AtriCure® Isolator™ Transpolar™ ablative handpiece and pen device Instructions For Use

The AtriCure ASB3 Switch Matrix is a reusable accessory interface module that allows simultaneous connection of AtriCure® Isolator™ Transpolar™ ablative handpiece and pen devices to the ASU RF generator. Devices will be operational only when the ASB3 selector switch is set to the device specific position. Please refer to the applicable handpiece and pen device Instructions For Use. Please refer to the ASU User’s Manual for descriptions of RF energy delivery, modes of operation, output power, operating frequency, and approved temporary cardiac pacing and stimulating accessories.

The ASB3 has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The ASB3 generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the ASB3 does cause harmful interference to other devices, which can be determined by turning the ASB3 off and on, the user is encouraged to try to correct the interference by one or more of the following measures; (1) reorient or relocate the receiving device, (2) increase the separation between the ASB3 and the other devices, (3) connect the ASB3 into an outlet on a circuit different from that to which the other device(s) are connected, and (4) contact the AtriCure service representative for assistance.

Inspect the following interface cables for any signs of physical damage to the cable and connectors. If physical damage is found or the interface cables do not perform within specification, notify AtriCure. All returns must have approval from AtriCure. The cables include: (1) A000442-ASB/ASU RF Interface Cable, (2) C001237-ASB/ASU Footswitch Interface Cable, and (3) A000479-ASB3 PSS Interface Cable.

Environmental Conditions: (1) operational temperature +10°C to +40°C, (2) storage temperature -35°C to +54°C, and (3) humidity 15% to 90% relative humidity.

Perform annual preventative maintenance procedures to ensure all ASB3 components are functioning properly, including but not limited to: (1) electrical power cords for fraying, damage, and proper grounding, (2) AC power switch, (3) indicator damage (Power On, Footswitch Present, or Handpiece Select), (4) handpiece connector damage, cracking or inability to insert and latch handpiece plug, (5) carrying handle damage, inability to latch or rotate, (6) rubber feet damage, cracking or inability for the ASB3 to remain stable on a flat surface, (7) interface cable fraying or damage, and (8) footswitch connector damage cracking or inability to insert and latch footswitch plug.

The ASB3 does not have any serviceable parts. For servicing issues, contact AtriCure, Inc.

The ASB3 Accessory Cleaning and Disinfection Instructions; (1) use a mild detergent (prepared to its specifications) and a damp cloth to clean the exterior of the Switch Matrix, (2) do not submerge or allow fluids to enter the chassis, (3) do not use caustic, corrosive, or abrasive cleaning materials, and (4) the ASB3 and auxiliary device cable cannot be sterilized.

Types and rating of fuses: (1) 100-120V, 220-240V, ~50/60 Hz, and (2) 1.25A/250V, T-lag, 5 x 20mm, UL Recognized, IEC Approved. Replace fuses as marked.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

Disclaimer - Under no circumstances will Atricure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse of this product, including any loss, damage, or expense which is related to personal injury or damage to property.