Safety Alert 001/20

LIFEPAK® 15 Monitor/Defibrillator defect correction - 2020

14 January 2020

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit
- NSW Ambulance

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Director Medical Services
- Director Nursing and Midwifery Services
- Biomedical Engineers
- Directors and Managers of Intensive Care Units
- Directors and Managers of Cardiology Services
- Directors and Managers of Emergency Departments
- Directors Mental Health
- Directors Community& Primary Health Services
- CERS/PACE Coordinators
- Staff who participate in Advanced Life Support
- Paramedics

Deadline for completion of action

16 January 2020

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- HealthShare NSW
- NSW Ambulance Service

Clinical Excellence Commission

Tel: 02 9269 5500

Fax: 02 9269 5599

Email: CEC-Recalls@health.nsw.gov.au

Internet Website: http://health.nsw.gov.au/sabs

Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

Review date

January 2021

Situation

On 14 January 2020, the Therapeutic Goods Administration (TGA) issued a Class I (high risk) Urgent Product Defect Correction Notice regarding LIFEPAK® 15 Monitor/Defibrillator devices.

This notice advises that LIFEPAK® 15 Monitor/Defibrillators with part numbers beginning V15-2 may not deliver a defibrillation shock when the device “Shock” button is pressed. This is due to oxidation that has formed over time within the button on the keypads. In cases where this has occurred, the device displayed a "DISARMING" message when the shock was not delivered, the service light illuminated. The manufacturer, Stryker, advises that high usage devices are less likely to experience this issue as each button press breaks through the oxide film.

Background

A similar notice was issued by Stryker regarding software issues with the LIFEPAK® 15 Monitor/Defibrillators in February 2019. This defect correction notice is different and relates to a hardware issue. This is a global issue.

Assessment

There have been no known adverse patient outcomes in NSW due to this issue, and the risk is considered low. Stryker will work with NSW Health to replace the affected keypads.

Clinical recommendations

- Continue to use LIFEPAK® 15 Monitor/Defibrillators
- All advanced life support equipment, including defibrillators, should be routinely checked at least daily.
- **Ensure checks include testing of the ‘Shock’ function** of affected LIFEPAK® 15 devices, as per LIFEPAK® 15 Monitor/Defibrillator Operator’s checklist (page 311).
- Where possible, ensure a backup defibrillator is accessible in event of failure.

In the event of LIFEPAK® 15 devices failing to deliver shocks, continue the patient resuscitation and immediately repeat the charge and shock cycle , as the device may deliver subsequent shocks. If the device fails to deliver the shock again, utilise a backup device where possible.

Actions required by Local Health Districts/Networks

1. Distribute this Safety Alert to all relevant clinical and biomedical engineering staff
2. Each health entity is to undertake a local risk assessment of LIFEPAK®15 Monitor/Defibrillators, using QARS or audit tool provided, by 5pm on Thursday 16 January 2020
3. Immediately attach this Safety Alert on, or next to, all LIFEPAK® 15 Monitor/Defibrillators to advise on actions to take in the event of device not delivering shock
4. Escalate concerns that are not able to be managed locally to CEC-Recalls@health.nsw.gov.au
5. Report all issues in the Incident Information Management System (IIMS) or IMS+, and to the TGA.

Made Obsolete September 2022
TGA Recall Action Completed