelink 4 graphical interface (Video Routing interface).

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

6 Electromagnetic compatibility

The Truelink 4 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 Truelink 4 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 Truelink 4 product is a Class A electromedical device according to IEC 60601-1-2 (CISPR 11), it is suitable for use in a specific electromagnetic environment. The customer and / or the user of the product must ensure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guide
Radiated and conducted RF emission CISPR 11	Group 1	Truelink 4 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	Truelink 4 is suitable for use in all buildings, except domestic buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic 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 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.

IMMUNITY test	IEC test level	Compliance level	Electromagnetic environment – guidance
Fast electrical transients (burst) IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input / output lines > 3 m	IEC 60601-1-2 Test level	The quality of the mains 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	3 V 150 kHz to 80 MHz 6V ISM frequencies	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the EUT, including cables. Minimum distance 30 cm.
Network frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should have the characteristic levels of a typical location in a typical commercial or hospital environment.
Voltage dips, brief interruptions and voltage variations on the power input lines IEC 61000-4-11	10 ms – 0% a 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	IEC 60601-1-2 Test level	The quality of the mains voltage should be that typical of commercial or hospital environments. If the user of the appliance requires it to continue to operate even when the mains power supply is interrupted, it is recommended to power the appliance with an uninterruptible power supply (UPS) or with batteries.

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

Test frequency (MHz)	Modulation	Minimum IMMUNITY level (V / m)	Applied IMMUNITY level (V / m)
385	** Pulse modulation: 18 Hz	27	27
450	<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

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

7 Disposal instructions

Electrical equipment that is no longer in use must not be disposed of as normal 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.

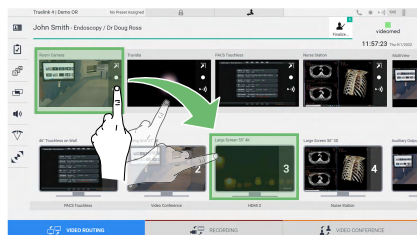
Assistance is always available to clear any doubts regarding the recycling and disposal of products.

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

8 SVHC (Substance of very high concern)

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

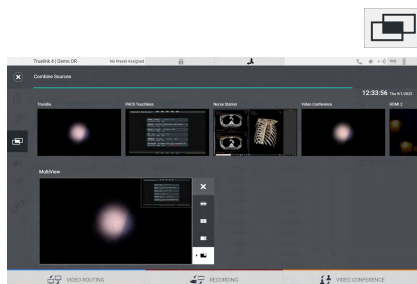
9 Annex I - Short manual



Video Routing

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

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

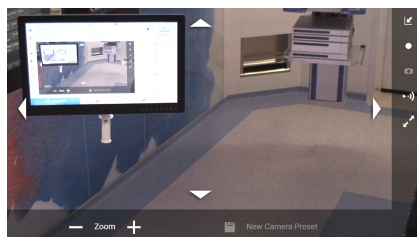


Multiview

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

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

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



PTZ camera control

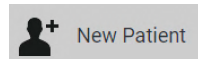
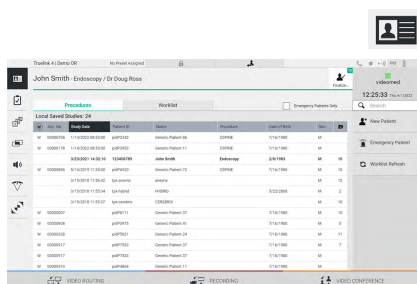
Press **PTZ** in the RoomCam Preview to open the Live Preview. The buttons for controlling the camera will appear. The system allows you to change the position and zoom level of the camera.

Recording

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

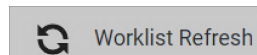
Patient data

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



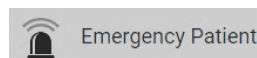
Manual insertion

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



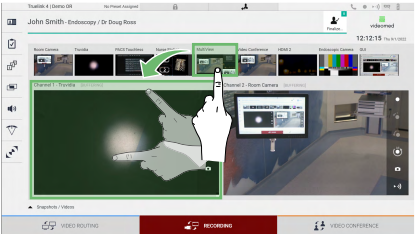
Access to the Worklist

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



Urgent insertion

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

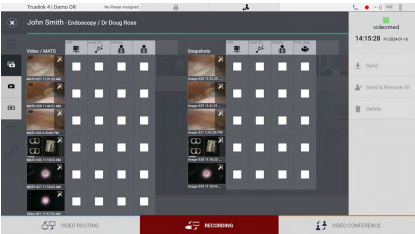





Selection of signals to be recorded




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

 **Recording start / stop**

 **Instant capture**



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

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