URGENT FIELD SAFETY NOTICE
FSCA 2019-02

Object: FMI kit collimator opening during zoom settings

Date …….

To the attention of
Hospital Administrators, Risk Managers,
Radiology Department Directors and Radiologists

GMM, manufacturer for GE Healthcare of Connexity, as part of continuous improvement of its products, has decided to take action in order to update the SW implemented in Connexity.

Involved product: CONNEXITY
Impacted serial number: 001/101 ,001/103,001/109,001/111,001/112,001/117

Problem Description:
Due to internal investigation at GMM products linked to collimation issues in SW, it has been observed that an update of the device SW is needed.
While performing fluoroscopy with a manual collimator and zoom, it has been evidenced that if the operator commands the collimator opening , the collimator can opens until the maximum detector full size (43x43 cm), but the useful diagnostic image remains equal to the previously selected zoom dimension.
This finding evidenced a bug in the device software that allows the manual opening command even if in zoom mode. This may result, in rare cases, into an overexposure related to the diagnostic image.

Corrective action:
FMI kit has been created for the purpose of being implemented on the impacted installed base.
The kit contains the parts and the instructions necessary to perform the software update that shall fix the abovementioned bug.
A GE Healthcare representative will contact you to arrange the software update.

We outline that, as of today, no event has been reported that has caused damage to property and / or injuries to people due to the event described above.
Nevertheless, action must be taken in order to mitigate potential risks that could affect safety in the future.

Therefore, the provided kit shall be implemented as soon as possible and, in any case, no later than 6 months from the receipt of the present communication.

It is agreed that GMM declines all responsibility in case of lack of implementation of the measures within the indicated timeframe as outlined in the present communication.

If you have any questions regarding this Field Safety Notice or the identification of affected products, please contact local GEHC Sales/Service representative.

GMM confirms that this notice has been notified to the appropriate Regulatory Agencies.
Please be assured that maintaining a high level of safety and quality is our highest priority.

Sincerely,

Monica Sordi
CEO GMM

Luca Bianchessi
Quality & Regulatory Manager GMM

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