**URGENT Field Safety Notice**

**Philips Azurion System R2.2.0, R2.2.1, R2.2.3, R2.2.5 and R2.2.6**

**Potential Loss of X-ray Functionality**

16 March 2023

Dear Distributor,

Philips is initiating a Field Safety Corrective Action due to a problem identified in the Philips Azurion Systems that could pose a risk for patients.

It is imperative that all end users with affected products receive the attached Field Safety Notice that informs about:

* The problem and under what circumstances it can occur
* The actions that the customer/user should take to prevent risk for patients
* The actions planned by Philips to correct the problem

Philips is requesting customers to return a Response Form to acknowledge receipt and understanding of the Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected product.

Together with this letter we are providing a list of affected products that Philips has sold to your organization. As distributor of the affected products, we kindly request that you:

* Submit this Field Safety Corrective Action to the Regulatory Agency when applicable. In case of any inquires from the Regulatory Agency, contact Philips.
* Add in the Response Form attached your contact information.
* Send the attached Field Safety Notice to each customer to whom you have distributed any affected product as soon as possible and no later than 10 days since receipt of this letter, together with the Response Form.
* Perform a good faith effort to get the Response Form by sending two reminders (one of them through a different communication method) and inform Philips about the responses received.
* Implement FCO72200529 to remove the Log Trace Files from the affected systems to free up disk capacity within the timeframe communicated by Philips and confirm Philips the implementation of this FCO. Prioritize these activities based on the time the affected software release has been installed in the affected Philips Azurion systems.
* Implement the Technical solution (reference FCO72200528) established by Philips as soon as available within the timeframe communicated by Philips and confirm to Philips the implementation in all affected products.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact <include contact>.

Sincerely,

<Name>, <Function>, <Signature>