PHILIPS

URGENT Field Safety Notice

Potential Loss of Electrical Grounding - IntelliVue Patient Monitor Power Supply

DDMMMYY,

Dear Distributor,

Philips is initiating an URGENT Field Safety Notice because we became aware of a potential safety issue related to IntelliVue Patient Monitors MX400/430/450/500/550 with a defective equipotential ground connector.

It is imperative that all customers with affected products receive the attached URGENT Field Safety Notice that informs about:

- The problem and under what circumstances it can occur
- Affected products and how to identify them
- The actions that the customer/user should take to prevent risk for patients
- The actions taken by Philips in order to prevent risks for patients or users

Philips is requesting customers to return a Response Form to acknowledge receipt and understanding of the URGENT Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected product.

Together with this letter we are providing a list of affected products that Philips has sold to your organization. As distributor of the affected products, we kindly request that you:

- Add in the Response Form attached your contact information.
- Send the attached URGENT Field Safety Notice to each customer to whom you have distributed any affected product as soon as possible and no later than three days, together with the Reply Card.
- Perform a good faith effort to get the Reply Form by following up with the customer with a minimum of three attempts, and if possible, using multiple contact methods. Inform Philips about the responses received.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market>*

Sincerely,

Deborah Currlin
Head of Quality

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URGENT Field Safety Notice

Potential Loss of Electrical Grounding - IntelliVue Patient Monitor Power Supply

<Date of letter deployment,>
<date format: DD-MMM-YYYY, e.g. 02-JAN-2021>

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code
<modify title block format as needed>

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.

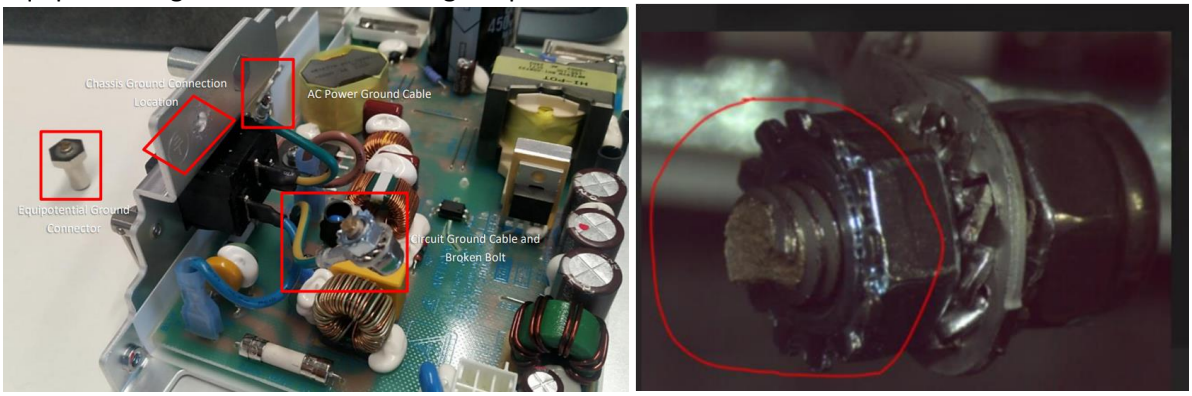

Figure 1. Power Supply Chassis and Circuit with Disconnected Ground Wires and Broken Ground Bolt

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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: *<Philips representative contact details to be completed by the Market/Business>*

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin,
Head of Quality

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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: *<Reply form return details to be completed by the KM/ country>*