

INNOMUSE

INNOMUSE, the Women's Health Solution by Fujifilm
— Innovation for all women —



Digital Mammography

AMULET SOPHINITY

The instructions for use of these products are provided in electronic form by PDF format.
Please access to the following address and find this product page.
<https://med-lib.fujifilm.com>

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- All brand names or trademarks are the property of their respective owners.
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- For the details and availability, please contact our local representative.

FUJIFILM Digital Mammography System FDR MS-4000 consists of a digital mammography device, FDR-4000DRLC, and FDR-4000AWS workstation.

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FUJIFILM Group support the Pink Ribbon Campaign
for early detection of breast cancer



Sophisticated features. Human comfort.

Smarter and more comfortable. Pursuing a design concept that is close to the senses of patients, doctors and technologists. This leads to a smooth and relaxed test experience and provides high-quality test results and diagnostic images more reliably. This is the birth of AMULET SOPHINITY, which has refined “gentleness” to meet the needs of all women.

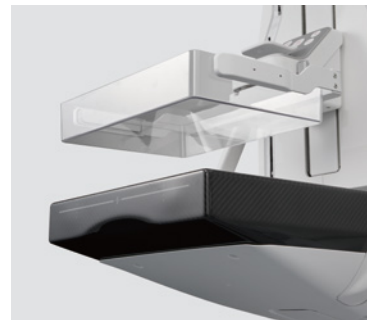


AMULET SOPHINITY

Concept Movie ↓



USABILITY



A more comfortable positioning experience

The thin and compact exposure table with reduced side bulging reduces stress during positioning. The curved shape of the front of the exposure table reduces the feeling of pressure on the abdomen associated with the CC view and improves the fit of the side of the body for the MLO view, providing for more comfortable positioning.



Armrest improves patient comfort for various imaging views

The bar on which the patient places her arms/hands during imaging has been made longer to support comfortable test postures for patient. Can also be used as a hand rest during the CC view.



Accessible button layout improves the test flow

Swivel arm rotation and height buttons have been added to the side of the tube head. Easy-to-operate buttons can be selected according to the situation, enabling smoother testing.



Smooth compression paddle operation

Allows fine adjustment of electric compression without removing the line of sight from the breast area during positioning. The compression paddle can be operated while confirming the breast condition, contributing to pain reduction for the patient.



Easy paddle attachment / removal

An array of compression paddles are tailored for the size of the breast and view to be performed. The attachment and removal of the paddles from the gantry is fast and easy for the technologist.



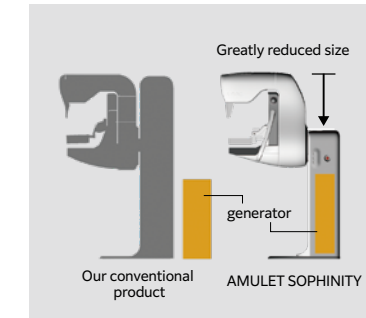
Displays and imaging information at a readily visible panel location

Displays the patient and positioning information on the panel at the bottom of the exposure stand. The technologist can easily see the information regardless of the situation during the test.



Tube parking option

The X-ray tube can be retracted to the parking position.



A new exterior design that significantly saves space and is aesthetically pleasing

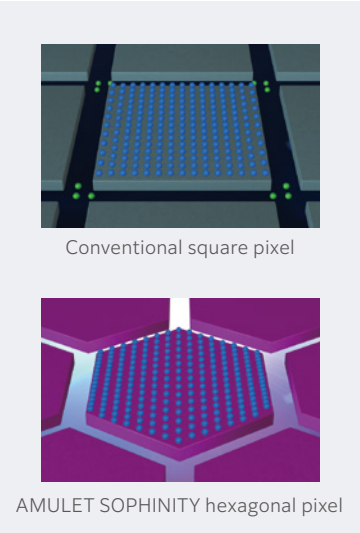
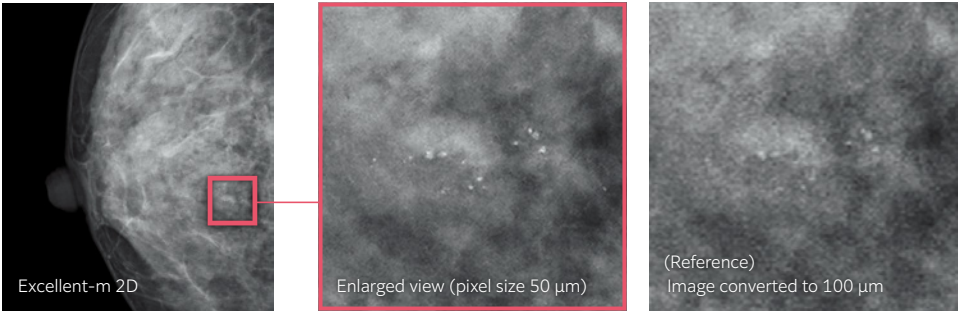
By integrating a generator within the main unit, the overall size has been significantly reduced. Can be installed in a limited space. The slim and rounded design is more aesthetically pleasing for patients and technologists alike of the patient.

HIGH QUALITY

Excellent-m 2D FUJIFILM's 2D diagnostic images

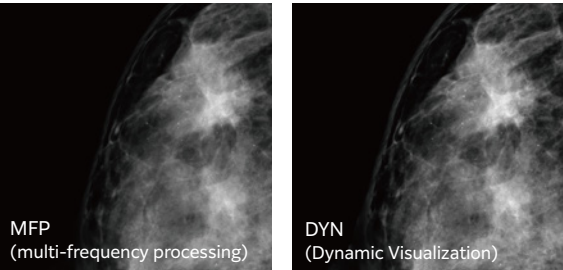
High-definition images with 50 μm pixel size.
Enables low-dose imaging.

The smallest direct conversion FPD pixel size of 50 μm enables high-definition imaging. It also includes ISC, which adjusts contrast and low X-ray dose using a Tungsten target.



Dynamic Visualization — Provides high contrast image

It has density/contrast adjustment processing, frequency enhancement processing, and dynamic range compression processing, which allow for automatic adjustment of the amount of dynamic range compression for each image. It recognizes image areas that include the characteristics of the mammary gland and fat areas, and increases the contrast of those areas independently making the density of each constant.

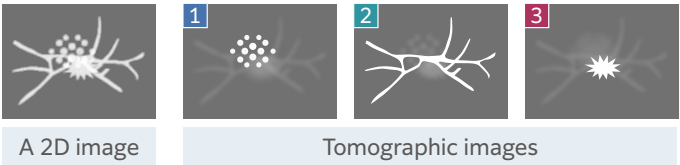
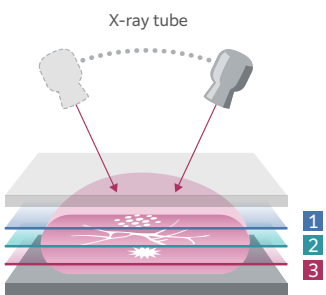


Excellent-m 3D FUJIFILM's 3D diagnostic images

Tomosynthesis Optional

Generates more projection images to reduce artifacts

Continuous tube motion for tomosynthesis sweep and images taken from multiple positions are reconstructed. It can provide images focused on the structures you want to see, further facilitating observation of lesions that are difficult to detect due to overlapping mammary gland structures.



Two modes for a wide range of clinical applications



ST (Standard) mode

Sweep angle: ±7.5°
Number of shots: 19
Pixel size: 100/150μm

This mode enables high-speed imaging by reducing the sweep angle and speeding up image readout. The depth of field is deep, and the cine display allows efficient viewing of tomographic images.

Exam / screening / follow-up, etc.



HR (High Resolution) mode

Sweep angle: ±20°
Number of shots: 35
Pixel size: 50/100μm

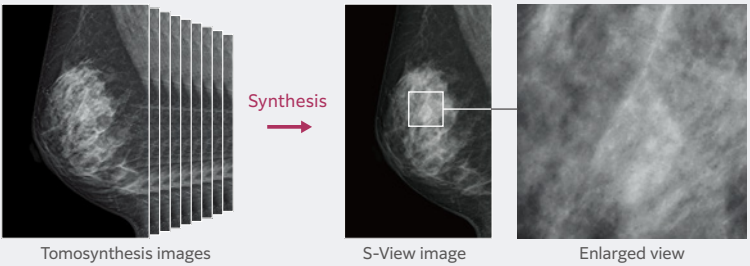
This mode has a larger sweep angle with improved depth resolution. The shallow depth of field allows for a better focus on an area of interest.

Additional imaging for close test / morphology, etc.

Functions to support diagnosis

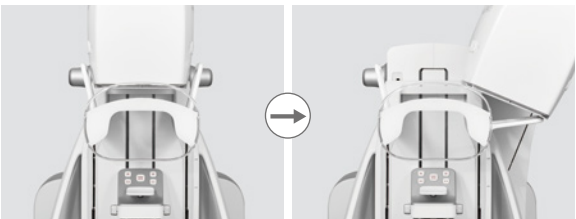
S-View (Synthesized View) Optional

A S-View image that includes breast thickness information is created from the tomosynthesis image at 50 μm. A single tomosynthesis imaging session produces a tomosynthesis (3D) image and a S-View image that includes features of tomosynthesis.



Fixed face guard for tomosynthesis imaging Optional
(Face Guard T Comfort)

To prevent movement of the face guard during tomosynthesis imaging, the face guard is secured to the supporting column of the device. The swivel arm connecting the face guard to the supporting column collapses in accordance with the tube movement, so the face guard will not be visible at either the ST (15 degrees) or HR (40 degrees) angles.



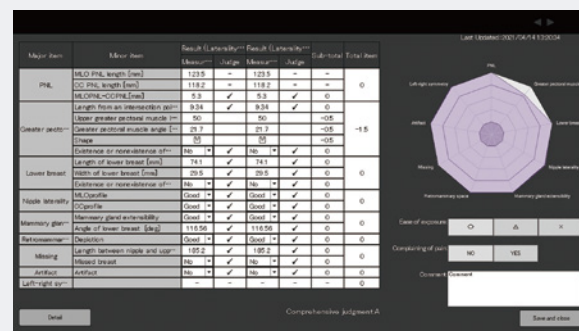
Positioning support function developed using AI technology

Projection Function (Positioning MAP) Optional

Skin lines and nipple positions extracted from past images are projected onto the exposure table surface, making it possible to capture images that can be easily compared with past images. To compare the right and left breasts, the image of the opposite side can be inverted and projected onto the table.

Positioning Analysis Optional

To further improve positioning techniques



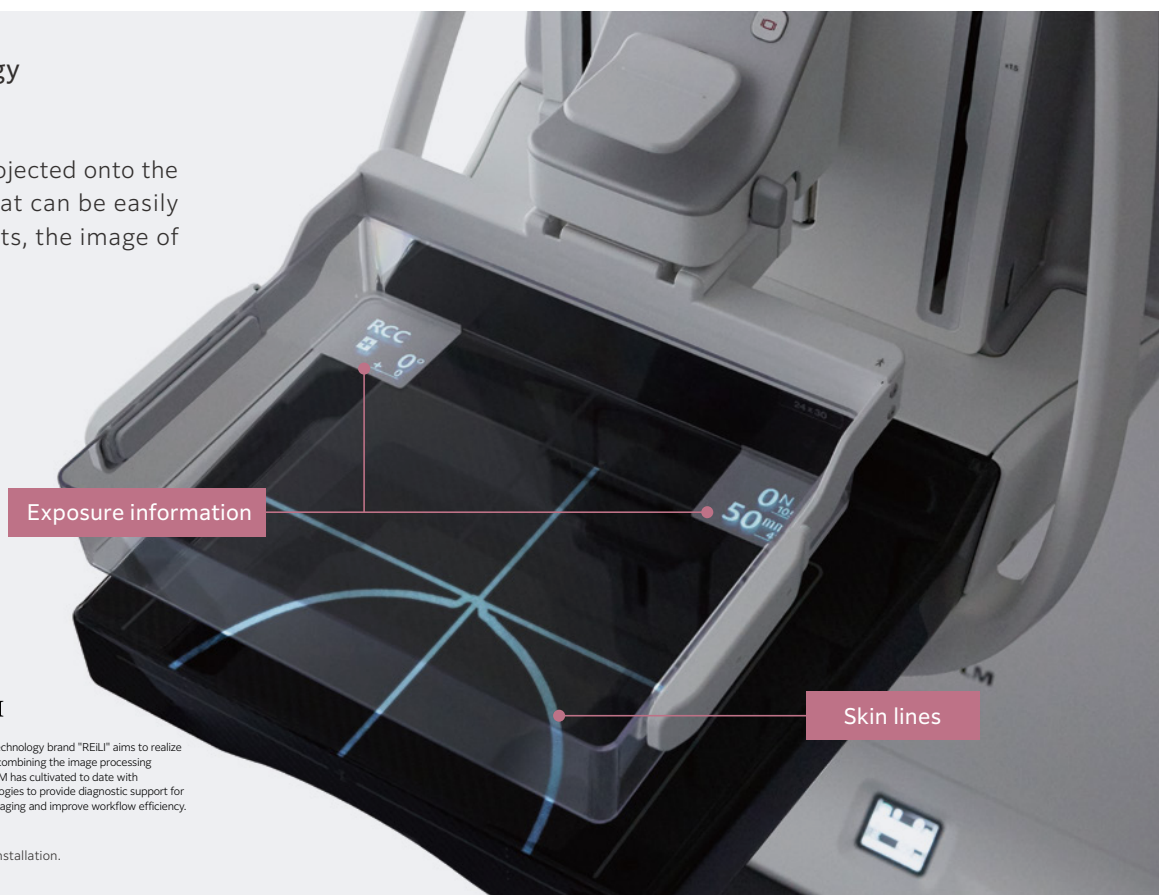
Supports technologists in improving their imaging skills by using AI technology to analyze positioning from the images taken.

*The extraction of the reference point of the pectoralis major muscle and nipple position for positioning was designed using an AI technique called deep learning. There is no automatic change in performance or accuracy of the system after installation.



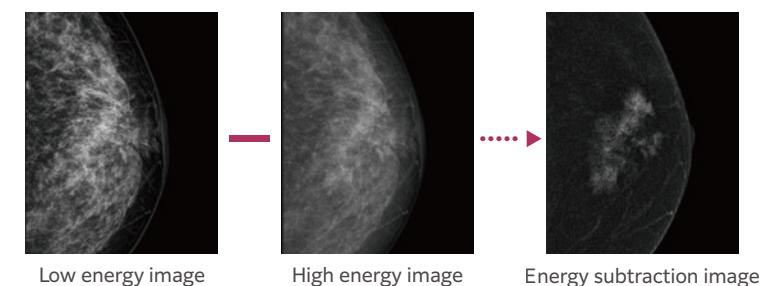
REiLI

FUJIFILM's medical AI technology brand "REILI" aims to realize better medical care by combining the image processing technology that FUJIFILM has cultivated to date with cutting-edge AI technologies to provide diagnostic support for doctors in diagnostic imaging and improve workflow efficiency.

CEDM function Optional

(Contrast Enhanced Digital Mammography)

With one compression, it continuously performs low tube voltage (low energy) imaging close to the conventional mammography imaging and high tube voltage (high energy) imaging with a Cu filter, and automatically generates and displays a subtraction image of the obtained images.

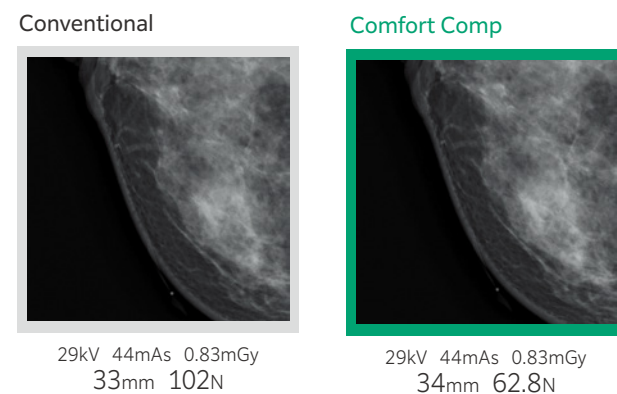


*When an iodinated contrast medium is used.

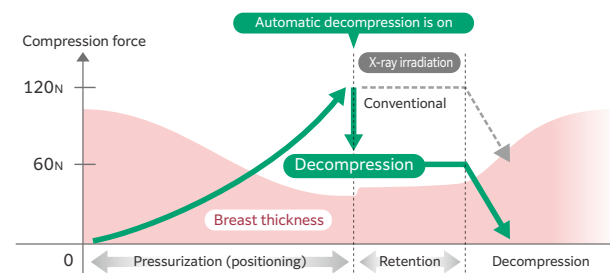
Compression automatic decompression control (Comfort Comp)

For the aim of reducing pain

This function reduces the compression pressure within the range (± 3 mm) where the thickness of the breast does not change after the completion of normal breast compression and therefore reduces the pain of the patient. The hysteresis* phenomenon is used to reduce the time that the pressure is at maximum pressure compared to normal compression methods.



■ Principle of automatic decompression



*Hysteresis: A phenomenon in which the state of a substance or system depends on the course of forces applied in the past.
L. Han, M. Burcher, and J.A. Novle. Non-invasive Measurement of Biomechanical Properties of *in vivo* Soft Tissues. MICCAI 2002, LNCS 2488, pp. 208-215, 2002.

A single button is all that is needed for automatic decompression

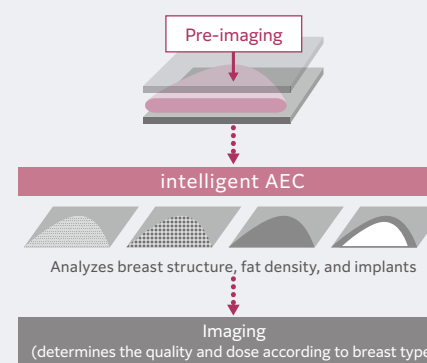
Easy to use.



Flexible for different types of breasts

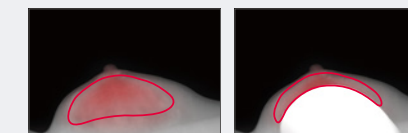
Intelligent AEC — Adjusts the x-ray dose according to breast type

The position of the mammary gland in the breast is analyzed from pre-shot images taken at a low dose. Only the mammary gland area is used, enabling imaging with appropriate technical factors and dose. Even breast implants, for which it is often difficult to determine the correct manual technique can be automatically imaged by identifying the area of the implant.



■ intelligent AEC

Automatically selects the appropriate mammary gland area from pre-shot images



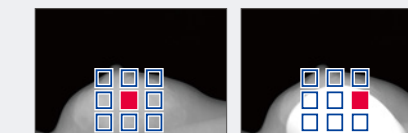
■ Manual sensor method

The technician can select the area manually during positioning, imagining the location of the mammary glands



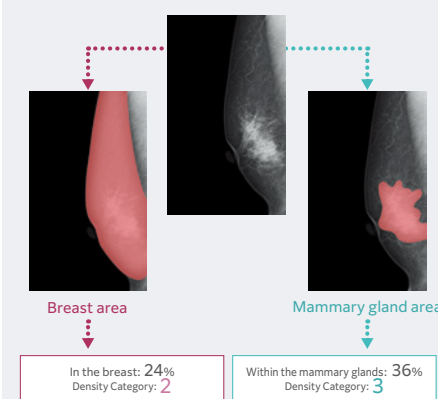
- Automatic sensor method

Automatically selects the appropriate sensor from pre-shot images



Breast Density
Assessment function
(Density Category)

Immediately after imaging, the AWS console automatically assesses the mammary gland volume and outputs the analyzed values to a DICOM Tag. Density Category thresholds can be set arbitrarily. It can assess not only the breast area but also the mammary gland volume in the mammary gland area.



FUNCTIONALITY

Biopsy System (FDR-4000BPY) Optional

Vertical biopsy kit

Use of high resolution (50 μ m) enables highly precise biopsy.
* An essential option in connection with introduction of a biopsy positioner.

Puncture at a 10° angle.

This reduces overlapping of needles, and increases visibility in the area of interest of the needle tip.



Positioner



Pre-biopsy QC automation

QC completed solely by imaging the position accuracy check needle.

* The user must check the evaluation results for the device.



Position accuracy check needle

A 7-inch, color, touch monitor is used for the operating panel.

A schematic diagram of the breast, the target coordinates, and needle information selected at the time of biopsy (diameter and aperture size) are displayed graphically as appropriate to the breast thickness. The needle position can be confirmed visually.



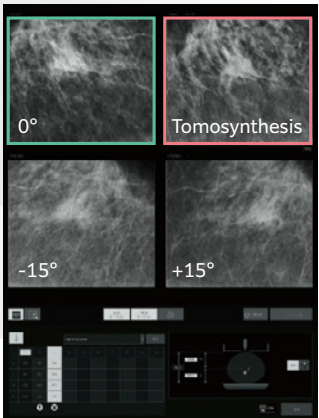
Specimen imaging kit

Using a specimen image collimator, specimen imaging is performed with the breast compressed. Use is possible even with the swivel arm rotated.



Tomosynthesis biopsy (S-View/Tomosynthesis)

When using S-View image for tomosynthesis biopsy, clicking on the S-View image displays the corresponding slice of the tomosynthesis image.



Synthetic 2D image (0°)



1. Click on the synthetic 2D image.

Tomosynthesis image



3. Automatic jump to the appropriate slice.

2. Look for the corresponding slice image with the clicked point from the tomosynthesis images.

Compression paddle



Fit Sweet Paddle for 18 × 24 (shift)

Compression plate size: 18 × 24 cm
Radiation field size: 18 × 24 cm

The compression paddle has a slit, and by using a flexible material for the slit, the compression paddle can bend along the breast to disperse the pressure during compression.



Compression paddle for 9 × 24 (shift)

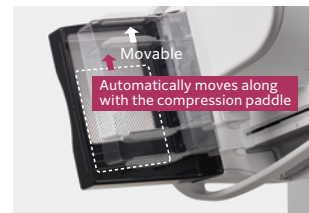
Compression plate size: 9 × 24 cm
Radiation field size: 18 × 24 cm



Compression paddle for 18 × 24 (shift)

Compression plate size: 18 × 24 cm
Radiation field size: 18 × 24 cm

The compression paddle (shift) can be moved to the center for the CC view and to the top for the MLO view. In addition, the radiation field automatically moves along with the compression paddle.



Compression paddle for 8 × 30 (shift)

Compression plate size: 8 × 30 cm
Radiation field size: 18 × 24 cm

The radiation field automatically moves along with the angle of swivel arm.



Compression paddle for 18 × 30 (shift)

Compression plate size: 18 × 30 cm
Radiation field size: 18 × 24 cm

The radiation field automatically moves along with the angle of swivel arm.



Fit Sweet Paddle for 24 × 30

Compression plate size: 24 × 30 cm
Radiation field size: 24 × 30 cm

The compression paddle has a slit, and by using a flexible material for the slit, the compression paddle can bend along the breast to disperse the pressure during compression.



Compression paddle for axilla

Compression plate size: 8 × 20 cm
Radiation field size: 18 × 24 cm
• Compression from axilla (lymph node) to the upper breast



Rectangular spot compression paddle

Compression plate size: 10 × 10 cm
Radiation field size: 9 × 9 cm
• Localized compression of the breast



Round spot compression paddle

Compression plate size: 9 cm radius
Radiation field size: 8.1 × 11.6 cm
• Localized compression of the breast



Focal spot compression paddle

Compression plate size: 18 × 24 cm radius
Radiation field size: 18 × 24 cm



Round 2D Biopsy compression paddle

Compression plate size: 18 × 23 cm
Radiation field size: 17.4 × 22.4 cm



Compression paddle for magnification exposures

Compression plate size: 17 × 23 cm
Radiation field size: 18 × 24 cm



Magnification rectangular spot compression paddle

Compression plate size: 10 × 10 cm
Radiation field size: 14.5 × 14.5 cm



Magnification round spot compression paddle

Compression plate size: 9 cm radius
Radiation field size: 8.1 × 11.6 cm



Magnification exposure table for magnification exposures (magnification: 1.5/1.8x)

• Used in a set with magnification compression paddle/magnification spot paddle



AWS — Operation workstation

User-friendly interface

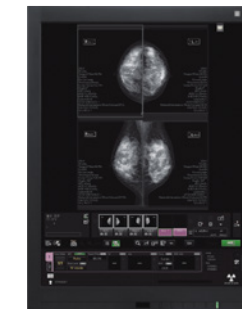
Equipped with an X-ray control section. Imaging conditions can be set and confirmed on the same screen

Enables setting and switching of 1, 2, or 4 divided displays on the test screen

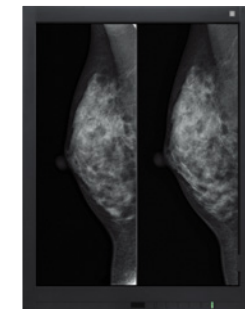
Left and right image alignment

Allows arbitrary image output even during testing

High-Definition 3M/5M Second Monitor Optional



AWS



5M Second Monitor (see past reference images)



- Second monitor allows for the display of current and/or past images for comparison* (*when connected to PACS)
- Automatically displays tomosynthesis reconstructed images
- Targeting for biopsy procedures. Displays stereotactic/tomo biopsy images.

Quality control tools for FUJIFILM Mammo QC Mammography Optional

Quality control program designed exclusively for the FUJIFILM Digital Mammography System. Provides high-quality images that enables highly reliable testing and diagnosis.



- 10-item image quality evaluation can be performed within 5 minutes
- Graphically represents day-to-day fluctuations
- Capable of data analysis and history management of daily inspection items, including the X-ray equipment
- Accumulated management data can be managed individually in a CSV file

