URGENT - Field Safety Notice

Philips IntelliVue Information Center iX (revision A.XX (where XX is 00 to 02) option LAB, PIIC iX revision B.00 option LAB and PIIC iX revision B.0 Enterprise Server (option LAB is bundled)):

Dear Customer,

A problem has been detected with the Philips IntelliVue Information Center iX (PIIC iX) product that, if it were to occur, could pose a risk for patients. Philips has identified a software defect in the Philips IntelliVue Information Center (PIIC) iX when it is used in conjunction with the LAB option.(i.e., option LAB is enabled and configured).

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 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. Please retain a copy of this Notice.

During internal testing, Philips has identified a software defect in the Philips IntelliVue Information Center (PIIC) iX when it is used in conjunction with the LAB option. i.e. option LAB is enabled and configured.

When HL7 lab messages are sent to a PIIC iX system that has been localized for comma delimiters, the lab result is incorrectly displayed on the bedside monitor. An expected delimiter is stripped from the lab value and the number shown is of a higher magnitude than expected. If lab results are incorrect, a clinician may initiate incorrect treatment or delay necessary treatment. This problem only happens when the PIIC iX is configured during set up for regional settings where the delimiter is a comma. The LAB option must be in use, and the workflow utilizes the automatic lab interface displayed at the bedside monitor.

Philips is conducting this voluntary correction to correct the software on affected devices. Please refer to the following pages, which provide 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.

Ensuring that you have the highest quality medical devices, accessories and supporting documentation is our top priority. Your satisfaction with Philips products is very important to us.

Should you have any questions or concerns about this Device Correction, please contact your local Philips representative at <key market add contact info here>.

[redacted]

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Director of Quality & Regulatory Affairs

Attachment

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AFFECTED PRODUCTS	The following products are affected (please note this issue does not affect units localized for use in the United States): Philips IntelliVue Information Center iX (PIIC iX) revision A.XX (where XX is 00 to 02) option LAB, PIIC iX revision B.00 option LAB and PIIC iX revision B.0 Enterprise Server (option LAB is bundled). 866023 option LAB (exclude US) 866024 option LAB (exclude US) 866389 options LAB or 30N or 30S or 30U or 35N or AB3 (exclude US) 866390 options LAB or 30N or 30S or 30U or 35N or AB3 or 13U or 23U (exclude US)
PROBLEM DESCRIPTION	When HL7 lab messages are sent to a PIIC iX system that has been localized for comma delimiters, the lab result is incorrectly displayed on the bedside monitor. An expected delimiter is stripped from the lab value and the number shown is of a higher magnitude than expected. If lab results are incorrect, a clinician may initiate incorrect treatment or delay necessary treatment This problem only happens when the PIIC iX is configured during set up for regional settings where the delimiter is a comma. The LAB option must be in use, and the workflow utilizes the automatic lab interface displayed at the bedside monitor.
HAZARD INVOLVED	Delayed or Incorrect Treatment: If lab results are incorrect, a clinician may initiate incorrect treatment or delay necessary treatment.

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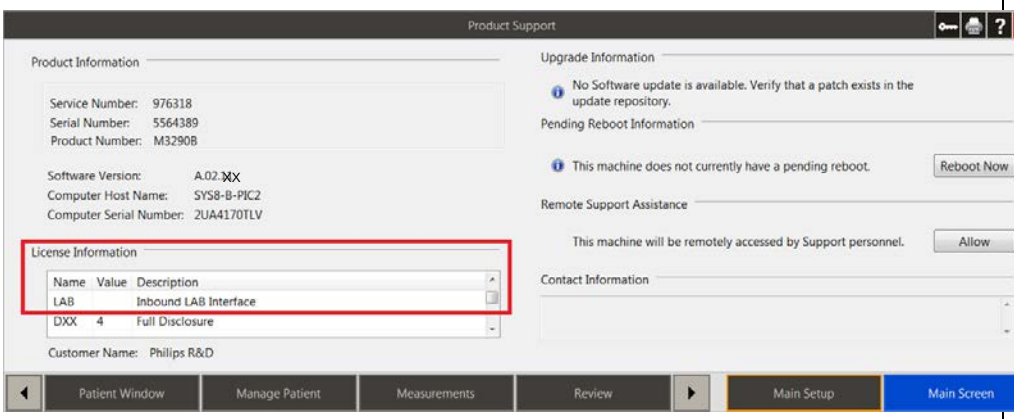
HOW TO IDENTIFY AFFECTED PRODUCTS	PIIC iX Revision – Identify the affected product by clicking on the Philips watermark on the PIIC iX surveillance display. This will bring up the Product Support Page.

This screen shows the licensed features that have been included. All affected units will show the option LAB active in the License Information.



When the LAB option is in use the bedside monitor shows the following screen:

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ACTIONS PLANNED BY PHILIPS	A Philips Healthcare representative will contact customers with affected devices to arrange for the installation of updated PIIX iX software resolving this issue on affected units. Philips will conduct these updates for all affected devices at no charge.
ACTION TO BE TAKEN BY CUSTOMER / USER	To prevent this issue from occurring, customers/users should stop using the LAB feature in the PIIC iX until the software is updated. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment. Contact your local Philips representative if you have a device impacted by this issue.
FURTHER INFORMATION AND SUPPORT	Should you have any questions or concerns about this Device Correction, please contact your local Philips representative at <key market add contact info here>.