
visura

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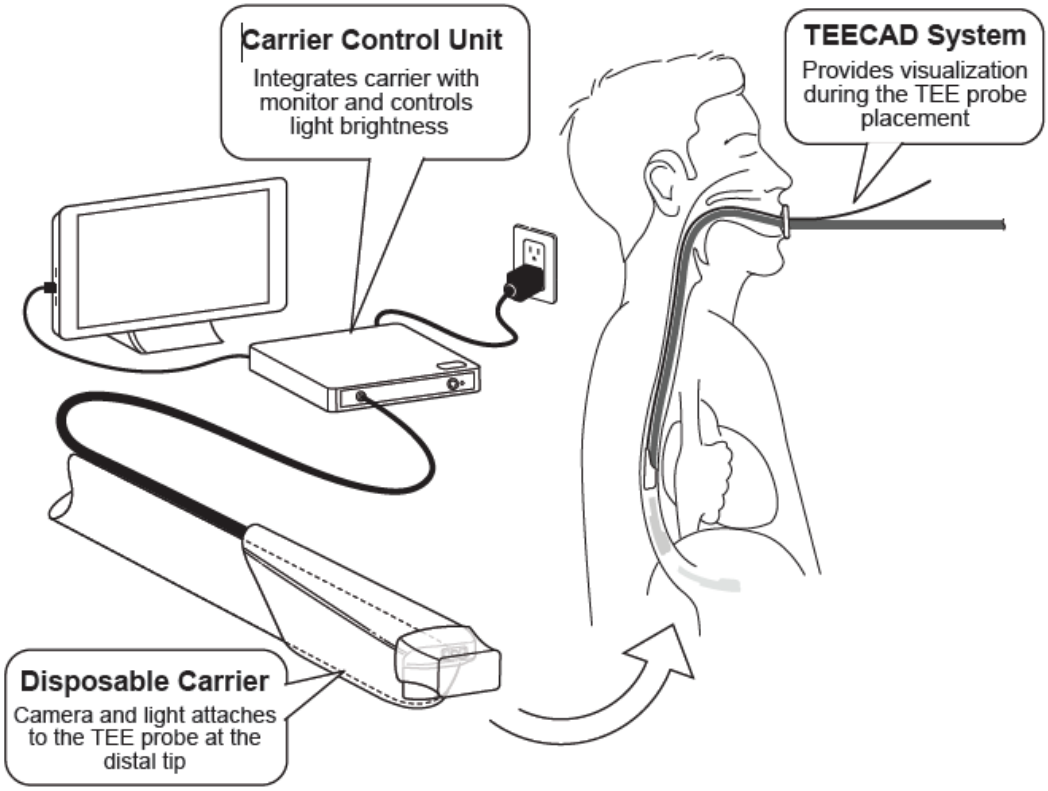
DESCRIPTION

The VISURA Transesophageal Echocardiogram Camera Assist Device (TEECAD) System is an endoscopic device that allows visualization of the esophagus and upper airway structures during Transesophageal Echocardiogram (TEE) probe placement. This device should only be used by physicians who have thoroughly studied all the characteristics of this device and who are familiar with the proper techniques of endoscopic visualization.

The TEECAD System consists of two components: a single-use Carrier with an integrated camera, and the Carrier Control Unit which provides HDMI connection to a monitor.



INTENDED USE

The TEECAD System is intended to provide visualization during the placement of a Transesophageal Echocardiogram (TEE) probe in adults. Do not use this system for any purpose other than the intended use.

COMPATIBLE TEE PROBES

This TEECAD System is designed for use with:

- Philips X7-2t TEE transducer probe
- Philips X8-2t TEE transducer probe

- Siemens Healthineers Acuson X300 TE-V5Ms transducer
- Siemens Healthineers Z6Ms True Volume transducer
- GE HealthCare 6VT-D KSVEE probe

ACCESSORIES USED WITH THE TEECAD SYSTEM

The following accessory is recommended for use with the TEECAD System; however, it will not be provided as part of the System.

- Ultrasound Gel - Standard hospital use ultrasound gel is recommended for use with the Disposable Carrier and TEE probe. Application of ultrasound gel on the TEE probe helps ease the Carrier onto the TEE probe during attachment. In addition, application of ultrasound gel to the Carrier and ultrasound probe aids in probe intubation.

IMPORTANT

Read this manual before operating the TEECAD System and save for future reference.

This manual describes the recommended procedures for inspecting and preparing the TEECAD the System after its use.

This manual does not describe how an actual TEE procedure is to be performed, nor does it attempt to teach proper technique or any medical aspects regarding the use of the TEE equipment.

Failure to follow the instructions in the manual may result in damage to and/or malfunction of the TEECAD System.

Do not use this TEECAD System for any purpose other than that for which it has been designed. If you have questions regarding information in this manual, or concerns pertaining to the safety and/or use of this System, please contact VISURA.

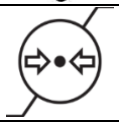
Refer to the requirements of IEC 60601-1:2005 +A1:2012 when incorporating this equipment into a Medical Electrical System (addition of TEE probe or other external parts).

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

DEFINITION OF SYMBOLS

The meaning(s) of the symbol(s) shown on the package with the components, the back cover of this instruction manual and/or this instrument are as follows:

Symbol and text	Meaning
	Shock protection for Type BF medical device
	For Prescription Use Only
	Follow operating instructions
Input power: 110-240 VAC, 50-60 Hz, 12 VA	Rated supply voltage and input power
	Keep Dry
IP20	Degree of enclosure protection
	At the end of its useful operating life, dispose of the Carrier, Carrier Control Unit, and Carrier Power Supply in accordance with the Waste Electrical and Electronic Equipment EC Directive - WEEE, hospital/facility procedures, and regional waste disposal and recycling requirements.
	Store and transport within given humidity range
	Do not reuse
	Do not use device if package is damaged
	Store and transport within given temperature range
	Store and transport within given pressure range
	Lot Number
	Serial Number
	Reference/ Catalogue Number

	Manufacturer
	Non-Sterile
	MR Unsafe
	IEC Class II Power Supply
	Alternating Current
	Direct Current
	Caution

WARNINGS

1. The TEECAD Carrier is single use only. Do not attempt to sterilize or reuse, as reuse may result in impaired performance, patient injury and/or transmission of infectious diseases from one patient to another.
2. When using the TEECAD System, if there is a concerning anatomical abnormality (e.g., esophageal diverticula or rings, large ulcerations etc.), do not attempt to use the TEECAD for guidance around the abnormality. Instead, immediately stop the procedure, withdraw the TEECAD Carrier and TEE probe, and have the patient fully evaluated with a formal endoscopy.
3. Do not stare directly into the distal end of the Carrier while the illumination lights are on. Do not shine the Carrier's illumination lights into the eyes of the patient. Otherwise, eye injury may result.
4. Use of TEE probes and accessories other than those specified for use with the TEECAD System could adversely affect the operation or safety of the TEECAD System.
5. The TEECAD System is MR Unsafe. Use of the TEECAD System will be hazardous in all MRI environments.
6. Only use the TEECAD Carrier Control Unit with IEC 60950/IEC 62368 certified monitors.
7. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify they are operating normally.
8. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30 cm (12 inches) to any part of the Carrier Control Unit, including CCU system cables. Otherwise, degradation of the performance of the equipment could result.

PRECAUTIONS

The following precautions should always be exercised with the use of all electro-medical equipment to ensure safety to all involved parties including user(s) and patient(s).

1. The physician must read and understand the Instructions for Use prior to using the TEECAD System.
2. The TEECAD System should only be used by trained physicians who are experienced and have an understanding of the proper techniques of endoscopic visualization.
3. Store the TEECAD System in a cool, dry environment and away from direct sunlight.
4. Do not use the TEECAD Carrier or Carrier Control Unit if the package is opened or damaged.
5. Inspect the TEECAD Carrier prior to use. Do not use if the Carrier does not function prior to use, or if the Carrier appears to be damaged in any way. Please contact VISURA if the TEECAD Carrier or the Carrier Control Unit are damaged.

CONTRAINDICATION

The TEECAD Carrier is contraindicated for use with a TEE probe sheath. The use of a sheath will impair visualization provided by the TEECAD System during the placement of a TEE probe.

TRAINING

This equipment should only be used under the supervision of a trained physician in a medical facility. Do not use in other locations or for any purposes other than the intended application.

INSTALLATION

1. The Carrier Control Unit should NEVER be installed or used in areas where it may get wet or be exposed to environmental conditions including high temperature, humidity, direct sunlight, dust, or salt, which may adversely affect the equipment.
2. The Carrier Control Unit should NEVER be installed or used in the presence of flammable or explosive gases or chemicals.
3. Plug the Visura provided AC/DC power adaptor into a properly grounded electrical outlet.
4. Do not allow the power cord to be twisted, crushed, or pulled taut.

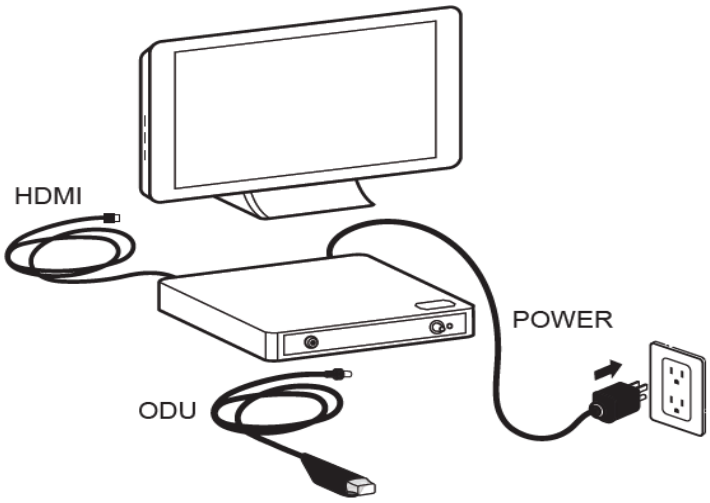
INSPECTION – PRIOR TO USE

1. Check the date of manufacture of the TEECAD Carrier to ensure that it is within its expected useful life of 5 years.
2. Inspect the outer surface of the Carrier to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.

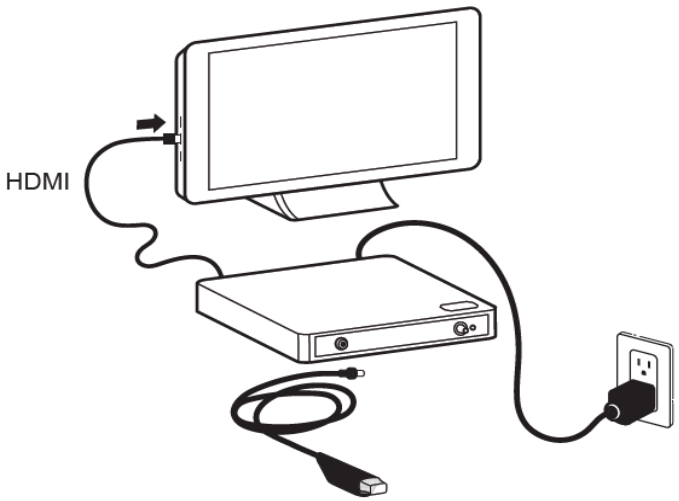
3. Check and confirm that all TEECAD System cords and cables are connected correctly and securely. If an appliance coupler, mains plug, or other separable plug is used to connect the CCU to a power source, ensure that the equipment is positioned such that it is not difficult to disconnect the CCU.
4. Confirm that the TEECAD System functions properly and check the operation of all switches, buttons, etc.
5. To prevent electrical shock, the Carrier Control Unit is insulated (type BF electro-medical equipment). Do not allow it to be grounded to other electrical devices being used for patient care. Non-conductive gloves should always be worn to prevent grounding through user(s).
6. Confirm that other devices used in conjunction with the TEECAD System function properly and will not adversely affect the operation or safety of the TEECAD System. If any component is not properly functioning, the procedure should not be performed.

CARRIER CONTROL UNIT SET-UP

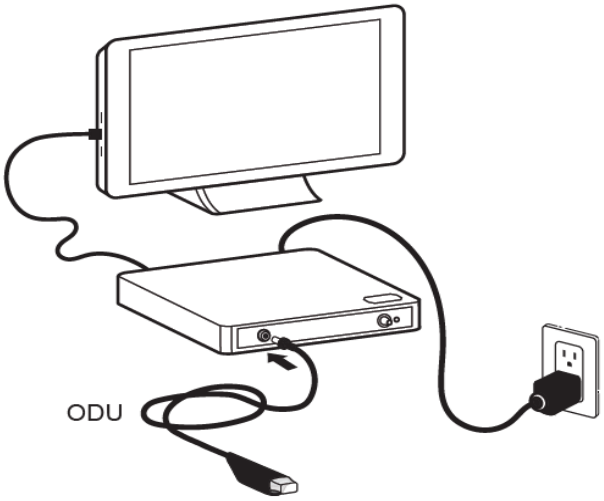
1. Plug the power cable of the Carrier Control Unit into a wall outlet.



2. Connect the Carrier Control Unit HDMI cable to an IEC 60950/IEC 62368 certified monitor.



3. Connect the TEECAD Carrier cable to the front panel of the Carrier Control Unit.



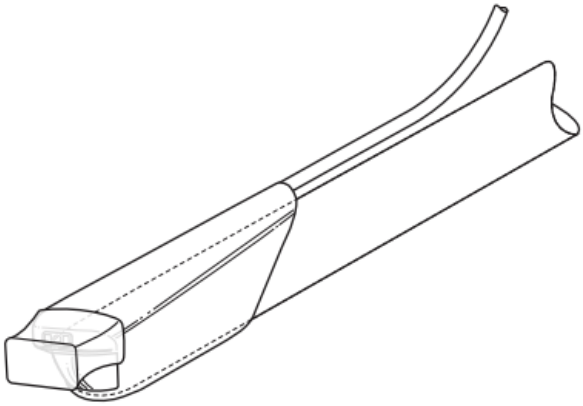
CARRIER CONTROL UNIT DIAL FUNCTIONALITY

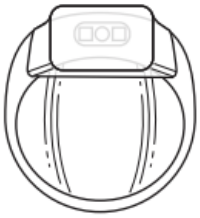
1. Illumination Rotary Dial
   - The illumination emitted from the light at the distal tip of the carrier can be adjusted by turning the rotary dial to the right to increase illumination and to the left to decrease illumination.

CARRIER SETUP

1. Remove the TEECAD Carrier from the packaging.

2. Plug the Carrier into the front of the Carrier Control Unit. Check functionality of the Camera by directing it near a surface and checking visualization on the monitor.
3. Apply a pea-sized amount of ultrasound gel to the inside of the Carrier using a gloved finger.
4. Slide the Carrier over the distal end of the TEE probe making sure the distal end of the TEE probe is visible as shown in the picture below.
5. Move the Carrier is respect to the TEE probe to ensure the Carrier is properly lubricated on the TEE probe.
6. Please note if the Carrier is not installed properly, the Carrier may become prematurely detached.
7. Apply ultrasound gel to the outside of the Carrier (avoid getting any gel on the camera lens) and TEE probe to aid probe intubation.





View of Distal Tip

TEECAD Carrier attached to TEE Probe

DURING USE

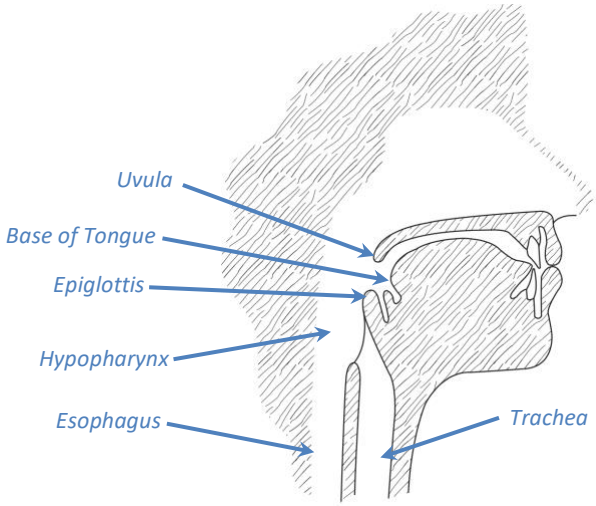
1. With the TEECAD Carrier securely attached to the TEE probe, utilize the visualization provided by the TEECAD System to aid intubation of the TEE probe in the patient. Refer to the KEY ANATOMICAL STRUCTURES section.
2. Make sure that no contact is made between the patient and the Carrier Control Unit.
3. Avoid looking directly at the light emitting from the TEECAD Carrier.
4. The illumination emitted from the light at the distal tip of the carrier can be adjusted by turning the rotary dial on the Carrier Control Unit “right” or “left”.
5. Monitor the TEECAD System and the patient for any signs of irregularities. If an irregularity is noted, take the appropriate action to ensure patient safety.
6. With the TEECAD Carrier attached, do not flex the distal end of the TEE probe more than 40 degrees in the anterior direction, more than 15 degrees in the posterior direction, or more than 15 degrees in the left or right direction.
7. If the operation of any component of the TEECAD System fails during the procedure and the visualization provided by the TEECAD System is lost or compromised, check the

connection between the Carrier cable and Carrier Control Unit. If visualization is not restored, place the TEE probe in a neutral position and withdraw the Carrier from the patient.

8. If difficulty occurs intubating the TEE probe, attempt to reposition the TEE probe/TEECAD Carrier assembly to aid intubation. If repositioning risks patient safety, place the TEE probe in a neutral position and retract the TEE probe (along with the Carrier) from the patient. If partial or complete retraction of the TEE probe with TEECAD Carrier attached is required during the procedure, keep gentle tension on the TEECAD's cable to avoid inadvertent detachment in the distal direction of the TEECAD Carrier from the TEE probe.
9. Prior to reinserting the probe with attached TEECAD Carrier into the patient, visually inspect the Carrier for physical damage, check that the camera works evidenced by the images displayed and verify the Carrier's securement on the TEE probe.
10. The TEECAD System should only be used according to the instructions and operating conditions described in this manual. Failure to do so could result in compromised patient safety, equipment malfunction or instrument damage.

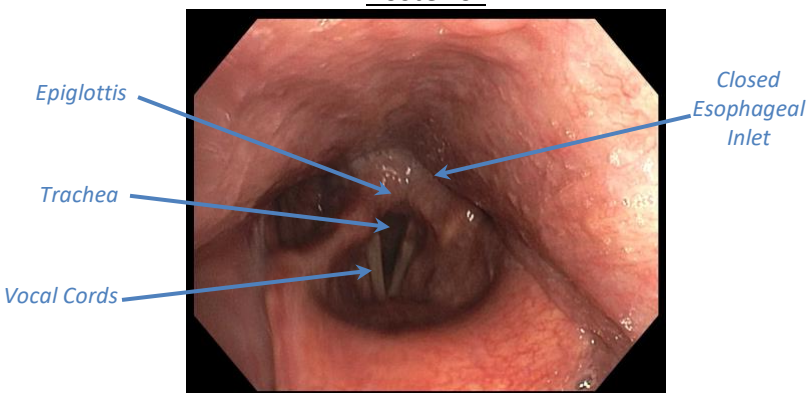
KEY ANATOMICAL STRUCTURES

Below is an overview of the anatomic structures of the oral cavity, hypopharynx, and esophagus:



Representative images of the anatomical structures are provided below:

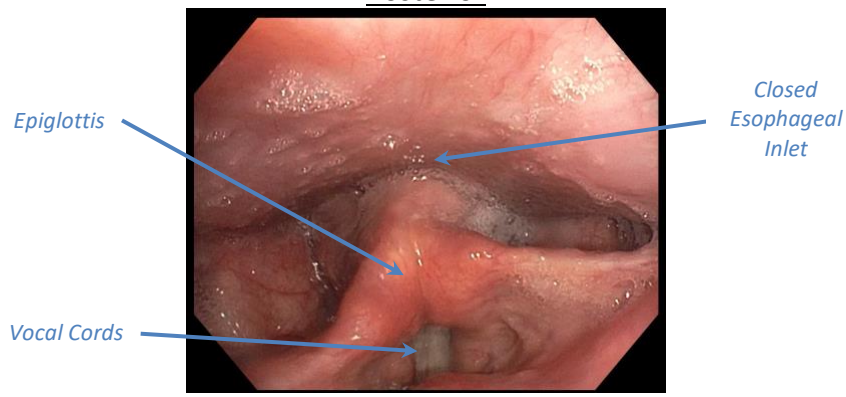
Posterior



Anterior

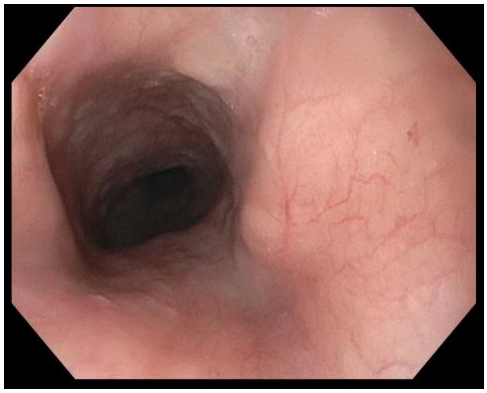
Normal Hypopharynx

Posterior



Anterior

Closed Vocal Cords



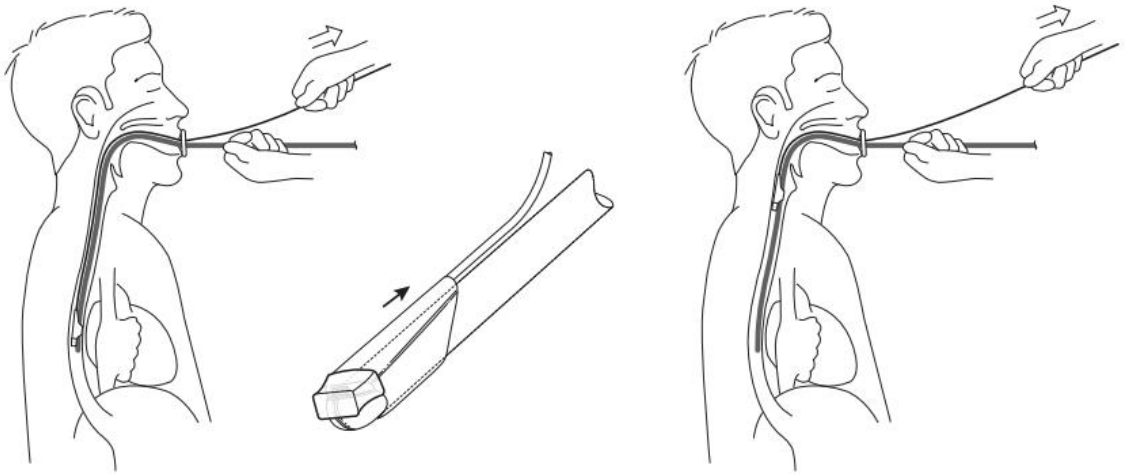
Normal Proximal Esophagus

REMOVAL OF THE CARRIER

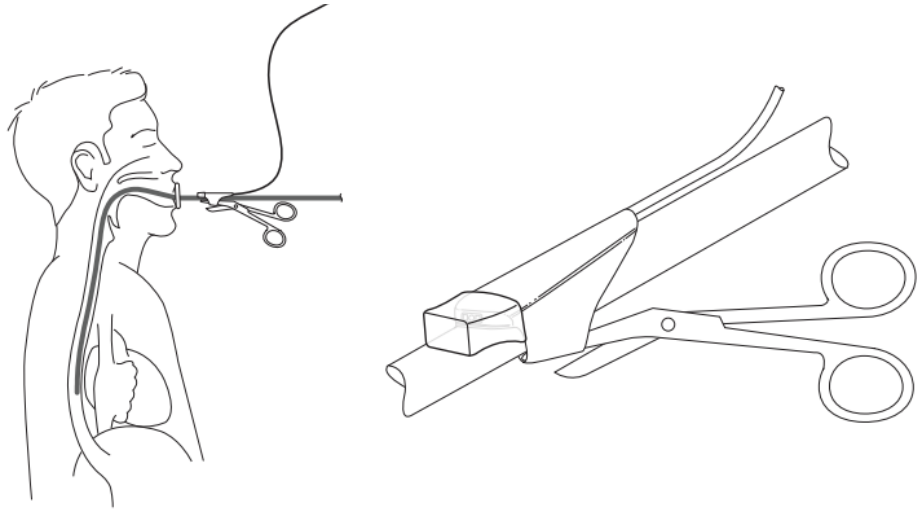
1. Once the TEE probe is appropriately positioned in the patient's esophagus, the TEECAD Carrier can be removed from the patient. If the TEECAD Carrier is left in place during the

procedure, remove the Carrier when the procedure is complete and before removal of the TEE probe.

2. To remove the Carrier, lock the TEE probe transducer controls to prevent flexing of the distal end of the TEE probe. Remove the Carrier by pulling on the Carrier cable while holding the TEE probe in place. With sufficient retraction force applied, the Carrier will release and retract along the probe as shown below:



After the TEECAD Carrier exits the patient, sever the TEECAD Carrier securement loop at the distal end as shown below:



3. Disconnect the TEECAD Carrier from the TEE probe.

AFTER USE

1. Disconnect the Carrier Control Unit HDMI cable from the monitor.
2. Turn off the Carrier Control Unit by unplugging the power cord.
3. Be sure connector interfaces are not allowed to become wet or splashed with liquids.

DISPOSAL

The equipment you have purchased requires the use of natural resources for its production. The equipment may also contain hazardous substances which could have a potential impact on the environment and human health if disposed on improperly. Sorting of waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. At the end of its useful operating life (5 years), dispose of the Carrier and Carrier Control Unit in accordance with the Waste Electrical and Electronic Equipment EC Directive - WEEE, hospital/facility procedures, and regional waste disposal and recycling requirements.

CARRIER CONTROL UNIT STORAGE

1. The Carrier Control Unit should NEVER be stored in areas where the unit may get wet or be exposed to environmental conditions including high temperature, humidity, direct sunlight, dust, salt, etc. which may adversely affect the equipment.
2. The Carrier Control Unit should NEVER be stored in the presence of flammable or explosive gases or chemicals.
3. Cords and accessories should be cleaned and neatly stored.
4. The Carrier Control Unit should be maintained in a clean condition during storage and be ready for subsequent use.

SYSTEM MESSAGES

1. The Carrier Control Unit will display a colored screen within 2 seconds of the video signal being lost (for example the Carrier is disconnected, or the Carrier cable is loose).
2. The small LED on the front of the Carrier Control Unit signifies the following:
    a. LED is off: Carrier Control Unit is not powered
    b. LED is constant green: Carrier Control Unit is powered, Carrier is attached
    c. LED is blinking green: Carrier Control Unit is powered, Carrier is not attached
    d. LED turns amber briefly, then constant green: Carrier Control Unit is powered, Carrier attached and then disconnected.
3. To troubleshoot the Carrier Control Unit, check the cable connections, disconnect and reconnect the power supply to the Carrier Control Unit, and/or replace the Carrier. If these actions do not correct the issue, contact Visura Technologies for service.

ELECTROMAGNETIC COMPATIBILITY

1. The TEECAD System has been manufactured, tested, and found to comply with electromagnetic compatibility standards to provide reasonable protection against harmful interference in a typical medical installation.

2. Using parts and accessories not recommended by Visura may result in increased emissions or decreased immunity of the system. Use only accessories recommended by Visura.
3. EMC precautions for other medical equipment must be followed according to the EMC information provided in that system's accompanying documents.

Essential Performance

The Essential Performance of the TEECAD System is as follows:

1. The TEECAD System will not have an unacceptable risk that the view or image provided to the operator has an unexpected image orientation.

2. The TEECAD System will not have an unacceptable risk that the operator is viewing a recorded image instead of the live image during an endoscope procedure.

Electromagnetic disturbances may interfere with the essential performance of the TEECAD System. An operator may expect distorted images, flashes on the display, system resetting, or degradation in essential performance.

Electrostatic Discharge Precautions

1. Electrostatic discharge (ESD), or static shock, results from the flow of an electrical charge from a person or object of a higher charge to that of a lower charge. ESD is most prevalent in low humidity environments, often caused by heating or air-conditioning.
2. To reduce ESD use anti-static spray on carpets, linoleum, and mats if necessary.

Electromagnetic Emissions

1. Ensure that the TEECAD System is used only in the operating environments indicated in the following table. Operating the system in an environment that does not meet these conditions may degrade system performance.

DECLARATION OF ELECTROMAGNETIC EMISSIONS

Emissions Test	Compliance	Electromagnetic Environment
RF emissions, CISPR 11	Group 1	The system has been tested for RF emissions and its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class A	The system is suitable for use in all establishments, except domestic establishment 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Radiated, radio frequency electromagnetic field immunity EN/IEC 61000-4-3	3 V/M 80% Amplitude modulated, 1 kHz sine wave field	3 V/M 80% Amplitude modulated, 1 kHz sine wave field
Proximity Fields Immunity Test EN/IEC 61000-4-3	28 V/M	28V/M
ESD IEC 51000-4-2	Up to ±15 kV Air	Up to ±15 kV Air
Electrical fast transient IEC 61000-4-4	±0.5kV, ±1.0kV	±0.5kV, ±1.0kV
Immunity to surge IEC 61000-4-5	0.5kV, 1.0kV, 2.0kV	0.5kV, 1.0kV, 2.0kV
Conducted Disturbances immunity test, induced by RF Fields IEC 61000-4-6	3 VRMS (@80% amplitude modulated with a 1 kHz sine wave)	3 VRMS (@80% amplitude modulated with a 1 kHz sine wave)
Power frequency magnetic field immunity test IEC 61000-4-8	N/A	N/A
Voltage dips/ interruptions IEC 61000-4-11	0% for 0.5 cycle @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 0% for 1 cycle @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 40% for 5 cycles @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 70% for 25/30 cycles @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 0% for 250/300 cycles @ 0°, 90°, 135°, 180°, 225°, 270°, and 315°	0% for 0.5 cycle @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 0% for 1 cycle @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 40% for 5 cycles @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 70% for 25/30 cycles @ 0°, 90°, 135°, 180°, 225°, 270°, and 315° 0% for 250/300 cycles @ 0°, 90°, 135°, 180°, 225°, 270°, and 315°

Electromagnetic Interference

1. The way electromagnetic interference (EMI) from other equipment affects the TEECAD System depends on the type and level of electromagnetic phenomena. Electromagnetic phenomena may be intermittent, making it difficult to identify the source. If you experience EMI, use caution if you continue using the system, or consider relocating your system.
2. Typical EMI interferences seen in visualization systems include change of system settings, system reset or brief flashes on the display. The EMI interference can also cause distortion of the images viewed on the screen. It is impossible to describe all

manifestations of interference because it depends on many parameters of the transmitting equipment, for example, the type of modulation used by the signal carrier, the source type, and the transmitted level. It is also possible for the interference to degrade the visualization system's performance.

3. Electromagnetic interference (EMI) from other equipment may affect the TEECAD System in different ways depending on the type and level of electromagnetic phenomena. Examples of possible electrostatic interference include:
   - ESD caused by charge buildup on insulated surfaces or persons.
   - RF energy from portable phones, hand-held radios, smart devices, commercial radio, and TV stations.
   - Conducted interference on power lines, switching power supplies, electrical controls, and lightning.

CUSTOMER SERVICE

1. Alterations/modifications to the equipment should NEVER be made.
2. Contact Visura Customer Service for troubleshooting product issues.
3. The expected service life of the Carrier Control Unit is 5 years.

CLEANING THE CARRIER CONTROL UNIT

1. Periodically, the Carrier Control Unit should be wiped with 70% isopropyl alcohol. Do not use other cleaning agents as this may damage the system.

TEECAD SYSTEM SPECIFICATIONS

Parameter	Specification
Disposable Carrier with Camera	
Carrier Dimensions	Carrier hood outside diameter: 17.2mm (0.7”) Carrier hood length: 82.7mm (2.1”) Cable diameter: 3.0mm (0.12”) Cable length: 152 cm (5 ft) Connector diameter: 14.0 mm (0.6”)
Direction of View	Forward
Camera Resolution	Number of pixels (horizontal): 249 Number of pixels (vertical): 250
Camera light source	Type of source: LED Power rating of source (watts): 0.2 W (105 mW x 2 LEDs)
Field of View	90°
Degree of protection against electric shock	Type BF (Use on heart is prohibited)

Applied Part		Type BF
Patient Contacting Subcomponent Materials		Listed Below
Carrier Hood (containing camera and electronics) Material		Silicone rubber
Camera Lens Material		Silicone rubber
Adhesive Material		Silicone medical adhesive
Carrier Cable Insulation Material		Medical silicone
Carrier Connector Material		Polysulfone
Operating and Storage Environment	Ambient Temperature	16°C – 28°C or 60.8°F - 82.4°F
	Relative Humidity	30 – 80 % RH
	Atmospheric Pressure	475 mmHg (633 hPa) to 760 mmHg (1013 hPa)
Carrier Control Unit		
Carrier Control Unit Dimension		Diagonal size: 30.8 cm (12.1 in.)
Power Supply Type		Medical grade AC to DC external power supply consisting of Visura part numbers VIS1271 and VIS1272
Power Supply AC Input		100-240 volts AC 50-60 hertz
Power Supply DC Output		40 watts 12.0 volts at 1.0A Max
Operating and Storage Environment	Ambient Temperature	16°C – 28 °C or 60.8°F - 82.4°F
	Relative Humidity	30 – 80 % RH
	Atmospheric Pressure	475 mmHg (633 hPa) to 760 mmHg (1013 hPa)
60601 Classification		IEC 60601 classifies this device as Class II

CONTACT INFORMATION

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