

AMULET Innovality; Technical Information

Medical Systems Research and Development Center, FUJIFILM Corporation



1. Introduction

FUJIFILM has developed a new mammographic system, AMULET Innovality (Fig. 1), equipped with a Flat Panel Detector (FPD), using a Hexagonal Close Pattern (HCP) structure, for Tomosynthesis mammography.

Tomosynthesis is a function (Fig. 2) where multiple images of a subject are acquired at different angles and these images are then reconstructed to create sliced images of the subject. In the field of mammography, lesions that were previously difficult to be seen have become more visible because the use of layered images allows normal structures such as mammary gland to be separated from abnormalities such as tumours. Thus, Tomosynthesis is a technology that expected to enhance detection performance.

The technology employed in AMULET Innovality and the characteristics of the Tomosynthesis implementation are going to be explained in this introduction.



2. Dual mode Tomosynthesis

The AMULET Innovality has 2 Tomosynthesis mode types available; 'ST-mode', which has been developed to ensure a shorter exposure time and low exposure dose and 'HR-mode', which has been developed to maximise image quality and achieve a high resolution. In this chapter, the characteristics of each mode are going to be introduced.

2-1. Exposure time

When exposure time increases, it can cause deterioration of workflow, patient discomfort due to an increase in the compression time and possible image degradation as a result of patient movement and image blurring. Hence, it is extremely important to minimize the exposure time.

Continuous movement of the X-Ray tube has been employed, allowing exposures while the tube is moving. Further optimizations of the system design including high power X-ray irradiation, rapid image readout, and operational speed and safety of the X-ray tube have been performed in order to minimize the X-ray irradiation time in both available modes as shown in Table 1.

Table 1 Time from start of X-ray irradiation to end in each mode

Mode	Time from start of X-ray irradiation to end
ST-mode	Approx. 4 seconds
HR-mode	Approx. 9 seconds

In a clinical study performed at the National Hospital Organization Nagoya Medical Center, patients indicated that the examinations were similar to 2D mammography despite the use of HR-mode, which has relatively long X-ray irradiation time.

2-2. Time to display an image

When the time to display an image is long, it can cause a delay in confirmation of patient position and a possible decrease in workflow. Therefore, it is extremely important to minimize the image display time.

Accordingly, image reconstruction by a separate Graphics Processing Unit (GPU*), and parallel image postprocessing with multicore CPU is used to optimize data flow and prevent data being withheld while each processing is performed. Through structuring the image processing flow in this manner, image display during an X-ray exposure has been achieved; allowing for prompt confirmation of patient positioning. Moreover, the time to display the reconstructed image after the completion of X-ray irradiation has been minimized as shown in Table 2. As a result, reconstructed images can be confirmed immediately after the completion of patient positioning for the subsequent exposure.

* Multiple sets of hardware perform high speed calculations for graphic display

Table 2 Time from start of X-ray irradiation to image display in each mode

Mode	Time from start of X-ray irradiation to image display in each mode
ST-mode	Approx. 4 seconds
HR-mode	Approx. 5 seconds

2-3. Resolution

Clear visualization of the characteristics of lesions and tissues as well as the accurate identification of their position is beneficial to improve detection performance and accuracy of diagnosis in Mammographic imaging. This can also provide additional information ahead of supplementary examinations including ultrasound and biopsy. Increasing the angle of the X-ray tube can achieve clearer separation of structures however an increase in the angle of the X-ray tube is also associated with an increase in exposure time because of the longer tube travel distance. For larger acquisition angles the available image area is also reduced because the X-ray beam travels at an oblique angle within the breast.

Because of these known limitations, the exposure angle of HR-mode has been set at $\pm 20^{\circ}$ to maximize the z-axis resolution (depth resolution) of the breast while avoiding the above problems. In ST-mode, the exposure angle has been set at $\pm 7.5^{\circ}$ to combine a high speed exposure with a good depth resolution (Fig. 3).

On the other hand, the resolution of the lateral direction has been defined as 150µm/pixel in ST-mode and 100µm/pixel in HR mode to optimize each mode for high speed exposure and maintain a balance between the visibility of breast architecture and image granularity while optimizing detection of microstructures such as calcifications. In the clinical study at the National Hospital Organization Nagoya Medical Center, spiculations and the marginal structures of tumors were evaluated as being more visible in HR-mode tomosynthesis than in 2D mammograms. The distribution of depth direction of microcalcification was evaluated as visible in ST-mode even though the depth resolution is less than in HR-mode.



Fig. 3 Tomosynthesis modes and depth resolutions

2-4. Exposure dose

AMULET Innovality realizes low X-ray dose mammography through the use of a Tungsten (W) anode, which has higher energy spectrum than a Molybdenum (Mo) anode.

Because 15 images are acquired in one Tomosynthesis scan, X-ray dose per exposure becomes as low as approximately 7% of 2D mammography. To allow high image quality with a low X-ray dose, a newly developed FPD with a highly sensitive HCP structure is mounted. Due to the development of this new FPD, low dose mammography in approximately 1mGy on 45mm average breasts has been achieved in ST-mode Tomosynthesis.

Compared to ST-mode, HR Mode Tomosynthesis provides a higher definition image readout and slice resolution. Additionally, because the effective breast thickness becomes even greater in exposures with large acquisition angles, more X-ray attenuation occurs. Thus, to maintain image quality at the increased depth resolution of HR Mode, a dose of approximately 2mGy for 45mm average breasts has been defined and the superior image quality required for detailed examinations has been achieved.

3. Original reconstructed image

AMULET Innovality is equipped with a number of FUJIFILM's original image processing technologies that are applied for Tomosynthesis imaging. In this chapter, the reconstruction processing, image processing and new functionality are going to be separately introduced.

3-1. Reconstruction processing

There are two methods to create reconstructed images from Tomosynthesis projection images: Filtered Back Projection (FBP) and Iterative Reconstruction. It is easier to reduce artifact in iterative reconstructed images than FBP. However, iterative reconstruction can cause a long waiting time before an image is confirmed, leading to a decrease in workflow and the possible need to add an additional calculation system because of the large scale of the calculation.

Because of this limitation the AMULET Innovality is equipped with original reconstruction processing to realize the reduction of artifacts and minimize the calculation system required (Fig. 4).



Fig. 4 Artifact associated with reconstruction (arrows) (Left) FBP, (Right) Original reconstruction processing in AMULET Innovality

3-2. Image processing

In order to allow doctors to utilize knowledge of 2D mammography diagnoses and allow comprehension of microstructures within breasts, two types of image processing have been newly developed for AMULET Innovality. This image processing allows the preparation of both 2D-like images and images with emphasized microstructures. Moreover, AMULET Innovality is equipped with a function making it possible to select between the two types of the image processing. Reconstruction images with natural density information similar to 2D

mammogram, have been developed in order to allow for interpretation of a mammogram using knowledge of 2D mammography diagnoses (Fig. 5, Pattern 1). Results from the clinical study at the National Hospital Organization Nagoya Medical Center indicate that knowledge of 2D mammographic reporting can be utilized for Tomosynthesis imaging; making it easier to distinguish lesions from mammary gland, identify the difference between a tumor and its surrounding structure and understand the volumetric structure of a breast thickness.

Furthermore, a reconstruction image with more emphasized microstructures and linear structures such as microcalcification, spiculation and mammary gland structure (Fig. 5, Pattern 2) has been developed in response to the requirement for better understanding of the microstructures within breasts.



Fig. 5 Images of the same breast (Left) 2D mammogram, (Middle) Pattern 1, (Right) Pattern 2

3-3. S-view

S-View is a function that creates pseudo projection images (2D mammograms) by re-projecting reconstructed images from a virtual focus. Distribution of microstructures such as microcalcification can be difficult to comprehend in Tomosynthesis slice imaging because reconstruction images are normally observed in a movie format in approximately 1mm slice intervals. However, because S-View projects reconstructed image information to one full thickness image, it is useful to comprehend the distribution condition of microstructures such as microcalcification.

4. Characteristics of other key technologies used in AMULET Innovality

AMULET Innovality is equipped with a number of other key technologies beyond those previously described. These technologies are going to be introduced in this chapter.

4-1. Image-based Spectral Conversion (ISC) dose correction technology

Compared to mammograms with a Molybdenum (Mo) anode, those taken with a Tungsten (W) anode display a reduced image contrast. (Fig. 6). In order to resolve this problem, Image-based Spectral Conversion (ISC) processing has been newly developed to use Image Analysis and information about the exposure subject to correct for the decrease in image contrast caused by differences in the amount of mammary gland and fat, breast thickness and X-ray spectrums. An equivalent contrast to mammograms exposed in Mo anode has been achieved in mammograms exposed with a W anode when using ISC technology for AMULET Innovality.



Fig. 6 Mammograms of the same specimen exposed with W anode and Mo anode

4-2. FPD with HCP (Hexagonal Close Pattern) configuration

A new FPD with HCP structure has been developed that can increase the electromagnetic intensity between the pixels compared with the conventional square structure (Fig. 7). It is easier to accumulate generated electric charge in FPDs with HCP structure and the sensitivity has been dramatically improved. Furthermore; graininess, especially in low-density field, has been dramatically improved by the original circuitry with an exclusive chip, which can be used at a low x-ray dose with high sensitivity.

Because AMULET Innovality is equipped with this newly developed FPD, high image guality is achieved in 2D mammography as well as with Tomosynthesis mammography, where projection images can be exposed at low X-ray doses.



Fig. 7 Intensity of electric field of FPD (Left) Square structure (Right) HCP structure

4-3. i-AEC

i-AEC is a newly developed technology that judges the existence of an implant immediately after a low-dose pre-shot exposure (Fig. 8). i-AEC locates the region of mammary gland tissue to determine the appropriate exposure technique. i-AEC is not dependent on the conditions of the subject or differences in positioning and can define the optimum X-ray irradiation condition according to the mammary gland distribution.



Fig. 8 Example of mammary gland extraction by i-AEC (red frame) (Left) Average breast, (Right) Implanted breast

4-4. High voltage X-ray generator

The new development of the rotor drive circuit for X-ray tube with an increase of the power output of the high voltage generator to 7kW has made it possible to provide large current, repeated X-ray irradiations in a short period of time as required for Tomosynthesis.

4-5. FS (Fit Sweet) Compression Paddle

In addition to the compression paddle tilting in accordance with the thickness of a breast when it is in contact with the paddle, FS has been designed to distribute the compression to breasts across the surface of the paddle (Fig. 9). This has been achieved by leaving a space in each of three sections (in front and both sides of the compression paddle). As a result of this new design, the pain of breast compression previously caused by concentrating compression to the thickest part of a breast has been reduced.



Fig. 9 FS Compression Paddle (Left) Areas of Gap in Paddle Structure, (Right) Distribution of pressure

4-6. Under-armrest

An Under-armrest can offer benefits for reduction of body movement and positioning time by allowing easier positional retention when positioning patients for other than the routine CC and MLO position. It is also beneficial for patients who have difficulty using the standard armrest. As a result, an optional bar handle can be attached to the back of the breast support that has been designed to allow subjects to maintain the required posture (Fig. 10).



Fig. 10 Under-armrest

5. Conclusion

The main Tomosynthesis technology equipped in AMULET Innovality and its characteristics have been introduced at this time. Each technology was developed for quality improvement of mammographic screenings and diagnostic examinations including improvements in diagnostic performance, workflow and patient sense of security. We are continuously contributing further technological developments in the field of breast cancer screening and diagnoses.

[Acknowledgement] : Once again, we would like to express our gratitude to the doctors and those related to the development who kindly advised us for the study FUJIFILM supports the Pink Ribbon Campaign for early detection of breast cancer

[Note] : The description of this introduction was written in January 2014. The provided information of the system is subjected to change due to upgrading and improvement without prior notice.

FUJIFILM Value from Innovation

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