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**Project Name:** SynCardia temporary Total Artificial Heart  
**Application:** Freedom® portable driver Verification Testing  
**Customer:** SynCardia Systems, Inc.  
**Website:** <http://www.syncardia.com>

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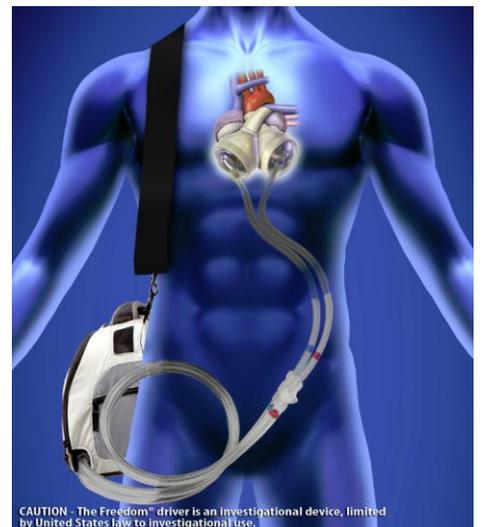


## The World's First and Only FDA-Approved Total Artificial Heart

### TESTIMONIAL

*"SynCardia has chosen to work with PADT based on their ability to develop close personal relationships, to create and implement engineering solutions rapidly, and to support SynCardia's innovative drive for our life-saving technology."*

Douglas A. Nutter  
Chief Operating Officer  
SynCardia Systems, Inc.



CAUTION - The Freedom® driver is an investigational device, limited by United States law to investigational use.

### BACKGROUND AND PROJECT CHALLENGE

Originally used as a permanent replacement heart, the SynCardia Total Artificial Heart is currently approved as a bridge to transplant for patients suffering from end-stage heart failure affecting both sides of their heart (biventricular failure). Similar to a heart transplant, the SynCardia Total Artificial Heart replaces both failing heart ventricles and the four heart valves, eliminating the symptoms and source of end-stage biventricular failure. The Freedom portable driver is the world's first wearable power supply for the Total Artificial Heart. Weighing 13.5 pounds (~6 kg), the Freedom portable driver allows stable Total Artificial Heart patients who meet discharge criteria to wait for a matching donor heart at home and in their communities instead of in the hospital.

PADT's challenge was to translate SynCardia's design requirements into a series of verification tests for the Freedom portable driver and meet a very strict delivery schedule. PADT's medical device engineering staff worked closely with SynCardia's engineering, QC, and regulatory personnel to translate design requirements into a series of successful verification tests.

## **PROCESS AND SOLUTION**

A core team of 3 PADT medical device engineers was chosen to “divide and conquer” the testing requirements to enable SynCardia to meet its deadlines. PADT completed all aspects of the testing tasks: generation of the test protocols, tooling design and fabrication, performing all test activities and writing detailed final test reports. To further accelerate the testing, numerous PADT engineering professionals were asked to participate in several life cycle tests on various components of the Freedom driver. For additional project collaboration PADT provided a desk within the PADT Medical Engineering offices to allow a SynCardia QC representative to be on-hand throughout the project.

The verification tests encompassed the full range of design requirements for the Freedom driver, including:

- Functional testing
- Battery testing and power management
- Physical requirements
- Electrical connection life cycle testing
- Driveline pull tests
- System integration and environmental testing
- Battery housing performance
- Battery physical life cycle testing

## **CONCLUSION**

The collaborative efforts of the multi-disciplined teams from both SynCardia and PADT resulted in a vast amount of verification testing being successfully completed within the time constraints set forth at the beginning of the project. Working as a cohesive team allowed us to maintain our momentum and resolve the project’s challenges as they surfaced.