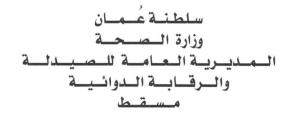
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





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. \$3. dated 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





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



سلطنة عُـمان وزارة الـصـحـة الـمـديـريـة الـعـامـة للـصـيـدلـة والـرقـابـة الـدوائـيـة مـسـقـط

Circular No. 183/2022

○b-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. 1. Return all impacted devices to the authorized distributor for replacement. 2. Contact the local agent for remedial action.
Product Image	2. Contact the local agent for femedial 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







