



#### CASE STUDY

## Impulse Dynamics addresses chronic heart failure with Quallion's Zero-Volt™ technology

**In patients with Chronic Heart Failure (CHF), the heart's pumping strength is weaker than normal – often as a result of damage to the heart muscle from a heart attack or other disease conditions. This means the heart cannot pump enough blood to meet the body's requirements, resulting in symptoms such as shortness of breath, fatigue, and difficulty with tasks like climbing stairs.**

More than 25 million people around the world are affected by heart failure, with CHF requiring management throughout their life<sup>1</sup>. All CHF patients receive medication, and some people also have an Implantable Cardioverter Defibrillator (ICD) or pacemaker fitted.

For around 70 per cent of CHF sufferers, however, there has been no effective device-based treatment<sup>2</sup>. To meet this need, Impulse Dynamics developed its innovative Optimizer<sup>®</sup> System.

The Optimizer System is an implantable device, based on Cardiac Contractility Modulation technology, which delivers electrical pulses to the heart during the ventricular 'absolute refractory' period. These pulses improve the heart's function, reducing the impact of CHF symptoms on patients. The system has been successfully implanted in over 3,000 people in the last decade<sup>3</sup>.





**WE HAVE BEEN QUALLION CUSTOMERS SINCE 2006, AND WE HAVE FOUND THE QL0200I-A TO BE HIGHLY RELIABLE. MOST IMPORTANTLY, ITS ZERO-VOLT TECHNOLOGY MEANS THERE ARE NO ISSUES DUE TO PATIENTS' LACK OF COMPLIANCE WITH RECHARGING INSTRUCTIONS.**

DAVID PRUTCHI, PH.D., EXECUTIVE VICE-PRESIDENT, PRODUCT DEVELOPMENT AT IMPULSE DYNAMICS

### Weekly charging

To power the Optimizer, Impulse Dynamics decided that a rechargeable battery would be the best option, because there would then be no need for invasive and costly surgical procedures to replace the battery. Patients are provided with a home-based charging system, which they are required to use on a weekly basis.

However, the company found that there was a risk of patients not following the required charging schedule. David Prutchi, Ph.D., Executive Vice-President, Product Development at Impulse Dynamics, said, "Our experience is that although patient compliance with recharge instructions is great, there are times – for example when vacationing for extended periods – when patients don't charge their devices, potentially leading to full discharge of the Optimizer's battery."

To overcome this problem, Impulse Dynamics selected the QL0200I-A, a lithium-ion rechargeable cell from Quallion. The QL0200I-A is a 200mAh battery, capable of supplying up to 200mA, with a nominal voltage of 3.6V.

The QL0200I-A battery uses Quallion's innovative Zero-Volt™ technology. This means that if the battery is fully discharged, for example if a patient simply forgets to charge it, the battery is not damaged. It also does not suffer a reduction in the peak capacity levels that it can achieve in future. Additionally, Zero-Volt technology means that batteries can be stored for long periods without maintenance, and without degrading their performance or peak capacity.

Competitors' batteries can be permanently damaged by full discharge, which means that a surgical procedure would be required to replace them – which is expensive, as well as inconvenient, and potentially risky for the patient.

"With other manufacturer's batteries, a fully-discharged cell would be an irrecoverable situation, requiring surgical replacement of the Optimizer," said Prutchi. "However, Quallion's Zero-Volt technology allows these deep discharges without damage to the battery."

### Highly reliable battery

The QL0200I-A is reliable, and has a long lifetime: after 500 cycles, it has capacity retention of 80% or more<sup>4</sup>. It is compact, measuring only 17mm x 35mm x 5.5mm, and weighs just 8g, making it well-suited to implantable applications.

The QL0200I-A is hermetically sealed, and it is certified to the UN 38.3 requirement for lithium-ion battery transportation. Quallion's certifications include the ISO 13485:2003 quality management standard for medical devices. Since 2003, more than 100,000 Quallion batteries have been manufactured, with an impeccable safety record.

"We have been Quallion customers since 2006, and we have found the QL0200I-A to be highly reliable," concluded Prutchi. "Most importantly, its Zero-Volt technology means there are no issues due to patients' lack of compliance with recharging instructions."



### CONTACT

Tel: **+1 818 833 4425**

Email: **joseph.macsalka@enersys.com**

Web: **medical.enersys.com**

<sup>1</sup> "Chronic Heart Failure: How common is CHF?", Impulse Dynamics, <https://www.impulse-dynamics.com/int/patients/what-is-heart-failure/>

<sup>2</sup> "Impulse Dynamics receives FDA approval for breakthrough Optimizer® Smart System delivering CCM™ therapy for treatment of heart failure", Impulse Dynamics, <https://www.impulse-dynamics.com/us/news/impulse-dynamics-receives-fda-approval-for-breakthrough-optimizer-smart-system-delivering-ccm-therapy-for-treatment-of-heart-failure/>

<sup>3</sup> "Clinical Data", Impulse Dynamics, <https://www.impulse-dynamics.com/int/physicians/clinical-data/>

<sup>4</sup> Quallion capacity retention test data

Any data, descriptions or specifications set forth herein are subject to change without notice. Before using the product(s), the user is advised and cautioned to make its own determination and assessment of the suitability of the product(s) for the specific use in question and is further advised against relying on the information contained herein as it may relate to any general use or indistinct application. It is the ultimate responsibility of the user to ensure that the product is suited and the information is applicable to the user's specific application. The product(s) featured herein will be used under conditions beyond the manufacturer's control and therefore all warranties, either express or implied, concerning the fitness or suitability of such product(s) for any particular use or in any specific application, are disclaimed. The user expressly assumes all risk and liability, whether based in contract, tort or otherwise, in connection with the use of the information contained herein or the product itself.