Pro•Project®

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Accurate Diagnostics for Busy Healthcare

Mammography

UNMATCHED SOLUTIONS FOR QUALITY CONTROL

ISO 9001 ISO 13485 ISO 14001 ISO 45001 ISO 27001

Mammography

Quality Control kits

Powered by:

DIAGNOMATIC

We have prepared several QA / QC kits consisting of must-have phantoms, accessories and software that you can use in different situations depending on your requirements.
These can be your go-to selections when you are not sure what to choose for tests of a given modality.
We have introduced gradation of kits depending on the purpose and level of sophistication required:

BASIC: these sets are meant for constancy level testing purposes - tests that can be done practically by everyone who can use a diagnostic device
PRO: sets meant for acceptance and specialized testing - performed by specialized personnel, for example a medical physicist

Pro-DigiMAM BASIC kit

03-001

Powered by:

DIAGNOMATIC

This kit is a versatile set of phantoms and software for carrying out constancy and acceptance tests of mammography units. Thanks to the Pro-Control.online subscription, all tests can be quickly and effortlessly automatically analysed online and with the desktop app.

Standard kit configuration:

- Pro-DigiMAM:
  - main module (03-303)
  - resolution module (03-310)
  - CNR module (03-311)
  - contrast details module (03-309)
  - full field ACR accreditation module (03-317)
- Pro-MAM Compress (03-103)
- Diagnomatic PRO annual subscription
- Carrying case with dedicated foam inlay

The kit can be used to measure:

- optical density / luminance in the reference point
- spatial resolution
- threshold contrast visibility
- contrast
- effective radiation field
- AEC tests
- CNR, SNR
- artefacts evaluation
- geometric distortion check
- contrast details
- breast compression force

Product features:

- complies with:
  - IEC 61223-3-2
  - "European Guidelines for Quality Assurance in Mammography Screening"
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-DigiMAM PRO kit

03-002

Powered by:

DIAGNOMATIC

This kit is a versatile set of phantoms and software for carrying out constancy and acceptance tests of mammography units. Thanks to the Pro-Control.online subscription, all tests can be quickly and effortlessly automatically analysed online and with the desktop app.

Standard kit configuration:

- Pro-DigiMAM (03-302)
  - main module (03-303)
  - CNR module (03-311)
  - contrast detail module (03-309)
  - ghosting module (03-304)
  - resolution and geometry module (03-310)
  - MTF module (03-305)
  - artefacts evaluation module (03-307)
  - filaments module (03-306)
  - geometric distortion module (mesh) (03-308)
  - noise evaluation module (03-315)
  - spacers sets (03-314)
  - compensation module (03-316)
  - full field ACR accreditation module (03-317)
  - Tomosynthesis modules (03-318)
- Pro-MAM Compress (03-103)
- Pro-Slit (05-101)
- Pro-Stand All (05-103)
- Pro-Stand Align (05-104)
- Diagnomatic PRO annual subscription
- carrying case with dedicated foam inlay

The kit can be used to measure:

- optical density / luminance in the reference point
- spatial resolution
- threshold contrast visibility
- contrast
- effective radiation field
- AEC tests
- CNR, SNR
- artefacts evaluation
- geometric distortion check
- contrast details
- breast compression force

Product features:

- complies with:
  - IEC 61223-3-2
  - "European Guidelines for Quality Assurance in Mammography Screening"
  - IEC 60336:2005
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM PRO kit

03-011

Powered by:

DIAGNOMATIC

This kit is a versatile set of phantoms and software for carrying out constancy and acceptance tests of mammography units. Thanks to the Pro-Control.online subscription, all tests can be quickly and effortlessly automatically analysed online and with the desktop app.

The kit can be used to measure:

- optical density / luminance in the reference point
- spatial resolution
- threshold contrast visibility
- contrast
- effective radiation field
- AEC tests
- CNR, SNR
- NPS
- MTF
- ghosting
- filaments
- artefacts evaluation
- geometric distortion check
- contrast details
- focal spot size

Standard kit configuration:

- Pro-DigiMAM (03-302)
- Pro-MAM Gold
- Pro-MAM Compress (03-103)
- Pro-Slit (05-101)
- Pro-Stand (all options)
- Pro-Stand ALIGN (05-104)
- Diagnomatic PRO annual subscription
- carrying case with dedicated foam inlay

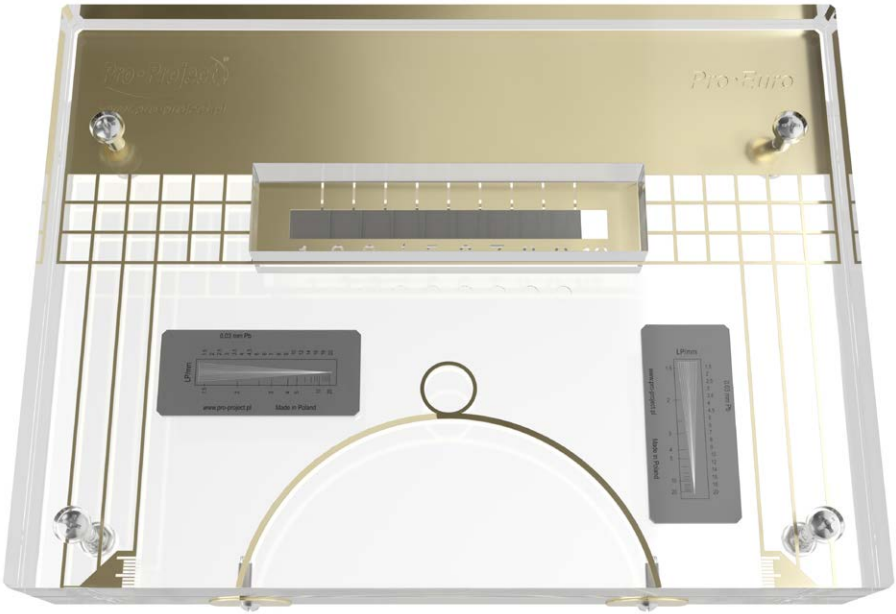
Product features:

- complies with:
  - IEC 61223-3-2
  - "European Guidelines for Quality Assurance in Mammography Screening"
  - IEC 60336:2005
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Phantoms

Pro-Euro

03-101



Pro-Euro phantom is used for **monitoring technical parameters** of mammography imaging systems according to the requirements of the „**European Guidelines for Quality Assurance in Mammography Screening**" and IEC 61223-3-2:

- optical density in the reference point
- spatial resolution
- dynamic range – image contrast
- threshold contrast visibility
- effective radiation field
- film processing
- automatic Exposure Control

Technical data (can be modified to customer specifications):

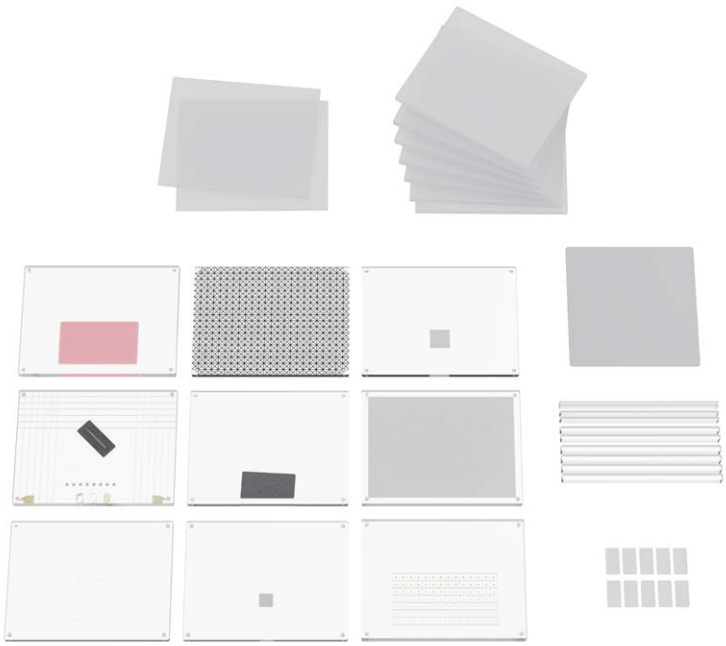
- dimensions: 182,5 x 245 x 45 mm
- additional 20 mm PMMA plate
- reference point (60mm from the thorax side)
- pattern for line pair resolution evaluation (from 1.5 to 20.0 LP/mm) perpendicular and parallel to the thorax side
- 10-step aluminium wedge
- 8 low contrast objects
- markings (graduations) for assessment of the effective radiation field
- space covered with brass for sensitometric measurements
- area for the measuring chamber of the automatic exposure timer

Product features:

- complies with:
  - IEC 61223-3-2
  - "European Guidelines for Quality Assurance in Mammography Screening"
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-DigiMAM

03-301 - basic model (03-303 + 03-310 + 03-311)
03-302 - complete set (03-303 to 03-318, without 03-312, 03-313)



This versatile phantom can be used for monitoring technical parameters of **digital mammography** imaging systems according to the requirements of the "**European Guidelines for Quality Assurance in Mammography Screening**" and **IEC 61223-3-2**:

- optical density / luminance in the reference point
- spatial resolution
- threshold contrast visibility
- contrast
- effective radiation field
- automatic exposure timer
- CNR, SNR
- NPS
- MTF
- ghosting
- filaments
- artefacts evaluation
- geometric distortion check
- contrast details

Technical data (can be modified to customer specifications):

- dimensions: 240 x 180 mm or 300 x 240 mm
- modular construction – different modules can be firmly placed on the main module
- optional carrying case (03-322)

Product features:

- complies with:
  - IEC 61223-3-2
  - "European Guidelines for Quality Assurance in Mammography Screening"
- plus supplement
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Main module (03-303)

set of PMMA attenuation plates: 6x 10 mm thick and 2x 5 mm thick; one plate contains marking of the reference point

CNR module (03-311)

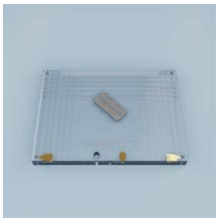
10mm thick module containing a 20 x 20 x 0.2 mm aluminium filter, located 6 cm from the chest side

Contrast detail module (03-309)

20 mm thick module containing gold (99.99%) discs organized in a 7x14 matrix (diameter x thickness). Discs have the following diameters: 0.1, 0.25, 0.5, 0.75, 1.0, 1.5, 2.0 mm and 14 thicknesses ranging from 0.03 to 2.0 µm. Thickness accuracy: 1 nm (0.001 µm), diameter accuracy 0.001 mm (1 µm)

Ghosting module (03-304)

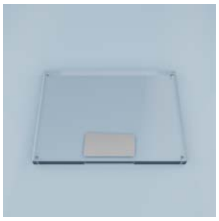
10mm thick module containing a 30 x 30 x 0.1 mm aluminium filter for a ghost test



Resolution and geometry module (03-310)

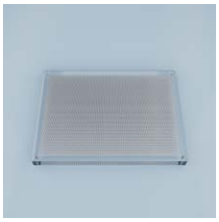
10 mm thick module containing:

- pattern for the line pair resolution evaluation (from 1,5 to 20,0 LP/mm) rotated 45°
- 8 low contrast objects (ø5.5 mm and depth from 0.1 mm to 0.45 mm)
- 3 objects of a different absorption level
- pattern for evaluation of the effective radiation field



MTF module (03-305)

10 mm thick module containing a straight stainless steel edge accurate to ±2 µm at a 3° angle



Artefacts evaluation module (03-307)

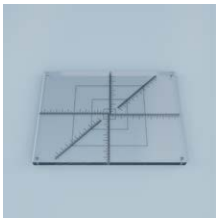
10 mm thick module containing a mesh for artefacts evaluation

Filaments module (03-306)

10 mm thick module containing 6 groups of multi-directional filaments 0.40 mm to 0.20 mm in diameter

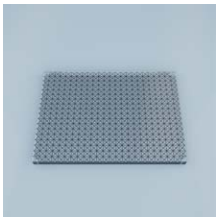
Dynamic range module (03-320)

10 mm thick module containing Al step wedge with 14 steps from 0.0 to 5.2 mm



Geometry distortion module (scales) (03-312)

10 mm thick module containing a grid with scales

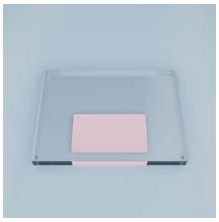


Geometric distortion module (mesh) (03-308)

10 mm thick module containing a wire mesh of horizontal, vertical and diagonal lines (45°)

ACR Accreditation module (03-319)

14 mm thick module containing a wax insert as in Pro-MAM Accreditation (when used with 3x10 mm plates from main module simulates 42 mm compressed breast of average glandular/adipose composition)



Full Field ACR Accreditation module (03-317)

14 mm thick module containing a wax insert as in Pro-MAM Accreditation FF (when used with 3x10 mm plates from main module simulates 42 mm compressed breast of average glandular/adipose composition)

Noise evaluation module (03-315)

2 mm thick aluminium plate 200 x 200 mm

Spacers sets (03-314)

180 x 15 mm or 240 x 15 mm PMMA plates:

- 4 pieces 10 mm thick,
- 2 pieces 8 mm thick,
- 2 pieces 5 mm thick,
- 2 pieces 2 mm thick

Compensation module (03-316)

set of 10 PMMA plates 40 x 20 x 2 mm

Tomosynthesis dedicated modules

NPS attenuator

2 mm thick high purity aluminium filter

MTF module

10 mm thick module containing a stainless steel square (50 x 50 mm) with straight edges accurate to ±2 µm rotated 3°

Z-resolution module

5 mm thick module containing 25 aluminium spheres 1 mm in diameter arranged in an array with 55 mm cell

Wire MTF module

15 mm module containing 25 µm tungsten wire at a 3° angle 60 mm from the chest wall

Protective steel plate

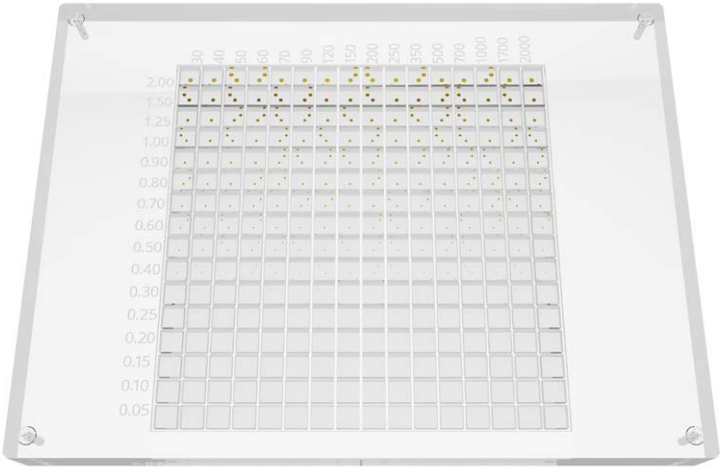
2 mm stainless steel plate 240 x 300 mm covering the whole image receptor

Spacers set

Two 240 x 20 x 30 mm spacers for appropriate positioning of test modules

Pro-MAM Gold

03-401



Contrast details mammography phantom according to **European Protocol** for quality assurance in Digital Mammography. It can be used to determine if mammographic images indicate objects with very low contrast and very small diameter, to find out the optimum exposure technique, or to compare image quality at various object thicknesses by varying the PMMA thickness.

Product highlights:

- unmatched accuracy – up to 30 times better than other products on the market
- gold disc objects positioned as per EUREF specs
- objects' diameter, thickness and layout can be modified according to individual specifications
- no materials other than PMMA are used, so there is no need to calculate PMMA-equivalent attenuation for other materials such as aluminium
- for full-field analog and digital units
- Pro-Control software provides automatic and semi-automatic analysis of phantom's images, providing all the necessary information like Contrast-Details curve, making quality assurance simple and quick

Technical data (can be modified to customer specifications):

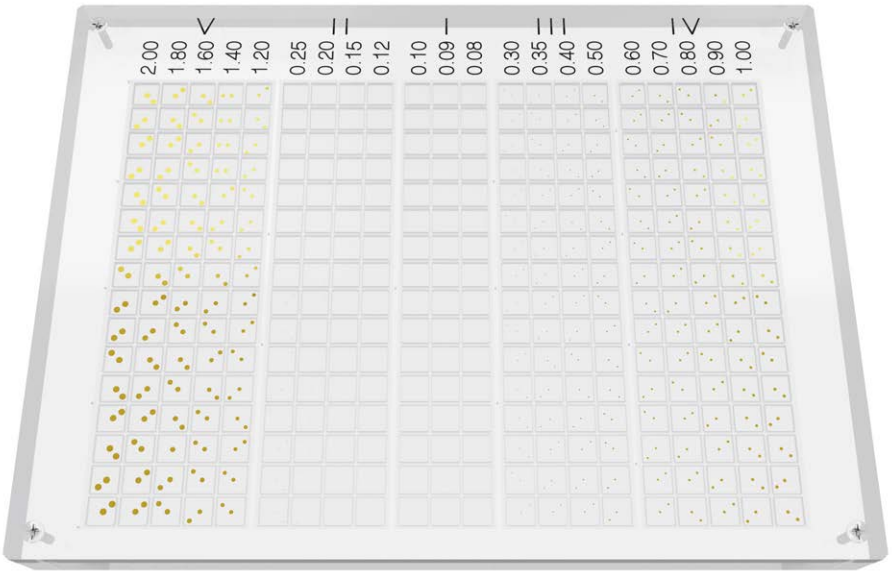
- main PMMA module size: 240 x 180 x 20 mm
- main module contains gold (99.99%) discs organized in a 16 x 16 matrix (diameter x thickness) placed at a depth of 10 mm
- one or multiple discs per cell configuration
- discs have the following standard diameters: 0.05, 0.1, 0.15, 0.2, 0.25, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.25, 1.5 and 2.0 mm
- discs have the following standard thicknesses: 30, 40, 50, 60, 70, 90, 120, 150, 200, 250, 350, 500, 700, 1000, 1700 and 2000 nm
- diameter accuracy 0.001 mm (1 µm)
- thickness accuracy: 0.1 nm (0.0001 µm)
- 2 additional 240 x 180 x 10 mm PMMA plates
- 2 additional 240 x 180 x 5 mm PMMA plates
- carrying case

Product features:

- Complies with:
  - 4th edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (EPQC)
  - EUREF type test protocol version 1.2
  - IEC 61223-3-2
  - NHSBSP Equipment Report 0604, Commissioning and Routine Testing of Full Field Digital Mammography Systems Published April 2009 (Version 3)
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM Gold mk II

03-402



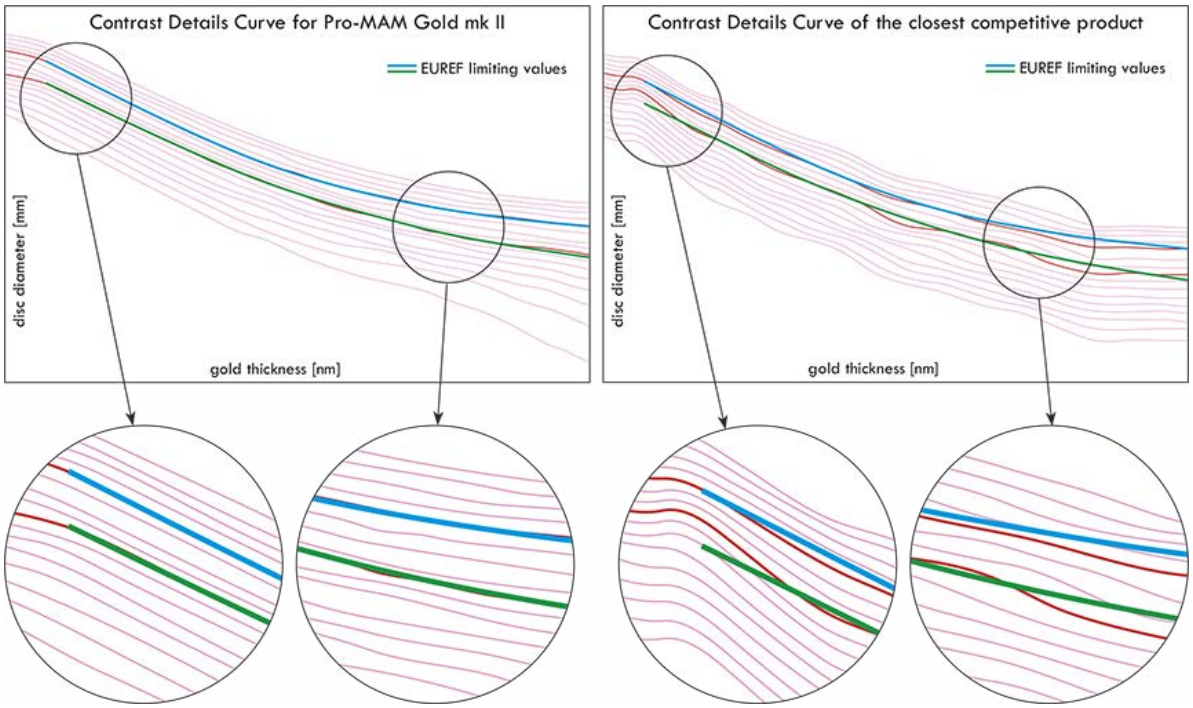
Upgraded contrast details mammography phantom according to European Protocol for quality assurance in Digital Mammography. It can be used to determine if mammographic images indicate objects with very low contrast and very small diameter, to find out the optimum exposure technique, or to compare image quality at various object thicknesses by varying the PMMA thickness.

Product highlights:

- unmatched accuracy – up to 30 times better than other products on the market
- gold disc objects positioned at depth suggested by EUREF
- smallest objects are positioned in the middle of the phantom where sensitivity of the x-ray device is the best
- discs are grouped into five sections relative to the EUREF limiting diameters values (2.0, 1.0, 0.5, 0.25 and 1.0 mm)
- disc thickness is optimized to result in contrast details curves for each diameter to correspond perfectly with EUREF limiting values
- no materials other than PMMA are used, so there is no need to calculate PMMA-equivalent attenuation for other materials such as aluminium
- for full-field analog and digital units
- Pro-Control software provides automatic and semi-automatic analysis of the phantom's images, providing all the necessary information like Contrast-Details curve, making quality assurance simple and quick

Technical data (can be modified to customer specifications):

- phantom size: 240 x 180 or 300 x 240 mm
- main 20 mm module contains 672 gold (99.99%) discs
- 21 diameters from 0.08 - 2.00 mm
- each diameter has its own optimized thickness range of 5 nm – 110 nm for the 2.00 mm diameter gold discs to 600 nm – 2800 nm for the 0.08 mm diameter, all in 16 steps
- discs are placed at a depth of 10 mm
- 2 discs per cell, one disc is placed in the middle and one near the random corner of the cell
- diameter accuracy 0.001 mm (1 µm)
- thickness accuracy: 0.1 nm (0.0001 µm)
- 2 additional 10 mm PMMA plates (thickness accuracy about 0.05 mm)
- 2 additional 5 mm PMMA plates (thickness accuracy about 0.05 mm)
- carrying case



Note a very good correlation of Contrast Details Curves of the Pro-MAM Gold mk II phantom against the limiting values set by EUREF. This ensures unmatched evaluation of a mammography system performance according to the requirements of European Protocol for quality assurance in Digital Mammography.

Product features:

- complies with:
  - 4th edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (EPQC)
  - Euref type test protocol version 1.2
  - EN-IEC 61223-3-2
  - IEC 61223-3-2
  - NHSBSP Equipment Report 0604, Commissioning and Routine Testing of Full Field Digital Mammography Systems Published April 2009 (Version 3)
  - DIN 6868-162
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM Accreditation

03-501

The phantom can test the performance of a mammographic system and its ability to image small structures similar to those found clinically: calcifications, fibrous calcifications in ducts and tumor masses.

Technical data (can be modified to customer specifications):

- dimensions: 102.0 x 108.0 x 44.0 mm
- simulates 42 mm compressed breast of average glandular/adipose composition
- total PMMA thickness: 36.75 mm
- wax insert:
  - thickness: 7.25 mm
  - nylon fibrils diameters: 1.56, 1.12, 0.89, 0.75, 0.54 and 0.40 mm
  - microcalcifications: 0.54, 0.40, 0.32, 0.24 and 0.16 mm Al_2O_3 specks
  - tumor-like masses: 2.00, l.00, 0.75, 0.50 and 0.25 mm thick
- 4 mm thick PMMA contrast disc
- rotating support plate
- comfortable carrying case

Product features:

- Complies with:
  - IEC 61223-3-2
  - ACR Mammography Accreditation Program Requirements (May 4, 2012)
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM Accreditation FF

03-502

This ACR accredited Full Field phantom was designed to **test the performance of a digital mammographic system by evaluating the system's ability to image small structures similar to those found clinically**: micro-calcifications, fibrous structures in ducts and tumor-like masses. It is similar to the Pro-MAM Accreditation phantom, the main difference being the size: the FF (Full Field) version is larger and covers the entire image detector, thus eliminating scatter.

Technical data (can be modified to customer specifications):

- dimensions: 311.2 x 190.5 x 41.3 mm
- simulates 42 mm compressed breast of average glandular/adipose composition (50% / 50%)
- wax insert:
  - nylon fibrils diameters: 0.89, 0.75, 0.61, 0.54, 0.40 and 0.30 mm
  - microcalcifications: 0.33, 0.28, 0.23, 0.20, 0.17 and 0.14 mm Al_2O_3 specks
  - tumor-like masses: 1.00, 0.75, 0.50, 0.38, 0.25 and 0.20 mm thick
- comfortable carrying case

Product features:

- Complies with:
  - IEC 61223-3-2
  - ACR Mammography Accreditation Program Requirements
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM Biopsy

03-503

This phantom was **designed to provide a fast and easy way to test image quality on digital biopsy mammography units and qualify for ACR accreditation**. The phantom contains test objects that are similar to those found in the Mammographic Accreditation Phantom specified by the American College of Radiology (ACR). **The extended top edge of the phantom allows ease of positioning on recumbent biopsy units**. The phantom's small size allows the phantom to be imaged in its entirety in a single exposure when used with a digital biopsy unit. Enables you to determine if the images are similar to, or better than screen-film. Can be used in both an upright and prone machine.

Technical data (can be modified to customer specifications):

- dimensions: 80 x 70 x 46 mm
- simulates 42 mm compressed breast of average glandular/adipose composition
- test elements contain:
  - nylon fibrils diameters (fibers): 0.93, 0.74, 0.54 and 0.32 mm
  - Al_2O_3 microcalcifications (specs): 0.54, 0.32, 0.24 and 0.2 mm
  - tumor-like masses: 1.00, 0.75, 0.50 and 0.25 mm thick

Product features:

- Complies with:
  - IEC 61223-3-2
  - ACR Mammography Accreditation Program Requirements (May 4, 2012)
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

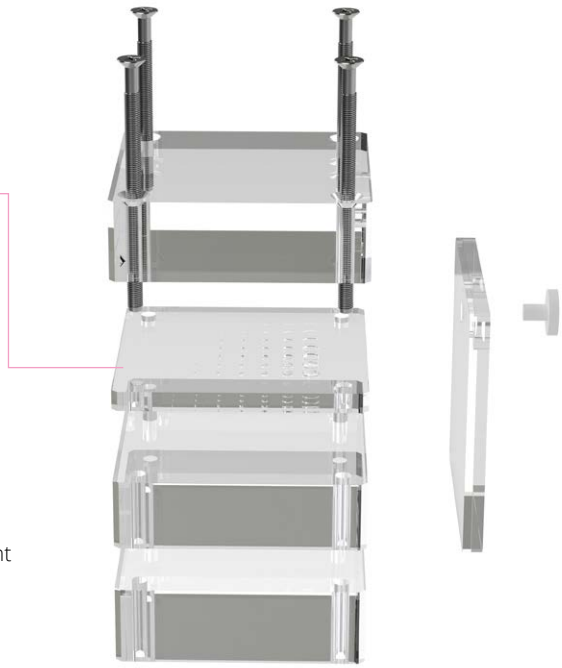
Pro-MAM Contrast

03-105

The phantom for **performance testing of mammography** X-ray units. It has **49 holes** that generate subtle changes in contrast. It can be used to **detect small variations** in system's performance.

Technical data (can be modified to customer specifications):

- dimensions: 62.7 x 62.7 x 62.7 mm
- typical contrast for mammographic energies: 6.60, 4.20, 2.60, 1.70, 1.00, 0.65, 0.41%
- hole depth (7 columns): 0.853, 0.533, 0.332, 0.208, 0.129, 0.080, 0.050 mm
- diameter of holes (7 rows): 4.292, 2.524, 1.485, 0.873, 0.513, 0.302, 0.177 mm
- optimized for digital units
- includes a rotating support plate
- comfortable carrying case

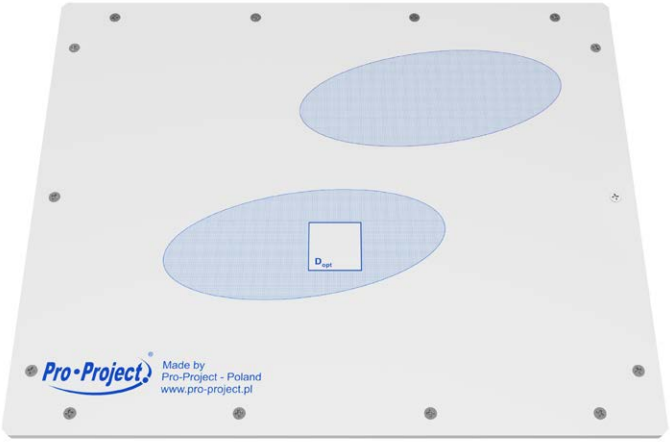


Product features:

- complies with:
  - IEC 61223-3-2
  - "European Guidelines for Quality Assurance in Mammography Screening"
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM Contact

03-104



Test grid for testing **mammography-cassette film-screen contact**.

Technical data (can be modified to customer specifications):

- dimensions: 240 x 300 x 8 mm
- 25 x 25 mm free field to measure optical density
- mesh size: 0.5 mm
- wire diameter: 0.1 mm
- includes a rotating support plate
- comfortable carrying case

Product features:

- complies with:
  – IEC 61223-3-2
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM AEC PMMA

03-201 - 180 x 240 mm version
03-203 - 180 x 240 mm, high precision with thickness accuracy of about 0.05 mm
03-204 - 240 x 300 mm version
03-205 - 240 x 300 mm, high precision with thickness accuracy of about 0.05 mm

Set of acrylic plates for testing Automated Exposure Control of mammography systems.

Technical data (can be modified to customer specifications):

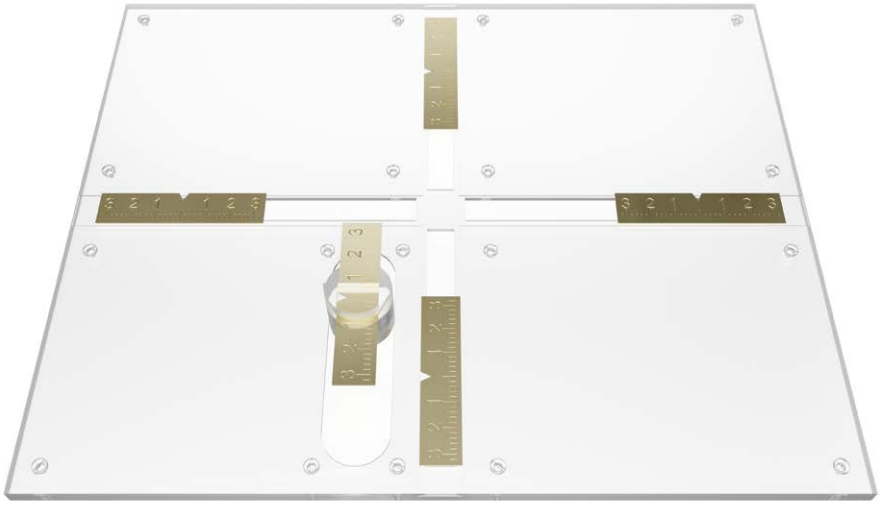
- dimensions: 240 x 180 mm and 240 x 300 mm
- 7x 10 mm thick
- 2x 5 mm thick
- made of a transparent PMMA
- other sizes upon request

Product features:

- Complies with:
  - IEC 61223-3-2
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM Geometry

03-107



This test device was developed to provide the user with a convenient, quick and accurate way of testing collimation of mammography units. It is very simple to use. Instead of using all those hard-to-find coins, you only use our test tool.

Technical data (can be modified to customer specifications):

- dimensions: 300 x 240 mm
- measurement can be quickly and easily repeated
- compression paddle rests on peg exactly 4.2 cm above the Bucky
  - no measurement of compression paddle height needed
- adaptable for 18 x 24 cm, 24 x 30 cm and magnification stand testing

Product features:

- Complies with:
  - IEC 61223-3-2
  - MQSA testing requirements as contained in the ACR Mammography QC Manual
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registrationv

Pro-MAM Compress

03-103

Calibrated scale for assessment of the **breast compression force** of mammography systems.

Technical data (can be modified to customer specifications):

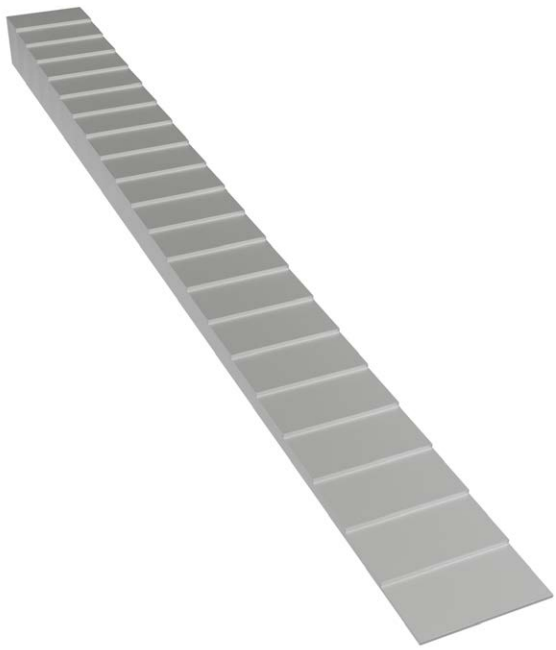
- measuring range up to 25 kg (03-103) or 34 kg (03-103-34)
- accuracy 10 g
- large, backlit, detachable (130 cm long cable) LCD display
- simple operation with three buttons
- scale size: 20 x 16 cm
- battery-operated

Product features:

- complies with:
  - IEC 61223-3-2
  - "European Guidelines for Quality Assurance in Mammography Screening"
- CE certified
- calibration certificate
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM 21 Steps

03-202



21 step aluminium wedge for determination of **the dose reproducibility and sensitometric curve shape, speed and mid-gradient** of mammography X-ray film.

Technical data (can be modified to customer specifications):

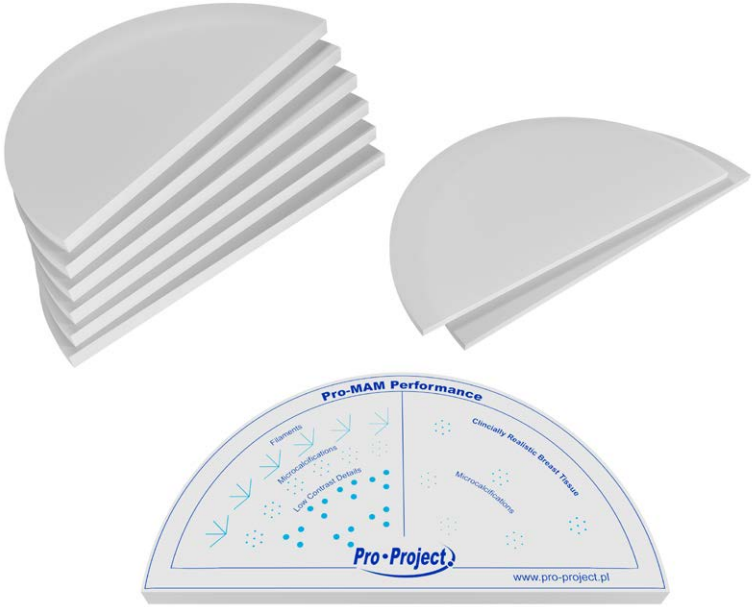
- dimensions: 10 x 105 x 6.3 mm
- 21 steps with a width of 5 mm
- 0.3 mm graduation per step
- made of a the highest purity aluminium
- other sizes of step wedges upon request

Product features:

- Complies with:
  - IEC 61223-3-2
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM Performance

03-601



The phantom designed **to be used for routine quick and ongoing checks of imaging performance of mammography systems**. It allows evaluating particularly those aspects which are most liable to deterioration.

Technical data (can be modified to customer specifications):

- 240 mm diameter semicircle
- first half of the test module contains:
  - 6 groups of 10 mm long multi-directional filaments of the following diameters: 0.40, 0.35, 0.30, 0.25, 0.225, 0.20 mm
  - 6 groups of microcalcifications in the following ranges: 354-224, 283-180, 226-150, 177-106, 141-90, 106-63 µm
  - 6 groups of 3 low contrast details, 3mm in diameter, producing nominal contrast at 28 kVp of: 0.04, 0.03, 0.02, 0.015, 0.01, 0.005 (each contrast is presented 3 times)
- second half of the test module contains:
  - clinically realistic breast tissue (not tissue equivalent to but simulating the appearance of the breast tissue) containing 6 groups of low contrast details with the same specifications as in the other half
- 6 PMMA plates 10 mm thick
- 2 PMMA plates 5 mm thick
- carrying case
- battery-operated

Product features:

- complies with:
  – IEC 61223-3-2
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

Pro-MAM CESM

Pro-MAM CESM Phantom is used for Image Quality Evaluation of Contrast-Enhanced Digital Mammography systems.
The phantom demonstrates the presence and absence of iodine in tissues by containing different iodine concentrations and non-iodine breast tissue substitutes. The Pro-MAM CESM represents an average human breast in size and shape.

Product highlights:

- daily and routine QC
- tests performance and stability of CESM
- contains clinically relevant iodine concentrations
- represents both dense and fatty breasts
- background provides clinically relevant challenge for target detection

Technical data (can be modified to customer specifications):

- thickness 55 mm
- top and bottom layer 10 mm adiopse tissue
- middle layer 25 mm 50% adiopse tissue and 50% glandular tissue
- breast tissue 10 mm with iodine targets

Product features:

- complies with:
  - Klausz, R, et al. Introduction of a Comprehensive Phantom for the Quality Control of Contrast Enhanced Spectral Mammography. 2018. Poster No.: ECR 2018, DOI: 10.1594/ ecr2018/C-2647
- CE certified
- the Manual provides detailed guidelines for carrying out each test, results assessment and registration

www.pro-project.pl

World Headquarters

Kwiatowa 43A Street
22-105 Okszów, Poland
E-mail: contact@pro-project.pl
Phone: +48 668 024 874, +48 606 161 554
Fax: +48 82 545 24 40

US office

200 S. Biscayne Blvd, Suite 2790
Miami, FL 33131, USA
E-mail: contact.us@pro-project.pl
Phone: 305 714 9539

Distributor