



## Product

iNod Ultrasound Guidance Console (iNod Console) – IFU 51748950

## Rx Statement

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

*Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.*

## INTENDED USE/INDICATIONS FOR USE

The iNod Ultrasound Guidance Console is intended to be used with iNod Ultrasound Guided Biopsy Needle, to observe and to store real-time ultrasound images of the endobronchial lesions, peripheral lung nodules, or lung masses located in airways and tracheobronchial tree.

## CONTRAINDICATIONS

Include but are not limited to:

- Patients whose general health and/or respiratory function are compromised to the point that the patient would not tolerate flexible bronchoscopy.
- Consult the iNod SUD Instructions for Use for a complete list of Contraindications, Adverse Events, Warnings and Precautions.

## WARNINGS

- The Console is intended for use by healthcare professionals only.
- No modification of this Console is allowed.
- The Console is not intended for use in the sterile field.
- Please read the User Guide and the Instructions for Use for the iNod SUD carefully and completely before attempting to use the Console.
- The use of accessories and cables other than those specified by Boston Scientific may impact the basic safety and essential performance, including increased emissions or decreased immunity, of the iNod Ultrasound Imaging System.
- Components connected to the Console 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.
- Inappropriate use of the Console, may lead to patient illness, or injury misinterpretation of patient data and subsequent misdiagnosis/mistreatment, potentially leading to injury.
- In an emergency, cut off the main electric supply to the Console by switching the power OFF on the Isolation Station.
- Console is suitable for hospital environment except for near active high frequency surgical equipment and the RF shielded room of medical equipment for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- If fuses for the AC Power Isolation Station are to be checked or replaced, disconnect the Isolation Station from the facility’s AC mains before starting, to avoid potential electrical shock.
- To avoid the risk of electrical shock, this Console must only be connected to a supply mains with protective earth.
- The Tablet battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 50 °C, or incinerate.
- To prevent fire or shock hazard, do not expose the Console to moisture or rain. If it is necessary to transport the Console through rain, place a protective cover over it. If moisture gets into the instrument, allow it to dry thoroughly before plugging the AC power cord into an electrical outlet.
- Spilling liquids on the Console can damage it or cause it to shut down. Never pour any liquid into an opening. This may cause fire or electrical shock.

- In the unlikely event that smoke, abnormal noise, or strange odor is present, immediately power off the tablet and disconnect all power sources in order to avoid patient injury or damage to the Console. Report the problem to Boston Scientific Technical Assistance immediately.
- Appropriately position the mobile pole/power cord to minimize tripping hazard which could result to injury to the patient or user.
- Do not connect the Console to AC mains through and extension cord. This may cause fire or electrical shock.
- 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.
- Do not use the iNod Console or iNod MDU 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 Console is not intended for use in the sterile field.
- Ensure the mobile pole is orientated in its lowest vertical height prior to repositioning the Console to prevent tipping and possible damage to the system and user.
- Appropriately position the mobile pole/power cord to minimize tripping hazard.
- Avoid rolling the mobile pole over objects to prevent tipping and possible damage to the system.
- Other than the fuses on the AC Power Isolation Station, the Console enclosures contain no operator-serviceable components. To avoid electrical shock, do not remove covers. As with any other electrical equipment, always observe care when operating this instrument. Refer servicing to BSC authorized personnel only. Failure to do so may void your warranty or service contract coverage.
- The use of accessories and cables other than those specified by Boston Scientific may impact the basic safety and essential performance, including increased emissions or decreased immunity of the iNod Ultrasound Imaging System.

## PRECAUTIONS

- Always adhere to your facility's personal protective equipment (PPE) precautions and cleaning measures.
- Never use the Console or Console Accessories that you suspect may have been damaged.
- Do not attempt to disassemble any component of the Console.
- Always exercise care and caution when operating and handling the Console.
- Avoid rolling equipment casters of any size or weight over the cables.
- In case of abnormal Console operation, the Console may require shutdown and restart to bring it to normal operation. Follow the normal shutdown and startup procedures listed in the Shutdown Console section of this User Manual.
- Do not depress the Tablet Power Switch at any time while using the Console. Power is controlled by software and the main AC Power Switch. If the Tablet Power Switch is pressed while recording a run, the recorded data may become corrupted and should not be used.
- Avoid sudden changes in temperature as condensation can form on the internal parts of the Console. If the Console has to be moved into a warm location after prolonged exposure to cold temperatures, allow it to acclimate for a minimum of 2 h to 3 h before plugging it into an electrical outlet.
- Before attempting to write DICOM files to removable media, make sure that a removable USB is inserted in the tablet.
- The power adapter, charger, and the tablet may become hot during normal use. Allow for proper ventilation around the power adapter, charger, and charging tablet.
- Only use your finger or the BSC supplied digital pen to tap to operate the Tablet touchscreen. Do not use sharp pointed objects to operate the touchscreen, as doing this could cause permanent damage to the touchscreen and void the warranty.
- If you have difficulty inserting the iNod SUD MDU connector into the Motor Drive, remove the MDU connector and press the Imaging button. After 1 s, the Motor Drive shaft will stop spinning; at this point, you can reinsert the SUD MDU connector.
- Never attempt to connect or disconnect an iNod SUD to the Motor Drive while it is running, or damage to the iNod SUD or Motor Drive may occur.
- Always turn the MDU "OFF" before withdrawing the iNod SUD because it could cause the MDU to overload.
- The Console can be susceptible to ESD (Electrostatic Discharge) and EFT (Electrical Fast Transients). BSC recommends that all staff involved with the operation of the Console be shown the ESD warning symbol, and be informed to avoid touching the connectors labeled with an ESD symbol.
  - Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). This Console needs to be installed and put into service according per the Electromagnetic Immunity (EMI) information contained within accompanying documents. Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment.
  - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the Console, including cables specified by the manufacturer. Otherwise, degradation of the performance of this Console could result.
  - The emissions characteristics of this Console make it suitable for use in industrial areas and hospitals. If it used in a residential area environment

- this Console 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 Console.
- The Console should not be used adjacent to other equipment. If adjacent use is necessary, the Console should be observed to verify normal operation in the configuration in which it will be used.
- The AC Power Isolation Station must be plugged into a grounded hospital grade AC power wall outlet.
- The AC Power Isolation Station is intended to be used only with iNod Console and Accessories. Do not use any outlet on the AC Power Isolation Station for devices other than the iNod Console and Accessories.
- Other than the fuses on the AC Power Isolation Station, the Console enclosures contain no operator-serviceable components. To avoid electrical shock, do not remove covers. As with any other electrical equipment, always observe care when operating this instrument. Refer servicing to BSC authorized personnel only. Failure to do so may void your warranty or service contract coverage.
- For continued protection against fire hazard, replace fuses only with those listed in this manual and on the manufacturer's replacement fuse label located on the AC Power Isolation Station. Do not use fuses with higher amp rating than those listed in this document.
- Avoid prolonged exposure of the display panel to any strong heat source. Wherever possible, the Tablet should face away from direct light to reduce glare.
- The anti-glare coating on the Tablet Liquid Crystal Display (LCD) panel can be scratched.
- Use of this Console adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this Console and the other equipment should be observed to verify that they are operating normally.
- To achieve proper grounding reliability, the power plug must be fully inserted into a receptacle marked "Hospital Grade." If there is any question of power outlet or power cord integrity, do not proceed. Obtain qualified technical assistance.
- The Console employs a floating double insulated patient isolation connection within the Console's Motor Drive Unit. This connection is intended for Type BF applied parts, and includes circuitry to limit the patient leakage current to the levels specified in UL 2601-1, EN 60601-1, and JIS-T-0601-1.
- Potential equalization connection must always be connected on the AC Power Isolation Station or Acquisition Processor to the hospital's potential equalization system (if present and required).
- Care should also be exercised in adjusting all settings to avoid obscuring low-level signals that may have diagnostic value. Improper settings can seriously degrade image quality.
- Avoid rolling the mobile pole over objects to prevent tipping and possible damage to the system.
- Exercise care when depressing the tablet touchscreen. Depressing the touchscreen too rapidly or too firmly can lead to it operating in an unintended manner.
- Fluctuations in AC power (voltage dips or surges), may result in unpredictable behavior of the Console and may affect the reliability of diagnostic images or waveforms.
- The top and bottom surfaces of the power supply enclosure are not intended to be touched while the power supply is in use. While the unit is in use, the top and bottom surfaces of the power supply enclosure may reach temperatures which cause discomfort when touched for more than 1 s. There is no user accessible parts on the top and bottom surface of the power supply. Use only the front panel and rear panel switches, knobs and connectors which are intended to be used while the power supply is in operation.
- The AC Power Isolation Station is intended to be used only with the Console equipment. Do not use any unused outlet on the AC Power Isolation Station for non-BSC equipment.
- The Mobile Pole height adjustment operates by pneumatic pressure and will travel upward when the foot pedal is engaged. Ensure that nothing obstructs the upward movement of the pole.
- If you have difficulty inserting the iNod SUD MDU connector into the Motor Drive, remove the MDU connector and press the Imaging button. After 1 s, the Motor Drive shaft will stop spinning; at this point, you can reinsert the catheter. Never attempt to connect or disconnect an Imaging Catheter to the Motor Drive while it is running, or damage to the Imaging Catheter or Motor Drive may occur.
- Only use your finger or the BSC supplied digital pen to tap to operate the touchscreen. Do not use sharp pointed objects to operate the touchscreen, as doing this could cause permanent damage to the touchscreen and void the warranty.
- After you select Yes in the Delete Current Case Confirmation window, the current case is deleted and cannot be recovered.
- The iNod Console must be shutdown using the application software controls. Avoid using the Power Button ("hold 4 + seconds" feature) to turn off the tablet — this form of hardware shutdown is intended to be a means of recovery from lockups, and not as normal operation. If the tablet power button is pressed while recording a run, the recorded data may become corrupted.
- Do not allow moisture to seep into the ports as this may cause damage to the console.
- Prior to use, disinfectants should first be tested in an inconspicuous product location to ensure no adverse material affect such as discoloration, hazing, cracking or other visible impacts. If visible impact is detected, do not continue use of the disinfectant.
- The AC Power Isolation Station is intended to be used only with iNod Console and Accessories. Do not use any outlet on the AC Power Isolation Station for devices other than the iNod Console and Accessories.

- For continued protection against fire hazard, replace fuses only with those listed in this manual and on the manufacturer's replacement fuse label located on the AC Power Isolation Station. Do not use fuses with higher amp rating than those listed in this document.

#### **POTENTIAL ADVERSE EVENTS**

- Bleeding/Hemorrhage
- Bronchospasm
- Infection
- Inflammation
- Laceration
- Perforation
- Pneumothorax
- Respiratory Distress
- Tissue Damage