MINNETRONIX™ MEDICAL

Accelerating Breakthroughs

CASE STUDY

Applying Know-How to Expedite Project Success

The Minnetronix team leveraged existing know-how to jump ahead with an updated design and allow the client to resume clinical trials as quickly as possible.

TECHNOLOGIES

- RF Energy
- Systems Integration

The Challenge

Based on the results of an interim analysis due to an observed significant change in therapy results in comparison to initial pilot trials, Cerephex®Corporation halted a pivotal trial of their NeuroPoint®System for the treatment of fibromyalgia. In order to assess and reconcile differences between the two versions of the NeuroPoint System, Cerephex needed a partner to evaluate the current system, determine areas for improvement, and update the software and hardware to allow resumption of trials as quickly as possible.

The Solution

Testing of the NeuroPoint units used in the pivotal study indicated that there was an unexpected lower level of delivered therapy from the stimulation circuit. Cerephex believed that a revised circuit design was needed. They selected Minnetronix to help re-design the system based on the company's extensive experience in software, electronics, and the mechanical design of medical devices, especially electrical stimulation devices.

One of the Minnetronix lead electrical engineers had an extensive background in neurostimulation, and he utilized his specific expertise to analyze the situation. Under his guidance, the Minnetronix team sidestepped the traditional path of debugging the system and working to restore the original design. Instead, the team leveraged their know-how and experience to jump ahead with a fresh design.

Although the existing user interfaces were retained, Minnetronix incorporated new technology throughout much of the system. An existing in-house software team was pulled in its entirety onto the project, having recently worked together on a similar project. They incorporated embedded communication protocols and a simple serial protocol, as well as embedded microprocessors technology and analog circuitry.

The Result

Minnetronix updated Cerephex's fleet of clinical devices to ensure that the appropriate level of therapy was being delivered and to improve reliability and usability. The updates to the system provided a predictable, consistent electrical stimulation therapy. In redesigning the circuit, the Minnetronix engineers also incorporated flexibility that allowed for a new modification of the therapy. Instead of one therapy arm and a sham arm, the NeuroPoint units could now deliver two therapy options and a sham.

Cerephex needed to resume clinical trials prior to the winter holidays in order to minimize enrollment delays. Given the ability to leverage existing know-how, the Minnetronix team was able to meet this target for Cerephex. A pilot trial was initiated, and patient enrollment successfully began.

NeuroPoint is an investigational device and is limited by Federal law to investigational use only. NeuroPoint is not currently approved or cleared by the FDA.

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Design and Engineering

- Reviewed existing documentation and identified areas of improvement in the system in preparation for detailed design updates and testing
- Redesigned stimulation electronics, stimulation software, and graphical user interface (GUI) software
- Built and tested five units for clinical trials

Regulatory Expertise

- Reviewed product safety design to ensure compliance to 60601-1 3rd Edition
- Documented NeuroPoint validation and verification activities performed to meet Cerephex quality goals as well as to meet compliance requirements defined by US and European regulatory agencies

CASE STUDY TAKEAWAY

"With our deep knowlege of neurostimulation we were able to sidestep the traditional process."

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