

Realheart Publishes Validating Data Showing Hemodynamic Balance and Automated Cardiac Output Control

Västerås, Sweden, June 18, 2025 – Scandinavian Real Heart AB (publ) announces today that the company's scientific collaborator at the Royal School of Technology (KTH) has published new results in the scientific journal Artificial Organs, validating the function of Realheart® TAH to produce systemic hemodynamic balance, as well as adaptively adjust the system's cardiac output based on pressure sensor data. The new data are based on simulations from a state-of-the-art semi-virtual system financed through a joint strategic initiative between Vinnova, Formas and the Swedish Energy Agency (Energimyndigheten).

The published results demonstrate that Realheart® TAH automatic control algorithm maintains proper left-right balance, balancing blood pressure between the systemic and pulmonary circulation in the cardiovascular system. Further, data show that Realheart® TAH automatically increased cardiac output by up to 2.1 times during exercise from rest and decreased cardiac output by 25% during sleep whilst maintaining stable pressure in the atria. This was shown in simulations evaluating a healthy state, as well as in varying levels of pulmonary hypertension. Collectively, these results demonstrate the device's ability to adapt to rapid transitions between physiological states.

"Our data show that Realheart® TAH stands out in its ability to enable different levels of physical activity for patients who want to remain active. The combination of pressure-sensor based feedback control and the power of the pump mechanism to provide exercise flow makes it unique. We look forward to pursuing further studies and evaluating it against currently approved devices," says Dr. Seraina Dual, Assistant Professor in Biomedical Signal Processing at the Department of Biomedical Engineering and Health Systems, Royal School of Technology, Sweden.

The study builds upon a joint project between Realheart and KTH, which has built a state-of-the-art cardiovascular "hybrid simulator", including a digital model of the heart, lungs, and vessels that can be physically coupled to Realheart® TAH. The setup allows simulations of patient-specific scenarios and refinement of the pump's control algorithms. The project is enabled by two back-to-back grants, totalling SEK 8 million, funded by Vinnova's Smart Electronics program, a joint effort with Formas and the Swedish Energy Agency (Energimyndigheten).

"Objective studies of our device's physiological control, performed by research field experts, are of pivotal importance to increase our innovation's overall credibility and confidence, demonstrate its performance and potential, and teach us about areas where we can continue to improve. By using the hybrid system, we can conduct rapid iterative development cycles to adjust the software and rapidly test a large number of different physiological scenarios," says Ina Laura Perkins, CEO, Realheart.

The article, "Physiological Control of Realheart® Total Artificial Heart", is featured in Artificial Organs vol. June 17, 2025. <https://onlinelibrary.wiley.com/doi/10.1111/aor.15036>

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About Us

Scandinavian Real Heart AB (publ) is developing the first artificial heart that mimics the shape, function, and blood flow pattern of the human heart. These unique product features provide completely new opportunities to save lives and give patients a good quality of life while waiting for a heart transplant. In the future, artificial hearts may also become an alternative to transplantation for broader groups of patients with severe heart failure. Realheart® TAH (Total Artificial Heart) is now being evaluated in extensive preclinical trials ahead of a first clinical study in patients. The company's shares are traded on Nasdaq Stockholm First North Growth Market. For more information, visit www.realheart.se