Boston Scientific

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EXALT™ Controller

User's Manual

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

INTRODUCTION

This user manual describes how to appropriately and safely use, maintain, and troubleshoot the EXALT Controller (hereafter called the Controller).

The Controller is used with a Boston Scientific single-use endoscope. Refer to "EXALT Controller Compatibility" for compatible Boston Scientific single-use endoscopes.

Where to Get Help

For technical support, ordering, service, and return authorization, contact Boston Scientific at 800-949-6708.

DEVICE DESCRIPTION

The Controller is an electronic device that:

- Receives video signals from a Boston Scientific single-use endoscope,
- Processes the video signals,
- Outputs video images to a video monitor, and
- Outputs electrical signal(s) that interface with external image capture systems.

The Controller also controls the light transmitted by the tip of the single-use endoscope to illuminate the area of interest within the anatomy. Buttons on the Controller's front panel enable the user to control the brightness level of the light.

To use the Controller, connect it to a video monitor with a video cable and then connect a Boston Scientific single-use endoscope to the Controller. The Controller provides direct visualization during an endoscopic procedure.

The Controller interfaces with external media capture equipment via the Controller's rear panel connectors. Image capture is initiated via a button on the Boston Scientific single-use endoscope. The Controller sends a signal to the video monitor notifying the user that an image capture has been initiated.

User Information

The Controller and these instructions are intended for use by physicians trained in endoscopic procedures.

A thorough understanding of the techniques, principles, clinical applications and risks associated with endoscopic procedures is required before using the Controller with the single-use endoscope.

Contents

- One (1) EXALT Controller
- For M00542430 – One (1) North American Power Cable
- For M00542460 – One (1) EU Power Cable & One (1) Brazil Power Cable
- One (1) 2.0-meter DVI cable
- One (1) 2.0-meter HDMI cable

Ensure the package contains the components listed above.

Model Numbers

EXALT Controller	M00542430
EXALT Controller (Alt-Language)	M00542460

Specifications

Electrical Specifications	
Input voltage	100 to 240 VAC, 50/60 Hz
Rated current	1A-0.5A
Fuse rating	250 V, 2A, Type F (F2AH250V)
Power Cord Specifications	
115 VAC Domestic (US)	Length—3.1 meters (10 feet) Voltage Rating—125 VAC Current Rating—10 amps Connector Type—IEC 60320 C13
250 VAC International:	Length—2.5 meters (8.2 feet) Voltage Rating—250 VAC Current Rating—10 amps Connector Type—IEC 60320 C13
Physical Specifications	
Height	11.5 cm (4.5 in)
Width	33.0 cm (13.0 in)
Depth	39.5 cm (15.5 in)
Weight (unpackaged)	6.4 kg (14 lb)

INTENDED USE/INDICATIONS FOR USE

The EXALT™ Controller is intended for use with a Boston Scientific single-use endoscope for endoscopic diagnosis, treatment, and video observation.

CONTRAINDICATIONS

None known.

WARNINGS

- Read this user manual, the single-use endoscope directions for use, the monitor user manual, and any external media capture device user manuals before using the Controller. Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to patient.
- Do not use the Controller in the presence of flammable fluids and gases such as alcohol or oxygen. Doing so can result in fire and burns to the operator and patient.
- Do not perform diagnostic or therapeutic procedures without a clear and adequate video display. Doing so can result in adverse events.
- Placing the Controller where other electrical medical devices can degrade the video image can delay the procedure and result in adverse events. In addition, placing the Controller where it can degrade the performance of other equipment in the endoscopy suite due to EMI emissions can delay the procedure or result in adverse events. To ensure the Controller displays a clear and adequate video image and does not degrade the performance of other equipment, locate the Controller as described in Table 6, Table 7, Table 8, and Table 9 in the Appendices. Verify operation in the endoscopy suite environment before starting a procedure. Follow ancillary equipment directions for use to locate ancillary equipment.
- 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 the other equipment should be observed to verify that they are operating normally.
- Using a Controller without cleaning the cabinet and front panel buttons can expose the operator to biohazardous materials. To prevent exposure to biohazardous materials, clean the cabinet between uses, following the procedure described in "Cleaning."
- If the Controller is connected to an improperly grounded power supply, electrical leakage can result in electrical shock to the user. To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.
- Do not touch connecting devices for electrical connections between the different components (such as signal input and output connections for video signals, data exchange, control circuits, etc.) and the patient at the same time. Doing so can result in electric shock to the patient.
- If the Controller experiences an unintended shutdown or lock up during a procedure, follow the procedure described in "Recovering from a Controller Failure." Failure to follow this recovery procedure after a Controller failure can result in patient injury.
- No modification of this equipment is allowed.
- The use of accessories and cables other than those specified or supplied as spare parts from Boston Scientific may result in increased emissions or decreased immunity of the Controller or single-use endoscope.
- Components connected to the EXALT™ Controller by the user must be certified to the respective IEC standards (IEC 60601-1 for medical equipment, IEC 60950 for data processing equipment, and IEC 60065 for A/V equipment). In addition, the user must ensure the new configuration complies with the IEC 60601-1 standard.
- Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the Controller, single-use endoscope, or ancillary equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Do not connect the output of any equipment to the Controller's video outputs.
- For hospital use only.

PRECAUTIONS

- Blocking the Controller's ventilation outlet can cause the Controller to overheat, resulting in a thermal shutdown or equipment damage. Leave at least 12.7 mm (0.5 in) between the Controller back panel and other objects and 12.7 mm (0.5 in) of space between the side panels and other objects. The Controller may be used on a dedicated equipment cart to ensure proper ventilation.
- Spilling liquids on the Controller can damage it or cause it to shut down. Do not place liquids above or near the Controller.
- Opening the cabinet for repair purposes can damage the Controller. The Controller does not use operator-serviceable components. To prevent damage, do not access the Controller cabinet.
- Connecting an incompatible single-use endoscope to the Controller can damage the Controller. Only connect a single-use endoscope listed in the "EXALT Controller Compatibility" section.
- Locate the Controller appropriately to avoid accidentally pulling cable connections, which can result in disconnection and loss of visualization.
- Before starting a procedure, ensure components such as the monitor and irrigation pump that support the EXALT Controller and single-use endoscope are present and operational. Starting a procedure without the supporting components present and operational can prolong the procedure.
- Do not use cleaning solutions that contain long-life surfactants. Doing so can leave conductive residues on the contacts of the single-use endoscope connector receptacle. The conductive residues can lead to malfunctions of the Controller.
- Use of a cardiac defibrillator while a connected single-use endoscope remains in a patient can damage the Controller. To prevent damage to the Controller when using a defibrillator, remove the single-use endoscope before using the defibrillator.
- Do not insert a wet connector into the Controller receptacle as poor video performance or damage to the Controller may result.
- Applied parts of other electrical medical equipment in application with this equipment have to be type BF. Hence, only connect a single-use endoscope listed in the "EXALT Controller Compatibility" section.

ADVERSE EVENTS

Please refer to single-use endoscope DFU.

CONFORMANCE TO STANDARDS

Essential Performance Statement

Per IEC 60601-1, the Controller does not have any functions that would present an unacceptable risk if failure occurred.

HOW SUPPLIED

Device supplied non-sterile. Inspect the Controller and cables for damage. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Do not use a component if it appears damaged.

Handling and Storage

Environmental Limits During Transportation, Use, and Storage

Table 1. Transportation, use, and storage environmental limits

Environmental Limits during Use	
Ambient temperature (°C)	10 to 35
Relative humidity (%)	30 to 85 (non-condensing)
Atmospheric pressure (hPa)	700 to 1060
Environmental Limits during Transport and Storage	
Ambient temperature (°C)	-40 to 70
Relative humidity (%)	10 to 90 (non-condensing)
Atmospheric pressure (hPa)	500 to 1060

EXALT™ CONTROLLER COMPATIBILITY

All attached equipment must comply with its applicable IEC standards.

The Controller is compatible with:

- EXALT Model D Single-use Duodenoscope (M00542420 and M00542421).
- Medical grade video monitors with standard video signal inputs (at a minimum: DVI 1.0 and/or HDMI 1.0). Controller incorporates standard video signal outputs (i.e. DVI 1.0, HDMI 1.0) to allow connection to a monitor. Controller was tested for compatibility with the NDS Radiance G3 26" medical grade monitor at the following factory default settings:

Input: DVI – 1920 x 1080p @ 60.00Hz

Parameter	**Setting**
Brightness	50
Contrast	50
Sharpness	0
Overscan	0
Gamma	2.2
Color Temperature	Default
Red	50
Green	45
Blue	46
Saturation	50
Hue	50
Video Level	Normal
Color Correction	Bypass
Backlight Control	Off

- External media capture devices that have a 9-pin RS-232 compliant DB9 signal input connector and/or a TRS jack with a maximum rating of 5 VDC. Controller was tested for compatibility with media capture devices listed in the following table. Call Boston Scientific for system specific setup instructions.

Image Capture Device	**Software Version**
Medicapture USB-300	170510
TEAC® UR-4MD	a1.15
ProVation® MD by ProVation® Medical	5.0.410.23
gMED gGastro™	v4.67
ENDOBASE™ by Olympus®	13.0.

SETUP AND OPERATION

Front Panel Features

Figure 1, Table 2, and Table 3 illustrate and describe the Controller's front panel features.

Figure 1. Illustration of front panel features

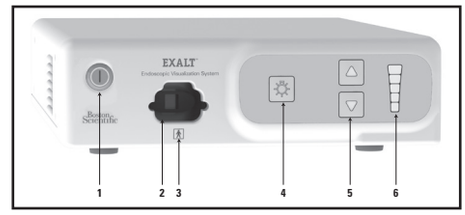


Table 2. Description of front panel features

	Feature	**Description**
1		***Power Button***—When the Controller is connected to a power source, pushing the power button alternates between powering up and powering down the Controller. The power button illuminates green when the Controller is powered up.
2		***Connection Cable Receptacle***—User plugs the umbilicus cable from the single-use endoscope into the receptacle during setup.
3		Indicates user must use BF applied parts.
4		***Light On/Off Button***—Pressing this button alternately turns the light off and on. When the Controller is on, each press of the Light On/Off button toggles the light between on and off. When the light is on, the button illuminates blue. When the light is off, the button illuminates white.
5		***Brightness Control Buttons***—When the light is on, the brightness control buttons are illuminated blue. Pressing the △ button increases the intensity of the light. Pressing the ▽ button decreases the intensity of the light.
6		***Brightness Indicator***—The bars of this indicator illuminate to indicate the brightness of the light. There are five levels of brightness (Table 3).

Table 3. Interpreting the brightness indicator

Illumination State of Brightness Indicator	**Setting Description**
	Low
	Med-Low
	Med
	Med-High
	High

Rear Panel Features

Figure 2 and Table 4 illustrate and describe the Controller's rear panel features.

Figure 2. Illustration of back panel features

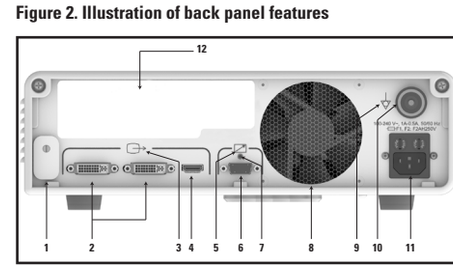
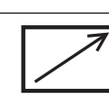
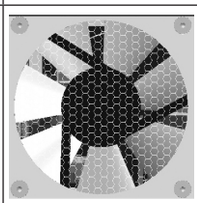


Table 4. Description of back panel features

	Feature	**Description**
1		***USB port access cover*** (tool required)—For Boston Scientific Service Personnel only. User shall not remove the access cover or plug any ancillary devices into the USB port.
2		***Two DVI Output Connectors***—Video output connector for compatible DVI-1.0 capable monitors.
3		***Video Output***—Symbol indicating video outputs.
4		***HDMI Output Connector***—Video output connector for compatible HDMI-1.0 capable monitors.
5		***Remote Control Lead***—Symbol indicating remote control lead.

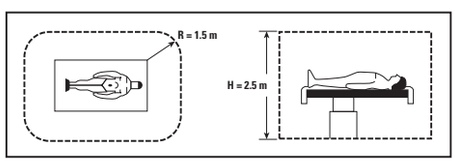
	Feature	Description
6		***RS232 DB9 Connector***—Image capture output connector for connection with external media capture devices. [A user-supplied RS-232 DB9 Straight Through cable is required to connect the EXALT™ Controller to an external media capture device. To configure system for connection call Boston Scientific for support.]
7		***3.5mm TRS Connector Jack***—Image capture output connector for connection with external media capture devices. To configure system for connection call Boston Scientific for support.
8		***Cabinet Ventilation Outlet***—The cabinet ventilation outlet enables the cooling fan to exhaust hot air from the cabinet to maintain the proper operating temperature inside the cabinet.
9		***Potential Equalization Conductor***—Symbol for potential equalization conductor.
10		***Potential Equalization Conductor***—Provides a means of securely linking the potential equalization conductor of the Controller to ground.
11		***Fuse Holder Module and Power Cord Connector***—The fuse holder module provides access to the Controller electrical fuses. The power cord connector accepts the AC power cord that connects to an AC Main. Removal of the detachable cord from the appliance inlet is the means by which AC main is disconnected from the device.
12		***Label***—Provides regulatory and manufacturing information.

Patient Environment

The Controller is patient equipment and can be used in the patient environment (Figure 3).

Place the Controller to allow easy access to the power cord in the event user must quickly disconnect the Controller from the main power source.

Figure 3. Typical positioning of equipment, patient, and operator



Note about Performance

To ensure the Controller performs within its design specifications, position it following the guidelines presented in the Appendices.

Isolating the Controller from the Main Power Supply

To isolate the Controller from the main power supply, disconnect the power cord from the power supply receptacle or from the power cord receptacle on the Controller.

Software

The revision level of the software installed on the Controller is displayed on the cable connect screen.

Setup of the Controller

All attached equipment must comply with its applicable IEC standards.

Upon receiving the Controller, complete these initial setup steps:

1. Inspect the Controller and its components to ensure they are not damaged.
2. Clean the Controller following the instructions in the "Cleaning" section.
3. Place the Controller and Video monitor on a stable, level surface, such as an equipment cart, in the procedure room. See the "EXALT™ Controller Compatibility" section for additional information if needed.
4. Use the DVI or HDMI cable, supplied by Boston Scientific, to connect one of the video input connectors on the video monitor to one of the video output connectors on the Controller.
5. Connect the Controller and video monitor power cords to electrical receptacles.
6. If required: Connect to external media capture devices following the steps in the respective device's Directions for Use. Contact Boston Scientific for specific setup instructions.
7. Power on and set the monitor video input based on the cable selected in Step 4.
8. Power on the Controller using the steps in the "Starting the Controller" section

   Note: Controller must be powered on in order to configure monitor, however a single-use endoscope does not need to be connected.
9. Configure the monitor for use in DVI or HDMI mode following the steps in the respective monitor's directions for use.

   Note: Monitor must be configured before beginning a procedure.

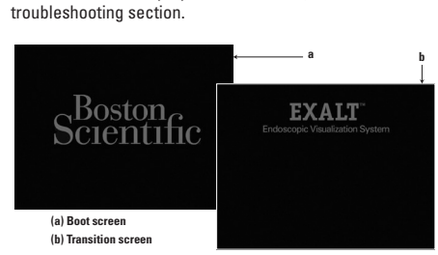
Contact Boston Scientific for specific setup instructions.

Starting the Controller

Follow the steps below to start the Controller. User can start the Controller with or without the single-use endoscope umbilicus cable plugged into the Controller.

Powering On the Controller

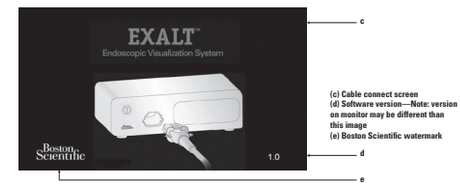
1. Press the power button to start the Controller. The power button will illuminate green, and the Controller will begin a self-test and boot sequence. The monitor displays the *boot screen* (a) followed by the *transition screen* (b). If monitor does not display the boot screen, consult the troubleshooting section.



(a) Boot screen
(b) Transition screen

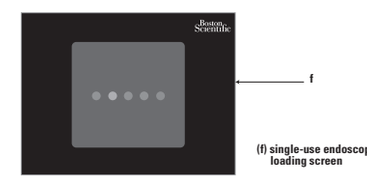
2. Upon a successful boot up, the monitor displays the *cable connect* screen (c) showing the software version (d). Connect the single-use endoscope connection cable to the Controller until it locks into place. Pull back on the cable connector to ensure the connector is fully seated in the Controller. If a single-use endoscope is already connected, this screen will not appear, proceed to step 3.

Note: To remove the Boston Scientific watermark (e) from the screen, simultaneously press the △ and ▽ buttons for at least 3 seconds while the cable connect screen is displayed on the monitor. To redisplay the watermark, press the △ and ▽ buttons for at least 3 seconds.



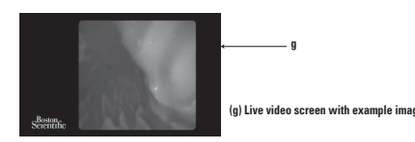
(c) Cable connect screen
(d) Software version—Note: version on monitor may be different than this image
(e) Boston Scientific watermark

3. The Controller briefly displays the *single-use endoscope loading* screen (f).



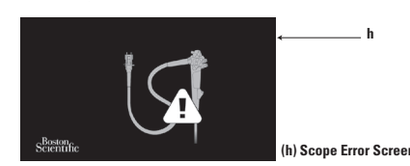
(f) single-use endoscope loading screen

4. Shortly after the single-use endoscope loading screen appears, a live video image will appear on the live video screen (g). If the live image does not appear, consult the troubleshooting section.



(g) Live video screen with example image

5. If a live image is lost during a procedure as a result of damage to the single-use endoscope, the Controller will display the Scope Error Screen (h). If the single-use endoscope is damaged, replace the single-use endoscope.

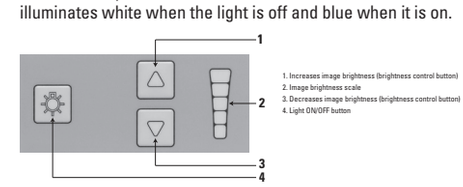


(h) Scope Error Screen

Adjusting the Brightness of the Video Image and Operating Light ON/OFF button

To increase the brightness of the video image as displayed on the *live video* screen, press the △ button. To decrease the brightness of the video image, press the ▽ button. The image brightness scale provides visual feedback of the relative brightness of the light source.

Pressing the light On/Off button toggles the light source between ON and OFF state. To operate the light On/Off button the Controller must be powered on and an single-use endoscope must be connected to the Controller. Button illuminates white when the light is off and blue when it is on.



Note: White balance is adjusted automatically by the system and no user adjustment is required.

Recovering from a Controller Failure

There are two possible failure modes: (1) unintended Controller shutdown, and (2) Controller that becomes unresponsive.

Recovery from Unintended Shutdown

Follow these steps to recover from an unintended Controller shutdown:

1. Press the Controller's ***Power*** button to restart the Controller.
2. If the Controller fails to start, contact Boston Scientific.
3. If the Controller starts and subsequently shuts down, remove any accessory from the single-use endoscope, and remove the single-use endoscope from the patient. Restart the Controller and plug in a new scope if available.

Recovery from a Controller that Becomes Unresponsive

Follow these steps to recover from a Controller that becomes unresponsive:

1. Unplug the single-use endoscope from the Controller and plug the single-use endoscope back in to the Controller.
2. If this does not resolve the issue, press the Controller's ***Power*** button to power off the Controller.
3. Press the Controller's ***Power*** button to restart the Controller.
4. If the Controller fails to start, contact Boston Scientific.
5 If the situation cannot be resolved, remove any accessory from the single-use endoscope, and remove the single-use endoscope from the patient.

Considerations When Using a Laser, HF or EHL Device

When activating energy from a high frequency (HF) generator, laser or electrohydraulic lithotripsy (EHL) generator during lithotripsy, a bright flash on the video monitor and possibly a momentary disruption in the video quality may occur. This reaction is normal and is not indicative of a defect or operating problem with the Controller or single-use endoscope.

COMPLETING A PROCEDURE

The procedure below describes the procedural use of the Controller and is to be performed only once the user has received, inspected, assembled, and tested the Controller following instructions in the "Setup and Operation" section.

Using the Controller In an Endoscopy Procedure

Using the Controller includes the following steps:

1. Clean the Controller as directed in the "Cleaning" section.
2. Power up the Controller.
3. Configure the monitor.
4. Connect a single-use endoscope to the front panel connector.
5. Complete the procedure as outlined in the single-use endoscope directions for use.

Shutting Down the Controller

To shut down the Controller at the end of a procedure or during a procedure, follow these steps:

1. Remove any accessory and the single-use endoscope from the patient following the instructions in the single-use endoscope directions for use.
2. Disconnect the single-use endoscope cable from the front of the Controller by pushing down on the umbilicus cable connector locking tab and pulling it out of the receptacle.
3. Power down the Controller by pressing the Power button. The power button indicator light shuts off indicating power has been cut to the Controller.
4. If the Controller is being shut down after finishing a procedure, dispose of the single-use endoscope as described in the single-use endoscope directions for use. Then clean the Controller as directed in the "Cleaning" section.

Routine Inspection and Maintenance

The Controller does not require routine maintenance and calibration because the self-test mode, activated automatically upon turning on the power to the Controller, verifies correct functionality of the Controller. Periodically check the power cord assembly for damage to the insulation or connectors. In the event that the Controller requires repair or replacement, contact Boston Scientific.

Cleaning

Disconnect the power cord before cleaning the unit. Use a 15 to 70 percent isopropyl alcohol in purified water solution and a cloth to clean the Controller enclosure, front panel, video cables, and power cable. Do not allow fluids to enter the enclosure, power cable connections, single-use endoscope cable receptacle, or component/accessory connections. Do not attempt to clean the unit while it is plugged into an electrical outlet.

Disposal of the Product, Accessories, and Packing Materials

For disposal, observe relevant country regulations and laws.

Note for users in California, USA. Perchlorate Material—special handling may apply. Battery in Controller contains Perchlorate.

See www.dtsc.ca.gov/hazardouswaste/perchlorate.

For further information, contact Boston Scientific.

TROUBLESHOOTING AND RESPONDING TO ERROR CODES

Troubleshooting Chart

Most operating problems are easily resolved. If the Controller does not operate as expected, try to resolve the problem with this troubleshooting chart before contacting Boston Scientific for technical support (Table 5).

Table 5. Controller troubleshooting chart

Symptom	Possible Cause	Corrective Action
Controller does not start or power button is not illuminated green when pressed	Power cord not connected or not connected tightly	Ensure both ends of the power cord are firmly connected to their connection points.
	No electrical power at the receptacle	Check the receptacle's circuit breaker to ensure it is not tripped.
		Confirm the receptacle has power by operating another electrical device from the receptacle.
	Boot problem	Reboot the Controller by powering it down and restarting it. If the problem reoccurs, call Boston Scientific for support.
	Defective power cord	Replace power cord.
	Controller fuse blown	Call Boston Scientific for support.
	Controller damaged	Call Boston Scientific for support.
Single-use endoscope umbilicus cable is plugged into the Controller, but no video image is displayed.	Video monitor is not powered up or not connected	Power up the video monitor. Check that the video cable is properly connected to the monitor and Controller. Verify that the monitor is set to the correct video input.
	Single-use endoscope umbilicus cable is not properly connected to Controller	Ensure the plug on the single-use endoscope umbilicus cable is firmly inserted into the connector with the locking tab facing up. Ensure connection terminals are dry and clean.
	Single-use endoscope is broken or defective	Replace single-use endoscope.
	Illumination light is off	Press illumination light button to turn on light. (The light On/Off button should be illuminated blue).
Single-use endoscope connection cable is plugged into the Controller, but cable connection screen is displayed.	Single-use endoscope cable is not properly connected to Controller	Ensure the plug on the single-use endoscope umbilicus cable is firmly inserted into the connector with the locking tab facing up. Ensure connection terminals are dry and clean.
	Single-use endoscope is broken or defective	Replace single-use endoscope.
Single-use endoscope experiences image loss and the scope error screen is displayed.	Single-use endoscope is broken or defective	Replace single-use endoscope.
Video image is too dark.	Brightness setting is too low	Adjust brightness using brightness control buttons.
	Debris covering the distal tip of the single-use endoscope	Clean the distal tip by irrigating it with a purified water solution using a cotton swab.
	Single-use endoscope illumination elements are damaged	Replace single-use endoscope.
Video image is too bright	Brightness setting is too high	Adjust brightness using brightness control buttons.
	Video cable connected to monitor output	Ensure video cable is connected into monitor video input and not output.

Symptom	Possible Cause	Corrective Action
Video image is blurry, scrambled, inadequate, distorted, or otherwise not acceptable	Controller is too close to other electrical medical equipment	Ensure Controller is placed as directed in Table 9 or Table 10 of Appendix 4. Shutdown other medical electrical equipment to determine which equipment is causing the symptom. Properly place other electrical medical devices according to their directions for use.
	Video cable not completely connected to either monitor or Controller	Ensure video cable is completely connected to video monitor and Controller.
	Video cable connected to monitor output	Ensure video cable is connected into monitor video input and not output.
	Debris covering the distal tip of the single-use endoscope	Clean the distal tip by irrigating it with a purified water solution using a cotton swab.
	Video monitor is not compatible with Controller	Replace monitor with compatible monitor.
Cabinet is warm-to-hot to the touch	Cabinet ventilation outlet is blocked with debris or too close to other objects	Reposition Controller to provide more clearance for ventilation. If not resolved, contact Boston Scientific for support.
Image Capture does not transfer to external media capture device.	Video and Image Capture Trigger cables not connected to external image capture device or controller	Ensure trigger and video cables are completely connected to controller and external device. Call Third party image capture manufacturer.
If any of these problems persist, please contact Boston Scientific for repair or replacement information.		

WARRANTY

Limited Warranty

Boston Scientific Corporation (BSC) warrants for one year from the date of purchase that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, cleaning and storage of the product as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Boston Scientific Corporation's control may directly affect the product and results obtained from it. Boston Scientific Corporation shall repair or replace, at its option, any part of the product that Boston Scientific Corporation determines was defective at time of shipment if notice thereof is received within one year of shipment. Boston Scientific Corporation shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the product. Boston Scientific Corporation neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the product. BSC assumes no liability with respect to product use by a non-qualified physician; use contrary to documentation; use with a non-Boston Scientific single-use endoscope. Buyer shall be responsible for the ongoing support and maintenance of the product not covered by this one year warranty and after the one year warranty period has expired. Buyer may, at its sole cost and expense, purchase an extended warranty from Boston Scientific Corporation (BSC) to extend the term of this warranty.

Obtaining Warranty Service from Boston Scientific Corporation

Contact Boston Scientific technical support at 800-949-6708 to report a problem with the Controller and obtain a return authorization number, if required.

Return the Controller to Boston Scientific Corporation. All shipments to Boston Scientific Corporation must be insured and safely and securely packaged, preferably in the original shipping carton, and should include a letter explaining the problem and making reference to the return authorization number.

All transportation and insurance charges and risk of loss are the responsibility of the customer and must be prepaid. A purchase order must be issued to Boston Scientific Corporation to cover all transportation and insurance charges for return shipment after service.

A return goods authorization (RGA) tracking number for the returning product will be provided. Include the RGA number on the outside of the return packaging.

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APPENDICES

The appendices include:

- Appendix 1—Guidance and Manufacturer's Declaration-Electromagnetic Emissions
- Appendix 2—Guidance and Manufacturer's Declaration-Electromagnetic Immunity
- Appendix 3—Guidance and Manufacturer's Declaration— electromagnetic IMMUNITY – for ME Equipment and ME Systems that are not LIFE-SUPPORTING
- Appendix 4—Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the EXALT™ Controller
- Appendix 5—Medical Design Criteria and Specifications

The Controller and Duodenoscope were tested for compliance to IEC 60601-1. An Olympus OEV262H was used during this testing as support equipment. Any additions or modifications to the Controller, Duodenoscope, or previously configured accessories require the end user to ensure the system remains compliant with the requirements of IEC 60601-1.

Appendix 1—Guidance and Manufacturer's Declaration-Electromagnetic Emissions

The EXALT Controller is intended for use in the electromagnetic environment specified below (Table 6). The customer or the user of the EXALT Controller should assure that it is used in such an environment.

Table 6. Guidance and manufacturer's declaration - electromagnetic emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11	Group 1	The EXALT Controller uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The EXALT Controller is suitable for use in all establishments other than domestic 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	Per section 5 of IEC 61000-3-3	

Appendix 2—Guidance and Manufacturer's Declaration-Electromagnetic Immunity

The EXALT Controller is intended for use in the electromagnetic environment specified below (Table 7). The customer or the user of the EXALT Controller should assure that it is used in such an environment.

Table 7. Guidance and manufacturer's declaration—electromagnetic immunity IEC 60601-1-2 (2nd edition and 3rd edition)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment (Guidance)
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 k/V air	± 6 kV contact ± 8 k/V air	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 / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% U (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% U (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EXALT™ Controller requires continued operation during power mains interruptions, it is recommended that the EXALT Controller be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note—UT is the a.c. mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment (Guidance)
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the EXALT Controller, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following Symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Note 1 —At 80 MHz and 800 MHz, the higher frequency range applies.			
Note 2 —These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EXALT Controller is used exceeds the applicable RF compliance level above, the EXALT Controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EXALT Controller. b) Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.			

Appendix 3—Guidance and Manufacturer's Declaration— electromagnetic IMMUNITY – for ME Equipment and ME Systems that are not LIFE-SUPPORTING

The EXALT™ Controller is intended for use in the electromagnetic environment specified below (Table 8). The customer or the user of the EXALT Controller should assure that it is used in such an environment.

Table 8. Guidance and manufacturer's declaration—electromagnetic immunity IEC 60601-1-2 (4th edition)

Immunity Test	IEC 60601 Test Level/ Compliance Level	Electromagnetic Environment (Guidance)
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 k/V air	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 / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EXALT Controller requires continued operation during power mains interruptions, it is recommended that the EXALT Controller be powered from an uninterruptible power supply or a battery.
	0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EXALT Controller requires continued operation during power mains interruptions, it is recommended that the EXALT Controller be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note—UT is the a.c. mains voltage prior to application of the test level.		

Immunity Test	IEC 60601 Test Level/ Compliance Level				Electromagnetic Environment (Guidance)
Conducted RF IEC 61000-4-6	3 V 0.15 MHz -80 MHz 6 V in ISM bands between 0.15 MHz -80 MHz 80% AM at 1 kHz				Portable and mobile RF communications equipment should be used no closer to any part of the EXALT ™ Controller, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=2\sqrt{P}$ 80 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following Symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz				
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Test Frequency (MHz)	Band (MHz)	Modulation	Immunity Test Level (V/m)	
	385	380 - 390	Pulse modulation 18 Hz	27	
	450	430 - 470	FM ± 5 kHz deviation 1 kHz sine	28	
	710	704 - 787	Pulse modulation 217 Hz	9	
	745				
	780				
	810	800 - 960	Pulse modulation 18 Hz	28	
	870				
	930				
	1720	1700 - 1990	Pulse modulation 217 Hz	28	
	1845				
	1970				
	2450	2400 - 2570	Pulse modulation 217 Hz	28	
	5240	5100 - 5800	Pulse modulation 217 Hz	9	
	5500				
	5785				

Note —These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EXALT Controller is used exceeds the applicable RF compliance level above, the EXALT Controller should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EXALT Controller.

b) Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Appendix 4—Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the EXALT™ Controller

The EXALT Controller is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EXALT Controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EXALT Controller as recommended below, according to the maximum output power of the communications equipment (Table 9 or Table 10).

Table 9. Recommended separation distances between portable and mobile RF communications equipment and the EXALT Controller IEC 60601-1-2 (2nd edition and 3rd edition)

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz D=1.2(Sqrt P)	Separation (m) 80 MHz to 800 MHz D=1.2(Sqrt P)	Separation (m) 800 MHz to 2.5 GHz D=2.3(Sqrt P)
0.01	.12	.12	.23
0.1	.38	.38	.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 10. Recommended separation distances between portable and mobile RF communications equipment and the EXALT Controller IEC 60601-1-2 (4th edition)

Max Output Power (Watts)	Separation Distance $D=2\sqrt{P}$
0.01	0.2
0.1	0.6
1	2.0
10	6.3
100	20.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the manufacturer.

NOTE —These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix 5—Medical Design Criteria and Specifications

The EXALT Controller meets medical design criteria and specifications (Table 11):

Table 11. Medical design criteria and specification

Design Criteria for EXALT Controller	Specification
Type of protection against electric shock	Class 1 equipment
Degree of protection against electric shock	Type BF applied part
Mode of operation	Continuous operation
Installation and use	Portable equipment

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Do not use if package is damaged.

CAUTION. Attention: Consult ACCOMPANYING DOCUMENTS.

Fuse

Separate Collection

SN Serial Number

Humidity limitation.

Atmospheric Pressure Limitation

Temperature limitation.

Type BF Applied Part

Non-Ionizing Electromagnetic Radiation

cTUVus Mark indicates compliance to UL 60601-1 and CAN/CSA 22.2 601.1 M90 covering electrical safety requirements for the US and Canada.

REF Catalog Number

Consult instructions for use.

Contents

EC REP EU Authorized Representative

Legal Manufacturer

Recyclable Package

Date of Manufacture

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ARG Argentina Local Contact

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Do not use if package is damaged.

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