



The Realtime Group of Companies

3035 W 15<sup>th</sup> St. Plano, TX 75075

972-985-9100 (Main)

972-985-9150 (Fax)

[www.TheRealtimeGroup.com](http://www.TheRealtimeGroup.com)

## ***Case Study – Neuro Stimulation***

### **The Challenge:**

Provide Software Development and Verification and Validation services to a start-up company evolving an existing product designed for pain management.

The company had an FDA cleared product and needed to outsource software development activities for improving the user interface and replicating the existing product performance in the updated product line. The company also outsourced the Verification and Validation activities for the product.

### **The Solution:**

Since software development and V&V services were contracted from Realtime, both activities were managed and achieved in parallel using two independent teams with same strategic overlap.

Software was developed on two fronts: a state-of-the-art Graphical User Interface (GUI) based on a color OLED screen and a real-time embedded system to deliver stimulation. Inter-processor communication was a key factor to the success of the software.

To establish the complete basis for V&V, The Realtime Group facilitated a formal Hazard Analysis in accordance with ISO 14971, the international standard for Application of Risk Management to Medical Devices. The Realtime Group also collected all existing requirements specifications and began development of a trace matrix from ‘parent’ specifications to ‘child’ specifications (and eventually down to test cases). In parallel, comprehensive V&V test procedures were developed to ensure the device continued to meet the functionality of the existing (cleared) product. Protocols were executed and formal test reports delivered. As additional functionality or modifications are made, the protocols have been re-used to show continuous compliance with requirements and to show no regressions created as a result of change.

The Realtime Group was an essential partner in support of the continuing FDA regulatory compliance plan.



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**To Learn More  
About the Neuro  
Research Group  
(NRG):**

NRG specializes in the development, design and manufacture of innovative medical products for injury management, rehabilitation, and pain management. The Company has extensive experience in the healthcare industry and is committed to providing products that both improve the quality of patients' lives and enhance athletes' performance in sport. <http://www.nrg-unlimited.com/>

The InterX™ devices are clinically proven in the most challenging field of severe chronic pain, the InterX™ products also play a powerful role worldwide in sports injury management and rehabilitation.

The Realtime Group is a leading medical device and aerospace engineering & product development firm that was instrumental in supporting NRG in preparing to market the InterX™ family of devices. The Realtime Group has been in the trenches of supporting clients develop real-time software solutions and get products through the FDA approval cycle. There is no better company to have as a partner than The Realtime Group.



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