

URGENT Field Safety Notice

**RE: IntelliBridge EC10 Module and IntelliBridge EC5 ID-Module Interfacing with driver
ED245 Hamilton Block (ACK)**

January 13, 2025

To: **Customer Name**
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 concerning IntelliVue Patient Monitor (host monitor) with IntelliBridge EC10 Module and EC5 ID-Module interfacing with the Hamilton ventilator failing to alarm for “No Device Data” INOP. This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

IntelliVue Patient Monitor (host monitor) with IntelliBridge EC10 Module and EC5 ID-Module interfacing with the Hamilton ventilator, fails to alarm after a Hamilton ventilator is disconnected from the EC10 Module or IntelliBridge I/O board. It was confirmed that in the case of interruption of the cable connection between the Hamilton ventilator and the EC10 Module or IntelliBridge I/O board, the expected “No Device Data” INOP doesn’t appear on host monitor. Lack of “No Device Data” INOP is the result of a software issue in the ED245 Driver Revision A.0 used by the EC10 Module or IntelliBridge I/O board.

Hazard/harm associated with the issue

The EC10 Module should trigger a “No Device Data” INOP in the case of loss of communication with a connected device. An INOP tone should also be announced following disconnection. The failure to trigger an INOP following disconnection of an external device and loss of data can result in incorrect/delayed treatment. Although unlikely, this scenario could potentially result in patient harm.

Affected products and how to identify them

This issue affects IntelliVue Patient monitor with IntelliBridge EC10 Module and EC5 ID-Module interfacing with the Hamilton ventilator.

#	Product name	Product number
1	IntelliBridge EC10 Module	865115
2	IntelliVue Patient Monitor MX400	866060
3	IntelliVue Patient Monitor MX450	866062
4	IntelliVue Patient Monitor MX500	866064
5	IntelliVue Patient Monitor MX550	866066

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

- If patient is monitored by an IntelliVue Patient Monitor with IntelliBridge EC10 Module and EC5 ID-Module for interface with the Hamilton ventilator, ensure that there is no interruption of the cable connection between the Hamilton ventilator and the EC10 Module or IntelliBridge I/O board before use. Furthermore, ensure to closely monitor patient condition and the status of alarms at the ventilator.
- 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.
- Complete the URGENT Field Safety Notice Response Form at the end of the notification to submit both their acknowledgment of this URGENT Field Safety Notice and confirm understanding of actions to be taken.

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 upgrade your ED245 Driver from revision A.0 to revision A.1.

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 may be reported to *<Markets to insert to whom the customer should report>*.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin
 Head of Quality, Hospital Patient Monitoring
 Philips Healthcare

URGENT Field Safety Notice

Reference: IntelliVue Patient Monitor (host monitor) with IntelliBridge EC10 Module and EC5 ID-Module interfacing with the Hamilton ventilator failing to alarm for “No Device Data” INOP

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, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

If patient is monitored by an IntelliVue Patient Monitor with IntelliBridge EC10 Module and EC5 ID-Module for interface with the Hamilton ventilator, ensure that there is no interruption of the cable connection between the Hamilton ventilator and the EC10 Module or IntelliBridge I/O board before use. Furthermore, ensure to closely monitor patient condition and the status of alarms at the ventilator.

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 IntelliVue Patient Monitor with IntelliBridge EC10 Module and EC5 ID-Module interfacing with the Hamilton ventilator.

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>](#)