Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 130 **dated** 25/9/2024 **Regarding SFDA Field Safety Corrective Action of IntelliVue Patient Monitor from (mfr: Philips medical Systems).**

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

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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سلطنة عُمان
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مسقط

Circular No. 130/ **2024**

21 -03-1446 H
25 -09-2024

Field Safety Corrective Action of IntelliVue Patient Monitor from Philips Medical Systems.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/93
Product	IntelliVue Patient Monitor.
Manufacturer	Philips Medical Systems.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Attached.
Reason	Potential Loss of Electrical Grounding.
Action	1. Please check if the equipotential connector is broken off. If yes, remove the device from use. (refer to the attachment). 2. A Philips distributor will contact you to schedule a visit to replace the power supply. 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: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة - مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

DSC مركز سلامة الدواء Drug Safety Center

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PHILIPS

URGENT Field Safety Notice

Potential Loss of Electrical Grounding - IntelliVue Patient Monitor Power Supply

02-SEP-2024

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue related to IntelliVue Patient Monitors MX400/430/450/500/550 with a defective equipotential ground connector.

This notification is intended to inform you about:

1. The problem and under what circumstances it can occur

Electrical grounding is crucial to ensure that hospital patient monitoring equipment is safe, reliable, and in compliance with industry standards. Grounding provides a path for electrical current to return to the ground during faults, thereby minimizing risk of electric shock and protecting equipment from damage. **It also controls leakage currents and dissipates static electricity that could pass through a patient's body** or impair device function. Additionally, grounding helps to reduce electromagnetic interference (EMI), ensuring accurate readings of patient vitals and reduction of interference with other electrical equipment in the healthcare environment. During a production process, Philips became aware of one IntelliVue power supply with a broken ground bolt upon disconnection of the ground cable from the equipotential ground connector. Image depicted below.

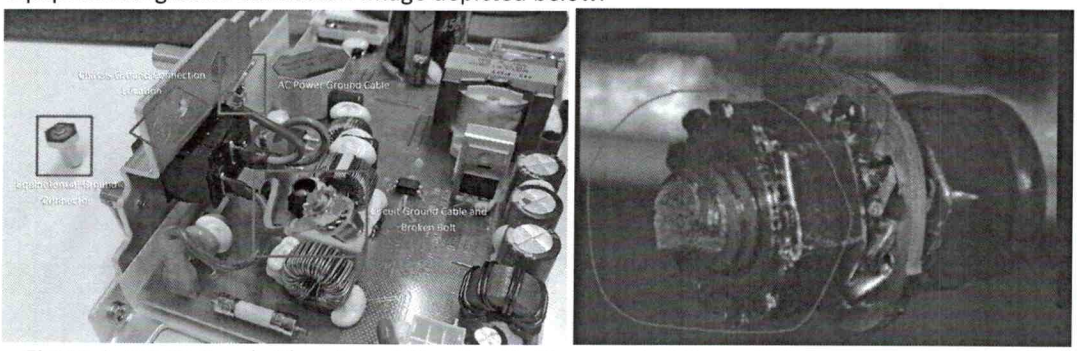

Figure 1. Power Supply Chassis and Circuit with Disconnected Ground Wires and Broken Ground Bolt

2. Hazard/harm associated with the issue

Loss of electrical grounding may negatively affect the device's electromagnetic immunity and emission. Degraded electromagnetic immunity can cause the monitor to generate unreadable or unusable waveforms, potentially leading to incorrect/delayed patient treatment. Excessive or unintended electromagnetic emissions can also negatively impact the function of equipment in the vicinity of the

patient monitor, potentially leading to delayed procedure. Although unlikely, these scenarios could potentially result in patient harm.

3. Affected products and how to identify them

NOTE: Only MX400-550 devices shipped after 26-April-2024 are affected.
Please refer to the manufacturing date on the back of your monitor.

#	Product Name(s)	Model Number(s)	UDI
1	IntelliVue Patient Monitor MX400	866060	00884838038752
2	IntelliVue Patient Monitor MX430	866061	00884838057562
3	IntelliVue Patient Monitor MX450	866062	00884838038769
4	IntelliVue Patient Monitor MX500	866064	00884838038776
5	IntelliVue Patient Monitor MX550	866066	00884838038783

4. Actions that should be taken by the customer / user to prevent risks for patients or users

- Please check if the equipotential connector is broken off (refer to Figure 1). If yes, remove the device from use.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.
- Please complete and return the response form at the end of this letter to Philips promptly upon receipt of this notice and no later than 30 days.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule a visit from a Philips Field Service Engineer who will replace the power supply.

If you need any further information, please contact your local Philips representative: *met.quality@philips.com*

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin,
Head of Quality

PHILIPS

URGENT Field Safety Notice Response Form

Reference: CR # 2024-CC-HPM-030, Potential Loss of Electrical Grounding - IntelliVue Patient Monitor Power Supply

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the URGENT Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

Customer Actions:

- Please check if the equipotential connector is broken off (refer to Figure 1). If yes, remove the device from the use.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: *met.quality@philips.com*