This manual describes detailed procedures in order to implement QC when the Digital Breast Tomosynthesis Option with an ASPIRE Cristalle FDR mammography system is used. Before using this product, be sure to read this Manual thoroughly. After reading this Manual, store it nearby so that you can refer to it whenever necessary. Please also read “Aspire Cristalle Quality Control Program Manual (897N120255*)”, “FDR MS-3500 Operation Manual (897N120114*)”, “FDR-3000AWS Operation Manual (897N120099*)”, “FDR Mammography QC Software Operation Manual (897N102528*, 897N120738*)” and “1 Shot Phantom M Plus 24×30 Operation Manual (897N120635*)".

FUJIFILM Corporation
## Revision history

<table>
<thead>
<tr>
<th>Version</th>
<th>Update</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>2016/03</td>
<td>New document</td>
</tr>
<tr>
<td>1.1</td>
<td>2016/06</td>
<td>Revised based on the comments from FDA</td>
</tr>
</tbody>
</table>
Introduction

The ASPIRE Cristalle Digital Breast Tomosynthesis Option Quality Control Program Manual (the “Manual” hereafter) provides the procedures for quality control and constancy test, technical explanation and other information necessary for managing the quality of the ASPIRE Cristalle Digital Breast Tomosynthesis Option.

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1 Quality Control

This Manual provides information required for a facility using the ASPIRE Cristalle FDR mammography system and ASPIRE Cristalle Digital Breast Tomosynthesis Option to maintain an effective QA & QC program and meet the requirements of the MQSA regulations and Fujifilm Corporation.

For details of quality management, see Chapter 1 of the FFDM QC program guidebook, "ASPIRE Cristalle Quality Control Program Manual" (the “2D QC Manual” hereafter).

This Manual contains QA and QC related to the ASPIRE Cristalle Digital Breast Tomosynthesis Option (the DBT QC Manual) functions. FFDM 2D QC testing must be performed and accepted before proceeding to DBT Option QC testing.

Detailed instructions for carrying out quality control (e.g. when and who carries out quality control) are established as a quality assurance program. In addition to quality control techniques, training for providing adequate information on quality control is included so that any quality assurance program may be effectively implemented.

Always follow applicable laws and regulations for your jurisdiction. If anything in this manual is in conflict with applicable laws or regulations, the applicable law or regulation shall take precedence.

Tests for quality control are called performance tests. There are three types of performance tests, acceptance test, constancy test and status test, depending on their purpose or implementation frequency.
2 Overview

2.1 Product Outline

QC test categories

- Weekly Test............................. Visual inspection with ACR Mammography Accreditation Program Phantom (ACR MAP Phantom) and PMMA 20 mm
- Quarterly Test......................... Repeat analysis
- Annual Test............................. Quantitative/Visual inspection

Comprehensive quality control on the FDR mammography system can be ensured by conducting these periodical tests and validating the results.

Test categories and their implementation frequencies

The QC test items are categorized by the required implementation frequency. The test categories, their implementation frequency and personnel responsibilities are as shown below.

<table>
<thead>
<tr>
<th>QC Installation*</th>
<th>QC Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Value Measure</td>
<td>3 months</td>
</tr>
<tr>
<td>Equipment Condition Check</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mammography Equipment Evaluation (MEE) (Medical Physicist)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekly Test (Technologist)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quarterly Test (Technologist)</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Test (Medical Physicist)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Points to be noted

- For ASPIRE Cristalle systems with the DBT Option and with established 2D and DBT QC programs, always perform and accept the ASPIRE Cristalle 2D QC prior to performing any digital breast tomosynthesis QC tests.
- When the ASPIRE Cristalle and the DBT Option are installed at the same time, perform and accept the 2D installation and baseline value setting tests first, before the DBT installation and baseline value setting tests.
- When the DBT Option is added to an existing ASPIRE Cristalle 2D system within six months of a mammography equipment evaluation (MEE), the DBT Option QC installation and baseline value setting may be performed without repeating the 2D annual testing. However, at the next annual test of the ASPIRE Cristalle 2D, both 2D and DBT Option QC operations tests must be performed to establish the next annual test schedule.
When implementing the QC Program

- Weekly Test
- Quarterly Test
- Quarterly Test
- Quarterly Test
- Annual Test
- Quarterly Test
- Quarterly Test
- Quarterly Test
- Annual Test
- Quarterly Test

## QC Test Items

### Weekly

<table>
<thead>
<tr>
<th>Section</th>
<th>Test Items</th>
<th>Contents</th>
<th>Baseline</th>
<th>QC software</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5</td>
<td>Weekly ACR MAP Phantom</td>
<td>Score of the ACR MAP Phantom, Check the variation of the mAs and S-value</td>
<td>•</td>
<td>N/A</td>
<td>Technologist</td>
</tr>
<tr>
<td>4.6</td>
<td>Weekly Homogeneity</td>
<td>Visual Inspection(Homogeneity, Artifact)</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

### Quarterly

<table>
<thead>
<tr>
<th>Section</th>
<th>Test Items</th>
<th>Contents</th>
<th>Baseline</th>
<th>QC software</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Repeat Analysis</td>
<td>Calculate data for analyzing the rejected images.</td>
<td>N/A</td>
<td>N/A</td>
<td>Technologist</td>
</tr>
</tbody>
</table>

### Annual

<table>
<thead>
<tr>
<th>Section</th>
<th>Test Items</th>
<th>Contents</th>
<th>Baseline</th>
<th>QC software</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.4</td>
<td>X-ray field at chest wall edges</td>
<td>Check the gap between the X-ray field and the light field.</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>6.5</td>
<td>Missed tissue at chest wall side</td>
<td>Check for missed tissue on chest wall edge</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>6.6</td>
<td>In-plane resolution</td>
<td>Check the Spatial Resolution</td>
<td>N/A</td>
<td>N/A</td>
<td>Medical Physicist</td>
</tr>
<tr>
<td>6.7</td>
<td>AEC performance</td>
<td>Check the SDNR under the AEC</td>
<td>N/A</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>6.8</td>
<td>AGD</td>
<td>Check the AGD under the AEC</td>
<td>N/A</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>6.9</td>
<td>Short term reproducibility</td>
<td>Check the variation of the SNR, mAs, S-value</td>
<td>N/A</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>6.10</td>
<td>Z-resolution</td>
<td>Check the variation of the FWHM</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE**
Reconstruction processed images will be used for image evaluation.
(Projection images will not be used for image evaluation.)
## 2.2 Tools

<table>
<thead>
<tr>
<th>No</th>
<th>Tools</th>
<th>Weekly Test</th>
<th>Annual Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Report Form*</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>2</td>
<td>Tomo QC Calculation Tool**</td>
<td>N/A</td>
<td>•</td>
</tr>
<tr>
<td>3</td>
<td>ACR MAP Phantom</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>4</td>
<td>PMMA phantoms (Weekly; 24×30 cm, thickness; 20 mm) (Annual; 24×30 cm, thickness; 10, 10, 10, 20, 40 mm)</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>5</td>
<td>X-ray ruler or Coins (4 items of known sizes) with Mammography Cassettes (2 cassettes of 24×30 cm)</td>
<td>N/A</td>
<td>•</td>
</tr>
<tr>
<td>6</td>
<td>1 Shot Phantom M Plus 24×30 (hereinafter referred to as “1 Shot Phantom 24×30”)</td>
<td>N/A</td>
<td>•</td>
</tr>
<tr>
<td>7</td>
<td>Aluminum plate for SDNR measurement (10×10 mm, thickness 0.2 mm, purity &gt;99%)</td>
<td>N/A</td>
<td>•</td>
</tr>
<tr>
<td>8</td>
<td>Aluminum plates for half value layer measurement (thickness; 0.5 and 0.6 mm, purity &gt;99%)</td>
<td>N/A</td>
<td>•</td>
</tr>
<tr>
<td>9</td>
<td>Dosimeter</td>
<td>N/A</td>
<td>•</td>
</tr>
<tr>
<td>10</td>
<td>Lead sheet or other component that can block X-rays</td>
<td>N/A</td>
<td>•</td>
</tr>
</tbody>
</table>

**NOTE**

* Quarterly Tests do not require tools. Only the Report Form is used.

** The Tomo QC Calculation Tool cannot be used on an AWS computer. Separate from an AWS computer, prepare and use a computer that satisfies the following specifications.

- Windows 7 Professional (32bit) English version
- Intel ® Core™ i3-4160 (3.6 GHz)
- Memory- 4GB DDR3 SDRAM
- 500GB HDD (SATA/600, 7200rpm)
- A USB connection or optical-drive reading slot must be available.
- Monitor resolution of 1024 × 768 pixels or greater

## 2.3 Others

- When you use AEC, use the mode typically used clinically.
- When you use the compression plate, use the 24x30 compression plate (High) used in baseline value setting.
- During a Tomo test, grid and magnification are not performed.
- When you use the “RAW batch output” function of AWS, you must use the “Tomo Max4.0 mammography” menu.
- Manage the RAW batch output images at your own discretion.
- Manage calculation results, judgment results, and other QC data according to local or governmental regulation.
3 Baseline value setting

Confirming the condition at the time of installation

Status check at installation

Before checking the Tomosynthesis function in accordance with this document, assure that the FFDM function meets the performance in accordance with the 2D QC Manual.

Conduct all of the test items provided in this Manual except for repeat analysis to check the equipment conditions at the time of program installation. This will help correct a test item judged as [Fail] in a future QC test by providing the baseline data for comparison.

Conduct the tests several times when installing the Program and set the averages of the measured values as the baseline values. Refer to the section “2.2 QC Test Items” for items that require Baseline value, Conduct tests in the order of their potential influence on displayed images.

NOTE

When a new equipment or system is installed or existing equipment is remodeled, perform the procedures of Baseline Value Settings.

The criteria should be specified on your own responsibility based on the measurement results obtained at the time of the Program installation.

Points to be noted

• Baseline values vary depending on the exposure environment.
• Measurements must be conducted several times under uniform conditions to specify the baseline values.
• It is recommended to specify the baseline values in the order of Annual Test → Weekly Test, according to their potential influence on images.
• It is recommended to save image data based on which baseline values are determined to later confirm that weekly and annual tests have been conducted properly.
4 Weekly Test

4.1 Test Flow
Weekly test is performed:

1) Weekly by the Technologist
2) Annually by the Medical Physicist during the Medical Equipment Evaluation (MEE) and subsequent Annual testing.

Weekly Test is comprised of constancy tests and performance verification tests of the system. The constancy tests are designed for determining if variations of regularly-measured system performance values are within the allowable range (criteria) based on baseline values that were established at the time of QC program / system installation. The performance test is intended to check that system performance values are within the upper or lower limits specified by the baselines. It is necessary to determine the criteria before conducting the Weekly Test.

NOTE
When conducting a Weekly Test for the first time after setting the criteria, specify the baseline values to be used in the future Weekly Tests.
In subsequent Weekly Test procedures, check that the variation from the specified baseline values are within criteria.
4.2 Test Items

<table>
<thead>
<tr>
<th>Test Items</th>
<th>Contents</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekly ACR MAP Phantom</td>
<td>Fibers</td>
<td>4 or more, ≤ Baseline value ± 0.5</td>
</tr>
<tr>
<td></td>
<td>Specks</td>
<td>3 or more, ≤ Baseline value ± 0.5</td>
</tr>
<tr>
<td></td>
<td>Masses</td>
<td>3 or more, ≤ Baseline value ± 0.5</td>
</tr>
<tr>
<td></td>
<td>mAs</td>
<td>≤ Baseline value ± 15%</td>
</tr>
<tr>
<td></td>
<td>S value</td>
<td>≤ Baseline value ± 20%</td>
</tr>
<tr>
<td>Weekly Homogeneity</td>
<td>Visual inspection</td>
<td>There shall not be any artifact or density unevenness that influences diagnosis.</td>
</tr>
</tbody>
</table>

4.3 Tools

Tools to be used for the Weekly Test based on this Manual are shown below.

- Report Form
- ACR MAP Phantom
- PMMA Phantom (20 mm)

4.4 Criteria Confirmation and Determination

Weekly ACR MAP Phantom requires the baseline setting:
Expose the ACR MAP phantom a minimum of 3 times and derive the average from the calculated results to determine it as the baseline value.
4.5 Weekly ACR MAP Phantom

4.5.1 Procedure

Exposure of the evaluation image (including determination of the exposure conditions)
1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo ACR MAP Phantom”, and then press “Start exam”.
3. Position the ACR MAP Phantom at the lateral center along the chest wall-side edge of the exposure table.

4. Lower the compression plate to lightly compress the ACR MAP Phantom.

TIP
Make sure that no excessive pressure is applied to the Phantom. The compression plate may be scratched.

TIP
• Use the 24×30H cm compression plate.
• Always the same compression plate used at the time of baseline value setting.
• Do not use the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS).

5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Perform Tomosynthesis exposure.
7. Record the exposure conditions on the report form.

Implementation of visual inspection
8. In AWS, check the reconstructed image. Display the image using pixel-for-pixel display, search for the slice with the best focus for each evaluation item of the ACR MAP Phantom, and then list it on the report form. (Example: 40th slice image)

TIP
To determine the most focused slice, visually select a slice and scroll 1mm up and down to confirm selection.
9. Perform the visual inspection.
10. Record the evaluation results on the report form.

**NOTE**
When there is concern that it is not possible to carry out an appropriate visual inspection of all items with 1 slice image, use slices lower and upper as well.
It is recommended to perform score evaluation and to confirm that no artifact is present in all the slice images to be reconstructed.

### 4.5.2 Test Result Evaluation and Judgment
1. Evaluate and judge the Weekly ACR MAP Phantom Test results. If all items are judged as [Pass], this test is finished.
2. If there is an item judged as [Fail], take corrective actions by following “4.5.3. Performance Criteria and Corrective Action”.

### 4.5.3 Performance Criteria and Corrective Action
**Performance Criteria**
1. Fibers = 4 or more, ≤ Baseline value ± 0.5
2. Specks = 3 or more, ≤ Baseline value ± 0.5
3. Masses = 3 or more, ≤ Baseline value ± 0.5
4. mAs; ≤ Baseline value ± 15%
5. S value; ≤ Baseline value ± 20%
Check points

- Is the exposure menu appropriate?
- Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage and mAs) appropriate?
- Are the components used in the exam (compression plate, ACR MAP Phantom, exposure table) scratched or soiled?
- Is the position of the ACR MAP Phantom appropriate?
- Is the height of the compression plate appropriate?
- Is the image used in the visual inspection appropriate?
- Is the environment used in the visual inspection under appropriate quality management?
- Is the correct paddle chosen?

If any of the above is not correct / appropriate, correct the problem.

Make sure that the ACR MAP Phantom is correctly positioned and then redo the test.

Fail → Contact an authorized FUJIFILM representative.
Pass → The test is finished.

If the item still results in [Fail], the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.
4.6 Weekly Homogeneity

4.6.1 Procedure

Exposure of the evaluation image (including determination of the exposure conditions)

1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo ACR MAP Phantom”, and then press “Start exam”.
3. Set the PMMA Phantom (20 mm) along the chest wall line of the exposure table.

4. Set the compression plate at a height of 21 mm from the top surface of the exposure table.

**TIP**

Use the 24x30 compression plate (High).
Always the same compression plate used at the time of baseline value setting
**Do not use** the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS).

5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Perform Tomosynthesis exposure.
7. Record the exposure conditions used for exposure on the report form.

Implementation of visual inspection

8. In AWS, check the reconstructed image. Display the image using pixel-for-pixel display, search for the evaluation slice, determined in the baseline value setting, and list it on the report form. (Example: 21st image)

**NOTE**

When there is concern that it is not possible to carry out an appropriate visual inspection with 1 slice image, use the slice before and after as well.

9. Carry out the visual inspection for artifacts and density non-uniformity.
10. Record the evaluation results on the report form.
4.6.2 Test Result Evaluation and Judgment
1. Evaluate and judge the Weekly Homogeneity Test result. If item is judged as [Pass], this test is finished.
2. If there is an item judged as [Fail], take corrective actions in accordance with "4.6.3. Performance Criteria and Corrective Action".

4.6.3 Performance Criteria and Corrective Action

Performance Criteria
• There shall not be any artifact or density non-uniformity that influences diagnosis.

Check points
• Is the exposure menu appropriate?
• Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage, and mAs) appropriate?
• Are the components used in the exam (compression plate, PMMA Phantom, exposure table) scratched or soiled?
• Is the position of the PMMA Phantom (20 mm) appropriate?
• Is the height of the compression plate appropriate?
• Is the correct paddle chosen?
• Is the image used in the visual inspection appropriate?
• Is the environment used in the visual inspection under appropriate quality management?

If any of the above is not correct / appropriate, correct the problem.

Make sure that the PMMA phantom is correctly positioned and then redo the test.

Fail

Contact an authorized FUJIFILM representative.

Pass

The test is finished.

If the item still results in [Fail], the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.
5 Quarterly Test

5.1 Test Flow

Use this Manual to manage tomosynthesis exposure. Even when an image captured using tomosynthesis cannot be used for diagnosis, a retake may not be necessary when it is possible to make a diagnosis using a 2D capture image only. It is necessary to determine in advance how to handle “reject or repeat” at each facility in such cases.

Performed by the technologist, the Quarterly Test is designed to determine the number and cause of repeated radiographs.

Analysis of this data will help identify ways to avoid multiple radiation exposure and reduce costs, as well as reduce patient exposures.

<table>
<thead>
<tr>
<th>Equipment use</th>
<th>Quarterly Test</th>
<th>The result is within the criteria</th>
<th>Rejected image analysis</th>
<th>Repeat analysis</th>
<th>Taking corrective actions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>YES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Repeated images shall be evaluated quarterly. In order for the repeat rates to be meaningful, a patient volume of at least 250 patients or 1,000 exposures is needed.

As described above, the Quarterly Test is neither a constancy test nor a performance test of the system.

Specify the criteria when conducting the test, not in advance.

The Retake Analysis software, a software module for the FDR-3000AWS, is convenient for organizing and managing the repeat analysis data. Detailed operation of the Repeat Analysis software module can be found in Aspire Cristalle Options Operation Manual.
5.2 Test Item

<table>
<thead>
<tr>
<th>Test Item</th>
<th>Content</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat Analysis</td>
<td>-</td>
<td>Repeat or reject rate ≤ previously determined rate ±2%</td>
</tr>
</tbody>
</table>

5.3 Conducting Quarterly Test

5.3.1 Procedure

Repeat analysis (collecting rejected images)

1. Start by removing all existing rejected images in the department taken prior to the start of the analysis.
2. Take inventory of the image supply as a starting point to determine the total number of images consumed during the test.
3. Start collecting all rejected images. Continue to collect for the length of time needed to radiograph at least 250 consecutive patients or 1,000 exposures.
4. Sort the rejected images into categories such as poor positioning, motion, compression, under exposure, (these might be due to exposure or processing), artifacts (streaks, spots, etc.).

NOTE

Rejected images are all images that are in the reject bin, including repeated images. Repeated images are images that are retaken because of inadequate quality. The reject bin does not include additional views required to image selected tissue seen on the first image. It also does not include images taken for the purposes of including tissue that could not be positioned on the image receptor due to the size of the breast. For facilities using softcopy for final interpretation maintain a list of repeated images using the “REPEAT RATE ANALYSIS” in “8. Report Forms”.

TIP

Good images (they appear to be acceptable mammograms when retrospectively evaluated during the Repeat analysis) may have also been repeated. Some images may not have resulted in an additional exposure of the patient but may have also been rejected. These include clear and QC images. Although it is appropriate to include wire localization images as part of the reject analysis, they should not be included in the repeat analysis because they are taken as part of the wire localization process.

Repeat analysis (calculating repeat rates)

5. Some facilities placing all images (repeated and good images) in the patient’s film jacket have no repeated images in the department. In this case, the reject / repeat analysis chart is completed as patient examinations are carried out.
6. Tabulate the counts from Steps 4 and 5, determining the total number of repeated images, rejected images, and the total number of images exposed during the analysis period.

7. Determine the overall percentage of repeated images by dividing the total number of repeated images by the total number of images exposed during the analysis period, and then multiply by 100. Next, determine the overall percentage of rejected images by dividing the total number rejected images by the total number of images exposed during the analysis period, and multiply by 100.

8. Determine the percentage of repeats in each “reason for repeat” category by dividing the repeats in the category by the total number of repeated images and multiply by 100.

Test result confirmation

9. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total images included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

5.3.2 Test Result Evaluation and judgment

Evaluate and judge the Quarterly Test results. If the criteria are satisfied, the test is completed. If not satisfied, take corrective actions in accordance with “5.3.3 Performance Criteria and Corrective Action”.

5.3.3 Performance Criteria and Corrective Action

If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total images included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

Any corrective action should be recorded on the bottom of the “REPEAT RATE ANALYSIS” in “8. Report Forms”.

The effectiveness of the corrective actions must be assessed by performing another repeat analysis after the corrective actions have been implemented.

It is important to study images that are too dark or too light to determine if the underlying cause is the exposure equipment, image printer, patient positioning, technique or sub-optimal setting of digital image processing.

If this test produces results that fall outside the action limits as specified, 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.
6 Annual Test

6.1 Test Flow

Performed by the Medical Physicist during the Medical Equipment Evaluation (MEE) and subsequent Annual testing, these tests are designed for checking the overall performance of the FDR Mammography system.

The Annual Test is comprised of constancy tests and performance verification tests of the system. The constancy tests are designed for determining if variations of regularly measured system performance values are within the allowable range (criteria) based on baseline values that were established at the time of QC program / system installation. The performance test is intended to check that system performance values are within the upper or lower limits specified by the baselines.

It is necessary to determine the criteria before conducting the Annual Test.

NOTE

When conducting the Annual Test the first time after setting the criteria, specify the baseline values to be used in the future Annual Tests.

In the subsequent Annual Test procedures, check that the variation from the specified baseline values are within the criteria.
6.2 Test Items

Check that the variation from the specified baseline values is within the criteria, or that the values indicating system performance satisfy the criteria. If the criteria are satisfied, equipment can be used as is until the next Annual test day. If the criteria are not satisfied, take corrective actions by following “Performance criteria and corrective action” for each test item.
<table>
<thead>
<tr>
<th>Test Items</th>
<th>Contents</th>
<th>Criteria</th>
<th>Evaluation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>[6.4] X-ray field at chest wall edges</td>
<td>X-ray field / light field gap</td>
<td>The difference between X-ray and light field &lt; SID×2%</td>
<td>Visual inspection</td>
</tr>
<tr>
<td></td>
<td>X-ray field / exposure table gap</td>
<td>X-ray field beyond the edge of the image receptor &lt; 5 mm</td>
<td></td>
</tr>
<tr>
<td>[6.5] Missed tissue at chest wall side</td>
<td>Missed tissue at chest wall side</td>
<td>Less than 7 mm</td>
<td>Visual inspection</td>
</tr>
<tr>
<td>[6.6] In-plane resolution</td>
<td>MTF 2lp/mm</td>
<td>Black and white of 2lp/mm can be separated</td>
<td>Visual inspection</td>
</tr>
<tr>
<td>[6.7] AEC performance</td>
<td>SDNR of the variable PMMA thickness</td>
<td>[ST-mode] PMMA20mm &gt;155% PMMA40mm &gt;90% PMMA60mm &gt;55% PMMA70mm &gt;45%</td>
<td>Calculation</td>
</tr>
<tr>
<td>[6.8] AGD</td>
<td>AGD of the variable PMMA thickness</td>
<td>[ST-mode] PMMA20mm &lt; 1.3 mGy PMMA40mm &lt; 2.0 mGy PMMA60mm &lt; 4.5 mGy PMMA70mm &lt; 6.5 mGy [2D+Tomo ST-mode] ACR MAP Phantom &lt;= 3.0 mGy</td>
<td>Calculation</td>
</tr>
<tr>
<td>[6.9] Short term reproducibility</td>
<td>SNR</td>
<td>Average value ±10%</td>
<td>Calculation</td>
</tr>
<tr>
<td></td>
<td>mAs</td>
<td>Average value ±5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>S-value</td>
<td>Average value ±10%</td>
<td></td>
</tr>
<tr>
<td>[6.10] Z-resolution</td>
<td>FWHM</td>
<td>Baseline value ±10% However, within 1 mm when Baseline value × 10% is less than 1 mm.</td>
<td>Calculation</td>
</tr>
</tbody>
</table>
6.3 Tools
Tools to be used for the Annual Test based on this Manual are shown below.

- Report Form
- Tomo QC Calculation Tool
- ACR MAP Phantom
- PMMA phantoms (Annual; 24×30 cm, thickness; 10, 10, 10, 20, 40 mm)
- X-ray ruler or Coins (4 items of known sizes) with Mammography, Cassettes (2 cassettes of 24×30 cm)
- 1 Shot Phantom24×30
- Aluminum plate for SDNR measurement (10×10 mm, thickness 0.2 mm, purity >99%)
- Aluminum plates for half value layer measurement (thickness; 0.5 and 0.6 mm, purity >99%)
- Dosimeter
- Lead sheet or other component that can block X-rays
6.4 X-ray field at chest wall edges

6.4.1 Procedure with X-ray ruler

Acquisition of image for difference check of X-ray radiation field and light field

* If an X-ray ruler cannot be prepared, carry out “6.4.2 Procedure with coins” instead.

1. Remove the compression plate.
2. In AWS, enter arbitrary patient information, and then press “Next”.
3. From the display group list “QC/TEST”, choose the exam menu “Tomo ACR MAP Phantom”, and then press “Start exam”.
4. Align the line marker of the X-ray ruler along the edge of the light field.
5. Attach the compression plate and move it near the X-ray ruler. However, be careful not to contact it.

TIP
Always the same compression plate used at the time of baseline value setting 24x30 compression plate (High).

Do not use the following: 24x30 compression plate (Shift), 24x30 compression plate (Shift Small), 24x30H compression plate (Flex), or 24x30H comfort paddle (FS).

6. Choose the following exposure conditions: [ST, Manu, W/Al, 29kV, 50mAs].

NOTE
When the X-ray ruler does not respond, adjust the exposure conditions appropriately. For example, increase the mAs value to be used.

7. Perform Tomosynthesis exposure.
8. Record the exposure conditions used for exposure on the report form.

Acquisition of image for difference check of X-ray radiation field and exposure table

9. Align the line marker of the X-ray ruler along the chest-wall edge of the exposure table.
10. Repeat Steps 6 through 8.
Run the difference check of the X-ray radiation field and light field as well as X-ray radiation field and exposure table.

11. At the AWS screen, determine the slice to be used in the evaluation, and list it on the report form.

12. Run the difference check of the X-ray radiation field and light field as well as X-ray radiation field and exposure table, and then list the results on the report form.

(a): sample of Step 4.
(b): sample of Step 9.
6.4.2 Procedure with coins

Acquisition of image for difference check of X-ray radiation field and light field

NOTE
The same size 2 cassettes (18×24 cm size are recommended, no need to be QC exclusive), a scale and 2 coins (familiar sized). A cassette for general exposure cannot be used.

1. Remove the compression plate.
2. Position 2 coins (Coin (a1) and Coin (a2), hereafter) on the exposure table while aligning the edge with the chest wall-side edge of the exposure table.

NOTE
Be careful not to position the Coin (a1) and Coin (a2) where it will be overlapped with the coins to be positioned in Substeps 3 and the boundary of the cassettes placed in Sub step 2.

3. Position 2 cassettes (Cassettes B1 and B2, hereafter) over the exposure table by aligning their chest wall-side edges.
4. Turn on the light field lamp of the X-ray equipment and position coins (Coin (b1), Coin (b2), hereafter) on the chest wall side of the light field on the Cassettes B1 and B2.

5. Attach the compression plate. Move the compression plate down onto the Cassettes B1 and B2.

**NOTE**
Take care that the compression plate is not scratched by the coins.

6. Choose the following exposure conditions: [ST, Manu, W/Al, 29kV, 50mAs].
7. Record the tomosynthesis exposure conditions on the Report Form.
Run the difference check of the X-ray radiation field and light field as well as X-ray radiation field and exposure table.

8. At the AWS screen, determine the slice to be used in the evaluation, and list it on the report form.

**NOTE**
Sometimes using an exposure image (projection image) is easier to understand than using a reconstruction image.

9. Measure and record the distances between the coins and the adjacent edges of the output image. If a part of coin image is missing, measure the length of the missing part.

<table>
<thead>
<tr>
<th>TIPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coins (a1), (a2) → Positioned on the chest wall-side edge of the exposure table.</td>
</tr>
<tr>
<td>Coins (b1), (b2) → Positioned on the chest wall-side edge of the light field.</td>
</tr>
</tbody>
</table>

10. Measure and record the distances between the coins and the adjacent edges of the X-ray field on the output images read from Cassettes B1 and B2. If a part of coin image is missing, measure the length of the missing part.

11. Record the X-ray / Light field gap to the report form.
   - B_b1: X-ray field / light field gap (left): _____mm
   - B_b2: X-ray field / light field gap (right): _____mm
12. Measure and record the distances between the coins and the adjacent edges of the X-ray field on the output images read from FDR Mammography system. If a part of coin image is missing, measure the length of the missing part.

13. Fill in the following items in the worksheet.

- A_a1: _____mm
- A_a2: _____mm
- A_b1: _____mm
- A_b2: _____mm
14. Calculate the X-ray field/exposure table gap. Observe how the coins are reflected in the images read from the FDR mammography system and Cassette B1/ B2 and judge which of the 3 examples the reflected images belongs to. Then calculate the size of the gap by using the corresponding formula (If the calculated value is a negative, derive the absolute value).

**TIP**
Check the image of the Coins (a1) (a2) (b1) (b2).
Assign the value recorded in Sub steps 10 and 12 for each coin to A and B in the corresponding formula.

Fill in the following items in the worksheet.

X-ray field / exposure table gap (left): _____mm
X-ray field / exposure table gap (right): _____mm

<table>
<thead>
<tr>
<th></th>
<th>FDR mammography system</th>
<th>Cassette B1/B2</th>
<th>X-ray field/ exposure table gap Y calculation formula</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eg:1</strong></td>
<td><img src="image1" alt="Diagram" /></td>
<td></td>
<td>Y = y (Measure the distance y between the edges of Coin (a1), Coin(a2) and X-ray field in the image read from the FDR mammography system.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eg:2</strong></td>
<td><img src="image2" alt="Diagram" /></td>
<td></td>
<td>Y = (A-b1)-{(A-a1)+(B-b1)} or Y = (A-b2)-{(A-a2)+(B-b2)}</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eg:3</strong></td>
<td><img src="image3" alt="Diagram" /></td>
<td></td>
<td>Y = (A-b1)+{(B-b1)-(A-a1)} or Y = (A-b2)+{(B-b2)-(A-a2)}</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**TIP**
When the X-ray field is inside of the image receptor edge in the image read from the FDR mammography system, as shown in Eg: 1, the size of the gap can be determined by measuring the distance (“y” in the figure) from the image receptor edge to the X-ray field.

**TIP**
When the X-ray field is outside of the image receptor edge in the image read from the FDR mammography system as shown in Egs: 2 and 3, the size of the gap can be calculated. Measure the distance “A-a1” between the image receptor edge and that of Coin (a1) (on the chest wall-side edge) and the distance “A-b1” between the image receptor edge and the edge of Coin (b1) (on the light field) in the image read from Cassette B1, and the distance “B-b1” between the edge of Coin (b1) and X-ray field edge, and then assign the measured values to the formula.

**6.4.3 Test Result Evaluation and Judgment**

1. Evaluate and judge “X-ray/light field gap” and “X-ray field/exposure table gap” at chest wall edges test results. If all items are judged as [Pass], this test is finished.
2. If there is an item judged as [Fail], take corrective actions by following “6.4.4. Performance Criteria and Corrective Action”.


6.4.4 Performance Criteria and Corrective Action

Performance Criteria

The difference between X-ray/light field gap < SID×2%
The difference between X-ray field/exposure table gap (X-ray field beyond the edge of the image receptor) < 5mm

Check points

• Is the exposure menu appropriate?
• Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage and mAs) appropriate?
• Is the position of the X-ray rulers or coins appropriate?
• Are images and slices used in the visual inspection appropriate?
• Is it possible to measure the missed tissue amount correctly?
• Are the units correct?

If any of the above is not correct/appropriate, correct the problem.

Redo the test.  →  The test is finished.

Fail  →  The X-ray equipment may be defective.

Contact an authorized FUJIFILM representative

If the item still results in [Fail], the source of the problem shall be identified and corrective action shall be taken within 30 days of the test date. Digital breast tomosynthesis imaging and mammographic image interpretation may be continued during this period.
6.5 Missed tissue at chest wall side

6.5.1 Procedure

Exposure of the evaluation image (including determination of the exposure conditions)

1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo ACR MAP Phantom”, and then press “Start exam”.
3. Set the 1 Shot Phantom 24×30 on the exposure table.
4. Set the compression plate at a height of 45 mm from the top surface of the exposure table.

TIP

Use the 24×30 compression plate (High). Do not use the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS). Use the same compression plate each time.

NOTE

Position the Phantom at the lateral center of the exposure table by pressing the corners against the chest wall-side edge of the exposure table. If there are obstacles at the time of positioning, the test may not be conducted accurately.

5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Perform Tomosynthesis exposure.
7. Record the exposure conditions used for exposure on the report form.
Implementation of visual inspection

8. In AWS, check the reconstructed image. Display the image using pixel-for-pixel display, search for the slice with the best focus for the Missed tissue on chest wall edge (right/left) chart, and then list it on the report form. (Example: 7th slice image)

TIP
To determine the most focused slice, visually select a slice and scroll 1mm up and down to confirm selection.

9. While referring to the following illustration, visually evaluate the amount of missed tissue on the chest wall edge (right/left).

10. The areas in the circles in Illustration A are the locations to check the amount of missed tissue on chest wall. Illustration B is an enlarged version of this area. Measure to what point the measurement section of the missed tissue on the chest wall in the image was exposed.

11. Record the evaluation results on the report form.
   Missed tissue on chest wall edge (Right) [mm]: Pass/Fail
   Missed tissue on chest wall edge (Left)  [mm]: Pass/Fail

6.5.2 Test Result Evaluation and Judgment

1. Evaluate and judge the Missed tissue at chest wall side test results. If all items are judged as [Pass], this test is finished.

2. If there is an item judged as [Fail], take corrective actions by following “6.5.3. Performance Criteria and Corrective Action”.
6.5.3 Performance Criteria and Corrective Action

Performance Criteria
Missed tissue of the chest wall edge < 7mm

Check points
• Is the exposure menu appropriate?
• Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage and mAs) appropriate?
• Is the position of the 1 Shot Phantom 24×30 appropriate?
• Are images and slices used in the visual inspection appropriate?
• Is it possible to measure the missed tissue amount correctly?
• Are the components used in the exam (compression plate, 1Shot Phantom 24x30 exposure table) scratched or soiled?
• Is the height of the compression plate appropriate?
• Is the correct paddle chosen?
• Is the environment used in the visual inspection under appropriate quality management?

• If any of the above is not correct/appropriate, correct the problem and repeat the test.

Redo the test.       The test is finished.

Pass

Fail
The X-ray equipment may be defective.

Contact an authorized FUJIFILM representative.

If any of the items still results in [Fail], the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.
6.6 In-plane resolution

6.6.1 Procedure

Exposure of the evaluation image (including determination of the exposure conditions)

1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo ACR MAP Phantom”, and then press “Start exam”.
3. Set the 1 Shot Phantom 24×30 on the exposure table.
4. Set the compression plate at a height of 45 mm from the top surface of the exposure table.

**TIP**
Always use the 24x30 compression plate (High).

**Do not use** the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS)

**NOTE**
Position the Phantom at the lateral center of the exposure table by pressing the corners against the chest wall-side edge of the exposure table. If there are obstacles at the time of positioning, the test may not be conducted accurately.

5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Perform Tomosynthesis exposure.
7. Record the exposure conditions used for exposure on the report form.
Implementation of visual inspection
8. In AWS, check the reconstructed image. Display the image using pixel-for-pixel display, search for the slice with the best focus for 2lp/mm sharpness chart, and then list it on the report form. (Example: 8th slice image)
9. Using this image, confirm that the black and white lines of the 2lp/mm sharpness chart are separated at a fixed interval.
10. Record the visual inspection results on the report form.

6.6.2 Test Result Evaluation and Judgment
1. Evaluate and judge the In-plane resolution test results. If all items are judged as [Pass], this test is finished.
2. If there is an item judged as [Fail], take corrective actions by following “6.6.3. Performance Criteria and Corrective Action”. 

Display the 2lp/mm sharpness chart on the right side of the 1 Shot Phantom 24×30 using pixel-for-pixel display and then confirm that the black and white lines are separated.
6.6.3 Performance Criteria and Corrective Action

Performance Criteria

Black and white of 2lp/mm can be separated.

Check points

• Is the exposure menu appropriate?
• Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage and mAs) appropriate?
• Is the position of the 1 Shot Phantom 24×30 appropriate?
• Is the correct paddle selected
• Is the height of the compression plate appropriate?
• Are images and slices used in the visual inspection appropriate?
• Is the area of the visual inspection scratched or soiled?

If any of the above is not correct/appropriate, correct the problem and repeat the test.

If any of the items still results in [Fail], the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.

Redo the test.  The test is finished.

Pass

Fail  The X-ray equipment may be defective.

Contact an authorized FUJIFILM representative.
6.7 AEC performance

6.7.1 Procedure

Determination of exposure conditions

1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo MAX4.0 Mammography”, and then press “Start exam”.
3. Set the PMMA Phantom (20 mm) on the exposure table.
4. Set the compression plate at a height of 21 mm from the top surface of the exposure table.

TIP
Use the 24x30 compression plate (High). Use the same compression plate each time
Do not use the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS).

5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Perform Tomosynthesis exposure.
7. Record the exposure conditions on the report form.
8. Similarly, repeat Steps 1 through 7 using PMMA 40 mm, PMMA 60 mm and PMMA 70 mm. However, set the compression plate at a height of 45 mm, 75 mm and 90 mm from the top surface of exposure table for each.
9. Because the evaluation image is exposed using [Manu], determine the smallest value that exceeds the recorded exposure conditions.
Exposure of the evaluation image

10. Set the PMMA Phantom (10 mm) on the exposure table.

11. Set the Aluminum plate for SDNR measurement on the PMMA Phantom. At this time, adjust the center of the aluminum piece so that the lateral center is 60 mm from the chest wall.

12. Stack the PMMA (10 mm) on top of this.

13. Set the compression plate at a height of 21 mm.

14. Use the exposure conditions of PMMA 20 mm determined by the procedure “Determination of exposure conditions”, and then perform [Manu] exposure.

15. Similarly, perform exposure for PMMA 40 mm, PMMA 60 mm and PMMA 70 mm. At this time, stack the PMMA to be added on top.

16. Use the exposure conditions determined by the procedure “Determination of exposure conditions”, and then perform [Manu] exposure. However, set the compression plate at a height of 45 mm, 75 mm and 90 mm from the top surface of exposure table for each.

TIP
Always use the same PMMA pieces as used in the baseline setting. Variation of PMMAs' thicknesses will affect the calculation result.

When handling the aluminum plate, use gloves to preserve quality. Use an aluminum piece that is 10×10 mm and has a thickness of 0.2 mm.

The aluminum piece is positioned between the PMMA 10 mm and PMMA 10 mm.

The aluminum piece is positioned between the PMMA 10 mm and PMMA 10 mm, and the PMMA to be added is stacked on top.

TIP
It may not be possible to operate correctly in Semi or Auto mode. Always perform exposure in Manu mode.
Running the SDNR calculation

17. In AWS, confirm the reconstructed image, confirm the slice with the best focus for the aluminum plate, and then record it on the report form. (Example: 12th slice image)

18. Use the RAW batch output function of AWS, and then store the image on external storage media. (For a detailed procedure, see 7.1.1) To output RAW images, that it is specified to output “Reconstructed images only”. There is no need to output 2D or Exposure images to perform those QC tests.

19. On another computer, start the Tomo QC Calculation Tool.

20. Choose “SDNR” to start the SDNR calculation screen.

21. Read the image of PMMA 20 mm. Use the QC tool to open the focus slice image recorded in Step 17.

   **HINT**
   
   You can open the image by dragging the reconstructed raw image file. (For a detailed procedure, see 7.2.3)

22. Check that the image that was read is the calculation target image. When the image is difficult to see, you can improve visual confirmation by changing Window Center and Window Width. (For a detailed procedure, see 7.2.4)

   **TIP**
   
   If an image not targeted for calculation is chosen, the expected result is not obtained.
23. Configure the calculation region of “AL_ROI_Position” within the aluminum piece in the image.

*Note: Configuring the calculation region of "AL_ROI_Position" within the aluminum piece configures BG_ROI_Position automatically.

**HINT**

If an image in the Tomo QC Calculation Tool is double-clicked, the ROI is configured centered on this location, and the coordinates appear on the right side. When fine adjustment is necessary, adjust using the arrow buttons. You can also change the size of the ROI between 1 to 15 mm.

**HINT**

Image of calculation region.

Take care not to include the region where the aluminum plate is present in the BG_ROI_Position.
HINT
These are examples of each ROI.
(* When the position is not allocated in the ideal location during exposure, the ROI is not near the center of the aluminum plate. In such cases, adjust the coordinates.)

<table>
<thead>
<tr>
<th></th>
<th>ST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AL</td>
</tr>
<tr>
<td>X Min</td>
<td>383</td>
</tr>
<tr>
<td>Y Min</td>
<td>971</td>
</tr>
<tr>
<td>X Max</td>
<td>415</td>
</tr>
<tr>
<td>Y Max</td>
<td>1003</td>
</tr>
</tbody>
</table>

TIP
Configure so that the ROI is within the aluminum plate. When settings are incorrect, an appropriate result is not obtained.

TIP
When there are artifacts in the AL_ROI_Position or BG_ROI_Position, an appropriate result is not obtained.

TIP
The BG_ROI_Position is configured automatically in correspondence with the AL_ROI_Position.

24. Press the Calculation button to run the calculation.
25. Check the calculation result on the screen, and then record them on the report form.
   When you manage data using an external tool, specify the save location of the file, and then press the Save button.

HINT
For the output procedure for CSV files, see 7.2.7.

26. Similarly, perform Steps 20 through 25 using images of PMMA 40 mm, PMMA 60 mm and PMMA 70 mm.
27. After acquiring SDNR of each thickness, acquire the ratio when SDNR of PMMA 40 mm is set to 100%, and then save this to the report form or external tool.

**NOTE**

The calculation formulas are as follows.

- PMMA 20 mm SDNR ratio = $\frac{SDNR_{PMMA20mm}}{SDNR_{PMMA40mm}}$
- PMMA 40 mm SDNR ratio = $\frac{SDNR_{PMMA40mm}}{SDNR_{PMMA40mm}}$
- PMMA 60 mm SDNR ratio = $\frac{SDNR_{PMMA60mm}}{SDNR_{PMMA40mm}}$
- PMMA 70 mm SDNR ratio = $\frac{SDNR_{PMMA70mm}}{SDNR_{PMMA40mm}}$

28. Confirm the SDNR ratio is within the criteria.

### 6.7.2 Test Result Evaluation and Judgment

1. Evaluate and judge the AEC performance test results. If all items are judged as [Pass], this test is finished.

2. If there is an item judged as [Fail], take corrective actions by following “6.7.3. Performance Criteria and Corrective Action”.
6.7.3 Performance Criteria and Corrective Action

Performance Criteria

<table>
<thead>
<tr>
<th>Thickness of the PMMA phantom</th>
<th>Height of the compression plate</th>
<th>(ref) Ratio of the SDNR ST mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>21</td>
<td>&gt;155%</td>
</tr>
<tr>
<td>40</td>
<td>45</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>60</td>
<td>75</td>
<td>&gt;55%</td>
</tr>
<tr>
<td>70</td>
<td>90</td>
<td>&gt;45%</td>
</tr>
</tbody>
</table>

Check points
- Is the exposure menu appropriate?
- Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage and mAs) appropriate?
- Are the components used in the exam (compression plate, PMMA, aluminum piece, exposure table) scratched or soiled?
- Is the purity of the aluminum piece appropriate?
- Is the size and position of the aluminum piece appropriate?
- Is the height of the compression plate appropriate?
- Are the images used in the calculation appropriate?
- Are there any artifacts in the calculation region?
- Is the AL_ROI_Position within the aluminum piece in the image?
- Is the ROI_Position and size appropriate?

Review the checkpoints above. If any inconstancies are found repeat the test.

If the item still results in Fail, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.

Contact an authorized FUJIFILM representative.

The test is finished.
6.8 AGD

6.8.1 Procedure

Determination of exposure conditions for DBT

1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo MAX4.0 Mammography” or “Stationary”, and then press “Start exam”.
3. Set the PMMA Phantom (20 mm) on the exposure table.
4. Set the compression plate at a height of 21 mm from the top surface of the exposure table.

**TIP**
Always use the 24x30 compression plate (High).

**Do not use** the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS)

5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Perform Tomosynthesis exposure.
7. Record the exposure conditions used for exposure on the report form.
8. Similarly, repeat Steps 1 through 7 using PMMA 40 mm, PMMA 60 mm, PMMA 70 mm and ACR MAP Phantom. However, set the compression plate at a height of 45 mm, 75 mm, 90 mm, and 45mm respectively, from the top surface of exposure table.
9. Because the evaluation image is exposed using [Manu], determine the smallest value that exceeds the recorded exposure conditions.
10. Remove the PMMA Phantom and ACR MAP Phantom.
Measurement of dose for DBT

11. For X-ray protection, place a lead sheet or similar items on the exposure table.

12. Allocate so that the detection surface of the dosimeter is at the lateral center of the exposure table about 6 cm from the chest wall.

13. Investigate the height from the exposure table top surface to the detection surface of the dosimeter, and then record it on the report form. At the same time, record the dose unit.

14. Move the compression plate as close to the dosimeter as possible to the extent that it does not touch.

TIP
Multiple exposures and dose measurements are carried out during this exam, but do not move the compression plate and dosimeter.

15. Use the exposure conditions of PMMA 20 mm determined by the procedure “Determination of exposure conditions for DBT”, perform [Manu] exposure, and then record the measured dose on the report form.

TIP
It may not be possible to operate correctly in Semi or Auto mode. Always perform exposure in Manu mode.
16. Place an aluminum plate with a thickness of 0.5 mm for half-value layer measurement on the compression plate so that it covers the detection surface of the dosimeter.

**TIP**
When handling the aluminum plate, use gloves to preserve quality.

17. Using the same exposure conditions as Step 15, take an exposure using [Manu] mode, and then record the measured dose on the report form.
18. Place an aluminum plate with a thickness of 0.6 mm for half-value layer measurement on the compression plate so that it covers the detection surface of the dosimeter.
19. Using the same exposure conditions as Step 15, take an exposure using [Manu] mode, and then record the measured dose on the report form.
20. Similarly, perform Steps 15 through 19 for PMMA 40 mm, PMMA 60 mm, PMMA 70 mm and ACR MAP Phantom and then record the measured dose on the report form. However, use the exposure conditions according to each thickness determined by the procedure “Determination of exposure conditions”.

**Implementation of AGD calculation for DBT**
21. On another computer, start the Tomo QC Calculation Tool.
22. Choose AGD to start the AGD calculation screen.
23. For PMMA 20 mm, enter the information necessary for calculation.

(1) Mode: Mode used for exposure (2D, ST, HR)
(2) Target/Filter: Target/Filter used for exposure (W/Rh, W/Al)
(3) Dosimeter Height: Height of the detection surface of the dosimeter
(4) Dose Unit: Display unit of dosimeter (mR, mGy)
(5) PMMA (Breast) Thickness: Subject thickness assumed by the exposure conditions used for exposure
(6) Aluminum Thickness: Thickness of added aluminum plate (Example: 0.5 mm, 0.6 mm)
(7) Measured Dose: Displayed dose of the dosimeter

![AGD Calculation Diagram]

24. Press the Calculation button to run the AGD calculation.
25. Check the calculation result on the screen, and then record them on the report form. When you manage data using an external tool, specify the save location of the file, and then press the Save button.

**HINT**
For the output procedure for CSV files, see 7.2.7.

26. Confirm AGD is within the criteria.
27. Similarly, perform Steps 23 through 26 in the order of PMMA 40 mm, PMMA 60 mm, PMMA 70 mm and ACR MAP Phantom.

**HINT**
AGD of ACR MAP Phantom is confirmed as total of 2D + DBT.

**Determination of exposure conditions for 2D**
1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “ACR phantom”, and then press “Start exam”.
3. Set the ACR MAP Phantom on the exposure table
4. Set the compression plate at a height of 45mm from the top surface of the exposure table
5. Choose the following exposure conditions: [Auto, N-mode], Set i-AEC to OFF.
6. Perform 2D exposure.
7. Record the exposure conditions used for exposure on the report form.
8. Because the evaluation image is exposed using [Manu], determine the smallest value that exceeds the recorded exposure conditions.
9. Remove the ACR MAP Phantom

**Measurement of dose for 2D**
10. For X-ray protection, place a lead sheet or similar items on the exposure table.
11. Allocate so that the detection surface of the dosimeter is at the lateral center of the exposure table about 6 cm from the chest wall.
12. Investigate the height from the exposure table top surface to the detection surface of the dosimeter, and then record it on the report form. At the same time, record the dose unit.

13. Move the compression plate as close to the dosimeter as possible to the extent that it does not touch.

**TIP**

Multiple exposures and dose measurements are carried out during this exam, but do not move the compression plate and dosimeter.

14. Use the exposure conditions of ACR MAP Phantom determined by the procedure “Determination of exposure conditions for 2D”, perform [Manu] exposure, and then record the measured dose on the report form.

**TIP**

It may not be possible to operate correctly in Semi or Auto mode. Always perform exposure in Manu mode.

15. Place an aluminum plate with a thickness of 0.5 mm for half-value layer measurement on the compression plate so that it covers the detection surface of the dosimeter.

**TIP**

When handling the aluminum plate, use gloves to preserve quality.
16. Using the same exposure conditions as Step 14, take an exposure using [Manu] mode, and then record the measured dose on the report form.

17. Place an aluminum plate with a thickness of 0.6 mm for half-value layer measurement on the compression plate so that it covers the detection surface of the dosimeter.

18. Using the same exposure conditions as Step 14, take an exposure using [Manu] mode, and then record the measured dose on the report form.

**Implementation of AGD calculation for 2D**

19. On another computer, start the Tomo QC Calculation Tool.

20. Choose AGD to start the AGD calculation screen.

![Tomo QC Calculation Tool](image)

21. For ACR MAP Phantom, enter the information necessary for calculation.
   
   (1) Mode: Mode used for exposure (2D, ST, HR)
   (2) Target/Filter: Target/Filter used for exposure (W/Rh, W/Al)
   (3) Dosimeter Height: Height of the detection surface of the dosimeter
   (4) Dose Unit: Display unit of dosimeter (mR, mGy)
   (5) PMMA (Breast) Thickness: Subject thickness assumed by the exposure conditions used for exposure
   (6) Aluminum Thickness: Thickness of added aluminum plate (Example: 0.5 mm, 0.6 mm)
(7) Measured Dose: Displayed dose of the dosimeter

22. Press the Calculation button to run the AGD calculation.

23. Check the calculation result on the screen, and then record them on the report form. When you manage data using an external tool, specify the save location of the file, and then press the Save button.

**HINT**

For the output procedure for CSV files, see 7.2.7

24. Confirm total AGD of ACR AMP Phantom is within the criteria.

**6.8.2 Test Result Evaluation and Judgment**

1. Evaluate and judge the AGD test results. If all items are judged as [Pass], this test is finished.

2. If there is an item judged as [Fail], take corrective actions by following “6.8.3. Performance Criteria and Corrective Action”.
6.8.3 Performance Criteria and Corrective Action

Performance Criteria:

<table>
<thead>
<tr>
<th>Thickness of the PMMA phantom</th>
<th>Height of the compression plate</th>
<th>AGD criteria (ST mode)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mm</td>
<td>21</td>
<td>&lt; 1.3mGy</td>
</tr>
<tr>
<td>40 mm</td>
<td>45</td>
<td>&lt; 2.0mGy</td>
</tr>
<tr>
<td>60 mm</td>
<td>75</td>
<td>&lt; 4.5mGy</td>
</tr>
<tr>
<td>70 mm</td>
<td>90</td>
<td>&lt; 6.5mGy</td>
</tr>
<tr>
<td>ACR MAP using Tomo Set</td>
<td>45</td>
<td>Combined AGD &lt;=3.0mGy</td>
</tr>
</tbody>
</table>

Check points

- Is the dosimeter under quality management?
- Is the position of the dosimeter appropriate?
- Is the usage method of the dosimeter appropriate?
- Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage and mAs) appropriate?
- Is the purity of the aluminum plate appropriate?
- Can the aluminum plate shield the detection surface of the dosimeter completely?
- Are there scratches or soiling on the aluminum plate?
- Is the unit of the dosimeter appropriate?
- Is the height of the compression plate appropriate?
- Is the correct paddle chosen?

Review the checkpoints above. If any inconsistencies are found correct and repeat the test.

Check the AEC reproducibility with the 2D QC Manual

Pass

Pass → The test is finished.

Fail → Redo the test.

Fail → The X-ray equipment may be defective.

Contact an authorized FUJIFILM representative.

If the item still results in [Fail], the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.
6.9 Short Term Reproducibility

6.9.1 Procedure

Exposure of the evaluation image (including determination of the exposure conditions)

1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo MAX4.0 Mammography”, and then press “Start exam”.
3. Set the PMMA Phantom (20 mm) on the exposure table.
4. Set the compression plate at a height of 21 mm from the top surface of the exposure table.

TIP
Use the 24x30 compression plate (High). Use the same compression plate each time.

Do not use the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS).
5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Repeat Tomosynthesis exposure 3 times.
7. Record the exposure conditions used for exposure on the report form.
Running the SNR calculation

8. In AWS, confirm the reconstructed image, and then determine the slice to be used for calculation. Record this slice number of the reconstructed image on the report form. (Example: 1st slice image)

9. Use the RAW batch output function of AWS, and then store the reconstructed image on external storage media. (For a detailed procedure, see 7.1.1)

10. On another computer, start the Tomo QC Calculation Tool.

11. Choose SNR to start the SNR calculation screen.

12. From the images saved to the external storage media, open the reconstructed image slice equivalent to the slice recorded in Step 8 using the QC tool.

   HINT
   You can open the image by dragging the image file. (For a detailed procedure, see 7.2.3)

13. Check that the image that was read is appropriate.

   HINT
   When the image is difficult to see, you can improve visual confirmation by changing Window Center, Window Width. (For a detailed procedure, see 7.2.4)

   TIP
   If an image not targeted for calculation is chosen, the expected result is not obtained. When there are artifacts in the ROI, an appropriate result is not obtained.
14. Configure the calculation region. (We recommend a 10×10 mm area at the lateral center 60 mm from the chest wall.)

HINT
If an image in the Tomo QC Calculation Tool is double-clicked, the ROI is configured centered on this location, and the coordinates appear on the right side. When fine adjustment is necessary, adjust using the arrow buttons. You can also change the size of the ROI between 1 to 15 mm.

HINT
Image of calculation region
These are examples of ROI_Position.

<table>
<thead>
<tr>
<th></th>
<th>ST</th>
</tr>
</thead>
<tbody>
<tr>
<td>X Min</td>
<td>367</td>
</tr>
<tr>
<td>Y Min</td>
<td>955</td>
</tr>
<tr>
<td>X Max</td>
<td>432</td>
</tr>
<tr>
<td>Y Max</td>
<td>1020</td>
</tr>
</tbody>
</table>

15. Press the Calculation button to run the calculation.
16. Check the calculation result on the screen, and then record them on the report form. Save the CSV file when necessary.

**HINT**
For the output procedure for CSV files, see 7.2.7.

17. Similarly, carry out Steps 8 through 16 for the image of the 3rd time.
18. After acquiring the SNR of the 3rd time, acquire the variance amount for the N3 average.

**NOTE**
The calculation formulas are as follows.

SNR Variation N1 [%] = SNR(N1) ÷ SNR_average(N1, N2, N3)
SNR Variation N2 [%] = SNR(N2) ÷ SNR_average(N1, N2, N3)
SNR Variation N3 [%] = SNR(N3) ÷ SNR_average(N1, N2, N3)

19. Confirm that the largest variance value of N1 through N3 is within the criteria.
20. Similarly, acquire the variance of mAs and S-Value, and then confirm that they are within the management width.

**6.9.2 Test Result Evaluation and Judgment**
1. Evaluate and judge the Short-term reproducibility test results. If all items are judged as [Pass], this test is finished.
2. If there is an item judged as [Fail], take corrective actions by following “6.9.3. Performance Criteria and Corrective Action”.

**6.9.3 Performance Criteria and Corrective Action**

<table>
<thead>
<tr>
<th>Items</th>
<th>Performance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Maximum variance of SNR</td>
<td>Average value ±10%</td>
</tr>
<tr>
<td>2 Maximum variance of mAs</td>
<td>Average value ±5%</td>
</tr>
<tr>
<td>3 Maximum variance of S-value</td>
<td>Average value ±10%</td>
</tr>
</tbody>
</table>
Check points
- Is the exposure menu appropriate?
- Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage, and mAs) appropriate?
- Is the PMMA Phantom allocated appropriately?
- Are the components used in the exam (compression plate, PMMA, exposure table) scratched or soiled?
- Is the height of the compression plate appropriate?
- Is the same compression plate used each time?
- Are the images used in the calculation appropriate?
- Are there any artifacts in the calculation region?

If any of the above is not correct/appropriate, make the correction and repeat the test.

Redo the test.  The test is finished.

Fail  Pass

The X-ray equipment may be defective.

Contact an authorized FUJIFILM dealer.

If the item still results in (Fail), the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.
6.10 Z-resolution

6.10.1 Procedure

Exposure of the evaluation image (including determination of the exposure conditions)

1. In AWS, enter arbitrary patient information, and then press “Next”.
2. From the display group list “QC/TEST”, choose the exam menu “Tomo MAX4.0 Mammography”, and then press “Start exam”.
3. Set the 1 Shot Phantom 24×30 on the exposure table.
4. Set the compression plate at a height of 45 mm from the top surface of the exposure table.

TIP
Use the 24x30 compression plate (High). Always the same compression plate used at the time of baseline value setting.

Do not use the following: 24×30 compression plate (Shift), 24×30 compression plate (Shift Small), 24×30H compression plate (Flex), or 24×30H comfort paddle (FS).

NOTE
Position the Phantom at the lateral center of the exposure table by pressing the corners against the chest wall-side edge of the exposure table. If there are obstacles at the time of positioning, the test may not be conducted accurately.

5. Choose the following exposure conditions: [ST, Auto, N-mode]. Set i-AEC to OFF.
6. Perform Tomosynthesis exposure.
7. Record the exposure conditions used for exposure on the report form.
Implementation of Z-resolution calculation

8. In AWS, confirm the reconstructed image, and then find the slice with the best focus for the aluminum ball. Record this slice number on the report form. (Example: 13th slice image)

TIP
To determine the most focused slice visually select a slice and scroll 1mm up and down to confirm selection.

9. Use the RAW batch output function of AWS, and then store the reconstructed images on external storage media. (For a detailed procedure, see 7.1.1)

10. On another computer, start the Tomo QC Calculation Tool.

11. Choose “Z-Resolution” to launch the Z-resolution calculation screen.

12. All reconstructed tomo exposure images saved to external storage media are collected and imported into the QC tool.

HINT
You can open the image by dragging the image file. (For a detailed procedure, see 7.2.3)

TIP
The Z-resolution calculation uses multiple images to analyze the resolution of the Z-axis orientation.
13. Check that the image that was read is appropriate.

**NOTE**
When the image is difficult to see, you can improve visual confirmation by changing Window Center and Window Width.

**TIP**
If an image not targeted for calculation is chosen, the expected result is not obtained.

14. Move the slide bar to display the slice recorded in Step 8, and then reconfirm that it is the slice with the best focus for the aluminum ball.

**TIP**
It is recommended to enlarge the image to check the aluminum ball. For instructions on how to enlarge the image, see 7.2.4.

**TIP**
The focus is on the aluminum ball in the figure above. Other test patterns are out of focus as the vertical positions of the aluminum ball and other test patterns are different. Choose the slice with which the aluminum ball is most focused. To determine the most focused slice, visually select a slice and scroll 1mm up and down to confirm selection.
If the Focus button is pressed while the slice with focus is displayed, the display switches to “ON”.

**TIP**
If the Focus button is not pressed, calculation is not possible.

17. Using the image, for which the Focus button was pressed, configure the calculation region.

**HINT**
If an image in the Tomo QC Calculation Tool is double-clicked, the ROI is configured centered on this location, and the coordinates appear on the right side. When fine adjustment is necessary, adjust using the arrow buttons.

You can also change the size of the ROI between 1 to 15 mm.
**TIP**
If an image not targeted for calculation is chosen, the expected result is not obtained.

**TIP**
Configure so that the aluminum ball is within the AL_ROI_Position. When settings are incorrect, an appropriate result is not obtained.

**TIP**
When there are artifacts in the AL_ROI_Position or BG_ROI_Position, an appropriate result is not obtained.

**TIP**
The BG_ROI_Position is configured automatically in correspondence with the AL_ROI_Position.

**HINT**
These are examples of each ROI.

("When the position is not allocated in the ideal location during exposure, the ROI is not near the center of the aluminum plate. In such cases, adjust the coordinates.)

<table>
<thead>
<tr>
<th></th>
<th>ST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AL</td>
</tr>
<tr>
<td>X Min</td>
<td>516</td>
</tr>
<tr>
<td>Y Min</td>
<td>971</td>
</tr>
<tr>
<td>X Max</td>
<td>548</td>
</tr>
<tr>
<td>Y Max</td>
<td>1003</td>
</tr>
</tbody>
</table>

18. Press the Calculation button to run the calculation.
19. Check the calculation results on the screen, and then record them on the report form. Save the CSV file when necessary.

**HINT**
For the output procedure for CSV files, see 7.2.7.

20. Confirm that the Z-resolution (FWHM) is within the management width.
TIP
To determine the most focused slice, visually select a slice and scroll 1mm up and down to confirm selection.

6.10.2 Test Results and Judgement
1. Evaluate and judge the Z-resolution test results. If all items are judged as [Pass], this test is finished.
2. If there is an item judged as [Fail], take corrective actions by following “6.10.3. Performance Criteria and Corrective Action”.

6.10.3 Performance Criteria and Corrective Action

<table>
<thead>
<tr>
<th>Items</th>
<th>Performance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>FWHM</td>
<td>baseline value ±10%</td>
</tr>
</tbody>
</table>

* However, when baseline value × 10% is less than 1 mm, the value shall be the baseline value ±1 mm.

Check points
- Is the exposure menu appropriate?
- Are the setting conditions of the X-ray equipment (setting conditions for target/filter, exposure mode, tube voltage, and mAs) appropriate?
- Are the components used in the exam (compression plate, 1 Shot Phantom 24×30, exposure table) scratched or soiled?
- Is the size and position of the 1 Shot Phantom 24×30 appropriate?
- Is the height of the compression plate appropriate?
- Are the images used in the calculation appropriate?
- Are there any artifacts in the calculation region?
- Is the aluminum ball in the image within the AL_ROI_Position?
- Is the ROI_Position and size appropriate?

If any of the above is not correct/appropriate make the correction and repeat the test.

If the item still results in (Fail), the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed with the DBT option.
7 Quick Guide

7.1 Storage method for images captured using AWS

7.1.1 Raw batch storage procedure

TIP
Available in AWS Version 6.0 or later.
Be sure to choose an external memory medium.
Images cannot be stored in an AWS computer.

1. Open the exam history screen, and then right-click the exam for which you want to export images.
2. From the pop-up menu, choose “QC Raw output”.
3. The image saving screen appears.
4. Specify the save location of the image. (Screen (1))
   TIP
   Be sure to choose an external memory medium.
   Images cannot be stored in an AWS computer.
5. Enter a file name. (Screen (2)) (Use a name that makes it easy to distinguish the exam content.)
6. From the exam, choose the type of image you want to export. (Screen (3)) (2D images, Tomosynthesis exposure images, Tomosynthesis reconstructed images)
7. Press the Save button to save. (Screen (4))
8. The Raw files are saved in the specified folder.

9. RAW file classification, naming rules, number of images output

<table>
<thead>
<tr>
<th>Image classification</th>
<th>Sample image file name</th>
<th>Image quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomosynthesis exposure images</td>
<td>Img-01-EXP-01.raw</td>
<td>15</td>
</tr>
<tr>
<td>Tomosynthesis reconstructed images</td>
<td>Img-01-REC1-001.raw</td>
<td>Compression plate height + 5</td>
</tr>
</tbody>
</table>

Raw batch output images are named using the following rules.
- Section 1 (Img) can be configured to an arbitrary name during saving.
- Section 2 (01) indicates the order in which the image was taken during the exam.
- Section 3 (EXP/REC) indicates exposure or reconstruction.
- Section 4 (01/001) is the serial number for images generated by 1 exposure. In the case of a reconstructed image, the side closest to the exposure table is No. 1.

Sample image file name :  
- Img-01-EXP-01.raw
- Img-01-REC1-001.raw

Section No. : 1 2 3 4
7.2 Tomo QC Calculation Tool

7.2.1 Usage conditions
• Windows 7 Professional (32bit) English ver.
• Intel® Core™ i3-4160 (3.6 GHz)
• Memory- 4GB DDR3 SDRAM
• 500GB HDD (SATA/600, 7200rpm)
• A USB connection or optical-drive reading slot must be available.
• Monitor resolution of 1024 × 768 pixels or greater

7.2.2 Start method
Click the executable file to start. The following screen appears

7.2.3 Opening an image
You can open an image by dragging an image file to the Tomo QC Calculation Tool.
In the case of SNR and SDNR, only 1 image is opened.
In the case of Z-resolution, all reconstructed images generated by 1 exposure are required.
In the case of AGD, images are not used.
7.2.4 Adjustment of Magnification, Window Center and Window Width

You can change Magnification, Window Center and Window Width using the buttons in the upper right of the Tomo QC Calculation Tool.

Because the entire image cannot be displayed depending on the Magnification Ratio, the area displayed in the Tomo QC Calculation Tool is indicated by the green frame.

You can change Magnification, Window Center and Window Width using the mouse as well.

<table>
<thead>
<tr>
<th>Change item</th>
<th>Mouse operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnification</td>
<td>Rotate the mouse wheel up to enlarge</td>
</tr>
<tr>
<td></td>
<td>Rotate the mouse wheel down to reduce</td>
</tr>
<tr>
<td>Window Center</td>
<td>When the left button of the mouse has been clicked,</td>
</tr>
<tr>
<td></td>
<td>Window Center rises if the mouse is moved up</td>
</tr>
<tr>
<td></td>
<td>Window Center lowers if the mouse is moved down</td>
</tr>
<tr>
<td>Window Width</td>
<td>When the right button of the mouse has been clicked,</td>
</tr>
<tr>
<td></td>
<td>The width narrows if the mouse is moved left</td>
</tr>
<tr>
<td></td>
<td>The width widens if the mouse is moved right</td>
</tr>
</tbody>
</table>
7.2.5 Adjustment of coordinates

You can adjust the coordinates at the right side of the Tomo QC Calculation Tool.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visibility</td>
<td>You can switch the ROI display in the image area on or off.</td>
</tr>
<tr>
<td>Size</td>
<td>You can change the size of the ROI.</td>
</tr>
<tr>
<td>Position</td>
<td>The ROI coordinates are displayed. You can use the arrow buttons to adjust</td>
</tr>
<tr>
<td></td>
<td>the coordinates in detail.</td>
</tr>
<tr>
<td></td>
<td>Multiple ROI are used in SDNR and Z-resolution calculation. If AL_ROI_Position is configured, BG_ROI_Position is configured in coordination with this.</td>
</tr>
<tr>
<td></td>
<td>In addition, BG (Left) and BG (Right) of the SDNR calculation are not used.</td>
</tr>
</tbody>
</table>
You can also configure the ROI location using mouse operations. If you double-click the location to which you want to move, the ROI moves and is centered on this position.

7.2.6 Implementation of calculation

Press the Calculation button to run the calculation.

**HINT**
Calculation is not possible in the following situations.
- There is no image with SDNR, SNR, or Z-resolution calculation.
- ROI is not configured.
- The number of images is insufficient with Z-resolution calculation.
- The entry items are insufficient for AGD calculation.
7.2.7 CSV save procedure

You can save information related to images and calculation results as a CSV file.

1. Press the Save button

2. The save screen for the item appears.

3. Enter in the necessary information. (Arbitrary entry)

4. Press the Select Path button, and then select the CSV file to be the output path.

5. Press the Save button.

**TIP**

When you want to save information as a new CSV file with a different name, you must create an empty CSV file in advance. When you save information, specify the file name of the empty CSV file that was created.
8 Report Forms

The forms on the following pages are provided for recording the test results. It is important to record test results to follow the changes in performance of the X-ray equipment and/or other equipment. Make copies of report forms as necessary.

The following report forms are provided on the following pages.

- Weekly Test Report Form
- Quarterly Test Report Form
- Annual Test Report Form

Facility Information

<table>
<thead>
<tr>
<th>Client</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure Room</td>
<td>Time</td>
</tr>
<tr>
<td>Operator</td>
<td>Department</td>
</tr>
<tr>
<td></td>
<td>Name</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>S/N</th>
<th>Installation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray Equipment</td>
<td>FUJIFILM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Workstation</td>
<td>FUJIFILM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Measurement Equipment/Tool Information

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>S/N</th>
<th>Installation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic monitor</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>S/N</th>
<th>Calibration Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR MAP Phantom</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PMMA Phantom</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X-ray ruler or Coin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Shot Phantom 24×30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aluminum plate (SDNR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aluminum plate (HVL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dosimeter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead Sheet</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature

897N120924
**Weekly Test Report Form**

### 4.5 Weekly ACR MAP Phantom

**Exposure Conditions**

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>AEC</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>Auto / Semi / Manu</td>
<td>ON / OFF</td>
<td>N</td>
<td>W/Al</td>
<td>Large</td>
</tr>
<tr>
<td>kVp</td>
<td>mAs</td>
<td>Grid</td>
<td>Compressed Thickness</td>
<td>Compression Force</td>
<td>S Value</td>
</tr>
<tr>
<td>kV</td>
<td>OUT</td>
<td>mm</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Image Information**

- Confirmed slice

**Test Result1**

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Measured value</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibers</td>
<td></td>
<td>$\geq 4, \leq \text{Baseline value} \pm 0.5$</td>
<td>PASS FAIL</td>
</tr>
<tr>
<td>Specks</td>
<td></td>
<td>$\geq 3, \leq \text{Baseline value} \pm 0.5$</td>
<td>PASS FAIL</td>
</tr>
<tr>
<td>Masses</td>
<td></td>
<td>$\geq 3, \leq \text{Baseline value} \pm 0.5$</td>
<td>PASS FAIL</td>
</tr>
</tbody>
</table>

**Test Result2**

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>mAs Variation</td>
<td>$% \leq \text{Baseline value} \pm 15%$</td>
<td>PASS FAIL</td>
</tr>
<tr>
<td>S-value Variation</td>
<td>$% \leq \text{Baseline value} \pm 20%$</td>
<td>PASS FAIL</td>
</tr>
</tbody>
</table>
Weekly Test Report Form

SOFT COPY ACR MAP PHANTOM CONTROL CHART

Room: ______________________   Year: ______________________

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
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No. Visible

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<td>3.5</td>
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<td>3.5</td>
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<td>1.5</td>
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<td>3.5</td>
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<td>3.5</td>
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</table>

S Value

<table>
<thead>
<tr>
<th></th>
<th>-25%</th>
<th>0%</th>
<th>+25%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

mA (optional)

<table>
<thead>
<tr>
<th></th>
<th>-16%</th>
<th>0%</th>
<th>+16%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Remarks

Signature ____________________________

897N120924
## Weekly Test Report Form

### 4.6 Weekly Homogeneity

**Exposure Conditions**

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>AEC</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>Auto / Semi / Manu</td>
<td>ON / OFF</td>
<td>N</td>
<td>W/AI</td>
<td>Large</td>
</tr>
<tr>
<td>kVp</td>
<td>mAs</td>
<td>Grid</td>
<td>Compressed Thickness</td>
<td>Compression Force</td>
<td>S Value</td>
</tr>
<tr>
<td>kV</td>
<td>OUT</td>
<td>mm</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Image Information**

Confirmed slice

**Test Result**

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Inspection</td>
<td>PASS</td>
</tr>
<tr>
<td></td>
<td>FAIL</td>
</tr>
</tbody>
</table>

**Remarks**

Signature

897N120924
## 5.1 Repeat Analysis

**TOTAL NUMBER OF EXAMS**

<table>
<thead>
<tr>
<th>REASON FOR REJECT</th>
<th>TOMOSYNTHESIS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CC</td>
</tr>
<tr>
<td>POSITIONING</td>
<td></td>
</tr>
<tr>
<td>PATIENT MOTION</td>
<td></td>
</tr>
<tr>
<td>COMPRESSION</td>
<td></td>
</tr>
<tr>
<td>ARTIFACTS</td>
<td></td>
</tr>
<tr>
<td>X-RAY EQUIP MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>SOFTWARE MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>AEC MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>UNDER EXPOSURE</td>
<td></td>
</tr>
<tr>
<td>OVER EXPOSURE</td>
<td></td>
</tr>
<tr>
<td>INCORRECT PATIENT ID</td>
<td></td>
</tr>
<tr>
<td>WASTE</td>
<td></td>
</tr>
<tr>
<td>SUB-TOTAL</td>
<td></td>
</tr>
</tbody>
</table>

**GRAND TOTAL**

REPEAT RATE = \( \frac{\text{REPEAT}}{\text{TOTAL INCLUDING REPEATS}} \)

REPEAT RATE = \( \text{_______}\)%

REJECT RATE = \( \frac{\text{ALL REJECT}}{\text{TOTAL INCLUDING REPEATS}} \)

REJECT RATE = \( \text{_______}\)%

COMMENTS FOR CORRECTIVE ACTION AND GOALS:

___________________________________________________________________________________

___________________________________________________________________________________

___________________________________________________________________________________

___________________________________________________________________________________

\[ \text{Signature} \]

---

897N120924
# Annual Test Report Form

## 6.4 X-ray field at chest wall edges

### Exposure Conditions

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>AEC</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>Manu</td>
<td>OFF</td>
<td>-</td>
<td>W/Al</td>
<td>Large</td>
</tr>
</tbody>
</table>

### Image Information

<table>
<thead>
<tr>
<th>Test tool</th>
<th>X-ray ruler / coins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirmed slice</td>
<td></td>
</tr>
</tbody>
</table>

### Test Result

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Measured value</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray field / light field gap (Left)</td>
<td></td>
<td>&lt; ±SID×0.02</td>
<td>PASS</td>
</tr>
<tr>
<td>X-ray field / light field gap (Right)</td>
<td></td>
<td>&lt; ±SID×0.02</td>
<td>PASS</td>
</tr>
<tr>
<td>X-ray field / exposure table gap (Left)</td>
<td></td>
<td>&lt; 5 mm</td>
<td>PASS</td>
</tr>
<tr>
<td>X-ray field / exposure table gap (Right)</td>
<td></td>
<td>&lt; 5 mm</td>
<td>PASS</td>
</tr>
</tbody>
</table>

### Remarks

Signature __________________________

---

897N120924
# Annual Test Report Form

## 6.5 Missed tissue at chest wall side

### Exposure Conditions

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>AEC</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>Auto / Semi / Manu</td>
<td>ON / OFF</td>
<td>N</td>
<td>W/Al</td>
<td>Large</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>kVp</th>
<th>mAs</th>
<th>Grid</th>
<th>Compressed Thickness</th>
<th>Compression Force</th>
<th>S Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>kV</td>
<td>OUT</td>
<td>mm</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Information

- Confirmed slice

### Test Result

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Measured value</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missed tissue on chest wall edge (Right)</td>
<td></td>
<td>&lt; 7 mm</td>
<td>PASS</td>
</tr>
<tr>
<td>Missed tissue on chest wall edge (Left)</td>
<td></td>
<td>&lt; 7 mm</td>
<td>FAIL</td>
</tr>
</tbody>
</table>

### Remarks

Signature ____________________________

897N120924
### Annual Test Report Form

#### 6.6 In-plane resolution

**Exposure Conditions**

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>AEC</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>Auto / Semi / Manu</td>
<td>ON / OFF</td>
<td>N</td>
<td>W/Al</td>
<td>Large</td>
</tr>
<tr>
<td>kVp</td>
<td>mAs</td>
<td>Grid</td>
<td>Compressed Thickness</td>
<td>Compression Force</td>
<td>S Value</td>
</tr>
<tr>
<td>kV</td>
<td>OUT</td>
<td>mm</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Image Information**

- Confirmed slice

**Test Result**

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>2lp/mm</td>
<td>PASS</td>
</tr>
</tbody>
</table>

**Remarks**

Signature

897N120924 82
### Annual Test Report Form

#### 6.7 AEC performance

**Exposure Conditions1**

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
<th>Grid</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>OFF</td>
<td>N</td>
<td>W/Al</td>
<td>Large</td>
<td>OUT</td>
</tr>
</tbody>
</table>

**Exposure Conditions2**

<table>
<thead>
<tr>
<th>PMMA20mm</th>
<th>PMMA40mm</th>
<th>PMMA60mm</th>
<th>PMMA70mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>kV</td>
<td>kV</td>
<td>kV</td>
<td>kV</td>
</tr>
<tr>
<td>mA (AEC)</td>
<td>mA (Manu)</td>
<td>mm</td>
<td>mm</td>
</tr>
<tr>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

**Image Information**

Confirmed slice

**Test Result**

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Measured value</th>
<th>SDNR Ratio</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDNR ratio</td>
<td></td>
<td>%</td>
<td>&gt;155%</td>
<td>PASS</td>
</tr>
<tr>
<td>PMMA20mm</td>
<td></td>
<td></td>
<td></td>
<td>FAIL</td>
</tr>
<tr>
<td>SDNR ratio</td>
<td></td>
<td>%</td>
<td>&gt;90%</td>
<td>PASS</td>
</tr>
<tr>
<td>PMMA40mm</td>
<td></td>
<td></td>
<td></td>
<td>FAIL</td>
</tr>
<tr>
<td>SDNR ratio</td>
<td></td>
<td>%</td>
<td>&gt;55%</td>
<td>PASS</td>
</tr>
<tr>
<td>PMMA60mm</td>
<td></td>
<td></td>
<td></td>
<td>FAIL</td>
</tr>
<tr>
<td>SDNR ratio</td>
<td></td>
<td>%</td>
<td>&gt;45%</td>
<td>PASS</td>
</tr>
<tr>
<td>PMMA70mm</td>
<td></td>
<td></td>
<td></td>
<td>FAIL</td>
</tr>
</tbody>
</table>

**Remarks**

Signature

897N120924
# Annual Test Report Form

## 6.8 AGD

### Exposure Conditions1

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
<th>Grid</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>OFF</td>
<td>N</td>
<td>W/Al</td>
<td>Large</td>
<td>OUT</td>
</tr>
</tbody>
</table>

### Exposure Conditions2

<table>
<thead>
<tr>
<th>Equivalent breast thickness</th>
<th>kVp</th>
<th>mAs (AEC)</th>
<th>mAs (Manu)</th>
<th>Compressed Thickness</th>
<th>Compression Force</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMMA20mm</td>
<td>21mm</td>
<td>kV</td>
<td>mm</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>PMMA40mm</td>
<td>45mm</td>
<td>kV</td>
<td>mm</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>PMMA60mm</td>
<td>75mm</td>
<td>kV</td>
<td>mm</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>PMMA70mm</td>
<td>90mm</td>
<td>kV</td>
<td>mm</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>ACR MAP Phantom</td>
<td>45mm</td>
<td>kV</td>
<td>mm</td>
<td>N</td>
<td></td>
</tr>
</tbody>
</table>

### Image Information

<table>
<thead>
<tr>
<th>Height of the detection surface of the dosimeter</th>
<th>mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit of the dosimeter</td>
<td>mGy / mR</td>
</tr>
</tbody>
</table>

### Measured Dose

<table>
<thead>
<tr>
<th>Entrance air kerma</th>
<th>w/o Al</th>
<th>Al 0.3 mm</th>
<th>Al 0.5 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>(20 mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(40 mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(60 mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(70 mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ACR)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Test Result

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>AGD</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMMA20mm</td>
<td>mGy</td>
<td>&lt; 1.3mGy</td>
<td>PASS</td>
</tr>
<tr>
<td>PMMA40mm</td>
<td>mGy</td>
<td>&lt; 2.0mGy</td>
<td>FAIL</td>
</tr>
<tr>
<td>PMMA60mm</td>
<td>mGy</td>
<td>&lt; 4.5mGy</td>
<td>PASS</td>
</tr>
<tr>
<td>PMMA70mm</td>
<td>mGy</td>
<td>&lt; 6.5mGy</td>
<td>FAIL</td>
</tr>
<tr>
<td>ACR MAP Phantom</td>
<td>DBT+2D</td>
<td>mGy ≤ 3.0mGy</td>
<td>PASS</td>
</tr>
<tr>
<td>TOMO SET</td>
<td>Total</td>
<td></td>
<td>FAIL</td>
</tr>
</tbody>
</table>

### Remarks

Signature ____________________________

897N120924
6.9 Short term reproducibility

### Exposure Conditions

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>AEC</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>Auto / Semi / Manu</td>
<td>ON / OFF</td>
<td>N</td>
<td>W/Al</td>
<td>Large / Small</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>kVp</th>
<th>mAs</th>
<th>Grid</th>
<th>Compression Thickness</th>
<th>Compression Force</th>
<th>S Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>kV</th>
<th>OUT</th>
<th>mm</th>
<th>N</th>
</tr>
</thead>
</table>

#### Measured value

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Average(N3)</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mAs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Image Information

Confirmed slice

#### Test Result

<table>
<thead>
<tr>
<th>Judgment Item (Maximum value in N3)</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Upper Limit</td>
<td></td>
</tr>
<tr>
<td>SNR Variation</td>
<td>%</td>
<td>≤ Average value ±10%</td>
</tr>
<tr>
<td>mAs Variation</td>
<td>%</td>
<td>≤ Average value ±5%</td>
</tr>
<tr>
<td>S-value Variation</td>
<td>%</td>
<td>≤ Average value ±10%</td>
</tr>
</tbody>
</table>

#### Remarks

Signature

897N120924
### Annual Test Report Form

#### 6.10 Z-resolution

**Exposure Conditions**

<table>
<thead>
<tr>
<th>Tomo Mode</th>
<th>AEC</th>
<th>i-AEC</th>
<th>Dose level</th>
<th>Target/Filter</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>Auto / Semi / Manu</td>
<td>ON / OFF</td>
<td>N</td>
<td>W/Al</td>
<td>Large</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>kVp</th>
<th>mAs</th>
<th>Grid</th>
<th>Compressed Thickness</th>
<th>Compression Force</th>
<th>S Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>kV</td>
<td>OUT</td>
<td>mm</td>
<td></td>
<td></td>
<td>N</td>
</tr>
</tbody>
</table>

**Information**

Confirmed slice

**Test Result**

<table>
<thead>
<tr>
<th>Judgment Item</th>
<th>Criteria</th>
<th>Judgment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>FWHM</td>
<td>mm ≤ Baseline value ±10% *</td>
<td>PASS</td>
</tr>
</tbody>
</table>

* When baseline value × 10% is less than 1 mm, the limit shall be 1 mm or less.

**Remarks**

Signature __________________________
9 Image Processing Parameters
(for Tomo Mammography QC)

This chapter describes the image processing parameters for study menus and exposure menus used in this Program.

How to Read This Chapter
How to read descriptions included in this chapter is described below.

1 Study Menu (Exposure Menu)
The Study Menu is an aggregate of menus to be used for exposure of a series of study. The Exposure Menu included in a Study Menu, as well as order of performing studies is determined by the default, which, however, can be changed in the User Utility. (For details, see the descriptions related to the User Utility in the Operation Manual for the system.)

* Exposure menu in other chapters is defined as study menu in this chapter.
* The Study menu field is grayed out for the parameters for high-density film.

2 Exposure Menu (Exposure Submenu)
The Exposure Menu is the name of a single study such as “L MAMMOGRAPHY, CC”.

* Exposure submenu in other chapters is defined as exposure menu in this chapter.
* Default settings for each exposure menu can be changed using the User Utility.

3 MPM Code
The MPM Code is a four-digit code number assigned for the purpose of management of exposure menus. The MPM Code determines EDR (a function that corrects image density and contrast automatically) and image processing conditions to be applied. If the assigned MPM Code is the same, images will be output according to the same conditions even though the Exposure Menu used is not the same.

► Note that when an exposure menu (for example, L MAMMOGRAPHY, CC: MPM Code 0329) was subject to change of image processing conditions, the change will affect all the menus concerned if there is an exposure menu of the same MPM code (such as R MAMMOGRAPHY, CC). Should you wish to change the image processing condition only for the specified menu, change the 3rd-digit figure to make a different MPM code so that specific conditions are set up appropriately.

1st digit : Represents an exposure technique to be used. (ex. 0: General exposure, 1: Contrast exposure, etc.)
2nd digit : Represents an anatomical part to be exposed. (ex. 3: Breast)
3rd digit : Any alphanumeric selected from 0 to 9 and A to F. Even if a figure in this digit is changed, EDR will not be affected.
4th digit : Any alphanumeric that determines EDR.
4 AP/PA - Flipping setting for images to be output -

AP : Outputs an image as is without processing it.
PA : Outputs an image flipped horizontally.
dV : Outputs an image rotated by 180 degrees.
Vb : Outputs an image flipped vertically.

* Default settings can be changed using the User Utility. It is also possible to change default settings by the currently used mode.

5 Menu Description

The Menu Description describes anatomical parts and exposure techniques suited to a specific exposure menu. Brief precautions to be observed when performing exposures are also included. For details on those precautions to be observed, see the Operation Manual for the system.

• When creating a new menu

A new menu can be created using the User Utility. (For how to create a new menu, see the descriptions related to the User Utility in the Operation Manual for the system.)

For a special exposure that cannot be handled by default exposure menus, the menu can be added as necessary. When doing so, select an exposure menu that involves similar images. See the descriptions related to the User Utility in the Operation Manual for the system to make sure that the MPM code to be used for the new menu is not used, and then determine proper image processing conditions. Also confirm that AP or PA is selected correctly.

EDR Mode Table

EDR mode (auto sensitivity adjustment system) applied to exposure menus pre-registered in the system are described below.

<table>
<thead>
<tr>
<th>EDR mode</th>
<th>S Value</th>
<th>L Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto</td>
<td>When recording a digital image, the X-ray dose that reaches the exposure unit is converted to a digital value. S value is the center X-ray dose of the histogram of the digital image.</td>
<td>A logarithmic value showing the range of X-ray dose when making an exposure.</td>
</tr>
<tr>
<td>Semi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fix</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 EDR Mode

EDR mode consists of AUTO mode, SEMI AUTO mode, and FIX mode.

A (AUTO mode) : A mode which adjusts density and contrast automatically. (S and L values are dependent on this mode.)

S (SEMI AUTO mode) : A mode where the dynamic range (L value) of X-ray dose to be recorded as an image has been determined, and the center point (S value) used for the purpose of image recording is decided based on the average X-ray dose that enters the preset photometric area so that the density is adjusted automatically.

F (FIX mode) : A mode where the range of X-ray dose to be recorded as an image has been determined.

* Default settings for this mode can be changed using the User Utility. It is also possible to change the mode type currently being used.
2 Auto - Parameters used in AUTO mode -

PRIEF (Pattern Recognizer for Iris of Exposure Field) ..... This is a generic denomination of processing that recognizes split exposures and irradiated field automatically.

PRIEF includes the following technique types:
- : Does not recognize split exposures and irradiated field. (SEMI AUTO mode and type IV described below.)
1 : Does not recognize split exposures and judges a rectangular area as an irradiated field.
1S : Recognizes split exposures and judges individually recognized areas as rectangular irradiated fields.
2 : Recognizes irradiated field of a breast.
4 : Does not recognize split exposures and judges a protrusive area as an irradiated field.
4S : Recognizes split exposures and judges individually recognized areas as protrusive irradiated field. (normal mode)
4* : Judges a protrusive area as an irradiated field by split areas determined.
AN : Auto neck algorithm
SP : Activates AUTO mode based on a specially determined area, irrespective of the image size specified by DR equipment.

TYPE ..... A type of technique for histogram or neuro analysis subjected after PRIEF processing.
I : A mode that captures regions covering from the skin to the bone in an image (Note that direct X-rays are needed to activate this mode.)
II : A mode that is activated in a stable manner even if there are no direct X-rays.
III : A mode applied to contrast exposure.
IV : A mode that attaches importance to improved representation of soft tissue.
V : A mode that attaches importance to improved representation of areas where X-rays are difficult to be penetrated.
VI : Neuro analysis mode applied when variations become large on the shape of a histogram.
VII : Neuro analysis mode applied when the position of a region of interest changes on a histogram.

3 Semi Fix - Parameters used in SEMI AUTO mode and FIX mode -

TYPE ..... Determines layout and size of a photometric area preset in SEMI AUTO mode.
I : A 10cm square located at the center of an image exposed by DR equipment.
II : A 7cm square located at the center of an image exposed by DR equipment.
III : A 5cm square located at the center of an image exposed by DR equipment
III* : A 5cm square located at a position other than the center of an image when it is divided into nine portions up-and-down and right-and-left.
IV : A special area determined for the chest.

L value....... A logarithmic value (L value) representing the width of an X-ray dose to be recorded as an image in SEMI AUTO and FIX modes.
S value....... A center point (S value) pre-determined in FIX mode for recording as an Image.

* Default settings for this mode can be changed using the User Utility. It is also possible to change default settings by the currently used mode.
1 Image Format
   **Monitor**: Image display suitable for reading on the monitor is set (monitor display parameters).
   **Film**: Conventional image display or equivalent is set (film output parameters).

2 Image Processing Parameters - MFP (Multi-Objective Frequency Processing) parameters -

Gradation processing ..... Processing that controls image gradation.
   **GA**: Adjusts contrast appropriately. As the numeric value increases, the contrast becomes enhanced.
   **GT**: A non-linear gradation curve.
   **GC**: Center of a density when the GA value is changed.
   **GS**: Adjusts density appropriately. As the numeric value increases, the density appears enhanced.

Frequency processing ..... Processing that controls the image sharpness.
   **MRB**: A factor that determines the range of frequency bands when applying image enhancement. As the numeric value decreases, the range of frequency bands is widened toward lower-frequency bands.
   (See the figure below.)
   **MRT**: A non-linear curve that changes the degree of enhancement according to the image density. This parameter enhances specific density areas.
   **Example** : F : Applies enhancement uniformly in all density areas.
   R : Applies stronger enhancement as density rises.

   **MRE**: This factor adjusts the degree of enhancement.

DR compression processing ....
   Processing to make image density areas that appear white or blackened easily visible, without affecting the density in the region of interest on an image.
   **MDB**: A factor that determines the smoothing mask for DR compression processing.
   **MDT**: A factor that determines density areas where DR compression processing is to be applied.
   **MDE**: A factor that determines the degree of DR compression processing to be applied.
Figure: MRB types and enhancement curves. A stronger enhancement is applied in high-frequency bands as going from A to F.
## Image Processing Parameters (for Tomo Mammography QC)

<table>
<thead>
<tr>
<th>Exposure Menu</th>
<th>MPM Code</th>
<th>AP/PA</th>
<th>Menu Description</th>
<th>EDR Mode</th>
<th>Auto</th>
<th>Semi Fix</th>
<th>Image Format</th>
<th>Image Processing Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomo ACR MAP Phantom</td>
<td>2301 AP</td>
<td>Use in the chapter of 4.5, 4.6, 6.4, 6.5, 6.6</td>
<td>S</td>
<td>V</td>
<td>III'</td>
<td>2</td>
<td>80</td>
<td>Monitor</td>
</tr>
<tr>
<td>Tomo Max4.0 Mammography</td>
<td>030F AP</td>
<td>Use in the chapter of 6.7, 6.8, 6.9, 6.10</td>
<td>A</td>
<td>IV</td>
<td>I</td>
<td>4</td>
<td>200</td>
<td>Monitor</td>
</tr>
</tbody>
</table>