Device Current Waveform Analyzer Speeds Medical Device Evaluation and Validation Time by 50 Percent

The progress in modern medical care is remarkable. Increasing development of Internet of Things (IoT) devices for the medical industry is a key factor in that progress. In recent years, pacemakers, defibrillators, and other medical device implants have gotten smaller and smarter. They monitor biometric information like a patient's heartbeat (HR), blood pressure (Bp), blood sugar/glucose level (BS/BD), and blood oxygen saturation (SpO_2). The medical data they collect travels through the internet via *Bluetooth*™ Low Energy (BLE), WiFi, or some other wireless communication protocol, providing doctors real-time diagnostic information.

While medical devices bring a host of benefits to patients and doctors alike, they also create new challenges for the engineers developing them. One such R&D team at a large multinational medical electronics company recently discovered how difficult it is to develop a smart, implantable medical device. They struggled to balance designing a high quality, reliable device with long battery life in a shorter development time frame. Using Keysight Technologies' CX3300 Series Device Current Waveform Analyzer, the engineering team was able to optimize device battery life, detect previously undetected defects, and speed device evaluation.

Company:

- R&D team at a multinational medical electronics company

Key Issues:

- Quickly evaluation device for validation & certification
- Identify device defects prior to shipment
- Lower power consumption

Solution:

- CX3300 Device Current Waveform Analyzer

Results:

- Reduced evaluation period for certification by 50%
- Located and resolved previously undetected power management issues

KEYSIGHT TECHNOLOGIES

Conflicting Priorities in Smart Medical Device Design

Various issues make developing a smart medical device challenging. These issues include:

1. Reducing the device design and validation period to ensure quick delivery of new products to the marketplace. With any medical device, certification is a requirement for use. Evaluation data is necessary for device certification. While efficiently capturing and analyzing evaluation data is difficult, it is critical to identifying defects prior to shipping a device. Without accurate, repeatable data or sufficient evaluation, critical device defects can be overlooked. In a medical device, a defect can negatively impact a patient's outcome. In the worst-case scenario, it can even result in death.

2. Lowering power consumption to reduce a device's battery replacement cycle. For battery-operated medical devices that are implanted, battery replacement requires surgical intervention. It's a key reason engineers need to optimize the battery life of their devices. Power consumption can be reduced using an intelligent power management program to switch between multiple sleep modes, but adding this into the medical device requires additional evaluation and verification to ensure the program operates as expected.

Adequately collecting and analyzing evaluation data and lowering device power consumption are goals often at odds with the engineer's need to get new medical devices to market quickly. Accomplishing these tacks requires accurate and in-depth measurement of the device's current waveform.

Measurement Challenges

In a conventional current waveform measurement, an oscilloscope and current probe or differential probe with shunt resistance, are typically used. Unfortunately, the noise coming from the test equipment can negatively impact the accuracy and measurement repeatability required for device certification. Also problematic is that the bandwidth of high-precision, low-noise measurement equipment is often too narrow. As a result, the fast spikes or inrush currents that lead to device failure can easily go unnoticed.

Another challenge engineers face, especially when validating the intelligent power management of a medical device during operation, is the need to measure the current waveform from a low sleep current (< 1 mA) to a high-current active mode without missing any signals.

Complicating matters, traditional current waveform measurement is:

- **Inefficient.** Test equipment often lacks a broad dynamic range, forcing engineers to remeasure by switching the shunt resistances for the various measurement ranges. Validating the software program becomes a series of activities, and the possibility of missing issues hidden in the operation is high.
- **Time Consuming.** Data post processing, such as noise reduction or combining data from multiple instruments, is required. These processes alone can take hours or days to finalize. With medical device certification requiring extensive measurement data and analysis, reducing the evaluation period is difficult at best.

Faster, More Accurate Measurement

For an answer to these challenges, the R&D team turned to Keysight Technologies with its CX3300 Series Device Current Waveform Analyzer (Figure 1). The instrument's wide dynamic range, up to 16-bits resolution, allows for easy capture of a device's dynamic current—from sleep mode to active mode. Its low measurement noise means that even small signals can be detected. A wide-bandwidth current measurement, up to 200 MHz, accurately captures fast spikes and inrush currents that cause circuit failure, while an extended memory depth of up to 256 Mpts/ch ensures elusive defective waveforms are captured. Such capabilities enable both efficient and accurate current profile measurement and analysis, all in one instrument.

Figure 1. CX3300 characterizes, validates, and debugs medical devices

To validate the operation of its medical implantable device, the R&D team used multiple instruments and shunted resistances within the current operating range. The team then summarized the measurement results into one operating waveform in the post-processing phase.

Using the CX3300, the team quickly captured the necessary current waveforms within a single unit and generated the simulation data using Keysight's automatic current profiler. This drastically reduced the evaluation device certification period and allowed the engineering team to quickly and easily identify and resolve a software defect in the control program.

A Better Plan For The Future

Using Keysight's CX3300, the R&D team quickly and accurately characterized, validated, and debugged a smart implantable medical device, effectively reducing the evaluation period for certification by 50%. The team also quickly located and resolved previously undetected software bugs in the design that were causing power management issues. The medical electronics company now has a solution for easily and efficiently capturing accurate current waveforms, while reducing the time to analyze the data, giving it a time-to-market edge in the highly competitive medical device marketplace.

More information on the CX3300 Device Current Waveform Analyzer is available here.

Learn more at: www.keysight.com

For more information on Keysight Technologies' products, applications or services, please contact your local Keysight office. The complete list is available at: www.keysight.com/find/contactus

KEYSIGHT TECHNOLOGIES

This information is subject to change without notice. © Keysight Technologies, 2019, Published in USA, September 7, 2019, 5992-4113EN