PHILIPS

[redacted]

22nd Jan 2018

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the IntelliVue Info Center iX due to FCO86201814, 815, 16. Please note that the serial number of the units affected are stated below:

[redacted]

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number). This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

| Acknowledged By: |
| --- |
| Customer Name/Signature: |
| Company Name/Stamp: |
| Date: |

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Reg. No 199705989C

# URGENT - Medical Device Correction
## Philips IntelliVue Information Center (PIIC) iX

**If a PIIC IX application restart occurs in 2018, the surveillance station will no longer perform patient discharge and transfer operations and will restart if those operations are attempted.**

Dear Customer,

A problem has been detected in the Philips IntelliVue Information Center iX that, if it were to occur, could pose a risk for patients or users. 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 with the equipment Instruction for Use.

The restart issue affects all PIIC iX Surveillance and Patient Link iX products. Once a surveillance station is restarted on January 1, 2018 or later, the station will be unable to perform patient discharge and transfer operations. Any subsequent attempt to perform these operations will cause the station to restart, resulting in a short period of loss of monitoring at the Surveillance station during such restart. ***Until this issue can be corrected, users should avoid intentionally restarting their Surveillance stations in 2018.*** Please refer to information below for details.

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>

This notice has been reported to the appropriate Regulatory Agencies, as required.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Kristen Phillips
Head of Quality & Regulatory
Patient Monitoring Andover

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| **AFFECTED PRODUCTS** | All PIIC iX Surveillance stations including:<br>866023 IntelliVue Info Center iX A.0<br>866117 PIIC Classic Upgrade<br>866389 IntelliVue Info Center iX B.0, C.0<br>867141 IntelliVue Info Center iX B.0 |
| **PROBLEM DESCRIPTION** | The issue affects all PIIC iX Surveillance and Patient Link revisions. The issue will occur after a surveillance station is first restarted during the year 2018. After that initial restart, the station will thereafter no longer perform patient Discharge and Transfer operations.<br><br>If any of the following Discharge or Transfer operations are attempted, the operation will not be completed and, instead, the Surveillance Station will restart:<br>• Discharging a patient under certain conditions<br>• Transferring a patient (from bedside or central station)<br>• Resolving patient conflicts (from bedside or central station) where bedside's patient must overwrite PIIC iX's patient (revision B.0x and C.0x only)<br>• Clearing a surveillance sector<br>• Assigning a bed to an empty surveillance sector<br><br>The Surveillance station will continue to monitor patients after any restart. |
| **HAZARD INVOLVED** | Potential harm is delay in treatment due to:<br>- Transient loss of central monitoring during the surveillance station restart. This is most significant for patients monitored through telemetry.<br>- Patient monitoring data not displaying the current patient identification because staff cannot discharge/transfer the previous patient assigned to that sector |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | PIIC iX revision A.0X or B.0X or C.0: Identify the affected product by clicking on the Philips icon on the PIIC iX surveillance display. This will bring up the Product Support Page which identifies the product. |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | To avoid this issue, do not intentionally restart any surveillance stations that have been running normally since the new year.<br><br>You may use the workflows described in attachment "Alternative Workflows for PIIC iX" to avoid operations that may cause the surveillance station to restart.<br><br>When a patient is discharged, confirm that the patient is discharged. |
| **ACTIONS PLANNED BY PHILIPS** | Philips has initiated a correction to address this issue and will provide this software update to customers with affected devices at no charge. Software updates for PIIC iX A.0x and B.0x are expected to be available by January 8th. A Philips Healthcare representative will contact customers with affected devices to arrange for correction of the issue.<br><br>Contact your local Philips representative if you have a question about any device affected by this issue. |

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| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative:<br><Philips representative contact details to be completed by the KM / country> |