

**URGENT - Medical Device Recall
Philips IntelliVue Information Center (PIIC) iX**

Patient discharge, transfer or conflict resolution in combination with dates containing 2018 can cause an application restart of the PIIC iX.

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:

0800 80 3000

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

AFFECTED PRODUCTS	866023 IntelliVue Info Center iX A.0 866117 PIIC Classic Upgrade 866389 IntelliVue Info Center iX B.0, C.0 867141 IntelliVue Info Center iX B.0
PROBLEM DESCRIPTION	<p>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.</p> <p>Subsequent application restarts will occur when any of the following operations are performed:</p> <ul style="list-style-type: none"> • Discharging a patient under certain conditions • Transferring a patient (from bedside or central station) • 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) • Clearing a surveillance sector • Assigning a bed to an empty surveillance sector <p>The Surveillance station will continue to monitor patients after any restart.</p>
HAZARD INVOLVED	<p>The potential harm is delay in treatment due to:</p> <ul style="list-style-type: none"> • Transient loss of central monitoring for telemetry devices during the surveillance station restart • Inability to discharge/transfer patient from surveillance station can cause misidentification of patient data if staff monitors new patients in the same bed
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	<p>To avoid this issue, do not intentionally restart any surveillance stations that have been running normally since the new year.</p> <p>You may use the workflows referenced in attachment "Alternative Workflows for PIIC iX" to avoid further occurrences.</p> <p>When a patient is discharged, confirm that the patient is discharged.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips has initiated a correction to address this issue and will provide this software correction to customers with impacted devices at no charge. Corrections for PIIC iX A.0x and B.0x are expected to be available by January 8th.</p> <p>A Philips Healthcare representative will contact customers with affected devices to arrange for correction of the issue.</p> <p>Contact your local Philips representative if you have a question about any device affected by this issue.</p>

**FURTHER
INFORMATION AND
SUPPORT**

If you need any further information or support concerning this issue, please contact your local Philips representative:

0800 80 3000

Instructions for Alternative PIIC iX Workflows

Alternative Workflow for ReAdmit/Discharge of Patients for PIIC iX B.02, C.0.

This issue can be avoided by performing Re-Admit and Discharge operations from a bedside. Do not use Transfer function – discharge instead.

Monitors can be any IVPM monitor (MX400, MP5, etc.) except MP5SC. Wired or wireless.

Non -Telemetry Units

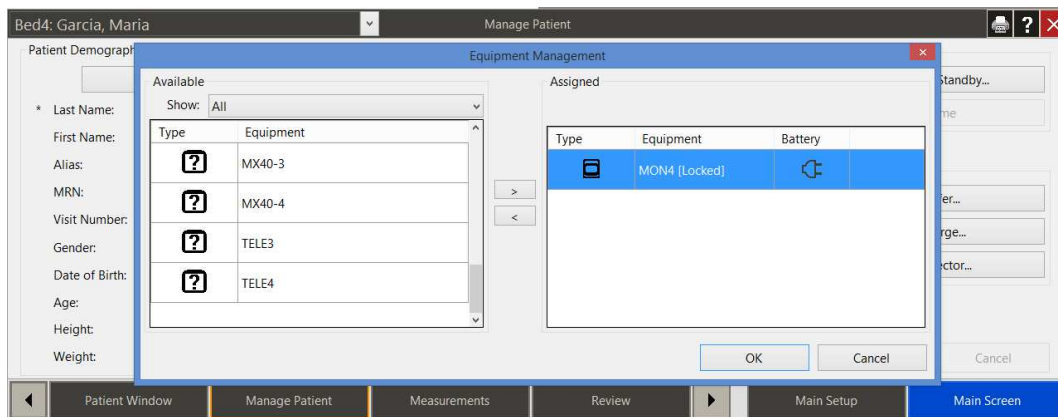
- Do NOT Transfer.
- Do NOT use the X2 to Transfer. Discharge Instead.
- Equipment can be brought to the new unit. Docking an X2 or MMS will bring up a "New Patient" window.
- Say NO to New Patient Question.
- A conflict screen will appear. **ALWAYS choose the PIIC iX Patient**

Telemetry Units

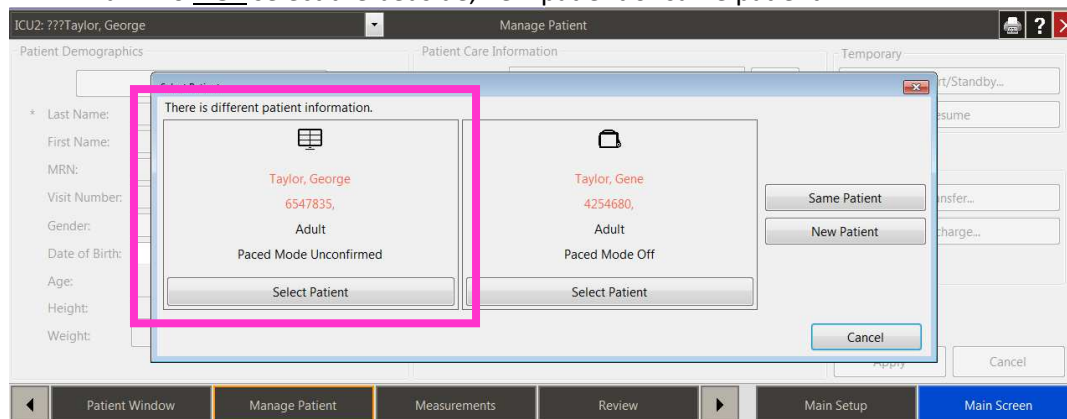
First Step: Add Monitoring Equipment at the PIIC iX

Add monitoring equipment by performing the following steps:

1. Click the bed label from the appropriate patient sector. The Equipment Management dialog box displays with a list of available monitoring devices listed on the left and assigned devices listed on the right.
2. Assign new equipment to this bed, if desired, by selecting the device from the Available equipment list, and then clicking the > button.
3. When you are finished selecting equipment, click the OK button.



4. You will then see a conflict - always select the PIIC iX patient.
 - a. Do **NOT** select the bedside, new patient or same patient.



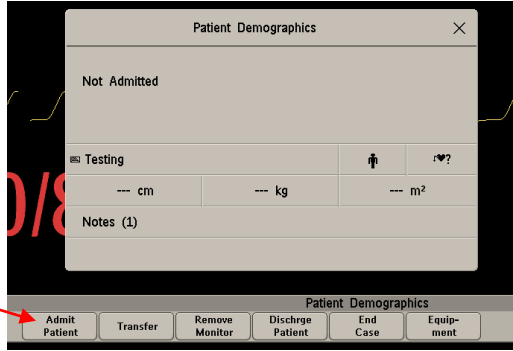
Second Step – Admit/Readmit at the bedside using one of the following:

Process 1: Admitting Patients from the IntelliVue Monitor (IVPM Release J.1 and higher)

1. Select Name field from the top gray line (picture below) or the Equipment or Patient Demographics SmartKey.

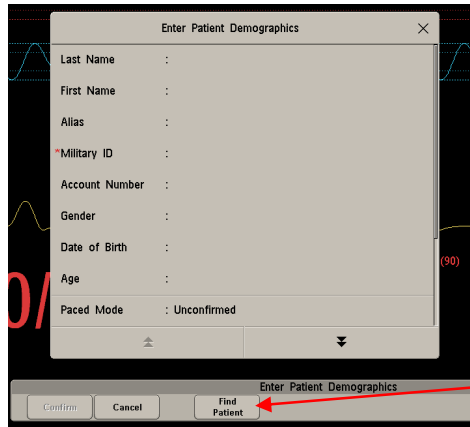


Then select Admit Patient from the pop up key at the bottom.



OR Select the Quick Admit  or Admit Patient  SmartKey.

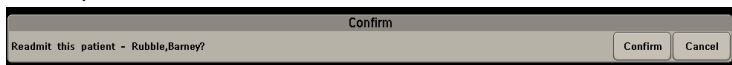
2. Select Find Patient pop up key at the bottom



3. Enter Patient name or ID



4. Choose patient from list. The IntelliVue Monitor will show up to 100 patients. If it is a common name, with multiple admission, you might not see the patient in the list. Using the encounter ID (account number or visit number) to search from makes it easier to find the patient.
5. Select Confirm at bottom to complete the process. (Readmit – patient is not currently admitted to a PIIC iX station.)



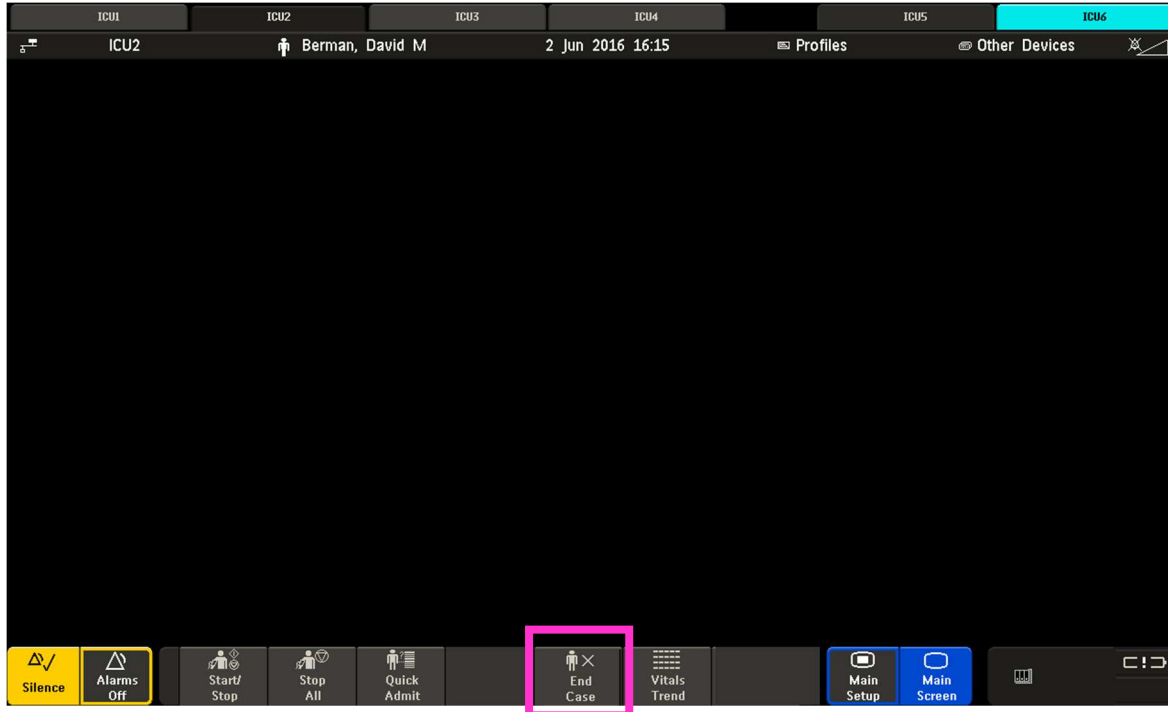
Process 2: Admitting Patients from the IntelliVue Monitor (Release J.1 and higher) using Bar Code Scanners

1. Select the Quick Admit or Admit Patient SmartKey.
2. Scan Armband
3. Select Confirm at bottom to complete the process. (Readmit – patient is not currently admitted to a PIIC iX station. Transfer – patient is currently being monitoring on another PIIC iX station.)

Optional Third Step: Once Admission is complete, you can remove the monitor for next patient use. You will need to add again to Discharge.

Fourth Step: Discharge the patient at the monitor

1. Add the monitor as per First Step. Assure name is showing on the monitor
2. Select either the Discharge or End Case SmartKey.



3. Confirm the discharge at the monitor via the pop up keys.
4. If using an X2 monitor, you will need to:
 - a. Select the gray SmartKey button on the right side
 - b. Select the Discharge or End Case.



5. Remove monitor and use for next patient.

Optional Fourth Step: Change the bed label in the sector

On Surveillance Sectors: Do not clear the sector. Do not attempt to add a bed to an empty sector.

NOTE: An Overview sector can be cleared and reassigned.

Change the bed location in a sector that currently has a bed label and is no longer needed:

1. Open the Manage Patient application.
2. Clicking the Location field ellipsis (...) button. The Change Bed Label dialog box displays a list of available beds in this unit.
3. Highlight the desired bed.
4. Select the OK button.

The screenshot shows the 'Manage Patient' application window. The 'Patient Demographics' section includes fields for Last Name, First Name, Alias, MRN, Visit Number, Gender, Date of Birth, Age, Height (cm), and Weight (kg). The 'Patient Care Information' section includes Equipment (MX40-1), Profile (Adult Enhanced), Category (Adult), Paced Mode (Unconfirmed), Location (Bed 7), Resuscitation, Nurse, Group (No Group), and Screen Notes. A red warning message is displayed: 'Warning: If the patient has a pacemaker, and the paced mode is not On, asystole may not be detected and may not alarm.' The 'Temporary' section has buttons for 'Transport/Standby...' and 'Resume'. The 'Permanent' section has buttons for 'Transfer...', 'Discharge...', and 'Clear Sector...'. The 'Location' field is set to 'Bed 7' and has an ellipsis (...) button highlighted with a pink box. The bottom navigation bar includes 'Patient Window', 'Manage Patient', 'Measurements', 'Review', 'Main Setup', and 'Main Screen'.

Alternative Workflow for ReAdmit/Discharge of Patients for PIIC iX A.02 systems only.

This issue can be avoided by performing Re-Admit and Discharge operations from a bedside. Do not use Transfer function – discharge instead.

Monitors can be any IVPM monitor (MX400, MP5, etc.) except MP5SC. Wired or wireless.

Non -Telemetry Units

Must discharge every patient in this manner.

Once complete, you can Admit and Readmit from the PIIC iX or bedside for that bed at the PIIC iX.

X2s or monitor should not be locked. They do not have to be automatically removed at discharge.

1. Undock X2
2. If X2 is networked, push “Remove Monitor” button at X2
3. Should see No Central Monitoring inop on X2
Discharge patient in X2 while off network.
Redock and resolve conflict to X2 Not Admitted Patient.
4. Ready for new patient

If the patient needs to transfer you must first complete the above process.

If using for X2 transfer:

1. Undock and bring to new unit.
2. Discharge from the X2 monitor PRIOR to dock to new monitor.
3. Dock to new monitor.
4. A conflict screen will appear. Resolve to X2 Not Admitted Patient.
5. **NEVER choose the PIIC iX Patient**
6. Readmit Patient from monitor

If using a monitor without an X2/MMS or a monitor with only an MMS:

1. Disconnect the LAN cable from the monitor.
2. Should see No Central Monitoring inop on the monitor
3. Discharge patient monitor while off network.
4. Reattach LAN cable and resolve conflict to Monitor Not Admitted Patient
5. **NEVER choose the PIIC iX Patient**
6. Ready for new patient.

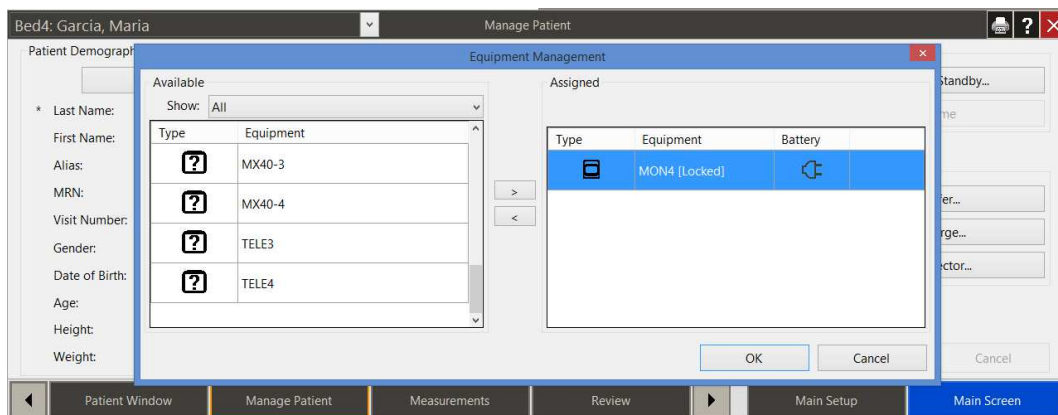
Telemetry Units

Must discharge every patient in this manner.

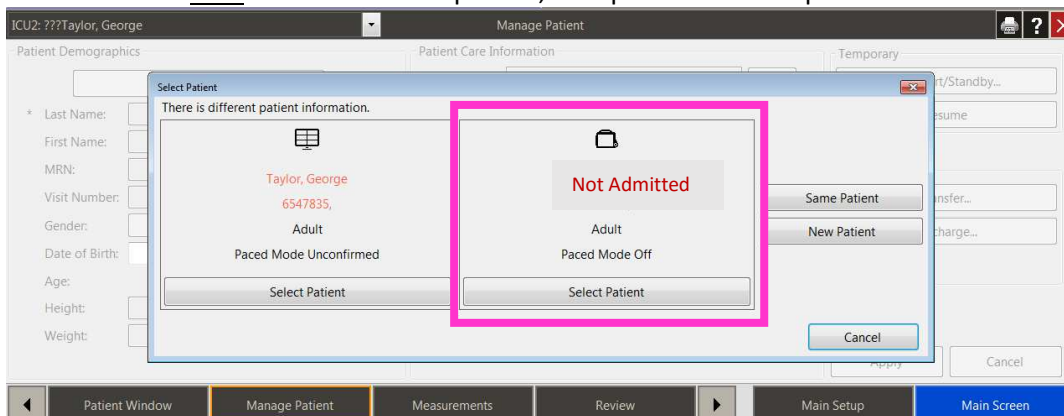
Once complete, you can Admit and Readmit from the PIIC iX.

To discharge a patient

5. Add monitoring equipment by performing the following steps:
 - a. Click the bed label from the appropriate patient sector. The Equipment Management dialog box displays with a list of available monitoring devices listed on the left and assigned devices listed on the right.
 - b. Assign new equipment to this bed, if desired, by selecting the device from the Available equipment list, and then clicking the > button.
 - c. When you are finished selecting equipment, click the OK button.



- d. You will then see a conflict - always select the bedside Not Admitted Patient.
 - a. Do **NOT** select the PIIC iX patient, new patient or same patient.



6. Ready for new patient.

Optional Fourth Step: Change the bed label in the sector

On Surveillance Sectors: Do not clear the sector. Do not attempt to add a bed to an empty sector.

NOTE: An Overview sector can be cleared and reassigned.

Change the bed location in a sector that currently has a bed label and is no longer needed:

5. Open the Manage Patient application.
6. Clicking the Location field ellipsis (...) button. The Change Bed Label dialog box displays a list of available beds in this unit.
7. Highlight the desired bed.
8. Select the OK button.

The screenshot shows the 'Manage Patient' application window. The 'Patient Demographics' section includes fields for Last Name, First Name, Alias, MRN, Visit Number, Gender, Date of Birth, Age, Height (cm), and Weight (kg). The 'Patient Care Information' section includes Equipment (MX40-1), Profile (Adult Enhanced), Category (Adult), Paced Mode (Unconfirmed), Location (Bed 7), Resuscitation, Nurse, Group (No Group), and Screen Notes. A red warning message is displayed: 'Warning: If the patient has a pacemaker, and the paced mode is not On, asystole may not be detected and may not alarm.' The 'Temporary' section has buttons for 'Transport/Standby...' and 'Resume'. The 'Permanent' section has buttons for 'Transfer...', 'Discharge...', and 'Clear Sector...'. The 'Location' field is set to 'Bed 7' and has an ellipsis (...) button highlighted with a pink box. The bottom navigation bar includes 'Patient Window', 'Manage Patient', 'Measurements', 'Review', 'Main Setup', and 'Main Screen'.