

**URGENT – Medical Device Correction**  
**Philips IntelliVue Clinical Information Portfolio**  
**Release D.03, E.00, and E.01**

Dear Customer,

A problem has been detected in the Orders Management scheduling function of the Philips IntelliVue Clinical Information Portfolio Release D.03, E.00 and E.01, which could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients
- the actions planned by Philips to correct the problem.

**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.

Under certain circumstances, edits to an order can result in unintended scheduled interventions on the IntelliVue Clinical Information Portfolio. If the clinical team does not recognize that such unintended interventions are scheduled in ICIP Order Management, a patient may receive interventions or additional medication doses that are not intended.

Please refer to the following page which provides instructions for actions to be taken. Follow the “Action to be taken by Customer/User” section of the instructions.

This issue has been reported to the appropriate regulatory agencies.

I sincerely regret the inconvenience that this may cause you. Philips has a well-earned reputation for providing products and services of the highest quality. Your satisfaction with Philips’ products and with our response to this issue is very important to us. Contact your local Philips representative if you have any questions or concerns: [<Philips representative contact details to be completed by the KM/country>](#)

Sincerely,



Tom Fallon,  
Director, Quality and Regulatory Affairs.

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<b>AFFECTED PRODUCTS</b>	865047 IntelliVue Clinical Information Portfolio Release D.03 865209 IntelliVue Clinical Information Portfolio Release E.00 and E.01 865300 IntelliVue Clinical Information Portfolio NICU Link
<b>PROBLEM DESCRIPTION</b>	Charting the administration of medications after the scheduled time and then changing the schedule time may lead to the generation of extra pending interventions in error. This will occur when: <ul style="list-style-type: none"> <li>• an order exists with a scheduled even frequency; AND</li> <li>• at least one intervention has been administered; AND</li> <li>• the scheduled time of an intervention has been changed forward in time; AND</li> <li>• the next pending administration has not been charted; AND</li> <li>• the order is edited without further changing the schedule.</li> </ul>
<b>HAZARD INVOLVED</b>	If it is not recognized that unintended interventions are scheduled in ICIP Order Management, a patient may receive interventions or additional medication doses that are not intended.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	The product release is identified on the splash screen when the application is launched. Affected product will display “Philips IntelliVue Clinical Information Portfolio Release D.03, E.00 or E.01”  Alternatively, select HELP/ABOUT from the menu bar in the application
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	Follow the instructions for use for the device, which includes the directions to: <ul style="list-style-type: none"> <li>• Always use the medication administration record (MAR) in determining patient care. Always review orders and pending administrations in the MAR after any changes to an order are stored.</li> </ul>
<b>ACTIONS PLANNED BY PHILIPS</b>	Philips is developing a software upgrade to address this problem in the short term. This upgrade is available immediately.  For the longer term, Philips is developing safeguards intended to minimize the potential for similar errors resulting from order changes. We expect this upgrade to be available in September 2011.  For both upgrades, a Philips representative will contact you to schedule the implementation when each becomes available. These upgrades will be provided at no charge.
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact <a href="#">&lt;Philips representative contact details to be completed by the KM / country&gt;</a>