URGENT – Field Safety Notice
IntelliSpace Critical Care & Anesthesia

Revisions D thru G
Base Unit Of Measure, Standard Content, Correction
Software configuration defect may cause an incorrect calculation of medication dosage.

Dear Customer,

A problem has been detected in the Philips IntelliSpace Critical Care & Anesthesia (ICCA) product. 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 to patients, and
- 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.

A software configuration defect has been identified that impacts one Standard Content (configuration that is shipped with the product) unit of measure (gm/m^2). The defect involves an incorrect multiplier in the configuration that causes an incorrect calculation of medication dosage. The error could result in a calculated dose that is 10 times the correct dose.

The following page provides additional instructions and actions that will be taken to address this problem.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Thomas J Fallon
Director, Quality and Regulatory

PHILIPS
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

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AFFECTED PRODUCT	Product: 865047 IntelliVue Clinical Information Portfolio (ICIP), Rev D 865209 IntelliVue Clinical Information Portfolio (ICIP), Rev E 866072 IntelliSpace Critical Care & Anesthesia (ICCA), Rev. F 866148 IntelliSpace Critical Care & Anesthesia (ICCA), Rev. G
PROBLEM DESCRIPTION	A software configuration defect has been identified that impacts one Standard Content (configuration that is shipped with the product) unit of measure (gm/m^2). The defect involves an incorrect multiplier in the configuration that causes an incorrect calculation of medication dosage. The error could result in a calculated dose that is 10 times the correct dose.
HAZARD INVOLVED	If the user does not identify that an incorrect multiplier exists in the Standard Content, a patient may receive a dose of medication that is incorrect (10 times the intended dosage).
HOW TO IDENTIFY AFFECTED PRODUCTS	The product release is identified on the splash screen when the application is launched. Affected product will display the product name and the product revision (ie: Philips IntelliSpace Critical Care & Anesthesia, Revision G.00) Alternatively, select HELP/ABOUT from the menu bar in the application.
ACTION TO BE TAKEN BY CUSTOMER / USER	Implement the instructions outlined in the Mandatory FCO if the BSA (gm/m^2) Standard Content is used in your configuration. Mitigation of this and any potential error will be identified by following the instructions for use for the device, which includes the directions to: • Clinician's Toolkit documentation indicates that Pharmacist should review and approve all formulary related configuration prior to use. Per the Clinician's Toolkit documentation: "Once the hospital Configuration Committee has reviewed the drug calculations, they should also be reviewed by the Pharmacy Department." • Configurations are tested prior to use with patients. • Doses that are outside normal bounds are highlighted in yellow. System will not allow user to enter a dose that is outside the hard bounds. • Always use the medication administration record (MAR) in determining patient care. Always review orders and pending administrations in the MAR.

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ACTIONS PLANNED BY PHILIPS	Philips has initiated a correction to address this issue. A Philips representative will contact you to schedule the implementation of this correction. A software correction will be provided to customers with impacted devices at no charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this problem, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

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