

SpyGlass™ DS Digital Controller

User's Manual

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Caution/Rx Only:

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

Warnings:

- Read this user manual, the SpyScope DS Catheter directions for use, and the monitor user manual 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.
- The LEDs in the catheter cable receptacle remain hot for a period of time after use. To prevent burns, do not insert fingers into catheter cable receptacle.
- Do not perform diagnostic or therapeutic procedures without a clear and adequate video display. Doing so can result in adverse events.
- 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.
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- 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. Verify operation in the endoscopy suite environment before starting a procedure. Follow ancillary equipment directions for use to locate ancillary equipment.
- Using a controller without disinfecting the cabinet and front panel buttons can expose the operator to biohazardous materials. To prevent exposure to biohazardous materials, disinfect the chassis between use using the cleaning procedure described in "Cleaning and Disinfection."
- 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.
- 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.
- 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 SpyGlass™ DS System.
- Components added to the SpyGlass DS System 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).
- 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 SpyGlass DS System, 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.

Intended Use/Indications for Use

The SpyGlass DS and DS II Direct Visualization System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system including the hepatic ducts. The SpyGlass DS and DS II Direct Visualization System comprises two components: the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter, and the SpyGlass DS Digital Controller. The SpyScope DS Access and Delivery Catheter and SpyScope DS II Access and Delivery Catheter are intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system including the hepatic ducts. The SpyGlass DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system including the hepatic ducts.

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Contraindications:

Contraindications associated with the use of this device include:

- Patients for whom ERCP is medically contraindicated.
- Contraindications specific to endoscopic pancreatico-biliary duct exploration and cannulation.

Precautions:

- If you block the controller's ventilation outlet, the controller can 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. Use the controller 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 catheters other than a SpyScope™ DS Catheter to the controller can damage the controller. Only connect a SpyScope DS Catheter to the controller. See the "SpyGlass DS Digital 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 SpyGlass™ DS System are present and operational. Starting a procedure without the supporting components present and operational can prolong the procedure.
- Do not use cleaners or disinfectant solutions that contain long-life surfactants. Doing so can leave conductive residues on the contacts of the catheter connector receptacle. The conductive residues can lead to malfunctions of the controller.
- Do not clean the LEDs located inside the catheter cable receptacle.
- Applied parts of other electrical medical equipment in application with this equipment have to be type BF. Hence, only use the controller with the SpyScope DS Catheter.
- Do not insert a wet connector into the controller receptacle as poor video performance or damage to the controller may result.
- Use of a cardiac defibrillator while a SpyScope DS Catheter remains in a patient can damage the controller. To prevent damage to the controller when using a defibrillator, remove the SpyScope DS Catheter before using the defibrillator.

Adverse Events:

See directions for use for SpyScope DS Catheter for adverse event information.