URGENT – Field Safety Notice
Philips IntelliVue Information Center (PIIC) iX

Sp02 and/or Non Invasive Blood Pressure (NBP) alarms may become disabled without visual notification to the user

Dear Customer,

A problem has been detected in the PIIC iX, revisions A.00, A.01, and A.02, that, if it were to occur, could pose a risk for patients. 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 the actions planned by Philips to correct the problem.
- 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 with the equipment Instruction for Use.

A software defect has been identified that involves the use of the “Change Bed Label” feature at the Information Center iX. If the configuration for this item is set to “optional” and a user selects the “Location” button within the “Manage Patient” menu and makes a change to the patient location, alarms for Sp02 and/or Non Invasive Blood Pressure (NBP) will become disabled without visual notification (bell with an “X”) to the user. This problem only happens when the patient is monitored using a networked IntelliVue TRx Telemetry M4841/TRx4851A Patient Worn Device (PWD). The predominant harm that is possible involves a drop in oxygenation (hypoxia) that is not immediately detected by the clinician.

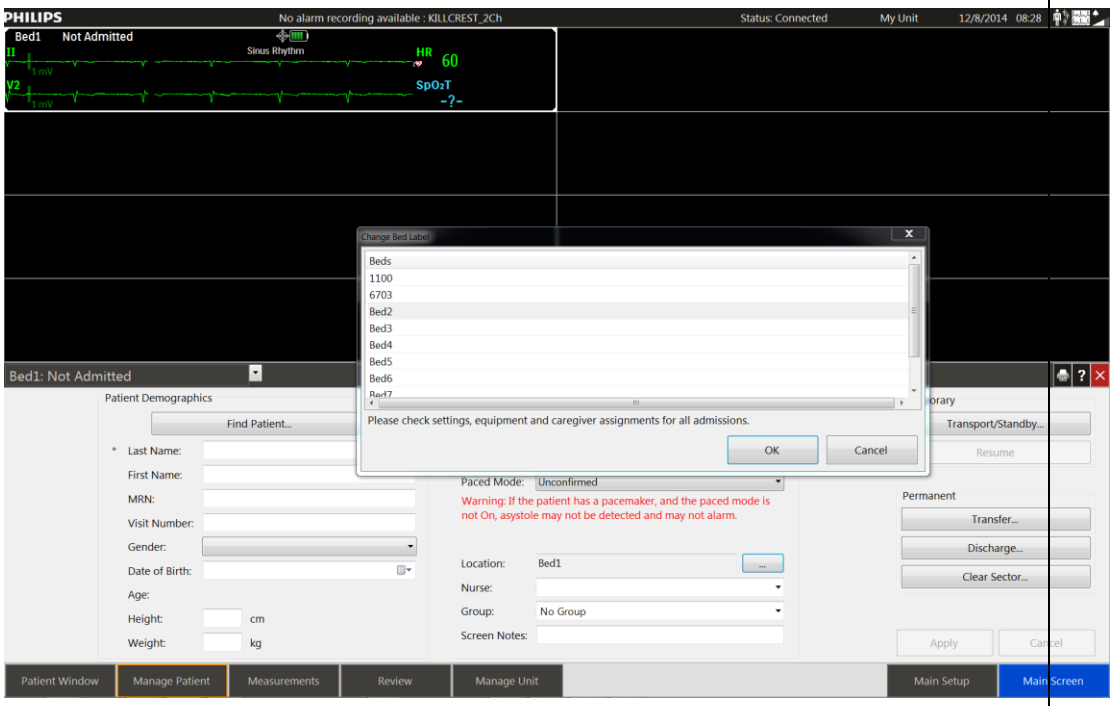
The following page provides additional instructions and actions that will be taken to address this problem.

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 & Regulatory
Connected Care Solutions

AFFECTED PRODUCTS	The below part numbers for PIIC iX, (release A.00, A.01, and A.02) are impacted by this issue: 866023 IntelliVue Info Center iX 866024 PIIC iX Upgrade 866117 PIIC Classic Upgrade
PROBLEM DESCRIPTION	A software defect has been identified that involves the use of the “Change Bed Label” feature at the Information Center iX. If the configuration for this item is set to “optional” and a user selects the “Location” button within the “Manage Patient” menu and makes a change to the patient location, alarms for Sp02 and/or Non Invasive Blood Pressure (NBP) will become disabled without visual notification (bell with an “X”) to the user. This problem only happens when the patient is monitored using a networked IntelliVue TRx Telemetry M4841/TRx4851A Patient Worn Device (PWD). Screen Shot showing Change Bed Label screen 
HAZARD INVOLVED	If alarms are disabled without the anticipated visual notification (bell with an X), a patient may experience a change in condition that is not immediately detected by staff. The predominant harm that is possible involves a drop in oxygenation (hypoxia) that is not immediately detected by the clinician.

HOW TO IDENTIFY AFFECTED PRODUCTS	PIIC iX Revision A.XX – Identify the affected product by clicking on the Philips watermark on the PIIC iX surveillance display. See Figure 1. This will bring up the Product Support Page. Software Version has the release that the product is running. See Figure 2

Figure 1 - Location of the Philips watermark

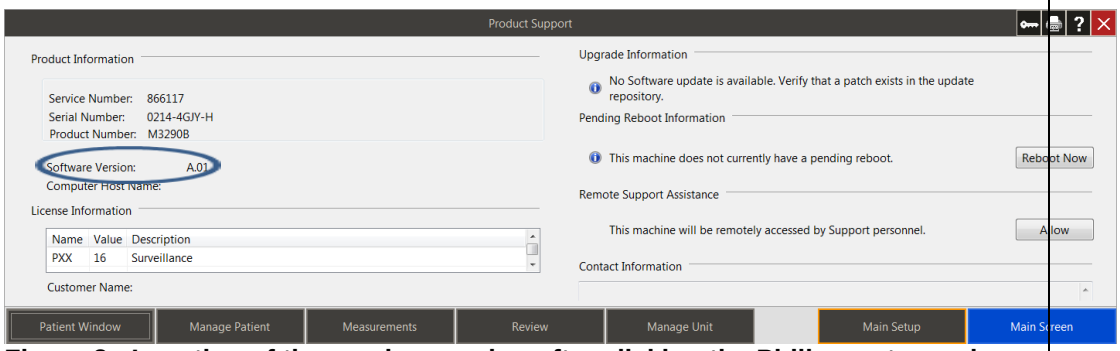
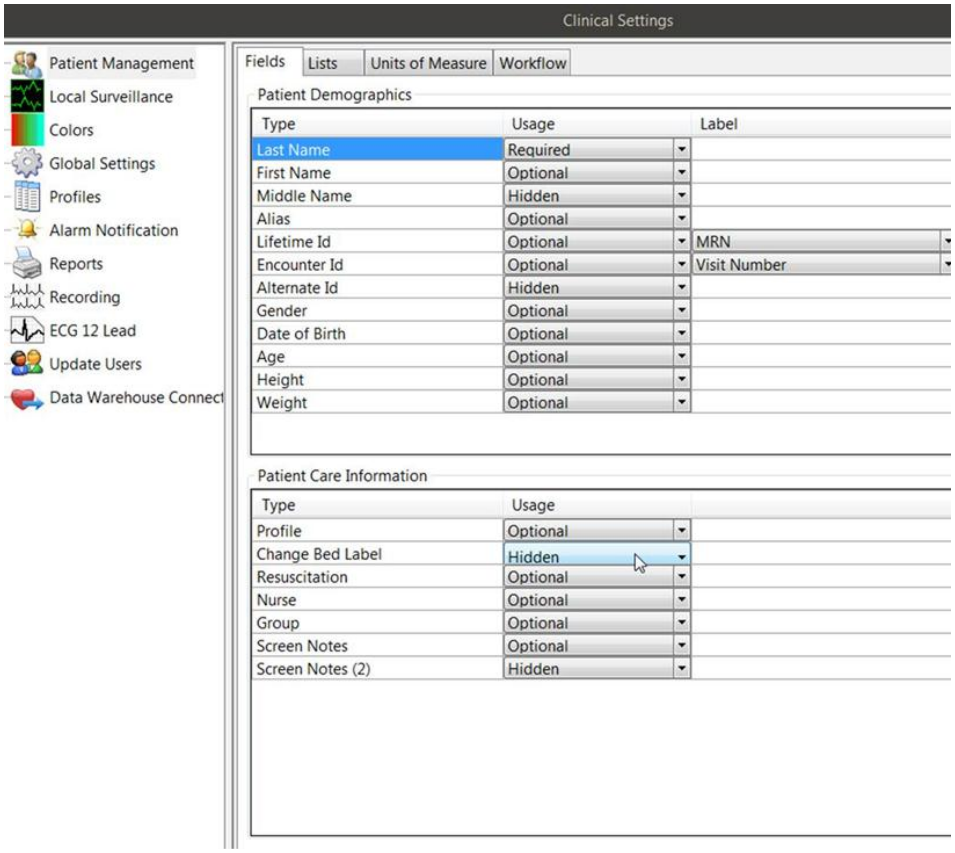


Figure 2 - Location of the version number after clicking the Philips watermark

ACTION TO BE TAKEN BY CUSTOMER / USER	To prevent this issue from occurring, customers/users should: 1) Disable the Change Bed Label field in Patient Management. This is accomplished by changing the feature from 'Optional to 'Hidden' (see capture below) 2) All patient transfers must be performed using the Transfer key in the Manage Patient application.  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.
ACTIONS PLANNED BY PHILIPS	Philips has initiated a correction to address this issue. Contact your local Philips representative if you have a question about any device impacted by this issue. 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 issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.