February 5, 2018

URGENT FIELD SAFETY NOTICE

Identifier:	**FSCA FEBRUARY2018**
Type of Action:	**EQUIPMENT ALARM CHECK RECOMMENDED**
Product:	**JHI-102 ILS FLOWMAKER CONTROLLER** **JHI-101 CONSTANT SPEED FLOWMAKER CONTROLLER**
Subject:	**CHECK ALARMS IN CASE DAMAGE HAS OCCURRED DURING USE FROM: DROP, SHOCK, OR IMPACT TO THE BUZZER COVER**

To: Distributors & Users of the Jarvik 2000® Ventricular Assist System (VAS)

Jarvik Heart, Inc. has received complaints in which the patient reported that the Controller alarm sounds weak, or is nearly inaudible. One patient reported the weak sound during a routine battery change.

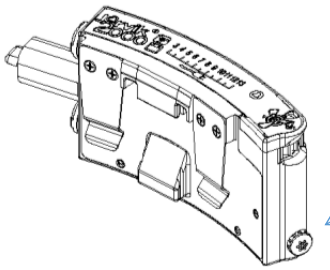
No clinical impact, harm or injury to any patient was reported by any hospital.

The affected Controller was replaced with a new Controller.

Affected Devices

No specific serial numbers are affected.

All JHI-102 or JHI-101 FlowMaker Controllers incorporate a buzzer cover feature to allow for sound pass thru while maintaining ingress protection. If the cover is subjected to drop, shock, or impact during use, this can cause damage to the buzzer resulting in a weak sound or near inaudible sound.



Jarvik Heart, Inc.
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Phone (212) 397-3911
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www.jarvikheart.com

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Description of Potential Issue

Investigation into complaints of this nature over the past three (3) years indicate an approximate 3.8% occurrence rate for Controller buzzers exhibiting faint volume after use in the field. The suspected cause of these complaints is due to damage to the buzzer during use from: drop, shock, or direct impact to the buzzer cover.

If the buzzer has been damaged during use and not detected, the Low Battery Alarm or Pump Stopped Alarm may sound weak or nearly inaudible. This can result in an operator failing to change a battery on time when the Low Battery Alarm sounds, resulting in the VAD stopping accompanied by a weak or nearly inaudible sound. This may also delay a caregiver responding to a Pump Stopped Alarm which may sound weak or nearly inaudible if the VAD stops for any reason.

Please note that safe operation of the Jarvik 2000 system requires a trained operator and back-up equipment present at all times. Back-up equipment includes Controllers, batteries, cables, & chargers. Per the IFU, return any failed or suspect component(s) to the Clinical Center for evaluation by Jarvik Heart, Inc. In addition, the Controller must be regularly maintained in accordance with the IFU below:

⚠	The patient must return to the implant center every (3) three months so that staff can replace the Alarm Battery, test the new Alarm Battery, and check all the equipment. Staff must only use Alarm Batteries that are obtained from Jarvik Heart, Inc.

Immediate Action Required

In order to ensure that Controllers that have been in use in the field (especially if the Buzzer Cover has been subject to drop, shock, or impact) have proper sounding alarms, Jarvik Heart, Inc. recommends the following:

- **All patients should return to centers to have ALL of their Controllers (including back-ups) checked to ensure alarms sound as usual (Alarm Check Procedure).**

Recommended Actions

In order to ensure that Controllers continue to have proper sounding alarms during use, Jarvik Heart, Inc. recommends the following:

- Avoid drop, shock, or impact to the Buzzer Cover.
- If you become aware of any drop, shock, or impact to the Buzzer Cover, replace the Controller with a back-up unit in accordance with IFUs. Return to the center to have the Controller suspected of damage evaluated.
- Maintain Controllers regularly in accordance with IFUs by returning to implant centers **every (3) three months** to replace the Alarm Battery and test the new Alarm Battery.

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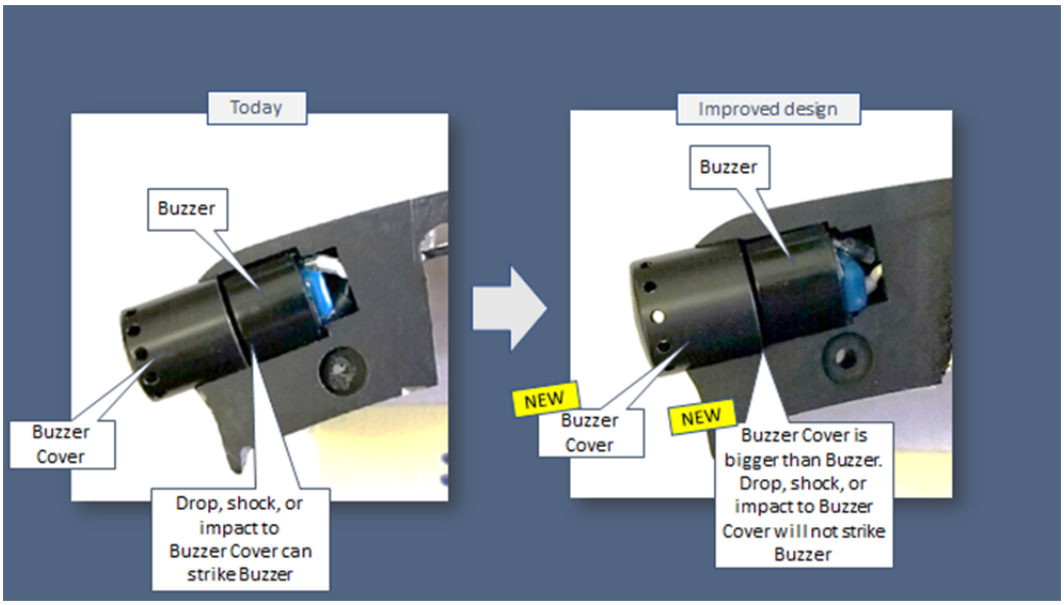
Product improvements (2018)

Jarvik Heart, Inc. will be making minor changes to the Controller enclosure affecting future units so that drop, shock, or impact to the Buzzer Cover is less likely to damage the buzzer. Jarvik Heart, Inc. believes Controllers in the field are safe to use provided the buzzers have not been damaged during use.



Transmission of this FSCA

Please transfer this notice to anyone in your organization that may be impacted.

This notice has been submitted to all competent authorities worldwide in markets where the JHI-102 ILS Controller, and JHI-101 Constant Speed Controller accessory of the Jarvik 2000 Ventricular Assist System (VAS), has been distributed.

Thank you for your attention to this matter.

Contact Person

Kamal Gandhi

VP Quality & Regulatory
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Alarm Check Procedure

- Implant centers should maintain enough FlowMaker Controllers in case replacement is necessary.
- ONLY clinicians trained on the Jarvik 2000 VAS are qualified to perform this test.
- Check alarms on all controllers that have been in use by a patient and will be put back into use.

1. Test Patient Backup Controller:

1.1. Replace the Alarm Battery on the FlowMaker Controller with a fresh Alarm Battery.

1.2. Finger-tighten the Alarm Battery Cap until fully tight.

1.3. Listen to the alarm sound for 2-3 seconds from arm's length and then untighten the Alarm Battery Cap to turn the alarm off.

1.3.1. If the alarm sounds normal, like that of a new FlowMaker Controller alarm, **ACCEPT** the unit.

1.3.2. If the alarm sound is weak, nearly inaudible, or inaudible **REJECT** the unit and replace the FlowMaker Controller with a new FlowMaker Controller from inventory. Return the Controller to Jarvik Heart, Inc. for evaluation.

1.3.3. If the alarm sounds unusual compared to a new unit, QUARANTINE the unit and return to Jarvik Heart, Inc. for evaluation.

1.4. Record the results in Appendix A – Test Data Sheet.

2. Test Patient Primary Controller (may be performed during a routine Alarm Battery replacement):

2.1. Replace the Alarm Battery on the patient's primary FlowMaker Controller with a fresh Alarm Battery.

2.2. Finger-tighten the Alarm Battery Cap until fully tight.

2.3. Listen to the alarm sound from arm's length by briefly (2-3 seconds) unplugging the Y Cable from the Lithium-ion Battery or Reserve Battery/Charger powering the Jarvik 2000 Ventricular Assist Device.

Note: **The Jarvik 2000 Ventricular Assist Device will stop while the main battery is briefly disconnected**.

2.4. Reconnect the Y Cable regardless of the alarm sound condition.

2.4.1. If the alarm sounds normal, like that of a new FlowMaker Controller alarm, **ACCEPT** the unit.

2.4.2. If the alarm sound is weak, nearly inaudible, or inaudible **REJECT** the unit and replace the patient's Primary FlowMaker Controller with a new FlowMaker Controller from inventory. Install a fresh alarm Battery and test the new Alarm Battery in accordance with IFUs. Return the Controller to Jarvik Heart, Inc. for evaluation.

2.4.3. If the alarm sounds unusual compared to a new unit, QUARANTINE the unit and return to Jarvik Heart, Inc. for evaluation.

2.5. Record the results in Appendix A – Test Data Sheet.

Patient's primary Controller must be an acceptable unit and patient must maintain a back-up Controller.

If the patient's back-up Controller is unacceptable and a replacement Controller is not immediately available, DO NOT replace the patient's back-up Controller until an acceptable unit is available.

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Appendix A -Test Data Sheet

FlowMaker Controller Alarm Check Results			Reference: FSCA FEBRUARY2018		
Case ID:					
Center:					
Country:					
Clinician Name: (please print)					
Signature:					
Date:					
	Part Number (Check one)	Serial Number (Write)	Alarm Status (Check one)		Comments (Check one, if applicable)
Backup Controller	☐ JHI-102 ☐ JHI-101		☐ Accept	☐ Reject	☐ Weak sound ☐ Nearly inaudible sound ☐ Inaudible sound
Primary Controller	☐ JHI-102 ☐ JHI-101		☐ Accept	☐ Reject	☐ Weak sound ☐ Nearly inaudible sound ☐ Inaudible sound

Notes

Please return any rejected units to Jarvik Heart, Inc.

Any FlowMaker Controller that exhibits an unacceptable alarm sound should be quarantined and returned to Jarvik Heart, Inc. for investigation.

We kindly request you send completed forms to returns@jarvikheart.com

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URGENT FIELD SAFETY NOTICE

(to be completed by the site representative)

Identifier: **FSCA FEBRUARY2018**

Type of Action: **EQUIPMENT ALARM CHECK REQUIRED**

Product: **JHI-102 ILS FLOWMAKER CONTROLLER**
JHI-101 CONSTANT SPEED FLOWMAKER CONTROLLER

Subject: **CHECK ALARMS IN CASE DAMAGE HAS OCCURRED DURING USE FROM: DROP, SHOCK, OR IMPACT TO THE BUZZER COVER**

The undersigned hereby acknowledges having received and understood the urgent field safety notice FSCA FEBRUARY2018, sent by Jarvik Heart, Inc.

Center:	
Country:	
Function/Title:	
Clinician Name: (please print)	
Signature:	
Date:	

No later than 30 days from the date of this notice, please:

- Return this signed form to your Jarvik Heart, Inc. representative; or
- Send by email an electronic copy of this signed form to returns@jarvikheart.com

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