

Customer Information Letter (CIL) Template

Philips Healthcare

Patient Care and Monitoring Solutions

-1/2-

2014 May

Customer Information Medical Device Correction IntelliSpace Critical Care and Anesthesia Release E.O, F.O and G.O

Dear Customer,

A problem has been detected in the Philips IntelliSpace Critical Care and Anesthesia (ICCA) software that, if it were to recur, could lead the user to select a drug concentration that is not typical for the case. This Customer Information is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

Under certain circumstances, a standard intervention row configured for a case template is not the same standard intervention row as what the anesthesia record displays. If the clinician starts an infusion with a concentration that is different than the concentration of the row label, and the clinician does not notice the discrepancy; the calculated dose per time that is documented may not match the actual drug amount being delivered.

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.

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 KM /country>

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Director, Quality & Regulatory Affairs

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AFFECTED PRODUCTS	865209 IntelliVue Clinical Information Portfolio Release E.O 866072 IntelliSpace Critical Care and Anesthesia Release F.O 866148 IntelliSpace Critical Care and Anesthesia Release G.O
PROBLEM DESCRIPTION	<p>Under certain circumstances, a standard intervention row configured for a case template is not the same standard intervention row as what the anesthesia record displays. If the clinician starts an infusion with a concentration that is different than the concentration of the row label, and the clinician does not notice the discrepancy; the calculated dose per time that is documented may not match the actual drug amount being delivered.</p> <p>This will only occur when:</p> <ul style="list-style-type: none"> • Create more than one standard intervention for a particular medication that has different concentrations. • Create more than one Row Family using standard interventions with different concentrations of the drug. • Add one Row Family to one case template and the other row family to another case template. • Configure that the default template is one of the two case templates created. • Start the anesthesia record for a new OR case • Change case template to the 2" case template. • Anesthesia Record shows the standard intervention from the 1st case template instead of the second template as a row. <p>If the clinician starts an infusion with a concentration that does not match what is displayed in the anesthesia record, discrepancies between the dose or rate displayed in the anesthesia record and the dose or rate displayed at the pump will occur.</p>
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 IntelliSpace Critical Care and Anesthesia Release E.O, F.O or G.O"</p> <p>Alternatively, select HELP/ABOUT from the menu bar in the application</p>
ADVICE ON ACTIONS BY CUSTOMER /USER	Review the entire list of standard interventions and their concentrations including the dialog information which will show complete information about the concentration displayed. Review the clinical notes on appropriate usage to be sure the desired concentration is selected.
ACTIONS PLANNED BY PHILIPS	Philips has developed a software upgrade to address this problem. This upgrade is available immediately for ICCA G.O, F.O & ICIP E.O.
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p><Philips representative contact details to be completed by the KM /country></p>