



AcuNav Diagnostic Ultrasound Catheter

AcuNav Diagnostic Ultrasound Catheters (ICE catheters) reprocessed by Innovative-Health are a safe and effective equivalent to costly options sold by the original equipment manufacturer. Clinical use improves efficacy and safety by enhanced visualization and imaging of cardiac anatomical structures during complex EP ablation and structural heart procedures. AcuNav technology offers combined ultrasound imaging, doppler imaging and a four-way (up to 160° deflection) steering system. This system is capable of imaging with remarkable maneuverability and precision placement for the evaluation of blood flow velocity, anatomical structures and myocardial wall motion. AcuNav reprocessed by Innovative Health provides highly reliable image quality aiding in the diagnosis and treatment of arrhythmias and structural heart disease. Both Siemens and GE Ultrasound console capable AcuNav catheters are available through Innovative Health.



Cleaning

Innovative Health's validated cleaning process has been specifically designed and tested to provide consistent and repeatable results with high confidence and reliability. The first step in the reprocessing process is the reduction of organic and inorganic contamination (e.g. hemoglobin, protein) and chemical residue (e.g. Total Organic Carbon (TOC)). This is achieved utilizing manual debris removal techniques, enzymatic cleaners, and Reverse Osmosis (RO) water.

The process has been validated in accordance with AAMI TIR-30: Compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices and FDA recommendations. This standard is considered to be the gold standard in cleaning medical devices.



A Validated Process

Exhaustive testing was conducted to verify and validate Innovative Health's decontamination, cleaning, assembly, packaging and sterilization processes. During the design and development phase, the following functionality tests/assessments are performed: Visual Inspection, Dimensional Inspection, Packaging Assessment, Simulated Use, Catheter Joint Tensile Testing and System Compatibility. These devices and related processes are validated according to accepted FDA and industry standards such as ISO, AAMI, etc. and to meet applicable confidence intervals as required.

Testing

Ultrasound Transducer Test

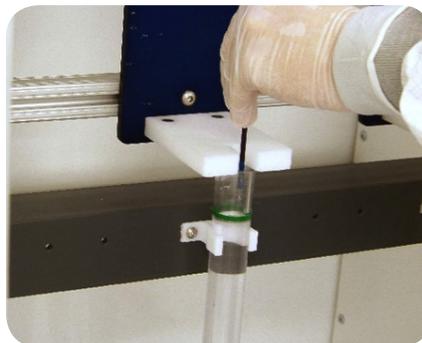
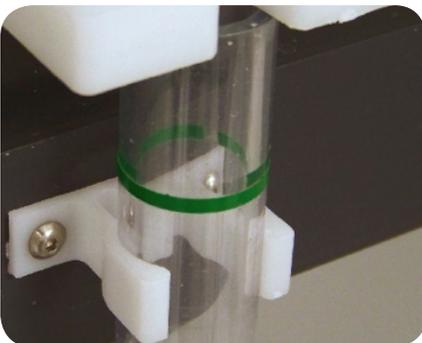


The purpose of the Ultrasound Transducer Test is to provide repeatable and quantifiable data required to determine the operational effectiveness of the Reprocessed Diagnostic Ultrasound Catheter transducer function. The Ultrasound Transducer Test can detect the failure of any element from one of number of root causes, such as dead or weak crystals within the ultrasound array, acoustic performance parameters of the ultrasound array, acoustic lens delamination, broken wires within the probe cable, broken wires within the flex circuit within the probe and also for defective electronics within the probe connector. A widely used probe testing device that is the industry standard for

testing the acoustic and electrical properties of ultrasound transducers. By independently exciting each crystal within the array of the probe, the Ultrasound Transducer Test measures the relative sensitivity of each element and analyzes the acoustic signature of the returning pulse for any variations in key performance characteristics.

High Potential (HIPOT) and Patient Leak Testing

The purpose of the HIPOT testing is to evaluate how well the outer shaft of the device contains and insulates from voltage leaks. Sparking or arcing is characterized by rapid variations in voltage or current that typically results in failure. If kinks, cuts or abrasions are present within the material, an escape path is created for the voltage. Maintaining an adequate dielectric barrier between the electrical power and the patient is critical in terms of power surges.

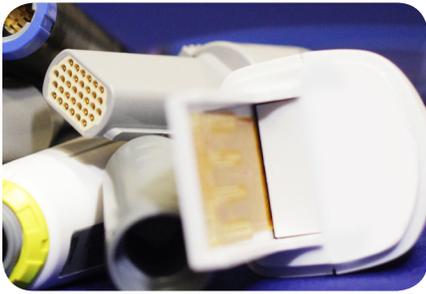


Inspection

Physical, mechanical and electrical testing is performed to provide objective evidence that the reprocessed device meets specifications and functions as intended.

The following tests are performed on 100% of the devices during reprocessing:

- Visual Inspection
- Curve Template / Functional (Steering Mechanism) Testing
- Ultrasound Transducer Testing
- HIPOT / Current Leakage Testing



Estimated Annual Savings: \$239,760

Estimated Percent Savings: 40%

*Based on average annual facility usage of 240 AcuNav devices

Innovative Health is proud to offer the following AcuNav devices for reprocessing:

Catalog Number	Description	Sheath Usable Length	French Size	System Compatibility
08255790	AcuNav Diagnostic Ultrasound Catheter	90cm	10F	Acuson/Siemens
10135936	AcuNav Diagnostic Ultrasound Catheter	90cm	8F	Acuson/Siemens
10135910	AcuNav Diagnostic Ultrasound Catheter	90cm	8F	GE Vivid I Ultrasound System
10043342	AcuNav Diagnostic Ultrasound Catheter	90cm	10F	GE Vivid I Ultrasound System

Developing a 510(k) to achieve FDA Clearance to Reprocess Single-Use Devices

The FDA requires reproprocessors to demonstrate that a reprocessed device is substantially equivalent to that of the Original Manufacturer (OM) device prior to marketing the device. The FDA is able to determine that the device is substantially equivalent from the evidence presented in a 510(k) submission.

Innovative Health evaluates OM devices to determine their eligibility for reprocessing. This evaluation includes, but is not limited to, reverse engineering, OM characterization, and testing to ensure the finished reprocessed devices meet the appropriate product specifications and are safe and effective as the original device.

Cleaning validations through independent laboratories, based on the industry standards AAMI TIR30 and FDA guidelines, are completed to ensure that the cleaning process reduces residual biomarkers (i.e. organic soil, bioburden and endotoxins) on devices to acceptable levels to ensure the cleanliness. Exhaustive extractions are performed to determine the number of viable organisms and contaminants that are present on inoculated devices. Repeated extractions are performed to calculate extraction efficiencies which determine the effectiveness of the cleaning process.

Biocompatibility testing was performed in accordance with AAMI/ANSI/ISO 10993 (and related subparts) Biological Evaluation of Medical Devices to ensure that devices are not toxic, injurious, or physiologically reactive and do not cause immunological rejection. In vitro and in vivo safety evaluation studies are conducted and may include: chronic cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and hemocompatibility testing.

Detailed test plans are developed for each device that are intended to test the mechanical, electrical, and simulated use properties of the device under worst case conditions. Innovative Health engineers work closely with clinicians to understand clinical use and translate this into appropriate testing methods.

During production, each device is inspected and function tested prior to packaging and labeling and all production lots are tested to ensure an acceptable level of bacterial endotoxins in accordance with ANSI/AAMI ST72 to support the non-pyrogenic labeling.

Innovative Health devices are sterilized using Ethylene Oxide (EO). The EO sterilization process includes preconditioning, sterilization and aeration. The EO sterilization cycle is validated in accordance with applicable industry standards and requirements such as AAMI/ANSI/ISO 11135 to achieve a minimum Sterility Assurance Level (SAL) of 10⁻⁶. In addition, devices are validated to have acceptable sterilant residual levels after aeration.

For a more detailed description of what goes into an Innovative Health 510(k) submission, please ask your contact for additional information.

*AcuNav is a trademark of or licensed to Siemens Medical or one of its subsidiaries.



INNOVATIVE HEALTH

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