

**MODEL 11-101
PRO-US MTF PHANTOM
INSTRUCTIONS FOR USE**

May 2025

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Table of Contents

Product Features	1
Product Description	1
Technical Data and Contents of Package	2
Working, Transport, and Storage Conditions	2
Recommendations for Washing and Storing Phantoms	3
General Information	4
Warranty and Phantom Lifetime	4
Proper Disposal	4
Test Procedure	5

Product Features

The Model 11-101 Pro-US MTF meets the requirements of:

- Complies with:
 - “Quality Assurance of Ultrasound Scanners using a durable tissue-mimicking Phantom and radial MTF,” Marcus Kaar, Friedrich Semturs, Michael Figl, Rainer Hoffmann and Johann Hummel, Center for Biomedical Engineering and Physics, Medical University of Vienna, Austria
 - Real-time B-mode US quality control test procedures: Report of AAPM Task Group No. 1
 - Quality assurance of U.S.-guided external beam radiotherapy for prostate cancer: Report of AAPM Task Group 154
- The manual provides guidelines for carrying out each test and results assessment.

Product Description

The Model 11-101 Pro-US MTF (Modulation Transfer Function) Ultrasound Phantom is a tissue-mimicking phantom for use as a routine technical quality assurance test device for resolution measurement. It provides a consistently comparable and reproducible result from a single image.

The phantom is a block of polyvinyl alcohol (PVA) containing test objects for radial MTF and geometry assessment, all wrapped in a polyvinyl chloride (PVC) cover. The PVA based material mimics the sound velocity and acoustic attenuation of human tissue and is nontoxic, durable, and easy to handle and maintain.

Technical Data and Contents of Package

Overall Dimensions: 110 x 110 x 60 mm (4.3 x 4.3 x 2.4 in.)

Top and Bottom Cover: made of PVC

Test Insert Dimensions: 100 x 100 x 50 mm (3.9 x 3.9 x 2 in.)

Tissue-Mimicking Material: based on Poly (vinyl alcohol) (PVA), a synthetic polymer
Carrying Case

Working, Transport, and Storage Conditions

Mode	Temperature and Humidity
Work	15 to 25 °C (59 to 77 °F); max 75% non-condensing
Storage Conditions	15 to 25 °C (59 to 77 °F); max 75% non-condensing
Transport	5 to 35 °C (41 to 95 °F); max 75% non-condensing

Note:

The product or its accessories cannot be used in the patient environment (further than 1.5 m [4.9 ft] away from the patient examination area). The product serves only as an evaluation of the physical parameters of the diagnostic equipment, using ionizing radiation. The device cannot be used to control radiographic, radio-therapeutic, or similar devices.

Recommendations for Washing and Storing Phantoms

1. Phantoms should be washed with water up to 25 °C (77 °F), using a soft cloth or anti-static fluid designed for plastics.
2. Do not use powders, rough cloths, scrapers, etc.
3. Protect from scratching.
4. Do not wash with agents containing alcohol, which destroy the phantom's structure, resulting in cracks and micro-cracks.
5. Ozonation method or cleaning with non-alcohol detergents (e.g. soap, dishwashing liquid) can be used to disinfect all phantoms.
6. Do not leave or store in aggressive environments like solvents, alcohols, etc.
7. When the washing is complete, dry with a soft cloth.
8. Protect from falling. A fall can result in damage to the product and injury to people.
9. Phantoms must not be washed in dishwashers or warmed up in microwaves, heaters, or similar devices.
10. Store at room temperature.
11. Protect from solar radiation.
12. Use the products only as intended, in accordance with the manual provided.

General Information

The user manual is an integral part of the product and should always be kept near the device. An understanding of the manual is a prerequisite for proper performance and correct operation of the device.

Operator safety, specific measuring accuracy, and interference-free operation is guaranteed only if original parts and accessories are used. Should accessories from other manufacturers be used, safe and proper performance cannot be guaranteed.

Dispose of packaging material according to the local rules and regulations.

The product should be kept out of reach of children.

Before using the device, the operator must ensure that it is in the correct working order and that working conditions are adequate. The product does not require any special installation.

These products do not require any special training to operate. All necessary information is contained in the operating instructions supplied with the products.

Ludlum Measurements, Inc. cannot be held liable for any damage resulting from using accessories from other manufacturers. The warranty period is one year and begins on the day of delivery, unless specified differently at purchase. It is unaffected by repairs under warranty. Ludlum Measurements, Inc. considers itself responsible for safety, reliability, and performance of the device only if assembly, extension, calibration, modification, or repairs are carried out by the factory.

This technical documentation is in agreement with the device specifications and all safety standards (if applicable) valid on the day of printing. All rights are reserved for devices, techniques, and names appearing in the manual.

Warranty and Phantom Lifetime

Ludlum Measurements, Inc. warrants the product covered in this manual to be free of defects due to workmanship, material, and design for a period of 12 months, which is calculated from the moment of delivery, unless otherwise specified at the time of purchase. It is not affected by warranty repairs. The phantom lifetime is 10 years.

Proper Disposal

When a service cycle of the product is over, the method of disposal should be handled in accordance with local rules and regulations.

Test Procedure

(This is an example. Be sure to comply with your local regulations.)

1. Ultrasound scanheads used in mammography are in the high-frequency ranges to increase resolution at the cost of penetration depth. Legal regulations require employed ultrasound scanheads to have a minimum frequency of 7.5 MHz. We limit our phantom's field of application to linear scanheads, which are predominant in ultrasound examinations of the mamma.
2. Low penetration depth and the restriction to linear scanheads influenced the design of the phantom, in a way that the surface of the phantom body would be ideally plane and the maximum penetration depth of acquired images could be assumed with around 10 cm (3.9 in.).
3. Scan the phantom from the selected side. Use ultrasound gel to get a better image.
4. You may check the geometry correctness by measuring the distance between small holes in the phantom versus their actual physical spacing.
5. To calculate the radial MTF – resolution – you need to export the image from the ultrasound scanner to DICOM or an image file and then open that file in the optional software. Next, use the Pro-US MTF to auto-analyze the image of the large hole in the phantom. See Figure 1.



Figure 1

6. The optional software will produce a report showing, among other things, the MTF diagram and values as shown in Figure 2 (see following page).

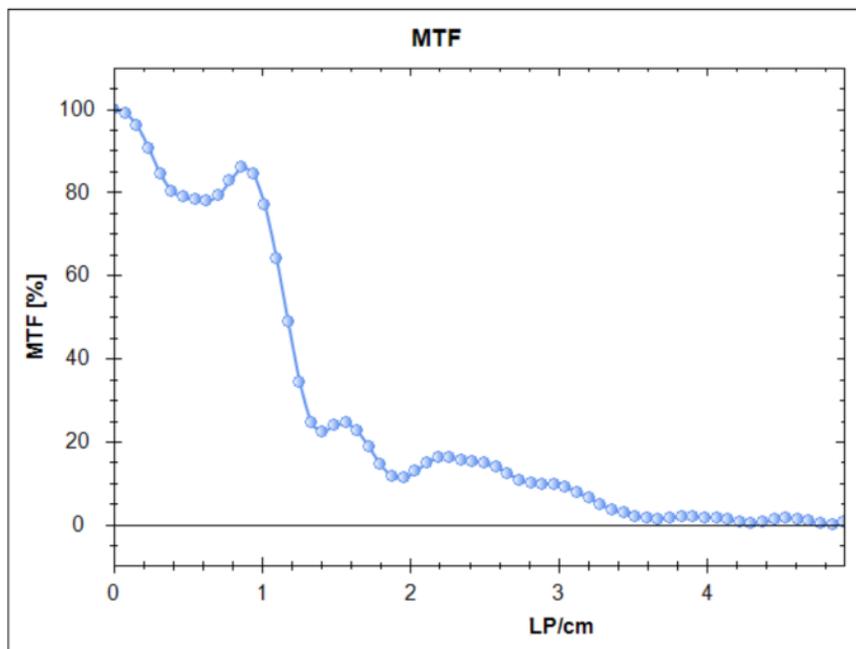


Figure 2

MTF	LP/cm
50%	1.17
10%	2.88
2%	3.55