

FDA-Approved Alternative Requirement-Giotto

Correction Period When Components of the Giotto Full-Field Digital Mammography (FFDM) System Fail Quality Control Tests

On January 25, 2012, the FDA approved an Alternative Standard regarding the time period allowed for corrective action to be taken for the Giotto 3D-3DL FFDM system, if certain quality control test results fall outside of specified action limits. The time period depends on the particular test which fails and also on whether the test pertains to the image acquisition system or the image display components. This division makes it clear that when the test failure is related to the acquisition of images only, image acquisition must cease until the problem is corrected but image interpretation can continue. Similarly if the test failure is related to the interpretation of images, image acquisition can continue but image interpretation with the failed component must cease until the problem is corrected. The Alternative Standard is described below. **[This alternative standard only applies to Annual Surveys and routine QC; it does not apply to Equipment Evaluations.]**

The original standard is 21 CFR 900.12(e)(8)(ii), which states:

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

(ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests, described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;

(B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

The approved alternative is:

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

(ii) If the test results for the Giotto Image 3D-3DL Full Field Digital Mammography imaging system, fall outside the action limits, *the source of the problem shall be identified and corrective actions shall be taken:*

A) If any of the quality control tests that evaluate the performance of the image acquisition system fail any of the following tests as defined in the Giotto Image 3D-3DL Quality Control Procedures, the source of the problem shall be identified

and corrective action shall be taken before any further examinations are performed using that component:

1. Daily Check
2. Phantom Image Quality
3. Automatic Exposure Control (AEC), Signal-to-Noise Ratio (SNR) and Contrast-to-Noise Ratio (CNR)
4. Compression Force
5. Spatial Resolution
6. Detector Response Function and Noise Evaluation
7. Ghost Factor
8. Flat Field Homogeneity
9. Mean Glandular Dose (MGD)
10. Inactive Border at Chest Wall
11. Post-Move and Pre-Examination tests for Mobile Giotto 3D-3DL systems

B) Before any further mammographic images are processed, interpreted or printed using the component of the imaging system that failed any tests as specified by the manufacturer as defined in the Giotto Image 3D-3DL Quality Control Procedures. Clinical imaging may be continued. If available, an alternative approved diagnostic device may be used for mammographic image interpretation:

1. Phantom Image Quality
2. Display System
3. Viewbox Luminance
4. Laser Printer Quality

C) If any of the following quality control tests that evaluate the performance of the X-ray unit or the exposure function or the diagnostic device used for mammographic image interpretation produce results that fall outside the action limits as specified by the Giotto Image 3D-3DL Quality Control Procedures, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period:

1. Collimation Assessment
2. AEC reproducibility
3. Artifact Evaluation
4. kVp Accuracy Reproducibility
5. Beam Quality (HVL)
6. Tube Output
7. Exposure Time
8. Repeat/ Reject Analysis