SynCardia Systems, LLC
1992 E. Silverlake Rd.
Tucson, Arizona 85713
Telephone: 520.545.1234
Facsimile: 520.903.1782

**<<Distributer Name>>**
<<User_Name>>
<<Department>>
<<Customer_Address>>
<<Postal Code>> <<City>>
<<Country_name>>

20 May 2021

# Urgent Field Safety Notice – FSN20213004-02 Rev 002

Type of Action: Advisory

**SynCardia Companion 2 (C2) Driver System (Catalog # 397002-001)**

This is to notify clinicians at our European implant centers of a possible mechanical valve timing issue affecting the C2 Driver, that may lead to a decrease in cardiac output, or a pressure imbalance between the left and right ventricles.

## The TAH-t system

The SynCardia TAH-t System is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The TAH-t System consists of the implantable TAH-t, an external pneumatic driver, drivelines, and other accessories.

The C2 Driver provides pneumatic power to operate the SynCardia TAH-t in the form of synchronized pulses of air that flex the heart's diaphragms to circulate blood in a patient's body. The C2 Driver operates and monitors the TAH-t throughout its implantation, surgical recovery phase, and the ambulatory and ongoing phases of patient support. The C2 Driver System includes a Driver, a Hospital Cart and a Caddy.

## Description of the problem

If an asynchronization of valve actuation between the C2 Driver's two pilot valves occurs, it will result in an activation timing difference between the valves. The timing issue will be observed on the C2 Driver Pressure and Flow monitor screens as a separation between the ventricles' systolic waveforms (Pressure Monitor Screen) and diastolic air flows at the beginning of the diastolic fill cycle (Flow

SynCardia Systems, LLC
1992 E. Silverlake Rd.
Tucson, Arizona 85713
Telephone: 520.545.1234
Facsimile: 520.903.1782

Monitor Screen). See **Figure 1** for an illustration of separated air flow waveforms at the beginning of a diastolic fill cycle.

## Recommended actions

A clinician/physician monitoring a patient on support with a C2 Driver should switch the patient to a backup driver **immediately** after observing:

1. A divergence between the Pressure waveforms and the Air Flow waveforms, as illustrated in **Figure 1**
2. An unexpected drop in cardiac output for one of the 2 ventricles,
3. "Low CO" alarm (Low cardiac Output)
4. A right/left cardiac output imbalance alarm.

Per SynCardia's Companion 2 Driver Operator Manual, a backup Driver must always be available in the event the primary Driver fails.

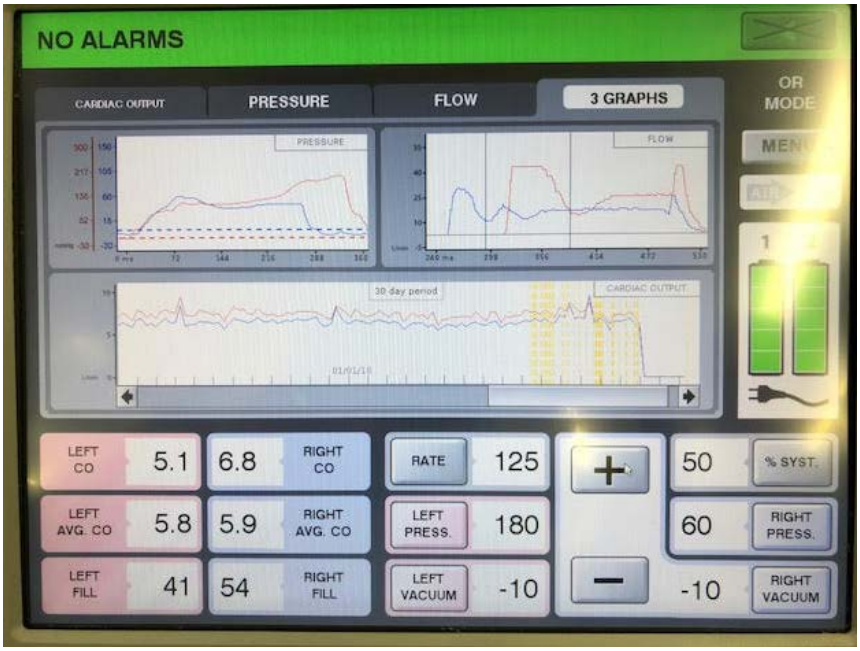


**Figure 1 – A waveform divergence between Pressure (Pressure Monitor Screen) and Air Flow (Flow Monitor Screen)**

The C2 Driver valve timing issue will trigger alarms for the following:

1. A "Low CO" alarm (Low cardiac Output), if the calculated cardiac output drops below 3.5 liters per minute on either the left or right ventricle; or
2. A right/left cardiac output Imbalance alarm, if the calculated cardiac outputs are not within approximately 50% of each other.

SynCardia Systems, LLC
1992 E. Silverlake Rd.
Tucson, Arizona 85713
Telephone: 520.545.1234
Facsimile: 520.903.1782

## Potential clinical effects

Immediate adverse patient impact: Dizziness, nausea and/or loss of consciousness.

If the C2 Driver exhibits a "Low CO" alarm (Low cardiac Output) or a right/left Imbalance alarm, and a patient is not immediately switched to their back-up driver, insufficient cardiac output could lead to thromboembolic events, low perfusion, end organ dysfunction and failure, flash pulmonary edema, circulatory collapse, or death.

## Actions taken by SynCardia

SynCardia has identified the root causes of the issue to be particulate contamination from the incoming air supply, and/or from the valve not completely closing due to residual electrical drop-off current applied to the valves when they are not activated.

- We have implemented a shorter change-out maintenance interval for the pilot valves on the Companion C2 Driver Console. Instead of replacing the pilot valves at the two-year service, we replace them at the customary 90 days of use service interval. It is important to note that since the pilot valve replacement at the shorter interval was fully implemented globally in October 2019, we have not received any reports of the issue since that date.

In addition, proposed changes to suppliers, valves, and the electrical timing current to ensure the valves close fully and are fully activated are currently under regulatory review by European Union regulatory authorities.

## Actions to be taken by SynCardia

SynCardia will update the Companion 2 Driver Operator Manual with information to enable the user to specifically identify the waveform timing discrepancy and the risks associated with this failure mode.

SynCardia will provide additional training to users to specifically identify the waveform timing discrepancy and the risks associated with this failure mode.

## Contact

If you have any questions or comments regarding this notice, please contact your SynCardia distributor or Eric Lambert, Sr. Director International (OUS), Sales & Marketing elambert@syncardia.com.

The applicable Competent Authorities will be notified of this action.

SynCardia Systems, LLC
1992 E. Silverlake Rd.
Tucson, Arizona 85713
Telephone: 520.545.1234
Facsimile: 520.903.1782

# Customer Acknowledgment Form - FSN20213004-02 Rev 002

Please complete this Customer Acknowledgment Form and return it via Email to SynCardia Systems, LLC. **within five business days of receipt of this letter.**

SynCardia Systems, LLC
Attn.: Regulatory Affairs
Email Address: regaffairs@syncardia.com

Please check the box to acknowledge receipt of the notification.

☐ I have read and understand the notification

| | |
|---|---|
| Printed name of person | Facility/Business Name |
| Signature | Date: |
| Address and City | |
| SynCardia Distributor or Sales Representative | |
| Telephone: | |
| Date the notification was received: | |