# FDA-Approved Alternative Requirement – Planmed

## Correction Period When Components of the Planmed Nuance and Nuance Excel Full Field Digital Mammography Imaging System Fail Quality Control Tests

FDA approved this alternative standard approved on October 18, 2011. It allows a 30-day period for corrective actions following the failure of specified quality control tests by the Planmed Nuance and Nuance Excel full-field digital mammography imaging system. The specified tests are equivalent to quality control tests for screen-film systems for which a 30-day correction period is already allowed. The alternative standard specifies the quality control tests whose failures require 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, image acquisition must cease until the problem is corrected but image interpretation can continue. Similarly if the test failure is related to devices used for image interpretation, image acquisition can continue but image interpretation with the failed component must cease until the problem is corrected. The alternative was approved for an indefinite period.

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 Planmed Nuance or Nuance Excel 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 Planmed Nuance and Nuance Excel 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) Modulation Transfer Function (MTF) Test

(2) Phantom Image Quality Test for AWS and RWS
(3) Signal-to-Noise and Contrast-to-Noise Measurements
(4) Compression Force Test
(5) Monitor Cleaning for AWS and RWS
(6) Linearity / Noise Linearity Test
(7) Small and Large Focus Calibration
(8) Signal Homogeneity Test
(9) Automatic Exposure Control (AEC) Test

(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 Planmed Nuance and Nuance Excel Control Procedures. Clinical imaging may be continued. If available, an alternative approved diagnostic device may be used for mammographic image interpretation:
(1) Printer quality control test
(2) Viewbox and Viewing Conditions
(3) Monitor Quality Test for AWS and RWS

(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 Planmed Nuance and Nuance Excel 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) Mammographic Unit Assembly Evaluation
(2) Uncorrected Defective Elements
(3) Beam Quality Assessment – HVL Measurement
(4) Visual Checklist
(5) Repeat Analysis
(6) Defect Acceptance Test
(7) Ghosting Test
(8) Breast Entrance Exposure and Average Glandular Dose
(9) System Fault Report