# AMULET *Innovality*
## FUJIFILM DIGITAL MAMMOGRAPHY SYSTEM

## Fujifilm Mammography Solution

### AMULET Bellus II (Diagnostic Workstation)

The multi-modality workstation optimized for mammography imaging can display images of MG, CT, PT, MR, CR, DX and US. Selection of a reading protocol and an image pattern is possible, providing efficient diagnosis workflow. Images can be printed at preferred positions and sizes with measurement information.

### Mammography QC Program

Fujifilm's Mammography QC Program is a dedicated quality control program that can be used on all Fujifilm digital mammography systems. This program monitors system performance to ensure stable image quality is maintained for both screening and diagnosis. Phantom for AMULET Innovality: 24 × 30 size.

### Main specifications

Standard components
- Exposure stand (FDR-3500DRLH): Approx. 624 (W) × 1270 (D) × 1974 (H) mm / Approx. 370 kg / AC 200 / 208 / 220 / 230 / 240 V
  - Control cabinet: Approx. 503 (W) × 205 (D) × 530 (H) mm / Approx. 20 kg
  - Generator: Approx. 445 (W) × 315 (D) × 825 (H) mm / Approx. 70 kg
- AWS (FDR-3000AWS): Approx. 700 (W) × 420 (D) × 1900 (H) mm / Approx. 90 kg (including protective shield and operation table) / Main unit: AC 100-240 V

- The appearance and specifications may be subject to change.   • For the details of regulatory information and availability in your country, please contact our local representative.
- Some items are optional, please contact your subsidiary for the details.   • Accessories : They are CE marked for their own class.

CE 0123

FUJIFILM supports the Pink Ribbon Campaign by creating and selling Pink Ribbon related goods to its affiliated companies, and donating a part of the sales to "JAPAN SOCIETY OF BREAST HEALTH".

# Lasting smiles for women worldwide
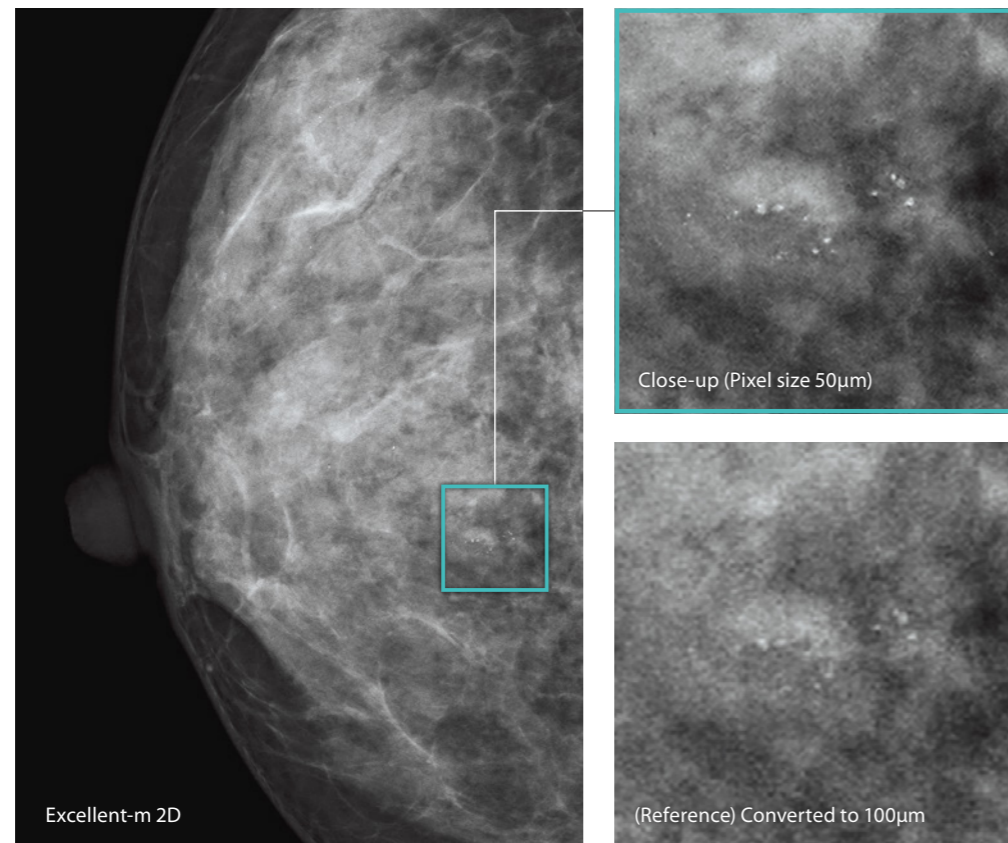
**Innova**tion and qua**lity** in mammography

AMULET Innovality — the result of Fujifilm's ongoing "innovation" and commitment to providing top "quality" mammography services. The Innovality utilises Fujifilm's unique a-Se direct conversion flat panel detector (FPD)* to produce clear images with a low X-ray dose. This system makes use of intelligent AEC (i-AEC) combined with a image analysis technology to automatically adjust the X-ray dosage for each breast type. AMULET Innovality is a highly advanced mammography system which offers an extremely fast image interval of just 15 seconds. With this system, Fujifilm furthers the provision of high quality examinations with superior image quality.

*Using a HCP (Hexagonal Close Pattern) TFT array.

| Origin of the name | With its mammography solutions Fujifilm hopes to be an "Amulet" — always there to protect women's health and allow them to be true to themselves, vibrant and beautiful. The AMULET series aims to provide top-class digital mammography solutions that can be customised to meet every sites needs. |
|---|---|

# 1 Fujifilm's unique Technology
## Solution to support diagnosis



Close-up (Pixel size 50μm)

Excellent-m 2D

(Reference) Converted to 100μm

## Unique detector for fast, low dose examinations

AMULET Innovality employs a direct-conversion flat panel detector made of Amorphous Selenium (a-Se) which exhibits excellent conversion efficiency in the mammographic X-ray spectrum. The HCP (Hexagonal Close Pattern) detector efficiently collects electrical signals converted from X-rays to realize both high resolution and low noise. This unique design makes it possible to realize a higher DQE (Detective Quantum Efficiency) than with the square pixel array of conventional TFT panels. With the information collected by the HCP detector, AMULET Innovality creates high definition images with a pixel size of 50 μm; the finest available with a direct-conversion detector.

This low-noise and high-speed switching technology allows tomosynthesis exposures with a low X-ray dosage and short acquisition time to be performed. Fast image display is also possible, realizing a smooth mammography workflow from exposure to image display.



Conventional square pixel



AMULET Innovality hexagonal pixel

## ISC – Adjusted contrast and low X-ray dose using a Tungsten Target

Image-based Spectrum Conversion* (ISC) technology can be used to adjust contrast in an image. ISC analyzes images to compensate for variations in contrast due to the density of mammary glands, amount of fat and X-ray spectrum. ISC aims to ensure that images display adequate contrast even with the use of a high energy, low-dose X-ray beam.
This technology allows sites that previously exploited the superior contrast of a Molybdenum target to realize the dose advantages offered by the use of Tungsten without having to compromise image contrast.

*Based on Image analysis the appearance is adjusted to emulate the image quality with the simulated "optimal" spectrum.
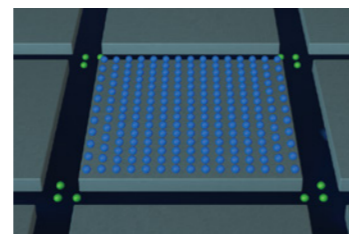
## DYN II – Provides high contrast image without saturation in breast region

Dynamic Visualization II (DYN II) provides consistent appropriate density of glandular and adipose tissue in each breast type, so the contrast of thick breast and dense breast is improved. Furthermore, it provides high contrast with no saturation in breast region, so the sites are possible to set high contrast parameter.
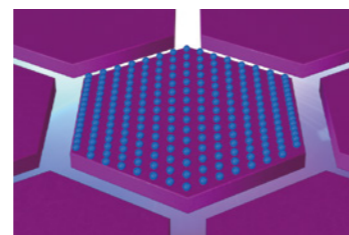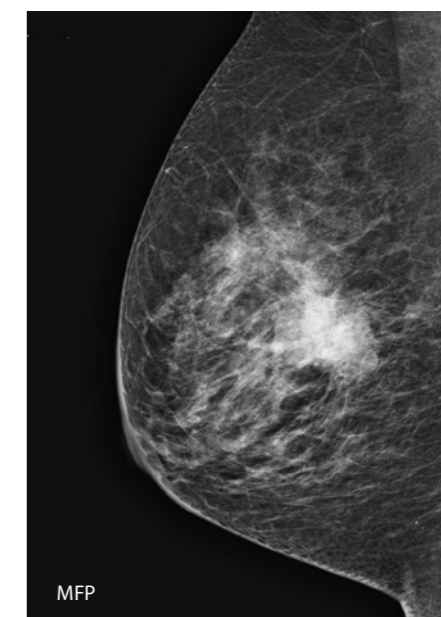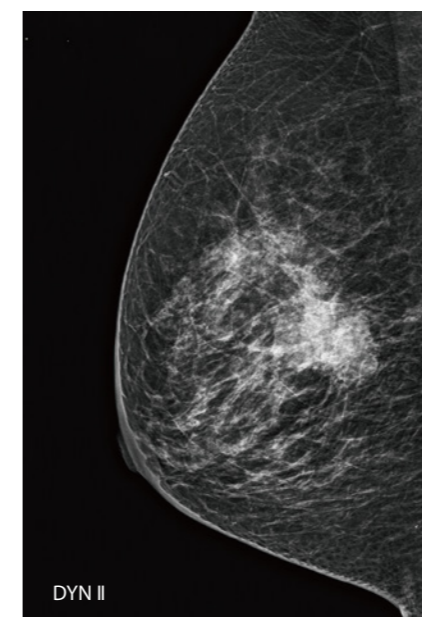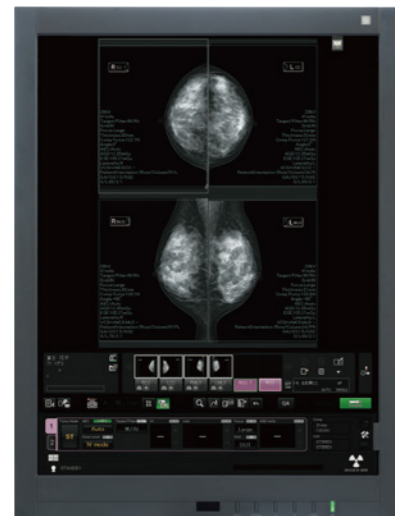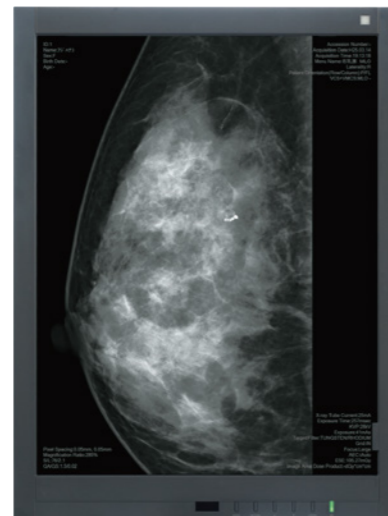


DYN II

MFP

# 1 Fujifilm's unique Technology
Solution to support diagnosis

## Dedicated mammography AWS (Acquisition Workstation)

AWS

High definition second monitor

### Optimal examination workflow

- Integrated X-ray controller allows setting and confirmation of exposure conditions on a single screen.
- Examination screen can be split and switched between 1, 2, or 4 image display.
- Individual images can be immediately output to a PACS, viewer or printer during an examination.
- Density and contrast can be easily adjusted while viewing images.
- Alignment of left and right images can be adjusted both automatically and manually.

### High definition second monitor (3M/5M: Optional)

- A second, high resolution monitor can be added to the AWS making it possible to display previous images recalled from a PACS to ensure the mammographer has access to previous images at all times.
- For Tomosynthesis, reconstructed images can be displayed.
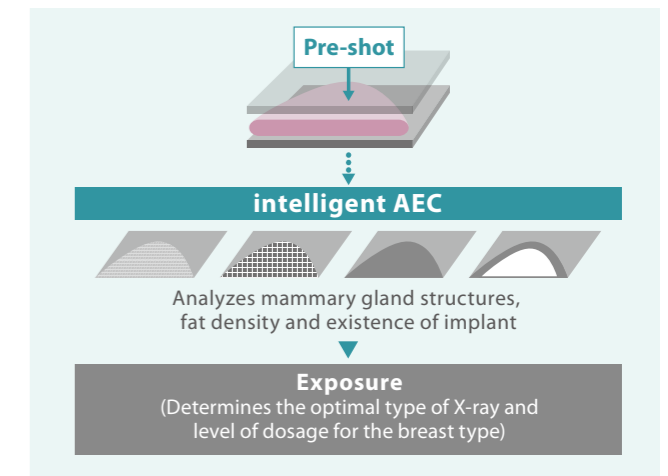
## Patient information display

The information shown on the display Ⓐ at the base of the exposure unit can be switched between patient information (ID, name, date of birth, etc.) and positioning information (angle of swivel arm, compression force and breast thickness). Positioning information can also be confirmed on the display Ⓑ on the compression arm.

Ⓐ
Ⓑ
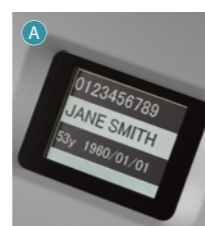
7 supported languages

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## Unique detector for fast, low dose examinations

Intelligent AEC has advantages in defining the appropriate dose for an examination compared to conventional AEC systems where the sensor position is fixed.
Through the analysis of information obtained from low- dose preshot images, Intelligent AEC makes it possible to consider the mammary gland density (breast type) when defining the x-ray energy and level of dose required.
Able to be used even in the presence of implants; intelligent AEC enables more accurate calculation of exposure parameters than is possible with conventional AEC systems.
By allowing the use of automatic exposure for the implanted breast, Intelligent AEC can further enhance examination workflow.

Pre-shot

intelligent AEC

Analyzes mammary gland structures, fat density and existence of implant

**Exposure**
(Determines the optimal type of X-ray and level of dosage for the breast type)

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

**Conventional AEC**

**Manual sensor AEC**
Requires manual adjustment of the setting based on the assured location of mammary gland

**Automatic sensor AEC**
Automatically selects the appropriate sensor from the pre-shot images

## Breast Density Measurement

As information for doctors to classify the breast more quantitatively, calculation in the mammary gland area was added to the "mammary gland volume measurement function" that automatically calculates the mammary gland volume in the breast area from a mammography image. This mammary gland volume measurement in the breast area/mammary gland area can also be calculated with Tomosynthesis images.

**Breast area**
▼
In the breast: 24%
Density Category: **b**

**Mammary gland area**
▼
In the mammary gland: 36%
Density Category: **c**
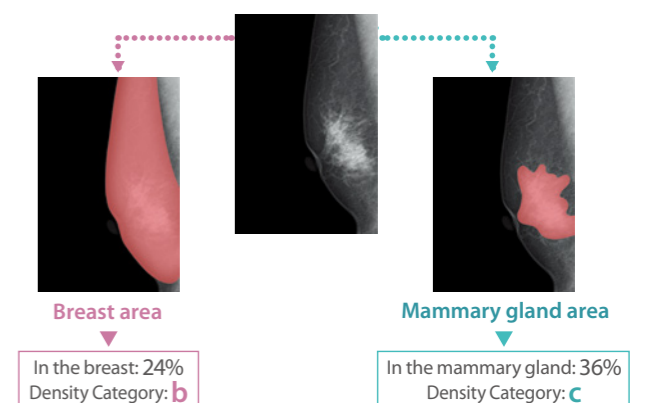
## CEDM function

With one compression, it continuously performs low tube voltage (low energy) imaging close to the ordinary 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.
This subtraction image constitutes an image emphasizing specific tissues.

Low energy image   High energy image   Energy subtraction image
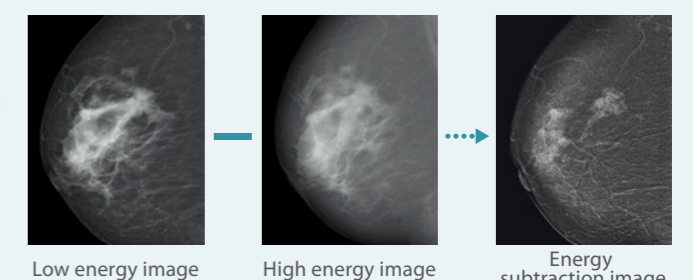
*When an iodine-based contrast agent is used
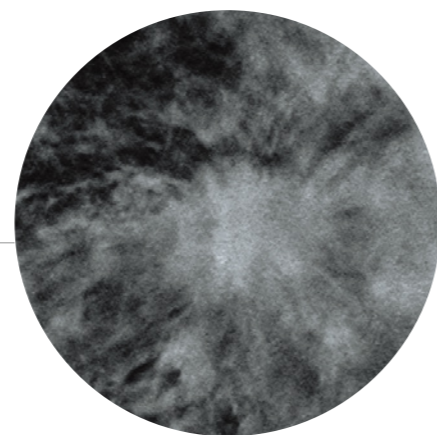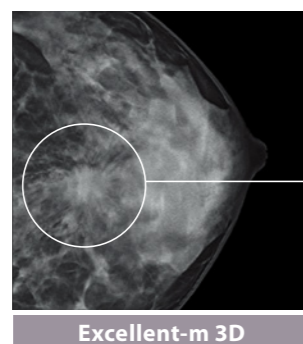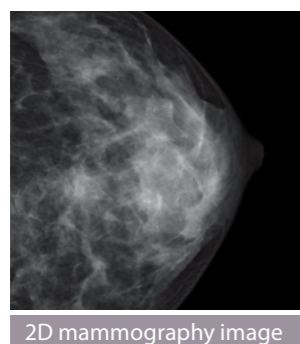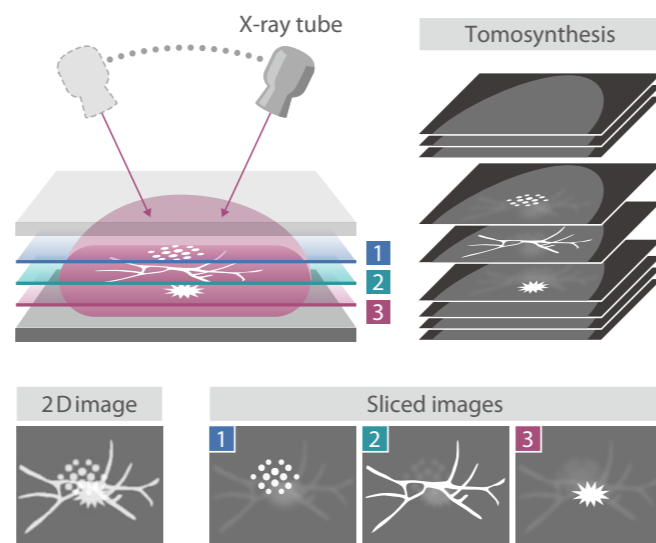
# 2 Tomosynthesis
## High quality images for easier diagnosis

## Tomosynthesis: making it possible to observe the internal structure of the breast

In breast tomosynthesis, the X-ray tube moves through an arc while acquiring a series of low-dose X-ray images. The images taken from different angles are reconstructed into a range of Tomosynthesis slices where the structure of interest is always in focus.

The reconstructed tomographic images make it easier to identify lesions which might be difficult to visualize in routine mammography because of the presence of overlapping breast structures.

The Tomosynthesis function on AMULET Innovality is suitable for a wide range of uses, offering two modes to cater for various clinical scenarios. Standard (ST) mode combines rapid exposure timing and efficient workflow with a low X-ray dose while High Resolution (HR) mode makes it possible to produce images with an even higher level of detail, allowing the region of interest to be brought into clearer focus.

X-ray tube

Tomosynthesis

2D image

Sliced images

1 2 3

2D mammography image

Excellent-m 3D

### S-View (synthesized 2D image) function is available

Tomosynthesis by AMULET Innovality automatically produces not only tomograms obtained at 1mm intervals but also a two- dimensional S-View image combining multiple slice images.

With the S-View image showing the overall view added to tomograms offering the views in detail, comprehensive image reading is possible.

Multiple slice images

S-View image
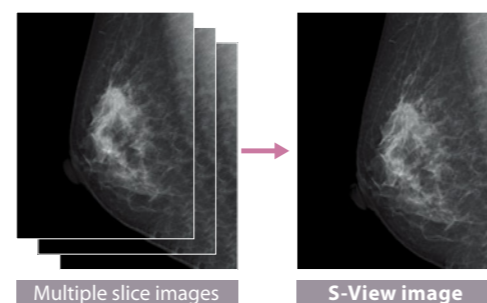
## ISR (Iterative Super Reconstruction)

# Excellent-m 3D

The tomosynthesis iterative super-resolution reconstruction (ISR) method is applied to optimize image quality, achieving significant X-ray dosage reduction.

### 1. Reducing graininess of image in low-dose tomography

The image patterns are recognized to selectively suppress the patterns that do not exist in human body architectures as noise, to reduce distractive noises in the event of low-dose tomography.
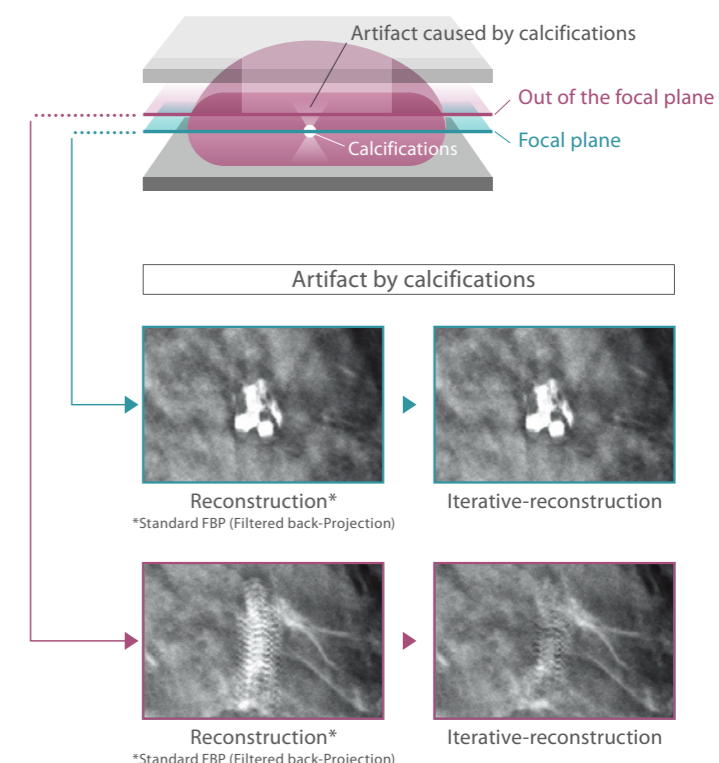
### 2. Suppressing interference of human body architectures at different depths
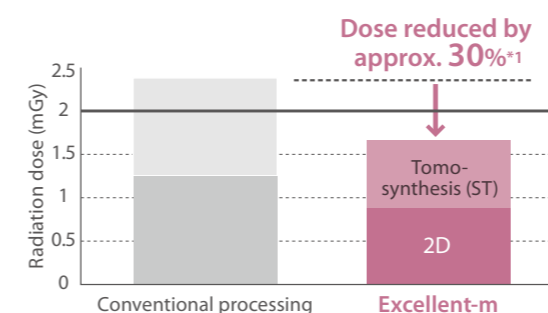(as illustrated on the right)

In the process of reconstructing the 3D breast architecture from multiple 2D images, calcification, mass, spicula, mammary gland and other signals that emerge from different depths in the breast architecture are selected off to reproduce the breast architecture at the focus depth with greater fidelity.

### 3. Restoring the fine-structure

Our super-resolution technology is introduced to restore the fine-structure of calcification and other phenomena, the visibility of which is impaired by the movement of the X-ray tube, to facilitate interpretation of tomosynthesis images.

Artifact caused by calcifications

Out of the focal plane

Calcifications

Focal plane

Artifact by calcifications

Reconstruction*
*Standard FBP (Filtered back-Projection)

Iterative-reconstruction

Reconstruction*
*Standard FBP (Filtered back-Projection)

Iterative-reconstruction

## Offers significantly lower doses than the conventional method

Dose reduced by approx. 30%*1

Radiation dose (mGy)

2.5
2
1.5
1
0.5
0

Conventional processing

Excellent-m

Tomo-synthesis (ST)

2D

### With combination of 2D and Tomosynthesis Dose of 2 or less mGy is available*2

*1: Equivalent to an image of 40 mm PMMA compared with previous images (Breast thickness of 45 mm, 50% mammary gland, 50% fat)
*2: IAEA guidance level: 3 mGy, guidelines of the Japan Association of Radiological Technicians: 2 mGy

*In-house comparison

# 2 Tomosynthesis
High quality images for easier diagnosis

## Two modes suitable for a range of clinical purposes



approx. 9 seconds

approx. 4 seconds

### HR (High Resolution) mode

• Acquisition angle: ±20°  • Pixel size: 100/50µm

With a larger acquisition angle the depth resolution is improved. This allows the region of interest to be defined more clearly and brought into clearer focus.
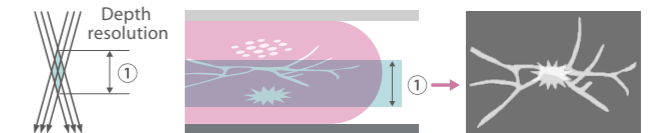
Depth resolution ②

Additional imaging for complete checkup, grasping morphology, etc.

### ST (Standard) mode

• Acquisition angle: ±7.5°  • Pixel size: 100/150µm

The smaller angular range and fast image acquisition allow Tomosynthesis scans to be quickly performed with a relatively low X-ray dose.

Depth resolution ①

Check-up, screening, follow-up, etc.

## Static face guard for Tomosynthesis imaging
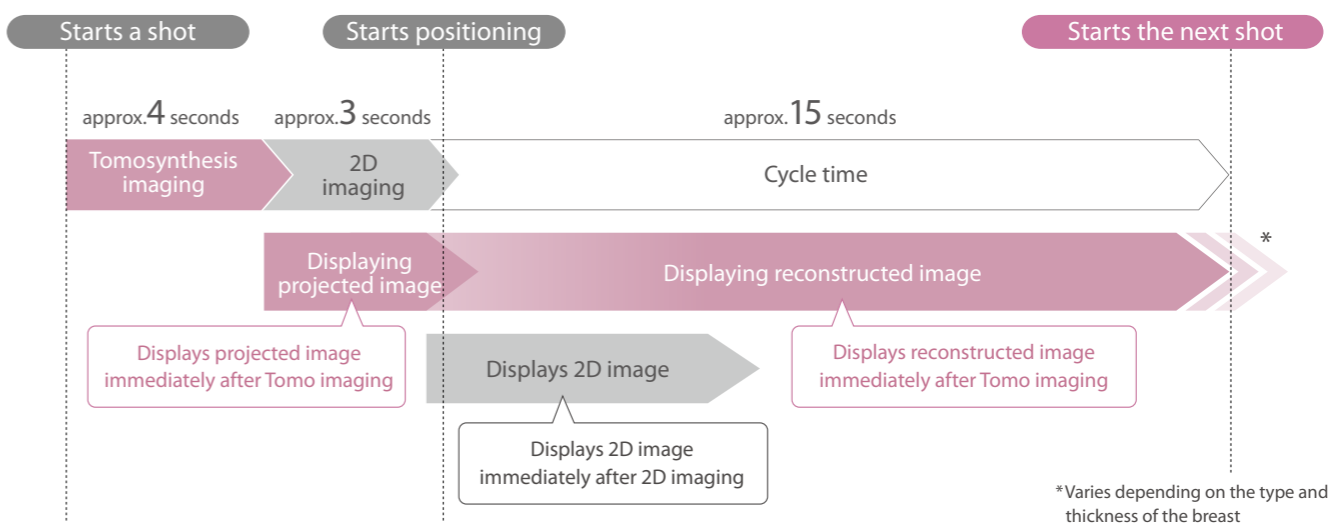[Face Guard Comfort (898Y200541)]  (Accessories)

Fixing the face guard to the device instead of the tube part eliminates movement of the face guard during Tomosynthesis imaging. It will not be reflected at any angle of the ST mode (15 degrees) or HR mode (40 degrees). It can also be used as-is for normal mammography imaging.



## Shortens the imaging cycle with a fast display and reconstruction

After a shot, the next shot in either 2D or 3D can be started with a cycle time of approx. 15 seconds.

In the case of ST mode

Starts a shot          Starts positioning                          Starts the next shot

approx. 4 seconds    approx. 3 seconds          approx. 15 seconds

Tomosynthesis imaging | 2D imaging | Cycle time

Displaying projected image | Displaying reconstructed image     *

Displays projected image immediately after Tomo imaging

Displays 2D image

Displays reconstructed image immediately after Tomo imaging

Displays 2D image immediately after 2D imaging

*Varies depending on the type and thickness of the breast

# 3 Advanced Biopsy System
## Supports a variety of approach for patients

## Biopsy – 50μm image solution (FDR-2000BPY) (Accessories)

The system is designed to support flexible positioning of tube and detector, from -90°to +90°. Ergonomically designed arm rests and disposable soft pads ensure patient comfort and safe positioning.

-90°   +90°

69cm
(minimum)

L   R
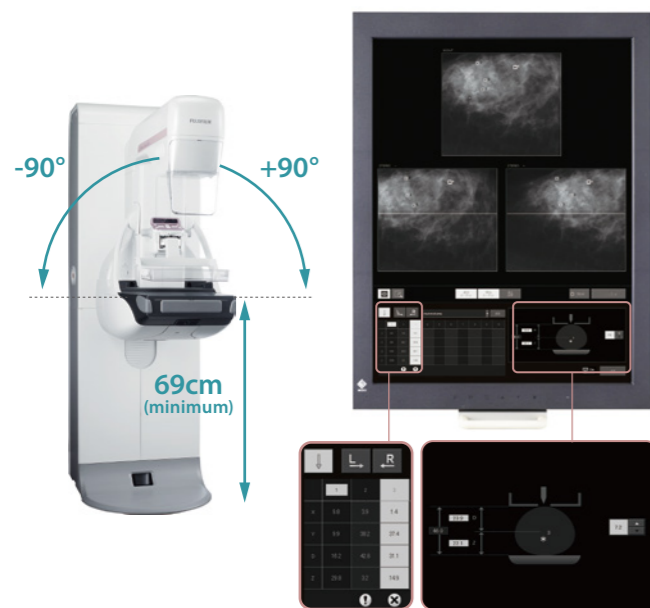
- Irradiation field size can be easily adjusted, depending on breast size and procedure needs. Convenient spacers can be used in order to perform needle positioning in extremely thin breasts, too.
- AEC full automatic function is available for both scout (2D) and Tomosynthesis exposures.
- Prior images and studies can be viewed during biopsy, to further improve accuracy.
- Variable image resolution for different needs

50μm
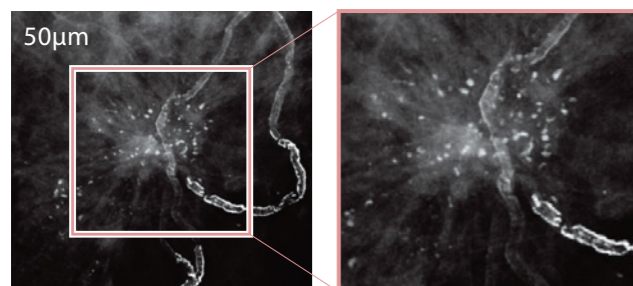
### Lateral approach (898Y101490) (Accessories)

Thanks to the adapter, needle positioning can be performed both vertically and laterally. Accessing to the compressed breast in two directions ensures precise targeting of lesions which might be in a difficult position.

### Supports a variety of needle

Both CNB/FNB/Hook wire and VAB needles can be used in a wide range of sizes, for various models and manufacturers.

Refer to technical specifications and to local representatives for further information.

## Tomosynthesis Biopsy

Targeting is supported using both tomosynthesis and stereoscopic images: the choice depends on operator confidence and lesion positioning. Tomosynthesis acquisition can be performed in both ST (Standard) and HR (High Resolution) modes, according to desired accuracy and lesion size.

HR: ±20°

ST: ±7.5°

2D image(0°)   Tomo

-15°   +15°
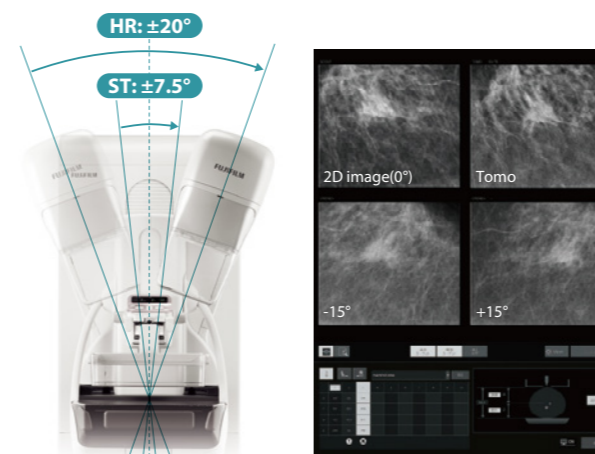
- Using a tomosynthesis image, it makes it possible to target the lesion which cannot be found on 2D image.
- Thanks to easier lesion position identification, tomosynthesis targeting results in a more efficient workflow and more simple operation.

**Stereo imaging**

2D image   -15°   +15°

-15°   +15°

- Overlapping breast structures make lesions less visible
- Difficult to identify a particular region

**Tomosynthesis**

① ② ③

①②③

- Reconstructed images show overlapping structures separately
- Easier to locate a target than with the conventional method

- Both Tomosynthesis and stereotactic support for needle positioning

2D   Tomosynthesis
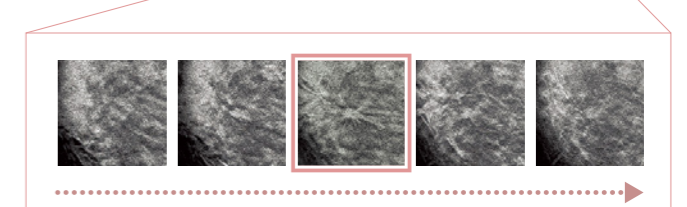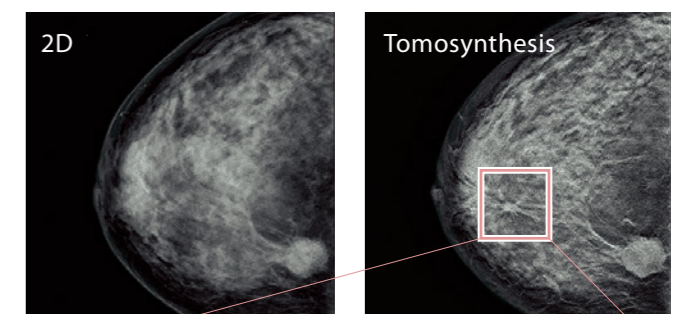
**The highest image quality and workflow efficiency for interventional procedures**

# 4 AMULET Harmony
## Easy operation and patient comfort

AMULET *Harmony*

AMULET Harmony incorporates a range of mammography solutions specifically designed to maintain a harmonious examination environment and foster an atmosphere of trust between mammographers and their patients.

## Mood lighting to ease patient anxiety

Warm indirect lighting is used to illuminate the exposure stand, helping patients to relax and allowing examinations to be performed with minimal stress.

## Decorative labels adaptable to each room environment

Five different stand labels are available to add a gentle ambience. Each site can choose a stand appearance that best suits the examination environment, thus relieving patient stress and anxiety.

## Automatic compression reduction control (Comfort Comp)

This function will reduce the compression pressure within a range (within + 3 mm) in which the thickness of the breast does not change after normal breast compression is completed for the purpose of alleviating the patient's pain. For breast compression, there is a phenomenon (hysteresis*) where the thickness of the breast becomes thinner during decompression after compression than during compression even with the same pressure. By utilizing this phenomenon, it is possible to automatically decompress it so that the breast condition remains almost the same even if the duration of maximum compression pressure is reduced.

Compression force

120N
60N
0

Automatic decompression ON
X-ray irradiation
Conventional
Breast thickness

Compression (positioning) — Retention — Decompression (compression release)

Decompression

* Hysteresis: A phenomenon where the state of a substance or system depends on the course of force added 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.
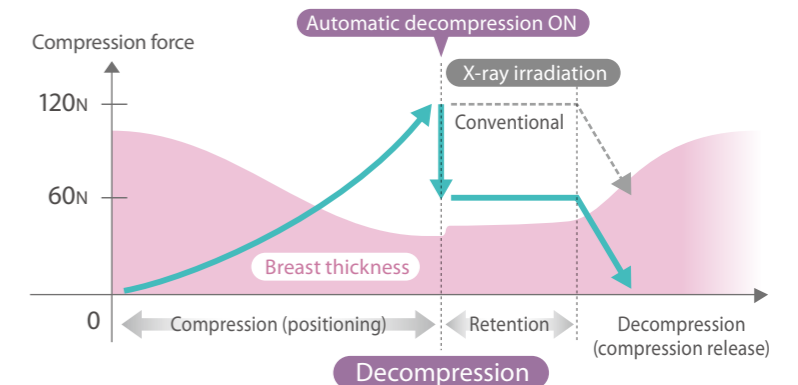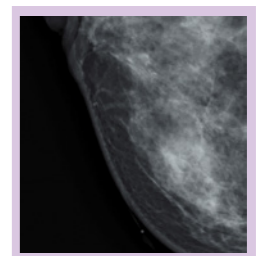
Conventional
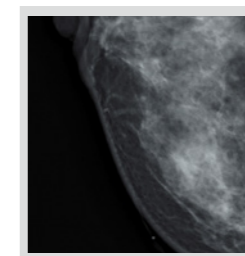
Comfort Comp

29kV   44mAs   0.83mGy
33mm   102N

29kV   44mAs   0.83mGy
34mm   62.8N

## Fit Sweet Paddle (401Y100131, 401Y120033, 401Y200001, 401Y100130) (Accessories)

This type of compression paddle fits to the shape of the breast, allowing pressure to be evenly applied while holding the breast securely and ensuring the breast tissue is adequately separated. Models with the lateral shift function are also available in the lineup.
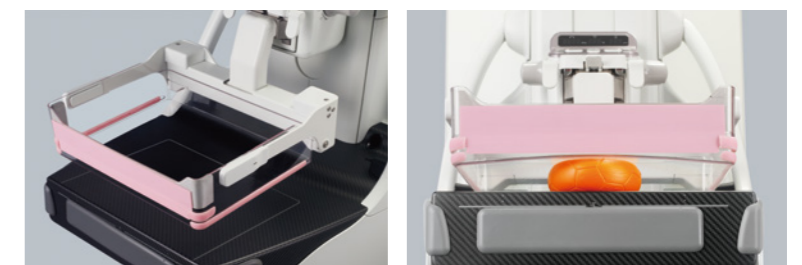
## Shift Compression Paddle

### 18×24 cm (401Y120038, 401Y120046, 401Y200001) (Accessories)

This small compression paddle can be positioned in the middle, right or left side of the detector at any time of examination according to the positioning of the patient.
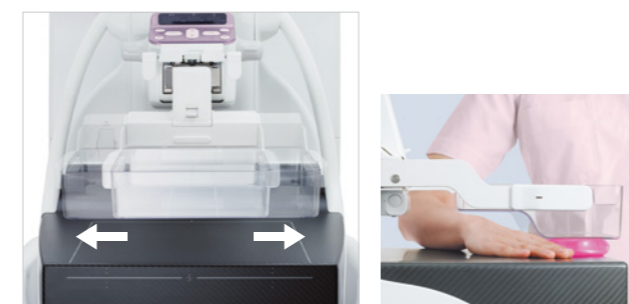
### 24×30 cm (401Y120025, 401Y100124) (Accessories)

When this compression paddle is used with 18×24 cm radiation field, the radiation field remains in the center for the CC position, while shifting to the upper portion of the detector when the C-arm is rotated to a MLO or ML position.