

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِيَّاطِنَا جَمَانَا
وَزَارَةُ الصِّحَّةِ
المديرية العامة للصحة
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.....⁸¹..... dated ^{6/4/2020}..... Regarding Recall of Olympic Brainz Monitor from Natus Medical Incorporated

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

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وزارة الصحة
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Circular No. 81 / 2020

12-08-1441 H

06-04-2020

Ref: 49/2020

Recall of Olympic Brainz Monitor from Natus Medical Incorporated

Source of Recall	Gulf Health Council
Product	Olympic Brainz Monitor
Manufacturer	Natus Medical Incorporated
Local Agent	Mustafa Sultan Science & Industry
The affected products	Model No.: OBM00002 Serial No.: OBM00002G2119 & OBM00002G2130 till OBM00002G2168
Reason for Recall	The system functionality test was not carried out for the above-mentioned products The manufacture cannot attest to the system functionality off the effected items
Action	1. Kindly check your stock, contact your local agent for remedial action 2. The product will be recalled to manufacturing site and retested and released to the customer
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 Med-device@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

