

URGENT – Medical Device Correction
Philips IntelliVue Clinical Information Portfolio Release D.00 to D.03

Dear Customer,

A problem has been detected in the scheduling function of the Philips Intellivue Clinical Information Portfolio Releases D.00 through D.03, which could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problems are and under what circumstances they can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- 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.

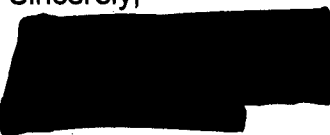
Edits to a scheduled even frequency order may result in pending interventions not being generated after the first 24 hours. If the clinical team is solely relying on the ICIP critical care worklist for administration of pending orders, this issue may result in a patient not receiving intended treatment.

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. Follow the "Action to be taken by Customer/User" section of the notice.

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,



Senior Manager, Quality and Regulatory Affairs

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AFFECTED PRODUCTS	865047 IntelliVue Clinical Information Portfolio Releases D.00 through D.03
PROBLEM DESCRIPTION	<p>Edits to a scheduled order may result in pending interventions not being generated after the first 24 hours. This will occur if:</p> <ol style="list-style-type: none"> 1. An edit is performed to an order which leads to the discontinuance of the old order and the creation of a new order; 2. Prior to storing the new order, the user now edits the frequency to an evenly spaced frequency; 3. As soon as the frequency is changed, the schedule time is earlier than the start time of the new order; <p>and</p> <ol style="list-style-type: none"> 4. After clicking "OK" and "Storing" the order, the first 24 hours of pending interventions will be generated. If the problem exists, interventions beyond the first 24 hours will not be generated.
HAZARDS INVOLVED	If the clinical team is solely relying on the ICIP critical care worklist for administration of pending orders, this issue may result in a patient not receiving intended treatment.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>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.XX", where XX is 00, 01, 02 or 03.</p> <p>Alternatively, select HELP ABOUT from the menu bar in the application.</p>
ACTION TO BE TAKEN BY CUSTOMER / USER	<ul style="list-style-type: none"> • Do not rely solely on the worklist within ICIP to determine actionable orders for the patient. • Always use the medication administration record (MAR) in determining patient care. • Always review orders and pending administrations in the administration record after any changes are stored.
ACTIONS PLANNED BY PHILIPS	Philips is developing a software upgrade. A Philips representative will contact you to schedule the implementation of this upgrade when it becomes available. The upgrade will be provided at no charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact <Philips representative contact details to be completed by the KM / country>