

Novel RF generator, remote control and irrigation pump technology to provide maximum safety and control in cardiac catheter ablation

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Introduction

The SmartAblate™ System is a newly developed, integrated System to treat cardiac arrhythmia with high frequency power. It consists of RF generator, Irrigation Pump and Remote Control and is the successor model of the market leading generators EP-SHUTTLE / STOCKERT-70 / STOCKERT J70. Latest technology and 26 years experience of ablation generator development have been brought together to create a unique new system.

Aims

We aimed to increase safety and ease of use into an integrated ablation platform.

Safety Architecture

The system is decomposed in a modular, task oriented fashion and structured as a dual-channel system. Critical functions are distributed between a network of microcontrollers for the primary functions, while the monitoring microcontrollers watch and verify the proper function and behaviour of the control system.

Both systems use different microcontroller architectures (RISC, CISC) and different softwares to minimize the potential for common or systematic faults. To minimize the dependencies between both systems, the information between the two networks is restricted to the bare minimum. They are running asynchronously and all processors are clocked independently.

An additional benefit of the modular and dual channel design is that maintenance and sustaining engineering will involve changes to certain modules, only. Thus, the impact of any change on the whole system can be easier defined and verified.

In addition to the dual-channel design, the SmartAblate® system includes several extensive diagnostic and self-tests. These have been incorporated to provide mitigation measures like the ability to shut down RF if an error is detected.

Operator and user errors are mitigated by workflow oriented graphical interface. Color coding of parameters and the step-by-step assisted setup minimize incorrect selection of catheters or treatment parameters. The consistent use of color coding throughout the device (including connectors) prevents misidentification and misconnection. Keyed connectors prevent the use of incompatible accessories.