Safety Alert 007/23

Issue date
12 September 2023

Distributed to:
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:

- Cardiac Catheter Laboratories
- Intensive Care Units
- Coronary Care Units
- Perioperative Units
- Perfusion/Cardiac Surgeons
- Aeromedical Retrieval

Deadline for completion of action:
14 September 2023

Interagency Management Team

Content reviewed by:

- Cardiac Clinicians

Representatives from:

- ACI Cardiac Network & Intensive Care NSW
- State Preparedness & Response Unit
- HealthShare NSW

Clinical Excellence Commission
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Intranet:
Clinical Quality, Safety and Governance - Intranet (nsw.gov.au)

Review date
September 2024

Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP)

Situation

On 30 August, the TGA issued a Class I Hospital Level Urgent Product Defect Correction (RC-2023-RN-00659-1) for the Cardiosave Hybrid and Cardio save Rescue IABP due to eight issues that could affect the IABP performance.

Background

An IABP is a device used to increase myocardial oxygen perfusion and indirectly increase cardiac output by reducing afterload. IABP are used in Cardiac Catheter Laboratories, Intensive Care Units, Coronary Care Units and in cardiothoracic surgery, and may also be required for use in an aeromedical retrieval environment.

Product codes affected are:

Product Description	Product Code/Part Number	UDI Code
Cardiosave Hybrid	0998-00-0800-31 0998-UC-0800-31	10607567109053 N/A
Cardiosave Hybrid	0998-00-0800-53 0998-UC-0800-53	10607567108391 N/A
Cardiosave Rescue	0998-00-0800-83	10607567108407

Eight potential issues have been identified:

1. IABP will not charge battery due to failure of the power management board charge path circuitry.
2. Unexpected shutdown due to failure of tantalum capacitors.
3. Docking/power battery failure which may lead to unexpected interruption of therapy.
4. Poor or no ECG signal.
5. Autofill failure conditions.
6. Gas loss and gas gain alarms during therapy.
7. System over-temperature alarm associated with a loss of counterpulsation therapy and/or system entering stand-by mode.
8. Failure in the fibre optic sensor input.

Assessment

Globally, there has been multiple reports of incidents resulting in adverse events and deaths due to the above issues. There has been one incident in NSW relating to a shutdown of a IABP which did not result in patient harm.

A customer letter outlining the issues and proposed actions for customers is available as is support from the sponsor.

Clinical Recommendations

Affected IABP consoles may continue to be used if there is no alternative console available, however, when considering initiation of an IABP with an affected console, a backup console must be available and on site.

	Issue	Clinical Recommendation
1	IABP will not charge battery due to failure of power management board charge path circuitry	Do not remove the battery when battery level is at 80% or higher and actively charging. Keep the battery in the charging bay until fully charged.
2	Failure of tantalum capacitors	Use a backup IABP console Use alternative methods for haemodynamic support
3	Docking/power battery failure	Ensure IABP in Hybrid mode where possible so batteries can charge, and carry spare charged batteries Follow instructions as outlined in Instructions for Use (IFU) as to how to ensure IABP console is properly docked Use a backup IABP console if unable to re- establish power
4	Poor or no ECG signal	Operate in Auto mode where possible, and adhere to IFU recommendations on use of ECG lead wires and electrodes
5	Autofill alarms	Follow instructions as outlined in IFU for responding to autofill alarms Use a backup IABP console Use alternative methods for haemodynamic support
6	Gas loss & gas gain alarms	Minimise patient movement Ensure all tubing connections are secure Follow instructions for responding to Gas loss in IAB circuit and Gas gain in IAB circuit as outlined in IFU Use a backup IABP console if prolonged interruption
7	System over temperature	**Power down device** if a System Over Temperature alarm occurs, wait 10 seconds and then turn the IABP back on Use a backup IABP console if alarm does not resolve Follow instructions for ways to prevent the alarm Use alternative methods for haemodynamic support
8	Fibre Optic Damage	Utilise Auto mode or connect to an alternative pressure monitoring source (e.g., standard fluid filled pressure bag system) Follow instructions as outlined in IFU to ensure no damage occurs to the fibre optic sensor connector on insertion

Sponsor details:

Name: Getinge Australia Pty Ltd
Tel: 1800 438 464
Email: Quality.AUNZ@getinge.com

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments with IABPs
2. Attach this Safety Notice to all affected IABPs
3. Include this Safety Notice in relevant handovers and safety huddles
4. Ensure that an alternate IABP console is available when this therapy is being initiated
5. Escalate any concerns to CEC-recalls@health.nsw.gov.au
6. Report any incidents associated with Getinge IAB pumps and consumables into ims+ and TGA.
7. Confirm receipt and distribution of this Safety Notice within 24 hours to CEC-recalls@health.nsw.gov.au