



Improved controller for clinical trials results in six-month delay

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Realheart has decided to equip patients in the first clinical trial with the full version of the controller – a kind of remote control – instead of a simpler version as previously envisaged. This will benefit patients and shorten the overall development time of the controller but will delay the human trial by six months, now set to begin in the first half of 2024 instead of the second half of 2023.

"Our goal is an artificial heart that allows the user to lead a good life with great freedom of movement. This also applies to the patients participating in our clinical trials. We want even the very first patient to be able to leave the hospital, and for this to work in practice, the external controller needs to be both safe and really easy to use" said Ina Laura Perkins, CEO of Realheart.

The controller that Realheart has used so far to test and refine the design in bench and animal trials was developed in-house, but to move to humans, a more advanced one is needed as it will be used by the patient themselves without supervision from healthcare professionals or experts. During fall 2021, Realheart started a collaboration with the Australian company Hydrix, which specialises in the development of control systems for heart pumps. Their platform is characterised precisely by a strong focus on the needs of the end user.

"The controller is technically very advanced, but for those who will live with our artificial heart in the future, it must be extremely easy to use. We already have an updated electronic architecture in place and by not producing a special test version but going straight to the final version we can save time overall, while somewhat delaying the first implantation in a human," said Ina Laura Perkins, CEO of Realheart.

This disclosure contains information that Real Heart is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 28-04-2022 12:00 CET.

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Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart TAH has a unique, patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atria and two ventricles) designed to generate a physiological blood flow pattern that mimics the body's natural circulation.