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. 183 **dated** 02/10/22 **..... Regarding GHC Recall of Omni Lab Advanced Plus, Flow Gen, DOM from (mfr: Philips Respironics).**

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. 183/ 2022

06-03-1444 H
02-10-2022

Recall of Omni Lab Advanced Plus, Flow Gen, DOM from Philips Respironics.

Source	GHC-Gulf Health Council.
Product	Omni Lab Advanced Plus, Flow Gen, DOM.
Manufacturer	Philips Respironics.
Local Agent	Muscat Pharmacy &Stores LLC.
The affected products	1109582 / OmniLab Advanced Plus, Flow Gen, DOM Serial No.: L30398476BABC.
Reason	"Philips Respironics" has determined that certain devices were built with motor assemblies that could contain non- conforming plastic material. If the nonconforming plastic is present in the device motor, it could lead to off-gassing and structural failure causing the immediate and sudden failure of the device during use. The patient may be exposed to the following hazards if the non-conforming material is present: 1. Exposure to off-gassing not normally present may create a potential biosafety or toxicological hazard. 2. Sudden failure of the device causing a Ventilator Inoperative condition with the potential for asphyxia if not immediately identified and addressed by the care provider.
Action	1. Return all impacted devices to the authorized distributor for replacement. 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

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

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