**IGT Systems** FSN for FSCA PH4052465 03 Nov 2015

# URGENT - Field Safety Notice

## Allura Xper FD R8.1.15, R8.1.16 and R7.2.8

## Unexpected system movements

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips Allura Xper we have identified a potential issue that may affect the performance of the equipment under certain conditions.

This Customer Information is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

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 Agency

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

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## Unexpected system movements

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| **AFFECTED PRODUCTS** | Allura Xper with release R8.1.15, R8.1.16 and R7.2.8 |
| **PROBLEM DESCRIPTION** | Philips Healthcare has discovered through customer complaints and internal testing that uncontrolled geometry movements can occur when the system is not switched on/off regularly.<br><br>Due to the nature of the problem the user will perceive a gradually increased sluggishness. Upon activation of the IU controls an uncontrolled geometry movement can occur. The uncontrolled movements are immediately stopped upon release of the IU controls. |
| **HAZARD INVOLVED** | User may perceive a gradually increased sluggishness. Upon activation of the IU controls an uncontrolled geometry movement may occur. |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | All Allura Xper systems as mentioned above. The affected systems will be clearly identified by the local Philips Organization. |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | Customers are strongly recommended to regularly restart the system as mentioned in the Instruction For Use (once a day is recommended) to avoid uncontrolled geo movements.<br><br>In the event that the system is not switched on/off regularly and an unintended movement occurs during a procedure patient/bystander safety remains unaffected as follows:<br>-All safety measures such as current sensing, 3D model and bodyguard remain intact avoiding serious harm to patient and bystander.<br>-The unintended movements are immediately stopped upon release of the buttons<br><br>A system reboot will restore normal system operation. |
| **ACTIONS PLANNED BY PHILIPS** | All possibly affected products in the field will be corrected by means of a software upgrade. The correction will be free of charge and Philips will contact all customers for the implementation. Philips Healthcare will actively contact you starting from December 2015. |
| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative:<br><br><Philips representative contact details to be completed by the KM / country> |