PHILIPS

URGENT Field Safety Notice

RE: Dual IBP Adapter Loss of Defibrillation Protection

September 24, 2026

To: Customer Name
Attention To:
Customer Street Address
City, State, Zip Code

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 with Dual IBP Adapter failing to maintain defibrillation protection if two non-defibrillation proof transducers are connected simultaneously.

The reusable dual IBP adapter allows the connection of a dedicated Philips measuring device with two third-party pressure transducers via existing third-party pressure cables. If the adapter is connected to a single pressure port, only sensor 1 will provide a measurement. The dual IBP adapter is for use only in combination with Philips instruments when listed as an accessory in the instrument's Instructions for Use (IFU).

This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

It was determined that when two non-defibrillation-proof transducers are used, the system fails to maintain defibrillation protection because the adapter lacks connector pin spacing and therefore the 12-pin connector cannot withstand required 5 kV for defibrillation protection. In clinical situations where defibrillation is needed the use of non-defibrillation-proof transducers can create hazardous situations where defibrillation energy may be partially shunted through the IBP system rather than fully through the patient.

In order for the issue to occur, the Dual IBP Adapter must be used with transducers not listed as compatible in the Instructions for Use (IFU). As a result, use of the adapter with catheter-tip transducers particularly increases risk, as these transducers are typically not defibrillation-proof due

to limitations inherent to their design. The Dual IBP Adapter design does not prevent use with non-defibrillation-proof transducers.

Hazard/harm associated with the issue

When this issue occurs, patients may be exposed to the operational hazard of "Loss of Function" caused by the delivery of insufficient defibrillation energy. In addition, this issue may cause the monitor to not recover fast enough, or at all, after defibrillation, which can expose patients to incorrect or delayed treatment. If the adapter is touched by the user during defibrillation, the user may be exposed to an electrical hazard which can cause electrical shock and contribute to death.

NOTE: It is possible that users may recognize the issue prior to the occurrence of the hazardous situation if they refer to the IFU and use only compatible pressure transducers.

Affected products and how to identify them

The Philips Dual IBP Adapter are identified below:

Product Name	Product/Model Number	UDI
Dual IBP Adapter	989803199741	00884838085299

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

- Ensure that compatible disposable pressure transducers and accessories (per IFU) are used in conjunction with Dual IBP Adapter.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
- Place this notification with the documentation of the Philips Dual IBP Adapter and associated devices in a place where it is most likely to be seen and viewed.
- Complete the URGENT Field Safety Notice Response Form at the end of the notification to submit both acknowledgment of this URGENT Field Safety Notice and confirm understanding of actions to be taken.

The actions planned by Philips to correct the problem

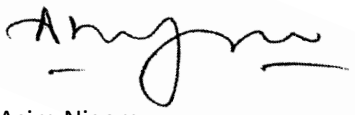
A Philips representative will send a follow up communication to provide instructions on how to obtain updated Instructions for Use (IFU) and Addendum once available.

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/Business>*

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product(s) may be reported to *< Markets to insert to whom the customer should report>*.

Philips regrets any inconvenience caused by this problem.

Sincerely,



Asim Nigam
Head of Quality
Connected Care & Hospital Patient Monitoring
Philips Healthcare

PHILIPS

URGENT Field Safety Notice

Reference: Dual IBP Adapter Loss of Defibrillation Protection.
Instructions: Please complete and return this Response Form to Philips promptly and no later than 30 days from receipt. Completing this Response Form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Ensure that compatible disposable pressure transducers and accessories (per IFU) are used in conjunction with Dual IBP Adapter.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
- Place this notification with the documentation of the Philips Dual IBP Adapter and associated devices in a place where it is most likely to be seen and viewed.
- Complete the URGENT Field Safety Notice Response Form to submit both acknowledgment of this URGENT Field Safety Notice and confirm understanding of actions to be taken.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected product(s).
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: <Response Form return details to be completed by the KM/country>