

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطِنَا عُمَانِ
وَزَارَةُ الصِّحَّةِ
وَالرِّقَابَةِ الدَّوَلِيَّةِ
مَسْقَط

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. 58..... dated 21.10.2022 Regarding recall of IntelliVue TRx481A and TRx4851A Telemetry Transceiver from Philips Healthcare

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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سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
والرقابة الدوائية
مسقط

Circular No. MUSCAT / 2020

58

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09 -03-2020

Ref:46/2020

Recall of IntelliVue TRx4841A and TRx4851A Telemetry Transceiver from Philips Healthcare

Source of Recall	NCMDR National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15089
Product	Philips IntelliVue TRx4841A and TRx4851A Telemetry Transceiver
Manufacturer	Philips Healthcare
The affected products	Philips IntelliVue TRx4841A and TRx4851A Telemetry Transceiver at facilities that are operating Philips Patient Information Center iX (PIC iX) C.02.00, C.02.02, C.02.03 (all released versions of C.02 collectively referred to as C.02.xx') and C.03.01. 862439 TRx4841A 1.4 GHz IntelliVue Tele TRX 453564007261 - M4841 TRx w/Sp02 Refurbished 453564007271 - TELE-1.4 PWD ECG/SPO2AAMI 453564007281 - TELE-1.4 PWD SPO2 UPGRADABLE AAMI 989803196951 - M4841 TRx w/Sp02 Refurbished 862231 TRx4851A 2.4 Ghz IntelliVue Tele TRX 453564052401 - ITS 2.4 PWD ECG ONLY AAMI 453564052411 - ITS 2.4 PWD ECG/SPO2 AAMI 453564052441 - ITS 2.4 PWD ECG ONLY IEC 453564052451 - ITS 2.4 PWD ECG/SPO2 IEC
Reason for Recall	The ECG signal from patients being monitored using a Philips TRx4841A or TRx4851A Telemetry Transceiver may not be properly analyzed when the transceiver is used with a Philips Patient Information Center IX Release C.02.00, C.02.02, C.02.03 (all released versions of C.02, collectively referred to as 'C.02.xx') or C.03.01. If this occurs, the Information Center will not display a heart rate or generate, display or announce any heart rate or arrhythmia alarms
Action	1. Kindly check your stock, contact your 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 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

