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. 25 **dated** 29/01/12 **Regarding NCMDR FeNOBreath, Factional Exhaled Nitric Oxide (Mfr: Bedfont Scientific)**

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. 25 / 2020

04 -06 1441 H
29 -01-2020

Ref: 14/2020

Recall FeNOBreath from Bedfont Scientific

Source of Recall	**NCMDR** National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=15034
Product	FeNOBreath, Factional Exhaled Nitric Oxide
Manufacturer	Bedfont Scientific Limited
The affected products	All Serial Numbers
Reason for Recall	The manufacturer has been notified by the device manufacturer that the FeNObreath V2 batteries are becoming drained outside of the device technical specifications. The internal, rechargeable batteries can become fully drained. This can result in the power needed to keep the sensor stable to be lost and result in the readings becoming lower than the technical specification states. This can also result in the power needed to run the internal real time clock to be lost and result in the device losing its date/time settings. If the latter occurs, the device will revert to its factory date settings and will prevent the user from performing tests. Devices affected may present the following symptoms: 1) Lower than expected reading or zero reading; 2) Time and date resetting; 3) Sensor warning screen shown; 4) Maintenance reminder screen shown; or 5) Battery going flat and then unable to fully recharge within 8 hours
Action	1. Kindly check your stock, contact your local agent for remedial action 2. Users are advised that any device showing symptoms of early battery depletion should immediately be quarantined.
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

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