

FDA approves significant Freedom Portable Driver software upgrades from SynCardia Systems Inc.



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This upgrade will further improve the accuracy of the cardiac output and fill volume measurements to 5% at normotensive conditions, on both the 50cc and 70cc hearts, and in so doing, eliminate a significant number of the unintended alarms that the current device has been experiencing. The upgrade will also ensure that even in extreme cases of hypervolemia and hypertension, the device will still display correct measurements.

The software upgrades will be implemented as the current fleet of drivers is returned to the company for routine maintenance and servicing. Customers can reasonably expect that drivers shipped after May 1st of this year will include the new, upgraded software. Drivers with the upgraded software will bear serial numbers ending with the letter "A".

The Freedom Driver is intended for use with the SynCardia temporary Total Artificial Heart (TAH-t) in clinically stable patients, both of which have been approved by the FDA. Together, they act to replace the full functions of a failed or failing heart for patients experiencing biventricular heart failure. The Freedom Driver also offers greater mobility and quality of life to patients who meet the discharge criteria, allowing them to spend more quality time at home with their families, while waiting for a matching donor heart.

Questions about the software upgrades should be directed to the clinical support team at salesandclinical@syncardia.com



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#SynCardia

About SynCardia Systems, LLC

Headquartered in Tucson, Ariz., SynCardia manufactures the world's only commercially approved total artificial heart. In clinical use for more than 35 years and with more than 1,800 implants, the SynCardia temporary Total Artificial Heart (TAH) is the most widely used and extensively studied TAH in the world.

By partnering with, training and supporting healthcare teams at more than 140 transplant hospitals and heart failure programs in more than 20 countries, SynCardia helps create better outcomes for critically ill adults and adolescents whose best chance at survival is total heart replacement. When a donor heart isn't an available option, SynCardia provides a new heart without the wait for patients with end-stage heart failure affecting both sides of the heart (biventricular failure).

SynCardia Systems, LLC – a Picard Medical Company

The SynCardia temporary Total Artificial Heart (TAH-t) is a treatment option for cardiac transplant-eligible patients at risk of imminent death from biventricular failure.

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