



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 42 dated 21/2/2023 Regarding NCMDR
FSCA of Vivo 45, Vivo 45 LS Ventilators from (mfr: BREAS Medical AB).

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





Circular No. 42 / 2023


30-07-1444 H

21-02-2023

نتقدم بثقة
Moving Forward
with Confidence



Field Safety Corrective Action of Vivo 45, Vivo 45 LS Ventilators from BREAS Medical AB

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18445
Product	Vivo 45, Vivo 45 LS Ventilators.
Description	Ventilators, Portable/Home Care.
Manufacturer	BREAS Medical AB.
The affected products	Model No.: 220000, 230000 Unique Device Identifier(s) (UDI-DI): 07321822200007, 07321822300004 Vivo 45: firmware version 1.1.4 or earlier (i.e. lower number) Vivo 45 LS: firmware version 3.1.4 or earlier (i.e. lower number) Vivo 45 serial number ranges Y*****, D*****, K*****, M01**** - M1403** Vivo 45LS serial number ranges Y*****, D*****, K*****, M01****- M1403** (* asterisk denotes any digit 0-9)
Reason	Breas has discovered an exceptional condition where a forced shutdown of one of the processors in the ventilator could cause the ventilator to stop treatment without alarming.
Action	1. Firmware upgrade to the following firmware versions: Vivo 45: Version 1.1.7 or later Vivo 45 LS: Version 3.1.7 or later 2. Contact the 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 the E-mail: Med-device@moh.gov.om

/Dr. Mohammed Hamdan Al Rubaie

Director General

