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. 176 **dated** 27.09.20 **Regarding NCMDR Recall of Blood Monitoring Unit BMU 40 (70104.0852) from (mfr: MAQUET Cardiopulmonary GmbH).**

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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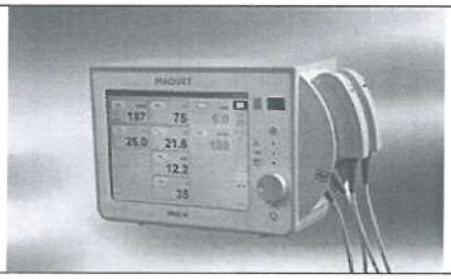
Circular No. 176 / 2020

09 -02-1442 H

27 -09-2020

Recall of Blood Monitoring Unit BMU 40 (70104.0852) from MAQUET Cardiopulmonary GmbH.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15359
Product	Blood Monitoring Unit BMU 40 (70104.0852)
Description	Heart-Lung Support System.
Manufacturer	MAQUET Cardiopulmonary GmbH.
Local agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Affected Serial Numbers: From 90002001 to 90002313
Reason	It has become known to Maquet Cardiopulmonary GmbH that the printed circuit board (PCBA Connector) of the BMU40 was designed with a short creepage distance.
Action	1. The PCBA Connector within the affected BMU40 with the serial numbers mentioned above will be replaced by a new one. 2. Contact 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 Department of Medical Device Control through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

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

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 029 09 20 000 Back
Date submitted: 9/22/2020

Manufacturer:	MAQUET Cardiopulmonary GmbH
Device Type:	Blood Monitoring Unit BMU 40 (70104.0852)
Description:	Heart-Lung Support System
Medical Device Identifier:	Affected Serial Numbers: From 90002001 to 90002313
Reason of Field Safety Corrective Action:	It has become known to Maquet Cardiopulmonary GmbH that the printed circuit board (PCBA Connector) of the BMU40 was designed with a short creepage distance.
Remedy Action:	The PCBA Connector within the affected BMU40 with the serial numbers mentioned above will be replaced by a new one.
Athorized Representative/Importer/Distributor:	Medical Elements
Report Source:	NCMDR
Source Ref. Number:	667B5B7A52208
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	**MAQUET Cardiopulmonary GmbH.pdf**

View History