Appendix A: Quality Control Procedures

Compliance Guide - Quality Control for Laser Imagers Used in Digital Mammography Systems

These Quality Control Procedures are intended to provide guidance for mammography facilities and their personnel. They represent the equipment manufacturer’s views on the appropriate procedures for conducting Quality Control tests for digital mammography and observing the Mammography Quality Standards Act (MQSA). The following procedures represent acceptable ways of doing the tests, but unlike regulations, they are not binding. Alternate procedures may be used if they satisfy the requirements of the applicable statute, regulations or both. It is the responsibility of the mammography facility to read, understand and follow the regulations. Under its own authority, a state may impose requirements more stringent than those imposed in the FDA Mammography Quality Standards Act. A facility should check with state or local authorities regarding their requirements.

Automatic Image Quality Control and the QC Process

The Kodak DryView 8900 Laser Imager has a built-in Automatic Image Quality Control (AIQC) system that automatically compensates for film lot variations, ensuring consistent print densities. The MQSA requires that the mammography facility establish a quality control (QC) process that verifies the effectiveness of the AIQC system. Kodak’s recommendations below are based on the MQSA and the QC process described in the Radiologic Technologist’s Section of the Mammography Quality Control Manual, 1999, published by the American College of Radiology. This QC process has been adapted to apply to the special features of Kodak DryView Mammography Laser Imaging Film and the characteristics of the 8900 Laser Imager. The procedures that follow assume that the user has been trained in operation of the 8900 Laser Imager.
Quality Control Procedures

Running a QC Baseline Test

Per the MQSA, a baseline test must be run when the 8900 is first installed and must be repeated every time a box of film with a different emulsion number is used. This test sets up a baseline set of film parameter values that shall be used as a standard for comparison in daily quality control tests. Kodak recommends the procedure described below as a means of complying with this regulation.

Procedure for the Installing Field Engineer

The installing field engineer verifies that the 8900 meets its performance specifications, runs the baseline test described below, and prints a clinical image of the site’s choice. The site’s responsible healthcare professional is asked to approve that the 8900 produces an acceptable clinical image. If the image is not acceptable, the field engineer repeats his procedures until the settings for the baseline print produce acceptable clinical images.

Procedure for the QC Technologist

After an acceptable installation, the user facility’s technologist must repeat the baseline test whenever a change occurs in film lot number.

NOTE: The following is an example of a film lot number: 020662-0211-A-019. The film emulsion number is underlined.

Baseline Test

1. Apply power to the 8900 and allow it to warm to READY, as indicated on the local panel. Request a Calibration Test Print (see “Requesting a Calibration Test Print” on page 3-19) to put its Automatic Image Quality Control (AIQC) system in control.

2. Print two QC Step Wedge test films (see “Requesting a QC Step Wedge” on page 3-20). See the figure on the next page for a sample step wedge.

3. Using a densitometer, read and record the density of each step (1 through 21) on each of the two test films. (For consistency from film to film, always read density at the center of each wedge.) The QC Step Wedge is positioned on the film to allow for the use of an automatic densitometer such as the X-Rite Model 391 Densitometer for automatic density recordings.

NOTE: You can choose to use a clear area on the test films instead of the actual step 1 area to take the “step 1” density reading.

4. Determine and record the average of the two densities read for each step.

5. Select from the average values calculated from the 21 steps to
determine the film parameter values as follows:
a. Determine which step has a density closest to 2.20. Then determine which step has a density closest to but not less than 0.45. Designate the difference between these densities as Density Difference (DD).
b. Determine which step has an average density closest to but not less than 1.20. Designate this step as Medium Density (MD).
c. Designate the average for Step 1 (or the clear area on the film) as Base Plus Fog.
d. Record the numeric values of DD, MD and Base Plus Fog on the center lines of the laser imager QC Chart. See the Quality Control Chart on the next page. Record also the step numbers involved.
### LASER IMAGER QUALITY CONTROL CHART

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<tr>
<th>Month</th>
<th>Date 1</th>
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<th>Date 3</th>
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<tr>
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<td>Step x</td>
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<tr>
<td>Base Plus Fog</td>
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**Remarks**

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**Quality Control Chart**

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A-4 5E6155 January 10, 2006
Running a Daily QC Test

The MQSA requires that a sensitometric test be run daily and that clinical images be made only when the control chart is within the control ranges. Kodak recommends the following laser imager test. Perform this test daily before clinical mammograms are performed, to ensure quality output. Plot the values obtained from the test on the chart for comparison with the film parameter values established in the baseline test.

1. Apply power to the 8900 and allow it to warm to READY, as indicated on the local panel. Request a Calibration Test Print (see “Requesting a Calibration Test Print” on page 3-19) to put the Automatic Image Quality Control (AIQC) system in control.

2. Print a QC Step Wedge film per the procedure on page 3-20 of this User Guide.

3. Use a densitometer to read the designated steps on the test film. Read at the center of each step. If a clear area on the film was used instead of the step 1 area in the baseline tests (see “Baseline Test” on page A-2), use a clear area in this QC test.

4. Record the date on the chart. Then plot the DD, MD, and Base Plus Fog values in the appropriate column on the chart.

5. Determine if any of the values exceeds the control limits for the parameter.

NOTE: The numbers above and below the center lines on the chart indicate the control limits. For example, for DD or MD, 0.10 above or below the center line is approaching the limit, but is acceptable. However, 0.15 above or below the line is not acceptable.

6. If the values did not exceed a control limit, examine the chart and see if there is a trend that suggests possible future problems. (This could be, for example, three or more data points for DD, MD or Base Plus Fog in succession moving upward or downward.) If the data points have not exceeded the limits, clinical mammograms can continue to be run.

7. If any value exceeds a control limit, DO NOT run clinical mammograms until the problem is corrected. Proceed as follows:
   a. Circle the out of control point(s) on the chart.
   b. Correct the problem. The fault could be in the film, imager or densitometer, or in the performance of the QC procedure.
c. Note the cause of the problem in the "Remarks" section of the chart.

d. Repeat the step wedge test and graph the parameters on the chart.