Easy Quality Control with -

PTW Equipment

Code of Practice -
Quality control of X-ray equipment in diagnostic radiology

Revised edition October 2010
Code of Practice-
Quality control of X-ray equipment in diagnostic radiology
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Introduction

The quality control of X-ray images is influenced by a number of parameters. To maintain the consistent performance of X-ray installations, quality checks have to be conducted regularly. Regular quality controls:

- ensure proper functioning of the medical X-ray devices
- reduce patient exposure
- avoid unnecessary double exposures
- reduce the costs of X-ray departments

The various components of the imaging chain are ideally tested independently to identify malfunctions and eliminate those detected easily.

PTW-Freiburg offers a variety of diagnostic test tools for different X-ray equipment. The PTW-Freiburg product line includes devices and phantoms for quality control in diagnostic radiology according to different standards such as DIN, DIN EN and IEC for direct as well as for indirect radiography, for analogue and digital mammography, for digital subtraction angiography as well as for the dental range and for computer tomography. Additionally, sensitometers and densitometers are available to check the quality of the film processing independently from X-ray units. The CD LUX meter is available for testing image display devices.

This code of practice tries to define in an easy and compact way how to perform quality control measurements on different diagnostic X-ray installations. The necessary equipment for measuring the main parameters as well as the acceptable limits are mentioned accordingly. In case the acceptable limits differ from the basic values, action has to be taken, to reestablish the basic situation.

This guideline was prepared conscientiously based on the actual status of standardization up to the time of publication. This guideline is not exhaustive. For a detailed and all-embracing performance of the constancy test, the relevant version of the DIN, DIN EN or IEC standard and the appropriate manual of the test equipment have to be used.

Olga Froescher

PTW-Freiburg, October 2010
FAQ

Why perform an acceptance test?
An acceptance test has to be conducted out after a new X-ray installation has been installed or major modifications have been made to existing X-ray equipment to facilitate verification of applicable safety and performance standards, regulations and contractual specifications, which influence the image quality, patient dose or positioning.

An acceptance test is therefore normally performed by a technician from the manufacturing company of the X-ray installation. Acceptance tests ensure that the required image quality is reached with the lowest amount of X-ray exposure to the patient.

During an acceptance test, the reference or basic values for the constancy tests are defined with the same equipment, which will be used later on for constancy tests. The results of an acceptance test have to be documented and archived together with the analogue or digital X-ray image.

Why perform a constancy test?
To avoid creeping deficiencies, which result in worse X-ray images, constancy tests have to be performed regularly and at least monthly. A constancy test enables the operator without mechanical or electrical interferences to check whether the image quality as well as the X-ray exposure is in accordance with those defined during the acceptance test.

When new X-ray equipment is brought into use or any component of the X-ray equipment, accessories or test equipment is changed, which may cause a variation in the test result, an initial constancy test has to be conducted immediately after an acceptance test has indicated that the performance is satisfactory. The purpose of the initial constancy test is to establish new baseline values for the parameters tested.

The methods for testing the constancy are designed to enable the operator to detect changes in image quality of images produced by the X-ray equipment. For the results of the constancy test, it is essential to ensure that they are not significantly influenced by anything other than changes in the parameters under test. All equipment under test and the test equipment have to be identified during the initial constancy test to ensure that the same items are used in subsequent constancy tests.

Constancy tests are normally performed with loading factors which are the same as those used most frequently in clinical practice. It is important to record and reproduce all significant settings of the X-ray equipment and accessories each time a test is conducted and to check that the same equipment, components and accessories are used. The test instrumentation has to be checked regularly and particularly when any significant variation in the X-ray equipment is suspected. Before performing a constancy test, the constancy of the radiographic cassettes, the radiographic film, the film processing and the film viewing conditions have to be checked.

Why use phantoms during quality control measurements?
Phantoms for constancy tests include various important structures to simulate important image details, which are characteristic for the image quality. Therefore using a phantom during constancy tests enables the operator to check whether a good X-ray image can be performed with low X-ray exposure.

How often do quality control measurements normally have to be performed?
Quality control measurements have to be performed whenever malfunction is suspected e.g., after maintenance work that could affect the parameters under test. Constancy tests should be conducted according to the corresponding standard.
## Quality control equipment for different X-ray installations

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<td>‣ coincidence of the radiation and light field, artifacts, homogeneity ‣ entrance dose ‣ optical density ‣ contact between intensifying screens &amp; film</td>
<td>‣ NORMI 3 ‣ CONNY II ‣ DensiX ‣ Screen-Film Contact Test Tool</td>
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<td>Scope of testing?</td>
<td>QC equipment?</td>
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I. Constancy tests - Equipment for analogue direct radiography acc. to DIN 6868-3 [1]

1. Test parameters
   - Entrance dose
   - Optical density
   - Coincidence of the radiation field with the light field
   - Contact between intensifying screen and film

1.2. Test equipment
   - CONNY II dosemeter
   - DensiX densitometer
   - NORMI 3 or REX phantom
   - Screen-film Contact Test Tool

1.3. Test adjustment
1.) Adjust the NORMI 3 phantom on the patient couch and put the cassette including the film into
    the position for exposure. Always use the same marked cassette.
    - For over couch tubes, the indication “focus” on the NORMI 3 structure plate has to face the
      X-ray focus above.
    - For under couch measurements, the NORMI 3 is assembled by using the additional
      supports. In this case, the NORMI 3 structure plate with the indication “focus” faces down in
      direction to the tube.
    - The NORMI 3 can also be used in combination with the NORMI 3 wall mount [T20005].
2.) Adjust the NORMI 3 phantom always in the same way, as defined in the initial constancy test.
    Therefore, use the light field of the X-ray installation. Adjust the light field beginning with the
    adjustment to the mid-marks and then to the edge-marks of the NORMI 3 structure plate
    [picture 1].
3.) Attach the CONNY II detector [picture 2].

Hint: The deviation of the focus-film-distance has to be within 1 % of the documented distance used
during the initial constancy test.
1.4 Test procedure
- Set up the loading factors identical to those used in the initial constancy test (normally 70 kV) and switch on the CONNY II dosemeter.
- Make an exposure using the automatic exposure control and the manual control if both operation modes are used in clinical routine. For each exposure the dose has to be measured.
- Note the dose value displayed at the CONNY II dosemeter.
- Develop and evaluate the film.

Hint:
For measurements at 100 kV an additional copper plate has to be used.

1.5 Data evaluation
Document and file the exposed film and the protocol with the results of the constancy test.

Hint:
If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

1.5.1 Entrance dose
The entrance dose of each exposure has to be documented.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Exposures taken under automatic exposure control: ± 30 % at 70 kV (± 25 % at 100 kV)
- Exposures taken under manual control: ± 30 % at 70 kV and at 100 kV

1.5.2 Optical density
Measure and document the optical density [OD] with the DensiX densitometer in the marked area in the middle of the exposed film.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Exposures taken with the AEC and manual control: ± 0.3 OD at 70 kV and 100 kV
1.5.3 Coincidence of the radiation field with the light field
- The conformity of the useful radiation field and light field by means of the mid and edge markings of the NORMI 3 has to be checked.
- Measure and record the outer dimension of the radiation field image by means of a ruler and enter the results into the protocol.
- Measure the distance between the mid-marks of the NORMI 3 and the middle of the exposed field on the film in both perpendicular directions as well as the outer dimensions of both lateral lengths of the exposed field (distances A, B, C, D) [picture 5].
- The deviation of the radiation and light field is given by the sum of A and B and the sum of C and D.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- |A| + |B| ≤ 0.02 x focus-film-distance
- |C| + |D| ≤ 0.02 x focus-film-distance
- Maximum deviations are therefore 2 % of the focus-film-distance

![Diagram of radiation field and light field](image)

Picture 5: Deviation of the useful beam from the light field

1.5.4 Artifacts and homogeneity
Check the image for any distortions and document the result.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Any visible deterioration in the homogeneity of the film density across the image not presented before or the more pronounced appearance of grid lines are not allowed and should lead to further action.
- The X-ray image must be free of artifacts.

1.5.5 Contact between intensifying screen and film
The uniformity and homogeneity of the contact between the intensifying screen and the film can be verified with the Screen-Film Contact Test Tool [L991077]. Place the radiographic cassette to be tested in the radiation beam and place the Screen-Film Contact Test Tool flat on the top of the incident face of the cassette. Irradiate the cassette and document the optical density and compare the image with the image made during the initial test.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Visible impairment of the film-screen contact is not allowed.

Hint:
A delay of 10 to 25 minutes between loading and irradiation allows any entrapped air to escape.
<table>
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<td>Entrance dose</td>
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II. Constancy tests - Equipment for analogue direct radiography acc. to IEC 61223-2-11 [2]

2.1 Test parameters
- Entrance dose
- Optical density
- Coincidence of the radiation field with the light field
- High contrast resolution

2.2 Test equipment
- CONNY II dosemeter
- DensiX densitometer
- X-Check RAD phantom

2.3 Test adjustment
1.) Adjust the X-Check RAD phantom on the patient couch as described in the X-Check RAD manual and put the film cassette into the position for exposure. Always use the same marked cassette.
   
   *Hint:* The tests should be performed with the cassette used for the initial constancy test. In combination with this test cassette, always use the same type of radiographic film used for the constancy test for the film processor.

2.) Adjust the X-Check RAD phantom always in the same way as defined in the initial constancy test. Therefore, use the light field of the X-ray installation. Adjust the light field beginning with the adjustment to the mid-marks and then to the edge-marks of the X-Check RAD structure plate [picture 1].
   
   *Hint:* Always use the same distance from the focal spot to the phantom as well as the same size of radiation field as used in the initial constancy test.

3.) Attach the CONNY II detector.

*Picture 1: Adjustment of the X-Check RAD phantom*

*Hint:* The measurement adjustment should be reproducible within ± 1 % of the focus-film distance used in the initial constancy test.
2.4 Test procedure
Whenever possible, carry out exposures under both manual control and automatic exposure control:
- Set up the loading factors identical to those used in the initial constancy test and switch on the CONNY II dosemeter.
- The arrangement of the X-ray source assembly and the X-ray image receptor has to be as in normal clinical praxis.
- Place the loaded test cassette into the cassette changer.
- Note the dose value displayed at the CONNY II dosemeter.
- Develop and evaluate the film.

![Diagram](image)

2.5 Data evaluation
Document and file the exposed film and the protocol with the results of the constancy test.

*Hint:* If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

2.5.1 Entrance dose
Compare the measured entrance dose of the radiation output with the established baseline values. The entrance dose of each exposure has to be documented.

**Criteria to be applied:**
The following criteria have to be applied in comparison to the baseline values:
- Exposures taken under automatic exposure control: - 20 % to + 25 % (PMMA, Al absorber) ± 25 % (copper absorber)
- Exposures taken under manual control: ± 20 %

2.5.2 Optical density
Measure and document the optical density [OD] with the DensiX densitometer in the marked areas of the exposed film. Compare the measured OD values with the established baseline values.

**Criteria to be applied:**
The following criteria have to be applied in comparison to the baseline values:
- OD of the exposure taken under manual control and automatic exposure control: ± 0.10 OD
2.5.3 Coincidence of the radiation field with the light field

- Place the X-Check RAD structure plate in the centre of the light field and align the edges to one of the field size markings on the X-Check RAD structure plate parallel to the edges of the light field.
- Note the settings of the field size indicators of the beam limiting device.
- Record the extent of any asymmetry in the light field, whereby one or more edges of the light field cannot be set to coincide with the edges of the field defined by the alignment test device.
- Make an exposure and process the film.
- Measure the distances between the edges of the radiation field as defined by the darker irradiated area and the edges of the light field as indicated by the image of the radio-opaque markers. For each pair of opposite edges, add these measurements to calculate the degree of misalignment.
- Measure the length of edges of the radiation field as determined by the darker irradiated area. Subtract the indicated dimensions of field size from the measured dimensions [refer to page 13].

   *Hint:* The radiation beam axis has to be within 1.5° of the perpendicular axis to the image reception area. This means that the image of the centre of the cross has to be within the image of the inner circle of the X-Check RAD structure plate for the perpendicular position.

**Criteria to be applied:**

The following criteria have to be applied in comparison to the baseline values:

- \[ |A| + |B| \leq 0.02 \times \text{focus-film-distance} \]
- \[ |C| + |D| \leq 0.02 \times \text{focus-film-distance} \]
- Maximum deviations are therefore 2% of the focus-film-distance.

2.5.4 High contrast resolution

Examine the resolution test pattern visible in the radiogram and note the maximum spatial frequencies. Compare the values with the established baseline values.

   *Hint:* The examination can be performed with a magnifying glass.

**Criteria to be applied:**

In comparison to the base line values the frequency should not decrease by more than 20 % for continuously varying resolution test patterns or by more than one line pair group.
Protocol

Example of a form for the standardized test report

Test report
on constancy test of equipment for general direct radiography
according to IEC 61223-2-11:1999

Identifications

Person performing test

Equipment and subsystems
- X-RAY SOURCE ASSEMBLY
- HIGH-VOLTAGE GENERATOR
- X-RAY TUBE ASSEMBLY
- BEAM LIMITING DEVICE

Components and accessories
- ADDED FILTERS
- PATIENT SUPPORT
- IONIZATION CHAMBER (AUTOMATIC CONTROL SYSTEM)
- ANTI-SCATTER GRID
- RADIOPHGRAPIC FILM (type, emulsion number, date of first use (batch))
- RADIOPHGRAPIC CASSETTE
- INTENSIFYING SCREENS

Darkrooms

Film processing equipment

Test equipment

Identification:
- ATTENUATION PHANTOM, film marker TEST DEVICE, TEST DEVICE for perpendicular position, TEST DEVICE for alignment, high-contrast TEST DEVICE
- RADIATION METER
- densitometer
- lead sheet
Test arrangement
- distance between FOCAL SPOT and RADIATION DETECTOR
- BEAM LIMITING DEVICE position
- orientations of
  - RADIOGRAPHIC CASSETTE
  - RADIATION METER
  - ANTI-SCATTER GRID
  - TEST DEVICE for perpendicular position

Test conditions
- X-RAY TUBE ASSEMBLY selected
- FOCAL SPOT selected
- TOTAL FILTRATION of the X-RAY SOURCE ASSEMBLY
- set field indicated by light
- set RADIATION FIELD
- X-RAY TUBE VOLTAGE selected
- X-RAY TUBE CURRENT selected/measured
- measuring field of AUTOMATIC CONTROL SYSTEM
- programme step of AUTOMATIC CONTROL SYSTEM
- time selected for manual IRRADIATION

NOTE – Manual settings of LOADING FACTORS should be approached from one direction and the same direction of the range of the scale.

History of tests
- most recent test on darkroom safe-light conditions Date:
- most recent test on film processing equipment Date:
- most recent initial CONSTANCY TEST Date:
- previous CONSTANCY TEST Date:

Test results

Results for testing under manual control
- magnitude RADIATION output (RADIATION METER)
- magnitude RADIATION input
  - optical density
  - RADIATION METER
- geometric characteristics
  - FOCAL SPOT to IMAGE RECEPTOR DISTANCE
  - alignment of RADIATION FIELD edges
  - centre coincidence RADIATION FIELD with LIGHT FIELD
- resolution of high-contrast detail
  - maximum spatial frequency visible parallel to X-RAY TUBE axis
  - maximum spatial frequency visible perpendicular to X-RAY TUBE axis
- variation in optical density throughout a radiogram
  - optical density difference

Results for testing under automatic exposure control
- magnitude radiation output (radiation meter)
- magnitude radiation input
  - optical density
  - radiation meter
III. Constancy tests - Equipment for analogue and digital fluoroscopy acc. to DIN 6868-4 [3]

Hint:
DIN 6868-4 allows fluoroscopy tests on analogue and digital units using dynamic flat panels as well as tests by film exposure from the image intensifier screen.

3.1 Test parameters
- Entrance dose, dose rate, dose per image
- Dose indicator
- High contrast resolution
- Contrast
- Limitation of the radiation field
- Artifacts

3.2 Test equipment
- CONNY II dosemeter
- NORMI 4 FLU plus phantom

3.3 Test adjustment
1.) Put the NORMI 4 FLU plus phantom as close as possible to the image receiver of the fluoroscopic equipment while the structure plate is faced to the focus. Use the additional supports if necessary. Centre the phantom, the image receiver and the front shutter under fluoroscopy control.

2.) Adjust the field size in the same way as during the initial state. The concentric rings and the mesh on the NORMI 4 FLU plus structure plate can be used for the adjustment and also allow evaluation of the field size and the image scale [picture 1].

Hint:
If the fluoroscopic equipment is applied with scattering grids, always use the same grid.

3.) Attach the CONNY II detector at the entrance beam side, always in the same orientation.

Picture 1: Adjustment of the NORMI 4 FLU plus phantom at a digital fluoroscopy unit using a dynamic flat panel

Hint:
The focus to image receiver distance as well as the focus to phantom distance should be reproducible to the one used in the initial constancy test, while the geometric enlargement should not exceed 1.3.
3.4 Test procedure

- Set up the loading factors identical to those used in the initial constancy test and switch on the CONNY II dosemeter.
- Start the fluoroscopy.
  
  **Hint:**
  For dose rate measurements the dose has to be measured during an interval of 20 seconds. In case of exposing an image, the dose per image has to be detected.
- Note the dose value displayed at the CONNY II dosemeter.
- Evaluate the image.
  
  **Hint:**
  The dose value under test is the average value out of three tests normally.

3.5 Data evaluation

Document and file the protocol with the results of the constancy test. Note also the parameters kV and mAs.

**Hint:**
If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

3.5.1 Entrance dose

Compare the measured values for entrance dose, entrance dose rate or the dose per image with the established baseline values.

**Criteria to be applied:**

- Fluoroscopy taken under automatic exposure control: ± 30 %
- Dose per image: ± 30 %

3.5.2 Dose indicator

The maximum deviation of the dose indicator is determined and documented by the manufacturer. Therefore, the deviation of the dose indicator is to be taken from the manufacturer data, in case a dose indicator is shown for an image after the test.

**Criteria to be applied:**

The following criteria have to be applied in comparison to the baseline values:

- The dose indicator variation from the reference value may not exceed variations that correspond to ± 50 % of the image receiver dose.
3.5.3 High contrast resolution
Examine the resolution test pattern visible and note the maximum spatial frequencies. Compare the values with the established baseline values.
Criteria to be applied:
The resolution (Lp/mm) has to be identical in comparison to the baseline values.

3.5.4 Contrast
Count and document the number of different visible steps and the visible low contrast objects.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- All NORMI 4 FLU plus steps have to be visible as defined during the initial test.
- The number of low contrast objects visible should not differ from the reference number determined in the initial test.

3.5.5 Limitation of the radiation field
While the shutters are completely open, all adjustable image receiver formats have to be checked.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- At least at two opposing sides the shutter edges have to be visible.
- During post processing of an image it is not allowed that the limitation of the radiation field is covered by an electronic mask.

3.5.6 Artifacts
The test image has to be checked for artifacts which may influence the diagnosis.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The X-ray image must be free of any artifacts, e.g. no ghost images or pixel deficiencies are allowed.
**Protocol**

**Constancy Test according to DIN 6868-4**

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Test object</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray unit:</td>
<td>Type:</td>
</tr>
<tr>
<td>Room:</td>
<td>Manufacturer:</td>
</tr>
<tr>
<td>Associated equip.:</td>
<td>Material:</td>
</tr>
<tr>
<td>Number of planes:</td>
<td>Material thickness (mm):</td>
</tr>
<tr>
<td>DSA mode:</td>
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</tr>
<tr>
<td>Operation:</td>
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<tr>
<td>Generator:</td>
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<td>Manufacturer:</td>
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<td>X-ray source assembly:</td>
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<tr>
<td>Serial number:</td>
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<tr>
<td>Additional filtration:</td>
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<tr>
<td>Automatic filtration:</td>
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**Test object**

<table>
<thead>
<tr>
<th>Test object</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type:</td>
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<td>Manufacturer:</td>
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<tr>
<td>Material:</td>
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<tr>
<td>Material thickness (mm):</td>
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</table>

**Dosemeter**

<table>
<thead>
<tr>
<th>Dosemeter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type/Serial number:</td>
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<td>Manufacturer:</td>
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<tr>
<td>Measuring time (s):</td>
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<td>Last calibration:</td>
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**Image documentation**

<table>
<thead>
<tr>
<th>Image documentation</th>
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<tbody>
<tr>
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<td>Manufacturer:</td>
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<td>Miscellaneous:</td>
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**General conditions**

<table>
<thead>
<tr>
<th>General conditions</th>
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<tbody>
<tr>
<td>Focus-image receiver-distance:</td>
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<tr>
<td>Focus-structure plate-distance:</td>
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</table>

**Fluoroscopy conditions**

<table>
<thead>
<tr>
<th>Fluoroscopy conditions</th>
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</thead>
<tbody>
<tr>
<td>Dose rate level:</td>
</tr>
<tr>
<td>Control characteristics/Program:</td>
</tr>
<tr>
<td>(Format/voltage/current) at cont. DR: ( / / ) ( / / ) ( / / ) ( / / ) ( / / ) ( / / )</td>
</tr>
<tr>
<td>(Format/voltage/current) at pulsed DR: ( / / ) pulse rate:</td>
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**Fluoroscopy conditions**

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Program:</td>
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<td>Measuring chamber:</td>
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<td>Additional filtration:</td>
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</table>

**City/Date**

**Signature**
### Test results

#### Constancy Test according to DIN 6868-4 (fluoroscopy mode)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Format</th>
<th>Reference values</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(min)</td>
<td>(max)</td>
</tr>
<tr>
<td>Dose (mGy)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(dose rate (mGy/s))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>continuous FLU</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Voltage/current (kV/mA)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>continuous FLU (optionally)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Resolution (lp/mm)</td>
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<td></td>
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</tr>
</tbody>
</table>

#### Test results

- **Operator:**
- **X-ray unit:**
- **Reasons for redetermination of the reference values:**
- **City, Date:**
- **Signature:**

**Test results**

<table>
<thead>
<tr>
<th>Parameters</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(min)</td>
<td>(max)</td>
</tr>
<tr>
<td>Pulsed FLU/ pulse rate</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resolution (lp/mm)</td>
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- **Operator:**
- **X-ray unit:**
- **Reasons for redetermination of the reference values:**
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- **Signature:**

**Test results**

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<td></td>
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<td><strong>Voltage/current (kV/mA)</strong></td>
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</tr>
<tr>
<td>Resolution (lp/mm)</td>
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</tr>
</tbody>
</table>
### Constancy Test according to DIN 6868-4 (fluoroscopy mode)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Format</th>
<th>Okay</th>
<th>Not in order</th>
<th>Test results</th>
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</thead>
<tbody>
<tr>
<td>Limitation of useful radiation field</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Dynamic/ contrast</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Artifacts: (yes/no)</td>
<td>all</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Operator:**
- X-ray unit:
- Room:
- Associated equipment:
- Type of check/change:
- by/at:

**Reasons for redetermination of the reference values:**

**City, Date**

**Signature**

**Test results**

- X-ray unit:
- Room:
- Associated equipment:
- Type of check/change:
- by/at:

**City, Date**

**Signature**
## Constancy Test according to DIN 6868-4 (radiography mode)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Format</th>
<th>(min)</th>
<th>(max)</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose (mGy)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Dose indicator</td>
<td></td>
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</tr>
<tr>
<td>Resolution (lp/mm)</td>
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<td></td>
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</tr>
</tbody>
</table>

**Operator:**

- X-ray unit:
- Room:
- Associated equipment:
- Type of check/change:
- by/at:

**Reasons for redetermination of the reference values:**

---

**Parameters**

- Dose (mGy)
- Dose indicator
- Resolution (lp/mm)

**City, Date**

**Signature**
## Constancy Test according to DIN 6868-4 (radiography mode)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Format</th>
<th>Okay</th>
<th>Not in order</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limitation of useful radiation field</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Dynamic/contrast</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artifacts: (yes/no)</td>
<td>all</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| operator:                           |        |      |              |              |
| Room:                               |        |      |              |              |
| Associated equipment:               |        |      |              |              |
| Type of check/change:               |        |      |              |              |
| by/at:                              |        |      |              |              |

| City, Date | Signature | Reason for redetermination of the reference values: |

<table>
<thead>
<tr>
<th>X-ray unit:</th>
<th>Reasons for redetermination of the reference values:</th>
<th></th>
</tr>
</thead>
</table>

Test results: X-ray unit: 
Room: 
Associated equipment: 
Type of check/change: 
by/at: 
City, Date: 
Signature: 

Operator:

Parameters

Limitation of useful radiation field

Dynamic/contrast

Artifacts: (yes/no)

Format

Okay

Not in order

Test results

Date:
IV. Constancy tests - Equipment for analogue indirect radiography acc. to IEC 61223-2-9 [4]

4.1 Test parameters
- Entrance dose
- Gray-scale
- Threshold contrast
- High contrast resolution

4.2 Test equipment
- CONNY II dosemeter
- X-Check FLU phantom

4.3 Test adjustment
1.) Always adjust the X-Check FLU phantom on the patient couch as described in the X-Check FLU manual in the same way as defined in the initial constancy test [picture 1 and 2].
2.) Place the device as close as possible to the input surface of the X-ray image intensifier. Ensure that the X-Check FLU structure plate is in the centre of the field of the X-ray image intensifier and has the same orientation with respect to the X-ray image intensifier as used in the initial constancy test.
3.) Select the largest field size available of the X-ray image intensifier, and collimate the X-ray beam to the main dimensions of the test object.
4.) Attach the CONNY II detector.

![Picture 1 and picture 2: Adjustment of the X-Check FLU phantom](image)

4.4 Test procedure
Whenever possible, carry out exposures under both manual and automatic exposure control:
- Set up the loading factors identical to those used in the initial constancy test and switch on the CONNY II dosemeter.
- Stand directly in front of the image display device and observe the image details visible under lighting conditions used during the initial constancy test.
- Note down the dose value displayed at the CONNY II dosemeter.
4.5 Data evaluation
Document and file the measured values in the protocol for the constancy test.

**Hint:**
If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

4.5.1 Entrance dose
Compare the measured entrance dose of the radiation output with the established baseline value. The entrance dose of each exposure has to be documented.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- Exposures taken under AEC:  - 20 % to + 25 % (PMMA, Al absorber)
  ± 25 % (copper absorber)
- Exposures taken under manual control: ± 20 %

4.5.2 Gray-scale image
Observe the visibility of the white and black spots on the image display device, and compare them with the established baseline values. Record and document the results.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Both the black and the white spots have to be visible on the image display device.

4.5.3 Threshold contrast
Count the number of the low contrast disks which are visible. Compare them with the established baseline values. Record and document the results.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The amount of disks visible should not differ by more than one from the number recorded at the initial test.

4.5.4 High contrast resolution
Count the number of line pair groups and compare them with the established baseline values. Record and document the results.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The amount of visible groups of the resolution test pattern should not be more than two and fewer than three than in the initial constancy test.
Protocol

Example of a form for the standardized test report

Test report
on constancy test of equipment for indirect radioscopy and indirect radiography according to IEC 61223-2-9:1999

Identifications

Person performing test Identification:
Equipment under test Identification:
  IMAGE DISPLAY DEVICE, according to IEC 61223-2-5 Identification:
    all user selectable settings
Test equipment Identification:
  - RADIOGRAPHIC CASSETTE Identification:
  - RADIATION METER Identification:
  - ATTENUATION PHANTOM Identification:
  - grey-scale TEST DEVICE Identification:
  - low-contrast TEST DEVICE Identification:
  - high-contrast TEST DEVICE Identification:
  - correction FILTER TEST DEVICE, if needed Identification:

Standard test conditions (including environmental influences)

History of tests
- most recent test on darkroom safe-light conditions Date:
- most recent test on film processing equipment Date:
- most recent initial CONSTANCY TEST Date:
- previous CONSTANCY TEST Date:

Test results

- RADIATION output
- IRRADIATION TIME
- CURRENT TIME PRODUCT

- X-RAY TUBE VOLTAGE
- X-RAY TUBE CURRENT
- optical density of test films

- number of disks visible during RADIOSCOPY
- number of disks visible using storage facility
- number of disks visible on RADIOGRAM

- number of line pairs resolved during RADIOSCOPY
- number of line pairs resolved using storage facility
- number of line pairs resolved on RADIOGRAM
V. Constancy test - Equipment for digital subtraction angiography acc. to DIN 6868-4 and IEC 61223-3-3 [3, 5]

**Hint:**
The following constancy test is carried out normally after the constancy test acc. to DIN 6868-4 or IEC 61223-2-11.

5.1 Test parameters
- Entrance dose
- Resolution
- Dynamic range
- Contrast
- Artifacts
- Logarithmic error

5.2 Test equipment
- CONNY II dosemeter
- X-Check DSA phantom
- NORMI 4 FLU plus or REX or X-Check FLU phantom

5.3 Test adjustment
1.) Put the X-Check DSA on table and move it till the step wedge is horizontally orientated within the image [picture 1]. Make sure that the X-Check DSA cannot shift during the movement.
2.) Adjust the minimal distance between the test object and the image intensifier [picture 2].
3.) Check whether the irradiation field is smaller than the X-Check DSA. Make sure that the image intensifier is not irradiated directly.
4.) Perform an image [picture 3].
   **Hint:**
   It is sufficient to make only one DSA picture and one basic picture.

Picture 1: Adjust the X-Check DSA
Picture 2: Choose the minimal distance
Picture 3: Centre the X-Check DSA
5.4 Test procedure
- Set up the loading factors identical to those used in the initial constancy test (normally 70 kV).
- The measuring time should be at least 20 seconds [s] at a picture frequency of at least 1 s⁻¹.
- Start the measurement and shift the pneumatic X-Check DSA slider after approx. five seconds.
- Evaluate and document the results.

5.5 Data evaluation
Document and file the measured values in the protocol of the constancy test.

Hint: If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

5.5.1 Entrance dose
This measurement is carried out according to DIN 6868-4 or IEC 61223-2-11 [refer to page 21, 29].

Hint: Adjust the field size so that the NORMI 4 FLU plus or X-Check FLU structure plate cannot be outshone. Divide the dose value at the number of pictures and document the result.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- Dose per picture: 30 %

5.5.2 Dynamic range
The dynamic range can be checked with the step wedge. The DSA installation should at least provide a dynamic range of 1 to 15. Start the measurement and shift the slider after 5 seconds. Observe the determinations. Low movements artifacts which appear through dark or light cut-off points can be ignored.

Criteria to be applied:
The following criteria has to be applied in comparison to the baseline values:
- All strips in the basic picture should be visible and the strips of the DSA image should be homogeneous.

5.5.3 Contrast sensitivity
The contrast sensitivity test shows, whether the DSA system is able to recognize vessels with very low contrast.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- The thinnest vessel simulation (0.05 mm Al) should be exactly recognizable in the area of the 0.8 mm Cu step if a dose of approx. 5 μGy per picture is used.

5.5.4 Resolution
The resolution has to be determined with the NORMI 4 or X-Check FLU for one selected image intensifier format.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The amount of visible groups of the resolution test pattern should not be more than two and less than three.

5.5.5 Artifacts
There are four reasons for artifacts, which should be examined if they occur:
- two pictures do not refer to the same coordinate system
- the beam quality was drifting during the runs
- the measuring values are not correctly digitized
- influences of the beam geometry occurred

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Any visible deterioration across the image not presented before is not allowed and should lead to further action.
5.5.6 Logarithmic error
The attenuation of X-rays is not proportional to the object thickness or to the object density. To compensate for this effect, a DSA unit works with logarithmic amplifiers. If these amplifiers are not working well, logarithmic errors occur. These errors can be checked by observing the step wedge. Criteria to be applied:
- If the DSA image shows a difference in gray values between the 1.4 copper step and the 0.2 copper step, a logarithmic error has caused this failure and has to be eliminated.
# Protocol

## Constancy Test according to DIN 6868-4 (radiography and DSA mode)

### Parameters

<table>
<thead>
<tr>
<th>Operator:</th>
<th>X-ray unit:</th>
<th>Room:</th>
<th>Associated equipment:</th>
<th>Type of check/change:</th>
<th>by/for:</th>
<th>(max)</th>
<th>(min)</th>
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</table>

### Test results

<table>
<thead>
<tr>
<th>Dose (mGy)</th>
<th>Dose indicator</th>
<th>Artifact</th>
<th>Contrast res.</th>
<th>Logarith. error</th>
<th>Resolution (lp/mm)</th>
</tr>
</thead>
<tbody>
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### Test results

<table>
<thead>
<tr>
<th>Format</th>
<th>Dose / picture</th>
<th>Artifacts</th>
<th>Contrast res.</th>
<th>Logarith. error</th>
<th>Resolution (lp/mm)</th>
</tr>
</thead>
<tbody>
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### Test results

<table>
<thead>
<tr>
<th>Constancy Test according to DIN 6868-4 (radiography and DSA mode)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Table continues]</td>
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</table>
### Constancy Test according to DIN 6868-4 (radiography and DSA mode)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Format</th>
<th>Okay</th>
<th>Not in order</th>
<th>Test results</th>
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</thead>
<tbody>
<tr>
<td>Limitation of useful radiation field</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Dynamic/contrast</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artifacts: (yes/no)</td>
<td>all</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| X-ray unit:                    |        |      |              |              |
| Room:                          |        |      |              |              |
| Associated equipment:          |        |      |              |              |
| Type of check/change:          |        |      |              |              |
| by/at:                         |        |      |              |              |

City, Date: ___________________  Signature: ___________________

Reasons for redetermination of the reference values:

---

**Test results**

**Operator:**

**X-ray unit:**

**Room:**

**Associated equipment:**

**Type of check/change:**

**by/at:**

**City, Date:** ___________________  **Signature:** ___________________
VI. Constancy test - Equipment for digital radiography acc. to DIN 6868-13 [6]

The following describes the constancy test of equipment for digital projection radiography. This standard applies to equipment that utilize imaging plates or semiconductor image detectors, which use film on an image viewer or image display device for diagnosis (monitor diagnosis).

6.1 Test parameters
- Entrance dose
- Dose indicator
- Coincidence of the radiation field with the light field
- Artifacts
- High resolution
- Contrast
- Luminance
- Optical density

6.2 Test equipment
- CONNY II dosemeter
- NORMI 13 phantom
- CD LUX Meter light measuring device
- DensiX densitometer

6.3 Test adjustment
1.) Adjust the NORMI 13 phantom on the patient couch and put the image plate including the film into the position for exposure. Always use the same marked image plate [picture 1].
   - For over couch tubes, the indication “focus” on the NORMI 13 structure plate has to face the X-ray focus above.
   - For under couch measurements, the NORMI 13 is assembled by using the additional supports. In this case the NORMI 13 structure plate with the indication “focus” faces down in direction to the tube.
   - The NORMI 13 can also be used in combination with the NORMI 13 wall mount [T20005].
2.) Adjust the NORMI 13 phantom always in the same way, as defined in the initial constancy test. Therefore, use the light field of the X-ray installation. Adjust the light field beginning with the adjustment to the mid-marks and then to the edge-marks of the NORMI 13 structure plate [picture 2].
   
   Hint:
   - If there is no light field, use the fluoroscopy control to center the NORMI 13 to the image display device.
   - Always use the same imaging plate with the same foil.
   - Always use the same scattering grid adjusted in the same spatial orientation and same distance.
3.) Attach the CONNY II detector with Velcro tape on the defined measuring area on the NORMI 13 structure plate [picture 5].

Hint:
The measurement adjustment should be reproducible within ± 1 % of the focus to image-receiver distance used in the initial constancy test.
Picture 1: Schematic adjustment with a PMMA attenuator

Picture 2: Applicatory adjustment

Picture 3: Schematic adjustment with an Al attenuator

Picture 4: Applicatory adjustment

Picture 5: Attach the CONNY II detector
6.4 Test procedure
Carry out exposures under both manual exposure control and automatic exposure control if both
are used in clinical routine:

- Set up the loading factors identical to those used in the initial constancy test and switch on the
  CONNY II dosemeter.
- Make an exposure.
- Note down the dose value displayed at the CONNY II dosemeter.
  
  Hint:
  For measurements at 100 kV an additional copper plate can be used to get a sufficient
  switching time.

6.5 Data evaluation
Document and file the measured values in the protocol of the constancy test.

  Hint:
  If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to
  restore the initial state and the baseline values of the X-ray equipment!

6.5.1 Entrance dose
Compare the measured entrance dose with the established baseline values.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:

- Exposures taken under manual control: ± 30 % at 70 kV and 100 kV
- Exposures taken under automatic exposure control with:
  - an aluminum attenuator: ± 25 % at 70 kV (± 20 % at 100 kV)
  - a PMMA and copper attenuator: ± 30 % at 70 kV (± 25 % at 100 kV)

6.5.2 Dose indicator
The maximum deviation of the dose indicator is determined by the manufacturer. Therefore, the
deviation of the dose indicator is to be taken from the manufacturer data.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:

- The dose indicator variation from the reference values may not exceed variations that
  correspond to ± 50 % of the image sensor dose.

6.5.3 Optical density
The optical density can be measured with the DensiX densitometer. The measurement should
always be carried out at the same position on the test image in the middle step of the dynamic
wedge of the NORMI 13.

  Hint:
  The measurement is not necessary if luminance is measured on the monitor.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:

- Exposures taken under automatic exposure control and manual exposure control: ± 0.3 OD

6.5.4 Luminance
Measurements of the luminance is always carried out at the same position on the test image on the
middle step of the dynamic step of the NORMI 13 with the CD LUX Meter.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:

- Exposures taken under automatic exposure control or manual exposure control: + 100 % and -
  50 %

  Hint:
  The measurement is not necessary if the optical density is measured on a film.
6.5.5 **High contrast resolution**
The spatial resolution is determined using the lead foil test pattern of the NORMI 13. The image of the lead foil can be evaluated visually using a 4 to 8 magnifying glass. The parameter is the number of line pairs per millimeter (Lp/mm) in the line group which can be distinguished at the resolution.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The threshold spatial resolution determined as valid in the initial test must met all X-ray images made with the NORMI 13.

6.5.6 **Contrast resolution**
Inspect the dynamic steps and observe the low contrast objects visually. Enter them into the test report.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The number of low contrast objects visible should not differ from the reference number determined in the initial test.

6.5.7 **Artifacts**
The test image has to be checked for artifacts which influence the diagnosis.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The X-ray image must be free of any artifacts.

6.5.8 **Coincidence of the radiation field with the light field**
From the test image any variation between the light and the radiation field must be determined [refer to page 13]. To measure the image geometry the lengths of the outer lines at the top bottom, left and right, the two middle lines of height and width are measured and recorded. Check whether the lines and shapes of the NORMI 13 are straight within themselves without any visible distortions.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The variation at the image sensor level must not exceed 2 % of the focal point - image sensor separation distance (r):
  \[ |A| + |B| \leq 0.02 \times r \times V \]
  \[ |C| + |D| \leq 0.02 \times r \times V \]
  \( V: \) imaging scale

**Hint:**
Workplace programming tools can be used for measuring the distances A, B, C and D.
VII. Constancy tests - X-ray equipment for analogue mammography acc. to DIN 6868-7 and IEC 61223-2-10 [7, 8]

7.1 Test parameters
- Entrance dose
- Optical density
- Artifacts
- Coincidence of the radiation field with the light field
- High contrast resolution
- Contact between intensifying screens and film
- Compression device

7.2 Test equipment
- CONNY II dosemeter
- DensiX densitometer
- NORMI MAM analog phantom
- Screen-Film Contact Test Tool
- Compression Test Set

7.3 Test adjustment
1.) Adjust the NORMI MAM phantom on the patient support (configuration with 40 mm PMMA absorber and 6 mm structure plate) and put the film cassette into the position for exposure [picture 1 and 2].
   Hint:
   The tests should be performed with the cassette used for the initial constancy test. In combination with this test cassette, always use the same type of mammography film used for the constancy test for the film processor.
2.) Attach the CONNY II detector [picture 3].
3.) Lower the compression plate [picture 4].

**Hint:**
The adjustment should be reproducible within ± 1 % of the focus-film-distance used in the initial constancy test.
7.4 Test procedure
Carry out exposures under both manual exposure control and automatic exposure control:
- Set up the loading factors identical to those used in the initial constancy test and switch on the CONNY II dosemeter. Use the settings of the X-ray tube voltage identical to those used in the initial constancy test.
- Make an exposure:
  - If other patient supports and cassettes are used and mammography tables with their own automatic exposure control, these units have to be taken into consideration, too.
  - Exposures are performed with 40 mm at 28 kV, 20 and 60 mm PMMA attenuator above and below 28 kV.
- Note down the dose values from the CONNY II dosemeter for each exposure.
- Develop and evaluate the film.

7.5 Data evaluation
Document and file the measured values in the constancy test protocol for each image. If the mammography unit displays the current time product (mAs) for the image, also log it.

Hint:
If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

7.5.1 Entrance dose
The entrance dose of each exposure has to be documented.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- Exposures taken under automatic exposure control: max. 10 %
- Exposures taken under manual exposure control: max. 25 %

7.5.2 Optical density
Measure and document the optical density \( [OD] \) with the DensiX densitometer in the marked area in the middle of the exposed film.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- \( OD \) of the exposure taken under automatic exposure and manual exposure control: \( 1.6 \pm 0.2 \) \( OD \)

Hint:
- If the measurement is not within the range of 1.4 to 1.8 \( OD \) the optical density has to be corrected using the correction switch for the automatic exposure control. An additional X-ray image must be taken to confirm that an optical density of \( 1.6 \pm 0.2 \) \( OD \) is upheld.
- The value should be attained with a correction step at which the switched dose does not deviate by more than \( \pm 20 \% \) from the correction switch reference value for optical density.
7.5.3 Artifacts
Take X-ray images of the 20 mm, 40 mm and 60 mm thick homogenous PMMA attenuators using the automatic exposure control and check the images for any distortions.
Criteria to be applied:
- Any visible deterioration in the homogeneity of the film density across the image not presented before or the more pronounced appearance of grid lines are not allowed and have to lead to further action.
- The X-ray image must not have any structures whose size, shape, border sharpness and difference in density from the surrounding area could impair the diagnosis.

*Hint:*
- Position two 20 mm PMMA attenuation phantoms next to each other for large film formats.
- Use different cassettes each time for this test, so that all of the cassettes used for patient imaging are checked cyclically.
- A magnifying lens with a magnification factor between 5 to 10 can be used.

7.5.4 Coincidence of the radiation field with the light field
Determine the number of steel balls completely shown on the X-ray film in the image for each of the four rows of steel balls.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The limit values have to be upheld for the radiation passing beyond the four film edges.
- The limit value for the number of steel balls completely visible on the film must be maintained. This requirement applies for each of the four rows of steel balls.

7.5.5 High contrast resolution
The lines of the resolution test pattern have to be recognizable and countable as separate lines. The parameter is the number of line pairs per millimetre (Lp/mm) in the line group that can be recognized.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The imaging of the resolution test pattern should not visibly worsen compared to the initial state.
- The measured frequency should not be reduced by more than one line pair group compared with the frequency in the initial constancy test.

*Hint:*
A magnifying lens with a magnification factor between 4 to 8 can be used.

7.5.6 Low contrast resolution
Count the number of the visible low-contrast objects in the NORMI MAM phantom.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The number of visible low-contrast objects should not deviate from the reference value set in the acceptance test by more than one.
- The limit value for contrast resolution that was valid must be met in all of the X-ray images taken for the test.

7.5.7 Image contrast
The difference between the lightest and second darkest as well as from the lightest and darkest contrast level in the NORMI MAM must be determined and filed.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The difference between the measured optical density of the lightest and second darkest contrast level must not deviate from the first reference value for image contrast by more than 0.15 OD.
- The difference between the measured optical density of the lightest and darkest contrast level must not deviate from the second reference value for image contrast by more than 0.2 OD.
7.5.8 Compensation for object and tube voltage
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Deviations from the target value for optical density attained with the 20 mm and 60 mm PMMA
  attenuation phantoms must not exceed the limit value valid for the last acceptance test. The
  same holds true for additional X-ray images if there is a second table having its own automatic
  exposure control measuring chamber.

7.5.9 Correction switch for automatic exposure control
The quotients of all selected dose values or current time products are to be compared with the
reference values and parameters. The reference values are the quotients of the selected dose
values or the current time products of all steps of the correction switch set by the user (density
correction keys).
Criteria to be applied:
- Any change of the correction switch setting by one step must lead to a change in the dose or
  current time product that deviates from the reference value for that step by no more than ± 3 %.

7.5.10 Attenuation and amplification factor for cassettes
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Deviation of the dose or the current time product (mAs) from the mean and the difference
  between the greatest and lowest values valid for the last acceptance test have to be upheld.

7.5.11 Contact between intensifying screen and film
The uniformity and homogeneity of the contact between the intensifying screen and the film can be
verified with the Screen-Film Contact Test Tool [L991078]. Place the mammography cassette to be
tested in the radiation beam on the top of the breast support and place the Screen-Film Contact
Test Tool flat on the top of the incident face of the mammography cassette. Irradiate the cassette.
Document the optical density and compare the image with the image made during the initial test.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- Visible impairment of the film-screen contact is not allowed.
- The deviation should be within ± 20 %

Hint:
A delay of 10 to 25 minutes between loading and irradiation allows any entrapped air to escape.

7.5.12 Compression device
The compression plates have to be visually checked at first. The compression is measured for the
selectable settings, including the highest value. To the extent possible, the measurement values
are to be compared with the values that the mammography unit displays. In addition, a foam cube
is to be subsequently placed in the three positions on the patient support (right, centre, left) and
compressed with a force of 150 N each time for each of the film formats. During compression, the
distance of the three compression plates to the patient support is to be measured on their four
edges. The distance on the left edge is to be compared with the distance on the right edge and the
distance of the edge on the thoracic wall side is to be compared to the distance of the edge
opposite to the thoracic wall side.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- The actual force of compression must correspond to the displayed value within the specified
tolerances. The greatest specified force must not be exceeded. For powered compression
(such with motors), a force of at least 150 N has to be attainable. Forces exceeding 200 N
must not be possible and the compression fixture for the force has to hold for at least 1 minute.
- Manually measured compression force: ± 10 N
- Motorized pre-compression: ± 20 %
- The difference between the values on the left and right margin must not exceed 5 mm for
  symmetrical loads or 15 mm for asymmetrical loads.

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Example of a form for the standardized test report

Test report
on constancy tests of X-ray equipment for mammography
according to IEC 61223-2-10:1999

Identifications

Person performing test  Identification:
a) X-RAY EQUIPMENT

Mammographic X-RAY EQUIPMENT  Identification:
– X-RAY SOURCE ASSEMBLY
– X-RAY TUBE ASSEMBLY
– HIGH-VOLTAGE GENERATOR
– BEAM LIMITING DEVICES

Components and accessories  Identification:
– ADDED FILTERS
– BEAM LIMITING DEVICES
– PATIENT SUPPORT/RADIOGRAPHIC CASSETTE HOLDER
– compression plates
– ANTI-SCATTER GRID
– RADIOGRAPHIC FILM, Type
– RADIOGRAPHIC FILM, Emulsion number
– RADIOGRAPHIC FILM, Date of first use (batch)
– RADIOGRAPHIC CASSETTE, dedicated for test
– RADIOGRAPHIC CASSETTE, to be tested
– INTENSIFYING SCREENS

Darkrooms  Identification:
– FILM PROCESSOR  Identification:

NOTE – It may be advisable to record data from the processing of the sensitometric wedge such as temperature of developer, FILM BASE PLUS FOG DENSITY, contrast and speed.

Test equipment  Identification:
– ATTENUATION PHANTOM, high-contrast TEST DEVICE, alternative high-contrast TEST DEVICE, film-screen contact TEST DEVICE
– densitometer
– sensimeter
– force balance/scales

Test arrangement  Values:
– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE
– reception area
– position and orientation of the TEST DEVICES
Standard test conditions (including environmental influences)

- Focal spot selected
- Anode material
- Added filters
- X-ray tube voltage
- X-ray tube current
- Current time product
- X-ray tube loading time
- Position of automatic exposure control device
- Programme step of the automatic control system
- Compression force selected

NOTE 1 - Variables should be set on the same scale range. The actual loading of the anode resulting from choosing for instance 100 mA for 0.20 s will usually differ from that obtained by setting 200 mA for 0.1 s.

NOTE 2 - Mechanical variables and those electrical variables set by continuous controls should be approached from the same direction, to eliminate backlash effects. It is a good practice to set all controls to zero and reset to desired values to eliminate backlash effects.

History of tests

- most recent test on darkroom conditions Date:
- most recent test on film processing equipment Date:
- most recent initial constancy test Date:
- previous constancy test Date:

b) Mammographic cassettes

c) Film processing

Test results

Initial constancy test

- Image density:
  - Manual exposure control optical density
  - Automatic exposure control optical density

Optical densities measured at position: (for example in x-y coordinates)

- Current time product of the X-ray tube
- Loading time of the X-ray tube
- Grid lines or other artefacts on radiograms absent present
- Maximum spatial frequency visible parallel to axis of X-ray tube
- Maximum spatial frequency visible perpendicular to axis of X-ray tube
- Compression force measured with scales
- Compression force indicated at X-ray equipment

Constancy test

(similar tests as for initial constancy test)
VIII. Constancy tests - Equipment for digital mammography acc. to DIN PAS 1054 [9]

8.1 Test parameter
- Coincidence of the radiation field with the light field
- Entrance dose
- Function of the automatic exposure control
- Signal-to-noise-ratio, contrast-to-noise-ratio
- Mean gray value
- Decay
- Artifacts
- High contrast resolution, low contrast resolution
- Dynamic range
- Compression device

8.2 Test equipment
- CONNY II dosemeter
- NORMI PAS phantom
- CDmon light meter
- Screen-Film Contact Test Tool
- Compression Test Set

8.3 Test adjustment
1.) Adjust the NORMI PAS phantom on the patient support (configuration with 40 mm PMMA attenuator and 6 mm structure plate). Choose the minimum distance adjustable at the given mammography unit. Put the cassette into the position for exposure.
2.) Attach the CONNY II detector.
3.) Lower the compression plate.

Picture 1: NORMI PAS with test element PMMA
Picture 2: NORMI PAS with test element HK
Picture 3: NORMI PAS with test element KRV
Picture 4: NORMI PAS with test element ACR
8.4 Test procedure

- Set up the loading factors identical to those used in the initial test and switch on the CONNY II dosemeter. Use the settings of the X-ray tube voltage identical to those used in the initial constancy test.
- Start the measurement using the automatic exposure control:
  - Take one image of all different combinations available (different patient supports, anode filter combinations, focal spot sizes intended by the manufacturer).
  - Exposures are performed with 40 mm at 28 kV, 20 mm and 60 mm PMMA attenuator above and below 28 kV.
  
  *Hint:* Once a dose measurement has to be performed under manual exposure control above and below 28 kV.
- Note down the dose values from the CONNY II dosemeter for each exposure.
- Evaluate the images.

8.5 Data evaluation

Document and file the measured values in the constancy test protocol for each image.

*Hint:* If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

8.5.1 Coincidence of the radiation field with the light field

For each row of steel balls in the test object, the number of balls that appear completely or in halves on the film has to be determined. The radiation beyond the image receptor must be determined for all four edges. Document the results.

*Criteria to be applied:*

The following criteria have to be applied in comparison to the baseline value:

- The width of the area not shown in the plane of the patient support and in the plane 40 mm above the patient support must not exceed 5 mm (this is equivalent to the full visibility of 2.5 of the 5 steel balls per row in the test object).

**Picture 5: Thoracic wall side limitation**

8.5.2 Mean gray scale

The mean gray scale value has to be documented and filed, while the irradiation time should be less than 2 seconds.

*Criteria to be applied:*

The following criteria has to be applied in comparison to the baseline value:

- Standard conditions (46 mm PMMA): max. 10 % from the target value (manufacturer’s data)
- With 20 and 60 mm PMMA: max. 15 % from the target value
  max. 10 % from the reference value
8.5.3 Signal-to-noise ratio (SNR)
The mean gray scale value and the standard deviation must be determined under standard conditions and compared with the manufacturer's data.
Criteria to be applied
The following criteria have to be applied in comparison to the baseline value:
- The SNR of the standard exposure must not exceed more than 10 % from the target value.
- For other exposures, the deviation must not exceed 15 % from the target value or 10 % from the reference value.

Hint:
As an alternative, the KRV value can be determined.

8.5.4 Contrast-to-noise-ratio (CNR)
Insert the test element CNR into the structure plate (configuration with 40 mm PMMA and 6 mm structure plate) and choose the most frequently used compression plate. Perform a measurement of the mean gray scale value in ROI 1 (area of the depicted aluminium plate) and ROI 2 (50 mm on the side of ROI 1, marked on the NORMI PAS). Determine the standard deviation $\sigma$ of ROI 2 (PMMA) with the following formula:

$$KRV = \frac{\text{mean gray value (Al)} - \text{mean gray value (PMMA)}}{\text{standard deviation (PMMA)}}$$

Choose two more exposures with different PMMA thicknesses (at least 14 mm) and calculate the CRV. Compare the results with the target value given in the manufacturer's data.
Criteria to be applied
The following criteria have to be applied in comparison to the baseline value:
- The CNR of the standard exposure must not exceed more than 10 % from the target value.
- Uncertainty of the respective CNR value has to be within $\leq$ 5 %.
- For CNR of other exposures, the deviation must not exceed 15 % from the target value or 10 % from the reference value.

Hint:
As an alternative, the SRV value can be determined.

8.5.5 Attenuation ratio
For the attenuation ratio, refer to the accompanying documents. Attenuation ratios have to be determined with all of the existing anti-scatter grids. Therefore position the 40 mm PMMA attenuator on the patient support. Choose a X-ray tube voltage of 28 kV or as specified by the manufacturer. Use the most frequently anode target filter combination. Now the entrance dose is measured on top of the patient support and in the plane in which the image is shot (without cassette). Both measuring points have to be on the same axis of the focal spot. Measure the source-to-image distances. The attenuation factor $T_R$ is calculated from the entrance dose values ($K_1$ and $K_2$) and the corresponding source-to-image-receptor distances ($f_1$ and $f_2$):

$$T_R = \frac{K_1 \cdot f_1}{K_2 \cdot f_2}$$

Criteria to be applied
The following criteria have to be applied in comparison to the baseline value:
- The attenuation ratio must be less than 2.
8.5.6 Compression device
The compression plates have to be visually checked at first. The compression is measured for the selectable settings, including the highest value. To the extent possible, the measurement values are to be compared with the values that the mammography unit displays. In addition, a foam cube is to be subsequently placed in the three positions con the patient support (right, center, left) and compressed with a force of 150 N each time for each of the film formats. During compression, the distance of the three compression plates to the patient support is to be measured on their four edges. The distance on the left edge is to be compared with the distance on the right edge and the distance of the edge on the thoracic wall side is to be compared to the distance of the edge opposite to the thoracic wall side.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- The actual force of compression must correspond to the displayed value within the specified tolerances. The greatest specified force must not be exceed. For powered compression (such with motors) a force of at least 150 N has to be attainable. Forces exceeding 200 N must not be possible and the compression fixture for the force has to hold for at least 1 minute.
- Manually measured compression force: ± 10 N
- Motorized pre-compression: ± 20 %
- The difference between the values on the left and right margin must not exceed 5 mm for symmetrical loads or 15 mm for asymmetrical loads.

8.5.7 Artifacts
An image is to be taken with the 20 mm PMMA attenuator and a loaded image plate. Choose a X-ray voltage of at least 25 kV and obtain an optical density of approx. 1.5. The structures on the film that could be the result of inhomogeneities caused by material within the radiation beam have to be studied.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- Any visible deterioration in the homogeneity of the film density across the image not presented before or the more pronounced appearance of grid lines are not allowed and should lead to further action.
- The X-ray image must not have any structures whose size, shape, border sharpness and difference in density from the surrounding area could impair the diagnosis.

Hint:
- Position two 20 mm PMMA attenuation phantoms next to each other for large film formats.
- Use a different cassette each time for this test so that all of the cassettes used for patient imaging are checked cyclically.
- A magnifying lens with a magnification factor between 5 to 10 can be used.

8.5.8 Spatial resolution
One image of each focal spot of the mammography unit is to be taken for all of the anode targets. Choose the main picture taking technique applied by the user and assemble the test object with an overall thickness of 46 mm at 28 kV (or according to manufacturer's data). The lines of the resolution test pattern have to be recognizable and countable as separate lines. The parameter is the number of line pairs per millimetre (Lp/mm) in the line group that can be recognized.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The imaging of the resolution test pattern should not visibly worsen compared to the initial state.

Hint:
A magnifying lens or a zoom function may be used at the viewer with a magnification factor between 4 to 8.
8.5.9 Contrast
An image is to be taken with the main picture-taking technique applied by the user (such as raster/halftone-image technique). Choose the preferred anode filter combination Mo/Mo and the choose the standard configuration with 46 mm PMMA and either the test element AP or KP-ACR [picture 4] at 28 kV or according to manufacturer’s data. Observe visually the structures and file the results.

Hint:
- For constancy tests, either the test element AP or test element KP-ACR can be used.
- A magnifying lens or a zoom function may be used at the viewer with a magnification factor between four to eight.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- Test element AP: Four of the five structures must be visible.
- Test element KP-ACR: The number of structures visible have to be the same as during the initial state.

8.5.10 Dynamic range
An image is to be taken with the basic 40 mm PMMA attenuator including the PMMA step wedge. Set the X-ray tube voltage to 28 kV (Mo/Mo) or according to the manufacturer’s data. The gray scale value has to be determined for each of the steps. The offset has to be determined at the Pb step. Step 0 (non attenuated primary radiation) must yield the maximum gray scale value and the value must decrease with each of the following steps. Determine the signal-to-noise ratio for all steps.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- A continuity of the gray scale according to the PMMA thickness has to be visible.
- Deviations of the gray scale: < 10 %

8.5.11 Entrance dose $K_E$
Adjust the CONNY II detector and take an image under standard exposure conditions with 46 mm PMMA at a distance of 60 mm from the thoracic wall side.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- Mean gray scale value has to be within 10 % of the manufacturer’s data.

Hint:
- Manufacturers provide different anode filter combinations. The above criteria to be applied refers to the reference Mo/30 µm Mo or W/60 µm Mo as anode filter combination.

8.5.12 Average parenchyma dose $D_{PD}$
In most cases, the average parenchyma dose $D_{PD}$ will be calculated by the system.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- $D_{PD} \leq 2.5 \text{ mGy at 46 mm PMMA}$

8.5.13 Decay
Two consecutive images have to be taken under automatic exposure control with a configuration of 46 mm PMMA including the test element HK. Choose the same settings as used in clinical routine. Make an image and move the NORMI PAS phantom to the side before taking the second picture.

Criteria to be applied:
The following criteria have to be applied in comparison to the baseline value:
- The second picture must be free of rests of the first picture. So-called ghost pictures are not allowed.
IX. Constancy tests - Equipment for computer tomography acc. to DIN EN 61223-2-6 [10]

9.1 Test Parameters
- Computed tomography dose index [CTDI_{100}]
- Weighted CTDI_{100} [CTDI_{w}]

9.2 Test Equipment
- DIADOS E dosemeter with CT chamber and CT adapter
- CT head & body phantom or CT body phantom or CT head phantom

9.3 Test adjustment
1.) Connect the CT chamber to the CT adapter and then to the DIADOS E.
2.) Adjust the head or body phantom in that way that one of the outer holes is on the top, in the so-called 12 o’clock position.
3.) Insert the CT chamber into the 12 o’clock hole and close the other holes with plugs [picture 1].
4.) Align the phantom with respect to the CT plane and rotational axis using the crosshair of the CT phantom.
5.) Switch on the DIADOS E [see picture 2].

9.4 Test procedure
- Set up the CT for the scan. Set up the loading factors identical to those used in the initial constancy test.
- Perform a CT scan and start the measurement of the dose length product.
- Read out and note down the measured data from the DIADOS E.
- Change the chamber position by insertion the CT chamber into the centre hole of the CT phantom and close the not used hole with the plug.
  
  Hint: Change the chamber and plugs carefully. If the phantom moves, the alignment has to be repeated.
- For the determination of the weighted computed dose index the dose length product has to be measured as described above.
- Evaluate the CT scan.
9.5 Evaluation data
Document and file the measured values with the protocol of the constancy test.

Hint:
If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

9.5.1 CTDI\textsubscript{100}
Determine the CTDI\textsubscript{100} from the measured dose length product and compare it with the base line value.

Hint:
Calculate the CTDI\textsubscript{100} with the following formula:

\[
\text{CTDI}_{100} = \int_{-50 \text{ mm}}^{+50 \text{ mm}} \frac{D\left(z\right)}{N \times T} \, dz
\]

with
- \(D(z)\): Dose profile along the line \(z\) perpendicular to the tomography plane
- \(N\): Number of tomography sections produced in a single axial scan
- \(T\): Nominal tomography section thickness

Criteria to be applied:
The following criteria has to be applied in comparison to the baseline value:
- \(\text{CTDI}_{100}\): ± 20 %

9.5.2 CTDI\textsubscript{w}
Determine the CTDI\textsubscript{w} from the measured dose length product and compare it with the base line value.

Hint:
Calculate the CTDI\textsubscript{w} with the following formula:

\[
\text{CTDI}_w = \frac{1}{3} \text{CTDI}_{100(centre)} + \frac{2}{3} \text{CTDI}_{100(peripheral)}
\]

with
- \(\text{CTDI}_{100(centre)}\): CT value measured in the centre of the CT phantom
- \(\text{CTDI}_{100(peripheral)}\): Average CT value measured in the outer or peripheral holes of the CT phantom

Criteria to be applied:
The following criteria has to be applied in comparison to the baseline value:
- \(\text{CTDI}_w\): ± 20 %

10.1 Test parameters
- Invariance of viewing conditions
- Gray-scale reproduction
- Geometry of the image
- Spatial resolution low-contrast resolution
- Image stability and image artifacts
- Colour-related aspects

10.2 Test equipment
- CDmon light meter
- Clinical reference image e.g. the SMPTE\(^0\) or IEC\(^2\) test image [picture 1, 2].

10.3 Test Adjustment
1.) Switch on the image display device and download the SMPTE\(^0\) or IEC\(^2\) test image.
2.) Switch on the CDmon light meter.

Hint:
- Always use the same equipment, accessories and test instrumentation as during the initial test.
- Geometrical arrangements and environmental conditions should be kept as constant as possible.
- Test images are used to check the constancy of the quality of images produced by an image display device and allow the testing of all test parameters.

Picture 1: SMPTE\(^0\) test picture

Picture 2: IEC\(^2\) test picture

\(^0\) Society of Motion Picture and Television Engineers
\(^2\) International Electrotechnical Commission
10.4 Test procedure and data evaluation

All tests have to be performed under the same conditions as those used when carrying out the initial constancy test. Document and file the measured values with the constancy test protocol.

Hint:
If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

10.4.1 Invariance of viewing conditions

The luminance measurement is performed with the image display device switched off. Place the CDmon light meter at the usual position of the observer, and measure the luminance in the middle of the image display device. Also perform a visual check for the presence of light spots reflected off the image and for light sources in the field of view. Record the values.

Criteria to be applied:
- The following criteria have to be applied in comparison to the baseline values:
  - Additional light sources or reflected light spots have to be eliminated.
  - The display-luminance shall not be greater than ±25 %.

10.4.2 Gray-scale reproduction

The image display device should have been switched on for at least 30 minutes beforehand. Measure the luminance in the white and black squares from normal observation distance. Identify the gray levels of the gray scale which are perceived distinctively and compare these with those recorded as baseline value. Particular attention should be paid to the ends of the gray scale.

Criteria to be applied:
- The following criteria have to be applied in comparison to the baseline values:
  - Luminance of the black square: ±25 %
  - Luminance of the white square: ±20 %

10.4.3 Image geometry

This test requires the inspection of the displayed image of the test pattern to check the accuracy of the image display in terms of the image size, position and degree of distortions. Images of the crosshatched pattern, inscribed circle and boundary pattern should be judged visually and the results compared with the results obtained from the initial constancy test.

Criteria to be applied:
- The results obtained visually should not deviate significantly.
- The measured lengths should not deviate by more than ±5 % from the corresponding lengths recorded.

10.4.4 Spatial resolution and low-contrast resolution

Check the constancy of the display image containing high- and low-contrast bar patterns visually. Look for deviations between present and past results. Compare the findings with the recorded baseline values.

Criteria to be applied:
- The following criteria have to be applied in comparison to the baseline values:
  - The results should not deviate significantly with respect to the results of the initial test.
  - Particular attention should be paid to the low-contrast bar patterns.

10.4.5 Image stability and image artefacts

Look for deviations between the past and present results and file the result.

Criteria to be applied:
- The following criteria have to be applied in comparison to the baseline values:
  - No artifacts should be visible within the image.

10.4.6 Colour-related aspects

Look for deviations between the present and past results.

Criteria to be applied:
- Results for the testing of the constancy of performance should not deviate significantly from the results obtained during the initial constancy test.
Protocols

Example of a form for the standardized test report

Test report
on constancy test of image display devices
according to IEC 1223-2-5: 1994

Identifications

Person performing test

IMAGE DISPLAY DEVICE
    - all user selectable settings

Test equipment
    - luminance meter
    - test image(s) used

Standard test conditions (including environmental influences)

History of tests
    - STATUS TEST
    - latest initial CONSTANCY TEST
    - previous CONSTANCY TEST

Test results

Invariance of viewing conditions
    - initial CONSTANCY TEST
        • luminance of screen
        • light spots reflected off screen
        • results of evaluation (visual)
        • light sources in field of view
        • results of evaluation (visual)
    - CONSTANCY TEST
        (similar tests as for initial CONSTANCY TEST)

Grey-scale reproduction
    - initial CONSTANCY TEST
        • luminance of black area
        • luminance of white area
        • grey scale: number of steps perceivable

Identification:

Identification:

Identification:

Date:

Date:

Date:

Date:
- CONSTANCY TEST
  (similar tests as for initial CONSTANCY TEST)

Geometry of image

- initial CONSTANCY TEST
  • crosshatched pattern
    • results of evaluation (visual)
    • results of evaluation (measurements)
      • number of lines between respectively t and b and l and r
      • lengths of T, B, L, R, H and V
  • inscribed circle
    • result of evaluation (visual)
  • boundary pattern
    • result of evaluation (visual)

- CONSTANCY TEST
  (similar tests as for initial CONSTANCY TEST)

Spatial and low contrast resolution

- initial CONSTANCY TEST
  • brightness deviations between horizontal and vertical bar patterns
    yes □   no □
  • brightness deviations between patterns placed in the centre and the four corners
    yes □   no □
  • sharpness of the horizontal bar pattern placed in the centre
    absent □ present □
  • sharpness of the vertical bar pattern placed in the four corners
    absent □ present □
  • brightness deviation of horizontal bar pattern (modulation 100 % to modulation 25 %)
    absent □ present □
  • brightness deviation of horizontal bar pattern (modulation 25 % to modulation 6.25 %)
    absent □ present □
  • brightness deviation of vertical bar pattern (modulation 100 % to modulation 25 %)
    absent □ present □
  • brightness deviation of vertical bar pattern (modulation 25 % to modulation 6.25 %)
    absent □ present □

- CONSTANCY TEST
  (similar tests as for initial CONSTANCY TEST)
- Image stability and image artifacts

- Initial Constancy Test
  Phenomena to look for:
  - Excessive flicker
    (caused by a missing field)
  - Incorrect interlacing
  - Horizontal or vertical movements
  - Time-dependent geometric distortion
  - Result of phosphor burn-in
  - Blemishes
  - Ghost-images
  - Echos on black-white transitions
  - Visible diagonal white lines
  - Reference clinical image

  Date:

  Absent □  Present □
  Absent □  Present □
  Absent □  Present □
  Absent □  Present □
  Absent □  Present □
  Absent □  Present □
  Absent □  Present □
  Acceptable □  Non-acceptable □

- Constancy Test
  (Similar tests as for initial Constancy Test)

  Date:

  Colour-related aspects

- Initial Constancy Test

  The following items are checked:
  - Convergence of colour components
    Yes □  No □
  - Constant hue over the grey scale
    Yes □  No □
  - Absence of non-significant coloured areas
    Yes □  No □
  - Colour balance
    Yes □  No □
  - Absence of permutation of colour channels
    Yes □  No □
  - Neutral rendition of resolution pattern
    Yes □  No □

  Constancy Test
  (Similar tests as for initial Constancy Test)
XI. Constancy tests - Equipment for film processing according to IEC 61223-2-1 [12]

11.1 Test parameter
- Speed or sensitivity index
- Contrast index
- Fog density
- Developer temperature

11.2 Test Equipment
- Control film
- SensiX sensitometer
- DensiX densitometer
- Thermometer

11.3 Test adjustment
1.) The control film should be of the same type as the radiographic material normally used in the X-ray department and should be stored under the same conditions. Control films should be of the same type and emulsion number and should be taken from the same package.
2.) To avoid error by means of a wrong developer temperature, the temperature should be measured daily.
3.) Ensure that the darkroom conditions as well as the film storage conditions are satisfactory.
4.) Switch on the SensiX sensitometer and the DensiX densitometer.

11.4 Test procedure
- Expose the control film by means of the SensiX sensitometer with a 21-stepwedge. This step wedge will enable differences in the sensitivity of different types of control film to be taken into account.
- Process the exposed control film and evaluate it with the DensiX densitometer.

11.5 Data evaluation
Document and file the measured values with the protocol of the constancy test.

Hint:
If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

11.5.1 Speed or sensitivity index
The measurement of the sensitivity index can be performed with the DensiX densitometer during the step defined during the initial constancy test.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The deviation of the sensitivity index should be within ± 0.2 OD.

11.5.2 Contrast index
The measurement of the contrast index can be performed with the DensiX densitometer.
Criteria to be applied:
The following criteria have to be applied in comparison to the baseline values:
- The deviation of the contrast index should be within ± 0.2 OD.

11.5.3 Fog density
The measurement of the fog density can be performed with the DensiX densitometer. The measuring area is an area of the radiogram on the processed control film that has not been exposed to light from the SensiX sensitometer.
11.5.4 Example

Time in days

FILM BASE PLUS FOG DENSITY

SPEED INDEX

CONTRAST INDEX
Protocol

Example of a form for the standardized test report

Test report
on constancy test of equipment for film processing
according to IEC 1223-2-1:1993

Identification

Person performing test

Equipment and subsystems

Identification:

Identification:

History of tests

STATUS TEST
latest test on darkroom conditions
latest test on film-processing equipment
latest initial CONSTANCY TEST
previous CONSTANCY TEST

Date:
Date:
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Date:

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<td>Person carrying out the current CONSTANCY TEST</td>
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<p>| Date of latest constancy test: * for darkroom safelight conditions | YES / NO | YES / NO | YES / NO | YES / NO |
| - darkroom safelight conditions satisfactory | YES / NO | YES / NO | YES / NO | YES / NO |
| * for film storage conditions | | | | |
| - film storage conditions satisfactory | YES / NO | YES / NO | YES / NO | YES / NO |
| Identity of instrumentation: * Thermometer | | | | |
| * Sensitometer | | | | |
| * Densitometer | | | | |
| - Date of latest calibration of densitometer | | | | |
| Date on processing solutions: * Development solution | | | | |
| - Type | | | | |
| - Concentration | | | | |
| - Rate of regeneration | | | | |
| - Optimum temperature selected | °C | °C | °C | °C |
| - Identification of point 1 for measuring | | | | |
| - Temperature at point 1 | °C | °C | °C | °C |
| - Identification of point 2 for measuring | | | | |
| - Temperature at point 2 | °C | °C | °C | °C |
| - Recommended temperature | °C | °C | °C | °C |
| - Difference in temperature | °C | °C | °C | °C |
| * Fixing solution | | | | |
| - Type | | | | |
| - Rate of regeneration | | | | |</p>
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<table>
<thead>
<tr>
<th>Difference in temperature</th>
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<tbody>
<tr>
<td>°C  °C  °C  °C</td>
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Radiographic/photographic material
* Identification of a list of materials taken into account see 6 c) and 4.2.1

* Control film 1
  - Material(s) chosen as control film

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<th>Speed</th>
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<th>Date of first issue</th>
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* Control film 2
  - Material(s) chosen as control film

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<th>Expiry date</th>
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<tbody>
<tr>
<td><strong>Indication of the nature of current test</strong></td>
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<tr>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>* for optimum temperature</td>
</tr>
<tr>
<td>* at temperature of</td>
</tr>
<tr>
<td>* for BASELINE VALUES</td>
</tr>
<tr>
<td>* for harmonization of FILM PROCESSORS</td>
</tr>
<tr>
<td>* for CONSISTENCY TEST</td>
</tr>
<tr>
<td>* for current batch (C) / replacement batch (R)</td>
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<tr>
<td>* Identification of feeding point</td>
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<table>
<thead>
<tr>
<th><strong>Measured values</strong></th>
<th>FILM BASE PLUS FOG DENSITY</th>
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<tbody>
<tr>
<td>* Sheet 1</td>
<td></td>
</tr>
<tr>
<td>* Sheet 2</td>
<td></td>
</tr>
<tr>
<td>* Sheet 3</td>
<td></td>
</tr>
<tr>
<td>* Sheet 4</td>
<td></td>
</tr>
<tr>
<td>* Sheet 5</td>
<td></td>
</tr>
<tr>
<td>* Sheet 6</td>
<td></td>
</tr>
</tbody>
</table>

* Average value FILM BASE PLUS FOG DENSITY. **Speed Index**

<p>| * Sheet 1 |                  |
| * Sheet 2 |                  |
| * Sheet 3 |                  |
| * Sheet 4 |                  |
| * Sheet 5 |                  |
| * Sheet 6 |                  |</p>
<table>
<thead>
<tr>
<th>Sheet 1</th>
<th>Sheet 2</th>
<th>Sheet 3</th>
<th>Sheet 4</th>
<th>Sheet 5</th>
<th>Sheet 6</th>
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<tbody>
<tr>
<td>Average value SPEED INDEX</td>
<td></td>
<td></td>
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<tr>
<td>CONTRAST INDEX</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Current BASELINE VALUES</td>
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<td></td>
<td></td>
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<tr>
<td>FILM BASE PLUS FOG DENSITY</td>
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<tr>
<td>SPEED INDEX</td>
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<tr>
<td>CONTRAST INDEX</td>
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<table>
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<tr>
<th>Duration of processing cycle</th>
<th>Specified duration</th>
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<th>s</th>
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<tr>
<td>Measured duration</td>
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<td>s</td>
<td>s</td>
<td>s</td>
<td>s</td>
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<tr>
<td>Hypo retention test</td>
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<td></td>
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<td></td>
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<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result satisfactorily negative</td>
<td></td>
<td>YES / NO</td>
<td>YES / NO</td>
<td>YES / NO</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Final decision:</td>
<td></td>
<td>YES / NO</td>
<td>YES / NO</td>
<td>YES / NO</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Performance of FILM PROCESSOR</td>
<td></td>
<td>YES / NO</td>
<td>YES / NO</td>
<td>YES / NO</td>
<td>YES / NO</td>
</tr>
<tr>
<td>satisfactory</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Labelling of date of next CONSTANCY TEST</td>
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66
<table>
<thead>
<tr>
<th>Bibliography</th>
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</table>
  Constancy test - Equipment for direct radiography                           |
  Constancy test - Equipment for analogue and digital fluoroscopy  
  Constancy test - Equipment for digital subtraction angiography             |
  Constancy test - Equipment for digital radiography                          |
| [7] DIN 6868-7                                                             | Sicherung der Bildqualität in röntgendiagnostischen Betrieben - Teil 7: Konstanzprüfung an Röntgen-Einrichtungen für Mammographie; April 2002  
  Constancy test - Equipment for analogue mammography                         |
| [8] IEC 61223-2-10                                                         | Evaluation and routine testing in medical imaging departments - Part 2-10: Constancy tests – X-ray equipment for mammography; September 1999  |
| [9] DIN PAS 1054                                                           | Anforderung und Prüfverfahren für digitale Mammographie-Einrichtungen; März 2005  
  Constancy test - Equipment for digital mammography                             |
| [12] IEC 61223-2-1                                                         | Evaluation and routine testing in medical imaging departments - Part 2-1: Constancy tests - Film processors; 1993  |
## List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACR</td>
<td>American College of Radiology</td>
</tr>
<tr>
<td>Al</td>
<td>Aluminium</td>
</tr>
<tr>
<td>CT</td>
<td>Computer tomography</td>
</tr>
<tr>
<td>CTDI</td>
<td>Computed Tomography Dose Index</td>
</tr>
<tr>
<td>Cu</td>
<td>Copper</td>
</tr>
<tr>
<td>DIN</td>
<td>Deutsches Institut für Normung corresponds to “German institute for standardization”</td>
</tr>
<tr>
<td>DSA</td>
<td>Digital subtraction angiography</td>
</tr>
<tr>
<td>EN</td>
<td>Europäische Norm corresponds to “European standard”</td>
</tr>
<tr>
<td>FAQ</td>
<td>Frequently asked questions</td>
</tr>
<tr>
<td>HK</td>
<td>High contrast</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>KRV</td>
<td>Contrast-to noise ratio</td>
</tr>
<tr>
<td>kV</td>
<td>Kilo Volt</td>
</tr>
<tr>
<td>Lp/mm</td>
<td>Line pairs per mm</td>
</tr>
<tr>
<td>mA</td>
<td>Milli ampere</td>
</tr>
<tr>
<td>mAs</td>
<td>Milli ampere per second</td>
</tr>
<tr>
<td>MAM</td>
<td>Mammography</td>
</tr>
<tr>
<td>mGy; nGy</td>
<td>Milli; nano gray</td>
</tr>
<tr>
<td>Mo</td>
<td>Molybdenum</td>
</tr>
<tr>
<td>N</td>
<td>Newton</td>
</tr>
<tr>
<td>OD</td>
<td>Optical density</td>
</tr>
<tr>
<td>PAS</td>
<td>Publicly Available Specification</td>
</tr>
<tr>
<td>PMMA</td>
<td>Polymethylmethacrylat</td>
</tr>
<tr>
<td>PTW</td>
<td>Physikalisch-Technische Werkstätten Dr. Pychlau GmbH</td>
</tr>
<tr>
<td>QC</td>
<td>Quality control</td>
</tr>
<tr>
<td>ROI</td>
<td>Region of Interest</td>
</tr>
<tr>
<td>s</td>
<td>Second</td>
</tr>
<tr>
<td>SMPTE</td>
<td>Society of Motion Picture and Television Engineers</td>
</tr>
<tr>
<td>SRV</td>
<td>Signal-to noise ratio</td>
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## Ordering Information

<table>
<thead>
<tr>
<th>Ordering information</th>
<th>Product</th>
<th>Scope of delivery</th>
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<tbody>
<tr>
<td>L981030</td>
<td>REX package</td>
<td>Set includes structure plate 250 mm x 250 mm x 25 mm, absorber, four 250 mm long distance supports for under-couch applications, mounting device for wall bucky, 1 mm thick Cu plate and a carrying case</td>
</tr>
<tr>
<td>L981301</td>
<td>NORMI 4 FLU plus</td>
<td>Test object for analogue and digital fluoroscopic X-ray installations, size 30 cm x 30 cm. Includes a 1 mm copper absorber, a 30 mm PMMA absorber, 4 x 35 cm long distance supports for use with under-couch tubes and a carrying case</td>
</tr>
<tr>
<td>T42024</td>
<td>NORMI MAM analog</td>
<td>Test object for mammographic constancy and acceptance tests acc. to DIN and IEC. Features contrast tests, res. test, test steel balls and 40 mm attenuation phantom. Incl. 40 mm and 20 mm thick acrylic plate for functionality tests of the AEC, storage case</td>
</tr>
<tr>
<td>L981248</td>
<td>NORMI PAS Set</td>
<td>Test object for constancy and acceptance tests for digital mammography acc. to DIN PAS 1054. Incl. basic phantom, structure plate, test elements, absorbers and a carrying case. Test element AP for acceptance tests necessary</td>
</tr>
<tr>
<td>T42028.1.020</td>
<td>Test element AP</td>
<td>For acceptance tests and annual constancy tests of digital mammography installations acc. to DIN PAS 1054. For use in combination with the test object NORMI PAS 1054 (L981248)</td>
</tr>
<tr>
<td>T42028.3.050</td>
<td>NORMI PAS step substitute</td>
<td>PMMA block for closing the step disruption within the NORMI PAS basic phantom</td>
</tr>
<tr>
<td>T42003</td>
<td>X-Check DSA</td>
<td>Test object for constancy and acceptance tests on DSA installations acc. to IEC 61223-3-3. Includes pneumatic control and carrying case</td>
</tr>
<tr>
<td>T42003.1.006</td>
<td>X-Check DSA frame</td>
<td>300 mm x 300 mm, with 4 x 260 mm long supports. For use with under couch tubes</td>
</tr>
<tr>
<td>L981247</td>
<td>NORMI 13 Set</td>
<td>Set for quality control of digital X-ray units acc. to DIN 6868-13-58. Evaluates dynamic range, contrast resolution, homogeneity, local resolution and geometry. Incl. a PMMA absorber, a bucky mounting device, Velcro tape and a carrying case</td>
</tr>
<tr>
<td>L981246</td>
<td>NORMI 13 Focus</td>
<td>Set for quality control of X-ray units acc. to DIN 6868-13. Set consists of a structure plate, a bucky mounting device, an Al absorber (mounting to the collimator, adaptation rails and a carrying case</td>
</tr>
<tr>
<td>T40017</td>
<td>CT head phantom</td>
<td>15 cm long acrylic cylinder, 16 cm in diameter. Features hole in the centre and four holes off-centre for accommodation of CT ionization chamber 30009. Includes four blind plugs. For dose measurements in accordance with IEC 61223-2-6</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Details</td>
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<tr>
<td>---------</td>
<td>---------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>T40016</td>
<td><strong>CT body phantom</strong></td>
<td>15 cm long acrylic cylinder, 32 cm in diameter. Features hole in the centre and four holes off-centre for accommodation of CT ionization chamber 30009. Includes 4 blind plugs. For dose measurements in accordance with IEC 61223-2-6</td>
</tr>
<tr>
<td>T40027</td>
<td><strong>CT head &amp; body phantom</strong></td>
<td>Two 15 cm long acrylic cylinders, 16 and 32 cm in diameter. The big cylinder can accommodate the small one. Both cylinders feature four holes off-centre and one central hole for CT chamber 30009. For dose measurements in accordance with IEC 61223-2-6</td>
</tr>
<tr>
<td>T11007</td>
<td><strong>CONNY II</strong></td>
<td>Diagnostic X-ray dosemeter with semi-conductor detector. For conventional X-rays (50-90 kV) and mammography (25-35 kV). Battery operated</td>
</tr>
<tr>
<td>L981263</td>
<td><strong>DensiX 52001</strong></td>
<td>Digital densitometer with built-in light source, 3 mm aperture. Suitable for constancy and acceptance tests. Including power supply</td>
</tr>
<tr>
<td>L981262</td>
<td><strong>SensiX 51003</strong></td>
<td>For reproducible exposures of a 21-step wedge (tolerance +/- 1 %) on X-ray films. Blue or green light selectable. Calibrated in accordance with DIN 6868-55. Suitable for acceptance tests. Battery operated. Including power supply</td>
</tr>
<tr>
<td>L981143</td>
<td><strong>Set for testing the compression device</strong></td>
<td>For mammographic installations acc. to IEC 61223-3-2. Comprises a compression scale and a foam cuboid</td>
</tr>
<tr>
<td>L991266</td>
<td><strong>CDmon light meter</strong></td>
<td>For quality control of imaging display devices and viewing boxes. Measures luminance in cd/m² and illuminance in lux. Incl. batteries, USB interface and case</td>
</tr>
<tr>
<td>L991262</td>
<td><strong>MAVO-MAX</strong></td>
<td>Monitoring of the ambient light (20 - 60 lux) acc. to IEC and DIN. Extends the repeating cycles to 6 months for constancy tests at image display systems. A LED indicates in continuous operation the permissible light value. Connection to mains plug</td>
</tr>
<tr>
<td>L981239</td>
<td><strong>DIADOS E</strong></td>
<td>Complies with IEC 61674. Measures dose, dose rate, dose/pulse and exposure time with a semi-conductor detector. Includes electrometer mode, RS232 interface, rechargeable batteries and power supply L991047</td>
</tr>
<tr>
<td>T30009</td>
<td><strong>CT ion chamber</strong></td>
<td>Ion chamber for dose length product measurements in CT. Length of measuring volume 100 mm, cable length 2.5 m, connecting system BNC + banana plug</td>
</tr>
<tr>
<td>T16018</td>
<td><strong>DIADOS CT adapter</strong></td>
<td>For connection of a CT chamber type TM30009 or TM77336 to the DIADOS or DIADOS E. Supplies the CT chamber with a voltage of 100V. Connecting system M</td>
</tr>
<tr>
<td>L991006</td>
<td><strong>Digital Thermometer</strong></td>
<td>For fast and precise measurement of film processor solution temperature. Includes immersion probe and battery</td>
</tr>
<tr>
<td>Model</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>L991077</td>
<td>Screen-film contact test tool For checks of the film-screen contact in conventional X-ray diagnostics. Screen measures 35.6 cm x 43 cm. Copper mesh with 8 wires per inch, 0.7 mm thick. Embedded in plastic plate</td>
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<tr>
<td>L991078</td>
<td>Screen-film contact test tool For checks of the film-screen contact in mammography. Screen measures 26 cm x 31 cm. Copper mesh with 40 wires per inch, 0.26 mm thick. Embedded in plastic plate</td>
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<tr>
<td>L653003</td>
<td>Magnifying glass Magnification 8 x, allows exact evaluation of test pattern on X-ray test films</td>
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Memorandum