

EXALT™ Accessories

User Manual

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INTRODUCTION

This user manual describes how to appropriately and safely use, maintain, and troubleshoot the installed EXALT™ Accessories. The EXALT Accessories are non-medical multimedia equipment used to integrate Boston Scientific Imaging Systems (e.g. EXALT, Spy DS) into an existing endoscopic suite environment which may include a variety of monitors, endoscopic report writers (ERWs) and/or third-party imaging systems.

WHERE TO GET HELP

For technical support, ordering, service, and return authorization, contact Boston Scientific at 888-541-0470.

PRODUCT DESCRIPTION

Boston Scientific (BSC) EXALT Accessories form a medical electrical system. This system is comprised of the products listed in Table 1.

Table 1. Components of Medical Electrical System

EXALT Controller	M00542430, M00542460
EXALT Model D Single Use Duodenoscope	M00542420, M00542421 M0054242CEO, M0054242CE1
SpyGlass™ DS Digital Controller	M00546650 or M0054665B0
SpyScope™ DS Catheter	M00546600
SpyScope DS II Catheter	M00546610
Powertronix Isolation Transformer Kit	PT-190101-UT, PT-190105-UT (Isolation Transformer Model: D1CSWFBBNC3) PT-190102-UT, PT-190106-UT (Isolation Transformer Model: P1CSWFBBNC3)
BSC approved Multimedia Accessories	To be provided at time of installation*

*Additionally, Boston Scientific offers an installation service that encompasses a variety of commercially available off-the-shelf non-medical multimedia accessories that are needed to integrate an imaging system into an existing endoscopy suite. BSC's offering of EXALT Accessories includes:

- Video cables to allow connection between processors, monitors, image capture systems, and other devices.
- Video signal converters which may be needed to convert video signals to match the available device input ports.
- Video switchers to allow selection between various video sources.
- Devices to facilitate picture in picture from multiple video sources
- Devices to simplify image triggering within various image capture systems.
- Power strips, isolation power transformers, and cords to enable access to power per facility requirements.

For a complete list of accessories that have been evaluated by Boston Scientific for use with this system, contact Boston Scientific

USER INFORMATION

The EXALT Accessories are intended for use by endoscopy suite personnel. A thorough understanding of equipment functionality and set-up is recommended before use of the EXALT Accessories.

CONTENTS AND MODEL NUMBERS

The accessories needed will vary depending on configuration of the room. A copy of the packing slip documenting the specific accessories installed will be provided, as well as, a schematic layout of the installed configuration.

Note: The packing slip and installation diagram reflect the "as installed" configuration.

SPECIFICATIONS

Reference individual accessory labeling for electrical rating specifications.

WARNINGS

- Read these instructions, the applicable EXALT Accessories instructions, and any other equipment connected to the system before using. Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to operator and/or patient.

- Do not use the EXALT Accessories 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 powered EXALT Accessories near electrical medical devices may degrade the video image, delaying the procedure and resulting in adverse events. In addition, placing the accessories where they can degrade the performance of other equipment in the endoscopy suite due to EMI (Electromagnetic interference) emissions can delay the procedure or result in adverse events. Verify operation in the endoscopy suite environment before starting a procedure. Follow ancillary equipment directions for use to locate ancillary equipment.
- EXALT Accessories located within the patient environment shall be cleaned between uses. To prevent exposure to biohazardous materials, clean the chassis between uses, following the procedure described in "Cleaning."
- If powered EXALT Accessories are 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.
- Only accessories that have been specified as part of the medical electrical system can be connected. Any person who connects additional equipment to the analog and digital interfaces installed by Boston Scientific is configuring a medical electrical system. No modification or reconfiguration of this equipment is allowed.
- The use of accessories and cables other than those supplied or installed by Boston Scientific may result in increased emissions or decreased immunity of the SpyGlass DS Direct Visualization or EXALT Endoscopic Visualization Systems.
- Multimedia accessories must be certified to the respective IEC standards (IEC 60065, 60950-1, or 62368 for A/V equipment). Any person who connects additional equipment to the analog and digital interfaces installed by Boston Scientific is configuring a medical electrical system, and is therefore responsible for ensuring that it complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical services department or your authorized representative. The use of component equipment not complying with IEC standards may lead to a reduced level of safety of the resulting capital. Power cords are considered part of the medical electrical system and must be compliant with the system.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the multimedia accessories, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

PRECAUTIONS

- Blocking the powered EXALT Accessories ventilation outlets can cause the Accessory to overheat, resulting in thermal shutdown or equipment damage.
- Do not operate any of the powered EXALT Accessories or medical electrical equipment connected to a multiple socket outlet or isolation transformer located on the floor.
- Medical electrical equipment installation requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the user manual for each component.
- Do not connect an additional multiple-socket outlet or extension cord to the installed medical system.
- Do not connect Integrated Image Accessories to a wall outlet, doing so may impact the basic safety of the medical system.
- Spilling liquids on the powered EXALT Accessories can damage them or cause shut down. Do not place liquids above or near any electronic equipment.
- Opening the EXALT Accessories for repair purposes can cause damage. To prevent damage, do not open the EXALT Accessories.
- Locate the multimedia accessories appropriately to avoid accidentally pulling cable connections, which can result in disconnection and loss of visualization.

CONFORMANCE TO STANDARDS

EXALT Accessories are non-medical multimedia devices which comply with their relevant IEC and ISO EMC standards.

ESSENTIAL PERFORMANCE STATEMENT

Per 60601, the EXALT Accessories do not have any functions that would present an unacceptable risk if failure occurred.

HOW SUPPLIED

EXALT Accessories are supplied non-sterile. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Inspect the components for damage. Do not use a component if it appears damaged.

HANDLING AND STORAGE

Environmental Limits During Transportation, Use, and Storage are listed in Table 2.

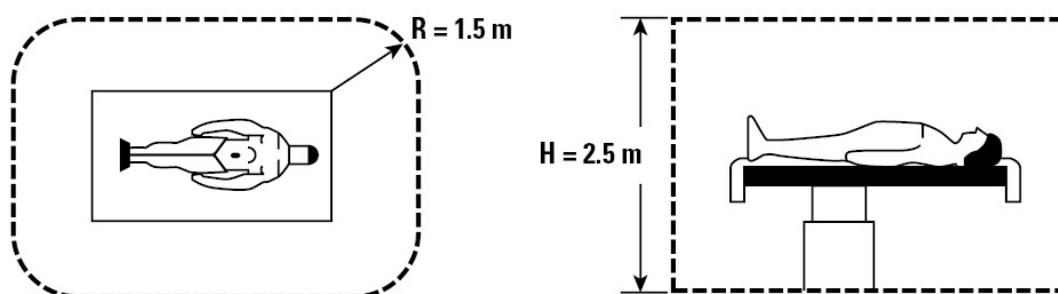
Table 2. Transportation, use, and storage environmental limits

Environmental Limits during Use	
Ambient temperature (°C)	10 to 35
Relative humidity (%)	30 to 85 (non-condensing)
Pressure (HPa)	700-1060
Environmental Limits during Transport and Storage – See Product Specific Labeling	

PATIENT ENVIRONMENT

The EXALT Accessories are non-medical equipment but may be used in the patient environment (Figure 1).

Figure 1. Typical positioning of equipment, patient, and operator



ROUTINE INSPECTION AND MAINTENANCE

The EXALT Accessories do not require routine maintenance. Periodically check any power cord assemblies for damage to the insulation or connectors. In the event that an EXALT Accessory requires repair or replacement, contact Boston Scientific.

CLEANING

Refer to the 'Directions for Use' for cleaning instructions for each applicable non-medical multimedia accessory and medical devices used for installation for cleaning instructions. Where not specified by the multimedia accessory manufacturer, the cleaning procedure is as follows:

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 device enclosure, front panel user interface buttons if present, and power cable. Do not allow fluids to enter the enclosure or power cable connections. Do not attempt to clean the unit while it is plugged into an electrical outlet.

INSTALLING EXALT ACCESSORIES

Installation of EXALT Accessories is performed by BSC field service representatives in conjunction with site personnel. Installation and functional test records will be provided to site personnel at completion of the installation.

The system is designed to be powered from an Isolation Transformer rated for a minimum of 1000 V/A. Do not use the system without confirming it receives power from an appropriate Isolation Transformer.

OPERATION INSTRUCTIONS

Directions for use of Boston Scientific Imaging Systems (e.g. EXALT, Spy DS) are provided separately with each system at the time of installation. Reference the manufacturer's labeling for specific instructions for each installed accessory. Definitions for presets for the tvOne Video Processor (if installed at site) are included in Appendix A.

Once the EXALT accessories are installed, the user will interface with only the preset buttons on the tvOne video processor, a site supplied image capture system, BSC or site supplied switches, and the intended image processor. Due to the variety of equipment that is pre-existing or installed, site specific operation instructions will be documented in a "Quick Start" guide at the time of installation. The Quick Start guide will include:

- How to select and display image from Imaging System(s) on procedure monitor and image capture system.
- How to enable image capture initiation for applicable systems.

USER CONFIRMATION OF INSTALLATION AND OPERATION INSTRUCTIONS

At the completion of installation, the user will verify the following attributes of the installation are acceptable and/or understood (Image color, noise, latency, aspect ratio, configuration and functionality of accessories).

TROUBLE SHOOTING

For troubleshooting of medical equipment please see their relevant Directions for Use. For System troubleshooting see the table below. Most operating problems are easily resolved. If unable to resolve the problem using this troubleshooting chart contact Boston Scientific for support 888-541-0470.

Symptom	Possible Cause	Corrective Action
Video processor image is not displayed on the monitor and processor is powered on	Video converter (if applicable) is not powered on or plugged in properly	Ensure all video converters are powered on and both the video and power cables are securely connected
	Video switcher (if applicable) set incorrectly	Refer to site specific installation instructions to ensure configured system matches installation record
Video image is blurry, scrambled, inadequate, or distorted	Defective power cord	Call Boston Scientific to replace power cable
	Defective video cable	Call Boston Scientific to replace video cable
Image capture does not transfer to external media capture device	Video processor has a defective video output	Call Boston Scientific
	Multimedia equipment is too close to other electrical medical equipment	Refer to the directions for use for the placement of medical device.
		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 cables are not completely connected between multimedia equipment	Ensure video cables are completely connected to multimedia equipment
	Video cable not properly connected to the monitor	Ensure video cable is connected into monitor video input and not output.
	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, multimedia device (if applicable), and external capture device.
	External image capture device is not set to the correct video input.	Ensure external image capture device is set to receive video input from Boston Scientific system
	Video processor has a defective video output	Call Boston Scientific
Video processor has a defective trigger output	Call Boston Scientific	

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. 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 888-541-0470 to report a problem with the Installation Accessories.

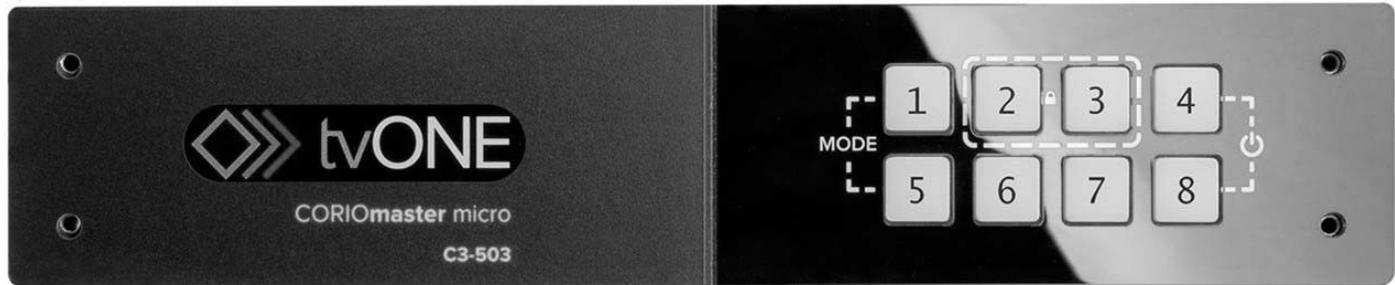
All transportation and insurance charges and risk of loss are the responsibility of the customer and must be prepaid. A purchase order must be issued to Boston Scientific Corporation to cover all transportation and insurance charges for return shipment after service.

EU Importer: Boston Scientific International B.V., Vestastraat 6, 6468 EX Kerkrade, The Netherlands

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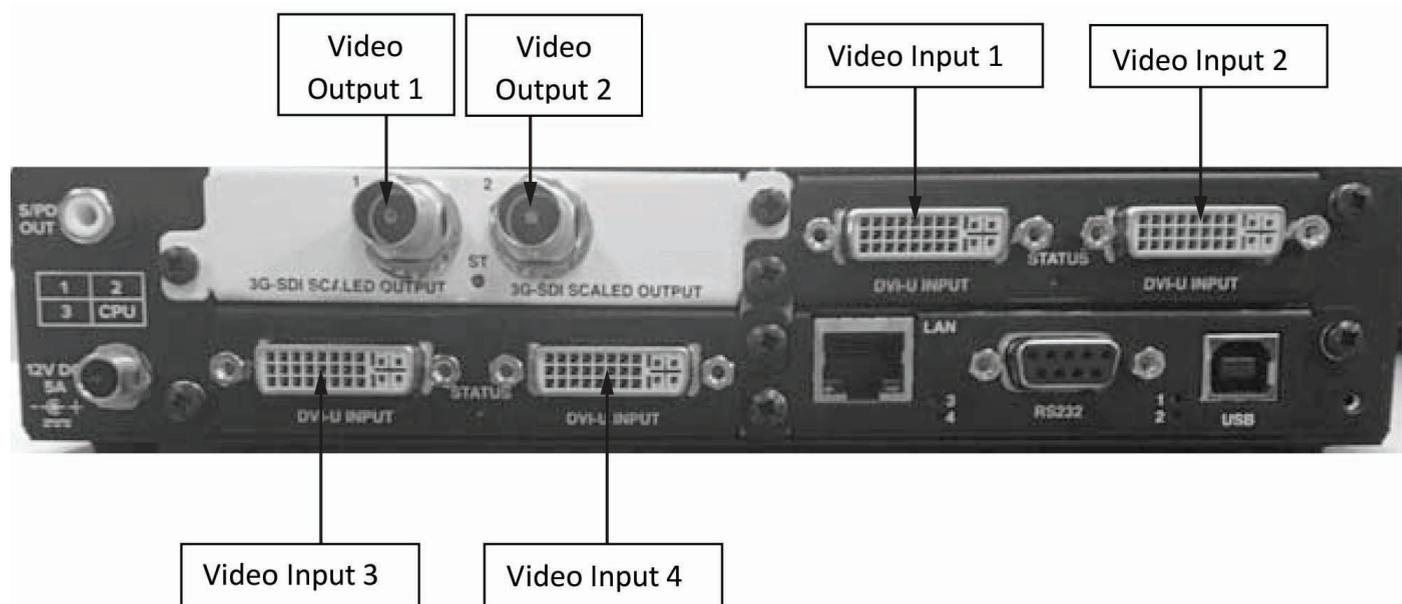
APPENDIX A – TVONE CONFIGURATION INSTRUCTIONS: INPUTS, OUTPUTS AND PRESETS

tvONE Front Panel:



- Buttons 1-8 on the front panel determine how the video inputs are displayed on the monitor.

tvONE Rear Panel:



Presets 1-8:

- Button 1:** Displays video from the source connected to Video Input 1 on tvONE's rear panel
- Button 2:** Displays video from the source connected to Video Input 2 on tvONE's rear panel
- Button 3:** Picture in picture display. Primary image displayed is from the source connected to Video Input 1 and the secondary image displayed is from the source connected to Video Input 2 on tvONE's rear panel
- Button 4:** Picture in picture display. Primary image displayed is from the source connected to Video Input 2 and the secondary image displayed is from the source connected to Video Input 1 on tvONE's rear panel
- Button 5:** Displays video from the source connected to Video Input 3 on tvONE's rear panel
- Button 6:** Displays video from the source connected to Video Input 4 on tvONE's rear panel
- Button 7:** Picture in picture display. Primary image displayed is from the source connected to Video Input 3 and the secondary image displayed is from the source connected to Video Input 2 on tvONE's rear panel
- Button 8:** Picture in picture display. Primary image displayed is from the source connected to Video Input 2 and the secondary image displayed is from the source connected to Video Input 3 on tvONE's rear panel

Caution: Video Input 2 is scaled to only accept 4:3 aspect ratio. All other inputs are tuned to only accept 16:9 aspect ratio.

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2020-01

