GE Healthcare

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To Whom it May Concern:

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Subject: **GE Senographe Essential/DS mammography equipment evaluation after FMI 12142 upgrade**

FMI 12142 applies to Senographe DS and Senographe Essential systems and will bring significant enhancements, such as:

- Software stability enhancement, especially on AUTOPUSH, AUTODELETE and AUTOPRINT functions,
- Stereo features enhancement,
- Enables Utilizatian Reporting, through the web-based iCenter application. It brings critical asset information, provides overview reports to download and detailed exam information to enhance system performance. This offer is only included in some performance service contract (please contact you local service sales representative).

This FMI consists of software and/or hardware upgrades af the several of the major sub-systems of the mammography machine (AWS, IDC, Generator, and Gantry).

According ta the MQSA policy, "Software changes or upgrades are considered by FDA to be major repairs, thus the facility must have a mammography equipment evaluation performed after installation of such a change or upgrade". The FDA also states that if any of the necessary tests after the software upgrade are required to be performed by the medical physicist, the mammography equipment evaluation must be performed in its entirety by the medical physicist on site.

Because of this requirement, we recommend that a medical physicist conducts a complete equipment evaluation after the application of the FMI 12142, by performing the QC tests described in "Chapter 2 QC Tests for the Medical Physicist" from the Quality Control Manual 5305863-6-S-1EN (Senographe Essential)/5305756-4-S-1EN (Senographe DS).

Best Regards,

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