

FDA-Approved Alternative Requirement – GE

Amendment to the Alternative Requirement for the Correction Period When Components of the Senographe™ 2000D Full Field Digital Mammography (FFDM) System Fail Quality Control Tests (Updated 9/11/07)

The following amended alternative standard was approved by the FDA on August 31, 2007 and became effective on the date of approval. (It supersedes Amended Alternative Requirement # 10 which was approved August 25, 2003.) The current amendment adds the Sub-System MTF Measurement test to the quality control tests already listed in the 2003 amendment. The 2003 amendment replaced the specific reference to the GE Senographe™ 2000D FFDM system with a generic reference to an “FDA-approved GE” FFDM system. Like the original standard, it allows a 30 day period for corrective actions following the failure of specified quality control tests by an FDA-approved GE FFDM system. However, it divides into two groups the tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, the review of already acquired images can continue and when the test failure is related to the image review components only, images can continue to be acquired. In approving the amendment, FDA stated that if GE introduces new FFDM systems having QC tests other than what is included in the original or amended standard, the amended alternative standard would not be applicable to such systems.

The amendment to this alternative approved on August 31, 2007 is:

21 CFR 900.12(e)(8): *Use of test results.*

For the image acquisition system

(i) If the test results for the image acquisition system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are acquired using the image acquisition system that failed any of the following tests:

- (1) Monitor cleaning for the acquisition work station (AWS)
- (2) Flat Field Test
- (3) CNR Test
- (4) Phantom Image Quality Test for the AWS
- (5) MTF Measurement
- (6) AOP Mode and SNR Check
- (7) Visual Check List
- (8) Compression Force Test
- (9) Average Glandular Dose
- (10) Post-move, Pre-examination Tests for a mobile FDA-approved GE FFDM
- (11) Sub-System MTF Measurement

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(B) Before any further films of mammographic images are printed or processed using the component of the FDA-approved GE FFDM equipment that failed any of the following tests:

- (1) Phantom Image Quality Test for the Printer
- (2) Viewbox and Viewing Conditions Test
- (3) Printer QC

(C) Within 30 days of the test date for the following tests:

- (1) Repeat Analysis
- (2) Collimation Assessment
- (3) Evaluation of Focal Spot Performance
- (4) Exposure and mAs Reproducibility
- (5) Artifact Evaluation; Flat Field Uniformity
- (6) kVp Accuracy and Reproducibility
- (7) Beam Quality Assessment (Half-Value Layer Measurement)
- (8) Radiation Output
- (9) Mammographic Unit Assembly Evaluation

For the image display system

(ii) If the test results for the image display system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are reviewed or any films are printed or processed using the component of the image display system that failed any of the following tests:

- (1) Monitor cleaning for the review workstation (RWS)
- (2) Viewing Conditions for the RWS (Radiologic Technologist's test)
- (3) Viewing Conditions Check and Setting (Medical Physicist's test for the RWS)
- (4) Phantom Image Quality Test for the RWS
- (5) Phantom Image Quality Test for the Printer
- (6) Viewbox and Viewing Conditions Test
- (7) Monitor Calibration Check (Radiologic Technologist's test for the RWS)
- (8) Image Quality—SMPTE Pattern (Medical Physicist's test for the RWS)
- (9) Printer QC

(B) Within 30 days of the test date for the following tests:

- (1) Monitor Calibration (Medical Physicist's test for the RWS)
- (2) Analysis of the RWS Screen Uniformity.