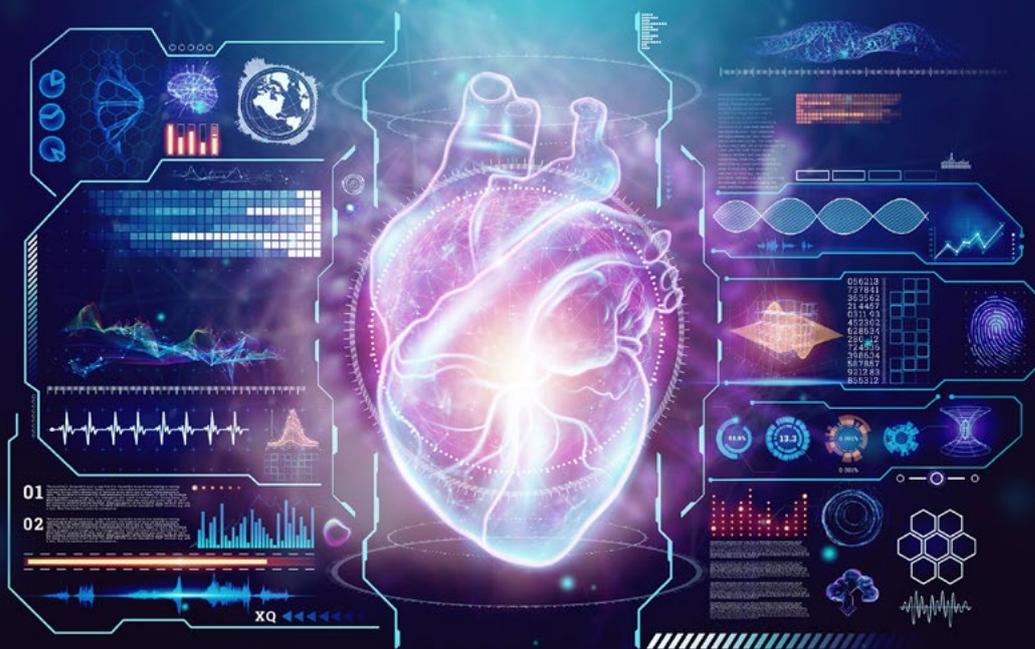


CLIENT CASE STUDY

Biotech: an artificial heart to fight heart failure

Technical support and intellectual services for the advanced electronics systems of an artificial heart



Life Sciences

The implantation of a total artificial heart is a technological feat that can extend patients' longevity and improve their quality of life. A complex project where Expleo brought its expertise in advanced electronics and offered first-class technical support.



FEBRUARY 2020

Full approval from the FDA (Food & Drug Administration) for a clinical feasibility study of the total artificial heart on 10 patients eligible for transplantation in the United States



DECEMBER 2021

CE marking obtained for the "Bridge to Transplant" (BTT) indication

Project background & challenge

Heart failure is the leading cause of death worldwide. Faced with this major public health issue, Expleo has been provided key technical support services since 2014 to a pioneering biotech that has developed an artificial heart to prolong the life of patients suffering from end-stage heart failure or awaiting a heart transplant. A unique feature of this revolutionary heart is the fact that it is silent (some patients report being disturbed by the sound of their artificial heart's beat) and mimics the organ's natural pulse. The heart circulates blood throughout the entire body by pulsation and suction, unlike most artificial hearts which work like a pump with a steady flow. This functionality requires state-of-the-art electronics.

Solution

Thanks to the experience it has acquired on complex projects in the technical-medical field, Expleo has been able to offer technical assistance and electronic development, specification and testing services, throughout the entire project, especially on the external part – an electronic box connected to the artificial heart. This communication device for patient use, which contains the power supply system for the artificial heart, has been adapted by Expleo to serve as an interface. It provides basic information on the heart's function and can raise an alarm in the event of a potential failure. Expleo provided intellectual services (electronic design and development),

ensured the monitoring and management of FMEA packages (analysis of failure modes and effects of their criticality), created acceptance test benches for the production of electronic cards (specifications, production monitoring, technical support and acceptance), updated the definition of the system (collection of inputs, definition of the new architecture), offered production support, expertise on equipment returned from hospitals & patients, and led the formal verification of the IDD etc. During the project, Expleo also provided technical support as part of the subcontracting of complete sub-assemblies, with subcontracting specification, including CEM expertise, specification of the particular need for a pressure sensor module and subcontracting management (PCB modifications).

Outcome

With the patient's life literally depending on the device developed by Expleo, the project required a long road of specifications, qualifications, development, tests – and multiple iterations in order to obtain the highest possible reliability, leading to a significant increase in FMEA skills. The client expressed its satisfaction with Expleo's operational excellence in terms of budget and deadline, and the very good quality of the deliverables. In December 2021, Expleo's client achieved a highly significant step in the commercialisation of the artificial heart when it obtained the CE Marking in the "Bridge to Transplant" (BTT) indication.

"This project allowed me to understand all the complexity of the heart's hydraulic system. The artificial heart developed can prolong the life of a patient by five years or allow them to survive while waiting for a donor, this is a highly motivating principle."

François Vincent
Electronics engineer, Expleo

For further information, or if you have any other questions, please write an email to info@expleogroup.com