Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 47 **dated** 02/03/20 **regarding recall of LIFEPAK 15 Monitor/Defibrillator from Stryker**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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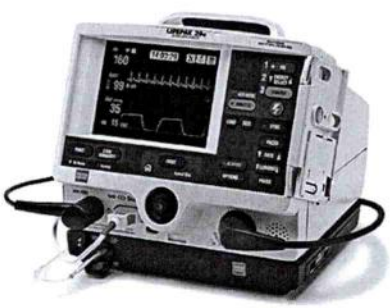
Circular No. 47 / 2020

07-07-1441 H

02-03-2020

Ref: 38/2020

Recall of LIFEPAK 15 Monitor/Defibrillator from Stryker

Source of Recall	**NCMDR National Centre for Medical Devices Reporting, SFDA** https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=15046
Product	LIFEPAK 15 Monitor/Defibrillator
Manufacturer	Stryker
Local Agent	Muscat Pharmacy
The affected products	All Part Numbers beginning with V15-2
Reason for Recall	tryker is advising that specific LIFEPAK 15 Monitor/Defibrillator devices may not deliver a shock after the "Shock" button on the keypad is pressed. The affected products include devices which were either manufactured with or received an upgrade kit that contained an affected keypad. The failure of the device to deliver a defibrillation shock when the device "Shock" button is pressed is as a result of oxidation that has formed over time within the button. In cases where this has occurred, the device displayed a "DISARMING" message when the shock was not delivered, the service light illuminated, and the device logged an "A00B" error code. High usage devices are less likely to see this issue as each button press breaks through the oxide film. The hard paddle shock button is not affected by this issue
Action	1. Kindly check your stock, contact your local agent for remedial action
Product image	
Comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ – فاكس: ٢٢٣٥٧١١١ – هاتف: ١٠٠ – الرمز البريدي: ٣٩٣ مسقط – ص . ب:
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