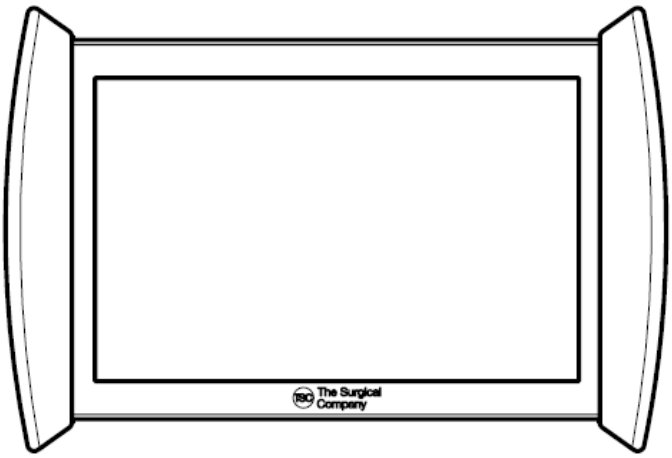
The Surgical Company

EN

Screeni™

User manual



REF Screeni™ **30030001**

CE 1639

30030511-G_23/04

EN

Table of Contents

1. IMPORTANT INFORMATION – READ BEFORE USE

	"WARNING" indicates a particularly hazardous situation. Failure to observe the instruction may damage the instrument, cause injury, or even death.
	"CAUTION" indicates that use or improper use of the instrument may cause a problem, such as product malfunction, failure or damage.

1.1. Foreword

This user manual contains essential information for the safe and optimal use of the Screeni. The information in this user manual is subject to change at any time, without notice. Make sure that you are using the latest version by logging onto the Axess Vision website https://www.tsc-group.com/endovision/ or contacting the local representative.

This user manual does not contain any explanations of information concerning endoscopic techniques per se.

Carefully read this manual, along with the manuals for all the instruments used, and use them as instructed. Keep all user manuals in a safe and readily accessible place. Should you have any questions or comments concerning this manual, do not hesitate to contact the local representative.

This manual describes the recommended inspection and preparation procedures prior to use of the equipment, the procedures for its use and the precautions to be followed for cleaning and maintenance after use.

Carefully follow all the instructions given in this user manual. Poor understanding of these instructions could lead to:

- severe injuries to the patient,
- severe injuries to the user,
- severe injuries to a third party,
- equipment damage.

1.2. Intended use

This product was developed by the company Axess Vision and is exclusively reserved for the endoscopic examinations claimed in the manual of the endoscope used (see list of compatible devices).

The Screeni is used for viewing the lungs and airways by means of a single-use endoscope. The Screeni should not be used for any purpose other than that described herein.

1.3. Indications for use

This device is designed for use exclusively in a hospital environment, in combination with an Axess Vision Broncoflex™ video-bronchoscope.

1.4. Contraindications

The images generated by this device should not be used for diagnostic purposes. Physicians must interpret and support any findings in other ways, based on the patient's clinical data.

1.5. User qualification

The Screeni can be used by an anaesthesia nurse, scrub nurse, or any other person authorised to interact with and prepare the equipment before a medical procedure under the responsibility of the physician in charge of examining the patient.

Where there are official standards and/or regulations relating to user qualification for performing endoscopy, and endoscopic treatment defined by the medical administration or by other official institutions, such as the academic endoscopy society, these must be respected.

Otherwise, this instrument should only be used by a doctor approved by the head of department responsible for accident prevention in the hospital or by the person in charge of the corresponding department (pulmonology department, etc.). The physician must be able to perform the video endoscopy and the planned endoscopic procedure, safely, in accordance with the guidelines set by the academic endoscopy society and considering the risks of complications related to endoscopy and the endoscopic procedure.

1.6. Warnings and cautions for use

Observe all the warnings and precautions described in this manual. Otherwise, Axess Vision cannot be held liable in case of injury to the patient or user or damage to the device.

⚠	The Screeni should only be used with endoscopes marketed by Axess Vision (see § 1.7 *"Instrument compatibility")*.
⚠	The use of incompatible instruments may result in injury to the patient and impede the correct operation of the video-endoscopic system.
⚠	Any modification of the Screeni by the user is strictly forbidden. Failure to comply with this instruction may result in injury to the patient or the user and/or impede the correct operation of the video-endoscopic system. If the Screeni malfunctions, see § 7 "*Troubleshooting*" or contact the local representative.
⚠	Do not expose the Screeni to water or moisture or allow prolonged exposure to the sun.
⚠	The Screeni power cable should be placed in an area where there is no risk of it being crushed.
⚠	If the power cord is damaged or bare, replace it immediately with another of the same type and rating provided by the manufacturer.
⚠	If the Screeni is exposed to liquids (in a manner contrary to the cleaning instructions), in the event of a fall, or if the case is damaged, switch off the Screeni and return it to the manufacturer.
⚠	Use only the cables and accessories supplied by the manufacturer for the Screeni (list available in § 2 "*Description of the Screeni and its accessories*").
⚠	Avoid touching the electrical contacts of the Screeni.
⚠	Do not simultaneously touch the patient and any metal part of the Screeni.
⚠	For battery-powered use, the charge must be checked before starting the examination. If the battery is low, connect the Screeni to the mains to perform the exam.
⚠	US federal law restricts this device for sale only by, or on the order of, a physician.

❗	Do not use sharp or hard objects to press the On/Off button.

1.7. Instrument compatibility

Compatible devices from the Axess Vision range	
Broncoflex™ Vortex *Reference: 10030001* *Applied part*	
Broncoflex™ Agile *Reference: 20030001* *Applied part*	

2. Description of the Screeni and accessories

2.1. Product description

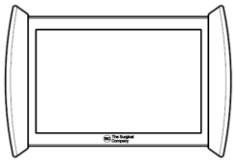
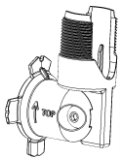
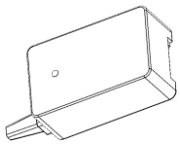
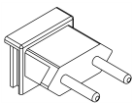
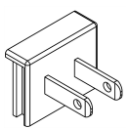
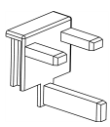
The Screeni is a non-sterile reusable medical device. It is a video processor with integrated touch interface designed to display live imaging data captured by sterile disposable endoscopes marketed by Axess Vision.

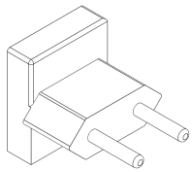
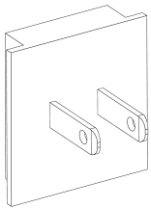
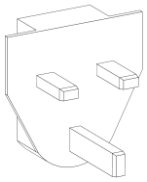
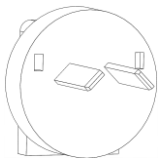
For more information on the endoscope used, see the user manual of the endoscope (found in its transport box and available on the Axess Vision website https://www.tsc-group.com/endovision/.

2.2. Inspecting package contents

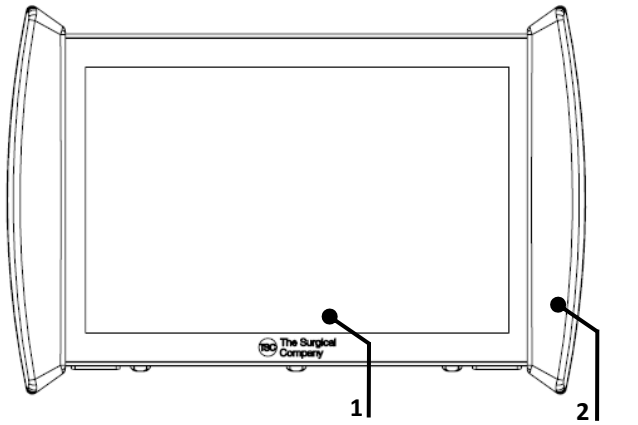
⚠	When unpacking, any defective instrument should be returned in its original box to the local Axess Vision-approved local representative.
⚠	When unpacking and handling the fastening system, take care not to pinch your fingers.

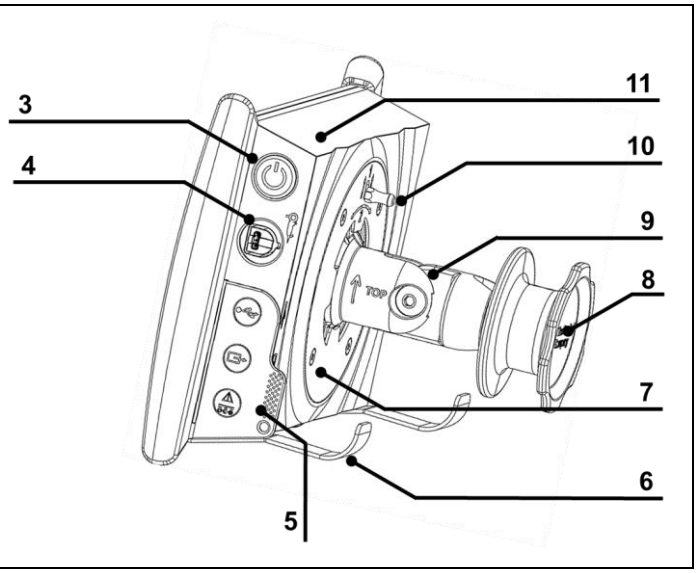
Compare the contents of the package with the items shown below. Ensure that all accessories and components shown below are present and in good condition.

Description	Illustration		
Screeni *Reference: 30030001*			
Quick mounting bracket (already attached to the Screeni) *Reference: 30030301 + 30030302*			
Knurled screw *Reference: 30030303*			
Video cable (HDMI/DVI) *Reference*: *00020019*			
Medical-grade power supply (FRIWO FOX30-XM) *Reference*: *00030001*			
EU adaptor *Reference: 00030002*	US adaptor *Reference: 00030006*	UK adaptor *Reference: 00030007*	AU adaptor *Reference: 00030008*
			

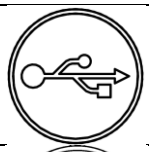
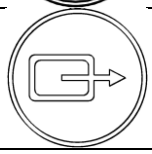
Medical-grade power supply (TR30RDM150) *Reference*: *00030029*			
EU adaptor *Reference: 00030025*	US adaptor *Reference: 00030026*	UK adaptor *Reference*: 00030027	AU adaptor *Reference: 00030028*
			

2.3. Screeni details





#	Symbol	Description	Material
1	Touch screen display.		Glass
2	Bumper for handling the Screeni.		TPE (thermoplastic elastomer)
3		Screeni On/Off button. The button lights up to indicate that the Screeni is switched on.	Silicone
4		Port for connecting the Axess Vision endoscope to the Screeni.	-
5	Flexible connector protection tab:		TPE (thermoplastic elastomer)

		USB port for USB key connection only (self-powered hard discs must not be connected).	
		Video output connector for DVI compatible monitor. Use only with the cable supplied with the Screeni (see §2.2)	
		Power connector 15V DC - 2A. Under this connector an LED indicates the charge status of the Screeni: • Orange: charging • White: switched on, not charging • Flashing orange: charging error (see § 7 *"Troubleshooting"*).	
6	Support feet / packaged endoscope support system when the system is attached to an IV pole (**maximum load: 4 endoscopes**).		Stainless steel
7	VESA 75 compatible mounting bracket.		Stainless steel
8	Screw knob for fixing to an IV pole and serving as a take-up reel for the power cable.		ABS (acrylonitrile butadiene styrene)
9	Quick-connect system for vertical tube, diameter between 15 and 25.4 mm (such as an IV pole, for example).		ABS (acrylonitrile butadiene styrene)
10	Lever to release the quick-connect system.		Stainless steel
11	Housing.		ABS (acrylonitrile butadiene styrene)

3. INSTALLATION AND CONNECTION

3.1. Precautions prior to use

- Perform a general inspection of the product:
  - No damage (e.g. deformations or cracks) should be visible.
  - It should be clean and free from cleaning agent or disinfectant residues.
  - Ensure that no parts are missing and that all parts are properly attached.
  - Ensure that the cables are neither broken nor damaged.
- Check that the accessories present with the system are those supplied by Axess Vision.
- Make sure the battery charge is sufficient before the examination starts. If not, mains operation is required.

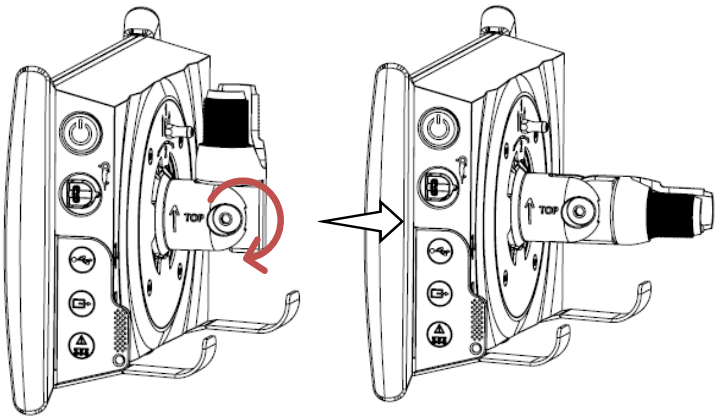
If you notice any anomalies, do not use the Screeni and refer to the instructions in § 7 *"Troubleshooting"*. If this section fails to eliminate the anomaly, please contact the local representative. Any physical damage or other defects may endanger the patient or user and seriously damage the endoscopic system.

3.2. Installation

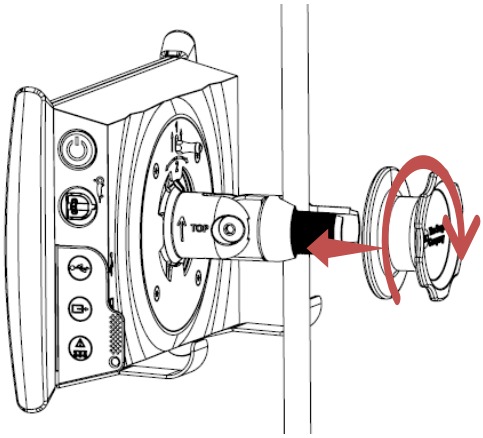
The Screeni offers two installation possibilities: on feet, in which case it must be placed on a flat and stable horizontal surface, or fixed to a stable vertical tubular support *.

3.2.1. Assembly and disassembly on vertical tubular support

a) Mounting



1) Unfold the quick-connect bracket.



2) Position the bracket on the vertical tube and tighten the knob until the assembly is immobilised.

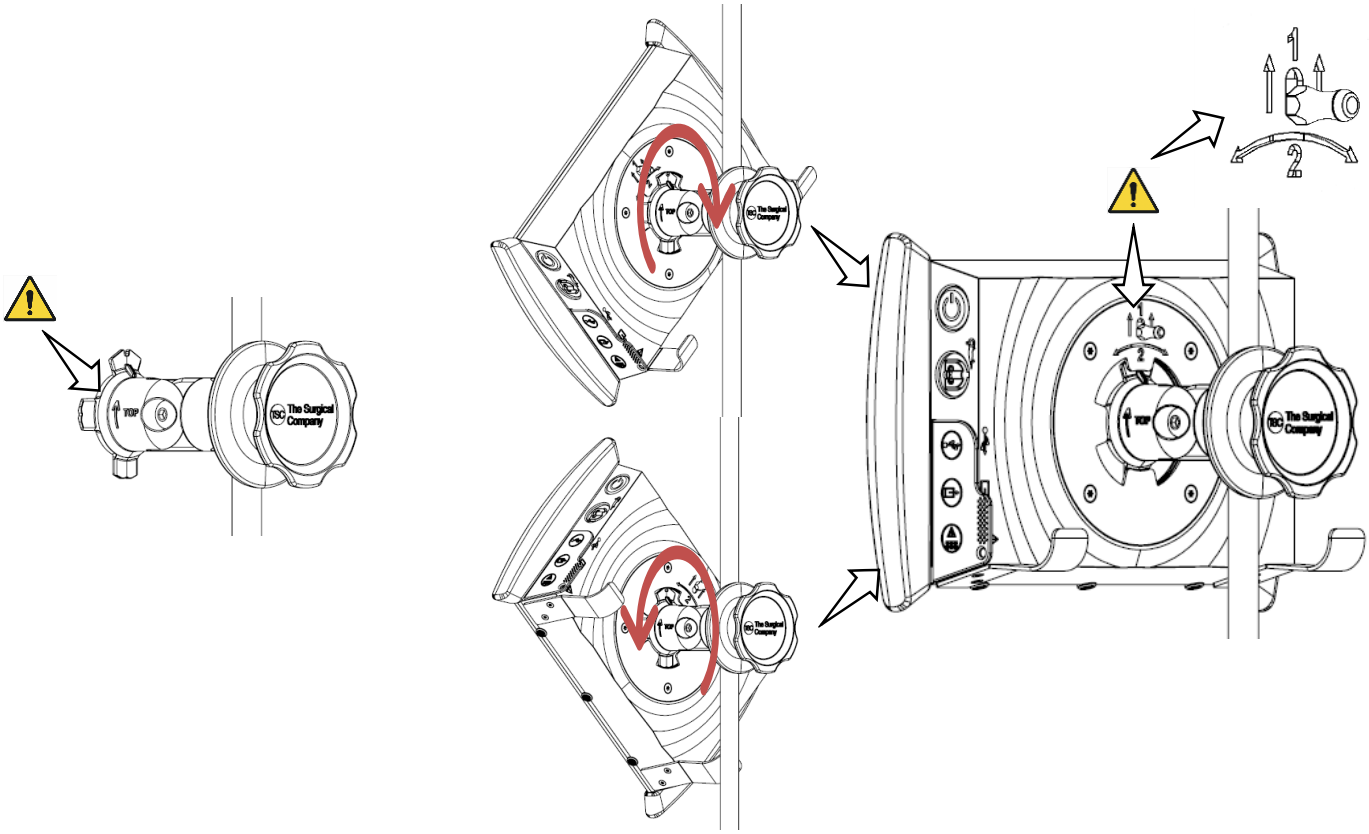
   Make sure the Screeni is secure, without risk of falling or tipping.

b) Removal

Unscrew the knob while holding the Screeni and place it on a stable horizontal surface.

3.2.2. Quick removal and mounting of the Screeni leaving the fixing system on the vertical support

a) Mounting

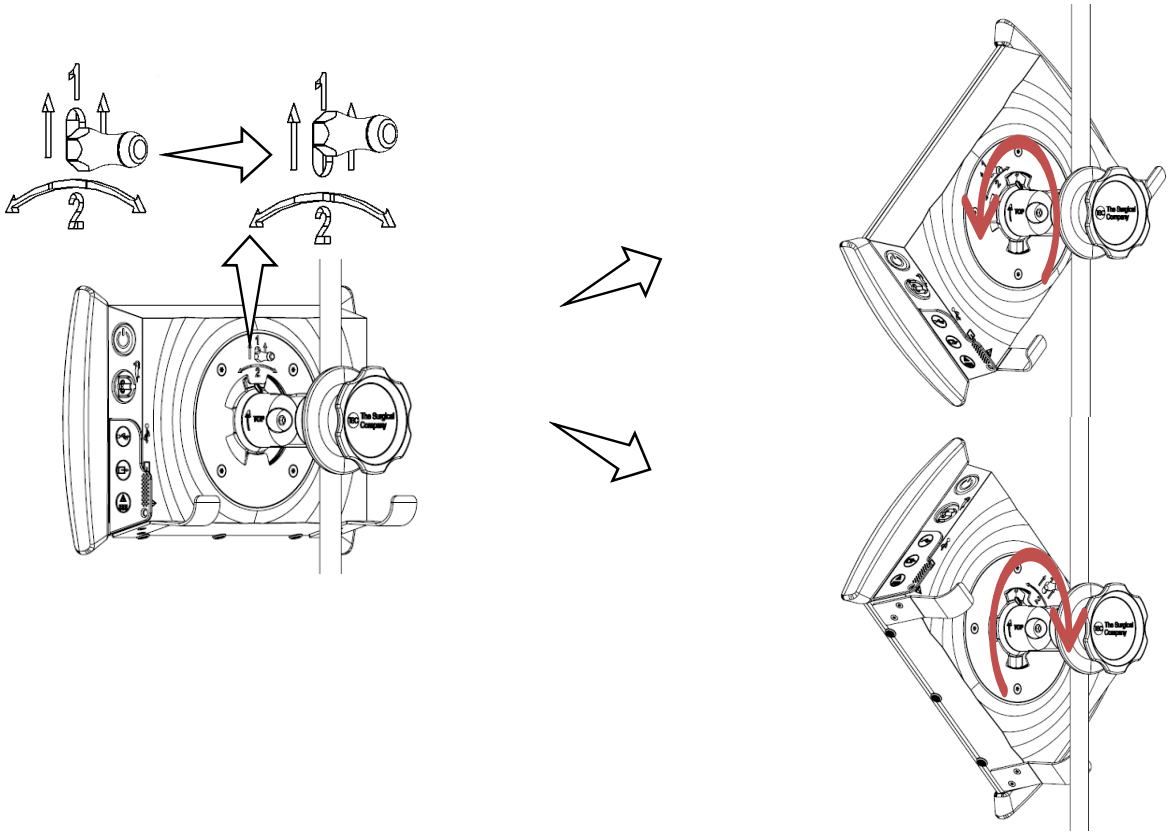


1) Ensure that the quick-connect bracket is properly installed ("Top" arrow on the side of the bracket facing upwards) and correctly tightened on the IV pole.

2) Present the Screeni at a 45° angle and slot it into the quick-connect bracket, then rotate it to the right or left until it locks.

   Check the stability of the assembly and that the lever is locked.

b) Removal

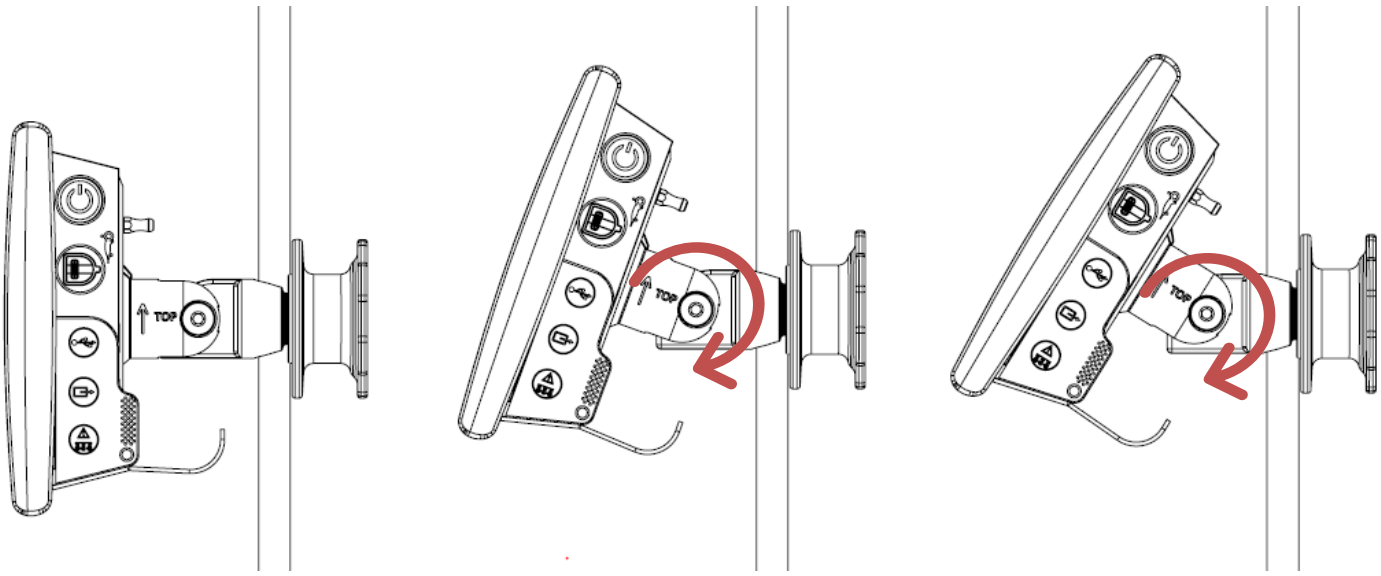


1) Raise the lever located on the back of the Screeni.

2) Holding the lever in the up position, rotate the Screeni to the right or left and remove it from its quick-connect bracket.

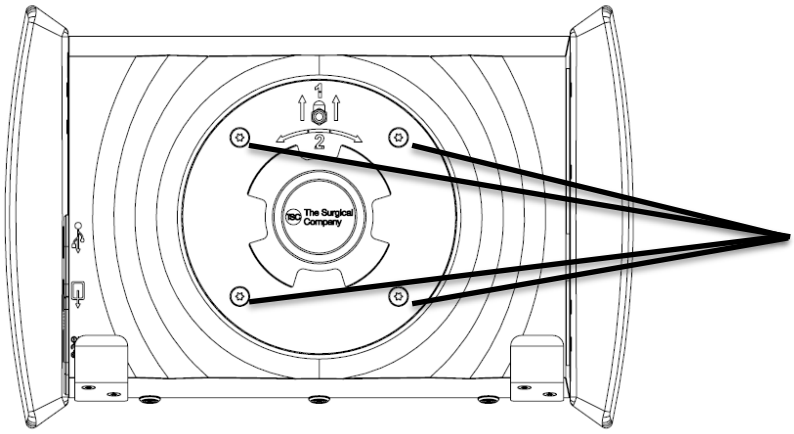
3.2.3. Tilting the Screeni

When the Screeni is in position on its quick-connect bracket, it is possible to adjust its vertical tilt, holding the bumpers:



3.2.4. VESA mounting

The Screeni can be mounted on a VESA 75x75 mount. To do this, remove the quick-connect bracket as described in § 3.2.2 "*Quick removal and mounting of the Screeni leaving the fixing system on the vertical support*".



Next, attach the Screeni to the VESA mounting bracket (not supplied) using four M4 x 10 mm screws (not supplied).

⚠	Comply with the size of the screws for VESA mounting to avoid any system damage.

3.3. Power connection

See the list of connectors contained in the package, connect the appropriate power adaptor to the power supply according to the geographical area of use of the system. To change the mains adaptor, see the power supply manual supplied in its packaging.

If used for the first time, connect the power cord to the Screeni and connect the power supply to a power socket.

⚠	Use only the power cable provided by Axess Vision to power and charge the Screeni (see list of components presented in § 2 "*Description of the Screeni and its accessories*").
⚠	When using a power strip to power the Screeni: • verify that it complies with the IEC 60884-1 standard, • make sure that it is not placed on the floor, to prevent possible ingress of liquids and to avoid mechanical or electrical damage.
⚠	The use of accessories, transducers or cables other than those described and supplied by Axess Vision may result in an increase in electromagnetic emissions or reduce the electromagnetic immunity of the Screeni and cause a malfunction.

The power connector LED lights up white when the Screeni is fully charged and connected to mains power, and orange if the Screeni is charging on mains power.

3.4. Video output

The Screeni can be connected to a secondary monitor in order to duplicate the live image from the endoscope. To ensure correct operation of the remote display, please follow the recommendations below:

- Only use the HDMI/DVI cable supplied with the Screeni (ref 00020019),
- Minimum monitor requirements:
  - Must have a DVI input,
  - Minimum accepted resolution 1,280 x 720 with an aspect ratio of 5:4 or 16:9.

	The Screeni was tested and validated with the NDS EndoVue 24” monitor.
	To avoid any risk of electric shock, the secondary monitor connected to the Screeni must meet the requirements of IEC 60601-1 standard. Correct operation of the assembly must be verified before use and the remote display must be checked before the start of the examination.

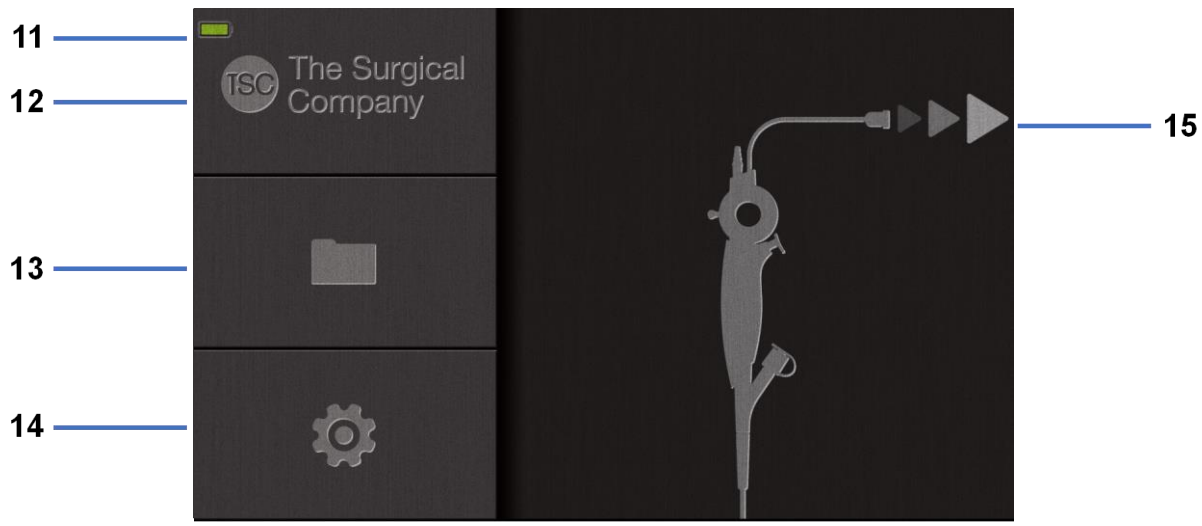
4. INSTRUCTIONS FOR USING THE SCREENI

The Screeni™ comes with built-in software. The version number of the installed software can be accessed by simply clicking the "TSC" button/logo **(12)** from the home page. For information concerning the latest software features, go to https://www.tsc-group.com/endovision/ or contact the local representative.

4.1. Using the Screeni™ for an examination

	Before each use, ensure that the orientation of the images observed using the endoscope is correct and check whether[VB1] the image displayed is live or not.
	If the following battery symbol is displayed , connect the Screeni™ to the mains supply immediately before continuing the examination. *A full battery charge takes about 3 hours.*
	In case of the Screeni™ is used with a secondary monitor, always check the main touchscreen to be sure to not miss any relevant message during an examination[LP2].
	Screeni™ automatically adjust the illumination to ensure adequate visibility and white balance is not needed

1) Switch on the Screeni™ by pressing the "On/Off" button.
   When the home interface below is displayed, the system is operational:



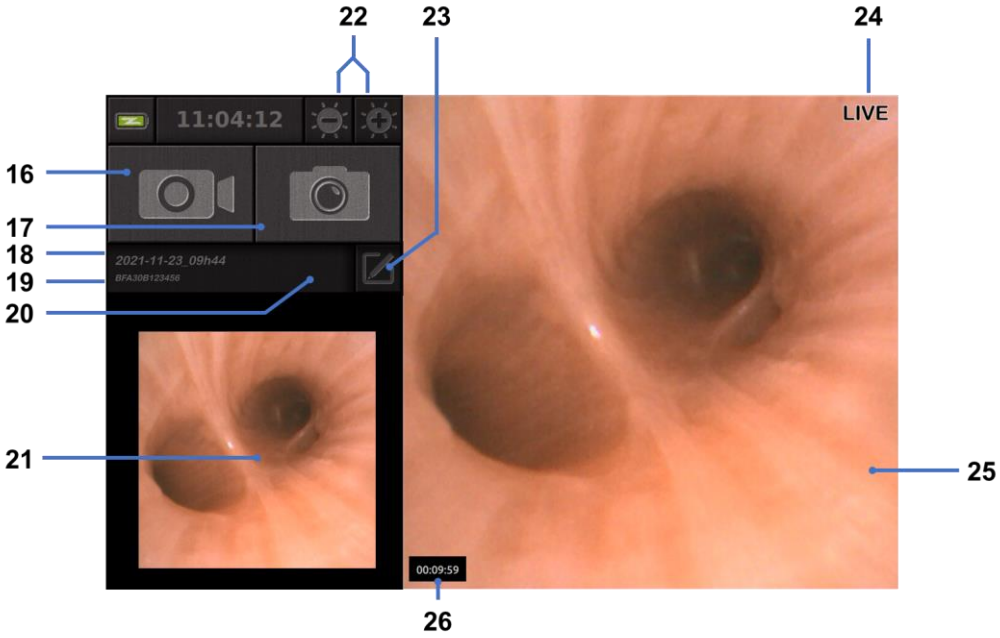
#	Meaning
11	Battery charge level.
12	Indication of software version.
13	Access the examination manager.
14	Access Screeni™ settings.
15	Indication of the location of endoscope connection.

2) Check the battery charge level indicator **(11)**

Logo displayed	Battery power indicator
	Battery charging
	100% - 80%
	70% - 50%
	40% - 20%
	15% - 5%
	Battery fault (See § 7 *"Troubleshooting and Serious incident"*)

3) Connect the endoscope to the Screeni™

The system automatically switches to "live":



#	Meaning
16	Start/Stop a video recording of the current examination.
17	Take a photo of the current examination.

18	Examination name.
19	Batch number of the endoscope in use[LP3].
20	Symbol indicating whether the endoscope has already been used (absent by default).
21	Last photo taken (pressing the last photo taken provides access to current examination management: see § 4.3 *"Examination management"*).
22	Adjust the "live" image brightness
23	Edit the examination name.
24	"Live" indicator[LP4].
25	"Live" area (double tap to enable full screen mode, see $4.1.1 "*Full screen mode"*)
26	Examination duration

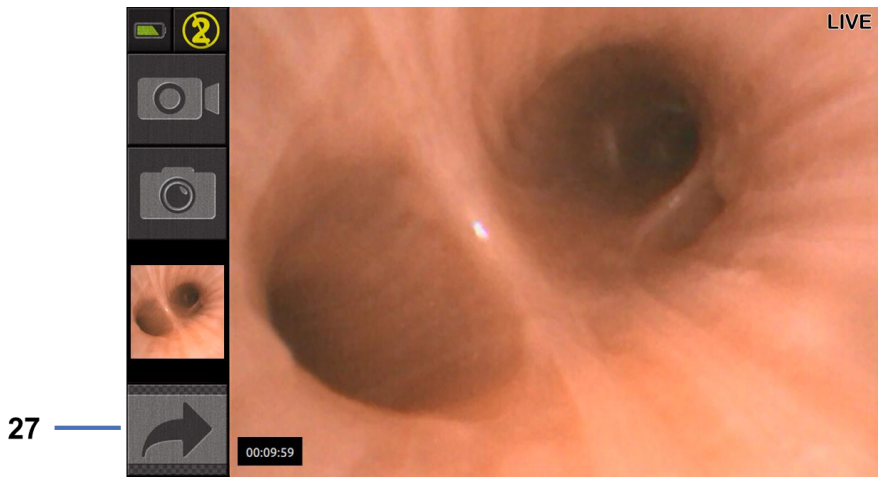
4) Check that a live video image appears on the screen. Point the distal tip of the endoscope display device to an object or the palm of your hand and make sure that the "LIVE" indicator appears.

⚠	If the symbol [VB5] is displayed, this indicates that the endoscope has already been connected to a Screeni™. The user is responsible for continuing the examination.

5) To finish the examination, disconnect the endoscope from the Screeni™ after removing it and moving it away from the patient. The home screen is displayed once more. See the instructions for use of the endoscope used for details concerning its disposal.

4.1.1. Full screen mode

If needed, during examination, you can enable the full screen mode by double taping on the live area.



#	Meaning
27	Full screen symbol

To exit from the full screen mode, simply double tap again on "live area" or click on the "full screen" symbol.

ℹ	The full screen mode will be automatically switch off when you power off the system or when the endoscope is disconnected.

4.2. System shutdown

Disconnect the endoscope from the Screeni™ if you have not already done so.

Switch off the Screeni™ by pressing the On/Off button once. You will be asked to confirm the shutdown request. If no response is given to the system, shutdown is automatically cancelled.

See § 5 "*Cleaning precautions*" for cleaning the Screeni™.

If the charge level of the Screeni™ battery is low, charge it (see § 3.3 "*Power connection* ").

4.3. Examination management

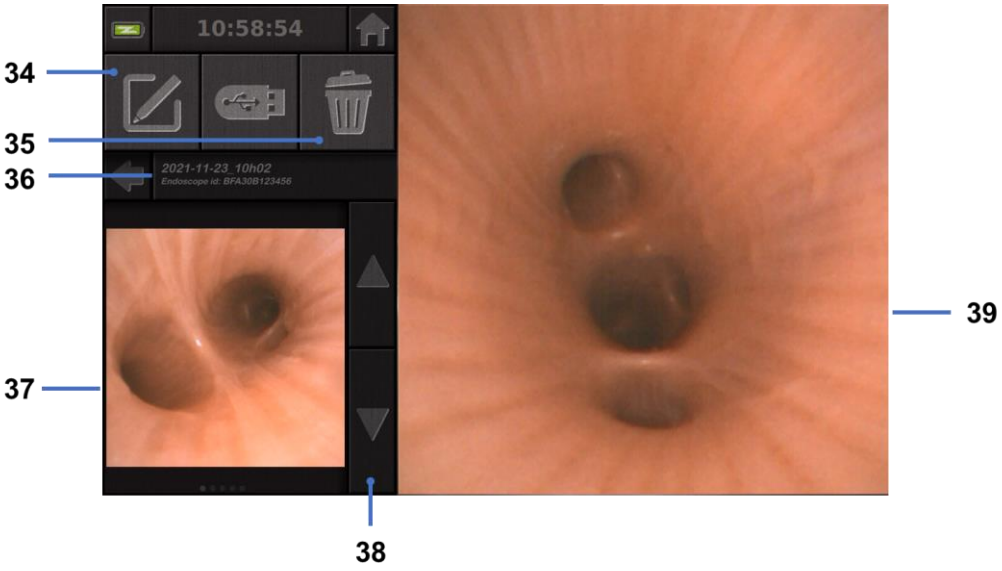
	The USB port is for connecting a USB flash drive only.
	Do not remove the USB drive while it is copying examination data as this may corrupt the contents of the USB key.
	At any moment during the examination, you can return to the "live" view by pressing the "home" or "back" buttons.

To access exam management:

- Press the dedicated button on the home page,
- Press the last photo taken from the "live" page.

#	Meaning
28	Export an examination (the button is enabled when a USB key is connected to the system).
29	Delete an examination.
30	Back to the previous screen (back to "live" if an examination is in progress).
31	List of examinations contained in the system.
32	Scroll through saved records. You can also swap with your finger to browse saved records
33	Back to the home screen (back to "live" if an examination is in progress).

When a record is selected from the examination list, the following interface is displayed:



#	Meaning
34	Rename the examination being viewed.
35	Delete a file.
36	Details of the selected examination.
37	Thumbnail display area.
38	Scroll through files. You can also swap with your finger to browse saved records
39	Selected file viewing area.

From the examination review page, the following actions are possible:

- Review photos and videos made during an examination,
- Rename the examination,
- Delete the file being viewed,
- Transfer the examination to a USB key connected to the system.

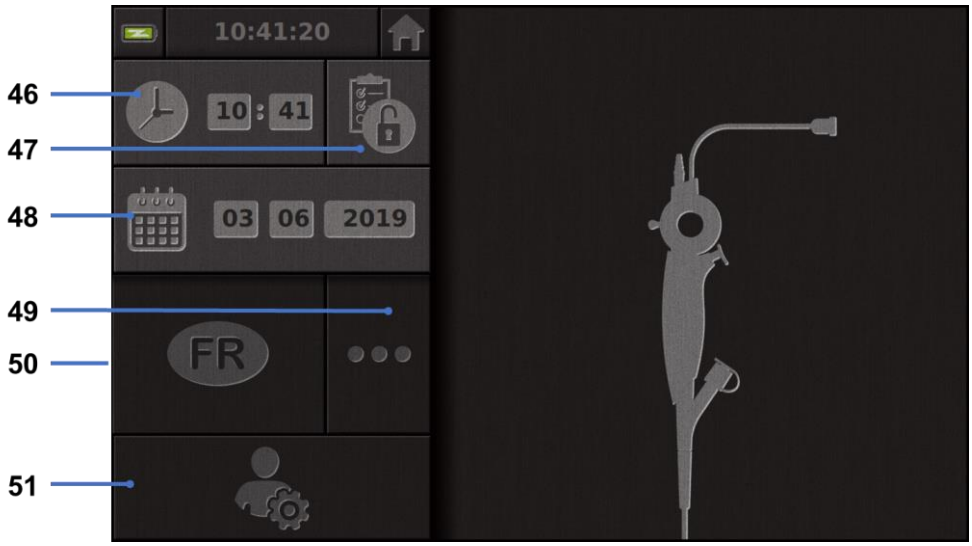
When replaying a video, a controller appears, allowing you to navigate easily within the video:

#	Meaning
40	Video navigation bar.
41	Rewind the video by 1 second (if video paused) or 5 seconds (if video in playback mode).
42	Resume video playback.
43	Pause video playback.
44	Fast forward the video by 1 second (if video paused) or 5 seconds (if video in playback mode).

45	Information on the current position of the video and its total duration.

4.4. Settings management

The settings are only accessible when no examination is in progress, from the home page using dedicated button **14**



#	Meaning
46	Set time.
47	Password locking of examination manager access.
48	Set date.
49	Language selection.
50	System language.
51	Access administrator settings. This feature can only be used by the manufacturer/local representative and is password-protected.

5. CLEANING PRECAUTIONS

	The Screeni must be switched off and the power plug must be removed from the socket before starting the cleaning procedure.
	Never immerse the Screeni in liquid, never clean the Screeni by autoclave or steam and never pour alcohol directly onto the Screeni.
	Do not spray or pour liquid solution directly onto the Screeni.
	Disinfect if necessary, in accordance with the hospital's standards and protocols or applicable local regulations.
	Check that no liquid comes into direct contact with any electrical components of the Screeni.
	Never use a solution containing a ketone or an abrasive solution.

It is recommended to clear the Screeni regularly, in accordance with the hospital's standards and protocols or applicable local regulations. The following solutions should be applied by wetting a non-abrasive sterile gauze compress and must be compatible with those recommended below:

- Mild detergent (pH 7 - 9) and water
- Isopropyl alcohol and water, 70% by volume

After cleaning, the Screeni should be stored in a clean, dry place, in accordance with the atmospheric conditions detailed in § 9.1 "*Conditions of transport, storage and use*".

6. WARRANTY

The Screeni has a two-year warranty from the date of purchase. Opening the Screeni will void the legal warranty.

7. TROUBLESHOOTING AND SERIOUS INCIDENT

Inspection indications and actions are proposed below to resolve most problems encountered.
In the event that the following instructions do not correct the problem, return the Screeni™ to the local authorised Axess Vision Technology representative for analysis and repair or replacement of the product.

Problem	Cause(s)	Actions
The Screeni™ will not switch on	The battery is uncharged	Connect the Screeni™ to the mains with the specific transformer, and check that the system is working again.
	The battery is uncharged and no power supply	Check the connection to the hospital electrical network. If the Screeni™ is connected to a power strip, check that the power strip is working properly.
The power connector light flashes orange	Battery fault	Return the Screeni™ to the local representative.
The following battery symbol is displayed: 		
No image despite a connected endoscope	Faulty endoscope/Screeni™ connection	First check that the endoscope has been detected, making sure that the "live" page is displayed. Disconnect and reconnect the consumable.
	Faulty endoscope	Connect another endoscope.
No display on the secondary monitor	Video cable incorrectly connected AND / OR Incompatible secondary monitor	Check that the video cable supplied with the Screeni™ is properly connected.
Poor image quality on the secondary monitor		Check that the monitor correctly meets the requirements listed in the § Video output section. Change the monitor if necessary.
Poor image quality.	The distal part of the endoscope is dirty.	Refer to dedicate endoscope IFU.

Any serious incident that has occurred in relation to the device should be reported to Axess Vision Technology (via local representative) and the competent authority of the Member State which the user is established.

Serious incident means incidents that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat (= an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time).

8. MAINTENANCE

8.1. Nature and frequency of maintenance and calibration

No calibration or maintenance is necessary.

	Any modification of the Screeni by the user is strictly forbidden. Failure to comply with this instruction may result in injury to the patient or the user and/or impede the correct operation of the video-endoscopic system. If the Screeni malfunctions, see § 7 "*Troubleshooting*" or contact the local representative.

8.2. Certificate of compliance with the specifications

The manufacturer, Axess Vision, certifies the compliance of its equipment, both in terms of design and manufacturing, with the applicable directives and regulatory standards.

It uses the appropriate components taking into account:

- their technical characteristics and their limitations,
- their intended use and the electromagnetic environment.

9. TRANSPORT, STORAGE, USE AND DISPOSAL

9.1. Conditions of transport, storage and use

	Parameters	Minimum	Maximum
Transport and storage conditions	Temperature	-10°C (14°F)	+60°C (140°F)
	Relative air humidity (no condensation)	10%	90%
	Atmospheric pressure	80kPa	109kPa
Conditions of use	Temperature	+ 10°C (50°F)	+ 40°C (104°F)
	Relative air humidity (no condensation)	30%	85%
	Altitude and atmospheric pressure	≤ 2000m – 80kPa ~ 109kPa	
Protection type	The Screeni has an IP30 protection rating. It must be stored away from projections of foreign bodies less than 2.5 mm in diameter. It must be stored away from liquid splashes as there is no protection against water drops.		

	If you do not use the Screeni for several months, perform a full charge and battery strength test before use.

9.2. Waste disposal

In accordance with Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), Screeni belongs to category 8 of WEEE (medical devices with the exception of all implanted and infected products).

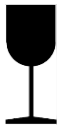
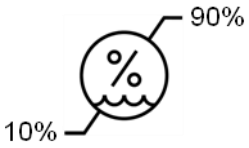
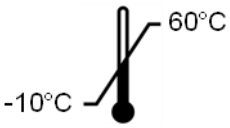
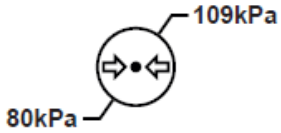
In order to preserve the environment, the Screeni electronic interface unit must not be discarded with household waste, but rather with waste electrical and electronic equipment for a cycle of reuse, recycling or any form of recovery of this electrical and electronic equipment.

If necessary, return the Screeni unit to the local representative for disposal.

10. LABELS AND MEANING OF SYMBOLS

The meanings of the various symbols and labels are described in the table below:

Symbol	Meaning
	Manufacturer
	Date manufactured
MD	Medical device
SN	Serial number
REF	Catalogue reference
	Class 2 electrical protection device
	Read the instructions for use before use
	Do not dispose of with normal household waste
	Keep out of sunlight and away from UV radiation.
CE 1639	Conformity marking as per the European medical devices directive (MDD) 93/42/EEC, accompanied by the identification number of the notified body SGS
15V – 2A	Input voltage: 15V DC; sink current: 2A
IP30	Symbol certifying protection against the effects of temporary immersion in water in accordance with IEC 60529. IPN_1N_2 with N1 = 3 Protection against 2.5 mm diameter solid foreign objects, N2 = 0 No protection from liquids
	Indicates that the instructions for use contain important cautionary information, such as warnings and precautions, that cannot, for various reasons, be displayed on the medical device itself

	Do not use if package is damaged
	Do not expose the box to rain
	Fragile contents
	Store in an environment with a relative humidity of between 10 and 90%
	Store in an environment with a temperature of between -10 and +60°C
	Store in an environment with an atmospheric pressure of between 80 and 109 kPa
Pat. Pending	Patented device
Rx only	Device to be used on prescription only
 E507080	**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. 60601-1:14" "IEC 60601-2-18:2009"

11. TECHNICAL INFORMATION

ELECTRICAL CHARACTERISTICS		
Power supply	Power requirement	100-240V AC / 50-60Hz / 0.6A
	Power output	15 VDC / 2A
Type of protection against electrocution	Class 2	
Battery type	Lithium-Ion battery (11,25V - 2950mAh or 10,8V – 3350mAh)	
Autonomy	At least 3 hours *(for a new and fully charged battery)*	

MECHANICAL CHARACTERISTICS	
Dimensions	L: 300 mm x H: 200 mm x D: 110 mm (mounting bracket folded)
Weight	1.8 kg (with mounting bracket)
Mounting interface	VESA 75 mm
TOUCH SCREEN	
Maximum resolution	1280x800
Display Type	10.1 inch TFT LCD
Viewing angle	Horizontal: 170° Vertical: 170°
MISCELLANEOUS CHARACTERISTICS	
Protection Rating	IP30
Exported file formats	Photos: .JPG Videos: .AVI (h264 compression)
TECHNICAL CHARACTERISTICS	
Internal storage capacity	16 Gb (can store up to 14 h of video or more than 100,000 photos)
Connections	USB Type A (for USB key connection only)
	Endoscope port
	DC 15V / 2A input
	HDMI port: video output to be used with a DVI compatible monitor only and with the HDMI/DVI cable supplied.

11.1. Essential performance

The following requirements are verified and validated:

- Viewing of the upper airways and of the bronchial tree,
- Correct image orientation in the view observed by the operator,
- Guarantee that the image viewed during an endoscopic procedure is a live one rather than a recorded image.

11.2. Information concerning the electrical protection class

The Screeni possesses class 2 protection meeting the following requirements:

- Protection ensured by a set of constructive provisions making power of the device's exposed conductive parts unlikely,
- Extra "insulation" added to the main insulation,
- Metal parts separated from live parts by main insulation inaccessible to the user,
- No possibility of grounding the exposed conductive parts (elimination of contact voltage risks).

11.3. Electromagnetic compatibility information

	The use of accessories, transducers or cables other than those described and supplied by Axess Vision may result in an increase in electromagnetic emissions or reduce the electromagnetic immunity of the Screeni and cause a malfunction.

⚠	RF portable communications equipment (including peripherals such as antenna cables and external antennas) should not be used less than 30 cm (12 inches) from any part of the Screeni, including cables specified by Axess Vision. Otherwise, the performance of these devices may be impaired.
⚠	Do not use the Screeni in a room exposed to strong electromagnetic radiation (for example near medical treatment equipment using microwaves or short waves, MRI, radio or mobile/cordless phone). In the event of interference, mitigation measures such as reorienting or moving this instrument or isolating the area may be necessary.
⚠	It is not recommended to use the Screeni near other devices or to stack it on other devices. If adjacent installation or stacking is necessary, it should then be checked that the Screeni is working correctly.
⚠	This medical electric equipment requires specific precautions with respect to electromagnetic compatibility (EMC) and should be installed and used in accordance with the instructions in this manual. It is very unlikely that this device will cause harmful interference with other nearby devices. However, there is no guarantee that interference will not occur in a particular installation. Loss of performance of this device or other devices when they are used simultaneously may cause interference. If this occurs, try to correct the interference by means of the following measures: • Switch nearby devices on and off in order to determine the source of the interference, • Reorient or move this device or other devices, • Increase the distance between the devices, • Connect the device to a socket on a different power circuit to that of the other devices, • Eliminate or reduce electromagnetic emissions using technical solutions (such as shielding), • Ensure other medical devices in the vicinity comply with IEC 60601-1-2 standards. Portable and mobile radiocommunications devices (mobile phones, etc.) can affect medical electrical equipment. Please ensure you take the necessary precautions during their operation.

The Screeni is designed to comply with standard IEC 60601-1-2, which contains requirements related to electromagnetic compatibility (EMC) for medical electrical equipment. The emissions and immunity limits specified in this standard are given to provide acceptable protection against the harmful interference encountered in a typical medical environment.

The system complies with the essential performance requirements specified in standards IEC 60601-1 and IEC 60601-2-18. The results of immunity tests demonstrated that the essential performance of the system is not lost when the system is subject to the conditions present in the following tables.

11.3.1. Table 201: Electromagnetic emissions

Comparison of emissions requirements		
Emissions tests	**Compliance**	**Electromagnetic environment – guidance**
Conducted emissions CISPR 11 / AMD1	Group 1 / Class A PASS	The Screeni uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment. The emissions characteristics of this device enable it to be used in industrial environments and hospital settings (class A defined in CISPR 11). When it is used in a residential environment (for which class B defined in CISPR 11 is normally required), this device may not provide adequate protection for RF communications services. The user may need to implement corrective measures, such as reinstallation or reorientation of the device.
Radiated emissions CISPR 11 / AMD1	Group 1 / Class A PASS	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker IEC 61000-3-3 / AMD1	Not applicable	
Device with motors or switching devices CISPR 14-1	Not applicable	

11.3.2. Table 202: Electromagnetic immunity

Comparison of immunity levels – Transient phenomena			
Immunity tests	**IEC 60601 test level**	**Verdict**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	PASS	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz PRR	PASS	Mains power quality should be that of a typical commercial or hospital environment.
Surge – AC mains power supply IEC 61000-4-5 AMD1	± 2 kV common mode ±1 kV differential mode 0°, 90°, 180° and 270° phase change	PASS	
Surge – 12 VDC power supply ISO 7637-2	600 V	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 / AMD1	UT = 0%, 0.5 cycles (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) UT = 0% 1 cycle – UT = 70% 25/30 cycles (0°) UT = 0% 250/300 cycles	PASS	
Conducted immunity IEC 61000-4-6	3V (0.15-80MHz) 6V (ISM bands)	PASS	
Magnetic immunity IEC 61000-4-8	30 A/m 50 and 60 Hz	PASS	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Proximity magnetic immunity IEC 61000-4-39	30kHz at 8A/m 134.2kHz at 65A/m 13.56MHz at 7.5A/m	PASS	
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Comparison of immunity levels – Field phenomena at steady state		
Immunity tests	**IEC 60601 test level**	**Verdict**
Radiated RF disturbances IEC 61000-4-3 / AMD1 / AMD2	3 V/m 80 MHz to 2.7GHz	PASS
Nearby fields emitted by wireless RF communications equipment IEC 61000-4-3 / AMD1 / AMD2	9V/m to 28 V/m 15 specific frequencies	PASS

Electromagnetic environment – guidance

RF portable communications equipment (including peripherals such as antenna cables and external antennas) should not be used any closer to any part of the Screeni, including cables specified by Axess Vision, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:

$$d = 1{,}17 \cdot \sqrt{P} \ (for\ a\ frequency\ ranging\ from\ 150kHz\ to\ 80MHz)$$
$$d = 1{,}17 \cdot \sqrt{P} \ (for\ a\ frequency\ ranging\ from\ 80MHz\ to\ 800MHz)$$
$$d = 2{,}33 \cdot \sqrt{P} \ (for\ a\ frequency\ ranging\ from\ 800MHz\ to\ 2{,}7GHz)$$

where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter's manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

Recommended separation distances between portable communication equipment and the Screeni

The Screeni is intended for use in an electromagnetic environment in which radiated radioelectrical disturbances are controlled. The customer or the user of the Screeni can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Screeni, as recommended below, according to the maximum output power of the communications equipment.

Maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1{,}17 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1{,}17 \cdot \sqrt{P}$	800 MHz to 2.7GHz $d = 2{,}33 \cdot \sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.33 m
10	3.7 m	3.7 m	7.37 m
100	11.70 m	11.70 m	23.30 m

11.4. Applicable standards

The Screeni meets the following standards:

- **Directive 93/42/EEC**: *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*
- **60601-1 edition 3.1**: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- **60601-1-2 edition 4.1**: *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests*

12. MANUFACTURER'S CONTACT DETAILS

Axess Vision Technology

Zone de la Liodière

6 rue de la Flottière

37300 Joué-lès-Tours – France

https://www.tsc-group.com/endovision/