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

سلطنة عُمان
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....10.2.... **dated** .22/5/22 **Regarding NCMDR FSCA of EP-TRACER from (mrf: Schwarzer Cardiotek 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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ISO 9001:2015 CERTIFIED

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

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Circular No. 102/ 2022

23 -10-1443 H

22 -05-2022

Field Safety Corrective Action of EP-TRACER from Schwarzer Cardiotek GmbH.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16127
Product	EP-TRACER.
Description	Electrophysiology recording system.
Manufacturer	Schwarzer Cardiotek GmbH.
The affected products	EP-TRACER 38 and EP-TRACER 102 manufactured after 01.01.2019
Reason	During an study of an external test house, one of our devices did not pass the test. There were no patients involved in this test. We examined the fail internally and concluded that there was an issue with regards to the creepance and air clearance at one point in the device. Because of this issue, the medical device is not in accordance with EN 60601-1 anymore. This issue was never detected when during the 60601 tests at the external test house.Further investigation identified only the EP-TRACER 38 and EP-TRACER 102 devices manufactured after 01.01.2019 to be impacted by the issue. Also the devices from the latest version are not having the above mentioned issue.
Action	1. The proposed remediation is to affix a reinforced insulation sheet with Kapton tape between the band wire connectors and the ESD shield PCB. 2. The remediation will be done either by onsite rework at the premises of the customer or at the CardioTek manufacturing site. 3. Contact the local agent for remedial action.
Product Picture	
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

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