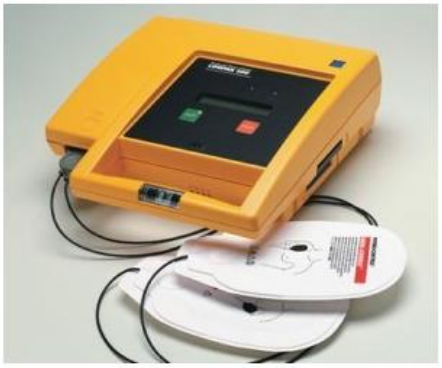
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Lifepak 500 Automated External Defibrillator



Priority 2 – Warning

HPRA Safety Notice: SN2020(09) **Issue Date: 10 August 2020**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Stryker Medical	V44148

ISSUE

Stryker has identified a component wear out issue for the LIFEPAK 500 AED. In high-use environments the device may not detect a patient connection due to mechanical wear-through of the contact plating on the therapy connector. The issue has been communicated in the attached field safety notice (FSN). There have been no reported incidents relating to this issue in Ireland.

The HPRA is issuing this notice to raise awareness as the LIFEPAK 500 AED has been discontinued by Stryker and the manufacturer is unable to resolve this issue, therefore **any devices remaining in service should be retired as soon as practically possible**.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Read the accompanying FSN carefully.

2 Follow the instructions in the FSN to identify whether you have affected devices in use at your facility.

3 If during use you experience the issue described in the FSN, remove and reinstall the electrodes to the device or replace the electrodes and check the patient connection. If the issue with patient detection continues, immediately obtain a backup device and remove the affected device from use.

4 If during maintenance testing you identify affected devices that exhibit the issue described in the FSN, remove the devices from use immediately.

5 Acknowledge receipt of the FSN if you have not already done so.

6 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.

7 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Ambulance Services	Risk managers
Clinics	Supplies managers
General practitioners	Health and safety managers
Hospitals	Volunteer Ambulance Services
Medical Directors	First Aid Organisations
Emergency Departments	Sports Centres
Nursing Homes	Schools
Paramedics/Advanced Paramedics	Gyms
Dental Clinics	Retailers
	Work Places/Employers

BACKGROUND

Stryker issued a FSN to advise users of the following issues relating to the LIFEPAK 500 AED:

1 Mechanical wear-through of the contact plating on the therapy connector of LIFEPAK 500 AEDs in high-use environments such as emergency services may cause an oxide layer to form on exposed base metal of the connector resulting in the device not recognising when a patient is connected. In such situations, the device provides the user with the "CONNECT ELECTRODES" message.

Stryker received five incident reports from one facility in the US, where the device failed to initially recognise a patient connection, which resulted in a delay to treatment.

2 Stryker is unable to service LIFEPAK 500 devices to resolve this issue, therefore any devices remaining in service should be retired as soon as practically possible, consistent with the needs of patients.

Stryker previously sent a product discontinuation notice to customers regarding the LIFEPAK 500 AED in February 2020. Supply of parts, accessories and disposables for the LIFEPAK 500 AED ended in June 2020.

The HPRA is issuing this Safety Notice to raise awareness of this issue. Please see the accompanying manufacturer's FSN for further information.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Stryker UK,
Stryker House,
Hambridge Road,
Newbury,
Berkshire,
RG14 5AW,
UK.

Telephone: +44 1635 262400
+44 7929 021221
E-mail:
raqa.uk@stryker.com
sharunyan.thavarajan@stryker.com

Website: www.stryker.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie