



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 260 dated 30/11/23 Regarding NCMDR Field Safety Notice of The neonatal ventilator family SOPHIE from (mfr: Fritz Stephan 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





نتقدم بثقة
Moving Forward
with Confidence



Circular No. 260/2023

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30-11-2023

Field Safety Notice of The neonatal ventilator family SOPHIE from Fritz Stephan GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19779
Product	The neonatal ventilator family SOPHIE.
Description	Invasive and non-invasive ventilation.
Manufacturer	Fritz Stephan GmbH.
Local agent	Al Mazroui Medical and Chemical Supplies.
The affected products	All device models of Sophie and Sophie 2020 Ref. 1038614xx.
Reason	A defective heating cable was identified as the cause of the measuring menu of a Sophie 2020 was opened without a user input.
Action	1. The Sophie unit can still be used without restrictions, If the measures in the attachment are followed. A software update will be provided by manufacture that intercepts the triggering of the unused signal inputs and makes them ineffective. At the same time, the internal error detection of the heating system will be adapted so that the heating no longer switches on independently in the event of a detected error. If a fault of the heating system is detected and alarmed, the heating must be switched on again manually by the user in the heating menu after the fault has been remedied. 2. Contact the local agent for remedial action.
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 the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



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



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