Caution:

Don't mark on the phantom with pen or leave printed materials contacted on its surface. Ink marks on the phantom will be irremovable.

US-4

Breast Ultrasound QA Phantom

Recommended by Japan Association of Breast and Thyroid Sonology

Product supervision:

Japan Association of Breast and Thyroid Sonology, Quality Assurance Committee Working Team.

Recommendation from: Japan Radiology Society, Imaging Committee Breast Imaging Group Instruction Manual



Contents

Please read General information · · · · · · · · · · · · · · · · · · P.1-P.3
Overview Overview of QA phantom · · · · · · · · · · · · · · · P.4
Preparation Imaging condition
Preparation for imaging, handling of probe, and maintenance P.6 Purpose of phantom use P.6
Imaging procedure for aged deterioration management for probe ••••••••••••••••••••••••••••••••••••
Imaging for image precision management · · · · · P.8-P.11 Saving, recording and reproduction · · · · · · P.11
Visual evaluation Image quality criteria (reference for image quality for precision management test) • • • • • • • • • • • • • • • • • • •

Visual evaluation of phantom image ····· P.12



Please read

Ultrasound QA phantom for high precision imaging in the high frequency sonography around 10MHz required in breast examination.

For monthly basic quality check of ultrasound images, as well as longer term quality assurance to maintain consistency of the performance of scanners and transducers.

• Features

- Four kinds of targets, gray scale, cyst targets, dot targets and 45 degrees line target at 2 depth, 10mm and 20mm.
- Back ground of each phantom block is of different attenuation rate and speed of sound.
- Detailed spatial resolution as minute as 0.5mm can be assessed.
- Stable and durable nonaqueous phantom materials. *Japanese patent No.3650096
- Comes with a thermometer to measure inner temperature of the phantom.

\Lambda DOs and DON'T s

DO s

Handle with care

The materials for phantom and models are special composition of soft resin. Please handle with care at all times.

Cleaning and care

Please clean the phantom completely every time after you finish the training. The remaining lubricating gel may deteriorate the phantom.

Keep the training set at room temperature, away from heat, moisture and direct sunlight.

DON'Ts

Never wipe the phantom or models with thinner or organic solvent.

Don't mark on the phantom with pen or leave printed materials contacted on their surface.

Ink marks on the models will be irremovable.

Please note: The color of the phantom may change over time, though, please be assured that this is not deterioration of the material and the ultrasonic features of the phantom stay unaffected.

This phantom has a thin layer of coating for protective purposes which may cause minor wrinkling.

Please read

Precautions regarding QA phantom use

Nowadays ultrasound diagnostic equipment is designed to produce images relying on a method unique to each manufacturer that adopts various configurations of sound velocity, harmonic, beam compound, and special filter processing. Therefore the following precautions should be taken into consideration during use:

- Do not compare images with those produced by a different model of diagnostic equipment.
- Criteria for image quality must be defined for each equipment and probe.
- The optimal imaging condition does not necessarily mean the optimal inspection condition.





Please read

General information

Set includes

Before your first use, please ensure that you have all components listed below.



Set includes:

а	mass	targets	block	1
---	------	---------	-------	---

- b dot targets block 1
- c thermometer 1
 - storage case 1

mass targets block phantom size: 180 x 75 x 110mm, 1.3kg dot targets block phantom size: 135 x 75 x 110mm, 1.0kg

Specifications are subject to change.

	mass targets block	dot targets block
Sound velocity - relation between temperature and sound velocity	25°C 1434 m/sec	25°C 1442 m/sec
Attenuation coefficient	0.59 dB/cmMHz (25°C)	0.73 dB/cmMHz (24°C)
Acoustic impedance	1.37rayl (25℃)	1.39rayl (25°C)
Integrated target	Gray scale targets Cyst targets	Dot targets 45 degrees line target

Overview of QA phantom

- For breast ultrasonography, it is important to able to distinguish points used for judgment on whether the detailed test is required or not. The resolution of direction, distance, contrast, and slice thickness of the ultrasound equipment is most important for this. In addition, the penetration capability to produce an image with sufficient quality even for a deeper part of the breast is also important.
- This breast ultrasound QA phantom 5G consists of two types of blocks with different attenuation coefficients and sound velocity (mass targets block and dot targets block) and four types of targets (gray scale targets, cyst targets, dot targets, and 45 degree line target).
- Each of the base parts is used for evaluation of the device's sensitivity to sound pressure and wave reception (important factors for penetration); the gray scale targets and the cyst targets are used for contrast resolution evaluation; and the dot targets and the 45 degree line target are used for spatial resolution evaluation.

These targets are implanted in the depths of 1cm and 2cm to enable evaluation of resolution for each depth.

• There is a hole in the middle of the phantom in which a thermometer is inserted to measure the internal temperature for determining the imaging condition. A viscous material is put in the hole to make the thermometer adhere to the phantom.





Mass targets block (contrast resolution)

Dot targets block (spatial resolution)

Preparation

Imaging condition

- Ultrasound equipment
 - 1. Wait for at least 15 minutes after the equipment is turned on before use.
 - 2. Use a probe that has characteristics regarding frequency and viewing width that are recommended by the Breast Ultrasound Diagnostic Guideline (edited by JABTS).
 - 3. Fix the viewing depth (Depth) to approximately 40mm.
 - 4. Adjust the focus as close as possible to the target position.
 - 5. Set the brightness of the monitor, the contrast, and the illumination (brightness of the room light) to the normal state.
 - 6. Do not adjust the conditions listed above after starting imaging.
 - 7. Use a right-angle coupler if available, because orthogonality of angle of incidence of probe beam is particularly important.
 - 8. Do not adjust the conditions above after starting imaging.



Internal temperature check



Example of right-angle coupler

• QA phantom

- 1. Place on a flat surface during use.
- 2. Take images when the internal temperature is 23 26°C. (The internal temperature can be measured by inserting the attached thermometer.)

The sound velocity within the phantom base is 1430 - 1450m/s under the temperature conditions described above and it doesn t seem to cause any problems in actual measurement. However, it can be adjusted appropriately if the sound velocity setting of the ultrasound equipment is changed, because the velocity is a little slower than that in a living body.

* Because the temperature of the phantom changes very slowly, it should be left for at least 6 hours in the ultrasonography room before conducting imaging procedure to let the temperature approach the level mentioned above.

Preparation

Preparation for imaging, handling of probe, and maintenance Purpose of phantom use

Preparation for imaging, handling of probe, and maintenance



1. Place the phantom on a flat surface and then apply ultrasound gel.



2. Always put the probe perpendicular to the phantom.



3.After use, wash with water and then carefully wipe off the moisture with a dry cloth.



because it can stick to or scratch the surface of the phantom. Never wipe off stains on the surface with

thinner or similar agents.

3 Purpose of phantom use

The most important purpose of the phantom is to produce an image using the ultrasound diagnostic equipment usually used for breast inspection under the same conditions and parameters to find a sign of deterioration of the equipment on the phantom image. If no change is found in the phantom image, the equipment can be relied on for continual use for inspection. Furthermore, the phantom image might be used for image precision management.

Imaging procedure for aged deterioration management for probe

1. Using single focus mode, adjust the focus to the target position.

If it is impossible to adjust the focus to the depth of the target exactly in single focus mode, adjust it to a position deeper than and nearest to the target. For equipment that cannot be set to single focus mode, use a multi-focus mode with the minimum number of focus levels and adjust the focus to a range including the target.

- 2. Fix all the STC (TGC) settings to the maximum position.
- 3. It is recommended that images using 3 types of GAIN setting are saved as digital data.

It is recommended that images using high, low, and middle settings (for example, approx. 90db, 70db, and 80db) are saved as digital data.

(Because the db indication varies due to the model of the equipment, the image taken should be saved for three levels of setting.)

4. Set parameters of the device (dynamic range echo enhancement and the others) according to the conditions defined at the delivery time, and record the set values.

Especially for latest digital models, record the set values for various parameters to always follow image procedures under the same conditions.

- 5. Record the imaging conditions of the observation monitor and the digital recording system to always take images under the same conditions.
- 6. For aged deterioration management, take the image under the same conditions as the first control data imaging.
- 7. Considering the above, take images of each base and the targets according to the same procedure for "Imaging for image precision management."

2 Imaging for image precision management

- 1. Always scan the phantom with the mode conditions that are usually used for breast ultrasound diagnostics.
 - * If tissue harmonic imaging (THI) and/or multistep communication functions are used in daily diagnostics, turn them on respectively. When a special filter processing is applied, take the image under the same conditions.
- 2. For image processing configuration, take two types of images for each of the conditions usually used and the other setting conditions.
 - * To improve the image recognition capability of a living body, improved THI and multi-step communication functions, special filters and software image correction solution are integrated to the latest high-end models. These image processing functions are intended for use with the living body, therefore they might give a negative effect to the directional resolution in the phantom.
 For these models, it is permissible for images to be taken under the conditions where the optimal evaluation is obtained for the phantom by combining the mode setting and the GAIN and STC configurations that are used for daily breast ultrasound diagnostics with modified settings for image processing such as THI, multi-step communication, special filter and software image correction.

2

Imaging for image precision management

- 3. If more than one condition is usually used on a case-by-case basis, it is recommended that images be taken under each condition.
- 4. Take a picture of each of the targets to the depth of 1cm and 2cm.
- 5. Always use single focus mode to adjust the focus to the position of the target (the depth is approx. 1cm and 2cm).
 - * If it is impossible to adjust the focus to the depth of the target exactly, adjust it to a position deeper than and nearest to the target. For equipment that cannot be set to single focus mode, use a multifocus mode with the minimum number of focus levels to adjust the focus to a range including the target.
- 6. Imaging of gray scale targets

Adjust the amplification (gain) to allow the brightness of the targets to be distinguished from each other continuously according to their echo characteristics.

Hold the gain value at a level where the targets can be distinguished by each other in the optimal gradation, and record the value.

* Use this value for imaging of the other type of targets and never change it.

Although the impressions of images of the dot targets and the 45 degree line target differ from those of the gray scale targets because they consist of different base material, use the gain value for the gray scale targets to take images.

In addition, the gray scale targets have to be taken as separate images because their width is generally wider than the aperture of the probe. Take the images of the gray scale targets so that the target on the border of the images is taken in both of the images.

When taking the image pay close attention so that the echo density of the targets appears to change gradually and the circular shape and boundary of the target are represented as clearly as possible.



Image example of gray scale targets (depth is 20mm)

Imaging for image precision management

7. Imaging of cyst targets

2

When taking image of cyst targets, ensure that the circular shape of the target is clearly represented and high resolution is achieved.

Because the sound velocity in the phantom is rather slow, the targets are represented in slightly elongated shape in equipment that does not have sound velocity correction function.



Image example of cyst scale targets (depth is 20mm)

8. Imaging of dot targets

When taking image ensure that the directional and distance resolutions are finely represented by the laterally and longitudinally aligned dots respectively.



Image example of dot scale targets (depth is 20mm)

Imaging for image precision management Saving, recording and reproduction

Zmm

2mm

Imaging for image precision management

9. Imaging of 45 degree line target

At first, hold the probe perpendicular to the edge of the phantom (use the rightangle coupler, if available). And then move the probe parallel to the middle of the phantom (see the figure in the right), and take the image so that the target appears in the middle of the two guidelines.

The distance between the two dots in the bottom is 2mm. You can use this distance to evaluate the resolution for slice thickness.



Image example of 45 degree line target (depth is 20mm)

A Caution

Right-angle coupler -

Perform the freeze operation carefully in all the processes. Save the taken images in appropriate format and conduct image evaluation. Use the right-angle coupler if available.

3 Saving, recording and reproduction

- 1. Keep the record of images as hardcopy output, and save the record as a digital data of non-compressed format in principle. (It is not recommended to save the hardcopy output as it will deteriorate.)
 - * If it is impossible to save in non-compressed format, save in a format of low compression rate and take a record of the compression rate.
- 2. In the time course inspection for precision management, the initial data and the later inspection data should be output or displayed by the same method.

Visual evaluation

Image quality criteria (reference for image quality for precision management test) Visual evaluation of phantom image

Image quality criteria (reference for image quality for precision management test)

There are two types of evaluation method, i.e. visual evaluation and quantitative evaluation using computer. The former method is used for regular quality management in the facilities and the later method is used for image evaluation for the facilities by a third party.

It is important to constantly check whether the images of the ultrasound equipment that is usually used maintain a certain level of quality or not by using the image of the breast ultrasound QA phantom.

If the image of the phantom does not satisfy the criteria, it is important to find the cause and fix it.On the other hand, when the image satisfies the criteria, it is expected that a certain level of quality will be satisfied for the clinical images.

Visual evaluation of phantom image

- 1. To evaluate a phantom image, first determine whether the image is taken by the specified imaging method.
- 2.After it is confirmed that the image deserves to be evaluated, conduct evaluation for image of the base part and the target.
- 3. It is required that the image of the base part represents a uniform image to the depth where the targeted specimen is embedded and the speckles are not rough.
- 4. Evaluate the targets for the following aspects:
 - (1) The gray scale targets are represented in almost circular shape and their brightness in the phantom changes gradually.
 - (2) The cyst targets are represented in almost circular shape and also the 1mm target clearly appears.
 - (3) The 5 or more and 4 or more dot targets can be distinguished in the longitudinal (distance resolution) and the lateral (directional resolution) directions respectively.
 - (4) The 45 degree line target (resolution for slice thickness) is represented to be 2mm or smaller.
 - * The conditions from (1) to (3) must be satisfied for both of the targets in the depth of 1cm and 2cm.

For condition (4), a depth of either 1cm or 2cm is required.

For condition (2), the 1mm target must be represented even when the targets of the size from 2mm to 4mm are hidden.

It is recommended that the criteria above are met under the conditions for usual use.

* These image evaluation criteria are defined broadly in order to be applied to the evaluation of the other equipment, and intend to define the minimum level. Currently their validity is under verification.



Don't mark on the phantom with pen or leave printed materials contacted on its surface. Ink marks on the phantom will be irremovale.

KYOTO KAGAKU co., ltd

Main Office and Factory

15 Kitanekoya-cho Fushimi-ku Kyoto 612-8388, Japan Telephone : 81-75-605-2510 Facsimile : 81-75-605-2519

URL: http://www.kyotokagaku.com e-mail: rw-kyoto@kyotokagaku.co.jp

KyotoKagaku America Inc. USA,Canada,and South America 3109 Lomita Boulevard, Torrance, CA 90505,USA Telephone : 1-310-325-8860 Facsimile : 1-310-325-8867