Medtronic

Nitron CryoConsole™ Cardiac Cryoablation System

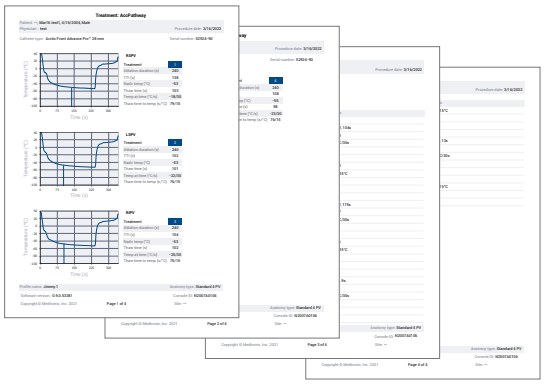
Intuitively elevated workflow

The Nitron CryoConsole™ system safely and effectively powers the Arctic Front™ family of cardiac cryoablation catheters and the Freezor™ family of cryoablation catheters. It is the next generation of the Medtronic cryoconsole, expertly elevating the cryoablation workflow.

Meaningful enhancements have been built into the Nitron CryoConsole system for efficient operation:

Enhanced data capture

Automated and customizable key procedural data captured real-time and post-procedure in exportable case summary report.



Simple graphic user interface[1]

Enhanced GUI with intuitive CryoConsole operation guidance, custom user profiles, and visual indicators of procedure parameters like TTI and previous freeze trace.

Optimized workflow

Simple, optimized workflow with touchscreen interface, wired remote control, and mirrored Nitron CryoConsole system display on external lab monitors. The console also includes an EP connectivity feature, which enables cryotherapy information to be transmitted to select external EP recording systems.

[1] Medtronic data on file. Based on a survey of 40 users after one hour of training.

Brief Statement

Intended Use

The Nitron CryoConsole (the console), together with its components and specified catheters, is for use in performing cardiac ablation procedures.

Contraindications

See Technical Manual for the compatible Medtronic catheter being used.

Warnings and Precautions

These warnings apply in general to using the Nitron CryoConsole for cardiac cryoablation. Refer to the technical manual for console-compatible catheters for more information related to catheter use.

- Connected EP lab equipment – Any equipment (e.g. EP recording system, HDMI, etc.) connected to the upper rear connection panel or to the auto connection box ECG cable receptacle of the device shall be IEC 60601-1 compliant or have a 60601-1-compliant isolation transformer on the interconnect cable between the Nitron CryoConsole and the EP lab equipment.
- Electric shock – To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- Cryoadhesion – Do not pull on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury.
- Improper connection – Do not connect a cryoablation catheter to a radiofrequency (RF) generator or use it to deliver RF energy. Doing this may cause catheter malfunction or patient harm.
- Other accessories, transducers, and cables – Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The console meets the requirements of IEC 60601-1. It is the user's responsibility after installation to verify and ensure that the console meets the applicable local electrical safety requirements. Perform cryoablation procedures only within the environmental parameters. Cryoablation procedures should be performed only in an electrophysiology facility by or under the supervision of physicians trained in cryoablation. Do not modify this equipment. Modifications may reduce system effectiveness and impact patient health. The system must be installed by a qualified/trained Medtronic representative. All information technology equipment that is attached to the console must be approved by a third party to the requirements of UL 1950 or EN 60950. Minimize exposure to nitrous oxide to prevent short-term behavioral and long-term reproductive health effects. The console and its accessories have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment and are unknown which may lead to patient injury. Use only compatible Medtronic cryoablation catheters and components and Medtronic-provided refrigerant tanks with the console. The safety and use of other catheters or components has not been tested.

Potential Adverse Events

Potential adverse events associated with console procedures include, but are not limited to, the following conditions:

- Electric shock
- Foreign body/biological reaction
- Long-term reproductive issues
- Thermal injury

Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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