EUREF typetest protocol

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1. Introduction

The aim of the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) is to improve the quality of mammography in Europe and to disseminate knowledge on high quality breast imaging. Within this context EUREF has produced European Guidelines. The current version of these guidelines is the fourth edition, published by the European Commission in 2006. A supplement of the fourth edition has been published by the EC in 2012. For tomosynthesis systems, a first EUREF QC protocol has been published in 2015, which is being updated regularly and made available on the EUREF website.
Some years ago, manufacturers and users have expressed the need for type testing at a European level. For that reason EUREF decided to organise and standardise voluntary type testing for mammography systems at the European level. The standards applied in the EUREF 2D type testing are based on chapter two of the fourth edition of the European Guidelines. The standards applied in the EUREF tomosynthesis type testing are based on the EUREF tomosynthesis QC protocol.

Type testing is defined as a test (1) to verify whether a type of system is able to pass the acceptability criteria of the European protocol, (2) to provide guidelines about the best practice in terms of dose and (clinical) image quality. After a successful type test, individual mammography units of the same and type brand still need to undergo an acceptance test before clinical use. Passing the type test only guarantees that the system is in principle capable of meeting the requirements of the European Protocol and the report may list suggestions for optimal use or conditions to be avoided in practice.

The physico-technical chapter of the fourth edition of the Guidelines has been written for acceptance testing and not for type testing. Therefore some small differences between the protocol for type testing and the European Guidelines are introduced. These differences are described in this document. For tomosynthesis the tests in a typetest procedure are also given. Some additional tests may be performed if deemed necessary.

In this document it is described how type testing is organised and the physico-technical evaluation and the clinical evaluation are specified in detail. Note: If the system does incorporate special features, it may be necessary to perform additional measurements in the physico-technical evaluation and/or perform additional evaluations during phase 3 of the type test.

Type tests are currently performed on digital mammography units (DR and CR systems) and tomosynthesis units. In future type testing may be performed on image processing algorithms, workstations and film digitisers.

2. Type testing procedure

A type test will consist of:

- Phase 1: Provision and evaluation of system specifications and a set of clinical images

  The specifications of the system under evaluation are provided. This list of specifications will be used to determine whether additional physico-technical measurements or additional evaluations during phase 3 of the type test will be necessary and to determine whether measurements needs to be adapted due to the specific configuration of the system under evaluation. If additional measurements or evaluations are deemed necessary this will be communicated and discussed with the applicant of the typetest.
  A set of 50 patient images including images with implants will be provided by the applicant to determine beforehand whether adjustments in image processing are required to fulfil the quality criteria. If multiple modalities like 2D and tomosynthesis are evaluated in the typetest, a set 50 images of each modality needs to be provided. This step is not meant to fully evaluate the quality of the clinical images, but has been introduced to avoid the situation that it is noted at the end of the type test procedure that major adjustments should have been made.

  After phase 1: Go – no go decision

- Phase 2: Technical evaluation:

  Two full physico-technical evaluations will be performed on different systems at different locations. If multiple modalities like 2D and tomosynthesis are evaluated in the typetest, two full physico-technical evaluations will be performed on each modality. The applicant of the test (i.e. the manufacturer) arranges the locations and all practicalities in co-operation with the EUREF physico-technical steering group. The systems must be available for the tests for at least three days. The 2D tests are primarily based on the measurements in chapter 2b of the European Guidelines, fourth edition and the Supplement to the European Guidelines. However, some tests are adapted and some additional tests will be performed, which are described in chapter 3 of this protocol. The tomosynthesis tests are primarily based on the latest version of the EUREF tomosynthesis QC protocol.
  Note: If the results indicate that major adjustments need to be made to the system under evaluation, this may result in a decision not to continue phase 2 of the type test. In this case the physico-technical evaluation has to be repeated before continuation of the type test. Minor adjustments to the system under evaluation are allowed after approval of the EUREF physico-technical steering group, these adjustments will be evaluated in the second physico-technical evaluation on the same modelity.
  It is decided by the EUREF physico-technical steering group whether an adjustment is minor or major. This decision will be discussed with the applicant of the type test.

  If the results of the physico-technical evaluations show undesirable and major differences, (some) tests may be repeated on a third system.

For CR systems the physico-technical tests must be performed on X-ray units of (at least) two different brands. The applicant should give guidance on the setup of the X-ray unit for their CR system and take care that the mammography unit is set up correctly for their CR plates at the sites of type testing.
Note: If the system does incorporate special features, it may be necessary to perform additional physico-technical measurements.

After the results from the physico-technical evaluations are available, it will be decided whether phase 3: clinical evaluation is allowed to start. If the system fails and it is not expected that the problems which cause the failure can be solved, the type test may be aborted by either the EUREF physico-technical steering group or the applicant. In this case only the costs of the technical evaluation(s) will be charged to the applicant.

After phase 2: Go – no go decision

- Phase 3: Clinical evaluation:

After the physico-technical eveluations one system will be used clinically for a period of at least three months. If multiple modalities, like 2D and tomosynthesis are evaluated, for each modality a system will be used clinically for a period of at least three months. The site at which the clinical evaluation(s) is (are) performed (one of the sites at which a technical evaluation was performed) must have sufficient workflow (with an average of at least 30 clients/patients per system per day) and will be selected by the applicant in co-operation with EUREF. In the clinical evaluation soft copy reading is expected and all workstations must pass the European protocol for viewing conditions.
At the start of the clinical evaluation an application specialist of the applicant and a EUREF representative will be present at the clinical site to help starting up the clinical evaluation.
In the first days of the clinical evaluation, an initial assessment of the images will be performed by a representative of EUREF. If image quality is not satisfactory or if dose is higher than allowed, adjustments to the equipment must be made. If image quality and dose levels remain unsatisfactory the clinical evaluation may be stopped.

Adjustments to the equipment are only allowed after consultation with the EUREF physico-technical steering group. Some adjustments might require an additional physico-technical evaluation.
In the clinical evaluation period an image of a 45 mm thick homogeneous phantom covering the whole image receptor has to be acquired every day in full-automatic mode to monitor the stability of the equipment. A record must be kept of all artifacts on clinical images and of all problems that occurred with the equipment by the radiographers/radiologists at the test site. When major problems occur, the steering group has the right to extend the clinical evaluation period appropriately or to stop the evaluation.

In addition to the stability test a dose survey and an automatic exposure control (AEC) evaluation will be conducted. For this dose survey and AEC evaluation the X-ray exposure data must be available and the images must be available for verification.

After the clinical test period, an evaluation of a set of clinical images of each modality will be performed, by two radiologists on invitation of EUREF with substantial experience in digital mammography and a physicist appointed by EUREF. If the clinical images include multiple reconstructed images, like in tomosynthesis a DBT stack of images and synthetic 2D images, both kinds of images will be evaluated.
For each clinical evaluation, the clinical images that are evaluated consist of three groups: images from 70 patients/clients will be selected based on breast thickness and dose from all patients for which images have been made during phase 3 of the type test. Additionally images of 10 patients/clients with breast implants are selected.

Note: If the system under valuation incorporates special features, it may be necessary to perform additional evaluations during phase 3 of the type test.

Final report

After the clinical evaluation a final report is presented. The report will be sent to the applicant. When a system passes, this will be published on the EUREF website. When a system fails it will not be published on the website.

Non-disclosure of confidential information

Typetests might be performed on systems using techniques which are completely different from existing systems. For these systems the current methods of measurement might be unsuitable and adaptations may be necessary. It might also be the case that new test items should be added. Therefore the physico-technical steering group will be provided with all relevant information on the system being type tested by the applicant.
Relevant information includes: basic principles of the mammography system and in specific the image receptor, philosophy and practice of the AEC system, pre-exposure parameters, reconstruction technique of bad pixels, accepted number of bad pixels, general information on image reconstruction/processing, etc. If requested by the applicant this information can be regarded as confidential and a non-disclosure agreement can be signed.

Publication of results

The full report on the results of the type test will be made available to the applicant. If a system passes the type test the full report will be published on the EUREF website. The applicant of the test will be able to comment on the report before publication on the EUREF website.
It will not be mentioned on the website that a specific system has failed the type test.

3. EUREF type testing protocol

By definition type testing will be performed on new types of equipment. Therefore type tests might be performed on systems using techniques which are completely different from existing systems. For these systems the current methods of measurement might be unsuitable and therefore adaptations may be necessary. It might also be the case that new tests should be added. Therefore the physico-technical steering group will be provided with all relevant information on the system being type tested by the firm applying for type testing. If measurements techniques need to be adapted this will be communicated in advance (if possible) by the physico-technical steering group and the applicant. If differences are noticed during type testing adaptations of methods of measurement will be made on the spot and discussed afterwards. This discussion will take place before the second physico-technical test is performed.

In section 3.1 an overview of all tests performed in a EUREF type test is given. Some additional tests will be performed, which are described in section 3.2.

For CR systems at least 4 cassettes of standard size (18 x 24 cm) and 4 cassettes of large size (24 x 30 cm) should be available during the type test, at the site of the clinical test at least 8 cassettes should be available. If large size cassettes are available they may also be used at the clinical site.

EUREF type testing

2D systems

Technical evaluation protocol

The following test-items described in the European Guidelines for quality assurance in breast cancer screening and diagnosis, fourth edition and its Supplement are measured in a EUREF typetest technical evaluation:

2b.2.1.1.5 Tube output
The method described in the Supplement to the European Guidelines is used. No limiting values are used. Measured for reference purposes and to calculate (mean glandular) dose.

2b.2.1.2 Tube voltage and beam quality

2b.2.1.2.1 Tube voltage
The method described in the Supplement to the European Guidelines is used.

2b.2.1.2.2 Half value layer
The method described in the Supplement to the European Guidelines is used.

2b.2.1.3 AEC-system

2b.2.1.3.2 Back-up timer and security cut-off
The method and limiting values of the European Guidelines are used.

2b.2.1.3.3 Short term reproducibility
The method and limiting values of the European Guidelines and its Supplement are used.

2b.2.1.3.4 Long term reproducibility
The method of the European Guidelines is used. The limiting values of the Guidelines are used as action limits for further investigation.
In the final report measurements on long term stability from the clinical test period will be presented.

2b.2.1.3.5 Breast thickness and composition compensation
The method and limiting values of the European Guidelines and its Supplement are used.

2b.2.1.3.6 Local dense area
The method and limiting values of the Supplement to the European Guidelines is used.

2b.2.2 Image receptor
2b.2.2.1 Image receptor response

2b.2.2.1.1 Response function
The method and limiting values of the Supplement to the European Guidelines is used.

2b.2.2.1.2 Noise evaluation
The method and limiting values of the Supplement to the European Guidelines is used.

2b.2.2.2 Missed tissue at chest wall side
The method and limiting values of the European Guidelines are used.

2b2.2.3 Image receptor homogeneity and stability

2b.2.2.3.1 Image receptor homogeneity
The method and limiting values of the European Guidelines and its Supplement are used.

2b.2.2.3.2 Detector element failure (DR systems)
The method and limiting values of the European Guidelines are used. The bad pixel map should be easily accessible for all users. If uncorrected bad pixels are visible on the images this should be taken into account when evaluating detector element failure.

2b.2.2.3.3 Uncorrected defective detector elements (DR systems)
The method and limiting values of the European Guidelines are used.

2b.2.2.4 Inter plate sensitivity variations (CR systems)
The method and limiting values of the European Guidelines and its Supplement are used. At least four cassettes of each size should be present.

2b.2.2.6 Fading of latent image (CR systems)
The method of the European Guidelines is used.

2b.2.3 Dosimetry
The method and limiting values of the European Guidelines and its Supplement are used.

2b.2.4 Image quality

2b.2.4.1 Threshold contrast visibility
The method and limiting values of the European Guidelines and its Supplement are used.

Threshold contrast visibility is determined at a number of dose levels: the clinical glandular dose level and two to four other dose levels, which will be chosen such that a large range of dose levels is covered (for example between ½ and 2 times the clinical dose level).

For details of 0.1, 0.25, 0.5 and 1.0 mm diameter, threshold contrast is plotted against glandular dose. The dose at which the minimum acceptable image quality standard and achievable image quality standard is achieved for the 0.1,

0.25, 0.5 and 1.0 mm diameter objects on the contrast threshold visibility phantom is calculated.

2b.2.4.2 Modulation Transfer Function (MTF), Noise Power Spectrum (NPS) and Detective Quantum Efficiency (DQE)
The method described in the Supplement to the European Guidelines, appendix 7 is used.

2b.2.4.3 Exposure time
The method and limiting values of the European Guidelines are used.

2b.2.4.4 Geometric distortion and artefact evaluation
The method and limiting values of the European Guidelines are used.

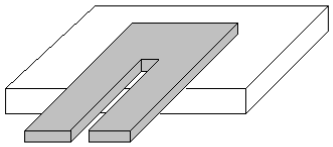
2b.2.4.5 Ghost image / erasure thoroughness
The method and limiting values of the European Guidelines are used.

Additional test performed in a EUREF typetest

Thickness indication

In the clinical test a dose survey will be conducted. For this dose survey the indicator of the height of the compression paddle needs to be checked.

For this measurement two foam blocks with compressed thickness of about 2 and 4 cm are used. A strip has been cut out of the foam block to allow measurement of thickness during compression (see figure below). Thickness indication can be checked when the foam blocks (18 x 24 cm) are placed on the bucky. Position the blocks such that half of the block is positioned on the bucky and half of the block is positioned over the edge of the bucky at chest wall side, see figure V.1. Apply compression (approximately 100 N), record the thickness indication and measure thickness at the reference point with an appropriate device (for example a calliper). Perform this measurement for the two foam blocks separately and together (so measurements can be done at about 2, 4 and 6 cm compressed thickness).



foam block

EUREF type testing

Tomosynthesis systems

Technical evaluation protocol

The following test-items described in the EUREF protocol for the quality control of the physical and technical aspects of digital breast tomosynthesis systems are measured in a EUREF typetest technical evaluation:

1.2	Focal spot motion The method described in the EUREF DBT protocol is used.
1.3	Alignment and collimation checks
1.4	Tube output
1.5.1	Tube voltage The method described in the EUREF DBT protocol is used.
1.5.2	Half value layer The method described in the EUREF DBT protocol is used.
1.6	Exposure distribution per projection image (optional) The method described in the EUREF DBT protocol is used.
2	AEC-system
2.1	Back-up timer and security cut-off The method described in the EUREF DBT protocol is used.
2.2	Short term reproducibility The method described in the EUREF DBT protocol is used.
2.3	Long term reproducibility The method described in the EUREF DBT protocol is used.
2.4	AEC performance The method described in the EUREF DBT protocol is used.
2.5	Exposure duration per projection and total scan duration The method described in the EUREF DBT protocol is used.
2.6	Local dense area The method described in the EUREF DBT protocol is used.
3.1	Compression force The method described in the EUREF DBT protocol is used. (if not already performed in a 2D test)
4	Image receptor
4.1	Image receptor response

4..1.1 Response function
The method described in the EUREF DBT protocol is used.

4.1.2 Noise evaluation
The method described in the EUREF DBT protocol is used.

4.2 Detector element failure
The method described in the EUREF DBT protocol is used.

4.3 Uncorrected defective detector elements
The method described in the EUREF DBT protocol is used.

4.4 System projection MTF
The method described in the EUREF DBT protocol is used.

5 Image quality of the reconstructed image

5.1 Stability of image quality in the x-y plane

5.1.1 CDMAM phantom
The method described in the EUREF DBT protocol is used.

5.2 Z-resolution
The method described in the EUREF DBT protocol is used.

5.5 Missed tissue

5.5.1 Missed tissue at chest wall side in the reconstructed tomosynthesis image
The method described in the EUREF DBT protocol is used.

5.5.2 Missed tissue at the top and bottom of the reconstructed tomosynthesis image
The method described in the EUREF DBT protocol is used.

5.6 Homogeneity of the reconstructed tomosynthesis image
The method described in the EUREF DBT protocol is used.

5.7 Geometric distortion
The method described in the EUREF DBT protocol is used.

6. Dosimetry for digital breast tomosynthesis

6.2 Assessing Average Glandular Dose

6.2.1 Assessing AGD using the standard breast model simulated with PMMA
The method described in the EUREF DBT protocol is used.

EUREF type testing

Clinical evaluation protocol

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Introduction:

The imaging chain consists of a different components: image acquisition, image processing and image presentation. During a physico-technical evaluation, the image acquisition is checked. In the clinical part of the type testing the image as presented to the radiologist is checked. The quality of clinical images is determined by all components of the imaging chain, including parts not evaluated in the physico-technical evaluation. The evaluation of the clinical images in the clinical phase of the type testing should not be performed separately and can only take place on a system that passed the technical evaluation.
The clinical phase of the type testing includes, next to an assessment of the clinical image quality by a team of experts including two radiologists, a long term system stability test and a dose evaluation. The duration of this clinical phase is at least three months. If problems occur, EUREF has the right to extend the clinical evaluation period accordingly or to stop the evaluation.
The choice of the site for the clinical phase is decided upon by the applicant together with EUREF. It must be a site at which one of the physico-technical evaluations in phase 2 of the typetest has been performed. The site should have sufficient workflow and softcopy reading is required. All clinical images made in the clinical phase of the typetest will be sent to the EUREF office in Nijmegen. The workstations, used to evaluate the images, fulfil all requirements from the European Guidelines.

Procedure of acquiring the images:

At the start of the clinical phase a EUREF representative will be present at the site of the clinical evaluation, together with a specialist of the applicant. The applicant will install a hard disk or other medium om which all images from the clinical test period can be copied to. On the hard disk all patient information will be anonimised. Alternatively the applicant of the typetest provides to EUREF all anonymized clinical images made in the clinical phase.
A record should be kept at the clinical evaluation site in which all occurring image quality issues like artefacts etc. are be recorded.

Procedure of scoring the images:

Images of 80 women will all be scored by a team of radiologists. These 80 cases will be selected from the images made in the clinical phase of the typetest. For the selection procedure it is important that the anonymized DICOM headers of all clinical images are correctly filled in. This also facilitates the calculating of patient dose. A plot of mean glandular dose as a function of compressed breast thickness will be made. The aim of this is twofold: (1) to learn about the dose distribution and (2) to make a representative selection of the clinical images for the evaluation by the team of experts (all breast thicknesses and breast compositions). All patient data is divided in 7 thickness classes: < 20 mm compressed breast thickness, between 20 and 30 mm breast thickness, between 30 and 40 mm breast thickness, … , between 70 and 80 mm breast thickness and > 80 mm breast thickness. In each thickness class, patients will be ranked as a function of glandular dose. From each thickness class, 10 patients will be selected per thickness class; in the ranked series, the image at 5^{th} percentile of the dose distribution, the image at 15^{th} percentile, the image at the 25^{th} percentile, etc will be selected for the evaluation of image quality by the team of experts. This makes in total 70 patients. Another 10 cases will be selected randomly from all patients with breast implants.

Different image features will be scored by an experienced team of experts in consensus, consisting of at least two radiologists and a physicist. The scoring form can be found in appendix 1 of this part of the protocol. In the case that consensus cannot be reached in the team of experts a third radiologist will be appointed as arbiter. This third radiologist will be an expert with a large experience in mammography and tomosynthesis.

The scoring form:

In the first part of the scoring form (consisting of 13 questions) the radiologist has to answer questions with “yes” or “no”. This part includes questions about the visibility of anatomical structures, the perception of noise and contrast in low and high attenuating areas of the breast. In the second part of the scoring form (consisting of 7 questions) the radiologist has to score the perception of contrast and sharpness of the images and how confident the radiologists are with the image on a scale from 1 to 10. In the last part the radiologists are asked about the quality of images with breast implants. The scoring will be done at a diagnostic workstation fulfilling at relevant standards and ambient light conditions.

Dose evaluation and AEC evaluation:

In the clinical evaluation period a patient dose survey and AEC evaluation will be performed. For this dose survey the X-ray exposure data and other relevant information, like breast thickness, must be available in the DICOM header contains all relevant values. When testing CR systems the applicant should take actions to connect the mammography unit and reader in order to fill in the DICOM header with exposure values, breast thickness and dose indicator.

Stability test:

In the clinical evaluation period an image of a 4.5 cm homogeneous block of PMMA covering the whole image receptor has to be acquired every day in full-automatic mode to monitor the long term stability of the equipment. A record will be kept of all artefacts on clinical images and of all problems that were noticed by the radiographers/radiologists at the test site. These QC images and records will be sent to the EUREF office for evaluation.

Additional comments:

Comments about potential special features, ergonomics and other remarkable points might be obtained by the EUREF representative who will be present at the start of the clinical evaluation period. Besides this, comments about specific features might be asked from the radiologists and radiographers at the clinical evaluation site. This data might be used in the type test report.

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Protocol for the Quality Control of the Physical and Technical Aspects of Digital Breast Tomosynthesis Systems, version 1.03, Euref 2018.

Appendix 1: Clinical evaluation scoring form

Number :

The following questions are to be answered by yes or no:

		Yes	No	N/A
1	Is there a good visualization of the skin line ?			
2	Are the vascular structures visible through the dense parenchyma ?			
3	Is there a sharp visualisation of the pectoral muscle ?			
4	Is there a good visualisation of the Coopers ligaments and vascular structures in the subcutaneous and prepectoral area ?			
5	Are the micro calcifications visualized and well outlined ?			
6	Is there sufficient contrast in the dark areas (e.g. no saturation of intensity of signals, no fully dark regions) ?			
7	Is there sufficient contrast in the white areas (e.g. no fully white regions) ?			
8	Is the glandular tissue sufficient white ?			
9	Is the background sufficient dark ?			
10	Do all images appear in the same way ? (if no, please place a remark)			
11	Is there disturbing noise in the dark areas?			
12	Is there disturbing noise in the white areas?			
13	Are there any artefacts ?			

For the following questions you score the images with a number from 1 (bad) to 10 (good). Please use the whole range

		1	2	3	4	5	6	7	8	9	10
1	Contrast in the white regions										
2	Contrast in the dark regions										
3	Overall contrast										
4	Sharpness										
5	How satisfied are you with the representation of micro calcifications ?										
6	How satisfied are you with the representation of opacities ?										
7	How satisfied are you with the representation of the image ?										

8	How satisfied are you with the images with implants ?										

Remarks:

Thank you very much for cooperating.