Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

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 90 **dated** 27/6/2024 **Regarding NCMDR Field Safety Notice of IntelliVue Multi-Measurement Module X3 from (mfr: Philips Medizin Systeme GmbH).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ISO

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Circular No. 90 **/ 2024**

20 -12-1445 H
27-06-2024

Field Safety Notice of IntelliVue Multi-Measurement Module X3 from Philips Medizin Systeme GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21077
Product	IntelliVue Multi-Measurement Module X3.
Description	Patient monitor with multi-measurement modules.
Manufacturer	Philips Medizin Systeme GmbH.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Product Number 867030, (only affects devices shipped with software version P.01.01 or P.01.02, and ordered with Option C99)
Reason	A potential safety issue related to disabled Invasive Blood Pressure calibration setting for reusable transducers with IntelliVue X3, software version P.0, as included in the Philips Interventional Hemodynamic System.
Action	1. If you use reusable transducers, the maximum measurement error can be ±10% without calibration. Please take this into consideration when using Invasive Blood Pressure measurement for treatment options or make use of disposable transducers. 2. You will be contacted by a Philips distributor to schedule a visit from a Philips Field Service Engineer who will update the configuration profile on your IntelliVue X3 to correct this issue. 3. Contact the local agent for remedial 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

NHP

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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