



Field Safety Notice

Philips Healthcare

Patient Monitoring

-1/2-

FSN86200855

February 2008

URGENT - Medical Device Correction
CareVue Chart Release C
IntelliVue Clinical Information Portfolio Critical Care Release D

Orders/Interventions Do Not Always Show in the Worklist

Dear Valued Customer:

This letter is to inform you that Philips Healthcare is conducting a voluntary correction of CareVue Chart Release C and IntelliVue Clinical Information Portfolio Critical Care Release D. Our records indicate that you have received affected product. The specific issue is that some orders and/or interventions do not always appear as expected in the Worklist feature of the system. However, system alerts operate properly, so that users will be notified if an order has not been acknowledged, regardless of whether it appears on the Worklist or not.

This issue only occurs in certain instances where the patient order and/or intervention has been entered with both a start and a stop date in the Medication Administration Record (MAR) and Administration Records. It does not occur if only a start date is recorded and the stop date is left blank.

Please see the attached **Device Correction Notice** that provides instructions for actions to be taken. Please follow the "PROCEDURE TO MITIGATE RISK" section of the notice. Currently shipping product is not affected by this action.

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. Correction of this issue is our highest priority. Your satisfaction with Philips' products and with our response to this issue is very important to us. Please contact your local Philips Customer Care Center with questions or concerns about this correction.

Sincerely,

Senior Director, Quality and Regulatory Affairs



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AFFECTED PRODUCTS	CareVue Release C (P/N 862246), Versions C.00.00 through C.00.06 IntelliVue Clinical Information Portfolio Critical Care Release D (P/N 865047), Version D.00.00
PROBLEM DESCRIPTION	Orders and interventions correctly show up on the Medication Administration Record (MAR) and Administration Records (AR) but do not always show in the Worklist feature of the system. This problem occurs only if both a start date and a stop date are entered. If only a start date is entered (and the stop date is left blank) the problem does not occur. However, system alerts operate properly, so that users will be notified if an order has not been acknowledged, regardless of whether it appears on the Worklist or not.
HOW TO IDENTIFY AFFECTED PRODUCTS	The product is identified on the splash screen when the device is turned on (display will indicate CareVue Release C or IntelliVue Clinical Information Portfolio Critical Care Release D). To identify the version, select HELP ABOUT from the menu bar in the application. Note: For IntelliVue Clinical Information Portfolio Critical Care Release D, if the version is D.00.00, contact the Philips Customer Care Center identified below to verify impact to your product.
PROCEDURE TO MITIGATE RISK	Philips recommends that you do not rely solely on the Worklist to remind you when to administer orders/interventions until your software has been upgraded. Additionally, Philips recommends that clinicians frequently review the reminders and verify orders/interventions on the Medication Administration Record and Administration record.
ACTIONS PLANNED BY PHILIPS	Philips is currently developing a software correction that will be available at no additional charge. A Philips representative will notify you when the software correction becomes available
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips Customer Care Center.

