CASE STUDY


VentriPace Medical

# VentriPace Medical

## Revolutionising pacing technologies

### MedTech innovator VentriPace Medical is developing ground-breaking pacing technologies in partnership with Camgenium

## Overview

MedTech innovator VentriPace Medical is developing ground-breaking pacing technology to keep patients safe in intensive care and hospital wards following open heart surgery. Cardiac Tech approached Cambridge-based software engineering company Camgenium to assist with the development of its new medical device product, Pace-Protect.

Research shows that there are around 1,500 adverse events reported each year in the US alone following open-heart surgery attributable to the management of temporary pacemakers. Cardiac Tech, with the help of Camgenium, is seeking to minimise these adverse events by developing a device that monitors all aspects of temporary pacing and reports acute changes immediately to the medical clinician in charge of the patient's care via a cloud-based platform and app. The Pace-Protect system has the potential to significantly improve patient outcomes following open heart surgery.

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## Project background


Will Simpson, CEO at VentriPace Medical, explains "Following open heart surgery, patients often experience rhythm disturbances which can lead to serious complications. To counter this a patient will typically be fitted with a temporary pacemaker. Research shows that these temporary pacing systems are often problematic. We wanted to develop a pioneering solution which enabled medical professionals working in high pressure environments to be alerted of any issues immediately, bringing help to the patient before an adverse event occurs. Partnering with Camgenium brought our vision to life."

VentriPace Medical is developing a new medical device system called "Pace-Protect" to be used in intensive care wards to monitor the operation of temporary pacemakers following cardiac surgery. When open heart surgery is performed, this can cause disruption to the heart's electrical conduction system, and the drugs used frequently cause transient bradycardia (slow heart rate). To correct this, pacing wires are normally attached to the epicardium (outer surface of the heart) during surgery which pass out of the patient's abdomen and are connected to the temporary pacemaker at the patient's bedside. The temporary pacemaker provides electronic impulses that cause the heart to contract and to pump blood around the body until the patient's normal heart function is restored.

Currently, temporary pacemakers are programmed manually according to the patient's requirements. This creates a situation where the patient's own heart 'conflicts' with the impulses from the external pacemaker. This can slow the patient's recovery, or, in extreme circumstances, can even lead to cardiac arrest. Unless sub-optimal pacemaker programming is detected immediately and rectified, therefore, the consequences for the patient can be serious.

VentriPace Medical identified the need for a device to safeguard patients that would minimise complications arising from this type of adverse event by detecting problems early, instantly alerting the whole clinical team and providing them with detailed pacing information.

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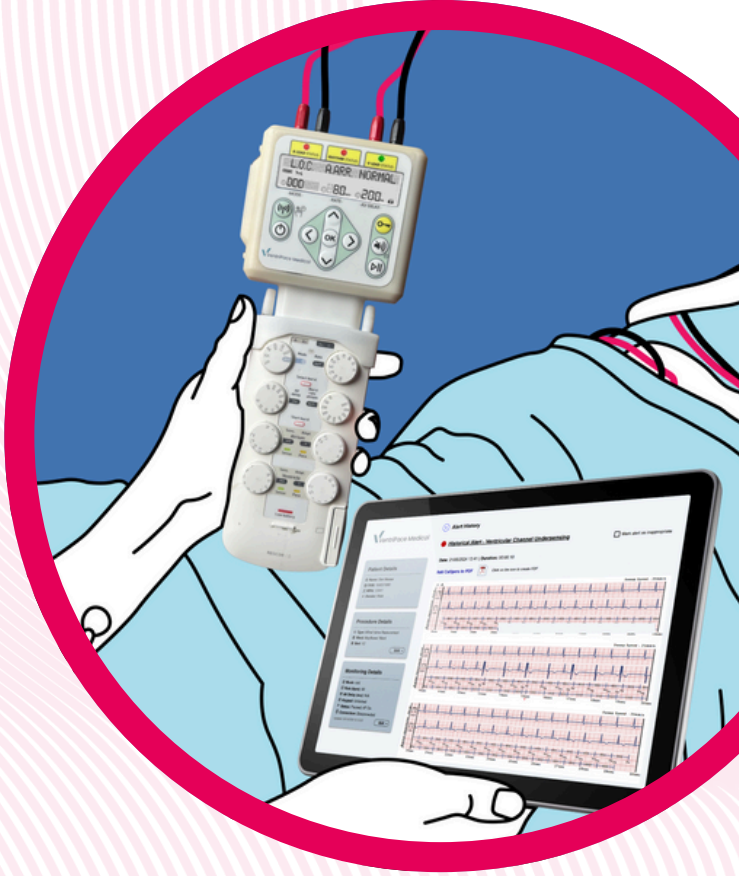
## The Solution

VentriPace Medical has developed the Pace-Protect system, an electronic module that attaches to the external pacemaker. It can detect both signals from the pacemaker, and the patient's own heart signals, and uses patented software algorithms to identify when dangerous programming parameters have developed. If it identifies that the patient's pacemaker is not programmed appropriately, it instantly sounds an audible alarm at the bedside to notify ward staff and concurrently sends an alert to the backend software (cloud platform), to the clinician's app, and it also sends push alerts to the clinical teams' mobile phones. This enables the whole team, even those working remotely from the hospital, (such as consultants on call) to access real time pacing status and electrogram (EGM) data and collaborate to rectify the issue immediately.

Camgenium was asked to provide the electronics that transmit alerts and EGM data from the Pace-Protect device, as well as the product website and the accompanying app.

Camgenium implemented its proprietary Soft Silicon™ medical device grade two-way device communications technology to transmit data from the medical devices to the website. Soft Silicon™ uses firmware running on BLE (Bluetooth Low Energy) electronics inside the Pace-Protect and specialised communications software running on the internet to create a digital twin of each Pace-Protect. This digital twin in Camgenium's secure medical cloud connects to the Pace-Protect website, which in turn connects to the clinicians' apps.



The Soft Silicon™ communications infrastructure is highly secure to ensure data privacy and is ultra-resilient. It keeps each Pace-Protect in contact with the website and the clinician's apps wherever the patient is, be it an operating theatre, intensive care or ward, or in transit from one location to another.

## Highly resilient & secure communication technology

The Soft Silicon™ communications infrastructure uses BLE and System on Chip (SOC) technology programmed with Camgenium's firmware in the Pace-Protect device. These connect via BLE to Soft Silicon™ hubs that plug into the mains, connect to the hospital Wi-Fi and in turn gain connection to the internet and the Pace-Protect website.

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Soft Silicon™ uses a mesh architecture with full encryption that allows individual Pace-Protects to connect to the internet via any hub, or even through another Pace-Protect. This ensures that the network is highly resilient with significant redundancy.

Soft Silicon™ enables two-way communications. In one direction, it lets clinicians monitor patients using the website and their app and it pushes alerts to clinicians' mobile phones if a patient is critical. In the other direction, it allows each Pace-Protect's settings to be configured for its patient and lets clinicians proactively request EGMs and other pacing data.

The Soft Silicon™ communications infrastructure also has a high data-rate mode in which high resolution EGMs can be prioritised over other network traffic and sent in real time from a Pace-Protect to the clinician's app to allow clinicians to treat the patient collaboratively, regardless of the actual physical location of each person.

## Website & app development

Camgenium rapidly developed a back-end website and mobile app for VentriPace Medical, built to Class II medical device grade standards. The website enables hospital wards to quickly assign a Pace-Protect device to each patient and to track detailed patient data. The website also allows the data for each patient to be easily viewed. The mobile app lets individual clinicians review real-time patient data remotely.

All data is encrypted at all times, both in transit and at rest, to ensure patient safety and privacy. The communication module allows clinicians to control the Pace-Protect from the website or the app.

Individual Pace-Protect units may be assigned to different patients and their details and requirements captured using the website. Whilst using the app, any clinician on the patient's team can review alerts, statistics, request EGM data and change monitoring settings on the device, all via the internet; clinicians do not even need to be in the hospital to collaborate in the patient's care and they can all receive alerts if a patient needs urgent treatment.

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Camgenium's CEO, Dr Philip Gaffney OBE explains how the close interaction with the technical team was crucial, "We worked incredibly closely with the team at VentriPace Medical to fully understand the needs of the patient and the clinician in the hospital. This enabled us to develop a user interface and user workflow that was optimised for clinical use in the hospital and met the regulated and other NHS standards for user interfaces within the highly demanding class II medical device environment".

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–Dr Philip Gaffney OBE
**CEO, Camgenium**

## In summary

The partnership between Camgenium and VentriPace Medical has produced a functioning Pace-Protect prototype that has been developed to ISO 13485 and IEC 62304 Class IIa standards.

Although the Pace-Protect system is currently positioned as a Class IIb medical device, it could be redeveloped in the future as a Class III device without need for change to the parts of the product that Camgenium has been responsible for or to the accompanying documentation.

The prototype is now being used to demonstrate the system and clinical trials are planned. The Pace-Protect will be the first device using a Soft Silicon™ mesh network to be deployed in a clinical environment.

Camgenium's Application Manager Dr Olga Zadvorna explains, "I thoroughly enjoyed collaborating with the team at VentriPace Medical to understand their needs and co-develop a powerful solution. This project was complex, with many interconnected elements. Together with my team, I embraced the many moving parts to create one comprehensive system."

Zadvorna continues, "Our collective expertise played a crucial role in this partnership. While VentriPace Medical provided invaluable insights into the new-to-us field of temporary pacemaker monitoring, we supported them with best practices in medical device development, device communication, and user experience".